

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

System Organ 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	311 (95%)	318 (97%)	0.5501 (0.2395, 1.2635) /0.159	-2.1407 (-5.0751, 0.7938) /0.153	0.9780 (0.9485, 1.0084) /0.154
Max Grade 1	101 (31%)	102 (31%)	0.9858 (0.7078, 1.3730) /0.933	-0.3058 (-7.3974, 6.7858) /0.933	0.9902 (0.7879, 1.2444) /0.933
Max Grade 2	176 (54%)	173 (53%)	1.0376 (0.7631, 1.4108) /0.814	0.9174 (-6.7289, 8.5638) /0.814	1.0173 (0.8815, 1.1741) /0.814
Max Grade 3	31 (9%)	41 (13%)	0.7306 (0.4458, 1.1973) /0.213	-3.0581 (-7.8501, 1.7339) /0.211	0.7561 (0.4867, 1.1747) /0.214
Max Grade 4	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 5	0	0			

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

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

System Organ 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	287 (88%)	279 (85%)	1.2344 (0.7865, 1.9375) /0.360	2.4465 (-2.7809, 7.6738) /0.359	1.0287 (0.9683, 1.0928) /0.360
Max Grade 1	159 (49%)	148 (45%)	1.1447 (0.8418, 1.5565) /0.389	3.3639 (-4.2815, 11.0093) /0.388	1.0743 (0.9126, 1.2647) /0.389
Max Grade 2	118 (36%)	112 (34%)	1.0838 (0.7862, 1.4942) /0.623	1.8349 (-5.4829, 9.1526) /0.623	1.0536 (0.8555, 1.2975) /0.623
Max Grade 3	10 (3%)	19 (6%)	0.5114 (0.2340, 1.1173) /0.093	-2.7523 (-5.9006, 0.3960) /0.087	0.5263 (0.2486, 1.1145) /0.094
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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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

Injection site pain					
Any Event	273 (83%)	261 (80%)	1.2784 (0.8590, 1.9027) /0.226	3.6697 (-2.2566, 9.5960) /0.225	1.0460 (0.9726, 1.1249) /0.226
Max Grade 1	159 (49%)	145 (44%)	1.1879 (0.8734, 1.6158) /0.273	4.2813 (-3.3567, 11.9194) /0.272	1.0966 (0.9299, 1.2930) /0.273
Max Grade 2	107 (33%)	98 (30%)	1.1365 (0.8165, 1.5819) /0.448	2.7523 (-4.3553, 9.8599) /0.448	1.0918 (0.8700, 1.3703) /0.448
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.

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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

Injection site nodule					
Any Event	41 (13%)	79 (24%)	0.4500 (0.2975, 0.6807) /<.001	-11.6208 (-17.4865, -5.7550) /<.001	0.5190 (0.3677, 0.7326) /<.001
Max Grade 1	32 (10%)	62 (19%)	0.4636 (0.2934, 0.7328) /<.001	-9.1743 (-14.5055, -3.8431) /<.001	0.5161 (0.3466, 0.7685) /0.001
Max Grade 2	9 (3%)	17 (5%)	0.5161 (0.2266, 1.1753) /0.115	-2.4465 (-5.4355, 0.5425) /0.109	0.5294 (0.2395, 1.1703) /0.116
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.

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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
Injection site discomfort					
Any Event	28 (9%)	35 (11%)	0.7813 (0.4633, 1.3173) /0.354	-2.1407 (-6.6602, 2.3788) /0.353	0.8000 (0.4986, 1.2835) /0.355
Max Grade 1	20 (6%)	28 (9%)	0.6957 (0.3835, 1.2619) /0.232	-2.4465 (-6.4394, 1.5464) /0.230	0.7143 (0.4109, 1.2417) /0.233
Max Grade 2	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 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.

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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

Injection site induration					
Any Event	28 (9%)	35 (11%)	0.7813 (0.4633, 1.3173) /0.354	-2.1407 (-6.6602, 2.3788) /0.353	0.8000 (0.4986, 1.2835) /0.355
Max Grade 1	23 (7%)	32 (10%)	0.6975 (0.3987, 1.2201) /0.207	-2.7523 (-7.0011, 1.4966) /0.204	0.7188 (0.4301, 1.2010) /0.207
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.
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Pyrexia					
Any Event	26 (8%)	36 (11%)	0.6982 (0.4112, 1.1857) /0.184	-3.0581 (-7.5422, 1.4260) /0.181	0.7222 (0.4466, 1.1678) /0.184
Max Grade 1	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 2	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 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.

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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

Injection site swelling					
Any Event	27 (8%)	23 (7%)	1.1896 (0.6670, 2.1216) /0.556	1.2232 (-2.8487, 5.2952) /0.556	1.1739 (0.6878, 2.0036) /0.557
Max Grade 1	16 (5%)	17 (5%)	0.9382 (0.4656, 1.8903) /0.858	-0.3058 (-3.6609, 3.0493) /0.858	0.9412 (0.4839, 1.8306) /0.858
Max Grade 2	10 (3%)	6 (2%)	1.6877 (0.6062, 4.6988) /0.316	1.2232 (-1.1429, 3.5894) /0.311	1.6667 (0.6129, 4.5325) /0.317
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			

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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
Fatigue					
Any Event	14 (4%)	29 (9%)	0.4596 (0.2382, 0.8869) /0.020	-4.5872 (-8.3698, -0.8045) /0.017	0.4828 (0.2599, 0.8967) /0.021
Max Grade 1	11 (3%)	24 (7%)	0.4395 (0.2116, 0.9127) /0.027	-3.9755 (-7.4118, -0.5392) /0.023	0.4583 (0.2283, 0.9202) /0.028
Max Grade 2	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 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			

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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

Injection site pruritus					
Any Event	11 (3%)	24 (7%)	0.4395 (0.2116, 0.9127) /0.027	-3.9755 (-7.4118, -0.5392) /0.023	0.4583 (0.2283, 0.9202) /0.028
Max Grade 1	9 (3%)	22 (7%)	0.3924 (0.1778, 0.8656) /0.020	-3.9755 (-7.2184, -0.7327) /0.016	0.4091 (0.1913, 0.8749) /0.021
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			

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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
Influenza like illness					
Any Event	10 (3%)	17 (5%)	0.5752 (0.2593, 1.2759) /0.174	-2.1407 (-5.1857, 0.9044) /0.168	0.5882 (0.2735, 1.2653) /0.175
Max Grade 1	7 (2%)	14 (4%)	0.4891 (0.1948, 1.2279) /0.128	-2.1407 (-4.8379, 0.5566) /0.120	0.5000 (0.2045, 1.2227) /0.129
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			

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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

Injection site erythema					
Any Event	12 (4%)	14 (4%)	0.8517 (0.3878, 1.8705) /0.689	-0.6116 (-3.6061, 2.3829) /0.689	0.8571 (0.4026, 1.8249) /0.689
Max Grade 1	12 (4%)	12 (4%)	1.0000 (0.4425, 2.2597) />0.999	<0.0001 (-2.8820, 2.8820) />0.999	1.0000 (0.4560, 2.1931) />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.

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Asthenia					
Any Event	14 (4%)	10 (3%)	1.4179 (0.6205, 3.2400) /0.408	1.2232 (-1.6572, 4.1037) /0.405	1.4000 (0.6310, 3.1061) /0.408
Max Grade 1	11 (3%)	8 (2%)	1.3881 (0.5510, 3.4967) /0.487	0.9174 (-1.6560, 3.4909) /0.485	1.3750 (0.5603, 3.3743) /0.487
Max Grade 2	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 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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Chills					
Any Event	14 (4%)	8 (2%)	1.7835 (0.7379, 4.3109) /0.199	1.8349 (-0.9252, 4.5949) /0.193	1.7500 (0.7442, 4.1150) /0.200
Max Grade 1	12 (4%)	7 (2%)	1.7415 (0.6769, 4.4807) /0.250	1.5291 (-1.0427, 4.1008) /0.244	1.7143 (0.6835, 4.2993) /0.251
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			

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Injection site bruising					
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	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 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			

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Pain					
Any Event	8 (2%)	8 (2%)	1.0000 (0.3708, 2.6971) />0.999	<0.0001 (-2.3680, 2.3680) />0.999	1.0000 (0.3799, 2.6325) />0.999
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	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.

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

System Organ 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	7 (2%)	8 (2%)	0.8723 (0.3126, 2.4339) /0.794	-0.3058 (-2.6003, 1.9887) /0.794	0.8750 (0.3210, 2.3850) /0.794
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	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.

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	2 (<1%)	12 (4%)	0.1615 (0.0359, 0.7276) /0.018	-3.0581 (-5.2642, -0.8520) /0.007	0.1667 (0.0376, 0.7388) /0.018
Max Grade 1	0	11 (3%)	<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.

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

System Organ 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	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 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	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
Chest pain					
Any Event	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 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%)	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	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 1	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 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	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	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%)	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 anaesthesia					
Any Event	5 (2%)	1 (<1%)	5.0621 (0.5882, 43.5684) /0.140	1.2232 (-0.2352, 2.6816) /0.100	5.0000 (0.5874, 42.5633) /0.141
Max Grade 1	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 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

Nodule					
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	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	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			
Feeling hot					
Any Event	5 (2%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	4 (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			

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

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

System Organ 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	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	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%)	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
Cyst					
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	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	0	0	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
Injection site discolouration					
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	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
Mass					
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.

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.

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

System Organ 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.

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

System Organ 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.

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

System Organ 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 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	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

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

Temperature regulation disorder					
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			
Vaccination site pain					
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
Adverse drug reaction					
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

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			
Enanthema					
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
Feeling abnormal					
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			
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
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 hypoaesthesia					
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

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			

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

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

System Organ 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.

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

System Organ 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

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			
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			

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

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

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

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	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

Infestations and infections					
Any Event	216 (66%)	239 (73%)	0.7165 (0.5126, 1.0015) /0.051	-7.0336 (-14.0655, -0.0018) /0.050	0.9038 (0.8163, 1.0006) /0.051
Max Grade 1	111 (34%)	126 (39%)	0.8198 (0.5957, 1.1282) /0.223	-4.5872 (-11.9468, 2.7725) /0.222	0.8810 (0.7184, 1.0803) /0.223
Max Grade 2	96 (29%)	107 (33%)	0.8545 (0.6133, 1.1905) /0.353	-3.3639 (-10.4509, 3.7231) /0.352	0.8972 (0.7136, 1.1280) /0.353
Max Grade 3	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 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	61 (19%)	66 (20%)	0.9069 (0.6154, 1.3364) /0.621	-1.5291 (-7.5914, 4.5332) /0.621	0.9242 (0.6762, 1.2633) /0.621
Max Grade 1	41 (13%)	52 (16%)	0.7581 (0.4875, 1.1790) /0.219	-3.3639 (-8.7112, 1.9833) /0.218	0.7885 (0.5394, 1.1525) /0.220
Max Grade 2	20 (6%)	14 (4%)	1.4565 (0.7226, 2.9356) /0.293	1.8349 (-1.5651, 5.2348) /0.290	1.4286 (0.7343, 2.7794) /0.294
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit 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	45 (14%)	66 (20%)	0.6310 (0.4169, 0.9553) /0.030	-6.4220 (-12.1550, -0.6891) /0.028	0.6818 (0.4821, 0.9642) /0.030
Max Grade 1	31 (9%)	42 (13%)	0.7107 (0.4346, 1.1621) /0.173	-3.3639 (-8.1838, 1.4560) /0.171	0.7381 (0.4763, 1.1438) /0.174
Max Grade 2	14 (4%)	24 (7%)	0.5647 (0.2867, 1.1122) /0.098	-3.0581 (-6.6363, 0.5201) /0.094	0.5833 (0.3073, 1.1075) /0.099
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	16 (5%)	31 (9%)	0.4912 (0.2632, 0.9168) /0.026	-4.5872 (-8.5302, -0.6441) /0.023	0.5161 (0.2880, 0.9251) /0.026
Max Grade 1	11 (3%)	19 (6%)	0.5643 (0.2642, 1.2054) /0.140	-2.4465 (-5.6477, 0.7548) /0.134	0.5789 (0.2800, 1.1973) /0.140
Max Grade 2	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 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit 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	18 (6%)	22 (7%)	0.8076 (0.4247, 1.5357) /0.515	-1.2232 (-4.8951, 2.4486) /0.514	0.8182 (0.4473, 1.4964) /0.515
Max Grade 1	11 (3%)	12 (4%)	0.9138 (0.3973, 2.1016) /0.832	-0.3058 (-3.1292, 2.5176) /0.832	0.9167 (0.4104, 2.0475) /0.832
Max Grade 2	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 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit 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	18 (6%)	13 (4%)	1.4070 (0.6777, 2.9210) /0.360	1.5291 (-1.7260, 4.7841) /0.357	1.3846 (0.6898, 2.7791) /0.360
Max Grade 1	13 (4%)	6 (2%)	2.2150 (0.8315, 5.9003) /0.112	2.1407 (-0.4285, 4.7098) /0.102	2.1667 (0.8337, 5.6311) /0.113
Max Grade 2	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 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit 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	14 (4%)	16 (5%)	0.8694 (0.4172, 1.8118) /0.709	-0.6116 (-3.8180, 2.5948) /0.709	0.8750 (0.4342, 1.7633) /0.709
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	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 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit 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	12 (4%)	18 (6%)	0.6540 (0.3098, 1.3805) /0.265	-1.8349 (-5.0385, 1.3688) /0.262	0.6667 (0.3264, 1.3617) /0.266
Max Grade 1	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 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
Gonorrhoea					
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%)	8 (2%)	1.3881 (0.5510, 3.4967) /0.487	0.9174 (-1.6560, 3.4909) /0.485	1.3750 (0.5603, 3.3743) /0.487
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.

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	10 (3%)	12 (4%)	0.8281 (0.3527, 1.9443) /0.665	-0.6116 (-3.3749, 2.1516) /0.664	0.8333 (0.3652, 1.9017) /0.665
Max Grade 1	5 (2%)	9 (3%)	0.5487 (0.1819, 1.6551) /0.287	-1.2232 (-3.4398, 0.9933) /0.279	0.5556 (0.1882, 1.6399) /0.287
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
Viral infection					
Any Event	8 (2%)	14 (4%)	0.5607 (0.2320, 1.3552) /0.199	-1.8349 (-4.5949, 0.9252) /0.193	0.5714 (0.2430, 1.3437) /0.200
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	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	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
Chlamydial infection					
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	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	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
Urinary tract infection					
Any Event	10 (3%)	9 (3%)	1.1146 (0.4469, 2.7798) /0.816	0.3058 (-2.2685, 2.8801) /0.816	1.1111 (0.4575, 2.6987) /0.816
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	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	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

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

System Organ 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	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	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	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 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit 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	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 1	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 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	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 gonococcal 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	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%)	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 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit 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	5 (2%)	11 (3%)	0.4461 (0.1532, 1.2985) /0.139	-1.8349 (-4.1987, 0.5290) /0.128	0.4545 (0.1597, 1.2937) /0.140
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	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	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
Anal chlamydia infection					
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	5 (2%)	1 (<1%)	5.0621 (0.5882, 43.5684) /0.140	1.2232 (-0.2352, 2.6816) /0.100	5.0000 (0.5874, 42.5633) /0.141
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	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

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

System Organ 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	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 1	7 (2%)	5 (2%)	1.4087 (0.4425, 4.4849) /0.562	0.6116 (-1.4450, 2.6683) /0.560	1.4000 (0.4489, 4.3659) /0.562
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
Oral herpes					
Any Event	3 (<1%)	11 (3%)	0.2660 (0.0735, 0.9624) /0.044	-2.4465 (-4.6571, -0.2359) /0.030	0.2727 (0.0768, 0.9686) /0.045
Max Grade 1	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 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
Urethritis					
Any Event	5 (2%)	9 (3%)	0.5487 (0.1819, 1.6551) /0.287	-1.2232 (-3.4398, 0.9933) /0.279	0.5556 (0.1882, 1.6399) /0.287
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	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
Folliculitis					
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	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 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.

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 gonococcal infection					
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	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	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	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
Rhinitis					
Any Event	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 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	0	0	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
Herpes zoster					
Any Event	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 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%)	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	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

Gastroenteritis viral					
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%)	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%)	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.

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

System Organ 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%)	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	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
Lower respiratory tract infection					
Any Event	7 (2%)	2 (<1%)	3.5547 (0.7329, 17.2411) /0.115	1.5291 (-0.2528, 3.3109) /0.093	3.5000 (0.7326, 16.7222) /0.116
Max Grade 1	5 (2%)	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.

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

System Organ 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	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.

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

System Organ 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	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.

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
Onychomycosis					
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%)	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%)	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 versicolour 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
Tooth infection Any Event	0	8 (2%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	5 (2%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
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
Fungal skin infection					
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.

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

System Organ 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	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	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />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.

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	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%)	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.

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
Furuncle					
Any Event	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 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	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

Gingivitis					
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%)	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	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Herpes simplex					
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%)	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	0	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
Hordeolum					
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.

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

System Organ 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	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	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	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
Urethritis chlamydial 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	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
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
Urethritis gonococcal 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	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
Abscess limb 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	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>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	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
Acarodermatitis					
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%)	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%)	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
Secondary syphilis					
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%)	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%)	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	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%)	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%)	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 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.

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
Otitis externa					
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

Pharyngotonsillitis					
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	1 (<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	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

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

System Organ 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	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	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.

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

Shigella infection					
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	0	NC	NC	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	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
Tracheitis					
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
Viral pharyngitis 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
Enteritis infectious					
Any Event	3 (<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	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	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	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
Helicobacter infection					
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

Injection site abscess					
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	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.

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

System Organ 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
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.

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

System Organ 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	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			

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

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

System Organ 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	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

Skin infection					
Any Event	3 (<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	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
Staphylococcal infection					
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.

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

System Organ 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	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%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>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
Tinea cruris					
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			
Tinea infection					
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

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
Varicella					
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			

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

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit 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	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	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

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
Acute sinusitis					
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
<hr/>					
Bronchitis viral					
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			
Chronic sinusitis					
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
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
Diarrhoea infectious 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
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
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.

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
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.

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

System Organ 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			
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			

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

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

System Organ 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	2 (<1%)	0	>999 (>999, >999) /NC	NC	>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	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			
Pulmonary tuberculosis					
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
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			

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

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit 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
Sexually transmitted disease					
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.

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

System Organ 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 pedis					
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
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
Urethritis mycoplasmal 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	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
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			
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			

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

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit 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
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			

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

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

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

Borrelia 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			
COVID-19					
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
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
Cellulitis of male external genital organ					
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.

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

System Organ 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	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

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

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			
Eczema infected					
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
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			
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			

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

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

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

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			
Eye 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
<hr/>					
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			
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

Gastrointestinal 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.

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

System Organ 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.

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

System Organ 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			
Giardiasis 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

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			
Gonococcal 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
<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			
Hepatitis C					
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
Herpes ophthalmic 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

Herpes virus 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			
Infected bite					
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/>					
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			
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			

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

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

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
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	NC	NC	NC
Latent syphilis					
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/>					
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			
Localised 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
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	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
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.

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 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 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			
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

Suspected COVID-19					
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			
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
<hr/>					
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	NC	NC	NC
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	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
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

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

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

System Organ 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 staphylococcal					
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/>					
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			
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			

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

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

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

Gastrointestinal disorders					
Any Event	98 (30%)	123 (38%)	0.7098 (0.5125, 0.9830) /0.039	-7.6453 (-14.8718, -0.4187) /0.038	0.7967 (0.6416, 0.9895) /0.040
Max Grade 1	67 (20%)	74 (23%)	0.8810 (0.6067, 1.2795) /0.506	-2.1407 (-8.4420, 4.1607) /0.506	0.9054 (0.6756, 1.2134) /0.506
Max Grade 2	29 (9%)	47 (14%)	0.5798 (0.3549, 0.9470) /0.029	-5.5046 (-10.3987, -0.6105) /0.027	0.6170 (0.3987, 0.9549) /0.030
Max Grade 3	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 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit 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
Diarrhoea					
Any Event	33 (10%)	37 (11%)	0.8798 (0.5355, 1.4455) /0.613	-1.2232 (-5.9611, 3.5146) /0.613	0.8919 (0.5724, 1.3898) /0.613
Max Grade 1	24 (7%)	21 (6%)	1.1542 (0.6291, 2.1174) /0.643	0.9174 (-2.9619, 4.7967) /0.643	1.1429 (0.6494, 2.0113) /0.643
Max Grade 2	9 (3%)	16 (5%)	0.5501 (0.2395, 1.2635) /0.159	-2.1407 (-5.0751, 0.7938) /0.153	0.5625 (0.2522, 1.2545) /0.160
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit 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	10 (3%)	22 (7%)	0.4373 (0.2037, 0.9388) /0.034	-3.6697 (-6.9643, -0.3751) /0.029	0.4545 (0.2187, 0.9447) /0.035
Max Grade 1	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 2	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 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit 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	4 (1%)	16 (5%)	0.2407 (0.0796, 0.7280) /0.012	-3.6697 (-6.2939, -1.0456) /0.006	0.2500 (0.0845, 0.7398) /0.012
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	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.

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
Constipation					
Any Event	3 (<1%)	16 (5%)	0.1800 (0.0519, 0.6237) /0.007	-3.9755 (-6.5318, -1.4192) /0.002	0.1875 (0.0552, 0.6374) /0.007
Max Grade 1	2 (<1%)	15 (5%)	0.1280 (0.0290, 0.5643) /0.007	-3.9755 (-6.3954, -1.5557) /0.001	0.1333 (0.0307, 0.5784) /0.007
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
Dyspepsia					
Any Event	8 (2%)	11 (3%)	0.7204 (0.2860, 1.8149) /0.487	-0.9174 (-3.4909, 1.6560) /0.485	0.7273 (0.2964, 1.7847) /0.487
Max Grade 1	7 (2%)	8 (2%)	0.8723 (0.3126, 2.4339) /0.794	-0.3058 (-2.6003, 1.9887) /0.794	0.8750 (0.3210, 2.3850) /0.794
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
Toothache					
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%)	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	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 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
Abdominal pain					
Any Event	8 (2%)	8 (2%)	1.0000 (0.3708, 2.6971) />0.999	<0.0001 (-2.3680, 2.3680) />0.999	1.0000 (0.3799, 2.6325) />0.999
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	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	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
Gastrooesophageal reflux disease					
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%)	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%)	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 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

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

System Organ 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	8 (2%)	4 (1%)	2.0251 (0.6038, 6.7921) /0.253	1.2232 (-0.8318, 3.2783) /0.243	2.0000 (0.6082, 6.5768) /0.254
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	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 upper					
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.

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
Vomiting					
Any Event	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 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%)	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
Anogenital dysplasia					
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%)	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%)	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

Gastritis					
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%)	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	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
Abdominal discomfort					
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	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	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
Rectal haemorrhage 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	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

Abdominal pain lower					
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
Anal fissure					
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	0	2 (<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.

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

System Organ 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	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			
Flatulence					
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

Haematochezia					
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%)	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	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			
Food poisoning					
Any Event	4 (1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	4 (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
Proctitis					
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%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /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
Rectal discharge					
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
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			

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

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit 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
Dry mouth					
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.

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
Hiatus hernia					
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	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	0	0	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
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.

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

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

Irritable bowel syndrome					
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
Oesophagitis 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
Proctalgia					
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	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	0	0	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
Anal pruritus					
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
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			
Diverticulum intestinal					
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

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			
Haemorrhoids thrombosed					
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
Large intestine polyp					
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

Mouth ulceration					
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			
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			

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

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

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

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

System Organ 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 disorder					
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

Tongue ulceration					
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			
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.

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 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 ulcer					
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
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	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

Anorectal 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			
Aphthous ulcer					
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/>					
Chapped lips					
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
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

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

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit 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
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			
Dental cyst 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
Dysphagia					
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
Enteritis					
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
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			
Faeces soft					
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
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			
Gastric ulcer					
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

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			
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
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

Oral lichen planus					
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			
Oral 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			

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

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

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

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			
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			

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

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

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
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			
Rectal prolapse					
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
Rectal tenesmus					
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
Salivary gland mucocoele					
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
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	91 (28%)	113 (35%)	0.7302 (0.5238, 1.0181) /0.064	-6.7278 (-13.8103, 0.3546) /0.063	0.8053 (0.6401, 1.0132) /0.065
Max Grade 1	58 (18%)	70 (21%)	0.7916 (0.5372, 1.1665) /0.237	-3.6697 (-9.7447, 2.4052) /0.236	0.8286 (0.6062, 1.1324) /0.238
Max Grade 2	28 (9%)	39 (12%)	0.6915 (0.4145, 1.1536) /0.158	-3.3639 (-8.0048, 1.2769) /0.155	0.7179 (0.4529, 1.1380) /0.159
Max Grade 3	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 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

System Organ 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	27 (8%)	32 (10%)	0.8297 (0.4851, 1.4192) /0.495	-1.5291 (-5.9188, 2.8607) /0.495	0.8438 (0.5176, 1.3755) /0.496
Max Grade 1	23 (7%)	23 (7%)	1.0000 (0.5491, 1.8211) />0.999	<0.0001 (-3.9196, 3.9196) />0.999	1.0000 (0.5728, 1.7459) />0.999
Max Grade 2	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 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit 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	21 (6%)	25 (8%)	0.8290 (0.4543, 1.5129) /0.541	-1.2232 (-5.1417, 2.6952) /0.541	0.8400 (0.4800, 1.4699) /0.541
Max Grade 1	13 (4%)	16 (5%)	0.8047 (0.3807, 1.7010) /0.569	-0.9174 (-4.0720, 2.2372) /0.569	0.8125 (0.3972, 1.6619) /0.570
Max Grade 2	8 (2%)	8 (2%)	1.0000 (0.3708, 2.6971) />0.999	<0.0001 (-2.3680, 2.3680) />0.999	1.0000 (0.3799, 2.6325) />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
Pain in extremity					
Any Event	11 (3%)	22 (7%)	0.4826 (0.2301, 1.0122) /0.054	-3.3639 (-6.7092, -0.0187) /0.049	0.5000 (0.2465, 1.0143) /0.055
Max Grade 1	9 (3%)	16 (5%)	0.5501 (0.2395, 1.2635) /0.159	-2.1407 (-5.0751, 0.7938) /0.153	0.5625 (0.2522, 1.2545) /0.160
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	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	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 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	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	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.

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 pain					
Any Event	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 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	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 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit 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	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%)	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%)	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	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 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	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 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
Tendonitis					
Any Event	7 (2%)	2 (<1%)	3.5547 (0.7329, 17.2411) /0.115	1.5291 (-0.2528, 3.3109) /0.093	3.5000 (0.7326, 16.7222) /0.116
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	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
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
Intervertebral disc protrusion					
Any Event	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 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	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.

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	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	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	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
Osteoarthritis 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	0	0	NC	NC	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	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.

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

System Organ 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	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
Muscular weakness					
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
Plantar fasciitis					
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%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>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.

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
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			

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

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

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

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

System Organ 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	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			
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			
Flank pain					
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
Groin 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%)	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
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.

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

System Organ 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 range of motion decreased					
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
Joint swelling					
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
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
Musculoskeletal 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

Musculoskeletal stiffness					
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			
Osteonecrosis					
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	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
Pain in jaw 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
Synovitis					
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.

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

Arthritis reactive					
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			
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			

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

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

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

Bone 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			
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			

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

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

System Organ 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					
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			
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			

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

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

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

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

System Organ 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			
Loose body in joint					
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
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			
Myosclerosis					
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
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			
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.

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

System Organ 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/>					
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			
Polyarthritis					
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/>					
Sacroiliitis					
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			
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
<hr/>					
Spinal 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
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	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
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			
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			

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

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

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

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

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
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	74 (23%)	84 (26%)	0.8461 (0.5911, 1.2112) /0.361	-3.0581 (-9.6151, 3.4989) /0.361	0.8810 (0.6710, 1.1567) /0.362
Max Grade 1	53 (16%)	63 (19%)	0.8106 (0.5420, 1.2123) /0.306	-3.0581 (-8.9085, 2.7923) /0.306	0.8413 (0.6038, 1.1721) /0.307
Max Grade 2	19 (6%)	21 (6%)	0.8989 (0.4738, 1.7054) /0.744	-0.6116 (-4.2844, 3.0611) /0.744	0.9048 (0.4959, 1.6508) /0.744
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
Pruritus					
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	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 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
Rash					
Any Event	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 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	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
Eczema					
Any Event	7 (2%)	13 (4%)	0.5284 (0.2081, 1.3417) /0.180	-1.8349 (-4.4703, 0.8006) /0.172	0.5385 (0.2176, 1.3323) /0.180
Max Grade 1	5 (2%)	11 (3%)	0.4461 (0.1532, 1.2985) /0.139	-1.8349 (-4.1987, 0.5290) /0.128	0.4545 (0.1597, 1.2937) /0.140
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	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
Skin lesion					
Any Event	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 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%)	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
Acne					
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%)	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	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
Dermatitis					
Any Event	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 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%)	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

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
Hyperhidrosis					
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	0	3 (<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.

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

System Organ 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	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.

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

System Organ 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	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%)	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%)	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
Seborrhoeic dermatitis					
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

Urticaria					
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.

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

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

Dermatitis atopic					
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	3 (<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
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			
Dry skin					
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
Pityriasis rosea 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

Skin exfoliation					
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			
Skin mass					
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

Actinic keratosis					
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			
Chloasma					
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
Ecchymosis					
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.

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

Psoriasis					
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			
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			

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

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

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

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

System Organ 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%)	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			
Rash papular 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
Actinic elastosis					
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

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			
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
<hr/>					
Dermatosis					
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			
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
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	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
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

Guttate psoriasis					
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			
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			

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

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

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

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

System Organ 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 bleeding					
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			
Nail dystrophy					
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
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			
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			

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

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

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

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			
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			

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

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

System Organ 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					
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			
Prurigo					
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

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			
Rash macular					
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 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
<hr/>					
Skin fissures					
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			
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			

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

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

System Organ 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 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			
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			

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

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

System Organ 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 ulcer					
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			
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
Solar lentigo					
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	65 (20%)	76 (23%)	0.8194 (0.5639, 1.1905) /0.296	-3.3639 (-9.6621, 2.9343) /0.295	0.8553 (0.6377, 1.1470) /0.296
Max Grade 1	45 (14%)	48 (15%)	0.9275 (0.5979, 1.4388) /0.737	-0.9174 (-6.2704, 4.4356) /0.737	0.9375 (0.6432, 1.3664) /0.737
Max Grade 2	18 (6%)	26 (8%)	0.6744 (0.3622, 1.2556) /0.214	-2.4465 (-6.2817, 1.3887) /0.211	0.6923 (0.3872, 1.2378) /0.215
Max Grade 3	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 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit 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	30 (9%)	34 (10%)	0.8705 (0.5192, 1.4595) /0.599	-1.2232 (-5.7766, 3.3302) /0.599	0.8824 (0.5535, 1.4067) /0.599
Max Grade 1	23 (7%)	21 (6%)	1.1024 (0.5975, 2.0340) /0.755	0.6116 (-3.2278, 4.4511) /0.755	1.0952 (0.6185, 1.9393) /0.755
Max Grade 2	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 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
Dizziness					
Any Event	17 (5%)	14 (4%)	1.2260 (0.5940, 2.5304) /0.581	0.9174 (-2.3389, 4.1738) /0.581	1.2143 (0.6087, 2.4223) /0.582
Max Grade 1	15 (5%)	10 (3%)	1.5240 (0.6744, 3.4440) /0.311	1.5291 (-1.4077, 4.4658) /0.307	1.5000 (0.6840, 3.2897) /0.312
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	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit 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
Presyncope					
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	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	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
Hypoaesthesia					
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%)	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	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
Migraine					
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%)	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	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
Paraesthesia 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	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	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
Sciatica					
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	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%)	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
Somnolence					
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
-----	-----	-----	-----	-----	-----
Syncope					
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%)	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	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
Lethargy					
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	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

Tension headache					
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			
Carpal tunnel syndrome					
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
Cervical radiculopathy 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
Disturbance in attention					
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.

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

System Organ 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.

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

Agnosia					
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			
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			

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

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

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

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

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			
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
<hr/>					
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
Memory impairment					
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 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
<hr/>					
Neuritis cranial					
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			
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.

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

System Organ 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

Transient ischaemic attack					
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			
Tremor					
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
Trigeminal neuralgia					
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
Respiratory, thoracic and mediastinal disorders					
Any Event	52 (16%)	77 (24%)	0.6139 (0.4151, 0.9079) /0.015	-7.6453 (-13.7164, -1.5741) /0.014	0.6753 (0.4920, 0.9269) /0.015
Max Grade 1	40 (12%)	56 (17%)	0.6745 (0.4351, 1.0456) /0.078	-4.8930 (-10.3045, 0.5186) /0.076	0.7143 (0.4906, 1.0400) /0.079
Max Grade 2	12 (4%)	20 (6%)	0.5848 (0.2810, 1.2168) /0.151	-2.4465 (-5.7478, 0.8548) /0.146	0.6000 (0.2982, 1.2071) /0.152
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	21 (6%)	27 (8%)	0.7625 (0.4218, 1.3785) /0.369	-1.8349 (-5.8297, 2.1600) /0.368	0.7778 (0.4491, 1.3471) /0.370
Max Grade 1	16 (5%)	23 (7%)	0.6800 (0.3524, 1.3122) /0.250	-2.1407 (-5.7668, 1.4854) /0.247	0.6957 (0.3745, 1.2923) /0.251
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	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit 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	11 (3%)	19 (6%)	0.5643 (0.2642, 1.2054) /0.140	-2.4465 (-5.6477, 0.7548) /0.134	0.5789 (0.2800, 1.1973) /0.140
Max Grade 1	10 (3%)	16 (5%)	0.6132 (0.2740, 1.3721) /0.234	-1.8349 (-4.8264, 1.1567) /0.229	0.6250 (0.2879, 1.3567) /0.235
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.

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

System Organ 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	6 (2%)	10 (3%)	0.5925 (0.2128, 1.6497) /0.316	-1.2232 (-3.5894, 1.1429) /0.311	0.6000 (0.2206, 1.6317) /0.317
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%)	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
Nasal congestion					
Any Event	5 (2%)	9 (3%)	0.5487 (0.1819, 1.6551) /0.287	-1.2232 (-3.4398, 0.9933) /0.279	0.5556 (0.1882, 1.6399) /0.287
Max Grade 1	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 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
Sinus congestion					
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

Asthma					
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.

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

System Organ 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%)	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 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	3 (<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
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
Dyspnoea					
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%)	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%)	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	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%)	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	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit 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
Rhinorrhoea					
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			
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			

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

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

System Organ 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
Nasal 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%)	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.

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 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

Respiratory disorder					
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			
Emphysema					
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
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			
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.

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
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	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

Pharyngeal 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			
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 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	43 (13%)	77 (24%)	0.4916 (0.3262, 0.7407) /<.001	-10.3976 (-16.2768, -4.5183) /<.001	0.5584 (0.3974, 0.7847) /<.001
Max Grade 1	26 (8%)	49 (15%)	0.4901 (0.2964, 0.8102) /0.005	-7.0336 (-11.8879, -2.1794) /0.005	0.5306 (0.3383, 0.8323) /0.006
Max Grade 2	15 (5%)	28 (9%)	0.5134 (0.2689, 0.9804) /0.043	-3.9755 (-7.7623, -0.1888) /0.040	0.5357 (0.2916, 0.9841) /0.044
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
Contusion					
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%)	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 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	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%)	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%)	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
Arthropod bite					
Any Event	2 (<1%)	10 (3%)	0.1951 (0.0424, 0.8973) /0.036	-2.4465 (-4.4951, -0.3979) /0.019	0.2000 (0.0442, 0.9057) /0.037
Max Grade 1	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 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
Exposure to communicable disease					
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%)	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%)	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	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
Muscle strain					
Any Event	3 (<1%)	9 (3%)	0.3272 (0.0878, 1.2195) /0.096	-1.8349 (-3.8872, 0.2175) /0.080	0.3333 (0.0911, 1.2202) /0.097
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	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
Limb injury					
Any Event	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 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	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
Skin laceration					
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%)	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	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.

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

System Organ 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%)	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
Arthropod sting					
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	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
Foot fracture					
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	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	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
Rib fracture 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.

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
Vaccination complication					
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	3 (<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
Bone contusion					
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.

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

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

Procedural pain					
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			
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.

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

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

Ankle fracture					
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			
Head injury					
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
<hr/>					
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
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			
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			
Eye 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	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
Face injury					
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			
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			

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

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

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

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

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

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

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

System Organ 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 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			
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			

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

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

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

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

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

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

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

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

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

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

System Organ 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/>					
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			
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			

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

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

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

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
Wound					
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
Psychiatric disorders					
Any Event	53 (16%)	56 (17%)	0.9361 (0.6203, 1.4125) /0.753	-0.9174 (-6.6295, 4.7946) /0.753	0.9464 (0.6717, 1.3335) /0.753
Max Grade 1	33 (10%)	34 (10%)	0.9673 (0.5834, 1.6036) /0.897	-0.3058 (-4.9538, 4.3421) /0.897	0.9706 (0.6166, 1.5279) /0.897
Max Grade 2	20 (6%)	20 (6%)	1.0000 (0.5275, 1.8958) />0.999	<0.0001 (-3.6730, 3.6730) />0.999	1.0000 (0.5485, 1.8231) />0.999
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.

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
Insomnia					
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	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 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

Anxiety					
Any Event	20 (6%)	12 (4%)	1.7101 (0.8219, 3.5583) /0.151	2.4465 (-0.8548, 5.7478) /0.146	1.6667 (0.8284, 3.3531) /0.152
Max Grade 1	10 (3%)	6 (2%)	1.6877 (0.6062, 4.6988) /0.316	1.2232 (-1.1429, 3.5894) /0.311	1.6667 (0.6129, 4.5325) /0.317
Max Grade 2	10 (3%)	6 (2%)	1.6877 (0.6062, 4.6988) /0.316	1.2232 (-1.1429, 3.5894) /0.311	1.6667 (0.6129, 4.5325) /0.317
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit 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	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	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	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
Sleep disorder Any Event	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 1	0	5 (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.

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	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
Depressed mood					
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	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 2	0	0	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
Libido decreased					
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	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	0	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
Nightmare 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
Major depression 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	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	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
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	1 (<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	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

System Organ 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%)	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.

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

System Organ 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	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

Stress					
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.

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

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

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

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

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Generalised anxiety disorder					
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
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			
Restlessness					
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
Suicidal ideation					
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
Acute 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.

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	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			
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			

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

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

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

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

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

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

Emotional distress					
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			
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			

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

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

System Organ 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/>					
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			
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			

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

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

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

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
Psychotic disorder					
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
Investigations					
Any Event	24 (7%)	41 (13%)	0.5525 (0.3255, 0.9378) /0.028	-5.1988 (-9.7673, -0.6302) /0.026	0.5854 (0.3623, 0.9459) /0.029
Max Grade 1	16 (5%)	26 (8%)	0.5956 (0.3132, 1.1325) /0.114	-3.0581 (-6.8084, 0.6922) /0.110	0.6154 (0.3365, 1.1254) /0.115
Max Grade 2	5 (2%)	13 (4%)	0.3751 (0.1322, 1.0644) /0.065	-2.4465 (-4.9472, 0.0542) /0.055	0.3846 (0.1387, 1.0666) /0.066
Max Grade 3	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 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit 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
Weight increased					
Any Event	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 1	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 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

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
Blood creatine phosphokinase increased					
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%)	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	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	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
Alanine aminotransferase 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	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	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 cholesterol increased					
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%)	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	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
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
Weight 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%)	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	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
Blood glucose increased					
Any Event	3 (<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	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
Blood triglycerides increased					
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
Lipase 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	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	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
Low density lipoprotein 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%)	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.

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

System Organ 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	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
Blood creatinine 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.

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
Creatinine renal clearance decreased					
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
Transaminases increased					
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
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 pressure decreased					
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.

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
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	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
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.

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
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
Electrocardiogram abnormal 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
Epstein-Barr virus 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

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 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	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
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 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	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
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
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

Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
Any Event	18 (6%)	29 (9%)	0.5986 (0.3255, 1.1009) /0.099	-3.3639 (-7.3142, 0.5864) /0.095	0.6207 (0.3518, 1.0951) /0.100
Max Grade 1	12 (4%)	23 (7%)	0.5035 (0.2462, 1.0298) /0.060	-3.3639 (-6.8040, 0.0762) /0.055	0.5217 (0.2641, 1.0308) /0.061
Max Grade 2	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 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	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 5	0	0			

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

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

System Organ 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	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	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	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

Skin papilloma					
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	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 2	0	0	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	3 (<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	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
Fibrous histiocytoma 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
Adenoma benign					
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
Breast cancer					
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%)	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			
Lipoma					
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
Lipoma of breast 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			
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			

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

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

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Adrenal adenoma 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			
Benign neoplasm of thyroid gland 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

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
Testicular neoplasm					
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.

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
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

Reproductive system and breast disorders					
Any Event	26 (8%)	21 (6%)	1.2587 (0.6931, 2.2858) /0.450	1.5291 (-2.4279, 5.4860) /0.449	1.2381 (0.7113, 2.1550) /0.450
Max Grade 1	17 (5%)	13 (4%)	1.3246 (0.6326, 2.7734) /0.456	1.2232 (-1.9821, 4.4286) /0.454	1.3077 (0.6457, 2.6483) /0.456
Max Grade 2	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 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
Erectile dysfunction 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%)	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 2	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 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

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

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

Genital lesion					
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	2 (<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			
Menorrhagia					
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
Breast cyst 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
Cervical dysplasia					
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
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			
Breast 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
<hr/>					
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			
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			

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

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit 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 odour					
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			
Haemospermia					
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

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			
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			

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

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

System Organ 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 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			
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
Penile 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			
Premenstrual 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			

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

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

System Organ 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
Sexual 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			
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 swelling					
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

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

Vascular disorders					
Any Event	19 (6%)	19 (6%)	1.0000 (0.5193, 1.9256) />0.999	<0.0001 (-3.5859, 3.5859) />0.999	1.0000 (0.5395, 1.8536) />0.999
Max Grade 1	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 2	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 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

System Organ 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	12 (4%)	11 (3%)	1.0944 (0.4758, 2.5170) /0.832	0.3058 (-2.5176, 3.1292) /0.832	1.0909 (0.4884, 2.4367) /0.832
Max Grade 1	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 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.

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

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

Haematoma					
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			
Varicose vein					
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	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	0	0	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
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			
Hot flush					
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
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
<hr/>					
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			
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			

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

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

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Phlebitis					
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			
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
Thrombophlebitis superficial					
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
Renal and urinary disorders					
Any Event	9 (3%)	28 (9%)	0.3022 (0.1403, 0.6511) /0.002	-5.8104 (-9.3235, -2.2973) /0.001	0.3214 (0.1541, 0.6705) /0.002
Max Grade 1	5 (2%)	21 (6%)	0.2263 (0.0843, 0.6076) /0.003	-4.8930 (-7.8643, -1.9217) /0.001	0.2381 (0.0909, 0.6238) /0.003
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	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%)	9 (3%)	0.3272 (0.0878, 1.2195) /0.096	-1.8349 (-3.8872, 0.2175) /0.080	0.3333 (0.0911, 1.2202) /0.097
Max Grade 1	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 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

Nephrolithiasis					
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
Nocturia					
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%)	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	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
Renal colic 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	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	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
Haematuria					
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			
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			

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

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

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

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

System Organ 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.

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 cyst					
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			
Urethral discharge					
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

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			
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			

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

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

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

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

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

Metabolism and nutrition disorders					
Any Event	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 1	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 2	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 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	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%)	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%)	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	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 deficiency					
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%)	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.

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

System Organ 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	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			
Gout					
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
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

Alcoholic ketoacidosis					
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			
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			

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

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

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

Diabetes mellitus					
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			
Dyslipidaemia					
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

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			
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			

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

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

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

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

System Organ 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
Hypertriglycerid aemia					
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	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

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			
Iron deficiency 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	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 1	5 (2%)	15 (5%)	0.3230 (0.1160, 0.8993) /0.031	-3.0581 (-5.6869, -0.4293) /0.023	0.3333 (0.1226, 0.9065) /0.031
Max Grade 2	9 (3%)	4 (1%)	2.2854 (0.6967, 7.4967) /0.173	1.5291 (-0.6072, 3.6653) /0.161	2.2500 (0.6999, 7.2334) /0.173
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
Cataract					
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	0	2 (<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.

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

System Organ 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	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.

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
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.

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
Retinal detachment					
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%)	0	>999 (>999, >999) /NC	NC	>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
Diplopia					
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

Dry eye					
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			
Astigmatism					
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
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			
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			

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

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

System Organ 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 eyelids					
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
<hr/>					
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
Macular 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			
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			

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

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

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

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

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

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			
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			

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

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

System Organ 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 tear					
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			
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.

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
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 detachment					
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
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

Ear and labyrinth disorders					
Any Event	10 (3%)	16 (5%)	0.6132 (0.2740, 1.3721) /0.234	-1.8349 (-4.8264, 1.1567) /0.229	0.6250 (0.2879, 1.3567) /0.235
Max Grade 1	10 (3%)	13 (4%)	0.7620 (0.3293, 1.7633) /0.525	-0.9174 (-3.7401, 1.9052) /0.524	0.7692 (0.3422, 1.7292) /0.526
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.

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
Tinnitus					
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
Vertigo					
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	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	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

Cerumen impaction					
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	NC	NC	NC
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.

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

System Organ 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 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			
Eustachian tube dysfunction					
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
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 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			

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

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

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

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

System Organ 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	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	7 (2%)	5 (2%)	1.4087 (0.4425, 4.4849) /0.562	0.6116 (-1.4450, 2.6683) /0.560	1.4000 (0.4489, 4.3659) /0.562
Max Grade 2	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 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
Seasonal allergy					
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
Max Grade 1	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 2	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 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit 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.

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
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	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
Drug hypersensitivity					
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.

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

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

Anaphylactic reaction					
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 and lymphatic system disorders					
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	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	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	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

Lymphadenopathy					
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	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	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Anaemia					
Any Event	0	5 (2%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	5 (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
Microcytic anaemia					
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	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

Iron deficiency anaemia					
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%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>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
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	NC	NC	NC
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	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
Polycythaemia					
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

Cardiac disorders					
Any Event	6 (2%)	11 (3%)	0.5370 (0.1962, 1.4695) /0.226	-1.5291 (-3.9652, 0.9071) /0.219	0.5455 (0.2041, 1.4575) /0.227
Max Grade 1	0	4 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />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	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.

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
Palpitations					
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
Tachycardia					
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
Ventricular extrasystoles 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.

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 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			

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

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit 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

Atrioventricular block first degree					
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
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			
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.

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

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

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

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit 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
Myocardial necrosis					
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
Sinus bradycardia					
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
Wolff-Parkinson-White 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	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

Hepatobiliary disorders					
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%)	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	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
<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			
Hepatic steatosis					
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

Hepatocellular injury					
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			
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			

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

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit 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%)	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	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
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			

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

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit 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

Gilbert's 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			
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	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.

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

System Organ 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/>					
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			
Androgen deficiency					
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

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			
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	34 (10%)	43 (13%)	0.7664 (0.4750, 1.2367) /0.276	-2.7523 (-7.6880, 2.1834) /0.274	0.7907 (0.5180, 1.2069) /0.276
General disorders and administration site conditions					
Any Event	10 (3%)	19 (6%)	0.5114 (0.2340, 1.1173) /0.093	-2.7523 (-5.9006, 0.3960) /0.087	0.5263 (0.2486, 1.1145) /0.094
Injection site pain	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
Pyrexia	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
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
Malaise	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

Infections and infestations					
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
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
Pneumonia	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
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

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

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit 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
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
Herpes zoster	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Injection site abscess	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Proctitis chlamydial	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
Tonsillitis	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Viral infection	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Musculoskeletal and connective tissue disorders 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
Intervertebral disc protrusion	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Myalgia	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
Osteonecrosis	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
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
Osteoarthritis	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
Investigations 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
Body temperature increased	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Creatinine renal clearance decreased	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Lipase 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

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

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit 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
White blood cell count decreased	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	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
Breast cancer	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.

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
Testicular neoplasm	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%)	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
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
Toothache	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Nervous system 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
Cerebrovascular accident	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Disturbance in attention	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Headache	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
Neuritis cranial	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Cardiac disorders Any Event	0	2 (<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
Myocardial infarction	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Ventricular extrasystoles	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

Immune system disorders					
Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Drug hypersensitivity	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
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

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, 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
Foot fracture	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
Psychiatric disorders Any Event	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
Major depression	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

Skin and subcutaneous tissue disorders					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Eczema	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Hyperhidrosis	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
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

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
Retinal detachment	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

Hepatobiliary disorders					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Hepatocellular injury	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.

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

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
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

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

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit 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

Reproductive system and breast disorders					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Genital odour	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.

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	22 (7%)	16 (5%)	1.4020 (0.7224, 2.7210) /0.318	1.8349 (-1.7482, 5.4180) /0.316	1.3750 (0.7356, 2.5700) /0.318
Infections and infestations					
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
Pneumonia	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
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 3.03

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
Cellulitis of male external genital organ	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
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
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.

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
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
Haemorrhoids	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.

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 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
Musculoskeletal and connective tissue 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
Osteonecrosis	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.

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
Intervertebral disc protrusion	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Osteoarthritis	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
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	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
Breast cancer	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
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
Testicular neoplasm	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%)	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
Gastrointestinal procedural complication	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
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
Nervous system 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
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

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

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit 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
Transient ischaemic attack	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Immune system disorders					
Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Drug hypersensitivity	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
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
Myocardial infarction	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

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

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, 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
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
Respiratory, thoracic and mediastinal 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 3.03

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
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	14 (4%)	15 (5%)	0.9304 (0.4417, 1.9598) /0.849	-0.3058 (-3.4611, 2.8495) /0.849	0.9333 (0.4579, 1.9023) /0.849
General disorders and administration site conditions					
Any Event	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
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
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

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, 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
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 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

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

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit 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 warmth	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Malaise	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Nervous system disorders					
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
Headache	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
Disturbance in attention	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 3.04
 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
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
Skin and subcutaneous tissue disorders					
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
Hyperhidrosis	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
Rash maculo-papular	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
Skin lesion	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
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.

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	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
Breast cancer	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
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
Testicular neoplasm	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	4 (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
Sleep disorder	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

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, 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

Gastrointestinal disorders					
Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Nausea	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Immune system disorders					
Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Drug hypersensitivity	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 3.04
 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	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
Myalgia	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Osteonecrosis	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
Myocardial infarction	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

Ear and labyrinth disorders					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Vertigo	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 3.06
 Analysis of AESI - Proportion of Subjects with Any Adverse Event of Hepatotoxicity
 by Severity (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Subjects with Any Adverse Event of Hepatotoxicity					
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	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 3.07

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	0	2 (<1%)	<0.0001 (<0.0001, -) NC />0.999		<0.0001 (<0.0001, -) />0.999
Max Grade 1 or 2	0	0	NC	NC	NC
Max Grade 3 or 4	0	2 (<1%)	<0.0001 (<0.0001, -) NC />0.999		<0.0001 (<0.0001, -) />0.999
Any Serious AE	0	2 (<1%)	<0.0001 (<0.0001, -) NC />0.999		<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	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 or 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 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)

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		7 (2%)	7 (2%)	1.0000 (0.3468, 2.8836) />0.999	<0.0001 (-2.2185, 2.2185) />0.999	1.0000 (0.3547, 2.8190) />0.999	
Age (years)	<35	2/ 84 (2%)	1/ 98 (1%)				
	35 - <50	2/154 (1%)	6/143 (4%)				
	>=50	3/ 89 (3%)	0/ 86				
Sex at Birth	Female	1/ 73 (1%)	0/ 75	>999 (>999, >999) /NC	3.6449 (-19.9869, 27.2768) /0.762	>999 (>999, >999) /NC	0.220
	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 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 3.12
 Analysis of AESI - Proportion of Subjects with Any Event of Weight Gain by Severity
 (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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)
Race	White	6/239 (3%)	7/256 (3%)	0.9160 (0.3034, 2.7655) /0.876	-0.2239 (-3.0390, 2.5912) /0.876	0.9181 (0.3130, 2.6930) /0.876	0.272
	Non-White	1/ 88 (1%)	0/ 71	>999 (>999, >999) /NC	3.4034 (-20.7049, 27.5117) /0.782	>999 (>999, >999) /NC	
Region	North America	4/118 (3%)	4/135 (3%)				
	Europe	2/165 (1%)	2/155 (1%)				
	Rest of World	1/ 44 (2%)	1/ 37 (3%)				

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 3.12
 Analysis of AESI - Proportion of Subjects with Any Event of Weight Gain by Severity
 (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

AE type: Maximum Toxicity Grade 1 or 2				OR (95%CI)	RD (95%CI)	RR (95%CI)	Interaction
Subgroup	Category	Q8W (N=327)	Q4W (N=327)	/p-value	/p-value	/p-value	p-value(RR)
Overall		7 (2%)	7 (2%)	1.0000 (0.3468, 2.8836) />0.999	<0.0001 (-2.2185, 2.2185) />0.999	1.0000 (0.3547, 2.8190) />0.999	
Age (years)	<35	2/ 84 (2%)	1/ 98 (1%)				
	35 - <50	2/154 (1%)	6/143 (4%)				
	>=50	3/ 89 (3%)	0/ 86				
Sex at Birth	Female	1/ 73 (1%)	0/ 75	>999 (>999, >999) /NC	3.6449 (-19.9869, 27.2768) /0.762	>999 (>999, >999) /NC	0.220
	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 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 3.12
 Analysis of AESI - Proportion of Subjects with Any Event of Weight Gain by Severity
 (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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)
Race	White	6/239 (3%)	7/256 (3%)	0.9160 (0.3034, 2.7655) /0.876	-0.2239 (-3.0390, 2.5912) /0.876	0.9181 (0.3130, 2.6930) /0.876	0.272
	Non-White	1/ 88 (1%)	0/ 71	>999 (>999, >999) /NC	3.4034 (-20.7049, 27.5117) /0.782	>999 (>999, >999) /NC	
Region	North America	4/118 (3%)	4/135 (3%)				
	Europe	2/165 (1%)	2/155 (1%)				
	Rest of World	1/ 44 (2%)	1/ 37 (3%)				

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 3.12
 Analysis of AESI - Proportion of Subjects with Any Event of Weight Gain by Severity
 (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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	0/239	0/256				
	Non-White	0/ 88	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 3.12
 Analysis of AESI - Proportion of Subjects with Any Event of Weight Gain by Severity
 (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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)
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. 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)

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	0/239	0/256				
	Non-White	0/ 88	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 3.12
 Analysis of AESI - Proportion of Subjects with Any Event of Weight Gain by Severity
 (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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. 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		285 (87%)	271 (83%)	1.4022 (0.9092, 2.1626) /0.126	4.2813 (-1.1797, 9.7424) /0.124	1.0517 (0.9860, 1.1217) /0.126	
Age (years)	<35	79/ 84 (94%)	81/ 98 (83%)	3.3160 (1.1672, 9.4211) /0.024	11.3946 (2.3501, 20.4391) /0.014	1.1379 (1.0240, 1.2644) /0.016	0.184
	35 - <50	135/154 (88%)	119/143 (83%)	1.4330 (0.7478, 2.7460) /0.278	4.4456 (-3.5855, 12.4766) /0.278	1.0534 (0.9584, 1.1578) /0.280	
	>=50	71/ 89 (80%)	71/ 86 (83%)	0.8333 (0.3897, 1.7820) /0.638	-2.7829 (-14.3570, 8.7913) /0.637	0.9663 (0.8377, 1.1146) /0.638	

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	57/ 73 (78%)	54/ 75 (72%)	1.3854 (0.6548, 2.9311) /0.394	6.0822 (-7.8216, 19.9860) /0.391	1.0845 (0.9002, 1.3065) /0.393	0.694
	Male	228/254 (90%)	217/252 (86%)	1.4144 (0.8239, 2.4281) /0.209	3.6527 (-2.0155, 9.3208) /0.207	1.0424 (0.9771, 1.1121) /0.208	
Race	White	210/239 (88%)	216/256 (84%)	1.3410 (0.8017, 2.2429) /0.264	3.4911 (-2.5850, 9.5672) /0.260	1.0414 (0.9703, 1.1177) /0.261	0.517
	Non-White	75/ 88 (85%)	55/ 71 (77%)	1.6783 (0.7464, 3.7740) /0.210	7.7625 (-4.4609, 19.9859) /0.213	1.1002 (0.9444, 1.2817) /0.220	

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	101/118 (86%)	106/135 (79%)	1.6254 (0.8419, 3.1379) /0.148	7.0747 (-2.3136, 16.4630) /0.140	1.0901 (0.9715, 1.2232) /0.142	0.567
	Europe	150/165 (91%)	135/155 (87%)	1.4815 (0.7293, 3.0094) /0.277	3.8123 (-3.0502, 10.6748) /0.276	1.0438 (0.9660, 1.1278) /0.278	
	Rest of World	34/ 44 (77%)	30/ 37 (81%)	0.7933 (0.2685, 2.3443) /0.675	-3.8084 (-21.4885, 13.8718) /0.673	0.9530 (0.7622, 1.1916) /0.673	

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		276 (84%)	253 (77%)	1.5829 (1.0659, 2.3505) /0.023	7.0336 (1.0309, 13.0364) /0.022	1.0909 (1.0122, 1.1757) /0.023	
Age (years)	<35	78/ 84 (93%)	77/ 98 (79%)	3.5455 (1.3570, 9.2631) /0.010	14.2857 (4.4709, 24.1005) /0.004	1.1818 (1.0490, 1.3314) /0.006	0.297
	35 - <50	130/154 (84%)	111/143 (78%)	1.5616 (0.8684, 2.8079) /0.137	6.7932 (-2.1218, 15.7082) /0.135	1.0875 (0.9731, 1.2153) /0.139	
	>=50	68/ 89 (76%)	65/ 86 (76%)	1.0462 (0.5227, 2.0938) /0.899	0.8231 (-11.8360, 13.4822) /0.899	1.0109 (0.8557, 1.1942) /0.899	

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	56/ 73 (77%)	52/ 75 (69%)	1.4570 (0.7009, 3.0287) /0.313	7.3790 (-6.8657, 21.6237) /0.310	1.1064 (0.9090, 1.3467) /0.313	0.862
	Male	220/254 (87%)	201/252 (80%)	1.6418 (1.0218, 2.6380) /0.040	6.8523 (0.3606, 13.3439) /0.039	1.0859 (1.0037, 1.1749) /0.040	
Race	White	203/239 (85%)	199/256 (78%)	1.6152 (1.0188, 2.5606) /0.041	7.2029 (0.3812, 14.0246) /0.039	1.0927 (1.0041, 1.1891) /0.040	0.985
	Non-White	73/ 88 (83%)	54/ 71 (76%)	1.5321 (0.7035, 3.3367) /0.283	6.8982 (-5.7609, 19.5574) /0.286	1.0907 (0.9283, 1.2816) /0.291	

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	96/118 (81%)	97/135 (72%)	1.7095 (0.9419, 3.1027) /0.078	9.5041 (-0.8366, 19.8448) /0.072	1.1323 (0.9879, 1.2978) /0.074	0.445
	Europe	146/165 (88%)	126/155 (81%)	1.7686 (0.9460, 3.3063) /0.074	7.1945 (-0.6423, 15.0313) /0.072	1.0885 (0.9914, 1.1951) /0.075	
	Rest of World	34/ 44 (77%)	30/ 37 (81%)	0.7933 (0.2685, 2.3443) /0.675	-3.8084 (-21.4885, 13.8718) /0.673	0.9530 (0.7622, 1.1916) /0.673	

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		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	
Age (years)	<35	1/ 84 (1%)	4/ 98 (4%)	0.2831 (0.0310, 2.5838) /0.263	-2.8912 (-7.4437, 1.6614) /0.213	0.2917 (0.0332, 2.5592) /0.266	0.846
	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	3/ 89 (3%)	6/ 86 (7%)	0.4651 (0.1125, 1.9222) /0.290	-3.6060 (-10.1671, 2.9552) /0.281	0.4831 (0.1248, 1.8709) /0.292	

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	0.978
	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	
Race	White	7/239 (3%)	17/256 (7%)	0.4242 (0.1727, 1.0418) /0.061	-3.7118 (-7.4364, 0.0129) /0.051	0.4411 (0.1862, 1.0447) /0.063	0.298
	Non-White	2/ 88 (2%)	1/ 71 (1%)	1.6279 (0.1446, 18.3272) /0.693	0.8643 (-3.2841, 5.0126) /0.683	1.6136 (0.1493, 17.4353) /0.694	

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	NC
	Europe	4/165 (2%)	9/155 (6%)	0.4030 (0.1215, 1.3367) /0.137	-3.3822 (-7.7482, 0.9838) /0.129	0.4175 (0.1312, 1.3281) /0.139	
	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	1/239 (<1%)	0/256				
	Non-White	0/ 88	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		12 (4%)	21 (6%)	0.5551 (0.2684, 1.1479) /0.112	-2.7523 (-6.1008, 0.5962) /0.107	0.5714 (0.2859, 1.1421) /0.113	
Age (years)	<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	0.878
	35 - <50	4/154 (3%)	7/143 (5%)	0.5181 (0.1484, 1.8087) /0.303	-2.2977 (-6.6356, 2.0402) /0.299	0.5306 (0.1587, 1.7744) /0.304	
	>=50	3/ 89 (3%)	6/ 86 (7%)	0.4651 (0.1125, 1.9222) /0.290	-3.6060 (-10.1671, 2.9552) /0.281	0.4831 (0.1248, 1.8709) /0.292	

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	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	0.653
	Male	9/254 (4%)	17/252 (7%)	0.5078 (0.2220, 1.1617) /0.108	-3.2027 (-7.0444, 0.6390) /0.102	0.5252 (0.2386, 1.1561) /0.110	
Race	White	8/239 (3%)	14/256 (5%)	0.5986 (0.2465, 1.4536) /0.257	-2.1215 (-5.7211, 1.4782) /0.248	0.6121 (0.2615, 1.4329) /0.258	0.703
	Non-White	4/ 88 (5%)	7/ 71 (10%)	0.4354 (0.1222, 1.5515) /0.200	-5.3137 (-13.5005, 2.8731) /0.203	0.4610 (0.1405, 1.5125) /0.201	

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: 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	4/118 (3%)	10/135 (7%)	0.4386 (0.1338, 1.4374) /0.174	-4.0176 (-9.5110, 1.4759) /0.152	0.4576 (0.1474, 1.4208) /0.176	0.795
	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	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 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		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		12 (4%)	21 (6%)	0.5551 (0.2684, 1.1479) /0.112	-2.7523 (-6.1008, 0.5962) /0.107	0.5714 (0.2859, 1.1421) /0.113	
Age (years)	<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	0.878
	35 - <50	4/154 (3%)	7/143 (5%)	0.5181 (0.1484, 1.8087) /0.303	-2.2977 (-6.6356, 2.0402) /0.299	0.5306 (0.1587, 1.7744) /0.304	
	>=50	3/ 89 (3%)	6/ 86 (7%)	0.4651 (0.1125, 1.9222) /0.290	-3.6060 (-10.1671, 2.9552) /0.281	0.4831 (0.1248, 1.8709) /0.292	

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		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	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	0.653
	Male	9/254 (4%)	17/252 (7%)	0.5078 (0.2220, 1.1617) /0.108	-3.2027 (-7.0444, 0.6390) /0.102	0.5252 (0.2386, 1.1561) /0.110	
Race	White	8/239 (3%)	14/256 (5%)	0.5986 (0.2465, 1.4536) /0.257	-2.1215 (-5.7211, 1.4782) /0.248	0.6121 (0.2615, 1.4329) /0.258	0.703
	Non-White	4/ 88 (5%)	7/ 71 (10%)	0.4354 (0.1222, 1.5515) /0.200	-5.3137 (-13.5005, 2.8731) /0.203	0.4610 (0.1405, 1.5125) /0.201	

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		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)
Region	North America	4/118 (3%)	10/135 (7%)	0.4386 (0.1338, 1.4374) /0.174	-4.0176 (-9.5110, 1.4759) /0.152	0.4576 (0.1474, 1.4208) /0.176	0.795
	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	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 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	0/239	0/256				
	Non-White	0/ 88	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		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)
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	0/239	0/256				
	Non-White	0/ 88	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: 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		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		51 (16%)	58 (18%)	0.8570 (0.5676, 1.2940) /0.463	-2.1407 (-7.8508, 3.5694) /0.462	0.8793 (0.6236, 1.2398) /0.463	
Age (years)	<35	19/ 84 (23%)	19/ 98 (19%)	1.2154 (0.5942, 2.4860) /0.593	3.2313 (-8.6559, 15.1185) /0.594	1.1667 (0.6630, 2.0531) /0.593	0.517
	35 - <50	23/154 (15%)	28/143 (20%)	0.7211 (0.3935, 1.3215) /0.290	-4.6454 (-13.2472, 3.9565) /0.290	0.7628 (0.4615, 1.2606) /0.291	
	>=50	9/ 89 (10%)	11/ 86 (13%)	0.7670 (0.3010, 1.9549) /0.578	-2.6783 (-12.1155, 6.7588) /0.578	0.7906 (0.3449, 1.8124) /0.579	

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	2/ 73 (3%)	10/ 75 (13%)	0.1831 (0.0387, 0.8670) /0.032	-10.5936 (-19.1498, -2.0374) /0.015	0.2055 (0.0466, 0.9059) /0.037	0.018
	Male	49/254 (19%)	48/252 (19%)	1.0159 (0.6525, 1.5816) /0.944	0.2437 (-6.6158, 7.1032) /0.944	1.0128 (0.7081, 1.4486) /0.944	
Race	White	41/239 (17%)	43/256 (17%)	1.0257 (0.6414, 1.6404) /0.916	0.3579 (-6.2613, 6.9772) /0.916	1.0213 (0.6916, 1.5082) /0.916	0.127
	Non-White	10/ 88 (11%)	15/ 71 (21%)	0.4786 (0.2004, 1.1432) /0.097	-9.7631 (-21.3444, 1.8181) /0.098	0.5379 (0.2575, 1.1235) /0.099	

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	20/118 (17%)	26/135 (19%)	0.8556 (0.4495, 1.6285) /0.635	-2.3101 (-11.8008, 7.1806) /0.633	0.8801 (0.5190, 1.4922) /0.635	0.439
	Europe	23/165 (14%)	28/155 (18%)	0.7347 (0.4027, 1.3403) /0.315	-4.1251 (-12.1633, 3.9130) /0.314	0.7716 (0.4652, 1.2800) /0.315	
	Rest of World	8/ 44 (18%)	4/ 37 (11%)	1.8333 (0.5047, 6.6590) /0.357	7.3710 (-7.7942, 22.5362) /0.341	1.6818 (0.5500, 5.1431) /0.362	

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		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		51 (16%)	55 (17%)	0.9138 (0.6027, 1.3855) /0.671	-1.2232 (-6.8712, 4.4248) /0.671	0.9273 (0.6542, 1.3143) /0.671	
Age (years)	<35	19/ 84 (23%)	18/ 98 (18%)	1.2991 (0.6305, 2.6770) /0.478	4.2517 (-7.5303, 16.0338) /0.479	1.2315 (0.6929, 2.1886) /0.478	0.516
	35 - <50	23/154 (15%)	27/143 (19%)	0.7543 (0.4100, 1.3878) /0.365	-3.9461 (-12.4804, 4.5883) /0.365	0.7910 (0.4762, 1.3139) /0.365	
	>=50	9/ 89 (10%)	10/ 86 (12%)	0.8550 (0.3294, 2.2190) /0.747	-1.5155 (-10.7423, 7.7113) /0.748	0.8697 (0.3716, 2.0355) /0.748	

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	2/ 73 (3%)	9/ 75 (12%)	0.2066 (0.0430, 0.9913) /0.049	-9.2603 (-17.5131, -1.0074) /0.028	0.2283 (0.0510, 1.0211) /0.053	0.026
	Male	49/254 (19%)	46/252 (18%)	1.0704 (0.6850, 1.6727) /0.765	1.0374 (-5.7666, 7.8414) /0.765	1.0568 (0.7353, 1.5189) /0.765	
Race	White	41/239 (17%)	40/256 (16%)	1.1182 (0.6944, 1.8005) /0.646	1.5298 (-4.9990, 8.0587) /0.646	1.0979 (0.7372, 1.6351) /0.646	0.091
	Non-White	10/ 88 (11%)	15/ 71 (21%)	0.4786 (0.2004, 1.1432) /0.097	-9.7631 (-21.3444, 1.8181) /0.098	0.5379 (0.2575, 1.1235) /0.099	

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	20/118 (17%)	24/135 (18%)	0.9439 (0.4914, 1.8128) /0.862	-0.8286 (-10.1785, 8.5212) /0.862	0.9534 (0.5558, 1.6353) /0.862	0.473
	Europe	23/165 (14%)	27/155 (17%)	0.7679 (0.4192, 1.4065) /0.392	-3.4800 (-11.4537, 4.4938) /0.392	0.8002 (0.4800, 1.3341) /0.393	
	Rest of World	8/ 44 (18%)	4/ 37 (11%)	1.8333 (0.5047, 6.6590) /0.357	7.3710 (-7.7942, 22.5362) /0.341	1.6818 (0.5500, 5.1431) /0.362	

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	0/239	3/256 (1%)				
	Non-White	0/ 88	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	0/239	1/256 (<1%)				
	Non-White	0/ 88	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	82/ 84 (98%)	96/ 98 (98%)				
35 - <50	144/154 (94%)	138/143 (97%)				
>=50	85/ 89 (96%)	84/ 86 (98%)				

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

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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	Q8W (N=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	79/ 84 (94%)	83/ 98 (85%)				
35 - <50	136/154 (88%)	124/143 (87%)				
>=50	72/ 89 (81%)	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)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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)
Injection site pain						
<35	78/ 84 (93%)	78/ 98 (80%)				
35 - <50	126/154 (82%)	116/143 (81%)				
>=50	69/ 89 (78%)	67/ 86 (78%)				

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

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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	15/ 84 (18%)	20/ 98 (20%)	0.8478 (0.4030, 1.7836) /0.664	-2.5510 (-13.9857, 8.8837) /0.662	0.8750 (0.4789, 1.5987) /0.664	0.137
35 - <50	18/154 (12%)	38/143 (27%)	0.3657 (0.1975, 0.6771) /0.001	-14.8851 (-23.7261, -6.0441) /<.001	0.4398 (0.2635, 0.7343) /0.002	
>=50	8/ 89 (9%)	21/ 86 (24%)	0.3057 (0.1271, 0.7350) /0.008	-15.4298 (-26.2811, -4.5786) /0.005	0.3681 (0.1724, 0.7859) /0.010	

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

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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%)	5/ 98 (5%)				
35 - <50	17/154 (11%)	15/143 (10%)				
>=50	7/ 89 (8%)	15/ 86 (17%)				
Injection site induration						
<35	7/ 84 (8%)	6/ 98 (6%)				
35 - <50	16/154 (10%)	17/143 (12%)				
>=50	5/ 89 (6%)	12/ 86 (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. NC = Not Calculable. 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)
Pyrexia						
<35	8/ 84 (10%)	10/ 98 (10%)				
35 - <50	13/154 (8%)	17/143 (12%)				
>=50	5/ 89 (6%)	9/ 86 (10%)				
Injection site swelling						
<35	10/ 84 (12%)	4/ 98 (4%)				
35 - <50	10/154 (6%)	14/143 (10%)				
>=50	7/ 89 (8%)	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)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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)
Fatigue <35	4/ 84 (5%)	10/ 98 (10%)	0.4400 (0.1327, 1.4585) /0.179	-5.4422 (-12.9693, 2.0849) /0.156	0.4667 (0.1519, 1.4336) /0.183	0.939
35 - <50	8/154 (5%)	14/143 (10%)	0.5049 (0.2052, 1.2423) /0.137	-4.5954 (-10.5962, 1.4054) /0.133	0.5306 (0.2295, 1.2270) /0.138	
>=50	2/ 89 (2%)	5/ 86 (6%)	0.3724 (0.0703, 1.9734) /0.246	-3.5668 (-9.3927, 2.2592) /0.230	0.3865 (0.0770, 1.9391) /0.248	

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

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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%)	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	0.232
35 - <50	7/154 (5%)	10/143 (7%)	0.6333 (0.2344, 1.7112) /0.368	-2.4476 (-7.7668, 2.8717) /0.367	0.6500 (0.2542, 1.6618) /0.368	
>=50	1/ 89 (1%)	8/ 86 (9%)	0.1108 (0.0136, 0.9058) /0.040	-8.1787 (-14.6965, -1.6609) /0.014	0.1208 (0.0154, 0.9454) /0.044	

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

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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)

Influenza like illness						
<35	3/ 84 (4%)	2/ 98 (2%)				
35 - <50	6/154 (4%)	9/143 (6%)				
>=50	1/ 89 (1%)	6/ 86 (7%)				
Injection site erythema						
<35	2/ 84 (2%)	1/ 98 (1%)				
35 - <50	8/154 (5%)	11/143 (8%)				
>=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), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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)

Asthenia						
<35	3/ 84 (4%)	2/ 98 (2%)				
35 - <50	6/154 (4%)	7/143 (5%)				
>=50	5/ 89 (6%)	1/ 86 (1%)				
Chills						
<35	3/ 84 (4%)	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)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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)

Injection site bruising						
<35	2/ 84 (2%)	3/ 98 (3%)				
35 - <50	7/154 (5%)	4/143 (3%)				
>=50	2/ 89 (2%)	4/ 86 (5%)				
Pain						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	7/154 (5%)	5/143 (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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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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)
Malaise						
<35	2/ 84 (2%)	3/ 98 (3%)				
35 - <50	4/154 (3%)	3/143 (2%)				
>=50	1/ 89 (1%)	2/ 86 (2%)				
Injection site haematoma						
<35	0/ 84	4/ 98 (4%)				
35 - <50	1/154 (<1%)	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)

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Table 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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	3/ 84 (4%)	0/ 98				
35 - <50	3/154 (2%)	4/143 (3%)				
>=50	0/ 89	2/ 86 (2%)				
Chest pain						
<35	1/ 84 (1%)	2/ 98 (2%)				
35 - <50	1/154 (<1%)	4/143 (3%)				
>=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

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Table 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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						
<35	1/ 84 (1%)	2/ 98 (2%)				
35 - <50	4/154 (3%)	0/143				
>=50	1/ 89 (1%)	2/ 86 (2%)				
Injection site reaction						
<35	0/ 84	2/ 98 (2%)				
35 - <50	3/154 (2%)	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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Table 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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	3/ 84 (4%)	1/ 98 (1%)				
35 - <50	1/154 (<1%)	0/143				
>=50	1/ 89 (1%)	0/ 86				
Nodule						
<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

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

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

System Organ Class Preferred Term	Q8W (N=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	1/ 84 (1%)	0/ 98				
35 - <50	2/154 (1%)	0/143				
>=50	2/ 89 (2%)	0/ 86				
Peripheral swelling						
<35	0/ 84	1/ 98 (1%)				
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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Table 3.17

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

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

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

Cyst						
<35	0/ 84	1/ 98 (1%)				
35 - <50	1/154 (<1%)	0/143				
>=50	1/ 89 (1%)	0/ 86				
Injection site discolouration						
<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

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

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

System Organ Class Preferred Term	Q8W (N=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	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	0/154	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

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

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

System Organ Class Preferred Term	Q8W (N=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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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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 haemorrhage						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	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)

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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)

Non-cardiac chest pain						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Temperature regulation disorder						
<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

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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)

Vaccination site pain						
<35	0/ 84	0/ 98				
35 - <50	0/154	2/143 (1%)				
>=50	0/ 89	0/ 86				
Adverse drug reaction						
<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.

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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)

Chronic fatigue syndrome						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Enanthema						
<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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Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=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 abnormal						
<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.

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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)
Inflammation						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Injection site discharge						
<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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OR and RR for each subgroup are obtained from genmod models (link = 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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Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=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						
<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.

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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)

Injection site hypoaesthesia						
<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				

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(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. NC = Not Calculable. 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)

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. NC = Not Calculable. 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)

Oedema peripheral						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Sensation of foreign body						
<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. NC = Not Calculable. 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)

Sluggishness						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
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, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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)

Thirst						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
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)

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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. NC = Not Calculable. 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)

Infections and infestations						
Any Event						
<35	65/ 84 (77%)	79/ 98 (81%)				
35 - <50	96/154 (62%)	102/143 (71%)				
>=50	55/ 89 (62%)	58/ 86 (67%)				

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

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, 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 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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	19/ 84 (23%)	19/ 98 (19%)				
35 - <50	22/154 (14%)	30/143 (21%)				
>=50	20/ 89 (22%)	17/ 86 (20%)				

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

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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)
Upper respiratory tract infection						
<35	10/ 84 (12%)	22/ 98 (22%)	0.4668 (0.2070, 1.0527) /0.066	-10.5442 (-21.3240, 0.2356) /0.055	0.5303 (0.2664, 1.0555) /0.071	0.532
35 - <50	22/154 (14%)	24/143 (17%)	0.8264 (0.4404, 1.5506) /0.553	-2.4975 (-10.7475, 5.7525) /0.553	0.8512 (0.5001, 1.4488) /0.553	
>=50	13/ 89 (15%)	20/ 86 (23%)	0.5645 (0.2608, 1.2218) /0.147	-8.6491 (-20.2058, 2.9077) /0.142	0.6281 (0.3338, 1.1820) /0.149	

Note: "Any Event" represents subjects with any 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)

Gastroenteritis						
<35	7/ 84 (8%)	11/ 98 (11%)	0.7190 (0.2656, 1.9467) /0.516	-2.8912 (-11.4931, 5.7108) /0.510	0.7424 (0.3013, 1.8292) /0.517	0.458
35 - <50	6/154 (4%)	16/143 (11%)	0.3218 (0.1223, 0.8470) /0.022	-7.2927 (-13.2955, -1.2899) /0.017	0.3482 (0.1401, 0.8653) /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)

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Table 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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	8/ 84 (10%)	14/ 98 (14%)				
35 - <50	6/154 (4%)	7/143 (5%)				
>=50	4/ 89 (4%)	1/ 86 (1%)				
Influenza						
<35	5/ 84 (6%)	4/ 98 (4%)				
35 - <50	10/154 (6%)	5/143 (3%)				
>=50	3/ 89 (3%)	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. NC = Not Calculable. 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)

Bronchitis						
<35	2/ 84 (2%)	4/ 98 (4%)				
35 - <50	7/154 (5%)	7/143 (5%)				
>=50	5/ 89 (6%)	5/ 86 (6%)				
Pharyngitis						
<35	5/ 84 (6%)	8/ 98 (8%)				
35 - <50	6/154 (4%)	5/143 (3%)				
>=50	1/ 89 (1%)	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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Table 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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	10/ 84 (12%)	6/ 98 (6%)				
35 - <50	3/154 (2%)	5/143 (3%)				
>=50	0/ 89	2/ 86 (2%)				
Sinusitis						
<35	4/ 84 (5%)	5/ 98 (5%)				
35 - <50	4/154 (3%)	5/143 (3%)				
>=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)

Viral infection						
<35	5/ 84 (6%)	4/ 98 (4%)				
35 - <50	2/154 (1%)	8/143 (6%)				
>=50	1/ 89 (1%)	2/ 86 (2%)				
Chlamydial infection						
<35	7/ 84 (8%)	2/ 98 (2%)				
35 - <50	3/154 (2%)	4/143 (3%)				
>=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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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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	3/ 84 (4%)	2/ 98 (2%)				
35 - <50	2/154 (1%)	4/143 (3%)				
>=50	5/ 89 (6%)	3/ 86 (3%)				
Conjunctivitis						
<35	1/ 84 (1%)	4/ 98 (4%)				
35 - <50	7/154 (5%)	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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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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	2/ 84 (2%)	2/ 98 (2%)				
35 - <50	5/154 (3%)	8/143 (6%)				
>=50	1/ 89 (1%)	0/ 86				
Proctitis gonococcal						
<35	3/ 84 (4%)	7/ 98 (7%)				
35 - <50	2/154 (1%)	2/143 (1%)				
>=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)

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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)

Tonsillitis						
<35	0/ 84	9/ 98 (9%)				
35 - <50	5/154 (3%)	2/143 (1%)				
>=50	0/ 89	0/ 86				
Anal chlamydia infection						
<35	6/ 84 (7%)	5/ 98 (5%)				
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)

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

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

System Organ Class Preferred Term	Q8W (N=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	2/ 84 (2%)	2/ 98 (2%)				
35 - <50	5/154 (3%)	4/143 (3%)				
>=50	1/ 89 (1%)	1/ 86 (1%)				
Oral herpes						
<35	0/ 84	4/ 98 (4%)				
35 - <50	3/154 (2%)	4/143 (3%)				
>=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)

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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)

Urethritis						
<35	2/ 84 (2%)	3/ 98 (3%)				
35 - <50	2/154 (1%)	5/143 (3%)				
>=50	1/ 89 (1%)	1/ 86 (1%)				
Folliculitis						
<35	1/ 84 (1%)	2/ 98 (2%)				
35 - <50	4/154 (3%)	5/143 (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. NC = Not Calculable. 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)

Oropharyngeal gonococcal infection						
<35	4/ 84 (5%)	5/ 98 (5%)				
35 - <50	1/154 (<1%)	2/143 (1%)				
>=50	1/ 89 (1%)	0/ 86				
Rhinitis						
<35	2/ 84 (2%)	0/ 98				
35 - <50	1/154 (<1%)	7/143 (5%)				
>=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. NC = Not Calculable. 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)

Herpes zoster						
<35	2/ 84 (2%)	4/ 98 (4%)				
35 - <50	3/154 (2%)	3/143 (2%)				
>=50	0/ 89	0/ 86				
Gastroenteritis viral						
<35	2/ 84 (2%)	0/ 98				
35 - <50	0/154	5/143 (3%)				
>=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), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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)
Viral upper respiratory tract infection						
<35	0/ 84	4/ 98 (4%)				
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, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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	2/ 84 (2%)	1/ 98 (1%)				
35 - <50	2/154 (1%)	0/143				
>=50	3/ 89 (3%)	1/ 86 (1%)				
Tooth abscess						
<35	0/ 84	1/ 98 (1%)				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	1/ 89 (1%)	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)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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	1/ 98 (1%)				
35 - <50	2/154 (1%)	2/143 (1%)				
>=50	1/ 89 (1%)	2/ 86 (2%)				
Onychomycosis						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	5/143 (3%)				
>=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. NC = Not Calculable. 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: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=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	2/ 84 (2%)	3/ 98 (3%)				
35 - <50	1/154 (<1%)	2/143 (1%)				
>=50	0/ 89	0/ 86				
Tooth infection						
<35	0/ 84	2/ 98 (2%)				
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)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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)

Fungal skin infection						
<35	0/ 84	2/ 98 (2%)				
35 - <50	2/154 (1%)	0/143				
>=50	1/ 89 (1%)	2/ 86 (2%)				
Cellulitis						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=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)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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	2/154 (1%)	2/143 (1%)				
>=50	0/ 89	2/ 86 (2%)				
Furuncle						
<35	1/ 84 (1%)	2/ 98 (2%)				
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

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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	2/154 (1%)	1/143 (<1%)				
>=50	0/ 89	2/ 86 (2%)				
Herpes simplex						
<35	1/ 84 (1%)	1/ 98 (1%)				
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, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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						
<35	2/ 84 (2%)	3/ 98 (3%)				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Pneumonia						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	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, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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	2/ 84 (2%)	1/ 98 (1%)				
35 - <50	0/154	3/143 (2%)				
>=50	0/ 89	0/ 86				
Urethritis gonococcal						
<35	1/ 84 (1%)	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)

(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)

Abscess limb						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	2/154 (1%)	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Acarodermatitis						
<35	1/ 84 (1%)	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, p-value and interaction p-values are 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)

Secondary syphilis						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	2/143 (1%)				
>=50	1/ 89 (1%)	1/ 86 (1%)				
Body tinea						
<35	2/ 84 (2%)	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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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	0/ 89	0/ 86				
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

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

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

System Organ Class Preferred Term	Q8W (N=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	1/154 (<1%)	1/143 (<1%)				
>=50	0/ 89	2/ 86 (2%)				
Pharyngotonsillitis						
<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

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Table 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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	1/154 (<1%)	0/143				
>=50	1/ 89 (1%)	0/ 86				
Shigella infection						
<35	1/ 84 (1%)	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

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Table 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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%)	2/143 (1%)				
>=50	0/ 89	1/ 86 (1%)				
Viral pharyngitis						
<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)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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	2/154 (1%)	0/143				
>=50	0/ 89	0/ 86				
Epididymitis						
<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)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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	2/ 98 (2%)				
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	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. NC = Not Calculable. 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)

Oral candidiasis						
<35	0/ 84	3/ 98 (3%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
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)

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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. NC = Not Calculable. 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)

Pharyngeal chlamydia infection						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	1/ 89 (1%)	0/ 86				
Pharyngitis streptococcal						
<35	1/ 84 (1%)	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. NC = Not Calculable. 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)

Skin infection						
<35	0/ 84	0/ 98				
35 - <50	2/154 (1%)	0/143				
>=50	1/ 89 (1%)	0/ 86				
Staphylococcal infection						
<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, p-value and interaction p-values are 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)

Subcutaneous abscess						
<35	1/ 84 (1%)	0/ 98				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Tinea cruris						
<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. NC = Not Calculable. 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: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=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	2/143 (1%)				
>=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, p-value and interaction p-values are 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. NC = Not Calculable. 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)

Varicella						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	1/ 89 (1%)	0/ 86				
Vulvovaginal mycotic infection						
<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, p-value and interaction p-values are 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. NC =

Not Calculable. 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: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=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				
Acute sinusitis						
<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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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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)

Bronchitis viral						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Chronic sinusitis						
<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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Table 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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	1/143 (<1%)				
>=50	0/ 89	1/ 86 (1%)				
Diarrhoea infectious						
<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)

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Table 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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%)				
Hepatitis E						
<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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Table 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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

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

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

System Organ Class Preferred Term	Q8W (N=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

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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)
Otitis media						
<35	0/ 84	1/ 98 (1%)				
35 - <50	1/154 (<1%)	0/143				
>=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

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

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

System Organ Class Preferred Term	Q8W (N=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						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Pulmonary tuberculosis						
<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

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Table 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	1/ 86 (1%)				
Sexually transmitted disease						
<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. NC = Not Calculable. 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: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=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	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Tinea pedis						
<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. NC = Not Calculable. 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: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=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	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Urethritis mycoplasmal						
<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), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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)

Abscess						
<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, p-value and interaction p-values are 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. NC =

Not Calculable. 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: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=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. NC = Not Calculable. 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: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=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)

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Table 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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				
Borrelia 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, p-value and interaction p-values are 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. NC = Not Calculable. 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)
COVID-19						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=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, p-value and interaction p-values are 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. NC = Not Calculable. 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: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=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 of male external genital organ						
<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. NC =

Not Calculable. 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: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=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						
<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)

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

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

System Organ Class Preferred Term	Q8W (N=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)

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

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

System Organ Class Preferred Term	Q8W (N=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%)				
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, p-value and interaction p-values are 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)

Eczema infected						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
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)

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

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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)

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.

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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)

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

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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)

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)

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

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

System Organ Class Preferred Term	Q8W (N=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 infection						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	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, p-value and interaction p-values are 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)

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)

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with the following variables: treatment, 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 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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 infection						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Genital candidiasis						
<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. NC = Not Calculable. 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: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=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						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=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, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

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

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

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Giardiasis						
<35	1/ 84 (1%)	0/ 98				
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. NC = Not Calculable. 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: Age (years) (<35 vs. 35 - <50 vs. >=50)

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

Gonococcal infection						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	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, p-value and interaction p-values are 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)

Hepatitis C						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Herpes ophthalmic						
<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)

Herpes virus infection						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Infected bite						
<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)
Infection						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Infectious mononucleosiss						
<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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Table 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Latent 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, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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)

Lice infestation						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Localised 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

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Table 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Oesophageal candidiasis						
<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

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Table 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Otitis media acute						
<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)

Penile infection						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Pericoronitis						
<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. NC = Not Calculable. 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: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=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				
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, p-value and interaction p-values are 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)

Pharyngitis bacterial						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Pharyngitis mycoplasmal						
<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)

Proctitis mycoplasmal						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Rectal abscess						
<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

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

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

System Organ Class Preferred Term	Q8W (N=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						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
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, p-value and interaction p-values are 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)

Skin bacterial infection						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Suspected COVID-19						
<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)

Syphilis genital						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Tinea capitis						
<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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Table 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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 staphylococcal						
<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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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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				
Wound 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

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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)

Gastrointestinal disorders						
Any Event						
<35	34/ 84 (40%)	33/ 98 (34%)	1.3394 (0.7318, 2.4513) /0.343	6.8027 (-7.2589, 20.8643) /0.343	1.2020 (0.8219, 1.7578) /0.343	0.035
35 - <50	37/154 (24%)	56/143 (39%)	0.4913 (0.2982, 0.8095) /0.005	-15.1349 (-25.6008, -4.6690) /0.005	0.6135 (0.4335, 0.8683) /0.006	
>=50	27/ 89 (30%)	34/ 86 (40%)	0.6660 (0.3564, 1.2448) /0.203	-9.1978 (-23.2689, 4.8733) /0.200	0.7673 (0.5097, 1.1553) /0.205	

Note: "Any Event" represents subjects with any 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: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=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	13/ 84 (15%)	11/ 98 (11%)				
35 - <50	14/154 (9%)	14/143 (10%)				
>=50	6/ 89 (7%)	12/ 86 (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: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=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	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	0.039
35 - <50	1/154 (<1%)	11/143 (8%)	0.0784 (0.0100, 0.6156) /0.015	-7.0430 (-11.5909, -2.4950) /0.002	0.0844 (0.0110, 0.6456) /0.017	
>=50	4/ 89 (4%)	4/ 86 (5%)	0.9647 (0.2335, 3.9860) /0.960	-0.1568 (-6.3484, 6.0349) /0.960	0.9663 (0.2495, 3.7418) /0.960	

Note: "Any Event" represents subjects with any 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)
Haemorrhoids						
<35	0/ 84	8/ 98 (8%)				
35 - <50	2/154 (1%)	5/143 (3%)				
>=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)

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Table 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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 <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	0.578
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	1/ 89 (1%)	3/ 86 (3%)	0.3144 (0.0321, 3.0828) /0.321	-2.3648 (-6.8183, 2.0887) /0.298	0.3221 (0.0342, 3.0367) /0.322	

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

System Organ Class Preferred Term	Q8W (N=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	4/154 (3%)	6/143 (4%)				
>=50	3/ 89 (3%)	4/ 86 (5%)				
Toothache						
<35	1/ 84 (1%)	3/ 98 (3%)				
35 - <50	2/154 (1%)	5/143 (3%)				
>=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

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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)

Abdominal pain						
<35	4/ 84 (5%)	1/ 98 (1%)				
35 - <50	2/154 (1%)	4/143 (3%)				
>=50	2/ 89 (2%)	3/ 86 (3%)				
Gastrooesophageal reflux disease						
<35	4/ 84 (5%)	1/ 98 (1%)				
35 - <50	1/154 (<1%)	3/143 (2%)				
>=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

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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)

Abdominal distension						
<35	3/ 84 (4%)	0/ 98				
35 - <50	3/154 (2%)	2/143 (1%)				
>=50	2/ 89 (2%)	2/ 86 (2%)				
Abdominal pain upper						
<35	1/ 84 (1%)	2/ 98 (2%)				
35 - <50	1/154 (<1%)	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

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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)

Vomiting						
<35	2/ 84 (2%)	0/ 98				
35 - <50	1/154 (<1%)	3/143 (2%)				
>=50	3/ 89 (3%)	1/ 86 (1%)				
Anogenital dysplasia						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	3/154 (2%)	2/143 (1%)				
>=50	0/ 89	1/ 86 (1%)				

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

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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)

Gastritis						
<35	1/ 84 (1%)	0/ 98				
35 - <50	2/154 (1%)	3/143 (2%)				
>=50	0/ 89	1/ 86 (1%)				
Abdominal discomfort						
<35	0/ 84	1/ 98 (1%)				
35 - <50	2/154 (1%)	1/143 (<1%)				
>=50	0/ 89	2/ 86 (2%)				

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

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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)
Rectal haemorrhage						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	4/143 (3%)				
>=50	1/ 89 (1%)	0/ 86				
Abdominal pain lower						
<35	0/ 84	1/ 98 (1%)				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	1/ 89 (1%)	1/ 86 (1%)				

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

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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)
Anal fissure						
<35	2/ 84 (2%)	1/ 98 (1%)				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	1/ 86 (1%)				
Dental caries						
<35	1/ 84 (1%)	0/ 98				
35 - <50	1/154 (<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

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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)

Flatulence						
<35	0/ 84	1/ 98 (1%)				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	1/ 89 (1%)	1/ 86 (1%)				
Haematochezi						
a						
<35	1/ 84 (1%)	0/ 98				
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, p-value and interaction p-values are only provided for AEs with

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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)

Food poisoning						
<35	2/ 84 (2%)	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	1/ 89 (1%)	0/ 86				
Proctitis						
<35	1/ 84 (1%)	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), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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)
Rectal discharge						
<35	2/ 84 (2%)	0/ 98				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	0/ 89	0/ 86				
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

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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)
Dry mouth						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	1/143 (<1%)				
>=50	1/ 89 (1%)	0/ 86				
Hiatus hernia						
<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, p-value and interaction p-values are 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. NC = Not Calculable. 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)

Inguinal hernia						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	2/ 86 (2%)				
Irritable bowel syndrome						
<35	1/ 84 (1%)	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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Table 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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	1/ 84 (1%)	0/ 98				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Proctalgia						
<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

(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)

Anal pruritus						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Colitis						
<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)

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

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

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

Diverticulum intestinal						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	1/ 86 (1%)				
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, p-value and interaction p-values are 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. NC =

Not Calculable. 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: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=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						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Large intestine polyp						
<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)

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Table 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Noninfective gingivitis						
<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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Table 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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 disorder						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Tongue ulceration						
<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

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Table 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Abdominal tenderness						
<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)
Anal ulcer						
<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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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

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

Anorectal discomfort						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Aphthous ulcer						
<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

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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)

Chapped lips						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Cheilitis						
<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.

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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)

Crohn's disease						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Dental 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, 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)
Dysphagia						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Enteritis						
<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)

Enterocolitis						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Faeces soft						
<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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Table 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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				
Gastric ulcer						
<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.

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Table 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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. 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 System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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)

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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. 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 System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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%)				
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, p-value and interaction p-values are 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)

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, 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)

Intestinal polyp						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Oral lichen planus						
<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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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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 pain						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
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

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

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

System Organ Class Preferred Term	Q8W (N=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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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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%)				
Rectal prolapse						
<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)
Rectal tenesmus						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Salivary gland mucocoele						
<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)
-----	-----	-----	-----	-----	-----	-----
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)

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

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

System Organ Class Preferred Term	Q8W (N=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	18/ 84 (21%)	28/ 98 (29%)				
35 - <50	45/154 (29%)	47/143 (33%)				
>=50	28/ 89 (31%)	38/ 86 (44%)				

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

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are 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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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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	4/ 84 (5%)	6/ 98 (6%)				
35 - <50	16/154 (10%)	20/143 (14%)				
>=50	7/ 89 (8%)	6/ 86 (7%)				
Arthralgia						
<35	2/ 84 (2%)	4/ 98 (4%)				
35 - <50	11/154 (7%)	6/143 (4%)				
>=50	8/ 89 (9%)	15/ 86 (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

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Table 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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%)	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	0.691
35 - <50	5/154 (3%)	10/143 (7%)	0.4463 (0.1488, 1.3390) /0.150	-3.7463 (-8.7769, 1.2844) /0.144	0.4643 (0.1626, 1.3256) /0.152	
>=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.

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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)

Myalgia						
<35	2/ 84 (2%)	2/ 98 (2%)				
35 - <50	5/154 (3%)	7/143 (5%)				
>=50	3/ 89 (3%)	2/ 86 (2%)				
Musculoskeletal pain						
<35	1/ 84 (1%)	3/ 98 (3%)				
35 - <50	4/154 (3%)	3/143 (2%)				
>=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

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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)
Muscle spasms						
<35	2/ 84 (2%)	1/ 98 (1%)				
35 - <50	0/154	2/143 (1%)				
>=50	1/ 89 (1%)	4/ 86 (5%)				
Musculoskeletal chest pain						
<35	2/ 84 (2%)	2/ 98 (2%)				
35 - <50	3/154 (2%)	0/143				
>=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)

Tendonitis						
<35	1/ 84 (1%)	0/ 98				
35 - <50	4/154 (3%)	1/143 (<1%)				
>=50	2/ 89 (2%)	1/ 86 (1%)				
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

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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)

Intervertebral disc protrusion						
<35	0/ 84	1/ 98 (1%)				
35 - <50	3/154 (2%)	1/143 (<1%)				
>=50	1/ 89 (1%)	0/ 86				
Muscle contracture						
<35	0/ 84	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.

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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)

Osteoarthritis						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	3/ 89 (3%)	2/ 86 (2%)				
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), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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)

Spinal osteoarthritis						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	3/ 86 (3%)				
Muscular weakness						
<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)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	1/ 89 (1%)	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.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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)

Arthritis						
<35	1/ 84 (1%)	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Bursitis						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=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. NC = Not Calculable. 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)

Exostosis						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	2/ 86 (2%)				
Flank pain						
<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.

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Table 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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	1/ 84 (1%)	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Joint contracture						
<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. NC = Not Calculable. 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: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=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	2/ 89 (2%)	0/ 86				
Joint swelling						
<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, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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	2/ 86 (2%)				
Musculoskeletal discomfort						
<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, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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)

Musculoskeletal stiffness						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	1/ 86 (1%)				
Osteonecrosi s						
<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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Table 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	1/ 86 (1%)				
Synovitis						
<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, p-value and interaction p-values are 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)

Arthritis reactive						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Arthropathy						
<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. NC = Not Calculable. 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)
Bone pain						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=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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Table 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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				
Loose body in joint						
<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

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

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

System Organ Class Preferred Term	Q8W (N=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						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Myosclerosis						
<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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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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				
Osteopenia						
<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)

Periarthriti s						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Polyarthriti s						
<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)

Sacroiliitis						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Scoliosis						
<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. NC = Not Calculable. 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)

Spinal disorder						
<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)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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)

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

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

System Organ Class Preferred Term	Q8W (N=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)

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

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

System Organ Class Preferred Term	Q8W (N=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	22/ 84 (26%)	21/ 98 (21%)				
35 - <50	29/154 (19%)	34/143 (24%)				
>=50	23/ 89 (26%)	29/ 86 (34%)				

Note: "Any Event" represents subjects with any 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)

Pruritus						
<35	5/ 84 (6%)	1/ 98 (1%)				
35 - <50	2/154 (1%)	4/143 (3%)				
>=50	5/ 89 (6%)	5/ 86 (6%)				
Rash						
<35	5/ 84 (6%)	6/ 98 (6%)				
35 - <50	3/154 (2%)	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

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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)

Eczema						
<35	2/ 84 (2%)	1/ 98 (1%)				
35 - <50	2/154 (1%)	5/143 (3%)				
>=50	3/ 89 (3%)	7/ 86 (8%)				
Skin lesion						
<35	2/ 84 (2%)	1/ 98 (1%)				
35 - <50	2/154 (1%)	0/143				
>=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

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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)

Acne						
<35	0/ 84	3/ 98 (3%)				
35 - <50	1/154 (<1%)	2/143 (1%)				
>=50	1/ 89 (1%)	3/ 86 (3%)				
Dermatitis						
<35	2/ 84 (2%)	3/ 98 (3%)				
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

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

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

System Organ Class Preferred Term	Q8W (N=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%)	1/ 86 (1%)				
Hyperhidrosi s						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	3/143 (2%)				
>=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

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

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

System Organ Class Preferred Term	Q8W (N=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	1/154 (<1%)	1/143 (<1%)				
>=50	2/ 89 (2%)	2/ 86 (2%)				
Erythema						
<35	0/ 84	0/ 98				
35 - <50	0/154	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, p-value and interaction p-values are 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)

Seborrhoeic dermatitis						
<35	0/ 84	0/ 98				
35 - <50	0/154	4/143 (3%)				
>=50	1/ 89 (1%)	0/ 86				
Urticaria						
<35	0/ 84	0/ 98				
35 - <50	3/154 (2%)	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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Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=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	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	2/154 (1%)	0/143				
>=50	0/ 89	0/ 86				
Dermatitis atopic						
<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

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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)
Night sweats						
<35	1/ 84 (1%)	0/ 98				
35 - <50	3/154 (2%)	0/143				
>=50	0/ 89	0/ 86				
Dry skin						
<35	0/ 84	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

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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)

Pityriasis rosea						
<35	1/ 84 (1%)	0/ 98				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Skin exfoliation						
<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

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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)

Skin mass						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	0/ 89	1/ 86 (1%)				
Actinic keratosis						
<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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Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=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						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Ecchymosis						
<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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Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=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						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	2/ 86 (2%)				
Rash erythematous						
<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.

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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)

Rash maculo-papular						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	1/ 86 (1%)				
Rash papular						
<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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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

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

Actinic elastosis						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Androgenetic alopecia						
<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. NC = Not Calculable. 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: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=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				
Dermatosis						
<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. NC = Not Calculable. 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: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=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%)				
Eczema asteatotic						
<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. NC = Not Calculable. 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)

Granuloma annulare						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Guttate psoriasis						
<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. NC = Not Calculable. 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: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=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						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Hyperkeratosis						
<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), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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)
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

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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. NC = Not Calculable. 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: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=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 bleeding						
<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)

Nail bed inflammation						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Nail dystrophy						
<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. NC = Not Calculable. 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)
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)

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

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

System Organ Class Preferred Term	Q8W (N=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)

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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. NC = Not Calculable. 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: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=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				
Prurigo						
<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)

Purpura						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Rash macular						
<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

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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. 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 System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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)

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Table 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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)

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

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

System Organ Class Preferred Term	Q8W (N=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	0/ 86				
Skin hypertrophy						
<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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with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC =

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

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

System Organ Class Preferred Term	Q8W (N=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						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	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, p-value and interaction p-values are 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)

Skin ulcer						
<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. NC = Not Calculable. 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: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=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 lentigo						
<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), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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	16/ 84 (19%)	22/ 98 (22%)				
35 - <50	35/154 (23%)	37/143 (26%)				
>=50	14/ 89 (16%)	17/ 86 (20%)				
Headache						
<35	6/ 84 (7%)	8/ 98 (8%)				
35 - <50	18/154 (12%)	19/143 (13%)				
>=50	6/ 89 (7%)	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

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

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

System Organ Class Preferred Term	Q8W (N=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	7/ 84 (8%)	5/ 98 (5%)				
35 - <50	8/154 (5%)	7/143 (5%)				
>=50	2/ 89 (2%)	2/ 86 (2%)				
Presyncope						
<35	1/ 84 (1%)	3/ 98 (3%)				
35 - <50	2/154 (1%)	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

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

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

System Organ Class Preferred Term	Q8W (N=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						
<35	2/ 84 (2%)	1/ 98 (1%)				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	2/ 89 (2%)	0/ 86				
Migraine						
<35	0/ 84	0/ 98				
35 - <50	2/154 (1%)	5/143 (3%)				
>=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)

Paraesthesia						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	3/143 (2%)				
>=50	1/ 89 (1%)	2/ 86 (2%)				
Sciatica						
<35	1/ 84 (1%)	2/ 98 (2%)				
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)

Somnolence						
<35	2/ 84 (2%)	1/ 98 (1%)				
35 - <50	0/154	2/143 (1%)				
>=50	0/ 89	0/ 86				
Syncope						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<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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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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%)	1/ 98 (1%)				
35 - <50	2/154 (1%)	0/143				
>=50	0/ 89	0/ 86				
Tension headache						
<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

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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)

Carpal tunnel syndrome						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	1/ 89 (1%)	0/ 86				
Cervical radiculopathy						
<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

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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)

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

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

Agnosia						
<35	0/ 84	0/ 98				
35 - <50	0/154	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

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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)

Anosmia						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Ataxia						
<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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Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Brain injury						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Brain stem infarction						
<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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Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=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				
Cerebral infarction						
<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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Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=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%)				
Dysarthria						
<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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Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=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						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
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.

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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)

Hypersomnia						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Hypertonia						
<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.

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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)
Memory impairment						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
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

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

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

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

Neuritis cranial						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	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, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Polyneuropathy						
<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)

Radiculopathy						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Transient ischaemic attack						
<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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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

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

Tremor						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Trigeminal neuralgia						
<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)

Respiratory, thoracic and mediastinal disorders						
Any Event						
<35	16/ 84 (19%)	18/ 98 (18%)	1.0458 (0.4955, 2.2072) /0.907	0.6803 (-10.6903, 12.0508) /0.907	1.0370 (0.5651, 1.9031) /0.907	0.061
35 - <50	17/154 (11%)	37/143 (26%)	0.3555 (0.1898, 0.6660) /0.001	-14.8352 (-23.5540, -6.1163) /<.001	0.4266 (0.2518, 0.7228) /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

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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)
>=50	19/ 89 (21%)	22/ 86 (26%)	0.7896 (0.3916, 1.5920) /0.509	-4.2331 (-16.7834, 8.3172) /0.509	0.8345 (0.4875, 1.4286) /0.510	
Cough						
<35	8/ 84 (10%)	6/ 98 (6%)				
35 - <50	4/154 (3%)	14/143 (10%)				
>=50	9/ 89 (10%)	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

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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)

Oropharyngeal pain						
<35	2/ 84 (2%)	4/ 98 (4%)				
35 - <50	4/154 (3%)	10/143 (7%)				
>=50	5/ 89 (6%)	5/ 86 (6%)				
Rhinitis allergic						
<35	1/ 84 (1%)	3/ 98 (3%)				
35 - <50	3/154 (2%)	5/143 (3%)				
>=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

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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)

Nasal congestion						
<35	2/ 84 (2%)	3/ 98 (3%)				
35 - <50	1/154 (<1%)	5/143 (3%)				
>=50	2/ 89 (2%)	1/ 86 (1%)				
Sinus congestion						
<35	3/ 84 (4%)	2/ 98 (2%)				
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, p-value and interaction p-values are only provided for AEs with

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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)

Asthma						
<35	1/ 84 (1%)	0/ 98				
35 - <50	2/154 (1%)	3/143 (2%)				
>=50	0/ 89	1/ 86 (1%)				
Sleep apnoea syndrome						
<35	1/ 84 (1%)	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.

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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)
<hr/>						
Epistaxis						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	2/ 86 (2%)				
Dyspnoea						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=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

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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)

Productive cough						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	1/ 89 (1%)	1/ 86 (1%)				
Rhinorrhoea						
<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.

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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)

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%)				

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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)

Nasal discomfort						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Oropharyngeal discomfort						
<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.

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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)

Rales						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Respiratory disorder						
<35	0/ 84	0/ 98				
35 - <50	0/154	2/143 (1%)				
>=50	0/ 89	0/ 86				

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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)

Bronchospasm						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Dry throat						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

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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)

Emphysema						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	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%)				

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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)
Nasal oedema						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Nasal septum deviation						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

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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)

Painful respiration						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Pharyngeal 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), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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)

Pleuritic pain						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
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, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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)
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

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Table 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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	13/ 84 (15%)	23/ 98 (23%)	0.5971 (0.2810, 1.2685) /0.180	-7.9932 (-19.4049, 3.4185) /0.170	0.6594 (0.3567, 1.2191) /0.184	0.015
35 - <50	11/154 (7%)	35/143 (24%)	0.2374 (0.1153, 0.4887) /<.001	-17.3327 (-25.4691, -9.1962) /<.001	0.2918 (0.1542, 0.5524) /<.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)

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Table 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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	19/ 89 (21%)	19/ 86 (22%)	0.9571 (0.4665, 1.9639) /0.905	-0.7447 (-12.9658, 11.4764) /0.905	0.9663 (0.5505, 1.6961) /0.905	
Contusion						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	4/154 (3%)	4/143 (3%)				
>=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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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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	3/ 84 (4%)	2/ 98 (2%)				
35 - <50	0/154	5/143 (3%)				
>=50	1/ 89 (1%)	2/ 86 (2%)				
Arthropod bite						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	0/154	7/143 (5%)				
>=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. NC = Not Calculable. 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)

Exposure to communicable disease						
<35	3/ 84 (4%)	8/ 98 (8%)				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Muscle strain						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	7/143 (5%)				
>=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. NC = Not Calculable. 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: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=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%)	2/ 98 (2%)				
35 - <50	2/154 (1%)	1/143 (<1%)				
>=50	4/ 89 (4%)	1/ 86 (1%)				
Skin laceration						
<35	0/ 84	3/ 98 (3%)				
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)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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%)	1/ 86 (1%)				
Arthropod sting						
<35	1/ 84 (1%)	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)

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Table 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	0/154	2/143 (1%)				
>=50	0/ 89	0/ 86				
Rib fracture						
<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)

Vaccination complication						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	2/143 (1%)				
>=50	0/ 89	1/ 86 (1%)				
Bone contusion						
<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)

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

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

System Organ Class Preferred Term	Q8W (N=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						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	1/ 86 (1%)				
Heat stroke						
<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

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

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

System Organ Class Preferred Term	Q8W (N=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	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	2/ 86 (2%)				
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

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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)

Ankle fracture						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Head injury						
<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

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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)

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, 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)
Musculoskeletal foreign body						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	1/ 86 (1%)				
Road traffic accident						
<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

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

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

System Organ Class Preferred Term	Q8W (N=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, 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)
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, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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)
Concussion						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Corneal abrasion						
<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. NC = Not Calculable. 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: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=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 injury						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Face 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), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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)
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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Table 3.17

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

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

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

Fractured coccyx						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Gastrointestinal procedural 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, p-value and interaction p-values are 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)

Hand fracture						
<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, p-value and interaction p-values are 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)

Injury corneal						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	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, p-value and interaction p-values are 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)

Lip injury						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
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, p-value and interaction p-values are 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)
Overdose						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Post-traumatic pain						
<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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Table 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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				
Sunburn						
<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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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Traumatic arthritis						
<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), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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

(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. NC = Not Calculable. 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)
Wound						
<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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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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	18/ 84 (21%)	18/ 98 (18%)				
35 - <50	26/154 (17%)	27/143 (19%)				
>=50	9/ 89 (10%)	11/ 86 (13%)				
Insomnia						
<35	5/ 84 (6%)	4/ 98 (4%)				
35 - <50	6/154 (4%)	14/143 (10%)				
>=50	4/ 89 (4%)	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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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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	10/ 84 (12%)	5/ 98 (5%)				
35 - <50	7/154 (5%)	7/143 (5%)				
>=50	3/ 89 (3%)	0/ 86				
Depression						
<35	2/ 84 (2%)	4/ 98 (4%)				
35 - <50	4/154 (3%)	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)

Sleep disorder						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	0/154	2/143 (1%)				
>=50	0/ 89	3/ 86 (3%)				
Abnormal dreams						
<35	1/ 84 (1%)	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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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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	1/ 84 (1%)	0/ 98				
35 - <50	2/154 (1%)	1/143 (<1%)				
>=50	1/ 89 (1%)	0/ 86				
Libido decreased						
<35	1/ 84 (1%)	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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Table 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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	1/143 (<1%)				
>=50	1/ 89 (1%)	2/ 86 (2%)				
Major depression						
<35	0/ 84	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, p-value and interaction p-values are 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. NC = Not Calculable. 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: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=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						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	1/ 89 (1%)	2/ 86 (2%)				
Adjustment disorder with depressed mood						
<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, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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)
Adjustment disorder with mixed anxiety and depressed mood						
<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)

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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)

Stress						
<35	0/ 84	1/ 98 (1%)				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	1/ 86 (1%)				
Attention deficit hyperactivity disorder						
<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)

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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. NC = Not Calculable. 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)
Drug abuse						
<35	0/ 84	0/ 98				
35 - <50	0/154	2/143 (1%)				
>=50	0/ 89	0/ 86				
Generalised anxiety disorder						
<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. 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 System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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				
Restlessness						
<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

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

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

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

Suicidal ideation						
<35	0/ 84	0/ 98				
35 - <50	2/154 (1%)	0/143				
>=50	0/ 89	0/ 86				
Acute 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

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

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

System Organ Class Preferred Term	Q8W (N=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	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, 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)

Alcohol withdrawal syndrome						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
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

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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)
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

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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)
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

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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)
Psychotic disorder						
<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.

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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)
Investigations						
Any Event						
<35	6/ 84 (7%)	10/ 98 (10%)	0.6769 (0.2352, 1.9480) /0.469	-3.0612 (-11.2006, 5.0781) /0.461	0.7000 (0.2656, 1.8452) /0.471	0.516
35 - <50	11/154 (7%)	23/143 (16%)	0.4013 (0.1880, 0.8568) /0.018	-8.9411 (-16.2076, -1.6745) /0.016	0.4441 (0.2247, 0.8779) /0.020	
>=50	7/ 89 (8%)	8/ 86 (9%)	0.8323 (0.2882, 2.4040) /0.734	-1.4372 (-9.7416, 6.8673) /0.734	0.8455 (0.3205, 2.2307) /0.735	

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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)

Weight increased						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	2/154 (1%)	6/143 (4%)				
>=50	2/ 89 (2%)	0/ 86				
Body temperature increased						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	1/154 (<1%)	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

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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)
Blood creatine phosphokinase increased						
<35	2/ 84 (2%)	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

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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)
Alanine aminotransferase increased						
<35	1/ 84 (1%)	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

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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)

Blood cholesterol increased						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	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, p-value and interaction p-values are only provided for AEs with

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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)

Weight decreased						
<35	0/ 84	1/ 98 (1%)				
35 - <50	2/154 (1%)	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Blood glucose increased						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=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)

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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)

Blood triglycerides increased						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	2/143 (1%)				
>=50	0/ 89	0/ 86				
Lipase increased						
<35	0/ 84	1/ 98 (1%)				
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. NC = Not Calculable. 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: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=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%)	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. NC =

Not Calculable. 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: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=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	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, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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)
Blood creatinine increased						
<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. NC =

Not Calculable. 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: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=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	2/143 (1%)				
>=50	0/ 89	0/ 86				
Transaminases 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. NC = Not Calculable. 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: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=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. NC = Not Calculable. 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: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=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. NC = Not Calculable. 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)

Blood pressure decreased						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
CD4 lymphocytes decreased						
<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. NC = Not Calculable. 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: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=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						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
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. NC = Not Calculable. 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: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=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				
Electrocardiogram abnormal						
<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. NC = Not Calculable. 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: Age (years) (<35 vs. 35 - <50 vs. >=50)

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

Epstein-Barr virus test positive						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=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. NC = Not Calculable. 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: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=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 decreased						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Haematocrit 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. NC = Not Calculable. 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: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=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 decreased						
<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. NC = Not Calculable. 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: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=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. NC = Not Calculable. 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: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=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. NC =

Not Calculable. 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: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=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				
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, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, 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 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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	6/ 84 (7%)	7/ 98 (7%)				
35 - <50	7/154 (5%)	11/143 (8%)				
>=50	5/ 89 (6%)	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. NC = Not Calculable. 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)

Anogenital warts						
<35	2/ 84 (2%)	4/ 98 (4%)				
35 - <50	1/154 (<1%)	4/143 (3%)				
>=50	2/ 89 (2%)	4/ 86 (5%)				
Skin papilloma						
<35	2/ 84 (2%)	3/ 98 (3%)				
35 - <50	1/154 (<1%)	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)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	2/ 89 (2%)	0/ 86				
Fibrous histiocyoma						
<35	0/ 84	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, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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)

Adenoma benign						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	1/ 86 (1%)				
Breast cancer						
<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)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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)
Lipoma						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Lipoma of breast						
<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), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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				
Adrenal adenoma						
<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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Table 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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 neoplasm of thyroid gland						
<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)

Diffuse large B-cell lymphoma						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Fibroma						
<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)

Glioblastoma						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Kaposi's sarcoma						
<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)

Testicular neoplasm						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=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)

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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. NC =

Not Calculable. 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: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=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)

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

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

System Organ Class Preferred Term	Q8W (N=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	5/ 84 (6%)	9/ 98 (9%)				
35 - <50	14/154 (9%)	9/143 (6%)				
>=50	7/ 89 (8%)	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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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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	5/ 98 (5%)				
35 - <50	4/154 (3%)	0/143				
>=50	3/ 89 (3%)	1/ 86 (1%)				
Balanoposthitis						
<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, p-value and interaction p-values are 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)

Benign prostatic hyperplasia						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	1/ 89 (1%)	1/ 86 (1%)				
Genital lesion						
<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, p-value and interaction p-values are 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)

Menorrhagia						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	2/143 (1%)				
>=50	0/ 89	0/ 86				
Breast cyst						
<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

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Table 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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%)	1/143 (<1%)				
>=50	0/ 89	0/ 86				
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

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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)

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

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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)
Breast mass						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=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

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

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

System Organ Class Preferred Term	Q8W (N=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				
Genital odour						
<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)

Haematospermia						
<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, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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)

Penile discharge						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Penile 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, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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)

Penile pain						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Penile 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. NC = Not Calculable. 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)

Premenstrual syndrome						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=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.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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)
Prostatitis						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Sexual dysfunction						
<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. NC = Not Calculable. 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: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=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 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, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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)

Testicular torsion						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Testis discomfort						
<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. NC = Not Calculable. 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)

Uterine polyp						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
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. NC = Not Calculable. 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)

Vascular disorders						
Any Event						
<35	5/ 84 (6%)	4/ 98 (4%)				
35 - <50	7/154 (5%)	8/143 (6%)				
>=50	7/ 89 (8%)	7/ 86 (8%)				
Hypertension						
<35	3/ 84 (4%)	2/ 98 (2%)				
35 - <50	5/154 (3%)	7/143 (5%)				
>=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)

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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. NC = Not Calculable. 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: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=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	1/143 (<1%)				
>=50	0/ 89	1/ 86 (1%)				
Varicose vein						
<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, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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)
Flushing						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	1/ 86 (1%)				
Hot flush						
<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)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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)
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. NC = Not Calculable. 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)

Blood pressure inadequately controlled						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
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, p-value and interaction p-values are 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)
Peripheral coldness						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Phlebitis						
<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 = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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				
Thrombophlebitis superficial						
<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. NC = Not Calculable. 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)
Renal and urinary disorders						
Any Event						
<35	1/ 84 (1%)	8/ 98 (8%)	0.1355 (0.0166, 1.1070) /0.062	-6.9728 (-12.8691, -1.0765) /0.020	0.1458 (0.0186, 1.1423) /0.067	0.304
35 - <50	7/154 (5%)	13/143 (9%)	0.4762 (0.1844, 1.2296) /0.125	-4.5455 (-10.2921, 1.2012) /0.121	0.5000 (0.2053, 1.2178) /0.127	
>=50	1/ 89 (1%)	7/ 86 (8%)	0.1282 (0.0154, 1.0654) /0.057	-7.0159 (-13.1960, -0.8358) /0.026	0.1380 (0.0173, 1.0986) /0.061	

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

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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%)	3/ 98 (3%)				
35 - <50	2/154 (1%)	3/143 (2%)				
>=50	0/ 89	3/ 86 (3%)				
Nephrolithiasis						
<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. NC = Not Calculable. 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: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=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%)	2/143 (1%)				
>=50	1/ 89 (1%)	0/ 86				
Renal colic						
<35	0/ 84	2/ 98 (2%)				
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. NC = Not Calculable. 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)

Haematuria						
<35	0/ 84	0/ 98				
35 - <50	0/154	2/143 (1%)				
>=50	0/ 89	0/ 86				
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, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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				
Renal cyst						
<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)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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 discharge						
<35	0/ 84	0/ 98				
35 - <50	0/154	2/143 (1%)				
>=50	0/ 89	0/ 86				
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, p-value and interaction p-values are 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. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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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)

Nephropathy						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
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, 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)

Urethral disorder						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Urethral 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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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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 incontinence						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=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, 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)

Metabolism and nutrition disorders						
Any Event						
<35	2/ 84 (2%)	5/ 98 (5%)				
35 - <50	8/154 (5%)	5/143 (3%)				
>=50	8/ 89 (9%)	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),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, 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 System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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	2/154 (1%)	2/143 (1%)				
>=50	2/ 89 (2%)	2/ 86 (2%)				
Vitamin D deficiency						
<35	1/ 84 (1%)	1/ 98 (1%)				
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, p-value and interaction p-values are 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)

Decreased appetite						
<35	0/ 84	2/ 98 (2%)				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Gout						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=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

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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)
Obesity						
<35	1/ 84 (1%)	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	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)

Alcoholic ketoacidosis						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
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

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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)

Diabetes mellitus						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Dyslipidaemia						
a <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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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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%)				
Hyperglycaemia						
<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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Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=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						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Hypertriglyceridaemia						
<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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Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=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%)				
Iron 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, p-value and interaction p-values are only provided for AEs with

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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)

Eye disorders						
Any Event						
<35	2/ 84 (2%)	5/ 98 (5%)				
35 - <50	7/154 (5%)	6/143 (4%)				
>=50	5/ 89 (6%)	9/ 86 (10%)				
Cataract						
<35	0/ 84	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, p-value and interaction p-values are only provided for AEs with

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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)

Conjunctivitis allergic						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	0/154	3/143 (2%)				
>=50	0/ 89	0/ 86				
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)

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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)

Retinal detachment						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	2/ 89 (2%)	1/ 86 (1%)				
Diplopia						
<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)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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/>						
Dry eye						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Astigmatism						
<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. NC = Not Calculable. 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)

Blepharospasm						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
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, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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 eyelids						
<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)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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

(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. NC = Not Calculable. 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)

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

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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)
Macular fibrosis						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Mydriasis						
<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. NC = Not Calculable. 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: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=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						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Pterygium						
<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. NC = Not Calculable. 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)
Retinal tear						
<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, p-value and interaction p-values are 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 detachment						
<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)
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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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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)

Ear and labyrinth disorders						
Any Event						
<35	1/ 84 (1%)	6/ 98 (6%)				
35 - <50	4/154 (3%)	6/143 (4%)				
>=50	5/ 89 (6%)	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. NC =

Not Calculable. 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: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=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	1/154 (<1%)	1/143 (<1%)				
>=50	1/ 89 (1%)	0/ 86				
Vertigo						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	1/154 (<1%)	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)

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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. NC = Not Calculable. 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)

Cerumen impaction						
<35	0/ 84	1/ 98 (1%)				
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

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

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

System Organ Class Preferred Term	Q8W (N=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	1/154 (<1%)	0/143				
>=50	0/ 89	1/ 86 (1%)				
Eustachian tube dysfunction						
<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)

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Table 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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

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Table 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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 pruritus						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
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, p-value and interaction p-values are 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)
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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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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%)	5/ 98 (5%)				
35 - <50	9/154 (6%)	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)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, 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 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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	5/154 (3%)	0/143				
>=50	1/ 89 (1%)	4/ 86 (5%)				
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), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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)
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	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), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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)

Allergy to arthropod bite						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Anaphylactic reaction						
<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. NC = Not Calculable. 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)

Blood and lymphatic system disorders						
Any Event						
<35	2/ 84 (2%)	4/ 98 (4%)				
35 - <50	3/154 (2%)	5/143 (3%)				
>=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), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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)

Lymphadenopathy						
<35	1/ 84 (1%)	2/ 98 (2%)				
35 - <50	0/154	2/143 (1%)				
>=50	1/ 89 (1%)	0/ 86				
Anaemia						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	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. NC = Not Calculable. 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: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=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	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	1/154 (<1%)	0/143				
>=50	1/ 89 (1%)	0/ 86				
Iron deficiency anaemia						
<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, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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				
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. NC = Not Calculable. 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: Age (years) (<35 vs. 35 - <50 vs. >=50)

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

Polycythaemi ^a						
<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. NC =

Not Calculable. 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: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=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	3/ 84 (4%)	4/ 98 (4%)				
35 - <50	0/154	4/143 (3%)				
>=50	3/ 89 (3%)	3/ 86 (3%)				
Palpitations						
<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, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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%)	1/ 98 (1%)				
35 - <50	0/154	2/143 (1%)				
>=50	0/ 89	0/ 86				
Ventricular extrasystoles						
<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. NC = Not Calculable. 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)

Acute myocardial infarction						
<35	0/ 84	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, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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)

Atrial fibrillation						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Atrioventricular block first 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, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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)

Cardiac aneurysm						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Extrasystoles						
<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)

Myocardial infarction						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Myocardial necrosis						
<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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Table 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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 bradycardia						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Wolff-Parkinson-White syndrome						
<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.

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Table 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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	2/ 84 (2%)	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. NC = Not Calculable. 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: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=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				
Hepatic steatosis						
<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. NC = Not Calculable. 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: Age (years) (<35 vs. 35 - <50 vs. >=50)

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

Hepatocellular injury						
<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. NC = Not Calculable. 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)
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. NC =

Not Calculable. 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: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=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	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

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, 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 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Gilbert's syndrome						
<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. NC = Not Calculable. 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)
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. NC = Not Calculable. 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)

Endocrine disorders						
Any Event						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	1/143 (<1%)				
>=50	1/ 89 (1%)	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. NC = Not Calculable. 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)

Androgen deficiency						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
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.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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	Q8W (N=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. NC =

Not Calculable. 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: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=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. NC = Not Calculable. 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: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=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),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, 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 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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. NC =

Not Calculable. 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)

Overall						
Any Event						
Female	66/ 73 (90%)	70/ 75 (93%)				
Male	245/254 (96%)	248/252 (98%)				

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

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, 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 3.17

Analysis of Proportion of 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	57/ 73 (78%)	56/ 75 (75%)				
Male	230/254 (91%)	223/252 (88%)				
Injection site pain						
Female	52/ 73 (71%)	52/ 75 (69%)				
Male	221/254 (87%)	209/252 (83%)				

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

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17
 Analysis of Proportion of 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	14/ 73 (19%)	22/ 75 (29%)	0.5716 (0.2658, 1.2296) /0.152	-10.1553 (-23.8570, 3.5465) /0.146	0.6538 (0.3633, 1.1765) /0.156	0.375
Male	27/254 (11%)	57/252 (23%)	0.4069 (0.2477, 0.6684) /<.001	-11.9891 (-18.3961, -5.5822) /<.001	0.4700 (0.3077, 0.7177) /<.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. NC =

Not Calculable. 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)

Injection site discomfort						
Female	2/ 73 (3%)	6/ 75 (8%)				
Male	26/254 (10%)	29/252 (12%)				
Injection site induration						
Female	9/ 73 (12%)	14/ 75 (19%)				
Male	19/254 (7%)	21/252 (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. NC =

Not Calculable. 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)
Pyrexia						
Female	5/ 73 (7%)	3/ 75 (4%)				
Male	21/254 (8%)	33/252 (13%)				
Injection site swelling						
Female	10/ 73 (14%)	7/ 75 (9%)				
Male	17/254 (7%)	16/252 (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

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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)
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	0.582
Male	13/254 (5%)	28/252 (11%)	0.4315 (0.2181, 0.8539) /0.016	-5.9930 (-10.7259, -1.2601) /0.013	0.4606 (0.2443, 0.8686) /0.017	

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

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, 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 3.17

Analysis of Proportion of 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 pruritus						
Female	3/ 73 (4%)	13/ 75 (17%)	0.2044 (0.0556, 0.7508) /0.017	-13.2237 (-22.9257, -3.5217) /0.008	0.2371 (0.0705, 0.7977) /0.020	0.132
Male	8/254 (3%)	11/252 (4%)	0.7125 (0.2817, 1.8020) /0.474	-1.2155 (-4.5286, 2.0977) /0.472	0.7215 (0.2952, 1.7639) /0.474	

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

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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)

Influenza like illness						
Female	1/ 73 (1%)	7/ 75 (9%)				
Male	9/254 (4%)	10/252 (4%)				
Injection site erythema						
Female	3/ 73 (4%)	6/ 75 (8%)				
Male	9/254 (4%)	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)
Asthenia						
Female	5/ 73 (7%)	5/ 75 (7%)				
Male	9/254 (4%)	5/252 (2%)				
Chills						
Female	1/ 73 (1%)	1/ 75 (1%)				
Male	13/254 (5%)	7/252 (3%)				
Injection site bruising						
Female	2/ 73 (3%)	4/ 75 (5%)				
Male	9/254 (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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Table 3.17

Analysis of Proportion of 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						
Female	0/ 73	0/ 75				
Male	8/254 (3%)	8/252 (3%)				
Malaise						
Female	1/ 73 (1%)	0/ 75				
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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Table 3.17

Analysis of Proportion of 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 haematoma						
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	0.229
Male	2/254 (<1%)	8/252 (3%)	0.2421 (0.0509, 1.1513) /0.075	-2.3872 (-4.8094, 0.0350) /0.053	0.2480 (0.0532, 1.1566) /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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Table 3.17

Analysis of Proportion of 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 warmth						
Female	2/ 73 (3%)	2/ 75 (3%)				
Male	4/254 (2%)	4/252 (2%)				
Chest pain						
Female	1/ 73 (1%)	3/ 75 (4%)				
Male	3/254 (1%)	3/252 (1%)				
Discomfort						
Female	3/ 73 (4%)	1/ 75 (1%)				
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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Table 3.17

Analysis of Proportion of 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	1/ 75 (1%)				
Male	4/254 (2%)	3/252 (1%)				
Injection site anaesthesia						
Female	1/ 73 (1%)	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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Table 3.17

Analysis of Proportion of 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)
Nodule						
Female	0/ 73	0/ 75				
Male	3/254 (1%)	3/252 (1%)				
Feeling hot						
Female	0/ 73	0/ 75				
Male	5/254 (2%)	0/252				
Peripheral swelling						
Female	0/ 73	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

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Table 3.17

Analysis of Proportion of 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)

Cyst						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	1/252 (<1%)				
Injection site discolouration						
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)
Mass						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	2/252 (<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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Analysis of Proportion of 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)

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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Analysis of Proportion of 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 haemorrhage						
Female	0/ 73	0/ 75				
Male	0/254	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, p-value and interaction p-values are 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)

Non-cardiac chest pain						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Temperature regulation disorder						
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)

Vaccination site pain						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				
Adverse drug reaction						
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)
Chronic fatigue syndrome						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Enanthema						
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)

Feeling abnormal						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
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, 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 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, 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 hypoaesthesia						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				
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, 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 necrosis						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				
Injection site 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

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative 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. NC =

Not Calculable. 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)

Oedema peripheral						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
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)

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Analysis of Proportion of 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)
Swelling						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
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

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Table 3.17

Analysis of Proportion of 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	37/ 73 (51%)	46/ 75 (61%)				
Male	179/254 (70%)	193/252 (77%)				
Nasopharyngitis						
Female	10/ 73 (14%)	15/ 75 (20%)				
Male	51/254 (20%)	51/252 (20%)				

Note: "Any Event" represents subjects with any 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)
Upper respiratory tract infection						
Female	5/ 73 (7%)	13/ 75 (17%)	0.3507 (0.1182, 1.0402) /0.059	-10.4840 (-20.8265, -0.1416) /0.047	0.3952 (0.1483, 1.0526) /0.063	0.214
Male	40/254 (16%)	53/252 (21%)	0.7018 (0.4459, 1.1047) /0.126	-5.2837 (-12.0205, 1.4531) /0.124	0.7488 (0.5163, 1.0859) /0.127	

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: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=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	3/ 73 (4%)	8/ 75 (11%)	0.3589 (0.0913, 1.4104) /0.142	-6.5571 (-14.8964, 1.7822) /0.123	0.3853 (0.1064, 1.3957) /0.146	0.604
Male	13/254 (5%)	23/252 (9%)	0.5371 (0.2657, 1.0856) /0.083	-4.0089 (-8.4796, 0.4619) /0.079	0.5608 (0.2906, 1.0821) /0.085	
Syphilis						
Female	0/ 73	0/ 75				
Male	18/254 (7%)	22/252 (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

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Analysis of Proportion of 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						
Female	3/ 73 (4%)	4/ 75 (5%)				
Male	15/254 (6%)	9/252 (4%)				
Bronchitis						
Female	4/ 73 (5%)	4/ 75 (5%)				
Male	10/254 (4%)	12/252 (5%)				
Pharyngitis						
Female	2/ 73 (3%)	3/ 75 (4%)				
Male	10/254 (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

(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)
Gonorrhoea						
Female	0/ 73	0/ 75				
Male	13/254 (5%)	13/252 (5%)				
Sinusitis						
Female	0/ 73	2/ 75 (3%)				
Male	10/254 (4%)	10/252 (4%)				
Viral infection						
Female	0/ 73	4/ 75 (5%)				
Male	8/254 (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)

Chlamydial infection						
Female	0/ 73	0/ 75				
Male	12/254 (5%)	8/252 (3%)				
Urinary tract infection						
Female	4/ 73 (5%)	4/ 75 (5%)				
Male	6/254 (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)

Conjunctivitis						
Female	0/ 73	3/ 75 (4%)				
Male	9/254 (4%)	6/252 (2%)				
Respiratory tract infection viral						
Female	2/ 73 (3%)	2/ 75 (3%)				
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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Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=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	7/254 (3%)	9/252 (4%)				
Tonsillitis						
Female	1/ 73 (1%)	1/ 75 (1%)				
Male	4/254 (2%)	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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Analysis of Proportion of 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 chlamydia infection						
Female	0/ 73	0/ 75				
Male	9/254 (4%)	6/252 (2%)				
Respiratory tract infection						
Female	3/ 73 (4%)	2/ 75 (3%)				
Male	5/254 (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)
Oral herpes						
Female	1/ 73 (1%)	3/ 75 (4%)	0.3333 (0.0339, 3.2806) /0.346	-2.6301 (-7.8049, 2.5446) /0.319	0.3425 (0.0365, 3.2173) /0.348	0.818
Male	2/254 (<1%)	8/252 (3%)	0.2421 (0.0509, 1.1513) /0.075	-2.3872 (-4.8094, 0.0350) /0.053	0.2480 (0.0532, 1.1566) /0.076	
Urethritis						
Female	0/ 73	0/ 75				
Male	5/254 (2%)	9/252 (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: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=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						
Female	1/ 73 (1%)	0/ 75				
Male	5/254 (2%)	7/252 (3%)				
Oropharyngeal gonococcal infection						
Female	0/ 73	0/ 75				
Male	6/254 (2%)	7/252 (3%)				
Rhinitis						
Female	0/ 73	0/ 75				
Male	5/254 (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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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=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						
Female	1/ 73 (1%)	2/ 75 (3%)				
Male	4/254 (2%)	5/252 (2%)				
Gastroenteritis viral						
Female	0/ 73	1/ 75 (1%)				
Male	4/254 (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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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=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%)	1/ 75 (1%)				
Male	1/254 (<1%)	7/252 (3%)				
Lower respiratory tract infection						
Female	2/ 73 (3%)	0/ 75				
Male	5/254 (2%)	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)

Tooth abscess						
Female	0/ 73	1/ 75 (1%)				
Male	2/254 (<1%)	6/252 (2%)				
Ear infection						
Female	0/ 73	3/ 75 (4%)				
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

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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)

Onychomycosis						
Female	1/ 73 (1%)	0/ 75				
Male	2/254 (<1%)	5/252 (2%)				
Tinea versicolour						
Female	0/ 73	1/ 75 (1%)				
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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Table 3.17

Analysis of Proportion of 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	3/ 75 (4%)				
Male	0/254	5/252 (2%)				
Fungal skin infection						
Female	0/ 73	0/ 75				
Male	3/254 (1%)	4/252 (2%)				
Cellulitis						
Female	0/ 73	2/ 75 (3%)				
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

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

Analysis of Proportion of 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)

Diverticulitis						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	4/252 (2%)				
Furuncle						
Female	1/ 73 (1%)	0/ 75				
Male	3/254 (1%)	2/252 (<1%)				
Gingivitis						
Female	0/ 73	2/ 75 (3%)				
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)

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Table 3.17

Analysis of Proportion of 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)

Herpes simplex						
Female	1/ 73 (1%)	1/ 75 (1%)				
Male	2/254 (<1%)	2/252 (<1%)				
Hordeolum						
Female	0/ 73	0/ 75				
Male	3/254 (1%)	3/252 (1%)				
Pneumonia						
Female	1/ 73 (1%)	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)

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Table 3.17

Analysis of Proportion of 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	2/254 (<1%)	4/252 (2%)				
Urethritis gonococcal						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	4/252 (2%)				
Abscess limb						
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)

Acarodermatitis						
Female	1/ 73 (1%)	0/ 75				
Male	1/254 (<1%)	3/252 (1%)				
Secondary syphilis						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	3/252 (1%)				
Body tinea						
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, p-value and interaction p-values are 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)

Genital herpes						
Female	1/ 73 (1%)	0/ 75				
Male	1/254 (<1%)	2/252 (<1%)				
Mycoplasma genitalium infection						
Female	0/ 73	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

(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 externa						
Female	0/ 73	1/ 75 (1%)				
Male	1/254 (<1%)	2/252 (<1%)				
Pharyngotonsillitis						
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

(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)
Primary syphilis						
Female	0/ 73	0/ 75				
Male	3/254 (1%)	1/252 (<1%)				
Shigella infection						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	2/252 (<1%)				
Tracheitis						
Female	0/ 73	2/ 75 (3%)				
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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Analysis of Proportion of 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	1/254 (<1%)	3/252 (1%)				
Enteritis infectious						
Female	0/ 73	0/ 75				
Male	3/254 (1%)	0/252				
Epididymitis						
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)

Helicobacter infection						
Female	0/ 73	0/ 75				
Male	0/254	3/252 (1%)				
Injection site abscess						
Female	2/ 73 (3%)	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)

Oral candidiasis						
Female	0/ 73	0/ 75				
Male	0/254	3/252 (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

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Table 3.17

Analysis of Proportion of 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)
Pharyngeal chlamydia infection						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	1/252 (<1%)				
Pharyngitis streptococcal						
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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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=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						
Female	0/ 73	0/ 75				
Male	3/254 (1%)	0/252				
Staphylococcal 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, 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)

Subcutaneous abscess						
Female	1/ 73 (1%)	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Tinea cruris						
Female	0/ 73	0/ 75				
Male	0/254	3/252 (1%)				
Tinea infection						
Female	0/ 73	0/ 75				
Male	0/254	3/252 (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)

Vaginal infection						
Female	1/ 73 (1%)	2/ 75 (3%)				
Male	0/254	0/252				
Varicella						
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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Analysis of Proportion of 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)

Vulvovaginal mycotic infection						
Female	1/ 73 (1%)	2/ 75 (3%)				
Male	0/254	0/252				
Acute hepatitis B						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	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)

Acute sinusitis						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	1/252 (<1%)				
Bronchitis viral						
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)

Chronic sinusitis						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	0/252				
Cystitis						
Female	0/ 73	2/ 75 (3%)				
Male	0/254	0/252				
Diarrhoea infectious						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	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)
Escherichia urinary tract infection						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	1/252 (<1%)				
Hepatitis E						
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)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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)
Laryngitis						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				
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%)				

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

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

Analysis of Proportion of 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)
Orchitis						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				
Otitis media						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<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

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

Analysis of Proportion of 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 chlamydial						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	0/252				
Pulmonary tuberculosis						
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)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

Analysis of Proportion of 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)

Pulpitis dental						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	1/252 (<1%)				
Sexually transmitted disease						
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)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, 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 3.17

Analysis of Proportion of 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 skin infection						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	0/252				
Tinea pedis						
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)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, 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 3.17

Analysis of Proportion of 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)

Ureaplasma infection						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				
Urethritis mycoplasmal						
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, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

Analysis of Proportion of 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 abscess						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
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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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative 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. NC =

Not Calculable. 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)

Bacterial vaginosis						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Borrelia infection						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
COVID-19						
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)

Candida infection						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Cellulitis of male external genital organ						
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)

Chest wall abscess						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	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)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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)

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 = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

Analysis of Proportion of 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%)				
Ear infection bacterial						
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. NC = Not Calculable. 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)

Eczema infected						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Enterobiasis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Enterovirus 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

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Table 3.17

Analysis of Proportion of 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)

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				
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, p-value and interaction p-values are 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)

Escherichia infection						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	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, p-value and interaction p-values are 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)
Eye infection						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
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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Table 3.17

Analysis of Proportion of 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				
Gastrointestinal infection						
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, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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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Table 3.17

Analysis of Proportion of 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 candidiasis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Genital herpes simplex						
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. NC =

Not Calculable. 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)

Genitourinary tract infection						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Giardiasis						
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)

Gingival abscess						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Gonococcal 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

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Table 3.17

Analysis of Proportion of 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)

Groin abscess						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Hepatitis C						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Herpes ophthalmic						
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)
Herpes virus infection						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Infected bite						
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)

Latent syphilis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Lice infestation						
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)
Localised infection						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
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

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Table 3.17

Analysis of Proportion of 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

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Analysis of Proportion of 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

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Table 3.17

Analysis of Proportion of 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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Table 3.17

Analysis of Proportion of 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

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Table 3.17

Analysis of Proportion of 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 mycoplasmal						
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)
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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Analysis of Proportion of 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

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Analysis of Proportion of 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)

Suspected COVID-19						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
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

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Table 3.17

Analysis of Proportion of 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				
Tracheobronchitis						
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)

Trichomoniasis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Urinary tract infection staphylococcal						
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)

Viral rash						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Viral rhinitis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Wound 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. NC = Not Calculable. 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)
Gastrointestinal disorders						
Any Event						
Female	11/ 73 (15%)	22/ 75 (29%)	0.4274 (0.1899, 0.9621) /0.040	-14.2648 (-27.4375, -1.0922) /0.034	0.5137 (0.2687, 0.9821) /0.044	0.135
Male	87/254 (34%)	101/252 (40%)	0.7789 (0.5426, 1.1180) /0.175	-5.8274 (-14.2338, 2.5790) /0.174	0.8546 (0.6806, 1.0731) /0.176	

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

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

Analysis of Proportion of 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%)	5/ 75 (7%)				
Male	31/254 (12%)	32/252 (13%)				
Nausea						
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	0.557
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	

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

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are 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)
Haemorrhoids 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	0.504
Male	4/254 (2%)	15/252 (6%)	0.2528 (0.0827, 0.7726) /0.016	-4.3776 (-7.6757, -1.0794) /0.009	0.2646 (0.0890, 0.7862) /0.017	

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

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, 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 3.17

Analysis of Proportion of 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)
Constipation						
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	0.910
Male	2/254 (<1%)	10/252 (4%)	0.1921 (0.0417, 0.8856) /0.034	-3.1809 (-5.8248, -0.5369) /0.018	0.1984 (0.0439, 0.8966) /0.036	
Dyspepsia						
Female	0/ 73	2/ 75 (3%)				
Male	8/254 (3%)	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

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

Analysis of Proportion of 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	1/ 73 (1%)	1/ 75 (1%)				
Male	6/254 (2%)	9/252 (4%)				
Abdominal pain						
Female	2/ 73 (3%)	2/ 75 (3%)				
Male	6/254 (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

(1) significant difference in occurrences between treatment arms 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)

Gastrooesophageal reflux disease						
Female	0/ 73	0/ 75				
Male	6/254 (2%)	7/252 (3%)				
Abdominal distension						
Female	1/ 73 (1%)	0/ 75				
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

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative 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)
Abdominal pain upper						
Female	0/ 73	1/ 75 (1%)				
Male	3/254 (1%)	6/252 (2%)				
Vomiting						
Female	0/ 73	2/ 75 (3%)				
Male	6/254 (2%)	2/252 (<1%)				
Anogenital dysplasia						
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, p-value and interaction p-values are 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)
Gastritis						
Female	0/ 73	2/ 75 (3%)				
Male	3/254 (1%)	2/252 (<1%)				
Abdominal discomfort						
Female	1/ 73 (1%)	2/ 75 (3%)				
Male	1/254 (<1%)	2/252 (<1%)				
Rectal haemorrhage						
Female	0/ 73	0/ 75				
Male	1/254 (<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)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

Analysis of Proportion of 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%)	2/252 (<1%)				
Anal fissure						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	3/252 (1%)				
Dental caries						
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

(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. NC = Not Calculable. 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)
Flatulence						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	3/252 (1%)				
Haematochezi ^a						
Female	0/ 73	0/ 75				
Male	4/254 (2%)	1/252 (<1%)				
Food poisoning						
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.

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Table 3.17

Analysis of Proportion of 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						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	3/252 (1%)				
Rectal discharge						
Female	0/ 73	0/ 75				
Male	3/254 (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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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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)
Dry mouth						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	2/252 (<1%)				
Hiatus hernia						
Female	1/ 73 (1%)	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Inguinal hernia						
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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Analysis of Proportion of 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%)	2/252 (<1%)				
Oesophagitis						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	1/252 (<1%)				
Proctalgia						
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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Analysis of Proportion of 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	1/254 (<1%)	1/252 (<1%)				
Colitis						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	1/252 (<1%)				
Diverticulum intestinal						
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

(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)

Gingival pain						
Female	0/ 73	1/ 75 (1%)				
Male	1/254 (<1%)	0/252				
Haemorrhoids thrombosed						
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)

(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: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=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%)	1/252 (<1%)				
Mouth ulceration						
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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Analysis of Proportion of 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)

Noninfective gingivitis						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	1/252 (<1%)				
Oral disorder						
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. NC = Not Calculable. 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)

Tongue ulceration						
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, p-value and interaction p-values are 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. NC =

Not Calculable. 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)
Abdominal tenderness						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Anal ulcer						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Angular 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

(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)

Anorectal discomfort						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Aphthous ulcer						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Chapped lips						
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)
Cheilitis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Crohn's disease						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Dental cyst						
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)
Dysphagia						
Female	0 / 73	0 / 75				
Male	1/254 (<1%)	0/252				
Enteritis						
Female	0 / 73	0 / 75				
Male	1/254 (<1%)	0/252				
Enterocolitis						
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)
Faeces soft						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Gastric disorder						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Gastric ulcer						
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)

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%)				

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

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are 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 ulceration						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Glossitis						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
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, 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)
Haemorrhoidal haemorrhage						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	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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Analysis of Proportion of 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)

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

(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)

Oral lichen planus						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				
Oral pain						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	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, p-value and interaction p-values are 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)
Pancreatitis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
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%)				

Note: "Any Event" represents subjects with any 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)
Rectal prolapse						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Rectal tenesmus						
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)

Salivary gland mucocoele						
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 Preferred Term	Q8W (N=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	17/ 73 (23%)	27/ 75 (36%)				
Male	74/254 (29%)	86/252 (34%)				
Back pain						
Female	5/ 73 (7%)	9/ 75 (12%)				
Male	22/254 (9%)	23/252 (9%)				

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)
Arthralgia						
Female	4/ 73 (5%)	7/ 75 (9%)				
Male	17/254 (7%)	18/252 (7%)				
Pain in extremity						
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	0.111
Male	11/254 (4%)	19/252 (8%)	0.5551 (0.2586, 1.1918) /0.131	-3.2090 (-7.3191, 0.9011) /0.126	0.5744 (0.2791, 1.1822) /0.132	

Note: "Any Event" represents subjects with any 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)
Myalgia						
Female	1/ 73 (1%)	2/ 75 (3%)				
Male	9/254 (4%)	9/252 (4%)				
Musculoskeletal pain						
Female	1/ 73 (1%)	1/ 75 (1%)				
Male	7/254 (3%)	6/252 (2%)				
Muscle spasms						
Female	0/ 73	0/ 75				
Male	3/254 (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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Analysis of Proportion of 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	5/254 (2%)	2/252 (<1%)				
Tendonitis						
Female	1/ 73 (1%)	1/ 75 (1%)				
Male	6/254 (2%)	1/252 (<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)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

Analysis of Proportion of 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)
Intervertebral disc protrusion						
Female	1/ 73 (1%)	0/ 75				
Male	3/254 (1%)	2/252 (<1%)				
Muscle contracture						
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, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, 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 3.17

Analysis of Proportion of 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%)	1/252 (<1%)				
Rotator cuff syndrome						
Female	1/ 73 (1%)	2/ 75 (3%)				
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)

Spinal osteoarthritis						
Female	0/ 73	2/ 75 (3%)				
Male	1/254 (<1%)	1/252 (<1%)				
Muscular weakness						
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)
Plantar fasciitis						
Female	1/ 73 (1%)	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Synovial cyst						
Female	0/ 73	2/ 75 (3%)				
Male	1/254 (<1%)	0/252				
Arthritis						
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)
Bursitis						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	0/252				
Exostosis						
Female	0/ 73	2/ 75 (3%)				
Male	0/254	0/252				
Flank pain						
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)

Groin pain						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	1/252 (<1%)				
Joint contracture						
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)

Joint range of motion decreased						
Female	1/ 73 (1%)	0/ 75				
Male	1/254 (<1%)	0/252				
Joint swelling						
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)
Limb discomfort						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				
Musculoskeletal 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, p-value and interaction p-values are 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)
Musculoskeletal stiffness						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				
Osteonecrosis						
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)
Pain in jaw						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				
Synovitis						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	1/252 (<1%)				
Arthritis reactive						
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)
Arthropathy						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Bone pain						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Cervical spinal stenosis						
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)

Costochondritis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Femoroacetabular impingement						
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)

Joint stiffness						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Loose body in joint						
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)
Muscle tightness						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Myosclerosis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Osteochondritis						
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)
Osteopenia						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Periarthriti s						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Polyarthriti s						
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)
Sacroiliitis						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Scoliosis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Spinal 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 Preferred Term	Q8W (N=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

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Analysis of Proportion of 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)

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

(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. NC =

Not Calculable. 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 and subcutaneous tissue disorders						
Any Event						
Female	14/ 73 (19%)	19/ 75 (25%)				
Male	60/254 (24%)	65/252 (26%)				
Pruritus						
Female	1/ 73 (1%)	5/ 75 (7%)				
Male	11/254 (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.

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Analysis of Proportion of 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	8/254 (3%)	9/252 (4%)				
Eczema						
Female	2/ 73 (3%)	7/ 75 (9%)				
Male	5/254 (2%)	6/252 (2%)				
Skin lesion						
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, p-value and interaction p-values are 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)
Acne						
Female	1/ 73 (1%)	1/ 75 (1%)				
Male	1/254 (<1%)	7/252 (3%)				
Dermatitis						
Female	0/ 73	0/ 75				
Male	4/254 (2%)	6/252 (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

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Table 3.17

Analysis of Proportion of 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)

Hyperhidrosi s						
Female	1/ 73 (1%)	1/ 75 (1%)				
Male	0/254	6/252 (2%)				
Dermatitis contact						
Female	1/ 73 (1%)	0/ 75				
Male	3/254 (1%)	3/252 (1%)				
Erythema						
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

(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)

Seborrhoeic dermatitis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	4/252 (2%)				
Urticaria						
Female	1/ 73 (1%)	0/ 75				
Male	2/254 (<1%)	2/252 (<1%)				
Dermal cyst						
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)

Dermatitis atopic						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	3/252 (1%)				
Night sweats						
Female	0/ 73	0/ 75				
Male	4/254 (2%)	0/252				
Dry skin						
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, 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)

Pityriasis rosea						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	1/252 (<1%)				
Skin exfoliation						
Female	0/ 73	0/ 75				
Male	0/254	3/252 (1%)				
Skin mass						
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)
Actinic keratosis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Chloasma						
Female	1/ 73 (1%)	1/ 75 (1%)				
Male	0/254	0/252				
Ecchymosis						
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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Analysis of Proportion of 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)
Psoriasis						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				
Rash erythematous						
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)

Rash maculo-papular						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Rash papular						
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)
Actinic elastosis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Androgenetic alopecia						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Cold sweat						
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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Subgroup: Sex at Birth (Female vs. Male)

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

Dermatosis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Drug eruption						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	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

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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)

Granuloma annulare						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Guttate psoriasis						
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)
Hand dermatitis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Hyperkeratosis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Intertrigo						
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)

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				
Macule						
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)
Miliaria						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Nail bed bleeding						
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

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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)

Nail dystrophy						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
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%)				

Note: "Any Event" represents subjects with any 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)

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				
Pityriasis						
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. NC = Not Calculable. 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)
Prurigo						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Purpura						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Rash macular						
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. NC = Not Calculable. 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)

Rash morbilliform						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
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, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Not Calculable. 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)
Rash vesicular						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Skin discolouration						
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)

Skin fissures						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
 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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Table 3.17

Analysis of Proportion of 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%)				
Skin ulcer						
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)

Solar dermatitis						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Solar lentigo						
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)

Nervous system disorders						
Any Event						
Female	6/ 73 (8%)	14/ 75 (19%)				
Male	59/254 (23%)	62/252 (25%)				
Headache						
Female	4/ 73 (5%)	7/ 75 (9%)				
Male	26/254 (10%)	27/252 (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. NC = Not Calculable. 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)

Dizziness						
Female	1/ 73 (1%)	4/ 75 (5%)				
Male	16/254 (6%)	10/252 (4%)				
Presyncope						
Female	0/ 73	3/ 75 (4%)				
Male	3/254 (1%)	5/252 (2%)				
Hypoaesthesia						
a Female	0/ 73	0/ 75				
Male	5/254 (2%)	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)
Migraine						
Female	1/ 73 (1%)	1/ 75 (1%)				
Male	1/254 (<1%)	4/252 (2%)				
Paraesthesia						
Female	1/ 73 (1%)	1/ 75 (1%)				
Male	1/254 (<1%)	4/252 (2%)				
Sciatica						
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)
Somnolence						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	3/252 (1%)				
Syncope						
Female	0/ 73	1/ 75 (1%)				
Male	1/254 (<1%)	3/252 (1%)				
Lethargy						
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, p-value and interaction p-values are 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)

Tension headache						
Female	1/ 73 (1%)	1/ 75 (1%)				
Male	0/254	1/252 (<1%)				
Carpal tunnel syndrome						
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)

Cervical radiculopathy						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Disturbance in attention						
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)
Head discomfort						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Agnosia						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Amnesia						
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. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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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)

Anosmia						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Ataxia						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Brain 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

(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)
Brain stem infarction						
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

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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)
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%)				
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, 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)
Dysgeusia						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Hyperaesthesia						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Hypersomnia						
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)
Hypertonia						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Memory impairment						
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. NC = Not Calculable. 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)
Muscle contractions involuntary						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Neuritis cranial						
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 = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, 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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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=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				
Periodic limb movement 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)

Polyneuropathy						
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, p-value and interaction p-values are 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)

Transient ischaemic attack						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Tremor						
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)
Trigeminal neuralgia						
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)

Respiratory, thoracic and mediastinal disorders						
Any Event						
Female	10/ 73 (14%)	17/ 75 (23%)	0.5415 (0.2295, 1.2781) /0.162	-8.9680 (-21.2966, 3.3605) /0.154	0.6044 (0.2967, 1.2311) /0.165	0.730
Male	42/254 (17%)	60/252 (24%)	0.6340 (0.4083, 0.9844) /0.042	-7.2741 (-14.2402, -0.3080) /0.041	0.6945 (0.4876, 0.9892) /0.043	

Note: "Any Event" represents subjects with any 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)
Cough						
Female	5/ 73 (7%)	6/ 75 (8%)				
Male	16/254 (6%)	21/252 (8%)				
Oropharyngeal pain						
Female	5/ 73 (7%)	5/ 75 (7%)				
Male	6/254 (2%)	14/252 (6%)				
Rhinitis allergic						
Female	0/ 73	0/ 75				
Male	6/254 (2%)	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

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

Analysis of Proportion of 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 congestion						
Female	0/ 73	3/ 75 (4%)				
Male	5/254 (2%)	6/252 (2%)				
Sinus congestion						
Female	0/ 73	1/ 75 (1%)				
Male	3/254 (1%)	7/252 (3%)				
Asthma						
Female	0/ 73	1/ 75 (1%)				
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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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=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%)	6/252 (2%)				
Epistaxis						
Female	0/ 73	1/ 75 (1%)				
Male	1/254 (<1%)	3/252 (1%)				
Dyspnoea						
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, p-value and interaction p-values are 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)

Productive cough						
Female	0/ 73	1/ 75 (1%)				
Male	2/254 (<1%)	1/252 (<1%)				
Rhinorrhoea						
Female	0/ 73	1/ 75 (1%)				
Male	1/254 (<1%)	2/252 (<1%)				
Catarrh						
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)
Haemoptysis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Nasal discomfort						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	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, p-value and interaction p-values are 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)

Rales						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Respiratory disorder						
Female	0/ 73	2/ 75 (3%)				
Male	0/254	0/252				
Bronchospasm						
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)
Dry throat						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Emphysema						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
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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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=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						
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				
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, 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)

Pharyngeal erythema						
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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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=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%)				
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

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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	Q8W (N=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	4/ 73 (5%)	13/ 75 (17%)	0.2765 (0.0856, 0.8926) /0.032	-11.8539 (-21.8861, -1.8216) /0.021	0.3161 (0.1081, 0.9247) /0.035	0.238
Male	39/254 (15%)	64/252 (25%)	0.5328 (0.3419, 0.8304) /0.005	-10.0425 (-17.0095, -3.0755) /0.005	0.6046 (0.4226, 0.8648) /0.006	

Note: "Any Event" represents subjects with any 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)
Contusion						
Female	0/ 73	2/ 75 (3%)				
Male	6/254 (2%)	6/252 (2%)				
Ligament sprain						
Female	1/ 73 (1%)	0/ 75				
Male	3/254 (1%)	9/252 (4%)				
Arthropod bite						
Female	0/ 73	4/ 75 (5%)				
Male	2/254 (<1%)	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)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

Analysis of Proportion of 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)

Exposure to communicable disease						
Female	0/ 73	0/ 75				
Male	4/254 (2%)	8/252 (3%)				
Muscle strain						
Female	0/ 73	2/ 75 (3%)				
Male	3/254 (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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OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, 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 3.17

Analysis of Proportion of 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	1/ 75 (1%)				
Male	7/254 (3%)	3/252 (1%)				
Skin laceration						
Female	0/ 73	2/ 75 (3%)				
Male	2/254 (<1%)	4/252 (2%)				
Skin abrasion						
Female	0/ 73	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)

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Table 3.17

Analysis of Proportion of 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 sting						
Female	0/ 73	3/ 75 (4%)				
Male	1/254 (<1%)	0/252				
Foot fracture						
Female	0/ 73	1/ 75 (1%)				
Male	1/254 (<1%)	2/252 (<1%)				
Rib fracture						
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

(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)

Vaccination complication						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	3/252 (1%)				
Bone contusion						
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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Table 3.17

Analysis of Proportion of 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	3/252 (1%)				
Heat stroke						
Female	0/ 73	2/ 75 (3%)				
Male	0/254	1/252 (<1%)				
Procedural pain						
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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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

Analysis of Proportion of 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%)				
Ankle fracture						
Female	1/ 73 (1%)	0/ 75				
Male	1/254 (<1%)	0/252				
Head injury						
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)
Joint injury						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Meniscus injury						
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

(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)
Musculoskeletal foreign body						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Road traffic accident						
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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Table 3.17

Analysis of Proportion of 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)

Wrist fracture						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				
Burns second degree						
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)
Chemical burns of eye						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
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%)				

Note: "Any Event" represents subjects with any 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)
Corneal abrasion						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Eye injury						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Face 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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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=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						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Fibula fracture						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Fractured coccyx						
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)

Gastrointestinal procedural complication						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Hand fracture						
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)

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

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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)

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.

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Analysis of Proportion of 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				
Post-traumatic 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 arthritis						
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)

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%)				
Wound						
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. NC =

Not Calculable. 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)

Psychiatric disorders						
Any Event						
Female	2/ 73 (3%)	11/ 75 (15%)				
Male	51/254 (20%)	45/252 (18%)				
Insomnia						
Female	2/ 73 (3%)	5/ 75 (7%)				
Male	13/254 (5%)	16/252 (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

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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)
Anxiety						
Female	0/ 73	1/ 75 (1%)				
Male	20/254 (8%)	11/252 (4%)				
Depression						
Female	0/ 73	2/ 75 (3%)				
Male	6/254 (2%)	6/252 (2%)				
Sleep disorder						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	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)

Abnormal dreams						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	5/252 (2%)				
Depressed mood						
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

(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)

Libido decreased						
Female	0/ 73	0/ 75				
Male	3/254 (1%)	2/252 (<1%)				
Nightmare						
Female	0/ 73	1/ 75 (1%)				
Male	1/254 (<1%)	3/252 (1%)				
Major depression						
Female	0/ 73	2/ 75 (3%)				
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)
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%)	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)
Adjustment disorder with mixed anxiety and depressed mood						
Female	0/ 73	1/ 75 (1%)				
Male	1/254 (<1%)	1/252 (<1%)				
Stress						
Female	0/ 73	2/ 75 (3%)				
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)
Attention deficit hyperactivity disorder						
Female	0 / 73	0 / 75				
Male	0 / 254	2 / 252 (<1%)				
Drug abuse						
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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Analysis of Proportion of 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)

Generalised anxiety disorder						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	1/252 (<1%)				
Irritability						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Restlessness						
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)

Suicidal ideation						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	0/252				
Acute 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)
Adjustment disorder						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Agoraphobia						
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)
Alcohol withdrawal syndrome						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Emotional distress						
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)
Loss of libido						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
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, 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)
Post-traumatic stress disorder						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Psychotic 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)
Investigations						
Any Event						
Female	0/ 73	8/ 75 (11%)	<0.0001 (<0.0001, -) />0.999	-12.5760 (-36.8856, 11.7335) /0.311	<0.0001 (<0.0001, -) />0.999	0.004
Male	24/254 (9%)	33/252 (13%)	0.6925 (0.3966, 1.2092) /0.196	-3.6464 (-9.1499, 1.8570) /0.194	0.7215 (0.4394, 1.1850) /0.197	

Note: "Any Event" represents subjects with any 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	5/254 (2%)	7/252 (3%)				
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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Analysis of Proportion of 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	4/254 (2%)	3/252 (1%)				
Alanine aminotransferase increased						
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

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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 cholesterol increased						
Female	0/ 73	1/ 75 (1%)				
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, 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 decreased						
Female	0/ 73	1/ 75 (1%)				
Male	2/254 (<1%)	1/252 (<1%)				
Blood glucose increased						
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, p-value and interaction p-values are 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. NC =

Not Calculable. 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)
Blood triglycerides increased						
Female	0/ 73	0/ 75				
Male	0/254	3/252 (1%)				
Lipase increased						
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)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

Analysis of Proportion of 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)
Low density lipoprotein increased						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	2/252 (<1%)				
Aspartate aminotransferase 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)

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Table 3.17

Analysis of Proportion of 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%)	1/252 (<1%)				
Creatinine renal clearance decreased						
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)
Transaminases increased						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	1/252 (<1%)				
Blood bilirubin 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)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative 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. NC =

Not Calculable. 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)
Blood bilirubin unconjugated increased						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Blood pressure decreased						
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)
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

(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. NC = Not Calculable. 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)
Chlamydia test positive						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Culture urine 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)

(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)

Electrocardiogram abnormal						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Epstein-Barr virus 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)

Escherichia test positive						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Haematocrit 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

(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)

Haematocrit increased						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Haemoglobin 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

(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)

Haemoglobin increased						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
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, 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)
Intraocular pressure increased						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Muscle enzyme 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)
Parasite stool test positive						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
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, p-value and interaction p-values are 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)
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

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=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	2/ 73 (3%)	6/ 75 (8%)				
Male	16/254 (6%)	23/252 (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: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=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	1/ 75 (1%)				
Male	5/254 (2%)	11/252 (4%)				
Skin papilloma						
Female	0/ 73	2/ 75 (3%)				
Male	3/254 (1%)	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)

(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)
Basal cell carcinoma						
Female	0/ 73	0/ 75				
Male	3/254 (1%)	0/252				
Fibrous histiocyctoma						
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.

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Table 3.17

Analysis of Proportion of 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)

Adenoma benign						
Female	0/ 73	1/ 75 (1%)				
Male	1/254 (<1%)	0/252				
Breast cancer						
Female	1/ 73 (1%)	1/ 75 (1%)				
Male	0/254	0/252				
Lipoma						
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)
Lipoma of breast						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				
Acrochordon						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Adrenal adenoma						
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 = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

Analysis of Proportion of 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 neoplasm of thyroid gland						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
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, p-value and interaction p-values are 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)
Fibroma						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Glioblastoma						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Kaposi's sarcoma						
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)

Testicular neoplasm						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Urethral papilloma						
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)

Uterine leiomyoma						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				
Reproductive system and breast disorders						
Any Event						
Female	5/ 73 (7%)	3/ 75 (4%)				
Male	21/254 (8%)	18/252 (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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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=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	7/254 (3%)	6/252 (2%)				
Balanoposthitis						
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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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=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	2/254 (<1%)	1/252 (<1%)				
Genital lesion						
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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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=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	1/ 73 (1%)	2/ 75 (3%)				
Male	0/254	0/252				
Breast cyst						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	1/252 (<1%)				
Cervical dysplasia						
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)

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

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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)

Atrophic vulvovaginitis						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				
Breast mass						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
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

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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)

Genital erythema						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Genital odour						
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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Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=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				
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, 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)

Penile discharge						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Penile discomfort						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Penile 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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System Organ Class Preferred Term	Q8W (N=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 rash						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Premenstrual syndrome						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Priapism						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

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)
Prostatitis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Sexual dysfunction						
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

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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)

Testicular swelling						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Testicular torsion						
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)

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				

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)

Vaginal discharge						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Vascular disorders						
Any Event						
Female	6/ 73 (8%)	5/ 75 (7%)				
Male	13/254 (5%)	14/252 (6%)				

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)
Hypertension						
Female	3/ 73 (4%)	2/ 75 (3%)				
Male	9/254 (4%)	9/252 (4%)				
Haematoma						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	2/252 (<1%)				
Varicose vein						
Female	1/ 73 (1%)	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				

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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)
Flushing						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	1/252 (<1%)				
Hot flush						
Female	1/ 73 (1%)	0/ 75				
Male	1/254 (<1%)	0/252				
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

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

Analysis of Proportion of 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 pressure inadequately controlled						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	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, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

Analysis of Proportion of 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 coldness						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Phlebitis						
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

(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. NC = Not Calculable. 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)
Thrombophlebitis superficial						
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. NC =

Not Calculable. 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	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	0.444
Male	6/254 (2%)	22/252 (9%)	0.2529 (0.1008, 0.6349) /0.003	-6.3680 (-10.3220, -2.4139) /0.002	0.2706 (0.1116, 0.6561) /0.004	

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

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are 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%)	2/ 75 (3%)				
Male	2/254 (<1%)	7/252 (3%)				
Nephrolithiasis						
Female	0/ 73	1/ 75 (1%)				
Male	1/254 (<1%)	2/252 (<1%)				
Nocturia						
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

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

Analysis of Proportion of 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 colic						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	3/252 (1%)				
Haematuria						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	1/252 (<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)
Pollakiuria						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	1/252 (<1%)				
Renal cyst						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Urethral discharge						
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), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

Analysis of Proportion of 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%)				
Nephropathy						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
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, 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)

Urethral disorder						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Urethral 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)

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Analysis of Proportion of 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 incontinence						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				
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, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

Analysis of Proportion of 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)

Metabolism and nutrition disorders						
Any Event						
Female	1/ 73 (1%)	5/ 75 (7%)				
Male	17/254 (7%)	12/252 (5%)				
Hypercholesterolaemia						
Female	0/ 73	1/ 75 (1%)				
Male	4/254 (2%)	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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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)
Vitamin D deficiency						
Female	0/ 73	1/ 75 (1%)				
Male	4/254 (2%)	3/252 (1%)				
Decreased appetite						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	2/252 (<1%)				
Gout						
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, p-value and interaction p-values are 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)
Obesity						
Female	1/ 73 (1%)	0/ 75				
Male	1/254 (<1%)	0/252				
Type 2 diabetes mellitus						
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

(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)

Alcoholic ketoacidosis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Cachexia						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Diabetes mellitus						
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)

Dyslipidaemi ^a						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Gluten sensitivity						
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)

Hyperglycaemia						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Hyperlipasemia						
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)

Hypertriglyceridaemia						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Hypokalaemia						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Iron deficiency						
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	Q8W (N=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%)	5/ 75 (7%)				
Male	11/254 (4%)	15/252 (6%)				
Cataract						
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

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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)

Conjunctivitis allergic						
Female	0/ 73	1/ 75 (1%)				
Male	1/254 (<1%)	3/252 (1%)				
Blepharitis						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	3/252 (1%)				
Retinal detachment						
Female	1/ 73 (1%)	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)
Diplopia						
Female	0/ 73	1/ 75 (1%)				
Male	1/254 (<1%)	0/252				
Dry eye						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	1/252 (<1%)				
Astigmatism						
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)

Blepharospasm						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Chalazion						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Eczema eyelids						
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)
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%)				
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, 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)
Glaucoma						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Iritis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Macular fibrosis						
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)
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%)				
Pterygium						
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)
Retinal tear						
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 Preferred Term	Q8W (N=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 detachment						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
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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Table 3.17

Analysis of Proportion of 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 and labyrinth disorders						
Any Event						
Female	1/ 73 (1%)	2/ 75 (3%)				
Male	9/254 (4%)	14/252 (6%)				
Tinnitus						
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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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vertigo						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	4/252 (2%)				
Cerumen impaction						
Female	1/ 73 (1%)	0/ 75				
Male	2/254 (<1%)	1/252 (<1%)				
Ear 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, p-value and interaction p-values are 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)
Ear pain						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Eustachian tube dysfunction						
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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Analysis of Proportion of 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)

Excessive cerumen production						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Deafness neurosensory						
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)
Ear pruritus						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Hypoacusis						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Tympanic membrane perforation						
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	Q8W (N=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%)	5/ 75 (7%)				
Male	11/254 (4%)	8/252 (3%)				
Seasonal allergy						
Female	1/ 73 (1%)	3/ 75 (4%)				
Male	7/254 (3%)	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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Table 3.17

Analysis of Proportion of 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)

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

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Analysis of Proportion of 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	1/ 75 (1%)				
Male	0/254	1/252 (<1%)				
Allergy to arthropod bite						
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)

Anaphylactic reaction						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Blood and lymphatic system disorders						
Any Event						
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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Analysis of Proportion of 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)

Lymphadenopathy						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	4/252 (2%)				
Anaemia						
Female	0/ 73	3/ 75 (4%)				
Male	0/254	2/252 (<1%)				
Microcytic anaemia						
Female	2/ 73 (3%)	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. NC =

Not Calculable. 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)
Iron deficiency anaemia						
Female	2/ 73 (3%)	1/ 75 (1%)				
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, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number 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. NC =

Not Calculable. 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)

Neutropenia						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Polycythaemi ^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

(1) significant difference in occurrences between treatment arms 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. NC =

Not Calculable. 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)

Cardiac disorders						
Any Event						
Female	0/ 73	1/ 75 (1%)				
Male	6/254 (2%)	10/252 (4%)				
Palpitations						
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, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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)
Tachycardia						
Female	0/ 73	1/ 75 (1%)				
Male	1/254 (<1%)	2/252 (<1%)				
Ventricular extrasystoles						
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. NC = Not Calculable. 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)
Acute myocardial infarction						
Female	0/ 73	0/ 75				
Male	0/254	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, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number 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. NC =

Not Calculable. 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)

Atrial fibrillation						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Atrioventricular block first degree						
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. NC = Not Calculable. 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)
Cardiac aneurysm						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
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,

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. NC =

Not Calculable. 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)
Myocardial infarction						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Myocardial necrosis						
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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with the following variables: treatment, 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 3.17

Analysis of Proportion of 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 bradycardia						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Wolff-Parkinson-White 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, p-value and interaction p-values are 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)

Hepatobiliary disorders						
Any Event						
Female	1/ 73 (1%)	0/ 75				
Male	1/254 (<1%)	3/252 (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)

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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. NC = Not Calculable. 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)

Hepatic steatosis						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				
Hepatocellular injury						
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, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

Analysis of Proportion of 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)
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	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)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

Analysis of Proportion of 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				
Gilbert's 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, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number 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. NC =

Not Calculable. 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)
Hydrocele						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
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, p-value and interaction p-values are 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)

Endocrine disorders						
Any Event						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	3/252 (1%)				
Hypogonadism						
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)
Androgen deficiency						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
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)

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Table 3.17

Analysis of Proportion of 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, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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)

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)

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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. NC =

Not Calculable. 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. NC =

Not Calculable. 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	225/239 (94%)	250/256 (98%)				
Non-White	86/ 88 (98%)	68/ 71 (96%)				

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

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number 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)

General disorders and administration site conditions						
Any Event						
White	212/239 (89%)	223/256 (87%)				
Non-White	75/ 88 (85%)	56/ 71 (79%)				
Injection site pain						
White	201/239 (84%)	210/256 (82%)				
Non-White	72/ 88 (82%)	51/ 71 (72%)				

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

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are 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. NC = Not Calculable. 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 nodule						
White	26/239 (11%)	54/256 (21%)	0.4566 (0.2753, 0.7573) /0.002	-10.2151 (-16.5837, -3.8465) /0.002	0.5157 (0.3344, 0.7955) /0.003	0.861
Non-White	15/ 88 (17%)	25/ 71 (35%)	0.3781 (0.1806, 0.7915) /0.010	-18.1658 (-31.7730, -4.5587) /0.009	0.4841 (0.2769, 0.8463) /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

(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)

Injection site discomfort						
White	23/239 (10%)	31/256 (12%)				
Non-White	5/ 88 (6%)	4/ 71 (6%)				
Injection site induration						
White	23/239 (10%)	30/256 (12%)				
Non-White	5/ 88 (6%)	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)
Pyrexia						
White	21/239 (9%)	33/256 (13%)				
Non-White	5/ 88 (6%)	3/ 71 (4%)				
Injection site swelling						
White	16/239 (7%)	14/256 (5%)				
Non-White	11/ 88 (13%)	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

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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)
Fatigue						
White	7/239 (3%)	23/256 (9%)	0.3057 (0.1287, 0.7262) /0.007	-6.0555 (-10.1592, -1.9518) /0.004	0.3260 (0.1425, 0.7457) /0.008	0.114
Non-White	7/ 88 (8%)	6/ 71 (8%)	0.9362 (0.3000, 2.9221) /0.910	-0.4962 (-9.0880, 8.0957) /0.910	0.9413 (0.3312, 2.6755) /0.910	

Note: "Any Event" represents subjects with any 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)
Injection site pruritus						
White	7/239 (3%)	15/256 (6%)	0.4848 (0.1941, 1.2105) /0.121	-2.9305 (-6.5148, 0.6538) /0.109	0.4999 (0.2074, 1.2047) /0.122	0.649
Non-White	4/ 88 (5%)	9/ 71 (13%)	0.3280 (0.0966, 1.1141) /0.074	-8.1306 (-17.0093, 0.7481) /0.073	0.3586 (0.1152, 1.1162) /0.077	

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

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are 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. NC = Not Calculable. 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)

Influenza like illness						
White	7/239 (3%)	12/256 (5%)				
Non-White	3/ 88 (3%)	5/ 71 (7%)				
Injection site erythema						
White	11/239 (5%)	12/256 (5%)				
Non-White	1/ 88 (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)

Asthenia						
White	11/239 (5%)	10/256 (4%)				
Non-White	3/ 88 (3%)	0/ 71				
Chills						
White	9/239 (4%)	6/256 (2%)				
Non-White	5/ 88 (6%)	2/ 71 (3%)				
Injection site bruising						
White	9/239 (4%)	7/256 (3%)				
Non-White	2/ 88 (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

(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)

Pain						
White	4/239 (2%)	5/256 (2%)				
Non-White	4/ 88 (5%)	3/ 71 (4%)				
Malaise						
White	4/239 (2%)	7/256 (3%)				
Non-White	3/ 88 (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

(1) significant difference in occurrences between treatment arms 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)

Injection site haematoma						
White	2/239 (<1%)	11/256 (4%)	0.1880 (0.0412, 0.8570) /0.031	-3.4601 (-6.1995, -0.7206) /0.013	0.1948 (0.0436, 0.8696) /0.032	0.521
Non-White	0/ 88	1/ 71 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Injection site warmth						
White	3/239 (1%)	3/256 (1%)				
Non-White	3/ 88 (3%)	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)

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Table 3.17

Analysis of Proportion of 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)
Chest pain						
White	3/239 (1%)	6/256 (2%)				
Non-White	1/ 88 (1%)	0/ 71				
Discomfort						
White	4/239 (2%)	4/256 (2%)				
Non-White	2/ 88 (2%)	0/ 71				
Injection site reaction						
White	4/239 (2%)	4/256 (2%)				
Non-White	0/ 88	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)

Injection site anaesthesia						
White	1/239 (<1%)	0/256				
Non-White	4/ 88 (5%)	1/ 71 (1%)				
Nodule						
White	3/239 (1%)	2/256 (<1%)				
Non-White	0/ 88	1/ 71 (1%)				
Feeling hot						
White	3/239 (1%)	0/256				
Non-White	2/ 88 (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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Table 3.17

Analysis of Proportion of 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)
Peripheral swelling						
White	1/239 (<1%)	2/256 (<1%)				
Non-White	2/ 88 (2%)	0/ 71				
Cyst						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	1/ 88 (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)

Injection site discolouration						
White	1/239 (<1%)	2/256 (<1%)				
Non-White	0/ 88	0/ 71				
Mass						
White	1/239 (<1%)	2/256 (<1%)				
Non-White	0/ 88	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)

Vessel puncture site haematoma						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	1/ 71 (1%)				
Chest discomfort						
White	1/239 (<1%)	0/256				
Non-White	1/ 88 (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)

Gait disturbance						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Injection site haemorrhage						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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. NC = Not Calculable. 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)

Injection site papule						
White	0/239	0/256				
Non-White	1/ 88 (1%)	1/ 71 (1%)				
Non-cardiac chest pain						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	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,

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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. NC =

Not Calculable. 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)
Temperature regulation disorder						
White	0/239	0/256				
Non-White	2/ 88 (2%)	0/ 71				
Vaccination site pain						
White	0/239	0/256				
Non-White	0/ 88	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)

Adverse drug reaction						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Chronic fatigue syndrome						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	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)

Enanthema						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Feeling abnormal						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Induration						
White	0/239	0/256				
Non-White	0/ 88	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)
Inflammation						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Injection site discharge						
White	0/239	0/256				
Non-White	1/ 88 (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.

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Table 3.17

Analysis of Proportion of 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 fibrosis						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Injection site hypoaesthesia						
White	0/239	0/256				
Non-White	1/ 88 (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)

Injection site mass						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Injection site necrosis						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	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)

Injection site rash						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Oedema peripheral						
White	0/239	0/256				
Non-White	0/ 88	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	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Sluggishness						
White	0/239	0/256				
Non-White	1/ 88 (1%)	0/ 71				
Swelling						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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)

Thirst						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Xerosis						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	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	160/239 (67%)	193/256 (75%)				
Non-White	56/ 88 (64%)	46/ 71 (65%)				
Nasopharyngitis						
White	49/239 (21%)	59/256 (23%)				
Non-White	12/ 88 (14%)	7/ 71 (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)

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Table 3.17

Analysis of Proportion of 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	29/239 (12%)	46/256 (18%)	0.6304 (0.3814, 1.0421) /0.072	-5.8349 (-12.1002, 0.4305) /0.068	0.6753 (0.4393, 1.0381) /0.074	0.902
Non-White	16/ 88 (18%)	20/ 71 (28%)	0.5667 (0.2680, 1.1983) /0.137	-9.9872 (-23.1938, 3.2194) /0.138	0.6455 (0.3620, 1.1508) /0.138	

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)

Gastroenteritis						
White	13/239 (5%)	26/256 (10%)	0.5088 (0.2551, 1.0151) /0.055	-4.7169 (-9.4030, -0.0308) /0.049	0.5356 (0.2818, 1.0177) /0.057	0.897
Non-White	3/ 88 (3%)	5/ 71 (7%)	0.4659 (0.1074, 2.0202) /0.308	-3.6332 (-10.6896, 3.4233) /0.313	0.4841 (0.1198, 1.9568) /0.309	
Syphilis						
White	15/239 (6%)	16/256 (6%)				
Non-White	3/ 88 (3%)	6/ 71 (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. NC = Not Calculable. 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)
Influenza						
White	13/239 (5%)	8/256 (3%)				
Non-White	5/ 88 (6%)	5/ 71 (7%)				
Bronchitis						
White	13/239 (5%)	13/256 (5%)				
Non-White	1/ 88 (1%)	3/ 71 (4%)				
Pharyngitis						
White	9/239 (4%)	16/256 (6%)				
Non-White	3/ 88 (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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Table 3.17

Analysis of Proportion of 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	10/239 (4%)	9/256 (4%)				
Non-White	3/ 88 (3%)	4/ 71 (6%)				
Sinusitis						
White	8/239 (3%)	11/256 (4%)				
Non-White	2/ 88 (2%)	1/ 71 (1%)				
Viral infection						
White	4/239 (2%)	13/256 (5%)				
Non-White	4/ 88 (5%)	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)

Chlamydial infection						
White	9/239 (4%)	7/256 (3%)				
Non-White	3/ 88 (3%)	1/ 71 (1%)				
Urinary tract infection						
White	8/239 (3%)	5/256 (2%)				
Non-White	2/ 88 (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

(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)

Conjunctivitis						
White	8/239 (3%)	7/256 (3%)				
Non-White	1/ 88 (1%)	2/ 71 (3%)				
Respiratory tract infection viral						
White	7/239 (3%)	10/256 (4%)				
Non-White	1/ 88 (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)

Proctitis gonococcal						
White	6/239 (3%)	8/256 (3%)				
Non-White	1/ 88 (1%)	1/ 71 (1%)				
Tonsillitis						
White	5/239 (2%)	9/256 (4%)				
Non-White	0/ 88	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.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, 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 3.17

Analysis of Proportion of 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 chlamydia infection						
White	6/239 (3%)	5/256 (2%)				
Non-White	3/ 88 (3%)	1/ 71 (1%)				
Respiratory tract infection						
White	8/239 (3%)	7/256 (3%)				
Non-White	0/ 88	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. NC = Not Calculable. 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)
Oral herpes						
White	2/239 (<1%)	10/256 (4%)	0.2076 (0.0450, 0.9574) /0.044	-3.0694 (-5.7088, -0.4300) /0.023	0.2142 (0.0474, 0.9677) /0.045	0.413
Non-White	1/ 88 (1%)	1/ 71 (1%)	0.8046 (0.0494, 13.0946) /0.879	-0.2721 (-3.7959, 3.2517) /0.880	0.8068 (0.0514, 12.6728) /0.879	
Urethritis						
White	5/239 (2%)	6/256 (2%)				
Non-White	0/ 88	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. NC = Not Calculable. 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)
<hr/>						
Folliculitis						
White	6/239 (3%)	6/256 (2%)				
Non-White	0/ 88	1/ 71 (1%)				
Oropharyngeal gonococcal infection						
White	4/239 (2%)	4/256 (2%)				
Non-White	2/ 88 (2%)	3/ 71 (4%)				
Rhinitis						
White	5/239 (2%)	7/256 (3%)				
Non-White	0/ 88	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. NC = Not Calculable. 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)

Herpes zoster						
White	4/239 (2%)	6/256 (2%)				
Non-White	1/ 88 (1%)	1/ 71 (1%)				
Gastroenteritis viral						
White	4/239 (2%)	6/256 (2%)				
Non-White	0/ 88	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)

Viral upper respiratory tract infection						
White	1/239 (<1%)	5/256 (2%)				
Non-White	1/ 88 (1%)	3/ 71 (4%)				
Lower respiratory tract infection						
White	1/239 (<1%)	2/256 (<1%)				
Non-White	6/ 88 (7%)	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. NC = Not Calculable. 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)

Tooth abscess						
White	1/239 (<1%)	6/256 (2%)				
Non-White	1/ 88 (1%)	1/ 71 (1%)				
Ear infection						
White	2/239 (<1%)	4/256 (2%)				
Non-White	1/ 88 (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)

Onychomycosis						
White	3/239 (1%)	5/256 (2%)				
Non-White	0/ 88	0/ 71				
Tinea versicolour						
White	3/239 (1%)	5/256 (2%)				
Non-White	0/ 88	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)

Tooth infection						
White	0/239	8/256 (3%)				
Non-White	0/ 88	0/ 71				
Fungal skin infection						
White	3/239 (1%)	4/256 (2%)				
Non-White	0/ 88	0/ 71				
Cellulitis						
White	1/239 (<1%)	4/256 (2%)				
Non-White	1/ 88 (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. NC = Not Calculable. 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)

Diverticulitis						
White	2/239 (<1%)	4/256 (2%)				
Non-White	0/ 88	0/ 71				
Furuncle						
White	3/239 (1%)	2/256 (<1%)				
Non-White	1/ 88 (1%)	0/ 71				
Gingivitis						
White	2/239 (<1%)	3/256 (1%)				
Non-White	1/ 88 (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. 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 System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=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						
White	1/239 (<1%)	2/256 (<1%)				
Non-White	2/ 88 (2%)	1/ 71 (1%)				
Hordeolum						
White	2/239 (<1%)	3/256 (1%)				
Non-White	1/ 88 (1%)	0/ 71				
Pneumonia						
White	0/239	1/256 (<1%)				
Non-White	3/ 88 (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)

Urethritis chlamydial						
White	0/239	4/256 (2%)				
Non-White	2/ 88 (2%)	0/ 71				
Urethritis gonococcal						
White	2/239 (<1%)	2/256 (<1%)				
Non-White	0/ 88	2/ 71 (3%)				
Abscess limb						
White	2/239 (<1%)	1/256 (<1%)				
Non-White	1/ 88 (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)

Acarodermatitis						
White	2/239 (<1%)	3/256 (1%)				
Non-White	0/ 88	0/ 71				
Secondary syphilis						
White	2/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	2/ 71 (3%)				
Body tinea						
White	2/239 (<1%)	1/256 (<1%)				
Non-White	1/ 88 (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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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=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						
White	2/239 (<1%)	2/256 (<1%)				
Non-White	0/ 88	0/ 71				
Mycoplasma genitalium infection						
White	0/239	4/256 (2%)				
Non-White	0/ 88	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 externa						
White	1/239 (<1%)	2/256 (<1%)				
Non-White	0/ 88	1/ 71 (1%)				
Pharyngotonsillitis						
White	0/239	3/256 (1%)				
Non-White	1/ 88 (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)
Primary syphilis						
White	3/239 (1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Shigella infection						
White	1/239 (<1%)	2/256 (<1%)				
Non-White	1/ 88 (1%)	0/ 71				
Tracheitis						
White	1/239 (<1%)	3/256 (1%)				
Non-White	0/ 88	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)

Viral pharyngitis						
White	0/239	1/256 (<1%)				
Non-White	1/ 88 (1%)	2/ 71 (3%)				
Enteritis infectious						
White	3/239 (1%)	0/256				
Non-White	0/ 88	0/ 71				
Epididymitis						
White	0/239	1/256 (<1%)				
Non-White	1/ 88 (1%)	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)

Helicobacter infection						
White	0/239	3/256 (1%)				
Non-White	0/ 88	0/ 71				
Injection site abscess						
White	2/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	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. NC = Not Calculable. 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)

Oral candidiasis						
White	0/239	2/256 (<1%)				
Non-White	0/ 88	1/ 71 (1%)				
Paronychia						
White	1/239 (<1%)	2/256 (<1%)				
Non-White	0/ 88	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. NC =

Not Calculable. 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)

Pharyngeal chlamydia infection						
White	1/239 (<1%)	0/256				
Non-White	1/ 88 (1%)	1/ 71 (1%)				
Pharyngitis streptococcal						
White	0/239	2/256 (<1%)				
Non-White	1/ 88 (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. NC = Not Calculable. 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)

Skin infection						
White	3/239 (1%)	0/256				
Non-White	0/ 88	0/ 71				
Staphylococcal infection						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	1/ 88 (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,

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Table 3.17

Analysis of Proportion of 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	1/239 (<1%)	1/256 (<1%)				
Non-White	1/ 88 (1%)	0/ 71				
Tinea cruris						
White	0/239	2/256 (<1%)				
Non-White	0/ 88	1/ 71 (1%)				
Tinea infection						
White	0/239	3/256 (1%)				
Non-White	0/ 88	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. NC = Not Calculable. 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)

Vaginal infection						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	1/ 71 (1%)				
Varicella						
White	2/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	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)

Vulvovaginal mycotic infection						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	1/ 71 (1%)				
Acute hepatitis B						
White	0/239	0/256				
Non-White	1/ 88 (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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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. NC =

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Table 3.17

Analysis of Proportion of 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)

Acute sinusitis						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	1/ 71 (1%)				
Bronchitis viral						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	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)

Chronic sinusitis						
White	2/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Cystitis						
White	0/239	2/256 (<1%)				
Non-White	0/ 88	0/ 71				
Diarrhoea infectious						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	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)
Escherichia urinary tract infection						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	1/ 71 (1%)				
Hepatitis E						
White	0/239	2/256 (<1%)				
Non-White	0/ 88	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)
Laryngitis						
White	0/239	2/256 (<1%)				
Non-White	0/ 88	0/ 71				
Lymphogranuloma venereum						
White	0/239	2/256 (<1%)				
Non-White	0/ 88	0/ 71				
Molluscum contagiosum						
White	0/239	1/256 (<1%)				
Non-White	1/ 88 (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)
Orchitis						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	1/ 71 (1%)				
Otitis media						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Postoperative wound infection						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	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. NC = Not Calculable. 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)

Proctitis chlamydial						
White	2/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Pulmonary tuberculosis						
White	1/239 (<1%)	0/256				
Non-White	1/ 88 (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)

Pulpitis dental						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Sexually transmitted disease						
White	0/239	2/256 (<1%)				
Non-White	0/ 88	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)

Staphylococcal skin infection						
White	1/239 (<1%)	0/256				
Non-White	1/ 88 (1%)	0/ 71				
Tinea pedis						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	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)

Ureaplasma infection						
White	0/239	2/256 (<1%)				
Non-White	0/ 88	0/ 71				
Urethritis mycoplasmal						
White	2/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Abscess						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	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)
Anal abscess						
White	0/239	0/256				
Non-White	1/ 88 (1%)	0/ 71				
Arthropod infestation						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Asymptomatic bacteriuria						
White	0/239	0/256				
Non-White	0/ 88	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	0/239	0/256				
Non-White	1/ 88 (1%)	0/ 71				
 Bacterial rhinitis						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Borrelia infection						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
COVID-19						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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. NC = Not Calculable. 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)
Candida infection						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Cellulitis of male external genital organ						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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)

Chest wall abscess						
White	0/239	0/256				
Non-White	1/ 88 (1%)	0/ 71				
Conjunctivitis viral						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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)

Cutaneous blastomycosis						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Dermatophytosis of nail						
White	0/239	0/256				
Non-White	0/ 88	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	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Ear infection bacterial						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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)

Eczema infected						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Enterobiasis						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Enterovirus infection						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	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)

Epiglottitis obstructive						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Erysipelas						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Erythema migrans						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	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. NC = Not Calculable. 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)

Escherichia infection						
White	0/239	0/256				
Non-White	1/ 88 (1%)	0/ 71				
External ear cellulitis						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	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)
Eye infection						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Gastritis viral						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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)

Gastroenteritis Escherichia coli						
White	0/239	0/256				
Non-White	1/ 88 (1%)	0/ 71				
Gastrointestinal infection						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	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)

Genital candidiasis						
White	0/239	0/256				
Non-White	1/ 88 (1%)	0/ 71				
Genital herpes simplex						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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)

Genitourinary tract infection						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Giardiasis						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	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)

Gingival abscess						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Gonococcal infection						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	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)

Groin abscess						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Hepatitis C						
White	0/239	0/256				
Non-White	1/ 88 (1%)	0/ 71				
Herpes ophthalmic						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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)
Herpes virus infection						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Infected bite						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Infection						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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)

Infectious mononucleosis						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Labyrinthitis						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	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)

Latent syphilis						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Lice infestation						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	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)
Localised infection						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Mycoplasma infection						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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)

Oesophageal candidiasis						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Ophthalmic herpes zoster						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	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)

Otitis media acute						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Penile infection						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	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. NC =

Not Calculable. 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)

Pericoroniti s						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Perirectal abscess						
White	0/239	0/256				
Non-White	1/ 88 (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)

Peritonsillar abscess						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Pharyngitis bacterial						
White	0/239	0/256				
Non-White	0/ 88	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)

Pharyngitis mycoplasmal						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Proctitis mycoplasmal						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Schistosomiasis cutaneous						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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)

Sialoadenitis						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Skin bacterial infection						
White	0/239	0/256				
Non-White	0/ 88	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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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

Analysis of Proportion of 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)

Suspected COVID-19						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Syphilis genital						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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 capitis						
White	0/239	0/256				
Non-White	1/ 88 (1%)	0/ 71				
Tracheobronchitis						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	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)

Trichomoniasis						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Urinary tract infection staphylococcal						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	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)

Viral rash						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Viral rhinitis						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Wound abscess						
White	0/239	0/256				
Non-White	1/ 88 (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)

Gastrointestinal disorders						
Any Event						
White	74/239 (31%)	99/256 (39%)	0.7112 (0.4902, 1.0318) /0.073	-7.7095 (-16.0729, 0.6538) /0.071	0.8006 (0.6272, 1.0221) /0.074	0.977
Non-White	24/ 88 (27%)	24/ 71 (34%)	0.7344 (0.3722, 1.4490) /0.373	-6.5301 (-20.9402, 7.8801) /0.374	0.8068 (0.5035, 1.2929) /0.372	

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

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are 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. NC = Not Calculable. 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)
Diarrhoea						
White	27/239 (11%)	30/256 (12%)				
Non-White	6/ 88 (7%)	7/ 71 (10%)				
Nausea						
White	6/239 (3%)	19/256 (7%)	0.3212 (0.1260, 0.8186) /0.017	-4.9114 (-8.6856, -1.1373) /0.011	0.3383 (0.1374, 0.8326) /0.018	0.182
Non-White	4/ 88 (5%)	3/ 71 (4%)	1.0794 (0.2336, 4.9882) /0.922	0.3201 (-6.0702, 6.7104) /0.922	1.0758 (0.2488, 4.6504) /0.922	

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)
Haemorrhoids						
White	2/239 (<1%)	9/256 (4%)	0.2316 (0.0495, 1.0830) /0.063	-2.6788 (-5.2133, -0.1443) /0.038	0.2380 (0.0520, 1.0905) /0.065	0.977
Non-White	2/ 88 (2%)	7/ 71 (10%)	0.2126 (0.0427, 1.0578) /0.059	-7.5864 (-15.1877, 0.0149) /0.050	0.2305 (0.0494, 1.0753) /0.062	

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

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are 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)
<hr/>						
Constipation						
White	2/239 (<1%)	12/256 (5%)	0.1716 (0.0380, 0.7749) /0.022	-3.8507 (-6.6858, -1.0155) /0.008	0.1785 (0.0404, 0.7894) /0.023	0.928
Non-White	1/ 88 (1%)	4/ 71 (6%)	0.1925 (0.0210, 1.7627) /0.145	-4.4974 (-10.2999, 1.3050) /0.129	0.2017 (0.0231, 1.7646) /0.148	
Dyspepsia						
White	7/239 (3%)	9/256 (4%)				
Non-White	1/ 88 (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)

Toothache						
White	5/239 (2%)	10/256 (4%)				
Non-White	2/ 88 (2%)	0/ 71				
Abdominal pain						
White	7/239 (3%)	6/256 (2%)				
Non-White	1/ 88 (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)

Gastrooesophageal reflux disease						
White	5/239 (2%)	6/256 (2%)				
Non-White	1/ 88 (1%)	1/ 71 (1%)				
Abdominal distension						
White	3/239 (1%)	4/256 (2%)				
Non-White	5/ 88 (6%)	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)
Abdominal pain upper						
White	2/239 (<1%)	7/256 (3%)				
Non-White	1/ 88 (1%)	0/ 71				
Vomiting						
White	4/239 (2%)	4/256 (2%)				
Non-White	2/ 88 (2%)	0/ 71				
Anogenital dysplasia						
White	4/239 (2%)	3/256 (1%)				
Non-White	0/ 88	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)
Gastritis						
White	1/239 (<1%)	4/256 (2%)				
Non-White	2/ 88 (2%)	0/ 71				
Abdominal discomfort						
White	2/239 (<1%)	3/256 (1%)				
Non-White	0/ 88	1/ 71 (1%)				
Rectal haemorrhage						
White	0/239	2/256 (<1%)				
Non-White	1/ 88 (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

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

Analysis of Proportion of 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	2/239 (<1%)	2/256 (<1%)				
Non-White	0/ 88	1/ 71 (1%)				
Anal fissure						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	1/ 88 (1%)	2/ 71 (3%)				
Dental caries						
White	0/239	2/256 (<1%)				
Non-White	2/ 88 (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

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, 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 3.17

Analysis of Proportion of 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	2/239 (<1%)	3/256 (1%)				
Non-White	0/ 88	0/ 71				
Haematochezi a						
White	3/239 (1%)	1/256 (<1%)				
Non-White	1/ 88 (1%)	0/ 71				
Food poisoning						
White	4/239 (2%)	0/256				
Non-White	0/ 88	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. NC = Not Calculable. 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)

Proctitis						
White	1/239 (<1%)	3/256 (1%)				
Non-White	0/ 88	0/ 71				
Rectal discharge						
White	1/239 (<1%)	0/256				
Non-White	2/ 88 (2%)	1/ 71 (1%)				
Anal fistula						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	1/ 88 (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)

Dry mouth						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	1/ 71 (1%)				
Hiatus hernia						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	1/ 88 (1%)	0/ 71				
Inguinal hernia						
White	1/239 (<1%)	2/256 (<1%)				
Non-White	0/ 88	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)
Irritable bowel syndrome						
White	0/239	1/256 (<1%)				
Non-White	1/ 88 (1%)	1/ 71 (1%)				
Oesophagitis						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	1/ 88 (1%)	0/ 71				
Proctalgia						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	1/ 88 (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)

Anal pruritus						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Colitis						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Diverticulum intestinal						
White	0/239	2/256 (<1%)				
Non-White	0/ 88	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 pain						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Haemorrhoids thrombosed						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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)

Large intestine polyp						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Mouth ulceration						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	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)

Noninfective gingivitis						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Oral disorder						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	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)

Tongue ulceration						
White	0/239	2/256 (<1%)				
Non-White	0/ 88	0/ 71				
Abdominal hernia						
White	0/239	0/256				
Non-White	0/ 88	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)
Abdominal tenderness						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Anal ulcer						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Angular cheilitis						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	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)

Anorectal discomfort						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Aphthous ulcer						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Chapped lips						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	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)

Cheilitis						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Crohn's disease						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Dental cyst						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	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)

Dysphagia						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Enteritis						
White	0/239	0/256				
Non-White	1/ 88 (1%)	0/ 71				
Enterocolitis						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	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)
Faeces soft						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Gastric disorder						
White	0/239	0/256				
Non-White	1/ 88 (1%)	0/ 71				
Gastric ulcer						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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)

Gastrointestinal disorder						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Gingival hypertrophy						
White	0/239	0/256				
Non-White	0/ 88	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)
Gingival ulceration						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Glossitis						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Haematemesis						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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)
Haemorrhoidal haemorrhage						
White	0/239	0/256				
Non-White	1/ 88 (1%)	0/ 71				
Hypertrophic anal papilla						
White	0/239	0/256				
Non-White	0/ 88	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. NC =

Not Calculable. 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)

Hypoaesthesia oral						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Intestinal polyp						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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)

Oral lichen planus						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Oral pain						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Oroantral fistula						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	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)
Pancreatitis						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Perianal erythema						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Periodontal disease						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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. NC = Not Calculable. 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)
Rectal prolapse						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Rectal tenesmus						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	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)

Salivary gland mucocoele						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Tooth disorder						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	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),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC =

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Table 3.17

Analysis of Proportion of 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	67/239 (28%)	93/256 (36%)				
Non-White	24/ 88 (27%)	20/ 71 (28%)				
Back pain						
White	20/239 (8%)	27/256 (11%)				
Non-White	7/ 88 (8%)	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

(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)

Arthralgia						
White	14/239 (6%)	23/256 (9%)				
Non-White	7/ 88 (8%)	2/ 71 (3%)				
Pain in extremity						
White	10/239 (4%)	17/256 (7%)	0.6139 (0.2753, 1.3688) /0.233	-2.4565 (-6.4247, 1.5117) /0.225	0.6301 (0.2944, 1.3485) /0.234	0.189
Non-White	1/ 88 (1%)	5/ 71 (7%)	0.1517 (0.0173, 1.3298) /0.089	-5.9059 (-12.2559, 0.4442) /0.068	0.1614 (0.0193, 1.3499) /0.092	

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

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are 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. NC = Not Calculable. 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)
Myalgia						
White	7/239 (3%)	7/256 (3%)				
Non-White	3/ 88 (3%)	4/ 71 (6%)				
Musculoskeletal pain						
White	6/239 (3%)	5/256 (2%)				
Non-White	2/ 88 (2%)	2/ 71 (3%)				
Muscle spasms						
White	1/239 (<1%)	5/256 (2%)				
Non-White	2/ 88 (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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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

Analysis of Proportion of 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 chest pain						
White	4/239 (2%)	3/256 (1%)				
Non-White	2/ 88 (2%)	1/ 71 (1%)				
Tendonitis						
White	3/239 (1%)	1/256 (<1%)				
Non-White	4/ 88 (5%)	1/ 71 (1%)				
Neck pain						
White	5/239 (2%)	2/256 (<1%)				
Non-White	0/ 88	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)
Intervertebral disc protrusion						
White	3/239 (1%)	2/256 (<1%)				
Non-White	1/ 88 (1%)	0/ 71				
Muscle contracture						
White	2/239 (<1%)	3/256 (1%)				
Non-White	0/ 88	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)

Osteoarthritis						
White	3/239 (1%)	2/256 (<1%)				
Non-White	0/ 88	0/ 71				
Rotator cuff syndrome						
White	2/239 (<1%)	2/256 (<1%)				
Non-White	0/ 88	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)

Spinal osteoarthritis						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	2/ 71 (3%)				
Muscular weakness						
White	1/239 (<1%)	2/256 (<1%)				
Non-White	0/ 88	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)
Plantar fasciitis						
White	1/239 (<1%)	0/256				
Non-White	1/ 88 (1%)	1/ 71 (1%)				
Synovial cyst						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	1/ 71 (1%)				
Arthritis						
White	2/239 (<1%)	0/256				
Non-White	0/ 88	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)

Bursitis						
White	2/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Exostosis						
White	0/239	2/256 (<1%)				
Non-White	0/ 88	0/ 71				
Flank pain						
White	2/239 (<1%)	0/256				
Non-White	0/ 88	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)
Groin pain						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Joint contracture						
White	0/239	2/256 (<1%)				
Non-White	0/ 88	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)

Joint range of motion decreased						
White	2/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Joint swelling						
White	0/239	1/256 (<1%)				
Non-White	1/ 88 (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)
Limb discomfort						
White	0/239	2/256 (<1%)				
Non-White	0/ 88	0/ 71				
Musculoskeletal discomfort						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	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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using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, 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 3.17

Analysis of Proportion of 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 stiffness						
White	0/239	2/256 (<1%)				
Non-White	0/ 88	0/ 71				
Osteonecrosis						
White	1/239 (<1%)	0/256				
Non-White	1/ 88 (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. NC =

Not Calculable. 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)
Pain in jaw						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	1/ 71 (1%)				
Synovitis						
White	0/239	1/256 (<1%)				
Non-White	1/ 88 (1%)	0/ 71				
Arthritis reactive						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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. NC = Not Calculable. 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)
Arthropathy						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Bone pain						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Cervical spinal stenosis						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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. NC = Not Calculable. 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)
Costochondritis						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Femoroacetabular impingement						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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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with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC =

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Table 3.17

Analysis of Proportion of 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)

Joint stiffness						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Loose body in joint						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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)
Muscle tightness						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Myosclerosis						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Osteochondritis						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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. NC = Not Calculable. 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)

Osteopenia						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Periarthriti s						
White	0/239	0/256				
Non-White	1/ 88 (1%)	0/ 71				
Polyarthriti s						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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. NC = Not Calculable. 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)
Sacroiliitis						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Scoliosis						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Spinal disorder						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	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. NC = Not Calculable. 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)

Temporomandibular joint syndrome						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Tendon disorder						
White	0/239	0/256				
Non-White	0/ 88	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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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)

Tenosynovitis						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Trigger finger						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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	54/239 (23%)	65/256 (25%)				
Non-White	20/ 88 (23%)	19/ 71 (27%)				
Pruritus						
White	7/239 (3%)	6/256 (2%)				
Non-White	5/ 88 (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

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Table 3.17

Analysis of Proportion of 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	7/239 (3%)	8/256 (3%)				
Non-White	3/ 88 (3%)	3/ 71 (4%)				
Eczema						
White	6/239 (3%)	9/256 (4%)				
Non-White	1/ 88 (1%)	4/ 71 (6%)				
Skin lesion						
White	7/239 (3%)	3/256 (1%)				
Non-White	0/ 88	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)
Acne						
White	2/239 (<1%)	5/256 (2%)				
Non-White	0/ 88	3/ 71 (4%)				
Dermatitis						
White	4/239 (2%)	4/256 (2%)				
Non-White	0/ 88	2/ 71 (3%)				
Alopecia						
White	5/239 (2%)	1/256 (<1%)				
Non-White	1/ 88 (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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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

Analysis of Proportion of 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)

Hyperhidrosi s						
White	1/239 (<1%)	5/256 (2%)				
Non-White	0/ 88	2/ 71 (3%)				
Dermatitis contact						
White	2/239 (<1%)	2/256 (<1%)				
Non-White	2/ 88 (2%)	1/ 71 (1%)				
Erythema						
White	2/239 (<1%)	3/256 (1%)				
Non-White	0/ 88	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)

Seborrhoeic dermatitis						
White	0/239	2/256 (<1%)				
Non-White	1/ 88 (1%)	2/ 71 (3%)				
Urticaria						
White	1/239 (<1%)	2/256 (<1%)				
Non-White	2/ 88 (2%)	0/ 71				
Dermal cyst						
White	3/239 (1%)	1/256 (<1%)				
Non-White	0/ 88	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)

Dermatitis atopic						
White	1/239 (<1%)	3/256 (1%)				
Non-White	0/ 88	0/ 71				
Night sweats						
White	3/239 (1%)	0/256				
Non-White	1/ 88 (1%)	0/ 71				
Dry skin						
White	3/239 (1%)	0/256				
Non-White	0/ 88	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. NC = Not Calculable. 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)

Pityriasis rosea						
White	2/239 (<1%)	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Skin exfoliation						
White	0/239	3/256 (1%)				
Non-White	0/ 88	0/ 71				
Skin mass						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	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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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

Analysis of Proportion of 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)
Actinic keratosis						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Chloasma						
White	0/239	1/256 (<1%)				
Non-White	1/ 88 (1%)	0/ 71				
Ecchymosis						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	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. NC = Not Calculable. 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)

Psoriasis						
White	0/239	2/256 (<1%)				
Non-White	0/ 88	0/ 71				
Rash erythematous						
White	0/239	2/256 (<1%)				
Non-White	0/ 88	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. NC = Not Calculable. 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)
Rash maculo-papular						
White	0/239	1/256 (<1%)				
Non-White	1/ 88 (1%)	0/ 71				
Rash papular						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	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)

Actinic elastosis						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Androgenetic alopecia						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Cold sweat						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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)

Dermatosis						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Drug eruption						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Eczema asteatotic						
White	0/239	0/256				
Non-White	1/ 88 (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)

Granuloma annulare						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Guttate psoriasis						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	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)
Hand dermatitis						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Hyperkeratosis						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Intertrigo						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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. NC = Not Calculable. 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)

Keratosis pilaris						
White	0/239	0/256				
Non-White	1/ 88 (1%)	0/ 71				
Lichen sclerosus						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Macule						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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)
Miliaria						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Nail bed bleeding						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Nail bed inflammation						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	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)

Nail dystrophy						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Pain of skin						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Penile ulceration						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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)
Petechiae						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Pigmentation disorder						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Pityriasis						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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)
Prurigo						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Purpura						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Rash macular						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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)

Rash morbilliform						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Rash pruritic						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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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with the following variables: treatment, 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 3.17

Analysis of Proportion of 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 vesicular						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Skin discolouration						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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	0/239	0/256				
Non-White	1/ 88 (1%)	0/ 71				
Skin hypertrophy						
White	0/239	0/256				
Non-White	1/ 88 (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 irritation						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Skin swelling						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Skin ulcer						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Solar lentigo						
White	0/239	0/256				
Non-White	0/ 88	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)

Nervous system disorders						
Any Event						
White	48/239 (20%)	56/256 (22%)				
Non-White	17/ 88 (19%)	20/ 71 (28%)				
Headache						
White	22/239 (9%)	27/256 (11%)				
Non-White	8/ 88 (9%)	7/ 71 (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,

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Table 3.17

Analysis of Proportion of 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)

Dizziness						
White	10/239 (4%)	9/256 (4%)				
Non-White	7/ 88 (8%)	5/ 71 (7%)				
Presyncope						
White	3/239 (1%)	5/256 (2%)				
Non-White	0/ 88	3/ 71 (4%)				
Hypoaesthesia ^a						
White	5/239 (2%)	1/256 (<1%)				
Non-White	0/ 88	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. NC = Not Calculable. 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)
Migraine						
White	2/239 (<1%)	4/256 (2%)				
Non-White	0/ 88	1/ 71 (1%)				
Paraesthesia						
White	1/239 (<1%)	3/256 (1%)				
Non-White	1/ 88 (1%)	2/ 71 (3%)				
Sciatica						
White	3/239 (1%)	3/256 (1%)				
Non-White	0/ 88	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. NC = Not Calculable. 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)

Somnolence						
White	1/239 (<1%)	2/256 (<1%)				
Non-White	1/ 88 (1%)	1/ 71 (1%)				
Syncope						
White	0/239	3/256 (1%)				
Non-White	1/ 88 (1%)	1/ 71 (1%)				
Lethargy						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	2/ 88 (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

(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. NC = Not Calculable. 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)

Tension headache						
White	0/239	1/256 (<1%)				
Non-White	1/ 88 (1%)	1/ 71 (1%)				
Carpal tunnel syndrome						
White	1/239 (<1%)	0/256				
Non-White	1/ 88 (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,

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Table 3.17

Analysis of Proportion of 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 radiculopathy						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Disturbance in attention						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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)

Head discomfort						
White	0/239	1/256 (<1%)				
Non-White	1/ 88 (1%)	0/ 71				
Agnosia						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Amnesia						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	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)

Anosmia						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Ataxia						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Brain injury						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	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)

Brain stem infarction						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Burning sensation						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	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)
Cerebral infarction						
White	0/239	0/256				
Non-White	1/ 88 (1%)	0/ 71				
Cerebrovascular accident						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Dysarthria						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	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)
Dysgeusia						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Hyperaesthesia						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Hypersomnia						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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)

Hypertonia						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Memory impairment						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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)
Muscle contractions involuntary						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Neuritis cranial						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	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)
Neuropathy peripheral						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Periodic limb movement disorder						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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)

Polyneuropathy						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Radiculopathy						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	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)

Transient ischaemic attack						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Tremor						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	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)
Trigeminal neuralgia						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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, thoracic and mediastinal disorders						
Any Event						
White	38/239 (16%)	62/256 (24%)	0.5916 (0.3774, 0.9272) /0.022	-8.3192 (-15.3215, -1.3168) /0.020	0.6565 (0.4565, 0.9441) /0.023	0.721
Non-White	14/ 88 (16%)	15/ 71 (21%)	0.7063 (0.3152, 1.5827) /0.398	-5.2177 (-17.4060, 6.9707) /0.401	0.7530 (0.3901, 1.4538) /0.398	

Note: "Any Event" represents subjects with any 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)

Cough						
White	15/239 (6%)	19/256 (7%)				
Non-White	6/ 88 (7%)	8/ 71 (11%)				
Oropharyngeal pain						
White	8/239 (3%)	16/256 (6%)				
Non-White	3/ 88 (3%)	3/ 71 (4%)				
Rhinitis allergic						
White	5/239 (2%)	8/256 (3%)				
Non-White	1/ 88 (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.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

Analysis of Proportion of 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 congestion						
White	3/239 (1%)	8/256 (3%)				
Non-White	2/ 88 (2%)	1/ 71 (1%)				
Sinus congestion						
White	2/239 (<1%)	8/256 (3%)				
Non-White	1/ 88 (1%)	0/ 71				
Asthma						
White	2/239 (<1%)	3/256 (1%)				
Non-White	1/ 88 (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. NC = Not Calculable. 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)

Sleep apnoea syndrome						
White	1/239 (<1%)	5/256 (2%)				
Non-White	0/ 88	1/ 71 (1%)				
Epistaxis						
White	1/239 (<1%)	4/256 (2%)				
Non-White	0/ 88	0/ 71				
Dyspnoea						
White	3/239 (1%)	1/256 (<1%)				
Non-White	0/ 88	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. NC = Not Calculable. 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)

Productive cough						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	1/ 88 (1%)	1/ 71 (1%)				
Rhinorrhoea						
White	1/239 (<1%)	3/256 (1%)				
Non-White	0/ 88	0/ 71				
Catarrh						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	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. NC = Not Calculable. 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)
Haemoptysis						
White	0/239	1/256 (<1%)				
Non-White	1/ 88 (1%)	0/ 71				
Nasal discomfort						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Oropharyngeal discomfort						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	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. NC = Not Calculable. 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)

Rales						
White	0/239	1/256 (<1%)				
Non-White	1/ 88 (1%)	0/ 71				
Respiratory disorder						
White	0/239	2/256 (<1%)				
Non-White	0/ 88	0/ 71				
Bronchospasm						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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)
Dry throat						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Emphysema						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Interstitial lung disease						
White	0/239	0/256				
Non-White	0/ 88	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)
Nasal oedema						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Nasal septum deviation						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Painful respiration						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	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)

Pharyngeal erythema						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Pleuritic pain						
White	0/239	0/256				
Non-White	1/ 88 (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 congestion						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Snoring						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	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)

Injury, poisoning and procedural complications						
Any Event						
White	36/239 (15%)	63/256 (25%)	0.5433 (0.3449, 0.8558) /0.009	-9.5466 (-16.5039, -2.5893) /0.007	0.6121 (0.4230, 0.8858) /0.009	0.370
Non-White	7/ 88 (8%)	14/ 71 (20%)	0.3519 (0.1336, 0.9268) /0.035	-11.7638 (-22.6086, -0.9189) /0.034	0.4034 (0.1721, 0.9455) /0.037	

Note: "Any Event" represents subjects with any 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)

Contusion						
White	5/239 (2%)	7/256 (3%)				
Non-White	1/ 88 (1%)	1/ 71 (1%)				
Ligament sprain						
White	2/239 (<1%)	8/256 (3%)				
Non-White	2/ 88 (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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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, 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 System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=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	2/239 (<1%)	9/256 (4%)	0.2316 (0.0495, 1.0830) /0.063	-2.6788 (-5.2133, -0.1443) /0.038	0.2380 (0.0520, 1.0905) /0.065	0.484
Non-White	0/ 88	1/ 71 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Exposure to communicable disease						
White	4/239 (2%)	6/256 (2%)				
Non-White	0/ 88	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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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=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	3/239 (1%)	8/256 (3%)				
Non-White	0/ 88	1/ 71 (1%)				
Limb injury						
White	5/239 (2%)	3/256 (1%)				
Non-White	2/ 88 (2%)	1/ 71 (1%)				
Skin laceration						
White	2/239 (<1%)	6/256 (2%)				
Non-White	0/ 88	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)

Skin abrasion						
White	2/239 (<1%)	2/256 (<1%)				
Non-White	1/ 88 (1%)	0/ 71				
Arthropod sting						
White	1/239 (<1%)	2/256 (<1%)				
Non-White	0/ 88	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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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=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	1/239 (<1%)	2/256 (<1%)				
Non-White	0/ 88	1/ 71 (1%)				
Rib fracture						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	1/ 88 (1%)	1/ 71 (1%)				
Vaccination complication						
White	1/239 (<1%)	3/256 (1%)				
Non-White	0/ 88	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)
Bone contusion						
White	1/239 (<1%)	2/256 (<1%)				
Non-White	0/ 88	0/ 71				
Epicondylitis						
White	0/239	2/256 (<1%)				
Non-White	0/ 88	1/ 71 (1%)				
Heat stroke						
White	0/239	3/256 (1%)				
Non-White	0/ 88	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)

Procedural pain						
White	1/239 (<1%)	2/256 (<1%)				
Non-White	0/ 88	0/ 71				
Animal bite						
White	0/239	2/256 (<1%)				
Non-White	0/ 88	0/ 71				
Ankle fracture						
White	1/239 (<1%)	0/256				
Non-White	1/ 88 (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)
Head injury						
White	2/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Joint injury						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Meniscus injury						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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. NC = Not Calculable. 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)
Musculoskeletal foreign body						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Road traffic accident						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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. NC =

Not Calculable. 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)

Wrist fracture						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	1/ 71 (1%)				
Burns second degree						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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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with the following variables: treatment, 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 3.17

Analysis of Proportion of 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)
Chemical burns of eye						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Clavicle fracture						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Concussion						
White	0/239	0/256				
Non-White	0/ 88	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. NC = Not Calculable. 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)
Corneal abrasion						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Eye injury						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Face injury						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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. NC = Not Calculable. 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)

Fall						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Fibula fracture						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Fractured coccyx						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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. NC = Not Calculable. 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)

Gastrointestinal procedural complication						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Hand fracture						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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. NC = Not Calculable. 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)

Injection related reaction						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Injury corneal						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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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with the following variables: treatment, 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 3.17

Analysis of Proportion of 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)
Joint dislocation						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Lip injury						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Nail injury						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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. NC = Not Calculable. 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)
Overdose						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Post-traumatic pain						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Scapula fracture						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	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. NC = Not Calculable. 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)
Sunburn						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Thermal burn						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Traumatic arthritis						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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. NC = Not Calculable. 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)

Traumatic haematoma						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Ulna fracture						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Wound						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	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. NC = Not Calculable. 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)
Psychiatric disorders						
Any Event						
White	44/239 (18%)	41/256 (16%)				
Non-White	9/ 88 (10%)	15/ 71 (21%)				
Insomnia						
White	10/239 (4%)	11/256 (4%)				
Non-White	5/ 88 (6%)	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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(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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)
Anxiety						
White	19/239 (8%)	9/256 (4%)				
Non-White	1/ 88 (1%)	3/ 71 (4%)				
Depression						
White	6/239 (3%)	6/256 (2%)				
Non-White	0/ 88	2/ 71 (3%)				
Sleep disorder						
White	1/239 (<1%)	5/256 (2%)				
Non-White	0/ 88	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. NC = Not Calculable. 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)

Abnormal dreams						
White	0/239	2/256 (<1%)				
Non-White	1/ 88 (1%)	3/ 71 (4%)				
Depressed mood						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	3/ 88 (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, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=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	3/239 (1%)	2/256 (<1%)				
Non-White	0/ 88	0/ 71				
Nightmare						
White	1/239 (<1%)	2/256 (<1%)				
Non-White	0/ 88	2/ 71 (3%)				
Major depression						
White	1/239 (<1%)	3/256 (1%)				
Non-White	0/ 88	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. NC = Not Calculable. 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)
Panic attack						
White	1/239 (<1%)	3/256 (1%)				
Non-White	0/ 88	0/ 71				
Adjustment disorder with depressed mood						
White	2/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	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. NC = Not Calculable. 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)
Adjustment disorder with mixed anxiety and depressed mood						
White	1/239 (<1%)	2/256 (<1%)				
Non-White	0/ 88	0/ 71				
Stress						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	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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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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)
Attention deficit hyperactivity disorder						
White	0/239	2/256 (<1%)				
Non-White	0/ 88	0/ 71				
Drug abuse						
White	0/239	2/256 (<1%)				
Non-White	0/ 88	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. NC = Not Calculable. 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)

Generalised anxiety disorder						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	1/ 71 (1%)				
Irritability						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Restlessness						
White	1/239 (<1%)	0/256				
Non-White	1/ 88 (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. NC = Not Calculable. 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)

Suicidal ideation						
White	2/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Acute stress disorder						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	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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with the following variables: treatment, 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 3.17

Analysis of Proportion of 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)

Adjustment disorder						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Agoraphobia						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	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)
Alcohol withdrawal syndrome						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Emotional distress						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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)
Loss of libido						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Mood swings						
White	0/239	0/256				
Non-White	1/ 88 (1%)	0/ 71				
Nervousness						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	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)
Post-traumatic stress disorder						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Psychotic disorder						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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)
Investigations						
Any Event						
White	18/239 (8%)	31/256 (12%)	0.5912 (0.3213, 1.0877) /0.091	-4.5780 (-9.7899, 0.6339) /0.085	0.6219 (0.3576, 1.0817) /0.093	0.656
Non-White	6/ 88 (7%)	10/ 71 (14%)	0.4463 (0.1539, 1.2948) /0.138	-7.2663 (-16.9206, 2.3880) /0.140	0.4841 (0.1849, 1.2676) /0.140	

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

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are 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)

Weight increased						
White	5/239 (2%)	7/256 (3%)				
Non-White	0/ 88	0/ 71				
Body temperature increased						
White	2/239 (<1%)	6/256 (2%)				
Non-White	0/ 88	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)
Blood creatine phosphokinase increased						
White	2/239 (<1%)	2/256 (<1%)				
Non-White	2/ 88 (2%)	1/ 71 (1%)				
Alanine aminotransferase increased						
White	2/239 (<1%)	3/256 (1%)				
Non-White	1/ 88 (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)

Blood cholesterol increased						
White	1/239 (<1%)	3/256 (1%)				
Non-White	0/ 88	2/ 71 (3%)				
Blood pressure increased						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	1/ 88 (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

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Analysis of Proportion of 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	2/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	1/ 71 (1%)				
Blood glucose increased						
White	3/239 (1%)	0/256				
Non-White	0/ 88	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)

Blood triglycerides increased						
White	0/239	3/256 (1%)				
Non-White	0/ 88	0/ 71				
Lipase increased						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	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)
Low density lipoprotein increased						
White	1/239 (<1%)	2/256 (<1%)				
Non-White	0/ 88	0/ 71				
Aspartate aminotransferase increased						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	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)

Blood creatinine increased						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
 Creatinine renal clearance decreased						
White	0/239	2/256 (<1%)				
Non-White	0/ 88	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)
Transaminases increased						
White	0/239	2/256 (<1%)				
Non-White	0/ 88	0/ 71				
Blood bilirubin increased						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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 bilirubin unconjugated increased						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Blood pressure decreased						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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)
CD4 lymphocytes decreased						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Campylobacter test positive						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Culture urine positive						
White	0/239	0/256				
Non-White	0/ 88	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)
Electrocardiogram abnormal						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Epstein-Barr virus test positive						
White	0/239	0/256				
Non-White	0/ 88	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. NC = Not Calculable. 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)

Escherichia test positive						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Haematocrit decreased						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	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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with the following variables: treatment, 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 3.17

Analysis of Proportion of 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	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Haemoglobin decreased						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	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)

Haemoglobin increased						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Hepatic enzyme increased						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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)
Intraocular pressure increased						
White	0/239	0/256				
Non-White	1/ 88 (1%)	0/ 71				
Muscle enzyme increased						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	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)
Parasite stool test positive						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Shigella test positive						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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. NC = Not Calculable. 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)
Vitamin D decreased						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
White blood cell count decreased						
White	0/239	0/256				
Non-White	1/ 88 (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 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)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
White	14/239 (6%)	25/256 (10%)				
Non-White	4/ 88 (5%)	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)

Anogenital warts						
White	3/239 (1%)	11/256 (4%)				
Non-White	2/ 88 (2%)	1/ 71 (1%)				
Skin papilloma						
White	2/239 (<1%)	6/256 (2%)				
Non-White	1/ 88 (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.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=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	3/239 (1%)	0/256				
Non-White	0/ 88	0/ 71				
Fibrous histiocyctoma						
White	0/239	3/256 (1%)				
Non-White	0/ 88	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)

Adenoma benign						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Breast cancer						
White	0/239	1/256 (<1%)				
Non-White	1/ 88 (1%)	0/ 71				
Lipoma						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	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)
Lipoma of breast						
White	0/239	2/256 (<1%)				
Non-White	0/ 88	0/ 71				
Acrochordon						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Adrenal adenoma						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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 neoplasm of thyroid gland						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Diffuse large B-cell lymphoma						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	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)
Fibroma						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Glioblastoma						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Kaposi's sarcoma						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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)

Testicular neoplasm						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Urethral papilloma						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	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)

Uterine leiomyoma						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Reproductive system and breast disorders						
Any Event						
White	23/239 (10%)	17/256 (7%)				
Non-White	3/ 88 (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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Analysis of Proportion of 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)

Erectile dysfunction						
White	7/239 (3%)	5/256 (2%)				
Non-White	0/ 88	1/ 71 (1%)				
Balanoposthitis						
White	2/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	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)

Benign prostatic hyperplasia						
White	1/239 (<1%)	0/256				
Non-White	1/ 88 (1%)	1/ 71 (1%)				
Genital lesion						
White	2/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	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)
Menorrhagia						
White	0/239	2/256 (<1%)				
Non-White	1/ 88 (1%)	0/ 71				
Breast cyst						
White	0/239	2/256 (<1%)				
Non-White	0/ 88	0/ 71				
Cervical dysplasia						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	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. NC = Not Calculable. 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)

Prostatomegaly						
White	0/239	2/256 (<1%)				
Non-White	0/ 88	0/ 71				
Testicular cyst						
White	2/239 (<1%)	0/256				
Non-White	0/ 88	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. NC = Not Calculable. 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)
Atrophic vulvovaginitis						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Breast mass						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Breast pain						
White	0/239	0/256				
Non-White	1/ 88 (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)

Genital erythema						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Genital odour						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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,

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with the following variables: treatment, 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 3.17

Analysis of Proportion of 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)

Haematospermia						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Penile burning sensation						
White	0/239	0/256				
Non-White	0/ 88	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)

Penile discharge						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Penile discomfort						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Penile pain						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	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)
Penile rash						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Premenstrual syndrome						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Priapism						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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)
Prostatitis						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Sexual dysfunction						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Testicular pain						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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)

Testicular swelling						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Testicular torsion						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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)

Testis discomfort						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Uterine polyp						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	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)

Vaginal discharge						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Vascular disorders						
Any Event						
White	16/239 (7%)	14/256 (5%)				
Non-White	3/ 88 (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

(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: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=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	10/239 (4%)	7/256 (3%)				
Non-White	2/ 88 (2%)	4/ 71 (6%)				
Haematoma						
White	0/239	3/256 (1%)				
Non-White	0/ 88	0/ 71				
Varicose vein						
White	2/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	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)
Flushing						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Hot flush						
White	1/239 (<1%)	0/256				
Non-White	1/ 88 (1%)	0/ 71				
Peripheral venous disease						
White	0/239	2/256 (<1%)				
Non-White	0/ 88	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)
Blood pressure inadequately controlled						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Hypotension						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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)
Peripheral coldness						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Phlebitis						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Thrombophlebitis						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	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)
Thrombophlebitis superficial						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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)

Renal and urinary disorders						
Any Event						
White	5/239 (2%)	20/256 (8%)	0.2521 (0.0931, 0.6830) /0.007	-5.7204 (-9.4754, -1.9655) /0.003	0.2678 (0.1021, 0.7022) /0.007	0.595
Non-White	4/ 88 (5%)	8/ 71 (11%)	0.3750 (0.1081, 1.3009) /0.122	-6.7222 (-15.2682, 1.8239) /0.123	0.4034 (0.1266, 1.2853) /0.125	

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

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are 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. NC = Not Calculable. 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)
Dysuria						
White	2/239 (<1%)	6/256 (2%)				
Non-White	1/ 88 (1%)	3/ 71 (4%)				
Nephrolithiasis						
White	0/239	2/256 (<1%)				
Non-White	1/ 88 (1%)	1/ 71 (1%)				
Nocturia						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	1/ 88 (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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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=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	1/239 (<1%)	3/256 (1%)				
Non-White	0/ 88	0/ 71				
Haematuria						
White	0/239	0/256				
Non-White	0/ 88	2/ 71 (3%)				
Micturition urgency						
White	0/239	2/256 (<1%)				
Non-White	0/ 88	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. NC = Not Calculable. 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)
Pollakiuria						
White	0/239	1/256 (<1%)				
Non-White	1/ 88 (1%)	0/ 71				
Renal cyst						
White	0/239	1/256 (<1%)				
Non-White	1/ 88 (1%)	0/ 71				
Urethral discharge						
White	0/239	2/256 (<1%)				
Non-White	0/ 88	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)
Leukocyturia						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Nephropathy						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Ureterolithiasis						
White	0/239	0/256				
Non-White	0/ 88	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.

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Table 3.17

Analysis of Proportion of 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)

Urethral disorder						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Urethral pain						
White	0/239	0/256				
Non-White	0/ 88	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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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)

Urinary incontinence						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Urinary tract disorder						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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,

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Table 3.17

Analysis of Proportion of 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)

Metabolism and nutrition disorders						
Any Event						
White	13/239 (5%)	11/256 (4%)				
Non-White	5/ 88 (6%)	6/ 71 (8%)				
Hypercholesterolaemia						
White	4/239 (2%)	3/256 (1%)				
Non-White	0/ 88	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)
Vitamin D deficiency						
White	2/239 (<1%)	3/256 (1%)				
Non-White	2/ 88 (2%)	1/ 71 (1%)				
Decreased appetite						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	1/ 71 (1%)				
Gout						
White	3/239 (1%)	0/256				
Non-White	0/ 88	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)
Obesity						
White	1/239 (<1%)	0/256				
Non-White	1/ 88 (1%)	0/ 71				
Type 2 diabetes mellitus						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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)

Alcoholic ketoacidosis						
White	0/239	0/256				
Non-White	1/ 88 (1%)	0/ 71				
Cachexia						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Diabetes mellitus						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	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)

Dyslipidaemi ^a						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Gluten sensitivity						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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)

Hyperglycaemia						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Hyperlipasemia						
White	0/239	0/256				
Non-White	1/ 88 (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,

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Analysis of Proportion of 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)

Hypertriglyceridaemia						
White	0/239	0/256				
Non-White	1/ 88 (1%)	0/ 71				
Hypokalaemia						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Iron deficiency						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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)

Eye disorders						
Any Event						
White	12/239 (5%)	16/256 (6%)				
Non-White	2/ 88 (2%)	4/ 71 (6%)				
Cataract						
White	2/239 (<1%)	3/256 (1%)				
Non-White	0/ 88	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)

Conjunctivitis allergic						
White	1/239 (<1%)	3/256 (1%)				
Non-White	0/ 88	1/ 71 (1%)				
Blepharitis						
White	0/239	3/256 (1%)				
Non-White	1/ 88 (1%)	0/ 71				
Retinal detachment						
White	2/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	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)
Diplopia						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Dry eye						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	1/ 71 (1%)				
Astigmatism						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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)

Blepharospasm						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Chalazion						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Eczema eyelids						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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)
Eye pain						
White	0/239	0/256				
Non-White	1/ 88 (1%)	0/ 71				
Eyelid cyst						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Eyelid oedema						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	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)

Glaucoma						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Iritis						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Macular fibrosis						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	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. 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 System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=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						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Ocular hyperaemia						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Pterygium						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	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. NC = Not Calculable. 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)
Retinal tear						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Ulcerative keratitis						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Vision blurred						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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. NC = Not Calculable. 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)

Vitreous detachment						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Vitreous floaters						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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)

Ear and labyrinth disorders						
Any Event						
White	6/239 (3%)	11/256 (4%)				
Non-White	4/ 88 (5%)	5/ 71 (7%)				
Tinnitus						
White	2/239 (<1%)	1/256 (<1%)				
Non-White	1/ 88 (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)
Vertigo						
White	2/239 (<1%)	4/256 (2%)				
Non-White	0/ 88	0/ 71				
Cerumen impaction						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	2/ 88 (2%)	0/ 71				
Ear discomfort						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	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)
Ear pain						
White	0/239	1/256 (<1%)				
Non-White	1/ 88 (1%)	0/ 71				
Eustachian tube dysfunction						
White	0/239	0/256				
Non-White	0/ 88	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)

Excessive cerumen production						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Deafness neurosensory						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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)
Ear pruritus						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Hypoacusis						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Tympanic membrane perforation						
White	0/239	0/256				
Non-White	0/ 88	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)

Immune system disorders						
Any Event						
White	10/239 (4%)	12/256 (5%)				
Non-White	3/ 88 (3%)	1/ 71 (1%)				
Seasonal allergy						
White	6/239 (3%)	6/256 (2%)				
Non-White	2/ 88 (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

(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: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=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	2/239 (<1%)	3/256 (1%)				
Non-White	1/ 88 (1%)	0/ 71				
Food allergy						
White	2/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	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	0/239	1/256 (<1%)				
Non-White	0/ 88	1/ 71 (1%)				
Allergy to arthropod bite						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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)

Anaphylactic reaction						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Blood and lymphatic system disorders						
Any Event						
White	9/239 (4%)	10/256 (4%)				
Non-White	0/ 88	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)

Lymphadenopathy						
White	2/239 (<1%)	4/256 (2%)				
Non-White	0/ 88	0/ 71				
Anaemia						
White	0/239	5/256 (2%)				
Non-White	0/ 88	0/ 71				
Microcytic anaemia						
White	3/239 (1%)	1/256 (<1%)				
Non-White	0/ 88	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)
Iron deficiency anaemia						
White	2/239 (<1%)	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Lymph node pain						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	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)

Neutropenia						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Polycythaemi						
^a White	1/239 (<1%)	0/256				
Non-White	0/ 88	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)

Cardiac disorders						
Any Event						
White	5/239 (2%)	11/256 (4%)				
Non-White	1/ 88 (1%)	0/ 71				
Palpitations						
White	1/239 (<1%)	3/256 (1%)				
Non-White	0/ 88	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)
Tachycardia						
White	1/239 (<1%)	3/256 (1%)				
Non-White	0/ 88	0/ 71				
Ventricular extrasystoles						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	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)
Acute myocardial infarction						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Angina pectoris						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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)

Atrial fibrillation						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Atrioventricular block first degree						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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. NC = Not Calculable. 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)

Cardiac aneurysm						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Extrasystoles						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	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. NC = Not Calculable. 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)
Myocardial infarction						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Myocardial necrosis						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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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with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC =

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Table 3.17

Analysis of Proportion of 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 bradycardia						
White	0/239	0/256				
Non-White	1/ 88 (1%)	0/ 71				
Wolff-Parkinson-White syndrome						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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,

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Analysis of Proportion of 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	1/239 (<1%)	3/256 (1%)				
Non-White	1/ 88 (1%)	0/ 71				
Cholelithiasis						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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)

Hepatic steatosis						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Hepatocellular injury						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Hepatomegaly						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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. NC = Not Calculable. 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)

Jaundice						
White	0/239	0/256				
Non-White	1/ 88 (1%)	0/ 71				
Congenital, familial and genetic disorders						
Any Event						
White	0/239	1/256 (<1%)				
Non-White	2/ 88 (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

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=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	0/239	0/256				
Non-White	1/ 88 (1%)	0/ 71				
Gilbert's syndrome						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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)
Hydrocele						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Type V hyperlipidaemia						
White	0/239	0/256				
Non-White	1/ 88 (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)

Endocrine disorders						
Any Event						
White	1/239 (<1%)	3/256 (1%)				
Non-White	0/ 88	0/ 71				
Hypogonadism						
White	0/239	2/256 (<1%)				
Non-White	0/ 88	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)
Androgen deficiency						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Goitre						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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)

Social circumstances						
Any Event						
White	2/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Menopause						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	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. 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 System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=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	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Pregnancy, puerperium and perinatal conditions						
Any Event						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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)

Abortion spontaneous						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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	113/118 (96%)	130/135 (96%)				
Europe	156/165 (95%)	153/155 (99%)				
Rest of World	42/ 44 (95%)	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)

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

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

System Organ Class Preferred Term	Q8W (N=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	103/118 (87%)	111/135 (82%)				
Europe	150/165 (91%)	137/155 (88%)				
Rest of World	34/ 44 (77%)	31/ 37 (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, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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	96/118 (81%)	98/135 (73%)				
Europe	143/165 (87%)	134/155 (86%)				
Rest of World	34/ 44 (77%)	29/ 37 (78%)				

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

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number 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: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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	22/118 (19%)	40/135 (30%)	0.5443 (0.3009, 0.9844) /0.044	-10.9856 (-21.4120, -0.5592) /0.039	0.6292 (0.3981, 0.9946) /0.047	0.576
Europe	15/165 (9%)	30/155 (19%)	0.4167 (0.2146, 0.8091) /0.010	-10.2639 (-17.8748, -2.6531) /0.008	0.4697 (0.2631, 0.8387) /0.011	
Rest of World	4/ 44 (9%)	9/ 37 (24%)	0.3111 (0.0871, 1.1111) /0.072	-15.2334 (-31.4589, 0.9921) /0.066	0.3737 (0.1252, 1.1157) /0.078	

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

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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	14/118 (12%)	17/135 (13%)				
Europe	14/165 (8%)	17/155 (11%)				
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), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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%)	9/135 (7%)				
Europe	18/165 (11%)	20/155 (13%)				
Rest of World	2/ 44 (5%)	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. NC = Not Calculable. 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)
Pyrexia						
North America	5/118 (4%)	10/135 (7%)				
Europe	20/165 (12%)	25/155 (16%)				
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 swelling						
North America	14/118 (12%)	13/135 (10%)				
Europe	9/165 (5%)	9/155 (6%)				
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	9/118 (8%)	20/135 (15%)	0.4748 (0.2072, 1.0879) /0.078	-7.1877 (-14.8589, 0.4835) /0.066	0.5148 (0.2439, 1.0865) /0.081	0.930
Europe	4/165 (2%)	8/155 (5%)	0.4565 (0.1347, 1.5477) /0.208	-2.7370 (-6.9369, 1.4628) /0.201	0.4697 (0.1443, 1.5286) /0.209	
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, p-value and interaction p-values are 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 pruritus						
North America	8/118 (7%)	12/135 (9%)	0.7455 (0.2939, 1.8909) /0.536	-2.1092 (-8.7138, 4.4953) /0.531	0.7627 (0.3228, 1.8021) /0.537	0.054
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	0/ 44	5/ 37 (14%)	<0.0001 (<0.0001, -) />0.999	-15.2864 (-47.2493, 16.6765) /0.349	<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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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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	2/118 (2%)	7/135 (5%)				
Europe	6/165 (4%)	7/155 (5%)				
Rest of World	2/ 44 (5%)	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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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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%)	7/135 (5%)				
Europe	7/165 (4%)	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

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

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

System Organ Class Preferred Term	Q8W (N=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/>						
Asthenia						
North America	3/118 (3%)	0/135				
Europe	10/165 (6%)	10/155 (6%)				
Rest of World	1/ 44 (2%)	0/ 37				
Chills						
North America	10/118 (8%)	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

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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 bruising						
North America	9/118 (8%)	7/135 (5%)				
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)

Pain						
North America	7/118 (6%)	4/135 (3%)				
Europe	1/165 (<1%)	2/155 (1%)				
Rest of World	0/ 44	2/ 37 (5%)				
Malaise						
North America	3/118 (3%)	2/135 (1%)				
Europe	4/165 (2%)	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

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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%)	8/155 (5%)				
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)
Injection site warmth						
North America	3/118 (3%)	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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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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%)	2/135 (1%)				
Europe	2/165 (1%)	4/155 (3%)				
Rest of World	0/ 44	0/ 37				
Discomfort						
North America	0/118	0/135				
Europe	6/165 (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

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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 reaction						
North America	4/118 (3%)	4/135 (3%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any 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	5/118 (4%)	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	2/118 (2%)	3/135 (2%)				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
Feeling hot						
North America	0/118	0/135				
Europe	4/165 (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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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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	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

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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)
Cyst						
North America	2/118 (2%)	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)
Injection site discolouration						
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. NC =

Not Calculable. 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)
Mass						
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. NC = Not Calculable. 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: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, 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 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, 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 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, 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 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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 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. NC = Not Calculable. 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 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

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, 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 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, 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 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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	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. NC =

Not Calculable. 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)
Vaccination site 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, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, 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 3.17

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

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

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Adverse drug reaction						
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. NC =

Not Calculable. 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)
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

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

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

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

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Enanthema						
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. NC = Not Calculable. 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: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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 abnormal						
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. NC = Not Calculable. 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)

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. NC = Not Calculable. 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 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

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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 hypoaesthesia						
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. NC =

Not Calculable. 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 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. NC = Not Calculable. 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: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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

(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)
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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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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				
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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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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	78/118 (66%)	96/135 (71%)				
Europe	108/165 (65%)	118/155 (76%)				
Rest of World	30/ 44 (68%)	25/ 37 (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

(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	8/118 (7%)	14/135 (10%)				
Europe	47/165 (28%)	50/155 (32%)				
Rest of World	6/ 44 (14%)	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.

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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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	28/118 (24%)	43/135 (32%)	0.6656 (0.3811, 1.1626) /0.153	-8.1230 (-19.1087, 2.8626) /0.147	0.7450 (0.4960, 1.1190) /0.156	0.933
Europe	8/165 (5%)	12/155 (8%)	0.6072 (0.2413, 1.5280) /0.289	-2.8935 (-8.2266, 2.4397) /0.288	0.6263 (0.2631, 1.4908) /0.290	
Rest of World	9/ 44 (20%)	11/ 37 (30%)	0.6078 (0.2199, 1.6799) /0.337	-9.2752 (-28.2212, 9.6708) /0.337	0.6880 (0.3202, 1.4783) /0.338	

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

System Organ Class Preferred Term	Q8W (N=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	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	0.951
Europe	9/165 (5%)	18/155 (12%)	0.4391 (0.1910, 1.0094) /0.053	-6.1584 (-12.2776, -0.0391) /0.049	0.4697 (0.2176, 1.0140) /0.054	
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, 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)
Syphilis						
North America	8/118 (7%)	7/135 (5%)				
Europe	8/165 (5%)	11/155 (7%)				
Rest of World	2/ 44 (5%)	4/ 37 (11%)				
Influenza						
North America	7/118 (6%)	3/135 (2%)				
Europe	9/165 (5%)	6/155 (4%)				
Rest of World	2/ 44 (5%)	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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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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						
North America	4/118 (3%)	4/135 (3%)				
Europe	10/165 (6%)	11/155 (7%)				
Rest of World	0/ 44	1/ 37 (3%)				
Pharyngitis						
North America	3/118 (3%)	6/135 (4%)				
Europe	8/165 (5%)	10/155 (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

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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)
Gonorrhoea						
North America	6/118 (5%)	9/135 (7%)				
Europe	7/165 (4%)	4/155 (3%)				
Rest of World	0/ 44	0/ 37				
Sinusitis						
North America	4/118 (3%)	5/135 (4%)				
Europe	5/165 (3%)	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

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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 infection						
North America	2/118 (2%)	2/135 (1%)				
Europe	6/165 (4%)	10/155 (6%)				
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)
Chlamydial infection						
North America	3/118 (3%)	3/135 (2%)				
Europe	8/165 (5%)	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)
Urinary tract infection						
North America	5/118 (4%)	4/135 (3%)				
Europe	3/165 (2%)	4/155 (3%)				
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

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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)
Conjunctivitis						
North America	2/118 (2%)	3/135 (2%)				
Europe	7/165 (4%)	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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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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	1/118 (<1%)	0/135				
Europe	5/165 (3%)	10/155 (6%)				
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

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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 gonococcal						
North America	5/118 (4%)	5/135 (4%)				
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. NC = Not Calculable. 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)
Tonsillitis						
North America	0/118	1/135 (<1%)				
Europe	5/165 (3%)	8/155 (5%)				
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)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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	6/118 (5%)	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

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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	7/165 (4%)	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)

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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. NC = Not Calculable. 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)
Oral herpes North America	0/118	3/135 (2%)	<0.0001 (<0.0001, -) />0.999	-4.4933 (-23.1777, 14.1911) /0.637	<0.0001 (<0.0001, -) />0.999	0.125
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%)	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, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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/>						
Urethritis						
North America	3/118 (3%)	5/135 (4%)				
Europe	2/165 (1%)	4/155 (3%)				
Rest of World	0/ 44	0/ 37				
Folliculitis						
North America	2/118 (2%)	2/135 (1%)				
Europe	3/165 (2%)	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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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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	3/118 (3%)	5/135 (4%)				
Europe	2/165 (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

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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	2/118 (2%)	1/135 (<1%)				
Europe	3/165 (2%)	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)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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	2/118 (2%)	2/135 (1%)				
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

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC =

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Table 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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%)	3/135 (2%)				
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

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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. 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 System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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%)	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. NC = Not Calculable. 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)
Lower respiratory tract infection						
North America	0/118	2/135 (1%)				
Europe	0/165	0/155				
Rest of World	7/ 44 (16%)	0/ 37				

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

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are 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 abscess						
North America	2/118 (2%)	4/135 (3%)				
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)
Ear infection						
North America	3/118 (3%)	1/135 (<1%)				
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

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

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

System Organ Class Preferred Term	Q8W (N=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	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, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms 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)
Tinea versicolour						
North America	1/118 (<1%)	2/135 (1%)				
Europe	2/165 (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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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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	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, p-value and interaction p-values are 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: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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%)	1/135 (<1%)				
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, p-value and interaction p-values are 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: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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						
North America	0/118	3/135 (2%)				
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. NC = Not Calculable. 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: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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	1/118 (<1%)	1/135 (<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)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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	2/165 (1%)	1/155 (<1%)				
Rest of World	0/ 44	1/ 37 (3%)				
Gingivitis						
North America	1/118 (<1%)	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)

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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. NC = Not Calculable. 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)
Herpes simplex						
North America	2/118 (2%)	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)

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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)
Hordeolum						
North America	1/118 (<1%)	2/135 (1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	2/ 44 (5%)	0/ 37				
Pneumonia						
North America	1/118 (<1%)	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

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

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

System Organ Class Preferred Term	Q8W (N=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	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, 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)
Urethritis gonococcal						
North America	0/118	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, 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)
Abscess limb						
North America	2/118 (2%)	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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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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	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

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

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

System Organ Class Preferred Term	Q8W (N=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	2/135 (1%)				
Europe	2/165 (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

(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)
Body tinea						
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)
Genital herpes						
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, p-value and interaction p-values are 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)
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)

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

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

System Organ Class Preferred Term	Q8W (N=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	1/118 (<1%)	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)
Pharyngotonsillitis						
North America	1/118 (<1%)	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)
Primary syphilis						
North America	1/118 (<1%)	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, p-value and interaction p-values are 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)
Shigella infection						
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)
Tracheitis						
North America	0/118	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

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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	1/118 (<1%)	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)
Enteritis infectious						
North America	1/118 (<1%)	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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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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	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

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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. NC = Not Calculable. 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)
Helicobacter infection						
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. NC = Not Calculable. 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: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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	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)

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Table 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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)

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Table 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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	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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Not Calculable. 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)
Pharyngitis streptococcal						
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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Not Calculable. 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)
Skin infection						
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, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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	2/118 (2%)	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	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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Table 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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	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, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms 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)
Tinea infection						
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 AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are 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)
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

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

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

System Organ Class Preferred Term	Q8W (N=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	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. 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 System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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	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)
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)
Acute sinusitis						
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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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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	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. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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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 sinusitis						
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)

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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

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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. 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 System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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	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. NC =

Not Calculable. 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)
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

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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				
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

(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)
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

(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)
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

(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)
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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Table 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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	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. NC = Not Calculable. 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)
Pulmonary tuberculosis						
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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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)
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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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)
Sexually transmitted 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

(1) significant difference in occurrences between treatment arms 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.

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Table 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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						
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)
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

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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 mycoplasmal						
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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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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				
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

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

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

System Organ Class Preferred Term	Q8W (N=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)

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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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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)
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)

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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)
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. NC = Not Calculable. 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)
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)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, 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 3.17

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

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

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Borrelia infection						
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. NC = Not Calculable. 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)
COVID-19						
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. NC = Not Calculable. 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: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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)
Cellulitis of male external genital organ						
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. NC = Not Calculable. 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)
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,

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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. NC =

Not Calculable. 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)
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)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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. NC = Not Calculable. 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)
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. NC =

Not Calculable. 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)
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. NC = Not Calculable. 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: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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. 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 System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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 infected						
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. NC = Not Calculable. 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)
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.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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),

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

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

System Organ Class Preferred Term	Q8W (N=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,

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

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

System Organ Class Preferred Term	Q8W (N=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

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Table 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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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Table 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative 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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Not Calculable. 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)
Eye 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. NC = Not Calculable. 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 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. NC =

Not Calculable. 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)
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 with the following variables: treatment, 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 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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 infection						
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. NC = Not Calculable. 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)
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.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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. NC = Not Calculable. 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)
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.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

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

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

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Giardiasis						
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. NC = Not Calculable. 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: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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. NC = Not Calculable. 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: Region (North America vs. Europe vs. Rest of World)

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

Not Calculable. 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. NC = Not Calculable. 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: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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 C						
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. NC = Not Calculable. 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)
Herpes ophthalmic						
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. NC =

Not Calculable. 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)
Herpes virus 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)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

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

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

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Infected bite						
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. NC = Not Calculable. 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)
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)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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						
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. NC = Not Calculable. 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: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Latent syphilis						
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. NC =

Not Calculable. 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)
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.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

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

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

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

Not Calculable. 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)
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

(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. NC = Not Calculable. 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)
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)

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Table 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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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Table 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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

(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)
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

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Table 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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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Table 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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

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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 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 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

(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)
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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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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

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

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

System Organ Class Preferred Term	Q8W (N=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

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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. 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 System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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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Table 3.17

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

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

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Suspected COVID-19						
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)
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

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

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

System Organ Class Preferred Term	Q8W (N=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

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

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

System Organ Class Preferred Term	Q8W (N=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

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

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

System Organ Class Preferred Term	Q8W (N=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. NC =

Not Calculable. 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)
Urinary tract infection staphylococcal						
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)
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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Table 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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

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Table 3.17

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

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

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Wound 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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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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	45/118 (38%)	59/135 (44%)	0.7941 (0.4799, 1.3139) /0.369	-5.5681 (-17.6848, 6.5486) /0.368	0.8726 (0.6470, 1.1768) /0.372	0.573
Europe	42/165 (25%)	55/155 (35%)	0.6208 (0.3839, 1.0039) /0.052	-10.0293 (-20.0749, 0.0163) /0.050	0.7174 (0.5124, 1.0043) /0.053	
Rest of World	11/ 44 (25%)	9/ 37 (24%)	1.0370 (0.3759, 2.8608) /0.944	0.6757 (-18.1608, 19.5121) /0.944	1.0278 (0.4784, 2.2083) /0.944	

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

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are 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. NC = Not Calculable. 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)
Diarrhoea						
North America	18/118 (15%)	16/135 (12%)				
Europe	12/165 (7%)	17/155 (11%)				
Rest of World	3/ 44 (7%)	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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with the following variables: treatment, 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 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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	8/118 (7%)	14/135 (10%)	0.6286 (0.2540, 1.5557) /0.315	-3.5907 (-10.4481, 3.2667) /0.305	0.6538 (0.2843, 1.5035) /0.317	0.095
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	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, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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	2/118 (2%)	8/135 (6%)	0.2737 (0.0570, 1.3154) /0.106	-4.2310 (-8.8448, 0.3828) /0.072	0.2860 (0.0620, 1.3204) /0.109	0.566
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	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, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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	3/118 (3%)	7/135 (5%)	0.4770 (0.1205, 1.8881) /0.292	-2.6428 (-7.3392, 2.0535) /0.270	0.4903 (0.1297, 1.8535) /0.293	NC
Europe	0/165	9/155 (6%)	<0.0001 (<0.0001, -) />0.999	-7.9417 (-23.9678, 8.0844) /0.331	<0.0001 (<0.0001, -) />0.999	
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, p-value and interaction p-values are 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: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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	6/165 (4%)	8/155 (5%)				
Rest of World	1/ 44 (2%)	0/ 37				
Toothache						
North America	4/118 (3%)	1/135 (<1%)				
Europe	3/165 (2%)	9/155 (6%)				
Rest of World	0/ 44	0/ 37				

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

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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	2/118 (2%)	5/135 (4%)				
Europe	4/165 (2%)	2/155 (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)

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

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

System Organ Class Preferred Term	Q8W (N=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	3/118 (3%)	4/135 (3%)				
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)

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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)
Abdominal distension						
North America	6/118 (5%)	3/135 (2%)				
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

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

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

System Organ Class Preferred Term	Q8W (N=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%)	4/135 (3%)				
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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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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%)	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

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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 dysplasia						
North America	2/118 (2%)	1/135 (<1%)				
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, 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)
Gastritis						
North America	2/118 (2%)	0/135				
Europe	0/165	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)

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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. NC = Not Calculable. 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%)	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, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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	1/118 (<1%)	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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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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%)	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

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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)
Anal fissure						
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

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

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

System Organ Class Preferred Term	Q8W (N=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	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, 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)
Flatulence						
North America	0/118	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, p-value and interaction p-values are 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. 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 System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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	3/118 (3%)	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. NC = Not Calculable. 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: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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	1/118 (<1%)	0/135				
Europe	3/165 (2%)	0/155				
Rest of World	0/ 44	0/ 37				

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

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC =

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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						
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

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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)
Rectal discharge						
North America	2/118 (2%)	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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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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	1/118 (<1%)	0/135				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Dry mouth						
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

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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)
Hiatus hernia						
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, 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)
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

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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)
Irritable bowel syndrome						
North America	1/118 (<1%)	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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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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	2/165 (1%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Proctalgia						
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, 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)
Anal pruritus						
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)
Colitis						
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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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diverticulum intestinal						
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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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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	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. NC = Not Calculable. 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: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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%)	1/155 (<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)
Mouth ulceration						
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)

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

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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)
Oral disorder						
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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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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	1/155 (<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)
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

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

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

System Organ Class Preferred Term	Q8W (N=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

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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)
Anal ulcer						
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)
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)

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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)

Anorectal 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, 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)

Aphthous ulcer						
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)
Chapped lips						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
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)

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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)
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)

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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)
Dental cyst						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
Dysphagia						
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)
Enteritis						
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. 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)
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

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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)
Faeces soft						
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)
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)

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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)
Gastric ulcer						
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. NC = Not Calculable. 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)
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)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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)

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

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

System Organ Class Preferred Term	Q8W (N=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)

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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)
<hr/>						
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

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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)
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)

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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)
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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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)

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)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative 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)
Oral lichen planus						
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)
Oral 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. NC = Not Calculable. 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)
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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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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

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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)
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

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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)
Rectal prolapse						
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)
Rectal tenesmus						
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)
Salivary gland mucocoele						
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)
-----	-----	-----	-----	-----	-----	-----
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

(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)

Musculoskeletal and connective tissue disorders						
Any Event						
North America	37/118 (31%)	41/135 (30%)				
Europe	43/165 (26%)	62/155 (40%)				
Rest of World	11/ 44 (25%)	10/ 37 (27%)				

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

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms 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)
Back pain						
North America	8/118 (7%)	9/135 (7%)				
Europe	16/165 (10%)	22/155 (14%)				
Rest of World	3/ 44 (7%)	1/ 37 (3%)				
Arthralgia						
North America	12/118 (10%)	10/135 (7%)				
Europe	6/165 (4%)	13/155 (8%)				
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)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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	6/118 (5%)	13/135 (10%)	0.5027 (0.1848, 1.3677) /0.178	-4.5449 (-10.9068, 1.8171) /0.161	0.5280 (0.2072, 1.3454) /0.181	0.352
Europe	4/165 (2%)	9/155 (6%)	0.4030 (0.1215, 1.3367) /0.137	-3.3822 (-7.7482, 0.9838) /0.129	0.4175 (0.1312, 1.3281) /0.139	
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, p-value and interaction p-values are 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)
Myalgia						
North America	6/118 (5%)	3/135 (2%)				
Europe	2/165 (1%)	5/155 (3%)				
Rest of World	2/ 44 (5%)	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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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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%)	2/135 (1%)				
Europe	3/165 (2%)	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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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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	3/118 (3%)	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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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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	3/118 (3%)	0/135				
Europe	2/165 (1%)	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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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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	4/118 (3%)	2/135 (1%)				
Europe	3/165 (2%)	0/155				
Rest of World	0/ 44	0/ 37				
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

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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)
Intervertebral disc protrusion						
North America	1/118 (<1%)	0/135				
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)
Muscle contracture						
North America	0/118	0/135				
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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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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%)	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)
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

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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)
Spinal osteoarthritis						
North America	1/118 (<1%)	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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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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	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)
Plantar fasciitis						
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, p-value and interaction p-values are 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)
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

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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)
Arthritis						
North America	0/118	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, 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)
Exostosis						
North America	0/118	1/135 (<1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Flank pain						
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)
Groin 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

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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)
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

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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. NC = Not Calculable. 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 range of motion decreased						
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. NC = Not Calculable. 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 swelling						
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)
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)

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

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

System Organ Class Preferred Term	Q8W (N=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	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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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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	1/155 (<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)

Osteonecrosi s						
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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using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC =

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

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

System Organ Class Preferred Term	Q8W (N=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	2/135 (1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Synovitis						
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. NC = Not Calculable. 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)
Arthritis reactive						
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. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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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)
Arthropathy						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Bone 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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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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. 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 System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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)

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

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

System Organ Class Preferred Term	Q8W (N=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

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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)
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)

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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)
Loose body in joint						
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)
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

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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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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Myosclerosis						
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)
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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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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				

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)

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)

Polyarthriti s						
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. NC =

Not Calculable. 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)
Sacroiliitis						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	1/ 37 (3%)				
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

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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 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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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative 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. NC =

Not Calculable. 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)
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. NC = Not Calculable. 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)
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)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Not Calculable. 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)
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

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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	30/118 (25%)	38/135 (28%)				
Europe	37/165 (22%)	36/155 (23%)				
Rest of World	7/ 44 (16%)	10/ 37 (27%)				

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

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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	5/165 (3%)	6/155 (4%)				
Rest of World	2/ 44 (5%)	2/ 37 (5%)				
Rash						
North America	3/118 (3%)	6/135 (4%)				
Europe	4/165 (2%)	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

(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)
<hr/>						
Eczema						
North America	3/118 (3%)	2/135 (1%)				
Europe	4/165 (2%)	9/155 (6%)				
Rest of World	0/ 44	2/ 37 (5%)				
Skin lesion						
North America	1/118 (<1%)	4/135 (3%)				
Europe	6/165 (4%)	0/155				
Rest of World	0/ 44	0/ 37				

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

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are 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)
Acne						
North America	1/118 (<1%)	2/135 (1%)				
Europe	1/165 (<1%)	4/155 (3%)				
Rest of World	0/ 44	2/ 37 (5%)				
Dermatitis						
North America	0/118	4/135 (3%)				
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, 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)
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

(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)
Hyperhidrosi s						
North America	0/118	4/135 (3%)				
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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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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	3/118 (3%)	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, p-value and interaction p-values are 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	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, p-value and interaction p-values are 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)
Seborrhoeic dermatitis						
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)
Urticaria						
North America	1/118 (<1%)	0/135				
Europe	1/165 (<1%)	2/155 (1%)				
Rest of World	1/ 44 (2%)	0/ 37				
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

(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)

Dermatitis atopic						
North America	1/118 (<1%)	2/135 (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

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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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				
Dry skin						
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. NC = Not Calculable. 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)

Pityriasis rosea						
North America	1/118 (<1%)	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

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, 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 System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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	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)
Skin mass						
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, p-value and interaction p-values are 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)
Actinic keratosis						
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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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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	1/118 (<1%)	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Ecchymosis						
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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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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	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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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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)

(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)
Rash maculo-papular						
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)
Rash papular						
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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Subgroup: Region (North America vs. Europe vs. Rest of World)

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

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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)
Cold sweat						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Dermatosis						
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)
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

(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)
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

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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

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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)
Guttate psoriasis						
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)
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

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

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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)
Hyperkeratosis						
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)
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

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, 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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Table 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative 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. NC =

Not Calculable. 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)
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.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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 bleeding						
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)
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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Table 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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 dystrophy						
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. NC = Not Calculable. 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)
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. NC = Not Calculable. 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)
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)

(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. NC =

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Table 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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				
Prurigo						
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)
Purpura						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Rash macular						
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)
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)

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Table 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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)

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Table 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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)

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Table 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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)

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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. NC = Not Calculable. 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: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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	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)

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

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Table 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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

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

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

System Organ Class Preferred Term	Q8W (N=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)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, 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 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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 ulcer						
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. 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 System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

System Organ Class Preferred Term	Q8W (N=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 lentigo						
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)

Nervous system disorders						
Any Event						
North America	35/118 (30%)	28/135 (21%)				
Europe	25/165 (15%)	39/155 (25%)				
Rest of World	5/ 44 (11%)	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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Table 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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	15/118 (13%)	11/135 (8%)				
Europe	14/165 (8%)	19/155 (12%)				
Rest of World	1/ 44 (2%)	4/ 37 (11%)				
Dizziness						
North America	11/118 (9%)	5/135 (4%)				
Europe	4/165 (2%)	6/155 (4%)				
Rest of World	2/ 44 (5%)	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)
Presyncope						
North America	2/118 (2%)	5/135 (4%)				
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)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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	3/118 (3%)	2/135 (1%)				
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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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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	1/165 (<1%)	5/155 (3%)				
Rest of World	0/ 44	0/ 37				
Paraesthesia						
North America	1/118 (<1%)	4/135 (3%)				
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)
Sciatica						
North America	2/118 (2%)	0/135				
Europe	1/165 (<1%)	3/155 (2%)				
Rest of World	0/ 44	0/ 37				
Somnolence						
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

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Table 3.17

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

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

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Syncope						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	0/165	3/155 (2%)				
Rest of World	0/ 44	0/ 37				
Lethargy						
North America	3/118 (3%)	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)
Tension headache						
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

(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)
Carpal tunnel syndrome						
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

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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)
Cervical radiculopathy						
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)
Disturbance in attention						
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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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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

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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)

Agnosia						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
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

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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)

Anosmia						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Ataxia						
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)
Brain injury						
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. 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)
Brain stem infarction						
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. NC =

Not Calculable. 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)
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.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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. NC = Not Calculable. 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)
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

(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)
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

(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)
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)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

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

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

System Organ Class Preferred Term	Q8W (N=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/>						
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

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Memory impairment						
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. NC = Not Calculable. 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)
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. NC = Not Calculable. 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)
Neuritis cranial						
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),

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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. 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 System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Transient ischaemic attack						
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. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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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)
Tremor						
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)
Trigeminal neuralgia						
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)

Respiratory, thoracic and mediastinal disorders						
Any Event						
North America	23/118 (19%)	35/135 (26%)	0.6917 (0.3810, 1.2558) /0.226	-6.4344 (-16.7170, 3.8482) /0.220	0.7518 (0.4725, 1.1963) /0.229	0.865
Europe	22/165 (13%)	33/155 (21%)	0.5688 (0.3149, 1.0271) /0.061	-7.9570 (-16.2295, 0.3155) /0.059	0.6263 (0.3826, 1.0252) /0.063	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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	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	
Cough North America	7/118 (6%)	13/135 (10%)				
Europe	9/165 (5%)	10/155 (6%)				
Rest of World	5/ 44 (11%)	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. 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 System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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	3/118 (3%)	11/135 (8%)				
Europe	7/165 (4%)	7/155 (5%)				
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.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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	4/165 (2%)	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), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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	5/118 (4%)	6/135 (4%)				
Europe	0/165	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)

(2) at least 1 level of the subgroup has number 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. NC =

Not Calculable. 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)
Sinus congestion						
North America	3/118 (3%)	8/135 (6%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are 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)
Asthma						
North America	3/118 (3%)	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, 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)
Sleep apnoea syndrome						
North America	1/118 (<1%)	3/135 (2%)				
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.

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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						
North America	0/118	2/135 (1%)				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	0/ 44	1/ 37 (3%)				
Dyspnoea						
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, p-value and interaction p-values are 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)
Productive cough						
North America	2/118 (2%)	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.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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	1/118 (<1%)	1/135 (<1%)				
Europe	0/165	2/155 (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, 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)
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)
Nasal discomfort						
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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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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				

Note: "Any Event" represents subjects with any 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)
Respiratory disorder						
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)
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

(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)
Emphysema						
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)
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.

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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 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)

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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)
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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using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, 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 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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 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

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, 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 System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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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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. NC =

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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

(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)
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

(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)
Injury, poisoning and procedural complications						
Any Event						
North America	20/118 (17%)	40/135 (30%)	0.4847 (0.2643, 0.8889) /0.019	-12.6805 (-22.9350, -2.4259) /0.015	0.5720 (0.3552, 0.9213) /0.022	0.924
Europe	18/165 (11%)	31/155 (20%)	0.4898 (0.2614, 0.9179) /0.026	-9.0909 (-16.9827, -1.1991) /0.024	0.5455 (0.3186, 0.9340) /0.027	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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	5/ 44 (11%)	6/ 37 (16%)	0.6624 (0.1847, 2.3755) /0.527	-4.8526 (-19.9852, 10.2801) /0.530	0.7008 (0.2325, 2.1123) /0.528	
Contusion North America	2/118 (2%)	4/135 (3%)				
Europe	4/165 (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)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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	2/118 (2%)	5/135 (4%)				
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)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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	5/135 (4%)				
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, p-value and interaction p-values are 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)
Exposure to communicable disease						
North America	4/118 (3%)	8/135 (6%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any 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)
Muscle strain						
North America	3/118 (3%)	4/135 (3%)				
Europe	0/165	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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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)
Limb injury						
North America	5/118 (4%)	3/135 (2%)				
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)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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%)	3/135 (2%)				
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)
Skin abrasion						
North America	2/118 (2%)	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, 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)
Arthropod sting						
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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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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	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, p-value and interaction p-values are 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)
Rib fracture						
North America	2/118 (2%)	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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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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	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

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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	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)

Epicondylitis						
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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with the following variables: treatment, 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 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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	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. NC = Not Calculable. 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	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. NC =

Not Calculable. 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)
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.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ankle fracture						
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, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	1/ 44 (2%)	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

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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. NC = Not Calculable. 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)
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. NC =

Not Calculable. 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. NC = Not Calculable. 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)
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. NC = Not Calculable. 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)
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. NC = Not Calculable. 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. NC = Not Calculable. 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)
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. NC =

Not Calculable. 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)
Eye injury						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
Face 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), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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. NC = Not Calculable. 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)
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. NC = Not Calculable. 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)
Fractured coccyx						
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. NC = Not Calculable. 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)
Gastrointestinal procedural 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, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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 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. NC = Not Calculable. 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 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. NC = Not Calculable. 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)
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)

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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. NC = Not Calculable. 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: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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 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)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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. NC =

Not Calculable. 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), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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 arthritis						
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. 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 System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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)

(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)
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

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Wound						
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. 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 System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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	21/118 (18%)	26/135 (19%)				
Europe	24/165 (15%)	25/155 (16%)				
Rest of World	8/ 44 (18%)	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),

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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%)	13/135 (10%)				
Europe	6/165 (4%)	8/155 (5%)				
Rest of World	6/ 44 (14%)	0/ 37				
Anxiety						
North America	10/118 (8%)	6/135 (4%)				
Europe	10/165 (6%)	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. NC = Not Calculable. 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)
Depression						
North America	4/118 (3%)	3/135 (2%)				
Europe	1/165 (<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)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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	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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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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	1/118 (<1%)	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,

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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	1/118 (<1%)	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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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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	3/118 (3%)	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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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

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Not Calculable. 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)
Nightmare North America	0/118	3/135 (2%)				
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

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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	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. NC = Not Calculable. 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)
Panic attack						
North America	0/118	0/135				
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)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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	1/155 (<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. NC = Not Calculable. 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: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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	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)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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	1/118 (<1%)	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)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Attention deficit hyperactivity disorder						
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. NC = Not Calculable. 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)
Drug abuse						
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. NC = Not Calculable. 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)
Generalised anxiety disorder						
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. NC = Not Calculable. 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)
Irritability						
North America	1/118 (<1%)	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Restlessness						
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. NC = Not Calculable. 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)
Suicidal ideation						
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. NC =

Not Calculable. 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)
Acute 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)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative 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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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 System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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	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. NC = Not Calculable. 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)
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)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Alcohol withdrawal 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, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, 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 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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. NC =

Not Calculable. 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)
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. NC =

Not Calculable. 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)
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.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Psychotic 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. NC =

Not Calculable. 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)
Investigations						
Any Event						
North America	14/118 (12%)	15/135 (11%)	1.0769 (0.4965, 2.3358) /0.851	0.7533 (-7.1300, 8.6365) /0.851	1.0678 (0.5382, 2.1187) /0.851	0.041
Europe	6/165 (4%)	21/155 (14%)	0.2408 (0.0944, 0.6139) /0.003	-9.9120 (-16.0101, -3.8139) /0.001	0.2684 (0.1113, 0.6473) /0.003	
Rest of World	4/ 44 (9%)	5/ 37 (14%)	0.6400 (0.1587, 2.5812) /0.531	-4.4226 (-18.3329, 9.4877) /0.533	0.6727 (0.1947, 2.3246) /0.531	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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	4/118 (3%)	4/135 (3%)				
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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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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

(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)
Blood creatine phosphokinase increased						
North America	3/118 (3%)	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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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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	2/118 (2%)	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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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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	2/135 (1%)				
Europe	1/165 (<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, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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	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. 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 System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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	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

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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. 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 System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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	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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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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	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)
Low density lipoprotein increased						
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)

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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)
Aspartate aminotransferase increased						
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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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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	1/155 (<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)
Creatinine renal clearance decreased						
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)
Transaminases increased						
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)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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 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. NC = Not Calculable. 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: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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. NC = Not Calculable. 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)

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)

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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. NC = Not Calculable. 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.

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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)

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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. 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 System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Electrocardiogram abnormal						
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. NC = Not Calculable. 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)
Epstein-Barr virus 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. NC =

Not Calculable. 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)
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.

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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 decreased						
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. NC = Not Calculable. 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: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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

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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)
Haemoglobin decreased						
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)
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

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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)
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.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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,

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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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)
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)

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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)
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.

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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)
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. 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 System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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	4/118 (3%)	7/135 (5%)				
Europe	13/165 (8%)	18/155 (12%)				
Rest of World	1/ 44 (2%)	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),

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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%)	3/135 (2%)				
Europe	4/165 (2%)	9/155 (6%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, 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 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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	1/118 (<1%)	1/135 (<1%)				
Europe	2/165 (1%)	6/155 (4%)				
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), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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	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)
Fibrous histiocytoma						
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)

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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)
Adenoma benign						
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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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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 cancer						
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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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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%)	1/155 (<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)
Lipoma of breast						
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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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Adrenal adenoma						
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)
Benign neoplasm of thyroid gland						
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)
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

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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)
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)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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

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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 neoplasm						
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)
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

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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)
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

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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)

Reproductive system and breast disorders						
Any Event						
North America	9/118 (8%)	10/135 (7%)				
Europe	13/165 (8%)	10/155 (6%)				
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)

(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)
Erectile dysfunction						
North America	4/118 (3%)	3/135 (2%)				
Europe	2/165 (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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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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	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, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, 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 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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	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)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, 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 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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 lesion						
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, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms 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)
Menorrhagia						
North America	0/118	0/135				
Europe	0/165	2/155 (1%)				
Rest of World	1/ 44 (2%)	0/ 37				
Breast 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, p-value and interaction p-values are 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)
Cervical dysplasia						
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)
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

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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

(1) significant difference in occurrences between treatment arms 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)
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. NC = Not Calculable. 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)
Breast mass						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
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

(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)
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

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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 odour						
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. NC = Not Calculable. 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)
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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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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

(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)
Penile 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

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number 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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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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				
Penile 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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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Premenstrual 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, p-value and interaction p-values are 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)
Priapism						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
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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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sexual 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,

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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 swelling						
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. NC = Not Calculable. 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 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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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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

(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)
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

(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)
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

(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)

Vascular disorders						
Any Event						
North America	4/118 (3%)	7/135 (5%)				
Europe	13/165 (8%)	8/155 (5%)				
Rest of World	2/ 44 (5%)	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.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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	4/118 (3%)	5/135 (4%)				
Europe	7/165 (4%)	4/155 (3%)				
Rest of World	1/ 44 (2%)	2/ 37 (5%)				
Haematoma						
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. NC = Not Calculable. 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)
Varicose vein						
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, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative 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)
Flushing North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	1/ 44 (2%)	0/ 37				
Hot flush 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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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number 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: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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						
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)
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.

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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)
Phlebitis						
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)
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

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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 superficial						
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)
Renal and urinary disorders						
Any Event						
North America	3/118 (3%)	10/135 (7%)	0.3261 (0.0876, 1.2144) /0.095	-4.8650 (-10.1170, 0.3869) /0.069	0.3432 (0.0967, 1.2177) /0.098	0.742
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	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, p-value and interaction p-values are 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%)	2/135 (1%)				
Europe	1/165 (<1%)	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)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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	1/118 (<1%)	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, p-value and interaction p-values are 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)
Nocturia						
North America	0/118	1/135 (<1%)				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	1/ 44 (2%)	0/ 37				
Renal colic						
North America	0/118	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. 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 System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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	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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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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)

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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. 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 System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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	1/118 (<1%)	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Renal cyst						
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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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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 discharge						
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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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
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, p-value and interaction p-values are 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)

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)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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.

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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)
Urethral 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

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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)
Urinary incontinence						
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)
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)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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	12/118 (10%)	9/135 (7%)				
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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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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	2/118 (2%)	1/135 (<1%)				
Europe	1/165 (<1%)	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)
Vitamin D deficiency						
North America	3/118 (3%)	1/135 (<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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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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	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

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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	3/118 (3%)	0/135				
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	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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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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)

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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. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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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)
Alcoholic ketoacidosis						
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,

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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)
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)

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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)
Diabetes mellitus						
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. NC =

Not Calculable. 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)

Dyslipidaemi ^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. NC =

Not Calculable. 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)
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

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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,

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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

(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: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypertriglyceridaemia						
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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Not Calculable. 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)
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. NC = Not Calculable. 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						
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. NC =

Not Calculable. 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)

Eye disorders						
Any Event						
North America	7/118 (6%)	7/135 (5%)				
Europe	6/165 (4%)	11/155 (7%)				
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. NC = Not Calculable. 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: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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	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)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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	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, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative 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)
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)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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	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. NC = Not Calculable. 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)
Diplopia						
North America	1/118 (<1%)	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Dry eye						
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. NC = Not Calculable. 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)
Astigmatism						
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. NC = Not Calculable. 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)

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.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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 eyelids						
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. NC = Not Calculable. 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)
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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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, 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 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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/>						
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)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Macular 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

(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)
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

(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)
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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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)
Pterygium						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
Retinal tear						
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, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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)

(2) at least 1 level of the subgroup has number 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)
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

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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 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, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative 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)
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)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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	7/118 (6%)	9/135 (7%)				
Europe	2/165 (1%)	4/155 (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.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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	1/ 44 (2%)	1/ 37 (3%)				
Vertigo						
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, p-value and interaction p-values are 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)
Cerumen impaction						
North America	2/118 (2%)	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)
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)

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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. 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 System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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	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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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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	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)
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

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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 pruritus						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	1/ 37 (3%)				
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)

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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. 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 System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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. NC = Not Calculable. 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)

Immune system disorders						
Any Event						
North America	6/118 (5%)	2/135 (1%)				
Europe	7/165 (4%)	9/155 (6%)				
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)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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	5/118 (4%)	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)

(2) at least 1 level of the subgroup has number 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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Not Calculable. 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)
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,

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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)

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Not Calculable. 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)
Drug hypersensitivity						
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)
Allergy to arthropod bite						
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. NC = Not Calculable. 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)

Anaphylactic reaction						
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),

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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	6/118 (5%)	2/135 (1%)				
Europe	3/165 (2%)	9/155 (6%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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	2/118 (2%)	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),

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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	1/135 (<1%)				
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)

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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. NC = Not Calculable. 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: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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	1/118 (<1%)	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, 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)
Iron deficiency anaemia						
North America	0/118	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. 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 System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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.

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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)

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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)

Polycythaemi ^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)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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	2/118 (2%)	4/135 (3%)				
Europe	4/165 (2%)	5/155 (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

(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. NC = Not Calculable. 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: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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%)	1/155 (<1%)				
Rest of World	0/ 44	1/ 37 (3%)				
Tachycardia						
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, p-value and interaction p-values are 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)
Ventricular extrasystoles						
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. NC = Not Calculable. 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: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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

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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. NC = Not Calculable. 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)
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. NC = Not Calculable. 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)
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. NC = Not Calculable. 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)
Atrioventricular block first degree						
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. NC = Not Calculable. 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: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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. NC = Not Calculable. 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)

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. NC = Not Calculable. 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)
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. NC =

Not Calculable. 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)
Myocardial necrosis						
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. NC = Not Calculable. 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)
Sinus bradycardia						
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. NC =

Not Calculable. 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)
Wolff-Parkinson-White 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, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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	1/165 (<1%)	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)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. 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: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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. NC =

Not Calculable. 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)
Hepatic steatosis						
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. NC =

Not Calculable. 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)
Hepatocellular 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), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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. NC = Not Calculable. 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	Q8W (N=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	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. NC = Not Calculable. 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: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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),

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with the following variables: treatment, 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 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gilbert's 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. NC = Not Calculable. 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. NC = Not Calculable. 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)
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. NC = Not Calculable. 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: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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	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. NC = Not Calculable. 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: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Androgen deficiency						
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. NC =

Not Calculable. 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)
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. NC = Not Calculable. 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)

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. NC = Not Calculable. 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: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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. NC = Not Calculable. 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)
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. NC =

Not Calculable. 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)

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. NC = Not Calculable. 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: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=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. 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	Q8W (N=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	23/ 84 (27%)	29/ 98 (30%)	0.8971 (0.4699, 1.7127) /0.742	-2.2109 (-15.3487, 10.9269) /0.742	0.9253 (0.5823, 1.4704) /0.742	0.167
35 - <50	48/154 (31%)	53/143 (37%)	0.7690 (0.4753, 1.2440) /0.284	-5.8941 (-16.6727, 4.8845) /0.284	0.8410 (0.6123, 1.1550) /0.285	
>=50	30/ 89 (34%)	20/ 86 (23%)	1.6780 (0.8621, 3.2658) /0.128	10.4521 (-2.8209, 23.7250) /0.123	1.4494 (0.8951, 2.3470) /0.131	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

General disorders and administration site conditions						
Any Event						
<35	37/ 84 (44%)	39/ 98 (40%)	1.1909 (0.6596, 2.1504) /0.562	4.2517 (-10.1227, 18.6261) /0.562	1.1068 (0.7857, 1.5591) /0.561	0.887
35 - <50	76/154 (49%)	69/143 (48%)	1.0450 (0.6627, 1.6477) /0.850	1.0989 (-10.2777, 12.4755) /0.850	1.0228 (0.8100, 1.2915) /0.850	
>=50	46/ 89 (52%)	40/ 86 (47%)	1.2302 (0.6795, 2.2274) /0.494	5.1738 (-9.6219, 19.9694) /0.493	1.1112 (0.8209, 1.5043) /0.495	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Injection site pain <35	40/ 84 (48%)	39/ 98 (40%)	1.3753 (0.7631, 2.4786) /0.289	7.8231 (-6.5985, 22.2448) /0.288	1.1966 (0.8593, 1.6662) /0.288	0.751
35 - <50	74/154 (48%)	67/143 (47%)	1.0493 (0.6651, 1.6552) /0.836	1.1988 (-10.1660, 12.5636) /0.836	1.0256 (0.8070, 1.3033) /0.836	
>=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.

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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 nodule <35	10/ 84 (12%)	16/ 98 (16%)	0.6926 (0.2959, 1.6208) /0.397	-4.4218 (-14.4970, 5.6535) /0.390	0.7292 (0.3499, 1.5197) /0.399	0.557
35 - <50	15/154 (10%)	30/143 (21%)	0.4065 (0.2085, 0.7925) /0.008	-11.2388 (-19.3913, -3.0862) /0.007	0.4643 (0.2609, 0.8263) /0.009	
>=50	7/ 89 (8%)	16/ 86 (19%)	0.3735 (0.1453, 0.9596) /0.041	-10.7395 (-20.6854, -0.7936) /0.034	0.4228 (0.1830, 0.9766) /0.044	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Injection site induration <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	0.425
35 - <50	12/154 (8%)	15/143 (10%)	0.7211 (0.3254, 1.5982) /0.421	-2.6973 (-9.2658, 3.8712) /0.421	0.7429 (0.3601, 1.5325) /0.421	
>=50	5/ 89 (6%)	11/ 86 (13%)	0.4058 (0.1348, 1.2217) /0.109	-7.1727 (-15.6999, 1.3544) /0.099	0.4392 (0.1592, 1.2117) /0.112	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
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	0.327
35 - <50	12/154 (8%)	11/143 (8%)	1.0141 (0.4327, 2.3768) /0.974	0.0999 (-5.9826, 6.1824) /0.974	1.0130 (0.4617, 2.2227) /0.974	
>=50	6/ 89 (7%)	14/ 86 (16%)	0.3718 (0.1358, 1.0178) /0.054	-9.5375 (-18.9191, -0.1559) /0.046	0.4141 (0.1668, 1.0281) /0.057	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
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	0.872
35 - <50	8/154 (5%)	12/143 (8%)	0.5982 (0.2372, 1.5088) /0.276	-3.1968 (-8.9358, 2.5422) /0.275	0.6190 (0.2606, 1.4705) /0.277	
>=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.

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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)
Fatigue <35	3/ 84 (4%)	7/ 98 (7%)	0.4815 (0.1205, 1.9239) /0.301	-3.5714 (-10.0327, 2.8899) /0.279	0.5000 (0.1335, 1.8731) /0.304	0.970
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	2/ 89 (2%)	5/ 86 (6%)	0.3724 (0.0703, 1.9734) /0.246	-3.5668 (-9.3927, 2.2592) /0.230	0.3865 (0.0770, 1.9391) /0.248	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Injection site swelling <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	0.195
35 - <50	6/154 (4%)	11/143 (8%)	0.4865 (0.1751, 1.3519) /0.167	-3.7962 (-9.1267, 1.5343) /0.163	0.5065 (0.1923, 1.3339) /0.169	
>=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.

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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 pruritus <35	2/ 84 (2%)	6/ 98 (6%)	0.3740 (0.0734, 1.9045) /0.236	-3.7415 (-9.4999, 2.0169) /0.203	0.3889 (0.0806, 1.8759) /0.239	0.365
35 - <50	6/154 (4%)	9/143 (6%)	0.6036 (0.2093, 1.7407) /0.350	-2.3976 (-7.4159, 2.6207) /0.349	0.6190 (0.2260, 1.6956) /0.351	
>=50	1/ 89 (1%)	7/ 86 (8%)	0.1282 (0.0154, 1.0654) /0.057	-7.0159 (-13.1960, -0.8358) /0.026	0.1380 (0.0173, 1.0986) /0.061	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
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	0.713
35 - <50	8/154 (5%)	9/143 (6%)	0.8158 (0.3059, 2.1755) /0.684	-1.0989 (-6.4025, 4.2047) /0.685	0.8254 (0.3274, 2.0811) /0.684	
>=50	2/ 89 (2%)	2/ 86 (2%)	0.9655 (0.1329, 7.0123) /0.972	-0.0784 (-4.5087, 4.3519) /0.972	0.9663 (0.1392, 6.7069) /0.972	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Influenza like illness <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	0.261
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	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.

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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)
Asthenia <35	1/ 84 (1%)	2/ 98 (2%)	0.5783 (0.0515, 6.4930) /0.657	-0.8503 (-4.4857, 2.7850) /0.647	0.5833 (0.0538, 6.3199) /0.657	0.426
35 - <50	6/154 (4%)	5/143 (3%)	1.1189 (0.3339, 3.7495) /0.855	0.3996 (-3.8904, 4.6896) /0.855	1.1143 (0.3476, 3.5715) /0.856	
>=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.

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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)
Chills <35	2/ 84 (2%)	0/ 98	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.200
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.

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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 bruising						
<35	2/ 84 (2%)	3/ 98 (3%)				
35 - <50	6/154 (4%)	2/143 (1%)				
>=50	2/ 89 (2%)	3/ 86 (3%)				
Pain						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	5/154 (3%)	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. 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)
Malaise						
<35	1/ 84 (1%)	3/ 98 (3%)				
35 - <50	3/154 (2%)	2/143 (1%)				
>=50	1/ 89 (1%)	2/ 86 (2%)				
Injection site haematoma						
<35	0/ 84	4/ 98 (4%)				
35 - <50	0/154	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. 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)
Discomfort <35	1/ 84 (1%)	2/ 98 (2%)				
35 - <50	3/154 (2%)	0/143				
>=50	1/ 89 (1%)	2/ 86 (2%)				
Injection site reaction <35	0/ 84	2/ 98 (2%)				
35 - <50	3/154 (2%)	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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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	2/ 84 (2%)	0/ 98				
35 - <50	1/154 (<1%)	3/143 (2%)				
>=50	0/ 89	0/ 86				
Chest pain						
<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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Injection site anaesthesia						
<35	2/ 84 (2%)	1/ 98 (1%)				
35 - <50	1/154 (<1%)	0/143				
>=50	1/ 89 (1%)	0/ 86				
Feeling hot						
<35	0/ 84	0/ 98				
35 - <50	2/154 (1%)	0/143				
>=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)

Nodule						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	3/143 (2%)				
>=50	0/ 89	0/ 86				
Cyst						
<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. 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)

Injection site discolouration						
<35	0/ 84	0/ 98				
35 - <50	0/154	2/143 (1%)				
>=50	0/ 89	0/ 86				
Injection site haemorrhage						
<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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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				
Mass						
<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. 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)

Peripheral swelling						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	1/ 86 (1%)				
Temperature regulation disorder						
<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. 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)

Vaccination site pain						
<35	0/ 84	0/ 98				
35 - <50	0/154	2/143 (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. 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)

Adverse drug reaction						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Chest discomfort						
<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= 1

System Organ Class Preferred Term	Q8W (N=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						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Enanthema						
<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)

Feeling abnormal						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Gait disturbance						
<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)

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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Injection site hypoaesthesia						
<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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Injection site rash						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
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%)				
Sensation of foreign body						
<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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
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. 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)

Thirst						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
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. 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)

Infections and infestations						
Any Event						
<35	27/ 84 (32%)	37/ 98 (38%)	0.7809 (0.4228, 1.4424) /0.430	-5.6122 (-19.4638, 8.2393) /0.427	0.8514 (0.5698, 1.2719) /0.432	0.651
35 - <50	52/154 (34%)	59/143 (41%)	0.7258 (0.4529, 1.1631) /0.183	-7.4925 (-18.4877, 3.5026) /0.182	0.8184 (0.6092, 1.0995) /0.183	
>=50	32/ 89 (36%)	30/ 86 (35%)	1.0480 (0.5639, 1.9476) /0.882	1.0713 (-13.1010, 15.2437) /0.882	1.0307 (0.6907, 1.5381) /0.882	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Nasopharyngitis						
<35	8/ 84 (10%)	10/ 98 (10%)	0.9263 (0.3480, 2.4658) /0.878	-0.6803 (-9.3592, 7.9986) /0.878	0.9333 (0.3860, 2.2566) /0.878	0.408
35 - <50	18/154 (12%)	28/143 (20%)	0.5436 (0.2860, 1.0331) /0.063	-7.8921 (-16.1413, 0.3570) /0.061	0.5969 (0.3456, 1.0312) /0.064	
>=50	15/ 89 (17%)	14/ 86 (16%)	1.0425 (0.4697, 2.3139) /0.919	0.5749 (-10.4416, 11.5914) /0.919	1.0353 (0.5323, 2.0138) /0.919	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Upper respiratory tract infection <35	5/ 84 (6%)	14/ 98 (14%)	0.3797 (0.1307, 1.1030) /0.075	-8.3333 (-16.9123, 0.2457) /0.057	0.4167 (0.1566, 1.1087) /0.080	0.259
35 - <50	18/154 (12%)	16/143 (11%)	1.0506 (0.5136, 2.1487) /0.893	0.4995 (-6.7422, 7.7412) /0.892	1.0446 (0.5543, 1.9689) /0.893	
>=50	8/ 89 (9%)	12/ 86 (14%)	0.6091 (0.2359, 1.5725) /0.306	-4.9647 (-14.3956, 4.4661) /0.302	0.6442 (0.2770, 1.4983) /0.307	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
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	0.916
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.

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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)
Syphilis <35	5/ 84 (6%)	9/ 98 (9%)	0.6259 (0.2013, 1.9461) /0.418	-3.2313 (-10.8663, 4.4037) /0.407	0.6481 (0.2260, 1.8590) /0.420	0.300
35 - <50	5/154 (3%)	3/143 (2%)	1.5660 (0.3674, 6.6749) /0.544	1.1489 (-2.5054, 4.8031) /0.538	1.5476 (0.3767, 6.3589) /0.545	
>=50	1/ 89 (1%)	0/ 86	>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. 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)
<hr/>						
Pharyngitis						
<35	2/ 84 (2%)	5/ 98 (5%)				
35 - <50	5/154 (3%)	3/143 (2%)				
>=50	1/ 89 (1%)	4/ 86 (5%)				
Gonorrhoea						
<35	8/ 84 (10%)	5/ 98 (5%)	1.9579 (0.6152, 6.2314) /0.255	4.4218 (-3.2192, 12.0628) /0.257	1.8667 (0.6348, 5.4895) /0.257	0.775
35 - <50	3/154 (2%)	3/143 (2%)	0.9272 (0.1841, 4.6697) /0.927	-0.1499 (-3.3564, 3.0567) /0.927	0.9286 (0.1905, 4.5264) /0.927	
>=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	5/ 84 (6%)	0/ 98				
35 - <50	6/154 (4%)	3/143 (2%)				
>=50	2/ 89 (2%)	3/ 86 (3%)				
Bronchitis						
<35	1/ 84 (1%)	2/ 98 (2%)				
35 - <50	4/154 (3%)	5/143 (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.

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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)

Sinusitis						
<35	1/ 84 (1%)	3/ 98 (3%)				
35 - <50	2/154 (1%)	4/143 (3%)				
>=50	2/ 89 (2%)	2/ 86 (2%)				
Chlamydial infection						
<35	5/ 84 (6%)	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.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Conjunctivitis						
<35	0/ 84	4/ 98 (4%)				
35 - <50	4/154 (3%)	2/143 (1%)				
>=50	1/ 89 (1%)	2/ 86 (2%)				
Rhinitis						
<35	2/ 84 (2%)	0/ 98				
35 - <50	1/154 (<1%)	7/143 (5%)				
>=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.

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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%)	1/ 98 (1%)				
35 - <50	2/154 (1%)	5/143 (3%)				
>=50	0/ 89	2/ 86 (2%)				
Respiratory tract infection						
<35	2/ 84 (2%)	2/ 98 (2%)				
35 - <50	4/154 (3%)	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.

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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)

Folliculitis						
<35	1/ 84 (1%)	2/ 98 (2%)				
35 - <50	2/154 (1%)	5/143 (3%)				
>=50	1/ 89 (1%)	0/ 86				
Oral herpes						
<35	0/ 84	3/ 98 (3%)				
35 - <50	2/154 (1%)	3/143 (2%)				
>=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. 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)

Respiratory tract infection viral						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	2/154 (1%)	6/143 (4%)				
>=50	1/ 89 (1%)	0/ 86				
Urethritis						
<35	1/ 84 (1%)	2/ 98 (2%)				
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.

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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)

Urinary tract infection						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	1/154 (<1%)	2/143 (1%)				
>=50	3/ 89 (3%)	2/ 86 (2%)				
Tonsillitis						
<35	0/ 84	4/ 98 (4%)				
35 - <50	2/154 (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.

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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 upper respiratory tract infection						
<35	0/ 84	3/ 98 (3%)				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	1/ 89 (1%)	2/ 86 (2%)				
Gastroenteritis viral						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	3/143 (2%)				
>=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.

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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)
Onychomycosis						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	5/143 (3%)				
>=50	1/ 89 (1%)	0/ 86				
Proctitis gonococcal						
<35	0/ 84	2/ 98 (2%)				
35 - <50	2/154 (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)

Tooth abscess						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	1/ 89 (1%)	4/ 86 (5%)				
Anal chlamydia infection						
<35	3/ 84 (4%)	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. 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)
Ear infection						
<35	0/ 84	1/ 98 (1%)				
35 - <50	1/154 (<1%)	2/143 (1%)				
>=50	1/ 89 (1%)	1/ 86 (1%)				
Fungal skin infection						
<35	0/ 84	1/ 98 (1%)				
35 - <50	2/154 (1%)	0/143				
>=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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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	2/154 (1%)	1/143 (<1%)				
>=50	0/ 89	2/ 86 (2%)				
Herpes simplex						
<35	1/ 84 (1%)	1/ 98 (1%)				
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. 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	1/154 (<1%)	2/143 (1%)				
>=50	0/ 89	0/ 86				
Herpes zoster						
<35	1/ 84 (1%)	1/ 98 (1%)				
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.

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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)

Hordeolum						
<35	1/ 84 (1%)	3/ 98 (3%)				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Lower respiratory tract infection						
<35	1/ 84 (1%)	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	3/ 89 (3%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Oropharyngeal gonococcal infection						
<35	1/ 84 (1%)	0/ 98				
35 - <50	1/154 (<1%)	2/143 (1%)				
>=50	1/ 89 (1%)	0/ 86				
Tooth infection						
<35	0/ 84	2/ 98 (2%)				
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.

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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)

Furuncle						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	1/154 (<1%)	0/143				
>=50	1/ 89 (1%)	0/ 86				
Otitis externa						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	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)

Acarodermatitis						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	0/154	1/143 (<1%)				
>=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 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)

Diverticulitis						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	2/ 86 (2%)				
Helicobacter infection						
<35	0/ 84	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. 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)

Secondary syphilis						
<35	0/ 84	0/ 98				
35 - <50	0/154	2/143 (1%)				
>=50	1/ 89 (1%)	0/ 86				
Tinea cruris						
<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. 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)

Tinea infection						
<35	0/ 84	0/ 98				
35 - <50	0/154	2/143 (1%)				
>=50	0/ 89	1/ 86 (1%)				
Urethritis gonococcal						
<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.

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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 infection						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Viral pharyngitis						
<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. 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)
Cellulitis						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	2/ 86 (2%)				
Chronic sinusitis						
<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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Enteritis infectious						
<35	1/ 84 (1%)	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=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. 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)

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. 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)

Oral candidiasis						
<35	0/ 84	2/ 98 (2%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Otitis media						
<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.

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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)

Paronychia						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Pneumonia						
<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.

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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)

Postoperative wound infection						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	1/ 86 (1%)				
Primary syphilis						
<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.

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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 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. 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)

Tinea pedis						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Tracheitis						
<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)

Urethritis chlamydial						
<35	2/ 84 (2%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Abscess limb						
<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)

Acute sinusitis						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
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. 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)

Borrelia infection						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Candida infection						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Cellulitis of male external genital organ						
<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)

Conjunctivitis viral						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Cystitis						
<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)

Diarrhoea infectious						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	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. 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)
Epididymitis						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Escherichia urinary tract infection						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Eye infection						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	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. 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)

Gastrointestinal infection						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Genital herpes						
<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)

Genital herpes simplex						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Giardiasis						
<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= 1

System Organ Class Preferred Term	Q8W (N=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. 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)

Hepatitis C						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Hepatitis E						
<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)

Infectious mononucleosis						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Injection site 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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
<hr/>						
Labyrinthitis						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Laryngitis						
<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)

Localised infection						
<35	0/ 84	1/ 98 (1%)				
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

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. 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)

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. 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)

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. 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)

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. 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)

Pharyngotonsillitis						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Proctitis mycoplasmal						
<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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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Rectal abscess						
<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)

Schistosomiasis cutaneous						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Sexually transmitted 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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Staphylococcal skin infection						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Subcutaneous 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. 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)

Syphilis genital						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Tinea capitis						
<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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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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.

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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)

Ureaplasma infection						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Urethritis mycoplasmal						
<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)

Varicella						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

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. 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)

Gastrointestinal disorders						
Any Event						
<35	23/ 84 (27%)	18/ 98 (18%)	1.6758 (0.8313, 3.3780) /0.149	9.0136 (-3.2218, 21.2490) /0.149	1.4907 (0.8656, 2.5674) /0.150	0.064
35 - <50	24/154 (16%)	35/143 (24%)	0.5697 (0.3194, 1.0162) /0.057	-8.8911 (-17.9726, 0.1904) /0.055	0.6367 (0.3992, 1.0156) /0.058	
>=50	20/ 89 (22%)	21/ 86 (24%)	0.8972 (0.4456, 1.8064) /0.761	-1.9467 (-14.5021, 10.6087) /0.761	0.9203 (0.5385, 1.5727) /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.

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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	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	0.087
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	4/ 89 (4%)	8/ 86 (9%)	0.4588 (0.1329, 1.5838) /0.218	-4.8079 (-12.3055, 2.6896) /0.209	0.4831 (0.1510, 1.5459) /0.220	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
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	0.093
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	2/ 89 (2%)	2/ 86 (2%)	0.9655 (0.1329, 7.0123) /0.972	-0.0784 (-4.5087, 4.3519) /0.972	0.9663 (0.1392, 6.7069) /0.972	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Constipation <35	0/ 84	2/ 98 (2%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.587
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	1/ 89 (1%)	3/ 86 (3%)	0.3144 (0.0321, 3.0828) /0.321	-2.3648 (-6.8183, 2.0887) /0.298	0.3221 (0.0342, 3.0367) /0.322	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Dyspepsia						
<35	1/ 84 (1%)	0/ 98				
35 - <50	3/154 (2%)	5/143 (3%)				
>=50	3/ 89 (3%)	3/ 86 (3%)				
Haemorrhoids						
<35	0/ 84	5/ 98 (5%)				
35 - <50	1/154 (<1%)	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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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	3/ 84 (4%)	1/ 98 (1%)				
35 - <50	2/154 (1%)	2/143 (1%)				
>=50	1/ 89 (1%)	3/ 86 (3%)				
Abdominal distension						
<35	3/ 84 (4%)	0/ 98				
35 - <50	2/154 (1%)	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. 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)

Toothache						
<35	1/ 84 (1%)	3/ 98 (3%)				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	4/ 89 (4%)	0/ 86				
Abdominal pain upper						
<35	1/ 84 (1%)	2/ 98 (2%)				
35 - <50	1/154 (<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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Gastrooesophageal reflux disease						
<35	3/ 84 (4%)	0/ 98				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	1/ 89 (1%)	1/ 86 (1%)				
Rectal haemorrhage						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	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. 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 discomfort						
<35	0/ 84	1/ 98 (1%)				
35 - <50	2/154 (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. 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)

Anogenital dysplasia						
<35	1/ 84 (1%)	0/ 98				
35 - <50	1/154 (<1%)	2/143 (1%)				
>=50	0/ 89	1/ 86 (1%)				
Dental caries						
<35	1/ 84 (1%)	0/ 98				
35 - <50	1/154 (<1%)	3/143 (2%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Flatulence						
<35	0/ 84	1/ 98 (1%)				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	1/ 89 (1%)	1/ 86 (1%)				
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Food poisoning						
<35	2/ 84 (2%)	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	1/ 89 (1%)	0/ 86				
Gastritis						
<35	0/ 84	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. 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)

Haematochezia						
<35	1/ 84 (1%)	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	1/ 89 (1%)	1/ 86 (1%)				
Hiatus hernia						
<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.

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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)
Proctalgia						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	1/ 89 (1%)	0/ 86				
Rectal discharge						
<35	2/ 84 (2%)	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)

Anal fissure						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	1/ 86 (1%)				
Anal pruritus						
<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. 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)

Diverticulum intestinal						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	1/ 86 (1%)				
Dry mouth						
<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.

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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 pain						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Inguinal hernia						
<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.

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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)

Irritable bowel syndrome						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Mouth ulceration						
<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.

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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				
Oesophagitis						
<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.

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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 hernia						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Abdominal tenderness						
<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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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Anal ulcer						
<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)

Angular cheilitis						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Anorectal 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= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Chapped lips						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Cheilitis						
<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= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dysphagia						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Enteritis						
<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= 1

System Organ Class Preferred Term	Q8W (N=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				
Faeces soft						
<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)

Gastric disorder						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Gastric ulcer						
<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)

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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Haematemesis						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Hypoaesthesia oral						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Large intestine polyp						
<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)
Oral disorder						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Oral lichen planus						
<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= 1

System Organ Class Preferred Term	Q8W (N=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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Proctitis						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Rectal tenesmus						
<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)

Salivary gland mucocoele						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
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. 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)

Musculoskeletal and connective tissue disorders						
Any Event						
<35	10/ 84 (12%)	16/ 98 (16%)	0.6926 (0.2959, 1.6208) /0.397	-4.4218 (-14.4970, 5.6535) /0.390	0.7292 (0.3499, 1.5197) /0.399	0.943
35 - <50	28/154 (18%)	31/143 (22%)	0.8029 (0.4536, 1.4209) /0.451	-3.4965 (-12.5915, 5.5985) /0.451	0.8387 (0.5308, 1.3253) /0.451	
>=50	20/ 89 (22%)	23/ 86 (27%)	0.7940 (0.3983, 1.5825) /0.512	-4.2723 (-17.0281, 8.4835) /0.512	0.8403 (0.4991, 1.4145) /0.512	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Back pain <35	3/ 84 (4%)	4/ 98 (4%)	0.8704 (0.1892, 4.0041) /0.858	-0.5102 (-6.0866, 5.0662) /0.858	0.8750 (0.2015, 3.7991) /0.859	0.764
35 - <50	14/154 (9%)	15/143 (10%)	0.8533 (0.3964, 1.8371) /0.685	-1.3986 (-8.1690, 5.3718) /0.686	0.8667 (0.4339, 1.7311) /0.685	
>=50	6/ 89 (7%)	4/ 86 (5%)	1.4819 (0.4033, 5.4454) /0.554	2.0904 (-4.7613, 8.9421) /0.550	1.4494 (0.4237, 4.9586) /0.554	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Arthralgia <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	0.486
35 - <50	5/154 (3%)	3/143 (2%)	1.5660 (0.3674, 6.6749) /0.544	1.1489 (-2.5054, 4.8031) /0.538	1.5476 (0.3767, 6.3589) /0.545	
>=50	7/ 89 (8%)	10/ 86 (12%)	0.6488 (0.2351, 1.7903) /0.403	-3.7627 (-12.5478, 5.0224) /0.401	0.6764 (0.2698, 1.6961) /0.405	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Pain in extremity <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	0.665
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	3/ 89 (3%)	5/ 86 (6%)	0.5651 (0.1308, 2.4411) /0.445	-2.4432 (-8.6495, 3.7632) /0.440	0.5798 (0.1429, 2.3519) /0.445	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Myalgia						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	5/154 (3%)	3/143 (2%)				
>=50	2/ 89 (2%)	2/ 86 (2%)				
Musculoskeletal pain						
<35	0/ 84	3/ 98 (3%)				
35 - <50	1/154 (<1%)	1/143 (<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.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
<hr/>						
Tendonitis						
<35	1/ 84 (1%)	0/ 98				
35 - <50	3/154 (2%)	0/143				
>=50	2/ 89 (2%)	1/ 86 (1%)				
Muscle spasms						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	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. 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)
Muscle contracture						
<35	0/ 84	2/ 98 (2%)				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	1/ 89 (1%)	0/ 86				
Musculoskeletal chest pain						
<35	1/ 84 (1%)	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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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	3/ 86 (3%)				
Intervertebral disc protrusion						
<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. 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)

Neck pain						
<35	1/ 84 (1%)	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	1/ 89 (1%)	0/ 86				
Bursitis						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=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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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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	1/154 (<1%)	0/143				
>=50	1/ 89 (1%)	0/ 86				
Joint contracture						
<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)

Joint swelling						
<35	0/ 84	1/ 98 (1%)				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Musculoskeletal stiffness						
<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)

Arthritis						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Arthropathy						
<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)

Cervical spinal stenosis						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Exostosis						
<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)

Femoroacetabular impingement						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Groin 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. 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)

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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 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. 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)
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. 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)
Myosclerosis						
<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. 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)
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	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)

Plantar fasciitis						
<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. 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)

Sacroiliitis						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Scoliosis						
<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)

Spinal disorder						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Synovial 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. 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)

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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
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. 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)

Skin and subcutaneous tissue disorders						
Any Event						
<35	13/ 84 (15%)	18/ 98 (18%)	0.8138 (0.3724, 1.7782) /0.605	-2.8912 (-13.7813, 7.9990) /0.603	0.8426 (0.4394, 1.6159) /0.606	0.988
35 - <50	22/154 (14%)	25/143 (17%)	0.7867 (0.4213, 1.4689) /0.451	-3.1968 (-11.5213, 5.1277) /0.452	0.8171 (0.4830, 1.3824) /0.452	
>=50	18/ 89 (20%)	20/ 86 (23%)	0.8366 (0.4074, 1.7181) /0.627	-3.0311 (-15.2524, 9.1902) /0.627	0.8697 (0.4950, 1.5280) /0.627	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Pruritus						
<35	3/ 84 (4%)	1/ 98 (1%)				
35 - <50	2/154 (1%)	3/143 (2%)				
>=50	4/ 89 (4%)	5/ 86 (6%)				
Rash						
<35	3/ 84 (4%)	5/ 98 (5%)				
35 - <50	3/154 (2%)	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. 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)

Eczema						
<35	2/ 84 (2%)	1/ 98 (1%)				
35 - <50	1/154 (<1%)	4/143 (3%)				
>=50	2/ 89 (2%)	6/ 86 (7%)				
Acne						
<35	0/ 84	3/ 98 (3%)				
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. 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)

Alopecia						
<35	0/ 84	1/ 98 (1%)				
35 - <50	2/154 (1%)	0/143				
>=50	4/ 89 (4%)	0/ 86				
Dermatitis						
<35	1/ 84 (1%)	2/ 98 (2%)				
35 - <50	2/154 (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.

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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)
<hr/>						
Skin lesion						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	2/154 (1%)	0/143				
>=50	1/ 89 (1%)	2/ 86 (2%)				
Dermatitis contact						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	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. 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)

Seborrhoeic dermatitis						
<35	0/ 84	0/ 98				
35 - <50	0/154	4/143 (3%)				
>=50	1/ 89 (1%)	0/ 86				
Hyperhidrosis						
<35	0/ 84	0/ 98				
35 - <50	0/154	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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	1/ 86 (1%)				
Dry skin						
<35	0/ 84	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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Erythema						
<35	0/ 84	0/ 98				
35 - <50	0/154	2/143 (1%)				
>=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.

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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 exfoliation						
<35	0/ 84	3/ 98 (3%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Skin mass						
<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.

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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)
Urticaria						
<35	0/ 84	0/ 98				
35 - <50	2/154 (1%)	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Actinic keratosis						
<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. 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)

Chloasma						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Dermal cyst						
<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 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= 1

System Organ Class Preferred Term	Q8W (N=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						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Psoriasis						
<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.

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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)

Rash erythematous						
<35	0/ 84	2/ 98 (2%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Rash papular						
<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. 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)
Actinic elastosis						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Androgenetic alopecia						
<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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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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				
Dermatosis						
<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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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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. 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)

Eczema asteatotic						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Hyperkeratosis						
<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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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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. 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)
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. 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)

Nail bed bleeding						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Penile ulceration						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Petechiae						
<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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Pityriasis						
<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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Prurigo						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Purpura						
<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)
Rash macular						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
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. 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)

Skin discolouration						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Skin hypertrophy						
<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= 1

System Organ Class Preferred Term	Q8W (N=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						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Skin ulcer						
<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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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				
Solar lentigo						
<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)

Respiratory, thoracic and mediastinal disorders						
Any Event						
<35	11/ 84 (13%)	14/ 98 (14%)	0.9041 (0.3866, 2.1146) /0.816	-1.1905 (-11.1926, 8.8117) /0.816	0.9167 (0.4400, 1.9097) /0.816	0.276
35 - <50	13/154 (8%)	25/143 (17%)	0.4352 (0.2132, 0.8882) /0.022	-9.0410 (-16.6589, -1.4230) /0.020	0.4829 (0.2571, 0.9069) /0.024	
>=50	16/ 89 (18%)	17/ 86 (20%)	0.8896 (0.4169, 1.8982) /0.762	-1.7899 (-13.3869, 9.8070) /0.762	0.9095 (0.4917, 1.6822) /0.762	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Cough <35	5/ 84 (6%)	5/ 98 (5%)	1.1772 (0.3288, 4.2144) /0.802	0.8503 (-5.8265, 7.5272) /0.803	1.1667 (0.3497, 3.8923) /0.802	0.055
35 - <50	3/154 (2%)	12/143 (8%)	0.2169 (0.0599, 0.7852) /0.020	-6.4436 (-11.4849, -1.4022) /0.012	0.2321 (0.0669, 0.8058) /0.021	
>=50	8/ 89 (9%)	6/ 86 (7%)	1.3169 (0.4372, 3.9667) /0.625	2.0120 (-6.0067, 10.0307) /0.623	1.2884 (0.4664, 3.5593) /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. 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)
Oropharyngeal pain						
<35	1/ 84 (1%)	4/ 98 (4%)	0.2831 (0.0310, 2.5838) /0.263	-2.8912 (-7.4437, 1.6614) /0.213	0.2917 (0.0332, 2.5592) /0.266	0.234
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	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. 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)

Nasal congestion						
<35	2/ 84 (2%)	3/ 98 (3%)				
35 - <50	1/154 (<1%)	4/143 (3%)				
>=50	1/ 89 (1%)	1/ 86 (1%)				
Rhinitis allergic						
<35	1/ 84 (1%)	2/ 98 (2%)				
35 - <50	2/154 (1%)	2/143 (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. 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)

Sinus congestion						
<35	2/ 84 (2%)	2/ 98 (2%)				
35 - <50	0/154	4/143 (3%)				
>=50	0/ 89	1/ 86 (1%)				
Epistaxis						
<35	1/ 84 (1%)	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. 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)
Rhinorrhoea						
<35	0/ 84	1/ 98 (1%)				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	0/ 89	1/ 86 (1%)				
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. 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)
Dyspnoea						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	2/ 89 (2%)	0/ 86				
Sleep apnoea syndrome						
<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. 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)

Catarrh						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Oropharyngeal discomfort						
<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.

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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)
Productive cough						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Respiratory disorder						
<35	0/ 84	0/ 98				
35 - <50	0/154	2/143 (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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Dry throat						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Emphysema						
<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)

Haemoptysis						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Nasal discomfort						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

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. 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)

Pharyngeal erythema						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Pleuritic 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. 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)

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. 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	Q8W (N=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%)	16/ 98 (16%)	0.7723 (0.3368, 1.7709) /0.542	-3.2313 (-13.5072, 7.0446) /0.538	0.8021 (0.3943, 1.6318) /0.543	0.814
35 - <50	25/154 (16%)	22/143 (15%)	1.0659 (0.5709, 1.9900) /0.841	0.8492 (-7.4509, 9.1492) /0.841	1.0552 (0.6237, 1.7852) /0.841	
>=50	9/ 89 (10%)	10/ 86 (12%)	0.8550 (0.3294, 2.2190) /0.747	-1.5155 (-10.7423, 7.7113) /0.748	0.8697 (0.3716, 2.0355) /0.748	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Headache <35	3/ 84 (4%)	4/ 98 (4%)	0.8704 (0.1892, 4.0041) /0.858	-0.5102 (-6.0866, 5.0662) /0.858	0.8750 (0.2015, 3.7991) /0.859	0.938
35 - <50	16/154 (10%)	13/143 (9%)	1.1594 (0.5368, 2.5042) /0.707	1.2987 (-5.4411, 8.0385) /0.706	1.1429 (0.5701, 2.2912) /0.707	
>=50	4/ 89 (4%)	4/ 86 (5%)	0.9647 (0.2335, 3.9860) /0.960	-0.1568 (-6.3484, 6.0349) /0.960	0.9663 (0.2495, 3.7418) /0.960	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Dizziness <35	6/ 84 (7%)	5/ 98 (5%)	1.4308 (0.4206, 4.8675) /0.566	2.0408 (-4.9814, 9.0630) /0.569	1.4000 (0.4431, 4.4236) /0.566	0.966
35 - <50	7/154 (5%)	4/143 (3%)	1.6548 (0.4740, 5.7766) /0.430	1.7483 (-2.5093, 6.0058) /0.421	1.6250 (0.4859, 5.4342) /0.431	
>=50	2/ 89 (2%)	1/ 86 (1%)	1.9540 (0.1739, 21.9526) /0.587	1.0844 (-2.7386, 4.9074) /0.578	1.9326 (0.1785, 20.9251) /0.588	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Presyncope						
<35	1/ 84 (1%)	3/ 98 (3%)				
35 - <50	2/154 (1%)	1/143 (<1%)				
>=50	0/ 89	2/ 86 (2%)				
Paraesthesia						
<35	0/ 84	0/ 98				
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. 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)
Migraine						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	4/143 (3%)				
>=50	0/ 89	0/ 86				
Somnolence						
<35	2/ 84 (2%)	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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Hypoaesthesia						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	1/154 (<1%)	0/143				
>=50	1/ 89 (1%)	0/ 86				
Lethargy						
<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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Carpal tunnel syndrome						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	1/ 89 (1%)	0/ 86				
Sciatica						
<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.

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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)
-----	-----	-----	-----	-----	-----	-----
Syncope						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	1/ 86 (1%)				
Tension 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.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Agnosia						
<35	0/ 84	0/ 98				
35 - <50	0/154	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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Ataxia						
<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.

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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)

Cervical radiculopathy						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Dysarthria						
<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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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Head 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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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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						
<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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Memory impairment						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Periodic limb movement disorder						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Polyneuropathy						
<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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tremor						
<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= 1

System Organ Class Preferred Term	Q8W (N=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	7/ 84 (8%)	12/ 98 (12%)	0.6515 (0.2441, 1.7386) /0.392	-3.9116 (-12.6897, 4.8665) /0.382	0.6806 (0.2808, 1.6497) /0.394	0.232
35 - <50	8/154 (5%)	23/143 (16%)	0.2859 (0.1234, 0.6622) /0.003	-10.8891 (-17.8564, -3.9219) /0.002	0.3230 (0.1493, 0.6987) /0.004	
>=50	11/ 89 (12%)	14/ 86 (16%)	0.7253 (0.3093, 1.7006) /0.460	-3.9195 (-14.2941, 6.4550) /0.459	0.7592 (0.3652, 1.5786) /0.461	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Contusion						
<35	0/ 84	1/ 98 (1%)				
35 - <50	4/154 (3%)	4/143 (3%)				
>=50	0/ 89	3/ 86 (3%)				
Arthropod bite						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	0/154	5/143 (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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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	2/ 84 (2%)	1/ 98 (1%)				
35 - <50	0/154	5/143 (3%)				
>=50	1/ 89 (1%)	1/ 86 (1%)				
Muscle strain						
<35	0/ 84	0/ 98				
35 - <50	0/154	5/143 (3%)				
>=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.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Limb injury						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	2/154 (1%)	1/143 (<1%)				
>=50	2/ 89 (2%)	1/ 86 (1%)				
Exposure to communicable disease						
<35	1/ 84 (1%)	4/ 98 (4%)				
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)

Skin laceration						
<35	0/ 84	3/ 98 (3%)				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	1/ 86 (1%)				
Bone contusion						
<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. 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)
Foot fracture						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	2/143 (1%)				
>=50	0/ 89	0/ 86				
Procedural pain						
<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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Skin abrasion						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	1/ 86 (1%)				
Vaccination complication						
<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. 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)
Animal bite						
<35	0/ 84	0/ 98				
35 - <50	0/154	2/143 (1%)				
>=50	0/ 89	0/ 86				
Arthropod sting						
<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. 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)

Epicondylitis						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Heat stroke						
<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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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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				
Eye 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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Fall						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Hand 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. 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)
Head injury						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
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. 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)

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. 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)
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. 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)
Rib fracture						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
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. 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)

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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Wound						
<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= 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						
<35	8/ 84 (10%)	10/ 98 (10%)	0.9263 (0.3480, 2.4658) /0.878	-0.6803 (-9.3592, 7.9986) /0.878	0.9333 (0.3860, 2.2566) /0.878	0.547
35 - <50	21/154 (14%)	17/143 (12%)	1.1703 (0.5903, 2.3199) /0.652	1.7483 (-5.8357, 9.3322) /0.651	1.1471 (0.6311, 2.0850) /0.653	
>=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.

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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)
Insomnia <35	3/ 84 (4%)	4/ 98 (4%)	0.8704 (0.1892, 4.0041) /0.858	-0.5102 (-6.0866, 5.0662) /0.858	0.8750 (0.2015, 3.7991) /0.859	0.216
35 - <50	6/154 (4%)	11/143 (8%)	0.4865 (0.1751, 1.3519) /0.167	-3.7962 (-9.1267, 1.5343) /0.163	0.5065 (0.1923, 1.3339) /0.169	
>=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. 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)
Anxiety						
<35	2/ 84 (2%)	3/ 98 (3%)				
35 - <50	5/154 (3%)	3/143 (2%)				
>=50	3/ 89 (3%)	0/ 86				
Abnormal dreams						
<35	1/ 84 (1%)	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	1/ 84 (1%)	0/ 98				
35 - <50	2/154 (1%)	1/143 (<1%)				
>=50	1/ 89 (1%)	0/ 86				
Libido decreased						
<35	1/ 84 (1%)	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. 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)
Sleep disorder						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	3/ 86 (3%)				
Depression						
<35	1/ 84 (1%)	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. 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)
Nightmare						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	2/ 86 (2%)				
Stress						
<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	Q8W (N=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	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.

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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	1/ 84 (1%)	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=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. 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)
Irritability						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Acute 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.

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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)

Agoraphobia						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Alcohol withdrawal 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. 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)

Attention deficit hyperactivity disorder						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Generalised anxiety 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.

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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)

Loss of libido						
<35	0/ 84	0/ 98				
35 - <50	0/154	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	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Mood swings						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Nervousness						
<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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=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.

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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)

Restlessness						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Suicidal ideation						
<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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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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%)	6/ 98 (6%)	0.3740 (0.0734, 1.9045) /0.236	-3.7415 (-9.4999, 2.0169) /0.203	0.3889 (0.0806, 1.8759) /0.239	0.755
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	5/ 89 (6%)	6/ 86 (7%)	0.7937 (0.2330, 2.7035) /0.712	-1.3588 (-8.5613, 5.8437) /0.712	0.8052 (0.2552, 2.5411) /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. 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)

Weight increased						
<35	0/ 84	1/ 98 (1%)				
35 - <50	2/154 (1%)	3/143 (2%)				
>=50	2/ 89 (2%)	0/ 86				
Body temperature increased						
<35	0/ 84	1/ 98 (1%)				
35 - <50	1/154 (<1%)	4/143 (3%)				
>=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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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	1/ 89 (1%)	0/ 86				
Blood creatine phosphokinase increased						
<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. 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)

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	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. 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)

Blood triglycerides increased						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	2/143 (1%)				
>=50	0/ 89	0/ 86				
Low density lipoprotein increased						
<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. 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)

Weight decreased						
<35	0/ 84	0/ 98				
35 - <50	2/154 (1%)	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Aspartate aminotransferase increased						
<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. 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)

Blood creatinine increased						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	0/ 89	0/ 86				
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. 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)

Blood bilirubin increased						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
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. 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)

Blood pressure decreased						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Electrocardiogram abnormal						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Epstein-Barr virus 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. 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)

Escherichia test positive						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Haematocrit 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. 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)

Haemoglobin increased						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Transaminases increased						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
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. 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)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
<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	0.344
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	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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	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	
Anogenital warts						
<35	2/ 84 (2%)	4/ 98 (4%)				
35 - <50	1/154 (<1%)	4/143 (3%)				
>=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. 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)

Skin papilloma						
<35	2/ 84 (2%)	3/ 98 (3%)				
35 - <50	1/154 (<1%)	3/143 (2%)				
>=50	0/ 89	2/ 86 (2%)				
Fibrous histiocyoma						
<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. 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)
Lipoma <35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Lipoma of breast <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= 1

System Organ Class Preferred Term	Q8W (N=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				
Adenoma benign						
<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)

Basal cell carcinoma						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Benign neoplasm of thyroid gland						
<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)
Fibroma						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Kaposi's sarcoma						
<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)

Urethral papilloma						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System 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)

Vascular disorders						
Any Event						
<35	3/ 84 (4%)	4/ 98 (4%)	0.8704 (0.1892, 4.0041) /0.858	-0.5102 (-6.0866, 5.0662) /0.858	0.8750 (0.2015, 3.7991) /0.859	0.958
35 - <50	6/154 (4%)	5/143 (3%)	1.1189 (0.3339, 3.7495) /0.855	0.3996 (-3.8904, 4.6896) /0.855	1.1143 (0.3476, 3.5715) /0.856	
>=50	7/ 89 (8%)	6/ 86 (7%)	1.1382 (0.3665, 3.5344) /0.823	0.8884 (-6.8748, 8.6516) /0.823	1.1273 (0.3947, 3.2195) /0.823	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Hypertension						
<35	2/ 84 (2%)	2/ 98 (2%)				
35 - <50	4/154 (3%)	4/143 (3%)				
>=50	4/ 89 (4%)	2/ 86 (2%)				
Haematoma						
<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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Varicose vein <35	0/ 84	1/ 98 (1%)				
35 - <50	1/154 (<1%)	0/143				
>=50	1/ 89 (1%)	0/ 86				
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. 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)
Hot flush						
<35	1/ 84 (1%)	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
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.

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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)

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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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	4/ 84 (5%)	5/ 98 (5%)	0.9300 (0.2415, 3.5814) /0.916	-0.3401 (-6.6424, 5.9622) /0.916	0.9333 (0.2590, 3.3638) /0.916	0.644
35 - <50	8/154 (5%)	6/143 (4%)	1.2511 (0.4232, 3.6985) /0.685	0.9990 (-3.8055, 5.8035) /0.684	1.2381 (0.4404, 3.4810) /0.686	
>=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.

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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	2/154 (1%)	0/143				
>=50	2/ 89 (2%)	1/ 86 (1%)				
Menorrhagia						
<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. 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)

Balanoposthitis						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Breast cyst						
<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.

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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)

Genital lesion						
<35	1/ 84 (1%)	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
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. 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)

Atrophic vulvovaginitis						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Breast mass						
<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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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Cervical dysplasia						
<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.

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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. 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)

Genital erythema						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Penile 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.

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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)

Penile pain						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Penile 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.

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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)

Premenstrual syndrome						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Sexual dysfunction						
<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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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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	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. 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)

Testicular swelling						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Testis discomfort						
<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.

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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 polyp <35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
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. 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)
Renal and urinary disorders						
Any Event						
<35	0/ 84	5/ 98 (5%)	<0.0001 (<0.0001, -) />0.999	-7.2683 (-29.4886, 14.9520) /0.521	<0.0001 (<0.0001, -) />0.999	0.323
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	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.

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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)

Dysuria						
<35	0/ 84	2/ 98 (2%)				
35 - <50	2/154 (1%)	3/143 (2%)				
>=50	0/ 89	3/ 86 (3%)				
Nocturia						
<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.

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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)

Haematuria						
<35	0/ 84	0/ 98				
35 - <50	0/154	2/143 (1%)				
>=50	0/ 89	0/ 86				
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. 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)

Nephrolithiasis						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Renal cyst						
<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.

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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)

Urethral discharge						
<35	0/ 84	0/ 98				
35 - <50	0/154	2/143 (1%)				
>=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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Pollakiuria						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Urethral pain						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Urinary incontinence						
<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)

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. 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)

Ear and labyrinth disorders						
Any Event						
<35	1/ 84 (1%)	4/ 98 (4%)				
35 - <50	4/154 (3%)	5/143 (3%)				
>=50	5/ 89 (6%)	4/ 86 (5%)				
Tinnitus						
<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. 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)

Vertigo						
<35	1/ 84 (1%)	0/ 98				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	0/ 89	2/ 86 (2%)				
Cerumen impaction						
<35	0/ 84	1/ 98 (1%)				
35 - <50	1/154 (<1%)	0/143				
>=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)

Ear discomfort						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	1/ 89 (1%)	0/ 86				
Ear pain						
<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.

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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)

Eustachian tube dysfunction						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Excessive cerumen production						
<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.

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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)

Deafness neurosensory						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Ear pruritus						
<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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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. 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)

Metabolism and nutrition disorders						
Any Event						
<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	0.093
35 - <50	5/154 (3%)	3/143 (2%)	1.5660 (0.3674, 6.6749) /0.544	1.1489 (-2.5054, 4.8031) /0.538	1.5476 (0.3767, 6.3589) /0.545	
>=50	7/ 89 (8%)	4/ 86 (5%)	1.7500 (0.4934, 6.2068) /0.386	3.2140 (-3.9335, 10.3616) /0.378	1.6910 (0.5133, 5.5707) /0.388	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Hypercholesterolaemia						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	1/ 89 (1%)	1/ 86 (1%)				
Decreased appetite						
<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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Gout						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	2/ 89 (2%)	0/ 86				
Vitamin D deficiency						
<35	0/ 84	0/ 98				
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. 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)

Alcoholic ketoacidosis						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Diabetes mellitus						
<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)
Dyslipidaemia						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	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. 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)

Hyperglycaemia ^a						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Hyperlipasaemia ^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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Hypokalaemia						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Iron 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.

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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. 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)

Eye disorders						
Any Event						
<35	1/ 84 (1%)	3/ 98 (3%)				
35 - <50	3/154 (2%)	5/143 (3%)				
>=50	1/ 89 (1%)	7/ 86 (8%)				
Conjunctivitis allergic						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	3/143 (2%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Blepharitis						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	1/ 86 (1%)				
Cataract						
<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.

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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 eye						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Astigmatism						
<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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Eczema eyelids						
<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)
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. 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)

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. 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)
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. 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)
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. 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)

Vitreous detachment						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
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. 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)

Blood and lymphatic system disorders						
Any Event						
<35	2/ 84 (2%)	4/ 98 (4%)				
35 - <50	0/154	4/143 (3%)				
>=50	3/ 89 (3%)	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)

Lymphadenopathy						
<35	1/ 84 (1%)	2/ 98 (2%)				
35 - <50	0/154	2/143 (1%)				
>=50	1/ 89 (1%)	0/ 86				
Anaemia						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	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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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=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.

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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)

Lymph node pain						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Polycythaemia						
<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= 1

System Organ Class Preferred Term	Q8W (N=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	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	4/154 (3%)	1/143 (<1%)				
>=50	2/ 89 (2%)	3/ 86 (3%)				
Seasonal allergy						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	3/154 (2%)	0/143				
>=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. 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)

Hypersensitivity						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	1/ 89 (1%)	1/ 86 (1%)				
Anaphylactic reaction						
<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)

Cardiac disorders						
Any Event						
<35	0/ 84	3/ 98 (3%)				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Palpitations						
<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)

Tachycardia						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Atrioventricular block first 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. 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)

Wolff-Parkinson-White syndrome						
<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)

Endocrine disorders						
Any Event						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	1/143 (<1%)				
>=50	1/ 89 (1%)	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.

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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)

Androgen deficiency						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
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.

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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)

Hepatobiliary disorders						
Any Event						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	1/ 86 (1%)				
Cholelithiasis						
<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)

Hepatic steatosis						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=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.

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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	Q8W (N=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	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.

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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)

Gilbert's syndrome						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

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.

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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)
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.

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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)

Overall						
Any Event						
<35	53/ 84 (63%)	58/ 98 (59%)	1.1791 (0.6478, 2.1461) /0.590	3.9116 (-10.2721, 18.0953) /0.589	1.0661 (0.8454, 1.3443) /0.589	0.467
35 - <50	77/154 (50%)	65/143 (45%)	1.2000 (0.7604, 1.8937) /0.433	4.5455 (-6.8108, 15.9017) /0.433	1.1000 (0.8660, 1.3972) /0.435	
>=50	46/ 89 (52%)	50/ 86 (58%)	0.7702 (0.4240, 1.3992) /0.391	-6.4541 (-21.1679, 8.2596) /0.390	0.8890 (0.6791, 1.1637) /0.392	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

General disorders and administration site conditions						
Any Event						
<35	42/ 84 (50%)	39/ 98 (40%)	1.5128 (0.8397, 2.7255) /0.168	10.2041 (-4.2266, 24.6347) /0.166	1.2564 (0.9086, 1.7373) /0.167	0.406
35 - <50	53/154 (34%)	47/143 (33%)	1.0718 (0.6620, 1.7355) /0.778	1.5485 (-9.2022, 12.2991) /0.778	1.0471 (0.7604, 1.4420) /0.778	
>=50	23/ 89 (26%)	26/ 86 (30%)	0.8042 (0.4152, 1.5576) /0.518	-4.3899 (-17.6915, 8.9118) /0.518	0.8548 (0.5309, 1.3764) /0.519	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Injection site pain <35	38/ 84 (45%)	35/ 98 (36%)	1.4870 (0.8192, 2.6989) /0.192	9.5238 (-4.7341, 23.7817) /0.190	1.2667 (0.8883, 1.8062) /0.192	0.598
35 - <50	48/154 (31%)	41/143 (29%)	1.1266 (0.6849, 1.8530) /0.639	2.4975 (-7.9166, 12.9116) /0.638	1.0871 (0.7667, 1.5414) /0.639	
>=50	21/ 89 (24%)	22/ 86 (26%)	0.8984 (0.4513, 1.7885) /0.760	-1.9859 (-14.7471, 10.7754) /0.760	0.9224 (0.5487, 1.5504) /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.

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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 nodule <35	5/ 84 (6%)	4/ 98 (4%)	1.4873 (0.3862, 5.7281) /0.564	1.8707 (-4.5283, 8.2698) /0.567	1.4583 (0.4046, 5.2560) /0.564	0.144
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.

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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 induration						
<35	1/ 84 (1%)	0/ 98				
35 - <50	4/154 (3%)	2/143 (1%)				
>=50	0/ 89	1/ 86 (1%)				
Injection site discomfort						
<35	2/ 84 (2%)	2/ 98 (2%)				
35 - <50	4/154 (3%)	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. 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)

Pyrexia						
<35	3/ 84 (4%)	3/ 98 (3%)				
35 - <50	3/154 (2%)	4/143 (3%)				
>=50	1/ 89 (1%)	2/ 86 (2%)				
Fatigue						
<35	1/ 84 (1%)	2/ 98 (2%)				
35 - <50	2/154 (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.

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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 swelling						
<35	6/ 84 (7%)	1/ 98 (1%)				
35 - <50	3/154 (2%)	3/143 (2%)				
>=50	1/ 89 (1%)	2/ 86 (2%)				
Injection site pruritus						
<35	1/ 84 (1%)	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)

Injection site erythema						
<35	0/ 84	0/ 98				
35 - <50	0/154	2/143 (1%)				
>=50	0/ 89	0/ 86				
Influenza like illness						
<35	1/ 84 (1%)	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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Asthenia						
<35	2/ 84 (2%)	0/ 98				
35 - <50	0/154	2/143 (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.

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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 bruising						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	2/143 (1%)				
>=50	0/ 89	1/ 86 (1%)				
Pain						
<35	0/ 84	0/ 98				
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. 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)
Malaise						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Injection site haematoma						
<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.

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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)
Discomfort						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
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. 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)

Injection site warmth						
<35	1/ 84 (1%)	0/ 98				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	0/ 89	2/ 86 (2%)				
Chest pain						
<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.

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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 anaesthesia						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	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. 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)

Nodule						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Peripheral swelling						
<35	0/ 84	1/ 98 (1%)				
35 - <50	2/154 (1%)	0/143				
>=50	0/ 89	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.

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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)

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. 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)

Non-cardiac chest pain						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Injection site discharge						
<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= 2

System Organ Class Preferred Term	Q8W (N=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						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	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. 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)

Infections and infestations						
Any Event						
<35	35/ 84 (42%)	40/ 98 (41%)	1.0357 (0.5730, 1.8721) /0.908	0.8503 (-13.4969, 15.1976) /0.908	1.0208 (0.7211, 1.4452) /0.907	0.685
35 - <50	39/154 (25%)	40/143 (28%)	0.8733 (0.5218, 1.4615) /0.606	-2.6474 (-12.7120, 7.4173) /0.606	0.9054 (0.6205, 1.3210) /0.606	
>=50	22/ 89 (25%)	27/ 86 (31%)	0.7175 (0.3698, 1.3922) /0.326	-6.6762 (-19.9627, 6.6102) /0.325	0.7873 (0.4879, 1.2706) /0.328	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Nasopharyngitis						
<35	11/ 84 (13%)	9/ 98 (9%)	1.4901 (0.5857, 3.7908) /0.402	3.9116 (-5.2937, 13.1168) /0.405	1.4259 (0.6209, 3.2745) /0.403	0.959
35 - <50	4/154 (3%)	2/143 (1%)	1.8800 (0.3390, 10.4243) /0.470	1.1988 (-1.9659, 4.3635) /0.458	1.8571 (0.3454, 9.9850) /0.471	
>=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. 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)
Upper respiratory tract infection <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	0.857
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	5/ 89 (6%)	8/ 86 (9%)	0.5804 (0.1821, 1.8496) /0.358	-3.6843 (-11.4672, 4.0985) /0.353	0.6039 (0.2056, 1.7736) /0.359	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Gastroenteritis						
<35	3/ 84 (4%)	2/ 98 (2%)				
35 - <50	0/154	8/143 (6%)				
>=50	2/ 89 (2%)	2/ 86 (2%)				
Syphilis						
<35	3/ 84 (4%)	5/ 98 (5%)				
35 - <50	1/154 (<1%)	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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Pharyngitis						
<35	3/ 84 (4%)	3/ 98 (3%)				
35 - <50	1/154 (<1%)	2/143 (1%)				
>=50	0/ 89	1/ 86 (1%)				
Gonorrhoea						
<35	2/ 84 (2%)	1/ 98 (1%)				
35 - <50	0/154	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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Analysis of Proportion of Subjects with Adverse Events by 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						
<35	0/ 84	4/ 98 (4%)				
35 - <50	4/154 (3%)	2/143 (1%)				
>=50	1/ 89 (1%)	1/ 86 (1%)				
Bronchitis						
<35	1/ 84 (1%)	2/ 98 (2%)				
35 - <50	3/154 (2%)	2/143 (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. 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)

Sinusitis						
<35	3/ 84 (4%)	2/ 98 (2%)				
35 - <50	2/154 (1%)	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Chlamydial infection						
<35	2/ 84 (2%)	0/ 98				
35 - <50	0/154	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. 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)

Conjunctivitis						
<35	1/ 84 (1%)	0/ 98				
35 - <50	3/154 (2%)	0/143				
>=50	0/ 89	1/ 86 (1%)				
Viral infection						
<35	2/ 84 (2%)	3/ 98 (3%)				
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.

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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 tract infection						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	2/143 (1%)				
>=50	0/ 89	0/ 86				
Folliculitis						
<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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Oral herpes						
<35	0/ 84	1/ 98 (1%)				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Respiratory tract infection viral						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	3/154 (2%)	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)

Urethritis						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Urinary tract infection						
<35	2/ 84 (2%)	1/ 98 (1%)				
35 - <50	1/154 (<1%)	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. 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)

Tonsillitis						
<35	0/ 84	5/ 98 (5%)				
35 - <50	2/154 (1%)	0/143				
>=50	0/ 89	0/ 86				
Viral upper respiratory tract 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. 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)

Gastroenteritis viral						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	2/143 (1%)				
>=50	0/ 89	1/ 86 (1%)				
Onychomycosis						
<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= 2

System Organ Class Preferred Term	Q8W (N=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	3/ 84 (4%)	5/ 98 (5%)				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
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. 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)

Anal chlamydia infection						
<35	3/ 84 (4%)	4/ 98 (4%)				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Ear 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.

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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)

Fungal skin infection						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Tinea versicolour						
<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. 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)

Herpes zoster <35	1/ 84 (1%)	3/ 98 (3%)				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Hordeolum <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.

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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)

Lower respiratory tract infection						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	1/ 86 (1%)				
Oropharyngeal gonococcal infection						
<35	3/ 84 (4%)	5/ 98 (5%)				
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)

Tooth infection						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	2/ 86 (2%)				
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. 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)

Acarodermatitis						
<35	0/ 84	1/ 98 (1%)				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Body tinea						
<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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Analysis of Proportion of Subjects with Adverse Events by 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%)	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Secondary syphilis						
<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.

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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)

Urethritis gonococcal						
<35	1/ 84 (1%)	2/ 98 (2%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Viral pharyngitis						
<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)
Cellulitis						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	1/ 86 (1%)				
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.

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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)

Mycoplasma genitalium infection						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Oral candidiasis						
<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)

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. 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)

Primary syphilis						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Skin 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.

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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 infection						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	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. 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)

Urethritis chlamydial						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	3/143 (2%)				
>=50	0/ 89	0/ 86				
Abscess limb						
<35	1/ 84 (1%)	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. 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)

Acute sinusitis						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Bronchitis viral						
<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= 2

System Organ Class Preferred Term	Q8W (N=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	1/143 (<1%)				
>=50	0/ 89	0/ 86				
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Epididymitis						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Escherichia urinary 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.

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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)

Genital herpes						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Injection site abscess						
<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)
Laryngitis						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Pharyngeal chlamydia infection						
<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. 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)

Pharyngitis streptococcal						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Pharyngotonsillitis						
<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. 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)

Pulpitis dental						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Sexually transmitted 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. 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)

Staphylococcal skin infection						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Subcutaneous 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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Ureaplasma infection						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Urethritis mycoplasmal						
<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)

Varicella						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Shigella infection						
<35	1/ 84 (1%)	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. 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)

Vulvovaginal mycotic infection						
<35	0/ 84	1/ 98 (1%)				
35 - <50	1/154 (<1%)	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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Pulmonary tuberculosis						
<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. 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)

Asymptomatic bacteriuria						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Bacterial diarrhoea						
<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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Analysis of Proportion of Subjects with Adverse Events by 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 rhinitis						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Bacterial vaginosis						
<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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Analysis of Proportion of Subjects with Adverse Events by 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)
COVID-19						
<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. 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)

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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Device related infection						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
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. 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)

Eczema infected						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

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. 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)

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. 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)

Gonococcal infection						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Herpes ophthalmic						
<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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Analysis of Proportion of Subjects with Adverse Events by 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)

Herpes virus infection						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Infected bite						
<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= 2

System Organ Class Preferred Term	Q8W (N=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				
Latent 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. 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)

Lice infestation						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Oesophageal candidiasis						
<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)

Ophthalmic herpes zoster						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Proctitis chlamydial						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	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. 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)

Skin bacterial infection						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Suspected COVID-19						
<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)

Urinary tract infection staphylococcal						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Wound 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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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=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	11/ 84 (13%)	15/ 98 (15%)	0.8338 (0.3603, 1.9298) /0.671	-2.2109 (-12.3528, 7.9311) /0.669	0.8556 (0.4159, 1.7601) /0.672	0.527
35 - <50	12/154 (8%)	19/143 (13%)	0.5515 (0.2575, 1.1814) /0.126	-5.4945 (-12.4854, 1.4964) /0.123	0.5865 (0.2954, 1.1645) /0.127	
>=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.

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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 <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	0.869
35 - <50	2/154 (1%)	4/143 (3%)	0.4572 (0.0825, 2.5354) /0.371	-1.4985 (-4.7391, 1.7421) /0.365	0.4643 (0.0864, 2.4963) /0.371	
>=50	2/ 89 (2%)	4/ 86 (5%)	0.4713 (0.0841, 2.6423) /0.392	-2.4040 (-7.8161, 3.0081) /0.384	0.4831 (0.0908, 2.5699) /0.394	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Nausea						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	0/154	1/143 (<1%)				
>=50	2/ 89 (2%)	2/ 86 (2%)				
Constipation						
<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.

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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						
<35	0/ 84	1/ 98 (1%)				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	0/ 89	1/ 86 (1%)				
Haemorrhoids						
<35	0/ 84	3/ 98 (3%)				
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. 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)

Abdominal pain						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	1/ 89 (1%)	0/ 86				
Abdominal distension						
<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.

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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)

Toothache						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	3/143 (2%)				
>=50	0/ 89	2/ 86 (2%)				
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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Analysis of Proportion of Subjects with Adverse Events by 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	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	0/154	2/143 (1%)				
>=50	0/ 89	2/ 86 (2%)				
Vomiting						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	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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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by 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 discomfort						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Anogenital dysplasia						
<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. 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)

Abdominal pain lower						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Gastritis						
<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.

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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)

Haematochezia						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Rectal 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. 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)

Anal fissure						
<35	2/ 84 (2%)	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Dry mouth						
<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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Analysis of Proportion of Subjects with Adverse Events by 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				
Irritable bowel 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.

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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)

Oesophagitis						
<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. 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)

Large intestine polyp						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Oral 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.

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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	2/143 (1%)				
>=50	0/ 89	0/ 86				
Colitis						
<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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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=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						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Tongue ulceration						
<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.

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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)

Aphthous ulcer						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Dental cyst						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=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. 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)

Glossitis						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Oral pain						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
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. 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)
Rectal prolapse						
<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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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=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	8/ 84 (10%)	11/ 98 (11%)	0.8325 (0.3184, 2.1772) /0.709	-1.7007 (-10.5588, 7.1574) /0.707	0.8485 (0.3580, 2.0108) /0.709	0.338
35 - <50	14/154 (9%)	14/143 (10%)	0.9214 (0.4230, 2.0070) /0.837	-0.6993 (-7.3582, 5.9596) /0.837	0.9286 (0.4588, 1.8792) /0.837	
>=50	6/ 89 (7%)	14/ 86 (16%)	0.3718 (0.1358, 1.0178) /0.054	-9.5375 (-18.9191, -0.1559) /0.046	0.4141 (0.1668, 1.0281) /0.057	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Back pain						
<35	1/ 84 (1%)	2/ 98 (2%)				
35 - <50	2/154 (1%)	5/143 (3%)				
>=50	1/ 89 (1%)	2/ 86 (2%)				
Arthralgia						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	6/154 (4%)	2/143 (1%)				
>=50	1/ 89 (1%)	5/ 86 (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.

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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)

Pain in extremity						
<35	0/ 84	4/ 98 (4%)				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	1/ 89 (1%)	0/ 86				
Myalgia						
<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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Musculoskeletal pain						
<35	1/ 84 (1%)	0/ 98				
35 - <50	3/154 (2%)	2/143 (1%)				
>=50	0/ 89	0/ 86				
Tendonitis						
<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)
Muscle spasms						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	0/154	1/143 (<1%)				
>=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.

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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)

Musculoskeletal chest pain						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	1/154 (<1%)	0/143				
>=50	1/ 89 (1%)	1/ 86 (1%)				
Intervertebral disc protrusion						
<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= 2

System Organ Class Preferred Term	Q8W (N=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				
Arthritis						
<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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Analysis of Proportion of Subjects with Adverse Events by 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%)				
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Joint range of motion decreased						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
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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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by 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%)	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Musculoskeletal discomfort						
<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)
Pain in jaw						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Plantar fasciitis						
<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)

Rotator cuff syndrome						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	2/ 86 (2%)				
Synovial cyst						
<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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Analysis of Proportion of Subjects with Adverse Events by 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)

Synovitis						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Osteoarthritis						
<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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Arthritis reactive						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Bone pain						
<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)

Loose body in joint						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Periarthritis						
<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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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Polyarthriti						
<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)

Skin and subcutaneous tissue disorders						
Any Event						
<35	9/ 84 (11%)	3/ 98 (3%)	3.8000 (0.9938, 14.5306) /0.051	7.6531 (0.2112, 15.0949) /0.044	3.5000 (0.9793, 12.5095) /0.054	0.026
35 - <50	5/154 (3%)	9/143 (6%)	0.4996 (0.1634, 1.5280) /0.224	-3.0470 (-7.9130, 1.8191) /0.220	0.5159 (0.1771, 1.5029) /0.225	
>=50	5/ 89 (6%)	9/ 86 (10%)	0.5093 (0.1635, 1.5862) /0.244	-4.8471 (-12.8933, 3.1990) /0.238	0.5368 (0.1874, 1.5376) /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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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=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	1/ 89 (1%)	0/ 86				
Rash						
<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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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=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%)	1/ 86 (1%)				
Acne						
<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.

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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)
<hr/>						
Alopecia						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
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. 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)

Skin lesion						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	2/ 89 (2%)	1/ 86 (1%)				
Dermatitis contact						
<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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Analysis of Proportion of Subjects with Adverse Events by 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)
Hyperhidrosis						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	2/ 86 (2%)				
Dermatitis atopic						
<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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Analysis of Proportion of Subjects with Adverse Events by 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)
Erythema						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	1/ 86 (1%)				
Night sweats						
<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= 2

System Organ Class Preferred Term	Q8W (N=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	1/ 86 (1%)				
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.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Pityriasis rosea						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Ecchymosis						
<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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Analysis of Proportion of Subjects with Adverse Events by 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	1/ 86 (1%)				
Granuloma annulare						
<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)

Guttate psoriasis						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
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. 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)

Lichen sclerosus						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Nail dystrophy						
<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= 2

System Organ Class Preferred Term	Q8W (N=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%)				
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. 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)

Rash vesicular						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=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. 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)
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. 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)
Respiratory, thoracic and mediastinal disorders						
Any Event						
<35	5/ 84 (6%)	4/ 98 (4%)	1.4873 (0.3862, 5.7281) /0.564	1.8707 (-4.5283, 8.2698) /0.567	1.4583 (0.4046, 5.2560) /0.564	0.230
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	3/ 89 (3%)	5/ 86 (6%)	0.5651 (0.1308, 2.4411) /0.445	-2.4432 (-8.6495, 3.7632) /0.440	0.5798 (0.1429, 2.3519) /0.445	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Cough						
<35	3/ 84 (4%)	1/ 98 (1%)				
35 - <50	1/154 (<1%)	2/143 (1%)				
>=50	1/ 89 (1%)	1/ 86 (1%)				
Oropharyngeal pain						
<35	1/ 84 (1%)	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. 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)

Nasal congestion						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	1/ 89 (1%)	0/ 86				
Rhinitis allergic						
<35	0/ 84	1/ 98 (1%)				
35 - <50	1/154 (<1%)	3/143 (2%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Sinus congestion						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
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. 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)

Asthma						
<35	1/ 84 (1%)	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. 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)

Sleep apnoea syndrome						
<35	0/ 84	0/ 98				
35 - <50	0/154	2/143 (1%)				
>=50	0/ 89	1/ 86 (1%)				
Productive cough						
<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. 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)

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. 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)
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. 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)

Nervous system disorders						
Any Event						
<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	0.735
35 - <50	9/154 (6%)	15/143 (10%)	0.5297 (0.2242, 1.2515) /0.147	-4.6454 (-10.8862, 1.5955) /0.145	0.5571 (0.2517, 1.2331) /0.149	
>=50	5/ 89 (6%)	5/ 86 (6%)	0.9643 (0.2690, 3.4565) /0.955	-0.1960 (-7.0768, 6.6849) /0.955	0.9663 (0.2900, 3.2199) /0.955	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Headache						
<35	2/ 84 (2%)	4/ 98 (4%)				
35 - <50	2/154 (1%)	6/143 (4%)				
>=50	2/ 89 (2%)	3/ 86 (3%)				
Dizziness						
<35	1/ 84 (1%)	0/ 98				
35 - <50	1/154 (<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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Presyncope						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	1/ 86 (1%)				
Paraesthesia						
<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)
Migraine						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Hypoaesthesia						
<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.

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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)
Sciatica						
<35	0/ 84	2/ 98 (2%)				
35 - <50	2/154 (1%)	0/143				
>=50	0/ 89	0/ 86				
Syncope						
<35	0/ 84	0/ 98				
35 - <50	0/154	3/143 (2%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Tension headache						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Cervical radiculopathy						
<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= 2

System Organ Class Preferred Term	Q8W (N=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	0/ 86				
Anosmia						
<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)
Brain injury						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Brain stem infarction						
<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= 2

System Organ Class Preferred Term	Q8W (N=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. 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)

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. 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)

Radiculopathy						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Transient ischaemic attack						
<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= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Trigeminal neuralgia						
<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)

Injury, poisoning and procedural complications						
Any Event						
<35	5/ 84 (6%)	11/ 98 (11%)	0.5006 (0.1666, 1.5040) /0.218	-5.2721 (-13.3133, 2.7691) /0.199	0.5303 (0.1920, 1.4650) /0.221	0.024
35 - <50	2/154 (1%)	12/143 (8%)	0.1436 (0.0316, 0.6535) /0.012	-7.0929 (-11.9764, -2.2094) /0.004	0.1548 (0.0352, 0.6795) /0.013	
>=50	8/ 89 (9%)	5/ 86 (6%)	1.6000 (0.5021, 5.0989) /0.427	3.1748 (-4.5563, 10.9059) /0.421	1.5461 (0.5264, 4.5405) /0.428	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Contusion						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Arthropod 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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Ligament sprain						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Muscle strain						
<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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Limb injury						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	2/ 89 (2%)	0/ 86				
Exposure to communicable disease						
<35	2/ 84 (2%)	4/ 98 (4%)				
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)

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)

Vaccination complication						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Arthropod sting						
<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)

Epicondylitis						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<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. 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)

Head injury						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Musculoskeletal foreign body						
<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)
Rib fracture						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	1/143 (<1%)				
>=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. 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)

Ankle fracture						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Meniscus injury						
<35	0/ 84	0/ 98				
35 - <50	0/154	2/143 (1%)				
>=50	0/ 89	0/ 86				
Wrist fracture						
<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)

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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Clavicle fracture						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Corneal abrasion						
<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= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Face injury						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=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. 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)

Fractured coccyx						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Gastrointestinal procedural 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.

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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 dislocation						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Post-traumatic pain						
<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= 2

System Organ Class Preferred Term	Q8W (N=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				
Traumatic arthritis						
<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	Q8W (N=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	10/ 84 (12%)	7/ 98 (7%)	1.7568 (0.6376, 4.8400) /0.276	4.7619 (-3.8381, 13.3619) /0.278	1.6667 (0.6636, 4.1858) /0.277	0.146
35 - <50	5/154 (3%)	10/143 (7%)	0.4463 (0.1488, 1.3390) /0.150	-3.7463 (-8.7769, 1.2844) /0.144	0.4643 (0.1626, 1.3256) /0.152	
>=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. 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	3/143 (2%)				
>=50	4/ 89 (4%)	0/ 86				
Anxiety						
<35	8/ 84 (10%)	2/ 98 (2%)	5.0526 (1.0423, 24.4921) /0.044	7.4830 (0.6097, 14.3563) /0.033	4.6667 (1.0188, 21.3762) /0.047	0.105
35 - <50	2/154 (1%)	4/143 (3%)	0.4572 (0.0825, 2.5354) /0.371	-1.4985 (-4.7391, 1.7421) /0.365	0.4643 (0.0864, 2.4963) /0.371	
>=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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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by 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. 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)
Depression <35	1/ 84 (1%)	2/ 98 (2%)				
35 - <50	3/154 (2%)	2/143 (1%)				
>=50	0/ 89	1/ 86 (1%)				
Nightmare <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	Q8W (N=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				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Adjustment disorder with mixed anxiety and depressed mood						
<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)

Attention deficit hyperactivity disorder						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Generalised anxiety 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.

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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)
Major depression						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Panic attack						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=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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Analysis of Proportion of Subjects with Adverse Events by 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)
Restlessness						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Suicidal ideation						
<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= 2

System Organ Class Preferred Term	Q8W (N=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	0/154	1/143 (<1%)				
>=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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Psychotic disorder						
<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= 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	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	0.587
35 - <50	2/154 (1%)	8/143 (6%)	0.2220 (0.0463, 1.0638) /0.060	-4.2957 (-8.4653, -0.1262) /0.043	0.2321 (0.0501, 1.0750) /0.062	
>=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.

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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)

Weight increased						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	3/143 (2%)				
>=50	0/ 89	0/ 86				
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.

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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 creatine phosphokinase increased						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Blood cholesterol increased						
<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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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by 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)

Weight decreased						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Blood glucose increased						
<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= 2

System Organ Class Preferred Term	Q8W (N=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						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
CD4 lymphocytes decreased						
<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)

Campylobacter test positive						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Culture urine positive						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Haematocrit decreased						
<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= 2

System Organ Class Preferred Term	Q8W (N=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 decreased						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Hepatic enzyme 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.

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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)

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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

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. 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)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
<35	1/ 84 (1%)	1/ 98 (1%)				
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.

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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	2/ 86 (2%)				
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. 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)

Adenoma benign						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Basal cell carcinoma						
<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. 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)
Adrenal adenoma						
<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)

Vascular disorders						
Any Event						
<35	2/ 84 (2%)	0/ 98				
35 - <50	1/154 (<1%)	3/143 (2%)				
>=50	0/ 89	1/ 86 (1%)				
Hypertension						
<35	1/ 84 (1%)	0/ 98				
35 - <50	1/154 (<1%)	3/143 (2%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Blood pressure inadequately controlled						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Phlebitis						
<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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Analysis of Proportion of Subjects with Adverse Events by 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)

Thrombophlebitis						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Thrombophlebitis superficial						
<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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Analysis of Proportion of Subjects with Adverse Events by 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	1/ 84 (1%)	4/ 98 (4%)				
35 - <50	6/154 (4%)	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. 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)

Erectile dysfunction						
<35	0/ 84	2/ 98 (2%)				
35 - <50	2/154 (1%)	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. 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)

Genital lesion						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
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. 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)

Testicular cyst						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Benign prostatic hyperplasia						
<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. 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)

Haemospermi 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. 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)

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. 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)
<hr/>						
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. 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)

Renal and urinary disorders						
Any Event						
<35	1/ 84 (1%)	2/ 98 (2%)				
35 - <50	3/154 (2%)	2/143 (1%)				
>=50	0/ 89	2/ 86 (2%)				
Dysuria						
<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. 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)

Nocturia						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Nephrolithiasis						
<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.

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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)
Pollakiuria						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Renal colic						
<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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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by 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)

Leukocyturia						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
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.

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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	2/ 98 (2%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
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. 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)
Vertigo						
<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	Q8W (N=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	2/ 84 (2%)	2/ 98 (2%)				
35 - <50	3/154 (2%)	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. 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)

Hypercholesterolaemia						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	1/ 89 (1%)	1/ 86 (1%)				
Vitamin D deficiency						
<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. 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)
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.

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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)

Cachexia						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Hypertriglyceridaemia						
<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= 2

System Organ Class Preferred Term	Q8W (N=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	4/154 (3%)	1/143 (<1%)				
>=50	4/ 89 (4%)	1/ 86 (1%)				
Conjunctivitis allergic						
<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)

Blepharitis <35	0/ 84	1/ 98 (1%)				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Cataract <35	0/ 84	0/ 98				
35 - <50	0/154	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= 2

System Organ Class Preferred Term	Q8W (N=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%)				
Retinal detachment						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=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= 2

System Organ Class Preferred Term	Q8W (N=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%)				
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.

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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)
Eyelid oedema						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Macular fibrosis						
<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= 2

System Organ Class Preferred Term	Q8W (N=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 tear						
<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.

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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)
Blood and lymphatic system disorders						
Any Event						
<35	0/ 84	0/ 98				
35 - <50	3/154 (2%)	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)

Microcytic anaemia						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Iron deficiency anaemia						
<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)

Neutropenia						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Immune system disorders						
Any Event						
<35	1/ 84 (1%)	4/ 98 (4%)				
35 - <50	5/154 (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.

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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)

Seasonal allergy						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	2/154 (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.

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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)
Food allergy						
<35	0/ 84	1/ 98 (1%)				
35 - <50	2/154 (1%)	0/143				
>=50	0/ 89	0/ 86				
Allergy to arthropod bite						
<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= 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)
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)

Cardiac disorders						
Any Event						
<35	3/ 84 (4%)	1/ 98 (1%)				
35 - <50	0/154	1/143 (<1%)				
>=50	3/ 89 (3%)	3/ 86 (3%)				
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.

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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/>						
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.

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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)

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.

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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)

Extrasystoles						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Myocardial necrosis						
<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)

Sinus bradycardia						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
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.

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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)

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.

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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)

Congenital, familial and genetic 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)

Benign familial pemphigus						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
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.

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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	Q8W (N=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	6/ 84 (7%)	9/ 98 (9%)	0.7607 (0.2592, 2.2328) /0.619	-2.0408 (-9.9796, 5.8980) /0.614	0.7778 (0.2887, 2.0953) /0.619	0.951
35 - <50	16/154 (10%)	19/143 (13%)	0.7567 (0.3728, 1.5358) /0.440	-2.8971 (-10.2574, 4.4632) /0.440	0.7820 (0.4186, 1.4607) /0.440	
>=50	9/ 89 (10%)	13/ 86 (15%)	0.6317 (0.2550, 1.5650) /0.321	-5.0039 (-14.8298, 4.8220) /0.318	0.6690 (0.3016, 1.4837) /0.323	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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	Q8W (N=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	5/ 98 (5%)	<0.0001 (<0.0001, -) />0.999	-7.2683 (-29.4886, 14.9520) /0.521	<0.0001 (<0.0001, -) />0.999	0.104
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	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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	Q8W (N=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	3/ 89 (3%)	6/ 86 (7%)	0.4651 (0.1125, 1.9222) /0.290	-3.6060 (-10.1671, 2.9552) /0.281	0.4831 (0.1248, 1.8709) /0.292	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Injection site pain <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	0.286
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	3/ 89 (3%)	6/ 86 (7%)	0.4651 (0.1125, 1.9222) /0.290	-3.6060 (-10.1671, 2.9552) /0.281	0.4831 (0.1248, 1.8709) /0.292	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

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	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. 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)
Fatigue						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=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.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Malaise						
<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.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Chest pain						
<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.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Infections and infestations						
Any Event						
<35	3/ 84 (4%)	2/ 98 (2%)				
35 - <50	4/154 (3%)	2/143 (1%)				
>=50	1/ 89 (1%)	1/ 86 (1%)				
Viral 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.

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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)

Tonsillitis						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Herpes zoster						
<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= 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				
Pneumonia						
<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.

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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)

Epididymitis						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=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. 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= 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				
Proctitis chlamydial						
<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= 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. 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= 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				
Gastrointestinal disorders						
Any Event						
<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. 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)

Abdominal pain						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Toothache						
<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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Analysis of Proportion of Subjects with Adverse Events by 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)

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.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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	Q8W (N=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	3/154 (2%)	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. 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)
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.

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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= 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	2/143 (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.

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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)

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.

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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)

Osteoarthritis						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Osteonecrosis						
<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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
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.

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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	Q8W (N=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	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.

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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)

Eczema						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Hyperhidrosis						
<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= 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						
<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= 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.

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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)

Nervous system disorders						
Any Event						
<35	1/ 84 (1%)	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	2/ 86 (2%)				
Headache						
<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= 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)

Disturbance in attention						
<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.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Neuritis cranial						
<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= 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.

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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)

Contusion						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Foot fracture						
<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= 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)

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.

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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)
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.

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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	Q8W (N=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	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.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by 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.

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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)

Lipase increased						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
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.

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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	Q8W (N=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.

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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)
Breast cancer						
<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.

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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	Q8W (N=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.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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= 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)
Genital odour						
<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= 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				
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.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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	Q8W (N=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.

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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)
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.

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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	Q8W (N=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.

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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)

Hypercholesterolaemia						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=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.

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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)
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.

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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)

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.

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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)
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.

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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)

Immune system disorders						
Any Event						
<35	0/ 84	0/ 98				
35 - <50	0/154	2/143 (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.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
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= 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						
<35	0/ 84	0/ 98				
35 - <50	0/154	2/143 (1%)				
>=50	0/ 89	0/ 86				
Ventricular extrasystoles						
<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= 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				
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.

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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)

Hepatobiliary disorders						
Any Event						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Hepatocellular 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. 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	Q8W (N=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.

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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)

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.

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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= 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	3/154 (2%)	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= 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						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Acute hepatitis B						
<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= 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						
<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= 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						
<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= 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.

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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= 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						
<35	0/ 84	0/ 98				
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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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by 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.

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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= 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)
Testicular neoplasm						
<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 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity 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	30/ 73 (41%)	22/ 75 (29%)	1.6808 (0.8502, 3.3227) /0.135	11.7626 (-3.5200, 27.0451) /0.131	1.4010 (0.8970, 2.1882) /0.138	0.077
Male	71/254 (28%)	80/252 (32%)	0.8342 (0.5697, 1.2215) /0.351	-3.7933 (-11.7612, 4.1747) /0.351	0.8805 (0.6736, 1.1510) /0.352	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

General disorders and administration site conditions						
Any Event						
Female	37/ 73 (51%)	29/ 75 (39%)	1.6303 (0.8485, 3.1325) /0.142	12.0183 (-3.8878, 27.9243) /0.139	1.3108 (0.9109, 1.8862) /0.145	0.219
Male	122/254 (48%)	119/252 (47%)	1.0330 (0.7287, 1.4643) /0.855	0.8093 (-7.8938, 9.5123) /0.855	1.0171 (0.8472, 1.2211) /0.855	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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	34/ 73 (47%)	29/ 75 (39%)	1.3828 (0.7192, 2.6590) /0.331	7.9087 (-7.9787, 23.7961) /0.329	1.2045 (0.8268, 1.7549) /0.332	0.575
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.

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)
Injection site nodule						
Female	10/ 73 (14%)	14/ 75 (19%)	0.6916 (0.2856, 1.6751) /0.414	-4.9680 (-16.7991, 6.8630) /0.410	0.7339 (0.3485, 1.5455) /0.415	0.292
Male	22/254 (9%)	48/252 (19%)	0.4030 (0.2352, 0.6906) /<.001	-10.3862 (-16.3419, -4.4305) /<.001	0.4547 (0.2832, 0.7302) /0.001	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Injection site induration						
Female	7/ 73 (10%)	12/ 75 (16%)	0.5568 (0.2061, 1.5046) /0.248	-6.4110 (-17.1096, 4.2877) /0.240	0.5993 (0.2499, 1.4372) /0.251	0.608
Male	16/254 (6%)	20/252 (8%)	0.7798 (0.3944, 1.5421) /0.475	-1.6373 (-6.1167, 2.8421) /0.474	0.7937 (0.4211, 1.4960) /0.475	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Injection site discomfort						
Female	1/ 73 (1%)	3/ 75 (4%)	0.3333 (0.0339, 3.2806) /0.346	-2.6301 (-7.8049, 2.5446) /0.319	0.3425 (0.0365, 3.2173) /0.348	0.481
Male	19/254 (7%)	25/252 (10%)	0.7341 (0.3934, 1.3699) /0.331	-2.4403 (-7.3484, 2.4678) /0.330	0.7540 (0.4262, 1.3340) /0.332	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Pyrexia 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	0.272
Male	13/254 (5%)	23/252 (9%)	0.5371 (0.2657, 1.0856) /0.083	-4.0089 (-8.4796, 0.4619) /0.079	0.5608 (0.2906, 1.0821) /0.085	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
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	0.555
Male	10/254 (4%)	23/252 (9%)	0.4081 (0.1901, 0.8760) /0.021	-5.1900 (-9.4752, -0.9048) /0.018	0.4314 (0.2096, 0.8877) /0.022	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Injection site swelling						
Female	5/ 73 (7%)	5/ 75 (7%)	1.0294 (0.2852, 3.7162) /0.965	0.1826 (-7.9071, 8.2724) /0.965	1.0274 (0.3104, 3.4008) /0.965	0.868
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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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)
Injection site pruritus						
Female	2/ 73 (3%)	11/ 75 (15%)	0.1639 (0.0350, 0.7676) /0.022	-11.9269 (-20.7658, -3.0880) /0.008	0.1868 (0.0429, 0.8139) /0.025	0.145
Male	7/254 (3%)	11/252 (4%)	0.6209 (0.2368, 1.6283) /0.333	-1.6092 (-4.8367, 1.6183) /0.328	0.6314 (0.2487, 1.6025) /0.333	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Injection site erythema						
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	0.206
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.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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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	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	0.175
Male	6/254 (2%)	8/252 (3%)	0.7379 (0.2523, 2.1581) /0.579	-0.8124 (-3.6714, 2.0466) /0.578	0.7441 (0.2619, 2.1138) /0.579	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only 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%)	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	0.872
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	0.703
Male	11/254 (4%)	6/252 (2%)	1.8560 (0.6757, 5.0977) /0.230	1.9498 (-1.1822, 5.0817) /0.222	1.8189 (0.6831, 4.8432) /0.231	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
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	0.406
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.

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)
Pain						
Female	0/ 73	0/ 75	NC	NC	NC	>0.999
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	
Malaise						
Female	0/ 73	0/ 75	NC	NC	NC	>0.999
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	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Injection site haematoma						
Female	0/ 73	4/ 75 (5%)				
Male	0/254	7/252 (3%)				
Discomfort						
Female	3/ 73 (4%)	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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 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	1/ 75 (1%)				
Male	3/254 (1%)	3/252 (1%)				
Injection site warmth						
Female	1/ 73 (1%)	1/ 75 (1%)				
Male	2/254 (<1%)	2/252 (<1%)				
Chest pain						
Female	1/ 73 (1%)	2/ 75 (3%)				
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)

Injection site anaesthesia						
Female	1/ 73 (1%)	0/ 75				
Male	3/254 (1%)	1/252 (<1%)				
Feeling hot						
Female	0/ 73	0/ 75				
Male	4/254 (2%)	0/252				
Nodule						
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.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Cyst						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	1/252 (<1%)				
Injection site discolouration						
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)

Injection site haemorrhage						
Female	0/ 73	0/ 75				
Male	0/254	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)
Mass						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Peripheral swelling						
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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity 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	2/254 (<1%)	0/252				
Vaccination site pain						
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)

Vessel puncture site haematoma						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	1/252 (<1%)				
Adverse drug reaction						
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)

Chest discomfort						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Chronic fatigue 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.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)
Enanthema						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				
Feeling abnormal						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity 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%)				
Injection site hypoaesthesia						
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)

Injection site mass						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Injection site 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.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only 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)

Non-cardiac chest pain						
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.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)

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				
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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity 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)
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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity 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	18/ 73 (25%)	21/ 75 (28%)	0.8416 (0.4043, 1.7516) /0.645	-3.3425 (-17.5206, 10.8356) /0.644	0.8806 (0.5128, 1.5124) /0.645	0.994
Male	93/254 (37%)	105/252 (42%)	0.8087 (0.5656, 1.1564) /0.245	-5.0525 (-13.5467, 3.4417) /0.244	0.8787 (0.7066, 1.0928) /0.245	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)
Nasopharyngitis						
Female	7/ 73 (10%)	15/ 75 (20%)	0.4242 (0.1620, 1.1112) /0.081	-10.4110 (-21.7058, 0.8838) /0.071	0.4795 (0.2075, 1.1076) /0.085	0.170
Male	34/254 (13%)	37/252 (15%)	0.8980 (0.5435, 1.4838) /0.675	-1.2967 (-7.3490, 4.7556) /0.675	0.9117 (0.5920, 1.4040) /0.675	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)
Upper respiratory tract infection						
Female	4/ 73 (5%)	5/ 75 (7%)	0.8116 (0.2091, 3.1501) /0.763	-1.1872 (-8.8764, 6.5020) /0.762	0.8219 (0.2297, 2.9405) /0.763	0.855
Male	27/254 (11%)	37/252 (15%)	0.6912 (0.4068, 1.1742) /0.172	-4.0526 (-9.8374, 1.7321) /0.170	0.7240 (0.4550, 1.1520) /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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity 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	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	0.423
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 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)
Syphilis Female	0/ 73	0/ 75	NC	NC	NC	NC
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	
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	0.624
Male	6/254 (2%)	10/252 (4%)	0.5855 (0.2095, 1.6359) /0.307	-1.6060 (-4.6552, 1.4431) /0.302	0.5953 (0.2196, 1.6133) /0.308	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)
Gonorrhoea Female	0/ 73	0/ 75	NC	NC	NC	NC
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	
Influenza 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	0.174
Male	12/254 (5%)	4/252 (2%)	3.0744 (0.9780, 9.6645) /0.055	3.1371 (0.1058, 6.1684) /0.043	2.9764 (0.9730, 9.1047) /0.056	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Bronchitis 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	0.384
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.

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)
Sinusitis 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	0.166
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	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Chlamydial infection						
Female	0/ 73	0/ 75	NC	NC	NC	>0.999
Male	8/254 (3%)	5/252 (2%)	1.6065 (0.5183, 4.9792) /0.411	1.1655 (-1.5873, 3.9183) /0.407	1.5874 (0.5265, 4.7864) /0.412	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Conjunctivitis						
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	0.064
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.

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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)
Rhinitis 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	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Viral infection						
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	0.144
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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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity 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						
Female	3/ 73 (4%)	1/ 75 (1%)				
Male	4/254 (2%)	4/252 (2%)				
Folliculitis						
Female	1/ 73 (1%)	0/ 75	>999 (>999, >999) /NC	3.6449 (-19.9869, 27.2768) /0.762	>999 (>999, >999) /NC	0.133
Male	3/254 (1%)	7/252 (3%)	0.4183 (0.1069, 1.6363) /0.210	-1.5967 (-4.0220, 0.8286) /0.197	0.4252 (0.1112, 1.6258) /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.

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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 herpes						
Female	0/ 73	2/ 75 (3%)				
Male	2/254 (<1%)	7/252 (3%)				
Respiratory tract infection viral						
Female	0/ 73	2/ 75 (3%)				
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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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity 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	NC	NC	NC	>0.999
Male	3/254 (1%)	7/252 (3%)	0.4183 (0.1069, 1.6363) /0.210	-1.5967 (-4.0220, 0.8286) /0.197	0.4252 (0.1112, 1.6258) /0.211	
Urinary tract infection						
Female	2/ 73 (3%)	1/ 75 (1%)				
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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity 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%)	6/252 (2%)				
Viral upper respiratory tract infection						
Female	1/ 73 (1%)	1/ 75 (1%)				
Male	1/254 (<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= 1

System Organ Class Preferred Term	Q8W (N=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	3/254 (1%)	4/252 (2%)				
Onychomycosis						
Female	1/ 73 (1%)	0/ 75				
Male	1/254 (<1%)	5/252 (2%)				
Proctitis gonococcal						
Female	0/ 73	0/ 75				
Male	4/254 (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.

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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)
-----	-----	-----	-----	-----	-----	-----
Tooth abscess						
Female	0/ 73	1/ 75 (1%)				
Male	2/254 (<1%)	4/252 (2%)				
Anal chlamydia infection						
Female	0/ 73	0/ 75				
Male	5/254 (2%)	1/252 (<1%)				
Ear infection						
Female	0/ 73	2/ 75 (3%)				
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)

Fungal skin infection						
Female	0/ 73	0/ 75				
Male	3/254 (1%)	3/252 (1%)				
Gingivitis						
Female	0/ 73	2/ 75 (3%)				
Male	3/254 (1%)	1/252 (<1%)				
Herpes simplex						
Female	1/ 73 (1%)	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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity 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	2/254 (<1%)	3/252 (1%)				
Herpes zoster						
Female	0/ 73	2/ 75 (3%)				
Male	2/254 (<1%)	1/252 (<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)
Lower respiratory tract infection						
Female	1/ 73 (1%)	0/ 75				
Male	4/254 (2%)	0/252				
Oropharyngeal gonococcal infection						
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.

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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)

Tooth infection						
Female	0/ 73	2/ 75 (3%)				
Male	0/254	3/252 (1%)				
Furuncle						
Female	1/ 73 (1%)	0/ 75				
Male	2/254 (<1%)	1/252 (<1%)				
Otitis externa						
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only 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)

Acarodermatitis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	2/252 (<1%)				
Body tinea						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	1/252 (<1%)				
Diverticulitis						
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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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 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	3/252 (1%)				
Secondary syphilis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	2/252 (<1%)				
Tinea cruris						
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.

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)

Tinea infection						
Female	0/ 73	0/ 75				
Male	0/254	3/252 (1%)				
Urethritis gonococcal						
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)
Vaginal infection						
Female	1/ 73 (1%)	2/ 75 (3%)				
Male	0/254	0/252				
Viral pharyngitis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	2/252 (<1%)				
Cellulitis						
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.

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)

Chronic sinusitis						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	0/252				
Enteritis infectious						
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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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)

Lymphogranulo ma 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%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only 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 genitalium infection						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				
Oral candidiasis						
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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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)
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.

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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)
Postoperative wound infection						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Primary syphilis						
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.

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)

Skin infection						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	0/252				
Staphylococcal infection						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Tinea pedis						
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)
Tracheitis Female	0/ 73	1/ 75 (1%)				
Male	0/254	1/252 (<1%)				
Urethritis chlamydial Female	0/ 73	0/ 75				
Male	2/254 (<1%)	0/252				
Abscess limb 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)
Acute sinusitis						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Arthropod infestation						
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)

Borrelia infection						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for 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 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity 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 of male external genital organ						
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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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)
Conjunctivitis viral						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Cystitis						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Diarrhoea 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				
Epididymitis						
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.

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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)
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.

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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 infection						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Gastritis viral						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Gastrointestinal infection						
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)

Genital herpes						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				
Genital herpes simplex						
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)
Giardiasis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
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				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Hepatitis C						
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.

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 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.

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)
Localised infection						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only 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 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				
Pericoronitis						
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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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)

Peritonsillar abscess						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Pharyngeal chlamydia 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.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only 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 bacterial						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Pharyngitis mycoplasmal						
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)

Pharyngitis streptococcal						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Pharyngotonsillitis						
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)
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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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity 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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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity 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)

Sexually transmitted disease						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Staphylococcal skin 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= 1

System Organ Class Preferred Term	Q8W (N=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	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Syphilis genital						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Tinea capitis						
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)

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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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity 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%)				
Urethritis mycoplasmal						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Varicella						
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)
Viral rash						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
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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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity 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	9/ 73 (12%)	14/ 75 (19%)	0.6127 (0.2472, 1.5190) /0.290	-6.3379 (-17.9414, 5.2656) /0.284	0.6605 (0.3049, 1.4306) /0.293	0.376
Male	58/254 (23%)	60/252 (24%)	0.9469 (0.6271, 1.4299) /0.795	-0.9749 (-8.3439, 6.3941) /0.795	0.9591 (0.6992, 1.3155) /0.795	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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%)	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	0.542
Male	22/254 (9%)	18/252 (7%)	1.2328 (0.6443, 2.3587) /0.527	1.5186 (-3.1799, 6.2170) /0.526	1.2126 (0.6668, 2.2052) /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.

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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	1/ 73 (1%)	3/ 75 (4%)	0.3333 (0.0339, 3.2806) /0.346	-2.6301 (-7.8049, 2.5446) /0.319	0.3425 (0.0365, 3.2173) /0.348	0.904
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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity 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)
Constipation 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	0.769
Male	1/254 (<1%)	9/252 (4%)	0.1067 (0.0134, 0.8487) /0.034	-3.1777 (-5.5949, -0.7605) /0.010	0.1102 (0.0141, 0.8637) /0.036	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for 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 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity 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)
Dyspepsia 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	0.097
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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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)
Haemorrhoids						
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	0.560
Male	2/254 (<1%)	10/252 (4%)	0.1921 (0.0417, 0.8856) /0.034	-3.1809 (-5.8248, -0.5369) /0.018	0.1984 (0.0439, 0.8966) /0.036	
Abdominal pain						
Female	2/ 73 (3%)	1/ 75 (1%)				
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)
Abdominal distension						
Female	1/ 73 (1%)	0/ 75				
Male	6/254 (2%)	3/252 (1%)				
Toothache						
Female	1/ 73 (1%)	0/ 75				
Male	5/254 (2%)	4/252 (2%)				
Abdominal pain upper						
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Gastrooesophageal reflux disease						
Female	0/ 73	0/ 75				
Male	5/254 (2%)	2/252 (<1%)				
Rectal haemorrhage						
Female	0/ 73	0/ 75				
Male	1/254 (<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= 1

System Organ Class Preferred Term	Q8W (N=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	2/ 75 (3%)				
Male	3/254 (1%)	1/252 (<1%)				
Abdominal discomfort						
Female	1/ 73 (1%)	2/ 75 (3%)				
Male	1/254 (<1%)	1/252 (<1%)				
Anogenital dysplasia						
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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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity 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)
Dental caries						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	3/252 (1%)				
Flatulence						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	3/252 (1%)				
Abdominal pain lower						
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only 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)
Food poisoning						
Female	0/ 73	0/ 75				
Male	4/254 (2%)	0/252				
Gastritis						
Female	0/ 73	1/ 75 (1%)				
Male	1/254 (<1%)	2/252 (<1%)				
Haematochezia						
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.

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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)
Hiatus hernia						
Female	1/ 73 (1%)	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Proctalgia						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	1/252 (<1%)				
Rectal discharge						
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)
Anal fissure						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				
Anal pruritus						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Diverticulum intestinal						
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= 1

System Organ Class Preferred Term	Q8W (N=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				
Inguinal hernia						
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)
Irritable bowel syndrome						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Mouth ulceration						
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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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity 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%)				
Oesophagitis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<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 ulcer						
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				
Anorectal discomfort						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Chapped lips						
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)
Cheilitis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Dysphagia						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Enteritis						
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)
Enterocolitis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Faeces soft						
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)
Gastric ulcer						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
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%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only 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)
Haematemesis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Hypertrophic anal papilla						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Hypoaesthesia oral						
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)
Large intestine polyp						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Oral 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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity 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 lichen planus						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				
Pancreatitis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Perianal 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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity 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						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Rectal tenesmus						
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)
Salivary gland mucocoele						
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.

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)
Musculoskeletal and connective tissue disorders						
Any Event						
Female	11/ 73 (15%)	17/ 75 (23%)	0.6053 (0.2617, 1.4003) /0.241	-7.5982 (-20.1332, 4.9369) /0.235	0.6648 (0.3346, 1.3208) /0.244	0.473
Male	47/254 (19%)	53/252 (21%)	0.8525 (0.5500, 1.3214) /0.476	-2.5278 (-9.4650, 4.4094) /0.475	0.8798 (0.6188, 1.2509) /0.476	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Back pain 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	0.266
Male	20/254 (8%)	17/252 (7%)	1.1815 (0.6037, 2.3122) /0.626	1.1280 (-3.4064, 5.6624) /0.626	1.1672 (0.6262, 2.1755) /0.626	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Arthralgia 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	0.644
Male	10/254 (4%)	11/252 (4%)	0.8979 (0.3744, 2.1533) /0.809	-0.4281 (-3.9042, 3.0481) /0.809	0.9019 (0.3900, 2.0860) /0.809	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)
Pain in extremity						
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	0.174
Male	9/254 (4%)	14/252 (6%)	0.6245 (0.2653, 1.4701) /0.281	-2.0122 (-5.6409, 1.6164) /0.277	0.6378 (0.2812, 1.4467) /0.282	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Myalgia						
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	
Musculoskeletal pain						
Female	1/ 73 (1%)	1/ 75 (1%)				
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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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)
Tendonitis						
Female	1/ 73 (1%)	0/ 75				
Male	5/254 (2%)	1/252 (<1%)				
Muscle spasms						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	4/252 (2%)				
Muscle contracture						
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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	3/254 (1%)	1/252 (<1%)				
Spinal osteoarthritis						
Female	0/ 73	2/ 75 (3%)				
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)
Intervertebral disc protrusion						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	2/252 (<1%)				
Neck pain						
Female	0/ 73	0/ 75				
Male	3/254 (1%)	0/252				
Bursitis						
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)
Flank pain						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	0/252				
Joint contracture						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				
Joint swelling						
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)
Musculoskeletal stiffness						
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%)				
Groin 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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only 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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity 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)

Limb discomfort						
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)
Muscular weakness						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Musculoskeletal discomfort						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Myosclerosis						
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)

Osteochondritis						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Osteopenia						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity 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)
Plantar fasciitis						
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				
Sacroiliitis						
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)
Scoliosis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Spinal disorder						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				
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.

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)

Skin and subcutaneous tissue disorders						
Any Event						
Female	8/ 73 (11%)	16/ 75 (21%)	0.4538 (0.1811, 1.1376) /0.092	-10.3744 (-22.0922, 1.3434) /0.083	0.5137 (0.2343, 1.1264) /0.096	0.155
Male	45/254 (18%)	47/252 (19%)	0.9391 (0.5977, 1.4756) /0.785	-0.9343 (-7.6555, 5.7870) /0.785	0.9499 (0.6563, 1.3749) /0.785	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)
Pruritus 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	0.107
Male	8/254 (3%)	5/252 (2%)	1.6065 (0.5183, 4.9792) /0.411	1.1655 (-1.5873, 3.9183) /0.407	1.5874 (0.5265, 4.7864) /0.412	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for 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 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity 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	0.685
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	
Eczema						
Female	1/ 73 (1%)	6/ 75 (8%)				
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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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity 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)
Acne						
Female	1/ 73 (1%)	1/ 75 (1%)				
Male	1/254 (<1%)	6/252 (2%)				
Alopecia						
Female	3/ 73 (4%)	0/ 75				
Male	3/254 (1%)	1/252 (<1%)				
Dermatitis						
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.

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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 lesion						
Female	0/ 73	1/ 75 (1%)				
Male	4/254 (2%)	2/252 (<1%)				
Dermatitis contact						
Female	1/ 73 (1%)	0/ 75				
Male	2/254 (<1%)	3/252 (1%)				
Seborrhoeic dermatitis						
Female	0/ 73	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)
Hyperhidrosis						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	3/252 (1%)				
Dermatitis atopic						
Female	0/ 73	0/ 75				
Male	0/254	3/252 (1%)				
Dry skin						
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)
Erythema						
Female	0/ 73	1/ 75 (1%)				
Male	1/254 (<1%)	1/252 (<1%)				
Night sweats						
Female	0/ 73	0/ 75				
Male	3/254 (1%)	0/252				
Skin exfoliation						
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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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity 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	1/ 73 (1%)	0/ 75				
Male	0/254	2/252 (<1%)				
Urticaria						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	1/252 (<1%)				
Actinic keratosis						
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)
Chloasma						
Female	1/ 73 (1%)	1/ 75 (1%)				
Male	0/254	0/252				
Dermal cyst						
Female	1/ 73 (1%)	0/ 75				
Male	1/254 (<1%)	0/252				
Pityriasis rosea						
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= 1

System Organ Class Preferred Term	Q8W (N=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	2/252 (<1%)				
Rash erythematous						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				
Rash papular						
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= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Actinic elastosis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Androgenetic alopecia						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Cold sweat						
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)

Dermatosis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
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				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)

Eczema asteatotic						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				
Hyperkeratosis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Intertrigo						
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)

Keratosis pilaris						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				
Macule						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Miliaria						
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)
Nail bed bleeding						
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.

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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)

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.

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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)
Pityriasis						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Prurigo						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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 macular						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Skin irritation						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Skin ulcer						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
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.

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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)
Solar lentigo						
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)
Respiratory, thoracic and mediastinal disorders						
Any Event						
Female	8/ 73 (11%)	15/ 75 (20%)	0.4923 (0.1948, 1.2441) /0.134	-9.0411 (-20.5867, 2.5045) /0.125	0.5479 (0.2474, 1.2137) /0.138	0.448
Male	32/254 (13%)	41/252 (16%)	0.7418 (0.4503, 1.2221) /0.241	-3.6714 (-9.7886, 2.4457) /0.239	0.7743 (0.5046, 1.1882) /0.242	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only 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)
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	0.610
Male	13/254 (5%)	17/252 (7%)	0.7457 (0.3543, 1.5694) /0.440	-1.6279 (-5.7430, 2.4872) /0.438	0.7587 (0.3765, 1.5290) /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.

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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)
Oropharyngeal pain						
Female	5/ 73 (7%)	5/ 75 (7%)	1.0294 (0.2852, 3.7162) /0.965	0.1826 (-7.9071, 8.2724) /0.965	1.0274 (0.3104, 3.4008) /0.965	0.307
Male	5/254 (2%)	11/252 (4%)	0.4399 (0.1506, 1.2850) /0.133	-2.3966 (-5.4432, 0.6501) /0.123	0.4510 (0.1590, 1.2793) /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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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity 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 congestion						
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	0.182
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	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only 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)
Rhinitis allergic						
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	
Sinus congestion						
Female	0/ 73	1/ 75 (1%)				
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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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity 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)
Epistaxis						
Female	0/ 73	1/ 75 (1%)				
Male	1/254 (<1%)	2/252 (<1%)				
Rhinorrhoea						
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.

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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)
Dyspnoea						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	1/252 (<1%)				
Sleep apnoea syndrome						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	2/252 (<1%)				
Catarrh						
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= 1

System Organ Class Preferred Term	Q8W (N=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%)				
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%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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 disorder						
Female	0/ 73	2/ 75 (3%)				
Male	0/254	0/252				
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.

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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)
Emphysema						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
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				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)
Nasal discomfort						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)
Painful respiration						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Pharyngeal 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.

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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)
Pleuritic pain						
Female	1/ 73 (1%)	0/ 75				
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for 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						
Female	4/ 73 (5%)	8/ 75 (11%)	0.4855 (0.1396, 1.6885) /0.256	-5.1872 (-13.9085, 3.5341) /0.244	0.5137 (0.1617, 1.6324) /0.259	0.261
Male	41/254 (16%)	40/252 (16%)	1.0202 (0.6343, 1.6409) /0.934	0.2687 (-6.1209, 6.6584) /0.934	1.0169 (0.6822, 1.5159) /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.

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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)
Headache 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	0.607
Male	20/254 (8%)	17/252 (7%)	1.1815 (0.6037, 2.3122) /0.626	1.1280 (-3.4064, 5.6624) /0.626	1.1672 (0.6262, 2.1755) /0.626	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)
Dizziness						
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	0.782
Male	14/254 (6%)	9/252 (4%)	1.5750 (0.6690, 3.7078) /0.298	1.9404 (-1.6826, 5.5634) /0.294	1.5433 (0.6804, 3.5008) /0.299	
Presyncope						
Female	0/ 73	3/ 75 (4%)				
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.

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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)
Paraesthesia						
Female	1/ 73 (1%)	1/ 75 (1%)				
Male	1/254 (<1%)	3/252 (1%)				
Migraine						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	4/252 (2%)				
Somnolence						
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.

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)
Hypoaesthesia						
Female	0/ 73	0/ 75				
Male	3/254 (1%)	1/252 (<1%)				
Lethargy						
Female	0/ 73	0/ 75				
Male	3/254 (1%)	1/252 (<1%)				
Carpal tunnel syndrome						
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.

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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	1/254 (<1%)	1/252 (<1%)				
Syncope Female	0/ 73	1/ 75 (1%)				
Male	1/254 (<1%)	0/252				
Tension headache 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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only 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)

Agnosia						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Amnesia						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Ataxia						
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)

Burning sensation						
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%)				
Memory impairment						
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)
Muscle contractions involuntary						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Periodic limb movement 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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity 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)

Polyneuropathy						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Tremor						
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)

Injury, poisoning and procedural complications						
Any Event						
Female	2/ 73 (3%)	6/ 75 (8%)	0.3239 (0.0632, 1.6604) /0.176	-5.2603 (-12.4519, 1.9314) /0.152	0.3425 (0.0714, 1.6420) /0.180	0.552
Male	24/254 (9%)	43/252 (17%)	0.5072 (0.2975, 0.8646) /0.013	-7.6147 (-13.4894, -1.7399) /0.011	0.5537 (0.3468, 0.8842) /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.

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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)
Contusion 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	0.182
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	
Arthropod bite Female	0/ 73	3/ 75 (4%)				
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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity 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	2/254 (<1%)	7/252 (3%)				
Muscle strain						
Female	0/ 73	1/ 75 (1%)				
Male	3/254 (1%)	5/252 (2%)				
Limb injury						
Female	0/ 73	1/ 75 (1%)				
Male	5/254 (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)

Exposure to communicable disease						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	4/252 (2%)				
Skin laceration						
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= 1

System Organ Class Preferred Term	Q8W (N=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						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	2/252 (<1%)				
Foot fracture						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	2/252 (<1%)				
Procedural pain						
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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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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	1/ 75 (1%)				
Male	2/254 (<1%)	0/252				
Vaccination complication						
Female	0/ 73	0/ 75				
Male	0/254	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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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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	1/ 75 (1%)				
Male	1/254 (<1%)	0/252				
Epicondylitis						
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%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)
Concussion						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Eye injury						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity 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)
Hand 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				
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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity 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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity 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%)				
Rib fracture						
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.

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)
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%)				
Thermal burn						
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.

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)

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%)				
Wound						
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	Q8W (N=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	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	0.036
Male	31/254 (12%)	26/252 (10%)	1.2083 (0.6950, 2.1008) /0.502	1.8873 (-3.6182, 7.3928) /0.502	1.1829 (0.7238, 1.9333) /0.503	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Insomnia 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	0.971
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)
Anxiety 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	0.153
Male	10/254 (4%)	5/252 (2%)	2.0246 (0.6821, 6.0096) /0.204	1.9529 (-0.9941, 4.8998) /0.194	1.9843 (0.6880, 5.7232) /0.205	
Abnormal dreams Female	0/ 73	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)

Depressed mood						
Female	0/ 73	0/ 75				
Male	4/254 (2%)	1/252 (<1%)				
Libido decreased						
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.

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)
Sleep disorder						
Female	0/ 73	0/ 75				
Male	0/254	5/252 (2%)				
Depression						
Female	0/ 73	1/ 75 (1%)				
Male	2/254 (<1%)	1/252 (<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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for 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 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity 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						
Female	0/ 73	2/ 75 (3%)				
Male	1/254 (<1%)	0/252				
Adjustment disorder with depressed mood						
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)

Adjustment disorder with mixed anxiety and depressed mood						
Female	0/ 73	1/ 75 (1%)				
Male	1/254 (<1%)	0/252				
Drug abuse						
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)
Irritability						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Acute stress disorder						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Agoraphobia						
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.

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)
Alcohol withdrawal syndrome						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Attention deficit hyperactivity 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)
Generalised anxiety disorder						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
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.

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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)

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.

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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)
Panic attack						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Post-traumatic stress disorder						
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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity 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)
Suicidal ideation						
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)
Investigations						
Any Event						
Female	0/ 73	6/ 75 (8%)	<0.0001 (<0.0001, -) />0.999	-10.0350 (-34.1728, 14.1027) /0.415	<0.0001 (<0.0001, -) />0.999	0.012
Male	16/254 (6%)	20/252 (8%)	0.7798 (0.3944, 1.5421) /0.475	-1.6373 (-6.1167, 2.8421) /0.474	0.7937 (0.4211, 1.4960) /0.475	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)

Weight increased						
Female	0/ 73	0/ 75				
Male	4/254 (2%)	4/252 (2%)				
Body temperature increased						
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)
Alanine aminotransferase increased						
Female	0/ 73	0/ 75				
Male	3/254 (1%)	2/252 (<1%)				
Blood creatine phosphokinase increased						
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.

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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)

Blood pressure increased						
Female	0/ 73	2/ 75 (3%)				
Male	2/254 (<1%)	1/252 (<1%)				
Blood cholesterol increased						
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only 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 triglycerides increased						
Female	0/ 73	0/ 75				
Male	0/254	3/252 (1%)				
Low density lipoprotein increased						
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)

Weight decreased						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	1/252 (<1%)				
Aspartate aminotransferase 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)
Blood creatinine increased						
Female	0/ 73	0/ 75				
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

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.

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 pressure decreased						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Chlamydia 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)
Electrocardiogram abnormal						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Epstein-Barr virus 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)

Escherichia test positive						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Haematocrit 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)
Haemoglobin increased						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)

Transaminases increased						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
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%)	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	0.463
Male	11/254 (4%)	19/252 (8%)	0.5551 (0.2586, 1.1918) /0.131	-3.2090 (-7.3191, 0.9011) /0.126	0.5744 (0.2791, 1.1822) /0.132	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)

Anogenital warts						
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	0.363
Male	5/254 (2%)	9/252 (4%)	0.5422 (0.1791, 1.6409) /0.279	-1.6029 (-4.4610, 1.2551) /0.272	0.5512 (0.1873, 1.6218) /0.279	
Skin papilloma						
Female	0/ 73	2/ 75 (3%)				
Male	3/254 (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= 1

System Organ Class Preferred Term	Q8W (N=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%)				
Lipoma						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Lipoma of breast						
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)
Acrochordon						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Adenoma benign						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)
Benign neoplasm of thyroid gland						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Fibroma						
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)

Kaposi's sarcoma						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Urethral papilloma						
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)
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 Preferred Term	Q8W (N=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	6/ 73 (8%)	4/ 75 (5%)	1.5896 (0.4296, 5.8820) /0.488	2.8858 (-5.2109, 10.9826) /0.485	1.5411 (0.4534, 5.2379) /0.488	0.476
Male	10/254 (4%)	11/252 (4%)	0.8979 (0.3744, 2.1533) /0.809	-0.4281 (-3.9042, 3.0481) /0.809	0.9019 (0.3900, 2.0860) /0.809	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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	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	0.785
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	
Haematoma						
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.

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)
Varicose vein						
Female	1/ 73 (1%)	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Flushing						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	1/252 (<1%)				
Hot flush						
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.

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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%)				
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.

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)
Peripheral coldness						
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)

Reproductive system and breast disorders						
Any Event						
Female	4/ 73 (5%)	2/ 75 (3%)	2.1159 (0.3755, 11.9232) /0.396	2.8128 (-3.5550, 9.1806) /0.387	2.0548 (0.3882, 10.8774) /0.397	0.543
Male	13/254 (5%)	11/252 (4%)	1.1818 (0.5192, 2.6902) /0.691	0.7530 (-2.9494, 4.4555) /0.690	1.1725 (0.5354, 2.5676) /0.691	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only 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)

Erectile dysfunction						
Female	0/ 73	0/ 75				
Male	4/254 (2%)	4/252 (2%)				
Menorrhagia						
Female	1/ 73 (1%)	2/ 75 (3%)				
Male	0/254	0/252				
Balanoposthitis						
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)
Breast cyst						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	1/252 (<1%)				
Genital lesion						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	0/252				
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				
Breast mass						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only 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 dysplasia						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
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.

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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 discomfort						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Penile pain						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Penile 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.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)

Premenstrual syndrome						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Sexual dysfunction						
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)

Testicular cyst						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
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.

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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)

Testicular swelling						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
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				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)
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.

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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)

Renal and urinary disorders						
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	0.450
Male	3/254 (1%)	16/252 (6%)	0.1763 (0.0507, 0.6128) /0.006	-5.1681 (-8.4589, -1.8773) /0.002	0.1860 (0.0549, 0.6306) /0.007	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)
Dysuria						
Female	1/ 73 (1%)	2/ 75 (3%)				
Male	1/254 (<1%)	6/252 (2%)				
Nocturia						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	1/252 (<1%)				
Haematuria						
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)

Micturition urgency						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				
Nephrolithiasis						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				
Renal cyst						
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= 1

System Organ Class Preferred Term	Q8W (N=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 discharge						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				
Nephropathy						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Pollakiuria						
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= 1

System Organ Class Preferred Term	Q8W (N=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						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Urethral pain						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Urinary incontinence						
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)
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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity 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 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	0.718
Male	9/254 (4%)	11/252 (4%)	0.8048 (0.3276, 1.9770) /0.636	-0.8218 (-4.2177, 2.5742) /0.635	0.8117 (0.3423, 1.9251) /0.636	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)
Tinnitus						
Female	0/ 73	0/ 75				
Male	3/254 (1%)	2/252 (<1%)				
Vertigo						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	3/252 (1%)				
Cerumen impaction						
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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity 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%)				
Ear 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.

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)

Eustachian tube dysfunction						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<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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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)

Deafness neurosensory						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Ear pruritus						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
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.

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%)	5/ 75 (7%)	0.1944 (0.0222, 1.7066) /0.139	-5.2968 (-11.5402, 0.9466) /0.096	0.2055 (0.0246, 1.7165) /0.144	0.025
Male	11/254 (4%)	5/252 (2%)	2.2362 (0.7656, 6.5315) /0.141	2.3466 (-0.6916, 5.3848) /0.130	2.1827 (0.7694, 6.1917) /0.142	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for 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 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity 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	2/254 (<1%)	1/252 (<1%)				
Decreased appetite						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	2/252 (<1%)				
Gout						
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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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)
Vitamin D deficiency						
Female	0/ 73	1/ 75 (1%)				
Male	2/254 (<1%)	0/252				
Alcoholic ketoacidosis						
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)

Diabetes mellitus						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Dyslipidaemia						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Gluten sensitivity						
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)

Hyperglycaemia ^a						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Hyperlipasaemia						
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only 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						
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.

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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 2 diabetes mellitus						
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)

Eye disorders						
Any Event						
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	0.108
Male	5/254 (2%)	11/252 (4%)	0.4399 (0.1506, 1.2850) /0.133	-2.3966 (-5.4432, 0.6501) /0.123	0.4510 (0.1590, 1.2793) /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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity 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 allergic						
Female	0/ 73	1/ 75 (1%)				
Male	1/254 (<1%)	2/252 (<1%)				
Blepharitis						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				
Cataract						
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)
Dry eye						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	1/252 (<1%)				
Astigmatism						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Diplopia						
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)

Eczema eyelids						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
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%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only 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)
Glaucoma						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Iritis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Mydriasis						
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)
Ocular hyperaemia						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
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%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only 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)

Vitreous detachment						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
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.

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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)
Blood and lymphatic system disorders						
Any Event						
Female	1/ 73 (1%)	3/ 75 (4%)	0.3333 (0.0339, 3.2806) /0.346	-2.6301 (-7.8049, 2.5446) /0.319	0.3425 (0.0365, 3.2173) /0.348	0.692
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	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)

Lymphadenopathy						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	4/252 (2%)				
Anaemia						
Female	0/ 73	3/ 75 (4%)				
Male	0/254	2/252 (<1%)				
Microcytic anaemia						
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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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity 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.

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)

Polycythaemia						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Immune system disorders						
Any Event						
Female	0/ 73	3/ 75 (4%)				
Male	7/254 (3%)	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.

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)

Seasonal allergy						
Female	0/ 73	3/ 75 (4%)				
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.

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)

Anaphylactic reaction						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Cardiac disorders						
Any Event						
Female	0/ 73	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.

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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)
Palpitations						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				
Tachycardia						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	1/252 (<1%)				
Atrioventricular block first degree						
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 Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Wolff-Parkinson-White syndrome						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Endocrine disorders						
Any Event						
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.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Hypogonadism						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				
Androgen deficiency						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
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)

Hepatobiliary disorders						
Any Event						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only 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)

Hepatic steatosis						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				
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 Preferred Term	Q8W (N=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	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Gilbert's 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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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity 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				
Social circumstances						
Any Event						
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.

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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)
Menopause						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				
Stress at work						
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	29/ 73 (40%)	40/ 75 (53%)	0.5767 (0.3004, 1.1073) /0.098	-13.6073 (-29.5284, 2.3138) /0.094	0.7449 (0.5233, 1.0603) /0.102	0.047
Male	147/254 (58%)	133/252 (53%)	1.2292 (0.8654, 1.7461) /0.249	5.0962 (-3.5562, 13.7486) /0.248	1.0966 (0.9372, 1.2830) /0.250	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for 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 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity 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	19/ 73 (26%)	25/ 75 (33%)	0.7037 (0.3460, 1.4310) /0.332	-7.3059 (-21.9735, 7.3616) /0.329	0.7808 (0.4726, 1.2899) /0.334	0.187
Male	99/254 (39%)	87/252 (35%)	1.2113 (0.8435, 1.7397) /0.299	4.4526 (-3.9397, 12.8448) /0.298	1.1290 (0.8976, 1.4200) /0.300	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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 pain						
Female	18/ 73 (25%)	21/ 75 (28%)	0.8416 (0.4043, 1.7516) /0.645	-3.3425 (-17.5206, 10.8356) /0.644	0.8806 (0.5128, 1.5124) /0.645	0.384
Male	89/254 (35%)	77/252 (31%)	1.2259 (0.8452, 1.7781) /0.283	4.4838 (-3.6875, 12.6552) /0.282	1.1467 (0.8928, 1.4730) /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.

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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 nodule						
Female	4/ 73 (5%)	8/ 75 (11%)	0.4855 (0.1396, 1.6885) /0.256	-5.1872 (-13.9085, 3.5341) /0.244	0.5137 (0.1617, 1.6324) /0.259	0.930
Male	5/254 (2%)	9/252 (4%)	0.5422 (0.1791, 1.6409) /0.279	-1.6029 (-4.4610, 1.2551) /0.272	0.5512 (0.1873, 1.6218) /0.279	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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 induration						
Female	2/ 73 (3%)	2/ 75 (3%)				
Male	3/254 (1%)	1/252 (<1%)				
Injection site discomfort						
Female	1/ 73 (1%)	3/ 75 (4%)				
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.

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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)
Pyrexia Female	1/ 73 (1%)	0/ 75	>999 (>999, >999) /NC	3.6449 (-19.9869, 27.2768) /0.762	>999 (>999, >999) /NC	0.181
Male	6/254 (2%)	9/252 (4%)	0.6532 (0.2290, 1.8630) /0.426	-1.2092 (-4.1652, 1.7468) /0.423	0.6614 (0.2389, 1.8309) /0.426	
Fatigue 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.

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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 swelling						
Female	5/ 73 (7%)	2/ 75 (3%)				
Male	5/254 (2%)	4/252 (2%)				
Injection site pruritus						
Female	1/ 73 (1%)	2/ 75 (3%)				
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)

Injection site erythema						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				
Influenza like illness						
Female	0/ 73	1/ 75 (1%)				
Male	3/254 (1%)	2/252 (<1%)				
Asthenia						
Female	0/ 73	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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for 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 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity 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)

Chills						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	1/252 (<1%)				
Injection site bruising						
Female	1/ 73 (1%)	2/ 75 (3%)				
Male	0/254	1/252 (<1%)				
Pain						
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.

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 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)
Malaise						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Injection site haematoma						
Female	0/ 73	0/ 75				
Male	2/254 (<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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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=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	1/254 (<1%)	0/252				
Injection site warmth						
Female	1/ 73 (1%)	1/ 75 (1%)				
Male	1/254 (<1%)	2/252 (<1%)				
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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity 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 anaesthesia						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Feeling hot						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Nodule						
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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity 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)
Mass						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
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)

Vessel puncture site haematoma						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
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.

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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)

Gait disturbance						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Non-cardiac chest 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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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=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.

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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)
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	Q8W (N=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	16/ 73 (22%)	25/ 75 (33%)	0.5614 (0.2696, 1.1690) /0.123	-11.4155 (-25.6941, 2.8631) /0.117	0.6575 (0.3838, 1.1266) /0.127	0.197
Male	80/254 (31%)	82/252 (33%)	0.9532 (0.6561, 1.3849) /0.801	-1.0436 (-9.1734, 7.0862) /0.801	0.9679 (0.7508, 1.2478) /0.801	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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	3/ 73 (4%)	0/ 75	>999 (>999, >999) /NC	6.3175 (-17.3129, 29.9479) /0.600	>999 (>999, >999) /NC	0.060
Male	17/254 (7%)	14/252 (6%)	1.2194 (0.5877, 2.5300) /0.594	1.1374 (-3.0391, 5.3139) /0.594	1.2047 (0.6070, 2.3912) /0.594	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 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%)	8/ 75 (11%)	0.1163 (0.0142, 0.9549) /0.045	-9.2968 (-16.7745, -1.8191) /0.015	0.1284 (0.0165, 1.0013) /0.050	0.049
Male	13/254 (5%)	16/252 (6%)	0.7956 (0.3745, 1.6903) /0.552	-1.2311 (-5.2818, 2.8196) /0.551	0.8061 (0.3960, 1.6409) /0.552	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for 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)
Gastroenteritis						
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	0.039
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	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for 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)
Syphilis						
Female	0/ 73	0/ 75	NC	NC	NC	>0.999
Male	7/254 (3%)	10/252 (4%)	0.6858 (0.2569, 1.8310) /0.452	-1.2123 (-4.3528, 1.9281) /0.449	0.6945 (0.2686, 1.7958) /0.452	
Pharyngitis						
Female	0/ 73	1/ 75 (1%)				
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= 2

System Organ Class Preferred Term	Q8W (N=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	2/254 (<1%)	5/252 (2%)				
Influenza						
Female	2/ 73 (3%)	2/ 75 (3%)				
Male	3/254 (1%)	5/252 (2%)				
Bronchitis						
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.

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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)
Sinusitis						
Female	0/ 73	0/ 75				
Male	5/254 (2%)	3/252 (1%)				
Chlamydial infection						
Female	0/ 73	0/ 75				
Male	4/254 (2%)	3/252 (1%)				
Conjunctivitis						
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for 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 infection						
Female	0/ 73	2/ 75 (3%)				
Male	3/254 (1%)	3/252 (1%)				
Respiratory tract infection						
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.

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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)
Folliculitis						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	0/252				
Oral herpes						
Female	1/ 73 (1%)	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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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=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	2/ 73 (3%)	0/ 75				
Male	2/254 (<1%)	3/252 (1%)				
Urethritis						
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.

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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)

Urinary tract infection						
Female	2/ 73 (3%)	3/ 75 (4%)				
Male	3/254 (1%)	1/252 (<1%)				
Tonsillitis						
Female	1/ 73 (1%)	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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Viral upper respiratory tract infection						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				
Gastroenteritis viral						
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only 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)
Onychomycosis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Proctitis gonococcal						
Female	0/ 73	0/ 75				
Male	3/254 (1%)	6/252 (2%)				
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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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)

Anal chlamydia infection						
Female	0/ 73	0/ 75				
Male	4/254 (2%)	5/252 (2%)				
Ear infection						
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)
Fungal skin infection						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Tinea versicolour						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Herpes zoster						
Female	0/ 73	0/ 75				
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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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)
Hordeolum						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Lower respiratory tract infection						
Female	1/ 73 (1%)	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)

Oropharyngeal gonococcal infection						
Female	0/ 73	0/ 75				
Male	3/254 (1%)	5/252 (2%)				
Tooth infection						
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.

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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)
Furuncle						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Acarodermatitis						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	1/252 (<1%)				
Body tinea						
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)

Diverticulitis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Secondary syphilis						
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)

Urethritis gonococcal						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	2/252 (<1%)				
Viral pharyngitis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Cellulitis						
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 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)
Enteritis infectious						
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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity 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%)				
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				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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	2/254 (<1%)	0/252				
Skin 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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity 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)
Staphylococcal 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				
Urethritis chlamydial						
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.

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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	2/254 (<1%)	2/252 (<1%)				
Acute sinusitis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Bronchitis viral						
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)
Cystitis						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Diarrhoea infectious						
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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity 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	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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity 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 abscess						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	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= 2

System Organ Class Preferred Term	Q8W (N=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	2/254 (<1%)	0/252				
Pharyngitis streptococcal						
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)

Pharyngotonsillitis						
Female	0/ 73	1/ 75 (1%)				
Male	1/254 (<1%)	1/252 (<1%)				
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.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)
Sexually transmitted disease						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Staphylococcal skin 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.

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)

Subcutaneous abscess						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	1/252 (<1%)				
Ureaplasma 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.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)
Urethritis mycoplasmal						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Varicella						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	0/252				
Shigella 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.

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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	1/ 73 (1%)	2/ 75 (3%)				
Male	0/254	0/252				
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)

Pulmonary tuberculosis						
Female	1/ 73 (1%)	0/ 75				
Male	1/254 (<1%)	0/252				
Abscess						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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 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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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 vaginosis						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
COVID-19						
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)

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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)

Device related infection						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Ear infection bacterial						
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)

Eczema infected						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Enterobiasis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
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 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)

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.

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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)

Genitourinary tract infection						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Gonococcal infection						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

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 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)
Herpes ophthalmic						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Herpes virus infection						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Infected bite						
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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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=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%)				
Latent syphilis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Lice infestation						
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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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=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 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)

Perirectal abscess						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Proctitis chlamydial						
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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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=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				
Suspected COVID-19						
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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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=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 staphylococcal						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Wound 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.

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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						
Female	2/ 73 (3%)	7/ 75 (9%)	0.2736 (0.0549, 1.3639) /0.114	-6.5936 (-14.1676, 0.9804) /0.088	0.2935 (0.0631, 1.3666) /0.118	0.284
Male	27/254 (11%)	40/252 (16%)	0.6304 (0.3737, 1.0634) /0.084	-5.2431 (-11.1358, 0.6496) /0.081	0.6697 (0.4245, 1.0566) /0.085	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for 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)
Diarrhoea 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	0.174
Male	9/254 (4%)	14/252 (6%)	0.6245 (0.2653, 1.4701) /0.281	-2.0122 (-5.6409, 1.6164) /0.277	0.6378 (0.2812, 1.4467) /0.282	
Nausea Female	0/ 73	1/ 75 (1%)				
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.

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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%)	1/252 (<1%)				
Dyspepsia						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	3/252 (1%)				
Haemorrhoids						
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.

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)

Abdominal pain						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	1/252 (<1%)				
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%)	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.

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)
Abdominal pain upper						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Gastrooesophageal reflux disease						
Female	0/ 73	0/ 75				
Male	1/254 (<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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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)
Vomiting						
Female	0/ 73	0/ 75				
Male	3/254 (1%)	1/252 (<1%)				
Abdominal discomfort						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Anogenital dysplasia						
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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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity 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)
Abdominal pain lower						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Gastritis						
Female	0/ 73	1/ 75 (1%)				
Male	2/254 (<1%)	0/252				
Haematochezia						
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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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)
Rectal discharge						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Anal fissure						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	1/252 (<1%)				
Dry mouth						
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)
Inguinal hernia						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Irritable bowel 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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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity 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)
Oesophagitis Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Anal fistula Female	0/ 73	0/ 75				
Male	2/254 (<1%)	0/252				
Large intestine 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.

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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 disorder						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Proctitis						
Female	0/ 73	0/ 75				
Male	0/254	3/252 (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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only 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)

Haemorrhoids thrombosed						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				
Tongue ulceration						
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)

Aphthous ulcer						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Crohn's disease						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Dental cyst						
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)

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				
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.

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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 pain						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Periodontal disease						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Rectal prolapse						
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)

Musculoskeletal and connective tissue disorders						
Any Event						
Female	5/ 73 (7%)	9/ 75 (12%)	0.5392 (0.1717, 1.6936) /0.290	-5.1507 (-14.5135, 4.2121) /0.281	0.5708 (0.2008, 1.6224) /0.293	0.626
Male	23/254 (9%)	30/252 (12%)	0.7368 (0.4152, 1.3075) /0.297	-2.8496 (-8.1827, 2.4834) /0.295	0.7606 (0.4547, 1.2724) /0.297	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for 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 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity 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	2/ 73 (3%)	3/ 75 (4%)				
Male	2/254 (<1%)	6/252 (2%)				
Arthralgia 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	0.981
Male	7/254 (3%)	7/252 (3%)	0.9919 (0.3428, 2.8700) /0.988	-0.0219 (-2.8802, 2.8364) /0.988	0.9921 (0.3531, 2.7875) /0.988	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only 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)

Pain in extremity						
Female	0/ 73	1/ 75 (1%)				
Male	2/254 (<1%)	4/252 (2%)				
Myalgia						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	3/252 (1%)				
Musculoskeletal pain						
Female	0/ 73	0/ 75				
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= 2

System Organ Class Preferred Term	Q8W (N=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	1/254 (<1%)	0/252				
Muscle spasms						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	2/252 (<1%)				
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.

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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)
Musculoskeletal chest pain						
Female	1/ 73 (1%)	1/ 75 (1%)				
Male	2/254 (<1%)	1/252 (<1%)				
Intervertebral disc protrusion						
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)
Neck pain						
Female	1/ 73 (1%)	1/ 75 (1%)				
Male	1/254 (<1%)	1/252 (<1%)				
Arthritis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity 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)
Groin pain						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Joint range of motion 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.

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)
Limb discomfort						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Muscular weakness						
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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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)
Musculoskeletal discomfort						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Pain in jaw						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Plantar fasciitis						
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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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity 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)
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				
Synovitis						
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)

Osteoarthritis						
Female	1/ 73 (1%)	1/ 75 (1%)				
Male	1/254 (<1%)	1/252 (<1%)				
Arthritis reactive						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Bone 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= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Loose body in joint						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Periarthritis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Polyarthritis						
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)

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	0.535
Male	15/254 (6%)	18/252 (7%)	0.8159 (0.4017, 1.6571) /0.574	-1.2373 (-5.5402, 3.0655) /0.573	0.8268 (0.4262, 1.6039) /0.574	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only 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	3/254 (1%)	0/252				
Rash						
Female	1/ 73 (1%)	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Eczema						
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.

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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)
Acne						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Alopecia						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity 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 lesion						
Female	1/ 73 (1%)	0/ 75				
Male	2/254 (<1%)	1/252 (<1%)				
Dermatitis contact						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Hyperhidrosis						
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.

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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)

Dermatitis atopic						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Erythema						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Night sweats						
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)

Urticaria						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	1/252 (<1%)				
Dermal cyst						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)
Ecchymosis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Rash maculo-papular						
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)
Granuloma annulare						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Guttate psoriasis						
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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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=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						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)

Nail dystrophy						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Pain of skin						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
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.

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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)

Rash vesicular						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Skin fissures						
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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, thoracic and mediastinal disorders						
Any Event						
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	0.558
Male	10/254 (4%)	18/252 (7%)	0.5328 (0.2409, 1.1781) /0.120	-3.2058 (-7.1846, 0.7729) /0.114	0.5512 (0.2595, 1.1705) /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.

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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)
Cough						
Female	2/ 73 (3%)	0/ 75				
Male	3/254 (1%)	4/252 (2%)				
Oropharyngeal pain						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	3/252 (1%)				
Nasal congestion						
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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity 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)
Rhinitis allergic						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	4/252 (2%)				
Sinus congestion						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
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.

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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)
Asthma						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	2/252 (<1%)				
Dyspnoea						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Sleep apnoea syndrome						
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.

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)

Productive cough						
Female	0/ 73	1/ 75 (1%)				
Male	1/254 (<1%)	0/252				
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.

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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)
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.

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)

Nervous system disorders						
Any Event						
Female	2/ 73 (3%)	6/ 75 (8%)	0.3239 (0.0632, 1.6604) /0.176	-5.2603 (-12.4519, 1.9314) /0.152	0.3425 (0.0714, 1.6420) /0.180	0.307
Male	16/254 (6%)	20/252 (8%)	0.7798 (0.3944, 1.5421) /0.475	-1.6373 (-6.1167, 2.8421) /0.474	0.7937 (0.4211, 1.4960) /0.475	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Headache Female	1/ 73 (1%)	3/ 75 (4%)	0.3333 (0.0339, 3.2806) /0.346	-2.6301 (-7.8049, 2.5446) /0.319	0.3425 (0.0365, 3.2173) /0.348	0.765
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	
Dizziness Female	0/ 73	3/ 75 (4%)				
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.

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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)
Presyncope						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				
Paraesthesia						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Migraine						
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only 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)
Hypoaesthesia						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	1/252 (<1%)				
Sciatica						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	2/252 (<1%)				
Syncope						
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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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity 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)

Tension headache						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Cervical 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.

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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)
Head discomfort						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Anosmia						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Brain 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.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only 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)
Brain stem infarction						
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)

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				
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only 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)

Radiculopathy						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Transient ischaemic attack						
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)
Trigeminal neuralgia						
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)

Injury, poisoning and procedural complications						
Any Event						
Female	2/ 73 (3%)	7/ 75 (9%)	0.2736 (0.0549, 1.3639) /0.114	-6.5936 (-14.1676, 0.9804) /0.088	0.2935 (0.0631, 1.3666) /0.118	0.367
Male	13/254 (5%)	21/252 (8%)	0.5934 (0.2903, 1.2127) /0.152	-3.2152 (-7.5729, 1.1424) /0.148	0.6142 (0.3145, 1.1995) /0.153	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)
Contusion						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Arthropod bite						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	1/252 (<1%)				
Ligament sprain						
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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity 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	2/252 (<1%)				
Limb injury						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	1/252 (<1%)				
Exposure to communicable disease						
Female	0/ 73	0/ 75				
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= 2

System Organ Class Preferred Term	Q8W (N=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	1/254 (<1%)	1/252 (<1%)				
Skin abrasion						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Vaccination complication						
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)

Arthropod sting						
Female	0/ 73	2/ 75 (3%)				
Male	0/254	0/252				
Epicondylitis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
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.

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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)
Head injury						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Musculoskeletal foreign body						
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%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)
Road traffic accident						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Ankle fracture						
Female	1/ 73 (1%)	0/ 75				
Male	1/254 (<1%)	0/252				
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.

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)

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.

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)

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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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)
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%)				
Face 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. 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)
Fibula fracture						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Fractured coccyx						
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)

Gastrointestinal procedural complication						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
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.

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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)

Post-traumatic 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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for 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 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity 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)
Traumatic arthritis						
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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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	Q8W (N=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	0.092
Male	20/254 (8%)	18/252 (7%)	1.1111 (0.5731, 2.1542) /0.755	0.7312 (-3.8603, 5.3226) /0.755	1.1024 (0.5975, 2.0338) /0.755	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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	6/254 (2%)	2/252 (<1%)				
Anxiety Female	0/ 73	0/ 75	NC	NC	NC	>0.999
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	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for 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 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity 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)
Abnormal dreams						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Sleep disorder						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Depression						
Female	0/ 73	1/ 75 (1%)				
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.

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)
Nightmare						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Adjustment disorder with depressed mood						
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)

Adjustment disorder with mixed anxiety and depressed mood						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Attention deficit hyperactivity 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.

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)
Generalised anxiety disorder						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Major depression						
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)
Panic attack						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	2/252 (<1%)				
Restlessness						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Suicidal ideation						
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)
Adjustment disorder						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Emotional distress						
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)
Psychotic 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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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	Q8W (N=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%)	<0.0001 (<0.0001, -) />0.999	-3.6076 (-27.5142, 20.2991) /0.767	<0.0001 (<0.0001, -) />0.999	0.418
Male	5/254 (2%)	12/252 (5%)	0.4016 (0.1394, 1.1571) /0.091	-2.7934 (-5.9290, 0.3422) /0.081	0.4134 (0.1478, 1.1563) /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.

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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%)	3/252 (1%)				
Alanine 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.

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)
Blood creatine phosphokinase increased						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Blood cholesterol increased						
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.

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)

Weight decreased						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Blood glucose 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.

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)

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.

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)

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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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity 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%)				
Haematocrit 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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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)

Haemoglobin decreased						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
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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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)
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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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity 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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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity 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	1/ 75 (1%)				
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.

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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)

Anogenital warts						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				
Fibrous histiocytoma						
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)

Adenoma benign						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Basal cell carcinoma						
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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity 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)

Adrenal adenoma						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Vascular disorders						
Any Event						
Female	0/ 73	1/ 75 (1%)				
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.

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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)
Hypertension						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	3/252 (1%)				
Blood pressure inadequately controlled						
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)
Phlebitis						
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)
Thrombophlebitis superficial						
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	Q8W (N=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	0.265
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. 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 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	3/254 (1%)	2/252 (<1%)				
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.

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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 lesion						
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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity 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 cyst						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Benign prostatic hyperplasia						
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)

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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity 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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity 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)

Testicular torsion						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Renal and urinary disorders						
Any Event						
Female	1/ 73 (1%)	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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)
Dysuria						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Nocturia						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Nephrolithiasis						
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.

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)
Pollakiuria						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				
Renal colic						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	2/252 (<1%)				
Leukocyturia						
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= 2

System Organ Class Preferred Term	Q8W (N=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						
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	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)
Tinnitus						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Vertigo						
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)

Metabolism and nutrition disorders						
Any Event						
Female	0 / 73	0 / 75	NC	NC	NC	>0.999
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	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only 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)

Hypercholesterolaemia						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	1/252 (<1%)				
Vitamin D deficiency						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	3/252 (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.

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)
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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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity 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)

Hypertriglyceridaemia						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Eye disorders						
Any Event						
Female	3/ 73 (4%)	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.

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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)
Conjunctivitis allergic						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Blepharitis						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	1/252 (<1%)				
Cataract						
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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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity 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)
Diplopia						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Retinal detachment						
Female	1/ 73 (1%)	0/ 75				
Male	1/254 (<1%)	0/252				
Blepharospasm						
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)
Chalazion						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Eyelid oedema						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Macular fibrosis						
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)
Retinal tear						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	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)

Blood and lymphatic system disorders						
Any Event						
Female	1/ 73 (1%)	1/ 75 (1%)				
Male	2/254 (<1%)	0/252				
Microcytic anaemia						
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)
Iron deficiency anaemia						
Female	1/ 73 (1%)	1/ 75 (1%)				
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only 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)

Immune system disorders						
Any Event						
Female	2/ 73 (3%)	0/ 75	>999 (>999, >999) /NC	4.9973 (-18.5796, 28.5743) /0.678	>999 (>999, >999) /NC	0.070
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	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Seasonal allergy						
Female	1/ 73 (1%)	0/ 75				
Male	2/254 (<1%)	2/252 (<1%)				
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)
Allergy to arthropod bite						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
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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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity 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)

Cardiac disorders						
Any Event						
Female	0/ 73	0/ 75	NC	NC	NC	>0.999
Male	6/254 (2%)	5/252 (2%)	1.1952 (0.3600, 3.9674) /0.771	0.3781 (-2.1621, 2.9183) /0.771	1.1906 (0.3680, 3.8511) /0.771	
Palpitations						
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)
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%)				
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)
Cardiac aneurysm						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Extrasystoles						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Myocardial necrosis						
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= 2

System Organ Class Preferred Term	Q8W (N=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 bradycardia						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)

Hepatobiliary disorders						
Any Event						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)

Congenital, familial and genetic disorders						
Any Event						
Female	1/ 73 (1%)	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.

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= 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	7/ 73 (10%)	8/ 75 (11%)	0.8883 (0.3047, 2.5891) /0.828	-1.0776 (-10.7950, 8.6398) /0.828	0.8990 (0.3436, 2.3521) /0.828	0.691
Male	24/254 (9%)	33/252 (13%)	0.6925 (0.3966, 1.2092) /0.196	-3.6464 (-9.1499, 1.8570) /0.194	0.7215 (0.4394, 1.1850) /0.197	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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= 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	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	0.986
Male	9/254 (4%)	17/252 (7%)	0.5078 (0.2220, 1.1617) /0.108	-3.2027 (-7.0444, 0.6390) /0.102	0.5252 (0.2386, 1.1561) /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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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= 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	0.245
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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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= 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	2/254 (<1%)	1/252 (<1%)				
Fatigue						
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)

Injection site swelling						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Malaise						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	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.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only 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	Q8W (N=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	3/ 73 (4%)	0/ 75	>999 (>999, >999) /NC	6.3175 (-17.3129, 29.9479) /0.600	>999 (>999, >999) /NC	0.058
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.

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= 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)

Viral infection						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Tonsillitis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)

Diverticulitis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Pneumonia						
Female	1/ 73 (1%)	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= 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						
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				
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)

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				
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.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)

Gastrointestinal disorders						
Any Event						
Female	0/ 73	1/ 75 (1%)				
Male	2/254 (<1%)	1/252 (<1%)				
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.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)
Toothache						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
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.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only 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)

Musculoskeletal and connective tissue disorders						
Any Event						
Female	1/ 73 (1%)	1/ 75 (1%)				
Male	4/254 (2%)	3/252 (1%)				
Arthralgia						
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)
Pain in extremity						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Myalgia						
Female	0/ 73	1/ 75 (1%)				
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.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only 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)

Intervertebral disc protrusion						
Female	1/ 73 (1%)	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.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)

Osteoarthritis						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				
Osteonecrosis						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	0/252				
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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= 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)

Skin and subcutaneous tissue disorders						
Any Event						
Female	2/ 73 (3%)	0/ 75				
Male	0/254	0/252				
Eczema						
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)

Hyperhidrosis						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				
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.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only 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)

Sleep apnoea syndrome						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Nervous system disorders						
Any Event						
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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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= 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)
Headache						
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%)				
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.

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= 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)

Neuritis cranial						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	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.

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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)
Contusion						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Foot fracture						
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)
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.

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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)
Major depression						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				

Investigations

Any Event

Female	0/ 73	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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for 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 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity 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)

Lipase increased						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
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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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity 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				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
Female	1/ 73 (1%)	1/ 75 (1%)				
Male	0/254	0/252				
Breast cancer						
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)

Reproductive system and breast disorders						
Any Event						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Genital odour						
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= 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						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Renal colic						
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= 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						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Tympanic membrane perforation						
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= 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						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
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= 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						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Retinal detachment						
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= 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						
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.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)

Immune system disorders						
Any Event						
Female	0/ 73	2/ 75 (3%)				
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.

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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)

Drug hypersensitivity						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Cardiac 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.

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)
Ventricular extrasystoles						
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.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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= 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)

Myocardial infarction						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Hepatobiliary 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	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatocellular injury						
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.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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= 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						
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= 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	3/254 (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 Preferred Term	Q8W (N=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	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.

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= 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 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity 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)
Testicular neoplasm						
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.

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)

Overall						
Any Event						
White	73/239 (31%)	81/256 (32%)	0.9501 (0.6491, 1.3907) /0.792	-1.0967 (-9.2548, 7.0614) /0.792	0.9653 (0.7424, 1.2553) /0.792	0.693
Non-White	28/ 88 (32%)	21/ 71 (30%)	1.1111 (0.5635, 2.1909) /0.761	2.2407 (-12.1606, 16.6420) /0.760	1.0758 (0.6713, 1.7239) /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 3.20

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)

General disorders and administration site conditions						
Any Event						
White	119/239 (50%)	120/256 (47%)	1.1239 (0.7897, 1.5995) /0.517	2.9158 (-5.8904, 11.7220) /0.516	1.0622 (0.8852, 1.2746) /0.516	0.696
Non-White	40/ 88 (45%)	28/ 71 (39%)	1.2798 (0.6785, 2.4137) /0.446	6.0179 (-9.3917, 21.4275) /0.444	1.1526 (0.7977, 1.6654) /0.450	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 pain						
White	119/239 (50%)	120/256 (47%)	1.1239 (0.7897, 1.5995) /0.517	2.9158 (-5.8904, 11.7220) /0.516	1.0622 (0.8852, 1.2746) /0.516	0.369
Non-White	40/ 88 (45%)	25/ 71 (35%)	1.5333 (0.8062, 2.9162) /0.192	10.2433 (-4.9771, 25.4637) /0.187	1.2909 (0.8742, 1.9062) /0.199	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 nodule						
White	20/239 (8%)	44/256 (17%)	0.4400 (0.2510, 0.7713) /0.004	-8.8193 (-14.6230, -3.0156) /0.003	0.4869 (0.2958, 0.8014) /0.005	0.814
Non-White	12/ 88 (14%)	18/ 71 (25%)	0.4649 (0.2068, 1.0454) /0.064	-11.7157 (-24.1175, 0.6860) /0.064	0.5379 (0.2780, 1.0408) /0.066	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 induration						
White	20/239 (8%)	28/256 (11%)	0.7436 (0.4069, 1.3591) /0.336	-2.5693 (-7.7599, 2.6213) /0.332	0.7651 (0.4432, 1.3209) /0.337	0.768
Non-White	3/ 88 (3%)	4/ 71 (6%)	0.5912 (0.1279, 2.7324) /0.501	-2.2247 (-8.7927, 4.3433) /0.507	0.6051 (0.1400, 2.6159) /0.501	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Injection site discomfort						
White	17/239 (7%)	26/256 (10%)	0.6774 (0.3577, 1.2828) /0.232	-3.0433 (-7.9740, 1.8874) /0.226	0.7004 (0.3900, 1.2576) /0.233	0.559
Non-White	3/ 88 (3%)	2/ 71 (3%)	1.2176 (0.1979, 7.4939) /0.832	0.5922 (-4.8102, 5.9946) /0.830	1.2102 (0.2079, 7.0461) /0.832	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Pyrexia						
White	14/239 (6%)	25/256 (10%)	0.5749 (0.2914, 1.1343) /0.110	-3.9079 (-8.6075, 0.7918) /0.103	0.5998 (0.3194, 1.1263) /0.112	0.205
Non-White	3/ 88 (3%)	1/ 71 (1%)	2.4706 (0.2514, 24.2792) /0.438	2.0006 (-2.6778, 6.6790) /0.402	2.4205 (0.2573, 22.7696) /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.

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)
Fatigue White	6/239 (3%)	20/256 (8%)	0.3039 (0.1199, 0.7702) /0.012	-5.3020 (-9.1415, -1.4626) /0.007	0.3213 (0.1313, 0.7865) /0.013	0.146
Non-White	5/ 88 (6%)	4/ 71 (6%)	1.0090 (0.2606, 3.9064) /0.990	0.0480 (-7.1740, 7.2701) /0.990	1.0085 (0.2812, 3.6167) /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.

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)
Injection site swelling						
White	11/239 (5%)	12/256 (5%)	0.9810 (0.4244, 2.2674) /0.964	-0.0850 (-3.7946, 3.6246) /0.964	0.9819 (0.4417, 2.1828) /0.964	0.790
Non-White	5/ 88 (6%)	5/ 71 (7%)	0.7952 (0.2209, 2.8630) /0.726	-1.3604 (-9.0294, 6.3085) /0.728	0.8068 (0.2431, 2.6774) /0.726	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 pruritus						
White	7/239 (3%)	14/256 (5%)	0.5216 (0.2068, 1.3153) /0.168	-2.5399 (-6.0509, 0.9711) /0.156	0.5356 (0.2199, 1.3042) /0.169	0.255
Non-White	2/ 88 (2%)	8/ 71 (11%)	0.1831 (0.0376, 0.8920) /0.036	-8.9949 (-16.9817, -1.0080) /0.027	0.2017 (0.0442, 0.9200) /0.039	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 erythema						
White	11/239 (5%)	11/256 (4%)	1.0746 (0.4570, 2.5266) /0.869	0.3056 (-3.3314, 3.9426) /0.869	1.0711 (0.4732, 2.4245) /0.869	0.847
Non-White	1/ 88 (1%)	1/ 71 (1%)	0.8046 (0.0494, 13.0946) /0.879	-0.2721 (-3.7959, 3.2517) /0.880	0.8068 (0.0514, 12.6728) /0.879	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only 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)
Influenza like illness						
White	5/239 (2%)	9/256 (4%)	0.5864 (0.1937, 1.7754) /0.345	-1.4236 (-4.3188, 1.4716) /0.335	0.5951 (0.2023, 1.7504) /0.346	0.529
Non-White	2/ 88 (2%)	5/ 71 (7%)	0.3070 (0.0577, 1.6322) /0.166	-4.7695 (-11.4863, 1.9472) /0.164	0.3227 (0.0645, 1.6141) /0.169	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Asthenia						
White	10/239 (4%)	8/256 (3%)	1.3537 (0.5252, 3.4894) /0.531	1.0591 (-2.2555, 4.3737) /0.531	1.3389 (0.5374, 3.3357) /0.531	0.338
Non-White	1/ 88 (1%)	0/ 71	>999 (>999, >999) /NC	3.4034 (-20.7049, 27.5117) /0.782	>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)
Chills						
White	8/239 (3%)	6/256 (2%)	1.4430 (0.4932, 4.2217) /0.503	1.0035 (-1.9349, 3.9420) /0.503	1.4282 (0.5029, 4.0557) /0.503	0.486
Non-White	4/ 88 (5%)	1/ 71 (1%)	3.3333 (0.3642, 30.5116) /0.287	3.1370 (-2.0063, 8.2803) /0.232	3.2273 (0.3689, 28.2339) /0.290	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only 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 bruising						
White	9/239 (4%)	6/256 (2%)	1.6304 (0.5715, 4.6518) /0.361	1.4219 (-1.6210, 4.4648) /0.360	1.6067 (0.5806, 4.4461) /0.361	0.279
Non-White	1/ 88 (1%)	2/ 71 (3%)	0.3966 (0.0352, 4.4647) /0.454	-1.6805 (-6.1208, 2.7597) /0.458	0.4034 (0.0373, 4.3588) /0.455	
Pain						
White	2/239 (<1%)	4/256 (2%)				
Non-White	4/ 88 (5%)	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.

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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	3/239 (1%)	6/256 (2%)				
Non-White	2/ 88 (2%)	1/ 71 (1%)				
Injection site haematoma						
White	0/239	10/256 (4%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	>0.999
Non-White	0/ 88	1/ 71 (1%)	<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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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)
Discomfort						
White	3/239 (1%)	4/256 (2%)				
Non-White	2/ 88 (2%)	0/ 71				
Injection site reaction						
White	3/239 (1%)	4/256 (2%)				
Non-White	0/ 88	0/ 71				
Injection site warmth						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	2/ 88 (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)
Chest pain						
White	1/239 (<1%)	3/256 (1%)				
Non-White	1/ 88 (1%)	0/ 71				
Injection site anaesthesia						
White	1/239 (<1%)	0/256				
Non-White	3/ 88 (3%)	1/ 71 (1%)				
Feeling hot						
White	3/239 (1%)	0/256				
Non-White	1/ 88 (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)
Nodule						
White	1/239 (<1%)	2/256 (<1%)				
Non-White	0/ 88	1/ 71 (1%)				
Cyst						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	1/ 88 (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)

Injection site discolouration						
White	0/239	2/256 (<1%)				
Non-White	0/ 88	0/ 71				
Injection site haemorrhage						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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 papule						
White	0/239	0/256				
Non-White	1/ 88 (1%)	1/ 71 (1%)				
Mass						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Peripheral swelling						
White	0/239	1/256 (<1%)				
Non-White	1/ 88 (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)
Temperature regulation disorder						
White	0/239	0/256				
Non-White	2/ 88 (2%)	0/ 71				
Vaccination site pain						
White	0/239	0/256				
Non-White	0/ 88	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)

Vessel puncture site haematoma						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	1/ 71 (1%)				
Adverse drug reaction						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for 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)

Chest discomfort						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Chronic fatigue syndrome						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)

Enanthema						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Feeling abnormal						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Gait disturbance						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Inflammation						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Injection site hypoaesthesia						
White	0/239	0/256				
Non-White	1/ 88 (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)

Injection site mass						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Injection site rash						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)

Non-cardiac chest pain						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Oedema peripheral						
White	0/239	0/256				
Non-White	0/ 88	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)

Sensation of foreign body						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Sluggishness						
White	0/239	0/256				
Non-White	1/ 88 (1%)	0/ 71				
Swelling						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)

Thirst						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Xerosis						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Infections and infestations						
Any Event						
White	85/239 (36%)	109/256 (43%)	0.7444 (0.5180, 1.0698) /0.111	-7.0133 (-15.5877, 1.5612) /0.109	0.8353 (0.6689, 1.0431) /0.112	0.174
Non-White	26/ 88 (30%)	17/ 71 (24%)	1.3321 (0.6537, 2.7146) /0.430	5.6018 (-8.1604, 19.3640) /0.425	1.2340 (0.7297, 2.0866) /0.433	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only 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)
Nasopharyngitis						
White	34/239 (14%)	47/256 (18%)	0.7375 (0.4557, 1.1937) /0.215	-4.1334 (-10.6222, 2.3553) /0.212	0.7749 (0.5171, 1.1612) /0.217	0.527
Non-White	7/ 88 (8%)	5/ 71 (7%)	1.1407 (0.3461, 3.7601) /0.829	0.9123 (-7.2963, 9.1209) /0.828	1.1295 (0.3744, 3.4077) /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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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)
Upper respiratory tract infection						
White	20/239 (8%)	33/256 (13%)	0.6171 (0.3435, 1.1087) /0.106	-4.5224 (-9.9238, 0.8789) /0.101	0.6492 (0.3834, 1.0993) /0.108	0.400
Non-White	11/ 88 (13%)	9/ 71 (13%)	0.9841 (0.3836, 2.5251) /0.973	-0.1761 (-10.5508, 10.1987) /0.973	0.9861 (0.4328, 2.2470) /0.973	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only 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)

Gastroenteritis						
White	9/239 (4%)	18/256 (7%)	0.5174 (0.2278, 1.1752) /0.115	-3.2656 (-7.2195, 0.6884) /0.106	0.5356 (0.2454, 1.1689) /0.117	0.372
Non-White	2/ 88 (2%)	1/ 71 (1%)	1.6279 (0.1446, 18.3272) /0.693	0.8643 (-3.2841, 5.0126) /0.683	1.6136 (0.1493, 17.4353) /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. 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)
Syphilis White	8/239 (3%)	9/256 (4%)	0.9505 (0.3606, 2.5050) /0.918	-0.1683 (-3.3761, 3.0395) /0.918	0.9521 (0.3734, 2.4275) /0.918	0.859
Non-White	3/ 88 (3%)	3/ 71 (4%)	0.8000 (0.1565, 4.0903) /0.789	-0.8163 (-6.8387, 5.2062) /0.791	0.8068 (0.1679, 3.8760) /0.789	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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 White	7/239 (3%)	10/256 (4%)	0.7422 (0.2779, 1.9824) /0.552	-0.9774 (-4.1715, 2.2167) /0.549	0.7498 (0.2901, 1.9381) /0.552	0.628
Non-White	1/ 88 (1%)	2/ 71 (3%)	0.3966 (0.0352, 4.4647) /0.454	-1.6805 (-6.1208, 2.7597) /0.458	0.4034 (0.0373, 4.3588) /0.455	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)
Gonorrhoea						
White	8/239 (3%)	5/256 (2%)	1.7385 (0.5607, 5.3902) /0.338	1.3942 (-1.4472, 4.2356) /0.336	1.7138 (0.5686, 5.1659) /0.339	0.442
Non-White	3/ 88 (3%)	3/ 71 (4%)	0.8000 (0.1565, 4.0903) /0.789	-0.8163 (-6.8387, 5.2062) /0.791	0.8068 (0.1679, 3.8760) /0.789	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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						
White	9/239 (4%)	4/256 (2%)	2.4652 (0.7490, 8.1137) /0.138	2.2032 (-0.6486, 5.0550) /0.130	2.4100 (0.7521, 7.7227) /0.139	0.702
Non-White	4/ 88 (5%)	2/ 71 (3%)	1.6429 (0.2921, 9.2389) /0.573	1.7286 (-4.0811, 7.5382) /0.560	1.6136 (0.3043, 8.5576) /0.574	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)
Bronchitis White	7/239 (3%)	8/256 (3%)	0.9353 (0.3339, 2.6201) /0.899	-0.1961 (-3.2148, 2.8226) /0.899	0.9372 (0.3452, 2.5450) /0.899	0.511
Non-White	1/ 88 (1%)	2/ 71 (3%)	0.3966 (0.0352, 4.4647) /0.454	-1.6805 (-6.1208, 2.7597) /0.458	0.4034 (0.0373, 4.3588) /0.455	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)
Sinusitis						
White	5/239 (2%)	8/256 (3%)	0.6624 (0.2136, 2.0537) /0.476	-1.0329 (-3.8320, 1.7661) /0.470	0.6695 (0.2221, 2.0179) /0.476	0.283
Non-White	0/ 88	1/ 71 (1%)	<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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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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	5/239 (2%)	5/256 (2%)	1.0726 (0.3066, 3.7526) /0.913	0.1389 (-2.3442, 2.6220) /0.913	1.0711 (0.3140, 3.6536) /0.913	0.089
Non-White	3/ 88 (3%)	0/ 71	>999 (>999, >999) /NC	5.6441 (-18.3993, 29.6875) /0.645	>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	Q8W (N=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	4/239 (2%)	6/256 (2%)	0.7092 (0.1977, 2.5448) /0.598	-0.6701 (-3.1358, 1.7956) /0.594	0.7141 (0.2040, 2.4994) /0.598	0.672
Non-White	1/ 88 (1%)	2/ 71 (3%)	0.3966 (0.0352, 4.4647) /0.454	-1.6805 (-6.1208, 2.7597) /0.458	0.4034 (0.0373, 4.3588) /0.455	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)
Rhinitis White	5/239 (2%)	7/256 (3%)	0.7601 (0.2379, 2.4280) /0.643	-0.6423 (-3.3411, 2.0564) /0.641	0.7651 (0.2462, 2.3780) /0.644	0.261
Non-White	0/ 88	1/ 71 (1%)	<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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Analysis of Proportion of Subjects with Adverse Events by 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 infection						
White	3/239 (1%)	7/256 (3%)	0.4522 (0.1156, 1.7691) /0.254	-1.4791 (-3.9252, 0.9669) /0.236	0.4591 (0.1201, 1.7548) /0.255	0.352
Non-White	2/ 88 (2%)	1/ 71 (1%)	1.6279 (0.1446, 18.3272) /0.693	0.8643 (-3.2841, 5.0126) /0.683	1.6136 (0.1493, 17.4353) /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 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						
White	7/239 (3%)	5/256 (2%)	1.5147 (0.4741, 4.8386) /0.484	0.9757 (-1.7525, 3.7040) /0.483	1.4996 (0.4825, 4.6609) /0.484	>0.999
Non-White	0/ 88	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.

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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)
Folliculitis						
White	4/239 (2%)	6/256 (2%)	0.7092 (0.1977, 2.5448) /0.598	-0.6701 (-3.1358, 1.7956) /0.594	0.7141 (0.2040, 2.4994) /0.598	0.275
Non-White	0/ 88	1/ 71 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Oral herpes						
White	1/239 (<1%)	8/256 (3%)				
Non-White	1/ 88 (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.

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 tract infection viral						
White	4/239 (2%)	7/256 (3%)	0.6055 (0.1750, 2.0951) /0.428	-1.0607 (-3.6368, 1.5153) /0.420	0.6121 (0.1815, 2.0644) /0.429	>0.999
Non-White	0/ 88	0/ 71	NC	NC	NC	
Urethritis						
White	3/239 (1%)	5/256 (2%)				
Non-White	0/ 88	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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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= 1

System Organ Class Preferred Term	Q8W (N=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	4/239 (2%)	3/256 (1%)				
Non-White	1/ 88 (1%)	2/ 71 (3%)				
Tonsillitis						
White	2/239 (<1%)	5/256 (2%)				
Non-White	0/ 88	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	1/239 (<1%)	5/256 (2%)				
Non-White	1/ 88 (1%)	1/ 71 (1%)				
Gastroenteritis viral						
White	3/239 (1%)	3/256 (1%)				
Non-White	0/ 88	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)
Onychomycosis						
White	2/239 (<1%)	5/256 (2%)				
Non-White	0/ 88	0/ 71				
Proctitis gonococcal						
White	3/239 (1%)	2/256 (<1%)				
Non-White	1/ 88 (1%)	1/ 71 (1%)				
Tooth abscess						
White	1/239 (<1%)	4/256 (2%)				
Non-White	1/ 88 (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)

Anal chlamydia infection						
White	3/239 (1%)	1/256 (<1%)				
Non-White	2/ 88 (2%)	0/ 71				
Ear infection						
White	1/239 (<1%)	4/256 (2%)				
Non-White	1/ 88 (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)
Fungal skin infection						
White	3/239 (1%)	3/256 (1%)				
Non-White	0/ 88	0/ 71				
Gingivitis						
White	2/239 (<1%)	3/256 (1%)				
Non-White	1/ 88 (1%)	0/ 71				
Herpes simplex						
White	1/239 (<1%)	2/256 (<1%)				
Non-White	2/ 88 (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)

Tinea versicolour						
White	2/239 (<1%)	4/256 (2%)				
Non-White	0/ 88	0/ 71				
Herpes zoster						
White	2/239 (<1%)	2/256 (<1%)				
Non-White	0/ 88	1/ 71 (1%)				
Hordeolum						
White	1/239 (<1%)	3/256 (1%)				
Non-White	1/ 88 (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)
Lower respiratory tract infection						
White	1/239 (<1%)	0/256				
Non-White	4/ 88 (5%)	0/ 71				
Oropharyngeal gonococcal infection						
White	2/239 (<1%)	1/256 (<1%)				
Non-White	1/ 88 (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)

Tooth infection						
White	0/239	5/256 (2%)				
Non-White	0/ 88	0/ 71				
Furuncle						
White	2/239 (<1%)	1/256 (<1%)				
Non-White	1/ 88 (1%)	0/ 71				
Otitis externa						
White	1/239 (<1%)	2/256 (<1%)				
Non-White	0/ 88	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)

Acarodermatitis						
White	1/239 (<1%)	2/256 (<1%)				
Non-White	0/ 88	0/ 71				
Body tinea						
White	2/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Diverticulitis						
White	1/239 (<1%)	2/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Helicobacter infection						
White	0/239	3/256 (1%)				
Non-White	0/ 88	0/ 71				
Secondary syphilis						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	2/ 71 (3%)				
Tinea cruris						
White	0/239	2/256 (<1%)				
Non-White	0/ 88	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)

Tinea infection						
White	0/239	3/256 (1%)				
Non-White	0/ 88	0/ 71				
Urethritis gonococcal						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	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)
Vaginal infection						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	1/ 71 (1%)				
Viral pharyngitis						
White	0/239	1/256 (<1%)				
Non-White	1/ 88 (1%)	1/ 71 (1%)				
Cellulitis						
White	0/239	2/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Chronic sinusitis						
White	2/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Enteritis infectious						
White	2/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Lymphogranulo ma venereum						
White	0/239	2/256 (<1%)				
Non-White	0/ 88	0/ 71				
Molluscum contagiosum						
White	0/239	1/256 (<1%)				
Non-White	1/ 88 (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)
Mycoplasma genitalium infection						
White	0/239	2/256 (<1%)				
Non-White	0/ 88	0/ 71				
Oral candidiasis						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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)
Otitis media						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Paronychia						
White	0/239	2/256 (<1%)				
Non-White	0/ 88	0/ 71				
Pneumonia						
White	0/239	0/256				
Non-White	1/ 88 (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)

Postoperative wound infection						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Primary syphilis						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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 infection						
White	2/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Staphylococcal infection						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Tinea pedis						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Tracheitis						
White	0/239	2/256 (<1%)				
Non-White	0/ 88	0/ 71				
Urethritis chlamydial						
White	0/239	0/256				
Non-White	2/ 88 (2%)	0/ 71				
Abscess limb						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for 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)
Acute sinusitis						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Arthropod infestation						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Borrelia infection						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Bronchitis viral						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Cellulitis of male external genital organ						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for 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	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Cystitis						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Diarrhoea infectious						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Enterovirus infection						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Epididymitis						
White	0/239	0/256				
Non-White	1/ 88 (1%)	0/ 71				
Erythema migrans						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Escherichia urinary tract infection						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
External ear cellulitis						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only 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)
Eye infection						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Gastritis viral						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Gastrointestinal infection						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only 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)

Genital herpes						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Genital herpes simplex						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only 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)
Giardiasis						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Gingival abscess						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Groin abscess						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only 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)
Hepatitis C						
White	0/239	0/256				
Non-White	1/ 88 (1%)	0/ 71				
Hepatitis E						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Infectious mononucleosis						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)

Injection site abscess						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Labyrinthitis						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Laryngitis						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only 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)

Localised infection						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Mycoplasma infection						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only 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)

Otitis media acute						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Penile infection						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Pericoronitis						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Peritonsillar abscess						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Pharyngeal chlamydia infection						
White	0/239	0/256				
Non-White	0/ 88	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)

Pharyngitis bacterial						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Pharyngitis mycoplasmal						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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 streptococcal						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Pharyngotonsillitis						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Proctitis mycoplasmal						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Pulpitis dental						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Rectal abscess						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Schistosomiasis cutaneous						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Sexually transmitted disease						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Staphylococcal skin infection						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)

Subcutaneous abscess						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Syphilis genital						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Tinea capitis						
White	0/239	0/256				
Non-White	1/ 88 (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)

Tracheobronchitis						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Trichomoniasis						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)

Ureaplasma infection						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Urethritis mycoplasmal						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Varicella						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Viral rash						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Viral rhinitis						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Gastrointestinal disorders						
Any Event						
White	52/239 (22%)	59/256 (23%)	0.9285 (0.6082, 1.4175) /0.731	-1.2896 (-8.6363, 6.0572) /0.731	0.9440 (0.6797, 1.3112) /0.731	0.670
Non-White	15/ 88 (17%)	15/ 71 (21%)	0.7671 (0.3461, 1.7002) /0.514	-4.0813 (-16.4054, 8.2428) /0.516	0.8068 (0.4238, 1.5359) /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.

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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)
Diarrhoea						
White	21/239 (9%)	19/256 (7%)	1.2016 (0.6290, 2.2954) /0.578	1.3647 (-3.4511, 6.1806) /0.579	1.1839 (0.6530, 2.1464) /0.578	0.981
Non-White	3/ 88 (3%)	2/ 71 (3%)	1.2176 (0.1979, 7.4939) /0.832	0.5922 (-4.8102, 5.9946) /0.830	1.2102 (0.2079, 7.0461) /0.832	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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	5/239 (2%)	15/256 (6%)	0.3433 (0.1228, 0.9597) /0.042	-3.7673 (-7.1687, -0.3659) /0.030	0.3570 (0.1318, 0.9673) /0.043	0.694
Non-White	2/ 88 (2%)	3/ 71 (4%)	0.5271 (0.0856, 3.2444) /0.490	-1.9526 (-7.5732, 3.6680) /0.496	0.5379 (0.0924, 3.1316) /0.490	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)
Constipation White	1/239 (<1%)	12/256 (5%)	0.0854 (0.0110, 0.6622) /0.019	-4.2691 (-6.9846, -1.5536) /0.002	0.0893 (0.0117, 0.6812) /0.020	0.480
Non-White	1/ 88 (1%)	3/ 71 (4%)	0.2605 (0.0265, 2.5607) /0.249	-3.0890 (-8.2658, 2.0878) /0.242	0.2689 (0.0286, 2.5300) /0.251	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Dyspepsia						
White	6/239 (3%)	7/256 (3%)	0.9160 (0.3034, 2.7655) /0.876	-0.2239 (-3.0390, 2.5912) /0.876	0.9181 (0.3130, 2.6930) /0.876	0.932
Non-White	1/ 88 (1%)	1/ 71 (1%)	0.8046 (0.0494, 13.0946) /0.879	-0.2721 (-3.7959, 3.2517) /0.880	0.8068 (0.0514, 12.6728) /0.879	
Haemorrhoids						
White	2/239 (<1%)	6/256 (2%)				
Non-White	0/ 88	5/ 71 (7%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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						
White	5/239 (2%)	6/256 (2%)	0.8903 (0.2681, 2.9563) /0.850	-0.2517 (-2.8453, 2.3419) /0.849	0.8926 (0.2760, 2.8865) /0.850	0.270
Non-White	1/ 88 (1%)	0/ 71	>999 (>999, >999) /NC	3.4034 (-20.7049, 27.5117) /0.782	>999 (>999, >999) /NC	
Abdominal distension						
White	2/239 (<1%)	3/256 (1%)				
Non-White	5/ 88 (6%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Toothache						
White	4/239 (2%)	4/256 (2%)				
Non-White	2/ 88 (2%)	0/ 71				
Abdominal pain upper						
White	2/239 (<1%)	6/256 (2%)				
Non-White	1/ 88 (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= 1

System Organ Class Preferred Term	Q8W (N=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						
White	4/239 (2%)	2/256 (<1%)				
Non-White	1/ 88 (1%)	0/ 71				
Rectal haemorrhage						
White	0/239	2/256 (<1%)				
Non-White	1/ 88 (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.

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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)
Vomiting						
White	2/239 (<1%)	3/256 (1%)				
Non-White	1/ 88 (1%)	0/ 71				
Abdominal discomfort						
White	2/239 (<1%)	2/256 (<1%)				
Non-White	0/ 88	1/ 71 (1%)				
Anogenital dysplasia						
White	2/239 (<1%)	2/256 (<1%)				
Non-White	0/ 88	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)
Dental caries						
White	0/239	2/256 (<1%)				
Non-White	2/ 88 (2%)	1/ 71 (1%)				
Flatulence						
White	2/239 (<1%)	3/256 (1%)				
Non-White	0/ 88	0/ 71				
Abdominal pain lower						
White	2/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	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)
Food poisoning						
White	4/239 (2%)	0/256				
Non-White	0/ 88	0/ 71				
Gastritis						
White	0/239	3/256 (1%)				
Non-White	1/ 88 (1%)	0/ 71				
Haematochezia						
White	2/239 (<1%)	1/256 (<1%)				
Non-White	1/ 88 (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)
Hiatus hernia						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	1/ 88 (1%)	0/ 71				
Proctalgia						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	1/ 88 (1%)	0/ 71				
Rectal discharge						
White	1/239 (<1%)	0/256				
Non-White	2/ 88 (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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Analysis of Proportion of Subjects with Adverse Events by 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 fissure						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	1/ 71 (1%)				
Anal pruritus						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Diverticulum intestinal						
White	0/239	2/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for 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						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Gingival pain						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Inguinal hernia						
White	0/239	2/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only 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)

Irritable bowel syndrome						
White	0/239	0/256				
Non-White	1/ 88 (1%)	1/ 71 (1%)				
Mouth ulceration						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)

Noninfective gingivitis						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Oesophagitis						
White	0/239	1/256 (<1%)				
Non-White	1/ 88 (1%)	0/ 71				
Abdominal hernia						
White	0/239	0/256				
Non-White	0/ 88	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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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)
Abdominal tenderness						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Anal fistula						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Anal ulcer						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Angular cheilitis						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Anorectal discomfort						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Chapped lips						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Cheilitis						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Dysphagia						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Enteritis						
White	0/239	0/256				
Non-White	1/ 88 (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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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)
Enterocolitis						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Faeces soft						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Gastric disorder						
White	0/239	0/256				
Non-White	1/ 88 (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)
Gastric ulcer						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Gastrointestinal disorder						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Gingival hypertrophy						
White	0/239	0/256				
Non-White	0/ 88	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= 1

System Organ Class Preferred Term	Q8W (N=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	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Hypertrophic anal papilla						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Hypoaesthesia oral						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)
Large intestine polyp						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Oral disorder						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)
Oral lichen planus						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Pancreatitis						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Perianal erythema						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Rectal tenesmus						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)

Salivary gland mucocoele						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Tooth disorder						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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	41/239 (17%)	60/256 (23%)	0.6764 (0.4341, 1.0540) /0.084	-6.2827 (-13.3374, 0.7721) /0.081	0.7319 (0.5128, 1.0448) /0.086	0.117
Non-White	17/ 88 (19%)	10/ 71 (14%)	1.4606 (0.6225, 3.4266) /0.384	5.2337 (-6.3210, 16.7883) /0.375	1.3716 (0.6704, 2.8060) /0.387	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Back pain						
White	16/239 (7%)	20/256 (8%)	0.8466 (0.4279, 1.6752) /0.633	-1.1179 (-5.6838, 3.4479) /0.631	0.8569 (0.4549, 1.6143) /0.633	0.275
Non-White	7/ 88 (8%)	3/ 71 (4%)	1.9588 (0.4877, 7.8675) /0.343	3.7292 (-3.6095, 11.0679) /0.319	1.8826 (0.5050, 7.0182) /0.346	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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	7/239 (3%)	15/256 (6%)	0.4848 (0.1941, 1.2105) /0.121	-2.9305 (-6.5148, 0.6538) /0.109	0.4999 (0.2074, 1.2047) /0.122	0.021
Non-White	6/ 88 (7%)	1/ 71 (1%)	5.1219 (0.6021, 43.5722) /0.135	5.4097 (-0.5272, 11.3467) /0.074	4.8409 (0.5965, 39.2868) /0.140	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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	8/239 (3%)	14/256 (5%)	0.5986 (0.2465, 1.4536) /0.257	-2.1215 (-5.7211, 1.4782) /0.248	0.6121 (0.2615, 1.4329) /0.258	0.742
Non-White	1/ 88 (1%)	2/ 71 (3%)	0.3966 (0.0352, 4.4647) /0.454	-1.6805 (-6.1208, 2.7597) /0.458	0.4034 (0.0373, 4.3588) /0.455	
Myalgia						
White	5/239 (2%)	3/256 (1%)				
Non-White	3/ 88 (3%)	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)
Musculoskeletal pain						
White	2/239 (<1%)	3/256 (1%)				
Non-White	2/ 88 (2%)	2/ 71 (3%)				
Tendonitis						
White	2/239 (<1%)	1/256 (<1%)				
Non-White	4/ 88 (5%)	0/ 71				
Muscle spasms						
White	1/239 (<1%)	3/256 (1%)				
Non-White	1/ 88 (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)
Muscle contracture						
White	2/239 (<1%)	3/256 (1%)				
Non-White	0/ 88	0/ 71				
Musculoskeletal chest pain						
White	2/239 (<1%)	1/256 (<1%)				
Non-White	1/ 88 (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)

Spinal osteoarthritis						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	2/ 71 (3%)				
Intervertebral disc protrusion						
White	1/239 (<1%)	2/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Neck pain						
White	3/239 (1%)	0/256				
Non-White	0/ 88	0/ 71				
Bursitis						
White	2/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Flank pain						
White	2/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Joint contracture						
White	0/239	2/256 (<1%)				
Non-White	0/ 88	0/ 71				
Joint swelling						
White	0/239	1/256 (<1%)				
Non-White	1/ 88 (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= 1

System Organ Class Preferred Term	Q8W (N=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						
White	0/239	2/256 (<1%)				
Non-White	0/ 88	0/ 71				
Arthritis						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Arthropathy						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Cervical spinal stenosis						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Exostosis						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)

Femoroacetabular impingement						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Groin pain						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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 range of motion decreased						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Joint stiffness						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)

Limb discomfort						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Muscle tightness						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)
Muscular weakness						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Musculoskeletal discomfort						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Myosclerosis						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Osteochondritis						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Osteopenia						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Pain in jaw						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Plantar fasciitis						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Rotator cuff syndrome						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Sacroiliitis						
White	0/239	0/256				
Non-White	0/ 88	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)
Scoliosis						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Spinal disorder						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Synovial cyst						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Synovitis						
White	0/239	0/256				
Non-White	1/ 88 (1%)	0/ 71				
Temporomandibular joint syndrome						
White	0/239	0/256				
Non-White	0/ 88	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)

Tendon disorder						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Tenosynovitis						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Trigger finger						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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	39/239 (16%)	49/256 (19%)	0.8238 (0.5183, 1.3093) /0.412	-2.8226 (-9.5437, 3.8984) /0.410	0.8525 (0.5819, 1.2490) /0.413	0.889
Non-White	14/ 88 (16%)	14/ 71 (20%)	0.7703 (0.3401, 1.7443) /0.531	-3.8092 (-15.8112, 8.1928) /0.534	0.8068 (0.4122, 1.5792) /0.531	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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	5/239 (2%)	5/256 (2%)	1.0726 (0.3066, 3.7526) /0.913	0.1389 (-2.3442, 2.6220) /0.913	1.0711 (0.3140, 3.6536) /0.913	0.761
Non-White	4/ 88 (5%)	4/ 71 (6%)	0.7976 (0.1923, 3.3084) /0.755	-1.0883 (-7.9952, 5.8185) /0.757	0.8068 (0.2091, 3.1128) /0.755	

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)
Rash						
White	6/239 (3%)	7/256 (3%)	0.9160 (0.3034, 2.7655) /0.876	-0.2239 (-3.0390, 2.5912) /0.876	0.9181 (0.3130, 2.6930) /0.876	0.609
Non-White	2/ 88 (2%)	3/ 71 (4%)	0.5271 (0.0856, 3.2444) /0.490	-1.9526 (-7.5732, 3.6680) /0.496	0.5379 (0.0924, 3.1316) /0.490	

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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						
White	4/239 (2%)	8/256 (3%)	0.5277 (0.1568, 1.7756) /0.302	-1.4514 (-4.1324, 1.2296) /0.289	0.5356 (0.1634, 1.7555) /0.303	0.584
Non-White	1/ 88 (1%)	3/ 71 (4%)	0.2605 (0.0265, 2.5607) /0.249	-3.0890 (-8.2658, 2.0878) /0.242	0.2689 (0.0286, 2.5300) /0.251	
Acne						
White	2/239 (<1%)	4/256 (2%)				
Non-White	0/ 88	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.

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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)
Alopecia						
White	5/239 (2%)	1/256 (<1%)				
Non-White	1/ 88 (1%)	0/ 71				
Dermatitis						
White	3/239 (1%)	3/256 (1%)				
Non-White	0/ 88	1/ 71 (1%)				
Skin lesion						
White	4/239 (2%)	2/256 (<1%)				
Non-White	0/ 88	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)

Dermatitis contact						
White	2/239 (<1%)	2/256 (<1%)				
Non-White	1/ 88 (1%)	1/ 71 (1%)				
Seborrhoeic dermatitis						
White	0/239	2/256 (<1%)				
Non-White	1/ 88 (1%)	2/ 71 (3%)				
Hyperhidrosis						
White	0/239	4/256 (2%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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	0/239	3/256 (1%)				
Non-White	0/ 88	0/ 71				
Dry skin						
White	3/239 (1%)	0/256				
Non-White	0/ 88	0/ 71				
Erythema						
White	1/239 (<1%)	2/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Night sweats						
White	2/239 (<1%)	0/256				
Non-White	1/ 88 (1%)	0/ 71				
Skin exfoliation						
White	0/239	3/256 (1%)				
Non-White	0/ 88	0/ 71				
Skin mass						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	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)

Urticaria						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	1/ 88 (1%)	0/ 71				
Actinic keratosis						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Chloasma						
White	0/239	1/256 (<1%)				
Non-White	1/ 88 (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)

Dermal cyst						
White	2/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Pityriasis rosea						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Psoriasis						
White	0/239	2/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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 erythematous						
White	0/239	2/256 (<1%)				
Non-White	0/ 88	0/ 71				
Rash papular						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Actinic elastosis						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Cold sweat						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Dermatosis						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)
Drug eruption						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Ecchymosis						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Eczema asteatotic						
White	0/239	0/256				
Non-White	1/ 88 (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)

Hyperkeratosis						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Intertrigo						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Keratosis pilaris						
White	0/239	0/256				
Non-White	1/ 88 (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)
Macule						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Miliaria						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Nail bed bleeding						
White	0/239	0/256				
Non-White	0/ 88	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)

Nail bed inflammation						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Penile ulceration						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Petechiae						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for 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)

Pigmentation disorder						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Pityriasis						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Prurigo						
White	0/239	0/256				
Non-White	0/ 88	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)
Purpura						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Rash macular						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Rash morbilliform						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for 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 discolouration						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Skin hypertrophy						
White	0/239	0/256				
Non-White	1/ 88 (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)

Skin irritation						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Skin ulcer						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Solar dermatitis						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, 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)
Solar lentigo						
White	0/239	0/256				
Non-White	0/ 88	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)
Respiratory, thoracic and mediastinal disorders						
Any Event						
White	31/239 (13%)	46/256 (18%)	0.6804 (0.4151, 1.1152) /0.127	-4.9980 (-11.3433, 1.3472) /0.123	0.7218 (0.4743, 1.0986) /0.128	0.990
Non-White	9/ 88 (10%)	10/ 71 (14%)	0.6949 (0.2660, 1.8159) /0.458	-3.8572 (-14.1310, 6.4165) /0.462	0.7261 (0.3121, 1.6896) /0.458	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Cough						
White	12/239 (5%)	16/256 (6%)	0.7930 (0.3671, 1.7129) /0.555	-1.2291 (-5.2858, 2.8277) /0.553	0.8033 (0.3881, 1.6627) /0.555	0.430
Non-White	4/ 88 (5%)	7/ 71 (10%)	0.4354 (0.1222, 1.5515) /0.200	-5.3137 (-13.5005, 2.8731) /0.203	0.4610 (0.1405, 1.5125) /0.201	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for 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)
Oropharyngeal pain						
White	7/239 (3%)	13/256 (5%)	0.5640 (0.2211, 1.4385) /0.231	-2.1493 (-5.5848, 1.2863) /0.220	0.5768 (0.2341, 1.4211) /0.232	0.716
Non-White	3/ 88 (3%)	3/ 71 (4%)	0.8000 (0.1565, 4.0903) /0.789	-0.8163 (-6.8387, 5.2062) /0.791	0.8068 (0.1679, 3.8760) /0.789	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Nasal congestion						
White	3/239 (1%)	8/256 (3%)	0.3941 (0.1033, 1.5032) /0.173	-1.8698 (-4.4261, 0.6866) /0.152	0.4017 (0.1078, 1.4963) /0.174	0.154
Non-White	1/ 88 (1%)	0/ 71	>999 (>999, >999) /NC	3.4034 (-20.7049, 27.5117) /0.782	>999 (>999, >999) /NC	
Rhinitis allergic						
White	4/239 (2%)	5/256 (2%)				
Non-White	1/ 88 (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. 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)
Sinus congestion						
White	2/239 (<1%)	7/256 (3%)				
Non-White	0/ 88	0/ 71				
Epistaxis						
White	1/239 (<1%)	3/256 (1%)				
Non-White	0/ 88	0/ 71				
Rhinorrhoea						
White	1/239 (<1%)	3/256 (1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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	1/239 (<1%)	2/256 (<1%)				
Non-White	0/ 88	0/ 71				
Dyspnoea						
White	2/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Sleep apnoea syndrome						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	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)

Catarrh						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Oropharyngeal discomfort						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Productive cough						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)

Rales						
White	0/239	1/256 (<1%)				
Non-White	1/ 88 (1%)	0/ 71				
Respiratory disorder						
White	0/239	2/256 (<1%)				
Non-White	0/ 88	0/ 71				
Bronchospasm						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Emphysema						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Haemoptysis						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)
Interstitial lung disease						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Nasal discomfort						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Nasal oedema						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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 septum deviation						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Painful respiration						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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 erythema						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Pleuritic pain						
White	0/239	0/256				
Non-White	1/ 88 (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)
Respiratory tract congestion						
White	0/239	0/256				
Non-White	0/ 88	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	32/239 (13%)	39/256 (15%)	0.8602 (0.5192, 1.4249) /0.559	-1.8453 (-8.0110, 4.3205) /0.557	0.8789 (0.5700, 1.3551) /0.559	0.537
Non-White	13/ 88 (15%)	9/ 71 (13%)	1.1941 (0.4787, 2.9785) /0.704	2.0967 (-8.6202, 12.8135) /0.701	1.1654 (0.5288, 2.5686) /0.704	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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	16/239 (7%)	19/256 (7%)	0.8950 (0.4490, 1.7838) /0.753	-0.7273 (-5.2384, 3.7838) /0.752	0.9020 (0.4750, 1.7128) /0.753	0.151
Non-White	7/ 88 (8%)	2/ 71 (3%)	2.9815 (0.5996, 14.8256) /0.182	5.1376 (-1.7015, 11.9767) /0.141	2.8238 (0.6054, 13.1727) /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.

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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	10/239 (4%)	7/256 (3%)	1.5533 (0.5816, 4.1488) /0.380	1.4497 (-1.7805, 4.6800) /0.379	1.5302 (0.5920, 3.9553) /0.380	0.881
Non-White	5/ 88 (6%)	3/ 71 (4%)	1.3655 (0.3150, 5.9198) /0.677	1.4565 (-5.2732, 8.1862) /0.671	1.3447 (0.3327, 5.4355) /0.678	
Presyncope						
White	3/239 (1%)	4/256 (2%)				
Non-White	0/ 88	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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Analysis of Proportion of Subjects with Adverse Events by 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)
Paraesthesia						
White	1/239 (<1%)	3/256 (1%)				
Non-White	1/ 88 (1%)	1/ 71 (1%)				
Migraine						
White	1/239 (<1%)	4/256 (2%)				
Non-White	0/ 88	0/ 71				
Somnolence						
White	1/239 (<1%)	2/256 (<1%)				
Non-White	1/ 88 (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)
Hypoaesthesia						
White	3/239 (1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Lethargy						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	2/ 88 (2%)	0/ 71				
Carpal tunnel syndrome						
White	1/239 (<1%)	0/256				
Non-White	1/ 88 (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= 1

System Organ Class Preferred Term	Q8W (N=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	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Syncope						
White	0/239	1/256 (<1%)				
Non-White	1/ 88 (1%)	0/ 71				
Tension headache						
White	0/239	0/256				
Non-White	1/ 88 (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)

Agnosia						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Amnesia						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Ataxia						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for 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)

Burning sensation						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Cervical radiculopathy						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Dysarthria						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for 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)
Dysgeusia						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Head discomfort						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Hyperaesthesia						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for 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)

Hypersomnia						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Memory impairment						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Muscle contractions involuntary						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Periodic limb movement disorder						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Polyneuropathy						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Tremor						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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	21/239 (9%)	39/256 (15%)	0.5360 (0.3053, 0.9410) /0.030	-6.4478 (-12.1275, -0.7680) /0.026	0.5768 (0.3497, 0.9512) /0.031	0.534
Non-White	5/ 88 (6%)	10/ 71 (14%)	0.3675 (0.1195, 1.1299) /0.081	-8.4027 (-17.8295, 1.0241) /0.081	0.4034 (0.1445, 1.1266) /0.083	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 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)
Contusion White	3/239 (1%)	7/256 (3%)	0.4522 (0.1156, 1.7691) /0.254	-1.4791 (-3.9252, 0.9669) /0.236	0.4591 (0.1201, 1.7548) /0.255	0.719
Non-White	1/ 88 (1%)	1/ 71 (1%)	0.8046 (0.0494, 13.0946) /0.879	-0.2721 (-3.7959, 3.2517) /0.880	0.8068 (0.0514, 12.6728) /0.879	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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	2/239 (<1%)	8/256 (3%)	0.2616 (0.0550, 1.2445) /0.092	-2.2882 (-4.7123, 0.1360) /0.064	0.2678 (0.0574, 1.2484) /0.093	>0.999
Non-White	0/ 88	0/ 71	NC	NC	NC	
Ligament sprain						
White	2/239 (<1%)	6/256 (2%)				
Non-White	1/ 88 (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)
Muscle strain						
White	3/239 (1%)	5/256 (2%)				
Non-White	0/ 88	1/ 71 (1%)				
Limb injury						
White	3/239 (1%)	2/256 (<1%)				
Non-White	2/ 88 (2%)	1/ 71 (1%)				
Exposure to communicable disease						
White	2/239 (<1%)	2/256 (<1%)				
Non-White	0/ 88	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)

Skin laceration						
White	1/239 (<1%)	4/256 (2%)				
Non-White	0/ 88	0/ 71				
Bone contusion						
White	1/239 (<1%)	2/256 (<1%)				
Non-White	0/ 88	0/ 71				
Foot fracture						
White	0/239	2/256 (<1%)				
Non-White	0/ 88	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)

Procedural pain						
White	1/239 (<1%)	2/256 (<1%)				
Non-White	0/ 88	0/ 71				
Skin abrasion						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	1/ 88 (1%)	0/ 71				
Vaccination complication						
White	0/239	3/256 (1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)
Animal bite						
White	0/239	2/256 (<1%)				
Non-White	0/ 88	0/ 71				
Arthropod sting						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Epicondylitis						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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)
Heat stroke						
White	0/239	2/256 (<1%)				
Non-White	0/ 88	0/ 71				
Concussion						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Eye injury						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Fall						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Hand fracture						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Head injury						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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 related reaction						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Injury corneal						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for 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)
Lip injury						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Musculoskeletal foreign body						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Nail injury						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Rib fracture						
White	0/239	0/256				
Non-White	1/ 88 (1%)	0/ 71				
Road traffic accident						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Sunburn						
White	0/239	0/256				
Non-White	0/ 88	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)
Thermal burn						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Traumatic haematoma						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Ulna fracture						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for 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	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Wound						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)

Psychiatric disorders						
Any Event						
White	25/239 (10%)	26/256 (10%)	1.0334 (0.5788, 1.8452) /0.911	0.3040 (-5.0576, 5.6656) /0.912	1.0299 (0.6124, 1.7323) /0.911	0.653
Non-White	8/ 88 (9%)	8/ 71 (11%)	0.7875 (0.2800, 2.2149) /0.651	-2.1767 (-11.6725, 7.3192) /0.653	0.8068 (0.3187, 2.0424) /0.651	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Insomnia						
White	4/239 (2%)	9/256 (4%)	0.4671 (0.1419, 1.5375) /0.210	-1.8420 (-4.6232, 0.9392) /0.194	0.4761 (0.1486, 1.5255) /0.212	0.940
Non-White	5/ 88 (6%)	9/ 71 (13%)	0.4150 (0.1325, 1.2997) /0.131	-6.9942 (-16.1202, 2.1318) /0.133	0.4482 (0.1572, 1.2778) /0.133	
Anxiety						
White	10/239 (4%)	6/256 (2%)	1.8195 (0.6510, 5.0857) /0.254	1.8404 (-1.3026, 4.9833) /0.251	1.7852 (0.6589, 4.8365) /0.254	>0.999
Non-White	0/ 88	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.

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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)

Abnormal dreams						
White	0/239	2/256 (<1%)				
Non-White	1/ 88 (1%)	2/ 71 (3%)				
Depressed mood						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	3/ 88 (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.

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)

Libido decreased						
White	3/239 (1%)	2/256 (<1%)				
Non-White	0/ 88	0/ 71				
Sleep disorder						
White	0/239	5/256 (2%)				
Non-White	0/ 88	0/ 71				
Depression						
White	2/239 (<1%)	2/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Nightmare						
White	1/239 (<1%)	2/256 (<1%)				
Non-White	0/ 88	1/ 71 (1%)				
Stress						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	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)

Adjustment disorder with depressed mood						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Adjustment disorder with mixed anxiety and depressed mood						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for 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)
Drug abuse						
White	0/239	2/256 (<1%)				
Non-White	0/ 88	0/ 71				
Irritability						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Acute stress disorder						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for 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)
Agoraphobia						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Alcohol withdrawal syndrome						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only 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)
Attention deficit hyperactivity disorder						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Generalised anxiety disorder						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only 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)
Loss of libido						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Major depression						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Mood swings						
White	0/239	0/256				
Non-White	1/ 88 (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= 1

System Organ Class Preferred Term	Q8W (N=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						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Panic attack						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Post-traumatic stress disorder						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only 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)
Restlessness						
White	0/239	0/256				
Non-White	1/ 88 (1%)	0/ 71				
Suicidal ideation						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)
Investigations						
Any Event						
White	11/239 (5%)	19/256 (7%)	0.6018 (0.2802, 1.2926) /0.193	-2.8194 (-6.9868, 1.3481) /0.185	0.6201 (0.3014, 1.2757) /0.194	0.913
Non-White	5/ 88 (6%)	7/ 71 (10%)	0.5508 (0.1670, 1.8160) /0.327	-4.1773 (-12.6318, 4.2771) /0.333	0.5763 (0.1910, 1.7386) /0.328	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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	4/239 (2%)	4/256 (2%)				
Non-White	0/ 88	0/ 71				
Body temperature increased						
White	1/239 (<1%)	6/256 (2%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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	2/239 (<1%)	2/256 (<1%)				
Non-White	1/ 88 (1%)	0/ 71				
Blood creatine phosphokinase increased						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	2/ 88 (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.

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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 pressure increased						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	1/ 88 (1%)	2/ 71 (3%)				
Blood cholesterol increased						
White	1/239 (<1%)	2/256 (<1%)				
Non-White	0/ 88	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)

Blood triglycerides increased						
White	0/239	3/256 (1%)				
Non-White	0/ 88	0/ 71				
Low density lipoprotein increased						
White	1/239 (<1%)	2/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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	2/239 (<1%)	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Aspartate aminotransferase increased						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Blood glucose increased						
White	2/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Blood bilirubin unconjugated increased						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 pressure decreased						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Chlamydia test positive						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)
Electrocardiogram abnormal						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Epstein-Barr virus test positive						
White	0/239	0/256				
Non-White	0/ 88	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)

Escherichia test positive						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Haematocrit increased						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Haemoglobin increased						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Intraocular pressure increased						
White	0/239	0/256				
Non-White	1/ 88 (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)

Transaminases increased						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Vitamin D decreased						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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	9/239 (4%)	20/256 (8%)	0.4617 (0.2059, 1.0352) /0.061	-4.0468 (-8.1250, 0.0314) /0.052	0.4820 (0.2239, 1.0376) /0.062	0.564
Non-White	3/ 88 (3%)	3/ 71 (4%)	0.8000 (0.1565, 4.0903) /0.789	-0.8163 (-6.8387, 5.2062) /0.791	0.8068 (0.1679, 3.8760) /0.789	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only 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)

Anogenital warts						
White	3/239 (1%)	10/256 (4%)	0.3127 (0.0850, 1.1503) /0.080	-2.6510 (-5.4123, 0.1103) /0.060	0.3213 (0.0895, 1.1536) /0.082	0.036
Non-White	2/ 88 (2%)	0/ 71	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Skin papilloma						
White	2/239 (<1%)	6/256 (2%)				
Non-White	1/ 88 (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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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)

Fibrous histiocytoma						
White	0/239	2/256 (<1%)				
Non-White	0/ 88	0/ 71				
Lipoma						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Lipoma of breast						
White	0/239	2/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)
Acrochordon						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Adenoma benign						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Basal cell carcinoma						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)

Benign neoplasm of thyroid gland						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Fibroma						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Urethral papilloma						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)
Uterine leiomyoma						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)

Vascular disorders						
Any Event						
White	13/239 (5%)	12/256 (5%)	1.1696 (0.5228, 2.6166) /0.703	0.7518 (-3.1174, 4.6211) /0.703	1.1604 (0.5402, 2.4926) /0.703	0.684
Non-White	3/ 88 (3%)	3/ 71 (4%)	0.8000 (0.1565, 4.0903) /0.789	-0.8163 (-6.8387, 5.2062) /0.791	0.8068 (0.1679, 3.8760) /0.789	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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	8/239 (3%)	5/256 (2%)	1.7385 (0.5607, 5.3902) /0.338	1.3942 (-1.4472, 4.2356) /0.336	1.7138 (0.5686, 5.1659) /0.339	0.268
Non-White	2/ 88 (2%)	3/ 71 (4%)	0.5271 (0.0856, 3.2444) /0.490	-1.9526 (-7.5732, 3.6680) /0.496	0.5379 (0.0924, 3.1316) /0.490	
Haematoma						
White	0/239	3/256 (1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, 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)
Varicose vein						
White	2/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Flushing						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Hot flush						
White	1/239 (<1%)	0/256				
Non-White	1/ 88 (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)
Peripheral venous disease						
White	0/239	2/256 (<1%)				
Non-White	0/ 88	0/ 71				
Hypotension						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Peripheral coldness						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for 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)

Reproductive system and breast disorders						
Any Event						
White	15/239 (6%)	11/256 (4%)	1.4915 (0.6709, 3.3155) /0.327	1.9793 (-1.9736, 5.9322) /0.326	1.4606 (0.6846, 3.1163) /0.327	0.577
Non-White	2/ 88 (2%)	2/ 71 (3%)	0.8023 (0.1102, 5.8425) /0.828	-0.5442 (-5.4946, 4.4063) /0.829	0.8068 (0.1165, 5.5857) /0.828	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Erectile dysfunction						
White	4/239 (2%)	3/256 (1%)				
Non-White	0/ 88	1/ 71 (1%)				
Menorrhagia						
White	0/239	2/256 (<1%)				
Non-White	1/ 88 (1%)	0/ 71				
Balanoposthitis						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, 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)
Breast cyst						
White	0/239	2/256 (<1%)				
Non-White	0/ 88	0/ 71				
Genital lesion						
White	2/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Prostatomegaly						
White	0/239	2/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, 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)

Atrophic vulvovaginitis						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Breast mass						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Breast pain						
White	0/239	0/256				
Non-White	1/ 88 (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)
Cervical dysplasia						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Genital erythema						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Penile discomfort						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Penile pain						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Penile rash						
White	0/239	0/256				
Non-White	0/ 88	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)

Premenstrual syndrome						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Sexual dysfunction						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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 cyst						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Testicular pain						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 swelling						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Testis discomfort						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Uterine polyp						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)
Vaginal discharge						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Renal and urinary disorders						
Any Event						
White	3/239 (1%)	17/256 (7%)	0.1787 (0.0517, 0.6179) /0.007	-5.3854 (-8.7462, -2.0246) /0.002	0.1890 (0.0561, 0.6368) /0.007	0.478
Non-White	2/ 88 (2%)	4/ 71 (6%)	0.3895 (0.0693, 2.1910) /0.285	-3.3611 (-9.5627, 2.8405) /0.288	0.4034 (0.0761, 2.1394) /0.286	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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	1/239 (<1%)	6/256 (2%)				
Non-White	1/ 88 (1%)	2/ 71 (3%)				
Nocturia						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	1/ 88 (1%)	0/ 71				
Haematuria						
White	0/239	0/256				
Non-White	0/ 88	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)

Micturition urgency						
White	0/239	2/256 (<1%)				
Non-White	0/ 88	0/ 71				
Nephrolithiasis						
White	0/239	2/256 (<1%)				
Non-White	0/ 88	0/ 71				
Renal cyst						
White	0/239	1/256 (<1%)				
Non-White	1/ 88 (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)

Urethral discharge						
White	0/239	2/256 (<1%)				
Non-White	0/ 88	0/ 71				
Nephropathy						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Pollakiuria						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)

Urethral disorder						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Urethral pain						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Urinary incontinence						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Ear and labyrinth disorders						
Any Event						
White	6/239 (3%)	10/256 (4%)	0.6335 (0.2266, 1.7706) /0.384	-1.3958 (-4.4888, 1.6972) /0.376	0.6427 (0.2372, 1.7411) /0.385	0.566
Non-White	4/ 88 (5%)	3/ 71 (4%)	1.0794 (0.2336, 4.9882) /0.922	0.3201 (-6.0702, 6.7104) /0.922	1.0758 (0.2488, 4.6504) /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. 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)
Tinnitus						
White	2/239 (<1%)	1/256 (<1%)				
Non-White	1/ 88 (1%)	1/ 71 (1%)				
Vertigo						
White	2/239 (<1%)	3/256 (1%)				
Non-White	0/ 88	0/ 71				
Cerumen impaction						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	2/ 88 (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)
Ear discomfort						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Ear pain						
White	0/239	1/256 (<1%)				
Non-White	1/ 88 (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= 1

System Organ Class Preferred Term	Q8W (N=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	0/239	0/256				
Non-White	0/ 88	2/ 71 (3%)				
Excessive cerumen production						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, 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)

Deafness neurosensory						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Ear pruritus						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Hypoacusis						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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	8/239 (3%)	6/256 (2%)	1.4430 (0.4932, 4.2217) /0.503	1.0035 (-1.9349, 3.9420) /0.503	1.4282 (0.5029, 4.0557) /0.503	0.512
Non-White	4/ 88 (5%)	4/ 71 (6%)	0.7976 (0.1923, 3.3084) /0.755	-1.0883 (-7.9952, 5.8185) /0.757	0.8068 (0.2091, 3.1128) /0.755	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Hypercholesterolaemia						
White	2/239 (<1%)	2/256 (<1%)				
Non-White	0/ 88	0/ 71				
Decreased appetite						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	1/ 71 (1%)				
Gout						
White	3/239 (1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for 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)

Vitamin D deficiency						
White	0/239	1/256 (<1%)				
Non-White	2/ 88 (2%)	0/ 71				
Alcoholic ketoacidosis						
White	0/239	0/256				
Non-White	1/ 88 (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)

Diabetes mellitus						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Dyslipidaemia						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Gluten sensitivity						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)

Hyperglycaemia ^a						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Hyperlipasaemia						
White	0/239	0/256				
Non-White	1/ 88 (1%)	0/ 71				
Hypokalaemia						
White	0/239	0/256				
Non-White	0/ 88	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)
Iron deficiency						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Obesity						
White	0/239	0/256				
Non-White	1/ 88 (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= 1

System Organ Class Preferred Term	Q8W (N=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	0/239	0/256				
Non-White	0/ 88	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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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)

Eye disorders						
Any Event						
White	4/239 (2%)	11/256 (4%)	0.3791 (0.1191, 1.2073) /0.101	-2.6232 (-5.5924, 0.3459) /0.083	0.3895 (0.1257, 1.2066) /0.102	0.585
Non-White	1/ 88 (1%)	4/ 71 (6%)	0.1925 (0.0210, 1.7627) /0.145	-4.4974 (-10.2999, 1.3050) /0.129	0.2017 (0.0231, 1.7646) /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.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Conjunctivitis allergic						
White	1/239 (<1%)	2/256 (<1%)				
Non-White	0/ 88	1/ 71 (1%)				
Blepharitis						
White	0/239	2/256 (<1%)				
Non-White	0/ 88	0/ 71				
Cataract						
White	0/239	2/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only 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)
Dry eye						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	1/ 71 (1%)				
Astigmatism						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Diplopia						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 eyelids						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Eye pain						
White	0/239	0/256				
Non-White	1/ 88 (1%)	0/ 71				
Eyelid cyst						
White	0/239	0/256				
Non-White	0/ 88	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)
Glaucoma						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Iritis						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Mydriasis						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only 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)
Ocular hyperaemia						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Pterygium						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Vision blurred						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Vitreous detachment						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Vitreous floaters						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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 and lymphatic system disorders						
Any Event						
White	5/239 (2%)	10/256 (4%)	0.5256 (0.1770, 1.5608) /0.247	-1.8142 (-4.8016, 1.1732) /0.234	0.5356 (0.1857, 1.5442) /0.248	>0.999
Non-White	0/ 88	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.

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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)

Lymphadenopathy						
White	2/239 (<1%)	4/256 (2%)				
Non-White	0/ 88	0/ 71				
Anaemia						
White	0/239	5/256 (2%)				
Non-White	0/ 88	0/ 71				
Microcytic anaemia						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)
Iron deficiency anaemia						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Lymph node pain						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)
Polycythaemia						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)

Immune system disorders						
Any Event						
White	5/239 (2%)	5/256 (2%)	1.0726 (0.3066, 3.7526) /0.913	0.1389 (-2.3442, 2.6220) /0.913	1.0711 (0.3140, 3.6536) /0.913	0.156
Non-White	2/ 88 (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. 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)

Seasonal allergy						
White	4/239 (2%)	4/256 (2%)				
Non-White	1/ 88 (1%)	0/ 71				
Hypersensitivity						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	1/ 88 (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)

Anaphylactic reaction						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Cardiac disorders						
Any Event						
White	0/239	4/256 (2%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)
Palpitations						
White	0/239	2/256 (<1%)				
Non-White	0/ 88	0/ 71				
Tachycardia						
White	0/239	2/256 (<1%)				
Non-White	0/ 88	0/ 71				
Atrioventricular block first degree						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only 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)

Wolff-Parkinson-White syndrome						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Endocrine disorders						
Any Event						
White	1/239 (<1%)	3/256 (1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Hypogonadism						
White	0/239	2/256 (<1%)				
Non-White	0/ 88	0/ 71				
Androgen deficiency						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Goitre						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Hepatobiliary disorders						
Any Event						
White	1/239 (<1%)	2/256 (<1%)				
Non-White	0/ 88	0/ 71				
Cholelithiasis						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)

Hepatic steatosis						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Hepatomegaly						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Congenital, familial and genetic disorders						
Any Event						
White	0/239	1/256 (<1%)				
Non-White	1/ 88 (1%)	0/ 71				
Gilbert's syndrome						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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	0/239	0/256				
Non-White	1/ 88 (1%)	0/ 71				
Social circumstances						
Any Event						
White	2/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)
Menopause						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Stress at work						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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	127/239 (53%)	133/256 (52%)	1.0487 (0.7367, 1.4927) /0.792	1.1850 (-7.6174, 9.9873) /0.792	1.0228 (0.8651, 1.2093) /0.792	0.836
Non-White	49/ 88 (56%)	40/ 71 (56%)	0.9737 (0.5186, 1.8282) /0.934	-0.6562 (-16.1743, 14.8619) /0.934	0.9884 (0.7493, 1.3037) /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.

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)

General disorders and administration site conditions						
Any Event						
White	85/239 (36%)	85/256 (33%)	1.1104 (0.7661, 1.6095) /0.580	2.3617 (-6.0117, 10.7351) /0.580	1.0711 (0.8396, 1.3665) /0.580	0.730
Non-White	33/ 88 (38%)	27/ 71 (38%)	0.9778 (0.5131, 1.8634) /0.946	-0.5282 (-15.6880, 14.6316) /0.946	0.9861 (0.6602, 1.4728) /0.946	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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 pain						
White	77/239 (32%)	73/256 (29%)	1.1915 (0.8118, 1.7488) /0.371	3.7019 (-4.4029, 11.8068) /0.371	1.1298 (0.8648, 1.4760) /0.371	0.550
Non-White	30/ 88 (34%)	25/ 71 (35%)	0.9517 (0.4935, 1.8356) /0.883	-1.1204 (-16.0037, 13.7630) /0.883	0.9682 (0.6305, 1.4867) /0.883	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for 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)
Injection site nodule						
White	6/239 (3%)	10/256 (4%)	0.6335 (0.2266, 1.7706) /0.384	-1.3958 (-4.4888, 1.6972) /0.376	0.6427 (0.2372, 1.7411) /0.385	0.456
Non-White	3/ 88 (3%)	7/ 71 (10%)	0.3227 (0.0803, 1.2967) /0.111	-6.4501 (-14.3531, 1.4530) /0.110	0.3458 (0.0928, 1.2891) /0.114	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Injection site induration						
White	3/239 (1%)	2/256 (<1%)				
Non-White	2/ 88 (2%)	1/ 71 (1%)				
Injection site discomfort						
White	5/239 (2%)	4/256 (2%)				
Non-White	2/ 88 (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.

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)
Pyrexia						
White	5/239 (2%)	7/256 (3%)	0.7601 (0.2379, 2.4280) /0.643	-0.6423 (-3.3411, 2.0564) /0.641	0.7651 (0.2462, 2.3780) /0.644	0.963
Non-White	2/ 88 (2%)	2/ 71 (3%)	0.8023 (0.1102, 5.8425) /0.828	-0.5442 (-5.4946, 4.4063) /0.829	0.8068 (0.1165, 5.5857) /0.828	
Fatigue						
White	1/239 (<1%)	2/256 (<1%)				
Non-White	2/ 88 (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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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 swelling						
White	4/239 (2%)	2/256 (<1%)	2.1617 (0.3923, 11.9117) /0.376	0.8924 (-1.0591, 2.8438) /0.370	2.1423 (0.3960, 11.5890) /0.376	0.588
Non-White	6/ 88 (7%)	4/ 71 (6%)	1.2256 (0.3321, 4.5227) /0.760	1.1844 (-6.3322, 8.7009) /0.757	1.2102 (0.3552, 4.1236) /0.760	
Injection site pruritus						
White	0/239	1/256 (<1%)				
Non-White	2/ 88 (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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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 erythema						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	1/ 71 (1%)				
Influenza like illness						
White	2/239 (<1%)	3/256 (1%)				
Non-White	1/ 88 (1%)	0/ 71				
Asthenia						
White	1/239 (<1%)	2/256 (<1%)				
Non-White	2/ 88 (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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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)

Chills						
White	1/239 (<1%)	0/256				
Non-White	1/ 88 (1%)	1/ 71 (1%)				
Injection site bruising						
White	0/239	1/256 (<1%)				
Non-White	1/ 88 (1%)	2/ 71 (3%)				
Pain						
White	2/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only 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)
Malaise						
White	0/239	1/256 (<1%)				
Non-White	1/ 88 (1%)	0/ 71				
Injection site haematoma						
White	2/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Discomfort						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Injection site reaction						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Injection site warmth						
White	1/239 (<1%)	2/256 (<1%)				
Non-White	1/ 88 (1%)	1/ 71 (1%)				
Chest pain						
White	2/239 (<1%)	2/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Injection site anaesthesia						
White	0/239	0/256				
Non-White	1/ 88 (1%)	0/ 71				
Feeling hot						
White	0/239	0/256				
Non-White	1/ 88 (1%)	0/ 71				
Nodule						
White	2/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Mass						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Peripheral swelling						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	1/ 88 (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 Preferred Term	Q8W (N=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	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Chest discomfort						
White	0/239	0/256				
Non-White	1/ 88 (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)

Gait disturbance						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Non-cardiac chest pain						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only 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 discharge						
White	0/239	0/256				
Non-White	1/ 88 (1%)	0/ 71				
Injection site fibrosis						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)
Injection site necrosis						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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	Q8W (N=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	69/239 (29%)	81/256 (32%)	0.8769 (0.5971, 1.2877) /0.503	-2.7703 (-10.8612, 5.3206) /0.502	0.9124 (0.6977, 1.1933) /0.503	0.745
Non-White	27/ 88 (31%)	26/ 71 (37%)	0.7661 (0.3951, 1.4853) /0.430	-5.9379 (-20.7169, 8.8411) /0.431	0.8378 (0.5404, 1.2990) /0.429	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only 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)

Nasopharyngitis						
White	15/239 (6%)	12/256 (5%)	1.3616 (0.6239, 2.9717) /0.438	1.5887 (-2.4311, 5.6084) /0.439	1.3389 (0.6399, 2.8016) /0.438	0.644
Non-White	5/ 88 (6%)	2/ 71 (3%)	2.0783 (0.3910, 11.0472) /0.391	2.8649 (-3.3161, 9.0459) /0.364	2.0170 (0.4033, 10.0883) /0.393	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only 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)
Upper respiratory tract infection						
White	9/239 (4%)	13/256 (5%)	0.7314 (0.3068, 1.7438) /0.480	-1.3124 (-4.9260, 2.3011) /0.477	0.7416 (0.3229, 1.7030) /0.481	0.286
Non-White	5/ 88 (6%)	11/ 71 (15%)	0.3286 (0.1085, 0.9951) /0.049	-9.8111 (-19.5184, -0.1039) /0.048	0.3667 (0.1336, 1.0067) /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 3.20

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)

Gastroenteritis						
White	4/239 (2%)	8/256 (3%)	0.5277 (0.1568, 1.7756) /0.302	-1.4514 (-4.1324, 1.2296) /0.289	0.5356 (0.1634, 1.7555) /0.303	0.417
Non-White	1/ 88 (1%)	4/ 71 (6%)	0.1925 (0.0210, 1.7627) /0.145	-4.4974 (-10.2999, 1.3050) /0.129	0.2017 (0.0231, 1.7646) /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.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Syphilis						
White	7/239 (3%)	7/256 (3%)	1.0733 (0.3708, 3.1066) /0.896	0.1945 (-2.7314, 3.1204) /0.896	1.0711 (0.3814, 3.0084) /0.896	0.035
Non-White	0/ 88	3/ 71 (4%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Pharyngitis						
White	2/239 (<1%)	6/256 (2%)				
Non-White	2/ 88 (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= 2

System Organ Class Preferred Term	Q8W (N=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	2/239 (<1%)	4/256 (2%)				
Non-White	0/ 88	1/ 71 (1%)				
Influenza						
White	4/239 (2%)	4/256 (2%)				
Non-White	1/ 88 (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.

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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)
<hr/>						
Bronchitis						
White	6/239 (3%)	5/256 (2%)	1.2927 (0.3893, 4.2925) /0.675	0.5573 (-2.0518, 3.1664) /0.675	1.2854 (0.3975, 4.1566) /0.675	0.181
Non-White	0/ 88	1/ 71 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Sinusitis						
White	3/239 (1%)	3/256 (1%)				
Non-White	2/ 88 (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= 2

System Organ Class Preferred Term	Q8W (N=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	4/239 (2%)	2/256 (<1%)				
Non-White	0/ 88	1/ 71 (1%)				
Conjunctivitis						
White	4/239 (2%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)

Viral infection						
White	1/239 (<1%)	5/256 (2%)				
Non-White	2/ 88 (2%)	0/ 71				
Respiratory tract infection						
White	1/239 (<1%)	2/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for 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)
Folliculitis						
White	2/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Oral herpes						
White	1/239 (<1%)	2/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for 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)
Respiratory tract infection viral						
White	3/239 (1%)	3/256 (1%)				
Non-White	1/ 88 (1%)	0/ 71				
Urethritis						
White	2/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	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)

Urinary tract infection						
White	4/239 (2%)	2/256 (<1%)				
Non-White	1/ 88 (1%)	2/ 71 (3%)				
Tonsillitis						
White	2/239 (<1%)	4/256 (2%)				
Non-White	0/ 88	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)

Viral upper respiratory tract infection						
White	0/239	0/256				
Non-White	0/ 88	2/ 71 (3%)				
Gastroenteritis viral						
White	1/239 (<1%)	3/256 (1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)
Onychomycosis						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Proctitis gonococcal						
White	3/239 (1%)	6/256 (2%)				
Non-White	0/ 88	0/ 71				
Tooth abscess						
White	0/239	2/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)

Anal chlamydia infection						
White	3/239 (1%)	4/256 (2%)				
Non-White	1/ 88 (1%)	1/ 71 (1%)				
Ear infection						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	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)
Fungal skin infection						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Tinea versicolour						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Herpes zoster						
White	1/239 (<1%)	4/256 (2%)				
Non-White	1/ 88 (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 Preferred Term	Q8W (N=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	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Lower respiratory tract infection						
White	0/239	2/256 (<1%)				
Non-White	2/ 88 (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= 2

System Organ Class Preferred Term	Q8W (N=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	2/239 (<1%)	3/256 (1%)				
Non-White	1/ 88 (1%)	2/ 71 (3%)				
Tooth infection						
White	0/239	3/256 (1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)
Furuncle						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Acarodermatitis						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Body tinea						
White	0/239	0/256				
Non-White	1/ 88 (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)

Diverticulitis						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Secondary syphilis						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)

Urethritis gonococcal						
White	1/239 (<1%)	2/256 (<1%)				
Non-White	0/ 88	0/ 71				
Viral pharyngitis						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Cellulitis						
White	1/239 (<1%)	2/256 (<1%)				
Non-White	1/ 88 (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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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)
Enteritis infectious						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Mycoplasma genitalium infection						
White	0/239	2/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)

Oral candidiasis						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Paronychia						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Pneumonia						
White	0/239	1/256 (<1%)				
Non-White	1/ 88 (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)
Primary syphilis						
White	2/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Skin infection						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)

Staphylococcal infection						
White	0/239	0/256				
Non-White	1/ 88 (1%)	0/ 71				
Tracheitis						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Urethritis chlamydial						
White	0/239	4/256 (2%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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	1/239 (<1%)	1/256 (<1%)				
Non-White	1/ 88 (1%)	1/ 71 (1%)				
Acute sinusitis						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Bronchitis viral						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)

Cystitis						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Diarrhoea infectious						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Epididymitis						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Genital herpes						
White	1/239 (<1%)	2/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, 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)

Injection site abscess						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Laryngitis						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, 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)
Pharyngeal chlamydia infection						
White	1/239 (<1%)	0/256				
Non-White	1/ 88 (1%)	0/ 71				
Pharyngitis streptococcal						
White	0/239	1/256 (<1%)				
Non-White	1/ 88 (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)

Pharyngotonsillitis						
White	0/239	2/256 (<1%)				
Non-White	1/ 88 (1%)	0/ 71				
Pulpitis dental						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Sexually transmitted disease						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Staphylococcal skin infection						
White	0/239	0/256				
Non-White	1/ 88 (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)

Subcutaneous abscess						
White	0/239	1/256 (<1%)				
Non-White	1/ 88 (1%)	0/ 71				
Ureaplasma infection						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Urethritis mycoplasmal						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Varicella						
White	2/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Shigella infection						
White	1/239 (<1%)	2/256 (<1%)				
Non-White	1/ 88 (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	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	1/ 71 (1%)				
Orchitis						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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)

Pulmonary tuberculosis						
White	1/239 (<1%)	0/256				
Non-White	1/ 88 (1%)	0/ 71				
Abscess						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Asymptomatic bacteriuria						
White	0/239	0/256				
Non-White	0/ 88	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)

Bacterial diarrhoea						
White	0/239	0/256				
Non-White	1/ 88 (1%)	0/ 71				
 Bacterial rhinitis						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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 vaginosis						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
COVID-19						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Chest wall abscess						
White	0/239	0/256				
Non-White	1/ 88 (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)

Cutaneous blastomycosis						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Dermatophytosis of nail						
White	0/239	0/256				
Non-White	0/ 88	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	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Ear infection bacterial						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)

Eczema infected						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Enterobiasis						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Escherichia infection						
White	0/239	0/256				
Non-White	1/ 88 (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)

Gastroenteritis						
Escherichia coli						
White	0/239	0/256				
Non-White	1/ 88 (1%)	0/ 71				
Genital candidiasis						
White	0/239	0/256				
Non-White	1/ 88 (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)

Genitourinary tract infection						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Gonococcal infection						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)
Herpes ophthalmic						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Herpes virus infection						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Infected bite						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)
Infection						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Latent syphilis						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Lice infestation						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)

Oesophageal candidiasis						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Ophthalmic herpes zoster						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)

Perirectal abscess						
White	0/239	0/256				
Non-White	1/ 88 (1%)	0/ 71				
Proctitis chlamydial						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Sialoadenitis						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Skin bacterial infection						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Suspected COVID-19						
White	0/239	0/256				
Non-White	0/ 88	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)
Urinary tract infection staphylococcal						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Wound abscess						
White	0/239	0/256				
Non-White	1/ 88 (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	Q8W (N=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	21/239 (9%)	39/256 (15%)	0.5360 (0.3053, 0.9410) /0.030	-6.4478 (-12.1275, -0.7680) /0.026	0.5768 (0.3497, 0.9512) /0.031	0.533
Non-White	8/ 88 (9%)	8/ 71 (11%)	0.7875 (0.2800, 2.2149) /0.651	-2.1767 (-11.6725, 7.3192) /0.653	0.8068 (0.3187, 2.0424) /0.651	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for 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)
Diarrhoea						
White	6/239 (3%)	11/256 (4%)	0.5735 (0.2087, 1.5759) /0.281	-1.7864 (-4.9652, 1.3923) /0.271	0.5843 (0.2195, 1.5551) /0.282	0.828
Non-White	3/ 88 (3%)	5/ 71 (7%)	0.4659 (0.1074, 2.0202) /0.308	-3.6332 (-10.6896, 3.4233) /0.313	0.4841 (0.1198, 1.9568) /0.309	
Nausea						
White	1/239 (<1%)	4/256 (2%)				
Non-White	2/ 88 (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= 2

System Organ Class Preferred Term	Q8W (N=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						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Dyspepsia						
White	1/239 (<1%)	2/256 (<1%)				
Non-White	0/ 88	1/ 71 (1%)				
Haemorrhoids						
White	0/239	3/256 (1%)				
Non-White	2/ 88 (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.

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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	2/239 (<1%)	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Abdominal distension						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Toothache						
White	1/239 (<1%)	5/256 (2%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Abdominal pain upper						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Gastrooesophageal reflux disease						
White	1/239 (<1%)	4/256 (2%)				
Non-White	0/ 88	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)
Vomiting						
White	2/239 (<1%)	1/256 (<1%)				
Non-White	1/ 88 (1%)	0/ 71				
Abdominal discomfort						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Anogenital dysplasia						
White	2/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Abdominal pain lower						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Gastritis						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	1/ 88 (1%)	0/ 71				
Haematochezia						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Rectal discharge						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Anal fissure						
White	1/239 (<1%)	0/256				
Non-White	1/ 88 (1%)	1/ 71 (1%)				
Dry mouth						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)
Inguinal hernia						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Irritable bowel syndrome						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)
Oesophagitis						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Anal fistula						
White	1/239 (<1%)	0/256				
Non-White	1/ 88 (1%)	0/ 71				
Large intestine polyp						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)
Oral disorder						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Proctitis						
White	0/239	3/256 (1%)				
Non-White	0/ 88	0/ 71				
Colitis						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)
Haemorrhoids thrombosed						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	1/ 71 (1%)				
Tongue ulceration						
White	0/239	2/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Aphthous ulcer						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Crohn's disease						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Dental cyst						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Gingival ulceration						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Glossitis						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Intestinal polyp						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, 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 pain						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Periodontal disease						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Rectal prolapse						
White	0/239	0/256				
Non-White	0/ 88	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	Q8W (N=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	22/239 (9%)	30/256 (12%)	0.7638 (0.4273, 1.3652) /0.363	-2.5137 (-7.8949, 2.8675) /0.360	0.7855 (0.4665, 1.3227) /0.364	0.502
Non-White	6/ 88 (7%)	9/ 71 (13%)	0.5041 (0.1704, 1.4908) /0.216	-5.8579 (-15.2187, 3.5029) /0.220	0.5379 (0.2010, 1.4397) /0.217	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for 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)
Back pain						
White	4/239 (2%)	7/256 (3%)	0.6055 (0.1750, 2.0951) /0.428	-1.0607 (-3.6368, 1.5153) /0.420	0.6121 (0.1815, 2.0644) /0.429	0.155
Non-White	0/ 88	2/ 71 (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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Analysis of Proportion of Subjects with Adverse Events by 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)
Arthralgia						
White	7/239 (3%)	7/256 (3%)	1.0733 (0.3708, 3.1066) /0.896	0.1945 (-2.7314, 3.1204) /0.896	1.0711 (0.3814, 3.0084) /0.896	0.850
Non-White	1/ 88 (1%)	1/ 71 (1%)	0.8046 (0.0494, 13.0946) /0.879	-0.2721 (-3.7959, 3.2517) /0.880	0.8068 (0.0514, 12.6728) /0.879	
Pain in extremity						
White	2/239 (<1%)	3/256 (1%)				
Non-White	0/ 88	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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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=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	2/239 (<1%)	2/256 (<1%)				
Non-White	0/ 88	1/ 71 (1%)				
Musculoskeletal pain						
White	4/239 (2%)	2/256 (<1%)				
Non-White	0/ 88	0/ 71				
Tendonitis						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	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)
Muscle spasms						
White	0/239	1/256 (<1%)				
Non-White	1/ 88 (1%)	1/ 71 (1%)				
Muscle contracture						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Musculoskeletal chest pain						
White	2/239 (<1%)	2/256 (<1%)				
Non-White	1/ 88 (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)
Intervertebral disc protrusion						
White	0/239	0/256				
Non-White	1/ 88 (1%)	0/ 71				
Neck pain						
White	2/239 (<1%)	2/256 (<1%)				
Non-White	0/ 88	0/ 71				
Arthritis						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for 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)
Exostosis						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Groin pain						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Joint range of motion decreased						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for 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)
Limb discomfort						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Muscular weakness						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for 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 discomfort						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Pain in jaw						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Plantar fasciitis						
White	0/239	0/256				
Non-White	1/ 88 (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. 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)
Rotator cuff syndrome						
White	0/239	2/256 (<1%)				
Non-White	0/ 88	0/ 71				
Synovial cyst						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	1/ 71 (1%)				
Synovitis						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Osteoarthritis						
White	2/239 (<1%)	2/256 (<1%)				
Non-White	0/ 88	0/ 71				
Arthritis reactive						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Bone pain						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Loose body in joint						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Periarthritis						
White	0/239	0/256				
Non-White	1/ 88 (1%)	0/ 71				
Polyarthritis						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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	13/239 (5%)	16/256 (6%)	0.8628 (0.4059, 1.8340) /0.701	-0.8107 (-4.9410, 3.3196) /0.700	0.8703 (0.4278, 1.7707) /0.701	0.877
Non-White	6/ 88 (7%)	5/ 71 (7%)	0.9659 (0.2822, 3.3053) /0.956	-0.2241 (-8.1710, 7.7228) /0.956	0.9682 (0.3081, 3.0421) /0.956	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Pruritus						
White	2/239 (<1%)	1/256 (<1%)				
Non-White	1/ 88 (1%)	0/ 71				
Rash						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	1/ 88 (1%)	0/ 71				
Eczema						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	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)
Acne						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Alopecia						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Dermatitis						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	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)

Skin lesion						
White	3/239 (1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Dermatitis contact						
White	0/239	0/256				
Non-White	1/ 88 (1%)	0/ 71				
Hyperhidrosis						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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= 2

System Organ Class Preferred Term	Q8W (N=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	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Erythema						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Night sweats						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, 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)

Urticaria						
White	0/239	1/256 (<1%)				
Non-White	1/ 88 (1%)	0/ 71				
Dermal cyst						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Pityriasis rosea						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, 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)
Ecchymosis						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Rash maculo-papular						
White	0/239	1/256 (<1%)				
Non-White	1/ 88 (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)

Granuloma annulare						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Guttate psoriasis						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for 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)
Hand dermatitis						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Lichen sclerosus						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)

Nail dystrophy						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Pain of skin						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Rash pruritic						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, 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)

Rash vesicular						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Skin fissures						
White	0/239	0/256				
Non-White	1/ 88 (1%)	0/ 71				
Skin swelling						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for 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)

Respiratory, thoracic and mediastinal disorders						
Any Event						
White	7/239 (3%)	15/256 (6%)	0.4848 (0.1941, 1.2105) /0.121	-2.9305 (-6.5148, 0.6538) /0.109	0.4999 (0.2074, 1.2047) /0.122	0.527
Non-White	5/ 88 (6%)	5/ 71 (7%)	0.7952 (0.2209, 2.8630) /0.726	-1.3604 (-9.0294, 6.3085) /0.728	0.8068 (0.2431, 2.6774) /0.726	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, 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)
Cough						
White	3/239 (1%)	3/256 (1%)				
Non-White	2/ 88 (2%)	1/ 71 (1%)				
Oropharyngeal pain						
White	1/239 (<1%)	3/256 (1%)				
Non-White	0/ 88	0/ 71				
Nasal congestion						
White	0/239	0/256				
Non-White	1/ 88 (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.

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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						
White	1/239 (<1%)	3/256 (1%)				
Non-White	0/ 88	1/ 71 (1%)				
Sinus congestion						
White	0/239	1/256 (<1%)				
Non-White	1/ 88 (1%)	0/ 71				
Epistaxis						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for 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)

Asthma						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	1/ 88 (1%)	1/ 71 (1%)				
Dyspnoea						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Sleep apnoea syndrome						
White	0/239	3/256 (1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for 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)
Productive cough						
White	0/239	0/256				
Non-White	1/ 88 (1%)	1/ 71 (1%)				
Haemoptysis						
White	0/239	0/256				
Non-White	1/ 88 (1%)	0/ 71				
Nasal discomfort						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Nervous system disorders						
Any Event						
White	14/239 (6%)	15/256 (6%)	0.9997 (0.4719, 2.1178) /0.999	-0.0016 (-4.1418, 4.1385) /0.999	0.9997 (0.4931, 2.0267) /0.999	0.056
Non-White	4/ 88 (5%)	11/ 71 (15%)	0.2597 (0.0789, 0.8550) /0.027	-10.9475 (-20.4226, -1.4724) /0.024	0.2934 (0.0976, 0.8821) /0.029	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
<hr/>						
Headache						
White	5/239 (2%)	8/256 (3%)	0.6624 (0.2136, 2.0537) /0.476	-1.0329 (-3.8320, 1.7661) /0.470	0.6695 (0.2221, 2.0179) /0.476	0.207
Non-White	1/ 88 (1%)	5/ 71 (7%)	0.1517 (0.0173, 1.3298) /0.089	-5.9059 (-12.2559, 0.4442) /0.068	0.1614 (0.0193, 1.3499) /0.092	
Dizziness						
White	0/239	2/256 (<1%)				
Non-White	2/ 88 (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.

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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)
Presyncope						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	1/ 71 (1%)				
Paraesthesia						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Migraine						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	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)

Hypoaesthesia						
White	2/239 (<1%)	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Sciatica						
White	2/239 (<1%)	2/256 (<1%)				
Non-White	0/ 88	0/ 71				
Syncope						
White	0/239	2/256 (<1%)				
Non-White	0/ 88	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)

Tension headache						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Cervical radiculopathy						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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	0/239	0/256				
Non-White	1/ 88 (1%)	0/ 71				
Anosmia						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Brain injury						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)
Brain stem infarction						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Cerebral infarction						
White	0/239	0/256				
Non-White	1/ 88 (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)

Disturbance in attention						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Hypertonia						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Neuropathy peripheral						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for 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)

Radiculopathy						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Transient ischaemic attack						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for 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)
Trigeminal neuralgia						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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	13/239 (5%)	24/256 (9%)	0.5560 (0.2763, 1.1190) /0.100	-3.9357 (-8.5200, 0.6487) /0.092	0.5802 (0.3024, 1.1131) /0.101	0.687
Non-White	2/ 88 (2%)	4/ 71 (6%)	0.3895 (0.0693, 2.1910) /0.285	-3.3611 (-9.5627, 2.8405) /0.288	0.4034 (0.0761, 2.1394) /0.286	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
<hr/>						
Contusion						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Arthropod bite						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	1/ 71 (1%)				
Ligament sprain						
White	0/239	2/256 (<1%)				
Non-White	1/ 88 (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)
Muscle strain						
White	0/239	3/256 (1%)				
Non-White	0/ 88	0/ 71				
Limb injury						
White	2/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Exposure to communicable disease						
White	2/239 (<1%)	4/256 (2%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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 laceration						
White	1/239 (<1%)	2/256 (<1%)				
Non-White	0/ 88	0/ 71				
Skin abrasion						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Vaccination complication						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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 sting						
White	0/239	2/256 (<1%)				
Non-White	0/ 88	0/ 71				
Epicondylitis						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Heat stroke						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, 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)
Head injury						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Musculoskeletal foreign body						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Rib fracture						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	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= 2

System Organ Class Preferred Term	Q8W (N=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	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Ankle fracture						
White	1/239 (<1%)	0/256				
Non-White	1/ 88 (1%)	0/ 71				
Joint injury						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Meniscus injury						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	1/ 71 (1%)				
Wrist fracture						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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= 2

System Organ Class Preferred Term	Q8W (N=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	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Chemical burns of eye						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Clavicle fracture						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Corneal abrasion						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Face injury						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)

Fibula fracture						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Fractured coccyx						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Gastrointestinal procedural complication						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Joint dislocation						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Post-traumatic pain						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Scapula fracture						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Traumatic arthritis						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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	19/239 (8%)	13/256 (5%)	1.6143 (0.7790, 3.3454) /0.198	2.8717 (-1.4867, 7.2300) /0.197	1.5655 (0.7907, 3.0996) /0.198	0.004
Non-White	1/ 88 (1%)	7/ 71 (10%)	0.1051 (0.0126, 0.8755) /0.037	-8.7228 (-16.0021, -1.4435) /0.019	0.1153 (0.0145, 0.9151) /0.041	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Insomnia						
White	6/239 (3%)	2/256 (<1%)				
Non-White	0/ 88	1/ 71 (1%)				
Anxiety						
White	9/239 (4%)	3/256 (1%)	3.3000 (0.8826, 12.3383) /0.076	2.5938 (-0.1562, 5.3438) /0.065	3.2134 (0.8804, 11.7285) /0.077	0.041
Non-White	1/ 88 (1%)	3/ 71 (4%)	0.2605 (0.0265, 2.5607) /0.249	-3.0890 (-8.2658, 2.0878) /0.242	0.2689 (0.0286, 2.5300) /0.251	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Abnormal dreams						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Sleep disorder						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Depression						
White	4/239 (2%)	3/256 (1%)				
Non-White	0/ 88	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.

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)
Nightmare						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Adjustment disorder with depressed mood						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only 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)

Adjustment disorder with mixed anxiety and depressed mood						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Attention deficit hyperactivity disorder						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)

Generalised anxiety disorder						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Major depression						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Panic attack						
White	1/239 (<1%)	2/256 (<1%)				
Non-White	0/ 88	0/ 71				
Restlessness						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Suicidal ideation						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Adjustment disorder						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Emotional distress						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)
Psychotic disorder						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only 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	Q8W (N=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	5/239 (2%)	10/256 (4%)	0.5256 (0.1770, 1.5608) /0.247	-1.8142 (-4.8016, 1.1732) /0.234	0.5356 (0.1857, 1.5442) /0.248	0.099
Non-White	0/ 88	3/ 71 (4%)	<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. 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)

Weight increased						
White	1/239 (<1%)	3/256 (1%)				
Non-White	0/ 88	0/ 71				
Alanine aminotransferase increased						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)

Blood creatine phosphokinase increased						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Blood cholesterol increased						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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)

Weight decreased						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Blood glucose increased						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only 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)

Lipase increased						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	1/ 71 (1%)				
CD4 lymphocytes decreased						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Campylobacter test positive						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Creatinine renal clearance decreased						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Culture urine positive						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Haematocrit decreased						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only 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)

Haemoglobin decreased						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Hepatic enzyme increased						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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 enzyme increased						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Parasite stool test positive						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)
Shigella test positive						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
White	3/239 (1%)	3/256 (1%)				
Non-White	0/ 88	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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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	0/239	1/256 (<1%)				
Non-White	0/ 88	1/ 71 (1%)				
Fibrous histiocytoma						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)

Adenoma benign						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Basal cell carcinoma						
White	2/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)

Adrenal adenoma						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Vascular disorders						
Any Event						
White	3/239 (1%)	2/256 (<1%)				
Non-White	0/ 88	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)

Hypertension						
White	2/239 (<1%)	2/256 (<1%)				
Non-White	0/ 88	1/ 71 (1%)				
Blood pressure inadequately controlled						
White	0/239	0/256				
Non-White	0/ 88	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)

Phlebitis						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Thrombophlebitis						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for 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)
Thrombophlebitis superficial						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for 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)

Reproductive system and breast disorders						
Any Event						
White	8/239 (3%)	5/256 (2%)	1.7385 (0.5607, 5.3902) /0.338	1.3942 (-1.4472, 4.2356) /0.336	1.7138 (0.5686, 5.1659) /0.339	0.264
Non-White	1/ 88 (1%)	2/ 71 (3%)	0.3966 (0.0352, 4.4647) /0.454	-1.6805 (-6.1208, 2.7597) /0.458	0.4034 (0.0373, 4.3588) /0.455	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)

Erectile dysfunction						
White	3/239 (1%)	2/256 (<1%)				
Non-White	0/ 88	0/ 71				
Balanoposthitis						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, 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)

Genital lesion						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Cervical dysplasia						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for 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)

Testicular cyst						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Benign prostatic hyperplasia						
White	1/239 (<1%)	0/256				
Non-White	1/ 88 (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= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Haemospermi a						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Penile burning sensation						
White	0/239	0/256				
Non-White	0/ 88	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)
Penile discharge						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Priapism						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Prostatitis						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for 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)

Testicular torsion						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Renal and urinary disorders						
Any Event						
White	2/239 (<1%)	2/256 (<1%)				
Non-White	2/ 88 (2%)	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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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=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	1/239 (<1%)	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Nocturia						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Nephrolithiasis						
White	0/239	0/256				
Non-White	1/ 88 (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. 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	0/239	0/256				
Non-White	1/ 88 (1%)	0/ 71				
Renal colic						
White	1/239 (<1%)	2/256 (<1%)				
Non-White	0/ 88	0/ 71				
Leukocyturia						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Ear and labyrinth disorders						
Any Event						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	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)
Tinnitus						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Vertigo						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Metabolism and nutrition disorders						
Any Event						
White	5/239 (2%)	5/256 (2%)	1.0726 (0.3066, 3.7526) /0.913	0.1389 (-2.3442, 2.6220) /0.913	1.0711 (0.3140, 3.6536) /0.913	0.854
Non-White	1/ 88 (1%)	1/ 71 (1%)	0.8046 (0.0494, 13.0946) /0.879	-0.2721 (-3.7959, 3.2517) /0.880	0.8068 (0.0514, 12.6728) /0.879	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Hypercholesterolaemia						
White	2/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Vitamin D deficiency						
White	2/239 (<1%)	2/256 (<1%)				
Non-White	0/ 88	1/ 71 (1%)				
Obesity						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 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	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Cachexia						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)
Hypertriglyceridaemia						
White	0/239	0/256				
Non-White	1/ 88 (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	Q8W (N=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						
White	8/239 (3%)	4/256 (2%)	2.1818 (0.6484, 7.3418) /0.208	1.7848 (-0.9553, 4.5249) /0.202	2.1423 (0.6535, 7.0222) /0.208	0.433
Non-White	1/ 88 (1%)	0/ 71	>999 (>999, >999) /NC	3.4034 (-20.7049, 27.5117) /0.782	>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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Analysis of Proportion of Subjects with Adverse Events by 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)
Conjunctivitis allergic						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Blepharitis						
White	0/239	1/256 (<1%)				
Non-White	1/ 88 (1%)	0/ 71				
Cataract						
White	2/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)
Diplopia						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Retinal detachment						
White	2/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Blepharospasm						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)
Chalazion						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Eyelid oedema						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Macular fibrosis						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)
Retinal tear						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Ulcerative keratitis						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)

Blood and lymphatic system disorders						
Any Event						
White	3/239 (1%)	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Microcytic anaemia						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)
Iron deficiency anaemia						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Neutropenia						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)

Immune system disorders						
Any Event						
White	5/239 (2%)	6/256 (2%)	0.8903 (0.2681, 2.9563) /0.850	-0.2517 (-2.8453, 2.3419) /0.849	0.8926 (0.2760, 2.8865) /0.850	0.270
Non-White	1/ 88 (1%)	0/ 71	>999 (>999, >999) /NC	3.4034 (-20.7049, 27.5117) /0.782	>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)

Seasonal allergy						
White	2/239 (<1%)	2/256 (<1%)				
Non-White	1/ 88 (1%)	0/ 71				
Hypersensitivity						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Food allergy						
White	2/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, 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)
Allergy to arthropod bite						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Drug hypersensitivity						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Cardiac disorders						
Any Event						
White	5/239 (2%)	5/256 (2%)	1.0726 (0.3066, 3.7526) /0.913	0.1389 (-2.3442, 2.6220) /0.913	1.0711 (0.3140, 3.6536) /0.913	0.303
Non-White	1/ 88 (1%)	0/ 71	>999 (>999, >999) /NC	3.4034 (-20.7049, 27.5117) /0.782	>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.

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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)
Palpitations						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Tachycardia						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Angina pectoris						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, 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)

Atrial fibrillation						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Cardiac aneurysm						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Extrasystoles						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for 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)
Myocardial necrosis						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Sinus bradycardia						
White	0/239	0/256				
Non-White	1/ 88 (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 Preferred Term	Q8W (N=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	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Hepatobiliary disorders						
Any Event						
White	0/239	0/256				
Non-White	1/ 88 (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= 2

System Organ Class Preferred Term	Q8W (N=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	0/239	0/256				
Non-White	1/ 88 (1%)	0/ 71				
Congenital, familial and genetic disorders						
Any Event						
White	0/239	0/256				
Non-White	1/ 88 (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.

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)

Benign familial pemphigus						
White	0/239	0/256				
Non-White	1/ 88 (1%)	0/ 71				
Hydrocele						
White	0/239	0/256				
Non-White	0/ 88	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	22/239 (9%)	35/256 (14%)	0.6402 (0.3638, 1.1266) /0.122	-4.4669 (-10.0475, 1.1138) /0.117	0.6733 (0.4070, 1.1137) /0.123	0.293
Non-White	9/ 88 (10%)	6/ 71 (8%)	1.2342 (0.4175, 3.6484) /0.704	1.7766 (-7.2754, 10.8285) /0.700	1.2102 (0.4522, 3.2393) /0.704	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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	8/239 (3%)	18/256 (7%)	0.4579 (0.1953, 1.0738) /0.072	-3.6840 (-7.5581, 0.1902) /0.062	0.4761 (0.2109, 1.0744) /0.074	0.324
Non-White	2/ 88 (2%)	1/ 71 (1%)	1.6279 (0.1446, 18.3272) /0.693	0.8643 (-3.2841, 5.0126) /0.683	1.6136 (0.1493, 17.4353) /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.

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 pain						
White	5/239 (2%)	17/256 (7%)	0.3004 (0.1091, 0.8275) /0.020	-4.5486 (-8.0975, -0.9996) /0.012	0.3150 (0.1181, 0.8406) /0.021	0.197
Non-White	2/ 88 (2%)	1/ 71 (1%)	1.6279 (0.1446, 18.3272) /0.693	0.8643 (-3.2841, 5.0126) /0.683	1.6136 (0.1493, 17.4353) /0.694	
Injection site discomfort						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Pyrexia						
White	2/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Fatigue						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Injection site swelling						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only 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)
Malaise						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Injection site warmth						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Chest pain						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only 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)

Injection site discolouration						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Infestations						
Any Event						
White	5/239 (2%)	3/256 (1%)				
Non-White	3/ 88 (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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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)

Viral infection						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Tonsillitis						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Herpes zoster						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Diverticulitis						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Pneumonia						
White	0/239	0/256				
Non-White	1/ 88 (1%)	1/ 71 (1%)				
Epididymitis						
White	0/239	0/256				
Non-White	0/ 88	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= 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						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Injection site abscess						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Proctitis chlamydial						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only 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)

Acute hepatitis B						
White	0/239	0/256				
Non-White	1/ 88 (1%)	0/ 71				
Anal abscess						
White	0/239	0/256				
Non-White	1/ 88 (1%)	0/ 71				
Erysipelas						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only 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)

Gastrointestinal disorders						
Any Event						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	1/ 88 (1%)	1/ 71 (1%)				
Abdominal pain						
White	0/239	0/256				
Non-White	0/ 88	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= 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)

Toothache						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Haemorrhoidal haemorrhage						
White	0/239	0/256				
Non-White	1/ 88 (1%)	0/ 71				
Oroantral fistula						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)

Musculoskeletal and connective tissue disorders						
Any Event						
White	4/239 (2%)	3/256 (1%)				
Non-White	1/ 88 (1%)	1/ 71 (1%)				
Arthralgia						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)
Pain in extremity						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Myalgia						
White	0/239	2/256 (<1%)				
Non-White	0/ 88	0/ 71				
Muscle spasms						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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	2/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Rotator cuff syndrome						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for 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= 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	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Osteonecrosis						
White	1/239 (<1%)	0/256				
Non-White	1/ 88 (1%)	0/ 71				
Costochondritis						
White	0/239	0/256				
Non-White	0/ 88	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 Preferred Term	Q8W (N=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	2/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Eczema						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)

Hyperhidrosis						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Respiratory, thoracic and mediastinal disorders						
Any Event						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only 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)

Sleep apnoea syndrome						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Nervous system disorders						
Any Event						
White	2/239 (<1%)	2/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only 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)

Headache						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Disturbance in attention						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Cerebrovascular accident						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Neuritis cranial						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Injury, poisoning and procedural complications						
Any Event						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)
Contusion						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Foot fracture						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Psychiatric disorders						
Any Event						
White	0/239	2/256 (<1%)				
Non-White	0/ 88	0/ 71				
Depression						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Major depression						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Investigations

Any Event

White	2/239 (<1%)	2/256 (<1%)
Non-White	1/ 88 (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= 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	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Transaminases increased						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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)

Lipase increased						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
 Creatinine renal clearance decreased						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
White blood cell count decreased						
White	0/239	0/256				
Non-White	1/ 88 (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)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
White	0/239	1/256 (<1%)				
Non-White	1/ 88 (1%)	0/ 71				
Breast cancer						
White	0/239	1/256 (<1%)				
Non-White	1/ 88 (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 Preferred Term	Q8W (N=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	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Genital odour						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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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 and urinary disorders						
Any Event						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Renal colic						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)

Ear and labyrinth disorders						
Any Event						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Tympenic membrane perforation						
White	0/239	0/256				
Non-White	0/ 88	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= 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						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Hypercholesterolaemia						
White	0/239	0/256				
Non-White	0/ 88	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= 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						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Retinal detachment						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Blood and lymphatic system disorders						
Any Event						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Microcytic anaemia						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Immune system disorders						
Any Event						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	1/ 71 (1%)				
Hypersensitivity						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Drug hypersensitivity						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Cardiac disorders						
Any Event						
White	0/239	2/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Ventricular extrasystoles						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Acute myocardial infarction						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Myocardial infarction						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Hepatobiliary disorders						
Any Event						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatocellular injury						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Pregnancy, puerperium and perinatal conditions						
Any Event						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)
Abortion spontaneous						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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	Q8W (N=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	3/239 (1%)	1/256 (<1%)				
Non-White	0/ 88	1/ 71 (1%)				
Infections and infestations						
Any Event						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	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= 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	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Epiglottitis obstructive						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Overdose						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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	2/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Glioblastoma						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Testicular neoplasm						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System 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)

Overall						
Any Event						
North America	24/118 (20%)	37/135 (27%)	0.6763 (0.3762, 1.2157) /0.191	-7.0684 (-17.5259, 3.3891) /0.185	0.7421 (0.4730, 1.1643) /0.194	0.341
Europe	62/165 (38%)	54/155 (35%)	1.1259 (0.7132, 1.7773) /0.611	2.7370 (-7.7925, 13.2666) /0.610	1.0786 (0.8058, 1.4437) /0.611	
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= 1

System Organ Class Preferred Term	Q8W (N=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	47/118 (40%)	53/135 (39%)	1.0242 (0.6180, 1.6973) /0.926	0.5712 (-11.5066, 12.6491) /0.926	1.0146 (0.7476, 1.3768) /0.926	0.475
Europe	94/165 (57%)	77/155 (50%)	1.3411 (0.8632, 2.0836) /0.192	7.2923 (-3.6178, 18.2023) /0.190	1.1468 (0.9327, 1.4100) /0.194	
Rest of World	18/ 44 (41%)	18/ 37 (49%)	0.7308 (0.3027, 1.7642) /0.485	-7.7396 (-29.4287, 13.9496) /0.484	0.8409 (0.5175, 1.3665) /0.484	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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	46/118 (39%)	47/135 (35%)	1.1962 (0.7168, 1.9962) /0.493	4.1682 (-7.7487, 16.0851) /0.493	1.1197 (0.8108, 1.5464) /0.492	0.560
Europe	95/165 (58%)	80/155 (52%)	1.2723 (0.8185, 1.9777) /0.285	5.9629 (-4.9350, 16.8607) /0.284	1.1155 (0.9124, 1.3638) /0.286	
Rest of World	18/ 44 (41%)	18/ 37 (49%)	0.7308 (0.3027, 1.7642) /0.485	-7.7396 (-29.4287, 13.9496) /0.484	0.8409 (0.5175, 1.3665) /0.484	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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	20/118 (17%)	36/135 (27%)	0.5612 (0.3038, 1.0369) /0.065	-9.7175 (-19.7908, 0.3558) /0.059	0.6356 (0.3903, 1.0350) /0.069	0.512
Europe	10/165 (6%)	20/155 (13%)	0.4355 (0.1970, 0.9628) /0.040	-6.8426 (-13.2541, -0.4311) /0.036	0.4697 (0.2271, 0.9715) /0.042	
Rest of World	2/ 44 (5%)	6/ 37 (16%)	0.2460 (0.0465, 1.3021) /0.099	-11.6708 (-25.0476, 1.7061) /0.087	0.2803 (0.0601, 1.3068) /0.105	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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%)	8/135 (6%)	0.8504 (0.2863, 2.5258) /0.771	-0.8412 (-6.4603, 4.7780) /0.769	0.8581 (0.3066, 2.4017) /0.771	0.262
Europe	16/165 (10%)	19/155 (12%)	0.7686 (0.3800, 1.5548) /0.464	-2.5611 (-9.4199, 4.2977) /0.464	0.7911 (0.4222, 1.4821) /0.464	
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%)	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	0.889
Europe	13/165 (8%)	15/155 (10%)	0.7982 (0.3669, 1.7368) /0.570	-1.7986 (-8.0084, 4.4111) /0.570	0.8141 (0.4004, 1.6553) /0.570	
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)
Pyrexia North America	3/118 (3%)	7/135 (5%)	0.4770 (0.1205, 1.8881) /0.292	-2.6428 (-7.3392, 2.0535) /0.270	0.4903 (0.1297, 1.8535) /0.293	0.396
Europe	13/165 (8%)	19/155 (12%)	0.6122 (0.2914, 1.2862) /0.195	-4.3793 (-10.9788, 2.2203) /0.193	0.6427 (0.3287, 1.2567) /0.196	
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)
Fatigue North America	7/118 (6%)	17/135 (13%)	0.4377 (0.1749, 1.0957) /0.078	-6.6604 (-13.6951, 0.3743) /0.063	0.4711 (0.2024, 1.0965) /0.081	0.348
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	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	8/118 (7%)	8/135 (6%)	1.1545 (0.4194, 3.1784) /0.781	0.8537 (-5.1826, 6.8901) /0.782	1.1441 (0.4432, 2.9533) /0.781	0.889
Europe	7/165 (4%)	8/155 (5%)	0.8141 (0.2880, 2.3008) /0.698	-0.9189 (-5.5653, 3.7276) /0.698	0.8220 (0.3053, 2.2130) /0.698	
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)
Injection site pruritus						
North America	6/118 (5%)	11/135 (8%)	0.6039 (0.2162, 1.6865) /0.336	-3.0634 (-9.1468, 3.0200) /0.324	0.6240 (0.2381, 1.6356) /0.337	0.089
Europe	3/165 (2%)	6/155 (4%)	0.4599 (0.1130, 1.8717) /0.278	-2.0528 (-5.7104, 1.6049) /0.271	0.4697 (0.1195, 1.8456) /0.279	
Rest of World	0/ 44	5/ 37 (14%)	<0.0001 (<0.0001, -) />0.999	-15.2864 (-47.2493, 16.6765) /0.349	<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%)	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	0.970
Europe	7/165 (4%)	6/155 (4%)	1.1002 (0.3614, 3.3490) /0.866	0.3715 (-3.9506, 4.6935) /0.866	1.0960 (0.3766, 3.1892) /0.866	
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)
Influenza like illness						
North America	1/118 (<1%)	4/135 (3%)	0.2799 (0.0308, 2.5400) /0.258	-2.1155 (-5.4196, 1.1886) /0.210	0.2860 (0.0324, 2.5235) /0.260	0.859
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	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)
Asthenia North America	1/118 (<1%)	0/135	>999 (>999, >999) /NC	3.0911 (-14.7233, 20.9055) /0.734	>999 (>999, >999) /NC	NC
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	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	8/118 (7%)	5/135 (4%)	1.8909 (0.6012, 5.9470) /0.276	3.0760 (-2.4669, 8.6188) /0.277	1.8305 (0.6156, 5.4428) /0.277	>0.999
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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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	8/118 (7%)	7/135 (5%)	1.3299 (0.4673, 3.7847) /0.593	1.5945 (-4.2847, 7.4736) /0.595	1.3075 (0.4888, 3.4972) /0.593	NC
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)

Pain						
North America	6/118 (5%)	3/135 (2%)				
Europe	0/165	2/155 (1%)				
Rest of World	0/ 44	2/ 37 (5%)				
Malaise						
North America	2/118 (2%)	2/135 (1%)				
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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	8/155 (5%)				
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	5/165 (3%)	4/155 (3%)				
Rest of World	0/ 44	0/ 37				
Injection site reaction						
North America	3/118 (3%)	4/135 (3%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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 warmth						
North America	2/118 (2%)	3/135 (2%)				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
Chest pain						
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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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	4/118 (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)
Feeling hot						
North America	0/118	0/135				
Europe	3/165 (2%)	0/155				
Rest of World	1/ 44 (2%)	0/ 37				
Nodule						
North America	1/118 (<1%)	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)
Cyst						
North America	2/118 (2%)	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 discolouration						
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)
Injection site 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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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				
Mass						
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)
Peripheral swelling						
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= 1

System Organ Class Preferred Term	Q8W (N=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	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)
Vaccination site 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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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)
Adverse drug reaction						
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)
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)

Enanthema						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
Feeling abnormal						
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)

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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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System 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)
Injection site hypoaesthesia						
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	Q8W (N=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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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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)

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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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Swelling						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Thirst						
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)
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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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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	42/118 (36%)	46/135 (34%)	1.0692 (0.6367, 1.7955) /0.800	1.5191 (-10.2516, 13.2899) /0.800	1.0446 (0.7453, 1.4640) /0.800	0.439
Europe	56/165 (34%)	67/155 (43%)	0.6748 (0.4292, 1.0610) /0.088	-9.2864 (-19.9175, 1.3447) /0.087	0.7852 (0.5940, 1.0379) /0.089	
Rest of World	13/ 44 (30%)	13/ 37 (35%)	0.7742 (0.3038, 1.9728) /0.592	-5.5897 (-26.0434, 14.8640) /0.592	0.8409 (0.4468, 1.5826) /0.591	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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)
Nasopharyngitis						
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	0.264
Europe	34/165 (21%)	45/155 (29%)	0.6344 (0.3800, 1.0591) /0.082	-8.4262 (-17.8682, 1.0158) /0.080	0.7098 (0.4817, 1.0459) /0.083	
Rest of World	4/ 44 (9%)	1/ 37 (3%)	3.6000 (0.3844, 33.7177) /0.262	6.3882 (-3.5845, 16.3609) /0.209	3.3636 (0.3929, 28.7971) /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. 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	21/118 (18%)	27/135 (20%)	0.8660 (0.4599, 1.6305) /0.656	-2.2034 (-11.8550, 7.4482) /0.655	0.8898 (0.5322, 1.4878) /0.656	0.655
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	5/ 44 (11%)	6/ 37 (16%)	0.6624 (0.1847, 2.3755) /0.527	-4.8526 (-19.9852, 10.2801) /0.530	0.7008 (0.2325, 2.1123) /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)

Gastroenteritis						
North America	3/118 (3%)	4/135 (3%)	0.8543 (0.1873, 3.8975) /0.839	-0.4206 (-4.4514, 3.6102) /0.838	0.8581 (0.1960, 3.7559) /0.839	0.509
Europe	8/165 (5%)	14/155 (9%)	0.5132 (0.2091, 1.2596) /0.145	-4.1838 (-9.7609, 1.3933) /0.141	0.5368 (0.2316, 1.2441) /0.147	
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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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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	6/118 (5%)	4/135 (3%)	1.7545 (0.4829, 6.3739) /0.393	2.1218 (-2.7663, 7.0098) /0.395	1.7161 (0.4962, 5.9350) /0.394	0.402
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%)	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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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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	0.853
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%)	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)
Gonorrhoea 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	0.866
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	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						
North America	5/118 (4%)	1/135 (<1%)				
Europe	6/165 (4%)	3/155 (2%)				
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)
Bronchitis 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	0.337
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	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)
Sinusitis						
North America	0/118	4/135 (3%)				
Europe	4/165 (2%)	4/155 (3%)				
Rest of World	1/ 44 (2%)	1/ 37 (3%)				
Chlamydial infection						
North America	3/118 (3%)	1/135 (<1%)				
Europe	5/165 (3%)	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= 1

System Organ Class Preferred Term	Q8W (N=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	0/118	2/135 (1%)				
Europe	5/165 (3%)	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)
Rhinitis North America	2/118 (2%)	1/135 (<1%)	2.3103 (0.2068, 25.8081) /0.496	0.9542 (-1.7874, 3.6958) /0.495	2.2881 (0.2101, 24.9145) /0.497	0.434
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	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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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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	2/118 (2%)	1/135 (<1%)	2.3103 (0.2068, 25.8081) /0.496	0.9542 (-1.7874, 3.6958) /0.495	2.2881 (0.2101, 24.9145) /0.497	0.434
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	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)
Respiratory tract infection						
North America	0/118	0/135	NC	NC	NC	NC
Europe	6/165 (4%)	5/155 (3%)	1.1321 (0.3384, 3.7873) /0.840	0.4106 (-3.5763, 4.3974) /0.840	1.1273 (0.3511, 3.6190) /0.840	
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)

Folliculitis						
North America	0/118	2/135 (1%)				
Europe	3/165 (2%)	3/155 (2%)				
Rest of World	1/ 44 (2%)	2/ 37 (5%)				
Oral herpes						
North America	0/118	3/135 (2%)				
Europe	1/165 (<1%)	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)
Respiratory tract infection viral						
North America	1/118 (<1%)	0/135				
Europe	2/165 (1%)	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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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)

Urethritis						
North America	2/118 (2%)	4/135 (3%)				
Europe	1/165 (<1%)	3/155 (2%)				
Rest of World	0/ 44	0/ 37				
Urinary tract infection						
North America	1/118 (<1%)	2/135 (1%)				
Europe	2/165 (1%)	3/155 (2%)				
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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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	0/135				
Europe	2/165 (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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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)
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%)	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)

Gastroenteritis viral						
North America	1/118 (<1%)	3/135 (2%)				
Europe	2/165 (1%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Onychomycosis						
North America	0/118	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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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)

Proctitis gonococcal						
North America	2/118 (2%)	1/135 (<1%)				
Europe	2/165 (1%)	2/155 (1%)				
Rest of World	0/ 44	0/ 37				
Tooth abscess						
North America	2/118 (2%)	3/135 (2%)				
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)
Anal chlamydia infection						
North America	4/118 (3%)	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= 1

System Organ Class Preferred Term	Q8W (N=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	3/155 (2%)				
Rest of World	0/ 44	0/ 37				
Fungal skin infection						
North America	1/118 (<1%)	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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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	1/118 (<1%)	1/135 (<1%)				
Europe	2/165 (1%)	2/155 (1%)				
Rest of World	0/ 44	0/ 37				
Herpes simplex						
North America	2/118 (2%)	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)

Tinea versicolour						
North America	0/118	2/135 (1%)				
Europe	2/165 (1%)	2/155 (1%)				
Rest of World	0/ 44	0/ 37				
Herpes zoster						
North America	0/118	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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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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	5/ 44 (11%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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%)	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.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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	1/135 (<1%)				
Europe	0/165	3/155 (2%)				
Rest of World	0/ 44	1/ 37 (3%)				
Furuncle						
North America	1/118 (<1%)	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)
Otitis externa						
North America	1/118 (<1%)	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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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	1/118 (<1%)	0/135				
Europe	0/165	2/155 (1%)				
Rest of World	0/ 44	0/ 37				
Body tinea						
North America	2/118 (2%)	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)

Diverticulitis						
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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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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	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)

Secondary syphilis						
North America	0/118	1/135 (<1%)				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	1/ 37 (3%)				
Tinea cruris						
North America	0/118	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)
Tinea infection						
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 AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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)
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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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)

Viral pharyngitis						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	1/ 37 (3%)				
Cellulitis						
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)
Chronic sinusitis						
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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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)
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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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				
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
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)
Primary syphilis						
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				
Tinea pedis						
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= 1

System Organ Class Preferred Term	Q8W (N=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	2/155 (1%)				
Rest of World	0/ 44	0/ 37				
Urethritis chlamydial						
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)
Abscess limb						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
Acute sinusitis						
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)
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)
Borrelia infection						
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)
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				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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 of male external genital organ						
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)
Conjunctivitis viral						
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)
Diarrhoea 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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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				
Epididymitis						
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)
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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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				
Eye 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)
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)
Gastrointestinal infection						
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						
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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Giardiasis						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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)

Groin abscess						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Hepatitis C						
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)
<hr/>						
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				
Localised 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= 1

System Organ Class Preferred Term	Q8W (N=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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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)
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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sexually transmitted 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= 1

System Organ Class Preferred Term	Q8W (N=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= 1

System Organ Class Preferred Term	Q8W (N=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	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)

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)
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.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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 mycoplasmal						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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	29/118 (25%)	39/135 (29%)	0.8021 (0.4579, 1.4048) /0.441	-4.3126 (-15.2122, 6.5870) /0.438	0.8507 (0.5633, 1.2848) /0.442	0.709
Europe	30/165 (18%)	30/155 (19%)	0.9259 (0.5281, 1.6234) /0.788	-1.1730 (-9.7356, 7.3896) /0.788	0.9394 (0.5953, 1.4823) /0.788	
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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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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%)	1.5849 (0.6431, 3.9062) /0.317	3.5028 (-3.3852, 10.3909) /0.319	1.5254 (0.6663, 3.4920) /0.318	0.556
Europe	10/165 (6%)	9/155 (6%)	1.0466 (0.4136, 2.6486) /0.923	0.2542 (-4.9237, 5.4320) /0.923	1.0438 (0.4358, 2.5000) /0.923	
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= 1

System Organ Class Preferred Term	Q8W (N=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	5/118 (4%)	12/135 (9%)	0.4535 (0.1549, 1.3276) /0.149	-4.6516 (-10.6728, 1.3696) /0.130	0.4767 (0.1730, 1.3135) /0.152	0.171
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	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)
Constipation						
North America	2/118 (2%)	6/135 (4%)				
Europe	0/165	9/155 (6%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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%)	0.5684 (0.0509, 6.3490) /0.646	-0.6340 (-3.2586, 1.9906) /0.636	0.5720 (0.0525, 6.2286) /0.647	0.468
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%)	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)

Haemorrhoids						
North America	1/118 (<1%)	5/135 (4%)				
Europe	1/165 (<1%)	5/155 (3%)				
Rest of World	0/ 44	1/ 37 (3%)				
Abdominal pain						
North America	2/118 (2%)	3/135 (2%)				
Europe	3/165 (2%)	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= 1

System Organ Class Preferred Term	Q8W (N=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	5/118 (4%)	2/135 (1%)				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	1/ 44 (2%)	0/ 37				
Toothache						
North America	3/118 (3%)	0/135				
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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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%)	3/135 (2%)				
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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)
Gastrooesophageal reflux disease						
North America	3/118 (3%)	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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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	1/118 (<1%)	4/135 (3%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Vomiting						
North America	0/118	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.

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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%)	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= 1

System Organ Class Preferred Term	Q8W (N=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%)	1/135 (<1%)				
Europe	1/165 (<1%)	2/155 (1%)				
Rest of World	0/ 44	0/ 37				
Dental caries						
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= 1

System Organ Class Preferred Term	Q8W (N=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	2/135 (1%)				
Europe	2/165 (1%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
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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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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	1/118 (<1%)	0/135				
Europe	3/165 (2%)	0/155				
Rest of World	0/ 44	0/ 37				
Gastritis						
North America	0/118	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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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/>						
Haematochezia						
North America	3/118 (3%)	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Hiatus hernia						
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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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	1/118 (<1%)	1/135 (<1%)				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
Rectal discharge						
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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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	2/135 (1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Anal pruritus						
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= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diverticulum intestinal						
North America	0/118	0/135				
Europe	0/165	2/155 (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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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)
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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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	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)

Noninfective gingivitis						
North America	0/118	0/135				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Oesophagitis						
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)
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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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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 ulcer						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
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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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anorectal discomfort						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Chapped lips						
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)
Cheilitis						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Dysphagia						
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)
Enteritis North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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)
Faeces soft						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
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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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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 ulcer						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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)

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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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)
Oral disorder						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
Oral lichen planus						
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)
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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Rectal tenesmus						
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)
Salivary gland mucocoele						
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)
-----	-----	-----	-----	-----	-----	-----
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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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	23/118 (19%)	22/135 (16%)	1.2435 (0.6524, 2.3702) /0.508	3.1952 (-6.2864, 12.6768) /0.509	1.1961 (0.7042, 2.0315) /0.508	0.221
Europe	28/165 (17%)	40/155 (26%)	0.5876 (0.3414, 1.0112) /0.055	-8.8368 (-17.7953, 0.1218) /0.053	0.6576 (0.4276, 1.0112) /0.056	
Rest of World	7/ 44 (16%)	8/ 37 (22%)	0.6858 (0.2227, 2.1121) /0.511	-5.7125 (-22.8223, 11.3972) /0.513	0.7358 (0.2946, 1.8377) /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. 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)
Back pain						
North America	8/118 (7%)	5/135 (4%)	1.8909 (0.6012, 5.9470) /0.276	3.0760 (-2.4669, 8.6188) /0.277	1.8305 (0.6156, 5.4428) /0.277	0.191
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%)	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)
Arthralgia North America	7/118 (6%)	5/135 (4%)	1.6396 (0.5062, 5.3107) /0.410	2.2285 (-3.0927, 7.5497) /0.412	1.6017 (0.5222, 4.9126) /0.410	0.246
Europe	4/165 (2%)	9/155 (6%)	0.4030 (0.1215, 1.3367) /0.137	-3.3822 (-7.7482, 0.9838) /0.129	0.4175 (0.1312, 1.3281) /0.139	
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)
Pain in extremity						
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	0.979
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	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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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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	5/118 (4%)	2/135 (1%)				
Europe	2/165 (1%)	1/155 (<1%)				
Rest of World	1/ 44 (2%)	3/ 37 (8%)				
Musculoskeletal pain						
North America	1/118 (<1%)	2/135 (1%)				
Europe	2/165 (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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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)

Tendonitis						
North America	4/118 (3%)	1/135 (<1%)				
Europe	2/165 (1%)	0/155				
Rest of World	0/ 44	0/ 37				
Muscle spasms						
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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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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	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)
Musculoskeletal chest pain						
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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	1/118 (<1%)	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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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%)	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)
Neck pain						
North America	0/118	0/135				
Europe	2/165 (1%)	0/155				
Rest of World	1/ 44 (2%)	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)
Flank pain						
North America	2/118 (2%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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	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)
Musculoskeletal stiffness						
North America	0/118	1/135 (<1%)				
Europe	0/165	1/155 (<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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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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)
Groin 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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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)
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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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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				
Myosclerosis						
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)

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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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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				
Plantar fasciitis						
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)

Rotator cuff syndrome						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
Sacroiliitis						
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)
<hr/>						
Scoliosis						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Spinal 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.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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	25/118 (21%)	27/135 (20%)	1.0753 (0.5839, 1.9801) /0.816	1.1864 (-8.8079, 11.1808) /0.816	1.0593 (0.6524, 1.7200) /0.816	0.202
Europe	24/165 (15%)	27/155 (17%)	0.8069 (0.4430, 1.4698) /0.483	-2.8739 (-10.9107, 5.1629) /0.483	0.8350 (0.5043, 1.3826) /0.483	
Rest of World	4/ 44 (9%)	9/ 37 (24%)	0.3111 (0.0871, 1.1111) /0.072	-15.2334 (-31.4589, 0.9921) /0.066	0.3737 (0.1252, 1.1157) /0.078	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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	4/165 (2%)	5/155 (3%)				
Rest of World	1/ 44 (2%)	2/ 37 (5%)				
Rash						
North America	3/118 (3%)	6/135 (4%)				
Europe	3/165 (2%)	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	3/118 (3%)	1/135 (<1%)	3.4957 (0.3587, 34.0682) /0.281	1.8016 (-1.3856, 4.9889) /0.268	3.4322 (0.3619, 32.5525) /0.283	0.042
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	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)

Acne						
North America	1/118 (<1%)	2/135 (1%)				
Europe	1/165 (<1%)	3/155 (2%)				
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)

Dermatitis						
North America	0/118	2/135 (1%)				
Europe	3/165 (2%)	1/155 (<1%)				
Rest of World	0/ 44	1/ 37 (3%)				
Skin lesion						
North America	1/118 (<1%)	3/135 (2%)				
Europe	3/165 (2%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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 contact						
North America	2/118 (2%)	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)

Seborrhoeic dermatitis						
North America	0/118	2/135 (1%)				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	0/ 44	1/ 37 (3%)				
Hyperhidrosis						
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= 1

System Organ Class Preferred Term	Q8W (N=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	2/135 (1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	1/ 37 (3%)				
Dry skin						
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)
Erythema						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Night sweats						
North America	3/118 (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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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)

Skin exfoliation						
North America	0/118	1/135 (<1%)				
Europe	0/165	2/155 (1%)				
Rest of World	0/ 44	0/ 37				
Skin mass						
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.

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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. 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)
Urticaria						
North America	0/118	0/135				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	1/ 44 (2%)	0/ 37				
Actinic keratosis						
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.

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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)
Chloasma						
North America	1/118 (<1%)	0/135				
Europe	0/165	1/155 (<1%)				
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.

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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)

Pityriasis rosea						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	1/ 37 (3%)				
Psoriasis						
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= 1

System Organ Class Preferred Term	Q8W (N=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%)				
Rash papular						
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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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Actinic elastosis						
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)

Androgenetic alopecia						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dermatosis						
North America	0/118	0/135				
Europe	1/165 (<1%)	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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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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				
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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)

Hyperkeratosis						
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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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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 bleeding						
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)
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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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Prurigo North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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)
Rash macular						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	1/ 37 (3%)				
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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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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)

Skin irritation						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Skin ulcer						
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)
Solar dermatitis						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Solar lentigo						
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	Q8W (N=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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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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	16/118 (14%)	27/135 (20%)	0.6275 (0.3195, 1.2323) /0.176	-6.4407 (-15.5886, 2.7073) /0.168	0.6780 (0.3846, 1.1951) /0.179	0.945
Europe	19/165 (12%)	23/155 (15%)	0.7469 (0.3893, 1.4330) /0.380	-3.3236 (-10.7425, 4.0954) /0.380	0.7760 (0.4403, 1.3677) /0.380	
Rest of World	5/ 44 (11%)	6/ 37 (16%)	0.6624 (0.1847, 2.3755) /0.527	-4.8526 (-19.9852, 10.2801) /0.530	0.7008 (0.2325, 2.1123) /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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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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%)	11/135 (8%)	0.4988 (0.1681, 1.4797) /0.210	-3.9109 (-9.7851, 1.9634) /0.192	0.5200 (0.1861, 1.4535) /0.212	0.776
Europe	7/165 (4%)	8/155 (5%)	0.8141 (0.2880, 2.3008) /0.698	-0.9189 (-5.5653, 3.7276) /0.698	0.8220 (0.3053, 2.2130) /0.698	
Rest of World	4/ 44 (9%)	4/ 37 (11%)	0.8250 (0.1915, 3.5543) /0.796	-1.7199 (-14.8447, 11.4049) /0.797	0.8409 (0.2257, 3.1326) /0.796	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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)
Oropharyngeal pain						
North America	3/118 (3%)	9/135 (7%)	0.3652 (0.0965, 1.3821) /0.138	-4.1243 (-9.2009, 0.9523) /0.111	0.3814 (0.1057, 1.3758) /0.141	0.556
Europe	6/165 (4%)	6/155 (4%)	0.9371 (0.2957, 2.9698) /0.912	-0.2346 (-4.4036, 3.9344) /0.912	0.9394 (0.3095, 2.8509) /0.912	
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)
Nasal congestion						
North America	4/118 (3%)	6/135 (4%)	0.7544 (0.2077, 2.7405) /0.668	-1.0546 (-5.8239, 3.7147) /0.665	0.7627 (0.2205, 2.6378) /0.669	NC
Europe	0/165	2/155 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5634 (-19.5289, 12.4021) /0.662	<0.0001 (<0.0001, -) />0.999	
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)
Rhinitis allergic						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	4/165 (2%)	2/155 (1%)				
Rest of World	0/ 44	3/ 37 (8%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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)

Sinus congestion						
North America	2/118 (2%)	7/135 (5%)				
Europe	0/165	0/155				
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)
Rhinorrhoea						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	0/165	2/155 (1%)				
Rest of World	0/ 44	0/ 37				
Asthma						
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)
Dyspnoea						
North America	2/118 (2%)	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Sleep apnoea syndrome						
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)

Catarrh						
North America	0/118	0/135				
Europe	1/165 (<1%)	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)

Respiratory disorder						
North America	0/118	0/135				
Europe	0/165	2/155 (1%)				
Rest of World	0/ 44	0/ 37				
Bronchospasm						
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)
Dry throat						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Emphysema						
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)
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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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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)
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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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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 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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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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.

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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	27/118 (23%)	17/135 (13%)	2.0595 (1.0585, 4.0070) /0.033	10.2888 (0.8672, 19.7103) /0.032	1.8170 (1.0439, 3.1629) /0.035	0.005
Europe	16/165 (10%)	25/155 (16%)	0.5584 (0.2857, 1.0914) /0.088	-6.4321 (-13.7746, 0.9105) /0.086	0.6012 (0.3340, 1.0824) /0.090	
Rest of World	2/ 44 (5%)	6/ 37 (16%)	0.2460 (0.0465, 1.3021) /0.099	-11.6708 (-25.0476, 1.7061) /0.087	0.2803 (0.0601, 1.3068) /0.105	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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	12/118 (10%)	5/135 (4%)	2.9434 (1.0052, 8.6184) /0.049	6.4658 (0.1501, 12.7815) /0.045	2.7458 (0.9965, 7.5660) /0.051	0.060
Europe	10/165 (6%)	15/155 (10%)	0.6022 (0.2620, 1.3839) /0.232	-3.6168 (-9.5260, 2.2923) /0.230	0.6263 (0.2901, 1.3519) /0.233	
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)
Dizziness North America	10/118 (8%)	4/135 (3%)	3.0324 (0.9251, 9.9397) /0.067	5.5116 (-0.2704, 11.2937) /0.062	2.8602 (0.9212, 8.8799) /0.069	0.223
Europe	4/165 (2%)	4/155 (3%)	0.9379 (0.2305, 3.8170) /0.929	-0.1564 (-3.5825, 3.2697) /0.929	0.9394 (0.2391, 3.6911) /0.929	
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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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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	2/118 (2%)	3/135 (2%)				
Europe	1/165 (<1%)	2/155 (1%)				
Rest of World	0/ 44	1/ 37 (3%)				
Paraesthesia						
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)
Migraine						
North America	1/118 (<1%)	0/135				
Europe	0/165	4/155 (3%)				
Rest of World	0/ 44	0/ 37				
Somnolence						
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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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	3/118 (3%)	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Lethargy						
North America	3/118 (3%)	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)

Carpal tunnel syndrome						
North America	2/118 (2%)	0/135				
Europe	0/165	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= 1

System Organ Class Preferred Term	Q8W (N=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/>						
Syncope						
North America	1/118 (<1%)	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Tension headache						
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= 1

System Organ Class Preferred Term	Q8W (N=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/>						
Agnosia						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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/>						
Ataxia						
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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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Memory impairment						
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)
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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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				
Tremor						
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	Q8W (N=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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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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	12/118 (10%)	26/135 (19%)	0.4746 (0.2277, 0.9892) /0.047	-9.0898 (-17.6914, -0.4881) /0.038	0.5280 (0.2790, 0.9993) /0.050	0.901
Europe	12/165 (7%)	21/155 (14%)	0.5005 (0.2373, 1.0555) /0.069	-6.2757 (-12.9636, 0.4123) /0.066	0.5368 (0.2734, 1.0538) /0.071	
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)
Contusion						
North America	1/118 (<1%)	4/135 (3%)				
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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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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	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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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)

Ligament sprain						
North America	2/118 (2%)	3/135 (2%)				
Europe	1/165 (<1%)	3/155 (2%)				
Rest of World	0/ 44	1/ 37 (3%)				
Muscle strain						
North America	3/118 (3%)	2/135 (1%)				
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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%)	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)
Exposure to communicable disease						
North America	2/118 (2%)	4/135 (3%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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 laceration						
North America	1/118 (<1%)	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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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	1/165 (<1%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Foot fracture						
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 AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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)

Procedural pain						
North America	0/118	2/135 (1%)				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
Skin abrasion						
North America	1/118 (<1%)	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)

Vaccination complication						
North America	0/118	1/135 (<1%)				
Europe	0/165	2/155 (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.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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	1/118 (<1%)	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Epicondylitis						
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)

Heat stroke						
North America	0/118	0/135				
Europe	0/165	2/155 (1%)				
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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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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 injury						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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 fracture						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Head injury						
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)
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.

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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)
Nail injury						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Rib fracture						
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)
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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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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				
Wound						
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)

Psychiatric disorders						
Any Event						
North America	11/118 (9%)	15/135 (11%)	0.8224 (0.3620, 1.8683) /0.641	-1.7891 (-9.2471, 5.6690) /0.638	0.8390 (0.4012, 1.7545) /0.641	0.377
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	6/ 44 (14%)	2/ 37 (5%)	2.7632 (0.5228, 14.6034) /0.231	8.2310 (-4.2553, 20.7172) /0.196	2.5227 (0.5411, 11.7608) /0.239	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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%)	12/135 (9%)	0.1767 (0.0387, 0.8066) /0.025	-7.1940 (-12.5297, -1.8583) /0.008	0.1907 (0.0436, 0.8347) /0.028	0.006
Europe	3/165 (2%)	6/155 (4%)	0.4599 (0.1130, 1.8717) /0.278	-2.0528 (-5.7104, 1.6049) /0.271	0.4697 (0.1195, 1.8456) /0.279	
Rest of World	4/ 44 (9%)	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)
Anxiety 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	0.999
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	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)
Abnormal dreams						
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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	1/118 (<1%)	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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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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	3/118 (3%)	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)
Sleep disorder						
North America	0/118	1/135 (<1%)				
Europe	0/165	4/155 (3%)				
Rest of World	0/ 44	0/ 37				
Depression						
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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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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%)				
Stress North America	1/118 (<1%)	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)
Adjustment disorder with depressed mood						
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= 1

System Organ Class Preferred Term	Q8W (N=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	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)
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)

Acute stress disorder						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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)
Alcohol withdrawal 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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Attention deficit hyperactivity 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)
Generalised anxiety 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)
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				
Panic attack						
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)
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)

Restlessness						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Suicidal ideation						
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)
Investigations						
Any Event						
North America	10/118 (8%)	9/135 (7%)	1.2963 (0.5081, 3.3069) /0.587	1.8079 (-4.7462, 8.3620) /0.589	1.2712 (0.5347, 3.0221) /0.587	0.049
Europe	3/165 (2%)	13/155 (8%)	0.2023 (0.0565, 0.7242) /0.014	-6.5689 (-11.3854, -1.7524) /0.008	0.2168 (0.0630, 0.7462) /0.015	
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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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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	3/118 (3%)	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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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)
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)
Alanine aminotransferase increased						
North America	2/118 (2%)	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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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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	2/118 (2%)	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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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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)
Blood cholesterol increased						
North America	0/118	1/135 (<1%)				
Europe	1/165 (<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= 1

System Organ Class Preferred Term	Q8W (N=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	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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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%)	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)
Weight decreased						
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= 1

System Organ Class Preferred Term	Q8W (N=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	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= 1

System Organ Class Preferred Term	Q8W (N=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	1/155 (<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 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)
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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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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 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= 1

System Organ Class Preferred Term	Q8W (N=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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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Electrocardiogram abnormal						
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)
Epstein-Barr virus 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= 1

System Organ Class Preferred Term	Q8W (N=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)
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= 1

System Organ Class Preferred Term	Q8W (N=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	3/118 (3%)	5/135 (4%)	0.6783 (0.1586, 2.9007) /0.601	-1.1613 (-5.4292, 3.1066) /0.594	0.6864 (0.1676, 2.8113) /0.601	0.120
Europe	9/165 (5%)	14/155 (9%)	0.5810 (0.2440, 1.3839) /0.220	-3.5777 (-9.2671, 2.1117) /0.218	0.6039 (0.2691, 1.3550) /0.221	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System 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						
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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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%)	2/135 (1%)	0.5684 (0.0509, 6.3490) /0.646	-0.6340 (-3.2586, 1.9906) /0.636	0.5720 (0.0525, 6.2286) /0.647	0.990
Europe	4/165 (2%)	8/155 (5%)	0.4565 (0.1347, 1.5477) /0.208	-2.7370 (-6.9369, 1.4628) /0.201	0.4697 (0.1443, 1.5286) /0.209	
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)

Skin papilloma						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	2/165 (1%)	6/155 (4%)				
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)

Fibrous histiocytoma						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	1/ 37 (3%)				
Lipoma						
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)

Lipoma of breast						
North America	0/118	1/135 (<1%)				
Europe	0/165	1/155 (<1%)				
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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Adenoma benign						
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)
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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)
Benign neoplasm of thyroid gland						
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)
Fibroma						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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)
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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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	3/118 (3%)	5/135 (4%)	0.6783 (0.1586, 2.9007) /0.601	-1.1613 (-5.4292, 3.1066) /0.594	0.6864 (0.1676, 2.8113) /0.601	0.732
Europe	11/165 (7%)	8/155 (5%)	1.3125 (0.5136, 3.3544) /0.570	1.5054 (-3.6539, 6.6646) /0.567	1.2917 (0.5337, 3.1264) /0.570	
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)
Hypertension						
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	0.938
Europe	6/165 (4%)	4/155 (3%)	1.4245 (0.3943, 5.1472) /0.589	1.0557 (-2.7376, 4.8490) /0.585	1.4091 (0.4053, 4.8986) /0.590	
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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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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	3/155 (2%)				
Rest of World	0/ 44	0/ 37				
Varicose vein						
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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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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 North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	1/ 44 (2%)	0/ 37				
Hot flush 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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	1/ 37 (3%)				
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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	Q8W (N=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)

Reproductive system and breast 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	0.188
Europe	8/165 (5%)	6/155 (4%)	1.2654 (0.4289, 3.7335) /0.670	0.9775 (-3.4905, 5.4455) /0.668	1.2525 (0.4447, 3.5279) /0.670	
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= 1

System Organ Class Preferred Term	Q8W (N=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	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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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	2/155 (1%)				
Rest of World	1/ 44 (2%)	0/ 37				
Balanoposthitis						
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= 1

System Organ Class Preferred Term	Q8W (N=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	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Genital lesion						
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)

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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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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 mass						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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 dysplasia						
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)
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)

Penile discomfort						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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 rash						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Premenstrual 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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sexual 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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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 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)
Testicular swelling						
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)

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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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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	6/135 (4%)	<0.0001 (<0.0001, -) />0.999	-6.6386 (-25.3736, 12.0963) /0.487	<0.0001 (<0.0001, -) />0.999	NC
Europe	3/165 (2%)	12/155 (8%)	0.2207 (0.0611, 0.7977) /0.021	-5.9238 (-10.5990, -1.2485) /0.013	0.2348 (0.0676, 0.8164) /0.023	
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= 1

System Organ Class Preferred Term	Q8W (N=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	1/135 (<1%)				
Europe	1/165 (<1%)	6/155 (4%)				
Rest of World	1/ 44 (2%)	1/ 37 (3%)				
Nocturia						
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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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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	2/ 37 (5%)				
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)

Nephrolithiasis						
North America	0/118	2/135 (1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Renal cyst						
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)

Urethral discharge						
North America	0/118	1/135 (<1%)				
Europe	0/165	1/155 (<1%)				
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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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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 pain						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	1/ 37 (3%)				
Urinary incontinence						
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)
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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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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	7/118 (6%)	7/135 (5%)	1.1532 (0.3924, 3.3890) /0.796	0.7470 (-4.9236, 6.4176) /0.796	1.1441 (0.4133, 3.1667) /0.796	0.555
Europe	2/165 (1%)	4/155 (3%)	0.4632 (0.0836, 2.5655) /0.378	-1.3685 (-4.3716, 1.6346) /0.372	0.4697 (0.0873, 2.5282) /0.379	
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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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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	1/ 44 (2%)	1/ 37 (3%)				
Vertigo						
North America	2/118 (2%)	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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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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%)	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)
Ear discomfort						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Ear 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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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	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)
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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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 pruritus						
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)
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.

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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	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	0.117
Europe	2/165 (1%)	5/155 (3%)	0.3681 (0.0704, 1.9258) /0.237	-2.0137 (-5.2579, 1.2305) /0.224	0.3758 (0.0740, 1.9084) /0.238	
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)
Hypercholesterolaemia						
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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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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	1/118 (<1%)	1/135 (<1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Gout						
North America	3/118 (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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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	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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Alcoholic ketoacidosis						
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)

Diabetes mellitus						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
Dyslipidaemia						
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)
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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)

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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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	2/165 (1%)	7/155 (5%)				
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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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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	1/118 (<1%)	0/135				
Europe	0/165	3/155 (2%)				
Rest of World	0/ 44	0/ 37				
Blepharitis						
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)
Cataract						
North America	0/118	1/135 (<1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Dry eye						
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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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Astigmatism						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Diplopia						
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)

Eczema eyelids						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
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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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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 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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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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	4/118 (3%)	1/135 (<1%)	4.7018 (0.5181, 42.6670) /0.169	2.6491 (-0.9221, 6.2203) /0.146	4.5763 (0.5187, 40.3756) /0.171	0.013
Europe	1/165 (<1%)	9/155 (6%)	0.0989 (0.0124, 0.7902) /0.029	-5.2004 (-9.0679, -1.3329) /0.008	0.1044 (0.0134, 0.8143) /0.031	
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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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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	2/118 (2%)	0/135				
Europe	0/165	4/155 (3%)				
Rest of World	0/ 44	0/ 37				
Anaemia						
North America	0/118	1/135 (<1%)				
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= 1

System Organ Class Preferred Term	Q8W (N=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%)	1/155 (<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)
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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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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				
Polycythaemia						
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	Q8W (N=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	3/118 (3%)	1/135 (<1%)				
Europe	4/165 (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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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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	3/118 (3%)	1/135 (<1%)				
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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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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)

Anaphylactic reaction						
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)

Cardiac disorders						
Any Event						
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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	1/155 (<1%)				
Rest of World	0/ 44	1/ 37 (3%)				
Tachycardia						
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)
Atrioventricular block first degree						
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)
Wolff-Parkinson-White 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= 1

System Organ Class Preferred Term	Q8W (N=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	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)

Hypogonadism						
North America	0/118	1/135 (<1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Androgen deficiency						
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)
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)

Hepatobiliary disorders						
Any Event						
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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 steatosis						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
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	Q8W (N=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	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)

Gilbert's 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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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=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= 1

System Organ Class Preferred Term	Q8W (N=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= 2

System Organ Class Preferred Term	Q8W (N=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	78/118 (66%)	74/135 (55%)	1.6074 (0.9652, 2.6770) /0.068	11.2869 (-0.6891, 23.2629) /0.065	1.2059 (0.9869, 1.4735) /0.067	0.113
Europe	74/165 (45%)	75/155 (48%)	0.8674 (0.5588, 1.3465) /0.526	-3.5386 (-14.4693, 7.3921) /0.526	0.9269 (0.7330, 1.1720) /0.526	
Rest of World	24/ 44 (55%)	24/ 37 (65%)	0.6500 (0.2646, 1.5967) /0.347	-10.3194 (-31.6050, 10.9662) /0.342	0.8409 (0.5872, 1.2043) /0.344	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by 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	50/118 (42%)	48/135 (36%)	1.3327 (0.8023, 2.2137) /0.267	6.8173 (-5.2116, 18.8462) /0.267	1.1917 (0.8744, 1.6242) /0.267	0.624
Europe	52/165 (32%)	51/155 (33%)	0.9384 (0.5870, 1.5002) /0.791	-1.3881 (-11.6332, 8.8571) /0.791	0.9578 (0.6969, 1.3164) /0.791	
Rest of World	16/ 44 (36%)	13/ 37 (35%)	1.0549 (0.4235, 2.6277) /0.909	1.2285 (-19.7154, 22.1724) /0.908	1.0350 (0.5755, 1.8613) /0.909	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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)
Injection site pain						
North America	45/118 (38%)	42/135 (31%)	1.3650 (0.8112, 2.2967) /0.241	7.0245 (-4.7139, 18.7629) /0.241	1.2258 (0.8722, 1.7227) /0.241	0.582
Europe	46/165 (28%)	45/155 (29%)	0.9449 (0.5813, 1.5361) /0.819	-1.1535 (-11.0466, 8.7397) /0.819	0.9603 (0.6783, 1.3594) /0.819	
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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Analysis of Proportion of Subjects with Adverse Events by 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	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	0.974
Europe	5/165 (3%)	10/155 (6%)	0.4531 (0.1513, 1.3569) /0.157	-3.4213 (-8.0903, 1.2476) /0.151	0.4697 (0.1642, 1.3434) /0.159	
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= 2

System Organ Class Preferred Term	Q8W (N=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	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)
Injection site discomfort						
North America	6/118 (5%)	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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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)
Pyrexia North America	1/118 (<1%)	3/135 (2%)	0.3761 (0.0386, 3.6650) /0.400	-1.3748 (-4.3611, 1.6116) /0.367	0.3814 (0.0402, 3.6169) /0.401	0.343
Europe	6/165 (4%)	5/155 (3%)	1.1321 (0.3384, 3.7873) /0.840	0.4106 (-3.5763, 4.3974) /0.840	1.1273 (0.3511, 3.6190) /0.840	
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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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=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	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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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=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	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	0.251
Europe	1/165 (<1%)	1/155 (<1%)	0.9390 (0.0582, 15.1440) /0.965	-0.0391 (-1.7686, 1.6904) /0.965	0.9394 (0.0593, 14.8887) /0.965	
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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Analysis of Proportion of Subjects with Adverse Events by 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 pruritus						
North America	2/118 (2%)	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= 2

System Organ Class Preferred Term	Q8W (N=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	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)
Influenza like illness						
North America	1/118 (<1%)	3/135 (2%)				
Europe	2/165 (1%)	0/155				
Rest of World	0/ 44	0/ 37				
Asthenia						
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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)

Chills						
North America	2/118 (2%)	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Injection site bruising						
North America	1/118 (<1%)	0/135				
Europe	0/165	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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
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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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=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	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)
Discomfort						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
Injection site reaction						
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)

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				
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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Analysis of Proportion of Subjects with Adverse Events by 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 anaesthesia						
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)
Feeling hot						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
Nodule						
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)
Mass						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
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)
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.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by 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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Analysis of Proportion of Subjects with Adverse Events by 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)
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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Analysis of Proportion of Subjects with Adverse Events by 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 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	34/118 (29%)	47/135 (35%)	0.7579 (0.4447, 1.2914) /0.308	-6.0013 (-17.4621, 5.4596) /0.305	0.8276 (0.5742, 1.1930) /0.311	0.794
Europe	47/165 (28%)	48/155 (31%)	0.8879 (0.5495, 1.4346) /0.627	-2.4829 (-12.5033, 7.5375) /0.627	0.9198 (0.6565, 1.2887) /0.627	
Rest of World	15/ 44 (34%)	12/ 37 (32%)	1.0776 (0.4258, 2.7274) /0.875	1.6585 (-18.9251, 22.2421) /0.875	1.0511 (0.5651, 1.9551) /0.875	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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)
Nasopharyngitis						
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	0.247
Europe	13/165 (8%)	5/155 (3%)	2.5658 (0.8927, 7.3746) /0.080	4.6530 (-0.3104, 9.6163) /0.066	2.4424 (0.8915, 6.6914) /0.082	
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= 2

System Organ Class Preferred Term	Q8W (N=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	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	0.773
Europe	3/165 (2%)	3/155 (2%)	0.9383 (0.1865, 4.7201) /0.938	-0.1173 (-3.0939, 2.8593) /0.938	0.9394 (0.1925, 4.5846) /0.938	
Rest of World	4/ 44 (9%)	5/ 37 (14%)	0.6400 (0.1587, 2.5812) /0.531	-4.4226 (-18.3329, 9.4877) /0.533	0.6727 (0.1947, 2.3246) /0.531	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by 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	2/118 (2%)	6/135 (4%)				
Europe	1/165 (<1%)	4/155 (3%)				
Rest of World	2/ 44 (5%)	2/ 37 (5%)				
Syphilis						
North America	2/118 (2%)	3/135 (2%)				
Europe	4/165 (2%)	5/155 (3%)				
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= 2

System Organ Class Preferred Term	Q8W (N=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						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	3/165 (2%)	4/155 (3%)				
Rest of World	0/ 44	1/ 37 (3%)				
Gonorrhoea						
North America	1/118 (<1%)	4/135 (3%)				
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= 2

System Organ Class Preferred Term	Q8W (N=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 North America	2/118 (2%)	2/135 (1%)				
Europe	3/165 (2%)	3/155 (2%)				
Rest of World	0/ 44	2/ 37 (5%)				
Bronchitis North America	1/118 (<1%)	2/135 (1%)				
Europe	5/165 (3%)	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)
Sinusitis						
North America	4/118 (3%)	1/135 (<1%)				
Europe	1/165 (<1%)	2/155 (1%)				
Rest of World	0/ 44	0/ 37				
Chlamydial infection						
North America	0/118	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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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)
Conjunctivitis						
North America	2/118 (2%)	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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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)
Viral infection						
North America	0/118	1/135 (<1%)				
Europe	3/165 (2%)	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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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=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	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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Analysis of Proportion of Subjects with Adverse Events by 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)

Folliculitis						
North America	2/118 (2%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Oral 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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by 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	3/165 (2%)	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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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by 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%)	1/135 (<1%)				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Urinary tract infection						
North America	4/118 (3%)	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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by 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)
Tonsillitis						
North America	0/118	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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Analysis of Proportion of Subjects with Adverse Events by 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)

Gastroenteritis viral						
North America	0/118	0/135				
Europe	1/165 (<1%)	3/155 (2%)				
Rest of World	0/ 44	0/ 37				
Onychomycosis						
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= 2

System Organ Class Preferred Term	Q8W (N=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	0/165	2/155 (1%)				
Rest of World	0/ 44	0/ 37				
Tooth abscess						
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)
Anal chlamydia infection						
North America	2/118 (2%)	4/135 (3%)				
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)
Ear infection						
North America	1/118 (<1%)	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
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)

Tinea versicolour						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	1/ 37 (3%)				
Herpes zoster						
North America	2/118 (2%)	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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Analysis of Proportion of Subjects with Adverse Events by 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)
Hordeolum						
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)
Lower respiratory tract infection						
North America	0/118	2/135 (1%)				
Europe	0/165	0/155				
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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Analysis of Proportion of Subjects with Adverse Events by 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	2/118 (2%)	4/135 (3%)				
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)

Tooth infection						
North America	0/118	1/135 (<1%)				
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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Analysis of Proportion of Subjects with Adverse Events by 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				
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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Analysis of Proportion of Subjects with Adverse Events by 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)

Diverticulitis						
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)
Secondary syphilis						
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)
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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Analysis of Proportion of Subjects with Adverse Events by 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				
Cellulitis						
North America	0/118	2/135 (1%)				
Europe	0/165	0/155				
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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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=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)
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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Analysis of Proportion of Subjects with Adverse Events by 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				
Paronychia						
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)
Pneumonia						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	1/ 44 (2%)	0/ 37				
Primary syphilis						
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)
Skin 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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Analysis of Proportion of Subjects with Adverse Events by 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 infection						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Tracheitis						
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= 2

System Organ Class Preferred Term	Q8W (N=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	2/135 (1%)				
Europe	0/165	2/155 (1%)				
Rest of World	0/ 44	0/ 37				
Abscess limb						
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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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by 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)
Acute sinusitis						
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)

Bronchitis viral						
North America	0/118	0/135				
Europe	1/165 (<1%)	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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Analysis of Proportion of Subjects with Adverse Events by 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)

Diarrhoea infectious						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
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.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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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Analysis of Proportion of Subjects with Adverse Events by 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	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)

Injection site abscess						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
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	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)
Pharyngitis streptococcal						
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)
Pharyngotonsillitis						
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)
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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Analysis of Proportion of Subjects with Adverse Events by 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)
Sexually transmitted disease						
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)
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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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=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	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)
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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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=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 mycoplasmal						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
Varicella						
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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Analysis of Proportion of Subjects with Adverse Events by 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 infection						
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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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by 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)
Vulvovaginal mycotic infection						
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)
Orchitis						
North America	0/118	0/135				
Europe	0/165	2/155 (1%)				
Rest of World	0/ 44	0/ 37				
Pulmonary tuberculosis						
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by 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				
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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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by 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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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by 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				
COVID-19						
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)
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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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by 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)

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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by 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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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by 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)
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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Analysis of Proportion of Subjects with Adverse Events by 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)
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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 infected						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
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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Analysis of Proportion of Subjects with Adverse Events by 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 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= 2

System Organ Class Preferred Term	Q8W (N=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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Analysis of Proportion of Subjects with Adverse Events by 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)
Gonococcal 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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Analysis of Proportion of Subjects with Adverse Events by 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)
Herpes ophthalmic						
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)

Herpes virus infection						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Infected bite						
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)
Infection						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Latent syphilis						
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)
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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Analysis of Proportion of Subjects with Adverse Events by 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)
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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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by 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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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=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				
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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Analysis of Proportion of Subjects with Adverse Events by 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 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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Analysis of Proportion of Subjects with Adverse Events by 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)
Suspected COVID-19						
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)
Urinary tract infection staphylococcal						
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)
Wound 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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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=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	15/118 (13%)	19/135 (14%)	0.8891 (0.4297, 1.8397) /0.751	-1.3622 (-9.7607, 7.0363) /0.751	0.9032 (0.4809, 1.6964) /0.752	0.288
Europe	11/165 (7%)	24/155 (15%)	0.3899 (0.1840, 0.8260) /0.014	-8.8172 (-15.6670, -1.9675) /0.012	0.4306 (0.2183, 0.8491) /0.015	
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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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=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	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	0.278
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%)	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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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=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	3/118 (3%)	2/135 (1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	1/ 37 (3%)				
Constipation						
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)
Dyspepsia						
North America	0/118	1/135 (<1%)				
Europe	1/165 (<1%)	2/155 (1%)				
Rest of World	0/ 44	0/ 37				
Haemorrhoids						
North America	1/118 (<1%)	3/135 (2%)				
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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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=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	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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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%)	1/135 (<1%)				
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.

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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 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.

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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	3/135 (2%)				
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.

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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	1/155 (<1%)				
Rest of World	1/ 44 (2%)	0/ 37				
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	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= 2

System Organ Class Preferred Term	Q8W (N=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	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Gastritis						
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.

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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)

Haematochezia						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
Rectal 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.

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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. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by 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 fissure						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
Dry mouth						
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)
Inguinal hernia						
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)
Irritable bowel 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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Analysis of Proportion of Subjects with Adverse Events by 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)
Oesophagitis						
North America	0/118	0/135				
Europe	1/165 (<1%)	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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Analysis of Proportion of Subjects with Adverse Events by 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)
Large intestine polyp						
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)
Oral disorder						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Proctitis						
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 AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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)

Colitis						
North America	0/118	0/135				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Haemorrhoids thrombosed						
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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Analysis of Proportion of Subjects with Adverse Events by 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	1/155 (<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)

Aphthous ulcer						
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)

Crohn's disease						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Dental 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= 2

System Organ Class Preferred Term	Q8W (N=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.

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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)
Intestinal polyp						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Oral 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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Analysis of Proportion of Subjects with Adverse Events by 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				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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)
Rectal prolapse						
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)

Musculoskeletal and connective tissue disorders						
Any Event						
North America	13/118 (11%)	17/135 (13%)	0.8594 (0.3985, 1.8533) /0.699	-1.5756 (-9.5276, 6.3764) /0.698	0.8749 (0.4439, 1.7244) /0.699	0.316
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	4/ 44 (9%)	2/ 37 (5%)	1.7500 (0.3020, 10.1408) /0.532	3.6855 (-7.5056, 14.8766) /0.519	1.6818 (0.3262, 8.6710) /0.534	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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)
Back pain						
North America	0/118	4/135 (3%)				
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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)
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	0.463
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	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= 2

System Organ Class Preferred Term	Q8W (N=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%)	3/135 (2%)				
Europe	0/165	2/155 (1%)				
Rest of World	1/ 44 (2%)	0/ 37				
Myalgia						
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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)
Musculoskeletal pain						
North America	3/118 (3%)	0/135				
Europe	1/165 (<1%)	2/155 (1%)				
Rest of World	0/ 44	0/ 37				
Tendonitis						
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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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=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%)	2/135 (1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Muscle contracture						
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)
Musculoskeletal chest pain						
North America	1/118 (<1%)	0/135				
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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)
Intervertebral disc protrusion						
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)
Neck pain North America	0/118	0/135				
Europe	1/165 (<1%)	2/155 (1%)				
Rest of World	1/ 44 (2%)	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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Analysis of Proportion of Subjects with Adverse Events by 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)
Exostosis						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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 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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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by 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	1/155 (<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)
Musculoskeletal discomfort						
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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%)	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)

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)

Synovitis						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Osteoarthritis						
North America	0/118	0/135				
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)
Arthritis reactive						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Bone 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= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Loose body in joint						
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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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Polyarthrititis						
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.

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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 and subcutaneous tissue disorders						
Any Event						
North America	5/118 (4%)	11/135 (8%)	0.4988 (0.1681, 1.4797) /0.210	-3.9109 (-9.7851, 1.9634) /0.192	0.5200 (0.1861, 1.4535) /0.212	0.295
Europe	11/165 (7%)	9/155 (6%)	1.1587 (0.4666, 2.8774) /0.751	0.8602 (-4.4352, 6.1556) /0.750	1.1481 (0.4892, 2.6949) /0.751	
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)
Pruritus						
North America	1/118 (<1%)	0/135				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	1/ 44 (2%)	0/ 37				
Rash						
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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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=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%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Acne						
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)
<hr/>						
Alopecia North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	1/ 37 (3%)				
<hr/>						
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)

Skin lesion						
North America	0/118	1/135 (<1%)				
Europe	3/165 (2%)	0/155				
Rest of World	0/ 44	0/ 37				
Dermatitis contact						
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)
Hyperhidrosis						
North America	0/118	2/135 (1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Dermatitis atopic						
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)
Erythema						
North America	0/118	1/135 (<1%)				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
Night sweats						
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)
Urticaria						
North America	1/118 (<1%)	0/135				
Europe	0/165	1/155 (<1%)				
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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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=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	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
Ecchymosis						
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%)	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)
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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Analysis of Proportion of Subjects with Adverse Events by 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)
Guttate psoriasis						
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)
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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Analysis of Proportion of Subjects with Adverse Events by 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)
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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)

Nail dystrophy						
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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Analysis of Proportion of Subjects with Adverse Events by 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)
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 fissures						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
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	7/118 (6%)	8/135 (6%)	1.0011 (0.3518, 2.8490) /0.998	0.0063 (-5.8272, 5.8398) /0.998	1.0011 (0.3743, 2.6776) /0.998	0.350
Europe	3/165 (2%)	9/155 (6%)	0.3004 (0.0798, 1.1309) /0.075	-3.9883 (-8.1967, 0.2202) /0.063	0.3131 (0.0864, 1.1354) /0.077	
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	2/118 (2%)	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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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=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	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= 2

System Organ Class Preferred Term	Q8W (N=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	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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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=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				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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				
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.

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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)

Asthma						
North America	2/118 (2%)	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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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=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	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)

Productive cough						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	1/ 37 (3%)				
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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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by 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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Analysis of Proportion of Subjects with Adverse Events by 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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Analysis of Proportion of Subjects with Adverse Events by 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	8/118 (7%)	11/135 (8%)	0.8198 (0.3183, 2.1118) /0.681	-1.3685 (-7.8393, 5.1023) /0.679	0.8320 (0.3463, 1.9991) /0.681	0.783
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	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)
<hr/>						
Headache						
North America	3/118 (3%)	6/135 (4%)				
Europe	3/165 (2%)	4/155 (3%)				
Rest of World	0/ 44	3/ 37 (8%)				
Dizziness						
North America	1/118 (<1%)	1/135 (<1%)				
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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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by 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				
Paraesthesia						
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)
Migraine North America	0/118	0/135				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Hypoaesthesia North America	0/118	1/135 (<1%)				
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by 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)
Sciatica North America	1/118 (<1%)	0/135				
Europe	1/165 (<1%)	2/155 (1%)				
Rest of World	0/ 44	0/ 37				
Syncope 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= 2

System Organ Class Preferred Term	Q8W (N=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				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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)
Cervical radiculopathy						
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)
Head discomfort						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Anosmia						
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)
Brain injury						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Brain stem infarction						
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)
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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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=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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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=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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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Transient ischaemic attack						
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)
Trigeminal neuralgia						
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)

Injury, poisoning and procedural complications						
Any Event						
North America	7/118 (6%)	14/135 (10%)	0.5450 (0.2122, 1.3997) /0.207	-4.4382 (-11.1176, 2.2413) /0.193	0.5720 (0.2389, 1.3695) /0.210	0.937
Europe	5/165 (3%)	10/155 (6%)	0.4531 (0.1513, 1.3569) /0.157	-3.4213 (-8.0903, 1.2476) /0.151	0.4697 (0.1642, 1.3434) /0.159	
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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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=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	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)
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)

Ligament sprain						
North America	0/118	2/135 (1%)				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
Muscle strain						
North America	0/118	2/135 (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)
Limb injury						
North America	1/118 (<1%)	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)
Exposure to communicable disease						
North America	2/118 (2%)	4/135 (3%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by 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 laceration						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Skin abrasion						
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)
Vaccination complication						
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)

Arthropod sting						
North America	0/118	0/135				
Europe	0/165	2/155 (1%)				
Rest of World	0/ 44	0/ 37				
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by 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				
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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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by 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)
Rib fracture						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
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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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by 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)

Ankle fracture						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	1/ 44 (2%)	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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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)
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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Analysis of Proportion of Subjects with Adverse Events by 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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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by 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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Analysis of Proportion of Subjects with Adverse Events by 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)
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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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=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				
Face 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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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)
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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)
Fractured coccyx						
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)
Gastrointestinal procedural 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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Analysis of Proportion of Subjects with Adverse Events by 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)
Post-traumatic 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= 2

System Organ Class Preferred Term	Q8W (N=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.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by 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)
Traumatic arthritis						
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)

Psychiatric disorders						
Any Event						
North America	10/118 (8%)	9/135 (7%)	1.2963 (0.5081, 3.3069) /0.587	1.8079 (-4.7462, 8.3620) /0.589	1.2712 (0.5347, 3.0221) /0.587	0.688
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	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)
Insomnia						
North America	1/118 (<1%)	1/135 (<1%)				
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by 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)
Anxiety 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	0.950
Europe	3/165 (2%)	2/155 (1%)	1.4167 (0.2335, 8.5942) /0.705	0.5279 (-2.1763, 3.2321) /0.702	1.4091 (0.2386, 8.3199) /0.705	
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= 2

System Organ Class Preferred Term	Q8W (N=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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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by 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 disorder						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Depression						
North America	4/118 (3%)	2/135 (1%)				
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by 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)
Nightmare 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)
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)

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.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by 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)
Attention deficit hyperactivity 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= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Generalised anxiety 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= 2

System Organ Class Preferred Term	Q8W (N=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	0/135				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Panic attack						
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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)
Restlessness						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
Suicidal ideation						
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)
Adjustment 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= 2

System Organ Class Preferred Term	Q8W (N=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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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)
Psychotic 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= 2

System Organ Class Preferred Term	Q8W (N=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	3/118 (3%)	6/135 (4%)				
Europe	2/165 (1%)	6/155 (4%)				
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)
Weight increased						
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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)
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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Analysis of Proportion of Subjects with Adverse Events by 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	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)
Blood cholesterol increased						
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)
Weight 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)
Blood glucose 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= 2

System Organ Class Preferred Term	Q8W (N=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)
Haematocrit decreased						
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)
Haemoglobin decreased						
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)
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	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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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by 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	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)
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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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by 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)
Adenoma benign						
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)
Basal cell carcinoma						
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by 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)
Adrenal adenoma						
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)

Vascular disorders						
Any Event						
North America	1/118 (<1%)	2/135 (1%)				
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	1/118 (<1%)	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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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by 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)
<hr/>						
Phlebitis						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
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)
Thrombophlebitis superficial						
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)

Reproductive system and breast disorders						
Any Event						
North America	3/118 (3%)	3/135 (2%)				
Europe	5/165 (3%)	3/155 (2%)				
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= 2

System Organ Class Preferred Term	Q8W (N=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%)	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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by 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)
Balanoposthitis						
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)
Genital lesion						
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)
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)
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	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= 2

System Organ Class Preferred Term	Q8W (N=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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Analysis of Proportion of Subjects with Adverse Events by 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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Analysis of Proportion of Subjects with Adverse Events by 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)
Renal and urinary disorders						
Any Event						
North America	3/118 (3%)	4/135 (3%)				
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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Analysis of Proportion of Subjects with Adverse Events by 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%)	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Nocturia						
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)

Nephrolithiasis						
North America	1/118 (<1%)	1/135 (<1%)				
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	1/165 (<1%)	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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Analysis of Proportion of Subjects with Adverse Events by 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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Analysis of Proportion of Subjects with Adverse Events by 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)

Ear and labyrinth disorders						
Any Event						
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)
Tinnitus						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Vertigo						
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)

Metabolism and nutrition disorders						
Any Event						
North America	3/118 (3%)	3/135 (2%)				
Europe	2/165 (1%)	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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Analysis of Proportion of Subjects with Adverse Events by 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	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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Analysis of Proportion of Subjects with Adverse Events by 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	1/118 (<1%)	1/135 (<1%)				
Europe	1/165 (<1%)	2/155 (1%)				
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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Analysis of Proportion of Subjects with Adverse Events by 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				
Hypertriglyceridaemia						
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	Q8W (N=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	4/118 (3%)	0/135				
Europe	4/165 (2%)	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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Analysis of Proportion of Subjects with Adverse Events by 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 allergic						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Blepharitis						
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)
Cataract						
North America	1/118 (<1%)	0/135				
Europe	1/165 (<1%)	1/155 (<1%)				
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)

Retinal detachment						
North America	0/118	0/135				
Europe	2/165 (1%)	0/155				
Rest of World	0/ 44	0/ 37				
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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				
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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)
Macular fibrosis						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
Retinal tear						
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)
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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Analysis of Proportion of Subjects with Adverse Events by 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	2/118 (2%)	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)
Microcytic anaemia						
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)
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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)
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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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=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	3/118 (3%)	1/135 (<1%)				
Europe	3/165 (2%)	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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Analysis of Proportion of Subjects with Adverse Events by 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	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= 2

System Organ Class Preferred Term	Q8W (N=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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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Allergy to arthropod bite						
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)
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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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by 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	2/118 (2%)	3/135 (2%)				
Europe	4/165 (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.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by 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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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by 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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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by 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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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by 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				
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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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by 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)
Myocardial necrosis						
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)
Sinus bradycardia						
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)
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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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by 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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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by 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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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by 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	1/155 (<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	10/118 (8%)	18/135 (13%)	0.6019 (0.2661, 1.3611) /0.223	-4.8588 (-12.4832, 2.7657) /0.212	0.6356 (0.3055, 1.3222) /0.225	0.089
Europe	18/165 (11%)	23/155 (15%)	0.7028 (0.3632, 1.3597) /0.295	-3.9296 (-11.2744, 3.4152) /0.294	0.7352 (0.4131, 1.3085) /0.296	
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	6/118 (5%)	10/135 (7%)	0.6696 (0.2358, 1.9017) /0.451	-2.3227 (-8.2580, 3.6127) /0.443	0.6864 (0.2572, 1.8318) /0.452	NC
Europe	4/165 (2%)	9/155 (6%)	0.4030 (0.1215, 1.3367) /0.137	-3.3822 (-7.7482, 0.9838) /0.129	0.4175 (0.1312, 1.3281) /0.139	
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= 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	0.474
Europe	2/165 (1%)	9/155 (6%)	0.1990 (0.0423, 0.9363) /0.041	-4.5943 (-8.6369, -0.5517) /0.026	0.2088 (0.0458, 0.9510) /0.043	
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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Analysis of Proportion of Subjects with Adverse Events by 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	1/118 (<1%)	0/135				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Fatigue						
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)

Injection site swelling						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
Malaise						
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)

Injection site warmth						
North America	0/118	0/135				
Europe	1/165 (<1%)	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.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by 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	1/118 (<1%)	2/135 (1%)				
Europe	5/165 (3%)	3/155 (2%)				
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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Analysis of Proportion of Subjects with Adverse Events by 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)

Viral infection						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Tonsillitis						
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= 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)
Herpes zoster						
North America	0/118	0/135				
Europe	1/165 (<1%)	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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Analysis of Proportion of Subjects with Adverse Events by 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	1/118 (<1%)	1/135 (<1%)				
Europe	0/165	0/155				
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.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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)
<hr/>						
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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Analysis of Proportion of Subjects with Adverse Events by 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)
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= 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						
North America	0/118	0/135				
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.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with 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)
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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Analysis of Proportion of Subjects with Adverse Events by 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%)	1/155 (<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= 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				
Toothache						
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= 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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Analysis of Proportion of Subjects with Adverse Events by 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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Analysis of Proportion of Subjects with Adverse Events by 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)
Musculoskeletal and connective tissue disorders						
Any Event						
North America	1/118 (<1%)	2/135 (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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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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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	2/155 (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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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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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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Analysis of Proportion of Subjects with Adverse Events by 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				
Osteonecrosis						
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= 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				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by 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)

Skin and subcutaneous 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.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by 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)

Eczema						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
Hyperhidrosis						
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)
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	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= 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)

Headache						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
Disturbance in attention						
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)
Neuritis cranial						
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)

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				
Foot 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.

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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)

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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Analysis of Proportion of Subjects with Adverse Events by 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)

Investigations						
Any Event						
North America	1/118 (<1%)	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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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by 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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Analysis of Proportion of Subjects with Adverse Events by 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)
Lipase 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= 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)
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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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)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
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= 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)
Breast cancer						
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= 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)

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.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by 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)
Genital odour						
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)

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.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by 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)

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)

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)

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)

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)

Immune system 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= 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)
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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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by 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	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= 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)
Ventricular extrasystoles						
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= 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 Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
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 Preferred Term	Q8W (N=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	1/155 (<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= 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)

Hepatocellular 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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by 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	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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Analysis of Proportion of Subjects with Adverse Events by 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	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= 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				
Testicular neoplasm						
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 3.22

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	6/ 84 (7%)	9/ 98 (9%)	0.7607 (0.2592, 2.2328) /0.619	-2.0408 (-9.9796, 5.8980) /0.614	0.7778 (0.2887, 2.0953) /0.619	0.779
35 - <50	19/154 (12%)	20/143 (14%)	0.8656 (0.4413, 1.6979) /0.674	-1.6484 (-9.3487, 6.0520) /0.675	0.8821 (0.4914, 1.5837) /0.674	
>=50	9/ 89 (10%)	14/ 86 (16%)	0.5786 (0.2362, 1.4172) /0.231	-6.1667 (-16.1723, 3.8389) /0.227	0.6212 (0.2838, 1.3594) /0.233	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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	5/ 98 (5%)	<0.0001 (<0.0001, -) />0.999	-7.2683 (-29.4886, 14.9520) /0.521	<0.0001 (<0.0001, -) />0.999	0.104
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	3/ 89 (3%)	6/ 86 (7%)	0.4651 (0.1125, 1.9222) /0.290	-3.6060 (-10.1671, 2.9552) /0.281	0.4831 (0.1248, 1.8709) /0.292	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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	4/ 98 (4%)	<0.0001 (<0.0001, -) />0.999	-6.2907 (-28.4646, 15.8832) /0.578	<0.0001 (<0.0001, -) />0.999	0.286
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	3/ 89 (3%)	6/ 86 (7%)	0.4651 (0.1125, 1.9222) /0.290	-3.6060 (-10.1671, 2.9552) /0.281	0.4831 (0.1248, 1.8709) /0.292	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.22

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	2/154 (1%)	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Injection site discomfort						
<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)
Chest pain						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=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. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Injection site discolouration						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=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 3.22

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 warmth						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Malaise						
<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)

Infections and infestations						
Any Event						
<35	3/ 84 (4%)	2/ 98 (2%)				
35 - <50	5/154 (3%)	3/143 (2%)				
>=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 3.22

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)

Pneumonia						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	1/ 86 (1%)				
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.

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)
<hr/>						
Hepatitis E						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Herpes zoster						
<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 abscess						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Proctitis chlamydial						
<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)

Tonsillitis						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Viral 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. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)

Musculoskeletal and connective tissue disorders						
Any Event						
<35	0/ 84	1/ 98 (1%)				
35 - <50	3/154 (2%)	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. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)

Intervertebral disc protrusion						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	1/ 89 (1%)	0/ 86				
Myalgia						
<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 3.22

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	2/154 (1%)	0/143				
>=50	0/ 89	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.

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)
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)

Osteoarthritis						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	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				
Investigations						
Any Event						
<35	2/ 84 (2%)	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. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)

Body temperature increased						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)

Lipase increased						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	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. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)
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)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
<35	0/ 84	0/ 98				
35 - <50	3/154 (2%)	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. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Breast cancer						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	1/ 86 (1%)				
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)

Glioblastoma						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Testicular neoplasm						
<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)

Gastrointestinal disorders						
Any Event						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	2/143 (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)

Toothache						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Nervous system disorders						
Any Event						
<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. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)

Cerebrovascular accident						
<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	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)

Headache						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Neuritis cranial						
<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)

Cardiac disorders						
Any Event						
<35	0/ 84	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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)
Myocardial infarction						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Ventricular extrasystoles						
<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)

Immune system disorders						
Any Event						
<35	0/ 84	0/ 98				
35 - <50	0/154	2/143 (1%)				
>=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. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)
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)

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)
Foot fracture						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	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 3.22

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)

Skin and subcutaneous tissue disorders						
Any Event						
<35	0/ 84	0/ 98				
35 - <50	2/154 (1%)	0/143				
>=50	0/ 89	0/ 86				
Eczema						
<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)
Hyperhidrosis						
<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)

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.

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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)

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)

Hepatobiliary disorders						
Any Event						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Hepatocellular 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. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)

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.

PPD

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)

Reproductive system and breast disorders						
Any Event						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Genital odour						
<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)

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	7/ 73 (10%)	8/ 75 (11%)	0.8883 (0.3047, 2.5891) /0.828	-1.0776 (-10.7950, 8.6398) /0.828	0.8990 (0.3436, 2.3521) /0.828	0.769
Male	27/254 (11%)	35/252 (14%)	0.7374 (0.4317, 1.2597) /0.265	-3.2590 (-8.9685, 2.4506) /0.263	0.7654 (0.4780, 1.2256) /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. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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	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	0.986
Male	9/254 (4%)	17/252 (7%)	0.5078 (0.2220, 1.1617) /0.108	-3.2027 (-7.0444, 0.6390) /0.102	0.5252 (0.2386, 1.1561) /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. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.22

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	0.245
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	
Pyrexia						
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. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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 discomfort						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
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%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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 discolouration						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
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 3.22

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)
Malaise						
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)

Infections and infestations						
Any Event						
Female	3/ 73 (4%)	0/ 75	>999 (>999, >999) /NC	6.3175 (-17.3129, 29.9479) /0.600	>999 (>999, >999) /NC	0.055
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	

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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 hepatitis B						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Pneumonia						
Female	1/ 73 (1%)	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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=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%)				
Epididymitis						
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. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=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				
Hepatitis E						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=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				
Proctitis chlamydial						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Tonsillitis						
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)

Viral infection						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Musculoskeletal and connective tissue disorders						
Any Event						
Female	1/ 73 (1%)	1/ 75 (1%)				
Male	4/254 (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. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)
Intervertebral disc protrusion						
Female	1/ 73 (1%)	0/ 75				
Male	1/254 (<1%)	0/252				
Myalgia						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	1/252 (<1%)				
Osteonecrosis						
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.

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)
Osteoarthritis						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				
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)
Investigations						
Any Event						
Female	0/ 73	1/ 75 (1%)				
Male	3/254 (1%)	1/252 (<1%)				
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)

Creatinine renal clearance decreased						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Lipase 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. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)
White blood cell count decreased						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
Female	1/ 73 (1%)	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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)
Breast cancer						
Female	1/ 73 (1%)	1/ 75 (1%)				
Male	0/254	0/252				
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)

Testicular neoplasm						
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%)	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)
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				
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)

Toothache						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Nervous system disorders						
Any Event						
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. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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%)				
Disturbance in attention						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Headache						
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)

Neuritis cranial						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Cardiac 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. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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%)				
Myocardial infarction						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Ventricular extrasystoles						
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)

Immune system disorders						
Any Event						
Female	0/ 73	2/ 75 (3%)				
Male	0/254	0/252				
Drug 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.

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				
Injury, poisoning and procedural complications						
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.

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)
Contusion						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Foot fracture						
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. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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				
Skin and subcutaneous tissue disorders						
Any Event						
Female	2/ 73 (3%)	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)
Eczema						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				
Hyperhidrosis						
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)

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.

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)

Ear and labyrinth disorders						
Any Event						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Tympanic membrane perforation						
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)

Eye disorders						
Any Event						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Retinal detachment						
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)

Hepatobiliary disorders						
Any Event						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Hepatocellular 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. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)

Metabolism and nutrition disorders						
Any Event						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Hypercholesterolemia						
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)

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.

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 and urinary disorders						
Any Event						
Female	0 / 73	0 / 75				
Male	0 / 254	1 / 252 (<1%)				
Renal colic						
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)

Reproductive system and breast disorders						
Any Event						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Genital odour						
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)

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 3.22

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	25/239 (10%)	36/256 (14%)	0.7139 (0.4144, 1.2298) /0.225	-3.6022 (-9.3632, 2.1587) /0.220	0.7438 (0.4608, 1.2007) /0.226	0.534
Non-White	9/ 88 (10%)	7/ 71 (10%)	1.0416 (0.3677, 2.9507) /0.939	0.3681 (-9.0214, 9.7576) /0.939	1.0373 (0.4065, 2.6474) /0.939	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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	8/239 (3%)	18/256 (7%)	0.4579 (0.1953, 1.0738) /0.072	-3.6840 (-7.5581, 0.1902) /0.062	0.4761 (0.2109, 1.0744) /0.074	0.324
Non-White	2/ 88 (2%)	1/ 71 (1%)	1.6279 (0.1446, 18.3272) /0.693	0.8643 (-3.2841, 5.0126) /0.683	1.6136 (0.1493, 17.4353) /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. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.22

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	5/239 (2%)	17/256 (7%)	0.3004 (0.1091, 0.8275) /0.020	-4.5486 (-8.0975, -0.9996) /0.012	0.3150 (0.1181, 0.8406) /0.021	0.197
Non-White	2/ 88 (2%)	1/ 71 (1%)	1.6279 (0.1446, 18.3272) /0.693	0.8643 (-3.2841, 5.0126) /0.683	1.6136 (0.1493, 17.4353) /0.694	
Pyrexia						
White	2/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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 discomfort						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Chest pain						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Fatigue						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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 discolouration						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Injection site swelling						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Injection site warmth						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=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	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Infections and infestations						
Any Event						
White	6/239 (3%)	3/256 (1%)				
Non-White	3/ 88 (3%)	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. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=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	0/239	0/256				
Non-White	1/ 88 (1%)	1/ 71 (1%)				
Pneumonia						
White	0/239	0/256				
Non-White	1/ 88 (1%)	1/ 71 (1%)				
Anal abscess						
White	0/239	0/256				
Non-White	1/ 88 (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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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)
Diverticulitis						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Epididymitis						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Epiglottitis obstructive						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=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						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Hepatitis E						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Herpes zoster						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=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	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Proctitis chlamydial						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Tonsillitis						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=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						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Musculoskeletal and connective tissue disorders						
Any Event						
White	4/239 (2%)	3/256 (1%)				
Non-White	1/ 88 (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)

Intervertebral disc protrusion						
White	2/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Myalgia						
White	0/239	2/256 (<1%)				
Non-White	0/ 88	0/ 71				
Osteonecrosis						
White	1/239 (<1%)	0/256				
Non-White	1/ 88 (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)
Arthralgia						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Costochondritis						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Muscle spasms						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)

Osteoarthritis						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Pain in extremity						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Rotator cuff syndrome						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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	2/239 (<1%)	2/256 (<1%)				
Non-White	1/ 88 (1%)	0/ 71				
Body temperature increased						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)

Creatinine renal clearance decreased						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Lipase increased						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Transaminases increased						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)

White blood cell count decreased						
White	0/239	0/256				
Non-White	1/ 88 (1%)	0/ 71				
Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
White	2/239 (<1%)	2/256 (<1%)				
Non-White	1/ 88 (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)
Breast cancer						
White	0/239	1/256 (<1%)				
Non-White	1/ 88 (1%)	0/ 71				
Diffuse large B-cell lymphoma						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Glioblastoma						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)

Testicular neoplasm						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Gastrointestinal disorders						
Any Event						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	1/ 88 (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)
Abdominal pain						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Haemorrhoidal haemorrhage						
White	0/239	0/256				
Non-White	1/ 88 (1%)	0/ 71				
Oroantral fistula						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)

Toothache						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Nervous system disorders						
Any Event						
White	2/239 (<1%)	2/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Disturbance in attention						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Headache						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)

Neuritis cranial						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Cardiac disorders						
Any Event						
White	0/239	2/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Myocardial infarction						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Ventricular extrasystoles						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)

Immune system disorders						
Any Event						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	1/ 71 (1%)				
Drug hypersensitivity						
White	0/239	0/256				
Non-White	0/ 88	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)

Hypersensitivity						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Injury, poisoning and procedural complications						
Any Event						
White	2/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)
Contusion						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Foot fracture						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Overdose						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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	0/239	2/256 (<1%)				
Non-White	0/ 88	0/ 71				
Depression						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Skin and subcutaneous tissue disorders						
Any Event						
White	2/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)
Eczema						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Hyperhidrosis						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)

Blood and lymphatic system disorders						
Any Event						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Microcytic anaemia						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)

Ear and labyrinth disorders						
Any Event						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Tympanic membrane perforation						
White	0/239	0/256				
Non-White	0/ 88	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)

Eye disorders						
Any Event						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Retinal detachment						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)

Hepatobiliary disorders						
Any Event						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Hepatocellular injury						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)

Metabolism and nutrition disorders						
Any Event						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Hypercholesterolemia						
White	0/239	0/256				
Non-White	0/ 88	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)

Pregnancy, puerperium and perinatal conditions						
Any Event						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Abortion spontaneous						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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 and urinary disorders						
Any Event						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Renal colic						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)

Reproductive system and breast disorders						
Any Event						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Genital odour						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)

Respiratory, thoracic and mediastinal disorders						
Any Event						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Sleep apnoea syndrome						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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	11/118 (9%)	19/135 (14%)	0.6276 (0.2855, 1.3797) /0.246	-4.7520 (-12.6216, 3.1175) /0.237	0.6624 (0.3288, 1.3342) /0.249	0.094
Europe	20/165 (12%)	24/155 (15%)	0.7529 (0.3975, 1.4260) /0.384	-3.3627 (-10.9279, 4.2025) /0.384	0.7828 (0.4510, 1.3588) /0.384	
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	6/118 (5%)	10/135 (7%)	0.6696 (0.2358, 1.9017) /0.451	-2.3227 (-8.2580, 3.6127) /0.443	0.6864 (0.2572, 1.8318) /0.452	NC
Europe	4/165 (2%)	9/155 (6%)	0.4030 (0.1215, 1.3367) /0.137	-3.3822 (-7.7482, 0.9838) /0.129	0.4175 (0.1312, 1.3281) /0.139	
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	0.474
Europe	2/165 (1%)	9/155 (6%)	0.1990 (0.0423, 0.9363) /0.041	-4.5943 (-8.6369, -0.5517) /0.026	0.2088 (0.0458, 0.9510) /0.043	
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)

Pyrexia						
North America	1/118 (<1%)	0/135				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
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. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)

Chest pain						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Fatigue						
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)

Injection site discolouration						
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. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 warmth						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
Malaise						
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)

Infections and infestations						
Any Event						
North America	2/118 (2%)	3/135 (2%)				
Europe	5/165 (3%)	3/155 (2%)				
Rest of World	2/ 44 (5%)	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.

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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)

Pneumonia						
North America	1/118 (<1%)	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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

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.

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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)

Hepatitis E						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Herpes zoster						
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)

Injection site abscess						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
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. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)

Tonsillitis						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
Viral 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. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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	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. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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				
Myalgia						
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. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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	1/165 (<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)

Osteoarthritis						
North America	0/118	0/135				
Europe	1/165 (<1%)	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				

Investigations

Any Event

North America	1/118 (<1%)	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. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)

Body temperature increased						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
 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. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)

Lipase increased						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
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.

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)
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)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
North America	1/118 (<1%)	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. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)
Breast cancer						
North America	1/118 (<1%)	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
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. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)

Glioblastoma						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Testicular neoplasm						
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%)	1/155 (<1%)				
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)

Toothache						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Nervous system disorders						
Any Event						
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. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)

Cerebrovascular accident						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Disturbance in attention						
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)

Headache						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
Neuritis cranial						
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	1/135 (<1%)				
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)

Myocardial infarction						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Ventricular extrasystoles						
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	2/155 (1%)				
Rest of World	0/ 44	0/ 37				
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. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)
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)

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)
Foot fracture						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	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.

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)

Skin and subcutaneous tissue disorders						
Any Event						
North America	0/118	0/135				
Europe	2/165 (1%)	0/155				
Rest of World	0/ 44	0/ 37				
Eczema						
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)
Hyperhidrosis						
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)

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)

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)

Hepatobiliary disorders						
Any Event						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Hepatocellular 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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)

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)

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				
Genital odour						
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	0.122
35 - <50	11/154 (7%)	10/143 (7%)	1.0231 (0.4208, 2.4871) /0.960	0.1499 (-5.6825, 5.9822) /0.960	1.0214 (0.4474, 2.3321) /0.960	
>=50	8/ 89 (9%)	6/ 86 (7%)	1.3169 (0.4372, 3.9667) /0.625	2.0120 (-6.0067, 10.0307) /0.623	1.2884 (0.4664, 3.5593) /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. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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	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. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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	2/ 89 (2%)	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				
Cellulitis of male external genital organ						
<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)

Diverticulitis						
<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. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)

Erysipelas						
<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. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)

Injection site abscess						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	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. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)

Sialoadenitis						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
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)

Musculoskeletal and connective tissue disorders						
Any Event						
<35	0/ 84	0/ 98				
35 - <50	3/154 (2%)	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)

Osteonecrosis						
<35	0/ 84	0/ 98				
35 - <50	2/154 (1%)	0/143				
>=50	0/ 89	0/ 86				
Intervertebral disc protrusion						
<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)

Osteoarthritis						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
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	2/154 (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. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)

Breast cancer						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)

Glioblastoma						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Testicular neoplasm						
<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%)	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. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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 procedural complication						
<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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)
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)

Nervous system disorders						
Any Event						
<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. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)
-----	-----	-----	-----	-----	-----	-----
Transient ischaemic attack						
<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)

Immune system disorders						
Any Event						
<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 3.23
 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)

Drug hypersensitivity						
<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)

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	Q8W (N=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				
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)

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
 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)
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	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	0.193
Male	19/254 (7%)	11/252 (4%)	1.7714 (0.8251, 3.8029) /0.142	3.1152 (-0.9873, 7.2177) /0.137	1.7137 (0.8326, 3.5271) /0.144	

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)

Infestations and infestations						
Any Event						
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	0.661
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. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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 3.23
 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)

Pneumonia						
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%)				
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.

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)
Cellulitis of male external genital organ						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Diverticulitis						
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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 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=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				
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. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Injection site abscess						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				
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%)				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Sinusitis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Gastrointestinal disorders						
Any Event						
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)
Haemorrhoids						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	0/252				
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%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)

Oroantral fistula						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Musculoskeletal and connective tissue disorders						
Any Event						
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Osteonecrosis						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	0/252				
Intervertebral disc protrusion						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Osteoarthritis						
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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 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)

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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 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)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
Female	0/ 73	1/ 75 (1%)				
Male	2/254 (<1%)	1/252 (<1%)				
Breast cancer						
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)
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%)				
Testicular neoplasm						
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%)	1/252 (<1%)				
Gastrointestinal procedural 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. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Head injury						
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. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Nervous system disorders						
Any Event						
Female	0 / 73	0 / 75				
Male	2 / 254 (<1%)	1 / 252 (<1%)				
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Cerebrovascular accident						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Transient ischaemic attack						
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)

Immune system disorders						
Any Event						
Female	0/ 73	2/ 75 (3%)				
Male	0/254	0/252				
Drug 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)

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. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

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.

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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)

Acute myocardial infarction						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
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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 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=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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Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=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.

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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)

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	14/239 (6%)	13/256 (5%)	1.1631 (0.5351, 2.5281) /0.703	0.7796 (-3.2325, 4.7917) /0.703	1.1535 (0.5537, 2.4033) /0.703	0.398
Non-White	8/ 88 (9%)	3/ 71 (4%)	2.2667 (0.5784, 8.8820) /0.240	4.8656 (-2.7484, 12.4795) /0.210	2.1515 (0.5925, 7.8124) /0.244	

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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	4/239 (2%)	5/256 (2%)				
Non-White	5/ 88 (6%)	2/ 71 (3%)				
Pneumonia						
White	0/239	1/256 (<1%)				
Non-White	2/ 88 (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. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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	0/239	0/256				
Non-White	1/ 88 (1%)	1/ 71 (1%)				
Anal abscess						
White	0/239	0/256				
Non-White	1/ 88 (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)
Cellulitis of male external genital organ						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Diverticulitis						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Erysipelas						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Gastroenteritis Escherichia coli						
White	0/239	0/256				
Non-White	1/ 88 (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	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Peritonsillar abscess						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Sialoadenitis						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Gastrointestinal disorders						
Any Event						
White	2/239 (<1%)	1/256 (<1%)				
Non-White	2/ 88 (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	0/239	0/256				
Non-White	2/ 88 (2%)	0/ 71				
Anal fistula						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Colitis						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Musculoskeletal and connective tissue disorders						
Any Event						
White	3/239 (1%)	1/256 (<1%)				
Non-White	1/ 88 (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)

Osteonecrosis						
White	1/239 (<1%)	0/256				
Non-White	1/ 88 (1%)	0/ 71				
Intervertebral disc protrusion						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Osteoarthritis						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
White	2/239 (<1%)	2/256 (<1%)				
Non-White	0/ 88	0/ 71				
Breast cancer						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)

Diffuse large B-cell lymphoma						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Glioblastoma						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Testicular neoplasm						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)

Injury, poisoning and procedural complications						
Any Event						
White	2/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Gastrointestinal procedural complication						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, 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)
Head injury						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Overdose						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=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	1/239 (<1%)	1/256 (<1%)				
Non-White	1/ 88 (1%)	0/ 71				
Cerebral infarction						
White	0/239	0/256				
Non-White	1/ 88 (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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 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)

Cerebrovascular accident						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Transient ischaemic attack						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)

Immune system disorders						
Any Event						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	1/ 71 (1%)				
Drug hypersensitivity						
White	0/239	0/256				
Non-White	0/ 88	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)

Hypersensitivity						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Blood and lymphatic system disorders						
Any Event						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)

Microcytic anaemia						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Cardiac disorders						
Any Event						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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 myocardial infarction						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Myocardial infarction						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Abortion spontaneous						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)

Reproductive system and breast disorders						
Any Event						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Priapism						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Sleep apnoea syndrome						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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	6/118 (5%)	4/135 (3%)	1.7545 (0.4829, 6.3739) /0.393	2.1218 (-2.7663, 7.0098) /0.395	1.7161 (0.4962, 5.9350) /0.394	0.018
Europe	10/165 (6%)	12/155 (8%)	0.7688 (0.3223, 1.8341) /0.553	-1.6813 (-7.2452, 3.8825) /0.554	0.7828 (0.3482, 1.7598) /0.554	
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	4/118 (3%)	4/135 (3%)				
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	1/118 (<1%)	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				
Cellulitis of male external genital organ						
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 Preferred Term	Q8W (N=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				
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. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)

Erysipelas						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
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. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)

Injection site abscess						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
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. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)

Sialoadenitis						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
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	Q8W (N=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.

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)
Musculoskeletal and connective tissue disorders						
Any Event						
North America	1/118 (<1%)	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. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)

Osteonecrosis						
North America	1/118 (<1%)	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
Intervertebral disc protrusion						
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)

Osteoarthritis						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
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
 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)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
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. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)

Breast cancer						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
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. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)

Glioblastoma						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Testicular neoplasm						
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)

Injury, poisoning and procedural complications						
Any Event						
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. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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 procedural complication						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
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. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)

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 3.23
 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	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. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)

Transient ischaemic attack						
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 3.23
 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)

Immune system 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. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*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)

Drug hypersensitivity						
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)

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 Preferred Term	Q8W (N=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				
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	Q8W (N=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 Preferred Term	Q8W (N=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	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	0.924
35 - <50	7/154 (5%)	7/143 (5%)	0.9252 (0.3163, 2.7061) /0.887	-0.3497 (-5.1797, 4.4804) /0.887	0.9286 (0.3340, 2.5819) /0.887	
>=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. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the 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 3.24

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	3/154 (2%)	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. 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)

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. 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)

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. 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)

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. 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 necrosis						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Injection site nodule						
<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. 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 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. 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)
-----	-----	-----	-----	-----	-----	-----
Malaise						
<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. 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 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	1/ 84 (1%)	0/ 98				
35 - <50	1/154 (<1%)	2/143 (1%)				
>=50	0/ 89	2/ 86 (2%)				
Headache						
<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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the 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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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	1/ 86 (1%)				
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. 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)
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. 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)

Skin and subcutaneous tissue disorders						
Any Event						
<35	0/ 84	0/ 98				
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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the 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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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	1/154 (<1%)	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. 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)

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. 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)

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. 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)

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. 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)

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. 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)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
<35	0/ 84	0/ 98				
35 - <50	3/154 (2%)	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. 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)

Breast cancer						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the 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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Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=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						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Testicular neoplasm						
<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. 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)

Psychiatric disorders						
Any Event						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	2/143 (1%)				
>=50	0/ 89	1/ 86 (1%)				
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. 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	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. 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)
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. 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	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Nausea						
<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. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the 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 3.24

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	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. 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)

Drug hypersensitivity						
<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. 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	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. 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				
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. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the 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 3.24

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	Q8W (N=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. 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)
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. 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)

Ear and labyrinth disorders						
Any Event						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Vertigo						
<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. 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)
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. 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. 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	5/ 73 (7%)	5/ 75 (7%)	1.0294 (0.2852, 3.7162) /0.965	0.1826 (-7.9071, 8.2724) /0.965	1.0274 (0.3104, 3.4008) /0.965	0.853
Male	9/254 (4%)	10/252 (4%)	0.8890 (0.3550, 2.2260) /0.802	-0.4249 (-3.7383, 2.8884) /0.802	0.8929 (0.3691, 2.1603) /0.802	

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the 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 3.24
 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	2/ 73 (3%)	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. 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. 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 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. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the 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 3.24

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 nodule						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Injection site swelling						
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. 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 warmth						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Malaise						
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. 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	2/254 (<1%)	3/252 (1%)				
Headache						
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. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the 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 3.24

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	2/252 (<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. 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	2/ 73 (3%)	0/ 75				
Male	1/254 (<1%)	2/252 (<1%)				
Hyperhidrosis						
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. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the 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 3.24

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. 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. 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. 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	1/ 73 (1%)	0/ 75				
Male	2/254 (<1%)	1/252 (<1%)				
Breast cancer						
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. 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)
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%)				
Testicular neoplasm						
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. 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	4/252 (2%)				
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. 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)
Sleep disorder						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				
Depression						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Insomnia						
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. 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)

Gastrointestinal disorders						
Any Event						
Female	0 / 73	0 / 75				
Male	0 / 254	2 / 252 (<1%)				
Nausea						
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. 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)

Immune system disorders						
Any Event						
Female	0/ 73	2/ 75 (3%)				
Male	0/254	0/252				
Drug 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. 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				
Musculoskeletal and connective tissue 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. 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%)				
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. 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%)				
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. 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)

Ear and labyrinth disorders						
Any Event						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Vertigo						
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. 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)

Investigations						
Any Event						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	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. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the 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 3.24
 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	11/239 (5%)	11/256 (4%)	1.0746 (0.4570, 2.5266) /0.869	0.3056 (-3.3314, 3.9426) /0.869	1.0711 (0.4732, 2.4245) /0.869	0.502
Non-White	3/ 88 (3%)	4/ 71 (6%)	0.5912 (0.1279, 2.7324) /0.501	-2.2247 (-8.7927, 4.3433) /0.507	0.6051 (0.1400, 2.6159) /0.501	

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the 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 3.24
 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	5/239 (2%)	2/256 (<1%)				
Non-White	1/ 88 (1%)	2/ 71 (3%)				
Injection site pain						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	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. 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	0/239	1/256 (<1%)				
Non-White	1/ 88 (1%)	1/ 71 (1%)				
Pyrexia						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Asthenia						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the 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 3.24
 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)
<hr/>						
Chills						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Injection site discolouration						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Injection site necrosis						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the 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 3.24

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 nodule						
White	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Injection site swelling						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the 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 3.24

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 warmth						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Malaise						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the 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 3.24
 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	1/239 (<1%)	3/256 (1%)				
Non-White	1/ 88 (1%)	1/ 71 (1%)				
Headache						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	1/ 88 (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. 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	0/239	1/256 (<1%)				
Non-White	0/ 88	1/ 71 (1%)				
Dizziness						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Presyncope						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the 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 3.24
 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	2/239 (<1%)	1/256 (<1%)				
Non-White	1/ 88 (1%)	1/ 71 (1%)				
Hyperhidrosis						
White	1/239 (<1%)	1/256 (<1%)				
Non-White	0/ 88	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. 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	0/239	0/256				
Non-White	1/ 88 (1%)	0/ 71				
Skin lesion						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the 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 3.24
 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	1/239 (<1%)	1/256 (<1%)				
Non-White	1/ 88 (1%)	1/ 71 (1%)				
Acute hepatitis B						
White	0/239	0/256				
Non-White	1/ 88 (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. 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	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Injection site abscess						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the 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 3.24
 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	2/239 (<1%)	1/256 (<1%)				
Non-White	1/ 88 (1%)	0/ 71				
Breast cancer						
White	0/239	0/256				
Non-White	1/ 88 (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. 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)

Diffuse large B-cell lymphoma						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				
Glioblastoma						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Testicular neoplasm						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the 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 3.24
 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	0/239	2/256 (<1%)				
Non-White	0/ 88	2/ 71 (3%)				
Abnormal dreams						
White	0/239	0/256				
Non-White	0/ 88	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. 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)
Sleep disorder						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	1/ 71 (1%)				
Depression						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Insomnia						
White	0/239	0/256				
Non-White	0/ 88	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. 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)

Gastrointestinal disorders						
Any Event						
White	0/239	2/256 (<1%)				
Non-White	0/ 88	0/ 71				
Nausea						
White	0/239	2/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the 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 3.24
 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)

Immune system disorders						
Any Event						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	1/ 71 (1%)				
Drug hypersensitivity						
White	0/239	0/256				
Non-White	0/ 88	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. 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	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Musculoskeletal and connective tissue disorders						
Any Event						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	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. 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	0/239	0/256				
Non-White	0/ 88	1/ 71 (1%)				
Osteonecrosis						
White	1/239 (<1%)	0/256				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the 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 3.24
 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)

Cardiac disorders						
Any Event						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Myocardial infarction						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the 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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 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)

Ear and labyrinth disorders						
Any Event						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Vertigo						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the 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 3.24
 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)

Investigations						
Any Event						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				
Transaminases increased						
White	0/239	1/256 (<1%)				
Non-White	0/ 88	0/ 71				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the 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 3.24
 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	5/118 (4%)	6/135 (4%)	0.9513 (0.2827, 3.2011) /0.936	-0.2072 (-5.2365, 4.8222) /0.936	0.9534 (0.2986, 3.0438) /0.936	0.997
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	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. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the 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 3.24
 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)

General disorders and administration site conditions						
Any Event						
North America	3/118 (3%)	4/135 (3%)				
Europe	3/165 (2%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the 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 3.24
 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. 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. 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. 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 necrosis						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
Injection site nodule						
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. 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 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. 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)
-----	-----	-----	-----	-----	-----	-----
Malaise						
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. 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	2/118 (2%)	2/135 (1%)				
Europe	0/165	2/155 (1%)				
Rest of World	0/ 44	0/ 37				
Headache						
North America	2/118 (2%)	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. 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	1/155 (<1%)				
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. 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. 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)

Skin and subcutaneous tissue disorders						
Any Event						
North America	1/118 (<1%)	2/135 (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 and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the 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 3.24

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	1/165 (<1%)	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. 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. 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)

Infections 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. 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. 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. 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	1/118 (<1%)	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. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the 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 3.24
 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)

Breast cancer						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
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. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the 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 3.24
 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)

Glioblastoma						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Testicular neoplasm						
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. 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	1/155 (<1%)				
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. 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)

Sleep disorder						
North America	0/118	1/135 (<1%)				
Europe	0/165	1/155 (<1%)				
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. 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)

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. 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)

Gastrointestinal disorders						
Any Event						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	1/ 37 (3%)				
Nausea						
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. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the 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 3.24

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)

Immune system 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. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the 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 3.24
 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)

Drug hypersensitivity						
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. 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)
Musculoskeletal and connective tissue disorders						
Any Event						
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. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the 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 3.24
 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)

Myalgia						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Osteonecrosis						
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. 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)

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. 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)
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. 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)

Ear and labyrinth disorders						
Any Event						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	1/ 37 (3%)				
Vertigo						
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. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the 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 3.24

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)

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. 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)
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. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Fatal Adverse Events (Maintenance Phase)
- Overall - ATLAS-2M ATLAS-2M (Prior CAB + RPV of 0 Weeks)

No data to report