Blinded Phase: Laboratory parameters

Haematological

Table 1 gives the mean difference (standard error) of change in haematological laboratory parameters from baseline to each treatment visit for the adalimumab group and for the placebo group. Differences marked by an asterisk were significant at the 5% level. None of the mean changes in haematological assessments were considered to be clinically significant.

Table 1: Mean difference in haematological variables from baseline to each treatment visit of adalimumab compared to placebo

Variable	Mean difference of change from baseline in adalimumab compared to placebo (Standard Error)							
	1 month	2 months	3 months	6 months	9 months	12 months	15 months	18 months
Haematocrit (%)	0.44 (0.60)	0.27 (0.56)	-0.73 (0.67)	-1.23 (0.76)	-0.81 (1.24)	-1.93 (1.54)	0.12 (1.69)	1.62 (1.88)
Haemoglobin (g/dL)	0.08 (0.17)	0.02 (0.17)	-0.12 (0.18)	-0.41 (0.25)	-0.38 (0.37)	-0.52 (0.41)	-0.37 (0.44)	-0.09 (0.68)
Red blood cell count (10^{12}/L)	0.00 (0.06)	-0.00 (0.06)	-0.06 (0.06)	-0.20 (0.08)*	-0.18 (0.11)	-0.18 (0.14)	-0.25 (0.14)	-0.17 (0.17)
White blood cell count (10^{12}/L)	0.33 (0.53)	0.09 (0.66)	-0.22 (1.17)	1.17 (0.69)	0.06 (0.99)	0.90 (1.36)	1.36 (1.32)	0.75 (1.63)
Neutrophils (10^9/L)	-0.07 (0.45)	-0.66 (0.52)	-0.83 (1.10)	0.64 (0.58)	-0.45 (0.70)	0.04 (0.95)	0.40 (1.08)	0.03 (1.29)
Lymphocytes (10^9/L)	0.39 (0.15)*	0.52 (0.20)*	0.42 (0.23)	0.32 (0.19)	0.53 (0.38)	0.72 (0.42)	0.61 (0.63)	0.34 (0.32)
Monocytes (10^9/L)	0.04 (0.04)	0.07 (0.05)	0.07 (0.06)	0.12 (0.06)	0.09 (0.09)	0.10 (0.10)	0.20 (0.11)	0.10 (0.13)
Basophils (10^9/L)	0.01 (0.01)	0.00 (0.01)	-0.00 (0.01)	-0.00 (0.01)	-0.01 (0.01)	-0.01 (0.01)	0.01 (0.01)	-0.01 (0.01)
Eosinophils (10^9/L)	0.04 (0.06)	0.06 (0.05)	0.14 (0.05)*	0.11 (0.08)	-0.02 (0.06)	-0.02 (0.26)	0.06 (0.10)	0.17 (0.13)
Platelet count (10^9/L)	-3.34 (12.80)	-6.79 (11.60)	-21.86 (13.48)	-17.27 (13.30)	-14.41 (20.23)	-6.78 (30.89)	-15.56 (37.23)	-15.05 (29.94)
ESR	0.09 (3.49)	-0.85 (2.71)	-0.03 (2.43)	-1.84 (4.25)	-2.49 (3.40)	3.40 (5.34)	-1.50 (6.25)	5.39 (8.31)
Plasma viscosity[**]	NA	NA	NA	NA	NA	NA	NA	NA

*In the placebo arm there was only 1 assessment done at baseline and months 1, 2, 3 and 6, none were done at months 9, 12, 15 and 18 and therefore no mean difference could be calculated between the two groups.

Tables 2-25 show the haematological summary data.

Table 2: Haematocrit Assessments – Placebo

Time point	Placebo						
	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
Baseline	30	24 (80.00%)	6 (20.00%)	4 (66.67%)	0 (0%)	0 (0%)	0 (0%)
1 month	30	23 (76.67%)	4 (13.33%)	3 (75.00%)	0 (0%)	3 (10.00%)	0 (0%)
2 months	25	20 (80.00%)	4 (16.00%)	3 (75.00%)	1 (25.00%)	1 (4.00%)	0 (0%)
3 months	19	18 (94.74%)	1 (5.26%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
6 months	12	10 (83.33%)	2 (16.67%)	2 (100.00%)	0 (0%)	0 (0%)	0 (0%)
9 months	6	5 (83.33%)	1 (16.67%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
12 months	5	4 (80.00%)	0 (0%)	0 (0%)	0 (0%)	1 (20.00%)	0 (0%)
15 months	3	2 (66.67%)	1 (33.33%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
18 months	3	1 (33.33%)	2 (66.67%)	1 (50.00%)	0 (0%)	0 (0%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 3: Haematocrit Assessments – Adalimumab

Time point	Adalimumab						
	Number of assessments, N	Normal assessments N (%)	Abnormal Assessment N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
Baseline	60	52 (86.67%)	8 (13.33%)	5 (62.50%)	0 (0%)	0 (0%)	0 (0%)
1 month	60	46 (76.67%)	11 (18.33%)	8 (72.73%)	1 (9.09%)	3 (5.00%)	0 (0%)
2 months	58	45 (77.59%)	9 (15.52%)	5 (55.56%)	0 (0%)	4 (6.90%)	0 (0%)
3 months	56	45 (80.36%)	6 (10.71%)	4 (66.67%)	0 (0%)	4 (7.14%)	1 (1.79%)
6 months	48	44 (91.67%)	3 (6.25%)	3 (100.00%)	0 (0%)	1 (2.08%)	0 (0%)
9 months	42	35 (83.33%)	5 (11.90%)	4 (80.00%)	0 (0%)	2 (4.76%)	0 (0%)
12 months	34	25 (73.53%)	7 (20.59%)	3 (42.86%)	0 (0%)	2 (5.88%)	0 (0%)
15 months	27	23 (85.19%)	3 (11.11%)	0 (0%)	0 (0%)	1 (3.70%)	0 (0%)
18 months	23	19 (82.61%)	1 (4.35%)	1 (100.00%)	0 (0%)	3 (13.04%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 4: Haemoglobin Assessments – Placebo

Time point	Placebo						
	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
Baseline	30	26 (86.67%)	4 (13.33%)	3 (75.00%)	0 (0%)	0 (0%)	0 (0%)
1 month	30	25 (83.33%)	3 (10.00%)	3 (100.00%)	0 (0%)	2 (6.67%)	0 (0%)
2 months	25	23 (92.00%)	2 (8.00%)	2 (100.00%)	2 (100.00%)	0 (0%)	0 (0%)
3 months	19	18 (94.74%)	1 (5.26%)	1 (100.00%)	0 (0%)	0 (0%)	0 (0%)
6 months	12	11 (91.67%)	1 (8.33%)	1 (100.00%)	0 (0%)	0 (0%)	0 (0%)
9 months	6	5 (83.33%)	1 (16.67%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
12 months	5	4 (80.00%)	0 (0%)	0 (0%)	0 (0%)	1 (20.00%)	0 (0%)
15 months	3	2 (66.67%)	1 (33.33%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
18 months	3	1 (33.33%)	2 (66.67%)	1 (50.00%)	0 (0%)	0 (0%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 5: Haemoglobin Assessments – Adalimumab

Time point	Adalimumab						
	Number of assessments, N	Normal assessments N (%)	Abnormal Assessment N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
Baseline	60	55 (91.67%)	5 (8.33%)	4 (80.00%)	0 (0%)	0 (0%)	0 (0%)
1 month	60	55 (91.67%)	3 (5.00%)	2 (66.67%)	0 (0%)	2 (3.33%)	0 (0%)
2 months	58	51 (87.93%)	5 (8.62%)	3 (60.00%)	0 (0%)	2 (3.45%)	0 (0%)
3 months	56	50 (89.29%)	4 (7.14%)	1 (25.00%)	0 (0%)	1 (1.79%)	1 (1.79%)
6 months	48	46 (95.83%)	1 (2.08%)	0 (0%)	0 (0%)	1 (2.08%)	0 (0%)
9 months	42	39 (92.86%)	2 (4.76%)	2 (100.00%)	0 (0%)	1 (2.38%)	0 (0%)
12 months	34	29 (85.29%)	3 (8.82%)	3 (100.00%)	0 (0%)	2 (5.88%)	0 (0%)
15 months	27	25 (92.59%)	2 (7.41%)	1 (50.00%)	0 (0%)	0 (0%)	0 (0%)
18 months	23	20 (86.96%)	1 (4.35%)	1 (100.00%)	0 (0%)	2 (8.70%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 6: Red blood cell count Assessments – Placebo

Time point	Placebo						
	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
Baseline	30	28 (93.33%)	2 (6.67%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
1 month	30	27 (90.00%)	1 (3.33%)	1 (100.00%)	0 (0%)	2 (6.67%)	0 (0%)
2 months	25	23 (92.00%)	2 (8.00%)	1 (50.00%)	0 (0%)	0 (0%)	0 (0%)
3 months	19	17 (89.47%)	2 (10.53%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
6 months	12	12 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
9 months	6	5 (83.33%)	1 (16.67%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
12 months	5	4 (80.00%)	0 (0%)	0 (0%)	0 (0%)	1 (20.00%)	0 (0%)
15 months	3	2 (66.67%)	1 (33.33%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
18 months	3	2 (66.67%)	1 (33.33%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 7: Red blood cell count Assessments – Adalimumab

Time point	Adalimumab						
	Number of assessments, N	Normal assessments N (%)	Abnormal Assessment N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
Baseline	60	54 (90.00%)	6 (10.00%)	5 (83.33%)	0 (0%)	0 (0%)	0 (0%)
1 month	60	52 (86.67%)	6 (10.00%)	5 (83.33%)	1 (16.67%)	2 (3.33%)	0 (0%)
2 months	58	50 (86.21%)	6 (10.34%)	3 (50.00%)	0 (0%)	2 (3.45%)	0 (0%)
3 months	56	50 (89.29%)	4 (7.14%)	2 (50.00%)	0 (0%)	1 (1.79%)	1 (1.79%)
6 months	48	46 (95.83%)	1 (2.08%)	1 (100.00%)	0 (0%)	1 (2.08%)	0 (0%)
9 months	42	37 (88.10%)	3 (7.14%)	2 (66.67%)	0 (0%)	2 (4.76%)	0 (0%)
12 months	34	31 (91.18%)	1 (2.94%)	0 (0%)	0 (0%)	2 (5.88%)	0 (0%)
15 months	27	23 (85.19%)	3 (11.11%)	0 (0%)	0 (0%)	1 (3.70%)	0 (0%)
18 months	23	18 (78.26%)	3 (13.04%)	0 (0%)	0 (0%)	2 (8.70%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 8: White blood cell count Assessments – Placebo

Time point	Placebo						
	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
Baseline	30	28 (93.33%)	2 (6.67%)	2 (100.00%)	0 (0%)	0 (0%)	0 (0%)
1 month	30	27 (90.00%)	1 (3.33%)	0 (0%)	0 (0%)	2 (6.67%)	0 (0%)
2 months	25	23 (92.00%)	1 (4.00%)	0 (0%)	0 (0%)	1 (4.00%)	0 (0%)
3 months	19	18 (94.74%)	1 (5.26%)	1 (100.00%)	1 (100.00%)	0 (0%)	0 (0%)
6 months	12	11 (91.67%)	1 (8.33%)	1 (100.00%)	0 (0%)	0 (0%)	0 (0%)
9 months	6	6 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
12 months	5	4 (80.00%)	0 (0%)	0 (0%)	0 (0%)	1 (20.00%)	0 (0%)
15 months	3	3 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
18 months	3	3 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 9: White blood cell count Assessments – Adalimumab

Time point	Adalimumab						
	Number of assessments, N	Normal assessments N (%)	Abnormal Assessment N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
Baseline	60	55 (91.67%)	5 (8.33%)	3 (60.00%)	0 (0%)	0 (0%)	0 (0%)
1 month	60	56 (93.33%)	1 (1.67%)	1 (100.00%)	0 (0%)	2 (3.33%)	1 (1.67%)
2 months	58	51 (87.93%)	5 (8.62%)	2 (40.00%)	1 (20.00%)	2 (3.45%)	0 (0%)
3 months	56	49 (87.50%)	5 (8.93%)	0 (0%)	1 (20.00%)	1 (1.79%)	1 (1.79%)
6 months	48	45 (93.75%)	2 (4.17%)	1 (50.00%)	1 (50.00%)	1 (2.08%)	0 (0%)
9 months	42	39 (92.86%)	2 (4.76%)	2 (100.00%)	0 (0%)	1 (2.38%)	0 (0%)
12 months	34	31 (91.18%)	1 (2.94%)	0 (0%)	0 (0%)	2 (5.88%)	0 (0%)
15 months	27	24 (88.89%)	3 (11.11%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
18 months	23	20 (86.96%)	1 (4.35%)	0 (0%)	0 (0%)	2 (8.70%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 10: Neutrophils Assessments – Placebo

Time point	Placebo						
	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
Baseline	30	25 (83.33%)	5 (16.67%)	4 (80.00%)	0 (0%)	0 (0%)	0 (0%)
1 month	30	27 (90.00%)	1 (3.33%)	0 (0%)	0 (0%)	2 (6.67%)	0 (0%)
2 months	25	24 (96.00%)	1 (4.00%)	1 (100.00%)	1 (100.00%)	0 (0%)	0 (0%)
3 months	19	18 (94.74%)	1 (5.26%)	1 (100.00%)	0 (0%)	0 (0%)	0 (0%)
6 months	12	12 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
9 months	6	6 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
12 months	5	3 (60.00%)	1 (20.00%)	1 (100.00%)	0 (0%)	1 (20.00%)	0 (0%)
15 months	3	3 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
18 months	3	3 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 11: Neutrophils Assessments – Adalimumab

Time point	Number of assessments, N	Normal assessments N (%)	Abnormal Assessment N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
			Adalimumab				
Baseline	60	57 (95.00%)	3 (5.00%)	1 (33.33%)	0 (0%)	0 (0%)	0 (0%)
1 month	60	56 (93.33%)	2 (3.33%)	2 (100.00%)	0 (0%)	2 (3.33%)	0 (0%)
2 months	58	54 (93.10%)	2 (3.45%)	0 (0%)	1 (50.00%)	2 (3.45%)	0 (0%)
3 months	56	50 (89.29%)	4 (7.14%)	0 (0%)	1 (25.00%)	1 (1.79%)	1 (1.79%)
6 months	48	45 (93.75%)	2 (4.17%)	1 (50.00%)	1 (50.00%)	1 (2.08%)	0 (0%)
9 months	42	40 (95.24%)	1 (2.38%)	1 (100.00%)	0 (0%)	1 (2.38%)	0 (0%)
12 months	34	31 (91.18%)	1 (2.94%)	0 (0%)	0 (0%)	2 (5.88%)	0 (0%)
15 months	27	26 (96.30%)	1 (3.70%)	1 (100.00%)	0 (0%)	0 (0%)	0 (0%)
18 months	23	20 (86.96%)	1 (4.35%)	0 (0%)	0 (0%)	2 (8.70%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 12: Lymphocytes Assessments – Placebo

Time point	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
			Placebo				
Baseline	30	28 (93.33%)	2 (6.67%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
1 month	30	24 (80.00%)	4 (13.33%)	2 (50.00%)	0 (0%)	2 (6.67%)	0 (0%)
2 months	25	24 (96.00%)	1 (4.00%)	1 (100.00%)	0 (0%)	0 (0%)	0 (0%)
3 months	19	19 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
6 months	12	12 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
9 months	6	6 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
12 months	5	4 (80.00%)	0 (0%)	0 (0%)	0 (0%)	1 (20.00%)	0 (0%)
15 months	3	3 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
18 months	3	3 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 13: Lymphocytes Assessments – Adalimumab

Time point	Number of assessments, N	Normal assessments N (%)	Abnormal Assessment N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
			Adalimumab				
Baseline	60	55 (91.67%)	5 (8.33%)	5 (100.00%)	0 (0%)	0 (0%)	0 (0%)
1 month	60	57 (95.00%)	2 (3.33%)	1 (50.00%)	0 (0%)	1 (1.67%)	0 (0%)
2 months	58	51 (87.93%)	5 (8.62%)	2 (40.00%)	1 (20.00%)	2 (3.45%)	0 (0%)
3 months	56	53 (94.64%)	1 (1.79%)	0 (0%)	0 (0%)	1 (1.79%)	1 (1.79%)
6 months	48	47 (97.92%)	0 (0%)	0 (0%)	0 (0%)	1 (2.08%)	0 (0%)
9 months	42	41 (97.62%)	0 (0%)	0 (0%)	0 (0%)	1 (2.38%)	0 (0%)
12 months	34	32 (94.12%)	0 (0%)	0 (0%)	0 (0%)	2 (5.88%)	0 (0%)
15 months	27	26 (96.30%)	1 (3.70%)	1 (100.00%)	0 (0%)	0 (0%)	0 (0%)
18 months	23	21 (91.30%)	0 (0%)	0 (0%)	0 (0%)	2 (8.70%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 14: Monocytes Assessments – Placebo

Time point	Placebo						
	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
Baseline	30	26 (86.67%)	4 (13.33%)	4 (100.00%)	0 (0%)	0 (0%)	0 (0%)
1 month	30	24 (80.00%)	4 (13.33%)	3 (75.00%)	0 (0%)	2 (6.67%)	0 (0%)
2 months	25	23 (92.00%)	2 (8.00%)	1 (50.00%)	0 (0%)	0 (0%)	0 (0%)
3 months	19	14 (73.68%)	5 (26.32%)	1 (20.00%)	0 (0%)	0 (0%)	0 (0%)
6 months	12	12 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
9 months	6	4 (66.67%)	2 (33.33%)	1 (50.00%)	0 (0%)	0 (0%)	0 (0%)
12 months	5	2 (40.00%)	2 (40.00%)	1 (50.00%)	0 (0%)	1 (20.00%)	0 (0%)
15 months	3	2 (66.67%)	1 (33.33%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
18 months	3	3 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 15: Monocytes Assessments – Adalimumab

Time point	Adalimumab						
	Number of assessments, N	Normal assessments N (%)	Abnormal Assessment N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
Baseline	60	59 (98.33%)	1 (1.67%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
1 month	60	54 (90.00%)	4 (6.67%)	2 (50.00%)	0 (0%)	2 (3.33%)	0 (0%)
2 months	58	55 (94.83%)	1 (1.72%)	0 (0%)	0 (0%)	2 (3.45%)	0 (0%)
3 months	56	51 (91.07%)	3 (5.36%)	1 (33.33%)	0 (0%)	1 (1.79%)	1 (1.79%)
6 months	48	44 (91.67%)	3 (6.25%)	1 (33.33%)	1 (33.33%)	1 (2.08%)	0 (0%)
9 months	42	40 (95.24%)	1 (2.38%)	1 (100.00%)	0 (0%)	1 (2.38%)	0 (0%)
12 months	34	31 (91.18%)	1 (2.94%)	0 (0%)	0 (0%)	2 (5.88%)	0 (0%)
15 months	27	24 (88.89%)	2 (7.41%)	2 (100.00%)	0 (0%)	1 (3.70%)	0 (0%)
18 months	23	20 (86.96%)	1 (4.35%)	0 (0%)	1 (100.00%)	2 (8.70%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 16: Basophils Assessments – Placebo

Time point	Placebo						
	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
Baseline	30	29 (96.67%)	1 (3.33%)	1 (100.00%)	0 (0%)	0 (0%)	0 (0%)
1 month	30	27 (90.00%)	1 (3.33%)	1 (100.00%)	0 (0%)	2 (6.67%)	0 (0%)
2 months	25	25 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
3 months	19	18 (94.74%)	1 (5.26%)	1 (100.00%)	0 (0%)	0 (0%)	0 (0%)
6 months	12	12 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
9 months	6	6 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
12 months	5	4 (80.00%)	0 (0%)	0 (0%)	0 (0%)	1 (20.00%)	0 (0%)
15 months	3	3 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
18 months	3	3 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 17: Basophils Assessments – Adalimumab

Time point	Number of assessments, N	Normal assessments N (%)	Abnormal Assessment N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
Baseline	60	56 (93.33%)	3 (5.00%)	3 (100.00%)	0 (0%)	1 (1.67%)	0 (0%)
1 month	60	56 (93.33%)	1 (1.67%)	1 (100.00%)	0 (0%)	3 (5.00%)	0 (0%)
2 months	58	52 (89.66%)	3 (5.17%)	2 (66.67%)	0 (0%)	3 (5.17%)	0 (0%)
3 months	56	50 (89.29%)	2 (3.57%)	2 (100.00%)	0 (0%)	3 (5.36%)	1 (1.79%)
6 months	48	45 (93.75%)	2 (4.17%)	1 (50.00%)	0 (0%)	1 (2.08%)	0 (0%)
9 months	42	41 (97.62%)	0 (0%)	0 (0%)	0 (0%)	1 (2.38%)	0 (0%)
12 months	34	31 (91.18%)	1 (2.94%)	0 (0%)	0 (0%)	2 (5.88%)	0 (0%)
15 months	27	26 (96.30%)	0 (0%)	0 (0%)	0 (0%)	1 (3.70%)	0 (0%)
18 months	23	21 (91.30%)	0 (0%)	0 (0%)	0 (0%)	2 (8.70%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 18: Eosinophils Assessments – Placebo

Time point	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
Baseline	30	24 (80.00%)	6 (20.00%)	3 (50.00%)	0 (0%)	0 (0%)	0 (0%)
1 month	30	23 (76.67%)	5 (16.67%)	1 (20.00%)	0 (0%)	2 (6.67%)	0 (0%)
2 months	25	21 (84.00%)	4 (16.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
3 months	19	15 (78.95%)	4 (21.05%)	2 (50.00%)	0 (0%)	0 (0%)	0 (0%)
6 months	12	9 (75.00%)	3 (25.00%)	3 (100.00%)	0 (0%)	0 (0%)	0 (0%)
9 months	6	5 (83.33%)	1 (16.67%)	1 (100.00%)	0 (0%)	0 (0%)	0 (0%)
12 months	5	3 (60.00%)	1 (20.00%)	1 (100.00%)	0 (0%)	1 (20.00%)	0 (0%)
15 months	3	3 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
18 months	3	3 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 19: Eosinophils Assessments – Adalimumab

Time point	Number of assessments, N	Normal assessments N (%)	Abnormal Assessment N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
Baseline	60	57 (95.00%)	3 (5.00%)	2 (66.67%)	0 (0%)	0 (0%)	0 (0%)
1 month	60	51 (85.00%)	7 (11.67%)	6 (85.71%)	0 (0%)	2 (3.33%)	0 (0%)
2 months	58	53 (91.38%)	3 (5.17%)	1 (33.33%)	0 (0%)	2 (3.45%)	0 (0%)
3 months	56	48 (85.71%)	6 (10.71%)	1 (16.67%)	0 (0%)	1 (1.79%)	1 (1.79%)
6 months	48	41 (85.42%)	6 (12.50%)	3 (50.00%)	0 (0%)	1 (2.08%)	0 (0%)
9 months	42	38 (90.48%)	3 (7.14%)	2 (66.67%)	0 (0%)	1 (2.38%)	0 (0%)
12 months	34	29 (85.29%)	3 (8.82%)	0 (0%)	0 (0%)	2 (5.88%)	0 (0%)
15 months	27	23 (85.19%)	3 (11.11%)	1 (33.33%)	0 (0%)	1 (3.70%)	0 (0%)
18 months	23	19 (82.61%)	2 (8.70%)	0 (0%)	0 (0%)	2 (8.70%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 20: Platelet count Assessments – Placebo

Time point	Placebo						
	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
Baseline	30	27 (90.00%)	3 (10.00%)	3 (100.00%)	0 (0%)	0 (0%)	0 (0%)
1 month	30	26 (86.67%)	2 (6.67%)	1 (50.00%)	0 (0%)	2 (6.67%)	0 (0%)
2 months	25	24 (96.00%)	1 (4.00%)	1 (100.00%)	0 (0%)	0 (0%)	0 (0%)
3 months	19	18 (94.74%)	1 (5.26%)	1 (100.00%)	0 (0%)	0 (0%)	0 (0%)
6 months	12	12 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
9 months	6	6 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
12 months	5	4 (80.00%)	0 (0%)	0 (0%)	0 (0%)	1 (20.00%)	0 (0%)
15 months	3	3 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
18 months	3	3 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 21: Platelet count Assessments – Adalimumab

Time point	Adalimumab						
	Number of assessments, N	Normal assessments N (%)	Abnormal Assessment N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
Baseline	60	50 (83.33%)	10 (16.67%)	8 (80.00%)	1 (10.00%)	0 (0%)	0 (0%)
1 month	60	48 (80.00%)	10 (16.67%)	9 (90.00%)	1 (10.00%)	2 (3.33%)	0 (0%)
2 months	58	50 (86.21%)	6 (10.34%)	4 (66.67%)	1 (16.67%)	2 (3.45%)	0 (0%)
3 months	56	49 (87.50%)	5 (8.93%)	2 (40.00%)	1 (20.00%)	1 (1.79%)	1 (1.79%)
6 months	48	42 (87.50%)	5 (10.42%)	3 (60.00%)	0 (0%)	1 (2.08%)	0 (0%)
9 months	42	39 (92.86%)	2 (4.76%)	1 (50.00%)	0 (0%)	1 (2.38%)	0 (0%)
12 months	34	29 (85.29%)	3 (8.82%)	2 (66.67%)	0 (0%)	2 (5.88%)	0 (0%)
15 months	27	23 (85.19%)	4 (14.81%)	3 (75.00%)	0 (0%)	0 (0%)	0 (0%)
18 months	23	18 (78.26%)	3 (13.04%)	2 (66.67%)	0 (0%)	2 (8.70%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 22: Erythrocyte sedimentation rate Assessments – Placebo

Time point	Placebo						
	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
Baseline	30	12 (40.00%)	17 (56.67%)	12 (70.59%)	2 (11.76%)	1 (3.33%)	0 (0%)
1 month	30	15 (50.00%)	8 (26.67%)	6 (75.00%)	2 (25.00%)	7 (23.33%)	0 (0%)
2 months	25	11 (44.00%)	10 (40.00%)	7 (70.00%)	3 (30.00%)	4 (16.00%)	0 (0%)
3 months	19	9 (47.37%)	8 (42.11%)	6 (75.00%)	0 (0%)	2 (10.53%)	0 (0%)
6 months	12	6 (50.00%)	4 (33.33%)	4 (100.00%)	1 (25.00%)	2 (16.67%)	0 (0%)
9 months	6	3 (50.00%)	2 (33.33%)	1 (50.00%)	0 (0%)	1 (16.67%)	0 (0%)
12 months	5	3 (60.00%)	1 (20.00%)	0 (0%)	0 (0%)	1 (20.00%)	0 (0%)
15 months	3	2 (66.67%)	1 (33.33%)	1 (100.00%)	0 (0%)	0 (0%)	0 (0%)
18 months	3	2 (66.67%)	1 (33.33%)	1 (100.00%)	0 (0%)	0 (0%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 23: Erythrocyte sedimentation rate Assessments – Adalimumab

Time point	Number of assessments, N	Adalimumab					
		Normal assessments N (%)	Abnormal Assessment N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
Baseline	60	32 (53.33%)	19 (31.67%)	17 (89.47%)	4 (21.05%)	8 (13.33%)	1 (1.67%)
1 month	60	32 (53.33%)	14 (23.33%)	11 (78.57%)	3 (21.43%)	14 (23.33%)	0 (0%)
2 months	58	39 (67.24%)	11 (18.97%)	9 (81.82%)	2 (18.18%)	8 (13.79%)	0 (0%)
3 months	56	33 (58.93%)	12 (21.43%)	8 (66.67%)	1 (8.33%)	10 (17.86%)	1 (1.79%)
6 months	48	28 (58.33%)	16 (33.33%)	11 (68.75%)	2 (12.50%)	4 (8.33%)	0 (0%)
9 months	42	27 (64.29%)	10 (23.81%)	7 (70.00%)	2 (20.00%)	5 (11.90%)	0 (0%)
12 months	34	19 (55.88%)	12 (35.29%)	7 (58.33%)	1 (8.33%)	3 (8.82%)	0 (0%)
15 months	27	17 (62.96%)	8 (29.63%)	4 (50.00%)	1 (12.50%)	2 (7.41%)	0 (0%)
18 months	23	11 (47.83%)	8 (34.78%)	4 (50.00%)	3 (37.50%)	4 (17.39%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 24: Plasma viscosity Assessments – Placebo

Time point	Number of assessments, N	Placebo					
		Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
Baseline	30	1 (3.33%)	0 (0%)	N/A	N/A	0 (0%)	29 (96.67%)
1 month	30	0 (0%)	0 (0%)	N/A	N/A	7 (23.33%)	23 (76.67%)
2 months	25	1 (4.00%)	0 (0%)	N/A	N/A	3 (12.00%)	21 (84.00%)
3 months	19	1 (5.26%)	0 (0%)	N/A	N/A	1 (5.26%)	17 (89.47%)
6 months	12	1 (8.33%)	0 (0%)	N/A	N/A	1 (8.33%)	10 (83.33%)
9 months	6	0 (0%)	0 (0%)	N/A	N/A	0 (0%)	6 (100.00%)
12 months	5	0 (0%)	0 (0%)	N/A	N/A	1 (20.00%)	4 (80.00%)
15 months	3	0 (0%)	0 (0%)	N/A	N/A	0 (0%)	3 (100.00%)
18 months	3	0 (0%)	0 (0%)	N/A	N/A	0 (0%)	3 (100.00%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 25: Plasma viscosity Assessments – Adalimumab

Time point	Number of assessments, N	Adalimumab					
		Normal assessments N (%)	Abnormal Assessment N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
Baseline	60	3 (5.00%)	1 (1.67%)	0 (0%)	0 (0%)	4 (6.67%)	52 (86.67%)
1 month	60	5 (8.33%)	0 (0%)	N/A	N/A	8 (13.33%)	47 (78.33%)
2 months	58	2 (3.45%)	0 (0%)	N/A	N/A	6 (10.34%)	50 (86.21%)
3 months	56	3 (5.36%)	0 (0%)	N/A	N/A	7 (12.50%)	46 (82.14%)
6 months	48	2 (4.17%)	0 (0%)	N/A	N/A	2 (4.17%)	44 (91.67%)
9 months	42	2 (4.76%)	0 (0%)	N/A	N/A	3 (7.14%)	37 (88.10%)
12 months	34	1 (2.94%)	0 (0%)	N/A	N/A	2 (5.88%)	31 (91.18%)
15 months	27	1 (3.70%)	0 (0%)	N/A	N/A	0 (0%)	26 (96.30%)
18 months	23	0 (0%)	0 (0%)	N/A	N/A	4 (17.39%)	19 (82.61%)

*Assessment missing but not recorded as 'Not done' on CRF

Biochemical

Table 2 gives the mean difference (standard error) of change in biochemical laboratory parameters from baseline to each treatment visit for the adalimumab group and for the placebo group. Differences marked by an asterisk were significant at the 5% level. None of the mean changes in biochemical assessments were considered to be clinically significant.

Table 26: Mean difference (standard error) in biochemical variables from baseline to each treatment visit of adalimumab compared to placebo

Variable	1 month	2 months	3 months	6 months	9 months	12 months	15 months	18 months
CRP (mg/L)	1.15 (2.43)	0.19 (1.43)	0.06 (3.09)	-0.99 (1.78)	-1.82 (2.16)	-0.25 (2.22)	1.26 (3.69)	6.06 (12.90)
Urea (mmol/L)	-0.43 (0.21)*	-0.55 (0.25)*	-0.57 (0.27)*	-0.38 (0.36)	-0.69 (0.49)	-1.02 (0.54)	-1.45 (0.86)	-1.57 (0.72)*
Creatinine (mmol/L)	-1.19 (1.86)	-2.22 (2.27)	0.51 (2.29)	0.45 (1.86)	-0.94 (5.36)	0.88 (3.09)	0.15 (3.89)	-23.64 (8.68)*
Sodium (mmol/L)	1.07 (0.61)	1.14 (0.64)	-0.05 (0.55)	0.19 (0.96)	0.05 (1.11)	0.39 (1.29)	-0.59 (1.88)	0.57 (2.04)
Potassium (mmol/L)	-0.05 (0.10)	0.01 (0.11)	0.00 (0.13)	-0.29 (0.14)*	0.15 (0.33)	0.18 (0.32)	0.07 (0.21)	-0.09 (0.19)
Calcium (mmol/L)	0.02 (0.02)	0.01 (0.03)	0.04 (0.03)	0.01 (0.03)	-0.03 (0.05)	0.03 (0.05)	0.02 (0.06)	-0.06 (0.08)
Inorganic phosphate (mmol/L)	0.05 (0.06)	0.05 (0.06)	-0.03 (0.06)	0.02 (0.07)	0.08 (0.12)	-0.11 (0.10)	-0.06 (0.14)	-0.09 (0.14)
Glucose (mmol/L)	-0.06 (0.30)	-0.33 (0.30)	0.15 (0.30)	0.43 (0.40)	0.11 (0.77)	0.10 (0.77)	0.69 (0.74)	0.17 (0.84)
Chloride (mmol/L)	0.86 (0.63)	0.31 (0.68)	1.19 (0.76)	1.24 (0.98)	0.41 (1.23)	0.45 (1.33)	-1.25 (1.78)	-0.38 (1.96)
Bicarbonate (mmol/L)	0.28 (1.08)	-0.41 (1.00)	-1.34 (1.01)	0.02 (1.53)	-3.70 (2.42)	1.52 (2.00)	0.39 (3.36)	0.20 (2.90)
Total bilirubin (mmol/L)	1.08 (0.89)	1.25 (0.93)	-0.35 (0.96)	0.84 (1.50)	2.11 (1.69)	2.74 (1.75)	0.06 (3.43)	-3.40 (2.13)
ALT (iu/L)	2.67 (8.05)	6.80 (7.31)	-0.86 (6.11)	1.51 (9.53)	25.83 (41.90)	0.66 (10.92)	9.19 (14.94)	4.29 (13.68)
AST (iu/L)	-3.32 (2.47)	-3.63 (2.72)	-1.02 (4.31)	-4.41 (4.89)	6.03 (26.32)	-11.75 (6.85)	-12.00 (13.41)	8.76 (13.63)

Tables show the biochemical summary data.

Table 27: C-Reactive Protein Assessments – Placebo

Time point	Placebo						
	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
Baseline	30	24 (80.00%)	5 (16.67%)	4 (80.00%)	1 (20.00%)	1 (3.33%)	0 (0%)
1 month	30	26 (86.67%)	2 (6.67%)	2 (100.00%)	0 (0%)	2 (6.67%)	0 (0%)
2 months	25	22 (88.00%)	2 (8.00%)	0 (0%)	0 (0%)	1 (4.00%)	0 (0%)
3 months	19	16 (84.21%)	2 (10.53%)	1 (50.00%)	0 (0%)	1 (5.26%)	0 (0%)
6 months	12	12 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
9 months	6	5 (83.33%)	1 (16.67%)	1 (100.00%)	0 (0%)	0 (0%)	0 (0%)
12 months	5	5 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
15 months	3	3 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
18 months	3	3 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 28: C-Reactive Protein Assessments – Adalimumab

Time point	Adalimumab						
	Number of assessments, N	Normal assessments N (%)	Abnormal Assessment N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
Baseline	60	53 (88.33%)	5 (8.33%)	5 (100.00%)	2 (40.00%)	2 (3.33%)	0 (0%)
1 month	59	52 (88.14%)	4 (6.78%)	3 (75.00%)	1 (25.00%)	3 (5.08%)	0 (0%)
2 months	58	50 (86.21%)	5 (8.62%)	5 (100.00%)	0 (0%)	3 (5.17%)	0 (0%)
3 months	56	48 (85.71%)	5 (8.93%)	4 (80.00%)	2 (40.00%)	2 (3.57%)	1 (1.79%)
6 months	48	41 (85.42%)	5 (10.42%)	4 (80.00%)	2 (40.00%)	2 (4.17%)	0 (0%)
9 months	42	37 (88.10%)	2 (4.76%)	2 (100.00%)	1 (50.00%)	3 (7.14%)	0 (0%)
12 months	34	30 (88.24%)	3 (8.82%)	3 (100.00%)	0 (0%)	1 (2.94%)	0 (0%)
15 months	27	26 (96.30%)	1 (3.70%)	1 (100.00%)	0 (0%)	0 (0%)	0 (0%)
18 months	22	18 (81.82%)	3 (13.64%)	2 (66.67%)	0 (0%)	1 (4.55%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 29: Urea Assessments – Placebo

Time point	Placebo						
	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
Baseline	30	30 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
1 month	30	27 (90.00%)	1 (3.33%)	1 (100.00%)	0 (0%)	2 (6.67%)	0 (0%)
2 months	25	24 (96.00%)	1 (4.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
3 months	19	17 (89.47%)	2 (10.53%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
6 months	12	12 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
9 months	6	6 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
12 months	5	5 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
15 months	3	3 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
18 months	3	3 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 30: Urea Assessments – Adalimumab

Time point	Adalimumab						
	Number of assessments, N	Normal assessments N (%)	Abnormal Assessment N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
Baseline	60	57 (95.00%)	3 (5.00%)	1 (33.33%)	0 (0%)	0 (0%)	0 (0%)
1 month	59	57 (96.61%)	0 (0%)	0 (0%)	0 (0%)	2 (3.39%)	0 (0%)
2 months	58	52 (89.66%)	3 (5.17%)	2 (66.67%)	0 (0%)	3 (5.17%)	0 (0%)
3 months	56	52 (92.86%)	1 (1.79%)	0 (0%)	0 (0%)	2 (3.57%)	1 (1.79%)
6 months	48	47 (97.92%)	0 (0%)	0 (0%)	0 (0%)	1 (2.08%)	0 (0%)
9 months	42	40 (95.24%)	2 (4.76%)	2 (100.00%)	0 (0%)	0 (0%)	0 (0%)
12 months	34	33 (97.06%)	0 (0%)	0 (0%)	0 (0%)	1 (2.94%)	0 (0%)
15 months	27	26 (96.30%)	1 (3.70%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
18 months	22	21 (95.45%)	0 (0%)	0 (0%)	0 (0%)	1 (4.55%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 31: Creatinine Assessments – Placebo

Time point	Placebo						
	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
Baseline	30	28 (93.33%)	2 (6.67%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
1 month	30	28 (93.33%)	0 (0%)	0 (0%)	0 (0%)	2 (6.67%)	0 (0%)
2 months	25	23 (92.00%)	2 (8.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
3 months	19	18 (94.74%)	1 (5.26%)	1 (100.00%)	0 (0%)	0 (0%)	0 (0%)
6 months	12	11 (91.67%)	1 (8.33%)	1 (100.00%)	1 (100.00%)	0 (0%)	0 (0%)
9 months	6	5 (83.33%)	1 (16.67%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
12 months	5	5 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
15 months	3	3 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
18 months	3	3 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 32: Creatinine Assessments – Adalimumab

Time point	Adalimumab						
	Number of assessments, N	Normal assessments N (%)	Abnormal Assessment N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
Baseline	60	53 (88.33%)	7 (11.67%)	6 (85.71%)	0 (0%)	0 (0%)	0 (0%)
1 month	59	50 (84.75%)	7 (11.86%)	5 (71.43%)	0 (0%)	2 (3.39%)	0 (0%)
2 months	58	52 (89.66%)	4 (6.90%)	3 (75.00%)	0 (0%)	2 (3.45%)	0 (0%)
3 months	56	49 (87.50%)	4 (7.14%)	1 (25.00%)	0 (0%)	2 (3.57%)	1 (1.79%)
6 months	48	44 (91.67%)	3 (6.25%)	1 (33.33%)	0 (0%)	1 (2.08%)	0 (0%)
9 months	42	38 (90.48%)	3 (7.14%)	3 (100.00%)	0 (0%)	0 (0%)	1 (2.38%)
12 months	34	31 (91.18%)	2 (5.88%)	2 (100.00%)	0 (0%)	1 (2.94%)	0 (0%)
15 months	27	24 (88.89%)	3 (11.11%)	2 (66.67%)	0 (0%)	0 (0%)	0 (0%)
18 months	22	19 (86.36%)	2 (9.09%)	2 (100.00%)	0 (0%)	1 (4.55%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 33: Sodium Assessments – Placebo

Time point	Placebo						
	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
Baseline	30	30 (100.00%)	0 (0%)	N/A	N/A	0 (0%)	0 (0%)
1 month	30	28 (93.33%)	0 (0%)	N/A	N/A	2 (6.67%)	0 (0%)
2 months	25	25 (100.00%)	0 (0%)	N/A	N/A	0 (0%)	0 (0%)
3 months	19	19 (100.00%)	0 (0%)	N/A	N/A	0 (0%)	0 (0%)
6 months	12	11 (91.67%)	0 (0%)	N/A	N/A	1 (8.33%)	0 (0%)
9 months	6	6 (100.00%)	0 (0%)	N/A	N/A	0 (0%)	0 (0%)
12 months	5	5 (100.00%)	0 (0%)	N/A	N/A	0 (0%)	0 (0%)
15 months	3	3 (100.00%)	0 (0%)	N/A	N/A	0 (0%)	0 (0%)
18 months	3	3 (100.00%)	0 (0%)	N/A	N/A	0 (0%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 34: Sodium Assessments – Adalimumab

Time point	Adalimumab						
	Number of assessments, N	Normal assessments N (%)	Abnormal Assessment N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
Baseline	60	59 (98.33%)	1 (1.67%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
1 month	59	57 (96.61%)	0 (0%)	N/A	N/A	2 (3.39%)	0 (0%)
2 months	58	52 (89.66%)	2 (3.45%)	0 (0%)	0 (0%)	4 (6.90%)	0 (0%)
3 months	56	52 (92.86%)	1 (1.79%)	1 (100.00%)	0 (0%)	2 (3.57%)	1 (1.79%)
6 months	48	47 (97.92%)	0 (0%)	N/A	N/A	1 (2.08%)	0 (0%)
9 months	42	42 (100.00%)	0 (0%)	N/A	N/A	0 (0%)	0 (0%)
12 months	34	33 (97.06%)	0 (0%)	N/A	N/A	1 (2.94%)	0 (0%)
15 months	27	27 (100.00%)	0 (0%)	N/A	N/A	0 (0%)	0 (0%)
18 months	22	21 (95.45%)	0 (0%)	N/A	N/A	1 (4.55%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 35: Potassium Assessments – Placebo

Time point	Placebo						
	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
Baseline	30	29 (96.67%)	1 (3.33%)	1 (100.00%)	0 (0%)	0 (0%)	0 (0%)
1 month	30	27 (90.00%)	1 (3.33%)	0 (0%)	0 (0%)	2 (6.67%)	0 (0%)
2 months	25	25 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
3 months	19	17 (89.47%)	1 (5.26%)	0 (0%)	0 (0%)	1 (5.26%)	0 (0%)
6 months	12	11 (91.67%)	1 (8.33%)	1 (100.00%)	0 (0%)	0 (0%)	0 (0%)
9 months	6	6 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
12 months	5	5 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
15 months	3	3 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
18 months	3	3 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 36: Potassium Assessments – Adalimumab

Time point	Number of assessments, N	Normal assessments N (%)	Abnormal Assessment N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
				Adalimumab			
Baseline	60	60 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
1 month	59	55 (93.22%)	2 (3.39%)	1 (50.00%)	0 (0%)	2 (3.39%)	0 (0%)
2 months	58	53 (91.38%)	1 (1.72%)	1 (100.00%)	0 (0%)	4 (6.90%)	0 (0%)
3 months	56	50 (89.29%)	3 (5.36%)	3 (100.00%)	0 (0%)	2 (3.57%)	1 (1.79%)
6 months	48	45 (93.75%)	1 (2.08%)	1 (100.00%)	0 (0%)	2 (4.17%)	0 (0%)
9 months	42	40 (95.24%)	1 (2.38%)	0 (0%)	1 (100.00%)	1 (2.38%)	0 (0%)
12 months	34	31 (91.18%)	2 (5.88%)	1 (50.00%)	1 (50.00%)	1 (2.94%)	0 (0%)
15 months	27	25 (92.59%)	2 (7.41%)	2 (100.00%)	0 (0%)	0 (0%)	0 (0%)
18 months	22	21 (95.45%)	0 (0%)	0 (0%)	0 (0%)	1 (4.55%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 37: Calcium Assessments – Placebo

Time point	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
				Placebo			
Baseline	30	26 (86.67%)	2 (6.67%)	1 (50.00%)	0 (0%)	2 (6.67%)	0 (0%)
1 month	30	26 (86.67%)	1 (3.33%)	0 (0%)	0 (0%)	3 (10.00%)	0 (0%)
2 months	25	23 (92.00%)	0 (0%)	0 (0%)	0 (0%)	2 (8.00%)	0 (0%)
3 months	19	18 (94.74%)	1 (5.26%)	1 (100.00%)	0 (0%)	0 (0%)	0 (0%)
6 months	12	12 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
9 months	6	5 (83.33%)	0 (0%)	0 (0%)	0 (0%)	1 (16.67%)	0 (0%)
12 months	5	5 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
15 months	3	3 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
18 months	3	2 (66.67%)	0 (0%)	0 (0%)	0 (0%)	1 (33.33%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 38: Calcium Assessments – Adalimumab

Time point	Number of assessments, N	Normal assessments N (%)	Abnormal Assessment N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
				Adalimumab			
Baseline	60	51 (85.00%)	1 (1.67%)	0 (0%)	0 (0%)	8 (13.33%)	0 (0%)
1 month	59	54 (91.53%)	0 (0%)	0 (0%)	0 (0%)	5 (8.47%)	0 (0%)
2 months	58	52 (89.66%)	1 (1.72%)	1 (100.00%)	0 (0%)	5 (8.62%)	0 (0%)
3 months	56	50 (89.29%)	1 (1.79%)	0 (0%)	0 (0%)	4 (7.14%)	1 (1.79%)
6 months	48	45 (93.75%)	0 (0%)	0 (0%)	0 (0%)	3 (6.25%)	0 (0%)
9 months	42	37 (88.10%)	1 (2.38%)	0 (0%)	0 (0%)	4 (9.52%)	0 (0%)
12 months	34	32 (94.12%)	1 (2.94%)	1 (100.00%)	0 (0%)	1 (2.94%)	0 (0%)
15 months	27	26 (96.30%)	1 (3.70%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
18 months	22	20 (90.91%)	1 (4.55%)	0 (0%)	0 (0%)	1 (4.55%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 39: Inorganic phosphate Assessments – Placebo

Time point	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
Baseline	30	24 (80.00%)	1 (3.33%)	0 (0%)	0 (0%)	5 (16.67%)	0 (0%)
1 month	30	23 (76.67%)	2 (6.67%)	0 (0%)	0 (0%)	5 (16.67%)	0 (0%)
2 months	25	19 (76.00%)	1 (4.00%)	1 (100.00%)	0 (0%)	5 (20.00%)	0 (0%)
3 months	19	16 (84.21%)	0 (0%)	0 (0%)	0 (0%)	3 (15.79%)	0 (0%)
6 months	12	10 (83.33%)	1 (8.33%)	1 (100.00%)	0 (0%)	1 (8.33%)	0 (0%)
9 months	6	5 (83.33%)	0 (0%)	0 (0%)	0 (0%)	1 (16.67%)	0 (0%)
12 months	5	5 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
15 months	3	3 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
18 months	3	2 (66.67%)	0 (0%)	0 (0%)	0 (0%)	1 (33.33%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 40: Inorganic phosphate Assessments – Adalimumab

Time point	Number of assessments, N	Normal assessments N (%)	Abnormal Assessment N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
Baseline	60	42 (70.00%)	5 (8.33%)	5 (100.00%)	0 (0%)	12 (20.00%)	1 (1.67%)
1 month	59	45 (76.27%)	6 (10.17%)	3 (50.00%)	0 (0%)	8 (13.56%)	0 (0%)
2 months	58	43 (74.14%)	3 (5.17%)	0 (0%)	0 (0%)	12 (20.69%)	0 (0%)
3 months	56	44 (78.57%)	3 (5.36%)	0 (0%)	0 (0%)	8 (14.29%)	1 (1.79%)
6 months	48	42 (87.50%)	4 (8.33%)	1 (25.00%)	0 (0%)	2 (4.17%)	0 (0%)
9 months	42	36 (85.71%)	1 (2.38%)	1 (100.00%)	0 (0%)	5 (11.90%)	0 (0%)
12 months	34	31 (91.18%)	2 (5.88%)	0 (0%)	0 (0%)	1 (2.94%)	0 (0%)
15 months	27	25 (92.59%)	1 (3.70%)	0 (0%)	0 (0%)	1 (3.70%)	0 (0%)
18 months	22	20 (90.91%)	1 (4.55%)	1 (100.00%)	0 (0%)	1 (4.55%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 41: Glucose Assessments – Placebo

Time point	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
Baseline	30	26 (86.67%)	2 (6.67%)	0 (0%)	0 (0%)	2 (6.67%)	0 (0%)
1 month	30	21 (70.00%)	0 (0%)	0 (0%)	0 (0%)	9 (30.00%)	0 (0%)
2 months	25	20 (80.00%)	0 (0%)	0 (0%)	0 (0%)	5 (20.00%)	0 (0%)
3 months	19	18 (94.74%)	0 (0%)	0 (0%)	0 (0%)	1 (5.26%)	0 (0%)
6 months	12	10 (83.33%)	1 (8.33%)	0 (0%)	1 (100.00%)	1 (8.33%)	0 (0%)
9 months	6	4 (66.67%)	0 (0%)	0 (0%)	0 (0%)	2 (33.33%)	0 (0%)
12 months	5	5 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
15 months	3	3 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
18 months	3	2 (66.67%)	0 (0%)	0 (0%)	0 (0%)	1 (33.33%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 42: Glucose Assessments – Adalimumab

Time point	Number of assessments, N	Normal assessments N (%)	Abnormal Assessment N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
				Adalimumab			
Baseline	60	47 (78.33%)	4 (6.67%)	2 (50.00%)	0 (0%)	9 (15.00%)	0 (0%)
1 month	59	50 (84.75%)	2 (3.39%)	2 (100.00%)	0 (0%)	7 (11.86%)	0 (0%)
2 months	58	48 (82.76%)	2 (3.45%)	2 (100.00%)	0 (0%)	7 (12.07%)	1 (1.72%)
3 months	56	47 (83.93%)	3 (5.36%)	2 (66.67%)	0 (0%)	5 (8.93%)	1 (1.79%)
6 months	48	39 (81.25%)	5 (10.42%)	1 (20.00%)	0 (0%)	4 (8.33%)	0 (0%)
9 months	42	37 (88.10%)	2 (4.76%)	0 (0%)	0 (0%)	2 (4.76%)	1 (2.38%)
12 months	34	32 (94.12%)	1 (2.94%)	1 (100.00%)	0 (0%)	1 (2.94%)	0 (0%)
15 months	27	25 (92.59%)	2 (7.41%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
18 months	22	18 (81.82%)	2 (9.09%)	1 (50.00%)	0 (0%)	2 (9.09%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 43: Chloride Assessments – Placebo

Time point	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
				Placebo			
Baseline	30	25 (83.33%)	1 (3.33%)	1 (100.00%)	0 (0%)	4 (13.33%)	0 (0%)
1 month	30	23 (76.67%)	0 (0%)	0 (0%)	0 (0%)	7 (23.33%)	0 (0%)
2 months	25	18 (72.00%)	1 (4.00%)	0 (0%)	0 (0%)	6 (24.00%)	0 (0%)
3 months	19	15 (78.95%)	0 (0%)	0 (0%)	0 (0%)	4 (21.05%)	0 (0%)
6 months	12	8 (66.67%)	1 (8.33%)	1 (100.00%)	0 (0%)	3 (25.00%)	0 (0%)
9 months	6	4 (66.67%)	1 (16.67%)	0 (0%)	0 (0%)	1 (16.67%)	0 (0%)
12 months	5	5 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
15 months	3	3 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
18 months	3	3 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 44: Chloride Assessments – Adalimumab

Time point	Number of assessments, N	Normal assessments N (%)	Abnormal Assessment N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
				Adalimumab			
Baseline	60	50 (83.33%)	1 (1.67%)	1 (100.00%)	0 (0%)	9 (15.00%)	0 (0%)
1 month	59	49 (83.05%)	0 (0%)	0 (0%)	0 (0%)	10 (16.95%)	0 (0%)
2 months	58	49 (84.48%)	0 (0%)	0 (0%)	0 (0%)	9 (15.52%)	0 (0%)
3 months	56	44 (78.57%)	3 (5.36%)	1 (33.33%)	0 (0%)	8 (14.29%)	1 (1.79%)
6 months	48	43 (89.58%)	1 (2.08%)	0 (0%)	0 (0%)	4 (8.33%)	0 (0%)
9 months	42	38 (90.48%)	2 (4.76%)	1 (50.00%)	0 (0%)	2 (4.76%)	0 (0%)
12 months	34	29 (85.29%)	1 (2.94%)	0 (0%)	0 (0%)	4 (11.76%)	0 (0%)
15 months	27	25 (92.59%)	0 (0%)	0 (0%)	0 (0%)	2 (7.41%)	0 (0%)
18 months	22	21 (95.45%)	0 (0%)	0 (0%)	0 (0%)	1 (4.55%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 45: Bicarbonate Assessments – Placebo

Time point	Placebo						
	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
Baseline	30	17 (56.67%)	2 (6.67%)	2 (100.00%)	0 (0%)	11 (36.67%)	0 (0%)
1 month	30	13 (43.33%)	2 (6.67%)	1 (50.00%)	0 (0%)	15 (50.00%)	0 (0%)
2 months	25	13 (52.00%)	0 (0%)	0 (0%)	0 (0%)	12 (48.00%)	0 (0%)
3 months	19	10 (52.63%)	0 (0%)	0 (0%)	0 (0%)	9 (47.37%)	0 (0%)
6 months	12	4 (33.33%)	2 (16.67%)	2 (100.00%)	0 (0%)	6 (50.00%)	0 (0%)
9 months	6	2 (33.33%)	1 (16.67%)	1 (100.00%)	0 (0%)	3 (50.00%)	0 (0%)
12 months	5	3 (60.00%)	0 (0%)	0 (0%)	0 (0%)	2 (40.00%)	0 (0%)
15 months	3	2 (66.67%)	0 (0%)	0 (0%)	0 (0%)	1 (33.33%)	0 (0%)
18 months	3	1 (33.33%)	1 (33.33%)	1 (100.00%)	0 (0%)	1 (33.33%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 46: Bicarbonate Assessments – Adalimumab

Time point	Adalimumab						
	Number of assessments, N	Normal assessments N (%)	Abnormal Assessment N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
Baseline	60	34 (56.67%)	5 (8.33%)	5 (100.00%)	0 (0%)	21 (35.00%)	0 (0%)
1 month	59	34 (57.63%)	6 (10.17%)	2 (33.33%)	0 (0%)	19 (32.20%)	0 (0%)
2 months	58	36 (62.07%)	4 (6.90%)	2 (50.00%)	0 (0%)	18 (31.03%)	0 (0%)
3 months	56	34 (60.71%)	5 (8.93%)	3 (60.00%)	0 (0%)	16 (28.57%)	1 (1.79%)
6 months	48	30 (62.50%)	4 (8.33%)	2 (50.00%)	0 (0%)	14 (29.17%)	0 (0%)
9 months	42	27 (64.29%)	4 (9.52%)	2 (50.00%)	0 (0%)	11 (26.19%)	0 (0%)
12 months	34	23 (67.65%)	2 (5.88%)	1 (50.00%)	0 (0%)	9 (26.47%)	0 (0%)
15 months	27	17 (62.96%)	4 (14.81%)	2 (50.00%)	0 (0%)	6 (22.22%)	0 (0%)
18 months	22	14 (63.64%)	2 (9.09%)	1 (50.00%)	0 (0%)	6 (27.27%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 47: Total bilirubin Assessments – Placebo

Time point	Placebo						
	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
Baseline	30	28 (93.33%)	1 (3.33%)	1 (100.00%)	0 (0%)	1 (3.33%)	0 (0%)
1 month	30	25 (83.33%)	0 (0%)	0 (0%)	0 (0%)	5 (16.67%)	0 (0%)
2 months	25	22 (88.00%)	1 (4.00%)	1 (100.00%)	0 (0%)	2 (8.00%)	0 (0%)
3 months	19	18 (94.74%)	0 (0%)	0 (0%)	0 (0%)	1 (5.26%)	0 (0%)
6 months	12	10 (83.33%)	2 (16.67%)	2 (100.00%)	0 (0%)	0 (0%)	0 (0%)
9 months	6	5 (83.33%)	1 (16.67%)	1 (100.00%)	0 (0%)	0 (0%)	0 (0%)
12 months	5	4 (80.00%)	1 (20.00%)	1 (100.00%)	0 (0%)	0 (0%)	0 (0%)
15 months	3	3 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
18 months	3	3 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 48: Total bilirubin Assessments – Adalimumab

Time point	Number of assessments, N	Normal assessments N (%)	Abnormal Assessment N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
				Adalimumab			
Baseline	60	58 (96.67%)	0 (0%)	0 (0%)	0 (0%)	2 (3.33%)	0 (0%)
1 month	59	54 (91.53%)	1 (1.69%)	1 (100.00%)	0 (0%)	4 (6.78%)	0 (0%)
2 months	58	51 (87.93%)	2 (3.45%)	2 (100.00%)	0 (0%)	4 (6.90%)	1 (1.72%)
3 months	56	53 (94.64%)	0 (0%)	0 (0%)	0 (0%)	2 (3.57%)	1 (1.79%)
6 months	48	46 (95.83%)	1 (2.08%)	1 (100.00%)	0 (0%)	1 (2.08%)	0 (0%)
9 months	42	40 (95.24%)	1 (2.38%)	1 (100.00%)	0 (0%)	1 (2.38%)	0 (0%)
12 months	34	31 (91.18%)	1 (2.94%)	1 (100.00%)	0 (0%)	2 (5.88%)	0 (0%)
15 months	27	26 (96.30%)	0 (0%)	0 (0%)	0 (0%)	1 (3.70%)	0 (0%)
18 months	22	19 (86.36%)	1 (4.55%)	1 (100.00%)	0 (0%)	2 (9.09%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 49: Alanine aminotransferase Assessments – Placebo

Time point	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
				Placebo			
Baseline	30	25 (83.33%)	4 (13.33%)	3 (75.00%)	0 (0%)	1 (3.33%)	0 (0%)
1 month	30	22 (73.33%)	5 (16.67%)	3 (60.00%)	0 (0%)	3 (10.00%)	0 (0%)
2 months	25	22 (88.00%)	3 (12.00%)	2 (66.67%)	0 (0%)	0 (0%)	0 (0%)
3 months	19	15 (78.95%)	4 (21.05%)	1 (25.00%)	0 (0%)	0 (0%)	0 (0%)
6 months	12	11 (91.67%)	1 (8.33%)	1 (100.00%)	0 (0%)	0 (0%)	0 (0%)
9 months	6	6 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
12 months	5	5 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
15 months	3	3 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
18 months	3	3 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 50: Alanine aminotransferase Assessments – Adalimumab

Time point	Number of assessments, N	Normal assessments N (%)	Abnormal Assessment N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
				Adalimumab			
Baseline	60	54 (90.00%)	5 (8.33%)	2 (40.00%)	0 (0%)	1 (1.67%)	0 (0%)
1 month	59	50 (84.75%)	6 (10.17%)	3 (50.00%)	1 (16.67%)	3 (5.08%)	0 (0%)
2 months	58	45 (77.59%)	8 (13.79%)	4 (50.00%)	1 (12.50%)	5 (8.62%)	0 (0%)
3 months	56	49 (87.50%)	4 (7.14%)	1 (25.00%)	1 (25.00%)	2 (3.57%)	1 (1.79%)
6 months	48	44 (91.67%)	3 (6.25%)	1 (33.33%)	2 (66.67%)	1 (2.08%)	0 (0%)
9 months	42	39 (92.86%)	3 (7.14%)	1 (33.33%)	2 (66.67%)	0 (0%)	0 (0%)
12 months	34	32 (94.12%)	1 (2.94%)	0 (0%)	0 (0%)	1 (2.94%)	0 (0%)
15 months	27	22 (81.48%)	5 (18.52%)	2 (40.00%)	2 (40.00%)	0 (0%)	0 (0%)
18 months	22	20 (90.91%)	1 (4.55%)	0 (0%)	1 (100.00%)	1 (4.55%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 51: Aspartate aminotransferase Assessments – Placebo

Time point	Placebo						
	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
Baseline	30	20 (66.67%)	4 (13.33%)	1 (25.00%)	0 (0%)	6 (20.00%)	0 (0%)
1 month	30	14 (46.67%)	5 (16.67%)	3 (60.00%)	0 (0%)	11 (36.67%)	0 (0%)
2 months	25	14 (56.00%)	4 (16.00%)	2 (50.00%)	0 (0%)	7 (28.00%)	0 (0%)
3 months	19	15 (78.95%)	1 (5.26%)	0 (0%)	0 (0%)	3 (15.79%)	0 (0%)
6 months	12	5 (41.67%)	3 (25.00%)	2 (66.67%)	0 (0%)	4 (33.33%)	0 (0%)
9 months	6	6 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
12 months	5	4 (80.00%)	1 (20.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
15 months	3	1 (33.33%)	2 (66.67%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
18 months	3	2 (66.67%)	0 (0%)	0 (0%)	0 (0%)	1 (33.33%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 52: Aspartate aminotransferase Assessments - Adalimumab

Time point	Adalimumab						
	Number of assessments, N	Normal assessments N (%)	Abnormal Assessment N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
Baseline	60	44 (73.33%)	4 (6.67%)	2 (50.00%)	1 (25.00%)	11 (18.33%)	1 (1.67%)
1 month	59	38 (64.41%)	8 (13.56%)	3 (37.50%)	0 (0%)	13 (22.03%)	0 (0%)
2 months	58	44 (75.86%)	4 (6.90%)	1 (25.00%)	0 (0%)	10 (17.24%)	0 (0%)
3 months	56	44 (78.57%)	2 (3.57%)	0 (0%)	1 (50.00%)	9 (16.07%)	1 (1.79%)
6 months	48	37 (77.08%)	6 (12.50%)	1 (16.67%)	2 (33.33%)	4 (8.33%)	1 (2.08%)
9 months	42	32 (76.19%)	4 (9.52%)	0 (0%)	2 (50.00%)	6 (14.29%)	0 (0%)
12 months	34	28 (82.35%)	2 (5.88%)	1 (50.00%)	0 (0%)	4 (11.76%)	0 (0%)
15 months	27	23 (85.19%)	3 (11.11%)	1 (33.33%)	1 (33.33%)	1 (3.70%)	0 (0%)
18 months	22	17 (77.27%)	3 (13.64%)	0 (0%)	1 (33.33%)	2 (9.09%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Urinalysis

Table 53 shows the number of abnormal urinalysis assessments in each treatment group over time. Details on the microscopic analysis are presented in Table 54. Overall the results from the urinalysis were not clinically significant.

Table 53: Number of abnormal urinalysis assessments at each visit

Visit	Allocation	Number of abnormal assessments (number of participants)
Baseline	Adalimumab	19 (17)
	Placebo	15 (13)
Month 1	Adalimumab	20 (15)
	Placebo	12 (8)
Month 2	Adalimumab	23 (18)
	Placebo	9 (7)
Month 3	Adalimumab	15 (13)
	Placebo	9 (7)
Month 6	Adalimumab	17 (11)
	Placebo	4 (4)
Month 9	Adalimumab	15 (12)
	Placebo	5 (4)
Month 12	Adalimumab	12 (11)
	Placebo	4 (3)
Month 15	Adalimumab	8 (8)
	Placebo	1 (1)
Month 18	Adalimumab	6 (6)
	Placebo	1 (1)

Table 54: Microscopic Urinalysis results

Time point	Allocation	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not applicable, N (%)	Missing*, N (%)
Baseline	Adalimumab	17	9 (53%)	7 (41%)	1 (14%)	1 (6%)	0 (0%)
	Placebo	13	7 (54%)	4 (31%)	0 (0%)	2 (15%)	0 (0%)
1 month	Adalimumab	15	8 (53%)	3 (20%)	0 (0%)	4 (27%)	0 (0%)
	Placebo	8	4 (50%)	3 (38%)	0 (0%)	1 (13%)	0 (0%)
2 months	Adalimumab	18	11 (61%)	3 (17%)	1 (33%)	3 (17%)	1 (6%)
	Placebo	7	3 (43%)	3 (43%)	0 (0%)	0 (0%)	1 (14%)
3 months	Adalimumab	13	9 (69%)	3 (23%)	0 (0%)	1 (8%)	0 (0%)
	Placebo	7	4 (57%)	2 (29%)	0 (0%)	0 (0%)	1 (14%)
6 months	Adalimumab	11	6 (55%)	3 (28%)	2 (67%)	2 (18%)	0 (0%)
	Placebo	4	4 (100%)	0 (0%)	N/A	0 (0%)	0 (0%)
9 months	Adalimumab	12	6 (50%)	6 (50%)	2 (33%)	0 (0%)	0 (0%)
	Placebo	4	3 (75%)	0 (0%)	N/A	0 (0%)	1 (25%)
12 months	Adalimumab	11	7 (64%)	3 (27%)	2 (67%)	1 (9%)	0 (0%)
	Placebo	3	1 (33%)	2 (67%)	0 (0%)	0 (0%)	0 (0%)
15 months	Adalimumab	8	5 (63%)	2 (25%)	0 (0%)	1 (13%)	0 (0%)
	Placebo	1	0 (0%)	0 (0%)	N/A	1 (100%)	0 (0%)
18 months	Adalimumab	6	2 (40%)	1 (20%)	1 (100%)	2 (40%)	0 (0%)
	Placebo	1	0 (0%)	1 (100%)	0 (0%)	0 (0%)	0 (0%)