

**Laboratory parameters (haematological and biochemical analysis and urinalysis)****Haematological Analysis**

Table 1: Haematocrit assessments

Weeks	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 (%)
0	21	15 (71.43%)	6 (28.57%)	2 (33.33%)	0 (0%)	0 (0%)	0 (0%)
4	20	17 (85.00%)	3 (15.00%)	2 (66.67%)	0 (0%)	0 (0%)	0 (0%)
8	19	15 (78.95%)	3 (15.79%)	1 (33.33%)	0 (0%)	1 (5.26%)	0 (0%)
12	15	13 (86.67%)	2 (13.33%)	1 (50.00%)	0 (0%)	0 (0%)	0 (0%)
16	6	5 (83.33%)	1 (16.67%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
20	6	4 (66.67%)	2 (33.33%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
24	4	4 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
36	20	17 (85.00%)	3 (15.00%)	1 (33.33%)	0 (0%)	0 (0%)	0 (0%)

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

Table 2: Haemoglobin assessments

Weeks	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 (%)
0	21	19 (90.48%)	2 (9.52%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
4	20	18 (90.00%)	2 (10.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
8	19	16 (84.21%)	2 (10.53%)	0 (0%)	0 (0%)	1 (5.26%)	0 (0%)
12	15	14 (93.33%)	1 (6.67%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
16	6	5 (83.33%)	1 (16.67%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
20	6	6 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
24	4	3 (75.00%)	1 (25.00%)	1 (100.00%)	0 (0%)	0 (0%)	0 (0%)
36	20	18 (90.00%)	2 (10.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

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

Table 3: Red Blood Cell Count assessments

Weeks	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 (%)
0	21	21 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
4	20	19 (95.00%)	1 (5.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
8	19	17 (89.47%)	1 (5.26%)	0 (0%)	0 (0%)	1 (5.26%)	0 (0%)
12	15	13 (86.67%)	2 (13.33%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
16	6	6 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
20	6	5 (83.33%)	1 (16.67%)	1 (100.00%)	0 (0%)	0 (0%)	0 (0%)
24	4	4 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
36	20	15 (75.00%)	5 (25.00%)	2 (40.00%)	0 (0%)	0 (0%)	0 (0%)

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

Table 4: White Blood Cell Count assessments

Weeks	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 (%)
0	21	20 (95.24%)	1 (4.76%)	1 (100.00%)	0 (0%)	0 (0%)	0 (0%)
4	20	16 (80.00%)	4 (20.00%)	2 (50.00%)	0 (0%)	0 (0%)	0 (0%)
8	19	13 (68.42%)	5 (26.32%)	3 (60.00%)	1 (20.00%)	1 (5.26%)	0 (0%)
12	15	10 (66.67%)	5 (33.33%)	3 (60.00%)	0 (0%)	0 (0%)	0 (0%)
16	6	4 (66.67%)	2 (33.33%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
20	6	3 (50.00%)	3 (50.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
24	4	3 (75.00%)	1 (25.00%)	1 (100.00%)	0 (0%)	0 (0%)	0 (0%)
36	20	16 (80.00%)	4 (20.00%)	1 (25.00%)	0 (0%)	0 (0%)	0 (0%)

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

Table 5: Neutrophils assessments

Weeks	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 (%)
0	21	18 (85.71%)	3 (14.29%)	3 (100.00%)	0 (0%)	0 (0%)	0 (0%)
4	20	16 (80.00%)	4 (20.00%)	1 (25.00%)	1 (25.00%)	0 (0%)	0 (0%)
8	19	14 (73.68%)	4 (21.05%)	0 (0%)	3 (75.00%)	1 (5.26%)	0 (0%)
12	15	11 (73.33%)	4 (26.67%)	2 (50.00%)	2 (50.00%)	0 (0%)	0 (0%)
16	6	6 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
20	6	5 (83.33%)	1 (16.67%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
24	4	4 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
36	20	16 (80.00%)	4 (20.00%)	1 (25.00%)	0 (0%)	0 (0%)	0 (0%)

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

Table 6: Lymphocytes assessments

Weeks	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 (%)
0	21	19 (90.48%)	2 (9.52%)	1 (50.00%)	0 (0%)	0 (0%)	0 (0%)
4	20	19 (95.00%)	1 (5.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
8	19	14 (73.68%)	4 (21.05%)	2 (50.00%)	0 (0%)	1 (5.26%)	0 (0%)
12	15	13 (86.67%)	2 (13.33%)	1 (50.00%)	0 (0%)	0 (0%)	0 (0%)
16	6	5 (83.33%)	1 (16.67%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
20	6	5 (83.33%)	1 (16.67%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
24	4	3 (75.00%)	1 (25.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
36	20	18 (90.00%)	2 (10.00%)	1 (50.00%)	0 (0%)	0 (0%)	0 (0%)

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

Table 7: Monocytes assessments

Weeks	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 (%)
0	21	18 (85.71%)	3 (14.29%)	1 (33.33%)	0 (0%)	0 (0%)	0 (0%)
4	20	18 (90.00%)	2 (10.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
8	19	17 (89.47%)	1 (5.26%)	0 (0%)	0 (0%)	1 (5.26%)	0 (0%)
12	15	13 (86.67%)	2 (13.33%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
16	6	5 (83.33%)	1 (16.67%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
20	6	4 (66.67%)	2 (33.33%)	1 (50.00%)	0 (0%)	0 (0%)	0 (0%)
24	4	3 (75.00%)	1 (25.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
36	20	18 (90.00%)	2 (10.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

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

Table 8: Basophils assessments

Weeks	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 (%)
0	21	21 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
4	20	19 (95.00%)	1 (5.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
8	19	18 (94.74%)	0 (0%)	0 (0%)	0 (0%)	1 (5.26%)	0 (0%)
12	15	15 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
16	6	6 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
20	6	6 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
24	4	4 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
36	20	20 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

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

Table 9: Eosinophils assessments

Weeks	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 (%)
0	21	17 (80.95%)	4 (19.05%)	3 (75.00%)	0 (0%)	0 (0%)	0 (0%)
4	20	13 (65.00%)	7 (35.00%)	1 (14.29%)	0 (0%)	0 (0%)	0 (0%)
8	19	12 (63.16%)	6 (31.58%)	1 (16.67%)	0 (0%)	1 (5.26%)	0 (0%)
12	15	10 (66.67%)	5 (33.33%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
16	6	6 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
20	6	6 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
24	4	4 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
36	20	15 (75.00%)	5 (25.00%)	2 (40.00%)	0 (0%)	0 (0%)	0 (0%)

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

Table 10: Platelet count assessments

Weeks	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 (%)
0	21	19 (90.48%)	2 (9.52%)	2 (100.00%)	0 (0%)	0 (0%)	0 (0%)
4	20	19 (95.00%)	1 (5.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
8	19	16 (84.21%)	2 (10.53%)	1 (50.00%)	0 (0%)	1 (5.26%)	0 (0%)
12	15	14 (93.33%)	1 (6.67%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
16	6	6 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
20	6	6 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
24	4	4 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
36	20	17 (85.00%)	3 (15.00%)	2 (66.67%)	0 (0%)	0 (0%)	0 (0%)

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

Table 11: Erythrocyte sedimentation rate assessments

Weeks	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 (%)
0	21	3 (14.29%)	13 (61.90%)	12 (92.31%)	3 (23.08%)	5 (23.81%)	0 (0%)
4	20	18 (90.00%)	2 (10.00%)	1 (50.00%)	0 (0%)	0 (0%)	0 (0%)
8	19	15 (78.95%)	2 (10.53%)	1 (50.00%)	1 (50.00%)	2 (10.53%)	0 (0%)
12	15	13 (86.67%)	2 (13.33%)	2 (100.00%)	0 (0%)	0 (0%)	0 (0%)
16	6	5 (83.33%)	1 (16.67%)	1 (100.00%)	0 (0%)	0 (0%)	0 (0%)
20	6	4 (66.67%)	2 (33.33%)	2 (100.00%)	0 (0%)	0 (0%)	0 (0%)
24	4	3 (75.00%)	1 (25.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
36	20	14 (70.00%)	3 (15.00%)	3 (100.00%)	1 (33.33%)	2 (10.00%)	1 (5.00%)

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

Table 12: Plasma viscosity assessments

Weeks	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 (%)
0	21	0 (0%)	0 (0%)	0 (0%)	0 (0%)	4 (19.05%)	17 (80.95%)
4	20	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	20 (100.00%)
8	19	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (10.53%)	17 (89.47%)
12	15	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	15 (100.00%)
16	6	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	6 (100.00%)
20	6	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	6 (100.00%)
24	4	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	4 (100.00%)
36	20	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (10.00%)	18 (90.00%)

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

**Biochemical Analysis****Table 1: C-Reactive Protein assessments**

<b>Weeks</b>	<b>N</b>	<b>Normal assessments N (%)</b>	<b>Abnormal Assessment N (%)</b>	<b>If abnormal, number expected, N (%)</b>	<b>If abnormal, number of clinically significant, N (%)</b>	<b>Assessment recorded as not done, N (%)</b>	<b>Missing*, N (%)</b>
0	21	17 (80.95%)	3 (14.29%)	3 (100.00%)	0 (0%)	1 (4.76%)	0 (0%)
4	20	20 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
8	19	19 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
12	15	15 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
16	6	6 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
20	6	6 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
24	4	4 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
36	20	19 (95.00%)	1 (5.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

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

**Table 2: Urea assessments**

<b>Weeks</b>	<b>N</b>	<b>Normal assessments N (%)</b>	<b>Abnormal Assessment N (%)</b>	<b>If abnormal, number expected, N (%)</b>	<b>If abnormal, number of clinically significant, N (%)</b>	<b>Assessment recorded as not done, N (%)</b>	<b>Missing*, N (%)</b>
0	21	18 (85.71%)	2 (9.52%)	0 (0%)	0 (0%)	1 (4.76%)	0 (0%)
4	20	20 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
8	19	19 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
12	15	15 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
16	6	5 (83.33%)	1 (16.67%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
20	6	5 (83.33%)	1 (16.67%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
24	4	4 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
36	20	18 (90.00%)	2 (10.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

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

**Table 3: Creatinine assessments**

<b>Weeks</b>	<b>N</b>	<b>Normal assessments N (%)</b>	<b>Abnormal Assessment N (%)</b>	<b>If abnormal, number expected, N (%)</b>	<b>If abnormal, number of clinically significant, N (%)</b>	<b>Assessment recorded as not done, N (%)</b>	<b>Missing*, N (%)</b>
0	21	19 (90.48%)	1 (4.76%)	0 (0%)	0 (0%)	1 (4.76%)	0 (0%)
4	20	18 (90.00%)	2 (10.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
8	19	17 (89.47%)	2 (10.53%)	1 (50.00%)	0 (0%)	0 (0%)	0 (0%)
12	15	15 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
16	6	6 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
20	6	6 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
24	4	3 (75.00%)	1 (25.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
36	20	20 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

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

Table 4: Sodium assessments

Weeks	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 (%)
0	21	19 (90.48%)	1 (4.76%)	0 (0%)	0 (0%)	1 (4.76%)	0 (0%)
4	20	20 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
8	19	19 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
12	15	15 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
16	6	6 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
20	6	6 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
24	4	4 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
36	20	20 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

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

Table 5: Potassium assessments

Weeks	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 (%)
0	21	19 (90.48%)	1 (4.76%)	0 (0%)	0 (0%)	1 (4.76%)	0 (0%)
4	20	20 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
8	19	17 (89.47%)	2 (10.53%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
12	15	15 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
16	6	6 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
20	6	6 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
24	4	4 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
36	20	19 (95.00%)	0 (0%)	0 (0%)	0 (0%)	1 (5.00%)	0 (0%)

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

Table 6: Calcium assessments

Weeks	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 (%)
0	21	19 (90.48%)	0 (0%)	0 (0%)	0 (0%)	2 (9.52%)	0 (0%)
4	20	18 (90.00%)	0 (0%)	0 (0%)	0 (0%)	2 (10.00%)	0 (0%)
8	19	15 (78.95%)	0 (0%)	0 (0%)	0 (0%)	4 (21.05%)	0 (0%)
12	15	15 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
16	6	5 (83.33%)	0 (0%)	0 (0%)	0 (0%)	1 (16.67%)	0 (0%)
20	6	4 (66.67%)	1 (16.67%)	0 (0%)	1 (100.00%)	1 (16.67%)	0 (0%)
24	4	3 (75.00%)	0 (0%)	0 (0%)	0 (0%)	1 (25.00%)	0 (0%)
36	20	18 (90.00%)	0 (0%)	0 (0%)	0 (0%)	2 (10.00%)	0 (0%)

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

Table 7: Inorganic Phosphate assessments

Weeks	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 (%)
0	21	18 (85.71%)	0 (0%)	0 (0%)	0 (0%)	3 (14.29%)	0 (0%)
4	20	18 (90.00%)	0 (0%)	0 (0%)	0 (0%)	2 (10.00%)	0 (0%)
8	19	16 (84.21%)	0 (0%)	0 (0%)	0 (0%)	3 (15.79%)	0 (0%)
12	15	13 (86.67%)	0 (0%)	0 (0%)	0 (0%)	2 (13.33%)	0 (0%)
16	6	5 (83.33%)	0 (0%)	0 (0%)	0 (0%)	1 (16.67%)	0 (0%)
20	6	4 (66.67%)	1 (16.67%)	0 (0%)	0 (0%)	1 (16.67%)	0 (0%)
24	4	3 (75.00%)	0 (0%)	0 (0%)	0 (0%)	1 (25.00%)	0 (0%)
36	20	17 (85.00%)	0 (0%)	0 (0%)	0 (0%)	3 (15.00%)	0 (0%)

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

Table 8: Glucose assessments

Weeks	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 (%)
0	21	16 (76.19%)	1 (4.76%)	1 (100.00%)	0 (0%)	4 (19.05%)	0 (0%)
4	20	14 (70.00%)	3 (15.00%)	0 (0%)	0 (0%)	3 (15.00%)	0 (0%)
8	19	14 (73.68%)	1 (5.26%)	0 (0%)	0 (0%)	4 (21.05%)	0 (0%)
12	15	12 (80.00%)	0 (0%)	0 (0%)	0 (0%)	3 (20.00%)	0 (0%)
16	6	3 (50.00%)	1 (16.67%)	0 (0%)	0 (0%)	2 (33.33%)	0 (0%)
20	6	3 (50.00%)	1 (16.67%)	0 (0%)	0 (0%)	2 (33.33%)	0 (0%)
24	4	2 (50.00%)	1 (25.00%)	0 (0%)	0 (0%)	1 (25.00%)	0 (0%)
36	20	14 (70.00%)	2 (10.00%)	0 (0%)	1 (50.00%)	4 (20.00%)	0 (0%)

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

Table 9: Chloride assessments

Weeks	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 (%)
0	21	18 (85.71%)	1 (4.76%)	0 (0%)	0 (0%)	2 (9.52%)	0 (0%)
4	20	19 (95.00%)	0 (0%)	0 (0%)	0 (0%)	1 (5.00%)	0 (0%)
8	19	16 (84.21%)	0 (0%)	0 (0%)	0 (0%)	3 (15.79%)	0 (0%)
12	15	14 (93.33%)	0 (0%)	0 (0%)	0 (0%)	1 (6.67%)	0 (0%)
16	6	5 (83.33%)	0 (0%)	0 (0%)	0 (0%)	1 (16.67%)	0 (0%)
20	6	6 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
24	4	4 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
36	20	18 (90.00%)	1 (5.00%)	0 (0%)	0 (0%)	1 (5.00%)	0 (0%)

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

Table 10: Bicarbonate assessments

Weeks	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 (%)
0	21	14 (66.67%)	0 (0%)	0 (0%)	0 (0%)	7 (33.33%)	0 (0%)
4	20	10 (50.00%)	3 (15.00%)	1 (33.33%)	0 (0%)	7 (35.00%)	0 (0%)
8	19	13 (68.42%)	1 (5.26%)	1 (100.00%)	0 (0%)	5 (26.32%)	0 (0%)
12	15	9 (60.00%)	1 (6.67%)	1 (100.00%)	0 (0%)	5 (33.33%)	0 (0%)
16	6	3 (50.00%)	0 (0%)	0 (0%)	0 (0%)	3 (50.00%)	0 (0%)
20	6	1 (16.67%)	0 (0%)	0 (0%)	0 (0%)	5 (83.33%)	0 (0%)
24	4	2 (50.00%)	0 (0%)	0 (0%)	0 (0%)	2 (50.00%)	0 (0%)
36	20	11 (55.00%)	4 (20.00%)	2 (50.00%)	0 (0%)	5 (25.00%)	0 (0%)

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

Table 11: Total bilirubin assessments

Weeks	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 (%)
0	21	21 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
4	20	16 (80.00%)	4 (20.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
8	19	17 (89.47%)	2 (10.53%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
12	15	13 (86.67%)	2 (13.33%)	2 (100.00%)	0 (0%)	0 (0%)	0 (0%)
16	6	4 (66.67%)	2 (33.33%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
20	6	5 (83.33%)	1 (16.67%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
24	4	4 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
36	20	16 (80.00%)	4 (20.00%)	1 (25.00%)	0 (0%)	0 (0%)	0 (0%)

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

Table 12: LDL assessments

Weeks	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 (%)
0	21	16 (76.19%)	2 (9.52%)	0 (0%)	0 (0%)	3 (14.29%)	0 (0%)
4	20	15 (75.00%)	0 (0%)	0 (0%)	0 (0%)	5 (25.00%)	0 (0%)
8	19	13 (68.42%)	1 (5.26%)	0 (0%)	1 (100.00%)	5 (26.32%)	0 (0%)
12	15	14 (93.33%)	1 (6.67%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
16	6	4 (66.67%)	0 (0%)	0 (0%)	0 (0%)	2 (33.33%)	0 (0%)
20	6	5 (83.33%)	0 (0%)	0 (0%)	0 (0%)	1 (16.67%)	0 (0%)
24	4	3 (75.00%)	0 (0%)	0 (0%)	0 (0%)	1 (25.00%)	0 (0%)
36	20	14 (70.00%)	1 (5.00%)	0 (0%)	1 (100.00%)	5 (25.00%)	0 (0%)

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

Table 13: HDL assessments

Weeks	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 (%)
0	21	16 (76.19%)	3 (14.29%)	0 (0%)	0 (0%)	2 (9.52%)	0 (0%)
4	20	15 (75.00%)	2 (10.00%)	0 (0%)	0 (0%)	3 (15.00%)	0 (0%)
8	19	12 (63.16%)	3 (15.79%)	2 (66.67%)	0 (0%)	4 (21.05%)	0 (0%)
12	15	13 (86.67%)	2 (13.33%)	1 (50.00%)	0 (0%)	0 (0%)	0 (0%)
16	6	4 (66.67%)	0 (0%)	0 (0%)	0 (0%)	2 (33.33%)	0 (0%)
20	6	4 (66.67%)	1 (16.67%)	0 (0%)	0 (0%)	1 (16.67%)	0 (0%)
24	4	3 (75.00%)	0 (0%)	0 (0%)	0 (0%)	1 (25.00%)	0 (0%)
36	20	14 (70.00%)	2 (10.00%)	0 (0%)	1 (50.00%)	4 (20.00%)	0 (0%)

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

Table 14: Triglycerides assessments

Weeks	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 (%)
0	21	18 (85.71%)	2 (9.52%)	0 (0%)	0 (0%)	1 (4.76%)	0 (0%)
4	20	14 (70.00%)	2 (10.00%)	0 (0%)	0 (0%)	4 (20.00%)	0 (0%)
8	19	10 (52.63%)	5 (26.32%)	0 (0%)	2 (40.00%)	4 (21.05%)	0 (0%)
12	15	12 (80.00%)	3 (20.00%)	1 (33.33%)	0 (0%)	0 (0%)	0 (0%)
16	6	4 (66.67%)	0 (0%)	0 (0%)	0 (0%)	2 (33.33%)	0 (0%)
20	6	4 (66.67%)	1 (16.67%)	0 (0%)	1 (100.00%)	1 (16.67%)	0 (0%)
24	4	2 (50.00%)	1 (25.00%)	0 (0%)	0 (0%)	1 (25.00%)	0 (0%)
36	20	13 (65.00%)	3 (15.00%)	1 (33.33%)	1 (33.33%)	4 (20.00%)	0 (0%)

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

Table 15: Total cholesterol assessments

Weeks	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 (%)
0	21	19 (90.48%)	1 (4.76%)	0 (0%)	0 (0%)	1 (4.76%)	0 (0%)
4	20	16 (80.00%)	1 (5.00%)	0 (0%)	0 (0%)	3 (15.00%)	0 (0%)
8	19	14 (73.68%)	1 (5.26%)	0 (0%)	1 (100.00%)	4 (21.05%)	0 (0%)
12	15	15 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
16	6	4 (66.67%)	0 (0%)	0 (0%)	0 (0%)	2 (33.33%)	0 (0%)
20	6	5 (83.33%)	0 (0%)	0 (0%)	0 (0%)	1 (16.67%)	0 (0%)
24	4	3 (75.00%)	0 (0%)	0 (0%)	0 (0%)	1 (25.00%)	0 (0%)
36	20	15 (75.00%)	1 (5.00%)	0 (0%)	1 (100.00%)	4 (20.00%)	0 (0%)

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

Table 16: Alanine aminotransferase assessments

Weeks	N	Normal assessments N (%)	Abnormal Assessment N (%)	If abnormal, number	If abnormal, number of clinically	Assessment recorded as	Missing*, N (%)
-------	---	-----------------------------	------------------------------	------------------------	---	---------------------------	--------------------

				<b>expected, N (%)</b>	<b>significant, N (%)</b>	<b>not done, N (%)</b>	
0	21	20 (95.24%)	1 (4.76%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
4	20	13 (65.00%)	7 (35.00%)	2 (28.57%)	2 (28.57%)	0 (0%)	0 (0%)
8	19	17 (89.47%)	2 (10.53%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
12	15	12 (80.00%)	3 (20.00%)	1 (33.33%)	1 (33.33%)	0 (0%)	0 (0%)
16	6	6 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
20	6	6 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
24	4	4 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
36	20	18 (90.00%)	1 (5.00%)	1 (100.00%)	0 (0%)	1 (5.00%)	0 (0%)

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

Table 17: Aspartate aminotransferase assessments

<b>Weeks</b>	<b>N</b>	<b>Normal assessments N (%)</b>	<b>Abnormal Assessment N (%)</b>	<b>If abnormal, number expected, N (%)</b>	<b>If abnormal, number of clinically significant, N (%)</b>	<b>Assessment recorded as not done, N (%)</b>	<b>Missing*, N (%)</b>
0	21	17 (80.95%)	2 (9.52%)	2 (100.00%)	0 (0%)	2 (9.52%)	0 (0%)
4	20	13 (65.00%)	3 (15.00%)	1 (33.33%)	1 (33.33%)	4 (20.00%)	0 (0%)
8	19	13 (68.42%)	2 (10.53%)	0 (0%)	0 (0%)	4 (21.05%)	0 (0%)
12	15	12 (80.00%)	3 (20.00%)	0 (0%)	1 (33.33%)	0 (0%)	0 (0%)
16	6	2 (33.33%)	0 (0%)	0 (0%)	0 (0%)	4 (66.67%)	0 (0%)
20	6	4 (66.67%)	1 (16.67%)	0 (0%)	0 (0%)	1 (16.67%)	0 (0%)
24	4	1 (25.00%)	1 (25.00%)	0 (0%)	0 (0%)	2 (50.00%)	0 (0%)
36	20	16 (80.00%)	1 (5.00%)	0 (0%)	0 (0%)	3 (15.00%)	0 (0%)

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

**Urinalysis**

Table 1: Line listings of urinalysis assessments at baseline

Participant	Protein	Glucose	Blood	Leukocyte esterase	Specific gravity	pH
0003601	Abnormal	Normal	Abnormal	Abnormal	Normal	Normal
0011401	Normal	Normal	Normal	Normal	Normal	Normal
0011601	Normal	Normal	Normal	Normal	Normal	Normal
0011602	Normal	Normal	Normal	Normal	Normal	Normal
0011603	Normal	Normal	Normal	Normal	Normal	Normal
0011604	Normal	Normal	Normal	Normal	Normal	Normal
0011605	Normal	Normal	Normal	Abnormal	Normal	Normal
0011606	Normal	Normal	Normal	Normal	Normal	Normal
0011607	Normal	Normal	Normal	Normal	Normal	Normal
0024301	Normal	Normal	Normal	Normal	Normal	Normal
0024302	Normal	Normal	Normal	Normal	Normal	Normal
0024801	Normal	Normal	Normal	Normal	Normal	Normal
0024802	Normal	Normal	Normal	Abnormal	Normal	Normal
0024901	Normal	Normal	Normal	Normal	Normal	Normal
0024902	Normal	Normal	Normal	Normal	Normal	Normal
0024903	Normal	Normal	Normal	Normal	Normal	Normal
0024904	Normal	Normal	Normal	Normal	Normal	Normal
0024905	Abnormal	Normal	Abnormal	Normal	Normal	Normal
0024906	Normal	Normal	Normal	Normal	Normal	Normal
0604501	Normal	Normal	Normal	Normal	Normal	Normal
0604502	Normal	Normal	Normal	Normal	Normal	Normal
0604503	Normal	Normal	Normal	Normal	Normal	Normal

Table 2: Line listings of urinalysis assessments at Week 4

Participant	Protein	Glucose	Blood	Leukocyte esterase	Specific gravity	pH
0003601	Abnormal	Normal	Abnormal	Abnormal	Abnormal	Normal
0011401	Normal	Normal	Normal	Normal	Normal	Normal
0011601	Normal	Normal	Normal	Normal	Normal	Normal
0011602	Normal	Normal	Normal	Normal	Normal	Normal
0011603	Normal	Normal	Normal	Normal	Normal	Normal
0011604	Normal	Normal	Normal	Normal	Normal	Normal
0011605	Normal	Normal	Normal	Normal	Normal	Normal
0011607	Normal	Normal	Normal	Abnormal	Normal	Normal
0024302	Normal	Normal	Normal	Normal	Normal	Normal
0024801	Normal	Normal	Normal	Normal	Normal	Normal
0024802	Normal	Normal	Normal	Abnormal	Normal	Normal
0024901	Abnormal	Normal	Normal	Normal	Normal	Normal
0024902	Normal	Normal	Normal	Normal	Normal	Normal
0024903	Normal	Normal	Abnormal	Normal	Normal	Normal
0024904	Normal	Normal	Normal	Normal	Normal	Normal
0024905	Abnormal	Normal	Abnormal	Normal	Normal	Normal
0024906	Normal	Normal	Abnormal	Normal	Normal	Normal
0604501	Normal	Normal	Normal	Normal	Normal	Normal
0604502	Normal	Normal	Normal	Normal	Normal	Normal
0604503	Normal	Normal	Normal	Abnormal	Normal	Normal

Table 3: Line listings of urinalysis assessments at Week 8

Participant	Protein	Glucose	Blood	Leukocyte esterase	Specific gravity	pH
0011401	Normal	Normal	Normal	Normal	Normal	Normal
0011601	Normal	Normal	Normal	Normal	Normal	Normal
0011602	Abnormal	Normal	Normal	Normal	Normal	Normal
0011603	Normal	Normal	Normal	Normal	Normal	Normal
0011604	Normal	Normal	Normal	Normal	Normal	Normal
0011605	Missing	Missing	Missing	Missing	Missing	Missing
0011607	Normal	Normal	Normal	Normal	Normal	Normal
0024301	Normal	Normal	Normal	Normal	Normal	Normal
0024302	Abnormal	Normal	Normal	Normal	Normal	Normal
0024801	Abnormal	Normal	Normal	Normal	Normal	Normal
0024802	Abnormal	Normal	Abnormal	Abnormal	Normal	Normal
0024901	Normal	Normal	Normal	Normal	Normal	Normal
0024902	Normal	Normal	Normal	Normal	Normal	Normal
0024903	Abnormal	Normal	Normal	Normal	Normal	Normal
0024904	Normal	Normal	Normal	Normal	Normal	Normal
0024906	Normal	Normal	Normal	Normal	Normal	Normal
0604501	Normal	Normal	Normal	Normal	Normal	Normal
0604502	Normal	Normal	Normal	Normal	Normal	Normal
0604503	Normal	Normal	Normal	Normal	Normal	Normal

Table 4: Line listings of urinalysis assessments at Week 12

Participant	Protein	Glucose	Blood	Leukocyte esterase	Specific gravity	pH
0011601	Normal	Normal	Normal	Normal	Normal	Normal
0011602	Normal	Normal	Normal	Abnormal	Normal	Normal
0011603	Normal	Normal	Normal	Normal	Normal	Normal
0011604	Normal	Normal	Normal	Normal	Normal	Normal
0011605	Normal	Normal	Normal	Normal	Normal	Normal
0024301	Normal	Normal	Normal	Normal	Normal	Normal
0024302	Abnormal	Normal	Normal	Normal	Normal	Normal
0024801	Missing	Missing	Missing	Missing	Missing	Missing
0024802	Abnormal	Normal	Normal	Abnormal	Normal	Normal
0024901	Normal	Normal	Abnormal	Normal	Abnormal	Abnormal
0024902	Normal	Normal	Normal	Normal	Normal	Normal
0024904	Abnormal	Normal	Normal	Abnormal	Normal	Normal
0604501	Missing	Missing	Missing	Missing	Missing	Missing
0604502	Normal	Normal	Normal	Normal	Normal	Normal
0604503	Normal	Normal	Normal	Normal	Normal	Normal

Table 5: Line listings of urinalysis assessments at Week 24

Participant	Protein	Glucose	Blood	Leukocyte esterase	Specific gravity	pH
0024302	Abnormal	Normal	Normal	Normal	Normal	Normal
0024901	Normal	Normal	Normal	Normal	Normal	Normal
0024902	Normal	Normal	Abnormal	Abnormal	Normal	Normal
0024904	Normal	Normal	Abnormal	Abnormal	Normal	Normal
0604502	Normal	Normal	Normal	Normal	Normal	Normal
0604503	Normal	Normal	Normal	Normal	Normal	Normal

Table 6: Line listings of urinalysis assessments at Week 36

Participant	Protein	Glucose	Blood	Leukocyte esterase	Specific gravity	pH
0003601	Missing	Missing	Missing	Missing	Missing	Missing
0011401	Normal	Normal	Normal	Normal	Normal	Normal
0011601	Normal	Normal	Normal	Normal	Normal	Normal
0011602	Normal	Normal	Normal	Normal	Normal	Normal
0011603	Normal	Normal	Normal	Normal	Normal	Normal
0011604	Normal	Normal	Normal	Abnormal	Normal	Normal
0011605	Normal	Normal	Normal	Normal	Normal	Normal
0011607	Normal	Normal	Abnormal	Abnormal	Normal	Normal
0024301	Normal	Normal	Normal	Normal	Normal	Normal
0024302	Abnormal	Normal	Normal	Normal	Normal	Normal
0024801	Normal	Normal	Normal	Normal	Normal	Normal
0024802	Normal	Normal	Normal	Normal	Normal	Normal
0024901	Missing	Missing	Missing	Missing	Missing	Missing
0024902	Normal	Normal	Normal	Abnormal	Normal	Normal
0024903	Normal	Normal	Normal	Normal	Normal	Normal
0024904	Normal	Normal	Abnormal	Abnormal	Normal	Normal
0024905	Abnormal	Normal	Normal	Normal	Normal	Normal
0604501	Normal	Normal	Normal	Normal	Normal	Normal
0604502	Normal	Normal	Normal	Normal	Normal	Normal
0604503	Normal	Normal	Normal	Normal	Normal	Normal

Table 7: Microscopic analysis abnormal results

Weeks	Number of abnormal results	Number of clinically significant abnormal results
0	2	0
4	5	0
8	2	0
12	3	0
16	0	0
20	2	0
24	1	1
36	2	0