

SSAT 058: Final locked data analysis

Version 4.0: 22<sup>nd</sup> May 2018

Lab Data

Lab data	Baseline	Week 4	Week 12	Week 24
Attended	41	40	39	39
DNA	0	0	0	0
Drop out	0	1	2	2
<b>Immunological</b>				
<b>CD4 T-cell count</b> cells/mm <sup>3</sup>	563(465 to 679) Range: 232 to 1228	Not done	590(481 to 719) Range: 308 to 1114	600(488 to 682) Range: 284 to 965
		<b>Baseline to week 4</b>	<b>Baseline to week 12</b>	<b>Baseline to week 24</b>
<b>Change from Baseline in</b> <b>CD4 T-cell count</b> cells/mm <sup>3</sup> (wk-baseline)		-	16(-34 to 60) Range: -326 to 249  <i>p=0.238</i>  <i>p-value using Wilcoxon</i> <i>signed rank test</i>	-2 (-55 to 75) Range: -436 to 204  <i>p=0.995</i>  <i>p-value using Wilcoxon</i> <i>signed rank test</i>
<b>CD4 percent</b>	35.9(29.0 to 38.6) Range: 16.5 to 51.0	-	34.6(28.0 to 38.8) Range: 22.3 to 51.2	36.6(30.0 to 40.0) Range: 20.8 to 51.5
		<b>Baseline to week 4</b>	<b>Baseline to week 12</b>	<b>Baseline to week 24</b>
<b>Change from Baseline in</b> <b>CD4 percent</b> (wk-baseline)		-	-0.1(-2.0 to 1.5) Range: -11.9 to 6.0  <i>p=0.288</i>  <i>p-value using Wilcoxon</i> <i>signed rank test</i>	1.0 (-3.0 to 2.3) Range: -8.2 to 6.0  <i>p=0.058</i>  <i>p-value using Wilcoxon</i> <i>signed rank test</i>
<b>CD8 T-cell count</b> cells/mm <sup>3</sup>	661(487 to 817) Range: 384 to 1547	-	690(529 to 908) Range: 413 to 1630	673(487 to 832) Range: 321 to 1427

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Attended	41	40	39	39
DNA	0	0	0	0
Drop out	0	1	2	2
		<b>Baseline to week 4</b>	<b>Baseline to week 12</b>	<b>Baseline to week 24</b>
Change from Baseline in CD8 T-cell count cells/mm <sup>3</sup> (wk-baseline)		-	1(-48 to 115) Range: -312 to 417  <i>p=0.450</i>  <i>p-value using Wilcoxon signed rank test</i>	-2(-90 to 71) Range: -412 to 368  <i>p=0.995</i>  <i>p-value using Wilcoxon signed rank test</i>
CD8 percent	42.5(37.0 to 47.0) Range: 26.7 to 60.1	-	42.7(34.8 to 47.0) Range: 24.2 to 59.2	41.0(34.7 to 47.2) Range: 27.1 to 57.0
		<b>Baseline to week 4</b>	<b>Baseline to week 12</b>	<b>Baseline to week 24</b>
Change from Baseline in CD8 percent (wk-baseline)		-	0.0(-2.5 to 2.0) Range: -7.0 to 6.4  <i>p=0.782</i>  <i>p-value using Wilcoxon signed rank test</i>	-0.5(-2.4 to 2.0) Range: -6.0 to 5.6  <i>p=0.492</i>  <i>p-value using Wilcoxon signed rank test</i>
<b>Virological</b>				
HIV RNA load copies/ml				
<50	40(97.6)	40(100.0)	38(97.4)	39(100.0)
>50	1(2.4)	0(0.0)	1(2.6)	0(0.0)
HIV RNA load copies/ml				
<400	41(100.0)	40(100.0)	39(100.0)	39(100.0)
>400	0(0.0)	0(0.0)	0(0.0)	0(0.0)

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Attended	41	40	39	39
DNA	0	0	0	0
Drop out	0	1	2	2
<b>Lipids</b>				
<b>Total cholesterol (mmol/L)</b>	N=39 5.2(4.6 to 5.7) Range: 3.6 to 7.7	N=39 4.7(4.2 to 5.0) Range: 2.8 to 7.1	N=39 4.5(3.8 to 5.0) Range: 2.5 to 7.2	N=38 4.4(4.0 to 5.2) Range: 2.6 to 6.4
		<b>Baseline to week 4</b>	<b>Baseline to week 12</b>	<b>Baseline to week 24</b>
<b>Change from Baseline in Total cholesterol (wk-baseline)</b>		N=37 -0.6(-0.8 to -0.2) Range: -1.6 to 0.4  <i>P</i> <0.001  <i>p</i> -value using Wilcoxon signed rank test	N=37 -0.7(-1.0 to -0.5) Range: -1.8 to 2.6  <i>P</i> <0.001  <i>p</i> -value using Wilcoxon signed rank test	N=36 -0.8(-1.2 to -0.3) Range: -1.9 to 1.9  <i>P</i> <0.001  <i>p</i> -value using Wilcoxon signed rank test
<b>Triglycerides (mmol/L)</b>	N=39 1.3(0.8 to 2.4) Range: 0.5 to 4.6)	N=39 0.9(0.7 to 1.8) Range: 0.4 to 3.2)	N=39 1.30(0.6 to 1.6) Range: 0.4 to 3.0)	N=38 0.9(0.7 to 1.6) Range: 0.4 to 3.2)
		<b>Baseline to week 4</b>	<b>Baseline to week 12</b>	<b>Baseline to week 24</b>
<b>Change from Baseline in Triglycerides (wk-baseline)</b>		N=37 -0.26(-0.71 to 0.01) Range: -1.46 to 1.08  <i>P</i> <0.001  <i>p</i> -value using Wilcoxon signed rank test	N=37 -0.17(-0.82 to 0.10) Range: -2.05 to 0.99  <i>P</i> =0.002  <i>p</i> -value using Wilcoxon signed rank test	N=36 -0.28(-0.72 to 0.08) Range: -2.5 to 0.6  <i>P</i> <0.001  <i>p</i> -value using Wilcoxon signed rank test

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Lab data	Baseline	Week 4	Week 12	Week 24
Attended	41	40	39	39
DNA	0	0	0	0
Drop out	0	1	2	2
HDL (mmol/L)	N=39 1.4(1.2 to 1.6) Range: 0.8 to 2.5)	N=39 1.3(1.1 to 1.5) Range: 0.7 to 2.6)	N=39 1.3(1.1 to 1.5) Range: 0.8 to 2.3	N=38 1.3(1.1 to 1.5) Range: 0.8 to 2.3
		<b>Baseline to week 4</b>	<b>Baseline to week 12</b>	<b>Baseline to week 24</b>
Change from Baseline in HDL (wk-baseline)		N=37 -0.11(-0.23 to 0.02) Range: -0.46 to 0.70  P=0.012  <i>p-value using Wilcoxon signed rank test</i>	N=37 -0.10(-0.26 to 0.00) Range: -0.61 to 0.30  P=0.001  <i>p-value using Wilcoxon signed rank test</i>	N=36 -0.13(-0.30 to 0.06) Range: -0.57 to 0.23  P=0.002  <i>p-value using Wilcoxon signed rank test</i>
LDL (mmol/L)	N=38 3.1(2.4 to 3.5) Range: 1.6 to 5.1	N=39 2.8(2.2 to 3.1) Range: 1.3 to 4.5	N=39 2.5(2.1 to 3.1) Range: 1.2 to 5.0	N=38 2.7(2.1 to 3.3) Range: 1.2 to 4.5
		<b>Baseline to week 4</b>	<b>Baseline to week 12</b>	<b>Baseline to week 24</b>
Change from Baseline in LDL (wk-baseline)		N=36 -0.36(-0.61 to -0.07) Range: -1.31 to 0.84  P<0.001  <i>p-value using Wilcoxon signed rank test</i>	N=36 -0.50(-0.79 to -0.28) Range: -1.65 to 2.45  P<0.001  <i>p-value using Wilcoxon signed rank test</i>	N=35 -0.40(-0.80 to -0.08) Range: -1.34 to 1.83  P=0.008  <i>p-value using Wilcoxon signed rank test</i>
Total cholesterol:HDL ratio	N=39 3.6(3.2 to 4.2) Range: 2.1 to 6.0	N=39 3.4(2.8 to 4.2) Range: 1.6 to 6.2	N=39 3.6(3.0 to 4.1) Range: 1.7 to 7.1	N=38 3.5(2.8 to 4.3) Range: 1.9 to 6.1
		<b>Baseline to week 4</b>	<b>Baseline to week 12</b>	<b>Baseline to week 24</b>
Change from Baseline in		N=37	N=37	N=36

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Lab data	Baseline	Week 4	Week 12	Week 24
Attended	41	40	39	39
DNA	0	0	0	0
Drop out	0	1	2	2
Total cholesterol:HDL ratio (wk-baseline)		-0.12(-0.49 to -0.10) Range: -1.35 to 0.66  <i>P=0.096</i> <i>p-value using Wilcoxon signed rank test</i>	-0.24(-0.50 to 0.01) Range: -1.38 to 3.66  <i>P=0.005</i> <i>p-value using Wilcoxon signed rank test</i>	-0.19(-0.47 to 0.21) Range: -1.65 to 2.32  <i>P=0.084</i> <i>p-value using Wilcoxon signed rank test</i>
<b>Blood Count</b>				
Haemoglobin	150(142 to 157) Range: 125 to 176	148(140 to 154) Range: 126 to 172	154(145 to 158) Range: 132 to 178	150(142 to 159) Range: 128 to 174
		Baseline to week 4	Baseline to week 12	Baseline to week 24
Change from Baseline in Haemoglobin (wk-baseline)		-1(-3 to 2) Range: -16 to 11  <i>p=0.296</i> <i>p-value using Wilcoxon signed rank test</i>	4(-2 to 8) Range: -16 to 15  <i>p=0.007</i> <i>p-value using Wilcoxon signed rank test</i>	2 (-2 to 7) Range: -15 to 16  <i>p=0.079</i> <i>p-value using Wilcoxon signed rank test</i>
WBC	4.9(4.3 to 6.1) Range: 2.9 to 9.1	5.1(4.3 to 6.2) Range: 3.1 to 9.6	5.3(4.3 to 6.1) Range: 3.4 to 12.1	5.5(4.4 to 6.9) Range: 3.2 to 11.0
		Baseline to week 4	Baseline to week 12	Baseline to week 24
Change from Baseline in WBC (wk-baseline)		0.0(-0.4 to 0.5) Range: -3.0 to 1.9  <i>p=0.907</i> <i>p-value using Wilcoxon signed rank test</i>	0.0(-0.7 to 0.7) Range: -3.0 to 4.5  <i>p=0.675</i> <i>p-value using Wilcoxon signed rank test</i>	0.5(-0.4 to 1.5) Range: -3.6 to 5.6  <i>p=0.025</i> <i>p-value using Wilcoxon signed rank test</i>
PLT	222(209 to 239) Range: 152 to 298	218(205 to 246) Range: 156 to 302	218(204 to 248) Range: 145 to 297	228(207 to 253) Range: 150 to 309

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Attended	41	40	39	39
DNA	0	0	0	0
Drop out	0	1	2	2
		Baseline to week 4	Baseline to week 12	Baseline to week 24
<b>Change from Baseline in PLT (wk-baseline)</b>		-5(-21 to 6) Range: -75 to 53  p=0.063  p-value using Wilcoxon signed rank test	-6(-12 to 3) Range: -68 to 56  p=0.077  p-value using Wilcoxon signed rank test	2(-26 to 19) Range: -72 to 86  p=0.921  p-value using Wilcoxon signed rank test
<b>Lym</b>	1.7(1.3 to 1.9) Range: 1.0 to 3.4	1.7(1.4 to 2.0)  Range: 1.0 to 3.3	1.7(1.4 to 1.9)  Range: 1.0 to 3.0	1.6(1.4 to 2.0)  Range: 1.0 to 3.0
		Baseline to week 4	Baseline to week 12	Baseline to week 24
<b>Change from Baseline in Lym (wk-baseline)</b>		0.1(-0.1 to 0.2) Range: -0.7 to 0.9  p=0.291  p-value using Wilcoxon signed rank test	0.0(-0.1 to 0.2) Range: -0.7 to 0.8  p=0.440  p-value using Wilcoxon signed rank test	0.0(-0.2 to 0.1) Range: -0.9 to 0.6  p=0.791  p-value using Wilcoxon signed rank test
<b>Monocytes</b>	0.4(0.4 to 0.5) Range: 0.2 to 0.8	0.4(0.4 to 0.6)  Range: 0.3 to 0.8	0.5(0.4 to 0.5)  Range: 0.2 to 0.9	0.5(0.4 to 0.6)  Range: 0.3 to 0.8
		Baseline to week 4	Baseline to week 12	Baseline to week 24
<b>Change from Baseline in Monocytes (wk-baseline)</b>		0.0(-0.1 to 0.1) Range: -0.2 to 0.2  p=0.477  p-value using Wilcoxon signed rank test	0.0(-0.1 to 0.1) Range: -0.3 to 0.3  p=0.373  p-value using Wilcoxon signed rank test	0.1(0.0 to 0.2) Range: -0.2 to 0.3  p=0.010  p-value using Wilcoxon signed rank test
<b>Neutrophils</b>	2.8(2.2 to 4.0) Range: 1.2 to 5.9	2.9(2.0 to 3.7)	2.9(2.2 to 3.7)	3.2(2.3 to 4.4)

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Attended	41	40	39	39
DNA	0	0	0	0
Drop out	0	1	2	2
		Range: 1.1 to 6.5	Range: 1.1 to 8.3	Range: 1.4 to 7.8
		<a href="#">Baseline to week 4</a>	<a href="#">Baseline to week 12</a>	<a href="#">Baseline to week 24</a>
<b>Change from Baseline in Neutrophils (wk-baseline)</b>		-0.1(-0.5 to 0.4) Range: -2.7 to 2.0  p=0.499  p-value using Wilcoxon signed rank test	0.0(-0.6 to 0.5) Range: -2.7 to 3.5  p=0.999  p-value using Wilcoxon signed rank test	0.4(-0.1 to 1.0) Range: -3.1 to 5.6  p=0.009  p-value using Wilcoxon signed rank test
<b>Eosinophils</b>	0.1(0.1 to 0.2) Range: 0.0 to 0.4	0.1(0.1 to 0.2)  Range: 0.0 to 0.4	0.1(0.1 to 0.3)  Range: 0.1 to 0.6	0.1(0.1 to 0.2)  Range: 0.0 to 0.5
		<a href="#">Baseline to week 4</a>	<a href="#">Baseline to week 12</a>	<a href="#">Baseline to week 24</a>
<b>Change from Baseline in Eosinophils (wk-baseline)</b>		0.0(0.0 to 0.1) Range: -0.1 to 0.1  p=0.103  p-value using Wilcoxon signed rank test	0.0(0.0 to 0.1) Range: -0.2 to 0.5  p=0.185  p-value using Wilcoxon signed rank test	0.0(0.0 to 0.1) Range: -0.2 to 0.3  p=0.103  p-value using Wilcoxon signed rank test
<b>Basophils</b>	N=38 0.0(0.0 to 0.0) Range: 0.0 to 0.1	N=37 0.0(0.0 to 0.0)  Range: 0.0 to 0.1	N=35 0.0(0.0 to 0.0)  Range: 0.0 to 0.1	N=33 0.0(0.0 to 0.0)  Range: 0.0 to 0.1
		<a href="#">Baseline to week 4</a>	<a href="#">Baseline to week 12</a>	<a href="#">Baseline to week 24</a>
<b>Change from Baseline in Basophils</b>		0.0(0.0 to 0.0) Range: 0.0 to 0.1	0.0(0.0 to 0.0) Range: -0.1 to 0.1	0.0(0.0 to 0.0) Range: 0.0 to 0.1

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Lab data	Baseline	Week 4	Week 12	Week 24
Attended	41	40	39	39
DNA	0	0	0	0
Drop out	0	1	2	2
(wk-baseline)		p=0.500 p-value using Wilcoxon signed rank test	p=0.999 p-value using Wilcoxon signed rank test	p=0.500 p-value using Wilcoxon signed rank test
<b>Renal Markers</b>				
<b>Sodium</b>	140(139 to 141) Range: 135 to 144	141(139 to 142) Range: 137 to 143	140(139 to 141) Range: 135 to 144	140(139 to 141) Range: 135 to 145
		Baseline to week 4	Baseline to week 12	Baseline to week 24
Change from Baseline in <b>Sodium</b>  (wk-baseline)		1.0(-1.0 to 2.0) Range: -3.0 to 6.0  p=0.084 p-value using Wilcoxon signed rank test	0(-1 to 1) Range: -5 to 5  p=0.920 p-value using Wilcoxon signed rank test	0(-1 to 2) Range: -4 to 5  p=0.782 p-value using Wilcoxon signed rank test
<b>Potassium</b>	4.4(4.1 to 4.5) Range: 3.5 to 5.1	4.5(4.4 to 4.5) Range: 3.5 to 5.1	4.3(4.1 to 4.4) Range: 3.7 to 5.0	4.3(4.2 to 4.5) Range: 3.6 to 5.5
		Baseline to week 4	Baseline to week 12	Baseline to week 24
Change from Baseline in <b>Potassium</b>  (wk-baseline)		0.1(-0.2 to 0.3) Range: -0.7 to 0.6  p=0.744 p-value using Wilcoxon signed rank test	0.0(-0.3 to 0.1) Range: -0.7 to 0.7  p=0.179 p-value using Wilcoxon signed rank test	0.0(-0.2 to 0.2) Range: -0.8 to 0.8  p=0.273 p-value using Wilcoxon signed rank test
<b>Creatinine</b>	80(72 to 87) Range: 50 to 104	81(76 to 91) Range: 49 to 118	88(81 to 95) Range: 54 to 120	85(79 to 97) Range: 51 to 135
		Baseline to week 4	Baseline to week 12	Baseline to week 24
Change from Baseline in <b>Creatinine</b>		2.5(-2.0 to 8.5) Range: -21.0 to 22.0	6(1 to 14) Range: -14 to 34	5(2 to 13) Range: -6 to 31

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Lab data	Baseline	Week 4	Week 12	Week 24
Attended	41	40	39	39
DNA	0	0	0	0
Drop out	0	1	2	2
(wk-baseline)		p=0.030 p-value using Wilcoxon signed rank test	P<0.001 p-value using Wilcoxon signed rank test	P<0.001 p-value using Wilcoxon signed rank test
<b>Liver Function</b>				
<b>Albumin</b>	46(42 to 48) Range: 35 to 51	45(42 to 47) Range: 37 to 51	46(42 to 49) Range: 37 to 54	45(41 to 48) Range: 35 to 53
		<b>Baseline to week 4</b>	<b>Baseline to week 12</b>	<b>Baseline to week 24</b>
Change from Baseline in Albumin (wk-baseline)		0(-1 to 1) Range: -8 to 4 p=0.359 p-value using Wilcoxon signed rank test	1(-1 to 2) Range: -3 to 5 p=0.045 p-value using Wilcoxon signed rank test	-1(-2 to 1) Range: -5 to 4 p=0.389 p-value using Wilcoxon signed rank test
<b>Glucose</b>	5.1(4.9 to 5.6) Range: 4.2 to 10.3	5.2(4.7 to 5.5) Range: 4.2 to 11.4	5.2(4.8 to 5.8) Range: 4.3 to 16.4	4.9(4.5 to 5.5) Range: 4.2 to 10.5
		<b>Baseline to week 4</b>	<b>Baseline to week 12</b>	<b>Baseline to week 24</b>
Change from Baseline in Glucose (wk-baseline)		-0.1(-0.3 to 0.2) Range: -1.0 to 4.3 p=0.282 p-value using Wilcoxon	-0.2(-0.4 to 0.3) Range: -0.9 to 9.3 p=0.285 p-value using Wilcoxon	-0.2(-0.5 to 0.2) Range: -1.7 to 3.4 p=0.006 p-value using Wilcoxon

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Attended	41	40	39	39
DNA	0	0	0	0
Drop out	0	1	2	2
		signed rank test	signed rank test	signed rank test
<b>ALT</b>	32(22 to 43) Range: 14 to 90	28(22 to 39) Range: 12 to 81	32(24 to 39) Range: 12 to 74	27(21 to 47) Range: 8 to 79
		<b>Baseline to week 4</b>	<b>Baseline to week 12</b>	<b>Baseline to week 24</b>
Change from Baseline in ALT  (wk-baseline)		-4.5(-8.5 to 2.5) Range: -33.0 to 34.0  p=0.044  p-value using Wilcoxon signed rank test	0.0 (-7.0 to 8.0) Range: -37.0 to 30.0  p=0.872  p-value using Wilcoxon signed rank test	-3.0 (-9.0 to 5.0) Range: -37.0 to 31.0  p=0.140  p-value using Wilcoxon signed rank test
<b>ALP</b>	80(66 to 93) Range: 44 to 245	67(59 to 84) Range: 43 to 215	68(58 to 75) Range: 44 to 209	65(57 to 75) Range: 43 to 198
		<b>Baseline to week 4</b>	<b>Baseline to week 12</b>	<b>Baseline to week 24</b>
Change from Baseline in <b>ALP</b>  (wk-baseline)		-5.0(-12.5 to -3.0) Range: -30.0 to 6.0  P<0.001  p-value using Wilcoxon signed rank test	-12.0(-17.0 to -4.0) Range: -36.0 to 2.0  P<0.001  p-value using Wilcoxon signed rank test	-12.0 (-17.0 to -4.0) Range: -36.0 to 2.0  P<0.001  p-value using Wilcoxon signed rank test
<b>AST</b>	N=40 30(22 to 35) Range: 14 to 50	N=38 27(23 to 32) Range: 13 to 47	N=36 28(25 to 36) Range: 9 to 60	N=38 26(22 to 33) Range: 10 to 45
		<b>Baseline to week 4</b>	<b>Baseline to week 12</b>	<b>Baseline to week 24</b>
Change from Baseline in <b>AST</b>  (wk-baseline)		N=37 -2(-7 to 0) Range: -18 to 12  P<0.001  p-value using Wilcoxon	N=35 0(-4 to 4) Range: -13 to 19  P=0.726  p-value using Wilcoxon	N=37 -2(-5 to 1) Range: -21 to 13  P=0.074  p-value using Wilcoxon

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Attended	41	40	39	39
DNA	0	0	0	0
Drop out	0	1	2	2
		signed rank test	signed rank test	signed rank test
<b>Total bilirubin</b>	6(4 to 8) Range: 3 to 10	5(7 to 11) Range: 3 to 21	9(7 to 12) Range: 3 to 22	9(6 to 11) Range: 4 to 30
		<b>Baseline to week 4</b>	<b>Baseline to week 12</b>	<b>Baseline to week 24</b>
Change from Baseline in <b>Total bilirubin</b>  (wk-baseline)		3(1 to 4) Range: -3 to 11  P<0.001  p-value using Wilcoxon signed rank test	3(1 to 5) Range: -3 to 17  P<0.001  p-value using Wilcoxon signed rank test	3(0 to 6) Range: -5 to 24  P<0.001  p-value using Wilcoxon signed rank test
<b>Total phosphotase</b>	0.97(0.85 to 1.08) Range: 0.63 to 1.40	1.00(0.83 to 1.10) Range: 0.60 to 1.20	1.05(0.91 to 1.11) Range: 0.70 to 1.35	1.04(0.89 to 1.10) Range: 0.70 to 1.37
		<b>Baseline to week 4</b>	<b>Baseline to week 12</b>	<b>Baseline to week 24</b>
Change from Baseline in <b>Total phosphotase</b>  (wk-baseline)		0.03(-0.07 to 0.09) Range: -0.28 to 0.20  P=0.449  p-value using Wilcoxon signed rank test	0.04(-0.02 to 0.16) Range: -0.35 to 0.48  P=0.024  p-value using Wilcoxon signed rank test	0.08(-0.02 to 0.19) Range: -0.30 to 0.40  P=0.036  p-value using Wilcoxon signed rank test
<b>Hepatitis</b>				
<sup>^</sup> HepB	No data	No data	No data	No data
<sup>^</sup> HepC	No data	No data	No data	No data

<sup>^</sup>It appears HepB/C were eligibility criteria and data should not have been collected so the database design should not have had these data fields.

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Lab Data Excluding Protocol Deviators

Lab data	Baseline	Week 4	Week 12	Week 24
Attended	41	40	39	39
DNA	0	0	0	0
Drop out	0	1	2	2
<b>Immunological(excluding protocol deviators)</b>	405 wk4 412 wk4 104 wk12 206 wk12 209 wk12 211 wk12 301 wk12 305 wk12			
<b>CD4 T-cell count cells/mm3</b>	563(465 to 679) Range: 232 to 1228	Not done	N=33 575(431 to 705) Range: 308 to 1114	600(488 to 682) Range: 284 to 965
		<b>Baseline to week 4</b>	<b>Baseline to week 12</b>	<b>Baseline to week 24</b>
<b>Change from Baseline in CD4 T-cell count cells/mm3 (wk-baseline)</b>		-	N=33 17(-8 to 60) Range: -186 to 249  <i>p=0.126</i>  <i>p-value using Wilcoxon signed rank test</i>	-2 (-55 to 75) Range: -436 to 204  <i>p=0.995</i>  <i>p-value using Wilcoxon signed rank test</i>
<b>CD4 percent</b>	35.9(29.0 to 38.6) Range: 16.5 to 51.0	-	N=33 34.6(28.0 to 38.6) Range: 22.3 to 50.0	36.6(30.0 to 40.0) Range: 20.8 to 51.5
		<b>Baseline to week 4</b>	<b>Baseline to week 12</b>	<b>Baseline to week 24</b>

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Lab data	Baseline	Week 4	Week 12	Week 24
Attended	41	40	39	39
DNA	0	0	0	0
Drop out	0	1	2	2
Change from Baseline in CD4 percent (wk-baseline)		-	N=33 -0.5(-1.9 to 1.0) Range: -11.9 to 5.0  p=0.230  p-value using Wilcoxon signed rank test	1.0 (-3.0 to 2.3) Range: -8.2 to 6.0  p=0.058  p-value using Wilcoxon signed rank test
CD8 T-cell count cells/mm3	661(487 to 817) Range: 384 to 1547	-	N=33 683(529 to 829)  Range: 413 to 1630	673(487 to 832) Range: 321 to 1427
		<b>Baseline to week 4</b>	<b>Baseline to week 12</b>	<b>Baseline to week 24</b>
Change from Baseline in CD8 T-cell count cells/mm3 (wk-baseline)		-	N=33 16(-32 to 115) Range: -298 to 417  p=0.316  p-value using Wilcoxon signed rank test	-2(-90 to 71) Range: -412 to 368  p=0.995  p-value using Wilcoxon signed rank test
CD8 percent	42.5(37.0 to 47.0) Range: 26.7 to 60.1	-	N=33 42.5(34.8 to 45.7)  Range: 24.2 to 59.2	41.0(34.7 to 47.2) Range: 27.1 to 57.0
		<b>Baseline to week 4</b>	<b>Baseline to week 12</b>	<b>Baseline to week 24</b>

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Lab data	Baseline	Week 4	Week 12	Week 24
Attended	41	40	39	39
DNA	0	0	0	0
Drop out	0	1	2	2
Change from Baseline in CD8 percent (wk-baseline)		-	N=33 0.0(-2.5 to 1.7) Range: -6.0 to 5.7  p=0.779  p-value using Wilcoxon signed rank test	-0.5(-2.4 to 2.0) Range: -6.0 to 5.6  p=0.492  p-value using Wilcoxon signed rank test
<b>Virological (excluding protocol deviators)</b>				
HIV RNA load copies/ml <50	40(97.6)	38(100.0)	32(97.0)	38(97.4)
>50	1(2.4)	0(0.0)	1(3.0)	1(2.6)
HIV RNA load copies/ml <400	41(100.0)	38(100.0)	33(100.0)	38(100.0)
>400	0(0.0)	0(0.0)	0(0.0)	0(0.0)
<b>Lipids (excluding protocol deviators)</b>	206 wk 4 305 wk 24			
Total cholesterol (mmol/L)	N=39 5.2(4.6 to 5.7)  Range: 3.6 to 7.7	N=38 4.7(4.2 to 5.0)  Range: 2.8 to 7.1	N=39 4.5(3.8 to 5.0)  Range: 2.5 to 7.2	N=37 4.4(4.0 to 5.1)  Range: 2.6 to 6.4
		<b>Baseline to week 4</b>	<b>Baseline to week 12</b>	<b>Baseline to week 24</b>

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Lab data	Baseline	Week 4	Week 12	Week 24
Attended	41	40	39	39
DNA	0	0	0	0
Drop out	0	1	2	2
<b>Change from Baseline in Total cholesterol (wk-baseline)</b>		N=36 -0.6(-0.8 to -0.2) Range: -1.6 to 0.4  P<0.001 <i>p-value using Wilcoxon signed rank test</i>	N=37 -0.7(-1.0 to -0.5) Range: -1.8 to 2.6  P<0.001 <i>p-value using Wilcoxon signed rank test</i>	N=35 -0.8(-1.2 to -0.3) Range: -1.9 to 1.9  P<0.001 <i>p-value using Wilcoxon signed rank test</i>
<b>Triglycerides (mmol/L)</b>	N=39 1.3(0.8 to 2.4)  Range: 0.5 to 4.6)	N=38 0.8(0.7 to 1.7)  Range: 0.4 to 3.3)	N=39 1.30(0.6 to 1.6)  Range: 0.4 to 3.0)	N=37 0.9(0.7 to 1.3)  Range: 0.4 to 3.2)
		<b>Baseline to week 4</b>	<b>Baseline to week 12</b>	<b>Baseline to week 24</b>
<b>Change from Baseline in Triglycerides (wk-baseline)</b>		N=36 -0.25(-0.66 to 0.03) Range: -1.46 to 1.08  P<0.001 <i>p-value using Wilcoxon signed rank test</i>	N=37 -0.17(-0.82 to 0.10) Range: -2.05 to 0.99  P=0.002 <i>p-value using Wilcoxon signed rank test</i>	N=35 -0.26(-0.60 to 0.10) Range: -2.5 to 0.6  P=0.002 <i>p-value using Wilcoxon signed rank test</i>
<b>HDL (mmol/L)</b>	N=39 1.4(1.2 to 1.6)  Range: 0.8 to 2.5)	N=38 1.3(1.2 to 1.5)  Range: 0.7 to 2.6)	N=39 1.3(1.1 to 1.5)  Range: 0.8 to 2.3)	N=37 1.3(1.2 to 1.5)  Range: 0.8 to 2.2)
		<b>Baseline to week 4</b>	<b>Baseline to week 12</b>	<b>Baseline to week 24</b>

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Lab data	Baseline	Week 4	Week 12	Week 24
Attended	41	40	39	39
DNA	0	0	0	0
Drop out	0	1	2	2
<b>Change from Baseline in HDL (wk-baseline)</b>		N=36 -0.11(-0.23 to 0.03) Range: -0.46 to 0.70  P=0.015 <i>p-value using Wilcoxon signed rank test</i>	N=37 -0.10(-0.26 to 0.00) Range: -0.61 to 0.30  P=0.001 <i>p-value using Wilcoxon signed rank test</i>	N=35 -0.15(-0.30 to 0.04) Range: -0.57 to 0.23  P=0.001 <i>p-value using Wilcoxon signed rank test</i>
<b>LDL (mmol/L)</b>	N=38 3.1(2.4 to 3.5)  Range: 1.6 to 5.1	N=39 2.8(2.2 to 3.1)  Range: 1.3 to 4.5	N=39 2.5(2.1 to 3.1)  Range: 1.2 to 5.0	N=37 2.6(2.1 to 3.3)  Range: 1.2 to 4.5
		<b>Baseline to week 4</b>	<b>Baseline to week 12</b>	<b>Baseline to week 24</b>
<b>Change from Baseline in LDL (wk-baseline)</b>		N=35 -0.40(-0.62 to -0.02) Range: -1.31 to 0.84  P<0.001 <i>p-value using Wilcoxon signed rank test</i>	N=36 -0.50(-0.79 to -0.28) Range: -1.65 to 2.45  P<0.001 <i>p-value using Wilcoxon signed rank test</i>	N=34 -0.40(-0.80 to -0.09) Range: -1.34 to 1.83  P=0.004 <i>p-value using Wilcoxon signed rank test</i>
<b>Total cholesterol:HDL ratio</b>	N=39 3.6(3.2 to 4.2)  Range: 2.1 to 6.0	N=38 3.4(2.8 to 4.0)  Range: 1.6 to 6.2	N=39 3.6(3.0 to 4.1)  Range: 1.7 to 7.1	N=37 3.5(2.8 to 4.3)  Range: 1.9 to 6.1
		<b>Baseline to week 4</b>	<b>Baseline to week 12</b>	<b>Baseline to week 24</b>
<b>Change from Baseline in Total cholesterol:HDL ratio (wk-baseline)</b>		N=36 -0.10(-0.49 to -0.11) Range: -1.35 to 0.66  P=0.121 <i>p-value using Wilcoxon signed rank test</i>	N=37 -0.24(-0.50 to 0.01) Range: -1.38 to 3.66  P=0.005 <i>p-value using Wilcoxon signed rank test</i>	N=35 -0.19(-0.48 to 0.26) Range: -1.65 to 2.32  P=0.106 <i>p-value using Wilcoxon signed rank test</i>

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**Protocol defined DAIDS AE definition**

**Laboratory reference ranges for each study sites (adult)**

SSAT058 Lab Normal Ranges	Site 1 ChelWest	Site 2 Brighton	Site 3 St Mary's	Site 4 Guys
<b>Sodium</b> mmol/L	133 - 146	136-145	133-146	135-145
<b>Potassium</b> mmol/L	3.5 - 5.3	3.2-5.1	3.5 - 5.3	3.5 - 5.0
<b>Creatinine</b> umol/L				
Male	Male: 60 - 125	Male: 62 - 106	Male: 60 - 125	Age 16- 19 years: 48 - 87 Male adult: 59 - 104;
Female	Female: 55 - 110	Female: 44 - 80	Female: 55 - 110	Female adult: 45 - 84
<b>Albumin</b> g/L	35 - 50	35 - 52	35 - 50	40 - 52
<b>Glucose</b> mmol/L	3.0 - 6.0	3.2 - 6.0	3.0 - 6.0	Not available Fasting Glucose greater >6.9 mmol/L or Random Glucose >11.0 mmol/L suggest diabetes mellitus. Fasting Glucose 6.1 - 6.9 mmol/L signify impaired fasting glycaemia.
<b>ALT</b> U/L				
Male	<=40	Male: ≤41;	<=40	Male: 4 - 59
Female		Female: ≤33		Female: 4 - 45
<b>ALP</b> U/L				
Male	30-130	Male: 40 - 129:	30-130	Male (age 15-19yrs): 43 - 120
Female		Female: 35 - 104		Female (age 15-19yrs): 57 - 261;

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<b>SSAT058 Lab Normal Ranges</b>	<b>Site 1 ChelWest</b>	<b>Site 2 Brighton</b>	<b>Site 3 St Mary's</b>	<b>Site 4 Guys</b>
				Adult: 35 - 129
<b>AST U/L</b>	<=40	Male: 0 - 40	<=40	0 - 49
Male		Female: 0 - 32		
<b>Total Bilirubin umol/L</b>	<=21	0 - 21	<=21	0 - 21
<b>Serum Phosphate mmol/L</b>	0.8 - 1.5	0.81 - 1.45	0.8 - 1.5	Male (age 17-19yrs): 1.0 - 1.7
				Female (age 17-19yrs): 1.0 - 1.5;
				Adult (> 19 yrs): 0.9 - 1.4
<b>Haemoglobin g/L</b>	Male: 130 - 168	Male: 135 - 180	Male: 130 - 168	Male: 130 - 170;
	Female: 114 - 150	Female: 115 - 165	Female: 114 - 150	Female: 120 - 150
<b>White Blood Cell 10*9/L</b>	Male: 4.2 - 10.6	4.0 - 11.0	Male: 4.2 - 10.6	4.0 - 11.0
	Female: 4.2 - 11.2		Female: 4.2 - 11.2	
<b>Platelets 10*9/L</b>	Male: 130 - 370	150 - 450	Male: 130 - 370	150 - 400
	Female: 135 - 400		Female: 135 - 400	
<b>Lymphocytes ABS 10*9/L</b>	1.1 - 3.6	1.3 - 3.5	1.1 - 3.6	1.2 - 3.5
<b>Monocytes 10*9/L</b>	0.3 - 0.9	0.2 - 0.8	0.3 - 0.9	0.2 - 1.0
<b>Neutrophils 10*9/L</b>	2.0 - 7.1	2.0 - 7.5	2.0 - 7.1	1.5 - 7.0
<b>Eosinophils 10*9/L</b>	0.0 - 0.5	0.0 - 0.4	0.0 - 0.5	0.0 - 0.4

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SSAT058 Lab Normal Ranges	Site 1 ChelWest	Site 2 Brighton	Site 3 St Mary's	Site 4 Guys
<b>Basophils 10<sup>9</sup>/L</b>	0.0 - 0.2	0.0 - 0.1	0.0 - 0.2	0.0 - 0.2

A reference range is defined as the set of values 95 percent of the normal population falls within (that is, 95% prediction interval)

#### DAIDS toxicity table grade range

Parameter	GRADE 1 Mild	GRADE 2 Moderate	GRADE 3 Severe	GRADE 4 Potentially life threatening
<b>Sodium mmol/L serum high</b>	146 – 150 mmol/L	151 – 154 mmol/L	155 – 159 mmol/L	≥ 160 mmol/L
<b>Sodium mmol/L serum low</b>	130 – 135 mmol/L	125 – 129 mmol/L	121 – 124 mmol/L	≤ 120 mmol/L
<b>Potassium mmol/L serum high</b>	5.6 – 6.0 mmol/L	6.1 – 6.5 mmol/L	6.6 – 7.0 mmol/L	> 7.0 mmol/L
<b>Potassium mmol/L serum low</b>	3.0 – 3.4 mmol/L	2.5 – 2.9 mmol/L	2.0 – 2.4 mmol/L	< 2.0 mmol/L
<b>Creatinine umol/L</b>	1.1 – 1.3 x ULN <sup>†</sup>	1.4 – 1.8 x ULN <sup>†</sup>	1.9 – 3.4 x ULN <sup>†</sup>	≥ 3.5 x ULN <sup>†</sup>
<b>Albumin g/L</b>	30 g/L – < LLN	20 – 29 g/L	< 20 g/L	NA
<b>Glucose mmol/L</b>	6.44 – 8.88 mmol/L	8.89 – 13.88 mmol/L	13.89 – 27.75 mmol/L	> 27.75 mmol/L
<b>ALT U/L</b>	1.25 – 2.5 x ULN	2.6 – 5.0 x ULN	5.1 – 10.0 x ULN	> 10.0 x ULN
<b>ALP U/L</b>	1.25 – 2.5 x ULN	2.6 – 5.0 x ULN	5.1 – 10.0 x ULN	> 10.0 x ULN
<b>AST U/L</b>	1.25 – 2.5 x ULN	2.6 – 5.0 x ULN	5.1 – 10.0 x ULN	> 10.0 x ULN
<b>Total Bilirubin</b>	1.1 – 1.5 x ULN	1.6 – 2.5 x ULN	2.6 – 5.0 x ULN	> 5.0 x ULN
<b>Serum Phosphate mmol/L</b>	0.81 mmol/L – < LLN	0.65 – 0.80 mmol/L	0.32 – 0.64 mmol/L	< 0.32 mmol/L
<b>Haemoglobin g/L</b>	1.32 – 1.55 mmol/L	1.16 – 1.31 mmol/L	1.01 – 1.15 mmol/L	< 1.01 mmol/L
<b>White Blood Cell 10<sup>9</sup>/L</b>	2.000 x 10 <sup>9</sup> – 2.500 x 10 <sup>9</sup> /L	1.500 x 10 <sup>9</sup> – 1.999 x 10 <sup>9</sup> /L	1.000 x 10 <sup>9</sup> – 1.499 x 10 <sup>9</sup> /L	< 1.000 x 10 <sup>9</sup> /L
<b>Platelets 10<sup>9</sup>/L</b>	100.000 x 10 <sup>9</sup> – 124.999 x 10 <sup>9</sup> /L	50.000 x 10 <sup>9</sup> – 99.999 x 10 <sup>9</sup> /L	25.000 x 10 <sup>9</sup> – 49.999 x 10 <sup>9</sup> /L	< 25.000 x 10 <sup>9</sup> /L
<b>Lymphocytes ABS 10<sup>9</sup>/L</b>	<i>n/a not included in DAIDS</i>			
<b>Monocytes 10<sup>9</sup>/L</b>	<i>n/a not included in DAIDS</i>			
<b>Neutrophils 10<sup>9</sup>/L</b>	1.000 x 10 <sup>9</sup> – 1.300 x 10 <sup>9</sup> /L	0.750 x 10 <sup>9</sup> – 0.999 x 10 <sup>9</sup> /L	0.500 x 10 <sup>9</sup> – 0.749 x 10 <sup>9</sup> /L	< 0.500 x 10 <sup>9</sup> /L
<b>Eosinophils 10<sup>9</sup>/L</b>	<i>n/a not included in DAIDS</i>			
<b>Basophils 10<sup>9</sup>/L</b>	<i>n/a not included in DAIDS</i>			

<sup>†</sup>Use age and sex appropriate values

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Laboratory results graded using DAIDS toxicity grading following 'normalization' of all four study sites laboratory values against a standard normal range

	N(%)															
	Baseline				Week 4				Week 12				Week 24			
Attended DNA Drop out	41 0 0				40 0 1				39 0 2				39 0 2			
DAIDS grades	Grade 1	Grade 2	Grade 3	Grade 4	Grade 1	Grade 2	Grade 3	Grade 4	Grade 1	Grade 2	Grade 3	Grade 4	Grade 1	Grade 2	Grade 3	Grade 4
<b>Sodium (High)</b>	41 (100.0)	-	-	-	40 (100.0)	-	-	-	39 (100.0)	-	-	-	39 (100.0)	-	-	-
<b>Sodium (Low)</b>	1 (2.4)	-	-	-	-	-	-	-	2 (5.1)	-	-	-	1 (2.6)	-	-	-
<b>Potassium (High)</b>	41 (100.0)	-	-	-	40 (100.0)	-	-	-	39 (100.0)	-	-	-	39 (100.0)	-	-	-
<b>Potassium (Low)</b>	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
<b>Creatinine</b>	1(2.4)	-	-	-	-	1(2.5)	-	-	-	2(2.6)	-	-	-	1(2.6)	-	-
<b>Albumin</b>	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
<b>Glucose</b>	5(12.2)	1(2.4)	-	-	2(5.0)	2(5.0)	-	-	5(5.1)	1(2.6)	1(2.6)	-	2(5.1)	2(5.1)	-	-
<b>ALT</b>	4(9.8)	-	-	-	4(10.0)	-	-	-	5(12.8)	-	-	-	6(15.4)	-	-	-
<b>ALP</b>	1(2.4)	-	-	-	1(2.5)	-	-	-	1(2.6)	-	-	-	1(2.6)	-	-	-
<b>AST</b>	1(2.4)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
<b>Total Bilirubin</b>	-	-	-	-	-	-	-	-	-	-	-	-	2(5.1)	-	-	-
<b>Serum Phosphate</b>	37(90.2)	4(9.8)	-	-	35(87.5)	2(5.0)	2(5.0)	-	38(97.4)	-	1(2.6)	-	35(89.7)	2(5.1)	1(2.6)	-
<b>^Haemoglobin</b>	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
<b>White Blood Cell 10<sup>9</sup>/L</b>	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
<b>Platelets 10<sup>9</sup>/L</b>	-	-	-	-	-	-	-	-	1(2.6)	-	-	-	-	-	-	-

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<b>Lymphocytes ABS 10<sup>9</sup>/L</b>	<i>n/a not included in DAIDS</i>															
<b>Monocytes 10<sup>9</sup>/L</b>	<i>n/a not included in DAIDS</i>															
<b>Neutrophils 10<sup>9</sup>/L</b>	-	-	-	-	1(2.50)	-	-	-	2(5.1)	-	-	-	-	-	-	-
<b>Eosinophils 10<sup>9</sup>/L</b>	<i>n/a not included in DAIDS</i>															
<b>Basophils 10<sup>9</sup>/L</b>	<i>n/a not included in DAIDS</i>															

<sup>^</sup>Database contains HB in g/L - to convert to mmol/l - multiply by 0.0155 (<http://unitslab.com/node/79> )

Data from CW were used as a standard laboratory values for normalisation.

**NORMALISATION**

The conversion to SI unit do not represent a true homogenisation of results obtained from different laboratories using different methods. To ensure a full comparability of lab data a standard laboratory (ChelWest) was used to 'normalize' all laboratory values against a standard normal range.

The below normalisation formula ('location-scale') was used:

$$s = L_s + (x - L_x) \frac{U_s - L_s}{U_x - L_x}$$

where s= the transformed individual laboratory value to a common standard laboratory reference range;

x=the original value

Lx and Ux=lower and upper limits of normal range for an individual local laboratory parameter test

Ls and Us lower and upper limits for the selected common standard laboratory (or theoretical / phantom laboratory)