表 2.7.4.7-付録-25　血液学的検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（5/50）

Laboratory Test: RBC (10^4 /μL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20						
N	65	65	146	145	148	148
Mean	468.3	8.6	471.0	4.5	463.5	-1.7
SD	47.64	18.27	38.99	18.28	40.51	19.98
Minimum	365	-31	372	-40	347	-60
Q1	443.0	-6.0	448.0	-6.0	435.5	-15.0
Median	466.0	3.0	470.0	3.0	461.5	-1.0
Q3	507.0	24.0	491.0	17.0	486.5	12.0
Maximum	552	45	571	60	572	56
Week 24						
N	64	64	146	145	148	148
Mean	471.4	12.7	472.9	6.4	465.8	0.7
SD	47.07	18.41	40.53	17.66	39.59	19.42
Minimum	359	-28	368	-40	342	-46
Q1	445.5	1.5	445.0	-6.0	434.5	-12.5
Median	474.5	13.5	475.5	7.0	461.5	2.0
Q3	507.5	23.5	501.0	18.0	490.0	12.0
Maximum	549	62	580	57	594	65

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-25　血液学的検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（6/50）

Laboratory Test: WBC (/μL)

Visit / Statistics	Placebo (N=71) Observed Value at Visit	Placebo (N=71) Change from Baseline	QD (N=152) Observed Value at Visit	QD (N=152) Change from Baseline	BID (N=151) Observed Value at Visit	BID (N=151) Change from Baseline
Week -12						
N	71		152		151	
Mean	6322.5		6567.1		6541.1	
SD	1371.36		1617.73		1881.96	
Minimum	3300		3400		2500	
Q1	5400.0		5400.0		5300.0	
Median	6200.0		6500.0		6500.0	
Q3	7100.0		7400.0		7600.0	
Maximum	9500		12900		14800	
Week -4						
N	71		152		151	
Mean	6293.0		6776.3		6772.2	
SD	1512.27		1801.76		2242.03	
Minimum	3000		3600		2600	
Q1	5400.0		5550.0		5300.0	
Median	6300.0		6450.0		6500.0	
Q3	7200.0		7650.0		7900.0	
Maximum	10600		12200		20300	

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-25　血液学的検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（7/50）

Laboratory Test: WBC (/μL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 0						
N	71		151		151	
Mean	6280.3		6765.6		6686.1	
SD	1482.72		2010.67		2016.47	
Minimum	3400		3100		2500	
Q1	5400.0		5300.0		5200.0	
Median	6100.0		6400.0		6400.0	
Q3	7300.0		7400.0		7800.0	
Maximum	10400		13700		14300	
Week 2						
N	71	71	152	151	151	151
Mean	6400.0	119.7	6919.7	161.6	6704.0	17.9
SD	1574.80	1024.22	2045.74	1371.12	2081.73	1155.86
Minimum	3300	-3300	3900	-4700	2700	-6300
Q1	5300.0	-400.0	5600.0	-500.0	5200.0	-500.0
Median	6400.0	100.0	6700.0	200.0	6500.0	100.0
Q3	7400.0	700.0	7900.0	600.0	7700.0	500.0
Maximum	9700	2900	16000	8000	15300	5000

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-25　血液学的検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（8/50）

Laboratory Test: WBC (/μL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 4						
N	70	70	150	149	150	150
Mean	6445.7	150.0	6778.0	17.4	6674.0	-22.0
SD	1682.71	984.19	1744.40	1259.87	1997.87	1103.13
Minimum	3400	-2700	3400	-5300	2300	-4800
Q1	5100.0	-200.0	5700.0	-500.0	5400.0	-600.0
Median	6350.0	150.0	6600.0	200.0	6400.0	0.0
Q3	7600.0	600.0	7800.0	600.0	7600.0	500.0
Maximum	12000	3200	13900	3000	13100	4900
Week 8						
N	68	68	149	148	149	149
Mean	6400.0	185.3	6743.6	-19.6	6677.9	-30.2
SD	1660.70	1187.78	1815.60	1431.60	1866.63	1196.77
Minimum	3300	-2900	3300	-5100	2500	-4200
Q1	5450.0	-500.0	5400.0	-500.0	5400.0	-600.0
Median	6300.0	200.0	6500.0	100.0	6600.0	-100.0
Q3	7200.0	600.0	7900.0	650.0	7800.0	700.0
Maximum	11800	4600	14100	5900	12100	3700

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-25　血液学的検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（9/50）

Laboratory Test: WBC (/μL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 12						
N	67	67	148	147	148	148
Mean	6332.8	85.1	6851.4	82.3	6827.0	114.9
SD	1473.13	942.47	1779.88	1290.15	2060.30	1362.09
Minimum	3500	-2700	3800	-6000	2800	-6500
Q1	5400.0	-500.0	5700.0	-400.0	5500.0	-550.0
Median	6200.0	100.0	6500.0	100.0	6700.0	100.0
Q3	7100.0	600.0	7750.0	800.0	7600.0	700.0
Maximum	10800	2600	13400	3700	17800	5200
Week 16						
N	66	66	148	147	147	147
Mean	6304.5	100.0	7007.4	238.8	6720.4	22.4
SD	1510.62	899.40	2025.89	1465.00	1949.11	1191.05
Minimum	3100	-1800	3000	-5800	2800	-6100
Q1	5100.0	-500.0	5600.0	-400.0	5400.0	-500.0
Median	6350.0	50.0	6700.0	200.0	6500.0	100.0
Q3	7100.0	400.0	7900.0	800.0	7600.0	700.0
Maximum	10400	3000	14100	6900	15600	3200

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-25　血液学的検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（10/50）

Laboratory Test: WBC (/μL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20						
N	65	65	146	145	148	148
Mean	6333.8	135.4	6774.7	-20.7	6689.2	-23.0
SD	1656.92	1002.88	1694.08	1269.13	1847.19	1115.69
Minimum	3100	-2100	3400	-5400	2600	-4300
Q1	5100.0	-300.0	5500.0	-500.0	5350.0	-500.0
Median	6400.0	0.0	6450.0	100.0	6450.0	100.0
Q3	7200.0	700.0	7900.0	600.0	7700.0	650.0
Maximum	11600	3000	12500	3400	13400	3200
Week 24						
N	64	64	146	145	148	148
Mean	6350.0	140.6	6923.3	131.0	6814.9	102.7
SD	1471.64	1078.46	1874.88	1322.48	1928.43	1159.69
Minimum	3300	-3200	3500	-5700	2500	-3200
Q1	5400.0	-600.0	5500.0	-500.0	5400.0	-400.0
Median	6300.0	150.0	6850.0	300.0	6650.0	0.0
Q3	7100.0	650.0	7900.0	800.0	7850.0	800.0
Maximum	10800	4100	12800	4500	12600	5300

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-25　血液学的検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（11/50）

Laboratory Test: Hemoglobin (g/dL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week -12						
N	71		152		151	
Mean	14.43		14.70		14.50	
SD	1.333		1.180		1.351	
Minimum	8.7		11.0		10.6	
Q1	13.70		14.00		13.50	
Median	14.50		14.60		14.40	
Q3	15.30		15.50		15.50	
Maximum	17.0		17.8		18.8	
Week -4						
N	71		152		151	
Mean	14.26		14.52		14.40	
SD	1.449		1.242		1.326	
Minimum	8.5		10.5		10.7	
Q1	13.60		13.80		13.40	
Median	14.30		14.60		14.40	
Q3	15.30		15.40		15.40	
Maximum	17.4		17.8		17.1	

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-25　血液学的検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（12/50）

Laboratory Test: Hemoglobin (g/dL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 0						
N	71		151		151	
Mean	14.22		14.43		14.33	
SD	1.429		1.187		1.369	
Minimum	8.2		10.7		10.8	
Q1	13.60		13.70		13.40	
Median	14.10		14.40		14.40	
Q3	15.20		15.30		15.20	
Maximum	17.9		17.5		17.5	
Week 2						
N	71	71	152	151	151	151
Mean	14.10	-0.12	14.36	-0.07	14.18	-0.16
SD	1.426	0.496	1.174	0.529	1.266	0.506
Minimum	8.0	-1.1	11.2	-1.4	10.6	-1.3
Q1	13.40	-0.50	13.55	-0.40	13.40	-0.50
Median	14.30	-0.10	14.40	-0.10	14.20	-0.20
Q3	14.90	0.20	15.10	0.30	15.10	0.20
Maximum	16.9	1.0	17.1	1.4	17.3	1.1

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-25　血液学的検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（13/50）

Laboratory Test: Hemoglobin (g/dL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 4						
N	70	70	150	149	150	150
Mean	14.18	-0.04	14.33	-0.11	14.12	-0.22
SD	1.522	0.581	1.198	0.516	1.309	0.491
Minimum	7.8	-1.8	11.0	-1.9	10.4	-1.4
Q1	13.60	-0.40	13.60	-0.40	13.20	-0.60
Median	14.40	0.10	14.35	-0.10	14.20	-0.20
Q3	15.10	0.30	15.00	0.30	14.90	0.10
Maximum	17.7	1.1	17.8	1.1	17.5	1.2
Week 8						
N	68	68	149	148	149	149
Mean	14.13	-0.08	14.28	-0.14	14.07	-0.27
SD	1.406	0.554	1.241	0.563	1.330	0.526
Minimum	7.9	-1.3	10.1	-1.7	10.5	-1.7
Q1	13.55	-0.50	13.60	-0.50	13.20	-0.60
Median	14.30	-0.05	14.30	-0.15	14.00	-0.20
Q3	15.00	0.30	15.10	0.30	14.80	0.10
Maximum	17.3	1.1	17.1	1.2	17.4	1.1

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-25　血液学的検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（14/50）

Laboratory Test: Hemoglobin (g/dL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 12						
N	67	67	148	147	148	148
Mean	14.17	-0.01	14.25	-0.17	14.13	-0.22
SD	1.490	0.597	1.203	0.531	1.298	0.588
Minimum	8.5	-1.3	10.5	-1.4	10.9	-1.8
Q1	13.40	-0.50	13.50	-0.50	13.30	-0.60
Median	14.30	0.00	14.30	-0.20	14.10	-0.20
Q3	15.00	0.30	15.00	0.20	14.95	0.10
Maximum	18.1	1.2	17.2	1.0	17.4	1.9
Week 16						
N	66	66	148	147	147	147
Mean	14.24	0.11	14.43	0.01	14.18	-0.18
SD	1.478	0.598	1.209	0.647	1.354	0.638
Minimum	7.8	-1.0	10.9	-1.6	10.6	-1.6
Q1	13.60	-0.30	13.75	-0.50	13.30	-0.60
Median	14.40	0.10	14.50	0.00	14.20	-0.20
Q3	15.10	0.50	15.20	0.50	15.00	0.20
Maximum	18.1	2.0	17.1	1.3	17.8	2.0

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-25　血液学的検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（15/50）

Laboratory Test: Hemoglobin (g/dL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20						
N	65	65	146	145	148	148
Mean	14.35	0.22	14.56	0.12	14.29	-0.06
SD	1.569	0.572	1.199	0.553	1.285	0.590
Minimum	7.9	-1.0	10.6	-1.4	10.8	-1.8
Q1	13.60	-0.20	13.80	-0.20	13.50	-0.40
Median	14.60	0.20	14.60	0.20	14.25	0.00
Q3	15.10	0.70	15.30	0.50	15.10	0.30
Maximum	17.9	1.6	17.6	1.7	17.4	1.9
Week 24						
N	64	64	146	145	148	148
Mean	14.44	0.34	14.58	0.15	14.34	-0.01
SD	1.552	0.582	1.211	0.540	1.263	0.604
Minimum	7.6	-0.9	10.9	-1.2	10.4	-1.7
Q1	13.65	0.00	13.70	-0.20	13.55	-0.40
Median	14.60	0.40	14.70	0.20	14.40	0.10
Q3	15.35	0.70	15.40	0.50	15.10	0.40
Maximum	17.8	1.8	17.3	1.4	17.2	2.1

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-25　血液学的検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（16/50）

Laboratory Test: Hematocrit (%)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week -12						
N	71		152		151	
Mean	42.53		43.28		42.79	
SD	3.666		3.318		3.810	
Minimum	27.9		34.6		33.2	
Q1	40.50		41.25		39.90	
Median	42.70		43.35		42.60	
Q3	45.10		45.30		45.50	
Maximum	48.7		51.9		56.2	
Week -4						
N	71		152		151	
Mean	42.26		42.96		42.64	
SD	3.968		3.540		3.720	
Minimum	27.7		33.0		32.1	
Q1	39.90		40.90		40.10	
Median	42.50		43.00		43.00	
Q3	45.00		45.20		45.20	
Maximum	50.7		54.3		51.3	

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-25　血液学的検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（17/50）

Laboratory Test: Hematocrit (%)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 0						
N	71		151		151	
Mean	41.99		42.62		42.47	
SD	3.851		3.311		3.884	
Minimum	27.2		33.1		33.0	
Q1	39.80		40.60		39.90	
Median	42.30		42.50		42.50	
Q3	44.70		44.90		45.50	
Maximum	51.7		52.7		52.4	
Week 2						
N	71	71	152	151	151	151
Mean	41.71	-0.28	42.46	-0.16	42.01	-0.46
SD	3.889	1.443	3.295	1.651	3.637	1.534
Minimum	26.3	-3.5	33.9	-4.4	33.4	-4.6
Q1	39.70	-1.40	40.30	-1.30	39.70	-1.60
Median	42.40	-0.20	42.30	-0.10	41.90	-0.60
Q3	44.00	0.80	44.50	0.90	44.60	0.50
Maximum	49.4	2.7	50.6	4.2	51.5	3.5

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-25　血液学的検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（18/50）

Laboratory Test: Hematocrit (%)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 4						
N	70	70	150	149	150	150
Mean	41.97	-0.03	42.35	-0.31	41.83	-0.68
SD	4.228	1.686	3.343	1.527	3.730	1.534
Minimum	25.6	-4.7	33.6	-4.7	32.7	-4.0
Q1	39.80	-1.10	40.10	-1.30	39.10	-1.80
Median	42.35	0.30	42.50	-0.30	42.05	-0.70
Q3	44.70	1.20	44.30	0.80	44.50	0.20
Maximum	51.7	3.1	52.6	4.0	51.5	3.7
Week 8						
N	68	68	149	148	149	149
Mean	41.81	-0.14	42.19	-0.39	41.71	-0.77
SD	3.797	1.619	3.442	1.666	3.827	1.639
Minimum	26.4	-3.8	31.5	-5.2	32.5	-5.6
Q1	40.25	-1.55	40.10	-1.45	39.50	-1.90
Median	42.20	-0.10	42.20	-0.40	41.50	-0.60
Q3	44.30	0.95	44.30	0.90	43.90	0.30
Maximum	49.7	3.4	51.4	3.7	51.4	2.9

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-25　血液学的検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（19/50）

Laboratory Test: Hematocrit (%)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 12						
N	67	67	148	147	148	148
Mean	41.86	-0.06	42.10	-0.50	41.84	-0.67
SD	4.149	1.820	3.375	1.640	3.750	1.895
Minimum	27.7	-4.0	32.9	-4.2	31.8	-5.6
Q1	40.00	-1.10	39.95	-1.60	39.45	-2.00
Median	42.10	-0.10	42.20	-0.60	41.50	-0.60
Q3	44.50	0.70	43.90	0.50	44.25	0.50
Maximum	52.2	3.8	53.1	4.1	52.6	5.7
Week 16						
N	66	66	148	147	147	147
Mean	42.23	0.47	42.62	0.02	42.11	-0.44
SD	4.162	1.745	3.483	1.943	3.862	2.016
Minimum	26.1	-3.5	32.3	-4.5	31.1	-5.5
Q1	41.00	-0.60	40.45	-1.40	39.90	-1.60
Median	43.05	0.60	42.60	0.10	42.20	-0.60
Q3	44.70	1.50	45.10	1.30	44.40	0.90
Maximum	52.6	5.3	50.7	5.5	52.0	6.2

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-25　血液学的検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（20/50）

Laboratory Test: Hematocrit (%)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20						
N	65	65	146	145	148	148
Mean	42.35	0.59	43.03	0.41	42.41	-0.11
SD	4.310	1.682	3.393	1.704	3.767	1.802
Minimum	26.3	-2.9	33.0	-3.5	32.6	-5.8
Q1	40.30	-0.50	41.10	-0.70	39.95	-1.20
Median	42.70	0.50	43.05	0.50	42.45	-0.15
Q3	44.80	1.80	45.20	1.40	44.95	1.00
Maximum	51.5	4.5	51.9	5.4	53.3	5.2
Week 24						
N	64	64	146	145	148	148
Mean	42.70	1.01	43.30	0.69	42.57	0.05
SD	4.464	1.748	3.432	1.728	3.624	1.873
Minimum	24.6	-2.9	33.5	-3.8	31.8	-4.0
Q1	40.60	-0.15	40.90	-0.50	40.05	-1.30
Median	43.05	0.85	43.20	0.70	42.80	0.10
Q3	45.65	2.00	45.60	1.90	44.75	1.35
Maximum	52.6	5.5	52.0	6.6	51.5	5.3

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-25　血液学的検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（21/50）

Laboratory Test: Platelets (10^4 /μL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week -12						
N	71		151		149	
Mean	21.74		22.26		22.01	
SD	4.742		6.403		5.035	
Minimum	14.0		10.9		12.5	
Q1	18.10		17.70		17.90	
Median	20.50		21.30		21.80	
Q3	24.90		25.80		25.80	
Maximum	35.3		50.0		38.3	
Week -4						
N	71		151		148	
Mean	21.36		22.03		21.78	
SD	4.332		6.591		5.043	
Minimum	13.2		10.0		12.0	
Q1	18.00		17.70		18.05	
Median	20.50		20.70		21.25	
Q3	24.10		24.70		24.90	
Maximum	30.8		53.3		36.3	

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-25　血液学的検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（22/50）

Laboratory Test: Platelets (10^4 /μL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 0						
N	71		151		150	
Mean	21.36		22.02		21.50	
SD	4.386		5.982		5.175	
Minimum	13.6		10.4		11.8	
Q1	18.00		18.20		17.70	
Median	20.70		21.10		21.25	
Q3	24.10		24.60		24.40	
Maximum	32.2		48.6		35.7	
Week 2						
N	71	71	152	151	149	149
Mean	21.67	0.31	22.44	0.50	21.74	0.22
SD	4.650	2.362	6.480	1.982	5.128	2.403
Minimum	14.7	-4.2	10.3	-6.8	11.8	-19.8
Q1	18.40	-1.20	17.75	-0.60	18.10	-0.50
Median	20.70	0.10	21.35	0.30	21.60	0.20
Q3	24.80	1.60	25.55	1.70	24.70	1.40
Maximum	33.1	9.4	48.5	9.6	40.4	5.1

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-25　血液学的検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（23/50）

Laboratory Test: Platelets (10^4 /μL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 4						
N	70	70	150	149	149	148
Mean	21.57	0.22	22.10	0.14	21.86	0.32
SD	4.746	2.084	6.062	1.939	5.174	2.236
Minimum	11.5	-5.2	11.0	-8.3	11.5	-16.5
Q1	18.00	-0.80	17.70	-0.70	18.00	-0.70
Median	21.15	0.15	21.25	0.20	21.60	0.40
Q3	24.70	1.90	25.10	1.10	25.40	1.60
Maximum	33.3	5.0	46.3	4.3	37.7	5.9
Week 8						
N	68	68	149	148	149	148
Mean	21.49	0.15	22.28	0.27	21.57	0.08
SD	4.274	1.814	6.311	2.067	4.891	2.267
Minimum	14.6	-3.9	9.5	-6.8	11.6	-14.7
Q1	17.75	-0.90	18.40	-0.70	18.20	-0.85
Median	21.40	0.15	21.50	0.30	21.10	0.35
Q3	24.25	1.40	25.10	1.55	23.90	1.40
Maximum	31.5	5.6	51.3	6.3	37.0	6.7

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-25　血液学的検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（24/50）

Laboratory Test: Platelets (10^4 /μL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 12						
N	67	67	147	146	148	147
Mean	21.62	0.18	22.43	0.42	22.02	0.51
SD	4.703	1.854	5.927	2.098	5.360	2.655
Minimum	13.3	-3.9	10.9	-7.3	11.4	-15.8
Q1	18.40	-1.40	18.30	-0.80	18.40	-0.80
Median	21.50	0.40	21.40	0.50	21.75	0.50
Q3	24.20	1.40	25.90	1.60	24.75	1.80
Maximum	34.3	5.3	47.8	7.4	40.5	10.4
Week 16						
N	65	65	147	146	147	146
Mean	21.67	0.10	22.93	0.93	22.56	1.08
SD	4.536	2.044	6.494	2.583	5.555	2.365
Minimum	13.6	-5.3	10.7	-5.5	12.1	-14.1
Q1	18.20	-1.00	18.60	-0.60	18.60	0.10
Median	21.40	0.00	21.80	0.80	21.80	1.10
Q3	24.40	1.40	26.90	2.20	25.90	2.30
Maximum	31.2	3.9	49.5	9.8	37.2	7.0

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-25　血液学的検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（25/50）

Laboratory Test: Platelets (10^4/μL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20						
N	65	65	145	144	147	147
Mean	21.97	0.52	23.01	0.89	22.85	1.34
SD	4.963	2.087	6.570	2.797	5.863	2.756
Minimum	14.8	-7.8	9.7	-10.0	12.6	-13.7
Q1	18.00	-0.60	18.50	-0.50	18.60	-0.10
Median	21.00	0.50	22.10	0.95	22.10	1.20
Q3	25.10	1.60	26.70	2.15	25.40	2.60
Maximum	35.9	4.7	52.7	15.6	46.6	10.9
Week 24						
N	64	64	146	145	148	147
Mean	22.39	0.88	23.15	1.05	22.88	1.37
SD	5.234	2.591	6.243	2.307	5.583	2.634
Minimum	12.8	-10.1	9.6	-9.2	11.9	-11.5
Q1	18.60	-0.45	18.90	-0.30	19.30	-0.20
Median	21.60	1.10	22.50	1.10	22.45	1.30
Q3	25.70	2.40	26.90	2.60	25.80	2.90
Maximum	37.2	6.9	42.3	6.6	40.1	8.6

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-25　血液学的検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（26/50）

Laboratory Test: Neutrophils (%)

Visit / Statistics	Placebo (N=71) Observed Value at Visit	Placebo (N=71) Change from Baseline	QD (N=152) Observed Value at Visit	QD (N=152) Change from Baseline	BID (N=151) Observed Value at Visit	BID (N=151) Change from Baseline
Week -12						
N	71		152		151	
Mean	59.83		58.59		58.76	
SD	8.565		7.298		8.966	
Minimum	43.3		39.6		27.1	
Q1	53.00		54.20		52.70	
Median	59.10		58.15		59.00	
Q3	67.00		63.00		66.00	
Maximum	77.5		78.5		77.5	
Week -4						
N	71		152		151	
Mean	58.74		59.07		58.96	
SD	7.301		8.465		9.331	
Minimum	37.2		35.7		27.0	
Q1	53.00		54.30		52.00	
Median	59.30		58.65		58.90	
Q3	64.00		65.90		66.00	
Maximum	76.0		84.0		82.5	

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-25　血液学的検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（27/50）

Laboratory Test: Neutrophils (%)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 0						
N	71		151		151	
Mean	59.60		59.78		58.96	
SD	7.912		7.999		8.527	
Minimum	42.5		35.4		31.5	
Q1	53.80		55.00		53.90	
Median	60.40		60.00		58.70	
Q3	65.00		65.00		65.20	
Maximum	79.0		83.5		81.0	
Week 2						
N	71	71	152	151	151	151
Mean	59.59	-0.01	59.81	0.00	58.57	-0.39
SD	7.658	5.934	8.352	5.934	8.000	6.315
Minimum	44.0	-15.3	36.0	-16.0	40.1	-23.8
Q1	53.70	-3.60	53.40	-2.90	52.40	-3.70
Median	58.30	0.10	59.80	0.30	57.70	-0.20
Q3	64.00	4.00	65.40	3.50	65.00	3.30
Maximum	80.0	24.1	84.0	22.7	80.5	19.0

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-25　血液学的検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（28/50）

Laboratory Test: Neutrophils (%)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 4						
N	70	70	150	149	150	150
Mean	59.13	-0.55	58.85	-1.00	58.68	-0.26
SD	6.853	5.643	7.884	6.639	8.215	6.405
Minimum	44.9	-12.6	32.9	-36.4	35.0	-29.9
Q1	54.60	-4.10	54.30	-4.90	53.10	-4.20
Median	59.00	-0.95	58.40	-0.10	58.45	0.00
Q3	64.50	2.60	65.00	3.20	64.00	3.00
Maximum	74.0	13.7	77.0	14.2	80.0	15.7
Week 8						
N	68	68	149	148	149	149
Mean	60.42	0.75	58.99	-0.92	58.46	-0.49
SD	7.058	6.940	7.543	6.329	8.122	6.870
Minimum	46.2	-14.7	38.4	-27.3	29.0	-20.0
Q1	55.05	-3.75	54.90	-3.65	52.80	-4.20
Median	61.00	1.55	59.50	-0.40	58.00	-0.30
Q3	65.00	5.75	64.20	2.50	63.00	3.40
Maximum	76.0	14.9	75.0	14.0	82.5	19.4

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-25　血液学的検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（29/50）

Laboratory Test: Neutrophils (%)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 12						
N	67	67	148	147	148	148
Mean	59.97	0.39	58.71	-1.15	59.77	0.83
SD	6.982	6.212	7.708	6.983	8.456	7.547
Minimum	38.5	-17.3	33.2	-31.6	29.7	-16.6
Q1	56.00	-3.70	53.65	-4.00	54.70	-3.80
Median	59.70	0.50	58.75	0.00	59.05	0.25
Q3	64.00	5.50	64.00	2.80	65.90	5.00
Maximum	78.5	13.5	74.3	17.1	84.5	33.8
Week 16						
N	66	66	148	147	146	146
Mean	59.63	0.15	59.50	-0.38	58.98	0.00
SD	7.371	6.157	8.401	7.381	7.808	6.381
Minimum	43.2	-11.9	39.7	-33.0	35.6	-22.1
Q1	54.50	-4.50	53.55	-5.00	53.80	-3.90
Median	59.95	1.20	59.80	-0.20	58.65	0.35
Q3	64.90	4.00	64.95	4.50	64.80	3.90
Maximum	77.9	20.5	81.5	18.3	77.4	20.7

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-25　血液学的検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（30/50）

Laboratory Test: Neutrophils (%)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20						
N	64	64	146	145	148	148
Mean	59.46	-0.31	59.35	-0.48	59.06	0.12
SD	7.337	6.373	7.563	7.051	7.667	6.326
Minimum	43.4	-14.8	36.3	-22.8	39.5	-22.4
Q1	54.20	-4.10	55.00	-4.70	53.50	-2.95
Median	59.25	-1.10	60.00	-0.30	58.95	0.20
Q3	64.80	3.00	64.40	3.60	65.00	3.75
Maximum	75.0	13.1	75.8	21.7	78.2	27.8
Week 24						
N	64	64	146	145	148	148
Mean	59.48	-0.21	60.24	0.43	58.90	-0.05
SD	7.774	6.116	7.802	6.484	8.270	6.967
Minimum	43.1	-18.2	36.2	-16.5	36.5	-24.3
Q1	54.10	-4.40	55.10	-2.80	53.40	-4.35
Median	58.80	0.30	59.85	1.00	58.85	-0.05
Q3	64.55	4.60	65.90	4.60	65.20	4.35
Maximum	74.5	10.2	80.5	21.0	76.7	26.7

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-25　血液学的検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（31/50）

Laboratory Test: Eosinophils (%)

Visit / Statistics	Placebo (N=71) Observed Value at Visit	Placebo (N=71) Change from Baseline	QD (N=152) Observed Value at Visit	QD (N=152) Change from Baseline	BID (N=151) Observed Value at Visit	BID (N=151) Change from Baseline
Week -12						
N	71		152		151	
Mean	2.89		2.69		2.69	
SD	2.651		1.913		2.179	
Minimum	0.3		0.0		0.0	
Q1	1.50		1.45		1.30	
Median	2.00		2.10		2.10	
Q3	3.20		3.60		3.40	
Maximum	16.5		11.0		18.3	
Week -4						
N	71		152		151	
Mean	2.78		2.59		3.07	
SD	2.805		1.811		2.309	
Minimum	0.0		0.0		0.0	
Q1	1.40		1.35		1.70	
Median	2.00		2.10		2.50	
Q3	3.00		3.00		4.00	
Maximum	21.0		12.5		16.5	

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-25　血液学的検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（32/50）

Laboratory Test: Eosinophils (%)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 0						
N	71		151		151	
Mean	2.77		2.59		2.81	
SD	2.442		1.889		2.080	
Minimum	0.0		0.0		0.0	
Q1	1.00		1.20		1.50	
Median	2.10		2.00		2.00	
Q3	4.00		3.10		3.80	
Maximum	15.3		12.5		15.1	
Week 2						
N	71	71	152	151	151	151
Mean	2.60	-0.17	2.40	-0.18	2.58	-0.24
SD	2.189	1.542	1.559	1.380	2.036	1.364
Minimum	0.0	-8.5	0.0	-8.7	0.0	-5.0
Q1	1.00	-0.50	1.20	-0.60	1.30	-1.00
Median	2.00	0.00	2.00	0.00	2.00	-0.10
Q3	3.60	0.50	3.00	0.40	3.20	0.50
Maximum	14.3	3.3	8.9	3.6	15.9	3.7

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-25　血液学的検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（33/50）

Laboratory Test: Eosinophils (%)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 4						
N	70	70	150	149	150	150
Mean	2.63	-0.04	2.59	0.03	2.65	-0.17
SD	2.264	1.280	1.775	1.494	2.036	1.442
Minimum	0.0	-3.6	0.0	-7.7	0.0	-6.5
Q1	1.30	-0.50	1.40	-0.50	1.30	-0.80
Median	2.00	-0.10	2.15	0.00	2.10	-0.10
Q3	3.00	0.80	3.50	0.60	3.20	0.50
Maximum	15.1	5.0	11.1	5.0	13.0	5.3
Week 8						
N	68	68	149	148	149	149
Mean	2.33	-0.34	2.49	-0.07	2.68	-0.13
SD	2.153	1.318	1.579	1.359	2.075	1.672
Minimum	0.0	-4.5	0.0	-6.9	0.0	-6.6
Q1	1.00	-1.00	1.20	-0.80	1.30	-0.80
Median	2.00	-0.20	2.00	0.00	2.00	-0.10
Q3	2.85	0.30	3.40	0.70	3.60	0.60
Maximum	14.8	3.5	9.1	2.8	14.0	8.8

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-25　血液学的検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（34/50）

Laboratory Test: Eosinophils (%)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 12						
N	67	67	148	147	148	148
Mean	2.45	-0.23	2.63	0.07	2.80	-0.01
SD	1.984	1.336	1.684	1.705	2.034	1.562
Minimum	0.0	-4.9	0.0	-9.3	0.0	-7.4
Q1	1.00	-0.70	1.40	-0.60	1.50	-0.75
Median	2.00	-0.10	2.15	0.00	2.10	0.00
Q3	3.00	0.50	3.25	0.90	3.40	0.70
Maximum	11.7	3.0	8.3	7.8	13.7	5.5
Week 16						
N	66	66	148	147	146	146
Mean	2.43	-0.28	2.74	0.19	2.87	0.07
SD	1.879	1.445	1.846	1.429	2.257	1.537
Minimum	0.0	-6.0	0.0	-7.7	0.0	-8.4
Q1	1.10	-0.80	1.40	-0.50	1.30	-0.60
Median	2.00	-0.10	2.15	0.10	2.30	0.00
Q3	3.20	0.50	3.85	1.00	3.90	0.80
Maximum	9.4	3.0	11.8	4.9	17.5	5.5

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-25　血液学的検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（35/50）

Laboratory Test: Eosinophils (%)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20						
N	64	64	146	145	148	148
Mean	2.54	-0.22	2.83	0.29	2.78	-0.03
SD	1.855	1.876	1.796	1.565	2.308	1.733
Minimum	0.5	-8.8	0.0	-7.5	0.0	-8.7
Q1	1.10	-0.60	1.70	-0.40	1.20	-0.70
Median	2.00	-0.10	2.40	0.20	2.10	0.00
Q3	3.40	0.60	3.40	1.00	3.65	0.50
Maximum	8.4	5.5	10.7	8.0	16.4	8.5
Week 24						
N	64	64	146	145	148	148
Mean	2.46	-0.27	2.75	0.21	2.78	-0.03
SD	2.060	1.488	1.774	1.504	1.970	1.613
Minimum	0.3	-5.0	0.0	-7.8	0.3	-10.9
Q1	1.00	-0.95	1.50	-0.40	1.50	-0.70
Median	1.95	0.00	2.15	0.10	2.10	-0.05
Q3	3.20	0.50	3.50	0.90	3.50	0.75
Maximum	10.3	3.4	11.0	6.7	15.1	4.3

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-25　血液学的検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（36/50）

Laboratory Test: Monocytes (%)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week -12						
N	71		152		151	
Mean	6.64		6.59		6.69	
SD	2.231		1.836		1.986	
Minimum	3.0		2.5		2.9	
Q1	5.10		5.20		5.00	
Median	6.00		6.45		6.60	
Q3	8.00		7.85		8.00	
Maximum	18.5		12.4		12.3	
Week -4						
N	71		152		151	
Mean	6.85		6.63		6.42	
SD	2.189		2.022		1.708	
Minimum	3.3		2.0		2.9	
Q1	5.40		5.00		5.00	
Median	6.70		6.60		6.40	
Q3	8.00		8.00		7.50	
Maximum	17.0		12.8		10.9	

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-25　血液学的検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（37/50）

Laboratory Test: Monocytes (%)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 0						
N	71		151		151	
Mean	6.59		6.32		6.41	
SD	2.213		1.884		1.685	
Minimum	3.8		2.8		3.0	
Q1	5.00		5.00		5.10	
Median	6.50		6.00		6.00	
Q3	7.50		7.50		7.50	
Maximum	18.0		12.3		14.5	
Week 2						
N	71	71	152	151	151	151
Mean	6.54	-0.06	6.39	0.08	6.27	-0.14
SD	2.065	1.903	2.040	1.616	1.809	1.572
Minimum	3.8	-6.4	2.1	-5.4	2.8	-4.0
Q1	5.00	-1.00	5.00	-1.00	5.00	-1.00
Median	6.30	0.00	6.20	0.00	6.00	0.00
Q3	8.00	1.20	7.45	1.10	7.60	0.90
Maximum	16.5	4.0	13.5	5.0	11.1	4.0

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-25　血液学的検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（38/50）

Laboratory Test: Monocytes (%)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 4						
N	70	70	150	149	150	150
Mean	6.49	-0.10	6.43	0.12	6.28	-0.14
SD	2.063	1.671	1.815	1.838	1.791	1.653
Minimum	3.0	-5.4	2.7	-8.5	1.1	-6.4
Q1	5.40	-1.00	5.00	-1.00	5.00	-1.00
Median	6.15	0.00	6.05	0.00	6.05	0.00
Q3	7.30	0.90	8.00	1.40	7.80	1.00
Maximum	17.5	5.2	11.5	5.2	10.0	4.2
Week 8						
N	68	68	149	148	149	149
Mean	6.31	-0.25	6.26	-0.02	6.38	-0.04
SD	2.442	1.925	1.707	1.582	1.736	1.470
Minimum	3.0	-7.4	3.0	-3.5	2.4	-4.5
Q1	5.00	-1.05	5.00	-1.00	5.10	-1.00
Median	6.00	-0.10	6.00	0.00	6.20	0.00
Q3	7.20	1.00	7.10	1.00	7.40	1.00
Maximum	20.5	4.5	11.5	4.8	10.7	4.5

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-25　血液学的検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（39/50）

Laboratory Test: Monocytes (%)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 12						
N	67	67	148	147	148	148
Mean	6.37	-0.17	6.52	0.26	6.27	-0.15
SD	2.188	1.698	1.859	1.751	1.849	1.745
Minimum	3.0	-5.7	2.5	-5.5	2.2	-7.5
Q1	5.00	-1.00	5.00	-0.90	5.00	-1.00
Median	6.00	0.00	6.35	0.40	6.00	0.00
Q3	7.10	1.00	7.70	1.40	7.55	1.00
Maximum	16.0	3.6	11.4	4.7	11.5	5.0
Week 16						
N	66	66	148	147	146	146
Mean	6.62	0.05	6.38	0.11	6.41	-0.01
SD	2.576	1.785	1.806	1.596	1.862	1.508
Minimum	2.6	-6.4	2.5	-4.5	3.0	-4.2
Q1	5.00	-0.90	5.00	-1.00	5.20	-1.00
Median	6.45	0.00	6.05	0.30	6.00	0.00
Q3	7.60	1.10	7.45	1.20	7.60	0.90
Maximum	22.5	4.5	11.5	4.2	11.9	4.0

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-25　血液学的検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（40/50）

Laboratory Test: Monocytes (%)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20						
N	64	64	146	145	148	148
Mean	6.60	0.20	6.31	0.05	6.45	0.03
SD	1.539	1.874	1.683	1.504	1.954	1.858
Minimum	3.0	-5.8	2.0	-3.7	1.6	-5.0
Q1	5.50	-0.50	5.20	-1.00	5.05	-1.20
Median	6.80	0.20	6.10	0.00	6.30	0.00
Q3	7.95	1.25	7.20	1.00	7.60	1.20
Maximum	9.5	4.0	12.4	4.0	11.8	5.8
Week 24						
N	64	64	146	145	148	148
Mean	6.92	0.39	6.43	0.15	6.66	0.24
SD	1.923	1.802	1.944	1.625	1.974	1.757
Minimum	3.0	-4.8	2.0	-3.5	2.0	-5.0
Q1	5.95	-0.50	5.00	-1.00	5.20	-0.85
Median	7.00	0.50	6.25	0.10	6.40	0.20
Q3	7.85	1.45	7.40	1.10	8.00	1.05
Maximum	16.5	4.3	12.9	5.7	12.3	5.9

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-25　血液学的検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（41/50）

Laboratory Test: Lymphocytes (%)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week -12						
N	71		152		151	
Mean	30.21		31.68		31.41	
SD	7.950		6.685		7.774	
Minimum	12.8		17.0		15.5	
Q1	24.70		26.55		25.80	
Median	30.00		31.20		30.30	
Q3	36.00		36.00		36.10	
Maximum	48.2		49.3		52.8	
Week -4						
N	71		152		151	
Mean	31.16		31.28		31.11	
SD	6.892		7.360		8.364	
Minimum	10.5		9.0		11.0	
Q1	26.50		26.45		25.00	
Median	30.80		30.65		31.20	
Q3	36.60		36.40		36.70	
Maximum	51.1		50.8		54.1	

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-25　血液学的検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（42/50）

Laboratory Test: Lymphocytes (%)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 0						
N	71		151		151	
Mean	30.63		30.90		31.43	
SD	6.864		7.032		7.722	
Minimum	16.0		13.0		13.5	
Q1	26.00		26.00		25.70	
Median	30.00		30.00		31.40	
Q3	36.10		35.50		36.60	
Maximum	45.4		52.0		49.5	
Week 2						
N	71	71	152	151	151	151
Mean	30.84	0.21	30.97	0.08	32.13	0.71
SD	7.025	4.881	7.242	5.023	7.472	5.404
Minimum	13.5	-14.2	9.5	-17.0	13.5	-18.5
Q1	26.10	-3.00	26.00	-3.00	27.00	-2.00
Median	31.00	0.50	30.50	-0.20	32.30	0.40
Q3	35.30	3.40	36.35	2.60	37.60	3.90
Maximum	44.3	13.5	47.9	17.8	46.2	21.9

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-25　血液学的検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（43/50）

Laboratory Test: Lymphocytes (%)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 4						
N	70	70	150	149	150	150
Mean	31.30	0.65	31.68	0.81	31.99	0.56
SD	6.143	4.982	7.238	5.545	7.557	5.375
Minimum	13.0	-11.2	18.0	-10.6	13.0	-13.4
Q1	27.00	-3.00	26.00	-2.50	27.00	-2.60
Median	30.80	1.10	31.70	0.10	32.00	0.55
Q3	35.80	4.00	36.20	4.30	37.50	4.00
Maximum	43.6	12.6	55.6	29.4	51.7	26.9
Week 8						
N	68	68	149	148	149	149
Mean	30.60	-0.08	31.87	1.03	32.12	0.69
SD	6.401	5.729	6.889	5.508	7.617	6.219
Minimum	13.0	-9.8	18.0	-13.0	10.5	-17.3
Q1	27.00	-3.90	27.60	-2.00	26.00	-2.70
Median	30.00	-0.85	31.00	0.75	32.00	0.70
Q3	35.15	3.75	36.00	3.10	37.70	4.80
Maximum	42.8	15.7	49.2	22.0	55.0	18.9

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-25　血液学的検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（44/50）

Laboratory Test: Lymphocytes (%)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 12						
N	67	67	148	147	148	148
Mean	30.86	0.08	31.77	0.85	30.76	-0.68
SD	6.272	5.249	7.028	5.931	7.580	6.198
Minimum	13.5	-10.1	17.5	-14.9	11.5	-26.3
Q1	27.00	-4.10	27.00	-3.00	25.40	-4.60
Median	30.50	0.20	31.95	0.20	31.10	-0.30
Q3	35.10	4.00	36.00	3.30	35.95	3.80
Maximum	43.0	11.1	55.4	20.6	49.8	14.6
Week 16						
N	66	66	148	147	146	146
Mean	30.93	0.10	31.01	0.13	31.32	-0.09
SD	6.709	4.786	7.447	6.155	7.303	5.514
Minimum	11.6	-10.0	11.8	-14.3	13.2	-19.3
Q1	26.10	-3.20	26.00	-4.00	26.00	-3.30
Median	30.90	-0.95	30.60	0.20	32.00	0.00
Q3	36.10	4.00	35.70	3.90	36.60	3.00
Maximum	44.2	11.2	49.4	25.9	47.0	19.8

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-25　血液学的検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（45/50）

Laboratory Test: Lymphocytes (%)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20						
N	64	64	146	145	148	148
Mean	31.03	0.36	31.14	0.19	31.33	-0.10
SD	6.874	5.110	6.715	5.923	6.753	5.358
Minimum	15.0	-10.8	17.0	-14.9	15.8	-25.0
Q1	26.10	-2.60	26.90	-3.40	26.00	-2.90
Median	31.35	0.35	30.00	-0.20	31.05	0.20
Q3	35.50	3.80	35.70	3.70	36.40	2.55
Maximum	44.5	11.9	49.8	17.5	47.8	20.0
Week 24						
N	64	64	146	145	148	148
Mean	30.76	0.14	30.17	-0.80	31.22	-0.21
SD	7.539	4.892	6.725	5.672	7.458	5.768
Minimum	13.5	-8.9	14.5	-20.2	15.0	-21.7
Q1	24.95	-3.65	26.00	-4.00	26.00	-3.40
Median	31.80	0.05	29.40	-1.40	30.10	0.00
Q3	34.95	3.70	35.40	2.00	37.05	3.70
Maximum	46.7	15.6	48.4	15.0	49.4	21.4

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-25　血液学的検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（46/50）

Laboratory Test: Basophils (%)

Visit / Statistics	Placebo (N=71) Observed Value at Visit	Placebo (N=71) Change from Baseline	QD (N=152) Observed Value at Visit	QD (N=152) Change from Baseline	BID (N=151) Observed Value at Visit	BID (N=151) Change from Baseline
Week -12						
N	71		152		151	
Mean	0.43		0.44		0.45	
SD	0.343		0.393		0.388	
Minimum	0.0		0.0		0.0	
Q1	0.20		0.20		0.00	
Median	0.40		0.40		0.40	
Q3	0.70		0.60		0.70	
Maximum	1.0		2.7		1.9	
Week -4						
N	71		152		151	
Mean	0.47		0.43		0.44	
SD	0.430		0.337		0.384	
Minimum	0.0		0.0		0.0	
Q1	0.20		0.20		0.10	
Median	0.40		0.40		0.40	
Q3	0.70		0.60		0.70	
Maximum	2.5		1.2		2.1	

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-25　血液学的検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（47/50）

Laboratory Test: Basophils (%)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 0						
N	71		151		151	
Mean	0.41		0.43		0.39	
SD	0.319		0.345		0.324	
Minimum	0.0		0.0		0.0	
Q1	0.10		0.20		0.20	
Median	0.40		0.40		0.40	
Q3	0.60		0.60		0.50	
Maximum	1.0		2.0		1.5	
Week 2						
N	71	71	152	151	151	151
Mean	0.44	0.03	0.43	0.01	0.44	0.05
SD	0.351	0.488	0.329	0.487	0.340	0.471
Minimum	0.0	-1.0	0.0	-1.0	0.0	-1.0
Q1	0.20	-0.20	0.20	-0.20	0.20	-0.20
Median	0.40	0.00	0.40	0.00	0.40	0.00
Q3	0.70	0.30	0.60	0.20	0.60	0.30
Maximum	1.0	1.0	1.1	1.0	1.9	1.5

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-25　血液学的検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（48/50）

Laboratory Test: Basophils (%)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 4						
N	70	70	150	149	150	150
Mean	0.45	0.04	0.45	0.03	0.40	0.01
SD	0.308	0.401	0.332	0.457	0.337	0.429
Minimum	0.0	-1.0	0.0	-1.1	0.0	-1.2
Q1	0.30	-0.10	0.20	-0.20	0.10	-0.20
Median	0.40	0.00	0.40	0.00	0.40	0.00
Q3	0.50	0.20	0.60	0.20	0.60	0.20
Maximum	1.0	1.0	1.1	1.0	1.5	1.0
Week 8						
N	68	68	149	148	149	149
Mean	0.34	-0.08	0.40	-0.01	0.36	-0.03
SD	0.315	0.423	0.319	0.430	0.344	0.448
Minimum	0.0	-1.0	0.0	-1.1	0.0	-1.0
Q1	0.00	-0.30	0.20	-0.20	0.00	-0.20
Median	0.30	0.00	0.40	0.00	0.30	0.00
Q3	0.50	0.10	0.60	0.20	0.50	0.10
Maximum	1.2	1.0	1.3	1.0	2.5	2.0

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-25　血液学的検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（49/50）

Laboratory Test: Basophils (%)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 12						
N	67	67	148	147	148	148
Mean	0.34	-0.06	0.38	-0.03	0.40	0.01
SD	0.306	0.417	0.322	0.413	0.307	0.442
Minimum	0.0	-1.0	0.0	-1.0	0.0	-1.0
Q1	0.00	-0.30	0.10	-0.20	0.20	-0.20
Median	0.30	0.00	0.40	0.00	0.40	0.00
Q3	0.50	0.20	0.50	0.10	0.50	0.20
Maximum	1.0	0.9	2.0	1.7	1.5	1.2
Week 16						
N	66	66	148	147	146	146
Mean	0.39	-0.02	0.36	-0.05	0.42	0.03
SD	0.299	0.419	0.289	0.447	0.381	0.489
Minimum	0.0	-1.0	0.0	-1.1	0.0	-1.5
Q1	0.30	-0.30	0.20	-0.30	0.20	-0.20
Median	0.30	0.00	0.30	0.00	0.30	0.00
Q3	0.50	0.20	0.50	0.20	0.50	0.30
Maximum	1.6	1.0	1.2	1.0	2.7	2.3

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-25　血液学的検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（50/50）

Laboratory Test: Basophils (%)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20						
N	64	64	146	145	148	148
Mean	0.37	-0.05	0.37	-0.04	0.38	-0.02
SD	0.226	0.401	0.303	0.438	0.300	0.423
Minimum	0.0	-1.0	0.0	-1.1	0.0	-1.1
Q1	0.20	-0.20	0.20	-0.30	0.20	-0.20
Median	0.40	0.00	0.30	0.00	0.30	0.00
Q3	0.50	0.20	0.50	0.20	0.50	0.20
Maximum	1.0	1.0	1.7	1.4	2.0	1.5
Week 24						
N	64	64	146	145	148	148
Mean	0.37	-0.05	0.42	0.01	0.44	0.04
SD	0.237	0.452	0.306	0.420	0.319	0.434
Minimum	0.0	-1.0	0.0	-1.0	0.0	-1.0
Q1	0.25	-0.30	0.20	-0.20	0.30	-0.20
Median	0.40	-0.10	0.40	0.00	0.40	0.00
Q3	0.50	0.20	0.50	0.20	0.50	0.25
Maximum	1.2	1.2	1.4	1.0	1.9	1.5

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-26　血液学的検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（1/20）

RBC

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 2												
Low	6	3	-	9	13	8	-	21	11	6	-	17
Normal	2	56	2	60	1	125	1	127	5	124	3	132
High	-	-	2	2	-	1	2	3	-	-	2	2
Total	8	59	4	71	14	134	3	151	16	130	5	151
Week 4												
Low	6	3	-	9	13	7	-	20	11	8	-	19
Normal	2	55	2	59	1	124	1	126	5	121	3	129
High	-	-	2	2	-	1	2	3	-	-	2	2
Total	8	58	4	70	14	132	3	149	16	129	5	150
Week 8												
Low	6	2	-	8	12	9	-	21	14	9	-	23
Normal	2	54	2	58	2	122	1	125	2	118	2	122
High	-	-	2	2	-	1	1	2	-	1	3	4
Total	8	56	4	68	14	132	2	148	16	128	5	149
Week 12												
Low	7	1	-	8	12	5	-	17	12	6	-	18
Normal	1	54	1	56	2	124	1	127	4	120	1	125
High	-	-	3	3	-	2	1	3	-	1	4	5
Total	8	55	4	67	14	131	2	147	16	127	5	148

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.3

表 2.7.4.7-付録-26　血液学的検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（2/20）

RBC

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 16												
Low	6	2	-	8	9	5	-	14	12	7	-	19
Normal	2	53	1	56	5	124	1	130	4	118	2	124
High	-	-	2	2	-	2	1	3	-	1	3	4
Total	8	55	3	66	14	131	2	147	16	126	5	147
Week 20												
Low	6	1	-	7	7	4	-	11	11	6	-	17
Normal	2	53	-	55	7	123	-	130	5	120	3	128
High	-	-	3	3	-	2	2	4	-	1	2	3
Total	8	54	3	65	14	129	2	145	16	127	5	148
Week 24												
Low	5	1	-	6	12	1	-	13	10	4	-	14
Normal	3	52	-	55	2	126	-	128	6	123	2	131
High	-	-	3	3	-	2	2	4	-	-	3	3
Total	8	53	3	64	14	129	2	145	16	127	5	148

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.3

表 2.7.4.7-付録-26　血液学的検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（3/20）

WBC

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 2												
Low	-	-	-	-	-	-	-	-	3	-	-	3
Normal	-	65	1	66	1	123	9	133	-	124	10	134
High	-	4	1	5	-	4	14	18	-	5	9	14
Total	-	69	2	71	1	127	23	151	3	129	19	151
Week 4												
Low	-	-	-	-	-	-	-	-	2	-	-	2
Normal	-	66	1	67	1	121	11	133	1	123	7	131
High	-	2	1	3	-	4	12	16	-	5	12	17
Total	-	68	2	70	1	125	23	149	3	128	19	150
Week 8												
Low	-	-	-	-	-	-	-	-	3	1	-	4
Normal	-	63	1	64	1	120	13	134	-	120	11	131
High	-	4	-	4	-	4	10	14	-	6	8	14
Total	-	67	1	68	1	124	23	148	3	127	19	149
Week 12												
Low	-	-	-	-	-	-	-	-	2	1	-	3
Normal	-	64	1	65	1	118	10	129	1	120	8	129
High	-	2	-	2	-	5	13	18	-	5	11	16
Total	-	66	1	67	1	123	23	147	3	126	19	148

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.3

表 2.7.4.7-付録-26　血液学的検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（4/20）

WBC

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 16												
Low	-	2	-	2	-	1	-	1	2	-	-	2
Normal	-	60	-	60	1	118	9	128	1	121	9	131
High	-	4	-	4	-	4	14	18	-	4	10	14
Total	-	66	-	66	1	123	23	147	3	125	19	147
Week 20												
Low	-	1	-	1	-	-	-	-	2	-	-	2
Normal	-	62	-	62	1	115	12	128	1	123	9	133
High	-	2	-	2	-	6	11	17	-	3	10	13
Total	-	65	-	65	1	121	23	145	3	126	19	148
Week 24												
Low	-	-	-	-	-	-	-	-	1	1	-	2
Normal	-	60	-	60	1	113	11	125	2	118	6	126
High	-	4	-	4	-	8	12	20	-	7	13	20
Total	-	64	-	64	1	121	23	145	3	126	19	148

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.3

表 2.7.4.7-付録-26　血液学的検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（5/20）

Hemoglobin

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 2												
Low	4	5	-	9	7	8	-	15	13	5	-	18
Normal	1	59	2	62	1	133	1	135	2	129	-	131
High	-	-	-	-	-	1	-	1	-	1	1	2
Total	5	64	2	71	8	142	1	151	15	135	1	151
Week 4												
Low	3	4	-	7	7	10	-	17	12	6	-	18
Normal	2	57	2	61	1	129	1	131	3	127	1	131
High	-	2	-	2	-	1	-	1	-	1	-	1
Total	5	63	2	70	8	140	1	149	15	134	1	150
Week 8												
Low	5	2	-	7	6	10	-	16	13	10	-	23
Normal	-	59	2	61	2	129	1	132	2	123	-	125
High	-	-	-	-	-	-	-	-	-	-	1	1
Total	5	61	2	68	8	139	1	148	15	133	1	149
Week 12												
Low	3	3	-	6	5	11	-	16	12	7	-	19
Normal	2	56	1	59	3	126	1	130	3	125	-	128
High	-	1	1	2	-	1	-	1	-	-	1	1
Total	5	60	2	67	8	138	1	147	15	132	1	148

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.3

表 2.7.4.7-付録-26　血液学的検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（6/20）

Hemoglobin

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 16												
Low	4	4	-	8	5	7	-	12	13	8	-	21
Normal	1	54	1	56	3	128	1	132	2	122	-	124
High	-	2	-	2	-	3	-	3	-	1	1	2
Total	5	60	1	66	8	138	1	147	15	131	1	147
Week 20												
Low	4	2	-	6	5	5	-	10	12	5	-	17
Normal	1	56	1	58	3	128	-	131	3	127	-	130
High	-	1	-	1	-	3	1	4	-	-	1	1
Total	5	59	1	65	8	136	1	145	15	132	1	148
Week 24												
Low	2	1	-	3	4	5	-	9	13	3	-	16
Normal	3	55	-	58	4	130	1	135	2	129	-	131
High	-	2	1	3	-	1	-	1	-	-	1	1
Total	5	58	1	64	8	136	1	145	15	132	1	148

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.3

表 2.7.4.7-付録-26　血液学的検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（7/20）

Hematocrit

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 2												
Low	3	7	-	10	6	4	-	10	9	6	-	15
Normal	1	60	-	61	-	139	2	141	4	131	-	135
High	-	-	-	-	-	-	-	-	-	-	1	1
Total	4	67	-	71	6	143	2	151	13	137	1	151
Week 4												
Low	3	3	-	6	5	10	-	15	10	8	-	18
Normal	1	62	-	63	1	130	2	133	3	127	1	131
High	-	1	-	1	-	1	-	1	-	1	-	1
Total	4	66	-	70	6	141	2	149	13	136	1	150
Week 8												
Low	4	4	-	8	5	10	-	15	9	7	-	16
Normal	-	60	-	60	1	130	2	133	4	128	-	132
High	-	-	-	-	-	-	-	-	-	-	1	1
Total	4	64	-	68	6	140	2	148	13	135	1	149
Week 12												
Low	3	4	-	7	5	11	-	16	9	6	-	15
Normal	1	58	-	59	1	126	2	129	4	127	1	132
High	-	1	-	1	-	2	-	2	-	1	-	1
Total	4	63	-	67	6	139	2	147	13	134	1	148

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.3

表 2.7.4.7-付録-26　血液学的検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（8/20）

Hematocrit

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 16												
Low	2	4	-	6	3	7	-	10	10	8	-	18
Normal	2	57	-	59	3	131	2	136	3	125	-	128
High	-	1	-	1	-	1	-	1	-	-	1	1
Total	4	62	-	66	6	139	2	147	13	133	1	147
Week 20												
Low	2	5	-	7	4	4	-	8	10	3	-	13
Normal	2	56	-	58	2	132	1	135	3	130	-	133
High	-	-	-	-	-	1	1	2	-	1	1	2
Total	4	61	-	65	6	137	2	145	13	134	1	148
Week 24												
Low	2	2	-	4	3	5	-	8	10	6	-	16
Normal	2	55	-	57	3	131	1	135	3	128	-	131
High	-	3	-	3	-	1	1	2	-	-	1	1
Total	4	60	-	64	6	137	2	145	13	134	1	148

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.3

表 2.7.4.7-付録-26　血液学的検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（9/20）

Platelets

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 2												
Low	-	-	-	-	5	1	-	6	6	3	-	9
Normal	1	70	-	71	3	133	-	136	2	135	1	138
High	-	-	-	-	-	2	7	9	-	1	1	2
Total	1	70	-	71	8	136	7	151	8	139	2	149
Week 4												
Low	-	2	-	2	6	2	-	8	5	-	-	5
Normal	1	67	-	68	2	132	1	135	2	139	1	142
High	-	-	-	-	-	-	6	6	-	-	1	1
Total	1	69	-	70	8	134	7	149	7	139	2	148
Week 8												
Low	-	-	-	-	5	4	-	9	4	2	-	6
Normal	1	67	-	68	2	129	1	132	4	135	1	140
High	-	-	-	-	-	1	6	7	-	1	1	2
Total	1	67	-	68	7	134	7	148	8	138	2	148
Week 12												
Low	-	1	-	1	6	1	-	7	5	3	-	8
Normal	1	64	-	65	1	131	3	135	3	132	2	137
High	-	1	-	1	-	-	4	4	-	2	-	2
Total	1	66	-	67	7	132	7	146	8	137	2	147

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.3

表 2.7.4.7-付録-26　血液学的検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（10/20）

Platelets

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 16												
Low	-	1	-	1	5	-	-	5	3	2	-	5
Normal	1	63	-	64	2	128	2	132	5	131	1	137
High	-	-	-	-	-	4	5	9	-	3	1	4
Total	1	64	-	65	7	132	7	146	8	136	2	146
Week 20												
Low	-	-	-	-	5	1	-	6	3	2	-	5
Normal	1	63	-	64	1	129	-	130	5	128	1	134
High	-	1	-	1	-	1	7	8	-	7	1	8
Total	1	64	-	65	6	131	7	144	8	137	2	147
Week 24												
Low	-	1	-	1	3	1	-	4	3	2	-	5
Normal	1	60	-	61	3	128	-	131	5	130	1	136
High	-	2	-	2	-	3	7	10	-	5	1	6
Total	1	63	-	64	6	132	7	145	8	137	2	147

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.3

表 2.7.4.7-付録-26　血液学的検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（11/20）

Neutrophils

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 2												
Low	-	-	-	-	-	1	-	1	-	-	-	-
Normal	-	67	2	69	1	142	1	144	2	145	1	148
High	-	2	-	2	-	4	2	6	-	2	1	3
Total	-	69	2	71	1	147	3	151	2	147	2	151
Week 4												
Low	-	-	-	-	-	2	-	2	1	1	-	2
Normal	-	68	2	70	1	143	2	146	1	141	2	144
High	-	-	-	-	-	-	1	1	-	4	-	4
Total	-	68	2	70	1	145	3	149	2	146	2	150
Week 8												
Low	-	-	-	-	1	-	-	1	1	-	-	1
Normal	-	65	2	67	-	144	3	147	1	143	2	146
High	-	1	-	1	-	-	-	-	-	2	-	2
Total	-	66	2	68	1	144	3	148	2	145	2	149
Week 12												
Low	-	1	-	1	1	1	-	2	1	1	-	2
Normal	-	64	1	65	-	142	3	145	1	138	2	141
High	-	-	1	1	-	-	-	-	-	5	-	5
Total	-	65	2	67	1	143	3	147	2	144	2	148

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.3

表 2.7.4.7-付録-26　血液学的検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（12/20）

Neutrophils

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 16												
Low	-	-	-	-	-	2	-	2	1	-	-	1
Normal	-	63	2	65	1	136	3	140	1	141	2	144
High	-	1	-	1	-	5	-	5	-	1	-	1
Total	-	64	2	66	1	143	3	147	2	142	2	146
Week 20												
Low	-	-	-	-	1	1	-	2	1	-	-	1
Normal	-	62	2	64	-	138	3	141	1	143	2	146
High	-	-	-	-	-	2	-	2	-	1	-	1
Total	-	62	2	64	1	141	3	145	2	144	2	148
Week 24												
Low	-	-	-	-	1	-	-	1	1	-	-	1
Normal	-	62	2	64	-	136	3	139	1	143	2	146
High	-	-	-	-	-	5	-	5	-	1	-	1
Total	-	62	2	64	1	141	3	145	2	144	2	148

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.3

表 2.7.4.7-付録-26　血液学的検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（13/20）

Eosinophils

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 2												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	68	2	70	-	147	2	149	-	147	2	149
High	-	-	1	1	-	1	1	2	-	-	2	2
Total	-	68	3	71	-	148	3	151	-	147	4	151
Week 4												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	67	-	67	-	144	2	146	-	145	1	146
High	-	1	2	3	-	2	1	3	-	1	3	4
Total	-	68	2	70	-	146	3	149	-	146	4	150
Week 8												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	66	-	66	-	145	2	147	-	144	3	147
High	-	-	2	2	-	-	1	1	-	1	1	2
Total	-	66	2	68	-	145	3	148	-	145	4	149
Week 12												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	65	-	65	-	141	3	144	-	143	1	144
High	-	-	2	2	-	3	-	3	-	1	3	4
Total	-	65	2	67	-	144	3	147	-	144	4	148

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.3

表 2.7.4.7-付録-26　血液学的検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（14/20）

Eosinophils

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 16												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	64	-	64	-	144	2	146	-	140	2	142
High	-	-	2	2	-	-	1	1	-	2	2	4
Total	-	64	2	66	-	144	3	147	-	142	4	146
Week 20												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	62	1	63	-	140	2	142	-	142	2	144
High	-	-	1	1	-	2	1	3	-	2	2	4
Total	-	62	2	64	-	142	3	145	-	144	4	148
Week 24												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	61	-	61	-	142	2	144	-	141	3	144
High	-	1	2	3	-	-	1	1	-	3	1	4
Total	-	62	2	64	-	142	3	145	-	144	4	148

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.3

表 2.7.4.7-付録-26　血液学的検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（15/20）

Monocytes

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 2												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	67	3	70	-	142	1	143	-	147	2	149
High	-	-	1	1	-	4	4	8	-	1	1	2
Total	-	67	4	71	-	146	5	151	-	148	3	151
Week 4												
Low	-	-	-	-	-	-	-	-	-	1	-	1
Normal	-	65	3	68	-	141	3	144	-	146	3	149
High	-	1	1	2	-	3	2	5	-	-	-	-
Total	-	66	4	70	-	144	5	149	-	147	3	150
Week 8												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	63	3	66	-	142	4	146	-	145	2	147
High	-	1	1	2	-	1	1	2	-	1	1	2
Total	-	64	4	68	-	143	5	148	-	146	3	149
Week 12												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	60	3	63	-	138	2	140	-	142	1	143
High	-	3	1	4	-	4	3	7	-	3	2	5
Total	-	63	4	67	-	142	5	147	-	145	3	148

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.3

表 2.7.4.7-付録-26　血液学的検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（16/20）

Monocytes

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 16												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	61	3	64	-	138	4	142	-	139	2	141
High	-	1	1	2	-	4	1	5	-	4	1	5
Total	-	62	4	66	-	142	5	147	-	143	3	146
Week 20												
Low	-	-	-	-	-	-	-	-	-	1	-	1
Normal	-	61	3	64	-	139	2	141	-	140	2	142
High	-	-	-	-	-	1	3	4	-	4	1	5
Total	-	61	3	64	-	140	5	145	-	145	3	148
Week 24												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	60	3	63	-	136	2	138	-	138	2	140
High	-	-	1	1	-	4	3	7	-	7	1	8
Total	-	60	4	64	-	140	5	145	-	145	3	148

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.3

表 2.7.4.7-付録-26　血液学的検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（17/20）

Lymphocytes

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 2												
Low	1	1	-	2	1	5	-	6	2	4	-	6
Normal	3	66	-	69	1	142	2	145	2	142	1	145
High	-	-	-	-	-	-	-	-	-	-	-	-
Total	4	67	-	71	2	147	2	151	4	146	1	151
Week 4												
Low	1	-	-	1	-	-	-	-	2	2	-	4
Normal	3	66	-	69	2	145	1	148	2	142	1	145
High	-	-	-	-	-	-	1	1	-	1	-	1
Total	4	66	-	70	2	145	2	149	4	145	1	150
Week 8												
Low	1	1	-	2	-	-	-	-	-	3	-	3
Normal	3	63	-	66	2	143	1	146	4	140	-	144
High	-	-	-	-	-	1	1	2	-	1	1	2
Total	4	64	-	68	2	144	2	148	4	144	1	149
Week 12												
Low	2	1	-	3	-	2	-	2	1	4	-	5
Normal	2	62	-	64	2	141	1	144	3	138	1	142
High	-	-	-	-	-	-	1	1	-	1	-	1
Total	4	63	-	67	2	143	2	147	4	143	1	148

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.3

表 2.7.4.7-付録-26　血液学的検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（18/20）

Lymphocytes

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 16												
Low	1	-	-	1	-	6	-	6	1	2	-	3
Normal	3	62	-	65	2	137	1	140	3	139	1	143
High	-	-	-	-	-	-	1	1	-	-	-	-
Total	4	62	-	66	2	143	2	147	4	141	1	146
Week 20												
Low	1	-	-	1	-	1	-	1	1	1	-	2
Normal	3	60	-	63	2	140	1	143	3	142	1	146
High	-	-	-	-	-	-	1	1	-	-	-	-
Total	4	60	-	64	2	141	2	145	4	143	1	148
Week 24												
Low	1	-	-	1	-	5	-	5	-	2	-	2
Normal	3	60	-	63	2	136	2	140	4	140	1	145
High	-	-	-	-	-	-	-	-	-	1	-	1
Total	4	60	-	64	2	141	2	145	4	143	1	148

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.3

表 2.7.4.7-付録-26　血液学的検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（19/20）

Basophils

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 2												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	71	-	71	-	151	-	151	-	151	-	151
High	-	-	-	-	-	-	-	-	-	-	-	-
Total	-	71	-	71	-	151	-	151	-	151	-	151
Week 4												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	70	-	70	-	149	-	149	-	150	-	150
High	-	-	-	-	-	-	-	-	-	-	-	-
Total	-	70	-	70	-	149	-	149	-	150	-	150
Week 8												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	68	-	68	-	148	-	148	-	148	-	148
High	-	-	-	-	-	-	-	-	-	1	-	1
Total	-	68	-	68	-	148	-	148	-	149	-	149
Week 12												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	67	-	67	-	147	-	147	-	148	-	148
High	-	-	-	-	-	-	-	-	-	-	-	-
Total	-	67	-	67	-	147	-	147	-	148	-	148

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.3

表 2.7.4.7-付録-26　血液学的検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（20/20）

Basophils

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 16												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	66	-	66	-	147	-	147	-	145	-	145
High	-	-	-	-	-	-	-	-	-	1	-	1
Total	-	66	-	66	-	147	-	147	-	146	-	146
Week 20												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	64	-	64	-	145	-	145	-	148	-	148
High	-	-	-	-	-	-	-	-	-	-	-	-
Total	-	64	-	64	-	145	-	145	-	148	-	148
Week 24												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	64	-	64	-	145	-	145	-	148	-	148
High	-	-	-	-	-	-	-	-	-	-	-	-
Total	-	64	-	64	-	145	-	145	-	148	-	148

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.3

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（1/125）

Laboratory Test: ALT (GPT) (U/L)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week -12						
N	71		152		151	
Mean	25.5		29.2		28.1	
SD	10.39		16.04		17.14	
Minimum	7		7		10	
Q1	18.0		17.0		17.0	
Median	26.0		24.0		24.0	
Q3	31.0		36.5		32.0	
Maximum	59		83		112	
Week -4						
N	71		152		151	
Mean	25.0		28.3		27.1	
SD	11.74		16.04		14.88	
Minimum	9		7		9	
Q1	17.0		17.0		16.0	
Median	23.0		24.0		23.0	
Q3	31.0		35.0		34.0	
Maximum	68		97		80	

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（2/125）

Laboratory Test: ALT (GPT) (U/L)

Visit / Statistics	Placebo (N=71) Observed Value at Visit	Placebo (N=71) Change from Baseline	QD (N=152) Observed Value at Visit	QD (N=152) Change from Baseline	BID (N=151) Observed Value at Visit	BID (N=151) Change from Baseline
Week 0						
N	71		152		151	
Mean	25.6		28.3		27.7	
SD	12.48		15.62		15.23	
Minimum	8		9		7	
Q1	16.0		17.0		17.0	
Median	22.0		24.0		23.0	
Q3	33.0		33.5		32.0	
Maximum	75		82		91	
Week 2						
N	71	71	152	152	151	151
Mean	25.2	-0.4	27.2	-1.1	26.2	-1.5
SD	12.28	6.55	15.73	5.86	14.61	6.81
Minimum	6	-24	9	-25	9	-26
Q1	17.0	-3.0	16.0	-4.0	16.0	-4.0
Median	22.0	-1.0	23.0	-1.0	22.0	-2.0
Q3	31.0	2.0	31.5	2.0	31.0	1.0
Maximum	76	27	91	19	86	20

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（3/125）

Laboratory Test: ALT (GPT) (U/L)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 4						
N	70	70	150	150	150	150
Mean	24.5	-0.9	28.5	0.1	26.7	-1.0
SD	11.09	5.33	17.95	6.46	14.46	8.04
Minimum	8	-28	8	-22	9	-45
Q1	17.0	-3.0	16.0	-3.0	17.0	-4.0
Median	22.5	-1.0	23.0	-1.0	22.0	0.0
Q3	30.0	3.0	33.0	3.0	33.0	3.0
Maximum	58	9	89	25	79	28
Week 8						
N	68	68	149	149	149	149
Mean	24.8	-0.4	29.7	1.4	27.3	-0.4
SD	12.23	6.16	19.06	7.90	15.77	9.68
Minimum	9	-21	7	-31	9	-37
Q1	15.0	-3.0	16.0	-2.0	16.0	-4.0
Median	22.0	0.0	23.0	0.0	23.0	0.0
Q3	31.0	3.0	35.0	4.0	33.0	4.0
Maximum	62	14	92	30	94	45

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（4/125）

Laboratory Test: ALT (GPT) (U/L)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 12						
N	67	67	148	148	148	148
Mean	26.1	0.9	30.5	2.1	29.0	1.2
SD	13.45	7.36	19.94	9.30	17.62	9.25
Minimum	9	-15	9	-33	8	-16
Q1	15.0	-3.0	17.0	-3.0	16.5	-4.0
Median	23.0	0.0	23.5	1.0	22.0	0.0
Q3	32.0	4.0	34.5	5.5	40.0	3.0
Maximum	67	29	103	45	93	32
Week 16						
N	66	66	148	148	148	148
Mean	25.9	0.6	30.9	2.6	30.3	2.5
SD	12.94	6.27	20.21	11.45	22.95	17.21
Minimum	8	-18	9	-33	7	-24
Q1	16.0	-2.0	17.5	-2.5	17.0	-3.0
Median	23.0	0.5	24.0	0.0	23.0	0.5
Q3	33.0	4.0	36.0	6.0	39.0	5.0
Maximum	69	23	124	66	213	177

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（5/125）

Laboratory Test: ALT (GPT) (U/L)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20						
N	65	65	146	146	148	148
Mean	26.0	0.5	32.3	3.9	31.1	3.3
SD	12.71	8.04	20.98	11.81	19.55	11.42
Minimum	8	-15	8	-33	9	-21
Q1	16.0	-4.0	18.0	-2.0	18.0	-3.0
Median	24.0	0.0	25.0	3.0	24.0	1.0
Q3	35.0	4.0	40.0	8.0	39.5	7.0
Maximum	69	28	115	66	93	46
Week 24						
N	64	64	146	146	148	148
Mean	26.4	1.7	31.4	3.0	31.3	3.6
SD	12.83	7.16	20.32	11.15	19.85	12.27
Minimum	8	-18	7	-32	9	-27
Q1	15.5	-2.0	17.0	-2.0	18.0	-2.0
Median	23.5	1.0	25.0	1.5	23.5	2.0
Q3	32.5	5.0	37.0	6.0	37.5	6.0
Maximum	59	22	124	51	119	57

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（6/125）

Laboratory Test: AST (GOT) (U/L)

Visit / Statistics	Placebo (N=71) Observed Value at Visit	Placebo (N=71) Change from Baseline	QD (N=152) Observed Value at Visit	QD (N=152) Change from Baseline	BID (N=151) Observed Value at Visit	BID (N=151) Change from Baseline
Week -12						
N	71		152		151	
Mean	24.5		26.6		26.3	
SD	6.72		10.42		11.51	
Minimum	14		14		13	
Q1	20.0		19.0		20.0	
Median	23.0		23.0		23.0	
Q3	26.0		31.0		30.0	
Maximum	55		62		91	
Week -4						
N	71		152		151	
Mean	24.4		25.6		25.7	
SD	8.12		10.34		11.31	
Minimum	13		13		12	
Q1	19.0		19.0		18.0	
Median	23.0		23.0		22.0	
Q3	27.0		28.5		30.0	
Maximum	62		73		79	

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（7/125）

Laboratory Test: AST (GOT) (U/L)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 0						
N	71		149		151	
Mean	24.6		25.5		26.0	
SD	9.17		9.82		11.37	
Minimum	13		12		13	
Q1	20.0		19.0		19.0	
Median	23.0		23.0		23.0	
Q3	27.0		29.0		29.0	
Maximum	77		63		90	
Week 2						
N	71	71	151	148	150	150
Mean	25.1	0.5	25.4	-0.1	25.6	-0.5
SD	11.59	8.30	10.11	4.47	10.90	5.57
Minimum	14	-31	14	-15	11	-22
Q1	20.0	-2.0	19.0	-2.0	19.0	-3.0
Median	23.0	0.0	22.0	0.0	22.0	0.0
Q3	27.0	2.0	29.0	2.0	29.0	2.0
Maximum	105	52	77	18	69	20

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（8/125）

Laboratory Test: AST (GOT) (U/L)

Visit / Statistics	Placebo (N=71) Observed Value at Visit	Placebo (N=71) Change from Baseline	QD (N=152) Observed Value at Visit	QD (N=152) Change from Baseline	BID (N=151) Observed Value at Visit	BID (N=151) Change from Baseline
Week 4						
N	70	70	150	147	149	149
Mean	24.0	-0.6	26.0	0.6	25.3	-0.7
SD	7.13	5.07	12.63	5.87	9.31	6.13
Minimum	15	-32	13	-18	11	-36
Q1	19.0	-2.0	18.0	-2.0	19.0	-3.0
Median	22.0	0.0	22.0	0.0	22.0	0.0
Q3	27.0	2.0	28.0	2.0	29.0	2.0
Maximum	53	10	102	43	64	17
Week 8						
N	68	68	147	144	148	148
Mean	24.9	0.4	26.1	0.9	25.8	-0.2
SD	9.03	5.64	12.22	6.26	12.22	8.98
Minimum	14	-30	13	-30	12	-36
Q1	19.0	-1.0	19.0	-2.0	19.0	-2.5
Median	23.0	0.0	22.0	0.0	23.0	-1.0
Q3	26.5	2.5	30.0	2.0	28.0	2.0
Maximum	61	14	78	33	92	66

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（9/125）

Laboratory Test: AST (GOT) (U/L)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 12						
N	66	66	146	143	146	146
Mean	25.8	1.2	27.0	1.8	26.5	0.2
SD	11.35	6.37	13.03	7.01	11.75	7.08
Minimum	14	-14	13	-32	12	-29
Q1	20.0	-2.0	18.0	-2.0	19.0	-3.0
Median	23.0	0.0	23.0	1.0	23.0	0.0
Q3	27.0	3.0	30.0	4.0	30.0	3.0
Maximum	79	26	81	32	78	34
Week 16						
N	66	66	146	143	146	146
Mean	25.7	0.9	27.3	1.9	27.1	0.9
SD	10.20	5.33	12.92	8.34	11.54	7.43
Minimum	15	-12	14	-31	13	-35
Q1	20.0	-2.0	20.0	-2.0	19.0	-2.0
Median	24.0	1.0	23.0	1.0	23.0	1.0
Q3	28.0	3.0	31.0	4.0	33.0	3.0
Maximum	71	25	88	49	83	39

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（10/125）

Laboratory Test: AST (GOT) (U/L)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20						
N	63	63	144	141	148	148
Mean	24.9	0.1	29.0	3.0	28.8	2.7
SD	7.93	5.97	15.36	8.81	15.00	9.99
Minimum	13	-20	13	-27	11	-27
Q1	20.0	-3.0	20.0	-1.0	20.0	-2.0
Median	23.0	0.0	24.0	2.0	24.0	1.0
Q3	29.0	4.0	32.0	5.0	33.0	5.0
Maximum	57	14	107	44	109	56
Week 24						
N	63	63	143	140	145	145
Mean	26.0	2.0	28.4	3.0	28.7	2.4
SD	12.09	7.92	15.22	10.29	15.00	10.57
Minimum	14	-11	12	-28	11	-42
Q1	19.0	-2.0	19.0	-2.0	20.0	-1.0
Median	23.0	1.0	23.0	1.0	24.0	1.0
Q3	29.0	4.0	31.0	4.0	31.0	5.0
Maximum	96	50	111	59	112	59

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（11/125）

Laboratory Test: GGT (U/L)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week -12						
N	71		152		151	
Mean	42.9		47.7		48.8	
SD	34.02		36.37		44.99	
Minimum	11		9		11	
Q1	21.0		23.5		23.0	
Median	31.0		36.0		35.0	
Q3	49.0		59.0		54.0	
Maximum	165		223		281	
Week -4						
N	71		152		151	
Mean	41.2		49.0		49.3	
SD	29.80		38.68		44.50	
Minimum	5		10		10	
Q1	22.0		24.0		24.0	
Median	33.0		38.0		37.0	
Q3	52.0		57.5		60.0	
Maximum	190		233		280	

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（12/125）

Laboratory Test: GGT (U/L)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 0						
N	71		152		151	
Mean	41.5		50.1		50.1	
SD	29.45		38.11		45.66	
Minimum	5		10		9	
Q1	21.0		25.0		24.0	
Median	32.0		38.5		37.0	
Q3	54.0		61.0		57.0	
Maximum	174		223		283	
Week 2						
N	71	71	152	152	151	151
Mean	42.4	0.9	45.5	-4.6	45.1	-5.1
SD	30.28	7.08	33.86	11.80	37.77	13.60
Minimum	8	-21	9	-81	8	-120
Q1	23.0	-2.0	24.5	-6.0	22.0	-7.0
Median	31.0	0.0	35.0	-2.0	34.0	-2.0
Q3	57.0	2.0	58.0	0.0	53.0	0.0
Maximum	162	22	198	28	226	29

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（13/125）

Laboratory Test: GGT (U/L)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 4						
N	70	70	150	150	150	150
Mean	43.5	2.2	46.1	-4.3	43.6	-6.1
SD	33.74	10.29	36.29	12.13	37.20	13.44
Minimum	10	-42	9	-96	8	-103
Q1	23.0	-2.0	24.0	-6.0	21.0	-8.0
Median	29.5	1.0	36.5	-3.0	31.0	-4.0
Q3	57.0	5.0	58.0	1.0	50.0	0.0
Maximum	189	42	231	20	216	18
Week 8						
N	68	68	149	149	149	149
Mean	44.1	3.1	47.6	-3.0	45.0	-4.7
SD	32.84	18.70	37.13	13.83	37.75	16.55
Minimum	11	-102	10	-68	8	-137
Q1	22.5	-2.5	24.0	-6.0	22.0	-6.0
Median	31.0	1.0	36.0	-2.0	32.0	-2.0
Q3	57.5	7.5	59.0	2.0	52.0	1.0
Maximum	158	50	215	59	234	25

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（14/125）

Laboratory Test: GGT (U/L)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 12						
N	67	67	148	148	148	148
Mean	47.8	6.6	48.7	-1.1	48.5	-1.4
SD	40.61	21.51	39.73	17.28	44.03	21.97
Minimum	8	-43	11	-85	10	-102
Q1	23.0	-3.0	24.5	-6.5	21.5	-6.0
Median	30.0	1.0	38.0	-2.0	35.0	-3.0
Q3	64.0	10.0	60.5	4.0	57.0	2.0
Maximum	212	103	265	99	273	152
Week 16						
N	66	66	148	148	148	148
Mean	47.5	6.9	49.1	-0.7	51.7	1.8
SD	43.61	25.23	38.76	18.41	63.99	50.64
Minimum	11	-31	10	-79	10	-88
Q1	23.0	-2.0	24.0	-5.5	23.0	-6.5
Median	30.0	2.0	36.5	0.0	33.0	-1.0
Q3	54.0	7.0	62.5	4.0	57.5	4.0
Maximum	246	177	256	80	640	573

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（15/125）

Laboratory Test: GGT (U/L)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20						
N	65	65	146	146	148	148
Mean	44.3	4.0	49.8	-0.2	48.6	-1.2
SD	35.32	13.19	39.41	19.19	41.28	17.87
Minimum	11	-42	8	-84	11	-107
Q1	22.0	-2.0	25.0	-6.0	22.0	-5.5
Median	32.0	1.0	38.0	-1.0	35.5	0.0
Q3	54.0	9.0	61.0	5.0	59.0	5.5
Maximum	197	46	264	88	286	62
Week 24						
N	64	64	146	146	148	148
Mean	44.3	3.9	50.9	0.9	48.0	-1.9
SD	35.25	12.48	43.74	25.39	40.84	21.39
Minimum	10	-21	11	-104	11	-94
Q1	22.0	-1.5	26.0	-5.0	22.5	-7.0
Median	32.0	1.5	36.5	-0.5	37.5	-1.0
Q3	47.0	5.0	62.0	4.0	59.5	4.0
Maximum	206	58	267	154	270	84

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（16/125）

Laboratory Test: Alkaline Phosphatase (U/L)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week -12						
N	71		152		151	
Mean	231.2		237.5		234.0	
SD	73.03		76.97		69.54	
Minimum	94		78		60	
Q1	181.0		190.0		183.0	
Median	220.0		223.5		225.0	
Q3	277.0		272.5		268.0	
Maximum	477		659		551	
Week -4						
N	71		152		151	
Mean	224.1		237.2		237.2	
SD	67.22		74.34		69.87	
Minimum	102		81		57	
Q1	171.0		192.0		184.0	
Median	222.0		227.0		230.0	
Q3	262.0		274.0		275.0	
Maximum	423		692		519	

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（17/125）

Laboratory Test: Alkaline Phosphatase (U/L)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 0						
N	71		152		151	
Mean	226.9		233.8		236.8	
SD	67.50		67.75		74.67	
Minimum	94		89		58	
Q1	174.0		188.0		183.0	
Median	221.0		222.5		230.0	
Q3	260.0		269.0		279.0	
Maximum	402		500		572	
Week 2						
N	71	71	152	152	151	151
Mean	224.6	-2.2	230.2	-3.6	227.3	-9.6
SD	67.10	22.57	71.67	27.60	65.69	25.51
Minimum	97	-59	80	-97	54	-135
Q1	176.0	-15.0	182.5	-19.5	178.0	-24.0
Median	215.0	1.0	221.0	-6.0	221.0	-8.0
Q3	262.0	9.0	260.5	7.0	266.0	6.0
Maximum	448	52	572	113	437	76

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（18/125）

Laboratory Test: Alkaline Phosphatase (U/L)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 4						
N	70	70	150	150	150	150
Mean	232.5	4.5	226.6	-6.2	224.0	-12.9
SD	74.47	37.66	67.93	24.65	66.26	30.86
Minimum	101	-87	73	-97	51	-123
Q1	181.0	-15.0	181.0	-17.0	176.0	-27.0
Median	221.0	-1.0	214.5	-7.0	214.5	-11.5
Q3	267.0	14.0	258.0	4.0	259.0	2.0
Maximum	452	192	544	90	484	178
Week 8						
N	68	68	149	149	149	149
Mean	227.6	-1.6	223.4	-9.3	224.5	-12.8
SD	73.94	31.50	67.19	26.95	65.64	27.00
Minimum	94	-78	83	-123	52	-109
Q1	177.5	-14.5	179.0	-23.0	176.0	-26.0
Median	216.0	-4.5	212.0	-8.0	219.0	-13.0
Q3	263.0	12.0	260.0	3.0	263.0	2.0
Maximum	511	112	568	111	463	64

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（19/125）

Laboratory Test: Alkaline Phosphatase (U/L)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 12						
N	67	67	148	148	148	148
Mean	226.9	-3.1	223.1	-8.7	226.5	-11.3
SD	70.86	27.14	73.56	34.87	69.29	30.51
Minimum	95	-73	77	-130	52	-152
Q1	178.0	-13.0	177.5	-25.5	180.5	-27.0
Median	218.0	-1.0	207.5	-8.0	216.5	-11.0
Q3	273.0	12.0	253.0	4.5	251.0	3.5
Maximum	419	70	657	157	509	92
Week 16						
N	66	66	148	148	148	148
Mean	232.6	3.9	225.1	-6.6	227.2	-10.6
SD	71.40	30.33	75.77	37.21	69.63	32.91
Minimum	110	-91	78	-158	49	-120
Q1	178.0	-7.0	175.5	-26.0	178.0	-28.0
Median	220.5	6.5	215.0	-6.0	220.0	-8.5
Q3	271.0	16.0	252.5	9.5	255.5	7.0
Maximum	488	91	590	149	516	114

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（20/125）

Laboratory Test: Alkaline Phosphatase (U/L)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20						
N	65	65	146	146	148	148
Mean	236.3	6.3	227.8	-4.0	225.9	-11.9
SD	69.68	35.17	71.90	32.79	65.13	31.47
Minimum	101	-108	86	-113	54	-168
Q1	190.0	-11.0	180.0	-21.0	179.0	-25.0
Median	229.0	8.0	215.0	-2.0	216.5	-7.5
Q3	276.0	26.0	260.0	10.0	260.0	8.0
Maximum	484	82	637	137	420	100
Week 24						
N	64	64	146	146	148	148
Mean	243.1	12.2	228.3	-3.5	231.1	-6.7
SD	73.35	39.73	77.28	42.49	67.70	31.53
Minimum	104	-94	87	-122	50	-157
Q1	195.5	-8.5	184.0	-20.0	182.0	-23.5
Median	232.0	11.0	221.0	-2.5	219.0	-6.0
Q3	283.5	29.0	261.0	13.0	264.5	12.0
Maximum	508	161	714	329	439	101

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（21/125）

Laboratory Test: Total Bilirubin (mg/dL)

Visit / Statistics	Placebo (N=71) Observed Value at Visit	Placebo (N=71) Change from Baseline	QD (N=152) Observed Value at Visit	QD (N=152) Change from Baseline	BID (N=151) Observed Value at Visit	BID (N=151) Change from Baseline
Week -12						
N	71		152		151	
Mean	0.84		0.85		0.82	
SD	0.274		0.327		0.299	
Minimum	0.4		0.3		0.4	
Q1	0.60		0.60		0.60	
Median	0.80		0.80		0.70	
Q3	0.90		1.00		0.90	
Maximum	1.6		2.9		2.2	
Week -4						
N	71		152		151	
Mean	0.90		0.87		0.84	
SD	0.341		0.345		0.352	
Minimum	0.4		0.3		0.2	
Q1	0.70		0.60		0.60	
Median	0.80		0.80		0.80	
Q3	1.10		1.00		1.00	
Maximum	2.3		2.7		3.0	

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（22/125）

Laboratory Test: Total Bilirubin (mg/dL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 0						
N	71		152		151	
Mean	0.89		0.89		0.85	
SD	0.358		0.301		0.312	
Minimum	0.4		0.4		0.3	
Q1	0.60		0.70		0.60	
Median	0.90		0.80		0.80	
Q3	1.00		1.10		1.00	
Maximum	2.3		1.8		2.7	
Week 2						
N	71	71	152	152	151	151
Mean	0.87	-0.02	0.86	-0.03	0.81	-0.03
SD	0.301	0.245	0.323	0.215	0.284	0.239
Minimum	0.3	-0.7	0.2	-0.7	0.3	-0.7
Q1	0.60	-0.20	0.60	-0.10	0.60	-0.20
Median	0.80	0.00	0.80	0.00	0.80	0.00
Q3	1.10	0.10	1.00	0.10	0.90	0.10
Maximum	1.8	0.6	2.5	0.7	2.1	1.0

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（23/125）

Laboratory Test: Total Bilirubin (mg/dL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 4						
N	70	70	150	150	150	150
Mean	0.87	-0.01	0.87	-0.02	0.82	-0.03
SD	0.331	0.227	0.327	0.221	0.308	0.267
Minimum	0.3	-0.8	0.3	-0.6	0.3	-0.7
Q1	0.70	-0.20	0.70	-0.10	0.60	-0.20
Median	0.90	0.00	0.80	0.00	0.80	0.00
Q3	1.00	0.10	1.00	0.10	0.90	0.10
Maximum	1.9	0.5	2.6	0.8	2.7	2.1
Week 8						
N	68	68	149	149	149	149
Mean	0.91	0.02	0.84	-0.04	0.82	-0.03
SD	0.352	0.225	0.311	0.248	0.294	0.225
Minimum	0.3	-0.5	0.3	-0.9	0.3	-0.7
Q1	0.70	-0.10	0.60	-0.20	0.60	-0.20
Median	0.85	0.00	0.80	0.00	0.80	-0.10
Q3	1.05	0.10	1.00	0.10	0.90	0.10
Maximum	2.2	0.7	2.0	0.7	2.1	0.7

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（24/125）

Laboratory Test: Total Bilirubin (mg/dL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 12						
N	67	67	148	148	148	148
Mean	0.90	0.01	0.88	0.00	0.82	-0.03
SD	0.329	0.237	0.357	0.235	0.320	0.255
Minimum	0.3	-0.5	0.3	-0.8	0.2	-0.9
Q1	0.70	-0.20	0.60	-0.10	0.60	-0.20
Median	0.80	0.00	0.85	0.00	0.70	0.00
Q3	1.00	0.20	1.00	0.10	0.90	0.10
Maximum	2.0	0.6	2.6	0.8	2.4	0.9
Week 16						
N	66	66	148	148	148	148
Mean	0.90	0.03	0.86	-0.02	0.82	-0.03
SD	0.307	0.283	0.347	0.245	0.313	0.226
Minimum	0.4	-0.5	0.3	-0.6	0.4	-0.8
Q1	0.70	-0.10	0.65	-0.20	0.60	-0.20
Median	0.80	0.05	0.80	0.00	0.80	0.00
Q3	1.00	0.10	1.00	0.10	0.90	0.10
Maximum	1.9	1.4	2.7	1.1	2.2	0.6

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（25/125）

Laboratory Test: Total Bilirubin (mg/dL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20						
N	65	65	146	146	148	148
Mean	0.83	-0.03	0.84	-0.04	0.84	-0.01
SD	0.256	0.238	0.346	0.249	0.303	0.265
Minimum	0.4	-0.7	0.2	-0.8	0.3	-0.7
Q1	0.70	-0.20	0.60	-0.20	0.70	-0.20
Median	0.80	0.00	0.80	0.00	0.80	0.00
Q3	1.00	0.10	1.00	0.10	1.00	0.10
Maximum	1.7	0.4	2.6	1.1	2.0	1.2
Week 24						
N	64	64	146	146	148	148
Mean	0.90	0.03	0.85	-0.03	0.80	-0.05
SD	0.319	0.254	0.293	0.211	0.251	0.249
Minimum	0.3	-0.7	0.3	-0.6	0.4	-1.1
Q1	0.70	-0.10	0.60	-0.10	0.60	-0.20
Median	0.80	0.10	0.80	0.00	0.80	0.00
Q3	1.10	0.20	1.00	0.10	0.90	0.10
Maximum	2.0	0.8	2.1	0.7	2.0	0.6

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（26/125）

Laboratory Test: Total Protein (g/dL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week -12						
N	71		152		151	
Mean	7.29		7.31		7.33	
SD	0.480		0.410		0.430	
Minimum	6.4		6.2		6.2	
Q1	6.90		7.05		7.00	
Median	7.30		7.30		7.30	
Q3	7.50		7.55		7.60	
Maximum	8.6		8.7		8.9	
Week -4						
N	71		152		151	
Mean	7.21		7.21		7.23	
SD	0.395		0.395		0.374	
Minimum	6.5		6.1		6.2	
Q1	6.90		6.90		7.00	
Median	7.20		7.20		7.20	
Q3	7.40		7.45		7.50	
Maximum	8.4		8.1		8.1	

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（27/125）

Laboratory Test: Total Protein (g/dL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 0						
N	71		152		151	
Mean	7.21		7.17		7.24	
SD	0.440		0.338		0.400	
Minimum	6.3		6.4		6.2	
Q1	6.90		6.95		7.00	
Median	7.20		7.20		7.20	
Q3	7.50		7.40		7.50	
Maximum	8.7		8.0		8.5	
Week 2						
N	71	71	152	152	151	151
Mean	7.17	-0.05	7.21	0.04	7.21	-0.03
SD	0.425	0.289	0.384	0.297	0.385	0.297
Minimum	6.3	-1.2	6.3	-0.7	6.2	-0.7
Q1	6.90	-0.20	7.00	-0.20	7.00	-0.20
Median	7.10	0.00	7.20	0.00	7.20	-0.10
Q3	7.50	0.10	7.40	0.30	7.50	0.10
Maximum	8.3	0.7	8.4	0.7	8.6	0.9

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（28/125）

Laboratory Test: Total Protein (g/dL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 4						
N	70	70	150	150	150	150
Mean	7.26	0.04	7.22	0.05	7.21	-0.03
SD	0.432	0.383	0.398	0.287	0.384	0.288
Minimum	6.5	-1.3	6.1	-0.6	5.8	-0.7
Q1	7.00	-0.10	7.00	-0.10	7.00	-0.20
Median	7.20	0.10	7.20	0.00	7.20	-0.10
Q3	7.40	0.20	7.40	0.20	7.40	0.10
Maximum	8.8	1.4	8.7	0.8	8.1	1.0
Week 8						
N	68	68	149	149	149	149
Mean	7.20	-0.03	7.18	0.00	7.20	-0.05
SD	0.382	0.290	0.386	0.312	0.387	0.296
Minimum	6.4	-1.0	6.2	-1.0	6.2	-0.7
Q1	6.95	-0.20	7.00	-0.20	6.90	-0.30
Median	7.20	0.00	7.20	0.00	7.20	-0.10
Q3	7.50	0.10	7.40	0.20	7.40	0.10
Maximum	8.1	0.6	8.3	1.0	8.2	1.1

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（29/125）

Laboratory Test: Total Protein (g/dL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 12						
N	67	67	148	148	148	148
Mean	7.20	-0.04	7.23	0.06	7.25	0.00
SD	0.345	0.277	0.378	0.285	0.371	0.337
Minimum	6.6	-0.9	6.3	-0.7	6.1	-0.8
Q1	6.90	-0.20	7.00	-0.10	7.00	-0.20
Median	7.10	0.00	7.20	0.10	7.20	0.00
Q3	7.50	0.20	7.50	0.20	7.50	0.20
Maximum	8.0	0.7	8.4	0.9	8.2	1.2
Week 16						
N	66	66	148	148	148	148
Mean	7.28	0.05	7.26	0.08	7.26	0.01
SD	0.415	0.317	0.432	0.344	0.426	0.330
Minimum	6.5	-0.8	5.7	-1.8	5.9	-0.9
Q1	7.00	-0.10	7.00	-0.10	7.00	-0.20
Median	7.20	0.00	7.20	0.10	7.20	0.00
Q3	7.50	0.30	7.50	0.30	7.50	0.20
Maximum	8.3	0.8	9.0	1.0	8.4	1.0

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（30/125）

Laboratory Test: Total Protein (g/dL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20						
N	65	65	146	146	148	148
Mean	7.27	0.04	7.32	0.14	7.30	0.05
SD	0.436	0.352	0.415	0.330	0.414	0.350
Minimum	6.1	-0.7	6.4	-0.7	6.3	-0.9
Q1	7.00	-0.20	7.00	-0.10	7.00	-0.20
Median	7.20	0.10	7.30	0.10	7.30	0.00
Q3	7.50	0.30	7.50	0.30	7.60	0.30
Maximum	8.3	0.9	8.6	1.2	8.5	0.9
Week 24						
N	64	64	146	146	148	148
Mean	7.33	0.11	7.32	0.14	7.31	0.06
SD	0.403	0.298	0.358	0.314	0.461	0.345
Minimum	6.5	-0.8	6.5	-0.7	5.9	-0.6
Q1	7.10	-0.10	7.10	-0.10	7.00	-0.15
Median	7.40	0.10	7.30	0.10	7.30	0.00
Q3	7.55	0.30	7.50	0.30	7.60	0.30
Maximum	8.2	0.6	8.6	1.3	8.5	1.3

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（31/125）

Laboratory Test: Albumin (g/dL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week -12						
N	71		152		151	
Mean	4.47		4.45		4.46	
SD	0.308		0.252		0.264	
Minimum	3.9		3.7		3.8	
Q1	4.20		4.30		4.30	
Median	4.40		4.50		4.50	
Q3	4.70		4.60		4.60	
Maximum	5.4		5.3		5.1	
Week -4						
N	71		152		151	
Mean	4.44		4.42		4.44	
SD	0.267		0.264		0.239	
Minimum	3.9		3.7		3.9	
Q1	4.30		4.20		4.30	
Median	4.40		4.40		4.40	
Q3	4.60		4.60		4.60	
Maximum	5.2		5.2		5.1	

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（32/125）

Laboratory Test: Albumin (g/dL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 0						
N	71		152		151	
Mean	4.44		4.41		4.44	
SD	0.272		0.253		0.234	
Minimum	3.8		3.8		3.9	
Q1	4.20		4.20		4.30	
Median	4.50		4.40		4.40	
Q3	4.60		4.60		4.60	
Maximum	5.2		5.2		5.0	
Week 2						
N	71	71	152	152	151	151
Mean	4.44	-0.01	4.45	0.05	4.46	0.03
SD	0.272	0.164	0.248	0.183	0.241	0.178
Minimum	4.0	-0.5	3.8	-0.6	3.8	-0.4
Q1	4.20	-0.10	4.30	-0.10	4.30	-0.10
Median	4.40	0.00	4.45	0.00	4.50	0.00
Q3	4.60	0.10	4.60	0.20	4.60	0.10
Maximum	5.2	0.4	5.1	0.6	5.1	0.4

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（33/125）

Laboratory Test: Albumin (g/dL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 4						
N	70	70	150	150	150	150
Mean	4.49	0.04	4.47	0.07	4.48	0.04
SD	0.303	0.194	0.238	0.184	0.228	0.179
Minimum	3.9	-0.4	3.9	-0.5	3.8	-0.4
Q1	4.30	-0.10	4.30	0.00	4.30	-0.10
Median	4.50	0.00	4.50	0.10	4.50	0.00
Q3	4.60	0.20	4.60	0.20	4.60	0.20
Maximum	5.4	0.7	5.2	0.6	5.1	0.6
Week 8						
N	68	68	149	149	149	149
Mean	4.48	0.03	4.47	0.06	4.46	0.02
SD	0.234	0.159	0.254	0.204	0.238	0.187
Minimum	3.9	-0.4	3.8	-0.5	3.8	-0.4
Q1	4.30	-0.10	4.30	-0.10	4.30	-0.10
Median	4.50	0.00	4.50	0.10	4.50	0.00
Q3	4.60	0.10	4.60	0.20	4.60	0.10
Maximum	5.1	0.4	5.3	0.7	5.2	0.6

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（34/125）

Laboratory Test: Albumin (g/dL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 12						
N	67	67	148	148	148	148
Mean	4.46	0.01	4.49	0.08	4.50	0.06
SD	0.282	0.163	0.252	0.189	0.249	0.212
Minimum	3.8	-0.3	3.9	-0.5	3.8	-0.5
Q1	4.30	-0.10	4.30	0.00	4.30	-0.10
Median	4.40	0.00	4.50	0.10	4.50	0.10
Q3	4.70	0.10	4.60	0.20	4.70	0.20
Maximum	5.2	0.3	5.3	0.5	5.2	0.8
Week 16						
N	66	66	148	148	148	148
Mean	4.50	0.06	4.52	0.11	4.51	0.07
SD	0.303	0.175	0.285	0.227	0.233	0.194
Minimum	3.9	-0.5	3.5	-1.1	3.9	-0.5
Q1	4.30	-0.10	4.30	0.00	4.40	0.00
Median	4.50	0.10	4.50	0.10	4.50	0.10
Q3	4.70	0.20	4.70	0.30	4.70	0.20
Maximum	5.2	0.5	5.1	0.7	5.2	0.7

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（35/125）

Laboratory Test: Albumin (g/dL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20						
N	65	65	146	146	148	148
Mean	4.51	0.08	4.56	0.15	4.53	0.09
SD	0.322	0.193	0.277	0.208	0.241	0.196
Minimum	3.8	-0.4	3.9	-0.3	3.7	-0.5
Q1	4.30	-0.10	4.40	0.00	4.40	0.00
Median	4.50	0.10	4.55	0.10	4.50	0.10
Q3	4.70	0.20	4.70	0.30	4.65	0.20
Maximum	5.3	0.6	5.5	0.9	5.3	0.6
Week 24						
N	64	64	146	146	148	148
Mean	4.54	0.10	4.54	0.13	4.52	0.08
SD	0.313	0.190	0.266	0.197	0.260	0.214
Minimum	3.8	-0.3	3.9	-0.4	3.5	-0.4
Q1	4.30	0.00	4.40	0.00	4.40	-0.10
Median	4.55	0.10	4.50	0.10	4.50	0.10
Q3	4.80	0.20	4.70	0.30	4.70	0.20
Maximum	5.2	0.5	5.3	0.9	5.1	0.7

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（36/125）

Laboratory Test: Creatinine (mg/dL)

Visit / Statistics	Placebo (N=71) Observed Value at Visit	Placebo (N=71) Change from Baseline	QD (N=152) Observed Value at Visit	QD (N=152) Change from Baseline	BID (N=151) Observed Value at Visit	BID (N=151) Change from Baseline
Week -12						
N	71		152		151	
Mean	0.694		0.670		0.677	
SD	0.1433		0.1417		0.1284	
Minimum	0.39		0.35		0.35	
Q1	0.590		0.570		0.590	
Median	0.670		0.670		0.690	
Q3	0.800		0.760		0.780	
Maximum	0.99		1.01		0.94	
Week -4						
N	71		152		151	
Mean	0.687		0.673		0.682	
SD	0.1343		0.1485		0.1313	
Minimum	0.42		0.34		0.36	
Q1	0.590		0.550		0.580	
Median	0.700		0.670		0.680	
Q3	0.790		0.775		0.780	
Maximum	0.99		1.00		1.02	

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（37/125）

Laboratory Test: Creatinine (mg/dL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 0						
N	71		152		151	
Mean	0.687		0.669		0.683	
SD	0.1380		0.1416		0.1333	
Minimum	0.41		0.35		0.41	
Q1	0.590		0.560		0.600	
Median	0.680		0.650		0.680	
Q3	0.810		0.765		0.780	
Maximum	1.05		0.95		0.96	
Week 2						
N	71	71	152	152	151	151
Mean	0.696	0.010	0.680	0.011	0.693	0.010
SD	0.1412	0.0556	0.1413	0.0486	0.1355	0.0509
Minimum	0.44	-0.12	0.38	-0.13	0.40	-0.13
Q1	0.600	-0.030	0.575	-0.020	0.590	-0.020
Median	0.670	-0.010	0.670	0.010	0.700	0.010
Q3	0.820	0.040	0.785	0.040	0.800	0.040
Maximum	1.12	0.27	1.00	0.14	1.01	0.19

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（38/125）

Laboratory Test: Creatinine (mg/dL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 4						
N	70	70	150	150	150	150
Mean	0.692	0.010	0.682	0.010	0.693	0.008
SD	0.1384	0.0519	0.1424	0.0486	0.1280	0.0478
Minimum	0.40	-0.12	0.36	-0.13	0.42	-0.11
Q1	0.590	-0.030	0.580	-0.020	0.600	-0.020
Median	0.710	0.010	0.660	0.020	0.690	0.010
Q3	0.790	0.060	0.770	0.040	0.790	0.040
Maximum	0.97	0.14	1.12	0.17	0.96	0.15
Week 8						
N	68	68	149	149	149	149
Mean	0.684	0.004	0.686	0.014	0.694	0.010
SD	0.1294	0.0447	0.1501	0.0573	0.1341	0.0565
Minimum	0.42	-0.09	0.33	-0.14	0.41	-0.15
Q1	0.600	-0.030	0.570	-0.020	0.590	-0.030
Median	0.685	0.010	0.680	0.020	0.690	0.010
Q3	0.785	0.040	0.800	0.050	0.790	0.040
Maximum	0.93	0.10	1.00	0.26	0.98	0.16

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（39/125）

Laboratory Test: Creatinine (mg/dL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 12						
N	67	67	148	148	148	148
Mean	0.679	-0.001	0.690	0.018	0.695	0.009
SD	0.1322	0.0525	0.1497	0.0495	0.1365	0.0554
Minimum	0.41	-0.17	0.41	-0.12	0.41	-0.12
Q1	0.590	-0.030	0.570	-0.010	0.600	-0.020
Median	0.680	0.000	0.675	0.020	0.700	0.005
Q3	0.770	0.030	0.780	0.050	0.800	0.040
Maximum	0.95	0.13	1.02	0.17	0.97	0.17
Week 16						
N	66	66	148	148	148	148
Mean	0.684	0.004	0.682	0.010	0.687	0.002
SD	0.1340	0.0476	0.1418	0.0521	0.1372	0.0560
Minimum	0.42	-0.12	0.37	-0.16	0.39	-0.14
Q1	0.580	-0.020	0.590	-0.020	0.590	-0.040
Median	0.680	0.000	0.655	0.010	0.680	0.000
Q3	0.800	0.030	0.780	0.045	0.790	0.040
Maximum	0.97	0.15	1.03	0.19	1.00	0.16

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（40/125）

Laboratory Test: Creatinine (mg/dL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20						
N	65	65	146	146	148	148
Mean	0.674	-0.004	0.675	0.001	0.685	0.000
SD	0.1326	0.0565	0.1433	0.0528	0.1331	0.0590
Minimum	0.41	-0.12	0.38	-0.14	0.39	-0.15
Q1	0.590	-0.040	0.560	-0.030	0.590	-0.040
Median	0.670	0.000	0.670	0.010	0.685	0.000
Q3	0.790	0.040	0.790	0.040	0.770	0.040
Maximum	0.96	0.17	1.07	0.16	1.02	0.15
Week 24						
N	64	64	146	146	148	148
Mean	0.680	0.001	0.677	0.003	0.689	0.004
SD	0.1349	0.0548	0.1412	0.0503	0.1407	0.0601
Minimum	0.39	-0.09	0.37	-0.15	0.37	-0.16
Q1	0.590	-0.040	0.560	-0.030	0.595	-0.040
Median	0.680	-0.010	0.670	0.010	0.685	0.010
Q3	0.780	0.025	0.790	0.040	0.790	0.040
Maximum	0.95	0.17	0.99	0.13	1.02	0.18

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（41/125）

Laboratory Test: Blood Urea Nitrogen (mg/dL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week -12						
N	71		152		151	
Mean	13.7		13.0		13.4	
SD	3.34		2.95		2.97	
Minimum	8		6		7	
Q1	11.0		11.0		11.0	
Median	13.0		13.0		13.0	
Q3	15.0		15.0		15.0	
Maximum	25		25		22	
Week -4						
N	71		152		151	
Mean	13.6		13.2		13.6	
SD	3.91		3.27		3.57	
Minimum	8		5		7	
Q1	11.0		11.0		11.0	
Median	13.0		13.0		13.0	
Q3	15.0		15.0		15.0	
Maximum	27		22		25	

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（42/125）

Laboratory Test: Blood Urea Nitrogen (mg/dL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 0						
N	71		152		151	
Mean	13.9		13.2		13.8	
SD	3.68		3.47		3.53	
Minimum	8		6		7	
Q1	12.0		11.0		11.0	
Median	13.0		13.0		13.0	
Q3	16.0		16.0		16.0	
Maximum	25		30		25	
Week 2						
N	71	71	152	152	151	151
Mean	13.7	-0.2	13.2	-0.1	13.7	-0.1
SD	3.54	2.84	3.64	2.64	3.44	2.98
Minimum	6	-7	6	-7	7	-7
Q1	11.0	-2.0	11.0	-1.5	11.0	-2.0
Median	13.0	0.0	13.0	0.0	13.0	0.0
Q3	16.0	1.0	15.0	1.0	16.0	2.0
Maximum	27	6	26	9	25	9

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（43/125）

Laboratory Test: Blood Urea Nitrogen (mg/dL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 4						
N	70	70	150	150	150	150
Mean	14.4	0.5	13.1	-0.1	13.4	-0.4
SD	3.40	2.94	3.38	2.47	3.47	2.93
Minimum	8	-9	6	-8	7	-9
Q1	12.0	-1.0	11.0	-1.0	11.0	-2.0
Median	14.0	1.0	13.0	0.0	13.0	-1.0
Q3	17.0	2.0	15.0	1.0	15.0	1.0
Maximum	24	8	28	6	22	9
Week 8						
N	68	68	149	149	149	149
Mean	13.8	0.0	13.5	0.3	13.8	0.1
SD	3.73	3.21	3.48	2.93	3.29	2.74
Minimum	8	-8	6	-7	8	-7
Q1	11.0	-2.0	11.0	-1.0	12.0	-2.0
Median	13.0	0.0	13.0	0.0	13.0	0.0
Q3	15.0	2.0	16.0	2.0	15.0	2.0
Maximum	25	7	26	9	25	8

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（44/125）

Laboratory Test: Blood Urea Nitrogen (mg/dL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 12						
N	67	67	148	148	148	148
Mean	13.5	-0.4	13.5	0.3	13.9	0.1
SD	3.14	2.78	3.59	2.78	3.47	3.08
Minimum	8	-9	6	-7	7	-9
Q1	12.0	-2.0	11.0	-2.0	12.0	-2.0
Median	13.0	0.0	13.0	0.0	14.0	0.0
Q3	15.0	2.0	15.0	2.0	15.5	2.0
Maximum	24	5	36	8	25	11
Week 16						
N	66	66	148	148	148	148
Mean	13.2	-0.8	13.2	0.0	13.5	-0.2
SD	2.53	3.08	3.09	3.06	3.41	2.88
Minimum	8	-10	6	-11	6	-8
Q1	12.0	-2.0	11.0	-2.0	11.0	-2.0
Median	13.0	-1.0	13.0	0.0	13.0	0.0
Q3	15.0	1.0	15.0	2.0	16.0	2.0
Maximum	20	7	23	6	25	7

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（45/125）

Laboratory Test: Blood Urea Nitrogen (mg/dL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20						
N	65	65	146	146	148	148
Mean	13.4	-0.6	13.0	-0.2	13.8	0.0
SD	3.07	3.41	3.51	2.69	3.23	3.33
Minimum	9	-12	5	-8	7	-10
Q1	11.0	-2.0	11.0	-2.0	11.0	-2.0
Median	13.0	0.0	13.0	0.0	13.0	0.0
Q3	15.0	1.0	14.0	2.0	16.0	2.0
Maximum	23	10	29	8	26	9
Week 24						
N	64	64	146	146	148	148
Mean	13.4	-0.5	12.8	-0.4	13.4	-0.4
SD	3.35	3.67	3.49	2.94	3.47	3.25
Minimum	8	-11	6	-7	7	-9
Q1	11.5	-2.0	10.0	-2.0	11.0	-3.0
Median	13.0	0.0	12.0	0.0	13.0	-1.0
Q3	15.0	2.0	14.0	1.0	15.0	2.0
Maximum	28	12	27	8	26	11

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（46/125）

Laboratory Test: Uric Acid (mg/dL)

Visit / Statistics	Placebo (N=71) Observed Value at Visit	Placebo (N=71) Change from Baseline	QD (N=152) Observed Value at Visit	QD (N=152) Change from Baseline	BID (N=151) Observed Value at Visit	BID (N=151) Change from Baseline
Week -12						
N	71		152		151	
Mean	5.14		5.07		5.12	
SD	1.188		1.316		1.255	
Minimum	2.6		2.0		0.7	
Q1	4.20		4.20		4.20	
Median	4.90		5.00		5.10	
Q3	6.00		6.00		5.90	
Maximum	8.0		10.1		10.8	
Week -4						
N	71		152		151	
Mean	5.22		5.08		5.10	
SD	1.292		1.316		1.210	
Minimum	2.6		2.1		0.6	
Q1	4.20		4.10		4.30	
Median	5.10		5.05		5.00	
Q3	6.10		5.90		5.80	
Maximum	8.2		10.1		8.6	

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（47/125）

Laboratory Test: Uric Acid (mg/dL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 0						
N	71		152		151	
Mean	5.26		5.09		5.19	
SD	1.292		1.321		1.203	
Minimum	3.0		2.1		0.7	
Q1	4.30		4.15		4.40	
Median	5.10		5.10		5.20	
Q3	6.10		5.85		6.00	
Maximum	8.9		9.7		8.3	
Week 2						
N	71	71	152	152	151	151
Mean	5.27	0.00	5.33	0.23	5.36	0.16
SD	1.124	0.551	1.284	0.560	1.232	0.600
Minimum	3.2	-1.2	2.4	-2.2	0.6	-1.5
Q1	4.50	-0.40	4.40	-0.10	4.50	-0.20
Median	5.20	-0.10	5.40	0.20	5.50	0.10
Q3	6.00	0.40	6.20	0.60	6.20	0.50
Maximum	8.1	1.7	9.1	2.2	8.4	2.6

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（48/125）

Laboratory Test: Uric Acid (mg/dL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 4						
N	70	70	150	150	150	150
Mean	5.25	0.00	5.38	0.28	5.31	0.12
SD	1.133	0.601	1.253	0.534	1.173	0.640
Minimum	2.9	-1.7	2.4	-2.0	0.6	-1.4
Q1	4.40	-0.30	4.50	0.00	4.60	-0.20
Median	5.15	0.10	5.40	0.30	5.25	0.10
Q3	6.10	0.30	6.10	0.60	6.00	0.50
Maximum	8.0	2.0	9.9	1.9	8.1	3.1
Week 8						
N	68	68	149	149	149	149
Mean	5.38	0.14	5.43	0.33	5.44	0.24
SD	1.195	0.676	1.312	0.658	1.189	0.683
Minimum	3.0	-2.0	2.5	-1.8	0.7	-1.7
Q1	4.45	-0.20	4.50	-0.10	4.70	-0.20
Median	5.35	0.10	5.30	0.30	5.50	0.20
Q3	6.10	0.60	6.20	0.80	6.10	0.70
Maximum	8.5	1.5	9.2	2.5	8.5	3.3

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（49/125）

Laboratory Test: Uric Acid (mg/dL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 12						
N	67	67	148	148	148	148
Mean	5.16	-0.09	5.43	0.32	5.44	0.23
SD	1.173	0.637	1.270	0.669	1.197	0.757
Minimum	2.9	-2.6	2.6	-2.1	0.7	-1.8
Q1	4.20	-0.50	4.55	-0.10	4.70	-0.20
Median	5.00	-0.10	5.40	0.40	5.50	0.30
Q3	6.20	0.30	6.20	0.70	6.20	0.70
Maximum	7.6	1.2	8.8	3.3	8.1	2.8
Week 16						
N	66	66	148	148	148	148
Mean	5.18	-0.07	5.37	0.26	5.38	0.17
SD	1.217	0.607	1.244	0.640	1.238	0.753
Minimum	2.9	-2.0	2.8	-2.2	0.7	-2.5
Q1	4.30	-0.40	4.50	-0.10	4.60	-0.30
Median	5.00	0.00	5.35	0.30	5.35	0.20
Q3	6.10	0.20	6.20	0.65	6.25	0.65
Maximum	8.0	1.4	9.3	2.2	8.8	2.9

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（50/125）

Laboratory Test: Uric Acid (mg/dL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20						
N	65	65	146	146	148	148
Mean	5.07	-0.15	5.29	0.17	5.31	0.10
SD	1.289	0.736	1.225	0.622	1.236	0.763
Minimum	3.0	-1.6	2.2	-2.4	0.7	-3.6
Q1	4.20	-0.40	4.50	-0.20	4.50	-0.20
Median	4.80	-0.20	5.30	0.20	5.30	0.05
Q3	6.00	0.00	6.10	0.60	6.10	0.50
Maximum	8.2	2.9	8.8	1.5	9.0	2.9
Week 24						
N	64	64	146	146	148	148
Mean	4.98	-0.20	5.18	0.06	5.24	0.03
SD	1.101	0.569	1.194	0.682	1.196	0.732
Minimum	3.0	-1.9	2.6	-2.4	0.7	-3.2
Q1	4.25	-0.60	4.40	-0.30	4.55	-0.40
Median	5.00	-0.20	5.20	0.10	5.25	0.00
Q3	5.60	0.20	5.90	0.50	6.00	0.40
Maximum	7.6	1.0	8.0	1.8	8.9	2.0

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（51/125）

Laboratory Test: CK (CPK) (U/L)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week -12						
N	71		152		151	
Mean	111.6		119.3		128.1	
SD	59.38		129.15		115.48	
Minimum	34		32		39	
Q1	71.0		77.5		73.0	
Median	93.0		95.5		101.0	
Q3	143.0		124.5		142.0	
Maximum	305		1518		1270	
Week -4						
N	71		152		151	
Mean	118.8		136.5		125.4	
SD	69.54		323.04		102.21	
Minimum	31		35		37	
Q1	69.0		71.5		72.0	
Median	102.0		92.5		105.0	
Q3	140.0		130.0		144.0	
Maximum	375		3980		986	

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（52/125）

Laboratory Test: CK (CPK) (U/L)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 0						
N	71		152		151	
Mean	114.8		107.2		122.8	
SD	79.62		53.14		64.72	
Minimum	31		35		29	
Q1	68.0		72.0		76.0	
Median	91.0		93.5		102.0	
Q3	128.0		127.0		157.0	
Maximum	514		326		440	
Week 2						
N	71	71	152	152	151	151
Mean	121.5	6.7	112.0	4.8	126.8	4.0
SD	80.44	70.18	69.80	56.80	97.29	84.99
Minimum	31	-335	39	-142	32	-175
Q1	68.0	-10.0	69.5	-11.0	75.0	-12.0
Median	101.0	2.0	92.0	1.5	108.0	-1.0
Q3	147.0	17.0	130.5	12.0	143.0	16.0
Maximum	472	272	534	453	959	889

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（53/125）

Laboratory Test: CK (CPK) (U/L)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 4						
N	70	70	150	150	150	150
Mean	109.1	-5.3	112.7	5.1	125.8	2.7
SD	52.90	55.62	70.32	48.76	82.91	64.10
Minimum	33	-366	39	-175	41	-250
Q1	71.0	-15.0	70.0	-11.0	77.0	-17.0
Median	97.5	2.0	99.0	2.0	105.5	0.0
Q3	140.0	14.0	128.0	15.0	142.0	21.0
Maximum	321	144	514	265	667	388
Week 8						
N	68	68	149	149	149	149
Mean	111.3	-3.1	113.1	5.5	119.4	-3.8
SD	64.06	66.43	76.75	63.47	67.29	53.07
Minimum	29	-412	39	-180	32	-203
Q1	68.5	-21.0	69.0	-14.0	72.0	-20.0
Median	90.0	1.5	99.0	2.0	103.0	-3.0
Q3	140.5	22.0	137.0	18.0	145.0	15.0
Maximum	384	190	790	589	438	347

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（54/125）

Laboratory Test: CK (CPK) (U/L)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 12						
N	67	67	148	148	148	148
Mean	115.3	0.8	112.9	5.1	118.3	-5.0
SD	67.13	76.26	90.54	79.51	67.76	52.21
Minimum	29	-428	42	-170	34	-277
Q1	72.0	-26.0	70.5	-14.0	73.0	-28.5
Median	91.0	3.0	98.5	1.0	102.0	-5.0
Q3	149.0	29.0	128.5	18.0	144.5	18.0
Maximum	338	267	1035	836	438	180
Week 16						
N	66	66	148	148	148	148
Mean	111.9	-3.6	104.4	-3.3	129.4	6.0
SD	60.11	66.58	48.19	43.41	107.80	99.95
Minimum	26	-385	6	-191	38	-223
Q1	70.0	-18.0	71.0	-15.0	76.0	-18.0
Median	90.0	1.5	96.5	-0.5	107.5	0.5
Q3	145.0	16.0	130.0	15.5	159.0	23.5
Maximum	318	125	321	170	1158	994

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（55/125）

Laboratory Test: CK (CPK) (U/L)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20						
N	65	65	146	146	148	148
Mean	113.8	-2.2	147.4	39.0	131.8	8.4
SD	74.44	74.44	358.97	351.96	85.83	69.81
Minimum	26	-442	41	-189	36	-171
Q1	69.0	-19.0	73.0	-11.0	74.5	-18.5
Median	91.0	2.0	98.0	4.0	108.0	0.0
Q3	133.0	23.0	130.0	15.0	159.5	18.5
Maximum	354	188	4020	3827	559	375
Week 24						
N	64	64	146	146	148	148
Mean	106.5	-5.2	119.8	11.4	119.3	-4.0
SD	56.94	71.24	126.79	123.47	60.48	51.28
Minimum	28	-437	33	-187	39	-236
Q1	69.5	-16.5	73.0	-15.0	74.5	-23.0
Median	87.5	-2.5	96.5	-1.0	101.5	2.0
Q3	124.0	12.5	128.0	19.0	145.0	17.0
Maximum	301	147	1433	1372	407	199

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（56/125）

Laboratory Test: LDH (U/L)

Visit / Statistics	Placebo (N=71) Observed Value at Visit	Placebo (N=71) Change from Baseline	QD (N=152) Observed Value at Visit	QD (N=152) Change from Baseline	BID (N=151) Observed Value at Visit	BID (N=151) Change from Baseline
Week -12						
N	71		152		151	
Mean	169.9		172.2		175.8	
SD	26.49		28.70		27.62	
Minimum	123		110		92	
Q1	153.0		152.0		159.0	
Median	167.0		167.0		175.0	
Q3	185.0		194.5		190.0	
Maximum	247		281		249	
Week -4						
N	71		152		151	
Mean	175.6		173.8		176.6	
SD	29.66		30.01		30.20	
Minimum	123		98		86	
Q1	152.0		152.5		157.0	
Median	173.0		168.5		171.0	
Q3	197.0		195.5		192.0	
Maximum	264		246		267	

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（57/125）

Laboratory Test: LDH (U/L)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 0						
N	71		149		151	
Mean	173.9		172.6		178.7	
SD	30.57		28.65		29.88	
Minimum	118		120		89	
Q1	150.0		151.0		161.0	
Median	173.0		171.0		173.0	
Q3	185.0		193.0		195.0	
Maximum	280		254		266	
Week 2						
N	71	71	151	148	150	150
Mean	173.3	-0.6	170.7	-1.9	174.1	-4.7
SD	27.11	13.18	27.35	12.07	29.55	14.58
Minimum	124	-46	118	-37	74	-40
Q1	151.0	-7.0	150.0	-9.0	154.0	-15.0
Median	173.0	0.0	165.0	-1.0	171.0	-4.0
Q3	188.0	7.0	192.0	5.0	195.0	4.0
Maximum	257	36	245	41	268	59

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（58/125）

Laboratory Test: LDH (U/L)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 4						
N	70	70	150	147	149	149
Mean	171.5	-2.3	171.2	-1.2	173.0	-5.9
SD	26.69	15.30	30.31	14.69	28.72	14.79
Minimum	124	-54	113	-44	91	-39
Q1	151.0	-9.0	147.0	-9.0	152.0	-18.0
Median	168.0	-1.0	167.5	0.0	169.0	-5.0
Q3	190.0	3.0	189.0	7.0	192.0	5.0
Maximum	230	53	269	60	274	29
Week 8						
N	68	68	147	144	148	148
Mean	172.8	-1.1	172.0	0.3	175.2	-4.0
SD	31.61	19.17	29.09	15.97	34.78	23.01
Minimum	119	-105	103	-40	87	-50
Q1	151.5	-7.0	150.0	-11.0	155.0	-13.5
Median	168.0	-0.5	169.0	0.0	171.5	-5.5
Q3	188.0	7.0	193.0	10.0	189.5	4.0
Maximum	320	69	261	63	400	189

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（59/125）

Laboratory Test: LDH (U/L)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 12						
N	66	66	146	143	146	146
Mean	172.7	-1.4	170.6	-1.9	172.6	-6.7
SD	31.11	18.75	29.13	14.27	28.05	14.99
Minimum	118	-108	112	-44	80	-44
Q1	148.0	-8.0	150.0	-10.0	154.0	-16.0
Median	169.0	-1.5	165.0	-3.0	168.5	-6.0
Q3	190.0	7.0	192.0	8.0	190.0	4.0
Maximum	272	35	247	36	250	24
Week 16						
N	66	66	146	143	146	146
Mean	170.9	-2.8	170.9	-1.7	173.8	-5.3
SD	27.37	18.71	31.61	19.39	30.26	16.96
Minimum	115	-98	34	-118	87	-44
Q1	148.0	-12.0	150.0	-12.0	154.0	-16.0
Median	174.5	0.0	169.0	0.0	170.0	-5.0
Q3	191.0	8.0	192.0	9.0	190.0	6.0
Maximum	235	32	272	50	269	60

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（60/125）

Laboratory Test: LDH (U/L)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20						
N	63	63	144	141	148	148
Mean	170.3	-2.9	173.7	0.5	177.0	-1.9
SD	26.36	20.82	30.96	16.31	29.45	16.26
Minimum	111	-105	105	-47	81	-44
Q1	149.0	-10.0	153.0	-11.0	160.0	-13.0
Median	166.0	0.0	167.5	1.0	173.0	-1.0
Q3	185.0	9.0	196.5	9.0	192.5	9.0
Maximum	226	38	261	56	273	44
Week 24						
N	63	63	143	140	145	145
Mean	172.2	-0.4	174.4	1.6	177.8	-0.8
SD	30.47	21.64	30.62	17.13	28.64	16.47
Minimum	122	-95	108	-54	85	-44
Q1	151.0	-10.0	153.0	-9.0	158.0	-12.0
Median	164.0	1.0	172.0	1.0	177.0	1.0
Q3	189.0	11.0	197.0	11.0	198.0	10.0
Maximum	267	57	263	65	251	42

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（61/125）

Laboratory Test: Total Cholesterol (mg/dL)

Visit / Statistics	Placebo (N=71) Observed Value at Visit	Placebo (N=71) Change from Baseline	QD (N=152) Observed Value at Visit	QD (N=152) Change from Baseline	BID (N=151) Observed Value at Visit	BID (N=151) Change from Baseline
Week -12						
N	71		152		151	
Mean	197.9		199.5		196.6	
SD	30.17		31.16		29.64	
Minimum	148		131		135	
Q1	178.0		177.5		176.0	
Median	194.0		197.0		197.0	
Q3	216.0		223.5		217.0	
Maximum	298		263		284	
Week -4						
N	71		152		151	
Mean	196.4		194.8		197.5	
SD	30.13		28.92		31.13	
Minimum	143		115		116	
Q1	173.0		174.0		176.0	
Median	195.0		195.5		197.0	
Q3	218.0		214.5		220.0	
Maximum	266		285		270	

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（62/125）

Laboratory Test: Total Cholesterol (mg/dL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 0						
N	71		152		151	
Mean	195.4		196.4		197.0	
SD	26.70		30.67		31.31	
Minimum	148		130		136	
Q1	177.0		173.5		177.0	
Median	193.0		195.0		196.0	
Q3	214.0		217.0		215.0	
Maximum	260		273		292	
Week 2						
N	71	71	152	152	151	151
Mean	194.5	-0.9	191.6	-4.9	187.7	-9.3
SD	27.55	15.94	29.78	16.97	29.26	20.02
Minimum	143	-41	132	-53	110	-66
Q1	171.0	-13.0	172.0	-14.0	169.0	-21.0
Median	194.0	-1.0	189.0	-5.0	184.0	-10.0
Q3	214.0	10.0	212.0	5.5	208.0	1.0
Maximum	265	37	262	53	282	67

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（63/125）

Laboratory Test: Total Cholesterol (mg/dL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 4						
N	70	70	150	150	150	150
Mean	197.1	2.4	191.4	-4.9	185.7	-11.2
SD	31.34	19.97	29.32	17.50	27.89	20.26
Minimum	142	-73	123	-54	131	-83
Q1	175.0	-10.0	170.0	-16.0	165.0	-23.0
Median	191.0	1.5	190.0	-3.0	181.0	-10.0
Q3	218.0	15.0	214.0	7.0	205.0	1.0
Maximum	293	54	257	42	263	40
Week 8						
N	68	68	149	149	149	149
Mean	193.5	-0.6	190.4	-6.0	184.9	-12.0
SD	26.02	18.30	30.60	19.99	27.38	21.73
Minimum	146	-48	119	-75	104	-105
Q1	173.0	-12.0	166.0	-19.0	165.0	-23.0
Median	188.0	-1.0	190.0	-5.0	183.0	-10.0
Q3	214.5	14.0	213.0	7.0	206.0	2.0
Maximum	263	48	258	57	250	36

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（64/125）

Laboratory Test: Total Cholesterol (mg/dL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 12						
N	67	67	148	148	148	148
Mean	192.2	-2.4	191.5	-4.8	187.0	-9.9
SD	29.65	21.61	30.25	20.89	29.31	20.39
Minimum	144	-76	119	-68	126	-72
Q1	169.0	-13.0	168.5	-17.5	164.0	-23.0
Median	188.0	-3.0	191.0	-6.0	186.0	-7.5
Q3	212.0	8.0	212.5	9.0	205.0	2.5
Maximum	301	56	279	68	281	46
Week 16						
N	66	66	148	148	148	148
Mean	194.6	0.2	191.8	-4.4	188.1	-8.8
SD	31.04	21.63	30.10	22.55	31.17	23.71
Minimum	140	-73	125	-87	103	-81
Q1	171.0	-13.0	171.5	-17.5	167.0	-22.5
Median	191.5	0.0	191.0	-3.0	184.0	-6.0
Q3	214.0	11.0	214.0	10.0	212.5	4.0
Maximum	279	44	284	55	285	78

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（65/125）

Laboratory Test: Total Cholesterol (mg/dL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20						
N	65	65	146	146	148	148
Mean	197.7	3.8	193.9	-2.4	190.8	-6.1
SD	33.58	23.14	33.35	23.08	31.38	22.14
Minimum	135	-54	115	-74	126	-75
Q1	167.0	-13.0	172.0	-16.0	169.5	-17.0
Median	199.0	5.0	189.5	-2.0	189.0	-5.0
Q3	221.0	19.0	214.0	11.0	209.0	7.5
Maximum	288	78	291	65	290	76
Week 24						
N	64	64	146	146	148	148
Mean	197.1	3.3	193.9	-2.4	191.2	-5.7
SD	32.29	26.76	29.26	19.08	29.64	22.75
Minimum	125	-83	125	-56	128	-80
Q1	173.5	-7.0	172.0	-13.0	169.0	-20.0
Median	192.0	4.0	193.0	-2.0	188.5	-5.0
Q3	218.5	18.0	212.0	9.0	212.5	11.0
Maximum	290	59	267	57	264	51

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（66/125）

Laboratory Test: Triglycerides (mg/dL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week -12						
N	71		152		151	
Mean	153.7		136.3		128.6	
SD	125.61		69.51		94.82	
Minimum	47		31		37	
Q1	80.0		84.0		76.0	
Median	124.0		122.5		107.0	
Q3	170.0		169.0		153.0	
Maximum	882		403		968	
Week -4						
N	71		152		151	
Mean	142.9		137.3		135.5	
SD	80.79		67.83		107.28	
Minimum	54		42		41	
Q1	90.0		84.0		83.0	
Median	117.0		117.0		112.0	
Q3	170.0		171.5		160.0	
Maximum	378		344		1190	

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（67/125）

Laboratory Test: Triglycerides (mg/dL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 0						
N	71		152		151	
Mean	139.6		137.3		133.4	
SD	70.87		75.60		89.16	
Minimum	40		40		40	
Q1	88.0		85.0		79.0	
Median	119.0		116.0		113.0	
Q3	177.0		173.0		152.0	
Maximum	378		480		640	
Week 2						
N	71	71	152	152	151	151
Mean	146.1	6.5	135.7	-1.6	127.0	-6.4
SD	94.00	67.64	83.69	56.88	75.67	66.90
Minimum	41	-229	47	-380	35	-364
Q1	85.0	-26.0	83.5	-19.5	74.0	-24.0
Median	113.0	-3.0	109.5	-0.5	109.0	-2.0
Q3	165.0	25.0	168.5	17.5	160.0	14.0
Maximum	434	271	639	203	553	313

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（68/125）

Laboratory Test: Triglycerides (mg/dL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 4						
N	70	70	150	150	150	150
Mean	152.6	12.1	136.4	1.4	135.6	2.3
SD	120.14	90.01	78.88	46.59	81.87	65.29
Minimum	49	-228	29	-154	38	-356
Q1	85.0	-32.0	81.0	-20.0	84.0	-21.0
Median	108.0	-2.0	112.0	-5.0	118.5	2.5
Q3	174.0	28.0	172.0	21.0	158.0	24.0
Maximum	628	337	519	151	579	339
Week 8						
N	68	68	149	149	149	149
Mean	156.6	17.7	138.1	3.0	135.8	2.4
SD	130.98	102.53	90.01	53.34	84.98	69.11
Minimum	46	-171	36	-169	37	-246
Q1	82.5	-28.5	79.0	-26.0	83.0	-17.0
Median	119.5	0.5	114.0	-1.0	113.0	5.0
Q3	171.0	25.5	176.0	25.0	163.0	23.0
Maximum	752	522	750	314	625	385

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（69/125）

Laboratory Test: Triglycerides (mg/dL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 12						
N	67	67	148	148	148	148
Mean	139.4	-0.8	141.0	6.7	131.6	-2.4
SD	79.26	66.96	103.94	76.84	74.68	54.54
Minimum	42	-207	33	-221	30	-235
Q1	87.0	-31.0	78.0	-24.5	85.5	-19.0
Median	115.0	-2.0	114.0	-1.5	110.5	3.0
Q3	174.0	34.0	170.5	23.0	158.5	20.5
Maximum	484	254	765	594	525	215
Week 16						
N	66	66	148	148	148	148
Mean	140.9	2.4	137.3	3.0	139.7	5.6
SD	121.60	105.40	99.07	71.67	106.44	99.00
Minimum	41	-237	38	-180	35	-378
Q1	85.0	-30.0	82.5	-26.0	80.5	-23.0
Median	109.5	-4.0	114.0	-4.0	115.0	2.0
Q3	141.0	21.0	166.0	21.0	154.5	21.0
Maximum	832	602	887	451	937	785

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（70/125）

Laboratory Test: Triglycerides (mg/dL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20						
N	65	65	146	146	148	148
Mean	161.7	23.6	140.8	5.5	131.3	-2.7
SD	204.45	184.93	98.76	86.33	93.31	87.15
Minimum	33	-167	37	-209	34	-419
Q1	85.0	-26.0	81.0	-27.0	79.0	-25.5
Median	116.0	-2.0	114.0	-2.5	106.0	0.0
Q3	160.0	34.0	180.0	20.0	160.0	20.5
Maximum	1625	1395	838	663	915	763
Week 24						
N	64	64	146	146	148	148
Mean	159.4	22.7	139.2	3.9	123.8	-10.2
SD	187.25	169.16	92.63	73.49	65.21	70.21
Minimum	35	-243	31	-208	35	-363
Q1	73.5	-27.5	83.0	-25.0	76.0	-25.0
Median	109.5	-2.0	115.0	-1.0	109.0	-3.0
Q3	156.5	24.5	168.0	18.0	149.5	17.0
Maximum	1330	1126	718	467	334	221

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（71/125）

Laboratory Test: HDL Cholesterol (mg/dL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week -12						
N	71		152		151	
Mean	55.8		56.4		57.6	
SD	14.86		16.57		16.00	
Minimum	31		30		29	
Q1	45.0		44.0		46.0	
Median	56.0		54.0		54.0	
Q3	65.0		63.5		66.0	
Maximum	119		137		129	
Week -4						
N	71		152		151	
Mean	54.2		54.7		56.2	
SD	13.27		15.72		16.89	
Minimum	30		31		29	
Q1	44.0		43.0		45.0	
Median	53.0		53.5		53.0	
Q3	64.0		62.0		65.0	
Maximum	95		131		146	

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（72/125）

Laboratory Test: HDL Cholesterol (mg/dL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 0						
N	71		152		151	
Mean	53.9		53.5		56.3	
SD	12.76		14.76		16.70	
Minimum	33		31		29	
Q1	45.0		43.0		45.0	
Median	51.0		51.0		54.0	
Q3	61.0		59.0		64.0	
Maximum	87		116		139	
Week 2						
N	71	71	152	152	151	151
Mean	52.6	-1.3	53.8	0.3	55.4	-0.8
SD	13.56	5.06	13.33	5.13	16.14	4.89
Minimum	33	-15	33	-20	31	-15
Q1	43.0	-4.0	43.5	-3.0	45.0	-4.0
Median	50.0	-2.0	52.5	1.0	52.0	-1.0
Q3	60.0	1.0	58.5	3.0	63.0	2.0
Maximum	97	10	107	19	135	18

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（73/125）

Laboratory Test: HDL Cholesterol (mg/dL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 4						
N	70	70	150	150	150	150
Mean	54.1	0.3	54.1	0.5	54.7	-1.6
SD	14.61	5.46	14.44	4.94	15.89	5.81
Minimum	30	-12	31	-16	30	-23
Q1	45.0	-3.0	44.0	-3.0	44.0	-4.0
Median	51.0	0.0	52.0	0.0	53.0	-1.0
Q3	61.0	3.0	58.0	3.0	62.0	2.0
Maximum	109	22	113	16	125	15
Week 8						
N	68	68	149	149	149	149
Mean	52.7	-1.6	53.5	-0.2	54.4	-1.9
SD	14.02	5.33	14.32	4.99	14.71	6.60
Minimum	32	-16	34	-15	30	-42
Q1	41.0	-4.5	43.0	-3.0	44.0	-5.0
Median	49.5	-1.5	51.0	0.0	52.0	-1.0
Q3	62.0	2.0	59.0	3.0	62.0	2.0
Maximum	94	8	114	12	102	11

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（74/125）

Laboratory Test: HDL Cholesterol (mg/dL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 12						
N	67	67	148	148	148	148
Mean	53.1	-1.1	54.2	0.4	55.2	-1.0
SD	13.21	5.59	14.94	6.44	16.25	6.86
Minimum	31	-19	31	-23	28	-43
Q1	43.0	-4.0	45.0	-3.0	45.0	-4.0
Median	51.0	0.0	52.0	0.5	51.5	0.0
Q3	60.0	3.0	59.5	4.0	62.0	2.0
Maximum	101	14	120	22	139	18
Week 16						
N	66	66	148	148	148	148
Mean	55.1	0.7	55.1	1.2	55.9	-0.4
SD	13.77	6.39	14.25	6.69	16.55	6.89
Minimum	31	-16	32	-24	30	-28
Q1	45.0	-2.0	45.0	-2.0	46.0	-3.0
Median	53.0	2.0	53.0	1.0	52.0	-1.0
Q3	61.0	5.0	61.0	5.0	64.0	3.0
Maximum	93	17	110	25	117	20

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（75/125）

Laboratory Test: HDL Cholesterol (mg/dL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20						
N	65	65	146	146	148	148
Mean	55.3	1.0	56.4	2.5	57.2	1.0
SD	15.24	6.79	16.06	6.46	17.27	6.94
Minimum	30	-16	33	-14	31	-20
Q1	46.0	-3.0	45.0	-2.0	45.0	-3.0
Median	53.0	2.0	55.0	2.0	54.0	2.0
Q3	62.0	5.0	63.0	6.0	66.0	5.0
Maximum	103	18	119	31	133	28
Week 24						
N	64	64	146	146	148	148
Mean	56.2	1.7	56.7	2.9	58.1	1.9
SD	15.77	6.66	16.48	6.18	17.22	6.25
Minimum	30	-16	30	-12	30	-13
Q1	45.0	-3.0	45.0	-1.0	47.0	-1.5
Median	53.5	2.0	53.5	3.0	55.5	2.0
Q3	64.0	6.0	63.0	6.0	65.0	5.0
Maximum	108	21	130	21	132	24

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（76/125）

Laboratory Test: LDL Cholesterol (mg/dL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week -12						
N	71		152		151	
Mean	121.4		125.1		120.9	
SD	28.11		29.23		27.96	
Minimum	63		55		57	
Q1	101.0		102.5		98.0	
Median	120.0		123.0		122.0	
Q3	140.0		146.0		139.0	
Maximum	217		192		218	
Week -4						
N	71		152		151	
Mean	122.6		121.0		122.8	
SD	27.39		26.23		27.89	
Minimum	62		60		61	
Q1	103.0		101.5		100.0	
Median	121.0		118.0		121.0	
Q3	141.0		139.0		143.0	
Maximum	188		195		190	

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（77/125）

Laboratory Test: LDL Cholesterol (mg/dL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 0						
N	71		152		151	
Mean	123.0		123.7		121.8	
SD	24.59		28.33		28.26	
Minimum	74		56		63	
Q1	104.0		105.0		103.0	
Median	122.0		122.5		121.0	
Q3	137.0		143.0		138.0	
Maximum	189		186		205	
Week 2						
N	71	71	152	152	151	151
Mean	120.6	-2.5	117.7	-6.0	113.5	-8.4
SD	24.88	14.84	28.35	15.67	26.22	17.27
Minimum	61	-46	55	-44	57	-50
Q1	103.0	-13.0	98.0	-14.0	95.0	-19.0
Median	117.0	-2.0	116.0	-7.0	111.0	-10.0
Q3	138.0	10.0	135.5	2.5	131.0	1.0
Maximum	179	33	192	51	185	55

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（78/125）

Laboratory Test: LDL Cholesterol (mg/dL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 4						
N	70	70	150	150	150	150
Mean	121.2	-1.2	117.5	-6.3	110.9	-10.9
SD	25.85	18.96	26.47	16.06	24.33	18.71
Minimum	66	-69	55	-50	63	-91
Q1	102.0	-12.0	100.0	-16.0	91.0	-22.0
Median	120.5	-1.5	116.0	-5.0	110.0	-9.0
Q3	137.0	9.0	135.0	4.0	126.0	3.0
Maximum	178	37	186	33	178	37
Week 8						
N	68	68	149	149	149	149
Mean	117.8	-3.6	117.3	-6.3	110.7	-11.0
SD	23.56	16.87	28.03	16.78	26.09	19.05
Minimum	62	-61	52	-65	54	-89
Q1	101.5	-12.0	98.0	-16.0	93.0	-22.0
Median	114.0	-3.0	118.0	-6.0	108.0	-9.0
Q3	138.5	6.5	136.0	3.0	128.0	2.0
Maximum	167	44	191	49	178	30

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（79/125）

Laboratory Test: LDL Cholesterol (mg/dL)

Visit / Statistics	Placebo (N=71) Observed Value at Visit	Placebo (N=71) Change from Baseline	QD (N=152) Observed Value at Visit	QD (N=152) Change from Baseline	BID (N=151) Observed Value at Visit	BID (N=151) Change from Baseline
Week 12						
N	67	67	148	148	148	148
Mean	119.3	-2.6	117.7	-5.8	113.4	-8.3
SD	25.22	19.27	28.01	20.00	27.62	17.89
Minimum	68	-64	50	-84	64	-81
Q1	100.0	-13.0	99.0	-16.0	90.5	-20.0
Median	117.0	-3.0	116.5	-5.0	111.0	-8.0
Q3	133.0	7.0	137.5	6.0	135.0	5.0
Maximum	195	51	209	58	193	46
Week 16						
N	66	66	148	148	148	148
Mean	119.8	-1.8	117.6	-5.9	112.4	-9.3
SD	25.59	18.45	28.59	21.37	27.81	19.71
Minimum	61	-69	51	-80	56	-92
Q1	102.0	-12.0	98.0	-16.5	92.0	-21.0
Median	115.5	-2.0	114.5	-6.0	108.0	-7.5
Q3	137.0	12.0	137.0	7.0	130.5	3.5
Maximum	176	38	219	44	205	41

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（80/125）

Laboratory Test: LDL Cholesterol (mg/dL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20						
N	65	65	146	146	148	148
Mean	121.3	0.0	117.6	-5.8	114.8	-6.9
SD	29.24	18.57	31.37	22.10	27.57	18.19
Minimum	64	-47	51	-89	62	-77
Q1	101.0	-13.0	98.0	-16.0	94.0	-18.0
Median	122.0	2.0	117.0	-5.0	112.5	-5.5
Q3	142.0	12.0	135.0	8.0	133.0	4.5
Maximum	204	40	201	48	212	39
Week 24						
N	64	64	146	146	148	148
Mean	118.9	-2.2	117.7	-5.7	115.6	-6.1
SD	25.87	23.29	27.65	18.39	27.63	19.64
Minimum	64	-92	56	-73	62	-80
Q1	103.5	-12.0	98.0	-15.0	94.5	-17.0
Median	116.5	1.5	117.0	-5.0	114.0	-5.0
Q3	137.0	8.5	133.0	6.0	132.0	6.0
Maximum	172	40	201	48	198	52

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（81/125）

Laboratory Test: Potassium (mEq/L)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week -12						
N	71		152		151	
Mean	4.29		4.25		4.26	
SD	0.330		0.322		0.332	
Minimum	3.6		3.2		3.5	
Q1	4.10		4.10		4.00	
Median	4.30		4.20		4.20	
Q3	4.50		4.40		4.50	
Maximum	5.0		5.8		5.2	
Week -4						
N	71		152		151	
Mean	4.23		4.24		4.20	
SD	0.317		0.303		0.301	
Minimum	3.5		3.6		3.4	
Q1	4.00		4.00		4.00	
Median	4.20		4.20		4.20	
Q3	4.40		4.40		4.40	
Maximum	5.1		5.3		5.1	

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（82/125）

Laboratory Test: Potassium (mEq/L)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 0						
N	71		149		151	
Mean	4.18		4.16		4.18	
SD	0.329		0.265		0.310	
Minimum	3.3		3.4		3.6	
Q1	4.00		4.00		4.00	
Median	4.20		4.20		4.20	
Q3	4.40		4.30		4.40	
Maximum	5.0		5.0		5.1	
Week 2						
N	71	71	151	148	150	150
Mean	4.20	0.02	4.21	0.04	4.20	0.02
SD	0.337	0.310	0.285	0.232	0.294	0.263
Minimum	3.4	-0.7	3.2	-1.0	3.5	-0.8
Q1	4.00	-0.20	4.00	-0.10	4.00	-0.10
Median	4.20	0.00	4.20	0.00	4.20	0.00
Q3	4.40	0.20	4.40	0.20	4.30	0.20
Maximum	5.4	1.0	5.0	0.7	5.2	0.6

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（83/125）

Laboratory Test: Potassium (mEq/L)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 4						
N	70	70	150	147	149	149
Mean	4.21	0.03	4.20	0.04	4.18	0.00
SD	0.308	0.286	0.316	0.260	0.303	0.279
Minimum	3.5	-0.8	3.6	-0.6	3.6	-0.9
Q1	4.00	-0.10	4.00	-0.10	4.00	-0.10
Median	4.20	0.00	4.20	0.00	4.10	0.00
Q3	4.40	0.20	4.40	0.20	4.30	0.20
Maximum	4.8	0.6	5.3	1.4	5.3	0.7
Week 8						
N	68	68	147	144	148	148
Mean	4.17	-0.02	4.19	0.03	4.19	0.01
SD	0.264	0.232	0.286	0.250	0.281	0.282
Minimum	3.5	-0.7	3.5	-0.6	3.5	-0.9
Q1	4.00	-0.15	4.00	-0.20	4.00	-0.20
Median	4.20	0.00	4.20	0.00	4.20	0.00
Q3	4.40	0.10	4.30	0.20	4.30	0.20
Maximum	4.6	0.5	5.1	0.7	5.0	0.9

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（84/125）

Laboratory Test: Potassium (mEq/L)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 12						
N	66	66	146	143	146	146
Mean	4.13	-0.06	4.17	0.01	4.20	0.01
SD	0.307	0.268	0.283	0.222	0.338	0.290
Minimum	3.3	-0.6	3.5	-0.5	3.3	-0.8
Q1	4.00	-0.30	4.00	-0.10	4.00	-0.20
Median	4.10	-0.10	4.20	0.00	4.20	0.00
Q3	4.40	0.10	4.30	0.20	4.40	0.20
Maximum	4.8	0.6	5.2	0.7	5.6	1.5
Week 16						
N	66	66	146	143	146	146
Mean	4.22	0.02	4.25	0.09	4.20	0.02
SD	0.292	0.237	0.471	0.386	0.288	0.289
Minimum	3.4	-0.4	3.4	-0.6	3.6	-0.9
Q1	4.00	-0.20	4.00	-0.10	4.00	-0.20
Median	4.20	0.00	4.20	0.10	4.20	0.00
Q3	4.40	0.20	4.50	0.20	4.40	0.20
Maximum	4.8	0.6	8.2	3.7	5.2	0.7

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（85/125）

Laboratory Test: Potassium (mEq/L)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20						
N	63	63	144	141	148	148
Mean	4.18	-0.01	4.19	0.02	4.19	0.00
SD	0.279	0.250	0.304	0.239	0.306	0.264
Minimum	3.6	-0.8	3.5	-0.6	3.2	-0.6
Q1	4.00	-0.20	4.00	-0.10	4.00	-0.20
Median	4.20	0.00	4.10	0.00	4.20	0.00
Q3	4.40	0.10	4.40	0.20	4.30	0.20
Maximum	4.9	0.5	5.0	0.6	5.2	0.8
Week 24						
N	63	63	143	140	145	145
Mean	4.22	0.03	4.21	0.05	4.21	0.02
SD	0.338	0.261	0.327	0.256	0.315	0.259
Minimum	3.5	-0.8	3.5	-0.6	3.3	-0.6
Q1	4.00	-0.10	4.00	-0.10	4.00	-0.10
Median	4.20	0.00	4.20	0.00	4.20	0.00
Q3	4.40	0.20	4.40	0.20	4.40	0.20
Maximum	5.2	0.8	5.2	0.9	5.2	0.7

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（86/125）

Laboratory Test: Sodium (mEq/L)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week -12						
N	71		152		151	
Mean	140.7		140.1		140.3	
SD	1.71		1.76		1.72	
Minimum	136		134		136	
Q1	139.0		139.0		139.0	
Median	141.0		140.0		140.0	
Q3	142.0		141.0		141.0	
Maximum	144		144		144	
Week -4						
N	71		152		151	
Mean	140.8		140.0		140.0	
SD	1.81		1.81		1.74	
Minimum	136		134		134	
Q1	140.0		139.0		139.0	
Median	141.0		140.0		140.0	
Q3	142.0		141.0		141.0	
Maximum	145		144		146	

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（87/125）

Laboratory Test: Sodium (mEq/L)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 0						
N	71		152		151	
Mean	140.6		140.1		140.1	
SD	1.62		1.75		1.87	
Minimum	137		135		135	
Q1	140.0		139.0		139.0	
Median	141.0		140.0		140.0	
Q3	141.0		141.0		141.0	
Maximum	145		144		146	
Week 2						
N	71	71	152	152	151	151
Mean	140.6	-0.1	140.4	0.3	140.6	0.5
SD	1.60	1.54	1.76	1.42	1.67	1.67
Minimum	137	-5	135	-4	136	-4
Q1	140.0	-1.0	139.0	-1.0	140.0	-1.0
Median	141.0	0.0	141.0	0.0	141.0	0.0
Q3	141.0	1.0	142.0	1.0	142.0	2.0
Maximum	145	3	145	4	145	5

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（88/125）

Laboratory Test: Sodium (mEq/L)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 4						
N	70	70	150	150	150	150
Mean	140.8	0.2	140.3	0.2	140.5	0.4
SD	1.71	1.64	1.73	1.56	1.76	1.57
Minimum	136	-4	135	-4	133	-7
Q1	140.0	-1.0	139.0	-1.0	139.0	-1.0
Median	141.0	0.0	140.0	0.0	141.0	0.0
Q3	142.0	1.0	142.0	1.0	142.0	1.0
Maximum	145	5	144	5	144	4
Week 8						
N	68	68	149	149	149	149
Mean	140.6	-0.1	140.3	0.1	140.5	0.4
SD	1.73	1.60	1.60	1.49	1.90	1.80
Minimum	136	-4	135	-4	133	-7
Q1	140.0	-1.0	139.0	-1.0	139.0	-1.0
Median	141.0	0.0	140.0	0.0	141.0	0.0
Q3	142.0	1.0	141.0	1.0	142.0	2.0
Maximum	145	3	144	4	146	4

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（89/125）

Laboratory Test: Sodium (mEq/L)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 12						
N	67	67	148	148	148	148
Mean	141.1	0.3	140.5	0.4	141.0	0.9
SD	1.70	1.56	1.77	1.71	1.70	1.58
Minimum	137	-3	135	-4	137	-3
Q1	140.0	-1.0	139.0	-1.0	140.0	0.0
Median	141.0	0.0	140.5	0.0	141.0	1.0
Q3	142.0	1.0	142.0	1.0	142.0	2.0
Maximum	146	5	145	6	146	5
Week 16						
N	66	66	148	148	148	148
Mean	140.9	0.2	140.5	0.3	140.7	0.5
SD	1.78	1.78	1.95	1.92	1.83	1.77
Minimum	137	-3	130	-12	136	-6
Q1	140.0	-1.0	140.0	-1.0	140.0	0.0
Median	141.0	0.0	141.0	0.0	141.0	1.0
Q3	142.0	1.0	142.0	1.0	142.0	2.0
Maximum	145	5	145	5	145	4

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（90/125）

Laboratory Test: Sodium (mEq/L)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20						
N	65	65	146	146	148	148
Mean	140.8	0.0	140.4	0.3	140.8	0.6
SD	2.14	2.02	1.70	1.60	1.85	1.85
Minimum	135	-5	136	-4	134	-4
Q1	140.0	-1.0	139.0	-1.0	139.0	0.0
Median	141.0	0.0	141.0	0.0	141.0	0.0
Q3	142.0	1.0	142.0	1.0	142.0	2.0
Maximum	147	6	144	4	145	5
Week 24						
N	64	64	146	146	148	148
Mean	140.6	-0.1	140.3	0.1	140.6	0.5
SD	1.79	1.65	1.75	1.66	1.84	1.84
Minimum	136	-4	135	-3	136	-4
Q1	139.5	-1.0	139.0	-1.0	139.0	-1.0
Median	141.0	0.0	140.0	0.0	141.0	0.0
Q3	141.5	1.0	141.0	1.0	142.0	2.0
Maximum	144	3	145	4	146	5

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（91/125）

Laboratory Test: Calcium (mg/dL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week -12						
N	71		152		151	
Mean	9.24		9.24		9.23	
SD	0.325		0.312		0.299	
Minimum	8.4		8.5		8.5	
Q1	9.00		9.10		9.00	
Median	9.20		9.20		9.20	
Q3	9.50		9.40		9.40	
Maximum	9.9		10.5		9.9	
Week -4						
N	71		152		151	
Mean	9.22		9.26		9.23	
SD	0.309		0.346		0.317	
Minimum	8.5		8.5		8.3	
Q1	9.00		9.00		9.00	
Median	9.20		9.30		9.20	
Q3	9.50		9.50		9.50	
Maximum	9.9		10.5		9.9	

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（92/125）

Laboratory Test: Calcium (mg/dL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 0						
N	71		152		151	
Mean	9.27		9.27		9.29	
SD	0.337		0.345		0.301	
Minimum	8.4		8.5		8.6	
Q1	9.10		9.10		9.10	
Median	9.30		9.20		9.30	
Q3	9.50		9.50		9.50	
Maximum	10.0		10.7		10.2	
Week 2						
N	71	71	152	152	151	151
Mean	9.26	-0.01	9.32	0.05	9.27	-0.01
SD	0.376	0.296	0.338	0.314	0.304	0.262
Minimum	8.4	-0.9	8.5	-0.7	8.4	-0.8
Q1	9.00	-0.20	9.10	-0.15	9.10	-0.20
Median	9.20	0.00	9.30	0.00	9.30	0.00
Q3	9.50	0.20	9.50	0.20	9.50	0.20
Maximum	10.7	0.9	11.0	0.9	10.0	0.5

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（93/125）

Laboratory Test: Calcium (mg/dL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 4						
N	70	70	150	150	150	150
Mean	9.31	0.04	9.28	0.02	9.26	-0.04
SD	0.381	0.345	0.315	0.291	0.320	0.272
Minimum	8.4	-0.6	8.6	-0.9	8.6	-0.9
Q1	9.10	-0.20	9.10	-0.20	9.00	-0.20
Median	9.30	0.05	9.30	0.00	9.20	-0.05
Q3	9.60	0.30	9.50	0.20	9.50	0.10
Maximum	10.2	1.0	10.3	1.1	10.0	0.9
Week 8						
N	68	68	149	149	149	149
Mean	9.29	0.01	9.28	0.01	9.28	-0.01
SD	0.346	0.308	0.359	0.301	0.316	0.270
Minimum	8.2	-0.7	8.3	-0.9	8.7	-0.8
Q1	9.10	-0.20	9.10	-0.20	9.10	-0.20
Median	9.30	0.00	9.20	0.00	9.30	0.00
Q3	9.50	0.20	9.50	0.20	9.50	0.10
Maximum	9.9	0.9	10.7	0.8	10.1	0.8

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（94/125）

Laboratory Test: Calcium (mg/dL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 12						
N	67	67	148	148	148	148
Mean	9.23	-0.05	9.30	0.04	9.31	0.02
SD	0.338	0.235	0.323	0.280	0.323	0.280
Minimum	8.2	-0.7	8.3	-0.9	8.6	-0.7
Q1	9.00	-0.20	9.10	-0.10	9.10	-0.20
Median	9.30	0.00	9.30	0.00	9.30	0.00
Q3	9.50	0.10	9.50	0.20	9.50	0.20
Maximum	10.0	0.4	10.7	0.7	10.2	0.7
Week 16						
N	66	66	148	148	148	148
Mean	9.30	0.02	9.31	0.05	9.30	0.00
SD	0.357	0.313	0.336	0.324	0.301	0.286
Minimum	8.5	-0.6	8.1	-1.1	8.4	-0.8
Q1	9.00	-0.10	9.10	-0.10	9.10	-0.20
Median	9.30	0.00	9.30	0.00	9.30	0.00
Q3	9.60	0.20	9.50	0.30	9.50	0.20
Maximum	10.3	1.1	10.4	1.0	10.1	0.8

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（95/125）

Laboratory Test: Calcium (mg/dL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20						
N	65	65	146	146	148	148
Mean	9.26	-0.01	9.33	0.07	9.29	-0.01
SD	0.348	0.296	0.354	0.301	0.282	0.261
Minimum	8.5	-0.8	8.7	-0.6	8.7	-0.8
Q1	9.10	-0.20	9.10	-0.10	9.10	-0.20
Median	9.30	0.00	9.30	0.10	9.30	0.00
Q3	9.50	0.10	9.50	0.30	9.50	0.20
Maximum	10.3	0.7	10.8	0.8	9.9	0.5
Week 24						
N	64	64	146	146	148	148
Mean	9.29	0.02	9.30	0.03	9.29	0.00
SD	0.368	0.291	0.305	0.292	0.323	0.276
Minimum	8.5	-0.7	8.7	-0.8	8.6	-0.9
Q1	9.10	-0.20	9.10	-0.10	9.10	-0.20
Median	9.30	0.00	9.20	0.00	9.30	0.00
Q3	9.50	0.25	9.50	0.20	9.50	0.20
Maximum	10.2	0.5	10.5	0.9	10.3	0.9

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（96/125）

Laboratory Test: Chloride (mEq/L)

Visit / Statistics	Placebo (N=71) Observed Value at Visit	Placebo (N=71) Change from Baseline	QD (N=152) Observed Value at Visit	QD (N=152) Change from Baseline	BID (N=151) Observed Value at Visit	BID (N=151) Change from Baseline
Week -12						
N	71		152		151	
Mean	102.4		102.0		102.0	
SD	2.19		1.98		2.11	
Minimum	98		97		96	
Q1	101.0		101.0		101.0	
Median	103.0		102.0		102.0	
Q3	104.0		103.0		103.0	
Maximum	107		107		107	
Week -4						
N	71		152		151	
Mean	102.9		102.3		102.1	
SD	2.07		2.13		2.13	
Minimum	99		96		97	
Q1	101.0		101.0		101.0	
Median	103.0		102.0		102.0	
Q3	104.0		104.0		103.0	
Maximum	109		107		108	

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（97/125）

Laboratory Test: Chloride (mEq/L)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 0						
N	71		152		151	
Mean	102.6		102.3		102.1	
SD	2.19		2.08		2.16	
Minimum	97		96		95	
Q1	101.0		101.0		101.0	
Median	102.0		102.0		102.0	
Q3	104.0		104.0		104.0	
Maximum	109		107		108	
Week 2						
N	71	71	152	152	151	151
Mean	102.9	0.2	102.5	0.2	102.5	0.4
SD	1.92	1.57	2.10	1.73	2.08	1.80
Minimum	98	-4	98	-6	97	-5
Q1	102.0	-1.0	101.0	-1.0	101.0	0.0
Median	103.0	0.0	103.0	0.0	103.0	1.0
Q3	104.0	1.0	104.0	1.0	104.0	2.0
Maximum	107	3	108	5	109	5

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（98/125）

Laboratory Test: Chloride (mEq/L)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 4						
N	70	70	150	150	150	150
Mean	102.7	0.1	102.6	0.3	102.8	0.6
SD	2.13	1.96	1.81	1.67	2.04	1.84
Minimum	98	-6	96	-4	96	-6
Q1	101.0	-1.0	102.0	-1.0	102.0	-1.0
Median	103.0	0.0	103.0	0.0	103.0	1.0
Q3	104.0	1.0	104.0	1.0	104.0	2.0
Maximum	107	5	107	5	108	6
Week 8						
N	68	68	149	149	149	149
Mean	102.9	0.3	102.8	0.4	102.6	0.5
SD	2.00	1.84	1.91	1.67	2.26	1.96
Minimum	99	-5	97	-4	95	-6
Q1	102.0	-1.0	102.0	-1.0	101.0	-1.0
Median	103.0	0.5	103.0	0.0	103.0	1.0
Q3	104.0	2.0	104.0	1.0	104.0	2.0
Maximum	108	3	107	5	109	4

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（99/125）

Laboratory Test: Chloride (mEq/L)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 12						
N	67	67	148	148	148	148
Mean	103.0	0.3	102.5	0.2	102.7	0.6
SD	1.80	1.90	2.09	1.86	2.08	1.81
Minimum	99	-5	97	-4	97	-4
Q1	102.0	-1.0	101.0	-1.0	102.0	-1.0
Median	103.0	0.0	103.0	0.0	103.0	1.0
Q3	104.0	2.0	104.0	1.0	104.0	2.0
Maximum	106	5	108	7	108	5
Week 16						
N	66	66	148	148	148	148
Mean	102.7	0.0	102.7	0.4	102.4	0.3
SD	2.07	1.95	4.11	3.88	2.07	2.03
Minimum	99	-4	97	-5	96	-7
Q1	101.0	-1.0	101.0	-1.0	101.0	-1.0
Median	102.5	0.0	103.0	0.0	102.0	0.0
Q3	104.0	1.0	104.0	1.0	104.0	2.0
Maximum	108	4	146	42	108	5

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（100/125）

Laboratory Test: Chloride (mEq/L)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20						
N	65	65	146	146	148	148
Mean	102.7	0.0	102.4	0.1	102.5	0.4
SD	2.34	2.14	2.11	1.89	1.98	2.06
Minimum	97	-5	94	-5	97	-4
Q1	101.0	-1.0	101.0	-1.0	101.0	-1.0
Median	102.0	0.0	102.0	0.0	103.0	0.0
Q3	105.0	1.0	104.0	1.0	104.0	2.0
Maximum	108	4	107	6	108	5
Week 24						
N	64	64	146	146	148	148
Mean	102.3	-0.4	102.1	-0.2	102.4	0.3
SD	2.25	2.16	2.07	1.97	2.13	2.15
Minimum	97	-6	94	-5	97	-6
Q1	101.0	-1.5	101.0	-1.0	101.0	-1.0
Median	102.0	0.0	102.0	0.0	102.0	0.0
Q3	104.0	1.0	103.0	1.0	104.0	2.0
Maximum	107	5	107	4	108	6

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（101/125）

Laboratory Test: Phosphorus (mg/dL)

Visit / Statistics	Placebo (N=71) Observed Value at Visit	Placebo (N=71) Change from Baseline	QD (N=152) Observed Value at Visit	QD (N=152) Change from Baseline	BID (N=151) Observed Value at Visit	BID (N=151) Change from Baseline
Week -12						
N	71		152		151	
Mean	3.29		3.23		3.22	
SD	0.489		0.406		0.426	
Minimum	2.4		2.1		2.1	
Q1	2.90		3.00		2.90	
Median	3.20		3.20		3.10	
Q3	3.60		3.50		3.50	
Maximum	4.9		4.1		4.6	
Week -4						
N	71		152		151	
Mean	3.22		3.21		3.16	
SD	0.434		0.419		0.425	
Minimum	2.3		2.0		2.4	
Q1	3.00		2.95		2.90	
Median	3.20		3.10		3.10	
Q3	3.40		3.50		3.40	
Maximum	4.3		4.4		4.7	

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（102/125）

Laboratory Test: Phosphorus (mg/dL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 0						
N	71		152		151	
Mean	3.21		3.15		3.19	
SD	0.504		0.428		0.451	
Minimum	2.0		2.2		2.3	
Q1	2.80		2.90		2.80	
Median	3.10		3.10		3.20	
Q3	3.60		3.40		3.50	
Maximum	4.6		4.4		4.4	
Week 2						
N	71	71	152	152	151	151
Mean	3.17	-0.04	3.22	0.07	3.21	0.02
SD	0.449	0.408	0.414	0.364	0.449	0.349
Minimum	1.8	-1.4	2.0	-1.1	2.3	-0.8
Q1	2.90	-0.30	3.00	-0.20	2.90	-0.20
Median	3.10	0.00	3.20	0.00	3.20	0.00
Q3	3.50	0.20	3.50	0.30	3.50	0.30
Maximum	4.3	0.9	4.6	1.3	4.7	0.9

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（103/125）

Laboratory Test: Phosphorus (mg/dL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 4						
N	70	70	150	150	150	150
Mean	3.17	-0.04	3.17	0.02	3.21	0.02
SD	0.420	0.446	0.435	0.324	0.463	0.369
Minimum	2.3	-1.1	1.9	-0.8	2.2	-1.4
Q1	2.90	-0.30	2.90	-0.20	2.90	-0.20
Median	3.10	0.00	3.10	0.00	3.20	0.00
Q3	3.50	0.20	3.50	0.20	3.50	0.20
Maximum	4.2	1.1	4.4	1.0	4.5	1.2
Week 8						
N	68	68	149	149	149	149
Mean	3.21	-0.01	3.19	0.04	3.24	0.05
SD	0.487	0.392	0.410	0.339	0.449	0.373
Minimum	2.1	-1.4	2.1	-0.9	2.3	-1.2
Q1	2.90	-0.20	2.90	-0.20	2.90	-0.20
Median	3.10	0.00	3.20	0.10	3.10	0.00
Q3	3.40	0.20	3.50	0.30	3.50	0.30
Maximum	4.7	1.1	4.1	1.2	4.8	0.9

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（104/125）

Laboratory Test: Phosphorus (mg/dL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 12						
N	67	67	148	148	148	148
Mean	3.24	0.02	3.26	0.11	3.28	0.09
SD	0.459	0.359	0.442	0.375	0.450	0.346
Minimum	2.3	-0.8	2.0	-1.4	2.4	-1.0
Q1	2.90	-0.20	3.00	-0.05	3.00	-0.20
Median	3.20	0.10	3.20	0.20	3.20	0.10
Q3	3.60	0.30	3.50	0.30	3.50	0.30
Maximum	4.7	0.9	4.4	1.0	4.9	1.1
Week 16						
N	66	66	148	148	148	148
Mean	3.21	-0.02	3.20	0.06	3.26	0.06
SD	0.478	0.395	0.401	0.354	0.438	0.381
Minimum	2.2	-1.0	2.3	-1.2	2.5	-1.1
Q1	2.90	-0.20	2.90	-0.10	2.90	-0.10
Median	3.20	0.00	3.20	0.10	3.20	0.10
Q3	3.60	0.30	3.50	0.30	3.50	0.30
Maximum	4.3	1.2	4.3	1.0	4.5	1.3

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（105/125）

Laboratory Test: Phosphorus (mg/dL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20						
N	65	65	146	146	148	148
Mean	3.18	-0.04	3.25	0.11	3.24	0.05
SD	0.472	0.413	0.402	0.325	0.434	0.359
Minimum	2.3	-0.9	2.3	-0.7	2.3	-0.9
Q1	2.80	-0.30	3.00	-0.10	2.90	-0.20
Median	3.10	0.00	3.20	0.10	3.20	0.10
Q3	3.50	0.20	3.50	0.30	3.60	0.30
Maximum	4.3	1.0	4.2	1.1	4.3	0.9
Week 24						
N	64	64	146	146	148	148
Mean	3.23	0.01	3.23	0.08	3.26	0.07
SD	0.460	0.377	0.391	0.338	0.478	0.399
Minimum	1.9	-1.3	2.3	-0.9	2.1	-0.9
Q1	2.90	-0.20	3.00	-0.10	2.90	-0.20
Median	3.20	0.05	3.20	0.10	3.30	0.10
Q3	3.50	0.20	3.50	0.30	3.50	0.30
Maximum	4.5	1.0	4.2	1.1	4.9	1.2

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（106/125）

Laboratory Test: Lactic Acid (mg/dL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week -12						
N	71		152		151	
Mean	11.60		10.70		11.22	
SD	5.603		3.922		4.473	
Minimum	3.6		2.8		3.2	
Q1	7.40		7.40		7.90	
Median	11.40		10.60		10.40	
Q3	14.60		13.40		13.60	
Maximum	31.9		22.9		24.0	
Week -4						
N	71		152		151	
Mean	11.19		11.51		11.12	
SD	4.426		4.367		4.257	
Minimum	3.2		3.4		3.2	
Q1	8.40		8.25		8.20	
Median	10.60		11.05		10.40	
Q3	13.60		14.60		13.80	
Maximum	29.4		24.6		27.4	

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（107/125）

Laboratory Test: Lactic Acid (mg/dL)

Visit / Statistics	Placebo (N=71) Observed Value at Visit	Placebo (N=71) Change from Baseline	QD (N=152) Observed Value at Visit	QD (N=152) Change from Baseline	BID (N=151) Observed Value at Visit	BID (N=151) Change from Baseline
Week 0						
N	71		152		151	
Mean	10.91		11.27		11.55	
SD	4.081		4.199		4.267	
Minimum	3.6		1.9		3.2	
Q1	7.70		8.10		8.60	
Median	10.40		11.10		11.50	
Q3	13.30		13.70		14.10	
Maximum	26.0		22.8		26.9	
Week 2						
N	71	71	152	152	151	151
Mean	11.06	0.15	11.47	0.20	11.19	-0.36
SD	5.502	3.807	4.720	3.242	4.162	3.625
Minimum	2.6	-8.4	3.0	-9.6	3.6	-13.1
Q1	7.20	-2.30	7.65	-1.80	8.10	-2.00
Median	10.00	0.10	10.80	0.40	10.70	-0.50
Q3	13.30	2.90	14.00	2.40	13.80	1.80
Maximum	36.4	10.4	25.8	12.1	26.7	10.1

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（108/125）

Laboratory Test: Lactic Acid (mg/dL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 4						
N	70	70	150	150	150	150
Mean	11.20	0.28	10.97	-0.35	11.75	0.20
SD	4.597	3.788	4.248	3.612	4.217	3.884
Minimum	3.3	-8.9	2.5	-11.0	3.5	-17.2
Q1	8.00	-2.00	7.80	-2.70	8.70	-1.60
Median	10.75	0.50	10.60	-0.20	11.20	0.25
Q3	14.00	2.50	13.80	1.70	14.40	2.00
Maximum	26.3	9.1	27.3	8.4	25.3	10.7
Week 8						
N	68	68	149	149	149	149
Mean	11.54	0.72	11.82	0.46	12.02	0.48
SD	4.156	2.795	4.724	3.651	4.329	4.013
Minimum	3.7	-5.4	3.5	-9.0	3.7	-13.4
Q1	8.55	-0.95	8.40	-1.60	8.70	-1.40
Median	11.00	0.45	11.10	0.40	11.50	0.40
Q3	14.65	3.05	14.00	2.00	14.70	2.10
Maximum	24.2	6.8	29.8	14.0	27.2	13.4

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（109/125）

Laboratory Test: Lactic Acid (mg/dL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 12						
N	67	67	148	148	148	148
Mean	11.82	1.05	11.40	0.10	11.96	0.41
SD	5.446	4.835	4.742	3.930	4.232	4.349
Minimum	3.6	-9.2	3.2	-12.8	3.3	-15.3
Q1	7.40	-1.80	8.25	-2.35	8.90	-1.95
Median	11.70	0.10	10.80	0.05	11.60	-0.05
Q3	14.40	3.80	13.60	2.25	14.65	2.85
Maximum	34.8	19.0	32.2	11.0	27.1	16.4
Week 16						
N	66	66	148	148	148	148
Mean	11.34	0.56	11.56	0.26	11.38	-0.17
SD	4.758	3.863	5.033	4.751	4.528	4.490
Minimum	3.7	-11.4	4.2	-12.8	3.8	-15.6
Q1	7.90	-2.00	8.60	-2.00	7.95	-2.65
Median	10.30	0.75	11.05	0.35	11.00	-0.05
Q3	14.40	2.50	13.60	2.30	13.75	1.95
Maximum	29.0	12.1	50.0	36.6	32.3	22.2

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（110/125）

Laboratory Test: Lactic Acid (mg/dL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20						
N	65	65	146	146	148	148
Mean	11.04	0.28	11.95	0.66	10.98	-0.56
SD	5.082	4.478	5.176	4.579	4.055	4.304
Minimum	2.6	-7.5	3.3	-10.9	3.4	-18.6
Q1	7.40	-2.60	8.00	-2.10	7.90	-2.70
Median	10.40	-0.20	11.65	0.65	10.90	-0.40
Q3	13.50	2.70	14.70	3.00	13.50	1.30
Maximum	27.9	20.2	38.5	29.5	25.6	15.2
Week 24						
N	64	64	146	146	148	148
Mean	10.75	-0.04	11.30	0.01	11.34	-0.20
SD	5.386	4.315	4.543	3.846	4.320	4.468
Minimum	2.9	-10.4	2.7	-9.7	3.1	-14.2
Q1	6.30	-2.85	7.90	-2.60	7.75	-2.35
Median	9.60	-0.25	11.20	0.20	11.30	-0.20
Q3	14.45	2.15	14.00	2.30	14.35	2.00
Maximum	30.8	12.0	27.1	12.2	30.9	19.3

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（111/125）

Laboratory Test: Pyruvic Acid (mg/dL)

Visit / Statistics	Placebo (N=71) Observed Value at Visit	Placebo (N=71) Change from Baseline	QD (N=152) Observed Value at Visit	QD (N=152) Change from Baseline	BID (N=151) Observed Value at Visit	BID (N=151) Change from Baseline
Week -12						
N	71		152		151	
Mean	0.540		0.475		0.485	
SD	0.2901		0.1966		0.1868	
Minimum	0.11		0.13		0.13	
Q1	0.350		0.335		0.350	
Median	0.460		0.450		0.470	
Q3	0.690		0.560		0.590	
Maximum	1.97		1.09		1.17	
Week -4						
N	71		152		151	
Mean	0.531		0.521		0.516	
SD	0.2510		0.2220		0.2553	
Minimum	0.16		0.00		0.00	
Q1	0.340		0.360		0.370	
Median	0.470		0.470		0.500	
Q3	0.690		0.650		0.640	
Maximum	1.29		1.34		1.88	

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（112/125）

Laboratory Test: Pyruvic Acid (mg/dL)

Visit / Statistics	Placebo (N=71) Observed Value at Visit	Placebo (N=71) Change from Baseline	QD (N=152) Observed Value at Visit	QD (N=152) Change from Baseline	BID (N=151) Observed Value at Visit	BID (N=151) Change from Baseline
Week 0						
N	71		152		151	
Mean	0.560		0.533		0.558	
SD	0.2735		0.2590		0.2261	
Minimum	0.11		0.00		0.00	
Q1	0.370		0.350		0.390	
Median	0.500		0.480		0.510	
Q3	0.690		0.670		0.680	
Maximum	1.50		1.43		1.22	
Week 2						
N	71	71	152	152	151	151
Mean	0.532	-0.028	0.536	0.003	0.529	-0.029
SD	0.3138	0.2019	0.2686	0.2172	0.2285	0.2076
Minimum	0.15	-0.40	0.00	-0.80	0.00	-0.55
Q1	0.310	-0.160	0.355	-0.110	0.360	-0.160
Median	0.430	-0.040	0.465	-0.020	0.500	-0.030
Q3	0.690	0.100	0.685	0.110	0.650	0.070
Maximum	1.50	0.53	1.38	0.70	1.49	0.64

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（113/125）

Laboratory Test: Pyruvic Acid (mg/dL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 4						
N	70	70	150	150	150	150
Mean	0.532	-0.033	0.536	0.003	0.560	0.006
SD	0.2531	0.2067	0.2775	0.2238	0.2257	0.2134
Minimum	0.12	-0.54	0.00	-0.76	0.00	-0.69
Q1	0.360	-0.160	0.350	-0.110	0.390	-0.120
Median	0.480	0.010	0.480	-0.010	0.540	-0.010
Q3	0.630	0.080	0.660	0.150	0.680	0.170
Maximum	1.46	0.49	1.68	0.55	1.16	0.53
Week 8						
N	68	68	149	149	149	149
Mean	0.550	-0.017	0.571	0.037	0.582	0.027
SD	0.2815	0.1772	0.3011	0.2501	0.2641	0.2394
Minimum	0.14	-0.42	0.00	-0.69	0.00	-0.55
Q1	0.325	-0.140	0.350	-0.090	0.380	-0.110
Median	0.460	-0.005	0.500	0.020	0.560	0.020
Q3	0.715	0.125	0.730	0.160	0.750	0.160
Maximum	1.31	0.42	1.83	0.96	1.64	0.99

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（114/125）

Laboratory Test: Pyruvic Acid (mg/dL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 12						
N	67	67	148	148	148	148
Mean	0.579	0.011	0.536	0.005	0.556	0.000
SD	0.3204	0.2802	0.2679	0.2325	0.2833	0.2408
Minimum	0.13	-0.92	0.00	-0.76	0.00	-0.55
Q1	0.360	-0.130	0.355	-0.120	0.355	-0.160
Median	0.510	0.020	0.485	0.005	0.515	-0.035
Q3	0.730	0.170	0.695	0.130	0.730	0.130
Maximum	1.69	0.72	1.41	0.90	1.54	0.87
Week 16						
N	66	66	148	148	148	148
Mean	0.528	-0.045	0.533	0.002	0.520	-0.036
SD	0.2585	0.2059	0.2868	0.2559	0.2226	0.2255
Minimum	0.12	-0.66	0.00	-0.78	0.00	-0.75
Q1	0.370	-0.120	0.320	-0.100	0.350	-0.180
Median	0.445	-0.030	0.460	-0.020	0.490	-0.030
Q3	0.670	0.060	0.675	0.140	0.660	0.120
Maximum	1.19	0.39	1.50	0.87	1.14	0.44

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（115/125）

Laboratory Test: Pyruvic Acid (mg/dL)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20						
N	65	65	146	146	148	148
Mean	0.501	-0.070	0.522	-0.013	0.494	-0.063
SD	0.2619	0.2232	0.3014	0.2538	0.2287	0.2312
Minimum	0.19	-0.61	0.00	-1.00	0.00	-0.76
Q1	0.310	-0.200	0.320	-0.170	0.310	-0.220
Median	0.400	-0.060	0.440	-0.020	0.460	-0.050
Q3	0.690	0.050	0.640	0.120	0.630	0.100
Maximum	1.23	0.50	1.59	0.60	1.13	0.45
Week 24						
N	64	64	146	146	148	148
Mean	0.463	-0.110	0.466	-0.069	0.483	-0.073
SD	0.2779	0.2610	0.2677	0.2296	0.2229	0.2195
Minimum	0.00	-0.81	0.00	-1.00	0.00	-0.84
Q1	0.280	-0.230	0.290	-0.180	0.330	-0.200
Median	0.410	-0.095	0.400	-0.050	0.460	-0.075
Q3	0.560	-0.005	0.590	0.060	0.600	0.065
Maximum	1.36	0.56	1.40	0.59	1.19	0.49

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（116/125）

Laboratory Test: Amylase (U/L)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week -12						
N	71		152		151	
Mean	73.9		68.9		68.6	
SD	35.98		25.11		23.67	
Minimum	29		28		27	
Q1	57.0		51.5		51.0	
Median	69.0		64.0		68.0	
Q3	85.0		84.0		82.0	
Maximum	291		178		162	
Week -4						
N	71		152		151	
Mean	69.1		67.4		66.5	
SD	25.70		26.50		23.81	
Minimum	27		29		25	
Q1	52.0		49.0		49.0	
Median	62.0		62.0		63.0	
Q3	79.0		83.5		78.0	
Maximum	170		231		177	

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（117/125）

Laboratory Test: Amylase (U/L)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 0						
N	71		152		151	
Mean	69.1		66.1		65.3	
SD	28.15		23.09		22.13	
Minimum	26		27		23	
Q1	50.0		49.0		49.0	
Median	64.0		65.0		64.0	
Q3	82.0		82.0		77.0	
Maximum	211		141		144	
Week 2						
N	71	71	152	152	151	151
Mean	70.2	1.2	68.9	2.8	69.9	4.6
SD	28.64	12.73	25.16	16.57	26.99	12.58
Minimum	27	-44	32	-67	25	-35
Q1	52.0	-5.0	51.5	-3.0	53.0	-2.0
Median	64.0	0.0	65.0	3.0	68.0	3.0
Q3	83.0	6.0	83.0	9.0	79.0	9.0
Maximum	167	50	198	112	191	71

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（118/125）

Laboratory Test: Amylase (U/L)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 4						
N	70	70	150	150	150	150
Mean	70.1	1.1	68.1	2.1	70.1	4.5
SD	26.89	13.83	23.69	14.49	26.73	12.43
Minimum	28	-48	32	-75	24	-37
Q1	54.0	-5.0	51.0	-2.0	51.0	-2.0
Median	67.0	1.0	63.5	2.0	68.0	4.0
Q3	79.0	7.0	85.0	9.0	82.0	9.0
Maximum	165	51	131	44	173	70
Week 8						
N	68	68	149	149	149	149
Mean	68.9	0.8	67.4	1.3	70.2	4.5
SD	24.94	15.61	23.12	13.84	27.45	14.68
Minimum	26	-64	30	-64	27	-55
Q1	52.0	-4.5	50.0	-4.0	53.0	-2.0
Median	62.0	2.5	65.0	2.0	68.0	4.0
Q3	82.0	6.5	82.0	9.0	81.0	9.0
Maximum	147	39	140	38	247	103

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（119/125）

Laboratory Test: Amylase (U/L)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 12						
N	67	67	148	148	148	148
Mean	66.5	-1.8	66.8	0.5	69.6	3.8
SD	23.73	13.72	23.06	14.19	25.54	14.64
Minimum	26	-52	28	-67	27	-43
Q1	50.0	-8.0	49.0	-3.0	51.5	-2.0
Median	62.0	0.0	64.0	2.0	69.0	3.0
Q3	79.0	5.0	82.5	7.0	80.0	9.0
Maximum	159	32	145	36	181	77
Week 16						
N	66	66	148	148	148	148
Mean	69.5	1.7	67.0	0.7	69.9	4.1
SD	24.16	12.45	22.63	15.56	25.32	13.07
Minimum	25	-58	30	-73	27	-49
Q1	55.0	-4.0	51.0	-4.0	50.5	-3.0
Median	68.0	2.0	62.5	3.0	68.5	3.0
Q3	80.0	9.0	82.0	8.0	83.5	8.0
Maximum	153	28	136	40	179	62

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（120/125）

Laboratory Test: Amylase (U/L)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20						
N	65	65	146	146	148	148
Mean	70.6	2.8	68.8	2.2	71.0	5.2
SD	27.05	11.72	22.89	13.81	27.19	15.28
Minimum	27	-27	26	-76	23	-46
Q1	53.0	-2.0	53.0	-2.0	54.0	-1.0
Median	67.0	1.0	66.0	3.0	69.0	4.0
Q3	82.0	9.0	85.0	9.0	82.0	10.0
Maximum	184	37	132	47	216	112
Week 24						
N	64	64	146	146	148	148
Mean	71.5	3.5	69.0	2.4	73.9	8.2
SD	30.03	14.38	23.71	13.81	31.38	18.89
Minimum	25	-35	30	-70	24	-30
Q1	51.0	-2.0	52.0	-2.0	54.0	-0.5
Median	63.5	3.0	64.0	3.0	71.0	6.0
Q3	82.5	10.0	87.0	9.0	84.0	12.0
Maximum	200	74	148	48	276	140

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（121/125）

Laboratory Test: Lipase (U/L)

Visit / Statistics	Placebo (N=71) Observed Value at Visit	Placebo (N=71) Change from Baseline	QD (N=152) Observed Value at Visit	QD (N=152) Change from Baseline	BID (N=151) Observed Value at Visit	BID (N=151) Change from Baseline
Week -12						
N	71		152		151	
Mean	14.1		12.7		12.4	
SD	11.43		7.00		10.10	
Minimum	3		2		3	
Q1	8.0		8.0		7.0	
Median	12.0		11.0		11.0	
Q3	16.0		15.0		15.0	
Maximum	85		44		100	
Week -4						
N	71		152		151	
Mean	12.9		14.0		12.1	
SD	8.34		11.98		9.53	
Minimum	3		2		3	
Q1	8.0		8.5		7.0	
Median	10.0		12.0		10.0	
Q3	15.0		16.5		13.0	
Maximum	51		126		96	

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（122/125）

Laboratory Test: Lipase (U/L)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 0						
N	71		152		151	
Mean	13.3		13.9		11.3	
SD	11.17		12.13		6.96	
Minimum	3		3		2	
Q1	8.0		8.0		7.0	
Median	11.0		11.0		10.0	
Q3	15.0		15.0		13.0	
Maximum	78		115		43	
Week 2						
N	71	71	152	152	151	151
Mean	15.5	2.2	14.2	0.3	13.9	2.7
SD	14.57	12.47	10.67	12.69	10.95	7.54
Minimum	4	-40	2	-99	3	-26
Q1	8.0	-1.0	9.0	-1.0	8.0	0.0
Median	11.0	1.0	11.0	1.0	11.0	1.0
Q3	16.0	3.0	16.0	3.0	15.0	3.0
Maximum	89	63	96	85	73	39

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（123/125）

Laboratory Test: Lipase (U/L)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 4						
N	70	70	150	150	150	150
Mean	13.8	0.4	13.4	-0.6	13.1	1.8
SD	10.04	10.66	7.01	11.40	9.59	7.15
Minimum	4	-43	3	-103	3	-39
Q1	8.0	-1.0	9.0	-2.0	8.0	0.0
Median	11.0	1.0	12.0	1.0	11.0	1.0
Q3	17.0	3.0	16.0	3.0	15.0	4.0
Maximum	73	58	50	24	75	44
Week 8						
N	68	68	149	149	149	149
Mean	13.0	-0.5	13.2	-0.9	14.8	3.4
SD	8.46	10.72	8.19	11.19	19.39	16.58
Minimum	2	-60	2	-90	2	-38
Q1	7.5	-1.0	9.0	-1.0	8.0	0.0
Median	11.0	0.0	11.0	0.0	11.0	1.0
Q3	16.5	3.0	16.0	2.0	15.0	3.0
Maximum	55	29	72	48	215	177

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（124/125）

Laboratory Test: Lipase (U/L)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 12						
N	67	67	148	148	148	148
Mean	12.8	-0.7	13.5	-0.5	13.7	2.3
SD	8.10	9.19	8.46	11.09	8.58	6.37
Minimum	3	-52	3	-95	3	-31
Q1	8.0	-2.0	9.0	-1.0	8.0	0.0
Median	11.0	0.0	11.0	0.0	12.0	2.0
Q3	15.0	2.0	16.5	2.0	16.5	4.0
Maximum	43	29	65	31	69	32
Week 16						
N	66	66	148	148	148	148
Mean	13.6	1.1	13.7	-0.3	13.6	2.3
SD	7.37	6.79	7.74	12.36	10.06	8.30
Minimum	4	-37	4	-105	3	-34
Q1	8.0	0.0	9.0	-1.0	8.0	-1.0
Median	12.0	1.0	11.0	1.0	11.0	1.0
Q3	16.0	3.0	16.5	3.0	16.0	4.0
Maximum	39	16	49	38	89	52

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-27　血液生化学検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（125/125）

Laboratory Test: Lipase (U/L)

Visit / Statistics	Placebo (N=71)		QD (N=152)		BID (N=151)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20						
N	65	65	146	146	148	148
Mean	13.6	1.1	13.9	-0.2	14.1	2.8
SD	7.26	6.73	8.20	12.36	12.04	11.02
Minimum	3	-36	3	-106	2	-36
Q1	9.0	0.0	9.0	0.0	7.5	-1.0
Median	12.0	1.0	11.0	1.0	12.0	1.0
Q3	16.0	3.0	16.0	3.0	16.0	4.0
Maximum	33	20	53	29	98	87
Week 24						
N	64	64	146	146	148	148
Mean	13.8	1.3	14.1	0.0	15.3	4.0
SD	9.75	7.99	7.96	10.95	17.82	15.83
Minimum	3	-37	4	-97	4	-17
Q1	9.0	-0.5	9.0	-1.0	8.0	0.0
Median	11.5	1.0	11.5	1.0	12.0	1.0
Q3	16.0	3.0	17.0	3.0	16.0	4.0
Maximum	68	43	51	33	188	167

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

表 2.7.4.7-付録-28　血液生化学検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（1/50）

ALT (GPT)

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 2												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	65	2	67	-	128	3	131	-	127	7	134
High	-	2	2	4	-	2	19	21	-	2	15	17
Total	-	67	4	71	-	130	22	152	-	129	22	151
Week 4												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	64	1	65	-	126	1	127	-	123	8	131
High	-	2	3	5	-	2	21	23	-	5	14	19
Total	-	66	4	70	-	128	22	150	-	128	22	150
Week 8												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	61	1	62	-	123	-	123	-	122	8	130
High	-	3	3	6	-	4	22	26	-	5	14	19
Total	-	64	4	68	-	127	22	149	-	127	22	149
Week 12												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	60	2	62	-	119	1	120	-	117	4	121
High	-	3	2	5	-	7	21	28	-	9	18	27
Total	-	63	4	67	-	126	22	148	-	126	22	148

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.3

表 2.7.4.7-付録-28　血液生化学検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（2/50）

ALT (GPT)

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 16												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	59	1	60	-	118	1	119	-	118	2	120
High	-	3	3	6	-	8	21	29	-	8	20	28
Total	-	62	4	66	-	126	22	148	-	126	22	148
Week 20												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	59	3	62	-	116	1	117	-	113	5	118
High	-	2	1	3	-	8	21	29	-	13	17	30
Total	-	61	4	65	-	124	22	146	-	126	22	148
Week 24												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	57	1	58	-	116	2	118	-	115	5	120
High	-	4	2	6	-	8	20	28	-	11	17	28
Total	-	61	3	64	-	124	22	146	-	126	22	148

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.3

表 2.7.4.7-付録-28　血液生化学検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（3/50）

AST (GOT)

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 2												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	67	1	68	-	128	5	133	-	136	1	137
High	-	1	2	3	-	5	10	15	-	2	11	13
Total	-	68	3	71	-	133	15	148	-	138	12	150
Week 4												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	67	1	68	-	128	2	130	-	131	5	136
High	-	-	2	2	-	5	12	17	-	6	7	13
Total	-	67	3	70	-	133	14	147	-	137	12	149
Week 8												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	62	-	62	-	126	2	128	-	130	2	132
High	-	3	3	6	-	5	11	16	-	6	10	16
Total	-	65	3	68	-	131	13	144	-	136	12	148
Week 12												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	61	-	61	-	123	4	127	-	127	1	128
High	-	2	3	5	-	6	10	16	-	7	11	18
Total	-	63	3	66	-	129	14	143	-	134	12	146

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.3

表 2.7.4.7-付録-28　血液生化学検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（4/50）

AST (GOT)

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 16												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	61	-	61	-	121	4	125	-	127	2	129
High	-	2	3	5	-	8	10	18	-	7	10	17
Total	-	63	3	66	-	129	14	143	-	134	12	146
Week 20												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	60	-	60	-	122	2	124	-	128	1	129
High	-	-	3	3	-	5	12	17	-	8	11	19
Total	-	60	3	63	-	127	14	141	-	136	12	148
Week 24												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	59	-	59	-	116	3	119	-	125	2	127
High	-	2	2	4	-	11	10	21	-	8	10	18
Total	-	61	2	63	-	127	13	140	-	133	12	145

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.3

表 2.7.4.7-付録-28　血液生化学検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（5/50）

GGT

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 2												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	57	2	59	-	110	10	120	-	118	5	123
High	-	3	9	12	-	2	30	32	-	-	28	28
Total	-	60	11	71	-	112	40	152	-	118	33	151
Week 4												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	57	3	60	-	110	9	119	-	118	8	126
High	-	2	8	10	-	-	31	31	-	-	24	24
Total	-	59	11	70	-	110	40	150	-	118	32	150
Week 8												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	52	3	55	-	109	7	116	-	116	4	120
High	-	5	8	13	-	-	33	33	-	1	28	29
Total	-	57	11	68	-	109	40	149	-	117	32	149
Week 12												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	50	1	51	-	106	9	115	-	114	2	116
High	-	6	10	16	-	3	30	33	-	2	30	32
Total	-	56	11	67	-	109	39	148	-	116	32	148

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.3

表 2.7.4.7-付録-28　血液生化学検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（6/50）

GGT

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 16												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	51	3	54	-	104	6	110	-	111	2	113
High	-	5	7	12	-	5	33	38	-	5	30	35
Total	-	56	10	66	-	109	39	148	-	116	32	148
Week 20												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	48	3	51	-	103	7	110	-	111	3	114
High	-	7	7	14	-	5	31	36	-	5	29	34
Total	-	55	10	65	-	108	38	146	-	116	32	148
Week 24												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	48	1	49	-	102	12	114	-	111	5	116
High	-	6	9	15	-	6	26	32	-	5	27	32
Total	-	54	10	64	-	108	38	146	-	116	32	148

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.3

表 2.7.4.7-付録-28　血液生化学検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（7/50）

Alkaline Phosphatase

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 2												
Low	1	-	-	1	1	-	-	1	1	1	-	2
Normal	-	63	2	65	-	131	6	137	-	130	6	136
High	-	1	4	5	-	4	10	14	-	1	12	13
Total	1	64	6	71	1	135	16	152	1	132	18	151
Week 4												
Low	-	-	-	-	1	-	-	1	1	-	-	1
Normal	1	56	2	59	-	131	8	139	-	128	9	137
High	-	7	4	11	-	2	8	10	-	3	9	12
Total	1	63	6	70	1	133	16	150	1	131	18	150
Week 8												
Low	1	-	-	1	1	1	-	2	1	-	-	1
Normal	-	60	2	62	-	130	7	137	-	129	7	136
High	-	1	4	5	-	1	9	10	-	1	11	12
Total	1	61	6	68	1	132	16	149	1	130	18	149
Week 12												
Low	1	-	-	1	1	1	-	2	1	-	-	1
Normal	-	58	1	59	-	124	7	131	-	127	7	134
High	-	2	5	7	-	7	8	15	-	2	11	13
Total	1	60	6	67	1	132	15	148	1	129	18	148

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.3

表 2.7.4.7-付録-28　血液生化学検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（8/50）

Alkaline Phosphatase

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 16												
Low	-	-	-	-	1	1	-	2	1	-	-	1
Normal	1	58	1	60	-	125	7	132	-	126	10	136
High	-	1	5	6	-	6	8	14	-	3	8	11
Total	1	59	6	66	1	132	15	148	1	129	18	148
Week 20												
Low	-	-	-	-	1	1	-	2	1	-	-	1
Normal	1	54	3	58	-	127	7	134	-	126	8	134
High	-	4	3	7	-	2	8	10	-	3	10	13
Total	1	58	6	65	1	130	15	146	1	129	18	148
Week 24												
Low	-	-	-	-	1	1	-	2	1	-	-	1
Normal	1	52	3	56	-	128	7	135	-	126	7	133
High	-	5	3	8	-	1	8	9	-	3	11	14
Total	1	57	6	64	1	130	15	146	1	129	18	148

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.3

表 2.7.4.7-付録-28　血液生化学検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（9/50）

Total Bilirubin

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 2												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	58	5	63	-	126	11	137	-	133	6	139
High	-	4	4	8	-	3	12	15	-	5	7	12
Total	-	62	9	71	-	129	23	152	-	138	13	151
Week 4												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	60	2	62	-	123	14	137	-	133	7	140
High	-	2	6	8	-	5	8	13	-	4	6	10
Total	-	62	8	70	-	128	22	150	-	137	13	150
Week 8												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	55	4	59	-	120	14	134	-	133	5	138
High	-	5	4	9	-	7	8	15	-	3	8	11
Total	-	60	8	68	-	127	22	149	-	136	13	149
Week 12												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	55	2	57	-	121	8	129	-	130	6	136
High	-	4	6	10	-	5	14	19	-	5	7	12
Total	-	59	8	67	-	126	22	148	-	135	13	148

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.3

表 2.7.4.7-付録-28　血液生化学検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（10/50）

Total Bilirubin

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 16												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	56	4	60	-	120	14	134	-	129	6	135
High	-	3	3	6	-	6	8	14	-	6	7	13
Total	-	59	7	66	-	126	22	148	-	135	13	148
Week 20												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	55	6	61	-	121	12	133	-	131	6	137
High	-	3	1	4	-	3	10	13	-	4	7	11
Total	-	58	7	65	-	124	22	146	-	135	13	148
Week 24												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	54	3	57	-	122	11	133	-	133	8	141
High	-	3	4	7	-	2	11	13	-	2	5	7
Total	-	57	7	64	-	124	22	146	-	135	13	148

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.3

表 2.7.4.7-付録-28　血液生化学検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（11/50）

Total Protein

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 2												
Low	5	3	-	8	4	9	-	13	4	3	-	7
Normal	4	58	1	63	4	134	-	138	4	138	1	143
High	-	-	-	-	-	1	-	1	-	1	-	1
Total	9	61	1	71	8	144	-	152	8	142	1	151
Week 4												
Low	3	2	-	5	5	4	-	9	3	9	-	12
Normal	6	57	1	64	3	137	-	140	4	133	1	138
High	-	1	-	1	-	1	-	1	-	-	-	-
Total	9	60	1	70	8	142	-	150	7	142	1	150
Week 8												
Low	4	2	-	6	4	10	-	14	4	5	-	9
Normal	4	57	1	62	4	131	-	135	3	136	1	140
High	-	-	-	-	-	-	-	-	-	-	-	-
Total	8	59	1	68	8	141	-	149	7	141	1	149
Week 12												
Low	2	-	-	2	4	4	-	8	4	5	-	9
Normal	5	59	1	65	4	135	-	139	3	135	1	139
High	-	-	-	-	-	1	-	1	-	-	-	-
Total	7	59	1	67	8	140	-	148	7	140	1	148

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.3

表 2.7.4.7-付録-28　血液生化学検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（12/50）

Total Protein

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 16												
Low	-	4	-	4	4	7	-	11	4	4	-	8
Normal	7	54	1	62	4	132	-	136	3	135	1	139
High	-	-	-	-	-	1	-	1	-	1	-	1
Total	7	58	1	66	8	140	-	148	7	140	1	148
Week 20												
Low	2	2	-	4	1	4	-	5	4	5	-	9
Normal	5	55	1	61	6	132	-	138	3	133	1	137
High	-	-	-	-	-	3	-	3	-	2	-	2
Total	7	57	1	65	7	139	-	146	7	140	1	148
Week 24												
Low	1	3	-	4	-	3	-	3	4	5	-	9
Normal	6	53	1	60	7	135	-	142	3	132	-	135
High	-	-	-	-	-	1	-	1	-	3	1	4
Total	7	56	1	64	7	139	-	146	7	140	1	148

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.3

表 2.7.4.7-付録-28　血液生化学検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（13/50）

Albumin

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 2												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	71	-	71	-	152	-	152	-	151	-	151
High	-	-	-	-	-	-	-	-	-	-	-	-
Total	-	71	-	71	-	152	-	152	-	151	-	151
Week 4												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	69	-	69	-	150	-	150	-	150	-	150
High	-	1	-	1	-	-	-	-	-	-	-	-
Total	-	70	-	70	-	150	-	150	-	150	-	150
Week 8												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	68	-	68	-	149	-	149	-	149	-	149
High	-	-	-	-	-	-	-	-	-	-	-	-
Total	-	68	-	68	-	149	-	149	-	149	-	149
Week 12												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	67	-	67	-	148	-	148	-	148	-	148
High	-	-	-	-	-	-	-	-	-	-	-	-
Total	-	67	-	67	-	148	-	148	-	148	-	148

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.3

表 2.7.4.7-付録-28　血液生化学検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（14/50）

Albumin

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 16												
Low	-	-	-	-	-	2	-	2	-	-	-	-
Normal	-	66	-	66	-	146	-	146	-	148	-	148
High	-	-	-	-	-	-	-	-	-	-	-	-
Total	-	66	-	66	-	148	-	148	-	148	-	148
Week 20												
Low	-	-	-	-	-	-	-	-	-	1	-	1
Normal	-	65	-	65	-	145	-	145	-	147	-	147
High	-	-	-	-	-	1	-	1	-	-	-	-
Total	-	65	-	65	-	146	-	146	-	148	-	148
Week 24												
Low	-	-	-	-	-	-	-	-	-	1	-	1
Normal	-	64	-	64	-	146	-	146	-	147	-	147
High	-	-	-	-	-	-	-	-	-	-	-	-
Total	-	64	-	64	-	146	-	146	-	148	-	148

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.3

表 2.7.4.7-付録-28　血液生化学検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（15/50）

Creatinine

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 2												
Low	3	3	-	6	21	2	-	23	12	8	-	20
Normal	6	57	1	64	5	123	1	129	9	121	-	130
High	-	1	-	1	-	-	-	-	-	1	-	1
Total	9	61	1	71	26	125	1	152	21	130	-	151
Week 4												
Low	4	5	-	9	18	5	-	23	12	6	-	18
Normal	5	56	-	61	7	118	1	126	9	123	-	132
High	-	-	-	-	-	1	-	1	-	-	-	-
Total	9	61	-	70	25	124	1	150	21	129	-	150
Week 8												
Low	5	4	-	9	17	7	-	24	9	8	-	17
Normal	4	55	-	59	8	116	1	125	12	118	-	130
High	-	-	-	-	-	-	-	-	-	2	-	2
Total	9	59	-	68	25	123	1	149	21	128	-	149
Week 12												
Low	7	4	-	11	17	6	-	23	13	5	-	18
Normal	2	54	-	56	8	116	1	125	8	121	-	129
High	-	-	-	-	-	-	-	-	-	1	-	1
Total	9	58	-	67	25	122	1	148	21	127	-	148

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.3

表 2.7.4.7-付録-28　血液生化学検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（16/50）

Creatinine

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 16												
Low	5	4	-	9	20	3	-	23	13	4	-	17
Normal	4	53	-	57	5	119	1	125	8	123	-	131
High	-	-	-	-	-	-	-	-	-	-	-	-
Total	9	57	-	66	25	122	1	148	21	127	-	148
Week 20												
Low	5	2	-	7	19	10	-	29	13	4	-	17
Normal	4	54	-	58	5	110	1	116	8	123	-	131
High	-	-	-	-	-	1	-	1	-	-	-	-
Total	9	56	-	65	24	121	1	146	21	127	-	148
Week 24												
Low	5	1	-	6	19	8	-	27	11	4	-	15
Normal	4	54	-	58	5	113	1	119	10	123	-	133
High	-	-	-	-	-	-	-	-	-	-	-	-
Total	9	55	-	64	24	121	1	146	21	127	-	148

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.3

表 2.7.4.7-付録-28　血液生化学検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（17/50）

Blood Urea Nitrogen

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 2												
Low	-	2	-	2	3	1	-	4	-	2	-	2
Normal	-	66	2	68	-	145	1	146	2	145	1	148
High	-	1	-	1	-	1	1	2	-	-	1	1
Total	-	69	2	71	3	147	2	152	2	147	2	151
Week 4												
Low	-	-	-	-	2	1	-	3	-	2	-	2
Normal	-	67	1	68	1	144	1	146	2	144	2	148
High	-	1	1	2	-	-	1	1	-	-	-	-
Total	-	68	2	70	3	145	2	150	2	146	2	150
Week 8												
Low	-	-	-	-	1	1	-	2	-	-	-	-
Normal	-	65	1	66	2	143	1	146	2	144	1	147
High	-	1	1	2	-	-	1	1	-	1	1	2
Total	-	66	2	68	3	144	2	149	2	145	2	149
Week 12												
Low	-	-	-	-	3	-	-	3	-	1	-	1
Normal	-	65	1	66	-	143	1	144	2	142	1	145
High	-	-	1	1	-	-	1	1	-	1	1	2
Total	-	65	2	67	3	143	2	148	2	144	2	148

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.3

表 2.7.4.7-付録-28　血液生化学検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（18/50）

Blood Urea Nitrogen

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 16												
Low	-	-	-	-	2	-	-	2	-	2	-	2
Normal	-	64	2	66	1	143	2	146	2	142	1	145
High	-	-	-	-	-	-	-	-	-	-	1	1
Total	-	64	2	66	3	143	2	148	2	144	2	148
Week 20												
Low	-	-	-	-	3	-	-	3	-	1	-	1
Normal	-	63	2	65	-	141	1	142	2	143	1	146
High	-	-	-	-	-	-	1	1	-	-	1	1
Total	-	63	2	65	3	141	2	146	2	144	2	148
Week 24												
Low	-	-	-	-	2	3	-	5	-	4	-	4
Normal	-	61	2	63	1	137	2	140	2	138	1	141
High	-	1	-	1	-	1	-	1	-	2	1	3
Total	-	62	2	64	3	141	2	146	2	144	2	148

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.3

表 2.7.4.7-付録-28　血液生化学検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（19/50）

Uric Acid

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 2												
Low	3	1	-	4	6	1	-	7	5	3	-	8
Normal	1	59	2	62	7	124	3	134	5	128	2	135
High	-	1	4	5	-	2	9	11	-	2	6	8
Total	4	61	6	71	13	127	12	152	10	133	8	151
Week 4												
Low	1	1	-	2	5	2	-	7	5	1	-	6
Normal	3	58	2	63	8	120	2	130	5	127	1	133
High	-	1	4	5	-	3	10	13	-	4	7	11
Total	4	60	6	70	13	125	12	150	10	132	8	150
Week 8												
Low	2	2	-	4	5	1	-	6	6	2	-	8
Normal	2	52	3	57	8	117	3	128	4	123	4	131
High	-	4	3	7	-	6	9	15	-	6	4	10
Total	4	58	6	68	13	124	12	149	10	131	8	149
Week 12												
Low	2	3	-	5	4	-	-	4	5	2	-	7
Normal	2	52	4	58	9	117	3	129	5	122	3	130
High	-	2	2	4	-	6	9	15	-	6	5	11
Total	4	57	6	67	13	123	12	148	10	130	8	148

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.3

表 2.7.4.7-付録-28　血液生化学検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（20/50）

Uric Acid

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 16												
Low	3	1	-	4	4	-	-	4	3	3	-	6
Normal	1	52	2	55	9	117	6	132	7	118	3	128
High	-	3	4	7	-	6	6	12	-	9	5	14
Total	4	56	6	66	13	123	12	148	10	130	8	148
Week 20												
Low	3	3	-	6	6	2	-	8	3	2	-	5
Normal	1	49	2	52	7	116	6	129	7	122	4	133
High	-	3	4	7	-	3	6	9	-	6	4	10
Total	4	55	6	65	13	121	12	146	10	130	8	148
Week 24												
Low	3	3	-	6	7	2	-	9	6	6	-	12
Normal	1	50	3	54	6	116	7	129	4	120	5	129
High	-	2	2	4	-	3	5	8	-	4	3	7
Total	4	55	5	64	13	121	12	146	10	130	8	148

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.3

表 2.7.4.7-付録-28　血液生化学検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（21/50）

CK (CPK)

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 2												
Low	3	1	-	4	4	6	-	10	6	3	-	9
Normal	4	54	3	61	6	124	3	133	3	123	5	131
High	-	2	4	6	-	6	3	9	-	3	8	11
Total	7	57	7	71	10	136	6	152	9	129	13	151
Week 4												
Low	4	3	-	7	7	5	-	12	5	5	-	10
Normal	3	52	2	57	3	121	5	129	4	117	6	127
High	-	1	5	6	-	8	1	9	-	6	7	13
Total	7	56	7	70	10	134	6	150	9	128	13	150
Week 8												
Low	5	3	-	8	5	7	-	12	6	3	-	9
Normal	2	49	2	53	5	121	4	130	3	120	5	128
High	-	2	5	7	-	5	2	7	-	4	8	12
Total	7	54	7	68	10	133	6	149	9	127	13	149
Week 12												
Low	1	2	-	3	5	5	-	10	7	5	-	12
Normal	5	48	5	58	5	120	5	130	2	115	7	124
High	1	3	2	6	-	7	1	8	-	6	6	12
Total	7	53	7	67	10	132	6	148	9	126	13	148

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.3

表 2.7.4.7-付録-28　血液生化学検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（22/50）

CK (CPK)

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 16												
Low	4	2	-	6	5	8	-	13	6	5	-	11
Normal	2	51	3	56	5	121	5	131	3	118	8	129
High	-	-	4	4	-	3	1	4	-	3	5	8
Total	6	53	7	66	10	132	6	148	9	126	13	148
Week 20												
Low	3	5	-	8	4	4	-	8	6	7	-	13
Normal	3	45	4	52	5	122	3	130	3	111	5	119
High	-	2	3	5	-	5	3	8	-	8	8	16
Total	6	52	7	65	9	131	6	146	9	126	13	148
Week 24												
Low	3	2	-	5	5	6	-	11	5	5	-	10
Normal	3	48	4	55	4	121	5	130	4	116	8	128
High	-	2	2	4	-	4	1	5	-	5	5	10
Total	6	52	6	64	9	131	6	146	9	126	13	148

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.3

表 2.7.4.7-付録-28　血液生化学検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（23/50）

LDH

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 2												
Low	-	-	-	-	-	1	-	1	2	-	-	2
Normal	1	66	3	70	-	144	2	146	-	141	4	145
High	-	1	-	1	-	1	-	1	-	-	3	3
Total	1	67	3	71	-	146	2	148	2	141	7	150
Week 4												
Low	-	-	-	-	-	2	-	2	2	-	-	2
Normal	1	66	3	70	-	141	1	142	-	139	5	144
High	-	-	-	-	-	2	1	3	-	1	2	3
Total	1	66	3	70	-	145	2	147	2	140	7	149
Week 8												
Low	1	-	-	1	-	3	-	3	2	-	-	2
Normal	-	64	2	66	-	138	2	140	-	137	5	142
High	-	-	1	1	-	1	-	1	-	2	2	4
Total	1	64	3	68	-	142	2	144	2	139	7	148
Week 12												
Low	1	-	-	1	-	3	-	3	1	-	-	1
Normal	-	61	1	62	-	137	1	138	-	138	6	144
High	-	1	2	3	-	1	1	2	-	-	1	1
Total	1	62	3	66	-	141	2	143	1	138	7	146

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.3

表 2.7.4.7-付録-28　血液生化学検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（24/50）

LDH

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 16												
Low	1	-	-	1	-	4	-	4	2	1	-	3
Normal	-	62	3	65	-	136	1	137	-	134	4	138
High	-	-	-	-	-	1	1	2	-	2	3	5
Total	1	62	3	66	-	141	2	143	2	137	7	146
Week 20												
Low	1	-	-	1	-	4	-	4	2	1	-	3
Normal	-	59	3	62	-	133	1	134	-	137	2	139
High	-	-	-	-	-	2	1	3	-	1	5	6
Total	1	59	3	63	-	139	2	141	2	139	7	148
Week 24												
Low	-	-	-	-	-	3	-	3	2	1	-	3
Normal	1	58	2	61	-	134	1	135	-	136	5	141
High	-	2	-	2	-	1	1	2	-	-	1	1
Total	1	60	2	63	-	138	2	140	2	137	6	145

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.3

表 2.7.4.7-付録-28　血液生化学検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（25/50）

Total Cholesterol

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 2												
Low	-	-	-	-	-	-	-	-	-	1	-	1
Normal	-	56	4	60	-	115	9	124	-	115	17	132
High	-	-	11	11	-	5	23	28	-	4	14	18
Total	-	56	15	71	-	120	32	152	-	120	31	151
Week 4												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	51	4	55	-	110	9	119	-	115	19	134
High	-	5	10	15	-	8	23	31	-	4	12	16
Total	-	56	14	70	-	118	32	150	-	119	31	150
Week 8												
Low	-	-	-	-	-	1	-	1	-	1	-	1
Normal	-	50	7	57	-	111	11	122	-	112	20	132
High	-	5	6	11	-	5	21	26	-	5	11	16
Total	-	55	13	68	-	117	32	149	-	118	31	149
Week 12												
Low	-	-	-	-	-	1	-	1	-	-	-	-
Normal	-	49	5	54	-	106	10	116	-	113	14	127
High	-	5	8	13	-	9	22	31	-	4	17	21
Total	-	54	13	67	-	116	32	148	-	117	31	148

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.3

表 2.7.4.7-付録-28　血液生化学検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（26/50）

Total Cholesterol

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 16												
Low	-	-	-	-	-	-	-	-	-	1	-	1
Normal	-	48	4	52	-	111	11	122	-	109	13	122
High	-	5	9	14	-	5	21	26	-	7	18	25
Total	-	53	13	66	-	116	32	148	-	117	31	148
Week 20												
Low	-	-	-	-	-	1	-	1	-	-	-	-
Normal	-	44	3	47	-	105	9	114	-	109	14	123
High	-	9	9	18	-	9	22	31	-	8	17	25
Total	-	53	12	65	-	115	31	146	-	117	31	148
Week 24												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	44	5	49	-	107	9	116	-	108	15	123
High	-	8	7	15	-	8	22	30	-	9	16	25
Total	-	52	12	64	-	115	31	146	-	117	31	148

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.3

表 2.7.4.7-付録-28　血液生化学検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（27/50）

Triglycerides

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 2												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	41	8	49	-	87	13	100	-	97	11	108
High	-	6	16	22	-	14	38	52	-	15	28	43
Total	-	47	24	71	-	101	51	152	-	112	39	151
Week 4												
Low	-	-	-	-	-	1	-	1	-	-	-	-
Normal	-	40	8	48	-	86	11	97	-	102	7	109
High	-	6	16	22	-	13	39	52	-	9	32	41
Total	-	46	24	70	-	100	50	150	-	111	39	150
Week 8												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	42	6	48	-	87	10	97	-	94	11	105
High	-	4	16	20	-	12	40	52	-	16	28	44
Total	-	46	22	68	-	99	50	149	-	110	39	149
Week 12												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	36	7	43	-	85	14	99	-	94	12	106
High	-	9	15	24	-	14	35	49	-	15	27	42
Total	-	45	22	67	-	99	49	148	-	109	39	148

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.3

表 2.7.4.7-付録-28　血液生化学検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（28/50）

Triglycerides

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 16												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	42	9	51	-	84	18	102	-	91	15	106
High	-	3	12	15	-	15	31	46	-	18	24	42
Total	-	45	21	66	-	99	49	148	-	109	39	148
Week 20												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	39	5	44	-	85	15	100	-	96	9	105
High	-	6	15	21	-	12	34	46	-	13	30	43
Total	-	45	20	65	-	97	49	146	-	109	39	148
Week 24												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	40	5	45	-	86	16	102	-	98	13	111
High	-	5	14	19	-	11	33	44	-	11	26	37
Total	-	45	19	64	-	97	49	146	-	109	39	148

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.3

表 2.7.4.7-付録-28　血液生化学検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（29/50）

HDL Cholesterol

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 2												
Low	8	2	-	10	9	5	-	14	15	4	-	19
Normal	2	58	-	60	10	123	2	135	-	123	2	125
High	-	1	-	1	-	-	3	3	-	1	6	7
Total	10	61	-	71	19	128	5	152	15	128	8	151
Week 4												
Low	8	2	-	10	11	4	-	15	15	8	-	23
Normal	2	57	-	59	7	123	1	131	-	119	1	120
High	-	1	-	1	-	-	4	4	-	-	7	7
Total	10	60	-	70	18	127	5	150	15	127	8	150
Week 8												
Low	6	3	-	9	10	5	-	15	14	4	-	18
Normal	2	57	-	59	7	121	1	129	1	122	1	124
High	-	-	-	-	-	1	4	5	-	-	7	7
Total	8	60	-	68	17	127	5	149	15	126	8	149
Week 12												
Low	5	2	-	7	5	7	-	12	15	7	-	22
Normal	3	56	-	59	11	119	1	131	-	117	2	119
High	-	1	-	1	-	1	4	5	-	1	6	7
Total	8	59	-	67	16	127	5	148	15	125	8	148

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.3

表 2.7.4.7-付録-28　血液生化学検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（30/50）

HDL Cholesterol

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 16												
Low	3	3	-	6	4	7	-	11	13	5	-	18
Normal	5	54	-	59	12	118	1	131	2	118	1	121
High	-	1	-	1	-	2	4	6	-	2	7	9
Total	8	58	-	66	16	127	5	148	15	125	8	148
Week 20												
Low	6	4	-	10	4	5	-	9	11	6	-	17
Normal	2	49	-	51	12	119	1	132	4	116	1	121
High	-	4	-	4	-	1	4	5	-	3	7	10
Total	8	57	-	65	16	125	5	146	15	125	8	148
Week 24												
Low	4	2	-	6	5	6	-	11	11	3	-	14
Normal	3	53	-	56	11	118	1	130	4	119	1	124
High	-	2	-	2	-	1	4	5	-	3	7	10
Total	7	57	-	64	16	125	5	146	15	125	8	148

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.3

表 2.7.4.7-付録-28　血液生化学検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（31/50）

LDL Cholesterol

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 2												
Low	-	1	-	1	1	4	-	5	-	2	-	2
Normal	-	52	2	54	-	98	15	113	1	105	20	126
High	-	3	13	16	-	5	29	34	-	7	16	23
Total	-	56	15	71	1	107	44	152	1	114	36	151
Week 4												
Low	-	-	-	-	1	1	-	2	-	1	-	1
Normal	-	51	4	55	-	98	22	120	1	109	18	128
High	-	5	10	15	-	6	22	28	-	3	18	21
Total	-	56	14	70	1	105	44	150	1	113	36	150
Week 8												
Low	-	1	-	1	1	5	-	6	-	4	-	4
Normal	-	49	3	52	-	95	17	112	1	102	19	122
High	-	5	10	15	-	5	26	31	-	6	17	23
Total	-	55	13	68	1	105	43	149	1	112	36	149
Week 12												
Low	-	-	-	-	-	3	-	3	-	1	-	1
Normal	-	50	3	53	1	93	19	113	1	104	16	121
High	-	4	10	14	-	8	24	32	-	6	20	26
Total	-	54	13	67	1	104	43	148	1	111	36	148

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.3

表 2.7.4.7-付録-28　血液生化学検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（32/50）

LDL Cholesterol

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 16												
Low	-	1	-	1	1	4	-	5	-	2	-	2
Normal	-	47	4	51	-	89	21	110	1	104	20	125
High	-	5	9	14	-	11	22	33	-	5	16	21
Total	-	53	13	66	1	104	43	148	1	111	36	148
Week 20												
Low	-	1	-	1	1	8	-	9	-	2	-	2
Normal	-	43	1	44	-	86	19	105	1	102	18	121
High	-	9	11	20	-	9	23	32	-	7	18	25
Total	-	53	12	65	1	103	42	146	1	111	36	148
Week 24												
Low	-	-	1	1	1	3	-	4	-	1	-	1
Normal	-	46	2	48	-	94	22	116	1	102	17	120
High	-	6	9	15	-	6	20	26	-	8	19	27
Total	-	52	12	64	1	103	42	146	1	111	36	148

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.3

表 2.7.4.7-付録-28　血液生化学検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（33/50）

Potassium

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 2												
Low	-	1	-	1	1	1	-	2	-	-	-	-
Normal	2	66	-	68	-	146	-	146	-	147	2	149
High	-	2	-	2	-	-	-	-	-	1	-	1
Total	2	69	-	71	1	147	-	148	-	148	2	150
Week 4												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	2	68	-	70	1	145	-	146	-	145	1	146
High	-	-	-	-	-	1	-	1	-	2	1	3
Total	2	68	-	70	1	146	-	147	-	147	2	149
Week 8												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	1	67	-	68	1	142	-	143	-	146	2	148
High	-	-	-	-	-	1	-	1	-	-	-	-
Total	1	67	-	68	1	143	-	144	-	146	2	148
Week 12												
Low	-	1	-	1	-	-	-	-	-	1	-	1
Normal	1	64	-	65	1	141	-	142	-	141	2	143
High	-	-	-	-	-	1	-	1	-	2	-	2
Total	1	65	-	66	1	142	-	143	-	144	2	146

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.3

表 2.7.4.7-付録-28　血液生化学検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（34/50）

Potassium

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 16												
Low	-	1	-	1	-	1	-	1	-	-	-	-
Normal	-	65	-	65	1	138	-	139	-	144	1	145
High	-	-	-	-	-	3	-	3	-	-	1	1
Total	-	66	-	66	1	142	-	143	-	144	2	146
Week 20												
Low	-	-	-	-	-	-	-	-	-	1	-	1
Normal	-	63	-	63	1	140	-	141	-	143	2	145
High	-	-	-	-	-	-	-	-	-	2	-	2
Total	-	63	-	63	1	140	-	141	-	146	2	148
Week 24												
Low	-	-	-	-	-	-	-	-	-	3	-	3
Normal	-	62	-	62	1	138	-	139	-	139	2	141
High	-	1	-	1	-	1	-	1	-	1	-	1
Total	-	63	-	63	1	139	-	140	-	143	2	145

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.3

表 2.7.4.7-付録-28　血液生化学検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（35/50）

Sodium

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 2												
Low	-	-	-	-	1	-	-	1	-	2	-	2
Normal	-	71	-	71	4	147	-	151	4	145	-	149
High	-	-	-	-	-	-	-	-	-	-	-	-
Total	-	71	-	71	5	147	-	152	4	147	-	151
Week 4												
Low	-	2	-	2	1	3	-	4	1	2	-	3
Normal	-	68	-	68	4	142	-	146	3	144	-	147
High	-	-	-	-	-	-	-	-	-	-	-	-
Total	-	70	-	70	5	145	-	150	4	146	-	150
Week 8												
Low	-	1	-	1	1	1	-	2	1	2	-	3
Normal	-	67	-	67	3	144	-	147	3	143	-	146
High	-	-	-	-	-	-	-	-	-	-	-	-
Total	-	68	-	68	4	145	-	149	4	145	-	149
Week 12												
Low	-	-	-	-	1	2	-	3	-	-	-	-
Normal	-	67	-	67	3	142	-	145	4	144	-	148
High	-	-	-	-	-	-	-	-	-	-	-	-
Total	-	67	-	67	4	144	-	148	4	144	-	148

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.3

表 2.7.4.7-付録-28　血液生化学検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（36/50）

Sodium

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 16												
Low	-	-	-	-	2	3	-	5	-	1	-	1
Normal	-	66	-	66	2	141	-	143	4	143	-	147
High	-	-	-	-	-	-	-	-	-	-	-	-
Total	-	66	-	66	4	144	-	148	4	144	-	148
Week 20												
Low	-	2	-	2	1	2	-	3	1	1	-	2
Normal	-	63	-	63	3	140	-	143	3	143	-	146
High	-	-	-	-	-	-	-	-	-	-	-	-
Total	-	65	-	65	4	142	-	146	4	144	-	148
Week 24												
Low	-	1	-	1	-	3	-	3	1	1	-	2
Normal	-	63	-	63	4	139	-	143	3	143	-	146
High	-	-	-	-	-	-	-	-	-	-	-	-
Total	-	64	-	64	4	142	-	146	4	144	-	148

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.3

表 2.7.4.7-付録-28　血液生化学検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（37/50）

Calcium

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 2												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	70	-	70	-	150	1	151	-	151	-	151
High	-	1	-	1	-	-	1	1	-	-	-	-
Total	-	71	-	71	-	150	2	152	-	151	-	151
Week 4												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	70	-	70	-	148	2	150	-	150	-	150
High	-	-	-	-	-	-	-	-	-	-	-	-
Total	-	70	-	70	-	148	2	150	-	150	-	150
Week 8												
Low	-	1	-	1	-	1	-	1	-	-	-	-
Normal	-	67	-	67	-	146	1	147	-	149	-	149
High	-	-	-	-	-	-	1	1	-	-	-	-
Total	-	68	-	68	-	147	2	149	-	149	-	149
Week 12												
Low	-	1	-	1	-	1	-	1	-	-	-	-
Normal	-	66	-	66	-	145	1	146	-	148	-	148
High	-	-	-	-	-	-	1	1	-	-	-	-
Total	-	67	-	67	-	146	2	148	-	148	-	148

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.3

表 2.7.4.7-付録-28　血液生化学検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（38/50）

Calcium

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 16												
Low	-	-	-	-	-	1	-	1	-	-	-	-
Normal	-	66	-	66	-	145	2	147	-	148	-	148
High	-	-	-	-	-	-	-	-	-	-	-	-
Total	-	66	-	66	-	146	2	148	-	148	-	148
Week 20												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	65	-	65	-	144	-	144	-	148	-	148
High	-	-	-	-	-	-	2	2	-	-	-	-
Total	-	65	-	65	-	144	2	146	-	148	-	148
Week 24												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	64	-	64	-	144	1	145	-	148	-	148
High	-	-	-	-	-	-	1	1	-	-	-	-
Total	-	64	-	64	-	144	2	146	-	148	-	148

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.3

表 2.7.4.7-付録-28　血液生化学検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（39/50）

Chloride

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 2												
Low	-	-	-	-	-	-	-	-	-	1	-	1
Normal	1	69	1	71	4	148	-	152	4	145	-	149
High	-	-	-	-	-	-	-	-	-	1	-	1
Total	1	69	1	71	4	148	-	152	4	147	-	151
Week 4												
Low	-	-	-	-	1	1	-	2	1	1	-	2
Normal	1	68	1	70	3	145	-	148	3	145	-	148
High	-	-	-	-	-	-	-	-	-	-	-	-
Total	1	68	1	70	4	146	-	150	4	146	-	150
Week 8												
Low	-	-	-	-	1	-	-	1	-	2	-	2
Normal	1	66	1	68	3	145	-	148	4	142	-	146
High	-	-	-	-	-	-	-	-	-	1	-	1
Total	1	66	1	68	4	145	-	149	4	145	-	149
Week 12												
Low	-	-	-	-	1	1	-	2	1	-	-	1
Normal	1	65	1	67	3	143	-	146	3	144	-	147
High	-	-	-	-	-	-	-	-	-	-	-	-
Total	1	65	1	67	4	144	-	148	4	144	-	148

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.3

表 2.7.4.7-付録-28　血液生化学検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（40/50）

Chloride

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 16												
Low	-	-	-	-	2	-	-	2	1	3	-	4
Normal	1	64	1	66	2	143	-	145	3	141	-	144
High	-	-	-	-	-	1	-	1	-	-	-	-
Total	1	64	1	66	4	144	-	148	4	144	-	148
Week 20												
Low	-	1	-	1	1	1	-	2	-	2	-	2
Normal	1	62	1	64	3	141	-	144	4	142	-	146
High	-	-	-	-	-	-	-	-	-	-	-	-
Total	1	63	1	65	4	142	-	146	4	144	-	148
Week 24												
Low	-	1	-	1	1	2	-	3	1	2	-	3
Normal	1	61	1	63	3	140	-	143	3	142	-	145
High	-	-	-	-	-	-	-	-	-	-	-	-
Total	1	62	1	64	4	142	-	146	4	144	-	148

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.3

表 2.7.4.7-付録-28　血液生化学検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（41/50）

Phosphorus

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 2												
Low	-	3	-	3	2	2	-	4	-	2	-	2
Normal	2	65	1	68	3	144	-	147	6	142	-	148
High	-	-	-	-	-	1	-	1	-	1	-	1
Total	2	68	1	71	5	147	-	152	6	145	-	151
Week 4												
Low	-	2	-	2	3	4	-	7	-	4	-	4
Normal	2	65	1	68	2	141	-	143	6	140	-	146
High	-	-	-	-	-	-	-	-	-	-	-	-
Total	2	67	1	70	5	145	-	150	6	144	-	150
Week 8												
Low	-	2	-	2	4	3	-	7	-	2	-	2
Normal	2	63	-	65	1	141	-	142	6	139	-	145
High	-	-	1	1	-	-	-	-	-	2	-	2
Total	2	65	1	68	5	144	-	149	6	143	-	149
Week 12												
Low	1	1	-	2	2	1	-	3	-	1	-	1
Normal	1	63	-	64	3	142	-	145	6	139	-	145
High	-	-	1	1	-	-	-	-	-	2	-	2
Total	2	64	1	67	5	143	-	148	6	142	-	148

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.3

表 2.7.4.7-付録-28　血液生化学検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（42/50）

Phosphorus

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 16												
Low	-	3	-	3	1	1	-	2	-	-	-	-
Normal	2	60	1	63	4	142	-	146	6	142	-	148
High	-	-	-	-	-	-	-	-	-	-	-	-
Total	2	63	1	66	5	143	-	148	6	142	-	148
Week 20												
Low	-	2	-	2	1	-	-	1	2	3	-	5
Normal	2	60	1	63	4	141	-	145	4	139	-	143
High	-	-	-	-	-	-	-	-	-	-	-	-
Total	2	62	1	65	5	141	-	146	6	142	-	148
Week 24												
Low	-	1	-	1	3	2	-	5	1	3	-	4
Normal	2	60	1	63	2	139	-	141	5	137	-	142
High	-	-	-	-	-	-	-	-	-	2	-	2
Total	2	61	1	64	5	141	-	146	6	142	-	148

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.3

表 2.7.4.7-付録-28　血液生化学検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（43/50）

Lactic Acid

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 2												
Low	1	1	-	2	-	1	-	1	1	-	-	1
Normal	-	59	2	61	2	121	3	126	1	122	9	132
High	-	4	4	8	-	10	15	25	-	9	9	18
Total	1	64	6	71	2	132	18	152	2	131	18	151
Week 4												
Low	1	-	-	1	1	1	-	2	1	-	-	1
Normal	-	60	3	63	1	124	9	134	1	112	8	121
High	-	3	3	6	-	5	9	14	-	18	10	28
Total	1	63	6	70	2	130	18	150	2	130	18	150
Week 8												
Low	-	-	-	-	1	1	-	2	-	-	-	-
Normal	1	57	-	58	1	117	10	128	2	114	9	125
High	-	4	6	10	-	11	8	19	-	15	9	24
Total	1	61	6	68	2	129	18	149	2	129	18	149
Week 12												
Low	-	1	-	1	1	1	-	2	1	-	-	1
Normal	1	53	2	56	1	116	9	126	1	110	11	122
High	-	6	4	10	-	12	8	20	-	18	7	25
Total	1	60	6	67	2	129	17	148	2	128	18	148

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.3

表 2.7.4.7-付録-28　血液生化学検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（44/50）

Lactic Acid

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 16												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	1	52	2	55	2	120	8	130	2	113	14	129
High	-	7	4	11	-	9	9	18	-	15	4	19
Total	1	59	6	66	2	129	17	148	2	128	18	148
Week 20												
Low	1	-	-	1	1	-	-	1	-	1	-	1
Normal	-	55	1	56	1	116	12	129	2	119	16	137
High	-	3	5	8	-	11	5	16	-	8	2	10
Total	1	58	6	65	2	127	17	146	2	128	18	148
Week 24												
Low	1	2	-	3	1	4	-	5	1	1	-	2
Normal	-	51	2	53	1	113	11	125	1	118	13	132
High	-	4	4	8	-	10	6	16	-	9	5	14
Total	1	57	6	64	2	127	17	146	2	128	18	148

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.3

表 2.7.4.7-付録-28　血液生化学検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（45/50）

Pyruvic Acid

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 2												
Low	3	12	-	15	9	16	-	25	8	12	-	20
Normal	4	42	-	46	12	92	6	110	5	110	8	123
High	-	3	7	10	-	9	8	17	-	5	3	8
Total	7	57	7	71	21	117	14	152	13	127	11	151
Week 4												
Low	2	7	-	9	10	13	-	23	5	10	-	15
Normal	4	49	2	55	11	93	6	110	8	106	9	123
High	-	1	5	6	-	9	8	17	-	11	1	12
Total	6	57	7	70	21	115	14	150	13	127	10	150
Week 8												
Low	5	7	-	12	10	14	-	24	7	12	-	19
Normal	1	45	1	47	11	89	6	106	6	99	7	112
High	-	3	6	9	-	11	8	19	-	15	3	18
Total	6	55	7	68	21	114	14	149	13	126	10	149
Week 12												
Low	2	7	-	9	9	12	-	21	8	19	-	27
Normal	4	43	3	50	12	93	6	111	5	94	9	108
High	-	4	4	8	-	9	7	16	-	12	1	13
Total	6	54	7	67	21	114	13	148	13	125	10	148

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.3

表 2.7.4.7-付録-28　血液生化学検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（46/50）

Pyruvic Acid

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 16												
Low	3	6	-	9	13	17	1	31	7	17	-	24
Normal	2	45	4	51	8	87	7	102	6	103	7	116
High	-	3	3	6	-	10	5	15	-	5	3	8
Total	5	54	7	66	21	114	13	148	13	125	10	148
Week 20												
Low	2	12	-	14	8	21	1	30	9	24	-	33
Normal	3	36	5	44	11	81	5	97	4	96	9	109
High	-	5	2	7	-	12	7	19	-	5	1	6
Total	5	53	7	65	19	114	13	146	13	125	10	148
Week 24												
Low	4	14	-	18	10	27	2	39	7	21	-	28
Normal	1	34	6	41	9	82	5	96	6	100	8	114
High	-	4	1	5	-	5	6	11	-	4	2	6
Total	5	52	7	64	19	114	13	146	13	125	10	148

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.3

表 2.7.4.7-付録-28　血液生化学検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（47/50）

Amylase

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 2												
Low	2	1	-	3	-	1	-	1	2	-	-	2
Normal	-	64	-	64	6	138	3	147	4	139	-	143
High	-	1	3	4	-	3	1	4	-	2	4	6
Total	2	66	3	71	6	142	4	152	6	141	4	151
Week 4												
Low	2	-	-	2	2	-	-	2	1	1	-	2
Normal	-	63	-	63	4	137	2	143	4	134	1	139
High	-	2	3	5	-	3	2	5	-	6	3	9
Total	2	65	3	70	6	140	4	150	5	141	4	150
Week 8												
Low	2	-	-	2	2	3	-	5	1	-	-	1
Normal	-	63	-	63	4	134	3	141	4	137	1	142
High	-	1	2	3	-	2	1	3	-	3	3	6
Total	2	64	2	68	6	139	4	149	5	140	4	149
Week 12												
Low	2	-	-	2	3	1	-	4	2	-	-	2
Normal	-	63	1	64	3	135	4	142	3	135	2	140
High	-	-	1	1	-	2	-	2	-	4	2	6
Total	2	63	2	67	6	138	4	148	5	139	4	148

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.3

表 2.7.4.7-付録-28　血液生化学検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（48/50）

Amylase

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 16												
Low	2	-	-	2	3	3	-	6	2	1	-	3
Normal	-	61	1	62	3	133	3	139	3	134	1	138
High	-	1	1	2	-	2	1	3	-	4	3	7
Total	2	62	2	66	6	138	4	148	5	139	4	148
Week 20												
Low	2	-	-	2	3	1	-	4	1	1	-	2
Normal	-	60	-	60	3	133	2	138	4	133	1	138
High	-	1	2	3	-	2	2	4	-	5	3	8
Total	2	61	2	65	6	136	4	146	5	139	4	148
Week 24												
Low	1	-	-	1	3	1	-	4	2	1	-	3
Normal	1	59	-	60	3	133	3	139	3	131	1	135
High	-	1	2	3	-	2	1	3	-	7	3	10
Total	2	60	2	64	6	136	4	146	5	139	4	148

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.3

表 2.7.4.7-付録-28　血液生化学検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（49/50）

Lipase

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 2												
Low	2	1	-	3	2	2	-	4	5	-	-	5
Normal	3	57	1	61	3	135	2	140	4	133	1	138
High	-	6	1	7	-	5	3	8	-	5	3	8
Total	5	64	2	71	5	142	5	152	9	138	4	151
Week 4												
Low	1	1	-	2	1	-	-	1	5	2	1	8
Normal	4	60	2	66	4	139	4	147	4	133	1	138
High	-	2	-	2	-	1	1	2	-	2	2	4
Total	5	63	2	70	5	140	5	150	9	137	4	150
Week 8												
Low	2	3	-	5	2	1	-	3	4	1	-	5
Normal	3	57	2	62	3	136	4	143	5	133	2	140
High	-	1	-	1	-	2	1	3	-	2	2	4
Total	5	61	2	68	5	139	5	149	9	136	4	149
Week 12												
Low	1	3	-	4	1	2	-	3	1	-	-	1
Normal	4	55	2	61	4	135	3	142	8	134	2	144
High	-	2	-	2	-	1	2	3	-	1	2	3
Total	5	60	2	67	5	138	5	148	9	135	4	148

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.3

表 2.7.4.7-付録-28　血液生化学検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（50/50）

Lipase

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 16												
Low	2	1	-	3	3	-	-	3	2	-	-	2
Normal	3	58	1	62	2	135	4	141	7	133	3	143
High	-	1	-	1	-	3	1	4	-	2	1	3
Total	5	60	1	66	5	138	5	148	9	135	4	148
Week 20												
Low	2	1	-	3	2	-	-	2	3	2	-	5
Normal	3	58	1	62	2	134	4	140	6	129	3	138
High	-	-	-	-	-	3	1	4	-	4	1	5
Total	5	59	1	65	4	137	5	146	9	135	4	148
Week 24												
Low	2	-	-	2	1	1	-	2	3	4	-	7
Normal	3	57	1	61	3	135	3	141	6	126	2	134
High	-	1	-	1	-	1	2	3	-	5	2	7
Total	5	58	1	64	4	137	5	146	9	135	4	148

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