

Dossier zur Nutzenbewertung gemäß § 35a SGB V

Obinutuzumab (Gazyvaro[®])

Roche Pharma AG

Modul 4 A - Anhang G

Patienten mit nicht vorbehandelter chronischer lymphatischer Leukämie (CLL), die aufgrund von Begleiterkrankungen für eine Therapie mit einer vollständigen Dosis Fludarabin nicht geeignet sind

Medizinischer Nutzen und
medizinischer Zusatznutzen,
Patientengruppen mit therapeutisch
bedeutsamem Zusatznutzen

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Anhang 4-G: Statistische Analysen

Anhang 4-G1: Subgruppenanalysen für Gesamtüberleben (OS), Progressionsfreies Überleben (PFS) (Bewertung durch IRC), Symptomatik (EORTC QLQ C30 Symptomskalen) und Gesundheitsbezogene Lebensqualität (EORTC QLQ C30 Funktionsskalen)

1 (Anhang): Ergebnisse für OS - Subgruppenanalysen aus RCT mit dem zu bewertenden Arzneimittel – Datenschnitt 09.05.2013

POPULATION: Labelpopulation, Intent-to-Treat Patients
 ENDPOINT: Overall Survival
 MODEL: Unstratified Analysis STUDY: CLL11(B021004), Stage 2
 Time to Event Analysis by Subgroups (Efficacy)

Name	Level	GC1b (N=255)												RC1b (N=242)												GC1b vs. RC1b				Interaction Test		
		Patients		Patients with Event		Censored		Time to event				Patients		Patients with Event		Censored		Time to event				log-rank	Hazard Ratio		p-value (likelihood ratio)							
		n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower EL for Median	95% Upper EL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1		95% Upper CL for Q1	Median (months)		95% Lower EL for Median	95% Upper EL for Median	p-value	Lower CL		Upper CL	Convergence Status
All	n/a	255	100,0	187,1	237	32,9	34,1	33,0	NE	NE	NE	NE	242	100,0	2012,0	213	88,0	NE	NE	NE	NE	NE	NE	NE	NE	0,0753	0,59	0,33	1,06	Convergence criterion (GCONV=1E-8) satisfied.		
Gender	Male	158	62,0	106,3	148	33,7	33,0	33,0	NE	NE	NE	NE	147	60,7	2114,3	126	85,7	11,9	27,3	NE	NE	NE	NE	NE	NE	0,0398	0,46	0,22	0,98	Convergence criterion (GCONV=1E-8) satisfied.		
	Female	97	38,0	80,8	89	31,8	NE	34,1	NE	NE	NE	95	39,3	80,4	87	91,6	NE	NE	NE	NE	NE	NE	NE	NE	NE	0,8717	0,92	0,35	0,46	Convergence criterion (GCONV=1E-8) satisfied.		
Age	<75 years	130	51,0	53,8	125	36,2	NE	NE	NE	NE	NE	120	49,6	1109,2	109	90,8	11,9	27,3	NE	NE	NE	NE	NE	NE	NE	0,1078	0,43	0,15	1,24	Convergence criterion (GCONV=1E-8) satisfied.		
	≥75 years	125	49,0	1310,4	112	89,6	33,0	33,0	NE	NE	NE	122	50,4	1814,8	104	85,2	NE	20,1	NE	NE	NE	NE	NE	NE	NE	NE	0,3583	0,72	0,35	1,46	Convergence criterion (GCONV=1E-8) satisfied.	
Race	White	246	96,5	187,3	228	32,7	34,1	33,0	NE	NE	NE	NE	231	95,5	2012,1	203	87,9	NE	11,9	NE	NE	NE	NE	NE	NE	NE	0,0935	0,61	0,33	1,10	Convergence criterion (GCONV=1E-8) satisfied.	
	Other	9	3,5	9	100,0	NE	NE	NE	NE	NE	NE	11	4,5	10,1	10	90,9	NE	1,5	NE	NE	NE	NE	NE	NE	NE	0,3938	<0,01	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.		
Geographical Region	North America	12	4,7	10,3	11	31,7	NE	NE	NE	NE	NE	13	5,4	17,7	12	92,3	NE	12,9	NE	NE	NE	NE	NE	NE	NE	NE	0,8091	1,41	0,09	23,08	Convergence criterion (GCONV=1E-8) satisfied.	
	Central and South America	3	1,2	3	100,0	NE	NE	NE	NE	NE	NE	NE	20,8	2100,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	Western Europe	175	68,6	140,0	161	32,0	33,0	33,0	NE	NE	NE	NE	165	68,2	2012,1	145	87,9	NE	27,3	NE	NE	NE	NE	NE	NE	NE	NE	0,2608	0,68	0,34	1,34	Convergence criterion (GCONV=1E-8) satisfied.
	Asia-Pacific	20	7,8	20	100,0	NE	NE	NE	NE	NE	NE	NE	18	7,4	15,6	17	94,4	NE	19,9	NE	NE	NE	NE	NE	NE	NE	NE	0,3173	<0,01	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.
	Other	45	17,6	36,7	42	33,3	34,1	34,1	NE	NE	NE	NE	44	18,2	715,9	37	84,1	NE	11,5	NE	NE	NE	NE	NE	NE	NE	NE	0,1474	0,37	0,09	1,49	Convergence criterion (GCONV=1E-8) satisfied.
FCgamma receptor Iia	131HR	58	22,7	46,9	54	33,1	34,1	33,0	NE	NE	NE	NE	76	31,4	1114,5	65	85,5	NE	20,1	NE	NE	NE	NE	NE	NE	NE	NE	0,1102	0,40	0,13	1,28	Convergence criterion (GCONV=1E-8) satisfied.
	131HR	125	49,0	97,2	116	32,8	NE	NE	NE	NE	NE	NE	114	47,1	1010,5	102	89,5	NE	27,3	NE	NE	NE	NE	NE	NE	NE	NE	0,4539	0,72	0,30	1,71	Convergence criterion (GCONV=1E-8) satisfied.

	I31RR	49	19,2	48,2	45	31,8		NE	NE	NE	NE	NE	NE	33	13,6		0,61	31	33,9	31,9	31,9		NE	NE	NE	NE	NE	31,9		NE	0,4799	1,87	3,32	10,90		Convergence criterion (GCONV=1E-8) satisfied.		
	Missing	23	9,0	14,3	22	95,7		NE	NE	NE	NE	NE	NE	NE	19	7,9		0,211	15	78,9			NE	NE	NE	NE	NE	NE		NE	0,1264	0,21	0,02	1,90		Convergence criterion (GCONV=1E-8) satisfied.		
	FCgamma receptor IIIa																																				Convergence criterion (GCONV=1E-8) satisfied.	
	158FF	103	40,4	87,8	85	32,2	33,0	33,0	NE		NE	33,0		NE	33	34,3		0,64	76	91,6			NE	NE	NE	NE	NE	NE		NE	0,8044	0,88	3,32	2,43		Convergence criterion (GCONV=1E-8) satisfied.		
	158FV	119	46,7	86,7	111	33,3		NE	34,1	NE		NE	34,1		NE	109	45,0		1614,7	93	85,3	31,9	24,5		NE	NE	NE	NE	NE	31,9		NE	0,0442	0,43	0,18	1,00		Convergence criterion (GCONV=1E-8) satisfied.
	158VV	16	6,3	16,3	15	33,8		NE	27,7	NE		NE	27,7		NE	33	13,6		0,01	30	90,9			NE	NE	NE	NE	NE		NE	0,8894	0,85	3,09	8,22		Convergence criterion (GCONV=1E-8) satisfied.		
	Missing	17	6,7	15,9	16	94,1		NE	NE	NE		NE	NE	NE	NE	17	7,0		317,6	14	82,4			NE	NE	NE	NE	NE		NE	0,3770	0,38	0,04	3,61		Convergence criterion (GCONV=1E-8) satisfied.		
	Binet Staging at baseline																																				Convergence criterion (GCONV=1E-8) satisfied.	
	A	69	33,1	20,4	67	86,6		NE	NE	NE		NE	NE	NE	57	33,6		0,14,0	49	86,0			NE	NE	NE	NE	NE	NE		NE	0,0287	0,21	0,04	0,98		Convergence criterion (GCONV=1E-8) satisfied.		
	B	104	40,8	76,7	87	33,3		NE	27,7	NE		NE	NE	NE	85	35,1		0,71	79	92,9			NE	NE	NE	NE	NE	NE		NE	0,8496	1,11	0,37	1,31		Convergence criterion (GCONV=1E-8) satisfied.		
	C	92	36,1	90,8	83	30,2	33,0	33,0	NE	34,1	33,0		NE	100	41,3		1615,0	85	85,0	31,9	00,1			NE	NE	NE	NE	NE		NE	0,2401	0,61	0,27	1,40		Convergence criterion (GCONV=1E-8) satisfied.		
	Total CIR score at baseline																																				Convergence criterion (GCONV=1E-8) satisfied.	
	<6	63	24,7	34,8	60	35,2	34,1	34,1	NE	34,1	34,1		NE	75	31,0		1013,3	65	86,7			NE	NE	NE	NE	NE	NE		NE	0,0916	0,35	0,09	1,26		Convergence criterion (GCONV=1E-8) satisfied.			
	>6	192	75,3	137,8	177	32,2		NE	33,0	NE		NE	NE	NE	167	69,0		1011,4	148	88,6			NE	NE	NE	NE	NE		NE	0,2683	0,68	0,35	1,35		Convergence criterion (GCONV=1E-8) satisfied.			
	Calculated creatinine clearance cat. 2																																				Convergence criterion (GCONV=1E-8) satisfied.	
	<70 ml/min	178	69,8	126,7	166	33,3	34,1	33,0	NE	NE	34,1		NE	176	72,7		2012,5	154	87,5			NE	NE	NE	NE	NE	NE		NE	0,0808	0,54	0,27	1,09		Convergence criterion (GCONV=1E-8) satisfied.			
	>70 ml/min	77	30,2	67,8	71	32,2		NE	27,7	NE		NE	NE	NE	66	27,3		710,6	59	89,4	31,9	31,9		NE	NE	NE	NE	NE		NE	0,5605	0,72	0,24	2,16		Convergence criterion (GCONV=1E-8) satisfied.		
	Beta2 microglobulin																																				Convergence criterion (GCONV=1E-8) satisfied.	
	< 3.5 ug/mL	154	60,4	117,1	143	32,9		NE	34,1	NE		NE	NE	NE	140	57,9		1011,4	124	88,6			NE	NE	NE	NE	NE		NE	0,2770	0,65	0,30	1,41		Convergence criterion (GCONV=1E-8) satisfied.			
	>= 3.5 ug/mL	99	38,4	77,1	91	32,9	33,0	33,0	NE	NE	33,0		NE	99	40,9		1313,1	86	86,9			NE	NE	NE	NE	NE	NE		NE	0,1519	0,52	0,21	1,30		Convergence criterion (GCONV=1E-8) satisfied.			
	Missing	1	0,2			100,0		NE	NE	NE		NE	NE	NE	1	0,2			100,0				NE	NE	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	Immunoglobulin VH, cytogenetics 2																																				Convergence criterion (GCONV=1E-8) satisfied.	
	12	45	17,6	48,9	41	31,1	33,0	33,0	NE		NE	33,0		NE	44	18,2		818,2	36	81,8	31,9	18,4		NE	NE	NE	NE	NE		NE	0,3287	0,55	0,17	1,84		Convergence criterion (GCONV=1E-8) satisfied.		
	11q-	16	18,0	12,2	45	37,8		NE	NE	NE		NE	NE	NE	43	17,8		716,3	16	83,7	27,3	14,3		NE	NE	NE	NE	NE		NE	0,0227	0,13	0,02	1,04		Convergence criterion (GCONV=1E-8) satisfied.		
	13q-	79	31,0	11,3	78	98,7		NE	NE	NE		NE	NE	NE	75	31,0		79,3	68	90,7			NE	NE	NE	NE	NE		NE	0,0248	0,13	0,02	1,06		Convergence criterion (GCONV=1E-8) satisfied.			
	Other Abn.	20	7,8	115,0	17	35,0		NE	13,5	NE		NE	NE	NE	22	9,1		0,9,1	20	90,9			NE	NE	NE	NE	NE		NE	0,4882	1,87	0,31	11,31		Convergence criterion (GCONV=1E-8) satisfied.			
	Norm. K.	65	25,5	913,8	56	86,2	34,1	27,7	NE	34,1	34,1		NE	58	24,0		58,6	53	91,4			NE	NE	NE	NE	NE	NE		NE	0,4548	1,51	0,51	4,53		Convergence criterion (GCONV=1E-8) satisfied.			
	Time from first diagnosis																																				Convergence criterion (GCONV=1E-8) satisfied.	
	<= 12 months	80	23,5	810,0	54	30,0	33,0	27,7	NE	33,0	33,0		NE	70	28,9		1217,1	58	82,9			NE	NE	NE	NE	NE	NE		NE	0,2856	0,59	0,22	1,57		Convergence criterion (GCONV=1E-8) satisfied.			
	13 - 24 months	41	16,1	37,3	38	32,7		NE	NE	NE		NE	NE	NE	31	12,8		39,7	28	90,3			NE	NE	NE	NE	NE		NE	0,6394	0,68	0,14	3,39		Convergence criterion (GCONV=1E-8) satisfied.			
	>24 months	153	60,0	95,9	144	94,1	34,1	34,1	NE		NE	34,1		NE	141	58,3		149,9	127	90,1			NE	NE	NE	NE	NE		NE	0,2568	0,62	0,27	1,43		Convergence criterion (GCONV=1E-8) satisfied.			
	Missing		0,4			100,0		NE	NE	NE		NE	NE	NE																							Convergence criterion (GCONV=1E-8) satisfied.	
	High circulating tumor burden																																				Convergence criterion (GCONV=1E-8) satisfied.	
	<25x10**9 cells/L	60	23,5	58,3	55	31,7	33,0	33,0	NE		NE	33,0		NE	67	27,7		69,0	61	91,0			NE	NE	NE	NE	NE		NE	0,8180	0,87	0,26	2,89		Convergence criterion (GCONV=1E-8) satisfied.			
	>=25x10**9 cells/L	195	76,5	136,7	182	33,3		NE	34,1	NE		NE	34,1		NE	173	71,5		2212,7	151	87,3			NE	NE	NE	NE	NE		NE	0,0663	0,53	0,27	1,06		Convergence criterion (GCONV=1E-8) satisfied.		

Missing														20,0	150,0	150,0	0,0,0	NE	NE0,0	NE	NE	NE	NE	NE	Convergence criterion (GCONV=1E- 8) satisfied.
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Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable. Clinical cut-off: 09MAY2013

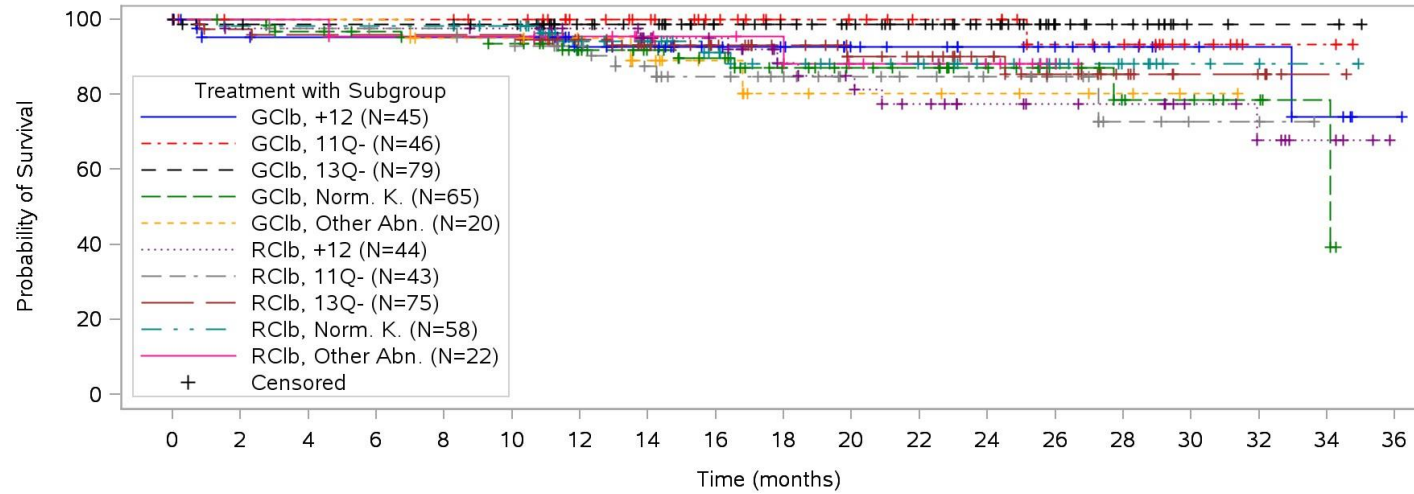
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: Overall Survival

STUDY: CLL11(BO21004), Stage 2

Immunoglobulin VH, cytogenetics 2 (N=497)



Patients at risk

GClb, +12	45	41	40	40	40	40	34	31	26	24	20	18	15	12	9	6	5	4	1
GClb, 11Q-	46	44	44	44	44	42	36	33	28	22	21	18	18	14	13	6	2	2	
GClb, 13Q-	79	76	75	75	75	73	62	59	49	45	41	36	29	15	11	3	2	2	
GClb, Norm. K.	65	64	62	60	59	58	49	43	38	31	27	25	19	14	8	7	4	2	
GClb, Other Abn.	20	20	20	20	18	18	16	14	10	7	6	6	5	4	3	1			
RClb, +12	44	43	43	43	43	42	38	34	31	25	23	20	16	14	13	9	7	4	
RClb, 11Q-	43	43	42	41	41	40	36	32	27	24	19	17	14	10	4	2	2		
RClb, 13Q-	75	73	72	72	72	72	59	52	44	37	31	28	21	16	11	6	5	1	
RClb, Norm. K.	58	57	57	57	57	55	42	37	31	27	24	22	16	13	8	3	2	1	
RClb, Other Abn.	22	22	22	21	21	21	18	15	14	13	11	10	8	2					

Clinical cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/g_km_sg.sas

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2 (Anhang): Ergebnisse für OS - Subgruppenanalysen aus RCT mit dem zu bewertenden Arzneimittel – Datenschnitt 10.10.2017

POPULATION: Labelpopulation, Intent-to-Treat Patients
 ENDPOINT: Overall Survival
 MODEL: Unstratified Analysis STUDY:
 CLL11(B021004), Final
 Time to Event Analysis by Subgroups (Efficacy)

Name	Level	GClb (N=256)														RClb (N=242)										GClb vs. RClb					Interaction Test
		Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event				log-rank p-value	Hazard Ratio			Convergence Status	p-value (likelihood ratio)		
		n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)		95% Lower CL for Median	95% Upper CL for Median	Hazard Ratio			95% Lower CL	
All	n/a	256	100,0	93	36,3	163	63,7	47,2	43,1	55,9	NE	74,6	NE	242	100,0	118	48,8	124	51,2	42,2	31,6	48,4	69,7	58,8	77,5	0,0127	0,71	0,54	0,93	Convergence criterion (GCONV=IE-8) satisfied.	
Gender	Male	159	62,1	63	39,6	96	60,4	45,5	41,1	53,0	NE	65,3	NE	147	60,7	78	53,1	69	46,9	31,6	26,8	44,2	62,0	54,9	74,9	0,0319	0,70	0,50	0,97	Convergence criterion (GCONV=IE-8) satisfied.	0,9343
	Female	97	37,9	30	30,9	67	69,1	55,6	34,6	76,8	NE	76,8	NE	95	39,3	40	42,1	55	57,9	49,6	44,9	56,7	NE	58,2	NE	0,1617	0,71	0,44	1,15	Convergence criterion (GCONV=IE-8) satisfied.	
Age	<75 years	131	51,2	38	29,0	93	71,0	56,4	46,8	76,8	NE	76,8	NE	120	49,6	53	44,2	67	55,8	44,9	33,1	54,8	73,1	60,8	NE	0,0218	0,62	0,41	0,94	Convergence criterion (GCONV=IE-8) satisfied.	0,3635
	≥75 years	125	48,8	55	44,0	70	56,0	42,9	33,0	49,3	74,2	62,3	NE	122	50,4	65	53,3	57	46,7	33,5	22,3	48,6	60,0	55,5	76,9	0,2244	0,80	0,56	1,15	Convergence criterion (GCONV=IE-8) satisfied.	
Race	White	247	96,5	92	37,2	155	62,8	46,8	42,9	55,4	NE	74,2	NE	231	95,5	110	47,6	121	52,4	44,2	31,9	49,0	71,4	60,0	NE	0,0460	0,75	0,57	1,00	Convergence criterion (GCONV=IE-8) satisfied.	0,0202
	Other	9	3,5	1	11,1	8	88,9	NE	56,4	NE	NE	NE	NE	11	4,5	8	72,7	3	27,3	27,6	1,5	46,7	46,7	27,6	NE	0,0089	0,10	0,01	0,82	Convergence criterion (GCONV=IE-8) satisfied.	
Geographical Region	North America	12	4,7	3	25,0	9	75,0	NE	41,0	NE	NE	NE	NE	13	5,4	6	46,2	7	53,8	53,8	45,0	67,7	67,7	53,8	NE	0,2216	0,43	0,11	1,73	Convergence criterion (GCONV=IE-8) satisfied.	0,8851
	Central and South America	3	1,2	1	33,3	2	66,7	46,3	46,3	NE	NE	46,3	NE	2	0,8	1	50,0	1	50,0	27,6	27,6	NE	NE	27,6	NE	0,6949	0,58	0,04	9,30	Convergence criterion (GCONV=IE-8) satisfied.	
	Western Europe	176	68,8	69	39,2	107	60,8	49,1	43,8	56,2	77,2	67,5	NE	165	68,2	80	48,5	85	51,5	44,7	31,9	50,3	69,7	58,2	NE	0,0911	0,76	0,55	1,05	Convergence criterion (GCONV=IE-8) satisfied.	
	Asia-Pacific	20	7,8	6	30,0	14	70,0	42,9	34,5	NE	NE	48,3	NE	18	7,4	10	55,6	8	44,4	45,4	19,9	58,8	66,0	46,7	NE	0,1628	0,49	0,18	1,36	Convergence criterion (GCONV=IE-8) satisfied.	
	Other	45	17,6	14	31,1	31	68,9	41,1	32,4	NE	NE	74,6	NE	44	18,2	21	47,7	23	52,3	29,7	14,6	49,0	74,9	44,9	NE	0,2921	0,70	0,35	1,37	Convergence criterion (GCONV=IE-8) satisfied.	
FCgamma receptor IIa	131HH	58	22,7	24	41,4	34	58,6	47,2	40,5	56,4	77,2	56,0	NE	76	31,4	39	51,3	37	48,7	31,6	20,2	51,4	67,0	56,3	NE	0,3141	0,77	0,46	1,28	Convergence criterion (GCONV=IE-8) satisfied.	0,7189
	131HR	126	49,2	43	34,1	83	65,9	49,1	41,0	63,0	NE	74,6	NE	114	47,1	56	49,1	58	50,9	44,2	31,4	51,3	71,4	58,2	NE	0,0549	0,68	0,46	1,01	Convergence criterion (GCONV=IE-8) satisfied.	
	131RR	49	19,1	20	40,8	29	59,2	44,7	37,5	66,8	76,8	55,6	NE	53	13,6	14	42,4	19	57,6	46,4	31,9	58,1	NE	54,8	NE	0,7558	0,90	0,45	1,78	Convergence criterion (GCONV=IE-8) satisfied.	
	Missing	23	9,0	6	26,1	17	73,9	67,5	35,8	NE	74,2	67,5	NE	19	7,9	9	47,4	10	52,6	47,3	13,8	58,8	68,8	48,4	NE	0,1379	0,46	0,16	1,31	Convergence criterion (GCONV=IE-8) satisfied.	
FCgamma receptor IIIa	158FF	104	40,6	42	40,4	62	59,6	46,3	38,6	55,9	NE	65,3	NE	83	34,3	38	45,8	45	54,2	45,0	33,5	56,1	69,7	58,1	NE	0,5481	0,87	0,56	1,36	Convergence criterion (GCONV=IE-8) satisfied.	0,6002
	158FV	119	46,5	42	35,3	77	64,7	47,2	42,9	64,9	NE	74,6	NE	109	45,0	57	52,3	52	47,7	31,9	27,3	46,4	65,0	54,9	76,9	0,0088	0,59	0,40	0,88	Convergence criterion (GCONV=IE-8) satisfied.	

	158VV	16	6,3	531,3	11	68,8	39,7	27,7	NE	NE	39,7	NE	34	13,6	18	48,5	17	51,5	46,7	20,2	39,6	71,4	55,5	NE	0,5006	0,71	0,26	1,94	Convergence criterion (GCONV=1E-8) satisfied.			
	Missing	17	6,6	423,5	13	76,5	74,2	34,6	NE	NE	74,2	NE	17	7,0	7	41,2	10	58,8	48,4	8,4	NE	NE	48,4	NE	0,3143	0,54	0,16	1,84	Convergence criterion (GCONV=1E-8) satisfied.			
	Binet Staging at baseline	A	59	23,0	1627,1	43	72,9	66,4	49,9	NE	NE	77,2	NE	57	23,6	26	45,6	31	54,4	45,4	19,9	51,8	73,1	51,8	NE	0,0169	0,47	0,25	0,89	Convergence criterion (GCONV=1E-8) satisfied.	0,3020	
		B	105	41,0	3836,2	67	63,8	48,8	44,6	64,9	76,8	66,8	NE	85	35,1	45	52,9	40	47,1	48,4	40,7	56,7	67,7	59,6	76,9	0,1487	0,73	0,47	1,12	Convergence criterion (GCONV=1E-8) satisfied.		
		C	92	35,9	3942,4	53	57,6	37,5	32,7	47,2	NE	54,8	NE	100	41,3	47	47,0	53	53,0	29,6	22,3	46,7	65,0	53,8	NE	0,5691	0,88	0,58	1,35	Convergence criterion (GCONV=1E-8) satisfied.		
	Total CIR score at baseline	<=6	63	24,6	2234,9	41	65,1	48,6	43,8	76,8	NE	76,8	NE	75	31,0	34	45,3	41	54,7	48,7	26,8	58,2	74,9	58,5	NE	0,1849	0,70	0,41	1,19	Convergence criterion (GCONV=1E-8) satisfied.	0,9768	
		>6	193	75,4	7136,8	122	63,2	46,8	41,0	56,2	77,2	69,7	NE	167	69,0	84	60,3	83	49,7	40,0	30,8	46,7	61,8	56,3	77,5	0,0283	0,70	0,51	0,96	Convergence criterion (GCONV=1E-8) satisfied.		
	Calculated creatinine clearance cat. 2	<70 ml/min	178	69,5	6737,6	111	62,4	47,2	42,4	56,2	NE	74,2	NE	176	72,7	84	47,7	92	52,3	45,6	33,1	49,6	67,7	58,3	NE	0,0671	0,74	0,54	1,02	Convergence criterion (GCONV=1E-8) satisfied.	0,5702	
		>=70 ml/min	78	30,5	2633,3	52	66,7	47,2	40,5	66,4	NE	66,4	NE	66	27,3	34	51,5	32	48,5	31,9	21,2	51,8	72,7	52,3	NE	0,0765	0,63	0,38	1,05	Convergence criterion (GCONV=1E-8) satisfied.		
	Beta2 microglobulin	< 3.5 ug/mL	155	60,5	4831,0	107	69,0	48,6	41,1	66,4	NE	77,2	NE	140	57,9	58	41,4	82	58,6	46,4	38,1	55,9	77,5	71,4	NE	0,1601	0,76	0,52	1,12	Convergence criterion (GCONV=1E-8) satisfied.	0,5866	
		>= 3.5 ug/mL	98	38,3	4545,9	53	54,1	45,4	34,6	52,9	69,7	56,2	NE	99	40,9	59	59,6	40	40,4	30,7	21,2	45,6	57,3	49,1	62,0	0,0270	0,65	0,44	0,95	Convergence criterion (GCONV=1E-8) satisfied.		
		Missing	3	1,2	3100,0	NE	NE	NE	NE	NE	NE	NE	NE	3	1,2	1	33,3	2	66,7	48,4	48,4	NE	NE	48,4	NE	0,3173	<0.01	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.		
	Immunoglobulin VH, cytogenetics 2	12	45	17,6	1328,9	32	71,1	56,4	32,2	NE	NE	77,2	NE	44	18,2	24	54,5	20	45,5	26,4	17,8	54,9	71,4	48,3	NE	0,0506	0,52	0,26	1,01	Convergence criterion (GCONV=1E-8) satisfied.	0,2539	
		11q-	46	18,0	2247,8	24	52,2	44,6	39,7	52,9	66,4	49,9	NE	43	17,8	29	67,4	14	32,6	26,8	16,7	39,3	45,0	33,1	62,0	0,0358	0,56	0,32	0,97	Convergence criterion (GCONV=1E-8) satisfied.		
		13q-	79	30,9	2025,3	59	74,7	67,5	55,4	NE	NE	74,6	NE	75	31,0	28	57,3	47	62,7	49,0	41,0	61,3	NE	67,7	NE	0,0832	0,61	0,34	1,07	Convergence criterion (GCONV=1E-8) satisfied.		
		Other Abn.	20	7,8	945,0	11	55,0	30,8	16,8	62,3	62,3	34,5	NE	22	9,1	12	54,5	10	45,5	50,3	27,6	56,7	56,7	51,8	NE	0,7066	0,85	0,36	2,02	Convergence criterion (GCONV=1E-8) satisfied.		
		Norm. K.	66	25,8	2943,9	37	56,1	43,0	32,4	49,1	76,8	53,0	NE	58	24,0	25	43,1	33	56,9	49,1	44,7	58,2	76,9	58,2	NE	0,5908	1,16	0,68	1,98	Convergence criterion (GCONV=1E-8) satisfied.		
	Time from first diagnosis	<= 12 months	60	23,4	1931,7	41	68,3	53,0	41,1	NE	NE	63,1	NE	70	28,9	36	51,4	34	48,6	22,3	16,4	44,9	60,7	51,4	NE	0,0346	0,55	0,32	0,97	Convergence criterion (GCONV=1E-8) satisfied.	0,5836	
		13 - 24 months	41	16,0	2253,7	19	46,3	45,5	32,4	56,4	66,8	55,6	77,2	31	12,8	19	61,3	12	38,7	41,0	29,6	58,1	68,5	49,1	NE	0,5332	0,82	0,44	1,52	Convergence criterion (GCONV=1E-8) satisfied.		
		>24 months	154	60,2	5233,8	102	66,2	46,8	42,4	62,3	NE	74,6	NE	141	58,3	63	44,7	78	55,3	46,7	40,0	53,8	72,7	61,3	NE	0,1076	0,74	0,51	1,07	Convergence criterion (GCONV=1E-8) satisfied.		
		Missing	1	0,4	1100,0	NE	NE	NE	NE	NE	NE	NE	NE	1	0,4	1	100,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	High circulating tumor burden	<25x10**9 cells/L	60	23,4	1931,7	41	68,3	56,0	34,5	NE	NE	77,2	NE	66	27,3	34	51,5	32	48,5	46,4	30,8	53,8	62,0	53,8	NE	0,0321	0,55	0,31	0,96	Convergence criterion (GCONV=1E-8) satisfied.	0,3027	
		>=25x10**9 cells/L	196	76,6	7437,8	122	62,2	47,2	41,1	55,6	NE	69,7	NE	174	71,9	83	47,7	81	52,3	41,0	29,6	48,6	73,1	58,5	NE	0,1022	0,77	0,56	1,05	Convergence criterion (GCONV=1E-8) satisfied.		
		Missing	1	0,4	1100,0	NE	NE	NE	NE	NE	NE	NE	NE	1	0,4	1	100,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable. Clinical cut-off: 10OCT2017

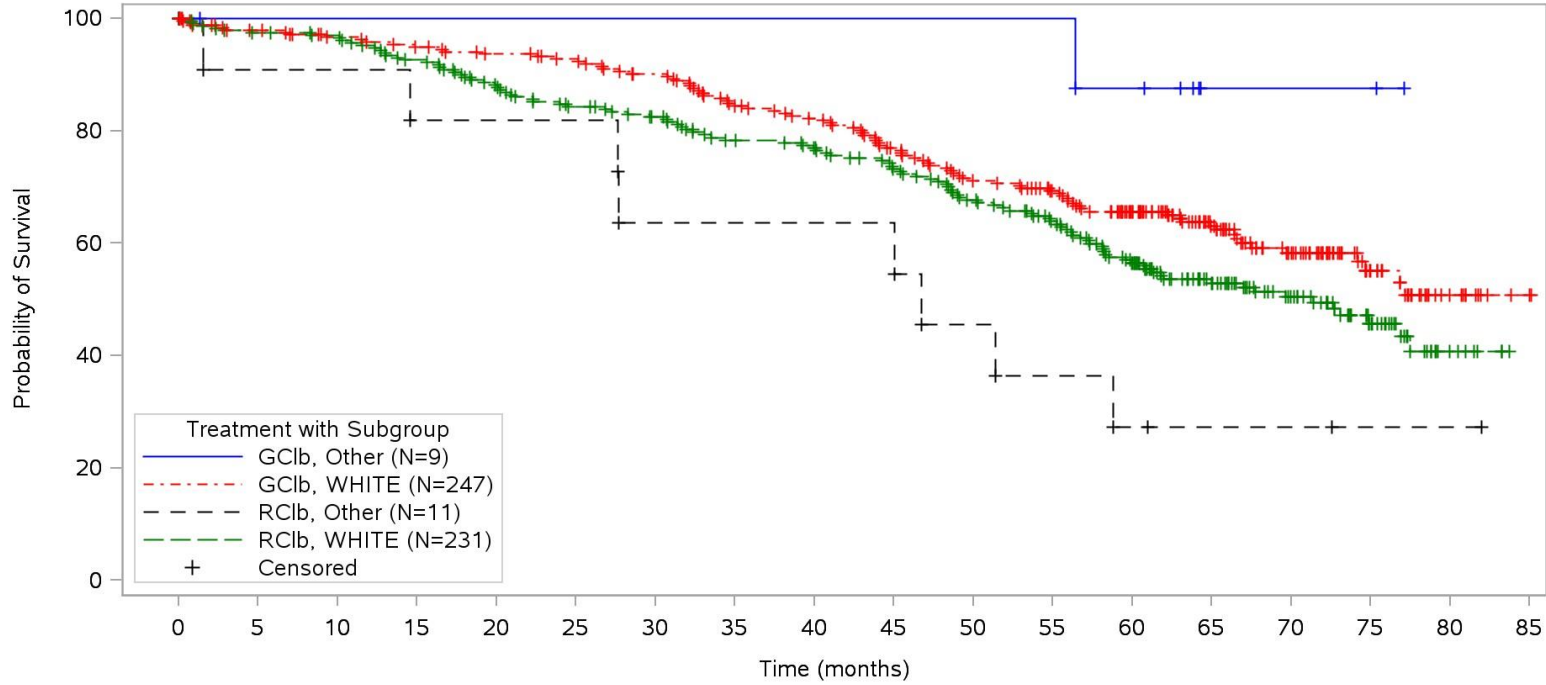
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: Overall Survival

STUDY: CLL11(BO21004), Final

Race/ethnicity (N=498)



Patients at risk

GClb, Other	9	8	8	8	8	8	8	8	8	8	8	7	2	2	2			
GClb, WHITE	247	233	226	222	217	213	206	192	186	173	160	149	127	90	64	31	11	1
RClb, Other	11	10	10	9	9	9	7	7	7	7	5	4	3	2	2	1	1	
RClb, WHITE	231	225	222	212	200	190	183	172	167	157	145	132	111	78	56	30	7	

Clinical cut-off: 10OCT2017

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSRFinal/qa/program/g_km_sg.sas

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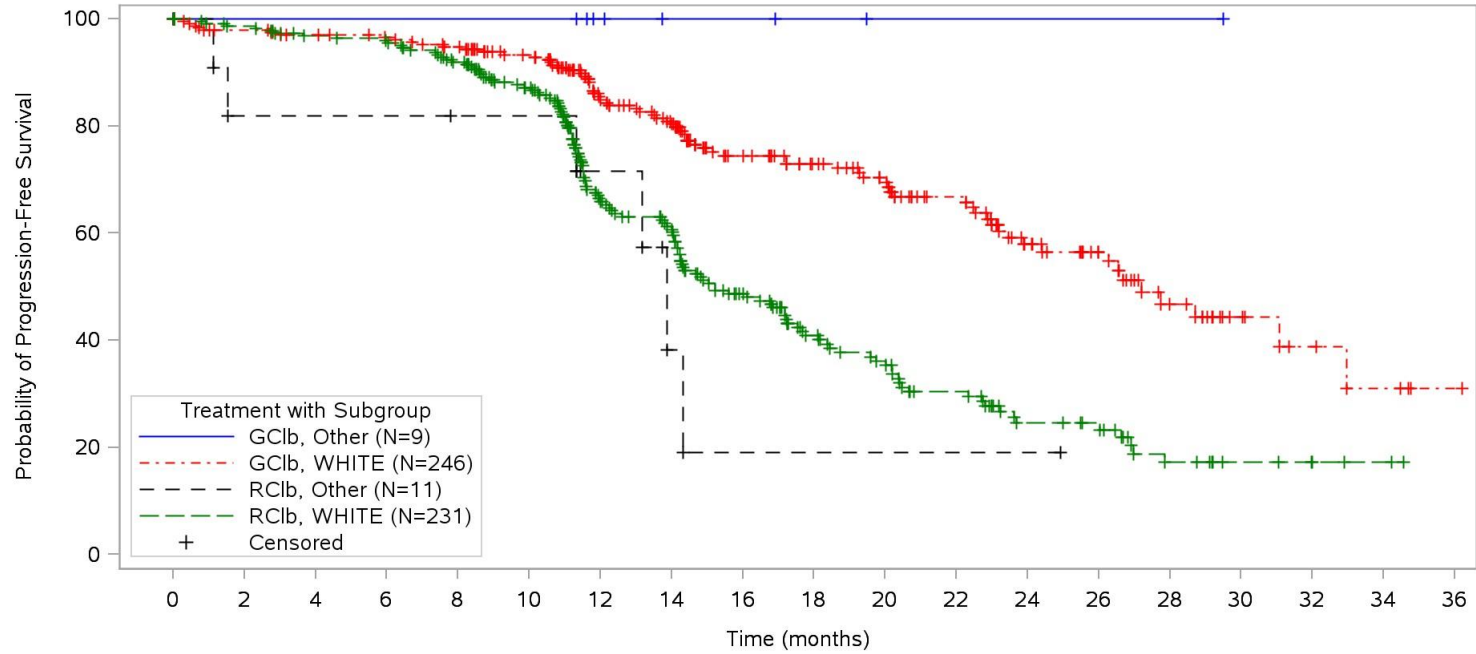
3 (Anhang): Ergebnisse für PFS (Bewertung durch IRC) - Subgruppenanalysen aus RCT mit dem zu bewertenden Arzneimittel

POPULATION: Labelpopulation, Intent-to-Treat Patients
 ENDPOINT: Progression-Free Survival (IRC)
 MODEL: Unstratified Analysis STUDY:
 CLL11 (N021004), Stage 2
 Time to Event Analysis by Subgroups (Efficacy)

Name	Level	GC1b (N=255)														GC1b vs. GC1b														Log-rank p-value	Hazard Ratio	95% Lower CI	95% Upper CI	Convergence Status	p-value (Likelihood ratio)
		Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event															
		n	%	n	%	n	%	95% Lower CI for Q1 (months)	95% Upper CI for Q1	95% Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	95% Lower CI for Q1 (months)	95% Upper CI for Q1	95% Median (months)	95% Lower CL for Median	95% Upper CL for Median												
All	n/a	355	100,0	74	29,0	181	71,0	17,2	14,1	20,3	27,2	24,4	33,0	242	100,0	138	57,0	104	43,0	11,4	11,1	11,6	15,0	14,2	17,2	<.0001	0,40	0,30	0,53	Convergence criterion (GCONV=1E-8) satisfied.					
Gender	Male	158	82,0	42	26,6	116	73,4	15,5	13,9	22,5	31,1	24,4	33,0	147	60,7	91	61,9	56	38,1	11,3	10,9	11,5	14,2	12,4	16,8	<.0001	0,35	0,24	0,51	Convergence criterion (GCONV=1E-8) satisfied.	0,1719				
	Female	97	18,0	32	33,0	65	67,0	17,2	12,3	22,9	26,3	22,9	NE	95	39,3	47	49,5	48	50,5	11,9	11,0	14,3	17,7	14,8	23,2	0,0033	0,51	0,33	0,81	Convergence criterion (GCONV=1E-8) satisfied.					
Age	<75 years	130	51,0	32	24,6	98	75,4	18,7	14,4	23,2	NE	23,2	NE	120	49,6	71	59,2	49	40,8	11,4	11,2	12,6	14,4	14,1	17,5	<.0001	0,32	0,21	0,49	Convergence criterion (GCONV=1E-8) satisfied.	0,2149				
	≥75 years	125	49,0	42	33,6	83	66,4	14,9	12,0	22,5	27,2	22,9	31,1	122	50,4	67	54,9	55	45,1	11,3	10,3	11,6	15,6	13,9	19,6	0,0002	0,49	0,33	0,72	Convergence criterion (GCONV=1E-8) satisfied.					
Race	White	246	69,5	74	30,1	172	69,9	15,5	14,0	20,3	27,2	23,9	33,0	231	85,5	132	57,1	89	42,9	11,4	11,1	11,6	15,2	14,2	17,5	<.0001	0,42	0,31	0,56	Convergence criterion (GCONV=1E-8) satisfied.	0,0275				
	Other	9	3,5			0	0,0	NE	NE	NE	NE	NE	NE	11	4,5	0	0,0	6	54,5	11,3	1,1	14,3	23,9	11,3	NE	0,0167	<.01	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.					
Geographical Region	North America	12	4,7	3	25,0	9	75,0	23,0	23,0	31,1	31,1	23,0	31,1	13	5,4	10	76,9	3	23,1	10,9	7,4	14,2	14,2	10,9	18,1	0,0008	0,06	<.01	0,49	Convergence criterion (GCONV=1E-8) satisfied.	0,7138				
	Central and South America	3	1,2			0	0,0	NE	NE	NE	NE	NE	NE	NE	2	0,8		0,0	0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		
	Western Europe	175	58,6	52	29,7	123	70,3	17,2	14,3	22,5	27,7	23,9	NE	165	68,2	88	53,3	77	46,7	11,5	11,2	12,6	16,9	14,3	19,6	<.0001	0,44	0,31	0,62	Convergence criterion (GCONV=1E-8) satisfied.					
	Asia-Pacific	20	7,8	5	25,0	15	75,0	19,4	10,6	NE	20,0	19,4	NE	18	7,4	10	55,6	8	44,4	11,3	9,7	20,4	20,4	11,4	27,9	0,1745	0,48	0,16	1,42	Convergence criterion (GCONV=1E-8) satisfied.					
	Other	45	17,6	14	31,1	31	68,9	13,0	11,1	26,7	26,7	14,4	NE	44	18,2	30	68,2	14	31,8	10,3	7,7	11,3	11,6	11,2	14,2	0,0027	0,39	0,21	0,74	Convergence criterion (GCONV=1E-8) satisfied.					
FCgamma receptor Ila	31RR	58	22,7	16	27,6	42	72,4	14,4	13,5	33,0	33,0	26,7	NE	76	31,4	47	61,8	29	38,2	11,2	9,0	12,3	14,2	12,3	17,5	<.0001	0,27	0,15	0,49	Convergence criterion (GCONV=1E-8) satisfied.	0,1882				
	31RR	125	49,0	41	32,8	84	67,2	19,3	14,0	22,5	24,4	22,9	27,7	114	47,1	65	57,0	49	43,0	11,5	11,3	12,2	16,5	14,3	18,4	0,0002	0,49	0,33	0,72	Convergence criterion (GCONV=1E-8) satisfied.					
	31RR	49	19,2	11	22,4	38	77,6	14,9	10,6	NE	NE	18,7	NE	33	13,6	13	39,4	20	60,6	12,4	10,9	23,6	23,6	14,2	27,0	0,2126	0,60	0,27	1,35	Convergence criterion (GCONV=1E-8) satisfied.					
	Missing	23	9,0	6	26,1	17	73,9	15,1	13,1	NE	28,7	28,7	NE	19	7,9	13	68,4	6	31,6	11,1	8,4	14,1	14,1	11,2	20,0	0,0057	0,27	0,10	0,73	Convergence criterion (GCONV=1E-8) satisfied.					
FCgamma receptor IIIa	35BP	103	40,4	33	32,0	70	68,0	14,7	12,3	22,5	23,9	22,5	33,0	83	34,3	47	56,6	36	43,4	11,5	10,9	12,4	14,3	13,2	17,8	<.0001	0,40	0,26	0,63	Convergence criterion (GCONV=1E-8) satisfied.	0,9253				
	35BP	119	46,7	32	26,9	87	73,1	19,3	13,6	24,4	26,7	24,4	NE	109	45,0	65	59,6	44	40,4	11,3	10,9	12,0	14,8	14,1	18,4	<.0001	0,34	0,22	0,52	Convergence criterion (GCONV=1E-8) satisfied.					
	35BV	16	6,3	4	25,0	12	75,0	22,9	11,6	NE	27,7	22,9	NE	33	13,6	16	48,5	17	51,5	12,3	11,2	17,2	17,2	13,9	NE	0,2474	0,53	0,18	1,58	Convergence criterion (GCONV=1E-8) satisfied.					
	Missing	17	6,7	5	29,4	12	70,6	13,9	11,7	NE	28,7	13,9	NE	17	7,0	10	58,8	7	41,2	11,1	8,4	11,6	14,1	11,1	NE	0,1184	0,43	0,15	1,28	Convergence criterion (GCONV=1E-8) satisfied.					
Binet Staging at Baseline	A	59	23,1	16	27,1	43	72,9	20,0	17,2	26,5	28,7	22,3	NE	57	23,6	27	47,4	30	52,6	11,4	10,6	14,0	14,8	13,8	27,0	0,0024	0,39	0,21	0,73	Convergence criterion (GCONV=1E-8) satisfied.	0,9001				
	B	104	40,8	29	27,9	75	72,1	14,4	13,6	23,0	27,2	23,0	NE	85	35,1	51	60,0	34	40,0	11,5	11,0	14,1	14,7	14,2	17,7	0,0004	0,45	0,29	0,71	Convergence criterion (GCONV=1E-8) satisfied.					
	C	92	36,1	29	31,5	63	68,5	14,9	12,0	23,2	26,7	23,2	33,0	100	41,3	60	60,0	40	40,0	11,2	10,3	12,0	16,1	12,6	18,4	<.0001	0,37	0,23	0,58	Convergence criterion (GCONV=1E-8) satisfied.					
Total CIR score at Baseline	≤6	63	24,7	23	36,5	40	63,5	18,7	12,0	23,5	24,4	22,9	31,1	75	31,0	45	60,0	30	40,0	11,9	11,0	14,2	15,2	14,3	18,4	0,0021	0,46	0,28	0,76	Convergence criterion (GCONV=1E-8) satisfied.	0,3230				
	>6	192	75,3	51	26,6	141	73,4	15,5	13,6	22,5	33,0	26,3	NE	167	69,0	93	55,7	74	44,3	11,3	10,9	11,6	14,4	13,7	17,8	<.0001	0,37	0,26	0,52	Convergence criterion (GCONV=1E-8) satisfied.					
Calculated creatinine Clearance cat. 2	<70 ml/min	178	69,8	58	32,6	120	67,4	15,5	13,9	20,3	26,5	23,2	31,1	176	72,7	101	57,4	75	42,6	11,4	11,0	11,9	15,0	14,1	17,2	<.0001	0,42	0,31	0,59	Convergence criterion (GCONV=1E-8) satisfied.	0,3924				
	≥70 ml/min	77	30,2	16	20,8	61	79,2	17,2	13,1	NE	NE	27,7	NE	66	27,3	37	56,1	29	43,9	11,3	10,6	13,8	17,2	13,8	20,4	<.0001	0,33	0,18	0,59	Convergence criterion (GCONV=1E-8) satisfied.					
Beta2 microglobulin	< 3.5 ug/mL	154	60,4	40	26,0	114	74,0	19,4	13,6	23,5	31,1	26,5	NE	140	57,9	83	59,3	57	40,7	11,5	11,2	14,0	16,1	14,3	18,7	<.0001	0,38	0,26	0,56	Convergence criterion (GCONV=1E-8) satisfied.	0,9147				
	≥ 3.5 ug/mL	98	38,4	34	34,7	64	65,3	14,7	13,0	20,1	24,4	20,1	33,0	99	40,9	55	55,6	44	44,4	11,0	9,7	11,5	13,9	11,9	16,8	<.0001	0,39	0,25	0,61	Convergence criterion (GCONV=1E-8) satisfied.					

POPULATION: Labelpopulation, Intent-to-Treat Patients
ENDPOINT: Progression-Free Survival (IRC)
STUDY: CLL11(BO21004), Stage 2

Race/ethnicity (N=497)



Patients at risk	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36
GClb, Other	9	8	8	8	8	8	5	3	3	2	1	1	1	1	1				
GClb, WHITE	246	225	220	216	210	193	153	137	105	90	80	65	45	32	20	10	6	4	1
RClb, Other	11	9	9	9	8	8	5	2	1	1	1	1	1						
RClb, WHITE	231	223	216	214	202	178	117	104	75	53	45	35	23	20	11	6	4	2	

Clinical cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/g_km_sg.sas
 Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/g_km_sg_PFSIRF_IT_label_09MAY2013_21004.pdf
 04MAR2020 17:37

		13 - 24 months	32	14.4	9	28.1	27	12.6	4	14.8	2.25	Convergence criterion (GCONV=1E-8) satisfied.	0.61	8.36	0.133	Algorithm converged.	-0.072	0.339	1.90	Algorithm converged.	0.66	5.48	0.2362	0.53	Algorithm converged.	0.18	1.92	
		>24 months	116	52.3	22	19.0	103	50.9	17	15.0	1.27	Convergence criterion (GCONV=1E-8) satisfied.	0.63	2.54	0.034	Algorithm converged.	-0.065	0.130	1.22	Algorithm converged.	0.65	2.16	0.5065	0.82	Algorithm converged.	0.46	1.46	
		Missing	1	0.5	1	100.0																						
	High circulating tumor burden	<25x10**9 cells/L	43	19.4	9	20.9	49	22.9	9	18.4	1.18	Convergence criterion (GCONV=1E-8) satisfied.	0.42	3.30	0.026	Algorithm converged.	-0.137	0.189	1.14	Algorithm converged.	0.50	2.61	0.7572	0.8504	0.88	Algorithm converged.	0.38	2.01
		>=25x10**9 cells/L	148	66.7	33	22.3	140	65.4	25	17.9	1.32	Convergence criterion (GCONV=1E-8) satisfied.	0.74	2.36	0.044	Algorithm converged.	-0.048	0.197	1.25	Algorithm converged.	0.78	1.99	0.3498	0.80	Algorithm converged.	0.50	1.28	
		Missing					1	0.5																				
	Pu Month 3	All	n/a		51	25.8	188	87.9	36	19.1	1.46	Convergence criterion (GCONV=1E-8) satisfied.	0.90	2.37	0.066	Algorithm converged.	-0.017	0.149	1.35	Algorithm converged.	0.92	1.96	0.1233	0.74	Algorithm converged.	0.51	1.08	
	Gender	Male	120	54.1	26	21.7	115	53.7	15	13.0	1.84	Convergence criterion (GCONV=1E-8) satisfied.	0.92	3.70	0.086	Algorithm converged.	-0.010	0.182	1.64	Algorithm converged.	0.93	2.97	0.0873	0.2987	0.60	Algorithm converged.	0.34	1.08
		Female	78	35.1	25	32.1	73	34.1	21	28.8	1.17	Convergence criterion (GCONV=1E-8) satisfied.	0.58	2.34	0.033	Algorithm converged.	-0.114	0.180	1.11	Algorithm converged.	0.69	1.81	0.6613	0.90	Algorithm converged.	0.55	1.46	
	Age	<75 years	104	46.8	29	27.9	95	44.4	18	18.9	1.65	Convergence criterion (GCONV=1E-8) satisfied.	0.85	3.23	0.089	Algorithm converged.	-0.027	0.206	1.47	Algorithm converged.	0.88	2.47	0.1433	0.6112	0.68	Algorithm converged.	0.40	1.14
		>=75 years	94	42.3	22	23.4	93	43.5	18	19.4	1.27	Convergence criterion (GCONV=1E-8) satisfied.	0.63	2.57	0.040	Algorithm converged.	-0.077	0.158	1.21	Algorithm converged.	0.70	2.10	0.5008	0.83	Algorithm converged.	0.46	1.44	
	Race	White	191	86.0	49	25.7	178	83.2	32	18.0	1.57	Convergence criterion (GCONV=1E-8) satisfied.	0.95	2.60	0.077	Algorithm converged.	-0.007	0.161	1.43	Algorithm converged.	0.94	2.12	0.0783	0.3274	0.70	Algorithm converged.	0.47	1.04
		Other	7	3.2	2	28.6	10	4.7	4	40.0	0.60	Convergence criterion (GCONV=1E-8) satisfied.	0.08	4.78	-0.114	Algorithm converged.	-0.566	0.338	0.71	Algorithm converged.	0.18	2.88	0.6366	1.40	Algorithm converged.	0.35	5.65	
	Geographical Region	North America	11	5.0	2	18.2	11	5.1	4	36.4	0.39	Convergence criterion (GCONV=1E-8) satisfied.	0.05	2.77	-0.182	Algorithm converged.	-0.546	0.183	0.50	Algorithm converged.	0.11	2.15	0.3578	0.2233	2.00	Algorithm converged.	0.46	8.76
		Central and South America	3	1.4		2	0.9	1	50.0			Quasi-complete separation of data points detected.				ERROR: The mean parameter is either invalid or at a limit of its range for some observations.				WARNING: Negative of Hessian not positive definite.					WARNING: Negative of Hessian not positive definite.			
		Western Europe	135	60.8	33	24.4	123	57.5	18	14.6	1.89	Convergence criterion (GCONV=1E-8) satisfied.	1.00	3.56	0.098	Algorithm converged.	0.002	0.194	1.67	Algorithm converged.	0.99	2.81	0.0530	0.60	Algorithm converged.	0.36	1.01	
		Asia-Pacific	16	7.0	5	31.3	16	7.5	5	31.3	1.00	Convergence criterion (GCONV=1E-8) satisfied.	0.22	4.46	0.000	Algorithm converged.	-0.321	0.321	1.00	Algorithm converged.	0.36	2.79	1.0000	1.00	Algorithm converged.	0.36	2.79	
		Other	33	14.9	11	33.3	38	16.8	8	22.2	1.75	Convergence criterion (GCONV=1E-8) satisfied.	0.60	5.08	0.111	Algorithm converged.	-0.099	0.322	1.50	Algorithm converged.	0.69	3.27	0.3074	0.67	Algorithm converged.	0.31	1.45	
	PCgamma receptor Iia	I11HR	46	20.7	10	21.7	53	24.8	12	22.4	0.95	Convergence criterion (GCONV=1E-8) satisfied.	0.37	2.46	-0.008	Algorithm converged.	-0.173	0.155	0.96	Algorithm converged.	0.46	2.01	0.9143	0.1367	1.04	Algorithm converged.	0.56	2.18
		I11HR	99	44.6	30	30.3	93	43.5	19	20.4	1.69	Convergence criterion (GCONV=1E-8) satisfied.	0.87	3.28	0.099	Algorithm converged.	-0.023	0.221	1.48	Algorithm converged.	0.90	2.45	0.1223	0.47	Algorithm converged.	0.41	1.11	
		I11RR	37	16.7	10	27.0	27	12.6	2	7.4	4.63	Convergence criterion (GCONV=1E-8) satisfied.	0.92	23.22	0.136	Algorithm converged.	0.022	0.370	3.65	Algorithm converged.	0.87	15.32	0.0771	0.27	Algorithm converged.	0.07	1.15	
		Missing	16	7.2	1	6.3	15	7.0	3	20.0	0.27	Convergence criterion (GCONV=1E-8) satisfied.	0.02	2.90	-0.138	Algorithm converged.	-0.372	0.097	0.31	Algorithm converged.	0.04	2.68	0.2892	3.20	Algorithm converged.	0.37	27.49	
	PCgamma receptor Iiia	I58FP	82	36.9	23	28.0	67	31.3	9	13.4	2.51	Convergence criterion (GCONV=1E-8) satisfied.	1.07	5.89	0.146	Algorithm converged.	0.019	0.273	2.09	Algorithm converged.	1.04	4.20	0.0392	0.1470	0.48	Algorithm converged.	0.24	0.96
		I58FV	91	41.0	23	25.3	82	38.3	17	20.7	1.29	Convergence criterion (GCONV=1E-8) satisfied.	0.63	2.64	0.045	Algorithm converged.	-0.080	0.171	1.22	Algorithm converged.	0.70	2.12	0.4812	0.82	Algorithm converged.	0.47	1.42	
		I58VV	12	5.4	4	33.0	26	12.1	6	23.1	1.67	Convergence criterion (GCONV=1E-8) satisfied.	0.37	7.53	0.103	Algorithm converged.	-0.209	0.415	1.44	Algorithm converged.	0.50	4.19	0.4983	0.69	Algorithm converged.	0.24	2.01	
		Missing	13	5.9	1	7.7	13	6.1	4	30.8	0.19	Convergence criterion (GCONV=1E-8) satisfied.	0.02	1.98	-0.231	Algorithm converged.	-0.520	0.059	0.25	Algorithm converged.	0.03	1.95	0.1855	4.00	Algorithm converged.	0.51	31.13	
	Binet Staging at baseline	A	55	24.5	10	23.8	47	22.0	9	19.1	1.18	Convergence criterion (GCONV=1E-8) satisfied.	0.45	3.10	0.027	Algorithm converged.	-0.130	0.183	1.14	Algorithm converged.	0.53	2.46	0.7403	0.6201	0.85	Algorithm converged.	0.41	1.90
		B	75	33.8	18	24.0	69	32.2	14	20.3	1.24	Convergence criterion (GCONV=1E-8) satisfied.	0.56	2.74	0.037	Algorithm converged.	-0.098	0.173	1.18	Algorithm converged.	0.64	2.19	0.5939	0.85	Algorithm converged.	0.46	1.57	
		C	68	30.6	21	30.8	70	33.6	13	18.1	2.03	Convergence criterion (GCONV=1E-8) satisfied.	0.92	4.47	0.128	Algorithm converged.	-0.013	0.270	1.71	Algorithm converged.	0.93	3.14	0.0821	0.38	Algorithm converged.	0.32	1.07	
	Total CR score at baseline	<=6	47	21.2	9	19.1	55	25.7	10	18.2	1.07	Convergence criterion (GCONV=1E-8) satisfied.	0.39	2.89	0.010	Algorithm converged.	-0.142	0.161	1.05	Algorithm converged.	0.47	2.37	0.9005	0.5205	0.95	Algorithm converged.	0.42	2.14
		>6	151	68.0	42	27.8	133	62.1	26	19.5	1.59	Convergence criterion (GCONV=1E-8) satisfied.	0.91	2.77	0.083	Algorithm converged.	-0.016	0.191	1.42	Algorithm converged.	0.93	2.19	0.1080	0.70	Algorithm converged.	0.46	1.08	
	Calculated creatinine clearance cat. 2	<70 ml/min	136	61.3	39	28.7	135	63.1	27	20.0	1.61	Convergence criterion (GCONV=1E-8) satisfied.	0.92	2.82	0.087	Algorithm converged.	-0.013	0.188	1.43	Algorithm converged.	0.93	2.20	0.0997	0.6160	0.70	Algorithm converged.	0.43	1.07
		>=70 ml/min	62	27.9	12	19.4	53	24.8	9	17.0	1.17	Convergence criterion (GCONV=1E-8) satisfied.	0.45	3.05	0.024	Algorithm converged.	-0.117	0.165	1.14	Algorithm converged.	0.52	2.49	0.7432	0.88	Algorithm converged.	0.40	1.92	
	Beta2 microglobulin	< 3.5 ug/mL	119	53.6	33	27.7	111	51.9	26	23.4	1.25	Convergence criterion (GCONV=1E-8) satisfied.	0.69	2.27	0.043	Algorithm converged.	-0.070	0.156	1.18	Algorithm converged.	0.76	1.85	0.4563	0.2351	0.84	Algorithm converged.	0.54	1.32
		>= 3.5 ug/mL	76	34.2	18	23.7	75	35.0	9	12.0	2.28	Convergence criterion (GCONV=1E-8) satisfied.	0.95	5.46	0.117	Algorithm converged.	-0.004	0.237	1.97	Algorithm converged.	0.95	4.11	0.0694	0.51	Algorithm converged.	0.24	1.06	
		Missing	0	1.4		2	0.9	1	50.0			Quasi-complete separation of data points detected.				ERROR: The mean parameter is either invalid or at a limit of its range for some observations.				WARNING: Negative of Hessian not positive definite.					WARNING: Negative of Hessian not positive definite.			
	Immunoglobulin VH, cytogenetics 2	I2	35	15.8	8	22.9	31	14.5	4	12.9	2.00	Convergence criterion (GCONV=1E-8) satisfied.	0.54	7.44	0.100	Algorithm converged.	-0.083	0.282	1.77	Algorithm converged.	0.59	5.31	0.3077	0.0605	0.36	Algorithm converged.	0.19	1.69
		I1q-	37	16.7	6	16.2	34	15.9	11	32.4	0.40	Convergence criterion (GCONV=1E-8) satisfied.	0.13	1.25	-0.161	Algorithm converged.	-0.338	0.036	0.50	Algorithm converged.	0.21	1.21	0.1235	2.00	Algorithm converged.	0.83	4.81	
		I1q-	66	29.7	15	22.7	59	27.6	11	18.6	1.28	Convergence criterion (GCONV=1E-8) satisfied.	0.54	3.07	0.041	Algorithm converged.	-0.101	0.183	1.22	Algorithm converged.	0.61	2.44	0.5761	0.82	Algorithm converged.	0.41	1.64	
		Other Abn.	14	6.3	4	28.6	17	7.9	1	5.9	6.40	Convergence criterion (GCONV=1E-8) satisfied.	0.62	65.74	0.227	Algorithm converged.	-0.035	0.489	4.86	Algorithm converged.	0.61	38.65	0.1353	0.21	Algorithm converged.	0.03	1.64	
		Norm. K.	46	20.7	18	39.1	47	22.0	9	19.1	2.71	Convergence criterion (GCONV=1E-8) satisfied.	1.06	6.93	0.200	Algorithm converged.	0.019	0.380	2.04	Algorithm converged.	1.03	4.07	0.0421	0.49	Algorithm converged.	0.25	0.97	
	Time from first diagnosis	<= 12 months	43	20.3	15	33.3	54	25.2	14	25.9	1.43	Convergence criterion (GCONV=1E-8) satisfied.	0.60	3.41	0.074	Algorithm converged.	-0.107	0.255	1.29	Algorithm converged.	0.70	2.37	0.4206	0.8487	0.78	Algorithm converged.	0.42	1.43
		13 - 24 months	32	14.4	7	21.9	28	12.1	3	11.3	2.15	Convergence criterion (GCONV=1E-8) satisfied.	0.50	9.30	0.103	Algorithm converged.	-0.085	0.292	1.90	Algorithm converged.	0.54	6.61	0.3157	0.53	Algorithm converged.	0.15	1.84	
		>24 months	120	54.1	28	23.3	108	50.5	19	17.6	1.43	Convergence criterion (GCONV=1E-8) satisfied.	0.74	2.73	0.057	Algorithm converged.	-0.047	0.162	1.33	Algorithm converged.	0.79	2.23	0.2884	0.75	Algorithm converged.	0.45	1.27	
		Missing	1	0.5	1	100.0																						
	High circulating tumor burden	<25x10**9 cells/L	48	20.7	12	26.1	49	22.9	10	20.4	1.38	Convergence criterion (GCONV=1E-8) satisfied.	0.53	3.58	0.057	Algorithm converged.	-0.113	0.227	1.28	Algorithm converged.	0.61	2.67	0.5135	0.8850	0.78	Algorithm converged.	0.37	1.63
		>=25x10**9 cells/L	152	68.5	39	25.7	138	64.5	26	18.8	1.49	Convergence criterion (GCONV=1E-8) satisfied.	0.85	2.60	0.068	Algorithm converged.	-0.027	0.163	1.36	Algorithm converged.	0.88	2.11	0.1684	0.73	Algorithm converged.	0.47	1.14	
		Missing					1	0.5																				

Test for interaction based on RR (Log-binomial regression)

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 09MAY2013
Program: root/clinical_studies/R05072759/CDPT7159/B021004/data_analysis/ACE_base/qa/program/t_pro_rsp2.sas
Output: root/clinical_studies/R05072759/CDPT7159/B021004/data_analysis/ACE_CSR_stage2/qa/output/t_pro_rsp2_sq_EQC301_OLQC30pop_17_label1_09MAY2013_21004.xls
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POPULATION: Labelpopulation, Intent-to-Treat Patients, Patients with Screening and post Screening EORTC Q5-Q-C30 result
 ENDPOINT: EORTC QoL 30 - Responder (MID=10), Improvement
 MODEL: Unstratified Analysis
 STUDY: CLL11 (8021004), Stage 2
 Dichotomous Analysis by Subgroups (Efficacy)

Financial Difficulties Scale

Visit	Name	Level	OC1b (N=225)				OC1b (N=214)				Odds Ratio			Absolute Risk Difference			Relative Risk				Relative Risk							
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio	95% Lower CL	95% Upper CL	Absolute Risk	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interacti on Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL		
			n	%	n	%	n	%	n	%																		
Cycle 4 Day 1	All	n/a	191	86.0	24	12.6	183	85.5	18	9.8	1.32	Convergence criterion (GCONV=1E-8) satisfied.	0.69	2.52	0.027	Algorithm converged.	-0.037	0.091	1.28	Algorithm converged.	0.72	2.27	0.4051	0.78	Algorithm converged.	0.44	1.39	
	Gender	Male	117	52.7	13	11.1	112	52.3	12	10.7	1.04	Convergence criterion (GCONV=1E-8) satisfied.	0.45	2.39	0.004	Algorithm converged.	-0.077	0.085	1.04	Algorithm converged.	0.49	2.17	0.9233	0.3924	0.96	Algorithm converged.	0.46	2.02
		Female	74	33.3	11	14.9	71	33.2	6	8.5	1.89	Convergence criterion (GCONV=1E-8) satisfied.	0.66	5.42	0.064	Algorithm converged.	-0.040	0.198	1.76	Algorithm converged.	0.69	4.50	0.2399	0.57	Algorithm converged.	0.22	1.46	
		Age																										
		<75 years	98	44.6	11	11.1	92	43.0	9	9.8	1.15	Convergence criterion (GCONV=1E-8) satisfied.	0.45	2.92	0.013	Algorithm converged.	-0.073	0.103	1.14	Algorithm converged.	0.49	2.62	0.7647	0.6969	0.88	Algorithm converged.	0.38	2.03
		>=75 years	92	41.4	13	14.1	91	42.5	9	9.9	1.50	Convergence criterion (GCONV=1E-8) satisfied.	0.61	3.70	0.042	Algorithm converged.	-0.052	0.136	1.43	Algorithm converged.	0.64	3.18	0.3814	0.70	Algorithm converged.	0.31	1.56	
		Race																										
		White	184	82.9	22	12.0	174	81.3	18	10.3	1.18	Convergence criterion (GCONV=1E-8) satisfied.	0.61	2.28	0.016	Algorithm converged.	-0.049	0.091	1.16	Algorithm converged.	0.64	2.08	0.6290	0.0739	0.87	Algorithm converged.	0.48	1.95
		Other	7	3.2	2	28.6	9	4.2				Quasi-complete separation of data points detected.							NE	NE	NE	NE	NE	NE	NE	NE	NE	
		Geographical Region																										
		North America	9	4.1					10	4.7	1	10.0	Quasi-complete separation of data points detected.							<0.01	Algorithm converged.	0.00	NE	1.0000	>999.99	Algorithm converged.	0.00	NE
		Central and South America	3	1.4					2	0.9	1	50.0	Quasi-complete separation of data points detected.								WARNING: Negative of Hessian not positive definite.					WARNING: Negative of Hessian not positive definite.		
		Western Europe	131	59.0	10	7.6	123	57.5	11	8.9	0.84	Convergence criterion (GCONV=1E-8) satisfied.	0.34	2.06	-0.013	Algorithm converged.	-0.081	0.055	0.85	Algorithm converged.	0.38	1.94	0.7052	1.17	Algorithm converged.	0.52	2.66	
		Asia-Pacific	15	6.8	4	26.7	14	6.5				Quasi-complete separation of data points detected.							NE	NE	NE	NE	NE	NE	NE	NE	NE	
		Other	33	14.9	10	30.3	34	15.9	5	14.7	2.52	Convergence criterion (GCONV=1E-8) satisfied.	0.76	8.41	0.156	Algorithm converged.	-0.041	0.353	2.06	Algorithm converged.	0.79	5.39	0.1402	0.49	Algorithm converged.	0.19	1.27	
		PCgamma receptor I1a																										
		I11H	42	18.9	4	9.5	58	27.1	8	13.8	0.66	Convergence criterion (GCONV=1E-8) satisfied.	0.18	2.35	-0.043	Algorithm converged.	-0.168	0.083	0.69	Algorithm converged.	0.22	2.14	0.5216	0.0056	1.45	Algorithm converged.	0.47	4.90
		I11R	95	42.8	18	18.9	93	43.5	5	5.4	4.11	Convergence criterion (GCONV=1E-8) satisfied.	1.46	11.60	0.136	Algorithm converged.	0.045	0.227	3.52	Algorithm converged.	1.36	9.10	0.0093	0.28	Algorithm converged.	0.11	0.73	
		I11R	38	17.1	2	5.3	20	9.3	4	20.0	0.22	Convergence criterion (GCONV=1E-8) satisfied.	0.04	1.34	-0.147	Algorithm converged.	-0.337	0.042	0.26	Algorithm converged.	0.05	1.31	0.1038	3.80	Algorithm converged.	0.76	18.99	
		Missing	16	7.2					12	5.6	1	8.3	Quasi-complete separation of data points detected.							<0.01	Algorithm converged.	0.00	NE	1.0000	>999.99	Algorithm converged.	0.00	NE
		PCgamma receptor I1i1a																										
		I18FV	81	36.3	9	11.1	63	29.4	7	11.1	1.00	Convergence criterion (GCONV=1E-8) satisfied.	0.35	2.85	0.005	Algorithm converged.	-0.103	0.103	1.00	Algorithm converged.	0.39	2.54	1.0000	0.5163	1.00	Algorithm converged.	0.39	2.84
		I18FV	88	39.6	14	15.9	81	37.9	8	9.9	1.73	Convergence criterion (GCONV=1E-8) satisfied.	0.68	4.36	0.060	Algorithm converged.	-0.045	0.161	1.61	Algorithm converged.	0.71	3.64	0.2513	0.82	Algorithm converged.	0.27	1.40	
		I18FV	11	5.0	1	9.1	28	13.1	2	7.1	1.30	Convergence criterion (GCONV=1E-8) satisfied.	0.11	15.98	0.019	Algorithm converged.	-0.175	0.214	1.27	Algorithm converged.	0.13	12.66	0.8370	0.79	Algorithm converged.	0.08	7.81	
		Missing	11	5.0					11	5.1	1	9.1	Quasi-complete separation of data points detected.							<0.01	Algorithm converged.	0.00	NE	1.0000	>999.99	Algorithm converged.	0.00	NE
		Binet Staging at baseline																										
		A	47	21.2	5	10.6	46	21.5	5	10.9	0.98	Convergence criterion (GCONV=1E-8) satisfied.	0.26	3.63	-0.002	Algorithm converged.	-0.128	0.124	0.98	Algorithm converged.	0.30	3.16	0.9713	0.4272	1.02	Algorithm converged.	0.32	3.20
		B	80	36.0	12	15.0	70	32.7	5	7.1	2.29	Convergence criterion (GCONV=1E-8) satisfied.	0.77	6.87	0.079	Algorithm converged.	-0.020	0.177	2.10	Algorithm converged.	0.78	5.67	0.1430	0.48	Algorithm converged.	0.18	1.29	
		C	64	28.8	7	10.9	67	31.3	8	11.9	0.91	Convergence criterion (GCONV=1E-8) satisfied.	0.31	2.66	-0.010	Algorithm converged.	-0.119	0.099	0.92	Algorithm converged.	0.33	2.98	0.8571	1.09	Algorithm converged.	0.42	2.84	
		Total CIR score at baseline																										
		<=6	43	19.4	3	7.0	54	25.2	4	7.4	0.94	Convergence criterion (GCONV=1E-8) satisfied.	0.20	4.43	-0.004	Algorithm converged.	-0.108	0.099	0.94	Algorithm converged.	0.22	3.98	0.9351	0.6817	1.06	Algorithm converged.	0.25	4.49
		>6	148	66.7	21	14.2	123	60.3	14	10.9	1.36	Convergence criterion (GCONV=1E-8) satisfied.	0.66	2.80	0.033	Algorithm converged.	-0.044	0.111	1.31	Algorithm converged.	0.69	2.46	0.4071	0.76	Algorithm converged.	0.41	1.44	
		Calculated creatinine clearance cat. 2																										
		<70 ml/min	129	58.1	12	12.4	133	62.1	12	9.0	1.43	Convergence criterion (GCONV=1E-8) satisfied.	0.65	3.15	0.034	Algorithm converged.	-0.041	0.103	1.37	Algorithm converged.	0.68	2.78	0.3783	0.6935	0.73	Algorithm converged.	0.36	1.46
		>=70 ml/min	62	27.9	8	12.9	50	23.4	6	12.0	1.09	Convergence criterion (GCONV=1E-8) satisfied.	0.35	3.37	0.009	Algorithm converged.	-0.114	0.130	1.08	Algorithm converged.	0.40	2.90	0.8856	0.93	Algorithm converged.	0.35	2.50	
		Beta2 microglobulin																										
		< 3.5 ug/mL	113	50.9	17	15.0	106	49.5	11	10.4	1.53	Convergence criterion (GCONV=1E-8) satisfied.	0.68	3.44	0.047	Algorithm converged.	-0.041	0.133	1.45	Algorithm converged.	0.71	2.95	0.3057	0.7360	0.69	Algorithm converged.	0.34	1.40
		>= 3.5 ug/mL	75	33.8	7	9.3	75	35.0	6	8.0	1.18	Convergence criterion (GCONV=1E-8) satisfied.	0.38	3.70	0.013	Algorithm converged.	-0.077	0.103	1.17	Algorithm converged.	0.41	3.31	0.7719	0.86	Algorithm converged.	0.30	2.43	
		Missing	3	1.4					2	0.9	1	50.0	Quasi-complete separation of data points detected.							<0.01	Algorithm converged.	0.00	NE	1.0000	>999.99	Algorithm converged.	0.00	NE
		Immunoglobulin VH, cytogenetics 2																										
		I2	31	14.0	8	25.8	32	15.0	3	9.4	3.36	Convergence criterion (GCONV=1E-8) satisfied.	0.86	14.12	0.164	Algorithm converged.	-0.020	0.349	2.75	Algorithm converged.	0.80	9.43	0.1071	0.4865	0.36	Algorithm converged.	0.11	1.24
		I1g-	38	17.6	5	12.8	35	15.0	4	12.3	1.03	Convergence criterion (GCONV=1E-8) satisfied.	0.25	4.20	0.003	Algorithm converged.	-0.153	0.199	1.03	Algorithm converged.	0.30	3.50	0.9678	0.88	Algorithm converged.	0.29	3.33	
		I3q-	58	26.1	4	6.9	57	26.6	5	8.8	0.77	Convergence criterion (GCONV=1E-8) satisfied.	0.20	3.03	-0.018	Algorithm converged.	-0.117	0.079	0.78	Algorithm converged.	0.22	2.78	0.7089	1.27	Algorithm converged.	0.36	4.50	

		Norm. K.	46	20.7	4	8.7	46	21.5	4	8.7	1.00		Convergence criterion (GCONV=1E-8) satisfied.	0.23	4.26	0.005	Algorithm converged.	-0.115	0.115	1.00	Algorithm converged.	0.27	3.76	1.0000		1.00	Algorithm converged.	0.27	3.76	
	Time from first diagnosis	<= 12 months	44	19.8	11	25.0	53	24.8	7	13.2	2.19		Convergence criterion (GCONV=1E-8) satisfied.	0.77	6.25	0.118	Algorithm converged.	-0.039	0.275	1.89	Algorithm converged.	0.80	4.47	0.1455	0.1445	0.33	Algorithm converged.	0.22	1.25	
		13 - 24 months	31	14.0	5	16.1	25	11.7	1	4.0	4.62		Convergence criterion (GCONV=1E-8) satisfied.	0.50	42.35	0.121	Algorithm converged.	-0.029	0.272	4.03	Algorithm converged.	0.50	32.32	0.1892		0.25	Algorithm converged.	0.03	1.89	
		>24 months	119	53.6	7	5.9	106	49.5	9	8.1	0.67		Convergence criterion (GCONV=1E-8) satisfied.	0.24	1.88	-0.026	Algorithm converged.	-0.094	0.042	0.69	Algorithm converged.	0.27	1.80	0.4501		1.44	Algorithm converged.	0.56	3.74	
		Missing	1	0.5																										
	High circulating tumor burden	<25x10**9 cells/L	45	20.3	6	13.3	49	22.9	6	12.2	1.10		Convergence criterion (GCONV=1E-8) satisfied.	0.33	3.70	0.011	Algorithm converged.	-0.124	0.146	1.09	Algorithm converged.	0.38	3.13	0.8745	0.7161	0.92	Algorithm converged.	0.32	2.64	
		>=25x10**9 cells/L	150	67.6	17	11.3	134	62.6	11	8.2	1.43		Convergence criterion (GCONV=1E-8) satisfied.	0.64	3.17	0.031	Algorithm converged.	-0.038	0.100	1.38	Algorithm converged.	0.67	2.84	0.3811		0.72	Algorithm converged.	0.35	1.49	
		Missing																												

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 09MAY2013

Program: root/clinical_studies/R05072759/CDPT7159/BO21004/data_analysis/ACE_base/qa/program/t_pro_rsp2.sas
 Output: root/clinical_studies/R05072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/t_pro_rsp2_sq_00301_OLQC3pop_IT_label_09MAY2013_21004.xls
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* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 09MAY2013
Program: root/clinical_studies/R05072759/CDPT7159/BO21004/data_analysis/ACE_base/qa/program/t_pro_rsp2.sas
Output: root/clinical_studies/R05072759/CDPT7159/BO21004/data_analysis/ACE_CBR_stage2/qa/output/t_pro_rsp2_sq_EQC301_OLQC30pop_IT_label1_09MAY2013_21004.xls
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6 (Anhang): Ergebnisse für EORTC QLQ-C30 Symptomskalen – Verschlechterung der Symptomatik um MID zehn - Subgruppenanalysen aus RCT mit dem zu bewertenden Arzneimittel

POPULATION: Labelpopulation, Intent-to-Treat Patients, Patients with Screening and post Screening EORTC QLQ-C30 result
 ENDPOINT: EORTC QoL 30 - Responder (MID=10), worsening
 MODEL: Unstratified Analysis
 STUDY: CL11 (B01104), Stage 2
 Dichotomous Analysis by Subgroups (Efficacy)

Appetite Loss Scale			GC1b (N=222)				RC1b (N=214)				GC1b vs. RC1b																	
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk				RC1b vs. GC1b Relative Risk							
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CI	95% Upper CI	Absolute Risk	Convergence Reason	95% Lower CI	95% Upper CI	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI	p-value (Main)	Interaction p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI	
Cycle 4 Day 1	All	n/a	191	86.0	23	12.0	190	88.6	27	14.2	0.83	0.46	1.50	-0.022	Algorithm converged.	-0.089	0.046	0.85	Algorithm converged.	0.50	1.42	0.5314		1.18	Algorithm converged.	0.70	1.98	
	Gender	Male	117	52.7	11	9.4	116	54.2	11	9.5	0.99	0.41	2.38	-0.001	Algorithm converged.	-0.076	0.074	0.99	Algorithm converged.	0.45	2.20	0.9831	0.9997	1.01	Algorithm converged.	0.45	2.21	
		Female	74	33.3	12	16.2	74	34.6	16	21.6	0.70	0.31	1.61	-0.054	Algorithm converged.	-0.180	0.072	0.75	Algorithm converged.	0.38	1.47	0.4039		1.33	Algorithm converged.	0.68	2.60	
	Age	<75 years	99	44.6	9	9.1	93	43.5	14	15.1	0.76	0.23	1.37	-0.060	Algorithm converged.	-0.152	0.033	0.60	Algorithm converged.	0.27	1.33	0.2097	0.2368	1.66	Algorithm converged.	0.75	3.61	
		>=75 years	92	41.4	14	15.2	87	45.3	13	13.4	1.18	0.51	2.82	0.018	Algorithm converged.	-0.082	0.118	1.14	Algorithm converged.	0.56	2.28	0.7217		0.88	Algorithm converged.	0.44	1.77	
	Race	White	184	82.8	21	11.4	181	84.6	25	13.8	0.80	0.43	1.49	-0.024	Algorithm converged.	-0.092	0.044	0.83	Algorithm converged.	0.48	1.42	0.4908	0.6281	1.21	Algorithm converged.	0.70	2.08	
		Other	7	3.2	2	28.6	8	4.2	2	22.2	1.40	0.14	13.57	0.063	Algorithm converged.	-0.368	0.495	1.29	Algorithm converged.	0.24	6.89	0.7711		0.78	Algorithm converged.	0.14	4.23	
	Geographical Region	North America	9	4.1	1	11.1	11	5.1			*				ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE	
		Central and South America	3	1.4			2	0.9																				
		Western Europe	131	59.0	17	13.0	127	59.3	20	15.7	0.80	0.40	1.60	-0.028	Algorithm converged.	-0.113	0.058	0.82	Algorithm converged.	0.45	1.50	0.5264		1.21	Algorithm converged.	0.67	2.21	
		Asia-Pacific	15	6.8			15	7.0	4	26.7	*				ERROR: Error in computing the link function, its derivatives, or the variance function.			<0.01	Algorithm converged.	0.00	NE	0.9999	>999.99		Algorithm converged.	0.00	NE	
		Other	33	14.9	3	15.2	35	16.4	3	8.6	1.90	0.42	8.70	0.066	Algorithm converged.	-0.088	0.219	1.77	Algorithm converged.	0.46	6.82	0.4882		0.57	Algorithm converged.	0.15	2.18	
	EGamma receptor IIa	131HR	42	18.9	5	11.9	59	27.6	10	16.9	0.66	0.21	2.10	-0.050	Algorithm converged.	-0.187	0.087	0.70	Algorithm converged.	0.26	1.91	0.4878	0.0694	1.42	Algorithm converged.	0.52	3.88	
		131HR	95	42.8	10	10.5	95	44.4	16	16.8	0.98	0.25	1.36	-0.063	Algorithm converged.	-0.160	0.034	0.63	Algorithm converged.	0.30	1.31	0.2114		1.60	Algorithm converged.	0.77	3.34	
		131BR	38	17.1	5	13.2	23	10.7	1	4.3	3.33	0.36	30.48	0.088	Algorithm converged.	-0.048	0.224	3.03	Algorithm converged.	0.38	24.31	0.2976		0.33	Algorithm converged.	0.04	2.63	
		Missing	16	7.2	3	18.8	13	6.1			*				ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE	
	EGamma receptor IIa	158FF	81	36.5	8	9.9	88	31.8	10	14.7	0.64	0.24	1.71	-0.048	Algorithm converged.	-0.155	0.058	0.67	Algorithm converged.	0.28	1.61	0.3709		1.49	Algorithm converged.	0.62	3.56	
		158FV	88	39.6	12	13.6	83	38.8	14	16.9	0.78	0.34	1.85	-0.032	Algorithm converged.	-0.140	0.076	0.81	Algorithm converged.	0.40	1.64	0.5574		1.24	Algorithm converged.	0.61	2.52	
		158VV	11	5.0			28	13.1	3	10.7	*				ERROR: Error in computing the link function, its derivatives, or the variance function.			<0.01	Algorithm converged.	0.00	NE	0.9999	>999.99		Algorithm converged.	0.00	NE	
		Missing	11	5.0	3	27.3	11	5.1			*				ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE	
	Binet Staging at baseline	A	47	21.2	8	17.0	47	22.0	5	10.6	1.72	0.52	5.72	0.064	Algorithm converged.	-0.075	0.203	1.60	Algorithm converged.	0.56	4.53	0.2765	0.3502	0.62	Algorithm converged.	0.22	1.77	
		B	80	36.0	9	11.3	71	33.2	11	15.5	0.69	0.27	1.78	-0.042	Algorithm converged.	-0.151	0.067	0.73	Algorithm converged.	0.32	1.65	0.4448		1.38	Algorithm converged.	0.61	3.11	
		C	64	28.8	6	9.4	72	33.6	11	15.3	0.57	0.20	1.85	-0.059	Algorithm converged.	-0.169	0.051	0.61	Algorithm converged.	0.24	1.56	0.3065		1.63	Algorithm converged.	0.64	4.10	
	Total CR score at baseline	<=6	42	18.9	5	11.9	59	27.6	7	11.9	1.00	0.35	3.41	0.000	Algorithm converged.	-0.128	0.128	1.00	Algorithm converged.	0.34	2.95	0.9951	0.7065	1.00	Algorithm converged.	0.34	2.93	
		>6	149	67.1	18	12.1	131	61.2	20	15.3	0.76	0.38	1.33	-0.032	Algorithm converged.	-0.113	0.049	0.79	Algorithm converged.	0.44	1.43	0.4382		1.26	Algorithm converged.	0.70	2.28	
	Calculated creatinine clearance cat. 2	<70 ml/min	129	58.1	13	10.1	139	65.0	22	15.8	0.60	0.29	1.24	-0.057	Algorithm converged.	-0.137	0.022	0.64	Algorithm converged.	0.33	1.21	0.1684	0.1083	1.57	Algorithm converged.	0.83	2.90	

Calculated creatinine clearance cat. 2	<70 ml/min	136	61.3	13	9.6	135	63.1	18	13.3	0.69	Convergence criterion (GCONV=1E-8) satisfied.	0.32	1.46	-0.038	Algorithm converged.	-0.113	0.038	0.72	Algorithm converged.	0.37	1.40	0.3321	0.6004	1.38	Algorithm converged.	0.71	2.73	
	>=70 ml/min	62	27.9	8	12.9	53	24.8	7	13.2	0.87	Convergence criterion (GCONV=1E-8) satisfied.	0.33	2.89	-0.001	Algorithm converged.	-0.127	0.121	0.98	Algorithm converged.	0.38	2.52	0.9615		1.02	Algorithm converged.	0.40	2.64	
Beta2 microglobulin	< 3.5 ug/mL	119	53.6	12	10.1	111	51.9	13	11.7	0.83	Convergence criterion (GCONV=1E-8) satisfied.	0.37	1.94	-0.016	Algorithm converged.	-0.097	0.064	0.86	Algorithm converged.	0.41	1.81	0.6922	0.6359	1.16	Algorithm converged.	0.35	2.44	
	>= 3.5 ug/mL	76	34.2	8	10.5	75	35.0	12	16.0	0.62	Convergence criterion (GCONV=1E-8) satisfied.	0.24	1.61	-0.055	Algorithm converged.	-0.163	0.053	0.66	Algorithm converged.	0.29	1.52	0.3262		1.52	Algorithm converged.	0.66	3.51	
	Missing	3	1.4	1	33.3	2	0.5				Quasi-complete separation of data points detected.								NE	Algorithm converged.	NE	NE	NE	NE	Algorithm converged.	NE	NE	
Immunoglobulin VH, cytogenetics 2	12	35	15.8	3	8.6	31	14.5	3	9.7	0.87	Convergence criterion (GCONV=1E-8) satisfied.	0.16	4.69	-0.011	Algorithm converged.	-0.150	0.128	0.89	Algorithm converged.	0.19	4.07	0.8761	0.7689	1.13	Algorithm converged.	0.23	5.19	
	11q-	37	16.7	4	10.8	34	15.9	3	8.8	1.25	Convergence criterion (GCONV=1E-8) satisfied.	0.26	6.05	0.020	Algorithm converged.	-0.118	0.158	1.23	Algorithm converged.	0.30	5.08	0.7796		0.82	Algorithm converged.	0.20	3.38	
	13q-	66	29.7	6	9.1	59	27.6	6	15.3	0.56	Convergence criterion (GCONV=1E-8) satisfied.	0.19	1.67	-0.062	Algorithm converged.	-0.177	0.053	0.60	Algorithm converged.	0.23	1.57	0.2964		1.68	Algorithm converged.	0.64	4.43	
	Other Abn.	14	6.3	2	14.3	17	7.9	1	5.9	2.67	Convergence criterion (GCONV=1E-8) satisfied.	0.22	32.96	0.084	Algorithm converged.	-0.131	0.299	2.43	Algorithm converged.	0.24	24.07	0.4484		0.41	Algorithm converged.	0.04	4.08	
	Norm. K.	46	20.7	6	13.0	47	22.0	6	19.1	0.63	Convergence criterion (GCONV=1E-8) satisfied.	0.21	1.95	-0.061	Algorithm converged.	-0.210	0.088	0.68	Algorithm converged.	0.26	1.76	0.4281		1.47	Algorithm converged.	0.57	3.79	
Time from first diagnosis	<= 12 months	45	20.3	4	8.9	54	25.2	10	18.5	0.43	Convergence criterion (GCONV=1E-8) satisfied.	0.12	1.48	-0.096	Algorithm converged.	-0.229	0.037	0.48	Algorithm converged.	0.16	1.43	0.1869	0.4426	2.08	Algorithm converged.	0.70	6.20	
	13 - 24 months	32	14.4	5	15.6	26	12.1	3	11.5	1.42	Convergence criterion (GCONV=1E-8) satisfied.	0.31	6.59	0.041	Algorithm converged.	-0.135	0.217	1.35	Algorithm converged.	0.36	5.14	0.6561		0.74	Algorithm converged.	0.19	2.80	
	>24 months	120	54.1	12	10.0	108	50.5	12	11.1	0.89	Convergence criterion (GCONV=1E-8) satisfied.	0.38	2.07	-0.011	Algorithm converged.	-0.091	0.065	0.90	Algorithm converged.	0.42	1.82	0.7849		1.11	Algorithm converged.	0.52	2.37	
	Missing	1	0.5																									
High circulating tumor burden	<25x10**9 cells/L	46	20.7	6	13.0	49	22.9	10	20.4	0.59	Convergence criterion (GCONV=1E-8) satisfied.	0.19	1.76	-0.074	Algorithm converged.	-0.223	0.075	0.64	Algorithm converged.	0.25	1.62	0.3448	0.5466	1.56	Algorithm converged.	0.62	3.94	
	>=25x10**9 cells/L	152	68.5	15	9.9	138	64.5	15	10.9	0.90	Convergence criterion (GCONV=1E-8) satisfied.	0.42	1.91	-0.010	Algorithm converged.	-0.080	0.060	0.91	Algorithm converged.	0.46	1.79	0.7799		1.10	Algorithm converged.	0.56	2.17	
	Missing					1	0.5																					

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable. Clinical cut-off: 0.9642013

Program: root/clinical_studies/R05072759/CDPT7159/B021004/data_analysis/ACE_base/ga/program/t_pro_rsp2.sas
 Output: root/clinical_studies/R05072759/CDPT7159/B021004/data_analysis/ACE_CBR_stage2/ga/output/t_pro_rsp2_ag_BQC30W_QQC30pop_IT_label_09MAY2013_21004.xls 12JAN2021 12:42

POPULATION: Labelpopulation, Intent-to-Treat Patients, Patients with Screening and post Screening EORTC QLQ-C30 result
 ENDPOINT: EORTC QoL 10 - Responder (RID=10), worsening
 MODEL: Unstratified Analysis
 STUDY: CLL11(B021004), Stage 2
 Dichotomous Analysis by Subgroups (Efficacy)

Constipation Scale			OC1b (N=222)				OC1b (N=214)				OC1b vs. OC1b						OC1b vs. OC1b											
Visit	Name	Level	Patients		Patients with Event		Patients		Patients with Event		Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interacti on Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
			n	%	n	%	n	%	n	%																		
Cycle 4 Day 1	All	n/a	190	85.6	35	18.4	189	88.3	33	17.5	1.07	Convergence criterion (GCONV-IR-8) satisfied.	0.63	1.80	0.010	Algorithm converged.	-0.068	0.087	1.06	Algorithm converged.	0.68	1.62	0.8075		0.95	Algorithm converged.	0.62	1.46
Gender	Male		115	51.8	21	18.3	116	54.2	20	17.2	1.07	Convergence criterion (GCONV-IR-8) satisfied.	0.55	2.11	0.010	Algorithm converged.	-0.088	0.109	1.06	Algorithm converged.	0.61	1.85	0.8393	0.9816	0.94	Algorithm converged.	0.54	1.60
	Female		75	33.8	14	18.7	73	34.1	13	17.8	1.06	Convergence criterion (GCONV-IR-8) satisfied.	0.46	2.44	0.009	Algorithm converged.	-0.116	0.133	1.05	Algorithm converged.	0.53	2.07	0.8925		0.95	Algorithm converged.	0.48	1.89
Age	<75 years		98	44.1	16	16.3	94	43.9	19	20.2	0.77	Convergence criterion (GCONV-IR-8) satisfied.	0.37	1.83	-0.039	Algorithm converged.	-0.148	0.070	0.81	Algorithm converged.	0.44	1.47	0.4668	0.2119	1.24	Algorithm converged.	0.68	2.26
	>=75 years		92	41.4	19	20.7	95	44.4	14	14.7	1.51	Convergence criterion (GCONV-IR-8) satisfied.	0.70	3.22	0.059	Algorithm converged.	-0.050	0.168	1.40	Algorithm converged.	0.75	2.63	0.2922		0.71	Algorithm converged.	0.38	1.34
Race	White		183	82.4	35	19.1	180	84.1	31	17.2	1.14	Convergence criterion (GCONV-IR-8) satisfied.	0.67	1.94	0.019	Algorithm converged.	-0.060	0.098	1.11	Algorithm converged.	0.72	1.72	0.6386	0.1014	0.90	Algorithm converged.	0.58	1.39
	Other		7	3.2			9	4.2	2	22.2	*	Quasi-complete separation of data points detected.							<0.01	Algorithm converged.	0.00	NE	0.9999	>999.99		Algorithm converged.	0.00	NE
Geographical Region	North America		9	4.1	2	22.2	11	5.1	1	9.1	2.88	Convergence criterion (GCONV-IR-8) satisfied.	0.21	37.99	0.131	Algorithm converged.	-0.189	0.452	2.44	Algorithm converged.	0.26	22.80	0.4327	0.9239	0.41	Algorithm converged.	0.04	3.82
	Central and South America		3	1.4			2	0.9																				
	Western Europe		130	58.6	25	19.2	127	59.3	23	18.1	1.08	Convergence criterion (GCONV-IR-8) satisfied.	0.57	2.02	0.011	Algorithm converged.	-0.084	0.106	1.06	Algorithm converged.	0.64	1.77	0.8178		0.94	Algorithm converged.	0.57	1.57
EGamma receptor IIfa	131HR		41	18.5	8	19.5	39	27.6	9	19.3	1.33	Convergence criterion (GCONV-IR-8) satisfied.	0.47	3.84	0.043	Algorithm converged.	-0.110	0.195	1.28	Algorithm converged.	0.54	3.04	0.5770	0.8948	0.78	Algorithm converged.	0.33	1.80
	131MR		95	42.8	18	18.9	95	44.4	18	18.9	1.00	Convergence criterion (GCONV-IR-8) satisfied.	0.48	2.07	0.000	Algorithm converged.	-0.111	0.111	1.00	Algorithm converged.	0.56	1.80	1.0000		1.00	Algorithm converged.	0.56	1.80
	131RR		37	16.7	5	13.5	23	10.7	4	17.4	0.74	Convergence criterion (GCONV-IR-8) satisfied.	0.18	3.11	-0.039	Algorithm converged.	-0.229	0.151	0.78	Algorithm converged.	0.23	2.60	0.6822		1.25	Algorithm converged.	0.38	4.30
EGamma receptor IIIfa	158FF		79	35.6	15	19.0	70	32.7	14	20.0	0.94	Convergence criterion (GCONV-IR-8) satisfied.	0.42	2.11	-0.010	Algorithm converged.	-0.138	0.117	0.95	Algorithm converged.	0.49	1.82	0.8762	0.8697	1.05	Algorithm converged.	0.55	2.02
	158FV		88	39.6	13	14.8	81	37.9	11	13.6	1.10	Convergence criterion (GCONV-IR-8) satisfied.	0.46	2.62	0.012	Algorithm converged.	-0.093	0.117	1.09	Algorithm converged.	0.52	2.29	0.8245		0.92	Algorithm converged.	0.44	1.93
EGamma receptor IIIfa	158VV		11	5.0	3	27.3	27	12.6	4	22.2	1.31	Convergence criterion (GCONV-IR-8) satisfied.	0.26	6.35	0.051	Algorithm converged.	-0.256	0.357	1.23	Algorithm converged.	0.37	4.06	0.7371		0.81	Algorithm converged.	0.25	2.48
	Missing		12	5.4	4	33.3	11	5.1	2	18.2	2.25	Convergence criterion (GCONV-IR-8) satisfied.	0.32	15.76	0.152	Algorithm converged.	-0.199	0.502	1.83	Algorithm converged.	0.41	8.11	0.4244		0.55	Algorithm converged.	0.12	2.41
Binet Staging at baseline	A		47	21.2	11	23.4	45	21.0	4	8.9	3.13	Convergence criterion (GCONV-IR-8) satisfied.	0.82	10.70	0.145	Algorithm converged.	-0.002	0.292	2.63	Algorithm converged.	0.90	7.67	0.3759	0.1071	0.38	Algorithm converged.	0.13	1.11
	B		78	35.1	15	19.2	72	33.6	15	20.8	0.90	Convergence criterion (GCONV-IR-8) satisfied.	0.41	2.01	-0.016	Algorithm converged.	-0.144	0.112	0.92	Algorithm converged.	0.49	1.75	0.8064		1.08	Algorithm converged.	0.37	2.05
	C		65	29.3	9	13.8	72	33.6	14	19.4	0.67	Convergence criterion (GCONV-IR-8) satisfied.	0.27	1.66	-0.056	Algorithm converged.	-0.180	0.068	0.71	Algorithm converged.	0.33	1.53	0.3858		1.40	Algorithm converged.	0.65	3.02
Total CIR score at baseline	<=6		42	18.9	7	16.7	39	27.6	12	20.3	0.78	Convergence criterion (GCONV-IR-8) satisfied.	0.28	2.19	-0.037	Algorithm converged.	-0.189	0.116	0.82	Algorithm converged.	0.35	1.91	0.6438	0.4739	1.22	Algorithm converged.	0.32	2.84
	>6		148	66.7	28	18.9	130	60.7	21	16.2	1.21	Convergence criterion (GCONV-IR-8) satisfied.	0.65	2.26	0.028	Algorithm converged.	-0.062	0.117	1.17	Algorithm converged.	0.70	1.96	0.5472		0.85	Algorithm converged.	0.51	1.43
Calculated creatinine clearance cat. 2	<70 ml/min		128	57.7	24	18.8	137	64.0	25	18.2	1.03	Convergence criterion (GCONV-IR-8) satisfied.	0.56	1.92	0.003	Algorithm converged.	-0.089	0.099	1.03	Algorithm converged.	0.62	1.70	0.9163	0.8160	0.97	Algorithm converged.	0.59	1.61
	>=70 ml/min		62	27.9	11	17.7	52	24.3	8	15.4	1.19	Convergence criterion (GCONV-IR-8) satisfied.	0.44	3.21	0.024	Algorithm converged.	-0.113	0.160	1.15	Algorithm converged.	0.50	2.65	0.7372		0.87	Algorithm converged.	0.39	1.99
Beta2 microglobulin	< 3.5 ug/mL		112	50.5	22	19.6	108	50.5	18	16.7	1.22	Convergence criterion (GCONV-IR-8) satisfied.	0.61	2.43	0.030	Algorithm converged.	-0.072	0.132	1.18	Algorithm converged.	0.67	2.07	0.5681	0.5613	0.85	Algorithm converged.	0.48	1.49
	>= 3.5 ug/mL		75	32.8	12	16.0	79	36.9	14	17.7	0.88	Convergence criterion (GCONV-IR-8) satisfied.	0.38	2.06	-0.017	Algorithm converged.	-0.135	0.101	0.90	Algorithm converged.	0.45	1.82	0.7158		1.11	Algorithm converged.	0.35	2.24
	Missing		3	1.4	1	33.3	2	0.9	1	50.0	0.50	Convergence criterion (GCONV-IR-8) satisfied.	0.01	19.55	-0.167	Algorithm converged.	-1.041	0.708	0.67	Algorithm converged.	0.08	5.54	0.7074		1.50	Algorithm converged.	0.18	12.46
Immunoglobulin VH, cytogenetics 2	12		29	13.1	5	17.2	33	15.4	7	21.2	0.77	Convergence criterion (GCONV-IR-8) satisfied.	0.22	2.77	-0.040	Algorithm converged.	-0.236	0.156	0.81	Algorithm converged.	0.29	2.28	0.6943	0.1580	1.23	Algorithm converged.	0.44	3.48
	11q-		38	17.1	8	21.1	34	15.9	2	5.9	4.27	Convergence criterion (GCONV-IR-8) satisfied.	0.84	21.72	0.152	Algorithm converged.	0.000	0.304	3.58	Algorithm converged.	0.82	15.70	0.0910		0.28	Algorithm converged.	0.06	1.23
	13q-		60	27.0	8	13.3	56	26.2	12	21.4	0.56	Convergence criterion (GCONV-IR-8) satisfied.	0.21	1.90	-0.081	Algorithm converged.	-0.219	0.057	0.62	Algorithm converged.	0.27	1.41	0.2551		1.61	Algorithm converged.	0.71	3.64
	Other Abn.		16	7.2	3	18.8	18	8.4	1	5.6	3.92	Convergence criterion (GCONV-IR-8) satisfied.	0.36	42.19	0.132	Algorithm converged.	-0.087	0.351	3.37	Algorithm converged.	0.39	29.28	0.2698		0.30	Algorithm converged.	0.03	2.57

	Norm. W.	46	20.7	9	19.6	47	22.0	6	12.8	1.66	Convergence criterion (GCONV=1E-8) satisfied.	0.34	5.12	0.068	Algorithm converged.	-0.081	0.217	1.33	Algorithm converged.	0.59	3.96	0.3782		0.65	Algorithm converged.	0.25	1.66
Time from first diagnosis	K= 12 months	43	19.4	7	16.3	54	25.2	13	24.1	0.61	Convergence criterion (GCONV=1E-8) satisfied.	0.22	1.70	-0.078	Algorithm converged.	-0.237	0.081	0.68	Algorithm converged.	0.30	1.55	0.3537	0.2713	1.48	Algorithm converged.	0.65	3.38
	13 - 24 months	31	14.0	4	19.4	26	12.1	2	7.7	2.88	Convergence criterion (GCONV=1E-8) satisfied.	0.33	15.89	0.117	Algorithm converged.	-0.056	0.289	2.52	Algorithm converged.	0.55	11.42	0.2320		0.40	Algorithm converged.	0.09	1.88
	>24 months	119	53.6	16	13.4	108	50.5	17	15.7	0.83	Convergence criterion (GCONV=1E-8) satisfied.	0.45	1.74	-0.023	Algorithm converged.	-0.115	0.069	0.85	Algorithm converged.	0.45	1.61	0.6245		1.17	Algorithm converged.	0.62	2.20
	Missing	1	0.5																								
High circulating tumor burden	<25x10**9 cells/L	44	19.8	3	20.5	49	22.3	5	18.4	1.14	Convergence criterion (GCONV=1E-8) satisfied.	0.41	3.20	0.021	Algorithm converged.	-0.140	0.182	1.11	Algorithm converged.	0.49	2.55	0.7892	0.5158	0.90	Algorithm converged.	0.39	2.06
	>=25x10**9 cells/L	150	67.6	20	12.3	138	64.5	23	16.7	0.77	Convergence criterion (GCONV=1E-8) satisfied.	0.40	1.47	-0.033	Algorithm converged.	-0.116	0.049	0.80	Algorithm converged.	0.46	1.39	0.4289		1.25	Algorithm converged.	0.72	2.17
	Missing																										

Test for interaction based on RR (Log-Binomial regression)
* indicates convergence problem. Result is uninterpretable. Clinical
out-off: 09MAY2013

Program: root/clinical_studies/R05072759/CDPT7159/R021004/data_analysis/ACE_base/qa/program/t_pco_rsp2.sas
Output: root/clinical_studies/R05072759/CDPT7159/R021004/data_analysis/ACE_CSR_stage2/qa/output/t_pco_rsp2_eq_EQC30W_GLQC30pop_IT_label_09MAY2013_21004.xls 12JAN2021
12:42

POPULATION: Labelpopulation, Intent-to-Treat Patients, Patients with Screening and post Screening EORTC QLQ-C30 result
 ENDPOINT: EORTC QoL 10 - Responder (RID=10), worsening
 MODEL: Unstratified Analysis
 STUDY: CLL11(B021004), Stage 2
 Dichotomous Analysis by Subgroups (Efficacy)

Visit	Name	Level	OC1b (N=222)				OC1b (N=214)				OC1b vs. OC1b					OC1b vs. OC1b Relative Risk													
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio	Absolute Risk Difference				Relative Risk													
			n	%	n	%	n	%	n	%		95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interacti on Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL		
Cycle 4 Day 1	All	n/a	192	86.5	27	14.1	188	87.9	27	14.4	0.88	Convergence criterion (GCQNV-IR-8) satisfied.	0.55	1.74	-0.003	Algorithm converged.	-0.073	0.067	0.98	Algorithm converged.	0.60	1.60	0.934		1.02	Algorithm converged.	0.62	1.67	
	Gender	Male	116	52.3	18	15.5	116	54.2	21	18.1	0.83	Convergence criterion (GCQNV-IR-8) satisfied.	0.42	1.66	-0.026	Algorithm converged.	-0.122	0.070	0.86	Algorithm converged.	0.48	1.52	0.5990	0.3793	1.17	Algorithm converged.	0.66	2.07	
		Female	76	34.2	9	11.8	72	33.6	6	8.3	1.48	Convergence criterion (GCQNV-IR-8) satisfied.	0.55	4.38	0.033	Algorithm converged.	-0.062	0.132	1.42	Algorithm converged.	0.53	3.79	0.4828		0.70	Algorithm converged.	0.26	1.88	
		Age	<75 years	98	44.1	11	11.2	92	43.0	14	15.2	0.70	Convergence criterion (GCQNV-IR-8) satisfied.	0.30	1.66	-0.040	Algorithm converged.	-0.136	0.056	0.74	Algorithm converged.	0.35	1.54	0.4181	0.2933	1.36	Algorithm converged.	0.65	2.83
			>=75 years	94	42.3	16	17.0	96	44.9	13	13.5	1.33	Convergence criterion (GCQNV-IR-8) satisfied.	0.59	2.90	0.035	Algorithm converged.	-0.067	0.137	1.26	Algorithm converged.	0.64	2.47	0.5062		0.86	Algorithm converged.	0.41	1.56
		Race	White	185	83.3	24	14.1	179	83.6	26	14.5	0.98	Convergence criterion (GCQNV-IR-8) satisfied.	0.53	1.73	-0.003	Algorithm converged.	-0.077	0.067	0.97	Algorithm converged.	0.58	1.60	0.8978	0.8331	1.03	Algorithm converged.	0.62	1.71
			Other	7	3.2	1	14.3	9	4.2	1	11.1	1.33	Convergence criterion (GCQNV-IR-8) satisfied.	0.07	25.91	0.032	Algorithm converged.	-0.299	0.362	1.29	Algorithm converged.	0.10	17.14	0.8492		0.78	Algorithm converged.	0.06	10.37
		Geographical Region	North America	9	4.1	1	11.1	11	5.1	1	9.1	1.25	Convergence criterion (GCQNV-IR-8) satisfied.	0.07	23.26	0.020	Algorithm converged.	-0.246	0.287	1.22	Algorithm converged.	0.09	16.92	0.8810		0.82	Algorithm converged.	0.06	11.33
			Central and South America	3	1.4			2	0.9																				
			Western Europe	132	59.5	20	15.2	127	59.3	18	14.2	1.08	Convergence criterion (GCQNV-IR-8) satisfied.	0.54	2.15	0.010	Algorithm converged.	-0.076	0.096	1.07	Algorithm converged.	0.59	1.93	0.8240		0.94	Algorithm converged.	0.52	1.68
			Asia-Pacific	15	6.8	3	20.0	14	6.5	3	21.4	0.92	Convergence criterion (GCQNV-IR-8) satisfied.	0.15	5.83	-0.014	Algorithm converged.	-0.310	0.281	0.93	Algorithm converged.	0.22	3.88	0.9244		1.07	Algorithm converged.	0.26	4.45
			Other	33	14.9	3	9.1	34	15.9	5	14.7	0.58	Convergence criterion (GCQNV-IR-8) satisfied.	0.13	2.65	-0.056	Algorithm converged.	-0.210	0.098	0.62	Algorithm converged.	0.16	2.38	0.4846		1.62	Algorithm converged.	0.42	6.23
		PDgamma receptor 1fa	131HR	42	18.9	9	21.4	39	27.6	7	11.9	2.03	Convergence criterion (GCQNV-IR-8) satisfied.	0.89	5.96	0.096	Algorithm converged.	-0.053	0.245	1.81	Algorithm converged.	0.73	4.46	0.2004	0.2259	0.55	Algorithm converged.	0.22	1.37
			131HR	96	43.2	11	11.5	95	44.4	14	14.7	0.75	Convergence criterion (GCQNV-IR-8) satisfied.	0.32	1.75	-0.033	Algorithm converged.	-0.128	0.063	0.78	Algorithm converged.	0.37	1.62	0.5034		1.29	Algorithm converged.	0.62	2.69
			131BR	37	16.7	1	13.5	22	10.3	2	9.1	1.56	Convergence criterion (GCQNV-IR-8) satisfied.	0.28	8.83	0.044	Algorithm converged.	-0.119	0.207	1.49	Algorithm converged.	0.31	7.02	0.6168		0.67	Algorithm converged.	0.14	3.18
			Missing	17	7.7	2	11.8	12	5.6	4	33.3	0.27	Convergence criterion (GCQNV-IR-8) satisfied.	0.04	1.79	-0.216	Algorithm converged.	-0.523	0.092	0.35	Algorithm converged.	0.08	1.63	0.1816		2.83	Algorithm converged.	0.61	13.05
		PDgamma receptor 1fa	158FF	81	36.5	11	13.6	68	31.8	9	13.2	1.03	Convergence criterion (GCQNV-IR-8) satisfied.	0.40	2.65	0.003	Algorithm converged.	-0.106	0.113	1.03	Algorithm converged.	0.45	2.33	0.9510	0.9815	0.97	Algorithm converged.	0.43	2.21
			158FV	88	39.6	12	13.6	81	37.8	15	18.5	0.83	Convergence criterion (GCQNV-IR-8) satisfied.	0.30	1.59	-0.049	Algorithm converged.	-0.160	0.062	0.74	Algorithm converged.	0.37	1.48	0.3892		1.36	Algorithm converged.	0.68	2.73
			158VV	11	5.0	2	18.2	28	13.1	2	7.1	2.89	Convergence criterion (GCQNV-IR-8) satisfied.	0.35	23.63	0.110	Algorithm converged.	-0.137	0.397	2.55	Algorithm converged.	0.41	15.89	0.3174		0.39	Algorithm converged.	0.06	2.41
			Missing	12	5.4	2	16.7	11	5.1	1	9.1	2.00	Convergence criterion (GCQNV-IR-8) satisfied.	0.16	25.75	0.078	Algorithm converged.	-0.195	0.347	1.83	Algorithm converged.	0.19	17.01	0.5986		0.55	Algorithm converged.	0.08	0.21
		Rinet Staging at baseline	A	48	21.6	7	14.6	46	21.5	3	6.5	2.45	Convergence criterion (GCQNV-IR-8) satisfied.	0.59	10.11	0.081	Algorithm converged.	-0.042	0.203	2.24	Algorithm converged.	0.62	8.13	0.2217	0.2493	0.45	Algorithm converged.	0.12	1.67
			B	79	35.6	8	10.1	71	33.2	11	15.5	0.83	Convergence criterion (GCQNV-IR-8) satisfied.	0.23	1.83	-0.054	Algorithm converged.	-0.161	0.054	0.85	Algorithm converged.	0.28	1.53	0.3282		1.53	Algorithm converged.	0.83	3.53
			C	65	29.3	12	18.5	71	33.2	13	18.3	1.01	Convergence criterion (GCQNV-IR-8) satisfied.	0.42	2.41	0.002	Algorithm converged.	-0.129	0.132	1.01	Algorithm converged.	0.50	2.05	0.9818		0.99	Algorithm converged.	0.49	2.01
		Total CIR score at baseline	<=6	43	19.4	7	16.3	38	27.1	14	24.1	0.81	Convergence criterion (GCQNV-IR-8) satisfied.	0.22	1.68	-0.079	Algorithm converged.	-0.234	0.077	0.67	Algorithm converged.	0.30	1.53	0.3447	0.1898	1.48	Algorithm converged.	0.65	3.38
			>6	149	67.1	20	13.4	130	60.7	13	10.0	1.40	Convergence criterion (GCQNV-IR-8) satisfied.	0.66	2.93	0.034	Algorithm converged.	-0.041	0.109	1.34	Algorithm converged.	0.70	2.59	0.3802		0.75	Algorithm converged.	0.39	1.44
		Calculated creatinine clearance cat. 2	<70 ml/min	131	59.0	19	14.5	137	64.0	20	14.6	0.99	Convergence criterion (GCQNV-IR-8) satisfied.	0.55	1.96	-0.001	Algorithm converged.	-0.085	0.084	0.99	Algorithm converged.	0.56	1.78	0.9825	0.9450	1.01	Algorithm converged.	0.56	1.80
			>=70 ml/min	61	27.3	8	13.1	51	23.8	7	13.7	0.83	Convergence criterion (GCQNV-IR-8) satisfied.	0.32	2.82	-0.068	Algorithm converged.	-0.133	0.121	0.96	Algorithm converged.	0.37	2.46	0.9247		1.05	Algorithm converged.	0.41	2.68
		Beta2 microglobulin	< 3.5 ug/mL	115	51.8	12	10.4	107	50.0	15	14.0	0.71	Convergence criterion (GCQNV-IR-8) satisfied.	0.32	1.61	-0.036	Algorithm converged.	-0.122	0.050	0.74	Algorithm converged.	0.37	1.52	0.4164	0.3116	1.34	Algorithm converged.	0.66	2.74
			>= 3.5 ug/mL	74	33.3	14	18.9	79	36.9	12	15.2	1.39	Convergence criterion (GCQNV-IR-8) satisfied.	0.56	3.04	0.037	Algorithm converged.	-0.082	0.157	1.25	Algorithm converged.	0.62	2.52	0.5404		0.80	Algorithm converged.	0.40	1.62
			Missing	3	1.4	1	33.3	2	0.9				Quasi-complete separation of data points detected.				ERROR: The mean parameter is either invalid or at a limit of its range for some observations.				NE	Algorithm converged.	NE	NE	NE	NE	Algorithm converged.	NE	NE
		Hemoglobin VR, cytogenetics 2	11q-	39	17.6	5	12.8	36	15.0	4	11.8	1.10	Convergence criterion (GCQNV-IR-8) satisfied.	0.27	4.49	0.011	Algorithm converged.	-0.140	0.161	1.09	Algorithm converged.	0.32	3.73	0.8912		0.92	Algorithm converged.	0.27	3.14
			13q-	60	27.0	13	21.7	57	26.6	6	10.5	2.39	Convergence criterion (GCQNV-IR-8) satisfied.	0.83	6.69	0.111	Algorithm converged.	-0.020	0.243	2.06	Algorithm converged.	0.84	5.05	0.1146		0.45	Algorithm converged.	0.20	1.19
			Other Abn.	16	7.2	2	12.5	18	8.4	2	11.1	1.14	Convergence criterion (GCQNV-IR-8) satisfied.	0.14	9.21	0.014	Algorithm converged.	-0.204	0.231	1.12	Algorithm converged.	0.18	7.09	0.9002		0.85	Algorithm converged.	0.14	5.60

	Time from first diagnosis	<= 12 months	44	19.8	8	18.2	53	24.8	4	7.5	2.72	Convergence criterion (GCONV=1E-8) satisfied.	0.76	9.74	0.108	Algorithm converged.	-0.028	0.241	2.41	Algorithm converged.	0.78	7.43	0.1278	0.3264	0.42	Algorithm converged.	0.13	1.28
		13 - 24 months	32	14.4	5	15.6	26	12.1	2	7.7	2.22	Convergence criterion (GCONV=1E-8) satisfied.	0.19	12.53	0.079	Algorithm converged.	-0.083	0.242	2.03	Algorithm converged.	0.43	9.63	0.3721		0.48	Algorithm converged.	0.10	2.31
		>24 months	119	53.6	15	12.6	108	50.5	14	13.0	0.97	Convergence criterion (GCONV=1E-8) satisfied.	0.44	2.11	-0.004	Algorithm converged.	-0.091	0.083	0.97	Algorithm converged.	0.49	1.92	0.9357		1.03	Algorithm converged.	0.52	2.05
		Missing	1	0.5																								
	High circulating tumor burden	<25x10**9 cells/L	45	20.3	6	13.3	49	22.0	6	12.2	1.10	Convergence criterion (GCONV=1E-8) satisfied.	0.33	3.70	0.011	Algorithm converged.	-0.124	0.146	1.05	Algorithm converged.	0.38	3.13	0.8745	0.6671	0.92	Algorithm converged.	0.32	2.61
		>=25x10**9 cells/L	151	68.0	22	14.6	137	64.0	14	10.2	1.50	Convergence criterion (GCONV=1E-8) satisfied.	0.73	3.06	0.044	Algorithm converged.	-0.032	0.119	1.43	Algorithm converged.	0.76	2.67	0.2690		0.70	Algorithm converged.	0.37	1.32
		Missing																										

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable. Clinical
 cut-off: 09MAY2013

Program: root/clinical_studies/R05072759/CDPT7159/BQ21004/data_analysis/ACE_base/qa/program/t_pro_rsp2.sas
 Output: root/clinical_studies/R05072759/CDPT7159/BQ21004/data_analysis/ACE_CBR_stage2/qa/output/t_pro_rsp2_sq_RQC30W_GLQC30pop_IT_label_09MAY2013_21004.xls 12JAN2021
 12:42

POPULATION: Labelpopulation, Intent-to-Treat Patients, Patients with Screening and post Screening EORTC QLQ-C30 result
 ENDPOINT: EORTC QoL 10 - Responder (RID=10), worsening
 MODEL: Unstratified Analysis
 STUDY: CLL11(B021004), Stage 2
 Dichotomous Analysis by Subgroups (Efficacy)

Dyspnea Scale			OC1b (N=222)				OC1b (N=214)				OC1b vs. OC1b					OC1b vs. OC1b Relative Risk												
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio	Absolute Risk Difference			Relative Risk		Relative Risk											
Visit	Name	Level	n	t	n	t	n	t	n	t	Odds Ratio	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interact on Test p-value (Likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	
Cycle 4 Day 1	All	n/a	195	85.6	14	7.4	195	88.8	23	12.1	0.88	0.29	1.16	-0.047	Algorithm converged.	-0.107	0.012	0.61	Algorithm converged.	0.32	1.15	0.1244		1.64	Algorithm converged.	0.87	3.08	
	Gender	Male	117	52.7	7	6.0	117	54.7	13	11.1	0.61	0.25	1.33	-0.051	Algorithm converged.	-0.123	0.020	0.54	Algorithm converged.	0.22	1.30	0.1691	0.6848	1.86	Algorithm converged.	0.77	4.40	
		Female	73	32.9	7	9.6	73	34.1	10	13.7	0.67	0.24	1.86	-0.041	Algorithm converged.	-0.145	0.063	0.70	Algorithm converged.	0.28	1.74	0.4422		1.43	Algorithm converged.	0.58	3.51	
	Age	<75 years	98	44.1	8	8.2	92	43.0	7	7.6	1.08	0.38	3.11	0.006	Algorithm converged.	-0.071	0.082	1.07	Algorithm converged.	0.41	2.84	0.8874	0.1368	0.93	Algorithm converged.	0.35	2.47	
		>=75 years	92	41.4	6	6.5	98	45.8	16	16.3	0.36	0.13	0.96	-0.098	Algorithm converged.	-0.187	-0.008	0.40	Algorithm converged.	0.16	0.98	0.0443		2.50	Algorithm converged.	1.02	6.12	
	Race	White	183	82.4	13	7.1	181	84.6	22	12.2	0.93	0.27	1.33	-0.051	Algorithm converged.	-0.111	0.010	0.58	Algorithm converged.	0.30	1.12	0.1076	0.5688	1.71	Algorithm converged.	0.89	3.23	
		Other	7	3.2	1	14.3	9	4.2	1	11.1	1.33	0.07	25.91	0.032	Algorithm converged.	-0.299	0.362	1.29	Algorithm converged.	0.10	17.14	0.8492		0.78	Algorithm converged.	0.06	10.37	
	Geographical Region	North America	9	4.1			11	5.1	1	9.1					ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			<0.01	Algorithm converged.	0.00	NE	1.0000		>999.99	Algorithm converged.	0.00	NE	
		Central and South America	3	1.4			2	0.9																				
		Western Europe	139	58.6	10	7.7	128	59.8	18	14.1	0.53	0.23	1.15	-0.064	Algorithm converged.	-0.139	0.012	0.55	Algorithm converged.	0.26	1.14	0.1069		1.83	Algorithm converged.	0.88	3.81	
		Asia-Pacific	15	6.8	1	6.7	15	7.0							ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE	
		Other	33	14.9	3	9.1	34	15.0	4	11.8	0.75	0.15	3.64	-0.027	Algorithm converged.	-0.173	0.119	0.77	Algorithm converged.	0.19	3.19	0.7216		1.28	Algorithm converged.	0.31	2.34	
	FCgamma receptor Iia	I31HR	42	18.9	1	2.4	38	27.1	8	13.8	0.15	0.02	1.27	-0.114	Algorithm converged.	-0.214	-0.014	0.17	Algorithm converged.	0.02	1.33	0.0916		5.79	Algorithm converged.	0.75	44.51	
		I31HR	94	42.3	8	8.5	87	45.3	14	14.4	0.55	0.22	1.38	-0.055	Algorithm converged.	-0.149	0.031	0.59	Algorithm converged.	0.26	1.34	0.2073		1.70	Algorithm converged.	0.75	3.85	
		I31RR	38	17.1	5	13.2	23	10.7	1	4.3	3.33	0.36	30.48	0.088	Algorithm converged.	-0.048	0.224	3.03	Algorithm converged.	0.38	24.31	0.2976		0.33	Algorithm converged.	0.04	2.65	
		Missing	16	7.2			12	5.6																				
	FCgamma receptor Iiia	I58FF	80	36.0	8	10.0	70	32.7	12	17.1	0.34	0.21	1.40	-0.071	Algorithm converged.	-0.182	0.038	0.58	Algorithm converged.	0.25	1.34	0.2059	0.9978	1.71	Algorithm converged.	0.74	3.95	
		I58FV	88	39.6	5	5.7	83	38.8	7	8.4	0.65	0.20	2.15	-0.028	Algorithm converged.	-0.104	0.049	0.67	Algorithm converged.	0.22	2.04	0.4847		1.48	Algorithm converged.	0.49	4.48	
		I58VV	11	5.0	1	9.1	27	12.6	4	14.8	0.58	0.06	5.81	-0.057	Algorithm converged.	-0.274	0.159	0.61	Algorithm converged.	0.08	4.89	0.6448		1.63	Algorithm converged.	0.20	12.99	
		Missing	11	5.0			10	4.7																				
	Binet Staging at baseline	A	46	20.7	5	10.9	47	22.0	5	10.6	1.02	0.28	3.80	0.002	Algorithm converged.	-0.124	0.128	1.02	Algorithm converged.	0.32	3.30	0.9713	0.0411	0.98	Algorithm converged.	0.30	3.16	
		B	80	36.0	7	8.8	71	33.2	5	7.0	1.27	0.38	4.18	0.017	Algorithm converged.	-0.069	0.103	1.24	Algorithm converged.	0.41	3.74	0.6994		0.80	Algorithm converged.	0.21	2.42	
		C	64	28.8	2	3.1	72	33.6	13	18.1	0.15	0.03	0.68	-0.149	Algorithm converged.	-0.248	-0.051	0.17	Algorithm converged.	0.04	0.74	0.0178		5.78	Algorithm converged.	1.36	24.61	
	Total CR score at baseline	<=6	42	18.9	1	2.4	80	28.0	6	10.0	0.22	0.03	1.90	-0.078	Algorithm converged.	-0.165	0.013	0.24	Algorithm converged.	0.03	1.91	0.1763	0.3092	4.20	Algorithm converged.	0.32	33.62	
		>6	148	66.7	13	8.8	130	60.7	17	13.1	0.64	0.30	1.37	-0.043	Algorithm converged.	-0.117	0.031	0.67	Algorithm converged.	0.34	1.33	0.2532		1.49	Algorithm converged.	0.75	2.95	
	Calculated creatinine clearance cat. 2	<70 ml/min	128	57.7	9	7.0	138	64.3	18	13.0	0.50	0.22	1.17	-0.060	Algorithm converged.	-0.132	0.011	0.54	Algorithm converged.	0.25	1.16	0.1125	0.5382	1.86	Algorithm converged.	0.86	3.98	
		>=70 ml/min	62	27.5	5	8.1	52	24.3	5	9.6	0.82	0.23	3.02	-0.018	Algorithm converged.	-0.120	0.089	0.84	Algorithm converged.	0.26	2.74	0.7708		1.15	Algorithm converged.	0.37	3.89	
	Beta2 microglobulin	< 3.5 ug/mL	113	50.9	8	7.1	109	50.9	11	10.1	0.68	0.26	1.76	-0.030	Algorithm converged.	-0.104	0.044	0.70	Algorithm converged.	0.29	1.68	0.4255	0.6730	1.43	Algorithm converged.	0.60	3.41	
		>= 3.5 ug/mL	74	33.3	6	8.1	78	36.9	12	15.2	0.49	0.17	1.39	-0.071	Algorithm converged.	-0.171	0.030	0.53	Algorithm converged.	0.21	1.35	0.1845		1.87	Algorithm converged.	0.74	4.74	
		Missing	3	1.4			2	0.9																				
	Immunoglobulin VH, cytogenetics 2	I2	31	14.0	1	3.2	32	15.0	5	15.6	0.18	0.02	1.64	-0.124	Algorithm converged.	-0.264	0.016	0.21	Algorithm converged.	0.03	1.67	0.1389	0.7199	4.84	Algorithm converged.	0.40	39.14	
		I1q	39	17.6	4	10.3	33	15.4	3	9.1	1.14	0.24	5.32	0.012	Algorithm converged.	-0.125	0.148	1.13	Algorithm converged.	0.27	4.68	0.8681		0.89	Algorithm converged.	0.21	3.68	
		I3q	38	26.1	4	6.9	38	27.1	7	12.1	0.34	0.15	1.89	-0.052	Algorithm converged.	-0.158	0.054	0.57	Algorithm converged.	0.18	1.85	0.3499		1.75	Algorithm converged.	0.34	5.46	
		Other Abn.	16	7.2	1	6.3	19	8.9	2	10.5	0.37	0.05	6.90	-0.043	Algorithm converged.	-0.225	0.138	0.59	Algorithm converged.	0.06	5.96	0.6578		1.68	Algorithm converged.	0.17	16.91	

	11q-	37	16.7	10	27.0	34	15.9	4	11.8	2.78	Convergence criterion (GCONV=1E-8) satisfied.	0.78	9.90	0.153	Algorithm converged.	-0.027	0.332	2.30	Algorithm converged.	0.79	6.64	0.1248	0.44	Algorithm converged.	0.15	1.26	
	13q-	64	28.8	6	9.4	58	27.1	11	19.0	0.44	Convergence criterion (GCONV=1E-8) satisfied.	0.15	1.28	-0.096	Algorithm converged.	-0.220	0.028	0.49	Algorithm converged.	0.20	1.25	0.1372	2.02	Algorithm converged.	0.80	5.12	
	Other Abn.	14	6.3	2	14.3	17	7.9	3	17.6	0.78	Convergence criterion (GCONV=1E-8) satisfied.	0.11	5.46	-0.038	Algorithm converged.	-0.291	0.224	0.81	Algorithm converged.	0.16	4.19	0.8010	1.24	Algorithm converged.	0.24	0.30	
	Norm. K.	45	20.3	6	13.3	47	22.0	6	12.8	1.05	Convergence criterion (GCONV=1E-8) satisfied.	0.31	3.54	0.006	Algorithm converged.	-0.132	0.143	1.04	Algorithm converged.	0.36	3.00	0.9356	0.96	Algorithm converged.	0.33	2.71	
	Time from first diagnosis																										
	<= 12 months	45	20.3	7	15.6	33	24.8	11	20.8	0.70	Convergence criterion (GCONV=1E-8) satisfied.	0.25	2.00	-0.052	Algorithm converged.	-0.204	0.100	0.75	Algorithm converged.	0.32	1.77	0.5112	0.6459	1.33	Algorithm converged.	0.36	3.11
	13 - 24 months	32	14.4	3	9.4	26	12.1	4	15.4	0.57	Convergence criterion (GCONV=1E-8) satisfied.	0.12	2.81	-0.060	Algorithm converged.	-0.232	0.111	0.61	Algorithm converged.	0.15	2.48	0.4895	1.64	Algorithm converged.	0.40	6.60	
	>24 months	117	52.7	19	16.2	108	50.5	16	14.8	1.11	Convergence criterion (GCONV=1E-8) satisfied.	0.54	2.30	0.014	Algorithm converged.	-0.080	0.109	1.10	Algorithm converged.	0.59	2.02	0.7685	0.91	Algorithm converged.	0.49	1.68	
	Missing	1	0.5																								
	High circulating tumor burden																										
	<25x10**9 cells/L	45	20.3	5	11.1	47	22.0	7	14.9	0.71	Convergence criterion (GCONV=1E-8) satisfied.	0.21	2.44	-0.038	Algorithm converged.	-0.175	0.099	0.75	Algorithm converged.	0.26	2.18	0.5923	0.7199	1.34	Algorithm converged.	0.46	3.92
	>=25x10**9 cells/L	150	67.6	24	16.0	139	65.0	24	17.3	0.91	Convergence criterion (GCONV=1E-8) satisfied.	0.49	1.70	-0.013	Algorithm converged.	-0.099	0.073	0.93	Algorithm converged.	0.55	1.55	0.7726	1.08	Algorithm converged.	0.64	1.81	
	Missing																										

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable. Clinical cut-off: 0.99412013

Program: root/clinical_studies/R05072759/CDPT7159/B021004/data_analysis/ACE_base/ga/program/t_pro_rsp2.aas
 Output: root/clinical_studies/R05072759/CDPT7159/B021004/data_analysis/ACE_CBR_stage2/ga/output/t_pro_rsp2_sq_EQC30W_GLQC30pop_IT_label1_09MAY2013_21004.xls 12JAN2021 12:42

POPULATION: Labelpopulation, Intent-to-Treat Patients, Patients with Screening and post Screening EORTC QLQ-C30 result
 ENDPOINT: EORTC QoL 10 - Responder (RID=10), worsening
 MODEL: Unstratified Analysis
 STUDY: CLL11(B021004), Stage 2
 Dichotomous Analysis by Subgroups (Efficacy)

Fatigue Scale			QC1b (N=222)				QC1b (N=214)				QC1b vs. QC1b											QC1b vs. QC1b Relative Risk						
Visit	Name	Level	n	t	n	t	n	t	n	t	Odds Ratio	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interacti on Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	
Circle 4 Day 1	All	n/a	189	85.3	44	23.3	192	89.7	81	26.6	0.84			-0.033	Algorithm converged.	-0.120	0.054	0.88	Algorithm converged.	0.62	1.24	0.4598		1.14	Algorithm converged.	0.80	1.62	
Gender	Male		116	52.3	23	19.8	118	55.1	28	23.7	0.79			-0.039	Algorithm converged.	-0.145	0.067	0.84	Algorithm converged.	0.51	1.16	0.4710	0.7733	1.20	Algorithm converged.	0.73	1.95	
	Female		73	32.9	21	28.8	74	34.6	23	31.1	0.90			-0.023	Algorithm converged.	-0.171	0.125	0.93	Algorithm converged.	0.56	1.52	0.7595		1.08	Algorithm converged.	0.66	1.77	
Age	<75 years		98	44.1	23	23.5	94	43.9	20	21.3	1.13			0.022	Algorithm converged.	-0.096	0.140	1.10	Algorithm converged.	0.65	1.87	0.7159	0.2514	0.91	Algorithm converged.	0.53	1.54	
	>=75 years		91	41.0	21	23.1	98	45.8	31	31.6	0.85			-0.084	Algorithm converged.	-0.212	0.041	0.73	Algorithm converged.	0.45	1.17	0.1930		1.37	Algorithm converged.	0.85	2.20	
Race	White		182	82.0	43	23.6	183	85.5	49	26.8	0.83			-0.031	Algorithm converged.	-0.121	0.058	0.88	Algorithm converged.	0.62	1.26	0.4890	0.7748	1.13	Algorithm converged.	0.80	1.62	
	Other		7	3.2	1	14.3	9	4.2	2	22.2	0.58			-0.079	Algorithm converged.	-0.455	0.296	0.64	Algorithm converged.	0.07	5.73	0.6922		1.56	Algorithm converged.	0.17	13.87	
Geographical Region	North America		9	4.3	1	11.1	11	5.3	2	18.2	0.56			-0.071	Algorithm converged.	-0.377	0.236	0.61	Algorithm converged.	0.07	5.70	0.6655		1.64	Algorithm converged.	0.18	15.21	
	Central and South America		3	1.4			2	0.9																				
	Western Europe		129	58.1	36	27.9	129	60.3	39	30.2	0.89			-0.021	Algorithm converged.	-0.134	0.088	0.92	Algorithm converged.	0.63	1.35	0.6810		1.08	Algorithm converged.	0.74	1.95	
	Asia-Pacific		15	6.8	2	13.3	15	7.0	4	28.7	0.42			-0.132	Algorithm converged.	-0.416	0.149	0.50	Algorithm converged.	0.11	2.33	0.3774		2.00	Algorithm converged.	0.43	9.22	
PDgamma receptor I1a	131HR		33	14.9	5	15.2	35	16.4	6	17.1	0.86			-0.020	Algorithm converged.	-0.195	0.155	0.88	Algorithm converged.	0.30	2.62	0.8239		1.13	Algorithm converged.	0.38	3.35	
	Missing																											
PDgamma receptor I1a	131HR		42	18.9	10	23.8	39	27.6	12	20.3	1.22			0.033	Algorithm converged.	-0.130	0.199	1.17	Algorithm converged.	0.56	2.45	0.6765	0.4158	0.85	Algorithm converged.	0.41	1.73	
	131HR		94	42.3	22	23.4	97	45.3	33	34.0	0.59			-0.106	Algorithm converged.	-0.234	0.021	0.69	Algorithm converged.	0.43	1.09	0.1101		1.45	Algorithm converged.	0.92	2.30	
	131HR		38	17.1	10	26.3	23	10.7	4	17.4	1.70			0.089	Algorithm converged.	-0.120	0.298	1.51	Algorithm converged.	0.54	4.27	0.4939		0.66	Algorithm converged.	0.23	1.82	
	Missing		15	6.8	2	13.3	13	6.1	2	15.4	0.85			-0.021	Algorithm converged.	-0.281	0.240	0.87	Algorithm converged.	0.14	5.32	0.8771		1.15	Algorithm converged.	0.19	7.09	
PDgamma receptor I1a	158FF		80	36.0	17	21.3	70	32.7	21	30.0	0.63			-0.088	Algorithm converged.	-0.227	0.052	0.71	Algorithm converged.	0.41	1.23	0.2218	0.0691	1.41	Algorithm converged.	0.81	2.41	
	158FF		88	39.6	23	28.4	83	38.6	19	22.9	1.34			0.053	Algorithm converged.	-0.075	0.186	1.24	Algorithm converged.	0.74	2.08	0.4118		0.81	Algorithm converged.	0.48	1.35	
	158VV		11	5.0	1	9.1	28	13.1	11	39.3	0.15			-0.302	Algorithm converged.	-0.550	-0.054	0.23	Algorithm converged.	0.03	1.59	0.1361		4.32	Algorithm converged.	0.63	29.61	
	Missing		10	4.5	1	10.0	11	5.1							ERROR: Error in computing the link function, its derivatives, or the variance function.													
Binet Staging at baseline	A		46	20.7	15	32.6	47	22.0	11	23.4	1.58			0.092	Algorithm converged.	-0.090	0.274	1.39	Algorithm converged.	0.72	2.70	0.3271	0.0533	0.72	Algorithm converged.	0.37	1.39	
	B		80	36.0	21	26.3	72	33.6	19	26.4	0.99			-0.001	Algorithm converged.	-0.142	0.139	0.99	Algorithm converged.	0.58	1.69	0.9845		1.01	Algorithm converged.	0.59	1.71	
	C		63	28.4	8	12.7	73	34.1	21	28.8	0.36			-0.161	Algorithm converged.	-0.293	-0.028	0.44	Algorithm converged.	0.21	0.93	0.0306		2.27	Algorithm converged.	1.08	4.71	
Total CIR score at baseline	<=6		41	18.5	10	24.4	60	28.0	18	30.0	0.75			-0.056	Algorithm converged.	-0.231	0.119	0.81	Algorithm converged.	0.42	1.58	0.5407	0.7591	1.23	Algorithm converged.	0.63	2.39	
	>6		148	66.7	34	23.0	132	61.7	33	25.0	0.89			-0.020	Algorithm converged.	-0.121	0.080	0.92	Algorithm converged.	0.61	1.40	0.6914		1.09	Algorithm converged.	0.72	1.65	
Calculated creatinine clearance cat. 2	<70 ml/min		127	57.2	30	23.6	140	65.4	41	29.3	0.75			-0.057	Algorithm converged.	-0.162	0.049	0.81	Algorithm converged.	0.54	1.21	0.2983	0.3708	1.24	Algorithm converged.	0.83	1.88	
	>=70 ml/min		62	27.8	14	22.6	52	24.3	10	19.2	1.22			0.033	Algorithm converged.	-0.116	0.183	1.17	Algorithm converged.	0.57	2.42	0.6633		0.85	Algorithm converged.	0.41	1.75	
Beta2 microglobulin	< 3.5 ug/mL		112	50.5	26	23.2	109	50.3	32	29.4	0.73			-0.061	Algorithm converged.	-0.177	0.054	0.79	Algorithm converged.	0.51	1.23	0.3014	0.4590	1.26	Algorithm converged.	0.81	1.97	
	>= 3.5 ug/mL		74	33.3	18	24.3	81	37.9	19	23.5	1.05			0.005	Algorithm converged.	-0.126	0.143	1.04	Algorithm converged.	0.59	1.82	0.6993		0.96	Algorithm converged.	0.55	1.65	
	Missing		3	1.4			2	0.9																				
Immunogloblin VH, cytogenetics 2	12		31	14.0	4	12.9	33	15.4	8	24.2	0.48			-0.113	Algorithm converged.	-0.301	0.075	0.53	Algorithm converged.	0.18	1.59	0.2592	0.4111	1.88	Algorithm converged.	0.63	0.62	
	11q-		39	17.6	11	28.2	34	19.9	5	14.7	2.28			0.135	Algorithm converged.	-0.050	0.320	1.92	Algorithm converged.	0.74	4.97	0.1799		0.52	Algorithm converged.	0.20	1.35	
	13q-		57	25.7	14	24.6	58	27.1	17	29.3	0.79			-0.047	Algorithm converged.	-0.209	0.114	0.84	Algorithm converged.	0.46	1.34	0.5673		1.19	Algorithm converged.	0.65	2.19	
	Other Abn.		16	7.2	5	31.3	19	8.9	8	42.1	0.63			-0.109	Algorithm converged.	-0.426	0.209	0.74	Algorithm converged.	0.30	1.82	0.5152		1.35	Algorithm converged.	0.55	3.31	
Norm. k.		46	20.7	10	21.7	48	22.4	13	27.1	0.75			-0.053	Algorithm converged.	-0.227	0.120	0.80	Algorithm converged.	0.59	1.65	0.5487		1.25	Algorithm converged.	0.61	2.95		

		Norm. W.	46	20.7	11	23.9	47	22.0	9	19.1	1.33	Convergence criterion (GCONV=1E-8) satisfied.	0.49	3.38	0.048	Algorithm converged.	-0.119	0.215	1.25	Algorithm converged.	0.57	2.73	0.9774	0.80	Algorithm converged.	0.37	1.75	
	Time from first diagnosis	K= 12 months	44	19.8	13	29.5	54	25.2	14	25.9	1.20	Convergence criterion (GCONV=1E-8) satisfied.	0.49	2.91	0.036	Algorithm converged.	-0.142	0.215	1.14	Algorithm converged.	0.60	2.16	0.6897	0.9897	0.88	Algorithm converged.	0.46	1.67
		13 - 24 months	31	14.0	5	16.1	26	12.1	4	15.4	1.08	Convergence criterion (GCONV=1E-8) satisfied.	0.25	4.43	0.007	Algorithm converged.	-0.182	0.197	1.05	Algorithm converged.	0.31	3.51	0.9388	0.95	Algorithm converged.	0.29	3.13	
		>24 months	119	53.6	38	31.9	109	50.9	32	29.4	1.13	Convergence criterion (GCONV=1E-8) satisfied.	0.64	1.98	0.026	Algorithm converged.	-0.094	0.145	1.09	Algorithm converged.	0.74	1.61	0.6742	0.92	Algorithm converged.	0.62	1.36	
		Missing	1	0.5																								
	High circulating tumor burden	<25x10**9 cells/L	46	20.7	15	32.6	49	22.9	13	26.5	1.34	Convergence criterion (GCONV=1E-8) satisfied.	0.55	3.24	0.061	Algorithm converged.	-0.123	0.244	1.23	Algorithm converged.	0.66	2.29	0.5172	0.6963	0.83	Algorithm converged.	0.44	1.52
		>=25x10**9 cells/L	149	67.1	41	27.5	139	65.0	36	25.9	1.09	Convergence criterion (GCONV=1E-8) satisfied.	0.64	1.83	0.016	Algorithm converged.	-0.086	0.118	1.05	Algorithm converged.	0.72	1.55	0.7558	0.94	Algorithm converged.	0.64	1.38	
		Missing																										

Test for interaction based on RR (Log-Binomial regression)
 * indicates convergence problem. Result is uninterpretable. Clinical
 out-off: 09MAY2013

Program: root/clinical_studies/R05072759/CDPT7159/R021004/data_analysis/ACE_base/qa/program/t_pro_rsp2.sas
 Output: root/clinical_studies/R05072759/CDPT7159/R021004/data_analysis/ACE_CSR_stage2/qa/output/t_pro_rsp2_eq_EQC30W_GLQC30pop_IT_label_09MAY2013_21004.xls 12JAN2021 12:42

POPULATION: Labelpopulation, Intent-to-Treat Patients, Patients with Screening and post Screening EORTC QLQ-C30 result
 ENDPOINT: EORTC QoL 10 - Responder (RID=10), worsening
 MODEL: Unstratified Analysis
 STUDY: CLL11(B021004), Stage 2
 Dichotomous Analysis by Subgroups (Efficacy)

Financial Difficulties Scale			OC1b (N=222)				OC1b (N=214)				OC1b vs. OC1b					OC1b vs. OC1b Relative Risk															
Visit	Name	Level	Patients		Patients with Event		Patients		Patients with Event		Odds Ratio	95% Lower CI	95% Upper CI	Absolute Risk	Convergence Reason	95% Lower CI	95% Upper CI	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI	p-value (Wald)	Interacti on Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI				
			n	%	n	%	n	%	n	%																					
Cycle 4 Day 1	All	n/a	191	86.0	17	8.9	183	85.3	26	14.2	0.89			Convergence criterion (GCONV-IR-8) satisfied.	0.33	1.13	-0.053	Algorithm converged.	-0.118	0.012	0.63		Algorithm converged.	0.35	1.12	0.1120	1.60	Algorithm converged.	0.80	2.84	
Gender	Male		117	52.7	7	6.0	112	52.3	15	13.4	0.41			Convergence criterion (GCONV-IR-8) satisfied.	0.16	1.05	-0.074	Algorithm converged.	-0.150	0.002	0.45		Algorithm converged.	0.19	1.05	0.0659	0.2574	2.24	Algorithm converged.	0.95	5.28
	Female		74	33.3	10	13.5	71	33.2	11	15.5	0.89			Convergence criterion (GCONV-IR-8) satisfied.	0.34	2.15	-0.020	Algorithm converged.	-0.134	0.095	0.87		Algorithm converged.	0.40	1.93	0.7352	1.15	Algorithm converged.	0.52	2.53	
Age	<75 years		99	44.6	13	12.1	92	43.0	14	15.2	0.77			Convergence criterion (GCONV-IR-8) satisfied.	0.34	1.76	-0.031	Algorithm converged.	-0.129	0.067	0.80		Algorithm converged.	0.39	1.63	0.5340	0.2901	1.26	Algorithm converged.	0.61	2.57
	>=75 years		92	41.4	5	5.4	91	42.5	12	13.2	0.38			Convergence criterion (GCONV-IR-8) satisfied.	0.13	1.12	-0.078	Algorithm converged.	-0.161	0.006	0.41		Algorithm converged.	0.15	1.12	0.0830	2.43	Algorithm converged.	0.89	6.61	
Race	White		184	82.9	15	8.2	174	81.3	23	13.2	0.98			Convergence criterion (GCONV-IR-8) satisfied.	0.29	1.16	-0.051	Algorithm converged.	-0.115	0.013	0.62		Algorithm converged.	0.33	1.14	0.1244	0.6949	1.62	Algorithm converged.	0.88	3.00
	Other		7	3.2	2	28.6	9	4.2	3	33.3	0.80			Convergence criterion (GCONV-IR-8) satisfied.	0.09	6.85	-0.048	Algorithm converged.	-0.502	0.407	0.86		Algorithm converged.	0.19	3.81	0.8395	1.17	Algorithm converged.	0.26	5.19	
Geographical Region	North America		9	4.1	1	11.1	10	4.7						* Quasi-complete separation of data points detected.				*													
	Central and South America		3	1.4	1	33.3	2	0.9						* Quasi-complete separation of data points detected.				*													
Western Europe			131	59.6	10	7.6	123	57.5	16	13.0	0.55			Convergence criterion (GCONV-IR-8) satisfied.	0.24	1.27	-0.054	Algorithm converged.	-0.128	0.021	0.59		Algorithm converged.	0.28	1.24	0.1641	1.70	Algorithm converged.	0.80	3.61	
	Asia-Pacific		15	6.8	1	6.7	14	6.5	3	21.4	0.26			Convergence criterion (GCONV-IR-8) satisfied.	0.02	2.88	-0.148	Algorithm converged.	-0.397	0.102	0.31		Algorithm converged.	0.04	2.65	0.2855	3.21	Algorithm converged.	0.38	27.41	
	Other		33	14.9	4	12.1	34	15.9	7	20.6	0.53			Convergence criterion (GCONV-IR-8) satisfied.	0.14	2.02	-0.085	Algorithm converged.	-0.260	0.091	0.59		Algorithm converged.	0.19	1.82	0.3987	1.70	Algorithm converged.	0.55	5.26	
FCgamma receptor IIa	131HR		42	18.9	3	7.1	38	27.1	7	12.1	0.56			Convergence criterion (GCONV-IR-8) satisfied.	0.14	2.31	-0.049	Algorithm converged.	-0.164	0.065	0.59		Algorithm converged.	0.16	2.16	0.4265	0.0533	1.69	Algorithm converged.	0.46	6.16
	131HR		95	42.8	8	8.4	93	43.5	14	17.2	0.44			Convergence criterion (GCONV-IR-8) satisfied.	0.18	1.09	-0.088	Algorithm converged.	-0.183	0.007	0.45		Algorithm converged.	0.22	1.09	0.0797	2.04	Algorithm converged.	0.92	4.54	
131RR			38	17.1	5	13.2	20	9.3						* Quasi-complete separation of data points detected.				*													
	Missing		16	7.2	1	6.3	12	5.6	3	25.0	0.20			Convergence criterion (GCONV-IR-8) satisfied.	0.02	2.23	-0.188	Algorithm converged.	-0.460	0.085	0.25		Algorithm converged.	0.03	2.10	0.2033	4.00	Algorithm converged.	0.47	31.80	
FCgamma receptor IIIa	158FF		81	36.5	9	11.1	63	29.4	10	15.9	0.66			Convergence criterion (GCONV-IR-8) satisfied.	0.25	1.74	-0.048	Algorithm converged.	-0.161	0.066	0.70		Algorithm converged.	0.30	1.62	0.4043	0.5785	1.43	Algorithm converged.	0.62	3.30
	158PV		88	39.6	4	4.5	81	37.9	10	12.3	0.34			Convergence criterion (GCONV-IR-8) satisfied.	0.10	1.12	-0.078	Algorithm converged.	-0.162	0.006	0.37		Algorithm converged.	0.12	1.13	0.6803	2.72	Algorithm converged.	0.89	8.32	
	158VV		11	5.0	2	18.2	28	13.1	4	14.3	1.33			Convergence criterion (GCONV-IR-8) satisfied.	0.21	8.88	0.039	Algorithm converged.	-0.223	0.301	1.27		Algorithm converged.	0.27	5.98	0.7600	0.78	Algorithm converged.	0.17	3.69	
	Missing		11	5.0	2	18.2	11	5.1	2	18.2	1.00			Convergence criterion (GCONV-IR-8) satisfied.	0.11	8.73	0.000	Algorithm converged.	-0.322	0.322	1.00		Algorithm converged.	0.17	5.89	1.0000	1.00	Algorithm converged.	0.17	5.89	
Binet Staging at baseline	A		47	21.2	5	10.6	46	21.5	4	8.7	1.25			Convergence criterion (GCONV-IR-8) satisfied.	0.31	4.98	0.019	Algorithm converged.	-0.101	0.139	1.22		Algorithm converged.	0.35	4.27	0.7519	0.4780	0.82	Algorithm converged.	0.23	2.80
	B		80	36.0	7	8.8	70	32.7	11	15.7	0.51			Convergence criterion (GCONV-IR-8) satisfied.	0.19	1.41	-0.070	Algorithm converged.	-0.175	0.036	0.56		Algorithm converged.	0.23	1.36	0.1981	1.80	Algorithm converged.	0.74	4.38	
	C		64	28.8	5	7.8	67	31.3	11	16.4	0.43			Convergence criterion (GCONV-IR-8) satisfied.	0.14	1.32	-0.086	Algorithm converged.	-0.196	0.024	0.48		Algorithm converged.	0.18	1.29	0.1455	2.10	Algorithm converged.	0.77	5.71	
Total CR score at baseline	<=6		43	19.4	5	11.6	54	25.2	8	14.8	0.76			Convergence criterion (GCONV-IR-8) satisfied.	0.23	2.50	-0.032	Algorithm converged.	-0.167	0.103	0.76		Algorithm converged.	0.28	2.23	0.6490	0.6401	1.27	Algorithm converged.	0.45	3.62
	>6		148	66.7	12	8.1	129	60.2	18	14.0	0.84			Convergence criterion (GCONV-IR-8) satisfied.	0.25	1.18	-0.058	Algorithm converged.	-0.133	0.016	0.38		Algorithm converged.	0.29	1.16	0.1237	1.72	Algorithm converged.	0.86	3.44	
Calculated creatinine clearance cat. 2	<70 ml/min		129	58.1	11	8.5	133	62.1	20	15.0	0.53			Convergence criterion (GCONV-IR-8) satisfied.	0.24	1.15	-0.065	Algorithm converged.	-0.143	0.012	0.57		Algorithm converged.	0.28	1.14	0.1095	0.5879	1.76	Algorithm converged.	0.88	3.53
	>=70 ml/min		62	27.9	6	9.7	50	23.4	6	12.0	0.79			Convergence criterion (GCONV-IR-8) satisfied.	0.24	2.60	-0.023	Algorithm converged.	-0.140	0.093	0.81		Algorithm converged.	0.28	2.35	0.6932	1.24	Algorithm converged.	0.43	3.61	
Beta2 microglobulin	< 3.5 ug/mL		113	50.9	12	10.6	106	49.5	15	14.2	0.72			Convergence criterion (GCONV-IR-8) satisfied.	0.32	1.62	-0.030	Algorithm converged.	-0.123	0.052	0.75		Algorithm converged.	0.37	1.53	0.4289	0.4191	1.33	Algorithm converged.	0.65	2.71
	>= 3.5 ug/mL		75	33.8	5	6.7	75	35.0	11	14.7	0.42			Convergence criterion (GCONV-IR-8) satisfied.	0.14	1.26	-0.080	Algorithm converged.	-0.178	0.018	0.45		Algorithm converged.	0.17	1.24	0.1251	2.20	Algorithm converged.	0.80	6.01	
	Missing		3	1.4			2	0.9																							
Immunoglobulin VH, cytogenetics 2	12		31	14.0	1	3.2	32	15.0	7	21.9	0.12			Convergence criterion (GCONV-IR-8) satisfied.	0.01	1.03	-0.186	Algorithm converged.	-0.343	-0.030	0.15		Algorithm converged.	0.02	1.13	0.0654	0.3492	6.78	Algorithm converged.	0.89	51.91
	11q-		39	17.6	3	7.7	32	15.0	3	9.4	0.81			Convergence criterion (GCONV-IR-8) satisfied.	0.10	4.29	-0.017	Algorithm converged.	-0.148	0.114	0.82		Algorithm converged.	0.18	3.79	0.8000	1.22	Algorithm converged.	0.26	5.61	

	11q-	37	16.7	3	8.1	32	15.0	2	6.3	1.32	Convergence criterion (GCONV=1E-8) satisfied.	0.21	8.46	0.019	Algorithm converged.	-0.103	0.140	1.30	Algorithm converged.	0.23	7.28	0.7679	0.77	Algorithm converged.	0.14	4.33	
	13q-	63	28.4	8	12.7	57	26.6	11	19.3	0.61	Convergence criterion (GCONV=1E-8) satisfied.	0.23	1.64	-0.046	Algorithm converged.	-0.197	0.065	0.66	Algorithm converged.	0.28	1.52	0.3272	1.52	Algorithm converged.	0.66	3.51	
	Other Abn.	14	6.3	3	21.4	17	7.9				Quasi-complete separation of data points detected.							NE	Algorithm converged.	NE	NE	NE	NE	Algorithm converged.	NE	NE	
	Norm. K.	46	20.7	5	10.9	46	21.5	7	15.2	0.68	Convergence criterion (GCONV=1E-8) satisfied.	0.25	2.32	-0.043	Algorithm converged.	-0.181	0.094	0.71	Algorithm converged.	0.24	2.09	0.5386	1.40	Algorithm converged.	0.48	4.09	
Time from first diagnosis	<= 12 months	44	19.8	7	15.9	53	24.8	8	15.1	1.06	Convergence criterion (GCONV=1E-8) satisfied.	0.35	3.21	0.008	Algorithm converged.	-0.137	0.153	1.05	Algorithm converged.	0.41	2.68	0.9120	0.9281	0.95	Algorithm converged.	0.37	2.41
	13 - 24 months	31	14.0	2	6.9	25	11.7	1	4.0	1.66	Convergence criterion (GCONV=1E-8) satisfied.	0.14	19.39	0.025	Algorithm converged.	-0.091	0.140	1.61	Algorithm converged.	0.16	16.78	0.6891	0.62	Algorithm converged.	0.06	6.45	
	>24 months	119	53.6	17	14.3	106	49.5	15	14.2	1.01	Convergence criterion (GCONV=1E-8) satisfied.	0.48	2.14	0.001	Algorithm converged.	-0.090	0.093	1.01	Algorithm converged.	0.53	1.92	0.9770	0.99	Algorithm converged.	0.52	1.88	
	Missing	1	0.5																								
High circulating tumor burden	<25x10**9 cells/L	45	20.3	7	15.6	49	22.9	4	8.2	2.07	Convergence criterion (GCONV=1E-8) satisfied.	0.56	7.62	0.074	Algorithm converged.	-0.057	0.205	1.91	Algorithm converged.	0.60	6.08	0.2759	0.2127	0.52	Algorithm converged.	0.16	1.67
	>=25x10**9 cells/L	150	67.6	19	12.7	134	62.6	20	14.9	0.83	Convergence criterion (GCONV=1E-8) satisfied.	0.42	1.63	-0.023	Algorithm converged.	-0.103	0.058	0.85	Algorithm converged.	0.47	1.52	0.5812	1.18	Algorithm converged.	0.66	2.11	
	Missing					1	0.5																				

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable. Clinical
 cut-off: 09MAY2013

Program: root/clinical_studies/R05072759/CDPT7159/R021004/data_analysis/ACE_base/ga/program/t_pro_rsp2.sas
 Output: root/clinical_studies/R05072759/CDPT7159/R021004/data_analysis/ACE_CBR_stage2/ga/output/t_pro_rsp2_ag_RQC30W_GLQC30pop_IT_label1_09MAY2013_21004.xls 12JAN2021
 12142

POPULATION: Labelpopulation, Intent-to-Treat Patients, Patients with Screening and post Screening EORTC QLQ-C30 result
 ENDPOINT: EORTC QoL 10 - Responder (RID=10), worsening
 MODEL: Unstratified Analysis
 STUDY: CLL11(B021004), Stage 2
 Dichotomous Analysis by Subgroups (Efficacy)

Nausea And Vomiting Scale			OC1b (N=222)				OC1b (N=214)				OC1b vs. OC1b					OC1b vs. OC1b Relative Risk												
Visit	Name	Level	Patients		Patients with Event		Patients		Patients with Event		Odds Ratio	95% Lower CI	95% Upper CI	Absolute Risk	Convergence Reason	95% Lower CI	95% Upper CI	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI	p-value (Wald)	Interacti on Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI	
			n	%	n	%	n	%	n	%																		
Cycle 4 Day 1	All	n/a	192	86.5	33	17.2	192	89.7	27	14.1	1.27			0.031	Algorithm converged.	-0.041	0.104	1.22	Algorithm converged.	0.77	1.95	0.4003		0.82	Algorithm converged.	0.51	1.31	
Gender	Male		117	52.7	16	13.7	118	55.1	11	9.3	1.04			0.044	Algorithm converged.	-0.038	0.123	1.47	Algorithm converged.	0.71	3.03	0.2994	0.4830	0.68	Algorithm converged.	0.33	1.41	
	Female		75	33.8	17	22.7	74	34.6	16	21.6	1.08			0.010	Algorithm converged.	-0.123	0.144	1.05	Algorithm converged.	0.57	1.91	0.8780		0.95	Algorithm converged.	0.52	1.71	
Age	<75 years		99	44.6	13	13.1	94	43.9	12	12.8	1.03			0.004	Algorithm converged.	-0.091	0.098	1.03	Algorithm converged.	0.49	2.14	0.9398	0.5203	0.97	Algorithm converged.	0.47	2.05	
	>=75 years		93	41.9	20	21.5	98	45.8	15	15.3	1.02			0.062	Algorithm converged.	-0.048	0.172	1.41	Algorithm converged.	0.77	2.58	0.2717		0.71	Algorithm converged.	0.39	1.31	
Race	White		185	83.3	33	17.8	183	85.5	25	13.7	1.37			0.042	Algorithm converged.	-0.033	0.116	1.31	Algorithm converged.	0.81	2.11	0.2739	0.0822	0.77	Algorithm converged.	0.47	1.23	
	Other		7	3.2			9	4.2	2	22.2	*			*	Quasi-complete separation of data points detected.			<0.01	Algorithm converged.	0.00	NE	0.9999	>999.99	>999.99	Algorithm converged.	0.00	NE	
Geographical Region	North America		9	4.1	1	11.1	11	5.1	1	9.1	1.29			0.020	Algorithm converged.	-0.246	0.287	1.22	Algorithm converged.	0.09	16.92	0.8810		0.82	Algorithm converged.	0.06	11.33	
	Central and South America		3	1.4			2	0.9																				
	Western Europe		132	59.5	29	22.0	129	60.3	19	14.7	1.63			0.072	Algorithm converged.	-0.021	0.166	1.49	Algorithm converged.	0.88	2.52	0.1356		0.67	Algorithm converged.	0.40	1.13	
Asia-Pacific	Other		15	6.8			15	7.0	4	26.7	*			*	Quasi-complete separation of data points detected.			<0.01	Algorithm converged.	0.00	NE	0.9999	>999.99	>999.99	Algorithm converged.	0.00	NE	
	Missing		33	14.9	3	9.1	35	16.4	3	8.6	1.07			0.005	Algorithm converged.	-0.130	0.140	1.06	Algorithm converged.	0.23	4.89	0.9398		0.94	Algorithm converged.	0.20	4.35	
PDgamma receptor Ii1a	131HR		42	18.9	12	28.6	39	27.6	7	11.9	2.97			0.167	Algorithm converged.	0.007	0.327	2.41	Algorithm converged.	1.04	5.60	0.0413	0.1734	0.42	Algorithm converged.	0.18	0.97	
	131BR		95	42.8	14	14.7	97	45.3	17	17.5	0.83			-0.028	Algorithm converged.	-0.132	0.076	0.84	Algorithm converged.	0.44	1.61	0.6003		1.15	Algorithm converged.	0.62	2.27	
	131ER		38	17.1	5	13.2	23	10.7	1	4.3	3.33			0.088	Algorithm converged.	-0.048	0.224	3.03	Algorithm converged.	0.38	24.31	0.2976		0.33	Algorithm converged.	0.04	2.65	
	Missing		17	7.7	2	11.8	13	6.1	2	15.4	0.73			-0.036	Algorithm converged.	-0.285	0.213	0.76	Algorithm converged.	0.12	4.73	0.7729		1.31	Algorithm converged.	0.21	8.03	
	Other		33	14.9	3	9.1	35	16.4	3	8.6	1.07			0.005	Algorithm converged.	-0.130	0.140	1.06	Algorithm converged.	0.23	4.89	0.9398		0.94	Algorithm converged.	0.20	4.35	
PDgamma receptor Ii1a	158FF		81	36.5	13	16.0	70	32.7	10	14.3	1.15			0.018	Algorithm converged.	-0.097	0.132	1.12	Algorithm converged.	0.53	2.10	0.7640	0.9901	0.88	Algorithm converged.	0.42	1.90	
	158FV		88	39.6	17	19.3	83	38.8	13	15.7	1.29			0.037	Algorithm converged.	-0.077	0.150	1.23	Algorithm converged.	0.64	2.38	0.5314		0.81	Algorithm converged.	0.42	1.51	
	158VV		11	5.0	1	9.1	28	13.1	2	7.1	1.30			0.019	Algorithm converged.	-0.178	0.214	1.27	Algorithm converged.	0.13	12.66	0.8370		0.78	Algorithm converged.	0.08	7.81	
	Missing		12	5.4	2	16.7	11	5.1	2	18.2	0.90			-0.015	Algorithm converged.	-0.326	0.295	0.92	Algorithm converged.	0.15	5.44	0.9237		1.09	Algorithm converged.	0.18	6.48	
Binet Staging at baseline	A		48	21.6	11	22.9	47	22.0	5	10.1	1.26			0.038	Algorithm converged.	-0.126	0.201	1.20	Algorithm converged.	0.55	2.62	0.6533	0.0974	0.84	Algorithm converged.	0.38	1.83	
	B		80	36.0	9	11.3	72	33.6	12	16.7	0.63			-0.054	Algorithm converged.	-0.165	0.056	0.68	Algorithm converged.	0.30	1.51	0.3377		1.48	Algorithm converged.	0.66	3.31	
	C		64	28.8	13	20.3	73	34.1	6	8.2	2.85			0.121	Algorithm converged.	0.004	0.238	2.47	Algorithm converged.	1.00	6.12	0.6506		0.40	Algorithm converged.	0.16	1.00	
Total CIR score at baseline	<=6		42	18.8	7	16.7	60	28.0	7	11.7	1.51			0.050	Algorithm converged.	-0.089	0.189	1.43	Algorithm converged.	0.54	3.77	0.4714	0.6946	0.70	Algorithm converged.	0.27	1.85	
	>6		150	67.6	26	17.3	132	61.7	20	15.2	1.17			0.022	Algorithm converged.	-0.064	0.108	1.14	Algorithm converged.	0.67	1.95	0.6214		0.87	Algorithm converged.	0.51	1.49	
Calculated creatinine clearance cat. 2	<70 ml/min		130	58.6	20	15.4	145	65.4	18	12.9	1.23			0.025	Algorithm converged.	-0.058	0.108	1.20	Algorithm converged.	0.66	2.16	0.5513	0.9900	0.84	Algorithm converged.	0.46	1.51	
	>=70 ml/min		62	27.5	13	21.0	52	24.3	9	17.3	1.27			0.037	Algorithm converged.	-0.108	0.181	1.21	Algorithm converged.	0.56	2.61	0.6235		0.83	Algorithm converged.	0.38	1.78	
Beta2 microglobulin	< 3.5 ug/mL		114	51.4	23	20.2	109	50.9	19	17.4	1.20			0.027	Algorithm converged.	-0.075	0.130	1.16	Algorithm converged.	0.67	2.00	0.6010	0.9280	0.86	Algorithm converged.	0.50	1.49	
	>= 3.5 ug/mL		75	33.8	9	12.0	81	37.9	8	9.9	1.24			0.021	Algorithm converged.	-0.077	0.119	1.21	Algorithm converged.	0.49	2.99	0.6712		0.82	Algorithm converged.	0.33	2.02	
Immunoglobulin VR, cytogenetics 2	Missing		3	1.4	1	33.3	2	0.9			*			*	Quasi-complete separation of data points detected.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	
	Other		31	14.0	5	16.1	33	15.4	4	18.2	0.87			-0.021	Algorithm converged.	-0.205	0.164	0.89	Algorithm converged.	0.30	2.61	0.8280	0.3369	1.13	Algorithm converged.	0.38	3.37	

		Missing	3	1.4	1	33.3	2	0.9							ERROR: The mean parameter is either invalid or at a limit of its range for some observations.																																				
															* Quasi-complete separation of data points detected.					NE						Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE																	
	Immunogloblin VH, cytogenetics 2	12	35	15.8	5	14.3	32	15.0	2	6.3	2.50				Convergence criterion (GCONV=IE=8) satisfied.	0.45	13.81	0.080								Algorithm converged.	-0.063	0.223	2.29			Algorithm converged.	0.48	10.97	0.3015	0.2559	0.44	Algorithm converged.	0.09	2.11											
	11q-	37	16.1		4	10.8	34	15.0	1	2.9	4.00				Convergence criterion (GCONV=IE=8) satisfied.	0.45	37.75	0.079								Algorithm converged.	-0.036	0.194	3.68			Algorithm converged.	0.43	31.28	0.2335		0.21	Algorithm converged.	0.03	2.32											
	13q-	67	30.2		3	4.5	59	27.6	5	8.5	0.51				Convergence criterion (GCONV=IE=8) satisfied.	0.12	2.22	-0.040								Algorithm converged.	-0.127	0.047	0.93			Algorithm converged.	0.13	2.12	0.3676		1.89	Algorithm converged.	0.47	7.58											
	Other Abn.	14	6.3				17	7.9	1	5.9					* Quasi-complete separation of data points detected.																																				
	Norm. K.	48	20.1		7	15.2	47	22.0	9	19.1	0.76				Convergence criterion (GCONV=IE=8) satisfied.	0.28	2.24	-0.038									Algorithm converged.	-0.192	0.114	0.79			Algorithm converged.	0.32	1.96	0.6168		1.26	Algorithm converged.	0.51	3.18										
	Time from first diagnosis																																																		
	<= 12 months	45	20.3		6	13.3	54	25.2	4	7.4	1.92				Convergence criterion (GCONV=IE=8) satisfied.	0.51	7.29	0.059									Algorithm converged.	-0.062	0.181	1.80			Algorithm converged.	0.54	5.99	0.3377	0.5481	0.56	Algorithm converged.	0.17	1.85										
	13 - 24 months	32	14.4		1	3.1	26	12.1	1	3.8	0.81				Convergence criterion (GCONV=IE=8) satisfied.	0.05	13.55	-0.007									Algorithm converged.	-0.103	0.088	0.81			Algorithm converged.	0.05	12.37	0.8812		1.23	Algorithm converged.	0.08	18.71										
	>24 months	121	56.1		12	9.9	109	50.9	13	11.9	0.81				Convergence criterion (GCONV=IE=8) satisfied.	0.35	1.87	-0.020									Algorithm converged.	-0.101	0.061	0.83			Algorithm converged.	0.40	1.74	0.6254		1.20	Algorithm converged.	0.57	2.52										
	Missing	1	0.5																																																
	High circulating tumor burden																																																		
	<25x10**9 cells/L	46	20.1		4	8.7	49	22.9	1	2.0	4.57				Convergence criterion (GCONV=IE=8) satisfied.	0.49	42.52	0.067									Algorithm converged.	-0.024	0.157	4.26			Algorithm converged.	0.49	36.73	0.1872	0.1028	0.23	Algorithm converged.	0.03	2.02										
	>=25x10**9 cells/L	153	68.9		15	9.8	139	65.0	17	12.2	0.78				Convergence criterion (GCONV=IE=8) satisfied.	0.37	1.63	-0.024									Algorithm converged.	-0.096	0.048	0.80			Algorithm converged.	0.42	1.54	0.5083		1.25	Algorithm converged.	0.65	2.48										
	Missing						1	0.3																																											

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable. Clinical
cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/B021004/data_analysis/ACE_base/ga/program/t_pro_rsp2.sas
Output: root/clinical_studies/RO5072759/CDPT7159/B021004/data_analysis/ACE_CSR_stage2/ga/output/t_pro_rsp2_sq_RQC30W_QQC30pop_IT_label1_09MAY2013_21004.klis 12JAN2021
12:42

POPULATION: Labelpopulation, Intent-to-Treat Patients, Patients with Screening and post Screening EORTC QLQ-C30 result
 ENDPOINT: EORTC QoL 10 - Responder (MID=10), worsening
 MODEL: Unstratified Analysis
 STUDY: CLL11(B021004), Stage 2
 Dichotomous Analysis by Subgroups (Efficacy)

Pain Scale			OC1b (N=222)				OC1b vs. OC1a				OC1b vs. OC1b				OC1b vs. OC1b Relative Risk													
Visit	Name	Level	Patients		Patients with Event		Patients		Patients with Event		Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interacti on Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
			n	%	n	%	n	%	n	%																		
Cycle 4 Day 1	All	n/a	193	86.9	34	17.6	192	89.7	37	19.3	0.80	Convergence criterion (GCONV-IR-8) satisfied.	0.53	1.30	-0.017	Algorithm converged.	-0.094	0.061	0.93	Algorithm converged.	0.60	1.39	0.6758		1.09	Algorithm converged.	0.72	1.67
Gender	Male		117	52.7	23	19.7	116	55.1	20	16.9	1.05	Convergence criterion (GCONV-IR-8) satisfied.	0.62	2.33	0.027	Algorithm converged.	-0.072	0.126	1.16	Algorithm converged.	0.67	1.99	0.5918	0.1676	0.86	Algorithm converged.	0.55	1.48
	Female		76	34.2	11	14.5	74	34.6	17	23.0	0.57	Convergence criterion (GCONV-IR-8) satisfied.	0.25	1.31	-0.083	Algorithm converged.	-0.209	0.039	0.63	Algorithm converged.	0.32	1.25	0.1879		1.59	Algorithm converged.	0.85	3.16
Age	<75 years		99	44.6	17	17.2	94	43.0	15	16.0	1.05	Convergence criterion (GCONV-IR-8) satisfied.	0.51	2.33	0.012	Algorithm converged.	-0.093	0.117	1.08	Algorithm converged.	0.57	2.03	0.8207	0.5031	0.93	Algorithm converged.	0.49	1.75
	>=75 years		94	42.3	17	18.1	98	45.8	22	22.4	0.76	Convergence criterion (GCONV-IR-8) satisfied.	0.38	1.55	-0.044	Algorithm converged.	-0.157	0.070	0.81	Algorithm converged.	0.46	1.42	0.4543		1.24	Algorithm converged.	0.70	2.19
Race	White		186	83.8	33	17.7	183	85.5	37	20.2	0.89	Convergence criterion (GCONV-IR-8) satisfied.	0.51	1.43	-0.023	Algorithm converged.	-0.105	0.055	0.88	Algorithm converged.	0.58	1.34	0.5445	0.1701	1.14	Algorithm converged.	0.73	1.71
	Other		7	3.2	1	14.3	9	4.2				Quasi-complete separation of data points detected.							NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Geographical Region	North America		9	4.1	2	22.2	11	5.1	2	18.2	1.29	Convergence criterion (GCONV-IR-8) satisfied.	0.14	11.34	0.040	Algorithm converged.	-0.314	0.395	1.22	Algorithm converged.	0.21	7.04	0.8223	0.9871	0.82	Algorithm converged.	0.14	4.71
	Central and South America		3	1.4			2	0.9																				
	Western Europe		133	59.9	24	18.0	129	60.3	26	20.2	0.87	Convergence criterion (GCONV-IR-8) satisfied.	0.47	1.82	-0.021	Algorithm converged.	-0.116	0.074	0.90	Algorithm converged.	0.54	1.47	0.6641		1.12	Algorithm converged.	0.68	1.84
Asia-Pacific	Asia-Pacific		15	6.8	2	13.3	15	7.0	3	20.0	0.62	Convergence criterion (GCONV-IR-8) satisfied.	0.09	4.34	-0.067	Algorithm converged.	-0.332	0.199	0.67	Algorithm converged.	0.13	3.44	0.6279		1.50	Algorithm converged.	0.29	7.73
	Other		33	14.9	6	18.2	35	16.4	6	17.1	1.07	Convergence criterion (GCONV-IR-8) satisfied.	0.31	3.74	0.010	Algorithm converged.	-0.171	0.192	1.06	Algorithm converged.	0.38	2.96	0.9106		0.94	Algorithm converged.	0.34	2.63
FCgamma receptor 1fa	131HR		42	18.9	9	21.4	59	27.6	9	13.3	1.52	Convergence criterion (GCONV-IR-8) satisfied.	0.34	4.22	0.062	Algorithm converged.	-0.093	0.216	1.40	Algorithm converged.	0.61	3.24	0.4250	0.1767	0.71	Algorithm converged.	0.31	1.64
	131HR		96	43.2	14	14.6	97	45.3	24	24.7	0.52	Convergence criterion (GCONV-IR-8) satisfied.	0.25	1.08	-0.102	Algorithm converged.	-0.213	0.010	0.59	Algorithm converged.	0.32	1.07	0.0820		1.70	Algorithm converged.	0.84	3.08
	131HR		38	17.1	8	21.1	23	10.7	3	13.0	1.78	Convergence criterion (GCONV-IR-8) satisfied.	0.42	7.92	0.080	Algorithm converged.	-0.109	0.269	1.01	Algorithm converged.	0.48	5.48	0.4425		0.62	Algorithm converged.	0.18	2.10
	Missing		17	7.7	3	17.6	13	6.1	1	7.7	2.57	Convergence criterion (GCONV-IR-8) satisfied.	0.24	28.09	0.100	Algorithm converged.	-0.132	0.332	2.29	Algorithm converged.	0.27	19.59	0.4480		0.44	Algorithm converged.	0.05	3.77
FCgamma receptor 1fa	158FP		81	36.5	12	14.8	70	32.7	7	10.0	1.56	Convergence criterion (GCONV-IR-8) satisfied.	0.38	4.22	0.048	Algorithm converged.	-0.056	0.153	1.48	Algorithm converged.	0.62	3.56	0.3789	0.1363	0.68	Algorithm converged.	0.28	1.62
	158FV		89	40.1	19	21.3	83	38.8	24	28.9	0.67	Convergence criterion (GCONV-IR-8) satisfied.	0.33	1.34	-0.076	Algorithm converged.	-0.205	0.054	0.74	Algorithm converged.	0.44	1.24	0.2549		1.35	Algorithm converged.	0.80	2.28
	158VV		11	5.0	1	9.1	28	13.1	6	21.4	0.37	Convergence criterion (GCONV-IR-8) satisfied.	0.04	3.46	-0.123	Algorithm converged.	-0.351	0.105	0.42	Algorithm converged.	0.06	3.13	0.4005		2.36	Algorithm converged.	0.32	17.42
Missing	Missing		12	5.4	2	16.7	11	5.1				Quasi-complete separation of data points detected.							NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
	Missing																											
Binet Staging at baseline	A		48	21.6	8	16.7	47	22.0	6	12.8	1.37	Convergence criterion (GCONV-IR-8) satisfied.	0.46	4.29	0.035	Algorithm converged.	-0.103	0.181	1.31	Algorithm converged.	0.49	3.48	0.5935	0.5236	0.77	Algorithm converged.	0.29	2.04
	B		80	36.0	13	18.8	72	33.6	19	26.4	0.64	Convergence criterion (GCONV-IR-8) satisfied.	0.35	1.39	-0.076	Algorithm converged.	-0.208	0.057	0.71	Algorithm converged.	0.39	1.29	0.2622		1.41	Algorithm converged.	0.77	2.56
	C		65	29.3	11	16.9	73	34.1	12	16.4	1.04	Convergence criterion (GCONV-IR-8) satisfied.	0.42	2.36	0.005	Algorithm converged.	-0.120	0.129	1.03	Algorithm converged.	0.49	2.17	0.9392		0.97	Algorithm converged.	0.46	2.05
Total CR score at baseline	<=6		43	19.4	8	18.6	60	28.0	12	20.0	0.91	Convergence criterion (GCONV-IR-8) satisfied.	0.34	2.47	-0.014	Algorithm converged.	-0.168	0.140	0.93	Algorithm converged.	0.42	2.08	0.8601	0.9731	1.07	Algorithm converged.	0.49	2.40
	>6		150	67.6	26	17.3	132	61.7	25	18.9	0.90	Convergence criterion (GCONV-IR-8) satisfied.	0.49	1.85	-0.016	Algorithm converged.	-0.106	0.074	0.92	Algorithm converged.	0.56	1.50	0.7266		1.09	Algorithm converged.	0.66	1.80
Calculated creatinine clearance est. 2	<70 ml/min		131	59.0	17	13.0	145	65.4	30	21.4	0.85	Convergence criterion (GCONV-IR-8) satisfied.	0.29	1.05	-0.085	Algorithm converged.	-0.174	0.005	0.41	Algorithm converged.	0.35	1.04	0.0714	0.0098	1.65	Algorithm converged.	0.96	2.85
	>=70 ml/min		62	27.5	17	27.4	52	24.3	7	13.5	2.43	Convergence criterion (GCONV-IR-8) satisfied.	0.92	6.42	0.140	Algorithm converged.	-0.005	0.284	2.04	Algorithm converged.	0.92	4.53	0.0831		0.49	Algorithm converged.	0.22	1.09
Beta2 microglobulin	< 3.5 ug/mL		115	51.8	23	20.0	109	50.9	26	23.9	0.80	Convergence criterion (GCONV-IR-8) satisfied.	0.42	1.91	-0.039	Algorithm converged.	-0.147	0.070	0.84	Algorithm converged.	0.51	1.98	0.4864	0.7419	1.19	Algorithm converged.	0.73	1.98
	>= 3.5 ug/mL		75	33.8	10	13.3	81	37.0	11	13.6	0.98	Convergence criterion (GCONV-IR-8) satisfied.	0.39	2.46	-0.002	Algorithm converged.	-0.110	0.105	0.98	Algorithm converged.	0.44	2.18	0.9640		1.02	Algorithm converged.	0.46	2.20
Missing	Missing		3	1.4	1	33.3	2	0.9				Quasi-complete separation of data points detected.							NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
	Missing																											
Immunogloblin VR, cytogenetics 2	12		31	14.0	5	16.1	33	15.4	6	24.2	0.65	Convergence criterion (GCONV-IR-8) satisfied.	0.17	2.09	-0.081	Algorithm converged.	-0.276	0.114	0.67	Algorithm converged.	0.24	1.82	0.4264	0.0137	1.50	Algorithm converged.	0.55	4.10

	11q-	37	16.7	7	18.9	34	15.9	6	17.6	1.09	Convergence criterion (GCONV=1E-8) satisfied.	0.33	3.84	0.013	Algorithm converged.	-0.167	0.193	1.07	Algorithm converged.	0.40	2.87	0.8900	0.93	Algorithm converged.	0.35	2.50	
	13q-	67	30.2	14	20.9	59	27.6	21	35.6	0.48	Convergence criterion (GCONV=1E-8) satisfied.	0.22	1.06	-0.147	Algorithm converged.	-0.303	0.008	0.59	Algorithm converged.	0.33	1.05	0.0712	1.70	Algorithm converged.	0.95	3.01	
	Other Abn.	14	6.3	4	28.6	17	7.9	3	17.6	1.87	Convergence criterion (GCONV=1E-8) satisfied.	0.34	10.25	0.109	Algorithm converged.	-0.189	0.407	1.62	Algorithm converged.	0.43	6.06	0.4741	0.62	Algorithm converged.	0.17	2.31	
	Norm. K.	46	20.7	14	30.4	47	22.0	10	21.3	1.62	Convergence criterion (GCONV=1E-8) satisfied.	0.63	4.14	0.092	Algorithm converged.	-0.086	0.269	1.43	Algorithm converged.	0.71	2.89	0.3178	0.70	Algorithm converged.	0.35	1.41	
	Time from first diagnosis										Convergence criterion (GCONV=1E-8) satisfied.																
	<= 12 months	45	20.3	6	13.3	34	25.2	16	29.6	0.37	Convergence criterion (GCONV=1E-8) satisfied.	0.13	1.03	-0.163	Algorithm converged.	-0.320	-0.006	0.45	Algorithm converged.	0.19	1.05	0.0658	0.1572	2.22	Algorithm converged.	0.95	5.20
	13 - 24 months	32	14.4	5	18.8	26	12.1	5	19.2	0.97	Convergence criterion (GCONV=1E-8) satisfied.	0.26	3.62	-0.005	Algorithm converged.	-0.208	0.139	0.98	Algorithm converged.	0.34	2.84	0.9629	1.03	Algorithm converged.	0.35	2.98	
	>24 months	121	54.5	36	29.8	109	50.9	30	27.5	1.12	Convergence criterion (GCONV=1E-8) satisfied.	0.83	1.98	0.022	Algorithm converged.	-0.095	0.139	1.08	Algorithm converged.	0.72	1.63	0.7094	0.93	Algorithm converged.	0.61	1.33	
	Missing	1	0.5																								
	High circulating tumor burden										Convergence criterion (GCONV=1E-8) satisfied.																
	<25x10**9 cells/L	46	20.7	13	28.3	49	22.9	12	24.5	1.21	Convergence criterion (GCONV=1E-8) satisfied.	0.49	3.03	0.038	Algorithm converged.	-0.140	0.215	1.15	Algorithm converged.	0.59	2.26	0.6769	0.3829	0.87	Algorithm converged.	0.44	1.70
	>=25x10**9 cells/L	153	68.9	35	22.9	139	65.0	39	28.1	0.76	Convergence criterion (GCONV=1E-8) satisfied.	0.45	1.29	-0.052	Algorithm converged.	-0.152	0.048	0.82	Algorithm converged.	0.55	1.21	0.3102	1.23	Algorithm converged.	0.83	1.82	
	Missing																										

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable. Clinical cut-off: 09MAY2013

Program: root/clinical_studies/R05072759/CDPT7159/B021004/data_analysis/ACE_base/ga/program/t_pro_rsp2.sas
Output: root/clinical_studies/R05072759/CDPT7159/B021004/data_analysis/ACE_CBR_stage2/ga/output/t_pro_rsp2_sq_EQC30W_QLQC30pop_IT_label1_09MAY2013_21004.xls 12JAN2021 12:42

		13 - 24 months	32	14.4	4	12.9	27	12.6	2	7.4	1.79	Convergence criterion (GCNV-IR-8) satisfied.	0.30	10.80	0.001	Algorithm converged.	-0.100	0.202	1.89	Algorithm converged.	0.33	8.31	0.5263	0.59	Algorithm converged.	0.12	2.99	
		>24 months	116	52.3	17	14.7	109	50.9	21	19.3	0.72	Convergence criterion (GCNV-IR-8) satisfied.	0.16	1.45	-0.044	Algorithm converged.	-0.144	0.052	0.76	Algorithm converged.	0.42	1.16	0.3582	1.31	Algorithm converged.	0.73	2.31	
		Missing	1	0.5																								
	High circulating tumor burden	<25x10**9 cells/L	43	19.4	10	23.3	50	23.4	11	22.0	1.07	Convergence criterion (GCNV-IR-8) satisfied.	0.41	2.84	0.011	Algorithm converged.	-0.158	0.183	1.06	Algorithm converged.	0.50	2.24	0.8851	0.5477	0.95	Algorithm converged.	0.45	2.01
		>=25x10**9 cells/L	148	66.7	22	14.9	139	65.0	26	18.7	0.76	Convergence criterion (GCNV-IR-8) satisfied.	0.41	1.41	-0.038	Algorithm converged.	-0.125	0.048	0.79	Algorithm converged.	0.47	1.33	0.3850	1.26	Algorithm converged.	0.75	2.11	
		Missing				1	0.5																					
	Pu Month 3	All	n/a	198	89.2	25	17.7	188	87.9	27	19.7	0.88	Convergence criterion (GCNV-IR-8) satisfied.	0.52	1.46	-0.020	Algorithm converged.	-0.098	0.058	0.90	Algorithm converged.	0.59	1.16	0.6136	1.11	Algorithm converged.	0.73	1.69
	Gender	Male	120	54.1	17	14.2	115	53.7	23	20.0	0.66	Convergence criterion (GCNV-IR-8) satisfied.	0.33	1.31	-0.058	Algorithm converged.	-0.154	0.038	0.71	Algorithm converged.	0.40	1.26	0.2376	0.2159	1.43	Algorithm converged.	0.80	2.50
		Female	78	35.1	18	23.1	73	34.1	14	19.2	1.26	Convergence criterion (GCNV-IR-8) satisfied.	0.58	2.77	0.039	Algorithm converged.	-0.091	0.169	1.20	Algorithm converged.	0.65	2.24	0.5593	0.93	Algorithm converged.	0.45	1.55	
	Age	<75 years	103	46.4	24	23.3	94	43.0	18	20.2	1.20	Convergence criterion (GCNV-IR-8) satisfied.	0.61	2.37	0.031	Algorithm converged.	-0.084	0.146	1.15	Algorithm converged.	0.68	1.96	0.6011	0.1432	0.87	Algorithm converged.	0.51	1.48
		>=75 years	95	42.8	11	11.6	94	43.9	18	19.1	0.95	Convergence criterion (GCNV-IR-8) satisfied.	0.29	1.29	-0.074	Algorithm converged.	-0.178	0.027	0.60	Algorithm converged.	0.30	1.21	0.1553	1.65	Algorithm converged.	0.83	3.31	
	Race	White	191	86.0	23	17.3	178	83.2	26	20.2	0.82	Convergence criterion (GCNV-IR-8) satisfied.	0.49	1.39	-0.029	Algorithm converged.	-0.109	0.050	0.85	Algorithm converged.	0.56	1.31	0.4686	0.2677	1.17	Algorithm converged.	0.76	1.70
		Other	7	3.2	2	28.6	10	4.7	1	10.0	3.60	Convergence criterion (GCNV-IR-8) satisfied.	0.26	50.33	0.184	Algorithm converged.	-0.197	0.569	2.86	Algorithm converged.	0.32	25.72	0.3491	0.35	Algorithm converged.	0.04	3.11	
	Geographical Region	North America	11	5.0	2	18.2	11	5.1	1	9.1	2.22	Convergence criterion (GCNV-IR-8) satisfied.	0.17	28.86	0.091	Algorithm converged.	-0.193	0.375	2.00	Algorithm converged.	0.21	18.98	0.5460	0.6411	0.50	Algorithm converged.	0.09	4.73
		Central and South America	3	1.4	1	33.3	2	0.9				Quasi-complete separation of data points detected.								ERROR: Error in computing the link function, its derivatives, or the variance function.								
		Western Europe	135	60.8	24	17.8	123	57.0	28	22.8	0.73	Convergence criterion (GCNV-IR-8) satisfied.	0.46	1.35	-0.050	Algorithm converged.	-0.148	0.048	0.78	Algorithm converged.	0.48	1.27	0.3201	1.28	Algorithm converged.	0.79	2.08	
		Asia-Pacific	16	7.2	3	18.8	16	7.5	2	12.5	1.62	Convergence criterion (GCNV-IR-8) satisfied.	0.23	11.26	0.063	Algorithm converged.	-0.188	0.313	1.50	Algorithm converged.	0.29	7.81	0.6300	0.67	Algorithm converged.	0.13	3.47	
		Other	33	14.9	5	15.2	36	16.8	6	16.7	0.89	Convergence criterion (GCNV-IR-8) satisfied.	0.24	3.26	-0.018	Algorithm converged.	-0.188	0.157	0.91	Algorithm converged.	0.31	2.70	0.8638	1.10	Algorithm converged.	0.37	3.27	
	FDgamma receptor Ii4	I3HR	46	20.7	7	15.2	53	24.8	11	20.8	0.69	Convergence criterion (GCNV-IR-8) satisfied.	0.24	1.94	-0.055	Algorithm converged.	-0.206	0.095	0.73	Algorithm converged.	0.31	1.74	0.4801	0.5180	1.36	Algorithm converged.	0.98	3.23
		I3HR	88	44.1	15	15.3	83	43.5	18	19.4	0.78	Convergence criterion (GCNV-IR-8) satisfied.	0.35	1.80	-0.040	Algorithm converged.	-0.148	0.067	0.79	Algorithm converged.	0.42	1.48	0.4608	1.26	Algorithm converged.	0.68	2.36	
		I3HR	37	16.7	11	29.7	27	12.6	5	18.5	1.86	Convergence criterion (GCNV-IR-8) satisfied.	0.56	6.18	0.112	Algorithm converged.	-0.096	0.320	1.61	Algorithm converged.	0.63	4.08	0.3203	0.62	Algorithm converged.	0.24	1.58	
		Missing	17	7.7	2	11.8	15	7.0	3	20.0	0.53	Convergence criterion (GCNV-IR-8) satisfied.	0.08	3.72	-0.082	Algorithm converged.	-0.336	0.171	0.59	Algorithm converged.	0.11	3.06	0.5282	1.70	Algorithm converged.	0.33	8.84	
	FDgamma receptor Ii4	I8FF	91	36.5	17	21.0	88	31.8	11	16.2	1.38	Convergence criterion (GCNV-IR-8) satisfied.	0.65	3.18	0.048	Algorithm converged.	-0.076	0.173	1.30	Algorithm converged.	0.65	2.58	0.4573	0.3016	0.77	Algorithm converged.	0.39	1.53
		I8FFV	91	41.0	15	16.5	82	38.3	15	18.3	0.88	Convergence criterion (GCNV-IR-8) satisfied.	0.46	1.94	-0.018	Algorithm converged.	-0.131	0.096	0.90	Algorithm converged.	0.47	1.73	0.7537	1.11	Algorithm converged.	0.58	2.13	
		I8FFV	12	5.4	1	8.3	25	11.7	8	32.0	0.19	Convergence criterion (GCNV-IR-8) satisfied.	0.02	1.77	-0.237	Algorithm converged.	-0.477	0.004	0.26	Algorithm converged.	0.04	1.85	0.1788	3.84	Algorithm converged.	0.54	27.31	
		Missing	14	6.3	2	14.3	13	6.1	3	23.1	0.56	Convergence criterion (GCNV-IR-8) satisfied.	0.08	4.01	-0.088	Algorithm converged.	-0.381	0.205	0.62	Algorithm converged.	0.12	3.13	0.5623	1.62	Algorithm converged.	0.32	8.18	
	Rinet Staging at baseline	A	56	25.2	10	17.9	47	22.0	8	17.0	1.06	Convergence criterion (GCNV-IR-8) satisfied.	0.38	2.95	0.008	Algorithm converged.	-0.139	0.155	1.05	Algorithm converged.	0.45	2.44	0.9115	0.8774	0.95	Algorithm converged.	0.41	2.22
		B	74	33.3	13	17.6	68	31.8	15	22.1	0.75	Convergence criterion (GCNV-IR-8) satisfied.	0.33	1.72	-0.045	Algorithm converged.	-0.176	0.086	0.80	Algorithm converged.	0.41	1.15	0.5027	1.26	Algorithm converged.	0.45	2.44	
		C	68	30.6	12	17.6	73	34.1	14	19.2	0.90	Convergence criterion (GCNV-IR-8) satisfied.	0.38	2.12	-0.015	Algorithm converged.	-0.143	0.113	0.92	Algorithm converged.	0.46	1.85	0.8149	1.08	Algorithm converged.	0.54	2.18	
	Total CIR score at baseline	<=6	47	21.2	3	6.4	55	25.7	6	10.9	0.56	Convergence criterion (GCNV-IR-8) satisfied.	0.13	2.36	-0.043	Algorithm converged.	-0.153	0.063	0.59	Algorithm converged.	0.15	2.21	0.4297	0.5288	1.71	Algorithm converged.	0.49	6.48
		>6	151	68.0	22	21.2	133	62.1	21	23.3	0.88	Convergence criterion (GCNV-IR-8) satisfied.	0.51	1.55	-0.021	Algorithm converged.	-0.118	0.076	0.91	Algorithm converged.	0.59	1.41	0.6684	1.10	Algorithm converged.	0.71	1.70	
	Calculated creatinine clearance cat. 2	<70 ml/min	137	61.7	19	13.9	135	63.1	26	19.3	0.88	Convergence criterion (GCNV-IR-8) satisfied.	0.35	1.29	-0.054	Algorithm converged.	-0.142	0.034	0.72	Algorithm converged.	0.42	1.24	0.2348	0.1977	1.39	Algorithm converged.	0.81	2.39
		>=70 ml/min	61	27.5	16	26.2	53	24.8	11	20.8	1.36	Convergence criterion (GCNV-IR-8) satisfied.	0.57	3.26	0.055	Algorithm converged.	-0.101	0.210	1.26	Algorithm converged.	0.64	2.48	0.4958	0.79	Algorithm converged.	0.40	1.55	
	Beta2 microglobulin	< 3.5 ug/mL	119	53.6	17	14.3	111	51.0	23	20.7	0.64	Convergence criterion (GCNV-IR-8) satisfied.	0.32	1.27	-0.064	Algorithm converged.	-0.163	0.036	0.69	Algorithm converged.	0.39	1.22	0.2018	0.2007	1.45	Algorithm converged.	0.82	2.57
		>= 3.5 ug/mL	76	34.2	17	22.4	75	35.0	14	18.7	1.26	Convergence criterion (GCNV-IR-8) satisfied.	0.57	2.77	0.037	Algorithm converged.	-0.092	0.166	1.20	Algorithm converged.	0.64	2.25	0.5744	0.83	Algorithm converged.	0.44	1.57	
		Missing	3	1.4	1	33.3	2	0.9				Quasi-complete separation of data points detected.								ERROR: The mean parameter is either invalid or at a limit of its range for some observations.								
	Immunoglobulin VH, cytogenetics 2	I1q	35	15.8	8	25.7	32	15.0	9	28.1	0.88	Convergence criterion (GCNV-IR-8) satisfied.	0.30	2.83	-0.024	Algorithm converged.	-0.237	0.189	0.91	Algorithm converged.	0.42	2.01	0.8240	0.2547	1.09	Algorithm converged.	0.90	2.41
		I3q	37	16.7	6	16.2	33	15.4	3	9.1	1.94	Convergence criterion (GCNV-IR-8) satisfied.	0.44	8.45	0.071	Algorithm converged.	-0.083	0.225	1.78	Algorithm converged.	0.48	6.57	0.3844	0.56	Algorithm converged.	0.15	2.07	
		I3q	66	29.7	10	15.2	59	27.6	17	28.8	0.44	Convergence criterion (GCNV-IR-8) satisfied.	0.18	1.06	-0.137	Algorithm converged.	-0.281	0.008	0.53	Algorithm converged.	0.26	1.06	0.0710	1.90	Algorithm converged.	0.93	3.82	
		Other Abn.	14	6.3	4	28.6	17	7.9	2	11.8	3.00	Convergence criterion (GCNV-IR-8) satisfied.	0.46	19.59	0.168	Algorithm converged.	-0.114	0.450	2.43	Algorithm converged.	0.52	11.16	0.2597	0.41	Algorithm converged.	0.09	1.99	

	Norm. W.	46	20.7	4	13.0	47	22.0	6	12.8	1.03	Convergence criterion (GCONV=1E-8) satisfied.	0.30	3.45	0.003	Algorithm converged.	-0.134	0.139	1.02	Algorithm converged.	0.36	2.94	0.9682	0.96	Algorithm converged.	0.34	2.81	
Time from first diagnosis	K= 12 months	45	20.3	12	26.7	54	25.2	10	18.5	1.60	Convergence criterion (GCONV=1E-8) satisfied.	0.62	4.15	0.081	Algorithm converged.	-0.084	0.247	1.44	Algorithm converged.	0.69	3.02	0.3342	0.3618	0.69	Algorithm converged.	0.33	1.40
	13 - 24 months	32	14.4	4	12.5	26	12.1	4	15.4	0.79	Convergence criterion (GCONV=1E-8) satisfied.	0.18	3.30	-0.029	Algorithm converged.	-0.209	0.151	0.81	Algorithm converged.	0.22	2.94	0.7516	1.23	Algorithm converged.	0.34	4.43	
	>24 months	120	54.1	19	15.8	108	50.5	23	21.3	0.76	Convergence criterion (GCONV=1E-8) satisfied.	0.35	1.35	-0.055	Algorithm converged.	-0.156	0.047	0.74	Algorithm converged.	0.43	1.29	0.2901	1.35	Algorithm converged.	0.78	2.33	
	Missing	1	0.5																								
High circulating tumor burden	<25x10**9 cells/L	46	20.7	12	26.1	49	22.9	5	18.4	1.57	Convergence criterion (GCONV=1E-8) satisfied.	0.59	4.17	0.077	Algorithm converged.	-0.090	0.244	1.42	Algorithm converged.	0.66	3.05	0.3686	0.1903	0.70	Algorithm converged.	0.33	1.51
	>=25x10**9 cells/L	152	68.5	23	15.1	138	64.5	27	19.6	0.73	Convergence criterion (GCONV=1E-8) satisfied.	0.40	1.35	-0.044	Algorithm converged.	-0.132	0.043	0.77	Algorithm converged.	0.47	1.28	0.3197	1.29	Algorithm converged.	0.78	2.14	
	Missing																										

Test for interaction based on RR (Log-Binomial regression)

* indicates convergence problem. Result is uninterpretable. Clinical

out-off: 09MAY2013

Program: root/clinical_studies/R05072759/CDPT7159/R021004/data_analysis/ACE_base/qa/program/t_pco_rsp2.sas

Output: root/clinical_studies/R05072759/CDPT7159/R021004/data_analysis/ACE_CSR_stage2/qa/output/t_pco_rsp2_eq_EQC30W_GLQC30pop_IT_label_09MAY2013_21004.xls 12JAN2021

12:42

7 (Anhang): Ergebnisse für EORTC QLQ-C30 Funktionsskalen – Verschlechterung der Gesundheitsbezogenen Lebensqualität um MID zehn - Subgruppenanalysen aus RCT mit dem zu bewertenden Arzneimittel

POPULATION: Labelpopulation, Intent-to-Treat Patients, Patients with Screening and post Screening EORTC QLQ-C30 result
 ENDPOINT: EORTC QoL 10 - Responder (MID=10), worsening
 MODEL: Unstratified Analysis
 STUDY: CLM1 (B021004), Stage 2
 Dichotomous Analysis by Subgroups (Efficacy)

Global Health Status Scale			CC1b (N=222)				CC1b (N=214)				CC1b vs. CC1b				CC1b vs. CC1b													
Visit	Name	Level	Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference		Relative Risk													
			n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CI	95% Upper CI	Absolute Risk	Convergence Reason	95% Lower CI	95% Upper CI	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI	p-value (I-squared ratio)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI	
Cycle 4 Day 1	All	n/a	190	85.6	33	17.4	188	87.0	44	23.4	0.69			-0.060	Algorithm converged.	-0.141	0.021	0.74	Algorithm converged.	0.50	1.11	0.1477		1.35	Algorithm converged.	0.95	2.02	
	Gender	Male	116	52.3	22	19.0	114	53.3	29	25.4	0.69			-0.061	Algorithm converged.	-0.172	0.042	0.75	Algorithm converged.	0.46	1.22	0.2403	0.9705	1.34	Algorithm converged.	0.82	2.13	
		Female	74	33.3	11	14.9	74	34.6	15	20.3	0.69			-0.054	Algorithm converged.	-0.176	0.068	0.73	Algorithm converged.	0.56	1.49	0.3907		1.36	Algorithm converged.	0.87	2.77	
	Age	<75 years	97	43.7	17	17.5	93	43.5	18	19.4	0.89			-0.018	Algorithm converged.	-0.129	0.092	0.91	Algorithm converged.	0.50	1.65	0.7452	0.3789	1.10	Algorithm converged.	0.61	2.01	
		>=75 years	93	41.9	16	17.2	85	44.4	26	27.4	0.55			-0.102	Algorithm converged.	-0.220	0.016	0.63	Algorithm converged.	0.36	1.09	0.1001		1.59	Algorithm converged.	0.91	2.77	
	Race	White	183	82.4	31	16.9	186	84.1	42	23.3	0.67			-0.064	Algorithm converged.	-0.146	0.018	0.73	Algorithm converged.	0.48	1.10	0.1314	0.6097	1.38	Algorithm converged.	0.91	2.02	
		Other	7	3.2	2	28.6	8	3.7	2	25.0	1.00			0.12	11.87	0.036	1.14	Algorithm converged.	0.21	6.11	0.8760		0.88	Algorithm converged.	0.16	4.68		
	Geographical Region	North America	9	4.1	4	44.4	10	4.7	3	30.0	1.87			0.28	12.31	0.144	1.48	Algorithm converged.	-0.287	0.576	0.5194		0.68	Algorithm converged.	0.20	2.23		
		Central and South America	3	1.4			2	0.9																				
		Western Europe	131	59.0	23	17.6	129	60.3	35	27.1	0.87			-0.096	Algorithm converged.	-0.196	0.005	0.85	Algorithm converged.	0.41	1.03	0.6675		1.55	Algorithm converged.	0.97	2.46	
		Asia-Pacific	15	6.8	1	6.7	14	6.5	1	7.1	0.93			-0.005	Algorithm converged.	-0.190	0.180	0.93	Algorithm converged.	0.56	13.54	0.9597		1.01	Algorithm converged.	0.07	15.54	
		Other	32	14.4	5	15.6	33	15.4	5	15.2	1.04			0.27	3.99	0.005	1.03	Algorithm converged.	-0.171	0.180	1.03		0.97	Algorithm converged.	0.31	3.03		
	PDgamma receptor 1fa	131HR	42	18.8	6	14.3	57	26.6	11	19.3	0.70			-0.050	Algorithm converged.	-0.197	0.097	0.74	Algorithm converged.	0.30	1.84	0.5178	0.9933	1.35	Algorithm converged.	0.54	3.35	
		131HR	94	42.3	17	18.1	97	45.3	25	25.8	0.64			-0.077	Algorithm converged.	-0.194	0.040	0.70	Algorithm converged.	0.41	1.21	0.2043		1.43	Algorithm converged.	0.82	2.48	
		131RR	37	16.7	7	18.9	22	10.3	5	22.7	0.79			-0.038	Algorithm converged.	-0.254	0.178	0.83	Algorithm converged.	0.30	2.31	0.7243		1.20	Algorithm converged.	0.43	3.33	
		Missing	17	7.7	3	17.6	12	5.6	3	25.0	0.64			-0.074	Algorithm converged.	-0.378	0.231	0.71	Algorithm converged.	0.17	2.92	0.6306		1.42	Algorithm converged.	0.34	5.88	
	PDgamma receptor 1fa	158FF	79	35.6	14	17.7	67	31.3	16	23.9	0.69			-0.062	Algorithm converged.	-0.194	0.071	0.74	Algorithm converged.	0.39	1.41	0.1604	0.8494	1.35	Algorithm converged.	0.71	2.55	
		158FV	88	39.6	14	15.9	82	38.3	20	24.4	0.59			-0.085	Algorithm converged.	-0.205	0.036	0.65	Algorithm converged.	0.35	1.20	0.1720		1.53	Algorithm converged.	0.83	2.83	
		158WV	11	5.0	2	18.2	28	13.1	6	21.4	0.81			-0.032	Algorithm converged.	-0.306	0.241	0.85	Algorithm converged.	0.20	3.58	0.8231		1.18	Algorithm converged.	0.28	4.98	
		Missing	12	5.4	3	25.0	11	5.1	2	18.2	1.00			0.20	11.24	0.068	1.37	Algorithm converged.	0.28	6.75	0.6949		0.73	Algorithm converged.	0.15	3.57		
	Binet Staging at baseline	A	47	21.2	10	21.3	46	21.5	9	19.6	1.11			0.40	3.05	0.017	1.09	Algorithm converged.	-0.147	0.181	0.1707		0.92	Algorithm converged.	0.41	2.03		
		B	80	36.0	14	17.5	72	33.6	13	18.1	0.96			-0.006	Algorithm converged.	-0.127	0.116	0.97	Algorithm converged.	0.49	1.92	0.9287		1.03	Algorithm converged.	0.52	2.05	
		C	63	28.4	9	14.3	70	32.7	22	31.4	0.38			-0.171	Algorithm converged.	-0.310	-0.033	0.45	Algorithm converged.	0.23	0.91	0.0266		2.20	Algorithm converged.	1.10	4.42	
	Total CIR score at baseline	<=6	43	19.4	7	16.3	59	27.6	15	23.4	0.87			-0.091	Algorithm converged.	-0.248	0.065	0.64	Algorithm converged.	0.29	1.43	0.2786	0.6620	1.56	Algorithm converged.	0.70	3.50	
		>=6	147	66.2	26	17.7	129	60.3	29	22.5	0.74			-0.048	Algorithm converged.	-0.143	0.047	0.79	Algorithm converged.	0.49	1.26	0.3210		1.27	Algorithm converged.	0.79	2.91	
	Calculated creatinine clearance cat. 2	<70 ml/min	128	57.7	20	15.6	138	64.5	36	26.1	0.52			-0.103	Algorithm converged.	-0.201	-0.008	0.60	Algorithm converged.	0.37	0.98	0.0407	0.0949	1.67	Algorithm converged.	1.02	2.73	
		>=70 ml/min	62	27.9	13	21.0	50	23.4	8	16.0	1.39			0.53	3.68	0.050	1.31	Algorithm converged.	-0.094	0.193	1.31		0.76	Algorithm converged.	0.34	1.69		
	Hsata2 microglobulin	< 3.5 ug/mL	114	51.4	22	19.3	106	49.5	24	22.6	0.82			-0.031	Algorithm converged.	-0.141	0.074	0.85	Algorithm converged.	0.51	1.43	0.5428	0.2175	1.17	Algorithm converged.	0.70	1.94	
		>= 3.5 ug/mL	73	32.8	9	12.3	80	37.4	20	25.0	0.42			-0.127	Algorithm converged.	-0.248	-0.006	0.49	Algorithm converged.	0.24	1.01	0.0543		2.03	Algorithm converged.	0.99	4.17	

Calculated creatinine clearance cat. 2	<70 ml/min	134	60.4	23	17.2	134	62.6	28	20.9	0.78	Convergence criterion (GCNV-IE-8) satisfied.	0.43	1.45	-0.037	Algorithm converged.	-0.131	0.057	0.82	Algorithm converged.	0.50	1.35	0.4378	0.8993	1.22	Algorithm converged.	0.74	2.00	
	>=70 ml/min	62	27.9	13	21.0	52	24.3	14	26.9	0.72	Convergence criterion (GCNV-IE-8) satisfied.	0.30	1.71	-0.040	Algorithm converged.	-0.217	0.098	0.78	Algorithm converged.	0.40	1.51	0.4570		1.28	Algorithm converged.	0.66	2.48	
Beta2 microglobulin	< 3.5 ug/mL	118	53.2	22	18.6	109	50.9	23	22.9	0.77	Convergence criterion (GCNV-IE-8) satisfied.	0.40	1.47	-0.043	Algorithm converged.	-0.149	0.063	0.81	Algorithm converged.	0.49	1.35	0.4263	0.8844	1.23	Algorithm converged.	0.74	2.03	
	>= 3.5 ug/mL	75	33.8	13	17.3	75	35.0	17	22.7	0.72	Convergence criterion (GCNV-IE-8) satisfied.	0.32	1.65	-0.053	Algorithm converged.	-0.181	0.074	0.76	Algorithm converged.	0.40	1.46	0.4166		1.33	Algorithm converged.	0.68	2.50	
	Missing	3	1.4	1	33.3	2	0.5				Quasi-complete separation of data points detected.								NE	Algorithm converged.	NE	NE	NE	NE	Algorithm converged.	NE	NE	
Immunoglobulin VH, cytogenetics 2	12	34	15.3	11	32.4	32	15.0	8	25.0	1.43	Convergence criterion (GCNV-IE-8) satisfied.	0.49	4.21	0.074	Algorithm converged.	-0.144	0.291	1.29	Algorithm converged.	0.60	2.80	0.5129	0.0912	0.73	Algorithm converged.	0.36	1.67	
	11q-	36	16.2	10	27.8	34	15.9	5	14.7	2.23	Convergence criterion (GCNV-IE-8) satisfied.	0.67	7.38	0.131	Algorithm converged.	-0.058	0.319	1.89	Algorithm converged.	0.72	4.96	0.1968		0.53	Algorithm converged.	0.20	1.38	
	13q-	66	29.7	6	9.1	38	27.1	13	22.4	0.35	Convergence criterion (GCNV-IE-8) satisfied.	0.12	0.98	-0.133	Algorithm converged.	-0.261	-0.005	0.41	Algorithm converged.	0.16	1.00	0.0496		2.47	Algorithm converged.	1.00	6.07	
	Other Abn.	14	6.3	3	21.4	17	7.9	5	29.4	0.63	Convergence criterion (GCNV-IE-8) satisfied.	0.13	3.40	-0.080	Algorithm converged.	-0.385	0.225	0.73	Algorithm converged.	0.21	2.53	0.6179		1.37	Algorithm converged.	0.40	4.76	
	Norm. K.	46	20.7	6	13.0	45	21.0	11	24.4	0.46	Convergence criterion (GCNV-IE-8) satisfied.	0.16	1.39	-0.114	Algorithm converged.	-0.273	0.045	0.53	Algorithm converged.	0.22	1.32	0.1741		1.87	Algorithm converged.	0.76	4.61	
Time from first diagnosis	<= 12 months	44	19.8	9	20.5	54	25.2	11	20.4	1.01	Convergence criterion (GCNV-IE-8) satisfied.	0.37	2.70	0.001	Algorithm converged.	-0.160	0.161	1.00	Algorithm converged.	0.46	2.20	0.9918	0.8308	1.00	Algorithm converged.	0.45	2.19	
	13 - 24 months	31	14.0	4	12.9	26	12.1	4	15.4	0.81	Convergence criterion (GCNV-IE-8) satisfied.	0.18	3.64	-0.025	Algorithm converged.	-0.207	0.157	0.84	Algorithm converged.	0.23	3.03	0.7893		1.18	Algorithm converged.	0.33	4.31	
	>24 months	120	56.1	23	19.2	106	49.5	27	25.5	0.69	Convergence criterion (GCNV-IE-8) satisfied.	0.37	1.30	-0.061	Algorithm converged.	-0.172	0.046	0.75	Algorithm converged.	0.46	1.23	0.2562		1.33	Algorithm converged.	0.81	2.11	
	Missing	1	0.5																									
High circulating tumor burden	<25x10**9 cells/L	45	20.3	11	24.4	48	22.4	10	20.8	1.23	Convergence criterion (GCNV-IE-8) satisfied.	0.46	3.25	0.034	Algorithm converged.	-0.134	0.206	1.17	Algorithm converged.	0.55	2.49	0.6776	0.2657	0.85	Algorithm converged.	0.40	1.81	
	>=25x10**9 cells/L	151	68.0	25	16.6	137	64.0	32	23.4	0.65	Convergence criterion (GCNV-IE-8) satisfied.	0.36	1.17	-0.068	Algorithm converged.	-0.160	0.024	0.71	Algorithm converged.	0.44	1.13	0.1506		1.41	Algorithm converged.	0.88	2.26	
	Missing																											

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable. Clinical cut-off: 0.9642013

Program: root/clinical_studies/R05072759/CDPT7159/B021004/data_analysis/ACE_base/ga/program/t_pro_rsp2.sas
 Output: root/clinical_studies/R05072759/CDPT7159/B021004/data_analysis/ACE_CSR_stage2/ga/output/t_pro_rsp2_ag_BQC30W_QQC30pop_IT_label1_09MAY2013_21004.xls 12JAN2021 12:42

POPULATION: Labelpopulation, Intent-to-Treat Patients, Patients with Screening and post Screening EORTC QLQ-C30 result
 ENDPOINT: EORTC QoL 10 - Responder (RID=10), worsening
 MODEL: Unstratified Analysis
 STUDY: CLL11(B021004), Stage 2
 Dichotomous Analysis by Subgroups (Efficacy)

Cognitive Functioning Scale			QC1b (N=222)				QC1b (N=214)				Odds Ratio					Absolute Risk Difference					Relative Risk					QC1b vs. QC1b Relative Risk			
Visit	Name	Level	n	t	n	t	n	t	n	t	Odds Ratio	95% Lower CI	95% Upper CI	Absolute Risk	Convergence Reason	95% Lower CI	95% Upper CI	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI	p-value (Wald)	Interacti on Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI		
Cycle 4 Day 1	All	n/a	193	86.9	44	22.8	195	88.8	46	24.2	0.92	0.58	1.48	-0.014	Algorithm converged.	-0.099	0.071	0.94	Algorithm converged.	0.66	1.33	0.7445		1.06	Algorithm converged.	0.74	1.52		
	Gender	Male	117	52.7	28	23.9	116	54.2	30	25.9	0.90	0.55	1.43	-0.019	Algorithm converged.	-0.130	0.092	0.93	Algorithm converged.	0.59	1.45	0.7334	0.8951	1.08	Algorithm converged.	0.69	1.60		
		Female	76	34.2	16	21.1	74	34.6	16	21.6	0.97	0.44	2.11	-0.006	Algorithm converged.	-0.137	0.125	0.97	Algorithm converged.	0.53	1.80	0.9322		1.03	Algorithm converged.	0.56	1.90		
	Age	<75 years	99	44.6	23	22.2	93	43.3	20	21.5	1.04	0.53	2.07	0.007	Algorithm converged.	-0.110	0.124	1.03	Algorithm converged.	0.60	1.76	0.9044	0.6494	0.97	Algorithm converged.	0.57	1.65		
		>=75 years	94	42.3	22	23.4	97	45.3	26	26.8	0.83	0.43	1.61	-0.034	Algorithm converged.	-0.157	0.088	0.87	Algorithm converged.	0.53	1.43	0.5888		1.15	Algorithm converged.	0.70	1.87		
	Race	White	186	83.8	42	22.6	181	84.6	43	23.8	0.94	0.58	1.52	-0.012	Algorithm converged.	-0.098	0.075	0.95	Algorithm converged.	0.65	1.38	0.7894	0.8946	1.05	Algorithm converged.	0.72	1.53		
		Other	7	3.2	2	28.6	9	4.2	3	33.3	0.80	0.09	6.85	-0.048	Algorithm converged.	-0.502	0.407	0.86	Algorithm converged.	0.19	3.81	0.8395		1.17	Algorithm converged.	0.26	5.19		
	Geographical Region	North America	9	4.1	3	33.3	11	5.1	3	27.3	1.33	0.20	9.08	0.061	Algorithm converged.	-0.345	0.466	1.22	Algorithm converged.	0.32	4.65	0.7685	0.7632	0.82	Algorithm converged.	0.22	3.11		
		Central and South America	3	1.4	1	33.3	2	0.9							Quasi-complete separation of data points detected.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE		
		Western Europe	133	59.9	27	20.3	129	60.3	21	24.0	0.83	0.45	1.44	-0.037	Algorithm converged.	-0.138	0.063	0.84	Algorithm converged.	0.54	1.33	0.4680		1.18	Algorithm converged.	0.75	1.87		
		Asia-Pacific	15	6.8	6	40.0	14	6.5	6	42.9	0.89	0.25	3.95	-0.029	Algorithm converged.	-0.387	0.330	0.93	Algorithm converged.	0.39	2.22	0.8759		1.07	Algorithm converged.	0.45	2.55		
		Other	33	14.9	7	21.2	34	15.9	6	17.6	1.28	0.37	4.23	0.038	Algorithm converged.	-0.154	0.225	1.20	Algorithm converged.	0.45	3.20	0.7128		0.83	Algorithm converged.	0.31	2.22		
	FCgamma receptor 1fa	131HR	42	18.9	10	23.8	39	27.6	12	20.3	1.22	0.47	3.17	0.035	Algorithm converged.	-0.130	0.199	1.17	Algorithm converged.	0.56	2.45	0.6745	0.8487	0.85	Algorithm converged.	0.41	1.73		
		131HR	96	43.2	24	25.0	97	45.3	26	26.8	0.91	0.48	1.73	-0.018	Algorithm converged.	-0.142	0.106	0.93	Algorithm converged.	0.58	1.50	0.7750		1.07	Algorithm converged.	0.66	1.70		
		131RR	38	17.1	7	18.4	22	10.3	6	27.3	0.80	0.17	2.09	-0.089	Algorithm converged.	-0.312	0.135	0.88	Algorithm converged.	0.26	1.76	0.4210		1.48	Algorithm converged.	0.37	3.85		
		Missing	17	7.7	3	17.6	12	5.8	2	16.7	1.07	0.15	7.64	0.010	Algorithm converged.	-0.268	0.288	1.06	Algorithm converged.	0.21	5.40	0.9452		0.94	Algorithm converged.	0.19	4.87		
	FCgamma receptor 1fa	158FP	81	36.5	13	16.0	89	32.2	15	21.7	0.89	0.30	1.87	-0.057	Algorithm converged.	-0.183	0.069	0.74	Algorithm converged.	0.38	1.44	0.3745	0.8749	1.35	Algorithm converged.	0.69	2.65		
		158PV	89	40.1	28	29.2	82	38.3	23	28.0	1.06	0.55	2.06	0.012	Algorithm converged.	-0.124	0.147	1.04	Algorithm converged.	0.65	1.67	0.8664		0.96	Algorithm converged.	0.60	1.51		
		158VV	11	5.0	2	18.2	28	13.1	5	17.9	1.02	0.17	6.26	0.003	Algorithm converged.	-0.265	0.272	1.02	Algorithm converged.	0.23	4.49	0.9810		0.98	Algorithm converged.	0.22	4.33		
		Missing	12	5.4	3	25.0	11	5.1	3	27.3	0.89	0.14	5.72	-0.023	Algorithm converged.	-0.382	0.337	0.92	Algorithm converged.	0.23	3.63	0.9013		1.09	Algorithm converged.	0.28	4.32		
	Binet Staging at baseline	A	48	21.6	13	27.1	47	22.0	10	21.3	1.37	0.53	3.54	0.058	Algorithm converged.	-0.114	0.230	1.27	Algorithm converged.	0.62	2.61	0.5110	0.3307	0.79	Algorithm converged.	0.38	1.61		
		B	80	36.0	14	17.5	72	33.6	19	26.4	0.59	0.27	1.29	-0.089	Algorithm converged.	-0.220	0.043	0.66	Algorithm converged.	0.36	1.22	0.1888		1.51	Algorithm converged.	0.82	2.78		
		C	65	29.3	17	26.2	71	33.2	17	23.9	1.13	0.52	2.45	0.022	Algorithm converged.	-0.124	0.168	1.09	Algorithm converged.	0.61	1.95	0.7662		0.92	Algorithm converged.	0.51	1.61		
	Total CIR score at baseline	<=6	43	19.4	6	14.0	39	27.6	14	23.7	0.82	0.18	1.49	-0.098	Algorithm converged.	-0.248	0.052	0.59	Algorithm converged.	0.25	1.41	0.2326	0.2331	1.70	Algorithm converged.	0.71	4.07		
		>6	150	67.6	38	25.3	131	61.2	32	24.4	1.05	0.61	1.81	0.009	Algorithm converged.	-0.092	0.110	1.04	Algorithm converged.	0.69	1.56	0.8610		0.96	Algorithm converged.	0.64	1.45		
	Calculated creatinine clearance cat. 2	<70 ml/min	131	59.0	21	16.0	139	65.0	32	23.0	0.64	0.35	1.18	-0.070	Algorithm converged.	-0.164	0.024	0.70	Algorithm converged.	0.42	1.14	0.1527	0.0745	1.44	Algorithm converged.	0.87	2.38		
		>=70 ml/min	62	27.8	23	37.1	51	23.8	14	27.5	1.56	0.75	3.48	0.096	Algorithm converged.	-0.075	0.268	1.35	Algorithm converged.	0.78	2.35	0.2845		0.74	Algorithm converged.	0.43	1.28		
	Beta2 microglobulin	< 3.5 ug/mL	115	51.8	29	25.2	108	50.3	25	23.1	1.12	0.61	2.07	0.021	Algorithm converged.	-0.092	0.133	1.09	Algorithm converged.	0.68	1.74	0.7188	0.2665	0.92	Algorithm converged.	0.58	1.46		
		>= 3.5 ug/mL	75	33.8	14	18.7	80	37.4	21	26.3	0.64	0.30	1.39	-0.076	Algorithm converged.	-0.206	0.055	0.71	Algorithm converged.	0.39	1.29	0.2641		1.41	Algorithm converged.	0.77	2.56		
		Missing	3	1.4	1	33.3	2	0.9							Quasi-complete separation of data points detected.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE		
	Immunoglobulin VH, cytogenetics 2	12	31	14.0	9	29.0	33	15.4	9	27.3	1.09	0.37	3.25	0.018	Algorithm converged.	-0.203	0.238	1.06	Algorithm converged.	0.49	2.33	0.8757	0.9631	0.94	Algorithm converged.	0.43	2.06		
		11q-	39	17.6	7	17.9	34	15.9	7	20.6	0.84	0.26	2.71	-0.024	Algorithm converged.	-0.208	0.155	0.87	Algorithm converged.	0.34	2.23	0.7751		1.15	Algorithm converged.	0.45	2.91		
		13q-	80	27.6	18	26.7	58	27.1	16	27.6	0.95	0.42	2.15	-0.009	Algorithm converged.	-0.176	0.151	0.97	Algorithm converged.	0.54	1.75	0.9106		1.03	Algorithm converged.	0.57	1.87		

		13q-	66	29.7	14	24.2	59	27.6	18	27.1	0.88		Convergence criterion (GCONV=1E-8) satisfied.	0.38	1.92	-0.029	Algorithm converged.	-0.182	0.125	0.89		Algorithm converged.	0.49	1.62	0.7130		1.12	Algorithm converged.	0.62	2.03
		Other Abn.	14	6.3	4	28.6	17	7.9	6	35.3	0.73		Convergence criterion (GCONV=1E-8) satisfied.	0.16	3.38	-0.047	Algorithm converged.	-0.395	0.261	0.81		Algorithm converged.	0.28	2.31	0.6930		1.24	Algorithm converged.	0.43	3.51
		Norm. K.	46	20.7	10	21.7	46	21.5	17	37.0	0.47		Convergence criterion (GCONV=1E-8) satisfied.	0.19	1.19	-0.152	Algorithm converged.	-0.336	0.031	0.59		Algorithm converged.	0.30	1.14	0.1182		1.70	Algorithm converged.	0.87	3.31
		Time from first diagnosis											Convergence criterion (GCONV=1E-8) satisfied.																	
		K ≤ 12 months	44	19.8	13	29.5	56	25.2	15	27.8	1.09		Convergence criterion (GCONV=1E-8) satisfied.	0.45	2.63	0.018	Algorithm converged.	-0.162	0.198	1.06		Algorithm converged.	0.57	1.99	0.8471	0.5446	0.94	Algorithm converged.	0.50	1.70
		13 - 24 months	32	14.4	6	18.8	26	12.1	6	23.1	0.77		Convergence criterion (GCONV=1E-8) satisfied.	0.22	2.75	-0.043	Algorithm converged.	-0.254	0.168	0.81		Algorithm converged.	0.30	2.22	0.6859		1.23	Algorithm converged.	0.45	3.37
		>24 months	121	54.5	28	23.1	108	50.5	36	33.3	0.60		Convergence criterion (GCONV=1E-8) satisfied.	0.34	1.08	-0.102	Algorithm converged.	-0.218	0.014	0.69		Algorithm converged.	0.46	1.06	0.0887		1.44	Algorithm converged.	0.95	2.10
		Missing	1	0.5																										
		High circulating tumor burden											Convergence criterion (GCONV=1E-8) satisfied.																	
		K ≥ 5x10 ⁹ cells/L	46	20.7	14	30.4	49	22.9	12	24.5	1.35		Convergence criterion (GCONV=1E-8) satisfied.	0.55	3.33	0.059	Algorithm converged.	-0.120	0.238	1.24		Algorithm converged.	0.64	2.40	0.5172	0.1219	0.80	Algorithm converged.	0.42	1.50
		>=25x10 ⁹ cells/L	152	68.5	33	21.7	138	64.5	44	31.9	0.59		Convergence criterion (GCONV=1E-8) satisfied.	0.35	1.00	-0.102	Algorithm converged.	-0.203	0.000	0.68		Algorithm converged.	0.46	1.00	0.0523		1.47	Algorithm converged.	1.00	2.16
		Missing																												

Test for interaction based on RR (Log-Binomial regression)
 * indicates convergence problem. Result is uninterpretable. Clinical
 out-off: 09MAY2013

Program: root/clinical_studies/R05072759/CDPT7159/R021004/data_analysis/ACT_base/qa/program/t_gro_rsp2.sas
 Output: root/clinical_studies/R05072759/CDPT7159/R021004/data_analysis/ACR_CSR_stage2/qa/output/t_gro_rsp2_eq_EQC30W_GLQC30pop_IT_label_09MAY2013_21004.xls 12JAN2021
 12:42

POPULATION: Labelpopulation, Intent-to-Treat Patients, Patients with Screening and post Screening EORTC QLQ-C30 result
 ENDPOINT: EORTC QoL 30 - Responder (MID=10), worsening
 MODEL: Unstratified Analysis
 STUDY: CLL1 (R021004), Stage 2
 Dichotomous Analysis by Subgroups (Efficacy)

Emotional Functioning Scale			GC1b (N=222)				RC1b (N=214)				GC1b vs. RC1b								RC1b vs. GC1b										
Visit	Name	Level	Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference				Relative Risk				Relative Risk								
			n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CI	95% Upper CI	Absolute Risk	Convergence Reason	95% Lower CI	95% Upper CI	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI	p-value (Wald)	Interacti on Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI		
Cycle 4 Day 1	All	n/a	192	86.5	20	10.4	190	88.8	26	13.7	0.73	Convergence criterion (GCONV-IR-8) satisfied.	0.39	1.36	-0.033	Algorithm converged.	-0.098	0.033	0.76	Algorithm converged.	0.44	1.32	0.3286		1.33	Algorithm converged.	0.76	2.27	
Gender	Male		117	52.7	13	11.1	116	54.2	14	12.1	0.91	Convergence criterion (GCONV-IR-8) satisfied.	0.41	2.03	-0.010	Algorithm converged.	-0.092	0.073	0.92	Algorithm converged.	0.45	1.87	0.8194	0.4108	1.05	Algorithm converged.	0.93	2.21	
	Female		75	33.8	7	9.3	74	34.6	12	16.2	0.53	Convergence criterion (GCONV-IR-8) satisfied.	0.20	1.44	-0.069	Algorithm converged.	-0.176	0.038	0.58	Algorithm converged.	0.24	1.38	0.2160		1.74	Algorithm converged.	0.72	4.17	
Age	<75 years		99	44.6	15	15.2	93	43.5	11	11.8	1.33	Convergence criterion (GCONV-IR-8) satisfied.	0.98	3.07	0.033	Algorithm converged.	-0.063	0.130	1.28	Algorithm converged.	0.62	2.64	0.5030	0.0273	0.78	Algorithm converged.	0.38	1.61	
	>=75 years		93	41.9	5	5.4	87	45.3	15	15.5	0.31	Convergence criterion (GCONV-IR-8) satisfied.	0.11	0.89	-0.101	Algorithm converged.	-0.186	-0.016	0.35	Algorithm converged.	0.13	0.92	0.0330		2.88	Algorithm converged.	1.09	7.60	
Race	White		185	83.3	19	10.3	181	84.6	25	13.8	0.71	Convergence criterion (GCONV-IR-8) satisfied.	0.38	1.35	-0.035	Algorithm converged.	-0.102	0.031	0.74	Algorithm converged.	0.42	1.30	0.2999	0.6877	1.34	Algorithm converged.	0.77	2.31	
	Other		7	3.2	1	14.3	9	4.2	1	11.1	1.33	Convergence criterion (GCONV-IR-8) satisfied.	0.07	25.91	0.032	Algorithm converged.	-0.299	0.362	1.29	Algorithm converged.	0.10	17.14	0.8492		0.78	Algorithm converged.	0.06	10.37	
Geographical Region	North America		9	4.1	2	22.2	11	5.1	1	9.1	2.84	Convergence criterion (GCONV-IR-8) satisfied.	0.21	37.99	0.131	Algorithm converged.	-0.189	0.452	2.44	Algorithm converged.	0.26	22.80	0.4327		0.41	Algorithm converged.	0.04	3.82	
	Central and South America		3	1.4			2	0.9																					
	Western Europe		132	59.5	13	9.8	129	60.3	21	16.3	0.56	Convergence criterion (GCONV-IR-8) satisfied.	0.27	1.18	-0.064	Algorithm converged.	-0.146	0.017	0.60	Algorithm converged.	0.32	1.16	0.1283		1.65	Algorithm converged.	0.86	3.10	
	Asia-Pacific		15	6.8	2	13.3	14	6.5				Quasi-complete separation of data points detected.				NE				NE						NE		NE	NE
Other	Other		33	14.9	3	9.1	34	15.9	4	11.8	0.75	Convergence criterion (GCONV-IR-8) satisfied.	0.15	3.64	-0.027	Algorithm converged.	-0.173	0.119	0.77	Algorithm converged.	0.19	3.19	0.7216		1.29	Algorithm converged.	0.31	5.34	
PDgamma receptor 1a	131HR		42	18.9	4	9.5	38	27.6	5	15.3	0.88	Convergence criterion (GCONV-IR-8) satisfied.	0.17	2.06	-0.057	Algorithm converged.	-0.185	0.070	0.62	Algorithm converged.	0.21	1.89	0.4053		1.60	Algorithm converged.	0.33	4.86	
	131HR		96	43.2	11	11.9	87	45.3	17	17.5	0.61	Convergence criterion (GCONV-IR-8) satisfied.	0.27	1.38	-0.061	Algorithm converged.	-0.160	0.038	0.65	Algorithm converged.	0.32	1.32	0.2368		1.53	Algorithm converged.	0.76	3.09	
	131RR		38	17.1	4	10.5	22	10.3				Quasi-complete separation of data points detected.				NE				NE					NE		NE	NE	
	Missing		16	7.2	1	6.3	12	5.6				Quasi-complete separation of data points detected.				NE				NE					NE		NE	NE	
PDgamma receptor 1a	158FF		81	36.5	6	7.4	69	32.2	11	15.9	0.42	Convergence criterion (GCONV-IR-8) satisfied.	0.19	1.21	-0.083	Algorithm converged.	-0.189	0.018	0.46	Algorithm converged.	0.18	1.19	0.1106	0.1808	2.15	Algorithm converged.	0.84	5.52	
	158VV		89	40.1	11	12.4	82	38.3	13	15.9	0.75	Convergence criterion (GCONV-IR-8) satisfied.	0.31	1.78	-0.035	Algorithm converged.	-0.139	0.070	0.78	Algorithm converged.	0.37	1.64	0.5123		1.28	Algorithm converged.	0.61	2.70	
	158VV		11	5.0	1	9.1	28	13.1	2	7.1	1.30	Convergence criterion (GCONV-IR-8) satisfied.	0.11	15.98	0.019	Algorithm converged.	-0.175	0.014	1.27	Algorithm converged.	0.13	12.66	0.8370		0.79	Algorithm converged.	0.08	7.81	
	Missing		11	5.0	2	18.2	11	5.1				Quasi-complete separation of data points detected.				NE				NE					NE		NE	NE	
Binet Staging at baseline	A		47	21.2	7	14.9	47	22.0	6	12.8	1.20	Convergence criterion (GCONV-IR-8) satisfied.	0.37	3.87	0.021	Algorithm converged.	-0.118	0.161	1.17	Algorithm converged.	0.42	3.21	0.7654	0.3801	0.86	Algorithm converged.	0.31	2.36	
	B		80	36.0	8	10.0	72	33.6	8	11.1	0.89	Convergence criterion (GCONV-IR-8) satisfied.	0.32	2.51	-0.011	Algorithm converged.	-0.109	0.087	0.90	Algorithm converged.	0.36	2.27	0.8237		1.11	Algorithm converged.	0.44	2.81	
	C		65	29.3	5	7.7	71	33.2	12	16.9	0.41	Convergence criterion (GCONV-IR-8) satisfied.	0.14	1.24	-0.092	Algorithm converged.	-0.201	0.017	0.46	Algorithm converged.	0.17	1.22	0.1182		2.20	Algorithm converged.	0.82	5.90	
Total CIR score at baseline	<=6		43	19.4	4	9.3	39	27.6	8	13.6	0.65	Convergence criterion (GCONV-IR-8) satisfied.	0.18	2.33	-0.042	Algorithm converged.	-0.166	0.081	0.69	Algorithm converged.	0.22	2.13	0.5149	0.8423	1.46	Algorithm converged.	0.47	4.95	
	>6		149	67.1	16	10.7	131	61.2	18	13.7	0.76	Convergence criterion (GCONV-IR-8) satisfied.	0.37	1.55	-0.030	Algorithm converged.	-0.107	0.047	0.78	Algorithm converged.	0.42	1.47	0.4440		1.28	Algorithm converged.	0.68	2.41	
Calculated creatinine clearance cat. 2	<70 ml/min		130	58.6	8	6.2	139	65.0	18	12.9	0.44	Convergence criterion (GCONV-IR-8) satisfied.	0.18	1.05	-0.068	Algorithm converged.	-0.137	0.001	0.48	Algorithm converged.	0.21	1.06	0.0676	0.0934	2.10	Algorithm converged.	0.99	4.67	
	>=70 ml/min		62	27.9	12	19.4	51	23.8	8	15.7	1.29	Convergence criterion (GCONV-IR-8) satisfied.	0.48	3.45	0.037	Algorithm converged.	-0.103	0.177	1.23	Algorithm converged.	0.55	2.79	0.6130		0.81	Algorithm converged.	0.36	1.83	
Beta2 microglobulin	< 3.5 ug/mL		114	51.4	14	12.3	108	50.5	13	12.0	1.02	Convergence criterion (GCONV-IR-8) satisfied.	0.46	2.29	0.002	Algorithm converged.	-0.084	0.088	1.02	Algorithm converged.	0.50	2.07	0.9557	0.2085	0.98	Algorithm converged.	0.48	1.99	
	>= 3.5 ug/mL		75	33.8	6	8.0	80	37.4	13	16.3	0.45	Convergence criterion (GCONV-IR-8) satisfied.	0.16	1.25	-0.083	Algorithm converged.	-0.184	0.019	0.49	Algorithm converged.	0.20	1.23	0.1289		2.03	Algorithm converged.	0.81	5.07	
	Missing		3	1.4			2	0.9																					

		13q-	65	29.3	11	16.9	59	27.6	15	23.4	0.60	Convergence criterion (GCONV=1E-8) satisfied.	0.25	1.43	-0.085	Algorithm converged.	-0.229	0.059	0.61	Algorithm converged.	0.33	1.33	0.2501	1.50	Algorithm converged.	0.75	3.01	
		Other Abn.	14	6.3	3	21.4	17	7.9	2	11.8	2.05	Convergence criterion (GCONV=1E-8) satisfied.	0.29	14.39	0.097	Algorithm converged.	-0.167	0.361	1.82	Algorithm converged.	0.35	9.42	0.4745	0.55	Algorithm converged.	0.11	2.81	
		Norm. K.	46	20.7	5	10.9	46	21.5	5	10.9	1.00	Convergence criterion (GCONV=1E-8) satisfied.	0.27	3.72	0.000	Algorithm converged.	-0.127	0.127	1.00	Algorithm converged.	0.31	3.22	1.0000	1.00	Algorithm converged.	0.31	3.22	
		Time from first diagnosis										Convergence criterion (GCONV=1E-8) satisfied.																
		K ≤ 12 months	44	19.8	11	25.0	56	25.2	6	16.7	1.67	Convergence criterion (GCONV=1E-8) satisfied.	0.62	4.48	0.083	Algorithm converged.	-0.079	0.245	1.50	Algorithm converged.	0.68	3.29	0.3119	0.7516	0.67	Algorithm converged.	0.30	1.40
		13 - 24 months	32	14.4	4	12.5	26	12.1	3	11.5	1.10	Convergence criterion (GCONV=1E-8) satisfied.	0.22	5.40	0.010	Algorithm converged.	-0.156	0.176	1.05	Algorithm converged.	0.27	4.41	0.9111	0.92	Algorithm converged.	0.23	3.76	
		>24 months	120	54.1	17	14.2	108	50.5	15	13.9	1.02	Convergence criterion (GCONV=1E-8) satisfied.	0.48	2.16	0.003	Algorithm converged.	-0.087	0.093	1.02	Algorithm converged.	0.54	1.94	0.9519	0.98	Algorithm converged.	0.51	1.87	
		Missing	1	0.5																								
		High circulating tumor burden										Convergence criterion (GCONV=1E-8) satisfied.																
		K ≥ 25x10 ⁹ cells/L	46	20.7	8	17.4	49	22.9	4	8.2	2.37	Convergence criterion (GCONV=1E-8) satisfied.	0.66	8.48	0.092	Algorithm converged.	-0.041	0.226	2.13	Algorithm converged.	0.69	6.60	0.1899	0.1933	0.47	Algorithm converged.	0.15	1.40
		>=25x10 ⁹ cells/L	151	68.0	24	15.9	138	64.5	23	16.7	0.94	Convergence criterion (GCONV=1E-8) satisfied.	0.93	1.77	-0.008	Algorithm converged.	-0.093	0.076	0.95	Algorithm converged.	0.57	1.61	0.8569	1.05	Algorithm converged.	0.62	1.77	
		Missing																										

Test for interaction based on RR (Log-Binomial regression)
 * indicates convergence problem. Result is uninterpretable. Clinical
 out-off: 09MAY2013

Program: root/clinical_studies/R05072759/CDPT7159/R021004/data_analysis/ACT_base/qa/program/t_gro_rsp2.sas
 Output: root/clinical_studies/R05072759/CDPT7159/R021004/data_analysis/ACT_base/qa/output/t_gro_rsp2_eq_EQC30W_GLQC30pop_IT_label_09MAY2013_21004.xls 12JAN2021
 12:42

POPULATION: Labelpopulation, Intent-to-Treat Patients, Patients with Screening and post Screening EORTC QLQ-C30 result
 ENDPOINT: EORTC QoL 30 - Responder (R1D=10), worsening
 MODEL: Unstratified Analysis
 STUDY: CLL1 (R021004), Stage 2
 Dichotomous Analysis by Subgroups (Efficacy)

Physical Functioning Scale

Visit	Name	Level	GC1b (N=222)				RC1b (N=214)				Odds Ratio					Absolute Risk Difference					Relative Risk					RC1b vs. GC1b Relative Risk				
			n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CI	95% Upper CI	Absolute Risk	Convergence Reason	95% Lower CI	95% Upper CI	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI	p-value (Wald)	Interacti on Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI		
Cycle 4 Day 1	All	n/a	192	86.5	31	16.1	192	89.7	38	19.8	0.78	Convergence criterion (GCQNV-IE-B) satisfied.	0.46	1.32	-0.036	Algorithm converged.	-0.113	0.040	0.82	Algorithm converged.	0.53	1.25	0.3535		1.23	Algorithm converged.	0.88	1.88		
	Gender	Male	117	52.7	16	13.7	118	55.1	24	20.3	0.62	Convergence criterion (GCQNV-IE-B) satisfied.	0.31	1.24	-0.067	Algorithm converged.	-0.162	0.029	0.67	Algorithm converged.	0.38	1.20	0.1787	0.3081	1.45	Algorithm converged.	0.83	2.65		
		Female	75	33.8	15	20.0	74	34.6	14	18.9	1.07	Convergence criterion (GCQNV-IE-B) satisfied.	0.68	2.41	0.011	Algorithm converged.	-0.116	0.138	1.06	Algorithm converged.	0.55	2.03	0.8677		0.95	Algorithm converged.	0.69	1.82		
		Age																												
		<75 years	99	44.6	16	16.2	94	43.9	13	16.0	1.02	Convergence criterion (GCQNV-IE-B) satisfied.	0.47	2.19	0.002	Algorithm converged.	-0.102	0.106	1.01	Algorithm converged.	0.53	1.93	0.9692	0.3813	0.99	Algorithm converged.	0.92	1.88		
		>=75 years	93	41.9	15	16.1	98	45.8	25	23.5	0.63	Convergence criterion (GCQNV-IE-B) satisfied.	0.35	1.29	-0.073	Algorithm converged.	-0.186	0.039	0.69	Algorithm converged.	0.38	1.23	0.2091		1.46	Algorithm converged.	0.81	2.61		
		Race																												
		White	185	83.3	29	15.7	183	85.5	36	19.7	0.76	Convergence criterion (GCQNV-IE-B) satisfied.	0.44	1.30	-0.040	Algorithm converged.	-0.118	0.038	0.80	Algorithm converged.	0.51	1.24	0.3165	0.5951	1.25	Algorithm converged.	0.80	1.94		
		Other	7	3.2	2	28.6	9	4.2	2	22.2	1.40	Convergence criterion (GCQNV-IE-B) satisfied.	0.16	13.97	0.063	Algorithm converged.	-0.368	0.695	1.29	Algorithm converged.	0.24	6.99	0.7711		0.78	Algorithm converged.	0.16	4.23		
		Geographical Region																												
		North America	9	4.1			11	5.1	2	18.2	*	Quasi-complete separation of data points detected.				*														
		Central and South America	3	1.4	1	33.3	2	0.9			*	Quasi-complete separation of data points detected.				*														
		Western Europe	132	59.5	24	18.2	129	60.3	28	21.7	0.80	Convergence criterion (GCQNV-IE-B) satisfied.	0.46	1.47	-0.035	Algorithm converged.	-0.132	0.062	0.84	Algorithm converged.	0.51	1.36	0.4776		1.19	Algorithm converged.	0.73	1.95		
		Asia-Pacific	15	6.8	1	6.7	15	7.0	3	20.0	0.29	Convergence criterion (GCQNV-IE-B) satisfied.	0.03	3.12	-0.133	Algorithm converged.	-0.372	0.105	0.33	Algorithm converged.	0.54	2.85	0.3159		3.06	Algorithm converged.	0.35	25.68		
		Other	33	14.9	5	15.2	35	16.4	5	14.3	1.87	Convergence criterion (GCQNV-IE-B) satisfied.	0.28	4.10	0.003	Algorithm converged.	-0.160	0.171	1.06	Algorithm converged.	0.34	3.33	0.9198		0.94	Algorithm converged.	0.30	2.96		
		PDgamma receptor I1a																												
		131HR	42	18.8	7	16.7	39	27.6	11	18.6	0.87	Convergence criterion (GCQNV-IE-B) satisfied.	0.31	2.48	-0.020	Algorithm converged.	-0.170	0.130	0.89	Algorithm converged.	0.38	2.11	0.7986	0.4937	1.12	Algorithm converged.	0.47	2.60		
		131HR	95	42.8	15	15.8	97	45.3	22	22.7	0.64	Convergence criterion (GCQNV-IE-B) satisfied.	0.31	1.32	-0.069	Algorithm converged.	-0.180	0.042	0.70	Algorithm converged.	0.39	1.26	0.2307		1.44	Algorithm converged.	0.79	2.65		
		131RR	38	17.1	5	13.2	25	10.7	4	17.4	0.72	Convergence criterion (GCQNV-IE-B) satisfied.	0.17	3.01	-0.042	Algorithm converged.	-0.291	0.146	0.76	Algorithm converged.	0.23	2.59	0.6510		1.32	Algorithm converged.	0.39	4.43		
		Missing	17	7.7	4	23.5	13	6.1	1	7.7	3.69	Convergence criterion (GCQNV-IE-B) satisfied.	0.36	37.84	0.158	Algorithm converged.	-0.090	0.407	3.06	Algorithm converged.	0.39	24.21	0.2895		0.33	Algorithm converged.	0.04	2.59		
		PDgamma receptor I1a																												
		158PF	81	36.3	13	16.0	70	32.7	11	15.7	1.03	Convergence criterion (GCQNV-IE-B) satisfied.	0.43	2.46	0.003	Algorithm converged.	-0.114	0.120	1.02	Algorithm converged.	0.49	2.13	0.9552		0.98	Algorithm converged.	0.47	2.04		
		158PV	88	39.6	14	15.9	83	38.8	19	22.9	0.64	Convergence criterion (GCQNV-IE-B) satisfied.	0.35	1.37	-0.070	Algorithm converged.	-0.188	0.045	0.69	Algorithm converged.	0.37	1.29	0.2514		1.44	Algorithm converged.	0.77	2.68		
		158VV	11	5.0			28	13.1	8	28.6	*	Quasi-complete separation of data points detected.				*														
		Missing	12	5.4	4	33.3	11	5.1			*	Quasi-complete separation of data points detected.				*														
		Rinet Staging at baseline																												
		A	48	21.6	8	16.7	47	22.0	7	14.9	1.14	Convergence criterion (GCQNV-IE-B) satisfied.	0.38	3.45	0.018	Algorithm converged.	-0.129	0.164	1.12	Algorithm converged.	0.44	2.84	0.8129	0.3187	0.89	Algorithm converged.	0.35	2.27		
		B	80	36.0	14	17.5	72	33.6	12	16.7	1.08	Convergence criterion (GCQNV-IE-B) satisfied.	0.45	2.47	0.008	Algorithm converged.	-0.111	0.128	1.05	Algorithm converged.	0.52	2.12	0.8917		0.95	Algorithm converged.	0.47	1.92		
		C	64	28.8	9	14.1	73	34.1	15	26.0	0.47	Convergence criterion (GCQNV-IE-B) satisfied.	0.19	1.12	-0.120	Algorithm converged.	-0.252	0.012	0.34	Algorithm converged.	0.26	1.11	0.0931		1.85	Algorithm converged.	0.90	3.80		
		Total CR score at baseline																												
		<=6	42	18.9	7	16.7	60	28.0	10	16.7	1.00	Convergence criterion (GCQNV-IE-B) satisfied.	0.35	2.88	0.000	Algorithm converged.	-0.147	0.147	1.00	Algorithm converged.	0.41	2.42	1.0000	0.9871	1.00	Algorithm converged.	0.41	2.42		
		>=6	150	67.6	24	16.0	132	61.7	28	21.2	0.71	Convergence criterion (GCQNV-IE-B) satisfied.	0.39	1.29	-0.052	Algorithm converged.	-0.142	0.095	0.75	Algorithm converged.	0.46	1.23	0.2618		1.32	Algorithm converged.	0.81	2.17		
		Calculated creatinine clearance cat. 2																												
		<70 ml/min	130	58.6	17	13.1	140	65.4	29	20.7	0.88	Convergence criterion (GCQNV-IE-B) satisfied.	0.30	1.11	-0.076	Algorithm converged.	-0.165	0.012	0.63	Algorithm converged.	0.36	1.09	0.1006	0.1204	1.58	Algorithm converged.	0.91	2.71		
		>=70 ml/min	62	27.9	14	22.6	52	24.3	9	17.3	1.39	Convergence criterion (GCQNV-IE-B) satisfied.	0.35	3.34	0.053	Algorithm converged.	-0.094	0.199	1.30	Algorithm converged.	0.62	2.77	0.4882		0.77	Algorithm converged.	0.36	1.63		
		Beta2 microglobulin																												
		< 3.5 ug/mL	114	51.4	19	16.7	109	50.8	23	21.1	0.75	Convergence criterion (GCQNV-IE-B) satisfied.	0.38	1.47	-0.044	Algorithm converged.	-0.147	0.058	0.79	Algorithm converged.	0.46	1.37	0.3988	0.9951	1.21	Algorithm converged.	0.73	2.10		
		>= 3.5 ug/mL	75	33.8	11	14.7	81	37.9	15	18.5	0.76	Convergence criterion (GCQNV-IE-B) satisfied.	0.32	1.77	-0.039	Algorithm converged.	-0.155	0.078	0.79	Algorithm converged.	0.39	1.61	0.5208		1.26	Algorithm converged.	0.62	2.57		

	Beta2 microglobulin	< 3.5 ug/mL	120	54.1	21	17.5	112	52.3	23	22.3	0.74	Convergence criterion (GCONV=IE-8) satisfied.	0.39	1.41	-0.048	Algorithm converged.	-0.151	0.055	0.78	Algorithm converged.	0.47	1.32	0.3569	0.3871	1.28	Algorithm converged.	0.76	2.11	
		>= 3.5 ug/mL	76	34.2	14	18.4	75	35.0	12	16.0	1.19	Convergence criterion (GCONV=IE-8) satisfied.	0.51	2.77	0.024	Algorithm converged.	-0.096	0.145	1.15	Algorithm converged.	0.57	2.32	0.6940		0.87	Algorithm converged.	0.43	1.75	
		Missing	3	1.4	1	33.3	2	0.0				Quasi-complete separation of data points detected.	*							NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	
	Immunoglobulin VR, cytogenetics 2		12	35	15.8	6	17.1	32	15.0	8	25.0	0.62	Convergence criterion (GCONV=IE-8) satisfied.	0.19	2.04	-0.079	Algorithm converged.	-0.274	0.117	0.69	Algorithm converged.	0.27	1.76	0.4333	0.2067	1.46	Algorithm converged.	0.57	3.75
		11q-	37	16.7	8	21.6	34	15.9	4	11.8	2.07	Convergence criterion (GCONV=IE-8) satisfied.	0.36	7.82	0.089	Algorithm converged.	-0.073	0.270	1.84	Algorithm converged.	0.61	5.36	0.2809		0.54	Algorithm converged.	0.18	1.64	
		13q-	67	30.2	9	13.4	59	27.6	14	23.7	0.59	Convergence criterion (GCONV=IE-8) satisfied.	0.20	1.26	-0.103	Algorithm converged.	-0.239	0.033	0.57	Algorithm converged.	0.26	1.21	0.1427		1.77	Algorithm converged.	0.83	3.78	
		Other Abn.	14	6.3	1	7.1	17	7.9	3	17.6	0.36	Convergence criterion (GCONV=IE-8) satisfied.	0.03	3.90	-0.105	Algorithm converged.	-0.331	0.121	0.40	Algorithm converged.	0.05	3.47	0.4096		2.47	Algorithm converged.	0.29	21.21	
		Norm. k.	46	20.7	12	26.1	47	22.0	8	17.0	1.72	Convergence criterion (GCONV=IE-8) satisfied.	0.63	4.70	0.091	Algorithm converged.	-0.076	0.257	1.53	Algorithm converged.	0.69	3.40	0.2937		0.65	Algorithm converged.	0.29	1.45	
	Time from first diagnosis	<= 12 months	45	20.3	9	20.0	54	25.2	10	18.5	1.10	Convergence criterion (GCONV=IE-8) satisfied.	0.40	3.00	0.015	Algorithm converged.	-0.141	0.171	1.08	Algorithm converged.	0.48	2.43	0.8521	0.7231	0.93	Algorithm converged.	0.41	2.08	
		13 - 24 months	32	14.4	5	15.6	26	12.1	3	11.5	1.42	Convergence criterion (GCONV=IE-8) satisfied.	0.31	6.59	0.041	Algorithm converged.	-0.135	0.217	1.35	Algorithm converged.	0.36	5.14	0.6561		0.74	Algorithm converged.	0.19	2.80	
		>24 months	121	54.5	22	18.2	109	50.9	24	22.0	0.79	Convergence criterion (GCONV=IE-8) satisfied.	0.41	1.50	-0.038	Algorithm converged.	-0.142	0.065	0.83	Algorithm converged.	0.49	1.39	0.4683		1.21	Algorithm converged.	0.72	2.03	
		Missing	1	0.5																									
	High circulating tumor burden	<25x10**9 cells/L	46	20.7	8	17.4	49	22.9	9	18.4	0.94	Convergence criterion (GCONV=IE-8) satisfied.	0.33	2.68	-0.010	Algorithm converged.	-0.164	0.144	0.95	Algorithm converged.	0.40	2.24	0.9013	0.9343	1.06	Algorithm converged.	0.45	2.50	
		>=25x10**9 cells/L	153	68.8	28	18.3	139	65.0	28	20.1	0.89	Convergence criterion (GCONV=IE-8) satisfied.	0.50	1.59	-0.018	Algorithm converged.	-0.109	0.072	0.91	Algorithm converged.	0.57	1.45	0.6895		1.10	Algorithm converged.	0.69	1.76	
		Missing																											

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable. Clinical cut-off: 0.964203

Program: root/clinical_studies/R05072759/CDPT7159/B021004/data_analysis/ACE_base/ga/program/t_pro_rsp2.sas
Output: root/clinical_studies/R05072759/CDPT7159/B021004/data_analysis/ACE_CBR_stage2/ga/output/t_pro_rsp2_sqEQ30W_QQC30pop_IT_label_09MAV2013_21004.xls 12JAN2021 12:42

POPULATION: Labelpopulation, Intent-to-Treat Patients, Patients with Screening and post Screening EORTC QLQ-C30 result
 ENDPOINT: EORTC QoL 10 - Responder (RID=10), worsening
 MODEL: Unstratified Analysis
 STUDY: CLL11(B021004), Stage 2
 Dichotomous Analysis by Subgroups (Efficacy)

Role Functioning Scale			OC1b (N=222)				OC1b (N=214)				OC1b vs. OC1b					OC1b vs. OC1b															
Visit	Name	Level	Patients		Patients with Event		Patients		Patients with Event		Odds Ratio	Absolute Risk Difference			Relative Risk																
			n	t	n	t	n	t	n	t		95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interacti on Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL				
Cycle 4 Day 1	All	n/a	191	86.0	44	23.0	191	89.3	46	24.1	0.84				Convergence criterion (GCONV-IR-#) satisfied.	0.59	1.33	-0.010	Algorithm converged.	-0.096	0.075	0.95	Algorithm converged.	0.67	1.37	0.8095		1.05	Algorithm converged.	0.73	1.50
Gender	Male		117	52.7	19	16.2	117	54.7	27	23.1	0.65				Convergence criterion (GCONV-IR-#) satisfied.	0.34	1.24	-0.068	Algorithm converged.	-0.170	0.033	0.70	Algorithm converged.	0.42	1.19	0.1921	0.0892	1.42	Algorithm converged.	0.84	2.41
	Female		74	33.3	25	33.8	74	34.6	19	25.7	1.48				Convergence criterion (GCONV-IR-#) satisfied.	0.73	3.00	0.081	Algorithm converged.	-0.066	0.228	1.32	Algorithm converged.	0.80	2.17	0.2840		0.76	Algorithm converged.	0.46	1.28
Age	<75 years		99	44.6	21	21.2	99	43.5	15	16.1	1.40				Convergence criterion (GCONV-IR-#) satisfied.	0.67	2.91	0.051	Algorithm converged.	-0.059	0.161	1.32	Algorithm converged.	0.72	2.39	0.3701	0.1921	0.76	Algorithm converged.	0.42	1.38
	>=75 years		92	41.4	23	25.0	98	45.8	31	31.6	0.72				Convergence criterion (GCONV-IR-#) satisfied.	0.38	1.36	-0.066	Algorithm converged.	-0.194	0.061	0.79	Algorithm converged.	0.50	1.25	0.3142		1.27	Algorithm converged.	0.80	2.00
Race	White		184	82.9	43	23.4	182	85.0	43	23.6	0.99				Convergence criterion (GCONV-IR-#) satisfied.	0.81	1.80	-0.003	Algorithm converged.	-0.089	0.084	0.99	Algorithm converged.	0.68	1.43	0.9538	0.3893	1.01	Algorithm converged.	0.78	1.48
	Other		7	3.2	1	14.3	9	4.2	3	33.3	0.33				Convergence criterion (GCONV-IR-#) satisfied.	0.03	4.19	-0.180	Algorithm converged.	-0.593	0.212	0.43	Algorithm converged.	0.06	3.28	0.4148		2.33	Algorithm converged.	0.30	17.89
Geographical Region	North America		9	4.1	2	22.2	11	5.1	4	36.4	0.50				Convergence criterion (GCONV-IR-#) satisfied.	0.07	3.67	-0.141	Algorithm converged.	-0.535	0.252	0.61	Algorithm converged.	0.14	2.61	0.5059	0.7238	1.64	Algorithm converged.	0.38	6.98
	Central and South America		3	1.4	1	33.3	2	0.9	1	50.0	0.50				Convergence criterion (GCONV-IR-#) satisfied.	0.01	19.36	-0.167	Algorithm converged.	-1.041	0.708	0.67	Algorithm converged.	0.08	5.34	0.7074		1.50	Algorithm converged.	0.18	12.46
	Western Europe		131	59.0	34	26.0	128	59.8	34	26.6	0.97				Convergence criterion (GCONV-IR-#) satisfied.	0.56	1.69	-0.006	Algorithm converged.	-0.113	0.101	0.98	Algorithm converged.	0.65	1.47	0.9114		1.02	Algorithm converged.	0.68	1.51
	Asia-Pacific		15	6.8	2	13.3	15	7.0	4	26.7	0.42				Convergence criterion (GCONV-IR-#) satisfied.	0.08	2.77	-0.132	Algorithm converged.	-0.416	0.149	0.50	Algorithm converged.	0.11	2.33	0.3774		2.00	Algorithm converged.	0.43	9.32
PDgamma receptor 1fa	131HR		42	18.9	9	21.4	38	27.1	11	19.0	1.17				Convergence criterion (GCONV-IR-#) satisfied.	0.43	3.33	0.023	Algorithm converged.	-0.135	0.385	1.13	Algorithm converged.	0.51	2.48	0.7609	0.2428	0.89	Algorithm converged.	0.40	1.94
	131R		95	42.8	21	22.1	97	45.3	30	30.9	0.63				Convergence criterion (GCONV-IR-#) satisfied.	0.33	1.21	-0.088	Algorithm converged.	-0.212	0.036	0.71	Algorithm converged.	0.44	1.16	0.1708		1.40	Algorithm converged.	0.87	2.20
	131BR		38	17.1	10	26.3	23	10.7	4	17.4	1.70				Convergence criterion (GCONV-IR-#) satisfied.	0.46	6.23	0.089	Algorithm converged.	-0.120	0.298	1.51	Algorithm converged.	0.54	4.27	0.4339		0.66	Algorithm converged.	0.23	1.87
	Missing		16	7.2	4	25.0	13	6.1	1	7.7	4.00				Convergence criterion (GCONV-IR-#) satisfied.	0.39	41.21	0.173	Algorithm converged.	-0.084	0.430	3.25	Algorithm converged.	0.41	25.64	0.2634		0.31	Algorithm converged.	0.04	2.43
PDgamma receptor 1fa	158FF		81	36.5	21	25.9	70	32.7	18	25.7	1.01				Convergence criterion (GCONV-IR-#) satisfied.	0.49	2.10	0.002	Algorithm converged.	-0.138	0.142	1.01	Algorithm converged.	0.59	1.73	0.9764	0.3550	0.99	Algorithm converged.	0.58	1.71
	158FV		88	39.6	17	19.3	82	38.3	20	24.4	0.74				Convergence criterion (GCONV-IR-#) satisfied.	0.36	1.54	-0.051	Algorithm converged.	-0.175	0.074	0.79	Algorithm converged.	0.46	1.40	0.4246		1.26	Algorithm converged.	0.71	2.21
	158VV		11	5.0	2	18.2	28	13.1	7	25.0	0.67				Convergence criterion (GCONV-IR-#) satisfied.	0.12	3.86	-0.068	Algorithm converged.	-0.347	0.211	0.73	Algorithm converged.	0.18	2.97	0.6576		1.37	Algorithm converged.	0.34	5.62
	Missing		11	5.0	4	36.4	11	5.1	1	9.1	5.71				Convergence criterion (GCONV-IR-#) satisfied.	0.32	62.66	0.273	Algorithm converged.	-0.058	0.604	4.00	Algorithm converged.	0.53	30.33	0.1798		0.25	Algorithm converged.	0.03	1.90
Binet Staging at baseline	A		47	21.2	14	29.8	47	22.0	12	25.5	1.24				Convergence criterion (GCONV-IR-#) satisfied.	0.55	3.06	0.043	Algorithm converged.	-0.138	0.223	1.17	Algorithm converged.	0.41	2.25	0.6454	0.6247	0.86	Algorithm converged.	0.44	1.65
	B		80	36.0	18	22.5	72	33.6	16	22.2	1.02				Convergence criterion (GCONV-IR-#) satisfied.	0.47	2.18	0.003	Algorithm converged.	-0.130	0.135	1.01	Algorithm converged.	0.56	1.83	0.9673		0.99	Algorithm converged.	0.35	1.78
	C		64	28.8	12	18.8	72	33.6	18	25.0	0.89				Convergence criterion (GCONV-IR-#) satisfied.	0.30	1.58	-0.063	Algorithm converged.	-0.201	0.076	0.75	Algorithm converged.	0.39	1.43	0.3844		1.33	Algorithm converged.	0.70	2.55
Total CIR score at baseline	<=6		42	18.9	11	26.2	39	27.6	10	16.9	1.74				Convergence criterion (GCONV-IR-#) satisfied.	0.66	4.57	0.092	Algorithm converged.	-0.071	0.256	1.55	Algorithm converged.	0.72	3.30	0.2614	0.1449	0.65	Algorithm converged.	0.30	1.38
	>6		149	67.1	33	22.1	132	61.7	36	27.3	0.75				Convergence criterion (GCONV-IR-#) satisfied.	0.44	1.31	-0.051	Algorithm converged.	-0.152	0.050	0.81	Algorithm converged.	0.54	1.22	0.3199		1.23	Algorithm converged.	0.82	1.80
Calculated creatinine clearance cat. 2	<70 ml/min		129	58.1	30	23.3	139	65.0	35	25.2	0.90				Convergence criterion (GCONV-IR-#) satisfied.	0.51	1.58	-0.019	Algorithm converged.	-0.122	0.083	0.92	Algorithm converged.	0.60	1.41	0.7138	0.7239	1.08	Algorithm converged.	0.71	1.66
	>=70 ml/min		62	27.9	14	22.6	52	24.3	11	21.2	1.09				Convergence criterion (GCONV-IR-#) satisfied.	0.45	2.66	0.014	Algorithm converged.	-0.138	0.166	1.07	Algorithm converged.	0.53	2.15	0.8547		0.94	Algorithm converged.	0.47	1.88
Beta2 microglobulin	< 3.5 ug/mL		113	50.8	29	25.7	108	50.5	27	25.0	1.04				Convergence criterion (GCONV-IR-#) satisfied.	0.56	1.99	0.007	Algorithm converged.	-0.108	0.121	1.03	Algorithm converged.	0.65	1.61	0.9097	0.5118	0.97	Algorithm converged.	0.62	1.53
	>= 3.5 ug/mL		75	33.8	14	18.7	81	37.9	19	23.5	0.79				Convergence criterion (GCONV-IR-#) satisfied.	0.34	1.63	-0.048	Algorithm converged.	-0.176	0.080	0.80	Algorithm converged.	0.43	1.47	0.4665		1.26	Algorithm converged.	0.68	2.32
	Missing		3	1.4	1	33.3	2	0.9							Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.				NE	Algorithm converged.	NE	NE	NE	NE	Algorithm converged.	NE	NE
Hemoglobin VR, cytogenetics 2	12		31	14.0	5	16.1	33	15.4	8	24.2	0.60				Convergence criterion (GCONV-IR-#) satisfied.	0.17	2.09	-0.081	Algorithm converged.	-0.276	0.114	0.67	Algorithm converged.	0.24	1.82	0.4264	0.9539	1.50	Algorithm converged.	0.55	4.10
	11q-		39	17.6	11	28.2	36	15.0	8	26.5	1.09				Convergence criterion (GCONV-IR-#) satisfied.	0.39	3.07	0.017	Algorithm converged.	-0.187	0.222	1.07	Algorithm converged.	0.50	2.26	0.8685		0.94	Algorithm converged.	0.44	1.99
	13q-		59	26.6	10	16.9	57	26.6	9	15.8	1.09				Convergence criterion (GCONV-IR-#) satisfied.	0.41	2.91	0.012	Algorithm converged.	-0.123	0.146	1.07	Algorithm converged.	0.47	2.45	0.8661		0.93	Algorithm converged.	0.41	2.12
	Other Abn.		16	7.2	5	31.3	19	8.9	6	31.6	0.98				Convergence criterion (GCONV-IR-#) satisfied.	0.23	4.13	-0.003	Algorithm converged.	-0.312	0.305	0.99	Algorithm converged.	0.37	2.64	0.9833		1.01	Algorithm converged.	0.38	2.70

	Norm. W.	46	20.7	11	23.9	47	22.0	11	23.4	1.03	Convergence criterion (GCONV=1E-8) satisfied.	0.45	2.88	0.003	Algorithm converged.	-0.168	0.178	1.02	Algorithm converged.	0.49	2.12	0.9340		0.98	Algorithm converged.	0.41	2.03
Time from first diagnosis	K= 12 months	45	20.3	12	26.7	54	25.2	14	25.9	1.04	Convergence criterion (GCONV=1E-8) satisfied.	0.42	2.55	0.007	Algorithm converged.	-0.167	0.182	1.03	Algorithm converged.	0.53	1.99	0.9335	0.5284	0.97	Algorithm converged.	0.50	1.88
	13 - 24 months	32	14.4	4	18.8	26	12.1	5	19.2	0.97	Convergence criterion (GCONV=1E-8) satisfied.	0.26	3.82	-0.003	Algorithm converged.	-0.208	0.198	0.98	Algorithm converged.	0.34	2.84	0.9629		1.03	Algorithm converged.	0.33	2.98
	>24 months	120	54.1	36	30.0	108	50.5	21	19.4	1.78	Convergence criterion (GCONV=1E-8) satisfied.	0.96	3.25	0.106	Algorithm converged.	-0.005	0.216	1.54	Algorithm converged.	0.96	2.47	0.0713		0.65	Algorithm converged.	0.45	1.04
	Missing	1	0.5																								
High circulating tumor burden	<25x10**9 cells/L	46	20.7	12	26.1	49	22.9	10	20.4	1.38	Convergence criterion (GCONV=1E-8) satisfied.	0.53	3.58	0.057	Algorithm converged.	-0.113	0.227	1.28	Algorithm converged.	0.61	2.67	0.5135	0.9895	0.78	Algorithm converged.	0.37	1.63
	>=25x10**9 cells/L	152	68.5	42	27.6	138	64.5	20	21.7	1.37	Convergence criterion (GCONV=1E-8) satisfied.	0.80	2.36	0.059	Algorithm converged.	-0.040	0.158	1.27	Algorithm converged.	0.85	1.81	0.2492		0.75	Algorithm converged.	0.52	1.18
	Missing																										

Test for interaction based on RR (Log-Binomial regression)

* indicates convergence problem. Result is uninterpretable. Clinical

out-off: 09MAY2013

Program: root/clinical_studies/R05072759/CDPT7159/R021004/data_analysis/ACE_base/qa/program/t_pro_rsp2.sas

Output: root/clinical_studies/R05072759/CDPT7159/R021004/data_analysis/ACE_CSR_stage2/qa/output/t_pro_rsp2_eq_EQC30W_GLQC30pop_IT_label_09MAY2013_21004.xls 12JAN2021

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	13 - 24 months	32	14.4	1	15.6	26	12.1	7	26.9	0.30	Convergence criterion (GCONV=1E-8) satisfied.	0.14	1.82	-0.113	Algorithm converged.	-0.325	0.099	0.38	Algorithm converged.	0.21	1.62	0.2978	1.72	Algorithm converged.	0.62	4.80	
	>24 months	121	54.5	27	22.3	108	50.5	29	26.9	0.78	Convergence criterion (GCONV=1E-8) satisfied.	0.43	1.43	-0.045	Algorithm converged.	+0.157	0.066	0.83	Algorithm converged.	0.53	1.31	0.4257	1.20	Algorithm converged.	0.76	1.90	
	Missing	1	0.5																								
High circulating tumor burden	<25x10**9 cells/L	46	20.1	9	19.6	49	22.9	14	28.6	0.61	Convergence criterion (GCONV=1E-8) satisfied.	0.23	1.58	-0.090	Algorithm converged.	-0.261	0.081	0.66	Algorithm converged.	0.33	1.43	0.3122	0.9954	1.46	Algorithm converged.	0.70	3.04
	>=25x10**9 cells/L	132	68.5	31	20.4	138	64.3	41	29.7	0.61	Convergence criterion (GCONV=1E-8) satisfied.	0.35	1.84	-0.093	Algorithm converged.	+0.193	0.006	0.65	Algorithm converged.	0.46	1.03	0.0691	1.46	Algorithm converged.	0.87	2.13	
	Missing																										

Test for interaction based on BR (log-binomial regression)
 * indicates convergence problem. Result is uninterpretable. Clinical
 cut-off: 0.99472013

Program: root/clinical_studies/R05072759/CDPT7159/R021004/data_analysis/ACE_base/qa/program/t_pro_rsp2.sas
 Output: root/clinical_studies/R05072759/CDPT7159/R021004/data_analysis/ACE_CBR_stage2/qa/output/t_pro_rsp2_sq_RQC30W_GLQC30pop_IT_label_09MAY2013_21004.xls 12JAN2021
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Anhang 4-G2: Weitere Analysen zu Symptomatik (EORTC QLQ-C30 Symptomskalen) und Gesundheitsbezogener Lebensqualität (EORTC QLQ-C30 Funktionsskalen und EORTC QLQ-CLL16): MMRM-Analysen und Mittelwerte pro Visite

8 (Anhang): Ergebnisse für EORTC QLQ-C30 Symptomskalen – MMRM - Hauptanalysen aus RCT mit dem zu bewertenden Arzneimittel

POPULATION: Labelpopulation, Intent-to-Treat Patients, Patients with Screening and post Screening EORTC QLQ-C30 result
 ENDPOINT: EORTC QoL 30
 MODEL: Stratified Analysis by Binet Staging at Baseline
 STUDY: CLL11(BO21004), Stage 2
 Analysis of MMRM for all Visits and Follow-Up Visits

Appetite Loss Scale

		GClb (N=222)					RClb (N=214)					Difference between Treatments (GClb - RClb)				
		N			Statistics		N			Statistics						
Name	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% CI (LL)	95% CI (UL)	Population/ Method[4]
All	n/a	222	222	222	-17,7	1,2	214	214	214	-13,4	1,3	-4,2	1,7	-7,6	-0,8	Labelpopulation, Intent-to-Treat Patients, Patients with Screening and post Screening EORTC QLQ-C30 result adjusted

[1] Patients with a value at baseline and at least one post-baseline value

[2] LSMeans of change from baseline from MMRM (including all available records from all visits) [3]

Contrasts from MMRM

[4] Factors/Covariates: treatment, visit, treatment-by-visit interaction, baseline value. In addition, for the total population, adjusted for randomization stratification factors. Clinical cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/t_pro_mmr_allfu.sas

Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/t_pro_mmr_allfu_str_EQC30_QLQC30pop_IT_label_09MAY2013_21004.xls 03JUN2020 9:51

POPULATION: Labelpopulation, Intent-to-Treat Patients, Patients with Screening and post Screening EORTC QLQ-C30 result
 ENDPOINT: EORTC QoL 30
 MODEL: Stratified Analysis by Binet Staging at Baseline
 STUDY: CLL11 (BO21004), Stage 2
 Analysis of MMRM for all Visits and Follow-Up Visits

Constipation Scale

		GClb (N=222)					RClb (N=214)					Difference between Treatments (GClb - RClb)				
		N			Statistics		N			Statistics						
Name	Level	Total	with baseline value	included in analysis [1]	LSMeans [2]	SE (LSMeans)	Total	with baseline value	included in analysis [1]	LSMeans [2]	SE (LSMeans)	LSMeans [3]	SE (LSMeans)	95% CI (LL)	95% CI (UL)	Population/ Method [4]
All	n/a	222	222	222	-14,8	1,3	214	214	214	-10,7	1,4	-4,1	1,9	-7,9	-0,3	Labelpopulation, Intent-to-Treat Patients, Patients with Screening and post Screening EORTC QLQ-C30 result adjusted

[1] Patients with a value at baseline and at least one post-baseline value

[2] LSMeans of change from baseline from MMRM (including all available records from all visits) [3]

Contrasts from MMRM

[4] Factors/Covariates: treatment, visit, treatment-by-visit interaction, baseline value. In addition, for the total population, adjusted for randomization stratification factors. Clinical cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/t_pro_mmr_allfu.sas

Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/t_pro_mmr_allfu_str_EQC30_QLQC30pop_IT_label_09MAY2013_21004.xls 03JUN2020 9:51

POPULATION: Labelpopulation, Intent-to-Treat Patients, Patients with Screening and post Screening EORTC QLQ-C30 result
 ENDPOINT: EORTC QoL 30
 MODEL: Stratified Analysis by Binet Staging at Baseline
 STUDY: CLL11 (BO21004), Stage 2
 Analysis of MMRM for all Visits and Follow-Up Visits

Diarrhoea Scale

		GClb (N=222)					RClb (N=214)					Difference between Treatments (GClb - RClb)					
		N			Statistics		N			Statistics							
Name	Level	Total	with baseline value	included in analysis [1]	LSMeans [2]	SE (LSMeans)	Total	with baseline value	included in analysis [1]	LSMeans [2]	SE (LSMeans)	LSMeans [3]	SE (LSMeans)	95% CI (LL)	95% CI (UL)	Population/ Method [4]	
All	n/a	222	222	222	-18,0	1,1	214	214	214	-15,9	1,2	-2,1	1,6	-5,2	0,9	Labelpopulation, Intent-to-Treat Patients, Patients with Screening and post Screening EORTC QLQ-C30 result	adjusted

[1] Patients with a value at baseline and at least one post-baseline value

[2] LSMeans of change from baseline from MMRM (including all available records from all visits) [3]

Contrasts from MMRM

[4] Factors/Covariates: treatment, visit, treatment-by-visit interaction, baseline value. In addition, for the total population, adjusted for randomization stratification factors. Clinical cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/t_pro_mmr_allfu.sas

Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/t_pro_mmr_allfu_str_EQC30_QLQC30pop_IT_label_09MAY2013_21004.xls 03JUN2020 9:51

POPULATION: Labelpopulation, Intent-to-Treat Patients, Patients with Screening and post Screening EORTC QLQ-C30 result
 ENDPOINT: EORTC QoL 30
 MODEL: Stratified Analysis by Binet Staging at Baseline
 STUDY: CLL11 (BO21004), Stage 2
 Analysis of MMRM for all Visits and Follow-Up Visits

Dyspnoea Scale

		GClb (N=222)					RClb (N=214)					Difference between Treatments (GClb - RClb)				
		N			Statistics		N			Statistics						
Name	Level	Total	with baseline value	included in analysis [1]	LSMeans [2]	SE (LSMeans)	Total	with baseline value	included in analysis [1]	LSMeans [2]	SE (LSMeans)	LSMeans [3]	SE (LSMeans)	95% CI (LL)	95% CI (UL)	Population/ Method [4]
All	n/a	222	222	222	-8,3	1,5	214	214	214	-3,2	1,6	-5,1	2,2	-9,5	-0,8	Labelpopulation, Intent-to-Treat Patients, Patients with Screening and post Screening EORTC QLQ-C30 result adjusted

[1] Patients with a value at baseline and at least one post-baseline value

[2] LSMeans of change from baseline from MMRM (including all available records from all visits) [3]

Contrasts from MMRM

[4] Factors/Covariates: treatment, visit, treatment-by-visit interaction, baseline value. In addition, for the total population, adjusted for randomization stratification factors. Clinical cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/t_pro_mmr_allfu.sas

Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/t_pro_mmr_allfu_str_EQC30_QLQC30pop_IT_label_09MAY2013_21004.xls 03JUN2020 9:51

POPULATION: Labelpopulation, Intent-to-Treat Patients, Patients with Screening and post Screening EORTC QLQ-C30 result
 ENDPOINT: EORTC QoL 30
 MODEL: Stratified Analysis by Binet Staging at Baseline
 STUDY: CLL11 (BO21004), Stage 2
 Analysis of MMRM for all Visits and Follow-Up Visits

Fatigue Scale

		GClb (N=222)					RClb (N=214)					Difference between Treatments (GClb - RClb)				
		N			Statistics		N			Statistics						
Name	Level	Total	with baseline value	included in analysis [1]	LSMeans [2]	SE (LSMeans)	Total	with baseline value	included in analysis [1]	LSMeans [2]	SE (LSMeans)	LSMeans [3]	SE (LSMeans)	95% CI (LL)	95% CI (UL)	Population/ Method [4]
All	n/a	222	222	222	0,8	1,3	214	214	214	4,6	1,4	-3,8	1,9	-7,6	0,0	Labelpopulation, Intent-to-Treat Patients, Patients with Screening and post Screening EORTC QLQ-C30 result adjusted

[1] Patients with a value at baseline and at least one post-baseline value

[2] LSMeans of change from baseline from MMRM (including all available records from all visits) [3]

Contrasts from MMRM

[4] Factors/Covariates: treatment, visit, treatment-by-visit interaction, baseline value. In addition, for the total population, adjusted for randomization stratification factors. Clinical cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/t_pro_mmr_allfu.sas

Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/t_pro_mmr_allfu_str_EQC30_QLQC30pop_IT_label_09MAY2013_21004.xls 03JUN2020 9:51

POPULATION: Labelpopulation, Intent-to-Treat Patients, Patients with Screening and post Screening EORTC QLQ-C30 result
 ENDPOINT: EORTC QoL 30
 MODEL: Stratified Analysis by Binet Staging at Baseline
 STUDY: CLL11 (BO21004), Stage 2
 Analysis of MMRM for all Visits and Follow-Up Visits

Financial Difficulties Scale

		GClb (N=222)					RC1b (N=214)					Difference between Treatments (GClb - RC1b)					
		N			Statistics		N			Statistics							
Name	Level	Total	with baseline value	included in analysis [1]	LSMeans [2]	SE (LSMeans)	Total	with baseline value	included in analysis [1]	LSMeans [2]	SE (LSMeans)	LSMeans [3]	SE (LSMeans)	95% CI (LL)	95% CI (UL)	Population/ Method [4]	
All	n/a	222	222	222	-17,8	1,1	214	214	214	-16,2	1,2	-1,6	1,6	-4,8	1,6	Labelpopulation, Intent-to-Treat Patients, Patients with Screening and post Screening EORTC QLQ-C30 result	adjusted

[1] Patients with a value at baseline and at least one post-baseline value

[2] LSMeans of change from baseline from MMRM (including all available records from all visits) [3]

Contrasts from MMRM

[4] Factors/Covariates: treatment, visit, treatment-by-visit interaction, baseline value. In addition, for the total population, adjusted for randomization stratification factors. Clinical cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/t_pro_mmr_allfu.sas

Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/t_pro_mmr_allfu_str_EQC30_QLQC30pop_IT_label_09MAY2013_21004.xls 03JUN2020 9:51

POPULATION: Labelpopulation, Intent-to-Treat Patients, Patients with Screening and post Screening EORTC QLQ-C30 result
 ENDPOINT: EORTC QoL 30
 MODEL: Stratified Analysis by Binet Staging at Baseline
 STUDY: CLL11 (BO21004), Stage 2
 Analysis of MMRM for all Visits and Follow-Up Visits

Nausea And Vomiting Scale

		GClb (N=222)					RClb (N=214)					Difference between Treatments (GClb - RClb)				
		N			Statistics		N			Statistics						
Name	Level	Total	with baseline value	included in analysis [1]	LSMeans [2]	SE (LSMeans)	Total	with baseline value	included in analysis [1]	LSMeans [2]	SE (LSMeans)	LSMeans [3]	SE (LSMeans)	95% CI (LL)	95% CI (UL)	Population/ Method [4]
All	n/a	222	222	222	-20,7	0,5	214	214	214	-20,5	0,6	-0,2	0,8	-1,8	1,4	Labelpopulation, Intent-to-Treat Patients, Patients with Screening and post Screening EORTC QLQ-C30 result adjusted

[1] Patients with a value at baseline and at least one post-baseline value

[2] LSMeans of change from baseline from MMRM (including all available records from all visits) [3]

Contrasts from MMRM

[4] Factors/Covariates: treatment, visit, treatment-by-visit interaction, baseline value. In addition, for the total population, adjusted for randomization stratification factors. Clinical cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/t_pro_mmr_allfu.sas

Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/t_pro_mmr_allfu_str_EQC30_QLQC30pop_IT_label_09MAY2013_21004.xls 03JUN2020 9:51

POPULATION: Labelpopulation, Intent-to-Treat Patients, Patients with Screening and post Screening EORTC QLQ-C30 result
 ENDPOINT: EORTC QoL 30
 MODEL: Stratified Analysis by Binet Staging at Baseline
 STUDY: CLL11 (BO21004), Stage 2
 Analysis of MMRM for all Visits and Follow-Up Visits

Pain Scale

		GClb (N=222)					RClb (N=214)					Difference between Treatments (GClb - RClb)				
		N			Statistics		N			Statistics						
Name	Level	Total	with baseline value	included in analysis [1]	LSMeans [2]	SE (LSMeans)	Total	with baseline value	included in analysis [1]	LSMeans [2]	SE (LSMeans)	LSMeans [3]	SE (LSMeans)	95% CI (LL)	95% CI (UL)	Population/ Method [4]
All	n/a	222	222	222	-7,2	1,5	214	214	214	-4,5	1,6	-2,6	2,1	-6,9	1,6	Labelpopulation, Intent-to-Treat Patients, Patients with Screening and post Screening EORTC QLQ-C30 result adjusted

[1] Patients with a value at baseline and at least one post-baseline value

[2] LSMeans of change from baseline from MMRM (including all available records from all visits) [3]

Contrasts from MMRM

[4] Factors/Covariates: treatment, visit, treatment-by-visit interaction, baseline value. In addition, for the total population, adjusted for randomization stratification factors. Clinical cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/t_pro_mmr_allfu.sas

Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/t_pro_mmr_allfu_str_EQC30_QLQC30pop_IT_label_09MAY2013_21004.xls 03JUN2020 9:51

POPULATION: Labelpopulation, Intent-to-Treat Patients, Patients with Screening and post Screening EORTC QLQ-C30 result
 ENDPOINT: EORTC QoL 30
 MODEL: Stratified Analysis by Binet Staging at Baseline
 STUDY: CLL11 (BO21004), Stage 2
 Analysis of MMRM for all Visits and Follow-Up Visits

Insomnia Scale

		GClb (N=222)					RClb (N=214)					Difference between Treatments (GClb - RClb)				
		N			Statistics		N			Statistics						
Name	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% CI (LL)	95% CI (UL)	Population/ Method[4]
All	n/a	222	221	221	-5,4	1,2	214	214	214	-4,7	1,4	-0,7	1,8	-4,3	2,8	Labelpopulation, Intent-to-Treat Patients, Patients with Screening and post Screening EORTC QLQ-C30 result adjusted

[1] Patients with a value at baseline and at least one post-baseline value

[2] LSMeans of change from baseline from MMRM (including all available records from all visits) [3]

Contrasts from MMRM

[4] Factors/Covariates: treatment, visit, treatment-by-visit interaction, baseline value. In addition, for the total population, adjusted for randomization stratification factors. Clinical cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/t_pro_mmr_allfu.sas

Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/t_pro_mmr_allfu_str_EQC30_QLQC30pop_IT_label_09MAY2013_21004.xls 03JUN2020 9:51

9 (Anhang): Ergebnisse für EORTC QLQ-C30 Funktionsskalen – MMRM - Hauptanalysen aus RCT mit dem zu bewertenden Arzneimittel

POPULATION: Labelpopulation, Intent-to-Treat Patients, Patients with Screening and post Screening EORTC QLQ-C30 result
 ENDPOINT: EORTC QoL 30
 MODEL: Stratified Analysis by Binet Staging at Baseline
 STUDY: CLL11(BO21004), Stage 2
 Analysis of MMRM for all Visits and Follow-Up Visits

Global Health Status Scale

		GClb (N=222)				RC1b (N=214)				Difference between Treatments (GClb - RC1b)						
		N		Statistics		N		Statistics								
Name	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% CI (LL)	95% CI (UL)	Population/ Method[4]
All	n/a	222	222	222	32,9	1,3	214	214	214	30,0	1,4	2,9	1,9	-0,9	6,6	Labelpopulation, Intent-to-Treat Patients, Patients with Screening and post Screening EORTC QLQ-C30 result adjusted

[1] Patients with a value at baseline and at least one post-baseline value

[2] LSMeans of change from baseline from MMRM (including all available records from all visits) [3]

Contrasts from MMRM

[4] Factors/Covariates: treatment, visit, treatment-by-visit interaction, baseline value. In addition, for the total population, adjusted for randomization stratification factors. Clinical cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/t_pro_mmr_allfu.sas

Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/t_pro_mmr_allfu_str_EQC30_QLQC30pop_IT_label_09MAY2013_21004.xls 03JUN2020

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POPULATION: Labelpopulation, Intent-to-Treat Patients, Patients with Screening and post Screening EORTC QLQ-C30 result
 ENDPOINT: EORTC QoL 30
 MODEL: Stratified Analysis by Binet Staging at Baseline
 STUDY: CLL11 (BO21004), Stage 2
 Analysis of MMRM for all Visits and Follow-Up Visits

Cognitive Functioning Scale

		GClb (N=222)					RClb (N=214)					Difference between Treatments (GClb - RClb)				
		N			Statistics		N			Statistics						
Name	Level	Total	with baseline value	included in analysis [1]	LSMeans [2]	SE (LSMeans)	Total	with baseline value	included in analysis [1]	LSMeans [2]	SE (LSMeans)	LSMeans [3]	SE (LSMeans)	95% CI (LL)	95% CI (UL)	Population/ Method [4]
All	n/a	222	222	222	44,0	1,2	214	214	214	44,1	1,3	-0,2	1,8	-3,7	3,4	Labelpopulation, Intent-to-Treat Patients, Patients with Screening and post Screening EORTC QLQ-C30 result adjusted

[1] Patients with a value at baseline and at least one post-baseline value

[2] LSMeans of change from baseline from MMRM (including all available records from all visits) [3]

Contrasts from MMRM

[4] Factors/Covariates: treatment, visit, treatment-by-visit interaction, baseline value. In addition, for the total population, adjusted for randomization stratification factors. Clinical cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/t_pro_mmr_allfu.sas

Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/t_pro_mmr_allfu_str_EQC30_QLQC30pop_IT_label_09MAY2013_21004.xls 03JUN2020 9:51

POPULATION: Labelpopulation, Intent-to-Treat Patients, Patients with Screening and post Screening EORTC QLQ-C30 result
 ENDPOINT: EORTC QoL 30
 MODEL: Stratified Analysis by Binet Staging at Baseline
 STUDY: CLL11 (BO21004), Stage 2
 Analysis of MMRM for all Visits and Follow-Up Visits

Emotional Functioning Scale

		GClb (N=222)					RClb (N=214)					Difference between Treatments (GClb - RClb)				
		N			Statistics		N			Statistics						
Name	Level	Total	with baseline value	included in analysis [1]	LSMeans [2]	SE (LSMeans)	Total	with baseline value	included in analysis [1]	LSMeans [2]	SE (LSMeans)	LSMeans [3]	SE (LSMeans)	95% CI (LL)	95% CI (UL)	Population/ Method [4]
All	n/a	222	222	222	44,2	1,3	214	214	214	44,1	1,4	0,1	1,9	-3,6	3,7	Labelpopulation, Intent-to-Treat Patients, Patients with Screening and post Screening EORTC QLQ-C30 result adjusted

[1] Patients with a value at baseline and at least one post-baseline value

[2] LSMeans of change from baseline from MMRM (including all available records from all visits) [3]

Contrasts from MMRM

[4] Factors/Covariates: treatment, visit, treatment-by-visit interaction, baseline value. In addition, for the total population, adjusted for randomization stratification factors. Clinical cut-off: 09MAY2013

Program: root/clinical_studies/R05072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/t_pro_mmr_allfu.sas

Output: root/clinical_studies/R05072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/t_pro_mmr_allfu_str_EQC30_QLQC30pop_IT_label_09MAY2013_21004.xls 03JUN2020 9:51

POPULATION: Labelpopulation, Intent-to-Treat Patients, Patients with Screening and post Screening EORTC QLQ-C30 result
 ENDPOINT: EORTC QoL 30
 MODEL: Stratified Analysis by Binet Staging at Baseline
 STUDY: CLL11 (BO21004), Stage 2
 Analysis of MMRM for all Visits and Follow-Up Visits

Physical Functioning Scale

		GClb (N=222)					RC1b (N=214)					Difference between Treatments (GClb - RC1b)				
		N			Statistics		N			Statistics						
Name	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% CI (LL)	95% CI (UL)	Population/ Method[4]
All	n/a	222	222	222	42,0	1,3	214	214	214	38,5	1,3	3,5	1,8	-0,2	7,1	Labelpopulation, Intent-to-Treat Patients, Patients with Screening and post Screening EORTC QLQ-C30 result adjusted

[1] Patients with a value at baseline and at least one post-baseline value

[2] LSMeans of change from baseline from MMRM (including all available records from all visits) [3]

Contrasts from MMRM

[4] Factors/Covariates: treatment, visit, treatment-by-visit interaction, baseline value. In addition, for the total population, adjusted for randomization stratification factors. Clinical cut-off: 09MAY2013

Program: root/clinical_studies/R05072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/t_pro_mmr_allfu.sas

Output: root/clinical_studies/R05072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/t_pro_mmr_allfu_str_EQC30_QLQC30pop_IT_label_09MAY2013_21004.xls 03JUN2020 9:51

POPULATION: Labelpopulation, Intent-to-Treat Patients, Patients with Screening and post Screening EORTC QLQ-C30 result
 ENDPOINT: EORTC QoL 30
 MODEL: Stratified Analysis by Binet Staging at Baseline
 STUDY: CLL11 (BO21004), Stage 2
 Analysis of MMRM for all Visits and Follow-Up Visits

Role Functioning Scale

		GClb (N=222)					RClb (N=214)					Difference between Treatments (GClb - RClb)					
		N			Statistics		N			Statistics							
Name	Level	Total	with baseline value	included in analysis [1]	LSMeans [2]	SE (LSMeans)	Total	with baseline value	included in analysis [1]	LSMeans [2]	SE (LSMeans)	LSMeans [3]	SE (LSMeans)	95% CI (LL)	95% CI (UL)	Population/ Method [4]	
All	n/a	222	222	222	40,6	1,6	214	214	214	39,8	1,7	0,8	2,4	-3,9	5,4	Labelpopulation, Intent-to-Treat Patients, Patients with Screening and post Screening EORTC QLQ-C30 result	adjusted

[1] Patients with a value at baseline and at least one post-baseline value

[2] LSMeans of change from baseline from MMRM (including all available records from all visits) [3]

Contrasts from MMRM

[4] Factors/Covariates: treatment, visit, treatment-by-visit interaction, baseline value. In addition, for the total population, adjusted for randomization stratification factors. Clinical cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/t_pro_mmr_allfu.sas

Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/t_pro_mmr_allfu_str_EQC30_QLQC30pop_IT_label_09MAY2013_21004.xls 03JUN2020 9:51

POPULATION: Labelpopulation, Intent-to-Treat Patients, Patients with Screening and post Screening EORTC QLQ-C30 result
 ENDPOINT: EORTC QoL 30
 MODEL: Stratified Analysis by Binet Staging at Baseline
 STUDY: CLL11 (BO21004), Stage 2
 Analysis of MMRM for all Visits and Follow-Up Visits

Social Functioning Scale

		GClb (N=222)					RClb (N=214)					Difference between Treatments (GClb - RClb)				
		N			Statistics		N			Statistics						
Name	Level	Total	with baseline value	included in analysis [1]	LSMeans [2]	SE (LSMeans)	Total	with baseline value	included in analysis [1]	LSMeans [2]	SE (LSMeans)	LSMeans [3]	SE (LSMeans)	95% CI (LL)	95% CI (UL)	Population/ Method [4]
All	n/a	222	222	222	47,7	1,3	214	214	214	46,7	1,4	1,0	1,9	-2,8	4,8	Labelpopulation, Intent-to-Treat Patients, Patients with Screening and post Screening EORTC QLQ-C30 result adjusted

[1] Patients with a value at baseline and at least one post-baseline value

[2] LSMeans of change from baseline from MMRM (including all available records from all visits) [3]

Contrasts from MMRM

[4] Factors/Covariates: treatment, visit, treatment-by-visit interaction, baseline value. In addition, for the total population, adjusted for randomization stratification factors. Clinical cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/t_pro_mmr_allfu.sas

Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/t_pro_mmr_allfu_str_EQC30_QLQC30pop_IT_label_09MAY2013_21004.xls 03JUN2020 9:51

10 (Anhang): Ergebnisse für EORTC QLQ-CLL16 – MMRM - Hauptanalysen aus RCT mit dem zu bewertenden Arzneimittel

POPULATION: Labelpopulation, Intent-to-Treat Patients, Patients with Screening and post Screening QLQ-CLL-16 result
 ENDPOINT: EORTC QoL 16
 MODEL: Stratified Analysis by Binet Staging at Baseline
 STUDY: CLL11(BO21004), Stage 2
 Analysis of MMRM for all Visits and Follow-Up Visits

Disease Effects Scale

		GClb (N=201)					RClb (N=190)					Difference between Treatments (GClb - RClb)					
		N			Statistics		N			Statistics							
Name	Level	Total	with baseline value	included in analysis [1]	LSMeans [2]	SE (LSMeans)	Total	with baseline value	included in analysis [1]	LSMeans [2]	SE (LSMeans)	LSMeans [3]	SE (LSMeans)	95% CI (LL)	95% CI (UL)	Population/ Method [4]	
All	n/a	201	201	201	-4,1	0,8	190	190	190	-1,6	0,9	-2,5	1,3	-5,0	-0,1	Labelpopulation, Intent-to-Treat Patients, Patients with Screening and post Screening QLQ-CLL-16 result	adjusted

[1] Patients with a value at baseline and at least one post-baseline value

[2] LSMeans of change from baseline from MMRM (including all available records from all visits) [3]

Contrasts from MMRM

[4] Factors/Covariates: treatment, visit, treatment-by-visit interaction, baseline value. In addition, for the total population, adjusted for randomization stratification factors. Clinical cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/t_pro_mmr_allfu.sas

Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/t_pro_mmr_allfu_str_EQCLL16_QLQCLL16pop_IT_label_09MAY2013_21004.xls 03JUN2020 9:51

POPULATION: Labelpopulation, Intent-to-Treat Patients, Patients with Screening and post Screening QLQ-CLL-16 result
 ENDPOINT: EORTC QoL 16
 MODEL: Stratified Analysis by Binet Staging at Baseline
 STUDY: CLL11 (BO21004), Stage 2
 Analysis of MMRM for all Visits and Follow-Up Visits

Fatigue Scale

		GC1b (N=201)					RC1b (N=190)					Difference between Treatments (GC1b - RC1b)					
		N			Statistics		N			Statistics							
Name	Level	Total	with baseline value	included in analysis [1]	LSMeans [2]	SE (LSMeans)	Total	with baseline value	included in analysis [1]	LSMeans [2]	SE (LSMeans)	LSMeans [3]	SE (LSMeans)	95% CI (LL)	95% CI (UL)	Population/ Method [4]	
All	n/a	201	201	201	6,0	1,3	190	190	190	8,1	1,4	-2,1	1,9	-5,8	1,7	Labelpopulation, Intent-to-Treat Patients, Patients with Screening and post Screening QLQ-CLL-16 result	adjusted

[1] Patients with a value at baseline and at least one post-baseline value

[2] LSMeans of change from baseline from MMRM (including all available records from all visits) [3]

Contrasts from MMRM

[4] Factors/Covariates: treatment, visit, treatment-by-visit interaction, baseline value. In addition, for the total population, adjusted for randomization stratification factors. Clinical cut-off: 09MAY2013

Program: root/clinical_studies/R05072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/t_pro_mmr_allfu.sas

Output: root/clinical_studies/R05072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/t_pro_mmr_allfu_str_EQCLL16_QLQCLL16pop_IT_label_09MAY2013_21004.xls
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POPULATION: Labelpopulation, Intent-to-Treat Patients, Patients with Screening and post Screening QLQ-CLL-16 result
 ENDPOINT: EORTC QoL 16
 MODEL: Stratified Analysis by Binet Staging at Baseline
 STUDY: CLL11 (BO21004), Stage 2
 Analysis of MMRM for all Visits and Follow-Up Visits

Future Health (Item 42)

		GC1b (N=201)					RC1b (N=190)					Difference between Treatments (GC1b - RC1b)					
		N			Statistics		N			Statistics							
Name	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% CI (LL)	95% CI (UL)	Population/ Method[4]	
All	n/a	201	201	201	8,8	1,6	190	190	190	11,3	1,8	-2,6	2,4	-7,3	2,2	Labelpopulation, Intent-to-Treat Patients, Patients with Screening and post Screening QLQ-CLL-16 result	adjusted

[1] Patients with a value at baseline and at least one post-baseline value

[2] LSMeans of change from baseline from MMRM (including all available records from all visits) [3]

Contrasts from MMRM

[4] Factors/Covariates: treatment, visit, treatment-by-visit interaction, baseline value. In addition, for the total population, adjusted for randomization stratification factors. Clinical cut-off: 09MAY2013

Program: root/clinical_studies/R05072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/t_pro_mmr_allfu.sas

Output: root/clinical_studies/R05072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/t_pro_mmr_allfu_str_EQCLL16_QLQCLL16pop_IT_label_09MAY2013_21004.xls

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POPULATION: Labelpopulation, Intent-to-Treat Patients, Patients with Screening and post Screening QLQ-CLL-16 result
 ENDPOINT: EORTC QoL 16
 MODEL: Stratified Analysis by Binet Staging at Baseline
 STUDY: CLL11 (BO21004), Stage 2
 Analysis of MMRM for all Visits and Follow-Up Visits

Infection Scale

		GC1b (N=201)					RC1b (N=190)					Difference between Treatments (GC1b - RC1b)				
		N			Statistics		N			Statistics						
Name	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% CI (LL)	95% CI (UL)	Population/ Method[4]
All	n/a	201	201	201	-7,0	0,8	190	190	190	-7,1	0,9	0,1	1,2	-2,3	2,5	Labelpopulation, Intent-to-Treat Patients, Patients with Screening and post Screening QLQ-CLL-16 result adjusted

[1] Patients with a value at baseline and at least one post-baseline value

[2] LSMeans of change from baseline from MMRM (including all available records from all visits) [3]

Contrasts from MMRM

[4] Factors/Covariates: treatment, visit, treatment-by-visit interaction, baseline value. In addition, for the total population, adjusted for randomization stratification factors. Clinical cut-off: 09MAY2013

Program: root/clinical_studies/R05072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/t_pro_mmr_allfu.sas

Output: root/clinical_studies/R05072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/t_pro_mmr_allfu_str_EQCLL16_QLQCLL16pop_IT_label_09MAY2013_21004.xls

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POPULATION: Labelpopulation, Intent-to-Treat Patients, Patients with Screening and post Screening QLQ-CLL-16 result
 ENDPOINT: EORTC QoL 16
 MODEL: Stratified Analysis by Binet Staging at Baseline
 STUDY: CLL11 (BO21004), Stage 2
 Analysis of MMRM for all Visits and Follow-Up Visits

Social Problems (Item 41)

		GC1b (N=201)					RC1b (N=190)					Difference between Treatments (GC1b - RC1b)					
		N			Statistics		N			Statistics							
Name	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% CI (LL)	95% CI (UL)	Population/ Method[4]	
All	n/a	201	201	201	2,5	1,6	190	190	190	5,3	1,8	-2,7	2,4	-7,5	2,0	Labelpopulation, Intent-to-Treat Patients, Patients with Screening and post Screening QLQ-CLL-16 result	adjusted

[1] Patients with a value at baseline and at least one post-baseline value

[2] LSMeans of change from baseline from MMRM (including all available records from all visits) [3]

Contrasts from MMRM

[4] Factors/Covariates: treatment, visit, treatment-by-visit interaction, baseline value. In addition, for the total population, adjusted for randomization stratification factors. Clinical cut-off: 09MAY2013

Program: root/clinical_studies/R05072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/t_pro_mmr_allfu.sas

Output: root/clinical_studies/R05072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/t_pro_mmr_allfu_str_EQCLL16_QLQCLL16pop_IT_label_09MAY2013_21004.xls

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POPULATION: Labelpopulation, Intent-to-Treat Patients, Patients with Screening and post Screening QLQ-CLL-16 result

ENDPOINT: EORTC QoL 16

MODEL: Stratified Analysis by Binet Staging at Baseline

STUDY: CLL11(BO21004), Stage 2

Analysis of MMRM for all Visits and Follow-Up Visits

Treatment Side Effects Scale

		GClb (N=201)				RClb (N=190)				Difference between Treatments (GClb - RClb)							
		N		Statistics		N		Statistics									
Name	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% CI (LL)	95% CI (UL)	Population/ Method[4]	
All	n/a	201	201	201	-4,6	0,7	190	190	190	-2,6	0,8	-2,1	1,0	-4,1	-0,1	Labelpopulation, Intent-to-Treat Patients, Patients with Screening and post Screening QLQ-CLL-16 result	adjusted

[1] Patients with a value at baseline and at least one post-baseline value

[2] LSMeans of change from baseline from MMRM (including all available records from all visits) [3]

Contrasts from MMRM

[4] Factors/Covariates: treatment, visit, treatment-by-visit interaction, baseline value. In addition, for the total population, adjusted for randomization stratification factors. Clinical cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/t_pro_mmr_allfu.sas

Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/t_pro_mmr_allfu_str_EQCLL16_QLQCLL16pop_IT_label_09MAY2013_21004.xls 03JUN2020

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11 (Anhang): Ergebnisse für EORTC QLQ-C30 Symptomskalen – Mittelwerte pro Visite - Hauptanalysen aus RCT mit dem zu bewertenden Arzneimittel

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

MODEL: Unadjusted Analysis

STUDY: CLL11 (BO21004), Stage 2

Compliance/Mean

Appetite Loss Scale

		GClb (N=255)						RC1b (N=242)					
		Patients			Statistics			Patients			Statistics		
Name Visit	Level	in study ¹	%	with value ¹	%	Mean ²	SD (mean)	in study ¹	%	with value ¹	%	Mean ²	SD (mean)
All													
Screening	n/a	255	100,0	241	94,5	16,18	27,91	242	100,0	227	93,8	16,15	27,04
Cycle 4 Day 1	n/a	213	83,5	195	91,5	10,94	21,27	224	92,6	197	87,9	13,87	25,41
FU Day 28	n/a	230	90,2	201	87,4	10,12	20,61	225	93,0	202	89,8	12,38	23,17
FU Month 3	n/a	225	88,2	203	90,2	8,87	21,45	221	91,3	196	88,7	12,41	23,12
FU Month 6	n/a	207	81,2	185	89,4	6,67	16,59	192	79,3	169	88,0	10,45	22,18
FU Month 9	n/a	164	64,3	137	83,5	8,76	19,91	149	61,6	121	81,2	9,37	21,18
FU Month 12	n/a	125	49,0	109	87,2	8,56	21,47	117	48,3	99	84,6	11,11	21,82
FU Month 15	n/a	104	40,8	90	86,5	7,78	21,81	85	35,1	69	81,2	11,11	21,13
FU Month 18	n/a	79	31,0	70	88,6	8,57	20,99	60	24,8	49	81,7	12,93	23,39
FU Month 21	n/a	52	20,4	40	76,9	6,67	17,21	40	16,5	32	80,0	10,42	27,35
FU Month 24	n/a	32	12,5	24	75,0	4,17	11,26	18	7,4	17	94,4	5,88	13,10
FU Month 27	n/a	13	5,1	11	84,6	3,03	10,05	9	3,7	7	77,8	4,76	12,60
FU Month 30	n/a	7	2,7	6	85,7	16,67	27,89	1	0,4	1	100,0	0,00	NE

¹ in study: number of subjects in study at respective visit; % based on baseline

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit

² mean: descriptive statistics - absolute values Clinical

cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/t_pro_mean.sas

Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/t_pro_mean_EQC30_IT_label_09MAY2013_21004.xls 04MAR2020

17:15

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

MODEL: Unadjusted Analysis

STUDY: CLL11(BO21004), Stage 2

Compliance/Mean

Constipation Scale

		GClb (N=255)						RC1b (N=242)					
		Patients			Statistics			Patients			Statistics		
Name	Level	in study ¹	%	with value ¹	%	Mean ²	SD(mean)	in study ¹	%	with value ¹	%	Mean ²	SD(mean)
All													
Screening	n/a	255	100,0	238	93,3	14,71	23,39	242	100,0	227	93,8	16,30	26,12
Cycle 4 Day 1	n/a	213	83,5	196	92,0	16,16	26,25	224	92,6	196	87,5	16,16	24,45
FU Day 28	n/a	230	90,2	201	87,4	14,76	24,90	225	93,0	201	89,3	13,60	23,63
FU Month 3	n/a	225	88,2	201	89,3	12,77	23,98	221	91,3	195	88,2	13,50	22,83
FU Month 6	n/a	207	81,2	188	90,8	10,11	19,46	192	79,3	168	87,5	17,26	26,04
FU Month 9	n/a	164	64,3	138	84,1	9,66	20,22	149	61,6	119	79,9	13,17	23,05
FU Month 12	n/a	125	49,0	108	86,4	9,88	18,38	117	48,3	99	84,6	14,14	22,88
FU Month 15	n/a	104	40,8	90	86,5	9,26	18,04	85	35,1	69	81,2	13,04	24,40
FU Month 18	n/a	79	31,0	68	86,1	10,29	20,97	60	24,8	49	81,7	17,69	27,30
FU Month 21	n/a	52	20,4	40	76,9	4,17	11,16	40	16,5	32	80,0	21,88	32,36
FU Month 24	n/a	32	12,5	24	75,0	5,56	12,69	18	7,4	16	88,9	10,42	20,07
FU Month 27	n/a	13	5,1	11	84,6	3,03	10,05	9	3,7	7	77,8	9,52	16,27
FU Month 30	n/a	7	2,7	6	85,7	22,22	27,22	1	0,4	1	100,0	0,00	NE

¹ in study: number of subjects in study at respective visit; % based on baseline

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit

² mean: descriptive statistics - absolute values Clinical

cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/t_pro_mean.sas

Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/t_pro_mean_EQC30_IT_label_09MAY2013_21004.xls 04MAR2020

17:15

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

MODEL: Unadjusted Analysis

STUDY: CLL11(BO21004), Stage 2

Compliance/Mean

Diarrhoea Scale

		GClb (N=255)						RCIb (N=242)					
		Patients			Statistics			Patients			Statistics		
Name	Level	in study ¹	%	with value ¹	%	Mean ²	SD(mean)	in study ¹	%	with value ¹	%	Mean ²	SD(mean)
All													
Screening	n/a	255	100,0	239	93,7	8,23	18,64	242	100,0	226	93,4	8,85	19,64
Cycle 4 Day 1	n/a	213	83,5	196	92,0	10,20	22,09	224	92,6	196	87,5	10,20	21,30
FU Day 28	n/a	230	90,2	201	87,4	9,29	20,33	225	93,0	200	88,9	9,83	20,27
FU Month 3	n/a	225	88,2	202	89,8	8,91	19,61	221	91,3	195	88,2	8,21	17,94
FU Month 6	n/a	207	81,2	188	90,8	7,98	19,54	192	79,3	167	87,0	10,38	20,34
FU Month 9	n/a	164	64,3	138	84,1	6,52	14,44	149	61,6	119	79,9	8,40	16,93
FU Month 12	n/a	125	49,0	109	87,2	8,26	19,85	117	48,3	98	83,8	7,82	17,12
FU Month 15	n/a	104	40,8	91	87,5	5,49	15,92	85	35,1	69	81,2	7,73	16,31
FU Month 18	n/a	79	31,0	68	86,1	9,31	22,93	60	24,8	49	81,7	8,84	18,97
FU Month 21	n/a	52	20,4	40	76,9	3,33	10,13	40	16,5	31	77,5	10,75	24,93
FU Month 24	n/a	32	12,5	25	78,1	9,33	22,61	18	7,4	16	88,9	8,33	25,82
FU Month 27	n/a	13	5,1	11	84,6	3,03	10,05	9	3,7	7	77,8	9,52	25,20
FU Month 30	n/a	7	2,7	5	71,4	0,00	0,00	1	0,4	1	100,0	0,00	NE

¹ in study: number of subjects in study at respective visit; % based on baseline

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit

² mean: descriptive statistics - absolute values Clinical

cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/t_pro_mean.sas

Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/t_pro_mean_EQC30_IT_label_09MAY2013_21004.xls 04MAR2020

17:15

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

MODEL: Unadjusted Analysis

STUDY: CLL11(BO21004), Stage 2

Compliance/Mean

Dyspnoea Scale

		GClb (N=255)						RC1b (N=242)					
		Patients			Statistics			Patients			Statistics		
Name	Level	in study ¹	%	with value ¹	%	Mean ²	SD(mean)	in study ¹	%	with value ¹	%	Mean ²	SD(mean)
All													
Screening	n/a	255	100,0	239	93,7	26,36	29,75	242	100,0	227	93,8	28,49	28,93
Cycle 4 Day 1	n/a	213	83,5	195	91,5	15,04	22,99	224	92,6	197	87,9	22,67	27,85
FU Day 28	n/a	230	90,2	199	86,5	18,09	25,00	225	93,0	200	88,9	21,83	27,88
FU Month 3	n/a	225	88,2	202	89,8	18,98	26,76	221	91,3	195	88,2	22,05	26,40
FU Month 6	n/a	207	81,2	185	89,4	18,20	23,81	192	79,3	169	88,0	23,87	28,68
FU Month 9	n/a	164	64,3	137	83,5	15,82	22,54	149	61,6	120	80,5	26,39	29,91
FU Month 12	n/a	125	49,0	109	87,2	17,74	23,38	117	48,3	98	83,8	25,85	28,93
FU Month 15	n/a	104	40,8	89	85,6	17,60	23,62	85	35,1	69	81,2	25,60	28,67
FU Month 18	n/a	79	31,0	69	87,3	21,26	27,99	60	24,8	48	80,0	27,78	30,23
FU Month 21	n/a	52	20,4	40	76,9	18,33	27,16	40	16,5	32	80,0	26,04	32,50
FU Month 24	n/a	32	12,5	24	75,0	15,28	24,04	18	7,4	16	88,9	22,92	33,82
FU Month 27	n/a	13	5,1	11	84,6	18,18	27,34	9	3,7	6	66,7	5,56	13,61
FU Month 30	n/a	7	2,7	6	85,7	5,56	13,61	1	0,4	1	100,0	0,00	NE

¹ in study: number of subjects in study at respective visit; % based on baseline

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit

² mean: descriptive statistics - absolute values Clinical

cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/t_pro_mean.sas

Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/t_pro_mean_EQC30_IT_label_09MAY2013_21004.xls 04MAR2020

17:15

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

MODEL: Unadjusted Analysis

STUDY: CLL11(BO21004), Stage 2

Compliance/Mean

Fatigue Scale

		GClb (N=255)						RC1b (N=242)					
		Patients			Statistics			Patients			Statistics		
Name	Level	in study ¹	%	with value ¹	%	Mean ²	SD(mean)	in study ¹	%	with value ¹	%	Mean ²	SD(mean)
All													
Screening	n/a	255	100,0	238	93,3	36,88	26,10	242	100,0	228	94,2	37,55	26,03
Cycle 4 Day 1	n/a	213	83,5	195	91,5	28,95	21,18	224	92,6	198	88,4	32,46	23,71
FU Day 28	n/a	230	90,2	201	87,4	31,65	24,83	225	93,0	203	90,2	31,55	24,25
FU Month 3	n/a	225	88,2	203	90,2	28,52	24,47	221	91,3	196	88,7	30,92	23,63
FU Month 6	n/a	207	81,2	186	89,9	27,00	23,59	192	79,3	170	88,5	30,26	24,72
FU Month 9	n/a	164	64,3	138	84,1	25,76	22,22	149	61,6	121	81,2	30,85	24,10
FU Month 12	n/a	125	49,0	109	87,2	29,05	23,42	117	48,3	99	84,6	29,52	24,39
FU Month 15	n/a	104	40,8	90	86,5	25,43	21,73	85	35,1	69	81,2	30,68	25,72
FU Month 18	n/a	79	31,0	70	88,6	28,49	24,70	60	24,8	49	81,7	33,33	24,85
FU Month 21	n/a	52	20,4	40	76,9	30,00	24,29	40	16,5	32	80,0	31,77	26,67
FU Month 24	n/a	32	12,5	25	78,1	30,22	24,54	18	7,4	17	94,4	25,49	25,99
FU Month 27	n/a	13	5,1	11	84,6	27,78	23,17	9	3,7	7	77,8	19,05	21,00
FU Month 30	n/a	7	2,7	6	85,7	29,63	25,01	1	0,4	1	100,0	0,00	NE

¹ in study: number of subjects in study at respective visit; % based on baseline

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit

² mean: descriptive statistics - absolute values Clinical

cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/t_pro_mean.sas

Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/t_pro_mean_EQC30_IT_label_09MAY2013_21004.xls 04MAR2020

17:15

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

MODEL: Unadjusted Analysis

STUDY: CLL11(BO21004), Stage 2

Compliance/Mean

Financial Difficulties Scale

		GClb (N=255)						RC1b (N=242)					
		Patients			Statistics			Patients			Statistics		
Name	Level	in study ¹	%	with value ¹	%	Mean ²	SD(mean)	in study ¹	%	with value ¹	%	Mean ²	SD(mean)
All													
Screening	n/a	255	100,0	239	93,7	9,07	19,24	242	100,0	224	92,6	8,04	18,27
Cycle 4 Day 1	n/a	213	83,5	196	92,0	7,14	16,71	224	92,6	193	86,2	8,64	19,70
FU Day 28	n/a	230	90,2	199	86,5	9,55	21,01	225	93,0	200	88,9	8,33	19,12
FU Month 3	n/a	225	88,2	202	89,8	10,56	23,48	221	91,3	194	87,8	10,14	22,13
FU Month 6	n/a	207	81,2	186	89,9	7,17	19,51	192	79,3	167	87,0	9,78	21,12
FU Month 9	n/a	164	64,3	138	84,1	5,80	16,56	149	61,6	119	79,9	7,56	16,49
FU Month 12	n/a	125	49,0	109	87,2	6,12	15,82	117	48,3	98	83,8	6,80	17,88
FU Month 15	n/a	104	40,8	91	87,5	7,69	19,29	85	35,1	69	81,2	6,28	16,44
FU Month 18	n/a	79	31,0	69	87,3	6,76	18,59	60	24,8	48	80,0	8,33	17,53
FU Month 21	n/a	52	20,4	40	76,9	5,00	14,22	40	16,5	32	80,0	11,46	20,05
FU Month 24	n/a	32	12,5	25	78,1	8,00	17,43	18	7,4	16	88,9	8,33	14,91
FU Month 27	n/a	13	5,1	11	84,6	6,06	13,48	9	3,7	7	77,8	0,00	0,00
FU Month 30	n/a	7	2,7	6	85,7	11,11	27,22	1	0,4	1	100,0	0,00	NE

¹ in study: number of subjects in study at respective visit; % based on baseline

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit

² mean: descriptive statistics - absolute values Clinical

cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/t_pro_mean.sas

Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/t_pro_mean_EQC30_IT_label_09MAY2013_21004.xls 04MAR2020

17:15

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

MODEL: Unadjusted Analysis

STUDY: CLL11(BO21004), Stage 2

Compliance/Mean

Nausea And Vomiting Scale

		GClb (N=255)						RC1b (N=242)					
		Patients				Statistics		Patients				Statistics	
Name	Level	in study ¹	%	with value ¹	%	Mean ²	SD(mean)	in study ¹	%	with value ¹	%	Mean ²	SD(mean)
All													
Screening	n/a	255	100,0	242	94,9	3,99	10,95	242	100,0	228	94,2	4,24	12,28
Cycle 4 Day 1	n/a	213	83,5	195	91,5	5,21	11,35	224	92,6	198	88,4	4,71	11,28
FU Day 28	n/a	230	90,2	201	87,4	3,90	11,90	225	93,0	202	89,8	4,46	12,85
FU Month 3	n/a	225	88,2	203	90,2	3,12	10,15	221	91,3	196	88,7	4,51	11,24
FU Month 6	n/a	207	81,2	186	89,9	2,51	8,65	192	79,3	169	88,0	3,35	8,83
FU Month 9	n/a	164	64,3	138	84,1	3,74	12,25	149	61,6	121	81,2	3,86	8,27
FU Month 12	n/a	125	49,0	109	87,2	2,75	8,93	117	48,3	99	84,6	2,36	6,74
FU Month 15	n/a	104	40,8	90	86,5	3,15	9,64	85	35,1	69	81,2	3,38	9,30
FU Month 18	n/a	79	31,0	70	88,6	3,57	9,79	60	24,8	49	81,7	3,06	8,10
FU Month 21	n/a	52	20,4	40	76,9	3,75	10,33	40	16,5	32	80,0	4,17	15,84
FU Month 24	n/a	32	12,5	25	78,1	6,00	12,62	18	7,4	17	94,4	0,98	4,04
FU Month 27	n/a	13	5,1	11	84,6	7,58	15,57	9	3,7	7	77,8	0,00	0,00
FU Month 30	n/a	7	2,7	6	85,7	8,33	20,41	1	0,4	1	100,0	0,00	NE

¹ in study: number of subjects in study at respective visit; % based on baseline

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit

² mean: descriptive statistics - absolute values Clinical

cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/t_pro_mean.sas

Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/t_pro_mean_EQC30_IT_label_09MAY2013_21004.xls 04MAR2020

17:15

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

MODEL: Unadjusted Analysis

STUDY: CLL11(BO21004), Stage 2

Compliance/Mean

Pain Scale

		GClb (N=255)						RC1b (N=242)					
		Patients				Statistics		Patients				Statistics	
Name	Level	in study ¹	%	with value ¹	%	Mean ²	SD(mean)	in study ¹	%	with value ¹	%	Mean ²	SD(mean)
All													
Screening	n/a	255	100,0	242	94,9	21,83	27,07	242	100,0	228	94,2	22,44	28,19
Cycle 4 Day 1	n/a	213	83,5	196	92,0	17,77	25,04	224	92,6	198	88,4	17,93	24,62
FU Day 28	n/a	230	90,2	201	87,4	21,48	28,61	225	93,0	203	90,2	19,13	27,54
FU Month 3	n/a	225	88,2	203	90,2	20,11	28,03	221	91,3	196	88,7	21,26	26,02
FU Month 6	n/a	207	81,2	188	90,8	19,41	26,14	192	79,3	170	88,5	21,47	26,92
FU Month 9	n/a	164	64,3	138	84,1	17,39	27,38	149	61,6	121	81,2	20,25	27,40
FU Month 12	n/a	125	49,0	108	86,4	20,22	26,68	117	48,3	99	84,6	21,72	28,62
FU Month 15	n/a	104	40,8	90	86,5	17,78	23,68	85	35,1	69	81,2	21,01	27,06
FU Month 18	n/a	79	31,0	69	87,3	19,57	24,91	60	24,8	49	81,7	21,43	29,46
FU Month 21	n/a	52	20,4	40	76,9	20,42	25,17	40	16,5	32	80,0	21,35	27,18
FU Month 24	n/a	32	12,5	25	78,1	19,33	32,87	18	7,4	17	94,4	22,55	28,22
FU Month 27	n/a	13	5,1	11	84,6	13,64	26,69	9	3,7	7	77,8	7,14	8,91
FU Month 30	n/a	7	2,7	6	85,7	19,44	26,70	1	0,4	1	100,0	16,67	NE

¹ in study: number of subjects in study at respective visit; % based on baseline

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit

² mean: descriptive statistics - absolute values Clinical

cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/t_pro_mean.sas

Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/t_pro_mean_EQC30_IT_label_09MAY2013_21004.xls 04MAR2020

17:15

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

MODEL: Unadjusted Analysis

STUDY: CLL11(BO21004), Stage 2

Compliance/Mean

Insomnia Scale

		GClb (N=255)						RC1b (N=242)					
		Patients				Statistics		Patients				Statistics	
Name	Level	in study ¹	%	with value ¹	%	Mean ²	SD(mean)	in study ¹	%	with value ¹	%	Mean ²	SD(mean)
All													
Screening	n/a	255	100,0	241	94,5	30,29	31,03	242	100,0	228	94,2	25,58	30,71
Cycle 4 Day 1	n/a	213	83,5	195	91,5	22,74	29,34	224	92,6	196	87,5	23,47	28,33
FU Day 28	n/a	230	90,2	199	86,5	24,79	29,77	225	93,0	203	90,2	21,51	25,95
FU Month 3	n/a	225	88,2	203	90,2	25,45	28,59	221	91,3	195	88,2	23,25	28,03
FU Month 6	n/a	207	81,2	185	89,4	25,23	29,70	192	79,3	169	88,0	22,09	29,74
FU Month 9	n/a	164	64,3	138	84,1	21,74	28,38	149	61,6	121	81,2	23,97	29,57
FU Month 12	n/a	125	49,0	109	87,2	22,02	27,30	117	48,3	98	83,8	24,83	29,24
FU Month 15	n/a	104	40,8	89	85,6	20,22	25,43	85	35,1	67	78,8	22,39	29,81
FU Month 18	n/a	79	31,0	70	88,6	20,48	27,97	60	24,8	49	81,7	19,05	30,43
FU Month 21	n/a	52	20,4	40	76,9	23,33	27,43	40	16,5	32	80,0	27,08	31,04
FU Month 24	n/a	32	12,5	25	78,1	21,33	25,24	18	7,4	17	94,4	13,73	16,91
FU Month 27	n/a	13	5,1	11	84,6	24,24	26,21	9	3,7	7	77,8	14,29	17,82
FU Month 30	n/a	7	2,7	5	71,4	13,33	29,81	1	0,4	1	100,0	0,00	NE

¹ in study: number of subjects in study at respective visit; % based on baseline

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit

² mean: descriptive statistics - absolute values Clinical

cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/t_pro_mean.sas

Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/t_pro_mean_EQC30_IT_label_09MAY2013_21004.xls 04MAR2020

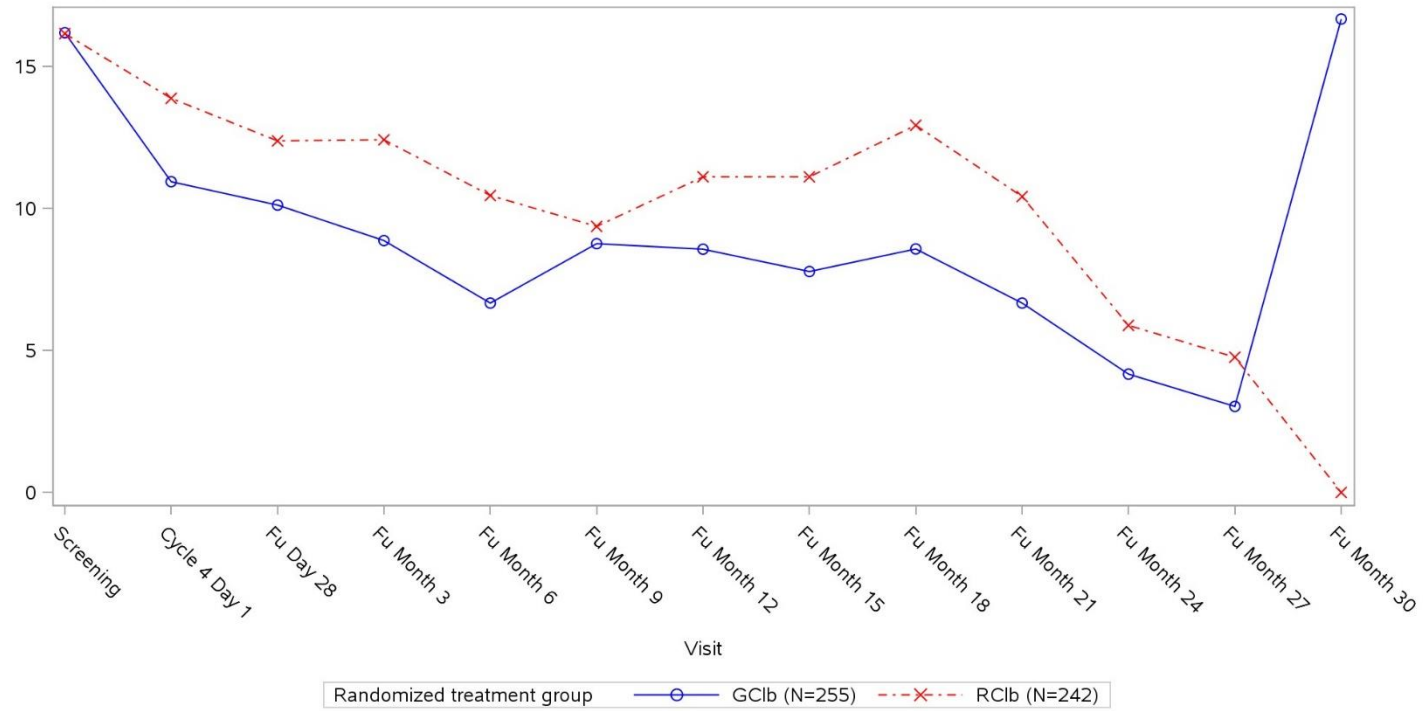
17:15

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Laboratory Test: Appetite Loss Scale



Clinical cut-off: 09MAY2013

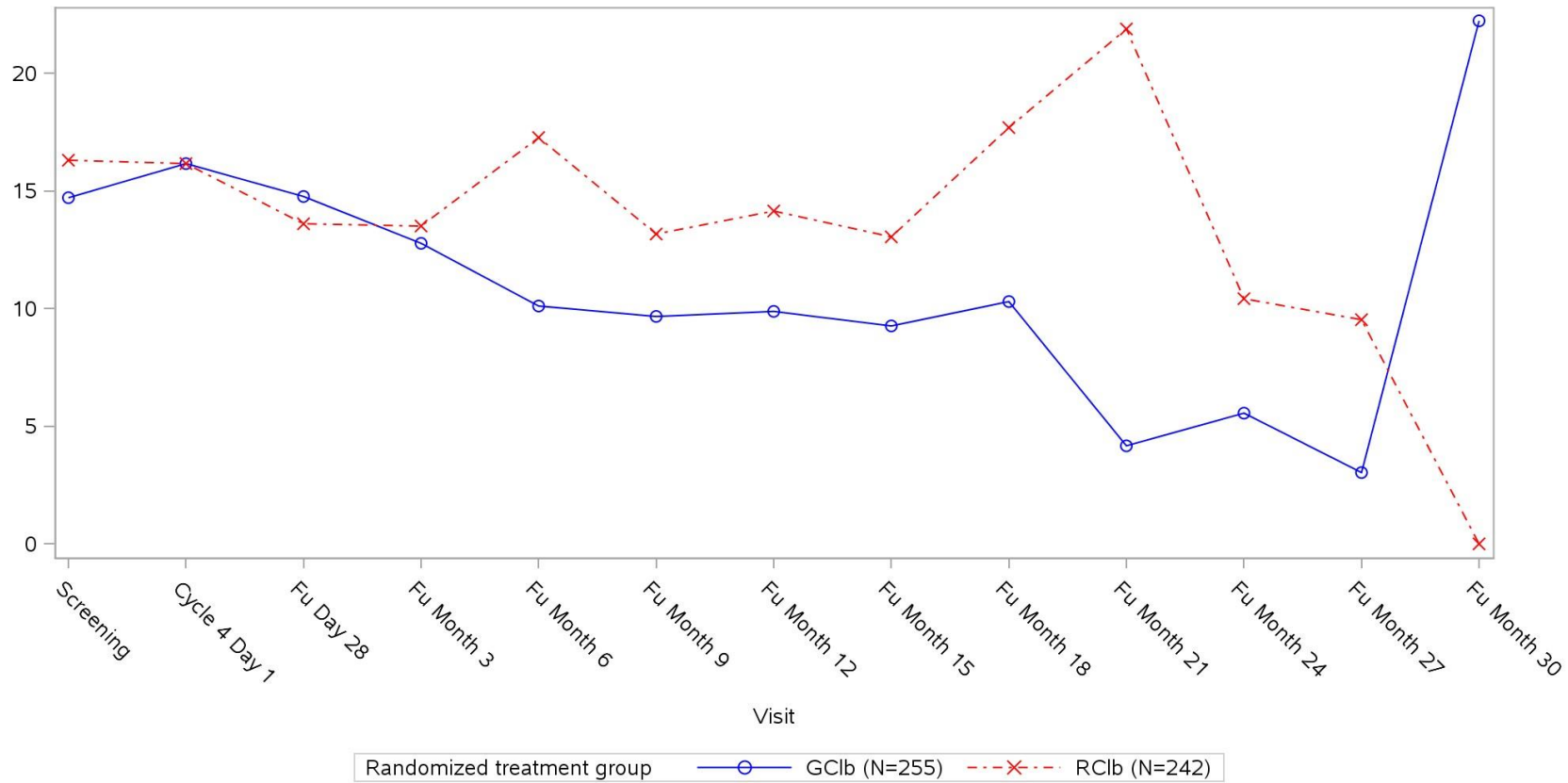
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04MAR2020 16:15

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Laboratory Test: Constipation Scale



Clinical cut-off: 09MAY2013

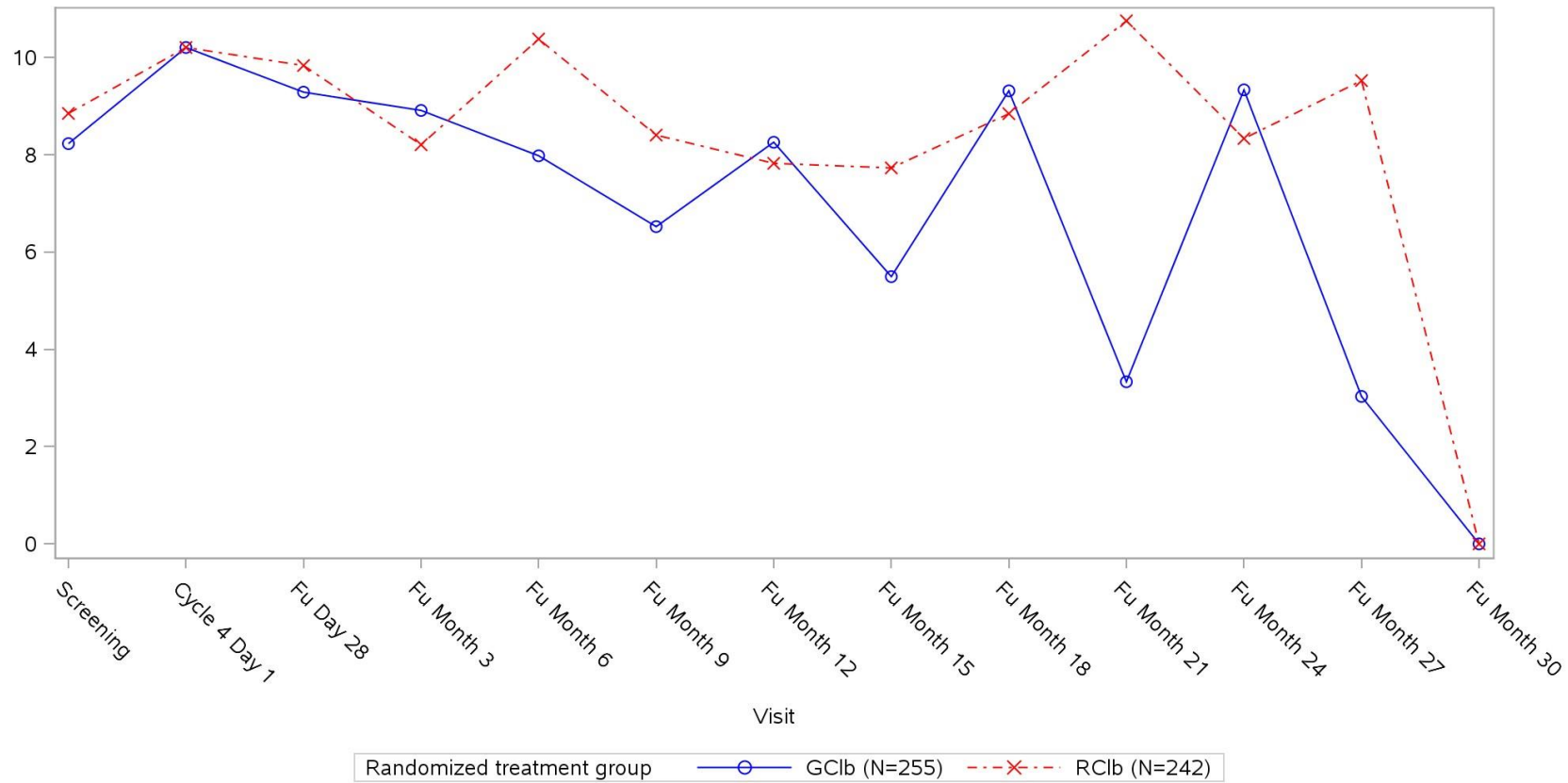
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04MAR2020 16:15

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Laboratory Test: Diarrhoea Scale



Clinical cut-off: 09MAY2013

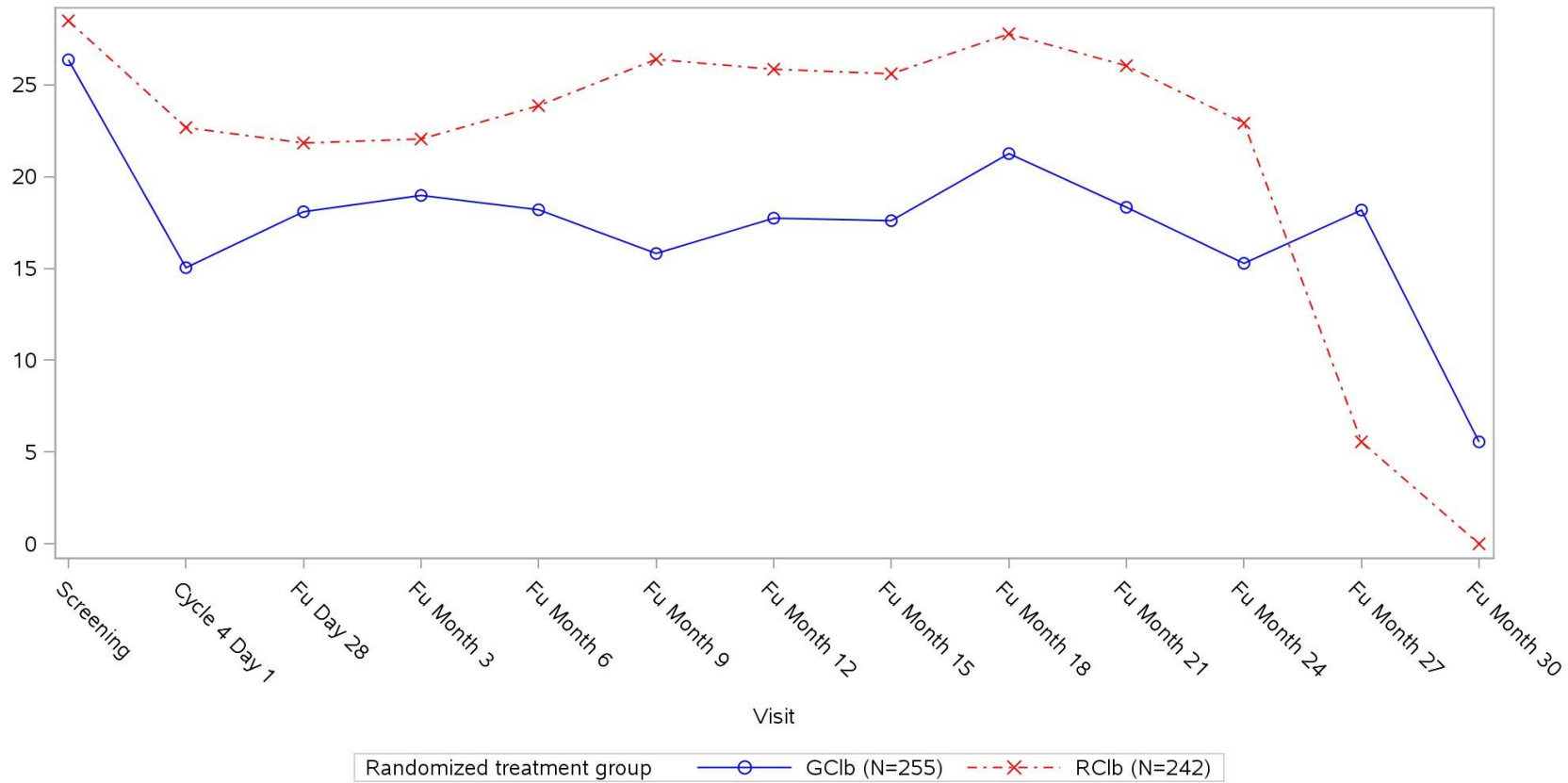
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04MAR2020 16:15

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Laboratory Test: Dyspnoea Scale

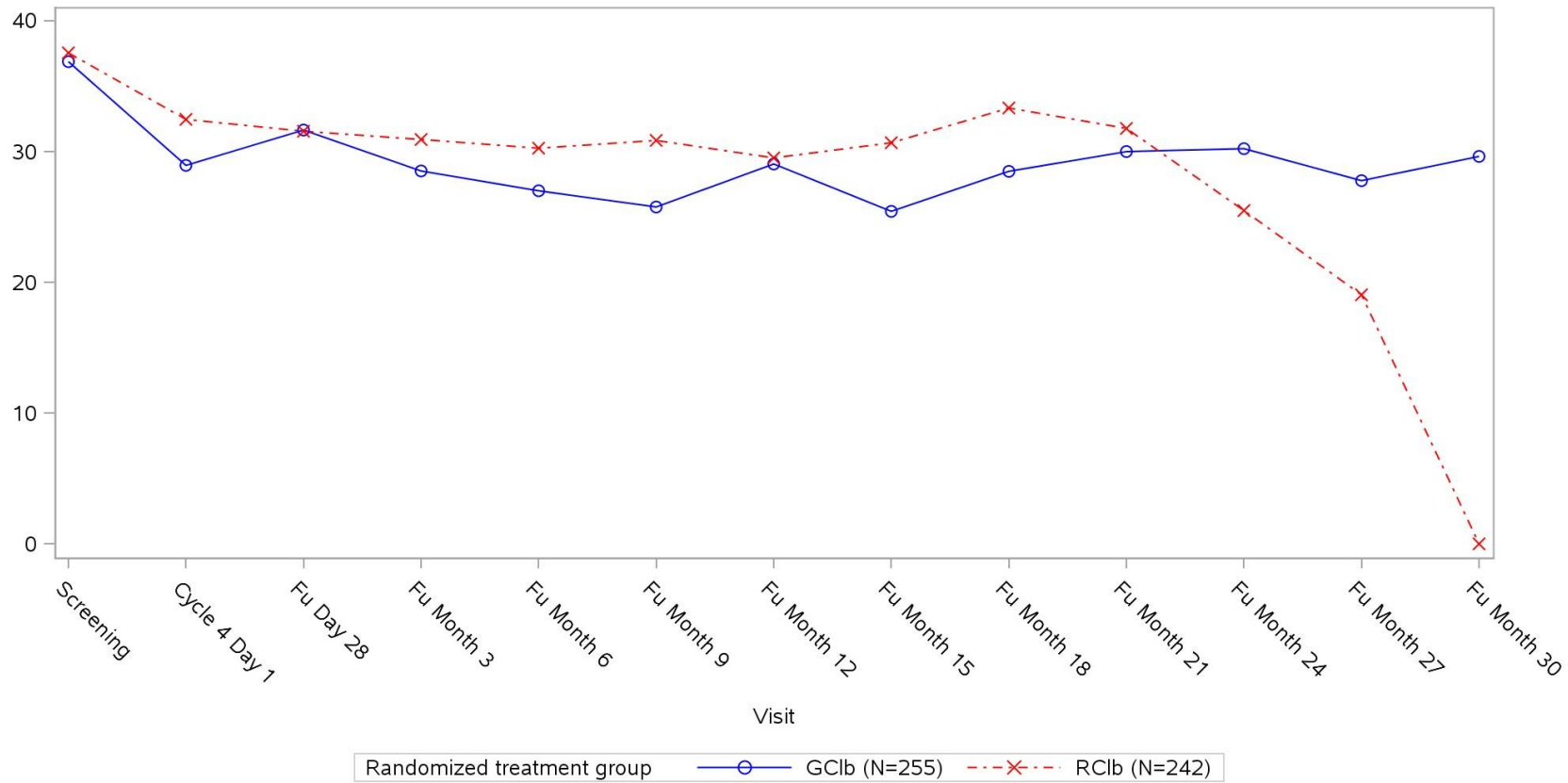


Clinical cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/g_pro_mean.sas
Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/g_pro_mean_EQC30_IT_label_09MAY2013_21004.pdf
04MAR2020 16:15

POPULATION: Labelpopulation, Intent-to-Treat Patients
ENDPOINT: EORTC QoL 30
STUDY: CLL11(BO21004), Stage 2

Laboratory Test: Fatigue Scale



Clinical cut-off: 09MAY2013

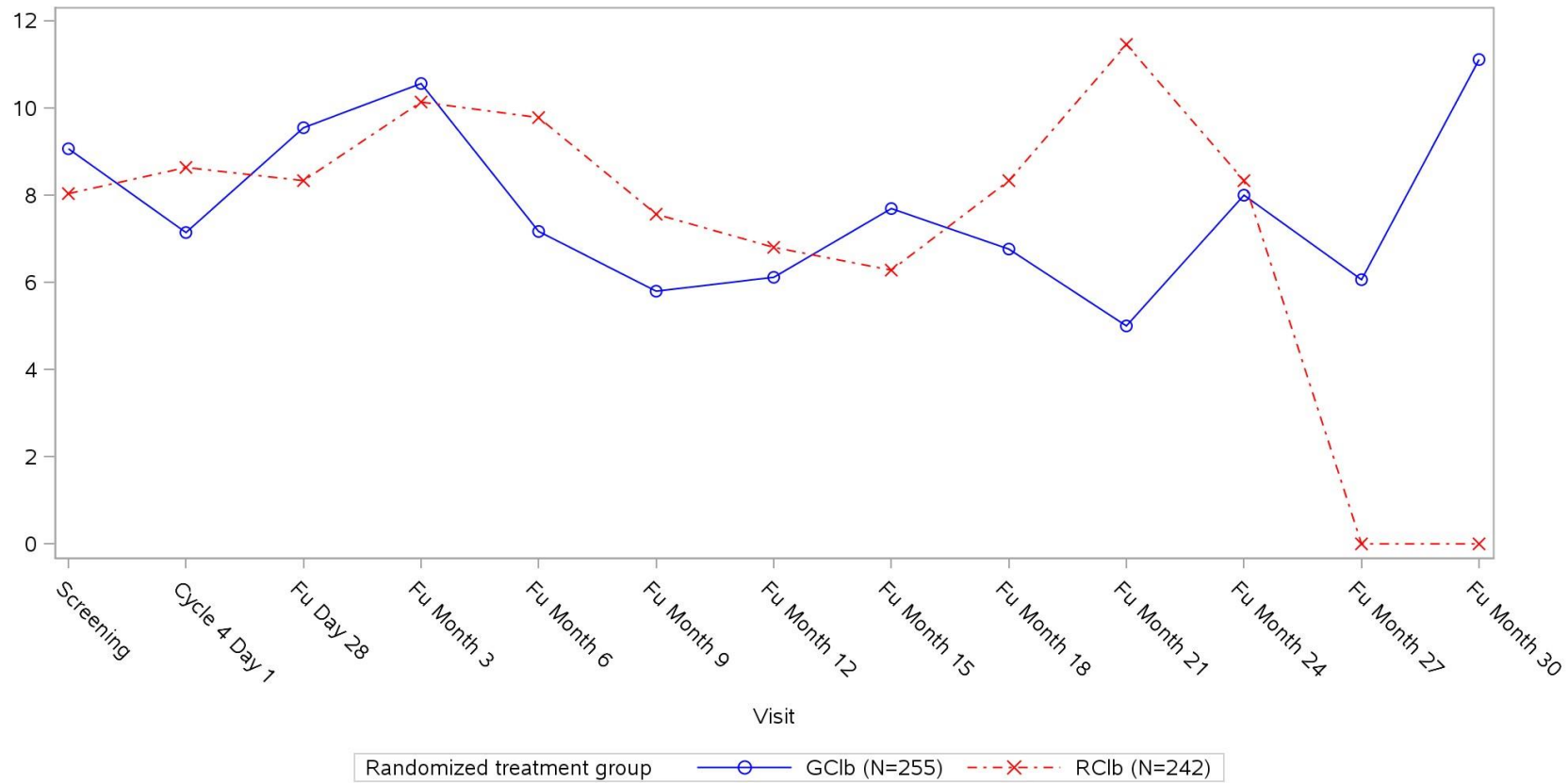
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 Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/g_pro_mean_EQC30_IT_label_09MAY2013_21004.pdf
 04MAR2020 16:15

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Laboratory Test: Financial Difficulties Scale



Clinical cut-off: 09MAY2013

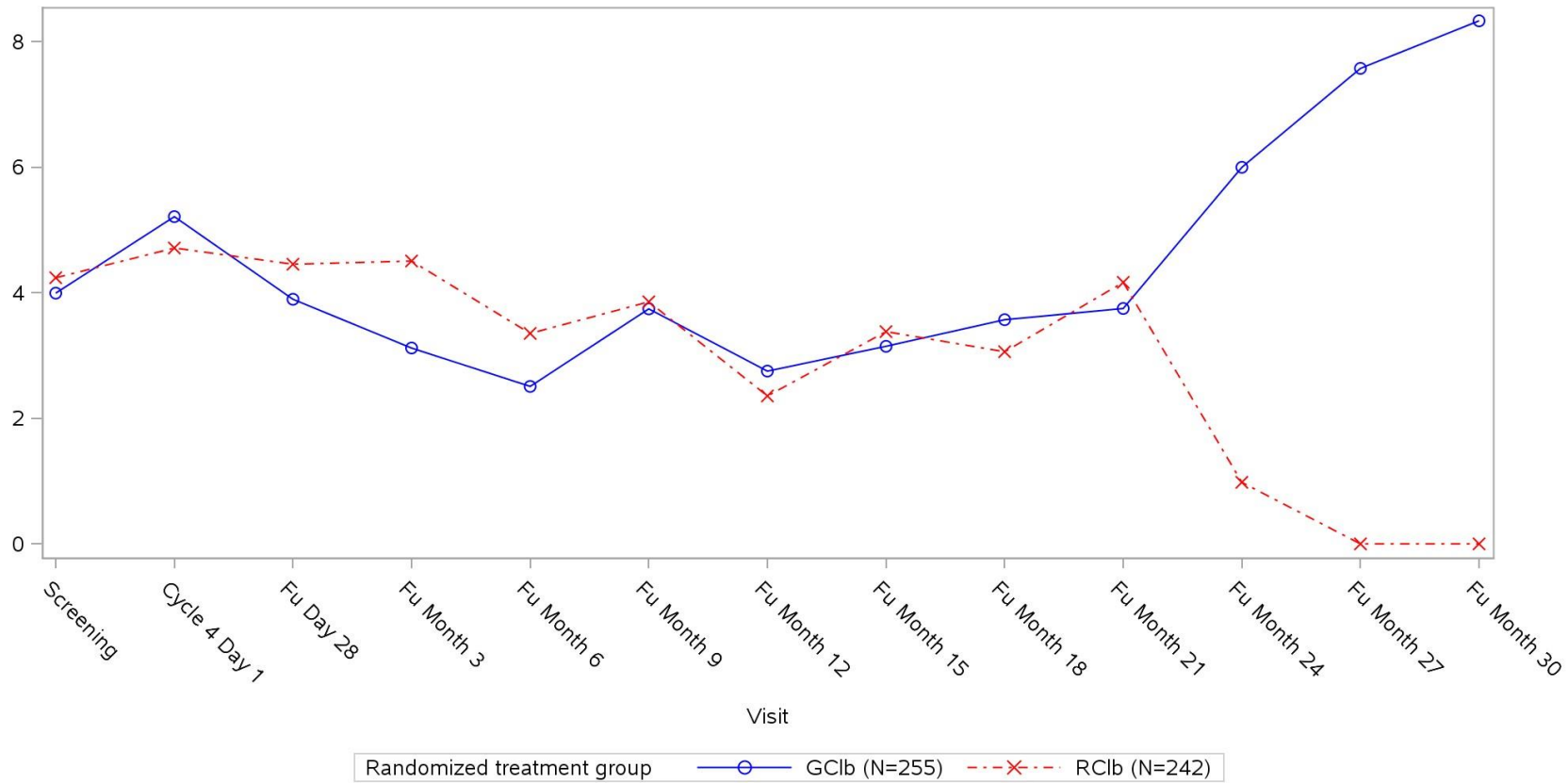
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Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/g_pro_mean_EQC30_IT_label_09MAY2013_21004.pdf
04MAR2020 16:15

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Laboratory Test: Nausia And Vomiting Scale



Clinical cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/g_pro_mean.sas
Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/g_pro_mean_EQC30_IT_label_09MAY2013_21004.pdf
04MAR2020 16:15

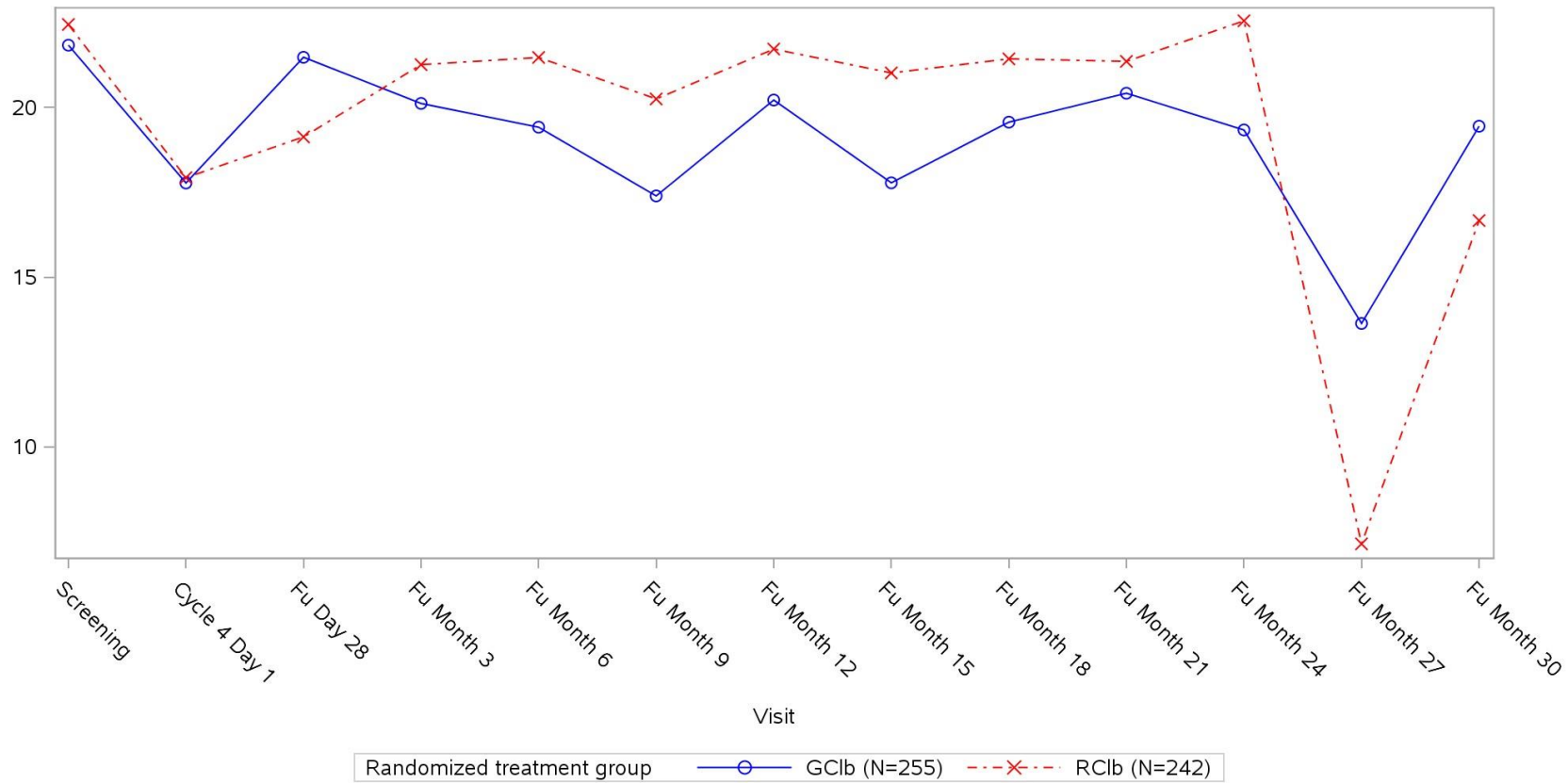
Page 9 of 15

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Laboratory Test: Pain Scale



Clinical cut-off: 09MAY2013

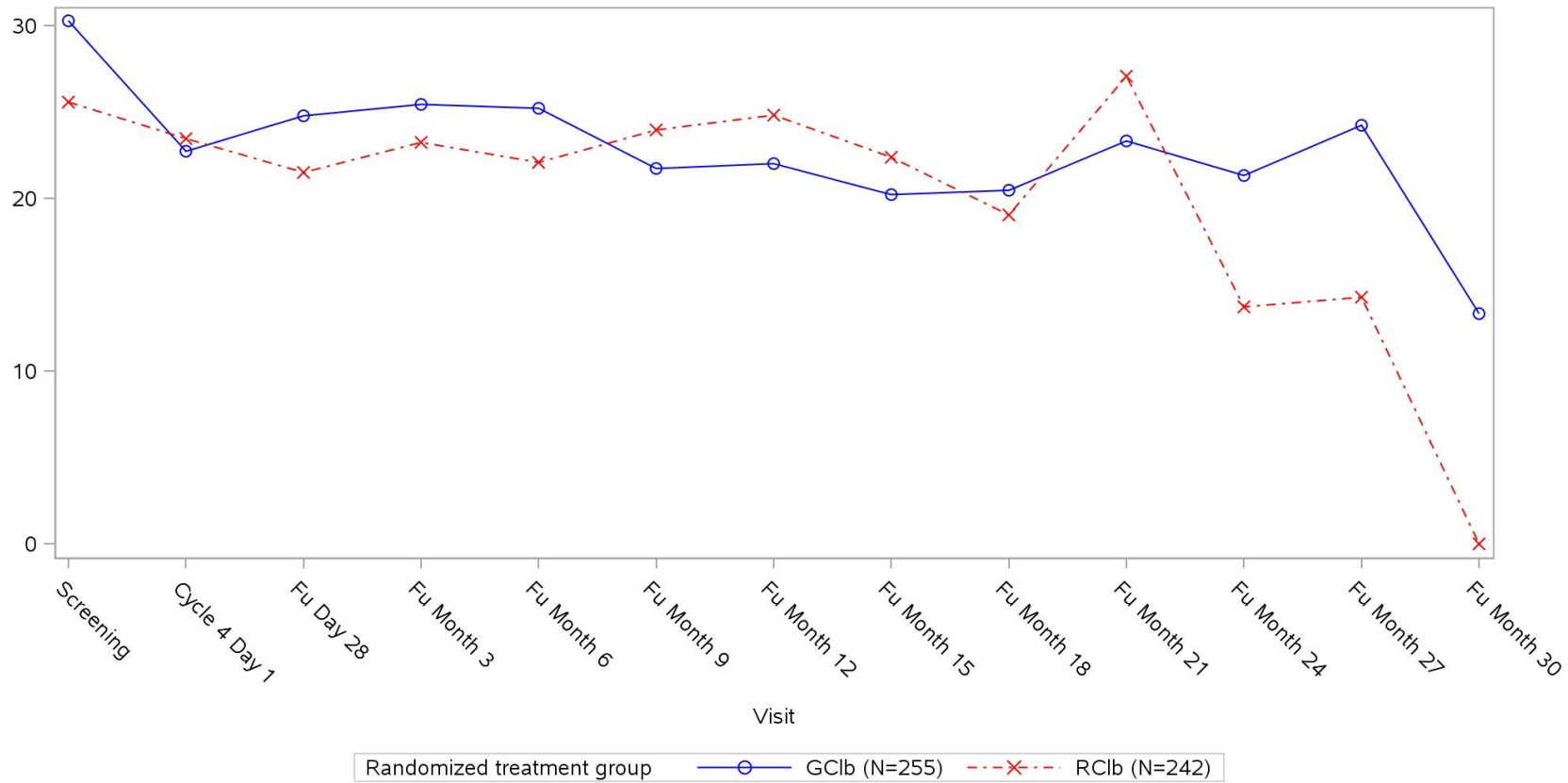
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Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/g_pro_mean_EQC30_IT_label_09MAY2013_21004.pdf
04MAR2020 16:15

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Laboratory Test: Insomnia Scale



Clinical cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/g_pro_mean.sas
Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/g_pro_mean_EQC30_IT_label_09MAY2013_21004.pdf
04MAR2020 16:15

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12 (Anhang): Ergebnisse für EORTC QLQ-C30 Funktionsskalen – Mittelwerte pro Visite - Hauptanalysen aus RCT mit dem zu bewertenden Arzneimittel

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

MODEL: Unadjusted Analysis

STUDY: CLL11 (BO21004), Stage 2

Compliance/Mean

Global Health Status Scale

		GClb (N=255)						RC1b (N=242)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study ¹	%	with value ¹	%	Mean ²	SD (mean)	in study ¹	%	with value ¹	%	Mean ²	SD (mean)
All													
Screening	n/a	255	100,0	240	94,1	59,65	24,00	242	100,0	227	93,8	58,55	23,36
Cycle 4 Day 1	n/a	213	83,5	193	90,6	67,53	20,46	224	92,6	195	87,1	65,21	20,67
FU Day 28	n/a	230	90,2	200	87,0	68,96	22,01	225	93,0	198	88,0	66,67	21,37
FU Month 3	n/a	225	88,2	201	89,3	69,28	21,45	221	91,3	193	87,3	66,75	20,76
FU Month 6	n/a	207	81,2	188	90,8	69,81	19,58	192	79,3	167	87,0	65,72	21,15
FU Month 9	n/a	164	64,3	137	83,5	68,49	21,43	149	61,6	119	79,9	67,02	18,71
FU Month 12	n/a	125	49,0	109	87,2	69,72	21,63	117	48,3	99	84,6	66,16	20,23
FU Month 15	n/a	104	40,8	91	87,5	69,51	19,65	85	35,1	68	80,0	63,24	20,78
FU Month 18	n/a	79	31,0	69	87,3	70,29	22,44	60	24,8	49	81,7	63,10	19,39
FU Month 21	n/a	52	20,4	40	76,9	71,46	19,87	40	16,5	32	80,0	61,98	22,69
FU Month 24	n/a	32	12,5	25	78,1	64,67	25,26	18	7,4	16	88,9	72,92	16,24
FU Month 27	n/a	13	5,1	11	84,6	68,18	18,94	9	3,7	7	77,8	66,67	23,07
FU Month 30	n/a	7	2,7	6	85,7	55,56	16,39	1	0,4	1	100,0	58,33	NE

¹ in study: number of subjects in study at respective visit; % based on baseline

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit

² mean: descriptive statistics - absolute values Clinical

cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/t_pro_mean.sas

Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/t_pro_mean_EQC30_IT_label_09MAY2013_21004.xls 04MAR2020

17:15

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

MODEL: Unadjusted Analysis

STUDY: CLL11(BO21004), Stage 2

Compliance/Mean

Cognitive Functioning Scale

		GClb (N=255)						RCIb (N=242)					
		Patients			Statistics			Patients			Statistics		
Name	Level	in study ¹	%	with value ¹	%	Mean ²	SD(mean)	in study ¹	%	with value ¹	%	Mean ²	SD(mean)
All													
Screening	n/a	255	100,0	241	94,5	82,16	21,51	242	100,0	227	93,8	81,57	21,08
Cycle 4 Day 1	n/a	213	83,5	196	92,0	84,01	20,94	224	92,6	197	87,9	82,40	18,07
FU Day 28	n/a	230	90,2	201	87,4	82,67	20,81	225	93,0	201	89,3	84,99	17,24
FU Month 3	n/a	225	88,2	203	90,2	83,83	20,03	221	91,3	195	88,2	81,37	19,82
FU Month 6	n/a	207	81,2	188	90,8	83,33	20,39	192	79,3	168	87,5	81,55	18,06
FU Month 9	n/a	164	64,3	138	84,1	82,13	21,18	149	61,6	119	79,9	81,79	18,15
FU Month 12	n/a	125	49,0	109	87,2	81,80	19,97	117	48,3	99	84,6	80,98	21,30
FU Month 15	n/a	104	40,8	91	87,5	82,42	21,13	85	35,1	69	81,2	80,43	21,76
FU Month 18	n/a	79	31,0	69	87,3	81,88	21,91	60	24,8	49	81,7	80,95	19,25
FU Month 21	n/a	52	20,4	40	76,9	80,00	23,93	40	16,5	32	80,0	79,69	20,62
FU Month 24	n/a	32	12,5	25	78,1	76,00	22,61	18	7,4	16	88,9	79,17	22,36
FU Month 27	n/a	13	5,1	11	84,6	69,70	31,46	9	3,7	7	77,8	80,95	24,40
FU Month 30	n/a	7	2,7	6	85,7	61,11	44,31	1	0,4	1	100,0	100,00	NE

¹ in study: number of subjects in study at respective visit; % based on baseline

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit

² mean: descriptive statistics - absolute values Clinical

cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/t_pro_mean.sas

Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/t_pro_mean_EQC30_IT_label_09MAY2013_21004.xls 04MAR2020

17:15

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

MODEL: Unadjusted Analysis

STUDY: CLL11(BO21004), Stage 2

Compliance/Mean

Emotional Functioning Scale

		GClb (N=255)						RC1b (N=242)					
		Patients				Statistics		Patients				Statistics	
Name	Level	in study ¹	%	with value ¹	%	Mean ²	SD(mean)	in study ¹	%	with value ¹	%	Mean ²	SD(mean)
All													
Screening	n/a	255	100,0	240	94,1	75,28	21,42	242	100,0	227	93,8	76,47	21,81
Cycle 4 Day 1	n/a	213	83,5	196	92,0	82,70	18,71	224	92,6	197	87,9	81,15	19,52
FU Day 28	n/a	230	90,2	200	87,0	81,10	22,64	225	93,0	201	89,3	82,61	17,83
FU Month 3	n/a	225	88,2	203	90,2	80,56	22,83	221	91,3	195	88,2	80,43	20,00
FU Month 6	n/a	207	81,2	188	90,8	81,63	20,05	192	79,3	169	88,0	81,30	20,44
FU Month 9	n/a	164	64,3	138	84,1	82,97	19,96	149	61,6	119	79,9	81,56	18,24
FU Month 12	n/a	125	49,0	109	87,2	82,98	19,17	117	48,3	98	83,8	82,54	19,88
FU Month 15	n/a	104	40,8	91	87,5	85,26	18,66	85	35,1	69	81,2	80,80	19,45
FU Month 18	n/a	79	31,0	69	87,3	83,90	18,21	60	24,8	49	81,7	79,71	24,11
FU Month 21	n/a	52	20,4	40	76,9	83,89	20,42	40	16,5	32	80,0	78,39	25,03
FU Month 24	n/a	32	12,5	25	78,1	80,67	18,43	18	7,4	16	88,9	88,54	13,57
FU Month 27	n/a	13	5,1	11	84,6	77,27	21,11	9	3,7	7	77,8	88,10	13,49
FU Month 30	n/a	7	2,7	6	85,7	70,37	29,17	1	0,4	1	100,0	100,00	NE

¹ in study: number of subjects in study at respective visit; % based on baseline

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit

² mean: descriptive statistics - absolute values Clinical

cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/t_pro_mean.sas

Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/t_pro_mean_EQC30_IT_label_09MAY2013_21004.xls 04MAR2020

17:15

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

MODEL: Unadjusted Analysis

STUDY: CLL11(BO21004), Stage 2

Compliance/Mean

Physical Functioning Scale

		GClb (N=255)						RC1b (N=242)					
		Patients				Statistics		Patients				Statistics	
Name	Level	in study ¹	%	with value ¹	%	Mean ²	SD(mean)	in study ¹	%	with value ¹	%	Mean ²	SD(mean)
All													
Screening	n/a	255	100,0	242	94,9	73,93	21,04	242	100,0	228	94,2	75,34	19,87
Cycle 4 Day 1	n/a	213	83,5	195	91,5	79,10	18,98	224	92,6	198	88,4	76,23	19,14
FU Day 28	n/a	230	90,2	201	87,4	78,20	20,20	225	93,0	203	90,2	78,19	18,98
FU Month 3	n/a	225	88,2	203	90,2	78,28	20,98	221	91,3	196	88,7	76,58	20,50
FU Month 6	n/a	207	81,2	186	89,9	78,78	20,25	192	79,3	170	88,5	76,99	20,15
FU Month 9	n/a	164	64,3	138	84,1	80,39	19,40	149	61,6	121	81,2	74,02	20,36
FU Month 12	n/a	125	49,0	109	87,2	79,53	19,09	117	48,3	99	84,6	74,28	21,95
FU Month 15	n/a	104	40,8	90	86,5	82,31	17,13	85	35,1	69	81,2	75,27	23,93
FU Month 18	n/a	79	31,0	70	88,6	80,62	18,78	60	24,8	49	81,7	76,73	21,52
FU Month 21	n/a	52	20,4	40	76,9	80,17	17,11	40	16,5	32	80,0	77,71	22,95
FU Month 24	n/a	32	12,5	25	78,1	79,20	15,79	18	7,4	17	94,4	83,53	18,43
FU Month 27	n/a	13	5,1	11	84,6	81,06	14,42	9	3,7	7	77,8	81,90	10,69
FU Month 30	n/a	7	2,7	6	85,7	72,22	23,63	1	0,4	1	100,0	73,33	NE

¹ in study: number of subjects in study at respective visit; % based on baseline

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit

² mean: descriptive statistics - absolute values Clinical

cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/t_pro_mean.sas

Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/t_pro_mean_EQC30_IT_label_09MAY2013_21004.xls 04MAR2020

17:15

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

MODEL: Unadjusted Analysis

STUDY: CLL11(BO21004), Stage 2

Compliance/Mean

Role Functioning Scale

		GClb (N=255)						RC1b (N=242)					
		Patients			Statistics			Patients			Statistics		
Name	Level	in study ¹	%	with value ¹	%	Mean ²	SD(mean)	in study ¹	%	with value ¹	%	Mean ²	SD(mean)
All													
Screening	n/a	255	100,0	241	94,5	74,69	27,30	242	100,0	228	94,2	76,39	29,46
Cycle 4 Day 1	n/a	213	83,5	195	91,5	79,15	24,37	224	92,6	197	87,9	77,75	26,99
FU Day 28	n/a	230	90,2	201	87,4	77,69	27,56	225	93,0	203	90,2	77,67	26,52
FU Month 3	n/a	225	88,2	203	90,2	77,50	27,66	221	91,3	195	88,2	78,72	25,13
FU Month 6	n/a	207	81,2	184	88,9	80,34	25,16	192	79,3	168	87,5	78,67	26,17
FU Month 9	n/a	164	64,3	137	83,5	82,00	25,09	149	61,6	121	81,2	77,82	23,51
FU Month 12	n/a	125	49,0	109	87,2	77,22	27,47	117	48,3	99	84,6	76,43	26,30
FU Month 15	n/a	104	40,8	90	86,5	80,74	23,16	85	35,1	69	81,2	79,71	25,38
FU Month 18	n/a	79	31,0	70	88,6	80,48	26,31	60	24,8	49	81,7	72,45	28,17
FU Month 21	n/a	52	20,4	40	76,9	82,50	21,33	40	16,5	32	80,0	73,44	28,35
FU Month 24	n/a	32	12,5	25	78,1	75,33	30,85	18	7,4	17	94,4	85,29	27,56
FU Month 27	n/a	13	5,1	11	84,6	77,27	23,89	9	3,7	7	77,8	88,10	15,85
FU Month 30	n/a	7	2,7	6	85,7	72,22	32,77	1	0,4	1	100,0	100,00	NE

¹ in study: number of subjects in study at respective visit; % based on baseline

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit

² mean: descriptive statistics - absolute values Clinical

cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/t_pro_mean.sas

Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/t_pro_mean_EQC30_IT_label_09MAY2013_21004.xls 04MAR2020

17:15

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

MODEL: Unadjusted Analysis

STUDY: CLL11(BO21004), Stage 2

Compliance/Mean

Social Functioning Scale

		GClb (N=255)						RC1b (N=242)					
		Patients			Statistics			Patients			Statistics		
Name	Level	in study ¹	%	with value ¹	%	Mean ²	SD(mean)	in study ¹	%	with value ¹	%	Mean ²	SD(mean)
All													
Screening	n/a	255	100,0	241	94,5	84,79	24,75	242	100,0	227	93,8	83,11	24,41
Cycle 4 Day 1	n/a	213	83,5	196	92,0	87,07	20,33	224	92,6	196	87,5	84,18	22,18
FU Day 28	n/a	230	90,2	201	87,4	83,75	24,35	225	93,0	201	89,3	85,57	21,65
FU Month 3	n/a	225	88,2	203	90,2	86,29	24,02	221	91,3	195	88,2	83,08	22,10
FU Month 6	n/a	207	81,2	188	90,8	85,82	22,73	192	79,3	167	87,0	85,23	21,60
FU Month 9	n/a	164	64,3	138	84,1	88,16	20,56	149	61,6	118	79,2	86,02	19,97
FU Month 12	n/a	125	49,0	109	87,2	87,16	21,47	117	48,3	98	83,8	84,69	22,28
FU Month 15	n/a	104	40,8	91	87,5	89,01	19,60	85	35,1	69	81,2	83,57	25,32
FU Month 18	n/a	79	31,0	69	87,3	88,41	18,37	60	24,8	49	81,7	82,65	27,21
FU Month 21	n/a	52	20,4	40	76,9	87,50	20,24	40	16,5	32	80,0	80,21	25,55
FU Month 24	n/a	32	12,5	25	78,1	80,67	25,31	18	7,4	16	88,9	83,33	31,03
FU Month 27	n/a	13	5,1	11	84,6	84,85	24,10	9	3,7	7	77,8	90,48	25,20
FU Month 30	n/a	7	2,7	6	85,7	72,22	32,77	1	0,4	1	100,0	100,00	NE

¹ in study: number of subjects in study at respective visit; % based on baseline

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit

² mean: descriptive statistics - absolute values Clinical

cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/t_pro_mean.sas

Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/t_pro_mean_EQC30_IT_label_09MAY2013_21004.xls 04MAR2020

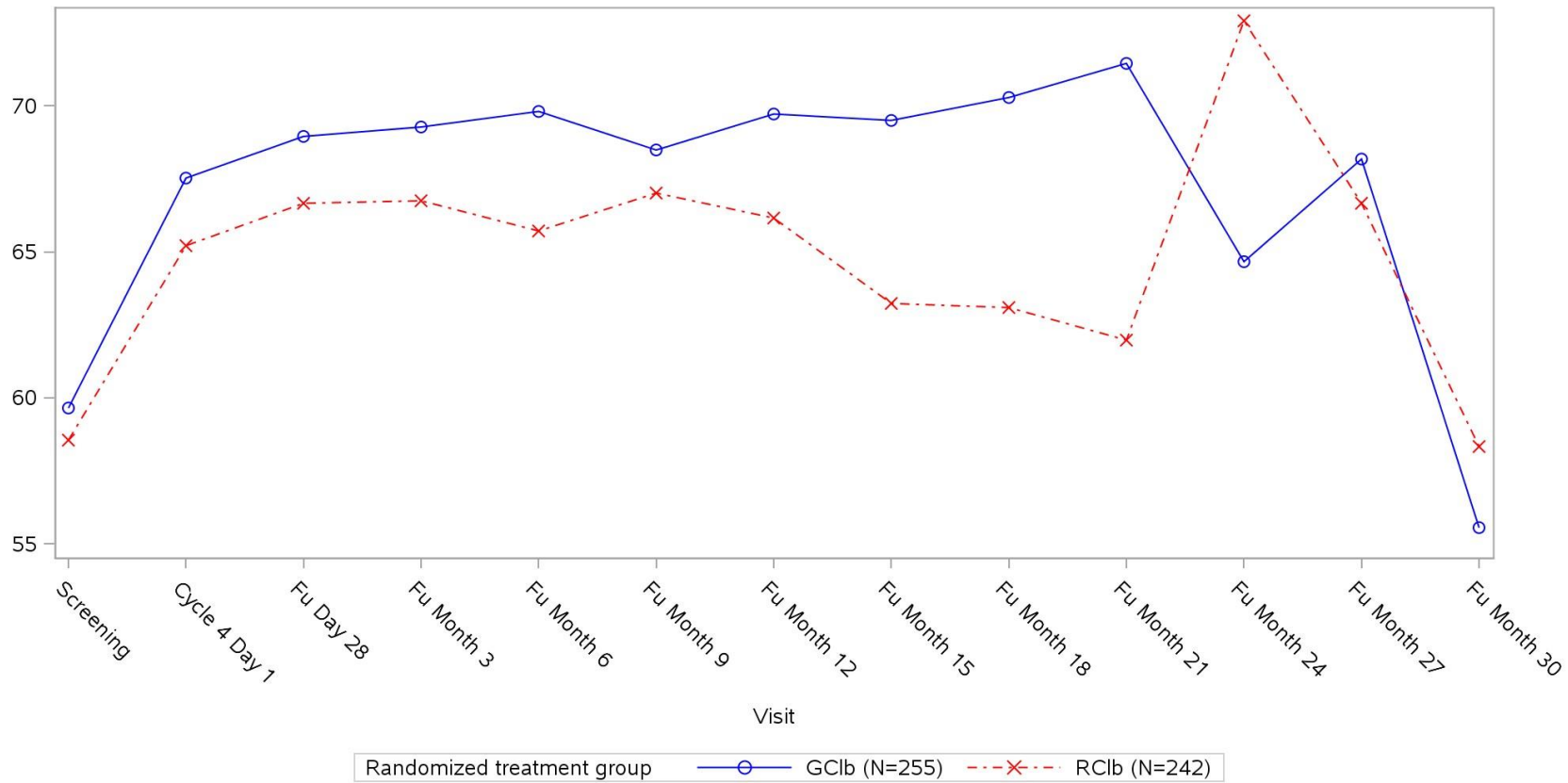
17:15

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Laboratory Test: Global Health Status Scale



Clinical cut-off: 09MAY2013

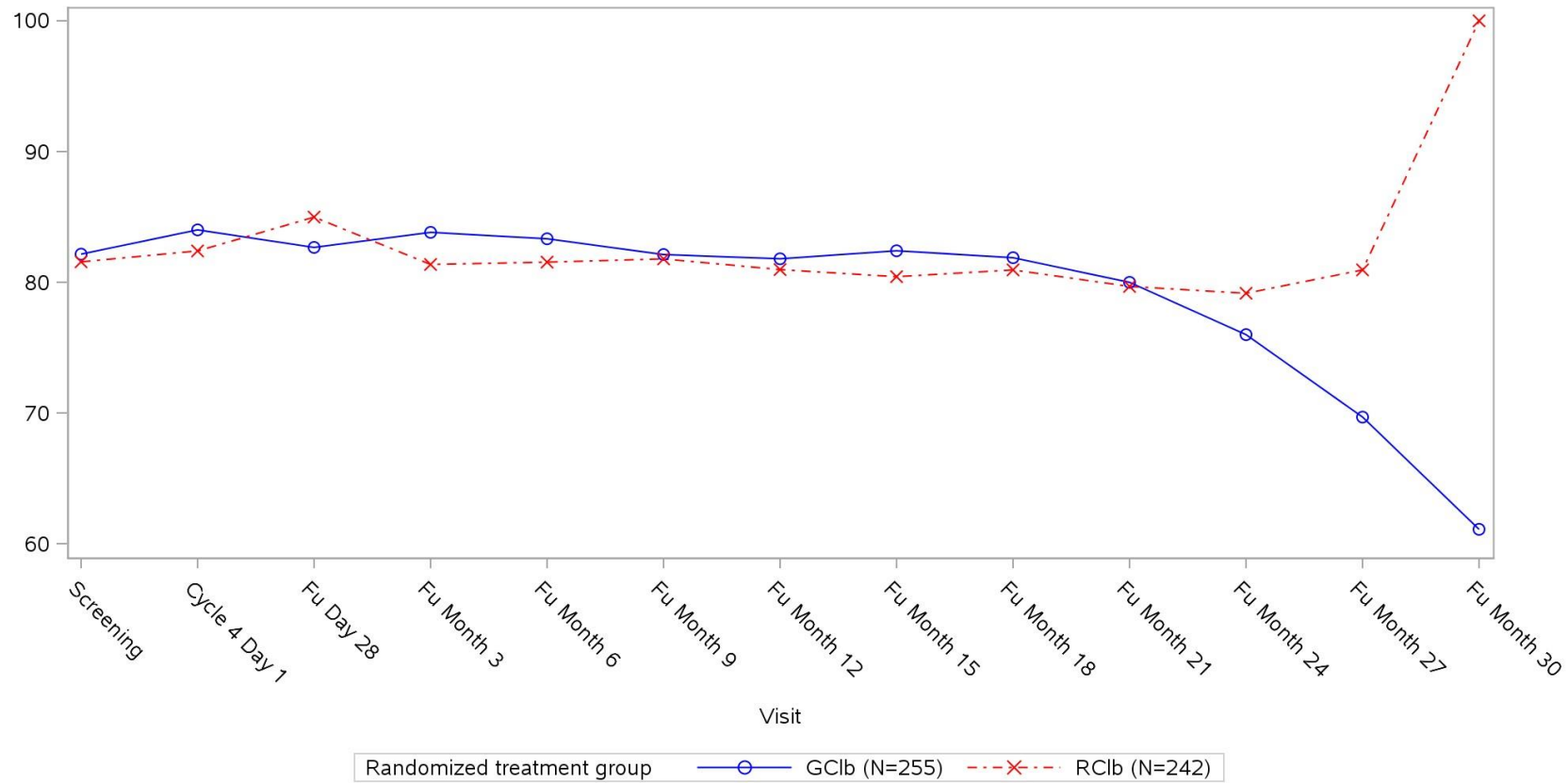
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Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/g_pro_mean_EQC30_IT_label_09MAY2013_21004.pdf
04MAR2020 16:15

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Laboratory Test: Cognitive Functioning Scale



Clinical cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/g_pro_mean.sas
Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/g_pro_mean_EQC30_IT_label_09MAY2013_21004.pdf
04MAR2020 16:15

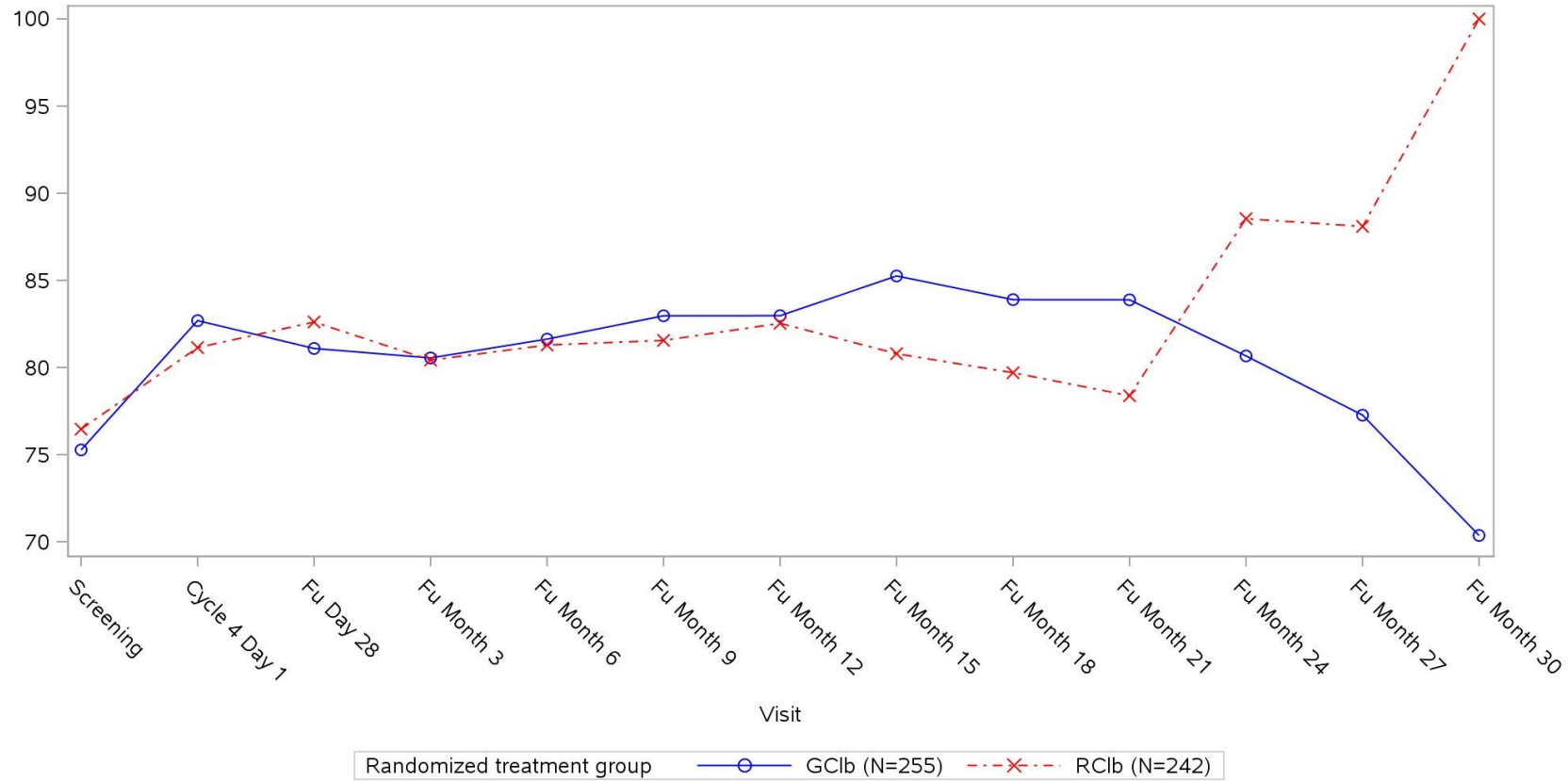
Page 2 of 15

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Laboratory Test: Emotional Functioning Scale



Clinical cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/g_pro_mean.sas
Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/g_pro_mean_EQC30_IT_label_09MAY2013_21004.pdf
04MAR2020 16:15

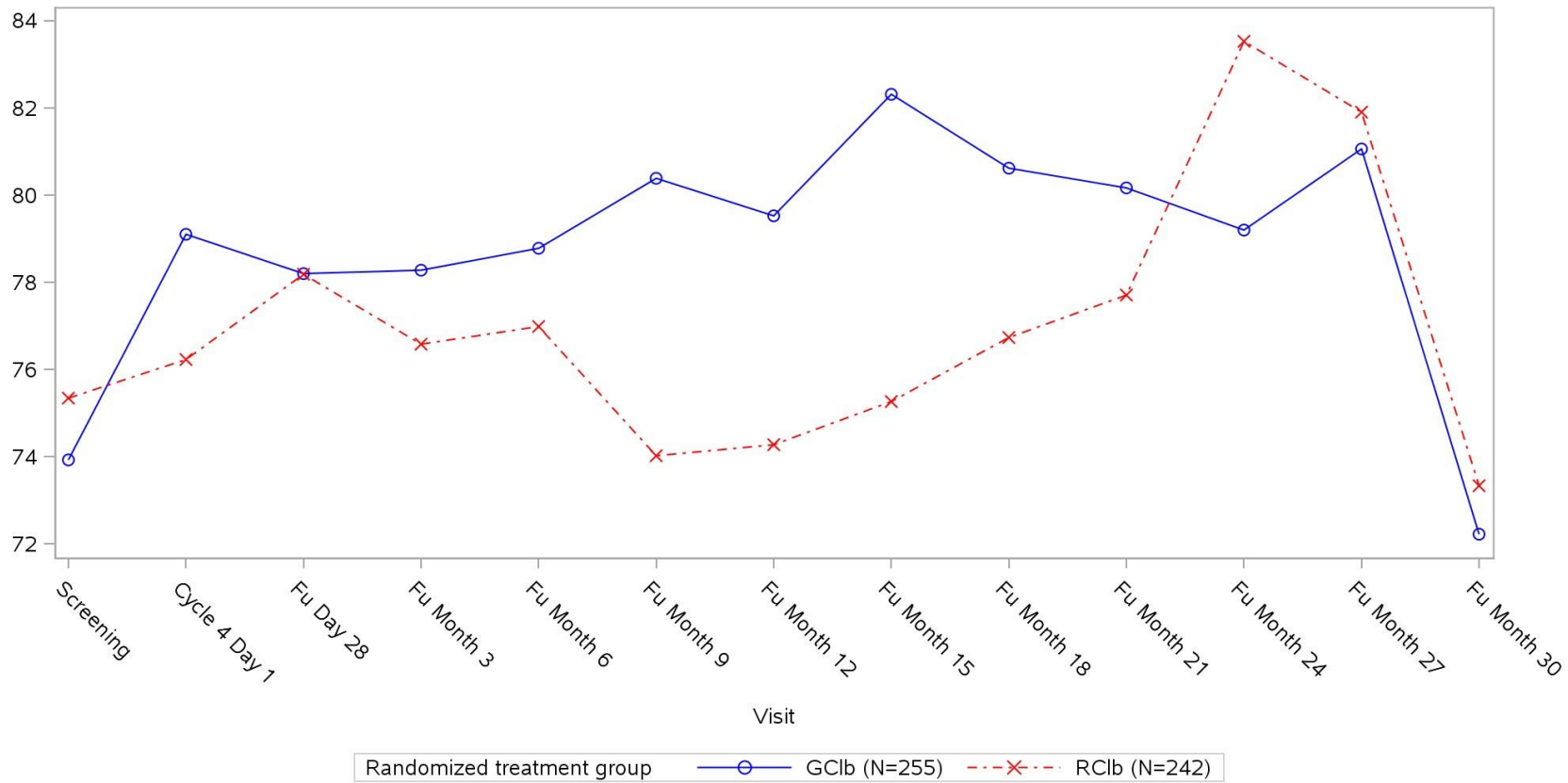
Page 6 of 15

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Laboratory Test: Physical Functioning Scale



Clinical cut-off: 09MAY2013

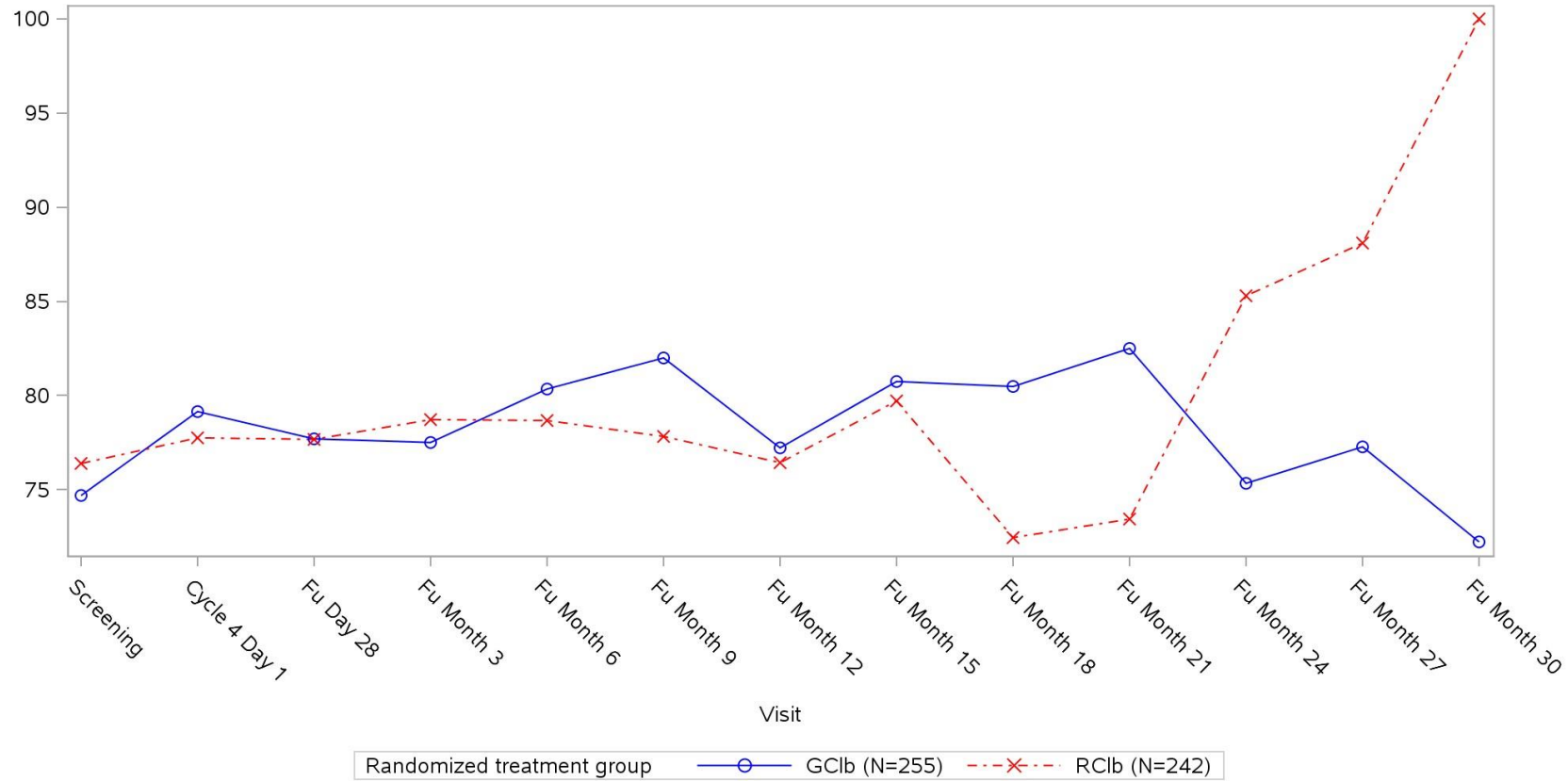
Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/g_pro_mean.sas
Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/g_pro_mean_EQC30_IT_label_09MAY2013_21004.pdf
04MAR2020 16:15

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

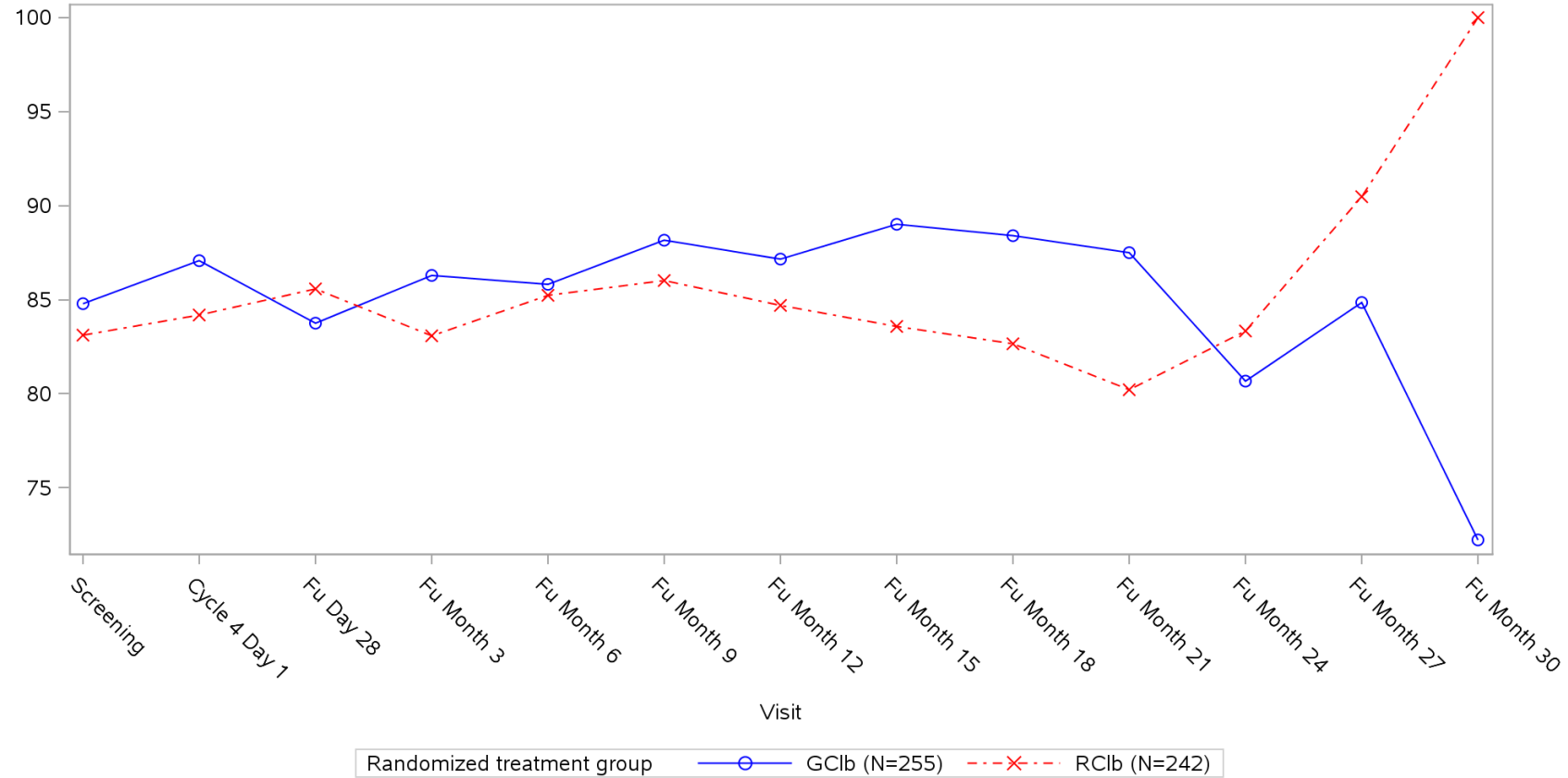
Laboratory Test: Role Functioning Scale



Clinical cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/g_pro_mean.sas
Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/g_pro_mean_EQC30_IT_label_09MAY2013_21004.pdf
04MAR2020 16:15

POPULATION: Labelpopulation, Intent-to-Treat Patients
ENDPOINT: EORTC QoL 30
STUDY: CLL11(BO21004), Stage 2
 Laboratory Test: Social Functioning Scale



Clinical cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/g_pro_mean.sas
 Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/g_pro_mean_EQC30_IT_label_09MAY2013_21004.pdf
 04MAR2020 16:15

13 (Anhang): Ergebnisse für EORTC QLQ-CLL16 – Mittelwerte pro Visite - Hauptanalysen aus RCT mit dem zu bewertenden Arzneimittel

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

MODEL: Unadjusted Analysis

STUDY: CLL11 (BO21004), Stage 2

Compliance/Mean

Disease Effects Scale

		GClb (N=255)						RClb (N=242)					
		Patients				Statistics		Patients				Statistics	
Name	Level	in study ¹	%	with value ¹	%	Mean ²	SD (mean)	in study ¹	%	with value ¹	%	Mean ²	SD (mean)
All													
Screening	n/a	255	100,0	216	84,7	20,58	17,29	242	100,0	202	83,5	22,58	17,67
Cycle 4 Day 1	n/a	213	83,5	174	81,7	14,26	15,96	224	92,6	175	78,1	16,79	15,98
FU Day 28	n/a	230	90,2	184	80,0	14,22	15,64	225	93,0	183	81,3	16,09	16,82
FU Month 3	n/a	225	88,2	183	81,3	12,20	14,65	221	91,3	174	78,7	14,64	15,22
FU Month 6	n/a	207	81,2	171	82,6	11,34	13,81	192	79,3	147	76,6	14,63	16,68
FU Month 9	n/a	164	64,3	126	76,8	11,79	13,68	149	61,6	111	74,5	15,62	15,15
FU Month 12	n/a	125	49,0	100	80,0	12,25	14,46	117	48,3	92	78,6	17,33	16,72
FU Month 15	n/a	104	40,8	84	80,8	12,30	14,14	85	35,1	63	74,1	16,45	16,23
FU Month 18	n/a	79	31,0	61	77,2	13,21	15,21	60	24,8	45	75,0	16,42	18,14
FU Month 21	n/a	52	20,4	36	69,2	15,74	17,11	40	16,5	28	70,0	17,86	20,88
FU Month 24	n/a	32	12,5	21	65,6	13,76	17,00	18	7,4	14	77,8	8,33	10,34
FU Month 27	n/a	13	5,1	8	61,5	18,75	14,60	9	3,7	6	66,7	4,17	6,97
FU Month 30	n/a	7	2,7	4	57,1	18,75	14,23	1	0,4	1	100,0	0,00	NE

¹ in study: number of subjects in study at respective visit; % based on baseline

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit

² mean: descriptive statistics - absolute values Clinical cut-off:

09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/t_pro_mean.sas

Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/t_pro_mean_EQCLL16_IT_label_09MAY2013_21004.xls 04MAR2020 17:16

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

MODEL: Unadjusted Analysis

STUDY: CLL11 (BO21004), Stage 2

Compliance/Mean

Fatigue Scale

		GClb (N=255)						RClb (N=242)					
		Patients			Statistics			Patients			Statistics		
Name Visit	Level	in study ¹	%	with value ¹	%	Mean ²	SD (mean)	in study ¹	%	with value ¹	%	Mean ²	SD (mean)
All													
Screening	n/a	255	100,0	216	84,7	29,09	25,29	242	100,0	202	83,5	29,87	24,36
Cycle 4 Day 1	n/a	213	83,5	174	81,7	21,07	21,50	224	92,6	175	78,1	24,48	20,97
FU Day 28	n/a	230	90,2	183	79,6	23,59	25,15	225	93,0	183	81,3	22,59	22,17
FU Month 3	n/a	225	88,2	183	81,3	22,50	24,01	221	91,3	174	78,7	23,47	22,17
FU Month 6	n/a	207	81,2	171	82,6	21,64	22,43	192	79,3	148	77,1	25,23	24,24
FU Month 9	n/a	164	64,3	126	76,8	21,83	23,61	149	61,6	111	74,5	23,87	23,21
FU Month 12	n/a	125	49,0	101	80,8	24,92	25,67	117	48,3	92	78,6	23,91	24,37
FU Month 15	n/a	104	40,8	84	80,8	19,44	19,84	85	35,1	63	74,1	24,87	25,20
FU Month 18	n/a	79	31,0	62	78,5	23,12	24,40	60	24,8	45	75,0	28,52	29,22
FU Month 21	n/a	52	20,4	36	69,2	23,15	24,33	40	16,5	28	70,0	29,76	28,09
FU Month 24	n/a	32	12,5	21	65,6	25,40	24,51	18	7,4	14	77,8	17,86	23,99
FU Month 27	n/a	13	5,1	8	61,5	35,42	32,66	9	3,7	6	66,7	16,67	40,82
FU Month 30	n/a	7	2,7	4	57,1	29,17	28,46	1	0,4	1	100,0	16,67	NE

¹ in study: number of subjects in study at respective visit; % based on baseline

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit

² mean: descriptive statistics - absolute values Clinical cut-off:

09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/t_pro_mean.sas

Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/t_pro_mean_EQCLL16_IT_label_09MAY2013_21004.xls 04MAR2020 17:16

POPULATION: Labelpopulation, Intent-to-Treat Patients
 ENDPOINT: EORTC QoL 16
 MODEL: Unadjusted Analysis
 STUDY: CLL11(BO21004), Stage 2
 Compliance/Mean

Future Health (Item 42)

		GClb (N=255)						RC1b (N=242)					
		Patients			Statistics			Patients			Statistics		
Name	Level	in study ¹	%	with value ¹	%	Mean ²	SD(mean)	in study ¹	%	with value ¹	%	Mean ²	SD(mean)
All													
Screening	n/a	255	100,0	212	83,1	48,11	31,99	242	100,0	201	83,1	46,10	32,79
Cycle 4 Day 1	n/a	213	83,5	173	81,2	27,75	30,30	224	92,6	173	77,2	34,87	31,09
FU Day 28	n/a	230	90,2	183	79,6	29,51	29,50	225	93,0	183	81,3	28,96	29,53
FU Month 3	n/a	225	88,2	182	80,9	28,39	29,83	221	91,3	173	78,3	28,90	28,07
FU Month 6	n/a	207	81,2	171	82,6	29,24	28,05	192	79,3	147	76,6	30,61	29,59
FU Month 9	n/a	164	64,3	123	75,0	25,20	28,42	149	61,6	109	73,2	27,22	26,90
FU Month 12	n/a	125	49,0	101	80,8	25,74	29,01	117	48,3	92	78,6	25,36	28,55
FU Month 15	n/a	104	40,8	84	80,8	18,25	22,79	85	35,1	63	74,1	29,10	30,23
FU Month 18	n/a	79	31,0	62	78,5	22,04	26,95	60	24,8	45	75,0	29,63	32,74
FU Month 21	n/a	52	20,4	36	69,2	19,44	21,64	40	16,5	28	70,0	28,57	26,78
FU Month 24	n/a	32	12,5	21	65,6	28,57	30,34	18	7,4	14	77,8	23,81	30,46
FU Month 27	n/a	13	5,1	8	61,5	25,00	23,57	9	3,7	6	66,7	5,56	13,61
FU Month 30	n/a	7	2,7	4	57,1	41,67	31,91	1	0,4	1	100,0	33,33	NE

¹ in study: number of subjects in study at respective visit; % based on baseline

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit

² mean: descriptive statistics - absolute values Clinical cut-off:

09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/t_pro_mean.sas

Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/t_pro_mean_EQCLL16_IT_label_09MAY2013_21004.xls 04MAR2020 17:16

POPULATION: Labelpopulation, Intent-to-Treat Patients
 ENDPOINT: EORTC QoL 16
 MODEL: Unadjusted Analysis
 STUDY: CLL11(BO21004), Stage 2
 Compliance/Mean

Infection Scale

		GClb (N=255)						RClb (N=242)					
		Patients			Statistics			Patients			Statistics		
Name	Level	in study ¹	%	with value ¹	%	Mean ²	SD(mean)	in study ¹	%	with value ¹	%	Mean ²	SD(mean)
All													
Screening	n/a	255	100,0	216	84,7	11,66	15,81	242	100,0	202	83,5	10,86	15,69
Cycle 4 Day 1	n/a	213	83,5	174	81,7	7,71	11,33	224	92,6	175	78,1	9,44	14,78
FU Day 28	n/a	230	90,2	184	80,0	9,75	16,30	225	93,0	183	81,3	10,93	14,18
FU Month 3	n/a	225	88,2	183	81,3	9,81	16,04	221	91,3	174	78,7	9,42	13,30
FU Month 6	n/a	207	81,2	171	82,6	10,14	15,88	192	79,3	146	76,0	9,11	13,37
FU Month 9	n/a	164	64,3	126	76,8	9,52	15,34	149	61,6	111	74,5	9,01	13,81
FU Month 12	n/a	125	49,0	101	80,8	11,47	18,44	117	48,3	91	77,8	8,97	11,87
FU Month 15	n/a	104	40,8	84	80,8	6,68	10,97	85	35,1	63	74,1	8,51	14,11
FU Month 18	n/a	79	31,0	62	78,5	10,53	17,11	60	24,8	45	75,0	8,15	12,24
FU Month 21	n/a	52	20,4	36	69,2	11,27	16,51	40	16,5	28	70,0	9,23	12,07
FU Month 24	n/a	32	12,5	21	65,6	6,75	13,34	18	7,4	14	77,8	6,55	11,87
FU Month 27	n/a	13	5,1	8	61,5	11,11	17,51	9	3,7	6	66,7	4,17	6,97
FU Month 30	n/a	7	2,7	4	57,1	6,25	7,98	1	0,4	1	100,0	0,00	NE

¹ in study: number of subjects in study at respective visit; % based on baseline

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit

² mean: descriptive statistics - absolute values Clinical cut-off:

09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/t_pro_mean.sas

Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/t_pro_mean_EQCLL16_IT_label_09MAY2013_21004.xls 04MAR2020 17:16

POPULATION: Labelpopulation, Intent-to-Treat Patients
 ENDPOINT: EORTC QoL 16
 MODEL: Unadjusted Analysis
 STUDY: CLL11(BO21004), Stage 2
 Compliance/Mean

Social Problems (Item 41)

		GClb (N=255)						RClb (N=242)					
		Patients			Statistics			Patients			Statistics		
Name Visit	Level	in study ¹	%	with value ¹	%	Mean ²	SD(mean)	in study ¹	%	with value ¹	%	Mean ²	SD(mean)
All													
Screening	n/a	255	100,0	213	83,5	23,32	31,12	242	100,0	199	82,2	24,96	32,60
Cycle 4 Day 1	n/a	213	83,5	173	81,2	20,81	29,04	224	92,6	174	77,7	21,07	26,15
FU Day 28	n/a	230	90,2	181	78,7	20,81	30,07	225	93,0	182	80,9	20,15	28,20
FU Month 3	n/a	225	88,2	178	79,1	17,98	27,01	221	91,3	173	78,3	19,27	29,22
FU Month 6	n/a	207	81,2	171	82,6	18,52	29,62	192	79,3	144	75,0	22,45	29,19
FU Month 9	n/a	164	64,3	126	76,8	17,20	29,13	149	61,6	108	72,5	16,98	27,15
FU Month 12	n/a	125	49,0	101	80,8	22,77	32,64	117	48,3	90	76,9	22,96	29,41
FU Month 15	n/a	104	40,8	81	77,9	16,87	27,95	85	35,1	62	72,9	21,51	30,24
FU Month 18	n/a	79	31,0	62	78,5	23,12	31,12	60	24,8	43	71,7	25,58	34,76
FU Month 21	n/a	52	20,4	36	69,2	16,67	27,02	40	16,5	28	70,0	29,76	31,87
FU Month 24	n/a	32	12,5	21	65,6	22,22	24,34	18	7,4	14	77,8	23,81	33,15
FU Month 27	n/a	13	5,1	8	61,5	12,50	17,25	9	3,7	6	66,7	16,67	27,89
FU Month 30	n/a	7	2,7	4	57,1	25,00	31,91	1	0,4	1	100,0	0,00	NE

¹ in study: number of subjects in study at respective visit; % based on baseline

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit

² mean: descriptive statistics - absolute values Clinical cut-off:

09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/t_pro_mean.sas

Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/t_pro_mean_EQCLL16_IT_label_09MAY2013_21004.xls 04MAR2020 17:16

POPULATION: Labelpopulation, Intent-to-Treat Patients
 ENDPOINT: EORTC QoL 16
 MODEL: Unadjusted Analysis
 STUDY: CLL11(BO21004), Stage 2
 Compliance/Mean

Treatment Side Effects Scale

		GClb (N=255)						RClb (N=242)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study ¹	%	with value ¹	%	Mean ²	SD(mean)	in study ¹	%	with value ¹	%	Mean ²	SD(mean)
All													
Screening	n/a	255	100,0	216	84,7	18,93	17,15	242	100,0	202	83,5	17,48	15,68
Cycle 4 Day 1	n/a	213	83,5	174	81,7	15,31	15,56	224	92,6	175	78,1	15,25	13,85
FU Day 28	n/a	230	90,2	184	80,0	12,02	12,84	225	93,0	183	81,3	15,13	13,97
FU Month 3	n/a	225	88,2	183	81,3	12,13	14,54	221	91,3	174	78,7	13,49	13,32
FU Month 6	n/a	207	81,2	171	82,6	10,83	12,62	192	79,3	148	77,1	14,56	15,44
FU Month 9	n/a	164	64,3	126	76,8	10,54	10,44	149	61,6	111	74,5	13,36	14,05
FU Month 12	n/a	125	49,0	101	80,8	13,01	13,78	117	48,3	92	78,6	14,34	14,31
FU Month 15	n/a	104	40,8	84	80,8	13,56	12,90	85	35,1	63	74,1	16,14	13,95
FU Month 18	n/a	79	31,0	62	78,5	15,37	16,61	60	24,8	45	75,0	15,06	13,69
FU Month 21	n/a	52	20,4	36	69,2	13,19	12,01	40	16,5	28	70,0	13,69	13,84
FU Month 24	n/a	32	12,5	21	65,6	12,30	10,08	18	7,4	14	77,8	13,49	10,44
FU Month 27	n/a	13	5,1	8	61,5	14,58	10,68	9	3,7	6	66,7	11,11	12,55
FU Month 30	n/a	7	2,7	4	57,1	18,75	10,49	1	0,4	1	100,0	0,00	NE

¹ in study: number of subjects in study at respective visit; % based on baseline

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit

² mean: descriptive statistics - absolute values Clinical cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/t_pro_mean.sas

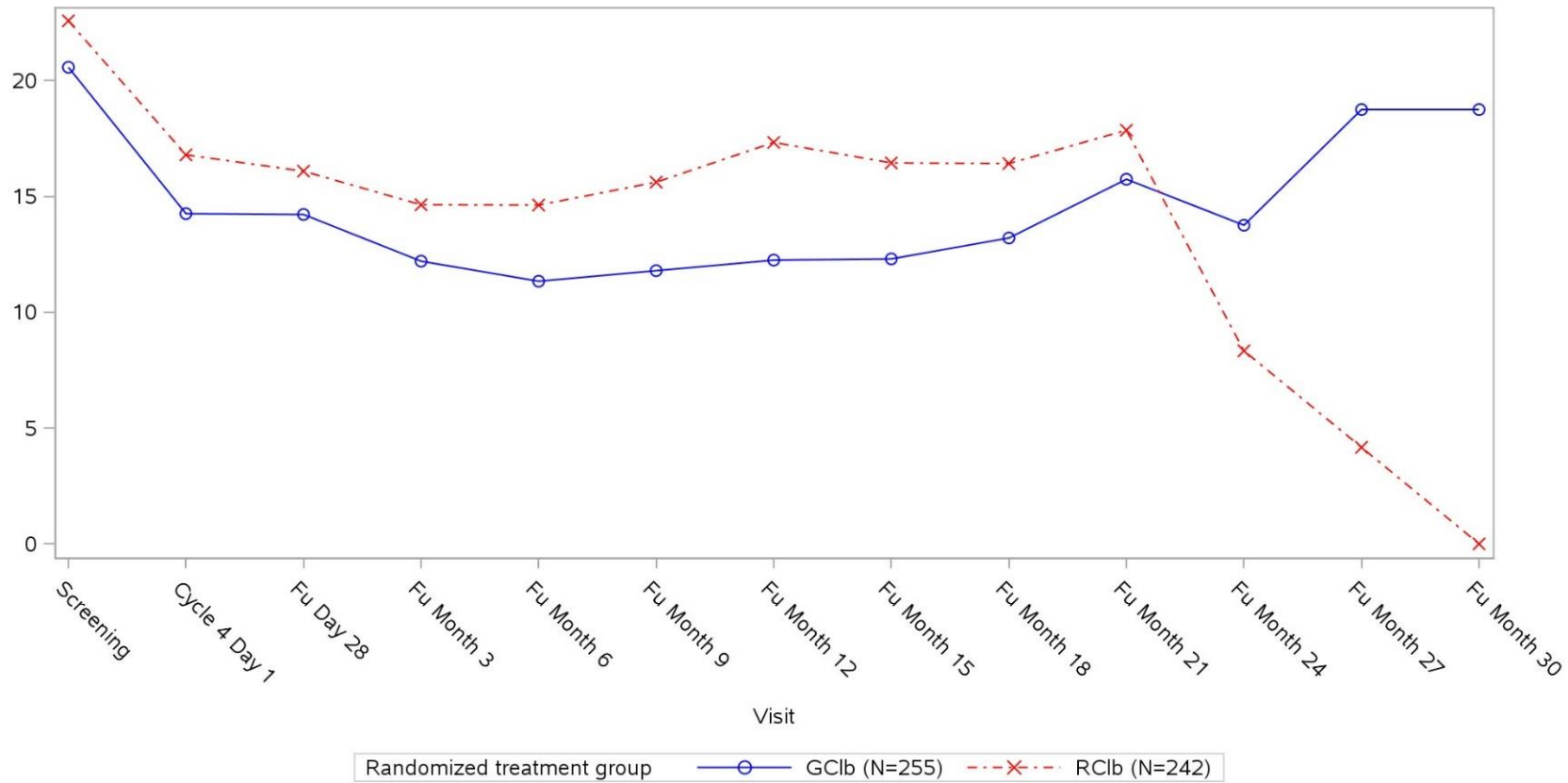
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

Laboratory Test: Disease Effects Scale



Clinical cut-off: 09MAY2013

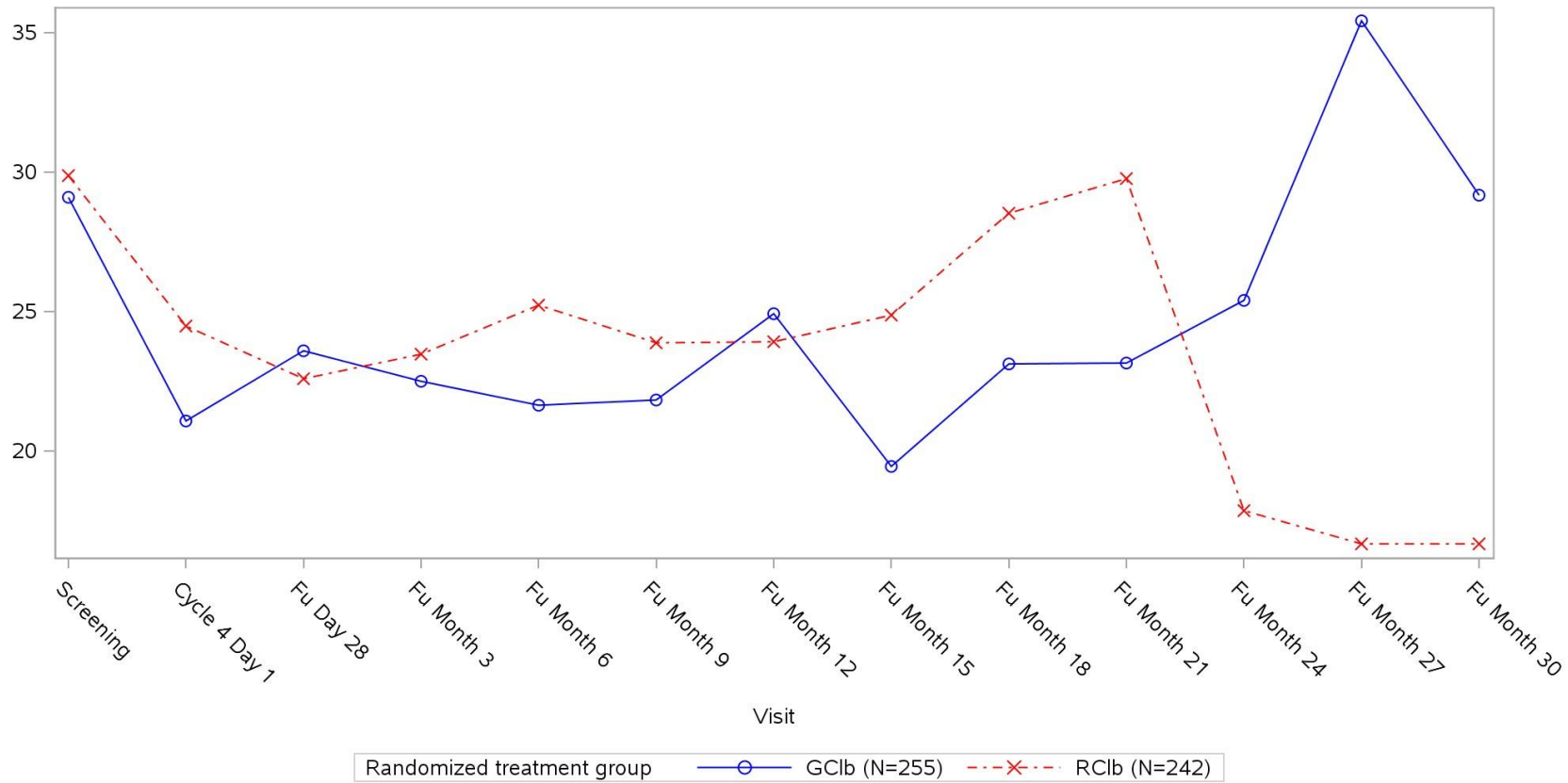
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04MAR2020 16:27

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

Laboratory Test: Fatigue Scale



Clinical cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/g_pro_mean.sas
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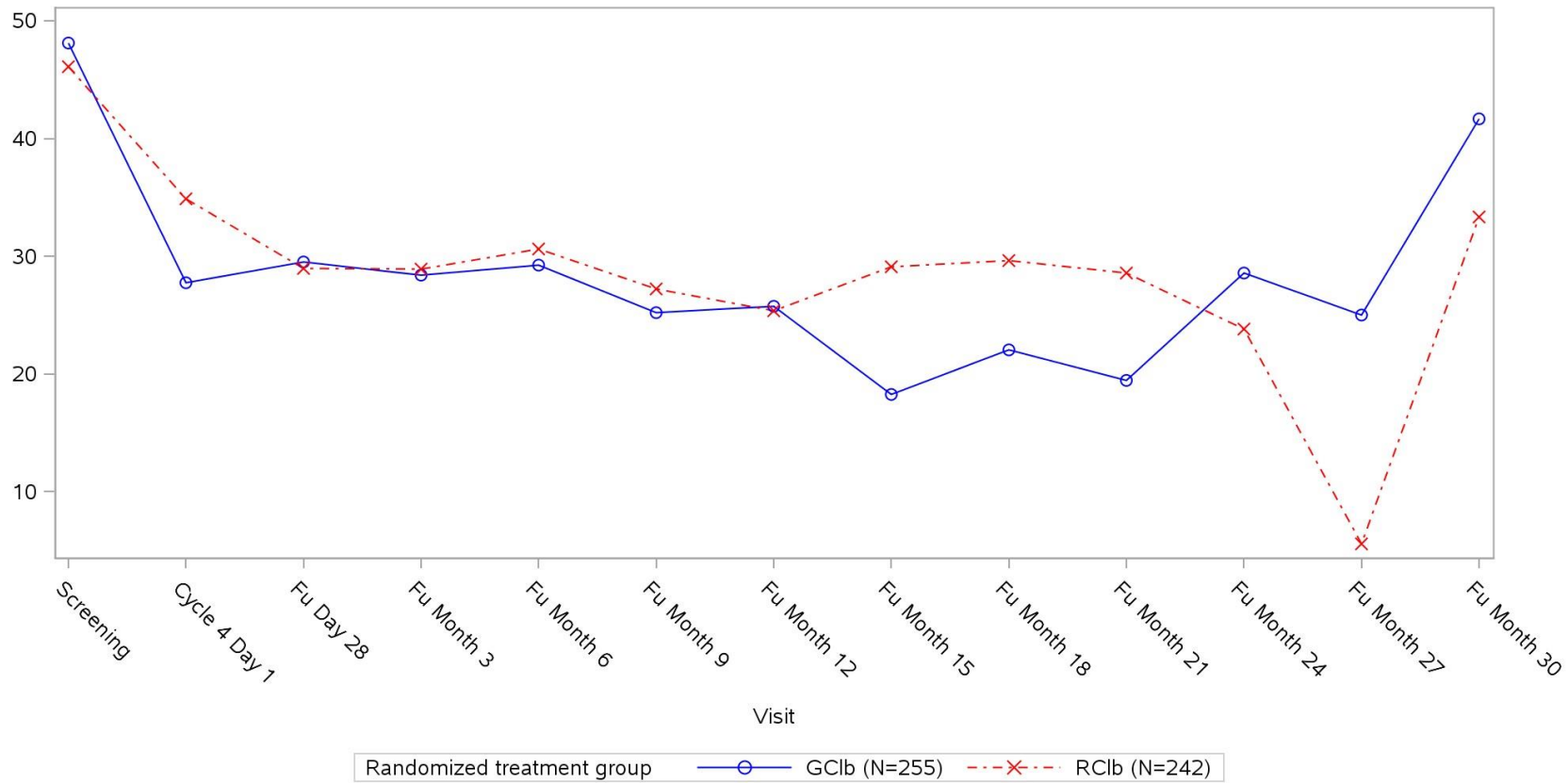
Page 2 of 6

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

Laboratory Test: Future Health



Clinical cut-off: 09MAY2013

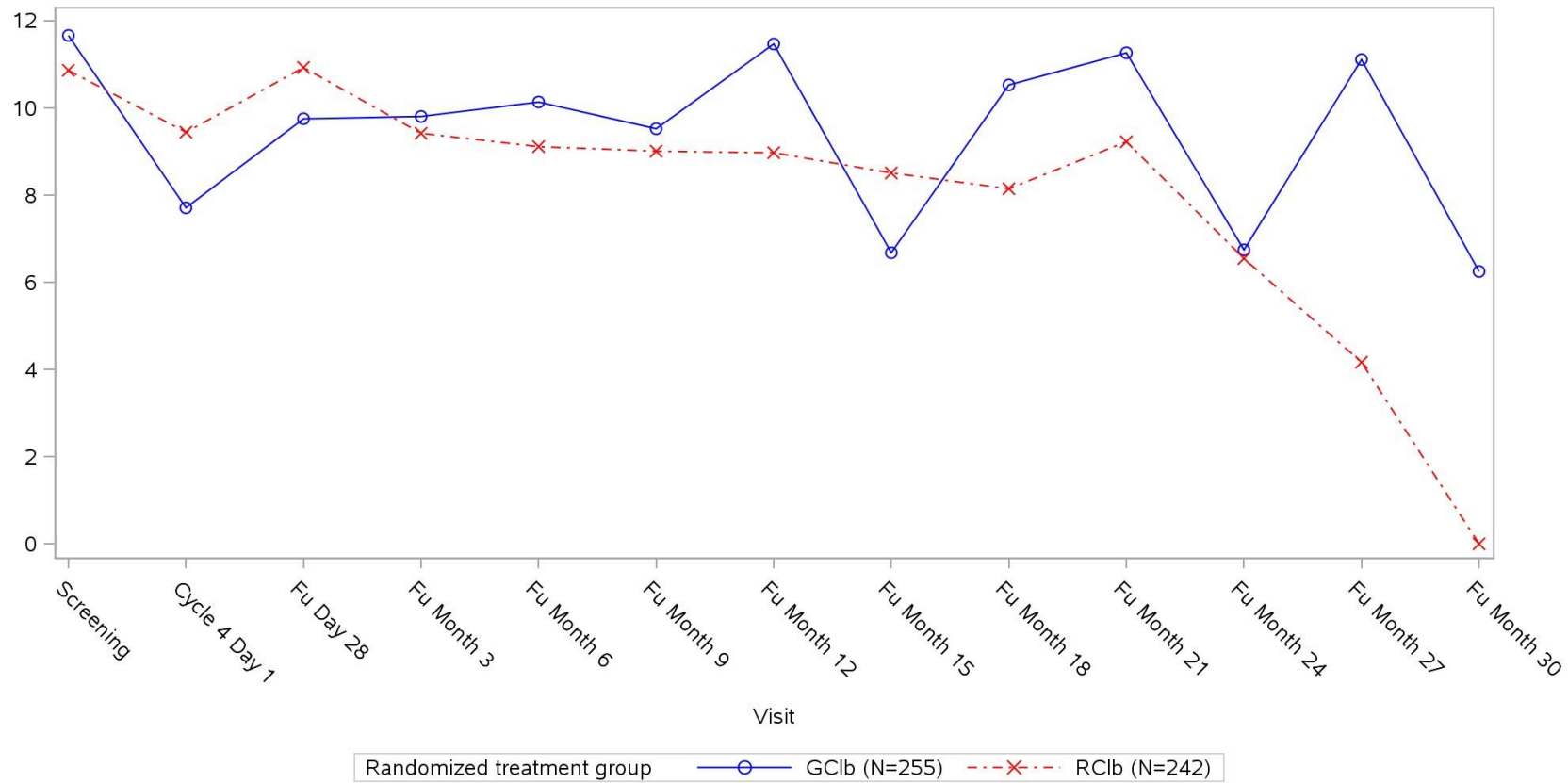
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04MAR2020 16:27

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

Laboratory Test: Infection Scale

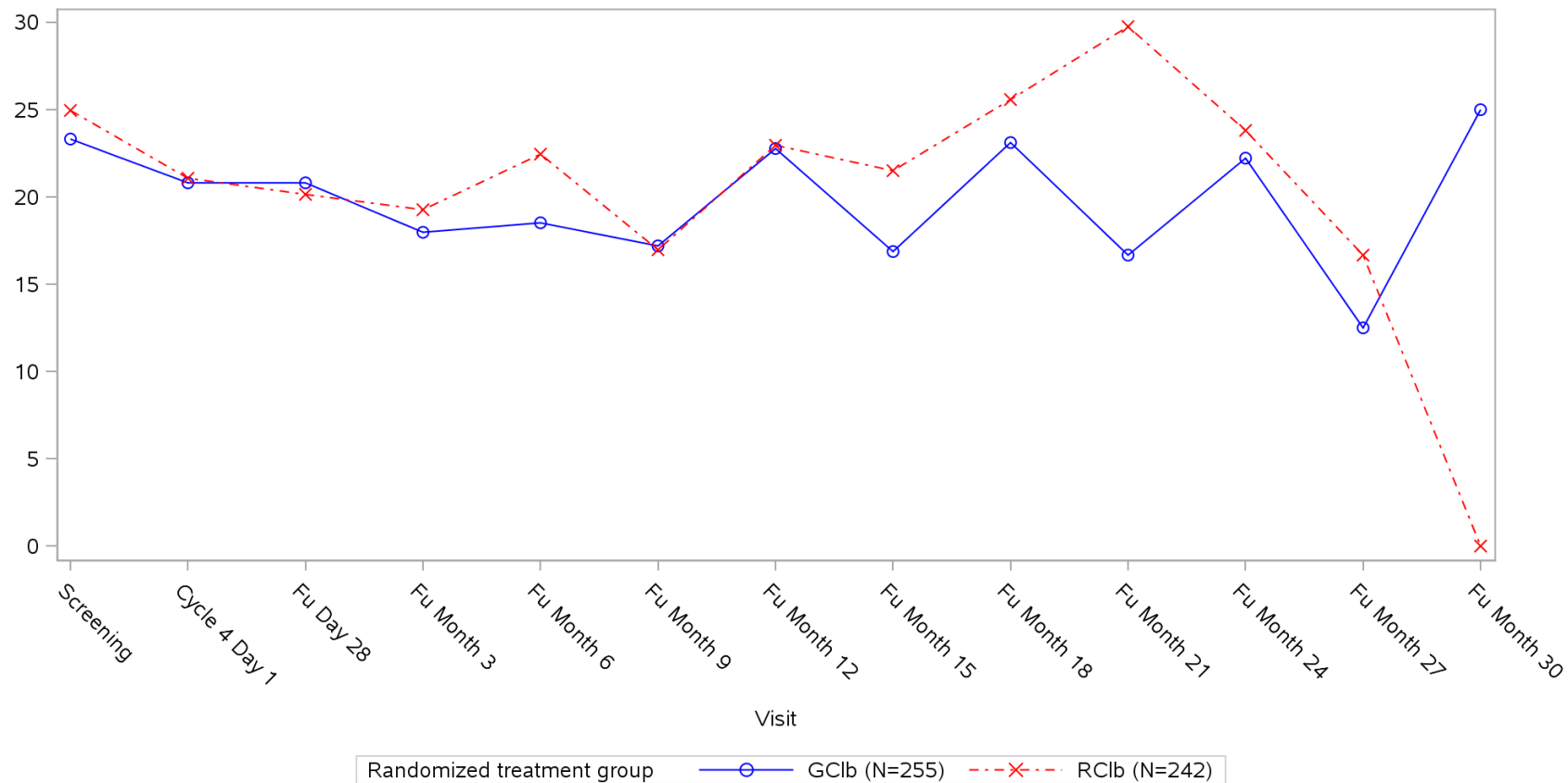


Clinical cut-off: 09MAY2013

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04MAR2020 16:27

POPULATION: Labelpopulation, Intent-to-Treat Patients
ENDPOINT: EORTC QoL 16
STUDY: CLL11(BO21004), Stage 2

Laboratory Test: Social Problems



Clinical cut-off: 09MAY2013

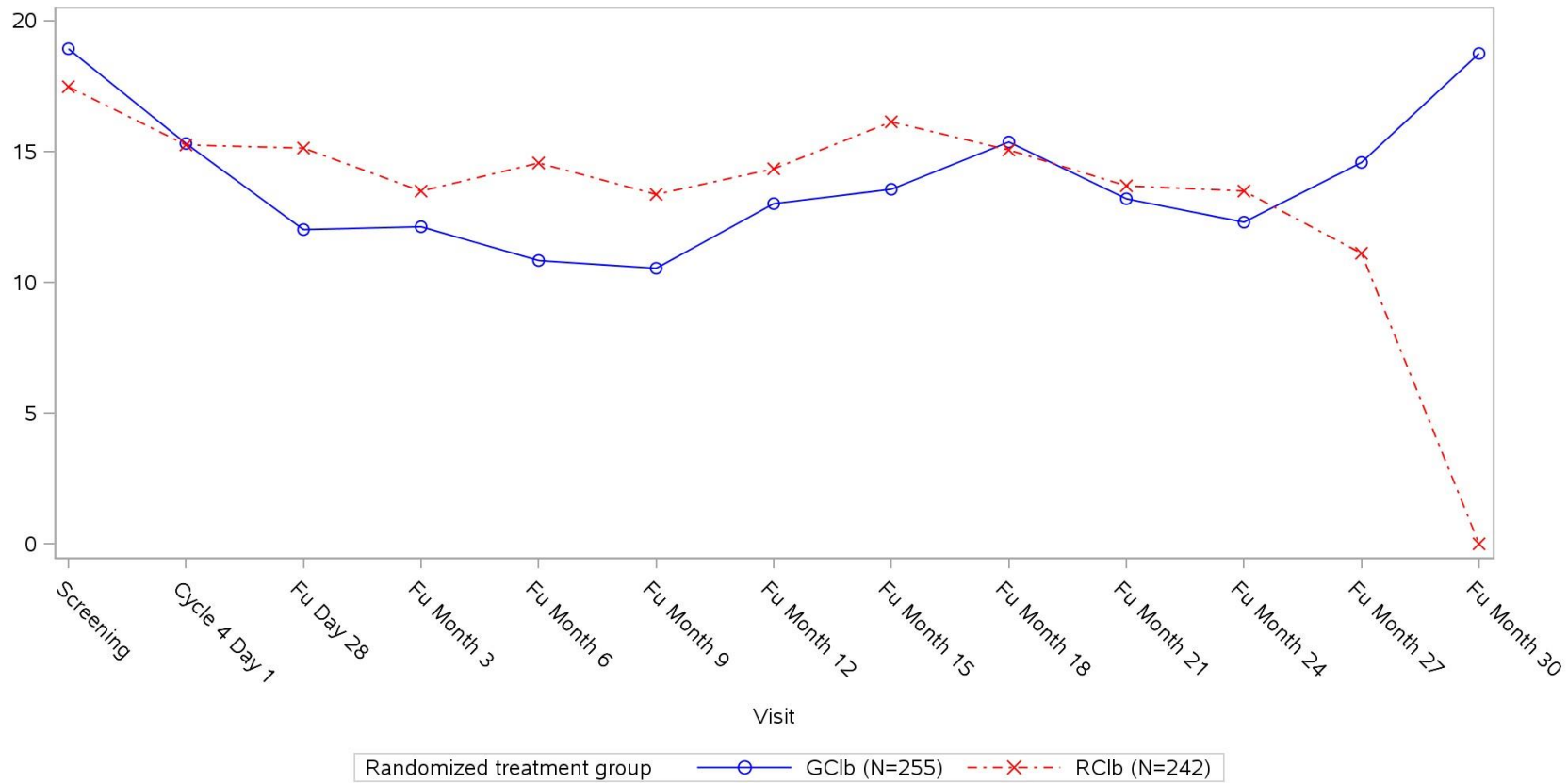
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 04MAR2020 16:27

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

Laboratory Test: Treatment Side Effects Scale



Clinical cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/g_pro_mean.sas
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14 (Anhang): Ergebnisse für EORTC QLQ-C30 – Symptomskalen Mittelwerte pro Visite - Subgruppenanalysen aus RCT mit dem zu bewertenden Arzneimittel

POPULATION: Labelpopulation, Intent-to-Treat Patients ENDPOINT: EORTC QoL 30

MODEL: Unadjusted Analysis STUDY: CLL11 (BO21004), Stage

2

Compliance/Mean

Appetite Loss Scale

		GClb (N=255)						RClb (N=242)					
		Patients			Statistics			Patients			Statistics		
Name	Level	in study ¹	%	with value ¹	%	Mean ²	SD (mean)	in study ¹	%	with value ¹	%	Mean ²	SD (mean)
All													
Screening	n/a	255	100,0	241	94,5	16,18	27,91	242	100,0	227	93,8	16,15	27,04
Cycle 4 Day 1	n/a	213	83,5	195	91,5	10,94	21,27	224	92,6	197	87,9	13,87	25,41
FU Day 28	n/a	230	90,2	201	87,4	10,12	20,61	225	93,0	202	89,8	12,38	23,17
FU Month 3	n/a	225	88,2	203	90,2	8,87	21,45	221	91,3	196	88,7	12,41	23,12
FU Month 6	n/a	207	81,2	185	89,4	6,67	16,59	192	79,3	169	88,0	10,45	22,18
FU Month 9	n/a	164	64,3	137	83,5	8,76	19,91	149	61,6	121	81,2	9,37	21,18
FU Month 12	n/a	125	49,0	109	87,2	8,56	21,47	117	48,3	99	84,6	11,11	21,82
FU Month 15	n/a	104	40,8	90	86,5	7,78	21,81	85	35,1	69	81,2	11,11	21,13
FU Month 18	n/a	79	31,0	70	88,6	8,57	20,99	60	24,8	49	81,7	12,93	23,39
FU Month 21	n/a	52	20,4	40	76,9	6,67	17,21	40	16,5	32	80,0	10,42	27,35
FU Month 24	n/a	32	12,5	24	75,0	4,17	11,26	18	7,4	17	94,4	5,88	13,10
FU Month 27	n/a	13	5,1	11	84,6	3,03	10,05	9	3,7	7	77,8	4,76	12,60
FU Month 30	n/a	7	2,7	6	85,7	16,67	27,89	1	0,4	1	100,0	0,00	NE
Gender													
Screening	Female	97	100,0	91	93,8	20,51	29,72	95	100,0	87	91,6	21,84	30,43
Cycle 4 Day 1	Female	84	86,6	76	90,5	16,23	24,64	88	92,6	78	88,6	19,66	29,15
FU Day 28	Female	90	92,8	83	92,2	12,85	21,98	91	95,8	78	85,7	15,38	25,02
FU Month 3	Female	88	90,7	81	92,0	13,17	25,65	87	91,6	77	88,5	15,15	26,24
FU Month 6	Female	84	86,6	72	85,7	7,87	18,12	77	81,1	67	87,0	9,45	20,76
FU Month 9	Female	70	72,2	58	82,9	12,07	23,11	61	64,2	46	75,4	10,87	21,15
FU Month 12	Female	56	57,7	49	87,5	8,84	21,27	47	49,5	40	85,1	13,33	22,39
FU Month 15	Female	47	48,5	40	85,1	10,83	25,47	33	34,7	28	84,8	17,86	26,42
FU Month 18	Female	34	35,1	29	85,3	12,64	24,26	26	27,4	22	84,6	19,70	30,27
FU Month 21	Female	21	21,6	15	71,4	6,67	13,80	17	17,9	15	88,2	20,00	37,37

FU Month 24	Female	12	12,4	10	83,3	6,67	14,05	6	6,3	5	83,3	0,00	0,00
FU Month 27	Female	6	6,2	5	83,3	6,67	14,91	2	2,1	1	50,0	0,00	NE
FU Month 30	Female	4	4,1	3	75,0	33,33	33,33	1	1,1	1	100,0	0,00	NE
Screening	Male	158	100,0	150	94,9	13,56	26,50	147	100,0	140	95,2	12,62	24,15
Cycle 4 Day 1	Male	129	81,6	119	92,2	7,56	18,12	136	92,5	119	87,5	10,08	21,94
FU Day 28	Male	140	88,6	118	84,3	8,19	19,46	134	91,2	124	92,5	10,48	21,83
FU Month 3	Male	137	86,7	122	89,1	6,01	17,68	134	91,2	119	88,8	10,64	20,78
FU Month 6	Male	123	77,8	113	91,9	5,90	15,58	115	78,2	102	88,7	11,11	23,14
FU Month 9	Male	94	59,5	79	84,0	6,33	16,94	88	59,9	75	85,2	8,44	21,29
FU Month 12	Male	69	43,7	60	87,0	8,33	21,81	70	47,6	59	84,3	9,60	21,49
FU Month 15	Male	57	36,1	50	87,7	5,33	18,27	52	35,4	41	78,8	6,50	15,31
FU Month 18	Male	45	28,5	41	91,1	5,69	18,11	34	23,1	27	79,4	7,41	14,12
FU Month 21	Male	31	19,6	25	80,6	6,67	19,25	23	15,6	17	73,9	1,96	8,08
FU Month 24	Male	20	12,7	14	70,0	2,38	8,91	12	8,2	12	100,0	8,33	15,08
FU Month 27	Male	7	4,4	6	85,7	0,00	0,00	7	4,8	6	85,7	5,56	13,61
FU Month 30	Male	3	1,9	3	100,0	0,00	0,00	0	NE	0	NE	NE	NE
Age													
Screening	<75 years	130	100,0	123	94,6	15,99	25,37	120	100,0	110	91,7	14,24	25,33
Cycle 4 Day 1	<75 years	106	81,5	100	94,3	8,33	15,98	112	93,3	97	86,6	13,75	25,35
FU Day 28	<75 years	119	91,5	105	88,2	9,21	17,60	110	91,7	102	92,7	9,48	20,65
FU Month 3	<75 years	116	89,2	106	91,4	6,60	17,47	109	90,8	99	90,8	11,45	22,42
FU Month 6	<75 years	108	83,1	97	89,8	5,84	15,22	99	82,5	88	88,9	7,58	19,40
FU Month 9	<75 years	85	65,4	73	85,9	9,13	20,98	74	61,7	62	83,8	10,22	23,83
FU Month 12	<75 years	63	48,5	59	93,7	3,95	13,96	60	50,0	53	88,3	8,81	19,78
FU Month 15	<75 years	54	41,5	47	87,0	5,67	16,03	44	36,7	35	79,5	11,43	24,18
FU Month 18	<75 years	43	33,1	39	90,7	4,27	15,63	27	22,5	22	81,5	9,09	18,35
FU Month 21	<75 years	26	20,0	22	84,6	7,58	20,40	17	14,2	13	76,5	0,00	0,00
FU Month 24	<75 years	18	13,8	13	72,2	2,56	9,25	6	5,0	5	83,3	0,00	0,00
FU Month 27	<75 years	7	5,4	5	71,4	0,00	0,00	2	1,7	1	50,0	0,00	NE
FU Month 30	<75 years	4	3,1	3	75,0	22,22	38,49	0	NE	0	NE	NE	NE
Screening	>=75 years	125	100,0	118	94,4	16,38	30,43	122	100,0	117	95,9	17,95	28,55
Cycle 4 Day 1	>=75 years	107	85,6	95	88,8	13,68	25,49	112	91,8	100	89,3	14,00	25,59
FU Day 28	>=75 years	111	88,8	96	86,5	11,11	23,53	115	94,3	100	87,0	15,33	25,26
FU Month 3	>=75 years	109	87,2	97	89,0	11,34	24,95	112	91,8	97	86,6	13,40	23,89
FU Month 6	>=75 years	99	79,2	88	88,9	7,58	18,03	93	76,2	81	87,1	13,58	24,60
FU Month 9	>=75 years	79	63,2	64	81,0	8,33	18,78	75	61,5	59	78,7	8,47	18,15
FU Month 12	>=75 years	62	49,6	50	80,6	14,00	27,01	57	46,7	46	80,7	13,77	23,91
FU Month 15	>=75 years	50	40,0	43	86,0	10,08	26,76	41	33,6	34	82,9	10,78	17,83

FU Month 18	>=75 years	36	28,8	31	86,1	13,98	25,49	33	27,0	27	81,8	16,05	26,75
FU Month 21	>=75 years	26	20,8	18	69,2	5,56	12,78	23	18,9	19	82,6	17,54	34,01
FU Month 24	>=75 years	14	11,2	11	78,6	6,06	13,48	12	9,8	12	100,0	8,33	15,08
FU Month 27	>=75 years	6	4,8	6	100,0	5,56	13,61	7	5,7	6	85,7	5,56	13,61
FU Month 30	>=75 years	3	2,4	3	100,0	11,11	19,25	1	0,8	1	100,0	0,00	NE
Race													
Screening	Other	9	100,0	9	100,0	18,52	33,79	11	100,0	11	100,0	21,21	22,47
Cycle 4 Day 1	Other	7	77,8	7	100,0	14,29	17,82	10	90,9	9	90,0	14,81	24,22
FU Day 28	Other	8	88,9	8	100,0	16,67	25,20	10	90,9	10	100,0	6,67	14,05
FU Month 3	Other	8	88,9	7	87,5	9,52	25,20	10	90,9	10	100,0	10,00	16,10
FU Month 6	Other	8	88,9	7	87,5	9,52	16,27	8	72,7	8	100,0	4,17	11,79
FU Month 9	Other	4	44,4	3	75,0	11,11	19,25	5	45,5	4	80,0	8,33	16,67
FU Month 12	Other	3	33,3	2	66,7	0,00	0,00	4	36,4	4	100,0	0,00	0,00
FU Month 15	Other	2	22,2	1	50,0	0,00	NE	4	36,4	4	100,0	8,33	16,67
FU Month 18	Other	2	22,2	1	50,0	0,00	NE	2	18,2	2	100,0	0,00	0,00
FU Month 21	Other	2	22,2	1	50,0	0,00	NE	2	18,2	2	100,0	0,00	0,00
FU Month 24	Other	2	22,2	1	50,0	0,00	NE	1	9,1	0	NE	NE	NE
FU Month 27	Other	1	11,1			NE	NE	1	9,1			NE	NE
FU Month 30	Other	1	11,1			NE	NE	0	NE			NE	NE
Race													
Screening	White	246	100,0	232	94,3	16,09	27,74	231	100,0	216	93,5	15,90	27,27
Cycle 4 Day 1	White	206	83,7	188	91,3	10,82	21,42	214	92,6	188	87,9	13,83	25,52
FU Day 28	White	222	90,2	193	86,9	9,84	20,44	215	93,1	192	89,3	12,67	23,54
FU Month 3	White	217	88,2	196	90,3	8,84	21,38	211	91,3	186	88,2	12,54	23,46
FU Month 6	White	199	80,9	178	89,4	6,55	16,64	184	79,7	161	87,5	10,77	22,55
FU Month 9	White	160	65,0	134	83,8	8,71	20,00	144	62,3	117	81,3	9,40	21,37
FU Month 12	White	122	49,6	107	87,7	8,72	21,64	113	48,9	95	84,1	11,58	22,16
FU Month 15	White	102	41,5	89	87,3	7,87	21,92	81	35,1	65	80,2	11,28	21,47
FU Month 18	White	77	31,3	69	89,6	8,70	21,12	58	25,1	47	81,0	13,48	23,73
FU Month 21	White	50	20,3	39	78,0	6,84	17,40	38	16,5	30	78,9	11,11	28,14
FU Month 24	White	30	12,2	23	76,7	4,35	11,48	17	7,4	17	100,0	5,88	13,10
FU Month 27	White	12	4,9	11	91,7	3,03	10,05	8	3,5	7	87,5	4,76	12,60
FU Month 30	White	6	2,4	6	100,0	16,67	27,89	1	0,4	1	100,0	0,00	NE
Geographical Region													
Screening	Asia-Pacific	20	100,0	20	100,0	18,33	25,31	18	100,0	18	100,0	16,67	28,58
Cycle 4 Day 1	Asia-Pacific	15	75,0	15	100,0	6,67	18,69	16	88,9	15	93,8	17,78	30,52
FU Day 28	Asia-Pacific	18	90,0	18	100,0	14,81	26,13	18	100,0	16	88,9	16,67	27,22
FU Month 3	Asia-Pacific	18	90,0	16	88,9	8,33	25,82	18	100,0	16	88,9	14,58	24,25
FU Month 6	Asia-Pacific	16	80,0	14	87,5	16,67	31,35	17	94,4	15	88,2	22,22	27,22

FU Month 9	Asia-Pacific	14	70,0	12	85,7	2,78	9,62	13	72,2	10	76,9	23,33	35,31
FU Month 12	Asia-Pacific	10	50,0	8	80,0	4,17	11,79	10	55,6	10	100,0	10,00	16,10
FU Month 15	Asia-Pacific	8	40,0	6	75,0	0,00	0,00	9	50,0	9	100,0	11,11	16,67
FU Month 18	Asia-Pacific	6	30,0	4	66,7	0,00	0,00	6	33,3	6	100,0	11,11	17,21
FU Month 21	Asia-Pacific	5	25,0	3	60,0	0,00	0,00	4	22,2	4	100,0	0,00	0,00
FU Month 24	Asia-Pacific	3	15,0	2	66,7	0,00	0,00	1	5,6	0	NE	NE	NE
FU Month 27	Asia-Pacific	1	5,0			NE	NE	1	5,6			NE	NE
FU Month 30	Asia-Pacific	1	5,0			NE	NE	0	NE			NE	NE
Screening	Central and South America	3	100,0	3	100,0	11,11	19,25	2	100,0	2	100,0	33,33	47,14
Cycle 4 Day 1	Central and South America	3	100,0	3	100,0	0,00	0,00	2	100,0	2	100,0	0,00	0,00
FU Day 28	Central and South America	3	100,0	3	100,0	0,00	0,00	2	100,0	2	100,0	0,00	0,00
FU Month 3	Central and South America	3	100,0	3	100,0	22,22	38,49	2	100,0	2	100,0	0,00	0,00
FU Month 6	Central and South America	2	66,7	2	100,0	16,67	23,57	2	100,0	2	100,0	0,00	0,00
FU Month 9	Central and South America	2	66,7	2	100,0	16,67	23,57	1	50,0	1	100,0	0,00	NE
FU Month 12	Central and South America	2	66,7	2	100,0	0,00	0,00	1	50,0	1	100,0	33,33	NE
FU Month 15	Central and South America	1	33,3	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 18	Central and South America	1	33,3	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 21	Central and South America	1	33,3	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 24	Central and South America	1	33,3	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
Screening	North America	12	100,0	12	100,0	22,22	35,77	13	100,0	12	92,3	16,67	22,47
Cycle 4 Day 1	North America	9	75,0	9	100,0	14,81	33,79	12	92,3	12	100,0	2,78	9,62
FU Day 28	North America	11	91,7	11	100,0	15,15	22,92	13	100,0	13	100,0	0,00	0,00
FU Month 3	North America	11	91,7	11	100,0	18,18	34,52	12	92,3	12	100,0	2,78	9,62
FU Month 6	North America	11	91,7	10	90,9	10,00	22,50	11	84,6	11	100,0	9,09	21,56
FU Month 9	North America	8	66,7	8	100,0	16,67	30,86	9	69,2	9	100,0	3,70	11,11
FU Month 12	North America	8	66,7	7	87,5	19,05	37,80	7	53,8	7	100,0	4,76	12,60
FU Month 15	North America	6	50,0	6	100,0	0,00	0,00	6	46,2	5	83,3	6,67	14,91
FU Month 18	North America	4	33,3	4	100,0	0,00	0,00	3	23,1	3	100,0	11,11	19,25
FU Month 21	North America	3	25,0	2	66,7	0,00	0,00	1	7,7	1	100,0	0,00	NE
FU Month 24	North America	3	25,0	1	33,3	0,00	NE	1	7,7	1	100,0	0,00	NE
FU Month 27	North America	2	16,7	1	50,0	0,00	NE	1	7,7	1	100,0	0,00	NE
Screening	Other	45	100,0	41	91,1	16,26	27,00	44	100,0	41	93,2	18,70	24,78
Cycle 4 Day 1	Other	37	82,2	33	89,2	12,12	18,29	40	90,9	35	87,5	10,48	21,04
FU Day 28	Other	37	82,2	33	89,2	10,10	19,52	39	88,6	37	94,9	10,81	26,12
FU Month 3	Other	38	84,4	34	89,5	5,88	12,90	38	86,4	36	94,7	16,67	29,28
FU Month 6	Other	35	77,8	31	88,6	4,30	11,36	33	75,0	31	93,9	5,38	15,15
FU Month 9	Other	26	57,8	22	84,6	7,58	17,61	24	54,5	19	79,2	5,26	16,72
FU Month 12	Other	17	37,8	16	94,1	8,33	19,25	16	36,4	14	87,5	4,76	12,10

FU Month 15	Other	12	26,7	11	91,7	0,00	0,00	9	20,5	8	88,9	8,33	23,57
FU Month 18	Other	10	22,2	9	90,0	0,00	0,00	7	15,9	6	85,7	0,00	0,00
FU Month 21	Other	7	15,6	6	85,7	0,00	0,00	4	9,1	4	100,0	0,00	0,00
FU Month 24	Other	6	13,3	5	83,3	6,67	14,91	3	6,8	3	100,0	11,11	19,25
FU Month 27	Other	4	8,9	4	100,0	0,00	0,00	1	2,3	1	100,0	0,00	NE
FU Month 30	Other	2	4,4	2	100,0	33,33	47,14	0	NE	0	NE	NE	NE
Screening	Western Europe	175	100,0	165	94,3	15,56	28,16	165	100,0	154	93,3	15,15	27,77
Cycle 4 Day 1	Western Europe	149	85,1	135	90,6	11,11	21,55	154	93,3	133	86,4	15,54	26,76
FU Day 28	Western Europe	161	92,0	136	84,5	9,31	20,16	153	92,7	134	87,6	13,68	22,84
FU Month 3	Western Europe	155	88,6	139	89,7	8,63	20,98	151	91,5	130	86,1	12,05	21,96
FU Month 6	Western Europe	143	81,7	128	89,5	5,73	14,56	129	78,2	110	85,3	10,61	22,99
FU Month 9	Western Europe	114	65,1	93	81,6	8,96	20,35	102	61,8	82	80,4	9,35	20,47
FU Month 12	Western Europe	88	50,3	76	86,4	8,33	21,17	83	50,3	67	80,7	12,94	24,59
FU Month 15	Western Europe	77	44,0	66	85,7	10,61	24,92	61	37,0	47	77,0	12,06	22,44
FU Month 18	Western Europe	58	33,1	52	89,7	11,54	23,69	44	26,7	34	77,3	15,69	26,25
FU Month 21	Western Europe	36	20,6	28	77,8	9,52	19,99	31	18,8	23	74,2	14,49	31,50
FU Month 24	Western Europe	19	10,9	15	78,9	4,44	11,73	13	7,9	13	100,0	5,13	12,52
FU Month 27	Western Europe	6	3,4	6	100,0	5,56	13,61	6	3,6	5	83,3	6,67	14,91
FU Month 30	Western Europe	4	2,3	4	100,0	8,33	16,67	1	0,6	1	100,0	0,00	NE
FCgamma receptor IIa													
Screening	131HH	58	100,0	54	93,1	16,05	28,03	76	100,0	72	94,7	14,35	22,95
Cycle 4 Day 1	131HH	49	84,5	43	87,8	13,18	24,28	65	85,5	60	92,3	11,11	22,69
FU Day 28	131HH	51	87,9	46	90,2	9,42	20,68	70	92,1	62	88,6	8,06	15,61
FU Month 3	131HH	51	87,9	47	92,2	12,77	25,59	64	84,2	54	84,4	9,88	21,11
FU Month 6	131HH	49	84,5	45	91,8	6,67	18,26	55	72,4	48	87,3	7,64	19,74
FU Month 9	131HH	39	67,2	29	74,4	5,75	12,81	41	53,9	33	80,5	8,08	22,10
FU Month 12	131HH	28	48,3	24	85,7	9,72	23,01	34	44,7	29	85,3	8,05	19,22
FU Month 15	131HH	23	39,7	19	82,6	8,77	24,45	24	31,6	20	83,3	6,67	17,44
FU Month 18	131HH	17	29,3	14	82,4	16,67	28,50	16	21,1	13	81,3	12,82	28,99
FU Month 21	131HH	13	22,4	8	61,5	8,33	15,43	11	14,5	10	90,9	20,00	42,16
FU Month 24	131HH	11	19,0	7	63,6	4,76	12,60	1	1,3	1	100,0	0,00	NE
FU Month 27	131HH	4	6,9	3	75,0	11,11	19,25	1	1,3	1	100,0	0,00	NE
FU Month 30	131HH	3	5,2	2	66,7	16,67	23,57	0	NE	0	NE	NE	NE
Screening	131HR	125	100,0	118	94,4	17,23	28,49	114	100,0	108	94,7	17,28	28,27
Cycle 4 Day 1	131HR	105	84,0	97	92,4	11,34	21,46	110	96,5	98	89,1	17,35	28,41
FU Day 28	131HR	116	92,8	102	87,9	10,78	21,06	105	92,1	96	91,4	14,93	25,07
FU Month 3	131HR	114	91,2	102	89,5	6,21	18,60	107	93,9	95	88,8	14,04	24,11
FU Month 6	131HR	104	83,2	93	89,4	6,81	16,71	95	83,3	85	89,5	12,55	24,65

FU Month 9	131HR	84	67,2	71	84,5	9,86	22,11	76	66,7	61	80,3	8,20	18,91
FU Month 12	131HR	64	51,2	57	89,1	8,77	21,39	57	50,0	48	84,2	10,42	21,91
FU Month 15	131HR	53	42,4	44	83,0	7,58	20,16	44	38,6	35	79,5	9,52	17,29
FU Month 18	131HR	43	34,4	38	88,4	7,02	19,23	32	28,1	26	81,3	12,82	21,24
FU Month 21	131HR	26	20,8	20	76,9	8,33	21,29	21	18,4	16	76,2	8,33	19,25
FU Month 24	131HR	12	9,6	10	83,3	0,00	0,00	12	10,5	11	91,7	6,06	13,48
FU Month 27	131HR	6	4,8	5	83,3	0,00	0,00	6	5,3	4	66,7	8,33	16,67
FU Month 30	131HR	3	2,4	3	100,0	22,22	38,49	1	0,9	1	100,0	0,00	NE
Screening	131RR	49	100,0	48	98,0	18,06	29,14	33	100,0	30	90,9	12,22	25,50
Cycle 4 Day 1	131RR	40	81,6	38	95,0	7,89	14,36	31	93,9	25	80,6	9,33	18,05
FU Day 28	131RR	42	85,7	35	83,3	10,48	21,04	32	97,0	28	87,5	11,90	26,00
FU Month 3	131RR	39	79,6	37	94,9	11,71	23,85	32	97,0	30	93,8	10,00	23,41
FU Month 6	131RR	35	71,4	31	88,6	8,60	17,14	27	81,8	22	81,5	6,06	16,70
FU Month 9	131RR	24	49,0	22	91,7	10,61	21,54	19	57,6	17	89,5	9,80	19,60
FU Month 12	131RR	18	36,7	17	94,4	5,88	24,25	17	51,5	15	88,2	15,56	17,21
FU Month 15	131RR	16	32,7	16	100,0	4,17	16,67	11	33,3	9	81,8	22,22	33,33
FU Month 18	131RR	14	28,6	14	100,0	4,76	17,82	8	24,2	7	87,5	19,05	26,23
FU Month 21	131RR	8	16,3	7	87,5	4,76	12,60	5	15,2	4	80,0	0,00	0,00
FU Month 24	131RR	5	10,2	4	80,0	16,67	19,25	3	9,1	3	100,0	0,00	0,00
FU Month 27	131RR	2	4,1	2	100,0	0,00	0,00	1	3,0	1	100,0	0,00	NE
FU Month 30	131RR	1	2,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
Screening	Missing	23	100,0	21	91,3	6,35	20,05	19	100,0	17	89,5	23,53	36,83
Cycle 4 Day 1	Missing	19	82,6	17	89,5	9,80	25,72	18	94,7	14	77,8	9,52	24,21
FU Day 28	Missing	21	91,3	18	85,7	7,41	18,28	18	94,7	16	88,9	14,58	29,74
FU Month 3	Missing	21	91,3	17	81,0	7,84	18,74	18	94,7	17	94,4	15,69	23,91
FU Month 6	Missing	19	82,6	16	84,2	2,08	8,33	15	78,9	14	93,3	14,29	21,54
FU Month 9	Missing	17	73,9	15	88,2	6,67	18,69	13	68,4	10	76,9	20,00	32,20
FU Month 12	Missing	15	65,2	11	73,3	9,09	15,57	9	47,4	7	77,8	19,05	37,80
FU Month 15	Missing	12	52,2	11	91,7	12,12	30,81	6	31,6	5	83,3	20,00	29,81
FU Month 18	Missing	5	21,7	4	80,0	8,33	16,67	4	21,1	3	75,0	0,00	0,00
FU Month 21	Missing	5	21,7	5	100,0	0,00	0,00	3	15,8	2	66,7	0,00	0,00
FU Month 24	Missing	4	17,4	3	75,0	0,00	0,00	2	10,5	2	100,0	16,67	23,57
FU Month 27	Missing	1	4,3	1	100,0	0,00	NE	1	5,3	1	100,0	0,00	NE
FCgamma receptor IIIa													
Screening	158FF	103	100,0	101	98,1	16,83	27,33	83	100,0	78	94,0	14,53	27,70
Cycle 4 Day 1	158FF	89	86,4	83	93,3	9,64	17,68	78	94,0	71	91,0	14,55	25,03
FU Day 28	158FF	96	93,2	84	87,5	9,92	21,20	78	94,0	74	94,9	11,71	21,67
FU Month 3	158FF	94	91,3	84	89,4	7,94	22,33	78	94,0	71	91,0	11,27	21,78

FU Month 6	158FF	86	83,5	73	84,9	7,31	18,63	64	77,1	58	90,6	6,32	18,16
FU Month 9	158FF	71	68,9	58	81,7	9,77	19,75	47	56,6	43	91,5	5,43	12,45
FU Month 12	158FF	48	46,6	42	87,5	9,52	22,43	38	45,8	35	92,1	5,71	12,75
FU Month 15	158FF	37	35,9	32	86,5	12,50	29,02	30	36,1	24	80,0	5,56	12,69
FU Month 18	158FF	27	26,2	25	92,6	8,00	19,91	21	25,3	17	81,0	13,73	26,51
FU Month 21	158FF	16	15,5	15	93,8	11,11	20,57	9	10,8	8	88,9	12,50	35,36
FU Month 24	158FF	8	7,8	6	75,0	5,56	13,61	3	3,6	3	100,0	0,00	0,00
FU Month 27	158FF	5	4,9	4	80,0	0,00	0,00	1	1,2	1	100,0	0,00	NE
FU Month 30	158FF	3	2,9	3	100,0	0,00	0,00	0	NE	0	NE	NE	NE
Screening	158FV	119	100,0	110	92,4	16,36	28,82	109	100,0	103	94,5	15,86	24,18
Cycle 4 Day 1	158FV	99	83,2	89	89,9	13,11	23,90	100	91,7	86	86,0	14,34	26,34
FU Day 28	158FV	105	88,2	91	86,7	9,52	18,11	101	92,7	86	85,1	12,02	23,38
FU Month 3	158FV	101	84,9	93	92,1	9,68	20,01	97	89,0	84	86,6	13,10	24,28
FU Month 6	158FV	94	79,0	87	92,6	6,51	13,29	83	76,1	72	86,7	12,96	24,10
FU Month 9	158FV	71	59,7	61	85,9	9,29	21,20	65	59,6	49	75,4	9,52	22,57
FU Month 12	158FV	60	50,4	55	91,7	7,88	19,21	52	47,7	42	80,8	16,67	24,69
FU Month 15	158FV	52	43,7	45	86,5	3,70	10,59	36	33,0	30	83,3	18,89	27,24
FU Month 18	158FV	44	37,0	38	86,4	8,77	21,48	24	22,0	20	83,3	16,67	25,36
FU Month 21	158FV	28	23,5	18	64,3	5,56	17,15	18	16,5	14	77,8	14,29	31,25
FU Month 24	158FV	18	15,1	13	72,2	5,13	12,52	6	5,5	5	83,3	0,00	0,00
FU Month 27	158FV	6	5,0	5	83,3	6,67	14,91	2	1,8	1	50,0	0,00	NE
FU Month 30	158FV	4	3,4	3	75,0	33,33	33,33	0	NE	0	NE	NE	NE
Screening	158VV	16	100,0	15	93,8	17,78	30,52	33	100,0	31	93,9	15,05	28,33
Cycle 4 Day 1	158VV	12	75,0	11	91,7	0,00	0,00	30	90,9	28	93,3	11,90	24,37
FU Day 28	158VV	14	87,5	13	92,9	15,38	32,25	30	90,9	28	93,3	10,71	20,39
FU Month 3	158VV	15	93,8	12	80,0	8,33	28,87	30	90,9	26	86,7	10,26	22,65
FU Month 6	158VV	14	87,5	13	92,9	7,69	27,74	30	90,9	25	83,3	10,67	24,94
FU Month 9	158VV	12	75,0	10	83,3	6,67	21,08	25	75,8	20	80,0	13,33	25,13
FU Month 12	158VV	8	50,0	7	87,5	14,29	37,80	20	60,6	17	85,0	5,88	17,62
FU Month 15	158VV	8	50,0	7	87,5	14,29	37,80	14	42,4	11	78,6	3,03	10,05
FU Month 18	158VV	4	25,0	4	100,0	16,67	33,33	11	33,3	9	81,8	7,41	14,70
FU Month 21	158VV	3	18,8	2	66,7	0,00	0,00	9	27,3	7	77,8	4,76	12,60
FU Month 24	158VV	2	12,5	2	100,0	0,00	0,00	7	21,2	7	100,0	9,52	16,27
FU Month 27	158VV	1	6,3	1	100,0	0,00	NE	5	15,2	4	80,0	8,33	16,67
FU Month 30	158VV	0	NE	0	NE	NE	NE	1	3,0	1	100,0	0,00	NE
Screening	Missing	17	100,0	15	88,2	8,89	23,46	17	100,0	15	88,2	28,89	37,52
Cycle 4 Day 1	Missing	13	76,5	12	92,3	13,89	30,01	16	94,1	12	75,0	11,11	25,95
FU Day 28	Missing	15	88,2	13	86,7	10,26	21,01	16	94,1	14	87,5	21,43	33,61

FU Month 3	Missing	15	88,2	14	93,3	9,52	20,37	16	94,1	15	93,8	17,78	24,77
FU Month 6	Missing	13	76,5	12	92,3	2,78	9,62	15	88,2	14	93,3	14,29	21,54
FU Month 9	Missing	10	58,8	8	80,0	0,00	0,00	12	70,6	9	75,0	18,52	33,79
FU Month 12	Missing	9	52,9	5	55,6	0,00	0,00	7	41,2	5	71,4	20,00	44,72
FU Month 15	Missing	7	41,2	6	85,7	5,56	13,61	5	29,4	4	80,0	8,33	16,67
FU Month 18	Missing	4	23,5	3	75,0	0,00	0,00	4	23,5	3	75,0	0,00	0,00
FU Month 21	Missing	5	29,4	5	100,0	0,00	0,00	4	23,5	3	75,0	0,00	0,00
FU Month 24	Missing	4	23,5	3	75,0	0,00	0,00	2	11,8	2	100,0	16,67	23,57
FU Month 27	Missing	1	5,9	1	100,0	0,00	NE	1	5,9	1	100,0	0,00	NE
Binet Staging at baseline													
Screening	A	59	100,0	57	96,6	16,37	29,63	57	100,0	53	93,0	20,13	29,48
Cycle 4 Day 1	A	51	86,4	48	94,1	14,58	25,64	54	94,7	50	92,6	14,67	27,07
FU Day 28	A	58	98,3	53	91,4	13,84	22,10	54	94,7	51	94,4	15,69	28,56
FU Month 3	A	57	96,6	56	98,2	12,50	25,08	53	93,0	50	94,3	16,00	28,76
FU Month 6	A	56	94,9	50	89,3	10,00	18,13	45	78,9	42	93,3	18,25	29,63
FU Month 9	A	43	72,9	37	86,0	14,41	25,51	34	59,6	30	88,2	12,22	25,50
FU Month 12	A	36	61,0	34	94,4	7,84	20,20	24	42,1	21	87,5	17,46	27,12
FU Month 15	A	30	50,8	27	90,0	6,17	13,19	19	33,3	19	100,0	19,30	27,92
FU Month 18	A	22	37,3	18	81,8	11,11	25,57	16	28,1	16	100,0	12,50	20,64
FU Month 21	A	17	28,8	15	88,2	2,22	8,61	8	14,0	7	87,5	4,76	12,60
FU Month 24	A	10	16,9	8	80,0	4,17	11,79	5	8,8	5	100,0	6,67	14,91
FU Month 27	A	5	8,5	4	80,0	8,33	16,67	2	3,5	1	50,0	0,00	NE
FU Month 30	A	4	6,8	3	75,0	11,11	19,25	0	NE	0	NE	NE	NE
Screening	B	104	100,0	100	96,2	13,00	23,64	85	100,0	83	97,6	16,87	27,73
Cycle 4 Day 1	B	88	84,6	83	94,3	8,84	18,83	79	92,9	72	91,1	14,81	26,77
FU Day 28	B	91	87,5	79	86,8	10,13	22,24	79	92,9	71	89,9	14,08	23,68
FU Month 3	B	88	84,6	78	88,6	8,97	21,94	79	92,9	71	89,9	13,15	23,56
FU Month 6	B	80	76,9	75	93,8	4,00	14,46	70	82,4	63	90,0	10,05	21,28
FU Month 9	B	63	60,6	52	82,5	5,13	15,32	59	69,4	49	83,1	8,84	18,97
FU Month 12	B	47	45,2	39	83,0	9,40	24,12	46	54,1	40	87,0	14,17	23,74
FU Month 15	B	37	35,6	34	91,9	7,84	21,80	34	40,0	28	82,4	10,71	20,39
FU Month 18	B	31	29,8	29	93,5	11,49	22,32	22	25,9	18	81,8	16,67	23,57
FU Month 21	B	18	17,3	13	72,2	2,56	9,25	17	20,0	14	82,4	7,14	19,30
FU Month 24	B	11	10,6	8	72,7	4,17	11,79	8	9,4	8	100,0	4,17	11,79
FU Month 27	B	5	4,8	4	80,0	0,00	0,00	4	4,7	4	100,0	8,33	16,67
FU Month 30	B	2	1,9	2	100,0	0,00	0,00	0	NE	0	NE	NE	NE
Screening	C	92	100,0	84	91,3	19,84	31,10	100	100,0	91	91,0	13,19	24,79
Cycle 4 Day 1	C	74	80,4	64	86,5	10,94	20,62	91	91,0	75	82,4	12,44	23,10

FU Day 28	C	81	88,0	69	85,2	7,25	17,03	92	92,0	80	87,0	8,75	18,18
FU Month 3	C	80	87,0	69	86,3	5,80	17,11	89	89,0	75	84,3	9,33	17,81
FU Month 6	C	71	77,2	60	84,5	7,22	17,46	77	77,0	64	83,1	5,73	15,21
FU Month 9	C	58	63,0	48	82,8	8,33	18,83	56	56,0	42	75,0	7,94	20,57
FU Month 12	C	42	45,7	36	85,7	8,33	20,12	47	47,0	38	80,9	4,39	13,80
FU Month 15	C	37	40,2	29	78,4	9,20	28,03	32	32,0	22	68,8	4,55	11,71
FU Month 18	C	26	28,3	23	88,5	2,90	13,90	22	22,0	15	68,2	8,89	26,63
FU Month 21	C	17	18,5	12	70,6	16,67	26,59	15	15,0	11	73,3	18,18	40,45
FU Month 24	C	11	12,0	8	72,7	4,17	11,79	5	5,0	4	80,0	8,33	16,67
FU Month 27	C	3	3,3	3	100,0	0,00	0,00	3	3,0	2	66,7	0,00	0,00
FU Month 30	C	1	1,1	1	100,0	66,67	NE	1	1,0	1	100,0	0,00	NE
Total CIR score at baseline													
Screening	<=6	63	100,0	59	93,7	11,30	21,98	75	100,0	70	93,3	15,24	27,62
Cycle 4 Day 1	<=6	52	82,5	42	80,8	9,52	21,19	72	96,0	60	83,3	10,56	20,80
FU Day 28	<=6	56	88,9	49	87,5	7,48	19,56	72	96,0	59	81,9	7,34	16,46
FU Month 3	<=6	55	87,3	47	85,5	7,80	18,67	69	92,0	56	81,2	8,33	17,12
FU Month 6	<=6	52	82,5	47	90,4	5,67	12,66	60	80,0	53	88,3	10,69	21,46
FU Month 9	<=6	43	68,3	35	81,4	3,81	15,70	47	62,7	38	80,9	7,02	17,60
FU Month 12	<=6	35	55,6	29	82,9	12,64	24,26	34	45,3	27	79,4	14,81	26,69
FU Month 15	<=6	32	50,8	28	87,5	8,33	26,64	25	33,3	17	68,0	17,65	23,91
FU Month 18	<=6	23	36,5	22	95,7	9,09	21,04	19	25,3	14	73,7	21,43	30,96
FU Month 21	<=6	14	22,2	8	57,1	8,33	23,57	14	18,7	10	71,4	20,00	35,83
FU Month 24	<=6	8	12,7	7	87,5	4,76	12,60	7	9,3	6	85,7	5,56	13,61
FU Month 27	<=6	2	3,2	2	100,0	0,00	0,00	4	5,3	2	50,0	0,00	0,00
FU Month 30	<=6	0	NE	0	NE	NE	NE	1	1,3	1	100,0	0,00	NE
Screening	>6	192	100,0	182	94,8	17,77	29,45	167	100,0	157	94,0	16,56	26,85
Cycle 4 Day 1	>6	161	83,9	153	95,0	11,33	21,34	152	91,0	137	90,1	15,33	27,12
FU Day 28	>6	174	90,6	152	87,4	10,96	20,93	153	91,6	143	93,5	14,45	25,19
FU Month 3	>6	170	88,5	156	91,8	9,19	22,26	152	91,0	140	92,1	14,05	24,99
FU Month 6	>6	155	80,7	138	89,0	7,00	17,76	132	79,0	116	87,9	10,34	22,59
FU Month 9	>6	121	63,0	102	84,3	10,46	20,97	102	61,1	83	81,4	10,44	22,65
FU Month 12	>6	90	46,9	80	88,9	7,08	20,33	83	49,7	72	86,7	9,72	19,73
FU Month 15	>6	72	37,5	62	86,1	7,53	19,48	60	35,9	52	86,7	8,97	19,93
FU Month 18	>6	56	29,2	48	85,7	8,33	21,19	41	24,6	35	85,4	9,52	19,08
FU Month 21	>6	38	19,8	32	84,2	6,25	15,70	26	15,6	22	84,6	6,06	22,15
FU Month 24	>6	24	12,5	17	70,8	3,92	11,07	11	6,6	11	100,0	6,06	13,48
FU Month 27	>6	11	5,7	9	81,8	3,70	11,11	5	3,0	5	100,0	6,67	14,91
FU Month 30	>6	7	3,6	6	85,7	16,67	27,89	0	NE	0	NE	NE	NE

Calculated creatinine clearance cat. 2													
Screening	<70 ml/min	178	100,0	165	92,7	17,98	29,10	176	100,0	166	94,3	16,67	28,37
Cycle 4 Day 1	<70 ml/min	149	83,7	133	89,3	11,28	22,43	164	93,2	143	87,2	12,82	23,38
FU Day 28	<70 ml/min	162	91,0	142	87,7	8,69	18,91	166	94,3	145	87,3	11,26	21,95
FU Month 3	<70 ml/min	157	88,2	141	89,8	8,75	20,95	159	90,3	139	87,4	12,23	23,45
FU Month 6	<70 ml/min	144	80,9	127	88,2	5,51	13,12	139	79,0	121	87,1	9,64	21,70
FU Month 9	<70 ml/min	117	65,7	96	82,1	7,29	18,23	112	63,6	90	80,4	9,63	20,75
FU Month 12	<70 ml/min	92	51,7	79	85,9	8,86	21,16	87	49,4	73	83,9	10,50	20,70
FU Month 15	<70 ml/min	78	43,8	69	88,5	7,73	21,50	60	34,1	48	80,0	11,11	22,10
FU Month 18	<70 ml/min	59	33,1	51	86,4	8,50	20,92	43	24,4	36	83,7	12,96	24,27
FU Month 21	<70 ml/min	38	21,3	27	71,1	7,41	19,25	31	17,6	27	87,1	11,11	29,24
FU Month 24	<70 ml/min	24	13,5	18	75,0	5,56	12,78	13	7,4	12	92,3	5,56	12,97
FU Month 27	<70 ml/min	10	5,6	8	80,0	4,17	11,79	7	4,0	5	71,4	0,00	0,00
FU Month 30	<70 ml/min	5	2,8	4	80,0	25,00	31,91	1	0,6	1	100,0	0,00	NE
Screening	>=70 ml/min	77	100,0	76	98,7	12,28	24,85	66	100,0	61	92,4	14,75	23,19
Cycle 4 Day 1	>=70 ml/min	64	83,1	62	96,9	10,22	18,69	60	90,9	54	90,0	16,67	30,20
FU Day 28	>=70 ml/min	68	88,3	59	86,8	13,56	24,07	59	89,4	57	96,6	15,20	26,03
FU Month 3	>=70 ml/min	68	88,3	62	91,2	9,14	22,72	62	93,9	57	91,9	12,87	22,50
FU Month 6	>=70 ml/min	63	81,8	58	92,1	9,20	22,33	53	80,3	48	90,6	12,50	23,44
FU Month 9	>=70 ml/min	47	61,0	41	87,2	12,20	23,28	37	56,1	31	83,8	8,60	22,72
FU Month 12	>=70 ml/min	33	42,9	30	90,9	7,78	22,63	30	45,5	26	86,7	12,82	25,08
FU Month 15	>=70 ml/min	26	33,8	21	80,8	7,94	23,34	25	37,9	21	84,0	11,11	19,25
FU Month 18	>=70 ml/min	20	26,0	19	95,0	8,77	21,78	17	25,8	13	76,5	12,82	21,68
FU Month 21	>=70 ml/min	14	18,2	13	92,9	5,13	12,52	9	13,6	5	55,6	6,67	14,91
FU Month 24	>=70 ml/min	8	10,4	6	75,0	0,00	0,00	5	7,6	5	100,0	6,67	14,91
FU Month 27	>=70 ml/min	3	3,9	3	100,0	0,00	0,00	2	3,0	2	100,0	16,67	23,57
FU Month 30	>=70 ml/min	2	2,6	2	100,0	0,00	0,00	0	NE	0	NE	NE	NE
Beta2 microglobulin													
Screening	Missing	3	100,0	3	100,0	0,00	0,00	3	100,0	3	100,0	55,56	50,92
Cycle 4 Day 1	Missing	3	100,0	3	100,0	0,00	0,00	3	100,0	2	66,7	0,00	0,00
FU Day 28	Missing	3	100,0	3	100,0	0,00	0,00	3	100,0	2	66,7	0,00	0,00
FU Month 3	Missing	3	100,0	3	100,0	11,11	19,25	3	100,0	2	66,7	16,67	23,57
FU Month 6	Missing	3	100,0	3	100,0	0,00	0,00	3	100,0	2	66,7	16,67	23,57
FU Month 9	Missing	2	66,7	1	50,0	0,00	NE	3	100,0	2	66,7	16,67	23,57
FU Month 12	Missing	1	33,3	1	100,0	0,00	NE	2	66,7	1	50,0	0,00	NE
FU Month 15	Missing	1	33,3	1	100,0	0,00	NE	2	66,7	1	50,0	0,00	NE
FU Month 18	Missing	1	33,3	1	100,0	0,00	NE	2	66,7	1	50,0	0,00	NE
FU Month 21	Missing	1	33,3	1	100,0	0,00	NE	2	66,7	1	50,0	0,00	NE
FU Month 24	Missing	1	33,3	1	100,0	0,00	NE	1	33,3	1	100,0	0,00	NE

Screening	< 3.5 ug/mL	154	100,0	144	93,5	15,05	25,80	140	100,0	131	93,6	14,50	24,14
Cycle 4 Day 1	< 3.5 ug/mL	127	82,5	116	91,3	12,93	23,99	129	92,1	112	86,8	14,88	26,03
FU Day 28	< 3.5 ug/mL	137	89,0	121	88,3	10,19	19,65	132	94,3	120	90,9	14,72	25,12
FU Month 3	< 3.5 ug/mL	134	87,0	123	91,8	7,59	19,00	130	92,9	116	89,2	11,21	22,39
FU Month 6	< 3.5 ug/mL	128	83,1	114	89,1	6,73	16,10	120	85,7	110	91,7	10,91	22,63
FU Month 9	< 3.5 ug/mL	104	67,5	86	82,7	7,36	18,01	98	70,0	81	82,7	11,52	24,24
FU Month 12	< 3.5 ug/mL	78	50,6	69	88,5	8,21	18,44	75	53,6	67	89,3	14,43	24,77
FU Month 15	< 3.5 ug/mL	65	42,2	56	86,2	8,93	22,47	60	42,9	51	85,0	11,76	20,90
FU Month 18	< 3.5 ug/mL	46	29,9	41	89,1	10,57	24,08	43	30,7	35	81,4	16,19	26,04
FU Month 21	< 3.5 ug/mL	30	19,5	21	70,0	7,94	17,97	27	19,3	22	81,5	15,15	32,08
FU Month 24	< 3.5 ug/mL	19	12,3	14	73,7	0,00	0,00	12	8,6	11	91,7	9,09	15,57
FU Month 27	< 3.5 ug/mL	10	6,5	8	80,0	4,17	11,79	7	5,0	5	71,4	6,67	14,91
FU Month 30	< 3.5 ug/mL	5	3,2	4	80,0	25,00	31,91	1	0,7	1	100,0	0,00	NE
Screening	>= 3.5 ug/mL	98	100,0	94	95,9	18,44	31,15	99	100,0	93	93,9	17,20	29,33
Cycle 4 Day 1	>= 3.5 ug/mL	83	84,7	76	91,6	8,33	16,44	92	92,9	83	90,2	12,85	24,87
FU Day 28	>= 3.5 ug/mL	90	91,8	77	85,6	10,39	22,46	90	90,9	80	88,9	9,17	19,83
FU Month 3	>= 3.5 ug/mL	88	89,8	77	87,5	10,82	25,04	88	88,9	78	88,6	14,10	24,33
FU Month 6	>= 3.5 ug/mL	76	77,6	68	89,5	6,86	17,81	69	69,7	57	82,6	9,36	21,60
FU Month 9	>= 3.5 ug/mL	58	59,2	50	86,2	11,33	22,95	48	48,5	38	79,2	4,39	11,42
FU Month 12	>= 3.5 ug/mL	46	46,9	39	84,8	9,40	26,43	40	40,4	31	77,5	4,30	11,36
FU Month 15	>= 3.5 ug/mL	38	38,8	33	86,8	6,06	21,17	23	23,2	17	73,9	9,80	22,87
FU Month 18	>= 3.5 ug/mL	32	32,7	28	87,5	5,95	15,85	15	15,2	13	86,7	5,13	12,52
FU Month 21	>= 3.5 ug/mL	21	21,4	18	85,7	5,56	17,15	11	11,1	9	81,8	0,00	0,00
FU Month 24	>= 3.5 ug/mL	12	12,2	9	75,0	11,11	16,67	5	5,1	5	100,0	0,00	0,00
FU Month 27	>= 3.5 ug/mL	3	3,1	3	100,0	0,00	0,00	2	2,0	2	100,0	0,00	0,00
FU Month 30	>= 3.5 ug/mL	2	2,0	2	100,0	0,00	0,00	0	NE	0	NE	NE	NE
Immunoglobulin VH, cytogenetics 2													
Screening	12	45	100,0	43	95,6	14,73	24,45	44	100,0	42	95,5	15,08	25,72
Cycle 4 Day 1	12	34	75,6	32	94,1	14,58	28,00	38	86,4	33	86,8	14,14	25,04
FU Day 28	12	39	86,7	37	94,9	11,71	21,11	40	90,9	35	87,5	10,48	21,04
FU Month 3	12	38	84,4	36	94,7	8,33	20,12	39	88,6	32	82,1	10,42	19,74
FU Month 6	12	36	80,0	30	83,3	1,11	6,09	34	77,3	28	82,4	15,48	26,42
FU Month 9	12	26	57,8	22	84,6	9,09	23,42	28	63,6	18	64,3	7,41	14,26
FU Month 12	12	22	48,9	18	81,8	3,70	10,78	23	52,3	15	65,2	4,44	11,73
FU Month 15	12	17	37,8	14	82,4	2,38	8,91	17	38,6	12	70,6	8,33	20,72
FU Month 18	12	15	33,3	12	80,0	8,33	20,72	13	29,5	9	69,2	7,41	14,70
FU Month 21	12	10	22,2	8	80,0	8,33	15,43	7	15,9	5	71,4	0,00	0,00
FU Month 24	12	8	17,8	6	75,0	5,56	13,61	6	13,6	6	100,0	5,56	13,61

FU Month 27	12		511,1	480,0	8,33	16,67		24,5		2100,0	16,67	23,57
FU Month 30	12		48,9	375,0	11,11	19,25		12,3		1100,0	0,00	NE
Screening	11q-	46	100,0	4393,5	7,75	20,36		43100,0	40	93,0	20,00	30,94
Cycle 4 Day 1	11q-	40	87,0	3997,5	6,84	15,63		4195,3	34	82,9	14,71	24,88
FU Day 28	11q-	42	91,3	3583,3	9,52	22,25		3990,7	35	89,7	9,52	15,28
FU Month 3	11q-	42	91,3	3890,5	7,02	17,60		3888,4	36	94,7	8,33	18,47
FU Month 6	11q-	38	82,6	3592,1	5,71	12,75		3274,4	28	87,5	10,71	18,27
FU Month 9	11q-	28	60,9	2692,9	8,97	17,78		2558,1	21	84,0	9,52	21,46
FU Month 12	11q-	20	43,5	1995,0	8,77	21,78		1841,9	17	94,4	15,69	23,91
FU Month 15	11q-	18	39,1	1688,9	6,25	13,44		1432,6	10	71,4	23,33	35,31
FU Month 18	11q-	15	32,6	1386,7	7,69	19,97		818,6	7	87,5	19,05	26,23
FU Month 21	11q-	12	26,1	1191,7	0,00	0,00		49,3	2	50,0	0,00	0,00
FU Month 24	11q-	7	15,2	571,4	0,00	0,00		12,3	1	100,0	0,00	NE
FU Month 27	11q-	3	6,5	3100,0	0,00	0,00		0	NE	0	NE	NE
FU Month 30	11q-	3	6,5	3100,0	22,22	38,49		0	NE	0	NE	NE
Screening	13q-	79	100,0	7696,2	15,35	28,51		75100,0	70	93,3	12,86	22,19
Cycle 4 Day 1	13q-	67	84,8	6089,6	11,67	23,63		6890,7	60	88,2	10,00	22,38
FU Day 28	13q-	72	91,1	6590,3	7,69	16,42		7296,0	65	90,3	12,82	24,79
FU Month 3	13q-	73	92,4	6791,8	8,96	22,91		6992,0	61	88,4	11,48	25,01
FU Month 6	13q-	67	84,8	6191,0	5,46	13,85		6384,0	56	88,9	7,74	21,07
FU Month 9	13q-	56	70,9	4885,7	7,64	19,74		5269,3	42	80,8	7,14	17,32
FU Month 12	13q-	44	55,7	3988,6	9,40	24,12		4053,3	38	95,0	9,65	18,84
FU Month 15	13q-	38	48,1	3386,8	10,10	26,98		2938,7	25	86,2	9,33	15,28
FU Month 18	13q-	28	35,4	2589,3	9,33	22,61		2128,0	19	90,5	12,28	25,36
FU Month 21	13q-	16	20,3	1381,3	5,13	12,52		1621,3	14	87,5	9,52	27,51
FU Month 24	13q-	7	8,9	571,4	0,00	0,00		79,3	6	85,7	11,11	17,21
FU Month 27	13q-	2	2,5	150,0	0,00		NE	68,0	4	66,7	0,00	0,00
Screening	Norm. K.	65	100,0	6193,8	25,14	33,70		58100,0	55	94,8	21,21	31,66
Cycle 4 Day 1	Norm. K.	54	83,1	4888,9	12,50	18,99		5594,8	50	90,9	21,33	30,68
FU Day 28	Norm. K.	59	90,8	5084,7	12,67	24,18		5391,4	50	94,3	14,00	24,36
FU Month 3	Norm. K.	54	83,1	4888,9	11,11	24,15		5493,1	48	88,9	19,44	26,48
FU Month 6	Norm. K.	49	75,4	4795,9	11,35	24,35		4577,6	40	88,9	12,50	25,81
FU Month 9	Norm. K.	39	60,0	3179,5	9,68	21,42		3051,7	27	90,0	12,35	26,39
FU Month 12	Norm. K.	32	49,2	2784,4	11,11	24,46		2441,4	20	83,3	11,67	24,84
FU Month 15	Norm. K.	26	40,0	2388,5	10,14	25,49		2034,5	18	90,0	9,26	19,15
FU Month 18	Norm. K.	18	27,7	1794,4	9,80	22,87		1525,9	12	80,0	16,67	26,59
FU Month 21	Norm. K.	12	18,5	650,0	22,22	34,43		1119,0	9	81,8	22,22	37,27
FU Month 24	Norm. K.	8	12,3	675,0	11,11	17,21		46,9	4	100,0	0,00	0,00

FU Month 27	Norm. K.	3	4,6	3	100,0	0,00	0,00	1	1,7	1	100,0	0,00	NE
Screening	Other Abn.	20	100,0	18	90,0	12,96	20,26	22	100,0	20	90,9	8,33	21,29
Cycle 4 Day 1	Other Abn.	18	90,0	16	88,9	6,25	13,44	22	100,0	20	90,9	5,00	16,31
FU Day 28	Other Abn.	18	90,0	14	77,8	9,52	20,37	21	95,5	17	81,0	15,69	31,44
FU Month 3	Other Abn.	18	90,0	14	77,8	7,14	19,30	21	95,5	19	90,5	8,77	18,73
FU Month 6	Other Abn.	17	85,0	12	70,6	11,11	16,41	18	81,8	17	94,4	5,88	13,10
FU Month 9	Other Abn.	15	75,0	10	66,7	10,00	16,10	14	63,6	13	92,9	12,82	28,99
FU Month 12	Other Abn.	7	35,0	6	85,7	5,56	13,61	12	54,5	9	75,0	18,52	33,79
FU Month 15	Other Abn.	5	25,0	4	80,0	0,00	0,00	5	22,7	4	80,0	8,33	16,67
FU Month 18	Other Abn.	3	15,0	3	100,0	0,00	0,00	3	13,6	2	66,7	0,00	0,00
FU Month 21	Other Abn.	2	10,0	2	100,0	0,00	0,00	2	9,1	2	100,0	0,00	0,00
FU Month 24	Other Abn.	2	10,0	2	100,0	0,00	0,00	0	NE	0	NE	NE	NE
Time from first diagnosis													
Screening	Missing	1	100,0	1	100,0	33,33	NE	0	NE	0	NE	NE	NE
Cycle 4 Day 1	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Day 28	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 3	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 6	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 9	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 12	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 15	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 18	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
Screening	13 - 24 months	41	100,0	39	95,1	17,95	31,39	31	100,0	31	100,0	7,53	14,17
Cycle 4 Day 1	13 - 24 months	35	85,4	34	97,1	14,71	27,45	30	96,8	27	90,0	8,64	21,86
FU Day 28	13 - 24 months	38	92,7	33	86,8	9,09	20,87	30	96,8	27	90,0	9,88	18,06
FU Month 3	13 - 24 months	36	87,8	34	94,4	15,69	28,70	30	96,8	26	86,7	7,69	17,15
FU Month 6	13 - 24 months	36	87,8	33	91,7	4,04	18,18	30	96,8	25	83,3	6,67	19,25
FU Month 9	13 - 24 months	32	78,0	29	90,6	3,45	10,33	21	67,7	18	85,7	3,70	10,78
FU Month 12	13 - 24 months	21	51,2	18	85,7	1,85	7,86	16	51,6	14	87,5	2,38	8,91
FU Month 15	13 - 24 months	19	46,3	18	94,7	1,85	7,86	16	51,6	10	62,5	6,67	21,08
FU Month 18	13 - 24 months	14	34,1	13	92,9	5,13	18,49	10	32,3	8	80,0	0,00	0,00
FU Month 21	13 - 24 months	11	26,8	9	81,8	3,70	11,11	6	19,4	4	66,7	0,00	0,00
FU Month 24	13 - 24 months	8	19,5	5	62,5	13,33	18,26	3	9,7	3	100,0	0,00	0,00
FU Month 27	13 - 24 months	5	12,2	5	100,0	6,67	14,91	2	6,5	2	100,0	0,00	0,00
FU Month 30	13 - 24 months	3	7,3	3	100,0	33,33	33,33	1	3,2	1	100,0	0,00	NE
Screening	<= 12 months	60	100,0	58	96,7	20,11	29,91	70	100,0	69	98,6	20,29	29,27
Cycle 4 Day 1	<= 12 months	48	80,0	42	87,5	11,90	19,23	60	85,7	55	91,7	16,36	28,60

FU Day 28	<= 12 months	54	90,0	45	83,3	11,85	23,74	62	88,6	57	91,9	12,28	23,26
FU Month 3	<= 12 months	53	88,3	45	84,9	8,15	20,30	59	84,3	55	93,2	14,55	23,80
FU Month 6	<= 12 months	46	76,7	40	87,0	10,83	20,52	47	67,1	43	91,5	10,08	22,46
FU Month 9	<= 12 months	35	58,3	26	74,3	10,26	20,59	37	52,9	31	83,8	10,75	26,37
FU Month 12	<= 12 months	27	45,0	23	85,2	15,94	29,93	29	41,4	27	93,1	14,81	26,69
FU Month 15	<= 12 months	22	36,7	17	77,3	23,53	38,67	17	24,3	16	94,1	8,33	14,91
FU Month 18	<= 12 months	16	26,7	13	81,3	10,26	25,04	13	18,6	12	92,3	13,89	22,29
FU Month 21	<= 12 months	9	15,0	5	55,6	6,67	14,91	7	10,0	6	85,7	5,56	13,61
FU Month 24	<= 12 months	6	10,0	3	50,0	11,11	19,25	2	2,9	1	50,0	0,00	NE
FU Month 27	<= 12 months	1	1,7			NE	NE	1	1,4			NE	NE
FU Month 30	<= 12 months	1	1,7			NE	NE	0	NE			NE	NE
Screening	>24 months	153	100,0	143	93,5	13,99	26,06	141	100,0	127	90,1	16,01	27,81
Cycle 4 Day 1	>24 months	129	84,3	118	91,5	9,60	20,02	134	95,0	115	85,8	13,91	24,58
FU Day 28	>24 months	137	89,5	122	89,1	9,84	19,49	133	94,3	118	88,7	12,99	24,28
FU Month 3	>24 months	135	88,2	123	91,1	7,32	19,34	132	93,6	115	87,1	12,46	23,96
FU Month 6	>24 months	124	81,0	111	89,5	6,01	14,35	115	81,6	101	87,8	11,55	22,82
FU Month 9	>24 months	96	62,7	81	84,4	10,29	22,14	91	64,5	72	79,1	10,19	20,66
FU Month 12	>24 months	76	49,7	67	88,2	7,96	20,18	72	51,1	58	80,6	11,49	21,22
FU Month 15	>24 months	62	40,5	54	87,1	4,94	15,06	52	36,9	43	82,7	13,18	23,16
FU Month 18	>24 months	48	31,4	43	89,6	9,30	20,99	37	26,2	29	78,4	16,09	26,16
FU Month 21	>24 months	32	20,9	26	81,3	7,69	19,57	27	19,1	22	81,5	13,64	31,97
FU Month 24	>24 months	18	11,8	16	88,9	0,00	0,00	13	9,2	13	100,0	7,69	14,62
FU Month 27	>24 months	7	4,6	6	85,7	0,00	0,00	6	4,3	5	83,3	6,67	14,91
FU Month 30	>24 months	3	2,0	3	100,0	0,00	0,00	0	NE	0	NE	NE	NE
High circulating tumor burden													
Screening	Missing	0	NE	0	NE	NE	NE	2	100,0	1	50,0	0,00	NE
Cycle 4 Day 1	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	0,00	NE
FU Day 28	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	0,00	NE
FU Month 3	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	0,00	NE
FU Month 6	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	66,67	NE
FU Month 9	Missing	0	NE			NE	NE	1	50,0			NE	NE
Screening	<25x10**9 cells/L	60	100,0	55	91,7	17,58	27,86	67	100,0	64	95,5	17,71	29,68
Cycle 4 Day 1	<25x10**9 cells/L	50	83,3	44	88,0	15,91	26,40	61	91,0	51	83,6	14,38	26,04
FU Day 28	<25x10**9 cells/L	56	93,3	47	83,9	12,06	22,44	61	91,0	52	85,2	12,18	21,92
FU Month 3	<25x10**9 cells/L	54	90,0	47	87,0	12,77	26,52	59	88,1	50	84,7	12,67	21,18
FU Month 6	<25x10**9 cells/L	50	83,3	42	84,0	11,90	21,87	51	76,1	42	82,4	8,73	20,90
FU Month 9	<25x10**9 cells/L	36	60,0	27	75,0	11,11	20,67	41	61,2	30	73,2	4,44	14,47
FU Month 12	<25x10**9 cells/L	29	48,3	24	82,8	8,33	17,72	34	50,7	25	73,5	8,00	17,43

FU Month 15	<25x10**9 cells/L	24	40,0	19	79,2	10,53	19,41	23	34,3	15	65,2	11,11	27,22
FU Month 18	<25x10**9 cells/L	20	33,3	18	90,0	9,26	22,30	19	28,4	14	73,7	9,52	24,21
FU Month 21	<25x10**9 cells/L	14	23,3	10	71,4	13,33	23,31	10	14,9	8	80,0	4,17	11,79
FU Month 24	<25x10**9 cells/L	8	13,3	5	62,5	6,67	14,91	6	9,0	6	100,0	0,00	0,00
FU Month 27	<25x10**9 cells/L	4	6,7	3	75,0	11,11	19,25	1	1,5	1	100,0	0,00	NE
FU Month 30	<25x10**9 cells/L	4	6,7	3	75,0	33,33	33,33	1	1,5	1	100,0	0,00	NE
Screening	>=25x10**9 cells/L	195	100,0	186	95,4	15,77	27,98	173	100,0	162	93,6	15,64	26,05
Cycle 4 Day 1	>=25x10**9 cells/L	163	83,6	151	92,6	9,49	19,39	162	93,6	145	89,5	13,79	25,33
FU Day 28	>=25x10**9 cells/L	174	89,2	154	88,5	9,52	20,06	163	94,2	149	91,4	12,53	23,72
FU Month 3	>=25x10**9 cells/L	171	87,7	156	91,2	7,69	19,62	161	93,1	145	90,1	12,41	23,88
FU Month 6	>=25x10**9 cells/L	157	80,5	143	91,1	5,13	14,43	140	80,9	126	90,0	10,58	22,17
FU Month 9	>=25x10**9 cells/L	128	65,6	110	85,9	8,18	19,78	107	61,8	91	85,0	10,99	22,80
FU Month 12	>=25x10**9 cells/L	96	49,2	85	88,5	8,63	22,51	83	48,0	74	89,2	12,16	23,13
FU Month 15	>=25x10**9 cells/L	80	41,0	71	88,8	7,04	22,48	62	35,8	54	87,1	11,11	19,43
FU Month 18	>=25x10**9 cells/L	59	30,3	52	88,1	8,33	20,74	41	23,7	35	85,4	14,29	23,27
FU Month 21	>=25x10**9 cells/L	38	19,5	30	78,9	4,44	14,47	30	17,3	24	80,0	12,50	30,79
FU Month 24	>=25x10**9 cells/L	24	12,3	19	79,2	3,51	10,51	12	6,9	11	91,7	9,09	15,57
FU Month 27	>=25x10**9 cells/L	9	4,6	8	88,9	0,00	0,00	6	4,6	6	75,0	5,56	13,61
FU Month 30	>=25x10**9 cells/L	3	1,5	3	100,0	0,00	0,00	0	NE	0	NE	NE	NE

¹ in study: number of subjects in study at respective visit; % based on baseline

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit

² mean: descriptive statistics - absolute values Clinical

cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/t_pro_mean.sas

Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/t_pro_mean_sg_EQC30_IT_label_09MAY2013_21004.xls 04MAR2020

17:18

POPULATION: Labelpopulation, Intent-to-Treat Patients ENDPOINT: EORTC QoL 30

MODEL: Unadjusted Analysis STUDY: CLL11(BO21004), Stage

2

Compliance/Mean

Constipation Scale

		GClb (N=255)						RC1b (N=242)						
		Patients			Statistics			Patients			Statistics			
Name	Level	in study ¹	%	with value ¹	%	Mean ²	SD(mean)	in study ¹	%	with value ¹	%	Mean ²	SD(mean)	
All														
Screening	n/a	255	100,0	238	93,3	14,71	23,39	242	100,0	227	93,8	16,30	26,12	
Cycle 4 Day 1	n/a	213	83,5	196	92,0	16,16	26,25	224	92,6	196	87,5	16,16	24,45	
FU Day 28	n/a	230	90,2	201	87,4	14,76	24,90	225	93,0	201	89,3	13,60	23,63	
FU Month 3	n/a	225	88,2	201	89,3	12,77	23,98	221	91,3	195	88,2	13,50	22,83	
FU Month 6	n/a	207	81,2	188	90,8	10,11	19,46	192	79,3	168	87,5	17,26	26,04	
FU Month 9	n/a	164	64,3	138	84,1	9,66	20,22	149	61,6	119	79,9	13,17	23,05	
FU Month 12	n/a	125	49,0	108	86,4	9,88	18,38	117	48,3	99	84,6	14,14	22,88	
FU Month 15	n/a	104	40,8	90	86,5	9,26	18,04	85	35,1	69	81,2	13,04	24,40	
FU Month 18	n/a		79	31,0	68	86,1	10,29	20,97	60	24,8	49	81,7	17,69	27,30
FU Month 21	n/a		52	20,4	40	76,9	4,17	11,16	40	16,5	32	80,0	21,88	32,36
FU Month 24	n/a		32	12,5	24	75,0	5,56	12,69	18	7,4	16	88,9	10,42	20,07
FU Month 27	n/a		13	5,1	11	84,6	3,03	10,05	9	3,7	7	77,8	9,52	16,27
FU Month 30	n/a		7	2,7	6	85,7	22,22	27,22	1	0,4	1	100,0	0,00	NE
Gender														
Screening	Female	97	100,0	90	92,8	17,04	23,57	95	100,0	87	91,6	22,99	28,89	
Cycle 4 Day 1	Female	84	86,6	77	91,7	19,05	32,19	88	92,6	77	87,5	19,48	26,68	
FU Day 28	Female	90	92,8	83	92,2	16,47	25,17	91	95,8	79	86,8	16,88	25,53	
FU Month 3	Female	88	90,7	80	90,9	13,33	25,77	87	91,6	76	87,4	15,35	21,39	
FU Month 6	Female	84	86,6	72	85,7	9,72	20,51	77	81,1	68	88,3	17,65	27,30	
FU Month 9	Female	70	72,2	59	84,3	11,86	23,78	61	64,2	46	75,4	15,94	25,08	
FU Month 12	Female	56	57,7	48	85,7	10,42	15,61	47	49,5	40	85,1	19,17	23,74	
FU Month 15	Female	47	48,5	40	85,1	9,17	16,86	33	34,7	28	84,8	22,62	31,50	
FU Month 18	Female	34	35,1	29	85,3	16,09	26,16	26	27,4	22	84,6	24,24	31,17	
FU Month 21	Female	21	21,6	15	71,4	4,44	11,73	17	17,9	15	88,2	35,56	34,43	
FU Month 24	Female	12	12,4	9	75,0	7,41	14,70	6	6,3	5	83,3	20,00	29,81	
FU Month 27	Female	6	6,2	5	83,3	0,00	0,00	2	2,1	1	50,0	0,00	NE	
FU Month 30	Female	4	4,1	3	75,0	0,00	0,00	1	1,1	1	100,0	0,00	NE	

Screening	Male	158	100,0	148	93,7	13,29	23,24	147	100,0	140	95,2	12,14	23,39
Cycle 4 Day 1	Male	129	81,6	119	92,2	14,29	21,51	136	92,5	119	87,5	14,01	22,76
FU Day 28	Male	140	88,6	118	84,3	13,56	24,74	134	91,2	122	91,0	11,48	22,17
FU Month 3	Male	137	86,7	121	88,3	12,40	22,82	134	91,2	119	88,8	12,32	23,72
FU Month 6	Male	123	77,8	116	94,3	10,34	18,86	115	78,2	100	87,0	17,00	25,29
FU Month 9	Male	94	59,5	79	84,0	8,02	17,06	88	59,9	73	83,0	11,42	21,67
FU Month 12	Male	69	43,7	60	87,0	9,44	20,44	70	47,6	59	84,3	10,73	21,83
FU Month 15	Male	57	36,1	50	87,7	9,33	19,10	52	35,4	41	78,8	6,50	15,31
FU Month 18	Male	45	28,5	39	86,7	5,98	15,05	34	23,1	27	79,4	12,35	22,92
FU Month 21	Male	31	19,6	25	80,6	4,00	11,06	23	15,6	17	73,9	9,80	25,72
FU Month 24	Male	20	12,7	15	75,0	4,44	11,73	12	8,2	11	91,7	6,06	13,48
FU Month 27	Male	7	4,4	6	85,7	5,56	13,61	7	4,8	6	85,7	11,11	17,21
FU Month 30	Male	3	1,9	3	100,0	44,44	19,25	0	NE	0	NE	NE	NE
Age													
Screening	<75 years	130	100,0	122	93,8	16,39	25,44	120	100,0	110	91,7	13,64	23,15
Cycle 4 Day 1	<75 years	106	81,5	100	94,3	15,33	24,81	112	93,3	98	87,5	17,35	25,88
FU Day 28	<75 years	119	91,5	105	88,2	13,33	21,98	110	91,7	103	93,6	11,97	22,31
FU Month 3	<75 years	116	89,2	106	91,4	11,32	22,48	109	90,8	99	90,8	13,13	23,24
FU Month 6	<75 years	108	83,1	98	90,7	10,88	20,74	99	82,5	88	88,9	15,53	26,24
FU Month 9	<75 years	85	65,4	73	85,9	11,42	23,05	74	61,7	62	83,8	12,90	24,41
FU Month 12	<75 years	63	48,5	58	92,1	10,34	20,90	60	50,0	53	88,3	12,58	21,90
FU Month 15	<75 years	54	41,5	46	85,2	8,70	16,38	44	36,7	35	79,5	5,71	18,94
FU Month 18	<75 years	43	33,1	39	90,7	7,69	17,87	27	22,5	22	81,5	9,09	23,42
FU Month 21	<75 years	26	20,0	22	84,6	3,03	9,81	17	14,2	13	76,5	10,26	21,01
FU Month 24	<75 years	18	13,8	13	72,2	2,56	9,25	6	5,0	5	83,3	0,00	0,00
FU Month 27	<75 years	7	5,4	5	71,4	6,67	14,91	2	1,7	1	50,0	0,00	NE
FU Month 30	<75 years	4	3,1	3	75,0	22,22	19,25	0	NE	0	NE	NE	NE
Screening	>=75 years	125	100,0	116	92,8	12,93	20,98	122	100,0	117	95,9	18,80	28,50
Cycle 4 Day 1	>=75 years	107	85,6	96	89,7	17,01	27,78	112	91,8	98	87,5	14,97	23,02
FU Day 28	>=75 years	111	88,8	96	86,5	16,32	27,78	115	94,3	98	85,2	15,31	24,95
FU Month 3	>=75 years	109	87,2	95	87,2	14,39	25,57	112	91,8	96	85,7	13,89	22,51
FU Month 6	>=75 years	99	79,2	90	90,9	9,26	18,04	93	76,2	80	86,0	19,17	25,86
FU Month 9	>=75 years	79	63,2	65	82,3	7,69	16,42	75	61,5	57	76,0	13,45	21,69
FU Month 12	>=75 years	62	49,6	50	80,6	9,33	15,12	57	46,7	46	80,7	15,94	24,08
FU Month 15	>=75 years	50	40,0	44	88,0	9,85	19,79	41	33,6	34	82,9	20,59	27,23
FU Month 18	>=75 years	36	28,8	29	80,6	13,79	24,43	33	27,0	27	81,8	24,69	28,63
FU Month 21	>=75 years	26	20,8	18	69,2	5,56	12,78	23	18,9	19	82,6	29,82	36,67
FU Month 24	>=75 years	14	11,2	11	78,6	9,09	15,57	12	9,8	11	91,7	15,15	22,92

FU Month 27	>=75 years	64,8	6100,0	0,00	0,00	75,7	685,7	11,11	17,21				
FU Month 30	>=75 years	32,4	3100,0	22,22	38,49	10,8	1100,0	0,00					NE
Race													
Screening	Other	9100,0	9100,0	7,41	14,70	11100,0	11100,0	18,18	27,34				
Cycle 4 Day 1	Other	777,8	7100,0	9,52	16,27	1090,9	990,0	25,93	32,39				
FU Day 28	Other	888,9	8100,0	12,50	24,80	1090,9	10100,0	20,00	23,31				
FU Month 3	Other	888,9	787,5	4,76	12,60	1090,9	10100,0	30,00	39,91				
FU Month 6	Other	888,9	787,5	0,00	0,00	872,7	8100,0	20,83	24,80				
FU Month 9	Other	444,4	375,0	11,11	19,25	545,5	480,0	25,00	31,91				
FU Month 12	Other	333,3	266,7	0,00	0,00	436,4	4100,0	16,67	33,33				
FU Month 15	Other	222,2	150,0	0,00		NE	436,4	4100,0	0,00	0,00			
FU Month 18	Other	222,2	150,0	0,00		NE	218,2	2100,0	0,00	0,00			
FU Month 21	Other	222,2	150,0	0,00		NE	218,2	2100,0	16,67	23,57			
FU Month 24	Other	222,2	150,0	0,00		NE	19,1	0	NE	NE			NE
FU Month 27	Other	111,1			NE	NE	19,1			NE			NE
FU Month 30	Other	111,1			NE	NE	0	NE			NE		NE
Geographical Region													
Screening	Asia-Pacific	20100,0	20100,0	18,33	25,31	18100,0	18100,0	12,96	23,26				
Cycle 4 Day 1	Asia-Pacific	1575,0	15100,0	15,56	27,79	1688,9	1593,8	17,78	17,21				
FU Day 28	Asia-Pacific	1890,0	18100,0	22,22	30,25	18100,0	1688,9	8,33	14,91				
FU Month 3	Asia-Pacific	1890,0	1688,9	22,92	29,11	18100,0	1688,9	12,50	26,87				
FU Month 6	Asia-Pacific	1680,0	1487,5	19,05	33,88	1794,4	1588,2	13,33	24,56				
FU Month 9	Asia-Pacific	1470,0	1285,7	16,67	30,15	1372,2	969,2	22,22	23,57				
FU Month 12	Asia-Pacific	1050,0	880,0	16,67	35,63	1055,6	10100,0	16,67	23,57				
FU Month 15	Asia-Pacific	840,0	675,0	0,00	0,00	950,0	9100,0	11,11	23,57				

FU Month 18	Asia-Pacific	630,0	466,7	0,00	0,00	633,3	6100,0	5,56	13,61
FU Month 21	Asia-Pacific	525,0	360,0	0,00	0,00	422,2	4100,0	8,33	16,67
FU Month 24	Asia-Pacific	315,0	266,7	0,00	0,00	15,6	0	NE	NE
FU Month 27	Asia-Pacific	15,0		NE	NE	15,6		NE	NE
FU Month 30	Asia-Pacific	15,0		NE	NE	0	NE		NE
Screening	Central and South America	3100,0	3100,0	11,11	19,25	2100,0	2100,0	16,67	23,57
Cycle 4 Day 1	Central and South America	3100,0	3100,0	11,11	19,25	2100,0	2100,0	16,67	23,57
FU Day 28	Central and South America	3100,0	3100,0	11,11	19,25	2100,0	2100,0	16,67	23,57
FU Month 3	Central and South America	3100,0	3100,0	11,11	19,25	2100,0	2100,0	16,67	23,57
FU Month 6	Central and South America	266,7	2100,0	0,00	0,00	2100,0	2100,0	33,33	0,00
FU Month 9	Central and South America	266,7	2100,0	0,00	0,00	150,0	1100,0	0,00	NE
FU Month 12	Central and South America	266,7	2100,0	0,00	0,00	150,0	1100,0	0,00	NE
FU Month 15	Central and South America	133,3	1100,0	0,00	NE	0	NE	0	NE
FU Month 18	Central and South America	133,3	1100,0	0,00	NE	0	NE	0	NE
FU Month 21	Central and South America	133,3	1100,0	0,00	NE	0	NE	0	NE
FU Month 24	Central and South America	133,3	1100,0	0,00	NE	0	NE	0	NE
Screening	North America	12100,0	12100,0	16,67	26,59	13100,0	1292,3	5,56	12,97
Cycle 4 Day 1	North America	975,0	9100,0	14,81	33,79	1292,3	12100,0	5,56	12,97
FU Day 28	North America	1191,7	11100,0	24,24	33,63	13100,0	13100,0	7,69	14,62
FU Month 3	North America	1191,7	11100,0	15,15	31,14	1292,3	12100,0	5,56	19,25
FU Month 6	North America	1191,7	1090,9	10,00	16,10	1184,6	11100,0	12,12	22,47
FU Month 9	North America	866,7	8100,0	8,33	15,43	969,2	9100,0	3,70	11,11
FU Month 12	North America	866,7	787,5	14,29	17,82	753,8	7100,0	4,76	12,60
FU Month 15	North America	650,0	6100,0	11,11	17,21	646,2	583,3	6,67	14,91
FU Month 18	North America	433,3	4100,0	8,33	16,67	323,1	3100,0	22,22	19,25
FU Month 21	North America	325,0	266,7	0,00	0,00	17,7	1100,0	33,33	NE
FU Month 24	North America	325,0	266,7	16,67	23,57	17,7	1100,0	33,33	NE
FU Month 27	North America	216,7	150,0	0,00	NE	17,7	1100,0	33,33	NE
Screening	Other	45100,0	4191,1	23,58	29,10	44100,0	4193,2	23,58	28,13
Cycle 4 Day 1	Other	3782,2	3389,2	21,21	27,41	4090,9	3485,0	20,59	29,60
FU Day 28	Other	3782,2	3389,2	14,14	25,04	3988,6	3794,9	14,41	25,51
FU Month 3	Other	3884,4	3489,5	14,71	24,88	3886,4	3694,7	15,74	27,01
FU Month 6	Other	3577,8	3188,6	11,83	18,36	3375,0	3193,9	15,05	24,10
FU Month 9	Other	2657,8	2284,6	9,09	18,35	2454,5	1979,2	15,79	23,22
FU Month 12	Other	1737,8	1694,1	12,50	20,64	1636,4	1487,5	16,67	21,68
FU Month 15	Other	1226,7	1083,3	13,33	17,21	920,5	888,9	4,17	11,79
FU Month 18	Other	1022,2	990,0	11,11	16,67	715,9	685,7	5,56	13,61
FU Month 21	Other	715,6	685,7	5,56	13,61	49,1	4100,0	16,67	19,25

FU Month 24	Other	6	13,3	4	66,7	0,00	0,00	3	6,8	3	100,0	11,11	19,25
FU Month 27	Other	4	8,9	4	100,0	0,00	0,00	1	2,3	1	100,0	0,00	NE
FU Month 30	Other	2	4,4	2	100,0	0,00	0,00	0	NE	0	NE	NE	NE
Screening	Western Europe	175	100,0	162	92,6	11,93	20,89	165	100,0	154	93,3	15,58	26,45
Cycle 4 Day 1	Western Europe	149	85,1	136	91,3	15,20	25,62	154	93,3	133	86,4	15,79	24,47
FU Day 28	Western Europe	161	92,0	136	84,5	13,24	23,41	153	92,7	133	86,9	14,54	24,74
FU Month 3	Western Europe	155	88,6	137	88,4	10,95	22,55	151	91,5	129	85,4	13,70	21,49
FU Month 6	Western Europe	143	81,7	131	91,6	8,91	17,94	129	78,2	109	84,5	18,65	27,38
FU Month 9	Western Europe	114	65,1	94	82,5	9,22	19,80	102	61,8	81	79,4	12,76	23,90
FU Month 12	Western Europe	88	50,3	75	85,2	8,44	15,59	83	50,3	67	80,7	14,43	24,08
FU Month 15	Western Europe	77	44,0	67	87,0	9,45	19,07	61	37,0	47	77,0	15,60	26,79
FU Month 18	Western Europe	58	33,1	50	86,2	11,33	22,95	44	26,7	34	77,3	21,57	30,58
FU Month 21	Western Europe	36	20,6	28	77,8	4,76	11,88	31	18,8	23	74,2	24,64	36,54
FU Month 24	Western Europe	19	10,9	15	78,9	6,67	13,80	13	7,9	12	92,3	8,33	20,72
FU Month 27	Western Europe	6	3,4	6	100,0	5,56	13,61	6	3,6	5	83,3	6,67	14,91
FU Month 30	Western Europe	4	2,3	4	100,0	33,33	27,22	1	0,6	1	100,0	0,00	NE
FCgamma receptor IIa													
Screening	131HH	58	100,0	52	89,7	16,03	25,13	76	100,0	72	94,7	17,59	28,51
Cycle 4 Day 1	131HH	49	84,5	43	87,8	22,48	32,30	65	85,5	60	92,3	12,78	22,21
FU Day 28	131HH	51	87,9	46	90,2	16,67	25,09	70	92,1	61	87,1	8,20	17,90
FU Month 3	131HH	51	87,9	45	88,2	13,33	25,03	64	84,2	54	84,4	14,20	25,58
FU Month 6	131HH	49	84,5	45	91,8	11,11	21,32	55	72,4	48	87,3	13,89	21,56
FU Month 9	131HH	39	67,2	30	76,9	11,11	23,71	41	53,9	32	78,0	7,29	16,36
FU Month 12	131HH	28	48,3	23	82,1	13,04	16,63	34	44,7	29	85,3	13,79	24,43
FU Month 15	131HH	23	39,7	19	82,6	5,26	12,49	24	31,6	20	83,3	8,33	23,88
FU Month 18	131HH	17	29,3	13	76,5	12,82	21,68	16	21,1	13	81,3	10,26	25,04
FU Month 21	131HH	13	22,4	8	61,5	4,17	11,79	11	14,5	10	90,9	30,00	48,30
FU Month 24	131HH	11	19,0	7	63,6	4,76	12,60	1	1,3	1	100,0	0,00	NE
FU Month 27	131HH	4	6,9	3	75,0	11,11	19,25	1	1,3	1	100,0	0,00	NE
FU Month 30	131HH	3	5,2	2	66,7	16,67	23,57	0	NE	0	NE	NE	NE
Screening	131HR	125	100,0	117	93,6	15,10	23,77	114	100,0	108	94,7	14,51	25,49
Cycle 4 Day 1	131HR	105	84,0	98	93,3	14,29	23,45	110	96,5	98	89,1	16,67	26,33
FU Day 28	131HR	116	92,8	102	87,9	13,07	24,44	105	92,1	95	90,5	16,49	26,58
FU Month 3	131HR	114	91,2	102	89,5	11,76	22,32	107	93,9	95	88,8	12,63	22,38
FU Month 6	131HR	104	83,2	93	89,4	9,32	18,63	95	83,3	83	87,4	17,27	27,23
FU Month 9	131HR	84	67,2	71	84,5	9,86	18,17	76	66,7	60	78,9	13,89	21,52
FU Month 12	131HR	64	51,2	57	89,1	8,77	20,44	57	50,0	48	84,2	13,19	20,33
FU Month 15	131HR	53	42,4	44	83,0	9,09	18,13	44	38,6	35	79,5	13,33	21,69

FU Month 18	131HR		43	34,4	37	86,0	10,81	22,30	32	28,1	26	81,3	21,79	24,84
FU Month 21	131HR		26	20,8	20	76,9	1,67	7,45	21	18,4	16	76,2	18,75	20,97
FU Month 24	131HR		12	9,6	10	83,3	3,33	10,54	12	10,5	10	83,3	10,00	16,10
FU Month 27	131HR			64,8		583,3	0,00	0,00	6	5,3	4	66,7	16,67	19,25
FU Month 30	131HR			32,4		3100,0	11,11	19,25	1	0,9	1	100,0	0,00	NE
Screening	131RR		49	100,0	47	95,9	12,77	21,48	33	100,0	30	90,9	17,78	24,34
Cycle 4 Day 1	131RR		40	81,6	38	95,0	12,28	23,79	31	93,9	25	80,6	20,00	23,57
FU Day 28	131RR		42	85,7	35	83,3	18,10	28,40	32	97,0	29	90,6	14,94	22,86
FU Month 3	131RR		39	79,6	37	94,9	12,61	25,28	32	97,0	29	90,6	12,64	16,46
FU Month 6	131RR		35	71,4	33	94,3	8,08	14,51	27	81,8	23	85,2	24,64	30,51
FU Month 9	131RR		24	49,0	22	91,7	9,09	25,58	19	57,6	17	89,5	13,73	26,51
FU Month 12	131RR		18	36,7	17	94,4	7,84	14,57	17	51,5	15	88,2	13,33	16,90
FU Month 15	131RR		16	32,7	16	100,0	6,25	13,44	11	33,3	9	81,8	29,63	35,14
FU Month 18	131RR		14	28,6	14	100,0	9,52	20,37	8	24,2	7	87,5	23,81	41,79
FU Month 21	131RR		8	16,3	7	87,5	4,76	12,60	5	15,2	4	80,0	16,67	33,33
FU Month 24	131RR		5	10,2	4	80,0	8,33	16,67	3	9,1	3	100,0	22,22	38,49
FU Month 27	131RR			24,1		2100,0	0,00	0,00	1	3,0	1	100,0	0,00	NE
FU Month 30	131RR			12,0		1100,0	66,67	NE	0	NE	0	NE	NE	NE
Screening	Missing		23	100,0	22	95,7	13,64	22,20	19	100,0	17	89,5	19,61	23,74
Cycle 4 Day 1	Missing		19	82,6	17	89,5	19,61	29,01	18	94,7	13	72,2	20,51	21,68
FU Day 28	Missing		21	91,3	18	85,7	12,96	20,26	18	94,7	16	88,9	14,58	24,25
FU Month 3	Missing		21	91,3	17	81,0	17,65	29,15	18	94,7	17	94,4	17,65	26,66
FU Month 6	Missing		19	82,6	17	89,5	15,69	26,66	15	78,9	14	93,3	16,67	25,32
FU Month 9	Missing		17	73,9	15	88,2	6,67	13,80	13	68,4	10	76,9	26,67	37,84
FU Month 12	Missing		15	65,2	11	73,3	12,12	16,82	9	47,4	7	77,8	23,81	41,79
FU Month 15	Missing		12	52,2	11	91,7	21,21	26,97	6	31,6	5	83,3	0,00	0,00
FU Month 18	Missing		5	21,7	4	80,0	0,00	0,00	4	21,1	3	75,0	0,00	0,00
FU Month 21	Missing		5	21,7	5	100,0	13,33	18,26	3	15,8	2	66,7	16,67	23,57
FU Month 24	Missing		4	17,4	3	75,0	11,11	19,25	2	10,5	2	100,0	0,00	0,00
FU Month 27	Missing			14,3		1100,0	0,00	NE	1	5,3	1	100,0	0,00	NE
FCgamma receptor IIIa														
Screening	158FF	103		100,0	98	95,1	15,31	24,01	83	100,0	79	95,2	13,92	23,64
Cycle 4 Day 1	158FF		89	86,4	83	93,3	15,66	26,20	78	94,0	72	92,3	19,44	28,39
FU Day 28	158FF		96	93,2	84	87,5	16,67	28,10	78	94,0	74	94,9	14,86	25,96
FU Month 3	158FF		94	91,3	84	89,4	11,51	24,54	78	94,0	70	89,7	12,38	19,80
FU Month 6	158FF		86	83,5	76	88,4	10,09	21,10	64	77,1	59	92,2	18,08	27,90
FU Month 9	158FF		71	68,9	59	83,1	11,86	24,58	47	56,6	43	91,5	9,30	18,29
FU Month 12	158FF		48	46,6	42	87,5	9,52	19,87	38	45,8	35	92,1	8,57	16,85

FU Month 15	158FF		37	35,9		32	86,5	7,29	16,36		30	36,1		24	80,0	8,33	22,52
FU Month 18	158FF		27	26,2		24	88,9	8,33	17,72		21	25,3		17	81,0	11,76	20,21
FU Month 21	158FF		16	15,5		15	93,8	6,67	13,80		9	10,8		8	88,9	20,83	39,59
FU Month 24	158FF		8	7,8		7	87,5	9,52	16,27		3	3,6		2	66,7	0,00	0,00
FU Month 27	158FF		5	4,9		4	80,0	0,00	0,00		1	1,2		1	100,0	0,00	NE
FU Month 30	158FF		3	2,9		3	100,0	44,44	19,25		0	NE		0	NE	NE	NE
Screening	158FV		119	100,0	109		91,6	14,68	22,88	109		100,0	103		94,5	18,45	29,05
Cycle 4 Day 1	158FV		99	83,2		90	90,9	14,44	24,51	100		91,7		84	84,0	14,29	23,87
FU Day 28	158FV		105	88,2		91	86,7	14,29	23,38	101		92,7		87	86,1	13,41	23,55
FU Month 3	158FV		101	84,9		91	90,1	13,55	22,76		97	89,0		84	86,6	11,90	22,93
FU Month 6	158FV		94	79,0		87	92,6	8,43	15,43		83	76,1		71	85,5	17,84	26,92
FU Month 9	158FV		71	59,7		61	85,9	9,29	17,35		65	59,6		49	75,4	11,56	22,10
FU Month 12	158FV		60	50,4		55	91,7	10,91	18,21		52	47,7		42	80,8	16,67	23,57
FU Month 15	158FV		52	43,7		45	86,5	8,89	16,51		36	33,0		30	83,3	20,00	28,50
FU Month 18	158FV		44	37,0		37	84,1	13,51	24,16		24	22,0		20	83,3	28,33	34,67
FU Month 21	158FV		28	23,5		18	64,3	0,00	0,00		18	16,5		14	77,8	30,95	35,72
FU Month 24	158FV		18	15,1		12	66,7	2,78	9,62		6	5,5		5	83,3	20,00	29,81
FU Month 27	158FV		6	5,0		5	83,3	0,00	0,00		2	1,8		1	50,0	33,33	NE
FU Month 30	158FV		4	3,4		3	75,0	0,00	0,00		0	NE		0	NE	NE	NE
Screening	158VV		16	100,0		15	93,8	6,67	18,69		33	100,0		30	90,9	14,44	24,26
Cycle 4 Day 1	158VV		12	75,0		11	91,7	15,15	22,92		30	90,9		28	93,3	13,10	16,58
FU Day 28	158VV		14	87,5		13	92,9	5,13	12,52		30	90,9		26	86,7	10,26	15,69
FU Month 3	158VV		15	93,8		12	80,0	5,56	12,97		30	90,9		26	86,7	17,95	27,05
FU Month 6	158VV		14	87,5		13	92,9	12,82	21,68		30	90,9		24	80,0	12,50	19,19
FU Month 9	158VV		12	75,0		10	83,3	3,33	10,54		25	75,8		18	72,0	20,37	23,26
FU Month 12	158VV		8	50,0		6	75,0	5,56	13,61		20	60,6		17	85,0	11,76	20,21
FU Month 15	158VV		8	50,0		7	87,5	4,76	12,60		14	42,4		11	78,6	9,09	15,57
FU Month 18	158VV		4	25,0		4	100,0	0,00	0,00		11	33,3		9	81,8	11,11	16,67
FU Month 21	158VV		3	18,8		2	66,7	0,00	0,00		9	27,3		7	77,8	9,52	16,27
FU Month 24	158VV		2	12,5		2	100,0	0,00	0,00		7	21,2		7	100,0	9,52	16,27
FU Month 27	158VV		1	6,3		1	100,0	33,33		NE	5	15,2		4	80,0	8,33	16,67
FU Month 30	158VV		0	NE		0	NE	NE	NE	NE	1	3,0		1	100,0	0,00	NE
Screening	Missing		17	100,0		16	94,1	18,75	27,13		17	100,0		15	88,2	17,78	21,33
Cycle 4 Day 1	Missing		13	76,5		12	92,3	33,33	37,61		16	94,1		12	75,0	16,67	17,41
FU Day 28	Missing		15	88,2		13	86,7	15,38	22,01		16	94,1		14	87,5	14,29	25,20
FU Month 3	Missing		15	88,2		14	93,3	21,43	33,61		16	94,1		15	93,8	20,00	27,60
FU Month 6	Missing		13	76,5		12	92,3	19,44	30,01		15	88,2		14	93,3	19,05	25,20
FU Month 9	Missing		10	58,8		8	80,0	4,17	11,79		12	70,6		9	75,0	25,93	40,06

FU Month 12	Missing		952,9	555,6	6,67	14,91		741,2	571,4	40,00	43,46	
FU Month 15	Missing		741,2	685,7	27,78	32,77		529,4	480,0	0,00	0,00	
FU Month 18	Missing		423,5	375,0	0,00	0,00		423,5	375,0	0,00	0,00	
FU Month 21	Missing		529,4	5100,0	13,33	18,26		423,5	375,0	11,11	19,25	
FU Month 24	Missing		423,5	375,0	11,11	19,25		211,8	2100,0	0,00	0,00	
FU Month 27	Missing		15,9	1100,0	0,00		NE	15,9	1100,0	0,00		NE
Binet Staging at baseline												
Screening	A		59100,0	5796,6	15,79	22,80		57100,0	5291,2	21,15	24,72	
Cycle 4 Day 1	A		5186,4	4894,1	21,53	32,61		5494,7	4990,7	15,65	23,67	
FU Day 28	A		5898,3	5391,4	16,98	26,65		5494,7	5296,3	17,31	26,81	
FU Month 3	A		5796,6	5596,5	11,52	23,32		5393,0	5094,3	13,33	22,34	
FU Month 6	A		5694,9	5089,3	9,33	19,10		4578,9	4191,1	19,51	29,79	
FU Month 9	A		4372,9	3786,0	11,71	21,11		3459,6	3088,2	17,78	28,68	
FU Month 12	A		3661,0	3391,7	13,13	18,52		2442,1	2187,5	23,81	26,13	
FU Month 15	A		3050,8	2790,0	11,11	20,67		1933,3	19100,0	21,05	29,84	
FU Month 18	A		2237,3	1881,8	14,81	28,52		1628,1	16100,0	20,83	31,91	
FU Month 21	A		1728,8	1588,2	2,22	8,61		814,0	787,5	23,81	25,20	
FU Month 24	A		1016,9	880,0	4,17	11,79		58,8	5100,0	20,00	29,81	
FU Month 27	A		58,5	480,0	0,00	0,00		23,5	150,0	0,00		NE
FU Month 30	A		46,8	375,0	22,22	19,25		0	NE	0	NE	NE
Screening												
Screening	B	104	100,0	9894,2	13,27	21,80		85100,0	8397,6	15,26	24,58	
Cycle 4 Day 1	B		8884,6	8394,3	13,65	20,85		7992,9	7392,4	15,53	23,62	
FU Day 28	B		9187,5	7986,8	15,61	22,54		7992,9	7189,9	10,80	22,38	
FU Month 3	B		8884,6	7787,5	13,85	21,87		7992,9	7088,6	12,38	21,36	
FU Month 6	B		8076,9	7796,3	11,26	17,61		7082,4	6390,0	14,81	22,22	
FU Month 9	B		6360,6	5282,5	9,62	20,17		5969,4	4881,4	12,50	20,19	
FU Month 12	B		4745,2	3983,0	11,11	17,66		4654,1	4087,0	15,83	22,63	
FU Month 15	B		3735,6	3491,9	10,78	17,83		3440,0	2882,4	10,71	20,39	
FU Month 18	B		3129,8	2787,1	9,88	20,29		2225,9	1881,8	22,22	28,01	
FU Month 21	B		1817,3	1372,2	5,13	12,52		1720,0	1482,4	16,67	28,50	
FU Month 24	B		1110,6	981,8	3,70	11,11		89,4	787,5	9,52	16,27	
FU Month 27	B		54,8	480,0	8,33	16,67		44,7	4100,0	16,67	19,25	
FU Month 30	B		21,9	2100,0	33,33	47,14		0	NE	0	NE	NE
Screening												
Screening	C		92100,0	8390,2	15,66	25,68	100	100,0	9292,0	14,49	28,09	
Cycle 4 Day 1	C		7480,4	6587,8	15,38	27,05		9191,0	7481,3	17,12	26,02	
FU Day 28	C		8188,0	6985,2	12,08	26,18		9292,0	7884,8	13,68	22,43	
FU Month 3	C		8087,0	6986,3	12,56	26,88		8989,0	7584,3	14,67	24,65	
FU Month 6	C		7177,2	6185,9	9,29	22,05		7777,0	6483,1	18,23	27,17	

FU Month 9	C	58	63,0	49	84,5	8,16	19,87	56	56,0	41	73,2	10,57	21,65
FU Month 12	C	42	45,7	36	85,7	5,56	18,69	47	47,0	38	80,9	7,02	19,23
FU Month 15	C	37	40,2	29	78,4	5,75	15,61	32	32,0	22	68,8	9,09	23,42
FU Month 18	C	26	28,3	23	88,5	7,25	14,06	22	22,0	15	68,2	8,89	19,79
FU Month 21	C	17	18,5	12	70,6	5,56	12,97	15	15,0	11	73,3	27,27	41,68
FU Month 24	C	11	12,0	7	63,6	9,52	16,27	5	5,0	4	80,0	0,00	0,00
FU Month 27	C	3	3,3	3	100,0	0,00	0,00	3	3,0	2	66,7	0,00	0,00
FU Month 30	C	1	1,1	1	100,0	0,00	NE	1	1,0	1	100,0	0,00	NE
Total CIR score at baseline													
Screening	<=6	63	100,0	57	90,5	12,87	22,50	75	100,0	69	92,0	17,39	28,93
Cycle 4 Day 1	<=6	52	82,5	43	82,7	17,83	31,16	72	96,0	61	84,7	18,03	26,23
FU Day 28	<=6	56	88,9	49	87,5	11,56	18,70	72	96,0	59	81,9	15,25	25,01
FU Month 3	<=6	55	87,3	46	83,6	10,87	19,94	69	92,0	56	81,2	11,31	21,35
FU Month 6	<=6	52	82,5	47	90,4	8,51	16,25	60	80,0	52	86,7	14,10	25,86
FU Month 9	<=6	43	68,3	36	83,7	5,56	14,91	47	62,7	38	80,9	14,91	21,50
FU Month 12	<=6	35	55,6	28	80,0	4,76	11,88	34	45,3	27	79,4	17,28	26,75
FU Month 15	<=6	32	50,8	28	87,5	8,33	17,27	25	33,3	17	68,0	21,57	33,21
FU Month 18	<=6	23	36,5	21	91,3	11,11	21,94	19	25,3	14	73,7	21,43	30,96
FU Month 21	<=6	14	22,2	8	57,1	4,17	11,79	14	18,7	10	71,4	26,67	34,43
FU Month 24	<=6	8	12,7	6	75,0	11,11	17,21	7	9,3	5	71,4	20,00	29,81
FU Month 27	<=6	2	3,2	2	100,0	0,00	0,00	4	5,3	2	50,0	16,67	23,57
FU Month 30	<=6	0	NE	0	NE	NE	NE	1	1,3	1	100,0	0,00	NE
Screening >6													
Screening	>6	192	100,0	181	94,3	15,29	23,69	167	100,0	158	94,6	15,82	24,87
Cycle 4 Day 1	>6	161	83,9	153	95,0	15,69	24,80	152	91,0	135	88,8	15,31	23,66
FU Day 28	>6	174	90,6	152	87,4	15,79	26,56	153	91,6	142	92,8	12,91	23,10
FU Month 3	>6	170	88,5	155	91,2	13,33	25,08	152	91,0	139	91,4	14,39	23,42
FU Month 6	>6	155	80,7	141	91,0	10,64	20,44	132	79,0	116	87,9	18,68	26,11
FU Month 9	>6	121	63,0	102	84,3	11,11	21,67	102	61,1	81	79,4	12,35	23,83
FU Month 12	>6	90	46,9	80	88,9	11,67	19,92	83	49,7	72	86,7	12,96	21,34
FU Month 15	>6	72	37,5	62	86,1	9,68	18,49	60	35,9	52	86,7	10,26	20,39
FU Month 18	>6	56	29,2	47	83,9	9,93	20,75	41	24,6	35	85,4	16,19	26,04
FU Month 21	>6	38	19,8	32	84,2	4,17	11,20	26	15,6	22	84,6	19,70	31,97
FU Month 24	>6	24	12,5	18	75,0	3,70	10,78	11	6,6	11	100,0	6,06	13,48
FU Month 27	>6	11	5,7	9	81,8	3,70	11,11	5	3,0	5	100,0	6,67	14,91
FU Month 30	>6	7	3,6	6	85,7	22,22	27,22	0	NE	0	NE	NE	NE
Calculated creatinine clearance cat. 2													
Screening	<70 ml/min	178	100,0	162	91,0	12,55	22,30	176	100,0	165	93,8	17,37	27,20
Cycle 4 Day 1	<70 ml/min	149	83,7	134	89,9	14,43	25,67	164	93,2	142	86,6	16,90	25,34

FU Day 28	<70 ml/min	162	91,0	142	87,7	13,62	24,20	166	94,3	144	86,7	14,12	23,18
FU Month 3	<70 ml/min	157	88,2	139	88,5	11,99	23,40	159	90,3	138	86,8	14,01	22,72
FU Month 6	<70 ml/min	144	80,9	129	89,6	8,01	16,02	139	79,0	120	86,3	17,22	26,63
FU Month 9	<70 ml/min	117	65,7	97	82,9	8,25	18,02	112	63,6	88	78,6	13,64	22,96
FU Month 12	<70 ml/min	92	51,7	78	84,8	9,83	17,91	87	49,4	73	83,9	13,70	22,11
FU Month 15	<70 ml/min	78	43,8	69	88,5	8,21	17,53	60	34,1	48	80,0	16,67	26,63
FU Month 18	<70 ml/min	59	33,1	49	83,1	10,88	21,93	43	24,4	36	83,7	19,44	28,03
FU Month 21	<70 ml/min	38	21,3	27	71,1	4,94	12,07	31	17,6	27	87,1	20,99	30,87
FU Month 24	<70 ml/min	24	13,5	18	75,0	7,41	14,26	13	7,4	11	84,6	12,12	22,47
FU Month 27	<70 ml/min	10	5,6	8	80,0	0,00	0,00	7	4,0	5	71,4	6,67	14,91
FU Month 30	<70 ml/min	5	2,8	4	80,0	16,67	33,33	1	0,6	1	100,0	0,00	NE
Screening	>=70 ml/min	77	100,0	76	98,7	19,30	25,10	66	100,0	62	93,9	13,44	22,95
Cycle 4 Day 1	>=70 ml/min	64	83,1	62	96,9	19,89	27,30	60	90,9	54	90,0	14,20	22,06
FU Day 28	>=70 ml/min	68	88,3	59	86,8	17,51	26,52	59	89,4	57	96,6	12,28	24,91
FU Month 3	>=70 ml/min	68	88,3	62	91,2	14,52	25,34	62	93,9	57	91,9	12,28	23,26
FU Month 6	>=70 ml/min	63	81,8	59	93,7	14,69	24,97	53	80,3	48	90,6	17,36	24,78
FU Month 9	>=70 ml/min	47	61,0	41	87,2	13,01	24,58	37	56,1	31	83,8	11,83	23,65
FU Month 12	>=70 ml/min	33	42,9	30	90,9	10,00	19,87	30	45,5	26	86,7	15,38	25,35
FU Month 15	>=70 ml/min	26	33,8	21	80,8	12,70	19,65	25	37,9	21	84,0	4,76	15,94
FU Month 18	>=70 ml/min	20	26,0	19	95,0	8,77	18,73	17	25,8	13	76,5	12,82	25,60
FU Month 21	>=70 ml/min	14	18,2	13	92,9	2,56	9,25	9	13,6	5	55,6	26,67	43,46
FU Month 24	>=70 ml/min	8	10,4	6	75,0	0,00	0,00	5	7,6	5	100,0	6,67	14,91
FU Month 27	>=70 ml/min	3	3,9	3	100,0	11,11	19,25	2	3,0	2	100,0	16,67	23,57
FU Month 30	>=70 ml/min	2	2,6	2	100,0	33,33	0,00	0	NE	0	NE	NE	NE
Beta2 microglobulin													
Screening	Missing	3	100,0	3	100,0	11,11	19,25	3	100,0	3	100,0	44,44	38,49
Cycle 4 Day 1	Missing	3	100,0	3	100,0	44,44	50,92	3	100,0	2	66,7	33,33	0,00
FU Day 28	Missing	3	100,0	3	100,0	33,33	57,74	3	100,0	2	66,7	16,67	23,57
FU Month 3	Missing	3	100,0	3	100,0	11,11	19,25	3	100,0	2	66,7	50,00	23,57
FU Month 6	Missing	3	100,0	3	100,0	11,11	19,25	3	100,0	2	66,7	33,33	47,14
FU Month 9	Missing	2	66,7	1	50,0	0,00	NE	3	100,0	2	66,7	16,67	23,57
FU Month 12	Missing	1	33,3	1	100,0	0,00	NE	2	66,7	1	50,0	33,33	NE
FU Month 15	Missing	1	33,3	1	100,0	0,00	NE	2	66,7	1	50,0	33,33	NE
FU Month 18	Missing	1	33,3	1	100,0	0,00	NE	2	66,7	1	50,0	33,33	NE
FU Month 21	Missing	1	33,3	1	100,0	0,00	NE	2	66,7	1	50,0	33,33	NE
FU Month 24	Missing	1	33,3	1	100,0	0,00	NE	1	33,3	1	100,0	33,33	NE
Screening	< 3.5 ug/mL	154	100,0	141	91,6	15,13	23,05	140	100,0	131	93,6	18,07	28,12
Cycle 4 Day 1	< 3.5 ug/mL	127	82,5	117	92,1	17,38	28,57	129	92,1	112	86,8	17,26	26,84

FU Day 28	< 3.5 ug/mL	137	89,0	121	88,3	14,88	23,94	132	94,3	120	90,9	16,11	26,28
FU Month 3	< 3.5 ug/mL	134	87,0	121	90,3	12,12	23,17	130	92,9	115	88,5	13,62	22,47
FU Month 6	< 3.5 ug/mL	128	83,1	115	89,8	11,88	21,26	120	85,7	110	91,7	18,18	28,07
FU Month 9	< 3.5 ug/mL	104	67,5	87	83,7	11,49	22,63	98	70,0	81	82,7	13,17	23,38
FU Month 12	< 3.5 ug/mL	78	50,6	69	88,5	11,59	20,47	75	53,6	67	89,3	16,42	24,19
FU Month 15	< 3.5 ug/mL	65	42,2	56	86,2	10,12	18,98	60	42,9	51	85,0	15,03	26,93
FU Month 18	< 3.5 ug/mL	46	29,9	40	87,0	10,83	21,86	43	30,7	35	81,4	19,05	28,34
FU Month 21	< 3.5 ug/mL	30	19,5	21	70,0	1,59	7,27	27	19,3	22	81,5	25,76	36,99
FU Month 24	< 3.5 ug/mL	19	12,3	14	73,7	4,76	12,10	12	8,6	10	83,3	10,00	22,50
FU Month 27	< 3.5 ug/mL	10	6,5	8	80,0	4,17	11,79	7	5,0	5	71,4	6,67	14,91
FU Month 30	< 3.5 ug/mL	5	3,2	4	80,0	25,00	31,91	1	0,7	1	100,0	0,00	NE
Screening	>= 3.5 ug/mL	98	100,0	94	95,9	14,18	24,19	99	100,0	93	93,9	12,90	22,00
Cycle 4 Day 1	>= 3.5 ug/mL	83	84,7	76	91,6	13,16	20,42	92	92,9	82	89,1	14,23	20,97
FU Day 28	>= 3.5 ug/mL	90	91,8	77	85,6	13,85	24,99	90	90,9	79	87,8	9,70	18,61
FU Month 3	>= 3.5 ug/mL	88	89,8	77	87,5	13,85	25,56	88	88,9	78	88,6	12,39	22,86
FU Month 6	>= 3.5 ug/mL	76	77,6	70	92,1	7,14	15,94	69	69,7	56	81,2	14,88	21,00
FU Month 9	>= 3.5 ug/mL	58	59,2	50	86,2	6,67	15,06	48	48,5	36	75,0	12,96	22,93
FU Month 12	>= 3.5 ug/mL	46	46,9	38	82,6	7,02	13,77	40	40,4	31	77,5	8,60	19,18
FU Month 15	>= 3.5 ug/mL	38	38,8	33	86,8	8,08	16,73	23	23,2	17	73,9	5,88	13,10
FU Month 18	>= 3.5 ug/mL	32	32,7	27	84,4	9,88	20,29	15	15,2	13	86,7	12,82	25,60
FU Month 21	>= 3.5 ug/mL	21	21,4	18	85,7	7,41	14,26	11	11,1	9	81,8	11,11	16,67
FU Month 24	>= 3.5 ug/mL	12	12,2	9	75,0	7,41	14,70	5	5,1	5	100,0	6,67	14,91
FU Month 27	>= 3.5 ug/mL	3	3,1	3	100,0	0,00	0,00	2	2,0	2	100,0	16,67	23,57
FU Month 30	>= 3.5 ug/mL	2	2,0	2	100,0	16,67	23,57	0	NE	0	NE	NE	NE
Immunoglobulin VH, cytogenetics 2													
Screening	12	45	100,0	41	91,1	15,45	26,97	44	100,0	43	97,7	14,73	27,51
Cycle 4 Day 1	12	34	75,6	32	94,1	16,67	29,33	38	86,4	33	86,8	17,17	23,75
FU Day 28	12	39	86,7	37	94,9	18,02	27,88	40	90,9	34	85,0	13,73	24,78
FU Month 3	12	38	84,4	35	92,1	9,52	19,08	39	88,6	32	82,1	13,54	18,66
FU Month 6	12	36	80,0	32	88,9	6,25	13,22	34	77,3	28	82,4	21,43	27,54
FU Month 9	12	26	57,8	22	84,6	4,55	11,71	28	63,6	18	64,3	7,41	14,26
FU Month 12	12	22	48,9	18	81,8	7,41	14,26	23	52,3	15	65,2	13,33	16,90
FU Month 15	12	17	37,8	14	82,4	7,14	14,19	17	38,6	12	70,6	8,33	15,08
FU Month 18	12	15	33,3	12	80,0	11,11	16,41	13	29,5	9	69,2	11,11	16,67
FU Month 21	12	10	22,2	8	80,0	8,33	15,43	7	15,9	5	71,4	13,33	18,26
FU Month 24	12	8	17,8	6	75,0	5,56	13,61	6	13,6	6	100,0	0,00	0,00
FU Month 27	12	5	11,1	4	80,0	8,33	16,67	2	4,5	2	100,0	0,00	0,00
FU Month 30	12	4	8,9	3	75,0	22,22	38,49	1	2,3	1	100,0	0,00	NE

Screening	11q-	46	100,0	42	91,3	13,49	23,35	43	100,0	40	93,0	13,33	23,63
Cycle 4 Day 1	11q-	40	87,0	39	97,5	15,38	27,41	41	95,3	35	85,4	6,67	13,53
FU Day 28	11q-	42	91,3	35	83,3	15,24	24,71	39	90,7	36	92,3	7,41	16,16
FU Month 3	11q-	42	91,3	38	90,5	14,91	21,50	38	88,4	36	94,7	7,41	14,05
FU Month 6	11q-	38	82,6	35	92,1	9,52	15,28	32	74,4	27	84,4	14,81	23,27
FU Month 9	11q-	28	60,9	26	92,9	12,82	21,24	25	58,1	20	80,0	11,67	27,09
FU Month 12	11q-	20	43,5	19	95,0	12,28	22,80	18	41,9	17	94,4	11,76	20,21
FU Month 15	11q-	18	39,1	16	88,9	8,33	22,77	14	32,6	10	71,4	13,33	32,20
FU Month 18	11q-	15	32,6	12	80,0	8,33	20,72	8	18,6	7	87,5	28,57	40,50
FU Month 21	11q-	12	26,1	11	91,7	3,03	10,05	4	9,3	2	50,0	50,00	70,71
FU Month 24	11q-	7	15,2	5	71,4	0,00	0,00	1	2,3	1	100,0	0,00	NE
FU Month 27	11q-	3	6,5	3	100,0	0,00	0,00	0	NE	0	NE	NE	NE
FU Month 30	11q-	3	6,5	3	100,0	22,22	19,25	0	NE	0	NE	NE	NE
Screening	13q-	79	100,0	76	96,2	13,60	21,21	75	100,0	69	92,0	15,46	24,64
Cycle 4 Day 1	13q-	67	84,8	60	89,6	13,33	22,30	68	90,7	59	86,8	16,38	21,77
FU Day 28	13q-	72	91,1	65	90,3	13,85	25,61	72	96,0	65	90,3	14,36	22,02
FU Month 3	13q-	73	92,4	66	90,4	11,11	25,71	69	92,0	61	88,4	15,85	27,63
FU Month 6	13q-	67	84,8	62	92,5	8,06	15,61	63	84,0	56	88,9	13,10	23,51
FU Month 9	13q-	56	70,9	49	87,5	8,16	19,87	52	69,3	41	78,8	12,20	20,76
FU Month 12	13q-	44	55,7	38	86,4	7,02	13,77	40	53,3	38	95,0	14,91	22,86
FU Month 15	13q-	38	48,1	34	89,5	5,88	12,90	29	38,7	25	86,2	14,67	25,60
FU Month 18	13q-	28	35,4	24	85,7	5,56	12,69	21	28,0	19	90,5	17,54	25,74
FU Month 21	13q-	16	20,3	13	81,3	5,13	12,52	16	21,3	14	87,5	21,43	30,96
FU Month 24	13q-	7	8,9	6	85,7	11,11	17,21	7	9,3	6	85,7	11,11	17,21
FU Month 27	13q-	2	2,5	1	50,0	0,00	NE	6	8,0	4	66,7	8,33	16,67
Screening	Norm. K.	65	100,0	61	93,8	16,39	22,46	58	100,0	55	94,8	20,61	28,32
Cycle 4 Day 1	Norm. K.	54	83,1	49	90,7	19,05	27,22	55	94,8	50	90,9	21,33	32,13
FU Day 28	Norm. K.	59	90,8	50	84,7	14,67	24,43	53	91,4	49	92,5	15,65	28,95
FU Month 3	Norm. K.	54	83,1	48	88,9	16,67	27,50	54	93,1	48	88,9	13,19	23,56
FU Month 6	Norm. K.	49	75,4	47	95,9	16,31	27,69	45	77,6	39	86,7	17,95	28,46
FU Month 9	Norm. K.	39	60,0	31	79,5	12,90	25,35	30	51,7	27	90,0	12,35	22,92
FU Month 12	Norm. K.	32	49,2	27	84,4	9,88	15,51	24	41,4	20	83,3	11,67	24,84
FU Month 15	Norm. K.	26	40,0	22	84,6	15,15	22,37	20	34,5	18	90,0	16,67	26,20
FU Month 18	Norm. K.	18	27,7	17	94,4	17,65	31,44	15	25,9	12	80,0	19,44	30,01
FU Month 21	Norm. K.	12	18,5	6	50,0	0,00	0,00	11	19,0	9	81,8	25,93	36,43
FU Month 24	Norm. K.	8	12,3	5	62,5	6,67	14,91	4	6,9	3	75,0	33,33	33,33
FU Month 27	Norm. K.	3	4,6	3	100,0	0,00	0,00	1	1,7	1	100,0	33,33	NE
Screening	Other Abn.	20	100,0	18	90,0	14,81	28,52	22	100,0	20	90,9	16,67	27,57

Cycle 4 Day 1	Other Abn.	18	90,0	16	88,9	18,75	29,74	22	100,0	19	86,4	17,54	23,22
FU Day 28	Other Abn.	18	90,0	14	77,8	9,52	15,63	21	95,5	17	81,0	17,65	23,91
FU Month 3	Other Abn.	18	90,0	14	77,8	9,52	20,37	21	95,5	18	85,7	18,52	23,49
FU Month 6	Other Abn.	17	85,0	12	70,6	8,33	20,72	18	81,8	18	100,0	25,93	29,27
FU Month 9	Other Abn.	15	75,0	10	66,7	10,00	16,10	14	63,6	13	92,9	28,21	29,96
FU Month 12	Other Abn.	7	35,0	6	85,7	27,78	38,97	12	54,5	9	75,0	22,22	33,33
FU Month 15	Other Abn.	5	25,0	4	80,0	16,67	19,25	5	22,7	4	80,0	0,00	0,00
FU Month 18	Other Abn.	3	15,0	3	100,0	11,11	19,25	3	13,6	2	66,7	0,00	0,00
FU Month 21	Other Abn.	2	10,0	2	100,0	0,00	0,00	2	9,1	2	100,0	0,00	0,00
FU Month 24	Other Abn.	2	10,0	2	100,0	0,00	0,00	0	NE	0	NE	NE	NE
Time from first diagnosis													
Screening	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
Cycle 4 Day 1	Missing	1	100,0	1	100,0	33,33	NE	0	NE	0	NE	NE	NE
FU Day 28	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 3	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 6	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 9	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 12	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 15	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 18	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
Screening	13 - 24 months	41	100,0	38	92,7	13,16	19,82	31	100,0	31	100,0	9,68	19,61
Cycle 4 Day 1	13 - 24 months	35	85,4	34	97,1	22,55	32,54	30	96,8	27	90,0	8,64	14,89
FU Day 28	13 - 24 months	38	92,7	33	86,8	21,21	27,41	30	96,8	27	90,0	6,17	13,19
FU Month 3	13 - 24 months	36	87,8	33	91,7	16,16	26,51	30	96,8	26	86,7	3,85	10,86
FU Month 6	13 - 24 months	36	87,8	33	91,7	10,10	21,22	30	96,8	24	80,0	6,94	16,97
FU Month 9	13 - 24 months	32	78,0	29	90,6	12,64	24,26	21	67,7	17	81,0	3,92	11,07
FU Month 12	13 - 24 months	21	51,2	18	85,7	7,41	14,26	16	51,6	14	87,5	4,76	12,10
FU Month 15	13 - 24 months	19	46,3	18	94,7	9,26	15,36	16	51,6	10	62,5	3,33	10,54
FU Month 18	13 - 24 months	14	34,1	13	92,9	7,69	19,97	10	32,3	8	80,0	8,33	15,43
FU Month 21	13 - 24 months	11	26,8	9	81,8	0,00	0,00	6	19,4	4	66,7	0,00	0,00
FU Month 24	13 - 24 months	8	19,5	5	62,5	6,67	14,91	3	9,7	2	66,7	0,00	0,00
FU Month 27	13 - 24 months	5	12,2	5	100,0	6,67	14,91	2	6,5	2	100,0	0,00	0,00
FU Month 30	13 - 24 months	3	7,3	3	100,0	11,11	19,25	1	3,2	1	100,0	0,00	NE
Screening	<= 12 months	60	100,0	56	93,3	11,31	19,36	70	100,0	69	98,6	15,46	25,93
Cycle 4 Day 1	<= 12 months	48	80,0	42	87,5	12,70	22,03	60	85,7	55	91,7	15,15	27,83
FU Day 28	<= 12 months	54	90,0	45	83,3	14,07	21,89	62	88,6	56	90,3	15,48	26,18
FU Month 3	<= 12 months	53	88,3	45	84,9	9,63	18,29	59	84,3	55	93,2	18,18	25,51
FU Month 6	<= 12 months	46	76,7	40	87,0	10,00	17,21	47	67,1	43	91,5	22,48	26,94

FU Month 9	<= 12 months	35	58,3	27	77,1	11,11	20,67	37	52,9	31	83,8	13,98	25,49
FU Month 12	<= 12 months	27	45,0	23	85,2	15,94	19,77	29	41,4	27	93,1	13,58	24,91
FU Month 15	<= 12 months	22	36,7	17	77,3	9,80	19,60	17	24,3	16	94,1	4,17	11,39
FU Month 18	<= 12 months	16	26,7	13	81,3	15,38	17,30	13	18,6	12	92,3	13,89	26,43
FU Month 21	<= 12 months	9	15,0	5	55,6	6,67	14,91	7	10,0	6	85,7	27,78	38,97
FU Month 24	<= 12 months	6	10,0	3	50,0	11,11	19,25	2	2,9	1	50,0	0,00	NE
FU Month 27	<= 12 months	1	1,7			NE	NE	1	1,4			NE	NE
FU Month 30	<= 12 months	1	1,7			NE	NE	0	NE			NE	NE
Screening	>24 months	153	100,0	143	93,5	16,55	25,60	141	100,0	127	90,1	18,37	27,45
Cycle 4 Day 1	>24 months	129	84,3	119	92,2	15,41	25,60	134	95,0	114	85,1	18,42	24,33
FU Day 28	>24 months	137	89,5	122	89,1	13,39	25,23	133	94,3	118	88,7	14,41	24,06
FU Month 3	>24 months	135	88,2	122	90,4	13,11	25,19	132	93,6	114	86,4	13,45	22,92
FU Month 6	>24 months	124	81,0	114	91,9	10,23	19,90	115	81,6	101	87,8	17,49	26,91
FU Month 9	>24 months	96	62,7	81	84,4	8,23	18,66	91	64,5	71	78,0	15,02	23,76
FU Month 12	>24 months	76	49,7	66	86,8	8,59	18,77	72	51,1	58	80,6	16,67	23,57
FU Month 15	>24 months	62	40,5	54	87,1	9,26	18,79	52	36,9	43	82,7	18,60	28,45
FU Month 18	>24 months	48	31,4	41	85,4	9,76	22,66	37	26,2	29	78,4	21,84	29,92
FU Month 21	>24 months	32	20,9	26	81,3	5,13	12,26	27	19,1	22	81,5	24,24	32,82
FU Month 24	>24 months	18	11,8	16	88,9	4,17	11,39	13	9,2	13	100,0	12,82	21,68
FU Month 27	>24 months	7	4,6	6	85,7	0,00	0,00	6	4,3	5	83,3	13,33	18,26
FU Month 30	>24 months	3	2,0	3	100,0	33,33	33,33	0	NE	0	NE	NE	NE
High circulating tumor burden													
Screening	Missing	0	NE	0	NE	NE	NE	2	100,0	1	50,0	0,00	NE
Cycle 4 Day 1	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	0,00	NE
FU Day 28	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	0,00	NE
FU Month 3	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	0,00	NE
FU Month 6	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	0,00	NE
FU Month 9	Missing	0	NE			NE	NE	1	50,0			NE	NE
Screening	<25x10**9 cells/L	60	100,0	53	88,3	15,09	24,95	67	100,0	64	95,5	16,15	28,48
Cycle 4 Day 1	<25x10**9 cells/L	50	83,3	45	90,0	19,26	31,37	61	91,0	52	85,2	14,10	21,23
FU Day 28	<25x10**9 cells/L	56	93,3	47	83,9	17,02	29,38	61	91,0	53	86,9	13,84	23,96
FU Month 3	<25x10**9 cells/L	54	90,0	46	85,2	13,77	23,91	59	88,1	50	84,7	16,00	22,58
FU Month 6	<25x10**9 cells/L	50	83,3	44	88,0	12,88	22,98	51	76,1	41	80,4	25,20	27,67
FU Month 9	<25x10**9 cells/L	36	60,0	27	75,0	14,81	26,69	41	61,2	29	70,7	14,94	24,54
FU Month 12	<25x10**9 cells/L	29	48,3	24	82,8	18,06	25,97	34	50,7	25	73,5	9,33	18,05
FU Month 15	<25x10**9 cells/L	24	40,0	20	83,3	11,67	22,36	23	34,3	15	65,2	15,56	30,52
FU Month 18	<25x10**9 cells/L	20	33,3	18	90,0	14,81	20,52	19	28,4	14	73,7	23,81	33,15
FU Month 21	<25x10**9 cells/L	14	23,3	10	71,4	10,00	16,10	10	14,9	8	80,0	12,50	24,80

FU Month 24	<25x10**9 cells/L	8	13,3	5	62,5	6,67	14,91	6	9,0	5	83,3	13,33	29,81
FU Month 27	<25x10**9 cells/L	4	6,7	3	75,0	0,00	0,00	1	1,5	1	100,0	0,00	NE
FU Month 30	<25x10**9 cells/L	4	6,7	3	75,0	22,22	38,49	1	1,5	1	100,0	0,00	NE
Screening	>=25x10**9 cells/L	195	100,0	185	94,9	14,59	22,99	173	100,0	162	93,6	16,46	25,27
Cycle 4 Day 1	>=25x10**9 cells/L	163	83,6	151	92,6	15,23	24,57	162	93,6	143	88,3	17,02	25,60
FU Day 28	>=25x10**9 cells/L	174	89,2	154	88,5	14,07	23,43	163	94,2	147	90,2	13,61	23,65
FU Month 3	>=25x10**9 cells/L	171	87,7	155	90,6	12,47	24,07	161	93,1	144	89,4	12,73	22,98
FU Month 6	>=25x10**9 cells/L	157	80,5	144	91,7	9,26	18,26	140	80,9	126	90,0	14,81	25,14
FU Month 9	>=25x10**9 cells/L	128	65,6	111	86,7	8,41	18,24	107	61,8	90	84,1	12,59	22,67
FU Month 12	>=25x10**9 cells/L	96	49,2	84	87,5	7,54	14,95	83	48,0	74	89,2	15,77	24,19
FU Month 15	>=25x10**9 cells/L	80	41,0	70	87,5	8,57	16,73	62	35,8	54	87,1	12,35	22,71
FU Month 18	>=25x10**9 cells/L	59	30,3	50	84,7	8,67	21,09	41	23,7	35	85,4	15,24	24,71
FU Month 21	>=25x10**9 cells/L	38	19,5	30	78,9	2,22	8,46	30	17,3	24	80,0	25,00	34,40
FU Month 24	>=25x10**9 cells/L	24	12,3	19	79,2	5,26	12,49	12	6,9	11	91,7	9,09	15,57
FU Month 27	>=25x10**9 cells/L	9	4,6	8	88,9	4,17	11,79	8	4,6	6	75,0	11,11	17,21
FU Month 30	>=25x10**9 cells/L	3	1,5	3	100,0	22,22	19,25	0	NE	0	NE	NE	NE

¹ in study: number of subjects in study at respective visit; % based on baseline

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit

² mean: descriptive statistics - absolute values Clinical

cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/t_pro_mean.sas

Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/t_pro_mean_sg_EQC30_IT_label_09MAY2013_21004.xls 04MAR2020

17:18

POPULATION: Labelpopulation, Intent-to-Treat Patients ENDPOINT: EORTC QoL 30

MODEL: Unadjusted Analysis STUDY: CLL11(BO21004), Stage

2

Compliance/Mean

Diarrhoea Scale

		GClb (N=255)						RC1b (N=242)					
		Patients			Statistics			Patients			Statistics		
Name	Level	in study ¹	%	with value ¹	%	Mean ²	SD(mean)	in study ¹	%	with value ¹	%	Mean ²	SD(mean)
All													
Screening	n/a	255	100,0	239	93,7	8,23	18,64	242	100,0	226	93,4	8,85	19,64
Cycle 4 Day 1	n/a	213	83,5	196	92,0	10,20	22,09	224	92,6	196	87,5	10,20	21,30
FU Day 28	n/a	230	90,2	201	87,4	9,29	20,33	225	93,0	200	88,9	9,83	20,27
FU Month 3	n/a	225	88,2	202	89,8	8,91	19,61	221	91,3	195	88,2	8,21	17,94
FU Month 6	n/a	207	81,2	188	90,8	7,98	19,54	192	79,3	167	87,0	10,38	20,34
FU Month 9	n/a	164	64,3	138	84,1	6,52	14,44	149	61,6	119	79,9	8,40	16,93
FU Month 12	n/a	125	49,0	109	87,2	8,26	19,85	117	48,3	98	83,8	7,82	17,12
FU Month 15	n/a	104	40,8	91	87,5	5,49	15,92	85	35,1	69	81,2	7,73	16,31
FU Month 18	n/a		79,31,0	68	86,1	9,31	22,93	60	24,8	49	81,7	8,84	18,97
FU Month 21	n/a		52,20,4	40	76,9	3,33	10,13	40	16,5	31	77,5	10,75	24,93
FU Month 24	n/a		32,12,5	25	78,1	9,33	22,61	18	7,4	16	88,9	8,33	25,82
FU Month 27	n/a		13,5,1	11	84,6	3,03	10,05	9	3,7	7	77,8	9,52	25,20
FU Month 30	n/a		7,2,7	5	71,4	0,00	0,00	1	0,4	1	100,0	0,00	NE
Gender													
Screening	Female	97	100,0	91	93,8	9,89	19,56	95	100,0	86	90,5	11,24	21,46
Cycle 4 Day 1	Female	84	86,6	77	91,7	11,26	22,69	88	92,6	77	87,5	7,36	19,21
FU Day 28	Female	90	92,8	83	92,2	9,24	22,28	91	95,8	79	86,8	10,55	19,64
FU Month 3	Female	88	90,7	81	92,0	9,05	19,01	87	91,6	76	87,4	8,77	18,35
FU Month 6	Female	84	86,6	72	85,7	8,33	19,98	77	81,1	68	88,3	8,82	17,86
FU Month 9	Female	70	72,2	59	84,3	7,34	16,46	61	64,2	46	75,4	6,52	15,10
FU Month 12	Female	56	57,7	49	87,5	8,16	19,87	47	49,5	39	83,0	4,27	11,29
FU Month 15	Female	47	48,5	41	87,2	7,32	19,02	33	34,7	28	84,8	8,33	17,27
FU Month 18	Female	34	35,1	29	85,3	13,79	28,89	26	27,4	22	84,6	12,12	21,93
FU Month 21	Female	21	21,6	15	71,4	8,89	15,26	17	17,9	14	82,4	16,67	31,35
FU Month 24	Female	12	12,4	10	83,3	13,33	32,20	6	6,3	5	83,3	0,00	0,00
FU Month 27	Female	6	6,2	5	83,3	6,67	14,91	2	2,1	1	50,0	0,00	NE
FU Month 30	Female	4	4,1	2	50,0	0,00	0,00	1	1,1	1	100,0	0,00	NE

Screening	Male	158	100,0	148	93,7	7,21	18,05	147	100,0	140	95,2	7,38	18,35
Cycle 4 Day 1	Male	129	81,6	119	92,2	9,52	21,76	136	92,5	119	87,5	12,04	22,44
FU Day 28	Male	140	88,6	118	84,3	9,32	18,94	134	91,2	121	90,3	9,37	20,74
FU Month 3	Male	137	86,7	121	88,3	8,82	20,08	134	91,2	119	88,8	7,84	17,74
FU Month 6	Male	123	77,8	116	94,3	7,76	19,34	115	78,2	99	86,1	11,45	21,91
FU Month 9	Male	94	59,5	79	84,0	5,91	12,81	88	59,9	73	83,0	9,59	17,98
FU Month 12	Male	69	43,7	60	87,0	8,33	20,00	70	47,6	59	84,3	10,17	19,82
FU Month 15	Male	57	36,1	50	87,7	4,00	12,85	52	35,4	41	78,8	7,32	15,83
FU Month 18	Male	45	28,5	39	86,7	5,98	16,88	34	23,1	27	79,4	6,17	16,11
FU Month 21	Male	31	19,6	25	80,6	0,00	0,00	23	15,6	17	73,9	5,88	17,62
FU Month 24	Male	20	12,7	15	75,0	6,67	13,80	12	8,2	11	91,7	12,12	30,81
FU Month 27	Male	7	4,4	6	85,7	0,00	0,00	7	4,8	6	85,7	11,11	27,22
FU Month 30	Male	3	1,9	3	100,0	0,00	0,00	0	NE	0	NE	NE	NE
Age													
Screening	<75 years	130	100,0	121	93,1	6,89	16,62	120	100,0	108	90,0	9,88	21,01
Cycle 4 Day 1	<75 years	106	81,5	100	94,3	8,00	19,02	112	93,3	98	87,5	10,88	23,34
FU Day 28	<75 years	119	91,5	105	88,2	8,57	17,31	110	91,7	102	92,7	8,82	19,86
FU Month 3	<75 years	116	89,2	106	91,4	6,92	15,75	109	90,8	99	90,8	9,76	18,60
FU Month 6	<75 years	108	83,1	98	90,7	4,76	12,66	99	82,5	88	88,9	11,36	21,96
FU Month 9	<75 years	85	65,4	73	85,9	7,76	15,24	74	61,7	62	83,8	9,14	18,28
FU Month 12	<75 years	63	48,5	59	93,7	6,78	17,26	60	50,0	53	88,3	10,06	19,15
FU Month 15	<75 years	54	41,5	47	87,0	6,38	14,97	44	36,7	35	79,5	7,62	16,34
FU Month 18	<75 years	43	33,1	39	90,7	8,55	21,24	27	22,5	22	81,5	9,09	21,04
FU Month 21	<75 years	26	20,0	22	84,6	3,03	9,81	17	14,2	13	76,5	5,13	18,49
FU Month 24	<75 years	18	13,8	14	77,8	9,52	15,63	6	5,0	5	83,3	20,00	44,72
FU Month 27	<75 years	7	5,4	5	71,4	6,67	14,91	2	1,7	1	50,0	0,00	NE
FU Month 30	<75 years	4	3,1	2	50,0	0,00	0,00	0	NE	0	NE	NE	NE
Screening	>=75 years	125	100,0	118	94,4	9,60	20,49	122	100,0	118	96,7	7,91	18,32
Cycle 4 Day 1	>=75 years	107	85,6	96	89,7	12,50	24,78	112	91,8	98	87,5	9,52	19,15
FU Day 28	>=75 years	111	88,8	96	86,5	10,07	23,26	115	94,3	98	85,2	10,88	20,74
FU Month 3	>=75 years	109	87,2	96	88,1	11,11	23,03	112	91,8	96	85,7	6,60	17,18
FU Month 6	>=75 years	99	79,2	90	90,9	11,48	24,56	93	76,2	79	84,9	9,28	18,44
FU Month 9	>=75 years	79	63,2	65	82,3	5,13	13,48	75	61,5	57	76,0	7,60	15,45
FU Month 12	>=75 years	62	49,6	50	80,6	10,00	22,59	57	46,7	45	78,9	5,19	14,13
FU Month 15	>=75 years	50	40,0	44	88,0	4,55	17,00	41	33,6	34	82,9	7,84	16,53
FU Month 18	>=75 years	36	28,8	29	80,6	10,34	25,36	33	27,0	27	81,8	8,64	17,52
FU Month 21	>=75 years	26	20,8	18	69,2	3,70	10,78	23	18,9	18	78,3	14,81	28,52
FU Month 24	>=75 years	14	11,2	11	78,6	9,09	30,15	12	9,8	11	91,7	3,03	10,05

FU Month 27	>=75 years	64,8	6100,0	0,00	0,00	75,7	685,7	11,11	27,22				
FU Month 30	>=75 years	32,4	3100,0	0,00	0,00	10,8	1100,0	0,00					NE
Race													
Screening	Other	9100,0	9100,0	7,41	14,70	11100,0	11100,0	0,00	0,00				
Cycle 4 Day 1	Other	777,8	7100,0	19,05	37,80	1090,9	990,0	3,70	11,11				
FU Day 28	Other	888,9	8100,0	4,17	11,79	1090,9	10100,0	3,33	10,54				
FU Month 3	Other	888,9	787,5	0,00	0,00	1090,9	10100,0	0,00	0,00				
FU Month 6	Other	888,9	787,5	4,76	12,60	872,7	8100,0	0,00	0,00				
FU Month 9	Other	444,4	375,0	22,22	19,25	545,5	480,0	0,00	0,00				
FU Month 12	Other	333,3	266,7	0,00	0,00	436,4	4100,0	0,00	0,00				
FU Month 15	Other	222,2	150,0	0,00		NE	436,4	4100,0	8,33	16,67			
FU Month 18	Other	222,2	150,0	0,00		NE	218,2	2100,0	0,00	0,00			
FU Month 21	Other	222,2	150,0	0,00		NE	218,2	2100,0	0,00	0,00			
FU Month 24	Other	222,2	150,0	0,00		NE	19,1	0	NE	NE	NE	NE	NE
FU Month 27	Other	111,1			NE	NE	19,1			NE	NE	NE	NE
FU Month 30	Other	111,1			NE	NE	0	NE			NE	NE	NE
Screening													
Screening	White	246	100,0	230	93,5	8,26	18,80	231	100,0	215	93,1	9,30	20,03
Cycle 4 Day 1	White	206	83,7	189	91,7	9,88	21,39	214	92,6	187	87,4	10,52	21,64
FU Day 28	White	222	90,2	193	86,9	9,50	20,60	215	93,1	190	88,4	10,18	20,62
FU Month 3	White	217	88,2	195	89,9	9,23	19,89	211	91,3	185	87,7	8,65	18,31
FU Month 6	White	199	80,9	181	91,0	8,10	19,77	184	79,7	159	86,4	10,90	20,71
FU Month 9	White	160	65,0	135	84,4	6,17	14,22	144	62,3	115	79,9	8,70	17,15
FU Month 12	White	122	49,6	107	87,7	8,41	20,01	113	48,9	94	83,2	8,16	17,41
FU Month 15	White	102	41,5	90	88,2	5,56	16,00	81	35,1	65	80,2	7,69	16,42
FU Month 18	White	77	31,3	67	87,0	9,45	23,07	58	25,1	47	81,0	9,22	19,29
FU Month 21	White	50	20,3	39	78,0	3,42	10,25	38	16,5	29	76,3	11,49	25,63
FU Month 24	White	30	12,2	24	80,0	9,72	23,01	17	7,4	16	94,1	8,33	25,82
FU Month 27	White	12	4,9	11	91,7	3,03	10,05	8	3,5	7	87,5	9,52	25,20
FU Month 30	White	6	2,4	5	83,3	0,00	0,00	1	0,4	1	100,0	0,00	NE
Geographical Region													
Screening	Asia-Pacific	20	100,0	20	100,0	5,00	12,21	18	100,0	17	94,4	5,88	13,10
Cycle 4 Day 1	Asia-Pacific	15	75,0	15	100,0	8,89	15,26	16	88,9	15	93,8	11,11	20,57
FU Day 28	Asia-Pacific	18	90,0	18	100,0	12,96	25,92	18	100,0	16	88,9	8,33	14,91
FU Month 3	Asia-Pacific	18	90,0	16	88,9	6,25	13,44	18	100,0	16	88,9	6,25	13,44
FU Month 6	Asia-Pacific	16	80,0	14	87,5	4,76	12,10	17	94,4	15	88,2	8,89	19,79
FU Month 9	Asia-Pacific	14	70,0	12	85,7	5,56	12,97	13	72,2	9	69,2	7,41	14,70
FU Month 12	Asia-Pacific	10	50,0	8	80,0	4,17	11,79	10	55,6	10	100,0	6,67	14,05
FU Month 15	Asia-Pacific	8	40,0	6	75,0	5,56	13,61	9	50,0	9	100,0	7,41	14,70

FU Month 18	Asia-Pacific	630,0	466,7	0,00	0,00	633,3	6100,0	5,56	13,61
FU Month 21	Asia-Pacific	525,0	360,0	0,00	0,00	422,2	4100,0	0,00	0,00
FU Month 24	Asia-Pacific	315,0	266,7	0,00	0,00	15,6	0	NE	NE
FU Month 27	Asia-Pacific	15,0		NE	NE	15,6		NE	NE
FU Month 30	Asia-Pacific	15,0		NE	NE	0	NE	NE	NE
Screening	Central and South America	3100,0	3100,0	0,00	0,00	2100,0	2100,0	0,00	0,00
Cycle 4 Day 1	Central and South America	3100,0	3100,0	0,00	0,00	2100,0	2100,0	0,00	0,00
FU Day 28	Central and South America	3100,0	3100,0	0,00	0,00	2100,0	2100,0	0,00	0,00
FU Month 3	Central and South America	3100,0	3100,0	0,00	0,00	2100,0	2100,0	0,00	0,00
FU Month 6	Central and South America	266,7	2100,0	0,00	0,00	2100,0	2100,0	0,00	0,00
FU Month 9	Central and South America	266,7	2100,0	16,67	23,57	150,0	1100,0	0,00	NE
FU Month 12	Central and South America	266,7	2100,0	0,00	0,00	150,0	1100,0	66,67	NE
FU Month 15	Central and South America	133,3	1100,0	0,00	NE	0	NE	NE	NE
FU Month 18	Central and South America	133,3	1100,0	0,00	NE	0	NE	NE	NE
FU Month 21	Central and South America	133,3	1100,0	0,00	NE	0	NE	NE	NE
FU Month 24	Central and South America	133,3	1100,0	0,00	NE	0	NE	NE	NE
Screening	North America	12100,0	12100,0	19,44	22,29	13100,0	1292,3	13,89	22,29
Cycle 4 Day 1	North America	975,0	9100,0	14,81	24,22	1292,3	12100,0	16,67	26,59
FU Day 28	North America	1191,7	11100,0	9,09	15,57	13100,0	13100,0	17,95	22,01
FU Month 3	North America	1191,7	11100,0	15,15	22,92	1292,3	12100,0	8,33	20,72
FU Month 6	North America	1191,7	1090,9	16,67	32,39	1184,6	11100,0	12,12	22,47
FU Month 9	North America	866,7	8100,0	12,50	17,25	969,2	9100,0	7,41	14,70
FU Month 12	North America	866,7	787,5	14,29	17,82	753,8	7100,0	4,76	12,60
FU Month 15	North America	650,0	6100,0	0,00	0,00	646,2	583,3	20,00	18,26
FU Month 18	North America	433,3	4100,0	0,00	0,00	323,1	3100,0	0,00	0,00
FU Month 21	North America	325,0	266,7	0,00	0,00	17,7	1100,0	33,33	NE
FU Month 24	North America	325,0	266,7	16,67	23,57	17,7	1100,0	0,00	NE
FU Month 27	North America	216,7	150,0	0,00	NE	17,7	1100,0	66,67	NE
Screening	Other	45100,0	4191,1	8,13	20,79	44100,0	4193,2	17,89	26,97
Cycle 4 Day 1	Other	3782,2	3389,2	8,08	22,10	4090,9	3485,0	15,69	27,51
FU Day 28	Other	3782,2	3389,2	7,07	13,84	3988,6	3692,3	12,04	25,39
FU Month 3	Other	3884,4	3489,5	8,82	22,19	3886,4	3694,7	12,96	22,93
FU Month 6	Other	3577,8	3188,6	3,23	10,02	3375,0	3193,9	10,75	18,03
FU Month 9	Other	2657,8	2284,6	1,52	7,11	2454,5	1979,2	15,79	23,22
FU Month 12	Other	1737,8	1694,1	2,08	8,33	1636,4	1487,5	4,76	12,10
FU Month 15	Other	1226,7	1191,7	3,03	10,05	920,5	888,9	4,17	11,79
FU Month 18	Other	1022,2	990,0	7,41	14,70	715,9	685,7	5,56	13,61
FU Month 21	Other	715,6	685,7	11,11	17,21	49,1	4100,0	0,00	0,00

FU Month 24	Other	6	13,3	5	83,3	6,67	14,91	3	6,8	3	100,0	0,00	0,00
FU Month 27	Other	4	8,9	4	100,0	8,33	16,67	1	2,3	1	100,0	0,00	NE
FU Month 30	Other	2	4,4	1	50,0	0,00	NE	0	NE	0	NE	NE	NE
Screening	Western Europe	175	100,0	163	93,1	7,98	18,46	165	100,0	154	93,3	6,49	17,08
Cycle 4 Day 1	Western Europe	149	85,1	136	91,3	10,78	22,91	154	93,3	133	86,4	8,27	18,98
FU Day 28	Western Europe	161	92,0	136	84,5	9,56	21,43	153	92,7	133	86,9	8,77	19,20
FU Month 3	Western Europe	155	88,6	138	89,0	8,94	19,54	151	91,5	129	85,4	7,24	16,65
FU Month 6	Western Europe	143	81,7	131	91,6	8,91	20,60	129	78,2	108	83,7	10,49	21,20
FU Month 9	Western Europe	114	65,1	94	82,5	7,09	15,36	102	61,8	81	79,4	7,00	15,56
FU Month 12	Western Europe	88	50,3	76	86,4	9,65	22,32	83	50,3	66	79,5	8,08	17,60
FU Month 15	Western Europe	77	44,0	67	87,0	6,47	17,64	61	37,0	47	77,0	7,09	16,93
FU Month 18	Western Europe	58	33,1	50	86,2	11,33	25,74	44	26,7	34	77,3	10,78	21,27
FU Month 21	Western Europe	36	20,6	28	77,8	2,38	8,74	31	18,8	22	71,0	13,64	28,47
FU Month 24	Western Europe	19	10,9	15	78,9	11,11	27,22	13	7,9	12	92,3	11,11	29,59
FU Month 27	Western Europe	6	3,4	6	100,0	0,00	0,00	6	3,6	5	83,3	0,00	0,00
FU Month 30	Western Europe	4	2,3	4	100,0	0,00	0,00	1	0,6	1	100,0	0,00	NE
FCgamma receptor IIa													
Screening	131HH	58	100,0	53	91,4	10,06	21,27	76	100,0	72	94,7	9,72	20,51
Cycle 4 Day 1	131HH	49	84,5	43	87,8	13,95	25,44	65	85,5	60	92,3	10,56	21,69
FU Day 28	131HH	51	87,9	46	90,2	12,32	24,70	70	92,1	60	85,7	8,89	19,28
FU Month 3	131HH	51	87,9	46	90,2	12,32	23,68	64	84,2	54	84,4	9,26	19,87
FU Month 6	131HH	49	84,5	45	91,8	10,37	22,27	55	72,4	47	85,5	13,48	23,73
FU Month 9	131HH	39	67,2	30	76,9	6,67	13,56	41	53,9	32	78,0	4,17	11,20
FU Month 12	131HH	28	48,3	24	85,7	11,11	25,38	34	44,7	29	85,3	5,75	15,61
FU Month 15	131HH	23	39,7	19	82,6	12,28	25,36	24	31,6	20	83,3	10,00	15,67
FU Month 18	131HH	17	29,3	13	76,5	12,82	28,99	16	21,1	13	81,3	2,56	9,25
FU Month 21	131HH	13	22,4	8	61,5	0,00	0,00	11	14,5	9	81,8	14,81	33,79
FU Month 24	131HH	11	19,0	7	63,6	19,05	37,80	1	1,3	1	100,0	0,00	NE
FU Month 27	131HH	4	6,9	3	75,0	0,00	0,00	1	1,3	1	100,0	0,00	NE
FU Month 30	131HH	3	5,2	2	66,7	0,00	0,00	0	NE	0	NE	NE	NE
Screening	131HR	125	100,0	117	93,6	5,98	14,26	114	100,0	108	94,7	8,02	16,97
Cycle 4 Day 1	131HR	105	84,0	98	93,3	7,48	18,25	110	96,5	98	89,1	10,20	21,09
FU Day 28	131HR	116	92,8	102	87,9	8,17	19,59	105	92,1	95	90,5	9,12	19,72
FU Month 3	131HR	114	91,2	102	89,5	7,52	16,85	107	93,9	95	88,8	8,07	18,65
FU Month 6	131HR	104	83,2	93	89,4	7,53	19,74	95	83,3	83	87,4	8,43	17,92
FU Month 9	131HR	84	67,2	71	84,5	7,04	14,82	76	66,7	60	78,9	10,00	17,68
FU Month 12	131HR	64	51,2	57	89,1	8,77	20,44	57	50,0	48	84,2	6,94	15,31
FU Month 15	131HR	53	42,4	45	84,9	5,19	14,13	44	38,6	35	79,5	6,67	15,76

FU Month 18	131HR		43	34,4	37	86,0	10,81	24,91	32	28,1	26	81,3	10,26	18,30
FU Month 21	131HR		26	20,8	20	76,9	5,00	12,21	21	18,4	16	76,2	8,33	19,25
FU Month 24	131HR		12	9,6	11	91,7	9,09	15,57	12	10,5	10	83,3	3,33	10,54
FU Month 27	131HR		6	4,8	5	83,3	6,67	14,91	6	5,3	4	66,7	16,67	33,33
FU Month 30	131HR		3	2,4	2	66,7	0,00	0,00	1	0,9	1	100,0	0,00	NE
Screening	131RR		49	100,0	47	95,9	9,22	19,29	33	100,0	29	87,9	8,05	22,98
Cycle 4 Day 1	131RR		40	81,6	38	95,0	11,40	24,84	31	93,9	25	80,6	8,00	22,11
FU Day 28	131RR		42	85,7	35	83,3	5,71	12,75	32	97,0	29	90,6	11,49	24,03
FU Month 3	131RR		39	79,6	37	94,9	5,41	18,45	32	97,0	29	90,6	8,05	14,52
FU Month 6	131RR		35	71,4	33	94,3	5,05	14,72	27	81,8	23	85,2	10,14	21,17
FU Month 9	131RR		24	49,0	22	91,7	6,06	16,70	19	57,6	17	89,5	13,73	23,74
FU Month 12	131RR		18	36,7	17	94,4	3,92	11,07	17	51,5	14	82,4	14,29	25,20
FU Month 15	131RR		16	32,7	16	100,0	2,08	8,33	11	33,3	9	81,8	11,11	23,57
FU Month 18	131RR		14	28,6	14	100,0	4,76	12,10	8	24,2	7	87,5	19,05	32,53
FU Month 21	131RR		8	16,3	7	87,5	4,76	12,60	5	15,2	4	80,0	16,67	33,33
FU Month 24	131RR		5	10,2	4	80,0	0,00	0,00	3	9,1	3	100,0	33,33	57,74
FU Month 27	131RR		2	4,1	2	100,0	0,00	0,00	1	3,0	1	100,0	0,00	NE
FU Month 30	131RR		1	2,0	1	100,0	0,00		0	NE	0	NE	NE	NE
Screening	Missing		23	100,0	22	95,7	13,64	28,47	19	100,0	17	89,5	11,76	26,20
Cycle 4 Day 1	Missing		19	82,6	17	89,5	13,73	26,51	18	94,7	13	72,2	12,82	21,68
FU Day 28	Missing		21	91,3	18	85,7	14,81	23,49	18	94,7	16	88,9	14,58	20,97
FU Month 3	Missing		21	91,3	17	81,0	15,69	23,91	18	94,7	17	94,4	5,88	13,10
FU Month 6	Missing		19	82,6	17	89,5	9,80	19,60	15	78,9	14	93,3	11,90	21,11
FU Month 9	Missing		17	73,9	15	88,2	4,44	11,73	13	68,4	10	76,9	3,33	10,54
FU Month 12	Missing		15	65,2	11	73,3	6,06	13,48	9	47,4	7	77,8	9,52	16,27
FU Month 15	Missing		12	52,2	11	91,7	0,00	0,00	6	31,6	5	83,3	0,00	0,00
FU Month 18	Missing		5	21,7	4	80,0	0,00	0,00	4	21,1	3	75,0	0,00	0,00
FU Month 21	Missing		5	21,7	5	100,0	0,00	0,00	3	15,8	2	66,7	0,00	0,00
FU Month 24	Missing		4	17,4	3	75,0	0,00	0,00	2	10,5	2	100,0	0,00	0,00
FU Month 27	Missing		1	4,3	1	100,0	0,00		1	5,3	1	100,0	0,00	NE
FCgamma receptor IIIa														
Screening	158FF	103		100,0	99	96,1	6,40	14,81	83	100,0	77	92,8	6,93	16,52
Cycle 4 Day 1	158FF		89	86,4	83	93,3	8,84	20,88	78	94,0	72	92,3	9,26	23,22
FU Day 28	158FF		96	93,2	84	87,5	7,94	19,78	78	94,0	74	94,9	8,56	19,94
FU Month 3	158FF		94	91,3	84	89,4	7,14	17,98	78	94,0	70	89,7	8,57	18,55
FU Month 6	158FF		86	83,5	76	88,4	3,95	14,37	64	77,1	59	92,2	12,99	23,17
FU Month 9	158FF		71	68,9	59	83,1	6,78	16,12	47	56,6	43	91,5	7,75	17,57
FU Month 12	158FF		48	46,6	42	87,5	5,56	12,57	38	45,8	34	89,5	5,88	15,29

FU Month 15	158FF		37	35,9		32	86,5	3,13	9,87		30	36,1		24	80,0	6,94	13,83	
FU Month 18	158FF		27	26,2		24	88,9	8,33	22,52		21	25,3		17	81,0	11,76	20,21	
FU Month 21	158FF		16	15,5		15	93,8	4,44	11,73		9	10,8		8	88,9	4,17	11,79	
FU Month 24	158FF		8	7,8		7	87,5	4,76	12,60		3	3,6		2	66,7	0,00	0,00	
FU Month 27	158FF		5	4,9		4	80,0	0,00	0,00		1	1,2		1	100,0	0,00	NE	
FU Month 30	158FF		3	2,9		3	100,0	0,00	0,00		0	NE		0	NE	NE	NE	
Screening	158FV		119	100,0	109		91,6	9,48	19,82	109		100,0	103		94,5	10,03	20,26	
Cycle 4 Day 1	158FV		99	83,2		90	90,9	11,11	22,90	100		91,7		84	84,0	14,29	22,72	
FU Day 28	158FV		105	88,2		91	86,7	9,52	18,78	101		92,7		86	85,1	11,24	21,46	
FU Month 3	158FV		101	84,9		92	91,1	9,42	19,97			97	89,0		84	86,6	9,92	19,89
FU Month 6	158FV		94	79,0		87	92,6	11,11	22,54			83	76,1		71	85,5	8,92	19,48
FU Month 9	158FV		71	59,7		61	85,9	7,65	14,13			65	59,6		49	75,4	8,84	16,35
FU Month 12	158FV		60	50,4		55	91,7	9,09	20,74			52	47,7		42	80,8	9,52	19,87
FU Month 15	158FV		52	43,7		46	88,5	7,97	20,10			36	33,0		30	83,3	11,11	20,22
FU Month 18	158FV		44	37,0		37	84,1	11,71	25,11			24	22,0		20	83,3	8,33	21,29
FU Month 21	158FV		28	23,5		18	64,3	3,70	10,78			18	16,5		13	72,2	20,51	34,80
FU Month 24	158FV		18	15,1		13	72,2	12,82	28,99			6	5,5		5	83,3	26,67	43,46
FU Month 27	158FV		6	5,0		5	83,3	6,67	14,91			2	1,8		1	50,0	0,00	NE
FU Month 30	158FV		4	3,4		2	50,0	0,00	0,00			0	NE		0	NE	NE	NE
Screening	158VV		16	100,0		15	93,8	2,22	8,61			33	100,0		31	93,9	8,60	21,03
Cycle 4 Day 1	158VV		12	75,0		11	91,7	6,06	13,48			30	90,9		28	93,3	3,57	10,50
FU Day 28	158VV		14	87,5		13	92,9	10,26	28,50			30	90,9		26	86,7	6,41	16,38
FU Month 3	158VV		15	93,8		12	80,0	5,56	12,97			30	90,9		26	86,7	2,56	9,06
FU Month 6	158VV		14	87,5		13	92,9	10,26	21,01			30	90,9		23	76,7	10,14	18,63
FU Month 9	158VV		12	75,0		10	83,3	3,33	10,54			25	75,8		18	72,0	12,96	20,26
FU Month 12	158VV		8	50,0		7	87,5	23,81	41,79			20	60,6		17	85,0	9,80	15,66
FU Month 15	158VV		8	50,0		7	87,5	4,76	12,60			14	42,4		11	78,6	3,03	10,05
FU Month 18	158VV		4	25,0		4	100,0	0,00	0,00			11	33,3		9	81,8	7,41	14,70
FU Month 21	158VV		3	18,8		2	66,7	0,00	0,00			9	27,3		7	77,8	4,76	12,60
FU Month 24	158VV		2	12,5		2	100,0	16,67	23,57			7	21,2		7	100,0	0,00	0,00
FU Month 27	158VV		1	6,3		1	100,0	0,00		NE		5	15,2		4	80,0	16,67	33,33
FU Month 30	158VV		0	NE		0	NE	NE	NE	NE		1	3,0		1	100,0	0,00	NE
Screening	Missing		17	100,0		16	94,1	16,67	32,20			17	100,0		15	88,2	11,11	27,22
Cycle 4 Day 1	Missing		13	76,5		12	92,3	16,67	30,15			16	94,1		12	75,0	2,78	9,62
FU Day 28	Missing		15	88,2		13	86,7	15,38	25,88			16	94,1		14	87,5	14,29	21,54
FU Month 3	Missing		15	88,2		14	93,3	19,05	28,39			16	94,1		15	93,8	6,67	13,80
FU Month 6	Missing		13	76,5		12	92,3	8,33	20,72			15	88,2		14	93,3	7,14	14,19
FU Month 9	Missing		10	58,8		8	80,0	0,00	0,00			12	70,6		9	75,0	0,00	0,00

FU Month 12	Missing		952,9	555,6	0,00	0,00	741,2	571,4	0,00	0,00
FU Month 15	Missing		741,2	685,7	0,00	0,00	529,4	480,0	0,00	0,00
FU Month 18	Missing		423,5	375,0	0,00	0,00	423,5	375,0	0,00	0,00
FU Month 21	Missing		529,4	5100,0	0,00	0,00	423,5	375,0	0,00	0,00
FU Month 24	Missing		423,5	375,0	0,00	0,00	211,8	2100,0	0,00	0,00
FU Month 27	Missing		15,9	1100,0	0,00	NE	15,9	1100,0	0,00	NE
Binet Staging at baseline										
Screening	A		59100,0	5898,3	9,77	19,75	57100,0	5393,0	12,58	23,77
Cycle 4 Day 1	A		5186,4	4894,1	10,42	20,81	5494,7	4990,7	6,12	14,71
FU Day 28	A		5898,3	5391,4	6,29	14,70	5494,7	5296,3	11,54	20,75
FU Month 3	A		5796,6	5698,2	8,93	18,52	5393,0	5094,3	8,67	17,57
FU Month 6	A		5694,9	5089,3	7,33	18,18	4578,9	4191,1	10,57	22,90
FU Month 9	A		4372,9	3786,0	9,91	17,33	3459,6	3088,2	4,44	11,52
FU Month 12	A		3661,0	3494,4	8,82	18,91	2442,1	2187,5	4,76	11,95
FU Month 15	A		3050,8	2790,0	6,17	16,11	1933,3	19100,0	3,51	10,51
FU Month 18	A		2237,3	1881,8	3,70	15,71	1628,1	16100,0	8,33	19,25
FU Month 21	A		1728,8	1588,2	0,00	0,00	814,0	787,5	0,00	0,00
FU Month 24	A		1016,9	880,0	0,00	0,00	58,8	5100,0	0,00	0,00
FU Month 27	A		58,5	480,0	0,00	0,00	23,5	150,0	0,00	NE
FU Month 30	A		46,8	375,0	0,00	0,00	0	NE	NE	NE
Screening	B	104	100,0	9995,2	5,72	16,52	85100,0	8296,5	7,72	17,61
Cycle 4 Day 1	B		8884,6	8394,3	8,03	20,55	7992,9	7392,4	10,50	21,43
FU Day 28	B		9187,5	7986,8	10,13	22,24	7992,9	7189,9	10,80	21,66
FU Month 3	B		8884,6	7787,5	7,79	17,01	7992,9	7088,6	8,57	19,40
FU Month 6	B		8076,9	7796,3	5,19	15,36	7082,4	6390,0	12,70	21,11
FU Month 9	B		6360,6	5282,5	4,49	13,25	5969,4	4881,4	9,03	14,97
FU Month 12	B		4745,2	3983,0	9,40	25,30	4654,1	3984,8	5,13	12,18
FU Month 15	B		3735,6	3491,9	6,86	19,73	3440,0	2882,4	9,52	17,82
FU Month 18	B		3129,8	2787,1	13,58	29,61	2225,9	1881,8	9,26	19,15
FU Month 21	B		1817,3	1372,2	5,13	12,52	1720,0	1482,4	16,67	31,35
FU Month 24	B		1110,6	981,8	14,81	33,79	89,4	787,5	4,76	12,60
FU Month 27	B		54,8	480,0	0,00	0,00	44,7	4100,0	16,67	33,33
FU Month 30	B		21,9	2100,0	0,00	0,00	0	NE	NE	NE
Screening	C		92100,0	8289,1	10,16	20,07	100100,0	9191,0	7,69	18,64
Cycle 4 Day 1	C		7480,4	6587,8	12,82	24,79	9191,0	7481,3	12,61	24,49
FU Day 28	C		8188,0	6985,2	10,63	21,76	9292,0	7783,7	7,79	18,65
FU Month 3	C		8087,0	6986,3	10,14	23,08	8989,0	7584,3	7,56	16,96
FU Month 6	C		7177,2	6185,9	12,02	24,37	7777,0	6381,8	7,94	17,67

FU Month 9	C	58	63,0	49	84,5	6,12	13,04	56	56,0	41	73,2	10,57	21,65
FU Month 12	C	42	45,7	36	85,7	6,48	13,38	47	47,0	38	80,9	12,28	22,49
FU Month 15	C	37	40,2	30	81,1	3,33	10,17	32	32,0	22	68,8	9,09	18,35
FU Month 18	C	26	28,3	23	88,5	8,70	18,03	22	22,0	15	68,2	8,89	19,79
FU Month 21	C	17	18,5	12	70,6	5,56	12,97	15	15,0	10	66,7	10,00	22,50
FU Month 24	C	11	12,0	8	72,7	12,50	17,25	5	5,0	4	80,0	25,00	50,00
FU Month 27	C	3	3,3	3	100,0	11,11	19,25	3	3,0	2	66,7	0,00	0,00
FU Month 30	C	1	1,1	0	NE	NE	NE	1	1,0	1	100,0	0,00	NE
Total CIR score at baseline													
Screening	<=6	63	100,0	58	92,1	8,62	19,31	75	100,0	68	90,7	6,37	17,52
Cycle 4 Day 1	<=6	52	82,5	43	82,7	13,95	25,44	72	96,0	61	84,7	13,11	22,18
FU Day 28	<=6	56	88,9	49	87,5	10,88	20,85	72	96,0	58	80,6	8,62	18,27
FU Month 3	<=6	55	87,3	46	83,6	13,04	23,81	69	92,0	56	81,2	7,14	16,47
FU Month 6	<=6	52	82,5	47	90,4	11,35	22,28	60	80,0	52	86,7	8,97	17,61
FU Month 9	<=6	43	68,3	36	83,7	5,56	12,60	47	62,7	38	80,9	9,65	17,17
FU Month 12	<=6	35	55,6	29	82,9	6,90	16,38	34	45,3	27	79,4	1,23	6,42
FU Month 15	<=6	32	50,8	29	90,6	3,45	10,33	25	33,3	17	68,0	1,96	8,08
FU Month 18	<=6	23	36,5	21	91,3	6,35	17,06	19	25,3	14	73,7	7,14	14,19
FU Month 21	<=6	14	22,2	8	57,1	4,17	11,79	14	18,7	10	71,4	6,67	14,05
FU Month 24	<=6	8	12,7	7	87,5	9,52	16,27	7	9,3	5	71,4	6,67	14,91
FU Month 27	<=6	2	3,2	2	100,0	16,67	23,57	4	5,3	2	50,0	0,00	0,00
FU Month 30	<=6	0	NE	0	NE	NE	NE	1	1,3	1	100,0	0,00	NE
Screening >6													
Screening	>6	192	100,0	181	94,3	8,10	18,48	167	100,0	158	94,6	9,92	20,44
Cycle 4 Day 1	>6	161	83,9	153	95,0	9,15	21,02	152	91,0	135	88,8	8,89	20,84
FU Day 28	>6	174	90,6	152	87,4	8,77	20,20	153	91,6	142	92,8	10,33	21,08
FU Month 3	>6	170	88,5	156	91,8	7,69	18,10	152	91,0	139	91,4	8,63	18,54
FU Month 6	>6	155	80,7	141	91,0	6,86	18,48	132	79,0	115	87,1	11,01	21,50
FU Month 9	>6	121	63,0	102	84,3	6,86	15,08	102	61,1	81	79,4	7,82	16,89
FU Month 12	>6	90	46,9	80	88,9	8,75	21,04	83	49,7	71	85,5	10,33	19,18
FU Month 15	>6	72	37,5	62	86,1	6,45	17,94	60	35,9	52	86,7	9,62	17,88
FU Month 18	>6	56	29,2	47	83,9	10,64	25,16	41	24,6	35	85,4	9,52	20,72
FU Month 21	>6	38	19,8	32	84,2	3,13	9,87	26	15,6	21	80,8	12,70	28,82
FU Month 24	>6	24	12,5	18	75,0	9,26	25,06	11	6,6	11	100,0	9,09	30,15
FU Month 27	>6	11	5,7	9	81,8	0,00	0,00	5	3,0	5	100,0	13,33	29,81
FU Month 30	>6	7	3,6	5	71,4	0,00	0,00	0	NE	0	NE	NE	NE
Calculated creatinine clearance cat. 2													
Screening	<70 ml/min	178	100,0	165	92,7	8,89	19,52	176	100,0	165	93,8	7,88	18,73
Cycle 4 Day 1	<70 ml/min	149	83,7	134	89,9	11,44	23,87	164	93,2	142	86,6	9,62	20,08

FU Day 28	<70 ml/min	162	91,0	142	87,7	9,39	19,99	166	94,3	143	86,1	8,62	18,00
FU Month 3	<70 ml/min	157	88,2	140	89,2	10,48	21,56	159	90,3	138	86,8	6,76	16,68
FU Month 6	<70 ml/min	144	80,9	129	89,6	9,04	21,55	139	79,0	119	85,6	10,08	20,15
FU Month 9	<70 ml/min	117	65,7	97	82,9	7,22	15,39	112	63,6	88	78,6	6,06	13,88
FU Month 12	<70 ml/min	92	51,7	79	85,9	8,02	17,88	87	49,4	72	82,8	6,02	15,14
FU Month 15	<70 ml/min	78	43,8	70	89,7	5,71	16,02	60	34,1	48	80,0	5,56	12,55
FU Month 18	<70 ml/min	59	33,1	49	83,1	9,52	21,52	43	24,4	36	83,7	5,56	14,91
FU Month 21	<70 ml/min	38	21,3	27	71,1	3,70	10,68	31	17,6	26	83,9	7,69	21,72
FU Month 24	<70 ml/min	24	13,5	19	79,2	10,53	24,98	13	7,4	11	84,6	0,00	0,00
FU Month 27	<70 ml/min	10	5,6	8	80,0	4,17	11,79	7	4,0	5	71,4	13,33	29,81
FU Month 30	<70 ml/min	5	2,8	3	60,0	0,00	0,00	1	0,6	1	100,0	0,00	NE
Screening	>=70 ml/min	77	100,0	74	96,1	6,76	16,53	66	100,0	61	92,4	11,48	21,85
Cycle 4 Day 1	>=70 ml/min	64	83,1	62	96,9	7,53	17,51	60	90,9	54	90,0	11,73	24,36
FU Day 28	>=70 ml/min	68	88,3	59	86,8	9,04	21,29	59	89,4	57	96,6	12,87	25,00
FU Month 3	>=70 ml/min	68	88,3	62	91,2	5,38	13,76	62	93,9	57	91,9	11,70	20,40
FU Month 6	>=70 ml/min	63	81,8	59	93,7	5,65	14,05	53	80,3	48	90,6	11,11	21,01
FU Month 9	>=70 ml/min	47	61,0	41	87,2	4,88	11,93	37	56,1	31	83,8	15,05	22,51
FU Month 12	>=70 ml/min	33	42,9	30	90,9	8,89	24,66	30	45,5	26	86,7	12,82	21,24
FU Month 15	>=70 ml/min	26	33,8	21	80,8	4,76	15,94	25	37,9	21	84,0	12,70	22,30
FU Month 18	>=70 ml/min	20	26,0	19	95,0	8,77	26,86	17	25,8	13	76,5	17,95	25,88
FU Month 21	>=70 ml/min	14	18,2	13	92,9	2,56	9,25	9	13,6	5	55,6	26,67	36,51
FU Month 24	>=70 ml/min	8	10,4	6	75,0	5,56	13,61	5	7,6	5	100,0	26,67	43,46
FU Month 27	>=70 ml/min	3	3,9	3	100,0	0,00	0,00	2	3,0	2	100,0	0,00	0,00
FU Month 30	>=70 ml/min	2	2,6	2	100,0	0,00	0,00	0	NE	0	NE	NE	NE
Beta2 microglobulin													
Screening	Missing	3	100,0	3	100,0	0,00	0,00	3	100,0	3	100,0	0,00	0,00
Cycle 4 Day 1	Missing	3	100,0	3	100,0	11,11	19,25	3	100,0	2	66,7	0,00	0,00
FU Day 28	Missing	3	100,0	3	100,0	0,00	0,00	3	100,0	2	66,7	0,00	0,00
FU Month 3	Missing	3	100,0	3	100,0	0,00	0,00	3	100,0	2	66,7	0,00	0,00
FU Month 6	Missing	3	100,0	3	100,0	0,00	0,00	3	100,0	2	66,7	0,00	0,00
FU Month 9	Missing	2	66,7	1	50,0	0,00	NE	3	100,0	2	66,7	0,00	0,00
FU Month 12	Missing	1	33,3	1	100,0	0,00	NE	2	66,7	1	50,0	0,00	NE
FU Month 15	Missing	1	33,3	1	100,0	0,00	NE	2	66,7	1	50,0	0,00	NE
FU Month 18	Missing	1	33,3	1	100,0	0,00	NE	2	66,7	1	50,0	33,33	NE
FU Month 21	Missing	1	33,3	1	100,0	0,00	NE	2	66,7	1	50,0	0,00	NE
FU Month 24	Missing	1	33,3	1	100,0	33,33	NE	1	33,3	1	100,0	0,00	NE
Screening	< 3.5 ug/mL	154	100,0	143	92,9	8,86	20,54	140	100,0	130	92,9	10,51	21,98
Cycle 4 Day 1	< 3.5 ug/mL	127	82,5	117	92,1	10,26	23,35	129	92,1	112	86,8	9,52	22,11

FU Day 28	< 3.5 ug/mL	137	89,0	121	88,3	9,09	19,72	132	94,3	119	90,2	10,92	21,75
FU Month 3	< 3.5 ug/mL	134	87,0	122	91,0	9,29	19,76	130	92,9	115	88,5	8,70	18,25
FU Month 6	< 3.5 ug/mL	128	83,1	115	89,8	9,28	20,96	120	85,7	110	91,7	9,70	19,86
FU Month 9	< 3.5 ug/mL	104	67,5	87	83,7	6,90	15,37	98	70,0	81	82,7	10,70	18,88
FU Month 12	< 3.5 ug/mL	78	50,6	69	88,5	5,80	17,11	75	53,6	66	88,0	7,58	17,34
FU Month 15	< 3.5 ug/mL	65	42,2	57	87,7	5,85	17,95	60	42,9	51	85,0	8,50	17,44
FU Month 18	< 3.5 ug/mL	46	29,9	40	87,0	9,17	25,02	43	30,7	35	81,4	11,43	21,30
FU Month 21	< 3.5 ug/mL	30	19,5	21	70,0	3,17	10,03	27	19,3	21	77,8	9,52	21,46
FU Month 24	< 3.5 ug/mL	19	12,3	15	78,9	13,33	27,60	12	8,6	10	83,3	13,33	32,20
FU Month 27	< 3.5 ug/mL	10	6,5	8	80,0	4,17	11,79	7	5,0	5	71,4	0,00	0,00
FU Month 30	< 3.5 ug/mL	5	3,2	3	60,0	0,00	0,00	1	0,7	1	100,0	0,00	NE
Screening	>= 3.5 ug/mL	98	100,0	93	94,9	7,53	15,64	99	100,0	93	93,9	6,81	15,97
Cycle 4 Day 1	>= 3.5 ug/mL	83	84,7	76	91,6	10,09	20,38	92	92,9	82	89,1	11,38	20,43
FU Day 28	>= 3.5 ug/mL	90	91,8	77	85,6	9,96	21,67	90	90,9	79	87,8	8,44	18,08
FU Month 3	>= 3.5 ug/mL	88	89,8	77	87,5	8,66	19,80	88	88,9	78	88,6	7,69	17,76
FU Month 6	>= 3.5 ug/mL	76	77,6	70	92,1	6,19	17,30	69	69,7	55	79,7	12,12	21,62
FU Month 9	>= 3.5 ug/mL	58	59,2	50	86,2	6,00	12,94	48	48,5	36	75,0	3,70	10,62
FU Month 12	>= 3.5 ug/mL	46	46,9	39	84,8	12,82	23,71	40	40,4	31	77,5	8,60	17,14
FU Month 15	>= 3.5 ug/mL	38	38,8	33	86,8	5,05	12,14	23	23,2	17	73,9	5,88	13,10
FU Month 18	>= 3.5 ug/mL	32	32,7	27	84,4	9,88	20,29	15	15,2	13	86,7	0,00	0,00
FU Month 21	>= 3.5 ug/mL	21	21,4	18	85,7	3,70	10,78	11	11,1	9	81,8	14,81	33,79
FU Month 24	>= 3.5 ug/mL	12	12,2	9	75,0	0,00	0,00	5	5,1	5	100,0	0,00	0,00
FU Month 27	>= 3.5 ug/mL	3	3,1	3	100,0	0,00	0,00	2	2,0	2	100,0	33,33	47,14
FU Month 30	>= 3.5 ug/mL	2	2,0	2	100,0	0,00	0,00	0	NE	0	NE	NE	NE
Immunoglobulin VH, cytogenetics 2													
Screening	12	45	100,0	42	93,3	10,32	21,45	44	100,0	42	95,5	7,94	20,57
Cycle 4 Day 1	12	34	75,6	32	94,1	12,50	26,44	38	86,4	33	86,8	11,11	23,07
FU Day 28	12	39	86,7	37	94,9	8,11	21,38	40	90,9	34	85,0	13,73	26,10
FU Month 3	12	38	84,4	36	94,7	9,26	18,87	39	88,6	32	82,1	9,38	19,37
FU Month 6	12	36	80,0	32	88,9	4,17	14,04	34	77,3	28	82,4	15,48	24,82
FU Month 9	12	26	57,8	22	84,6	6,06	13,16	28	63,6	18	64,3	11,11	22,87
FU Month 12	12	22	48,9	18	81,8	1,85	7,86	23	52,3	15	65,2	15,56	24,77
FU Month 15	12	17	37,8	14	82,4	7,14	14,19	17	38,6	12	70,6	5,56	19,25
FU Month 18	12	15	33,3	12	80,0	5,56	12,97	13	29,5	9	69,2	18,52	24,22
FU Month 21	12	10	22,2	8	80,0	0,00	0,00	7	15,9	5	71,4	13,33	29,81
FU Month 24	12	8	17,8	6	75,0	0,00	0,00	6	13,6	6	100,0	16,67	40,82
FU Month 27	12	5	11,1	4	80,0	0,00	0,00	2	4,5	2	100,0	0,00	0,00
FU Month 30	12	4	8,9	3	75,0	0,00	0,00	1	2,3	1	100,0	0,00	NE

Screening	11q-	46	100,0	43	93,5	8,53	20,69	43	100,0	40	93,0	4,17	11,16
Cycle 4 Day 1	11q-	40	87,0	39	97,5	6,84	17,40	41	95,3	35	85,4	9,52	20,72
FU Day 28	11q-	42	91,3	35	83,3	13,33	24,52	39	90,7	36	92,3	6,48	17,49
FU Month 3	11q-	42	91,3	38	90,5	11,40	23,60	38	88,4	36	94,7	7,41	18,01
FU Month 6	11q-	38	82,6	35	92,1	6,67	19,47	32	74,4	27	84,4	6,17	16,11
FU Month 9	11q-	28	60,9	26	92,9	5,13	12,26	25	58,1	20	80,0	3,33	10,26
FU Month 12	11q-	20	43,5	19	95,0	10,53	22,37	18	41,9	17	94,4	11,76	20,21
FU Month 15	11q-	18	39,1	16	88,9	8,33	19,25	14	32,6	10	71,4	10,00	16,10
FU Month 18	11q-	15	32,6	12	80,0	16,67	30,15	8	18,6	7	87,5	0,00	0,00
FU Month 21	11q-	12	26,1	11	91,7	3,03	10,05	4	9,3	2	50,0	0,00	0,00
FU Month 24	11q-	7	15,2	5	71,4	0,00	0,00	1	2,3	1	100,0	0,00	NE
FU Month 27	11q-	3	6,5	3	100,0	0,00	0,00	0	NE	0	NE	NE	NE
FU Month 30	11q-	3	6,5	2	66,7	0,00	0,00	0	NE	0	NE	NE	NE
Screening	13q-	79	100,0	76	96,2	9,65	18,71	75	100,0	70	93,3	12,38	22,82
Cycle 4 Day 1	13q-	67	84,8	60	89,6	13,33	25,45	68	90,7	59	86,8	8,47	17,06
FU Day 28	13q-	72	91,1	65	90,3	7,69	16,42	72	96,0	64	88,9	10,42	18,66
FU Month 3	13q-	73	92,4	66	90,4	10,61	22,00	69	92,0	61	88,4	7,65	16,55
FU Month 6	13q-	67	84,8	62	92,5	9,68	21,24	63	84,0	56	88,9	6,55	14,80
FU Month 9	13q-	56	70,9	49	87,5	6,80	15,18	52	69,3	41	78,8	7,32	15,83
FU Month 12	13q-	44	55,7	39	88,6	9,40	17,01	40	53,3	38	95,0	4,39	13,80
FU Month 15	13q-	38	48,1	34	89,5	3,92	10,90	29	38,7	25	86,2	5,33	12,47
FU Month 18	13q-	28	35,4	24	85,7	9,72	23,01	21	28,0	19	90,5	8,77	18,73
FU Month 21	13q-	16	20,3	13	81,3	5,13	12,52	16	21,3	14	87,5	4,76	12,10
FU Month 24	13q-	7	8,9	6	85,7	11,11	17,21	7	9,3	6	85,7	0,00	0,00
FU Month 27	13q-	2	2,5	1	50,0	0,00	NE	6	8,0	4	66,7	16,67	33,33
Screening	Norm. K.	65	100,0	60	92,3	4,44	12,97	58	100,0	54	93,1	9,26	19,87
Cycle 4 Day 1	Norm. K.	54	83,1	49	90,7	7,48	17,03	55	94,8	50	90,9	13,33	26,08
FU Day 28	Norm. K.	59	90,8	50	84,7	11,33	22,95	53	91,4	49	92,5	10,88	21,93
FU Month 3	Norm. K.	54	83,1	48	88,9	6,25	14,84	54	93,1	48	88,9	9,72	20,58
FU Month 6	Norm. K.	49	75,4	47	95,9	9,93	21,89	45	77,6	39	86,7	17,09	26,35
FU Month 9	Norm. K.	39	60,0	31	79,5	7,53	16,58	30	51,7	27	90,0	13,58	19,08
FU Month 12	Norm. K.	32	49,2	27	84,4	11,11	27,74	24	41,4	20	83,3	6,67	13,68
FU Month 15	Norm. K.	26	40,0	23	88,5	5,80	21,68	20	34,5	18	90,0	12,96	20,26
FU Month 18	Norm. K.	18	27,7	17	94,4	7,84	25,08	15	25,9	12	80,0	8,33	20,72
FU Month 21	Norm. K.	12	18,5	6	50,0	5,56	13,61	11	19,0	8	72,7	25,00	38,83
FU Month 24	Norm. K.	8	12,3	6	75,0	27,78	38,97	4	6,9	3	75,0	11,11	19,25
FU Month 27	Norm. K.	3	4,6	3	100,0	11,11	19,25	1	1,7	1	100,0	0,00	NE
Screening	Other Abn.	20	100,0	18	90,0	9,26	22,30	22	100,0	20	90,9	6,67	17,44

Cycle 4 Day 1	Other Abn.	18	90,0	16	88,9	10,42	23,47	22	100,0	19	86,4	7,02	17,84
FU Day 28	Other Abn.	18	90,0	14	77,8	2,38	8,91	21	95,5	17	81,0	3,92	11,07
FU Month 3	Other Abn.	18	90,0	14	77,8	2,38	8,91	21	95,5	18	85,7	5,56	12,78
FU Month 6	Other Abn.	17	85,0	12	70,6	5,56	12,97	18	81,8	17	94,4	5,88	13,10
FU Month 9	Other Abn.	15	75,0	10	66,7	6,67	14,05	14	63,6	13	92,9	5,13	12,52
FU Month 12	Other Abn.	7	35,0	6	85,7	0,00	0,00	12	54,5	8	66,7	4,17	11,79
FU Month 15	Other Abn.	5	25,0	4	80,0	0,00	0,00	5	22,7	4	80,0	0,00	0,00
FU Month 18	Other Abn.	3	15,0	3	100,0	0,00	0,00	3	13,6	2	66,7	0,00	0,00
FU Month 21	Other Abn.	2	10,0	2	100,0	0,00	0,00	2	9,1	2	100,0	0,00	0,00
FU Month 24	Other Abn.	2	10,0	2	100,0	0,00	0,00	0	NE	0	NE	NE	NE
Time from first diagnosis													
Screening	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
Cycle 4 Day 1	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Day 28	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 3	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 6	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 9	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 12	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 15	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 18	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
Screening	13 - 24 months	41	100,0	39	95,1	7,69	17,87	31	100,0	31	100,0	4,30	14,25
Cycle 4 Day 1	13 - 24 months	35	85,4	34	97,1	7,84	20,20	30	96,8	27	90,0	7,41	14,12
FU Day 28	13 - 24 months	38	92,7	33	86,8	12,12	27,41	30	96,8	27	90,0	4,94	15,20
FU Month 3	13 - 24 months	36	87,8	34	94,4	11,76	19,90	30	96,8	26	86,7	5,13	15,47
FU Month 6	13 - 24 months	36	87,8	33	91,7	8,08	18,69	30	96,8	25	83,3	5,33	12,47
FU Month 9	13 - 24 months	32	78,0	29	90,6	4,60	11,70	21	67,7	17	81,0	5,88	13,10
FU Month 12	13 - 24 months	21	51,2	18	85,7	1,85	7,86	16	51,6	14	87,5	9,52	15,63
FU Month 15	13 - 24 months	19	46,3	18	94,7	0,00	0,00	16	51,6	10	62,5	3,33	10,54
FU Month 18	13 - 24 months	14	34,1	13	92,9	0,00	0,00	10	32,3	8	80,0	0,00	0,00
FU Month 21	13 - 24 months	11	26,8	9	81,8	0,00	0,00	6	19,4	4	66,7	0,00	0,00
FU Month 24	13 - 24 months	8	19,5	5	62,5	0,00	0,00	3	9,7	2	66,7	0,00	0,00
FU Month 27	13 - 24 months	5	12,2	5	100,0	0,00	0,00	2	6,5	2	100,0	0,00	0,00
FU Month 30	13 - 24 months	3	7,3	2	66,7	0,00	0,00	1	3,2	1	100,0	0,00	NE
Screening	<= 12 months	60	100,0	57	95,0	6,43	15,98	70	100,0	68	97,1	7,35	15,07
Cycle 4 Day 1	<= 12 months	48	80,0	42	87,5	9,52	23,61	60	85,7	55	91,7	7,88	18,10
FU Day 28	<= 12 months	54	90,0	45	83,3	9,63	20,87	62	88,6	56	90,3	10,12	20,02
FU Month 3	<= 12 months	53	88,3	45	84,9	7,41	17,25	59	84,3	55	93,2	7,27	17,79
FU Month 6	<= 12 months	46	76,7	40	87,0	10,83	21,86	47	67,1	42	89,4	11,11	24,04

FU Month 9	<= 12 months	35	58,3	27	77,1	9,88	18,06	37	52,9	31	83,8	4,30	11,36
FU Month 12	<= 12 months	27	45,0	23	85,2	8,70	22,96	29	41,4	27	93,1	6,17	18,58
FU Month 15	<= 12 months	22	36,7	17	77,3	5,88	13,10	17	24,3	16	94,1	8,33	19,25
FU Month 18	<= 12 months	16	26,7	13	81,3	2,56	9,25	13	18,6	12	92,3	11,11	21,71
FU Month 21	<= 12 months	9	15,0	5	55,6	0,00	0,00	7	10,0	6	85,7	27,78	44,31
FU Month 24	<= 12 months	6	10,0	3	50,0	0,00	0,00	2	2,9	1	50,0	0,00	NE
FU Month 27	<= 12 months	1	1,7			NE	NE	1	1,4			NE	NE
FU Month 30	<= 12 months	1	1,7			NE	NE	0	NE			NE	NE
Screening	>24 months	153	100,0	142	92,8	9,15	19,91	141	100,0	127	90,1	10,76	22,57
Cycle 4 Day 1	>24 months	129	84,3	119	92,2	11,20	22,25	134	95,0	114	85,1	11,99	23,93
FU Day 28	>24 months	137	89,5	122	89,1	8,47	17,96	133	94,3	117	88,0	10,83	21,37
FU Month 3	>24 months	135	88,2	122	90,4	8,74	20,46	132	93,6	114	86,4	9,36	18,56
FU Month 6	>24 months	124	81,0	114	91,9	7,02	19,06	115	81,6	100	87,0	11,33	20,22
FU Month 9	>24 months	96	62,7	81	84,4	6,17	14,05	91	64,5	71	78,0	10,80	19,33
FU Month 12	>24 months	76	49,7	67	88,2	9,95	20,93	72	51,1	57	79,2	8,19	17,00
FU Month 15	>24 months	62	40,5	55	88,7	7,27	18,91	52	36,9	43	82,7	8,53	16,42
FU Month 18	>24 months	48	31,4	41	85,4	14,63	27,94	37	26,2	29	78,4	10,34	20,13
FU Month 21	>24 months	32	20,9	26	81,3	5,13	12,26	27	19,1	21	77,8	7,94	17,97
FU Month 24	>24 months	18	11,8	17	94,4	13,73	26,51	13	9,2	13	100,0	10,26	28,50
FU Month 27	>24 months	7	4,6	6	85,7	5,56	13,61	6	4,3	5	83,3	13,33	29,81
FU Month 30	>24 months	3	2,0	3	100,0	0,00	0,00	0	NE	0	NE	NE	NE
High circulating tumor burden													
Screening	Missing	0	NE	0	NE	NE	NE	2	100,0	1	50,0	0,00	NE
Cycle 4 Day 1	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	0,00	NE
FU Day 28	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	66,67	NE
FU Month 3	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	0,00	NE
FU Month 6	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	33,33	NE
FU Month 9	Missing	0	NE			NE	NE	1	50,0			NE	NE
Screening	<25x10**9 cells/L	60	100,0	54	90,0	9,26	20,90	67	100,0	64	95,5	8,85	18,06
Cycle 4 Day 1	<25x10**9 cells/L	50	83,3	45	90,0	5,93	17,82	61	91,0	52	85,2	11,54	20,75
FU Day 28	<25x10**9 cells/L	56	93,3	47	83,9	9,93	25,93	61	91,0	52	85,2	8,33	18,52
FU Month 3	<25x10**9 cells/L	54	90,0	47	87,0	7,80	17,32	59	88,1	50	84,7	9,33	20,25
FU Month 6	<25x10**9 cells/L	50	83,3	44	88,0	9,85	23,38	51	76,1	41	80,4	13,01	23,43
FU Month 9	<25x10**9 cells/L	36	60,0	27	75,0	11,11	18,49	41	61,2	29	70,7	5,75	15,61
FU Month 12	<25x10**9 cells/L	29	48,3	24	82,8	8,33	17,72	34	50,7	25	73,5	14,67	23,73
FU Month 15	<25x10**9 cells/L	24	40,0	20	83,3	8,33	18,34	23	34,3	15	65,2	8,89	19,79
FU Month 18	<25x10**9 cells/L	20	33,3	18	90,0	11,11	22,87	19	28,4	14	73,7	7,14	19,30
FU Month 21	<25x10**9 cells/L	14	23,3	10	71,4	6,67	14,05	10	14,9	8	80,0	8,33	23,57

FU Month 24	<25x10**9 cells/L	8	13,3	5	62,5	0,00	0,00	6	9,0	5	83,3	0,00	0,00
FU Month 27	<25x10**9 cells/L	4	6,7	3	75,0	0,00	0,00	1	1,5	1	100,0	0,00	NE
FU Month 30	<25x10**9 cells/L	4	6,7	2	50,0	0,00	0,00	1	1,5	1	100,0	0,00	NE
Screening	>=25x10**9 cells/L	195	100,0	185	94,9	7,93	17,98	173	100,0	161	93,1	8,90	20,33
Cycle 4 Day 1	>=25x10**9 cells/L	163	83,6	151	92,6	11,48	23,11	162	93,6	143	88,3	9,79	21,61
FU Day 28	>=25x10**9 cells/L	174	89,2	154	88,5	9,09	18,39	163	94,2	147	90,2	9,98	20,43
FU Month 3	>=25x10**9 cells/L	171	87,7	155	90,6	9,25	20,29	161	93,1	144	89,4	7,87	17,18
FU Month 6	>=25x10**9 cells/L	157	80,5	144	91,7	7,41	18,26	140	80,9	125	89,3	9,33	19,21
FU Month 9	>=25x10**9 cells/L	128	65,6	111	86,7	5,41	13,14	107	61,8	90	84,1	9,26	17,33
FU Month 12	>=25x10**9 cells/L	96	49,2	85	88,5	8,24	20,51	83	48,0	73	88,0	5,48	13,62
FU Month 15	>=25x10**9 cells/L	80	41,0	71	88,8	4,69	15,22	62	35,8	54	87,1	7,41	15,41
FU Month 18	>=25x10**9 cells/L	59	30,3	50	84,7	8,67	23,14	41	23,7	35	85,4	9,52	19,08
FU Month 21	>=25x10**9 cells/L	38	19,5	30	78,9	2,22	8,46	30	17,3	23	76,7	11,59	25,84
FU Month 24	>=25x10**9 cells/L	24	12,3	20	83,3	11,67	24,84	12	6,9	11	91,7	12,12	30,81
FU Month 27	>=25x10**9 cells/L	9	4,6	8	88,9	4,17	11,79	8	4,6	6	75,0	11,11	27,22
FU Month 30	>=25x10**9 cells/L	3	1,5	3	100,0	0,00	0,00	0	NE	0	NE	NE	NE

¹ in study: number of subjects in study at respective visit; % based on baseline

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit

² mean: descriptive statistics - absolute values Clinical

cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/t_pro_mean.sas

Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/t_pro_mean_sg_EQC30_IT_label_09MAY2013_21004.xls 04MAR2020

17:18

POPULATION: Labelpopulation, Intent-to-Treat Patients ENDPOINT: EORTC QoL 30

MODEL: Unadjusted Analysis STUDY: CLL11(BO21004), Stage

2

Compliance/Mean

Dyspnoea Scale

		GClb (N=255)						RC1b (N=242)					
		Patients			Statistics			Patients			Statistics		
Name	Level	in study ¹	%	with value ¹	%	Mean ²	SD(mean)	in study ¹	%	with value ¹	%	Mean ²	SD(mean)
All													
Screening	n/a	255	100,0	239	93,7	26,36	29,75	242	100,0	227	93,8	28,49	28,93
Cycle 4 Day 1	n/a	213	83,5	195	91,5	15,04	22,99	224	92,6	197	87,9	22,67	27,85
FU Day 28	n/a	230	90,2	199	86,5	18,09	25,00	225	93,0	200	88,9	21,83	27,88
FU Month 3	n/a	225	88,2	202	89,8	18,98	26,76	221	91,3	195	88,2	22,05	26,40
FU Month 6	n/a	207	81,2	185	89,4	18,20	23,81	192	79,3	169	88,0	23,87	28,68
FU Month 9	n/a	164	64,3	137	83,5	15,82	22,54	149	61,6	120	80,5	26,39	29,91
FU Month 12	n/a	125	49,0	109	87,2	17,74	23,38	117	48,3	98	83,8	25,85	28,93
FU Month 15	n/a	104	40,8	89	85,6	17,60	23,62	85	35,1	69	81,2	25,60	28,67
FU Month 18	n/a		79	31,0	69	87,3	21,26	60	24,8	48	80,0	27,78	30,23
FU Month 21	n/a		52	20,4	40	76,9	18,33	40	16,5	32	80,0	26,04	32,50
FU Month 24	n/a		32	12,5	24	75,0	15,28	24	10,0	16	66,7	5,56	13,61
FU Month 27	n/a		13	5,1	11	84,6	18,18	9	3,7	6	66,7	5,56	13,61
FU Month 30	n/a		7	2,7	6	85,7	5,56	1	0,4	1	100,0	0,00	NE
Gender													
Screening	Female	97	100,0	90	92,8	25,93	29,04	95	100,0	86	90,5	34,50	30,87
Cycle 4 Day 1	Female	84	86,6	76	90,5	16,23	23,41	88	92,6	78	88,6	26,07	28,75
FU Day 28	Female	90	92,8	82	91,1	15,04	19,70	91	95,8	79	86,8	27,43	31,01
FU Month 3	Female	88	90,7	81	92,0	18,11	26,38	87	91,6	77	88,5	25,11	28,18
FU Month 6	Female	84	86,6	72	85,7	18,52	21,59	77	81,1	67	87,0	24,38	28,77
FU Month 9	Female	70	72,2	59	84,3	17,51	25,03	61	64,2	46	75,4	26,81	30,32
FU Month 12	Female	56	57,7	49	87,5	18,37	23,63	47	49,5	40	85,1	25,83	24,45
FU Month 15	Female	47	48,5	39	83,0	23,08	26,66	33	34,7	28	84,8	27,38	28,77
FU Month 18	Female	34	35,1	29	85,3	28,74	31,78	26	27,4	21	80,8	31,75	28,82
FU Month 21	Female	21	21,6	15	71,4	20,00	24,56	17	17,9	15	88,2	31,11	32,04
FU Month 24	Female	12	12,4	9	75,0	18,52	24,22	6	6,3	4	66,7	41,67	31,91
FU Month 27	Female	6	6,2	5	83,3	26,67	27,89	2	2,1	1	50,0	0,00	NE
FU Month 30	Female	4	4,1	3	75,0	11,11	19,25	1	1,1	1	100,0	0,00	NE

Screening	Male	158	100,0	149	94,3	26,62	30,26	147	100,0	141	95,9	24,82	27,14
Cycle 4 Day 1	Male	129	81,6	119	92,2	14,29	22,79	136	92,5	119	87,5	20,45	27,14
FU Day 28	Male	140	88,6	117	83,6	20,23	28,01	134	91,2	121	90,3	18,18	25,09
FU Month 3	Male	137	86,7	121	88,3	19,56	27,10	134	91,2	118	88,1	20,06	25,09
FU Month 6	Male	123	77,8	113	91,9	17,99	25,21	115	78,2	102	88,7	23,53	28,76
FU Month 9	Male	94	59,5	78	83,0	14,53	20,52	88	59,9	74	84,1	26,13	29,85
FU Month 12	Male	69	43,7	60	87,0	17,22	23,36	70	47,6	58	82,9	25,86	31,86
FU Month 15	Male	57	36,1	50	87,7	13,33	20,20	52	35,4	41	78,8	24,39	28,89
FU Month 18	Male	45	28,5	40	88,9	15,83	23,86	34	23,1	27	79,4	24,69	31,48
FU Month 21	Male	31	19,6	25	80,6	17,33	29,06	23	15,6	17	73,9	21,57	33,21
FU Month 24	Male	20	12,7	15	75,0	13,33	24,56	12	8,2	12	100,0	16,67	33,33
FU Month 27	Male	7	4,4	6	85,7	11,11	27,22	7	4,8	5	71,4	6,67	14,91
FU Month 30	Male	3	1,9	3	100,0	0,00	0,00	0	NE	0	NE	NE	NE
Age													
Screening	<75 years	130	100,0	122	93,8	25,14	28,85	120	100,0	109	90,8	28,44	28,63
Cycle 4 Day 1	<75 years	106	81,5	100	94,3	15,67	21,95	112	93,3	97	86,6	21,31	25,99
FU Day 28	<75 years	119	91,5	104	87,4	17,63	24,12	110	91,7	101	91,8	20,13	27,11
FU Month 3	<75 years	116	89,2	105	90,5	19,05	25,68	109	90,8	99	90,8	20,88	25,90
FU Month 6	<75 years	108	83,1	97	89,8	16,15	22,62	99	82,5	87	87,9	24,14	27,70
FU Month 9	<75 years	85	65,4	73	85,9	15,07	21,55	74	61,7	62	83,8	27,42	28,00
FU Month 12	<75 years	63	48,5	59	93,7	18,08	22,59	60	50,0	53	88,3	22,01	28,45
FU Month 15	<75 years	54	41,5	47	87,0	17,02	21,84	44	36,7	35	79,5	23,81	26,29
FU Month 18	<75 years	43	33,1	38	88,4	22,81	31,10	27	22,5	22	81,5	24,24	29,42
FU Month 21	<75 years	26	20,0	22	84,6	18,18	24,62	17	14,2	13	76,5	20,51	28,99
FU Month 24	<75 years	18	13,8	14	77,8	16,67	28,50	6	5,0	4	66,7	33,33	47,14
FU Month 27	<75 years	7	5,4	5	71,4	20,00	29,81	2	1,7	1	50,0	0,00	NE
FU Month 30	<75 years	4	3,1	3	75,0	0,00	0,00	0	NE	0	NE	NE	NE
Screening	>=75 years	125	100,0	117	93,6	27,64	30,73	122	100,0	118	96,7	28,53	29,32
Cycle 4 Day 1	>=75 years	107	85,6	95	88,8	14,39	24,14	112	91,8	100	89,3	24,00	29,62
FU Day 28	>=75 years	111	88,8	95	85,6	18,60	26,05	115	94,3	99	86,1	23,57	28,67
FU Month 3	>=75 years	109	87,2	97	89,0	18,90	28,02	112	91,8	96	85,7	23,26	26,98
FU Month 6	>=75 years	99	79,2	88	88,9	20,45	24,98	93	76,2	82	88,2	23,58	29,85
FU Month 9	>=75 years	79	63,2	64	81,0	16,67	23,76	75	61,5	58	77,3	25,29	32,03
FU Month 12	>=75 years	62	49,6	50	80,6	17,33	24,50	57	46,7	45	78,9	30,37	29,15
FU Month 15	>=75 years	50	40,0	42	84,0	18,25	25,72	41	33,6	34	82,9	27,45	31,22
FU Month 18	>=75 years	36	28,8	31	86,1	19,35	24,00	33	27,0	26	78,8	30,77	31,16
FU Month 21	>=75 years	26	20,8	18	69,2	18,52	30,73	23	18,9	19	82,6	29,82	34,95
FU Month 24	>=75 years	14	11,2	10	71,4	13,33	17,21	12	9,8	12	100,0	19,44	30,01

FU Month 27	>=75 years	64,8	6100,0	16,67	27,89	75,7	571,4	6,67	14,91				
FU Month 30	>=75 years	32,4	3100,0	11,11	19,25	10,8	1100,0	0,00					NE
Race													
Screening	Other	9100,0	9100,0	29,63	35,14	11100,0	11100,0	18,18	17,41				
Cycle 4 Day 1	Other	777,8	7100,0	23,81	25,20	1090,9	990,0	11,11	16,67				
FU Day 28	Other	888,9	8100,0	29,17	45,21	1090,9	10100,0	10,00	22,50				
FU Month 3	Other	888,9	787,5	42,86	41,79	1090,9	10100,0	20,00	28,11				
FU Month 6	Other	888,9	787,5	33,33	38,49	872,7	8100,0	12,50	17,25				
FU Month 9	Other	444,4	375,0	0,00	0,00	545,5	480,0	16,67	19,25				
FU Month 12	Other	333,3	266,7	0,00	0,00	436,4	4100,0	8,33	16,67				
FU Month 15	Other	222,2	150,0	33,33		436,4	4100,0	8,33	16,67				
FU Month 18	Other	222,2	150,0	0,00		218,2	2100,0	0,00	0,00				
FU Month 21	Other	222,2	150,0	0,00		218,2	2100,0	0,00	0,00				
FU Month 24	Other	222,2	150,0	0,00		19,1	0	NE	NE				NE
FU Month 27	Other	111,1			NE	19,1			NE				NE
FU Month 30	Other	111,1			NE	0	NE		NE				NE
Geographical Region													
Screening	Asia-Pacific	20100,0	20100,0	26,67	33,51	18100,0	18100,0	33,33	25,57				
Cycle 4 Day 1	Asia-Pacific	1575,0	15100,0	8,89	15,26	1688,9	1593,8	24,44	26,63				
FU Day 28	Asia-Pacific	1890,0	18100,0	12,96	25,92	18100,0	1688,9	16,67	24,34				
FU Month 3	Asia-Pacific	1890,0	1688,9	6,25	13,44	18100,0	1688,9	25,00	25,82				
FU Month 6	Asia-Pacific	1680,0	1487,5	21,43	24,83	1794,4	1482,4	26,19	23,31				
FU Month 9	Asia-Pacific	1470,0	1285,7	8,33	15,08	1372,2	1076,9	23,33	22,50				
FU Month 12	Asia-Pacific	1050,0	880,0	20,83	24,80	1055,6	10100,0	23,33	35,31				
FU Month 15	Asia-Pacific	840,0	675,0	11,11	17,21	950,0	9100,0	22,22	23,57				

FU Month 18	Asia-Pacific	630,0	466,7	8,33	16,67	633,3	6100,0	16,67	27,89
FU Month 21	Asia-Pacific	525,0	360,0	0,00	0,00	422,2	4100,0	8,33	16,67
FU Month 24	Asia-Pacific	315,0	266,7	0,00	0,00	15,6	0	NE	NE
FU Month 27	Asia-Pacific	15,0		NE	NE	15,6		NE	NE
FU Month 30	Asia-Pacific	15,0		NE	NE	0	NE	NE	NE
Screening	Central and South America	3100,0	3100,0	11,11	19,25	2100,0	2100,0	16,67	23,57
Cycle 4 Day 1	Central and South America	3100,0	3100,0	11,11	19,25	2100,0	2100,0	16,67	23,57
FU Day 28	Central and South America	3100,0	3100,0	11,11	19,25	2100,0	2100,0	16,67	23,57
FU Month 3	Central and South America	3100,0	3100,0	11,11	19,25	2100,0	2100,0	0,00	0,00
FU Month 6	Central and South America	266,7	2100,0	0,00	0,00	2100,0	2100,0	16,67	23,57
FU Month 9	Central and South America	266,7	2100,0	0,00	0,00	150,0	1100,0	0,00	NE
FU Month 12	Central and South America	266,7	2100,0	0,00	0,00	150,0	1100,0	33,33	NE
FU Month 15	Central and South America	133,3	1100,0	0,00	NE	0	NE	NE	NE
FU Month 18	Central and South America	133,3	1100,0	0,00	NE	0	NE	NE	NE
FU Month 21	Central and South America	133,3	1100,0	0,00	NE	0	NE	NE	NE
FU Month 24	Central and South America	133,3	1100,0	0,00	NE	0	NE	NE	NE
Screening	North America	12100,0	12100,0	27,78	31,25	13100,0	1292,3	16,67	22,47
Cycle 4 Day 1	North America	975,0	9100,0	11,11	23,57	1292,3	12100,0	11,11	21,71
FU Day 28	North America	1191,7	11100,0	24,24	33,63	13100,0	13100,0	17,95	32,25
FU Month 3	North America	1191,7	11100,0	33,33	36,51	1292,3	12100,0	13,89	22,29
FU Month 6	North America	1191,7	1090,9	26,67	30,63	1184,6	11100,0	27,27	35,96
FU Month 9	North America	866,7	8100,0	16,67	17,82	969,2	9100,0	25,93	36,43
FU Month 12	North America	866,7	787,5	9,52	16,27	753,8	7100,0	23,81	16,27
FU Month 15	North America	650,0	6100,0	22,22	17,21	646,2	583,3	33,33	33,33
FU Month 18	North America	433,3	4100,0	25,00	16,67	323,1	3100,0	33,33	33,33
FU Month 21	North America	325,0	266,7	33,33	0,00	17,7	1100,0	0,00	NE
FU Month 24	North America	325,0	266,7	16,67	23,57	17,7	1100,0	0,00	NE
FU Month 27	North America	216,7	150,0	0,00	NE	17,7	1100,0	0,00	NE
Screening	Other	45100,0	4191,1	30,89	28,27	44100,0	4090,9	36,67	28,04
Cycle 4 Day 1	Other	3782,2	3389,2	22,22	23,07	4090,9	3587,5	24,76	28,40
FU Day 28	Other	3782,2	3389,2	22,22	23,07	3988,6	3794,9	26,13	30,57
FU Month 3	Other	3884,4	3489,5	27,45	28,98	3886,4	3694,7	26,85	26,21
FU Month 6	Other	3577,8	3188,6	20,43	23,85	3375,0	3193,9	27,96	31,15
FU Month 9	Other	2657,8	2284,6	16,67	17,06	2454,5	1979,2	33,33	31,43
FU Month 12	Other	1737,8	1694,1	22,92	23,47	1636,4	1487,5	26,19	29,75
FU Month 15	Other	1226,7	1191,7	9,09	15,57	920,5	888,9	8,33	15,43
FU Month 18	Other	1022,2	990,0	7,41	14,70	715,9	685,7	16,67	18,26
FU Month 21	Other	715,6	685,7	16,67	18,26	49,1	4100,0	16,67	19,25

FU Month 24	Other	6	13,3	4	66,7	8,33	16,67	3	6,8	2	66,7	16,67	23,57
FU Month 27	Other	4	8,9	4	100,0	16,67	19,25	1	2,3	1	100,0	0,00	NE
FU Month 30	Other	2	4,4	2	100,0	0,00	0,00	0	NE	0	NE	NE	NE
Screening	Western Europe	175	100,0	163	93,1	25,36	29,82	165	100,0	155	93,9	26,88	29,69
Cycle 4 Day 1	Western Europe	149	85,1	135	90,6	14,32	23,58	154	93,3	133	86,4	23,06	28,48
FU Day 28	Western Europe	161	92,0	134	83,2	17,41	24,77	153	92,7	132	86,3	21,72	27,32
FU Month 3	Western Europe	155	88,6	138	89,0	17,39	25,86	151	91,5	129	85,4	21,45	26,94
FU Month 6	Western Europe	143	81,7	128	89,5	16,93	23,29	129	78,2	111	86,0	22,22	28,19
FU Month 9	Western Europe	114	65,1	93	81,6	16,85	24,88	102	61,8	81	79,4	25,51	29,94
FU Month 12	Western Europe	88	50,3	76	86,4	17,54	24,02	83	50,3	66	79,5	26,26	29,53
FU Month 15	Western Europe	77	44,0	65	84,4	19,49	25,61	61	37,0	47	77,0	28,37	30,28
FU Month 18	Western Europe	58	33,1	51	87,9	24,84	30,44	44	26,7	33	75,0	31,31	32,21
FU Month 21	Western Europe	36	20,6	28	77,8	20,24	30,55	31	18,8	23	74,2	31,88	35,50
FU Month 24	Western Europe	19	10,9	15	78,9	20,00	27,60	13	7,9	13	100,0	25,64	36,40
FU Month 27	Western Europe	6	3,4	6	100,0	22,22	34,43	6	3,6	4	66,7	8,33	16,67
FU Month 30	Western Europe	4	2,3	4	100,0	8,33	16,67	1	0,6	1	100,0	0,00	NE
FCgamma receptor IIa													
Screening	131HH	58	100,0	53	91,4	29,56	30,42	76	100,0	72	94,7	24,07	25,77
Cycle 4 Day 1	131HH	49	84,5	43	87,8	14,73	24,45	65	85,5	59	90,8	18,08	22,59
FU Day 28	131HH	51	87,9	46	90,2	15,22	22,99	70	92,1	62	88,6	19,35	24,55
FU Month 3	131HH	51	87,9	47	92,2	21,99	26,26	64	84,2	54	84,4	13,58	21,00
FU Month 6	131HH	49	84,5	45	91,8	20,00	22,92	55	72,4	48	87,3	19,44	24,63
FU Month 9	131HH	39	67,2	30	76,9	21,11	23,95	41	53,9	33	80,5	22,22	27,22
FU Month 12	131HH	28	48,3	24	85,7	22,22	25,38	34	44,7	29	85,3	22,99	26,88
FU Month 15	131HH	23	39,7	18	78,3	18,52	23,49	24	31,6	20	83,3	18,33	25,31
FU Month 18	131HH	17	29,3	13	76,5	35,90	34,59	16	21,1	12	75,0	25,00	28,87
FU Month 21	131HH	13	22,4	8	61,5	29,17	33,03	11	14,5	10	90,9	40,00	30,63
FU Month 24	131HH	11	19,0	7	63,6	33,33	27,22	1	1,3	1	100,0	0,00	NE
FU Month 27	131HH	4	6,9	3	75,0	44,44	38,49	1	1,3	1	100,0	0,00	NE
FU Month 30	131HH	3	5,2	2	66,7	16,67	23,57	0	NE	0	NE	NE	NE
Screening	131HR	125	100,0	117	93,6	27,35	29,56	114	100,0	109	95,6	30,58	30,81
Cycle 4 Day 1	131HR	105	84,0	97	92,4	17,87	25,03	110	96,5	99	90,0	26,26	30,96
FU Day 28	131HR	116	92,8	100	86,2	21,67	27,37	105	92,1	93	88,6	23,30	31,39
FU Month 3	131HR	114	91,2	102	89,5	17,97	26,40	107	93,9	94	87,9	24,11	28,67
FU Month 6	131HR	104	83,2	92	88,5	17,39	23,94	95	83,3	84	88,4	26,59	30,95
FU Month 9	131HR	84	67,2	71	84,5	15,96	21,72	76	66,7	60	78,9	27,78	31,99
FU Month 12	131HR	64	51,2	57	89,1	20,47	25,00	57	50,0	47	82,5	26,24	31,03
FU Month 15	131HR	53	42,4	44	83,0	19,70	25,23	44	38,6	35	79,5	24,76	28,40

FU Month 18	131HR		43	34,4	38	88,4	17,54	24,18	32	28,1	26	81,3	24,36	29,15		
FU Month 21	131HR		26	20,8	20	76,9	13,33	19,94	21	18,4	16	76,2	14,58	27,13		
FU Month 24	131HR		12	9,6	11	91,7	6,06	13,48	12	10,5	11	91,7	18,18	27,34		
FU Month 27	131HR		6	4,8	5	83,3	6,67	14,91	6	5,3	3	50,0	11,11	19,25		
FU Month 30	131HR		3	2,4	3	100,0	0,00	0,00	1	0,9	1	100,0	0,00	NE		
Screening	131RR		49	100,0	48	98,0	20,83	28,04	33	100,0	30	90,9	31,11	30,24		
Cycle 4 Day 1	131RR		40	81,6	38	95,0	10,53	15,70	31	93,9	25	80,6	26,67	28,87		
FU Day 28	131RR		42	85,7	35	83,3	17,14	23,39	32	97,0	29	90,6	25,29	24,65		
FU Month 3	131RR		39	79,6	36	92,3	22,22	30,86	32	97,0	30	93,8	28,89	25,87		
FU Month 6	131RR		35	71,4	32	91,4	23,96	27,09	27	81,8	23	85,2	26,09	30,08		
FU Month 9	131RR		24	49,0	22	91,7	13,64	26,55	19	57,6	17	89,5	27,45	26,97		
FU Month 12	131RR		18	36,7	17	94,4	11,76	16,42	17	51,5	15	88,2	31,11	29,46		
FU Month 15	131RR		16	32,7	16	100,0	16,67	21,08	11	33,3	9	81,8	37,04	30,93		
FU Month 18	131RR		14	28,6	14	100,0	21,43	30,96	8	24,2	7	87,5	42,86	37,09		
FU Month 21	131RR		8	16,3	7	87,5	19,05	26,23	5	15,2	4	80,0	50,00	43,03		
FU Month 24	131RR		5	10,2	3	60,0	22,22	38,49	3	9,1	3	100,0	55,56	50,92		
FU Month 27	131RR		2	4,1	2	100,0	16,67	23,57	1	3,0	1	100,0	0,00	NE		
FU Month 30	131RR		1	2,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE		
Screening	Missing		23	100,0	21	91,3	25,40	33,17	19	100,0	16	84,2	29,17	26,87		
Cycle 4 Day 1	Missing		19	82,6	17	89,5	9,80	19,60	18	94,7	14	77,8	9,52	15,63		
FU Day 28	Missing		21	91,3	18	85,7	7,41	14,26	18	94,7	16	88,9	16,67	24,34		
FU Month 3	Missing		21	91,3	17	81,0	9,80	19,60	18	94,7	17	94,4	25,49	25,08		
FU Month 6	Missing		19	82,6	16	84,2	6,25	13,44	15	78,9	14	93,3	19,05	25,20		
FU Month 9	Missing		17	73,9	14	82,4	7,14	14,19	13	68,4	10	76,9	30,00	33,15		
FU Month 12	Missing		15	65,2	11	73,3	3,03	10,05	9	47,4	7	77,8	23,81	25,20		
FU Month 15	Missing		12	52,2	11	91,7	9,09	21,56	6	31,6	5	83,3	40,00	36,51		
FU Month 18	Missing		5	21,7	4	80,0	8,33	16,67	4	21,1	3	75,0	33,33	33,33		
FU Month 21	Missing		5	21,7	5	100,0	20,00	44,72	3	15,8	2	66,7	0,00	0,00		
FU Month 24	Missing		4	17,4	3	75,0	0,00	0,00	2	10,5	1	50,0	0,00	NE		
FU Month 27	Missing		1	4,3	1	100,0	0,00	NE	1	5,3	1	100,0	0,00	NE		
FCgamma receptor IIIa																
Screening	158FF	103		100,0	100		97,1	21,00	30,21		83	100,0	79	95,2	27,00	28,78
Cycle 4 Day 1	158FF		89	86,4	83	93,3	14,06	22,76		78	94,0	72	92,3	25,00	28,94	
FU Day 28	158FF		96	93,2	84	87,5	16,27	22,85		78	94,0	73	93,6	22,83	28,26	
FU Month 3	158FF		94	91,3	84	89,4	19,84	28,40		78	94,0	71	91,0	20,19	26,11	
FU Month 6	158FF		86	83,5	73	84,9	15,53	23,62		64	77,1	59	92,2	23,73	30,98	
FU Month 9	158FF		71	68,9	59	83,1	13,56	22,42		47	56,6	43	91,5	25,58	30,72	
FU Month 12	158FF		48	46,6	42	87,5	14,29	21,01		38	45,8	34	89,5	22,55	25,58	

FU Month 15	158FF	37	35,9	32	86,5	18,75	23,85	30	36,1	24	80,0	19,44	23,91
FU Month 18	158FF	27	26,2	25	92,6	21,33	25,24	21	25,3	16	76,2	27,08	27,81
FU Month 21	158FF	16	15,5	15	93,8	22,22	27,22	9	10,8	8	88,9	16,67	25,20
FU Month 24	158FF	8	7,8	7	87,5	9,52	16,27	3	3,6	3	100,0	11,11	19,25
FU Month 27	158FF	5	4,9	4	80,0	0,00	0,00	1	1,2	1	100,0	0,00	NE
FU Month 30	158FF	3	2,9	3	100,0	0,00	0,00	0	NE	0	NE	NE	NE
Screening	158FV	119	100,0	109	91,6	27,83	26,65	109	100,0	103	94,5	28,80	29,17
Cycle 4 Day 1	158FV	99	83,2	89	89,9	15,36	23,06	100	91,7	86	86,0	20,93	26,59
FU Day 28	158FV	105	88,2	89	84,8	18,73	25,60	101	92,7	86	85,1	21,32	28,43
FU Month 3	158FV	101	84,9	92	91,1	17,03	24,46	97	89,0	83	85,6	24,10	27,70
FU Month 6	158FV	94	79,0	87	92,6	19,16	22,52	83	76,1	71	85,5	25,35	28,43
FU Month 9	158FV	71	59,7	61	85,9	16,94	21,62	65	59,6	49	75,4	28,57	30,43
FU Month 12	158FV	60	50,4	55	91,7	20,61	24,42	52	47,7	42	80,8	26,98	32,29
FU Month 15	158FV	52	43,7	44	84,6	17,42	23,28	36	33,0	30	83,3	35,56	31,48
FU Month 18	158FV	44	37,0	38	86,4	21,05	30,43	24	22,0	20	83,3	31,67	36,63
FU Month 21	158FV	28	23,5	18	64,3	11,11	19,80	18	16,5	14	77,8	40,48	39,61
FU Month 24	158FV	18	15,1	12	66,7	13,89	22,29	6	5,5	5	83,3	60,00	36,51
FU Month 27	158FV	6	5,0	5	83,3	26,67	27,89	2	1,8	1	50,0	33,33	NE
FU Month 30	158FV	4	3,4	3	75,0	11,11	19,25	0	NE	0	NE	NE	NE
Screening	158VV	16	100,0	15	93,8	42,22	34,43	33	100,0	31	93,9	32,26	29,17
Cycle 4 Day 1	158VV	12	75,0	11	91,7	15,15	22,92	30	90,9	27	90,0	28,40	31,63
FU Day 28	158VV	14	87,5	13	92,9	33,33	36,00	30	90,9	27	90,0	22,22	27,74
FU Month 3	158VV	15	93,8	12	80,0	33,33	31,78	30	90,9	26	86,7	20,51	23,24
FU Month 6	158VV	14	87,5	13	92,9	35,90	31,80	30	90,9	25	83,3	22,67	26,74
FU Month 9	158VV	12	75,0	10	83,3	33,33	27,22	25	75,8	19	76,0	24,56	31,12
FU Month 12	158VV	8	50,0	7	87,5	28,57	29,99	20	60,6	17	85,0	29,41	28,58
FU Month 15	158VV	8	50,0	7	87,5	23,81	31,71	14	42,4	11	78,6	12,12	22,47
FU Month 18	158VV	4	25,0	3	75,0	44,44	19,25	11	33,3	9	81,8	22,22	23,57
FU Month 21	158VV	3	18,8	2	66,7	50,00	23,57	9	27,3	7	77,8	14,29	17,82
FU Month 24	158VV	2	12,5	2	100,0	66,67	0,00	7	21,2	7	100,0	4,76	12,60
FU Month 27	158VV	1	6,3	1	100,0	66,67	NE	5	15,2	3	60,0	0,00	0,00
FU Month 30	158VV	0	NE	0	NE	NE	NE	1	3,0	1	100,0	0,00	NE
Screening	Missing	17	100,0	15	88,2	35,56	36,66	17	100,0	14	82,4	26,19	29,75
Cycle 4 Day 1	Missing	13	76,5	12	92,3	19,44	26,43	16	94,1	12	75,0	8,33	15,08
FU Day 28	Missing	15	88,2	13	86,7	10,26	16,01	16	94,1	14	87,5	19,05	25,20
FU Month 3	Missing	15	88,2	14	93,3	14,29	25,20	16	94,1	15	93,8	22,22	27,22
FU Month 6	Missing	13	76,5	12	92,3	8,33	15,08	15	88,2	14	93,3	19,05	25,20
FU Month 9	Missing	10	58,8	7	70,0	0,00	0,00	12	70,6	9	75,0	22,22	23,57

FU Month 12	Missing		952,9	555,6	0,00	0,00	741,2	571,4	26,67	27,89	
FU Month 15	Missing		741,2	685,7	5,56	13,61	529,4	480,0	25,00	31,91	
FU Month 18	Missing		423,5	375,0	0,00	0,00	423,5	375,0	22,22	19,25	
FU Month 21	Missing		529,4	5100,0	20,00	44,72	423,5	375,0	11,11	19,25	
FU Month 24	Missing		423,5	375,0	0,00	0,00	211,8	150,0	0,00		NE
FU Month 27	Missing		15,9	1100,0	0,00		NE	15,9	1100,0	0,00	NE
Binet Staging at baseline											
Screening	A		59100,0	5694,9	20,24	26,73	57100,0	5393,0	28,30	29,52	
Cycle 4 Day 1	A		5186,4	4894,1	18,06	25,69	5494,7	5092,6	21,33	28,38	
FU Day 28	A		5898,3	5299,7	16,03	21,38	5494,7	5296,3	24,36	29,61	
FU Month 3	A		5796,6	5698,2	16,07	22,91	5393,0	5094,3	22,67	29,69	
FU Month 6	A		5694,9	4987,5	15,65	23,67	4578,9	4293,3	25,40	29,27	
FU Month 9	A		4372,9	3786,0	13,51	19,97	3459,6	3088,2	23,33	26,48	
FU Month 12	A		3661,0	3494,4	21,57	27,07	2442,1	2187,5	28,57	21,82	
FU Month 15	A		3050,8	2686,7	16,67	25,39	1933,3	19100,0	24,56	26,86	
FU Month 18	A		2237,3	1881,8	22,22	34,30	1628,1	16100,0	29,17	26,87	
FU Month 21	A		1728,8	1588,2	11,11	20,57	814,0	787,5	23,81	25,20	
FU Month 24	A		1016,9	770,0	4,76	12,60	58,8	5100,0	33,33	33,33	
FU Month 27	A		58,5	480,0	25,00	31,91	23,5	150,0	0,00		NE
FU Month 30	A		46,8	375,0	11,11	19,25	0	NE	0	NE	NE
Screening	B	104	100,0	9995,2	23,91	26,95	85100,0	8296,5	28,86	28,57	
Cycle 4 Day 1	B		8884,6	8394,3	12,05	20,55	7992,9	7392,4	22,37	27,25	
FU Day 28	B		9187,5	7986,8	18,14	26,04	7992,9	7189,9	23,47	29,49	
FU Month 3	B		8884,6	7787,5	22,08	29,42	7992,9	7189,9	22,07	24,52	
FU Month 6	B		8076,9	7695,0	18,86	23,94	7082,4	6390,0	24,87	28,06	
FU Month 9	B		6360,6	5181,0	20,26	26,73	5969,4	4983,1	29,25	31,65	
FU Month 12	B		4745,2	3983,0	17,09	24,03	4654,1	4087,0	24,17	27,20	
FU Month 15	B		3735,6	3491,9	17,65	22,07	3440,0	2882,4	28,57	29,70	
FU Month 18	B		3129,8	2890,3	23,81	28,48	2225,9	1881,8	29,63	32,11	
FU Month 21	B		1817,3	1372,2	28,21	32,90	1720,0	1482,4	23,81	35,63	
FU Month 24	B		1110,6	981,8	18,52	29,40	89,4	787,5	9,52	25,20	
FU Month 27	B		54,8	480,0	16,67	33,33	44,7	375,0	11,11	19,25	
FU Month 30	B		21,9	2100,0	0,00	0,00	0	NE	0	NE	NE
Screening	C		92100,0	8491,3	33,33	33,53	100100,0	9292,0	28,26	29,21	
Cycle 4 Day 1	C		7480,4	6486,5	16,67	23,76	9191,0	7481,3	23,87	28,41	
FU Day 28	C		8188,0	6884,0	19,61	26,54	9292,0	7783,7	18,61	25,07	
FU Month 3	C		8087,0	6986,3	17,87	26,56	8989,0	7483,1	21,62	26,13	
FU Month 6	C		7177,2	6084,5	19,44	24,00	7777,0	6483,1	21,88	29,23	

FU Month 9	C	58	63,0	49	84,5	12,93	19,02	56	56,0	41	73,2	25,20	30,53
FU Month 12	C	42	45,7	36	85,7	14,81	18,59	47	47,0	37	78,7	26,13	34,37
FU Month 15	C	37	40,2	29	78,4	18,39	24,54	32	32,0	22	68,8	22,73	29,79
FU Month 18	C	26	28,3	23	88,5	17,39	22,18	22	22,0	14	63,6	23,81	33,15
FU Month 21	C	17	18,5	12	70,6	16,67	26,59	15	15,0	11	73,3	30,30	34,82
FU Month 24	C	11	12,0	8	72,7	20,83	24,80	5	5,0	4	80,0	33,33	47,14
FU Month 27	C	3	3,3	3	100,0	11,11	19,25	3	3,0	2	66,7	0,00	0,00
FU Month 30	C	1	1,1	1	100,0	0,00	NE	1	1,0	1	100,0	0,00	NE
Total CIR score at baseline													
Screening	<=6	63	100,0	58	92,1	22,99	27,36	75	100,0	70	93,3	25,24	27,47
Cycle 4 Day 1	<=6	52	82,5	42	80,8	12,70	19,41	72	96,0	61	84,7	18,58	23,19
FU Day 28	<=6	56	88,9	49	87,5	18,37	22,63	72	96,0	58	80,6	20,11	27,88
FU Month 3	<=6	55	87,3	47	85,5	17,73	23,93	69	92,0	56	81,2	20,24	25,17
FU Month 6	<=6	52	82,5	47	90,4	17,02	22,92	60	80,0	53	88,3	20,75	27,13
FU Month 9	<=6	43	68,3	36	83,7	12,96	18,31	47	62,7	38	80,9	26,32	29,16
FU Month 12	<=6	35	55,6	29	82,9	14,94	22,86	34	45,3	27	79,4	23,46	27,45
FU Month 15	<=6	32	50,8	28	87,5	17,86	24,82	25	33,3	17	68,0	21,57	28,73
FU Month 18	<=6	23	36,5	22	95,7	25,76	28,97	19	25,3	13	68,4	20,51	28,99
FU Month 21	<=6	14	22,2	8	57,1	4,17	11,79	14	18,7	10	71,4	30,00	36,68
FU Month 24	<=6	8	12,7	7	87,5	19,05	26,23	7	9,3	6	85,7	27,78	32,77
FU Month 27	<=6	2	3,2	2	100,0	16,67	23,57	4	5,3	2	50,0	16,67	23,57
FU Month 30	<=6	0	NE	0	NE	NE	NE	1	1,3	1	100,0	0,00	NE
Screening >6													
Screening	>6	192	100,0	181	94,3	27,44	30,46	167	100,0	157	94,0	29,94	29,52
Cycle 4 Day 1	>6	161	83,9	153	95,0	15,69	23,90	152	91,0	136	89,5	24,51	29,60
FU Day 28	>6	174	90,6	150	86,2	18,00	25,80	153	91,6	142	92,8	22,54	27,94
FU Month 3	>6	170	88,5	155	91,2	19,35	27,62	152	91,0	139	91,4	22,78	26,93
FU Month 6	>6	155	80,7	138	89,0	18,60	24,17	132	79,0	116	87,9	25,29	29,36
FU Month 9	>6	121	63,0	101	83,5	16,83	23,86	102	61,1	82	80,4	26,42	30,42
FU Month 12	>6	90	46,9	80	88,9	18,75	23,63	83	49,7	71	85,5	26,76	29,61
FU Month 15	>6	72	37,5	61	84,7	17,49	23,26	60	35,9	52	86,7	26,92	28,80
FU Month 18	>6	56	29,2	47	83,9	19,15	27,58	41	24,6	35	85,4	30,48	30,65
FU Month 21	>6	38	19,8	32	84,2	21,88	28,85	26	15,6	22	84,6	24,24	31,17
FU Month 24	>6	24	12,5	17	70,8	13,73	23,74	11	6,6	10	90,9	20,00	35,83
FU Month 27	>6	11	5,7	9	81,8	18,52	29,40	5	3,0	4	80,0	0,00	0,00
FU Month 30	>6	7	3,6	6	85,7	5,56	13,61	0	NE	0	NE	NE	NE
Calculated creatinine clearance cat. 2													
Screening	<70 ml/min	178	100,0	163	91,6	25,97	29,87	176	100,0	165	93,8	27,88	28,82
Cycle 4 Day 1	<70 ml/min	149	83,7	133	89,3	15,54	23,41	164	93,2	143	87,2	22,14	26,81

FU Day 28	<70 ml/min	162	91,0	140	86,4	17,38	23,81	166	94,3	145	87,3	21,61	27,65
FU Month 3	<70 ml/min	157	88,2	141	89,8	17,73	26,89	159	90,3	138	86,8	21,26	25,77
FU Month 6	<70 ml/min	144	80,9	127	88,2	16,27	22,56	139	79,0	122	87,8	20,49	26,22
FU Month 9	<70 ml/min	117	65,7	96	82,1	14,93	22,09	112	63,6	89	79,5	25,47	28,44
FU Month 12	<70 ml/min	92	51,7	79	85,9	16,88	22,57	87	49,4	73	83,9	23,74	26,34
FU Month 15	<70 ml/min	78	43,8	68	87,2	16,67	23,39	60	34,1	48	80,0	24,31	27,28
FU Month 18	<70 ml/min	59	33,1	51	86,4	20,26	27,55	43	24,4	35	81,4	24,76	27,23
FU Month 21	<70 ml/min	38	21,3	27	71,1	16,05	26,75	31	17,6	27	87,1	22,22	27,74
FU Month 24	<70 ml/min	24	13,5	18	75,0	12,96	20,26	13	7,4	11	84,6	18,18	27,34
FU Month 27	<70 ml/min	10	5,6	8	80,0	16,67	25,20	7	4,0	5	71,4	0,00	0,00
FU Month 30	<70 ml/min	5	2,8	4	80,0	8,33	16,67	1	0,6	1	100,0	0,00	NE
Screening	>=70 ml/min	77	100,0	76	98,7	27,19	29,67	66	100,0	62	93,9	30,11	29,39
Cycle 4 Day 1	>=70 ml/min	64	83,1	62	96,9	13,98	22,22	60	90,9	54	90,0	24,07	30,66
FU Day 28	>=70 ml/min	68	88,3	59	86,8	19,77	27,76	59	89,4	55	93,2	22,42	28,73
FU Month 3	>=70 ml/min	68	88,3	61	89,7	21,86	26,45	62	93,9	57	91,9	23,98	28,00
FU Month 6	>=70 ml/min	63	81,8	58	92,1	22,41	26,04	53	80,3	47	88,7	32,62	32,96
FU Month 9	>=70 ml/min	47	61,0	41	87,2	17,89	23,68	37	56,1	31	83,8	29,03	34,15
FU Month 12	>=70 ml/min	33	42,9	30	90,9	20,00	25,67	30	45,5	25	83,3	32,00	35,33
FU Month 15	>=70 ml/min	26	33,8	21	80,8	20,63	24,67	25	37,9	21	84,0	28,57	32,12
FU Month 18	>=70 ml/min	20	26,0	18	90,0	24,07	29,83	17	25,8	13	76,5	35,90	37,17
FU Month 21	>=70 ml/min	14	18,2	13	92,9	23,08	28,50	9	13,6	5	55,6	46,67	50,55
FU Month 24	>=70 ml/min	8	10,4	6	75,0	22,22	34,43	5	7,6	5	100,0	33,33	47,14
FU Month 27	>=70 ml/min	3	3,9	3	100,0	22,22	38,49	2	3,0	1	50,0	33,33	NE
FU Month 30	>=70 ml/min	2	2,6	2	100,0	0,00	0,00	0	NE	0	NE	NE	NE
Beta2 microglobulin													
Screening	Missing	3	100,0	3	100,0	22,22	19,25	3	100,0	3	100,0	55,56	19,25
Cycle 4 Day 1	Missing	3	100,0	3	100,0	11,11	19,25	3	100,0	2	66,7	16,67	23,57
FU Day 28	Missing	3	100,0	3	100,0	22,22	19,25	3	100,0	2	66,7	16,67	23,57
FU Month 3	Missing	3	100,0	3	100,0	33,33	33,33	3	100,0	2	66,7	16,67	23,57
FU Month 6	Missing	3	100,0	3	100,0	11,11	19,25	3	100,0	2	66,7	0,00	0,00
FU Month 9	Missing	2	66,7	1	50,0	33,33	NE	3	100,0	2	66,7	16,67	23,57
FU Month 12	Missing	1	33,3	1	100,0	33,33	NE	2	66,7	1	50,0	33,33	NE
FU Month 15	Missing	1	33,3	1	100,0	66,67	NE	2	66,7	1	50,0	0,00	NE
FU Month 18	Missing	1	33,3	1	100,0	66,67	NE	2	66,7	1	50,0	33,33	NE
FU Month 21	Missing	1	33,3	1	100,0	66,67	NE	2	66,7	1	50,0	33,33	NE
FU Month 24	Missing	1	33,3	1	100,0	66,67	NE	1	33,3	1	100,0	33,33	NE
Screening	< 3.5 ug/mL	154	100,0	143	92,9	27,74	31,15	140	100,0	132	94,3	27,02	29,45
Cycle 4 Day 1	< 3.5 ug/mL	127	82,5	116	91,3	14,94	23,40	129	92,1	112	86,8	22,32	27,72

FU Day 28	< 3.5 ug/mL	137	89,0	120	87,6	17,78	23,64	132	94,3	118	89,4	24,29	28,47
FU Month 3	< 3.5 ug/mL	134	87,0	123	91,8	16,53	25,74	130	92,9	116	89,2	22,99	27,25
FU Month 6	< 3.5 ug/mL	128	83,1	113	88,3	18,29	23,98	120	85,7	110	91,7	26,06	30,75
FU Month 9	< 3.5 ug/mL	104	67,5	87	83,7	18,01	23,74	98	70,0	80	81,6	30,83	31,28
FU Month 12	< 3.5 ug/mL	78	50,6	69	88,5	19,81	26,39	75	53,6	66	88,0	29,29	31,77
FU Month 15	< 3.5 ug/mL	65	42,2	55	84,6	19,39	24,59	60	42,9	51	85,0	27,45	29,59
FU Month 18	< 3.5 ug/mL	46	29,9	40	87,0	21,67	29,77	43	30,7	34	79,1	31,37	31,72
FU Month 21	< 3.5 ug/mL	30	19,5	21	70,0	14,29	22,54	27	19,3	22	81,5	30,30	36,96
FU Month 24	< 3.5 ug/mL	19	12,3	15	78,9	13,33	21,08	12	8,6	11	91,7	27,27	38,92
FU Month 27	< 3.5 ug/mL	10	6,5	8	80,0	20,83	30,54	7	5,0	4	57,1	8,33	16,67
FU Month 30	< 3.5 ug/mL	5	3,2	4	80,0	8,33	16,67	1	0,7	1	100,0	0,00	NE
Screening	>= 3.5 ug/mL	98	100,0	93	94,9	24,37	27,86	99	100,0	92	92,9	29,71	28,15
Cycle 4 Day 1	>= 3.5 ug/mL	83	84,7	76	91,6	15,35	22,73	92	92,9	83	90,2	23,29	28,39
FU Day 28	>= 3.5 ug/mL	90	91,8	76	84,4	18,42	27,43	90	90,9	80	88,9	18,33	26,99
FU Month 3	>= 3.5 ug/mL	88	89,8	76	86,4	22,37	27,96	88	88,9	77	87,5	20,78	25,39
FU Month 6	>= 3.5 ug/mL	76	77,6	69	90,8	18,36	23,94	69	69,7	57	82,6	20,47	24,20
FU Month 9	>= 3.5 ug/mL	58	59,2	49	84,5	11,56	19,90	48	48,5	38	79,2	17,54	25,39
FU Month 12	>= 3.5 ug/mL	46	46,9	39	84,8	13,68	16,61	40	40,4	31	77,5	18,28	20,80
FU Month 15	>= 3.5 ug/mL	38	38,8	33	86,8	13,13	20,31	23	23,2	17	73,9	21,57	26,20
FU Month 18	>= 3.5 ug/mL	32	32,7	28	87,5	19,05	24,73	15	15,2	13	86,7	17,95	25,88
FU Month 21	>= 3.5 ug/mL	21	21,4	18	85,7	20,37	30,55	11	11,1	9	81,8	14,81	17,57
FU Month 24	>= 3.5 ug/mL	12	12,2	8	66,7	12,50	24,80	5	5,1	4	80,0	8,33	16,67
FU Month 27	>= 3.5 ug/mL	3	3,1	3	100,0	11,11	19,25	2	2,0	2	100,0	0,00	0,00
FU Month 30	>= 3.5 ug/mL	2	2,0	2	100,0	0,00	0,00	0	NE	0	NE	NE	NE
Immunoglobulin VH, cytogenetics 2													
Screening	12	45	100,0	43	95,6	31,01	33,65	44	100,0	42	95,5	33,33	34,53
Cycle 4 Day 1	12	34	75,6	32	94,1	11,46	24,84	38	86,4	33	86,8	30,30	31,58
FU Day 28	12	39	86,7	37	94,9	21,62	29,62	40	90,9	34	85,0	31,37	33,78
FU Month 3	12	38	84,4	36	94,7	24,07	29,40	39	88,6	32	82,1	28,13	29,46
FU Month 6	12	36	80,0	31	86,1	21,51	23,65	34	77,3	28	82,4	39,29	31,50
FU Month 9	12	26	57,8	22	84,6	15,15	19,86	28	63,6	18	64,3	38,89	32,84
FU Month 12	12	22	48,9	18	81,8	20,37	25,92	23	52,3	14	60,9	35,71	35,72
FU Month 15	12	17	37,8	13	76,5	12,82	16,88	17	38,6	12	70,6	33,33	34,82
FU Month 18	12	15	33,3	11	73,3	18,18	31,14	13	29,5	9	69,2	40,74	32,39
FU Month 21	12	10	22,2	8	80,0	33,33	30,86	7	15,9	5	71,4	33,33	40,82
FU Month 24	12	8	17,8	6	75,0	22,22	27,22	6	13,6	5	83,3	33,33	47,14
FU Month 27	12	5	11,1	4	80,0	33,33	38,49	2	4,5	1	50,0	0,00	NE
FU Month 30	12	4	8,9	3	75,0	11,11	19,25	1	2,3	1	100,0	0,00	NE

Screening	11q-	46	100,0	43	93,5	20,16	28,30	43	100,0	40	93,0	26,67	28,44
Cycle 4 Day 1	11q-	40	87,0	39	97,5	12,82	21,10	41	95,3	34	82,9	19,61	27,36
FU Day 28	11q-	42	91,3	35	83,3	16,19	21,95	39	90,7	36	92,3	20,37	26,76
FU Month 3	11q-	42	91,3	38	90,5	21,05	26,19	38	88,4	36	94,7	20,37	24,27
FU Month 6	11q-	38	82,6	35	92,1	14,29	21,82	32	74,4	28	87,5	23,81	21,96
FU Month 9	11q-	28	60,9	26	92,9	14,10	19,26	25	58,1	21	84,0	30,16	33,17
FU Month 12	11q-	20	43,5	19	95,0	14,04	23,08	18	41,9	17	94,4	35,29	27,56
FU Month 15	11q-	18	39,1	16	88,9	14,58	24,25	14	32,6	10	71,4	33,33	35,14
FU Month 18	11q-	15	32,6	13	86,7	10,26	28,50	8	18,6	7	87,5	38,10	35,63
FU Month 21	11q-	12	26,1	11	91,7	6,06	13,48	4	9,3	2	50,0	66,67	47,14
FU Month 24	11q-	7	15,2	5	71,4	0,00	0,00	1	2,3	1	100,0	0,00	NE
FU Month 27	11q-	3	6,5	3	100,0	0,00	0,00	0	NE	0	NE	NE	NE
FU Month 30	11q-	3	6,5	3	100,0	0,00	0,00	0	NE	0	NE	NE	NE
Screening	13q-	79	100,0	74	93,7	27,93	28,15	75	100,0	70	93,3	24,76	24,53
Cycle 4 Day 1	13q-	67	84,8	60	89,6	16,11	22,54	68	90,7	60	88,2	20,00	27,58
FU Day 28	13q-	72	91,1	65	90,3	15,90	23,65	72	96,0	63	87,5	16,93	24,59
FU Month 3	13q-	73	92,4	67	91,8	17,41	27,44	69	92,0	60	87,0	20,56	27,51
FU Month 6	13q-	67	84,8	61	91,0	16,94	23,27	63	84,0	55	87,3	17,58	27,11
FU Month 9	13q-	56	70,9	48	85,7	17,36	24,78	52	69,3	42	80,8	23,02	27,04
FU Month 12	13q-	44	55,7	39	88,6	17,09	20,05	40	53,3	38	95,0	21,05	27,31
FU Month 15	13q-	38	48,1	33	86,8	22,22	24,53	29	38,7	25	86,2	17,33	21,77
FU Month 18	13q-	28	35,4	25	89,3	25,33	25,96	21	28,0	18	85,7	20,37	25,92
FU Month 21	13q-	16	20,3	13	81,3	25,64	33,76	16	21,3	14	87,5	11,90	21,11
FU Month 24	13q-	7	8,9	6	85,7	16,67	27,89	7	9,3	6	85,7	5,56	13,61
FU Month 27	13q-	2	2,5	1	50,0	0,00	NE	6	8,0	4	66,7	0,00	0,00
Screening	Norm. K.	65	100,0	61	93,8	27,32	29,51	58	100,0	55	94,8	34,55	30,74
Cycle 4 Day 1	Norm. K.	54	83,1	48	88,9	15,97	22,79	55	94,8	50	90,9	26,00	27,18
FU Day 28	Norm. K.	59	90,8	48	81,4	19,44	24,63	53	91,4	50	94,3	24,00	26,97
FU Month 3	Norm. K.	54	83,1	47	87,0	17,02	25,89	54	93,1	48	88,9	24,31	26,40
FU Month 6	Norm. K.	49	75,4	46	93,9	21,74	25,55	45	77,6	40	88,9	27,50	31,93
FU Month 9	Norm. K.	39	60,0	31	79,5	17,20	25,63	30	51,7	26	86,7	26,92	31,30
FU Month 12	Norm. K.	32	49,2	27	84,4	20,99	27,96	24	41,4	20	83,3	25,00	30,35
FU Month 15	Norm. K.	26	40,0	23	88,5	15,94	26,34	20	34,5	18	90,0	29,63	27,75
FU Month 18	Norm. K.	18	27,7	17	94,4	27,45	29,43	15	25,9	12	80,0	27,78	31,25
FU Month 21	Norm. K.	12	18,5	6	50,0	11,11	17,21	11	19,0	9	81,8	37,04	35,14
FU Month 24	Norm. K.	8	12,3	5	62,5	26,67	27,89	4	6,9	4	100,0	41,67	31,91
FU Month 27	Norm. K.	3	4,6	3	100,0	22,22	19,25	1	1,7	1	100,0	33,33	NE
Screening	Other Abn.	20	100,0	18	90,0	20,37	30,55	22	100,0	20	90,9	18,33	22,88

Cycle 4 Day 1	Other Abn.	18	90,0	16	88,9	20,83	26,87	22	100,0	20	90,9	15,00	22,88
FU Day 28	Other Abn.	18	90,0	14	77,8	19,05	28,39	21	95,5	17	81,0	17,65	29,15
FU Month 3	Other Abn.	18	90,0	14	77,8	14,29	21,54	21	95,5	19	90,5	14,04	20,23
FU Month 6	Other Abn.	17	85,0	12	70,6	13,89	26,43	18	81,8	18	100,0	11,11	19,80
FU Month 9	Other Abn.	15	75,0	10	66,7	10,00	16,10	14	63,6	13	92,9	12,82	21,68
FU Month 12	Other Abn.	7	35,0	6	85,7	11,11	17,21	12	54,5	9	75,0	14,81	17,57
FU Month 15	Other Abn.	5	25,0	4	80,0	16,67	19,25	5	22,7	4	80,0	16,67	33,33
FU Month 18	Other Abn.	3	15,0	3	100,0	11,11	19,25	3	13,6	2	66,7	0,00	0,00
FU Month 21	Other Abn.	2	10,0	2	100,0	0,00	0,00	2	9,1	2	100,0	16,67	23,57
FU Month 24	Other Abn.	2	10,0	2	100,0	0,00	0,00	0	NE	0	NE	NE	NE
Time from first diagnosis													
Screening	Missing	1	100,0	1	100,0	33,33	NE	0	NE	0	NE	NE	NE
Cycle 4 Day 1	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Day 28	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 3	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 6	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 9	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 12	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 15	Missing	1	100,0	1	100,0	33,33	NE	0	NE	0	NE	NE	NE
FU Month 18	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
Screening	13 - 24 months	41	100,0	39	95,1	23,93	32,40	31	100,0	31	100,0	16,13	20,85
Cycle 4 Day 1	13 - 24 months	35	85,4	34	97,1	13,73	24,78	30	96,8	26	86,7	11,54	20,96
FU Day 28	13 - 24 months	38	92,7	33	86,8	14,14	20,46	30	96,8	27	90,0	9,88	22,29
FU Month 3	13 - 24 months	36	87,8	34	94,4	15,69	26,25	30	96,8	26	86,7	10,26	18,30
FU Month 6	13 - 24 months	36	87,8	33	91,7	14,14	20,46	30	96,8	25	83,3	24,00	31,21
FU Month 9	13 - 24 months	32	78,0	28	87,5	14,29	21,14	21	67,7	18	85,7	25,93	35,34
FU Month 12	13 - 24 months	21	51,2	18	85,7	11,11	22,87	16	51,6	14	87,5	21,43	24,83
FU Month 15	13 - 24 months	19	46,3	17	89,5	9,80	19,60	16	51,6	10	62,5	13,33	23,31
FU Month 18	13 - 24 months	14	34,1	12	85,7	13,89	30,01	10	32,3	8	80,0	16,67	25,20
FU Month 21	13 - 24 months	11	26,8	9	81,8	25,93	36,43	6	19,4	4	66,7	8,33	16,67
FU Month 24	13 - 24 months	8	19,5	4	50,0	41,67	31,91	3	9,7	3	100,0	0,00	0,00
FU Month 27	13 - 24 months	5	12,2	5	100,0	33,33	33,33	2	6,5	2	100,0	0,00	0,00
FU Month 30	13 - 24 months	3	7,3	3	100,0	11,11	19,25	1	3,2	1	100,0	0,00	NE
Screening	<= 12 months	60	100,0	58	96,7	28,16	32,32	70	100,0	68	97,1	30,39	27,46
Cycle 4 Day 1	<= 12 months	48	80,0	42	87,5	15,08	23,52	60	85,7	56	93,3	25,00	28,60
FU Day 28	<= 12 months	54	90,0	45	83,3	22,22	31,78	62	88,6	57	91,9	20,47	27,28
FU Month 3	<= 12 months	53	88,3	45	84,9	25,19	31,91	59	84,3	55	93,2	22,42	24,89
FU Month 6	<= 12 months	46	76,7	40	87,0	25,00	28,99	47	67,1	42	89,4	17,46	25,75

FU Month 9	<= 12 months	35	58,3	27	77,1	17,28	21,42	37	52,9	30	81,1	16,67	27,33
FU Month 12	<= 12 months	27	45,0	23	85,2	17,39	24,35	29	41,4	27	93,1	20,99	29,45
FU Month 15	<= 12 months	22	36,7	17	77,3	21,57	23,40	17	24,3	16	94,1	27,08	32,70
FU Month 18	<= 12 months	16	26,7	13	81,3	20,51	32,03	13	18,6	12	92,3	22,22	32,82
FU Month 21	<= 12 months	9	15,0	5	55,6	20,00	29,81	7	10,0	6	85,7	22,22	40,37
FU Month 24	<= 12 months	6	10,0	3	50,0	11,11	19,25	2	2,9	0	NE	NE	NE
FU Month 27	<= 12 months	1	1,7			NE	NE	1	1,4			NE	NE
FU Month 30	<= 12 months	1	1,7			NE	NE	0	NE			NE	NE
Screening	>24 months	153	100,0	141	92,2	26,24	28,12	141	100,0	128	90,8	30,47	30,75
Cycle 4 Day 1	>24 months	129	84,3	118	91,5	15,54	22,51	134	95,0	115	85,8	24,06	28,46
FU Day 28	>24 months	137	89,5	120	87,6	17,78	23,24	133	94,3	116	87,2	25,29	28,70
FU Month 3	>24 months	135	88,2	122	90,4	17,76	24,69	132	93,6	114	86,4	24,56	28,07
FU Month 6	>24 months	124	81,0	111	89,5	17,12	22,41	115	81,6	102	88,7	26,47	29,04
FU Month 9	>24 months	96	62,7	81	84,4	16,05	23,64	91	64,5	72	79,1	30,56	28,94
FU Month 12	>24 months	76	49,7	67	88,2	19,90	23,25	72	51,1	57	79,2	29,24	29,59
FU Month 15	>24 months	62	40,5	54	87,1	18,52	24,80	52	36,9	43	82,7	27,91	28,11
FU Month 18	>24 months	48	31,4	43	89,6	24,03	26,55	37	26,2	28	75,7	33,33	30,09
FU Month 21	>24 months	32	20,9	26	81,3	15,38	23,53	27	19,1	22	81,5	30,30	32,38
FU Month 24	>24 months	18	11,8	17	94,4	9,80	19,60	13	9,2	13	100,0	28,21	35,61
FU Month 27	>24 months	7	4,6	6	85,7	5,56	13,61	6	4,3	4	66,7	8,33	16,67
FU Month 30	>24 months	3	2,0	3	100,0	0,00	0,00	0	NE	0	NE	NE	NE
High circulating tumor burden													
Screening	Missing	0	NE	0	NE	NE	NE	2	100,0	1	50,0	0,00	NE
Cycle 4 Day 1	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	0,00	NE
FU Day 28	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	0,00	NE
FU Month 3	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	0,00	NE
FU Month 6	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	0,00	NE
FU Month 9	Missing	0	NE			NE	NE	1	50,0			NE	NE
Screening	<25x10**9 cells/L	60	100,0	55	91,7	28,48	31,04	67	100,0	63	94,0	26,98	29,85
Cycle 4 Day 1	<25x10**9 cells/L	50	83,3	44	88,0	15,15	24,33	61	91,0	51	83,6	24,18	29,87
FU Day 28	<25x10**9 cells/L	56	93,3	45	80,4	11,11	23,57	61	91,0	52	85,2	22,44	30,76
FU Month 3	<25x10**9 cells/L	54	90,0	46	85,2	14,49	23,99	59	88,1	49	83,1	19,73	27,99
FU Month 6	<25x10**9 cells/L	50	83,3	43	86,0	22,48	23,82	51	76,1	42	82,4	21,43	30,19
FU Month 9	<25x10**9 cells/L	36	60,0	27	75,0	12,35	16,40	41	61,2	30	73,2	15,56	24,34
FU Month 12	<25x10**9 cells/L	29	48,3	24	82,8	19,44	23,91	34	50,7	25	73,5	21,33	28,67
FU Month 15	<25x10**9 cells/L	24	40,0	18	75,0	16,67	20,61	23	34,3	15	65,2	20,00	27,60
FU Month 18	<25x10**9 cells/L	20	33,3	18	90,0	16,67	32,84	19	28,4	14	73,7	23,81	27,51
FU Month 21	<25x10**9 cells/L	14	23,3	10	71,4	30,00	29,19	10	14,9	8	80,0	16,67	25,20

FU Month 24	<25x10**9 cells/L	8	13,3	5	62,5	13,33	18,26	6	9,0	5	83,3	20,00	29,81
FU Month 27	<25x10**9 cells/L	4	6,7	3	75,0	22,22	38,49	1	1,5	1	100,0	0,00	NE
FU Month 30	<25x10**9 cells/L	4	6,7	3	75,0	11,11	19,25	1	1,5	1	100,0	0,00	NE
Screening	>=25x10**9 cells/L	195	100,0	184	94,4	25,72	29,41	173	100,0	163	94,2	29,24	28,63
Cycle 4 Day 1	>=25x10**9 cells/L	163	83,6	151	92,6	15,01	22,67	162	93,6	145	89,5	22,30	27,23
FU Day 28	>=25x10**9 cells/L	174	89,2	154	88,5	20,13	25,11	163	94,2	147	90,2	21,77	26,93
FU Month 3	>=25x10**9 cells/L	171	87,7	156	91,2	20,30	27,45	161	93,1	145	90,1	22,99	25,91
FU Month 6	>=25x10**9 cells/L	157	80,5	142	90,4	16,90	23,74	140	80,9	126	90,0	24,87	28,26
FU Month 9	>=25x10**9 cells/L	128	65,6	110	85,9	16,67	23,79	107	61,8	90	84,1	30,00	30,82
FU Month 12	>=25x10**9 cells/L	96	49,2	85	88,5	17,25	23,35	83	48,0	73	88,0	27,40	29,05
FU Month 15	>=25x10**9 cells/L	80	41,0	71	88,8	17,84	24,45	62	35,8	54	87,1	27,16	29,01
FU Month 18	>=25x10**9 cells/L	59	30,3	51	86,4	22,88	26,24	41	23,7	34	82,9	29,41	31,53
FU Month 21	>=25x10**9 cells/L	38	19,5	30	78,9	14,44	25,80	30	17,3	24	80,0	29,17	34,49
FU Month 24	>=25x10**9 cells/L	24	12,3	19	79,2	15,79	25,74	12	6,9	11	91,7	24,24	36,79
FU Month 27	>=25x10**9 cells/L	9	4,6	8	88,9	16,67	25,20	8	4,6	5	62,5	6,67	14,91
FU Month 30	>=25x10**9 cells/L	3	1,5	3	100,0	0,00	0,00	0	NE	0	NE	NE	NE

¹ in study: number of subjects in study at respective visit; % based on baseline

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit

² mean: descriptive statistics - absolute values Clinical

cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/t_pro_mean.sas

Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/t_pro_mean_sg_EQC30_IT_label_09MAY2013_21004.xls 04MAR2020

17:18

POPULATION: Labelpopulation, Intent-to-Treat Patients ENDPOINT: EORTC QoL 30

MODEL: Unadjusted Analysis STUDY: CLL11(BO21004), Stage

2

Compliance/Mean

Fatigue Scale

		GClb (N=255)						RClb (N=242)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study ¹	%	with value ¹	%	Mean ²	SD (mean)	in study ¹	%	with value ¹	%	Mean ²	SD (mean)
All													
Screening	n/a	255	100,0	238	93,3	36,88	26,10	242	100,0	228	94,2	37,55	26,03
Cycle 4 Day 1	n/a	213	83,5	195	91,5	28,95	21,18	224	92,6	198	88,4	32,46	23,71
FU Day 28	n/a	230	90,2	201	87,4	31,65	24,83	225	93,0	203	90,2	31,55	24,25
FU Month 3	n/a	225	88,2	203	90,2	28,52	24,47	221	91,3	196	88,7	30,92	23,63
FU Month 6	n/a	207	81,2	186	89,9	27,00	23,59	192	79,3	170	88,5	30,26	24,72
FU Month 9	n/a	164	64,3	138	84,1	25,76	22,22	149	61,6	121	81,2	30,85	24,10
FU Month 12	n/a	125	49,0	109	87,2	29,05	23,42	117	48,3	99	84,6	29,52	24,39
FU Month 15	n/a	104	40,8	90	86,5	25,43	21,73	85	35,1	69	81,2	30,68	25,72
FU Month 18	n/a	79	31,0	70	88,6	28,49	24,70	60	24,8	49	81,7	33,33	24,85
FU Month 21	n/a	52	20,4	40	76,9	30,00	24,29	40	16,5	32	80,0	31,77	26,67
FU Month 24	n/a	32	12,5	25	78,1	30,22	24,54	18	7,4	17	94,4	25,49	25,99
FU Month 27	n/a	13	5,1	11	84,6	27,78	23,17	9	3,7	7	77,8	19,05	21,00
FU Month 30	n/a	7	2,7	6	85,7	29,63	25,01	1	0,4	1	100,0	0,00	NE
Gender													
Screening	Female	97	100,0	89	91,8	40,20	27,94	95	100,0	87	91,6	44,13	26,47
Cycle 4 Day 1	Female	84	86,6	76	90,5	32,60	21,95	88	92,6	78	88,6	39,46	25,55
FU Day 28	Female	90	92,8	83	92,2	33,13	24,49	91	95,8	79	86,8	36,43	26,51
FU Month 3	Female	88	90,7	81	92,0	32,72	24,44	87	91,6	77	88,5	37,16	25,01
FU Month 6	Female	84	86,6	72	85,7	29,63	20,43	77	81,1	68	88,3	30,15	22,46
FU Month 9	Female	70	72,2	59	84,3	31,64	22,87	61	64,2	46	75,4	30,92	25,86
FU Month 12	Female	56	57,7	49	87,5	33,11	22,05	47	49,5	40	85,1	31,67	25,11
FU Month 15	Female	47	48,5	40	85,1	31,67	22,72	33	34,7	28	84,8	32,34	25,66
FU Month 18	Female	34	35,1	29	85,3	33,91	24,32	26	27,4	22	84,6	33,84	26,67
FU Month 21	Female	21	21,6	15	71,4	40,74	28,38	17	17,9	15	88,2	35,56	30,63
FU Month 24	Female	12	12,4	10	83,3	41,11	25,69	6	6,3	5	83,3	13,33	19,88

FU Month 27	Female	6	6,2	5	83,3	41,11	24,09	2	2,1	1	50,0	0,00	NE
FU Month 30	Female	4	4,1	3	75,0	44,44	29,40	1	1,1	1	100,0	0,00	NE
Screening	Male	158	100,0	149	94,3	34,90	24,82	147	100,0	141	95,9	33,49	24,99
Cycle 4 Day 1	Male	129	81,6	119	92,2	26,61	20,42	136	92,5	120	88,2	27,92	21,33
FU Day 28	Male	140	88,6	118	84,3	30,60	25,12	134	91,2	124	92,5	28,45	22,25
FU Month 3	Male	137	86,7	122	89,1	25,73	24,18	134	91,2	119	88,8	26,89	21,87
FU Month 6	Male	123	77,8	114	92,7	25,34	25,32	115	78,2	102	88,7	30,34	26,23
FU Month 9	Male	94	59,5	79	84,0	21,38	20,81	88	59,9	75	85,2	30,81	23,13
FU Month 12	Male	69	43,7	60	87,0	25,74	24,16	70	47,6	59	84,3	28,06	24,00
FU Month 15	Male	57	36,1	50	87,7	20,44	19,74	52	35,4	41	78,8	29,54	26,01
FU Month 18	Male	45	28,5	41	91,1	24,66	24,53	34	23,1	27	79,4	32,92	23,77
FU Month 21	Male	31	19,6	25	80,6	23,56	19,33	23	15,6	17	73,9	28,43	23,06
FU Month 24	Male	20	12,7	15	75,0	22,96	21,61	12	8,2	12	100,0	30,56	27,27
FU Month 27	Male	7	4,4	6	85,7	16,67	16,85	7	4,8	6	85,7	22,22	21,08
FU Month 30	Male	3	1,9	3	100,0	14,81	6,42	0	NE	0	NE	NE	NE
Age													
Screening	<75 years	130	100,0	122	93,8	35,25	26,28	120	100,0	110	91,7	36,31	25,39
Cycle 4 Day 1	<75 years	106	81,5	100	94,3	27,39	20,61	112	93,3	98	87,5	29,59	24,71
FU Day 28	<75 years	119	91,5	105	88,2	29,95	24,22	110	91,7	103	93,6	29,34	23,64
FU Month 3	<75 years	116	89,2	106	91,4	25,26	23,57	109	90,8	99	90,8	28,73	23,76
FU Month 6	<75 years	108	83,1	98	90,7	25,28	23,87	99	82,5	88	88,9	28,72	24,07
FU Month 9	<75 years	85	65,4	73	85,9	23,59	20,62	74	61,7	62	83,8	28,67	25,01
FU Month 12	<75 years	63	48,5	59	93,7	26,18	22,58	60	50,0	53	88,3	27,67	24,90
FU Month 15	<75 years	54	41,5	47	87,0	24,59	21,10	44	36,7	35	79,5	25,24	22,76
FU Month 18	<75 years	43	33,1	39	90,7	24,79	25,17	27	22,5	22	81,5	31,31	28,41
FU Month 21	<75 years	26	20,0	22	84,6	29,80	23,60	17	14,2	13	76,5	21,79	25,71
FU Month 24	<75 years	18	13,8	14	77,8	30,16	27,71	6	5,0	5	83,3	20,00	29,81
FU Month 27	<75 years	7	5,4	5	71,4	26,67	16,85	2	1,7	1	50,0	0,00	NE
FU Month 30	<75 years	4	3,1	3	75,0	29,63	23,13	0	NE	0	NE	NE	NE
Screening	>=75 years	125	100,0	116	92,8	38,60	25,91	122	100,0	118	96,7	38,70	26,66
Cycle 4 Day 1	>=75 years	107	85,6	95	88,8	30,58	21,74	112	91,8	100	89,3	35,28	22,45
FU Day 28	>=75 years	111	88,8	96	86,5	33,51	25,47	115	94,3	100	87,0	33,83	24,77
FU Month 3	>=75 years	109	87,2	97	89,0	32,07	25,05	112	91,8	97	86,6	33,16	23,41
FU Month 6	>=75 years	99	79,2	88	88,9	28,91	23,25	93	76,2	82	88,2	31,91	25,45
FU Month 9	>=75 years	79	63,2	65	82,3	28,21	23,82	75	61,5	59	78,7	33,15	23,09
FU Month 12	>=75 years	62	49,6	50	80,6	32,44	24,16	57	46,7	46	80,7	31,64	23,88
FU Month 15	>=75 years	50	40,0	43	86,0	26,36	22,62	41	33,6	34	82,9	36,27	27,67
FU Month 18	>=75 years	36	28,8	31	86,1	33,15	23,68	33	27,0	27	81,8	34,98	21,94

FU Month 21	>=75 years	26	20,8	18	69,2	30,25	25,79	23	18,9	19	82,6	38,60	25,76
FU Month 24	>=75 years	14	11,2	11	78,6	30,30	21,14	12	9,8	12	100,0	27,78	25,29
FU Month 27	>=75 years	6	4,8	6	100,0	28,70	29,06	7	5,7	6	85,7	22,22	21,08
FU Month 30	>=75 years	3	2,4	3	100,0	29,63	32,08	1	0,8	1	100,0	0,00	NE
Race													
Screening	Other	9	100,0	9	100,0	39,51	35,62	11	100,0	11	100,0	33,33	8,61
Cycle 4 Day 1	Other	7	77,8	7	100,0	33,33	18,14	10	90,9	9	90,0	29,63	22,91
FU Day 28	Other	8	88,9	8	100,0	33,33	31,43	10	90,9	10	100,0	28,89	10,73
FU Month 3	Other	8	88,9	7	87,5	25,40	25,43	10	90,9	10	100,0	34,44	19,91
FU Month 6	Other	8	88,9	7	87,5	28,57	28,59	8	72,7	8	100,0	23,61	23,34
FU Month 9	Other	4	44,4	3	75,0	29,63	6,42	5	45,5	4	80,0	38,89	32,08
FU Month 12	Other	3	33,3	2	66,7	33,33	0,00	4	36,4	4	100,0	19,44	22,91
FU Month 15	Other	2	22,2	1	50,0	33,33	NE	4	36,4	4	100,0	16,67	14,34
FU Month 18	Other	2	22,2	1	50,0	0,00	NE	2	18,2	2	100,0	16,67	7,86
FU Month 21	Other	2	22,2	1	50,0	0,00	NE	2	18,2	2	100,0	16,67	23,57
FU Month 24	Other	2	22,2	1	50,0	0,00	NE	1	9,1	0	NE	NE	NE
FU Month 27	Other	1	11,1			NE	NE	1	9,1			NE	NE
FU Month 30	Other	1	11,1			NE	NE	0	NE			NE	NE
Geographical Region													
Screening	White	246	100,0	229	93,1	36,78	25,75	231	100,0	217	93,9	37,76	26,60
Cycle 4 Day 1	White	206	83,7	188	91,3	28,78	21,30	214	92,6	189	88,3	32,60	23,80
FU Day 28	White	222	90,2	193	86,9	31,58	24,62	215	93,1	193	89,8	31,69	24,75
FU Month 3	White	217	88,2	196	90,3	28,63	24,49	211	91,3	186	88,2	30,73	23,85
FU Month 6	White	199	80,9	179	89,9	26,94	23,46	184	79,7	162	88,0	30,59	24,81
FU Month 9	White	160	65,0	135	84,4	25,68	22,45	144	62,3	117	81,3	30,58	23,91
FU Month 12	White	122	49,6	107	87,7	28,97	23,63	113	48,9	95	84,1	29,94	24,48
FU Month 15	White	102	41,5	89	87,3	25,34	21,84	81	35,1	65	80,2	31,54	26,08
FU Month 18	White	77	31,3	69	89,6	28,90	24,64	58	25,1	47	81,0	34,04	25,10
FU Month 21	White	50	20,3	39	78,0	30,77	24,11	38	16,5	30	78,9	32,78	26,92
FU Month 24	White	30	12,2	24	80,0	31,48	24,23	17	7,4	17	100,0	25,49	25,99
FU Month 27	White	12	4,9	11	91,7	27,78	23,17	8	3,5	7	87,5	19,05	21,00
FU Month 30	White	6	2,4	6	100,0	29,63	25,01	1	0,4	1	100,0	0,00	NE
Geographical Region													
Screening	Asia-Pacific	20	100,0	20	100,0	33,89	32,54	18	100,0	18	100,0	38,27	27,01
Cycle 4 Day 1	Asia-Pacific	15	75,0	15	100,0	22,22	16,27	16	88,9	15	93,8	34,81	27,17
FU Day 28	Asia-Pacific	18	90,0	18	100,0	32,10	25,82	18	100,0	16	88,9	30,56	20,08
FU Month 3	Asia-Pacific	18	90,0	16	88,9	28,47	30,35	18	100,0	16	88,9	40,97	21,36
FU Month 6	Asia-Pacific	16	80,0	14	87,5	30,95	35,45	17	94,4	15	88,2	38,52	25,50
FU Month 9	Asia-Pacific	14	70,0	12	85,7	25,93	23,37	13	72,2	10	76,9	45,00	29,91

FU Month 12	Asia-Pacific	10	50,0	8	80,0	26,39	28,44	10	55,6	10	100,0	36,67	31,88
FU Month 15	Asia-Pacific	8	40,0	6	75,0	11,11	17,21	9	50,0	9	100,0	43,21	31,64
FU Month 18	Asia-Pacific	6	30,0	4	66,7	8,33	16,67	6	33,3	6	100,0	37,04	24,00
FU Month 21	Asia-Pacific	5	25,0	3	60,0	7,41	12,83	4	22,2	4	100,0	36,11	31,91
FU Month 24	Asia-Pacific	3	15,0	2	66,7	0,00	0,00	1	5,6	0	NE	NE	NE
FU Month 27	Asia-Pacific	1	5,0			NE	NE	1	5,6			NE	NE
FU Month 30	Asia-Pacific	1	5,0			NE	NE	0	NE			NE	NE
Screening	Central and South America	3	100,0	3	100,0	37,04	6,42	2	100,0	2	100,0	66,67	31,43
Cycle 4 Day 1	Central and South America	3	100,0	3	100,0	29,63	12,83	2	100,0	2	100,0	27,78	7,86
FU Day 28	Central and South America	3	100,0	3	100,0	29,63	16,97	2	100,0	2	100,0	11,11	0,00
FU Month 3	Central and South America	3	100,0	3	100,0	25,93	27,96	2	100,0	2	100,0	5,56	7,86
FU Month 6	Central and South America	2	66,7	2	100,0	27,78	7,86	2	100,0	2	100,0	5,56	7,86
FU Month 9	Central and South America	2	66,7	2	100,0	27,78	7,86	1	50,0	1	100,0	0,00	NE
FU Month 12	Central and South America	2	66,7	2	100,0	27,78	7,86	1	50,0	1	100,0	22,22	NE
FU Month 15	Central and South America	1	33,3	1	100,0	11,11	NE	0	NE	0	NE	NE	NE
FU Month 18	Central and South America	1	33,3	1	100,0	11,11	NE	0	NE	0	NE	NE	NE
FU Month 21	Central and South America	1	33,3	1	100,0	22,22	NE	0	NE	0	NE	NE	NE
FU Month 24	Central and South America	1	33,3	1	100,0	11,11	NE	0	NE	0	NE	NE	NE
Screening	North America	12	100,0	12	100,0	55,56	25,95	13	100,0	12	92,3	37,04	27,76
Cycle 4 Day 1	North America	9	75,0	9	100,0	29,63	12,42	12	92,3	12	100,0	27,78	18,65
FU Day 28	North America	11	91,7	11	100,0	32,32	24,07	13	100,0	13	100,0	31,62	19,69
FU Month 3	North America	11	91,7	11	100,0	45,45	27,87	12	92,3	12	100,0	25,00	15,80
FU Month 6	North America	11	91,7	10	90,9	38,89	18,33	11	84,6	11	100,0	35,35	27,13
FU Month 9	North America	8	66,7	8	100,0	31,94	23,34	9	69,2	9	100,0	37,04	24,85
FU Month 12	North America	8	66,7	7	87,5	30,16	24,61	7	53,8	7	100,0	30,16	15,33
FU Month 15	North America	6	50,0	6	100,0	29,63	15,18	6	46,2	5	83,3	35,56	27,67
FU Month 18	North America	4	33,3	4	100,0	36,11	13,98	3	23,1	3	100,0	37,04	16,97
FU Month 21	North America	3	25,0	2	66,7	33,33	0,00	1	7,7	1	100,0	11,11	NE
FU Month 24	North America	3	25,0	2	66,7	44,44	31,43	1	7,7	1	100,0	33,33	NE
FU Month 27	North America	2	16,7	1	50,0	22,22	NE	1	7,7	1	100,0	55,56	NE
Screening	Other	45	100,0	41	91,1	37,13	22,99	44	100,0	41	93,2	37,94	25,09
Cycle 4 Day 1	Other	37	82,2	33	89,2	29,12	19,50	40	90,9	35	87,5	25,87	25,17
FU Day 28	Other	37	82,2	33	89,2	24,92	22,57	39	88,6	37	94,9	28,23	25,06
FU Month 3	Other	38	84,4	34	89,5	22,55	16,06	38	86,4	36	94,7	32,10	25,99
FU Month 6	Other	35	77,8	31	88,6	21,51	17,67	33	75,0	31	93,9	28,85	25,35
FU Month 9	Other	26	57,8	22	84,6	21,21	16,05	24	54,5	19	79,2	22,22	21,91
FU Month 12	Other	17	37,8	16	94,1	22,22	17,68	16	36,4	14	87,5	23,02	20,66
FU Month 15	Other	12	26,7	11	91,7	20,20	14,76	9	20,5	8	88,9	18,06	19,64

FU Month 18	Other	10	22,2	9	90,0	17,28	13,73	7	15,9	6	85,7	16,67	16,85
FU Month 21	Other	7	15,6	6	85,7	27,78	19,56	4	9,1	4	100,0	13,89	10,64
FU Month 24	Other	6	13,3	5	83,3	26,67	20,18	3	6,8	3	100,0	11,11	19,25
FU Month 27	Other	4	8,9	4	100,0	30,56	5,56	1	2,3	1	100,0	22,22	NE
FU Month 30	Other	2	4,4	2	100,0	33,33	31,43	0	NE	0	NE	NE	NE
Screening	Western Europe	175	100,0	162	92,6	35,80	25,92	165	100,0	155	93,9	37,03	26,11
Cycle 4 Day 1	Western Europe	149	85,1	135	90,6	29,59	22,66	154	93,3	134	87,0	34,41	23,36
FU Day 28	Western Europe	161	92,0	136	84,5	33,21	25,45	153	92,7	135	88,2	32,88	25,03
FU Month 3	Western Europe	155	88,6	139	89,7	28,70	24,80	151	91,5	130	86,1	30,30	23,65
FU Month 6	Western Europe	143	81,7	129	90,2	26,96	23,64	129	78,2	111	86,0	29,48	24,27
FU Month 9	Western Europe	114	65,1	94	82,5	26,24	23,55	102	61,8	82	80,4	30,83	23,13
FU Month 12	Western Europe	88	50,3	76	86,4	30,70	24,27	83	50,3	67	80,7	29,85	24,94
FU Month 15	Western Europe	77	44,0	66	85,7	27,44	23,24	61	37,0	47	77,0	29,91	24,83
FU Month 18	Western Europe	58	33,1	52	89,7	31,73	26,32	44	26,7	34	77,3	35,29	26,30
FU Month 21	Western Europe	36	20,6	28	77,8	32,94	26,45	31	18,8	23	74,2	35,02	27,50
FU Month 24	Western Europe	19	10,9	15	78,9	34,81	25,15	13	7,9	13	100,0	28,21	27,82
FU Month 27	Western Europe	6	3,4	6	100,0	26,85	32,28	6	3,6	5	83,3	11,11	15,71
FU Month 30	Western Europe	4	2,3	4	100,0	27,78	26,45	1	0,6	1	100,0	0,00	NE
FCgamma receptor IIa													
Screening	131HH	58	100,0	53	91,4	37,53	26,44	76	100,0	72	94,7	39,20	27,02
Cycle 4 Day 1	131HH	49	84,5	43	87,8	30,75	19,37	65	85,5	60	92,3	29,44	22,76
FU Day 28	131HH	51	87,9	46	90,2	30,80	25,60	70	92,1	62	88,6	28,94	22,56
FU Month 3	131HH	51	87,9	47	92,2	29,91	25,31	64	84,2	54	84,4	27,78	22,71
FU Month 6	131HH	49	84,5	45	91,8	26,42	22,26	55	72,4	48	87,3	25,81	24,32
FU Month 9	131HH	39	67,2	30	76,9	28,52	20,77	41	53,9	33	80,5	27,78	25,08
FU Month 12	131HH	28	48,3	24	85,7	30,56	25,01	34	44,7	29	85,3	25,29	25,70
FU Month 15	131HH	23	39,7	19	82,6	25,15	21,55	24	31,6	20	83,3	18,33	18,83
FU Month 18	131HH	17	29,3	14	82,4	34,52	20,92	16	21,1	13	81,3	28,21	25,91
FU Month 21	131HH	13	22,4	8	61,5	33,33	28,48	11	14,5	10	90,9	47,22	35,26
FU Month 24	131HH	11	19,0	7	63,6	36,51	23,76	1	1,3	1	100,0	22,22	NE
FU Month 27	131HH	4	6,9	3	75,0	42,59	41,70	1	1,3	1	100,0	0,00	NE
FU Month 30	131HH	3	5,2	2	66,7	38,89	39,28	0	NE	0	NE	NE	NE
Screening	131HR	125	100,0	117	93,6	38,51	26,68	114	100,0	109	95,6	35,93	25,60
Cycle 4 Day 1	131HR	105	84,0	97	92,4	30,81	22,55	110	96,5	99	90,0	34,57	23,00
FU Day 28	131HR	116	92,8	102	87,9	34,75	25,20	105	92,1	96	91,4	32,64	25,12
FU Month 3	131HR	114	91,2	102	89,5	28,92	24,45	107	93,9	95	88,8	31,58	24,00
FU Month 6	131HR	104	83,2	93	89,4	26,88	23,93	95	83,3	85	89,5	33,92	25,17
FU Month 9	131HR	84	67,2	71	84,5	27,23	23,74	76	66,7	61	80,3	32,70	22,86

FU Month 12	131HR	64	51,2	57	89,1	30,99	24,82	57	50,0	48	84,2	29,86	22,48
FU Month 15	131HR	53	42,4	44	83,0	27,78	22,29	44	38,6	35	79,5	34,92	27,89
FU Month 18	131HR	43	34,4	38	88,4	30,99	24,26	32	28,1	26	81,3	32,91	21,66
FU Month 21	131HR	26	20,8	20	76,9	33,89	26,85	21	18,4	16	76,2	25,69	18,47
FU Month 24	131HR	12	9,6	11	91,7	23,23	19,53	12	10,5	11	91,7	26,26	27,79
FU Month 27	131HR	6	4,8	5	83,3	26,67	6,09	6	5,3	4	66,7	27,78	23,13
FU Month 30	131HR	3	2,4	3	100,0	29,63	23,13	1	0,9	1	100,0	0,00	NE
Screening	131RR	49	100,0	48	98,0	33,33	24,01	33	100,0	30	90,9	35,93	24,01
Cycle 4 Day 1	131RR	40	81,6	38	95,0	25,73	19,99	31	93,9	25	80,6	33,78	26,54
FU Day 28	131RR	42	85,7	35	83,3	28,89	23,52	32	97,0	29	90,6	32,95	26,31
FU Month 3	131RR	39	79,6	37	94,9	26,73	23,49	32	97,0	30	93,8	32,41	26,18
FU Month 6	131RR	35	71,4	32	91,4	30,21	23,65	27	81,8	23	85,2	27,54	24,36
FU Month 9	131RR	24	49,0	22	91,7	22,73	22,08	19	57,6	17	89,5	28,76	26,37
FU Month 12	131RR	18	36,7	17	94,4	24,18	18,94	17	51,5	15	88,2	34,81	25,15
FU Month 15	131RR	16	32,7	16	100,0	20,14	22,67	11	33,3	9	81,8	37,65	18,79
FU Month 18	131RR	14	28,6	14	100,0	20,63	29,19	8	24,2	7	87,5	46,03	34,80
FU Month 21	131RR	8	16,3	7	87,5	23,81	13,50	5	15,2	4	80,0	27,78	23,13
FU Month 24	131RR	5	10,2	4	80,0	41,67	37,82	3	9,1	3	100,0	29,63	33,95
FU Month 27	131RR	2	4,1	2	100,0	22,22	15,71	1	3,0	1	100,0	0,00	NE
FU Month 30	131RR	1	2,0	1	100,0	11,11	NE	0	NE	0	NE	NE	NE
Screening	Missing	23	100,0	20	87,0	34,17	27,47	19	100,0	17	89,5	43,79	28,73
Cycle 4 Day 1	Missing	19	82,6	17	89,5	20,92	18,79	18	94,7	14	77,8	28,17	27,95
FU Day 28	Missing	21	91,3	18	85,7	21,60	21,38	18	94,7	16	88,9	32,64	22,76
FU Month 3	Missing	21	91,3	17	81,0	26,14	26,04	18	94,7	17	94,4	34,64	20,37
FU Month 6	Missing	19	82,6	16	84,2	22,92	26,44	15	78,9	14	93,3	27,78	22,96
FU Month 9	Missing	17	73,9	15	88,2	17,78	16,69	13	68,4	10	76,9	33,33	26,71
FU Month 12	Missing	15	65,2	11	73,3	23,23	18,89	9	47,4	7	77,8	33,33	32,08
FU Month 15	Missing	12	52,2	11	91,7	24,24	19,76	6	31,6	5	83,3	37,78	33,88
FU Month 18	Missing	5	21,7	4	80,0	11,11	15,71	4	21,1	3	75,0	29,63	23,13
FU Month 21	Missing	5	21,7	5	100,0	17,78	16,85	3	15,8	2	66,7	11,11	15,71
FU Month 24	Missing	4	17,4	3	75,0	25,93	27,96	2	10,5	2	100,0	16,67	23,57
FU Month 27	Missing	1	4,3	1	100,0	0,00	NE	1	5,3	1	100,0	22,22	NE
FCgamma receptor IIIa													
Screening	158FF	103	100,0	99	96,1	36,76	27,00	83	100,0	79	95,2	35,65	22,67
Cycle 4 Day 1	158FF	89	86,4	83	93,3	28,11	22,70	78	94,0	72	92,3	33,64	23,06
FU Day 28	158FF	96	93,2	84	87,5	32,14	25,82	78	94,0	74	94,9	29,88	21,44
FU Month 3	158FF	94	91,3	84	89,4	27,71	26,09	78	94,0	71	91,0	27,93	22,48
FU Month 6	158FF	86	83,5	74	86,0	25,83	25,09	64	77,1	59	92,2	28,63	26,03

FU Month 9	158FF	71	68,9	59	83,1	25,80	24,80	47	56,6	43	91,5	30,49	22,63
FU Month 12	158FF	48	46,6	42	87,5	26,98	25,75	38	45,8	35	92,1	26,03	19,42
FU Month 15	158FF	37	35,9	32	86,5	23,61	24,40	30	36,1	24	80,0	29,17	25,34
FU Month 18	158FF	27	26,2	25	92,6	28,89	26,06	21	25,3	17	81,0	32,68	23,40
FU Month 21	158FF	16	15,5	15	93,8	32,59	24,66	9	10,8	8	88,9	22,22	31,98
FU Month 24	158FF	8	7,8	7	87,5	23,81	21,69	3	3,6	3	100,0	11,11	19,25
FU Month 27	158FF	5	4,9	4	80,0	13,89	10,64	1	1,2	1	100,0	0,00	NE
FU Month 30	158FF	3	2,9	3	100,0	14,81	6,42	0	NE	0	NE	NE	NE
Screening	158FV	119	100,0	110	92,4	36,46	24,82	109	100,0	103	94,5	38,83	27,21
Cycle 4 Day 1	158FV	99	83,2	89	89,9	30,34	20,92	100	91,7	86	86,0	33,01	22,58
FU Day 28	158FV	105	88,2	91	86,7	33,15	24,18	101	92,7	87	86,1	34,23	26,04
FU Month 3	158FV	101	84,9	93	92,1	29,03	23,97	97	89,0	84	86,6	32,80	24,69
FU Month 6	158FV	94	79,0	87	92,6	27,84	21,56	83	76,1	72	86,7	31,79	25,47
FU Month 9	158FV	71	59,7	61	85,9	24,95	18,99	65	59,6	49	75,4	33,56	25,81
FU Month 12	158FV	60	50,4	55	91,7	30,30	22,47	52	47,7	42	80,8	35,71	27,50
FU Month 15	158FV	52	43,7	45	86,5	25,68	20,63	36	33,0	30	83,3	37,22	25,23
FU Month 18	158FV	44	37,0	38	86,4	28,22	25,39	24	22,0	20	83,3	41,11	26,76
FU Month 21	158FV	28	23,5	18	64,3	29,63	26,68	18	16,5	14	77,8	47,22	23,75
FU Month 24	158FV	18	15,1	13	72,2	32,48	26,24	6	5,5	5	83,3	55,56	22,22
FU Month 27	158FV	6	5,0	5	83,3	41,11	24,09	2	1,8	1	50,0	33,33	NE
FU Month 30	158FV	4	3,4	3	75,0	44,44	29,40	0	NE	0	NE	NE	NE
Screening	158VV	16	100,0	15	93,8	42,96	29,95	33	100,0	31	93,9	34,41	29,17
Cycle 4 Day 1	158VV	12	75,0	11	91,7	26,26	14,29	30	90,9	28	93,3	31,75	26,31
FU Day 28	158VV	14	87,5	13	92,9	23,93	25,60	30	90,9	28	93,3	26,39	24,50
FU Month 3	158VV	15	93,8	12	80,0	27,31	16,32	30	90,9	26	86,7	29,06	24,56
FU Month 6	158VV	14	87,5	13	92,9	27,35	26,30	30	90,9	25	83,3	30,22	21,64
FU Month 9	158VV	12	75,0	10	83,3	33,33	29,16	25	75,8	20	80,0	27,22	23,97
FU Month 12	158VV	8	50,0	7	87,5	36,51	24,61	20	60,6	17	85,0	21,57	20,21
FU Month 15	158VV	8	50,0	7	87,5	34,92	23,51	14	42,4	11	78,6	23,23	27,42
FU Month 18	158VV	4	25,0	4	100,0	38,89	11,11	11	33,3	9	81,8	24,69	21,36
FU Month 21	158VV	3	18,8	2	66,7	44,44	0,00	9	27,3	7	77,8	19,05	13,93
FU Month 24	158VV	2	12,5	2	100,0	44,44	31,43	7	21,2	7	100,0	12,70	13,50
FU Month 27	158VV	1	6,3	1	100,0	44,44	NE	5	15,2	4	80,0	19,44	26,25
FU Month 30	158VV	0	NE	0	NE	NE	NE	1	3,0	1	100,0	0,00	NE
Screening	Missing	17	100,0	14	82,4	34,52	27,23	17	100,0	15	88,2	45,19	28,00
Cycle 4 Day 1	Missing	13	76,5	12	92,3	26,85	18,63	16	94,1	12	75,0	23,15	29,76
FU Day 28	Missing	15	88,2	13	86,7	25,64	22,40	16	94,1	14	87,5	34,13	26,32
FU Month 3	Missing	15	88,2	14	93,3	30,95	25,48	16	94,1	15	93,8	37,78	20,91

FU Month 6	Missing	13	76,5	12	92,3	27,78	27,83	15	88,2	14	93,3	29,37	22,05
FU Month 9	Missing	10	58,8	8	80,0	22,22	16,80	12	70,6	9	75,0	25,93	23,57
FU Month 12	Missing	9	52,9	5	55,6	22,22	7,86	7	41,2	5	71,4	28,89	34,78
FU Month 15	Missing	7	41,2	6	85,7	22,22	12,17	5	29,4	4	80,0	11,11	15,71
FU Month 18	Missing	4	23,5	3	75,0	14,81	16,97	4	23,5	3	75,0	11,11	11,11
FU Month 21	Missing	5	29,4	5	100,0	17,78	16,85	4	23,5	3	75,0	14,81	12,83
FU Month 24	Missing	4	23,5	3	75,0	25,93	27,96	2	11,8	2	100,0	16,67	23,57
FU Month 27	Missing	1	5,9	1	100,0	0,00	NE	1	5,9	1	100,0	22,22	NE
Binet Staging at baseline													
Screening	A	59	100,0	56	94,9	37,00	27,14	57	100,0	53	93,0	41,93	27,10
Cycle 4 Day 1	A	51	86,4	48	94,1	33,10	24,01	54	94,7	50	92,6	35,56	27,68
FU Day 28	A	58	98,3	53	91,4	38,89	24,22	54	94,7	52	96,3	39,10	28,98
FU Month 3	A	57	96,6	56	98,2	33,23	28,55	53	93,0	50	94,3	36,89	27,81
FU Month 6	A	56	94,9	50	89,3	30,67	22,62	45	78,9	42	93,3	33,86	28,93
FU Month 9	A	43	72,9	37	86,0	29,73	23,72	34	59,6	30	88,2	32,22	28,79
FU Month 12	A	36	61,0	34	94,4	32,68	26,93	24	42,1	21	87,5	35,45	29,11
FU Month 15	A	30	50,8	27	90,0	25,10	25,34	19	33,3	19	100,0	35,38	30,04
FU Month 18	A	22	37,3	18	81,8	27,47	25,88	16	28,1	16	100,0	37,50	31,39
FU Month 21	A	17	28,8	15	88,2	26,67	28,73	8	14,0	7	87,5	23,81	10,00
FU Month 24	A	10	16,9	8	80,0	30,56	26,39	5	8,8	5	100,0	22,22	15,71
FU Month 27	A	5	8,5	4	80,0	34,72	35,25	2	3,5	1	50,0	0,00	NE
FU Month 30	A	4	6,8	3	75,0	33,33	29,40	0	NE	0	NE	NE	NE
Screening	B	104	100,0	100	96,2	33,94	25,30	85	100,0	83	97,6	37,28	26,62
Cycle 4 Day 1	B	88	84,6	83	94,3	26,24	20,70	79	92,9	73	92,4	31,35	22,63
FU Day 28	B	91	87,5	79	86,8	26,86	24,56	79	92,9	71	89,9	29,73	24,04
FU Month 3	B	88	84,6	78	88,6	25,93	24,07	79	92,9	71	89,9	29,19	22,67
FU Month 6	B	80	76,9	76	95,0	22,51	22,22	70	82,4	64	91,4	32,03	24,02
FU Month 9	B	63	60,6	52	82,5	24,57	23,53	59	69,4	49	83,1	32,77	21,46
FU Month 12	B	47	45,2	39	83,0	26,50	20,81	46	54,1	40	87,0	30,56	22,33
FU Month 15	B	37	35,6	34	91,9	25,82	20,96	34	40,0	28	82,4	28,17	21,91
FU Month 18	B	31	29,8	29	93,5	29,89	24,86	22	25,9	18	81,8	29,63	17,88
FU Month 21	B	18	17,3	13	72,2	35,04	22,15	17	20,0	14	82,4	26,98	24,15
FU Month 24	B	11	10,6	9	81,8	33,33	27,78	8	9,4	8	100,0	23,61	32,22
FU Month 27	B	5	4,8	4	80,0	19,44	18,98	4	4,7	4	100,0	27,78	23,13
FU Month 30	B	2	1,9	2	100,0	11,11	0,00	0	NE	0	NE	NE	NE
Screening	C	92	100,0	82	89,1	40,38	26,22	100	100,0	92	92,0	35,27	24,80
Cycle 4 Day 1	C	74	80,4	64	86,5	29,34	19,23	91	91,0	75	82,4	31,48	21,96
FU Day 28	C	81	88,0	69	85,2	31,56	24,60	92	92,0	80	87,0	28,26	19,95

FU Month 3	C	80	87,0	69	86,3	27,62	20,87	89	89,0	75	84,3	28,59	21,00	
FU Month 6	C	71	77,2	60	84,5	29,63	25,44	77	77,0	64	83,1	26,13	22,10	
FU Month 9	C	58	63,0	49	84,5	24,04	19,56	56	56,0	42	75,0	27,65	23,62	
FU Month 12	C	42	45,7	36	85,7	28,40	22,76	47	47,0	38	80,9	25,15	23,49	
FU Month 15	C	37	40,2	29	78,4	25,29	19,67	32	32,0	22	68,8	29,80	26,87	
FU Month 18	C	26	28,3	23	88,5	27,54	24,59	22	22,0	15	68,2	33,33	25,20	
FU Month 21	C	17	18,5	12	70,6	28,70	21,43	15	15,0	11	73,3	42,93	34,25	
FU Month 24	C	11	12,0	8	72,7	26,39	21,36	5	5,0	4	80,0	33,33	27,22	
FU Month 27	C	3	3,3	3	100,0	29,63	6,42	3	3,0	2	66,7	11,11	15,71	
FU Month 30	C	1	1,1	1	100,0	55,56		NE	1	1,0	1	100,0	0,00	NE
Total CIR score at baseline														
Screening	<=6	63	100,0	57	90,5	29,82	24,68	75	100,0	70	93,3	31,67	21,05	
Cycle 4 Day 1	<=6	52	82,5	42	80,8	25,66	18,93	72	96,0	61	84,7	27,69	16,93	
FU Day 28	<=6	56	88,9	49	87,5	26,98	19,77	72	96,0	59	81,9	27,31	22,44	
FU Month 3	<=6	55	87,3	47	85,5	25,41	23,31	69	92,0	56	81,2	26,39	19,14	
FU Month 6	<=6	52	82,5	47	90,4	24,11	21,65	60	80,0	53	88,3	29,04	21,97	
FU Month 9	<=6	43	68,3	36	83,7	20,99	20,19	47	62,7	38	80,9	27,19	18,75	
FU Month 12	<=6	35	55,6	29	82,9	29,89	23,78	34	45,3	27	79,4	26,75	21,63	
FU Month 15	<=6	32	50,8	28	87,5	25,00	21,73	25	33,3	17	68,0	33,33	22,22	
FU Month 18	<=6	23	36,5	22	95,7	32,83	28,58	19	25,3	14	73,7	33,33	24,27	
FU Month 21	<=6	14	22,2	8	57,1	27,78	30,86	14	18,7	10	71,4	36,67	25,69	
FU Month 24	<=6	8	12,7	7	87,5	25,40	31,89	7	9,3	6	85,7	24,07	24,76	
FU Month 27	<=6	2	3,2	2	100,0	27,78	7,86	4	5,3	2	50,0	16,67	23,57	
FU Month 30	<=6	0	NE	0	NE	NE	NE	1	1,3	1	100,0	0,00	NE	
Screening	>6	192	100,0	181	94,3	39,10	26,20	167	100,0	158	94,6	40,15	27,61	
Cycle 4 Day 1	>6	161	83,9	153	95,0	29,85	21,72	152	91,0	137	90,1	34,59	25,94	
FU Day 28	>6	174	90,6	152	87,4	33,15	26,13	153	91,6	144	94,1	33,29	24,81	
FU Month 3	>6	170	88,5	156	91,8	29,45	24,80	152	91,0	140	92,1	32,74	25,04	
FU Month 6	>6	155	80,7	139	89,7	27,98	24,20	132	79,0	117	88,6	30,82	25,94	
FU Month 9	>6	121	63,0	102	84,3	27,45	22,75	102	61,1	83	81,4	32,53	26,12	
FU Month 12	>6	90	46,9	80	88,9	28,75	23,43	83	49,7	72	86,7	30,56	25,42	
FU Month 15	>6	72	37,5	62	86,1	25,63	21,91	60	35,9	52	86,7	29,81	26,90	
FU Month 18	>6	56	29,2	48	85,7	26,50	22,75	41	24,6	35	85,4	33,33	25,42	
FU Month 21	>6	38	19,8	32	84,2	30,56	22,93	26	15,6	22	84,6	29,55	27,40	
FU Month 24	>6	24	12,5	18	75,0	32,10	21,86	11	6,6	11	100,0	26,26	27,79	
FU Month 27	>6	11	5,7	9	81,8	27,78	25,76	5	3,0	5	100,0	20,00	22,77	
FU Month 30	>6	7	3,6	6	85,7	29,63	25,01	0	NE	0	NE	NE	NE	
Calculated creatinine clearance cat. 2														

Screening	<70 ml/min	178	100,0	162	91,0	37,59	26,86	176	100,0	166	94,3	36,65	26,89
Cycle 4 Day 1	<70 ml/min	149	83,7	133	89,3	28,82	21,05	164	93,2	144	87,8	31,75	24,38
FU Day 28	<70 ml/min	162	91,0	142	87,7	31,34	23,22	166	94,3	146	88,0	30,40	25,05
FU Month 3	<70 ml/min	157	88,2	141	89,8	27,50	23,43	159	90,3	139	87,4	31,06	23,43
FU Month 6	<70 ml/min	144	80,9	127	88,2	26,51	22,00	139	79,0	122	87,8	28,60	23,61
FU Month 9	<70 ml/min	117	65,7	97	82,9	25,09	21,83	112	63,6	90	80,4	29,51	24,25
FU Month 12	<70 ml/min	92	51,7	79	85,9	28,41	22,56	87	49,4	73	83,9	27,85	23,21
FU Month 15	<70 ml/min	78	43,8	69	88,5	24,15	21,22	60	34,1	48	80,0	29,05	26,78
FU Month 18	<70 ml/min	59	33,1	51	86,4	30,61	25,10	43	24,4	36	83,7	31,48	26,63
FU Month 21	<70 ml/min	38	21,3	27	71,1	31,28	23,88	31	17,6	27	87,1	29,42	27,81
FU Month 24	<70 ml/min	24	13,5	19	79,2	32,16	24,82	13	7,4	12	92,3	17,59	16,72
FU Month 27	<70 ml/min	10	5,6	8	80,0	29,86	24,66	7	4,0	5	71,4	15,56	24,34
FU Month 30	<70 ml/min	5	2,8	4	80,0	36,11	29,22	1	0,6	1	100,0	0,00	NE
Screening	>=70 ml/min	77	100,0	76	98,7	35,38	24,51	66	100,0	62	93,9	39,96	23,59
Cycle 4 Day 1	>=70 ml/min	64	83,1	62	96,9	29,21	21,62	60	90,9	54	90,0	34,36	21,93
FU Day 28	>=70 ml/min	68	88,3	59	86,8	32,39	28,54	59	89,4	57	96,6	34,50	21,99
FU Month 3	>=70 ml/min	68	88,3	62	91,2	30,82	26,72	62	93,9	57	91,9	30,60	24,33
FU Month 6	>=70 ml/min	63	81,8	59	93,7	28,06	26,85	53	80,3	48	90,6	34,49	27,14
FU Month 9	>=70 ml/min	47	61,0	41	87,2	27,37	23,32	37	56,1	31	83,8	34,77	23,61
FU Month 12	>=70 ml/min	33	42,9	30	90,9	30,74	25,88	30	45,5	26	86,7	34,19	27,38
FU Month 15	>=70 ml/min	26	33,8	21	80,8	29,63	23,39	25	37,9	21	84,0	34,39	23,28
FU Month 18	>=70 ml/min	20	26,0	19	95,0	22,81	23,27	17	25,8	13	76,5	38,46	19,04
FU Month 21	>=70 ml/min	14	18,2	13	92,9	27,35	25,91	9	13,6	5	55,6	44,44	15,71
FU Month 24	>=70 ml/min	8	10,4	6	75,0	24,07	24,76	5	7,6	5	100,0	44,44	36,00
FU Month 27	>=70 ml/min	3	3,9	3	100,0	22,22	22,22	2	3,0	2	100,0	27,78	7,86
FU Month 30	>=70 ml/min	2	2,6	2	100,0	16,67	7,86	0	NE	0	NE	NE	NE
Beta2 microglobulin													
Screening	Missing	3	100,0	3	100,0	29,63	6,42	3	100,0	3	100,0	66,67	38,49
Cycle 4 Day 1	Missing	3	100,0	3	100,0	25,93	6,42	3	100,0	2	66,7	11,11	0,00
FU Day 28	Missing	3	100,0	3	100,0	22,22	11,11	3	100,0	2	66,7	11,11	15,71
FU Month 3	Missing	3	100,0	3	100,0	37,04	35,72	3	100,0	2	66,7	22,22	15,71
FU Month 6	Missing	3	100,0	3	100,0	14,81	12,83	3	100,0	2	66,7	11,11	15,71
FU Month 9	Missing	2	66,7	1	50,0	11,11	NE	3	100,0	2	66,7	16,67	23,57
FU Month 12	Missing	1	33,3	1	100,0	33,33	NE	2	66,7	1	50,0	0,00	NE
FU Month 15	Missing	1	33,3	1	100,0	33,33	NE	2	66,7	1	50,0	0,00	NE
FU Month 18	Missing	1	33,3	1	100,0	44,44	NE	2	66,7	1	50,0	0,00	NE
FU Month 21	Missing	1	33,3	1	100,0	44,44	NE	2	66,7	1	50,0	11,11	NE
FU Month 24	Missing	1	33,3	1	100,0	66,67	NE	1	33,3	1	100,0	0,00	NE

Screening	< 3.5 ug/mL	154	100,0	142	92,2	37,25	26,87	140	100,0	132	94,3	37,08	23,57
Cycle 4 Day 1	< 3.5 ug/mL	127	82,5	116	91,3	30,80	22,09	129	92,1	112	86,8	34,03	24,15
FU Day 28	< 3.5 ug/mL	137	89,0	121	88,3	32,37	24,85	132	94,3	121	91,7	33,52	24,00
FU Month 3	< 3.5 ug/mL	134	87,0	123	91,8	28,82	24,01	130	92,9	116	89,2	32,33	22,99
FU Month 6	< 3.5 ug/mL	128	83,1	114	89,1	27,19	22,90	120	85,7	111	92,5	32,53	24,66
FU Month 9	< 3.5 ug/mL	104	67,5	87	83,7	27,33	22,66	98	70,0	81	82,7	34,02	24,80
FU Month 12	< 3.5 ug/mL	78	50,6	69	88,5	29,47	24,32	75	53,6	67	89,3	33,83	25,62
FU Month 15	< 3.5 ug/mL	65	42,2	56	86,2	26,79	22,00	60	42,9	51	85,0	31,92	25,60
FU Month 18	< 3.5 ug/mL	46	29,9	41	89,1	29,67	25,39	43	30,7	35	81,4	36,83	25,82
FU Month 21	< 3.5 ug/mL	30	19,5	21	70,0	30,69	28,52	27	19,3	22	81,5	35,35	29,22
FU Month 24	< 3.5 ug/mL	19	12,3	15	78,9	28,15	20,94	12	8,6	11	91,7	26,26	24,48
FU Month 27	< 3.5 ug/mL	10	6,5	8	80,0	31,25	25,19	7	5,0	5	71,4	15,56	14,91
FU Month 30	< 3.5 ug/mL	5	3,2	4	80,0	38,89	26,45	1	0,7	1	100,0	0,00	NE
Screening	>= 3.5 ug/mL	98	100,0	93	94,9	36,56	25,40	99	100,0	93	93,9	37,28	28,64
Cycle 4 Day 1	>= 3.5 ug/mL	83	84,7	76	91,6	26,24	19,93	92	92,9	84	91,3	30,89	23,18
FU Day 28	>= 3.5 ug/mL	90	91,8	77	85,6	30,88	25,27	90	90,9	80	88,9	29,10	24,55
FU Month 3	>= 3.5 ug/mL	88	89,8	77	87,5	27,71	25,06	88	88,9	78	88,6	29,06	24,76
FU Month 6	>= 3.5 ug/mL	76	77,6	69	90,8	27,21	25,10	69	69,7	57	82,6	26,51	24,65
FU Month 9	>= 3.5 ug/mL	58	59,2	50	86,2	23,33	21,56	48	48,5	38	79,2	24,85	21,64
FU Month 12	>= 3.5 ug/mL	46	46,9	39	84,8	28,21	22,35	40	40,4	31	77,5	21,15	18,89
FU Month 15	>= 3.5 ug/mL	38	38,8	33	86,8	22,90	21,68	23	23,2	17	73,9	28,76	26,37
FU Month 18	>= 3.5 ug/mL	32	32,7	28	87,5	26,19	24,23	15	15,2	13	86,7	26,50	20,05
FU Month 21	>= 3.5 ug/mL	21	21,4	18	85,7	28,40	19,52	11	11,1	9	81,8	25,31	19,47
FU Month 24	>= 3.5 ug/mL	12	12,2	9	75,0	29,63	29,40	5	5,1	5	100,0	28,89	32,01
FU Month 27	>= 3.5 ug/mL	3	3,1	3	100,0	18,52	16,97	2	2,0	2	100,0	27,78	39,28
FU Month 30	>= 3.5 ug/mL	2	2,0	2	100,0	11,11	0,00	0	NE	0	NE	NE	NE
Immunoglobulin VH, cytogenetics 2													
Screening	12	45	100,0	43	95,6	40,57	26,41	44	100,0	43	97,7	38,11	28,29
Cycle 4 Day 1	12	34	75,6	32	94,1	27,78	20,20	38	86,4	33	86,8	35,02	24,24
FU Day 28	12	39	86,7	37	94,9	35,29	25,33	40	90,9	35	87,5	36,67	25,36
FU Month 3	12	38	84,4	36	94,7	30,56	23,06	39	88,6	32	82,1	37,85	23,76
FU Month 6	12	36	80,0	31	86,1	25,45	18,41	34	77,3	28	82,4	38,69	24,36
FU Month 9	12	26	57,8	22	84,6	25,25	17,88	28	63,6	18	64,3	39,51	21,97
FU Month 12	12	22	48,9	18	81,8	27,78	21,64	23	52,3	15	65,2	34,07	20,77
FU Month 15	12	17	37,8	14	82,4	24,60	22,72	17	38,6	12	70,6	42,59	29,14
FU Month 18	12	15	33,3	12	80,0	25,46	20,16	13	29,5	9	69,2	38,27	18,52
FU Month 21	12	10	22,2	8	80,0	37,50	26,52	7	15,9	5	71,4	31,11	19,88
FU Month 24	12	8	17,8	6	75,0	31,48	19,14	6	13,6	6	100,0	33,33	34,43
FU Month 27	12	5	11,1	4	80,0	40,28	31,87	2	4,5	2	100,0	11,11	15,71

FU Month 30	12	48,9	375,0	29,63	32,08	12,3	100,0	0,00	NE
Screening	11q-	46100,0	4393,5	27,39	17,37	43100,0	4093,0	36,11	21,61
Cycle 4 Day 1	11q-	4087,0	3997,5	24,50	18,59	4195,3	3585,4	26,03	22,70
FU Day 28	11q-	4291,3	3583,3	27,94	24,46	3990,7	3692,3	29,32	23,78
FU Month 3	11q-	4291,3	3890,5	26,02	24,54	3888,4	3694,7	26,54	23,65
FU Month 6	11q-	3882,6	3592,1	22,54	21,64	3274,4	2887,5	30,16	22,60
FU Month 9	11q-	2860,9	2692,9	22,22	21,77	2558,1	2184,0	35,19	27,52
FU Month 12	11q-	2043,5	1995,0	28,07	23,24	1841,9	1794,4	39,87	25,17
FU Month 15	11q-	1839,1	1688,9	19,44	20,08	1432,6	1071,4	29,44	14,83
FU Month 18	11q-	1532,6	1386,7	26,50	31,93	818,6	787,5	44,44	32,71
FU Month 21	11q-	1226,1	1191,7	26,26	22,37	49,3	250,0	44,44	31,43
FU Month 24	11q-	715,2	571,4	11,11	11,11	12,3	100,0	0,00	NE
FU Month 27	11q-	36,5	3100,0	18,52	16,97	0	NE	NE	NE
FU Month 30	11q-	36,5	3100,0	29,63	23,13	0	NE	NE	NE
Screening	13q-	79100,0	7392,4	35,16	28,02	75100,0	7093,3	34,29	24,50
Cycle 4 Day 1	13q-	6784,8	6089,6	29,63	21,81	6890,7	6088,2	28,52	21,49
FU Day 28	13q-	7291,1	6590,3	29,57	23,84	7296,0	6590,3	28,21	24,30
FU Month 3	13q-	7392,4	6791,8	29,02	23,82	6992,0	6188,4	31,33	24,80
FU Month 6	13q-	6784,8	6191,0	26,05	21,74	6384,0	5688,9	25,69	25,46
FU Month 9	13q-	5670,9	4987,5	25,62	22,70	5269,3	4280,8	25,79	23,28
FU Month 12	13q-	4455,7	3988,6	27,92	23,62	4053,3	3895,0	24,85	25,63
FU Month 15	13q-	3848,1	3386,8	26,26	22,88	2938,7	2586,2	27,11	29,06
FU Month 18	13q-	2835,4	2589,3	31,56	25,99	2128,0	1990,5	29,24	23,78
FU Month 21	13q-	1620,3	1381,3	32,48	25,44	1621,3	1487,5	22,22	23,87
FU Month 24	13q-	78,9	685,7	40,74	26,91	79,3	685,7	18,52	15,18
FU Month 27	13q-	22,5	150,0	22,22	NE	68,0	466,7	19,44	26,25
Screening	Norm. K.	65100,0	6193,8	43,90	25,79	58100,0	5594,8	46,67	29,04
Cycle 4 Day 1	Norm. K.	5483,1	4888,9	31,37	20,99	5594,8	5090,9	42,44	26,24
FU Day 28	Norm. K.	5990,8	5084,7	33,78	24,48	5391,4	5094,3	36,22	24,88
FU Month 3	Norm. K.	5483,1	4888,9	28,47	24,68	5493,1	4888,9	34,26	22,90
FU Month 6	Norm. K.	4975,4	4795,9	34,75	27,57	4577,6	4088,9	36,11	25,88
FU Month 9	Norm. K.	3960,0	3179,5	28,67	25,46	3051,7	2790,0	32,92	23,97
FU Month 12	Norm. K.	3249,2	2784,4	31,69	24,21	2441,4	2083,3	29,44	18,83
FU Month 15	Norm. K.	2640,0	2388,5	29,95	21,04	2034,5	1890,0	32,72	23,02
FU Month 18	Norm. K.	1827,7	1794,4	30,72	20,98	1525,9	1280,0	33,33	26,80
FU Month 21	Norm. K.	1218,5	650,0	31,48	23,74	1119,0	981,8	49,38	28,39
FU Month 24	Norm. K.	812,3	675,0	44,44	24,34	46,9	4100,0	30,56	27,78
FU Month 27	Norm. K.	34,6	3100,0	22,22	19,25	11,7	100,0	33,33	NE

Screening	Other Abn.	20	100,0	18	90,0	33,95	29,88	22	100,0	20	90,9	25,56	18,77
Cycle 4 Day 1	Other Abn.	18	90,0	16	88,9	32,29	27,23	22	100,0	20	90,9	26,39	16,41
FU Day 28	Other Abn.	18	90,0	14	77,8	33,33	31,12	21	95,5	17	81,0	24,84	18,23
FU Month 3	Other Abn.	18	90,0	14	77,8	27,78	32,25	21	95,5	19	90,5	17,84	15,34
FU Month 6	Other Abn.	17	85,0	12	70,6	18,52	28,56	18	81,8	18	100,0	18,52	16,61
FU Month 9	Other Abn.	15	75,0	10	66,7	27,78	21,75	14	63,6	13	92,9	23,93	21,68
FU Month 12	Other Abn.	7	35,0	6	85,7	31,48	30,97	12	54,5	9	75,0	22,22	30,93
FU Month 15	Other Abn.	5	25,0	4	80,0	19,44	22,91	5	22,7	4	80,0	11,11	15,71
FU Month 18	Other Abn.	3	15,0	3	100,0	11,11	19,25	3	13,6	2	66,7	11,11	0,00
FU Month 21	Other Abn.	2	10,0	2	100,0	0,00	0,00	2	9,1	2	100,0	8,33	11,79
FU Month 24	Other Abn.	2	10,0	2	100,0	0,00	0,00	0	NE	0	NE	NE	NE
Time from first diagnosis													
Screening	Missing	1	100,0	1	100,0	44,44	NE	0	NE	0	NE	NE	NE
Cycle 4 Day 1	Missing	1	100,0	1	100,0	33,33	NE	0	NE	0	NE	NE	NE
FU Day 28	Missing	1	100,0	1	100,0	11,11	NE	0	NE	0	NE	NE	NE
FU Month 3	Missing	1	100,0	1	100,0	11,11	NE	0	NE	0	NE	NE	NE
FU Month 6	Missing	1	100,0	1	100,0	11,11	NE	0	NE	0	NE	NE	NE
FU Month 9	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 12	Missing	1	100,0	1	100,0	11,11	NE	0	NE	0	NE	NE	NE
FU Month 15	Missing	1	100,0	1	100,0	22,22	NE	0	NE	0	NE	NE	NE
FU Month 18	Missing	1	100,0	1	100,0	11,11	NE	0	NE	0	NE	NE	NE
Screening	13 - 24 months	41	100,0	38	92,7	39,18	29,54	31	100,0	31	100,0	32,26	22,84
Cycle 4 Day 1	13 - 24 months	35	85,4	34	97,1	28,10	23,57	30	96,8	27	90,0	27,57	22,09
FU Day 28	13 - 24 months	38	92,7	33	86,8	31,14	25,61	30	96,8	27	90,0	21,81	13,25
FU Month 3	13 - 24 months	36	87,8	34	94,4	30,07	29,53	30	96,8	26	86,7	24,79	19,20
FU Month 6	13 - 24 months	36	87,8	33	91,7	19,19	24,10	30	96,8	25	83,3	23,56	23,86
FU Month 9	13 - 24 months	32	78,0	29	90,6	20,31	20,16	21	67,7	18	85,7	28,09	22,10
FU Month 12	13 - 24 months	21	51,2	18	85,7	20,99	20,13	16	51,6	14	87,5	19,05	15,97
FU Month 15	13 - 24 months	19	46,3	18	94,7	23,46	23,46	16	51,6	10	62,5	20,00	21,47
FU Month 18	13 - 24 months	14	34,1	13	92,9	25,21	22,29	10	32,3	8	80,0	25,00	22,81
FU Month 21	13 - 24 months	11	26,8	9	81,8	37,04	31,43	6	19,4	4	66,7	15,28	13,89
FU Month 24	13 - 24 months	8	19,5	5	62,5	51,11	28,97	3	9,7	3	100,0	0,00	0,00
FU Month 27	13 - 24 months	5	12,2	5	100,0	38,89	29,92	2	6,5	2	100,0	0,00	0,00
FU Month 30	13 - 24 months	3	7,3	3	100,0	44,44	29,40	1	3,2	1	100,0	0,00	NE
Screening	<= 12 months	60	100,0	57	95,0	39,18	27,79	70	100,0	69	98,6	36,47	24,91
Cycle 4 Day 1	<= 12 months	48	80,0	42	87,5	29,37	25,57	60	85,7	56	93,3	30,65	21,66
FU Day 28	<= 12 months	54	90,0	45	83,3	30,37	25,34	62	88,6	57	91,9	30,80	22,22

FU Month 3	<= 12 months	53	88,3	45	84,9	27,04	23,20	59	84,3	55	93,2	30,30	21,85
FU Month 6	<= 12 months	46	76,7	40	87,0	28,61	24,77	47	67,1	43	91,5	29,59	23,59
FU Month 9	<= 12 months	35	58,3	27	77,1	30,04	27,70	37	52,9	31	83,8	26,52	23,60
FU Month 12	<= 12 months	27	45,0	23	85,2	31,40	24,77	29	41,4	27	93,1	32,10	26,03
FU Month 15	<= 12 months	22	36,7	17	77,3	28,76	25,78	17	24,3	16	94,1	31,94	18,98
FU Month 18	<= 12 months	16	26,7	13	81,3	24,79	20,86	13	18,6	12	92,3	30,56	17,81
FU Month 21	<= 12 months	9	15,0	5	55,6	22,22	20,79	7	10,0	6	85,7	31,48	27,59
FU Month 24	<= 12 months	6	10,0	3	50,0	11,11	19,25	2	2,9	1	50,0	0,00	NE
FU Month 27	<= 12 months	1	1,7			NE	NE	1	1,4			NE	NE
FU Month 30	<= 12 months	1	1,7			NE	NE	0	NE			NE	NE
Screening	>24 months	153	100,0	142	92,8	35,29	24,55	141	100,0	128	90,8	39,41	27,28
Cycle 4 Day 1	>24 months	129	84,3	118	91,5	29,00	18,90	134	95,0	115	85,8	34,49	24,95
FU Day 28	>24 months	137	89,5	122	89,1	32,42	24,64	133	94,3	119	89,5	34,13	26,55
FU Month 3	>24 months	135	88,2	123	91,1	28,77	23,60	132	93,6	115	87,1	32,61	25,23
FU Month 6	>24 months	124	81,0	112	90,3	28,87	22,79	115	81,6	102	88,7	32,19	25,31
FU Month 9	>24 months	96	62,7	81	84,4	26,61	20,69	91	64,5	72	79,1	33,41	24,75
FU Month 12	>24 months	76	49,7	67	88,2	30,68	23,70	72	51,1	58	80,6	30,84	24,98
FU Month 15	>24 months	62	40,5	54	87,1	25,10	20,27	52	36,9	43	82,7	32,69	28,49
FU Month 18	>24 months	48	31,4	43	89,6	31,01	26,73	37	26,2	29	78,4	36,78	27,71
FU Month 21	>24 months	32	20,9	26	81,3	29,06	22,46	27	19,1	22	81,5	34,85	27,92
FU Month 24	>24 months	18	11,8	17	94,4	27,45	20,83	13	9,2	13	100,0	33,33	24,85
FU Month 27	>24 months	7	4,6	6	85,7	18,52	11,48	6	4,3	5	83,3	26,67	20,18
FU Month 30	>24 months	3	2,0	3	100,0	14,81	6,42	0	NE	0	NE	NE	NE
High circulating tumor burden													
Screening	Missing	0	NE	0	NE	NE	NE	2	100,0	1	50,0	44,44	NE
Cycle 4 Day 1	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	0,00	NE
FU Day 28	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	33,33	NE
FU Month 3	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	55,56	NE
FU Month 6	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	11,11	NE
FU Month 9	Missing	0	NE			NE	NE	1	50,0			NE	NE
Screening	<25x10**9 cells/L	60	100,0	55	91,7	38,28	27,27	67	100,0	64	95,5	38,54	24,80
Cycle 4 Day 1	<25x10**9 cells/L	50	83,3	44	88,0	31,06	21,24	61	91,0	52	85,2	31,62	24,44
FU Day 28	<25x10**9 cells/L	56	93,3	47	83,9	34,40	25,79	61	91,0	53	86,9	29,77	23,14
FU Month 3	<25x10**9 cells/L	54	90,0	47	87,0	29,79	24,42	59	88,1	50	84,7	30,00	23,68
FU Month 6	<25x10**9 cells/L	50	83,3	43	86,0	33,33	24,96	51	76,1	42	82,4	26,19	23,03
FU Month 9	<25x10**9 cells/L	36	60,0	27	75,0	28,40	24,52	41	61,2	30	73,2	27,59	24,61
FU Month 12	<25x10**9 cells/L	29	48,3	24	82,8	34,26	22,44	34	50,7	25	73,5	26,67	25,46
FU Month 15	<25x10**9 cells/L	24	40,0	19	79,2	30,99	20,81	23	34,3	15	65,2	27,04	22,89

FU Month 18	<25x10**9 cells/L	20	33,3	18	90,0	29,94	22,48	19	28,4	14	73,7	27,78	27,13
FU Month 21	<25x10**9 cells/L	14	23,3	10	71,4	38,89	22,98	10	14,9	8	80,0	15,97	16,65
FU Month 24	<25x10**9 cells/L	8	13,3	5	62,5	26,67	25,58	6	9,0	6	100,0	22,22	30,63
FU Month 27	<25x10**9 cells/L	4	6,7	3	75,0	42,59	36,99	1	1,5	1	100,0	0,00	NE
FU Month 30	<25x10**9 cells/L	4	6,7	3	75,0	44,44	29,40	1	1,5	1	100,0	0,00	NE
Screening	>=25x10**9 cells/L	195	100,0	183	93,8	36,46	25,80	173	100,0	163	94,2	37,12	26,63
Cycle 4 Day 1	>=25x10**9 cells/L	163	83,6	151	92,6	28,33	21,19	162	93,6	145	89,5	32,99	23,44
FU Day 28	>=25x10**9 cells/L	174	89,2	154	88,5	30,81	24,55	163	94,2	149	91,4	32,18	24,76
FU Month 3	>=25x10**9 cells/L	171	87,7	156	91,2	28,13	24,54	161	93,1	145	90,1	31,07	23,68
FU Month 6	>=25x10**9 cells/L	157	80,5	143	91,1	25,10	22,90	140	80,9	127	90,7	31,76	25,23
FU Month 9	>=25x10**9 cells/L	128	65,6	111	86,7	25,13	21,70	107	61,8	91	85,0	31,93	23,97
FU Month 12	>=25x10**9 cells/L	96	49,2	85	88,5	27,58	23,61	83	48,0	74	89,2	30,48	24,12
FU Month 15	>=25x10**9 cells/L	80	41,0	71	88,8	23,94	21,87	62	35,8	54	87,1	31,69	26,56
FU Month 18	>=25x10**9 cells/L	59	30,3	52	88,1	27,99	25,61	41	23,7	35	85,4	35,56	23,92
FU Month 21	>=25x10**9 cells/L	38	19,5	30	78,9	27,04	24,36	30	17,3	24	80,0	37,04	27,54
FU Month 24	>=25x10**9 cells/L	24	12,3	20	83,3	31,11	24,87	12	6,9	11	91,7	27,27	24,53
FU Month 27	>=25x10**9 cells/L	9	4,6	8	88,9	22,22	15,71	8	4,6	6	75,0	22,22	21,08
FU Month 30	>=25x10**9 cells/L	3	1,5	3	100,0	14,81	6,42	0	NE	0	NE	NE	NE

¹ in study: number of subjects in study at respective visit; % based on baseline

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit

² mean: descriptive statistics - absolute values Clinical

cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/t_pro_mean.sas

Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/t_pro_mean_sg_EQC30_IT_label_09MAY2013_21004.xls 04MAR2020

17:18

POPULATION: Labelpopulation, Intent-to-Treat Patients ENDPOINT: EORTC QoL 30

MODEL: Unadjusted Analysis STUDY: CLL11(BO21004), Stage

2

Compliance/Mean

Financial Difficulties Scale

		GClb (N=255)						RClb (N=242)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study ¹	%	with value ¹	%	Mean ²	SD (mean)	in study ¹	%	with value ¹	%	Mean ²	SD (mean)
All													
Screening	n/a	255	100,0	239	93,7	9,07	19,24	242	100,0	224	92,6	8,04	18,27
Cycle 4 Day 1	n/a	213	83,5	196	92,0	7,14	16,71	224	92,6	193	86,2	8,64	19,70
FU Day 28	n/a	230	90,2	199	86,5	9,55	21,01	225	93,0	200	88,9	8,33	19,12
FU Month 3	n/a	225	88,2	202	89,8	10,56	23,48	221	91,3	194	87,8	10,14	22,13
FU Month 6	n/a	207	81,2	186	89,9	7,17	19,51	192	79,3	167	87,0	9,78	21,12
FU Month 9	n/a	164	64,3	138	84,1	5,80	16,56	149	61,6	119	79,9	7,56	16,49
FU Month 12	n/a	125	49,0	109	87,2	6,12	15,82	117	48,3	98	83,8	6,80	17,88
FU Month 15	n/a	104	40,8	91	87,5	7,69	19,29	85	35,1	69	81,2	6,28	16,44
FU Month 18	n/a	79	31,0	69	87,3	6,76	18,59	60	24,8	48	80,0	8,33	17,53
FU Month 21	n/a	52	20,4	40	76,9	5,00	14,22	40	16,5	32	80,0	11,46	20,05
FU Month 24	n/a	32	12,5	25	78,1	8,00	17,43	18	7,4	16	88,9	8,33	14,91
FU Month 27	n/a	13	5,1	11	84,6	6,06	13,48	9	3,7	7	77,8	0,00	0,00
FU Month 30	n/a	7	2,7	6	85,7	11,11	27,22	1	0,4	1	100,0	0,00	NE
Gender													
Screening	Female	97	100,0	89	91,8	8,99	17,95	95	100,0	85	89,5	8,24	18,48
Cycle 4 Day 1	Female	84	86,6	77	91,7	9,09	18,45	88	92,6	77	87,5	9,52	19,39
FU Day 28	Female	90	92,8	81	90,0	8,64	18,09	91	95,8	78	85,7	9,83	20,18
FU Month 3	Female	88	90,7	81	92,0	11,52	23,07	87	91,6	76	87,4	11,40	23,45
FU Month 6	Female	84	86,6	72	85,7	10,19	22,12	77	81,1	67	87,0	9,95	18,36
FU Month 9	Female	70	72,2	59	84,3	9,04	21,29	61	64,2	46	75,4	9,42	18,14
FU Month 12	Female	56	57,7	49	87,5	8,16	18,67	47	49,5	39	83,0	7,69	20,89
FU Month 15	Female	47	48,5	41	87,2	13,01	25,69	33	34,7	28	84,8	8,33	19,51
FU Month 18	Female	34	35,1	29	85,3	12,64	25,84	26	27,4	21	80,8	11,11	21,94
FU Month 21	Female	21	21,6	15	71,4	8,89	19,79	17	17,9	15	88,2	11,11	20,57
FU Month 24	Female	12	12,4	10	83,3	10,00	22,50	6	6,3	5	83,3	0,00	0,00

FU Month 27	Female	6	6,2	5	83,3	6,67	14,91	2	2,1	1	50,0	0,00	NE
FU Month 30	Female	4	4,1	3	75,0	22,22	38,49	1	1,1	1	100,0	0,00	NE
Screening	Male	158	100,0	150	94,9	9,11	20,03	147	100,0	139	94,6	7,91	18,21
Cycle 4 Day 1	Male	129	81,6	119	92,2	5,88	15,43	136	92,5	116	85,3	8,05	19,96
FU Day 28	Male	140	88,6	118	84,3	10,17	22,86	134	91,2	122	91,0	7,38	18,44
FU Month 3	Male	137	86,7	121	88,3	9,92	23,82	134	91,2	118	88,1	9,32	21,30
FU Month 6	Male	123	77,8	114	92,7	5,26	17,50	115	78,2	100	87,0	9,67	22,87
FU Month 9	Male	94	59,5	79	84,0	3,38	11,44	88	59,9	73	83,0	6,39	15,37
FU Month 12	Male	69	43,7	60	87,0	4,44	12,97	70	47,6	59	84,3	6,21	15,75
FU Month 15	Male	57	36,1	50	87,7	3,33	10,10	52	35,4	41	78,8	4,88	14,07
FU Month 18	Male	45	28,5	40	88,9	2,50	8,89	34	23,1	27	79,4	6,17	13,19
FU Month 21	Male	31	19,6	25	80,6	2,67	9,23	23	15,6	17	73,9	11,76	20,21
FU Month 24	Male	20	12,7	15	75,0	6,67	13,80	12	8,2	11	91,7	12,12	16,82
FU Month 27	Male	7	4,4	6	85,7	5,56	13,61	7	4,8	6	85,7	0,00	0,00
FU Month 30	Male	3	1,9	3	100,0	0,00	0,00	0	NE	0	NE	NE	NE
Age													
Screening	<75 years	130	100,0	123	94,6	9,49	18,86	120	100,0	109	90,8	8,56	18,92
Cycle 4 Day 1	<75 years	106	81,5	100	94,3	10,00	19,82	112	93,3	97	86,6	9,97	22,13
FU Day 28	<75 years	119	91,5	105	88,2	11,11	21,52	110	91,7	103	93,6	11,33	22,65
FU Month 3	<75 years	116	89,2	106	91,4	11,95	23,99	109	90,8	99	90,8	12,79	25,07
FU Month 6	<75 years	108	83,1	98	90,7	8,84	21,16	99	82,5	88	88,9	11,74	24,78
FU Month 9	<75 years	85	65,4	73	85,9	6,39	17,26	74	61,7	62	83,8	8,06	16,73
FU Month 12	<75 years	63	48,5	59	93,7	7,34	17,58	60	50,0	53	88,3	6,92	15,13
FU Month 15	<75 years	54	41,5	47	87,0	9,93	22,96	44	36,7	35	79,5	7,62	18,23
FU Month 18	<75 years	43	33,1	39	90,7	6,84	20,49	27	22,5	22	81,5	7,58	14,30
FU Month 21	<75 years	26	20,0	22	84,6	4,55	11,71	17	14,2	13	76,5	12,82	21,68
FU Month 24	<75 years	18	13,8	14	77,8	7,14	14,19	6	5,0	5	83,3	6,67	14,91
FU Month 27	<75 years	7	5,4	5	71,4	13,33	18,26	2	1,7	1	50,0	0,00	NE
FU Month 30	<75 years	4	3,1	3	75,0	22,22	38,49	0	NE	0	NE	NE	NE
Screening	>=75 years	125	100,0	116	92,8	8,62	19,72	122	100,0	115	94,3	7,54	17,69
Cycle 4 Day 1	>=75 years	107	85,6	96	89,7	4,17	12,09	112	91,8	96	85,7	7,29	16,90
FU Day 28	>=75 years	111	88,8	94	84,7	7,80	20,41	115	94,3	97	84,3	5,15	13,89
FU Month 3	>=75 years	109	87,2	96	88,1	9,03	22,93	112	91,8	95	84,8	7,37	18,31
FU Month 6	>=75 years	99	79,2	88	88,9	5,30	17,42	93	76,2	79	84,9	7,59	15,97
FU Month 9	>=75 years	79	63,2	65	82,3	5,13	15,85	75	61,5	57	76,0	7,02	16,35
FU Month 12	>=75 years	62	49,6	50	80,6	4,67	13,49	57	46,7	45	78,9	6,67	20,84
FU Month 15	>=75 years	50	40,0	44	88,0	5,30	14,28	41	33,6	34	82,9	4,90	14,52
FU Month 18	>=75 years	36	28,8	30	83,3	6,67	16,14	33	27,0	26	78,8	8,97	20,13

FU Month 21	>=75 years	26	20,8	18	69,2	5,56	17,15	23	18,9	19	82,6	10,53	19,41
FU Month 24	>=75 years	14	11,2	11	78,6	9,09	21,56	12	9,8	11	91,7	9,09	15,57
FU Month 27	>=75 years	6	4,8	6	100,0	0,00	0,00	7	5,7	6	85,7	0,00	0,00
FU Month 30	>=75 years	3	2,4	3	100,0	0,00	0,00	1	0,8	1	100,0	0,00	NE
Race													
Screening	Other	9	100,0	9	100,0	18,52	33,79	11	100,0	11	100,0	15,15	27,34
Cycle 4 Day 1	Other	7	77,8	7	100,0	23,81	37,09	10	90,9	9	90,0	33,33	37,27
FU Day 28	Other	8	88,9	8	100,0	25,00	34,50	10	90,9	10	100,0	20,00	35,83
FU Month 3	Other	8	88,9	7	87,5	19,05	37,80	10	90,9	10	100,0	26,67	37,84
FU Month 6	Other	8	88,9	7	87,5	33,33	47,14	8	72,7	8	100,0	20,83	35,36
FU Month 9	Other	4	44,4	3	75,0	11,11	19,25	5	45,5	4	80,0	0,00	0,00
FU Month 12	Other	3	33,3	2	66,7	16,67	23,57	4	36,4	4	100,0	8,33	16,67
FU Month 15	Other	2	22,2	1	50,0	33,33	NE	4	36,4	4	100,0	8,33	16,67
FU Month 18	Other	2	22,2	1	50,0	0,00	NE	2	18,2	2	100,0	16,67	23,57
FU Month 21	Other	2	22,2	1	50,0	0,00	NE	2	18,2	2	100,0	16,67	23,57
FU Month 24	Other	2	22,2	1	50,0	0,00	NE	1	9,1	0	NE	NE	NE
FU Month 27	Other	1	11,1			NE	NE	1	9,1			NE	NE
FU Month 30	Other	1	11,1			NE	NE	0	NE			NE	NE
Geographical Region													
Screening	White	246	100,0	230	93,5	8,70	18,48	231	100,0	213	92,2	7,67	17,69
Cycle 4 Day 1	White	206	83,7	189	91,7	6,53	15,33	214	92,6	184	86,0	7,43	17,75
FU Day 28	White	222	90,2	191	86,0	8,90	20,14	215	93,1	190	88,4	7,72	17,79
FU Month 3	White	217	88,2	195	89,9	10,26	22,90	211	91,3	184	87,2	9,24	20,74
FU Month 6	White	199	80,9	179	89,9	6,15	17,11	184	79,7	159	86,4	9,22	20,17
FU Month 9	White	160	65,0	135	84,4	5,68	16,56	144	62,3	115	79,9	7,83	16,71
FU Month 12	White	122	49,6	107	87,7	5,92	15,74	113	48,9	94	83,2	6,74	18,01
FU Month 15	White	102	41,5	90	88,2	7,41	19,21	81	35,1	65	80,2	6,15	16,55
FU Month 18	White	77	31,3	68	88,3	6,86	18,71	58	25,1	46	79,3	7,97	17,48
FU Month 21	White	50	20,3	39	78,0	5,13	14,38	38	16,5	30	78,9	11,11	20,22
FU Month 24	White	30	12,2	24	80,0	8,33	17,72	17	7,4	16	94,1	8,33	14,91
FU Month 27	White	12	4,9	11	91,7	6,06	13,48	8	3,5	7	87,5	0,00	0,00
FU Month 30	White	6	2,4	6	100,0	11,11	27,22	1	0,4	1	100,0	0,00	NE
Geographical Region													
Screening	Asia-Pacific	20	100,0	20	100,0	11,67	27,09	18	100,0	17	94,4	7,84	22,14
Cycle 4 Day 1	Asia-Pacific	15	75,0	15	100,0	6,67	13,80	16	88,9	15	93,8	11,11	20,57
FU Day 28	Asia-Pacific	18	90,0	18	100,0	18,52	26,13	18	100,0	16	88,9	6,25	18,13
FU Month 3	Asia-Pacific	18	90,0	16	88,9	12,50	26,87	18	100,0	16	88,9	8,33	19,25
FU Month 6	Asia-Pacific	16	80,0	14	87,5	11,90	30,96	17	94,4	15	88,2	15,56	27,79
FU Month 9	Asia-Pacific	14	70,0	12	85,7	5,56	19,25	13	72,2	9	69,2	3,70	11,11

FU Month 12	Asia-Pacific	10	50,0	8	80,0	0,00	0,00	10	55,6	10	100,0	6,67	14,05
FU Month 15	Asia-Pacific	8	40,0	6	75,0	5,56	13,61	9	50,0	9	100,0	3,70	11,11
FU Month 18	Asia-Pacific	6	30,0	4	66,7	0,00	0,00	6	33,3	6	100,0	11,11	17,21
FU Month 21	Asia-Pacific	5	25,0	3	60,0	0,00	0,00	4	22,2	4	100,0	33,33	27,22
FU Month 24	Asia-Pacific	3	15,0	2	66,7	0,00	0,00	1	5,6	0	NE	NE	NE
FU Month 27	Asia-Pacific	1	5,0			NE	NE	1	5,6			NE	NE
FU Month 30	Asia-Pacific	1	5,0			NE	NE	0	NE			NE	NE
Screening	Central and South America	3	100,0	3	100,0	11,11	19,25	2	100,0	2	100,0	33,33	0,00
Cycle 4 Day 1	Central and South America	3	100,0	3	100,0	22,22	19,25	2	100,0	2	100,0	16,67	23,57
FU Day 28	Central and South America	3	100,0	3	100,0	22,22	19,25	2	100,0	2	100,0	0,00	0,00
FU Month 3	Central and South America	3	100,0	3	100,0	22,22	19,25	2	100,0	2	100,0	0,00	0,00
FU Month 6	Central and South America	2	66,7	2	100,0	16,67	23,57	2	100,0	2	100,0	0,00	0,00
FU Month 9	Central and South America	2	66,7	2	100,0	16,67	23,57	1	50,0	1	100,0	0,00	NE
FU Month 12	Central and South America	2	66,7	2	100,0	33,33	0,00	1	50,0	1	100,0	0,00	NE
FU Month 15	Central and South America	1	33,3	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 18	Central and South America	1	33,3	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 21	Central and South America	1	33,3	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 24	Central and South America	1	33,3	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
Screening	North America	12	100,0	12	100,0	5,56	12,97	13	100,0	12	92,3	2,78	9,62
Cycle 4 Day 1	North America	9	75,0	9	100,0	7,41	14,70	12	92,3	11	91,7	0,00	0,00
FU Day 28	North America	11	91,7	11	100,0	9,09	15,57	13	100,0	13	100,0	2,56	9,25
FU Month 3	North America	11	91,7	11	100,0	18,18	31,14	12	92,3	11	91,7	0,00	0,00
FU Month 6	North America	11	91,7	10	90,9	3,33	10,54	11	84,6	11	100,0	6,06	13,48
FU Month 9	North America	8	66,7	8	100,0	0,00	0,00	9	69,2	9	100,0	3,70	11,11
FU Month 12	North America	8	66,7	7	87,5	4,76	12,60	7	53,8	7	100,0	4,76	12,60
FU Month 15	North America	6	50,0	6	100,0	5,56	13,61	6	46,2	5	83,3	0,00	0,00
FU Month 18	North America	4	33,3	4	100,0	8,33	16,67	3	23,1	3	100,0	11,11	19,25
FU Month 21	North America	3	25,0	2	66,7	16,67	23,57	1	7,7	1	100,0	0,00	NE
FU Month 24	North America	3	25,0	2	66,7	33,33	0,00	1	7,7	1	100,0	33,33	NE
FU Month 27	North America	2	16,7	1	50,0	0,00	NE	1	7,7	1	100,0	0,00	NE
Screening	Other	45	100,0	41	91,1	19,51	24,69	44	100,0	41	93,2	11,38	20,56
Cycle 4 Day 1	Other	37	82,2	33	89,2	12,12	21,76	40	90,9	34	85,0	14,71	27,45
FU Day 28	Other	37	82,2	33	89,2	10,10	25,66	39	88,6	37	94,9	15,32	28,97
FU Month 3	Other	38	84,4	34	89,5	13,73	27,36	38	86,4	36	94,7	15,74	28,16
FU Month 6	Other	35	77,8	31	88,6	11,83	26,59	33	75,0	31	93,9	12,90	26,77
FU Month 9	Other	26	57,8	22	84,6	4,55	11,71	24	54,5	19	79,2	7,02	13,96
FU Month 12	Other	17	37,8	16	94,1	8,33	19,25	16	36,4	14	87,5	7,14	14,19
FU Month 15	Other	12	26,7	11	91,7	6,06	13,48	9	20,5	8	88,9	4,17	11,79

FU Month 18	Other	10	22,2	9	90,0	3,70	11,11	7	15,9	6	85,7	5,56	13,61
FU Month 21	Other	7	15,6	6	85,7	5,56	13,61	4	9,1	4	100,0	0,00	0,00
FU Month 24	Other	6	13,3	5	83,3	6,67	14,91	3	6,8	3	100,0	11,11	19,25
FU Month 27	Other	4	8,9	4	100,0	8,33	16,67	1	2,3	1	100,0	0,00	NE
FU Month 30	Other	2	4,4	2	100,0	33,33	47,14	0	NE	0	NE	NE	NE
Screening	Western Europe	175	100,0	163	93,1	6,34	15,95	165	100,0	152	92,1	7,24	17,55
Cycle 4 Day 1	Western Europe	149	85,1	136	91,3	5,64	15,48	154	93,3	131	85,1	7,38	17,68
FU Day 28	Western Europe	161	92,0	134	83,2	7,96	19,25	153	92,7	132	86,3	7,32	16,12
FU Month 3	Western Europe	155	88,6	138	89,0	8,70	21,43	151	91,5	129	85,4	9,82	21,41
FU Month 6	Western Europe	143	81,7	129	90,2	5,68	16,20	129	78,2	108	83,7	8,64	18,99
FU Month 9	Western Europe	114	65,1	94	82,5	6,38	17,81	102	61,8	81	79,4	8,64	18,09
FU Month 12	Western Europe	88	50,3	76	86,4	5,70	15,77	83	50,3	66	79,5	7,07	19,84
FU Month 15	Western Europe	77	44,0	67	87,0	8,46	21,20	61	37,0	47	77,0	7,80	18,67
FU Month 18	Western Europe	58	33,1	51	87,9	7,84	20,64	44	26,7	33	75,0	8,08	18,69
FU Month 21	Western Europe	36	20,6	28	77,8	4,76	14,95	31	18,8	23	74,2	10,14	18,63
FU Month 24	Western Europe	19	10,9	15	78,9	6,67	18,69	13	7,9	12	92,3	5,56	12,97
FU Month 27	Western Europe	6	3,4	6	100,0	5,56	13,61	6	3,6	5	83,3	0,00	0,00
FU Month 30	Western Europe	4	2,3	4	100,0	0,00	0,00	1	0,6	1	100,0	0,00	NE
FCgamma receptor IIa													
Screening	131HH	58	100,0	53	91,4	8,18	17,18	76	100,0	72	94,7	10,19	19,89
Cycle 4 Day 1	131HH	49	84,5	43	87,8	6,98	13,72	65	85,5	59	90,8	9,60	22,36
FU Day 28	131HH	51	87,9	46	90,2	10,87	21,15	70	92,1	61	87,1	8,74	20,09
FU Month 3	131HH	51	87,9	46	90,2	11,59	22,46	64	84,2	54	84,4	10,49	24,93
FU Month 6	131HH	49	84,5	43	87,8	8,53	19,37	55	72,4	48	87,3	10,42	25,87
FU Month 9	131HH	39	67,2	30	76,9	10,00	21,71	41	53,9	32	78,0	3,13	9,87
FU Month 12	131HH	28	48,3	24	85,7	11,11	18,82	34	44,7	29	85,3	3,45	13,64
FU Month 15	131HH	23	39,7	19	82,6	15,79	28,04	24	31,6	20	83,3	3,33	10,26
FU Month 18	131HH	17	29,3	14	82,4	14,29	21,54	16	21,1	12	75,0	5,56	12,97
FU Month 21	131HH	13	22,4	8	61,5	12,50	24,80	11	14,5	10	90,9	16,67	23,57
FU Month 24	131HH	11	19,0	7	63,6	9,52	25,20	1	1,3	1	100,0	0,00	NE
FU Month 27	131HH	4	6,9	3	75,0	0,00	0,00	1	1,3	1	100,0	0,00	NE
FU Month 30	131HH	3	5,2	2	66,7	0,00	0,00	0	NE	0	NE	NE	NE
Screening	131HR	125	100,0	117	93,6	10,83	20,91	114	100,0	107	93,9	4,36	13,02
Cycle 4 Day 1	131HR	105	84,0	98	93,3	6,12	14,63	110	96,5	97	88,2	7,90	18,49
FU Day 28	131HR	116	92,8	100	86,2	9,00	20,02	105	92,1	94	89,5	8,87	19,66
FU Month 3	131HR	114	91,2	102	89,5	8,50	20,81	107	93,9	94	87,9	10,28	21,88
FU Month 6	131HR	104	83,2	93	89,4	5,38	16,51	95	83,3	83	87,4	10,44	20,78
FU Month 9	131HR	84	67,2	71	84,5	4,23	12,51	76	66,7	60	78,9	9,44	18,51

FU Month 12	131HR	64	51,2	57	89,1	5,85	16,81	57	50,0	48	84,2	9,72	21,70
FU Month 15	131HR	53	42,4	45	84,9	4,44	11,46	44	38,6	35	79,5	6,67	15,76
FU Month 18	131HR	43	34,4	37	86,0	4,50	13,97	32	28,1	26	81,3	10,26	20,59
FU Month 21	131HR	26	20,8	20	76,9	5,00	12,21	21	18,4	16	76,2	12,50	20,64
FU Month 24	131HR	12	9,6	11	91,7	12,12	16,82	12	10,5	10	83,3	10,00	16,10
FU Month 27	131HR	6	4,8	5	83,3	13,33	18,26	6	5,3	4	66,7	0,00	0,00
FU Month 30	131HR	3	2,4	3	100,0	22,22	38,49	1	0,9	1	100,0	0,00	NE
Screening	131RR	49	100,0	48	98,0	6,94	18,14	33	100,0	28	84,8	9,52	19,99
Cycle 4 Day 1	131RR	40	81,6	38	95,0	10,53	23,39	31	93,9	24	77,4	2,78	9,41
FU Day 28	131RR	42	85,7	35	83,3	10,48	26,53	32	97,0	29	90,6	4,60	14,70
FU Month 3	131RR	39	79,6	37	94,9	15,32	32,96	32	97,0	29	90,6	2,30	8,60
FU Month 6	131RR	35	71,4	33	94,3	10,10	26,98	27	81,8	22	81,5	6,06	13,16
FU Month 9	131RR	24	49,0	22	91,7	7,58	22,84	19	57,6	17	89,5	7,84	14,57
FU Month 12	131RR	18	36,7	17	94,4	3,92	11,07	17	51,5	14	82,4	4,76	12,10
FU Month 15	131RR	16	32,7	16	100,0	8,33	25,82	11	33,3	9	81,8	7,41	22,22
FU Month 18	131RR	14	28,6	14	100,0	7,14	26,73	8	24,2	7	87,5	4,76	12,60
FU Month 21	131RR	8	16,3	7	87,5	0,00	0,00	5	15,2	4	80,0	0,00	0,00
FU Month 24	131RR	5	10,2	4	80,0	0,00	0,00	3	9,1	3	100,0	0,00	0,00
FU Month 27	131RR	2	4,1	2	100,0	0,00	0,00	1	3,0	1	100,0	0,00	NE
FU Month 30	131RR	1	2,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
Screening	Missing	23	100,0	21	91,3	6,35	17,06	19	100,0	17	89,5	19,61	29,01
Cycle 4 Day 1	Missing	19	82,6	17	89,5	5,88	17,62	18	94,7	13	72,2	20,51	25,60
FU Day 28	Missing	21	91,3	18	85,7	7,41	14,26	18	94,7	16	88,9	10,42	20,07
FU Month 3	Missing	21	91,3	17	81,0	9,80	15,66	18	94,7	17	94,4	21,57	26,20
FU Month 6	Missing	19	82,6	17	89,5	7,84	18,74	15	78,9	14	93,3	9,52	15,63
FU Month 9	Missing	17	73,9	15	88,2	2,22	8,61	13	68,4	10	76,9	10,00	22,50
FU Month 12	Missing	15	65,2	11	73,3	0,00	0,00	9	47,4	7	77,8	4,76	12,60
FU Month 15	Missing	12	52,2	11	91,7	6,06	13,48	6	31,6	5	83,3	13,33	29,81
FU Month 18	Missing	5	21,7	4	80,0	0,00	0,00	4	21,1	3	75,0	11,11	19,25
FU Month 21	Missing	5	21,7	5	100,0	0,00	0,00	3	15,8	2	66,7	0,00	0,00
FU Month 24	Missing	4	17,4	3	75,0	0,00	0,00	2	10,5	2	100,0	16,67	23,57
FU Month 27	Missing	1	4,3	1	100,0	0,00	NE	1	5,3	1	100,0	0,00	NE
FCgamma receptor IIIa													
Screening	158FF	103	100,0	100	97,1	9,67	21,86	83	100,0	76	91,6	5,70	14,80
Cycle 4 Day 1	158FF	89	86,4	83	93,3	8,84	19,54	78	94,0	68	87,2	8,33	19,42
FU Day 28	158FF	96	93,2	84	87,5	9,13	20,92	78	94,0	73	93,6	7,76	18,86
FU Month 3	158FF	94	91,3	84	89,4	14,68	29,88	78	94,0	70	89,7	5,71	16,02
FU Month 6	158FF	86	83,5	76	88,4	7,89	20,99	64	77,1	58	90,6	7,47	18,78

FU Month 9	158FF	71	68,9	59	83,1	8,47	21,97	47	56,6	43	91,5	7,75	14,25
FU Month 12	158FF	48	46,6	42	87,5	6,35	15,16	38	45,8	34	89,5	2,94	9,60
FU Month 15	158FF	37	35,9	32	86,5	9,38	22,77	30	36,1	24	80,0	5,56	12,69
FU Month 18	158FF	27	26,2	24	88,9	11,11	25,38	21	25,3	16	76,2	2,08	8,33
FU Month 21	158FF	16	15,5	15	93,8	6,67	13,80	9	10,8	8	88,9	12,50	17,25
FU Month 24	158FF	8	7,8	7	87,5	14,29	17,82	3	3,6	2	66,7	16,67	23,57
FU Month 27	158FF	5	4,9	4	80,0	8,33	16,67	1	1,2	1	100,0	0,00	NE
FU Month 30	158FF	3	2,9	3	100,0	0,00	0,00	0	NE	0	NE	NE	NE
Screening	158FV	119	100,0	109	91,6	9,48	17,62	109	100,0	102	93,6	9,15	19,99
Cycle 4 Day 1	158FV	99	83,2	90	90,9	5,19	13,14	100	91,7	85	85,0	8,63	21,30
FU Day 28	158FV	105	88,2	89	84,8	8,99	19,95	101	92,7	87	86,1	9,58	20,90
FU Month 3	158FV	101	84,9	92	91,1	7,61	17,89	97	89,0	84	86,6	10,71	23,23
FU Month 6	158FV	94	79,0	85	90,4	7,06	19,31	83	76,1	72	86,7	11,11	22,38
FU Month 9	158FV	71	59,7	61	85,9	3,28	10,01	65	59,6	49	75,4	6,80	16,64
FU Month 12	158FV	60	50,4	55	91,7	6,67	17,45	52	47,7	42	80,8	11,11	24,04
FU Month 15	158FV	52	43,7	46	88,5	7,25	18,48	36	33,0	30	83,3	8,89	21,32
FU Month 18	158FV	44	37,0	38	86,4	5,26	14,55	24	22,0	20	83,3	15,00	22,88
FU Month 21	158FV	28	23,5	18	64,3	5,56	17,15	18	16,5	14	77,8	14,29	25,20
FU Month 24	158FV	18	15,1	13	72,2	7,69	19,97	6	5,5	5	83,3	6,67	14,91
FU Month 27	158FV	6	5,0	5	83,3	6,67	14,91	2	1,8	1	50,0	0,00	NE
FU Month 30	158FV	4	3,4	3	75,0	22,22	38,49	0	NE	0	NE	NE	NE
Screening	158VV	16	100,0	15	93,8	2,22	8,61	33	100,0	31	93,9	5,38	12,46
Cycle 4 Day 1	158VV	12	75,0	11	91,7	6,06	13,48	30	90,9	28	93,3	7,14	13,93
FU Day 28	158VV	14	87,5	13	92,9	12,82	32,03	30	90,9	26	86,7	7,69	17,15
FU Month 3	158VV	15	93,8	12	80,0	2,78	9,62	30	90,9	25	83,3	16,00	29,06
FU Month 6	158VV	14	87,5	13	92,9	0,00	0,00	30	90,9	23	76,7	10,14	25,49
FU Month 9	158VV	12	75,0	10	83,3	6,67	14,05	25	75,8	18	72,0	7,41	18,28
FU Month 12	158VV	8	50,0	7	87,5	4,76	12,60	20	60,6	17	85,0	3,92	11,07
FU Month 15	158VV	8	50,0	7	87,5	4,76	12,60	14	42,4	11	78,6	3,03	10,05
FU Month 18	158VV	4	25,0	4	100,0	0,00	0,00	11	33,3	9	81,8	3,70	11,11
FU Month 21	158VV	3	18,8	2	66,7	0,00	0,00	9	27,3	7	77,8	9,52	16,27
FU Month 24	158VV	2	12,5	2	100,0	0,00	0,00	7	21,2	7	100,0	4,76	12,60
FU Month 27	158VV	1	6,3	1	100,0	0,00	NE	5	15,2	4	80,0	0,00	0,00
FU Month 30	158VV	0	NE	0	NE	NE	NE	1	3,0	1	100,0	0,00	NE
Screening	Missing	17	100,0	15	88,2	8,89	19,79	17	100,0	15	88,2	17,78	27,79
Cycle 4 Day 1	Missing	13	76,5	12	92,3	11,11	21,71	16	94,1	12	75,0	13,89	22,29
FU Day 28	Missing	15	88,2	13	86,7	12,82	16,88	16	94,1	14	87,5	4,76	12,10
FU Month 3	Missing	15	88,2	14	93,3	11,90	16,57	16	94,1	15	93,8	17,78	24,77

FU Month 6	Missing	13	76,5	12	92,3	11,11	21,71	15	88,2	14	93,3	11,90	16,57
FU Month 9	Missing	10	58,8	8	80,0	4,17	11,79	12	70,6	9	75,0	11,11	23,57
FU Month 12	Missing	9	52,9	5	55,6	0,00	0,00	7	41,2	5	71,4	6,67	14,91
FU Month 15	Missing	7	41,2	6	85,7	5,56	13,61	5	29,4	4	80,0	0,00	0,00
FU Month 18	Missing	4	23,5	3	75,0	0,00	0,00	4	23,5	3	75,0	11,11	19,25
FU Month 21	Missing	5	29,4	5	100,0	0,00	0,00	4	23,5	3	75,0	0,00	0,00
FU Month 24	Missing	4	23,5	3	75,0	0,00	0,00	2	11,8	2	100,0	16,67	23,57
FU Month 27	Missing	1	5,9	1	100,0	0,00	NE	1	5,9	1	100,0	0,00	NE
Binet Staging at baseline													
Screening	A	59	100,0	57	96,6	8,77	19,44	57	100,0	52	91,2	8,97	19,93
Cycle 4 Day 1	A	51	86,4	48	94,1	8,33	17,53	54	94,7	50	92,6	6,67	16,50
FU Day 28	A	58	98,3	53	91,4	10,69	21,46	54	94,7	51	94,4	5,88	15,92
FU Month 3	A	57	96,6	56	98,2	10,71	21,18	53	93,0	50	94,3	13,33	26,94
FU Month 6	A	56	94,9	49	87,5	8,16	19,87	45	78,9	42	93,3	11,90	21,87
FU Month 9	A	43	72,9	37	86,0	5,41	12,46	34	59,6	30	88,2	8,89	19,44
FU Month 12	A	36	61,0	34	94,4	10,78	19,63	24	42,1	21	87,5	9,52	23,90
FU Month 15	A	30	50,8	27	90,0	8,64	21,86	19	33,3	19	100,0	7,02	21,02
FU Month 18	A	22	37,3	18	81,8	5,56	17,15	16	28,1	16	100,0	8,33	19,25
FU Month 21	A	17	28,8	15	88,2	4,44	17,21	8	14,0	7	87,5	0,00	0,00
FU Month 24	A	10	16,9	8	80,0	12,50	24,80	5	8,8	5	100,0	0,00	0,00
FU Month 27	A	5	8,5	4	80,0	8,33	16,67	2	3,5	1	50,0	0,00	NE
FU Month 30	A	4	6,8	3	75,0	0,00	0,00	0	NE	0	NE	NE	NE
Screening	B	104	100,0	100	96,2	9,67	17,28	85	100,0	83	97,6	7,63	17,52
Cycle 4 Day 1	B	88	84,6	83	94,3	6,02	13,91	79	92,9	71	89,9	11,27	22,50
FU Day 28	B	91	87,5	78	85,7	11,11	23,21	79	92,9	71	89,9	9,86	21,38
FU Month 3	B	88	84,6	77	87,5	12,12	26,44	79	92,9	69	87,3	7,73	18,21
FU Month 6	B	80	76,9	76	95,0	6,58	17,23	70	82,4	62	88,6	7,53	19,48
FU Month 9	B	63	60,6	52	82,5	7,05	17,88	59	69,4	48	81,4	7,64	15,74
FU Month 12	B	47	45,2	39	83,0	5,98	16,88	46	54,1	39	84,8	5,98	16,88
FU Month 15	B	37	35,6	34	91,9	8,82	20,61	34	40,0	28	82,4	7,14	16,62
FU Month 18	B	31	29,8	28	90,3	10,71	24,09	22	25,9	18	81,8	9,26	19,15
FU Month 21	B	18	17,3	13	72,2	5,13	12,52	17	20,0	14	82,4	9,52	20,37
FU Month 24	B	11	10,6	9	81,8	3,70	11,11	8	9,4	7	87,5	9,52	16,27
FU Month 27	B	5	4,8	4	80,0	0,00	0,00	4	4,7	4	100,0	0,00	0,00
FU Month 30	B	2	1,9	2	100,0	0,00	0,00	0	NE	0	NE	NE	NE
Screening	C	92	100,0	82	89,1	8,54	21,48	100	100,0	89	89,0	7,87	18,13
Cycle 4 Day 1	C	74	80,4	65	87,8	7,69	19,34	91	91,0	72	79,1	7,41	18,74
FU Day 28	C	81	88,0	68	84,0	6,86	17,81	92	92,0	78	84,8	8,55	18,94

FU Month 3	C	80	87,0	69	86,3	8,70	21,88	89	89,0	75	84,3	10,22	21,90
FU Month 6	C	71	77,2	61	85,9	7,10	22,04	77	77,0	63	81,8	10,58	22,26
FU Month 9	C	58	63,0	49	84,5	4,76	18,00	56	56,0	41	73,2	6,50	15,31
FU Month 12	C	42	45,7	36	85,7	1,85	7,74	47	47,0	38	80,9	6,14	15,22
FU Month 15	C	37	40,2	30	81,1	5,56	15,37	32	32,0	22	68,8	4,55	11,71
FU Month 18	C	26	28,3	23	88,5	2,90	9,60	22	22,0	14	63,6	7,14	14,19
FU Month 21	C	17	18,5	12	70,6	5,56	12,97	15	15,0	11	73,3	21,21	22,47
FU Month 24	C	11	12,0	8	72,7	8,33	15,43	5	5,0	4	80,0	16,67	19,25
FU Month 27	C	3	3,3	3	100,0	11,11	19,25	3	3,0	2	66,7	0,00	0,00
FU Month 30	C	1	1,1	1	100,0	66,67	NE	1	1,0	1	100,0	0,00	NE
Total CIR score at baseline													
Screening	<=6	63	100,0	58	92,1	7,47	16,57	75	100,0	66	88,0	7,58	20,08
Cycle 4 Day 1	<=6	52	82,5	43	82,7	9,30	16,79	72	96,0	59	81,9	8,47	18,15
FU Day 28	<=6	56	88,9	48	85,7	13,89	23,65	72	96,0	59	81,9	7,91	17,87
FU Month 3	<=6	55	87,3	46	83,6	8,70	16,38	69	92,0	56	81,2	10,12	20,02
FU Month 6	<=6	52	82,5	46	88,5	7,25	15,58	60	80,0	53	88,3	9,43	17,76
FU Month 9	<=6	43	68,3	36	83,7	7,41	19,70	47	62,7	38	80,9	7,89	14,36
FU Month 12	<=6	35	55,6	29	82,9	6,90	16,38	34	45,3	27	79,4	4,94	15,20
FU Month 15	<=6	32	50,8	29	90,6	9,20	17,59	25	33,3	17	68,0	9,80	19,60
FU Month 18	<=6	23	36,5	22	95,7	4,55	11,71	19	25,3	13	68,4	10,26	21,01
FU Month 21	<=6	14	22,2	8	57,1	0,00	0,00	14	18,7	10	71,4	16,67	23,57
FU Month 24	<=6	8	12,7	7	87,5	4,76	12,60	7	9,3	5	71,4	6,67	14,91
FU Month 27	<=6	2	3,2	2	100,0	0,00	0,00	4	5,3	2	50,0	0,00	0,00
FU Month 30	<=6	0	NE	0	NE	NE	NE	1	1,3	1	100,0	0,00	NE
Screening >6													
Screening	>6	192	100,0	181	94,3	9,58	20,04	167	100,0	158	94,6	8,23	17,52
Cycle 4 Day 1	>6	161	83,9	153	95,0	6,54	16,69	152	91,0	134	88,2	8,71	20,41
FU Day 28	>6	174	90,6	151	86,8	8,17	19,99	153	91,6	141	92,2	8,51	19,68
FU Month 3	>6	170	88,5	156	91,8	11,11	25,21	152	91,0	138	90,8	10,14	23,00
FU Month 6	>6	155	80,7	140	90,3	7,14	20,69	132	79,0	114	86,4	9,94	22,58
FU Month 9	>6	121	63,0	102	84,3	5,23	15,38	102	61,1	81	79,4	7,41	17,48
FU Month 12	>6	90	46,9	80	88,9	5,83	15,71	83	49,7	71	85,5	7,51	18,85
FU Month 15	>6	72	37,5	62	86,1	6,99	20,14	60	35,9	52	86,7	5,13	15,32
FU Month 18	>6	56	29,2	47	83,9	7,80	21,10	41	24,6	35	85,4	7,62	16,34
FU Month 21	>6	38	19,8	32	84,2	6,25	15,70	26	15,6	22	84,6	9,09	18,35
FU Month 24	>6	24	12,5	18	75,0	9,26	19,15	11	6,6	11	100,0	9,09	15,57
FU Month 27	>6	11	5,7	9	81,8	7,41	14,70	5	3,0	5	100,0	0,00	0,00
FU Month 30	>6	7	3,6	6	85,7	11,11	27,22	0	NE	0	NE	NE	NE
Calculated creatinine clearance cat. 2													

Screening	<70 ml/min	178	100,0	163	91,6	8,79	18,82	176	100,0	163	92,6	7,98	18,08
Cycle 4 Day 1	<70 ml/min	149	83,7	134	89,9	6,22	14,83	164	93,2	140	85,4	8,33	17,94
FU Day 28	<70 ml/min	162	91,0	140	86,4	9,05	20,33	166	94,3	143	86,1	7,46	16,98
FU Month 3	<70 ml/min	157	88,2	140	89,2	9,52	21,64	159	90,3	137	86,2	9,49	20,59
FU Month 6	<70 ml/min	144	80,9	128	88,9	6,25	16,60	139	79,0	119	85,6	8,68	18,13
FU Month 9	<70 ml/min	117	65,7	97	82,9	5,84	18,01	112	63,6	88	78,6	7,95	16,76
FU Month 12	<70 ml/min	92	51,7	79	85,9	5,06	14,21	87	49,4	72	82,8	6,94	18,50
FU Month 15	<70 ml/min	78	43,8	70	89,7	8,57	20,99	60	34,1	48	80,0	7,64	18,50
FU Month 18	<70 ml/min	59	33,1	50	84,7	7,33	19,39	43	24,4	35	81,4	9,52	19,08
FU Month 21	<70 ml/min	38	21,3	27	71,1	6,17	16,11	31	17,6	27	87,1	11,11	20,67
FU Month 24	<70 ml/min	24	13,5	19	79,2	8,77	18,73	13	7,4	11	84,6	9,09	15,57
FU Month 27	<70 ml/min	10	5,6	8	80,0	4,17	11,79	7	4,0	5	71,4	0,00	0,00
FU Month 30	<70 ml/min	5	2,8	4	80,0	16,67	33,33	1	0,6	1	100,0	0,00	NE
Screening	>=70 ml/min	77	100,0	76	98,7	9,65	20,23	66	100,0	61	92,4	8,20	18,91
Cycle 4 Day 1	>=70 ml/min	64	83,1	62	96,9	9,14	20,17	60	90,9	53	88,3	9,43	23,91
FU Day 28	>=70 ml/min	68	88,3	59	86,8	10,73	22,69	59	89,4	57	96,6	10,53	23,70
FU Month 3	>=70 ml/min	68	88,3	62	91,2	12,90	27,23	62	93,9	57	91,9	11,70	25,58
FU Month 6	>=70 ml/min	63	81,8	58	92,1	9,20	24,81	53	80,3	48	90,6	12,50	27,18
FU Month 9	>=70 ml/min	47	61,0	41	87,2	5,69	12,70	37	56,1	31	83,8	6,45	15,91
FU Month 12	>=70 ml/min	33	42,9	30	90,9	8,89	19,44	30	45,5	26	86,7	6,41	16,38
FU Month 15	>=70 ml/min	26	33,8	21	80,8	4,76	11,95	25	37,9	21	84,0	3,17	10,03
FU Month 18	>=70 ml/min	20	26,0	19	95,0	5,26	16,72	17	25,8	13	76,5	5,13	12,52
FU Month 21	>=70 ml/min	14	18,2	13	92,9	2,56	9,25	9	13,6	5	55,6	13,33	18,26
FU Month 24	>=70 ml/min	8	10,4	6	75,0	5,56	13,61	5	7,6	5	100,0	6,67	14,91
FU Month 27	>=70 ml/min	3	3,9	3	100,0	11,11	19,25	2	3,0	2	100,0	0,00	0,00
FU Month 30	>=70 ml/min	2	2,6	2	100,0	0,00	0,00	0	NE	0	NE	NE	NE
Beta2 microglobulin													
Screening	Missing	3	100,0	3	100,0	0,00	0,00	3	100,0	3	100,0	33,33	33,33
Cycle 4 Day 1	Missing	3	100,0	3	100,0	0,00	0,00	3	100,0	2	66,7	16,67	23,57
FU Day 28	Missing	3	100,0	3	100,0	0,00	0,00	3	100,0	2	66,7	0,00	0,00
FU Month 3	Missing	3	100,0	3	100,0	0,00	0,00	3	100,0	2	66,7	16,67	23,57
FU Month 6	Missing	3	100,0	3	100,0	0,00	0,00	3	100,0	2	66,7	16,67	23,57
FU Month 9	Missing	2	66,7	1	50,0	0,00	NE	3	100,0	2	66,7	16,67	23,57
FU Month 12	Missing	1	33,3	1	100,0	0,00	NE	2	66,7	1	50,0	0,00	NE
FU Month 15	Missing	1	33,3	1	100,0	0,00	NE	2	66,7	1	50,0	0,00	NE
FU Month 18	Missing	1	33,3	1	100,0	0,00	NE	2	66,7	1	50,0	0,00	NE
FU Month 21	Missing	1	33,3	1	100,0	0,00	NE	2	66,7	1	50,0	0,00	NE
FU Month 24	Missing	1	33,3	1	100,0	0,00	NE	1	33,3	1	100,0	0,00	NE

Screening	< 3.5 ug/mL	154	100,0	142	92,2	9,62	20,08	140	100,0	130	92,9	7,69	18,35
Cycle 4 Day 1	< 3.5 ug/mL	127	82,5	117	92,1	8,83	18,77	129	92,1	111	86,0	8,11	19,70
FU Day 28	< 3.5 ug/mL	137	89,0	119	86,9	10,92	22,59	132	94,3	119	90,2	8,12	19,39
FU Month 3	< 3.5 ug/mL	134	87,0	122	91,0	10,38	23,89	130	92,9	115	88,5	10,14	20,79
FU Month 6	< 3.5 ug/mL	128	83,1	113	88,3	7,37	21,24	120	85,7	109	90,8	11,31	22,78
FU Month 9	< 3.5 ug/mL	104	67,5	87	83,7	6,13	18,70	98	70,0	81	82,7	7,00	16,43
FU Month 12	< 3.5 ug/mL	78	50,6	69	88,5	7,73	18,21	75	53,6	66	88,0	7,07	17,06
FU Month 15	< 3.5 ug/mL	65	42,2	57	87,7	9,94	22,68	60	42,9	51	85,0	4,58	13,37
FU Month 18	< 3.5 ug/mL	46	29,9	41	89,1	9,76	22,66	43	30,7	34	79,1	8,82	17,03
FU Month 21	< 3.5 ug/mL	30	19,5	21	70,0	7,94	17,97	27	19,3	22	81,5	13,64	22,20
FU Month 24	< 3.5 ug/mL	19	12,3	15	78,9	13,33	21,08	12	8,6	10	83,3	3,33	10,54
FU Month 27	< 3.5 ug/mL	10	6,5	8	80,0	8,33	15,43	7	5,0	5	71,4	0,00	0,00
FU Month 30	< 3.5 ug/mL	5	3,2	4	80,0	16,67	33,33	1	0,7	1	100,0	0,00	NE
Screening	>= 3.5 ug/mL	98	100,0	94	95,9	8,51	18,25	99	100,0	91	91,9	7,69	17,27
Cycle 4 Day 1	>= 3.5 ug/mL	83	84,7	76	91,6	4,82	13,00	92	92,9	80	87,0	9,17	19,83
FU Day 28	>= 3.5 ug/mL	90	91,8	77	85,6	7,79	18,65	90	90,9	79	87,8	8,86	19,03
FU Month 3	>= 3.5 ug/mL	88	89,8	77	87,5	11,26	23,33	88	88,9	77	87,5	9,96	24,22
FU Month 6	>= 3.5 ug/mL	76	77,6	70	92,1	7,14	16,92	69	69,7	56	81,2	6,55	17,31
FU Month 9	>= 3.5 ug/mL	58	59,2	50	86,2	5,33	12,34	48	48,5	36	75,0	8,33	16,67
FU Month 12	>= 3.5 ug/mL	46	46,9	39	84,8	3,42	10,25	40	40,4	31	77,5	6,45	20,04
FU Month 15	>= 3.5 ug/mL	38	38,8	33	86,8	4,04	11,05	23	23,2	17	73,9	11,76	23,40
FU Month 18	>= 3.5 ug/mL	32	32,7	27	84,4	2,47	8,90	15	15,2	13	86,7	7,69	19,97
FU Month 21	>= 3.5 ug/mL	21	21,4	18	85,7	1,85	7,86	11	11,1	9	81,8	7,41	14,70
FU Month 24	>= 3.5 ug/mL	12	12,2	9	75,0	0,00	0,00	5	5,1	5	100,0	20,00	18,26
FU Month 27	>= 3.5 ug/mL	3	3,1	3	100,0	0,00	0,00	2	2,0	2	100,0	0,00	0,00
FU Month 30	>= 3.5 ug/mL	2	2,0	2	100,0	0,00	0,00	0	NE	0	NE	NE	NE
Immunoglobulin VH, cytogenetics 2													
Screening	12	45	100,0	43	95,6	12,40	20,60	44	100,0	43	97,7	5,43	14,42
Cycle 4 Day 1	12	34	75,6	32	94,1	4,17	11,20	38	86,4	32	84,2	10,42	19,74
FU Day 28	12	39	86,7	37	94,9	11,71	21,11	40	90,9	34	85,0	7,84	18,46
FU Month 3	12	38	84,4	36	94,7	12,96	22,93	39	88,6	32	82,1	9,38	25,73
FU Month 6	12	36	80,0	32	88,9	9,38	25,73	34	77,3	28	82,4	14,29	26,34
FU Month 9	12	26	57,8	22	84,6	3,03	9,81	28	63,6	18	64,3	7,41	18,28
FU Month 12	12	22	48,9	18	81,8	5,56	17,15	23	52,3	15	65,2	4,44	11,73
FU Month 15	12	17	37,8	14	82,4	9,52	27,51	17	38,6	12	70,6	11,11	21,71
FU Month 18	12	15	33,3	12	80,0	8,33	20,72	13	29,5	9	69,2	3,70	11,11
FU Month 21	12	10	22,2	8	80,0	12,50	24,80	7	15,9	5	71,4	6,67	14,91
FU Month 24	12	8	17,8	6	75,0	11,11	27,22	6	13,6	6	100,0	5,56	13,61
FU Month 27	12	5	11,1	4	80,0	0,00	0,00	2	4,5	2	100,0	0,00	0,00

FU Month 30	12		48,9		375,0	0,00	0,00		12,3		100,0	0,00		NE
Screening	11q-		46100,0		4393,5	6,98	15,53		43100,0		3888,4	8,77		18,48
Cycle 4 Day 1	11q-		4087,0		3997,5	5,13	12,18		4195,3		3585,4	3,81		10,76
FU Day 28	11q-		4291,3		3583,3	7,62	19,94		3990,7		3692,3	10,19		17,49
FU Month 3	11q-		4291,3		3890,5	5,26	18,22		3888,4		3694,7	8,33		16,67
FU Month 6	11q-		3882,6		3592,1	3,81	10,76		3274,4		2784,4	4,94		12,07
FU Month 9	11q-		2860,9		2692,9	3,85	10,86		2558,1		2080,0	8,33		14,81
FU Month 12	11q-		2043,5		1995,0	8,77	18,73		1841,9		1794,4	13,73		23,74
FU Month 15	11q-		1839,1		1688,9	2,08	8,33		1432,6		1071,4	16,67		23,57
FU Month 18	11q-		1532,6		1280,0	2,78	9,62		818,6		787,5	14,29		17,82
FU Month 21	11q-		1226,1		1191,7	3,03	10,05		49,3		250,0	16,67		23,57
FU Month 24	11q-		715,2		571,4	13,33	18,26		12,3		1100,0	0,00		NE
FU Month 27	11q-		36,5		3100,0	22,22	19,25		0	NE	0	NE		NE
FU Month 30	11q-		36,5		3100,0	22,22	38,49		0	NE	0	NE		NE
Screening	13q-		79100,0		7493,7	6,76	18,28		75100,0		6992,0	8,21		18,44
Cycle 4 Day 1	13q-		6784,8		6089,6	7,78	20,69		6890,7		6088,2	11,11		24,29
FU Day 28	13q-		7291,1		6387,5	8,47	21,56		7296,0		6590,3	8,21		21,27
FU Month 3	13q-		7392,4		6690,4	12,63	27,90		6992,0		6087,0	15,00		27,74
FU Month 6	13q-		6784,8		6191,0	5,46	17,41		6384,0		5688,9	8,93		19,58
FU Month 9	13q-		5670,9		4987,5	6,80	21,49		5269,3		4178,8	5,69		14,72
FU Month 12	13q-		4455,7		3988,6	6,84	17,40		4053,3		3895,0	4,39		17,62
FU Month 15	13q-		3848,1		3489,5	11,76	23,04		2938,7		2586,2	2,67		13,33
FU Month 18	13q-		2835,4		2589,3	10,67	24,94		2128,0		1885,7	9,26		19,15
FU Month 21	13q-		1620,3		1381,3	5,13	12,52		1621,3		1487,5	9,52		15,63
FU Month 24	13q-		78,9		685,7	11,11	17,21		79,3		685,7	11,11		17,21
FU Month 27	13q-		22,5		150,0	0,00		NE	68,0		466,7	0,00		0,00
Screening	Norm. K.		65100,0		6193,8	9,29	19,37		58100,0		5493,1	6,79		17,59
Cycle 4 Day 1	Norm. K.		5483,1		4990,7	9,52	18,00		5594,8		4887,3	7,64		18,50
FU Day 28	Norm. K.		5990,8		5084,7	11,33	22,95		5391,4		4890,6	9,03		20,33
FU Month 3	Norm. K.		5483,1		4888,9	10,42	21,91		5493,1		4888,9	8,33		17,53
FU Month 6	Norm. K.		4975,4		4693,9	8,70	21,59		4577,6		3986,7	11,97		25,92
FU Month 9	Norm. K.		3960,0		3179,5	4,30	11,36		3051,7		2790,0	9,88		18,06
FU Month 12	Norm. K.		3249,2		2784,4	2,47	8,90		2441,4		2083,3	6,67		17,44
FU Month 15	Norm. K.		2640,0		2388,5	2,90	9,60		2034,5		1890,0	1,85		7,86
FU Month 18	Norm. K.		1827,7		1794,4	1,96	8,08		1525,9		1280,0	8,33		20,72
FU Month 21	Norm. K.		1218,5		650,0	0,00	0,00		1119,0		981,8	18,52		29,40
FU Month 24	Norm. K.		812,3		675,0	0,00	0,00		46,9		375,0	11,11		19,25
FU Month 27	Norm. K.		34,6		3100,0	0,00	0,00		11,7		1100,0	0,00		NE

Screening	Other Abn.	20	100,0	18	90,0	14,81	26,13	22	100,0	20	90,9	15,00	25,31
Cycle 4 Day 1	Other Abn.	18	90,0	16	88,9	8,33	14,91	22	100,0	18	81,8	9,26	19,15
FU Day 28	Other Abn.	18	90,0	14	77,8	7,14	14,19	21	95,5	17	81,0	3,92	11,07
FU Month 3	Other Abn.	18	90,0	14	77,8	9,52	20,37	21	95,5	18	85,7	3,70	10,78
FU Month 6	Other Abn.	17	85,0	12	70,6	13,89	22,29	18	81,8	17	94,4	7,84	14,57
FU Month 9	Other Abn.	15	75,0	10	66,7	16,67	23,57	14	63,6	13	92,9	7,69	19,97
FU Month 12	Other Abn.	7	35,0	6	85,7	11,11	17,21	12	54,5	8	66,7	8,33	15,43
FU Month 15	Other Abn.	5	25,0	4	80,0	16,67	19,25	5	22,7	4	80,0	8,33	16,67
FU Month 18	Other Abn.	3	15,0	3	100,0	11,11	19,25	3	13,6	2	66,7	0,00	0,00
FU Month 21	Other Abn.	2	10,0	2	100,0	0,00	0,00	2	9,1	2	100,0	0,00	0,00
FU Month 24	Other Abn.	2	10,0	2	100,0	0,00	0,00	0	NE	0	NE	NE	NE
Time from first diagnosis													
Screening	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
Cycle 4 Day 1	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Day 28	Missing	1	100,0	1	100,0	33,33	NE	0	NE	0	NE	NE	NE
FU Month 3	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 6	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 9	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 12	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 15	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 18	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
Screening	13 - 24 months	41	100,0	38	92,7	7,89	16,32	31	100,0	30	96,8	4,44	14,47
Cycle 4 Day 1	13 - 24 months	35	85,4	34	97,1	7,84	14,35	30	96,8	27	90,0	4,94	15,20
FU Day 28	13 - 24 months	38	92,7	33	86,8	9,09	19,14	30	96,8	27	90,0	6,17	16,11
FU Month 3	13 - 24 months	36	87,8	34	94,4	6,86	15,95	30	96,8	26	86,7	3,85	10,86
FU Month 6	13 - 24 months	36	87,8	33	91,7	5,05	18,86	30	96,8	25	83,3	1,33	6,67
FU Month 9	13 - 24 months	32	78,0	29	90,6	5,75	12,81	21	67,7	17	81,0	1,96	8,08
FU Month 12	13 - 24 months	21	51,2	18	85,7	5,56	17,15	16	51,6	14	87,5	4,76	12,10
FU Month 15	13 - 24 months	19	46,3	18	94,7	5,56	12,78	16	51,6	10	62,5	0,00	0,00
FU Month 18	13 - 24 months	14	34,1	13	92,9	7,69	19,97	10	32,3	8	80,0	4,17	11,79
FU Month 21	13 - 24 months	11	26,8	9	81,8	11,11	23,57	6	19,4	4	66,7	8,33	16,67
FU Month 24	13 - 24 months	8	19,5	5	62,5	20,00	29,81	3	9,7	2	66,7	0,00	0,00
FU Month 27	13 - 24 months	5	12,2	5	100,0	6,67	14,91	2	6,5	2	100,0	0,00	0,00
FU Month 30	13 - 24 months	3	7,3	3	100,0	22,22	38,49	1	3,2	1	100,0	0,00	NE
Screening	<= 12 months	60	100,0	57	95,0	14,04	20,84	70	100,0	68	97,1	11,76	22,13
Cycle 4 Day 1	<= 12 months	48	80,0	42	87,5	10,32	21,45	60	85,7	53	88,3	11,95	22,73
FU Day 28	<= 12 months	54	90,0	45	83,3	14,07	25,11	62	88,6	56	90,3	11,31	22,27

FU Month 3	<= 12 months	53	88,3	45	84,9	14,81	28,92	59	84,3	55	93,2	13,33	24,51	
FU Month 6	<= 12 months	46	76,7	40	87,0	12,50	25,81	47	67,1	42	89,4	8,73	20,90	
FU Month 9	<= 12 months	35	58,3	27	77,1	8,64	21,86	37	52,9	31	83,8	9,68	19,61	
FU Month 12	<= 12 months	27	45,0	23	85,2	8,70	18,03	29	41,4	27	93,1	9,88	20,29	
FU Month 15	<= 12 months	22	36,7	17	77,3	17,65	29,15	17	24,3	16	94,1	8,33	14,91	
FU Month 18	<= 12 months	16	26,7	13	81,3	5,13	12,52	13	18,6	12	92,3	8,33	15,08	
FU Month 21	<= 12 months	9	15,0	5	55,6	6,67	14,91	7	10,0	6	85,7	11,11	17,21	
FU Month 24	<= 12 months	6	10,0	3	50,0	0,00	0,00	2	2,9	1	50,0	0,00	NE	
FU Month 27	<= 12 months	1	1,7				NE	NE	1	1,4		NE	NE	
FU Month 30	<= 12 months	1	1,7				NE	NE	0	NE		NE	NE	
Screening	>24 months	153	100,0	143	93,5	7,46	19,14	141	100,0	126	89,4	6,88	16,50	
Cycle 4 Day 1	>24 months	129	84,3	119	92,2	5,88	15,43	134	95,0	113	84,3	7,96	19,04	
FU Day 28	>24 months	137	89,5	120	87,6	7,78	19,68	133	94,3	117	88,0	7,41	18,11	
FU Month 3	>24 months	135	88,2	122	90,4	10,11	23,03	132	93,6	113	85,6	10,03	22,66	
FU Month 6	>24 months	124	81,0	112	90,3	5,95	16,87	115	81,6	100	87,0	12,33	23,04	
FU Month 9	>24 months	96	62,7	81	84,4	4,94	15,91	91	64,5	71	78,0	7,98	16,39	
FU Month 12	>24 months	76	49,7	67	88,2	5,47	14,90	72	51,1	57	79,2	5,85	17,95	
FU Month 15	>24 months	62	40,5	55	88,7	5,45	16,68	52	36,9	43	82,7	6,98	18,63	
FU Month 18	>24 months	48	31,4	42	87,5	7,14	20,21	37	26,2	28	75,7	9,52	19,99	
FU Month 21	>24 months	32	20,9	26	81,3	2,56	9,06	27	19,1	22	81,5	12,12	21,93	
FU Month 24	>24 months	18	11,8	17	94,4	5,88	13,10	13	9,2	13	100,0	10,26	16,01	
FU Month 27	>24 months	7	4,6	6	85,7	5,56	13,61	6	4,3	5	83,3	0,00	0,00	
FU Month 30	>24 months	3	2,0	3	100,0	0,00	0,00	0	NE	0	NE	NE	NE	
High circulating tumor burden														
Screening	Missing	0	NE	0	NE	NE	NE	NE	2	100,0	1	50,0	0,00	NE
Cycle 4 Day 1	Missing	0	NE	0	NE	NE	NE	NE	1	50,0	1	100,0	33,33	NE
FU Day 28	Missing	0	NE	0	NE	NE	NE	NE	1	50,0	1	100,0	0,00	NE
FU Month 3	Missing	0	NE	0	NE	NE	NE	NE	1	50,0	1	100,0	0,00	NE
FU Month 6	Missing	0	NE	0	NE	NE	NE	NE	1	50,0	1	100,0	33,33	NE
FU Month 9	Missing	0	NE				NE	NE	1	50,0			NE	NE
Screening	<25x10**9 cells/L	60	100,0	54	90,0	11,73	22,58	67	100,0	64	95,5	10,94	19,75	
Cycle 4 Day 1	<25x10**9 cells/L	50	83,3	45	90,0	7,41	15,71	61	91,0	51	83,6	8,50	16,12	
FU Day 28	<25x10**9 cells/L	56	93,3	46	82,1	13,77	23,91	61	91,0	53	86,9	8,81	18,66	
FU Month 3	<25x10**9 cells/L	54	90,0	47	87,0	14,18	28,44	59	88,1	50	84,7	7,33	18,18	
FU Month 6	<25x10**9 cells/L	50	83,3	44	88,0	12,12	26,01	51	76,1	41	80,4	5,69	14,72	
FU Month 9	<25x10**9 cells/L	36	60,0	27	75,0	7,41	16,88	41	61,2	29	70,7	5,75	12,81	
FU Month 12	<25x10**9 cells/L	29	48,3	24	82,8	6,94	16,97	34	50,7	25	73,5	8,00	17,43	
FU Month 15	<25x10**9 cells/L	24	40,0	20	83,3	11,67	24,84	23	34,3	15	65,2	6,67	18,69	

FU Month 18	<25x10**9 cells/L	20	33,3	18	90,0	7,41	18,28	19	28,4	14	73,7	2,38	8,91
FU Month 21	<25x10**9 cells/L	14	23,3	10	71,4	13,33	23,31	10	14,9	8	80,0	4,17	11,79
FU Month 24	<25x10**9 cells/L	8	13,3	5	62,5	20,00	29,81	6	9,0	5	83,3	13,33	18,26
FU Month 27	<25x10**9 cells/L	4	6,7	3	75,0	11,11	19,25	1	1,5	1	100,0	0,00	NE
FU Month 30	<25x10**9 cells/L	4	6,7	3	75,0	22,22	38,49	1	1,5	1	100,0	0,00	NE
Screening	>=25x10**9 cells/L	195	100,0	185	94,9	8,29	18,15	173	100,0	159	91,9	6,92	17,62
Cycle 4 Day 1	>=25x10**9 cells/L	163	83,6	151	92,6	7,06	17,04	162	93,6	141	87,0	8,51	20,86
FU Day 28	>=25x10**9 cells/L	174	89,2	153	87,9	8,28	19,97	163	94,2	146	89,6	8,22	19,40
FU Month 3	>=25x10**9 cells/L	171	87,7	155	90,6	9,46	21,74	161	93,1	143	88,8	11,19	23,38
FU Month 6	>=25x10**9 cells/L	157	80,5	142	90,4	5,63	16,83	140	80,9	125	89,3	10,93	22,71
FU Month 9	>=25x10**9 cells/L	128	65,6	111	86,7	5,41	16,54	107	61,8	90	84,1	8,15	17,53
FU Month 12	>=25x10**9 cells/L	96	49,2	85	88,5	5,88	15,58	83	48,0	73	88,0	6,39	18,14
FU Month 15	>=25x10**9 cells/L	80	41,0	71	88,8	6,57	17,48	62	35,8	54	87,1	6,17	15,96
FU Month 18	>=25x10**9 cells/L	59	30,3	51	86,4	6,54	18,88	41	23,7	34	82,9	10,78	19,63
FU Month 21	>=25x10**9 cells/L	38	19,5	30	78,9	2,22	8,46	30	17,3	24	80,0	13,89	21,80
FU Month 24	>=25x10**9 cells/L	24	12,3	20	83,3	5,00	12,21	12	6,9	11	91,7	6,06	13,48
FU Month 27	>=25x10**9 cells/L	9	4,6	8	88,9	4,17	11,79	8	4,6	6	75,0	0,00	0,00
FU Month 30	>=25x10**9 cells/L	3	1,5	3	100,0	0,00	0,00	0	NE	0	NE	NE	NE

¹ in study: number of subjects in study at respective visit; % based on baseline

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit

² mean: descriptive statistics - absolute values Clinical

cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/t_pro_mean.sas

Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/t_pro_mean_sg_EQC30_IT_label_09MAY2013_21004.xls 04MAR2020

17:18

POPULATION: Labelpopulation, Intent-to-Treat Patients ENDPOINT: EORTC QoL 30

MODEL: Unadjusted Analysis STUDY: CLL11(BO21004), Stage

2

Compliance/Mean

Nausea And Vomiting Scale

		GClb (N=255)						RC1b (N=242)					
		Patients			Statistics			Patients			Statistics		
Name	Level	in study ¹	%	with value ¹	%	Mean ²	SD(mean)	in study ¹	%	with value ¹	%	Mean ²	SD(mean)
All													
Screening	n/a	255	100,0	242	94,9	3,99	10,95	242	100,0	228	94,2	4,24	12,28
Cycle 4 Day 1	n/a	213	83,5	195	91,5	5,21	11,35	224	92,6	198	88,4	4,71	11,28
FU Day 28	n/a	230	90,2	201	87,4	3,90	11,90	225	93,0	202	89,8	4,46	12,85
FU Month 3	n/a	225	88,2	203	90,2	3,12	10,15	221	91,3	196	88,7	4,51	11,24
FU Month 6	n/a	207	81,2	186	89,9	2,51	8,65	192	79,3	169	88,0	3,35	8,83
FU Month 9	n/a	164	64,3	138	84,1	3,74	12,25	149	61,6	121	81,2	3,86	8,27
FU Month 12	n/a	125	49,0	109	87,2	2,75	8,93	117	48,3	99	84,6	2,36	6,74
FU Month 15	n/a	104	40,8	90	86,5	3,15	9,64	85	35,1	69	81,2	3,38	9,30
FU Month 18	n/a	79	31,0	70	88,6	3,57	9,79	60	24,8	49	81,7	3,06	8,10
FU Month 21	n/a	52	20,4	40	76,9	3,75	10,33	40	16,5	32	80,0	4,17	15,84
FU Month 24	n/a	32	12,5	25	78,1	6,00	12,62	18	7,4	17	94,4	0,98	4,04
FU Month 27	n/a	13	5,1	11	84,6	7,58	15,57	9	3,7	7	77,8	0,00	0,00
FU Month 30	n/a	7	2,7	6	85,7	8,33	20,41	1	0,4	1	100,0	0,00	NE
Gender													
Screening	Female	97	100,0	92	94,8	3,26	8,64	95	100,0	87	91,6	7,66	17,39
Cycle 4 Day 1	Female	84	86,6	76	90,5	6,14	10,83	88	92,6	78	88,6	6,84	13,55
FU Day 28	Female	90	92,8	83	92,2	4,62	9,85	91	95,8	78	85,7	6,41	14,52
FU Month 3	Female	88	90,7	81	92,0	3,29	9,29	87	91,6	77	88,5	7,79	14,46
FU Month 6	Female	84	86,6	72	85,7	2,55	8,69	77	81,1	67	87,0	4,23	10,19
FU Month 9	Female	70	72,2	59	84,3	6,21	17,20	61	64,2	46	75,4	6,16	10,75
FU Month 12	Female	56	57,7	49	87,5	3,40	11,27	47	49,5	40	85,1	2,92	7,44
FU Month 15	Female	47	48,5	40	85,1	4,58	11,31	33	34,7	28	84,8	4,17	11,68
FU Month 18	Female	34	35,1	29	85,3	7,47	13,79	26	27,4	22	84,6	5,30	10,77
FU Month 21	Female	21	21,6	15	71,4	6,67	15,17	17	17,9	15	88,2	8,89	22,60
FU Month 24	Female	12	12,4	10	83,3	8,33	16,20	6	6,3	5	83,3	0,00	0,00
FU Month 27	Female	6	6,2	5	83,3	13,33	21,73	2	2,1	1	50,0	0,00	NE
FU Month 30	Female	4	4,1	3	75,0	16,67	28,87	1	1,1	1	100,0	0,00	NE

Screening	Male	158	100,0	150	94,9	4,44	12,16	147	100,0	141	95,9	2,13	6,86
Cycle 4 Day 1	Male	129	81,6	119	92,2	4,62	11,67	136	92,5	120	88,2	3,33	9,32
FU Day 28	Male	140	88,6	118	84,3	3,39	13,18	134	91,2	124	92,5	3,23	11,58
FU Month 3	Male	137	86,7	122	89,1	3,01	10,72	134	91,2	119	88,8	2,38	7,91
FU Month 6	Male	123	77,8	114	92,7	2,49	8,65	115	78,2	102	88,7	2,78	7,81
FU Month 9	Male	94	59,5	79	84,0	1,90	5,96	88	59,9	75	85,2	2,44	5,94
FU Month 12	Male	69	43,7	60	87,0	2,22	6,49	70	47,6	59	84,3	1,98	6,26
FU Month 15	Male	57	36,1	50	87,7	2,00	8,00	52	35,4	41	78,8	2,85	7,36
FU Month 18	Male	45	28,5	41	91,1	0,81	3,63	34	23,1	27	79,4	1,23	4,45
FU Month 21	Male	31	19,6	25	80,6	2,00	5,53	23	15,6	17	73,9	0,00	0,00
FU Month 24	Male	20	12,7	15	75,0	4,44	9,89	12	8,2	12	100,0	1,39	4,81
FU Month 27	Male	7	4,4	6	85,7	2,78	6,80	7	4,8	6	85,7	0,00	0,00
FU Month 30	Male	3	1,9	3	100,0	0,00	0,00	0	NE	0	NE	NE	NE
Age													
Screening	<75 years	130	100,0	123	94,6	3,79	11,45	120	100,0	110	91,7	4,39	10,27
Cycle 4 Day 1	<75 years	106	81,5	100	94,3	3,67	9,05	112	93,3	98	87,5	4,08	9,59
FU Day 28	<75 years	119	91,5	105	88,2	3,65	10,84	110	91,7	103	93,6	5,50	15,19
FU Month 3	<75 years	116	89,2	106	91,4	2,36	7,07	109	90,8	99	90,8	5,39	12,10
FU Month 6	<75 years	108	83,1	98	90,7	1,70	6,10	99	82,5	88	88,9	4,17	9,87
FU Month 9	<75 years	85	65,4	73	85,9	3,65	13,39	74	61,7	62	83,8	4,30	8,50
FU Month 12	<75 years	63	48,5	59	93,7	1,69	5,08	60	50,0	53	88,3	2,20	6,57
FU Month 15	<75 years	54	41,5	47	87,0	3,19	9,60	44	36,7	35	79,5	4,29	10,95
FU Month 18	<75 years	43	33,1	39	90,7	2,14	6,82	27	22,5	22	81,5	3,79	8,81
FU Month 21	<75 years	26	20,0	22	84,6	4,55	9,17	17	14,2	13	76,5	1,28	4,62
FU Month 24	<75 years	18	13,8	14	77,8	2,38	6,05	6	5,0	5	83,3	0,00	0,00
FU Month 27	<75 years	7	5,4	5	71,4	6,67	9,13	2	1,7	1	50,0	0,00	NE
FU Month 30	<75 years	4	3,1	3	75,0	0,00	0,00	0	NE	0	NE	NE	NE
Screening	>=75 years	125	100,0	119	95,2	4,20	10,46	122	100,0	118	96,7	4,10	13,94
Cycle 4 Day 1	>=75 years	107	85,6	95	88,8	6,84	13,20	112	91,8	100	89,3	5,33	12,73
FU Day 28	>=75 years	111	88,8	96	86,5	4,17	13,02	115	94,3	99	86,1	3,37	9,81
FU Month 3	>=75 years	109	87,2	97	89,0	3,95	12,68	112	91,8	97	86,6	3,61	10,27
FU Month 6	>=75 years	99	79,2	88	88,9	3,41	10,77	93	76,2	81	87,1	2,47	7,51
FU Month 9	>=75 years	79	63,2	65	82,3	3,85	10,93	75	61,5	59	78,7	3,39	8,06
FU Month 12	>=75 years	62	49,6	50	80,6	4,00	11,93	57	46,7	46	80,7	2,54	7,00
FU Month 15	>=75 years	50	40,0	43	86,0	3,10	9,80	41	33,6	34	82,9	2,45	7,26
FU Month 18	>=75 years	36	28,8	31	86,1	5,38	12,46	33	27,0	27	81,8	2,47	7,60
FU Month 21	>=75 years	26	20,8	18	69,2	2,78	11,79	23	18,9	19	82,6	6,14	20,19
FU Month 24	>=75 years	14	11,2	11	78,6	10,61	17,12	12	9,8	12	100,0	1,39	4,81

FU Month 27	>=75 years	64,8	6100,0	8,33	20,41	75,7	685,7	0,00	0,00				
FU Month 30	>=75 years	32,4	3100,0	16,67	28,87	10,8	1100,0	0,00					NE
Race													
Screening	Other	9100,0	9100,0	12,96	33,10	11100,0	11100,0	0,00	0,00				
Cycle 4 Day 1	Other	777,8	7100,0	0,00	0,00	1090,9	990,0	3,70	7,35				
FU Day 28	Other	888,9	8100,0	10,42	23,46	1090,9	10100,0	3,33	7,03				
FU Month 3	Other	888,9	787,5	0,00	0,00	1090,9	10100,0	0,00	0,00				
FU Month 6	Other	888,9	787,5	2,38	6,30	872,7	8100,0	0,00	0,00				
FU Month 9	Other	444,4	375,0	0,00	0,00	545,5	480,0	4,17	8,33				
FU Month 12	Other	333,3	266,7	0,00	0,00	436,4	4100,0	0,00	0,00				
FU Month 15	Other	222,2	150,0	0,00	NE	436,4	4100,0	0,00	0,00				
FU Month 18	Other	222,2	150,0	0,00	NE	218,2	2100,0	0,00	0,00				
FU Month 21	Other	222,2	150,0	0,00	NE	218,2	2100,0	0,00	0,00				
FU Month 24	Other	222,2	150,0	0,00	NE	19,1	0	NE	NE				NE
FU Month 27	Other	111,1		NE	NE	19,1			NE				NE
FU Month 30	Other	111,1		NE	NE	0	NE		NE				NE
Geographical Region													
Screening	Asia-Pacific	20100,0	20100,0	1,67	5,13	18100,0	18100,0	2,78	6,39				
Cycle 4 Day 1	Asia-Pacific	1575,0	15100,0	1,11	4,30	1688,9	1593,8	8,89	21,70				
FU Day 28	Asia-Pacific	1890,0	18100,0	3,70	7,13	18100,0	1688,9	5,21	10,03				
FU Month 3	Asia-Pacific	1890,0	1688,9	2,08	5,69	18100,0	1688,9	3,13	9,07				
FU Month 6	Asia-Pacific	1680,0	1487,5	5,95	14,03	1794,4	1588,2	3,33	6,90				
FU Month 9	Asia-Pacific	1470,0	1285,7	1,39	4,81	1372,2	1076,9	5,00	8,05				
FU Month 12	Asia-Pacific	1050,0	880,0	2,08	5,89	1055,6	10100,0	3,33	7,03				
FU Month 15	Asia-Pacific	840,0	675,0	0,00	0,00	950,0	9100,0	5,56	8,33				

FU Month 18	Asia-Pacific	630,0	466,7	0,00	0,00	633,3	6100,0	2,78	6,80
FU Month 21	Asia-Pacific	525,0	360,0	0,00	0,00	422,2	4100,0	0,00	0,00
FU Month 24	Asia-Pacific	315,0	266,7	0,00	0,00	15,6	0	NE	NE
FU Month 27	Asia-Pacific	15,0		NE	NE	15,6		NE	NE
FU Month 30	Asia-Pacific	15,0		NE	NE	0	NE		NE
Screening	Central and South America	3100,0	3100,0	0,00	0,00	2100,0	2100,0	0,00	0,00
Cycle 4 Day 1	Central and South America	3100,0	3100,0	0,00	0,00	2100,0	2100,0	0,00	0,00
FU Day 28	Central and South America	3100,0	3100,0	0,00	0,00	2100,0	2100,0	0,00	0,00
FU Month 3	Central and South America	3100,0	3100,0	0,00	0,00	2100,0	2100,0	0,00	0,00
FU Month 6	Central and South America	266,7	2100,0	0,00	0,00	2100,0	2100,0	0,00	0,00
FU Month 9	Central and South America	266,7	2100,0	0,00	0,00	150,0	1100,0	0,00	NE
FU Month 12	Central and South America	266,7	2100,0	0,00	0,00	150,0	1100,0	0,00	NE
FU Month 15	Central and South America	133,3	1100,0	0,00	NE	0	NE	NE	NE
FU Month 18	Central and South America	133,3	1100,0	0,00	NE	0	NE	NE	NE
FU Month 21	Central and South America	133,3	1100,0	0,00	NE	0	NE	NE	NE
FU Month 24	Central and South America	133,3	1100,0	0,00	NE	0	NE	NE	NE
Screening	North America	12100,0	12100,0	8,33	13,30	13100,0	1292,3	6,94	11,14
Cycle 4 Day 1	North America	975,0	9100,0	5,56	8,33	1292,3	12100,0	2,78	6,49
FU Day 28	North America	1191,7	11100,0	3,03	6,74	13100,0	13100,0	3,85	7,31
FU Month 3	North America	1191,7	11100,0	3,03	6,74	1292,3	12100,0	0,00	0,00
FU Month 6	North America	1191,7	1090,9	1,67	5,27	1184,6	11100,0	3,03	10,05
FU Month 9	North America	866,7	8100,0	0,00	0,00	969,2	9100,0	3,70	7,35
FU Month 12	North America	866,7	787,5	0,00	0,00	753,8	7100,0	0,00	0,00
FU Month 15	North America	650,0	6100,0	2,78	6,80	646,2	583,3	3,33	7,45
FU Month 18	North America	433,3	4100,0	0,00	0,00	323,1	3100,0	0,00	0,00
FU Month 21	North America	325,0	266,7	0,00	0,00	17,7	1100,0	0,00	NE
FU Month 24	North America	325,0	266,7	16,67	0,00	17,7	1100,0	0,00	NE
FU Month 27	North America	216,7	150,0	0,00	NE	17,7	1100,0	0,00	NE
Screening	Other	45100,0	4191,1	4,47	16,68	44100,0	4193,2	6,91	12,90
Cycle 4 Day 1	Other	3782,2	3389,2	2,02	6,92	4090,9	3587,5	4,29	10,95
FU Day 28	Other	3782,2	3389,2	5,05	13,49	3988,6	3794,9	8,11	22,78
FU Month 3	Other	3884,4	3489,5	0,98	3,98	3886,4	3694,7	6,94	13,44
FU Month 6	Other	3577,8	3188,6	0,54	2,99	3375,0	3193,9	4,84	12,32
FU Month 9	Other	2657,8	2284,6	2,27	5,85	2454,5	1979,2	4,39	9,37
FU Month 12	Other	1737,8	1694,1	1,04	4,17	1636,4	1487,5	1,19	4,45
FU Month 15	Other	1226,7	1191,7	1,52	5,03	920,5	888,9	0,00	0,00
FU Month 18	Other	1022,2	990,0	1,85	5,56	715,9	685,7	0,00	0,00
FU Month 21	Other	715,6	685,7	8,33	13,94	49,1	4100,0	0,00	0,00

FU Month 24	Other	6	13,3	5	83,3	3,33	7,45	3	6,8	3	100,0	0,00	0,00
FU Month 27	Other	4	8,9	4	100,0	4,17	8,33	1	2,3	1	100,0	0,00	NE
FU Month 30	Other	2	4,4	2	100,0	0,00	0,00	0	NE	0	NE	NE	NE
Screening	Western Europe	175	100,0	166	94,9	3,92	9,52	165	100,0	155	93,9	3,55	12,74
Cycle 4 Day 1	Western Europe	149	85,1	135	90,6	6,54	12,73	154	93,3	134	87,0	4,60	10,09
FU Day 28	Western Europe	161	92,0	136	84,5	3,80	12,50	153	92,7	134	87,6	3,48	9,38
FU Month 3	Western Europe	155	88,6	139	89,7	3,84	11,75	151	91,5	130	86,1	4,49	11,33
FU Month 6	Western Europe	143	81,7	129	90,2	2,71	9,03	129	78,2	110	85,3	3,03	7,88
FU Month 9	Western Europe	114	65,1	94	82,5	4,79	14,38	102	61,8	82	80,4	3,66	8,29
FU Month 12	Western Europe	88	50,3	76	86,4	3,51	10,30	83	50,3	67	80,7	2,74	7,45
FU Month 15	Western Europe	77	44,0	66	85,7	3,79	10,86	61	37,0	47	77,0	3,55	10,39
FU Month 18	Western Europe	58	33,1	52	89,7	4,49	11,00	44	26,7	34	77,3	3,92	9,23
FU Month 21	Western Europe	36	20,6	28	77,8	3,57	10,50	31	18,8	23	74,2	5,80	18,54
FU Month 24	Western Europe	19	10,9	15	78,9	6,67	15,17	13	7,9	13	100,0	1,28	4,62
FU Month 27	Western Europe	6	3,4	6	100,0	11,11	20,18	6	3,6	5	83,3	0,00	0,00
FU Month 30	Western Europe	4	2,3	4	100,0	12,50	25,00	1	0,6	1	100,0	0,00	NE
FCgamma receptor IIa													
Screening	131HH	58	100,0	54	93,1	5,25	10,15	76	100,0	72	94,7	5,09	13,88
Cycle 4 Day 1	131HH	49	84,5	43	87,8	10,47	17,07	65	85,5	60	92,3	4,44	9,14
FU Day 28	131HH	51	87,9	46	90,2	6,16	13,31	70	92,1	62	88,6	2,96	6,42
FU Month 3	131HH	51	87,9	47	92,2	4,96	10,94	64	84,2	54	84,4	3,70	10,07
FU Month 6	131HH	49	84,5	45	91,8	4,81	11,58	55	72,4	48	87,3	2,78	7,16
FU Month 9	131HH	39	67,2	30	76,9	6,11	14,17	41	53,9	33	80,5	3,54	6,92
FU Month 12	131HH	28	48,3	24	85,7	7,64	16,28	34	44,7	29	85,3	1,72	5,17
FU Month 15	131HH	23	39,7	19	82,6	6,14	13,84	24	31,6	20	83,3	2,50	6,11
FU Month 18	131HH	17	29,3	14	82,4	10,71	15,48	16	21,1	13	81,3	3,85	9,99
FU Month 21	131HH	13	22,4	8	61,5	10,42	17,68	11	14,5	10	90,9	13,33	26,99
FU Month 24	131HH	11	19,0	7	63,6	14,29	20,25	1	1,3	1	100,0	0,00	NE
FU Month 27	131HH	4	6,9	3	75,0	22,22	25,46	1	1,3	1	100,0	0,00	NE
FU Month 30	131HH	3	5,2	2	66,7	25,00	35,36	0	NE	0	NE	NE	NE
Screening	131HR	125	100,0	118	94,4	3,39	9,39	114	100,0	109	95,6	2,60	7,91
Cycle 4 Day 1	131HR	105	84,0	97	92,4	3,61	8,06	110	96,5	99	90,0	4,71	10,92
FU Day 28	131HR	116	92,8	102	87,9	2,45	10,85	105	92,1	95	90,5	4,39	14,43
FU Month 3	131HR	114	91,2	102	89,5	3,10	11,42	107	93,9	95	88,8	4,04	10,23
FU Month 6	131HR	104	83,2	93	89,4	2,33	8,72	95	83,3	85	89,5	3,92	9,84
FU Month 9	131HR	84	67,2	71	84,5	3,52	13,49	76	66,7	61	80,3	3,28	7,34
FU Month 12	131HR	64	51,2	57	89,1	1,75	5,16	57	50,0	48	84,2	2,43	6,87
FU Month 15	131HR	53	42,4	44	83,0	2,27	8,50	44	38,6	35	79,5	2,38	7,17

FU Month 18	131HR		43	34,4	38	88,4	1,75	6,47	32	28,1	26	81,3	2,56	6,13
FU Month 21	131HR		26	20,8	20	76,9	2,50	8,16	21	18,4	16	76,2	0,00	0,00
FU Month 24	131HR		12	9,6	11	91,7	4,55	7,78	12	10,5	11	91,7	1,52	5,03
FU Month 27	131HR		6	4,8	5	83,3	3,33	7,45	6	5,3	4	66,7	0,00	0,00
FU Month 30	131HR		3	2,4	3	100,0	0,00	0,00	1	0,9	1	100,0	0,00	NE
Screening	131RR		49	100,0	48	98,0	4,17	15,18	33	100,0	30	90,9	3,89	9,47
Cycle 4 Day 1	131RR		40	81,6	38	95,0	4,82	10,90	31	93,9	25	80,6	3,33	8,33
FU Day 28	131RR		42	85,7	35	83,3	5,24	12,64	32	97,0	29	90,6	5,75	15,61
FU Month 3	131RR		39	79,6	37	94,9	0,90	3,82	32	97,0	30	93,8	5,56	14,73
FU Month 6	131RR		35	71,4	32	91,4	1,04	4,10	27	81,8	22	81,5	0,76	3,55
FU Month 9	131RR		24	49,0	22	91,7	2,27	7,79	19	57,6	17	89,5	3,92	11,07
FU Month 12	131RR		18	36,7	17	94,4	0,00	0,00	17	51,5	15	88,2	3,33	9,34
FU Month 15	131RR		16	32,7	16	100,0	3,13	9,07	11	33,3	9	81,8	5,56	16,67
FU Month 18	131RR		14	28,6	14	100,0	2,38	8,91	8	24,2	7	87,5	4,76	12,60
FU Month 21	131RR		8	16,3	7	87,5	2,38	6,30	5	15,2	4	80,0	0,00	0,00
FU Month 24	131RR		5	10,2	4	80,0	0,00	0,00	3	9,1	3	100,0	0,00	0,00
FU Month 27	131RR		2	4,1	2	100,0	0,00	0,00	1	3,0	1	100,0	0,00	NE
FU Month 30	131RR		1	2,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
Screening	Missing		23	100,0	22	95,7	3,79	10,20	19	100,0	17	89,5	11,76	24,84
Cycle 4 Day 1	Missing		19	82,6	17	89,5	1,96	5,54	18	94,7	14	77,8	8,33	22,41
FU Day 28	Missing		21	91,3	18	85,7	3,70	12,20	18	94,7	16	88,9	8,33	16,10
FU Month 3	Missing		21	91,3	17	81,0	2,94	8,81	18	94,7	17	94,4	7,84	13,33
FU Month 6	Missing		19	82,6	16	84,2	0,00	0,00	15	78,9	14	93,3	5,95	12,42
FU Month 9	Missing		17	73,9	15	88,2	2,22	5,86	13	68,4	10	76,9	8,33	11,79
FU Month 12	Missing		15	65,2	11	73,3	1,52	5,03	9	47,4	7	77,8	2,38	6,30
FU Month 15	Missing		12	52,2	11	91,7	1,52	5,03	6	31,6	5	83,3	10,00	14,91
FU Month 18	Missing		5	21,7	4	80,0	0,00	0,00	4	21,1	3	75,0	0,00	0,00
FU Month 21	Missing		5	21,7	5	100,0	0,00	0,00	3	15,8	2	66,7	0,00	0,00
FU Month 24	Missing		4	17,4	3	75,0	0,00	0,00	2	10,5	2	100,0	0,00	0,00
FU Month 27	Missing		1	4,3	1	100,0	0,00	NE	1	5,3	1	100,0	0,00	NE
FCgamma receptor IIIa														
Screening	158FF		103	100,0	101	98,1	3,14	11,72	83	100,0	79	95,2	2,74	8,62
Cycle 4 Day 1	158FF		89	86,4	83	93,3	4,82	10,90	78	94,0	72	92,3	3,47	8,36
FU Day 28	158FF		96	93,2	84	87,5	2,38	8,64	78	94,0	73	93,6	5,25	17,32
FU Month 3	158FF		94	91,3	84	89,4	1,39	4,63	78	94,0	71	91,0	4,93	13,91
FU Month 6	158FF		86	83,5	74	86,0	1,58	6,85	64	77,1	58	90,6	3,45	9,75
FU Month 9	158FF		71	68,9	59	83,1	4,24	11,82	47	56,6	43	91,5	2,71	8,08
FU Month 12	158FF		48	46,6	42	87,5	1,59	4,95	38	45,8	35	92,1	1,43	6,22

FU Month 15	158FF		37	35,9		32	86,5	4,17	11,97		30	36,1		24	80,0	2,78	6,34
FU Month 18	158FF		27	26,2		25	92,6	2,67	7,88		21	25,3		17	81,0	2,94	8,81
FU Month 21	158FF		16	15,5		15	93,8	3,33	6,90		9	10,8		8	88,9	10,42	29,46
FU Month 24	158FF		8	7,8		7	87,5	9,52	13,11		3	3,6		3	100,0	0,00	0,00
FU Month 27	158FF		5	4,9		4	80,0	0,00	0,00		1	1,2		1	100,0	0,00	NE
FU Month 30	158FF		3	2,9		3	100,0	0,00	0,00		0	NE		0	NE	NE	NE
Screening	158FV		119	100,0		110	92,4	4,85	10,43		109	100,0		103	94,5	4,05	12,23
Cycle 4 Day 1	158FV		99	83,2		89	89,9	6,37	12,69		100	91,7		86	86,0	5,23	11,22
FU Day 28	158FV		105	88,2		91	86,7	3,85	9,96		101	92,7		87	86,1	3,26	8,37
FU Month 3	158FV		101	84,9		93	92,1	3,76	9,24		97	89,0		84	86,6	3,17	8,37
FU Month 6	158FV		94	79,0		87	92,6	3,07	9,35		83	76,1		72	86,7	3,47	8,36
FU Month 9	158FV		71	59,7		61	85,9	3,83	14,07		65	59,6		49	75,4	4,08	8,00
FU Month 12	158FV		60	50,4		55	91,7	3,94	11,55		52	47,7		42	80,8	3,57	7,84
FU Month 15	158FV		52	43,7		45	86,5	2,96	8,91		36	33,0		30	83,3	3,33	10,17
FU Month 18	158FV		44	37,0		38	86,4	3,95	11,25		24	22,0		20	83,3	3,33	8,72
FU Month 21	158FV		28	23,5		18	64,3	4,63	13,77		18	16,5		14	77,8	2,38	8,91
FU Month 24	158FV		18	15,1		13	72,2	6,41	14,50		6	5,5		5	83,3	0,00	0,00
FU Month 27	158FV		6	5,0		5	83,3	13,33	21,73		2	1,8		1	50,0	0,00	NE
FU Month 30	158FV		4	3,4		3	75,0	16,67	28,87		0	NE		0	NE	NE	NE
Screening	158VV		16	100,0		15	93,8	2,22	8,61		33	100,0		31	93,9	3,76	8,29
Cycle 4 Day 1	158VV		12	75,0		11	91,7	1,52	5,03		30	90,9		28	93,3	4,17	9,76
FU Day 28	158VV		14	87,5		13	92,9	10,26	27,67		30	90,9		28	93,3	3,57	6,96
FU Month 3	158VV		15	93,8		12	80,0	8,33	28,87		30	90,9		26	86,7	4,49	8,89
FU Month 6	158VV		14	87,5		13	92,9	6,41	14,50		30	90,9		25	83,3	1,33	4,61
FU Month 9	158VV		12	75,0		10	83,3	3,33	7,03		25	75,8		20	80,0	4,17	7,40
FU Month 12	158VV		8	50,0		7	87,5	2,38	6,30		20	60,6		17	85,0	0,98	4,04
FU Month 15	158VV		8	50,0		7	87,5	2,38	6,30		14	42,4		11	78,6	3,03	10,05
FU Month 18	158VV		4	25,0		4	100,0	8,33	9,62		11	33,3		9	81,8	3,70	7,35
FU Month 21	158VV		3	18,8		2	66,7	8,33	11,79		9	27,3		7	77,8	2,38	6,30
FU Month 24	158VV		2	12,5		2	100,0	0,00	0,00		7	21,2		7	100,0	2,38	6,30
FU Month 27	158VV		1	6,3		1	100,0	16,67	NE		5	15,2		4	80,0	0,00	0,00
FU Month 30	158VV		0	NE		0	NE	NE	NE		1	3,0		1	100,0	0,00	NE
Screening	Missing		17	100,0		16	94,1	5,21	11,74		17	100,0		15	88,2	14,44	25,87
Cycle 4 Day 1	Missing		13	76,5		12	92,3	2,78	6,49		16	94,1		12	75,0	9,72	24,06
FU Day 28	Missing		15	88,2		13	86,7	7,69	16,12		16	94,1		14	87,5	9,52	16,94
FU Month 3	Missing		15	88,2		14	93,3	4,76	10,19		16	94,1		15	93,8	10,00	13,80
FU Month 6	Missing		13	76,5		12	92,3	0,00	0,00		15	88,2		14	93,3	5,95	12,42
FU Month 9	Missing		10	58,8		8	80,0	0,00	0,00		12	70,6		9	75,0	7,41	12,11

FU Month 12	Missing		952,9	555,6	0,00	0,00	741,2	571,4	3,33	7,45	
FU Month 15	Missing		741,2	685,7	0,00	0,00	529,4	480,0	8,33	16,67	
FU Month 18	Missing		423,5	375,0	0,00	0,00	423,5	375,0	0,00	0,00	
FU Month 21	Missing		529,4	5100,0	0,00	0,00	423,5	375,0	0,00	0,00	
FU Month 24	Missing		423,5	375,0	0,00	0,00	211,8	2100,0	0,00	0,00	
FU Month 27	Missing		15,9	1100,0	0,00	NE	15,9	1100,0	0,00		NE
Binet Staging at baseline											
Screening	A		59100,0	5898,3	4,31	10,61	57100,0	5393,0	9,12	20,30	
Cycle 4 Day 1	A		5186,4	4894,1	7,99	14,17	5494,7	5092,6	5,67	10,44	
FU Day 28	A		5898,3	5391,4	3,77	9,61	5494,7	5194,4	6,54	12,94	
FU Month 3	A		5796,6	5698,2	4,17	9,67	5393,0	5094,3	6,00	12,03	
FU Month 6	A		5694,9	5089,3	3,33	11,17	4578,9	4293,3	5,16	10,72	
FU Month 9	A		4372,9	3786,0	3,60	16,73	3459,6	3088,2	5,00	9,93	
FU Month 12	A		3661,0	3494,4	3,43	12,16	2442,1	2187,5	2,38	5,98	
FU Month 15	A		3050,8	2790,0	3,09	10,37	1933,3	19100,0	7,02	13,96	
FU Month 18	A		2237,3	1881,8	5,56	14,00	1628,1	16100,0	3,13	9,07	
FU Month 21	A		1728,8	1588,2	4,44	13,31	814,0	787,5	0,00	0,00	
FU Month 24	A		1016,9	880,0	6,25	17,68	58,8	5100,0	0,00	0,00	
FU Month 27	A		58,5	480,0	12,50	25,00	23,5	150,0	0,00		NE
FU Month 30	A		46,8	375,0	16,67	28,87	0	NE	0	NE	NE
Screening	B	104	100,0	100	96,2	3,50	7,96	85100,0	8397,6	3,41	8,54
Cycle 4 Day 1	B		8884,6	8394,3	3,21	8,42	7992,9	7392,4	6,16	13,75	
FU Day 28	B		9187,5	7986,8	4,01	12,86	7992,9	7189,9	4,46	14,90	
FU Month 3	B		8884,6	7888,6	3,21	12,90	7992,9	7189,9	5,16	12,47	
FU Month 6	B		8076,9	7695,0	2,41	8,48	7082,4	6390,0	2,38	5,88	
FU Month 9	B		6360,6	5282,5	3,53	8,31	5969,4	4983,1	3,74	7,81	
FU Month 12	B		4745,2	3983,0	2,99	8,44	4654,1	4087,0	2,92	7,44	
FU Month 15	B		3735,6	3491,9	2,45	7,26	3440,0	2882,4	1,19	6,30	
FU Month 18	B		3129,8	2993,5	4,02	9,61	2225,9	1881,8	3,70	7,13	
FU Month 21	B		1817,3	1372,2	3,85	7,31	1720,0	1482,4	1,19	4,45	
FU Month 24	B		1110,6	981,8	3,70	7,35	89,4	8100,0	2,08	5,89	
FU Month 27	B		54,8	480,0	4,17	8,33	44,7	4100,0	0,00	0,00	
FU Month 30	B		21,9	2100,0	0,00	0,00	0	NE	0	NE	NE
Screening	C		92100,0	8491,3	4,37	13,96	100	100,0	9292,0	2,17	7,50
Cycle 4 Day 1	C		7480,4	6486,5	5,73	11,96	9191,0	7582,4	2,67	8,68	
FU Day 28	C		8188,0	6985,2	3,86	12,51	9292,0	8087,0	3,13	10,64	
FU Month 3	C		8087,0	6986,3	2,17	6,34	8989,0	7584,3	2,89	9,24	
FU Month 6	C		7177,2	6084,5	1,94	6,21	7777,0	6483,1	3,13	9,79	

FU Month 9	C	58	63,0	49	84,5	4,08	12,04	56	56,0	42	75,0	3,17	7,58
FU Month 12	C	42	45,7	36	85,7	1,85	5,31	47	47,0	38	80,9	1,75	6,47
FU Month 15	C	37	40,2	29	78,4	4,02	11,49	32	32,0	22	68,8	3,03	6,58
FU Month 18	C	26	28,3	23	88,5	1,45	4,80	22	22,0	15	68,2	2,22	8,61
FU Month 21	C	17	18,5	12	70,6	2,78	9,62	15	15,0	11	73,3	10,61	26,11
FU Month 24	C	11	12,0	8	72,7	8,33	12,60	5	5,0	4	80,0	0,00	0,00
FU Month 27	C	3	3,3	3	100,0	5,56	9,62	3	3,0	2	66,7	0,00	0,00
FU Month 30	C	1	1,1	1	100,0	0,00	NE	1	1,0	1	100,0	0,00	NE
Total CIR score at baseline													
Screening	<=6	63	100,0	59	93,7	2,54	7,46	75	100,0	70	93,3	5,24	17,15
Cycle 4 Day 1	<=6	52	82,5	42	80,8	3,97	8,07	72	96,0	61	84,7	4,92	11,12
FU Day 28	<=6	56	88,9	49	87,5	2,72	9,22	72	96,0	59	81,9	2,26	11,35
FU Month 3	<=6	55	87,3	47	85,5	2,48	6,93	69	92,0	56	81,2	3,57	10,40
FU Month 6	<=6	52	82,5	47	90,4	1,77	7,15	60	80,0	53	88,3	2,83	9,66
FU Month 9	<=6	43	68,3	36	83,7	3,24	11,83	47	62,7	38	80,9	3,51	8,80
FU Month 12	<=6	35	55,6	29	82,9	2,87	7,80	34	45,3	27	79,4	0,62	3,21
FU Month 15	<=6	32	50,8	28	87,5	2,38	7,47	25	33,3	17	68,0	0,98	4,04
FU Month 18	<=6	23	36,5	22	95,7	2,27	5,85	19	25,3	14	73,7	3,57	9,65
FU Month 21	<=6	14	22,2	8	57,1	4,17	11,79	14	18,7	10	71,4	8,33	26,35
FU Month 24	<=6	8	12,7	7	87,5	4,76	8,13	7	9,3	6	85,7	0,00	0,00
FU Month 27	<=6	2	3,2	2	100,0	8,33	11,79	4	5,3	2	50,0	0,00	0,00
FU Month 30	<=6	0	NE	0	NE	NE	NE	1	1,3	1	100,0	0,00	NE
Screening >6													
Screening	>6	192	100,0	183	95,3	4,46	11,84	167	100,0	158	94,6	3,80	9,39
Cycle 4 Day 1	>6	161	83,9	153	95,0	5,56	12,09	152	91,0	137	90,1	4,62	11,38
FU Day 28	>6	174	90,6	152	87,4	4,28	12,65	153	91,6	143	93,5	5,36	13,36
FU Month 3	>6	170	88,5	156	91,8	3,31	10,94	152	91,0	140	92,1	4,88	11,57
FU Month 6	>6	155	80,7	139	89,7	2,76	9,11	132	79,0	116	87,9	3,59	8,46
FU Month 9	>6	121	63,0	102	84,3	3,92	12,45	102	61,1	83	81,4	4,02	8,06
FU Month 12	>6	90	46,9	80	88,9	2,71	9,35	83	49,7	72	86,7	3,01	7,57
FU Month 15	>6	72	37,5	62	86,1	3,49	10,51	60	35,9	52	86,7	4,17	10,37
FU Month 18	>6	56	29,2	48	85,7	4,17	11,14	41	24,6	35	85,4	2,86	7,55
FU Month 21	>6	38	19,8	32	84,2	3,65	10,14	26	15,6	22	84,6	2,27	7,79
FU Month 24	>6	24	12,5	18	75,0	6,48	14,16	11	6,6	11	100,0	1,52	5,03
FU Month 27	>6	11	5,7	9	81,8	7,41	16,90	5	3,0	5	100,0	0,00	0,00
FU Month 30	>6	7	3,6	6	85,7	8,33	20,41	0	NE	0	NE	NE	NE
Calculated creatinine clearance cat. 2													
Screening	<70 ml/min	178	100,0	166	93,3	3,92	9,70	176	100,0	166	94,3	5,02	13,79
Cycle 4 Day 1	<70 ml/min	149	83,7	133	89,3	4,76	10,37	164	93,2	144	87,8	5,09	12,19

FU Day 28	<70 ml/min	162	91,0	142	87,7	3,52	9,69	166	94,3	145	87,3	3,91	11,46
FU Month 3	<70 ml/min	157	88,2	141	89,8	2,96	8,04	159	90,3	139	87,4	4,80	11,57
FU Month 6	<70 ml/min	144	80,9	127	88,2	2,36	7,78	139	79,0	121	87,1	2,62	8,05
FU Month 9	<70 ml/min	117	65,7	97	82,9	3,78	10,35	112	63,6	90	80,4	4,26	8,85
FU Month 12	<70 ml/min	92	51,7	79	85,9	2,74	9,78	87	49,4	73	83,9	2,28	6,98
FU Month 15	<70 ml/min	78	43,8	69	88,5	3,62	10,64	60	34,1	48	80,0	3,47	9,70
FU Month 18	<70 ml/min	59	33,1	51	86,4	4,25	10,98	43	24,4	36	83,7	4,17	9,24
FU Month 21	<70 ml/min	38	21,3	27	71,1	3,70	11,63	31	17,6	27	87,1	4,94	17,18
FU Month 24	<70 ml/min	24	13,5	19	79,2	7,89	14,02	13	7,4	12	92,3	0,00	0,00
FU Month 27	<70 ml/min	10	5,6	8	80,0	8,33	17,82	7	4,0	5	71,4	0,00	0,00
FU Month 30	<70 ml/min	5	2,8	4	80,0	12,50	25,00	1	0,6	1	100,0	0,00	NE
Screening	>=70 ml/min	77	100,0	76	98,7	4,17	13,37	66	100,0	62	93,9	2,15	6,39
Cycle 4 Day 1	>=70 ml/min	64	83,1	62	96,9	6,18	13,24	60	90,9	54	90,0	3,70	8,36
FU Day 28	>=70 ml/min	68	88,3	59	86,8	4,80	16,10	59	89,4	57	96,6	5,85	15,90
FU Month 3	>=70 ml/min	68	88,3	62	91,2	3,49	13,87	62	93,9	57	91,9	3,80	10,45
FU Month 6	>=70 ml/min	63	81,8	59	93,7	2,82	10,34	53	80,3	48	90,6	5,21	10,40
FU Month 9	>=70 ml/min	47	61,0	41	87,2	3,66	16,03	37	56,1	31	83,8	2,69	6,23
FU Month 12	>=70 ml/min	33	42,9	30	90,9	2,78	6,32	30	45,5	26	86,7	2,56	6,13
FU Month 15	>=70 ml/min	26	33,8	21	80,8	1,59	5,01	25	37,9	21	84,0	3,17	8,53
FU Month 18	>=70 ml/min	20	26,0	19	95,0	1,75	5,26	17	25,8	13	76,5	0,00	0,00
FU Month 21	>=70 ml/min	14	18,2	13	92,9	3,85	7,31	9	13,6	5	55,6	0,00	0,00
FU Month 24	>=70 ml/min	8	10,4	6	75,0	0,00	0,00	5	7,6	5	100,0	3,33	7,45
FU Month 27	>=70 ml/min	3	3,9	3	100,0	5,56	9,62	2	3,0	2	100,0	0,00	0,00
FU Month 30	>=70 ml/min	2	2,6	2	100,0	0,00	0,00	0	NE	0	NE	NE	NE
Beta2 microglobulin													
Screening	Missing	3	100,0	3	100,0	0,00	0,00	3	100,0	3	100,0	33,33	57,74
Cycle 4 Day 1	Missing	3	100,0	3	100,0	5,56	9,62	3	100,0	2	66,7	0,00	0,00
FU Day 28	Missing	3	100,0	3	100,0	0,00	0,00	3	100,0	2	66,7	0,00	0,00
FU Month 3	Missing	3	100,0	3	100,0	5,56	9,62	3	100,0	2	66,7	0,00	0,00
FU Month 6	Missing	3	100,0	3	100,0	0,00	0,00	3	100,0	2	66,7	0,00	0,00
FU Month 9	Missing	2	66,7	1	50,0	0,00	NE	3	100,0	2	66,7	16,67	23,57
FU Month 12	Missing	1	33,3	1	100,0	0,00	NE	2	66,7	1	50,0	0,00	NE
FU Month 15	Missing	1	33,3	1	100,0	0,00	NE	2	66,7	1	50,0	0,00	NE
FU Month 18	Missing	1	33,3	1	100,0	0,00	NE	2	66,7	1	50,0	0,00	NE
FU Month 21	Missing	1	33,3	1	100,0	0,00	NE	2	66,7	1	50,0	0,00	NE
FU Month 24	Missing	1	33,3	1	100,0	0,00	NE	1	33,3	1	100,0	0,00	NE
Screening	< 3.5 ug/mL	154	100,0	145	94,2	4,83	12,25	140	100,0	132	94,3	4,67	10,15
Cycle 4 Day 1	< 3.5 ug/mL	127	82,5	116	91,3	6,18	11,74	129	92,1	112	86,8	5,51	10,82

FU Day 28	< 3.5 ug/mL	137	89,0	121	88,3	4,13	10,16	132	94,3	120	90,9	6,67	15,79
FU Month 3	< 3.5 ug/mL	134	87,0	123	91,8	2,71	7,80	130	92,9	116	89,2	5,75	12,65
FU Month 6	< 3.5 ug/mL	128	83,1	114	89,1	2,63	9,03	120	85,7	110	91,7	4,24	9,95
FU Month 9	< 3.5 ug/mL	104	67,5	87	83,7	2,87	9,91	98	70,0	81	82,7	4,32	8,65
FU Month 12	< 3.5 ug/mL	78	50,6	69	88,5	4,11	10,85	75	53,6	67	89,3	3,23	7,81
FU Month 15	< 3.5 ug/mL	65	42,2	56	86,2	3,87	10,05	60	42,9	51	85,0	3,92	10,32
FU Month 18	< 3.5 ug/mL	46	29,9	41	89,1	5,28	12,04	43	30,7	35	81,4	3,81	9,12
FU Month 21	< 3.5 ug/mL	30	19,5	21	70,0	4,76	13,06	27	19,3	22	81,5	6,06	18,93
FU Month 24	< 3.5 ug/mL	19	12,3	15	78,9	7,78	13,90	12	8,6	11	91,7	1,52	5,03
FU Month 27	< 3.5 ug/mL	10	6,5	8	80,0	10,42	17,68	7	5,0	5	71,4	0,00	0,00
FU Month 30	< 3.5 ug/mL	5	3,2	4	80,0	12,50	25,00	1	0,7	1	100,0	0,00	NE
Screening	>= 3.5 ug/mL	98	100,0	94	95,9	2,84	8,69	99	100,0	93	93,9	2,69	11,07
Cycle 4 Day 1	>= 3.5 ug/mL	83	84,7	76	91,6	3,73	10,75	92	92,9	84	91,3	3,77	11,95
FU Day 28	>= 3.5 ug/mL	90	91,8	77	85,6	3,68	14,46	90	90,9	80	88,9	1,25	5,15
FU Month 3	>= 3.5 ug/mL	88	89,8	77	87,5	3,68	13,14	88	88,9	78	88,6	2,78	8,67
FU Month 6	>= 3.5 ug/mL	76	77,6	69	90,8	2,42	8,22	69	69,7	57	82,6	1,75	6,05
FU Month 9	>= 3.5 ug/mL	58	59,2	50	86,2	5,33	15,59	48	48,5	38	79,2	2,19	5,71
FU Month 12	>= 3.5 ug/mL	46	46,9	39	84,8	0,43	2,67	40	40,4	31	77,5	0,54	2,99
FU Month 15	>= 3.5 ug/mL	38	38,8	33	86,8	2,02	9,09	23	23,2	17	73,9	1,96	5,54
FU Month 18	>= 3.5 ug/mL	32	32,7	28	87,5	1,19	4,37	15	15,2	13	86,7	1,28	4,62
FU Month 21	>= 3.5 ug/mL	21	21,4	18	85,7	2,78	6,39	11	11,1	9	81,8	0,00	0,00
FU Month 24	>= 3.5 ug/mL	12	12,2	9	75,0	3,70	11,11	5	5,1	5	100,0	0,00	0,00
FU Month 27	>= 3.5 ug/mL	3	3,1	3	100,0	0,00	0,00	2	2,0	2	100,0	0,00	0,00
FU Month 30	>= 3.5 ug/mL	2	2,0	2	100,0	0,00	0,00	0	NE	0	NE	NE	NE
Immunoglobulin VH, cytogenetics 2													
Screening	12	45	100,0	43	95,6	5,81	12,00	44	100,0	43	97,7	3,88	13,53
Cycle 4 Day 1	12	34	75,6	32	94,1	6,25	11,79	38	86,4	33	86,8	5,05	11,40
FU Day 28	12	39	86,7	37	94,9	5,41	14,19	40	90,9	35	87,5	2,38	5,92
FU Month 3	12	38	84,4	36	94,7	5,56	11,95	39	88,6	32	82,1	3,13	8,92
FU Month 6	12	36	80,0	31	86,1	3,23	6,69	34	77,3	28	82,4	4,17	9,76
FU Month 9	12	26	57,8	22	84,6	7,58	21,66	28	63,6	18	64,3	3,70	7,13
FU Month 12	12	22	48,9	18	81,8	5,56	16,17	23	52,3	15	65,2	2,22	5,86
FU Month 15	12	17	37,8	14	82,4	4,76	13,76	17	38,6	12	70,6	2,78	9,62
FU Month 18	12	15	33,3	12	80,0	6,94	15,01	13	29,5	9	69,2	3,70	7,35
FU Month 21	12	10	22,2	8	80,0	10,42	17,68	7	15,9	5	71,4	0,00	0,00
FU Month 24	12	8	17,8	6	75,0	13,89	22,15	6	13,6	6	100,0	2,78	6,80
FU Month 27	12	5	11,1	4	80,0	16,67	23,57	2	4,5	2	100,0	0,00	0,00
FU Month 30	12	4	8,9	3	75,0	16,67	28,87	1	2,3	1	100,0	0,00	NE

Screening	11q-	46	100,0	43	93,5	2,33	5,84	43	100,0	40	93,0	3,33	8,61
Cycle 4 Day 1	11q-	40	87,0	39	97,5	4,27	9,14	41	95,3	35	85,4	2,86	7,55
FU Day 28	11q-	42	91,3	35	83,3	3,81	9,12	39	90,7	36	92,3	3,70	8,08
FU Month 3	11q-	42	91,3	38	90,5	2,19	5,71	38	88,4	36	94,7	2,78	8,45
FU Month 6	11q-	38	82,6	35	92,1	3,33	10,54	32	74,4	28	87,5	2,38	7,47
FU Month 9	11q-	28	60,9	26	92,9	1,92	5,43	25	58,1	21	84,0	4,76	9,34
FU Month 12	11q-	20	43,5	19	95,0	1,75	5,26	18	41,9	17	94,4	3,92	9,37
FU Month 15	11q-	18	39,1	16	88,9	2,08	5,69	14	32,6	10	71,4	5,00	15,81
FU Month 18	11q-	15	32,6	13	86,7	0,00	0,00	8	18,6	7	87,5	4,76	12,60
FU Month 21	11q-	12	26,1	11	91,7	1,52	5,03	4	9,3	2	50,0	0,00	0,00
FU Month 24	11q-	7	15,2	5	71,4	0,00	0,00	1	2,3	1	100,0	0,00	NE
FU Month 27	11q-	3	6,5	3	100,0	0,00	0,00	0	NE	0	NE	NE	NE
FU Month 30	11q-	3	6,5	3	100,0	0,00	0,00	0	NE	0	NE	NE	NE
Screening	13q-	79	100,0	77	97,5	4,76	14,01	75	100,0	70	93,3	3,33	8,32
Cycle 4 Day 1	13q-	67	84,8	60	89,6	4,17	9,01	68	90,7	60	88,2	3,06	8,40
FU Day 28	13q-	72	91,1	65	90,3	3,08	10,16	72	96,0	65	90,3	3,33	8,94
FU Month 3	13q-	73	92,4	67	91,8	1,49	5,60	69	92,0	61	88,4	3,83	9,33
FU Month 6	13q-	67	84,8	61	91,0	1,09	5,15	63	84,0	56	88,9	2,08	7,15
FU Month 9	13q-	56	70,9	49	87,5	4,08	12,04	52	69,3	42	80,8	1,59	4,95
FU Month 12	13q-	44	55,7	39	88,6	1,71	6,39	40	53,3	38	95,0	0,00	0,00
FU Month 15	13q-	38	48,1	33	86,8	3,03	8,79	29	38,7	25	86,2	2,67	6,24
FU Month 18	13q-	28	35,4	25	89,3	2,00	7,33	21	28,0	19	90,5	3,51	8,92
FU Month 21	13q-	16	20,3	13	81,3	1,28	4,62	16	21,3	14	87,5	7,14	22,37
FU Month 24	13q-	7	8,9	6	85,7	5,56	8,61	7	9,3	6	85,7	0,00	0,00
FU Month 27	13q-	2	2,5	1	50,0	0,00	NE	6	8,0	4	66,7	0,00	0,00
Screening	Norm. K.	65	100,0	61	93,8	3,55	9,68	58	100,0	55	94,8	6,97	17,77
Cycle 4 Day 1	Norm. K.	54	83,1	48	88,9	6,94	14,52	55	94,8	50	90,9	8,00	15,88
FU Day 28	Norm. K.	59	90,8	50	84,7	4,33	14,99	53	91,4	49	92,5	6,80	19,22
FU Month 3	Norm. K.	54	83,1	48	88,9	5,21	15,81	54	93,1	48	88,9	6,60	13,20
FU Month 6	Norm. K.	49	75,4	47	95,9	3,55	12,01	45	77,6	40	88,9	5,00	10,81
FU Month 9	Norm. K.	39	60,0	31	79,5	2,15	7,13	30	51,7	27	90,0	6,17	10,49
FU Month 12	Norm. K.	32	49,2	27	84,4	3,09	8,06	24	41,4	20	83,3	4,17	7,40
FU Month 15	Norm. K.	26	40,0	23	88,5	3,62	11,19	20	34,5	18	90,0	2,78	6,39
FU Month 18	Norm. K.	18	27,7	17	94,4	6,86	11,87	15	25,9	12	80,0	1,39	4,81
FU Month 21	Norm. K.	12	18,5	6	50,0	5,56	13,61	11	19,0	9	81,8	3,70	11,11
FU Month 24	Norm. K.	8	12,3	6	75,0	5,56	8,61	4	6,9	4	100,0	0,00	0,00
FU Month 27	Norm. K.	3	4,6	3	100,0	5,56	9,62	1	1,7	1	100,0	0,00	NE
Screening	Other Abn.	20	100,0	18	90,0	1,85	5,39	22	100,0	20	90,9	2,50	8,16

Cycle 4 Day 1	Other Abn.	18	90,0	16	88,9	4,17	12,91	22	100,0	20	90,9	4,17	9,17
FU Day 28	Other Abn.	18	90,0	14	77,8	2,38	6,05	21	95,5	17	81,0	7,84	19,65
FU Month 3	Other Abn.	18	90,0	14	77,8	0,00	0,00	21	95,5	19	90,5	7,02	17,84
FU Month 6	Other Abn.	17	85,0	12	70,6	1,39	4,81	18	81,8	17	94,4	3,92	9,37
FU Month 9	Other Abn.	15	75,0	10	66,7	3,33	10,54	14	63,6	13	92,9	5,13	10,51
FU Month 12	Other Abn.	7	35,0	6	85,7	2,78	6,80	12	54,5	9	75,0	5,56	11,79
FU Month 15	Other Abn.	5	25,0	4	80,0	0,00	0,00	5	22,7	4	80,0	8,33	16,67
FU Month 18	Other Abn.	3	15,0	3	100,0	0,00	0,00	3	13,6	2	66,7	0,00	0,00
FU Month 21	Other Abn.	2	10,0	2	100,0	0,00	0,00	2	9,1	2	100,0	0,00	0,00
FU Month 24	Other Abn.	2	10,0	2	100,0	0,00	0,00	0	NE	0	NE	NE	NE
Time from first diagnosis													
Screening	Missing	1	100,0	1	100,0	16,67	NE	0	NE	0	NE	NE	NE
Cycle 4 Day 1	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Day 28	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 3	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 6	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 9	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 12	Missing	1	100,0	1	100,0	16,67	NE	0	NE	0	NE	NE	NE
FU Month 15	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 18	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
Screening	13 - 24 months	41	100,0	39	95,1	5,13	12,77	31	100,0	31	100,0	2,15	5,68
Cycle 4 Day 1	13 - 24 months	35	85,4	34	97,1	3,43	8,97	30	96,8	27	90,0	4,32	8,76
FU Day 28	13 - 24 months	38	92,7	33	86,8	2,53	6,07	30	96,8	27	90,0	1,85	5,34
FU Month 3	13 - 24 months	36	87,8	34	94,4	2,45	8,34	30	96,8	26	86,7	1,28	4,53
FU Month 6	13 - 24 months	36	87,8	33	91,7	0,51	2,90	30	96,8	25	83,3	3,33	8,33
FU Month 9	13 - 24 months	32	78,0	29	90,6	2,30	7,35	21	67,7	18	85,7	2,78	6,39
FU Month 12	13 - 24 months	21	51,2	18	85,7	4,63	15,97	16	51,6	14	87,5	2,38	6,05
FU Month 15	13 - 24 months	19	46,3	18	94,7	2,78	11,79	16	51,6	10	62,5	3,33	10,54
FU Month 18	13 - 24 months	14	34,1	13	92,9	5,13	14,25	10	32,3	8	80,0	2,08	5,89
FU Month 21	13 - 24 months	11	26,8	9	81,8	9,26	16,90	6	19,4	4	66,7	0,00	0,00
FU Month 24	13 - 24 months	8	19,5	5	62,5	10,00	22,36	3	9,7	3	100,0	0,00	0,00
FU Month 27	13 - 24 months	5	12,2	5	100,0	13,33	21,73	2	6,5	2	100,0	0,00	0,00
FU Month 30	13 - 24 months	3	7,3	3	100,0	16,67	28,87	1	3,2	1	100,0	0,00	NE
Screening	<= 12 months	60	100,0	58	96,7	4,02	14,07	70	100,0	69	98,6	4,11	12,26
Cycle 4 Day 1	<= 12 months	48	80,0	42	87,5	3,97	8,87	60	85,7	56	93,3	3,57	8,83
FU Day 28	<= 12 months	54	90,0	45	83,3	6,30	18,22	62	88,6	57	91,9	3,80	8,92
FU Month 3	<= 12 months	53	88,3	45	84,9	4,44	16,05	59	84,3	55	93,2	1,52	5,80
FU Month 6	<= 12 months	46	76,7	40	87,0	3,75	11,00	47	67,1	43	91,5	3,49	9,31

FU Month 9	<= 12 months	35	58,3	27	77,1	4,32	13,55	37	52,9	31	83,8	2,69	6,23
FU Month 12	<= 12 months	27	45,0	23	85,2	2,17	5,74	29	41,4	27	93,1	3,09	8,06
FU Month 15	<= 12 months	22	36,7	17	77,3	3,92	9,37	17	24,3	16	94,1	3,13	9,07
FU Month 18	<= 12 months	16	26,7	13	81,3	3,85	7,31	13	18,6	12	92,3	2,78	6,49
FU Month 21	<= 12 months	9	15,0	5	55,6	0,00	0,00	7	10,0	6	85,7	0,00	0,00
FU Month 24	<= 12 months	6	10,0	3	50,0	11,11	19,25	2	2,9	1	50,0	0,00	NE
FU Month 27	<= 12 months	1	1,7			NE	NE	1	1,4			NE	NE
FU Month 30	<= 12 months	1	1,7			NE	NE	0	NE			NE	NE
Screening	>24 months	153	100,0	144	94,1	3,59	8,85	141	100,0	128	90,8	4,82	13,42
Cycle 4 Day 1	>24 months	129	84,3	118	91,5	6,21	12,67	134	95,0	115	85,8	5,36	12,79
FU Day 28	>24 months	137	89,5	122	89,1	3,42	10,04	133	94,3	118	88,7	5,37	15,39
FU Month 3	>24 months	135	88,2	123	91,1	2,85	7,61	132	93,6	115	87,1	6,67	13,57
FU Month 6	>24 months	124	81,0	112	90,3	2,68	8,82	115	81,6	101	87,8	3,30	8,83
FU Month 9	>24 months	96	62,7	81	84,4	4,12	13,32	91	64,5	72	79,1	4,63	9,37
FU Month 12	>24 months	76	49,7	67	88,2	2,24	7,04	72	51,1	58	80,6	2,01	6,30
FU Month 15	>24 months	62	40,5	54	87,1	3,09	9,20	52	36,9	43	82,7	3,49	9,31
FU Month 18	>24 months	48	31,4	43	89,6	3,10	9,10	37	26,2	29	78,4	3,45	9,32
FU Month 21	>24 months	32	20,9	26	81,3	2,56	7,73	27	19,1	22	81,5	6,06	18,93
FU Month 24	>24 months	18	11,8	17	94,4	3,92	7,29	13	9,2	13	100,0	1,28	4,62
FU Month 27	>24 months	7	4,6	6	85,7	2,78	6,80	6	4,3	5	83,3	0,00	0,00
FU Month 30	>24 months	3	2,0	3	100,0	0,00	0,00	0	NE	0	NE	NE	NE
High circulating tumor burden													
Screening	Missing	0	NE	0	NE	NE	NE	2	100,0	1	50,0	0,00	NE
Cycle 4 Day 1	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	0,00	NE
FU Day 28	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	0,00	NE
FU Month 3	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	0,00	NE
FU Month 6	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	0,00	NE
FU Month 9	Missing	0	NE			NE	NE	1	50,0			NE	NE
Screening	<25x10**9 cells/L	60	100,0	55	91,7	4,55	10,37	67	100,0	64	95,5	5,47	14,26
Cycle 4 Day 1	<25x10**9 cells/L	50	83,3	44	88,0	6,82	11,55	61	91,0	52	85,2	6,41	14,82
FU Day 28	<25x10**9 cells/L	56	93,3	47	83,9	2,13	5,62	61	91,0	53	86,9	1,89	5,33
FU Month 3	<25x10**9 cells/L	54	90,0	47	87,0	3,19	8,25	59	88,1	50	84,7	2,00	7,25
FU Month 6	<25x10**9 cells/L	50	83,3	43	86,0	3,88	10,81	51	76,1	42	82,4	1,59	6,17
FU Month 9	<25x10**9 cells/L	36	60,0	27	75,0	3,09	8,06	41	61,2	30	73,2	2,78	7,69
FU Month 12	<25x10**9 cells/L	29	48,3	24	82,8	4,86	14,31	34	50,7	25	73,5	2,67	7,88
FU Month 15	<25x10**9 cells/L	24	40,0	19	79,2	6,14	15,92	23	34,3	15	65,2	6,67	15,17
FU Month 18	<25x10**9 cells/L	20	33,3	18	90,0	3,70	12,20	19	28,4	14	73,7	4,76	10,19
FU Month 21	<25x10**9 cells/L	14	23,3	10	71,4	8,33	16,20	10	14,9	8	80,0	0,00	0,00

FU Month 24	<25x10**9 cells/L	8	13,3	5	62,5	16,67	23,57	6	9,0	6	100,0	0,00	0,00
FU Month 27	<25x10**9 cells/L	4	6,7	3	75,0	16,67	28,87	1	1,5	1	100,0	0,00	NE
FU Month 30	<25x10**9 cells/L	4	6,7	3	75,0	16,67	28,87	1	1,5	1	100,0	0,00	NE
Screening	>=25x10**9 cells/L	195	100,0	187	95,9	3,83	11,14	173	100,0	163	94,2	3,78	11,46
Cycle 4 Day 1	>=25x10**9 cells/L	163	83,6	151	92,6	4,75	11,28	162	93,6	145	89,5	4,14	9,73
FU Day 28	>=25x10**9 cells/L	174	89,2	154	88,5	4,44	13,21	163	94,2	148	90,8	5,41	14,58
FU Month 3	>=25x10**9 cells/L	171	87,7	156	91,2	3,10	10,68	161	93,1	145	90,1	5,40	12,25
FU Month 6	>=25x10**9 cells/L	157	80,5	143	91,1	2,10	7,88	140	80,9	126	90,0	3,97	9,53
FU Month 9	>=25x10**9 cells/L	128	65,6	111	86,7	3,90	13,10	107	61,8	91	85,0	4,21	8,46
FU Month 12	>=25x10**9 cells/L	96	49,2	85	88,5	2,16	6,70	83	48,0	74	89,2	2,25	6,37
FU Month 15	>=25x10**9 cells/L	80	41,0	71	88,8	2,35	7,07	62	35,8	54	87,1	2,47	6,80
FU Month 18	>=25x10**9 cells/L	59	30,3	52	88,1	3,53	8,94	41	23,7	35	85,4	2,38	7,17
FU Month 21	>=25x10**9 cells/L	38	19,5	30	78,9	2,22	7,24	30	17,3	24	80,0	5,56	18,17
FU Month 24	>=25x10**9 cells/L	24	12,3	20	83,3	3,33	6,84	12	6,9	11	91,7	1,52	5,03
FU Month 27	>=25x10**9 cells/L	9	4,6	8	88,9	4,17	7,72	8	4,6	6	75,0	0,00	0,00
FU Month 30	>=25x10**9 cells/L	3	1,5	3	100,0	0,00	0,00	0	NE	0	NE	NE	NE

¹ in study: number of subjects in study at respective visit; % based on baseline

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit

² mean: descriptive statistics - absolute values Clinical

cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/t_pro_mean.sas

Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/t_pro_mean_sg_EQC30_IT_label_09MAY2013_21004.xls 04MAR2020

17:18

POPULATION: Labelpopulation, Intent-to-Treat Patients ENDPOINT: EORTC QoL 30

MODEL: Unadjusted Analysis STUDY: CLL11(BO21004), Stage

2

Compliance/Mean

Pain Scale

		GClb (N=255)						RC1b (N=242)						
		Patients			Statistics			Patients			Statistics			
Name	Level	in study ¹	%	with value ¹	%	Mean ²	SD(mean)	in study ¹	%	with value ¹	%	Mean ²	SD(mean)	
All														
Screening	n/a	255	100,0	242	94,9	21,83	27,07	242	100,0	228	94,2	22,44	28,19	
Cycle 4 Day 1	n/a	213	83,5	196	92,0	17,77	25,04	224	92,6	198	88,4	17,93	24,62	
FU Day 28	n/a	230	90,2	201	87,4	21,48	28,61	225	93,0	203	90,2	19,13	27,54	
FU Month 3	n/a	225	88,2	203	90,2	20,11	28,03	221	91,3	196	88,7	21,26	26,02	
FU Month 6	n/a	207	81,2	188	90,8	19,41	26,14	192	79,3	170	88,5	21,47	26,92	
FU Month 9	n/a	164	64,3	138	84,1	17,39	27,38	149	61,6	121	81,2	20,25	27,40	
FU Month 12	n/a	125	49,0	108	86,4	20,22	26,68	117	48,3	99	84,6	21,72	28,62	
FU Month 15	n/a	104	40,8	90	86,5	17,78	23,68	85	35,1	69	81,2	21,01	27,06	
FU Month 18	n/a		79	31,0	69	87,3	19,57	24,91	60	24,8	49	81,7	21,43	29,46
FU Month 21	n/a		52	20,4	40	76,9	20,42	25,17	40	16,5	32	80,0	21,35	27,18
FU Month 24	n/a		32	12,5	25	78,1	19,33	32,87	18	7,4	17	94,4	22,55	28,22
FU Month 27	n/a		13	5,1	11	84,6	13,64	26,69	9	3,7	7	77,8	7,14	8,91
FU Month 30	n/a		7	2,7	6	85,7	19,44	26,70	1	0,4	1	100,0	16,67	NE
Gender														
Screening	Female	97	100,0	92	94,8	27,72	28,95	95	100,0	87	91,6	29,89	30,73	
Cycle 4 Day 1	Female	84	86,6	77	91,7	22,94	28,10	88	92,6	78	88,6	26,50	28,86	
FU Day 28	Female	90	92,8	83	92,2	27,91	31,46	91	95,8	79	86,8	28,27	32,07	
FU Month 3	Female	88	90,7	81	92,0	23,25	30,01	87	91,6	77	88,5	28,14	27,87	
FU Month 6	Female	84	86,6	72	85,7	23,84	26,36	77	81,1	68	88,3	26,72	27,03	
FU Month 9	Female	70	72,2	59	84,3	28,53	34,33	61	64,2	46	75,4	28,26	29,79	
FU Month 12	Female	56	57,7	48	85,7	25,69	29,37	47	49,5	40	85,1	28,33	31,85	
FU Month 15	Female	47	48,5	40	85,1	25,83	26,94	33	34,7	28	84,8	28,57	28,64	
FU Month 18	Female	34	35,1	29	85,3	21,84	24,44	26	27,4	22	84,6	34,85	32,08	
FU Month 21	Female	21	21,6	15	71,4	28,89	29,19	17	17,9	15	88,2	35,56	30,12	
FU Month 24	Female	12	12,4	10	83,3	35,00	43,35	6	6,3	5	83,3	36,67	29,81	
FU Month 27	Female	6	6,2	5	83,3	23,33	36,51	2	2,1	1	50,0	16,67	NE	
FU Month 30	Female	4	4,1	3	75,0	38,89	25,46	1	1,1	1	100,0	16,67	NE	

Screening	Male	158	100,0	150	94,9	18,22	25,28	147	100,0	141	95,9	17,85	25,56
Cycle 4 Day 1	Male	129	81,6	119	92,2	14,43	22,33	136	92,5	120	88,2	12,36	19,62
FU Day 28	Male	140	88,6	118	84,3	16,95	25,60	134	91,2	124	92,5	13,31	22,49
FU Month 3	Male	137	86,7	122	89,1	18,03	26,56	134	91,2	119	88,8	16,81	23,82
FU Month 6	Male	123	77,8	116	94,3	16,67	25,73	115	78,2	102	88,7	17,97	26,40
FU Month 9	Male	94	59,5	79	84,0	9,07	16,62	88	59,9	75	85,2	15,33	24,78
FU Month 12	Male	69	43,7	60	87,0	15,83	23,65	70	47,6	59	84,3	17,23	25,52
FU Month 15	Male	57	36,1	50	87,7	11,33	18,58	52	35,4	41	78,8	15,85	24,99
FU Month 18	Male	45	28,5	40	88,9	17,92	25,43	34	23,1	27	79,4	10,49	22,24
FU Month 21	Male	31	19,6	25	80,6	15,33	21,47	23	15,6	17	73,9	8,82	16,79
FU Month 24	Male	20	12,7	15	75,0	8,89	18,76	12	8,2	12	100,0	16,67	26,59
FU Month 27	Male	7	4,4	6	85,7	5,56	13,61	7	4,8	6	85,7	5,56	8,61
FU Month 30	Male	3	1,9	3	100,0	0,00	0,00	0	NE	0	NE	NE	NE
Age													
Screening	<75 years	130	100,0	123	94,6	20,87	25,66	120	100,0	110	91,7	21,82	28,08
Cycle 4 Day 1	<75 years	106	81,5	100	94,3	17,83	23,00	112	93,3	98	87,5	18,20	24,88
FU Day 28	<75 years	119	91,5	105	88,2	20,79	26,83	110	91,7	103	93,6	21,36	28,72
FU Month 3	<75 years	116	89,2	106	91,4	18,40	26,92	109	90,8	99	90,8	23,23	27,75
FU Month 6	<75 years	108	83,1	98	90,7	19,39	25,07	99	82,5	88	88,9	21,59	28,04
FU Month 9	<75 years	85	65,4	73	85,9	15,30	24,02	74	61,7	62	83,8	22,85	28,83
FU Month 12	<75 years	63	48,5	59	93,7	18,08	25,95	60	50,0	53	88,3	21,38	30,73
FU Month 15	<75 years	54	41,5	47	87,0	17,73	23,93	44	36,7	35	79,5	17,62	24,57
FU Month 18	<75 years	43	33,1	39	90,7	15,81	22,28	27	22,5	22	81,5	21,21	29,63
FU Month 21	<75 years	26	20,0	22	84,6	21,97	23,79	17	14,2	13	76,5	16,67	24,53
FU Month 24	<75 years	18	13,8	14	77,8	25,00	36,84	6	5,0	5	83,3	23,33	22,36
FU Month 27	<75 years	7	5,4	5	71,4	6,67	14,91	2	1,7	1	50,0	0,00	NE
FU Month 30	<75 years	4	3,1	3	75,0	11,11	19,25	0	NE	0	NE	NE	NE
Screening	>=75 years	125	100,0	119	95,2	22,83	28,53	122	100,0	118	96,7	23,02	28,40
Cycle 4 Day 1	>=75 years	107	85,6	96	89,7	17,71	27,12	112	91,8	100	89,3	17,67	24,48
FU Day 28	>=75 years	111	88,8	96	86,5	22,22	30,56	115	94,3	100	87,0	16,83	26,22
FU Month 3	>=75 years	109	87,2	97	89,0	21,99	29,22	112	91,8	97	86,6	19,24	24,10
FU Month 6	>=75 years	99	79,2	90	90,9	19,44	27,40	93	76,2	82	88,2	21,34	25,83
FU Month 9	>=75 years	79	63,2	65	82,3	19,74	30,74	75	61,5	59	78,7	17,51	25,79
FU Month 12	>=75 years	62	49,6	49	79,0	22,79	27,57	57	46,7	46	80,7	22,10	26,31
FU Month 15	>=75 years	50	40,0	43	86,0	17,83	23,68	41	33,6	34	82,9	24,51	29,37
FU Month 18	>=75 years	36	28,8	30	83,3	24,44	27,59	33	27,0	27	81,8	21,60	29,89
FU Month 21	>=75 years	26	20,8	18	69,2	18,52	27,35	23	18,9	19	82,6	24,56	29,06
FU Month 24	>=75 years	14	11,2	11	78,6	12,12	26,97	12	9,8	12	100,0	22,22	31,25

FU Month 27	>=75 years	64,8	6100,0	19,44	34,02	75,7	685,7	8,33	9,13				
FU Month 30	>=75 years	32,4	3100,0	27,78	34,69	10,8	1100,0	16,67					NE
Race													
Screening	Other	9100,0	9100,0	18,52	26,93	11100,0	11100,0	28,79	18,40				
Cycle 4 Day 1	Other	777,8	7100,0	14,29	11,50	1090,9	990,0	16,67	14,43				
FU Day 28	Other	888,9	8100,0	22,92	23,46	1090,9	10100,0	21,67	17,66				
FU Month 3	Other	888,9	787,5	11,90	15,85	1090,9	10100,0	23,33	16,10				
FU Month 6	Other	888,9	787,5	21,43	26,73	872,7	8100,0	18,75	18,77				
FU Month 9	Other	444,4	375,0	5,56	9,62	545,5	480,0	25,00	16,67				
FU Month 12	Other	333,3	266,7	0,00	0,00	436,4	4100,0	20,83	15,96				
FU Month 15	Other	222,2	150,0	16,67		436,4	4100,0	25,00	16,67				
FU Month 18	Other	222,2	150,0	0,00		218,2	2100,0	8,33	11,79				
FU Month 21	Other	222,2	150,0	0,00		218,2	2100,0	33,33	47,14				
FU Month 24	Other	222,2	150,0	0,00		19,1	0						
FU Month 27	Other	111,1				19,1							
FU Month 30	Other	111,1				0							
Geographical Region													
Screening	Asia-Pacific	20100,0	20100,0	17,50	28,85	18100,0	18100,0	24,07	26,95				
Cycle 4 Day 1	Asia-Pacific	1575,0	15100,0	20,00	30,34	1688,9	1593,8	18,89	23,46				
FU Day 28	Asia-Pacific	1890,0	18100,0	20,37	30,01	18100,0	1688,9	16,67	21,08				
FU Month 3	Asia-Pacific	1890,0	1688,9	25,00	37,02	18100,0	1688,9	21,88	22,54				
FU Month 6	Asia-Pacific	1680,0	1487,5	28,57	40,52	1794,4	1588,2	16,67	25,97				
FU Month 9	Asia-Pacific	1470,0	1285,7	12,50	20,26	1372,2	1076,9	43,33	36,18				
FU Month 12	Asia-Pacific	1050,0	880,0	25,00	37,80	1055,6	10100,0	28,33	29,45				
FU Month 15	Asia-Pacific	840,0	675,0	19,44	19,48	950,0	9100,0	33,33	37,27				

FU Month 18	Asia-Pacific	630,0	466,7	16,67	23,57	633,3	6100,0	27,78	32,77
FU Month 21	Asia-Pacific	525,0	360,0	11,11	19,25	422,2	4100,0	33,33	38,49
FU Month 24	Asia-Pacific	315,0	266,7	0,00	0,00	15,6	0	NE	NE
FU Month 27	Asia-Pacific	15,0		NE	NE	15,6		NE	NE
FU Month 30	Asia-Pacific	15,0		NE	NE	0	NE	NE	NE
Screening	Central and South America	3100,0	3100,0	16,67	16,67	2100,0	2100,0	58,33	58,93
Cycle 4 Day 1	Central and South America	3100,0	3100,0	0,00	0,00	2100,0	2100,0	16,67	0,00
FU Day 28	Central and South America	3100,0	3100,0	11,11	9,62	2100,0	2100,0	33,33	23,57
FU Month 3	Central and South America	3100,0	3100,0	0,00	0,00	2100,0	2100,0	8,33	11,79
FU Month 6	Central and South America	266,7	2100,0	8,33	11,79	2100,0	2100,0	8,33	11,79
FU Month 9	Central and South America	266,7	2100,0	8,33	11,79	150,0	1100,0	0,00	NE
FU Month 12	Central and South America	266,7	2100,0	8,33	11,79	150,0	1100,0	0,00	NE
FU Month 15	Central and South America	133,3	1100,0	0,00	NE	0	NE	NE	NE
FU Month 18	Central and South America	133,3	1100,0	0,00	NE	0	NE	NE	NE
FU Month 21	Central and South America	133,3	1100,0	16,67	NE	0	NE	NE	NE
FU Month 24	Central and South America	133,3	1100,0	0,00	NE	0	NE	NE	NE
Screening	North America	12100,0	12100,0	25,00	29,73	13100,0	1292,3	25,00	28,87
Cycle 4 Day 1	North America	975,0	9100,0	18,52	13,03	1292,3	12100,0	18,06	24,06
FU Day 28	North America	1191,7	11100,0	28,79	27,98	13100,0	13100,0	14,10	27,93
FU Month 3	North America	1191,7	11100,0	25,76	31,94	1292,3	12100,0	18,06	30,53
FU Month 6	North America	1191,7	1090,9	25,00	27,50	1184,6	11100,0	21,21	31,70
FU Month 9	North America	866,7	8100,0	14,58	28,78	969,2	9100,0	16,67	18,63
FU Month 12	North America	866,7	787,5	21,43	18,54	753,8	7100,0	28,57	24,93
FU Month 15	North America	650,0	6100,0	11,11	13,61	646,2	583,3	20,00	21,73
FU Month 18	North America	433,3	4100,0	20,83	20,97	323,1	3100,0	0,00	0,00
FU Month 21	North America	325,0	266,7	8,33	11,79	17,7	1100,0	0,00	NE
FU Month 24	North America	325,0	266,7	16,67	23,57	17,7	1100,0	0,00	NE
FU Month 27	North America	216,7	150,0	0,00	NE	17,7	1100,0	16,67	NE
Screening	Other	45100,0	4191,1	25,20	20,79	44100,0	4193,2	21,14	26,09
Cycle 4 Day 1	Other	3782,2	3389,2	17,17	21,84	4090,9	3587,5	13,33	17,53
FU Day 28	Other	3782,2	3389,2	15,66	20,81	3988,6	3794,9	21,17	29,57
FU Month 3	Other	3884,4	3489,5	18,14	20,25	3886,4	3694,7	24,54	26,87
FU Month 6	Other	3577,8	3188,6	17,20	19,95	3375,0	3193,9	22,58	28,40
FU Month 9	Other	2657,8	2284,6	9,09	19,74	2454,5	1979,2	17,54	19,62
FU Month 12	Other	1737,8	1694,1	11,46	27,02	1636,4	1487,5	15,48	19,02
FU Month 15	Other	1226,7	1191,7	10,61	13,48	920,5	888,9	10,42	15,27
FU Month 18	Other	1022,2	990,0	7,41	12,11	715,9	685,7	16,67	27,89
FU Month 21	Other	715,6	685,7	13,89	16,39	49,1	4100,0	16,67	33,33

FU Month 24	Other	6	13,3	5	83,3	16,67	28,87	3	6,8	3	100,0	38,89	25,46
FU Month 27	Other	4	8,9	4	100,0	8,33	16,67	1	2,3	1	100,0	0,00	NE
FU Month 30	Other	2	4,4	2	100,0	25,00	11,79	0	NE	0	NE	NE	NE
Screening	Western Europe	175	100,0	166	94,9	21,39	28,30	165	100,0	155	93,9	21,94	28,54
Cycle 4 Day 1	Western Europe	149	85,1	136	91,3	18,01	26,06	154	93,3	134	87,0	19,03	26,58
FU Day 28	Western Europe	161	92,0	136	84,5	22,67	30,34	153	92,7	135	88,2	19,14	27,88
FU Month 3	Western Europe	155	88,6	139	89,7	20,02	28,53	151	91,5	130	86,1	20,77	26,09
FU Month 6	Western Europe	143	81,7	131	91,6	18,70	25,66	129	78,2	111	86,0	22,07	26,61
FU Month 9	Western Europe	114	65,1	94	82,5	20,39	29,55	102	61,8	82	80,4	18,70	27,76
FU Month 12	Western Europe	88	50,3	75	85,2	21,78	26,28	83	50,3	67	80,7	21,64	30,71
FU Month 15	Western Europe	77	44,0	66	85,7	19,70	25,97	61	37,0	47	77,0	20,57	26,74
FU Month 18	Western Europe	58	33,1	51	87,9	22,22	26,81	44	26,7	34	77,3	23,04	30,43
FU Month 21	Western Europe	36	20,6	28	77,8	23,81	28,12	31	18,8	23	74,2	21,01	25,23
FU Month 24	Western Europe	19	10,9	15	78,9	24,44	38,25	13	7,9	13	100,0	20,51	28,99
FU Month 27	Western Europe	6	3,4	6	100,0	19,44	34,02	6	3,6	5	83,3	6,67	9,13
FU Month 30	Western Europe	4	2,3	4	100,0	16,67	33,33	1	0,6	1	100,0	16,67	NE
FCgamma receptor IIa													
Screening	131HH	58	100,0	54	93,1	23,77	26,42	76	100,0	72	94,7	24,31	28,38
Cycle 4 Day 1	131HH	49	84,5	43	87,8	23,64	28,23	65	85,5	60	92,3	15,83	21,57
FU Day 28	131HH	51	87,9	46	90,2	21,74	28,95	70	92,1	62	88,6	14,52	22,28
FU Month 3	131HH	51	87,9	47	92,2	23,76	29,64	64	84,2	54	84,4	20,06	24,31
FU Month 6	131HH	49	84,5	45	91,8	26,30	29,41	55	72,4	48	87,3	24,31	29,16
FU Month 9	131HH	39	67,2	30	76,9	24,44	32,08	41	53,9	33	80,5	18,18	26,47
FU Month 12	131HH	28	48,3	23	82,1	26,81	29,62	34	44,7	29	85,3	21,26	28,14
FU Month 15	131HH	23	39,7	19	82,6	22,81	20,94	24	31,6	20	83,3	15,83	20,57
FU Month 18	131HH	17	29,3	13	76,5	37,18	25,60	16	21,1	13	81,3	26,92	36,35
FU Month 21	131HH	13	22,4	8	61,5	31,25	35,00	11	14,5	10	90,9	33,33	34,25
FU Month 24	131HH	11	19,0	7	63,6	23,81	30,21	1	1,3	1	100,0	0,00	NE
FU Month 27	131HH	4	6,9	3	75,0	38,89	41,94	1	1,3	1	100,0	0,00	NE
FU Month 30	131HH	3	5,2	2	66,7	33,33	47,14	0	NE	0	NE	NE	NE
Screening	131HR	125	100,0	118	94,4	23,02	27,21	114	100,0	109	95,6	20,03	27,38
Cycle 4 Day 1	131HR	105	84,0	98	93,3	15,82	24,10	110	96,5	99	90,0	17,85	25,00
FU Day 28	131HR	116	92,8	102	87,9	23,53	30,34	105	92,1	96	91,4	21,53	30,00
FU Month 3	131HR	114	91,2	102	89,5	20,42	29,00	107	93,9	95	88,8	20,00	25,68
FU Month 6	131HR	104	83,2	93	89,4	17,92	24,73	95	83,3	85	89,5	19,80	26,41
FU Month 9	131HR	84	67,2	71	84,5	15,02	24,75	76	66,7	61	80,3	21,58	29,40
FU Month 12	131HR	64	51,2	57	89,1	21,35	27,77	57	50,0	48	84,2	20,14	27,50
FU Month 15	131HR	53	42,4	44	83,0	17,42	23,83	44	38,6	35	79,5	21,90	29,64

FU Month 18	131HR	43	34,4	38	88,4	19,30	25,56	32	28,1	26	81,3	19,23	23,89
FU Month 21	131HR	26	20,8	20	76,9	22,50	24,94	21	18,4	16	76,2	21,88	23,35
FU Month 24	131HR	12	9,6	11	91,7	13,64	30,57	12	10,5	11	91,7	30,30	31,46
FU Month 27	131HR	6	4,8	5	83,3	6,67	14,91	6	5,3	4	66,7	12,50	8,33
FU Month 30	131HR	3	2,4	3	100,0	16,67	16,67	1	0,9	1	100,0	16,67	NE
Screening	131RR	49	100,0	48	98,0	19,10	29,57	33	100,0	30	90,9	20,56	25,40
Cycle 4 Day 1	131RR	40	81,6	38	95,0	14,47	17,40	31	93,9	25	80,6	20,67	28,98
FU Day 28	131RR	42	85,7	35	83,3	17,62	23,55	32	97,0	29	90,6	18,97	29,12
FU Month 3	131RR	39	79,6	37	94,9	16,22	22,73	32	97,0	30	93,8	21,11	28,34
FU Month 6	131RR	35	71,4	33	94,3	16,67	23,94	27	81,8	23	85,2	21,01	27,62
FU Month 9	131RR	24	49,0	22	91,7	19,70	29,38	19	57,6	17	89,5	16,67	25,69
FU Month 12	131RR	18	36,7	17	94,4	13,73	19,75	17	51,5	15	88,2	22,22	29,99
FU Month 15	131RR	16	32,7	16	100,0	13,54	27,36	11	33,3	9	81,8	24,07	30,17
FU Month 18	131RR	14	28,6	14	100,0	9,52	15,63	8	24,2	7	87,5	23,81	40,66
FU Month 21	131RR	8	16,3	7	87,5	9,52	13,11	5	15,2	4	80,0	0,00	0,00
FU Month 24	131RR	5	10,2	4	80,0	41,67	50,00	3	9,1	3	100,0	0,00	0,00
FU Month 27	131RR	2	4,1	2	100,0	0,00	0,00	1	3,0	1	100,0	0,00	NE
FU Month 30	131RR	1	2,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
Screening	Missing	23	100,0	22	95,7	16,67	22,42	19	100,0	17	89,5	33,33	35,84
Cycle 4 Day 1	Missing	19	82,6	17	89,5	21,57	34,24	18	94,7	14	77,8	22,62	27,43
FU Day 28	Missing	21	91,3	18	85,7	16,67	27,42	18	94,7	16	88,9	22,92	27,81
FU Month 3	Missing	21	91,3	17	81,0	16,67	28,87	18	94,7	17	94,4	32,35	28,55
FU Month 6	Missing	19	82,6	17	89,5	14,71	27,56	15	78,9	14	93,3	22,62	22,27
FU Month 9	Missing	17	73,9	15	88,2	11,11	25,72	13	68,4	10	76,9	25,00	22,57
FU Month 12	Missing	15	65,2	11	73,3	10,61	21,44	9	47,4	7	77,8	33,33	38,49
FU Month 15	Missing	12	52,2	11	91,7	16,67	23,57	6	31,6	5	83,3	30,00	29,81
FU Month 18	Missing	5	21,7	4	80,0	0,00	0,00	4	21,1	3	75,0	11,11	19,25
FU Month 21	Missing	5	21,7	5	100,0	10,00	14,91	3	15,8	2	66,7	0,00	0,00
FU Month 24	Missing	4	17,4	3	75,0	0,00	0,00	2	10,5	2	100,0	25,00	11,79
FU Month 27	Missing	1	4,3	1	100,0	0,00	NE	1	5,3	1	100,0	0,00	NE
FCgamma receptor IIIa													
Screening	158FF	103	100,0	101	98,1	23,10	30,18	83	100,0	79	95,2	21,73	25,79
Cycle 4 Day 1	158FF	89	86,4	83	93,3	15,46	22,81	78	94,0	72	92,3	17,36	24,30
FU Day 28	158FF	96	93,2	84	87,5	20,63	28,41	78	94,0	74	94,9	20,50	30,41
FU Month 3	158FF	94	91,3	84	89,4	19,64	30,08	78	94,0	71	91,0	18,31	26,15
FU Month 6	158FF	86	83,5	76	88,4	19,30	27,63	64	77,1	59	92,2	17,51	26,16
FU Month 9	158FF	71	68,9	59	83,1	19,49	29,71	47	56,6	43	91,5	14,34	22,30
FU Month 12	158FF	48	46,6	42	87,5	22,62	28,94	38	45,8	35	92,1	18,10	28,69

FU Month 15	158FF	37	35,9	32	86,5	20,31	29,25	30	36,1	24	80,0	15,97	27,13
FU Month 18	158FF	27	26,2	25	92,6	21,33	23,33	21	25,3	17	81,0	16,67	32,81
FU Month 21	158FF	16	15,5	15	93,8	25,56	25,09	9	10,8	8	88,9	6,25	12,40
FU Month 24	158FF	8	7,8	7	87,5	4,76	12,60	3	3,6	3	100,0	11,11	19,25
FU Month 27	158FF	5	4,9	4	80,0	0,00	0,00	1	1,2	1	100,0	0,00	NE
FU Month 30	158FF	3	2,9	3	100,0	0,00	0,00	0	NE	0	NE	NE	NE
Screening	158FV	119	100,0	110	92,4	20,91	24,47	109	100,0	103	94,5	24,11	30,04
Cycle 4 Day 1	158FV	99	83,2	90	90,9	18,89	25,50	100	91,7	86	86,0	20,35	26,00
FU Day 28	158FV	105	88,2	91	86,7	23,63	29,51	101	92,7	87	86,1	18,01	26,80
FU Month 3	158FV	101	84,9	93	92,1	20,43	26,93	97	89,0	84	86,6	22,82	25,45
FU Month 6	158FV	94	79,0	87	92,6	19,35	24,49	83	76,1	72	86,7	22,69	27,88
FU Month 9	158FV	71	59,7	61	85,9	16,94	25,91	65	59,6	49	75,4	24,15	31,93
FU Month 12	158FV	60	50,4	54	90,0	19,75	26,32	52	47,7	42	80,8	26,59	29,69
FU Month 15	158FV	52	43,7	45	86,5	15,56	18,94	36	33,0	30	83,3	23,89	27,57
FU Month 18	158FV	44	37,0	37	84,1	18,92	26,40	24	22,0	20	83,3	25,00	29,86
FU Month 21	158FV	28	23,5	18	64,3	17,59	27,70	18	16,5	14	77,8	35,71	30,56
FU Month 24	158FV	18	15,1	13	72,2	26,92	40,56	6	5,5	5	83,3	23,33	34,56
FU Month 27	158FV	6	5,0	5	83,3	23,33	36,51	2	1,8	1	50,0	0,00	NE
FU Month 30	158FV	4	3,4	3	75,0	38,89	25,46	0	NE	0	NE	NE	NE
Screening	158VV	16	100,0	15	93,8	17,78	27,07	33	100,0	31	93,9	16,13	23,37
Cycle 4 Day 1	158VV	12	75,0	11	91,7	16,67	25,82	30	90,9	28	93,3	11,90	19,70
FU Day 28	158VV	14	87,5	13	92,9	12,82	20,59	30	90,9	28	93,3	14,88	20,46
FU Month 3	158VV	15	93,8	12	80,0	18,06	20,67	30	90,9	26	86,7	15,38	22,57
FU Month 6	158VV	14	87,5	13	92,9	19,23	26,22	30	90,9	25	83,3	25,33	28,10
FU Month 9	158VV	12	75,0	10	83,3	10,00	14,05	25	75,8	20	80,0	22,50	26,09
FU Month 12	158VV	8	50,0	7	87,5	21,43	23,00	20	60,6	17	85,0	15,69	19,96
FU Month 15	158VV	8	50,0	7	87,5	21,43	24,93	14	42,4	11	78,6	25,76	25,13
FU Month 18	158VV	4	25,0	4	100,0	29,17	28,46	11	33,3	9	81,8	25,93	26,50
FU Month 21	158VV	3	18,8	2	66,7	33,33	23,57	9	27,3	7	77,8	19,05	24,40
FU Month 24	158VV	2	12,5	2	100,0	50,00	0,00	7	21,2	7	100,0	26,19	33,13
FU Month 27	158VV	1	6,3	1	100,0	33,33	NE	5	15,2	4	80,0	12,50	8,33
FU Month 30	158VV	0	NE	0	NE	NE	NE	1	3,0	1	100,0	16,67	NE
Screening	Missing	17	100,0	16	94,1	23,96	25,07	17	100,0	15	88,2	27,78	36,00
Cycle 4 Day 1	Missing	13	76,5	12	92,3	26,39	35,15	16	94,1	12	75,0	18,06	27,02
FU Day 28	Missing	15	88,2	13	86,7	20,51	31,29	16	94,1	14	87,5	27,38	28,95
FU Month 3	Missing	15	88,2	14	93,3	22,62	30,39	16	94,1	15	93,8	36,67	29,68
FU Month 6	Missing	13	76,5	12	92,3	20,83	31,08	15	88,2	14	93,3	25,00	23,34
FU Month 9	Missing	10	58,8	8	80,0	14,58	35,00	12	70,6	9	75,0	22,22	25,00

FU Month 12	Missing		952,9	555,6	3,33	7,45		741,2	571,4	26,67	43,46	
FU Month 15	Missing		741,2	685,7	16,67	25,82		529,4	480,0	16,67	33,33	
FU Month 18	Missing		423,5	375,0	0,00	0,00		423,5	375,0	11,11	19,25	
FU Month 21	Missing		529,4	5100,0	10,00	14,91		423,5	375,0	0,00	0,00	
FU Month 24	Missing		423,5	375,0	0,00	0,00		211,8	2100,0	25,00	11,79	
FU Month 27	Missing		15,9	1100,0	0,00		NE	15,9	1100,0	0,00		NE
Binet Staging at baseline												
Screening	A		59100,0	5898,3	25,57	29,16		57100,0	5393,0	33,02	34,82	
Cycle 4 Day 1	A		5186,4	4894,1	21,88	28,80		5494,7	5092,6	25,00	32,69	
FU Day 28	A		5898,3	5391,4	33,33	33,97		5494,7	5296,3	30,77	34,83	
FU Month 3	A		5796,6	5698,2	25,60	32,87		5393,0	5094,3	25,00	28,02	
FU Month 6	A		5694,9	5089,3	26,33	28,19		4578,9	4293,3	25,40	30,18	
FU Month 9	A		4372,9	3786,0	26,13	32,99		3459,6	3088,2	30,56	33,07	
FU Month 12	A		3661,0	3494,4	27,94	29,51		2442,1	2187,5	30,16	35,60	
FU Month 15	A		3050,8	2790,0	24,69	26,30		1933,3	19100,0	30,70	32,04	
FU Month 18	A		2237,3	1881,8	23,15	27,50		1628,1	16100,0	30,21	31,16	
FU Month 21	A		1728,8	1588,2	28,89	30,52		814,0	787,5	23,81	26,97	
FU Month 24	A		1016,9	880,0	31,25	40,27		58,8	5100,0	16,67	28,87	
FU Month 27	A		58,5	480,0	20,83	41,67		23,5	150,0	0,00		NE
FU Month 30	A		46,8	375,0	22,22	38,49		0	NE	0	NE	NE
Screening												
Screening	B	104	100,0	100	96,2	19,67	24,55	85100,0	8397,6	17,67	21,36	
Cycle 4 Day 1	B		8884,6	8394,3	17,47	22,53		7992,9	7392,4	15,30	19,40	
FU Day 28	B		9187,5	7986,8	18,78	25,51		7992,9	7189,9	12,44	20,06	
FU Month 3	B		8884,6	7888,6	16,67	23,42		7992,9	7189,9	19,48	25,51	
FU Month 6	B		8076,9	7796,3	16,67	23,72		7082,4	6491,4	20,31	27,13	
FU Month 9	B		6360,6	5282,5	15,71	24,12		5969,4	4983,1	15,99	23,31	
FU Month 12	B		4745,2	3983,0	17,95	25,18		4654,1	4087,0	19,58	24,43	
FU Month 15	B		3735,6	3491,9	16,18	23,02		3440,0	2882,4	13,69	20,31	
FU Month 18	B		3129,8	2890,3	16,07	22,90		2225,9	1881,8	15,74	22,49	
FU Month 21	B		1817,3	1372,2	16,67	18,00		1720,0	1482,4	15,48	20,11	
FU Month 24	B		1110,6	981,8	20,37	35,14		89,4	8100,0	22,92	30,78	
FU Month 27	B		54,8	480,0	16,67	19,25		44,7	4100,0	8,33	9,62	
FU Month 30	B		21,9	2100,0	8,33	11,79		0	NE	0	NE	NE
Screening												
Screening	C		92100,0	8491,3	21,83	28,46	100	100,0	9292,0	20,65	28,10	
Cycle 4 Day 1	C		7480,4	6587,8	15,13	25,13		9191,0	7582,4	15,78	22,24	
FU Day 28	C		8188,0	6985,2	15,46	24,97		9292,0	8087,0	17,50	25,83	
FU Month 3	C		8087,0	6986,3	19,57	28,29		8989,0	7584,3	20,44	25,20	
FU Month 6	C		7177,2	6185,9	17,21	26,70		7777,0	6483,1	20,05	24,52	

FU Month 9	C	58	63,0	49	84,5	12,59	24,89	56	56,0	42	75,0	17,86	26,13
FU Month 12	C	42	45,7	35	83,3	15,24	24,38	47	47,0	38	80,9	19,30	28,35
FU Month 15	C	37	40,2	29	78,4	13,22	21,07	32	32,0	22	68,8	21,97	28,35
FU Month 18	C	26	28,3	23	88,5	21,01	25,73	22	22,0	15	68,2	18,89	34,43
FU Month 21	C	17	18,5	12	70,6	13,89	23,39	15	15,0	11	73,3	27,27	35,18
FU Month 24	C	11	12,0	8	72,7	6,25	17,68	5	5,0	4	80,0	29,17	28,46
FU Month 27	C	3	3,3	3	100,0	0,00	0,00	3	3,0	2	66,7	8,33	11,79
FU Month 30	C	1	1,1	1	100,0	33,33	NE	1	1,0	1	100,0	16,67	NE
Total CIR score at baseline													
Screening	<=6	63	100,0	59	93,7	16,67	25,14	75	100,0	70	93,3	19,52	25,06
Cycle 4 Day 1	<=6	52	82,5	43	82,7	15,50	23,96	72	96,0	61	84,7	10,66	16,95
FU Day 28	<=6	56	88,9	49	87,5	12,93	21,59	72	96,0	59	81,9	13,28	22,91
FU Month 3	<=6	55	87,3	47	85,5	13,83	22,07	69	92,0	56	81,2	16,67	21,08
FU Month 6	<=6	52	82,5	47	90,4	13,48	21,32	60	80,0	53	88,3	18,24	24,95
FU Month 9	<=6	43	68,3	36	83,7	18,98	31,41	47	62,7	38	80,9	12,28	16,30
FU Month 12	<=6	35	55,6	29	82,9	17,82	25,95	34	45,3	27	79,4	15,43	22,61
FU Month 15	<=6	32	50,8	28	87,5	11,90	17,48	25	33,3	17	68,0	18,63	22,73
FU Month 18	<=6	23	36,5	21	91,3	17,46	27,12	19	25,3	14	73,7	14,29	27,62
FU Month 21	<=6	14	22,2	8	57,1	8,33	8,91	14	18,7	10	71,4	16,67	22,22
FU Month 24	<=6	8	12,7	7	87,5	14,29	37,80	7	9,3	6	85,7	19,44	26,70
FU Month 27	<=6	2	3,2	2	100,0	0,00	0,00	4	5,3	2	50,0	8,33	11,79
FU Month 30	<=6	0	NE	0	NE	NE	NE	1	1,3	1	100,0	16,67	NE
Screening >6													
Screening	>6	192	100,0	183	95,3	23,50	27,52	167	100,0	158	94,6	23,73	29,46
Cycle 4 Day 1	>6	161	83,9	153	95,0	18,41	25,37	152	91,0	137	90,1	21,17	26,78
FU Day 28	>6	174	90,6	152	87,4	24,23	30,07	153	91,6	144	94,1	21,53	28,96
FU Month 3	>6	170	88,5	156	91,8	22,01	29,39	152	91,0	140	92,1	23,10	27,60
FU Month 6	>6	155	80,7	141	91,0	21,39	27,34	132	79,0	117	88,6	22,93	27,74
FU Month 9	>6	121	63,0	102	84,3	16,83	25,96	102	61,1	83	81,4	23,90	30,60
FU Month 12	>6	90	46,9	79	87,8	21,10	27,05	83	49,7	72	86,7	24,07	30,37
FU Month 15	>6	72	37,5	62	86,1	20,43	25,68	60	35,9	52	86,7	21,79	28,50
FU Month 18	>6	56	29,2	48	85,7	20,49	24,13	41	24,6	35	85,4	24,29	30,07
FU Month 21	>6	38	19,8	32	84,2	23,44	27,06	26	15,6	22	84,6	23,48	29,39
FU Month 24	>6	24	12,5	18	75,0	21,30	31,73	11	6,6	11	100,0	24,24	30,15
FU Month 27	>6	11	5,7	9	81,8	16,67	28,87	5	3,0	5	100,0	6,67	9,13
FU Month 30	>6	7	3,6	6	85,7	19,44	26,70	0	NE	0	NE	NE	NE
Calculated creatinine clearance cat. 2													
Screening	<70 ml/min	178	100,0	166	93,3	23,29	28,00	176	100,0	166	94,3	22,49	28,24
Cycle 4 Day 1	<70 ml/min	149	83,7	134	89,9	15,80	24,97	164	93,2	144	87,8	17,82	25,37

FU Day 28	<70 ml/min	162	91,0	142	87,7	20,77	28,15	166	94,3	146	88,0	19,98	28,41
FU Month 3	<70 ml/min	157	88,2	141	89,8	19,03	26,77	159	90,3	139	87,4	21,46	26,03
FU Month 6	<70 ml/min	144	80,9	129	89,6	18,48	25,28	139	79,0	122	87,8	21,58	26,30
FU Month 9	<70 ml/min	117	65,7	97	82,9	17,53	28,20	112	63,6	90	80,4	20,93	27,32
FU Month 12	<70 ml/min	92	51,7	78	84,8	18,59	25,90	87	49,4	73	83,9	21,92	28,72
FU Month 15	<70 ml/min	78	43,8	69	88,5	17,87	24,47	60	34,1	48	80,0	22,92	26,55
FU Month 18	<70 ml/min	59	33,1	50	84,7	19,33	25,50	43	24,4	36	83,7	25,46	31,49
FU Month 21	<70 ml/min	38	21,3	27	71,1	17,90	26,92	31	17,6	27	87,1	22,84	28,92
FU Month 24	<70 ml/min	24	13,5	19	79,2	14,04	30,05	13	7,4	12	92,3	19,44	25,46
FU Month 27	<70 ml/min	10	5,6	8	80,0	14,58	30,13	7	4,0	5	71,4	6,67	9,13
FU Month 30	<70 ml/min	5	2,8	4	80,0	29,17	28,46	1	0,6	1	100,0	16,67	NE
Screening	>=70 ml/min	77	100,0	76	98,7	18,64	24,79	66	100,0	62	93,9	22,31	28,30
Cycle 4 Day 1	>=70 ml/min	64	83,1	62	96,9	22,04	24,84	60	90,9	54	90,0	18,21	22,73
FU Day 28	>=70 ml/min	68	88,3	59	86,8	23,16	29,85	59	89,4	57	96,6	16,96	25,29
FU Month 3	>=70 ml/min	68	88,3	62	91,2	22,58	30,79	62	93,9	57	91,9	20,76	26,22
FU Month 6	>=70 ml/min	63	81,8	59	93,7	21,47	28,03	53	80,3	48	90,6	21,18	28,71
FU Month 9	>=70 ml/min	47	61,0	41	87,2	17,07	25,68	37	56,1	31	83,8	18,28	28,01
FU Month 12	>=70 ml/min	33	42,9	30	90,9	24,44	28,61	30	45,5	26	86,7	21,15	28,89
FU Month 15	>=70 ml/min	26	33,8	21	80,8	17,46	21,39	25	37,9	21	84,0	16,67	28,38
FU Month 18	>=70 ml/min	20	26,0	19	95,0	20,18	23,95	17	25,8	13	76,5	10,26	19,88
FU Month 21	>=70 ml/min	14	18,2	13	92,9	25,64	21,10	9	13,6	5	55,6	13,33	13,94
FU Month 24	>=70 ml/min	8	10,4	6	75,0	36,11	38,61	5	7,6	5	100,0	30,00	36,13
FU Month 27	>=70 ml/min	3	3,9	3	100,0	11,11	19,25	2	3,0	2	100,0	8,33	11,79
FU Month 30	>=70 ml/min	2	2,6	2	100,0	0,00	0,00	0	NE	0	NE	NE	NE
Beta2 microglobulin													
Screening	Missing	3	100,0	3	100,0	11,11	9,62	3	100,0	3	100,0	61,11	34,69
Cycle 4 Day 1	Missing	3	100,0	3	100,0	22,22	9,62	3	100,0	2	66,7	25,00	11,79
FU Day 28	Missing	3	100,0	3	100,0	16,67	16,67	3	100,0	2	66,7	16,67	23,57
FU Month 3	Missing	3	100,0	3	100,0	11,11	19,25	3	100,0	2	66,7	41,67	11,79
FU Month 6	Missing	3	100,0	3	100,0	16,67	28,87	3	100,0	2	66,7	33,33	0,00
FU Month 9	Missing	2	66,7	1	50,0	0,00	NE	3	100,0	2	66,7	33,33	0,00
FU Month 12	Missing	1	33,3	1	100,0	16,67	NE	2	66,7	1	50,0	50,00	NE
FU Month 15	Missing	1	33,3	1	100,0	0,00	NE	2	66,7	1	50,0	33,33	NE
FU Month 18	Missing	1	33,3	1	100,0	33,33	NE	2	66,7	1	50,0	66,67	NE
FU Month 21	Missing	1	33,3	1	100,0	16,67	NE	2	66,7	1	50,0	66,67	NE
FU Month 24	Missing	1	33,3	1	100,0	50,00	NE	1	33,3	1	100,0	66,67	NE
Screening	< 3.5 ug/mL	154	100,0	145	94,2	22,18	28,87	140	100,0	132	94,3	23,11	27,68
Cycle 4 Day 1	< 3.5 ug/mL	127	82,5	117	92,1	19,66	27,82	129	92,1	112	86,8	20,54	25,01

FU Day 28	< 3.5 ug/mL	137	89,0	121	88,3	22,45	29,64	132	94,3	121	91,7	20,80	28,24
FU Month 3	< 3.5 ug/mL	134	87,0	123	91,8	21,54	29,85	130	92,9	116	89,2	22,27	26,19
FU Month 6	< 3.5 ug/mL	128	83,1	115	89,8	20,87	27,82	120	85,7	111	92,5	23,72	28,48
FU Month 9	< 3.5 ug/mL	104	67,5	87	83,7	18,97	28,77	98	70,0	81	82,7	23,05	29,65
FU Month 12	< 3.5 ug/mL	78	50,6	68	87,2	23,04	29,09	75	53,6	67	89,3	24,63	30,48
FU Month 15	< 3.5 ug/mL	65	42,2	56	86,2	18,45	24,14	60	42,9	51	85,0	22,88	28,67
FU Month 18	< 3.5 ug/mL	46	29,9	40	87,0	21,25	25,59	43	30,7	35	81,4	22,86	30,27
FU Month 21	< 3.5 ug/mL	30	19,5	21	70,0	16,67	23,57	27	19,3	22	81,5	20,45	27,67
FU Month 24	< 3.5 ug/mL	19	12,3	15	78,9	10,00	21,64	12	8,6	11	91,7	15,15	22,92
FU Month 27	< 3.5 ug/mL	10	6,5	8	80,0	14,58	30,13	7	5,0	5	71,4	6,67	9,13
FU Month 30	< 3.5 ug/mL	5	3,2	4	80,0	25,00	31,91	1	0,7	1	100,0	16,67	NE
Screening	>= 3.5 ug/mL	98	100,0	94	95,9	21,63	24,54	99	100,0	93	93,9	20,25	28,11
Cycle 4 Day 1	>= 3.5 ug/mL	83	84,7	76	91,6	14,69	20,36	92	92,9	84	91,3	14,29	24,01
FU Day 28	>= 3.5 ug/mL	90	91,8	77	85,6	20,13	27,48	90	90,9	80	88,9	16,67	26,65
FU Month 3	>= 3.5 ug/mL	88	89,8	77	87,5	18,18	25,24	88	88,9	78	88,6	19,23	25,91
FU Month 6	>= 3.5 ug/mL	76	77,6	70	92,1	17,14	23,22	69	69,7	57	82,6	16,67	23,57
FU Month 9	>= 3.5 ug/mL	58	59,2	50	86,2	15,00	25,03	48	48,5	38	79,2	13,60	21,52
FU Month 12	>= 3.5 ug/mL	46	46,9	39	84,8	15,38	21,76	40	40,4	31	77,5	14,52	23,07
FU Month 15	>= 3.5 ug/mL	38	38,8	33	86,8	17,17	23,38	23	23,2	17	73,9	14,71	21,96
FU Month 18	>= 3.5 ug/mL	32	32,7	28	87,5	16,67	24,43	15	15,2	13	86,7	14,10	25,32
FU Month 21	>= 3.5 ug/mL	21	21,4	18	85,7	25,00	27,56	11	11,1	9	81,8	18,52	24,22
FU Month 24	>= 3.5 ug/mL	12	12,2	9	75,0	31,48	44,44	5	5,1	5	100,0	30,00	34,16
FU Month 27	>= 3.5 ug/mL	3	3,1	3	100,0	11,11	19,25	2	2,0	2	100,0	8,33	11,79
FU Month 30	>= 3.5 ug/mL	2	2,0	2	100,0	8,33	11,79	0	NE	0	NE	NE	NE
Immunoglobulin VH, cytogenetics 2													
Screening	12	45	100,0	43	95,6	26,36	30,70	44	100,0	43	97,7	17,44	25,71
Cycle 4 Day 1	12	34	75,6	32	94,1	22,40	30,71	38	86,4	33	86,8	15,66	19,96
FU Day 28	12	39	86,7	37	94,9	25,23	31,82	40	90,9	35	87,5	15,71	25,87
FU Month 3	12	38	84,4	36	94,7	22,22	30,86	39	88,6	32	82,1	19,27	25,79
FU Month 6	12	36	80,0	32	88,9	18,23	23,33	34	77,3	28	82,4	19,05	23,88
FU Month 9	12	26	57,8	22	84,6	21,21	31,78	28	63,6	18	64,3	25,93	33,44
FU Month 12	12	22	48,9	18	81,8	19,44	29,29	23	52,3	15	65,2	27,78	32,53
FU Month 15	12	17	37,8	14	82,4	15,48	21,15	17	38,6	12	70,6	23,61	32,14
FU Month 18	12	15	33,3	12	80,0	22,22	28,72	13	29,5	9	69,2	22,22	25,00
FU Month 21	12	10	22,2	8	80,0	31,25	38,25	7	15,9	5	71,4	10,00	14,91
FU Month 24	12	8	17,8	6	75,0	36,11	42,71	6	13,6	6	100,0	33,33	34,96
FU Month 27	12	5	11,1	4	80,0	37,50	34,36	2	4,5	2	100,0	16,67	0,00
FU Month 30	12	4	8,9	3	75,0	27,78	34,69	1	2,3	1	100,0	16,67	NE

Screening	11q-	46	100,0	43	93,5	18,22	21,15	43	100,0	40	93,0	22,92	27,13
Cycle 4 Day 1	11q-	40	87,0	39	97,5	13,68	17,04	41	95,3	35	85,4	10,48	19,00
FU Day 28	11q-	42	91,3	35	83,3	16,19	21,95	39	90,7	36	92,3	16,67	23,57
FU Month 3	11q-	42	91,3	38	90,5	17,11	21,40	38	88,4	36	94,7	14,35	22,94
FU Month 6	11q-	38	82,6	35	92,1	15,71	19,36	32	74,4	28	87,5	20,24	22,84
FU Month 9	11q-	28	60,9	26	92,9	14,10	20,92	25	58,1	21	84,0	13,49	23,93
FU Month 12	11q-	20	43,5	19	95,0	20,18	28,64	18	41,9	17	94,4	19,61	27,79
FU Month 15	11q-	18	39,1	16	88,9	9,38	13,57	14	32,6	10	71,4	16,67	22,22
FU Month 18	11q-	15	32,6	13	86,7	24,36	35,10	8	18,6	7	87,5	14,29	31,07
FU Month 21	11q-	12	26,1	11	91,7	13,64	16,36	4	9,3	2	50,0	8,33	11,79
FU Month 24	11q-	7	15,2	5	71,4	0,00	0,00	1	2,3	1	100,0	50,00	NE
FU Month 27	11q-	3	6,5	3	100,0	0,00	0,00	0	NE	0	NE	NE	NE
FU Month 30	11q-	3	6,5	3	100,0	11,11	19,25	0	NE	0	NE	NE	NE
Screening	13q-	79	100,0	77	97,5	20,56	27,69	75	100,0	70	93,3	23,33	28,71
Cycle 4 Day 1	13q-	67	84,8	60	89,6	14,17	19,36	68	90,7	60	88,2	16,94	23,47
FU Day 28	13q-	72	91,1	65	90,3	17,18	24,29	72	96,0	65	90,3	19,74	27,62
FU Month 3	13q-	73	92,4	67	91,8	17,91	24,50	69	92,0	61	88,4	25,41	25,93
FU Month 6	13q-	67	84,8	62	92,5	16,13	23,76	63	84,0	56	88,9	21,73	30,14
FU Month 9	13q-	56	70,9	49	87,5	16,67	28,67	52	69,3	42	80,8	19,84	28,33
FU Month 12	13q-	44	55,7	38	86,4	18,86	21,98	40	53,3	38	95,0	20,61	28,06
FU Month 15	13q-	38	48,1	33	86,8	21,21	24,75	29	38,7	25	86,2	25,33	29,71
FU Month 18	13q-	28	35,4	24	85,7	17,36	20,55	21	28,0	19	90,5	24,56	33,04
FU Month 21	13q-	16	20,3	13	81,3	23,08	18,68	16	21,3	14	87,5	20,24	25,47
FU Month 24	13q-	7	8,9	6	85,7	16,67	21,08	7	9,3	6	85,7	13,89	26,70
FU Month 27	13q-	2	2,5	1	50,0	0,00	NE	6	8,0	4	66,7	4,17	8,33
Screening	Norm. K.	65	100,0	61	93,8	21,86	25,38	58	100,0	55	94,8	27,27	31,16
Cycle 4 Day 1	Norm. K.	54	83,1	49	90,7	19,73	28,19	55	94,8	50	90,9	28,33	30,54
FU Day 28	Norm. K.	59	90,8	50	84,7	24,00	30,33	53	91,4	50	94,3	23,00	30,28
FU Month 3	Norm. K.	54	83,1	48	88,9	21,18	31,46	54	93,1	48	88,9	25,69	29,37
FU Month 6	Norm. K.	49	75,4	47	95,9	26,24	31,61	45	77,6	40	88,9	26,67	29,67
FU Month 9	Norm. K.	39	60,0	31	79,5	17,20	27,72	30	51,7	27	90,0	25,31	27,10
FU Month 12	Norm. K.	32	49,2	27	84,4	21,60	28,43	24	41,4	20	83,3	23,33	27,25
FU Month 15	Norm. K.	26	40,0	23	88,5	19,57	29,15	20	34,5	18	90,0	16,67	22,14
FU Month 18	Norm. K.	18	27,7	17	94,4	18,63	21,15	15	25,9	12	80,0	22,22	30,43
FU Month 21	Norm. K.	12	18,5	6	50,0	19,44	32,35	11	19,0	9	81,8	35,19	35,79
FU Month 24	Norm. K.	8	12,3	6	75,0	27,78	44,31	4	6,9	4	100,0	12,50	15,96
FU Month 27	Norm. K.	3	4,6	3	100,0	0,00	0,00	1	1,7	1	100,0	0,00	NE
Screening	Other Abn.	20	100,0	18	90,0	25,00	33,94	22	100,0	20	90,9	15,83	24,47

Cycle 4 Day 1	Other Abn.	18	90,0	16	88,9	26,04	34,94	22	100,0	20	90,9	11,67	20,30
FU Day 28	Other Abn.	18	90,0	14	77,8	35,71	41,27	21	95,5	17	81,0	17,65	31,44
FU Month 3	Other Abn.	18	90,0	14	77,8	29,76	39,32	21	95,5	19	90,5	13,16	19,70
FU Month 6	Other Abn.	17	85,0	12	70,6	23,61	35,86	18	81,8	18	100,0	14,81	19,71
FU Month 9	Other Abn.	15	75,0	10	66,7	21,67	28,38	14	63,6	13	92,9	14,10	20,24
FU Month 12	Other Abn.	7	35,0	6	85,7	25,00	39,09	12	54,5	9	75,0	16,67	33,33
FU Month 15	Other Abn.	5	25,0	4	80,0	20,83	20,97	5	22,7	4	80,0	16,67	33,33
FU Month 18	Other Abn.	3	15,0	3	100,0	11,11	19,25	3	13,6	2	66,7	8,33	11,79
FU Month 21	Other Abn.	2	10,0	2	100,0	0,00	0,00	2	9,1	2	100,0	8,33	11,79
FU Month 24	Other Abn.	2	10,0	2	100,0	0,00	0,00	0	NE	0	NE	NE	NE
Time from first diagnosis													
Screening	Missing	1	100,0	1	100,0	16,67	NE	0	NE	0	NE	NE	NE
Cycle 4 Day 1	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Day 28	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 3	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 6	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 9	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 12	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 15	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 18	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
Screening	13 - 24 months	41	100,0	39	95,1	25,21	29,09	31	100,0	31	100,0	15,59	21,49
Cycle 4 Day 1	13 - 24 months	35	85,4	34	97,1	20,10	26,84	30	96,8	27	90,0	9,88	15,51
FU Day 28	13 - 24 months	38	92,7	33	86,8	32,32	33,58	30	96,8	27	90,0	6,17	17,99
FU Month 3	13 - 24 months	36	87,8	34	94,4	23,53	29,62	30	96,8	26	86,7	10,90	23,07
FU Month 6	13 - 24 months	36	87,8	33	91,7	21,72	26,84	30	96,8	25	83,3	13,33	25,00
FU Month 9	13 - 24 months	32	78,0	29	90,6	10,34	20,13	21	67,7	18	85,7	12,04	18,79
FU Month 12	13 - 24 months	21	51,2	18	85,7	15,74	25,87	16	51,6	14	87,5	3,57	9,65
FU Month 15	13 - 24 months	19	46,3	18	94,7	13,89	17,39	16	51,6	10	62,5	8,33	21,15
FU Month 18	13 - 24 months	14	34,1	13	92,9	16,67	25,46	10	32,3	8	80,0	10,42	17,68
FU Month 21	13 - 24 months	11	26,8	9	81,8	27,78	34,36	6	19,4	4	66,7	4,17	8,33
FU Month 24	13 - 24 months	8	19,5	5	62,5	56,67	36,51	3	9,7	3	100,0	22,22	38,49
FU Month 27	13 - 24 months	5	12,2	5	100,0	23,33	36,51	2	6,5	2	100,0	8,33	11,79
FU Month 30	13 - 24 months	3	7,3	3	100,0	33,33	33,33	1	3,2	1	100,0	16,67	NE
Screening	<= 12 months	60	100,0	58	96,7	19,54	24,61	70	100,0	69	98,6	26,33	29,48
Cycle 4 Day 1	<= 12 months	48	80,0	42	87,5	15,87	23,27	60	85,7	56	93,3	16,37	24,31
FU Day 28	<= 12 months	54	90,0	45	83,3	22,22	25,87	62	88,6	57	91,9	22,22	28,75
FU Month 3	<= 12 months	53	88,3	45	84,9	18,52	25,43	59	84,3	55	93,2	20,00	20,64
FU Month 6	<= 12 months	46	76,7	40	87,0	15,00	20,60	47	67,1	43	91,5	16,28	21,67

FU Month 9	<= 12 months	35	58,3	27	77,1	16,05	27,53	37	52,9	31	83,8	18,82	25,36
FU Month 12	<= 12 months	27	45,0	23	85,2	17,39	28,19	29	41,4	27	93,1	21,60	30,25
FU Month 15	<= 12 months	22	36,7	17	77,3	16,67	25,69	17	24,3	16	94,1	18,75	23,47
FU Month 18	<= 12 months	16	26,7	13	81,3	15,38	22,01	13	18,6	12	92,3	19,44	25,46
FU Month 21	<= 12 months	9	15,0	5	55,6	0,00	0,00	7	10,0	6	85,7	30,56	30,58
FU Month 24	<= 12 months	6	10,0	3	50,0	0,00	0,00	2	2,9	1	50,0	33,33	NE
FU Month 27	<= 12 months	1	1,7			NE	NE	1	1,4			NE	NE
FU Month 30	<= 12 months	1	1,7			NE	NE	0	NE			NE	NE
Screening	>24 months	153	100,0	144	94,1	21,88	27,63	141	100,0	128	90,8	22,01	28,75
Cycle 4 Day 1	>24 months	129	84,3	119	92,2	17,93	25,32	134	95,0	115	85,8	20,58	26,15
FU Day 28	>24 months	137	89,5	122	89,1	18,44	27,67	133	94,3	119	89,5	20,59	28,10
FU Month 3	>24 months	135	88,2	123	91,1	19,92	28,68	132	93,6	115	87,1	24,20	28,38
FU Month 6	>24 months	124	81,0	114	91,9	20,47	27,70	115	81,6	102	88,7	25,65	28,69
FU Month 9	>24 months	96	62,7	81	84,4	20,58	29,38	91	64,5	72	79,1	22,92	29,79
FU Month 12	>24 months	76	49,7	66	86,8	22,73	26,58	72	51,1	58	80,6	26,15	29,47
FU Month 15	>24 months	62	40,5	54	87,1	19,75	25,09	52	36,9	43	82,7	24,81	28,95
FU Month 18	>24 months	48	31,4	42	87,5	22,22	25,94	37	26,2	29	78,4	25,29	33,22
FU Month 21	>24 months	32	20,9	26	81,3	21,79	22,49	27	19,1	22	81,5	21,97	27,88
FU Month 24	>24 months	18	11,8	17	94,4	11,76	26,85	13	9,2	13	100,0	21,79	28,37
FU Month 27	>24 months	7	4,6	6	85,7	5,56	13,61	6	4,3	5	83,3	6,67	9,13
FU Month 30	>24 months	3	2,0	3	100,0	5,56	9,62	0	NE	0	NE	NE	NE
High circulating tumor burden													
Screening	Missing	0	NE	0	NE	NE	NE	2	100,0	1	50,0	0,00	NE
Cycle 4 Day 1	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	0,00	NE
FU Day 28	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	33,33	NE
FU Month 3	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	0,00	NE
FU Month 6	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	0,00	NE
FU Month 9	Missing	0	NE			NE	NE	1	50,0			NE	NE
Screening	<25x10**9 cells/L	60	100,0	55	91,7	23,33	28,07	67	100,0	64	95,5	21,35	26,97
Cycle 4 Day 1	<25x10**9 cells/L	50	83,3	45	90,0	22,22	32,57	61	91,0	52	85,2	16,99	23,22
FU Day 28	<25x10**9 cells/L	56	93,3	47	83,9	25,89	30,26	61	91,0	53	86,9	17,61	27,62
FU Month 3	<25x10**9 cells/L	54	90,0	47	87,0	24,82	32,39	59	88,1	50	84,7	17,33	22,58
FU Month 6	<25x10**9 cells/L	50	83,3	44	88,0	23,11	31,17	51	76,1	42	82,4	16,67	25,24
FU Month 9	<25x10**9 cells/L	36	60,0	27	75,0	16,67	22,17	41	61,2	30	73,2	12,22	19,54
FU Month 12	<25x10**9 cells/L	29	48,3	24	82,8	21,53	29,68	34	50,7	25	73,5	12,00	23,33
FU Month 15	<25x10**9 cells/L	24	40,0	19	79,2	21,93	29,42	23	34,3	15	65,2	13,33	23,74
FU Month 18	<25x10**9 cells/L	20	33,3	18	90,0	24,07	26,34	19	28,4	14	73,7	20,24	28,63
FU Month 21	<25x10**9 cells/L	14	23,3	10	71,4	31,67	35,53	10	14,9	8	80,0	8,33	12,60

FU Month 24	<25x10**9 cells/L	8	13,3	5	62,5	13,33	29,81	6	9,0	6	100,0	36,11	34,02
FU Month 27	<25x10**9 cells/L	4	6,7	3	75,0	27,78	48,11	1	1,5	1	100,0	16,67	NE
FU Month 30	<25x10**9 cells/L	4	6,7	3	75,0	33,33	33,33	1	1,5	1	100,0	16,67	NE
Screening	>=25x10**9 cells/L	195	100,0	187	95,9	21,39	26,83	173	100,0	163	94,2	23,01	28,76
Cycle 4 Day 1	>=25x10**9 cells/L	163	83,6	151	92,6	16,45	22,28	162	93,6	145	89,5	18,39	25,21
FU Day 28	>=25x10**9 cells/L	174	89,2	154	88,5	20,13	28,05	163	94,2	149	91,4	19,57	27,65
FU Month 3	>=25x10**9 cells/L	171	87,7	156	91,2	18,70	26,53	161	93,1	145	90,1	22,76	27,06
FU Month 6	>=25x10**9 cells/L	157	80,5	144	91,7	18,29	24,41	140	80,9	127	90,7	23,23	27,39
FU Month 9	>=25x10**9 cells/L	128	65,6	111	86,7	17,57	28,59	107	61,8	91	85,0	22,89	29,15
FU Month 12	>=25x10**9 cells/L	96	49,2	84	87,5	19,84	25,93	83	48,0	74	89,2	25,00	29,62
FU Month 15	>=25x10**9 cells/L	80	41,0	71	88,8	16,67	22,00	62	35,8	54	87,1	23,15	27,74
FU Month 18	>=25x10**9 cells/L	59	30,3	51	86,4	17,97	24,46	41	23,7	35	85,4	21,90	30,19
FU Month 21	>=25x10**9 cells/L	38	19,5	30	78,9	16,67	20,06	30	17,3	24	80,0	25,69	29,48
FU Month 24	>=25x10**9 cells/L	24	12,3	20	83,3	20,83	34,15	12	6,9	11	91,7	15,15	22,92
FU Month 27	>=25x10**9 cells/L	9	4,6	8	88,9	8,33	15,43	8	4,6	6	75,0	5,56	8,61
FU Month 30	>=25x10**9 cells/L	3	1,5	3	100,0	5,56	9,62	0	NE	0	NE	NE	NE

¹ in study: number of subjects in study at respective visit; % based on baseline

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit

² mean: descriptive statistics - absolute values Clinical

cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/t_pro_mean.sas

Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/t_pro_mean_sg_EQC30_IT_label_09MAY2013_21004.xls 04MAR2020

17:18

POPULATION: Labelpopulation, Intent-to-Treat Patients ENDPOINT: EORTC QoL 30

MODEL: Unadjusted Analysis STUDY: CLL11(BO21004), Stage

2

Compliance/Mean

Insomnia Scale

		GClb (N=255)						RC1b (N=242)						
		Patients			Statistics			Patients			Statistics			
Name	Level	in study ¹	%	with value ¹	%	Mean ²	SD(mean)	in study ¹	%	with value ¹	%	Mean ²	SD(mean)	
All														
Screening	n/a	255	100,0	241	94,5	30,29	31,03	242	100,0	228	94,2	25,58	30,71	
Cycle 4 Day 1	n/a	213	83,5	195	91,5	22,74	29,34	224	92,6	196	87,5	23,47	28,33	
FU Day 28	n/a	230	90,2	199	86,5	24,79	29,77	225	93,0	203	90,2	21,51	25,95	
FU Month 3	n/a	225	88,2	203	90,2	25,45	28,59	221	91,3	195	88,2	23,25	28,03	
FU Month 6	n/a	207	81,2	185	89,4	25,23	29,70	192	79,3	169	88,0	22,09	29,74	
FU Month 9	n/a	164	64,3	138	84,1	21,74	28,38	149	61,6	121	81,2	23,97	29,57	
FU Month 12	n/a	125	49,0	109	87,2	22,02	27,30	117	48,3	98	83,8	24,83	29,24	
FU Month 15	n/a	104	40,8	89	85,6	20,22	25,43	85	35,1	67	78,8	22,39	29,81	
FU Month 18	n/a		79	31,0	70	88,6	20,48	27,97	60	24,8	49	81,7	19,05	30,43
FU Month 21	n/a		52	20,4	40	76,9	23,33	27,43	40	16,5	32	80,0	27,08	31,04
FU Month 24	n/a		32	12,5	25	78,1	21,33	25,24	18	7,4	17	94,4	13,73	16,91
FU Month 27	n/a		13	5,1	11	84,6	24,24	26,21	9	3,7	7	77,8	14,29	17,82
FU Month 30	n/a		7	2,7	5	71,4	13,33	29,81	1	0,4	1	100,0	0,00	NE
Gender														
Screening	Female	97	100,0	91	93,8	32,97	30,83	95	100,0	87	91,6	35,63	32,86	
Cycle 4 Day 1	Female	84	86,6	76	90,5	27,63	31,92	88	92,6	78	88,6	29,06	31,49	
FU Day 28	Female	90	92,8	82	91,1	29,27	31,60	91	95,8	79	86,8	29,11	28,43	
FU Month 3	Female	88	90,7	81	92,0	30,86	30,17	87	91,6	77	88,5	30,74	29,99	
FU Month 6	Female	84	86,6	72	85,7	29,17	32,59	77	81,1	67	87,0	26,37	32,07	
FU Month 9	Female	70	72,2	59	84,3	29,38	31,00	61	64,2	46	75,4	32,61	29,39	
FU Month 12	Female	56	57,7	49	87,5	25,17	26,81	47	49,5	40	85,1	31,67	33,72	
FU Month 15	Female	47	48,5	40	85,1	26,67	27,43	33	34,7	28	84,8	28,57	31,05	
FU Month 18	Female	34	35,1	29	85,3	25,29	29,08	26	27,4	22	84,6	27,27	36,57	
FU Month 21	Female	21	21,6	15	71,4	33,33	30,86	17	17,9	15	88,2	33,33	35,63	
FU Month 24	Female	12	12,4	10	83,3	26,67	26,29	6	6,3	5	83,3	6,67	14,91	
FU Month 27	Female	6	6,2	5	83,3	33,33	23,57	2	2,1	1	50,0	0,00	NE	
FU Month 30	Female	4	4,1	2	50,0	33,33	47,14	1	1,1	1	100,0	0,00	NE	

Screening	Male	158	100,0	150	94,9	28,67	31,14	147	100,0	141	95,9	19,39	27,65
Cycle 4 Day 1	Male	129	81,6	119	92,2	19,61	27,24	136	92,5	118	86,8	19,77	25,50
FU Day 28	Male	140	88,6	117	83,6	21,65	28,13	134	91,2	124	92,5	16,67	23,09
FU Month 3	Male	137	86,7	122	89,1	21,86	27,03	134	91,2	118	88,1	18,36	25,63
FU Month 6	Male	123	77,8	113	91,9	22,71	27,55	115	78,2	102	88,7	19,28	27,92
FU Month 9	Male	94	59,5	79	84,0	16,03	24,96	88	59,9	75	85,2	18,67	28,60
FU Month 12	Male	69	43,7	60	87,0	19,44	27,65	70	47,6	58	82,9	20,11	24,93
FU Month 15	Male	57	36,1	49	86,0	14,97	22,63	52	35,4	39	75,0	17,95	28,46
FU Month 18	Male	45	28,5	41	91,1	17,07	27,00	34	23,1	27	79,4	12,35	22,92
FU Month 21	Male	31	19,6	25	80,6	17,33	23,80	23	15,6	17	73,9	21,57	26,20
FU Month 24	Male	20	12,7	15	75,0	17,78	24,77	12	8,2	12	100,0	16,67	17,41
FU Month 27	Male	7	4,4	6	85,7	16,67	27,89	7	4,8	6	85,7	16,67	18,26
FU Month 30	Male	3	1,9	3	100,0	0,00	0,00	0	NE	0	NE	NE	NE
Age													
Screening	<75 years	130	100,0	122	93,8	26,50	29,05	120	100,0	110	91,7	23,33	28,40
Cycle 4 Day 1	<75 years	106	81,5	100	94,3	24,67	28,28	112	93,3	98	87,5	22,11	27,89
FU Day 28	<75 years	119	91,5	104	87,4	24,36	27,57	110	91,7	103	93,6	20,71	24,75
FU Month 3	<75 years	116	89,2	106	91,4	25,79	27,71	109	90,8	98	89,9	23,47	29,59
FU Month 6	<75 years	108	83,1	98	90,7	25,17	28,34	99	82,5	87	87,9	19,92	27,12
FU Month 9	<75 years	85	65,4	73	85,9	21,92	27,34	74	61,7	62	83,8	23,12	28,04
FU Month 12	<75 years	63	48,5	59	93,7	24,86	27,40	60	50,0	53	88,3	20,75	24,66
FU Month 15	<75 years	54	41,5	46	85,2	23,91	28,69	44	36,7	35	79,5	19,05	25,93
FU Month 18	<75 years	43	33,1	39	90,7	21,37	28,08	27	22,5	22	81,5	16,67	28,64
FU Month 21	<75 years	26	20,0	22	84,6	22,73	27,96	17	14,2	13	76,5	15,38	22,01
FU Month 24	<75 years	18	13,8	14	77,8	21,43	28,06	6	5,0	5	83,3	13,33	18,26
FU Month 27	<75 years	7	5,4	5	71,4	33,33	33,33	2	1,7	1	50,0	0,00	NE
FU Month 30	<75 years	4	3,1	3	75,0	22,22	38,49	0	NE	0	NE	NE	NE
Age													
Screening	>=75 years	125	100,0	119	95,2	34,17	32,61	122	100,0	118	96,7	27,68	32,70
Cycle 4 Day 1	>=75 years	107	85,6	95	88,8	20,70	30,43	112	91,8	98	87,5	24,83	28,84
FU Day 28	>=75 years	111	88,8	95	85,6	25,26	32,15	115	94,3	100	87,0	22,33	27,24
FU Month 3	>=75 years	109	87,2	97	89,0	25,09	29,67	112	91,8	97	86,6	23,02	26,51
FU Month 6	>=75 years	99	79,2	87	87,9	25,29	31,32	93	76,2	82	88,2	24,39	32,31
FU Month 9	>=75 years	79	63,2	65	82,3	21,54	29,72	75	61,5	59	78,7	24,86	31,31
FU Month 12	>=75 years	62	49,6	50	80,6	18,67	27,07	57	46,7	45	78,9	29,63	33,50
FU Month 15	>=75 years	50	40,0	43	86,0	16,28	21,05	41	33,6	32	78,0	26,04	33,58
FU Month 18	>=75 years	36	28,8	31	86,1	19,35	28,25	33	27,0	27	81,8	20,99	32,22
FU Month 21	>=75 years	26	20,8	18	69,2	24,07	27,55	23	18,9	19	82,6	35,09	34,20
FU Month 24	>=75 years	14	11,2	11	78,6	21,21	22,47	12	9,8	12	100,0	13,89	17,16

FU Month 27	>=75 years	64,8	6100,0	16,67	18,26	75,7	685,7	16,67	18,26				
FU Month 30	>=75 years	32,4	266,7	0,00	0,00	10,8	1100,0	0,00					NE
Race													
Screening	Other	9100,0	9100,0	25,93	36,43	11100,0	11100,0	27,27	29,13				
Cycle 4 Day 1	Other	777,8	7100,0	33,33	33,33	1090,9	990,0	44,44	40,82				
FU Day 28	Other	888,9	8100,0	37,50	37,53	1090,9	10100,0	23,33	22,50				
FU Month 3	Other	888,9	787,5	28,57	23,00	1090,9	10100,0	26,67	21,08				
FU Month 6	Other	888,9	787,5	23,81	37,09	872,7	8100,0	16,67	25,20				
FU Month 9	Other	444,4	375,0	22,22	19,25	545,5	480,0	33,33	47,14				
FU Month 12	Other	333,3	266,7	16,67	23,57	436,4	4100,0	8,33	16,67				
FU Month 15	Other	222,2	150,0	0,00		436,4	4100,0	8,33	16,67				
FU Month 18	Other	222,2	150,0	0,00		218,2	2100,0	16,67	23,57				
FU Month 21	Other	222,2	150,0	0,00		218,2	2100,0	16,67	23,57				
FU Month 24	Other	222,2	150,0	0,00		19,1	0			NE	NE	NE	NE
FU Month 27	Other	111,1			NE	19,1					NE		NE
FU Month 30	Other	111,1			NE	0	NE				NE		NE
Geographical Region													
Screening	Asia-Pacific	20100,0	20100,0	26,67	27,78	18100,0	18100,0	27,78	34,77				
Cycle 4 Day 1	Asia-Pacific	1575,0	15100,0	26,67	36,08	1688,9	1593,8	26,67	31,37				
FU Day 28	Asia-Pacific	1890,0	18100,0	37,04	27,75	18100,0	1688,9	25,00	25,82				
FU Month 3	Asia-Pacific	1890,0	1688,9	25,00	25,82	18100,0	1688,9	22,92	26,44				
FU Month 6	Asia-Pacific	1680,0	1487,5	23,81	33,15	1794,4	1588,2	28,89	30,52				
FU Month 9	Asia-Pacific	1470,0	1285,7	22,22	29,59	1372,2	1076,9	33,33	38,49				
FU Month 12	Asia-Pacific	1050,0	880,0	12,50	17,25	1055,6	10100,0	23,33	22,50				
FU Month 15	Asia-Pacific	840,0	675,0	11,11	17,21	950,0	9100,0	18,52	29,40				

FU Month 18	Asia-Pacific	630,0	466,7	8,33	16,67	633,3	6100,0	22,22	27,22
FU Month 21	Asia-Pacific	525,0	360,0	0,00	0,00	422,2	4100,0	16,67	19,25
FU Month 24	Asia-Pacific	315,0	266,7	0,00	0,00	15,6	0	NE	NE
FU Month 27	Asia-Pacific	15,0		NE	NE	15,6		NE	NE
FU Month 30	Asia-Pacific	15,0		NE	NE	0	NE	NE	NE
Screening	Central and South America	3100,0	3100,0	22,22	38,49	2100,0	2100,0	16,67	23,57
Cycle 4 Day 1	Central and South America	3100,0	3100,0	11,11	19,25	2100,0	2100,0	33,33	47,14
FU Day 28	Central and South America	3100,0	3100,0	22,22	19,25	2100,0	2100,0	16,67	23,57
FU Month 3	Central and South America	3100,0	3100,0	22,22	19,25	2100,0	2100,0	16,67	23,57
FU Month 6	Central and South America	266,7	2100,0	16,67	23,57	2100,0	2100,0	16,67	23,57
FU Month 9	Central and South America	266,7	2100,0	16,67	23,57	150,0	1100,0	0,00	NE
FU Month 12	Central and South America	266,7	2100,0	16,67	23,57	150,0	1100,0	0,00	NE
FU Month 15	Central and South America	133,3	1100,0	0,00	NE	0	NE	NE	NE
FU Month 18	Central and South America	133,3	1100,0	0,00	NE	0	NE	NE	NE
FU Month 21	Central and South America	133,3	1100,0	0,00	NE	0	NE	NE	NE
FU Month 24	Central and South America	133,3	1100,0	33,33	NE	0	NE	NE	NE
Screening	North America	12100,0	12100,0	52,78	30,01	13100,0	1292,3	30,56	33,21
Cycle 4 Day 1	North America	975,0	9100,0	18,52	17,57	1292,3	12100,0	19,44	22,29
FU Day 28	North America	1191,7	11100,0	27,27	29,13	13100,0	13100,0	25,64	19,97
FU Month 3	North America	1191,7	11100,0	33,33	29,81	1292,3	12100,0	16,67	17,41
FU Month 6	North America	1191,7	1090,9	20,00	32,20	1184,6	11100,0	24,24	26,21
FU Month 9	North America	866,7	8100,0	25,00	34,50	969,2	9100,0	25,93	27,78
FU Month 12	North America	866,7	787,5	38,10	35,63	753,8	7100,0	33,33	27,22
FU Month 15	North America	650,0	6100,0	22,22	17,21	646,2	583,3	20,00	18,26
FU Month 18	North America	433,3	4100,0	33,33	27,22	323,1	3100,0	0,00	0,00
FU Month 21	North America	325,0	266,7	33,33	0,00	17,7	1100,0	33,33	NE
FU Month 24	North America	325,0	266,7	16,67	23,57	17,7	1100,0	33,33	NE
FU Month 27	North America	216,7	150,0	33,33	NE	17,7	1100,0	0,00	NE
Screening	Other	45100,0	4191,1	26,02	27,40	44100,0	4193,2	24,39	25,85
Cycle 4 Day 1	Other	3782,2	3389,2	20,20	26,27	4090,9	3587,5	20,95	28,11
FU Day 28	Other	3782,2	3389,2	25,25	32,31	3988,6	3794,9	17,12	21,69
FU Month 3	Other	3884,4	3489,5	23,53	22,52	3886,4	3694,7	23,15	31,69
FU Month 6	Other	3577,8	3188,6	23,66	27,48	3375,0	3090,9	18,89	25,80
FU Month 9	Other	2657,8	2284,6	19,70	22,20	2454,5	1979,2	19,30	20,23
FU Month 12	Other	1737,8	1694,1	25,00	25,82	1636,4	1487,5	16,67	25,32
FU Month 15	Other	1226,7	1191,7	24,24	26,21	920,5	888,9	12,50	24,80
FU Month 18	Other	1022,2	990,0	22,22	28,87	715,9	685,7	0,00	0,00
FU Month 21	Other	715,6	685,7	27,78	25,09	49,1	4100,0	0,00	0,00

FU Month 24	Other	6	13,3	5	83,3	26,67	27,89	3	6,8	3	100,0	0,00	0,00
FU Month 27	Other	4	8,9	4	100,0	33,33	27,22	1	2,3	1	100,0	33,33	NE
FU Month 30	Other	2	4,4	2	100,0	33,33	47,14	0	NE	0	NE	NE	NE
Screening	Western Europe	175	100,0	165	94,3	30,30	31,84	165	100,0	155	93,9	25,38	31,57
Cycle 4 Day 1	Western Europe	149	85,1	135	90,6	23,46	30,22	154	93,3	132	85,7	23,99	28,63
FU Day 28	Western Europe	161	92,0	134	83,2	22,89	29,59	153	92,7	135	88,2	21,98	27,67
FU Month 3	Western Europe	155	88,6	139	89,7	25,42	30,45	151	91,5	129	85,4	24,03	28,25
FU Month 6	Western Europe	143	81,7	128	89,5	26,30	30,06	129	78,2	111	86,0	21,92	31,30
FU Month 9	Western Europe	114	65,1	94	82,5	21,99	29,55	102	61,8	82	80,4	23,98	30,66
FU Month 12	Western Europe	88	50,3	76	86,4	21,05	27,67	83	50,3	66	79,5	26,26	31,22
FU Month 15	Western Europe	77	44,0	65	84,4	20,51	26,80	61	37,0	45	73,8	25,19	31,91
FU Month 18	Western Europe	58	33,1	52	89,7	20,51	28,89	44	26,7	34	77,3	23,53	33,36
FU Month 21	Western Europe	36	20,6	28	77,8	25,00	29,57	31	18,8	23	74,2	33,33	33,33
FU Month 24	Western Europe	19	10,9	15	78,9	22,22	27,22	13	7,9	13	100,0	15,38	17,30
FU Month 27	Western Europe	6	3,4	6	100,0	16,67	27,89	6	3,6	5	83,3	13,33	18,26
FU Month 30	Western Europe	4	2,3	3	75,0	0,00	0,00	1	0,6	1	100,0	0,00	NE
FCgamma receptor IIa													
Screening	131HH	58	100,0	54	93,1	29,01	30,40	76	100,0	72	94,7	24,54	31,15
Cycle 4 Day 1	131HH	49	84,5	43	87,8	24,81	32,61	65	85,5	60	92,3	23,33	30,87
FU Day 28	131HH	51	87,9	44	86,3	28,03	33,68	70	92,1	62	88,6	20,43	24,41
FU Month 3	131HH	51	87,9	47	92,2	25,53	31,25	64	84,2	54	84,4	25,31	26,65
FU Month 6	131HH	49	84,5	45	91,8	25,19	32,69	55	72,4	48	87,3	19,44	29,04
FU Month 9	131HH	39	67,2	30	76,9	24,44	33,83	41	53,9	33	80,5	22,22	30,81
FU Month 12	131HH	28	48,3	24	85,7	19,44	29,35	34	44,7	29	85,3	26,44	28,70
FU Month 15	131HH	23	39,7	19	82,6	21,05	25,36	24	31,6	20	83,3	13,33	25,13
FU Month 18	131HH	17	29,3	14	82,4	16,67	25,32	16	21,1	13	81,3	20,51	32,03
FU Month 21	131HH	13	22,4	8	61,5	16,67	30,86	11	14,5	10	90,9	30,00	36,68
FU Month 24	131HH	11	19,0	7	63,6	28,57	35,63	1	1,3	1	100,0	33,33	NE
FU Month 27	131HH	4	6,9	3	75,0	33,33	33,33	1	1,3	1	100,0	33,33	NE
FU Month 30	131HH	3	5,2	1	33,3	0,00	NE	0	NE	0	NE	NE	NE
Screening	131HR	125	100,0	117	93,6	30,20	28,70	114	100,0	109	95,6	24,77	29,88
Cycle 4 Day 1	131HR	105	84,0	97	92,4	24,74	29,77	110	96,5	97	88,2	22,34	26,67
FU Day 28	131HR	116	92,8	102	87,9	23,86	27,50	105	92,1	96	91,4	20,14	26,26
FU Month 3	131HR	114	91,2	102	89,5	23,20	26,03	107	93,9	94	87,9	20,92	28,50
FU Month 6	131HR	104	83,2	92	88,5	23,55	26,40	95	83,3	85	89,5	23,53	31,63
FU Month 9	131HR	84	67,2	71	84,5	22,54	25,68	76	66,7	61	80,3	24,04	30,51
FU Month 12	131HR	64	51,2	57	89,1	25,73	27,47	57	50,0	47	82,5	24,82	29,87
FU Month 15	131HR	53	42,4	43	81,1	18,60	25,51	44	38,6	33	75,0	26,26	32,01

FU Month 18	131HR	43	34,4	38	88,4	18,42	25,35	32	28,1	26	81,3	19,23	28,55
FU Month 21	131HR	26	20,8	20	76,9	25,00	30,35	21	18,4	16	76,2	33,33	29,81
FU Month 24	131HR	12	9,6	11	91,7	15,15	22,92	12	10,5	11	91,7	18,18	17,41
FU Month 27	131HR	6	4,8	5	83,3	26,67	27,89	6	5,3	4	66,7	8,33	16,67
FU Month 30	131HR	3	2,4	3	100,0	22,22	38,49	1	0,9	1	100,0	0,00	NE
Screening	131RR	49	100,0	48	98,0	29,86	35,22	33	100,0	30	90,9	26,67	30,83
Cycle 4 Day 1	131RR	40	81,6	38	95,0	16,67	22,92	31	93,9	25	80,6	28,00	26,67
FU Day 28	131RR	42	85,7	35	83,3	25,71	32,42	32	97,0	29	90,6	22,99	28,32
FU Month 3	131RR	39	79,6	37	94,9	32,43	31,90	30	93,8	21,11	28,34		
FU Month 6	131RR	35	71,4	32	91,4	31,25	32,72	27	81,8	23	85,2	20,29	24,08
FU Month 9	131RR	24	49,0	22	91,7	24,24	32,82	19	57,6	17	89,5	27,45	26,97
FU Month 12	131RR	18	36,7	17	94,4	23,53	28,30	17	51,5	15	88,2	28,89	33,01
FU Month 15	131RR	16	32,7	16	100,0	29,17	29,50	11	33,3	9	81,8	25,93	27,78
FU Month 18	131RR	14	28,6	14	100,0	28,57	31,64	8	24,2	7	87,5	23,81	41,79
FU Month 21	131RR	8	16,3	7	87,5	23,81	16,27	5	15,2	4	80,0	8,33	16,67
FU Month 24	131RR	5	10,2	4	80,0	25,00	16,67	3	9,1	3	100,0	0,00	0,00
FU Month 27	131RR	2	4,1	2	100,0	16,67	23,57	1	3,0	1	100,0	0,00	NE
FU Month 30	131RR	1	2,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
Screening	Missing	23	100,0	22	95,7	34,85	36,34	19	100,0	17	89,5	33,33	35,36
Cycle 4 Day 1	Missing	19	82,6	17	89,5	19,61	31,31	18	94,7	14	77,8	23,81	33,15
FU Day 28	Missing	21	91,3	18	85,7	20,37	28,33	18	94,7	16	88,9	31,25	25,73
FU Month 3	Missing	21	91,3	17	81,0	23,53	28,30	18	94,7	17	94,4	33,33	28,87
FU Month 6	Missing	19	82,6	16	84,2	22,92	33,82	15	78,9	13	86,7	25,64	30,89
FU Month 9	Missing	17	73,9	15	88,2	8,89	19,79	13	68,4	10	76,9	23,33	27,44
FU Month 12	Missing	15	65,2	11	73,3	6,06	13,48	9	47,4	7	77,8	9,52	16,27
FU Month 15	Missing	12	52,2	11	91,7	12,12	16,82	6	31,6	5	83,3	26,67	36,51
FU Month 18	Missing	5	21,7	4	80,0	25,00	50,00	4	21,1	3	75,0	0,00	0,00
FU Month 21	Missing	5	21,7	5	100,0	26,67	27,89	3	15,8	2	66,7	0,00	0,00
FU Month 24	Missing	4	17,4	3	75,0	22,22	19,25	2	10,5	2	100,0	0,00	0,00
FU Month 27	Missing	1	4,3	1	100,0	0,00	NE	1	5,3	1	100,0	33,33	NE
FCgamma receptor IIIa													
Screening	158FF	103	100,0	100	97,1	28,00	30,23	83	100,0	79	95,2	25,74	32,00
Cycle 4 Day 1	158FF	89	86,4	83	93,3	22,09	32,63	78	94,0	72	92,3	27,78	29,60
FU Day 28	158FF	96	93,2	84	87,5	25,00	32,26	78	94,0	74	94,9	22,52	27,09
FU Month 3	158FF	94	91,3	84	89,4	25,79	30,76	78	94,0	71	91,0	21,60	31,42
FU Month 6	158FF	86	83,5	74	86,0	22,07	29,34	64	77,1	59	92,2	20,34	29,70
FU Month 9	158FF	71	68,9	59	83,1	18,64	26,46	47	56,6	43	91,5	24,81	33,41
FU Month 12	158FF	48	46,6	42	87,5	17,46	24,68	38	45,8	35	92,1	22,86	28,89

FU Month 15	158FF	37	35,9	31	83,8	19,35	25,49	30	36,1	24	80,0	15,28	24,04
FU Month 18	158FF	27	26,2	25	92,6	20,00	30,43	21	25,3	17	81,0	13,73	29,01
FU Month 21	158FF	16	15,5	15	93,8	20,00	30,34	9	10,8	8	88,9	20,83	30,54
FU Month 24	158FF	8	7,8	7	87,5	9,52	16,27	3	3,6	3	100,0	11,11	19,25
FU Month 27	158FF	5	4,9	4	80,0	8,33	16,67	1	1,2	1	100,0	0,00	NE
FU Month 30	158FF	3	2,9	3	100,0	0,00	0,00	0	NE	0	NE	NE	NE
Screening	158FV	119	100,0	110	92,4	30,61	31,33	109	100,0	103	94,5	27,51	30,04
Cycle 4 Day 1	158FV	99	83,2	89	89,9	22,85	25,92	100	91,7	86	86,0	22,48	29,12
FU Day 28	158FV	105	88,2	89	84,8	24,34	27,87	101	92,7	87	86,1	21,07	23,90
FU Month 3	158FV	101	84,9	93	92,1	25,09	27,65	97	89,0	84	86,6	23,02	25,34
FU Month 6	158FV	94	79,0	86	91,5	26,36	28,52	83	76,1	72	86,7	22,69	30,04
FU Month 9	158FV	71	59,7	61	85,9	26,23	30,50	65	59,6	49	75,4	24,49	26,15
FU Month 12	158FV	60	50,4	55	91,7	24,85	27,38	52	47,7	41	78,8	30,08	31,45
FU Month 15	158FV	52	43,7	45	86,5	19,26	26,10	36	33,0	29	80,6	32,18	35,05
FU Month 18	158FV	44	37,0	38	86,4	17,54	22,91	24	22,0	20	83,3	28,33	36,31
FU Month 21	158FV	28	23,5	18	64,3	24,07	25,06	18	16,5	14	77,8	38,10	34,24
FU Month 24	158FV	18	15,1	13	72,2	20,51	25,60	6	5,5	5	83,3	0,00	0,00
FU Month 27	158FV	6	5,0	5	83,3	33,33	23,57	2	1,8	1	50,0	0,00	NE
FU Month 30	158FV	4	3,4	2	50,0	33,33	47,14	0	NE	0	NE	NE	NE
Screening	158VV	16	100,0	15	93,8	33,33	25,20	33	100,0	31	93,9	17,20	25,63
Cycle 4 Day 1	158VV	12	75,0	11	91,7	24,24	26,21	30	90,9	26	86,7	20,51	23,24
FU Day 28	158VV	14	87,5	13	92,9	28,21	26,69	30	90,9	28	93,3	15,48	27,94
FU Month 3	158VV	15	93,8	12	80,0	25,00	20,72	30	90,9	25	83,3	22,67	24,94
FU Month 6	158VV	14	87,5	13	92,9	30,77	34,59	30	90,9	25	83,3	21,33	30,25
FU Month 9	158VV	12	75,0	10	83,3	23,33	27,44	25	75,8	20	80,0	20,00	31,34
FU Month 12	158VV	8	50,0	7	87,5	42,86	37,09	20	60,6	17	85,0	21,57	26,20
FU Month 15	158VV	8	50,0	7	87,5	33,33	27,22	14	42,4	10	71,4	13,33	17,21
FU Month 18	158VV	4	25,0	4	100,0	41,67	31,91	11	33,3	9	81,8	14,81	17,57
FU Month 21	158VV	3	18,8	2	66,7	33,33	47,14	9	27,3	7	77,8	23,81	25,20
FU Month 24	158VV	2	12,5	2	100,0	66,67	0,00	7	21,2	7	100,0	28,57	12,60
FU Month 27	158VV	1	6,3	1	100,0	66,67	NE	5	15,2	4	80,0	16,67	19,25
FU Month 30	158VV	0	NE	0	NE	NE	NE	1	3,0	1	100,0	0,00	NE
Screening	Missing	17	100,0	16	94,1	39,58	38,91	17	100,0	15	88,2	28,89	37,52
Cycle 4 Day 1	Missing	13	76,5	12	92,3	25,00	35,18	16	94,1	12	75,0	11,11	21,71
FU Day 28	Missing	15	88,2	13	86,7	23,08	31,58	16	94,1	14	87,5	30,95	27,62
FU Month 3	Missing	15	88,2	14	93,3	26,19	29,75	16	94,1	15	93,8	33,33	30,86
FU Month 6	Missing	13	76,5	12	92,3	30,56	36,12	15	88,2	13	86,7	28,21	29,96
FU Month 9	Missing	10	58,8	8	80,0	8,33	23,57	12	70,6	9	75,0	25,93	27,78

FU Month 12	Missing		952,9	555,6	0,00	0,00		741,2	571,4	6,67	14,91	
FU Month 15	Missing		741,2	685,7	16,67	18,26		529,4	480,0	16,67	33,33	
FU Month 18	Missing		423,5	375,0	33,33	57,74		423,5	375,0	0,00	0,00	
FU Month 21	Missing		529,4	5100,0	26,67	27,89		423,5	375,0	0,00	0,00	
FU Month 24	Missing		423,5	375,0	22,22	19,25		211,8	2100,0	0,00	0,00	
FU Month 27	Missing		15,9	1100,0	0,00		NE	15,9	1100,0	33,33		NE
Binet Staging at baseline												
Screening	A		59100,0	5898,3	27,59	28,71		57100,0	5393,0	27,04	32,72	
Cycle 4 Day 1	A		5186,4	4894,1	28,47	33,68		5494,7	4990,7	18,37	28,92	
FU Day 28	A		5898,3	5391,4	29,56	29,71		5494,7	5296,3	26,92	29,55	
FU Month 3	A		5796,6	5698,2	23,81	25,99		5393,0	5094,3	25,33	31,27	
FU Month 6	A		5694,9	5089,3	26,00	31,79		4578,9	4191,1	24,39	29,84	
FU Month 9	A		4372,9	3786,0	23,42	27,06		3459,6	3088,2	28,89	31,24	
FU Month 12	A		3661,0	3494,4	20,59	27,23		2442,1	2187,5	26,98	30,95	
FU Month 15	A		3050,8	2686,7	20,51	28,40		1933,3	1894,7	27,78	32,84	
FU Month 18	A		2237,3	1881,8	11,11	22,87		1628,1	16100,0	22,92	31,55	
FU Month 21	A		1728,8	1588,2	13,33	24,56		814,0	787,5	23,81	25,20	
FU Month 24	A		1016,9	880,0	20,83	24,80		58,8	5100,0	13,33	18,26	
FU Month 27	A		58,5	480,0	16,67	19,25		23,5	150,0	33,33		NE
FU Month 30	A		46,8	250,0	0,00	0,00		0	NE	0	NE	NE
Screening												
Screening	B	104	100,0	9995,2	28,62	30,12		85100,0	8397,6	27,31	31,30	
Cycle 4 Day 1	B		8884,6	8394,3	20,08	27,52		7992,9	7392,4	28,31	29,75	
FU Day 28	B		9187,5	7885,7	20,09	28,09		7992,9	7189,9	20,19	24,87	
FU Month 3	B		8884,6	7888,6	23,50	28,98		7992,9	7088,6	25,24	29,18	
FU Month 6	B		8076,9	7695,0	24,12	28,07		7082,4	6491,4	21,88	30,41	
FU Month 9	B		6360,6	5282,5	21,79	30,17		5969,4	4983,1	25,85	29,86	
FU Month 12	B		4745,2	3983,0	26,50	30,76		4654,1	3984,8	33,33	31,53	
FU Month 15	B		3735,6	3491,9	20,59	27,23		3440,0	2779,4	25,93	31,12	
FU Month 18	B		3129,8	2993,5	22,99	33,46		2225,9	1881,8	22,22	32,34	
FU Month 21	B		1817,3	1372,2	38,46	29,96		1720,0	1482,4	26,19	32,50	
FU Month 24	B		1110,6	981,8	18,52	24,22		89,4	8100,0	12,50	17,25	
FU Month 27	B		54,8	480,0	16,67	33,33		44,7	4100,0	8,33	16,67	
FU Month 30	B		21,9	2100,0	0,00	0,00		0	NE	0	NE	NE
Screening												
Screening	C		92100,0	8491,3	34,13	33,52	100	100,0	9292,0	23,19	29,13	
Cycle 4 Day 1	C		7480,4	6486,5	21,88	28,00		9191,0	7481,3	22,07	26,04	
FU Day 28	C		8188,0	6884,0	26,47	31,31		9292,0	8087,0	19,17	24,17	
FU Month 3	C		8087,0	6986,3	28,99	30,20		8989,0	7584,3	20,00	24,51	
FU Month 6	C		7177,2	5983,1	25,99	30,37		7777,0	6483,1	20,83	29,40	

FU Month 9	C	58	63,0	49	84,5	20,41	27,90	56	56,0	42	75,0	18,25	27,74
FU Month 12	C	42	45,7	36	85,7	18,52	23,16	47	47,0	38	80,9	14,91	22,86
FU Month 15	C	37	40,2	29	78,4	19,54	20,93	32	32,0	22	68,8	13,64	24,47
FU Month 18	C	26	28,3	23	88,5	24,64	22,96	22	22,0	15	68,2	11,11	27,22
FU Month 21	C	17	18,5	12	70,6	19,44	22,29	15	15,0	11	73,3	30,30	34,82
FU Month 24	C	11	12,0	8	72,7	25,00	29,55	5	5,0	4	80,0	16,67	19,25
FU Month 27	C	3	3,3	3	100,0	44,44	19,25	3	3,0	2	66,7	16,67	23,57
FU Month 30	C	1	1,1	1	100,0	66,67	NE	1	1,0	1	100,0	0,00	NE
Total CIR score at baseline													
Screening	<=6	63	100,0	59	93,7	25,42	28,59	75	100,0	70	93,3	30,00	30,64
Cycle 4 Day 1	<=6	52	82,5	42	80,8	19,05	27,69	72	96,0	60	83,3	27,22	30,37
FU Day 28	<=6	56	88,9	48	85,7	18,75	26,55	72	96,0	59	81,9	19,21	27,82
FU Month 3	<=6	55	87,3	47	85,5	18,44	25,83	69	92,0	56	81,2	20,83	27,39
FU Month 6	<=6	52	82,5	47	90,4	21,99	27,17	60	80,0	53	88,3	21,38	30,73
FU Month 9	<=6	43	68,3	36	83,7	16,67	24,56	47	62,7	38	80,9	22,81	30,12
FU Month 12	<=6	35	55,6	29	82,9	22,99	26,88	34	45,3	26	76,5	24,36	35,97
FU Month 15	<=6	32	50,8	27	84,4	20,99	24,72	25	33,3	15	60,0	20,00	30,34
FU Month 18	<=6	23	36,5	22	95,7	21,21	24,22	19	25,3	14	73,7	19,05	36,31
FU Month 21	<=6	14	22,2	8	57,1	20,83	24,80	14	18,7	10	71,4	36,67	33,15
FU Month 24	<=6	8	12,7	7	87,5	19,05	17,82	7	9,3	6	85,7	16,67	18,26
FU Month 27	<=6	2	3,2	2	100,0	33,33	0,00	4	5,3	2	50,0	0,00	0,00
FU Month 30	<=6	0	NE	0	NE	NE	NE	1	1,3	1	100,0	0,00	NE
Screening >6													
Screening	>6	192	100,0	182	94,8	31,87	31,70	167	100,0	158	94,6	23,63	30,63
Cycle 4 Day 1	>6	161	83,9	153	95,0	23,75	29,78	152	91,0	136	89,5	21,81	27,33
FU Day 28	>6	174	90,6	151	86,8	26,71	30,56	153	91,6	144	94,1	22,45	25,19
FU Month 3	>6	170	88,5	156	91,8	27,56	29,12	152	91,0	139	91,4	24,22	28,32
FU Month 6	>6	155	80,7	138	89,0	26,33	30,53	132	79,0	116	87,9	22,41	29,41
FU Month 9	>6	121	63,0	102	84,3	23,53	29,51	102	61,1	83	81,4	24,50	29,49
FU Month 12	>6	90	46,9	80	88,9	21,67	27,61	83	49,7	72	86,7	25,00	26,68
FU Month 15	>6	72	37,5	62	86,1	19,89	25,93	60	35,9	52	86,7	23,08	29,92
FU Month 18	>6	56	29,2	48	85,7	20,14	29,77	41	24,6	35	85,4	19,05	28,34
FU Month 21	>6	38	19,8	32	84,2	23,96	28,38	26	15,6	22	84,6	22,73	29,79
FU Month 24	>6	24	12,5	18	75,0	22,22	28,01	11	6,6	11	100,0	12,12	16,82
FU Month 27	>6	11	5,7	9	81,8	22,22	28,87	5	3,0	5	100,0	20,00	18,26
FU Month 30	>6	7	3,6	5	71,4	13,33	29,81	0	NE	0	NE	NE	NE
Calculated creatinine clearance cat. 2													
Screening	<70 ml/min	178	100,0	166	93,3	30,92	31,69	176	100,0	166	94,3	26,51	30,82
Cycle 4 Day 1	<70 ml/min	149	83,7	133	89,3	21,55	29,64	164	93,2	142	86,6	23,24	29,17

FU Day 28	<70 ml/min	162	91,0	140	86,4	25,48	30,61	166	94,3	146	88,0	21,23	26,23
FU Month 3	<70 ml/min	157	88,2	141	89,8	24,82	28,84	159	90,3	139	87,4	22,54	27,57
FU Month 6	<70 ml/min	144	80,9	126	87,5	24,60	29,57	139	79,0	121	87,1	21,21	30,43
FU Month 9	<70 ml/min	117	65,7	97	82,9	19,59	27,53	112	63,6	90	80,4	22,59	28,19
FU Month 12	<70 ml/min	92	51,7	79	85,9	21,10	26,78	87	49,4	72	82,8	26,39	30,61
FU Month 15	<70 ml/min	78	43,8	68	87,2	20,10	24,53	60	34,1	46	76,7	21,01	28,42
FU Month 18	<70 ml/min	59	33,1	51	86,4	19,61	28,42	43	24,4	36	83,7	20,37	32,15
FU Month 21	<70 ml/min	38	21,3	27	71,1	23,46	25,84	31	17,6	27	87,1	24,69	31,48
FU Month 24	<70 ml/min	24	13,5	19	79,2	21,05	22,80	13	7,4	12	92,3	13,89	17,16
FU Month 27	<70 ml/min	10	5,6	8	80,0	25,00	23,57	7	4,0	5	71,4	13,33	18,26
FU Month 30	<70 ml/min	5	2,8	3	60,0	22,22	38,49	1	0,6	1	100,0	0,00	NE
Screening	>=70 ml/min	77	100,0	75	97,4	28,89	29,68	66	100,0	62	93,9	23,12	30,53
Cycle 4 Day 1	>=70 ml/min	64	83,1	62	96,9	25,27	28,75	60	90,9	54	90,0	24,07	26,24
FU Day 28	>=70 ml/min	68	88,3	59	86,8	23,16	27,86	59	89,4	57	96,6	22,22	25,46
FU Month 3	>=70 ml/min	68	88,3	62	91,2	26,88	28,21	62	93,9	56	90,3	25,00	29,30
FU Month 6	>=70 ml/min	63	81,8	59	93,7	26,55	30,18	53	80,3	48	90,6	24,31	28,13
FU Month 9	>=70 ml/min	47	61,0	41	87,2	26,83	30,02	37	56,1	31	83,8	27,96	33,44
FU Month 12	>=70 ml/min	33	42,9	30	90,9	24,44	28,94	30	45,5	26	86,7	20,51	25,08
FU Month 15	>=70 ml/min	26	33,8	21	80,8	20,63	28,82	25	37,9	21	84,0	25,40	33,17
FU Month 18	>=70 ml/min	20	26,0	19	95,0	22,81	27,34	17	25,8	13	76,5	15,38	25,88
FU Month 21	>=70 ml/min	14	18,2	13	92,9	23,08	31,58	9	13,6	5	55,6	40,00	27,89
FU Month 24	>=70 ml/min	8	10,4	6	75,0	22,22	34,43	5	7,6	5	100,0	13,33	18,26
FU Month 27	>=70 ml/min	3	3,9	3	100,0	22,22	38,49	2	3,0	2	100,0	16,67	23,57
FU Month 30	>=70 ml/min	2	2,6	2	100,0	0,00	0,00	0	NE	0	NE	NE	NE
Beta2 microglobulin													
Screening	Missing	3	100,0	3	100,0	44,44	19,25	3	100,0	3	100,0	44,44	19,25
Cycle 4 Day 1	Missing	3	100,0	3	100,0	33,33	33,33	3	100,0	2	66,7	0,00	0,00
FU Day 28	Missing	3	100,0	3	100,0	44,44	19,25	3	100,0	2	66,7	0,00	0,00
FU Month 3	Missing	3	100,0	3	100,0	55,56	19,25	3	100,0	2	66,7	16,67	23,57
FU Month 6	Missing	3	100,0	3	100,0	33,33	33,33	3	100,0	2	66,7	16,67	23,57
FU Month 9	Missing	2	66,7	1	50,0	0,00	NE	3	100,0	2	66,7	33,33	47,14
FU Month 12	Missing	1	33,3	1	100,0	33,33	NE	2	66,7	1	50,0	0,00	NE
FU Month 15	Missing	1	33,3	1	100,0	33,33	NE	2	66,7	1	50,0	0,00	NE
FU Month 18	Missing	1	33,3	1	100,0	33,33	NE	2	66,7	1	50,0	0,00	NE
FU Month 21	Missing	1	33,3	1	100,0	0,00	NE	2	66,7	1	50,0	0,00	NE
FU Month 24	Missing	1	33,3	1	100,0	66,67	NE	1	33,3	1	100,0	0,00	NE
Screening	< 3.5 ug/mL	154	100,0	144	93,5	32,87	31,78	140	100,0	132	94,3	29,04	32,54
Cycle 4 Day 1	< 3.5 ug/mL	127	82,5	116	91,3	24,14	29,35	129	92,1	110	85,3	24,55	28,80

FU Day 28	< 3.5 ug/mL	137	89,0	119	86,9	24,93	28,53	132	94,3	121	91,7	24,24	26,87
FU Month 3	< 3.5 ug/mL	134	87,0	123	91,8	25,47	28,66	130	92,9	115	88,5	26,67	30,97
FU Month 6	< 3.5 ug/mL	128	83,1	114	89,1	23,98	27,52	120	85,7	110	91,7	23,64	30,74
FU Month 9	< 3.5 ug/mL	104	67,5	87	83,7	22,22	27,22	98	70,0	81	82,7	27,57	31,53
FU Month 12	< 3.5 ug/mL	78	50,6	69	88,5	23,19	25,76	75	53,6	66	88,0	28,79	30,32
FU Month 15	< 3.5 ug/mL	65	42,2	56	86,2	20,24	26,73	60	42,9	49	81,7	25,85	29,86
FU Month 18	< 3.5 ug/mL	46	29,9	41	89,1	22,76	29,29	43	30,7	35	81,4	22,86	33,11
FU Month 21	< 3.5 ug/mL	30	19,5	21	70,0	30,16	29,64	27	19,3	22	81,5	30,30	32,38
FU Month 24	< 3.5 ug/mL	19	12,3	15	78,9	24,44	26,63	12	8,6	11	91,7	15,15	17,41
FU Month 27	< 3.5 ug/mL	10	6,5	8	80,0	29,17	27,82	7	5,0	5	71,4	20,00	18,26
FU Month 30	< 3.5 ug/mL	5	3,2	3	60,0	22,22	38,49	1	0,7	1	100,0	0,00	NE
Screening	>= 3.5 ug/mL	98	100,0	94	95,9	25,89	29,80	99	100,0	93	93,9	20,07	27,43
Cycle 4 Day 1	>= 3.5 ug/mL	83	84,7	76	91,6	20,18	29,35	92	92,9	84	91,3	22,62	27,94
FU Day 28	>= 3.5 ug/mL	90	91,8	77	85,6	23,81	31,93	90	90,9	80	88,9	17,92	24,27
FU Month 3	>= 3.5 ug/mL	88	89,8	77	87,5	24,24	28,43	88	88,9	78	88,6	18,38	22,57
FU Month 6	>= 3.5 ug/mL	76	77,6	68	89,5	26,96	33,21	69	69,7	57	82,6	19,30	28,13
FU Month 9	>= 3.5 ug/mL	58	59,2	50	86,2	21,33	30,68	48	48,5	38	79,2	15,79	22,91
FU Month 12	>= 3.5 ug/mL	46	46,9	39	84,8	19,66	30,32	40	40,4	31	77,5	17,20	25,63
FU Month 15	>= 3.5 ug/mL	38	38,8	32	84,2	19,79	23,74	23	23,2	17	73,9	13,73	29,01
FU Month 18	>= 3.5 ug/mL	32	32,7	28	87,5	16,67	26,45	15	15,2	13	86,7	10,26	21,01
FU Month 21	>= 3.5 ug/mL	21	21,4	18	85,7	16,67	23,57	11	11,1	9	81,8	22,22	28,87
FU Month 24	>= 3.5 ug/mL	12	12,2	9	75,0	11,11	16,67	5	5,1	5	100,0	13,33	18,26
FU Month 27	>= 3.5 ug/mL	3	3,1	3	100,0	11,11	19,25	2	2,0	2	100,0	0,00	0,00
FU Month 30	>= 3.5 ug/mL	2	2,0	2	100,0	0,00	0,00	0	NE	0	NE	NE	NE
Immunoglobulin VH, cytogenetics 2													
Screening	12	45	100,0	43	95,6	31,01	34,42	44	100,0	43	97,7	27,13	31,08
Cycle 4 Day 1	12	34	75,6	32	94,1	17,71	28,06	38	86,4	33	86,8	21,21	24,75
FU Day 28	12	39	86,7	36	92,3	25,00	29,14	40	90,9	35	87,5	23,81	26,29
FU Month 3	12	38	84,4	36	94,7	25,93	24,05	39	88,6	32	82,1	26,04	30,21
FU Month 6	12	36	80,0	31	86,1	19,35	22,40	34	77,3	28	82,4	29,76	36,67
FU Month 9	12	26	57,8	22	84,6	16,67	19,92	28	63,6	18	64,3	31,48	37,00
FU Month 12	12	22	48,9	18	81,8	24,07	27,55	23	52,3	15	65,2	22,22	27,22
FU Month 15	12	17	37,8	14	82,4	14,29	21,54	17	38,6	12	70,6	22,22	32,82
FU Month 18	12	15	33,3	12	80,0	16,67	26,59	13	29,5	9	69,2	3,70	11,11
FU Month 21	12	10	22,2	8	80,0	25,00	29,55	7	15,9	5	71,4	13,33	29,81
FU Month 24	12	8	17,8	6	75,0	22,22	34,43	6	13,6	6	100,0	11,11	17,21
FU Month 27	12	5	11,1	4	80,0	25,00	31,91	2	4,5	2	100,0	16,67	23,57
FU Month 30	12	4	8,9	2	50,0	0,00	0,00	1	2,3	1	100,0	0,00	NE

Screening	11q-	46	100,0	43	93,5	28,68	26,81	43	100,0	40	93,0	21,67	28,79
Cycle 4 Day 1	11q-	40	87,0	39	97,5	23,08	28,77	41	95,3	35	85,4	24,76	26,00
FU Day 28	11q-	42	91,3	35	83,3	18,10	27,23	39	90,7	36	92,3	22,22	26,43
FU Month 3	11q-	42	91,3	38	90,5	21,93	26,02	38	88,4	35	92,1	20,95	25,67
FU Month 6	11q-	38	82,6	35	92,1	27,62	28,57	32	74,4	28	87,5	23,81	28,48
FU Month 9	11q-	28	60,9	26	92,9	28,21	33,59	25	58,1	21	84,0	22,22	26,53
FU Month 12	11q-	20	43,5	19	95,0	36,84	33,14	18	41,9	17	94,4	31,37	27,56
FU Month 15	11q-	18	39,1	16	88,9	22,92	31,55	14	32,6	10	71,4	33,33	31,43
FU Month 18	11q-	15	32,6	13	86,7	23,08	28,50	8	18,6	7	87,5	23,81	41,79
FU Month 21	11q-	12	26,1	11	91,7	24,24	30,15	4	9,3	2	50,0	33,33	47,14
FU Month 24	11q-	7	15,2	5	71,4	26,67	27,89	1	2,3	1	100,0	33,33	
FU Month 27	11q-	3	6,5	3	100,0	22,22	38,49	0	NE	0	NE	NE	NE
FU Month 30	11q-	3	6,5	3	100,0	22,22	38,49	0	NE	0	NE	NE	NE
Screening	13q-	79	100,0	76	96,2	32,89	34,64	75	100,0	70	93,3	24,76	29,86
Cycle 4 Day 1	13q-	67	84,8	60	89,6	23,89	31,35	68	90,7	59	86,8	23,16	29,85
FU Day 28	13q-	72	91,1	64	88,9	28,13	33,71	72	96,0	65	90,3	18,46	25,02
FU Month 3	13q-	73	92,4	67	91,8	29,85	33,90	69	92,0	61	88,4	24,59	28,48
FU Month 6	13q-	67	84,8	61	91,0	27,32	34,70	63	84,0	55	87,3	16,36	27,12
FU Month 9	13q-	56	70,9	49	87,5	22,45	32,19	52	69,3	42	80,8	19,84	29,50
FU Month 12	13q-	44	55,7	39	88,6	15,38	25,18	40	53,3	37	92,5	23,42	30,29
FU Month 15	13q-	38	48,1	32	84,2	20,83	26,44	29	38,7	23	79,3	18,84	28,12
FU Month 18	13q-	28	35,4	25	89,3	20,00	31,91	21	28,0	19	90,5	24,56	29,06
FU Month 21	13q-	16	20,3	13	81,3	23,08	31,58	16	21,3	14	87,5	23,81	24,21
FU Month 24	13q-	7	8,9	6	85,7	22,22	27,22	7	9,3	6	85,7	16,67	18,26
FU Month 27	13q-	2	2,5	1	50,0	33,33	NE	6	8,0	4	66,7	16,67	19,25
Screening	Norm. K.	65	100,0	61	93,8	31,69	28,82	58	100,0	55	94,8	28,48	32,97
Cycle 4 Day 1	Norm. K.	54	83,1	48	88,9	25,69	30,16	55	94,8	49	89,1	23,81	29,66
FU Day 28	Norm. K.	59	90,8	50	84,7	25,33	27,40	53	91,4	50	94,3	23,33	26,30
FU Month 3	Norm. K.	54	83,1	48	88,9	23,61	27,47	54	93,1	48	88,9	21,53	27,92
FU Month 6	Norm. K.	49	75,4	46	93,9	27,54	29,23	45	77,6	40	88,9	21,67	27,79
FU Month 9	Norm. K.	39	60,0	31	79,5	19,35	25,49	30	51,7	27	90,0	27,16	26,21
FU Month 12	Norm. K.	32	49,2	27	84,4	19,75	24,91	24	41,4	20	83,3	25,00	30,35
FU Month 15	Norm. K.	26	40,0	23	88,5	23,19	23,43	20	34,5	18	90,0	22,22	30,25
FU Month 18	Norm. K.	18	27,7	17	94,4	25,49	25,08	15	25,9	12	80,0	22,22	35,77
FU Month 21	Norm. K.	12	18,5	6	50,0	27,78	13,61	11	19,0	9	81,8	44,44	37,27
FU Month 24	Norm. K.	8	12,3	6	75,0	22,22	17,21	4	6,9	4	100,0	8,33	16,67
FU Month 27	Norm. K.	3	4,6	3	100,0	22,22	19,25	1	1,7	1	100,0	0,00	NE
Screening	Other Abn.	20	100,0	18	90,0	16,67	20,61	22	100,0	20	90,9	25,00	32,22

Cycle 4 Day 1	Other Abn.	18	90,0	16	88,9	18,75	24,25	22	100,0	20	90,9	25,00	32,22
FU Day 28	Other Abn.	18	90,0	14	77,8	23,81	27,51	21	95,5	17	81,0	21,57	28,73
FU Month 3	Other Abn.	18	90,0	14	77,8	19,05	21,54	21	95,5	19	90,5	22,81	29,51
FU Month 6	Other Abn.	17	85,0	12	70,6	13,89	22,29	18	81,8	18	100,0	25,93	31,43
FU Month 9	Other Abn.	15	75,0	10	66,7	20,00	17,21	14	63,6	13	92,9	23,08	31,58
FU Month 12	Other Abn.	7	35,0	6	85,7	22,22	17,21	12	54,5	9	75,0	22,22	33,33
FU Month 15	Other Abn.	5	25,0	4	80,0	8,33	16,67	5	22,7	4	80,0	16,67	33,33
FU Month 18	Other Abn.	3	15,0	3	100,0	0,00	0,00	3	13,6	2	66,7	0,00	0,00
FU Month 21	Other Abn.	2	10,0	2	100,0	0,00	0,00	2	9,1	2	100,0	0,00	0,00
FU Month 24	Other Abn.	2	10,0	2	100,0	0,00	0,00	0	NE	0	NE	NE	NE
Time from first diagnosis													
Screening	Missing	1	100,0	1	100,0	66,67	NE	0	NE	0	NE	NE	NE
Cycle 4 Day 1	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Day 28	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 3	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 6	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 9	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 12	Missing	1	100,0	1	100,0	33,33	NE	0	NE	0	NE	NE	NE
FU Month 15	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 18	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
Screening	13 - 24 months	41	100,0	39	95,1	33,33	33,33	31	100,0	31	100,0	24,73	29,77
Cycle 4 Day 1	13 - 24 months	35	85,4	34	97,1	24,51	31,04	30	96,8	27	90,0	20,99	27,96
FU Day 28	13 - 24 months	38	92,7	32	84,2	34,38	36,40	30	96,8	27	90,0	17,28	25,10
FU Month 3	13 - 24 months	36	87,8	34	94,4	33,33	31,78	30	96,8	26	86,7	25,64	30,27
FU Month 6	13 - 24 months	36	87,8	32	88,9	31,25	35,86	30	96,8	25	83,3	17,33	27,42
FU Month 9	13 - 24 months	32	78,0	29	90,6	24,14	31,99	21	67,7	18	85,7	24,07	33,93
FU Month 12	13 - 24 months	21	51,2	18	85,7	29,63	32,11	16	51,6	14	87,5	14,29	21,54
FU Month 15	13 - 24 months	19	46,3	18	94,7	25,93	26,95	16	51,6	10	62,5	10,00	22,50
FU Month 18	13 - 24 months	14	34,1	13	92,9	38,46	35,61	10	32,3	8	80,0	0,00	0,00
FU Month 21	13 - 24 months	11	26,8	9	81,8	40,74	32,39	6	19,4	4	66,7	0,00	0,00
FU Month 24	13 - 24 months	8	19,5	5	62,5	53,33	18,26	3	9,7	3	100,0	11,11	19,25
FU Month 27	13 - 24 months	5	12,2	5	100,0	40,00	27,89	2	6,5	2	100,0	0,00	0,00
FU Month 30	13 - 24 months	3	7,3	2	66,7	33,33	47,14	1	3,2	1	100,0	0,00	NE
Screening	<= 12 months	60	100,0	58	96,7	29,31	28,67	70	100,0	69	98,6	22,22	28,96
Cycle 4 Day 1	<= 12 months	48	80,0	42	87,5	26,98	30,57	60	85,7	55	91,7	24,24	29,01
FU Day 28	<= 12 months	54	90,0	45	83,3	23,70	27,18	62	88,6	57	91,9	23,98	24,20
FU Month 3	<= 12 months	53	88,3	45	84,9	25,93	25,51	59	84,3	55	93,2	18,79	22,92
FU Month 6	<= 12 months	46	76,7	40	87,0	22,50	25,47	47	67,1	43	91,5	27,13	33,54

FU Month 9	<= 12 months	35	58,3	27	77,1	23,46	27,45	37	52,9	31	83,8	17,20	22,56
FU Month 12	<= 12 months	27	45,0	23	85,2	20,29	24,08	29	41,4	27	93,1	24,69	28,63
FU Month 15	<= 12 months	22	36,7	17	77,3	15,69	23,91	17	24,3	16	94,1	18,75	29,74
FU Month 18	<= 12 months	16	26,7	13	81,3	12,82	16,88	13	18,6	12	92,3	22,22	29,59
FU Month 21	<= 12 months	9	15,0	5	55,6	20,00	18,26	7	10,0	6	85,7	22,22	27,22
FU Month 24	<= 12 months	6	10,0	3	50,0	11,11	19,25	2	2,9	1	50,0	0,00	NE
FU Month 27	<= 12 months	1	1,7			NE	NE	1	1,4			NE	NE
FU Month 30	<= 12 months	1	1,7			NE	NE	0	NE			NE	NE
Screening	>24 months	153	100,0	143	93,5	29,60	31,43	141	100,0	128	90,8	27,60	31,89
Cycle 4 Day 1	>24 months	129	84,3	118	91,5	20,90	28,51	134	95,0	114	85,1	23,68	28,30
FU Day 28	>24 months	137	89,5	121	88,3	22,87	28,56	133	94,3	119	89,5	21,29	27,01
FU Month 3	>24 months	135	88,2	123	91,1	23,31	28,61	132	93,6	114	86,4	24,85	29,69
FU Month 6	>24 months	124	81,0	112	90,3	24,70	29,25	115	81,6	101	87,8	21,12	28,57
FU Month 9	>24 months	96	62,7	81	84,4	20,58	27,67	91	64,5	72	79,1	26,85	30,97
FU Month 12	>24 months	76	49,7	67	88,2	20,40	27,19	72	51,1	57	79,2	27,49	30,94
FU Month 15	>24 months	62	40,5	53	85,5	20,13	25,60	52	36,9	41	78,8	26,83	30,93
FU Month 18	>24 months	48	31,4	43	89,6	17,83	26,58	37	26,2	29	78,4	22,99	33,46
FU Month 21	>24 months	32	20,9	26	81,3	17,95	25,35	27	19,1	22	81,5	33,33	32,53
FU Month 24	>24 months	18	11,8	17	94,4	13,73	20,61	13	9,2	13	100,0	15,38	17,30
FU Month 27	>24 months	7	4,6	6	85,7	11,11	17,21	6	4,3	5	83,3	20,00	18,26
FU Month 30	>24 months	3	2,0	3	100,0	0,00	0,00	0	NE	0	NE	NE	NE
High circulating tumor burden													
Screening	Missing	0	NE	0	NE	NE	NE	2	100,0	1	50,0	0,00	NE
Cycle 4 Day 1	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	0,00	NE
FU Day 28	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	33,33	NE
FU Month 3	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	33,33	NE
FU Month 6	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	0,00	NE
FU Month 9	Missing	0	NE			NE	NE	1	50,0			NE	NE
Screening	<25x10**9 cells/L	60	100,0	55	91,7	29,09	30,13	67	100,0	64	95,5	26,56	34,21
Cycle 4 Day 1	<25x10**9 cells/L	50	83,3	44	88,0	26,52	29,27	61	91,0	52	85,2	26,28	30,49
FU Day 28	<25x10**9 cells/L	56	93,3	46	82,1	21,74	25,55	61	91,0	53	86,9	22,64	28,32
FU Month 3	<25x10**9 cells/L	54	90,0	47	87,0	28,37	32,58	59	88,1	50	84,7	22,67	28,92
FU Month 6	<25x10**9 cells/L	50	83,3	43	86,0	30,23	30,70	51	76,1	42	82,4	21,43	31,94
FU Month 9	<25x10**9 cells/L	36	60,0	27	75,0	30,86	36,89	41	61,2	30	73,2	20,00	29,81
FU Month 12	<25x10**9 cells/L	29	48,3	24	82,8	26,39	24,04	34	50,7	25	73,5	21,33	28,67
FU Month 15	<25x10**9 cells/L	24	40,0	19	79,2	19,30	27,92	23	34,3	15	65,2	13,33	21,08
FU Month 18	<25x10**9 cells/L	20	33,3	18	90,0	20,37	25,92	19	28,4	14	73,7	16,67	33,97
FU Month 21	<25x10**9 cells/L	14	23,3	10	71,4	26,67	26,29	10	14,9	8	80,0	16,67	25,20

FU Month 24	<25x10**9 cells/L	8	13,3	5	62,5	26,67	36,51	6	9,0	6	100,0	11,11	17,21
FU Month 27	<25x10**9 cells/L	4	6,7	3	75,0	33,33	33,33	1	1,5	1	100,0	0,00	NE
FU Month 30	<25x10**9 cells/L	4	6,7	2	50,0	33,33	47,14	1	1,5	1	100,0	0,00	NE
Screening	>=25x10**9 cells/L	195	100,0	186	95,4	30,65	31,36	173	100,0	163	94,2	25,36	29,36
Cycle 4 Day 1	>=25x10**9 cells/L	163	83,6	151	92,6	21,63	29,36	162	93,6	143	88,3	22,61	27,58
FU Day 28	>=25x10**9 cells/L	174	89,2	153	87,9	25,71	30,94	163	94,2	149	91,4	21,03	25,22
FU Month 3	>=25x10**9 cells/L	171	87,7	156	91,2	24,57	27,33	161	93,1	144	89,4	23,38	27,90
FU Month 6	>=25x10**9 cells/L	157	80,5	142	90,4	23,71	29,33	140	80,9	126	90,0	22,49	29,16
FU Month 9	>=25x10**9 cells/L	128	65,6	111	86,7	19,52	25,61	107	61,8	91	85,0	25,27	29,54
FU Month 12	>=25x10**9 cells/L	96	49,2	85	88,5	20,78	28,16	83	48,0	73	88,0	26,03	29,53
FU Month 15	>=25x10**9 cells/L	80	41,0	70	87,5	20,48	24,93	62	35,8	52	83,9	25,00	31,57
FU Month 18	>=25x10**9 cells/L	59	30,3	52	88,1	20,51	28,89	41	23,7	35	85,4	20,00	29,37
FU Month 21	>=25x10**9 cells/L	38	19,5	30	78,9	22,22	28,14	30	17,3	24	80,0	30,56	32,48
FU Month 24	>=25x10**9 cells/L	24	12,3	20	83,3	20,00	22,69	12	6,9	11	91,7	15,15	17,41
FU Month 27	>=25x10**9 cells/L	9	4,6	8	88,9	20,83	24,80	8	4,6	6	75,0	16,67	18,26
FU Month 30	>=25x10**9 cells/L	3	1,5	3	100,0	0,00	0,00	0	NE	0	NE	NE	NE

¹ in study: number of subjects in study at respective visit; % based on baseline

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit

² mean: descriptive statistics - absolute values Clinical

cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/t_pro_mean.sas

Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/t_pro_mean_sg_EQC30_IT_label_09MAY2013_21004.xls 04MAR2020

17:18

15 (Anhang): Ergebnisse für EORTCQLQ-C30 – Funktionsskalen Mittelwerte pro Visite - Subgruppenanalysen aus RCT mit dem zu bewertenden Arzneimittel

MODEL: Unadjusted Analysis STUDY: CLL11(BO21004), Stage
 POPULATION: Labelpopulation, Intent-to-Treat Patients ENDPOINT: EORTC QoL 30

Compliance/Mean

Global Health Status Scale

		GClb (N=255)						RC1b (N=242)					
		Patients			Statistics			Patients			Statistics		
Name	Level	in study ¹	%	with value ¹	%	Mean ²	SD(mean)	in study ¹	%	with value ¹	%	Mean ²	SD(mean)
All													
Screening	n/a	255	100,0	240	94,1	59,65	24,00	242	100,0	227	93,8	58,55	23,36
Cycle 4 Day 1	n/a	213	83,5	193	90,6	67,53	20,46	224	92,6	195	87,1	65,21	20,67
FU Day 28	n/a	230	90,2	200	87,0	68,96	22,01	225	93,0	198	88,0	66,67	21,37
FU Month 3	n/a	225	88,2	201	89,3	69,28	21,45	221	91,3	193	87,3	66,75	20,76
FU Month 6	n/a	207	81,2	188	90,8	69,81	19,58	192	79,3	167	87,0	65,72	21,15
FU Month 9	n/a	164	64,3	137	83,5	68,49	21,43	149	61,6	119	79,9	67,02	18,71
FU Month 12	n/a	125	49,0	109	87,2	69,72	21,63	117	48,3	99	84,6	66,16	20,23
FU Month 15	n/a	104	40,8	91	87,5	69,51	19,65	85	35,1	68	80,0	63,24	20,78
FU Month 18	n/a		79,31,0	69	87,3	70,29	22,44	60	24,8	49	81,7	63,10	19,39
FU Month 21	n/a		52,20,4	40	76,9	71,46	19,87	40	16,5	32	80,0	61,98	22,69
FU Month 24	n/a		32,12,5	25	78,1	64,67	25,26	18	7,4	16	88,9	72,92	16,24
FU Month 27	n/a		13,5,1	11	84,6	68,18	18,94	9	3,7	7	77,8	66,67	23,07
FU Month 30	n/a		7,2,7	6	85,7	55,56	16,39	1	0,4	1	100,0	58,33	NE
Gender													
Screening	Female	97	100,0	90	92,8	56,94	23,31	95	100,0	87	91,6	53,93	22,51
Cycle 4 Day 1	Female	84	86,6	75	89,3	63,78	21,02	88	92,6	78	88,6	62,07	21,97
FU Day 28	Female	90	92,8	83	92,2	66,27	20,90	91	95,8	77	84,6	63,20	23,31
FU Month 3	Female	88	90,7	79	89,8	66,46	19,66	87	91,6	76	87,4	62,61	20,88
FU Month 6	Female	84	86,6	72	85,7	68,52	16,02	77	81,1	68	88,3	64,46	20,80
FU Month 9	Female	70	72,2	59	84,3	63,14	20,60	61	64,2	46	75,4	65,94	18,33
FU Month 12	Female	56	57,7	49	87,5	66,67	19,25	47	49,5	40	85,1	66,04	20,18
FU Month 15	Female	47	48,5	41	87,2	63,62	16,64	33	34,7	27	81,8	61,73	18,95
FU Month 18	Female	34	35,1	29	85,3	62,36	20,49	26	27,4	22	84,6	60,61	20,92
FU Month 21	Female	21	21,6	15	71,4	61,67	21,55	17	17,9	15	88,2	58,89	24,89
FU Month 24	Female	12	12,4	10	83,3	55,83	21,89	6	6,3	5	83,3	75,00	11,79
FU Month 27	Female	6	6,2	5	83,3	65,00	19,90	2	2,1	1	50,0	41,67	NE
FU Month 30	Female	4	4,1	3	75,0	52,78	20,97	1	1,1	1	100,0	58,33	NE

Screening	Male	158	100,0	150	94,9	61,28	24,33	147	100,0	140	95,2	61,43	23,49
Cycle 4 Day 1	Male	129	81,6	118	91,5	69,92	19,82	136	92,5	117	86,0	67,31	19,58
FU Day 28	Male	140	88,6	117	83,6	70,87	22,65	134	91,2	121	90,3	68,87	19,83
FU Month 3	Male	137	86,7	122	89,1	71,11	22,43	134	91,2	117	87,3	69,44	20,32
FU Month 6	Male	123	77,8	116	94,3	70,62	21,52	115	78,2	99	86,1	66,58	21,44
FU Month 9	Male	94	59,5	78	83,0	72,54	21,28	88	59,9	73	83,0	67,69	19,04
FU Month 12	Male	69	43,7	60	87,0	72,22	23,25	70	47,6	59	84,3	66,24	20,44
FU Month 15	Male	57	36,1	50	87,7	74,33	20,75	52	35,4	41	78,8	64,23	22,07
FU Month 18	Male	45	28,5	40	88,9	76,04	22,26	34	23,1	27	79,4	65,12	18,20
FU Month 21	Male	31	19,6	25	80,6	77,33	16,58	23	15,6	17	73,9	64,71	20,94
FU Month 24	Male	20	12,7	15	75,0	70,56	26,33	12	8,2	11	91,7	71,97	18,36
FU Month 27	Male	7	4,4	6	85,7	70,83	19,54	7	4,8	6	85,7	70,83	22,20
FU Month 30	Male	3	1,9	3	100,0	58,33	14,43	0	NE	0	NE	NE	NE
Age													
Screening	<75 years	130	100,0	123	94,6	60,91	23,55	120	100,0	109	90,8	59,25	23,06
Cycle 4 Day 1	<75 years	106	81,5	98	92,5	68,88	20,04	112	93,3	98	87,5	65,65	20,56
FU Day 28	<75 years	119	91,5	105	88,2	70,08	22,07	110	91,7	102	92,7	66,91	21,76
FU Month 3	<75 years	116	89,2	106	91,4	72,17	20,34	109	90,8	97	89,0	67,61	20,65
FU Month 6	<75 years	108	83,1	98	90,7	72,19	19,95	99	82,5	88	88,9	64,77	21,21
FU Month 9	<75 years	85	65,4	72	84,7	68,98	21,77	74	61,7	62	83,8	68,28	18,35
FU Month 12	<75 years	63	48,5	59	93,7	73,59	19,89	60	50,0	53	88,3	65,88	20,95
FU Month 15	<75 years	54	41,5	47	87,0	72,70	18,85	44	36,7	35	79,5	64,52	22,17
FU Month 18	<75 years	43	33,1	39	90,7	72,86	24,01	27	22,5	22	81,5	66,29	20,49
FU Month 21	<75 years	26	20,0	22	84,6	69,32	22,62	17	14,2	13	76,5	67,31	23,19
FU Month 24	<75 years	18	13,8	14	77,8	60,71	29,86	6	5,0	5	83,3	86,67	9,50
FU Month 27	<75 years	7	5,4	5	71,4	63,33	27,39	2	1,7	1	50,0	100,00	NE
FU Month 30	<75 years	4	3,1	3	75,0	47,22	17,35	0	NE	0	NE	NE	NE
Screening	>=75 years	125	100,0	117	93,6	58,33	24,49	122	100,0	118	96,7	57,91	23,72
Cycle 4 Day 1	>=75 years	107	85,6	95	88,8	66,14	20,91	112	91,8	97	86,6	64,78	20,89
FU Day 28	>=75 years	111	88,8	95	85,6	67,72	21,99	115	94,3	96	83,5	66,41	21,06
FU Month 3	>=75 years	109	87,2	95	87,2	66,05	22,29	112	91,8	96	85,7	65,89	20,95
FU Month 6	>=75 years	99	79,2	90	90,9	67,22	18,94	93	76,2	79	84,9	66,77	21,16
FU Month 9	>=75 years	79	63,2	65	82,3	67,95	21,21	75	61,5	57	76,0	65,64	19,16
FU Month 12	>=75 years	62	49,6	50	80,6	65,17	22,88	57	46,7	46	80,7	66,49	19,60
FU Month 15	>=75 years	50	40,0	44	88,0	66,10	20,13	41	33,6	33	80,5	61,87	19,44
FU Month 18	>=75 years	36	28,8	30	83,3	66,94	20,12	33	27,0	27	81,8	60,49	18,43
FU Month 21	>=75 years	26	20,8	18	69,2	74,07	16,14	23	18,9	19	82,6	58,33	22,22
FU Month 24	>=75 years	14	11,2	11	78,6	69,70	17,98	12	9,8	11	91,7	66,67	14,91

FU Month 27	>=75 years	64,8	6100,0	72,22	8,61	75,7	685,7	61,11	19,48				
FU Month 30	>=75 years	32,4	3100,0	63,89	12,73	10,8	1100,0	58,33					NE
Race													
Screening	Other	9100,0	9100,0	54,63	27,99	11100,0	11100,0	57,58	21,56				
Cycle 4 Day 1	Other	777,8	7100,0	63,10	28,00	1090,9	880,0	66,67	29,88				
FU Day 28	Other	888,9	8100,0	69,79	25,95	1090,9	10100,0	76,67	13,49				
FU Month 3	Other	888,9	787,5	70,24	17,91	1090,9	10100,0	68,33	22,15				
FU Month 6	Other	888,9	787,5	73,81	20,65	872,7	8100,0	70,83	17,82				
FU Month 9	Other	444,4	375,0	75,00	14,43	545,5	480,0	75,00	18,00				
FU Month 12	Other	333,3	266,7	87,50	5,89	436,4	4100,0	68,75	17,18				
FU Month 15	Other	222,2	150,0	100,00		436,4	4100,0	75,00	9,62				
FU Month 18	Other	222,2	150,0	91,67		218,2	2100,0	66,67	23,57				
FU Month 21	Other	222,2	150,0	91,67		218,2	2100,0	58,33	11,79				
FU Month 24	Other	222,2	150,0	83,33		19,1	0			NE	NE	NE	NE
FU Month 27	Other	111,1			NE	19,1					NE		NE
FU Month 30	Other	111,1			NE	0	NE				NE		NE
Geographical Region													
Screening	Asia-Pacific	20100,0	20100,0	56,25	21,78	18100,0	1794,4	53,92	25,87				
Cycle 4 Day 1	Asia-Pacific	1575,0	15100,0	68,89	17,95	1688,9	1593,8	66,67	26,73				
FU Day 28	Asia-Pacific	1890,0	18100,0	69,91	22,53	18100,0	1688,9	69,27	20,12				
FU Month 3	Asia-Pacific	1890,0	1688,9	71,88	24,51	18100,0	1688,9	60,94	20,35				
FU Month 6	Asia-Pacific	1680,0	1487,5	64,88	26,39	1794,4	1588,2	62,78	23,12				
FU Month 9	Asia-Pacific	1470,0	1285,7	70,83	20,57	1372,2	969,2	63,89	21,65				
FU Month 12	Asia-Pacific	1050,0	880,0	78,13	14,04	1055,6	10100,0	60,00	22,50				
FU Month 15	Asia-Pacific	840,0	675,0	87,50	14,67	950,0	9100,0	58,33	20,83				

FU Month 18	Asia-Pacific	630,0	466,7	87,50	4,81	633,3	6100,0	56,94	17,01
FU Month 21	Asia-Pacific	525,0	360,0	88,89	4,81	422,2	4100,0	45,83	20,97
FU Month 24	Asia-Pacific	315,0	266,7	87,50	5,89	15,6	0	NE	NE
FU Month 27	Asia-Pacific	15,0		NE	NE	15,6		NE	NE
FU Month 30	Asia-Pacific	15,0		NE	NE	0	NE	NE	NE
Screening	Central and South America	3100,0	3100,0	77,78	9,62	2100,0	2100,0	54,17	5,89
Cycle 4 Day 1	Central and South America	3100,0	3100,0	83,33	8,33	2100,0	2100,0	87,50	17,68
FU Day 28	Central and South America	3100,0	3100,0	80,56	12,73	2100,0	2100,0	95,83	5,89
FU Month 3	Central and South America	3100,0	3100,0	77,78	9,62	2100,0	2100,0	95,83	5,89
FU Month 6	Central and South America	266,7	2100,0	87,50	5,89	2100,0	2100,0	95,83	5,89
FU Month 9	Central and South America	266,7	2100,0	83,33	23,57	150,0	1100,0	100,00	NE
FU Month 12	Central and South America	266,7	2100,0	87,50	5,89	150,0	1100,0	83,33	NE
FU Month 15	Central and South America	133,3	1100,0	75,00	NE	0	NE	NE	NE
FU Month 18	Central and South America	133,3	1100,0	91,67	NE	0	NE	NE	NE
FU Month 21	Central and South America	133,3	1100,0	83,33	NE	0	NE	NE	NE
FU Month 24	Central and South America	133,3	1100,0	91,67	NE	0	NE	NE	NE
Screening	North America	12100,0	12100,0	58,33	27,75	13100,0	1292,3	56,94	30,53
Cycle 4 Day 1	North America	975,0	9100,0	57,41	14,70	1292,3	1191,7	71,97	18,74
FU Day 28	North America	1191,7	11100,0	67,42	15,57	13100,0	13100,0	71,79	22,70
FU Month 3	North America	1191,7	11100,0	58,33	21,73	1292,3	12100,0	75,69	12,03
FU Month 6	North America	1191,7	1090,9	63,33	21,59	1184,6	11100,0	67,42	17,26
FU Month 9	North America	866,7	8100,0	70,83	29,55	969,2	9100,0	68,52	12,34
FU Month 12	North America	866,7	787,5	55,95	23,92	753,8	7100,0	73,81	15,54
FU Month 15	North America	650,0	6100,0	63,89	16,39	646,2	583,3	58,33	8,33
FU Month 18	North America	433,3	4100,0	70,83	15,96	323,1	3100,0	50,00	16,67
FU Month 21	North America	325,0	266,7	66,67	23,57	17,7	1100,0	66,67	NE
FU Month 24	North America	325,0	266,7	50,00	47,14	17,7	1100,0	41,67	NE
FU Month 27	North America	216,7	150,0	66,67	NE	17,7	1100,0	41,67	NE
Screening	Other	45100,0	4191,1	49,19	21,63	44100,0	4193,2	51,63	21,43
Cycle 4 Day 1	Other	3782,2	3286,5	62,24	18,08	4090,9	3382,5	64,39	22,75
FU Day 28	Other	3782,2	3389,2	67,17	20,19	3988,6	3692,3	62,27	22,23
FU Month 3	Other	3884,4	3489,5	63,73	21,01	3886,4	3489,5	66,67	22,75
FU Month 6	Other	3577,8	3188,6	67,74	17,04	3375,0	3193,9	64,52	23,47
FU Month 9	Other	2657,8	2284,6	66,67	14,09	2454,5	1979,2	66,67	17,35
FU Month 12	Other	1737,8	1694,1	68,23	19,30	1636,4	1487,5	70,24	15,92
FU Month 15	Other	1226,7	1191,7	70,45	17,23	920,5	888,9	67,71	19,64
FU Month 18	Other	1022,2	990,0	68,52	24,22	715,9	685,7	73,61	8,19
FU Month 21	Other	715,6	685,7	70,83	24,58	49,1	4100,0	75,00	9,62

FU Month 24	Other	6	13,3	5	83,3	63,33	26,74	3	6,8	3	100,0	72,22	19,25
FU Month 27	Other	4	8,9	4	100,0	66,67	22,57	1	2,3	1	100,0	66,67	NE
FU Month 30	Other	2	4,4	2	100,0	54,17	29,46	0	NE	0	NE	NE	NE
Screening	Western Europe	175	100,0	164	93,7	62,45	24,04	165	100,0	155	93,9	61,08	22,87
Cycle 4 Day 1	Western Europe	149	85,1	134	89,9	68,97	21,42	154	93,3	134	87,0	64,37	19,56
FU Day 28	Western Europe	161	92,0	135	83,9	69,14	23,08	153	92,7	131	85,6	66,60	21,04
FU Month 3	Western Europe	155	88,6	137	88,4	71,05	21,08	151	91,5	129	85,4	66,21	20,66
FU Month 6	Western Europe	143	81,7	131	91,6	71,06	19,21	129	78,2	108	83,7	65,74	20,55
FU Month 9	Western Europe	114	65,1	93	81,6	68,10	22,44	102	61,8	81	79,4	66,87	19,27
FU Month 12	Western Europe	88	50,3	76	86,4	69,96	22,36	83	50,3	67	80,7	65,17	21,12
FU Month 15	Western Europe	77	44,0	67	87,0	68,16	20,25	61	37,0	46	75,4	63,95	22,09
FU Month 18	Western Europe	58	33,1	51	87,9	68,79	23,20	44	26,7	34	77,3	63,48	20,82
FU Month 21	Western Europe	36	20,6	28	77,8	69,64	19,80	31	18,8	23	74,2	62,32	23,95
FU Month 24	Western Europe	19	10,9	15	78,9	62,22	23,75	13	7,9	12	92,3	75,69	13,97
FU Month 27	Western Europe	6	3,4	6	100,0	69,44	20,18	6	3,6	5	83,3	71,67	24,72
FU Month 30	Western Europe	4	2,3	4	100,0	56,25	12,50	1	0,6	1	100,0	58,33	NE
FCgamma receptor IIa													
Screening	131HH	58	100,0	53	91,4	55,82	19,65	76	100,0	72	94,7	56,37	23,47
Cycle 4 Day 1	131HH	49	84,5	43	87,8	62,21	19,53	65	85,5	58	89,2	68,53	17,87
FU Day 28	131HH	51	87,9	46	90,2	67,93	20,93	70	92,1	59	84,3	70,34	21,29
FU Month 3	131HH	51	87,9	46	90,2	62,50	18,98	64	84,2	53	82,8	67,61	23,38
FU Month 6	131HH	49	84,5	45	91,8	64,81	18,37	55	72,4	47	85,5	62,23	20,91
FU Month 9	131HH	39	67,2	30	76,9	63,33	18,13	41	53,9	32	78,0	70,31	17,70
FU Month 12	131HH	28	48,3	24	85,7	67,01	21,49	34	44,7	29	85,3	67,24	22,15
FU Month 15	131HH	23	39,7	19	82,6	71,49	21,21	24	31,6	20	83,3	66,25	19,40
FU Month 18	131HH	17	29,3	14	82,4	70,83	17,83	16	21,1	13	81,3	66,03	19,08
FU Month 21	131HH	13	22,4	8	61,5	69,79	17,78	11	14,5	10	90,9	42,50	26,19
FU Month 24	131HH	11	19,0	7	63,6	63,10	22,49	1	1,3	1	100,0	83,33	NE
FU Month 27	131HH	4	6,9	3	75,0	69,44	26,79	1	1,3	1	100,0	83,33	NE
FU Month 30	131HH	3	5,2	2	66,7	58,33	11,79	0	NE	0	NE	NE	NE
Screening	131HR	125	100,0	118	94,4	59,39	24,86	114	100,0	109	95,6	60,40	23,82
Cycle 4 Day 1	131HR	105	84,0	96	91,4	67,19	19,90	110	96,5	99	90,0	64,48	21,61
FU Day 28	131HR	116	92,8	102	87,9	68,95	23,07	105	92,1	94	89,5	65,07	21,80
FU Month 3	131HR	114	91,2	102	89,5	71,90	21,11	107	93,9	94	87,9	66,76	19,61
FU Month 6	131HR	104	83,2	93	89,4	71,15	19,56	95	83,3	83	87,4	66,47	22,20
FU Month 9	131HR	84	67,2	70	83,3	67,74	23,09	76	66,7	60	78,9	64,44	20,06
FU Month 12	131HR	64	51,2	57	89,1	68,57	22,60	57	50,0	48	84,2	65,10	19,72
FU Month 15	131HR	53	42,4	45	84,9	68,70	18,39	44	38,6	34	77,3	62,99	19,91

FU Month 18	131HR	43	34,4	37	86,0	66,22	25,38	32	28,1	26	81,3	61,54	19,30
FU Month 21	131HR	26	20,8	20	76,9	65,42	22,67	21	18,4	16	76,2	67,71	13,90
FU Month 24	131HR	12	9,6	11	91,7	65,15	30,46	12	10,5	10	83,3	69,17	15,74
FU Month 27	131HR		64,8		583,3	61,67	20,07		65,3		466,7	54,17	19,84
FU Month 30	131HR		32,4		3100,0	50,00	22,05		10,9		1100,0	58,33	NE
Screening	131RR	49	100,0	47	95,9	63,30	26,79	33	100,0	29	87,9	63,51	20,34
Cycle 4 Day 1	131RR	40	81,6	37	92,5	74,55	17,23	31	93,9	25	80,6	65,67	19,88
FU Day 28	131RR	42	85,7	35	83,3	67,86	20,02	32	97,0	29	90,6	67,82	18,19
FU Month 3	131RR	39	79,6	36	92,3	71,30	22,13	32	97,0	29	90,6	68,39	19,72
FU Month 6	131RR	35	71,4	33	94,3	69,70	20,92	27	81,8	23	85,2	71,01	20,70
FU Month 9	131RR	24	49,0	22	91,7	71,59	22,22	19	57,6	17	89,5	70,59	17,46
FU Month 12	131RR	18	36,7	17	94,4	75,49	15,16	17	51,5	15	88,2	65,56	19,12
FU Month 15	131RR	16	32,7	16	100,0	69,79	16,35	11	33,3	9	81,8	62,04	24,34
FU Month 18	131RR	14	28,6	14	100,0	76,79	19,39	8	24,2	7	87,5	60,71	25,78
FU Month 21	131RR		816,3		787,5	82,14	8,91		515,2		480,0	81,25	14,23
FU Month 24	131RR		510,2		480,0	58,33	26,35		39,1		3100,0	86,11	12,73
FU Month 27	131RR		24,1		2100,0	75,00	0,00		13,0		1100,0	100,00	NE
FU Month 30	131RR		12,0		1100,0	66,67			0		0	NE	NE
Screening	Missing	23	100,0	22	95,7	62,50	22,53	19	100,0	17	89,5	47,55	22,20
Cycle 4 Day 1	Missing	19	82,6	17	89,5	67,65	28,55	18	94,7	13	72,2	55,13	24,89
FU Day 28	Missing	21	91,3	17	81,0	74,02	23,36	18	94,7	16	88,9	60,42	23,86
FU Month 3	Missing	21	91,3	17	81,0	67,65	25,83	18	94,7	17	94,4	61,27	21,03
FU Month 6	Missing	19	82,6	17	89,5	75,98	18,84	15	78,9	14	93,3	64,29	15,13
FU Month 9	Missing	17	73,9	15	88,2	77,78	15,64	13	68,4	10	76,9	65,83	14,93
FU Month 12	Missing	15	65,2	11	73,3	72,73	25,84		947,4	7	77,8	70,24	21,44
FU Month 15	Missing	12	52,2	11	91,7	68,94	27,66		631,6		583,3	55,00	29,23
FU Month 18	Missing		521,7		480,0	83,33	6,80		421,1		375,0	69,44	4,81
FU Month 21	Missing		521,7		5100,0	83,33	13,18		315,8		266,7	75,00	11,79
FU Month 24	Missing		417,4		375,0	75,00	14,43		210,5		2100,0	66,67	23,57
FU Month 27	Missing		14,3		1100,0	83,33			15,3		1100,0	66,67	NE
FCgamma receptor IIIa													
Screening	158FF	103	100,0	99	96,1	61,11	23,60	83	100,0	78	94,0	59,94	23,61
Cycle 4 Day 1	158FF		8986,4		8191,0	68,11	19,89		7894,0		7089,7	65,95	22,42
FU Day 28	158FF		9693,2		8487,5	68,55	20,87		7894,0		7393,6	68,04	19,15
FU Month 3	158FF		9491,3		8388,3	70,38	22,55		7894,0		6988,5	70,77	19,99
FU Month 6	158FF		8683,5		7688,4	69,74	20,94		6477,1		5992,2	66,95	23,67
FU Month 9	158FF		7168,9		5983,1	71,47	21,95		4756,6		4391,5	66,28	16,96
FU Month 12	158FF		4846,6		4287,5	72,42	21,19		3845,8		3592,1	67,86	17,87

FU Month 15	158FF	37	35,9	32	86,5	69,53	20,59	30	36,1	24	80,0	70,49	20,26
FU Month 18	158FF	27	26,2	24	88,9	69,10	24,14	21	25,3	17	81,0	67,16	22,34
FU Month 21	158FF	16	15,5	15	93,8	62,78	22,24	9	10,8	8	88,9	70,83	25,20
FU Month 24	158FF	8	7,8	7	87,5	61,90	29,60	3	3,6	2	66,7	91,67	11,79
FU Month 27	158FF	5	4,9	4	80,0	72,92	20,83	1	1,2	1	100,0	100,00	NE
FU Month 30	158FF	3	2,9	3	100,0	58,33	14,43	0	NE	0	NE	NE	NE
Screening	158FV	119	100,0	110	92,4	59,02	24,61	109	100,0	103	94,5	58,09	22,97
Cycle 4 Day 1	158FV	99	83,2	89	89,9	68,07	19,75	100	91,7	85	85,0	64,51	19,42
FU Day 28	158FV	105	88,2	91	86,7	68,77	22,35	101	92,7	86	85,1	65,89	21,90
FU Month 3	158FV	101	84,9	92	91,1	69,75	19,83	97	89,0	83	85,6	64,56	21,10
FU Month 6	158FV	94	79,0	87	92,6	68,87	19,29	83	76,1	71	85,5	66,20	20,06
FU Month 9	158FV	71	59,7	60	84,5	64,72	21,88	65	59,6	49	75,4	67,18	18,59
FU Month 12	158FV	60	50,4	55	91,7	66,36	21,03	52	47,7	42	80,8	64,09	22,12
FU Month 15	158FV	52	43,7	46	88,5	70,65	17,28	36	33,0	29	80,6	58,62	18,70
FU Month 18	158FV	44	37,0	38	86,4	71,71	21,97	24	22,0	20	83,3	58,33	18,54
FU Month 21	158FV	28	23,5	18	64,3	76,39	17,68	18	16,5	14	77,8	52,38	24,55
FU Month 24	158FV	18	15,1	13	72,2	66,67	26,13	6	5,5	5	83,3	68,33	13,69
FU Month 27	158FV	6	5,0	5	83,3	65,00	19,90	2	1,8	1	50,0	83,33	NE
FU Month 30	158FV	4	3,4	3	75,0	52,78	20,97	0	NE	0	NE	NE	NE
Screening	158VV	16	100,0	15	93,8	57,22	24,77	33	100,0	31	93,9	60,75	23,59
Cycle 4 Day 1	158VV	12	75,0	11	91,7	71,21	16,40	30	90,9	28	93,3	67,26	19,50
FU Day 28	158VV	14	87,5	13	92,9	71,15	27,56	30	90,9	25	83,3	69,67	23,68
FU Month 3	158VV	15	93,8	12	80,0	67,36	22,04	30	90,9	26	86,7	65,71	21,39
FU Month 6	158VV	14	87,5	13	92,9	75,64	13,38	30	90,9	23	76,7	64,13	20,94
FU Month 9	158VV	12	75,0	10	83,3	65,83	19,82	25	75,8	18	72,0	66,20	23,99
FU Month 12	158VV	8	50,0	7	87,5	71,43	29,21	20	60,6	17	85,0	68,63	20,10
FU Month 15	158VV	8	50,0	7	87,5	65,48	20,65	14	42,4	11	78,6	58,33	22,67
FU Month 18	158VV	4	25,0	4	100,0	54,17	19,84	11	33,3	9	81,8	62,04	16,72
FU Month 21	158VV	3	18,8	2	66,7	62,50	5,89	9	27,3	7	77,8	66,67	13,61
FU Month 24	158VV	2	12,5	2	100,0	45,83	17,68	7	21,2	7	100,0	72,62	16,47
FU Month 27	158VV	1	6,3	1	100,0	50,00	NE	5	15,2	4	80,0	54,17	19,84
FU Month 30	158VV	0	NE	0	NE	NE	NE	1	3,0	1	100,0	58,33	NE
Screening	Missing	17	100,0	16	94,1	57,29	23,15	17	100,0	15	88,2	50,00	24,60
Cycle 4 Day 1	Missing	13	76,5	12	92,3	56,25	30,18	16	94,1	12	75,0	61,11	23,12
FU Day 28	Missing	15	88,2	12	80,0	70,83	23,44	16	94,1	14	87,5	58,93	24,99
FU Month 3	Missing	15	88,2	14	93,3	61,31	25,02	16	94,1	15	93,8	62,22	20,38
FU Month 6	Missing	13	76,5	12	92,3	70,83	19,30	15	88,2	14	93,3	60,71	16,16
FU Month 9	Missing	10	58,8	8	80,0	78,13	8,84	12	70,6	9	75,0	71,30	18,22

FU Month 12	Missing		952,9		555,6	81,67	19,00		741,2		571,4	63,33	24,01
FU Month 15	Missing		741,2		685,7	65,28	32,67		529,4		480,0	66,67	28,05
FU Month 18	Missing		423,5		375,0	83,33	8,33		423,5		375,0	75,00	8,33
FU Month 21	Missing		529,4		5100,0	83,33	13,18		423,5		375,0	72,22	9,62
FU Month 24	Missing		423,5		375,0	75,00	14,43		211,8		2100,0	66,67	23,57
FU Month 27	Missing		15,9		1100,0	83,33		NE	15,9		1100,0	66,67	NE
Binet Staging at baseline													
Screening	A		59100,0		5898,3	59,63	22,66		57100,0		5393,0	56,60	24,91
Cycle 4 Day 1	A		5186,4		4792,2	64,18	21,97		5494,7		4990,7	63,78	21,28
FU Day 28	A		5898,3		5391,4	67,77	23,46		5494,7		5194,4	61,93	20,70
FU Month 3	A		5796,6		5596,5	69,24	23,78		5393,0		5094,3	62,83	19,36
FU Month 6	A		5694,9		5089,3	69,17	19,51		4578,9		4293,3	64,88	20,46
FU Month 9	A		4372,9		3786,0	65,09	22,72		3459,6		3088,2	61,39	20,12
FU Month 12	A		3661,0		3494,4	70,34	20,94		2442,1		2187,5	57,54	16,85
FU Month 15	A		3050,8		2790,0	70,68	20,20		1933,3		19100,0	53,07	21,73
FU Month 18	A		2237,3		1881,8	70,83	23,09		1628,1		16100,0	59,90	19,77
FU Month 21	A		1728,8		1588,2	71,67	17,76		814,0		787,5	69,05	11,50
FU Month 24	A		1016,9		880,0	62,50	27,82		58,8		5100,0	75,00	11,79
FU Month 27	A		58,5		480,0	70,83	22,05		23,5		150,0	83,33	NE
FU Month 30	A		46,8		375,0	52,78	12,73		0	NE	0	NE	NE
Screening													
Screening	B	104	100,0	100	96,2	59,75	22,66		85100,0		8397,6	59,24	20,62
Cycle 4 Day 1	B		8884,6		8394,3	68,67	19,55		7992,9		7392,4	66,32	18,91
FU Day 28	B		9187,5		7986,8	68,67	20,90		7992,9		7088,6	68,45	20,46
FU Month 3	B		8884,6		7888,6	68,38	19,89		7992,9		6987,3	68,60	21,92
FU Month 6	B		8076,9		7796,3	71,65	16,46		7082,4		6390,0	66,93	21,58
FU Month 9	B		6360,6		5282,5	69,07	19,96		5969,4		4881,4	67,88	18,19
FU Month 12	B		4745,2		3983,0	69,02	21,71		4654,1		4087,0	68,54	20,63
FU Month 15	B		3735,6		3491,9	67,40	20,55		3440,0		2779,4	68,83	19,83
FU Month 18	B		3129,8		2890,3	66,96	23,29		2225,9		1881,8	64,35	17,81
FU Month 21	B		1817,3		1372,2	68,59	23,36		1720,0		1482,4	68,45	17,04
FU Month 24	B		1110,6		981,8	65,74	26,50		89,4		787,5	73,81	21,21
FU Month 27	B		54,8		480,0	70,83	14,43		44,7		4100,0	68,75	27,53
FU Month 30	B		21,9		2100,0	70,83	5,89		0	NE	0	NE	NE
Screening													
Screening	C		92100,0		8289,1	59,55	26,65	100	100,0		9191,0	59,07	24,93
Cycle 4 Day 1	C		7480,4		6385,1	68,52	20,55		9191,0		7380,2	65,07	22,12
FU Day 28	C		8188,0		6884,0	70,22	22,37		9292,0		7783,7	68,18	22,41
FU Month 3	C		8087,0		6885,0	70,34	21,47		8989,0		7483,1	67,68	20,50
FU Month 6	C		7177,2		6185,9	68,03	23,08		7777,0		6280,5	65,05	21,44

FU Month 9	C	58	63,0	48	82,8	70,49	22,08	56	56,0	41	73,2	70,12	17,77	
FU Month 12	C	42	45,7	36	85,7	69,91	22,74	47	47,0	38	80,9	68,42	20,70	
FU Month 15	C	37	40,2	30	81,1	70,83	18,54	32	32,0	22	68,8	65,15	18,66	
FU Month 18	C	26	28,3	23	88,5	73,91	21,22	22	22,0	15	68,2	65,00	21,64	
FU Month 21	C	17	18,5	12	70,6	74,31	19,61	15	15,0	11	73,3	49,24	29,45	
FU Month 24	C	11	12,0	8	72,7	65,63	24,57	5	5,0	4	80,0	68,75	14,23	
FU Month 27	C	3	3,3	3	100,0	61,11	25,46	3	3,0	2	66,7	54,17	17,68	
FU Month 30	C	1	1,1	1	100,0	33,33		NE	1	1,0	1	100,0	58,33	NE
Total CIR score at baseline														
Screening	<=6	63	100,0	58	92,1	64,94	22,12	75	100,0	69	92,0	59,54	20,92	
Cycle 4 Day 1	<=6	52	82,5	43	82,7	69,19	20,13	72	96,0	61	84,7	66,12	19,83	
FU Day 28	<=6	56	88,9	48	85,7	69,44	23,78	72	96,0	58	80,6	69,97	17,38	
FU Month 3	<=6	55	87,3	47	85,5	70,39	21,55	69	92,0	55	79,7	68,33	19,40	
FU Month 6	<=6	52	82,5	47	90,4	72,16	19,83	60	80,0	53	88,3	63,21	22,13	
FU Month 9	<=6	43	68,3	36	83,7	75,46	21,63	47	62,7	38	80,9	65,79	15,11	
FU Month 12	<=6	35	55,6	29	82,9	69,83	24,84	34	45,3	27	79,4	65,43	20,37	
FU Month 15	<=6	32	50,8	29	90,6	74,71	17,03	25	33,3	16	64,0	67,71	20,38	
FU Month 18	<=6	23	36,5	22	95,7	71,59	23,10	19	25,3	14	73,7	60,71	21,54	
FU Month 21	<=6	14	22,2	8	57,1	82,29	18,60	14	18,7	10	71,4	63,33	19,33	
FU Month 24	<=6	8	12,7	7	87,5	77,38	25,78	7	9,3	5	71,4	75,00	8,33	
FU Month 27	<=6	2	3,2	2	100,0	75,00	11,79	4	5,3	2	50,0	62,50	29,46	
FU Month 30	<=6	0	NE	0	NE	NE	NE	1	1,3	1	100,0	58,33	NE	
Screening >6														
Screening	>6	192	100,0	182	94,8	57,97	24,38	167	100,0	158	94,6	58,12	24,40	
Cycle 4 Day 1	>6	161	83,9	150	93,2	67,06	20,60	152	91,0	134	88,2	64,80	21,11	
FU Day 28	>6	174	90,6	152	87,4	68,80	21,50	153	91,6	140	91,5	65,30	22,74	
FU Month 3	>6	170	88,5	154	90,6	68,94	21,48	152	91,0	138	90,8	66,12	21,32	
FU Month 6	>6	155	80,7	141	91,0	69,03	19,50	132	79,0	114	86,4	66,89	20,67	
FU Month 9	>6	121	63,0	101	83,5	66,01	20,91	102	61,1	81	79,4	67,59	20,24	
FU Month 12	>6	90	46,9	80	88,9	69,69	20,51	83	49,7	72	86,7	66,44	20,32	
FU Month 15	>6	72	37,5	62	86,1	67,07	20,44	60	35,9	52	86,7	61,86	20,90	
FU Month 18	>6	56	29,2	47	83,9	69,68	22,35	41	24,6	35	85,4	64,05	18,72	
FU Month 21	>6	38	19,8	32	84,2	68,75	19,51	26	15,6	22	84,6	61,36	24,47	
FU Month 24	>6	24	12,5	18	75,0	59,72	23,96	11	6,6	11	100,0	71,97	19,10	
FU Month 27	>6	11	5,7	9	81,8	66,67	20,41	5	3,0	5	100,0	68,33	23,86	
FU Month 30	>6	7	3,6	6	85,7	55,56	16,39	0	NE	0	NE	NE	NE	
Calculated creatinine clearance cat. 2														
Screening	<70 ml/min	178	100,0	164	92,1	58,94	23,85	176	100,0	166	94,3	58,89	23,64	
Cycle 4 Day 1	<70 ml/min	149	83,7	131	87,9	67,30	20,43	164	93,2	142	86,6	65,85	20,90	

FU Day 28	<70 ml/min	162	91,0	141	87,0	68,91	20,60	166	94,3	141	84,9	66,55	21,84
FU Month 3	<70 ml/min	157	88,2	139	88,5	69,72	21,21	159	90,3	137	86,2	66,30	20,98
FU Month 6	<70 ml/min	144	80,9	129	89,6	69,38	19,01	139	79,0	119	85,6	65,55	22,31
FU Month 9	<70 ml/min	117	65,7	97	82,9	69,24	21,16	112	63,6	88	78,6	68,18	18,29
FU Month 12	<70 ml/min	92	51,7	79	85,9	69,83	20,69	87	49,4	73	83,9	67,81	20,05
FU Month 15	<70 ml/min	78	43,8	70	89,7	70,24	19,22	60	34,1	47	78,3	63,83	22,61
FU Month 18	<70 ml/min	59	33,1	50	84,7	71,33	20,63	43	24,4	36	83,7	61,34	20,72
FU Month 21	<70 ml/min	38	21,3	27	71,1	73,46	18,35	31	17,6	27	87,1	62,04	23,49
FU Month 24	<70 ml/min	24	13,5	19	79,2	67,11	24,29	13	7,4	11	84,6	72,73	17,52
FU Month 27	<70 ml/min	10	5,6	8	80,0	68,75	16,52	7	4,0	5	71,4	66,67	25,69
FU Month 30	<70 ml/min	5	2,8	4	80,0	56,25	18,48	1	0,6	1	100,0	58,33	NE
Screening	>=70 ml/min	77	100,0	76	98,7	61,18	24,40	66	100,0	61	92,4	57,65	22,74
Cycle 4 Day 1	>=70 ml/min	64	83,1	62	96,9	68,01	20,70	60	90,9	53	88,3	63,52	20,16
FU Day 28	>=70 ml/min	68	88,3	59	86,8	69,07	25,24	59	89,4	57	96,6	66,96	20,35
FU Month 3	>=70 ml/min	68	88,3	62	91,2	68,28	22,12	62	93,9	56	90,3	67,86	20,38
FU Month 6	>=70 ml/min	63	81,8	59	93,7	70,76	20,90	53	80,3	48	90,6	66,15	18,14
FU Month 9	>=70 ml/min	47	61,0	40	85,1	66,67	22,25	37	56,1	31	83,8	63,71	19,78
FU Month 12	>=70 ml/min	33	42,9	30	90,9	69,44	24,30	30	45,5	26	86,7	61,54	20,42
FU Month 15	>=70 ml/min	26	33,8	21	80,8	67,06	21,32	25	37,9	21	84,0	61,90	16,37
FU Month 18	>=70 ml/min	20	26,0	19	95,0	67,54	27,06	17	25,8	13	76,5	67,95	14,77
FU Month 21	>=70 ml/min	14	18,2	13	92,9	67,31	22,94	9	13,6	5	55,6	61,67	20,07
FU Month 24	>=70 ml/min	8	10,4	6	75,0	56,94	29,07	5	7,6	5	100,0	73,33	14,91
FU Month 27	>=70 ml/min	3	3,9	3	100,0	66,67	28,87	2	3,0	2	100,0	66,67	23,57
FU Month 30	>=70 ml/min	1	2,6	2	100,0	54,17	17,68	0	NE	0	NE	NE	NE
Beta2 microglobulin													
Screening	Missing	3	100,0	3	100,0	72,22	25,46	3	100,0	3	100,0	36,11	26,79
Cycle 4 Day 1	Missing	3	100,0	3	100,0	63,89	20,97	3	100,0	2	66,7	75,00	11,79
FU Day 28	Missing	3	100,0	3	100,0	63,89	4,81	3	100,0	2	66,7	83,33	0,00
FU Month 3	Missing	3	100,0	3	100,0	55,56	19,25	3	100,0	2	66,7	75,00	11,79
FU Month 6	Missing	3	100,0	3	100,0	72,22	9,62	3	100,0	2	66,7	75,00	35,36
FU Month 9	Missing	2	66,7	1	50,0	83,33	NE	3	100,0	2	66,7	66,67	23,57
FU Month 12	Missing	1	33,3	1	100,0	83,33	NE	2	66,7	1	50,0	83,33	NE
FU Month 15	Missing	1	33,3	1	100,0	83,33	NE	2	66,7	1	50,0	83,33	NE
FU Month 18	Missing	1	33,3	1	100,0	66,67	NE	2	66,7	1	50,0	66,67	NE
FU Month 21	Missing	1	33,3	1	100,0	66,67	NE	2	66,7	1	50,0	83,33	NE
FU Month 24	Missing	1	33,3	1	100,0	33,33	NE	1	33,3	1	100,0	83,33	NE
Screening	< 3.5 ug/mL	154	100,0	144	93,5	58,80	23,97	140	100,0	131	93,6	58,46	21,78
Cycle 4 Day 1	< 3.5 ug/mL	127	82,5	116	91,3	65,95	21,58	129	92,1	110	85,3	63,71	21,70

FU Day 28	< 3.5 ug/mL	137	89,0	121	88,3	69,15	21,91	132	94,3	117	88,6	66,74	20,86
FU Month 3	< 3.5 ug/mL	134	87,0	122	91,0	70,36	20,78	130	92,9	113	86,9	65,49	19,48
FU Month 6	< 3.5 ug/mL	128	83,1	115	89,8	70,94	17,98	120	85,7	109	90,8	62,69	20,40
FU Month 9	< 3.5 ug/mL	104	67,5		8682,7	67,15	21,67		9870,0		8182,7	65,02	19,07
FU Month 12	< 3.5 ug/mL		7850,6		6988,5	68,24	22,34		7553,6		6789,3	63,31	21,42
FU Month 15	< 3.5 ug/mL		6542,2		5787,7	67,54	19,90		6042,9		5083,3	63,00	21,11
FU Month 18	< 3.5 ug/mL		4629,9		4189,1	70,53	21,17		4330,7		3581,4	63,57	20,82
FU Month 21	< 3.5 ug/mL		3019,5		2170,0	69,05	21,11		2719,3		2281,5	59,85	23,66
FU Month 24	< 3.5 ug/mL		1912,3		1578,9	64,44	23,46		128,6		1083,3	72,50	12,45
FU Month 27	< 3.5 ug/mL		106,5		880,0	62,50	17,82		75,0		571,4	65,00	19,00
FU Month 30	< 3.5 ug/mL		53,2		480,0	47,92	14,23		10,7		1100,0	58,33	NE
Screening	>= 3.5 ug/mL	98	100,0	93	94,9	60,57	24,11	99	100,0	93	93,9	59,41	25,25
Cycle 4 Day 1	>= 3.5 ug/mL	83	84,7	74	89,2	70,16	18,56	92	92,9	83	90,2	66,97	19,37
FU Day 28	>= 3.5 ug/mL	90	91,8	76	84,4	68,86	22,70	90	90,9	79	87,8	66,14	22,34
FU Month 3	>= 3.5 ug/mL	88	89,8	76	86,4	68,09	22,58	88	88,9	78	88,6	68,38	22,69
FU Month 6	>= 3.5 ug/mL	76	77,6	70	92,1	67,86	22,27	69	69,7	56	81,2	71,28	21,37
FU Month 9	>= 3.5 ug/mL	58	59,2	50	86,2	70,50	21,18	48	48,5	36	75,0	71,53	17,41
FU Month 12	>= 3.5 ug/mL	46	46,9	39	84,8	72,01	20,55	40	40,4	31	77,5	71,77	16,34
FU Month 15	>= 3.5 ug/mL	38	38,8	33	86,8	72,47	19,26	23	23,2	17	73,9	62,75	20,44
FU Month 18	>= 3.5 ug/mL	32	32,7	27	84,4	70,06	25,03	15	15,2	13	86,7	61,54	16,51
FU Month 21	>= 3.5 ug/mL	21	21,4	18	85,7	74,54	19,06	11	11,1	9	81,8	64,81	21,15
FU Month 24	>= 3.5 ug/mL	12	12,2		975,0	68,52	28,50		55,1		5100,0	71,67	24,72
FU Month 27	>= 3.5 ug/mL	3	3,1	3	100,0	83,33	14,43		22,0		2100,0	70,83	41,25
FU Month 30	>= 3.5 ug/mL		22,0	2	100,0	70,83	5,89		0	NE	0	NE	NE
Immunoglobulin VH, cytogenetics 2													
Screening	12	45	100,0	43	95,6	56,59	24,50	44	100,0	43	97,7	58,33	22,93
Cycle 4 Day 1	12	34	75,6	32	94,1	62,76	23,09	38	86,4	33	86,8	63,89	20,59
FU Day 28	12	39	86,7	37	94,9	61,04	22,83	40	90,9	34	85,0	66,67	21,52
FU Month 3	12	38	84,4	35	92,1	65,71	19,04	39	88,6	32	82,1	66,15	21,58
FU Month 6	12	36	80,0	32	88,9	71,35	16,79	34	77,3	27	79,4	65,12	21,44
FU Month 9	12	26	57,8	21	80,8	65,87	22,35	28	63,6	18	64,3	61,57	21,22
FU Month 12	12	22	48,9	18	81,8	73,61	17,91	23	52,3	15	65,2	62,22	16,33
FU Month 15	12	17	37,8	14	82,4	69,64	18,08	17	38,6	12	70,6	57,64	17,57
FU Month 18	12	15	33,3	12	80,0	72,22	17,88	13	29,5	9	69,2	65,74	17,40
FU Month 21	12	10	22,2	8	80,0	68,75	18,23	7	15,9	5	71,4	71,67	13,94
FU Month 24	12	8	17,8	6	75,0	56,94	17,01	6	13,6	6	100,0	68,06	12,27
FU Month 27	12	5	11,1	4	80,0	64,58	12,50	2	4,5	2	100,0	45,83	5,89
FU Month 30	12	4	8,9	3	75,0	63,89	12,73	1	2,3	1	100,0	58,33	NE

Screening	11q-	46	100,0	42	91,3	66,87	20,94	43	100,0	40	93,0	59,79	25,52
Cycle 4 Day 1	11q-	40	87,0	37	92,5	72,75	18,60	41	95,3	34	82,9	70,34	18,49
FU Day 28	11q-	42	91,3	34	81,0	74,75	20,46	39	90,7	36	92,3	70,60	24,03
FU Month 3	11q-	42	91,3	37	88,1	67,79	23,25	38	88,4	36	94,7	71,30	18,20
FU Month 6	11q-	38	82,6	35	92,1	70,24	19,31	32	74,4	27	84,4	67,90	19,02
FU Month 9	11q-	28	60,9	26	92,9	67,95	22,20	25	58,1	20	80,0	65,42	16,28
FU Month 12	11q-	20	43,5	19	95,0	71,49	21,75	18	41,9	17	94,4	64,71	21,76
FU Month 15	11q-	18	39,1	16	88,9	74,48	17,34	14	32,6	10	71,4	57,50	18,19
FU Month 18	11q-	15	32,6	12	80,0	68,75	31,00	8	18,6	7	87,5	57,14	21,21
FU Month 21	11q-	12	26,1	11	91,7	74,24	18,43	4	9,3	2	50,0	54,17	17,68
FU Month 24	11q-	7	15,2	5	71,4	71,67	31,51	1	2,3	1	100,0	91,67	NE
FU Month 27	11q-	3	6,5	3	100,0	61,11	34,69	0	NE	0	NE	NE	NE
FU Month 30	11q-	3	6,5	3	100,0	47,22	17,35	0	NE	0	NE	NE	NE
Screening	13q-	79	100,0	76	96,2	60,20	24,67	75	100,0	70	93,3	60,24	21,05
Cycle 4 Day 1	13q-	67	84,8	60	89,6	65,97	18,81	68	90,7	60	88,2	65,97	19,67
FU Day 28	13q-	72	91,1	65	90,3	73,59	19,80	72	96,0	64	88,9	66,67	20,95
FU Month 3	13q-	73	92,4	67	91,8	71,89	21,75	69	92,0	60	87,0	64,86	20,01
FU Month 6	13q-	67	84,8	62	92,5	72,98	17,77	63	84,0	56	88,9	66,96	21,32
FU Month 9	13q-	56	70,9	49	87,5	71,26	23,08	52	69,3	41	78,8	69,92	19,53
FU Month 12	13q-	44	55,7	39	88,6	71,37	22,36	40	53,3	38	95,0	66,89	21,62
FU Month 15	13q-	38	48,1	34	89,5	67,40	21,45	29	38,7	25	86,2	67,33	22,56
FU Month 18	13q-	28	35,4	25	89,3	68,67	22,08	21	28,0	19	90,5	61,84	19,31
FU Month 21	13q-	16	20,3	13	81,3	66,03	23,44	16	21,3	14	87,5	67,26	21,30
FU Month 24	13q-	7	8,9	6	85,7	62,50	32,38	7	9,3	6	85,7	70,83	22,20
FU Month 27	13q-	2	2,5	1	50,0	66,67	NE	6	8,0	4	66,7	72,92	24,88
Screening	Norm. K.	65	100,0	61	93,8	54,78	23,64	58	100,0	54	93,1	51,39	24,48
Cycle 4 Day 1	Norm. K.	54	83,1	48	88,9	67,36	21,80	55	94,8	49	89,1	60,88	23,40
FU Day 28	Norm. K.	59	90,8	50	84,7	64,50	21,81	53	91,4	47	88,7	62,59	21,20
FU Month 3	Norm. K.	54	83,1	48	88,9	67,71	21,79	54	93,1	47	87,0	62,41	22,45
FU Month 6	Norm. K.	49	75,4	47	95,9	63,65	22,48	45	77,6	39	86,7	59,83	23,01
FU Month 9	Norm. K.	39	60,0	31	79,5	66,94	18,19	30	51,7	27	90,0	66,36	19,95
FU Month 12	Norm. K.	32	49,2	27	84,4	60,49	22,12	24	41,4	20	83,3	64,58	19,28
FU Month 15	Norm. K.	26	40,0	23	88,5	66,67	18,63	20	34,5	17	85,0	63,24	20,21
FU Month 18	Norm. K.	18	27,7	17	94,4	69,12	20,78	15	25,9	12	80,0	63,19	21,46
FU Month 21	Norm. K.	12	18,5	6	50,0	73,61	16,17	11	19,0	9	81,8	52,78	28,26
FU Month 24	Norm. K.	8	12,3	6	75,0	59,72	21,35	4	6,9	3	75,0	80,56	4,81
FU Month 27	Norm. K.	3	4,6	3	100,0	80,56	4,81	1	1,7	1	100,0	83,33	NE
Screening	Other Abn.	20	100,0	18	90,0	64,35	25,21	22	100,0	20	90,9	70,00	20,30

Cycle 4 Day 1	Other Abn.	18	90,0	16	88,9	71,35	20,18	22	100,0	19	86,4	67,11	19,73
FU Day 28	Other Abn.	18	90,0	14	77,8	70,24	27,09	21	95,5	17	81,0	69,61	17,16
FU Month 3	Other Abn.	18	90,0	14	77,8	75,00	19,88	21	95,5	18	85,7	76,39	19,44
FU Month 6	Other Abn.	17	85,0	12	70,6	72,22	21,71	18	81,8	18	100,0	72,22	17,85
FU Month 9	Other Abn.	15	75,0	10	66,7	66,67	21,15	14	63,6	13	92,9	69,23	12,90
FU Month 12	Other Abn.	7	35,0	6	85,7	83,33	13,94	12	54,5	9	75,0	75,93	20,17
FU Month 15	Other Abn.	5	25,0	4	80,0	83,33	23,57	5	22,7	4	80,0	68,75	29,17
FU Month 18	Other Abn.	3	15,0	3	100,0	88,89	12,73	3	13,6	2	66,7	83,33	0,00
FU Month 21	Other Abn.	2	10,0	2	100,0	95,83	5,89	2	9,1	2	100,0	50,00	23,57
FU Month 24	Other Abn.	2	10,0	2	100,0	91,67	11,79	0	NE	0	NE	NE	NE
Time from first diagnosis													
Screening	Missing	1	100,0	1	100,0	41,67	NE	0	NE	0	NE	NE	NE
Cycle 4 Day 1	Missing	1	100,0	1	100,0	58,33	NE	0	NE	0	NE	NE	NE
FU Day 28	Missing	1	100,0	1	100,0	75,00	NE	0	NE	0	NE	NE	NE
FU Month 3	Missing	1	100,0	1	100,0	83,33	NE	0	NE	0	NE	NE	NE
FU Month 6	Missing	1	100,0	1	100,0	83,33	NE	0	NE	0	NE	NE	NE
FU Month 9	Missing	1	100,0	1	100,0	83,33	NE	0	NE	0	NE	NE	NE
FU Month 12	Missing	1	100,0	1	100,0	83,33	NE	0	NE	0	NE	NE	NE
FU Month 15	Missing	1	100,0	1	100,0	83,33	NE	0	NE	0	NE	NE	NE
FU Month 18	Missing	1	100,0	1	100,0	83,33	NE	0	NE	0	NE	NE	NE
Screening	13 - 24 months	41	100,0	39	95,1	56,62	24,27	31	100,0	31	100,0	62,37	21,29
Cycle 4 Day 1	13 - 24 months	35	85,4	34	97,1	66,42	18,29	30	96,8	27	90,0	68,21	18,06
FU Day 28	13 - 24 months	38	92,7	33	86,8	67,17	21,44	30	96,8	27	90,0	77,78	14,06
FU Month 3	13 - 24 months	36	87,8	33	91,7	68,69	20,52	30	96,8	26	86,7	68,91	21,16
FU Month 6	13 - 24 months	36	87,8	33	91,7	70,71	18,76	30	96,8	25	83,3	73,33	19,84
FU Month 9	13 - 24 months	32	78,0	29	90,6	70,11	19,48	21	67,7	17	81,0	72,06	15,29
FU Month 12	13 - 24 months	21	51,2	18	85,7	71,30	21,43	16	51,6	14	87,5	75,60	17,74
FU Month 15	13 - 24 months	19	46,3	18	94,7	68,52	26,13	16	51,6	10	62,5	76,67	19,16
FU Month 18	13 - 24 months	14	34,1	13	92,9	73,08	20,17	10	32,3	8	80,0	71,88	18,33
FU Month 21	13 - 24 months	11	26,8	9	81,8	65,74	15,28	6	19,4	4	66,7	66,67	30,43
FU Month 24	13 - 24 months	8	19,5	5	62,5	45,00	9,50	3	9,7	2	66,7	83,33	23,57
FU Month 27	13 - 24 months	5	12,2	5	100,0	63,33	25,41	2	6,5	2	100,0	70,83	41,25
FU Month 30	13 - 24 months	3	7,3	3	100,0	50,00	16,67	1	3,2	1	100,0	58,33	NE
Screening	<= 12 months	60	100,0	57	95,0	58,77	25,46	70	100,0	69	98,6	56,28	22,39
Cycle 4 Day 1	<= 12 months	48	80,0	42	87,5	70,44	24,22	60	85,7	54	90,0	67,59	20,96
FU Day 28	<= 12 months	54	90,0	45	83,3	68,33	24,66	62	88,6	56	90,3	64,43	23,16
FU Month 3	<= 12 months	53	88,3	45	84,9	69,63	23,04	59	84,3	55	93,2	68,33	22,48
FU Month 6	<= 12 months	46	76,7	40	87,0	73,75	20,72	47	67,1	42	89,4	71,43	22,40

FU Month 9	<= 12 months	35	58,3	26	74,3	71,15	22,51	37	52,9	31	83,8	69,62	17,94
FU Month 12	<= 12 months	27	45,0	23	85,2	67,39	26,46	29	41,4	27	93,1	64,51	21,13
FU Month 15	<= 12 months	22	36,7	17	77,3	68,14	20,03	17	24,3	16	94,1	56,77	18,06
FU Month 18	<= 12 months	16	26,7	13	81,3	79,49	19,72	13	18,6	12	92,3	63,89	12,48
FU Month 21	<= 12 months	9	15,0	5	55,6	81,67	18,07	7	10,0	6	85,7	56,94	15,29
FU Month 24	<= 12 months	6	10,0	3	50,0	77,78	25,46	2	2,9	1	50,0	83,33	NE
FU Month 27	<= 12 months	1	1,7			NE	NE	1	1,4			NE	NE
FU Month 30	<= 12 months	1	1,7			NE	NE	0	NE			NE	NE
Screening	>24 months	153	100,0	143	93,5	60,96	23,43	141	100,0	127	90,1	58,86	24,37
Cycle 4 Day 1	>24 months	129	84,3	116	89,9	66,88	19,73	134	95,0	114	85,1	63,38	21,08
FU Day 28	>24 months	137	89,5	121	88,3	69,63	21,35	133	94,3	115	86,5	65,14	21,25
FU Month 3	>24 months	135	88,2	122	90,4	69,19	21,32	132	93,6	112	84,8	65,48	19,88
FU Month 6	>24 months	124	81,0	114	91,9	68,06	19,39	115	81,6	100	87,0	61,42	19,98
FU Month 9	>24 months	96	62,7	81	84,4	66,87	21,93	91	64,5	71	78,0	64,67	19,59
FU Month 12	>24 months	76	49,7	67	88,2	69,90	20,20	72	51,1	58	80,6	64,66	20,07
FU Month 15	>24 months	62	40,5	55	88,7	70,00	17,47	52	36,9	42	80,8	62,50	21,09
FU Month 18	>24 months	48	31,4	42	87,5	66,27	23,49	37	26,2	29	78,4	60,34	21,67
FU Month 21	>24 months	32	20,9	26	81,3	71,47	21,37	27	19,1	22	81,5	62,50	23,68
FU Month 24	>24 months	18	11,8	17	94,4	68,14	26,23	13	9,2	13	100,0	70,51	15,82
FU Month 27	>24 months	7	4,6	6	85,7	72,22	12,55	6	4,3	5	83,3	65,00	19,00
FU Month 30	>24 months	3	2,0	3	100,0	61,11	17,35	0	NE	0	NE	NE	NE
High circulating tumor burden													
Screening	Missing	0	NE	0	NE	NE	NE	2	100,0	1	50,0	66,67	NE
Cycle 4 Day 1	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	33,33	NE
FU Day 28	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	41,67	NE
FU Month 3	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	66,67	NE
FU Month 6	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	50,00	NE
FU Month 9	Missing	0	NE			NE	NE	1	50,0			NE	NE
Screening	<25x10**9 cells/L	60	100,0	55	91,7	59,55	25,33	67	100,0	64	95,5	57,03	23,53
Cycle 4 Day 1	<25x10**9 cells/L	50	83,3	44	88,0	66,67	22,59	61	91,0	50	82,0	64,33	18,75
FU Day 28	<25x10**9 cells/L	56	93,3	47	83,9	70,04	21,82	61	91,0	53	86,9	64,62	23,73
FU Month 3	<25x10**9 cells/L	54	90,0	46	85,2	67,75	20,46	59	88,1	49	83,1	70,24	18,56
FU Month 6	<25x10**9 cells/L	50	83,3	44	88,0	67,99	21,71	51	76,1	41	80,4	72,97	22,11
FU Month 9	<25x10**9 cells/L	36	60,0	26	72,2	62,82	19,75	41	61,2	29	70,7	70,98	14,88
FU Month 12	<25x10**9 cells/L	29	48,3	24	82,8	69,44	16,42	34	50,7	25	73,5	69,67	18,30
FU Month 15	<25x10**9 cells/L	24	40,0	20	83,3	69,17	17,54	23	34,3	15	65,2	70,00	21,08
FU Month 18	<25x10**9 cells/L	20	33,3	18	90,0	68,52	21,87	19	28,4	14	73,7	71,43	21,36
FU Month 21	<25x10**9 cells/L	14	23,3	10	71,4	64,17	20,05	10	14,9	8	80,0	64,58	16,52

FU Month 24	<25x10**9 cells/L	8	13,3	5	62,5	58,33	16,67	6	9,0	5	83,3	73,33	14,91
FU Month 27	<25x10**9 cells/L	4	6,7	3	75,0	55,56	20,97	1	1,5	1	100,0	41,67	NE
FU Month 30	<25x10**9 cells/L	4	6,7	3	75,0	50,00	16,67	1	1,5	1	100,0	58,33	NE
Screening	>=25x10**9 cells/L	195	100,0	185	94,9	59,68	23,66	173	100,0	162	93,6	59,10	23,40
Cycle 4 Day 1	>=25x10**9 cells/L	163	83,6	149	91,4	67,79	19,87	162	93,6	144	88,9	65,74	21,25
FU Day 28	>=25x10**9 cells/L	174	89,2	153	87,9	68,63	22,13	163	94,2	144	88,3	67,59	20,44
FU Month 3	>=25x10**9 cells/L	171	87,7	155	90,6	69,73	21,78	161	93,1	143	88,8	65,56	21,47
FU Month 6	>=25x10**9 cells/L	157	80,5	144	91,7	70,37	18,93	140	80,9	125	89,3	63,47	20,41
FU Month 9	>=25x10**9 cells/L	128	65,6	111	86,7	69,82	21,67	107	61,8	90	84,1	65,74	19,69
FU Month 12	>=25x10**9 cells/L	96	49,2	85	88,5	69,80	22,97	83	48,0	74	89,2	64,98	20,83
FU Month 15	>=25x10**9 cells/L	80	41,0	71	88,8	69,60	20,32	62	35,8	53	85,5	61,32	20,48
FU Month 18	>=25x10**9 cells/L	59	30,3	51	86,4	70,92	22,81	41	23,7	35	85,4	59,76	17,79
FU Month 21	>=25x10**9 cells/L	38	19,5	30	78,9	73,89	19,54	30	17,3	24	80,0	61,11	24,66
FU Month 24	>=25x10**9 cells/L	24	12,3	20	83,3	66,25	27,10	12	6,9	11	91,7	72,73	17,52
FU Month 27	>=25x10**9 cells/L	9	4,6	8	88,9	72,92	17,11	8	4,6	6	75,0	70,83	22,20
FU Month 30	>=25x10**9 cells/L	3	1,5	3	100,0	61,11	17,35	0	NE	0	NE	NE	NE

¹ in study: number of subjects in study at respective visit; % based on baseline

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit

² mean: descriptive statistics - absolute values Clinical

cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/t_pro_mean.sas

Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/t_pro_mean_sg_EQC30_IT_label_09MAY2013_21004.xls 04MAR2020

17:18

POPULATION: Labelpopulation, Intent-to-Treat Patients ENDPOINT: EORTC QoL 30

MODEL: Unadjusted Analysis STUDY: CLL11(BO21004), Stage

2

Compliance/Mean

Cognitive Functioning Scale

		GClb (N=255)						RC1b (N=242)					
		Patients			Statistics			Patients			Statistics		
Name	Level	in study ¹	%	with value ¹	%	Mean ²	SD(mean)	in study ¹	%	with value ¹	%	Mean ²	SD(mean)
All													
Screening	n/a	255	100,0	241	94,5	82,16	21,51	242	100,0	227	93,8	81,57	21,08
Cycle 4 Day 1	n/a	213	83,5	196	92,0	84,01	20,94	224	92,6	197	87,9	82,40	18,07
FU Day 28	n/a	230	90,2	201	87,4	82,67	20,81	225	93,0	201	89,3	84,99	17,24
FU Month 3	n/a	225	88,2	203	90,2	83,83	20,03	221	91,3	195	88,2	81,37	19,82
FU Month 6	n/a	207	81,2	188	90,8	83,33	20,39	192	79,3	168	87,5	81,55	18,06
FU Month 9	n/a	164	64,3	138	84,1	82,13	21,18	149	61,6	119	79,9	81,79	18,15
FU Month 12	n/a	125	49,0	109	87,2	81,80	19,97	117	48,3	99	84,6	80,98	21,30
FU Month 15	n/a	104	40,8	91	87,5	82,42	21,13	85	35,1	69	81,2	80,43	21,76
FU Month 18	n/a		79	31,0	69	87,3	81,88	60	24,8	49	81,7	80,95	19,25
FU Month 21	n/a		52	20,4	40	76,9	80,00	40	16,5	32	80,0	79,69	20,62
FU Month 24	n/a		32	12,5	25	78,1	76,00	22	9,1	16	88,9	79,17	22,36
FU Month 27	n/a		13	5,1	11	84,6	69,70	9	3,7	7	77,8	80,95	24,40
FU Month 30	n/a		7	2,7	6	85,7	61,11	4	1,6	1	100,0	100,00	NE
Gender													
Screening	Female	97	100,0	91	93,8	80,40	23,39	95	100,0	87	91,6	77,59	25,27
Cycle 4 Day 1	Female	84	86,6	77	91,7	82,47	22,11	88	92,6	78	88,6	80,34	19,32
FU Day 28	Female	90	92,8	83	92,2	81,33	20,72	91	95,8	79	86,8	82,49	18,85
FU Month 3	Female	88	90,7	81	92,0	82,30	20,30	87	91,6	76	87,4	78,29	22,77
FU Month 6	Female	84	86,6	72	85,7	82,87	19,17	77	81,1	67	87,0	79,60	19,21
FU Month 9	Female	70	72,2	59	84,3	80,51	21,03	61	64,2	46	75,4	81,16	18,46
FU Month 12	Female	56	57,7	49	87,5	80,27	19,15	47	49,5	40	85,1	77,50	21,20
FU Month 15	Female	47	48,5	41	87,2	78,46	23,64	33	34,7	28	84,8	81,55	18,34
FU Month 18	Female	34	35,1	29	85,3	78,16	21,87	26	27,4	22	84,6	75,76	21,04
FU Month 21	Female	21	21,6	15	71,4	74,44	27,36	17	17,9	15	88,2	73,33	24,23
FU Month 24	Female	12	12,4	10	83,3	78,33	17,66	6	6,3	5	83,3	83,33	16,67
FU Month 27	Female	6	6,2	5	83,3	66,67	42,49	2	2,1	1	50,0	100,00	NE
FU Month 30	Female	4	4,1	3	75,0	55,56	38,49	1	1,1	1	100,0	100,00	NE

Screening	Male	158	100,0	150	94,9	83,22	20,30	147	100,0	140	95,2	84,05	17,64
Cycle 4 Day 1	Male	129	81,6	119	92,2	85,01	20,17	136	92,5	119	87,5	83,75	17,15
FU Day 28	Male	140	88,6	118	84,3	83,62	20,90	134	91,2	122	91,0	86,61	15,98
FU Month 3	Male	137	86,7	122	89,1	84,84	19,87	134	91,2	119	88,8	83,33	17,49
FU Month 6	Male	123	77,8	116	94,3	83,62	21,19	115	78,2	101	87,8	82,84	17,23
FU Month 9	Male	94	59,5	79	84,0	83,33	21,35	88	59,9	73	83,0	82,19	18,07
FU Month 12	Male	69	43,7	60	87,0	83,06	20,70	70	47,6	59	84,3	83,33	21,22
FU Month 15	Male	57	36,1	50	87,7	85,67	18,45	52	35,4	41	78,8	79,67	24,01
FU Month 18	Male	45	28,5	40	88,9	84,58	21,81	34	23,1	27	79,4	85,19	16,88
FU Month 21	Male	31	19,6	25	80,6	83,33	21,52	23	15,6	17	73,9	85,29	15,46
FU Month 24	Male	20	12,7	15	75,0	74,44	25,87	12	8,2	11	91,7	77,27	25,03
FU Month 27	Male	7	4,4	6	85,7	72,22	22,77	7	4,8	6	85,7	77,78	25,09
FU Month 30	Male	3	1,9	3	100,0	66,67	57,74	0	NE	0	NE	NE	NE
Age													
Screening	<75 years	130	100,0	123	94,6	81,71	22,12	120	100,0	109	90,8	85,47	16,99
Cycle 4 Day 1	<75 years	106	81,5	100	94,3	84,17	20,57	112	93,3	98	87,5	85,88	16,98
FU Day 28	<75 years	119	91,5	105	88,2	84,13	18,25	110	91,7	103	93,6	85,44	16,78
FU Month 3	<75 years	116	89,2	106	91,4	85,69	17,73	109	90,8	99	90,8	82,15	18,02
FU Month 6	<75 years	108	83,1	98	90,7	83,50	20,09	99	82,5	88	88,9	82,58	19,23
FU Month 9	<75 years	85	65,4	73	85,9	81,96	19,98	74	61,7	62	83,8	84,95	16,17
FU Month 12	<75 years	63	48,5	59	93,7	81,64	17,15	60	50,0	53	88,3	82,08	21,64
FU Month 15	<75 years	54	41,5	47	87,0	82,27	20,38	44	36,7	35	79,5	84,76	18,69
FU Month 18	<75 years	43	33,1	39	90,7	81,20	23,63	27	22,5	22	81,5	89,39	14,13
FU Month 21	<75 years	26	20,0	22	84,6	78,79	20,04	17	14,2	13	76,5	89,74	10,84
FU Month 24	<75 years	18	13,8	14	77,8	73,81	25,08	6	5,0	5	83,3	83,33	16,67
FU Month 27	<75 years	7	5,4	5	71,4	66,67	26,35	2	1,7	1	50,0	100,00	NE
FU Month 30	<75 years	4	3,1	3	75,0	44,44	50,92	0	NE	0	NE	NE	NE
Screening	>=75 years	125	100,0	118	94,4	82,63	20,95	122	100,0	118	96,7	77,97	23,76
Cycle 4 Day 1	>=75 years	107	85,6	96	89,7	83,85	21,42	112	91,8	99	88,4	78,96	18,53
FU Day 28	>=75 years	111	88,8	96	86,5	81,08	23,27	115	94,3	98	85,2	84,52	17,79
FU Month 3	>=75 years	109	87,2	97	89,0	81,79	22,19	112	91,8	96	85,7	80,56	21,58
FU Month 6	>=75 years	99	79,2	90	90,9	83,15	20,83	93	76,2	80	86,0	80,42	16,72
FU Month 9	>=75 years	79	63,2	65	82,3	82,31	22,61	75	61,5	57	76,0	78,36	19,66
FU Month 12	>=75 years	62	49,6	50	80,6	82,00	23,04	57	46,7	46	80,7	79,71	21,06
FU Month 15	>=75 years	50	40,0	44	88,0	82,58	22,14	41	33,6	34	82,9	75,98	23,99
FU Month 18	>=75 years	36	28,8	30	83,3	82,78	19,81	33	27,0	27	81,8	74,07	20,32
FU Month 21	>=75 years	26	20,8	18	69,2	81,48	28,52	23	18,9	19	82,6	72,81	23,05
FU Month 24	>=75 years	14	11,2	11	78,6	78,79	19,85	12	9,8	11	91,7	77,27	25,03

FU Month 27	>=75 years	64,8	6100,0	72,22	37,52	75,7	685,7	77,78	25,09				
FU Month 30	>=75 years	32,4	3100,0	77,78	38,49	10,8	1100,0	100,00					NE
Race													
Screening	Other	9100,0	9100,0	88,89	11,79	11100,0	11100,0	86,36	16,36				
Cycle 4 Day 1	Other	777,8	7100,0	83,33	16,67	1090,9	990,0	81,48	25,61				
FU Day 28	Other	888,9	8100,0	81,25	16,52	1090,9	10100,0	85,00	19,95				
FU Month 3	Other	888,9	787,5	88,10	15,85	1090,9	10100,0	86,67	10,54				
FU Month 6	Other	888,9	787,5	80,95	24,40	872,7	8100,0	85,42	13,91				
FU Month 9	Other	444,4	375,0	72,22	19,25	545,5	480,0	87,50	8,33				
FU Month 12	Other	333,3	266,7	50,00	0,00	436,4	4100,0	95,83	8,33				
FU Month 15	Other	222,2	150,0	50,00		NE	436,4	4100,0	95,83	8,33			
FU Month 18	Other	222,2	150,0	66,67		NE	218,2	2100,0	91,67	11,79			
FU Month 21	Other	222,2	150,0	66,67		NE	218,2	2100,0	91,67	11,79			
FU Month 24	Other	222,2	150,0	66,67		NE	19,1	0	NE	NE	NE	NE	NE
FU Month 27	Other	111,1			NE	NE	19,1			NE	NE	NE	NE
FU Month 30	Other	111,1			NE	NE	0	NE			NE	NE	NE
Geographical Region													
Screening	Asia-Pacific	20100,0	20100,0	80,00	23,94	18100,0	1794,4	86,27	16,91				
Cycle 4 Day 1	Asia-Pacific	1575,0	15100,0	75,56	20,77	1688,9	1593,8	81,11	20,77				
FU Day 28	Asia-Pacific	1890,0	18100,0	77,78	24,25	18100,0	1688,9	86,46	18,48				
FU Month 3	Asia-Pacific	1890,0	1688,9	82,29	23,15	18100,0	1688,9	82,29	12,87				
FU Month 6	Asia-Pacific	1680,0	1487,5	73,81	31,16	1794,4	1588,2	80,00	15,69				
FU Month 9	Asia-Pacific	1470,0	1285,7	79,17	16,09	1372,2	969,2	81,48	15,47				
FU Month 12	Asia-Pacific	1050,0	880,0	79,17	17,25	1055,6	10100,0	80,00	26,99				
FU Month 15	Asia-Pacific	840,0	675,0	83,33	18,26	950,0	9100,0	79,63	23,24				

FU Month 18	Asia-Pacific	630,0	466,7	87,50	15,96	633,3	6100,0	83,33	14,91
FU Month 21	Asia-Pacific	525,0	360,0	88,89	19,25	422,2	4100,0	87,50	8,33
FU Month 24	Asia-Pacific	315,0	266,7	83,33	23,57	15,6	0	NE	NE
FU Month 27	Asia-Pacific	15,0		NE	NE	15,6			NE
FU Month 30	Asia-Pacific	15,0		NE	NE	0	NE		NE
Screening	Central and South America	3100,0	3100,0	83,33	0,00	2100,0	2100,0	58,33	35,36
Cycle 4 Day 1	Central and South America	3100,0	3100,0	77,78	9,62	2100,0	2100,0	83,33	0,00
FU Day 28	Central and South America	3100,0	3100,0	72,22	9,62	2100,0	2100,0	83,33	0,00
FU Month 3	Central and South America	3100,0	3100,0	77,78	9,62	2100,0	2100,0	91,67	11,79
FU Month 6	Central and South America	266,7	2100,0	83,33	0,00	2100,0	2100,0	83,33	0,00
FU Month 9	Central and South America	266,7	2100,0	83,33	0,00	150,0	1100,0	100,00	NE
FU Month 12	Central and South America	266,7	2100,0	58,33	11,79	150,0	1100,0	66,67	NE
FU Month 15	Central and South America	133,3	1100,0	83,33	NE	0	NE	0	NE
FU Month 18	Central and South America	133,3	1100,0	83,33	NE	0	NE	0	NE
FU Month 21	Central and South America	133,3	1100,0	83,33	NE	0	NE	0	NE
FU Month 24	Central and South America	133,3	1100,0	83,33	NE	0	NE	0	NE
Screening	North America	12100,0	12100,0	76,39	25,08	13100,0	1292,3	83,33	17,41
Cycle 4 Day 1	North America	975,0	9100,0	77,78	25,00	1292,3	12100,0	80,56	13,91
FU Day 28	North America	1191,7	11100,0	74,24	25,13	13100,0	13100,0	82,05	10,68
FU Month 3	North America	1191,7	11100,0	78,79	27,98	1292,3	12100,0	84,72	19,41
FU Month 6	North America	1191,7	1090,9	75,00	25,15	1184,6	11100,0	78,79	13,10
FU Month 9	North America	866,7	8100,0	81,25	18,77	969,2	9100,0	75,93	14,70
FU Month 12	North America	866,7	787,5	76,19	21,21	753,8	7100,0	83,33	9,62
FU Month 15	North America	650,0	6100,0	86,11	12,55	646,2	583,3	60,00	36,51
FU Month 18	North America	433,3	4100,0	95,83	8,33	323,1	3100,0	61,11	19,25
FU Month 21	North America	325,0	266,7	91,67	11,79	17,7	1100,0	50,00	NE
FU Month 24	North America	325,0	266,7	83,33	0,00	17,7	1100,0	33,33	NE
FU Month 27	North America	216,7	150,0	83,33	NE	17,7	1100,0	33,33	NE
Screening	Other	45100,0	4191,1	76,83	24,97	44100,0	4193,2	76,02	20,77
Cycle 4 Day 1	Other	3782,2	3389,2	79,29	24,31	4090,9	3485,0	80,88	20,16
FU Day 28	Other	3782,2	3389,2	88,89	12,95	3988,6	3794,9	81,08	18,49
FU Month 3	Other	3884,4	3489,5	86,27	18,10	3886,4	3694,7	78,24	16,82
FU Month 6	Other	3577,8	3188,6	84,95	13,85	3375,0	3193,9	76,88	21,38
FU Month 9	Other	2657,8	2284,6	85,61	12,91	2454,5	1979,2	77,19	15,92
FU Month 12	Other	1737,8	1694,1	82,29	14,23	1636,4	1487,5	73,81	16,94
FU Month 15	Other	1226,7	1191,7	77,27	18,67	920,5	888,9	81,25	13,91
FU Month 18	Other	1022,2	990,0	83,33	16,67	715,9	685,7	77,78	22,77
FU Month 21	Other	715,6	685,7	80,56	19,48	49,1	4100,0	79,17	8,33

FU Month 24	Other	6	13,3	5	83,3	80,00	7,45	3	6,8	3	100,0	83,33	16,67
FU Month 27	Other	4	8,9	4	100,0	83,33	23,57	1	2,3	1	100,0	100,00	NE
FU Month 30	Other	2	4,4	2	100,0	66,67	47,14	0	NE	0	NE	NE	NE
Screening	Western Europe	175	100,0	165	94,3	84,14	20,06	165	100,0	155	93,9	82,69	21,48
Cycle 4 Day 1	Western Europe	149	85,1	136	91,3	86,64	19,65	154	93,3	134	87,0	83,08	17,82
FU Day 28	Western Europe	161	92,0	136	84,5	82,72	21,41	153	92,7	133	86,9	86,22	17,35
FU Month 3	Western Europe	155	88,6	139	89,7	83,93	19,70	151	91,5	129	85,4	81,65	21,43
FU Month 6	Western Europe	143	81,7	131	91,6	84,61	19,89	129	78,2	109	84,5	83,33	17,86
FU Month 9	Western Europe	114	65,1	94	82,5	81,74	23,71	102	61,8	81	79,4	83,33	19,18
FU Month 12	Western Europe	88	50,3	76	86,4	83,11	21,17	83	50,3	67	80,7	82,59	22,18
FU Month 15	Western Europe	77	44,0	67	87,0	82,84	22,65	61	37,0	47	77,0	82,62	20,25
FU Month 18	Western Europe	58	33,1	51	87,9	80,07	23,81	44	26,7	34	77,3	82,84	19,02
FU Month 21	Western Europe	36	20,6	28	77,8	77,98	26,47	31	18,8	23	74,2	79,71	23,00
FU Month 24	Western Europe	19	10,9	15	78,9	72,22	27,94	13	7,9	12	92,3	81,94	20,67
FU Month 27	Western Europe	6	3,4	6	100,0	58,33	36,13	6	3,6	5	83,3	86,67	13,94
FU Month 30	Western Europe	4	2,3	4	100,0	58,33	50,00	1	0,6	1	100,0	100,00	NE
FCgamma receptor IIa													
Screening	131HH	58	100,0	53	91,4	75,16	25,66	76	100,0	72	94,7	82,18	20,04
Cycle 4 Day 1	131HH	49	84,5	43	87,8	80,62	21,19	65	85,5	60	92,3	86,94	16,55
FU Day 28	131HH	51	87,9	46	90,2	82,25	19,37	70	92,1	61	87,1	86,61	14,54
FU Month 3	131HH	51	87,9	47	92,2	80,14	21,32	64	84,2	54	84,4	83,33	17,13
FU Month 6	131HH	49	84,5	45	91,8	81,85	21,27	55	72,4	48	87,3	81,60	16,93
FU Month 9	131HH	39	67,2	30	76,9	78,89	20,50	41	53,9	32	78,0	84,90	16,59
FU Month 12	131HH	28	48,3	24	85,7	80,56	17,49	34	44,7	29	85,3	86,78	12,89
FU Month 15	131HH	23	39,7	19	82,6	78,07	24,88	24	31,6	20	83,3	87,50	16,11
FU Month 18	131HH	17	29,3	14	82,4	76,19	25,08	16	21,1	13	81,3	89,74	16,01
FU Month 21	131HH	13	22,4	8	61,5	81,25	31,42	11	14,5	10	90,9	70,00	28,11
FU Month 24	131HH	11	19,0	7	63,6	76,19	30,21	1	1,3	1	100,0	100,00	NE
FU Month 27	131HH	4	6,9	3	75,0	55,56	50,92	1	1,3	1	100,0	83,33	NE
FU Month 30	131HH	3	5,2	2	66,7	66,67	47,14	0	NE	0	NE	NE	NE
Screening	131HR	125	100,0	118	94,4	84,18	18,85	114	100,0	109	95,6	82,11	21,24
Cycle 4 Day 1	131HR	105	84,0	98	93,3	83,67	22,57	110	96,5	99	90,0	80,13	20,02
FU Day 28	131HR	116	92,8	102	87,9	82,19	22,53	105	92,1	95	90,5	84,21	19,66
FU Month 3	131HR	114	91,2	102	89,5	85,13	19,18	107	93,9	95	88,8	80,18	21,37
FU Month 6	131HR	104	83,2	93	89,4	84,59	17,42	95	83,3	84	88,4	80,95	18,32
FU Month 9	131HR	84	67,2	71	84,5	83,10	20,80	76	66,7	60	78,9	81,67	19,09
FU Month 12	131HR	64	51,2	57	89,1	80,41	21,62	57	50,0	48	84,2	79,51	23,38
FU Month 15	131HR	53	42,4	45	84,9	82,59	20,09	44	38,6	35	79,5	78,57	21,98

FU Month 18	131HR	43	34,4	37	86,0	81,08	22,28	32	28,1	26	81,3	76,92	20,59
FU Month 21	131HR	26	20,8	20	76,9	75,00	25,65	21	18,4	16	76,2	82,29	16,63
FU Month 24	131HR	12	9,6	11	91,7	74,24	22,81	12	10,5	10	83,3	71,67	23,64
FU Month 27	131HR	6	4,8	5	83,3	70,00	27,39	6	5,3	4	66,7	70,83	28,46
FU Month 30	131HR	3	2,4	3	100,0	44,44	50,92	1	0,9	1	100,0	100,00	NE
Screening	131RR	49	100,0	48	98,0	86,11	17,64	33	100,0	29	87,9	83,91	15,74
Cycle 4 Day 1	131RR	40	81,6	38	95,0	89,47	14,20	31	93,9	25	80,6	83,33	10,76
FU Day 28	131RR	42	85,7	35	83,3	85,71	18,14	32	97,0	29	90,6	86,21	14,82
FU Month 3	131RR	39	79,6	37	94,9	87,39	19,01	32	97,0	29	90,6	84,48	17,21
FU Month 6	131RR	35	71,4	33	94,3	84,34	19,96	27	81,8	22	81,5	86,36	19,68
FU Month 9	131RR	24	49,0	22	91,7	82,58	24,92	19	57,6	17	89,5	85,29	13,02
FU Month 12	131RR	18	36,7	17	94,4	84,31	17,15	17	51,5	15	88,2	82,22	20,38
FU Month 15	131RR	16	32,7	16	100,0	86,46	21,27	11	33,3	9	81,8	83,33	14,43
FU Month 18	131RR	14	28,6	14	100,0	86,90	18,70	8	24,2	7	87,5	80,95	15,00
FU Month 21	131RR	8	16,3	7	87,5	88,10	12,60	5	15,2	4	80,0	91,67	9,62
FU Month 24	131RR	5	10,2	4	80,0	79,17	20,97	3	9,1	3	100,0	88,89	19,25
FU Month 27	131RR	2	4,1	2	100,0	83,33	23,57	1	3,0	1	100,0	100,00	NE
FU Month 30	131RR	1	2,0	1	100,0	100,00	NE	0	NE	0	NE	NE	NE
Screening	Missing	23	100,0	22	95,7	79,55	28,14	19	100,0	17	89,5	71,57	29,91
Cycle 4 Day 1	Missing	19	82,6	17	89,5	82,35	22,42	18	94,7	13	72,2	76,92	17,40
FU Day 28	Missing	21	91,3	18	85,7	80,56	20,01	18	94,7	16	88,9	81,25	15,96
FU Month 3	Missing	21	91,3	17	81,0	78,43	22,64	18	94,7	17	94,4	76,47	22,87
FU Month 6	Missing	19	82,6	17	89,5	78,43	32,15	15	78,9	14	93,3	77,38	18,03
FU Month 9	Missing	17	73,9	15	88,2	83,33	19,92	13	68,4	10	76,9	66,67	19,25
FU Month 12	Missing	15	65,2	11	73,3	87,88	21,20	9	47,4	7	77,8	64,29	29,55
FU Month 15	Missing	12	52,2	11	91,7	83,33	19,72	6	31,6	5	83,3	60,00	38,37
FU Month 18	Missing	5	21,7	4	80,0	91,67	16,67	4	21,1	3	75,0	77,78	25,46
FU Month 21	Missing	5	21,7	5	100,0	86,67	13,94	3	15,8	2	66,7	83,33	0,00
FU Month 24	Missing	4	17,4	3	75,0	77,78	9,62	2	10,5	2	100,0	91,67	11,79
FU Month 27	Missing	1	4,3	1	100,0	83,33	NE	1	5,3	1	100,0	100,00	NE
FCgamma receptor IIIa													
Screening	158FF	103	100,0	100	97,1	85,17	18,33	83	100,0	78	94,0	84,40	17,68
Cycle 4 Day 1	158FF	89	86,4	83	93,3	88,55	17,45	78	94,0	72	92,3	83,80	18,55
FU Day 28	158FF	96	93,2	84	87,5	83,93	22,02	78	94,0	74	94,9	85,36	18,50
FU Month 3	158FF	94	91,3	84	89,4	84,72	21,05	78	94,0	70	89,7	81,67	20,49
FU Month 6	158FF	86	83,5	76	88,4	85,96	20,56	64	77,1	58	90,6	83,62	18,34
FU Month 9	158FF	71	68,9	59	83,1	82,49	21,98	47	56,6	43	91,5	82,17	19,72
FU Month 12	158FF	48	46,6	42	87,5	80,95	23,73	38	45,8	35	92,1	84,29	20,98

FU Month 15	158FF	37	35,9	32	86,5	83,33	23,95	30	36,1	24	80,0	79,86	26,91
FU Month 18	158FF	27	26,2	24	88,9	84,72	25,50	21	25,3	17	81,0	83,33	18,63
FU Month 21	158FF	16	15,5	15	93,8	81,11	22,60	9	10,8	8	88,9	81,25	24,30
FU Month 24	158FF	8	7,8	7	87,5	73,81	30,21	3	3,6	2	66,7	83,33	23,57
FU Month 27	158FF	5	4,9	4	80,0	70,83	28,46	1	1,2	1	100,0	100,00	NE
FU Month 30	158FF	3	2,9	3	100,0	66,67	57,74	0	NE	0	NE	NE	NE
Screening	158FV	119	100,0	110	92,4	81,21	21,19	109	100,0	103	94,5	82,20	19,56
Cycle 4 Day 1	158FV	99	83,2	90	90,9	80,93	22,70	100	91,7	85	85,0	82,35	16,34
FU Day 28	158FV	105	88,2	91	86,7	82,42	19,93	101	92,7	87	86,1	84,67	16,32
FU Month 3	158FV	101	84,9	93	92,1	83,87	19,26	97	89,0	84	86,6	80,95	17,38
FU Month 6	158FV	94	79,0	87	92,6	82,57	17,77	83	76,1	72	86,7	80,79	17,39
FU Month 9	158FV	71	59,7	61	85,9	82,51	21,82	65	59,6	49	75,4	82,99	15,40
FU Month 12	158FV	60	50,4	55	91,7	81,82	17,65	52	47,7	42	80,8	79,76	20,01
FU Month 15	158FV	52	43,7	46	88,5	82,97	20,03	36	33,0	30	83,3	80,56	19,12
FU Month 18	158FV	44	37,0	38	86,4	81,14	20,20	24	22,0	20	83,3	77,50	18,95
FU Month 21	158FV	28	23,5	18	64,3	78,70	27,89	18	16,5	14	77,8	77,38	23,21
FU Month 24	158FV	18	15,1	13	72,2	79,49	19,43	6	5,5	5	83,3	70,00	24,72
FU Month 27	158FV	6	5,0	5	83,3	66,67	42,49	2	1,8	1	50,0	83,33	NE
FU Month 30	158FV	4	3,4	3	75,0	55,56	38,49	0	NE	0	NE	NE	NE
Screening	158VV	16	100,0	15	93,8	80,00	27,60	33	100,0	31	93,9	77,96	26,66
Cycle 4 Day 1	158VV	12	75,0	11	91,7	87,88	16,82	30	90,9	28	93,3	80,95	23,00
FU Day 28	158VV	14	87,5	13	92,9	83,33	20,41	30	90,9	26	86,7	87,82	17,99
FU Month 3	158VV	15	93,8	12	80,0	88,89	12,97	30	90,9	26	86,7	82,69	24,71
FU Month 6	158VV	14	87,5	13	92,9	84,62	15,90	30	90,9	24	80,0	80,56	20,06
FU Month 9	158VV	12	75,0	10	83,3	80,00	15,32	25	75,8	18	72,0	81,48	19,71
FU Month 12	158VV	8	50,0	7	87,5	80,95	11,50	20	60,6	17	85,0	82,35	19,07
FU Month 15	158VV	8	50,0	7	87,5	73,81	18,90	14	42,4	11	78,6	80,30	20,84
FU Month 18	158VV	4	25,0	4	100,0	66,67	13,61	11	33,3	9	81,8	81,48	24,22
FU Month 21	158VV	3	18,8	2	66,7	66,67	23,57	9	27,3	7	77,8	80,95	17,82
FU Month 24	158VV	2	12,5	2	100,0	58,33	35,36	7	21,2	7	100,0	80,95	24,40
FU Month 27	158VV	1	6,3	1	100,0	66,67	NE	5	15,2	4	80,0	70,83	28,46
FU Month 30	158VV	0	NE	0	NE	NE	NE	1	3,0	1	100,0	100,00	NE
Screening	Missing	17	100,0	16	94,1	71,88	32,04	17	100,0	15	88,2	70,00	30,34
Cycle 4 Day 1	Missing	13	76,5	12	92,3	72,22	25,95	16	94,1	12	75,0	77,78	14,79
FU Day 28	Missing	15	88,2	13	86,7	75,64	19,97	16	94,1	14	87,5	79,76	14,88
FU Month 3	Missing	15	88,2	14	93,3	73,81	22,37	16	94,1	15	93,8	80,00	22,00
FU Month 6	Missing	13	76,5	12	92,3	70,83	34,91	15	88,2	14	93,3	78,57	17,82
FU Month 9	Missing	10	58,8	8	80,0	79,17	19,42	12	70,6	9	75,0	74,07	22,22

FU Month 12	Missing		952,9	555,6	90,00	22,36		741,2	571,4	63,33	36,13	
FU Month 15	Missing		741,2	685,7	83,33	18,26		529,4	480,0	83,33	13,61	
FU Month 18	Missing		423,5	375,0	88,89	19,25		423,5	375,0	88,89	9,62	
FU Month 21	Missing		529,4	5100,0	86,67	13,94		423,5	375,0	83,33	0,00	
FU Month 24	Missing		423,5	375,0	77,78	9,62		211,8	2100,0	91,67	11,79	
FU Month 27	Missing		15,9	1100,0	83,33		NE	15,9	1100,0	100,00		NE
Binet Staging at baseline												
Screening	A		59100,0	5898,3	79,02	24,30		57100,0	5393,0	77,36	25,55	
Cycle 4 Day 1	A		5186,4	4894,1	81,25	24,70		5494,7	5092,6	80,00	19,92	
FU Day 28	A		5898,3	5391,4	78,62	24,10		5494,7	5296,3	84,94	15,92	
FU Month 3	A		5796,6	5698,2	80,95	22,79		5393,0	5094,3	75,00	24,57	
FU Month 6	A		5694,9	5089,3	81,33	23,24		4578,9	4293,3	75,40	19,90	
FU Month 9	A		4372,9	3786,0	81,08	20,09		3459,6	3088,2	80,56	18,09	
FU Month 12	A		3661,0	3494,4	78,43	22,30		2442,1	2187,5	70,63	27,34	
FU Month 15	A		3050,8	2790,0	83,95	21,42		1933,3	19100,0	77,19	20,94	
FU Month 18	A		2237,3	1881,8	80,56	30,38		1628,1	16100,0	76,04	21,92	
FU Month 21	A		1728,8	1588,2	78,89	30,52		814,0	787,5	85,71	15,00	
FU Month 24	A		1016,9	880,0	70,83	29,21		58,8	5100,0	86,67	18,26	
FU Month 27	A		58,5	480,0	58,33	50,00		23,5	150,0	83,33		NE
FU Month 30	A		46,8	375,0	44,44	50,92		0	NE	NE	NE	NE
Screening												
Screening	B	104	100,0	100	96,2	83,00	19,24	85100,0	8397,6	82,13	19,44	
Cycle 4 Day 1	B		8884,6	8394,3	85,94	19,21		7992,9	7392,4	81,96	16,84	
FU Day 28	B		9187,5	7986,8	85,23	19,79		7992,9	7189,9	83,33	15,94	
FU Month 3	B		8884,6	7888,6	86,11	17,08		7992,9	7088,6	84,29	15,77	
FU Month 6	B		8076,9	7796,3	86,58	16,00		7082,4	6288,6	80,91	19,29	
FU Month 9	B		6360,6	5282,5	84,29	22,96		5969,4	4881,4	80,90	17,53	
FU Month 12	B		4745,2	3983,0	84,19	18,71		4654,1	4087,0	80,42	17,66	
FU Month 15	B		3735,6	3491,9	80,39	22,27		3440,0	2882,4	81,55	17,77	
FU Month 18	B		3129,8	2890,3	83,33	19,25		2225,9	1881,8	81,48	18,86	
FU Month 21	B		1817,3	1372,2	79,49	20,59		1720,0	1482,4	79,76	17,52	
FU Month 24	B		1110,6	981,8	77,78	22,05		89,4	787,5	76,19	30,21	
FU Month 27	B		54,8	480,0	79,17	15,96		44,7	4100,0	70,83	28,46	
FU Month 30	B		21,9	2100,0	100,00	0,00		0	NE	NE	NE	NE
Screening												
Screening	C		92100,0	8390,2	83,33	22,09	100	100,0	9191,0	83,52	19,48	
Cycle 4 Day 1	C		7480,4	6587,8	83,59	20,09		9191,0	7481,3	84,46	17,95	
FU Day 28	C		8188,0	6985,2	82,85	18,95		9292,0	7884,8	86,54	19,19	
FU Month 3	C		8087,0	6986,3	83,57	20,71		8989,0	7584,3	82,89	18,98	
FU Month 6	C		7177,2	6185,9	80,87	22,53		7777,0	6483,1	86,20	14,10	

FU Month 9	C	58	63,0	49	84,5	80,61	20,23	56	56,0	41	73,2	83,74	19,18
FU Month 12	C	42	45,7	36	85,7	82,41	19,08	47	47,0	38	80,9	87,28	19,15
FU Month 15	C	37	40,2	30	81,1	83,33	20,06	32	32,0	22	68,8	81,82	27,17
FU Month 18	C	26	28,3	23	88,5	81,16	17,63	22	22,0	15	68,2	85,56	16,51
FU Month 21	C	17	18,5	12	70,6	81,94	19,41	15	15,0	11	73,3	75,76	27,25
FU Month 24	C	11	12,0	8	72,7	79,17	17,25	5	5,0	4	80,0	75,00	9,62
FU Month 27	C	3	3,3	3	100,0	72,22	19,25	3	3,0	2	66,7	100,00	0,00
FU Month 30	C	1	1,1	1	100,0	33,33	NE	1	1,0	1	100,0	100,00	NE
Total CIR score at baseline													
Screening	<=6	63	100,0	58	92,1	78,74	26,82	75	100,0	69	92,0	82,13	21,83
Cycle 4 Day 1	<=6	52	82,5	43	82,7	82,56	24,38	72	96,0	61	84,7	83,61	16,52
FU Day 28	<=6	56	88,9	49	87,5	84,69	15,53	72	96,0	59	81,9	86,72	14,77
FU Month 3	<=6	55	87,3	47	85,5	84,04	18,04	69	92,0	56	81,2	83,93	17,97
FU Month 6	<=6	52	82,5	47	90,4	83,69	21,28	60	80,0	53	88,3	81,76	16,43
FU Month 9	<=6	43	68,3	36	83,7	85,19	19,01	47	62,7	38	80,9	81,58	15,40
FU Month 12	<=6	35	55,6	29	82,9	81,03	18,75	34	45,3	27	79,4	87,04	19,25
FU Month 15	<=6	32	50,8	29	90,6	84,48	17,21	25	33,3	17	68,0	86,27	14,71
FU Month 18	<=6	23	36,5	22	95,7	82,58	16,65	19	25,3	14	73,7	84,52	16,62
FU Month 21	<=6	14	22,2	8	57,1	81,25	31,42	14	18,7	10	71,4	80,00	21,94
FU Month 24	<=6	8	12,7	7	87,5	85,71	17,82	7	9,3	5	71,4	86,67	13,94
FU Month 27	<=6	2	3,2	2	100,0	83,33	0,00	4	5,3	2	50,0	91,67	11,79
FU Month 30	<=6	0	NE	0	NE	NE	NE	1	1,3	1	100,0	100,00	NE
Screening >6													
Screening	>6	192	100,0	183	95,3	83,24	19,49	167	100,0	158	94,6	81,33	20,81
Cycle 4 Day 1	>6	161	83,9	153	95,0	84,42	19,93	152	91,0	136	89,5	81,86	18,75
FU Day 28	>6	174	90,6	152	87,4	82,02	22,25	153	91,6	142	92,8	84,27	18,17
FU Month 3	>6	170	88,5	156	91,8	83,76	20,65	152	91,0	139	91,4	80,34	20,49
FU Month 6	>6	155	80,7	141	91,0	83,22	20,17	132	79,0	115	87,1	81,45	18,83
FU Month 9	>6	121	63,0	102	84,3	81,05	21,88	102	61,1	81	79,4	81,89	19,40
FU Month 12	>6	90	46,9	80	88,9	82,08	20,50	83	49,7	72	86,7	78,70	21,71
FU Month 15	>6	72	37,5	62	86,1	81,45	22,81	60	35,9	52	86,7	78,53	23,42
FU Month 18	>6	56	29,2	47	83,9	81,56	24,14	41	24,6	35	85,4	79,52	20,25
FU Month 21	>6	38	19,8	32	84,2	79,69	22,29	26	15,6	22	84,6	79,55	20,53
FU Month 24	>6	24	12,5	18	75,0	72,22	23,57	11	6,6	11	100,0	75,76	25,13
FU Month 27	>6	11	5,7	9	81,8	66,67	34,36	5	3,0	5	100,0	76,67	27,89
FU Month 30	>6	7	3,6	6	85,7	61,11	44,31	0	NE	0	NE	NE	NE
Calculated creatinine clearance cat. 2													
Screening	<70 ml/min	178	100,0	165	92,7	82,32	21,68	176	100,0	166	94,3	81,43	21,97
Cycle 4 Day 1	<70 ml/min	149	83,7	134	89,9	86,19	19,55	164	93,2	143	87,2	82,63	17,57

FU Day 28	<70 ml/min	162	91,0	142	87,7	82,75	20,19	166	94,3	144	86,7	85,65	16,56
FU Month 3	<70 ml/min	157	88,2	141	89,8	84,28	19,29	159	90,3	138	86,8	81,88	20,48
FU Month 6	<70 ml/min	144	80,9	129	89,6	84,11	19,42	139	79,0	120	86,3	82,22	18,04
FU Month 9	<70 ml/min	117	65,7	97	82,9	82,13	21,42	112	63,6	88	78,6	80,68	17,85
FU Month 12	<70 ml/min	92	51,7	79	85,9	82,07	20,46	87	49,4	73	83,9	81,05	20,28
FU Month 15	<70 ml/min	78	43,8	70	89,7	81,67	22,19	60	34,1	48	80,0	79,17	22,41
FU Month 18	<70 ml/min	59	33,1	50	84,7	83,67	20,62	43	24,4	36	83,7	80,09	20,63
FU Month 21	<70 ml/min	38	21,3	27	71,1	80,86	25,61	31	17,6	27	87,1	79,01	21,97
FU Month 24	<70 ml/min	24	13,5	19	79,2	80,70	18,64	13	7,4	11	84,6	81,82	21,67
FU Month 27	<70 ml/min	10	5,6	8	80,0	70,83	33,03	7	4,0	5	71,4	83,33	28,87
FU Month 30	<70 ml/min	5	2,8	4	80,0	66,67	38,49	1	0,6	1	100,0	100,00	NE
Screening	>=70 ml/min	77	100,0	76	98,7	81,80	21,29	66	100,0	61	92,4	81,97	18,58
Cycle 4 Day 1	>=70 ml/min	64	83,1	62	96,9	79,30	23,12	60	90,9	54	90,0	81,79	19,50
FU Day 28	>=70 ml/min	68	88,3	59	86,8	82,49	22,41	59	89,4	57	96,6	83,33	18,90
FU Month 3	>=70 ml/min	68	88,3	62	91,2	82,80	21,76	62	93,9	57	91,9	80,12	18,21
FU Month 6	>=70 ml/min	63	81,8	59	93,7	81,64	22,47	53	80,3	48	90,6	79,86	18,18
FU Month 9	>=70 ml/min	47	61,0	41	87,2	82,11	20,88	37	56,1	31	83,8	84,95	18,93
FU Month 12	>=70 ml/min	33	42,9	30	90,9	81,11	18,94	30	45,5	26	86,7	80,77	24,35
FU Month 15	>=70 ml/min	26	33,8	21	80,8	84,92	17,40	25	37,9	21	84,0	83,33	20,41
FU Month 18	>=70 ml/min	20	26,0	19	95,0	77,19	24,98	17	25,8	13	76,5	83,33	15,21
FU Month 21	>=70 ml/min	14	18,2	13	92,9	78,21	20,84	9	13,6	5	55,6	83,33	11,79
FU Month 24	>=70 ml/min	8	10,4	6	75,0	61,11	29,19	5	7,6	5	100,0	73,33	25,28
FU Month 27	>=70 ml/min	3	3,9	3	100,0	66,67	33,33	2	3,0	2	100,0	75,00	11,79
FU Month 30	>=70 ml/min	2	2,6	2	100,0	50,00	70,71	0	NE	0	NE	NE	NE
Beta2 microglobulin													
Screening	Missing	3	100,0	3	100,0	83,33	28,87	3	100,0	3	100,0	16,67	16,67
Cycle 4 Day 1	Missing	3	100,0	3	100,0	77,78	25,46	3	100,0	2	66,7	75,00	11,79
FU Day 28	Missing	3	100,0	3	100,0	88,89	9,62	3	100,0	2	66,7	83,33	0,00
FU Month 3	Missing	3	100,0	3	100,0	94,44	9,62	3	100,0	2	66,7	66,67	23,57
FU Month 6	Missing	3	100,0	3	100,0	94,44	9,62	3	100,0	2	66,7	75,00	11,79
FU Month 9	Missing	2	66,7	1	50,0	83,33	NE	3	100,0	2	66,7	75,00	11,79
FU Month 12	Missing	1	33,3	1	100,0	83,33	NE	2	66,7	1	50,0	66,67	NE
FU Month 15	Missing	1	33,3	1	100,0	83,33	NE	2	66,7	1	50,0	66,67	NE
FU Month 18	Missing	1	33,3	1	100,0	66,67	NE	2	66,7	1	50,0	50,00	NE
FU Month 21	Missing	1	33,3	1	100,0	83,33	NE	2	66,7	1	50,0	66,67	NE
FU Month 24	Missing	1	33,3	1	100,0	83,33	NE	1	33,3	1	100,0	66,67	NE
Screening	< 3.5 ug/mL	154	100,0	144	93,5	82,75	21,36	140	100,0	131	93,6	81,30	19,28
Cycle 4 Day 1	< 3.5 ug/mL	127	82,5	117	92,1	83,19	21,72	129	92,1	112	86,8	83,93	16,43

FU Day 28	< 3.5 ug/mL	137	89,0	121	88,3	80,72	21,30	132	94,3	120	90,9	85,14	17,92
FU Month 3	< 3.5 ug/mL	134	87,0	123	91,8	80,62	20,29	130	92,9	115	88,5	82,46	18,58
FU Month 6	< 3.5 ug/mL	128	83,1	115	89,8	81,59	21,22	120	85,7	110	91,7	81,97	18,08
FU Month 9	< 3.5 ug/mL	104	67,5	87	83,7	79,89	22,03	98	70,0	81	82,7	83,54	17,18
FU Month 12	< 3.5 ug/mL	78	50,6	69	88,5	79,71	19,98	75	53,6	67	89,3	81,09	22,27
FU Month 15	< 3.5 ug/mL	65	42,2	57	87,7	80,99	22,15	60	42,9	51	85,0	83,01	18,41
FU Month 18	< 3.5 ug/mL	46	29,9	41	89,1	78,46	25,34	43	30,7	35	81,4	82,38	17,12
FU Month 21	< 3.5 ug/mL	30	19,5	21	70,0	73,02	27,63	27	19,3	22	81,5	81,06	21,39
FU Month 24	< 3.5 ug/mL	19	12,3	15	78,9	66,67	24,40	12	8,6	10	83,3	86,67	13,15
FU Month 27	< 3.5 ug/mL	10	6,5	8	80,0	58,33	29,55	7	5,0	5	71,4	86,67	13,94
FU Month 30	< 3.5 ug/mL	5	3,2	4	80,0	41,67	41,94	1	0,7	1	100,0	100,00	NE
Screening	>= 3.5 ug/mL	98	100,0	94	95,9	81,21	21,76	99	100,0	93	93,9	84,05	20,40
Cycle 4 Day 1	>= 3.5 ug/mL	83	84,7	76	91,6	85,53	19,69	92	92,9	83	90,2	80,52	20,13
FU Day 28	>= 3.5 ug/mL	90	91,8	77	85,6	85,50	20,11	90	90,9	79	87,8	84,81	16,49
FU Month 3	>= 3.5 ug/mL	88	89,8	77	87,5	88,53	18,98	88	88,9	78	88,6	80,13	21,50
FU Month 6	>= 3.5 ug/mL	76	77,6	70	92,1	85,71	19,10	69	69,7	56	81,2	80,95	18,38
FU Month 9	>= 3.5 ug/mL	58	59,2	50	86,2	86,00	19,45	48	48,5	36	75,0	78,24	20,24
FU Month 12	>= 3.5 ug/mL	46	46,9	39	84,8	85,47	19,93	40	40,4	31	77,5	81,18	19,60
FU Month 15	>= 3.5 ug/mL	38	38,8	33	86,8	84,85	19,70	23	23,2	17	73,9	73,53	29,50
FU Month 18	>= 3.5 ug/mL	32	32,7	27	84,4	87,65	14,32	15	15,2	13	86,7	79,49	23,72
FU Month 21	>= 3.5 ug/mL	21	21,4	18	85,7	87,96	16,96	11	11,1	9	81,8	77,78	20,41
FU Month 24	>= 3.5 ug/mL	12	12,2	9	75,0	90,74	8,78	5	5,1	5	100,0	66,67	33,33
FU Month 27	>= 3.5 ug/mL	3	3,1	3	100,0	100,00	0,00	2	2,0	2	100,0	66,67	47,14
FU Month 30	>= 3.5 ug/mL	2	2,0	2	100,0	100,00	0,00	0	NE	0	NE	NE	NE
Immunoglobulin VH, cytogenetics 2													
Screening	12	45	100,0	43	95,6	76,74	20,30	44	100,0	43	97,7	82,95	21,67
Cycle 4 Day 1	12	34	75,6	32	94,1	80,21	21,77	38	86,4	33	86,8	85,35	18,52
FU Day 28	12	39	86,7	37	94,9	77,48	20,87	40	90,9	34	85,0	85,29	20,83
FU Month 3	12	38	84,4	36	94,7	80,56	18,90	39	88,6	32	82,1	81,77	20,89
FU Month 6	12	36	80,0	32	88,9	79,17	18,93	34	77,3	28	82,4	82,14	16,93
FU Month 9	12	26	57,8	22	84,6	79,55	21,78	28	63,6	18	64,3	75,00	25,08
FU Month 12	12	22	48,9	18	81,8	82,41	17,59	23	52,3	15	65,2	81,11	23,46
FU Month 15	12	17	37,8	14	82,4	73,81	26,73	17	38,6	12	70,6	75,00	26,11
FU Month 18	12	15	33,3	12	80,0	76,39	27,94	13	29,5	9	69,2	77,78	18,63
FU Month 21	12	10	22,2	8	80,0	79,17	30,54	7	15,9	5	71,4	83,33	0,00
FU Month 24	12	8	17,8	6	75,0	63,89	28,71	6	13,6	6	100,0	75,00	25,28
FU Month 27	12	5	11,1	4	80,0	58,33	41,94	2	4,5	2	100,0	83,33	23,57
FU Month 30	12	4	8,9	3	75,0	77,78	38,49	1	2,3	1	100,0	100,00	NE

Screening	11q-	46	100,0	43	93,5	82,17	21,02	43	100,0	40	93,0	81,67	17,62
Cycle 4 Day 1	11q-	40	87,0	39	97,5	84,62	22,42	41	95,3	35	85,4	83,33	14,57
FU Day 28	11q-	42	91,3	35	83,3	84,29	21,37	39	90,7	36	92,3	85,65	15,51
FU Month 3	11q-	42	91,3	38	90,5	83,77	23,08	38	88,4	36	94,7	85,65	14,99
FU Month 6	11q-	38	82,6	35	92,1	85,71	17,69	32	74,4	27	84,4	79,01	17,04
FU Month 9	11q-	28	60,9	26	92,9	80,13	27,90	25	58,1	20	80,0	83,33	15,29
FU Month 12	11q-	20	43,5	19	95,0	75,44	27,42	18	41,9	17	94,4	79,41	20,86
FU Month 15	11q-	18	39,1	16	88,9	82,29	26,85	14	32,6	10	71,4	83,33	17,57
FU Month 18	11q-	15	32,6	12	80,0	80,56	31,65	8	18,6	7	87,5	85,71	17,82
FU Month 21	11q-	12	26,1	11	91,7	72,73	32,72	4	9,3	2	50,0	75,00	11,79
FU Month 24	11q-	7	15,2	5	71,4	70,00	32,06	1	2,3	1	100,0	83,33	NE
FU Month 27	11q-	3	6,5	3	100,0	61,11	34,69	0	NE	0	NE	NE	NE
FU Month 30	11q-	3	6,5	3	100,0	44,44	50,92	0	NE	0	NE	NE	NE
Screening	13q-	79	100,0	76	96,2	84,87	23,28	75	100,0	70	93,3	84,05	17,82
Cycle 4 Day 1	13q-	67	84,8	60	89,6	85,83	18,87	68	90,7	60	88,2	84,17	16,36
FU Day 28	13q-	72	91,1	65	90,3	85,13	18,89	72	96,0	65	90,3	85,90	15,37
FU Month 3	13q-	73	92,4	67	91,8	85,82	20,36	69	92,0	61	88,4	81,42	19,27
FU Month 6	13q-	67	84,8	62	92,5	87,90	18,89	63	84,0	56	88,9	84,52	17,65
FU Month 9	13q-	56	70,9	49	87,5	82,65	19,83	52	69,3	41	78,8	85,37	16,33
FU Month 12	13q-	44	55,7	39	88,6	86,32	17,04	40	53,3	38	95,0	83,33	17,76
FU Month 15	13q-	38	48,1	34	89,5	85,78	18,86	29	38,7	25	86,2	82,00	19,20
FU Month 18	13q-	28	35,4	25	89,3	84,00	18,31	21	28,0	19	90,5	80,70	21,70
FU Month 21	13q-	16	20,3	13	81,3	85,90	11,48	16	21,3	14	87,5	82,14	21,15
FU Month 24	13q-	7	8,9	6	85,7	86,11	6,80	7	9,3	6	85,7	80,56	26,70
FU Month 27	13q-	2	2,5	1	50,0	83,33	NE	6	8,0	4	66,7	79,17	31,55
Screening	Norm. K.	65	100,0	61	93,8	83,33	19,25	58	100,0	54	93,1	75,62	25,84
Cycle 4 Day 1	Norm. K.	54	83,1	49	90,7	85,71	18,63	55	94,8	50	90,9	77,67	20,65
FU Day 28	Norm. K.	59	90,8	50	84,7	83,33	20,76	53	91,4	49	92,5	80,95	18,94
FU Month 3	Norm. K.	54	83,1	48	88,9	83,33	19,75	54	93,1	48	88,9	76,74	21,94
FU Month 6	Norm. K.	49	75,4	47	95,9	78,37	24,06	45	77,6	40	88,9	79,17	20,59
FU Month 9	Norm. K.	39	60,0	31	79,5	85,48	17,07	30	51,7	27	90,0	81,48	15,56
FU Month 12	Norm. K.	32	49,2	27	84,4	81,48	18,68	24	41,4	20	83,3	80,00	22,03
FU Month 15	Norm. K.	26	40,0	23	88,5	82,61	15,47	20	34,5	18	90,0	77,78	25,57
FU Month 18	Norm. K.	18	27,7	17	94,4	83,33	15,59	15	25,9	12	80,0	77,78	17,88
FU Month 21	Norm. K.	12	18,5	6	50,0	80,56	19,48	11	19,0	9	81,8	70,37	26,06
FU Month 24	Norm. K.	8	12,3	6	75,0	80,56	16,39	4	6,9	3	75,0	83,33	16,67
FU Month 27	Norm. K.	3	4,6	3	100,0	88,89	9,62	1	1,7	1	100,0	83,33	NE
Screening	Other Abn.	20	100,0	18	90,0	79,63	24,63	22	100,0	20	90,9	85,83	21,13

Cycle 4 Day 1	Other Abn.	18	90,0	16	88,9	78,13	29,01	22	100,0	19	86,4	82,46	20,39
FU Day 28	Other Abn.	18	90,0	14	77,8	78,57	27,29	21	95,5	17	81,0	91,18	13,33
FU Month 3	Other Abn.	18	90,0	14	77,8	84,52	13,81	21	95,5	18	85,7	84,26	21,75
FU Month 6	Other Abn.	17	85,0	12	70,6	83,33	20,10	18	81,8	17	94,4	80,39	16,91
FU Month 9	Other Abn.	15	75,0	10	66,7	80,00	20,49	14	63,6	13	92,9	78,21	20,84
FU Month 12	Other Abn.	7	35,0	6	85,7	72,22	20,18	12	54,5	9	75,0	75,93	32,39
FU Month 15	Other Abn.	5	25,0	4	80,0	83,33	23,57	5	22,7	4	80,0	91,67	16,67
FU Month 18	Other Abn.	3	15,0	3	100,0	83,33	16,67	3	13,6	2	66,7	100,00	0,00
FU Month 21	Other Abn.	2	10,0	2	100,0	83,33	23,57	2	9,1	2	100,0	100,00	0,00
FU Month 24	Other Abn.	2	10,0	2	100,0	83,33	23,57	0	NE	0	NE	NE	NE
Time from first diagnosis													
Screening	Missing	1	100,0	1	100,0	66,67	NE	0	NE	0	NE	NE	NE
Cycle 4 Day 1	Missing	1	100,0	1	100,0	100,00	NE	0	NE	0	NE	NE	NE
FU Day 28	Missing	1	100,0	1	100,0	100,00	NE	0	NE	0	NE	NE	NE
FU Month 3	Missing	1	100,0	1	100,0	100,00	NE	0	NE	0	NE	NE	NE
FU Month 6	Missing	1	100,0	1	100,0	83,33	NE	0	NE	0	NE	NE	NE
FU Month 9	Missing	1	100,0	1	100,0	100,00	NE	0	NE	0	NE	NE	NE
FU Month 12	Missing	1	100,0	1	100,0	83,33	NE	0	NE	0	NE	NE	NE
FU Month 15	Missing	1	100,0	1	100,0	83,33	NE	0	NE	0	NE	NE	NE
FU Month 18	Missing	1	100,0	1	100,0	83,33	NE	0	NE	0	NE	NE	NE
Screening	13 - 24 months	41	100,0	39	95,1	80,77	22,47	31	100,0	31	100,0	83,87	19,48
Cycle 4 Day 1	13 - 24 months	35	85,4	34	97,1	82,84	23,39	30	96,8	27	90,0	89,51	12,36
FU Day 28	13 - 24 months	38	92,7	33	86,8	83,84	21,03	30	96,8	27	90,0	88,89	14,62
FU Month 3	13 - 24 months	36	87,8	34	94,4	83,82	22,28	30	96,8	26	86,7	81,41	21,77
FU Month 6	13 - 24 months	36	87,8	33	91,7	87,37	22,83	30	96,8	25	83,3	86,00	12,44
FU Month 9	13 - 24 months	32	78,0	29	90,6	85,63	18,75	21	67,7	17	81,0	89,22	17,62
FU Month 12	13 - 24 months	21	51,2	18	85,7	82,41	20,19	16	51,6	14	87,5	88,10	17,82
FU Month 15	13 - 24 months	19	46,3	18	94,7	79,63	24,63	16	51,6	10	62,5	91,67	16,20
FU Month 18	13 - 24 months	14	34,1	13	92,9	83,33	27,22	10	32,3	8	80,0	91,67	17,82
FU Month 21	13 - 24 months	11	26,8	9	81,8	68,52	35,79	6	19,4	4	66,7	87,50	15,96
FU Month 24	13 - 24 months	8	19,5	5	62,5	63,33	29,81	3	9,7	2	66,7	91,67	11,79
FU Month 27	13 - 24 months	5	12,2	5	100,0	63,33	41,50	2	6,5	2	100,0	100,00	0,00
FU Month 30	13 - 24 months	3	7,3	3	100,0	55,56	38,49	1	3,2	1	100,0	100,00	NE
Screening	<= 12 months	60	100,0	57	95,0	84,50	17,78	70	100,0	69	98,6	80,92	19,65
Cycle 4 Day 1	<= 12 months	48	80,0	42	87,5	84,13	16,85	60	85,7	55	91,7	81,82	17,35
FU Day 28	<= 12 months	54	90,0	45	83,3	79,26	21,37	62	88,6	56	90,3	83,93	17,97
FU Month 3	<= 12 months	53	88,3	45	84,9	83,33	17,77	59	84,3	55	93,2	81,21	15,73
FU Month 6	<= 12 months	46	76,7	40	87,0	80,42	20,29	47	67,1	43	91,5	81,78	14,00

FU Month 9	<= 12 months	35	58,3	27	77,1	79,63	20,32	37	52,9	31	83,8	82,80	14,58
FU Month 12	<= 12 months	27	45,0	23	85,2	76,09	20,61	29	41,4	27	93,1	78,40	23,03
FU Month 15	<= 12 months	22	36,7	17	77,3	73,53	24,34	17	24,3	16	94,1	84,38	15,48
FU Month 18	<= 12 months	16	26,7	13	81,3	79,49	19,43	13	18,6	12	92,3	83,33	17,41
FU Month 21	<= 12 months	9	15,0	5	55,6	86,67	18,26	7	10,0	6	85,7	77,78	17,21
FU Month 24	<= 12 months	6	10,0	3	50,0	83,33	16,67	2	2,9	1	50,0	100,00	NE
FU Month 27	<= 12 months	1	1,7			NE	NE	1	1,4			NE	NE
FU Month 30	<= 12 months	1	1,7			NE	NE	0	NE			NE	NE
Screening	>24 months	153	100,0	144	94,1	81,71	22,67	141	100,0	127	90,1	81,36	22,28
Cycle 4 Day 1	>24 months	129	84,3	119	92,2	84,17	21,68	134	95,0	115	85,8	81,01	19,23
FU Day 28	>24 months	137	89,5	122	89,1	83,47	20,61	133	94,3	118	88,7	84,60	17,45
FU Month 3	>24 months	135	88,2	123	91,1	83,88	20,35	132	93,6	114	86,4	81,43	21,24
FU Month 6	>24 months	124	81,0	114	91,9	83,19	19,77	115	81,6	100	87,0	80,33	20,57
FU Month 9	>24 months	96	62,7	81	84,4	81,48	22,36	91	64,5	71	78,0	79,58	19,35
FU Month 12	>24 months	76	49,7	67	88,2	83,58	19,78	72	51,1	58	80,6	80,46	21,21
FU Month 15	>24 months	62	40,5	55	88,7	86,06	18,36	52	36,9	43	82,7	76,36	23,91
FU Month 18	>24 months	48	31,4	42	87,5	82,14	21,59	37	26,2	29	78,4	77,01	19,63
FU Month 21	>24 months	32	20,9	26	81,3	82,69	19,14	27	19,1	22	81,5	78,79	22,53
FU Month 24	>24 months	18	11,8	17	94,4	78,43	21,05	13	9,2	13	100,0	75,64	23,19
FU Month 27	>24 months	7	4,6	6	85,7	75,00	22,97	6	4,3	5	83,3	73,33	25,28
FU Month 30	>24 months	3	2,0	3	100,0	66,67	57,74	0	NE	0	NE	NE	NE
High circulating tumor burden													
Screening	Missing	0	NE	0	NE	NE	NE	2	100,0	1	50,0	100,00	NE
Cycle 4 Day 1	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	66,67	NE
FU Day 28	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	66,67	NE
FU Month 3	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	83,33	NE
FU Month 6	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	83,33	NE
FU Month 9	Missing	0	NE			NE	NE	1	50,0			NE	NE
Screening	<25x10**9 cells/L	60	100,0	55	91,7	81,21	21,29	67	100,0	64	95,5	81,51	20,81
Cycle 4 Day 1	<25x10**9 cells/L	50	83,3	45	90,0	82,22	20,23	61	91,0	52	85,2	84,29	15,97
FU Day 28	<25x10**9 cells/L	56	93,3	47	83,9	79,79	24,56	61	91,0	53	86,9	85,85	16,47
FU Month 3	<25x10**9 cells/L	54	90,0	47	87,0	82,98	19,81	59	88,1	50	84,7	83,00	18,29
FU Month 6	<25x10**9 cells/L	50	83,3	44	88,0	75,38	24,77	51	76,1	41	80,4	82,52	17,06
FU Month 9	<25x10**9 cells/L	36	60,0	27	75,0	79,63	19,25	41	61,2	29	70,7	86,21	16,10
FU Month 12	<25x10**9 cells/L	29	48,3	24	82,8	75,69	19,65	34	50,7	25	73,5	82,67	21,77
FU Month 15	<25x10**9 cells/L	24	40,0	20	83,3	75,00	27,31	23	34,3	15	65,2	83,33	16,67
FU Month 18	<25x10**9 cells/L	20	33,3	18	90,0	79,63	25,28	19	28,4	14	73,7	80,95	20,52
FU Month 21	<25x10**9 cells/L	14	23,3	10	71,4	75,00	26,35	10	14,9	8	80,0	87,50	14,77

FU Month 24	<25x10**9 cells/L	8	13,3	5	62,5	63,33	24,72	6	9,0	5	83,3	76,67	27,89
FU Month 27	<25x10**9 cells/L	4	6,7	3	75,0	38,89	34,69	1	1,5	1	100,0	100,00	NE
FU Month 30	<25x10**9 cells/L	4	6,7	3	75,0	55,56	38,49	1	1,5	1	100,0	100,00	NE
Screening	>=25x10**9 cells/L	195	100,0	186	95,4	82,44	21,63	173	100,0	162	93,6	81,48	21,26
Cycle 4 Day 1	>=25x10**9 cells/L	163	83,6	151	92,6	84,55	21,18	162	93,6	144	88,9	81,83	18,79
FU Day 28	>=25x10**9 cells/L	174	89,2	154	88,5	83,55	19,52	163	94,2	147	90,2	84,81	17,55
FU Month 3	>=25x10**9 cells/L	171	87,7	156	91,2	84,08	20,16	161	93,1	144	89,4	80,79	20,42
FU Month 6	>=25x10**9 cells/L	157	80,5	144	91,7	85,76	18,28	140	80,9	126	90,0	81,22	18,50
FU Month 9	>=25x10**9 cells/L	128	65,6	111	86,7	82,73	21,66	107	61,8	90	84,1	80,37	18,63
FU Month 12	>=25x10**9 cells/L	96	49,2	85	88,5	83,53	19,84	83	48,0	74	89,2	80,41	21,25
FU Month 15	>=25x10**9 cells/L	80	41,0	71	88,8	84,51	18,76	62	35,8	54	87,1	79,63	23,05
FU Month 18	>=25x10**9 cells/L	59	30,3	51	86,4	82,68	20,81	41	23,7	35	85,4	80,95	19,02
FU Month 21	>=25x10**9 cells/L	38	19,5	30	78,9	81,67	23,30	30	17,3	24	80,0	77,08	21,88
FU Month 24	>=25x10**9 cells/L	24	12,3	20	83,3	79,17	21,54	12	6,9	11	91,7	80,30	20,84
FU Month 27	>=25x10**9 cells/L	9	4,6	8	88,9	81,25	22,60	8	4,6	6	75,0	77,78	25,09
FU Month 30	>=25x10**9 cells/L	3	1,5	3	100,0	66,67	57,74	0	NE	0	NE	NE	NE

¹ in study: number of subjects in study at respective visit; % based on baseline

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit

² mean: descriptive statistics - absolute values Clinical

cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/t_pro_mean.sas

Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/t_pro_mean_sg_EQC30_IT_label_09MAY2013_21004.xls 04MAR2020

17:18

POPULATION: Labelpopulation, Intent-to-Treat Patients ENDPOINT: EORTC QoL 30

MODEL: Unadjusted Analysis STUDY: CLL11(BO21004), Stage

2

Compliance/Mean

Emotional Functioning Scale

		GClb (N=255)						RC1b (N=242)						
		Patients			Statistics			Patients			Statistics			
Name	Level	in study ¹	%	with value ¹	%	Mean ²	SD(mean)	in study ¹	%	with value ¹	%	Mean ²	SD(mean)	
All														
Screening	n/a	255	100,0	240	94,1	75,28	21,42	242	100,0	227	93,8	76,47	21,81	
Cycle 4 Day 1	n/a	213	83,5	196	92,0	82,70	18,71	224	92,6	197	87,9	81,15	19,52	
FU Day 28	n/a	230	90,2	200	87,0	81,10	22,64	225	93,0	201	89,3	82,61	17,83	
FU Month 3	n/a	225	88,2	203	90,2	80,56	22,83	221	91,3	195	88,2	80,43	20,00	
FU Month 6	n/a	207	81,2	188	90,8	81,63	20,05	192	79,3	169	88,0	81,30	20,44	
FU Month 9	n/a	164	64,3	138	84,1	82,97	19,96	149	61,6	119	79,9	81,56	18,24	
FU Month 12	n/a	125	49,0	109	87,2	82,98	19,17	117	48,3	98	83,8	82,54	19,88	
FU Month 15	n/a	104	40,8	91	87,5	85,26	18,66	85	35,1	69	81,2	80,80	19,45	
FU Month 18	n/a		79	31,0	69	87,3	83,90	18,21	60	24,8	49	81,7	79,71	24,11
FU Month 21	n/a		52	20,4	40	76,9	83,89	20,42	40	16,5	32	80,0	78,39	25,03
FU Month 24	n/a		32	12,5	25	78,1	80,67	18,43	18	7,4	16	88,9	88,54	13,57
FU Month 27	n/a		13	5,1	11	84,6	77,27	21,11	9	3,7	7	77,8	88,10	13,49
FU Month 30	n/a		7	2,7	6	85,7	70,37	29,17	1	0,4	1	100,0	100,00	NE
Gender														
Screening	Female	97	100,0	90	92,8	72,10	23,31	95	100,0	87	91,6	71,97	22,77	
Cycle 4 Day 1	Female	84	86,6	77	91,7	78,93	19,94	88	92,6	78	88,6	76,03	20,62	
FU Day 28	Female	90	92,8	83	92,2	77,61	24,06	91	95,8	79	86,8	78,20	20,66	
FU Month 3	Female	88	90,7	81	92,0	77,95	24,00	87	91,6	76	87,4	75,33	21,71	
FU Month 6	Female	84	86,6	72	85,7	81,29	18,95	77	81,1	68	88,3	81,13	19,46	
FU Month 9	Female	70	72,2	59	84,3	79,38	23,08	61	64,2	46	75,4	78,14	19,59	
FU Month 12	Female	56	57,7	49	87,5	81,52	19,91	47	49,5	39	83,0	78,35	21,42	
FU Month 15	Female	47	48,5	41	87,2	84,28	19,09	33	34,7	28	84,8	78,57	20,21	
FU Month 18	Female	34	35,1	29	85,3	82,18	17,50	26	27,4	22	84,6	72,22	28,52	
FU Month 21	Female	21	21,6	15	71,4	77,78	23,92	17	17,9	15	88,2	73,89	26,89	
FU Month 24	Female	12	12,4	10	83,3	75,00	23,90	6	6,3	5	83,3	98,33	3,73	
FU Month 27	Female	6	6,2	5	83,3	70,00	24,01	2	2,1	1	50,0	100,00	NE	
FU Month 30	Female	4	4,1	3	75,0	62,96	39,02	1	1,1	1	100,0	100,00	NE	

Screening	Male	158	100,0	150	94,9	77,19	20,04	147	100,0	140	95,2	79,27	20,79
Cycle 4 Day 1	Male	129	81,6	119	92,2	85,13	17,53	136	92,5	119	87,5	84,50	18,09
FU Day 28	Male	140	88,6	117	83,6	83,57	21,34	134	91,2	122	91,0	85,47	15,13
FU Month 3	Male	137	86,7	122	89,1	82,29	21,95	134	91,2	119	88,8	83,68	18,18
FU Month 6	Male	123	77,8	116	94,3	81,85	20,79	115	78,2	101	87,8	81,41	21,17
FU Month 9	Male	94	59,5	79	84,0	85,65	16,93	88	59,9	73	83,0	83,71	17,13
FU Month 12	Male	69	43,7	60	87,0	84,17	18,63	70	47,6	59	84,3	85,31	18,46
FU Month 15	Male	57	36,1	50	87,7	86,06	18,45	52	35,4	41	78,8	82,32	19,02
FU Month 18	Male	45	28,5	40	88,9	85,14	18,84	34	23,1	27	79,4	85,80	18,17
FU Month 21	Male	31	19,6	25	80,6	87,56	17,52	23	15,6	17	73,9	82,35	23,36
FU Month 24	Male	20	12,7	15	75,0	84,44	13,31	12	8,2	11	91,7	84,09	14,17
FU Month 27	Male	7	4,4	6	85,7	83,33	18,26	7	4,8	6	85,7	86,11	13,61
FU Month 30	Male	3	1,9	3	100,0	77,78	20,97	0	NE	0	NE	NE	NE
Age													
Screening	<75 years	130	100,0	123	94,6	75,11	20,19	120	100,0	109	90,8	77,24	20,34
Cycle 4 Day 1	<75 years	106	81,5	100	94,3	81,36	17,72	112	93,3	98	87,5	81,26	18,98
FU Day 28	<75 years	119	91,5	105	88,2	82,67	20,67	110	91,7	103	93,6	82,82	17,72
FU Month 3	<75 years	116	89,2	106	91,4	82,21	19,81	109	90,8	99	90,8	80,39	20,32
FU Month 6	<75 years	108	83,1	98	90,7	81,52	20,09	99	82,5	88	88,9	80,87	21,03
FU Month 9	<75 years	85	65,4	73	85,9	81,39	20,58	74	61,7	62	83,8	81,77	18,64
FU Month 12	<75 years	63	48,5	59	93,7	83,80	17,58	60	50,0	53	88,3	83,18	21,40
FU Month 15	<75 years	54	41,5	47	87,0	83,27	19,94	44	36,7	35	79,5	81,90	21,81
FU Month 18	<75 years	43	33,1	39	90,7	84,83	17,51	27	22,5	22	81,5	78,41	28,48
FU Month 21	<75 years	26	20,0	22	84,6	85,23	18,89	17	14,2	13	76,5	83,33	25,00
FU Month 24	<75 years	18	13,8	14	77,8	81,55	15,04	6	5,0	5	83,3	93,33	9,13
FU Month 27	<75 years	7	5,4	5	71,4	75,00	18,63	2	1,7	1	50,0	100,00	NE
FU Month 30	<75 years	4	3,1	3	75,0	66,67	8,33	0	NE	0	NE	NE	NE
Screening	>=75 years	125	100,0	117	93,6	75,45	22,73	122	100,0	118	96,7	75,75	23,15
Cycle 4 Day 1	>=75 years	107	85,6	96	89,7	84,09	19,69	112	91,8	99	88,4	81,03	20,15
FU Day 28	>=75 years	111	88,8	95	85,6	79,36	24,64	115	94,3	98	85,2	82,40	18,02
FU Month 3	>=75 years	109	87,2	97	89,0	78,75	25,71	112	91,8	96	85,7	80,47	19,77
FU Month 6	>=75 years	99	79,2	90	90,9	81,76	20,13	93	76,2	81	87,1	81,76	19,90
FU Month 9	>=75 years	79	63,2	65	82,3	84,74	19,24	75	61,5	57	76,0	81,34	17,95
FU Month 12	>=75 years	62	49,6	50	80,6	82,00	21,04	57	46,7	45	78,9	81,79	18,14
FU Month 15	>=75 years	50	40,0	44	88,0	87,37	17,15	41	33,6	34	82,9	79,66	16,94
FU Month 18	>=75 years	36	28,8	30	83,3	82,69	19,32	33	27,0	27	81,8	80,76	20,38
FU Month 21	>=75 years	26	20,8	18	69,2	82,25	22,61	23	18,9	19	82,6	75,00	25,15
FU Month 24	>=75 years	14	11,2	11	78,6	79,55	22,78	12	9,8	11	91,7	86,36	15,03

FU Month 27	>=75 years	64,8	6100,0	79,17	24,58	75,7	685,7	86,11	13,61				
FU Month 30	>=75 years	32,4	3100,0	74,07	44,91	10,8	1100,0	100,00					NE
Race													
Screening	Other	9100,0	9100,0	78,70	10,30	11100,0	11100,0	78,79	12,56				
Cycle 4 Day 1	Other	777,8	7100,0	86,90	12,60	1090,9	990,0	75,00	20,83				
FU Day 28	Other	888,9	8100,0	80,21	19,38	1090,9	10100,0	83,33	12,42				
FU Month 3	Other	888,9	787,5	80,95	22,93	1090,9	10100,0	79,17	18,11				
FU Month 6	Other	888,9	787,5	88,10	24,47	872,7	8100,0	84,38	14,39				
FU Month 9	Other	444,4	375,0	75,00	0,00	545,5	480,0	87,50	14,43				
FU Month 12	Other	333,3	266,7	75,00	0,00	436,4	4100,0	83,33	19,25				
FU Month 15	Other	222,2	150,0	91,67		436,4	4100,0	87,50	14,43				
FU Month 18	Other	222,2	150,0	100,00		218,2	2100,0	83,33	23,57				
FU Month 21	Other	222,2	150,0	100,00		218,2	2100,0	83,33	23,57				
FU Month 24	Other	222,2	150,0	91,67		19,1	0	NE	NE				NE
FU Month 27	Other	111,1				19,1			NE				NE
FU Month 30	Other	111,1				0	NE		NE				NE
Screening													
Screening	White	246	100,0	231	93,9	75,14	21,74	231	100,0	216	93,5	76,35	22,19
Cycle 4 Day 1	White	206	83,7	189	91,7	82,54	18,91	214	92,6	188	87,9	81,44	19,47
FU Day 28	White	222	90,2	192	86,5	81,13	22,81	215	93,1	191	88,8	82,58	18,09
FU Month 3	White	217	88,2	196	90,3	80,54	22,88	211	91,3	185	87,7	80,50	20,14
FU Month 6	White	199	80,9	181	91,0	81,38	19,90	184	79,7	161	87,5	81,14	20,72
FU Month 9	White	160	65,0	135	84,4	83,15	20,14	144	62,3	115	79,9	81,35	18,37
FU Month 12	White	122	49,6	107	87,7	83,13	19,32	113	48,9	94	83,2	82,51	20,01
FU Month 15	White	102	41,5	90	88,2	85,19	18,75	81	35,1	65	80,2	80,38	19,73
FU Month 18	White	77	31,3	68	88,3	83,66	18,24	58	25,1	47	81,0	79,55	24,37
FU Month 21	White	50	20,3	39	78,0	83,48	20,52	38	16,5	30	78,9	78,06	25,47
FU Month 24	White	30	12,2	24	80,0	80,21	18,68	17	7,4	16	94,1	88,54	13,57
FU Month 27	White	12	4,9	11	91,7	77,27	21,11	8	3,5	7	87,5	88,10	13,49
FU Month 30	White	6	2,4	6	100,0	70,37	29,17	1	0,4	1	100,0	100,00	NE
Geographical Region													
Screening	Asia-Pacific	20	100,0	20	100,0	77,78	23,22	18	100,0	17	94,4	75,98	26,17
Cycle 4 Day 1	Asia-Pacific	15	75,0	15	100,0	82,41	25,90	16	88,9	15	93,8	80,37	18,71
FU Day 28	Asia-Pacific	18	90,0	18	100,0	81,02	28,98	18	100,0	16	88,9	85,94	18,44
FU Month 3	Asia-Pacific	18	90,0	16	88,9	78,65	28,54	18	100,0	16	88,9	82,29	16,63
FU Month 6	Asia-Pacific	16	80,0	14	87,5	72,22	33,62	17	94,4	15	88,2	82,22	17,21
FU Month 9	Asia-Pacific	14	70,0	12	85,7	75,00	29,94	13	72,2	9	69,2	83,33	17,18
FU Month 12	Asia-Pacific	10	50,0	8	80,0	88,54	17,78	10	55,6	10	100,0	82,50	15,93
FU Month 15	Asia-Pacific	8	40,0	6	75,0	84,72	23,22	9	50,0	9	100,0	74,07	19,30

FU Month 18	Asia-Pacific	630,0	466,7	97,92	4,17	633,3	6100,0	66,67	27,89
FU Month 21	Asia-Pacific	525,0	360,0	100,00	0,00	422,2	4100,0	64,58	34,94
FU Month 24	Asia-Pacific	315,0	266,7	91,67	0,00	15,6	0	NE	NE
FU Month 27	Asia-Pacific	15,0		NE	NE	15,6		NE	NE
FU Month 30	Asia-Pacific	15,0		NE	NE	0	NE	NE	NE
Screening	Central and South America	3100,0	3100,0	75,00	8,33	2100,0	2100,0	66,67	11,79
Cycle 4 Day 1	Central and South America	3100,0	3100,0	91,67	8,33	2100,0	2100,0	83,33	11,79
FU Day 28	Central and South America	3100,0	3100,0	77,78	12,73	2100,0	2100,0	87,50	5,89
FU Month 3	Central and South America	3100,0	3100,0	86,11	12,73	2100,0	2100,0	91,67	11,79
FU Month 6	Central and South America	266,7	2100,0	100,00	0,00	2100,0	2100,0	83,33	11,79
FU Month 9	Central and South America	266,7	2100,0	87,50	17,68	150,0	1100,0	100,00	NE
FU Month 12	Central and South America	266,7	2100,0	83,33	11,79	150,0	1100,0	83,33	NE
FU Month 15	Central and South America	133,3	1100,0	100,00	NE	0	NE	0	NE
FU Month 18	Central and South America	133,3	1100,0	100,00	NE	0	NE	0	NE
FU Month 21	Central and South America	133,3	1100,0	91,67	NE	0	NE	0	NE
FU Month 24	Central and South America	133,3	1100,0	83,33	NE	0	NE	0	NE
Screening	North America	12100,0	12100,0	77,08	21,06	13100,0	1292,3	81,94	15,42
Cycle 4 Day 1	North America	975,0	9100,0	83,33	20,41	1292,3	12100,0	88,89	12,97
FU Day 28	North America	1191,7	11100,0	78,79	19,14	13100,0	13100,0	85,04	15,57
FU Month 3	North America	1191,7	11100,0	73,48	26,83	1292,3	12100,0	86,81	11,49
FU Month 6	North America	1191,7	1090,9	70,83	24,61	1184,6	11100,0	81,82	17,80
FU Month 9	North America	866,7	8100,0	82,29	18,60	969,2	9100,0	86,11	8,33
FU Month 12	North America	866,7	787,5	73,81	22,27	753,8	7100,0	86,90	11,64
FU Month 15	North America	650,0	6100,0	86,11	18,76	646,2	583,3	81,67	9,13
FU Month 18	North America	433,3	4100,0	83,33	18,00	323,1	3100,0	91,67	8,33
FU Month 21	North America	325,0	266,7	79,17	17,68	17,7	1100,0	91,67	NE
FU Month 24	North America	325,0	266,7	87,50	5,89	17,7	1100,0	75,00	NE
FU Month 27	North America	216,7	150,0	100,00	NE	17,7	1100,0	83,33	NE
Screening	Other	45100,0	4191,1	72,97	17,75	44100,0	4193,2	75,27	19,52
Cycle 4 Day 1	Other	3782,2	3389,2	82,58	17,97	4090,9	3485,0	82,35	18,66
FU Day 28	Other	3782,2	3389,2	86,28	14,28	3988,6	3794,9	83,78	17,23
FU Month 3	Other	3884,4	3489,5	83,09	13,37	3886,4	3694,7	79,40	21,31
FU Month 6	Other	3577,8	3188,6	84,95	13,34	3375,0	3193,9	82,53	21,01
FU Month 9	Other	2657,8	2284,6	85,98	13,46	2454,5	1979,2	84,21	13,86
FU Month 12	Other	1737,8	1694,1	83,33	19,25	1636,4	1487,5	86,90	12,96
FU Month 15	Other	1226,7	1191,7	90,66	11,47	920,5	888,9	88,54	12,55
FU Month 18	Other	1022,2	990,0	85,19	11,62	715,9	685,7	93,06	6,27
FU Month 21	Other	715,6	685,7	88,89	12,55	49,1	4100,0	85,42	12,50

FU Month 24	Other	6	13,3	5	83,3	81,67	17,08	3	6,8	3	100,0	94,44	4,81
FU Month 27	Other	4	8,9	4	100,0	79,17	14,43	1	2,3	1	100,0	75,00	NE
FU Month 30	Other	2	4,4	2	100,0	83,33	23,57	0	NE	0	NE	NE	NE
Screening	Western Europe	175	100,0	164	93,7	75,42	22,35	165	100,0	155	93,9	76,54	22,50
Cycle 4 Day 1	Western Europe	149	85,1	136	91,3	82,52	18,22	154	93,3	134	87,0	80,20	20,41
FU Day 28	Western Europe	161	92,0	135	83,9	80,10	23,84	153	92,7	133	86,9	81,58	18,33
FU Month 3	Western Europe	155	88,6	139	89,7	80,60	23,88	151	91,5	129	85,4	79,72	20,74
FU Month 6	Western Europe	143	81,7	131	91,6	82,40	18,85	129	78,2	110	85,3	80,73	21,29
FU Month 9	Western Europe	114	65,1	94	82,5	83,24	19,99	102	61,8	81	79,4	80,01	20,00
FU Month 12	Western Europe	88	50,3	76	86,4	83,15	19,32	83	50,3	66	79,5	81,14	22,37
FU Month 15	Western Europe	77	44,0	67	87,0	84,12	19,43	61	37,0	47	77,0	80,67	21,08
FU Month 18	Western Europe	58	33,1	51	87,9	82,30	19,63	44	26,7	34	77,3	78,59	25,30
FU Month 21	Western Europe	36	20,6	28	77,8	81,15	22,71	31	18,8	23	74,2	78,99	25,36
FU Month 24	Western Europe	19	10,9	15	78,9	77,78	21,52	13	7,9	12	92,3	88,19	14,85
FU Month 27	Western Europe	6	3,4	6	100,0	72,22	25,09	6	3,6	5	83,3	91,67	14,43
FU Month 30	Western Europe	4	2,3	4	100,0	63,89	32,63	1	0,6	1	100,0	100,00	NE
FCgamma receptor IIa													
Screening	131HH	58	100,0	53	91,4	68,92	24,38	76	100,0	72	94,7	74,85	21,98
Cycle 4 Day 1	131HH	49	84,5	43	87,8	78,88	18,84	65	85,5	60	92,3	81,85	19,26
FU Day 28	131HH	51	87,9	46	90,2	76,99	25,71	70	92,1	61	87,1	85,25	14,06
FU Month 3	131HH	51	87,9	47	92,2	75,35	24,69	64	84,2	54	84,4	80,71	20,08
FU Month 6	131HH	49	84,5	45	91,8	77,10	19,77	55	72,4	48	87,3	82,29	18,96
FU Month 9	131HH	39	67,2	30	76,9	78,33	20,95	41	53,9	32	78,0	85,94	14,88
FU Month 12	131HH	28	48,3	24	85,7	74,19	21,23	34	44,7	29	85,3	84,77	16,22
FU Month 15	131HH	23	39,7	19	82,6	79,53	18,89	24	31,6	20	83,3	83,33	16,88
FU Month 18	131HH	17	29,3	14	82,4	78,37	17,78	16	21,1	13	81,3	77,56	28,54
FU Month 21	131HH	13	22,4	8	61,5	80,21	31,48	11	14,5	10	90,9	61,67	34,74
FU Month 24	131HH	11	19,0	7	63,6	72,62	29,55	1	1,3	1	100,0	75,00	NE
FU Month 27	131HH	4	6,9	3	75,0	72,22	34,69	1	1,3	1	100,0	91,67	NE
FU Month 30	131HH	3	5,2	2	66,7	48,61	37,32	0	NE	0	NE	NE	NE
Screening	131HR	125	100,0	118	94,4	76,51	21,40	114	100,0	109	95,6	78,72	20,70
Cycle 4 Day 1	131HR	105	84,0	98	93,3	81,80	19,41	110	96,5	99	90,0	80,67	21,21
FU Day 28	131HR	116	92,8	101	87,1	80,64	22,76	105	92,1	95	90,5	81,11	19,71
FU Month 3	131HR	114	91,2	102	89,5	81,32	22,03	107	93,9	95	88,8	81,58	19,80
FU Month 6	131HR	104	83,2	93	89,4	83,24	19,24	95	83,3	84	88,4	79,93	21,80
FU Month 9	131HR	84	67,2	71	84,5	83,80	19,51	76	66,7	60	78,9	80,37	18,76
FU Month 12	131HR	64	51,2	57	89,1	84,75	18,03	57	50,0	48	84,2	83,16	18,63
FU Month 15	131HR	53	42,4	45	84,9	86,60	17,70	44	38,6	35	79,5	81,67	17,24

FU Month 18	131HR	43	34,4	37	86,0	84,68	17,62	32	28,1	26	81,3	80,98	16,92
FU Month 21	131HR	26	20,8	20	76,9	82,36	18,65	21	18,4	16	76,2	82,81	15,66
FU Month 24	131HR	12	9,6	11	91,7	81,06	12,96	12	10,5	10	83,3	85,00	14,59
FU Month 27	131HR	6	4,8	5	83,3	73,33	18,07	6	5,3	4	66,7	87,50	15,96
FU Month 30	131HR	3	2,4	3	100,0	75,00	22,05	1	0,9	1	100,0	100,00	NE
Screening	131RR	49	100,0	48	98,0	77,78	17,97	33	100,0	29	87,9	78,45	20,84
Cycle 4 Day 1	131RR	40	81,6	38	95,0	87,06	14,33	31	93,9	25	80,6	82,11	15,34
FU Day 28	131RR	42	85,7	35	83,3	86,43	15,93	32	97,0	29	90,6	84,96	16,69
FU Month 3	131RR	39	79,6	37	94,9	83,78	22,04	32	97,0	29	90,6	79,89	21,31
FU Month 6	131RR	35	71,4	33	94,3	82,15	20,93	27	81,8	23	85,2	83,33	21,90
FU Month 9	131RR	24	49,0	22	91,7	82,20	20,78	19	57,6	17	89,5	80,88	19,93
FU Month 12	131RR	18	36,7	17	94,4	84,80	18,92	17	51,5	14	82,4	77,18	26,20
FU Month 15	131RR	16	32,7	16	100,0	81,25	24,06	11	33,3	9	81,8	77,78	22,44
FU Month 18	131RR	14	28,6	14	100,0	85,71	20,26	8	24,2	7	87,5	72,62	40,46
FU Month 21	131RR	8	16,3	7	87,5	89,29	15,75	5	15,2	4	80,0	95,83	8,33
FU Month 24	131RR	5	10,2	4	80,0	87,50	10,76	3	9,1	3	100,0	100,00	0,00
FU Month 27	131RR	2	4,1	2	100,0	91,67	11,79	1	3,0	1	100,0	100,00	NE
FU Month 30	131RR	1	2,0	1	100,0	100,00	NE	0	NE	0	NE	NE	NE
Screening	Missing	23	100,0	21	91,3	78,70	18,89	19	100,0	17	89,5	65,52	27,31
Cycle 4 Day 1	Missing	19	82,6	17	89,5	87,75	21,47	18	94,7	13	72,2	79,70	15,77
FU Day 28	Missing	21	91,3	18	85,7	83,80	24,16	18	94,7	16	88,9	77,26	20,22
FU Month 3	Missing	21	91,3	17	81,0	83,33	23,57	18	94,7	17	94,4	74,02	19,07
FU Month 6	Missing	19	82,6	17	89,5	83,82	23,29	15	78,9	14	93,3	82,74	15,14
FU Month 9	Missing	17	73,9	15	88,2	89,44	18,49	13	68,4	10	76,9	75,83	21,68
FU Month 12	Missing	15	65,2	11	73,3	90,15	16,59	9	47,4	7	77,8	79,76	29,21
FU Month 15	Missing	12	52,2	11	91,7	95,45	5,73	6	31,6	5	83,3	70,00	36,61
FU Month 18	Missing	5	21,7	4	80,0	89,58	20,83	4	21,1	3	75,0	94,44	4,81
FU Month 21	Missing	5	21,7	5	100,0	88,33	13,94	3	15,8	2	66,7	91,67	0,00
FU Month 24	Missing	4	17,4	3	75,0	88,89	4,81	2	10,5	2	100,0	95,83	5,89
FU Month 27	Missing	1	4,3	1	100,0	83,33	NE	1	5,3	1	100,0	75,00	NE
FCgamma receptor IIIa													
Screening	158FF	103	100,0	100	97,1	77,11	21,59	83	100,0	78	94,0	76,64	17,08
Cycle 4 Day 1	158FF	89	86,4	83	93,3	85,98	17,54	78	94,0	72	92,3	78,20	19,99
FU Day 28	158FF	96	93,2	84	87,5	80,89	23,35	78	94,0	74	94,9	82,92	17,82
FU Month 3	158FF	94	91,3	84	89,4	83,40	22,19	78	94,0	70	89,7	82,02	19,28
FU Month 6	158FF	86	83,5	76	88,4	84,80	19,63	64	77,1	59	92,2	82,34	20,36
FU Month 9	158FF	71	68,9	59	83,1	83,90	20,52	47	56,6	43	91,5	82,56	16,73
FU Month 12	158FF	48	46,6	42	87,5	86,31	16,34	38	45,8	34	89,5	83,74	19,25

FU Month 15	158FF	37	35,9	32	86,5	88,28	18,56	30	36,1	24	80,0	83,33	15,73
FU Month 18	158FF	27	26,2	24	88,9	85,76	18,95	21	25,3	17	81,0	80,39	22,23
FU Month 21	158FF	16	15,5	15	93,8	87,59	18,03	9	10,8	8	88,9	81,25	25,49
FU Month 24	158FF	8	7,8	7	87,5	83,33	11,79	3	3,6	2	66,7	91,67	11,79
FU Month 27	158FF	5	4,9	4	80,0	83,33	23,57	1	1,2	1	100,0	100,00	NE
FU Month 30	158FF	3	2,9	3	100,0	77,78	20,97	0	NE	0	NE	NE	NE
Screening	158FV	119	100,0	110	92,4	73,59	21,96	109	100,0	103	94,5	76,81	23,51
Cycle 4 Day 1	158FV	99	83,2	90	90,9	79,88	18,85	100	91,7	85	85,0	81,14	20,29
FU Day 28	158FV	105	88,2	90	85,7	81,11	21,77	101	92,7	87	86,1	81,99	18,37
FU Month 3	158FV	101	84,9	93	92,1	78,20	23,18	97	89,0	84	86,6	79,56	21,89
FU Month 6	158FV	94	79,0	87	92,6	79,05	19,65	83	76,1	72	86,7	81,60	20,60
FU Month 9	158FV	71	59,7	61	85,9	81,28	19,46	65	59,6	49	75,4	81,46	19,64
FU Month 12	158FV	60	50,4	55	91,7	79,90	20,37	52	47,7	42	80,8	80,16	21,70
FU Month 15	158FV	52	43,7	46	88,5	83,88	17,82	36	33,0	30	83,3	79,17	19,91
FU Month 18	158FV	44	37,0	38	86,4	83,48	17,50	24	22,0	20	83,3	74,58	29,68
FU Month 21	158FV	28	23,5	18	64,3	80,56	24,42	18	16,5	14	77,8	70,83	30,62
FU Month 24	158FV	18	15,1	13	72,2	78,85	22,21	6	5,5	5	83,3	88,33	21,73
FU Month 27	158FV	6	5,0	5	83,3	70,00	24,01	2	1,8	1	50,0	100,00	NE
FU Month 30	158FV	4	3,4	3	75,0	62,96	39,02	0	NE	0	NE	NE	NE
Screening	158VV	16	100,0	15	93,8	77,22	19,02	33	100,0	31	93,9	79,39	21,94
Cycle 4 Day 1	158VV	12	75,0	11	91,7	85,61	16,28	30	90,9	28	93,3	87,10	16,72
FU Day 28	158VV	14	87,5	13	92,9	82,69	23,19	30	90,9	26	86,7	88,14	12,73
FU Month 3	158VV	15	93,8	12	80,0	80,56	22,84	30	90,9	26	86,7	83,01	13,93
FU Month 6	158VV	14	87,5	13	92,9	83,97	19,68	30	90,9	24	80,0	76,27	22,96
FU Month 9	158VV	12	75,0	10	83,3	85,00	19,16	25	75,8	18	72,0	80,40	17,37
FU Month 12	158VV	8	50,0	7	87,5	79,76	26,73	20	60,6	17	85,0	87,25	11,46
FU Month 15	158VV	8	50,0	7	87,5	72,62	26,23	14	42,4	11	78,6	82,58	15,57
FU Month 18	158VV	4	25,0	4	100,0	75,00	21,52	11	33,3	9	81,8	84,88	14,97
FU Month 21	158VV	3	18,8	2	66,7	75,00	11,79	9	27,3	7	77,8	84,52	13,11
FU Month 24	158VV	2	12,5	2	100,0	70,83	29,46	7	21,2	7	100,0	85,71	9,27
FU Month 27	158VV	1	6,3	1	100,0	83,33	NE	5	15,2	4	80,0	85,42	14,23
FU Month 30	158VV	0	NE	0	NE	NE	NE	1	3,0	1	100,0	100,00	NE
Screening	Missing	17	100,0	15	88,2	73,52	19,21	17	100,0	15	88,2	67,22	30,12
Cycle 4 Day 1	Missing	13	76,5	12	92,3	78,47	24,99	16	94,1	12	75,0	84,95	14,86
FU Day 28	Missing	15	88,2	13	86,7	80,77	26,00	16	94,1	14	87,5	74,60	20,73
FU Month 3	Missing	15	88,2	14	93,3	79,17	24,84	16	94,1	15	93,8	73,33	20,94
FU Month 6	Missing	13	76,5	12	92,3	77,78	24,96	15	88,2	14	93,3	83,93	15,49
FU Month 9	Missing	10	58,8	8	80,0	86,46	23,12	12	70,6	9	75,0	79,63	21,70

FU Month 12	Missing		952,9	555,6	93,33	10,87		741,2	571,4	78,33	31,51
FU Month 15	Missing		741,2	685,7	94,44	6,80		529,4	480,0	72,92	43,23
FU Month 18	Missing		423,5	375,0	86,11	24,06		423,5	375,0	94,44	4,81
FU Month 21	Missing		529,4	5100,0	88,33	13,94		423,5	375,0	91,67	0,00
FU Month 24	Missing		423,5	375,0	88,89	4,81		211,8	2100,0	95,83	5,89
FU Month 27	Missing		15,9	1100,0	83,33		NE	15,9	1100,0	75,00	NE
Binet Staging at baseline											
Screening	A		59100,0	5796,6	76,41	20,14		57100,0	5393,0	74,21	22,01
Cycle 4 Day 1	A		5186,4	4894,1	80,67	22,35		5494,7	5092,6	77,28	23,23
FU Day 28	A		5898,3	5391,4	79,51	24,70		5494,7	5296,3	77,56	22,51
FU Month 3	A		5796,6	5698,2	80,21	24,08		5393,0	5094,3	76,50	21,67
FU Month 6	A		5694,9	5089,3	81,89	21,64		4578,9	4293,3	77,65	25,02
FU Month 9	A		4372,9	3786,0	80,86	22,38		3459,6	3088,2	79,17	21,53
FU Month 12	A		3661,0	3494,4	79,82	21,62		2442,1	2187,5	76,19	24,90
FU Month 15	A		3050,8	2790,0	86,73	19,78		1933,3	19100,0	77,63	26,21
FU Month 18	A		2237,3	1881,8	84,26	22,12		1628,1	16100,0	76,04	27,70
FU Month 21	A		1728,8	1588,2	81,67	27,85		814,0	787,5	85,71	13,36
FU Month 24	A		1016,9	880,0	78,13	28,15		58,8	5100,0	90,00	10,87
FU Month 27	A		58,5	480,0	70,83	34,36		23,5	150,0	91,67	NE
FU Month 30	A		46,8	375,0	51,85	26,98		0	NE	NE	NE
Screening	B	104	100,0	100	96,2	75,50	19,03	85100,0	8397,6	74,60	23,39
Cycle 4 Day 1	B		8884,6	8394,3	82,97	15,71		7992,9	7392,4	82,80	15,23
FU Day 28	B		9187,5	7986,8	82,49	20,91		7992,9	7189,9	84,15	16,38
FU Month 3	B		8884,6	7888,6	81,84	22,06		7992,9	7088,6	81,39	19,85
FU Month 6	B		8076,9	7796,3	82,83	17,84		7082,4	6390,0	81,61	18,76
FU Month 9	B		6360,6	5282,5	83,97	19,58		5969,4	4881,4	79,80	17,84
FU Month 12	B		4745,2	3983,0	84,90	18,78		4654,1	3984,8	81,98	17,37
FU Month 15	B		3735,6	3491,9	82,92	20,07		3440,0	2882,4	82,44	15,60
FU Month 18	B		3129,8	2890,3	83,53	18,64		2225,9	1881,8	82,25	18,94
FU Month 21	B		1817,3	1372,2	84,40	15,82		1720,0	1482,4	85,12	15,04
FU Month 24	B		1110,6	981,8	83,33	9,32		89,4	787,5	84,52	17,63
FU Month 27	B		54,8	480,0	81,25	4,17		44,7	4100,0	87,50	15,96
FU Month 30	B		21,9	2100,0	100,00	0,00		0	NE	NE	NE
Screening	C		92100,0	8390,2	74,23	24,92	100	100,0	9191,0	79,49	20,03
Cycle 4 Day 1	C		7480,4	6587,8	83,85	19,48		9191,0	7481,3	82,13	20,45
FU Day 28	C		8188,0	6884,0	80,72	23,15		9292,0	7884,8	84,58	14,93
FU Month 3	C		8087,0	6986,3	79,39	22,91		8989,0	7584,3	82,15	18,86
FU Month 6	C		7177,2	6185,9	79,92	21,52		7777,0	6483,1	83,38	18,63

FU Month 9	C	58	63,0	49	84,5	83,50	18,67	56	56,0	41	73,2	85,37	15,76
FU Month 12	C	42	45,7	36	85,7	83,87	17,21	47	47,0	38	80,9	86,62	18,74
FU Month 15	C	37	40,2	30	81,1	86,57	16,15	32	32,0	22	68,8	81,44	17,62
FU Month 18	C	26	28,3	23	88,5	84,06	14,85	22	22,0	15	68,2	80,56	26,66
FU Month 21	C	17	18,5	12	70,6	86,11	14,36	15	15,0	11	73,3	65,15	35,32
FU Month 24	C	11	12,0	8	72,7	80,21	16,02	5	5,0	4	80,0	93,75	7,98
FU Month 27	C	3	3,3	3	100,0	80,56	17,35	3	3,0	2	66,7	87,50	17,68
FU Month 30	C	1	1,1	1	100,0	66,67	NE	1	1,0	1	100,0	100,00	NE
Total CIR score at baseline													
Screening	<=6	63	100,0	58	92,1	78,11	21,38	75	100,0	69	92,0	76,89	19,89
Cycle 4 Day 1	<=6	52	82,5	43	82,7	82,62	19,97	72	96,0	61	84,7	82,88	18,55
FU Day 28	<=6	56	88,9	49	87,5	84,75	16,58	72	96,0	59	81,9	84,46	16,48
FU Month 3	<=6	55	87,3	47	85,5	85,93	15,73	69	92,0	56	81,2	84,52	16,24
FU Month 6	<=6	52	82,5	47	90,4	86,82	16,07	60	80,0	53	88,3	81,03	18,96
FU Month 9	<=6	43	68,3	36	83,7	89,58	15,61	47	62,7	38	80,9	79,75	19,90
FU Month 12	<=6	35	55,6	29	82,9	88,60	14,42	34	45,3	27	79,4	81,69	18,64
FU Month 15	<=6	32	50,8	29	90,6	92,24	10,30	25	33,3	17	68,0	83,82	16,53
FU Month 18	<=6	23	36,5	22	95,7	85,86	14,67	19	25,3	14	73,7	79,17	24,19
FU Month 21	<=6	14	22,2	8	57,1	81,25	19,29	14	18,7	10	71,4	79,17	23,98
FU Month 24	<=6	8	12,7	7	87,5	85,71	9,27	7	9,3	5	71,4	91,67	8,33
FU Month 27	<=6	2	3,2	2	100,0	87,50	17,68	4	5,3	2	50,0	100,00	0,00
FU Month 30	<=6	0	NE	0	NE	NE	NE	1	1,3	1	100,0	100,00	NE
Screening >6													
Screening	>6	192	100,0	182	94,8	74,37	21,41	167	100,0	158	94,6	76,28	22,66
Cycle 4 Day 1	>6	161	83,9	153	95,0	82,72	18,41	152	91,0	136	89,5	80,37	19,97
FU Day 28	>6	174	90,6	151	86,8	79,91	24,22	153	91,6	142	92,8	81,85	18,36
FU Month 3	>6	170	88,5	156	91,8	78,94	24,38	152	91,0	139	91,4	78,78	21,15
FU Month 6	>6	155	80,7	141	91,0	79,91	20,98	132	79,0	116	87,9	81,42	21,16
FU Month 9	>6	121	63,0	102	84,3	80,64	20,85	102	61,1	81	79,4	82,41	17,47
FU Month 12	>6	90	46,9	80	88,9	80,94	20,32	83	49,7	71	85,5	82,86	20,46
FU Month 15	>6	72	37,5	62	86,1	81,99	20,75	60	35,9	52	86,7	79,81	20,37
FU Month 18	>6	56	29,2	47	83,9	82,98	19,73	41	24,6	35	85,4	79,92	24,43
FU Month 21	>6	38	19,8	32	84,2	84,55	20,94	26	15,6	22	84,6	78,03	26,04
FU Month 24	>6	24	12,5	18	75,0	78,70	20,85	11	6,6	11	100,0	87,12	15,53
FU Month 27	>6	11	5,7	9	81,8	75,00	22,05	5	3,0	5	100,0	83,33	13,18
FU Month 30	>6	7	3,6	6	85,7	70,37	29,17	0	NE	0	NE	NE	NE
Calculated creatinine clearance cat. 2													
Screening	<70 ml/min	178	100,0	164	92,1	75,10	22,07	176	100,0	166	94,3	75,92	22,10
Cycle 4 Day 1	<70 ml/min	149	83,7	134	89,9	83,75	18,46	164	93,2	143	87,2	81,02	19,61

FU Day 28	<70 ml/min	162	91,0	141	87,0	82,23	20,87	166	94,3	144	86,7	82,58	18,28
FU Month 3	<70 ml/min	157	88,2	141	89,8	81,46	21,43	159	90,3	138	86,8	79,95	19,73
FU Month 6	<70 ml/min	144	80,9	129	89,6	83,18	18,08	139	79,0	121	87,1	81,80	20,01
FU Month 9	<70 ml/min	117	65,7	97	82,9	85,82	18,56	112	63,6	88	78,6	80,37	18,98
FU Month 12	<70 ml/min	92	51,7	79	85,9	85,69	17,98	87	49,4	72	82,8	82,25	19,33
FU Month 15	<70 ml/min	78	43,8	70	89,7	86,90	17,32	60	34,1	48	80,0	80,38	18,47
FU Month 18	<70 ml/min	59	33,1	50	84,7	85,78	17,04	43	24,4	36	83,7	76,54	26,25
FU Month 21	<70 ml/min	38	21,3	27	71,1	84,47	20,86	31	17,6	27	87,1	78,09	25,96
FU Month 24	<70 ml/min	24	13,5	19	79,2	80,70	18,23	13	7,4	11	84,6	90,91	10,18
FU Month 27	<70 ml/min	10	5,6	8	80,0	77,08	21,25	7	4,0	5	71,4	90,00	10,87
FU Month 30	<70 ml/min	5	2,8	4	80,0	72,22	36,85	1	0,6	1	100,0	100,00	NE
Screening	>=70 ml/min	77	100,0	76	98,7	75,66	20,08	66	100,0	61	92,4	77,96	21,12
Cycle 4 Day 1	>=70 ml/min	64	83,1	62	96,9	80,42	19,20	60	90,9	54	90,0	81,48	19,46
FU Day 28	>=70 ml/min	68	88,3	59	86,8	78,39	26,40	59	89,4	57	96,6	82,70	16,79
FU Month 3	>=70 ml/min	68	88,3	62	91,2	78,49	25,81	62	93,9	57	91,9	81,58	20,76
FU Month 6	>=70 ml/min	63	81,8	59	93,7	78,25	23,62	53	80,3	48	90,6	80,03	21,66
FU Month 9	>=70 ml/min	47	61,0	41	87,2	76,22	21,70	37	56,1	31	83,8	84,95	15,73
FU Month 12	>=70 ml/min	33	42,9	30	90,9	75,83	20,66	30	45,5	26	86,7	83,33	21,73
FU Month 15	>=70 ml/min	26	33,8	21	80,8	79,76	22,14	25	37,9	21	84,0	81,75	21,99
FU Month 18	>=70 ml/min	20	26,0	19	95,0	78,95	20,67	17	25,8	13	76,5	88,46	14,25
FU Month 21	>=70 ml/min	14	18,2	13	92,9	82,69	20,26	9	13,6	5	55,6	80,00	21,73
FU Month 24	>=70 ml/min	8	10,4	6	75,0	80,56	20,86	5	7,6	5	100,0	83,33	19,54
FU Month 27	>=70 ml/min	3	3,9	3	100,0	77,78	25,46	2	3,0	2	100,0	83,33	23,57
FU Month 30	>=70 ml/min	2	2,6	2	100,0	66,67	11,79	0	NE	0	NE	NE	NE
Beta2 microglobulin													
Screening	Missing	3	100,0	3	100,0	80,56	26,79	3	100,0	3	100,0	38,89	20,97
Cycle 4 Day 1	Missing	3	100,0	3	100,0	91,67	14,43	3	100,0	2	66,7	80,56	3,93
FU Day 28	Missing	3	100,0	3	100,0	86,11	24,06	3	100,0	2	66,7	83,33	11,79
FU Month 3	Missing	3	100,0	3	100,0	86,11	24,06	3	100,0	2	66,7	79,17	17,68
FU Month 6	Missing	3	100,0	3	100,0	86,11	24,06	3	100,0	2	66,7	79,17	29,46
FU Month 9	Missing	2	66,7	1	50,0	66,67	NE	3	100,0	2	66,7	66,67	35,36
FU Month 12	Missing	1	33,3	1	100,0	41,67	NE	2	66,7	1	50,0	91,67	NE
FU Month 15	Missing	1	33,3	1	100,0	41,67	NE	2	66,7	1	50,0	83,33	NE
FU Month 18	Missing	1	33,3	1	100,0	66,67	NE	2	66,7	1	50,0	83,33	NE
FU Month 21	Missing	1	33,3	1	100,0	66,67	NE	2	66,7	1	50,0	66,67	NE
FU Month 24	Missing	1	33,3	1	100,0	50,00	NE	1	33,3	1	100,0	91,67	NE
Screening	< 3.5 ug/mL	154	100,0	143	92,9	74,92	21,21	140	100,0	131	93,6	75,61	20,57
Cycle 4 Day 1	< 3.5 ug/mL	127	82,5	117	92,1	81,24	20,08	129	92,1	112	86,8	80,26	21,27

FU Day 28	< 3.5 ug/mL	137	89,0	121	88,3	79,66	23,04	132	94,3	120	90,9	80,90	19,46
FU Month 3	< 3.5 ug/mL	134	87,0	123	91,8	80,56	22,45	130	92,9	115	88,5	79,59	19,78
FU Month 6	< 3.5 ug/mL	128	83,1	115	89,8	80,87	20,46	120	85,7	111	92,5	78,13	22,21
FU Month 9	< 3.5 ug/mL	104	67,5	87	83,7	81,61	20,61	98	70,0	81	82,7	81,28	18,55
FU Month 12	< 3.5 ug/mL	78	50,6	69	88,5	82,05	19,13	75	53,6	66	88,0	79,88	22,12
FU Month 15	< 3.5 ug/mL	65	42,2	57	87,7	85,23	18,86	60	42,9	51	85,0	79,74	20,63
FU Month 18	< 3.5 ug/mL	46	29,9	41	89,1	82,25	19,20	43	30,7	35	81,4	75,63	26,28
FU Month 21	< 3.5 ug/mL	30	19,5	21	70,0	79,37	24,53	27	19,3	22	81,5	77,27	28,77
FU Month 24	< 3.5 ug/mL	19	12,3	15	78,9	78,89	20,38	12	8,6	10	83,3	91,67	8,78
FU Month 27	< 3.5 ug/mL	10	6,5	8	80,0	71,88	21,33	7	5,0	5	71,4	86,67	15,14
FU Month 30	< 3.5 ug/mL	5	3,2	4	80,0	61,81	31,94	1	0,7	1	100,0	100,00	NE
Screening	>= 3.5 ug/mL	98	100,0	94	95,9	75,65	21,81	99	100,0	93	93,9	78,88	22,54
Cycle 4 Day 1	>= 3.5 ug/mL	83	84,7	76	91,6	84,58	16,46	92	92,9	83	90,2	82,36	17,21
FU Day 28	>= 3.5 ug/mL	90	91,8	76	84,4	83,19	22,06	90	90,9	79	87,8	85,20	14,96
FU Month 3	>= 3.5 ug/mL	88	89,8	77	87,5	80,34	23,66	88	88,9	78	88,6	81,70	20,53
FU Month 6	>= 3.5 ug/mL	76	77,6	70	92,1	82,70	19,45	69	69,7	56	81,2	87,65	14,56
FU Month 9	>= 3.5 ug/mL	58	59,2	50	86,2	85,67	18,75	48	48,5	36	75,0	83,02	16,85
FU Month 12	>= 3.5 ug/mL	46	46,9	39	84,8	85,68	18,33	40	40,4	31	77,5	87,90	13,06
FU Month 15	>= 3.5 ug/mL	38	38,8	33	86,8	86,62	17,17	23	23,2	17	73,9	83,82	16,26
FU Month 18	>= 3.5 ug/mL	32	32,7	27	84,4	87,04	16,56	15	15,2	13	86,7	90,38	13,96
FU Month 21	>= 3.5 ug/mL	21	21,4	18	85,7	90,12	12,86	11	11,1	9	81,8	82,41	14,70
FU Month 24	>= 3.5 ug/mL	12	12,2	9	75,0	87,04	11,11	5	5,1	5	100,0	81,67	20,75
FU Month 27	>= 3.5 ug/mL	3	3,1	3	100,0	91,67	14,43	2	2,0	2	100,0	91,67	11,79
FU Month 30	>= 3.5 ug/mL	2	2,0	2	100,0	87,50	17,68	0	NE	0	NE	NE	NE
Immunoglobulin VH, cytogenetics 2													
Screening	12	45	100,0	43	95,6	74,16	21,30	44	100,0	43	97,7	76,81	21,15
Cycle 4 Day 1	12	34	75,6	32	94,1	81,34	18,43	38	86,4	33	86,8	81,31	17,45
FU Day 28	12	39	86,7	37	94,9	76,35	24,10	40	90,9	34	85,0	80,80	19,59
FU Month 3	12	38	84,4	36	94,7	76,62	24,06	39	88,6	32	82,1	79,43	22,00
FU Month 6	12	36	80,0	32	88,9	80,03	19,94	34	77,3	28	82,4	78,57	24,99
FU Month 9	12	26	57,8	22	84,6	79,55	21,32	28	63,6	18	64,3	77,16	22,98
FU Month 12	12	22	48,9	18	81,8	78,40	24,26	23	52,3	15	65,2	81,67	19,47
FU Month 15	12	17	37,8	14	82,4	79,17	23,05	17	38,6	12	70,6	81,94	17,71
FU Month 18	12	15	33,3	12	80,0	84,03	18,62	13	29,5	9	69,2	83,95	14,75
FU Month 21	12	10	22,2	8	80,0	76,04	29,69	7	15,9	5	71,4	90,00	6,97
FU Month 24	12	8	17,8	6	75,0	73,61	29,54	6	13,6	6	100,0	90,28	20,01
FU Month 27	12	5	11,1	4	80,0	68,75	23,94	2	4,5	2	100,0	83,33	23,57
FU Month 30	12	4	8,9	3	75,0	74,07	44,91	1	2,3	1	100,0	100,00	NE

Screening	11q-	46	100,0	43	93,5	77,65	15,82	43	100,0	40	93,0	76,18	21,10
Cycle 4 Day 1	11q-	40	87,0	39	97,5	82,48	16,20	41	95,3	35	85,4	81,43	21,09
FU Day 28	11q-	42	91,3	35	83,3	85,24	16,55	39	90,7	36	92,3	84,95	16,16
FU Month 3	11q-	42	91,3	38	90,5	83,55	19,23	38	88,4	36	94,7	85,34	17,04
FU Month 6	11q-	38	82,6	35	92,1	86,43	15,00	32	74,4	27	84,4	78,40	18,81
FU Month 9	11q-	28	60,9	26	92,9	80,45	24,03	25	58,1	20	80,0	83,33	16,45
FU Month 12	11q-	20	43,5	19	95,0	80,26	21,91	18	41,9	17	94,4	77,94	24,46
FU Month 15	11q-	18	39,1	16	88,9	86,98	17,47	14	32,6	10	71,4	79,17	19,34
FU Month 18	11q-	15	32,6	12	80,0	81,94	24,06	8	18,6	7	87,5	77,38	36,23
FU Month 21	11q-	12	26,1	11	91,7	77,02	19,92	4	9,3	2	50,0	70,83	29,46
FU Month 24	11q-	7	15,2	5	71,4	76,67	13,69	1	2,3	1	100,0	83,33	NE
FU Month 27	11q-	3	6,5	3	100,0	72,22	25,46	0	NE	0	NE	NE	NE
FU Month 30	11q-	3	6,5	3	100,0	66,67	8,33	0	NE	0	NE	NE	NE
Screening	13q-	79	100,0	75	94,9	77,30	20,94	75	100,0	70	93,3	80,20	18,97
Cycle 4 Day 1	13q-	67	84,8	60	89,6	84,91	16,46	68	90,7	60	88,2	83,66	16,83
FU Day 28	13q-	72	91,1	65	90,3	84,19	18,89	72	96,0	65	90,3	83,63	15,68
FU Month 3	13q-	73	92,4	67	91,8	81,55	22,99	69	92,0	61	88,4	76,91	20,66
FU Month 6	13q-	67	84,8	62	92,5	83,83	17,39	63	84,0	56	88,9	82,64	20,06
FU Month 9	13q-	56	70,9	49	87,5	84,52	16,75	52	69,3	41	78,8	82,72	18,58
FU Month 12	13q-	44	55,7	39	88,6	84,26	18,29	40	53,3	38	95,0	83,99	18,42
FU Month 15	13q-	38	48,1	34	89,5	84,64	19,11	29	38,7	25	86,2	82,67	15,58
FU Month 18	13q-	28	35,4	25	89,3	83,89	17,84	21	28,0	19	90,5	78,07	21,55
FU Month 21	13q-	16	20,3	13	81,3	86,54	16,15	16	21,3	14	87,5	82,14	18,74
FU Month 24	13q-	7	8,9	6	85,7	83,33	17,48	7	9,3	6	85,7	86,11	10,09
FU Month 27	13q-	2	2,5	1	50,0	100,00	NE	6	8,0	4	66,7	87,50	10,76
Screening	Norm. K.	65	100,0	61	93,8	71,58	24,50	58	100,0	54	93,1	70,52	26,19
Cycle 4 Day 1	Norm. K.	54	83,1	49	90,7	81,63	21,45	55	94,8	50	90,9	76,67	21,59
FU Day 28	Norm. K.	59	90,8	49	83,1	78,17	26,44	53	91,4	49	92,5	79,02	21,22
FU Month 3	Norm. K.	54	83,1	48	88,9	80,15	24,04	54	93,1	48	88,9	79,40	20,76
FU Month 6	Norm. K.	49	75,4	47	95,9	74,35	25,22	45	77,6	40	88,9	80,28	21,37
FU Month 9	Norm. K.	39	60,0	31	79,5	83,33	22,26	30	51,7	27	90,0	79,94	17,76
FU Month 12	Norm. K.	32	49,2	27	84,4	85,39	16,30	24	41,4	20	83,3	84,58	16,28
FU Month 15	Norm. K.	26	40,0	23	88,5	87,92	17,54	20	34,5	18	90,0	79,17	19,65
FU Month 18	Norm. K.	18	27,7	17	94,4	83,82	15,99	15	25,9	12	80,0	77,08	28,23
FU Month 21	Norm. K.	12	18,5	6	50,0	95,83	10,21	11	19,0	9	81,8	63,89	35,84
FU Month 24	Norm. K.	8	12,3	6	75,0	83,33	10,54	4	6,9	3	75,0	91,67	8,33
FU Month 27	Norm. K.	3	4,6	3	100,0	86,11	12,73	1	1,7	1	100,0	100,00	NE
Screening	Other Abn.	20	100,0	18	90,0	76,39	24,46	22	100,0	20	90,9	79,31	19,42

Cycle 4 Day 1	Other Abn.	18	90,0	16	88,9	80,90	24,82	22	100,0	19	86,4	84,21	22,03
FU Day 28	Other Abn.	18	90,0	14	77,8	79,17	31,48	21	95,5	17	81,0	87,75	13,57
FU Month 3	Other Abn.	18	90,0	14	77,8	79,17	25,27	21	95,5	18	85,7	87,04	15,45
FU Month 6	Other Abn.	17	85,0	12	70,6	89,12	16,98	18	81,8	18	100,0	87,96	12,85
FU Month 9	Other Abn.	15	75,0	10	66,7	88,33	12,55	14	63,6	13	92,9	84,62	14,37
FU Month 12	Other Abn.	7	35,0	6	85,7	86,11	11,39	12	54,5	8	66,7	81,94	27,62
FU Month 15	Other Abn.	5	25,0	4	80,0	89,58	7,98	5	22,7	4	80,0	77,08	45,83
FU Month 18	Other Abn.	3	15,0	3	100,0	91,67	14,43	3	13,6	2	66,7	100,00	0,00
FU Month 21	Other Abn.	2	10,0	2	100,0	100,00	0,00	2	9,1	2	100,0	95,83	5,89
FU Month 24	Other Abn.	2	10,0	2	100,0	95,83	5,89	0	NE	0	NE	NE	NE
Time from first diagnosis													
Screening	Missing	1	100,0	1	100,0	41,67	NE	0	NE	0	NE	NE	NE
Cycle 4 Day 1	Missing	1	100,0	1	100,0	75,00	NE	0	NE	0	NE	NE	NE
FU Day 28	Missing	1	100,0	1	100,0	91,67	NE	0	NE	0	NE	NE	NE
FU Month 3	Missing	1	100,0	1	100,0	83,33	NE	0	NE	0	NE	NE	NE
FU Month 6	Missing	1	100,0	1	100,0	91,67	NE	0	NE	0	NE	NE	NE
FU Month 9	Missing	1	100,0	1	100,0	100,00	NE	0	NE	0	NE	NE	NE
FU Month 12	Missing	1	100,0	1	100,0	77,78	NE	0	NE	0	NE	NE	NE
FU Month 15	Missing	1	100,0	1	100,0	83,33	NE	0	NE	0	NE	NE	NE
FU Month 18	Missing	1	100,0	1	100,0	91,67	NE	0	NE	0	NE	NE	NE
Screening	13 - 24 months	41	100,0	39	95,1	69,44	23,52	31	100,0	31	100,0	84,95	14,66
Cycle 4 Day 1	13 - 24 months	35	85,4	34	97,1	80,88	18,75	30	96,8	27	90,0	83,13	21,87
FU Day 28	13 - 24 months	38	92,7	33	86,8	72,73	29,19	30	96,8	27	90,0	86,93	14,65
FU Month 3	13 - 24 months	36	87,8	34	94,4	75,00	28,05	30	96,8	26	86,7	84,94	18,11
FU Month 6	13 - 24 months	36	87,8	33	91,7	82,32	22,61	30	96,8	25	83,3	87,00	16,33
FU Month 9	13 - 24 months	32	78,0	29	90,6	83,62	22,21	21	67,7	17	81,0	90,20	9,88
FU Month 12	13 - 24 months	21	51,2	18	85,7	86,11	23,04	16	51,6	14	87,5	88,69	12,49
FU Month 15	13 - 24 months	19	46,3	18	94,7	84,72	20,86	16	51,6	10	62,5	86,67	18,51
FU Month 18	13 - 24 months	14	34,1	13	92,9	82,69	18,47	10	32,3	8	80,0	88,19	14,90
FU Month 21	13 - 24 months	11	26,8	9	81,8	73,15	29,98	6	19,4	4	66,7	89,58	10,49
FU Month 24	13 - 24 months	8	19,5	5	62,5	70,00	32,60	3	9,7	2	66,7	100,00	0,00
FU Month 27	13 - 24 months	5	12,2	5	100,0	76,67	27,89	2	6,5	2	100,0	100,00	0,00
FU Month 30	13 - 24 months	3	7,3	3	100,0	54,63	28,37	1	3,2	1	100,0	100,00	NE
Screening	<= 12 months	60	100,0	57	95,0	76,22	19,75	70	100,0	69	98,6	75,93	19,86
Cycle 4 Day 1	<= 12 months	48	80,0	42	87,5	82,28	15,84	60	85,7	55	91,7	81,52	19,62
FU Day 28	<= 12 months	54	90,0	45	83,3	79,51	21,75	62	88,6	56	90,3	81,45	17,66
FU Month 3	<= 12 months	53	88,3	45	84,9	78,52	23,87	59	84,3	55	93,2	80,81	21,68
FU Month 6	<= 12 months	46	76,7	40	87,0	79,86	22,04	47	67,1	43	91,5	82,43	17,88

FU Month 9	<= 12 months	35	58,3	27	77,1	82,72	18,19	37	52,9	31	83,8	85,93	15,86
FU Month 12	<= 12 months	27	45,0	23	85,2	77,54	20,48	29	41,4	27	93,1	81,38	21,96
FU Month 15	<= 12 months	22	36,7	17	77,3	79,90	21,66	17	24,3	16	94,1	78,13	22,54
FU Month 18	<= 12 months	16	26,7	13	81,3	85,26	16,72	13	18,6	12	92,3	81,25	13,35
FU Month 21	<= 12 months	9	15,0	5	55,6	83,33	16,67	7	10,0	6	85,7	76,39	18,57
FU Month 24	<= 12 months	6	10,0	3	50,0	86,11	4,81	2	2,9	1	50,0	100,00	NE
FU Month 27	<= 12 months	1	1,7			NE	NE	1	1,4			NE	NE
FU Month 30	<= 12 months	1	1,7			NE	NE	0	NE			NE	NE
Screening	>24 months	153	100,0	143	93,5	76,73	21,23	141	100,0	127	90,1	74,69	23,84
Cycle 4 Day 1	>24 months	129	84,3	119	92,2	83,43	19,77	134	95,0	115	85,8	80,51	19,04
FU Day 28	>24 months	137	89,5	121	88,3	83,88	20,51	133	94,3	118	88,7	82,18	18,54
FU Month 3	>24 months	135	88,2	123	91,1	82,81	20,72	132	93,6	114	86,4	79,22	19,58
FU Month 6	>24 months	124	81,0	114	91,9	81,97	18,73	115	81,6	101	87,8	79,40	22,17
FU Month 9	>24 months	96	62,7	81	84,4	82,61	19,95	91	64,5	71	78,0	77,58	19,70
FU Month 12	>24 months	76	49,7	67	88,2	84,08	17,62	72	51,1	57	79,2	81,58	20,34
FU Month 15	>24 months	62	40,5	55	88,7	87,12	17,07	52	36,9	43	82,7	80,43	18,62
FU Month 18	>24 months	48	31,4	42	87,5	83,66	19,13	37	26,2	29	78,4	76,72	28,99
FU Month 21	>24 months	32	20,9	26	81,3	87,71	16,18	27	19,1	22	81,5	76,89	28,28
FU Month 24	>24 months	18	11,8	17	94,4	82,84	13,97	13	9,2	13	100,0	85,90	13,77
FU Month 27	>24 months	7	4,6	6	85,7	77,78	16,39	6	4,3	5	83,3	83,33	13,18
FU Month 30	>24 months	3	2,0	3	100,0	86,11	24,06	0	NE	0	NE	NE	NE
High circulating tumor burden													
Screening	Missing	0	NE	0	NE	NE	NE	2	100,0	1	50,0	58,33	NE
Cycle 4 Day 1	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	66,67	NE
FU Day 28	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	58,33	NE
FU Month 3	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	50,00	NE
FU Month 6	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	91,67	NE
FU Month 9	Missing	0	NE			NE	NE	1	50,0			NE	NE
Screening	<25x10**9 cells/L	60	100,0	55	91,7	73,23	24,31	67	100,0	64	95,5	73,74	23,48
Cycle 4 Day 1	<25x10**9 cells/L	50	83,3	45	90,0	78,95	22,93	61	91,0	52	85,2	81,25	16,82
FU Day 28	<25x10**9 cells/L	56	93,3	46	82,1	80,25	24,99	61	91,0	53	86,9	81,03	17,48
FU Month 3	<25x10**9 cells/L	54	90,0	47	87,0	76,89	22,52	59	88,1	50	84,7	82,28	20,57
FU Month 6	<25x10**9 cells/L	50	83,3	44	88,0	73,86	23,63	51	76,1	41	80,4	84,76	19,36
FU Month 9	<25x10**9 cells/L	36	60,0	27	75,0	79,32	24,17	41	61,2	29	70,7	87,93	13,83
FU Month 12	<25x10**9 cells/L	29	48,3	24	82,8	79,28	21,96	34	50,7	25	73,5	83,22	21,12
FU Month 15	<25x10**9 cells/L	24	40,0	20	83,3	81,25	21,27	23	34,3	15	65,2	83,33	19,42
FU Month 18	<25x10**9 cells/L	20	33,3	18	90,0	84,26	19,36	19	28,4	14	73,7	81,94	27,32
FU Month 21	<25x10**9 cells/L	14	23,3	10	71,4	80,83	28,88	10	14,9	8	80,0	86,46	18,33

FU Month 24	<25x10**9 cells/L	8	13,3	5	62,5	70,00	31,51	6	9,0	5	83,3	86,67	21,73
FU Month 27	<25x10**9 cells/L	4	6,7	3	75,0	61,11	25,46	1	1,5	1	100,0	100,00	NE
FU Month 30	<25x10**9 cells/L	4	6,7	3	75,0	62,96	39,02	1	1,5	1	100,0	100,00	NE
Screening	>=25x10**9 cells/L	195	100,0	185	94,9	75,89	20,52	173	100,0	162	93,6	77,66	21,11
Cycle 4 Day 1	>=25x10**9 cells/L	163	83,6	151	92,6	83,81	17,19	162	93,6	144	88,9	81,21	20,50
FU Day 28	>=25x10**9 cells/L	174	89,2	154	88,5	81,35	21,98	163	94,2	147	90,2	83,35	17,92
FU Month 3	>=25x10**9 cells/L	171	87,7	156	91,2	81,66	22,88	161	93,1	144	89,4	80,00	19,74
FU Month 6	>=25x10**9 cells/L	157	80,5	144	91,7	84,01	18,26	140	80,9	127	90,7	80,10	20,78
FU Month 9	>=25x10**9 cells/L	128	65,6	111	86,7	83,86	18,81	107	61,8	90	84,1	79,51	19,06
FU Month 12	>=25x10**9 cells/L	96	49,2	85	88,5	84,02	18,32	83	48,0	73	88,0	82,31	19,59
FU Month 15	>=25x10**9 cells/L	80	41,0	71	88,8	86,38	17,86	62	35,8	54	87,1	80,09	19,59
FU Month 18	>=25x10**9 cells/L	59	30,3	51	86,4	83,77	17,99	41	23,7	35	85,4	78,81	23,07
FU Month 21	>=25x10**9 cells/L	38	19,5	30	78,9	84,91	17,26	30	17,3	24	80,0	75,69	26,68
FU Month 24	>=25x10**9 cells/L	24	12,3	20	83,3	83,33	13,52	12	6,9	11	91,7	89,39	9,20
FU Month 27	>=25x10**9 cells/L	9	4,6	8	88,9	83,33	17,25	8	4,6	6	75,0	86,11	13,61
FU Month 30	>=25x10**9 cells/L	3	1,5	3	100,0	77,78	20,97	0	NE	0	NE	NE	NE

¹ in study: number of subjects in study at respective visit; % based on baseline

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit

² mean: descriptive statistics - absolute values Clinical

cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/t_pro_mean.sas

Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/t_pro_mean_sg_EQC30_IT_label_09MAY2013_21004.xls 04MAR2020

17:18

POPULATION: Labelpopulation, Intent-to-Treat Patients ENDPOINT: EORTC QoL 30

MODEL: Unadjusted Analysis STUDY: CLL11(BO21004), Stage

2

Compliance/Mean

Physical Functioning Scale

		GClb (N=255)						RClb (N=242)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study ¹	%	with value ¹	%	Mean ²	SD (mean)	in study ¹	%	with value ¹	%	Mean ²	SD (mean)
All													
Screening	n/a	255	100,0	242	94,9	73,93	21,04	242	100,0	228	94,2	75,34	19,87
Cycle 4 Day 1	n/a	213	83,5	195	91,5	79,10	18,98	224	92,6	198	88,4	76,23	19,14
FU Day 28	n/a	230	90,2	201	87,4	78,20	20,20	225	93,0	203	90,2	78,19	18,98
FU Month 3	n/a	225	88,2	203	90,2	78,28	20,98	221	91,3	196	88,7	76,58	20,50
FU Month 6	n/a	207	81,2	186	89,9	78,78	20,25	192	79,3	170	88,5	76,99	20,15
FU Month 9	n/a	164	64,3	138	84,1	80,39	19,40	149	61,6	121	81,2	74,02	20,36
FU Month 12	n/a	125	49,0	109	87,2	79,53	19,09	117	48,3	99	84,6	74,28	21,95
FU Month 15	n/a	104	40,8	90	86,5	82,31	17,13	85	35,1	69	81,2	75,27	23,93
FU Month 18	n/a	79	31,0	70	88,6	80,62	18,78	60	24,8	49	81,7	76,73	21,52
FU Month 21	n/a	52	20,4	40	76,9	80,17	17,11	40	16,5	32	80,0	77,71	22,95
FU Month 24	n/a	32	12,5	25	78,1	79,20	15,79	18	7,4	17	94,4	83,53	18,43
FU Month 27	n/a	13	5,1	11	84,6	81,06	14,42	9	3,7	7	77,8	81,90	10,69
FU Month 30	n/a	7	2,7	6	85,7	72,22	23,63	1	0,4	1	100,0	73,33	NE
Gender													
Screening	Female	97	100,0	92	94,8	71,34	22,00	95	100,0	87	91,6	69,75	19,13
Cycle 4 Day 1	Female	84	86,6	76	90,5	74,50	20,28	88	92,6	78	88,6	71,82	19,10
FU Day 28	Female	90	92,8	83	92,2	74,84	19,80	91	95,8	79	86,8	75,04	18,36
FU Month 3	Female	88	90,7	81	92,0	74,98	20,33	87	91,6	77	88,5	72,29	20,28
FU Month 6	Female	84	86,6	72	85,7	74,49	18,44	77	81,1	68	88,3	74,53	20,03
FU Month 9	Female	70	72,2	59	84,3	73,90	20,16	61	64,2	46	75,4	68,77	20,10
FU Month 12	Female	56	57,7	49	87,5	76,29	17,68	47	49,5	40	85,1	70,08	23,06
FU Month 15	Female	47	48,5	40	85,1	76,00	19,44	33	34,7	28	84,8	71,67	23,91
FU Month 18	Female	34	35,1	29	85,3	72,53	20,27	26	27,4	22	84,6	71,82	20,46
FU Month 21	Female	21	21,6	15	71,4	68,00	16,37	17	17,9	15	88,2	69,33	24,14
FU Month 24	Female	12	12,4	10	83,3	70,00	16,10	6	6,3	5	83,3	88,00	12,82

FU Month 27	Female	6	6,2	5	83,3	74,33	12,22	2	2,1	1	50,0	73,33	NE
FU Month 30	Female	4	4,1	3	75,0	55,56	21,43	1	1,1	1	100,0	73,33	NE
Screening	Male	158	100,0	150	94,9	75,51	20,34	147	100,0	141	95,9	78,79	19,59
Cycle 4 Day 1	Male	129	81,6	119	92,2	82,04	17,56	136	92,5	120	88,2	79,10	18,68
FU Day 28	Male	140	88,6	118	84,3	80,56	20,23	134	91,2	124	92,5	80,19	19,17
FU Month 3	Male	137	86,7	122	89,1	80,47	21,20	134	91,2	119	88,8	79,36	20,24
FU Month 6	Male	123	77,8	114	92,7	81,49	20,95	115	78,2	102	88,7	78,62	20,16
FU Month 9	Male	94	59,5	79	84,0	85,23	17,40	88	59,9	75	85,2	77,24	19,97
FU Month 12	Male	69	43,7	60	87,0	82,17	19,93	70	47,6	59	84,3	77,12	20,89
FU Month 15	Male	57	36,1	50	87,7	87,37	13,18	52	35,4	41	78,8	77,72	23,93
FU Month 18	Male	45	28,5	41	91,1	86,34	15,49	34	23,1	27	79,4	80,74	21,90
FU Month 21	Male	31	19,6	25	80,6	87,47	13,10	23	15,6	17	73,9	85,10	19,65
FU Month 24	Male	20	12,7	15	75,0	85,33	12,65	12	8,2	12	100,0	81,67	20,52
FU Month 27	Male	7	4,4	6	85,7	86,67	14,61	7	4,8	6	85,7	83,33	10,95
FU Month 30	Male	3	1,9	3	100,0	88,89	10,18	0	NE	0	NE	NE	NE
Age													
Screening	<75 years	130	100,0	123	94,6	75,20	21,37	120	100,0	110	91,7	77,08	19,31
Cycle 4 Day 1	<75 years	106	81,5	100	94,3	80,40	18,27	112	93,3	98	87,5	77,48	19,79
FU Day 28	<75 years	119	91,5	105	88,2	79,79	20,67	110	91,7	103	93,6	79,82	19,09
FU Month 3	<75 years	116	89,2	106	91,4	78,40	21,76	109	90,8	99	90,8	78,74	20,18
FU Month 6	<75 years	108	83,1	98	90,7	79,29	19,83	99	82,5	88	88,9	76,41	21,69
FU Month 9	<75 years	85	65,4	73	85,9	82,37	17,72	74	61,7	62	83,8	76,61	20,26
FU Month 12	<75 years	63	48,5	59	93,7	80,99	18,60	60	50,0	53	88,3	76,48	20,21
FU Month 15	<75 years	54	41,5	47	87,0	83,69	15,78	44	36,7	35	79,5	77,33	24,80
FU Month 18	<75 years	43	33,1	39	90,7	82,22	20,48	27	22,5	22	81,5	79,09	20,91
FU Month 21	<75 years	26	20,0	22	84,6	81,21	17,65	17	14,2	13	76,5	80,51	22,68
FU Month 24	<75 years	18	13,8	14	77,8	79,52	17,24	6	5,0	5	83,3	90,67	14,61
FU Month 27	<75 years	7	5,4	5	71,4	81,00	16,98	2	1,7	1	50,0	100,00	NE
FU Month 30	<75 years	4	3,1	3	75,0	75,56	26,94	0	NE	0	NE	NE	NE
Screening	>=75 years	125	100,0	119	95,2	72,61	20,70	122	100,0	118	96,7	73,73	20,32
Cycle 4 Day 1	>=75 years	107	85,6	95	88,8	77,74	19,71	112	91,8	100	89,3	75,00	18,49
FU Day 28	>=75 years	111	88,8	96	86,5	76,46	19,63	115	94,3	100	87,0	76,50	18,81
FU Month 3	>=75 years	109	87,2	97	89,0	78,15	20,20	112	91,8	97	86,6	74,38	20,69
FU Month 6	>=75 years	99	79,2	88	88,9	78,22	20,82	93	76,2	82	88,2	77,60	18,46
FU Month 9	>=75 years	79	63,2	65	82,3	78,15	21,03	75	61,5	59	78,7	71,30	20,28
FU Month 12	>=75 years	62	49,6	50	80,6	77,80	19,71	57	46,7	46	80,7	71,74	23,78
FU Month 15	>=75 years	50	40,0	43	86,0	80,81	18,57	41	33,6	34	82,9	73,14	23,18
FU Month 18	>=75 years	36	28,8	31	86,1	78,60	16,51	33	27,0	27	81,8	74,81	22,21

FU Month 21	>=75 years	26	20,8	18	69,2	78,89	16,84	23	18,9	19	82,6	75,79	23,54
FU Month 24	>=75 years	14	11,2	11	78,6	78,79	14,55	12	9,8	12	100,0	80,56	19,58
FU Month 27	>=75 years	6	4,8	6	100,0	81,11	13,61	7	5,7	6	85,7	78,89	7,79
FU Month 30	>=75 years	3	2,4	3	100,0	68,89	25,24	1	0,8	1	100,0	73,33	NE
Race													
Screening	Other	9	100,0	9	100,0	84,07	19,42	11	100,0	11	100,0	80,61	20,10
Cycle 4 Day 1	Other	7	77,8	7	100,0	81,90	17,94	10	90,9	9	90,0	82,59	14,12
FU Day 28	Other	8	88,9	8	100,0	79,17	25,06	10	90,9	10	100,0	88,67	12,19
FU Month 3	Other	8	88,9	7	87,5	67,62	24,17	10	90,9	10	100,0	84,67	18,87
FU Month 6	Other	8	88,9	7	87,5	77,14	23,05	8	72,7	8	100,0	86,04	17,09
FU Month 9	Other	4	44,4	3	75,0	95,56	7,70	5	45,5	4	80,0	88,33	11,39
FU Month 12	Other	3	33,3	2	66,7	86,67	18,86	4	36,4	4	100,0	88,33	15,75
FU Month 15	Other	2	22,2	1	50,0	93,33	NE	4	36,4	4	100,0	88,33	15,75
FU Month 18	Other	2	22,2	1	50,0	100,00	NE	2	18,2	2	100,0	86,67	18,86
FU Month 21	Other	2	22,2	1	50,0	100,00	NE	2	18,2	2	100,0	86,67	18,86
FU Month 24	Other	2	22,2	1	50,0	100,00	NE	1	9,1	0	NE	NE	NE
FU Month 27	Other	1	11,1			NE	NE	1	9,1			NE	NE
FU Month 30	Other	1	11,1			NE	NE	0	NE			NE	NE
Geographical Region													
Screening	White	246	100,0	233	94,7	73,53	21,04	231	100,0	217	93,9	75,08	19,86
Cycle 4 Day 1	White	206	83,7	188	91,3	79,00	19,06	214	92,6	189	88,3	75,93	19,32
FU Day 28	White	222	90,2	193	86,9	78,16	20,05	215	93,1	193	89,8	77,64	19,13
FU Month 3	White	217	88,2	196	90,3	78,66	20,83	211	91,3	186	88,2	76,15	20,54
FU Month 6	White	199	80,9	179	89,9	78,85	20,21	184	79,7	162	88,0	76,54	20,23
FU Month 9	White	160	65,0	135	84,4	80,05	19,45	144	62,3	117	81,3	73,53	20,45
FU Month 12	White	122	49,6	107	87,7	79,39	19,16	113	48,9	95	84,1	73,68	22,04
FU Month 15	White	102	41,5	89	87,3	82,19	17,19	81	35,1	65	80,2	74,46	24,20
FU Month 18	White	77	31,3	69	89,6	80,34	18,77	58	25,1	47	81,0	76,31	21,71
FU Month 21	White	50	20,3	39	78,0	79,66	17,03	38	16,5	30	78,9	77,11	23,34
FU Month 24	White	30	12,2	24	80,0	78,33	15,51	17	7,4	17	100,0	83,53	18,43
FU Month 27	White	12	4,9	11	91,7	81,06	14,42	8	3,5	7	87,5	81,90	10,69
FU Month 30	White	6	2,4	6	100,0	72,22	23,63	1	0,4	1	100,0	73,33	NE
Geographical Region													
Screening	Asia-Pacific	20	100,0	20	100,0	78,83	21,93	18	100,0	18	100,0	74,44	25,08
Cycle 4 Day 1	Asia-Pacific	15	75,0	15	100,0	86,22	18,60	16	88,9	15	93,8	78,89	19,91
FU Day 28	Asia-Pacific	18	90,0	18	100,0	79,63	24,89	18	100,0	16	88,9	83,33	17,55
FU Month 3	Asia-Pacific	18	90,0	16	88,9	77,92	29,28	18	100,0	16	88,9	79,17	20,78
FU Month 6	Asia-Pacific	16	80,0	14	87,5	77,62	27,99	17	94,4	15	88,2	70,96	23,36
FU Month 9	Asia-Pacific	14	70,0	12	85,7	86,67	17,52	13	72,2	10	76,9	72,50	24,54

FU Month 12	Asia-Pacific	10	50,0	8	80,0	81,67	27,77	10	55,6	10	100,0	71,67	30,19
FU Month 15	Asia-Pacific	8	40,0	6	75,0	94,44	7,79	9	50,0	9	100,0	66,67	33,50
FU Month 18	Asia-Pacific	6	30,0	4	66,7	98,33	3,33	6	33,3	6	100,0	72,22	29,34
FU Month 21	Asia-Pacific	5	25,0	3	60,0	97,78	3,85	4	22,2	4	100,0	68,33	34,16
FU Month 24	Asia-Pacific	3	15,0	2	66,7	100,00	0,00	1	5,6	0	NE	NE	NE
FU Month 27	Asia-Pacific	1	5,0			NE	NE	1	5,6			NE	NE
FU Month 30	Asia-Pacific	1	5,0			NE	NE	0	NE			NE	NE
Screening	Central and South America	3	100,0	3	100,0	66,67	17,64	2	100,0	2	100,0	56,67	42,43
Cycle 4 Day 1	Central and South America	3	100,0	3	100,0	73,33	17,64	2	100,0	2	100,0	76,67	14,14
FU Day 28	Central and South America	3	100,0	3	100,0	86,67	6,67	2	100,0	2	100,0	86,67	9,43
FU Month 3	Central and South America	3	100,0	3	100,0	73,33	17,64	2	100,0	2	100,0	96,67	4,71
FU Month 6	Central and South America	2	66,7	2	100,0	76,67	4,71	2	100,0	2	100,0	93,33	9,43
FU Month 9	Central and South America	2	66,7	2	100,0	83,33	4,71	1	50,0	1	100,0	93,33	NE
FU Month 12	Central and South America	2	66,7	2	100,0	76,67	4,71	1	50,0	1	100,0	73,33	NE
FU Month 15	Central and South America	1	33,3	1	100,0	75,00	NE	0	NE	0	NE	NE	NE
FU Month 18	Central and South America	1	33,3	1	100,0	66,67	NE	0	NE	0	NE	NE	NE
FU Month 21	Central and South America	1	33,3	1	100,0	66,67	NE	0	NE	0	NE	NE	NE
FU Month 24	Central and South America	1	33,3	1	100,0	73,33	NE	0	NE	0	NE	NE	NE
Screening	North America	12	100,0	12	100,0	67,78	20,27	13	100,0	12	92,3	73,89	20,59
Cycle 4 Day 1	North America	9	75,0	9	100,0	80,74	9,09	12	92,3	12	100,0	82,92	10,30
FU Day 28	North America	11	91,7	11	100,0	72,73	20,54	13	100,0	13	100,0	83,59	13,77
FU Month 3	North America	11	91,7	11	100,0	68,64	24,46	12	92,3	12	100,0	80,00	15,31
FU Month 6	North America	11	91,7	10	90,9	74,83	23,76	11	84,6	11	100,0	80,61	14,84
FU Month 9	North America	8	66,7	8	100,0	79,17	22,94	9	69,2	9	100,0	72,59	23,91
FU Month 12	North America	8	66,7	7	87,5	76,19	22,06	7	53,8	7	100,0	65,71	23,55
FU Month 15	North America	6	50,0	6	100,0	83,33	10,11	6	46,2	5	83,3	62,67	26,08
FU Month 18	North America	4	33,3	4	100,0	83,33	13,88	3	23,1	3	100,0	71,11	32,89
FU Month 21	North America	3	25,0	2	66,7	86,67	0,00	1	7,7	1	100,0	93,33	NE
FU Month 24	North America	3	25,0	2	66,7	73,33	18,86	1	7,7	1	100,0	86,67	NE
FU Month 27	North America	2	16,7	1	50,0	86,67	NE	1	7,7	1	100,0	80,00	NE
Screening	Other	45	100,0	41	91,1	67,32	20,16	44	100,0	41	93,2	71,50	18,59
Cycle 4 Day 1	Other	37	82,2	33	89,2	75,76	18,99	40	90,9	35	87,5	75,43	18,84
FU Day 28	Other	37	82,2	33	89,2	79,55	16,79	39	88,6	37	94,9	76,80	19,21
FU Month 3	Other	38	84,4	34	89,5	77,25	16,17	38	86,4	36	94,7	75,88	21,11
FU Month 6	Other	35	77,8	31	88,6	79,78	12,59	33	75,0	31	93,9	71,40	25,07
FU Month 9	Other	26	57,8	22	84,6	78,48	15,25	24	54,5	19	79,2	74,74	17,86
FU Month 12	Other	17	37,8	16	94,1	76,67	20,07	16	36,4	14	87,5	78,10	19,29
FU Month 15	Other	12	26,7	11	91,7	83,03	10,05	9	20,5	8	88,9	85,00	9,92

FU Month 18	Other	10	22,2	9	90,0	84,44	10,54	7	15,9	6	85,7	87,78	12,94
FU Month 21	Other	7	15,6	6	85,7	75,56	16,15	4	9,1	4	100,0	83,33	16,78
FU Month 24	Other	6	13,3	5	83,3	74,67	9,89	3	6,8	3	100,0	84,44	16,78
FU Month 27	Other	4	8,9	4	100,0	77,92	10,66	1	2,3	1	100,0	86,67	NE
FU Month 30	Other	2	4,4	2	100,0	63,33	23,57	0	NE	0	NE	NE	NE
Screening	Western Europe	175	100,0	166	94,9	75,54	21,01	165	100,0	155	93,9	76,82	19,23
Cycle 4 Day 1	Western Europe	149	85,1	135	90,6	79,15	19,51	154	93,3	134	87,0	75,53	19,85
FU Day 28	Western Europe	161	92,0	136	84,5	77,94	20,57	153	92,7	135	88,2	77,31	19,58
FU Month 3	Western Europe	155	88,6	139	89,7	79,44	20,76	151	91,5	130	86,1	75,83	20,85
FU Month 6	Western Europe	143	81,7	129	90,2	79,01	20,85	129	78,2	111	86,0	78,71	18,41
FU Month 9	Western Europe	114	65,1	94	82,5	80,07	20,47	102	61,8	82	80,4	73,96	20,36
FU Month 12	Western Europe	88	50,3	76	86,4	80,29	18,14	83	50,3	67	80,7	74,78	21,34
FU Month 15	Western Europe	77	44,0	66	85,7	81,11	18,91	61	37,0	47	77,0	76,60	22,96
FU Month 18	Western Europe	58	33,1	52	89,7	78,65	20,31	44	26,7	34	77,3	76,08	20,57
FU Month 21	Western Europe	36	20,6	28	77,8	79,29	17,99	31	18,8	23	74,2	77,68	22,62
FU Month 24	Western Europe	19	10,9	15	78,9	79,11	17,25	13	7,9	13	100,0	83,08	20,11
FU Month 27	Western Europe	6	3,4	6	100,0	82,22	18,22	6	3,6	5	83,3	81,33	12,82
FU Month 30	Western Europe	4	2,3	4	100,0	76,67	25,82	1	0,6	1	100,0	73,33	NE
FCgamma receptor IIa													
Screening	131HH	58	100,0	54	93,1	74,10	19,98	76	100,0	72	94,7	76,30	18,92
Cycle 4 Day 1	131HH	49	84,5	43	87,8	80,54	18,02	65	85,5	60	92,3	77,56	19,74
FU Day 28	131HH	51	87,9	46	90,2	79,53	19,02	70	92,1	62	88,6	79,65	17,78
FU Month 3	131HH	51	87,9	47	92,2	79,30	19,42	64	84,2	54	84,4	78,80	21,59
FU Month 6	131HH	49	84,5	45	91,8	79,70	18,25	55	72,4	48	87,3	80,03	17,76
FU Month 9	131HH	39	67,2	30	76,9	80,00	18,86	41	53,9	33	80,5	81,01	15,10
FU Month 12	131HH	28	48,3	24	85,7	78,26	19,97	34	44,7	29	85,3	76,90	23,30
FU Month 15	131HH	23	39,7	19	82,6	82,11	16,93	24	31,6	20	83,3	81,00	21,44
FU Month 18	131HH	17	29,3	14	82,4	76,90	23,98	16	21,1	13	81,3	73,85	26,17
FU Month 21	131HH	13	22,4	8	61,5	82,50	15,09	11	14,5	10	90,9	64,00	32,23
FU Month 24	131HH	11	19,0	7	63,6	78,10	15,26	1	1,3	1	100,0	93,33	NE
FU Month 27	131HH	4	6,9	3	75,0	73,33	23,09	1	1,3	1	100,0	86,67	NE
FU Month 30	131HH	3	5,2	2	66,7	70,00	42,43	0	NE	0	NE	NE	NE
Screening	131HR	125	100,0	118	94,4	72,61	21,75	114	100,0	109	95,6	75,44	20,56
Cycle 4 Day 1	131HR	105	84,0	97	92,4	77,06	18,07	110	96,5	99	90,0	75,96	19,62
FU Day 28	131HR	116	92,8	102	87,9	75,13	21,60	105	92,1	96	91,4	76,53	20,32
FU Month 3	131HR	114	91,2	102	89,5	77,79	21,74	107	93,9	95	88,8	76,32	18,76
FU Month 6	131HR	104	83,2	93	89,4	77,89	19,37	95	83,3	85	89,5	74,54	20,96
FU Month 9	131HR	84	67,2	71	84,5	79,62	18,37	76	66,7	61	80,3	72,40	20,98

FU Month 12	131HR	64	51,2	57	89,1	78,22	19,81	57	50,0	48	84,2	71,88	20,23
FU Month 15	131HR	53	42,4	44	83,0	80,15	17,70	44	38,6	35	79,5	75,43	21,56
FU Month 18	131HR	43	34,4	38	88,4	78,77	17,11	32	28,1	26	81,3	78,72	19,42
FU Month 21	131HR	26	20,8	20	76,9	76,67	18,67	21	18,4	16	76,2	80,00	14,40
FU Month 24	131HR	12	9,6	11	91,7	81,21	13,60	12	10,5	11	91,7	80,00	20,66
FU Month 27	131HR	6	4,8	5	83,3	82,33	9,69	6	5,3	4	66,7	75,00	6,38
FU Month 30	131HR	3	2,4	3	100,0	68,89	19,25	1	0,9	1	100,0	73,33	NE
Screening	131RR	49	100,0	48	98,0	76,11	21,65	33	100,0	30	90,9	77,89	16,85
Cycle 4 Day 1	131RR	40	81,6	38	95,0	82,63	18,18	31	93,9	25	80,6	77,60	18,45
FU Day 28	131RR	42	85,7	35	83,3	83,38	16,25	32	97,0	29	90,6	82,53	16,27
FU Month 3	131RR	39	79,6	37	94,9	76,62	20,28	32	97,0	30	93,8	77,28	22,17
FU Month 6	131RR	35	71,4	32	91,4	80,16	20,22	27	81,8	23	85,2	80,72	21,51
FU Month 9	131RR	24	49,0	22	91,7	83,33	20,44	19	57,6	17	89,5	73,33	18,10
FU Month 12	131RR	18	36,7	17	94,4	82,75	16,68	17	51,5	15	88,2	79,56	16,80
FU Month 15	131RR	16	32,7	16	100,0	87,60	13,85	11	33,3	9	81,8	74,81	21,80
FU Month 18	131RR	14	28,6	14	100,0	85,24	18,52	8	24,2	7	87,5	76,19	17,58
FU Month 21	131RR	8	16,3	7	87,5	86,67	12,77	5	15,2	4	80,0	95,00	6,38
FU Month 24	131RR	5	10,2	4	80,0	65,00	19,91	3	9,1	3	100,0	86,67	17,64
FU Month 27	131RR	2	4,1	2	100,0	80,00	9,43	1	3,0	1	100,0	100,00	NE
FU Month 30	131RR	1	2,0	1	100,0	86,67	NE	0	NE	0	NE	NE	NE
Screening	Missing	23	100,0	22	95,7	75,76	19,03	19	100,0	17	89,5	66,18	23,18
Cycle 4 Day 1	Missing	19	82,6	17	89,5	79,22	27,07	18	94,7	14	77,8	70,00	14,02
FU Day 28	Missing	21	91,3	18	85,7	82,13	20,27	18	94,7	16	88,9	74,58	19,51
FU Month 3	Missing	21	91,3	17	81,0	81,96	23,19	18	94,7	17	94,4	69,80	23,47
FU Month 6	Missing	19	82,6	16	84,2	78,65	30,40	15	78,9	14	93,3	75,24	20,33
FU Month 9	Missing	17	73,9	15	88,2	80,44	24,75	13	68,4	10	76,9	62,00	28,98
FU Month 12	Missing	15	65,2	11	73,3	84,09	17,94	9	47,4	7	77,8	68,57	35,84
FU Month 15	Missing	12	52,2	11	91,7	83,64	19,86	6	31,6	5	83,3	52,00	42,53
FU Month 18	Missing	5	21,7	4	80,0	95,00	6,38	4	21,1	3	75,0	73,33	35,28
FU Month 21	Missing	5	21,7	5	100,0	81,33	20,22	3	15,8	2	66,7	93,33	9,43
FU Month 24	Missing	4	17,4	3	75,0	93,33	6,67	2	10,5	2	100,0	93,33	9,43
FU Month 27	Missing	1	4,3	1	100,0	100,00	NE	1	5,3	1	100,0	86,67	NE
FCgamma receptor IIIa													
Screening	158FF	103	100,0	101	98,1	73,66	21,59	83	100,0	79	95,2	78,23	16,12
Cycle 4 Day 1	158FF	89	86,4	83	93,3	78,59	18,13	78	94,0	72	92,3	79,24	18,35
FU Day 28	158FF	96	93,2	84	87,5	79,13	19,93	78	94,0	74	94,9	80,81	17,52
FU Month 3	158FF	94	91,3	84	89,4	77,94	20,12	78	94,0	71	91,0	78,97	18,41
FU Month 6	158FF	86	83,5	74	86,0	77,48	20,00	64	77,1	59	92,2	81,30	19,94

FU Month 9	158FF	71	68,9	59	83,1	80,90	20,43	47	56,6	43	91,5	76,09	19,44
FU Month 12	158FF	48	46,6	42	87,5	78,69	21,18	38	45,8	35	92,1	75,52	19,95
FU Month 15	158FF	37	35,9	32	86,5	81,09	19,44	30	36,1	24	80,0	78,61	21,98
FU Month 18	158FF	27	26,2	25	92,6	80,40	16,95	21	25,3	17	81,0	81,96	20,79
FU Month 21	158FF	16	15,5	15	93,8	76,00	18,14	9	10,8	8	88,9	80,00	23,37
FU Month 24	158FF	8	7,8	7	87,5	80,00	13,88	3	3,6	3	100,0	91,11	7,70
FU Month 27	158FF	5	4,9	4	80,0	90,00	6,67	1	1,2	1	100,0	100,00	NE
FU Month 30	158FF	3	2,9	3	100,0	88,89	10,18	0	NE	0	NE	NE	NE
Screening	158FV	119	100,0	110	92,4	75,18	20,26	109	100,0	103	94,5	74,11	21,88
Cycle 4 Day 1	158FV	99	83,2	89	89,9	80,17	18,41	100	91,7	86	86,0	74,21	20,45
FU Day 28	158FV	105	88,2	91	86,7	77,00	20,49	101	92,7	87	86,1	77,47	19,51
FU Month 3	158FV	101	84,9	93	92,1	78,32	22,12	97	89,0	84	86,6	75,99	21,13
FU Month 6	158FV	94	79,0	87	92,6	79,77	18,84	83	76,1	72	86,7	75,62	20,07
FU Month 9	158FV	71	59,7	61	85,9	80,33	17,53	65	59,6	49	75,4	73,84	21,19
FU Month 12	158FV	60	50,4	55	91,7	79,58	18,56	52	47,7	42	80,8	71,03	24,20
FU Month 15	158FV	52	43,7	45	86,5	82,52	16,41	36	33,0	30	83,3	72,00	25,03
FU Month 18	158FV	44	37,0	38	86,4	80,35	21,02	24	22,0	20	83,3	68,33	23,08
FU Month 21	158FV	28	23,5	18	64,3	83,33	16,53	18	16,5	14	77,8	70,95	27,38
FU Month 24	158FV	18	15,1	13	72,2	75,38	17,93	6	5,5	5	83,3	66,67	24,49
FU Month 27	158FV	6	5,0	5	83,3	74,33	12,22	2	1,8	1	50,0	66,67	NE
FU Month 30	158FV	4	3,4	3	75,0	55,56	21,43	0	NE	0	NE	NE	NE
Screening	158VV	16	100,0	15	93,8	68,00	23,53	33	100,0	31	93,9	77,42	18,35
Cycle 4 Day 1	158VV	12	75,0	11	91,7	83,03	12,42	30	90,9	28	93,3	76,90	17,35
FU Day 28	158VV	14	87,5	13	92,9	82,05	17,51	30	90,9	28	93,3	77,56	19,68
FU Month 3	158VV	15	93,8	12	80,0	83,33	11,19	30	90,9	26	86,7	79,49	18,08
FU Month 6	158VV	14	87,5	13	92,9	83,59	17,35	30	90,9	25	83,3	74,40	17,50
FU Month 9	158VV	12	75,0	10	83,3	80,67	18,18	25	75,8	20	80,0	75,00	16,60
FU Month 12	158VV	8	50,0	7	87,5	77,14	14,84	20	60,6	17	85,0	80,39	16,24
FU Month 15	158VV	8	50,0	7	87,5	80,00	17,21	14	42,4	11	78,6	78,79	14,85
FU Month 18	158VV	4	25,0	4	100,0	75,00	11,39	11	33,3	9	81,8	80,00	17,00
FU Month 21	158VV	3	18,8	2	66,7	80,00	9,43	9	27,3	7	77,8	82,86	14,33
FU Month 24	158VV	2	12,5	2	100,0	80,00	9,43	7	21,2	7	100,0	89,52	11,45
FU Month 27	158VV	1	6,3	1	100,0	60,00	NE	5	15,2	4	80,0	80,00	5,44
FU Month 30	158VV	0	NE	0	NE	NE	NE	1	3,0	1	100,0	73,33	NE
Screening	Missing	17	100,0	16	94,1	72,50	21,34	17	100,0	15	88,2	64,33	23,35
Cycle 4 Day 1	Missing	13	76,5	12	92,3	71,11	30,92	16	94,1	12	75,0	71,11	17,13
FU Day 28	Missing	15	88,2	13	86,7	76,79	23,73	16	94,1	14	87,5	70,00	20,88
FU Month 3	Missing	15	88,2	14	93,3	75,71	25,57	16	94,1	15	93,8	63,56	26,41

FU Month 6	Missing	13	76,5	12	92,3	74,44	32,76	15	88,2	14	93,3	70,48	24,21	
FU Month 9	Missing	10	58,8	8	80,0	76,67	28,73	12	70,6	9	75,0	62,96	26,90	
FU Month 12	Missing	9	52,9	5	55,6	89,33	11,16	7	41,2	5	71,4	72,00	32,80	
FU Month 15	Missing	7	41,2	6	85,7	90,00	8,16	5	29,4	4	80,0	70,00	46,98	
FU Month 18	Missing	4	23,5	3	75,0	93,33	6,67	4	23,5	3	75,0	93,33	6,67	
FU Month 21	Missing	5	29,4	5	100,0	81,33	20,22	4	23,5	3	75,0	91,11	7,70	
FU Month 24	Missing	4	23,5	3	75,0	93,33	6,67	2	11,8	2	100,0	93,33	9,43	
FU Month 27	Missing	1	5,9	1	100,0	100,00		NE	1	5,9	1	100,0	86,67	NE
Binet Staging at baseline														
Screening	A	59	100,0	58	98,3	71,64	23,30	57	100,0	53	93,0	70,41	23,31	
Cycle 4 Day 1	A	51	86,4	48	94,1	72,95	20,82	54	94,7	50	92,6	72,90	21,38	
FU Day 28	A	58	98,3	53	91,4	71,79	21,92	54	94,7	52	96,3	74,01	20,55	
FU Month 3	A	57	96,6	56	98,2	74,08	23,91	53	93,0	50	94,3	73,17	20,61	
FU Month 6	A	56	94,9	50	89,3	73,83	21,99	45	78,9	42	93,3	74,55	20,17	
FU Month 9	A	43	72,9	37	86,0	73,15	21,52	34	59,6	30	88,2	66,00	22,98	
FU Month 12	A	36	61,0	34	94,4	74,61	21,03	24	42,1	21	87,5	69,84	23,25	
FU Month 15	A	30	50,8	27	90,0	78,83	18,66	19	33,3	19	100,0	69,12	28,91	
FU Month 18	A	22	37,3	18	81,8	74,07	23,64	16	28,1	16	100,0	77,92	19,43	
FU Month 21	A	17	28,8	15	88,2	76,89	18,49	8	14,0	7	87,5	81,90	16,20	
FU Month 24	A	10	16,9	8	80,0	75,00	16,23	5	8,8	5	100,0	85,33	10,95	
FU Month 27	A	5	8,5	4	80,0	80,00	17,21	2	3,5	1	50,0	86,67	NE	
FU Month 30	A	4	6,8	3	75,0	73,33	30,55	0	NE	0	NE	NE	NE	
Screening	B	104	100,0	100	96,2	74,27	20,28	85	100,0	83	97,6	76,27	17,66	
Cycle 4 Day 1	B	88	84,6	83	94,3	80,40	17,71	79	92,9	73	92,4	77,35	17,56	
FU Day 28	B	91	87,5	79	86,8	80,63	18,82	79	92,9	71	89,9	80,02	17,16	
FU Month 3	B	88	84,6	78	88,6	78,98	21,19	79	92,9	71	89,9	78,76	19,38	
FU Month 6	B	80	76,9	76	95,0	81,43	17,32	70	82,4	64	91,4	78,67	19,13	
FU Month 9	B	63	60,6	52	82,5	82,56	16,81	59	69,4	49	83,1	76,43	16,43	
FU Month 12	B	47	45,2	39	83,0	82,35	17,06	46	54,1	40	87,0	75,58	21,15	
FU Month 15	B	37	35,6	34	91,9	83,53	17,15	34	40,0	28	82,4	78,57	17,53	
FU Month 18	B	31	29,8	29	93,5	83,33	16,28	22	25,9	18	81,8	77,04	19,70	
FU Month 21	B	18	17,3	13	72,2	79,49	17,94	17	20,0	14	82,4	82,38	16,25	
FU Month 24	B	11	10,6	9	81,8	77,04	18,29	8	9,4	8	100,0	82,50	25,43	
FU Month 27	B	5	4,8	4	80,0	81,67	16,67	4	4,7	4	100,0	81,67	13,74	
FU Month 30	B	2	1,9	2	100,0	83,33	4,71	0	NE	0	NE	NE	NE	
Screening	C	92	100,0	84	91,3	75,10	20,41	100	100,0	92	92,0	77,36	19,34	
Cycle 4 Day 1	C	74	80,4	64	86,5	82,03	18,39	91	91,0	75	82,4	77,36	19,03	
FU Day 28	C	81	88,0	69	85,2	80,34	19,57	92	92,0	80	87,0	79,27	19,29	

FU Month 3	C	80	87,0	69	86,3	80,89	17,74	89	89,0	75	84,3	76,80	21,40	
FU Month 6	C	71	77,2	60	84,5	79,56	21,75	77	77,0	64	83,1	76,90	21,24	
FU Month 9	C	58	63,0	49	84,5	83,54	19,25	56	56,0	42	75,0	76,94	21,47	
FU Month 12	C	42	45,7	36	85,7	81,11	18,89	47	47,0	38	80,9	75,35	22,32	
FU Month 15	C	37	40,2	29	78,4	84,14	15,68	32	32,0	22	68,8	76,36	26,33	
FU Month 18	C	26	28,3	23	88,5	82,32	17,01	22	22,0	15	68,2	75,11	26,60	
FU Month 21	C	17	18,5	12	70,6	85,00	14,53	15	15,0	11	73,3	69,09	31,73	
FU Month 24	C	11	12,0	8	72,7	85,83	11,51	5	5,0	4	80,0	83,33	11,55	
FU Month 27	C	3	3,3	3	100,0	81,67	13,23	3	3,0	2	66,7	80,00	9,43	
FU Month 30	C	1	1,1	1	100,0	46,67		NE	1	1,0	1	100,0	73,33	NE
Total CIR score at baseline														
Screening	<=6	63	100,0	59	93,7	80,00	20,64	75	100,0	70	93,3	79,57	18,07	
Cycle 4 Day 1	<=6	52	82,5	42	80,8	82,38	20,76	72	96,0	61	84,7	80,22	16,24	
FU Day 28	<=6	56	88,9	49	87,5	83,74	18,28	72	96,0	59	81,9	82,82	14,07	
FU Month 3	<=6	55	87,3	47	85,5	81,89	20,34	69	92,0	56	81,2	83,36	15,71	
FU Month 6	<=6	52	82,5	47	90,4	83,40	19,10	60	80,0	53	88,3	80,22	17,17	
FU Month 9	<=6	43	68,3	36	83,7	82,78	21,10	47	62,7	38	80,9	79,30	15,87	
FU Month 12	<=6	35	55,6	29	82,9	82,30	15,25	34	45,3	27	79,4	79,51	21,48	
FU Month 15	<=6	32	50,8	28	87,5	81,43	19,23	25	33,3	17	68,0	83,53	14,93	
FU Month 18	<=6	23	36,5	22	95,7	81,06	18,44	19	25,3	14	73,7	82,86	20,37	
FU Month 21	<=6	14	22,2	8	57,1	89,17	16,31	14	18,7	10	71,4	80,67	21,19	
FU Month 24	<=6	8	12,7	7	87,5	85,71	21,23	7	9,3	6	85,7	83,33	15,06	
FU Month 27	<=6	2	3,2	2	100,0	89,17	3,54	4	5,3	2	50,0	70,00	4,71	
FU Month 30	<=6	0	NE	0	NE	NE	NE	1	1,3	1	100,0	73,33	NE	
Screening														
Screening	>6	192	100,0	183	95,3	71,97	20,84	167	100,0	158	94,6	73,47	20,39	
Cycle 4 Day 1														
Cycle 4 Day 1	>6	161	83,9	153	95,0	78,20	18,43	152	91,0	137	90,1	74,45	20,10	
FU Day 28														
FU Day 28	>6	174	90,6	152	87,4	76,41	20,52	153	91,6	144	94,1	76,28	20,40	
FU Month 3														
FU Month 3	>6	170	88,5	156	91,8	77,19	21,11	152	91,0	140	92,1	73,87	21,58	
FU Month 6														
FU Month 6	>6	155	80,7	139	89,7	77,22	20,46	132	79,0	117	88,6	75,52	21,27	
FU Month 9														
FU Month 9	>6	121	63,0	102	84,3	79,54	18,79	102	61,1	83	81,4	71,61	21,78	
FU Month 12														
FU Month 12	>6	90	46,9	80	88,9	78,52	20,30	83	49,7	72	86,7	72,31	21,95	
FU Month 15														
FU Month 15	>6	72	37,5	62	86,1	82,72	16,25	60	35,9	52	86,7	72,56	25,76	
FU Month 18														
FU Month 18	>6	56	29,2	48	85,7	80,42	19,13	41	24,6	35	85,4	74,29	21,76	
FU Month 21														
FU Month 21	>6	38	19,8	32	84,2	77,92	16,80	26	15,6	22	84,6	76,36	24,06	
FU Month 24														
FU Month 24	>6	24	12,5	18	75,0	76,67	12,99	11	6,6	11	100,0	83,64	20,73	
FU Month 27														
FU Month 27	>6	11	5,7	9	81,8	79,26	15,44	5	3,0	5	100,0	86,67	8,16	
FU Month 30														
FU Month 30	>6	7	3,6	6	85,7	72,22	23,63	0	NE	0	NE	NE	NE	
Calculated creatinine clearance cat. 2														

Screening	<70 ml/min	178	100,0	166	93,3	74,80	20,31	176	100,0	166	94,3	75,67	20,05
Cycle 4 Day 1	<70 ml/min	149	83,7	133	89,3	80,24	18,18	164	93,2	144	87,8	76,64	19,17
FU Day 28	<70 ml/min	162	91,0	142	87,7	78,50	18,30	166	94,3	146	88,0	79,06	18,39
FU Month 3	<70 ml/min	157	88,2	141	89,8	79,26	19,85	159	90,3	139	87,4	77,17	20,49
FU Month 6	<70 ml/min	144	80,9	127	88,2	79,99	18,65	139	79,0	122	87,8	78,03	19,91
FU Month 9	<70 ml/min	117	65,7	97	82,9	80,27	19,65	112	63,6	90	80,4	75,24	20,40
FU Month 12	<70 ml/min	92	51,7	79	85,9	80,08	18,07	87	49,4	73	83,9	75,43	22,90
FU Month 15	<70 ml/min	78	43,8	69	88,5	83,02	16,38	60	34,1	48	80,0	76,67	24,02
FU Month 18	<70 ml/min	59	33,1	51	86,4	80,33	19,51	43	24,4	36	83,7	76,11	24,14
FU Month 21	<70 ml/min	38	21,3	27	71,1	80,25	17,68	31	17,6	27	87,1	75,80	24,33
FU Month 24	<70 ml/min	24	13,5	19	79,2	78,60	16,72	13	7,4	12	92,3	88,89	8,68
FU Month 27	<70 ml/min	10	5,6	8	80,0	80,63	13,33	7	4,0	5	71,4	85,33	9,89
FU Month 30	<70 ml/min	5	2,8	4	80,0	63,33	23,41	1	0,6	1	100,0	73,33	NE
Screening	>=70 ml/min	77	100,0	76	98,7	72,02	22,58	66	100,0	62	93,9	74,46	19,51
Cycle 4 Day 1	>=70 ml/min	64	83,1	62	96,9	76,67	20,55	60	90,9	54	90,0	75,12	19,19
FU Day 28	>=70 ml/min	68	88,3	59	86,8	77,49	24,34	59	89,4	57	96,6	75,94	20,42
FU Month 3	>=70 ml/min	68	88,3	62	91,2	76,05	23,36	62	93,9	57	91,9	75,15	20,63
FU Month 6	>=70 ml/min	63	81,8	59	93,7	76,19	23,30	53	80,3	48	90,6	74,34	20,72
FU Month 9	>=70 ml/min	47	61,0	41	87,2	80,65	19,02	37	56,1	31	83,8	70,48	20,16
FU Month 12	>=70 ml/min	33	42,9	30	90,9	78,06	21,82	30	45,5	26	86,7	71,03	19,06
FU Month 15	>=70 ml/min	26	33,8	21	80,8	80,00	19,66	25	37,9	21	84,0	72,06	24,00
FU Month 18	>=70 ml/min	20	26,0	19	95,0	81,40	17,15	17	25,8	13	76,5	78,46	12,22
FU Month 21	>=70 ml/min	14	18,2	13	92,9	80,00	16,56	9	13,6	5	55,6	88,00	8,69
FU Month 24	>=70 ml/min	8	10,4	6	75,0	81,11	13,61	5	7,6	5	100,0	70,67	29,29
FU Month 27	>=70 ml/min	3	3,9	3	100,0	82,22	20,37	2	3,0	2	100,0	73,33	9,43
FU Month 30	>=70 ml/min	2	2,6	2	100,0	90,00	14,14	0	NE	0	NE	NE	NE
Beta2 microglobulin													
Screening	Missing	3	100,0	3	100,0	75,56	13,88	3	100,0	3	100,0	35,56	15,40
Cycle 4 Day 1	Missing	3	100,0	3	100,0	73,33	24,04	3	100,0	2	66,7	66,67	9,43
FU Day 28	Missing	3	100,0	3	100,0	86,67	0,00	3	100,0	2	66,7	76,67	23,57
FU Month 3	Missing	3	100,0	3	100,0	80,00	17,64	3	100,0	2	66,7	70,00	33,00
FU Month 6	Missing	3	100,0	3	100,0	93,33	0,00	3	100,0	2	66,7	80,00	18,86
FU Month 9	Missing	2	66,7	1	50,0	93,33	NE	3	100,0	2	66,7	70,00	14,14
FU Month 12	Missing	1	33,3	1	100,0	86,67	NE	2	66,7	1	50,0	73,33	NE
FU Month 15	Missing	1	33,3	1	100,0	86,67	NE	2	66,7	1	50,0	66,67	NE
FU Month 18	Missing	1	33,3	1	100,0	86,67	NE	2	66,7	1	50,0	66,67	NE
FU Month 21	Missing	1	33,3	1	100,0	86,67	NE	2	66,7	1	50,0	60,00	NE
FU Month 24	Missing	1	33,3	1	100,0	86,67	NE	1	33,3	1	100,0	66,67	NE

Screening	< 3.5 ug/mL	154	100,0	145	94,2	74,69	22,11	140	100,0	132	94,3	76,25	18,84
Cycle 4 Day 1	< 3.5 ug/mL	127	82,5	116	91,3	77,83	20,63	129	92,1	112	86,8	75,77	19,92
FU Day 28	< 3.5 ug/mL	137	89,0	121	88,3	77,38	20,63	132	94,3	121	91,7	78,40	19,04
FU Month 3	< 3.5 ug/mL	134	87,0	123	91,8	79,16	19,97	130	92,9	116	89,2	75,96	20,59
FU Month 6	< 3.5 ug/mL	128	83,1	114	89,1	78,79	19,68	120	85,7	111	92,5	76,23	20,64
FU Month 9	< 3.5 ug/mL	104	67,5	87	83,7	79,16	19,76	98	70,0	81	82,7	73,79	20,10
FU Month 12	< 3.5 ug/mL	78	50,6	69	88,5	79,44	20,38	75	53,6	67	89,3	73,43	22,32
FU Month 15	< 3.5 ug/mL	65	42,2	56	86,2	81,58	18,23	60	42,9	51	85,0	74,90	23,91
FU Month 18	< 3.5 ug/mL	46	29,9	41	89,1	78,86	20,43	43	30,7	35	81,4	76,57	19,70
FU Month 21	< 3.5 ug/mL	30	19,5	21	70,0	80,32	18,07	27	19,3	22	81,5	76,36	25,09
FU Month 24	< 3.5 ug/mL	19	12,3	15	78,9	82,22	13,25	12	8,6	11	91,7	86,06	14,13
FU Month 27	< 3.5 ug/mL	10	6,5	8	80,0	79,79	15,34	7	5,0	5	71,4	78,67	8,69
FU Month 30	< 3.5 ug/mL	5	3,2	4	80,0	63,33	23,41	1	0,7	1	100,0	73,33	NE
Screening	>= 3.5 ug/mL	98	100,0	94	95,9	72,70	19,58	99	100,0	93	93,9	75,34	20,26
Cycle 4 Day 1	>= 3.5 ug/mL	83	84,7	76	91,6	81,27	15,99	92	92,9	84	91,3	77,06	18,28
FU Day 28	>= 3.5 ug/mL	90	91,8	77	85,6	79,16	19,93	90	90,9	80	88,9	77,90	19,06
FU Month 3	>= 3.5 ug/mL	88	89,8	77	87,5	76,80	22,75	88	88,9	78	88,6	77,67	20,33
FU Month 6	>= 3.5 ug/mL	76	77,6	69	90,8	78,14	21,51	69	69,7	57	82,6	78,36	19,45
FU Month 9	>= 3.5 ug/mL	58	59,2	50	86,2	82,27	18,89	48	48,5	38	79,2	74,74	21,54
FU Month 12	>= 3.5 ug/mL	46	46,9	39	84,8	79,49	17,06	40	40,4	31	77,5	76,13	21,76
FU Month 15	>= 3.5 ug/mL	38	38,8	33	86,8	83,43	15,56	23	23,2	17	73,9	76,86	25,29
FU Month 18	>= 3.5 ug/mL	32	32,7	28	87,5	82,98	16,46	15	15,2	13	86,7	77,95	27,27
FU Month 21	>= 3.5 ug/mL	21	21,4	18	85,7	79,63	16,88	11	11,1	9	81,8	82,96	17,67
FU Month 24	>= 3.5 ug/mL	12	12,2	9	75,0	73,33	19,44	5	5,1	5	100,0	81,33	27,65
FU Month 27	>= 3.5 ug/mL	3	3,1	3	100,0	84,44	13,88	2	2,0	2	100,0	90,00	14,14
FU Month 30	>= 3.5 ug/mL	2	2,0	2	100,0	90,00	14,14	0	NE	0	NE	NE	NE
Immunoglobulin VH, cytogenetics 2													
Screening	12	45	100,0	43	95,6	69,65	22,10	44	100,0	43	97,7	77,60	17,33
Cycle 4 Day 1	12	34	75,6	32	94,1	75,21	20,82	38	86,4	33	86,8	73,54	19,96
FU Day 28	12	39	86,7	37	94,9	72,25	20,64	40	90,9	35	87,5	73,14	23,06
FU Month 3	12	38	84,4	36	94,7	73,19	22,45	39	88,6	32	82,1	72,50	24,11
FU Month 6	12	36	80,0	31	86,1	77,53	21,15	34	77,3	28	82,4	73,81	20,60
FU Month 9	12	26	57,8	22	84,6	78,18	21,40	28	63,6	18	64,3	70,37	18,75
FU Month 12	12	22	48,9	18	81,8	80,37	18,36	23	52,3	15	65,2	74,67	18,89
FU Month 15	12	17	37,8	14	82,4	81,43	18,34	17	38,6	12	70,6	73,33	20,89
FU Month 18	12	15	33,3	12	80,0	76,67	26,13	13	29,5	9	69,2	80,74	16,48
FU Month 21	12	10	22,2	8	80,0	74,17	15,71	7	15,9	5	71,4	90,67	7,60
FU Month 24	12	8	17,8	6	75,0	68,89	11,67	6	13,6	6	100,0	80,00	25,99
FU Month 27	12	5	11,1	4	80,0	71,67	13,74	2	4,5	2	100,0	76,67	4,71

FU Month 30	12	48,9	375,0	68,89	25,24	12,3	100,0	73,33	NE
Screening	11q-	46100,0	4393,5	77,05	18,82	43100,0	4093,0	77,17	15,46
Cycle 4 Day 1	11q-	4087,0	3997,5	80,00	18,61	4195,3	3585,4	80,67	16,37
FU Day 28	11q-	4291,3	3583,3	80,29	19,21	3990,7	3692,3	81,48	14,96
FU Month 3	11q-	4291,3	3890,5	78,42	20,59	3888,4	3694,7	80,09	15,58
FU Month 6	11q-	3882,6	3592,1	81,33	17,17	3274,4	2887,5	77,86	16,86
FU Month 9	11q-	2860,9	2692,9	82,56	18,29	2558,1	2184,0	74,29	16,90
FU Month 12	11q-	2043,5	1995,0	81,32	20,78	1841,9	1794,4	72,55	18,69
FU Month 15	11q-	1839,1	1688,9	83,44	19,57	1432,6	1071,4	75,33	18,61
FU Month 18	11q-	1532,6	1386,7	82,05	21,15	818,6	787,5	74,29	15,12
FU Month 21	11q-	1226,1	1191,7	84,24	15,85	49,3	250,0	90,00	4,71
FU Month 24	11q-	715,2	571,4	86,67	13,33	12,3	100,0	100,00	NE
FU Month 27	11q-	36,5	3100,0	84,44	16,78	0	NE	NE	NE
FU Month 30	11q-	36,5	3100,0	75,56	26,94	0	NE	NE	NE
Screening	13q-	79100,0	7797,5	78,29	19,17	75100,0	7093,3	74,45	21,85
Cycle 4 Day 1	13q-	6784,8	6089,6	82,44	16,56	6890,7	6088,2	76,58	17,94
FU Day 28	13q-	7291,1	6590,3	81,51	18,61	7296,0	6590,3	79,08	20,08
FU Month 3	13q-	7392,4	6791,8	81,10	17,43	6992,0	6188,4	75,87	22,18
FU Month 6	13q-	6784,8	6191,0	81,17	17,37	6384,0	5688,9	77,02	20,81
FU Month 9	13q-	5670,9	4987,5	80,68	19,92	5269,3	4280,8	75,79	22,13
FU Month 12	13q-	4455,7	3988,6	80,68	16,53	4053,3	3895,0	74,04	23,61
FU Month 15	13q-	3848,1	3386,8	82,22	18,31	2938,7	2586,2	77,07	21,78
FU Month 18	13q-	2835,4	2589,3	81,33	17,11	2128,0	1990,5	76,49	20,05
FU Month 21	13q-	1620,3	1381,3	75,90	18,96	1621,3	1487,5	77,14	18,99
FU Month 24	13q-	78,9	685,7	80,00	10,33	79,3	685,7	86,67	11,16
FU Month 27	13q-	22,5	150,0	86,67	NE	68,0	466,7	88,33	8,39
Screening	Norm. K.	65100,0	6193,8	70,60	19,45	58100,0	5594,8	71,03	21,40
Cycle 4 Day 1	Norm. K.	5483,1	4888,9	78,47	18,82	5594,8	5090,9	72,93	21,10
FU Day 28	Norm. K.	5990,8	5084,7	78,33	18,80	5391,4	5094,3	76,50	16,69
FU Month 3	Norm. K.	5483,1	4888,9	79,48	21,38	5493,1	4888,9	74,65	20,08
FU Month 6	Norm. K.	4975,4	4795,9	73,01	23,94	4577,6	4088,9	75,94	22,15
FU Month 9	Norm. K.	3960,0	3179,5	78,71	18,97	3051,7	2790,0	73,83	20,67
FU Month 12	Norm. K.	3249,2	2784,4	76,67	19,74	2441,4	2083,3	73,33	24,28
FU Month 15	Norm. K.	2640,0	2388,5	80,58	14,48	2034,5	1890,0	74,07	26,56
FU Month 18	Norm. K.	1827,7	1794,4	79,02	14,61	1525,9	1280,0	71,67	29,97
FU Month 21	Norm. K.	1218,5	650,0	83,33	16,19	1119,0	981,8	63,70	30,57
FU Month 24	Norm. K.	812,3	675,0	75,56	20,94	46,9	4100,0	80,00	18,05
FU Month 27	Norm. K.	34,6	3100,0	88,33	13,64	11,7	100,0	66,67	NE

Screening	Other Abn.	20	100,0	18	90,0	69,26	31,53	22	100,0	20	90,9	81,83	20,16
Cycle 4 Day 1	Other Abn.	18	90,0	16	88,9	74,06	24,32	22	100,0	20	90,9	80,08	20,15
FU Day 28	Other Abn.	18	90,0	14	77,8	72,86	29,98	21	95,5	17	81,0	83,14	18,58
FU Month 3	Other Abn.	18	90,0	14	77,8	73,33	30,61	21	95,5	19	90,5	83,95	16,17
FU Month 6	Other Abn.	17	85,0	12	70,6	85,00	22,04	18	81,8	18	100,0	82,78	18,09
FU Month 9	Other Abn.	15	75,0	10	66,7	83,33	19,18	14	63,6	13	92,9	73,33	23,25
FU Month 12	Other Abn.	7	35,0	6	85,7	76,67	31,48	12	54,5	9	75,0	80,00	23,57
FU Month 15	Other Abn.	5	25,0	4	80,0	91,67	8,39	5	22,7	4	80,0	75,00	50,00
FU Month 18	Other Abn.	3	15,0	3	100,0	93,33	11,55	3	13,6	2	66,7	100,00	0,00
FU Month 21	Other Abn.	2	10,0	2	100,0	100,00	0,00	2	9,1	2	100,0	100,00	0,00
FU Month 24	Other Abn.	2	10,0	2	100,0	100,00	0,00	0	NE	0	NE	NE	NE
Time from first diagnosis													
Screening	Missing	1	100,0	1	100,0	86,67	NE	0	NE	0	NE	NE	NE
Cycle 4 Day 1	Missing	1	100,0	1	100,0	86,67	NE	0	NE	0	NE	NE	NE
FU Day 28	Missing	1	100,0	1	100,0	100,00	NE	0	NE	0	NE	NE	NE
FU Month 3	Missing	1	100,0	1	100,0	100,00	NE	0	NE	0	NE	NE	NE
FU Month 6	Missing	1	100,0	1	100,0	93,33	NE	0	NE	0	NE	NE	NE
FU Month 9	Missing	1	100,0	1	100,0	100,00	NE	0	NE	0	NE	NE	NE
FU Month 12	Missing	1	100,0	1	100,0	93,33	NE	0	NE	0	NE	NE	NE
FU Month 15	Missing	1	100,0	1	100,0	100,00	NE	0	NE	0	NE	NE	NE
FU Month 18	Missing	1	100,0	1	100,0	100,00	NE	0	NE	0	NE	NE	NE
Screening	13 - 24 months	41	100,0	39	95,1	76,07	19,26	31	100,0	31	100,0	82,58	13,41
Cycle 4 Day 1	13 - 24 months	35	85,4	34	97,1	80,20	20,60	30	96,8	27	90,0	85,68	11,01
FU Day 28	13 - 24 months	38	92,7	33	86,8	80,00	19,65	30	96,8	27	90,0	86,23	12,05
FU Month 3	13 - 24 months	36	87,8	34	94,4	80,93	22,49	30	96,8	26	86,7	84,87	15,38
FU Month 6	13 - 24 months	36	87,8	33	91,7	82,42	20,13	30	96,8	25	83,3	83,93	15,24
FU Month 9	13 - 24 months	32	78,0	29	90,6	83,68	19,40	21	67,7	18	85,7	79,63	16,08
FU Month 12	13 - 24 months	21	51,2	18	85,7	83,70	19,30	16	51,6	14	87,5	84,76	14,66
FU Month 15	13 - 24 months	19	46,3	18	94,7	84,07	19,56	16	51,6	10	62,5	87,33	14,21
FU Month 18	13 - 24 months	14	34,1	13	92,9	83,59	16,01	10	32,3	8	80,0	85,83	15,71
FU Month 21	13 - 24 months	11	26,8	9	81,8	76,30	17,98	6	19,4	4	66,7	91,67	10,00
FU Month 24	13 - 24 months	8	19,5	5	62,5	60,00	14,14	3	9,7	3	100,0	93,33	6,67
FU Month 27	13 - 24 months	5	12,2	5	100,0	72,00	16,60	2	6,5	2	100,0	86,67	18,86
FU Month 30	13 - 24 months	3	7,3	3	100,0	62,22	32,89	1	3,2	1	100,0	73,33	NE
Screening	<= 12 months	60	100,0	58	96,7	75,00	21,94	70	100,0	69	98,6	74,54	19,82
Cycle 4 Day 1	<= 12 months	48	80,0	42	87,5	81,79	18,66	60	85,7	56	93,3	76,55	16,72
FU Day 28	<= 12 months	54	90,0	45	83,3	77,04	21,58	62	88,6	57	91,9	79,01	15,79

FU Month 3	<= 12 months	53	88,3	45	84,9	77,52	22,79	59	84,3	55	93,2	78,67	18,87
FU Month 6	<= 12 months	46	76,7	40	87,0	82,58	15,59	47	67,1	43	91,5	79,38	18,73
FU Month 9	<= 12 months	35	58,3	27	77,1	81,73	20,30	37	52,9	31	83,8	78,01	18,61
FU Month 12	<= 12 months	27	45,0	23	85,2	78,84	22,17	29	41,4	27	93,1	74,81	21,69
FU Month 15	<= 12 months	22	36,7	17	77,3	80,78	18,54	17	24,3	16	94,1	72,92	27,70
FU Month 18	<= 12 months	16	26,7	13	81,3	81,03	25,65	13	18,6	12	92,3	78,89	20,27
FU Month 21	<= 12 months	9	15,0	5	55,6	92,00	11,93	7	10,0	6	85,7	82,22	18,70
FU Month 24	<= 12 months	6	10,0	3	50,0	88,89	19,25	2	2,9	1	50,0	100,00	NE
FU Month 27	<= 12 months	1	1,7			NE	NE	1	1,4			NE	NE
FU Month 30	<= 12 months	1	1,7			NE	NE	0	NE			NE	NE
Screening	>24 months	153	100,0	144	94,1	72,82	21,24	141	100,0	128	90,8	74,02	20,92
Cycle 4 Day 1	>24 months	129	84,3	118	91,5	77,77	18,73	134	95,0	115	85,8	73,86	21,06
FU Day 28	>24 months	137	89,5	122	89,1	77,96	19,94	133	94,3	119	89,5	75,97	21,13
FU Month 3	>24 months	135	88,2	123	91,1	77,65	19,95	132	93,6	115	87,1	73,71	21,72
FU Month 6	>24 months	124	81,0	112	90,3	76,22	21,54	115	81,6	102	88,7	74,28	21,36
FU Month 9	>24 months	96	62,7	81	84,4	78,52	19,12	91	64,5	72	79,1	70,90	21,62
FU Month 12	>24 months	76	49,7	67	88,2	78,43	18,10	72	51,1	58	80,6	71,49	23,02
FU Month 15	>24 months	62	40,5	54	87,1	81,88	16,08	52	36,9	43	82,7	73,33	23,86
FU Month 18	>24 months	48	31,4	43	89,6	79,15	17,44	37	26,2	29	78,4	73,33	23,09
FU Month 21	>24 months	32	20,9	26	81,3	79,23	17,21	27	19,1	22	81,5	73,94	24,94
FU Month 24	>24 months	18	11,8	17	94,4	83,14	11,33	13	9,2	13	100,0	80,00	19,63
FU Month 27	>24 months	7	4,6	6	85,7	88,61	6,70	6	4,3	5	83,3	80,00	8,16
FU Month 30	>24 months	3	2,0	3	100,0	82,22	3,85	0	NE	0	NE	NE	NE
High circulating tumor burden													
Screening	Missing	0	NE	0	NE	NE	NE	2	100,0	1	50,0	86,67	NE
Cycle 4 Day 1	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	80,00	NE
FU Day 28	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	93,33	NE
FU Month 3	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	80,00	NE
FU Month 6	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	100,00	NE
FU Month 9	Missing	0	NE			NE	NE	1	50,0			NE	NE
Screening	<25x10**9 cells/L	60	100,0	55	91,7	73,39	23,29	67	100,0	64	95,5	76,09	19,74
Cycle 4 Day 1	<25x10**9 cells/L	50	83,3	44	88,0	76,52	17,52	61	91,0	52	85,2	77,66	19,14
FU Day 28	<25x10**9 cells/L	56	93,3	47	83,9	76,45	19,75	61	91,0	53	86,9	80,63	18,36
FU Month 3	<25x10**9 cells/L	54	90,0	47	87,0	76,24	22,35	59	88,1	50	84,7	80,60	17,32
FU Month 6	<25x10**9 cells/L	50	83,3	43	86,0	74,03	22,84	51	76,1	42	82,4	82,74	18,78
FU Month 9	<25x10**9 cells/L	36	60,0	27	75,0	81,48	17,57	41	61,2	30	73,2	83,11	16,30
FU Month 12	<25x10**9 cells/L	29	48,3	24	82,8	73,26	22,11	34	50,7	25	73,5	79,87	18,82
FU Month 15	<25x10**9 cells/L	24	40,0	19	79,2	79,65	16,85	23	34,3	15	65,2	80,89	21,51

FU Month 18	<25x10**9 cells/L	20	33,3	18	90,0	77,41	22,19	19	28,4	14	73,7	81,90	20,83
FU Month 21	<25x10**9 cells/L	14	23,3	10	71,4	72,67	17,90	10	14,9	8	80,0	86,67	15,94
FU Month 24	<25x10**9 cells/L	8	13,3	5	62,5	76,00	18,01	6	9,0	6	100,0	82,22	24,46
FU Month 27	<25x10**9 cells/L	4	6,7	3	75,0	71,11	13,88	1	1,5	1	100,0	73,33	NE
FU Month 30	<25x10**9 cells/L	4	6,7	3	75,0	57,78	25,24	1	1,5	1	100,0	73,33	NE
Screening	>=25x10**9 cells/L	195	100,0	187	95,9	74,08	20,39	173	100,0	163	94,2	74,98	20,01
Cycle 4 Day 1	>=25x10**9 cells/L	163	83,6	151	92,6	79,86	19,38	162	93,6	145	89,5	75,69	19,24
FU Day 28	>=25x10**9 cells/L	174	89,2	154	88,5	78,73	20,37	163	94,2	149	91,4	77,21	19,20
FU Month 3	>=25x10**9 cells/L	171	87,7	156	91,2	78,89	20,58	161	93,1	145	90,1	75,17	21,43
FU Month 6	>=25x10**9 cells/L	157	80,5	143	91,1	80,21	19,27	140	80,9	127	90,7	74,90	20,25
FU Month 9	>=25x10**9 cells/L	128	65,6	111	86,7	80,12	19,88	107	61,8	91	85,0	71,03	20,75
FU Month 12	>=25x10**9 cells/L	96	49,2	85	88,5	81,29	17,90	83	48,0	74	89,2	72,39	22,72
FU Month 15	>=25x10**9 cells/L	80	41,0	71	88,8	83,03	17,25	62	35,8	54	87,1	73,70	24,52
FU Month 18	>=25x10**9 cells/L	59	30,3	52	88,1	81,73	17,56	41	23,7	35	85,4	74,67	21,74
FU Month 21	>=25x10**9 cells/L	38	19,5	30	78,9	82,67	16,39	30	17,3	24	80,0	74,72	24,39
FU Month 24	>=25x10**9 cells/L	24	12,3	20	83,3	80,00	15,60	12	6,9	11	91,7	84,24	15,57
FU Month 27	>=25x10**9 cells/L	9	4,6	8	88,9	84,79	13,55	8	4,6	6	75,0	83,33	10,95
FU Month 30	>=25x10**9 cells/L	3	1,5	3	100,0	86,67	11,55	0	NE	0	NE	NE	NE

¹ in study: number of subjects in study at respective visit; % based on baseline

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit

² mean: descriptive statistics - absolute values Clinical

cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/t_pro_mean.sas

Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/t_pro_mean_sg_EQC30_IT_label_09MAY2013_21004.xls 04MAR2020

17:18

POPULATION: Labelpopulation, Intent-to-Treat Patients ENDPOINT: EORTC QoL 30

MODEL: Unadjusted Analysis STUDY: CLL11 (BO21004), Stage

2

Compliance/Mean

Role Functioning Scale

		GClb (N=255)						RC1b (N=242)					
		Patients			Statistics			Patients			Statistics		
Name	Level	in study ¹	%	with value ¹	%	Mean ²	SD (mean)	in study ¹	%	with value ¹	%	Mean ²	SD (mean)
All													
Screening	n/a	255	100,0	241	94,5	74,69	27,30	242	100,0	228	94,2	76,39	29,46
Cycle 4 Day 1	n/a	213	83,5	195	91,5	79,15	24,37	224	92,6	197	87,9	77,75	26,99
FU Day 28	n/a	230	90,2	201	87,4	77,69	27,56	225	93,0	203	90,2	77,67	26,52
FU Month 3	n/a	225	88,2	203	90,2	77,50	27,66	221	91,3	195	88,2	78,72	25,13
FU Month 6	n/a	207	81,2	184	88,9	80,34	25,16	192	79,3	168	87,5	78,67	26,17
FU Month 9	n/a	164	64,3	137	83,5	82,00	25,09	149	61,6	121	81,2	77,82	23,51
FU Month 12	n/a	125	49,0	109	87,2	77,22	27,47	117	48,3	99	84,6	76,43	26,30
FU Month 15	n/a	104	40,8	90	86,5	80,74	23,16	85	35,1	69	81,2	79,71	25,38
FU Month 18	n/a		79,31,0	70	88,6	80,48	26,31	60	24,8	49	81,7	72,45	28,17
FU Month 21	n/a		52,20,4	40	76,9	82,50	21,33	40	16,5	32	80,0	73,44	28,35
FU Month 24	n/a		32,12,5	25	78,1	75,33	30,85	18	7,4	17	94,4	85,29	27,56
FU Month 27	n/a		13,5,1	11	84,6	77,27	23,89	9	3,7	7	77,8	88,10	15,85
FU Month 30	n/a		7,2,7		6,85,7	72,22	32,77	1	0,4	1	100,0	100,00	NE
Gender													
Screening	Female	97	100,0	91	93,8	74,18	25,25	95	100,0	87	91,6	73,56	30,98
Cycle 4 Day 1	Female	84	86,6	76	90,5	74,34	23,48	88	92,6	78	88,6	73,50	27,71
FU Day 28	Female	90	92,8	83	92,2	75,30	27,59	91	95,8	79	86,8	76,79	26,21
FU Month 3	Female	88	90,7	81	92,0	74,28	27,52	87	91,6	77	88,5	72,94	26,50
FU Month 6	Female	84	86,6	72	85,7	78,47	23,48	77	81,1	67	87,0	78,11	27,25
FU Month 9	Female	70	72,2	59	84,3	75,14	27,05	61	64,2	46	75,4	76,81	23,95
FU Month 12	Female	56	57,7	49	87,5	72,79	25,16	47	49,5	40	85,1	75,42	24,75
FU Month 15	Female	47	48,5	40	85,1	72,50	26,03	33	34,7	28	84,8	78,57	26,78
FU Month 18	Female	34	35,1	29	85,3	74,71	29,42	26	27,4	22	84,6	73,48	30,71
FU Month 21	Female	21	21,6	15	71,4	73,33	25,04	17	17,9	15	88,2	65,56	34,20
FU Month 24	Female	12	12,4	10	83,3	65,00	37,23	6	6,3	5	83,3	100,00	0,00
FU Month 27	Female	6	6,2	5	83,3	73,33	25,28	2	2,1	1	50,0	100,00	NE
FU Month 30	Female	4	4,1	3	75,0	55,56	38,49	1	1,1	1	100,0	100,00	NE

Screening	Male	158	100,0	150	94,9	75,00	28,56	147	100,0	141	95,9	78,13	28,46
Cycle 4 Day 1	Male	129	81,6	119	92,2	82,21	24,52	136	92,5	119	87,5	80,53	26,25
FU Day 28	Male	140	88,6	118	84,3	79,38	27,54	134	91,2	124	92,5	78,23	26,81
FU Month 3	Male	137	86,7	122	89,1	79,64	27,65	134	91,2	118	88,1	82,49	23,55
FU Month 6	Male	123	77,8	112	91,1	81,55	26,22	115	78,2	101	87,8	79,04	25,57
FU Month 9	Male	94	59,5	78	83,0	87,18	22,30	88	59,9	75	85,2	78,44	23,37
FU Month 12	Male	69	43,7	60	87,0	80,83	28,92	70	47,6	59	84,3	77,12	27,49
FU Month 15	Male	57	36,1	50	87,7	87,33	18,31	52	35,4	41	78,8	80,49	24,69
FU Month 18	Male	45	28,5	41	91,1	84,55	23,39	34	23,1	27	79,4	71,60	26,48
FU Month 21	Male	31	19,6	25	80,6	88,00	17,02	23	15,6	17	73,9	80,39	20,61
FU Month 24	Male	20	12,7	15	75,0	82,22	24,77	12	8,2	12	100,0	79,17	31,08
FU Month 27	Male	7	4,4	6	85,7	80,56	24,53	7	4,8	6	85,7	86,11	16,39
FU Month 30	Male	3	1,9	3	100,0	88,89	19,25	0	NE	0	NE	NE	NE
Age													
Screening	<75 years	130	100,0	123	94,6	76,02	27,42	120	100,0	110	91,7	79,55	26,00
Cycle 4 Day 1	<75 years	106	81,5	100	94,3	81,83	22,23	112	93,3	97	86,6	81,62	23,26
FU Day 28	<75 years	119	91,5	105	88,2	81,27	25,39	110	91,7	103	93,6	80,26	25,11
FU Month 3	<75 years	116	89,2	106	91,4	79,56	26,66	109	90,8	98	89,9	79,93	23,32
FU Month 6	<75 years	108	83,1	97	89,8	81,27	23,97	99	82,5	88	88,9	79,55	22,13
FU Month 9	<75 years	85	65,4	72	84,7	82,41	23,05	74	61,7	62	83,8	77,15	23,23
FU Month 12	<75 years	63	48,5	59	93,7	77,97	25,42	60	50,0	53	88,3	77,67	24,67
FU Month 15	<75 years	54	41,5	47	87,0	80,85	20,55	44	36,7	35	79,5	82,38	22,49
FU Month 18	<75 years	43	33,1	39	90,7	80,34	26,46	27	22,5	22	81,5	74,24	31,17
FU Month 21	<75 years	26	20,0	22	84,6	83,33	17,82	17	14,2	13	76,5	82,05	18,59
FU Month 24	<75 years	18	13,8	14	77,8	75,00	29,78	6	5,0	5	83,3	83,33	23,57
FU Month 27	<75 years	7	5,4	5	71,4	70,00	21,73	2	1,7	1	50,0	100,00	NE
FU Month 30	<75 years	4	3,1	3	75,0	66,67	33,33	0	NE	0	NE	NE	NE
Screening	>=75 years	125	100,0	118	94,4	73,31	27,23	122	100,0	118	96,7	73,45	32,19
Cycle 4 Day 1	>=75 years	107	85,6	95	88,8	76,32	26,25	112	91,8	100	89,3	74,00	29,81
FU Day 28	>=75 years	111	88,8	96	86,5	73,78	29,39	115	94,3	100	87,0	75,00	27,78
FU Month 3	>=75 years	109	87,2	97	89,0	75,26	28,68	112	91,8	97	86,6	77,49	26,90
FU Month 6	>=75 years	99	79,2	87	87,9	79,31	26,53	93	76,2	80	86,0	77,71	30,11
FU Month 9	>=75 years	79	63,2	65	82,3	81,54	27,34	75	61,5	59	78,7	78,53	23,98
FU Month 12	>=75 years	62	49,6	50	80,6	76,33	29,95	57	46,7	46	80,7	75,00	28,27
FU Month 15	>=75 years	50	40,0	43	86,0	80,62	25,96	41	33,6	34	82,9	76,96	28,13
FU Month 18	>=75 years	36	28,8	31	86,1	80,65	26,56	33	27,0	27	81,8	70,99	25,98
FU Month 21	>=75 years	26	20,8	18	69,2	81,48	25,49	23	18,9	19	82,6	67,54	32,62
FU Month 24	>=75 years	14	11,2	11	78,6	75,76	33,63	12	9,8	12	100,0	86,11	30,01

FU Month 27	>=75 years	64,8	6100,0	83,33	25,82	75,7	685,7	86,11	16,39				
FU Month 30	>=75 years	32,4	3100,0	77,78	38,49	10,8	1100,0	100,00					NE
Race													
Screening	Other	9100,0	9100,0	81,48	32,75	11100,0	11100,0	81,82	24,10				
Cycle 4 Day 1	Other	777,8	7100,0	92,86	13,11	1090,9	990,0	75,93	18,84				
FU Day 28	Other	888,9	8100,0	93,75	12,40	1090,9	10100,0	86,67	15,32				
FU Month 3	Other	888,9	787,5	83,33	23,57	1090,9	10100,0	76,67	26,29				
FU Month 6	Other	888,9	787,5	85,71	26,23	872,7	8100,0	83,33	19,92				
FU Month 9	Other	444,4	375,0	88,89	19,25	545,5	480,0	87,50	25,00				
FU Month 12	Other	333,3	266,7	83,33	23,57	436,4	4100,0	83,33	19,25				
FU Month 15	Other	222,2	150,0	100,00		436,4	4100,0	87,50	25,00				
FU Month 18	Other	222,2	150,0	100,00		218,2	2100,0	91,67	11,79				
FU Month 21	Other	222,2	150,0	100,00		218,2	2100,0	83,33	23,57				
FU Month 24	Other	222,2	150,0	100,00		19,1	0	NE	NE				NE
FU Month 27	Other	111,1		NE	NE	19,1		NE	NE				NE
FU Month 30	Other	111,1		NE	NE	0	NE		NE				NE
Geographical Region													
Screening	White	246100,0	23294,3	74,43	27,12	231100,0	21793,9	76,11	29,73				
Cycle 4 Day 1	White	20683,7	18891,3	78,63	24,56	21492,6	18887,9	77,84	27,35				
FU Day 28	White	22290,2	19386,9	77,03	27,83	21593,1	19389,8	77,20	26,92				
FU Month 3	White	21788,2	19690,3	77,30	27,82	21191,3	18587,7	78,83	25,14				
FU Month 6	White	19980,9	17788,9	80,13	25,17	18479,7	16087,0	78,44	26,47				
FU Month 9	White	16065,0	13483,8	81,84	25,24	14462,3	11781,3	77,49	23,50				
FU Month 12	White	12249,6	10787,7	77,10	27,62	11348,9	9584,1	76,14	26,59				
FU Month 15	White	10241,5	8987,3	80,52	23,20	8135,1	6580,2	79,23	25,52				
FU Month 18	White	7731,3	6989,6	80,19	26,39	5825,1	4781,0	71,63	28,43				
FU Month 21	White	5020,3	3978,0	82,05	21,42	3816,5	3078,9	72,78	28,86				
FU Month 24	White	3012,2	2480,0	74,31	31,08	177,4	17100,0	85,29	27,56				
FU Month 27	White	124,9	1191,7	77,27	23,89	83,5	787,5	88,10	15,85				
FU Month 30	White	62,4	6100,0	72,22	32,77	10,4	1100,0	100,00					NE
Geographical Region													
Screening	Asia-Pacific	20100,0	20100,0	73,33	36,83	18100,0	18100,0	77,78	32,84				
Cycle 4 Day 1	Asia-Pacific	1575,0	15100,0	76,67	31,37	1688,9	1593,8	80,00	23,74				
FU Day 28	Asia-Pacific	1890,0	18100,0	71,30	34,68	18100,0	1688,9	83,33	21,94				
FU Month 3	Asia-Pacific	1890,0	1688,9	76,04	31,01	18100,0	1688,9	81,25	17,08				
FU Month 6	Asia-Pacific	1680,0	1487,5	75,00	32,52	1794,4	1588,2	70,00	34,04				
FU Month 9	Asia-Pacific	1470,0	1285,7	86,11	18,58	1372,2	1076,9	66,67	35,14				
FU Month 12	Asia-Pacific	1050,0	880,0	77,08	34,43	1055,6	10100,0	68,33	32,82				
FU Month 15	Asia-Pacific	840,0	675,0	88,89	17,21	950,0	9100,0	70,37	34,13				

FU Month 18	Asia-Pacific	630,0	466,7	100,00	0,00	633,3	6100,0	61,11	27,22
FU Month 21	Asia-Pacific	525,0	360,0	88,89	19,25	422,2	4100,0	75,00	21,52
FU Month 24	Asia-Pacific	315,0	266,7	100,00	0,00	15,6	0	NE	NE
FU Month 27	Asia-Pacific	15,0		NE	NE	15,6		NE	NE
FU Month 30	Asia-Pacific	15,0		NE	NE	0	NE	NE	NE
Screening	Central and South America	3100,0	3100,0	88,89	19,25	2100,0	2100,0	75,00	35,36
Cycle 4 Day 1	Central and South America	3100,0	3100,0	77,78	19,25	2100,0	2100,0	75,00	35,36
FU Day 28	Central and South America	3100,0	3100,0	88,89	19,25	2100,0	2100,0	100,00	0,00
FU Month 3	Central and South America	3100,0	3100,0	83,33	28,87	2100,0	2100,0	91,67	11,79
FU Month 6	Central and South America	266,7	2100,0	83,33	23,57	2100,0	2100,0	100,00	0,00
FU Month 9	Central and South America	266,7	2100,0	83,33	23,57	150,0	1100,0	100,00	NE
FU Month 12	Central and South America	266,7	2100,0	83,33	23,57	150,0	1100,0	100,00	NE
FU Month 15	Central and South America	133,3	1100,0	100,00	NE	0	NE	NE	NE
FU Month 18	Central and South America	133,3	1100,0	100,00	NE	0	NE	NE	NE
FU Month 21	Central and South America	133,3	1100,0	100,00	NE	0	NE	NE	NE
FU Month 24	Central and South America	133,3	1100,0	100,00	NE	0	NE	NE	NE
Screening	North America	12100,0	12100,0	75,00	25,13	13100,0	1292,3	79,17	27,64
Cycle 4 Day 1	North America	975,0	9100,0	88,89	14,43	1292,3	12100,0	76,39	21,86
FU Day 28	North America	1191,7	11100,0	83,33	18,26	13100,0	13100,0	75,64	26,01
FU Month 3	North America	1191,7	11100,0	74,24	28,25	1292,3	12100,0	87,50	20,26
FU Month 6	North America	1191,7	1090,9	88,33	15,81	1184,6	11100,0	77,27	31,86
FU Month 9	North America	866,7	8100,0	87,50	14,77	969,2	9100,0	85,19	19,44
FU Month 12	North America	866,7	787,5	76,19	33,13	753,8	7100,0	71,43	34,31
FU Month 15	North America	650,0	6100,0	80,56	16,39	646,2	583,3	73,33	30,28
FU Month 18	North America	433,3	4100,0	83,33	19,25	323,1	3100,0	66,67	28,87
FU Month 21	North America	325,0	266,7	100,00	0,00	17,7	1100,0	100,00	NE
FU Month 24	North America	325,0	266,7	41,67	35,36	17,7	1100,0	100,00	NE
FU Month 27	North America	216,7	150,0	83,33	NE	17,7	1100,0	66,67	NE
Screening	Other	45100,0	4191,1	75,20	23,90	44100,0	4193,2	73,58	26,61
Cycle 4 Day 1	Other	3782,2	3389,2	82,83	20,19	4090,9	3587,5	82,86	25,08
FU Day 28	Other	3782,2	3389,2	83,33	19,09	3988,6	3794,9	81,53	24,78
FU Month 3	Other	3884,4	3489,5	77,45	24,23	3886,4	3694,7	77,78	27,60
FU Month 6	Other	3577,8	3085,7	83,89	20,29	3375,0	3193,9	82,26	20,61
FU Month 9	Other	2657,8	2284,6	83,33	21,21	2454,5	1979,2	83,33	20,03
FU Month 12	Other	1737,8	1694,1	78,13	24,88	1636,4	1487,5	82,14	21,15
FU Month 15	Other	1226,7	1191,7	84,85	18,94	920,5	888,9	100,00	0,00
FU Month 18	Other	1022,2	990,0	92,59	14,70	715,9	685,7	94,44	8,61
FU Month 21	Other	715,6	685,7	88,89	17,21	49,1	4100,0	100,00	0,00

FU Month 24	Other	6	13,3	5	83,3	80,00	29,81	3	6,8	3	100,0	100,00	0,00
FU Month 27	Other	4	8,9	4	100,0	83,33	13,61	1	2,3	1	100,0	100,00	NE
FU Month 30	Other	2	4,4	2	100,0	66,67	47,14	0	NE	0	NE	NE	NE
Screening	Western Europe	175	100,0	165	94,3	74,44	27,27	165	100,0	155	93,9	76,77	30,18
Cycle 4 Day 1	Western Europe	149	85,1	135	90,6	77,90	25,09	154	93,3	133	86,4	76,32	28,29
FU Day 28	Western Europe	161	92,0	136	84,5	76,47	28,94	153	92,7	135	88,2	75,80	27,60
FU Month 3	Western Europe	155	88,6	139	89,7	77,82	28,33	151	91,5	129	85,4	77,65	25,81
FU Month 6	Western Europe	143	81,7	128	89,5	79,43	26,00	129	78,2	109	84,5	78,59	25,97
FU Month 9	Western Europe	114	65,1	93	81,6	80,65	27,51	102	61,8	82	80,4	76,83	22,79
FU Month 12	Western Europe	88	50,3	76	86,4	76,97	27,48	83	50,3	67	80,7	76,62	25,63
FU Month 15	Western Europe	77	44,0	66	85,7	79,04	24,86	61	37,0	47	77,0	78,72	24,00
FU Month 18	Western Europe	58	33,1	52	89,7	76,28	28,27	44	26,7	34	77,3	71,08	29,39
FU Month 21	Western Europe	36	20,6	28	77,8	78,57	22,62	31	18,8	23	74,2	67,39	29,51
FU Month 24	Western Europe	19	10,9	15	78,9	73,33	31,37	13	7,9	13	100,0	80,77	30,31
FU Month 27	Western Europe	6	3,4	6	100,0	72,22	31,03	6	3,6	5	83,3	90,00	14,91
FU Month 30	Western Europe	4	2,3	4	100,0	75,00	31,91	1	0,6	1	100,0	100,00	NE
FCgamma receptor IIa													
Screening	131HH	58	100,0	54	93,1	75,31	25,85	76	100,0	72	94,7	74,07	29,46
Cycle 4 Day 1	131HH	49	84,5	43	87,8	76,36	23,91	65	85,5	59	90,8	78,25	27,73
FU Day 28	131HH	51	87,9	46	90,2	74,64	27,38	70	92,1	62	88,6	80,65	24,18
FU Month 3	131HH	51	87,9	47	92,2	76,24	22,99	64	84,2	54	84,4	80,86	26,58
FU Month 6	131HH	49	84,5	45	91,8	80,00	22,92	55	72,4	47	85,5	80,85	24,07
FU Month 9	131HH	39	67,2	30	76,9	78,89	21,86	41	53,9	33	80,5	78,79	25,78
FU Month 12	131HH	28	48,3	24	85,7	72,92	25,45	34	44,7	29	85,3	80,46	23,18
FU Month 15	131HH	23	39,7	19	82,6	78,07	24,88	24	31,6	20	83,3	85,83	16,47
FU Month 18	131HH	17	29,3	14	82,4	67,86	30,29	16	21,1	13	81,3	71,79	30,72
FU Month 21	131HH	13	22,4	8	61,5	75,00	28,17	11	14,5	10	90,9	60,00	36,18
FU Month 24	131HH	11	19,0	7	63,6	69,05	33,92	1	1,3	1	100,0	100,00	NE
FU Month 27	131HH	4	6,9	3	75,0	61,11	34,69	1	1,3	1	100,0	100,00	NE
FU Month 30	131HH	3	5,2	2	66,7	66,67	47,14	0	NE	0	NE	NE	NE
Screening	131HR	125	100,0	118	94,4	75,99	27,00	114	100,0	109	95,6	78,59	28,34
Cycle 4 Day 1	131HR	105	84,0	97	92,4	80,24	24,10	110	96,5	99	90,0	77,44	27,59
FU Day 28	131HR	116	92,8	102	87,9	74,51	29,36	105	92,1	96	91,4	75,00	28,61
FU Month 3	131HR	114	91,2	102	89,5	78,76	27,86	107	93,9	94	87,9	78,90	23,84
FU Month 6	131HR	104	83,2	92	88,5	80,62	25,23	95	83,3	85	89,5	75,88	27,64
FU Month 9	131HR	84	67,2	70	83,3	81,19	27,35	76	66,7	61	80,3	77,05	22,39
FU Month 12	131HR	64	51,2	57	89,1	76,90	29,34	57	50,0	48	84,2	76,74	26,57
FU Month 15	131HR	53	42,4	44	83,0	79,17	19,73	44	38,6	35	79,5	79,52	27,44

FU Month 18	131HR	43	34,4	38	88,4	80,70	24,97	32	28,1	26	81,3	74,36	25,49
FU Month 21	131HR	26	20,8	20	76,9	80,83	21,13	21	18,4	16	76,2	75,00	23,57
FU Month 24	131HR	12	9,6	11	91,7	77,27	27,15	12	10,5	11	91,7	81,82	31,14
FU Month 27	131HR	6	4,8	5	83,3	76,67	19,00	6	5,3	4	66,7	79,17	15,96
FU Month 30	131HR	3	2,4	3	100,0	66,67	33,33	1	0,9	1	100,0	100,00	NE
Screening	131RR	49	100,0	48	98,0	70,14	30,74	33	100,0	30	90,9	78,33	28,08
Cycle 4 Day 1	131RR	40	81,6	38	95,0	82,46	20,12	31	93,9	25	80,6	76,00	26,39
FU Day 28	131RR	42	85,7	35	83,3	88,10	19,63	32	97,0	29	90,6	81,03	25,87
FU Month 3	131RR	39	79,6	37	94,9	74,32	32,06	32	97,0	30	93,8	75,56	28,94
FU Month 6	131RR	35	71,4	32	91,4	80,73	25,44	27	81,8	22	81,5	78,03	29,27
FU Month 9	131RR	24	49,0	22	91,7	87,12	19,88	19	57,6	17	89,5	74,51	25,76
FU Month 12	131RR	18	36,7	17	94,4	79,41	24,67	17	51,5	15	88,2	71,11	23,96
FU Month 15	131RR	16	32,7	16	100,0	85,42	25,00	11	33,3	9	81,8	77,78	25,00
FU Month 18	131RR	14	28,6	14	100,0	88,10	25,68	8	24,2	7	87,5	64,29	37,80
FU Month 21	131RR	8	16,3	7	87,5	92,86	13,11	5	15,2	4	80,0	87,50	15,96
FU Month 24	131RR	5	10,2	4	80,0	62,50	43,83	3	9,1	3	100,0	83,33	28,87
FU Month 27	131RR	2	4,1	2	100,0	91,67	11,79	1	3,0	1	100,0	100,00	NE
FU Month 30	131RR	1	2,0	1	100,0	100,00	NE	0	NE	0	NE	NE	NE
Screening	Missing	23	100,0	21	91,3	76,19	25,04	19	100,0	17	89,5	68,63	38,59
Cycle 4 Day 1	Missing	19	82,6	17	89,5	72,55	34,33	18	94,7	14	77,8	80,95	22,51
FU Day 28	Missing	21	91,3	18	85,7	83,33	26,81	18	94,7	16	88,9	76,04	23,55
FU Month 3	Missing	21	91,3	17	81,0	80,39	29,60	18	94,7	17	94,4	76,47	21,29
FU Month 6	Missing	19	82,6	15	78,9	78,89	32,41	15	78,9	14	93,3	89,29	15,48
FU Month 9	Missing	17	73,9	15	88,2	84,44	27,79	13	68,4	10	76,9	85,00	19,95
FU Month 12	Missing	15	65,2	11	73,3	84,85	27,34	9	47,4	7	77,8	69,05	41,31
FU Month 15	Missing	12	52,2	11	91,7	84,85	31,14	6	31,6	5	83,3	60,00	36,51
FU Month 18	Missing	5	21,7	4	80,0	95,83	8,33	4	21,1	3	75,0	77,78	25,46
FU Month 21	Missing	5	21,7	5	100,0	86,67	18,26	3	15,8	2	66,7	100,00	0,00
FU Month 24	Missing	4	17,4	3	75,0	100,00	0,00	2	10,5	2	100,0	100,00	0,00
FU Month 27	Missing	1	4,3	1	100,0	100,00	NE	1	5,3	1	100,0	100,00	NE
FCgamma receptor IIIa													
Screening	158FF	103	100,0	101	98,1	74,75	29,40	83	100,0	79	95,2	80,80	23,13
Cycle 4 Day 1	158FF	89	86,4	83	93,3	79,72	24,15	78	94,0	72	92,3	77,78	24,70
FU Day 28	158FF	96	93,2	84	87,5	80,16	25,15	78	94,0	74	94,9	78,15	26,31
FU Month 3	158FF	94	91,3	84	89,4	76,79	29,39	78	94,0	71	91,0	80,05	24,82
FU Month 6	158FF	86	83,5	73	84,9	80,82	24,32	64	77,1	58	90,6	83,05	21,96
FU Month 9	158FF	71	68,9	58	81,7	82,47	26,20	47	56,6	43	91,5	80,62	21,50
FU Month 12	158FF	48	46,6	42	87,5	73,02	29,67	38	45,8	35	92,1	75,24	26,93

FU Month 15	158FF	37	35,9	32	86,5	77,08	26,35	30	36,1	24	80,0	80,56	23,40
FU Month 18	158FF	27	26,2	25	92,6	79,33	25,13	21	25,3	17	81,0	72,55	31,15
FU Month 21	158FF	16	15,5	15	93,8	80,00	18,04	9	10,8	8	88,9	77,08	29,46
FU Month 24	158FF	8	7,8	7	87,5	71,43	31,50	3	3,6	3	100,0	77,78	19,25
FU Month 27	158FF	5	4,9	4	80,0	83,33	23,57	1	1,2	1	100,0	100,00	NE
FU Month 30	158FF	3	2,9	3	100,0	88,89	19,25	0	NE	0	NE	NE	NE
Screening	158FV	119	100,0	110	92,4	75,45	25,11	109	100,0	103	94,5	74,76	31,39
Cycle 4 Day 1	158FV	99	83,2	89	89,9	80,71	23,29	100	91,7	85	85,0	76,67	28,89
FU Day 28	158FV	105	88,2	91	86,7	74,91	29,01	101	92,7	87	86,1	77,78	26,49
FU Month 3	158FV	101	84,9	93	92,1	78,32	26,44	97	89,0	83	85,6	77,31	26,10
FU Month 6	158FV	94	79,0	87	92,6	81,23	23,82	83	76,1	71	85,5	75,12	29,53
FU Month 9	158FV	71	59,7	61	85,9	82,24	21,70	65	59,6	49	75,4	72,11	26,44
FU Month 12	158FV	60	50,4	55	91,7	79,70	24,78	52	47,7	42	80,8	74,21	28,08
FU Month 15	158FV	52	43,7	45	86,5	80,74	20,71	36	33,0	30	83,3	75,56	28,94
FU Month 18	158FV	44	37,0	38	86,4	82,02	28,04	24	22,0	20	83,3	70,83	31,47
FU Month 21	158FV	28	23,5	18	64,3	82,41	25,87	18	16,5	14	77,8	54,76	24,83
FU Month 24	158FV	18	15,1	13	72,2	71,79	34,95	6	5,5	5	83,3	63,33	41,50
FU Month 27	158FV	6	5,0	5	83,3	73,33	25,28	2	1,8	1	50,0	66,67	NE
FU Month 30	158FV	4	3,4	3	75,0	55,56	38,49	0	NE	0	NE	NE	NE
Screening	158VV	16	100,0	15	93,8	67,78	33,01	33	100,0	31	93,9	76,34	29,43
Cycle 4 Day 1	158VV	12	75,0	11	91,7	80,30	12,51	30	90,9	28	93,3	79,76	25,80
FU Day 28	158VV	14	87,5	13	92,9	74,36	30,14	30	90,9	28	93,3	77,98	26,47
FU Month 3	158VV	15	93,8	12	80,0	77,78	22,84	30	90,9	26	86,7	83,33	21,08
FU Month 6	158VV	14	87,5	13	92,9	74,36	29,36	30	90,9	25	83,3	78,00	22,93
FU Month 9	158VV	12	75,0	10	83,3	76,67	31,62	25	75,8	20	80,0	85,00	16,13
FU Month 12	158VV	8	50,0	7	87,5	66,67	36,00	20	60,6	17	85,0	81,37	19,44
FU Month 15	158VV	8	50,0	7	87,5	80,95	27,94	14	42,4	11	78,6	87,88	15,08
FU Month 18	158VV	4	25,0	4	100,0	62,50	20,97	11	33,3	9	81,8	68,52	15,47
FU Month 21	158VV	3	18,8	2	66,7	91,67	11,79	9	27,3	7	77,8	95,24	8,13
FU Month 24	158VV	2	12,5	2	100,0	75,00	11,79	7	21,2	7	100,0	100,00	0,00
FU Month 27	158VV	1	6,3	1	100,0	50,00	NE	5	15,2	4	80,0	87,50	15,96
FU Month 30	158VV	0	NE	0	NE	NE	NE	1	3,0	1	100,0	100,00	NE
Screening	Missing	17	100,0	15	88,2	75,56	23,46	17	100,0	15	88,2	64,44	42,20
Cycle 4 Day 1	Missing	13	76,5	12	92,3	62,50	36,32	16	94,1	12	75,0	80,56	31,65
FU Day 28	Missing	15	88,2	13	86,7	84,62	30,02	16	94,1	14	87,5	73,81	30,46
FU Month 3	Missing	15	88,2	14	93,3	76,19	31,16	16	94,1	15	93,8	72,22	27,94
FU Month 6	Missing	13	76,5	11	84,6	77,27	36,72	15	88,2	14	93,3	79,76	29,37
FU Month 9	Missing	10	58,8	8	80,0	83,33	35,63	12	70,6	9	75,0	79,63	26,06

FU Month 12	Missing		952,9		555,6	100,00	0,00		741,2		571,4	86,67	29,81
FU Month 15	Missing		741,2		685,7	100,00	0,00		529,4		480,0	83,33	33,33
FU Month 18	Missing		423,5		375,0	94,44	9,62		423,5		375,0	94,44	9,62
FU Month 21	Missing		529,4		5100,0	86,67	18,26		423,5		375,0	100,00	0,00
FU Month 24	Missing		423,5		375,0	100,00	0,00		211,8		2100,0	100,00	0,00
FU Month 27	Missing		15,9		1100,0	100,00		NE	15,9		1100,0	100,00	NE
Binet Staging at baseline													
Screening	A		59100,0		5796,6	76,61	25,17		57100,0		5393,0	75,16	33,59
Cycle 4 Day 1	A		5186,4		4894,1	75,69	27,92		5494,7		5092,6	74,33	29,01
FU Day 28	A		5898,3		5391,4	69,81	29,97		5494,7		5296,3	71,79	29,92
FU Month 3	A		5796,6		5698,2	72,32	27,94		5393,0		4992,5	77,55	24,66
FU Month 6	A		5694,9		5089,3	75,33	25,92		4578,9		4191,1	77,64	29,49
FU Month 9	A		4372,9		3786,0	70,72	30,02		3459,6		3088,2	75,56	27,59
FU Month 12	A		3661,0		3494,4	71,57	28,58		2442,1		2187,5	69,84	29,64
FU Month 15	A		3050,8		2790,0	77,16	24,52		1933,3		19100,0	71,05	32,79
FU Month 18	A		2237,3		1881,8	72,22	33,33		1628,1		16100,0	72,92	31,55
FU Month 21	A		1728,8		1588,2	75,56	27,36		814,0		787,5	83,33	28,87
FU Month 24	A		1016,9		880,0	68,75	38,25		58,8		5100,0	100,00	0,00
FU Month 27	A		58,5		480,0	66,67	30,43		23,5		150,0	100,00	NE
FU Month 30	A		46,8		375,0	66,67	33,33		0	NE	0	NE	NE
Screening													
Screening	B	104	100,0	100	96,2	75,67	26,10		85100,0		8397,6	78,11	27,66
Cycle 4 Day 1	B		8884,6		8394,3	80,72	19,91		7992,9		7392,4	80,82	25,41
FU Day 28	B		9187,5		7986,8	82,28	27,00		7992,9		7189,9	82,39	22,69
FU Month 3	B		8884,6		7888,6	80,56	27,84		7992,9		7189,9	80,28	25,40
FU Month 6	B		8076,9		7695,0	84,87	24,06		7082,4		6390,0	79,10	24,31
FU Month 9	B		6360,6		5282,5	86,54	21,14		5969,4		4983,1	78,23	19,60
FU Month 12	B		4745,2		3983,0	81,62	26,43		4654,1		4087,0	79,58	20,84
FU Month 15	B		3735,6		3491,9	84,80	21,46		3440,0		2882,4	83,93	17,85
FU Month 18	B		3129,8		2993,5	84,48	23,54		2225,9		1881,8	75,00	22,32
FU Month 21	B		1817,3		1372,2	85,90	16,45		1720,0		1482,4	73,81	24,21
FU Month 24	B		1110,6		981,8	75,93	35,46		89,4		8100,0	79,17	35,36
FU Month 27	B		54,8		480,0	87,50	25,00		44,7		4100,0	79,17	15,96
FU Month 30	B		21,9		2100,0	100,00	0,00		0	NE	0	NE	NE
Screening													
Screening	C		92100,0		8491,3	72,22	30,10	100	100,0		9292,0	75,54	28,76
Cycle 4 Day 1	C		7480,4		6486,5	79,69	26,80		9191,0		7481,3	77,03	27,13
FU Day 28	C		8188,0		6985,2	78,50	25,26		9292,0		8087,0	77,29	28,22
FU Month 3	C		8087,0		6986,3	78,26	27,01		8989,0		7584,3	78,00	25,43
FU Month 6	C		7177,2		5881,7	78,74	25,32		7777,0		6483,1	78,91	26,10

FU Month 9	C	58	63,0	48	82,8	85,76	22,54	56	56,0	42	75,0	78,97	24,98	
FU Month 12	C	42	45,7	36	85,7	77,78	27,31	47	47,0	38	80,9	76,75	29,39	
FU Month 15	C	37	40,2	29	78,4	79,31	23,84	32	32,0	22	68,8	81,82	25,67	
FU Month 18	C	26	28,3	23	88,5	81,88	22,98	22	22,0	15	68,2	68,89	32,04	
FU Month 21	C	17	18,5	12	70,6	87,50	16,09	15	15,0	11	73,3	66,67	33,33	
FU Month 24	C	11	12,0	8	72,7	81,25	16,52	5	5,0	4	80,0	79,17	25,00	
FU Month 27	C	3	3,3	3	100,0	77,78	9,62	3	3,0	2	66,7	100,00	0,00	
FU Month 30	C	1	1,1	1	100,0	33,33		NE	1	1,0	1	100,0	100,00	NE
Total CIR score at baseline														
Screening	<=6	63	100,0	59	93,7	77,40	26,58	75	100,0	70	93,3	79,29	26,23	
Cycle 4 Day 1	<=6	52	82,5	42	80,8	78,17	23,71	72	96,0	60	83,3	85,28	22,15	
FU Day 28	<=6	56	88,9	49	87,5	81,29	25,15	72	96,0	59	81,9	83,33	22,95	
FU Month 3	<=6	55	87,3	47	85,5	82,62	24,56	69	92,0	56	81,2	83,93	20,34	
FU Month 6	<=6	52	82,5	46	88,5	82,25	24,44	60	80,0	52	86,7	78,53	25,42	
FU Month 9	<=6	43	68,3	36	83,7	82,41	28,16	47	62,7	38	80,9	82,46	21,21	
FU Month 12	<=6	35	55,6	29	82,9	76,44	27,28	34	45,3	27	79,4	82,10	22,61	
FU Month 15	<=6	32	50,8	28	87,5	77,38	26,53	25	33,3	17	68,0	83,33	21,25	
FU Month 18	<=6	23	36,5	22	95,7	77,27	24,42	19	25,3	14	73,7	77,38	27,43	
FU Month 21	<=6	14	22,2	8	57,1	87,50	24,80	14	18,7	10	71,4	71,67	29,45	
FU Month 24	<=6	8	12,7	7	87,5	80,95	31,07	7	9,3	6	85,7	83,33	18,26	
FU Month 27	<=6	2	3,2	2	100,0	83,33	0,00	4	5,3	2	50,0	83,33	23,57	
FU Month 30	<=6	0	NE	0	NE	NE	NE	1	1,3	1	100,0	100,00	NE	
Screening	>6	192	100,0	182	94,8	73,81	27,55	167	100,0	158	94,6	75,11	30,78	
Cycle 4 Day 1	>6	161	83,9	153	95,0	79,41	24,61	152	91,0	137	90,1	74,45	28,30	
FU Day 28	>6	174	90,6	152	87,4	76,54	28,28	153	91,6	144	94,1	75,35	27,59	
FU Month 3	>6	170	88,5	156	91,8	75,96	28,41	152	91,0	139	91,4	76,62	26,60	
FU Month 6	>6	155	80,7	138	89,0	79,71	25,45	132	79,0	116	87,9	78,74	26,61	
FU Month 9	>6	121	63,0	101	83,5	81,85	24,05	102	61,1	83	81,4	75,70	24,32	
FU Month 12	>6	90	46,9	80	88,9	77,50	27,70	83	49,7	72	86,7	74,31	27,40	
FU Month 15	>6	72	37,5	62	86,1	82,26	21,52	60	35,9	52	86,7	78,53	26,68	
FU Month 18	>6	56	29,2	48	85,7	81,94	27,25	41	24,6	35	85,4	70,48	28,61	
FU Month 21	>6	38	19,8	32	84,2	81,25	20,63	26	15,6	22	84,6	74,24	28,51	
FU Month 24	>6	24	12,5	18	75,0	73,15	31,38	11	6,6	11	100,0	86,36	32,33	
FU Month 27	>6	11	5,7	9	81,8	75,93	26,50	5	3,0	5	100,0	90,00	14,91	
FU Month 30	>6	7	3,6	6	85,7	72,22	32,77	0	NE	0	NE	NE	NE	
Calculated creatinine clearance cat. 2														
Screening	<70 ml/min	178	100,0	165	92,7	75,76	26,89	176	100,0	166	94,3	76,91	30,19	
Cycle 4 Day 1	<70 ml/min	149	83,7	133	89,3	79,20	23,78	164	93,2	143	87,2	77,16	27,67	

FU Day 28	<70 ml/min	162	91,0	142	87,7	78,17	25,59	166	94,3	146	88,0	78,54	26,55
FU Month 3	<70 ml/min	157	88,2	141	89,8	78,61	26,90	159	90,3	139	87,4	78,66	25,62
FU Month 6	<70 ml/min	144	80,9	125	86,8	81,47	23,01	139	79,0	120	86,3	79,44	26,88
FU Month 9	<70 ml/min	117	65,7	96	82,1	82,12	25,39	112	63,6	90	80,4	79,07	24,17
FU Month 12	<70 ml/min	92	51,7	79	85,9	77,43	26,56	87	49,4	73	83,9	78,31	25,86
FU Month 15	<70 ml/min	78	43,8	69	88,5	79,95	23,67	60	34,1	48	80,0	79,86	25,95
FU Month 18	<70 ml/min	59	33,1	51	86,4	80,07	26,88	43	24,4	36	83,7	72,22	29,00
FU Month 21	<70 ml/min	38	21,3	27	71,1	82,10	23,08	31	17,6	27	87,1	74,69	29,73
FU Month 24	<70 ml/min	24	13,5	19	79,2	74,56	33,96	13	7,4	12	92,3	94,44	12,97
FU Month 27	<70 ml/min	10	5,6	8	80,0	81,25	22,60	7	4,0	5	71,4	93,33	14,91
FU Month 30	<70 ml/min	5	2,8	4	80,0	66,67	38,49	1	0,6	1	100,0	100,00	NE
Screening	>=70 ml/min	77	100,0	76	98,7	72,37	28,23	66	100,0	62	93,9	75,00	27,62
Cycle 4 Day 1	>=70 ml/min	64	83,1	62	96,9	79,03	25,77	60	90,9	54	90,0	79,32	25,27
FU Day 28	>=70 ml/min	68	88,3	59	86,8	76,55	32,03	59	89,4	57	96,6	75,44	26,56
FU Month 3	>=70 ml/min	68	88,3	62	91,2	75,00	29,38	62	93,9	56	90,3	78,87	24,10
FU Month 6	>=70 ml/min	63	81,8	59	93,7	77,97	29,27	53	80,3	48	90,6	76,74	24,49
FU Month 9	>=70 ml/min	47	61,0	41	87,2	81,71	24,67	37	56,1	31	83,8	74,19	21,45
FU Month 12	>=70 ml/min	33	42,9	30	90,9	76,67	30,20	30	45,5	26	86,7	71,15	27,31
FU Month 15	>=70 ml/min	26	33,8	21	80,8	83,33	21,73	25	37,9	21	84,0	79,37	24,67
FU Month 18	>=70 ml/min	20	26,0	19	95,0	81,58	25,39	17	25,8	13	76,5	73,08	26,82
FU Month 21	>=70 ml/min	14	18,2	13	92,9	83,33	18,00	9	13,6	5	55,6	66,67	20,41
FU Month 24	>=70 ml/min	8	10,4	6	75,0	77,78	20,18	5	7,6	5	100,0	63,33	41,50
FU Month 27	>=70 ml/min	3	3,9	3	100,0	66,67	28,87	2	3,0	2	100,0	75,00	11,79
FU Month 30	>=70 ml/min	2	2,6	2	100,0	83,33	23,57	0	NE	0	NE	NE	NE
Beta2 microglobulin													
Screening	Missing	3	100,0	3	100,0	88,89	19,25	3	100,0	3	100,0	16,67	28,87
Cycle 4 Day 1	Missing	3	100,0	3	100,0	83,33	16,67	3	100,0	2	66,7	75,00	35,36
FU Day 28	Missing	3	100,0	3	100,0	77,78	19,25	3	100,0	2	66,7	83,33	23,57
FU Month 3	Missing	3	100,0	3	100,0	77,78	38,49	3	100,0	2	66,7	75,00	35,36
FU Month 6	Missing	3	100,0	3	100,0	94,44	9,62	3	100,0	2	66,7	83,33	23,57
FU Month 9	Missing	2	66,7	1	50,0	100,00	NE	3	100,0	2	66,7	75,00	11,79
FU Month 12	Missing	1	33,3	1	100,0	100,00	NE	2	66,7	1	50,0	83,33	NE
FU Month 15	Missing	1	33,3	1	100,0	100,00	NE	2	66,7	1	50,0	100,00	NE
FU Month 18	Missing	1	33,3	1	100,0	66,67	NE	2	66,7	1	50,0	83,33	NE
FU Month 21	Missing	1	33,3	1	100,0	100,00	NE	2	66,7	1	50,0	100,00	NE
FU Month 24	Missing	1	33,3	1	100,0	66,67	NE	1	33,3	1	100,0	100,00	NE
Screening	< 3.5 ug/mL	154	100,0	144	93,5	73,96	28,27	140	100,0	132	94,3	77,90	27,82
Cycle 4 Day 1	< 3.5 ug/mL	127	82,5	116	91,3	76,58	26,10	129	92,1	111	86,0	76,88	27,45

FU Day 28	< 3.5 ug/mL	137	89,0	121	88,3	77,00	26,81	132	94,3	121	91,7	76,72	26,39
FU Month 3	< 3.5 ug/mL	134	87,0	123	91,8	78,32	25,87	130	92,9	115	88,5	79,13	24,47
FU Month 6	< 3.5 ug/mL	128	83,1	113	88,3	80,24	24,45	120	85,7	110	91,7	76,21	27,13
FU Month 9	< 3.5 ug/mL	104	67,5	86	82,7	80,81	24,72	98	70,0	81	82,7	76,13	24,29
FU Month 12	< 3.5 ug/mL	78	50,6	69	88,5	75,36	28,53	75	53,6	67	89,3	74,13	26,00
FU Month 15	< 3.5 ug/mL	65	42,2	56	86,2	78,27	24,19	60	42,9	51	85,0	79,41	24,85
FU Month 18	< 3.5 ug/mL	46	29,9	41	89,1	77,64	28,29	43	30,7	35	81,4	70,00	29,92
FU Month 21	< 3.5 ug/mL	30	19,5	21	70,0	80,95	24,88	27	19,3	22	81,5	71,97	30,60
FU Month 24	< 3.5 ug/mL	19	12,3	15	78,9	75,56	32,04	12	8,6	11	91,7	89,39	18,67
FU Month 27	< 3.5 ug/mL	10	6,5	8	80,0	70,83	24,80	7	5,0	5	71,4	90,00	14,91
FU Month 30	< 3.5 ug/mL	5	3,2	4	80,0	58,33	31,91	1	0,7	1	100,0	100,00	NE
Screening	>= 3.5 ug/mL	98	100,0	94	95,9	75,35	26,06	99	100,0	93	93,9	76,16	30,04
Cycle 4 Day 1	>= 3.5 ug/mL	83	84,7	76	91,6	82,89	21,43	92	92,9	84	91,3	78,97	26,53
FU Day 28	>= 3.5 ug/mL	90	91,8	77	85,6	78,79	29,20	90	90,9	80	88,9	78,96	27,01
FU Month 3	>= 3.5 ug/mL	88	89,8	77	87,5	76,19	30,28	88	88,9	78	88,6	78,21	26,22
FU Month 6	>= 3.5 ug/mL	76	77,6	68	89,5	79,90	26,79	69	69,7	56	81,2	83,33	23,99
FU Month 9	>= 3.5 ug/mL	58	59,2	50	86,2	83,67	25,97	48	48,5	38	79,2	81,58	22,19
FU Month 12	>= 3.5 ug/mL	46	46,9	39	84,8	79,91	25,70	40	40,4	31	77,5	81,18	27,13
FU Month 15	>= 3.5 ug/mL	38	38,8	33	86,8	84,34	21,22	23	23,2	17	73,9	79,41	27,97
FU Month 18	>= 3.5 ug/mL	32	32,7	28	87,5	85,12	23,28	15	15,2	13	86,7	78,21	23,94
FU Month 21	>= 3.5 ug/mL	21	21,4	18	85,7	83,33	17,15	11	11,1	9	81,8	74,07	23,73
FU Month 24	>= 3.5 ug/mL	12	12,2	9	75,0	75,93	32,39	5	5,1	5	100,0	73,33	43,46
FU Month 27	>= 3.5 ug/mL	3	3,1	3	100,0	94,44	9,62	2	2,0	2	100,0	83,33	23,57
FU Month 30	>= 3.5 ug/mL	2	2,0	2	100,0	100,00	0,00	0	NE	0	NE	NE	NE
Immunoglobulin VH, cytogenetics 2													
Screening	12	45	100,0	43	95,6	67,83	29,64	44	100,0	43	97,7	74,03	30,49
Cycle 4 Day 1	12	34	75,6	32	94,1	78,65	25,48	38	86,4	33	86,8	70,71	29,76
FU Day 28	12	39	86,7	37	94,9	70,72	32,96	40	90,9	35	87,5	69,52	31,18
FU Month 3	12	38	84,4	36	94,7	78,70	26,61	39	88,6	32	82,1	75,00	27,44
FU Month 6	12	36	80,0	31	86,1	80,11	26,67	34	77,3	28	82,4	69,64	32,41
FU Month 9	12	26	57,8	22	84,6	80,30	28,47	28	63,6	18	64,3	67,59	22,49
FU Month 12	12	22	48,9	18	81,8	80,56	19,17	23	52,3	15	65,2	66,67	29,55
FU Month 15	12	17	37,8	14	82,4	80,95	24,33	17	38,6	12	70,6	72,22	26,91
FU Month 18	12	15	33,3	12	80,0	80,56	32,44	13	29,5	9	69,2	72,22	27,64
FU Month 21	12	10	22,2	8	80,0	75,00	28,17	7	15,9	5	71,4	76,67	19,00
FU Month 24	12	8	17,8	6	75,0	69,44	37,14	6	13,6	6	100,0	75,00	41,83
FU Month 27	12	5	11,1	4	80,0	70,83	34,36	2	4,5	2	100,0	91,67	11,79
FU Month 30	12	4	8,9	3	75,0	77,78	38,49	1	2,3	1	100,0	100,00	NE

Screening	11q-	46	100,0	43	93,5	85,27	22,19	43	100,0	40	93,0	84,17	21,99
Cycle 4 Day 1	11q-	40	87,0	39	97,5	84,62	20,73	41	95,3	35	85,4	85,71	19,02
FU Day 28	11q-	42	91,3	35	83,3	83,33	25,24	39	90,7	36	92,3	83,33	23,23
FU Month 3	11q-	42	91,3	38	90,5	77,19	27,51	38	88,4	36	94,7	86,57	19,03
FU Month 6	11q-	38	82,6	34	89,5	86,76	18,25	32	74,4	28	87,5	82,14	20,25
FU Month 9	11q-	28	60,9	26	92,9	84,62	23,06	25	58,1	21	84,0	78,57	21,18
FU Month 12	11q-	20	43,5	19	95,0	85,09	21,44	18	41,9	17	94,4	74,51	20,51
FU Month 15	11q-	18	39,1	16	88,9	87,50	17,74	14	32,6	10	71,4	80,00	24,60
FU Month 18	11q-	15	32,6	13	86,7	80,77	31,80	8	18,6	7	87,5	76,19	38,32
FU Month 21	11q-	12	26,1	11	91,7	80,30	24,52	4	9,3	2	50,0	66,67	47,14
FU Month 24	11q-	7	15,2	5	71,4	83,33	23,57	1	2,3	1	100,0	100,00	NE
FU Month 27	11q-	3	6,5	3	100,0	72,22	25,46	0	NE	0	NE	NE	NE
FU Month 30	11q-	3	6,5	3	100,0	66,67	33,33	0	NE	0	NE	NE	NE
Screening	13q-	79	100,0	76	96,2	79,61	24,28	75	100,0	70	93,3	77,86	29,86
Cycle 4 Day 1	13q-	67	84,8	60	89,6	83,89	21,47	68	90,7	59	86,8	82,77	25,52
FU Day 28	13q-	72	91,1	65	90,3	84,36	19,29	72	96,0	65	90,3	82,31	25,83
FU Month 3	13q-	73	92,4	67	91,8	78,11	28,31	69	92,0	60	87,0	80,00	26,18
FU Month 6	13q-	67	84,8	60	89,6	84,72	19,72	63	84,0	56	88,9	79,17	27,93
FU Month 9	13q-	56	70,9	48	85,7	85,07	20,98	52	69,3	42	80,8	82,14	23,68
FU Month 12	13q-	44	55,7	39	88,6	82,48	21,95	40	53,3	38	95,0	81,14	25,46
FU Month 15	13q-	38	48,1	33	86,8	79,29	25,01	29	38,7	25	86,2	83,33	26,35
FU Month 18	13q-	28	35,4	25	89,3	82,00	23,53	21	28,0	19	90,5	68,42	27,16
FU Month 21	13q-	16	20,3	13	81,3	83,33	16,67	16	21,3	14	87,5	80,95	27,62
FU Month 24	13q-	7	8,9	6	85,7	75,00	32,91	7	9,3	6	85,7	100,00	0,00
FU Month 27	13q-	2	2,5	1	50,0	83,33	NE	6	8,0	4	66,7	91,67	16,67
Screening	Norm. K.	65	100,0	61	93,8	66,12	28,05	58	100,0	55	94,8	68,18	32,28
Cycle 4 Day 1	Norm. K.	54	83,1	48	88,9	72,22	27,14	55	94,8	50	90,9	69,33	28,64
FU Day 28	Norm. K.	59	90,8	50	84,7	71,67	29,21	53	91,4	50	94,3	72,00	24,15
FU Month 3	Norm. K.	54	83,1	48	88,9	76,39	27,68	54	93,1	48	88,9	71,53	26,84
FU Month 6	Norm. K.	49	75,4	47	95,9	71,28	29,63	45	77,6	40	88,9	77,08	24,95
FU Month 9	Norm. K.	39	60,0	31	79,5	75,81	30,07	30	51,7	27	90,0	76,54	24,13
FU Month 12	Norm. K.	32	49,2	27	84,4	62,35	35,38	24	41,4	20	83,3	72,50	29,75
FU Month 15	Norm. K.	26	40,0	23	88,5	77,54	24,42	20	34,5	18	90,0	78,70	23,44
FU Month 18	Norm. K.	18	27,7	17	94,4	76,47	24,34	15	25,9	12	80,0	72,22	26,91
FU Month 21	Norm. K.	12	18,5	6	50,0	88,89	17,21	11	19,0	9	81,8	59,26	31,30
FU Month 24	Norm. K.	8	12,3	6	75,0	66,67	34,96	4	6,9	4	100,0	75,00	16,67
FU Month 27	Norm. K.	3	4,6	3	100,0	88,89	9,62	1	1,7	1	100,0	66,67	NE
Screening	Other Abn.	20	100,0	18	90,0	74,07	31,43	22	100,0	20	90,9	83,33	27,04

Cycle 4 Day 1	Other Abn.	18	90,0	16	88,9	69,79	26,68	22	100,0	20	90,9	81,67	28,05
FU Day 28	Other Abn.	18	90,0	14	77,8	72,62	36,75	21	95,5	17	81,0	81,37	27,56
FU Month 3	Other Abn.	18	90,0	14	77,8	76,19	31,16	21	95,5	19	90,5	84,21	18,82
FU Month 6	Other Abn.	17	85,0	12	70,6	76,39	35,15	18	81,8	16	88,9	90,63	13,57
FU Month 9	Other Abn.	15	75,0	10	66,7	83,33	24,85	14	63,6	13	92,9	79,49	25,60
FU Month 12	Other Abn.	7	35,0	6	85,7	75,00	39,09	12	54,5	9	75,0	85,19	24,22
FU Month 15	Other Abn.	5	25,0	4	80,0	83,33	19,25	5	22,7	4	80,0	83,33	33,33
FU Month 18	Other Abn.	3	15,0	3	100,0	88,89	19,25	3	13,6	2	66,7	100,00	0,00
FU Month 21	Other Abn.	2	10,0	2	100,0	100,00	0,00	2	9,1	2	100,0	83,33	23,57
FU Month 24	Other Abn.	2	10,0	2	100,0	100,00	0,00	0	NE	0	NE	NE	NE
Time from first diagnosis													
Screening	Missing	1	100,0	1	100,0	83,33	NE	0	NE	0	NE	NE	NE
Cycle 4 Day 1	Missing	1	100,0	1	100,0	66,67	NE	0	NE	0	NE	NE	NE
FU Day 28	Missing	1	100,0	1	100,0	100,00	NE	0	NE	0	NE	NE	NE
FU Month 3	Missing	1	100,0	1	100,0	100,00	NE	0	NE	0	NE	NE	NE
FU Month 6	Missing	1	100,0	1	100,0	100,00	NE	0	NE	0	NE	NE	NE
FU Month 9	Missing	1	100,0	1	100,0	100,00	NE	0	NE	0	NE	NE	NE
FU Month 12	Missing	1	100,0	1	100,0	100,00	NE	0	NE	0	NE	NE	NE
FU Month 15	Missing	1	100,0	1	100,0	100,00	NE	0	NE	0	NE	NE	NE
FU Month 18	Missing	1	100,0	1	100,0	100,00	NE	0	NE	0	NE	NE	NE
Screening	13 - 24 months	41	100,0	39	95,1	72,65	30,23	31	100,0	31	100,0	83,33	23,96
Cycle 4 Day 1	13 - 24 months	35	85,4	34	97,1	77,94	20,81	30	96,8	27	90,0	89,51	15,43
FU Day 28	13 - 24 months	38	92,7	33	86,8	76,77	28,55	30	96,8	27	90,0	87,65	23,84
FU Month 3	13 - 24 months	36	87,8	34	94,4	77,94	26,50	30	96,8	26	86,7	84,62	22,07
FU Month 6	13 - 24 months	36	87,8	32	88,9	82,29	21,97	30	96,8	25	83,3	86,67	24,53
FU Month 9	13 - 24 months	32	78,0	29	90,6	83,91	22,49	21	67,7	18	85,7	87,04	16,72
FU Month 12	13 - 24 months	21	51,2	18	85,7	81,48	21,30	16	51,6	14	87,5	85,71	15,82
FU Month 15	13 - 24 months	19	46,3	18	94,7	83,33	26,81	16	51,6	10	62,5	90,00	14,05
FU Month 18	13 - 24 months	14	34,1	13	92,9	83,33	22,57	10	32,3	8	80,0	91,67	15,43
FU Month 21	13 - 24 months	11	26,8	9	81,8	70,37	29,79	6	19,4	4	66,7	87,50	15,96
FU Month 24	13 - 24 months	8	19,5	5	62,5	40,00	34,56	3	9,7	3	100,0	88,89	19,25
FU Month 27	13 - 24 months	5	12,2	5	100,0	66,67	26,35	2	6,5	2	100,0	100,00	0,00
FU Month 30	13 - 24 months	3	7,3	3	100,0	55,56	38,49	1	3,2	1	100,0	100,00	NE
Screening	<= 12 months	60	100,0	58	96,7	74,14	28,64	70	100,0	69	98,6	77,05	25,42
Cycle 4 Day 1	<= 12 months	48	80,0	42	87,5	83,33	22,09	60	85,7	56	93,3	81,55	24,55
FU Day 28	<= 12 months	54	90,0	45	83,3	77,04	30,63	62	88,6	57	91,9	81,58	22,42
FU Month 3	<= 12 months	53	88,3	45	84,9	77,41	29,12	59	84,3	55	93,2	78,18	24,40
FU Month 6	<= 12 months	46	76,7	40	87,0	81,67	25,54	47	67,1	43	91,5	80,62	26,71

FU Month 9	<= 12 months	35	58,3	27	77,1	79,01	30,87	37	52,9	31	83,8	86,02	17,27
FU Month 12	<= 12 months	27	45,0	23	85,2	73,91	33,64	29	41,4	27	93,1	79,63	22,80
FU Month 15	<= 12 months	22	36,7	17	77,3	74,51	31,80	17	24,3	16	94,1	85,42	20,97
FU Month 18	<= 12 months	16	26,7	13	81,3	80,77	34,59	13	18,6	12	92,3	83,33	22,47
FU Month 21	<= 12 months	9	15,0	5	55,6	93,33	14,91	7	10,0	6	85,7	69,44	26,70
FU Month 24	<= 12 months	6	10,0	3	50,0	88,89	19,25	2	2,9	1	50,0	100,00	NE
FU Month 27	<= 12 months	1	1,7			NE	NE	1	1,4			NE	NE
FU Month 30	<= 12 months	1	1,7			NE	NE	0	NE			NE	NE
Screening	>24 months	153	100,0	143	93,5	75,41	26,15	141	100,0	128	90,8	74,35	32,46
Cycle 4 Day 1	>24 months	129	84,3	118	91,5	78,11	26,12	134	95,0	114	85,1	73,10	29,21
FU Day 28	>24 months	137	89,5	122	89,1	78,01	26,35	133	94,3	119	89,5	73,53	28,16
FU Month 3	>24 months	135	88,2	123	91,1	77,24	27,68	132	93,6	114	86,4	77,63	26,13
FU Month 6	>24 months	124	81,0	111	89,5	79,13	26,06	115	81,6	100	87,0	75,83	26,10
FU Month 9	>24 months	96	62,7	80	83,3	82,08	24,13	91	64,5	72	79,1	71,99	25,61
FU Month 12	>24 months	76	49,7	67	88,2	76,87	26,90	72	51,1	58	80,6	72,70	29,24
FU Month 15	>24 months	62	40,5	54	87,1	81,48	18,50	52	36,9	43	82,7	75,19	28,02
FU Month 18	>24 months	48	31,4	43	89,6	79,07	25,22	37	26,2	29	78,4	62,64	29,09
FU Month 21	>24 months	32	20,9	26	81,3	84,62	17,59	27	19,1	22	81,5	71,97	30,60
FU Month 24	>24 months	18	11,8	17	94,4	83,33	24,30	13	9,2	13	100,0	83,33	30,43
FU Month 27	>24 months	7	4,6	6	85,7	86,11	19,48	6	4,3	5	83,3	83,33	16,67
FU Month 30	>24 months	3	2,0	3	100,0	88,89	19,25	0	NE	0	NE	NE	NE
High circulating tumor burden													
Screening	Missing	0	NE	0	NE	NE	NE	2	100,0	1	50,0	100,00	NE
Cycle 4 Day 1	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	100,00	NE
FU Day 28	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	100,00	NE
FU Month 3	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	100,00	NE
FU Month 6	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	100,00	NE
FU Month 9	Missing	0	NE			NE	NE	1	50,0			NE	NE
Screening	<25x10**9 cells/L	60	100,0	55	91,7	72,42	30,30	67	100,0	64	95,5	76,04	30,27
Cycle 4 Day 1	<25x10**9 cells/L	50	83,3	44	88,0	76,14	27,93	61	91,0	52	85,2	79,49	23,71
FU Day 28	<25x10**9 cells/L	56	93,3	47	83,9	72,70	29,37	61	91,0	53	86,9	77,04	27,00
FU Month 3	<25x10**9 cells/L	54	90,0	47	87,0	74,47	26,20	59	88,1	50	84,7	82,00	23,29
FU Month 6	<25x10**9 cells/L	50	83,3	43	86,0	76,74	29,35	51	76,1	42	82,4	82,94	27,42
FU Month 9	<25x10**9 cells/L	36	60,0	27	75,0	79,63	26,28	41	61,2	30	73,2	86,67	21,62
FU Month 12	<25x10**9 cells/L	29	48,3	24	82,8	71,53	28,86	34	50,7	25	73,5	82,67	21,77
FU Month 15	<25x10**9 cells/L	24	40,0	19	79,2	73,68	23,12	23	34,3	15	65,2	85,56	23,46
FU Month 18	<25x10**9 cells/L	20	33,3	18	90,0	81,48	30,19	19	28,4	14	73,7	79,76	33,45
FU Month 21	<25x10**9 cells/L	14	23,3	10	71,4	68,33	22,84	10	14,9	8	80,0	83,33	17,82

FU Month 24	<25x10**9 cells/L	8	13,3	5	62,5	66,67	40,82	6	9,0	6	100,0	72,22	38,97
FU Month 27	<25x10**9 cells/L	4	6,7	3	75,0	66,67	33,33	1	1,5	1	100,0	100,00	NE
FU Month 30	<25x10**9 cells/L	4	6,7	3	75,0	55,56	38,49	1	1,5	1	100,0	100,00	NE
Screening	>=25x10**9 cells/L	195	100,0	186	95,4	75,36	26,41	173	100,0	163	94,2	76,38	29,27
Cycle 4 Day 1	>=25x10**9 cells/L	163	83,6	151	92,6	80,02	23,26	162	93,6	144	88,9	76,97	28,15
FU Day 28	>=25x10**9 cells/L	174	89,2	154	88,5	79,22	26,90	163	94,2	149	91,4	77,74	26,47
FU Month 3	>=25x10**9 cells/L	171	87,7	156	91,2	78,42	28,09	161	93,1	144	89,4	77,43	25,73
FU Month 6	>=25x10**9 cells/L	157	80,5	141	89,8	81,44	23,75	140	80,9	125	89,3	77,07	25,72
FU Month 9	>=25x10**9 cells/L	128	65,6	110	85,9	82,58	24,87	107	61,8	91	85,0	74,91	23,49
FU Month 12	>=25x10**9 cells/L	96	49,2	85	88,5	78,82	27,02	83	48,0	74	89,2	74,32	27,47
FU Month 15	>=25x10**9 cells/L	80	41,0	71	88,8	82,63	22,96	62	35,8	54	87,1	78,09	25,87
FU Month 18	>=25x10**9 cells/L	59	30,3	52	88,1	80,13	25,14	41	23,7	35	85,4	69,52	25,72
FU Month 21	>=25x10**9 cells/L	38	19,5	30	78,9	87,22	18,92	30	17,3	24	80,0	70,14	30,68
FU Month 24	>=25x10**9 cells/L	24	12,3	20	83,3	77,50	28,75	12	6,9	11	91,7	92,42	17,26
FU Month 27	>=25x10**9 cells/L	9	4,6	8	88,9	81,25	20,77	8	4,6	6	75,0	86,11	16,39
FU Month 30	>=25x10**9 cells/L	3	1,5	3	100,0	88,89	19,25	0	NE	0	NE	NE	NE

¹ in study: number of subjects in study at respective visit; % based on baseline

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit

² mean: descriptive statistics - absolute values Clinical

cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/t_pro_mean.sas

Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/t_pro_mean_sg_EQC30_IT_label_09MAY2013_21004.xls 04MAR2020

17:18

POPULATION: Labelpopulation, Intent-to-Treat Patients ENDPOINT: EORTC QoL 30

MODEL: Unadjusted Analysis STUDY: CLL11(BO21004), Stage

2

Compliance/Mean

Social Functioning Scale

		GClb (N=255)						RC1b (N=242)					
		Patients			Statistics			Patients			Statistics		
Name	Level	in study ¹	%	with value ¹	%	Mean ²	SD(mean)	in study ¹	%	with value ¹	%	Mean ²	SD(mean)
All													
Screening	n/a	255	100,0	241	94,5	84,79	24,75	242	100,0	227	93,8	83,11	24,41
Cycle 4 Day 1	n/a	213	83,5	196	92,0	87,07	20,33	224	92,6	196	87,5	84,18	22,18
FU Day 28	n/a	230	90,2	201	87,4	83,75	24,35	225	93,0	201	89,3	85,57	21,65
FU Month 3	n/a	225	88,2	203	90,2	86,29	24,02	221	91,3	195	88,2	83,08	22,10
FU Month 6	n/a	207	81,2	188	90,8	85,82	22,73	192	79,3	167	87,0	85,23	21,60
FU Month 9	n/a	164	64,3	138	84,1	88,16	20,56	149	61,6	118	79,2	86,02	19,97
FU Month 12	n/a	125	49,0	109	87,2	87,16	21,47	117	48,3	98	83,8	84,69	22,28
FU Month 15	n/a	104	40,8	91	87,5	89,01	19,60	85	35,1	69	81,2	83,57	25,32
FU Month 18	n/a		79,31,0	69	87,3	88,41	18,37	60	24,8	49	81,7	82,65	27,21
FU Month 21	n/a		52,20,4	40	76,9	87,50	20,24	40	16,5	32	80,0	80,21	25,55
FU Month 24	n/a		32,12,5	25	78,1	80,67	25,31	18	7,4	16	88,9	83,33	31,03
FU Month 27	n/a		13,5,1	11	84,6	84,85	24,10	9	3,7	7	77,8	90,48	25,20
FU Month 30	n/a		7,2,7	6	85,7	72,22	32,77	1	0,4	1	100,0	100,00	NE
Gender													
Screening	Female	97	100,0	91	93,8	86,63	22,94	95	100,0	87	91,6	82,38	25,96
Cycle 4 Day 1	Female	84	86,6	77	91,7	88,53	17,78	88	92,6	77	87,5	80,95	23,68
FU Day 28	Female	90	92,8	83	92,2	83,53	23,35	91	95,8	79	86,8	83,76	24,31
FU Month 3	Female	88	90,7	81	92,0	86,83	22,47	87	91,6	76	87,4	80,26	22,56
FU Month 6	Female	84	86,6	72	85,7	85,42	22,01	77	81,1	67	87,0	85,57	19,44
FU Month 9	Female	70	72,2	59	84,3	85,03	23,51	61	64,2	46	75,4	83,33	23,57
FU Month 12	Female	56	57,7	49	87,5	86,39	18,53	47	49,5	39	83,0	84,19	25,35
FU Month 15	Female	47	48,5	41	87,2	84,55	24,26	33	34,7	28	84,8	85,71	21,62
FU Month 18	Female	34	35,1	29	85,3	86,78	19,61	26	27,4	22	84,6	78,79	31,78
FU Month 21	Female	21	21,6	15	71,4	83,33	24,40	17	17,9	15	88,2	77,78	24,12
FU Month 24	Female	12	12,4	10	83,3	76,67	23,83	6	6,3	5	83,3	100,00	0,00
FU Month 27	Female	6	6,2	5	83,3	83,33	23,57	2	2,1	1	50,0	100,00	NE
FU Month 30	Female	4	4,1	3	75,0	66,67	33,33	1	1,1	1	100,0	100,00	NE

Screening	Male	158	100,0	150	94,9	83,67	25,80	147	100,0	140	95,2	83,57	23,48
Cycle 4 Day 1	Male	129	81,6	119	92,2	86,13	21,84	136	92,5	119	87,5	86,27	21,00
FU Day 28	Male	140	88,6	118	84,3	83,90	25,12	134	91,2	122	91,0	86,75	19,75
FU Month 3	Male	137	86,7	122	89,1	85,93	25,08	134	91,2	119	88,8	84,87	21,70
FU Month 6	Male	123	77,8	116	94,3	86,06	23,25	115	78,2	100	87,0	85,00	23,03
FU Month 9	Male	94	59,5	79	84,0	90,51	17,84	88	59,9	72	81,8	87,73	17,24
FU Month 12	Male	69	43,7	60	87,0	87,78	23,74	70	47,6	59	84,3	85,03	20,22
FU Month 15	Male	57	36,1	50	87,7	92,67	13,95	52	35,4	41	78,8	82,11	27,74
FU Month 18	Male	45	28,5	40	88,9	89,58	17,58	34	23,1	27	79,4	85,80	22,98
FU Month 21	Male	31	19,6	25	80,6	90,00	17,35	23	15,6	17	73,9	82,35	27,30
FU Month 24	Male	20	12,7	15	75,0	83,33	26,73	12	8,2	11	91,7	75,76	35,25
FU Month 27	Male	7	4,4	6	85,7	86,11	26,70	7	4,8	6	85,7	88,89	27,22
FU Month 30	Male	3	1,9	3	100,0	77,78	38,49	0	NE	0	NE	NE	NE
Age													
Screening	<75 years	130	100,0	123	94,6	83,47	25,56	120	100,0	109	90,8	83,94	23,12
Cycle 4 Day 1	<75 years	106	81,5	100	94,3	87,33	20,53	112	93,3	97	86,6	84,19	23,49
FU Day 28	<75 years	119	91,5	105	88,2	83,97	25,42	110	91,7	103	93,6	83,82	21,57
FU Month 3	<75 years	116	89,2	106	91,4	88,52	22,34	109	90,8	99	90,8	83,00	21,16
FU Month 6	<75 years	108	83,1	98	90,7	86,39	21,18	99	82,5	88	88,9	85,23	20,90
FU Month 9	<75 years	85	65,4	73	85,9	88,58	20,01	74	61,7	62	83,8	86,02	19,83
FU Month 12	<75 years	63	48,5	59	93,7	87,57	22,01	60	50,0	53	88,3	85,53	19,35
FU Month 15	<75 years	54	41,5	47	87,0	87,94	20,47	44	36,7	35	79,5	86,19	22,68
FU Month 18	<75 years	43	33,1	39	90,7	87,61	20,49	27	22,5	22	81,5	80,30	33,98
FU Month 21	<75 years	26	20,0	22	84,6	86,36	18,99	17	14,2	13	76,5	84,62	28,43
FU Month 24	<75 years	18	13,8	14	77,8	76,19	29,75	6	5,0	5	83,3	93,33	14,91
FU Month 27	<75 years	7	5,4	5	71,4	76,67	27,89	2	1,7	1	50,0	100,00	NE
FU Month 30	<75 years	4	3,1	3	75,0	55,56	38,49	0	NE	0	NE	NE	NE
Screening	>=75 years	125	100,0	118	94,4	86,16	23,90	122	100,0	118	96,7	82,34	25,63
Cycle 4 Day 1	>=75 years	107	85,6	96	89,7	86,81	20,22	112	91,8	99	88,4	84,18	20,94
FU Day 28	>=75 years	111	88,8	96	86,5	83,51	23,26	115	94,3	98	85,2	87,41	21,68
FU Month 3	>=75 years	109	87,2	97	89,0	83,85	25,62	112	91,8	96	85,7	83,16	23,13
FU Month 6	>=75 years	99	79,2	90	90,9	85,19	24,41	93	76,2	79	84,9	85,23	22,49
FU Month 9	>=75 years	79	63,2	65	82,3	87,69	21,30	75	61,5	56	74,7	86,01	20,29
FU Month 12	>=75 years	62	49,6	50	80,6	86,67	21,03	57	46,7	45	78,9	83,70	25,50
FU Month 15	>=75 years	50	40,0	44	88,0	90,15	18,79	41	33,6	34	82,9	80,88	27,87
FU Month 18	>=75 years	36	28,8	30	83,3	89,44	15,46	33	27,0	27	81,8	84,57	20,63
FU Month 21	>=75 years	26	20,8	18	69,2	88,89	22,14	23	18,9	19	82,6	77,19	23,71
FU Month 24	>=75 years	14	11,2	11	78,6	86,36	17,98	12	9,8	11	91,7	78,79	35,82

FU Month 27	>=75 years	64,8	6100,0	91,67	20,41	75,7	685,7	88,89	27,22				
FU Month 30	>=75 years	32,4	3100,0	88,89	19,25	10,8	1100,0	100,00					NE
Race													
Screening	Other	9100,0	9100,0	88,89	16,67	11100,0	11100,0	90,91	13,67				
Cycle 4 Day 1	Other	777,8	7100,0	90,48	16,27	1090,9	990,0	77,78	22,05				
FU Day 28	Other	888,9	8100,0	83,33	29,55	1090,9	10100,0	83,33	20,79				
FU Month 3	Other	888,9	787,5	90,48	16,27	1090,9	10100,0	73,33	27,44				
FU Month 6	Other	888,9	787,5	71,43	39,34	872,7	8100,0	87,50	17,25				
FU Month 9	Other	444,4	375,0	88,89	19,25	545,5	480,0	91,67	16,67				
FU Month 12	Other	333,3	266,7	83,33	23,57	436,4	4100,0	87,50	25,00				
FU Month 15	Other	222,2	150,0	100,00		NE	436,4	4100,0	83,33	33,33			
FU Month 18	Other	222,2	150,0	100,00		NE	218,2	2100,0	83,33	23,57			
FU Month 21	Other	222,2	150,0	100,00		NE	218,2	2100,0	83,33	23,57			
FU Month 24	Other	222,2	150,0	100,00		NE	19,1	0	NE	NE			NE
FU Month 27	Other	111,1				NE	NE	19,1					NE
FU Month 30	Other	111,1				NE	NE	0	NE				NE
Screening													
Screening	White	246	100,0	232	94,3	84,63	25,02	231	100,0	216	93,5	82,72	24,79
Cycle 4 Day 1	White	206	83,7	189	91,7	86,95	20,49	214	92,6	187	87,4	84,49	22,20
FU Day 28	White	222	90,2	193	86,9	83,77	24,20	215	93,1	191	88,8	85,69	21,74
FU Month 3	White	217	88,2	196	90,3	86,14	24,27	211	91,3	185	87,7	83,60	21,74
FU Month 6	White	199	80,9	181	91,0	86,37	21,84	184	79,7	159	86,4	85,12	21,83
FU Month 9	White	160	65,0	135	84,4	88,15	20,65	144	62,3	114	79,2	85,82	20,11
FU Month 12	White	122	49,6	107	87,7	87,23	21,55	113	48,9	94	83,2	84,57	22,30
FU Month 15	White	102	41,5	90	88,2	88,89	19,67	81	35,1	65	80,2	83,59	25,09
FU Month 18	White	77	31,3	68	88,3	88,24	18,45	58	25,1	47	81,0	82,62	27,57
FU Month 21	White	50	20,3	39	78,0	87,18	20,40	38	16,5	30	78,9	80,00	26,04
FU Month 24	White	30	12,2	24	80,0	79,86	25,53	17	7,4	16	94,1	83,33	31,03
FU Month 27	White	12	4,9	11	91,7	84,85	24,10	8	3,5	7	87,5	90,48	25,20
FU Month 30	White	6	2,4	6	100,0	72,22	32,77	1	0,4	1	100,0	100,00	NE
Geographical Region													
Screening	Asia-Pacific	20	100,0	20	100,0	80,00	30,87	18	100,0	17	94,4	86,27	25,16
Cycle 4 Day 1	Asia-Pacific	15	75,0	15	100,0	80,00	26,87	16	88,9	15	93,8	84,44	18,33
FU Day 28	Asia-Pacific	18	90,0	18	100,0	67,59	34,05	18	100,0	16	88,9	87,50	14,27
FU Month 3	Asia-Pacific	18	90,0	16	88,9	82,29	33,59	18	100,0	16	88,9	84,38	19,69
FU Month 6	Asia-Pacific	16	80,0	14	87,5	73,81	35,63	17	94,4	15	88,2	73,33	34,39
FU Month 9	Asia-Pacific	14	70,0	12	85,7	90,28	20,67	13	72,2	9	69,2	74,07	32,39
FU Month 12	Asia-Pacific	10	50,0	8	80,0	85,42	30,13	10	55,6	10	100,0	75,00	34,47
FU Month 15	Asia-Pacific	8	40,0	6	75,0	94,44	13,61	9	50,0	9	100,0	68,52	36,75

FU Month 18	Asia-Pacific	630,0	466,7	100,00	0,00	633,3	6100,0	63,89	30,58
FU Month 21	Asia-Pacific	525,0	360,0	100,00	0,00	422,2	4100,0	58,33	41,94
FU Month 24	Asia-Pacific	315,0	266,7	100,00	0,00	15,6	0	NE	NE
FU Month 27	Asia-Pacific	15,0			NE	15,6			NE
FU Month 30	Asia-Pacific	15,0			NE	0	NE		NE
Screening	Central and South America	3100,0	3100,0	100,00	0,00	2100,0	2100,0	66,67	23,57
Cycle 4 Day 1	Central and South America	3100,0	3100,0	100,00	0,00	2100,0	2100,0	75,00	35,36
FU Day 28	Central and South America	3100,0	3100,0	94,44	9,62	2100,0	2100,0	91,67	11,79
FU Month 3	Central and South America	3100,0	3100,0	83,33	16,67	2100,0	2100,0	91,67	11,79
FU Month 6	Central and South America	266,7	2100,0	83,33	23,57	2100,0	2100,0	91,67	11,79
FU Month 9	Central and South America	266,7	2100,0	83,33	23,57	150,0	1100,0	100,00	NE
FU Month 12	Central and South America	266,7	2100,0	83,33	23,57	150,0	1100,0	66,67	NE
FU Month 15	Central and South America	133,3	1100,0	100,00		0	NE	0	NE
FU Month 18	Central and South America	133,3	1100,0	100,00		0	NE	0	NE
FU Month 21	Central and South America	133,3	1100,0	100,00		0	NE	0	NE
FU Month 24	Central and South America	133,3	1100,0	100,00		0	NE	0	NE
Screening	North America	12100,0	12100,0	80,56	25,46	13100,0	1292,3	88,89	14,79
Cycle 4 Day 1	North America	975,0	9100,0	79,63	21,70	1292,3	12100,0	81,94	15,01
FU Day 28	North America	1191,7	11100,0	89,39	18,67	13100,0	13100,0	80,77	28,74
FU Month 3	North America	1191,7	11100,0	84,85	26,30	1292,3	12100,0	84,72	22,98
FU Month 6	North America	1191,7	1090,9	75,00	30,68	1184,6	11100,0	89,39	18,67
FU Month 9	North America	866,7	8100,0	81,25	22,60	969,2	9100,0	87,04	16,20
FU Month 12	North America	866,7	787,5	80,95	27,94	753,8	7100,0	78,57	23,00
FU Month 15	North America	650,0	6100,0	91,67	13,94	646,2	583,3	56,67	43,46
FU Month 18	North America	433,3	4100,0	91,67	16,67	323,1	3100,0	77,78	19,25
FU Month 21	North America	325,0	266,7	83,33	23,57	17,7	1100,0	66,67	NE
FU Month 24	North America	325,0	266,7	66,67	47,14	17,7	1100,0	16,67	NE
FU Month 27	North America	216,7	150,0	100,00		17,7	1100,0	33,33	NE
Screening	Other	45100,0	4191,1	84,15	21,72	44100,0	4193,2	79,67	26,49
Cycle 4 Day 1	Other	3782,2	3389,2	87,88	17,81	4090,9	3485,0	82,84	21,51
FU Day 28	Other	3782,2	3389,2	92,93	17,69	3988,6	3794,9	86,49	19,18
FU Month 3	Other	3884,4	3489,5	90,20	22,52	3886,4	3694,7	81,48	22,46
FU Month 6	Other	3577,8	3188,6	87,10	22,65	3375,0	3193,9	84,41	19,69
FU Month 9	Other	2657,8	2284,6	95,45	11,71	2454,5	1979,2	88,60	16,72
FU Month 12	Other	1737,8	1694,1	88,54	23,35	1636,4	1487,5	89,29	15,48
FU Month 15	Other	1226,7	1191,7	93,94	13,48	920,5	888,9	95,83	7,72
FU Month 18	Other	1022,2	990,0	92,59	14,70	715,9	685,7	100,00	0,00
FU Month 21	Other	715,6	685,7	94,44	13,61	49,1	4100,0	100,00	0,00

FU Month 24	Other	6	13,3	5	83,3	86,67	18,26	3	6,8	3	100,0	94,44	9,62
FU Month 27	Other	4	8,9	4	100,0	91,67	16,67	1	2,3	1	100,0	100,00	NE
FU Month 30	Other	2	4,4	2	100,0	66,67	47,14	0	NE	0	NE	NE	NE
Screening	Western Europe	175	100,0	165	94,3	85,56	24,87	165	100,0	155	93,9	83,44	24,43
Cycle 4 Day 1	Western Europe	149	85,1	136	91,3	87,87	20,13	154	93,3	133	86,4	84,84	23,34
FU Day 28	Western Europe	161	92,0	136	84,5	82,97	23,87	153	92,7	133	86,9	85,46	22,51
FU Month 3	Western Europe	155	88,6	139	89,7	85,97	23,25	151	91,5	129	85,4	83,07	22,53
FU Month 6	Western Europe	143	81,7	131	91,6	87,66	20,00	129	78,2	108	83,7	86,57	20,05
FU Month 9	Western Europe	114	65,1	94	82,5	86,88	21,84	102	61,8	80	78,4	86,46	19,32
FU Month 12	Western Europe	88	50,3	76	86,4	87,72	19,88	83	50,3	66	79,5	86,11	21,20
FU Month 15	Western Europe	77	44,0	67	87,0	87,31	21,34	61	37,0	47	77,0	87,23	19,42
FU Month 18	Western Europe	58	33,1	51	87,9	86,27	19,64	44	26,7	34	77,3	83,33	28,13
FU Month 21	Western Europe	36	20,6	28	77,8	84,52	22,19	31	18,8	23	74,2	81,16	22,64
FU Month 24	Western Europe	19	10,9	15	78,9	76,67	26,58	13	7,9	12	92,3	86,11	29,16
FU Month 27	Western Europe	6	3,4	6	100,0	77,78	29,19	6	3,6	5	83,3	100,00	0,00
FU Month 30	Western Europe	4	2,3	4	100,0	75,00	31,91	1	0,6	1	100,0	100,00	NE
FCgamma receptor IIa													
Screening	131HH	58	100,0	53	91,4	83,65	22,53	76	100,0	72	94,7	84,26	24,85
Cycle 4 Day 1	131HH	49	84,5	43	87,8	82,56	20,88	65	85,5	60	92,3	86,39	20,47
FU Day 28	131HH	51	87,9	46	90,2	85,51	23,20	70	92,1	61	87,1	87,98	16,70
FU Month 3	131HH	51	87,9	47	92,2	85,11	23,88	64	84,2	54	84,4	87,04	20,90
FU Month 6	131HH	49	84,5	45	91,8	85,93	20,09	55	72,4	48	87,3	89,58	19,94
FU Month 9	131HH	39	67,2	30	76,9	87,78	18,54	41	53,9	32	78,0	89,06	17,76
FU Month 12	131HH	28	48,3	24	85,7	81,94	24,53	34	44,7	29	85,3	87,93	17,19
FU Month 15	131HH	23	39,7	19	82,6	85,96	20,23	24	31,6	20	83,3	85,83	24,35
FU Month 18	131HH	17	29,3	14	82,4	82,14	16,62	16	21,1	13	81,3	87,18	24,68
FU Month 21	131HH	13	22,4	8	61,5	83,33	25,20	11	14,5	10	90,9	63,33	34,96
FU Month 24	131HH	11	19,0	7	63,6	80,95	17,82	1	1,3	1	100,0	100,00	NE
FU Month 27	131HH	4	6,9	3	75,0	77,78	25,46	1	1,3	1	100,0	100,00	NE
FU Month 30	131HH	3	5,2	2	66,7	83,33	23,57	0	NE	0	NE	NE	NE
Screening	131HR	125	100,0	118	94,4	84,75	25,93	114	100,0	109	95,6	85,78	23,11
Cycle 4 Day 1	131HR	105	84,0	98	93,3	88,27	18,72	110	96,5	98	89,1	84,69	22,66
FU Day 28	131HR	116	92,8	102	87,9	81,21	25,55	105	92,1	95	90,5	85,26	23,68
FU Month 3	131HR	114	91,2	102	89,5	86,11	25,16	107	93,9	95	88,8	81,58	23,25
FU Month 6	131HR	104	83,2	93	89,4	88,17	20,20	95	83,3	83	87,4	83,53	22,31
FU Month 9	131HR	84	67,2	71	84,5	87,79	20,11	76	66,7	59	77,6	87,01	20,78
FU Month 12	131HR	64	51,2	57	89,1	86,26	22,08	57	50,0	48	84,2	85,76	24,79
FU Month 15	131HR	53	42,4	45	84,9	89,63	16,01	44	38,6	35	79,5	85,24	23,84

FU Month 18	131HR	43	34,4	37	86,0	89,64	18,15	32	28,1	26	81,3	85,26	21,25
FU Month 21	131HR	26	20,8	20	76,9	83,33	22,30	21	18,4	16	76,2	83,33	16,10
FU Month 24	131HR	12	9,6	11	91,7	80,30	30,57	12	10,5	10	83,3	75,00	37,06
FU Month 27	131HR	6	4,8	5	83,3	80,00	29,81	6	5,3	4	66,7	83,33	33,33
FU Month 30	131HR	3	2,4	3	100,0	55,56	38,49	1	0,9	1	100,0	100,00	NE
Screening	131RR	49	100,0	48	98,0	84,03	26,17	33	100,0	29	87,9	79,89	21,54
Cycle 4 Day 1	131RR	40	81,6	38	95,0	89,91	19,58	31	93,9	25	80,6	78,67	27,01
FU Day 28	131RR	42	85,7	35	83,3	87,14	23,25	32	97,0	29	90,6	83,91	23,77
FU Month 3	131RR	39	79,6	37	94,9	86,94	23,94	32	97,0	29	90,6	85,63	20,76
FU Month 6	131RR	35	71,4	33	94,3	81,31	29,69	27	81,8	22	81,5	81,82	24,07
FU Month 9	131RR	24	49,0	22	91,7	87,12	26,19	19	57,6	17	89,5	80,39	18,85
FU Month 12	131RR	18	36,7	17	94,4	92,16	18,74	17	51,5	14	82,4	75,00	24,24
FU Month 15	131RR	16	32,7	16	100,0	88,54	27,70	11	33,3	9	81,8	85,19	17,57
FU Month 18	131RR	14	28,6	14	100,0	89,29	22,27	8	24,2	7	87,5	61,90	45,86
FU Month 21	131RR	8	16,3	7	87,5	97,62	6,30	5	15,2	4	80,0	100,00	0,00
FU Month 24	131RR	5	10,2	4	80,0	75,00	31,91	3	9,1	3	100,0	100,00	0,00
FU Month 27	131RR	2	4,1	2	100,0	100,00	0,00	1	3,0	1	100,0	100,00	NE
FU Month 30	131RR	1	2,0	1	100,0	100,00	NE	0	NE	0	NE	NE	NE
Screening	Missing	23	100,0	22	95,7	89,39	20,92	19	100,0	17	89,5	66,67	30,05
Cycle 4 Day 1	Missing	19	82,6	17	89,5	85,29	28,19	18	94,7	13	72,2	80,77	14,98
FU Day 28	Missing	21	91,3	18	85,7	87,04	22,55	18	94,7	16	88,9	81,25	22,67
FU Month 3	Missing	21	91,3	17	81,0	89,22	18,58	18	94,7	17	94,4	74,51	19,65
FU Month 6	Missing	19	82,6	17	89,5	81,37	26,93	15	78,9	14	93,3	85,71	18,32
FU Month 9	Missing	17	73,9	15	88,2	92,22	18,76	13	68,4	10	76,9	80,00	23,31
FU Month 12	Missing	15	65,2	11	73,3	95,45	10,78	9	47,4	7	77,8	83,33	16,67
FU Month 15	Missing	12	52,2	11	91,7	92,42	20,23	6	31,6	5	83,3	60,00	43,46
FU Month 18	Missing	5	21,7	4	80,0	95,83	8,33	4	21,1	3	75,0	88,89	19,25
FU Month 21	Missing	5	21,7	5	100,0	96,67	7,45	3	15,8	2	66,7	100,00	0,00
FU Month 24	Missing	4	17,4	3	75,0	88,89	19,25	2	10,5	2	100,0	91,67	11,79
FU Month 27	Missing	1	4,3	1	100,0	100,00	NE	1	5,3	1	100,0	100,00	NE
FCgamma receptor IIIa													
Screening	158FF	103	100,0	100	97,1	85,50	26,02	83	100,0	78	94,0	85,47	17,89
Cycle 4 Day 1	158FF	89	86,4	83	93,3	89,76	18,37	78	94,0	72	92,3	83,56	22,64
FU Day 28	158FF	96	93,2	84	87,5	83,33	25,48	78	94,0	74	94,9	85,36	20,45
FU Month 3	158FF	94	91,3	84	89,4	86,71	24,51	78	94,0	70	89,7	88,33	18,68
FU Month 6	158FF	86	83,5	76	88,4	86,18	23,79	64	77,1	58	90,6	89,66	19,45
FU Month 9	158FF	71	68,9	59	83,1	87,01	22,76	47	56,6	43	91,5	89,15	14,94
FU Month 12	158FF	48	46,6	42	87,5	85,32	22,45	38	45,8	34	89,5	86,76	20,42

FU Month 15	158FF		37	35,9		32	86,5	85,94	25,44		30	36,1		24	80,0	85,42	27,06
FU Month 18	158FF		27	26,2		24	88,9	85,42	22,69		21	25,3		17	81,0	79,41	31,47
FU Month 21	158FF		16	15,5		15	93,8	88,89	19,59		9	10,8		8	88,9	87,50	19,42
FU Month 24	158FF		8	7,8		7	87,5	76,19	35,82		3	3,6		2	66,7	83,33	23,57
FU Month 27	158FF		5	4,9		4	80,0	83,33	33,33		1	1,2		1	100,0	100,00	NE
FU Month 30	158FF		3	2,9		3	100,0	77,78	38,49		0	NE		0	NE	NE	NE
Screening	158FV		119	100,0		110	92,4	83,79	24,57		109	100,0		103	94,5	81,88	27,72
Cycle 4 Day 1	158FV		99	83,2		90	90,9	86,11	19,87		100	91,7		84	84,0	83,13	23,50
FU Day 28	158FV		105	88,2		91	86,7	83,15	23,89		101	92,7		87	86,1	86,02	23,28
FU Month 3	158FV		101	84,9		93	92,1	85,13	25,36		97	89,0		84	86,6	80,36	24,70
FU Month 6	158FV		94	79,0		87	92,6	86,59	21,09		83	76,1		72	86,7	84,26	22,18
FU Month 9	158FV		71	59,7		61	85,9	88,80	18,19		65	59,6		49	75,4	82,99	23,69
FU Month 12	158FV		60	50,4		55	91,7	86,67	22,31		52	47,7		42	80,8	80,16	25,57
FU Month 15	158FV		52	43,7		46	88,5	90,22	15,55		36	33,0		30	83,3	79,44	27,57
FU Month 18	158FV		44	37,0		38	86,4	91,67	14,37		24	22,0		20	83,3	77,50	28,75
FU Month 21	158FV		28	23,5		18	64,3	86,11	23,04		18	16,5		14	77,8	70,24	31,47
FU Month 24	158FV		18	15,1		13	72,2	82,05	23,04		6	5,5		5	83,3	76,67	43,46
FU Month 27	158FV		6	5,0		5	83,3	83,33	23,57		2	1,8		1	50,0	100,00	NE
FU Month 30	158FV		4	3,4		3	75,0	66,67	33,33		0	NE		0	NE	NE	NE
Screening	158VV		16	100,0		15	93,8	85,56	19,79		33	100,0		31	93,9	88,17	19,81
Cycle 4 Day 1	158VV		12	75,0		11	91,7	87,88	15,08		30	90,9		28	93,3	88,69	20,31
FU Day 28	158VV		14	87,5		13	92,9	89,74	21,01		30	90,9		26	86,7	88,46	15,47
FU Month 3	158VV		15	93,8		12	80,0	90,28	13,22		30	90,9		26	86,7	84,62	16,95
FU Month 6	158VV		14	87,5		13	92,9	87,18	20,59		30	90,9		23	76,7	81,16	24,26
FU Month 9	158VV		12	75,0		10	83,3	88,33	20,86		25	75,8		17	68,0	90,20	16,73
FU Month 12	158VV		8	50,0		7	87,5	92,86	13,11		20	60,6		17	85,0	91,18	16,79
FU Month 15	158VV		8	50,0		7	87,5	85,71	20,25		14	42,4		11	78,6	87,88	16,82
FU Month 18	158VV		4	25,0		4	100,0	70,83	20,97		11	33,3		9	81,8	94,44	11,79
FU Month 21	158VV		3	18,8		2	66,7	66,67	0,00		9	27,3		7	77,8	83,33	16,67
FU Month 24	158VV		2	12,5		2	100,0	75,00	11,79		7	21,2		7	100,0	85,71	31,07
FU Month 27	158VV		1	6,3		1	100,0	83,33	NE		5	15,2		4	80,0	83,33	33,33
FU Month 30	158VV		0	NE		0	NE	NE	NE		1	3,0		1	100,0	100,00	NE
Screening	Missing		17	100,0		16	94,1	86,46	23,74		17	100,0		15	88,2	68,89	33,25
Cycle 4 Day 1	Missing		13	76,5		12	92,3	75,00	34,45		16	94,1		12	75,0	84,72	13,22
FU Day 28	Missing		15	88,2		13	86,7	84,62	24,96		16	94,1		14	87,5	78,57	27,29
FU Month 3	Missing		15	88,2		14	93,3	88,10	20,07		16	94,1		15	93,8	71,11	23,96
FU Month 6	Missing		13	76,5		12	92,3	76,39	29,69		15	88,2		14	93,3	78,57	21,11
FU Month 9	Missing		10	58,8		8	80,0	91,67	23,57		12	70,6		9	75,0	79,63	23,24

FU Month 12	Missing		952,9		555,6	100,00	0,00		741,2		571,4	86,67	18,26
FU Month 15	Missing		741,2		685,7	100,00	0,00		529,4		480,0	91,67	16,67
FU Month 18	Missing		423,5		375,0	94,44	9,62		423,5		375,0	100,00	0,00
FU Month 21	Missing		529,4		5100,0	96,67	7,45		423,5		375,0	100,00	0,00
FU Month 24	Missing		423,5		375,0	88,89	19,25		211,8		2100,0	91,67	11,79
FU Month 27	Missing		15,9		1100,0	100,00		NE	15,9		1100,0	100,00	NE
Binet Staging at baseline													
Screening	A		59100,0		5898,3	84,48	26,83		57100,0		5393,0	82,08	25,91
Cycle 4 Day 1	A		5186,4		4894,1	88,89	18,30		5494,7		5092,6	80,00	25,20
FU Day 28	A		5898,3		5391,4	79,87	24,75		5494,7		5296,3	82,37	25,86
FU Month 3	A		5796,6		5698,2	83,63	27,43		5393,0		5094,3	84,00	23,32
FU Month 6	A		5694,9		5089,3	80,67	26,80		4578,9		4293,3	82,54	24,68
FU Month 9	A		4372,9		3786,0	83,33	21,87		3459,6		3088,2	79,44	24,24
FU Month 12	A		3661,0		3494,4	83,33	22,10		2442,1		2187,5	74,60	29,16
FU Month 15	A		3050,8		2790,0	90,74	14,86		1933,3		19100,0	80,70	26,80
FU Month 18	A		2237,3		1881,8	89,81	19,08		1628,1		16100,0	75,00	36,51
FU Month 21	A		1728,8		1588,2	85,56	27,36		814,0		787,5	92,86	13,11
FU Month 24	A		1016,9		880,0	75,00	30,86		58,8		5100,0	96,67	7,45
FU Month 27	A		58,5		480,0	70,83	34,36		23,5		150,0	100,00	NE
FU Month 30	A		46,8		375,0	66,67	33,33		0	NE	0	NE	NE
Screening	B	104	100,0	100	96,2	86,00	22,06		85100,0		8397,6	83,94	25,30
Cycle 4 Day 1	B		8884,6		8394,3	87,35	20,09		7992,9		7291,1	86,11	19,58
FU Day 28	B		9187,5		7986,8	87,13	23,10		7992,9		7189,9	88,26	18,98
FU Month 3	B		8884,6		7888,6	88,46	23,62		7992,9		7088,6	85,48	20,05
FU Month 6	B		8076,9		7796,3	89,39	17,71		7082,4		6288,6	89,78	17,69
FU Month 9	B		6360,6		5282,5	90,38	19,90		5969,4		4881,4	86,81	18,50
FU Month 12	B		4745,2		3983,0	90,60	19,04		4654,1		3984,8	88,89	18,07
FU Month 15	B		3735,6		3491,9	85,78	23,26		3440,0		2882,4	86,90	18,90
FU Month 18	B		3129,8		2890,3	85,12	20,95		2225,9		1881,8	88,89	16,17
FU Month 21	B		1817,3		1372,2	85,90	14,98		1720,0		1482,4	83,33	18,49
FU Month 24	B		1110,6		981,8	81,48	28,19		89,4		787,5	71,43	43,79
FU Month 27	B		54,8		480,0	95,83	8,33		44,7		4100,0	83,33	33,33
FU Month 30	B		21,9		2100,0	100,00	0,00		0	NE	0	NE	NE
Screening	C		92100,0		8390,2	83,53	26,48	100	100,0		9191,0	82,97	22,90
Cycle 4 Day 1	C		7480,4		6587,8	85,38	22,15		9191,0		7481,3	85,14	22,34
FU Day 28	C		8188,0		6985,2	82,85	25,24		9292,0		7884,8	85,26	20,80
FU Month 3	C		8087,0		6986,3	85,99	21,51		8989,0		7584,3	80,22	23,04
FU Month 6	C		7177,2		6185,9	85,52	24,24		7777,0		6381,8	82,54	22,49

FU Month 9	C	58	63,0	49	84,5	89,46	20,04	56	56,0	40	71,4	90,00	17,21	
FU Month 12	C	42	45,7	36	85,7	87,04	23,27	47	47,0	38	80,9	85,96	20,70	
FU Month 15	C	37	40,2	30	81,1	91,11	18,94	32	32,0	22	68,8	81,82	31,25	
FU Month 18	C	26	28,3	23	88,5	91,30	14,10	22	22,0	15	68,2	83,33	25,97	
FU Month 21	C	17	18,5	12	70,6	91,67	15,08	15	15,0	11	73,3	68,18	34,52	
FU Month 24	C	11	12,0	8	72,7	85,42	16,52	5	5,0	4	80,0	87,50	15,96	
FU Month 27	C	3	3,3	3	100,0	88,89	19,25	3	3,0	2	66,7	100,00	0,00	
FU Month 30	C	1	1,1	1	100,0	33,33		NE	1	1,0	1	100,0	100,00	NE
Total CIR score at baseline														
Screening	<=6	63	100,0	58	92,1	85,92	23,11	75	100,0	69	92,0	85,51	22,31	
Cycle 4 Day 1	<=6	52	82,5	43	82,7	86,05	21,80	72	96,0	61	84,7	89,07	17,18	
FU Day 28	<=6	56	88,9	49	87,5	85,71	22,31	72	96,0	59	81,9	90,68	14,61	
FU Month 3	<=6	55	87,3	47	85,5	85,11	25,59	69	92,0	56	81,2	87,20	18,25	
FU Month 6	<=6	52	82,5	47	90,4	85,82	20,85	60	80,0	53	88,3	83,02	22,76	
FU Month 9	<=6	43	68,3	36	83,7	88,43	21,01	47	62,7	38	80,9	85,96	18,79	
FU Month 12	<=6	35	55,6	29	82,9	86,78	21,07	34	45,3	27	79,4	88,89	19,61	
FU Month 15	<=6	32	50,8	29	90,6	87,93	20,84	25	33,3	17	68,0	88,24	21,05	
FU Month 18	<=6	23	36,5	22	95,7	88,64	16,58	19	25,3	14	73,7	84,52	22,13	
FU Month 21	<=6	14	22,2	8	57,1	87,50	24,80	14	18,7	10	71,4	85,00	19,95	
FU Month 24	<=6	8	12,7	7	87,5	85,71	26,23	7	9,3	5	71,4	86,67	13,94	
FU Month 27	<=6	2	3,2	2	100,0	100,00	0,00	4	5,3	2	50,0	100,00	0,00	
FU Month 30	<=6	0	NE	0	NE	NE	NE	1	1,3	1	100,0	100,00	NE	
Screening >6														
Screening	>6	192	100,0	183	95,3	84,43	25,29	167	100,0	158	94,6	82,07	25,28	
Cycle 4 Day 1	>6	161	83,9	153	95,0	87,36	19,96	152	91,0	135	88,8	81,98	23,84	
FU Day 28	>6	174	90,6	152	87,4	83,11	25,01	153	91,6	142	92,8	83,45	23,69	
FU Month 3	>6	170	88,5	156	91,8	86,65	23,60	152	91,0	139	91,4	81,41	23,32	
FU Month 6	>6	155	80,7	141	91,0	85,82	23,40	132	79,0	114	86,4	86,26	21,06	
FU Month 9	>6	121	63,0	102	84,3	88,07	20,50	102	61,1	80	78,4	86,04	20,62	
FU Month 12	>6	90	46,9	80	88,9	87,29	21,75	83	49,7	71	85,5	83,10	23,14	
FU Month 15	>6	72	37,5	62	86,1	89,52	19,14	60	35,9	52	86,7	82,05	26,58	
FU Month 18	>6	56	29,2	47	83,9	88,30	19,32	41	24,6	35	85,4	81,90	29,25	
FU Month 21	>6	38	19,8	32	84,2	87,50	19,40	26	15,6	22	84,6	78,03	27,88	
FU Month 24	>6	24	12,5	18	75,0	78,70	25,44	11	6,6	11	100,0	81,82	36,86	
FU Month 27	>6	11	5,7	9	81,8	81,48	25,61	5	3,0	5	100,0	86,67	29,81	
FU Month 30	>6	7	3,6	6	85,7	72,22	32,77	0	NE	0	NE	NE	NE	
Calculated creatinine clearance cat. 2														
Screening	<70 ml/min	178	100,0	165	92,7	85,45	25,51	176	100,0	166	94,3	83,84	24,58	
Cycle 4 Day 1	<70 ml/min	149	83,7	134	89,9	87,44	20,58	164	93,2	142	86,6	83,80	21,83	

FU Day 28	<70 ml/min	162	91,0	142	87,7	83,45	23,36	166	94,3	144	86,7	86,34	20,92
FU Month 3	<70 ml/min	157	88,2	141	89,8	86,17	24,48	159	90,3	138	86,8	81,88	22,83
FU Month 6	<70 ml/min	144	80,9	129	89,6	86,95	20,51	139	79,0	119	85,6	84,73	22,71
FU Month 9	<70 ml/min	117	65,7	97	82,9	87,97	21,35	112	63,6	87	77,7	85,63	21,29
FU Month 12	<70 ml/min	92	51,7	79	85,9	87,13	20,66	87	49,4	72	82,8	83,80	24,22
FU Month 15	<70 ml/min	78	43,8	70	89,7	88,81	20,41	60	34,1	48	80,0	82,29	26,94
FU Month 18	<70 ml/min	59	33,1	50	84,7	90,00	16,50	43	24,4	36	83,7	81,02	29,59
FU Month 21	<70 ml/min	38	21,3	27	71,1	88,89	20,15	31	17,6	27	87,1	80,86	26,43
FU Month 24	<70 ml/min	24	13,5	19	79,2	81,58	23,50	13	7,4	11	84,6	86,36	25,62
FU Month 27	<70 ml/min	10	5,6	8	80,0	89,58	19,80	7	4,0	5	71,4	86,67	29,81
FU Month 30	<70 ml/min	5	2,8	4	80,0	75,00	31,91	1	0,6	1	100,0	100,00	NE
Screening	>=70 ml/min	77	100,0	76	98,7	83,33	23,09	66	100,0	61	92,4	81,15	24,05
Cycle 4 Day 1	>=70 ml/min	64	83,1	62	96,9	86,29	19,91	60	90,9	54	90,0	85,19	23,27
FU Day 28	>=70 ml/min	68	88,3	59	86,8	84,46	26,78	59	89,4	57	96,6	83,63	23,46
FU Month 3	>=70 ml/min	68	88,3	62	91,2	86,56	23,15	62	93,9	57	91,9	85,96	20,12
FU Month 6	>=70 ml/min	63	81,8	59	93,7	83,33	26,98	53	80,3	48	90,6	86,46	18,72
FU Month 9	>=70 ml/min	47	61,0	41	87,2	88,62	18,80	37	56,1	31	83,8	87,10	15,93
FU Month 12	>=70 ml/min	33	42,9	30	90,9	87,22	23,85	30	45,5	26	86,7	87,18	15,85
FU Month 15	>=70 ml/min	26	33,8	21	80,8	89,68	17,06	25	37,9	21	84,0	86,51	21,49
FU Month 18	>=70 ml/min	20	26,0	19	95,0	84,21	22,55	17	25,8	13	76,5	87,18	19,43
FU Month 21	>=70 ml/min	14	18,2	13	92,9	84,62	20,93	9	13,6	5	55,6	76,67	22,36
FU Month 24	>=70 ml/min	8	10,4	6	75,0	77,78	32,77	5	7,6	5	100,0	76,67	43,46
FU Month 27	>=70 ml/min	3	3,9	3	100,0	72,22	34,69	2	3,0	2	100,0	100,00	0,00
FU Month 30	>=70 ml/min	2	2,6	2	100,0	66,67	47,14	0	NE	0	NE	NE	NE
Beta2 microglobulin													
Screening	Missing	3	100,0	3	100,0	88,89	19,25	3	100,0	3	100,0	22,22	19,25
Cycle 4 Day 1	Missing	3	100,0	3	100,0	77,78	19,25	3	100,0	2	66,7	83,33	23,57
FU Day 28	Missing	3	100,0	3	100,0	100,00	0,00	3	100,0	2	66,7	100,00	0,00
FU Month 3	Missing	3	100,0	3	100,0	100,00	0,00	3	100,0	2	66,7	75,00	35,36
FU Month 6	Missing	3	100,0	3	100,0	100,00	0,00	3	100,0	2	66,7	75,00	35,36
FU Month 9	Missing	2	66,7	1	50,0	83,33	NE	3	100,0	2	66,7	66,67	47,14
FU Month 12	Missing	1	33,3	1	100,0	100,00	NE	2	66,7	1	50,0	100,00	NE
FU Month 15	Missing	1	33,3	1	100,0	100,00	NE	2	66,7	1	50,0	100,00	NE
FU Month 18	Missing	1	33,3	1	100,0	66,67	NE	2	66,7	1	50,0	100,00	NE
FU Month 21	Missing	1	33,3	1	100,0	66,67	NE	2	66,7	1	50,0	100,00	NE
FU Month 24	Missing	1	33,3	1	100,0	66,67	NE	1	33,3	1	100,0	100,00	NE
Screening	< 3.5 ug/mL	154	100,0	144	93,5	84,95	24,17	140	100,0	131	93,6	84,86	22,69
Cycle 4 Day 1	< 3.5 ug/mL	127	82,5	117	92,1	84,33	21,92	129	92,1	111	86,0	83,63	23,57

FU Day 28	< 3.5 ug/mL	137	89,0	121	88,3	83,06	24,91	132	94,3	120	90,9	85,83	20,23
FU Month 3	< 3.5 ug/mL	134	87,0	123	91,8	86,72	22,38	130	92,9	115	88,5	83,48	19,93
FU Month 6	< 3.5 ug/mL	128	83,1	115	89,8	86,52	21,39	120	85,7	109	90,8	84,10	22,27
FU Month 9	< 3.5 ug/mL	104	67,5	87	83,7	86,59	21,99	98	70,0	80	81,6	86,46	20,73
FU Month 12	< 3.5 ug/mL	78	50,6	69	88,5	85,27	23,49	75	53,6	66	88,0	84,85	23,34
FU Month 15	< 3.5 ug/mL	65	42,2	57	87,7	87,13	21,37	60	42,9	51	85,0	85,95	23,89
FU Month 18	< 3.5 ug/mL	46	29,9	41	89,1	86,99	19,19	43	30,7	35	81,4	80,00	30,20
FU Month 21	< 3.5 ug/mL	30	19,5	21	70,0	82,54	24,99	27	19,3	22	81,5	79,55	29,06
FU Month 24	< 3.5 ug/mL	19	12,3	15	78,9	77,78	27,22	12	8,6	10	83,3	95,00	8,05
FU Month 27	< 3.5 ug/mL	10	6,5	8	80,0	79,17	26,35	7	5,0	5	71,4	100,00	0,00
FU Month 30	< 3.5 ug/mL	5	3,2	4	80,0	58,33	31,91	1	0,7	1	100,0	100,00	NE
Screening	>= 3.5 ug/mL	98	100,0	94	95,9	84,40	25,96	99	100,0	93	93,9	82,62	24,56
Cycle 4 Day 1	>= 3.5 ug/mL	83	84,7	76	91,6	91,67	16,89	92	92,9	83	90,2	84,94	20,43
FU Day 28	>= 3.5 ug/mL	90	91,8	77	85,6	84,20	23,86	90	90,9	79	87,8	84,81	23,90
FU Month 3	>= 3.5 ug/mL	88	89,8	77	87,5	85,06	26,84	88	88,9	78	88,6	82,69	24,97
FU Month 6	>= 3.5 ug/mL	76	77,6	70	92,1	84,05	25,13	69	69,7	56	81,2	87,80	19,97
FU Month 9	>= 3.5 ug/mL	58	59,2	50	86,2	91,00	17,88	48	48,5	36	75,0	86,11	16,67
FU Month 12	>= 3.5 ug/mL	46	46,9	39	84,8	90,17	17,40	40	40,4	31	77,5	83,87	20,41
FU Month 15	>= 3.5 ug/mL	38	38,8	33	86,8	91,92	16,20	23	23,2	17	73,9	75,49	28,94
FU Month 18	>= 3.5 ug/mL	32	32,7	27	84,4	91,36	16,90	15	15,2	13	86,7	88,46	17,19
FU Month 21	>= 3.5 ug/mL	21	21,4	18	85,7	94,44	9,90	11	11,1	9	81,8	79,63	16,20
FU Month 24	>= 3.5 ug/mL	12	12,2	9	75,0	87,04	23,24	5	5,1	5	100,0	56,67	46,55
FU Month 27	>= 3.5 ug/mL	3	3,1	3	100,0	100,00	0,00	2	2,0	2	100,0	66,67	47,14
FU Month 30	>= 3.5 ug/mL	2	2,0	2	100,0	100,00	0,00	0	NE	0	NE	NE	NE
Immunoglobulin VH, cytogenetics 2													
Screening	12	45	100,0	43	95,6	83,33	24,67	44	100,0	43	97,7	81,01	24,55
Cycle 4 Day 1	12	34	75,6	32	94,1	88,54	17,68	38	86,4	32	84,2	81,77	23,71
FU Day 28	12	39	86,7	37	94,9	79,73	29,17	40	90,9	34	85,0	80,88	25,34
FU Month 3	12	38	84,4	36	94,7	87,96	24,76	39	88,6	32	82,1	82,29	22,77
FU Month 6	12	36	80,0	32	88,9	86,98	23,08	34	77,3	28	82,4	85,71	19,09
FU Month 9	12	26	57,8	22	84,6	91,67	17,63	28	63,6	18	64,3	84,26	22,49
FU Month 12	12	22	48,9	18	81,8	88,89	18,08	23	52,3	15	65,2	87,78	13,31
FU Month 15	12	17	37,8	14	82,4	91,67	15,68	17	38,6	12	70,6	81,94	25,08
FU Month 18	12	15	33,3	12	80,0	91,67	15,08	13	29,5	9	69,2	88,89	22,05
FU Month 21	12	10	22,2	8	80,0	83,33	23,57	7	15,9	5	71,4	93,33	14,91
FU Month 24	12	8	17,8	6	75,0	86,11	19,48	6	13,6	6	100,0	83,33	40,82
FU Month 27	12	5	11,1	4	80,0	83,33	23,57	2	4,5	2	100,0	100,00	0,00
FU Month 30	12	4	8,9	3	75,0	88,89	19,25	1	2,3	1	100,0	100,00	NE

Screening	11q-	46	100,0	43	93,5	94,57	13,95	43	100,0	40	93,0	85,83	20,17
Cycle 4 Day 1	11q-	40	87,0	39	97,5	91,88	15,71	41	95,3	35	85,4	86,19	20,80
FU Day 28	11q-	42	91,3	35	83,3	87,62	21,52	39	90,7	36	92,3	89,35	21,88
FU Month 3	11q-	42	91,3	38	90,5	88,16	24,78	38	88,4	36	94,7	88,43	16,82
FU Month 6	11q-	38	82,6	35	92,1	92,86	14,73	32	74,4	27	84,4	86,42	18,51
FU Month 9	11q-	28	60,9	26	92,9	88,46	18,72	25	58,1	20	80,0	85,00	17,01
FU Month 12	11q-	20	43,5	19	95,0	89,47	21,67	18	41,9	17	94,4	77,45	23,53
FU Month 15	11q-	18	39,1	16	88,9	90,63	14,87	14	32,6	10	71,4	81,67	24,15
FU Month 18	11q-	15	32,6	12	80,0	88,89	21,71	8	18,6	7	87,5	80,95	36,55
FU Month 21	11q-	12	26,1	11	91,7	80,30	26,69	4	9,3	2	50,0	75,00	35,36
FU Month 24	11q-	7	15,2	5	71,4	76,67	36,51	1	2,3	1	100,0	100,00	NE
FU Month 27	11q-	3	6,5	3	100,0	66,67	33,33	0	NE	0	NE	NE	NE
FU Month 30	11q-	3	6,5	3	100,0	55,56	38,49	0	NE	0	NE	NE	NE
Screening	13q-	79	100,0	76	96,2	87,06	21,36	75	100,0	70	93,3	87,38	22,24
Cycle 4 Day 1	13q-	67	84,8	60	89,6	86,67	19,36	68	90,7	60	88,2	88,06	17,65
FU Day 28	13q-	72	91,1	65	90,3	87,18	20,79	72	96,0	65	90,3	87,44	19,33
FU Month 3	13q-	73	92,4	67	91,8	86,57	23,43	69	92,0	61	88,4	82,51	22,45
FU Month 6	13q-	67	84,8	62	92,5	88,71	20,42	63	84,0	56	88,9	86,31	22,50
FU Month 9	13q-	56	70,9	49	87,5	89,12	22,19	52	69,3	41	78,8	88,62	19,87
FU Month 12	13q-	44	55,7	39	88,6	88,03	19,48	40	53,3	38	95,0	84,65	24,93
FU Month 15	13q-	38	48,1	34	89,5	86,76	24,88	29	38,7	25	86,2	87,33	21,67
FU Month 18	13q-	28	35,4	25	89,3	88,67	19,67	21	28,0	19	90,5	80,70	29,01
FU Month 21	13q-	16	20,3	13	81,3	91,03	14,62	16	21,3	14	87,5	83,33	17,30
FU Month 24	13q-	7	8,9	6	85,7	77,78	27,22	7	9,3	6	85,7	80,56	32,35
FU Month 27	13q-	2	2,5	1	50,0	100,00	NE	6	8,0	4	66,7	83,33	33,33
Screening	Norm. K.	65	100,0	61	93,8	76,50	30,94	58	100,0	54	93,1	76,85	29,21
Cycle 4 Day 1	Norm. K.	54	83,1	49	90,7	85,03	22,63	55	94,8	50	90,9	78,00	27,65
FU Day 28	Norm. K.	59	90,8	50	84,7	81,33	24,89	53	91,4	49	92,5	84,69	19,20
FU Month 3	Norm. K.	54	83,1	48	88,9	84,03	23,31	54	93,1	48	88,9	78,82	25,20
FU Month 6	Norm. K.	49	75,4	47	95,9	76,95	27,04	45	77,6	39	86,7	80,34	26,46
FU Month 9	Norm. K.	39	60,0	31	79,5	87,10	18,11	30	51,7	26	86,7	82,05	23,06
FU Month 12	Norm. K.	32	49,2	27	84,4	85,80	23,89	24	41,4	20	83,3	84,17	23,86
FU Month 15	Norm. K.	26	40,0	23	88,5	89,13	17,12	20	34,5	18	90,0	78,70	32,74
FU Month 18	Norm. K.	18	27,7	17	94,4	85,29	17,56	15	25,9	12	80,0	79,17	25,75
FU Month 21	Norm. K.	12	18,5	6	50,0	94,44	13,61	11	19,0	9	81,8	64,81	35,79
FU Month 24	Norm. K.	8	12,3	6	75,0	75,00	25,28	4	6,9	3	75,0	83,33	16,67
FU Month 27	Norm. K.	3	4,6	3	100,0	100,00	0,00	1	1,7	1	100,0	100,00	NE
Screening	Other Abn.	20	100,0	18	90,0	83,33	27,42	22	100,0	20	90,9	84,17	23,24

Cycle 4 Day 1	Other Abn.	18	90,0	16	88,9	80,21	29,32	22	100,0	19	86,4	88,60	15,77
FU Day 28	Other Abn.	18	90,0	14	77,8	77,38	29,68	21	95,5	17	81,0	82,35	27,93
FU Month 3	Other Abn.	18	90,0	14	77,8	83,33	27,74	21	95,5	18	85,7	87,04	19,43
FU Month 6	Other Abn.	17	85,0	12	70,6	81,94	26,07	18	81,8	17	94,4	90,20	13,25
FU Month 9	Other Abn.	15	75,0	10	66,7	78,33	29,45	14	63,6	13	92,9	89,74	14,50
FU Month 12	Other Abn.	7	35,0	6	85,7	75,00	32,91	12	54,5	8	66,7	95,83	11,79
FU Month 15	Other Abn.	5	25,0	4	80,0	91,67	16,67	5	22,7	4	80,0	91,67	16,67
FU Month 18	Other Abn.	3	15,0	3	100,0	88,89	19,25	3	13,6	2	66,7	100,00	0,00
FU Month 21	Other Abn.	2	10,0	2	100,0	100,00	0,00	2	9,1	2	100,0	100,00	0,00
FU Month 24	Other Abn.	2	10,0	2	100,0	100,00	0,00	0	NE	0	NE	NE	NE
Time from first diagnosis													
Screening	Missing	1	100,0	1	100,0	83,33	NE	0	NE	0	NE	NE	NE
Cycle 4 Day 1	Missing	1	100,0	1	100,0	83,33	NE	0	NE	0	NE	NE	NE
FU Day 28	Missing	1	100,0	1	100,0	100,00	NE	0	NE	0	NE	NE	NE
FU Month 3	Missing	1	100,0	1	100,0	100,00	NE	0	NE	0	NE	NE	NE
FU Month 6	Missing	1	100,0	1	100,0	100,00	NE	0	NE	0	NE	NE	NE
FU Month 9	Missing	1	100,0	1	100,0	100,00	NE	0	NE	0	NE	NE	NE
FU Month 12	Missing	1	100,0	1	100,0	100,00	NE	0	NE	0	NE	NE	NE
FU Month 15	Missing	1	100,0	1	100,0	100,00	NE	0	NE	0	NE	NE	NE
FU Month 18	Missing	1	100,0	1	100,0	100,00	NE	0	NE	0	NE	NE	NE
Screening	13 - 24 months	41	100,0	39	95,1	80,34	28,06	31	100,0	31	100,0	91,40	18,69
Cycle 4 Day 1	13 - 24 months	35	85,4	34	97,1	81,86	25,08	30	96,8	27	90,0	93,83	12,36
FU Day 28	13 - 24 months	38	92,7	33	86,8	77,78	27,85	30	96,8	27	90,0	95,06	15,20
FU Month 3	13 - 24 months	36	87,8	34	94,4	86,76	24,88	30	96,8	26	86,7	88,46	20,96
FU Month 6	13 - 24 months	36	87,8	33	91,7	86,87	19,44	30	96,8	25	83,3	92,00	14,53
FU Month 9	13 - 24 months	32	78,0	29	90,6	94,83	10,06	21	67,7	17	81,0	95,10	11,43
FU Month 12	13 - 24 months	21	51,2	18	85,7	89,81	18,20	16	51,6	14	87,5	94,05	12,42
FU Month 15	13 - 24 months	19	46,3	18	94,7	89,81	18,20	16	51,6	10	62,5	95,00	8,05
FU Month 18	13 - 24 months	14	34,1	13	92,9	85,90	19,06	10	32,3	8	80,0	100,00	0,00
FU Month 21	13 - 24 months	11	26,8	9	81,8	75,93	27,78	6	19,4	4	66,7	91,67	16,67
FU Month 24	13 - 24 months	8	19,5	5	62,5	60,00	19,00	3	9,7	2	66,7	100,00	0,00
FU Month 27	13 - 24 months	5	12,2	5	100,0	80,00	21,73	2	6,5	2	100,0	100,00	0,00
FU Month 30	13 - 24 months	3	7,3	3	100,0	66,67	33,33	1	3,2	1	100,0	100,00	NE
Screening	<= 12 months	60	100,0	57	95,0	86,55	22,59	70	100,0	69	98,6	83,57	21,29
Cycle 4 Day 1	<= 12 months	48	80,0	42	87,5	92,06	13,39	60	85,7	55	91,7	84,24	21,85
FU Day 28	<= 12 months	54	90,0	45	83,3	83,33	26,35	62	88,6	56	90,3	86,31	20,13
FU Month 3	<= 12 months	53	88,3	45	84,9	86,30	27,36	59	84,3	55	93,2	82,73	22,90
FU Month 6	<= 12 months	46	76,7	40	87,0	86,67	22,71	47	67,1	42	89,4	87,70	20,18

FU Month 9	<= 12 months	35	58,3	27	77,1	83,95	24,67	37	52,9	30	81,1	90,56	15,59
FU Month 12	<= 12 months	27	45,0	23	85,2	85,51	22,64	29	41,4	27	93,1	86,42	20,69
FU Month 15	<= 12 months	22	36,7	17	77,3	84,31	24,63	17	24,3	16	94,1	90,63	13,57
FU Month 18	<= 12 months	16	26,7	13	81,3	91,03	17,50	13	18,6	12	92,3	87,50	17,59
FU Month 21	<= 12 months	9	15,0	5	55,6	100,00	0,00	7	10,0	6	85,7	75,00	20,41
FU Month 24	<= 12 months	6	10,0	3	50,0	94,44	9,62	2	2,9	1	50,0	100,00	NE
FU Month 27	<= 12 months	1	1,7			NE	NE	1	1,4			NE	NE
FU Month 30	<= 12 months	1	1,7			NE	NE	0	NE			NE	NE
Screening	>24 months	153	100,0	144	94,1	85,30	24,74	141	100,0	127	90,1	80,84	26,81
Cycle 4 Day 1	>24 months	129	84,3	119	92,2	86,83	20,68	134	95,0	114	85,1	81,87	23,63
FU Day 28	>24 months	137	89,5	122	89,1	85,38	22,53	133	94,3	118	88,7	83,05	23,06
FU Month 3	>24 months	135	88,2	123	91,1	86,04	22,72	132	93,6	114	86,4	82,02	21,97
FU Month 6	>24 months	124	81,0	114	91,9	85,09	23,82	115	81,6	100	87,0	82,50	23,26
FU Month 9	>24 months	96	62,7	81	84,4	87,04	21,57	91	64,5	71	78,0	81,92	22,14
FU Month 12	>24 months	76	49,7	67	88,2	86,82	22,20	72	51,1	57	79,2	81,58	24,33
FU Month 15	>24 months	62	40,5	55	88,7	90,00	18,59	52	36,9	43	82,7	78,29	29,67
FU Month 18	>24 months	48	31,4	42	87,5	88,10	18,87	37	26,2	29	78,4	75,86	31,68
FU Month 21	>24 months	32	20,9	26	81,3	89,10	17,60	27	19,1	22	81,5	79,55	28,14
FU Month 24	>24 months	18	11,8	17	94,4	84,31	26,00	13	9,2	13	100,0	79,49	33,44
FU Month 27	>24 months	7	4,6	6	85,7	88,89	27,22	6	4,3	5	83,3	86,67	29,81
FU Month 30	>24 months	3	2,0	3	100,0	77,78	38,49	0	NE	0	NE	NE	NE
High circulating tumor burden													
Screening	Missing	0	NE	0	NE	NE	NE	2	100,0	1	50,0	83,33	NE
Cycle 4 Day 1	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	83,33	NE
FU Day 28	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	100,00	NE
FU Month 3	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	83,33	NE
FU Month 6	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	66,67	NE
FU Month 9	Missing	0	NE			NE	NE	1	50,0			NE	NE
Screening	<25x10**9 cells/L	60	100,0	55	91,7	80,30	27,98	67	100,0	64	95,5	80,21	24,10
Cycle 4 Day 1	<25x10**9 cells/L	50	83,3	45	90,0	88,52	20,67	61	91,0	52	85,2	83,33	22,63
FU Day 28	<25x10**9 cells/L	56	93,3	47	83,9	82,62	27,35	61	91,0	53	86,9	82,39	27,62
FU Month 3	<25x10**9 cells/L	54	90,0	47	87,0	85,82	23,82	59	88,1	50	84,7	84,33	21,93
FU Month 6	<25x10**9 cells/L	50	83,3	44	88,0	86,74	22,33	51	76,1	41	80,4	86,99	22,21
FU Month 9	<25x10**9 cells/L	36	60,0	27	75,0	89,51	20,23	41	61,2	29	70,7	91,38	13,82
FU Month 12	<25x10**9 cells/L	29	48,3	24	82,8	86,11	22,88	34	50,7	25	73,5	85,33	22,22
FU Month 15	<25x10**9 cells/L	24	40,0	20	83,3	90,83	15,74	23	34,3	15	65,2	90,00	20,70
FU Month 18	<25x10**9 cells/L	20	33,3	18	90,0	93,52	12,96	19	28,4	14	73,7	86,90	29,37
FU Month 21	<25x10**9 cells/L	14	23,3	10	71,4	85,00	22,84	10	14,9	8	80,0	91,67	15,43

FU Month 24	<25x10**9 cells/L	8	13,3	5	62,5	80,00	21,73	6	9,0	5	83,3	73,33	43,46
FU Month 27	<25x10**9 cells/L	4	6,7	3	75,0	72,22	25,46	1	1,5	1	100,0	100,00	NE
FU Month 30	<25x10**9 cells/L	4	6,7	3	75,0	66,67	33,33	1	1,5	1	100,0	100,00	NE
Screening	>=25x10**9 cells/L	195	100,0	186	95,4	86,11	23,63	173	100,0	162	93,6	84,26	24,59
Cycle 4 Day 1	>=25x10**9 cells/L	163	83,6	151	92,6	86,64	20,28	162	93,6	143	88,3	84,50	22,17
FU Day 28	>=25x10**9 cells/L	174	89,2	154	88,5	84,09	23,44	163	94,2	147	90,2	86,62	19,08
FU Month 3	>=25x10**9 cells/L	171	87,7	156	91,2	86,43	24,16	161	93,1	144	89,4	82,64	22,29
FU Month 6	>=25x10**9 cells/L	157	80,5	144	91,7	85,53	22,92	140	80,9	125	89,3	84,80	21,48
FU Month 9	>=25x10**9 cells/L	128	65,6	111	86,7	87,84	20,71	107	61,8	89	83,2	84,27	21,37
FU Month 12	>=25x10**9 cells/L	96	49,2	85	88,5	87,45	21,19	83	48,0	73	88,0	84,47	22,45
FU Month 15	>=25x10**9 cells/L	80	41,0	71	88,8	88,50	20,62	62	35,8	54	87,1	81,79	26,36
FU Month 18	>=25x10**9 cells/L	59	30,3	51	86,4	86,60	19,73	41	23,7	35	85,4	80,95	26,55
FU Month 21	>=25x10**9 cells/L	38	19,5	30	78,9	88,33	19,65	30	17,3	24	80,0	76,39	27,33
FU Month 24	>=25x10**9 cells/L	24	12,3	20	83,3	80,83	26,64	12	6,9	11	91,7	87,88	24,82
FU Month 27	>=25x10**9 cells/L	9	4,6	8	88,9	89,58	23,46	8	4,6	6	75,0	88,89	27,22
FU Month 30	>=25x10**9 cells/L	3	1,5	3	100,0	77,78	38,49	0	NE	0	NE	NE	NE

¹ in study: number of subjects in study at respective visit; % based on baseline

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit

² mean: descriptive statistics - absolute values Clinical

cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/t_pro_mean.sas

Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/t_pro_mean_sg_EQC30_IT_label_09MAY2013_21004.xls 04MAR2020

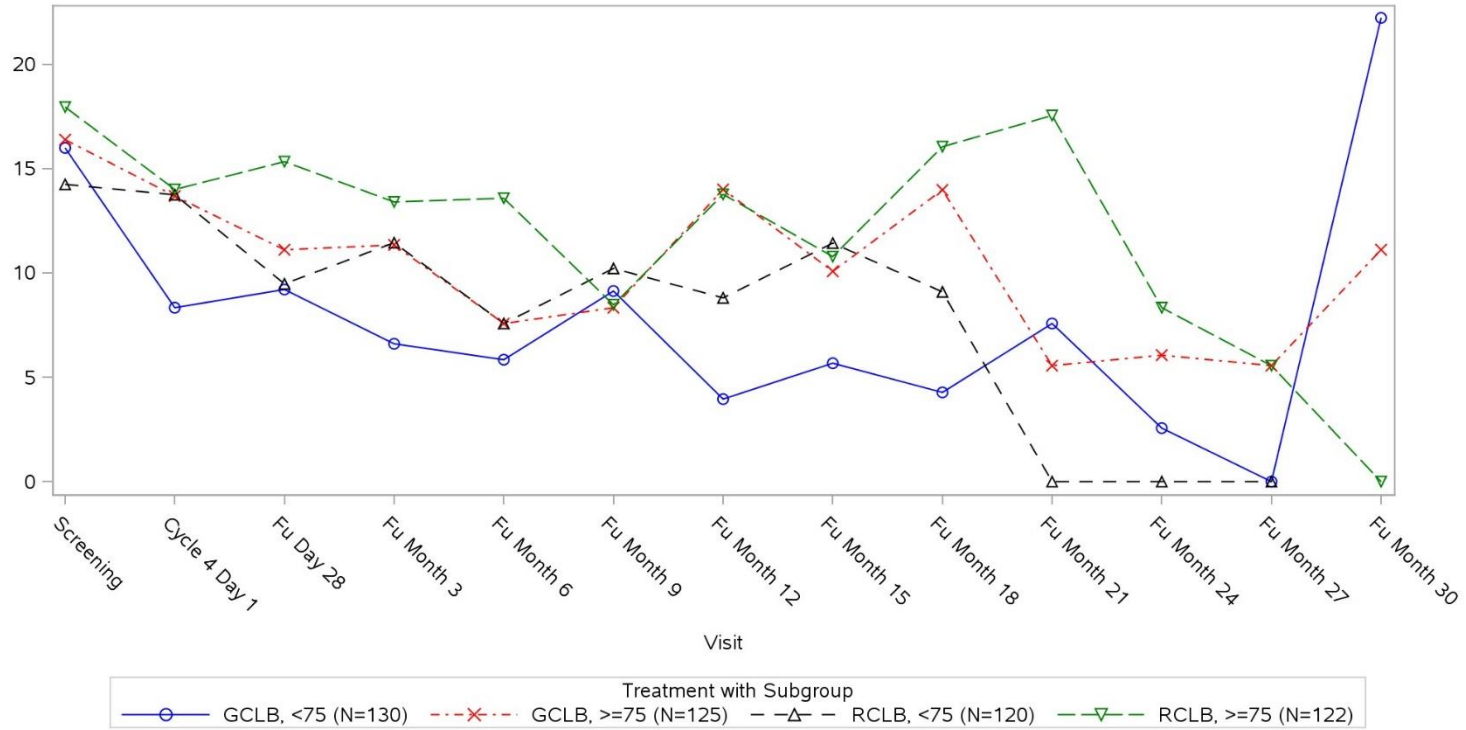
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Age (N=497) Laboratory Test: Appetite Loss Scale



Clinical cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/g_pro_mean.sas
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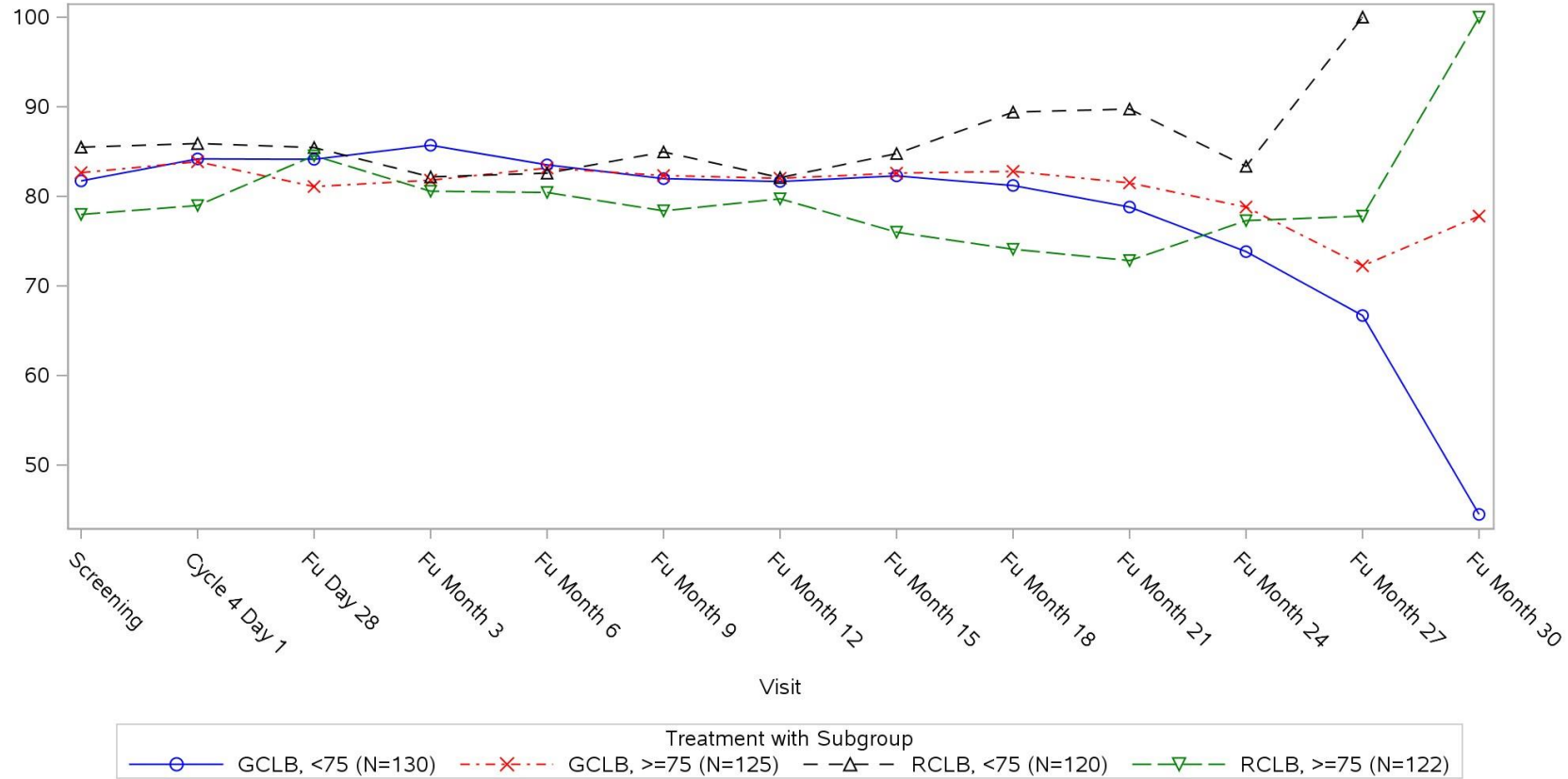
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Age (N=497) Laboratory Test: Cognitive Functioning Scale



Clinical cut-off: 09MAY2013

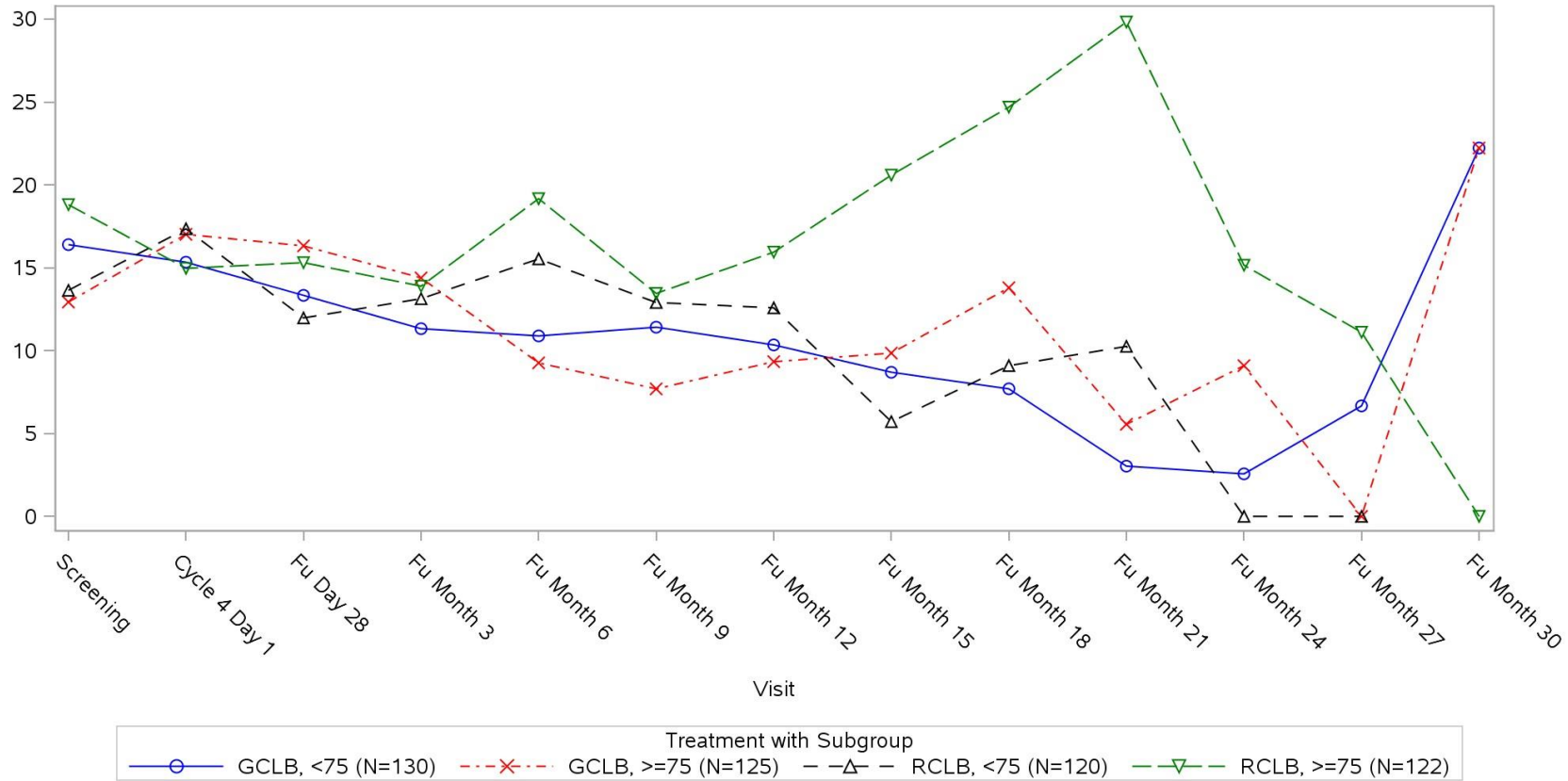
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Age (N=497) Laboratory Test: Constipation Scale



Clinical cut-off: 09MAY2013

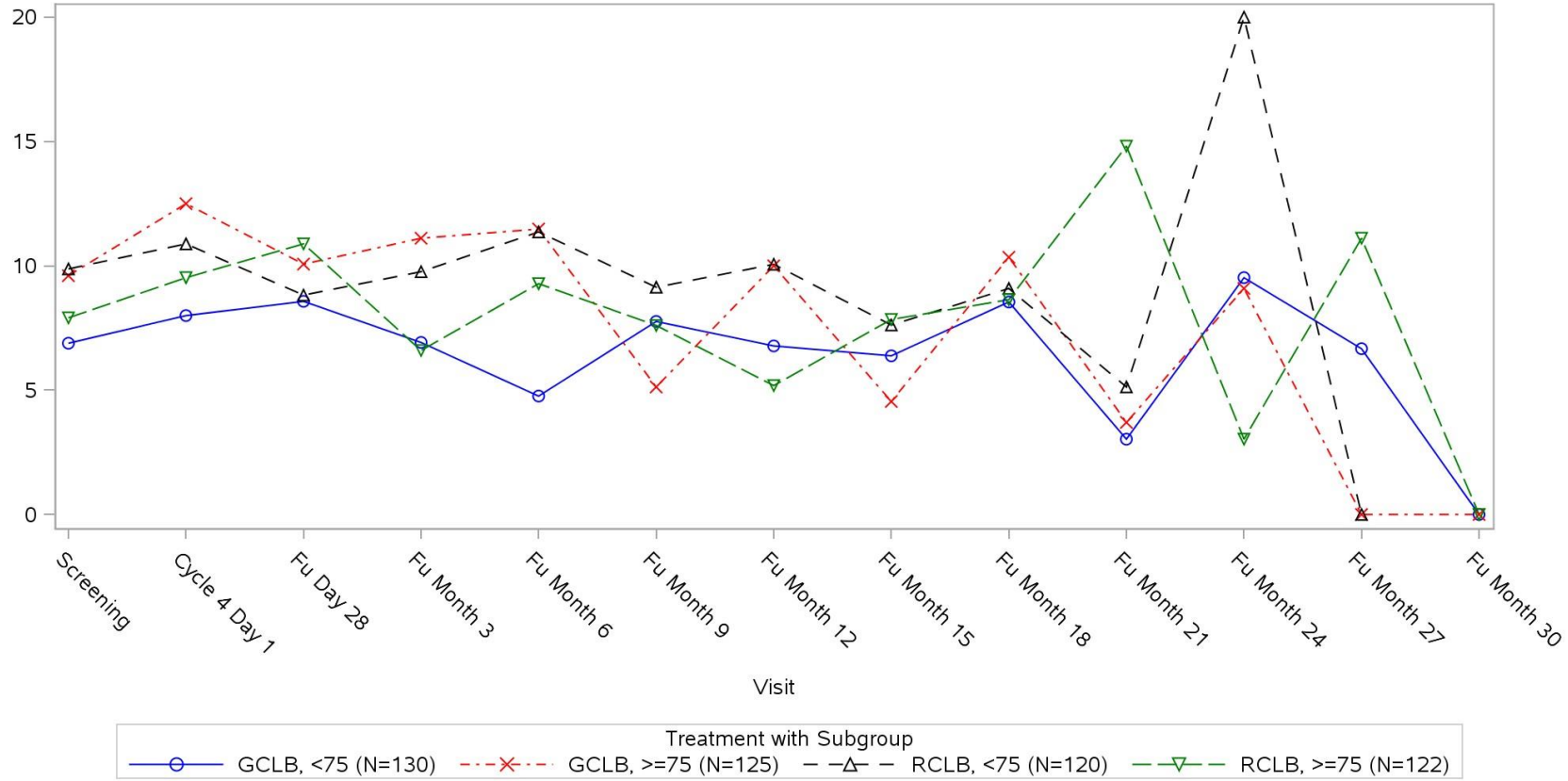
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Age (N=497) Laboratory Test: Diarrhoea Scale



Clinical cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/g_pro_mean.sas
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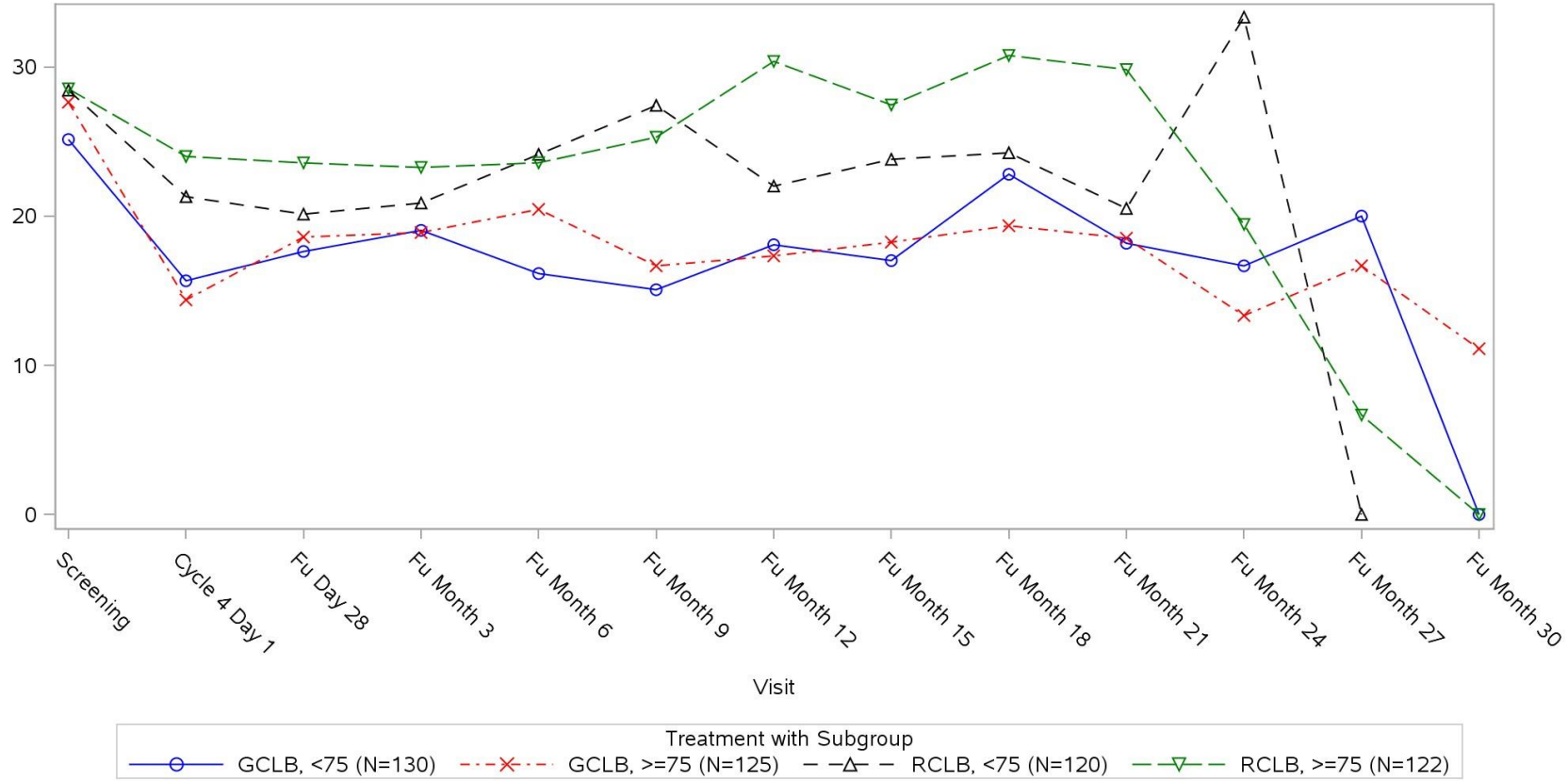
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Age (N=497) Laboratory Test: Dyspnoea Scale



Clinical cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/g_pro_mean.sas
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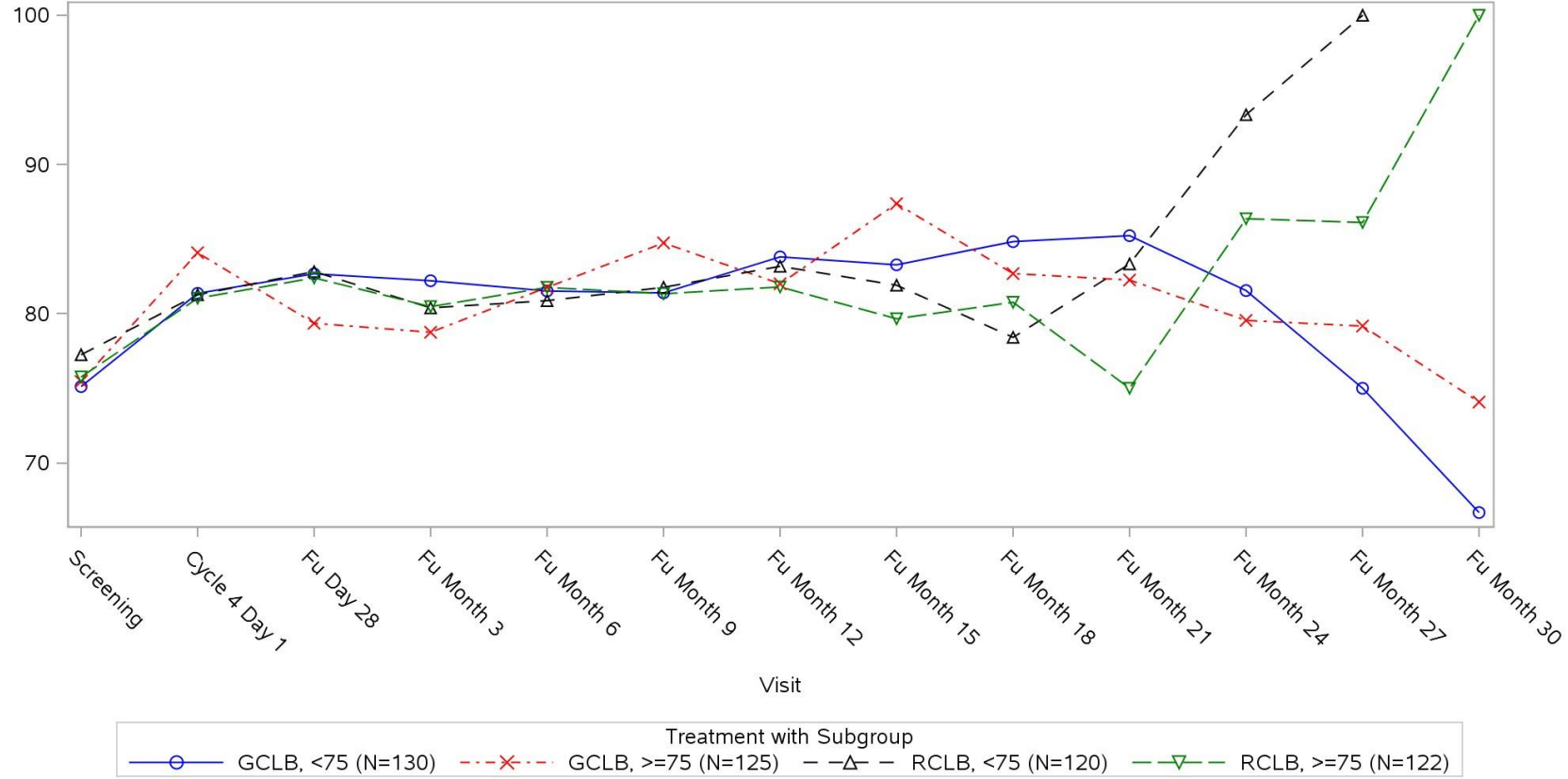
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Age (N=497) Laboratory Test: Emotional Functioning Scale



Clinical cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/g_pro_mean.sas
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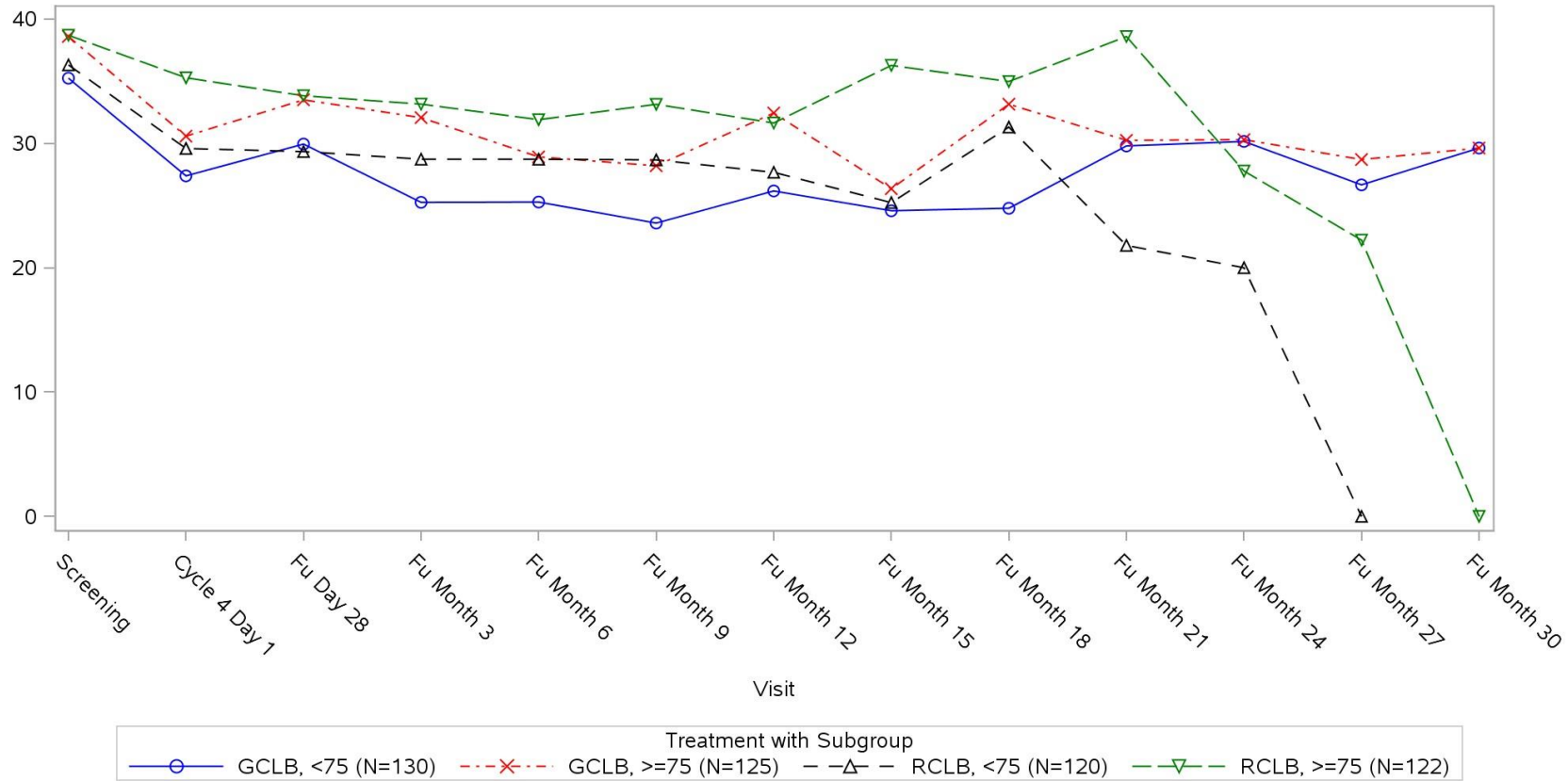
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Age (N=497) Laboratory Test: Fatigue Scale



Clinical cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/g_pro_mean.sas
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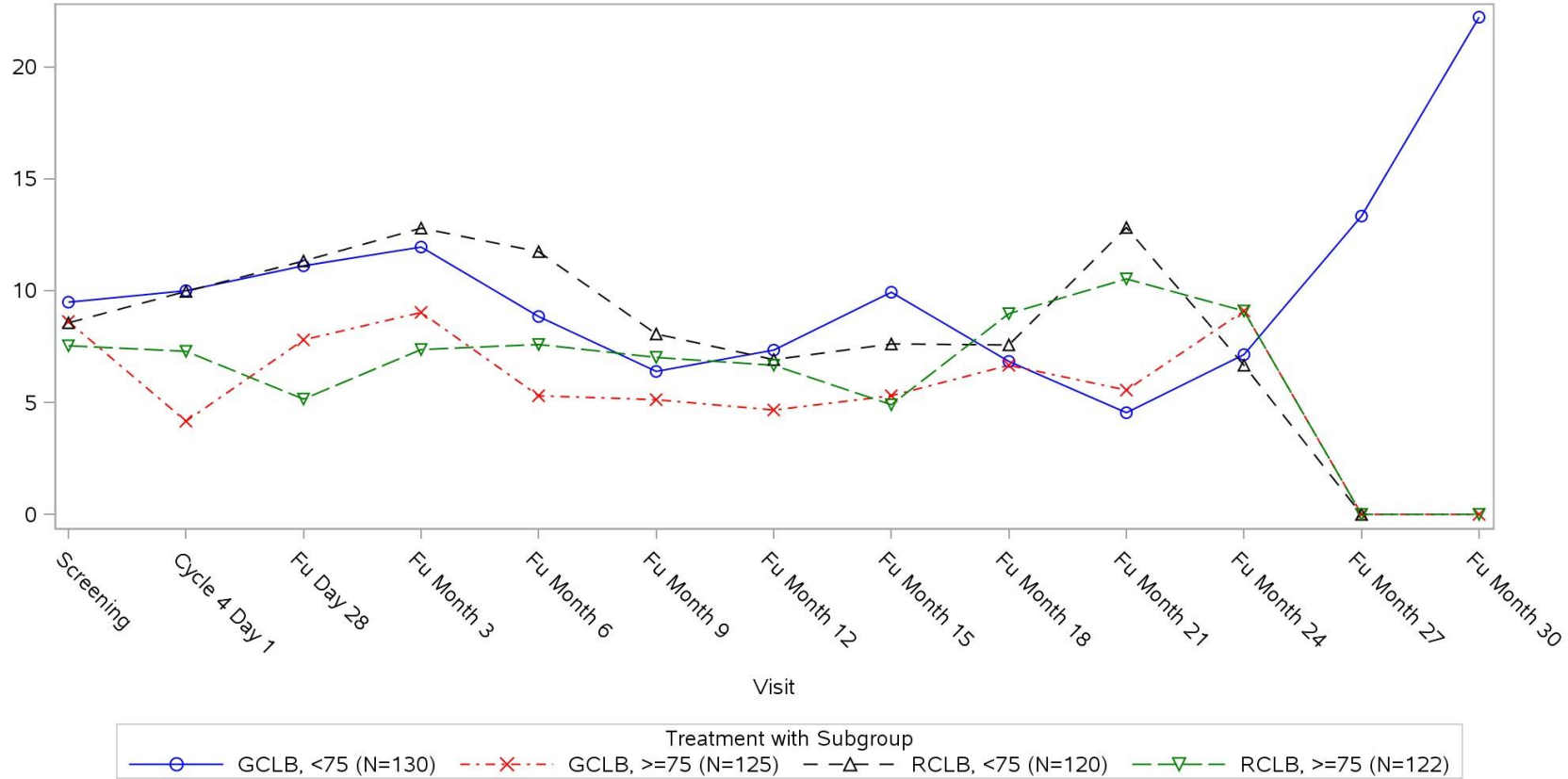
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Age (N=497) Laboratory Test: Financial Difficulties Scale



Clinical cut-off: 09MAY2013

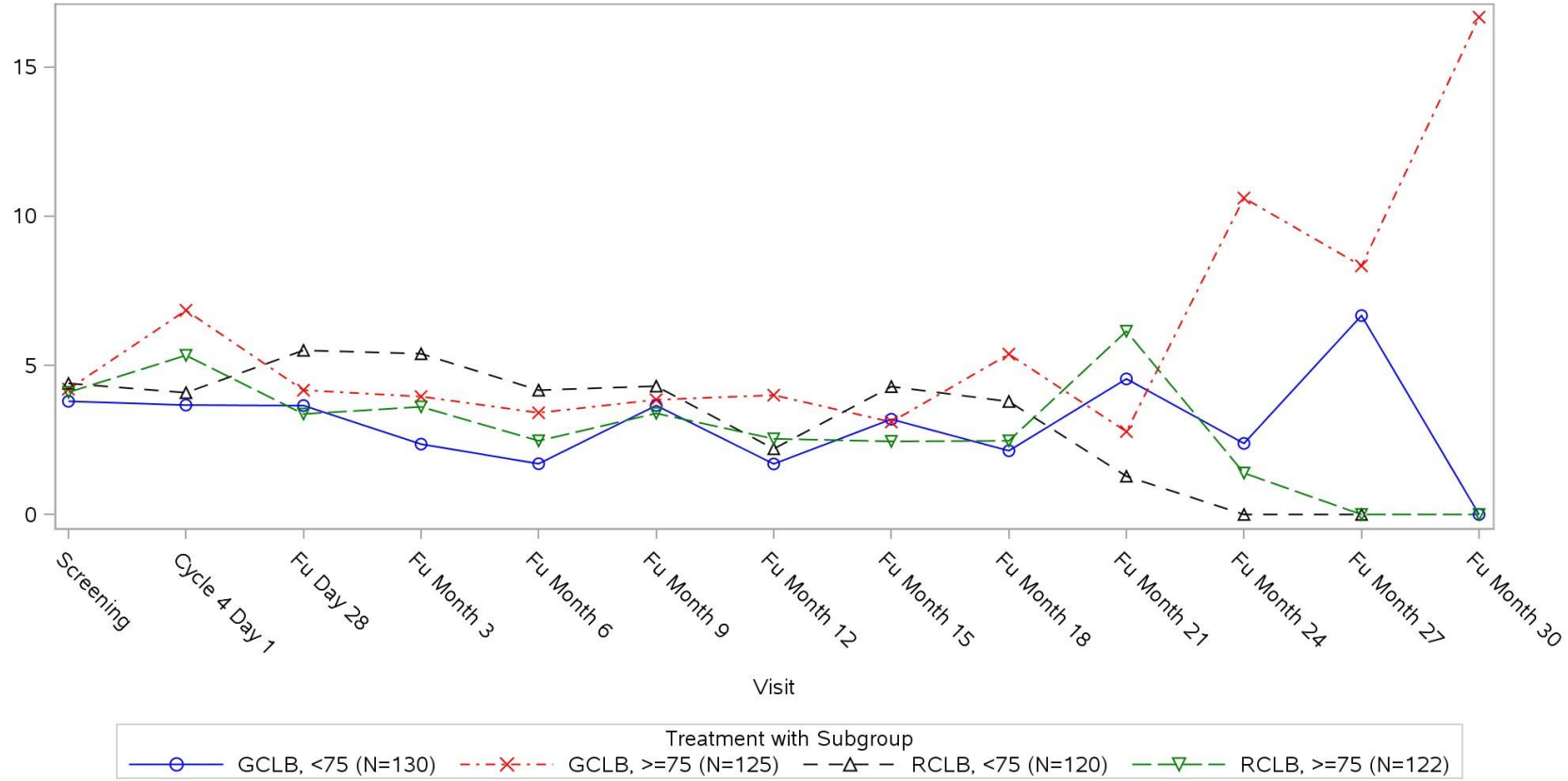
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Age (N=497) Laboratory Test: Nausia And Vomiting Scale



Clinical cut-off: 09MAY2013

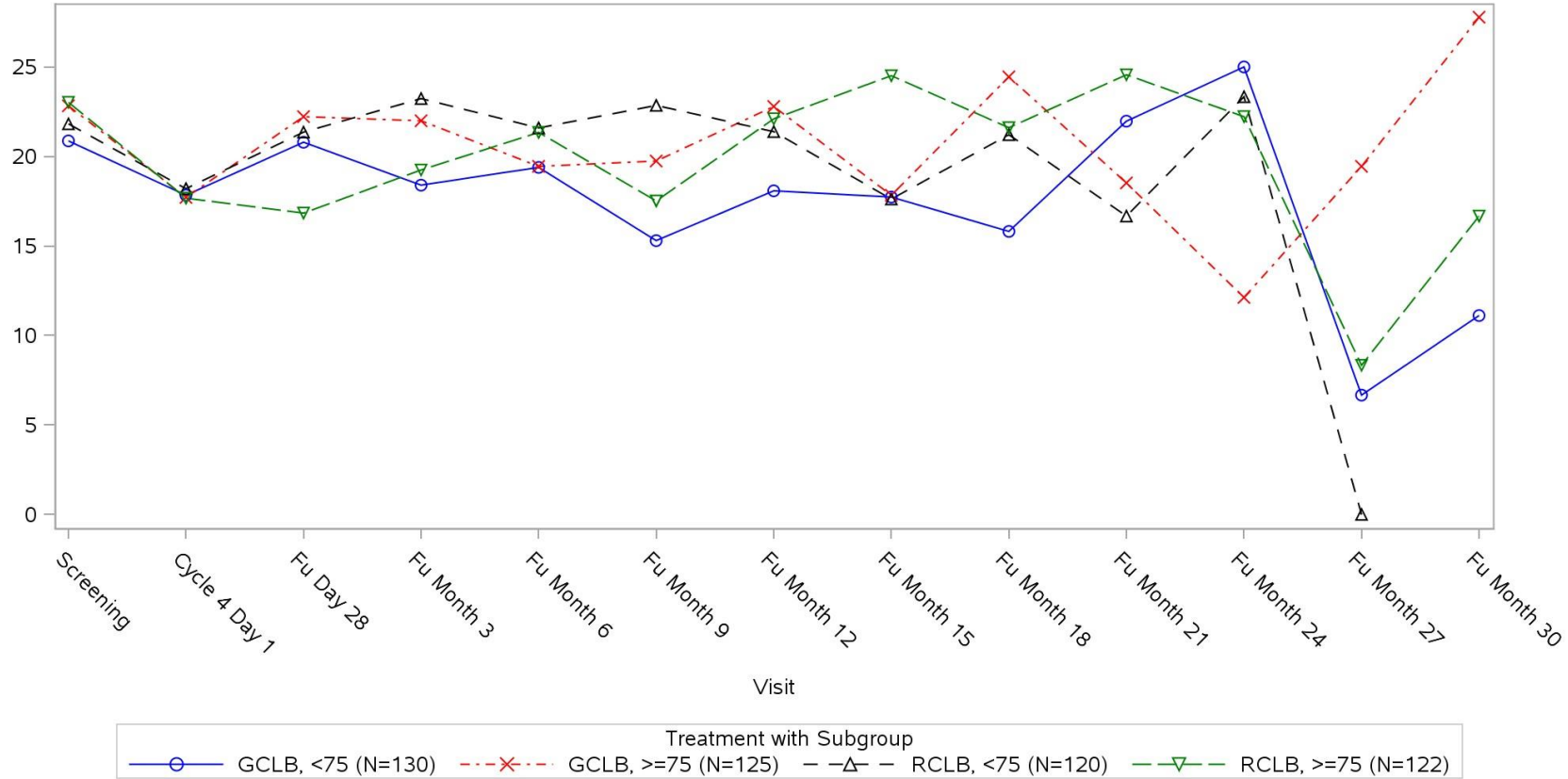
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Age (N=497) Laboratory Test: Pain Scale



Clinical cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/g_pro_mean.sas
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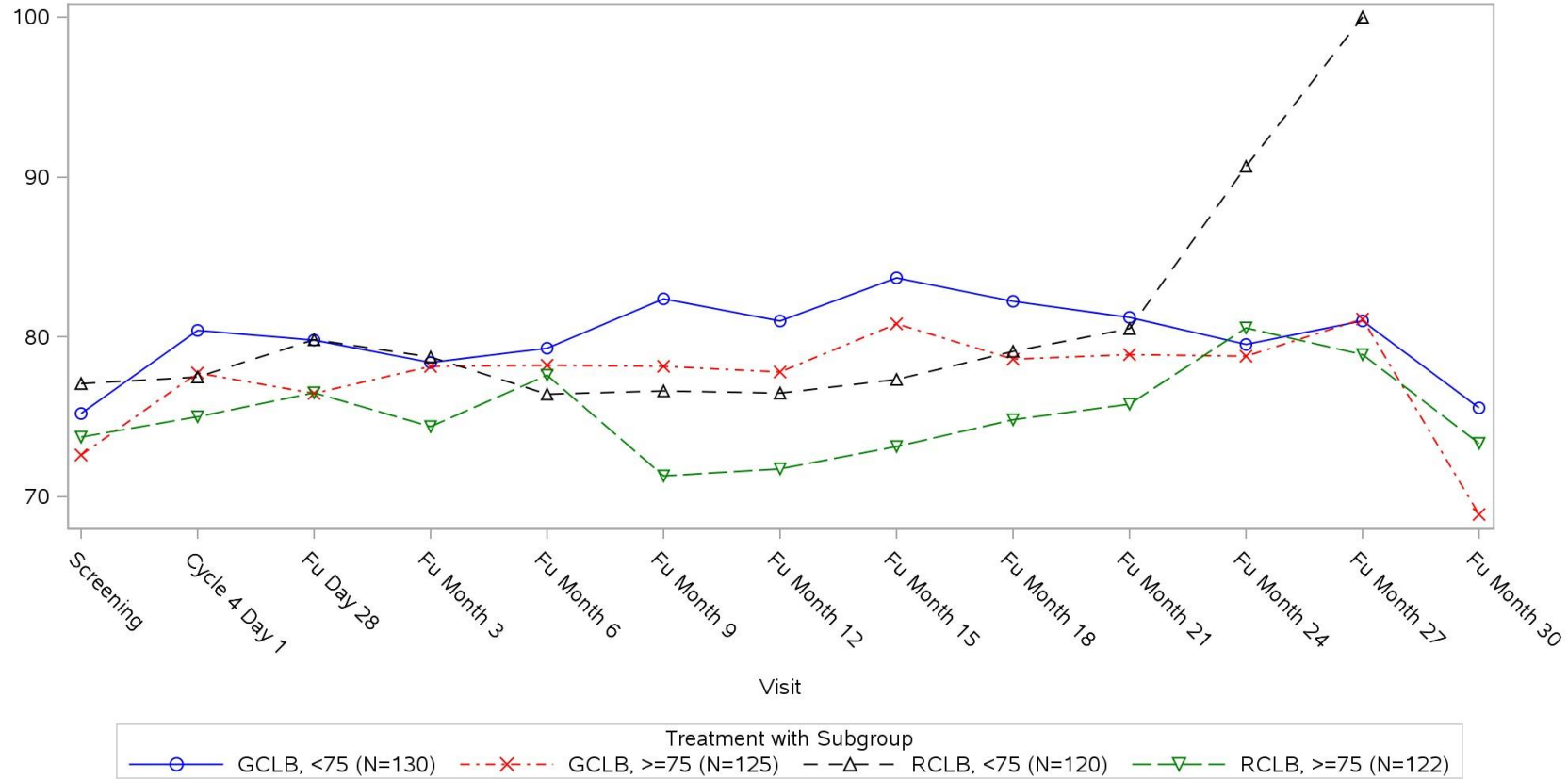
Page 10 of 195

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Age (N=497) Laboratory Test: Physical Functioning Scale



Clinical cut-off: 09MAY2013

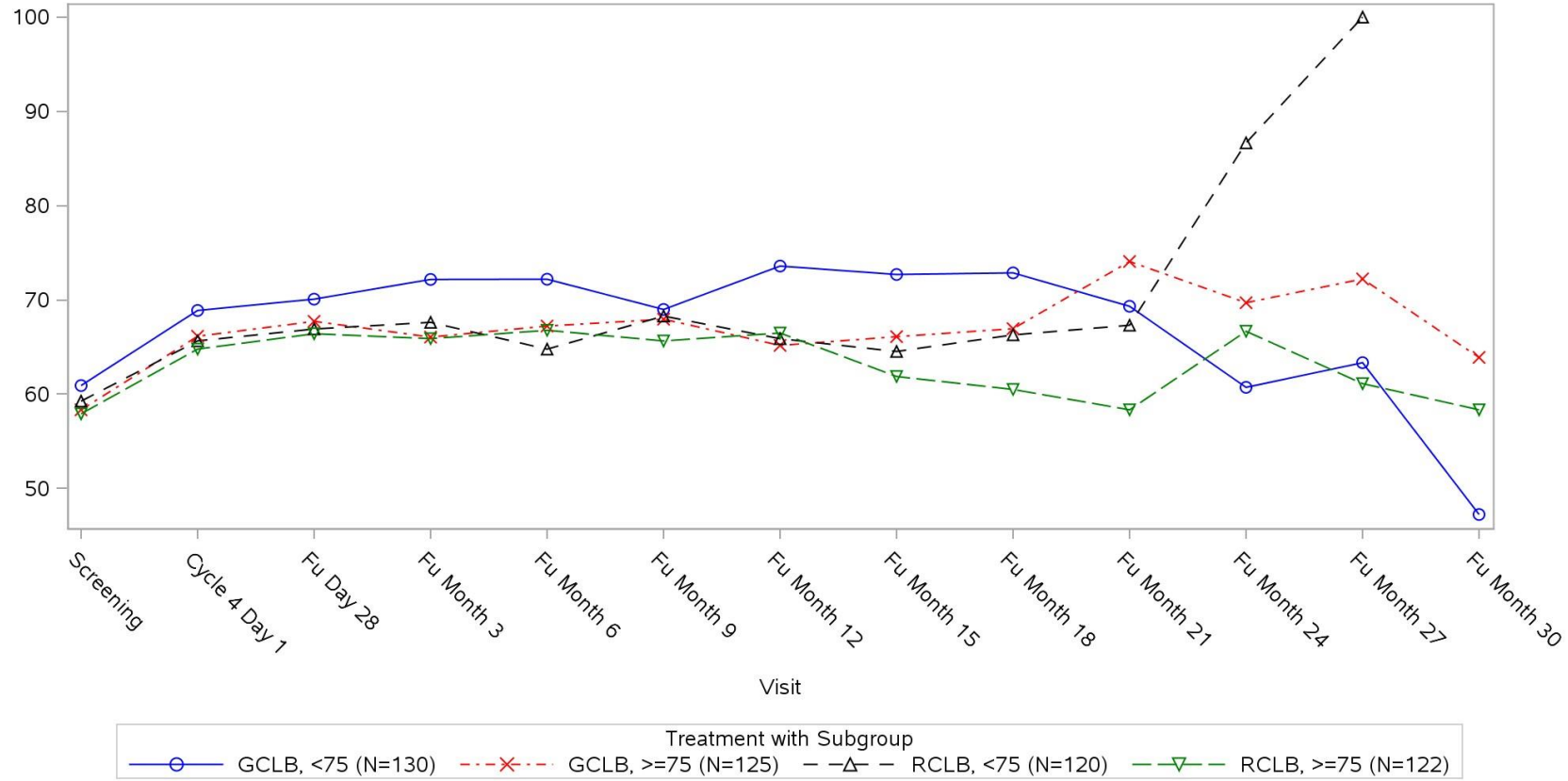
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Age (N=497) Laboratory Test: Global Health Status Scale



Clinical cut-off: 09MAY2013

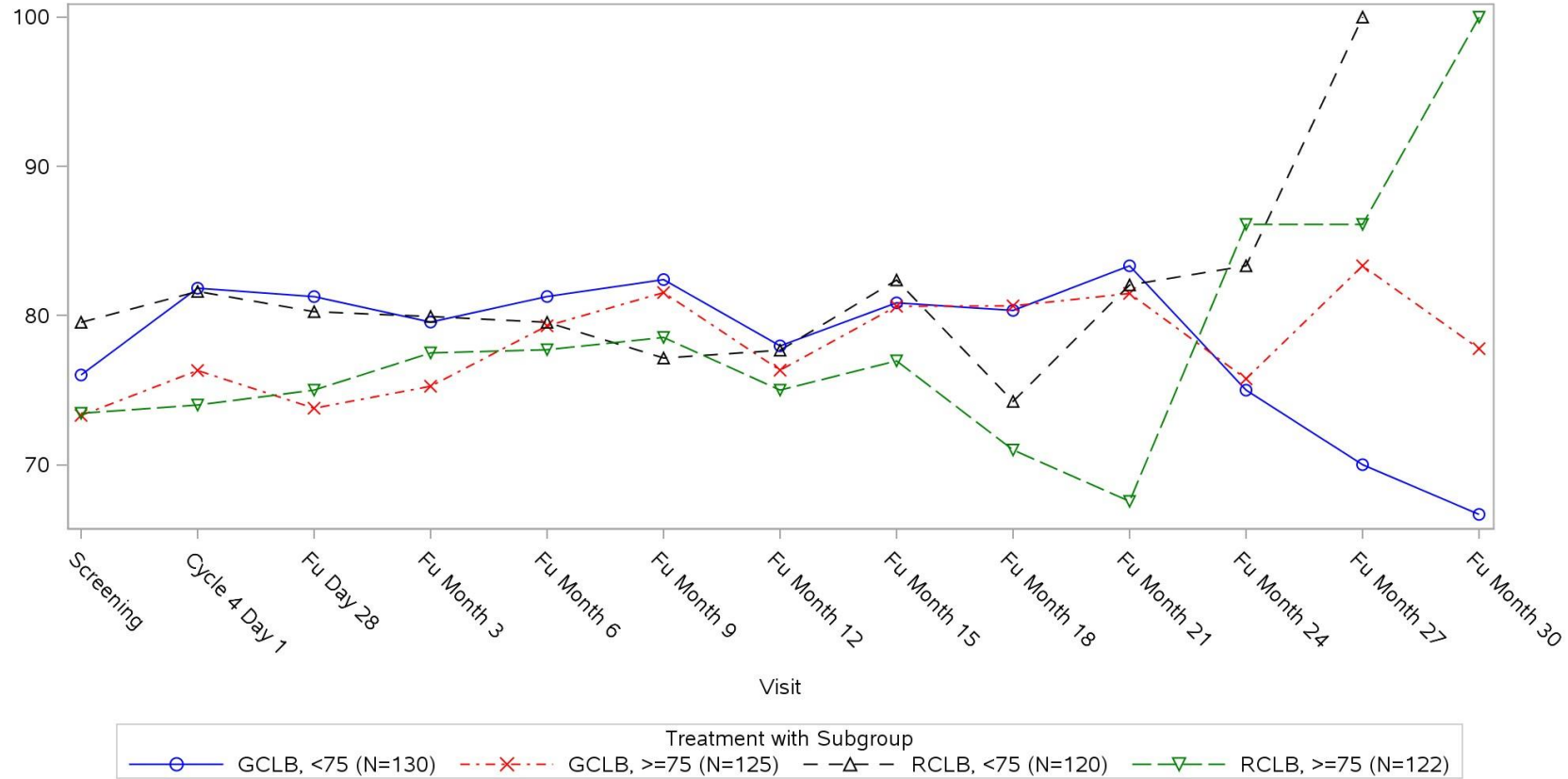
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04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Age (N=497) Laboratory Test: Role Functioning Scale



Clinical cut-off: 09MAY2013

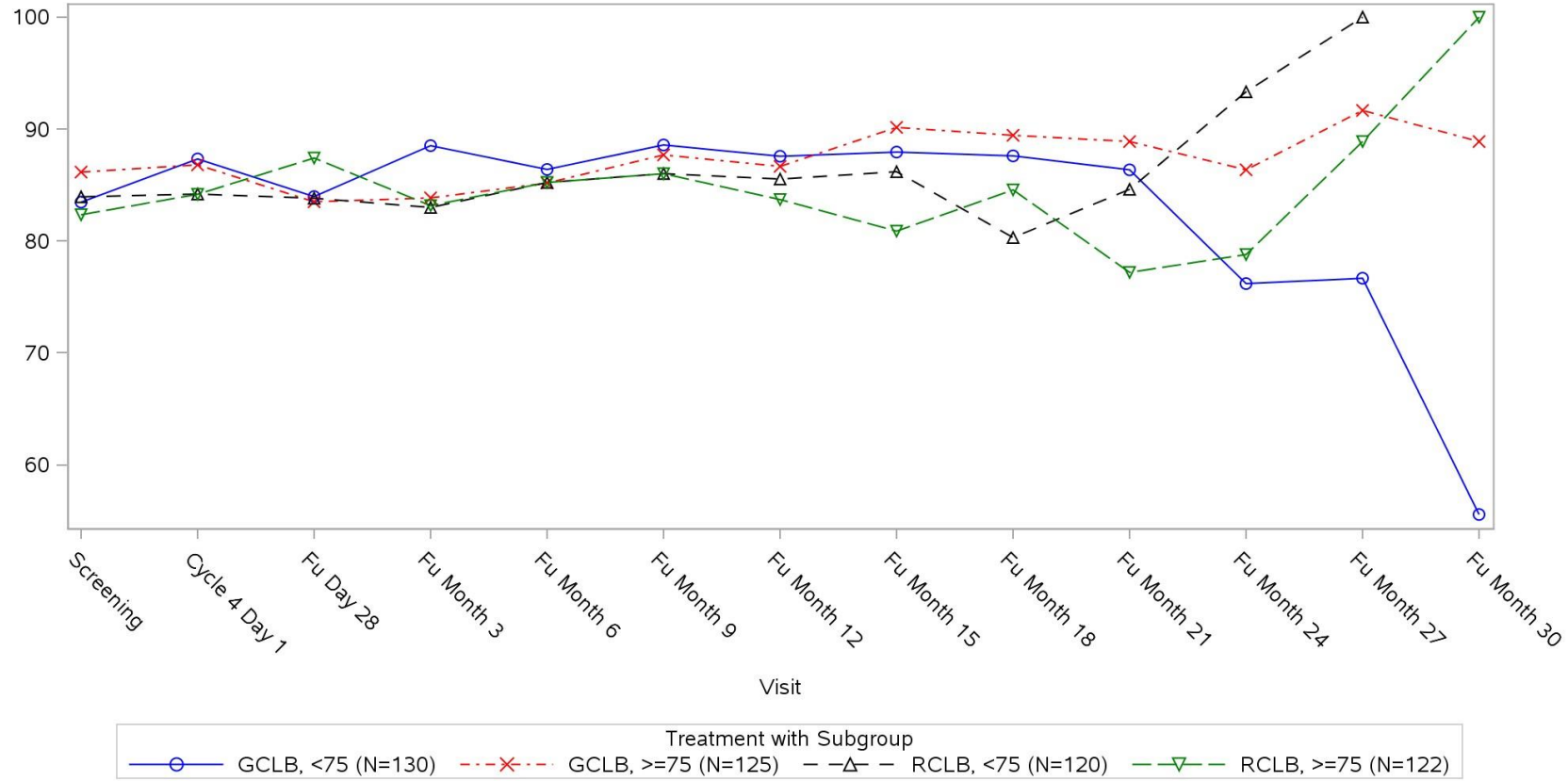
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 04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Age (N=497) Laboratory Test: Social Functioning Scale



Clinical cut-off: 09MAY2013

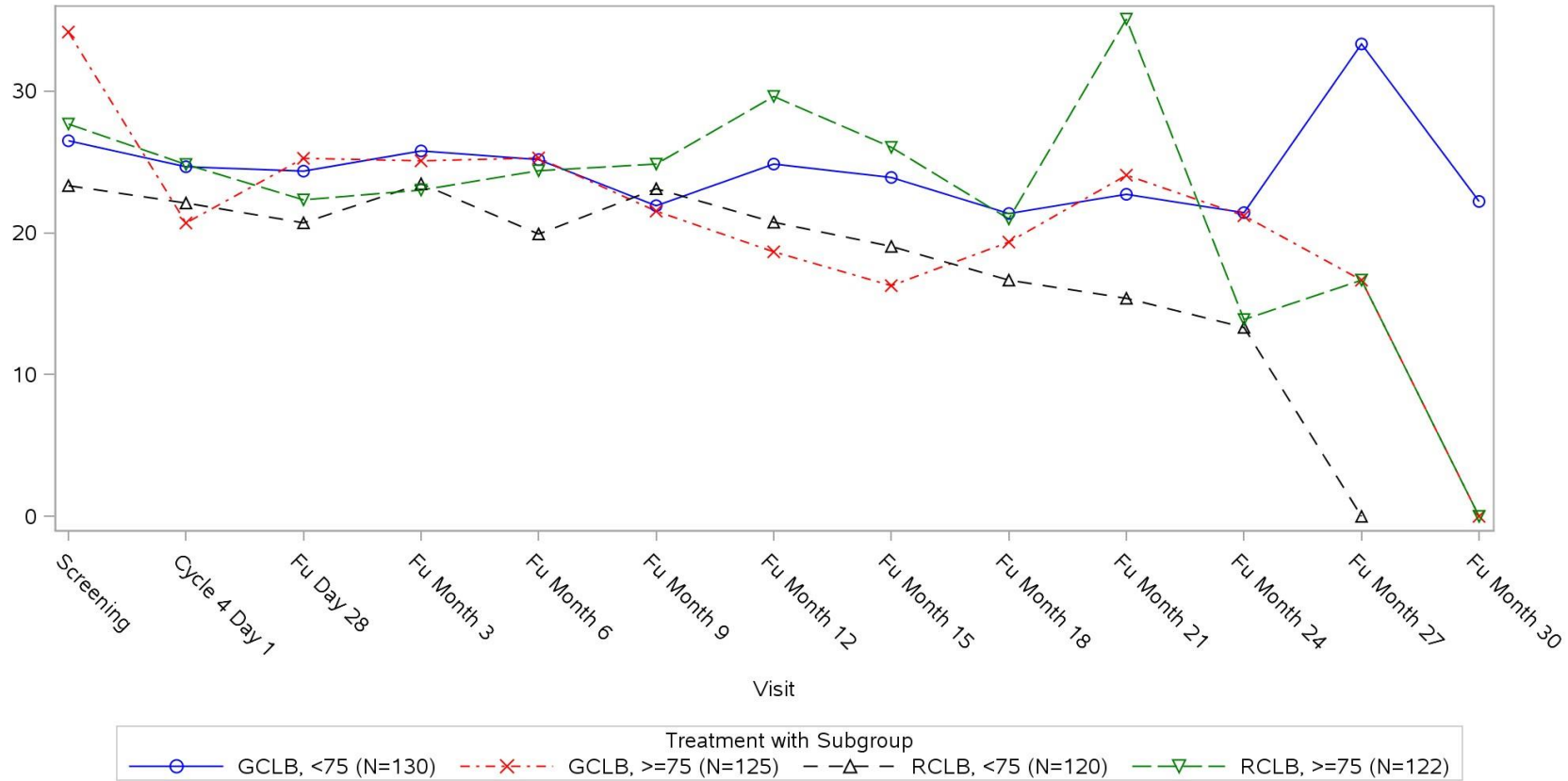
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 04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Age (N=497) Laboratory Test: Insomnia Scale



Clinical cut-off: 09MAY2013

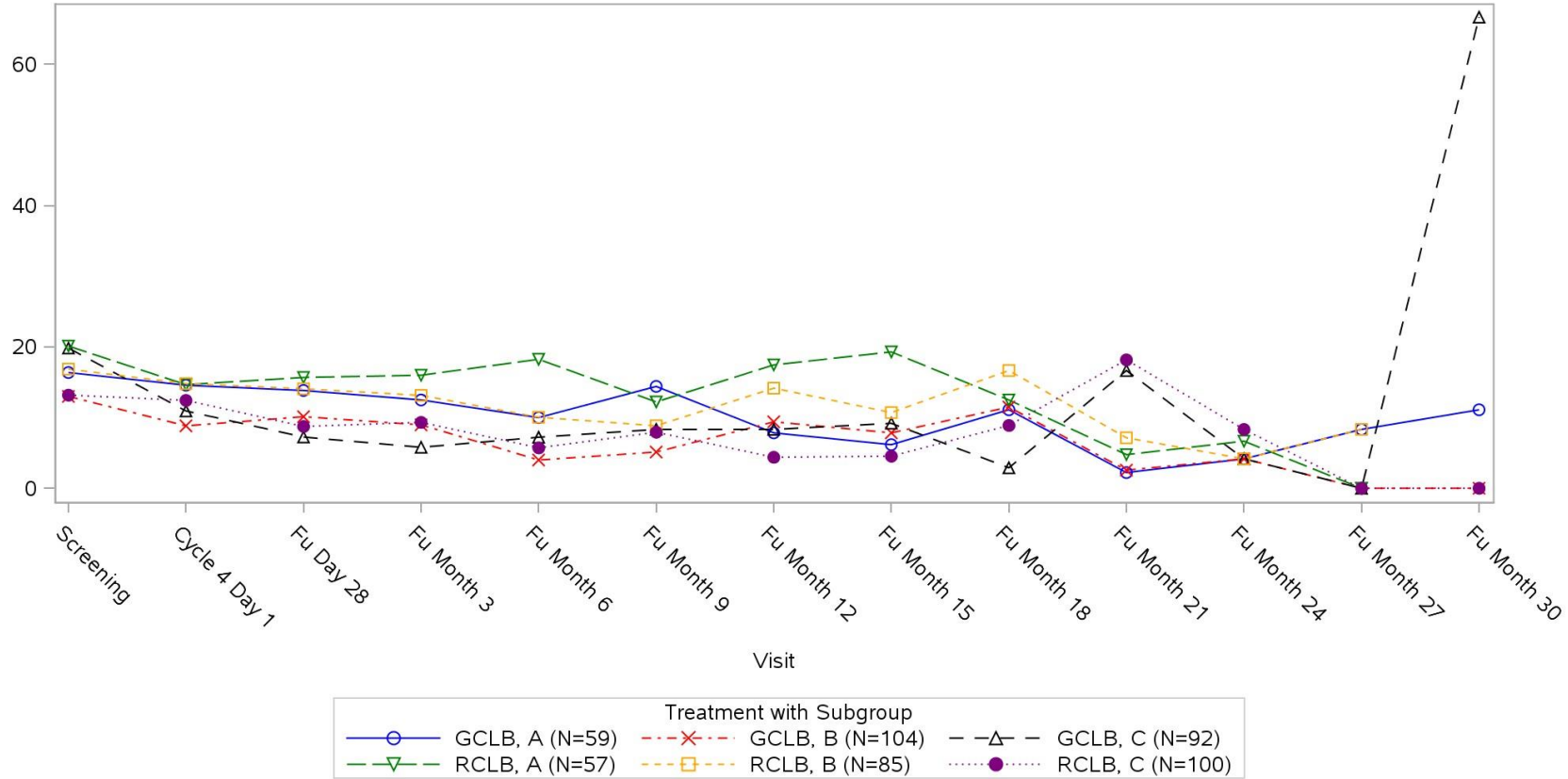
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04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Binet Staging at baseline (N=497) Laboratory Test: Appetite Loss Scale



Clinical cut-off: 09MAY2013

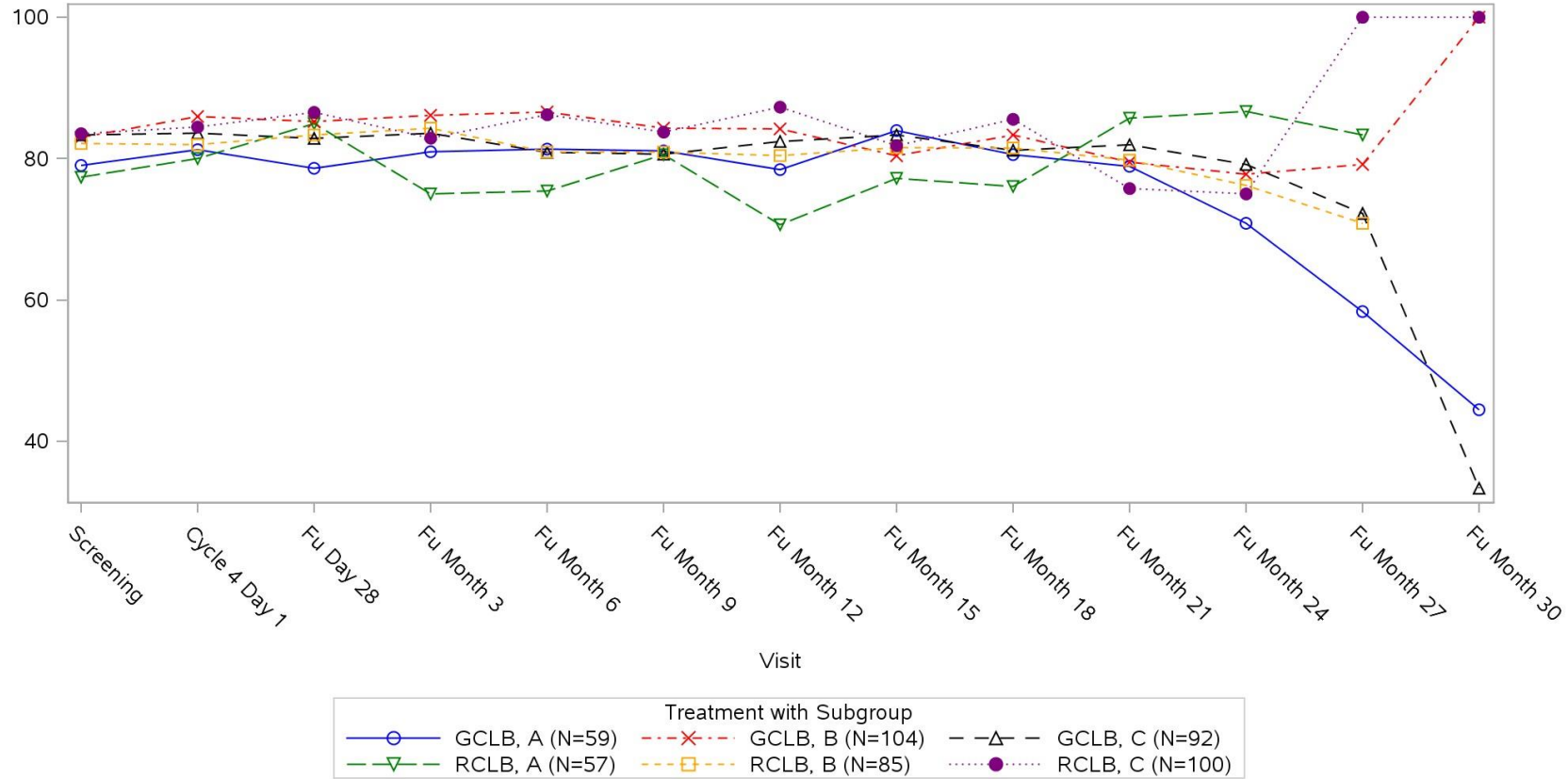
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Binet Staging at baseline (N=497) Laboratory Test: Cognitive Functioning Scale



Clinical cut-off: 09MAY2013

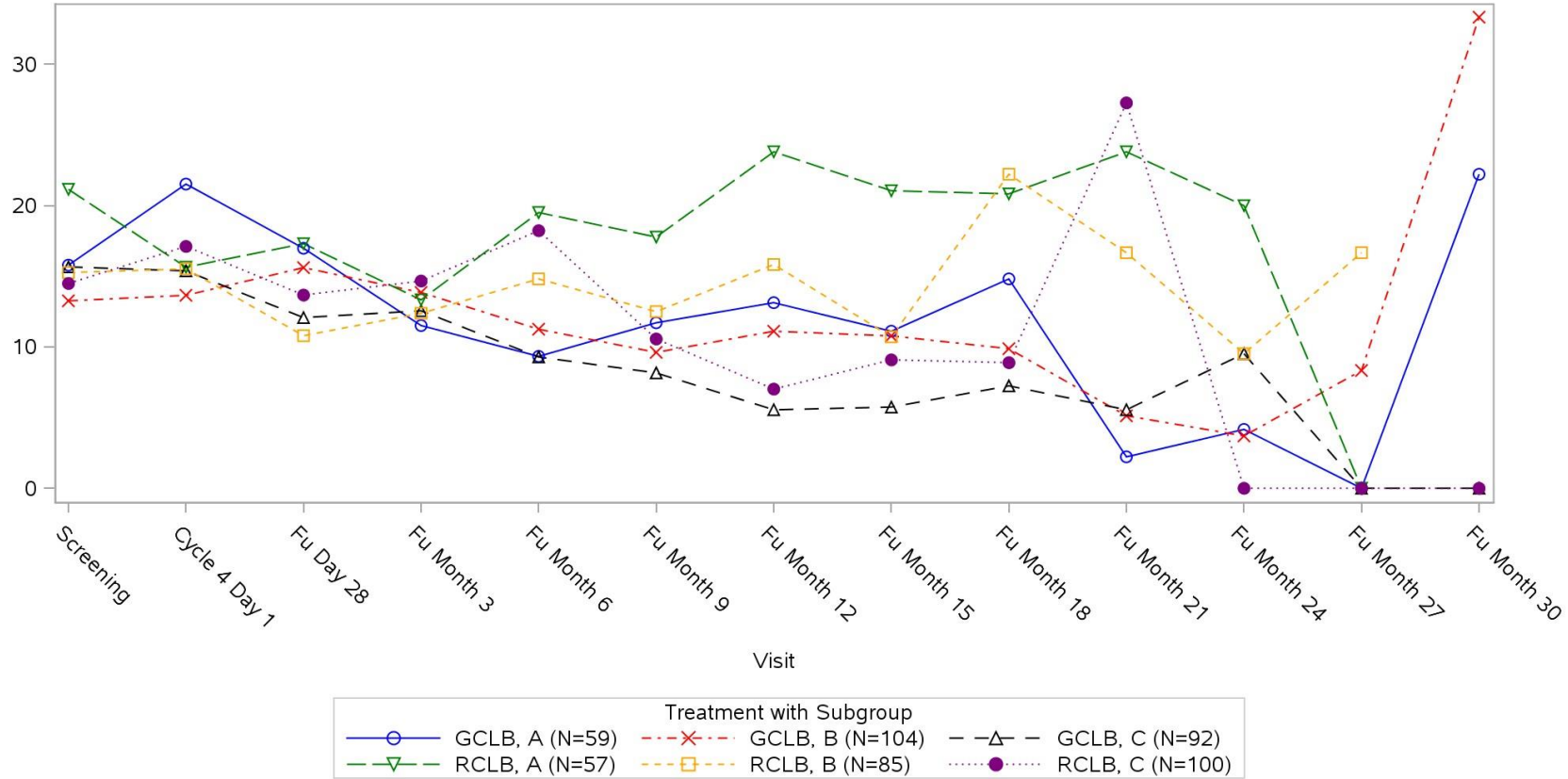
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 04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Binet Staging at baseline (N=497) Laboratory Test: Constipation Scale



Clinical cut-off: 09MAY2013

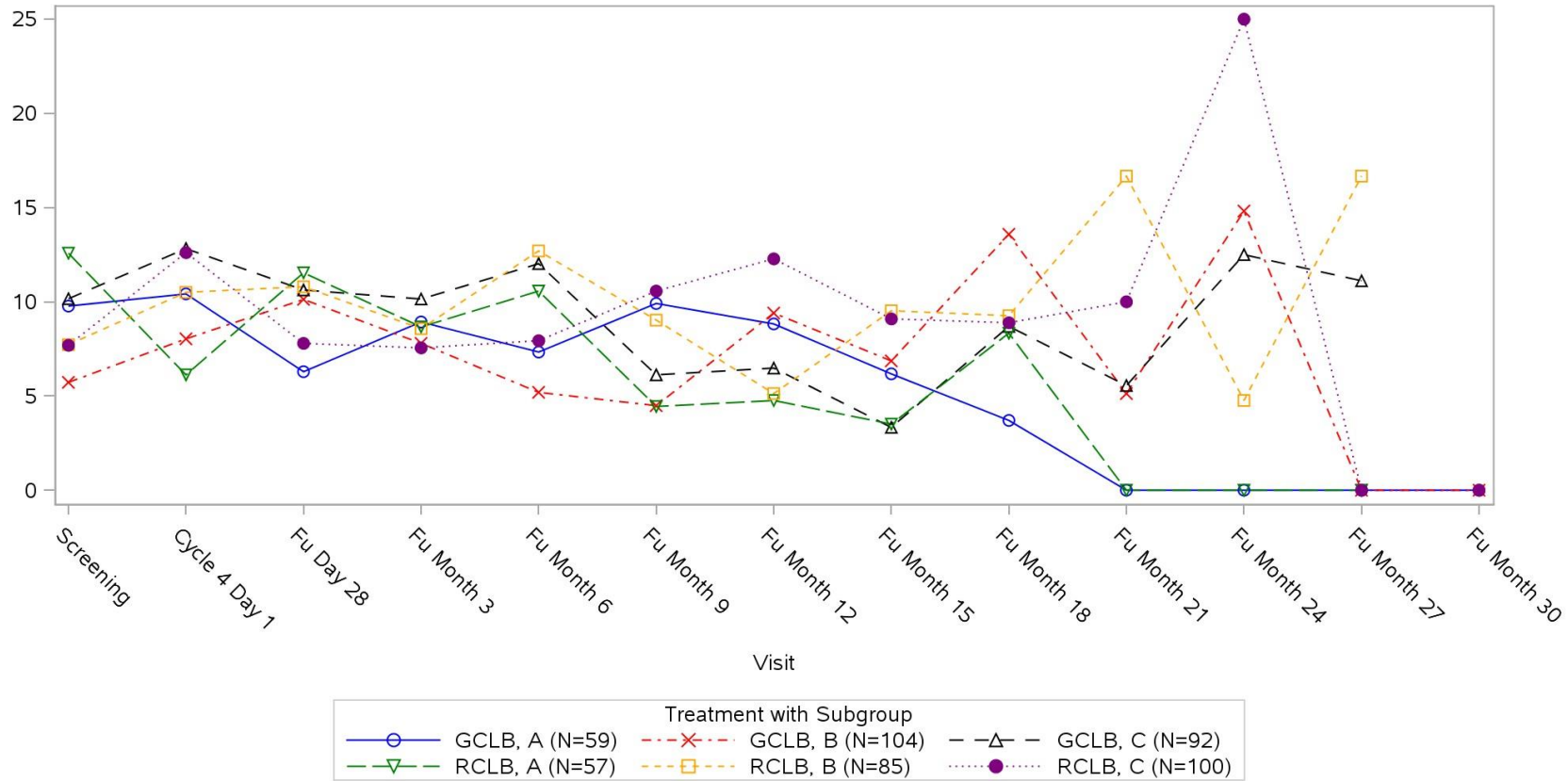
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Binet Staging at baseline (N=497) Laboratory Test: Diarrhoea Scale



Clinical cut-off: 09MAY2013

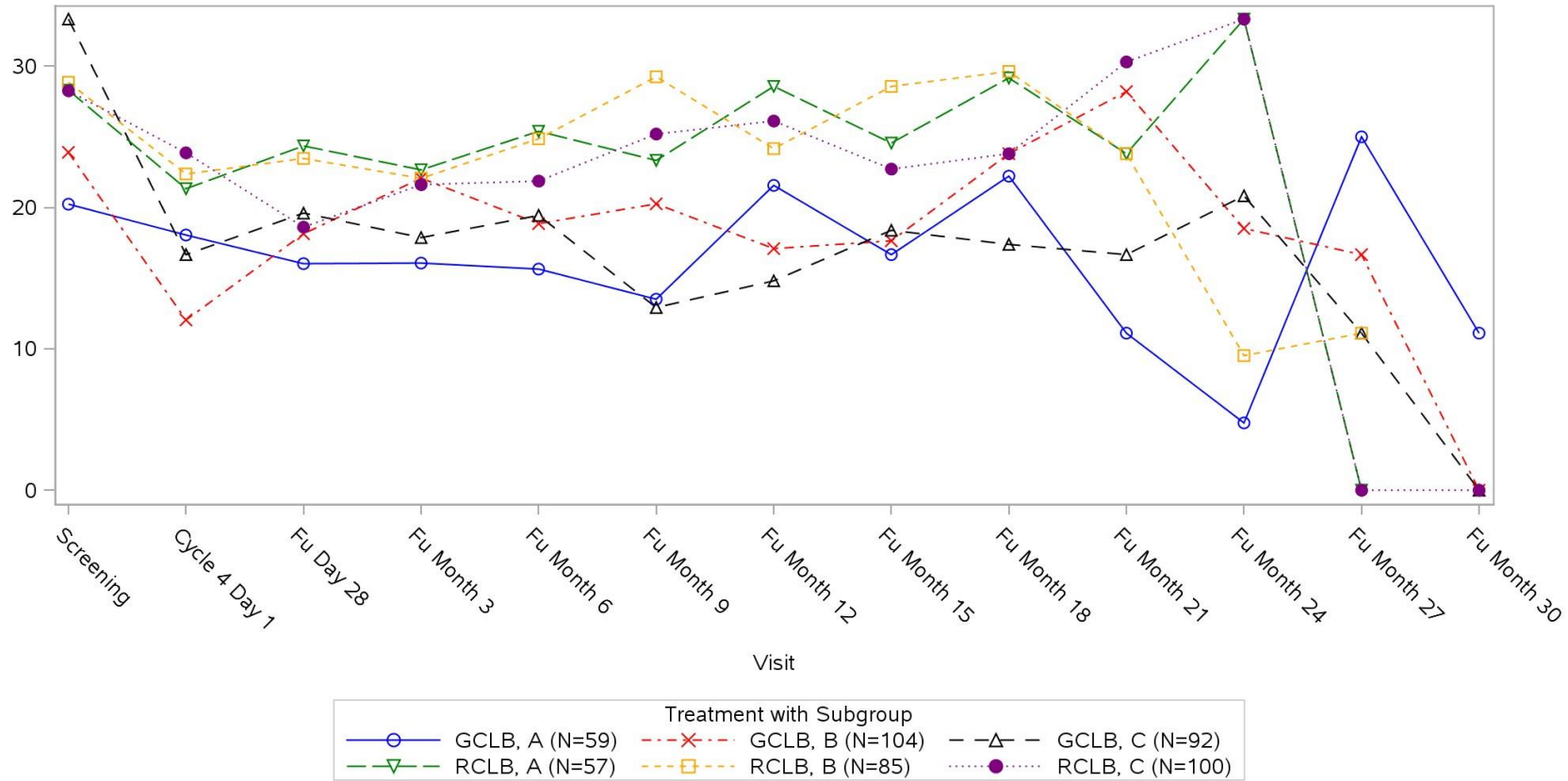
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Binet Staging at baseline (N=497) Laboratory Test: Dyspnoea Scale



Clinical cut-off: 09MAY2013

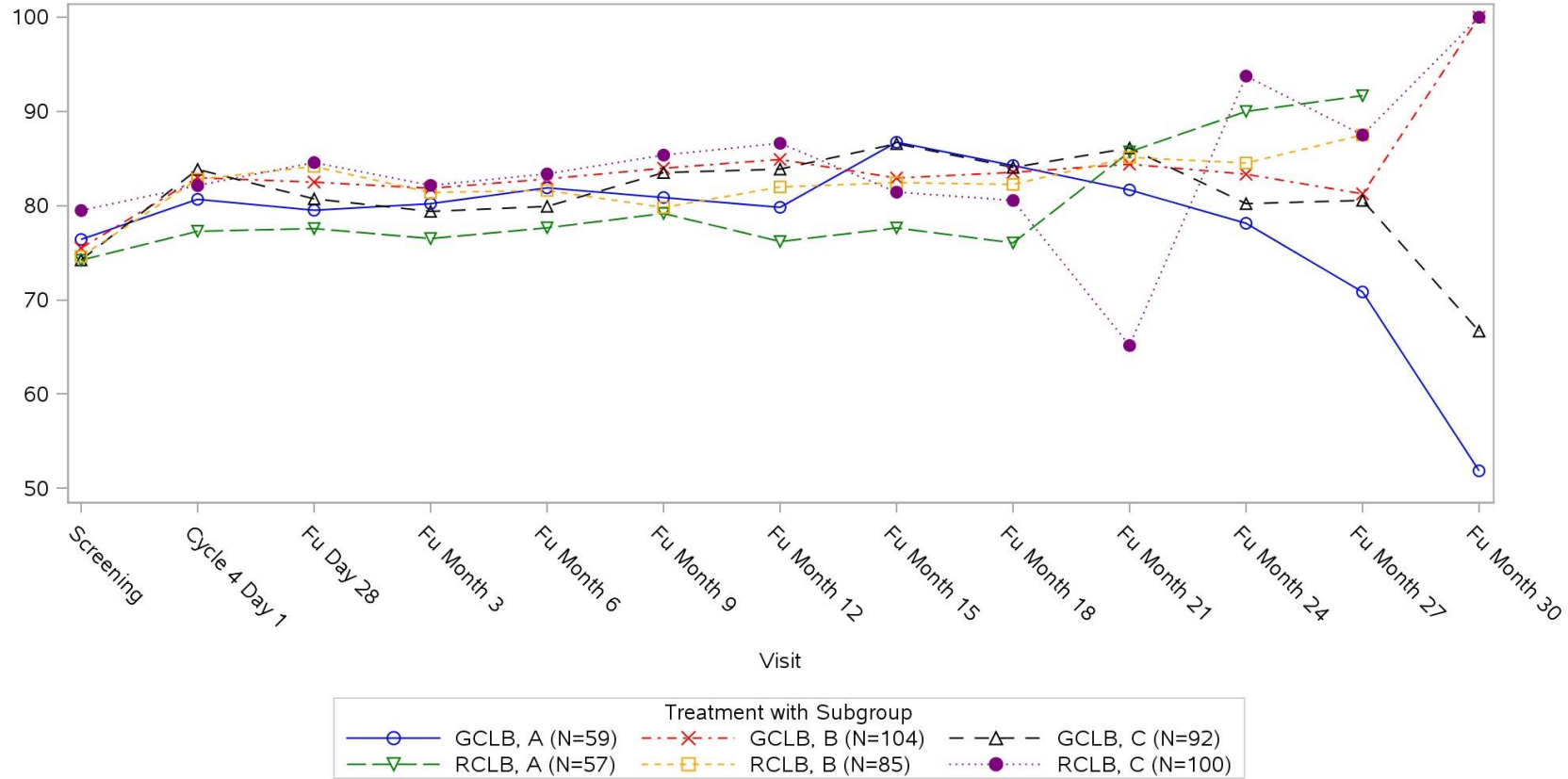
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 04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Binet Staging at baseline (N=497) Laboratory Test: Emotional Functioning Scale



Clinical cut-off: 09MAY2013

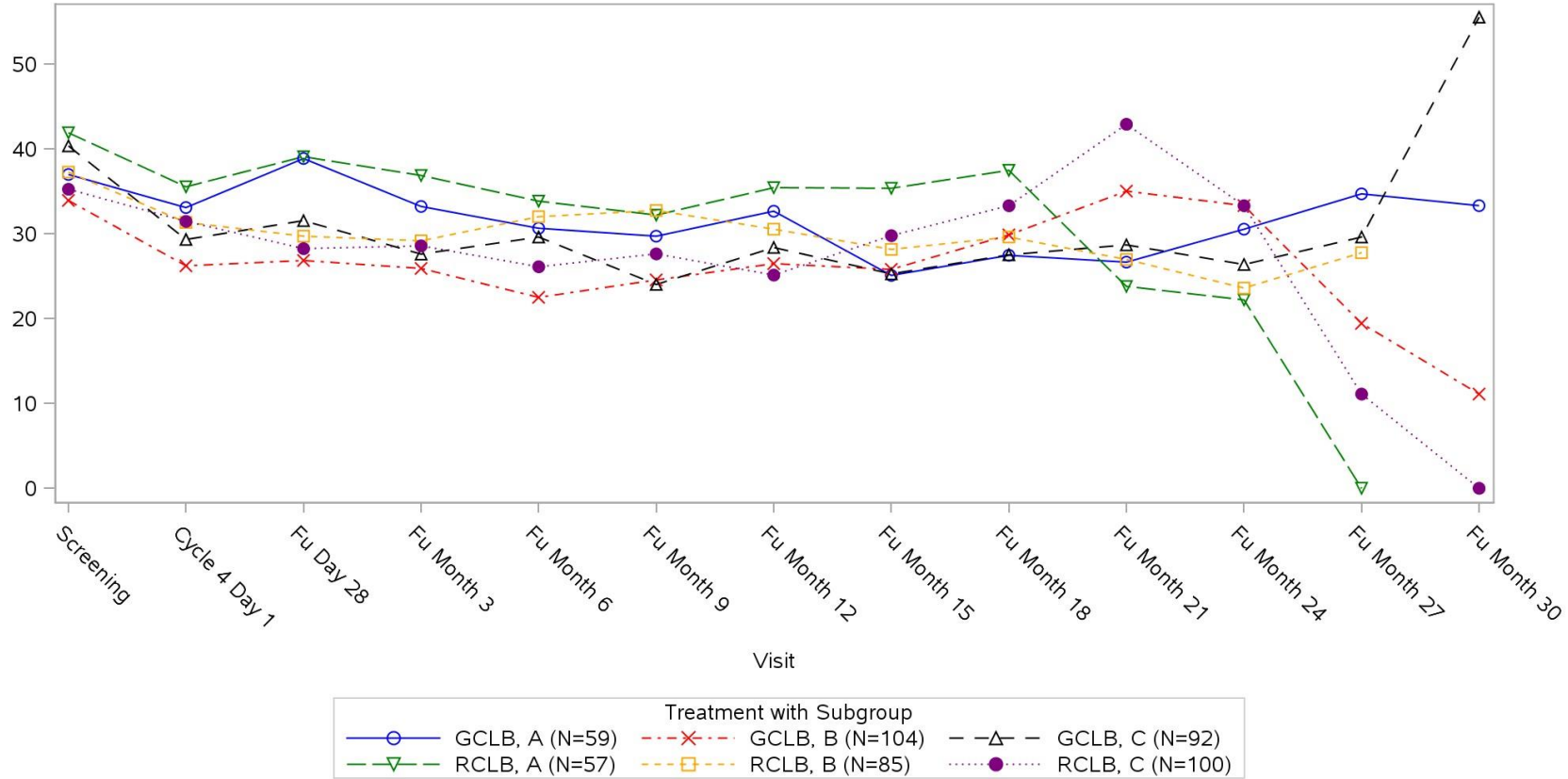
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 04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Binet Staging at baseline (N=497) Laboratory Test: Fatigue Scale



Clinical cut-off: 09MAY2013

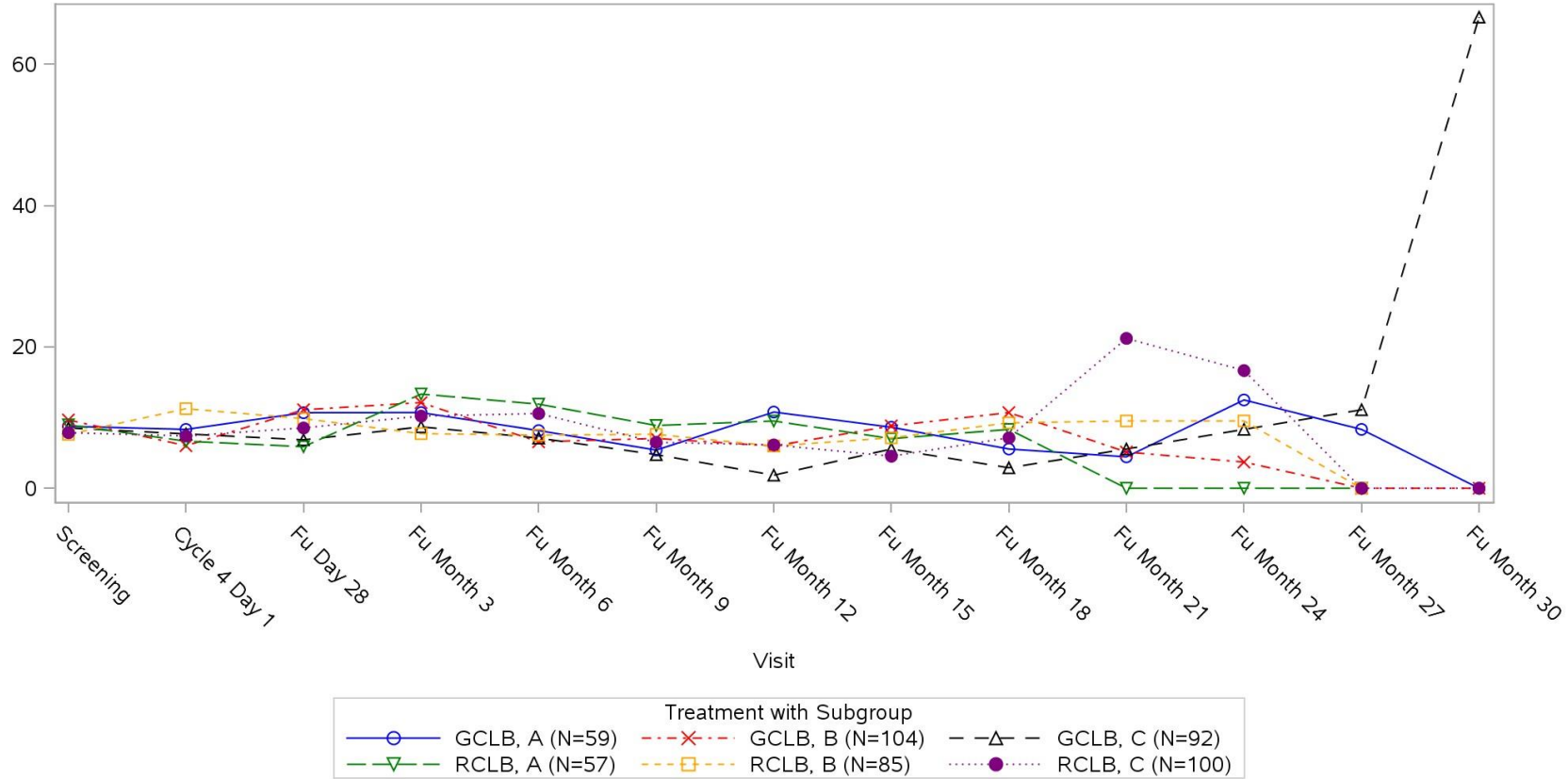
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Binet Staging at baseline (N=497) Laboratory Test: Financial Difficulties Scale



Clinical cut-off: 09MAY2013

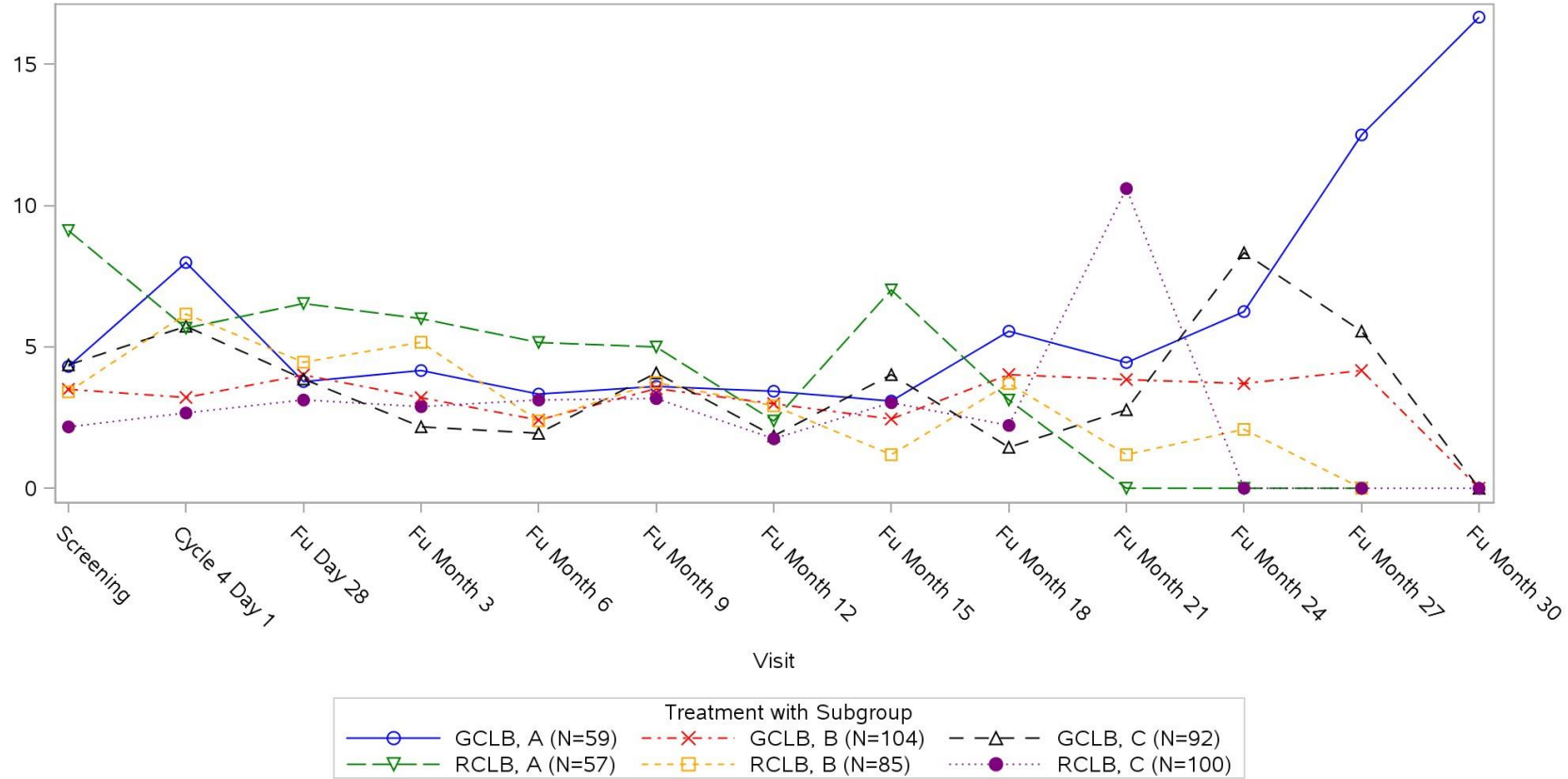
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04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Binet Staging at baseline (N=497) Laboratory Test: Nausea And Vomiting Scale



Clinical cut-off: 09MAY2013

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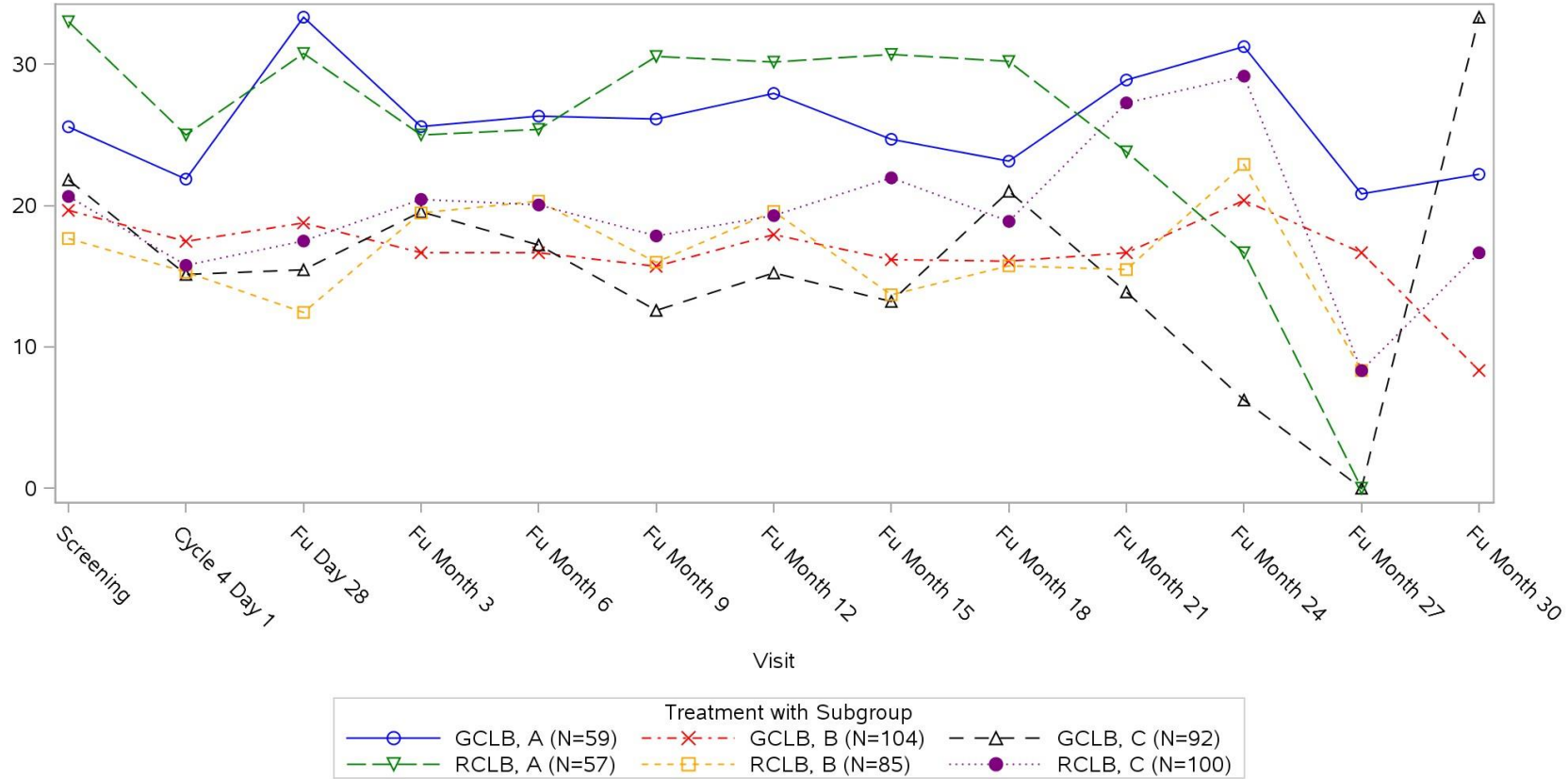
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Binet Staging at baseline (N=497) Laboratory Test: Pain Scale



Clinical cut-off: 09MAY2013

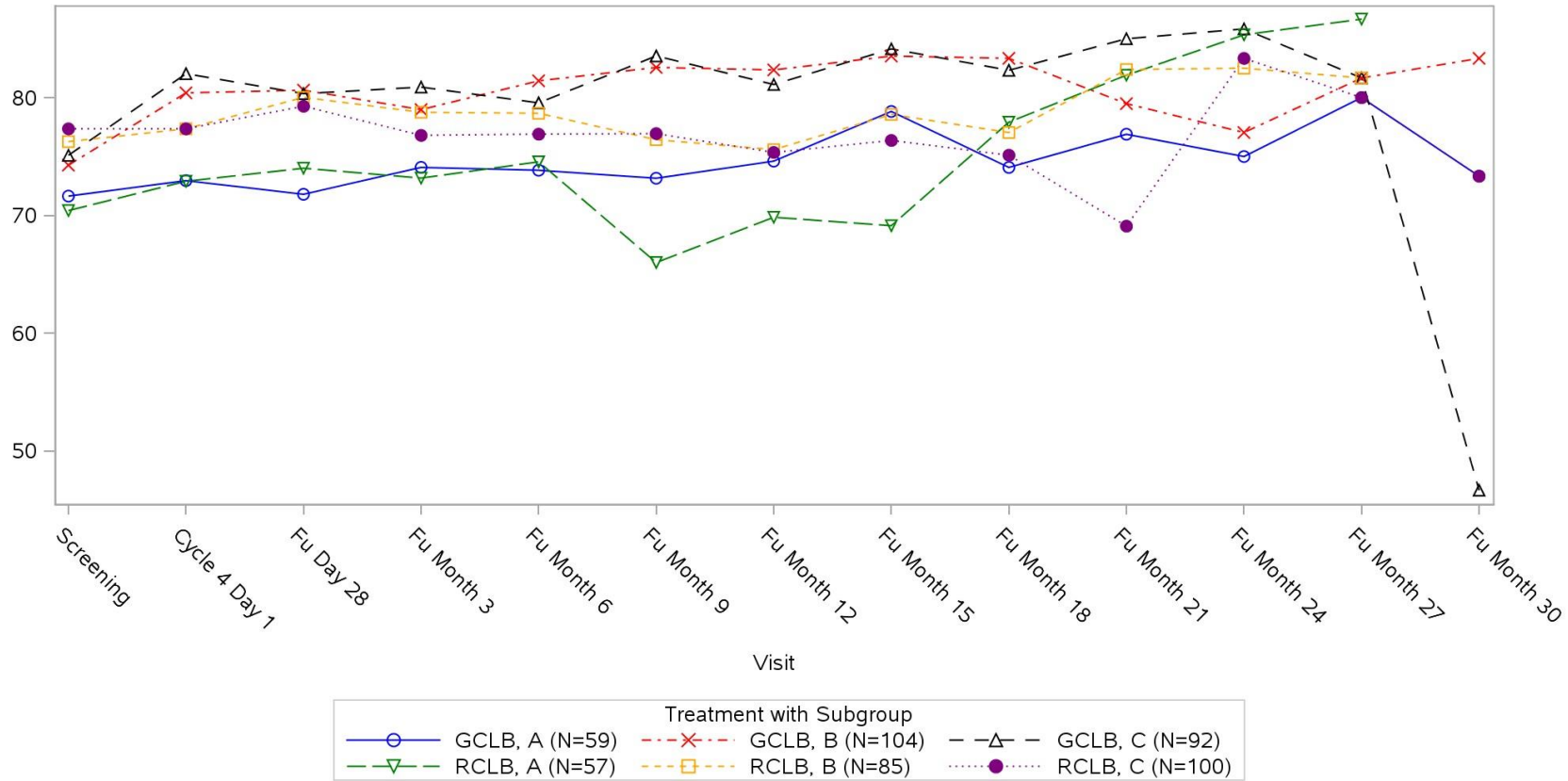
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Binet Staging at baseline (N=497) Laboratory Test: Physical Functioning Scale



Clinical cut-off: 09MAY2013

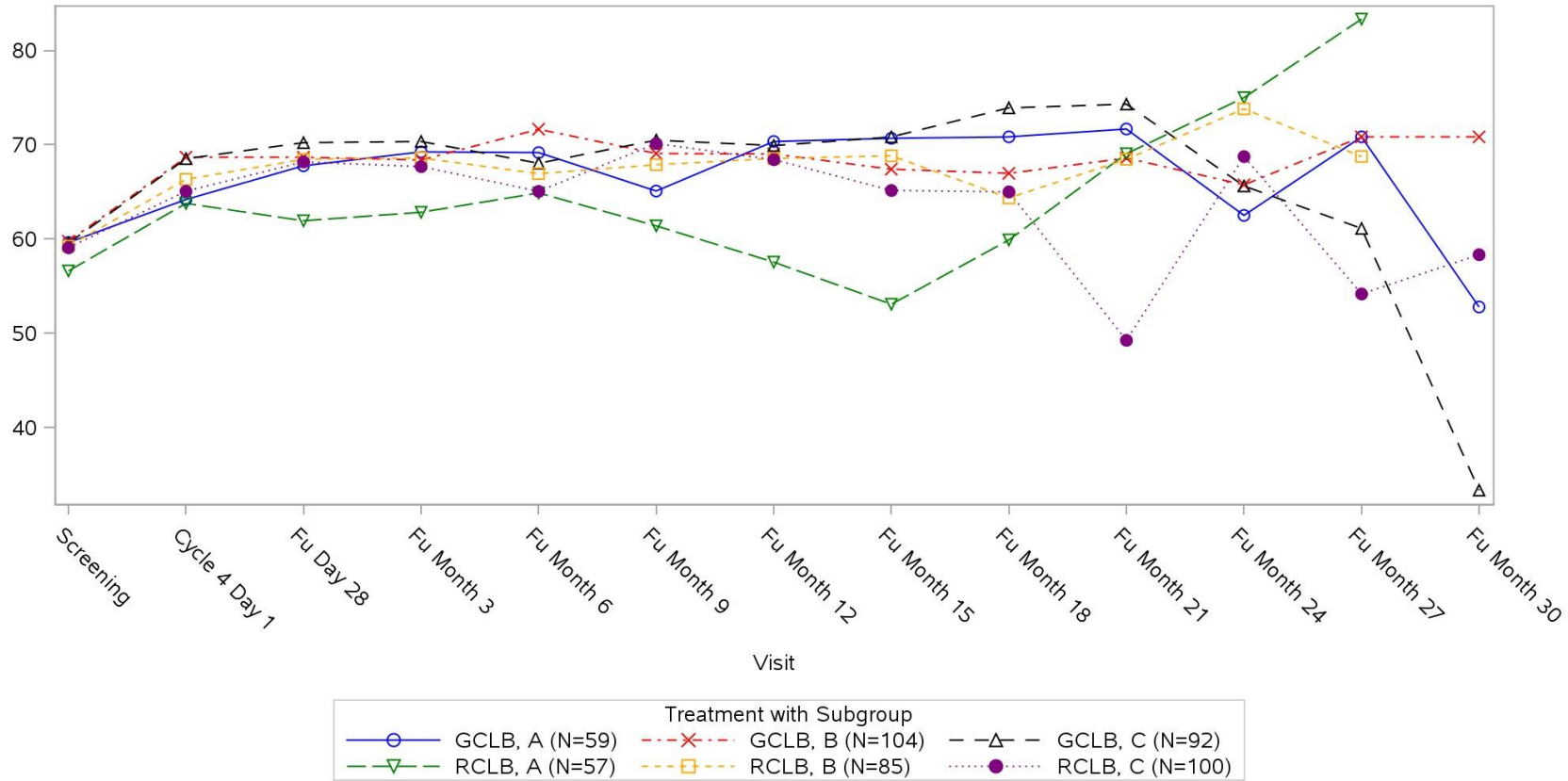
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 04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Binet Staging at baseline (N=497) Laboratory Test: Global Health Status Scale



Clinical cut-off: 09MAY2013

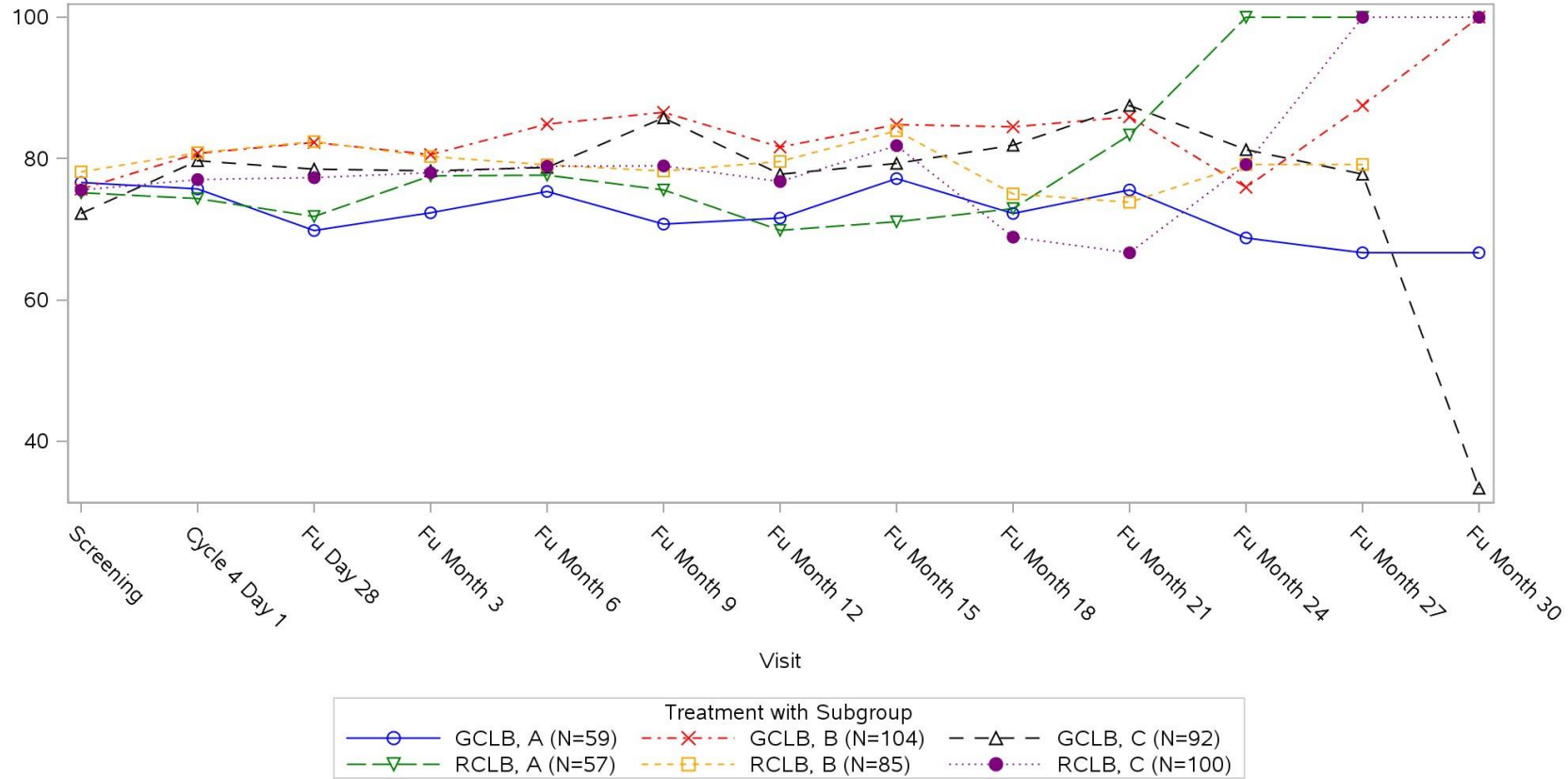
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Binet Staging at baseline (N=497) Laboratory Test: Role Functioning Scale



Clinical cut-off: 09MAY2013

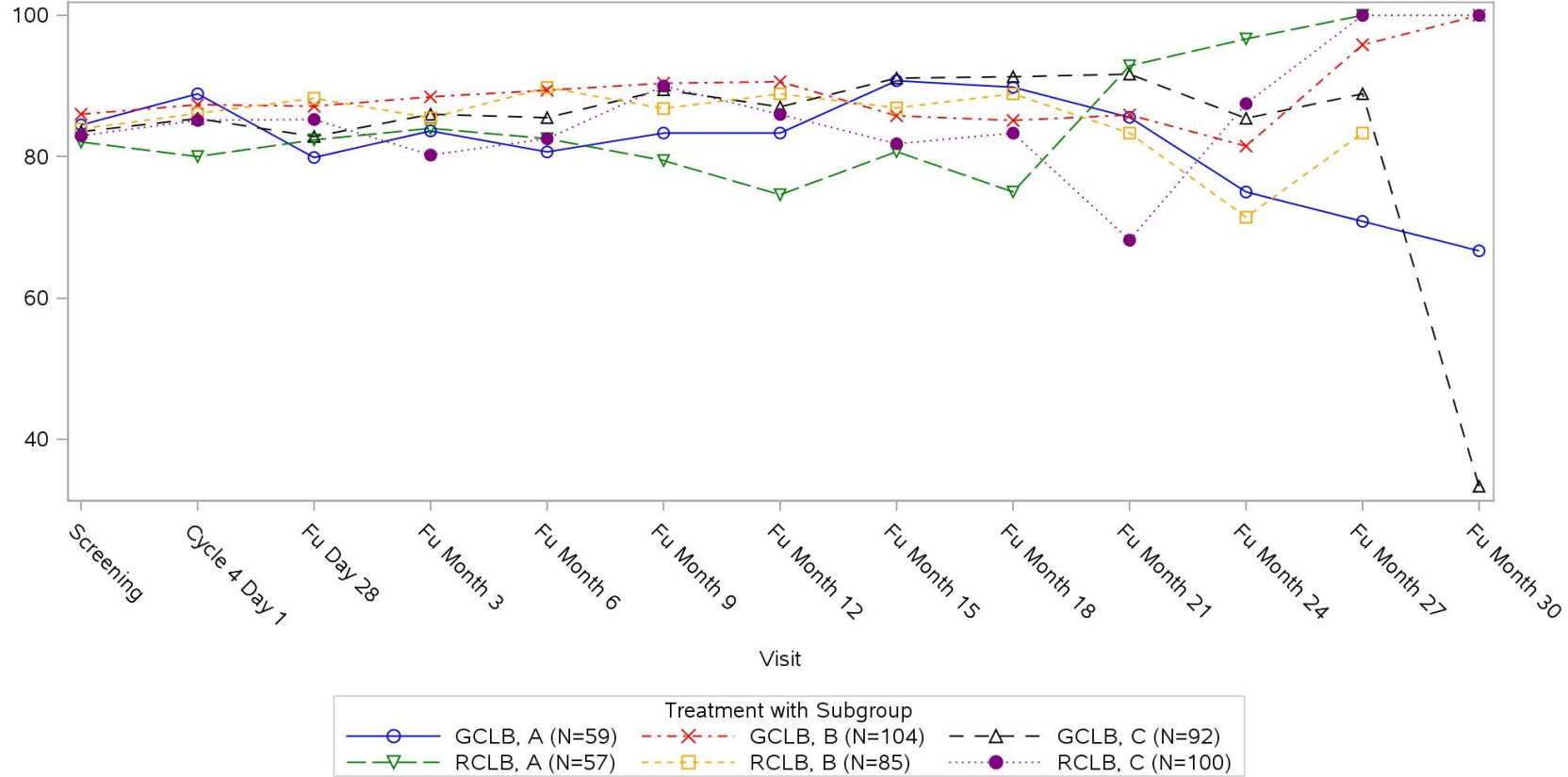
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Binet Staging at baseline (N=497) Laboratory Test: Social Functioning Scale



Clinical cut-off: 09MAY2013

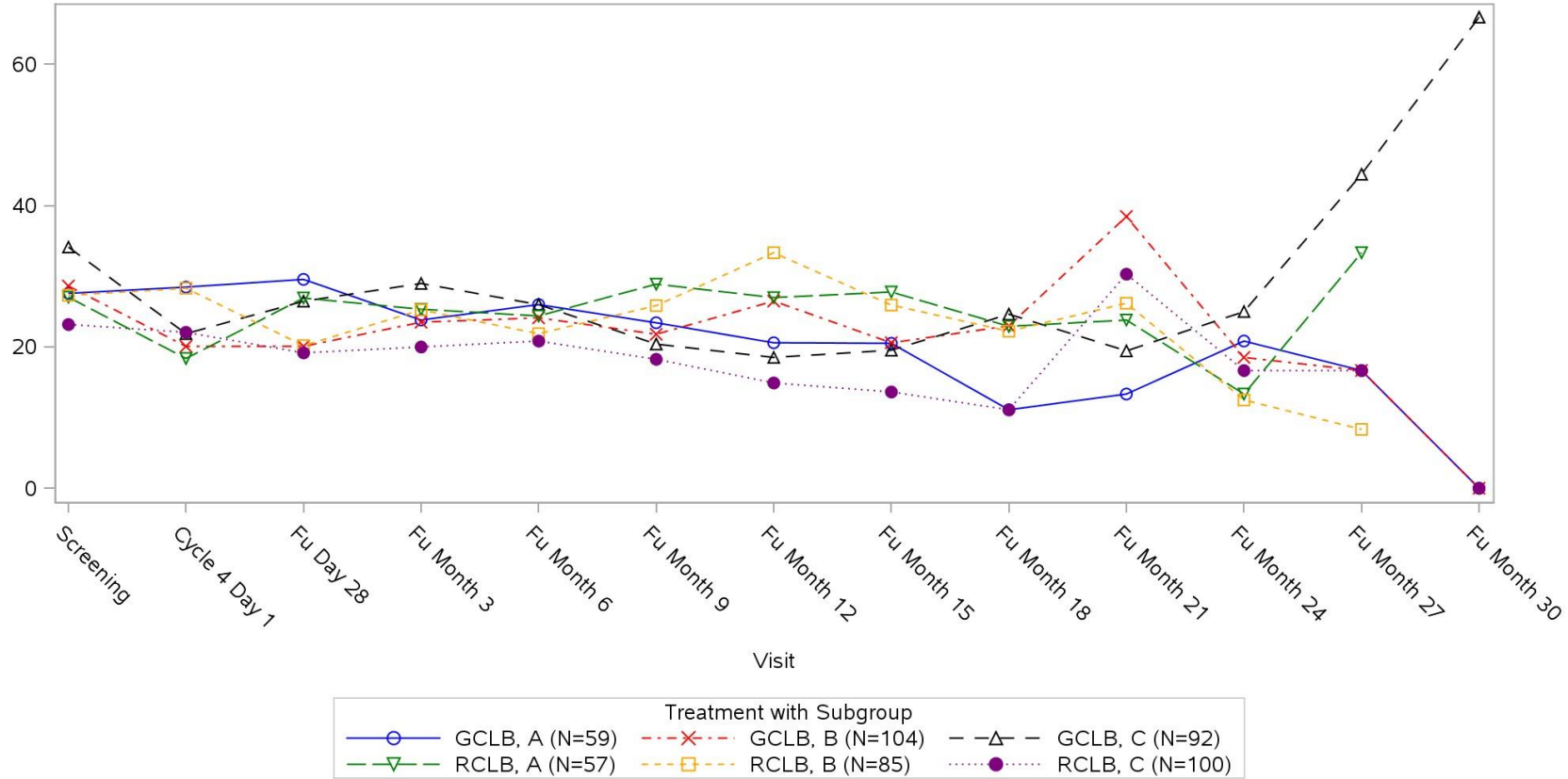
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 04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Binet Staging at baseline (N=497) Laboratory Test: Insomnia Scale



Clinical cut-off: 09MAY2013

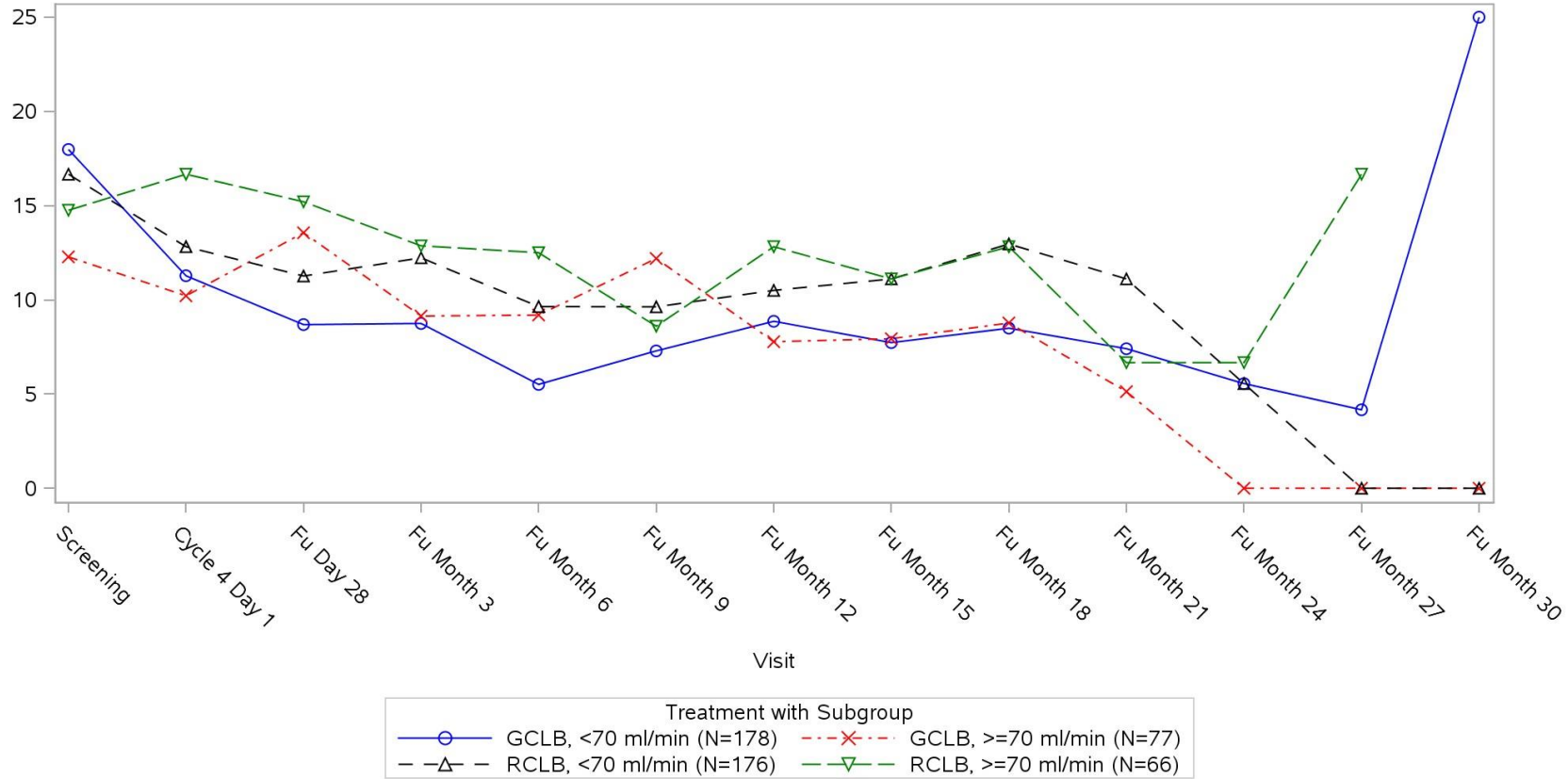
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 04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Calculated creatinine clearance cat. 2 (N=497) Laboratory Test: Appetite Loss Scale



Clinical cut-off: 09MAY2013

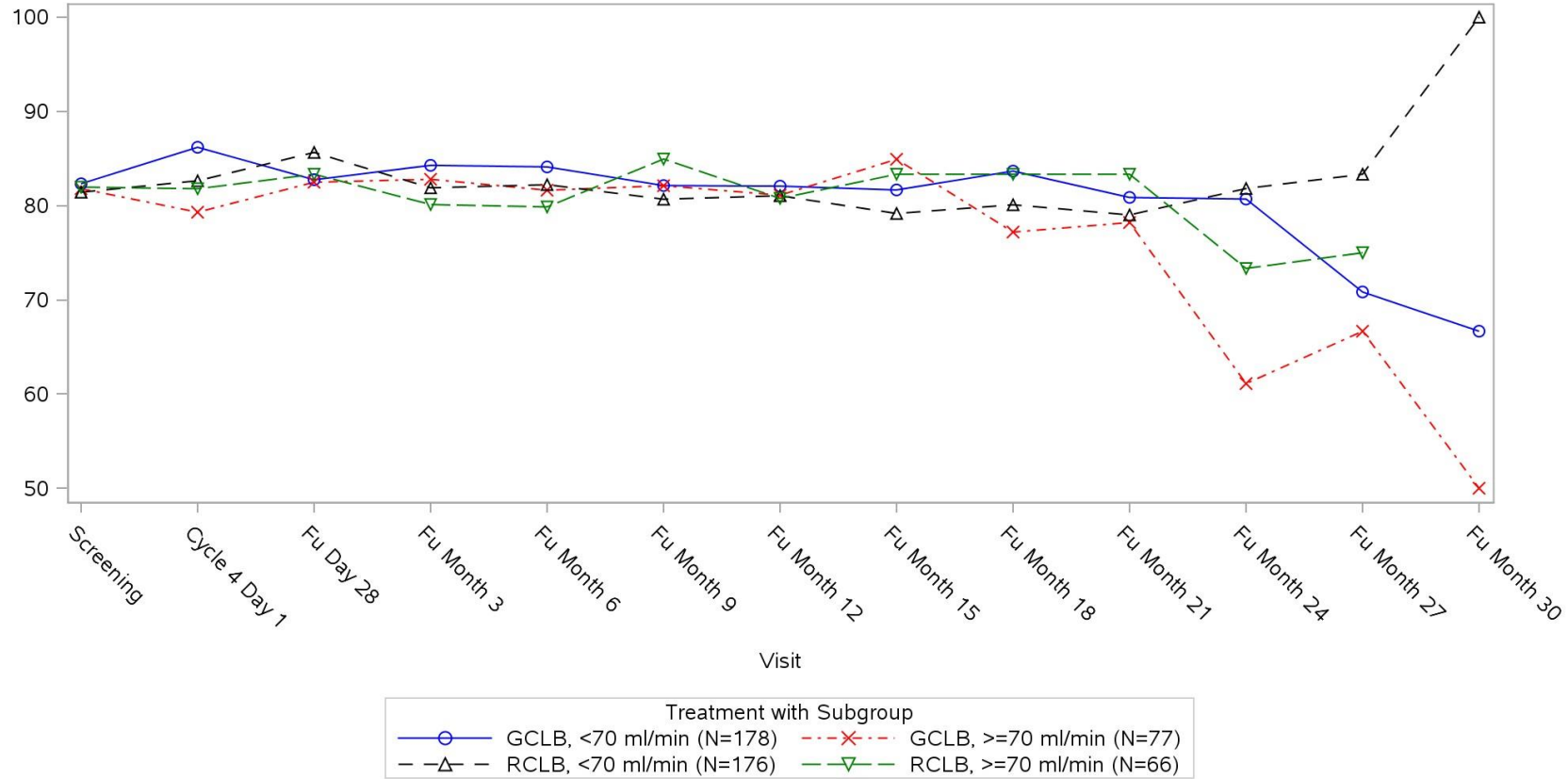
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Calculated creatinine clearance cat. 2 (N=497) Laboratory Test: Cognitive Functioning Scale



Clinical cut-off: 09MAY2013

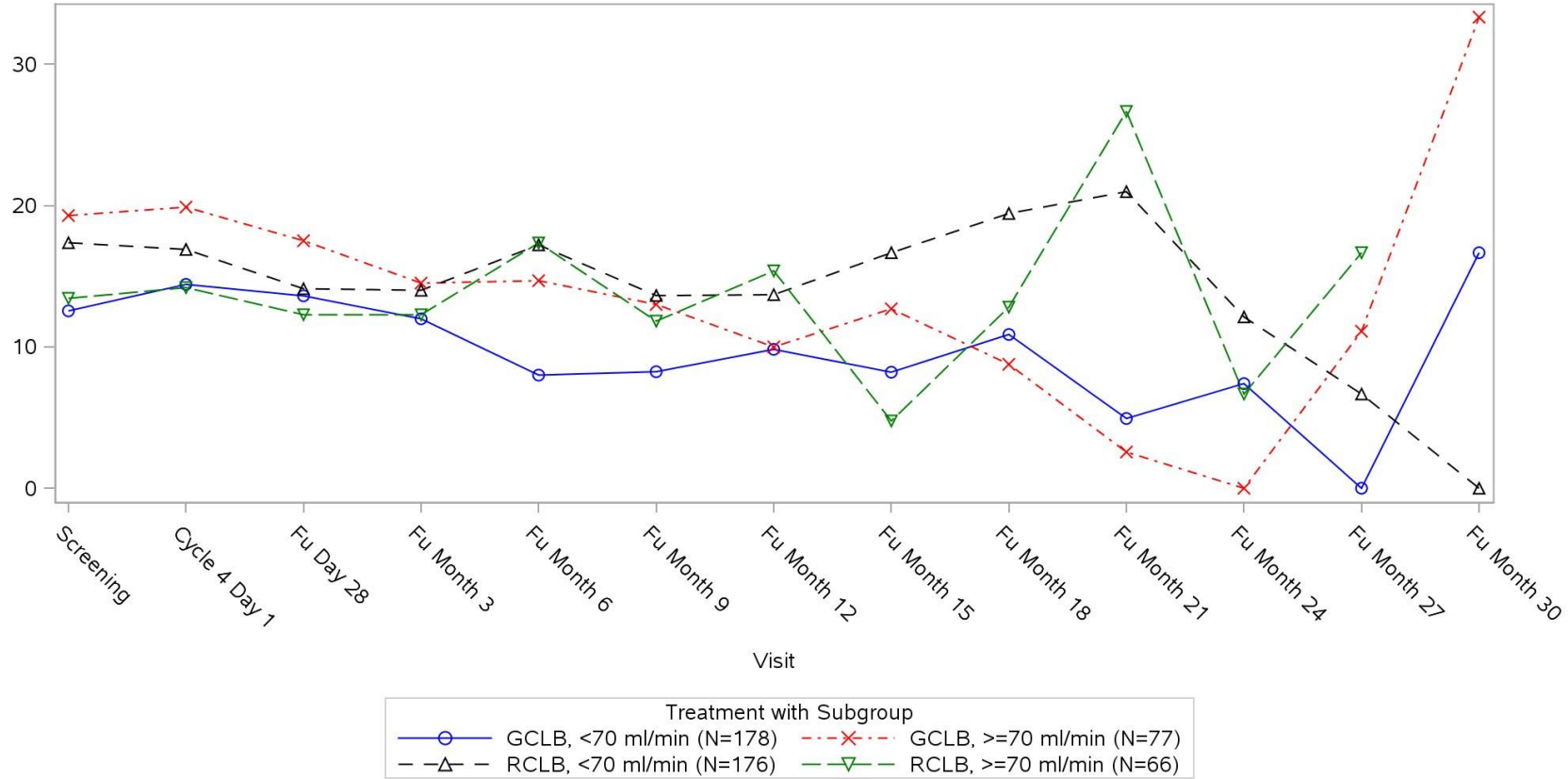
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04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Calculated creatinine clearance cat. 2 (N=497) Laboratory Test: Constipation Scale



Clinical cut-off: 09MAY2013

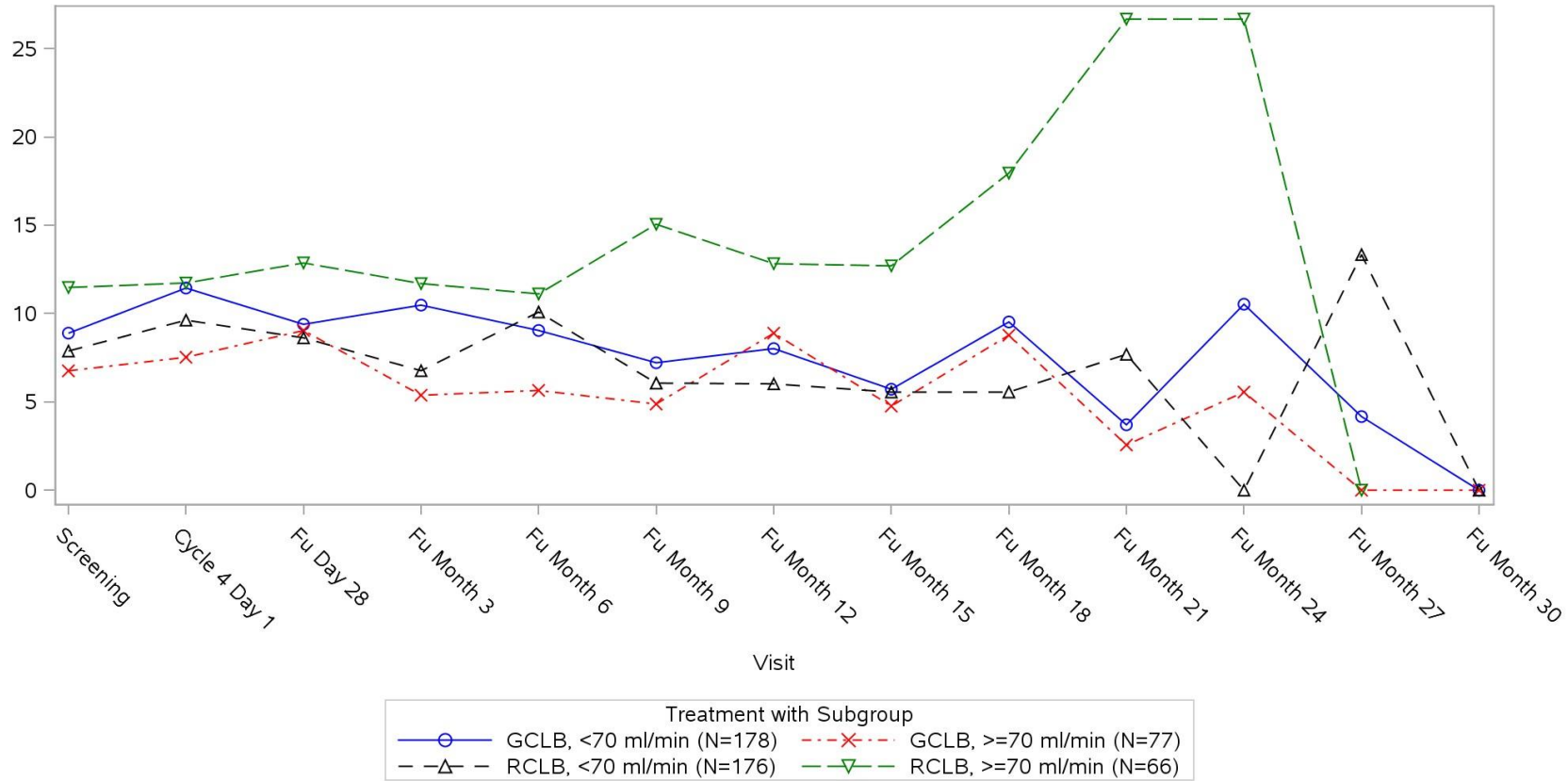
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Calculated creatinine clearance cat. 2 (N=497) Laboratory Test: Diarrhoea Scale



Clinical cut-off: 09MAY2013

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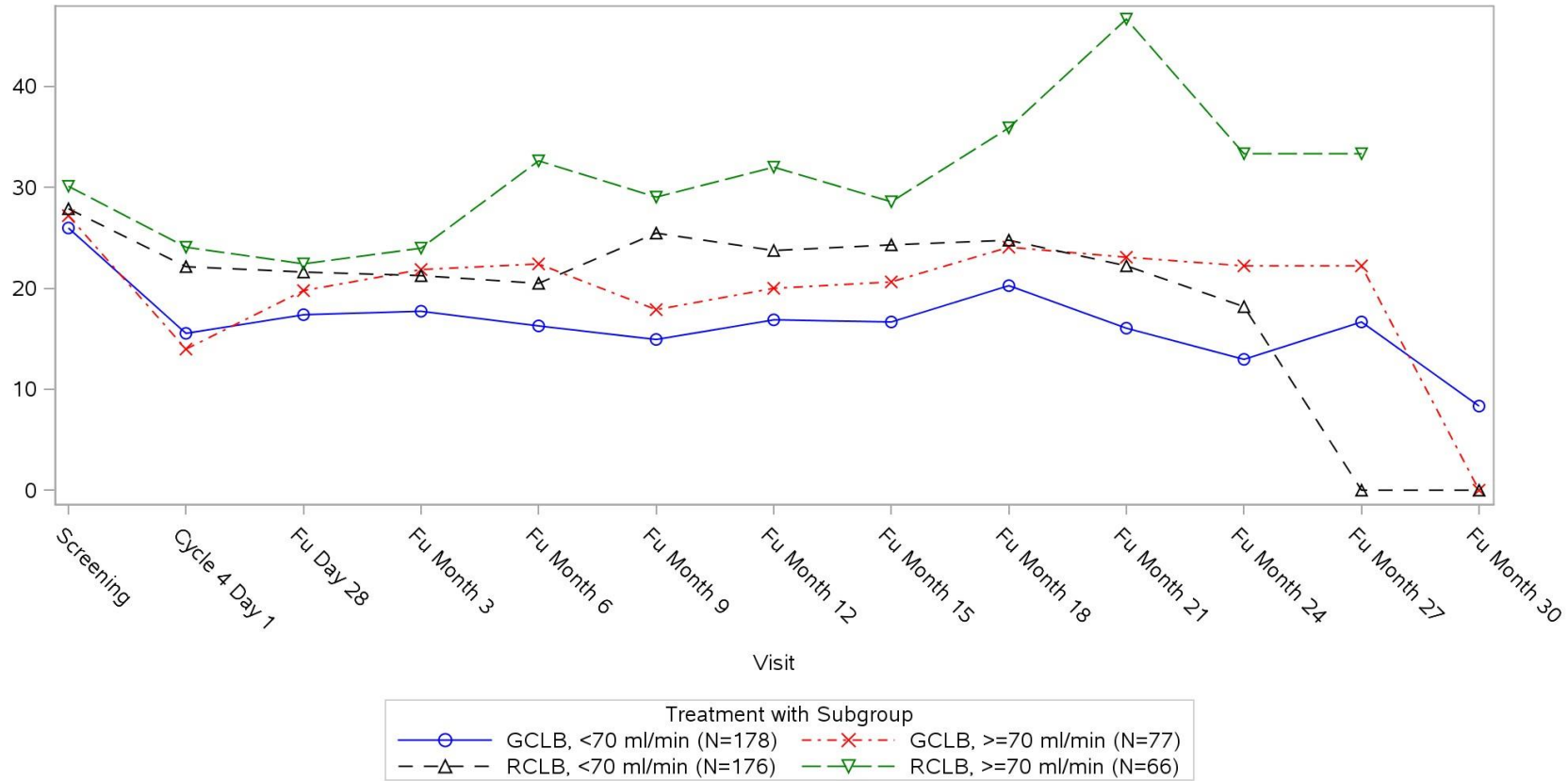
Page 34 of 195

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Calculated creatinine clearance cat. 2 (N=497) Laboratory Test: Dyspnoea Scale



Clinical cut-off: 09MAY2013

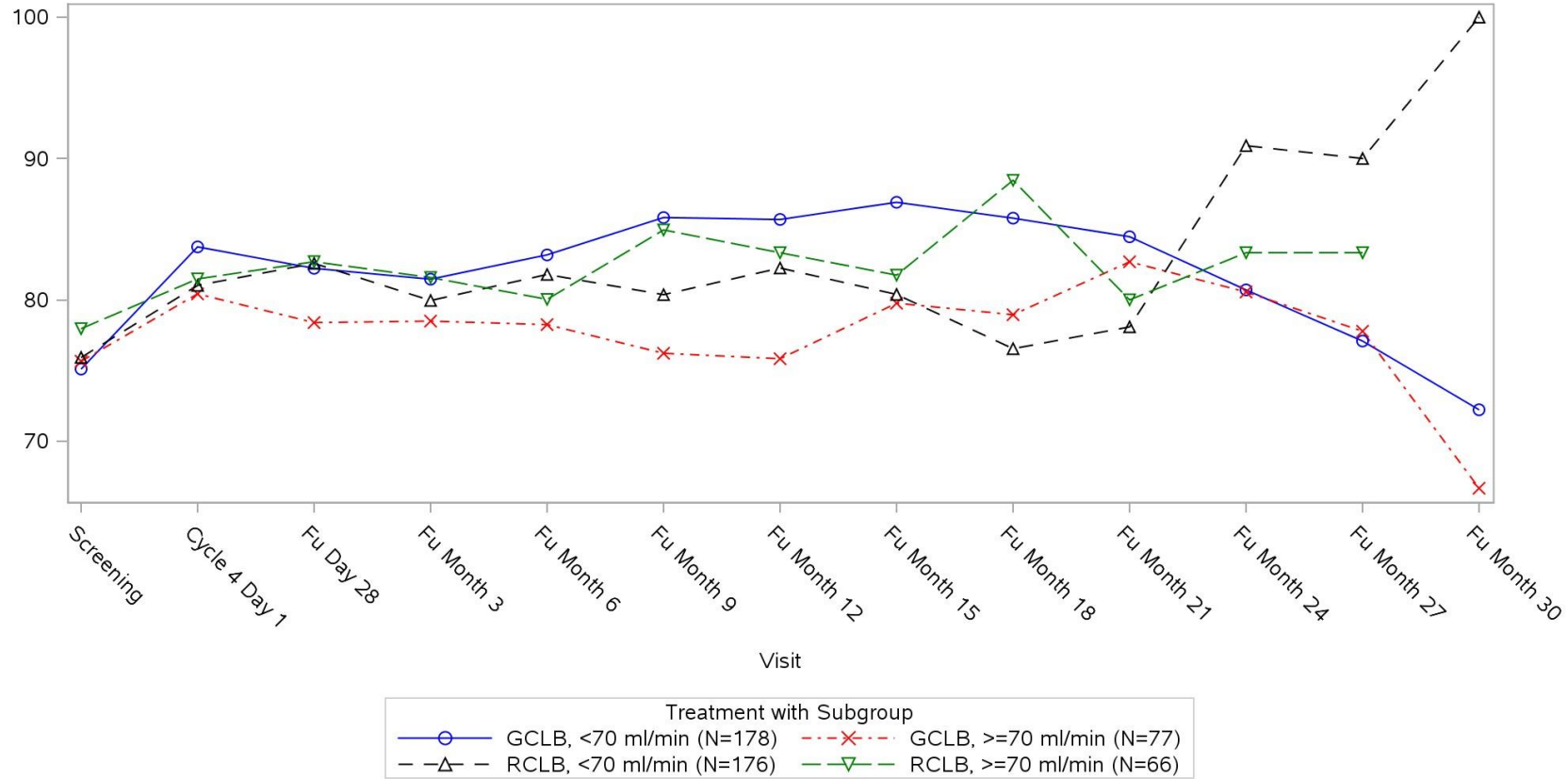
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04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Calculated creatinine clearance cat. 2 (N=497) Laboratory Test: Emotional Functioning Scale



Clinical cut-off: 09MAY2013

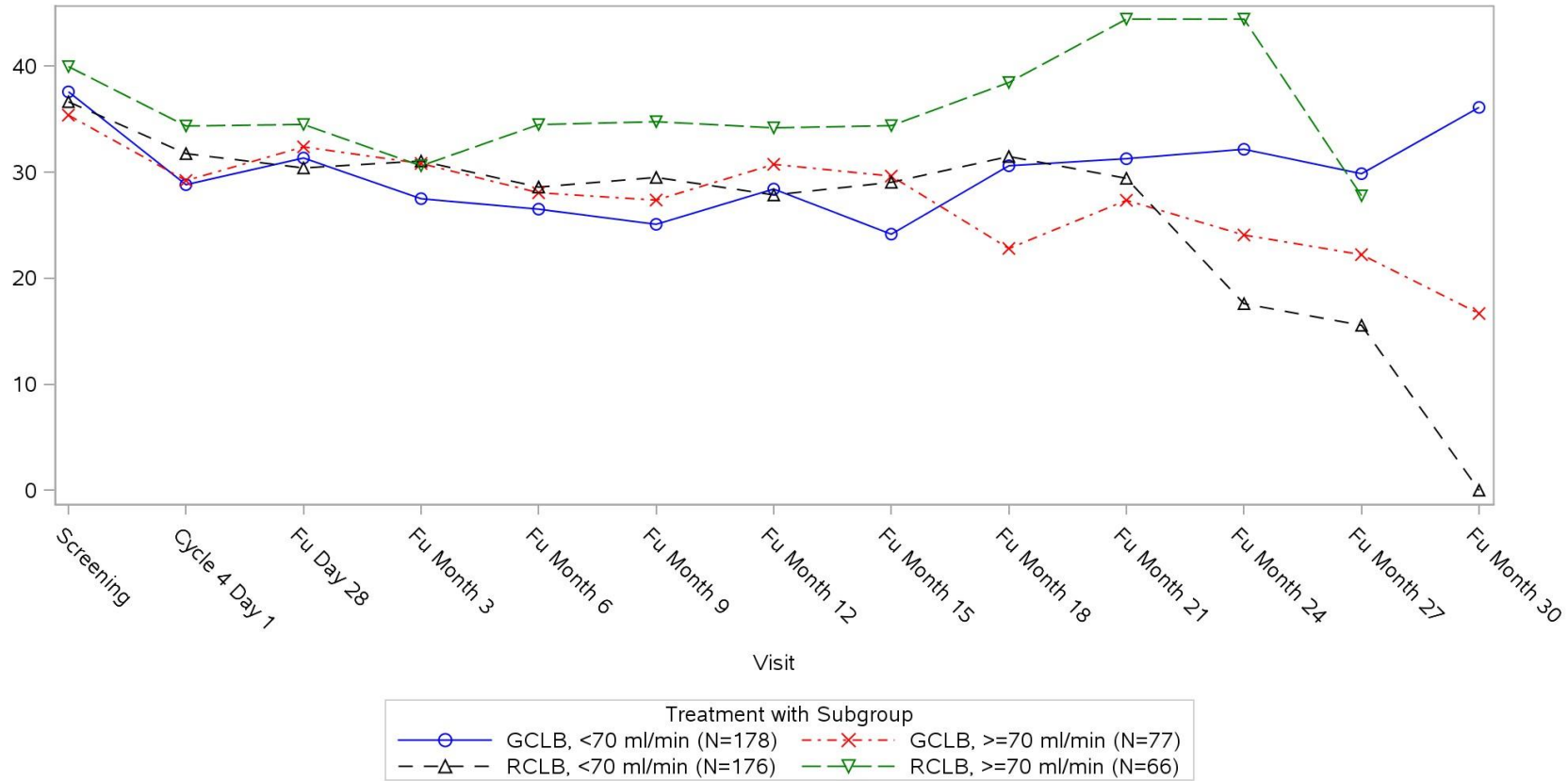
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Calculated creatinine clearance cat. 2 (N=497) Laboratory Test: Fatigue Scale



Clinical cut-off: 09MAY2013

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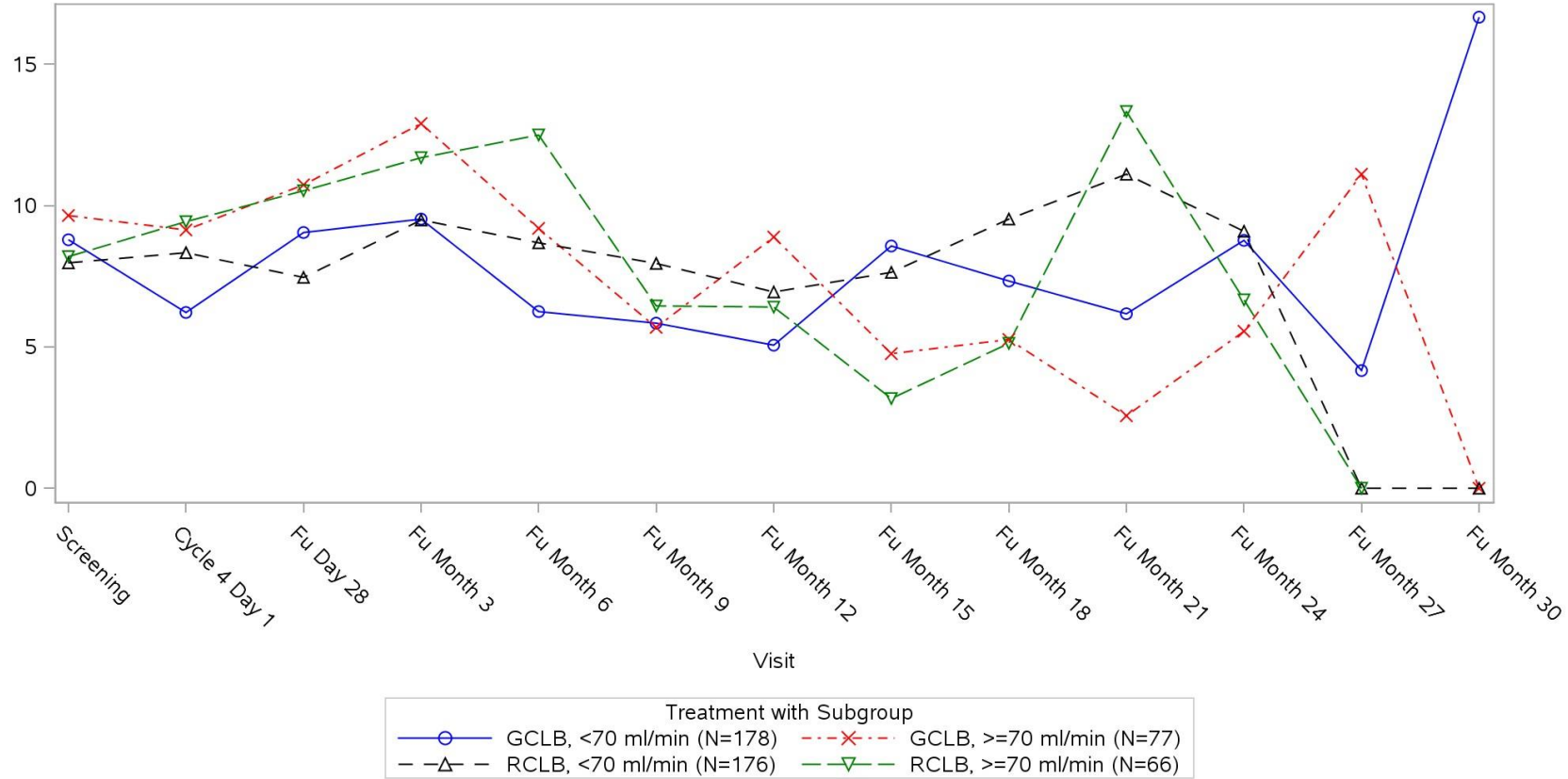
Page 37 of 195

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Calculated creatinine clearance cat. 2 (N=497) Laboratory Test: Financial Difficulties Scale



Clinical cut-off: 09MAY2013

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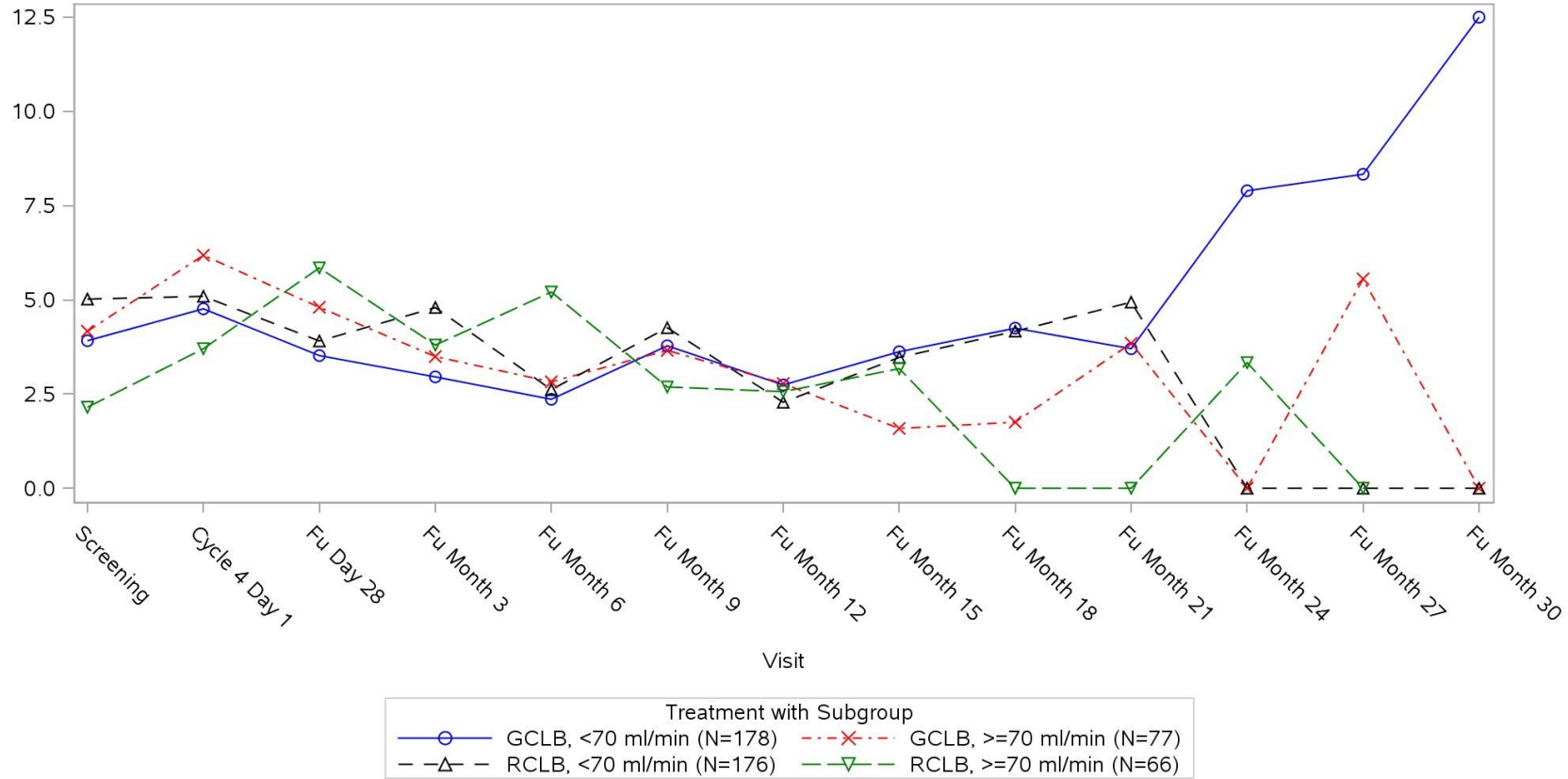
Page 38 of 195

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Calculated creatinine clearance cat. 2 (N=497) Laboratory Test: Nausea And Vomiting Scale



Clinical cut-off: 09MAY2013

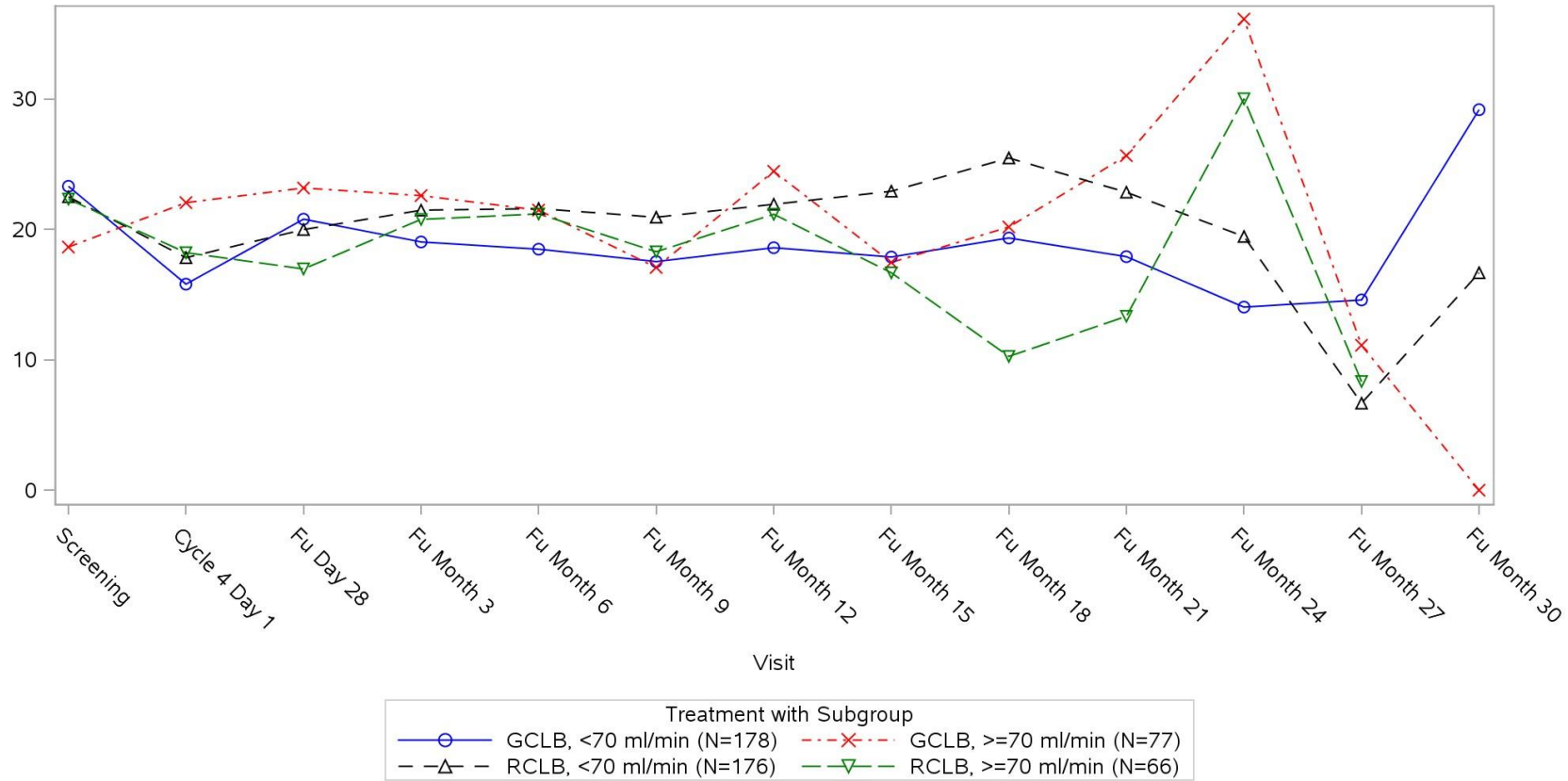
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04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Calculated creatinine clearance cat. 2 (N=497) Laboratory Test: Pain Scale



Clinical cut-off: 09MAY2013

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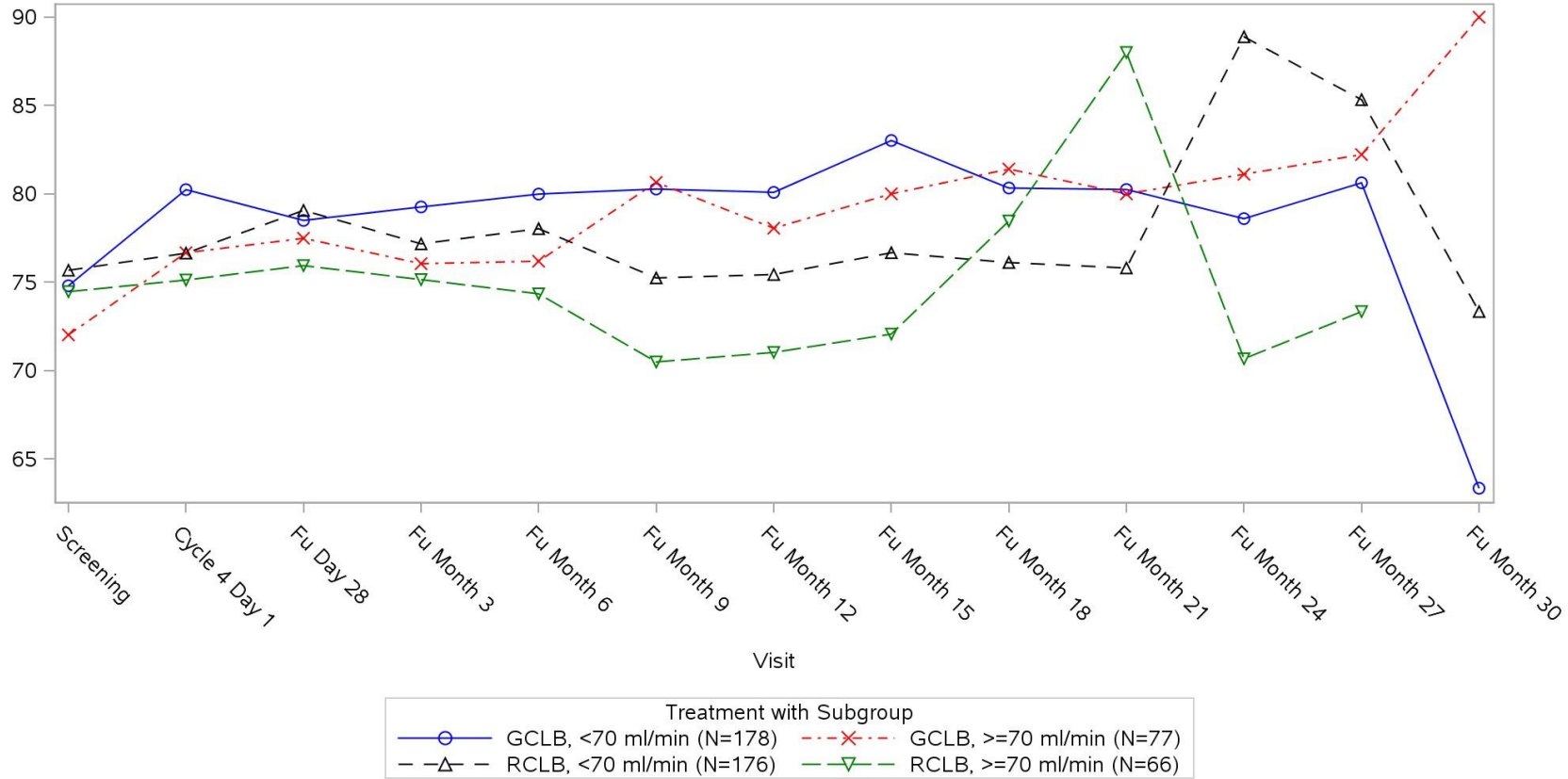
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Calculated creatinine clearance cat. 2 (N=497) Laboratory Test: Physical Functioning Scale



Clinical cut-off: 09MAY2013

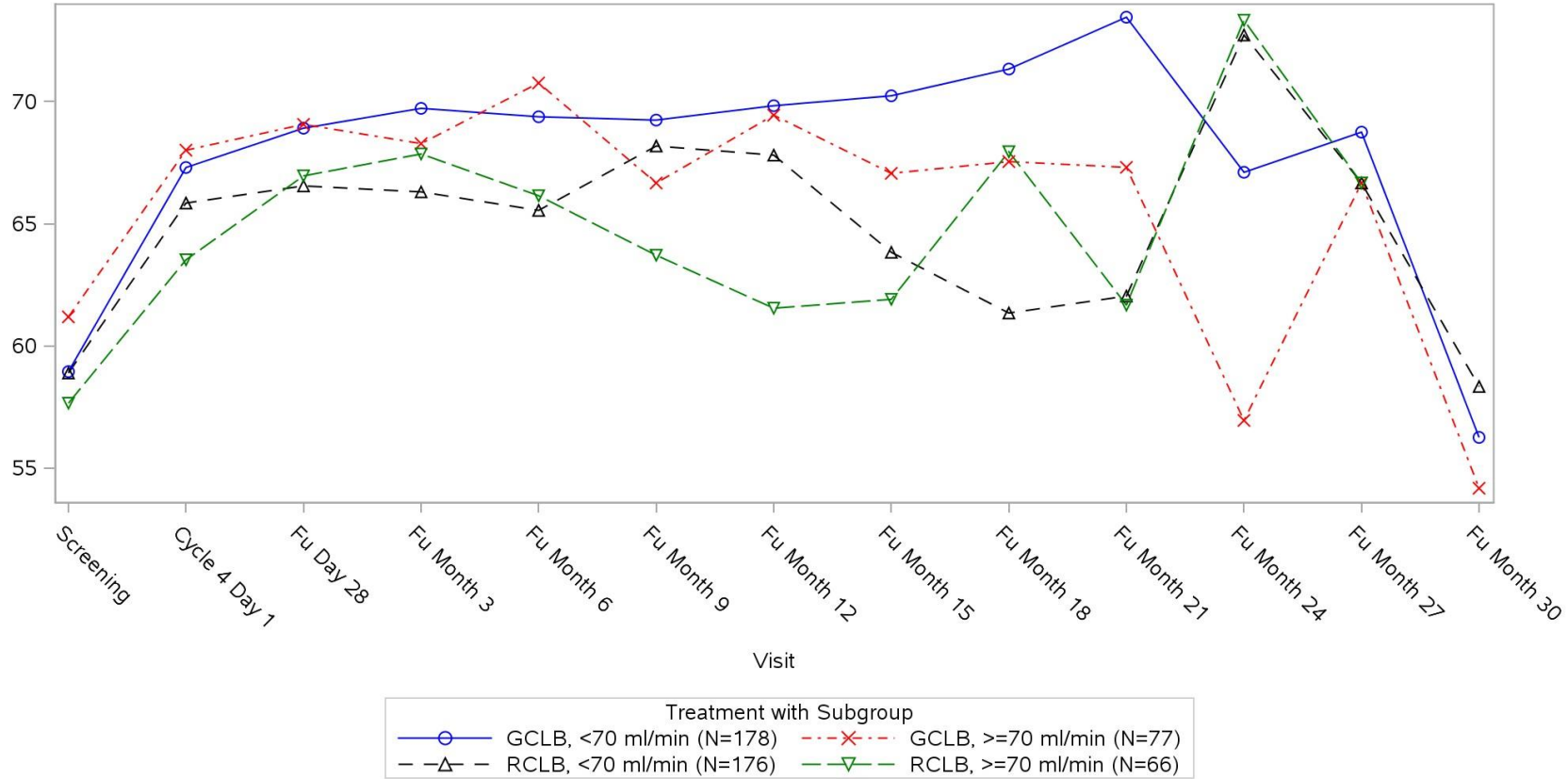
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04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Calculated creatinine clearance cat. 2 (N=497) Laboratory Test: Global Health Status Scale



Clinical cut-off: 09MAY2013

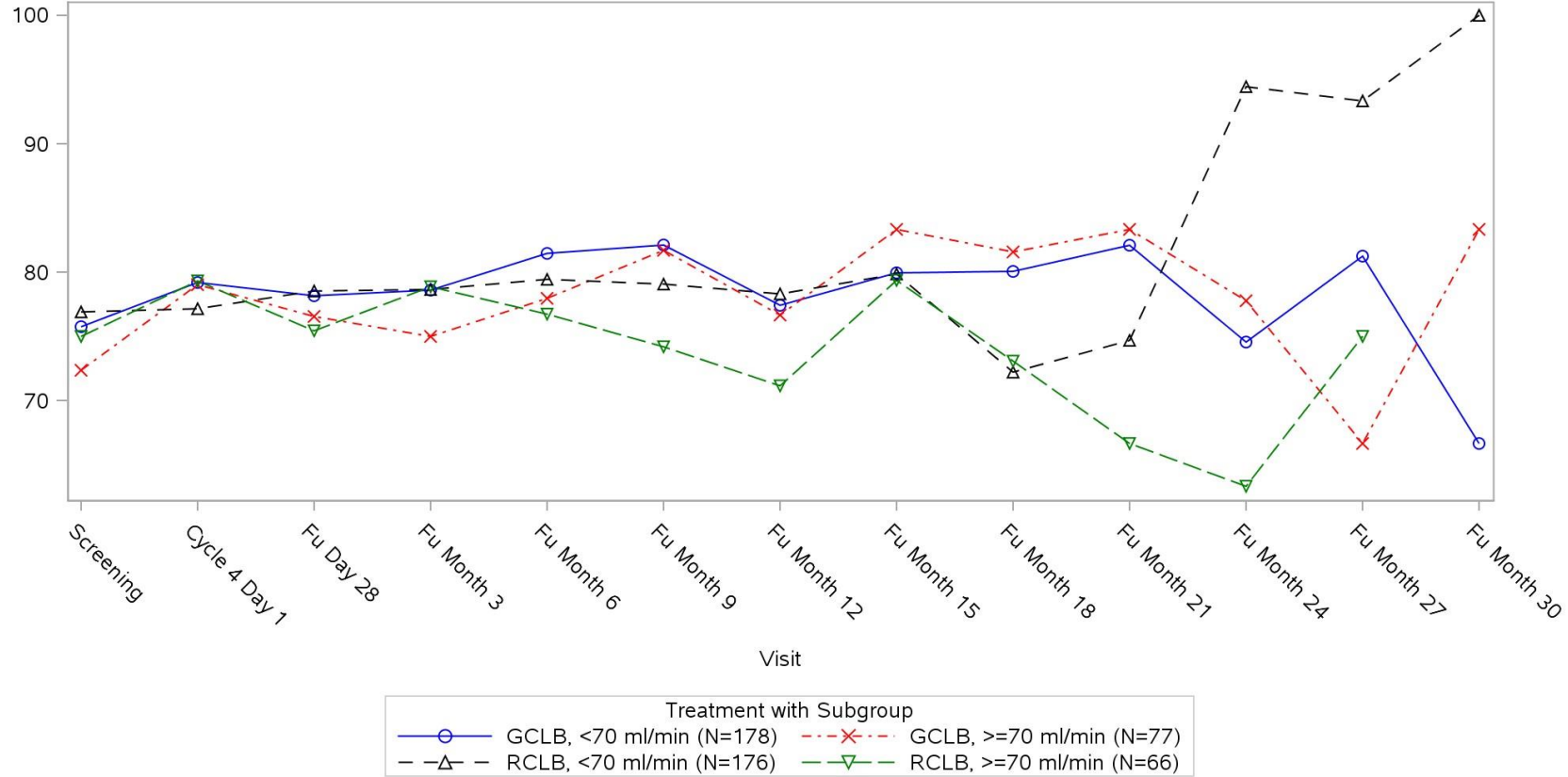
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04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Calculated creatinine clearance cat. 2 (N=497) Laboratory Test: Role Functioning Scale



Clinical cut-off: 09MAY2013

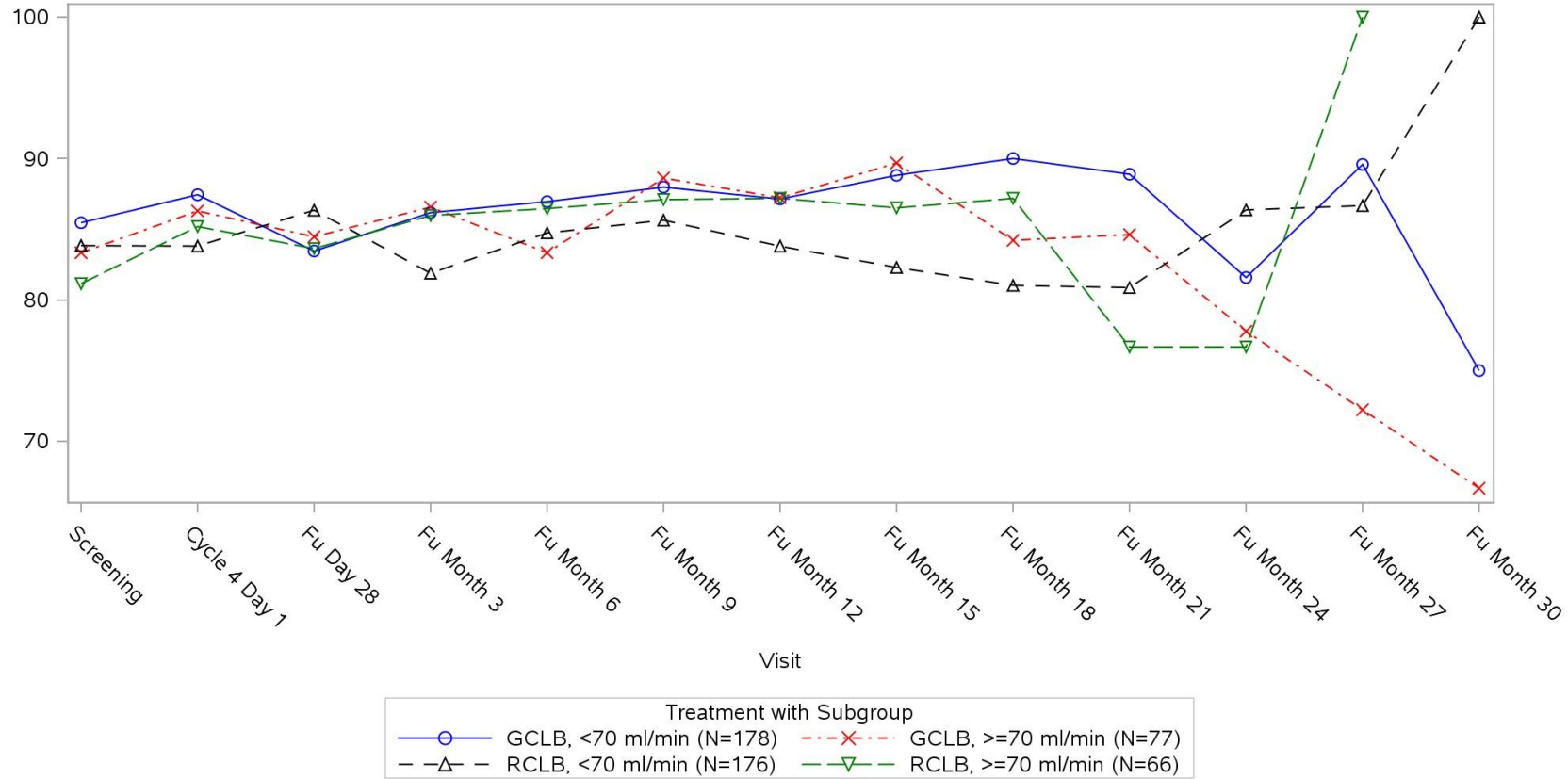
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 04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Calculated creatinine clearance cat. 2 (N=497) Laboratory Test: Social Functioning Scale



Clinical cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/g_pro_mean.sas
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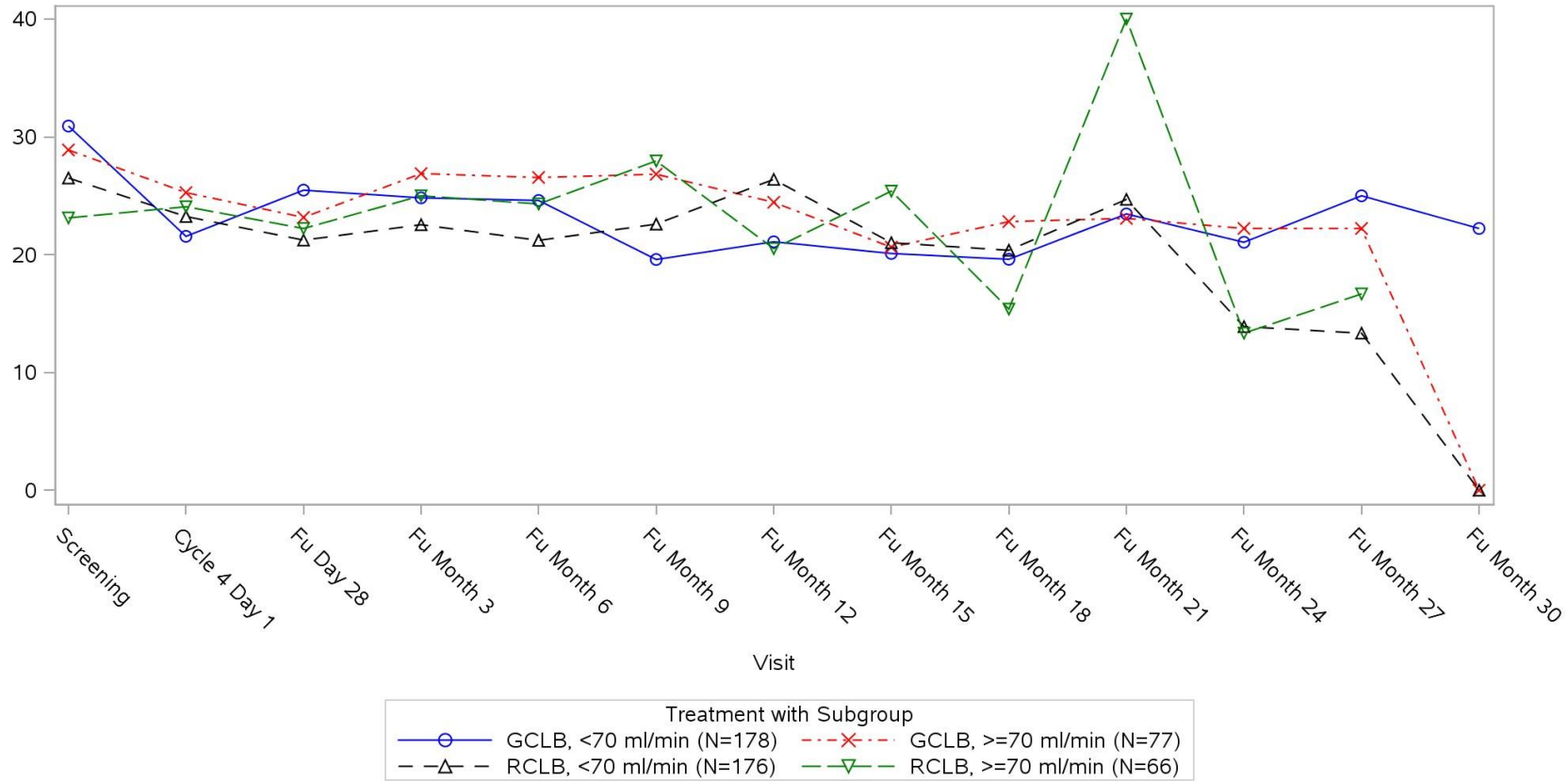
Page 44 of 195

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Calculated creatinine clearance cat. 2 (N=497) Laboratory Test: Insomnia Scale



Clinical cut-off: 09MAY2013

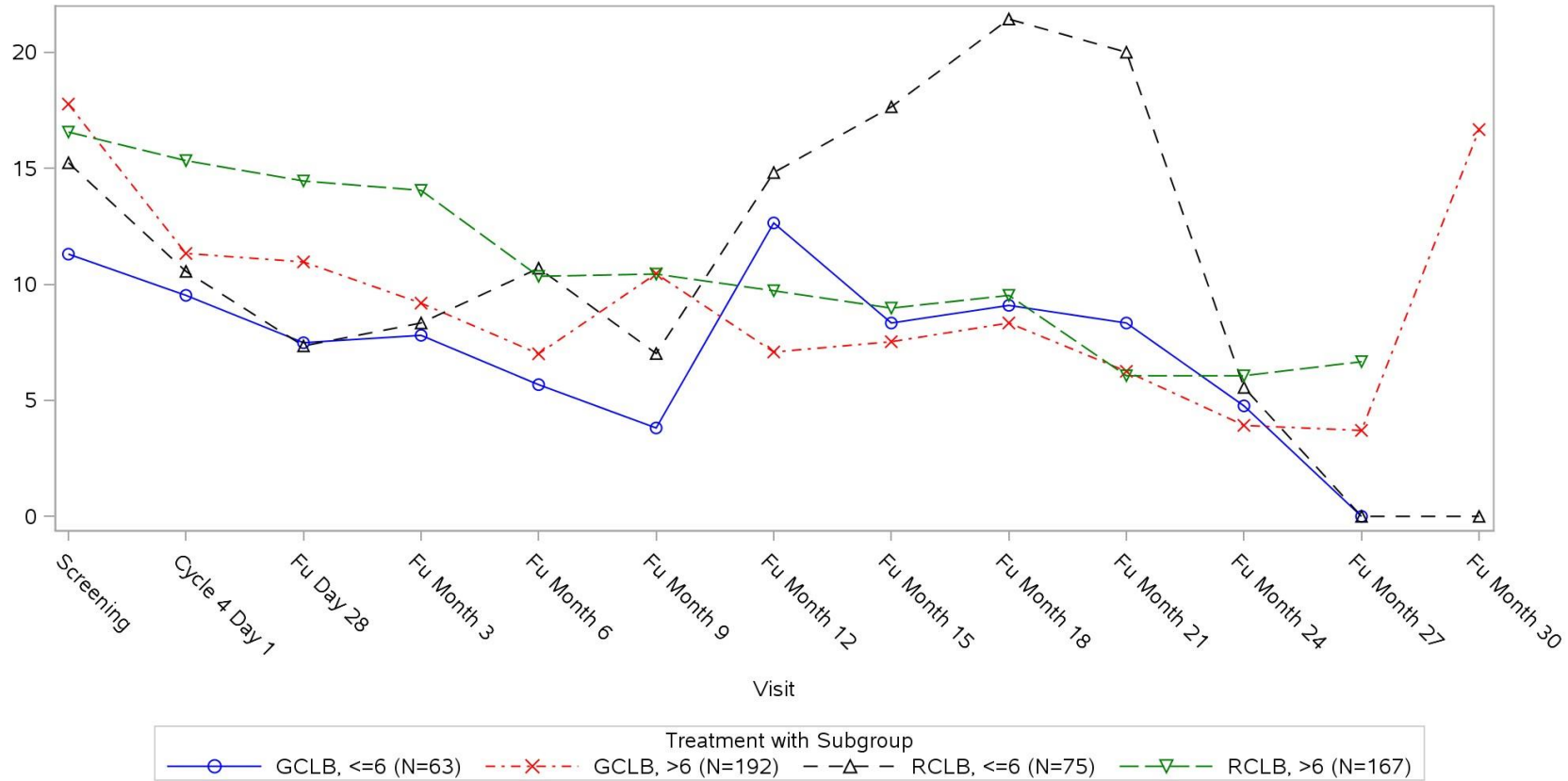
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04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Total CIR score at baseline (N=497) Laboratory Test: Appetite Loss Scale



Clinical cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/g_pro_mean.sas
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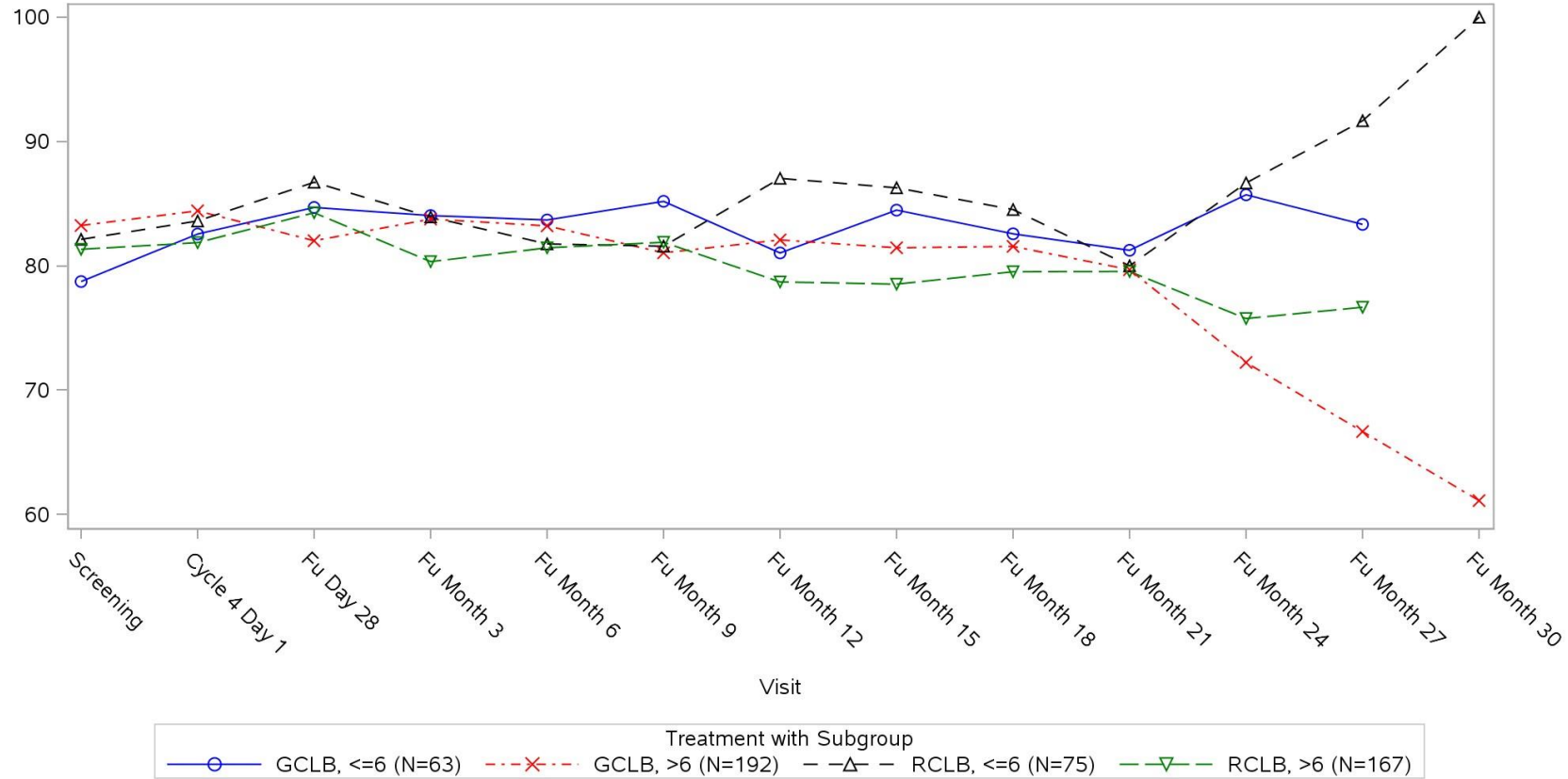
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Total CIR score at baseline (N=497) Laboratory Test: Cognitive Functioning Scale



Clinical cut-off: 09MAY2013

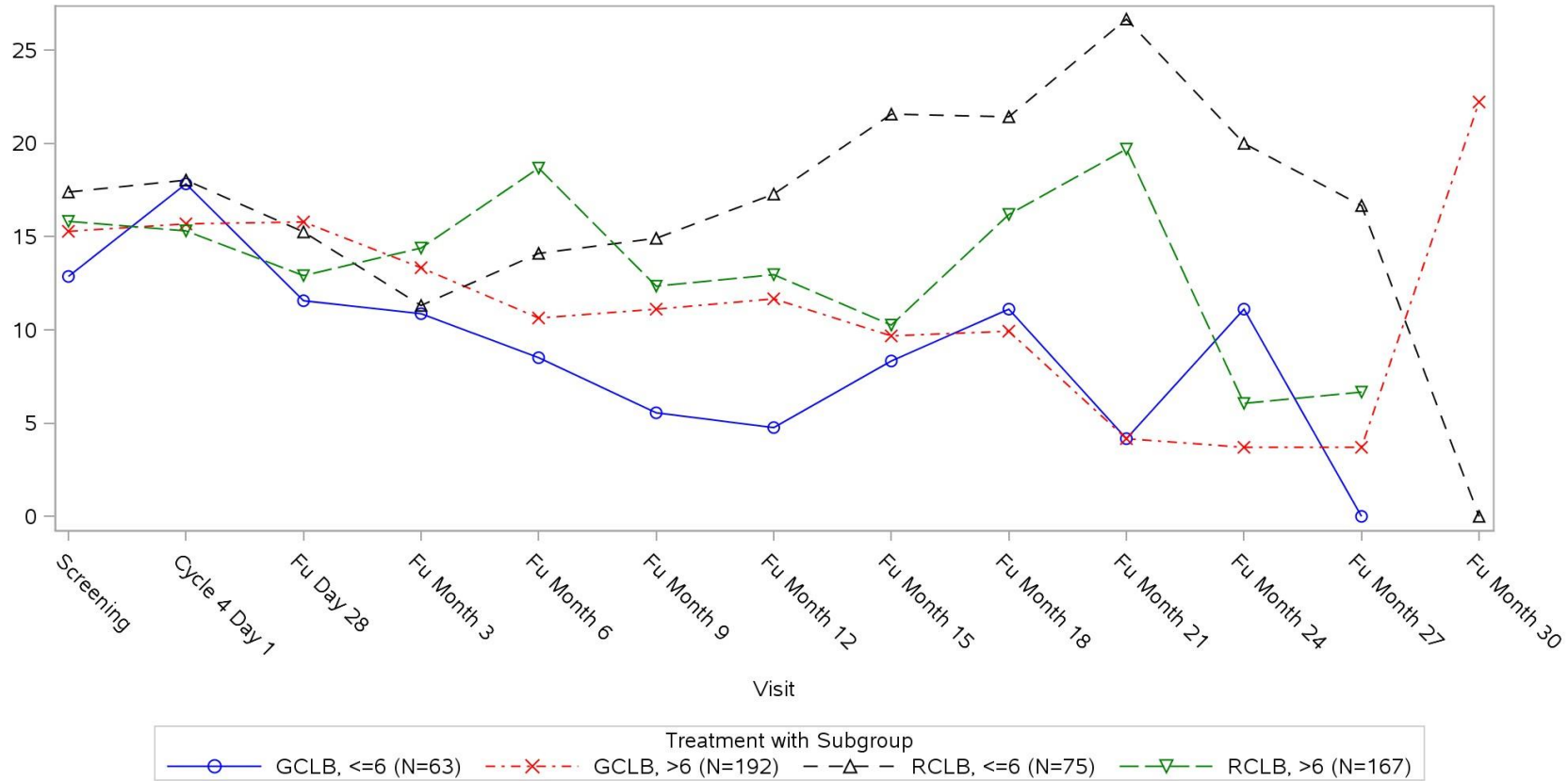
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Total CIR score at baseline (N=497) Laboratory Test: Constipation Scale



Clinical cut-off: 09MAY2013

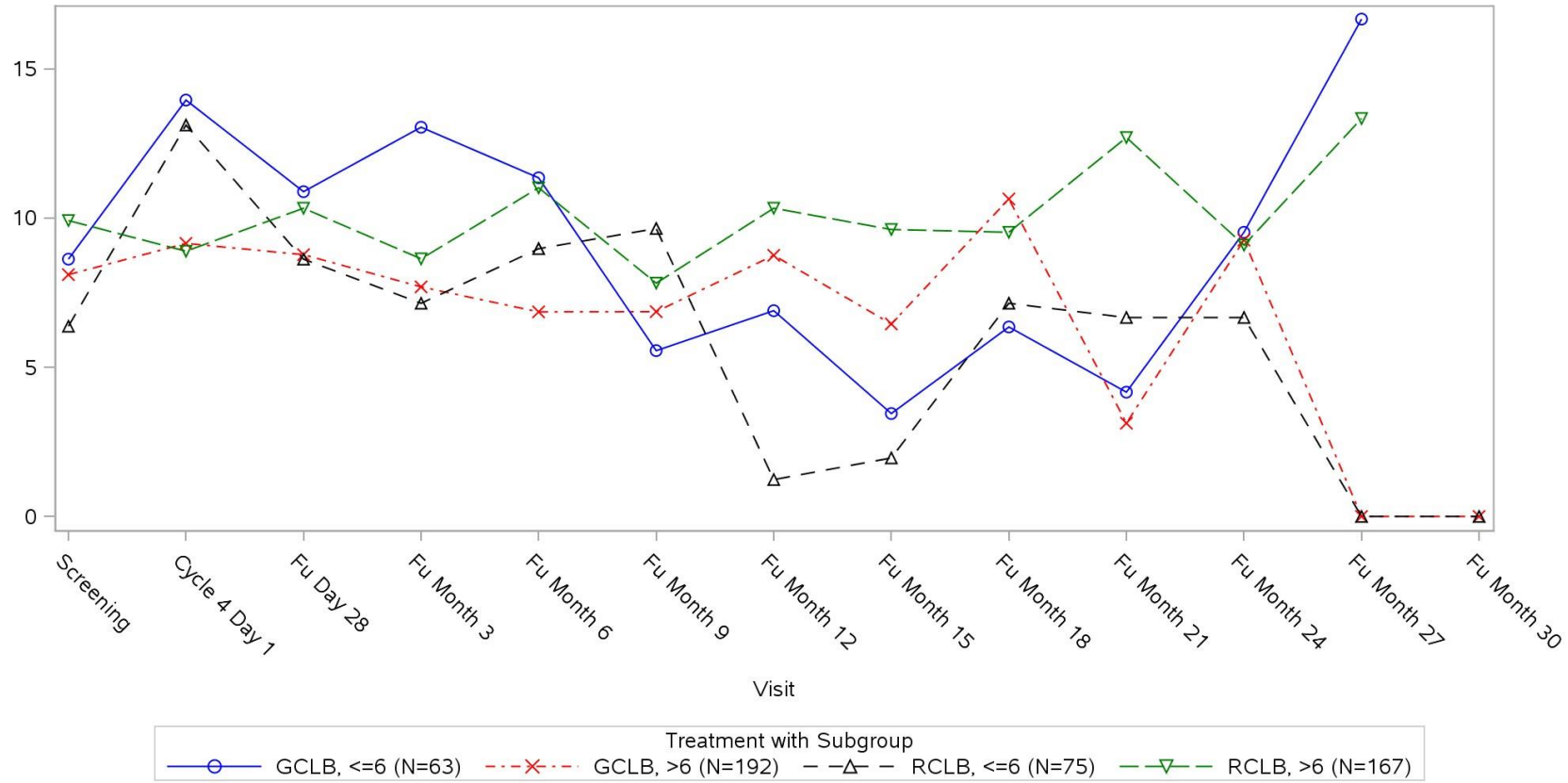
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Total CIR score at baseline (N=497) Laboratory Test: Diarrhoea Scale



Clinical cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/g_pro_mean.sas
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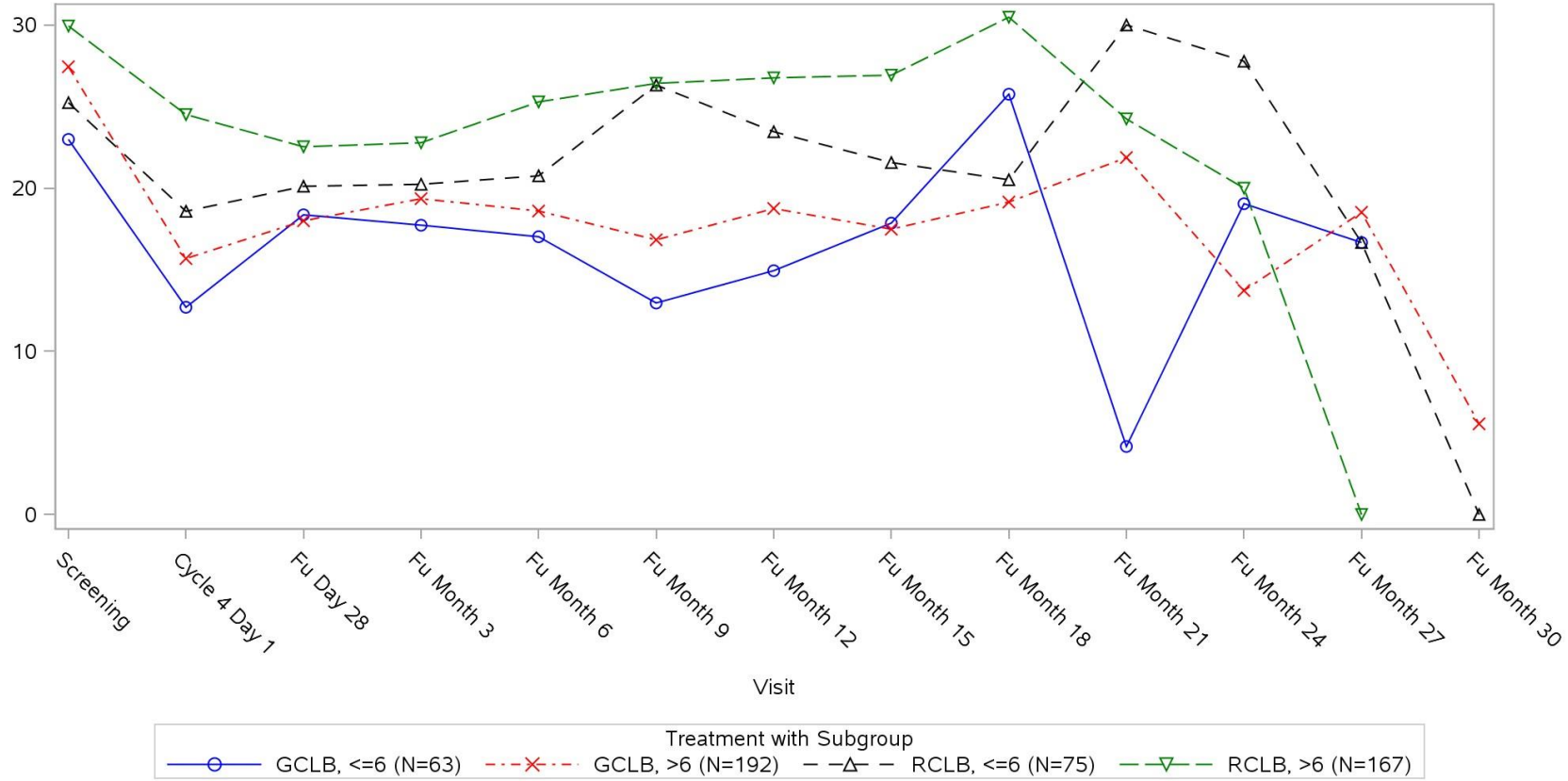
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Total CIR score at baseline (N=497) Laboratory Test: Dyspnoea Scale



Clinical cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/g_pro_mean.sas
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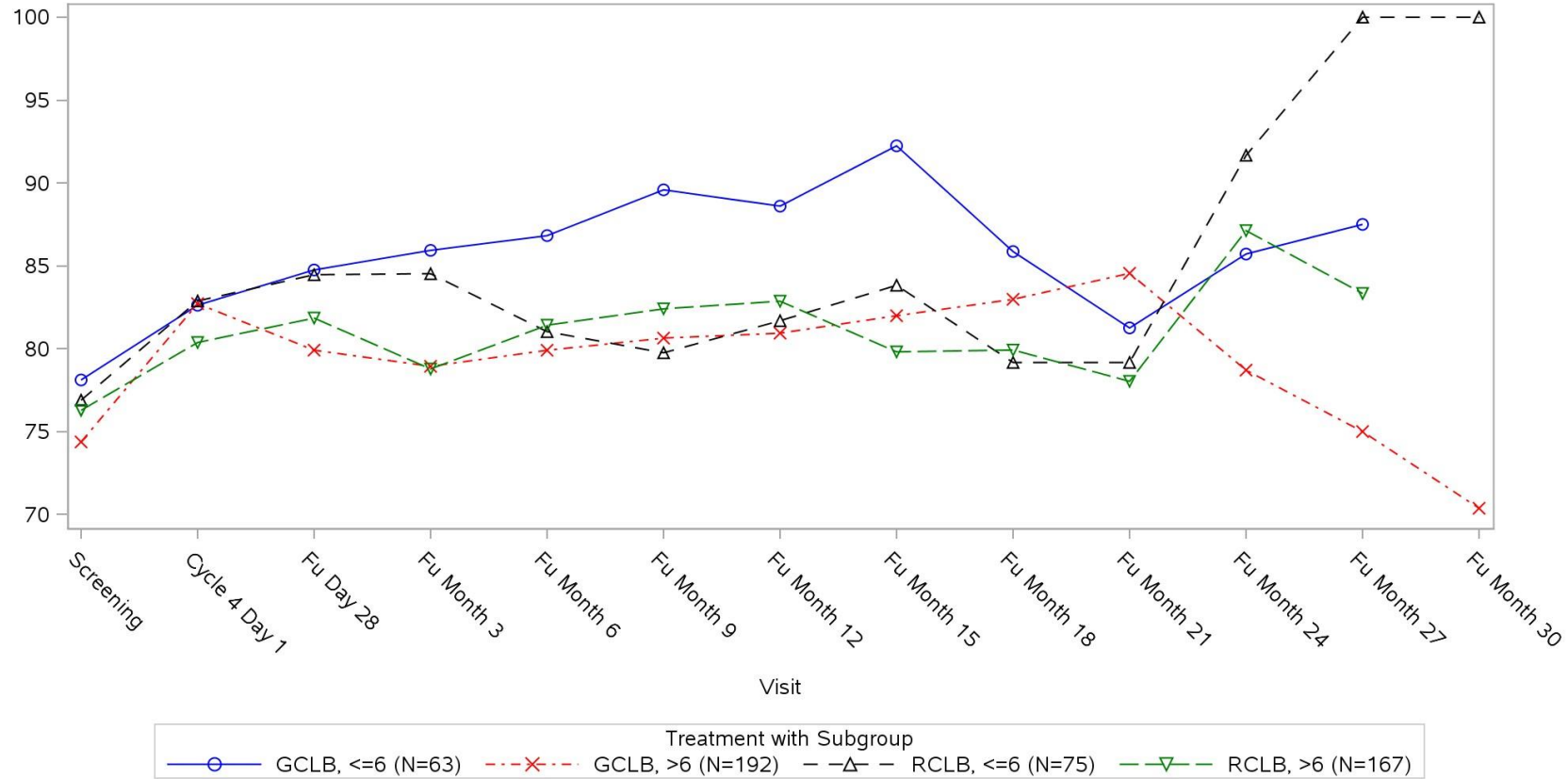
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Total CIR score at baseline (N=497) Laboratory Test: Emotional Functioning Scale



Clinical cut-off: 09MAY2013

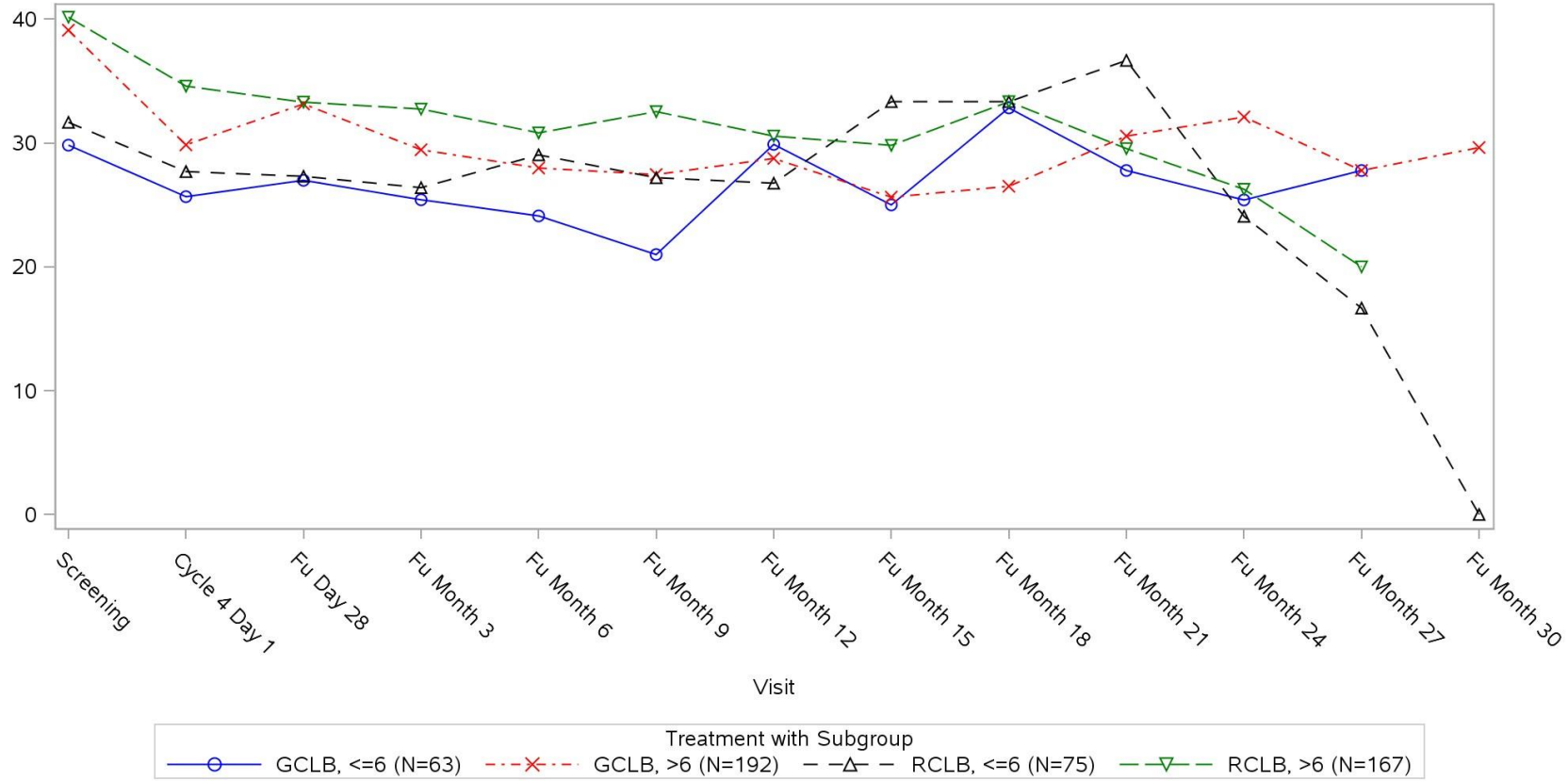
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Total CIR score at baseline (N=497) Laboratory Test: Fatigue Scale



Clinical cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/g_pro_mean.sas
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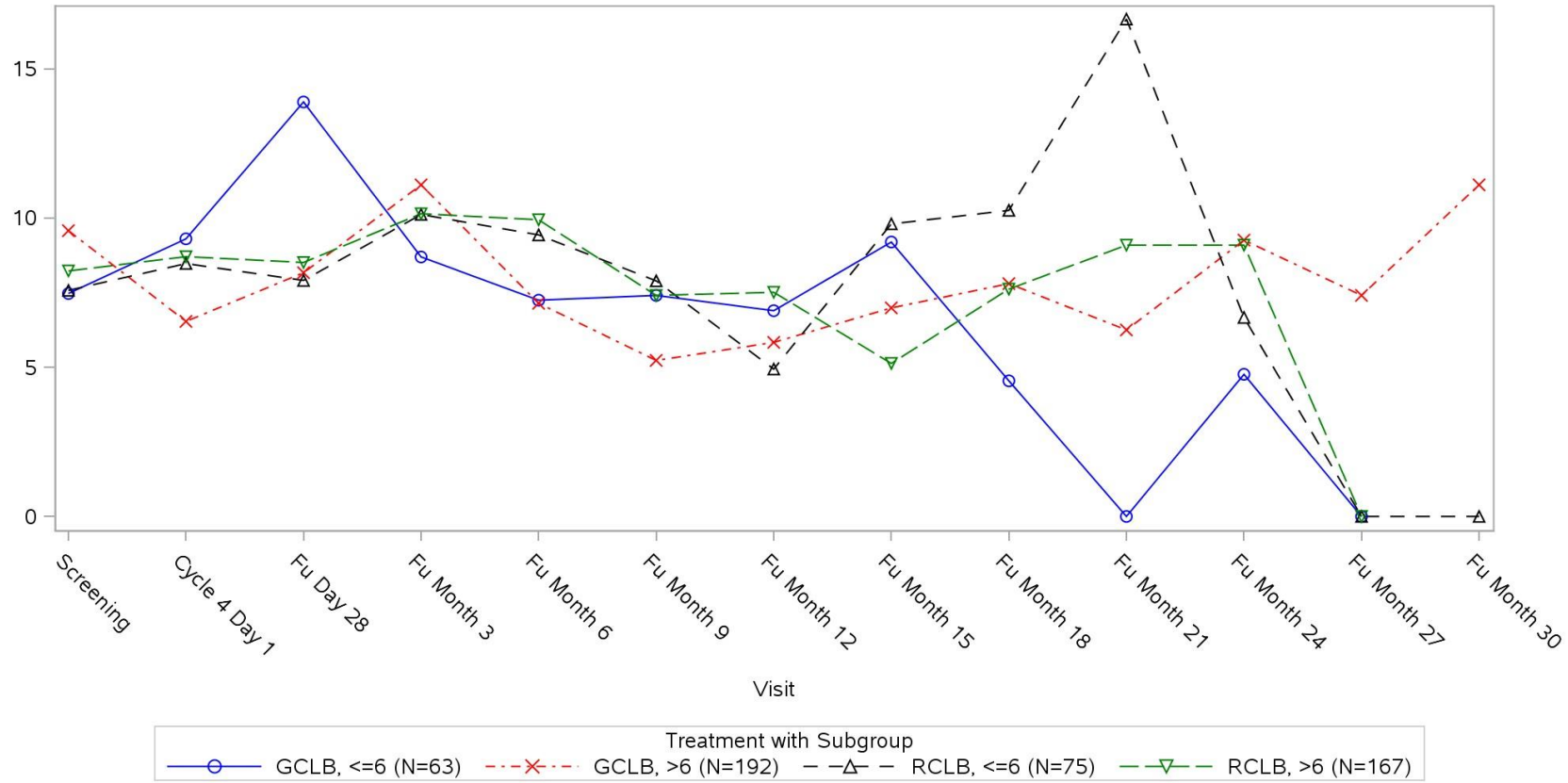
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Total CIR score at baseline (N=497) Laboratory Test: Financial Difficulties Scale



Clinical cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/g_pro_mean.sas
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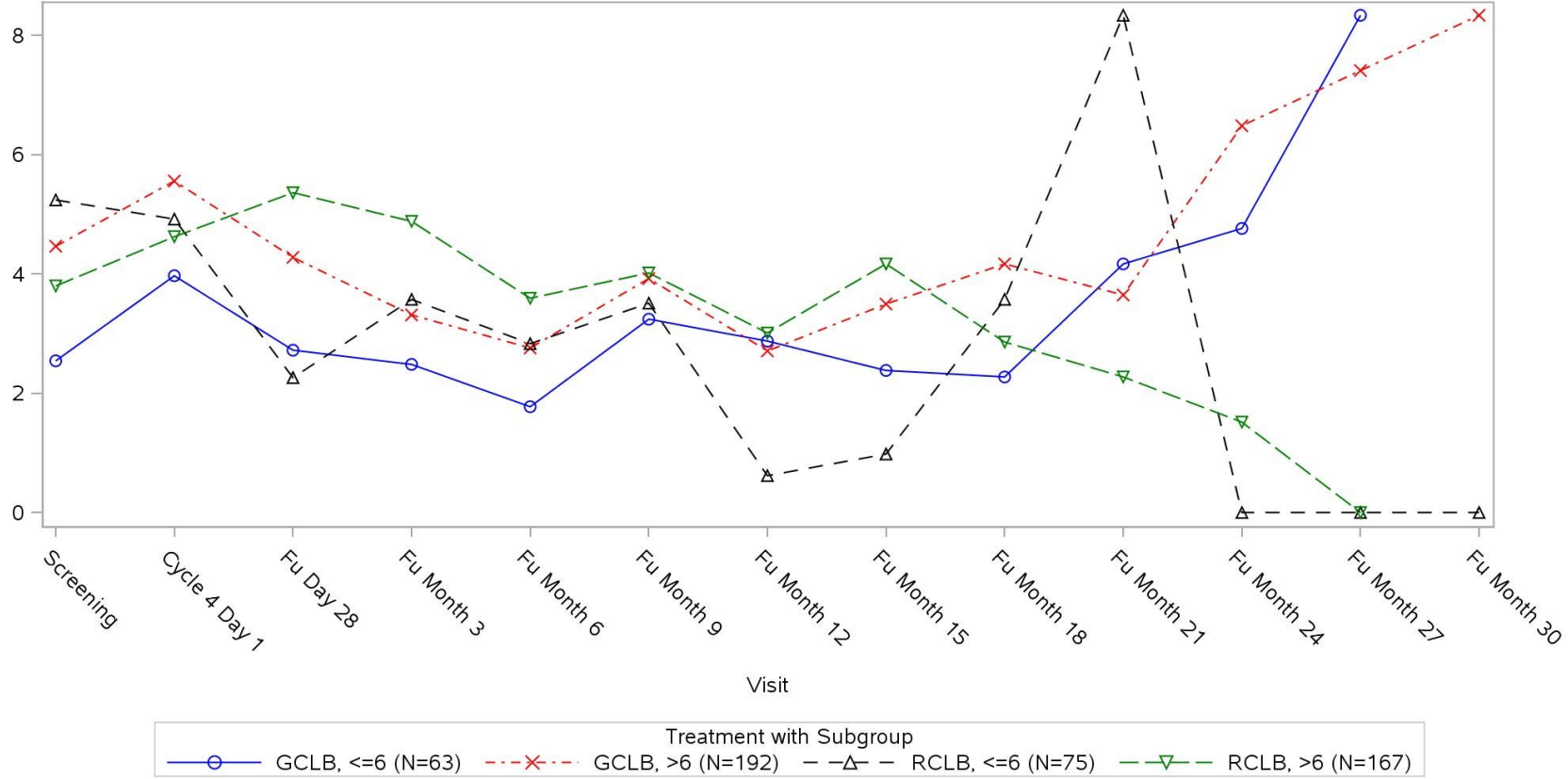
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Total CIR score at baseline (N=497) Laboratory Test: Nausea And Vomiting Scale



Clinical cut-off: 09MAY2013

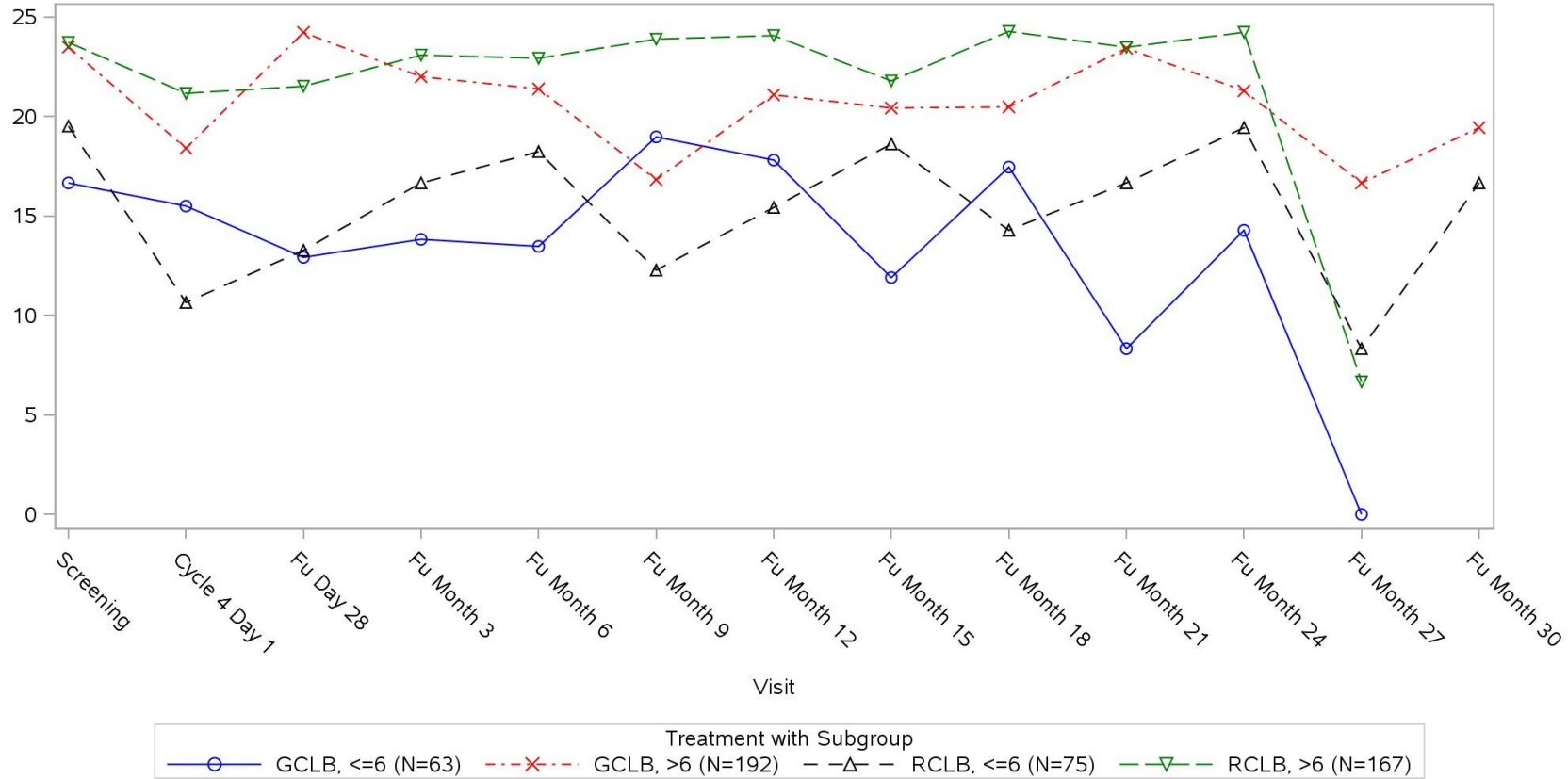
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Total CIR score at baseline (N=497) Laboratory Test: Pain Scale



Clinical cut-off: 09MAY2013

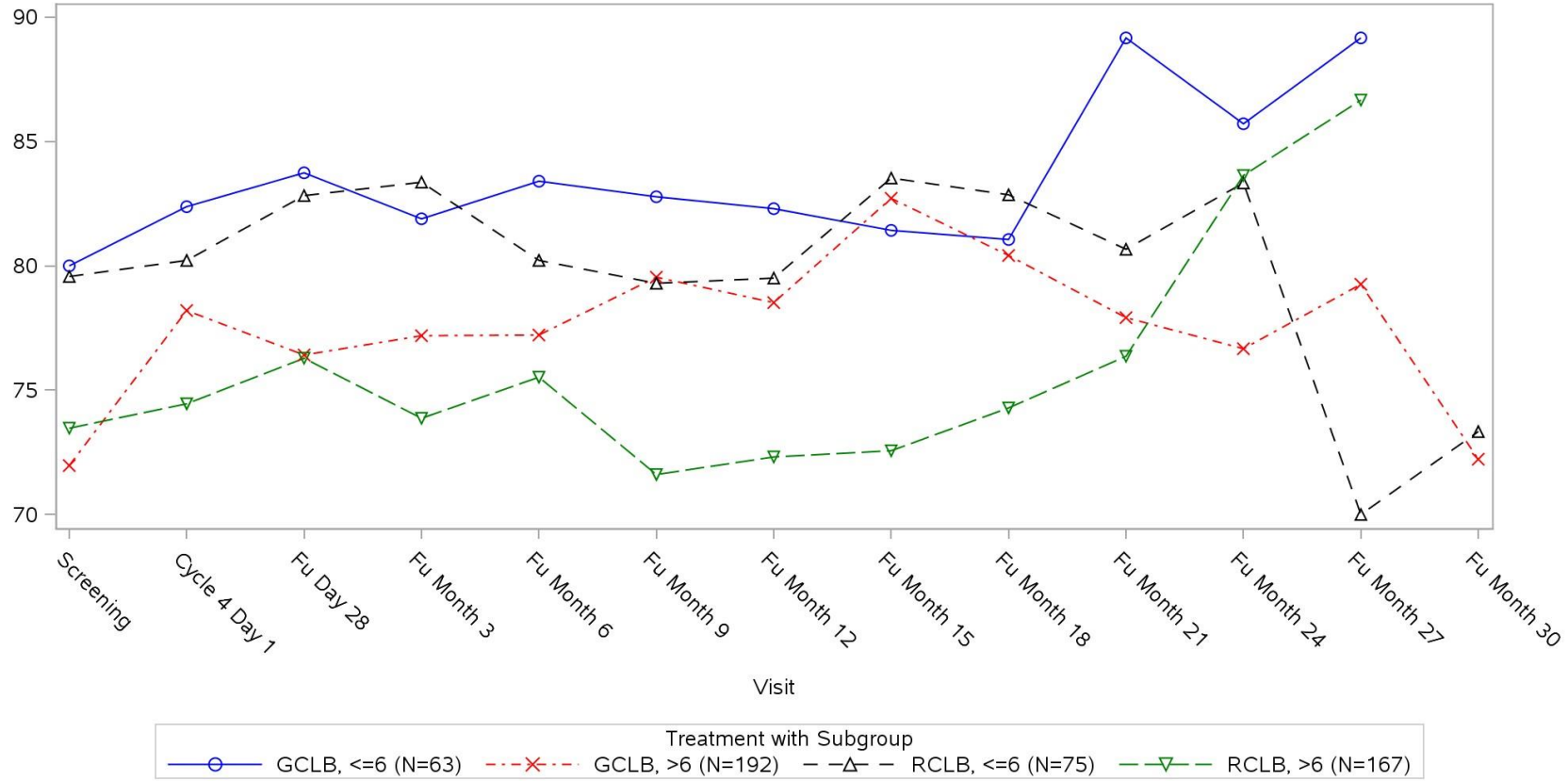
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 04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Total CIR score at baseline (N=497) Laboratory Test: Physical Functioning Scale



Clinical cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/g_pro_mean.sas
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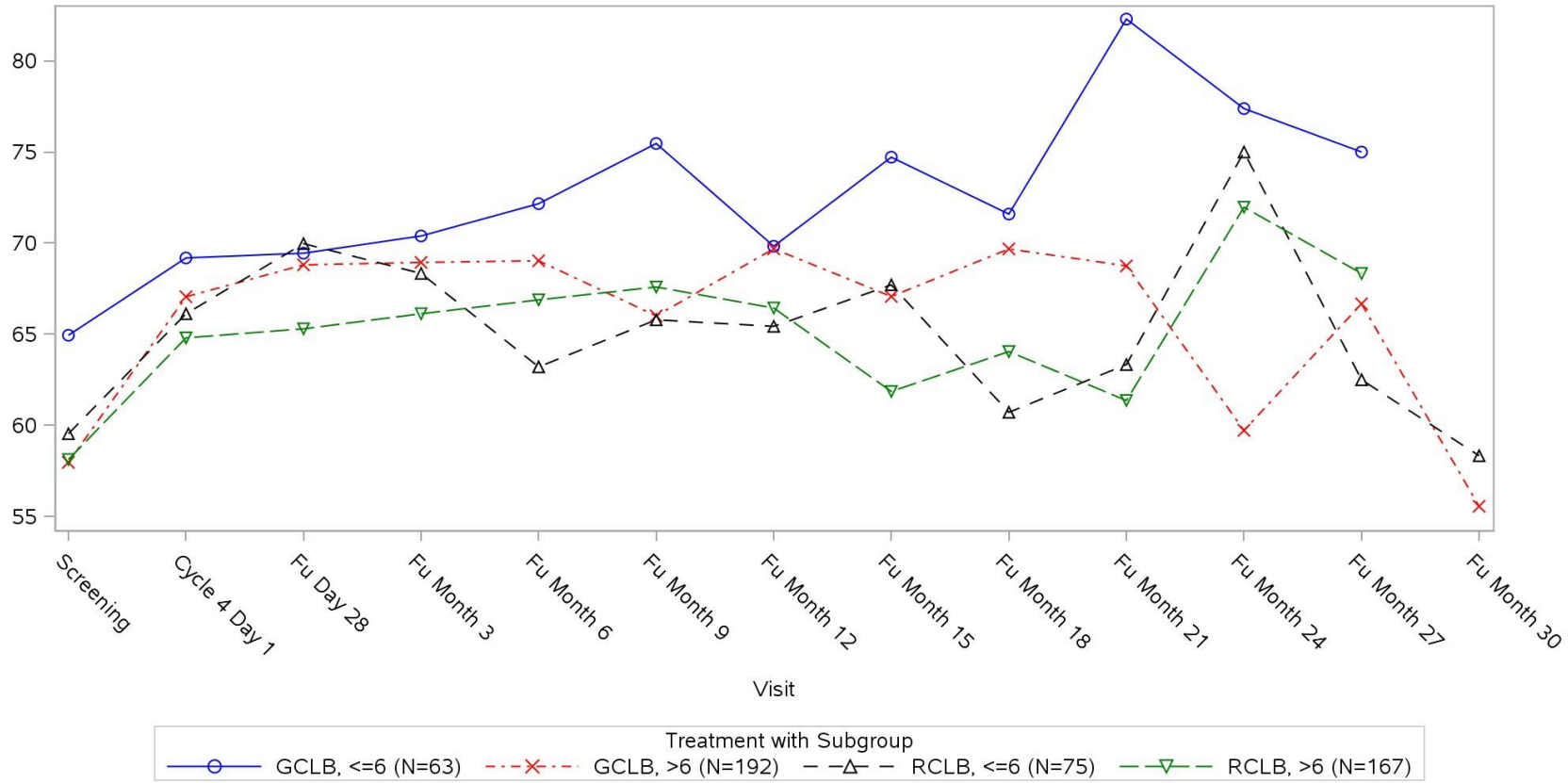
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Total CIR score at baseline (N=497) Laboratory Test: Global Health Status Scale



Clinical cut-off: 09MAY2013

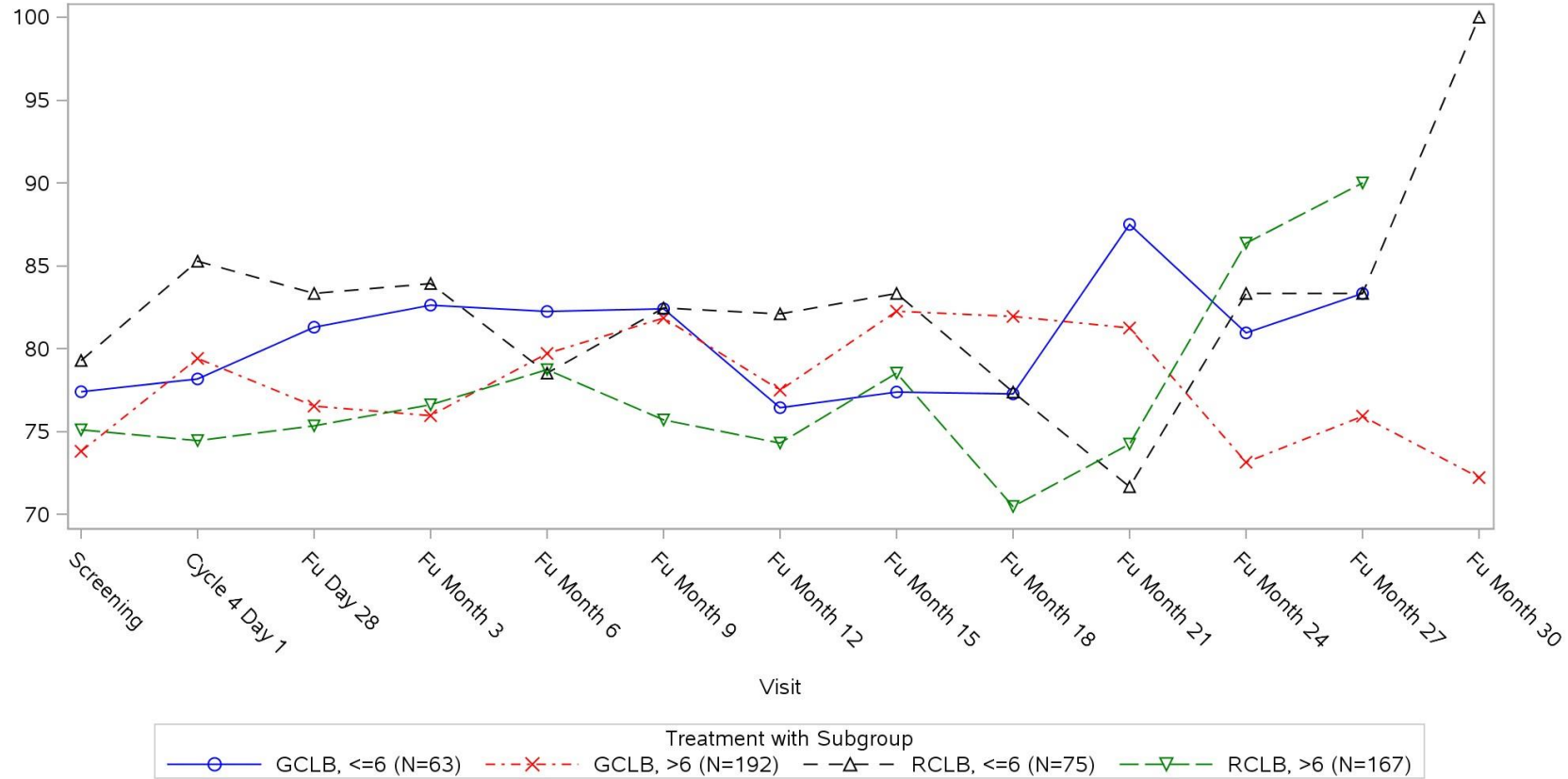
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04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Total CIR score at baseline (N=497) Laboratory Test: Role Functioning Scale



Clinical cut-off: 09MAY2013

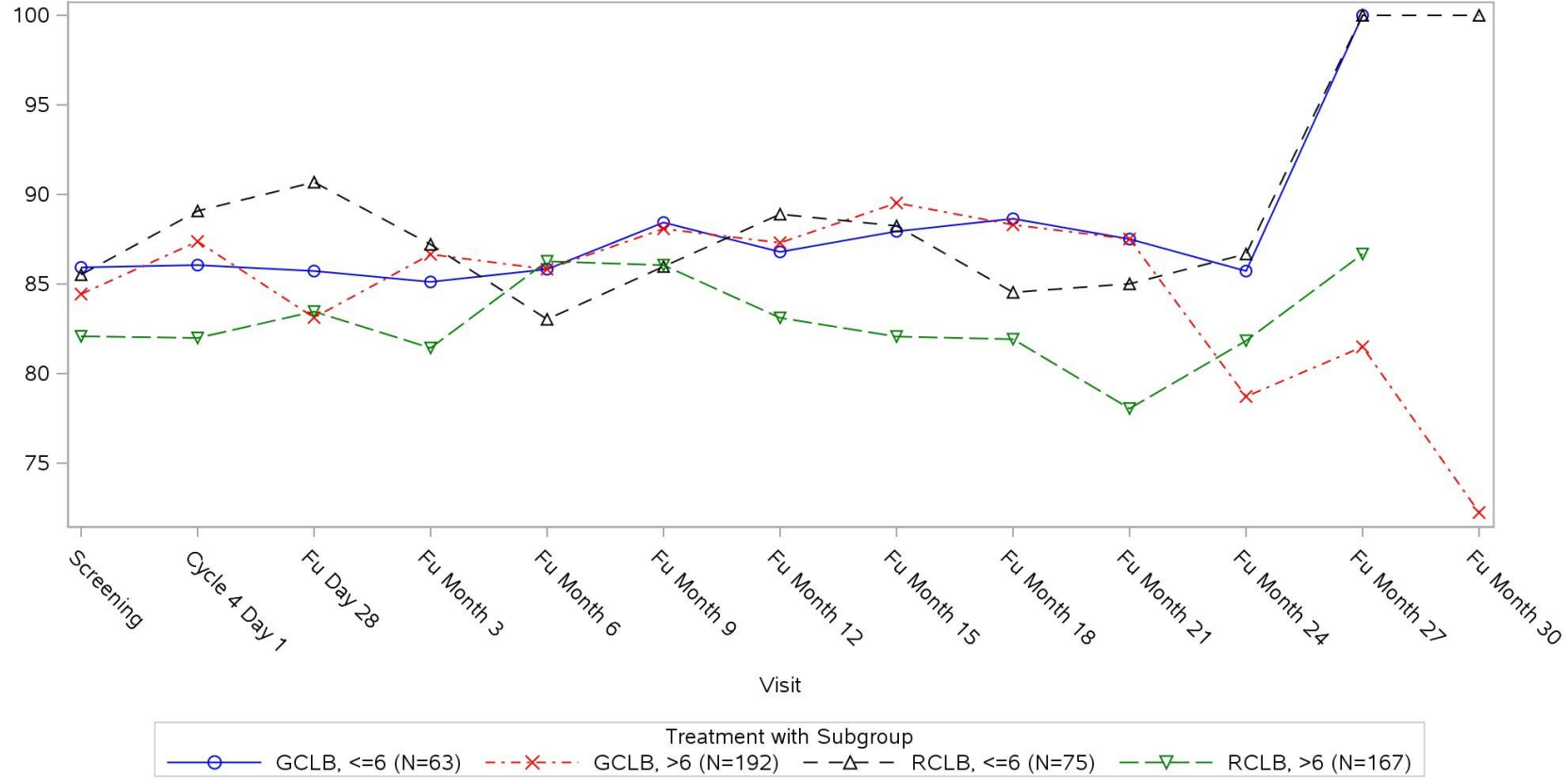
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 04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Total CIR score at baseline (N=497) Laboratory Test: Social Functioning Scale



Clinical cut-off: 09MAY2013

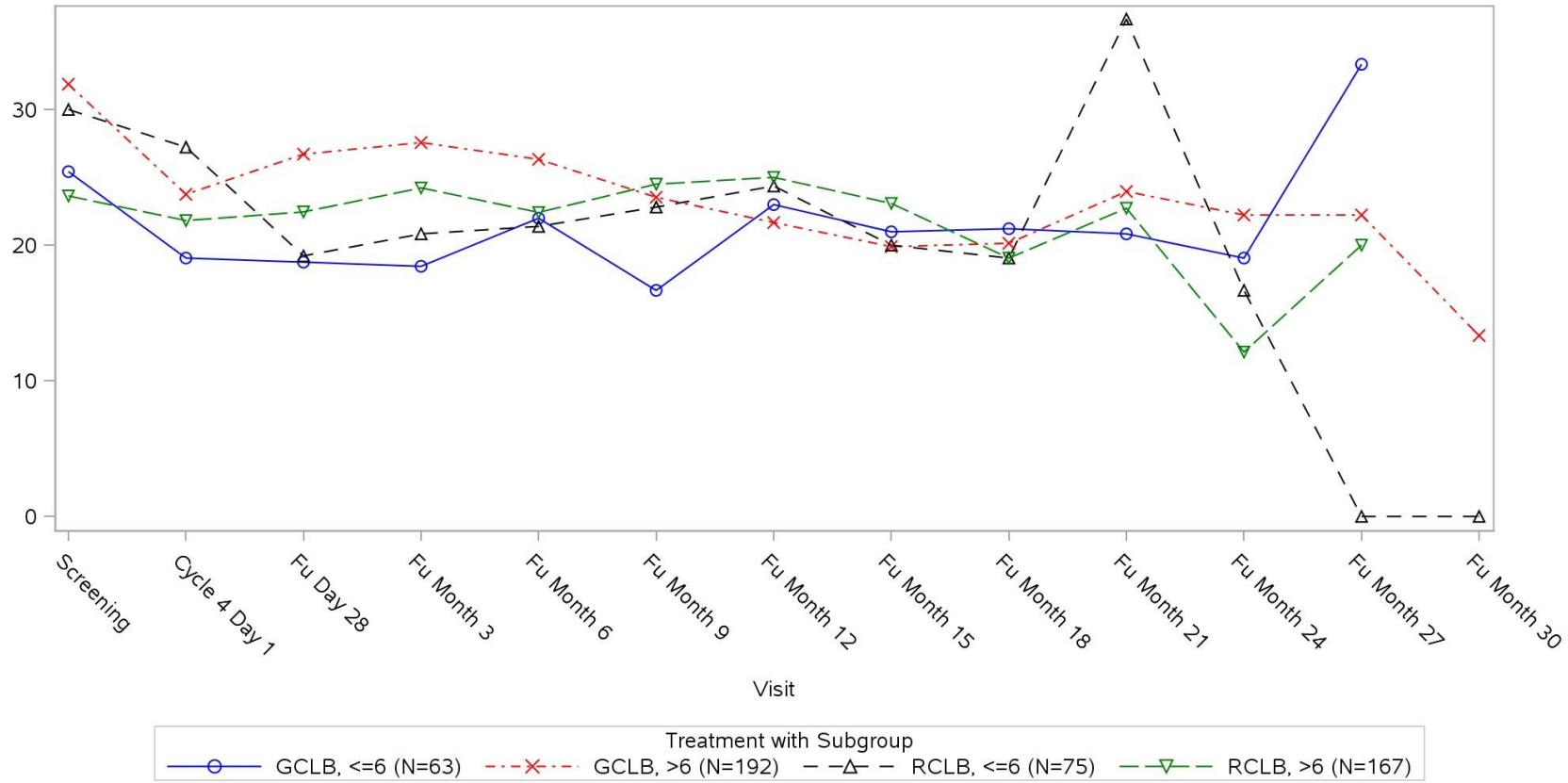
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Total CIR score at baseline (N=497) Laboratory Test: Insomnia Scale



Clinical cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/g_pro_mean.sas
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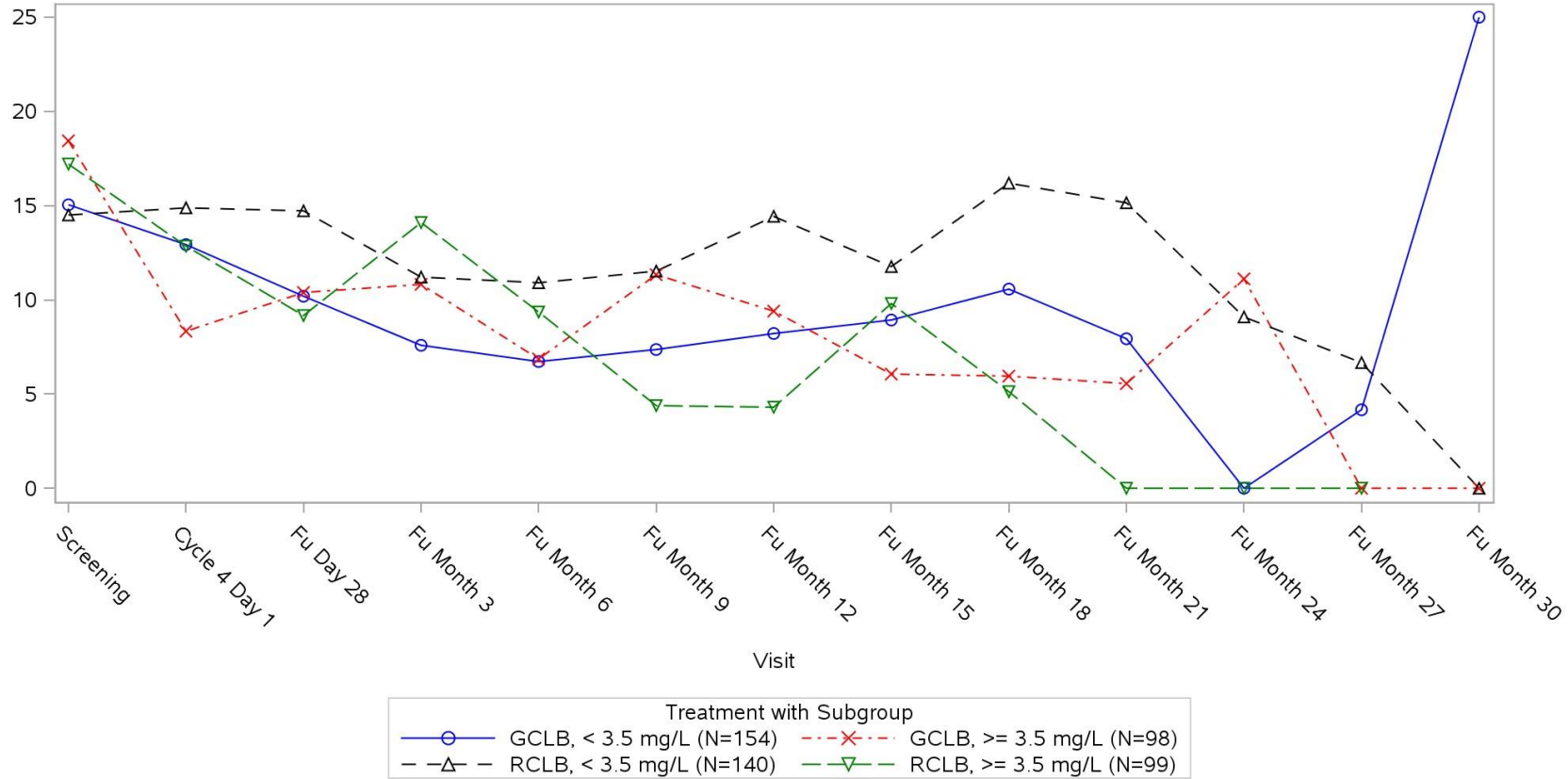
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Beta2 microglobulin (N=491) Laboratory Test: Appetite Loss Scale



Clinical cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/g_pro_mean.sas
Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/g_pro_mean_sg_EQC30_IT_label_09MAY2013_21004.pdf
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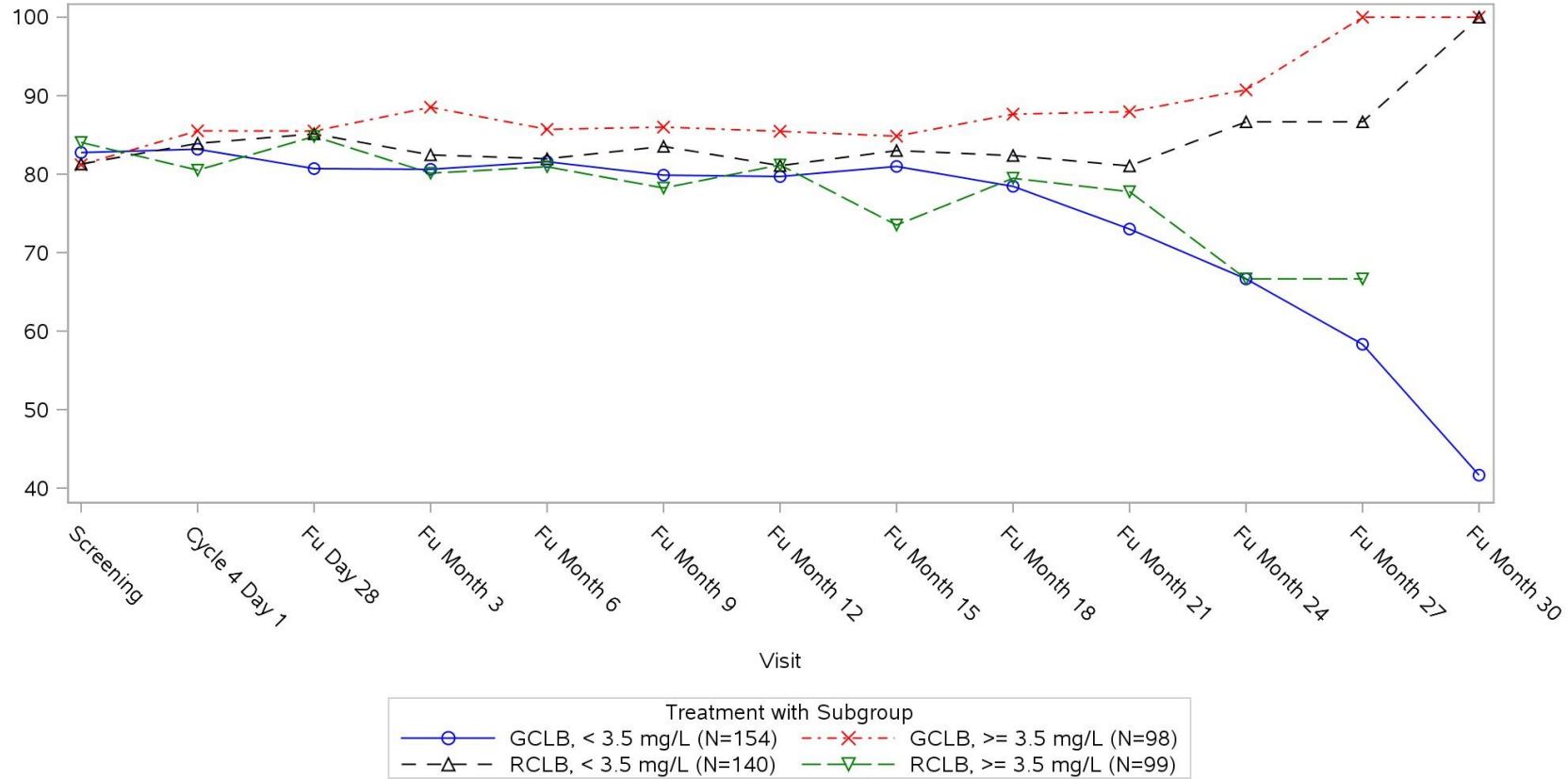
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Beta2 microglobulin (N=491) Laboratory Test: Cognitive Functioning Scale



Clinical cut-off: 09MAY2013

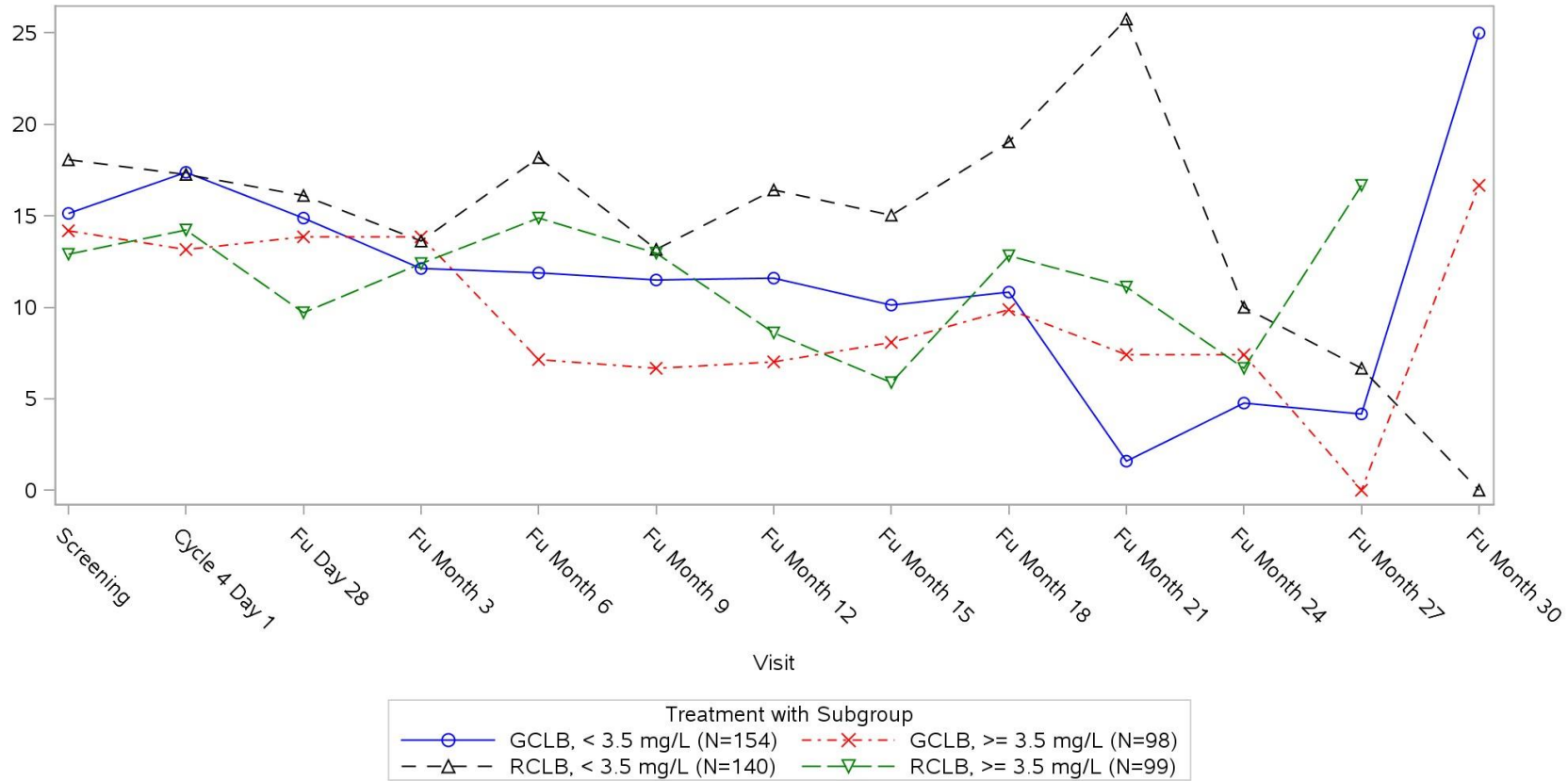
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04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Beta2 microglobulin (N=491) Laboratory Test: Constipation Scale



Clinical cut-off: 09MAY2013

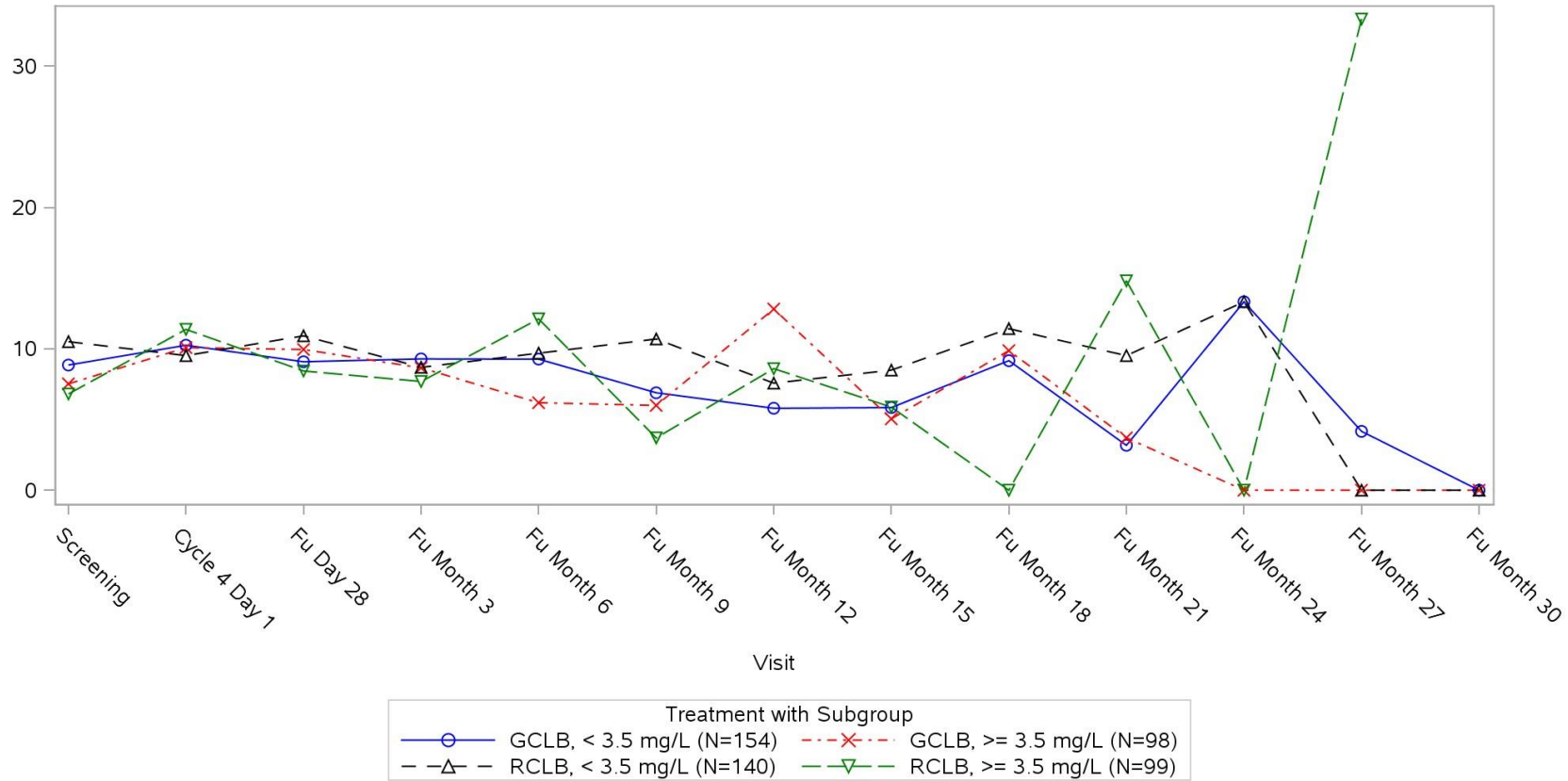
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Beta2 microglobulin (N=491) Laboratory Test: Diarrhoea Scale



Clinical cut-off: 09MAY2013

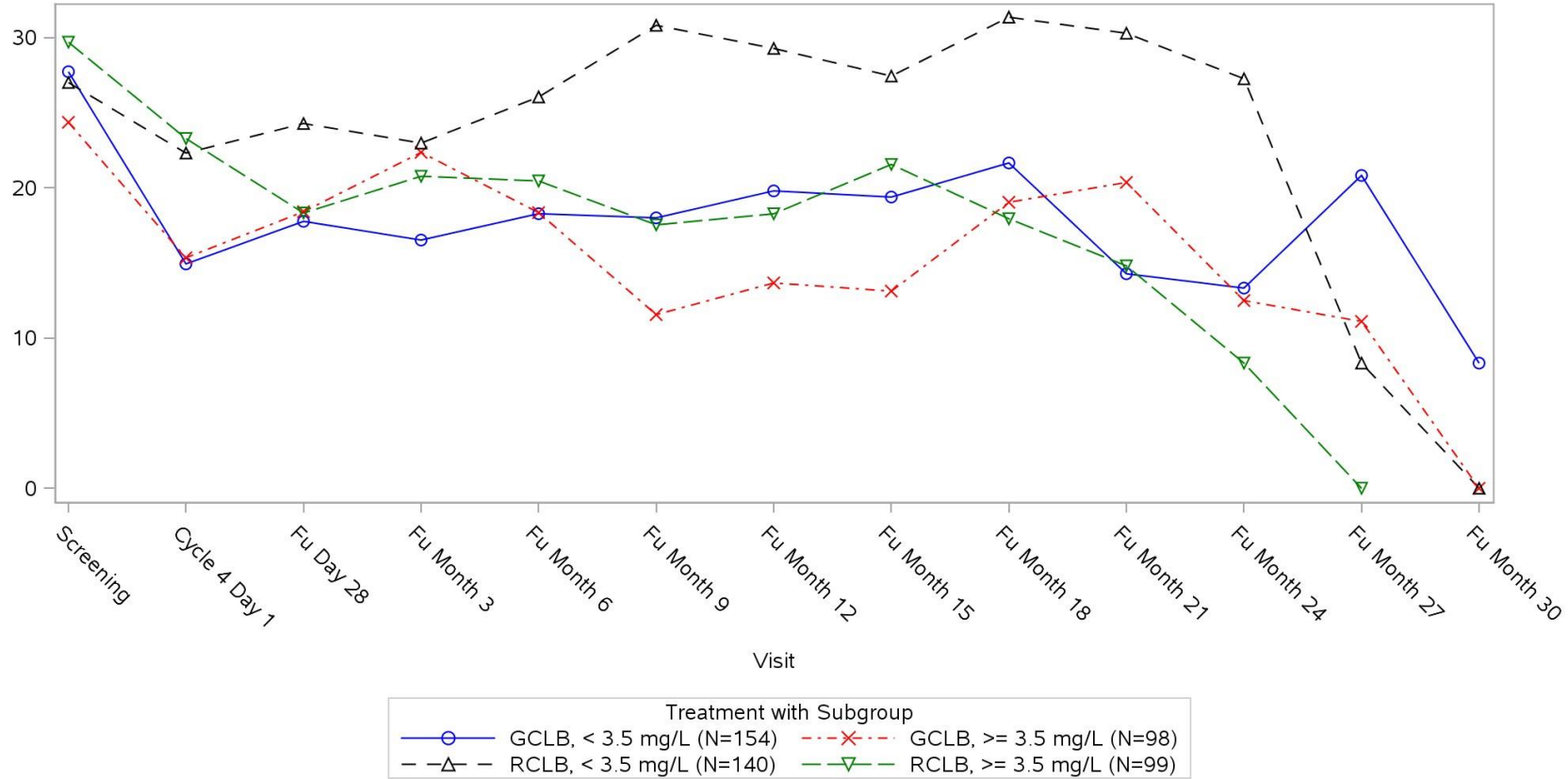
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04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Beta2 microglobulin (N=491) Laboratory Test: Dyspnoea Scale



Clinical cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/g_pro_mean.sas
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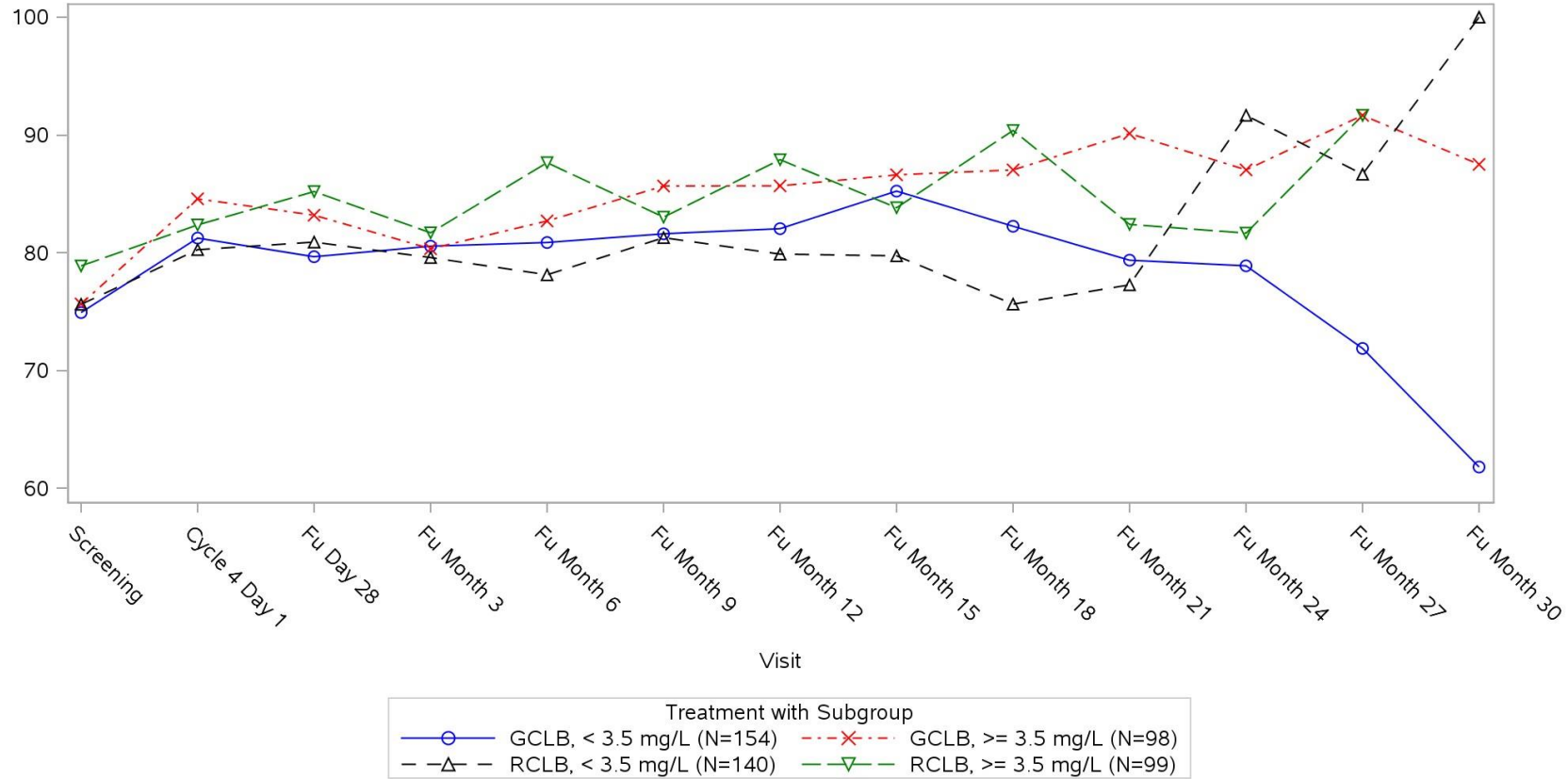
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Beta2 microglobulin (N=491) Laboratory Test: Emotional Functioning Scale



Clinical cut-off: 09MAY2013

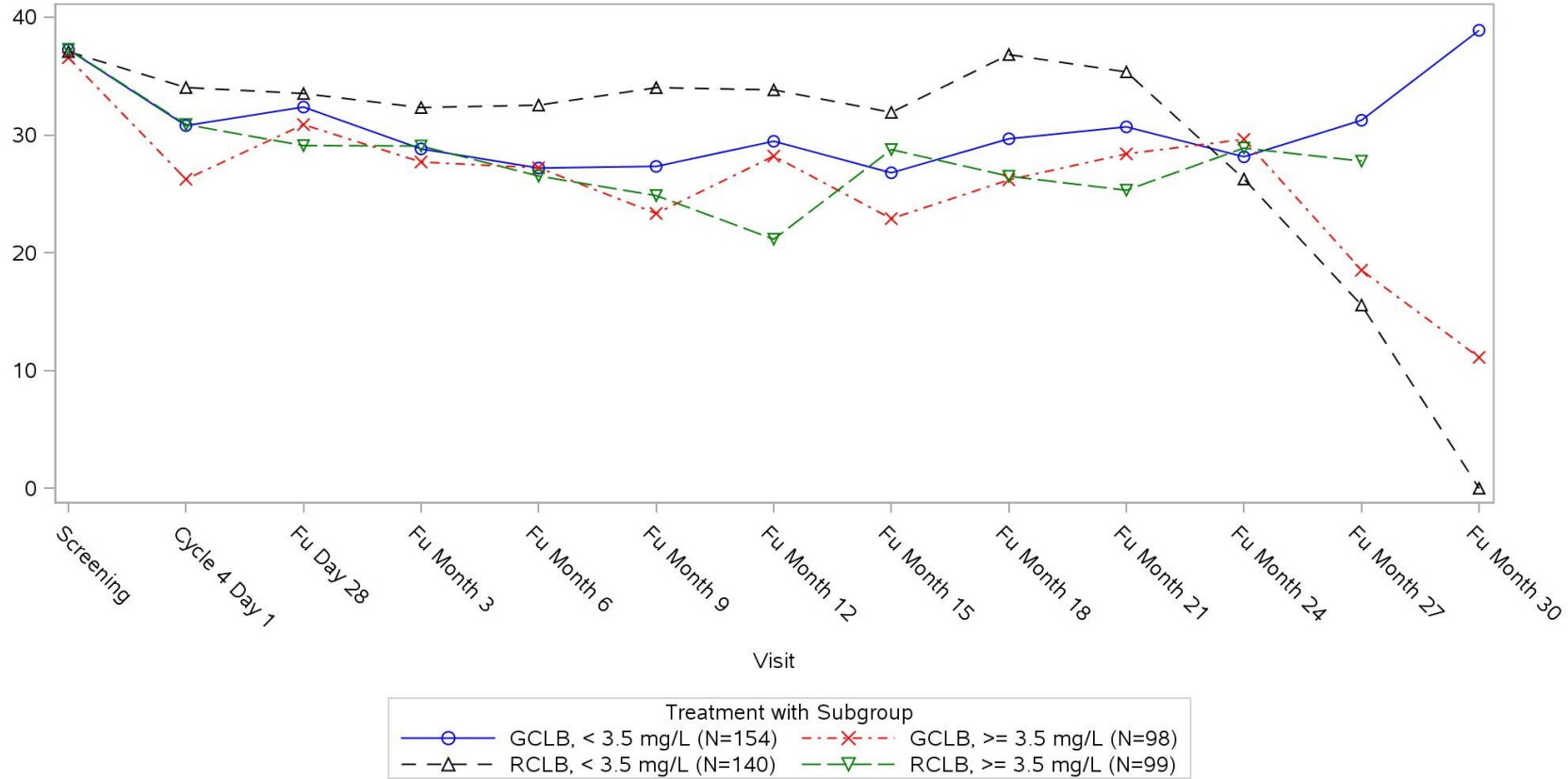
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 04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Beta2 microglobulin (N=491) Laboratory Test: Fatigue Scale



Clinical cut-off: 09MAY2013

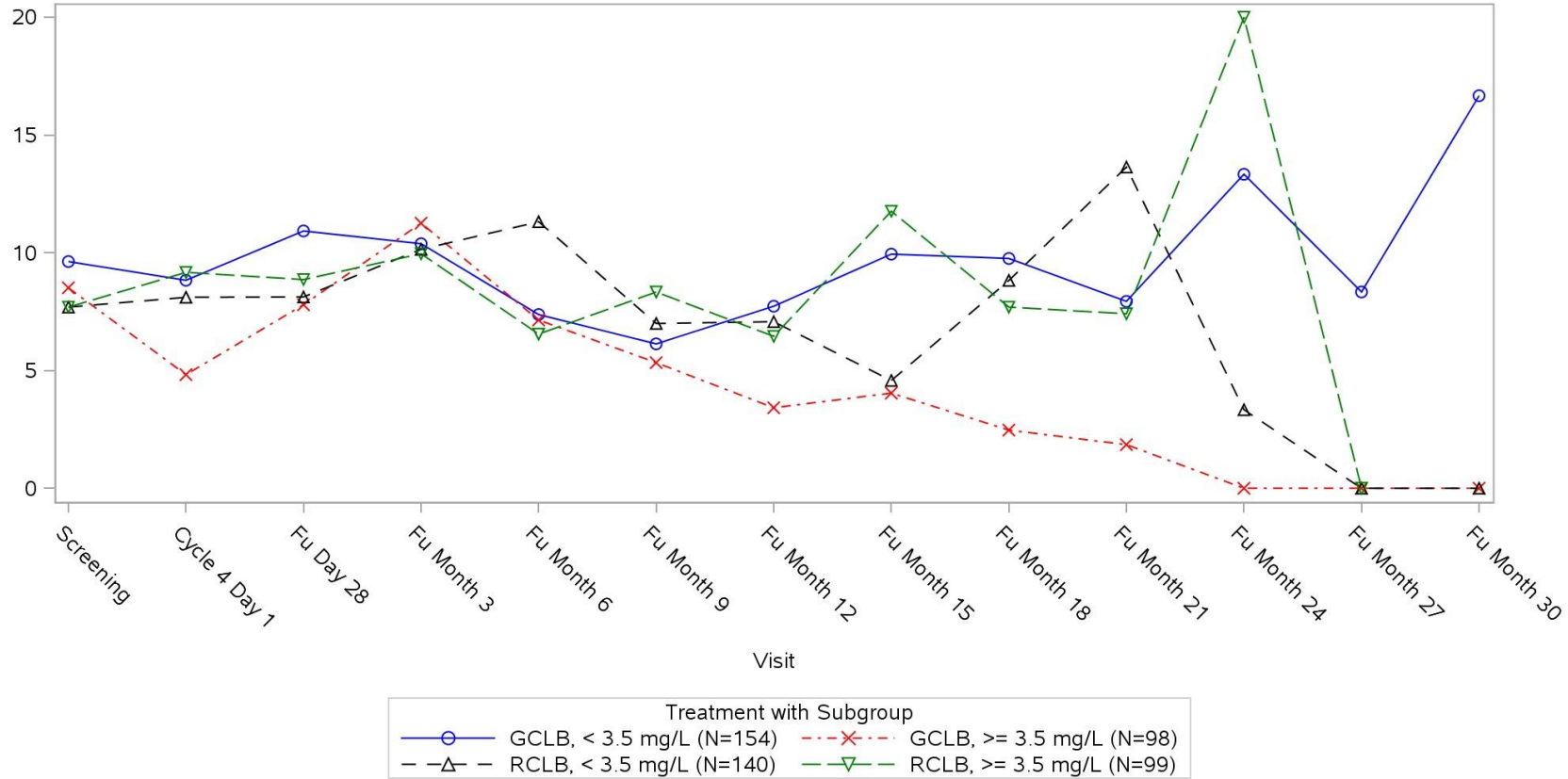
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Beta2 microglobulin (N=491) Laboratory Test: Financial Difficulties Scale



Clinical cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/g_pro_mean.sas
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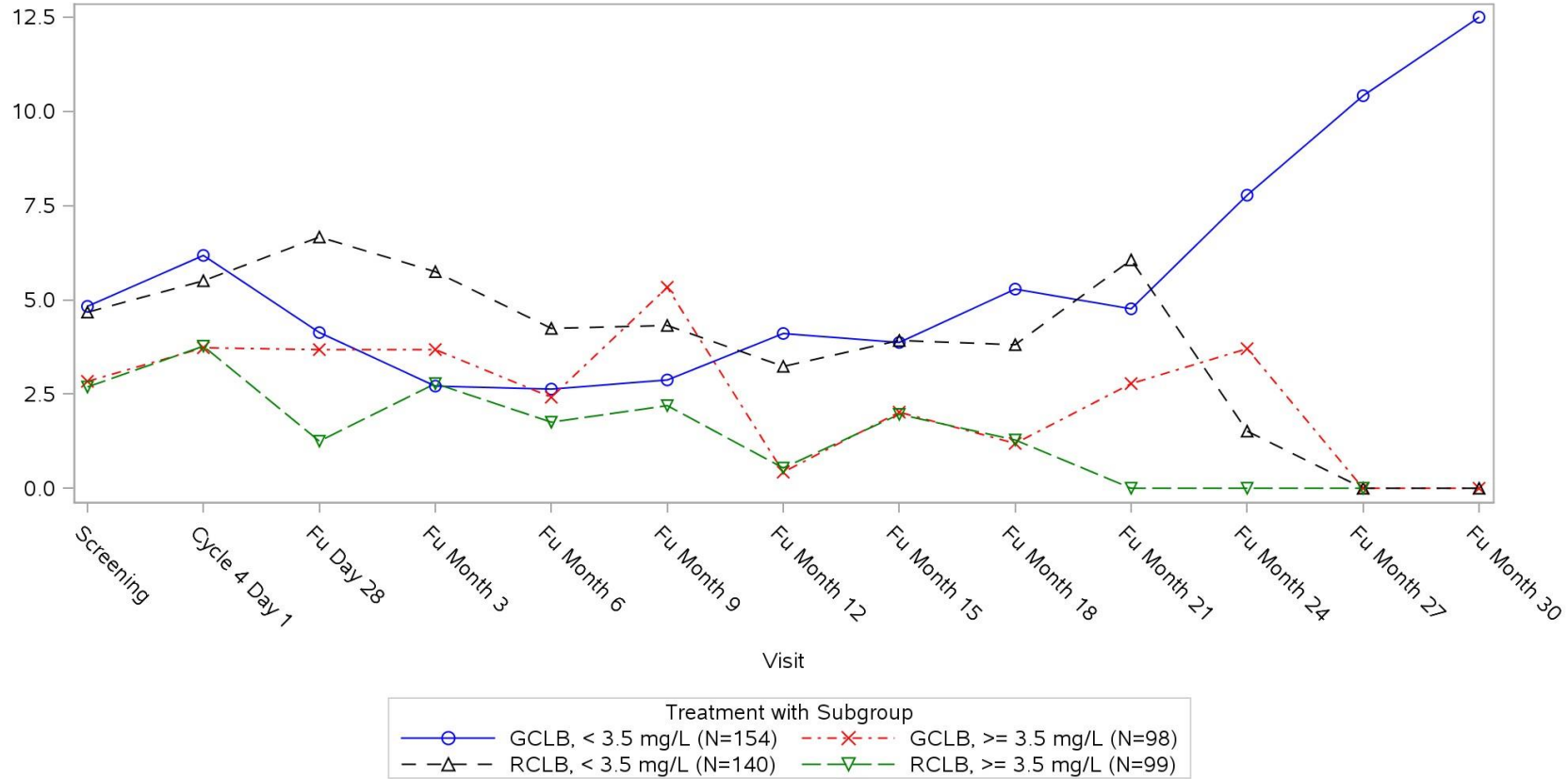
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Beta2 microglobulin (N=491) Laboratory Test: Nausia And Vomiting Scale



Clinical cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/g_pro_mean.sas
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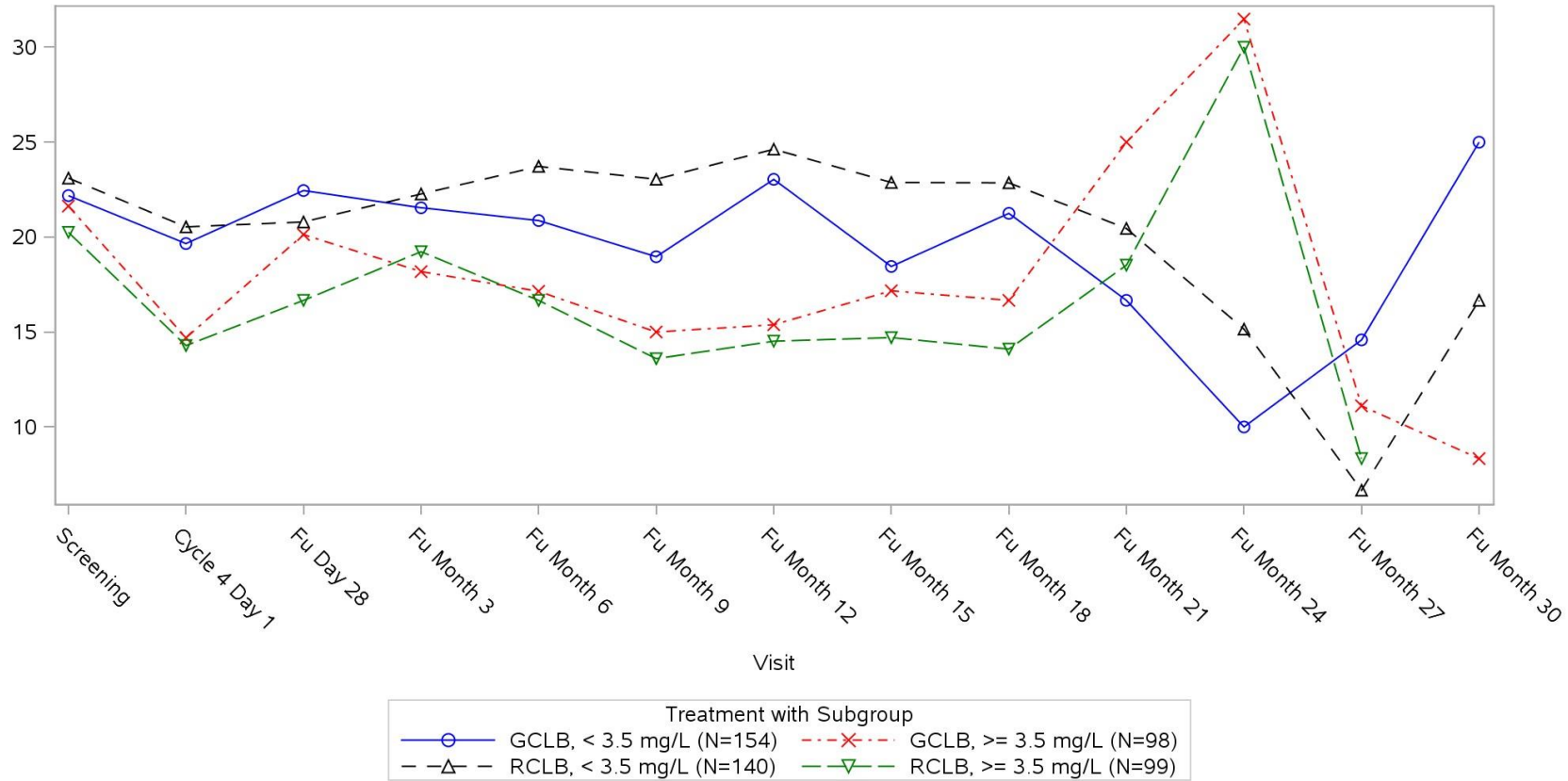
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Beta2 microglobulin (N=491) Laboratory Test: Pain Scale



Clinical cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/g_pro_mean.sas
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04MAR2020 18:19

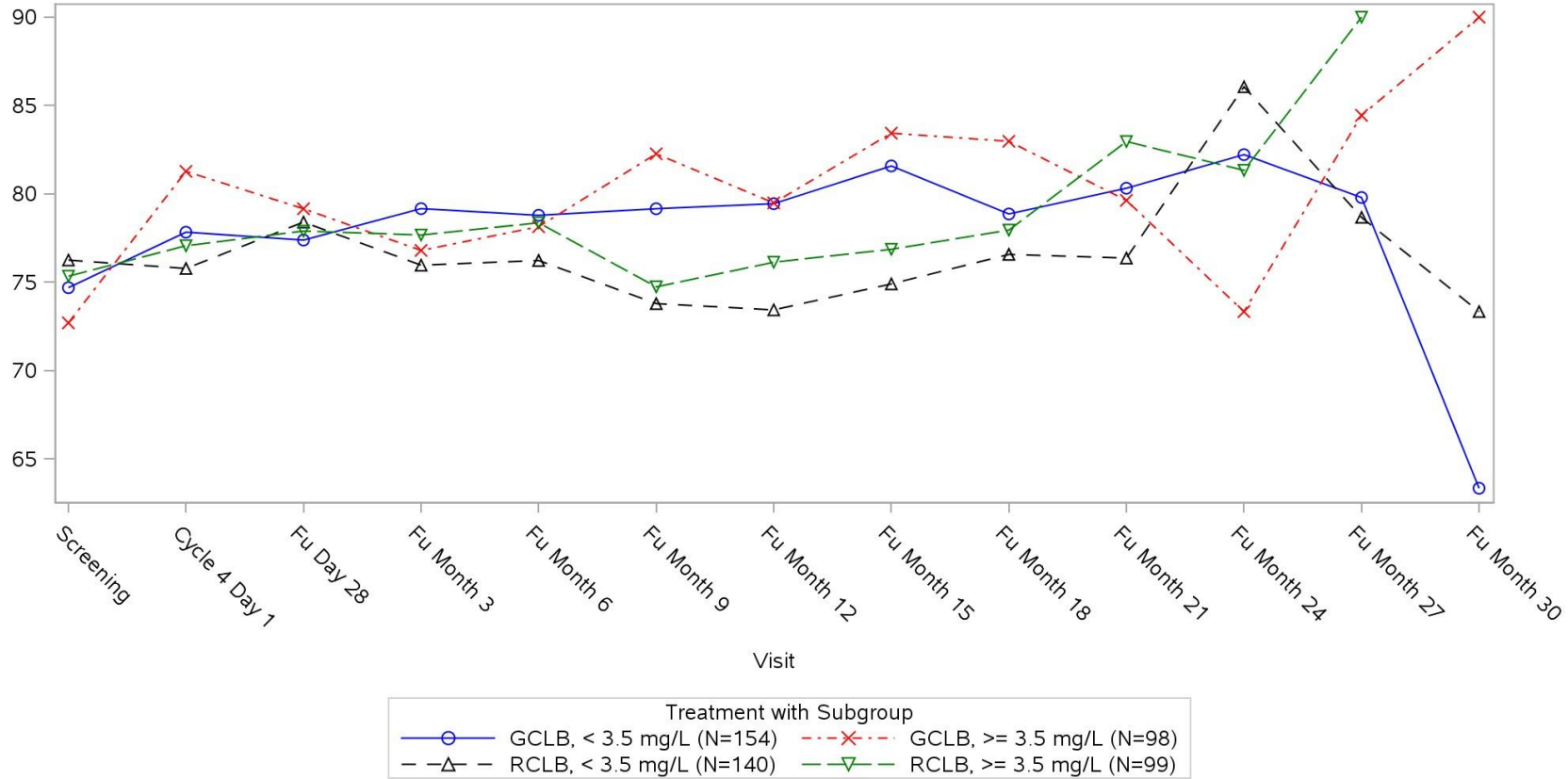
Page 70 of 195

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Beta2 microglobulin (N=491) Laboratory Test: Physical Functioning Scale



Clinical cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/g_pro_mean.sas
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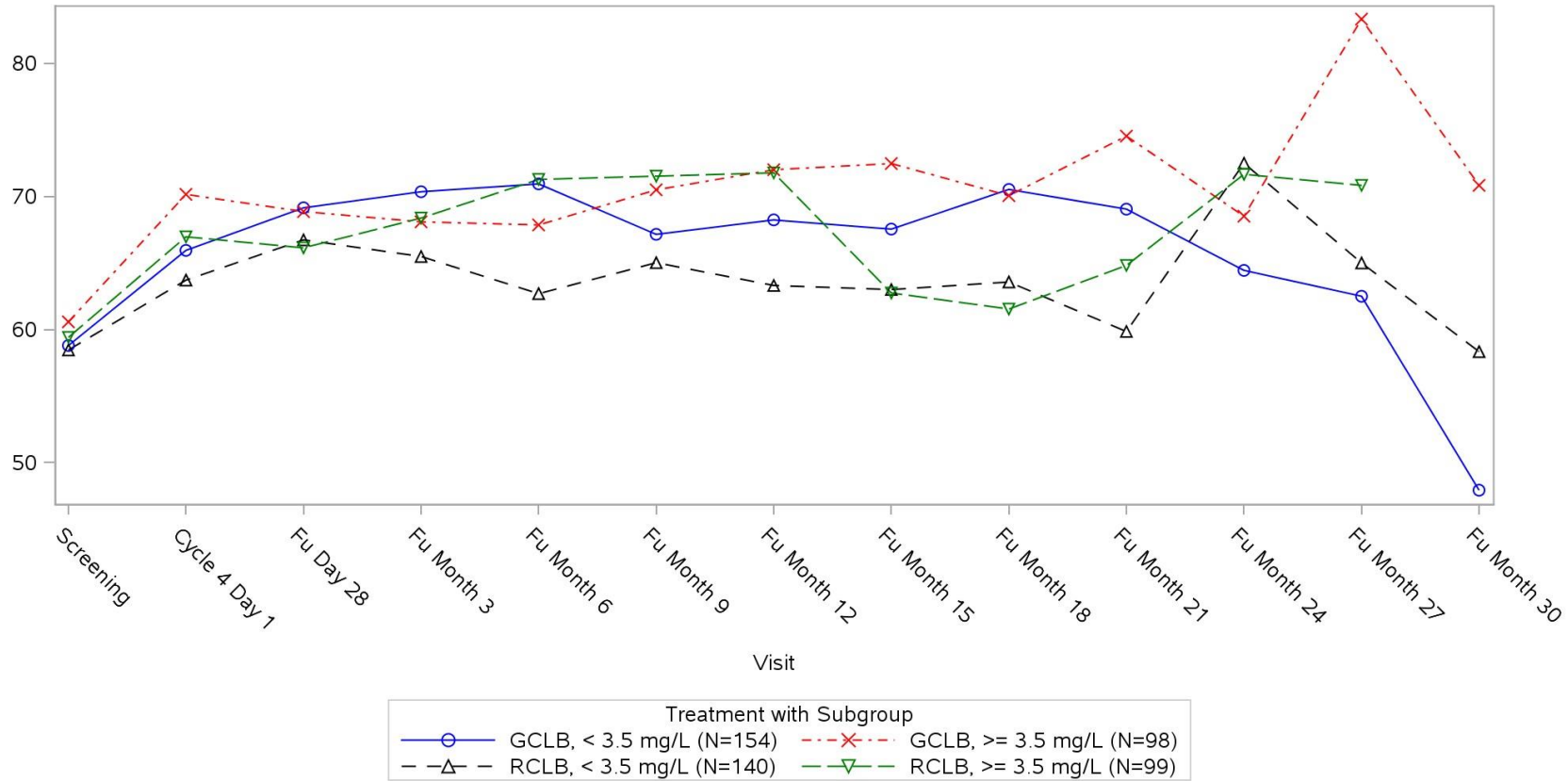
Page 71 of 195

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Beta2 microglobulin (N=491) Laboratory Test: Global Health Status Scale



Clinical cut-off: 09MAY2013

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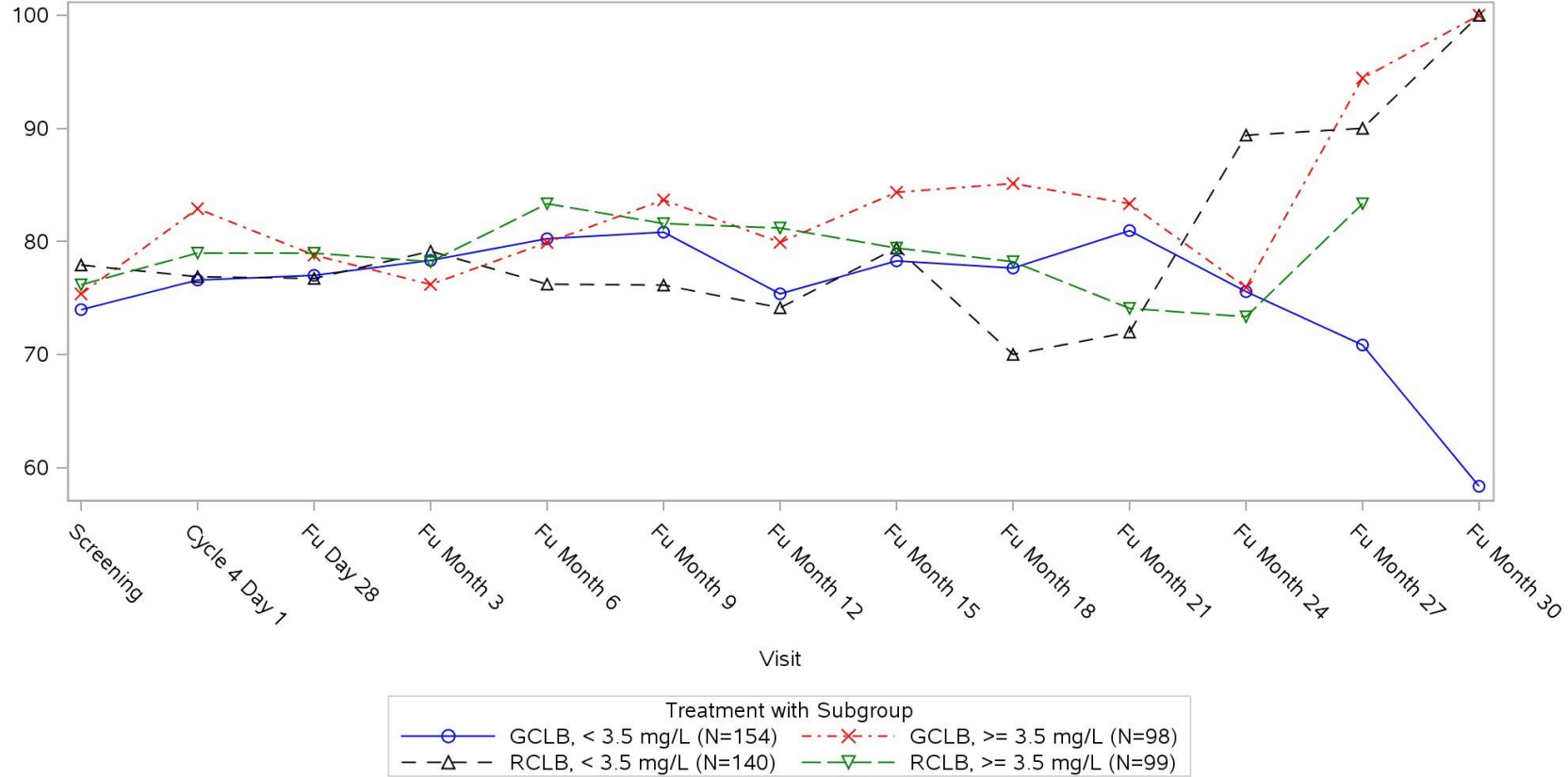
Page 72 of 195

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Beta2 microglobulin (N=491) Laboratory Test: Role Functioning Scale



Clinical cut-off: 09MAY2013

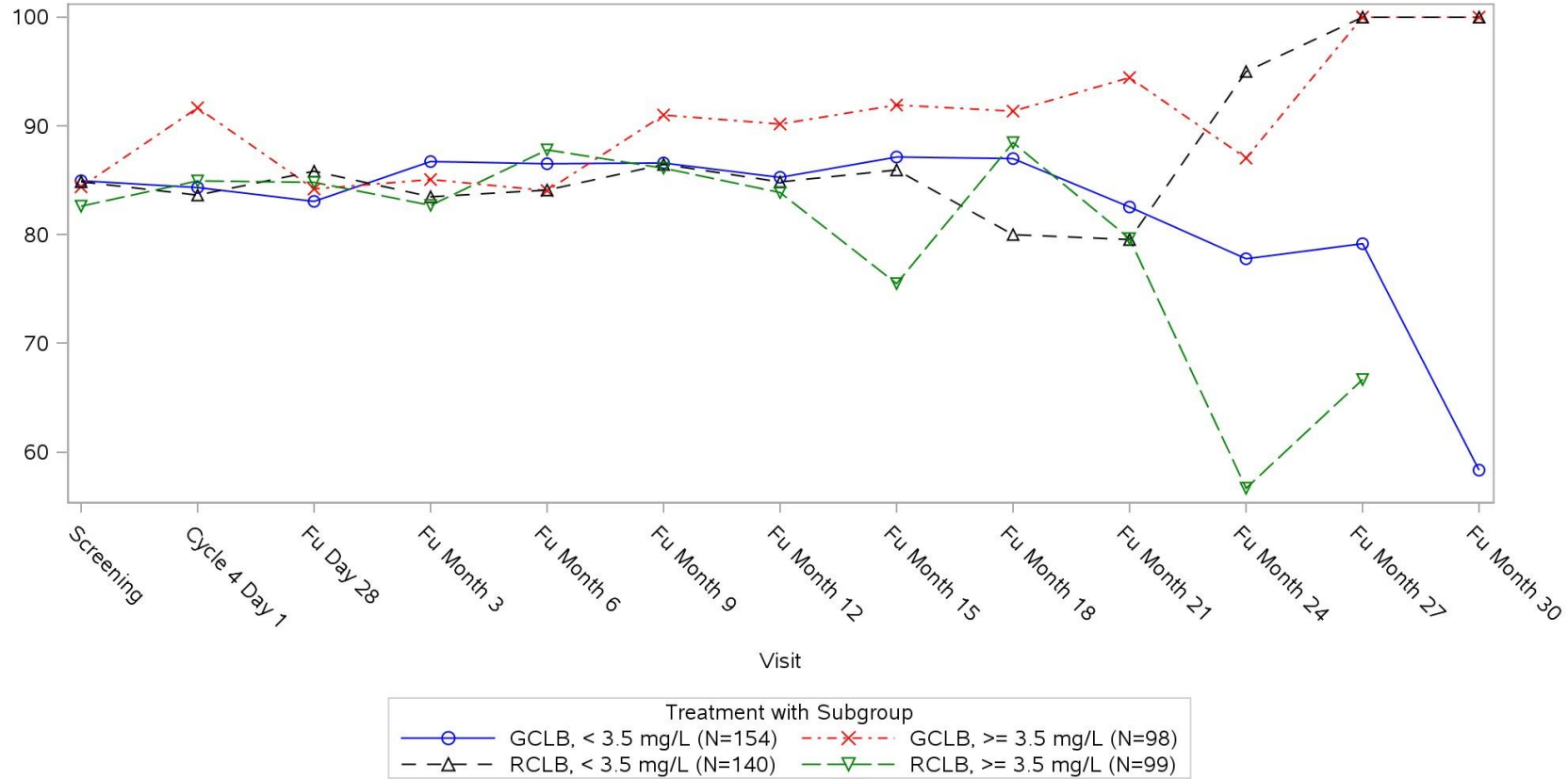
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 04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Beta2 microglobulin (N=491) Laboratory Test: Social Functioning Scale



Clinical cut-off: 09MAY2013

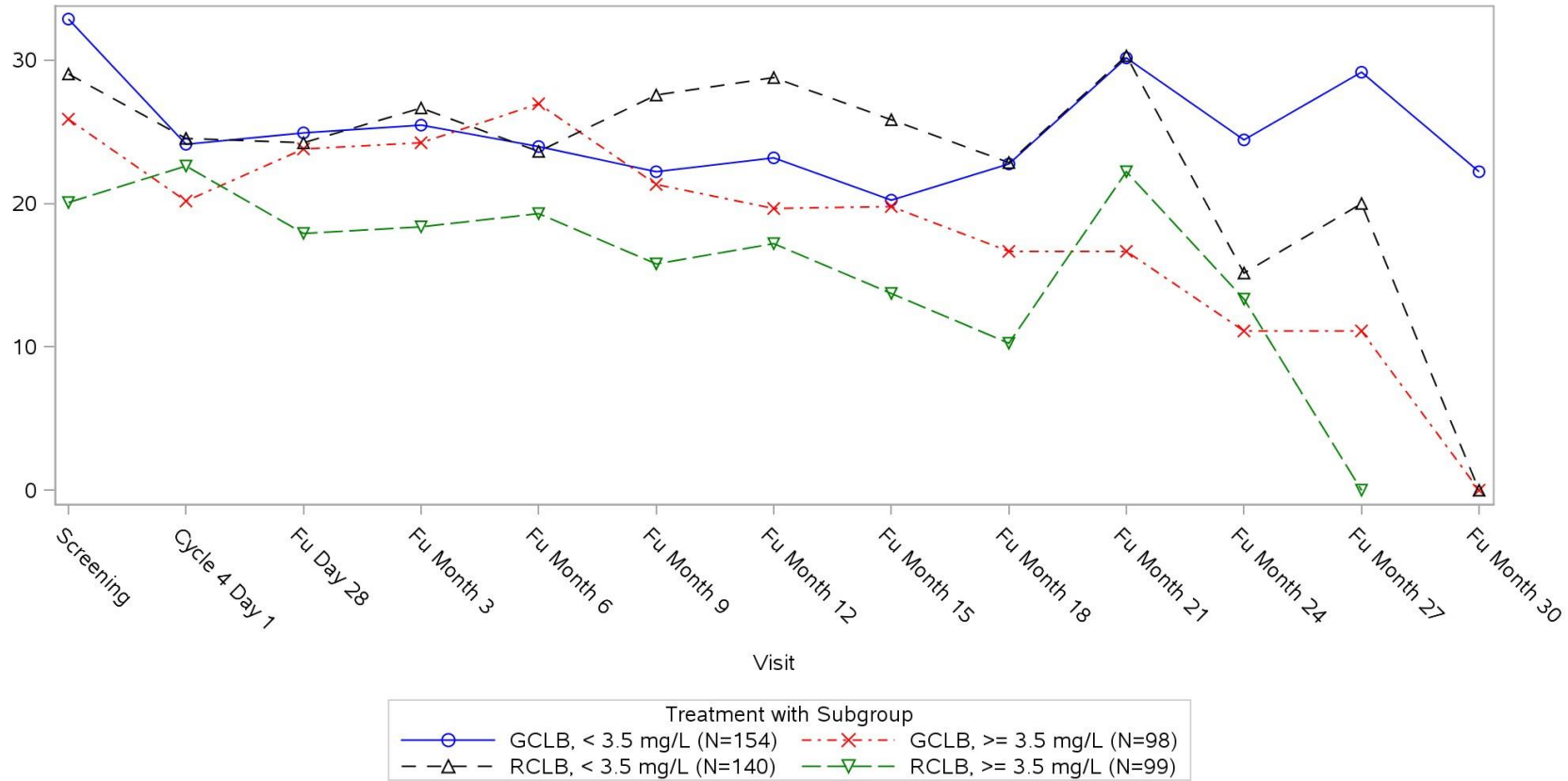
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04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Beta2 microglobulin (N=491) Laboratory Test: Insomnia Scale



Clinical cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/g_pro_mean.sas
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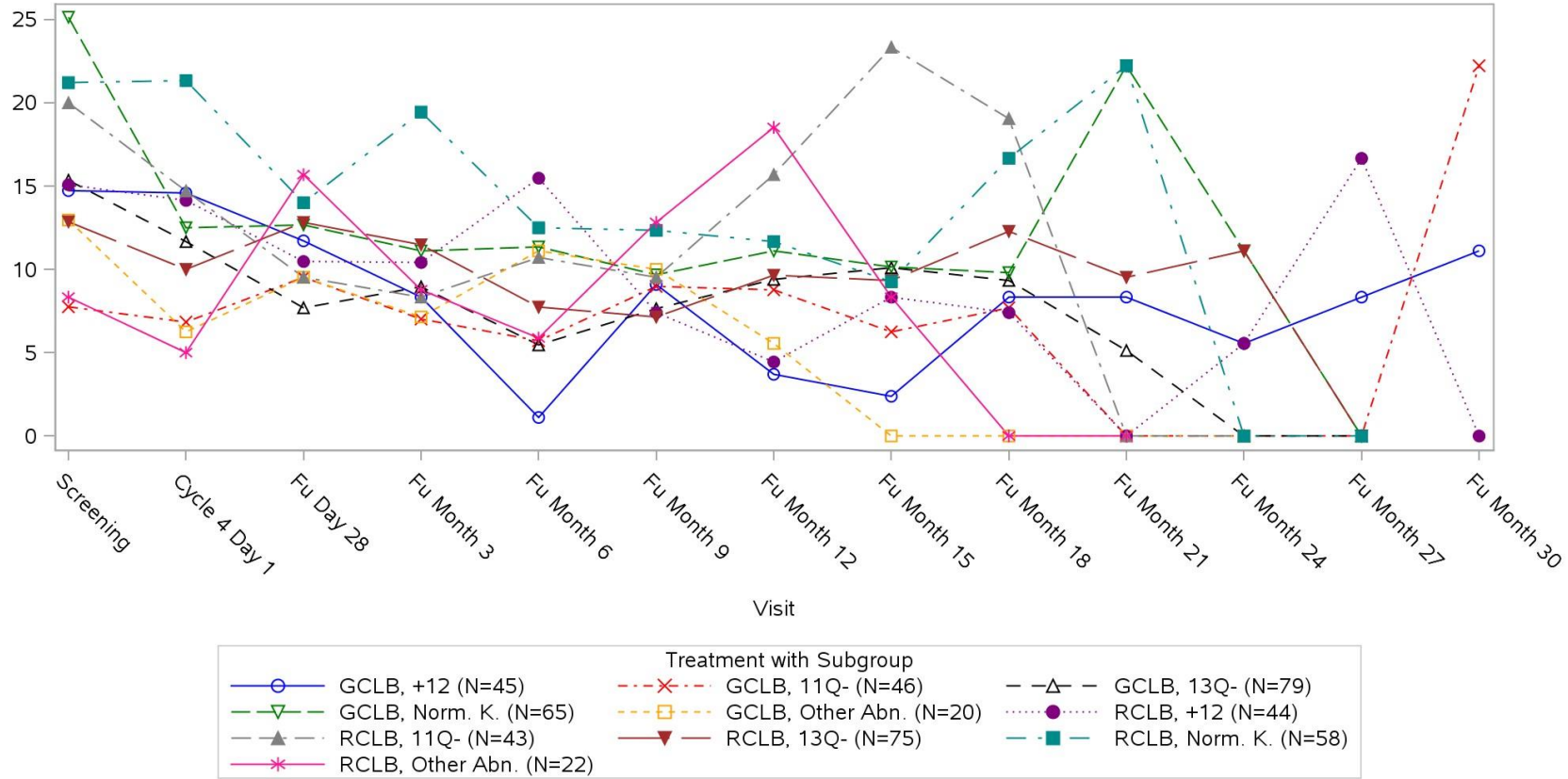
Page 75 of 195

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Immunogloblin VH, cytogenetics 2 (N=497) Laboratory Test: Appetite Loss Scale



Clinical cut-off: 09MAY2013

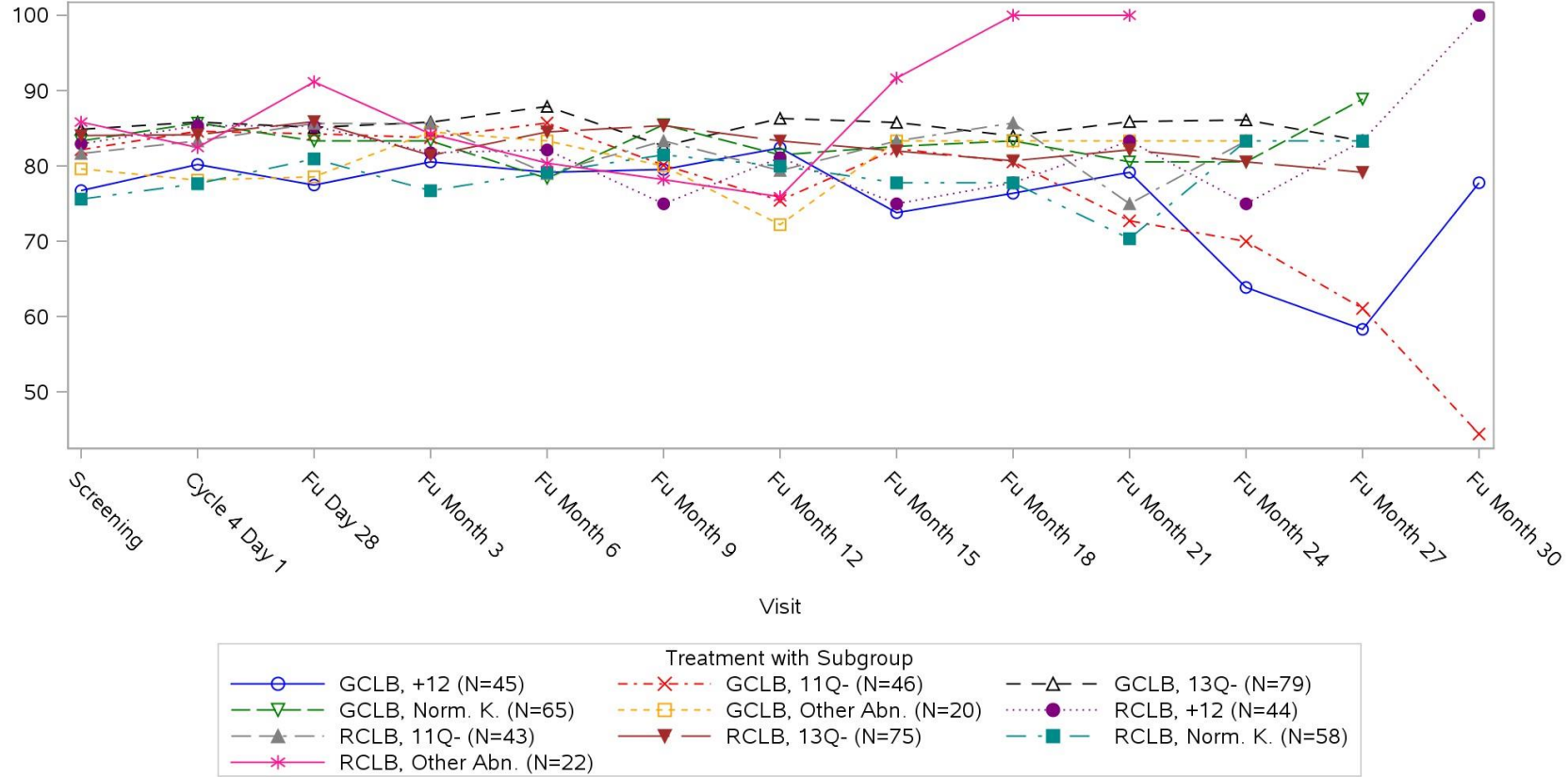
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 04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Immunogloblin VH, cytogenetics 2 (N=497) Laboratory Test: Cognitive Functioning Scale



Clinical cut-off: 09MAY2013

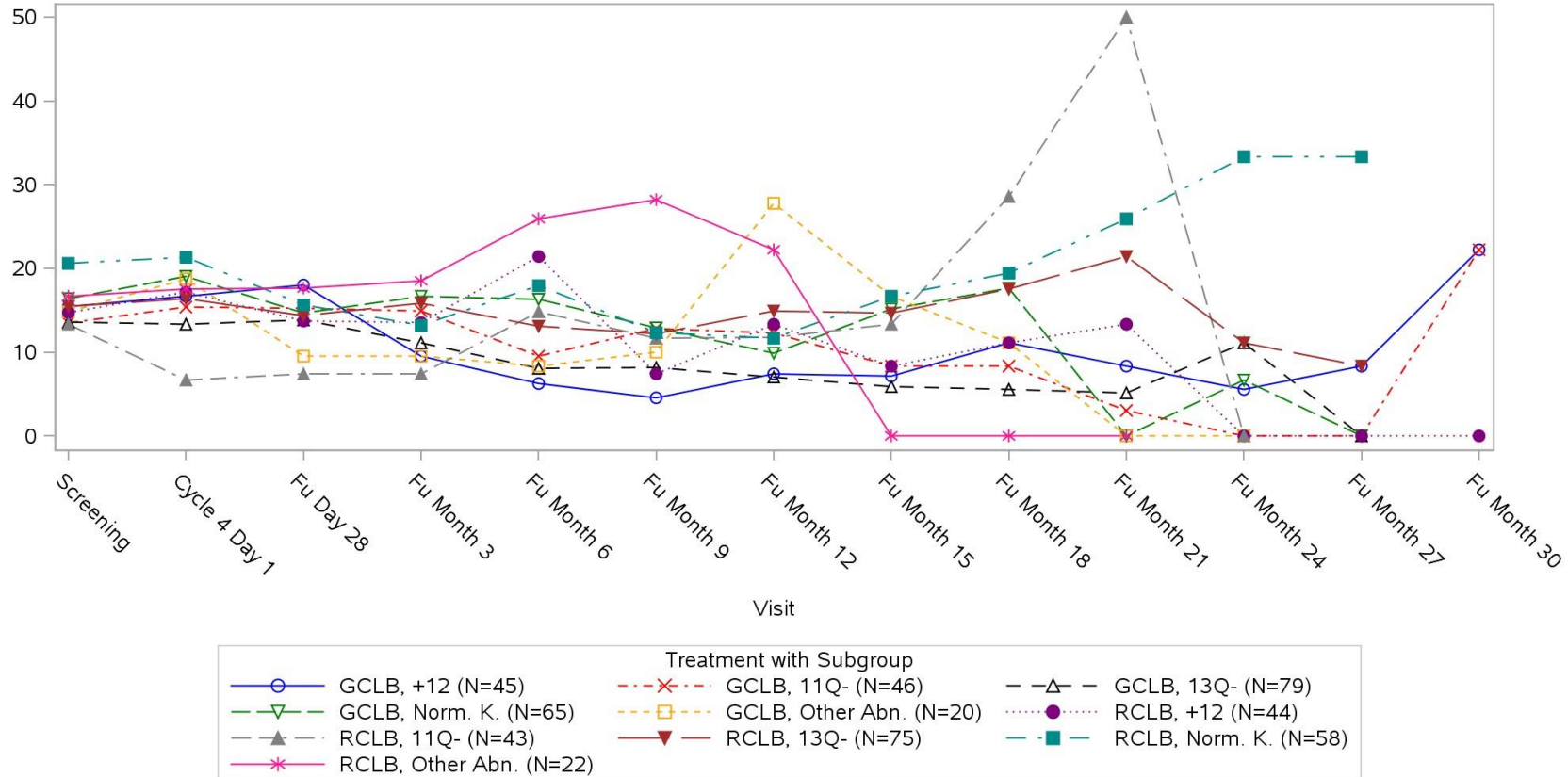
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 04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Immunogloblin VH, cytogenetics 2 (N=497) Laboratory Test: Constipation Scale



Clinical cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/g_pro_mean.sas
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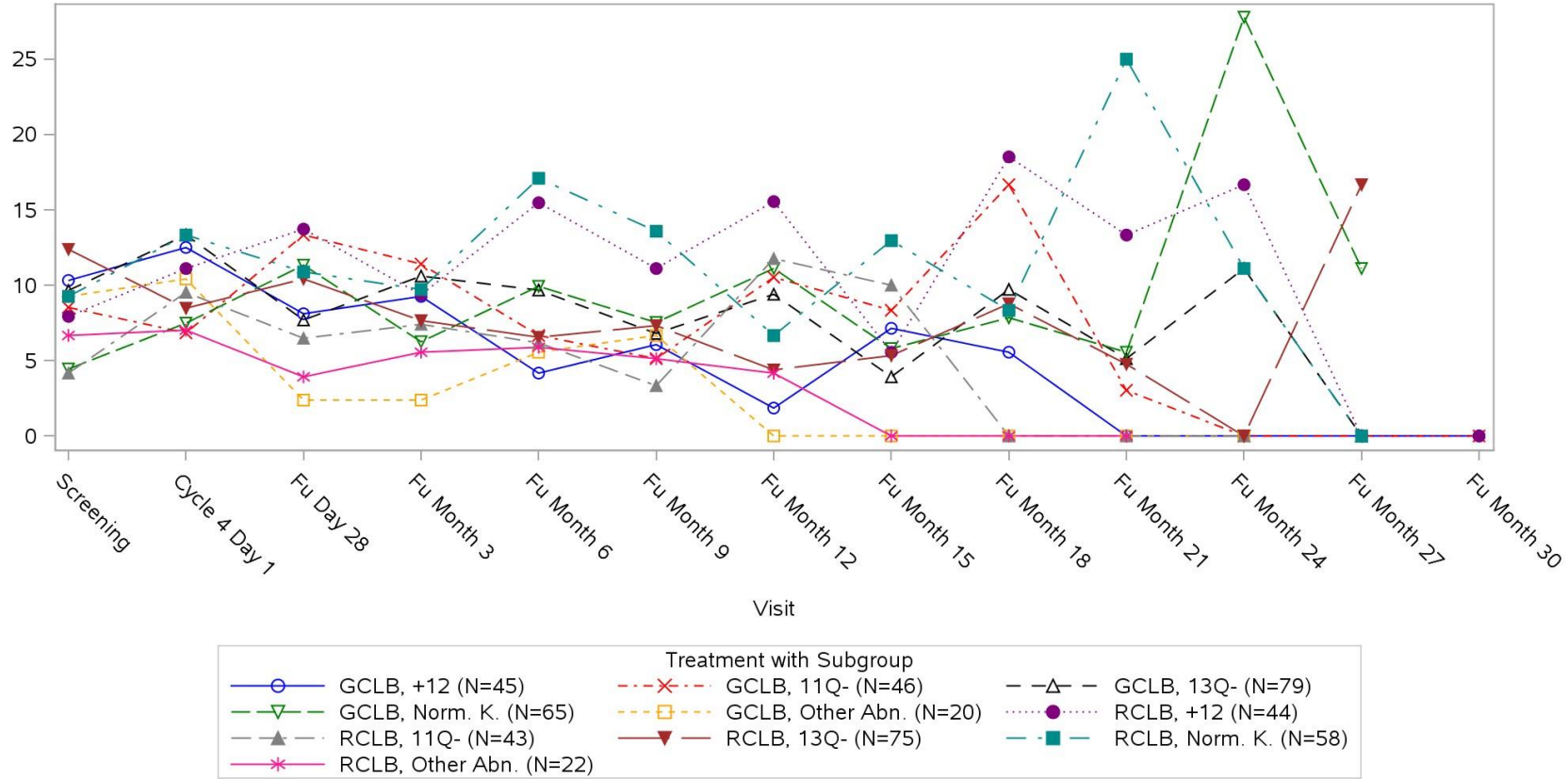
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Immunoglobulin VH, cytogenetics 2 (N=497) Laboratory Test: Diarrhoea Scale



Clinical cut-off: 09MAY2013

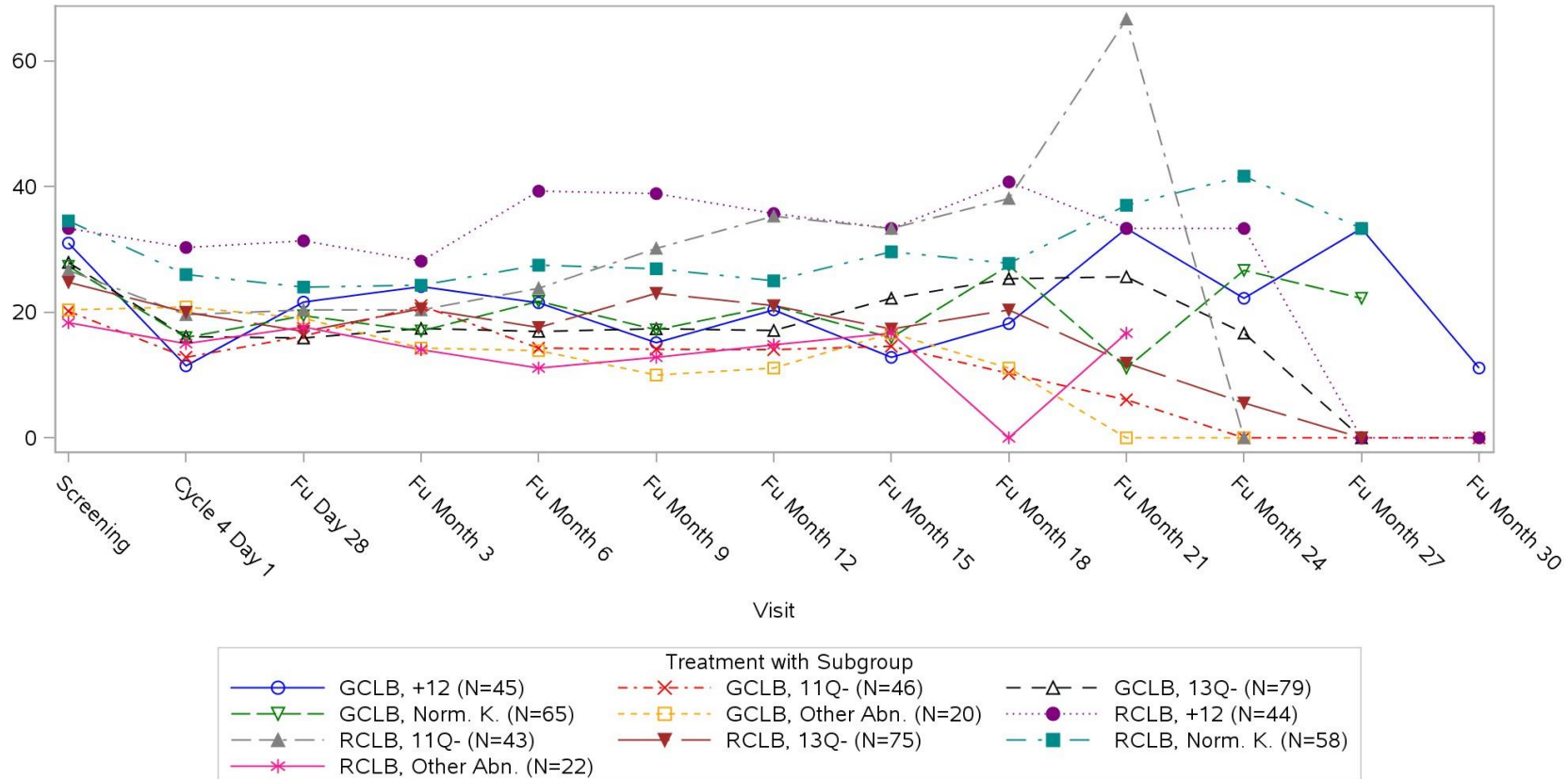
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 04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Immunoglobulin VH, cytogenetics 2 (N=497) Laboratory Test: Dyspnoea Scale



Clinical cut-off: 09MAY2013

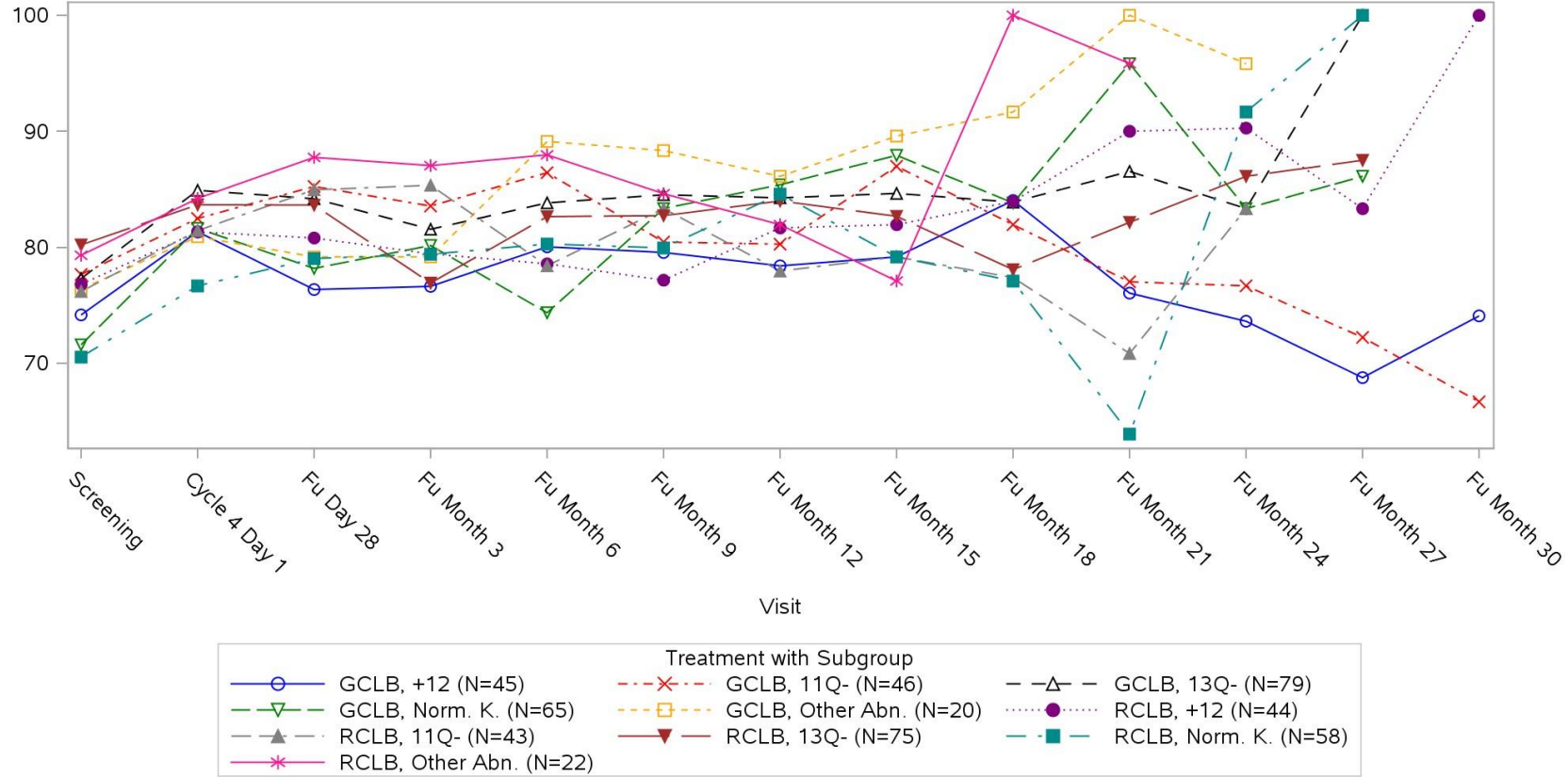
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 04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Immunogloblin VH, cytogenetics 2 (N=497) Laboratory Test: Emotional Functioning Scale



Clinical cut-off: 09MAY2013

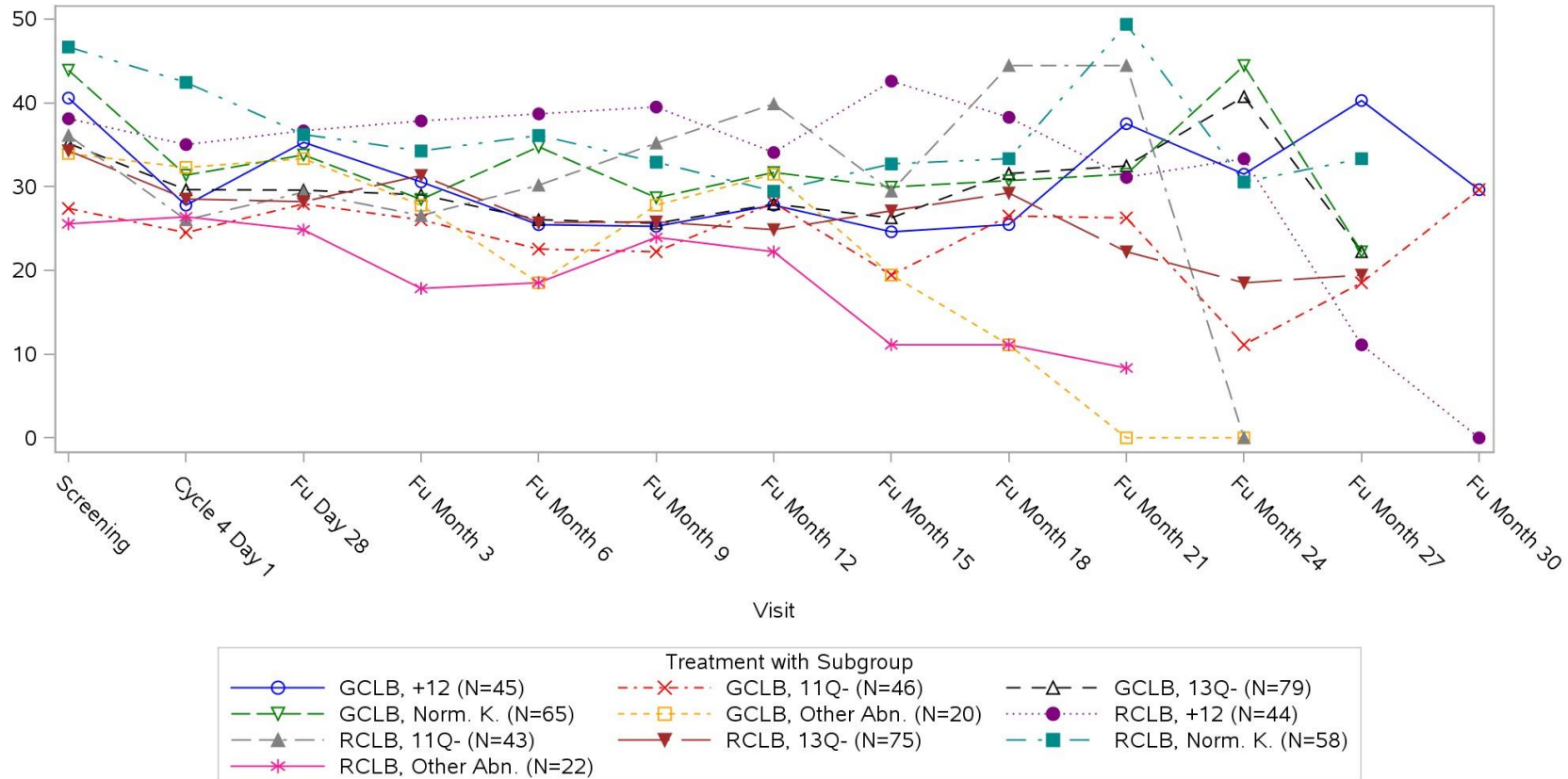
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 04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Immunogloblin VH, cytogenetics 2 (N=497) Laboratory Test: Fatigue Scale



Clinical cut-off: 09MAY2013

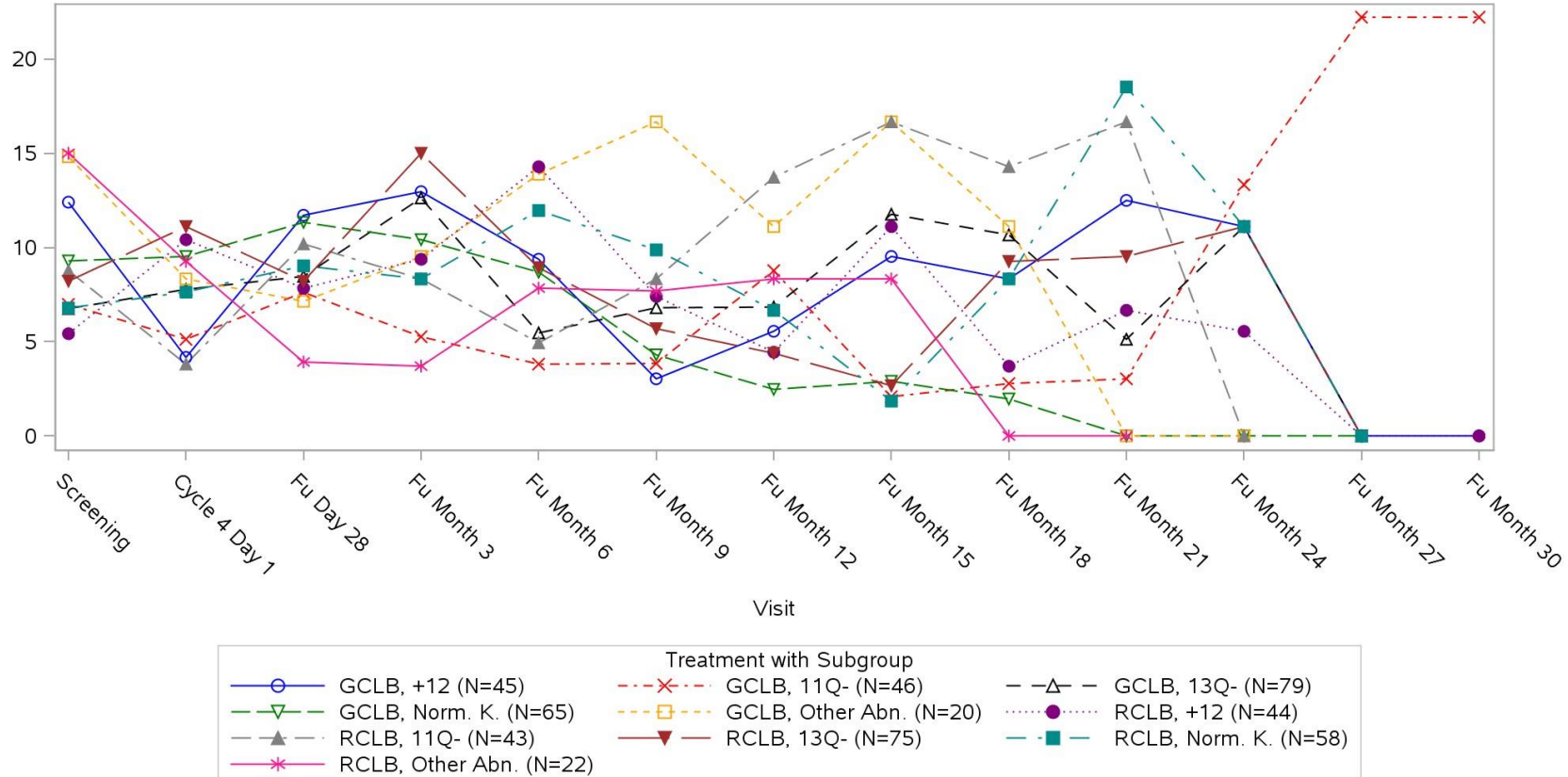
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Immunoglobulin VH, cytogenetics 2 (N=497) Laboratory Test: Financial Difficulties Scale



Clinical cut-off: 09MAY2013

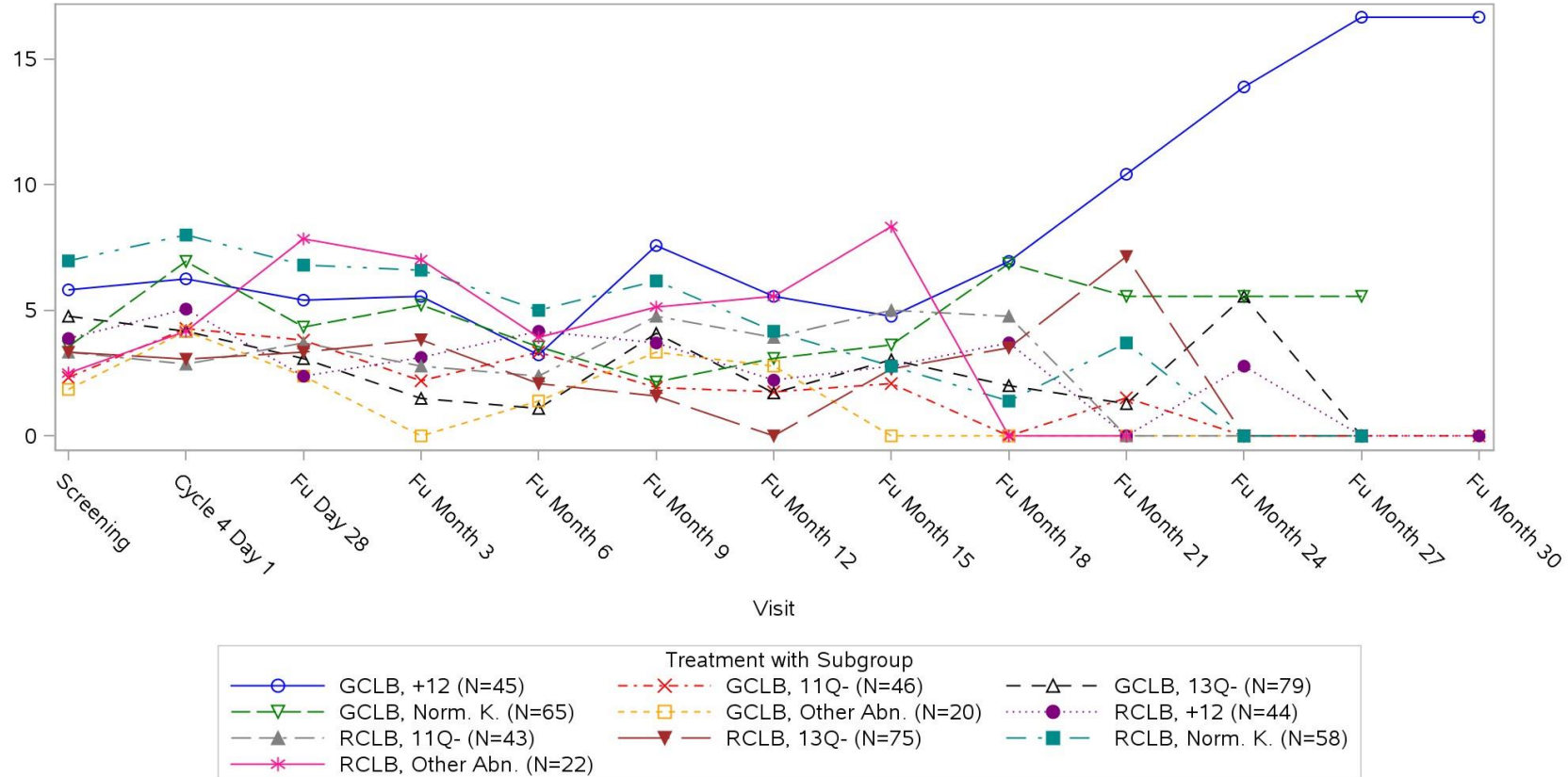
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Immunoglobulin VH, cytogenetics 2 (N=497) Laboratory Test: Nausea And Vomiting Scale



Clinical cut-off: 09MAY2013

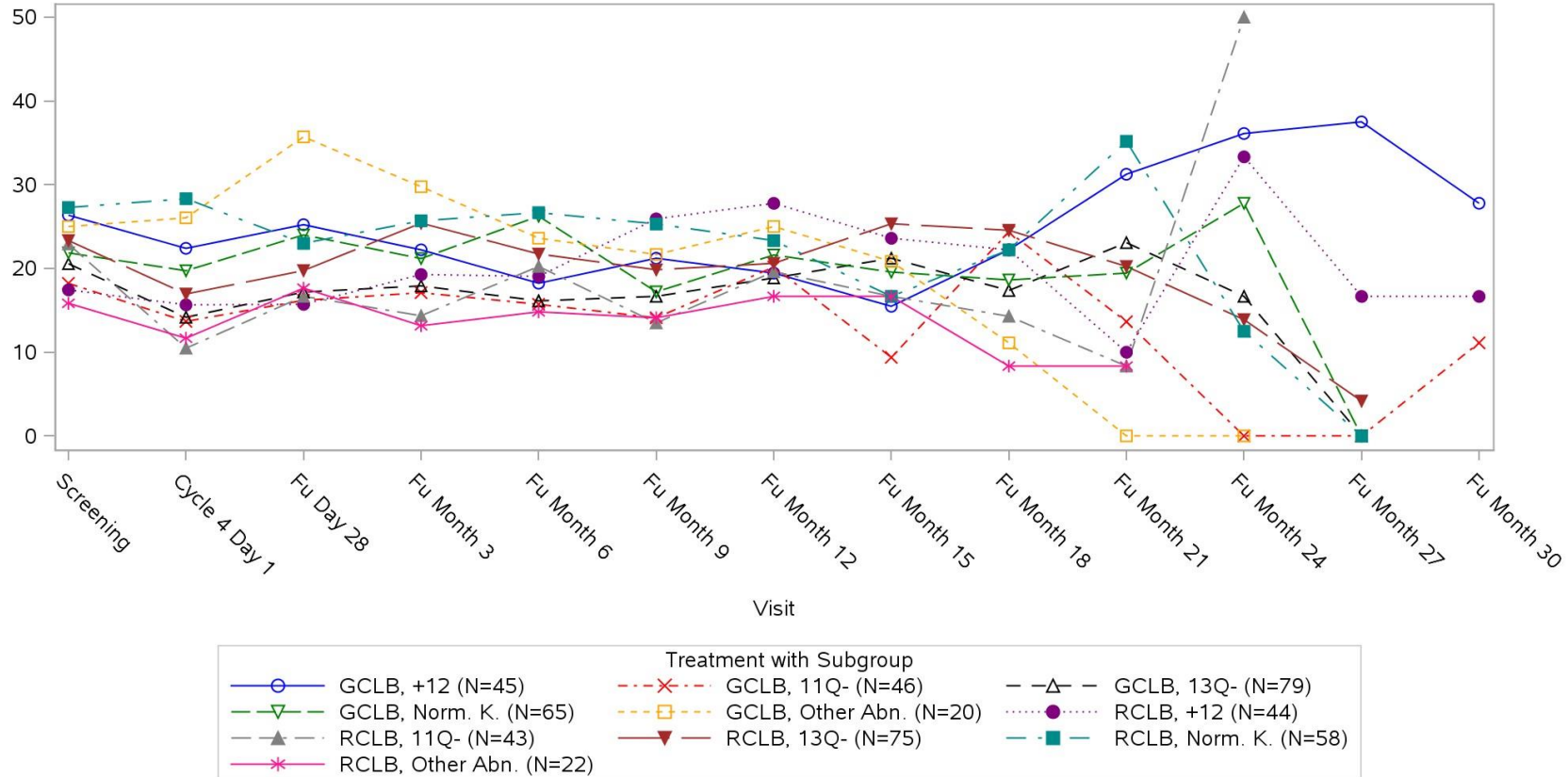
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Immunogloblin VH, cytogenetics 2 (N=497) Laboratory Test: Pain Scale



Clinical cut-off: 09MAY2013

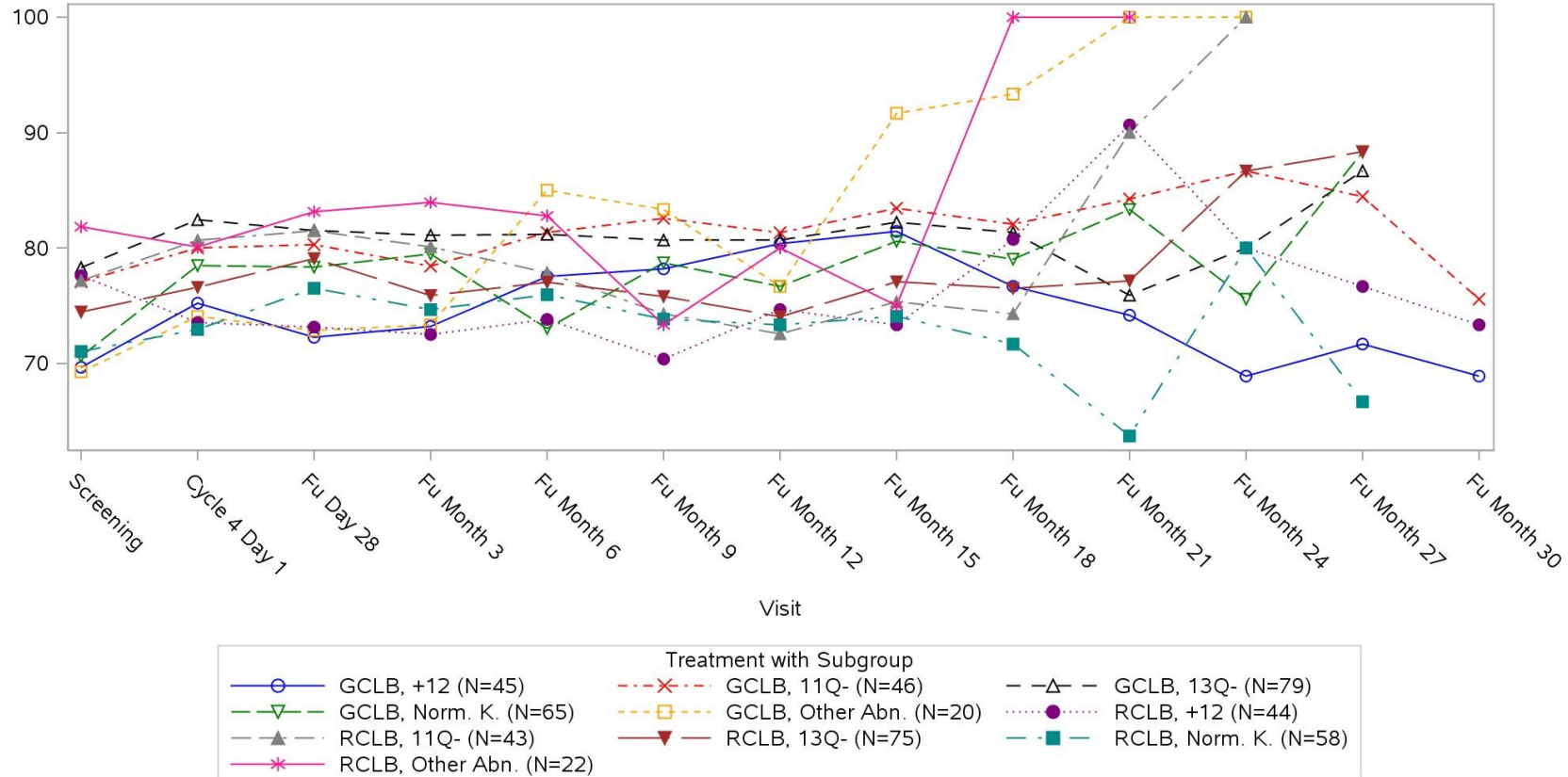
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Immunogloblin VH, cytogenetics 2 (N=497) Laboratory Test: Physical Functioning Scale



Clinical cut-off: 09MAY2013

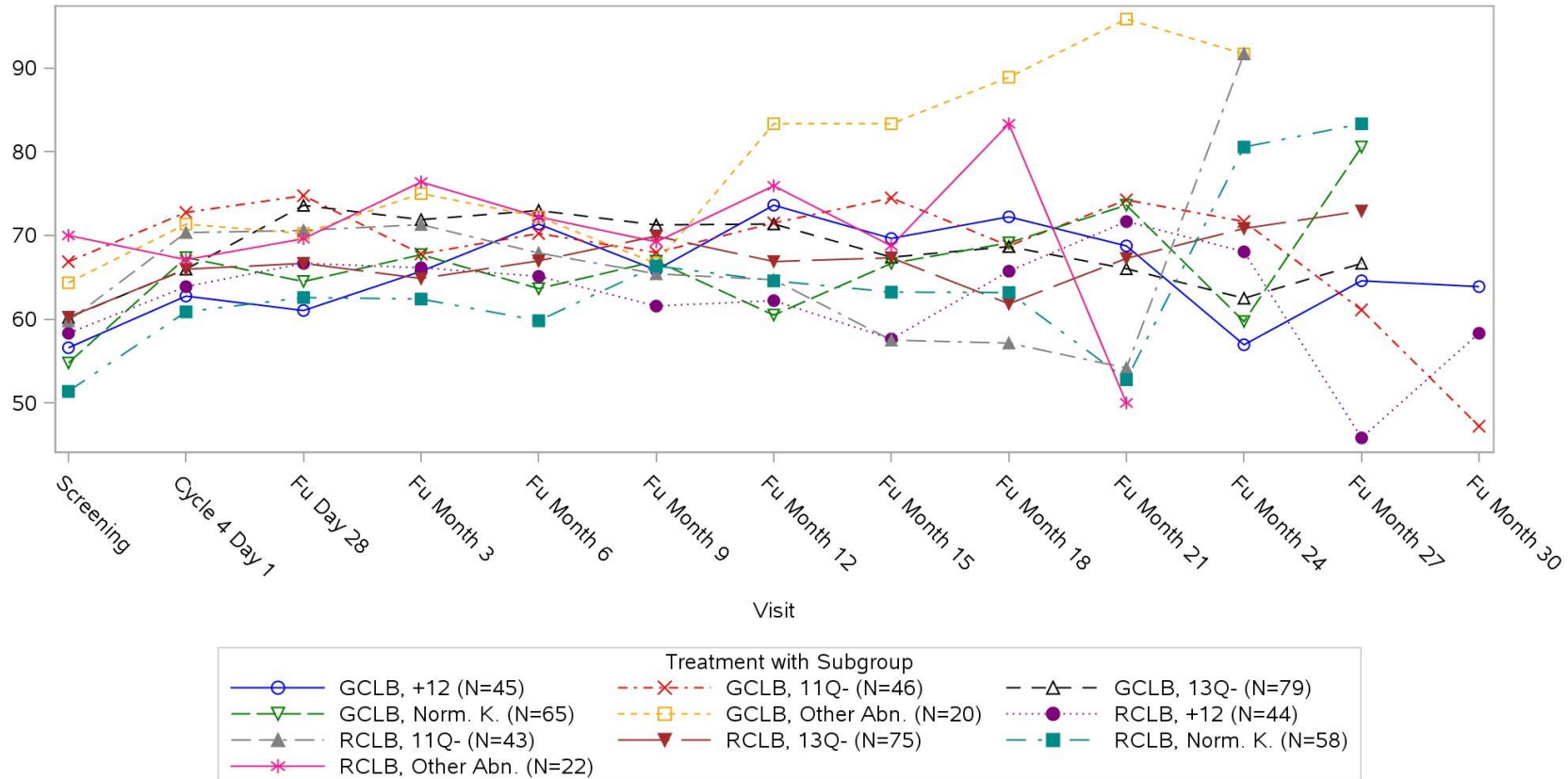
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Immunogloblin VH, cytogenetics 2 (N=497) Laboratory Test: Global Health Status Scale



Clinical cut-off: 09MAY2013

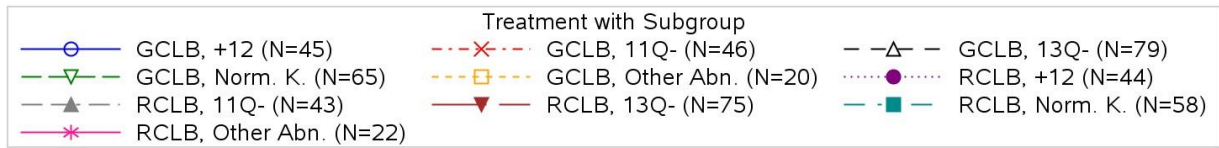
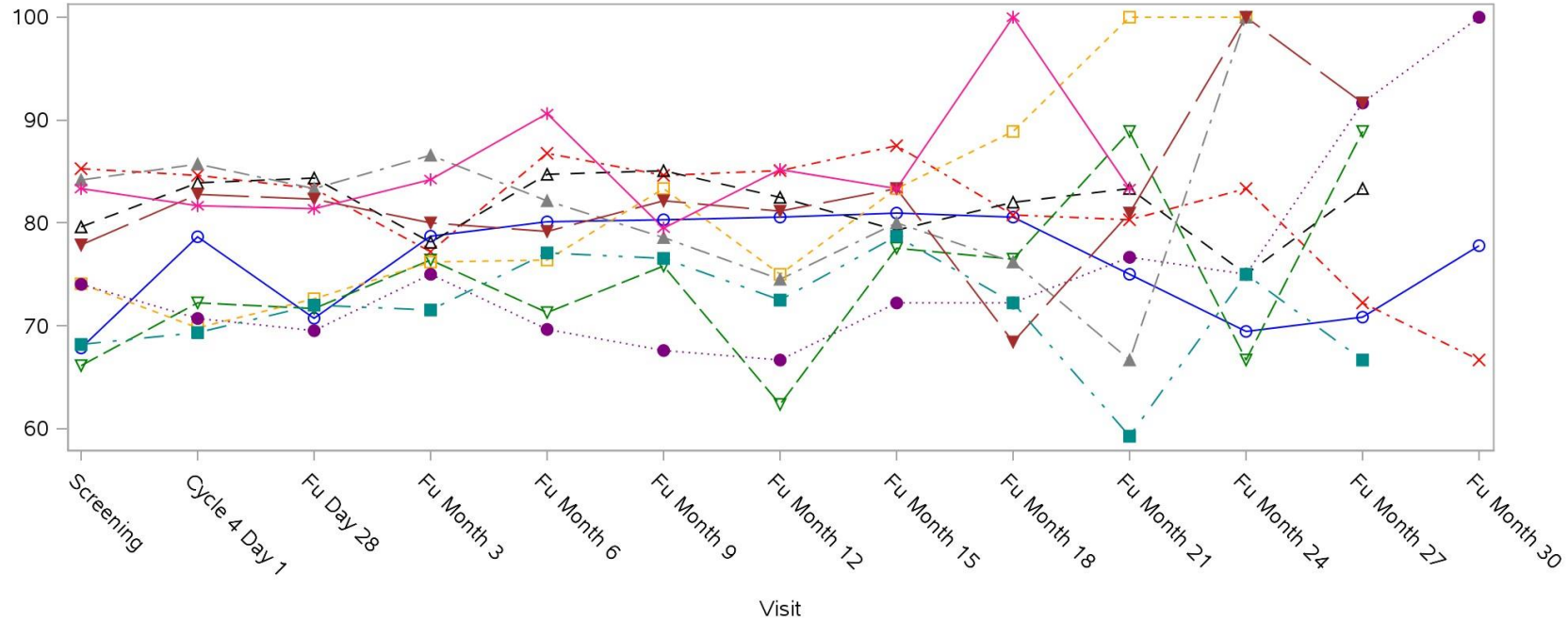
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Immunoglobulin VH, cytogenetics 2 (N=497) Laboratory Test: Role Functioning Scale



Clinical cut-off: 09MAY2013

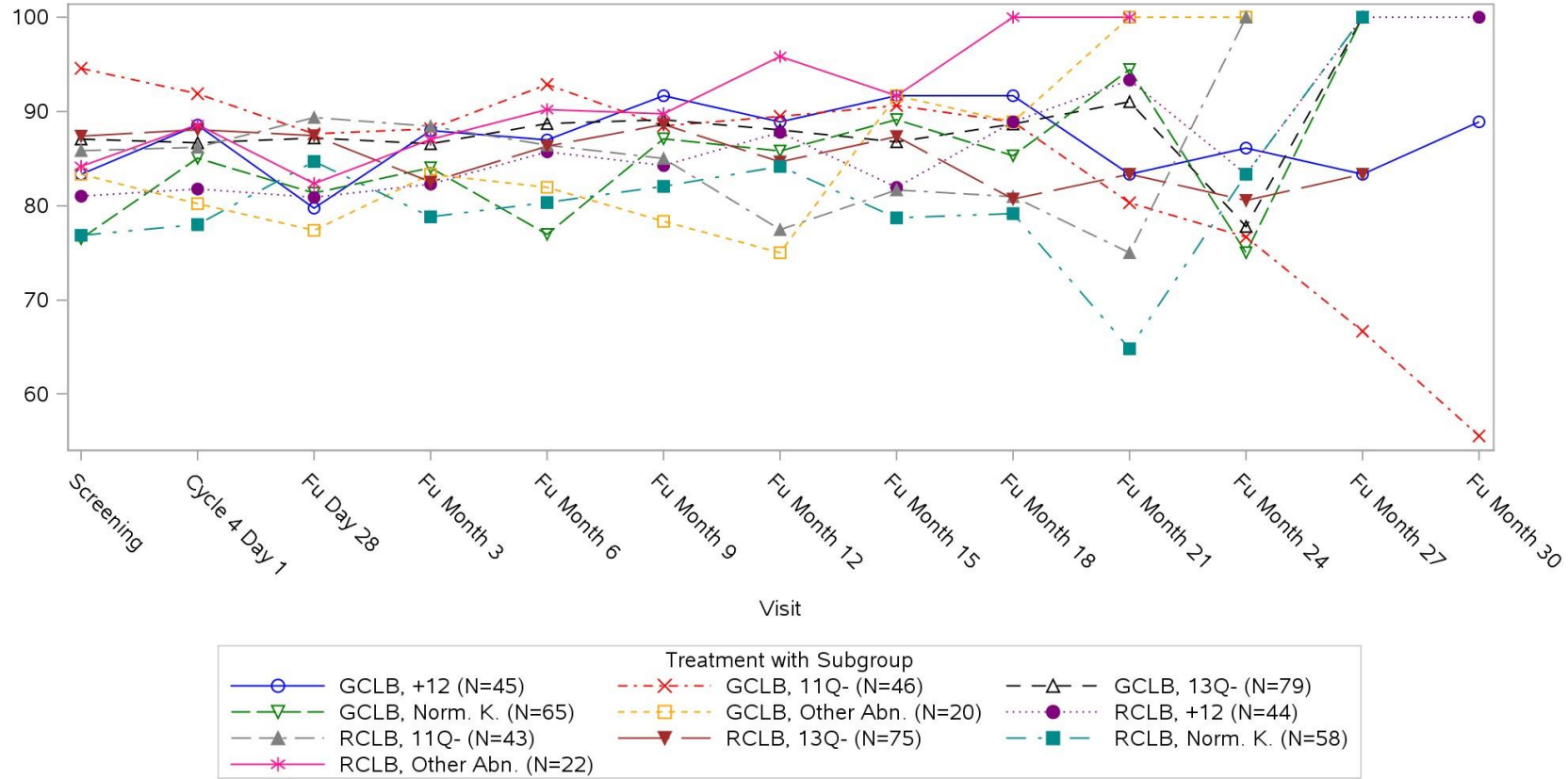
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 04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Immunoglobulin VH, cytogenetics 2 (N=497) Laboratory Test: Social Functioning Scale



Clinical cut-off: 09MAY2013

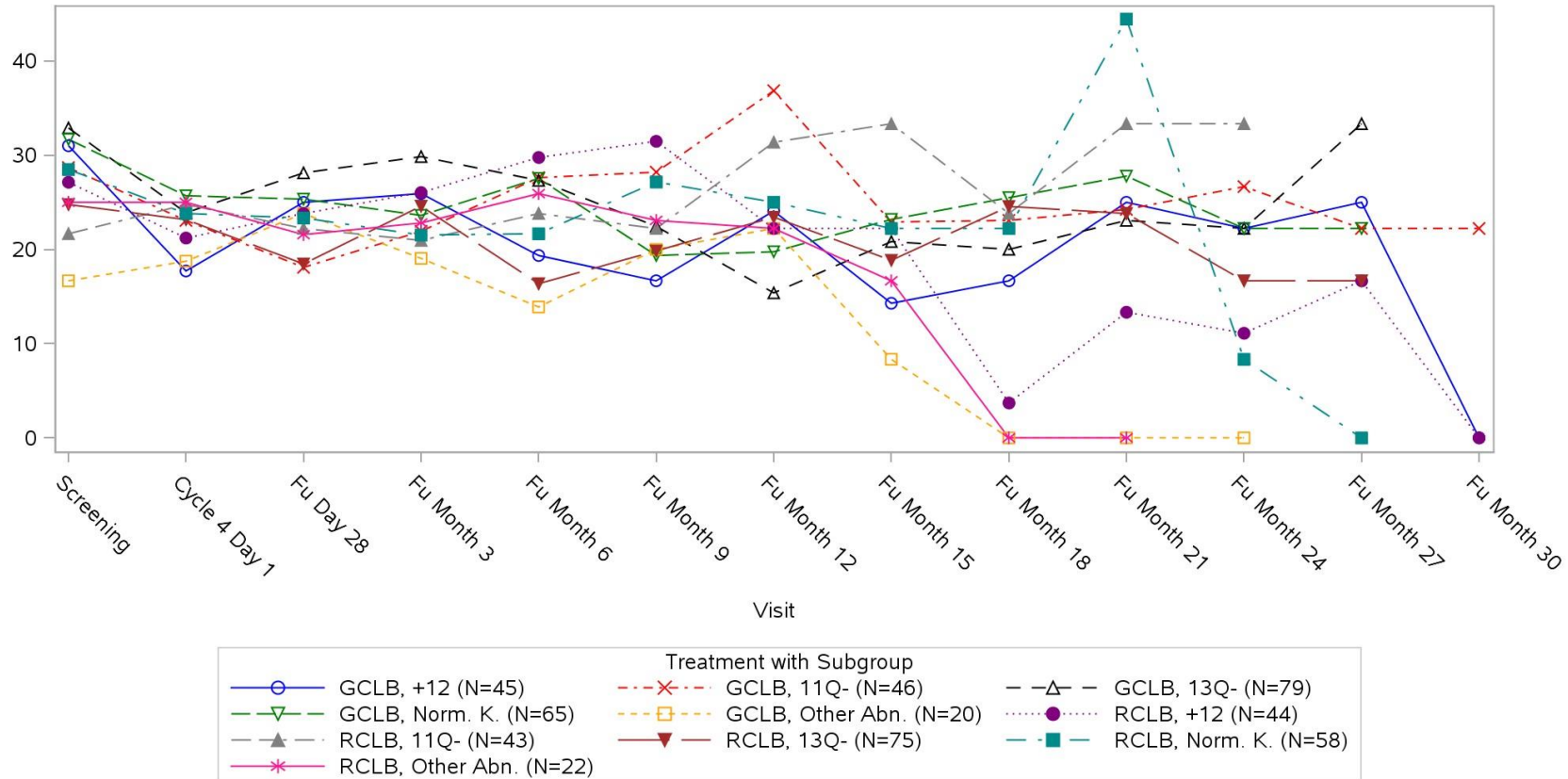
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 04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Immunogloblin VH, cytogenetics 2 (N=497) Laboratory Test: Insomnia Scale



Clinical cut-off: 09MAY2013

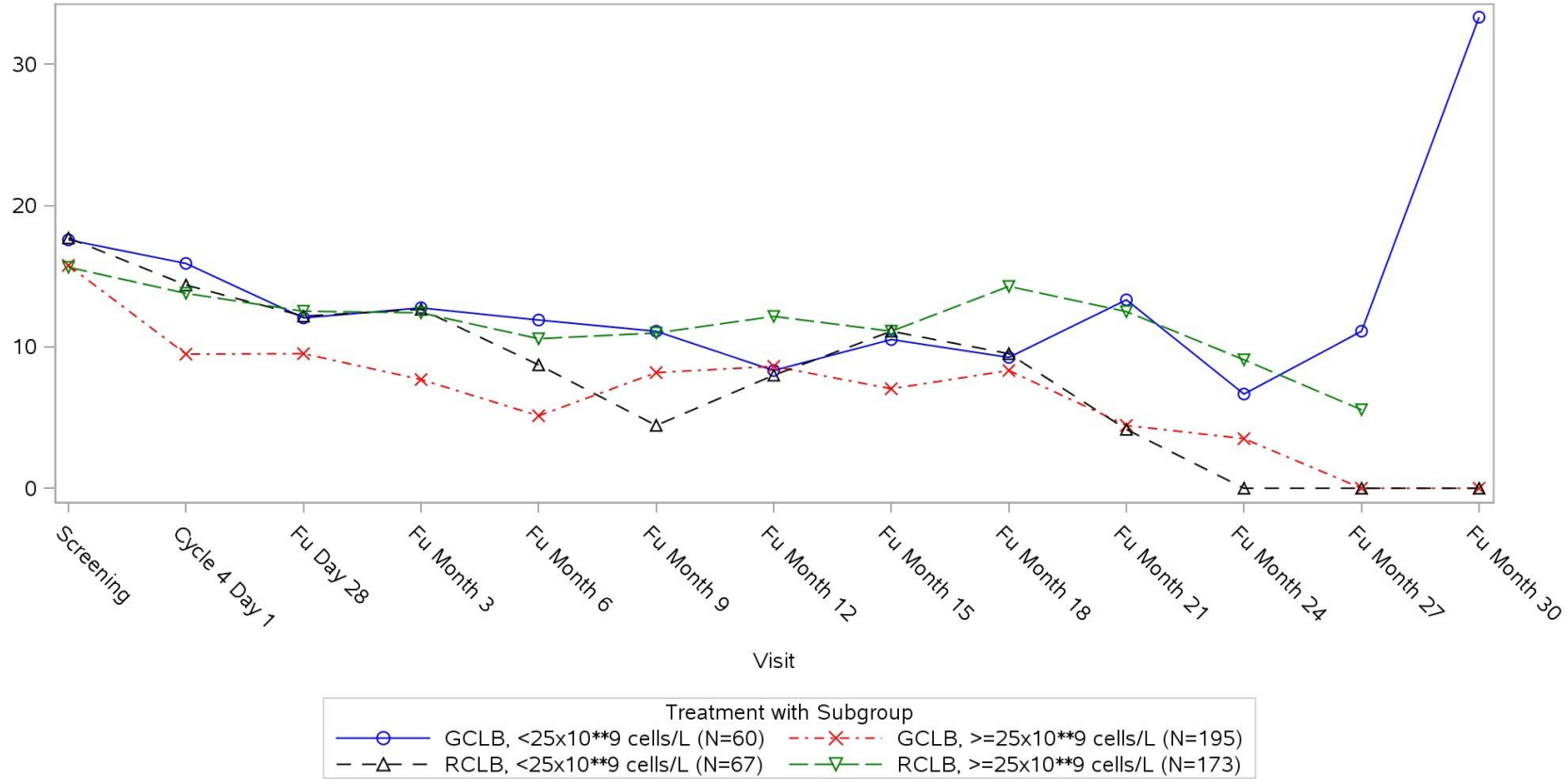
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 04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

High circulating tumor burden (N=495) Laboratory Test: Appetite Loss Scale



Clinical cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/g_pro_mean.sas
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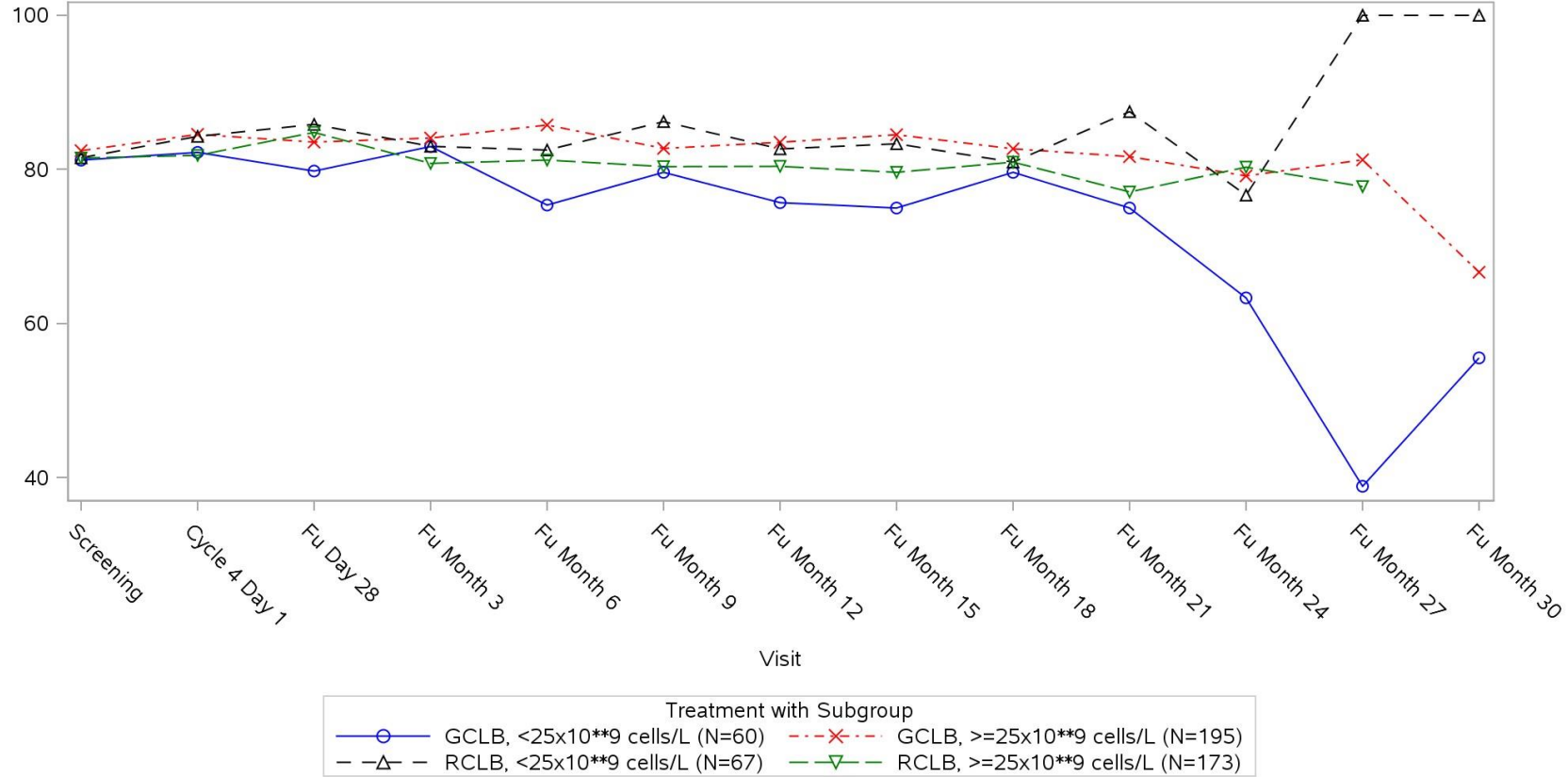
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

High circulating tumor burden (N=495) Laboratory Test: Cognitive Functioning Scale



Clinical cut-off: 09MAY2013

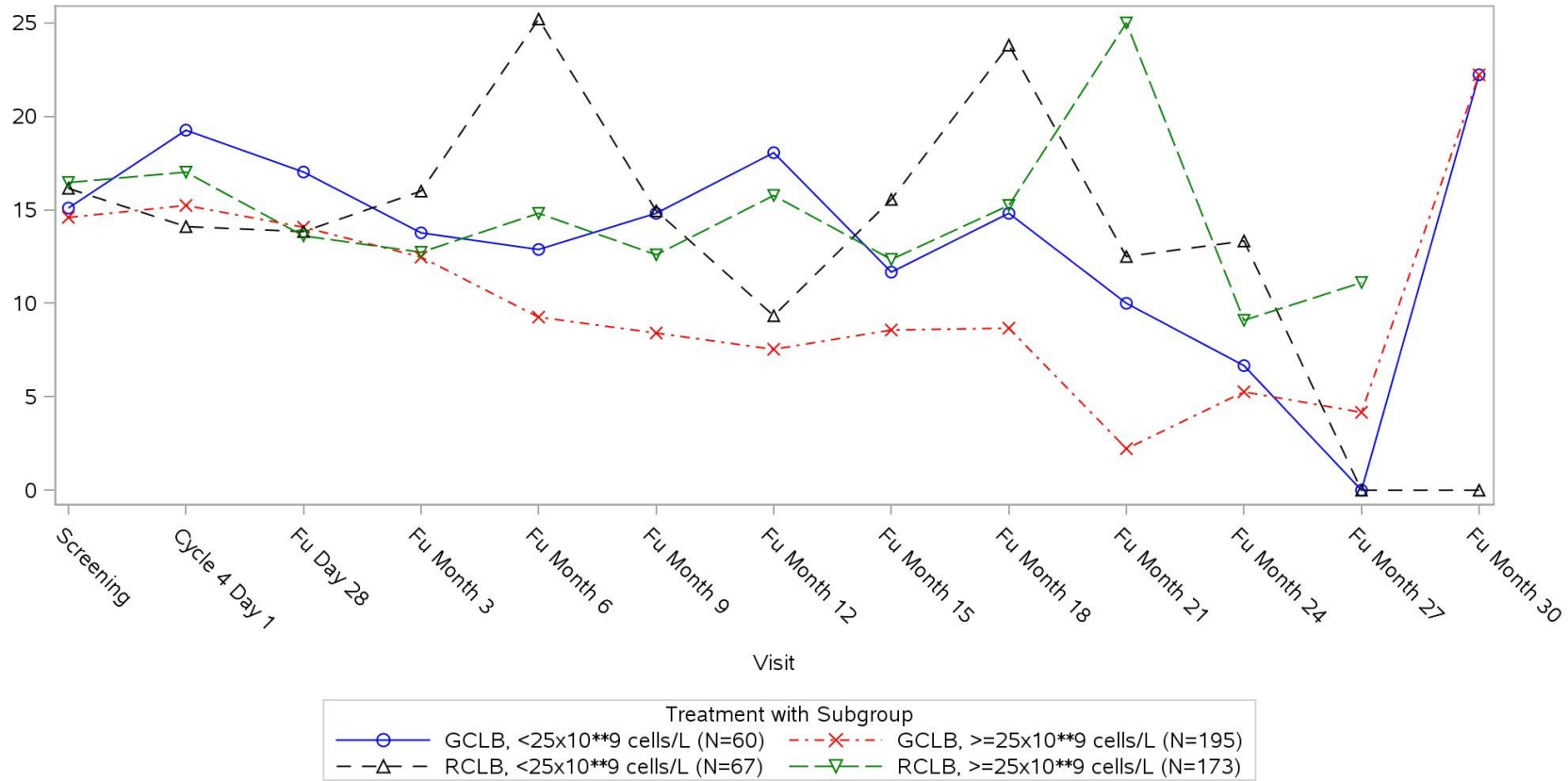
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04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

High circulating tumor burden (N=495) Laboratory Test: Constipation Scale



Clinical cut-off: 09MAY2013

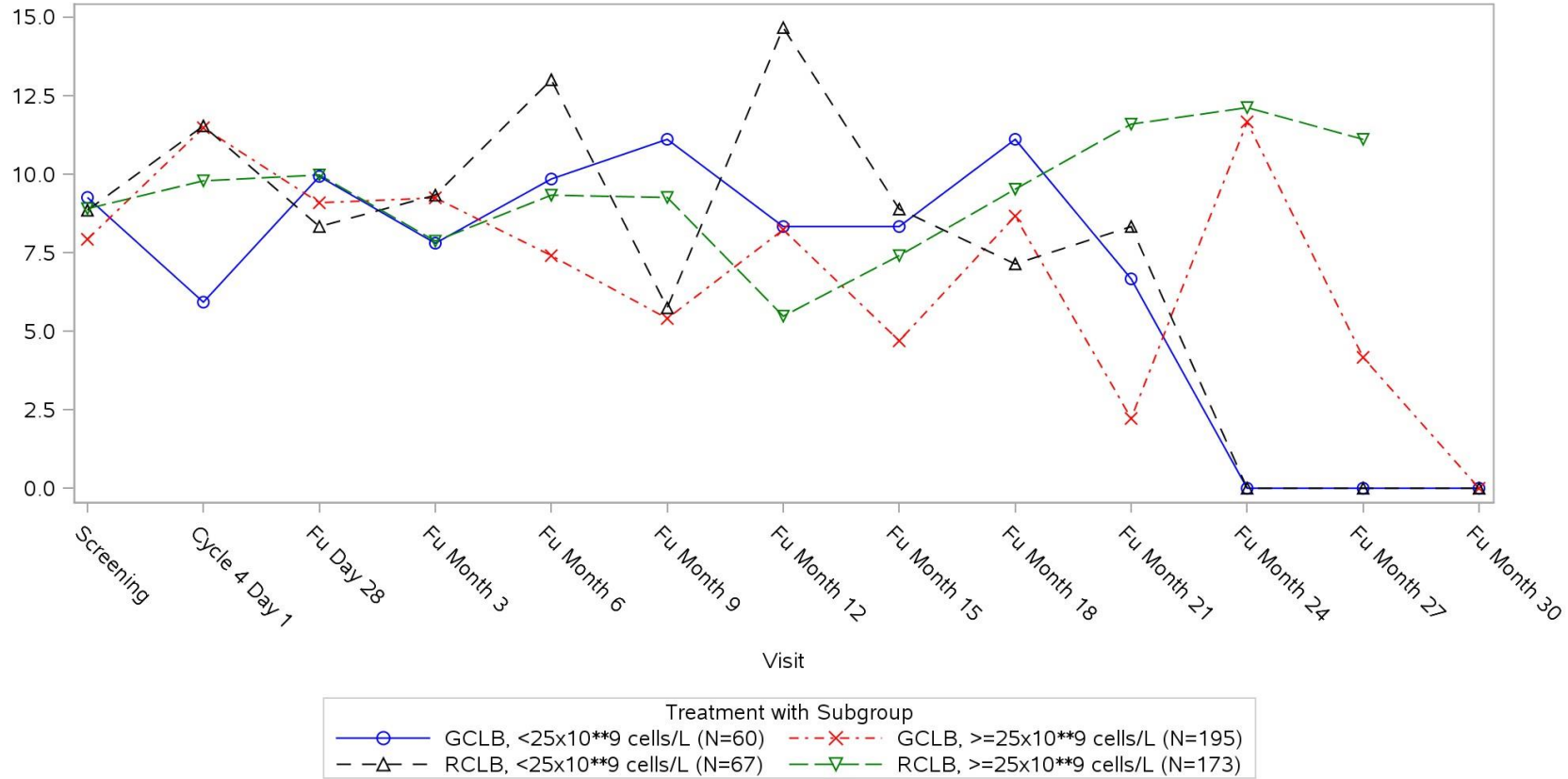
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 04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

High circulating tumor burden (N=495) Laboratory Test: Diarrhoea Scale



Clinical cut-off: 09MAY2013

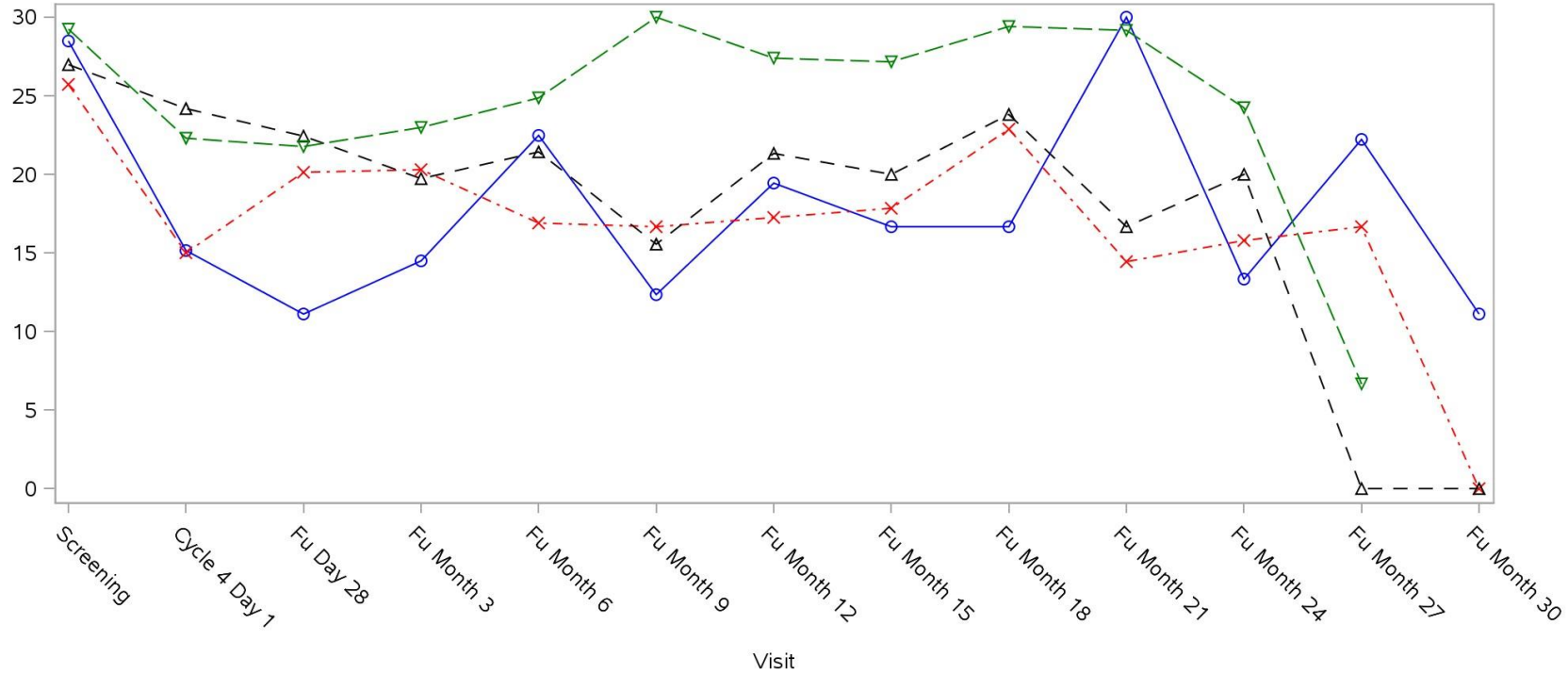
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 04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

High circulating tumor burden (N=495) Laboratory Test: Dyspnoea Scale



Treatment with Subgroup
—○— GCLB, <25x10⁹ cells/L (N=60) - -x- - GCLB, ≥25x10⁹ cells/L (N=195)
- -△- - RCLB, <25x10⁹ cells/L (N=67) - -▽- - RCLB, ≥25x10⁹ cells/L (N=173)

Clinical cut-off: 09MAY2013

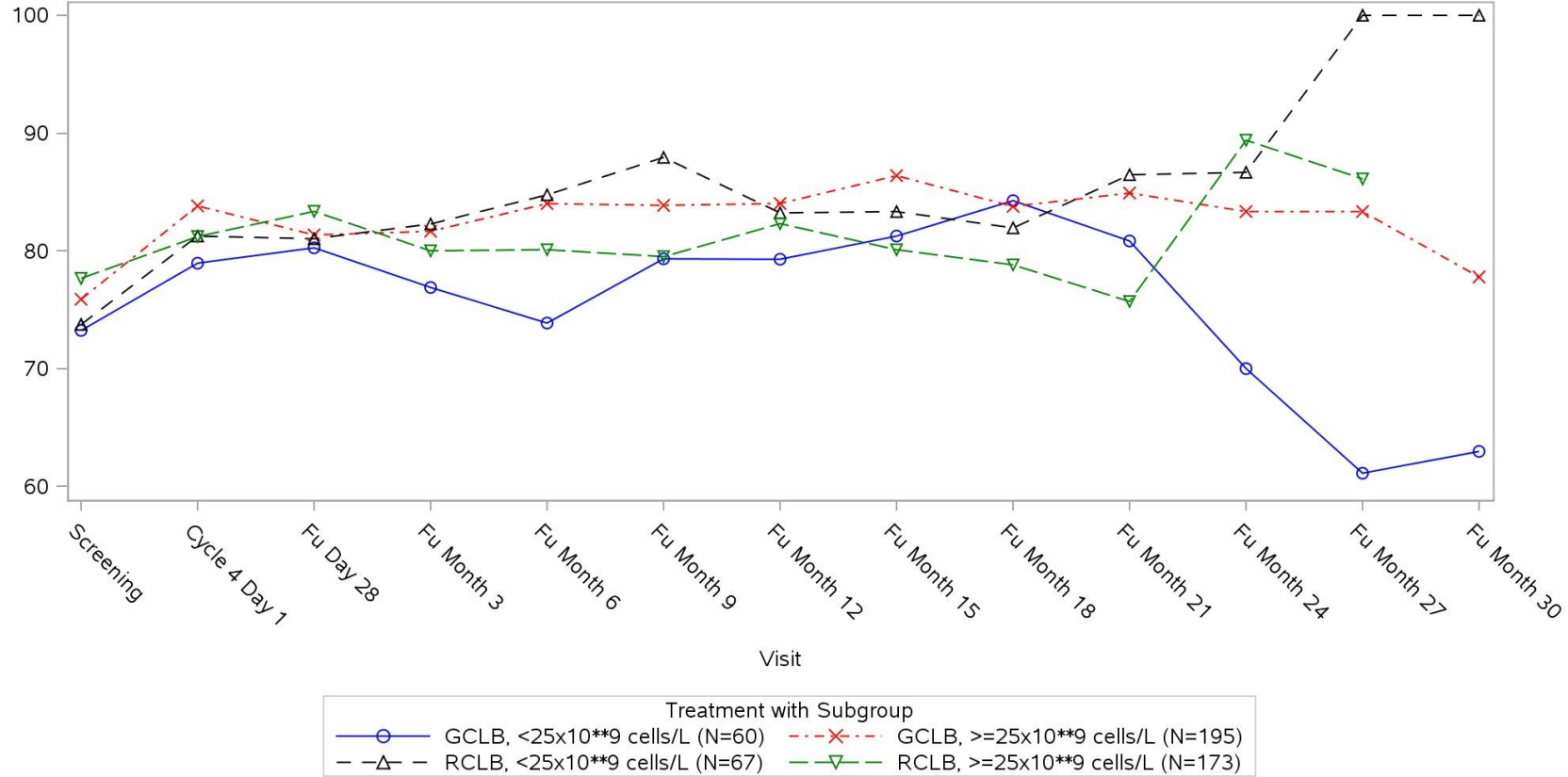
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04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

High circulating tumor burden (N=495) Laboratory Test: Emotional Functioning Scale



Clinical cut-off: 09MAY2013

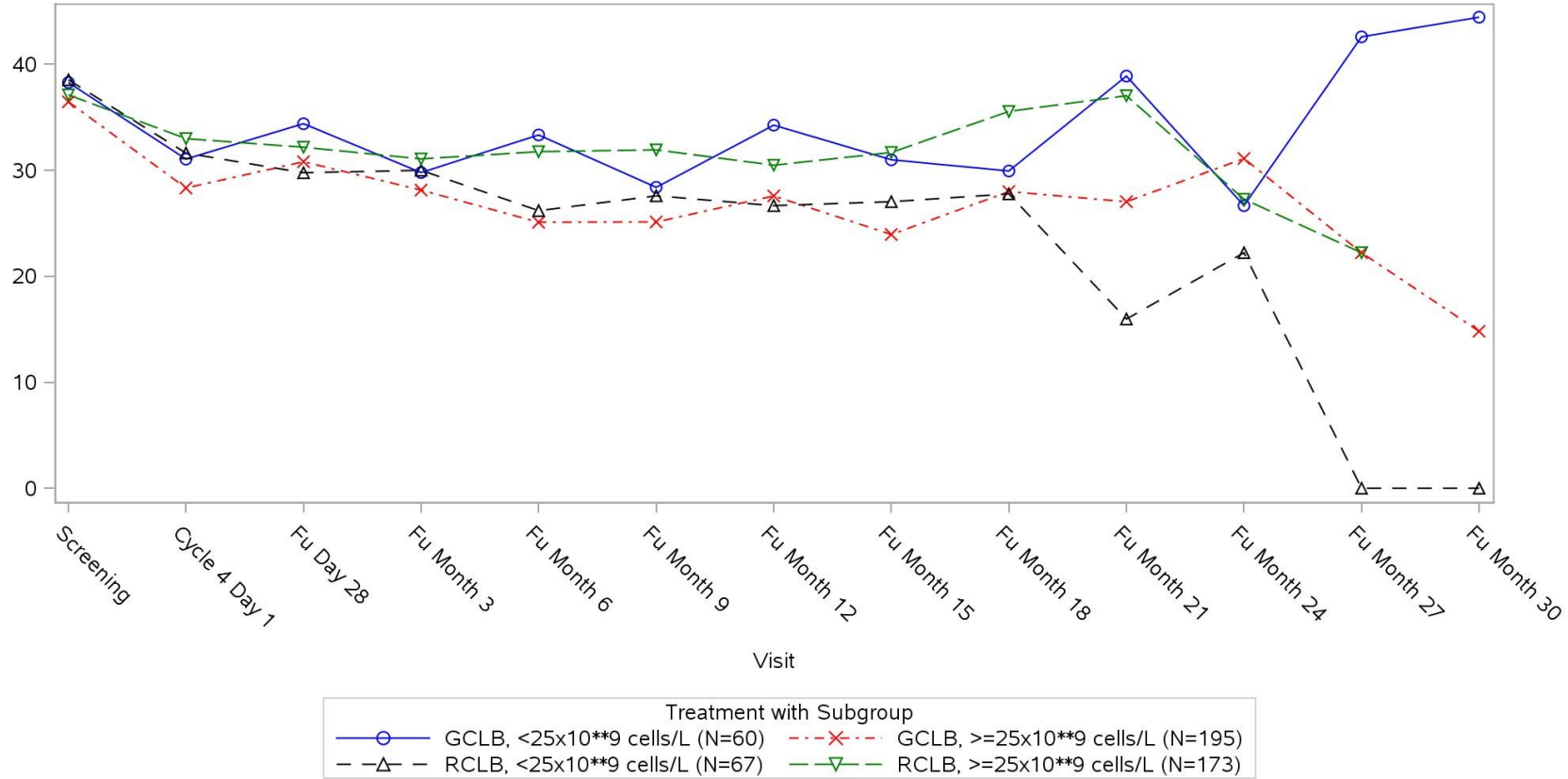
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 04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

High circulating tumor burden (N=495) Laboratory Test: Fatigue Scale



Clinical cut-off: 09MAY2013

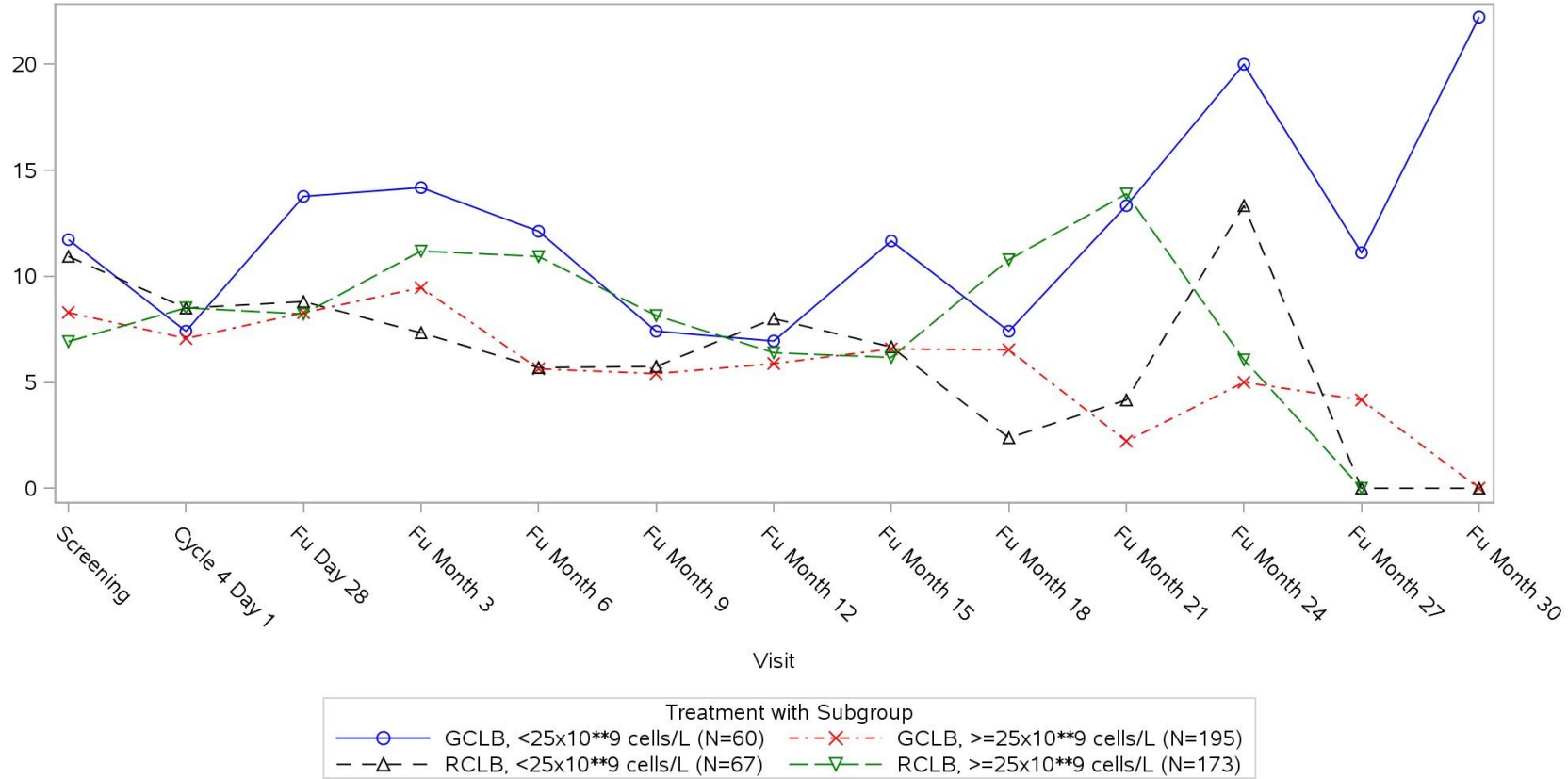
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04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

High circulating tumor burden (N=495) Laboratory Test: Financial Difficulties Scale



Clinical cut-off: 09MAY2013

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Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/g_pro_mean_sg_EQC30_IT_label_09MAY2013_21004.pdf
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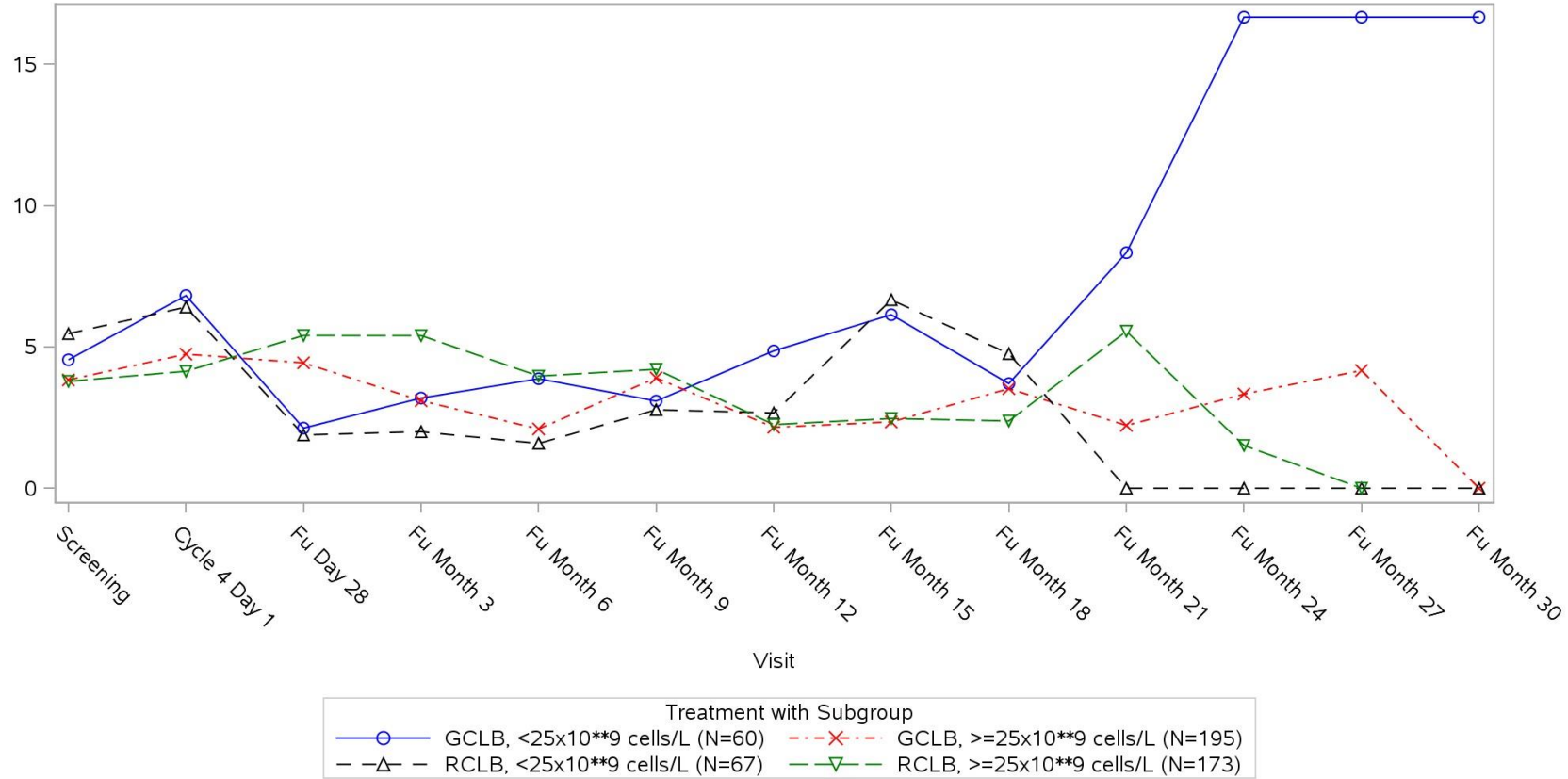
Page 98 of 195

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

High circulating tumor burden (N=495) Laboratory Test: Nausia And Vomiting Scale



Clinical cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/g_pro_mean.sas
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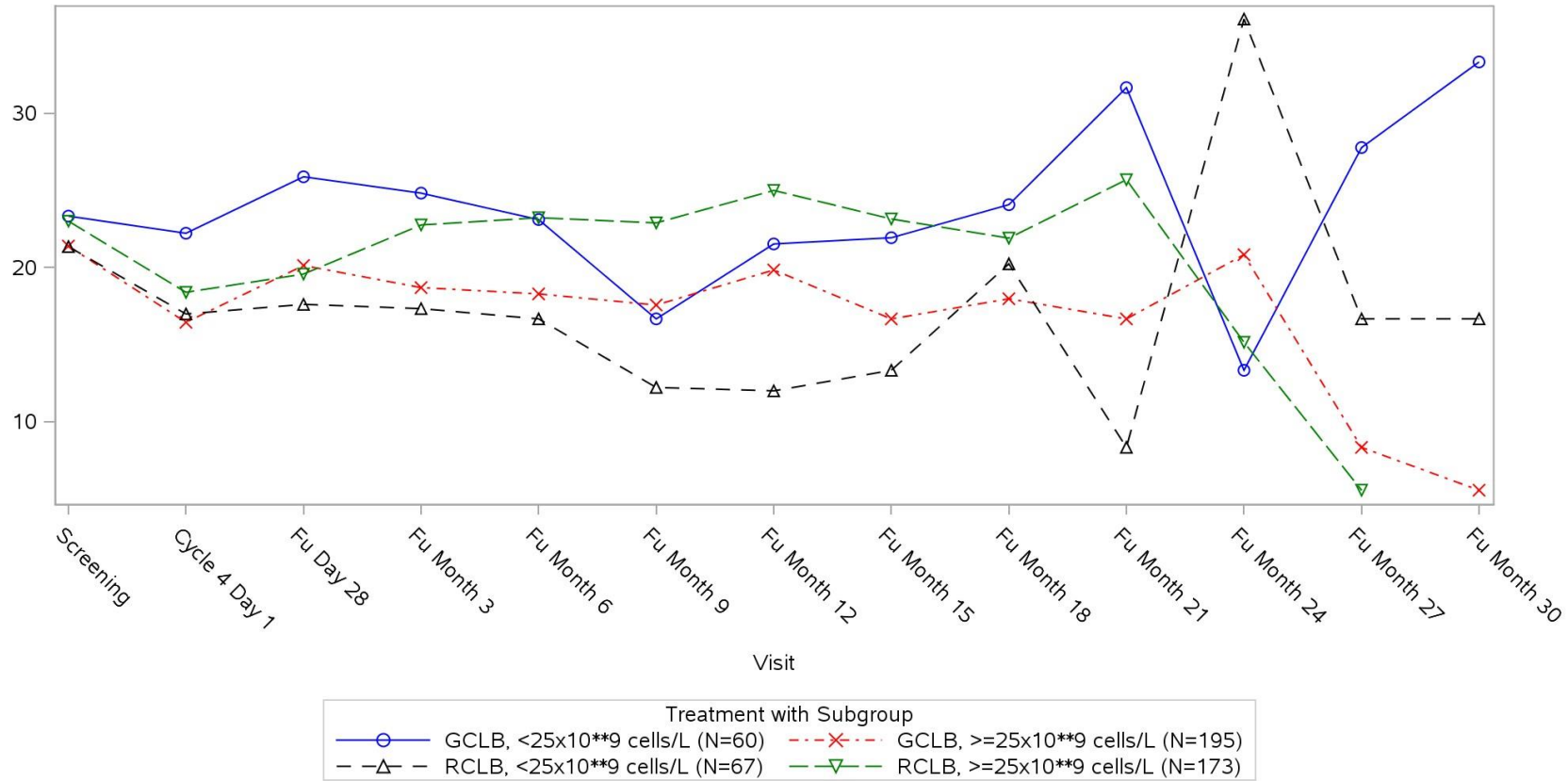
Page 99 of 195

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

High circulating tumor burden (N=495) Laboratory Test: Pain Scale



Clinical cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/g_pro_mean.sas
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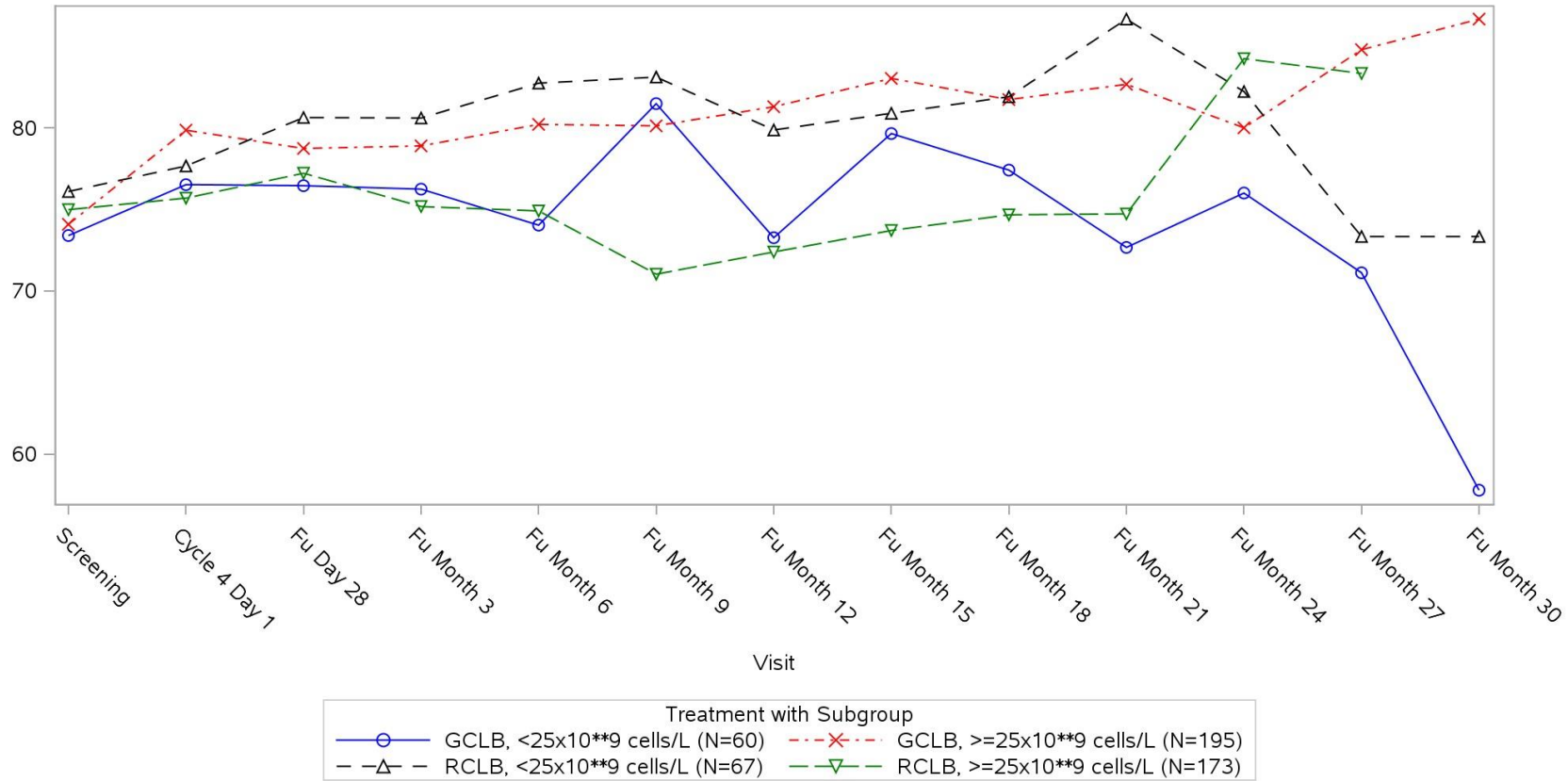
Page 100 of 195

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

High circulating tumor burden (N=495) Laboratory Test: Physical Functioning Scale



Clinical cut-off: 09MAY2013

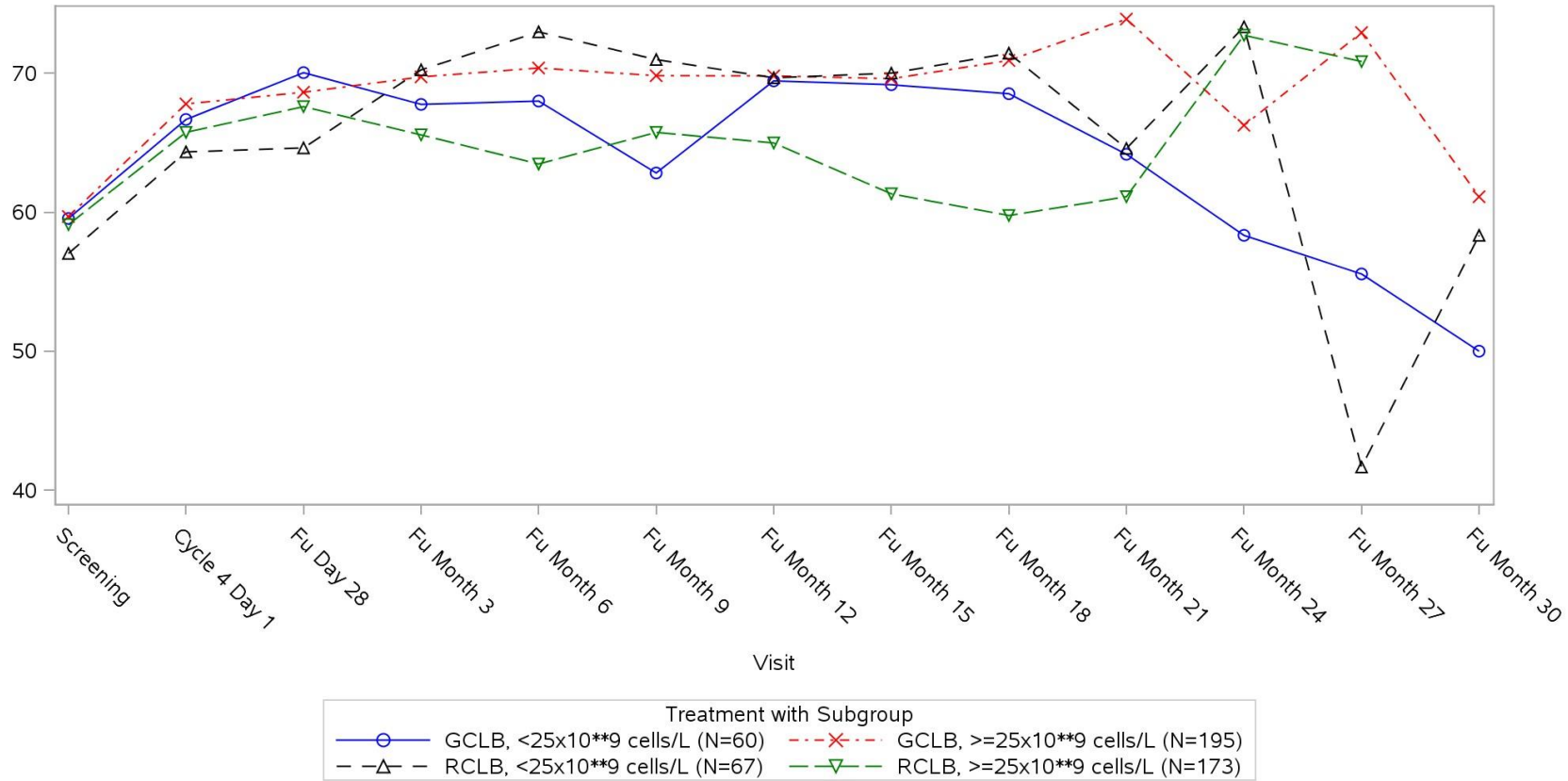
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

High circulating tumor burden (N=495) Laboratory Test: Global Health Status Scale



Clinical cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/g_pro_mean.sas
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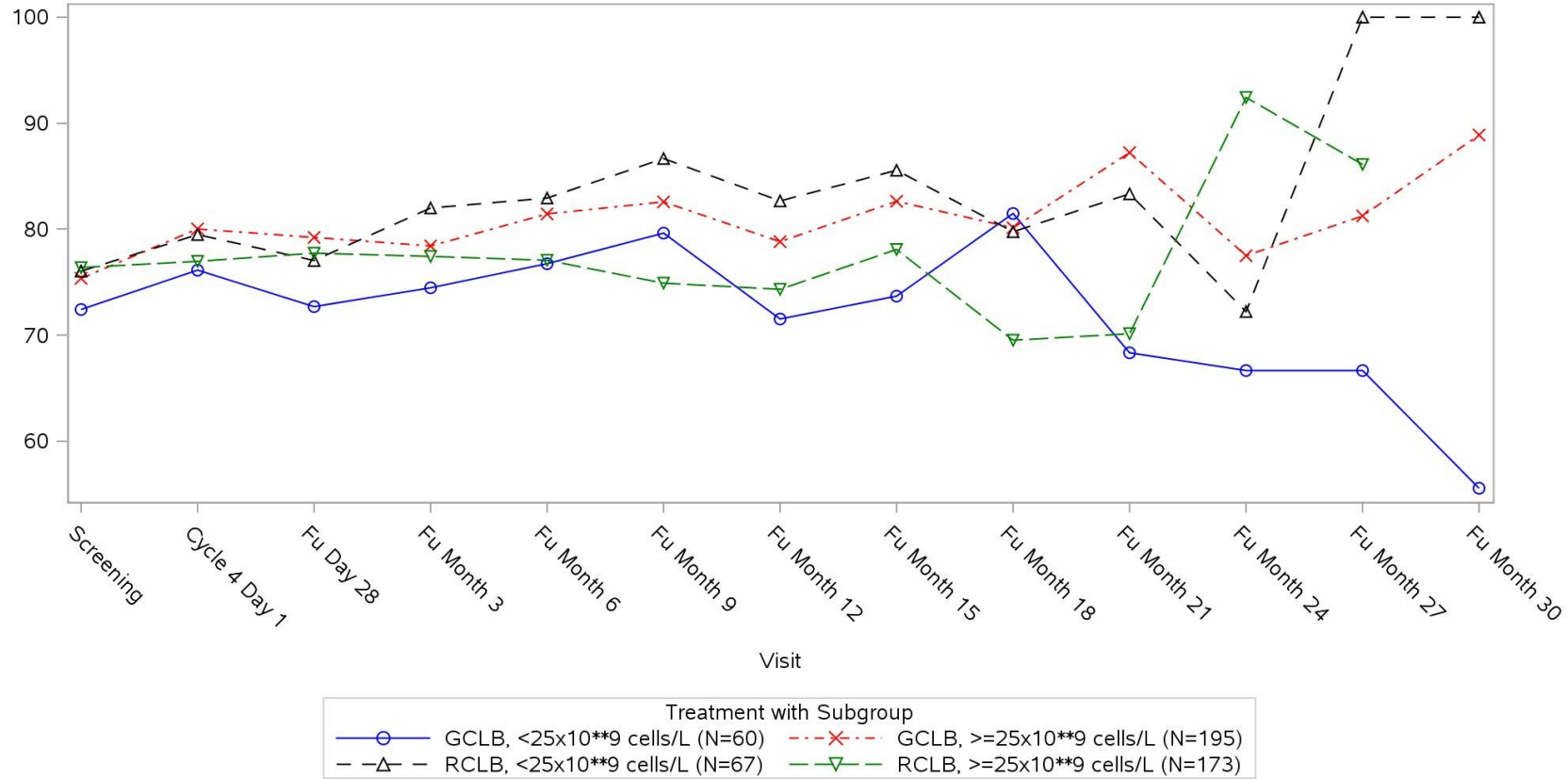
Page 102 of 195

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

High circulating tumor burden (N=495) Laboratory Test: Role Functioning Scale



Clinical cut-off: 09MAY2013

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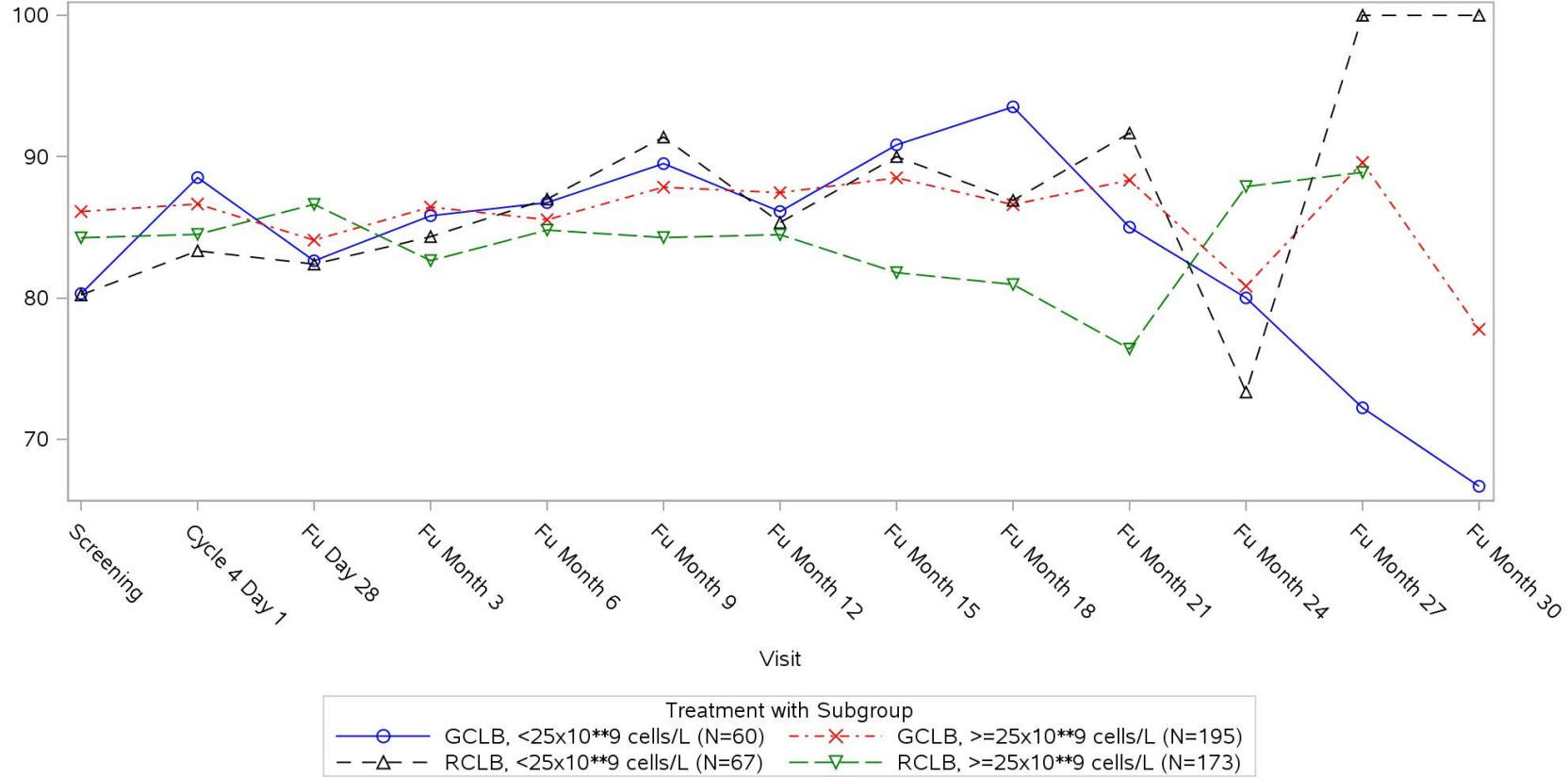
Page 103 of 195

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

High circulating tumor burden (N=495) Laboratory Test: Social Functioning Scale



Clinical cut-off: 09MAY2013

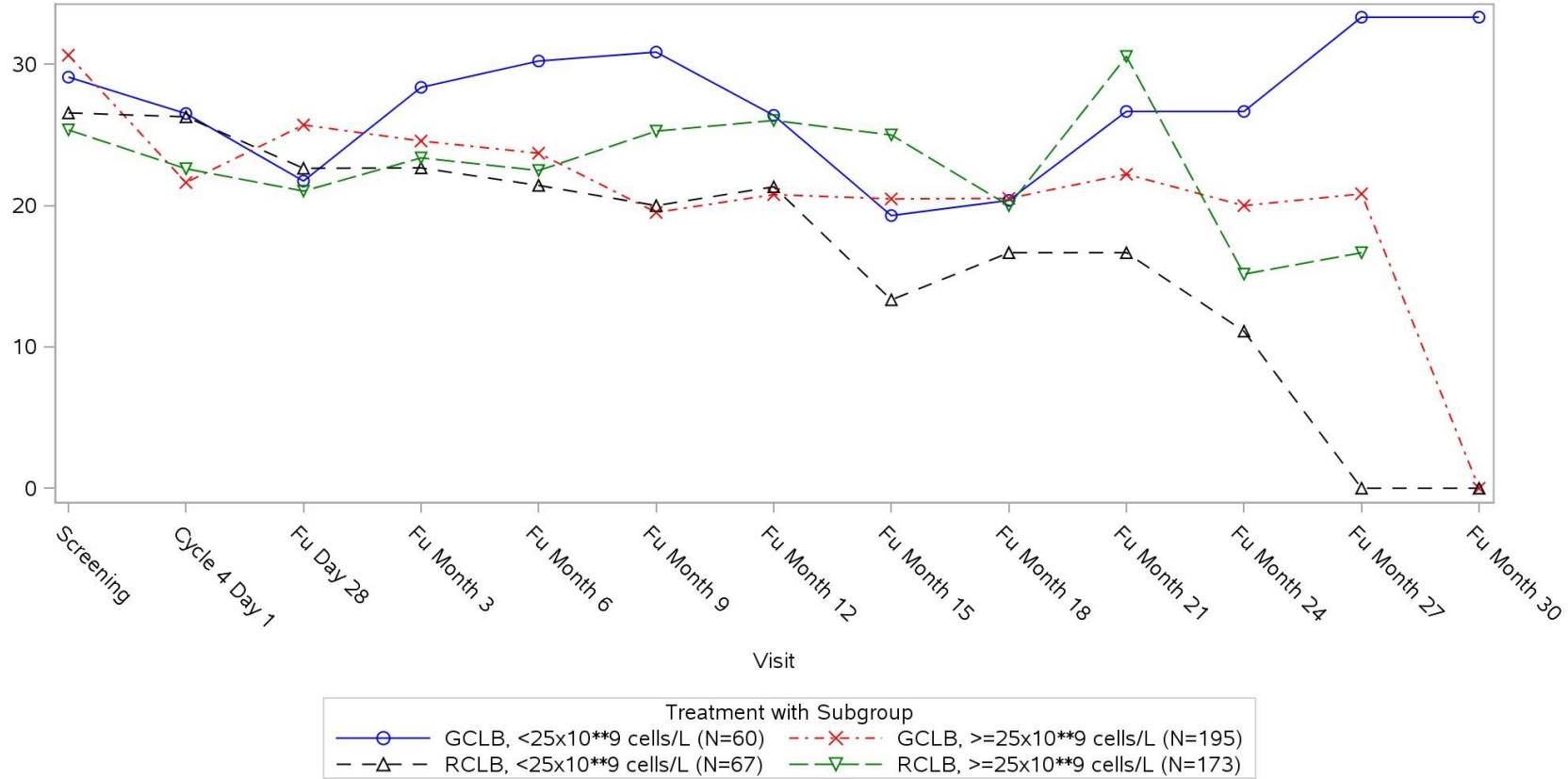
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

High circulating tumor burden (N=495) Laboratory Test: Insomnia Scale



Clinical cut-off: 09MAY2013

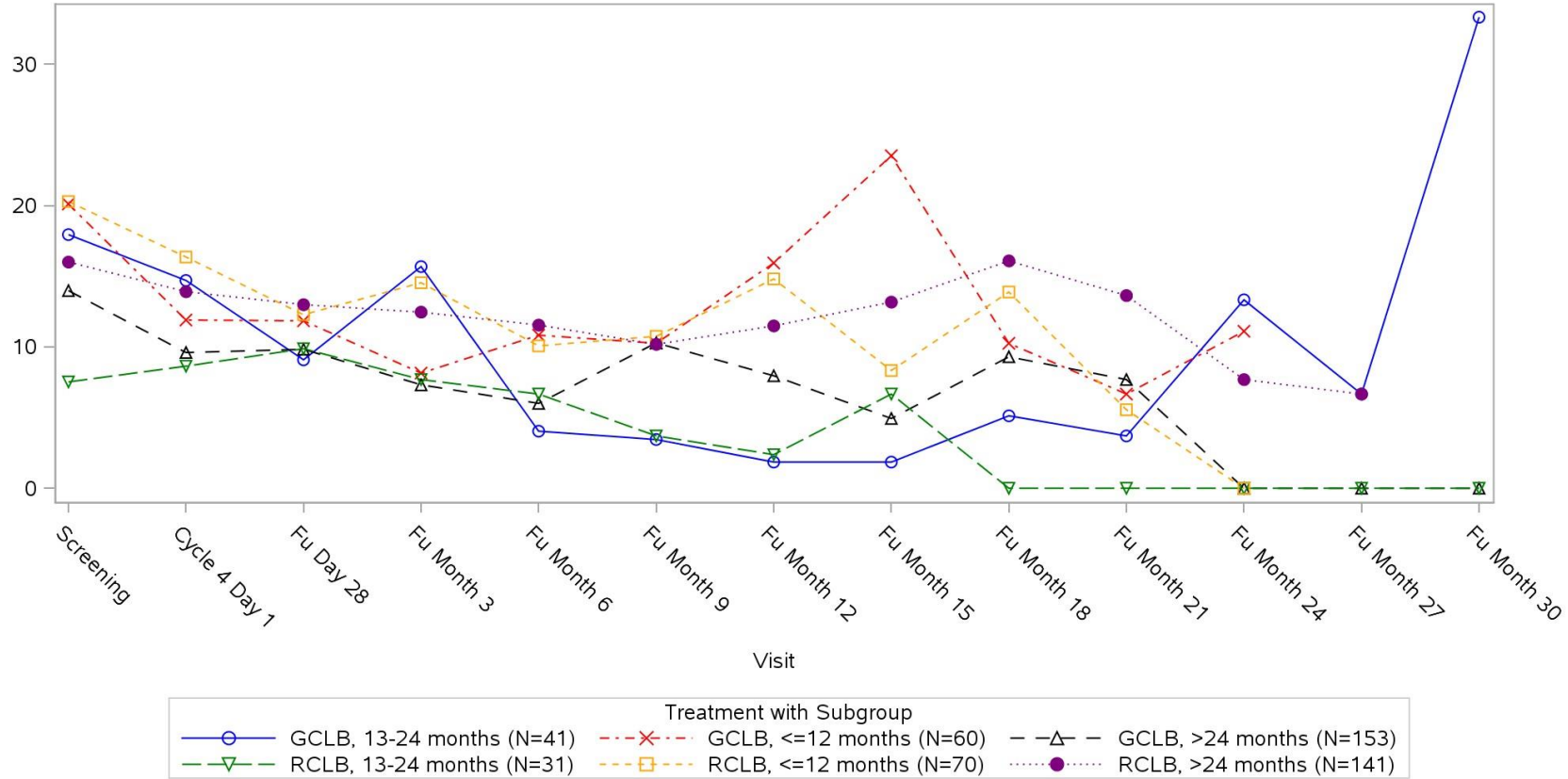
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Time from first diagnosis (N=496) Laboratory Test: Appetite Loss Scale



Clinical cut-off: 09MAY2013

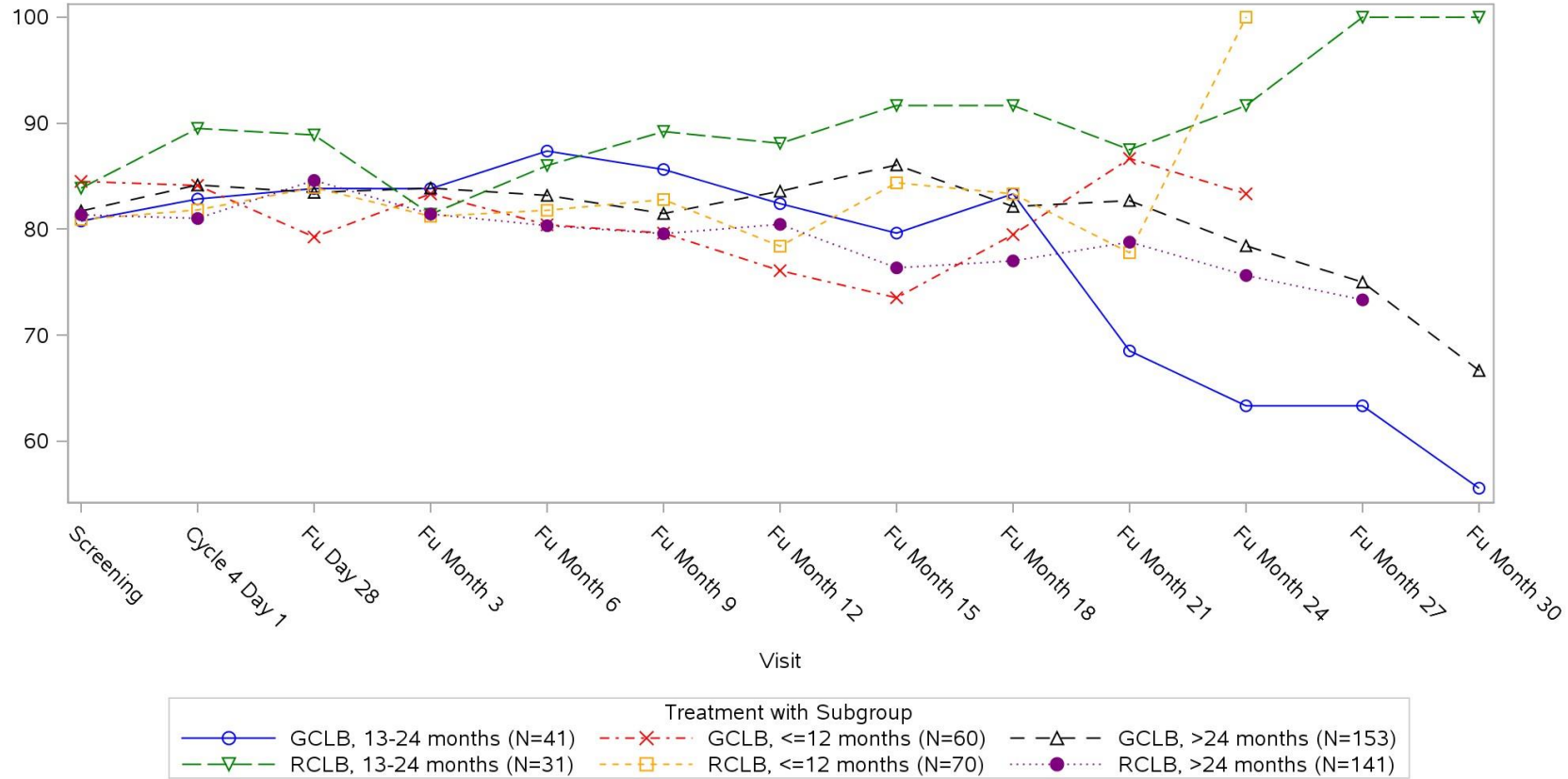
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Time from first diagnosis (N=496) Laboratory Test: Cognitive Functioning Scale



Clinical cut-off: 09MAY2013

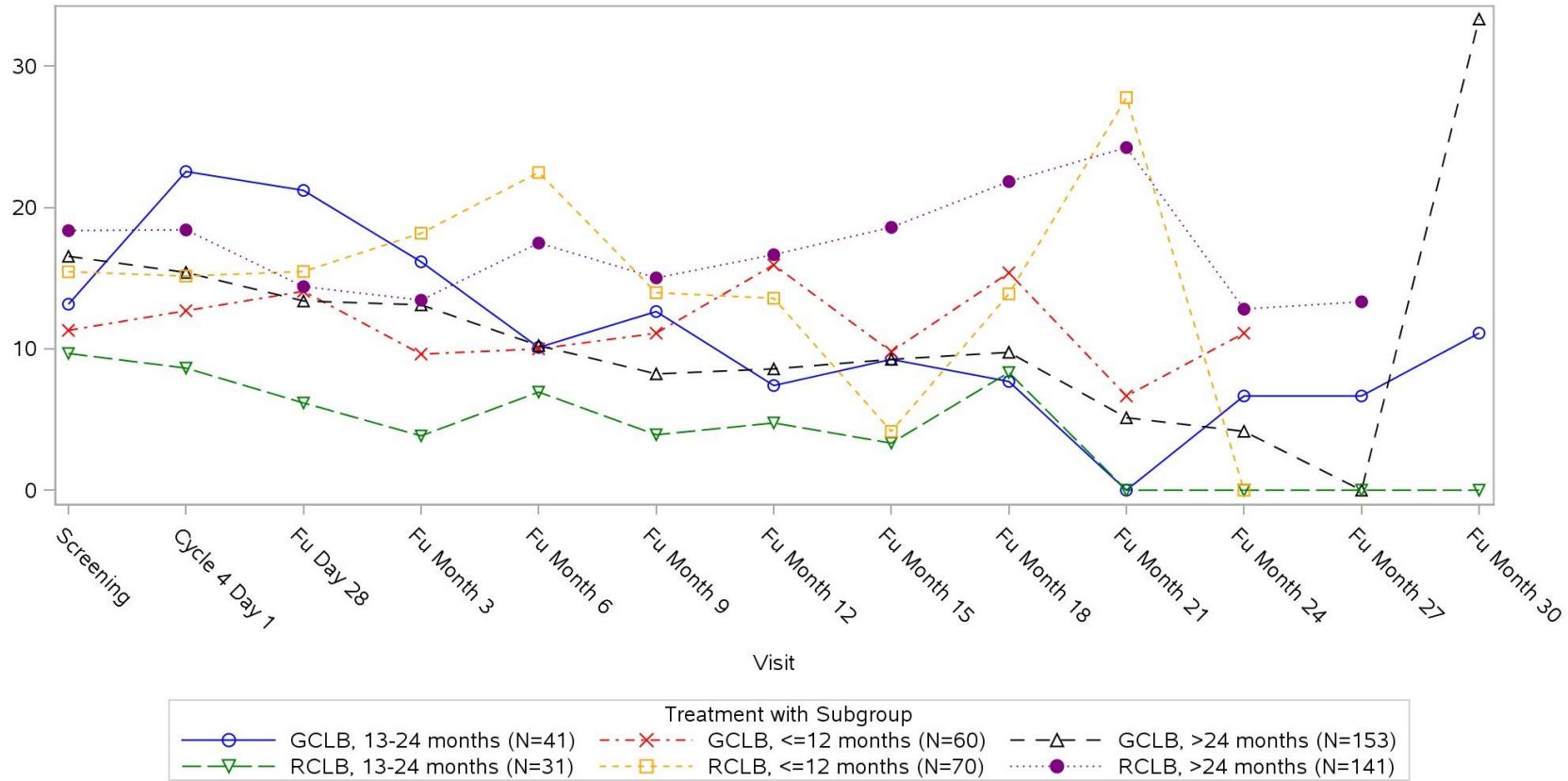
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 04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Time from first diagnosis (N=496) Laboratory Test: Constipation Scale



Clinical cut-off: 09MAY2013

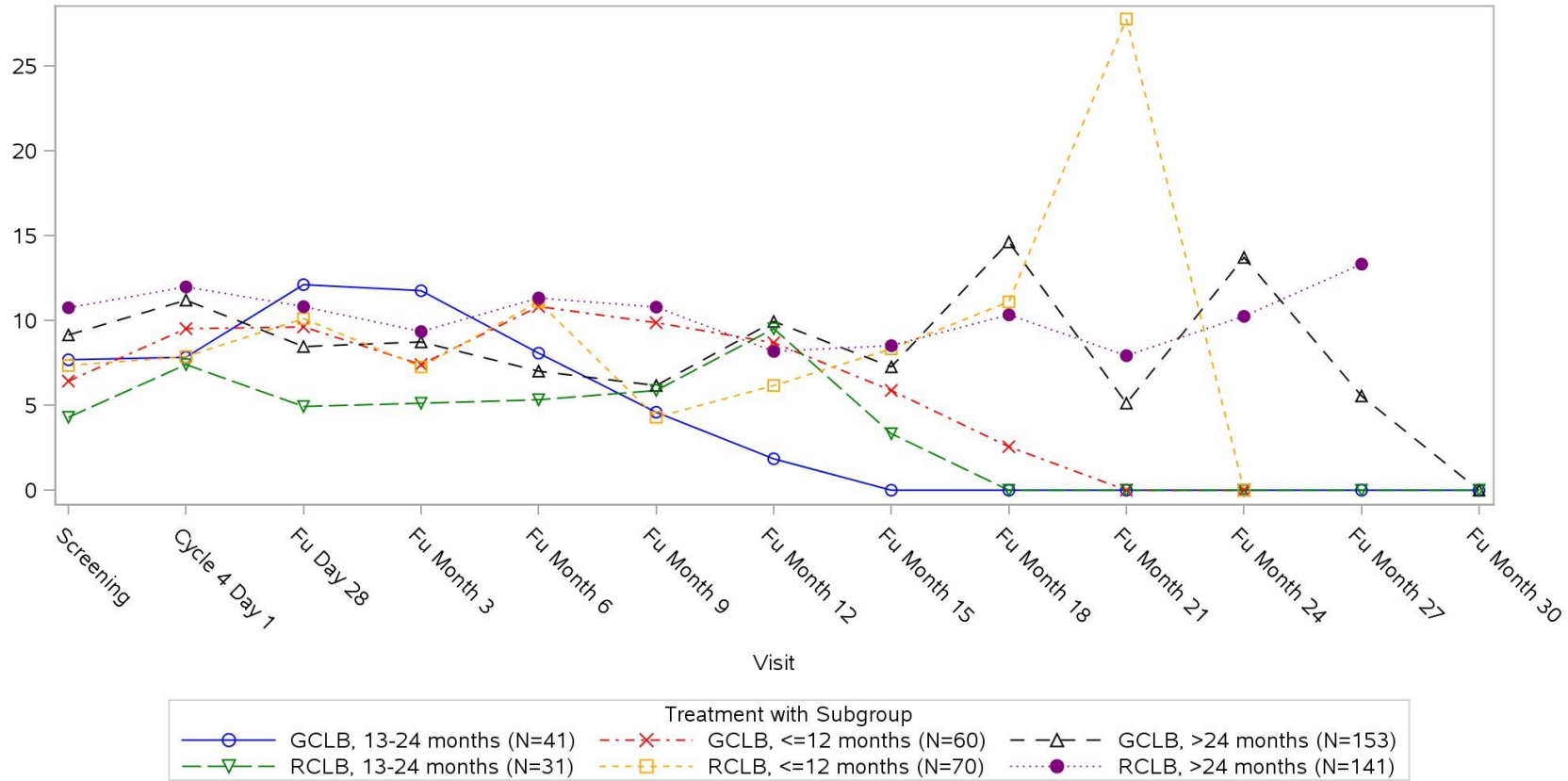
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Time from first diagnosis (N=496) Laboratory Test: Diarrhoea Scale



Clinical cut-off: 09MAY2013

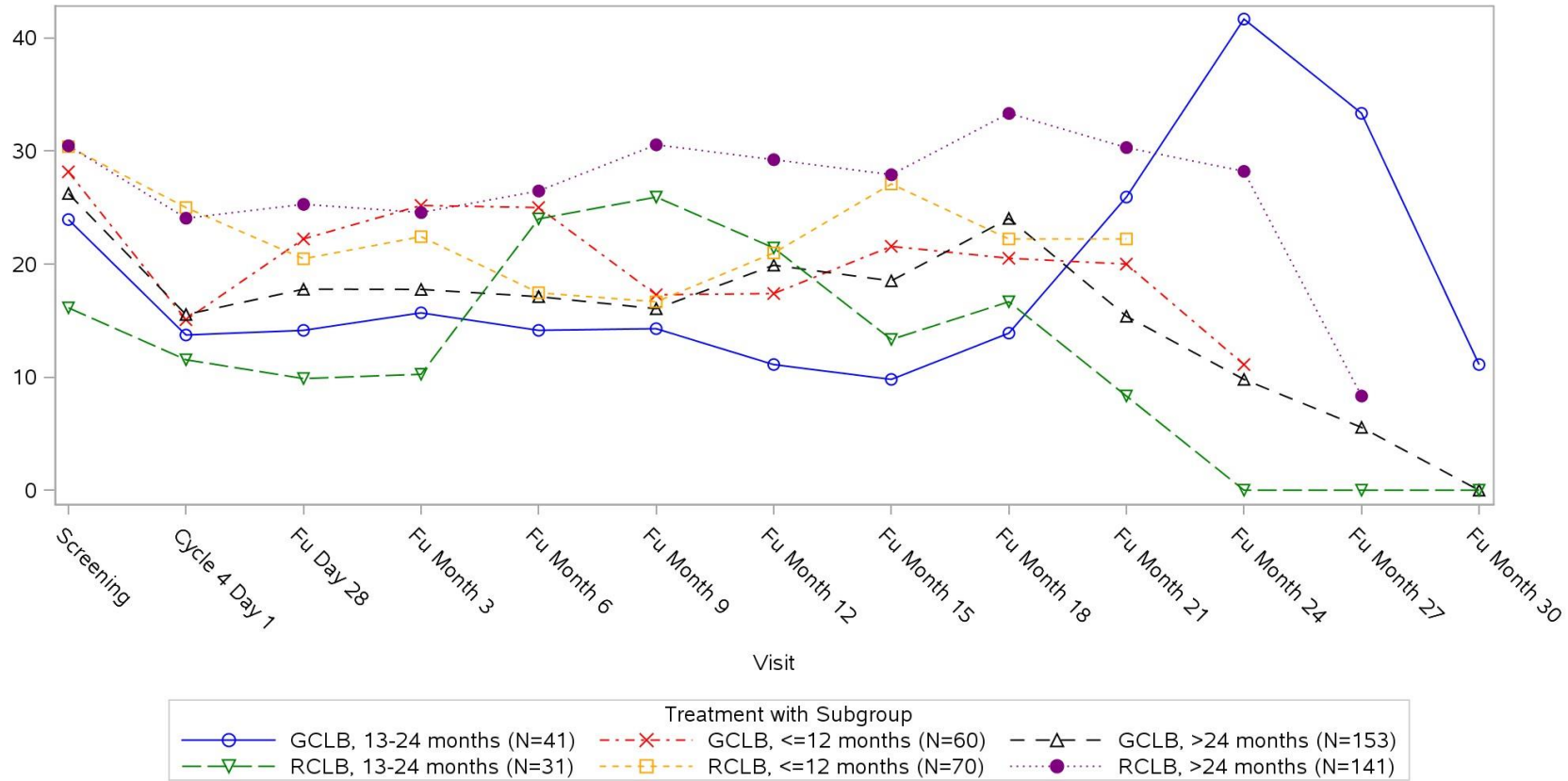
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Time from first diagnosis (N=496) Laboratory Test: Dyspnoea Scale



Clinical cut-off: 09MAY2013

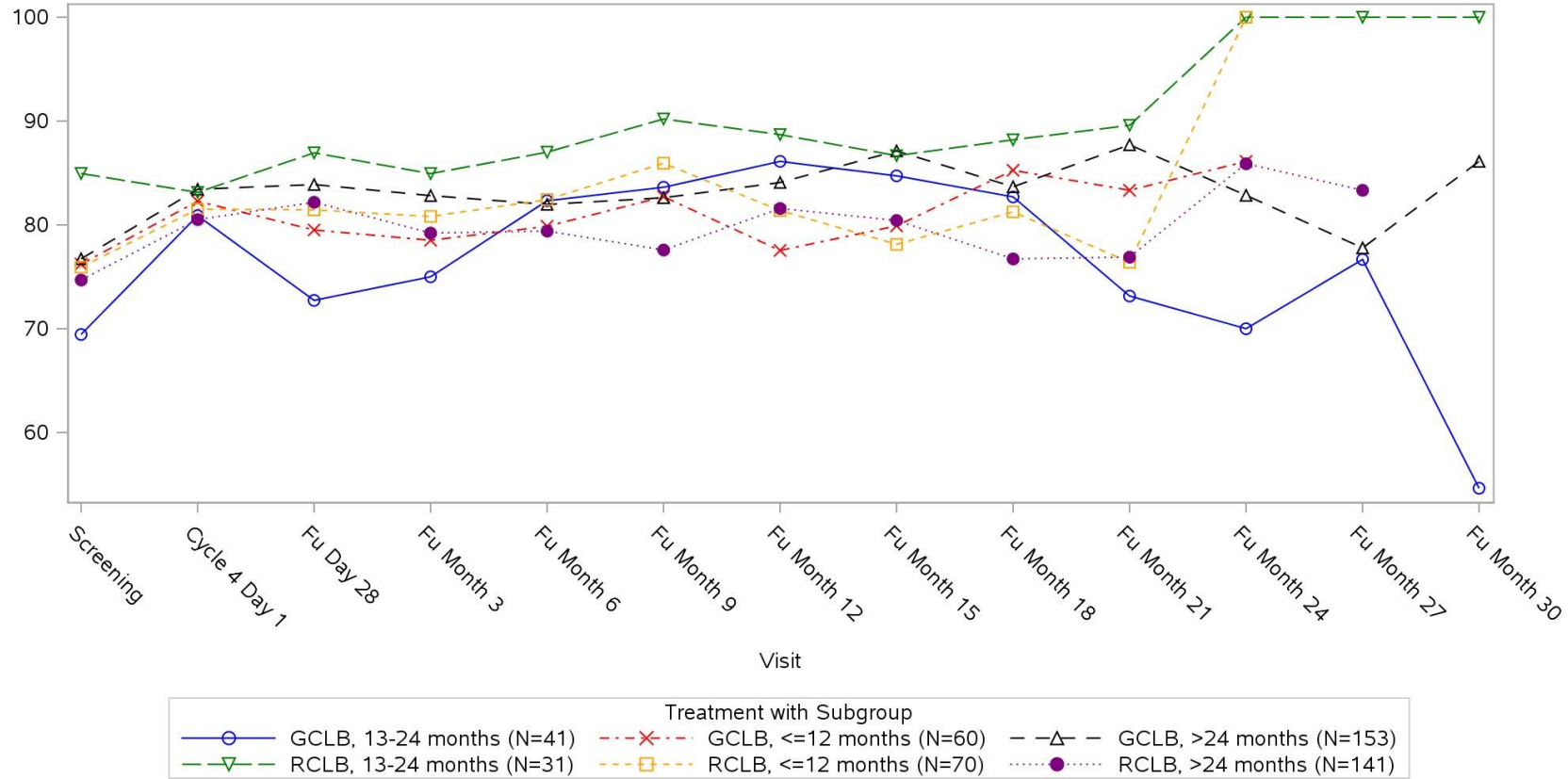
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Time from first diagnosis (N=496) Laboratory Test: Emotional Functioning Scale



Clinical cut-off: 09MAY2013

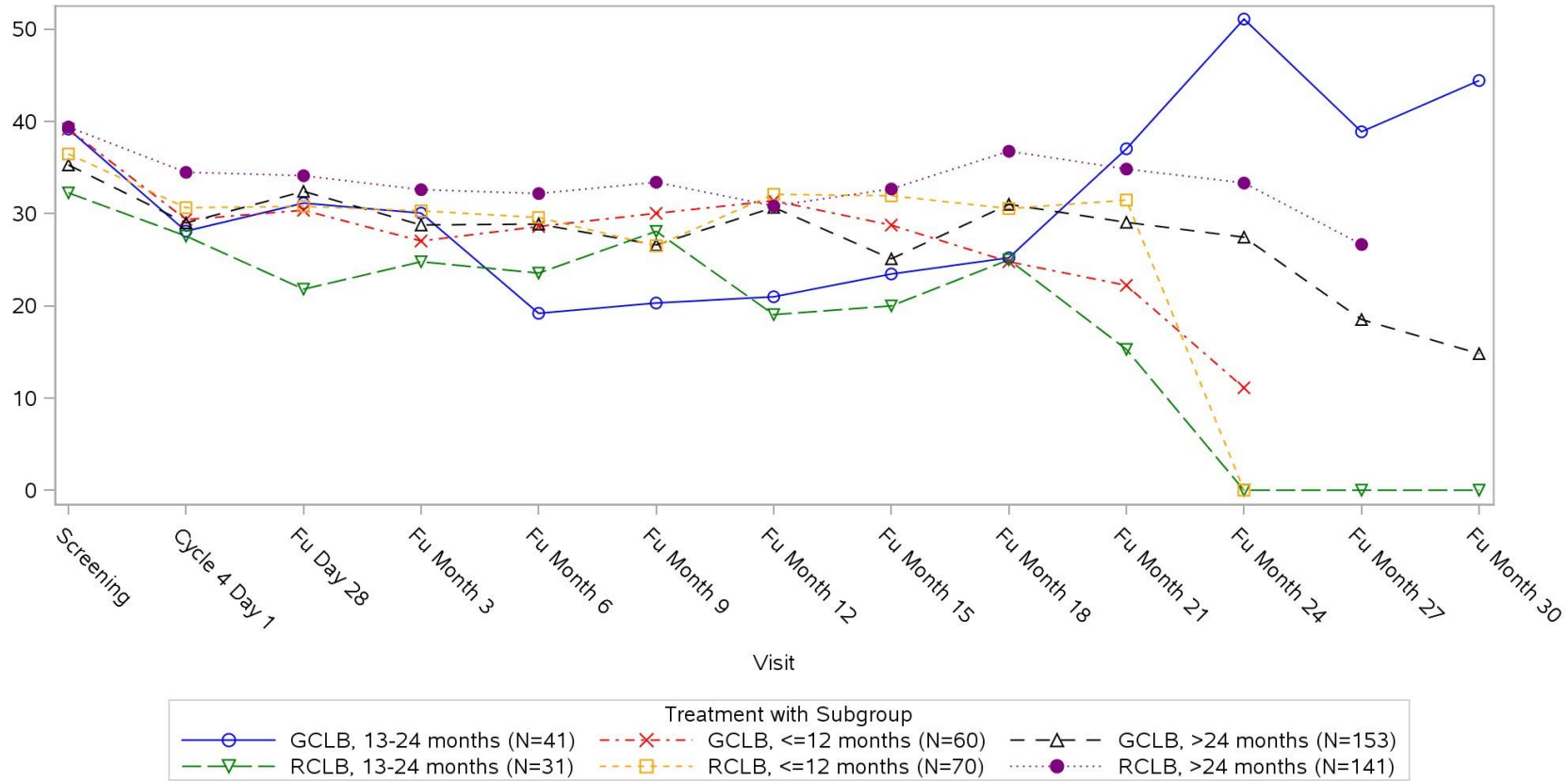
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Time from first diagnosis (N=496) Laboratory Test: Fatigue Scale



Clinical cut-off: 09MAY2013

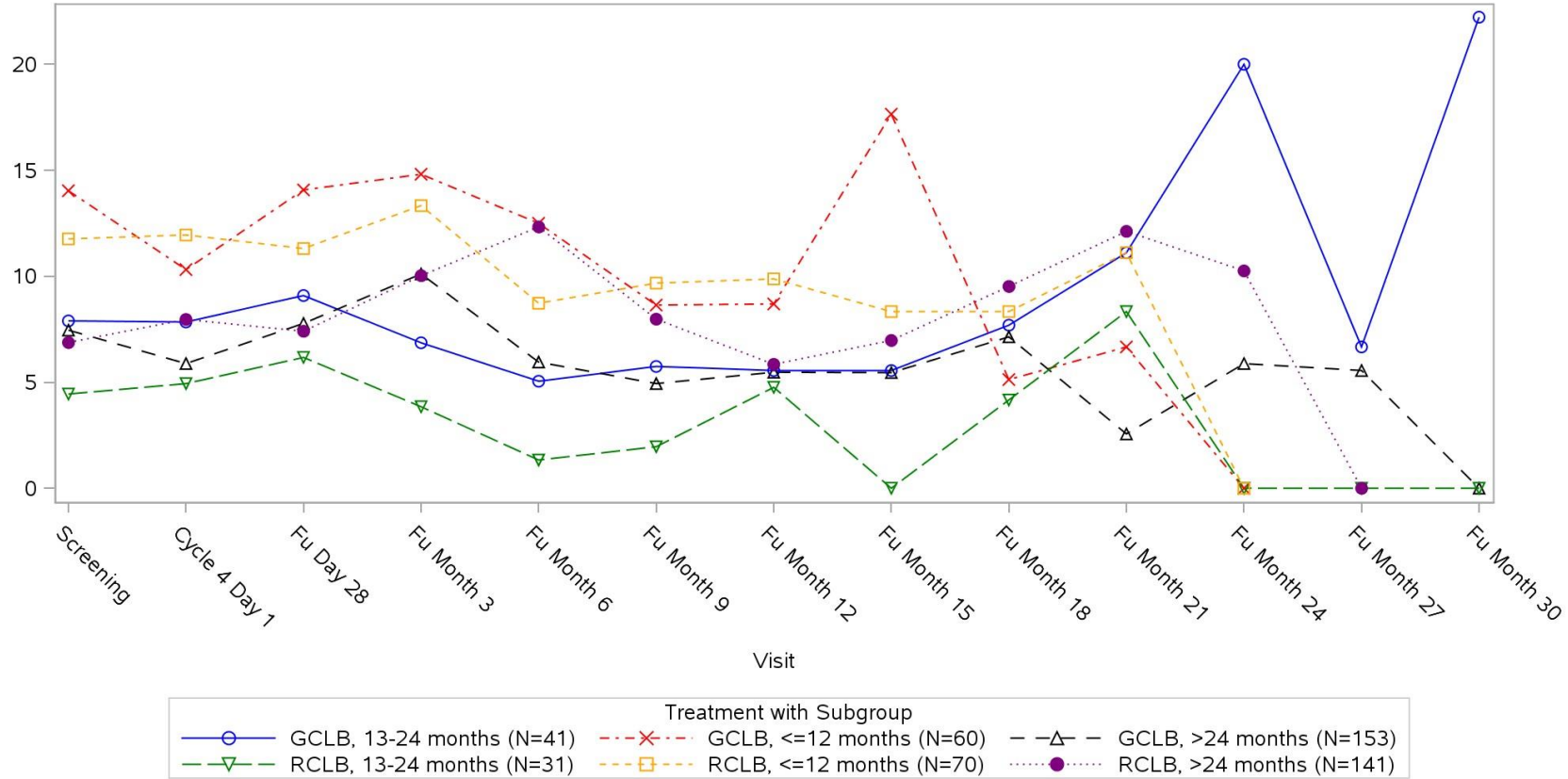
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 04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Time from first diagnosis (N=496) Laboratory Test: Financial Difficulties Scale



Clinical cut-off: 09MAY2013

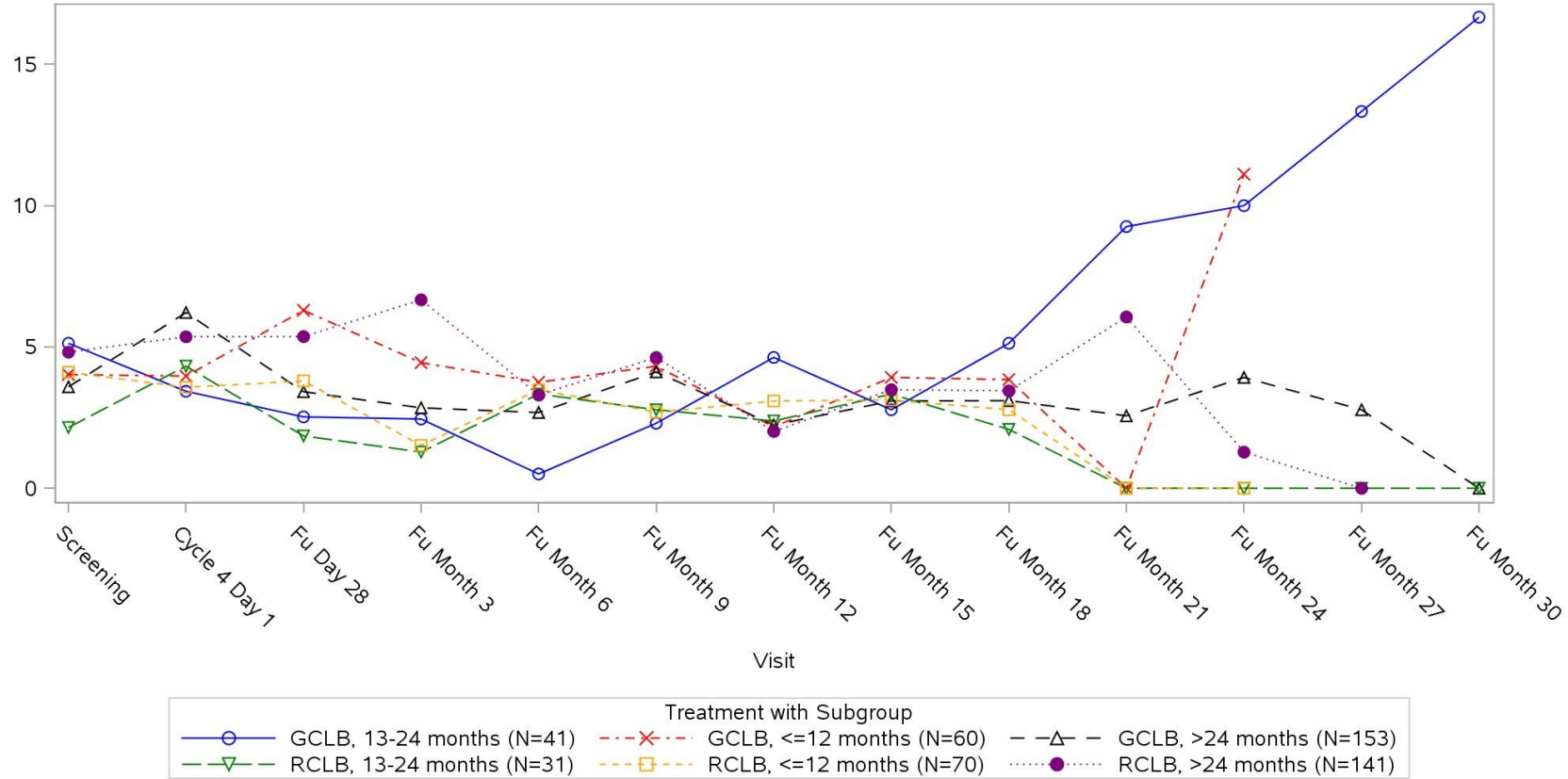
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 04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Time from first diagnosis (N=496) Laboratory Test: Nausea And Vomiting Scale



Clinical cut-off: 09MAY2013

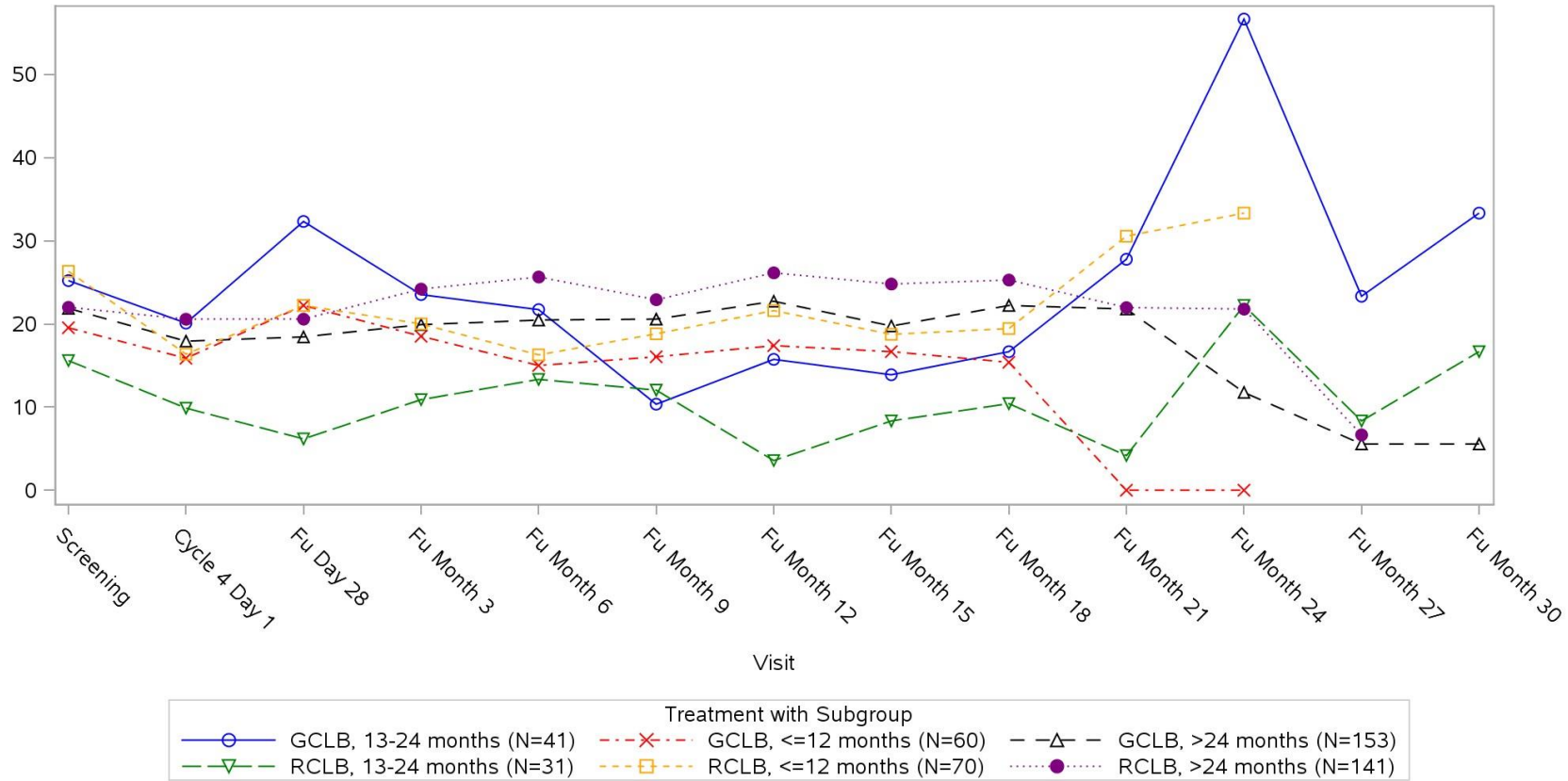
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Time from first diagnosis (N=496) Laboratory Test: Pain Scale



Clinical cut-off: 09MAY2013

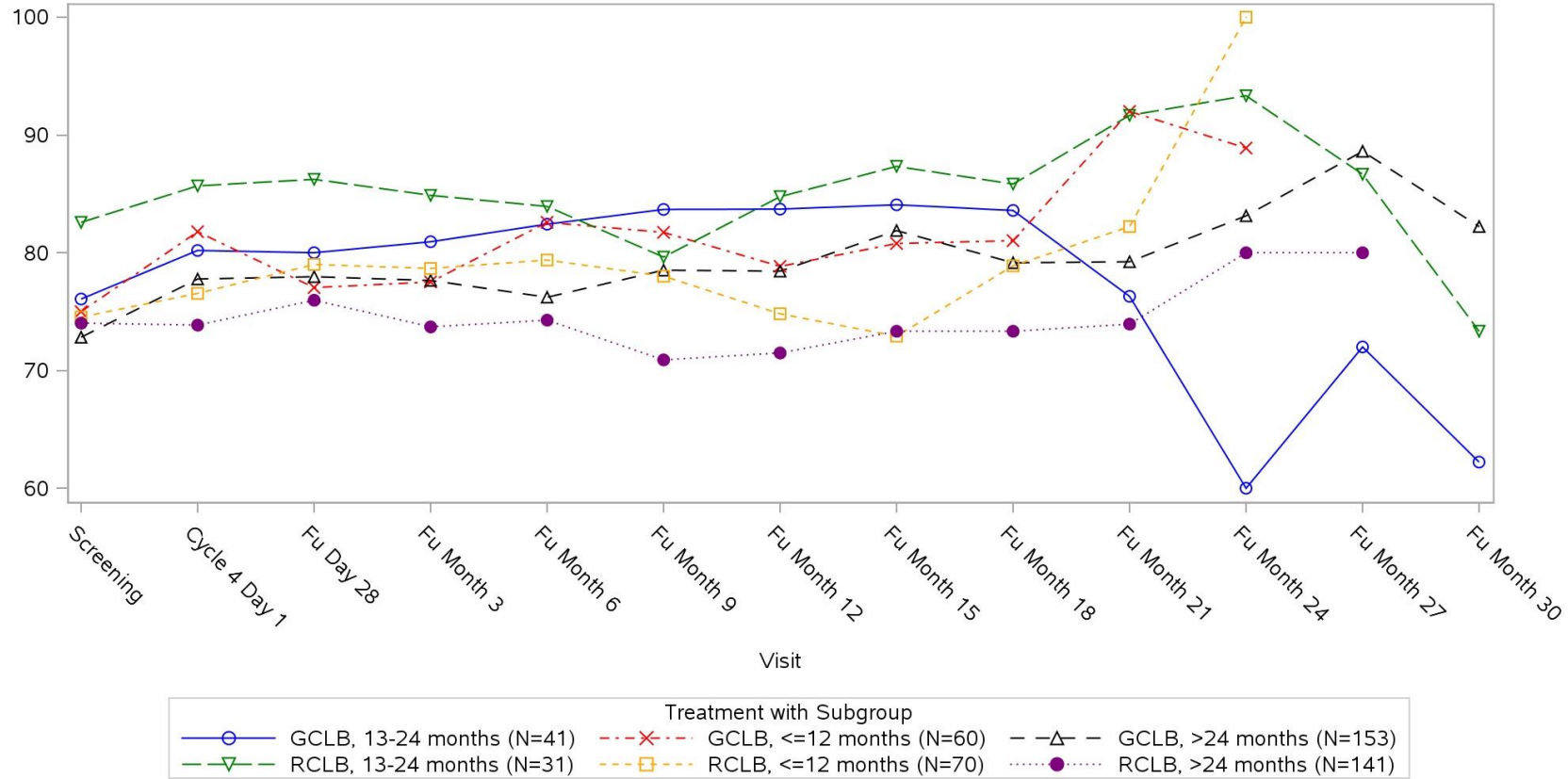
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 04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Time from first diagnosis (N=496) Laboratory Test: Physical Functioning Scale



Clinical cut-off: 09MAY2013

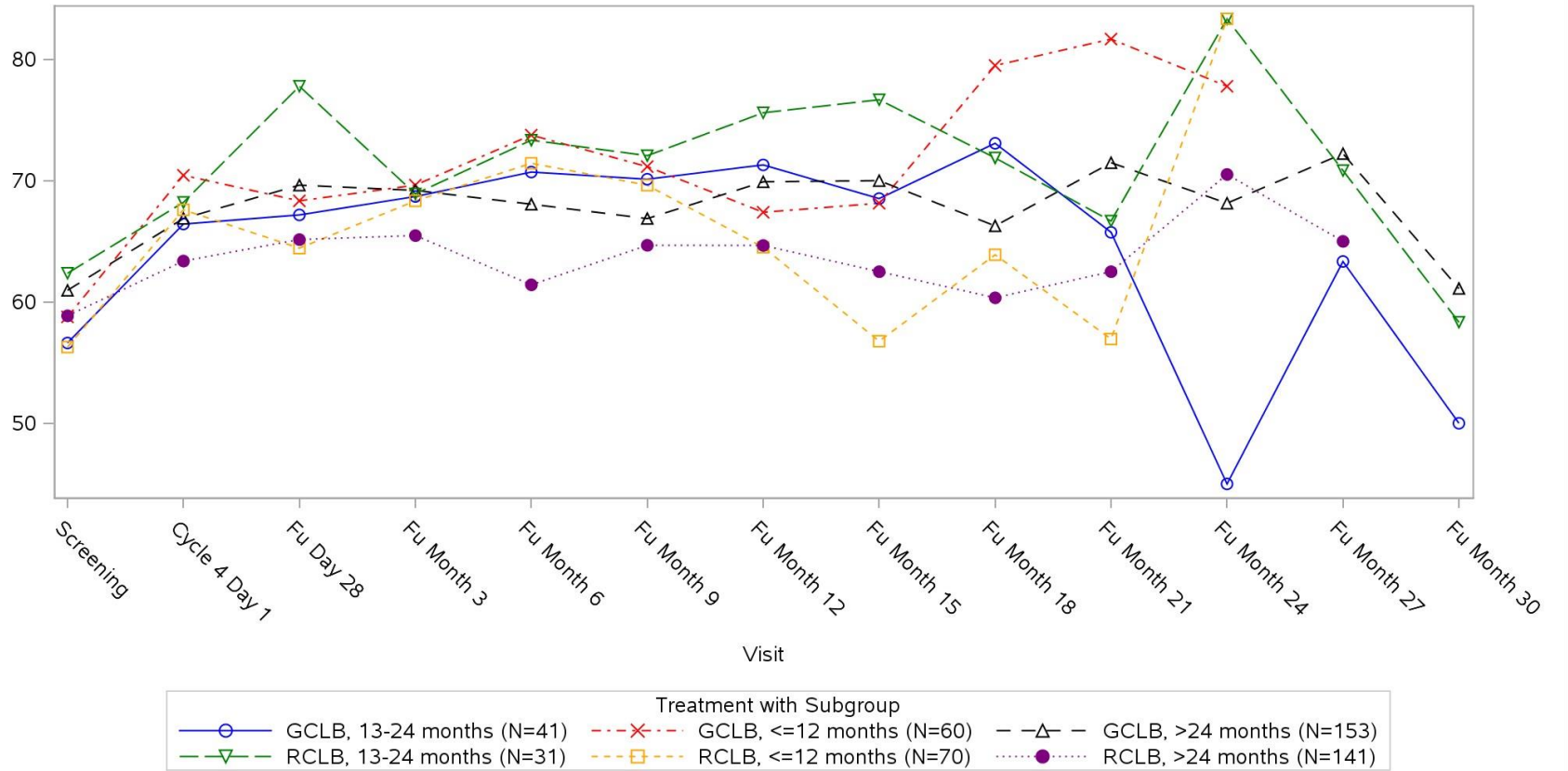
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 04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Time from first diagnosis (N=496) Laboratory Test: Global Health Status Scale



Clinical cut-off: 09MAY2013

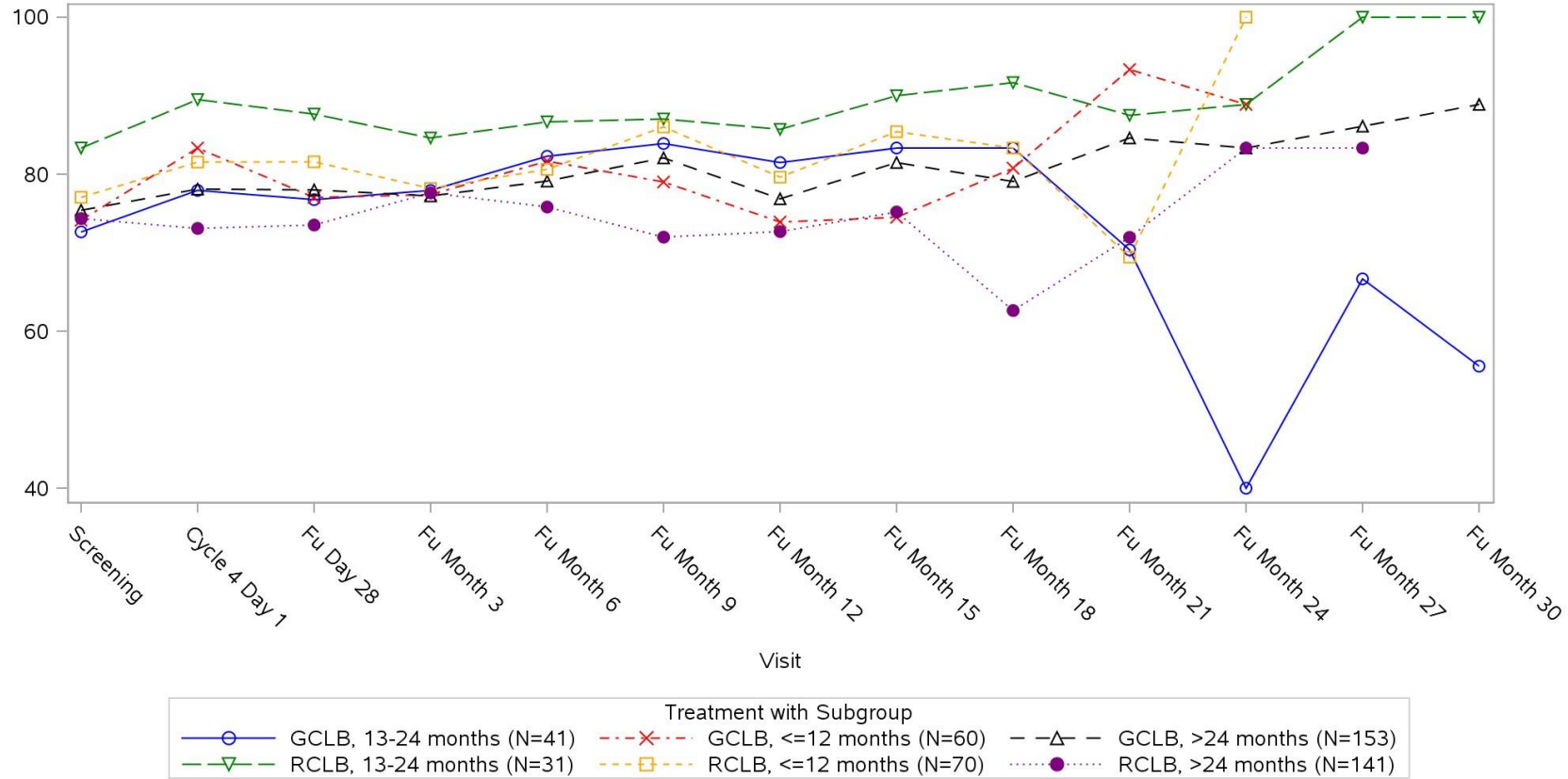
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 04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Time from first diagnosis (N=496) Laboratory Test: Role Functioning Scale



Clinical cut-off: 09MAY2013

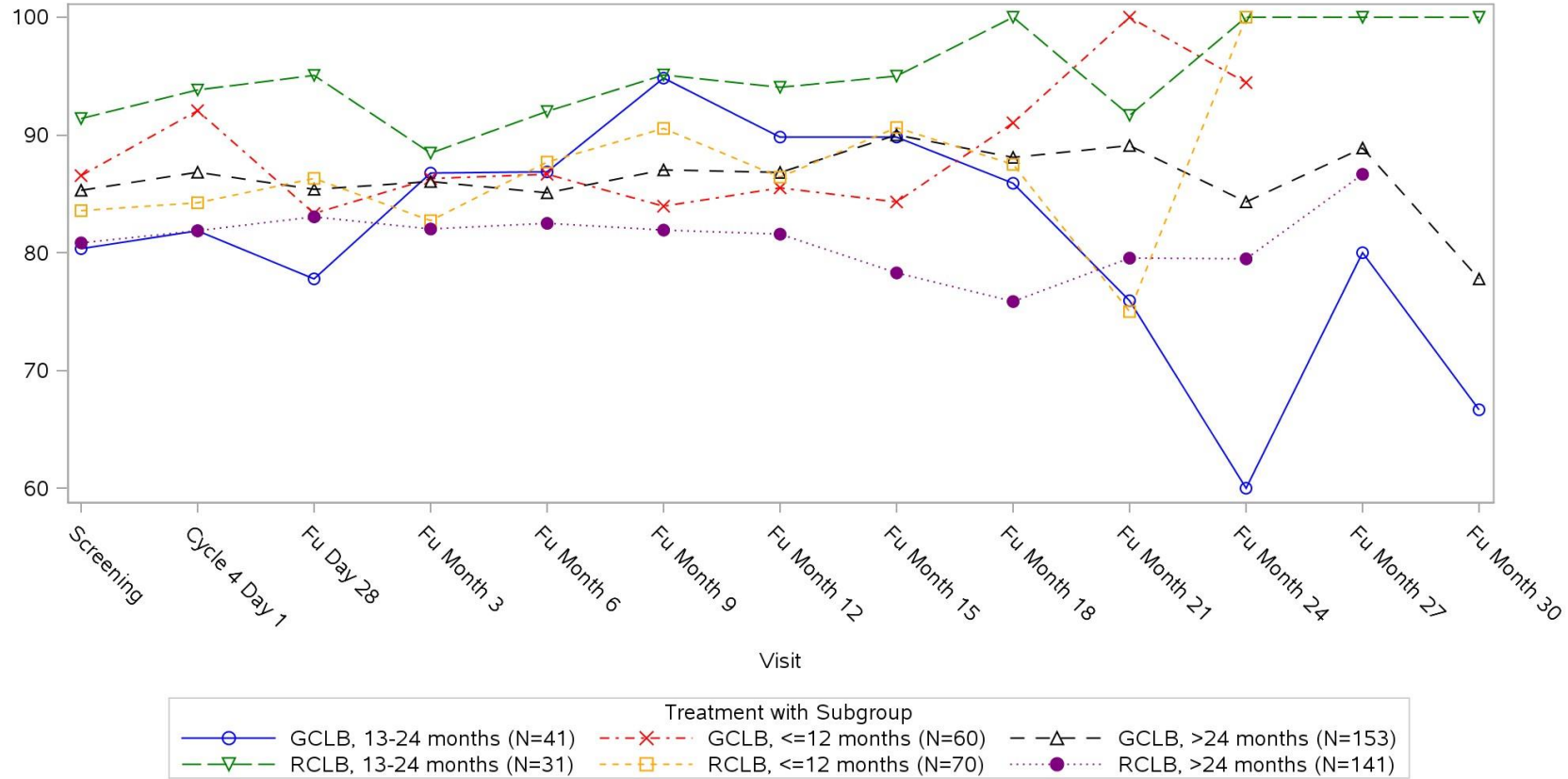
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04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Time from first diagnosis (N=496) Laboratory Test: Social Functioning Scale



Clinical cut-off: 09MAY2013

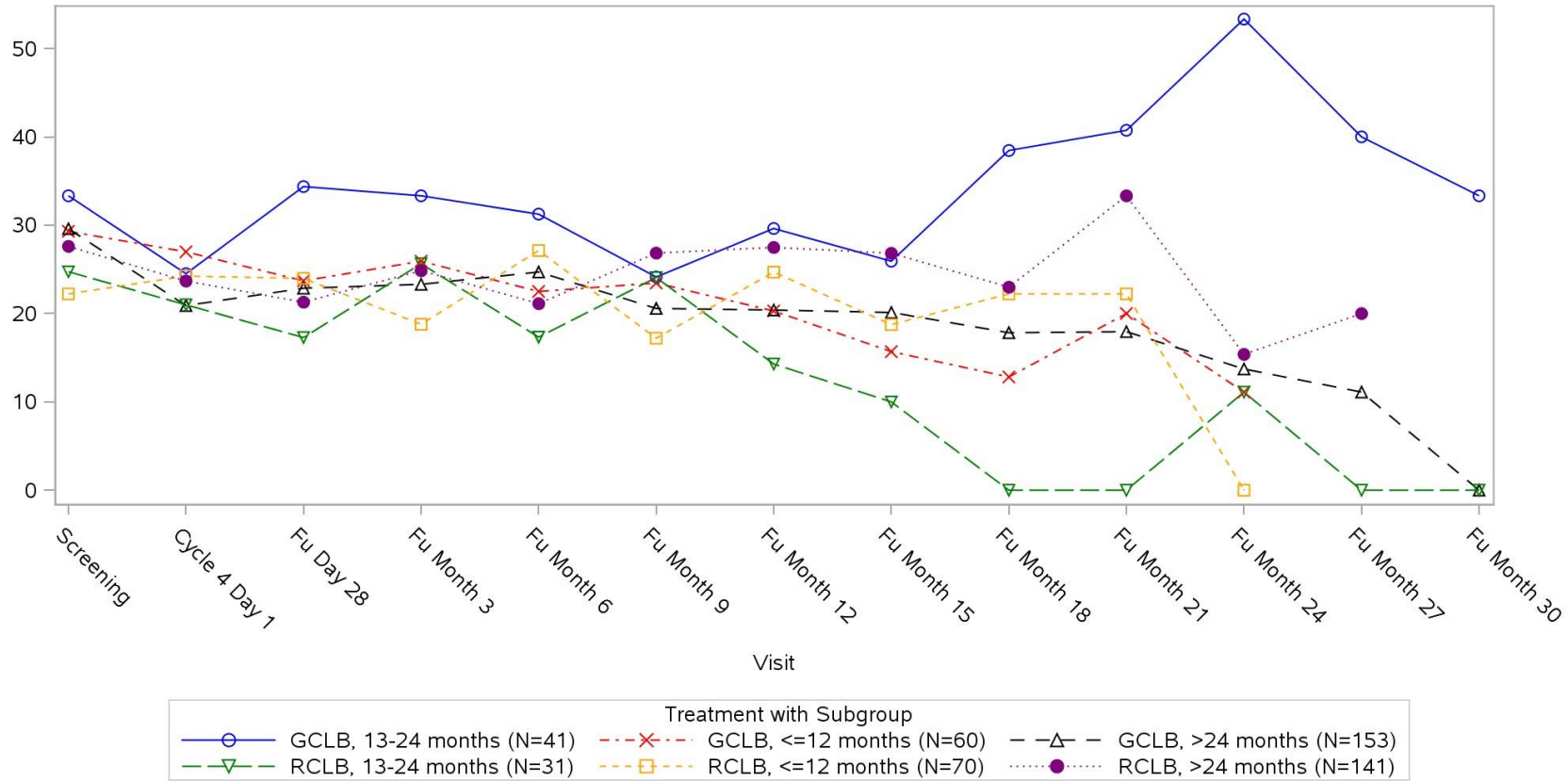
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Time from first diagnosis (N=496) Laboratory Test: Insomnia Scale



Clinical cut-off: 09MAY2013

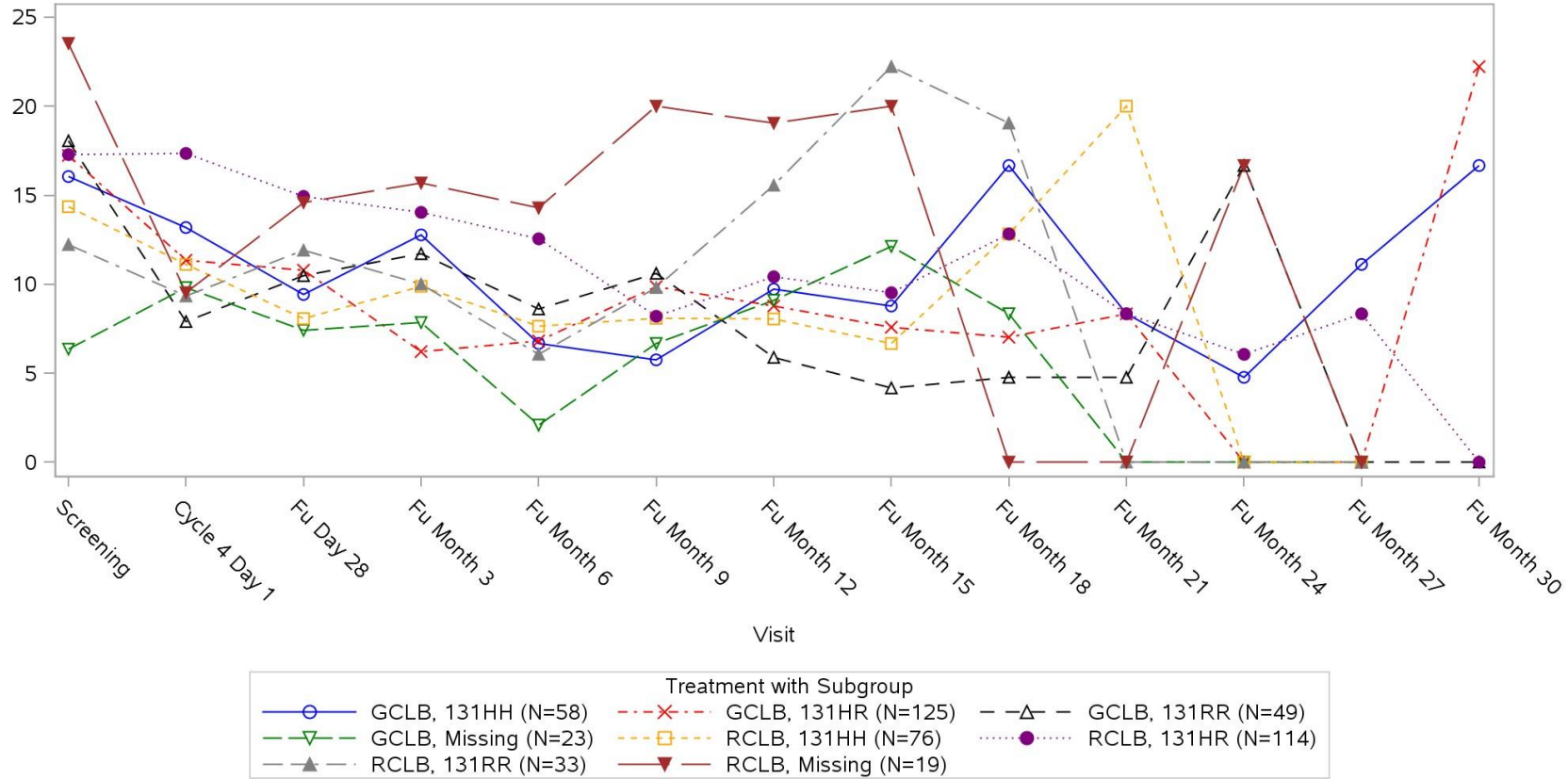
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

FCgamma receptor IIa (N=497) Laboratory Test: Appetite Loss Scale



Clinical cut-off: 09MAY2013

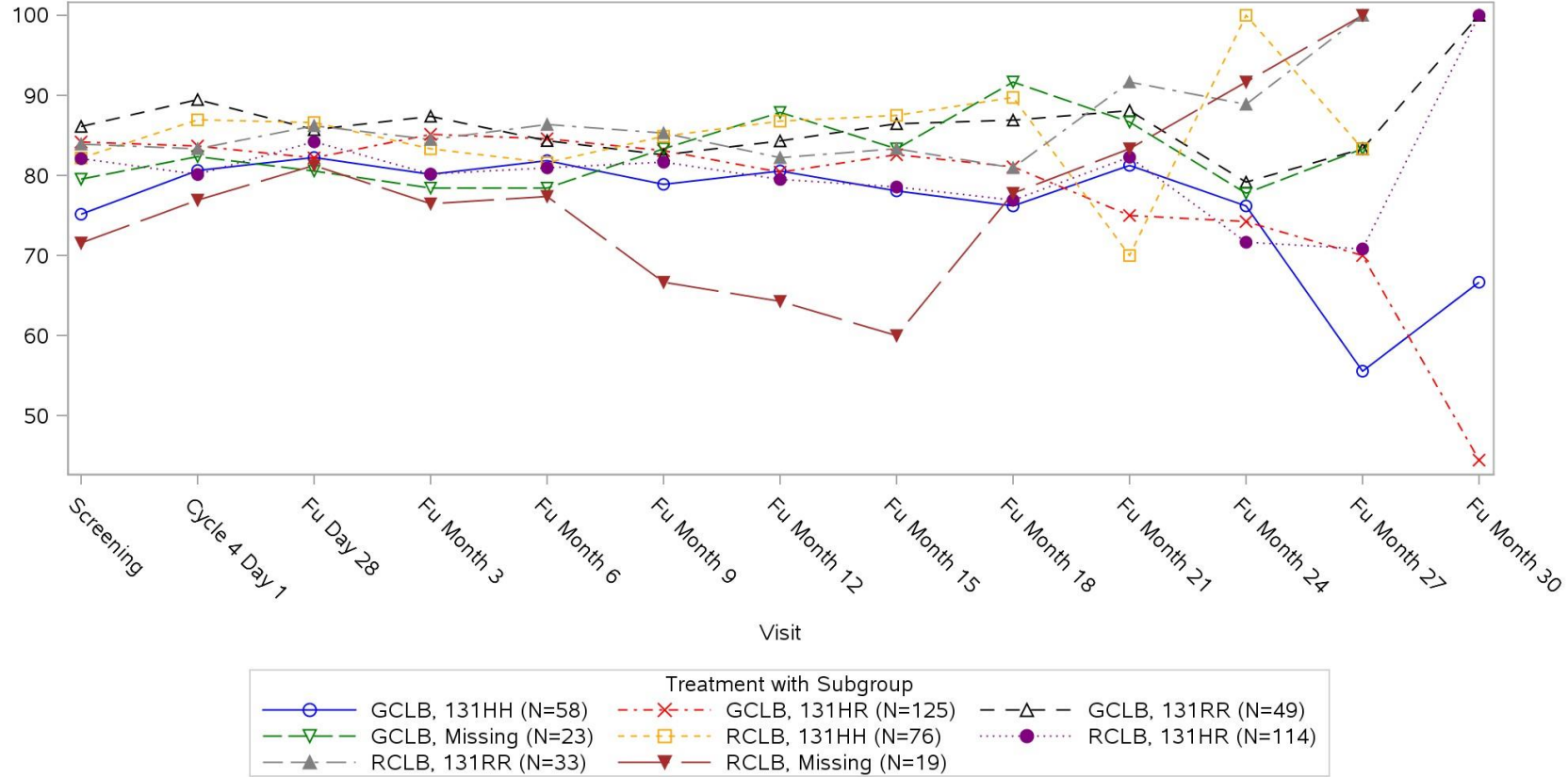
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

FCgamma receptor IIa (N=497) Laboratory Test: Cognitive Functioning Scale



Clinical cut-off: 09MAY2013

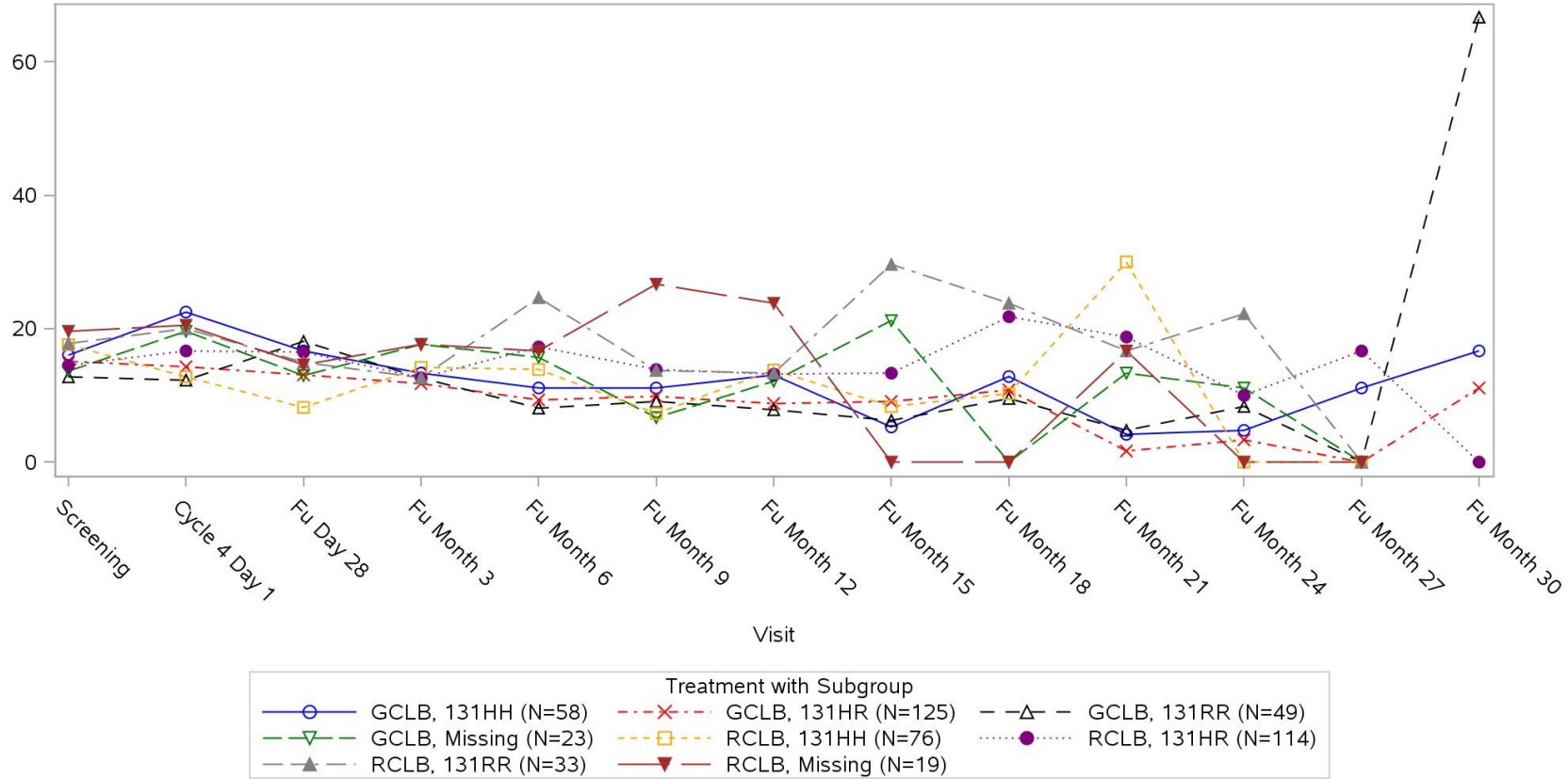
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 04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

FCgamma receptor IIa (N=497) Laboratory Test: Constipation Scale



Clinical cut-off: 09MAY2013

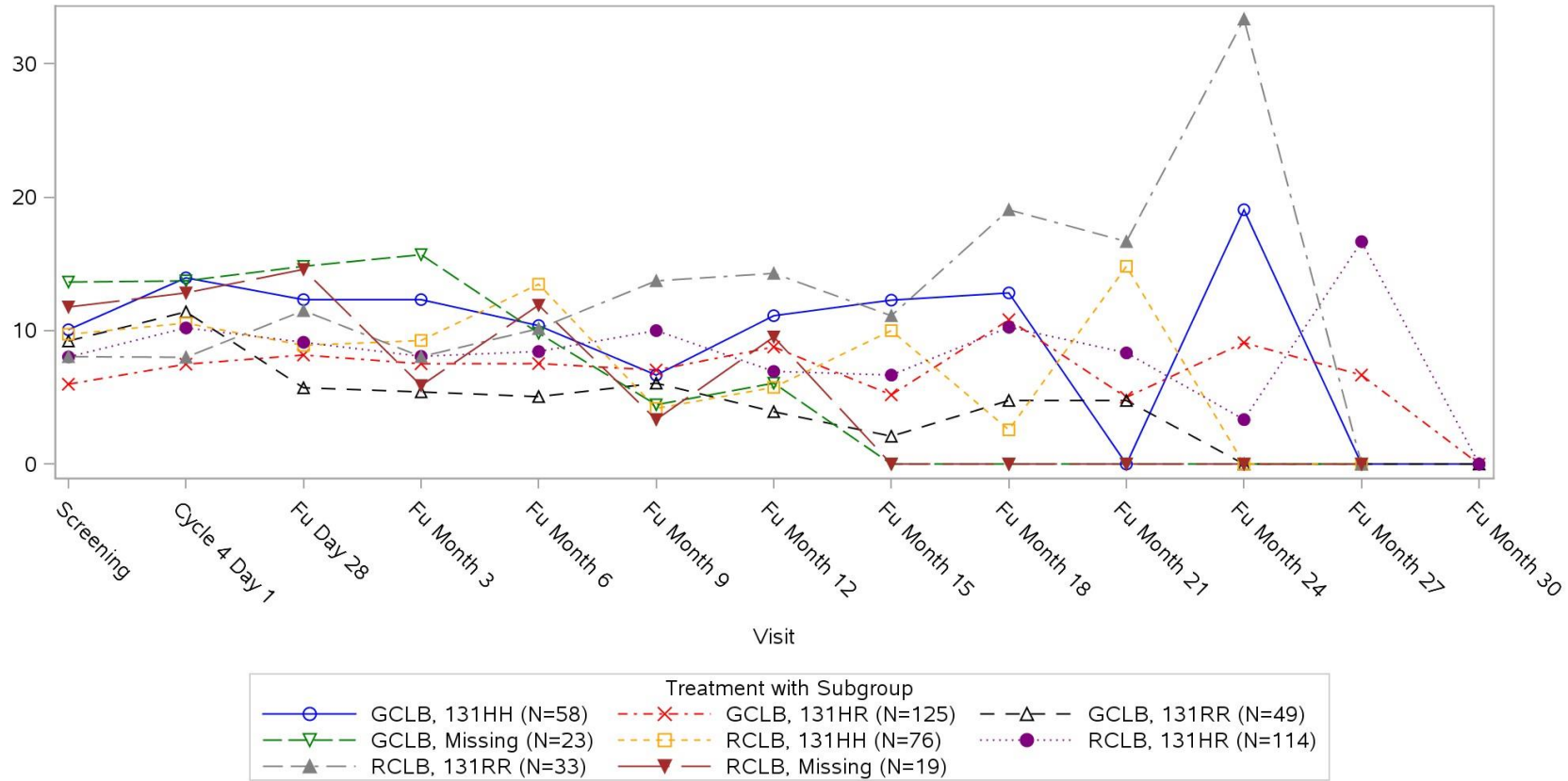
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

FCgamma receptor IIa (N=497) Laboratory Test: Diarrhoea Scale



Clinical cut-off: 09MAY2013

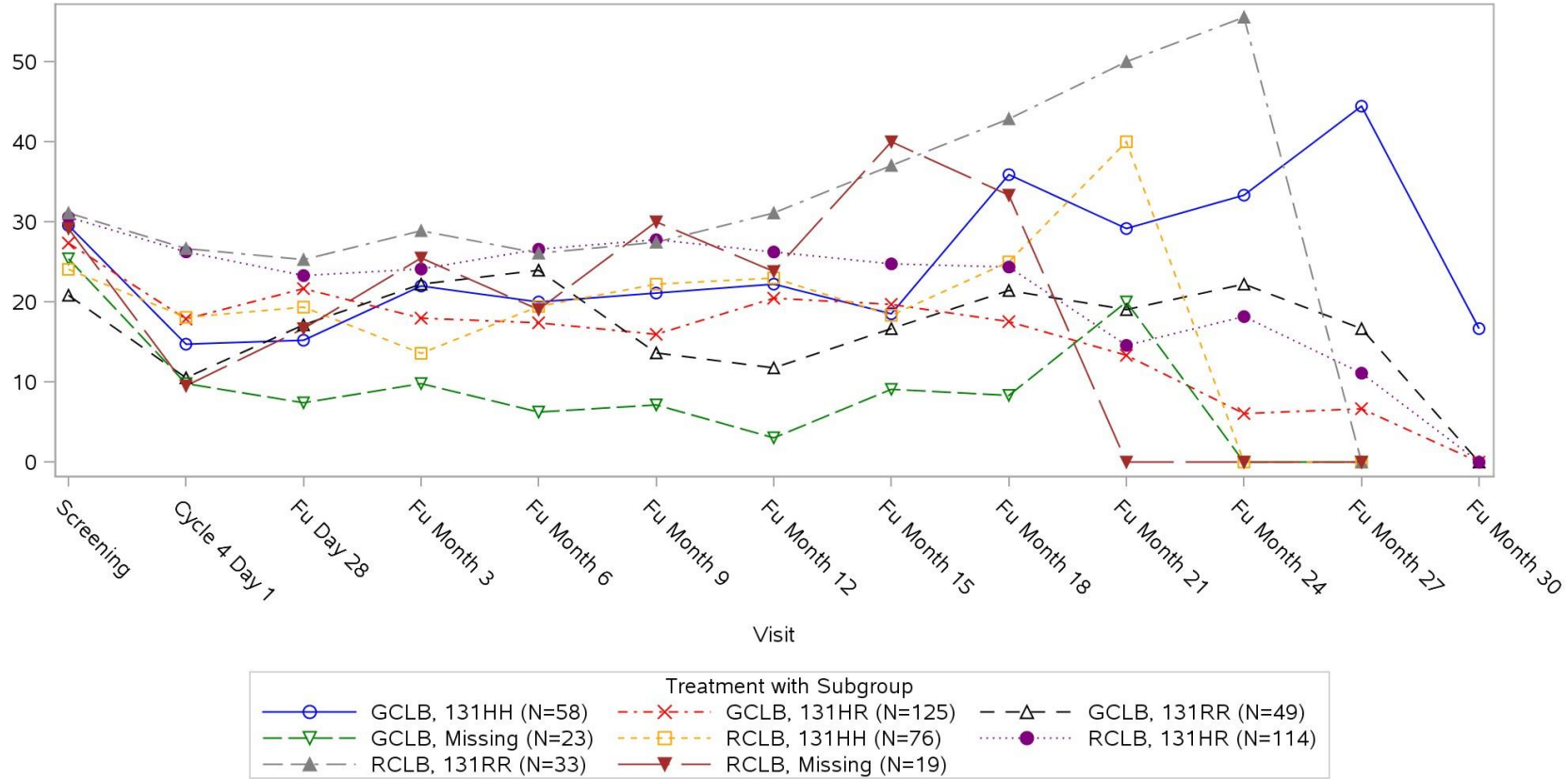
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

FCgamma receptor IIa (N=497) Laboratory Test: Dyspnoea Scale



Clinical cut-off: 09MAY2013

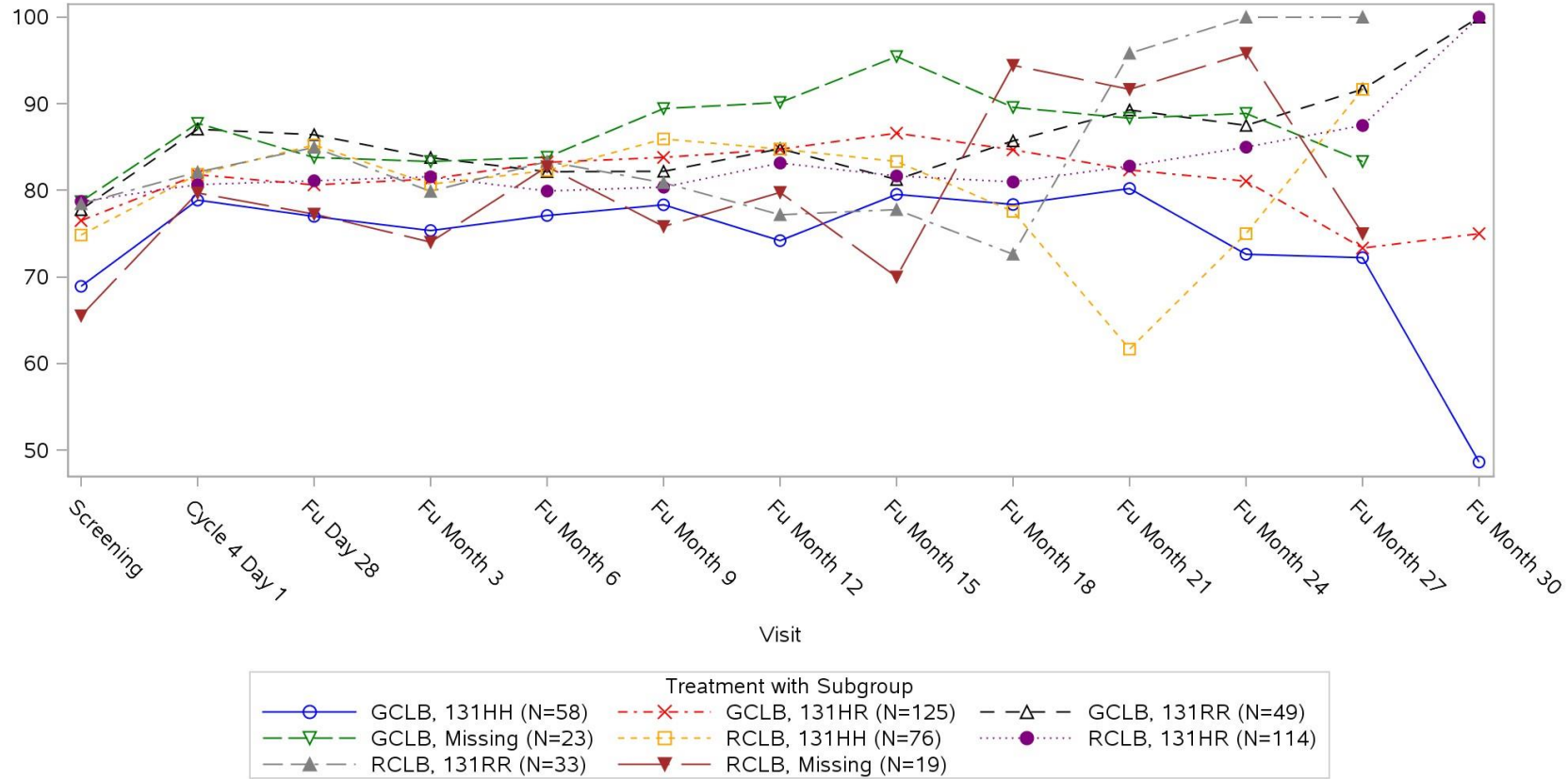
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

FCgamma receptor IIa (N=497) Laboratory Test: Emotional Functioning Scale



Clinical cut-off: 09MAY2013

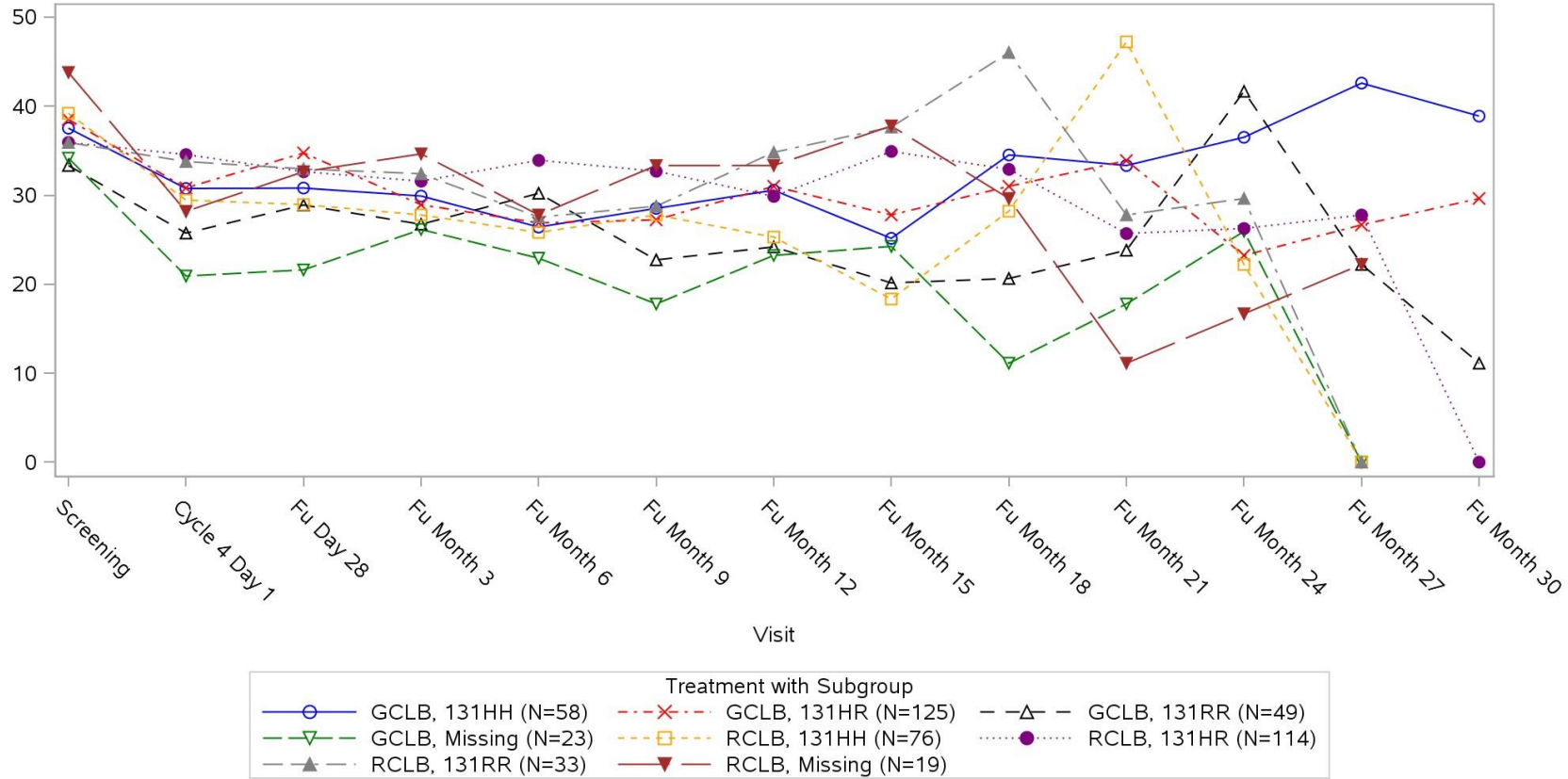
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 04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

FCgamma receptor IIa (N=497) Laboratory Test: Fatigue Scale



Clinical cut-off: 09MAY2013

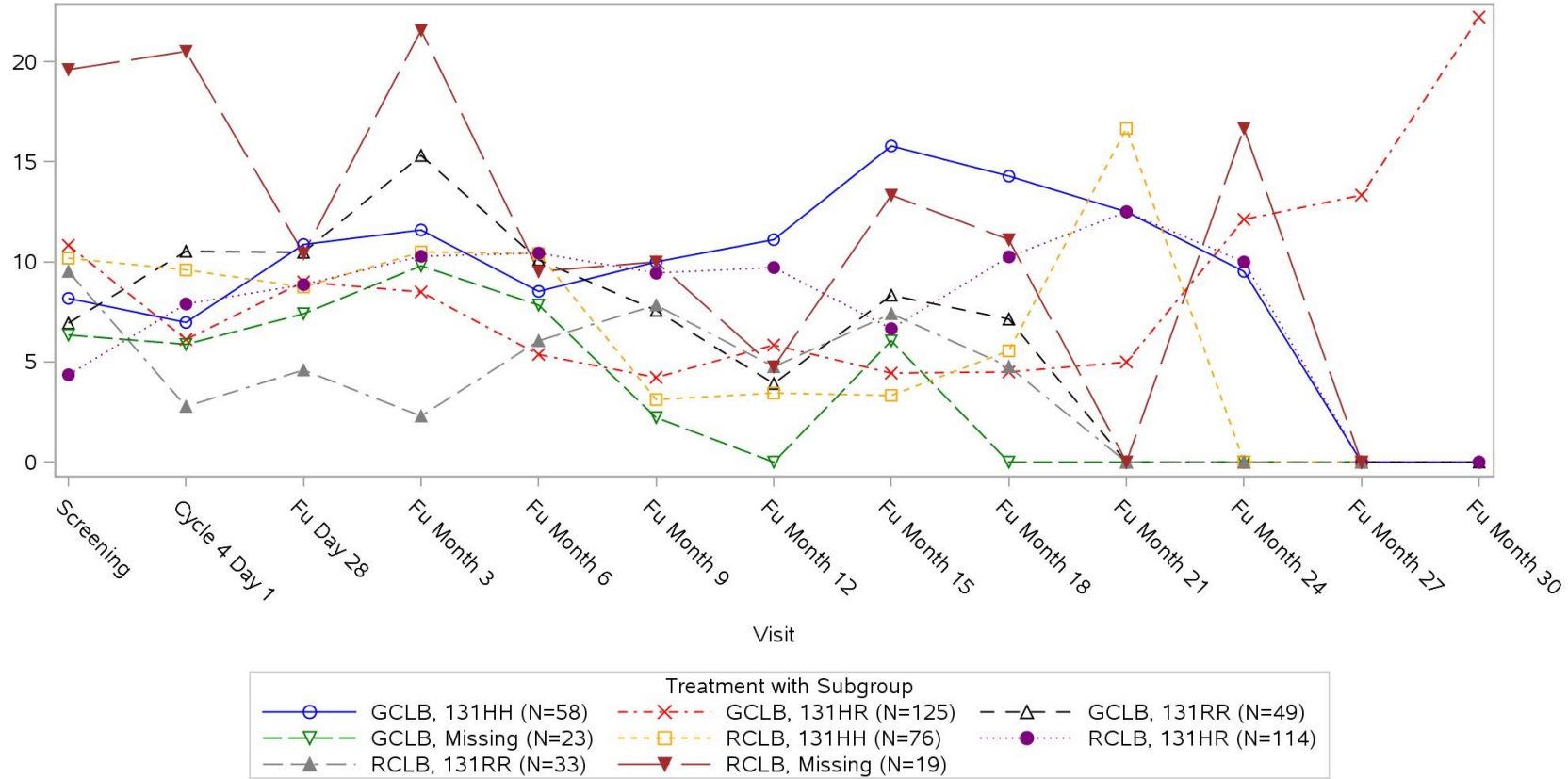
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 04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

FCgamma receptor IIa (N=497) Laboratory Test: Financial Difficulties Scale



Clinical cut-off: 09MAY2013

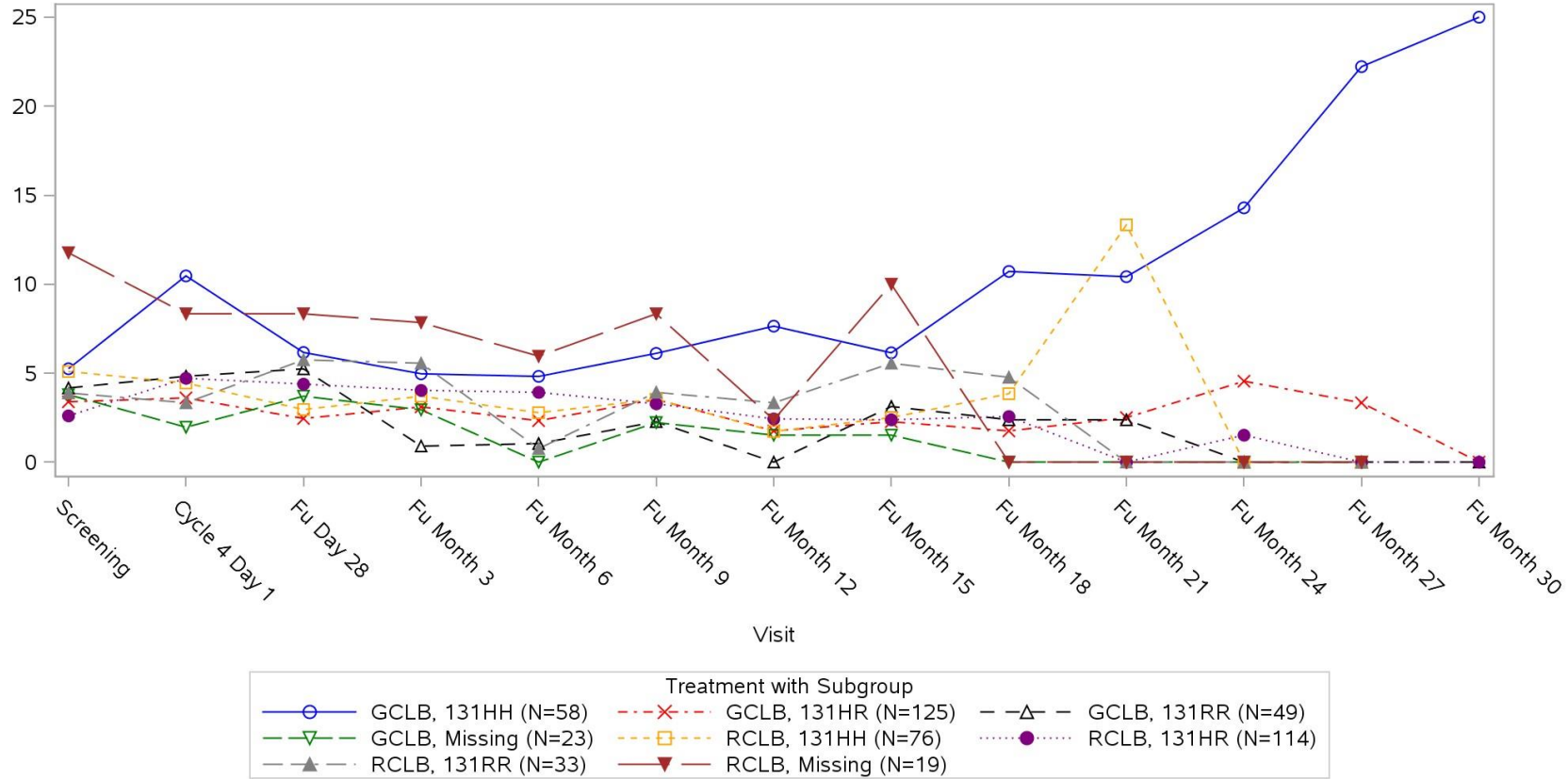
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 04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

FCgamma receptor IIa (N=497) Laboratory Test: Nausia And Vomiting Scale



Clinical cut-off: 09MAY2013

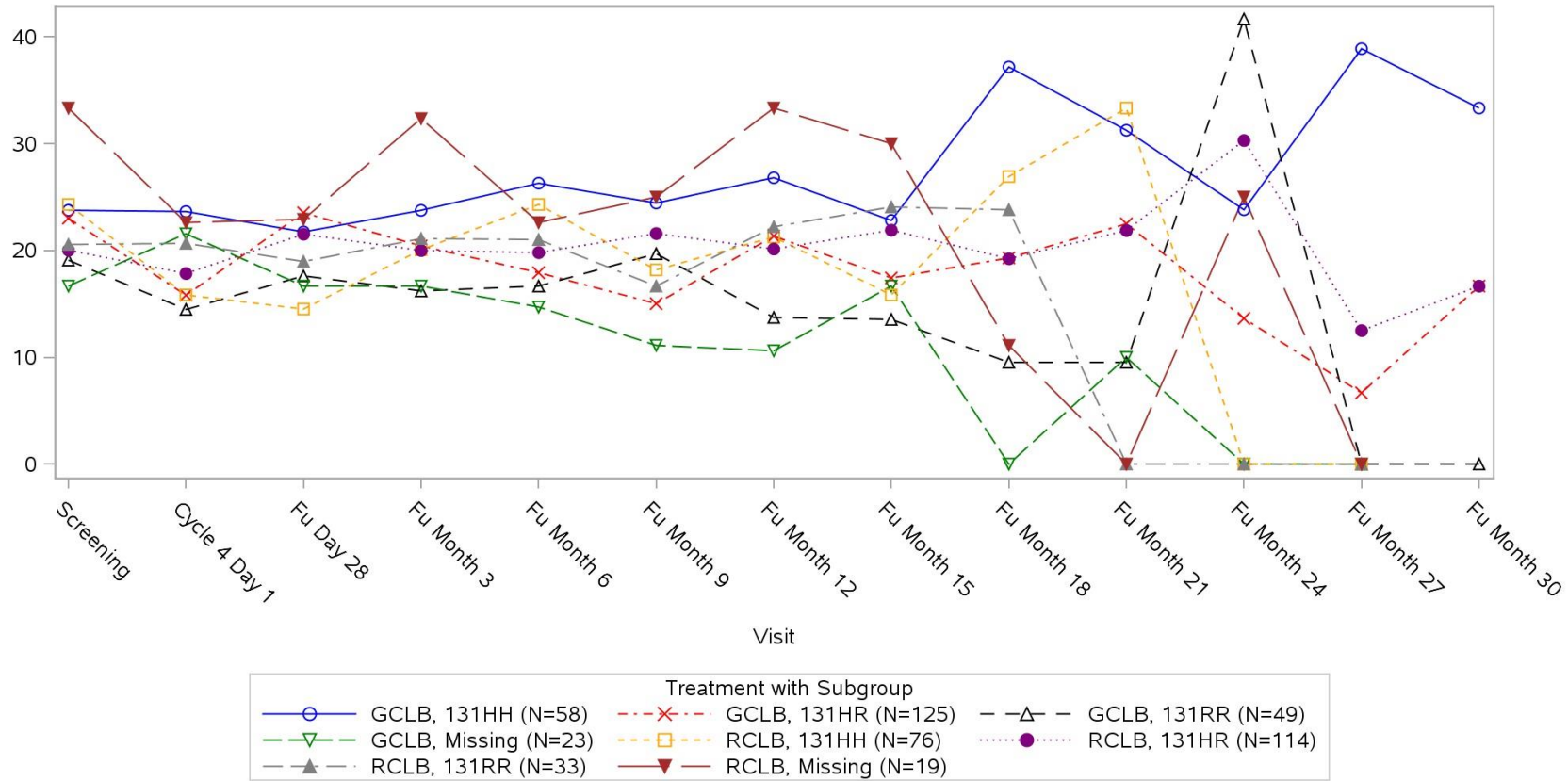
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 04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

FCgamma receptor IIa (N=497) Laboratory Test: Pain Scale



Clinical cut-off: 09MAY2013

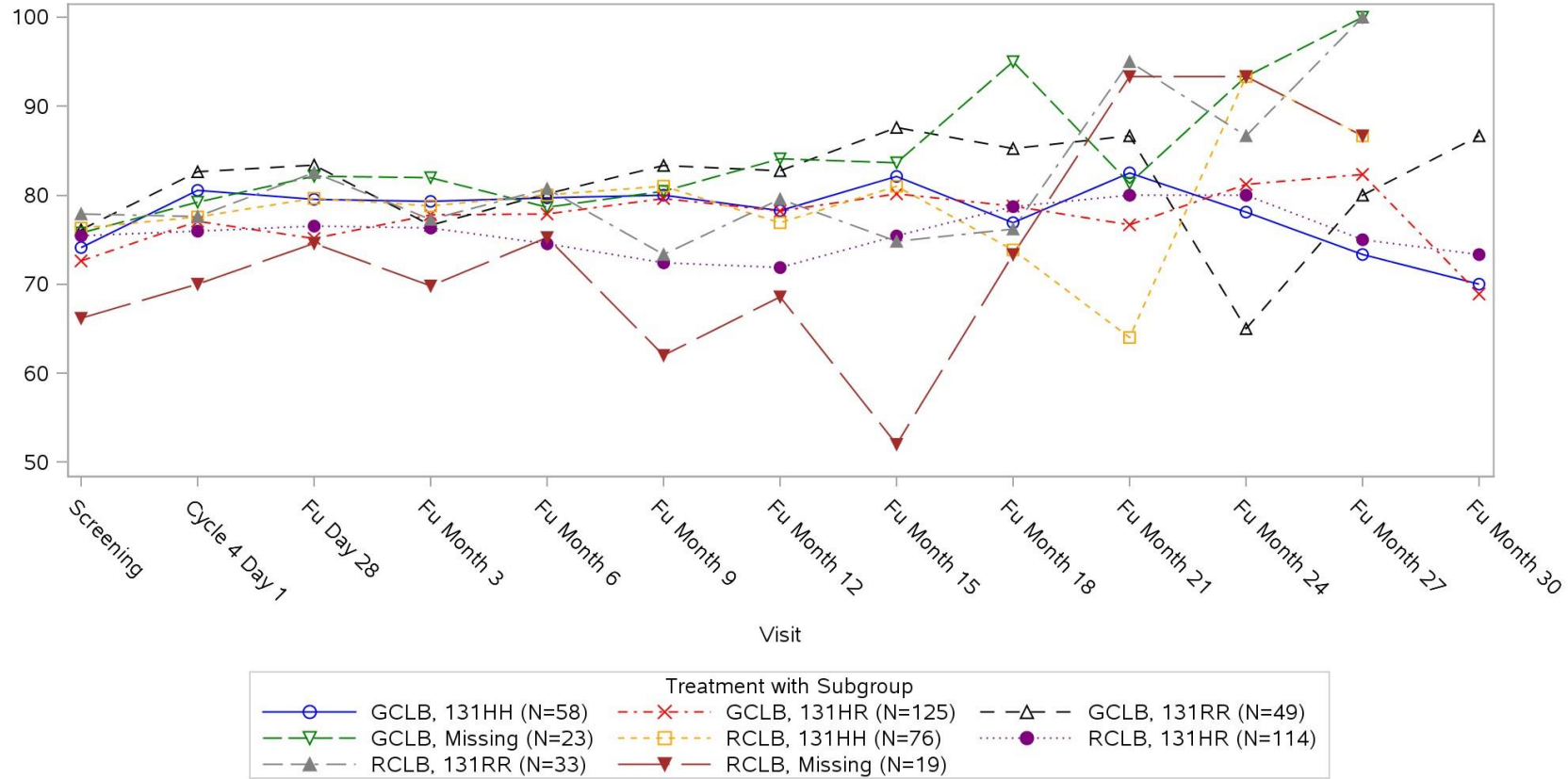
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

FCgamma receptor IIa (N=497) Laboratory Test: Physical Functioning Scale



Clinical cut-off: 09MAY2013

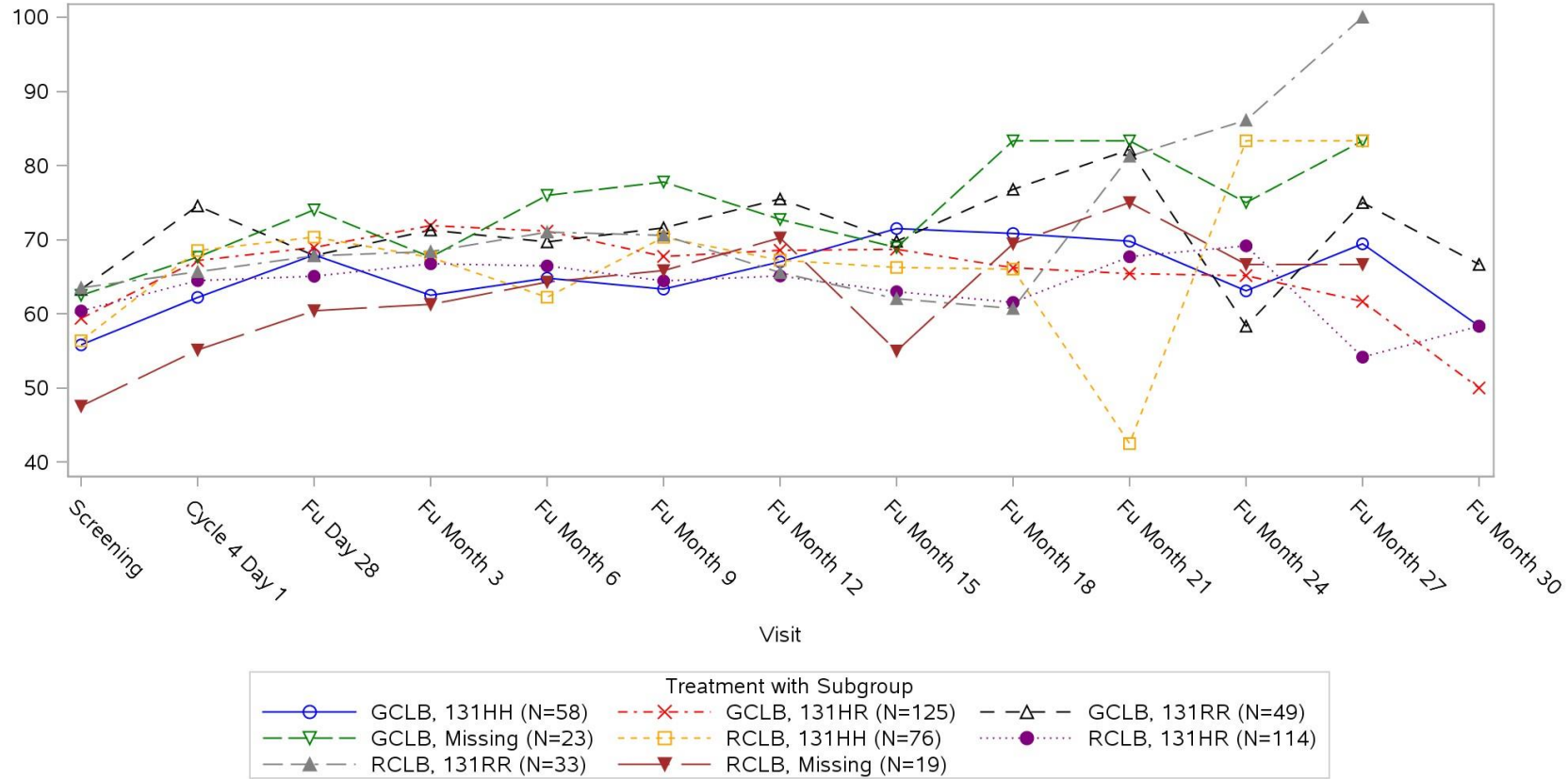
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

FCgamma receptor IIa (N=497) Laboratory Test: Global Health Status Scale



Clinical cut-off: 09MAY2013

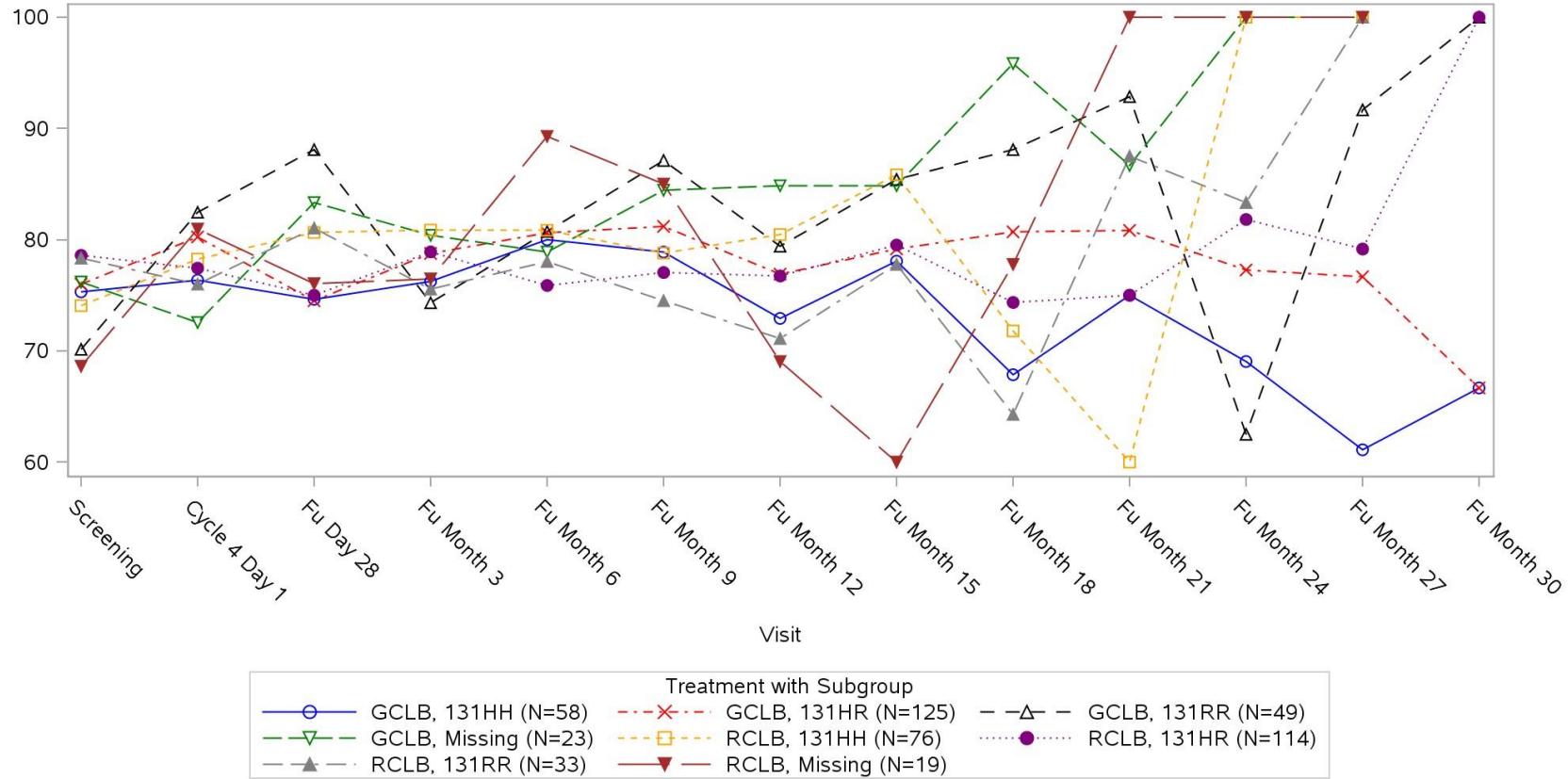
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

FCgamma receptor IIa (N=497) Laboratory Test: Role Functioning Scale



Clinical cut-off: 09MAY2013

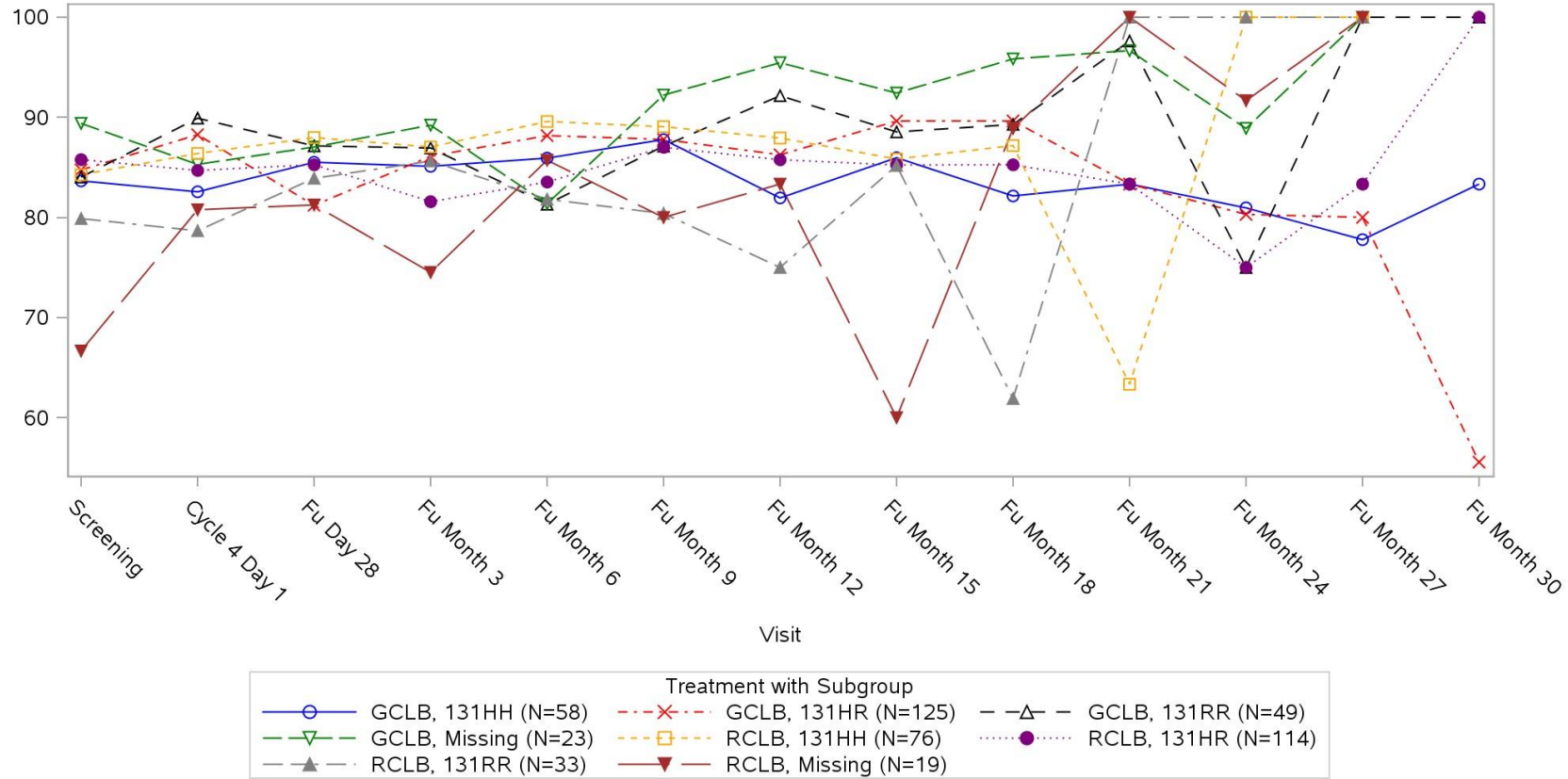
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

FCgamma receptor IIa (N=497) Laboratory Test: Social Functioning Scale



Clinical cut-off: 09MAY2013

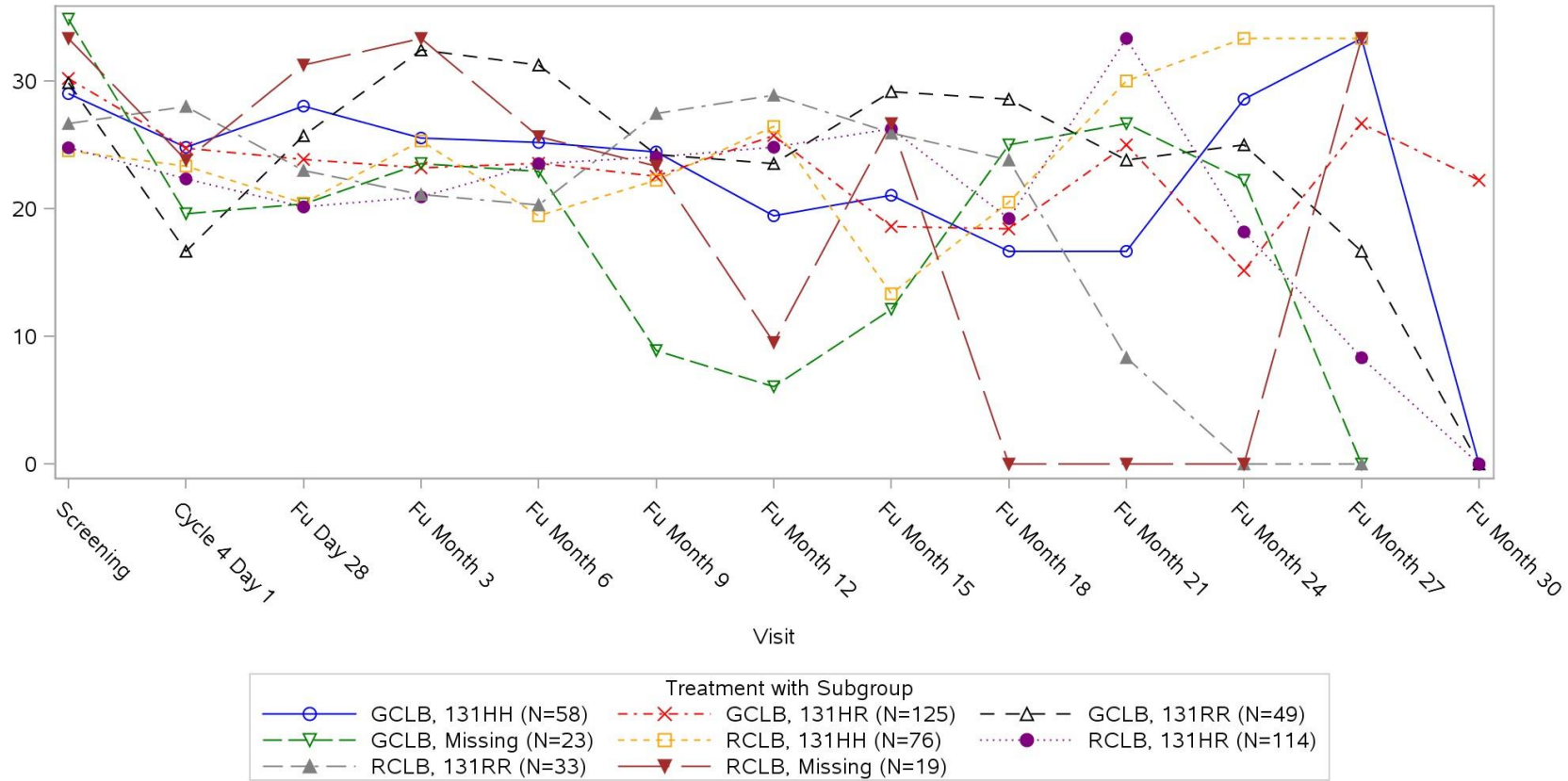
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04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

FCgamma receptor IIa (N=497) Laboratory Test: Insomnia Scale



Clinical cut-off: 09MAY2013

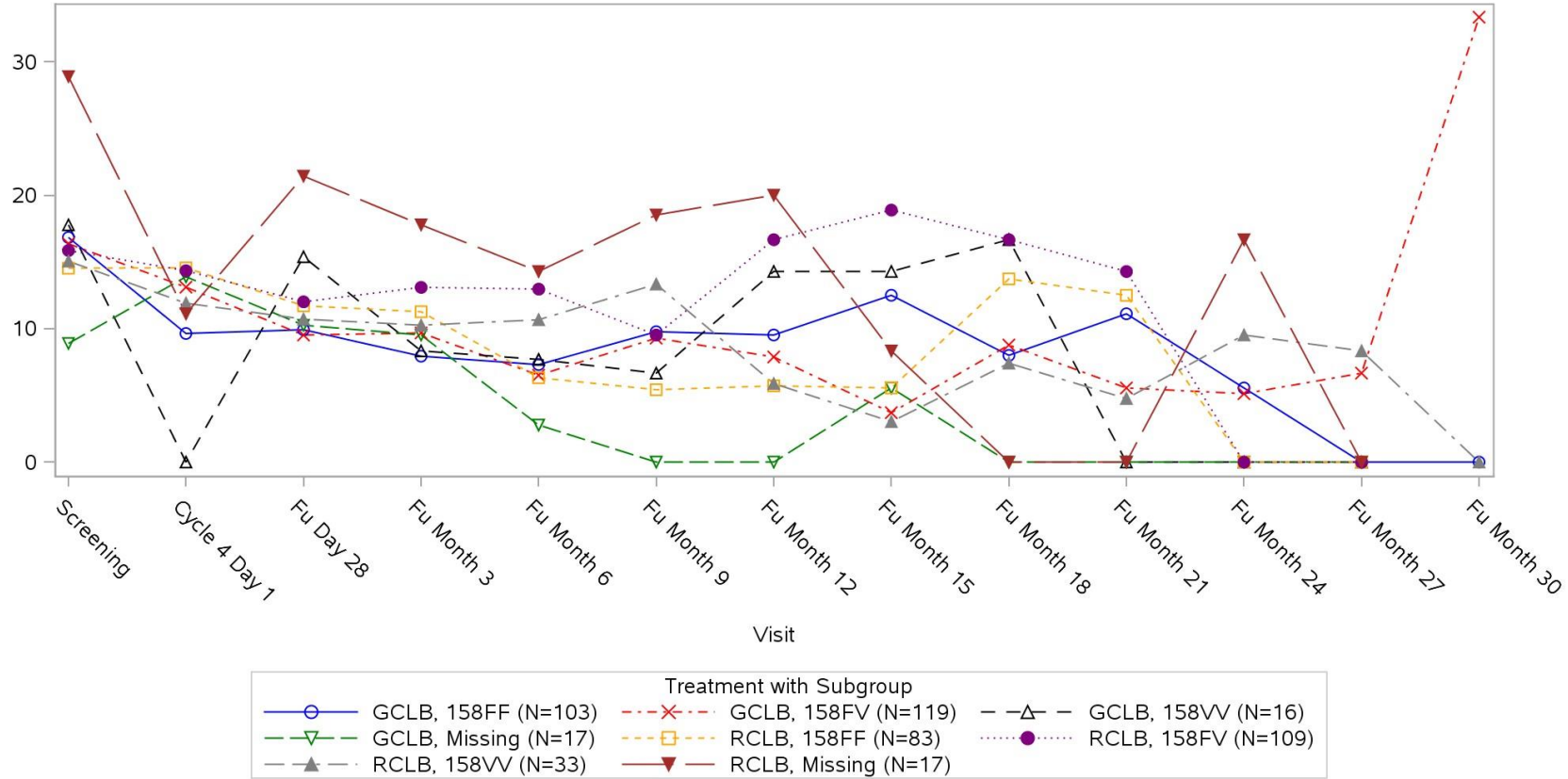
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 04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

FCgamma receptor IIIa (N=497) Laboratory Test: Appetite Loss Scale



Clinical cut-off: 09MAY2013

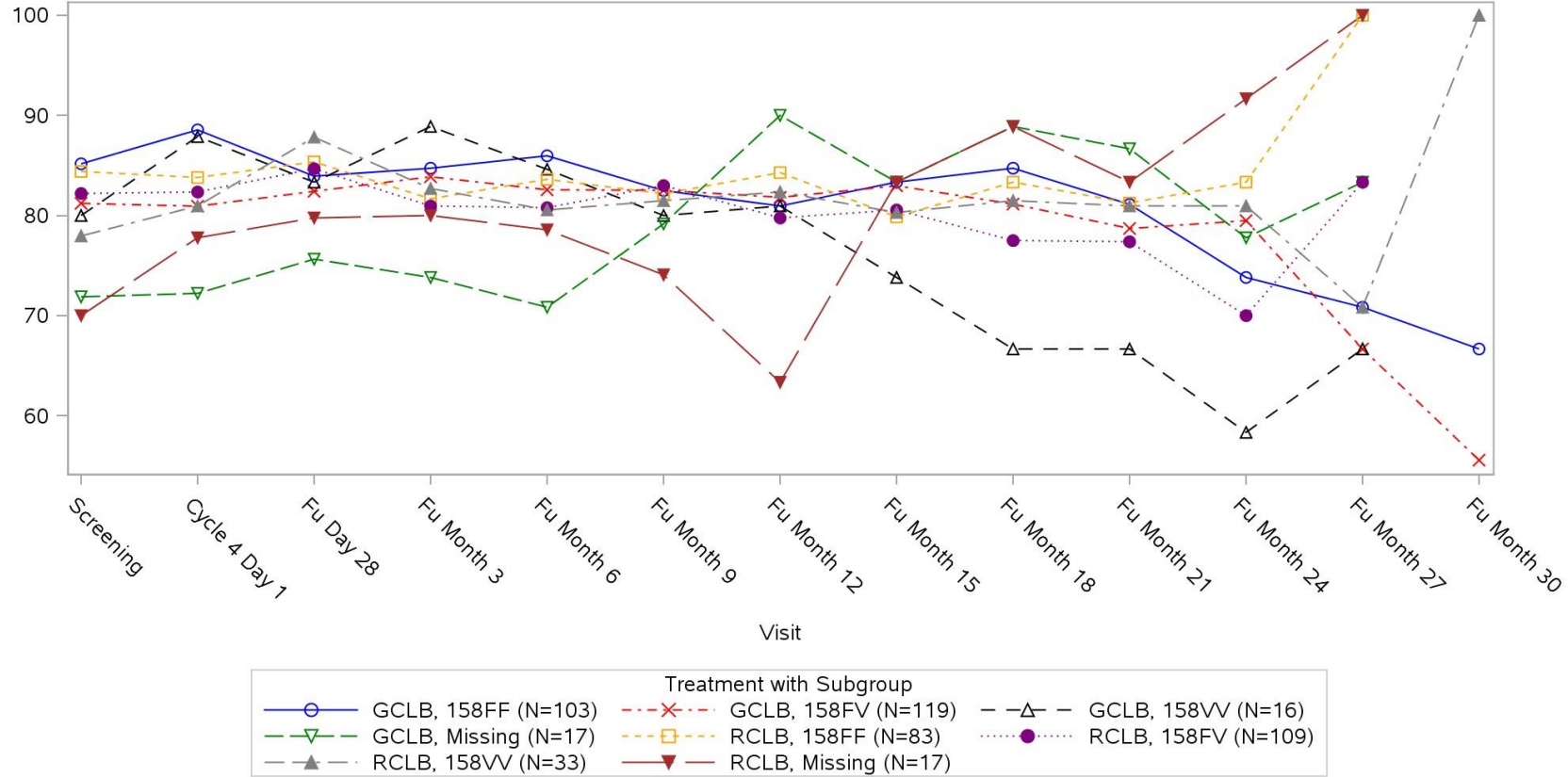
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

FCgamma receptor IIIa (N=497) Laboratory Test: Cognitive Functioning Scale



Clinical cut-off: 09MAY2013

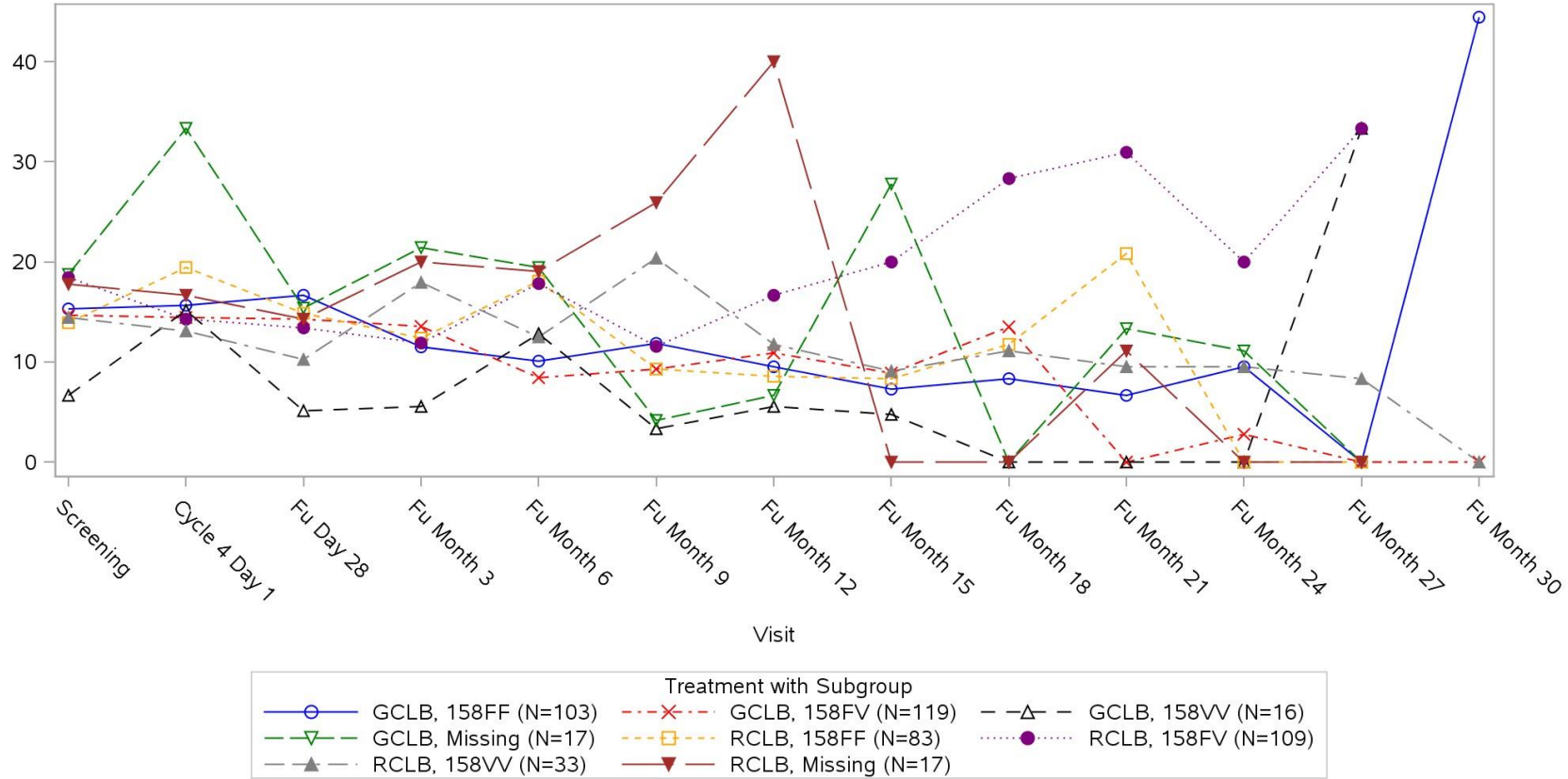
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

FCgamma receptor IIIa (N=497) Laboratory Test: Constipation Scale



Clinical cut-off: 09MAY2013

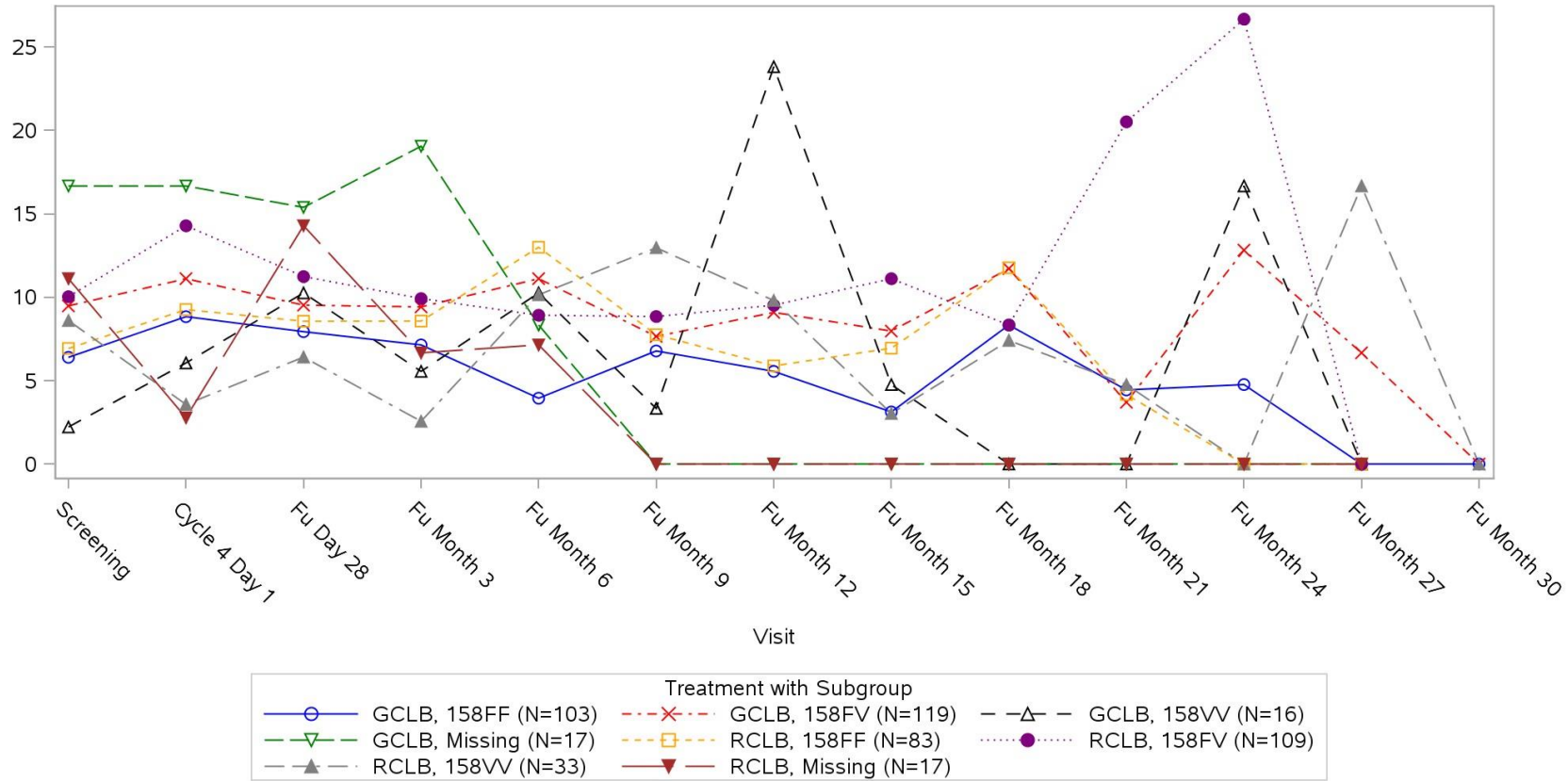
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

FCgamma receptor IIIa (N=497) Laboratory Test: Diarrhoea Scale



Clinical cut-off: 09MAY2013

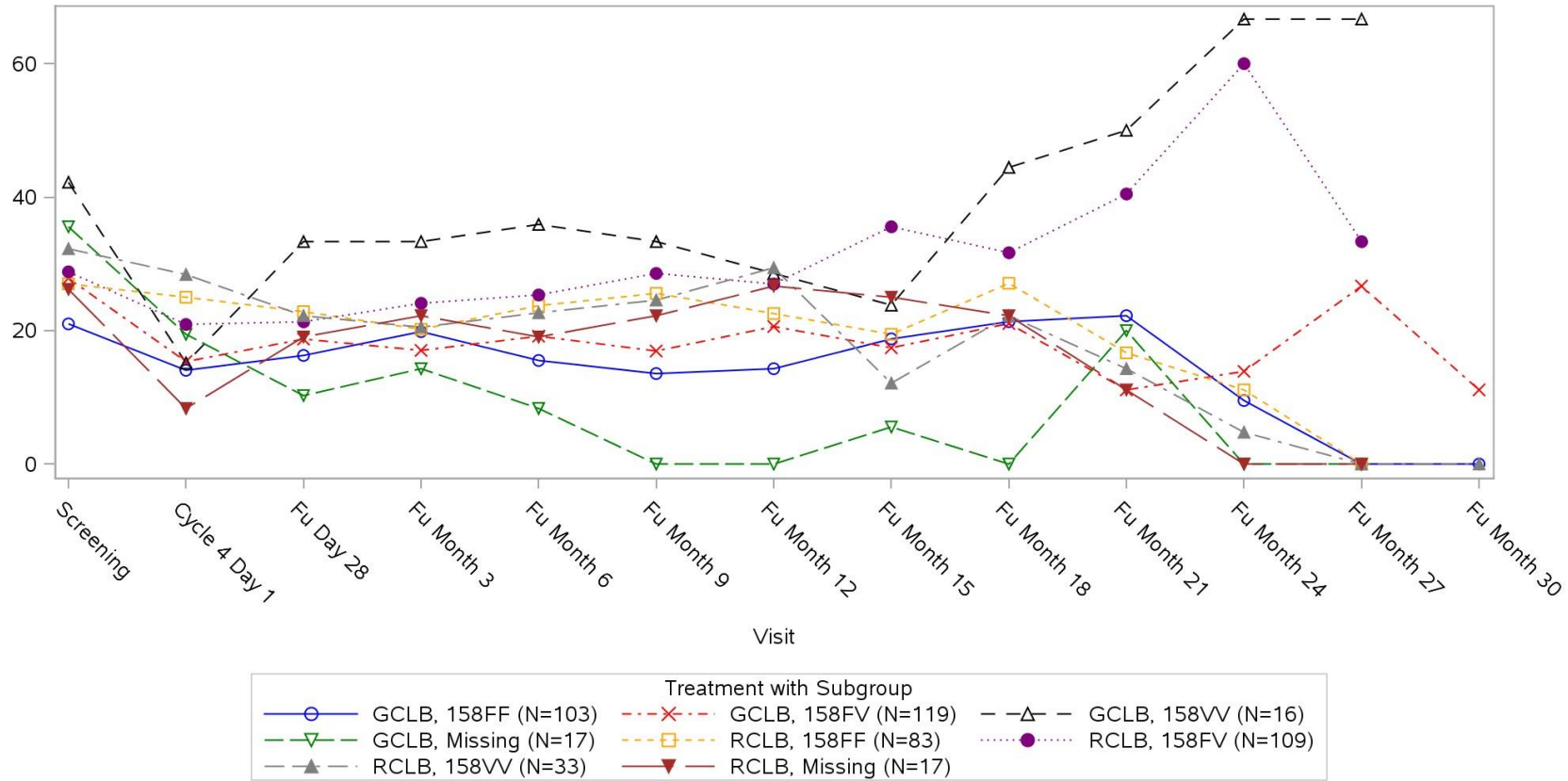
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

FCgamma receptor IIIa (N=497) Laboratory Test: Dyspnoea Scale



Clinical cut-off: 09MAY2013

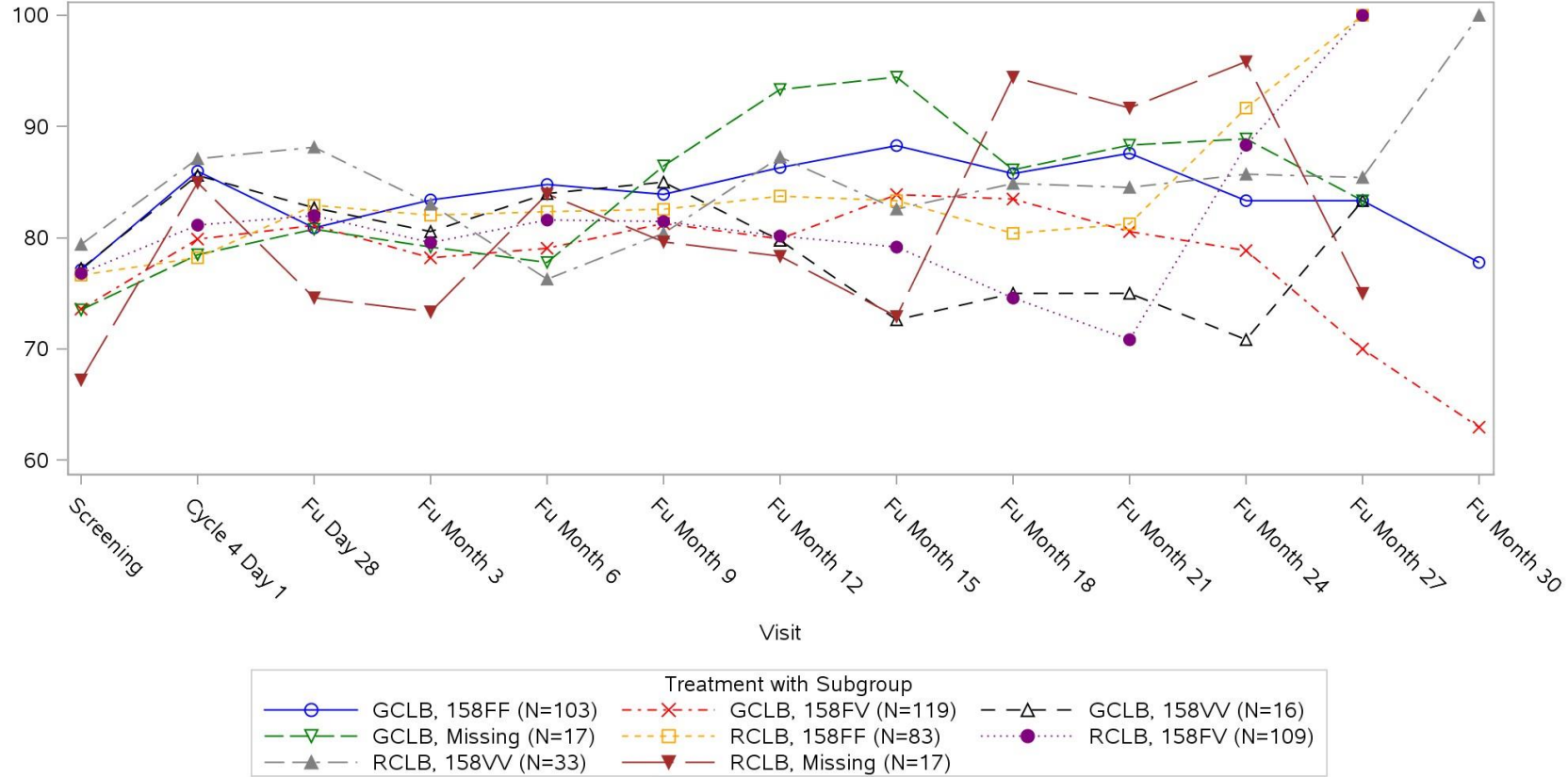
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 04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

FCgamma receptor IIIa (N=497) Laboratory Test: Emotional Functioning Scale



Clinical cut-off: 09MAY2013

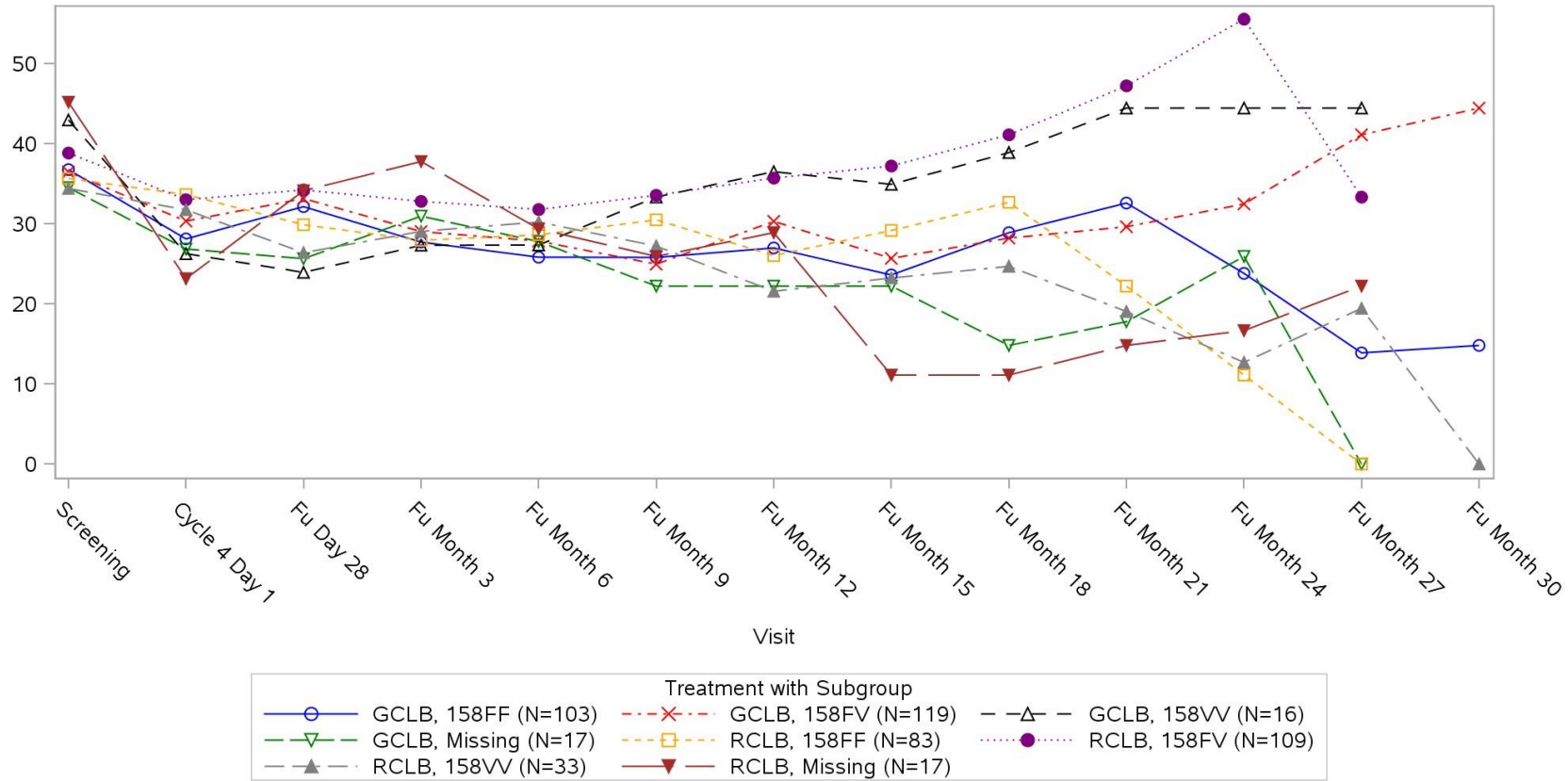
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 04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

FCgamma receptor IIIa (N=497) Laboratory Test: Fatigue Scale



Clinical cut-off: 09MAY2013

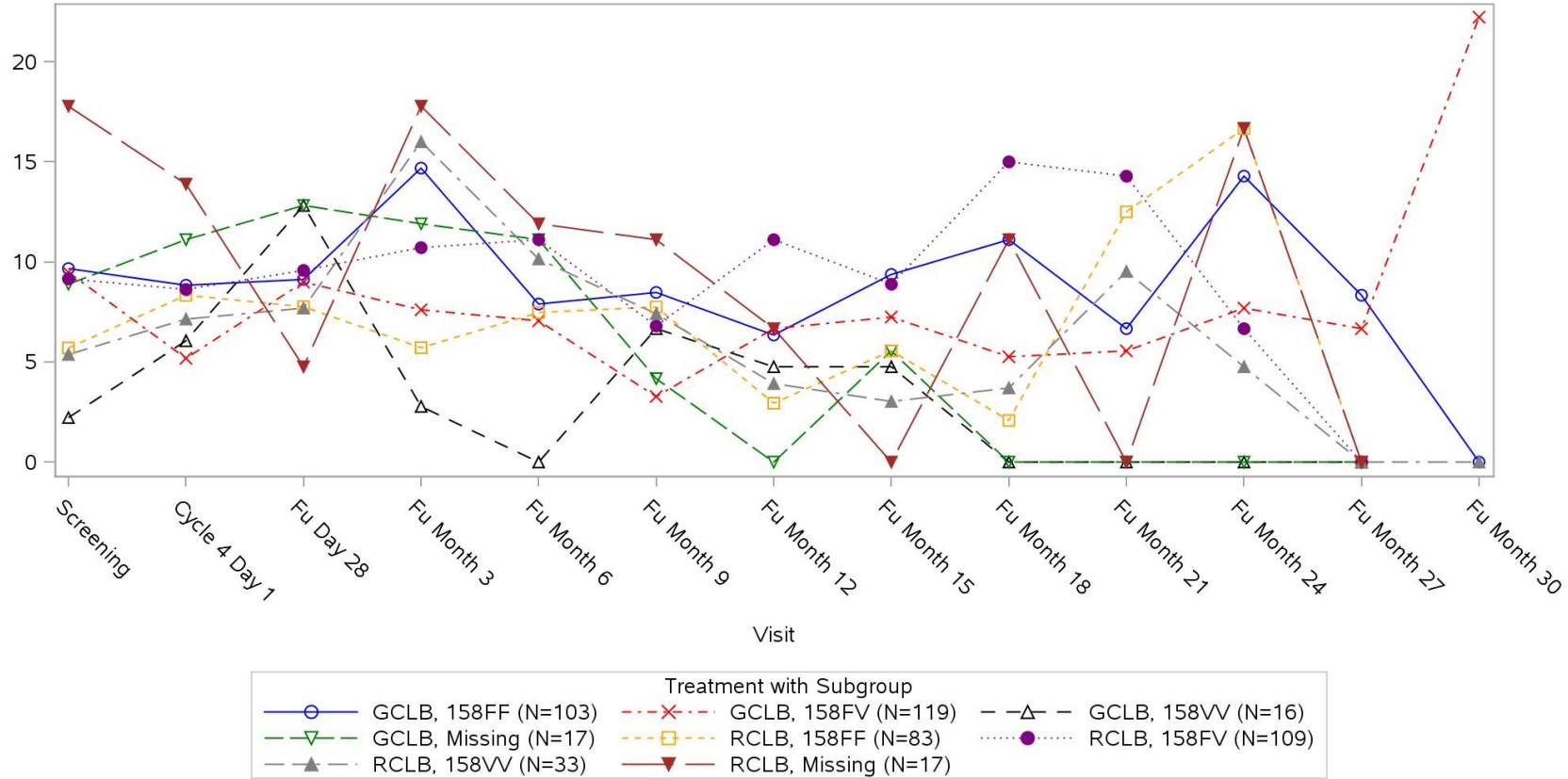
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 04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

FCgamma receptor IIIa (N=497) Laboratory Test: Financial Difficulties Scale



Clinical cut-off: 09MAY2013

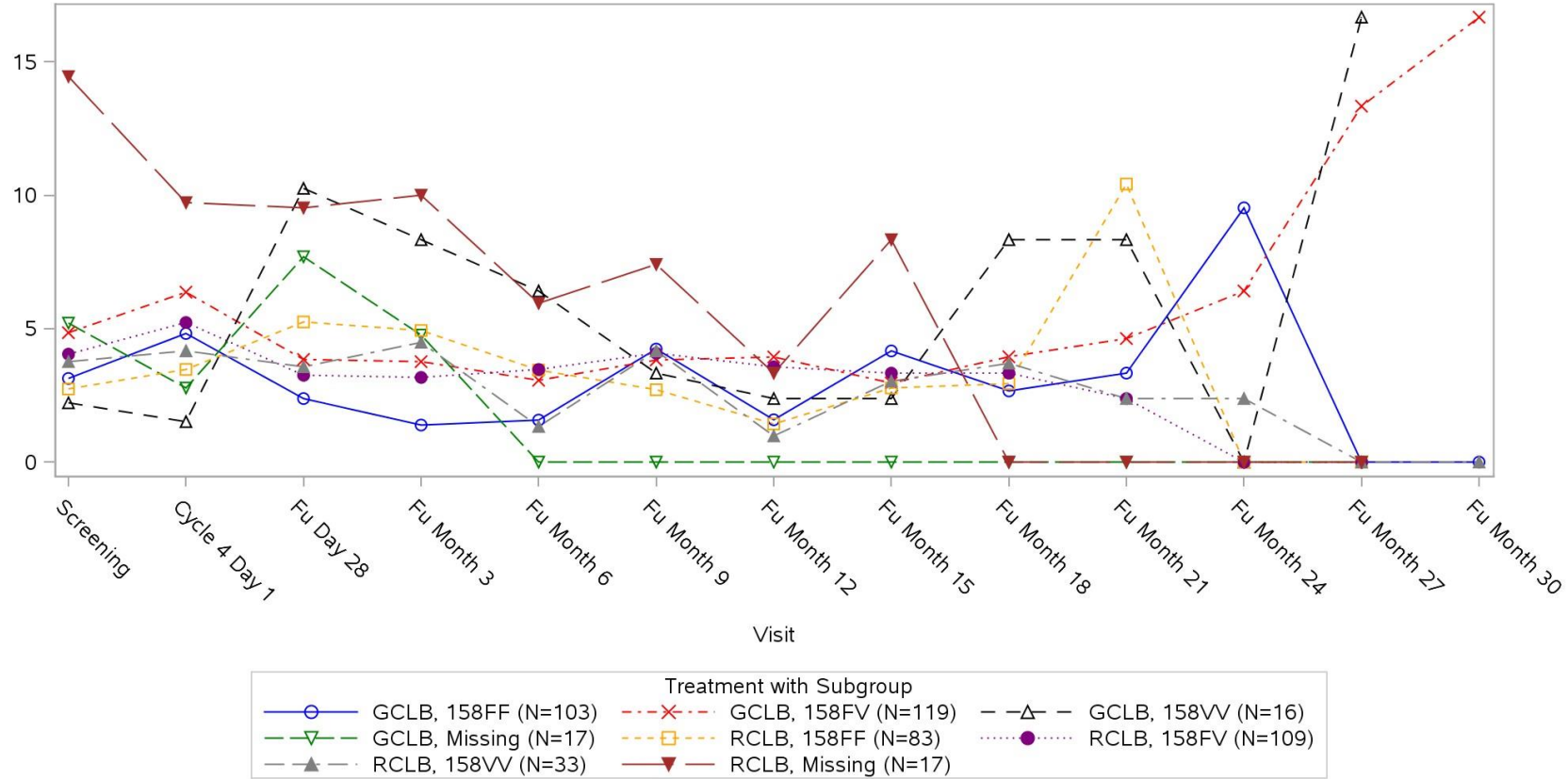
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 04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

FCgamma receptor IIIa (N=497) Laboratory Test: Nausea And Vomiting Scale



Clinical cut-off: 09MAY2013

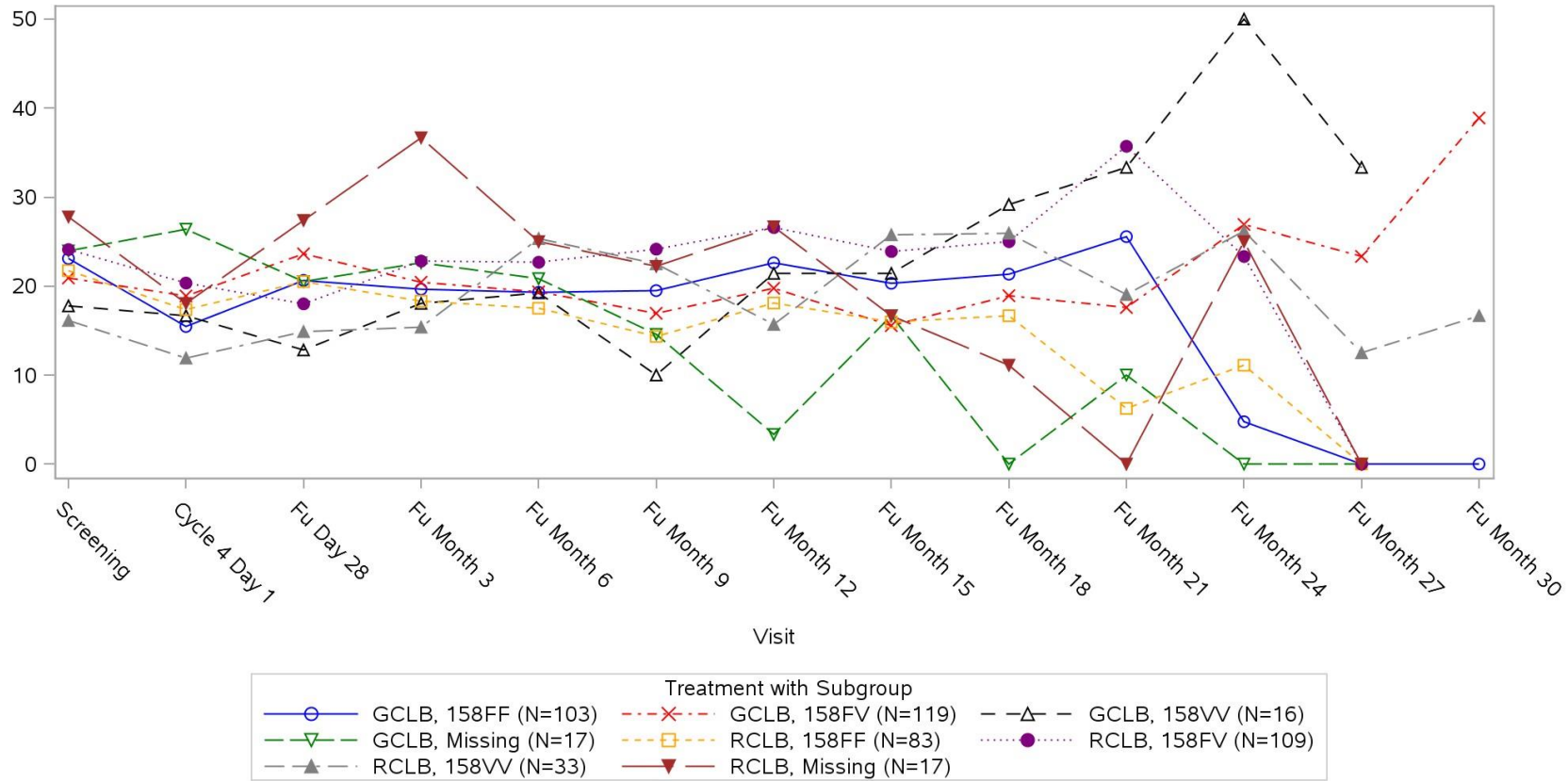
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

FCgamma receptor IIIa (N=497) Laboratory Test: Pain Scale



Clinical cut-off: 09MAY2013

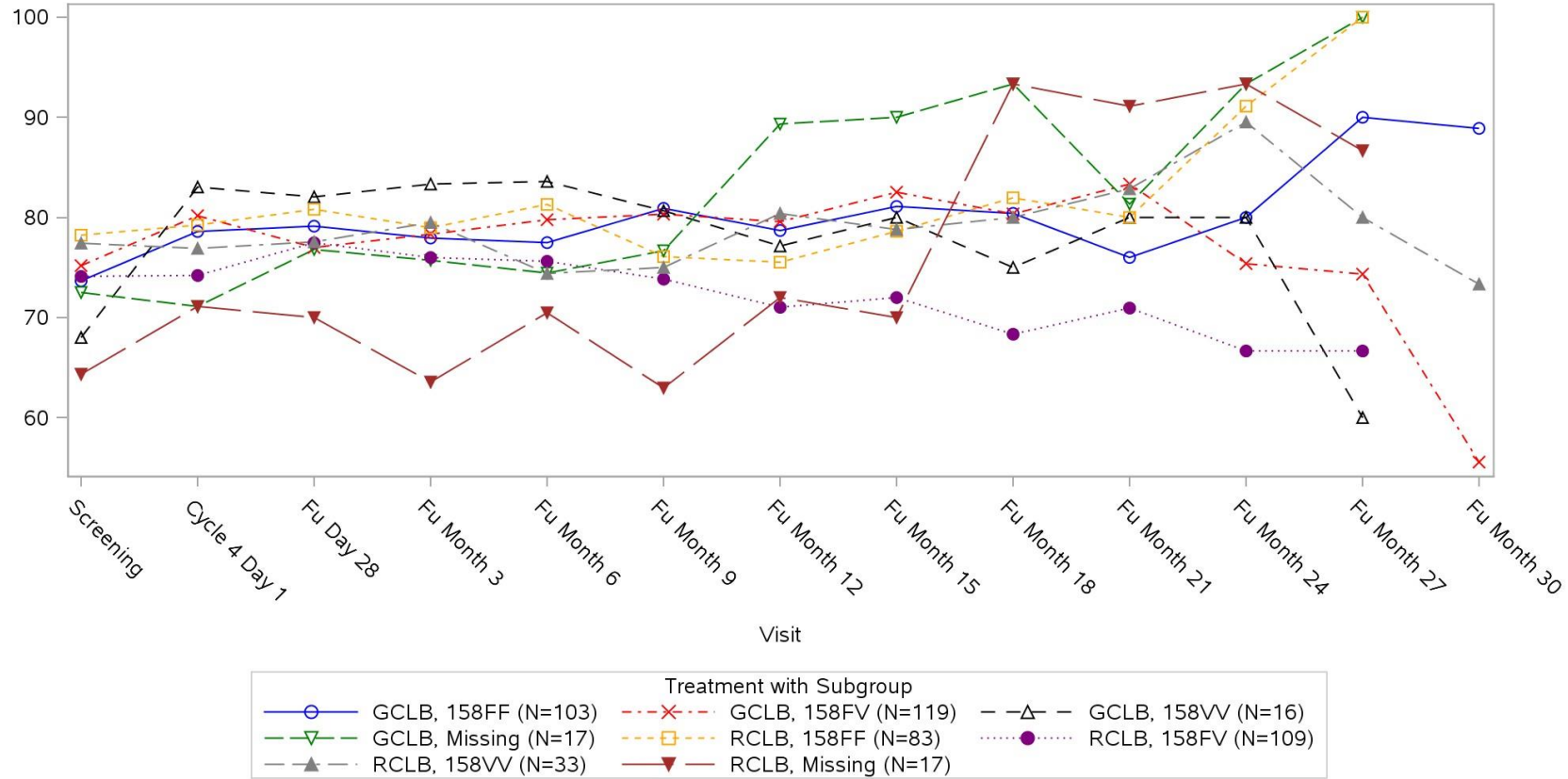
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

FCgamma receptor IIIa (N=497) Laboratory Test: Physical Functioning Scale



Clinical cut-off: 09MAY2013

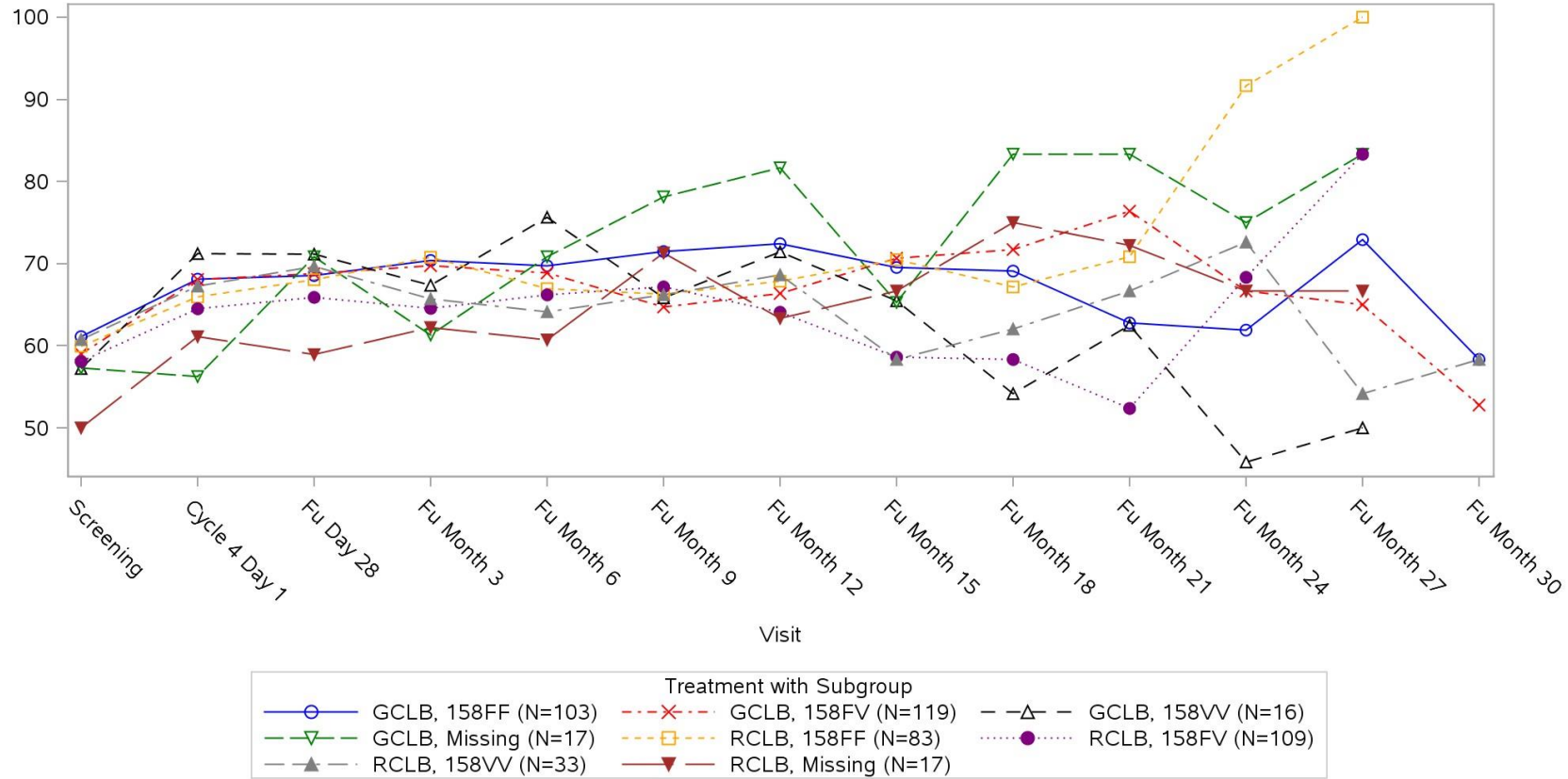
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

FCgamma receptor IIIa (N=497) Laboratory Test: Global Health Status Scale



Clinical cut-off: 09MAY2013

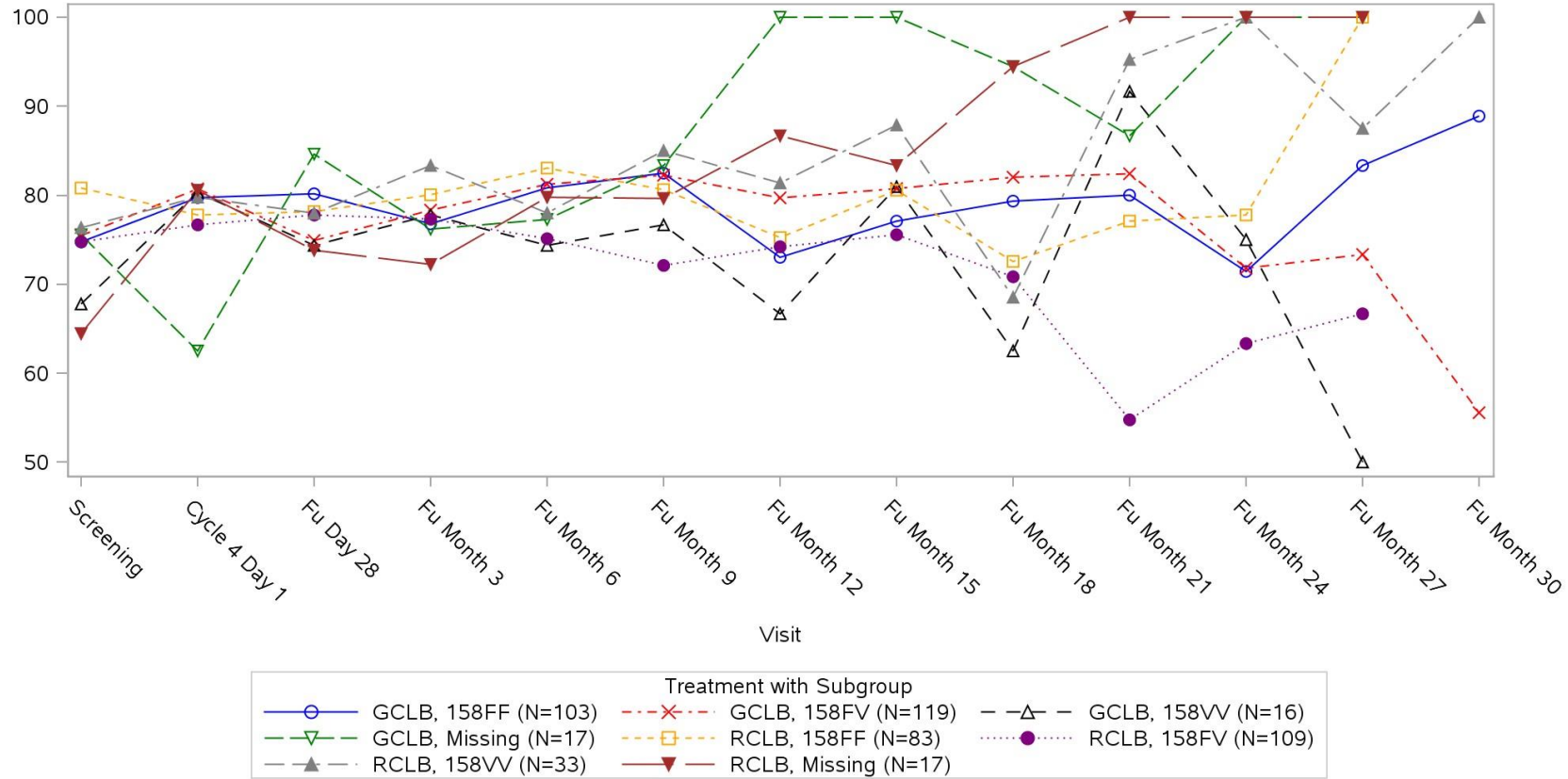
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

FCgamma receptor IIIa (N=497) Laboratory Test: Role Functioning Scale



Clinical cut-off: 09MAY2013

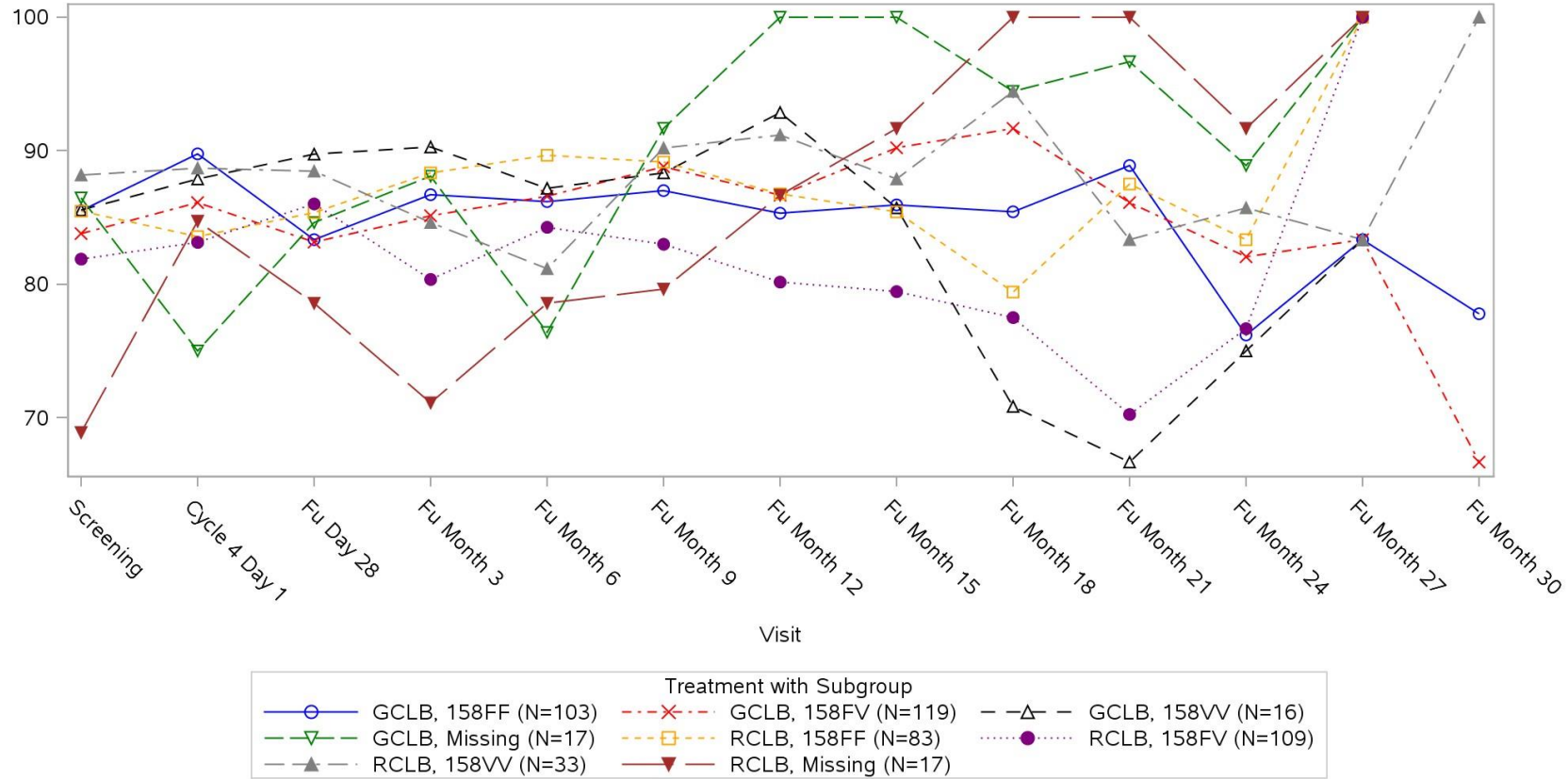
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

FCgamma receptor IIIa (N=497) Laboratory Test: Social Functioning Scale



Clinical cut-off: 09MAY2013

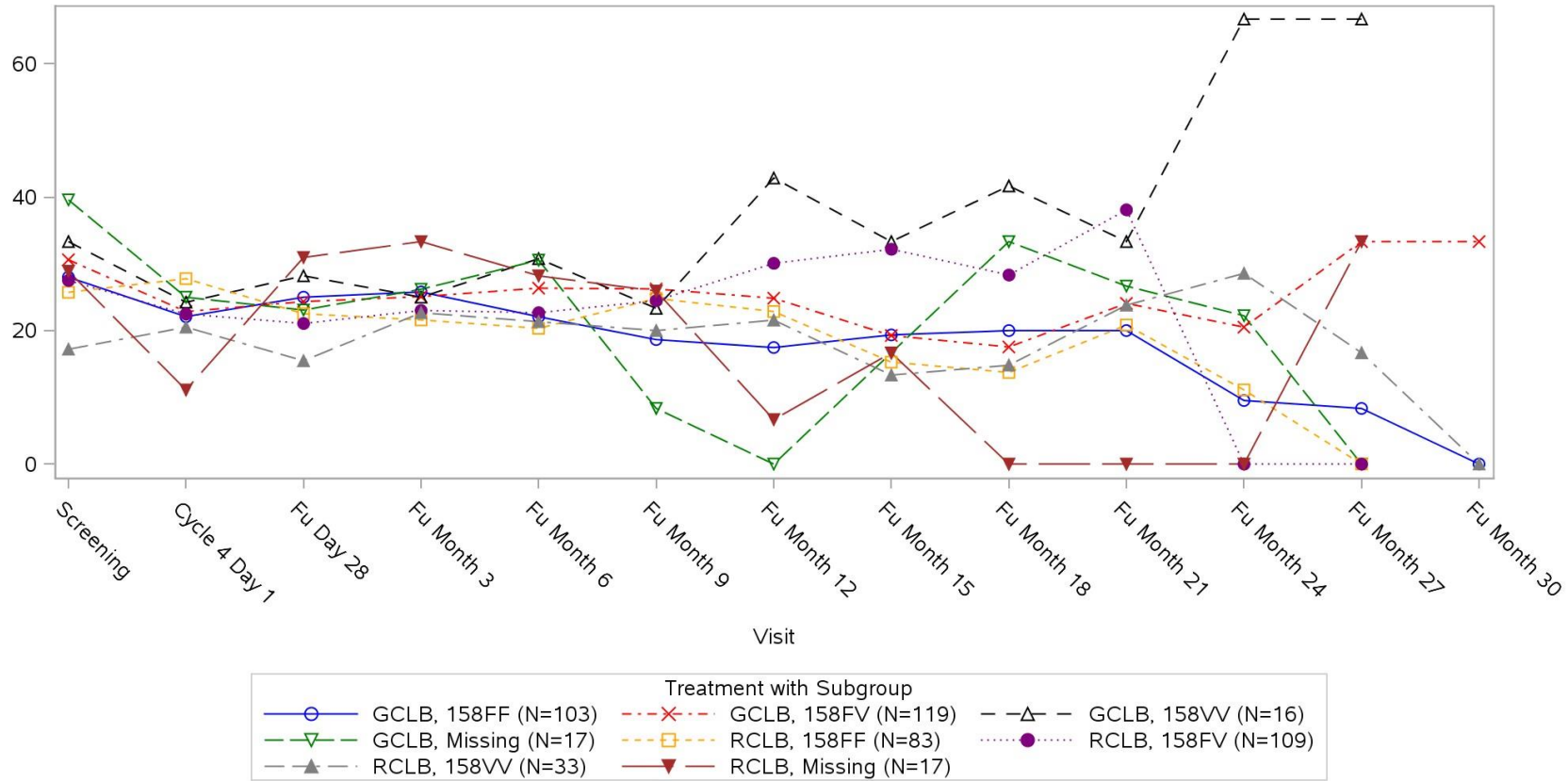
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

FCgamma receptor IIIa (N=497) Laboratory Test: Insomnia Scale



Clinical cut-off: 09MAY2013

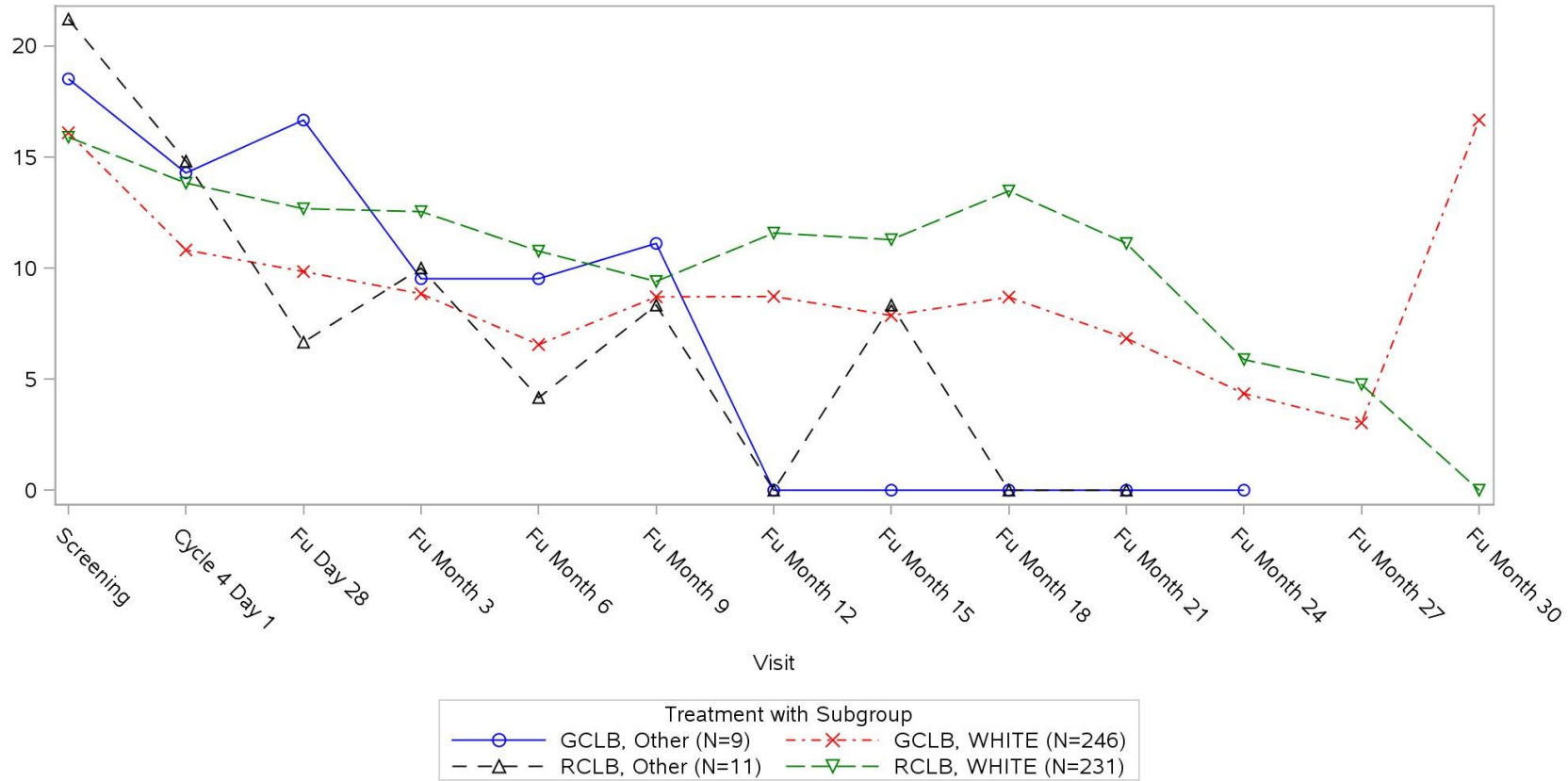
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 04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Race/ethnicity (N=497) Laboratory Test: Appetite Loss Scale



Clinical cut-off: 09MAY2013

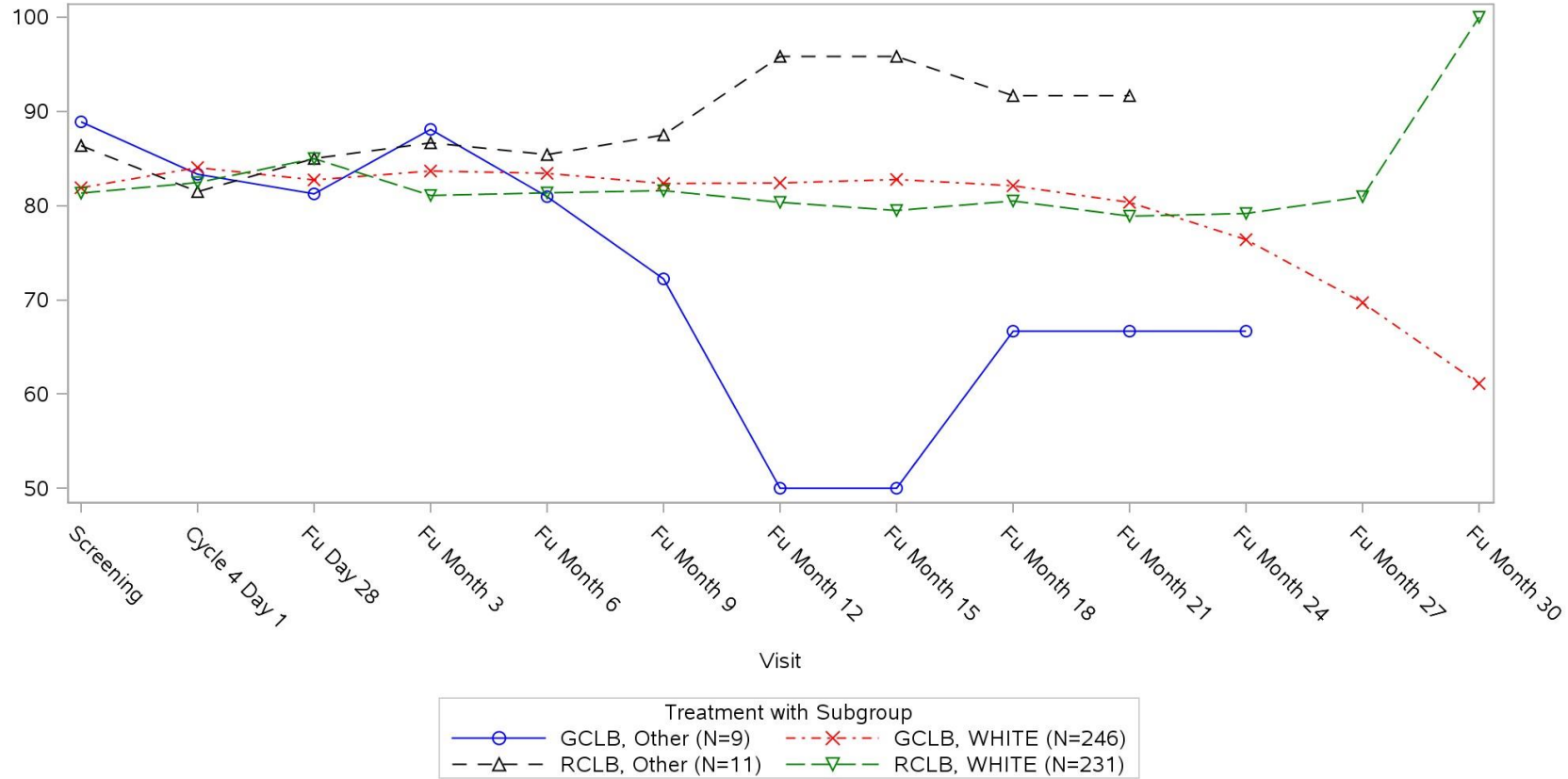
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04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Race/ethnicity (N=497) Laboratory Test: Cognitive Functioning Scale



Clinical cut-off: 09MAY2013

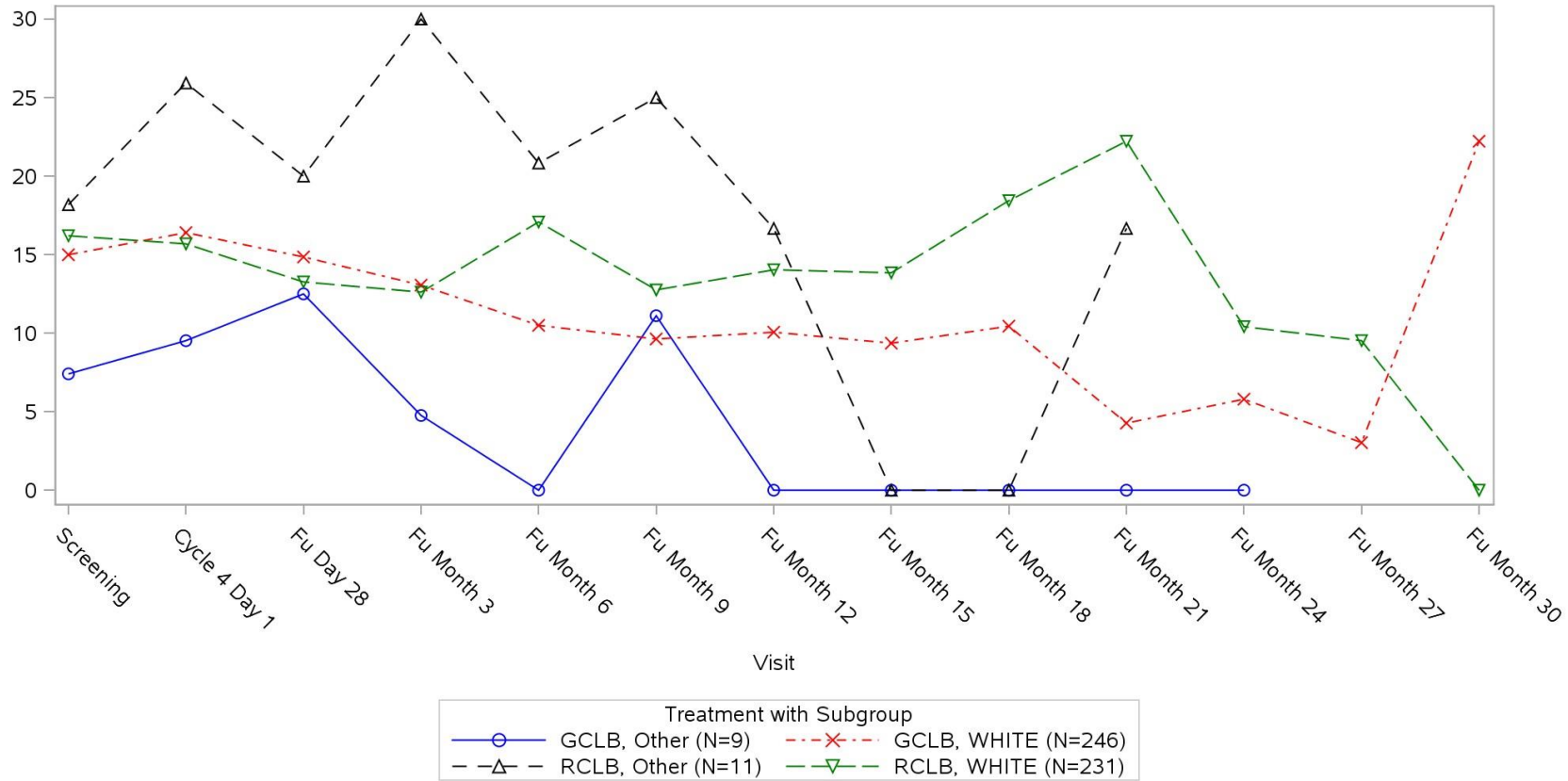
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04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Race/ethnicity (N=497) Laboratory Test: Constipation Scale



Clinical cut-off: 09MAY2013

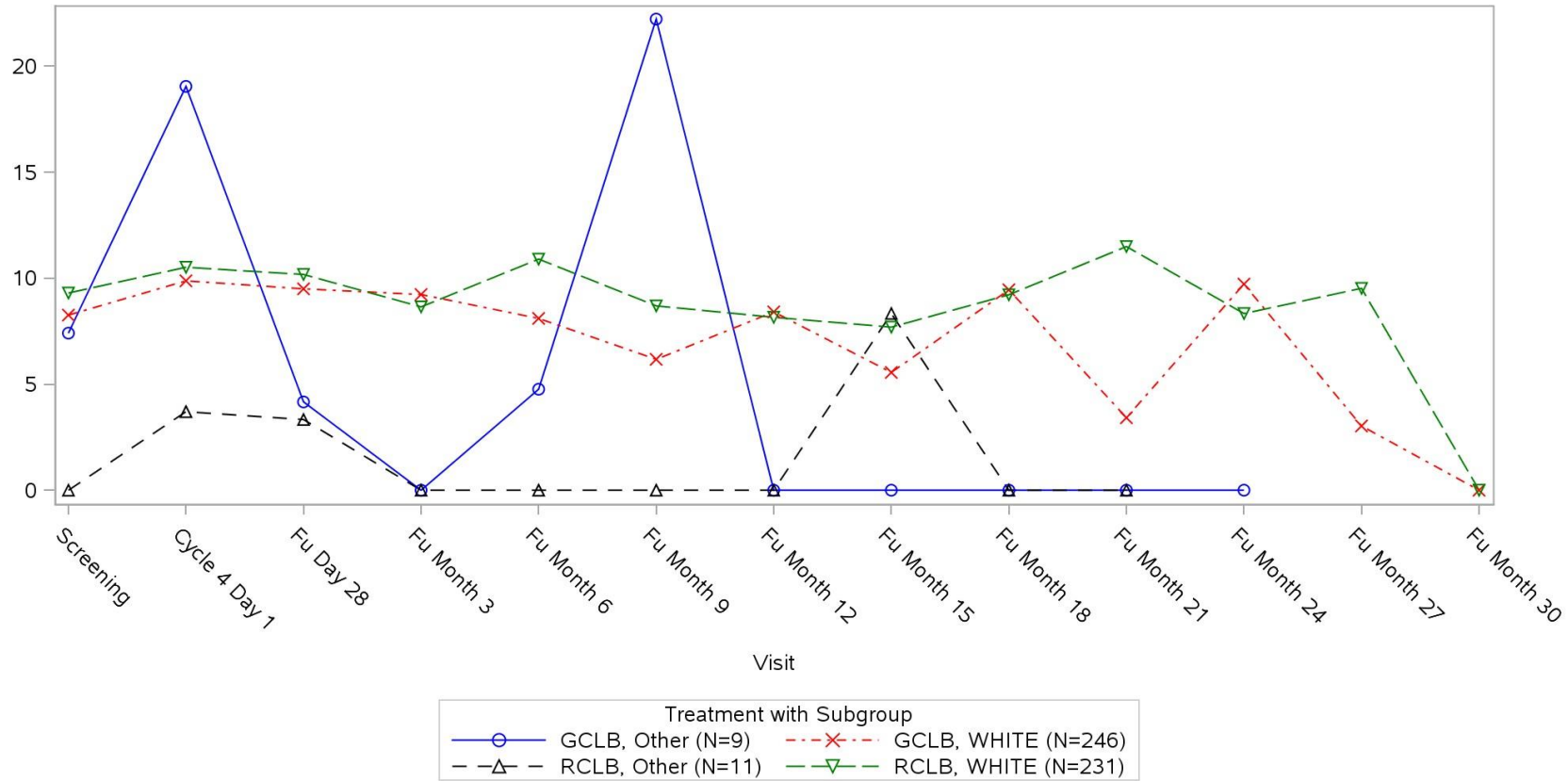
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04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Race/ethnicity (N=497) Laboratory Test: Diarrhoea Scale



Clinical cut-off: 09MAY2013

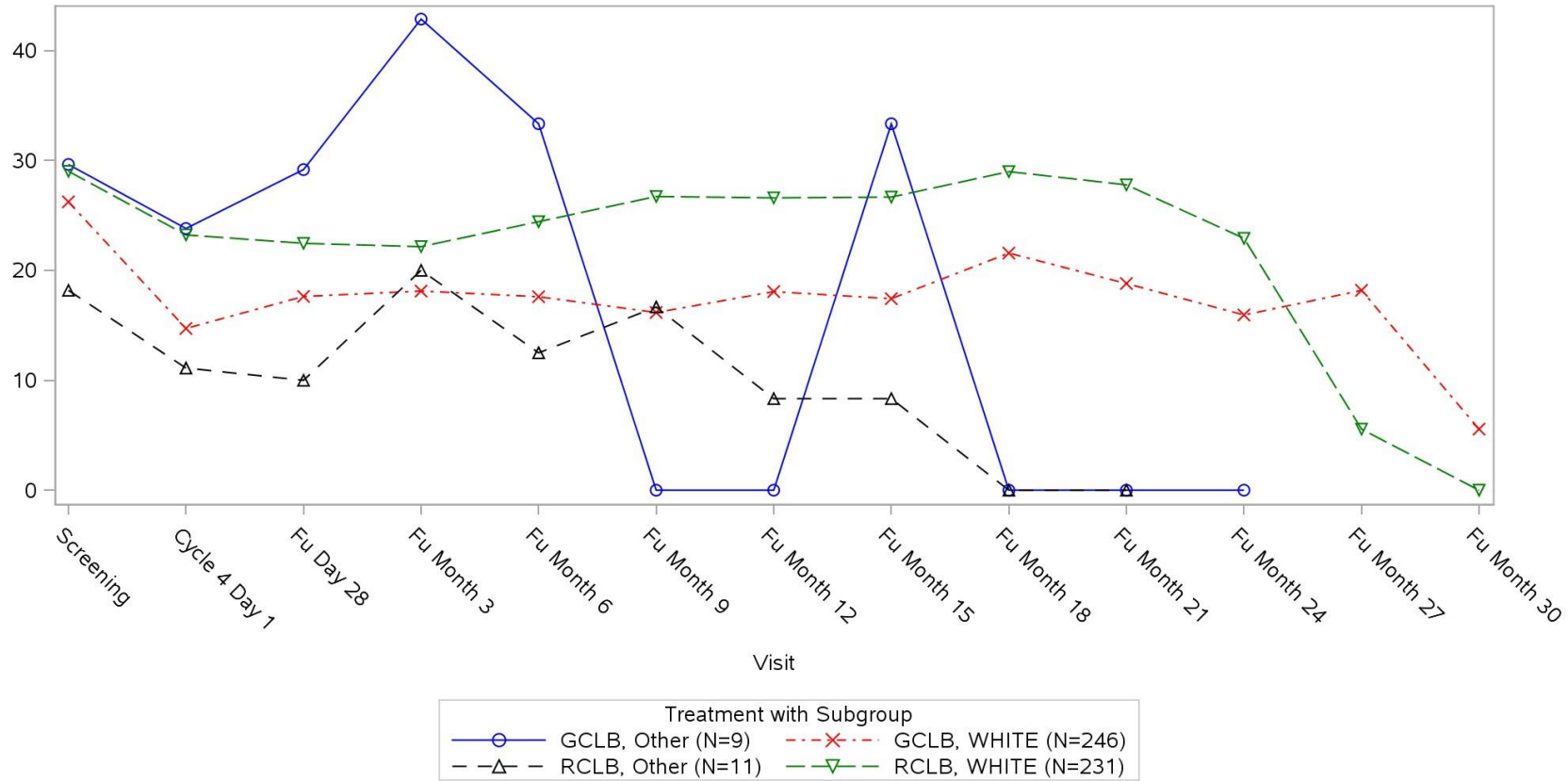
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04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Race/ethnicity (N=497) Laboratory Test: Dyspnoea Scale



Clinical cut-off: 09MAY2013

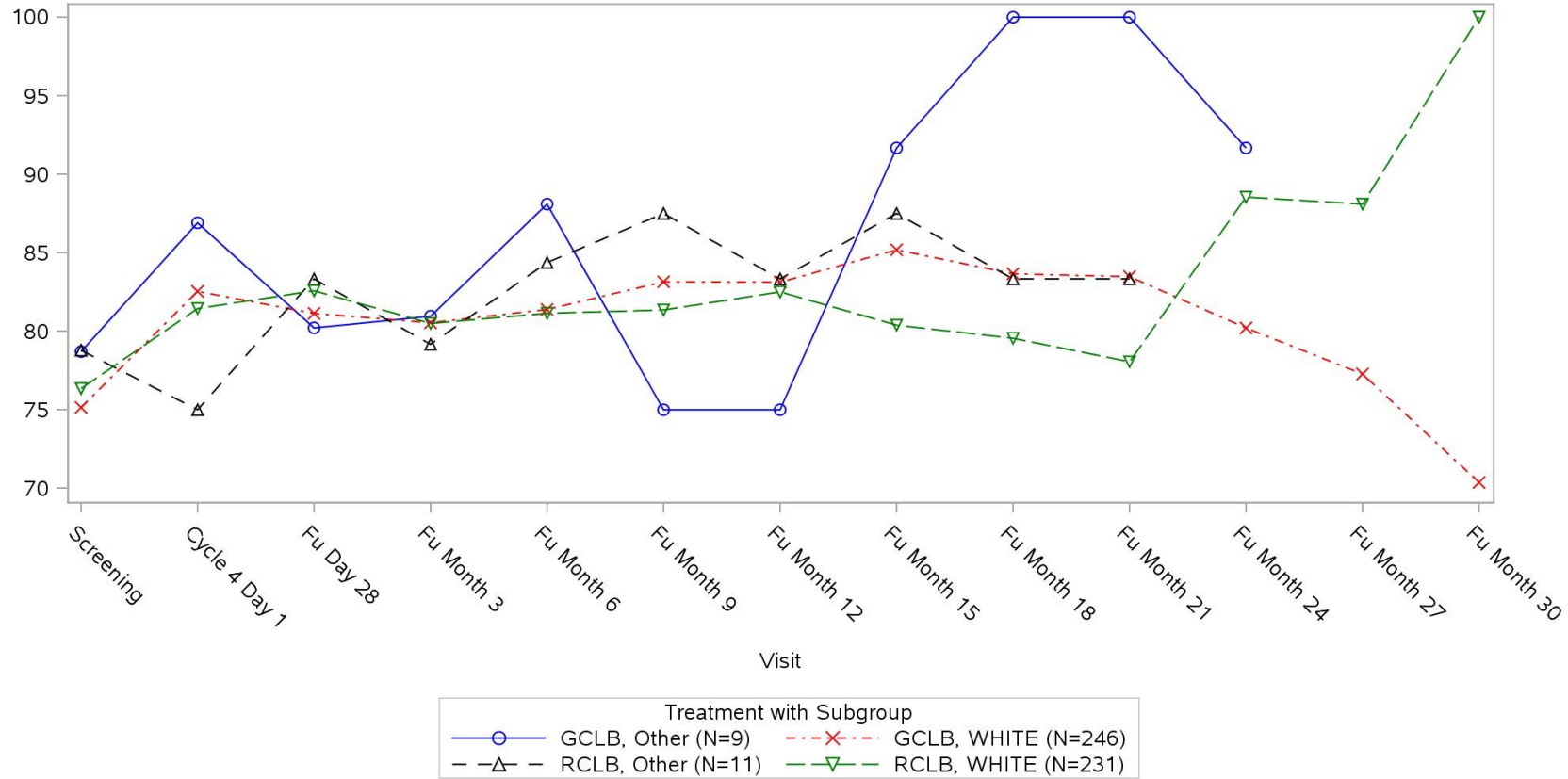
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04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Race/ethnicity (N=497) Laboratory Test: Emotional Functioning Scale



Clinical cut-off: 09MAY2013

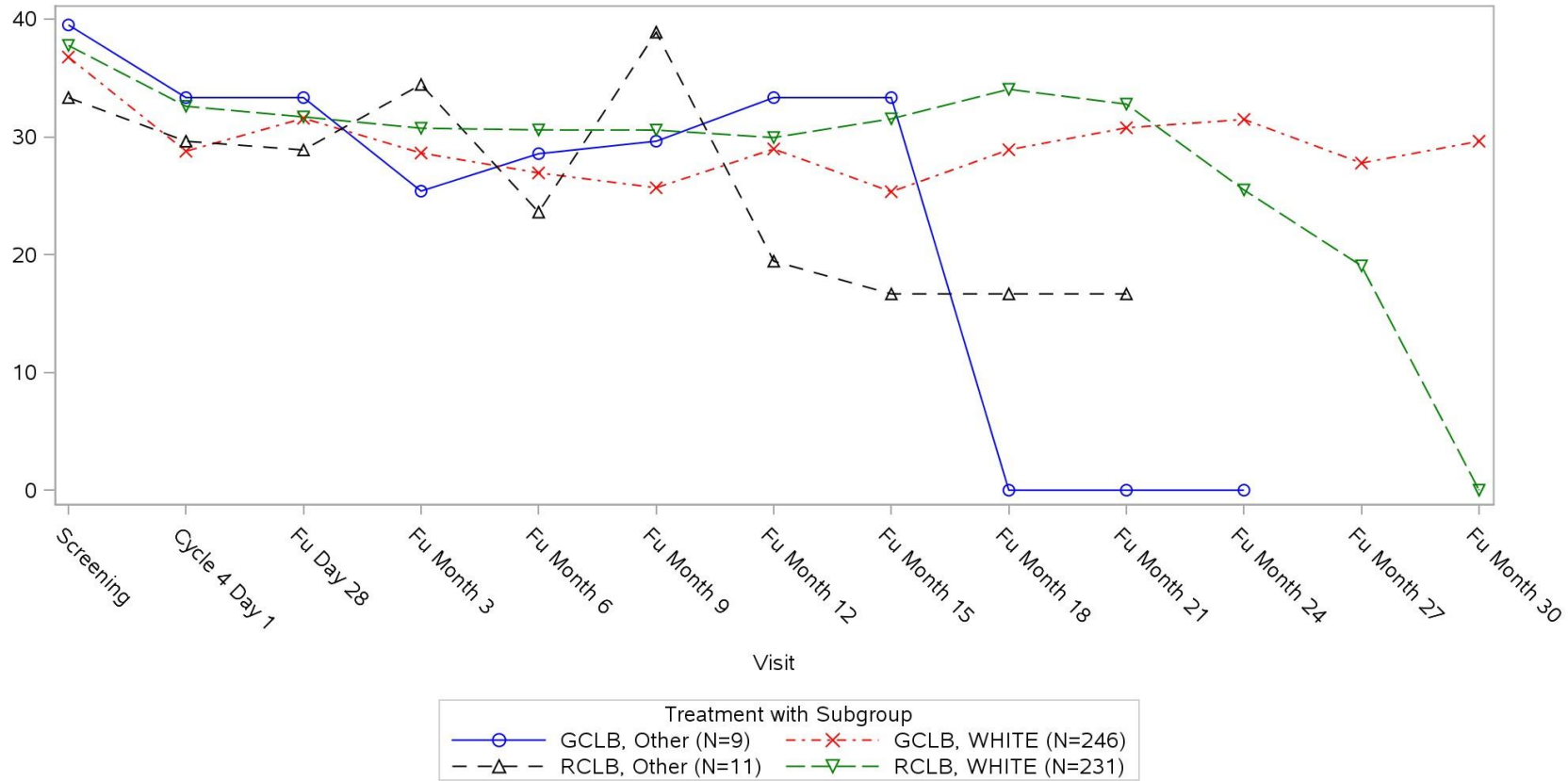
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04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Race/ethnicity (N=497) Laboratory Test: Fatigue Scale



Clinical cut-off: 09MAY2013

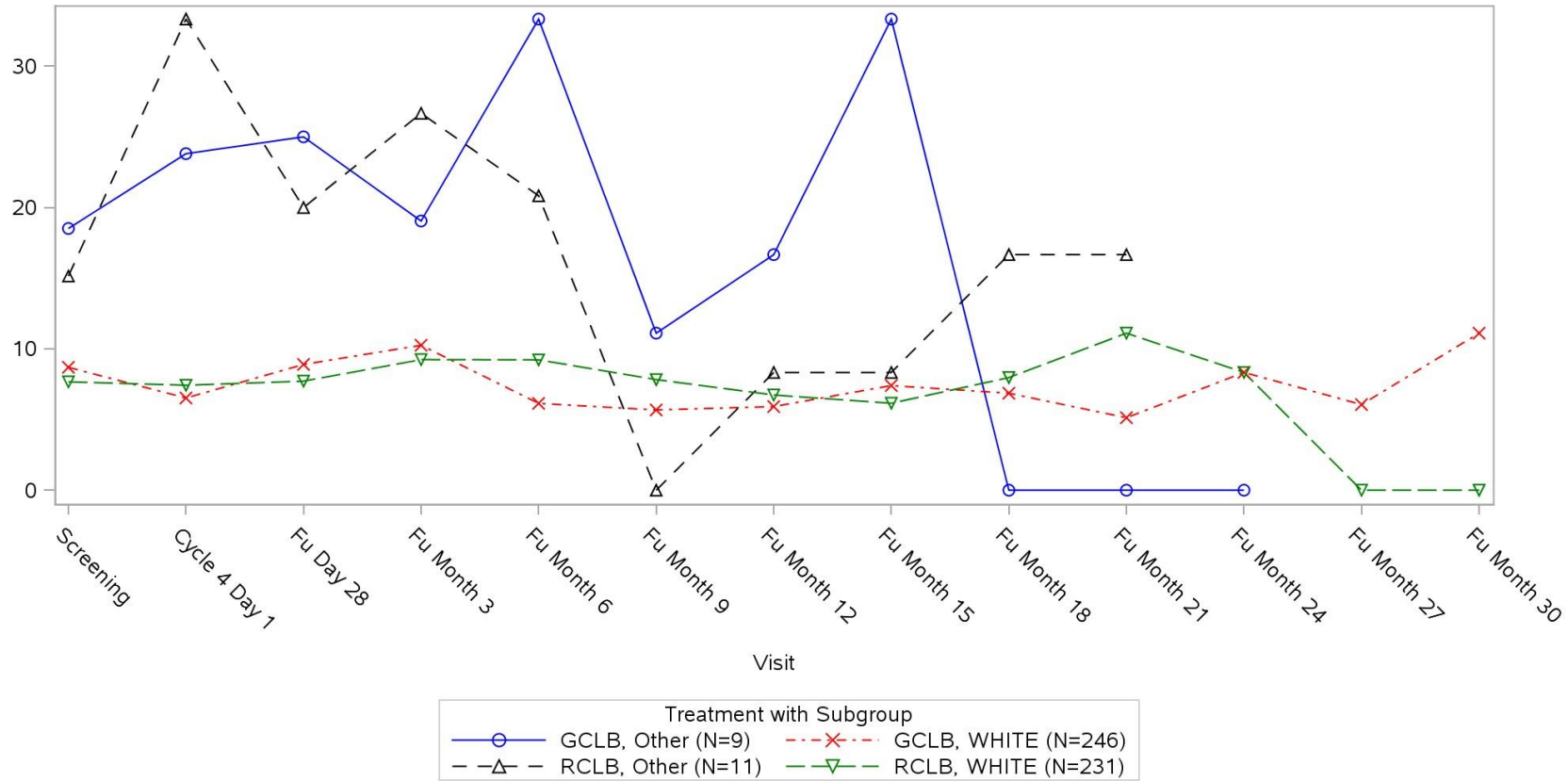
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04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Race/ethnicity (N=497) Laboratory Test: Financial Difficulties Scale



Clinical cut-off: 09MAY2013

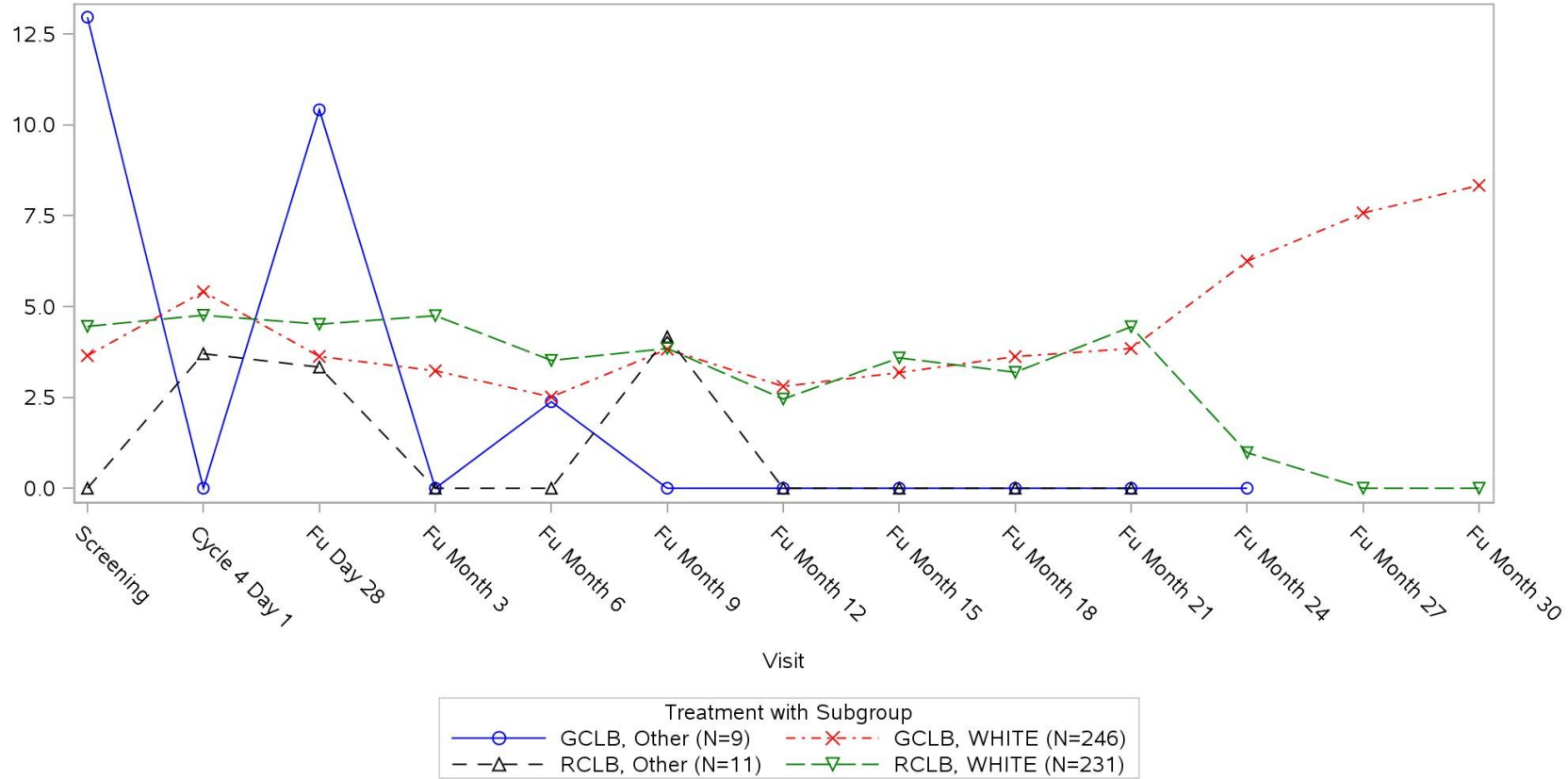
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Race/ethnicity (N=497) Laboratory Test: Nausia And Vomiting Scale



Clinical cut-off: 09MAY2013

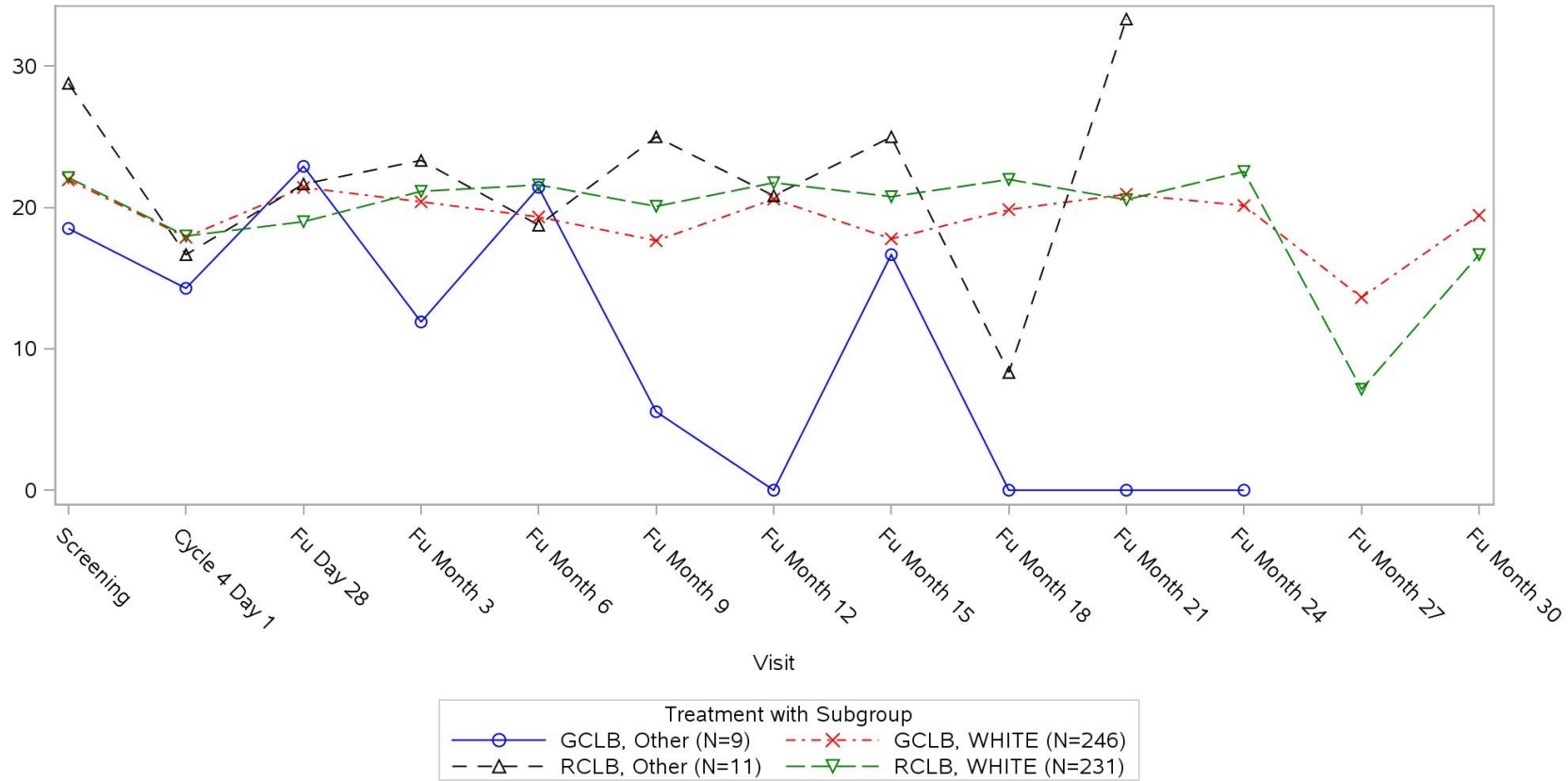
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Race/ethnicity (N=497) Laboratory Test: Pain Scale



Clinical cut-off: 09MAY2013

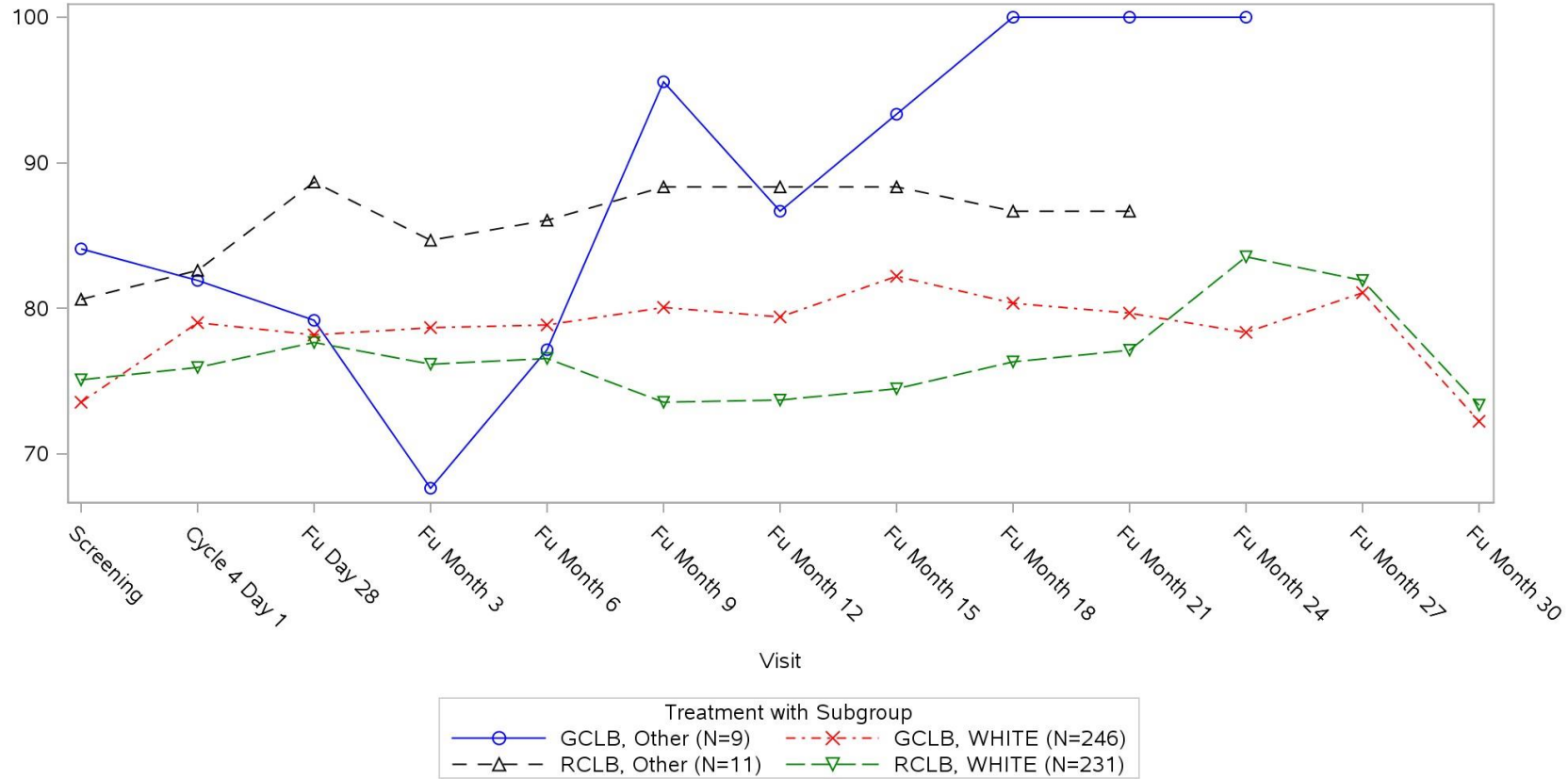
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Race/ethnicity (N=497) Laboratory Test: Physical Functioning Scale



Clinical cut-off: 09MAY2013

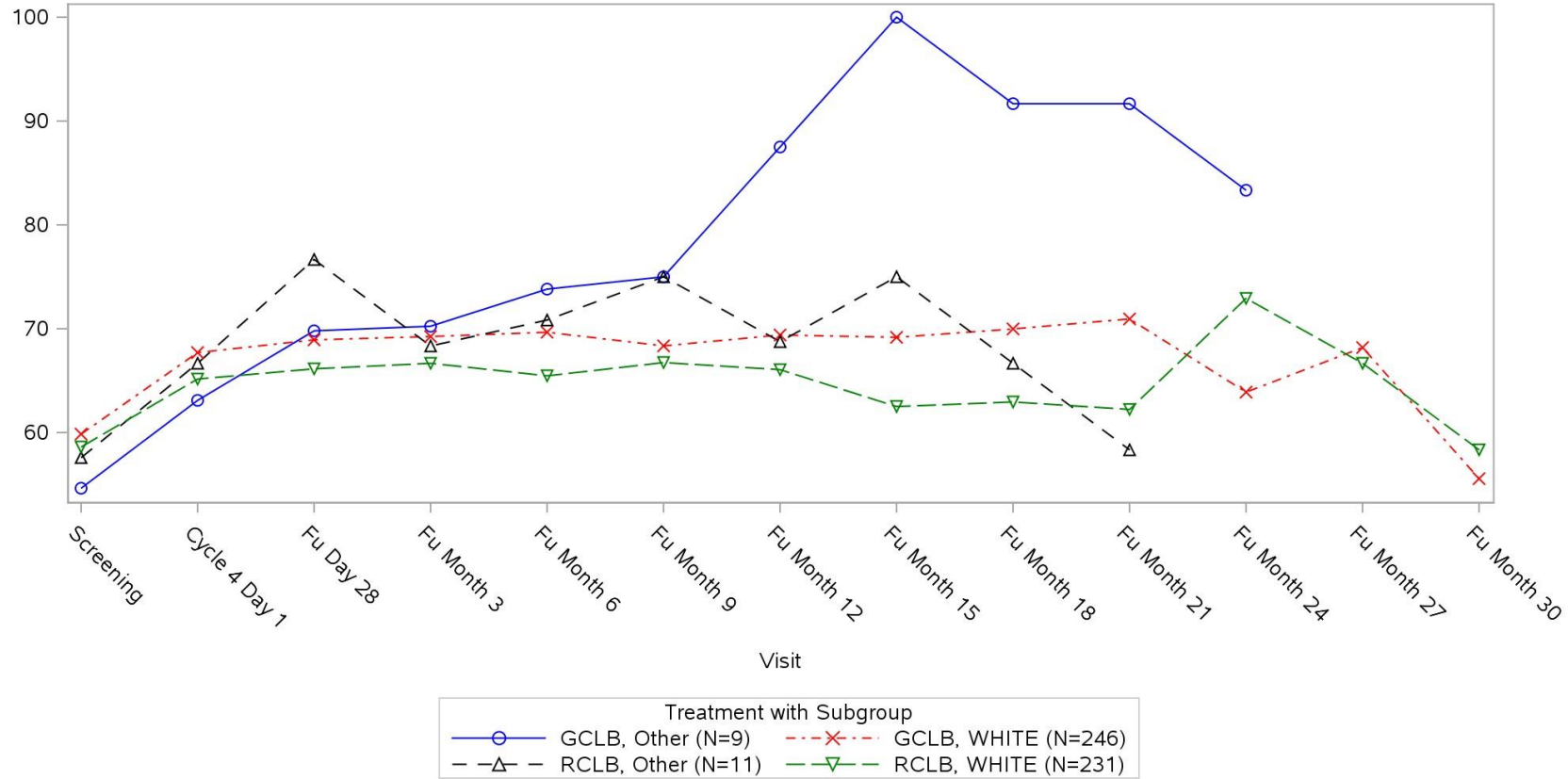
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04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Race/ethnicity (N=497) Laboratory Test: Global Health Status Scale



Clinical cut-off: 09MAY2013

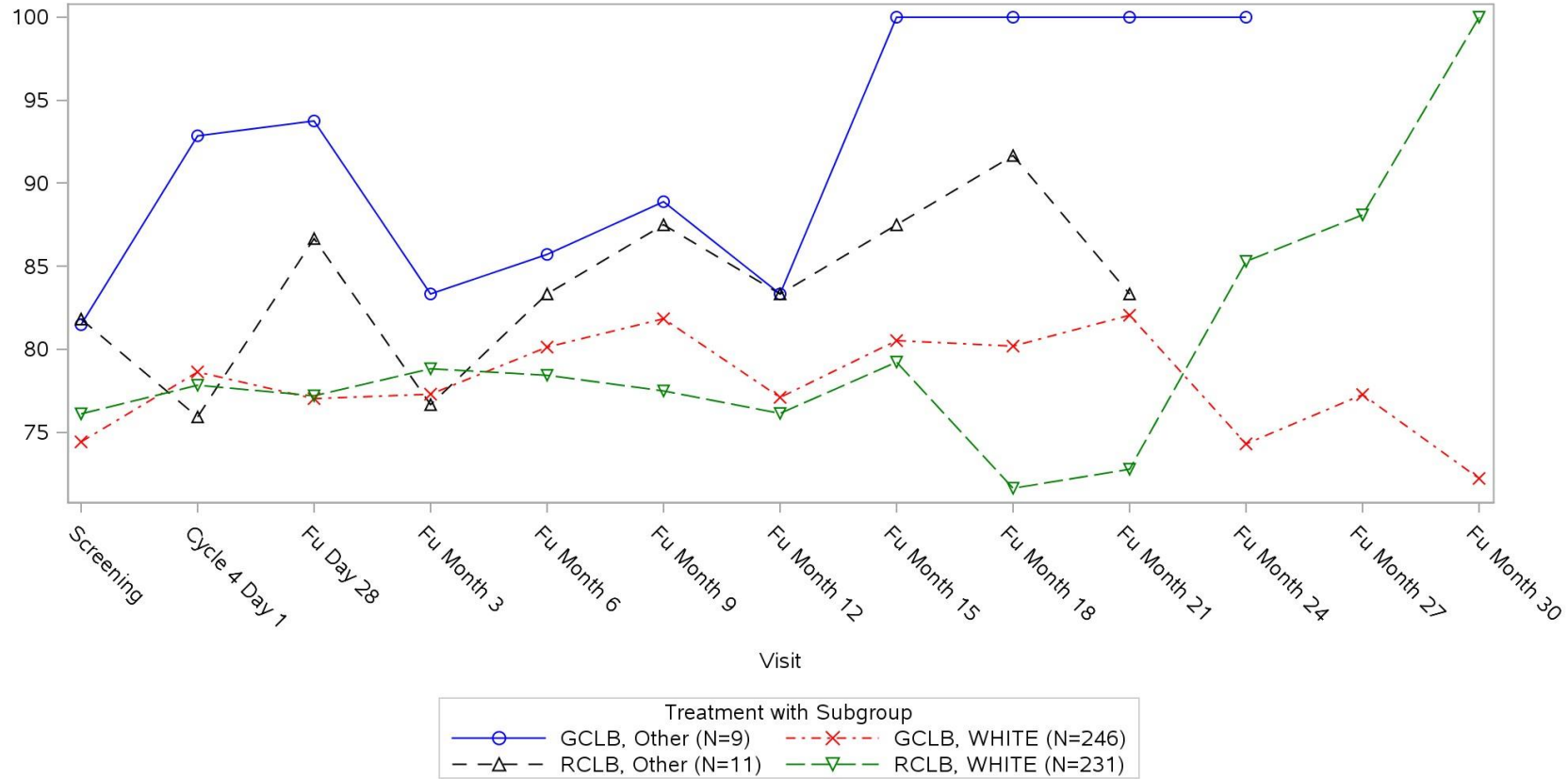
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Race/ethnicity (N=497) Laboratory Test: Role Functioning Scale



Clinical cut-off: 09MAY2013

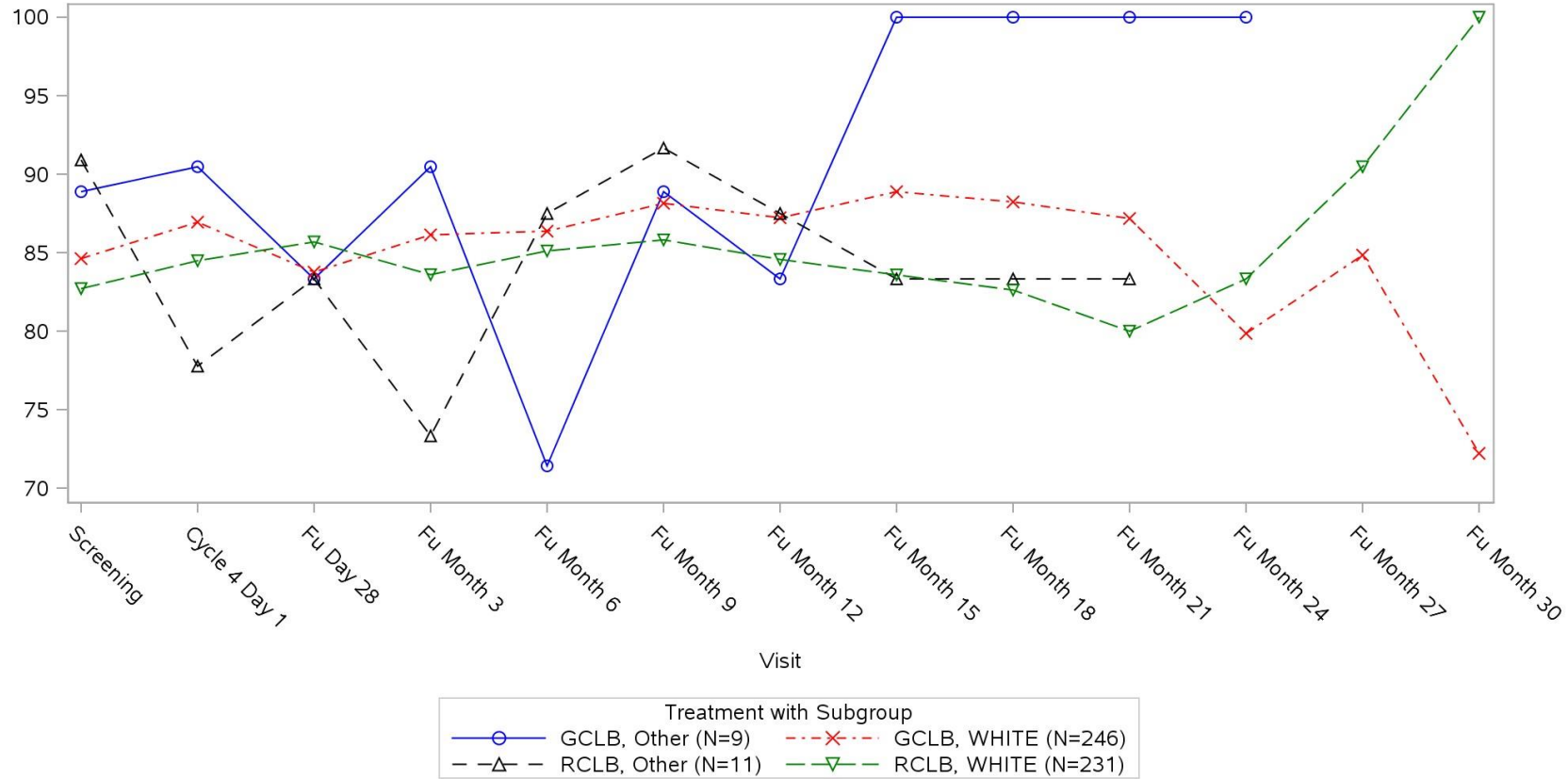
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Race/ethnicity (N=497) Laboratory Test: Social Functioning Scale



Clinical cut-off: 09MAY2013

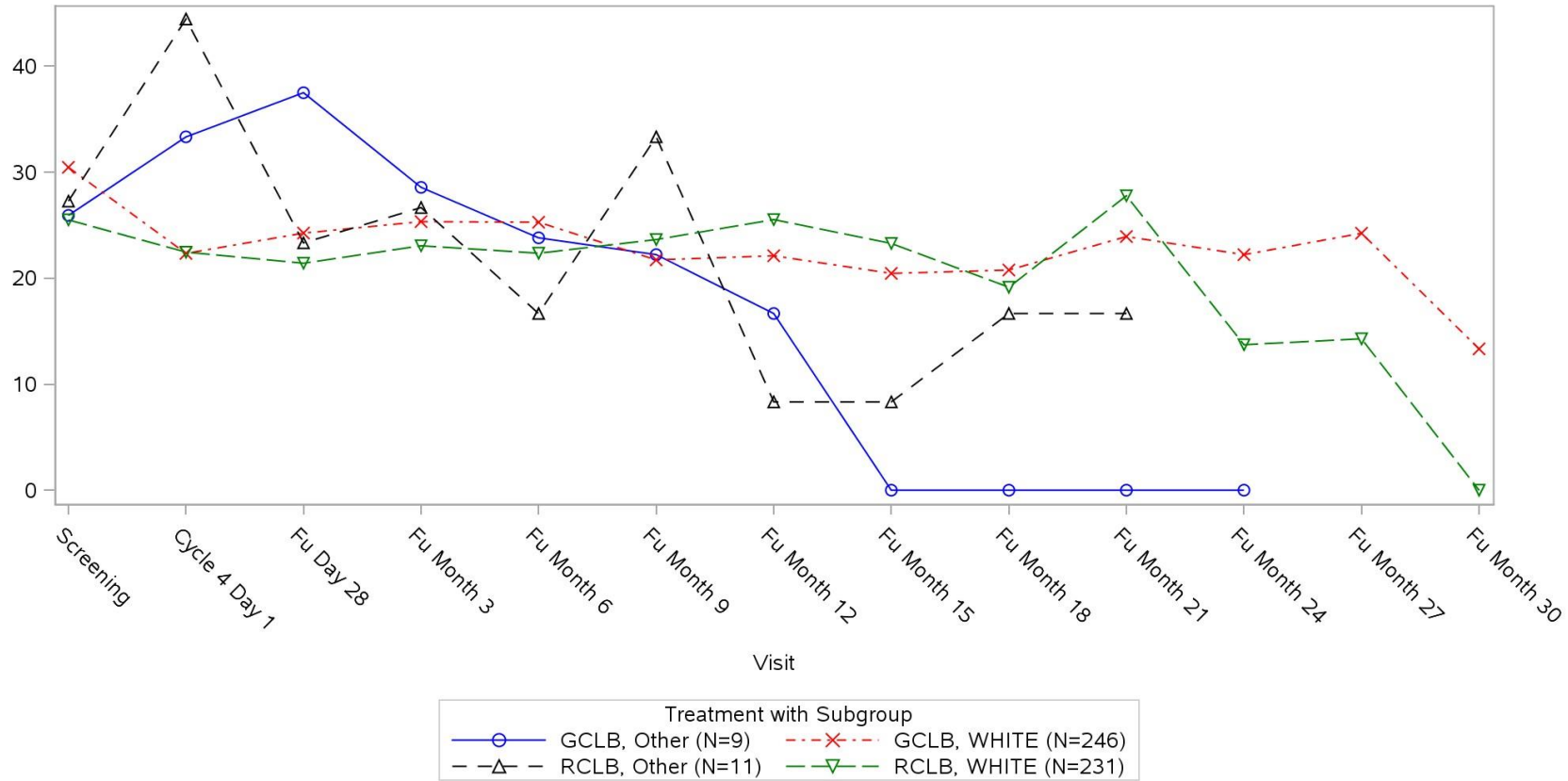
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 04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Race/ethnicity (N=497) Laboratory Test: Insomnia Scale



Clinical cut-off: 09MAY2013

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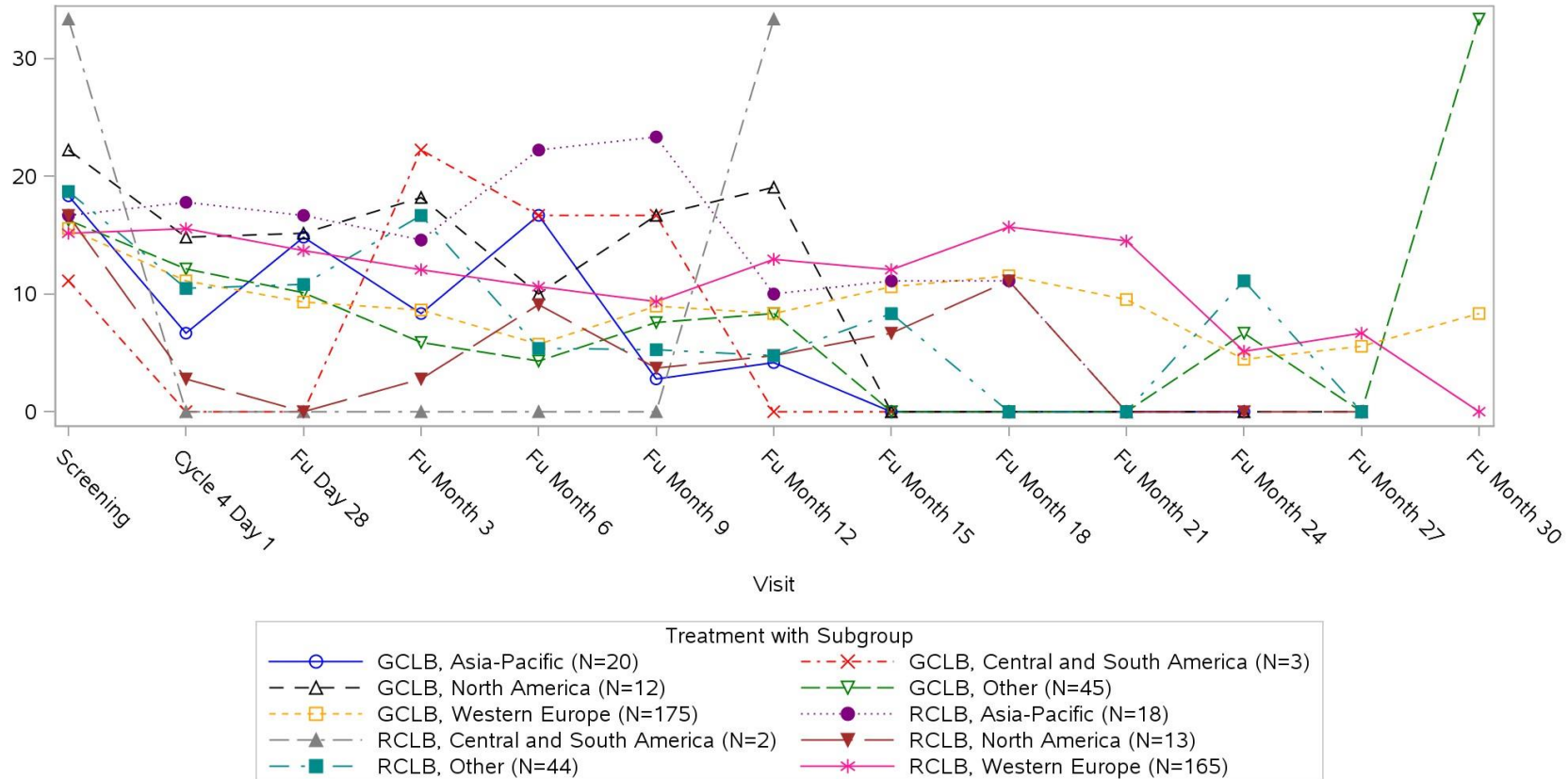
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Geographic Region (N=497) Laboratory Test: Appetite Loss Scale



Clinical cut-off: 09MAY2013

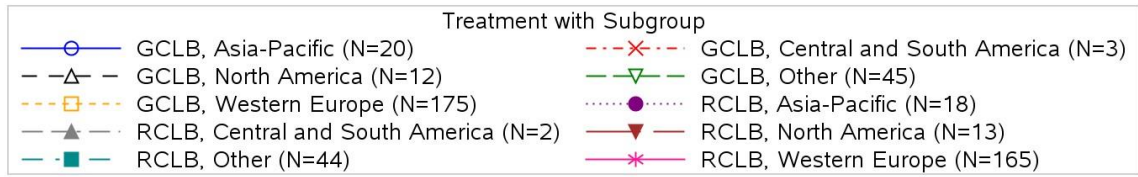
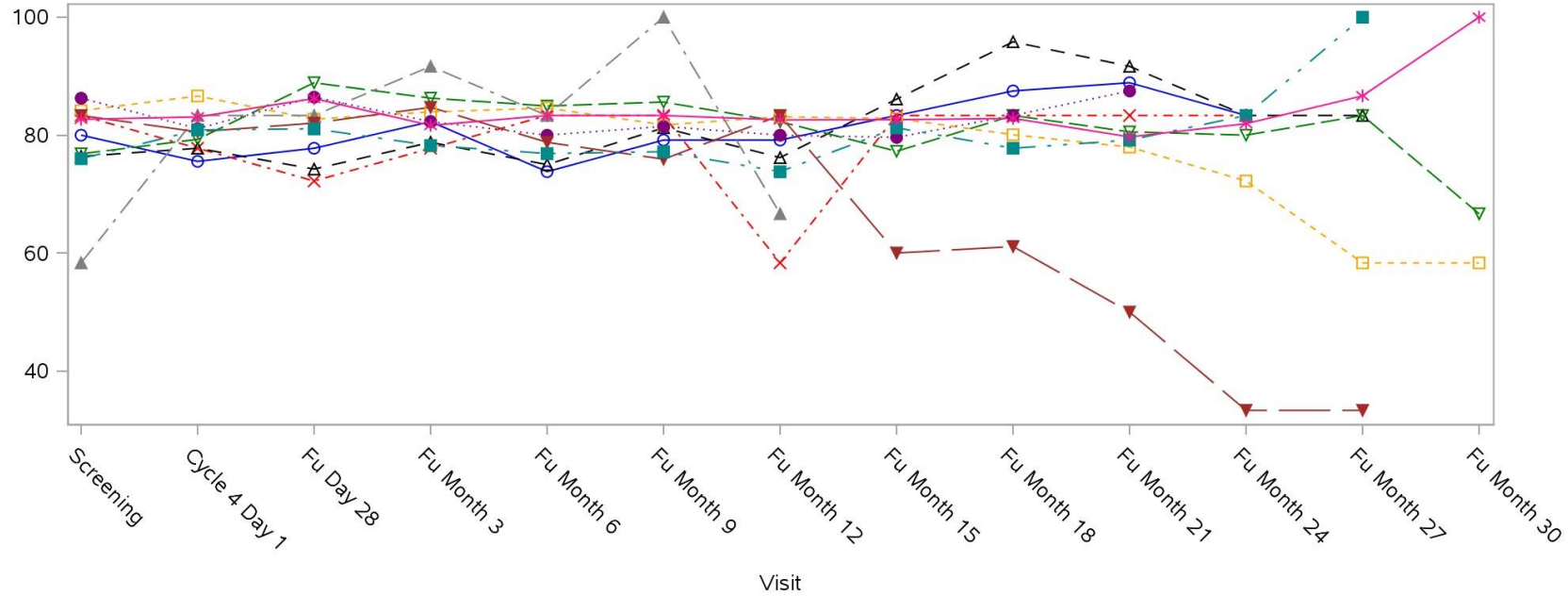
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Geographic Region (N=497) Laboratory Test: Cognitive Functioning Scale



Clinical cut-off: 09MAY2013

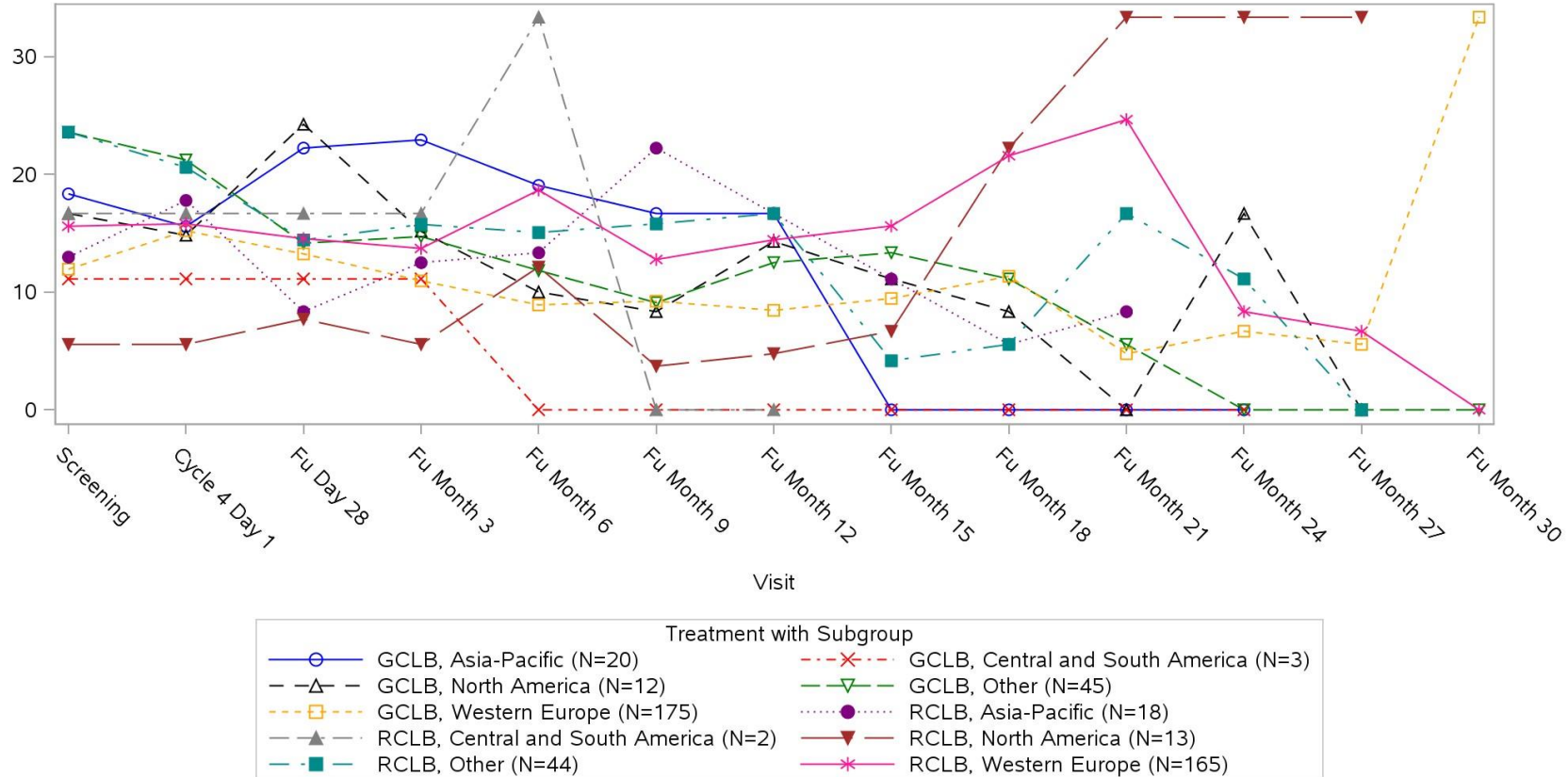
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 04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Geographic Region (N=497) Laboratory Test: Constipation Scale



Clinical cut-off: 09MAY2013

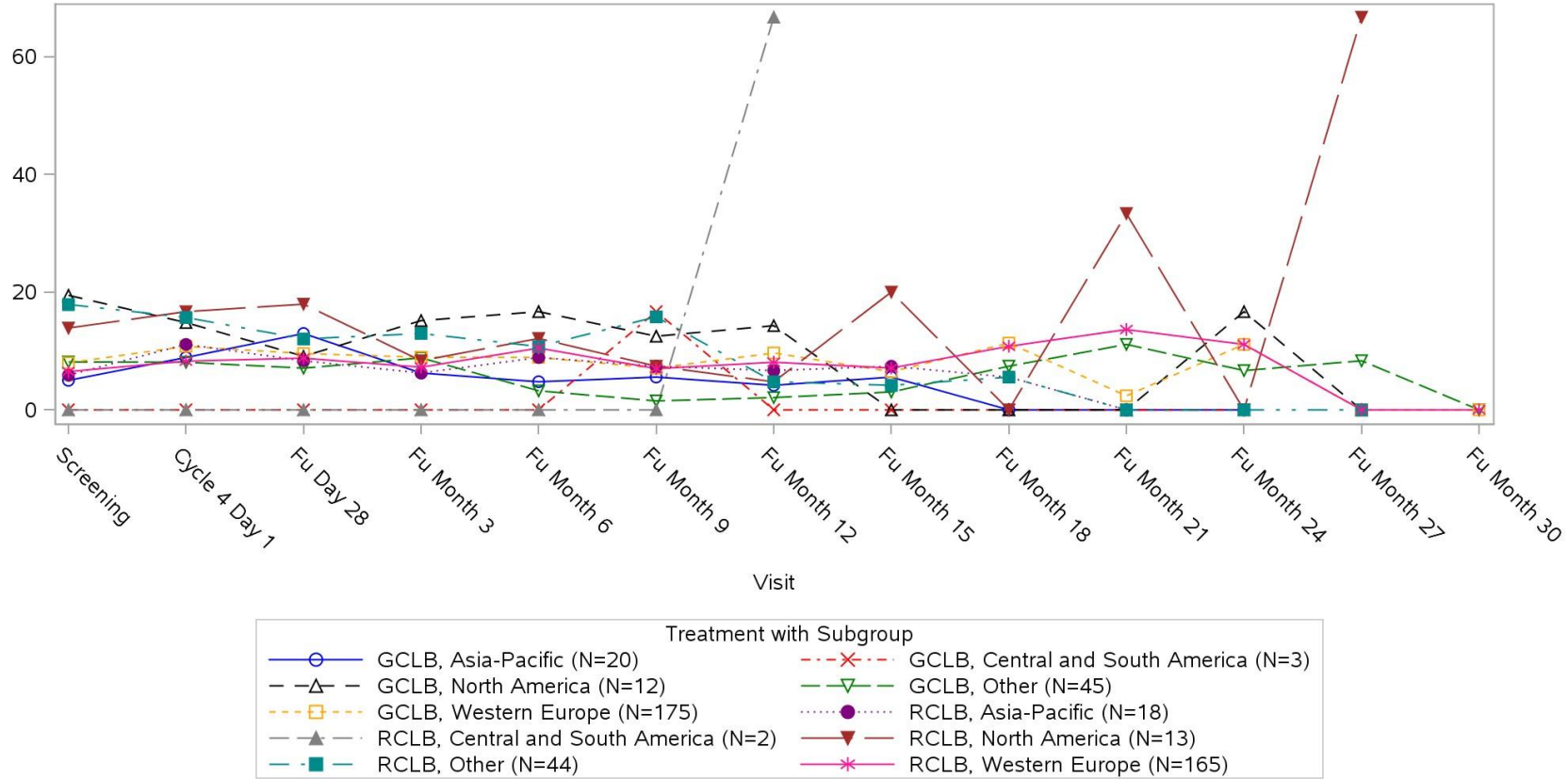
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Geographic Region (N=497) Laboratory Test: Diarrhoea Scale



Clinical cut-off: 09MAY2013

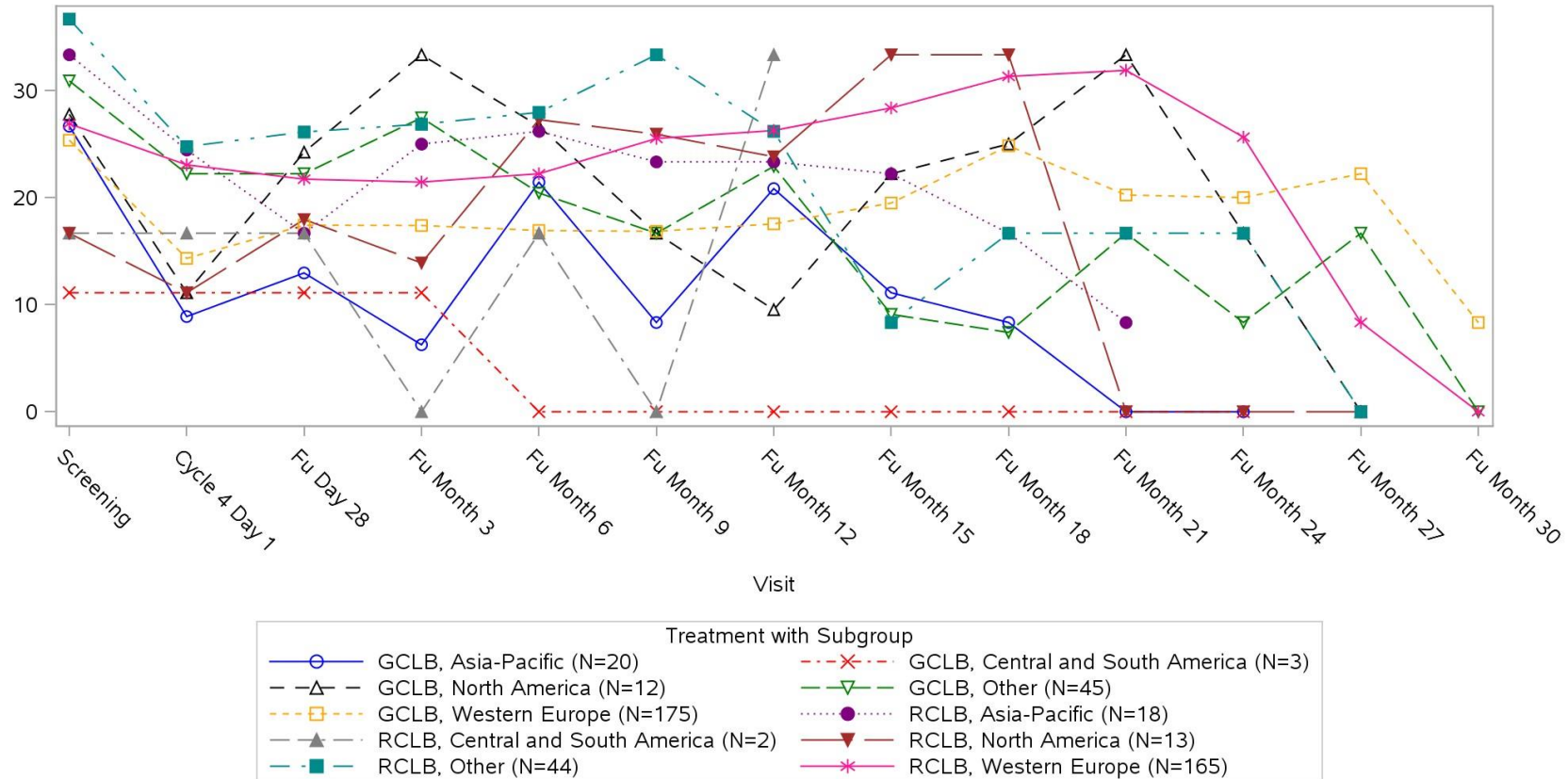
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Geographic Region (N=497) Laboratory Test: Dyspnoea Scale



Clinical cut-off: 09MAY2013

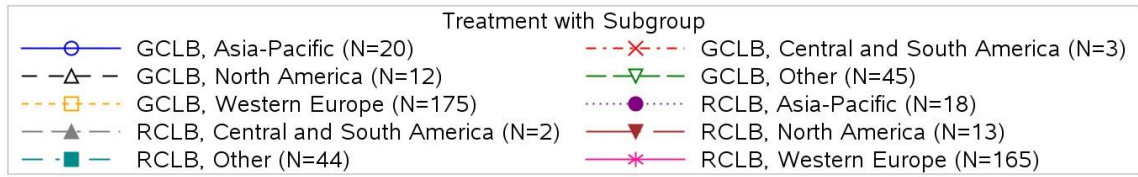
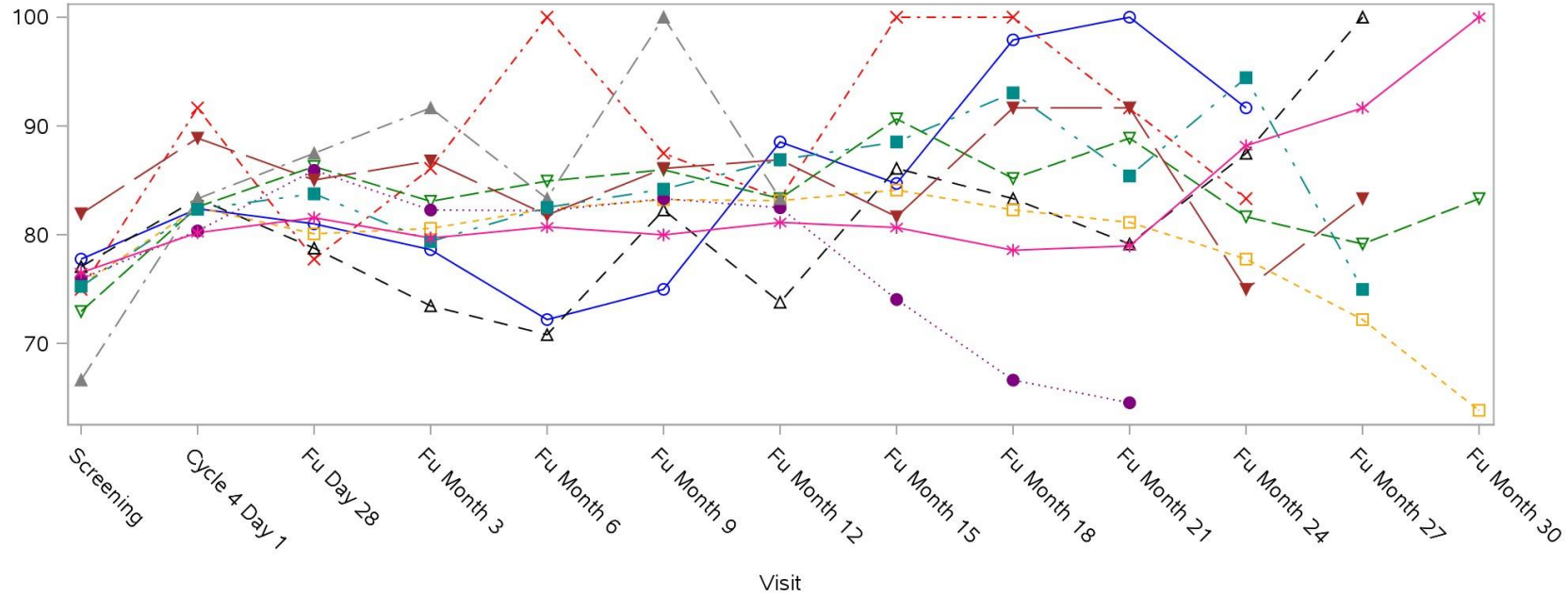
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 04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Geographic Region (N=497) Laboratory Test: Emotional Functioning Scale



Clinical cut-off: 09MAY2013

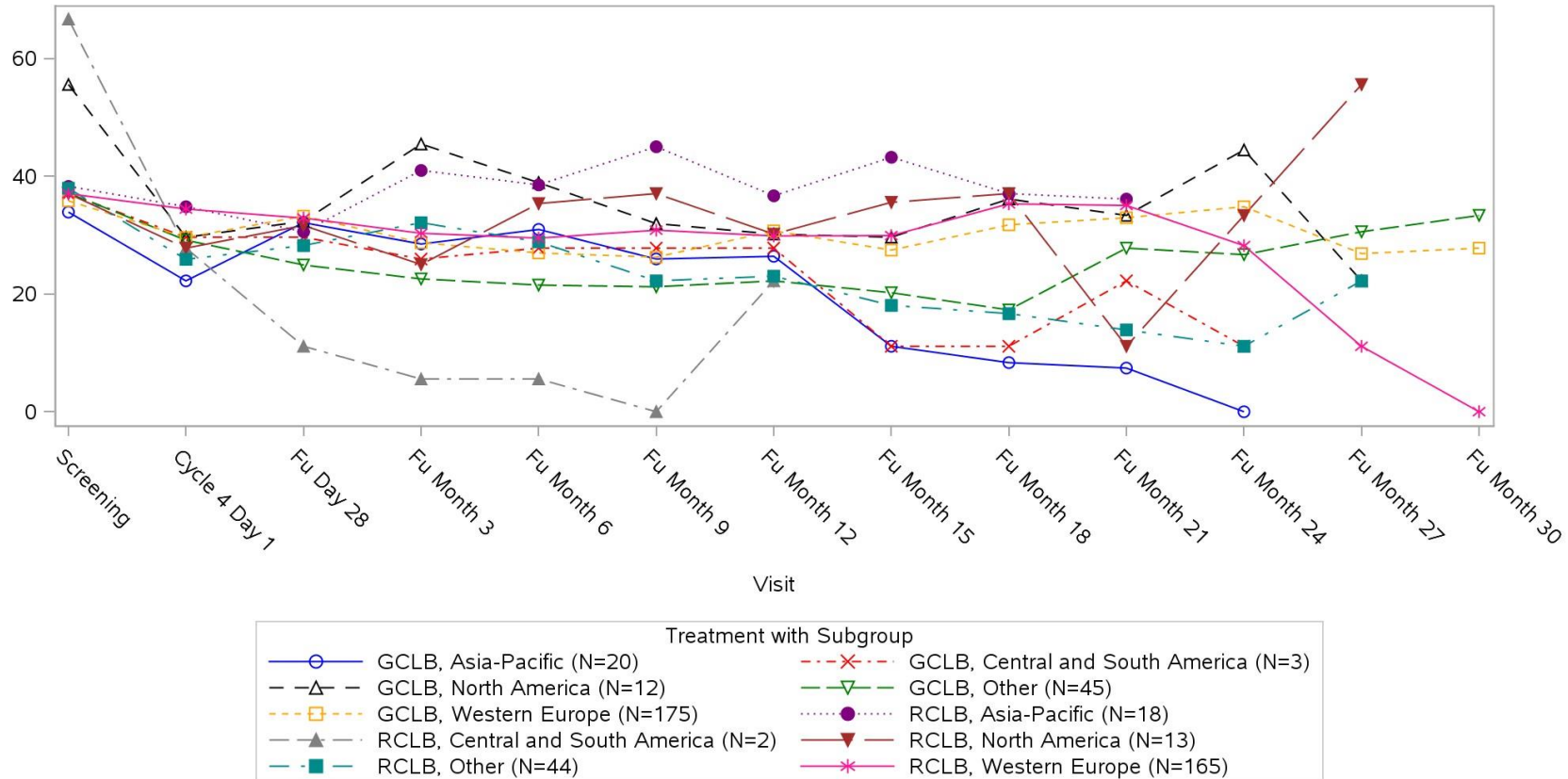
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 04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Geographic Region (N=497) Laboratory Test: Fatigue Scale



Clinical cut-off: 09MAY2013

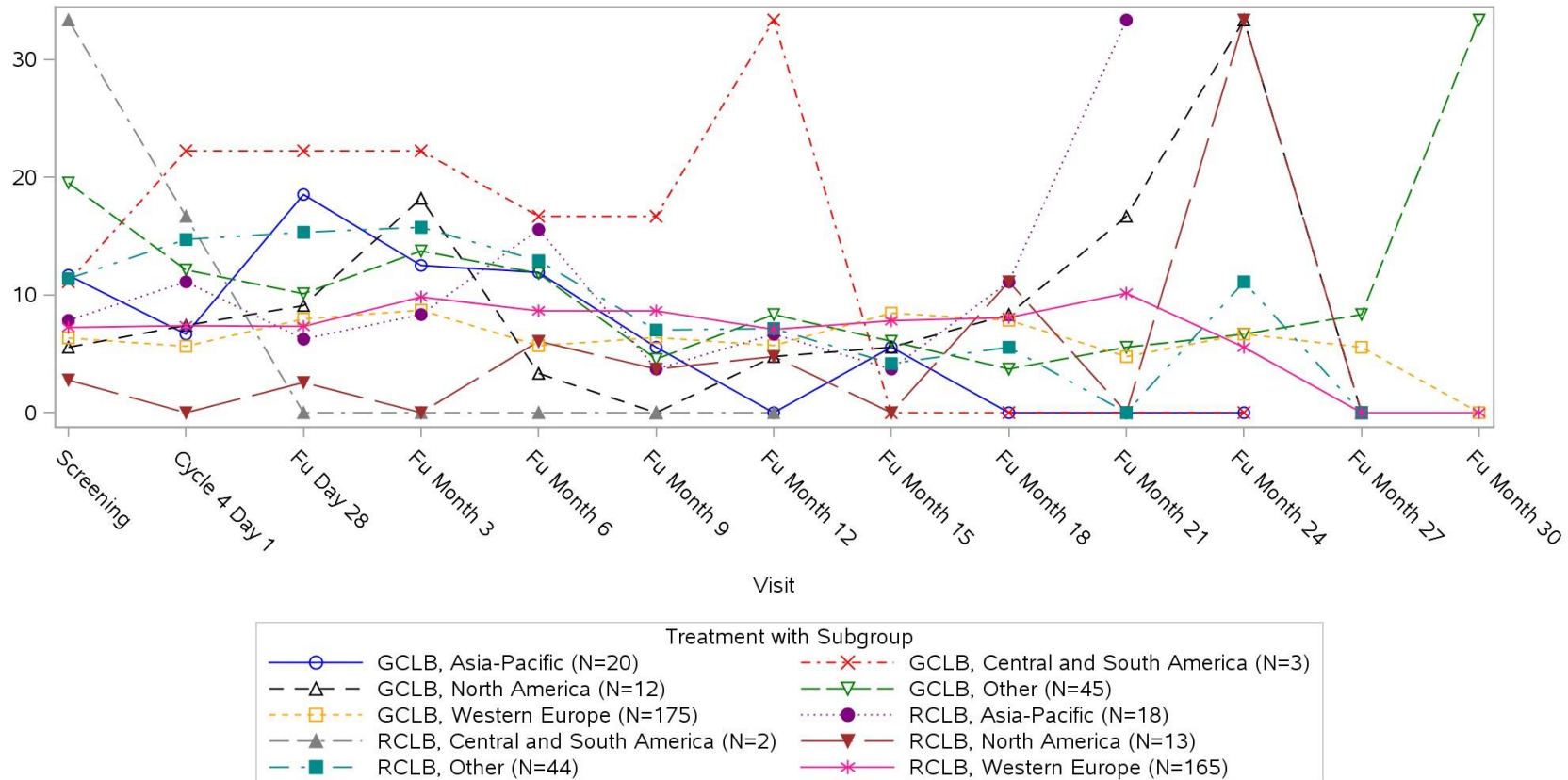
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 04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Geographic Region (N=497) Laboratory Test: Financial Difficulties Scale



Clinical cut-off: 09MAY2013

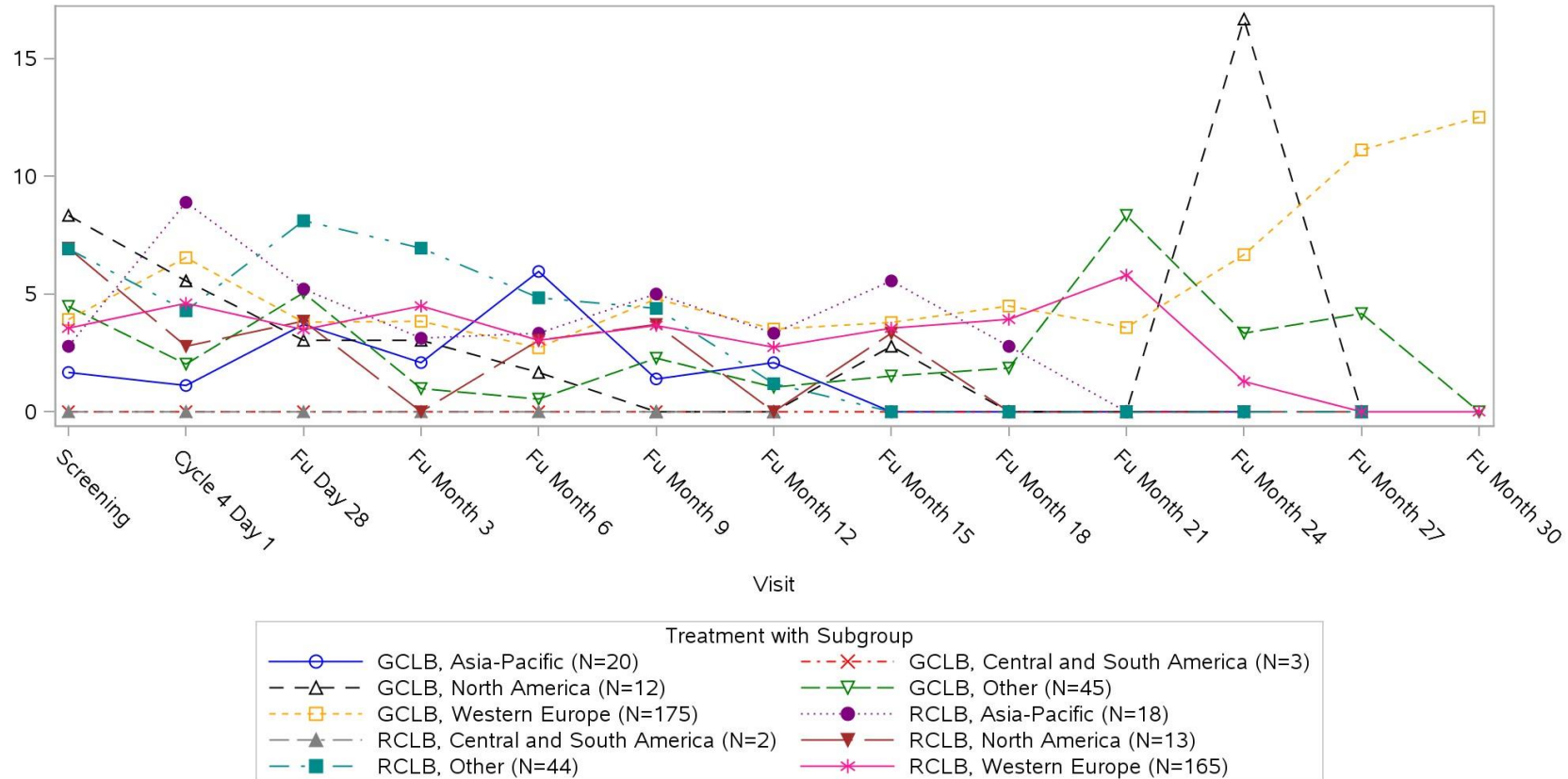
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 04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Geographic Region (N=497) Laboratory Test: Nausea And Vomiting Scale



Clinical cut-off: 09MAY2013

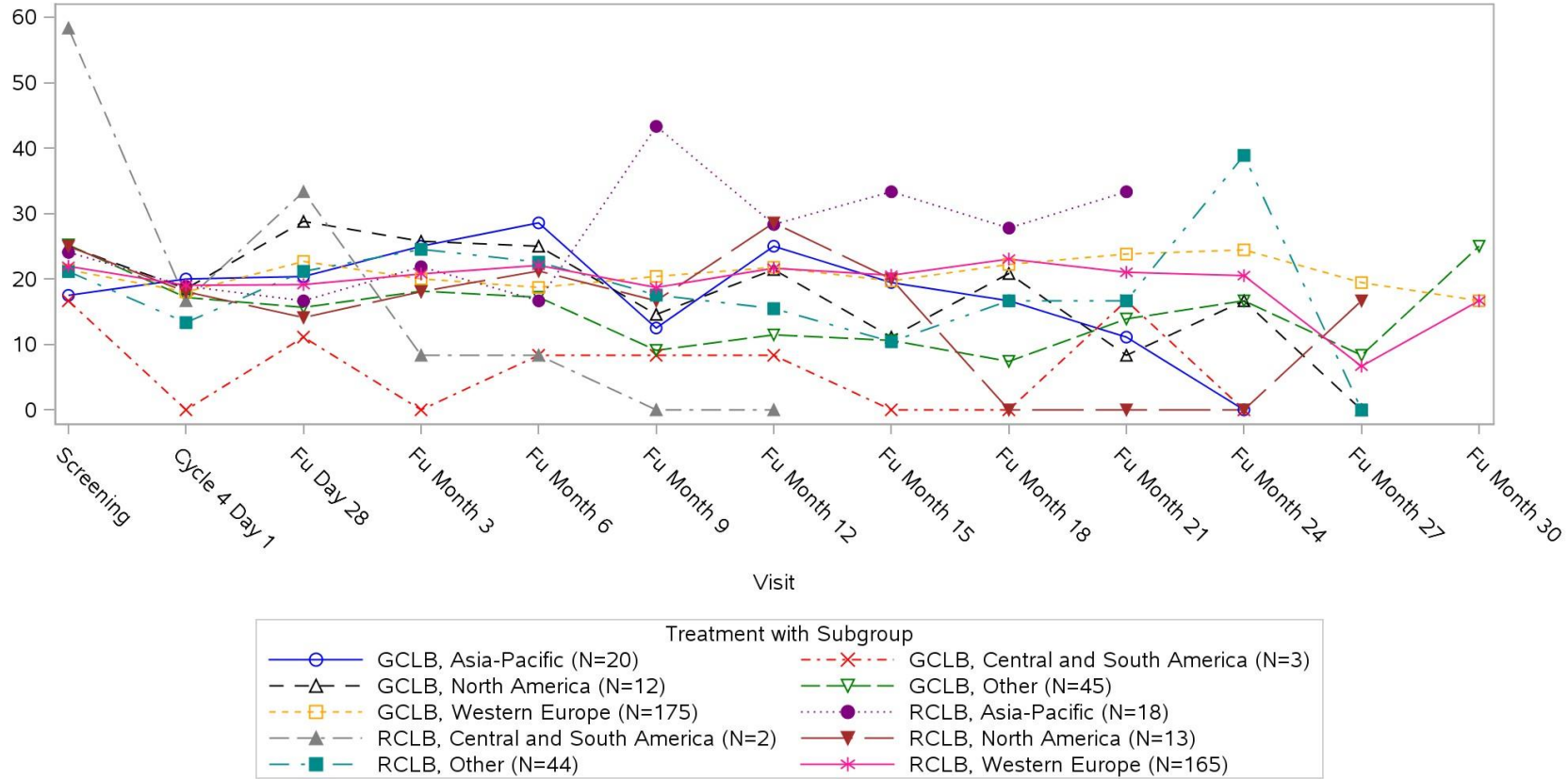
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Geographic Region (N=497) Laboratory Test: Pain Scale



Clinical cut-off: 09MAY2013

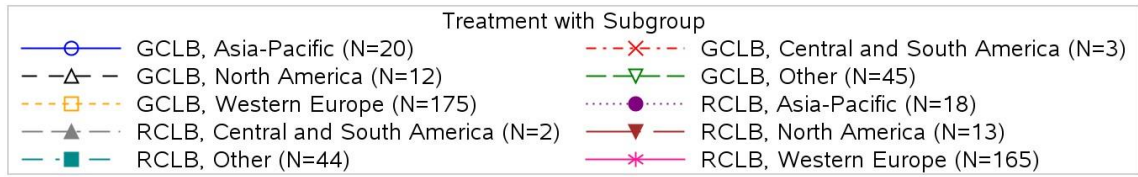
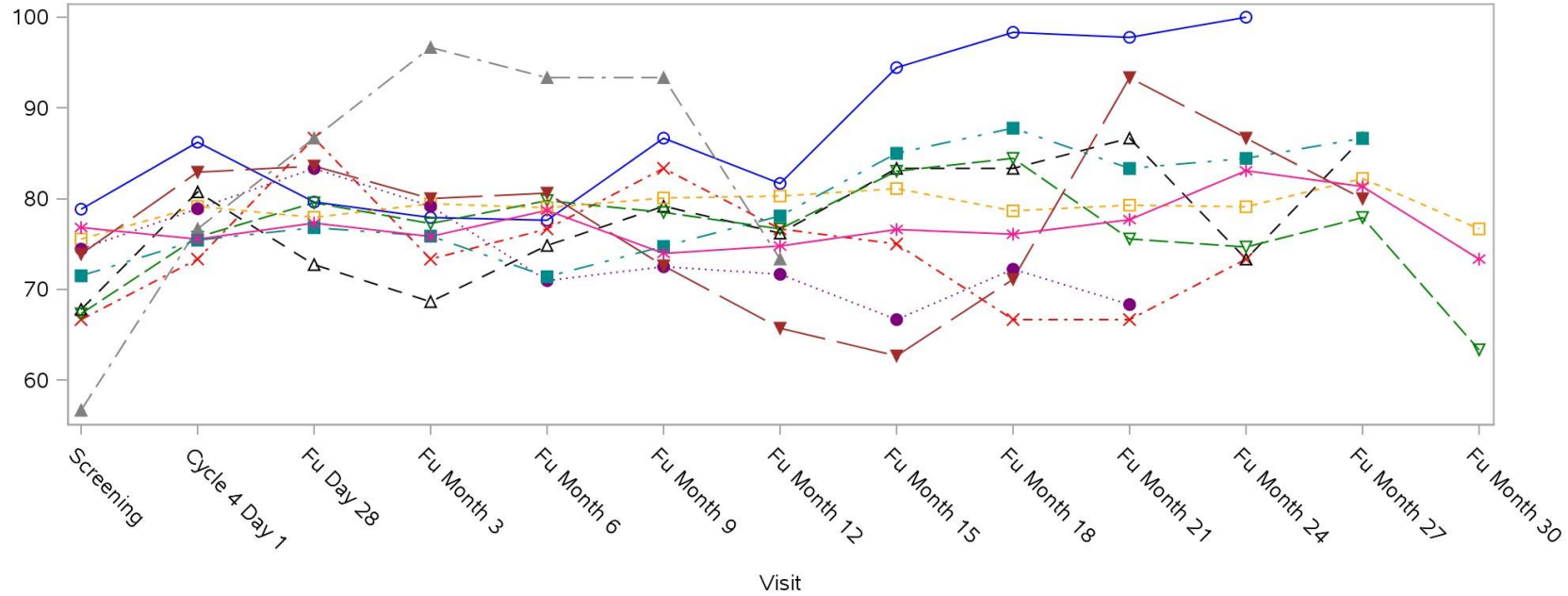
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 04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Geographic Region (N=497) Laboratory Test: Physical Functioning Scale



Clinical cut-off: 09MAY2013

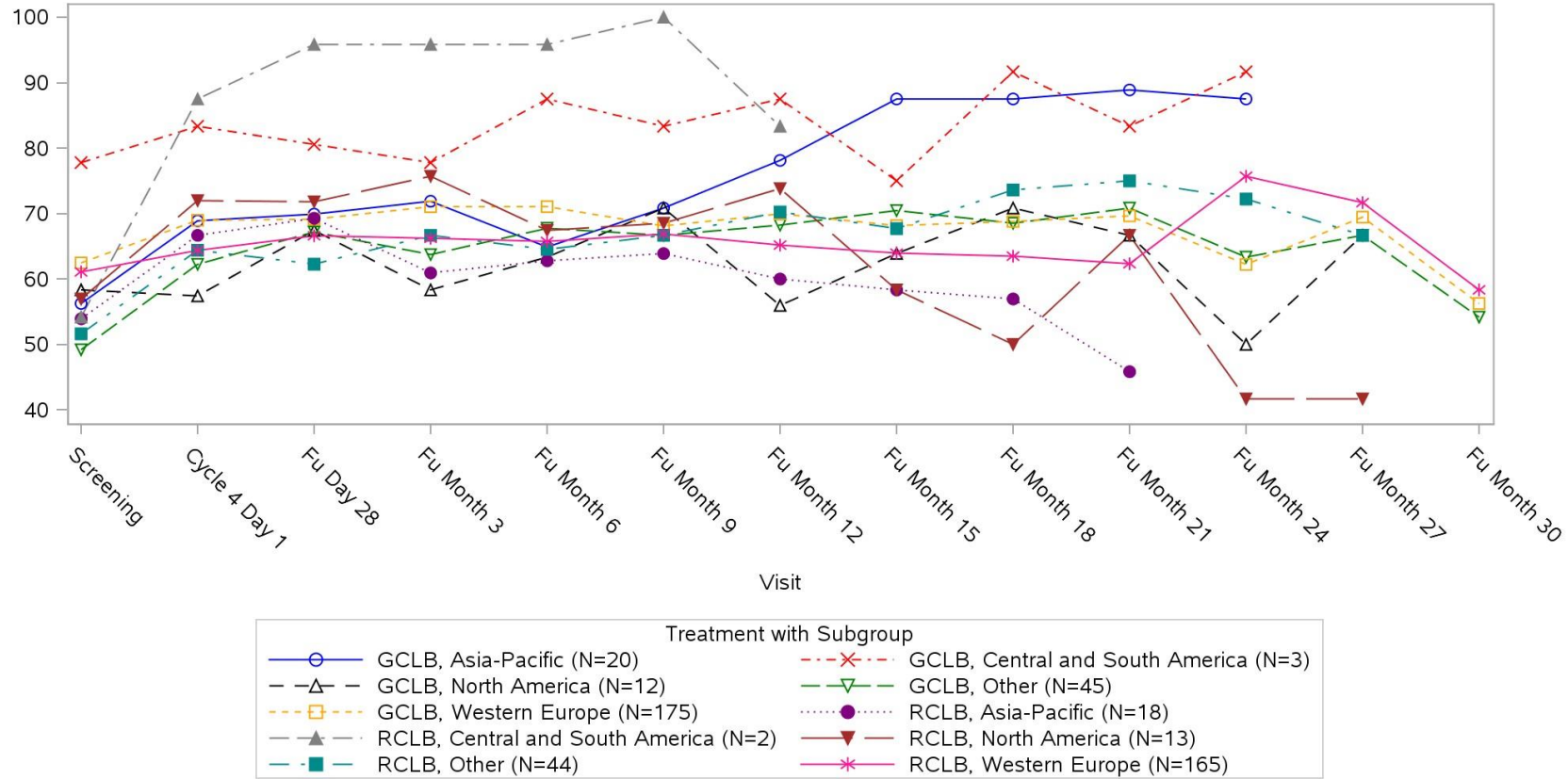
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 04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Geographic Region (N=497) Laboratory Test: Global Health Status Scale



Clinical cut-off: 09MAY2013

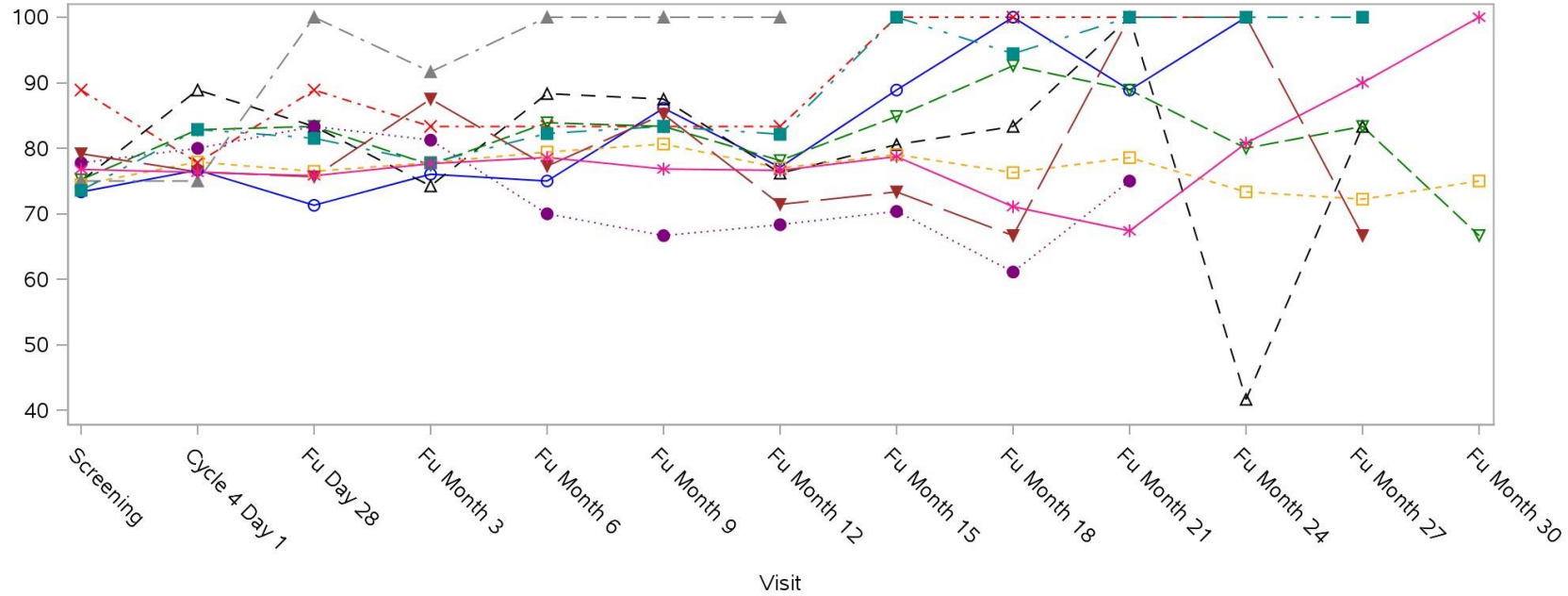
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Geographic Region (N=497) Laboratory Test: Role Functioning Scale



Clinical cut-off: 09MAY2013

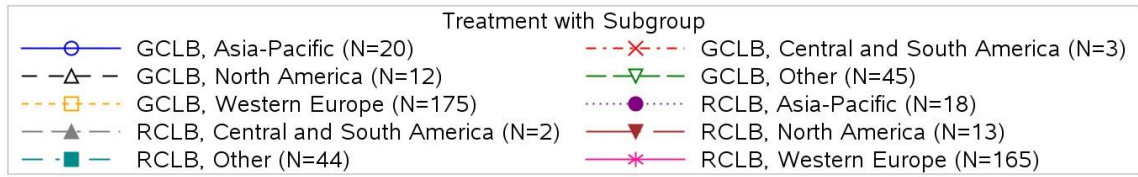
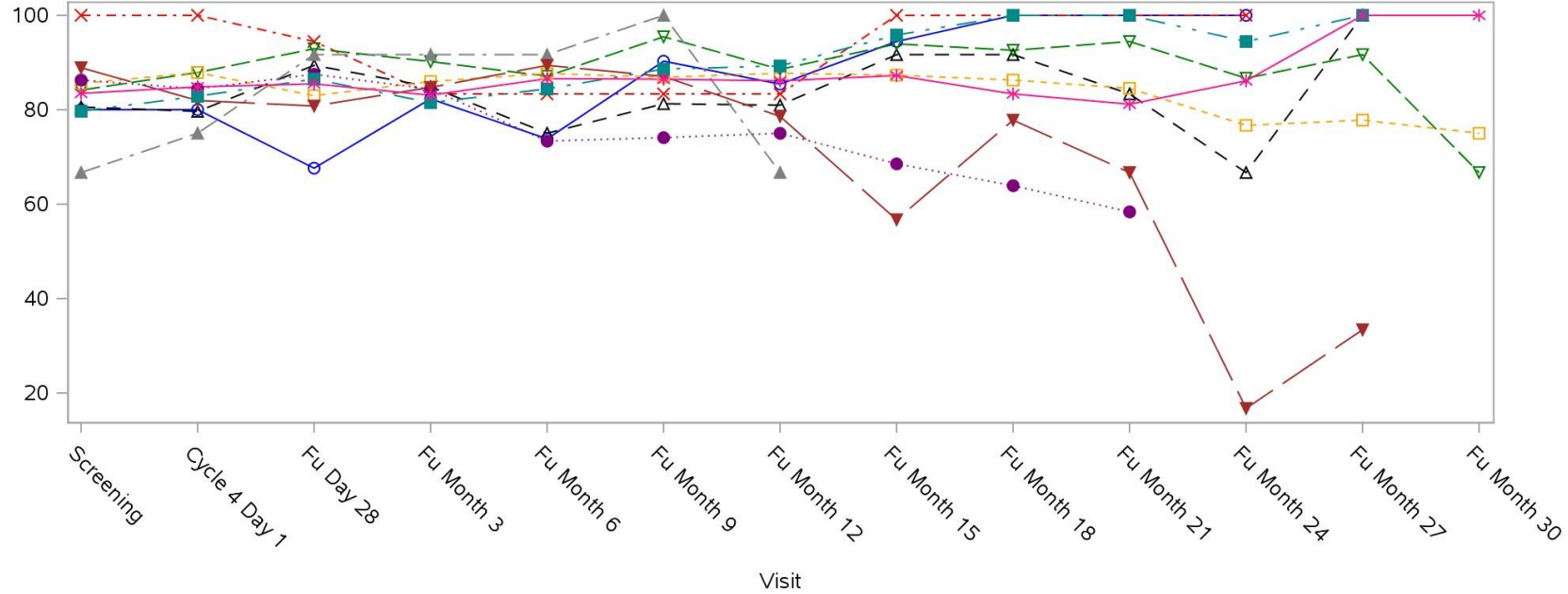
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Geographic Region (N=497) Laboratory Test: Social Functioning Scale



Clinical cut-off: 09MAY2013

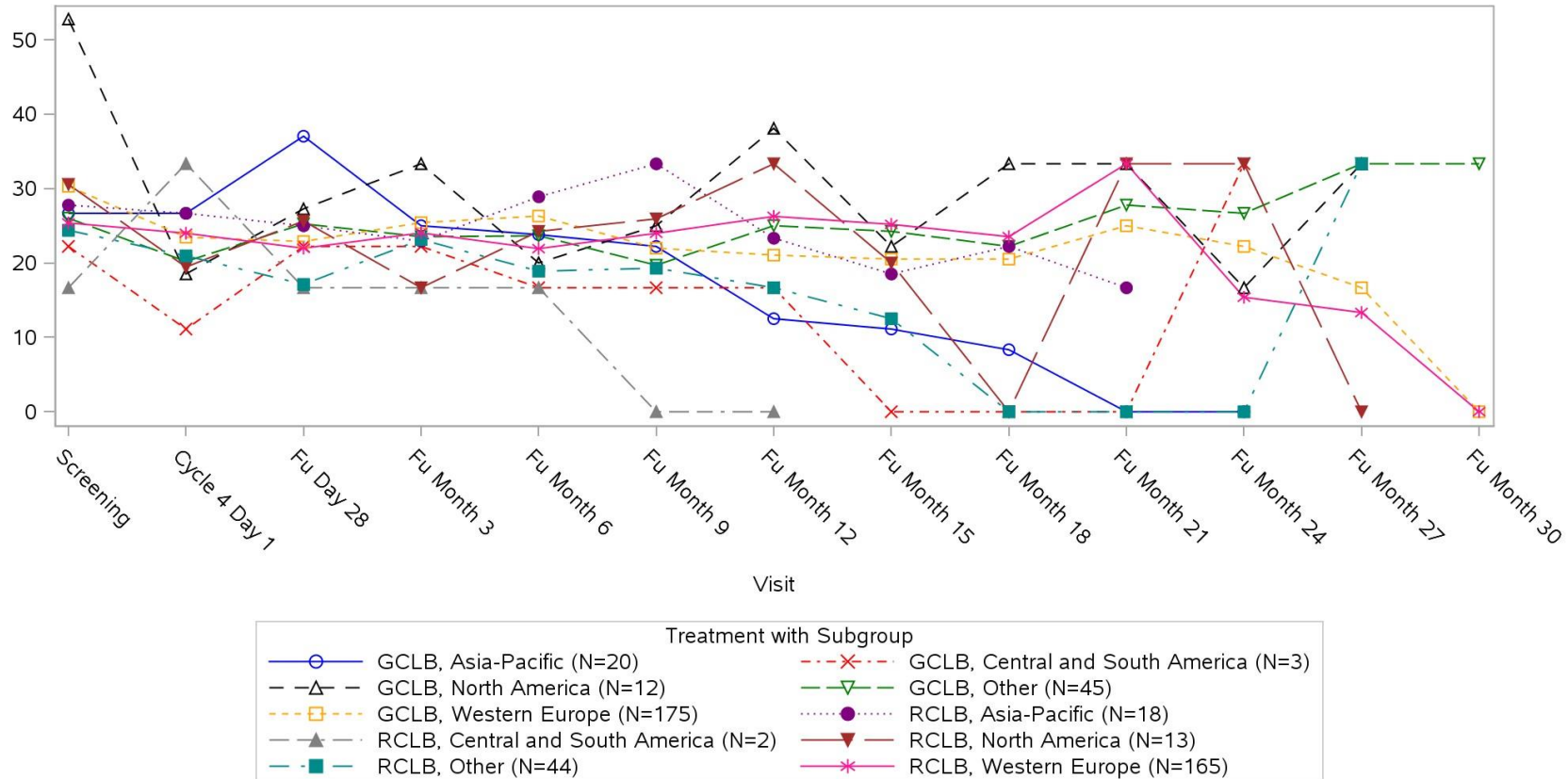
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 04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Geographic Region (N=497) Laboratory Test: Insomnia Scale



Clinical cut-off: 09MAY2013

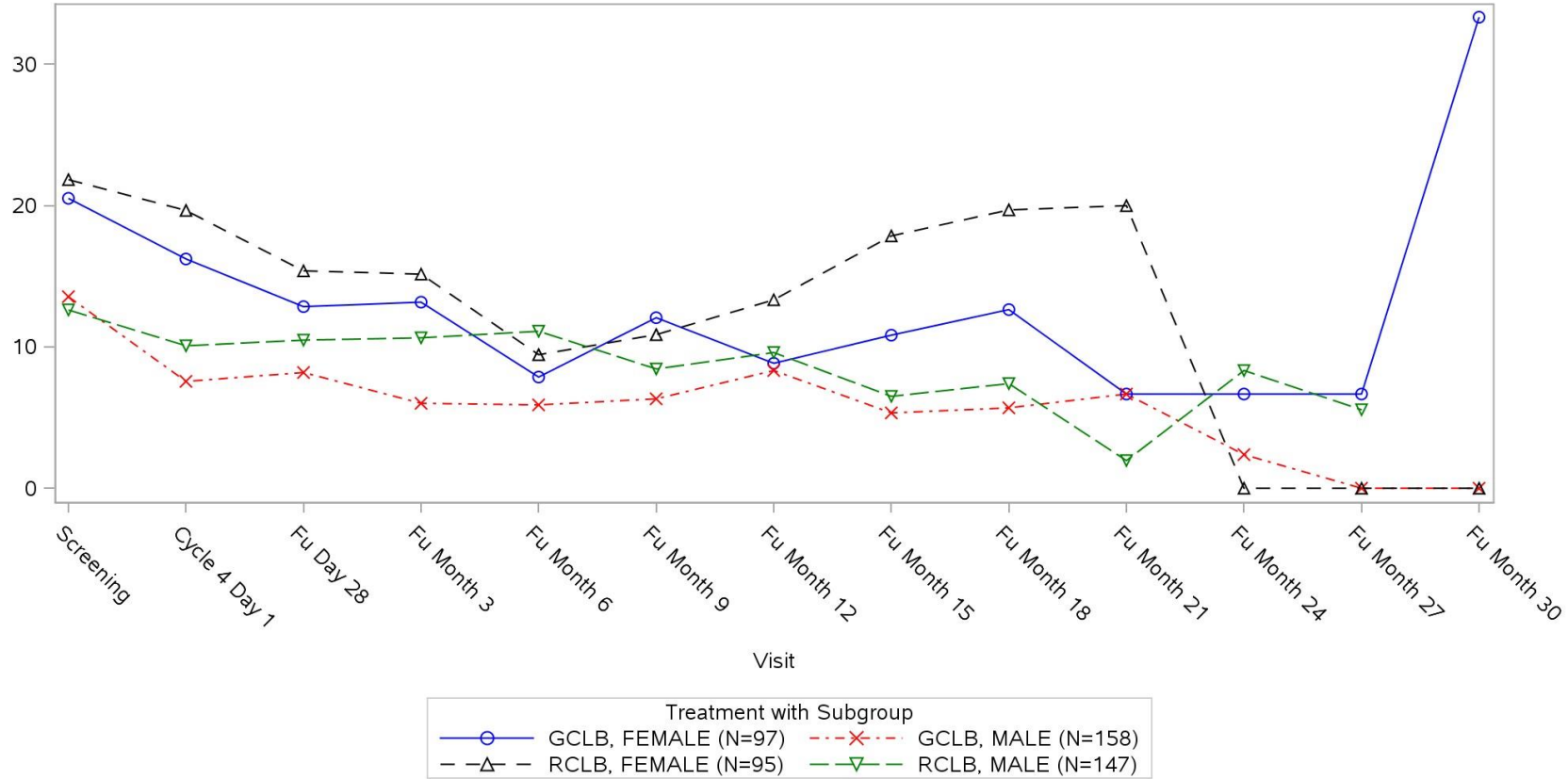
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 04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Sex (N=497) Laboratory Test: Appetite Loss Scale



Clinical cut-off: 09MAY2013

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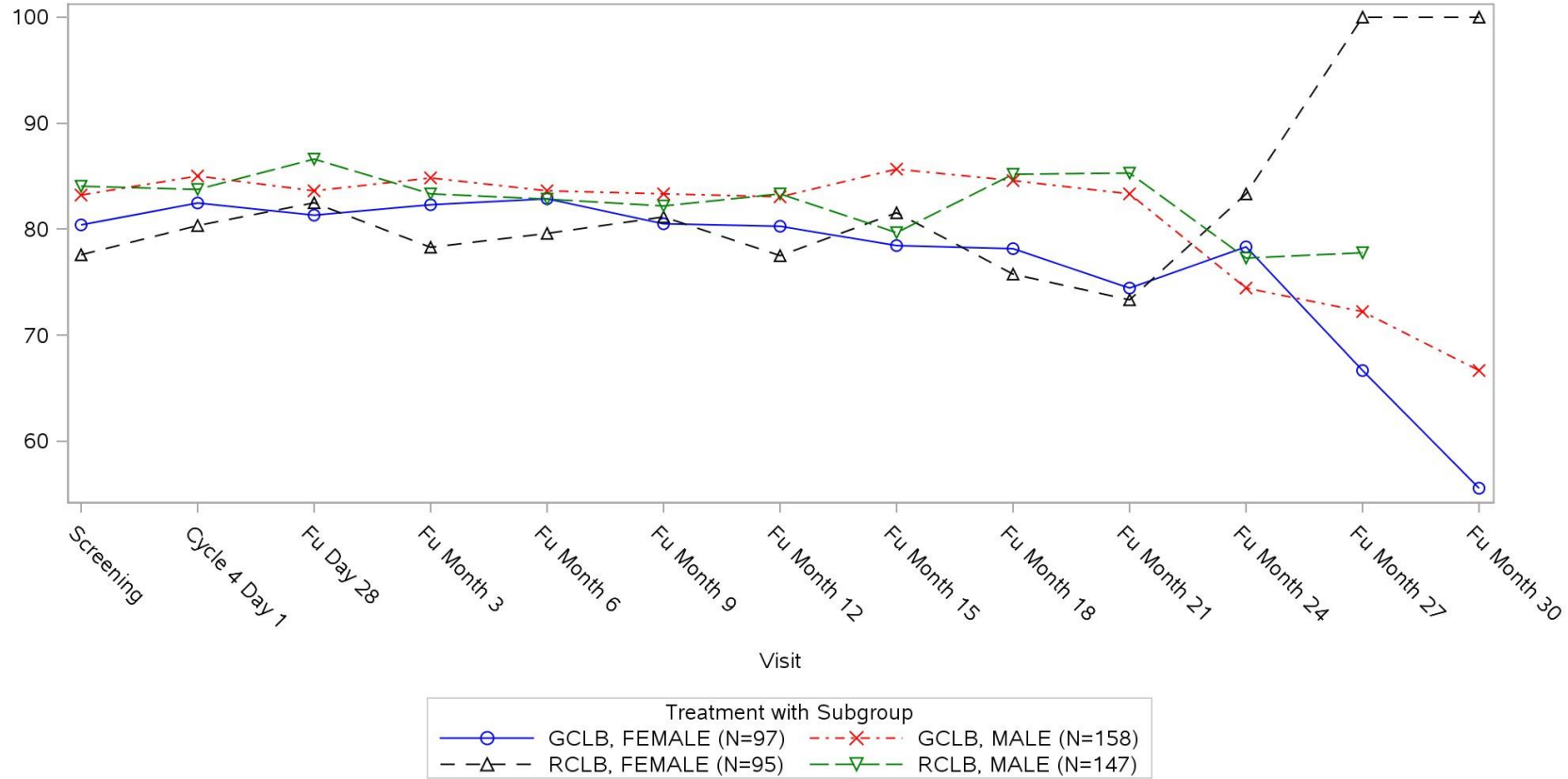
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Sex (N=497) Laboratory Test: Cognitive Functioning Scale



Clinical cut-off: 09MAY2013

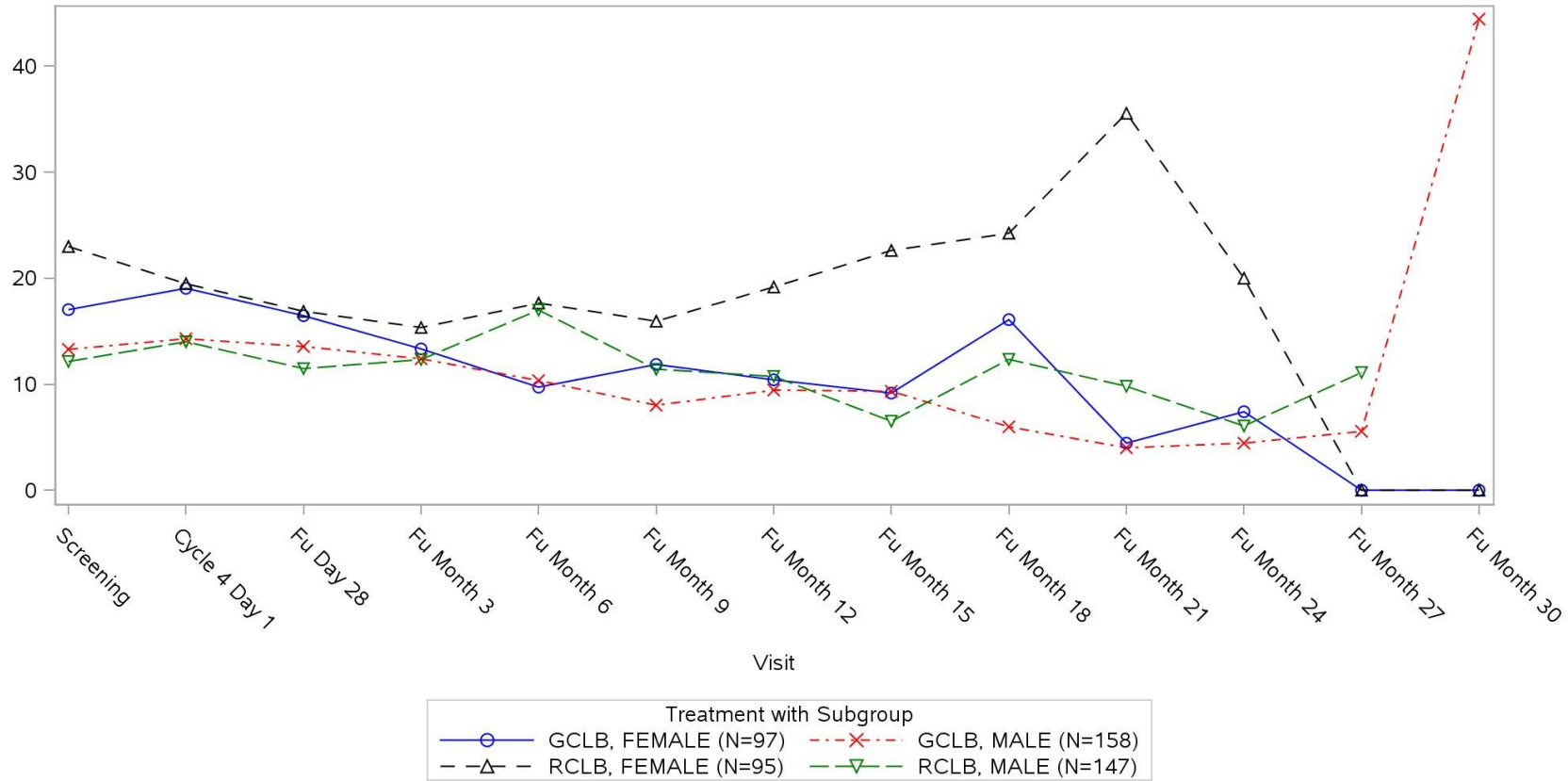
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 04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Sex (N=497) Laboratory Test: Constipation Scale



Clinical cut-off: 09MAY2013

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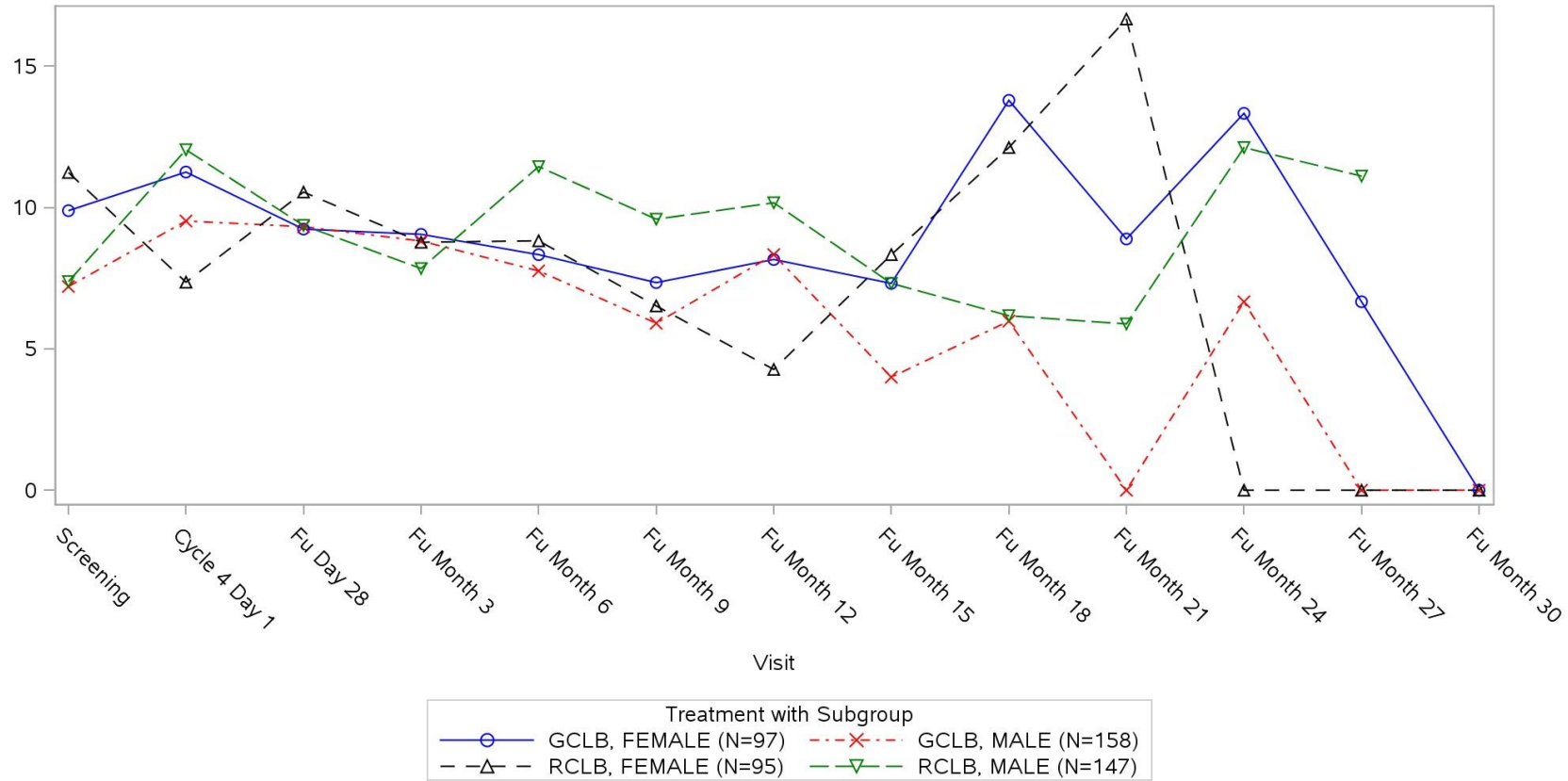
Page 183 of 195

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Sex (N=497) Laboratory Test: Diarrhoea Scale



Clinical cut-off: 09MAY2013

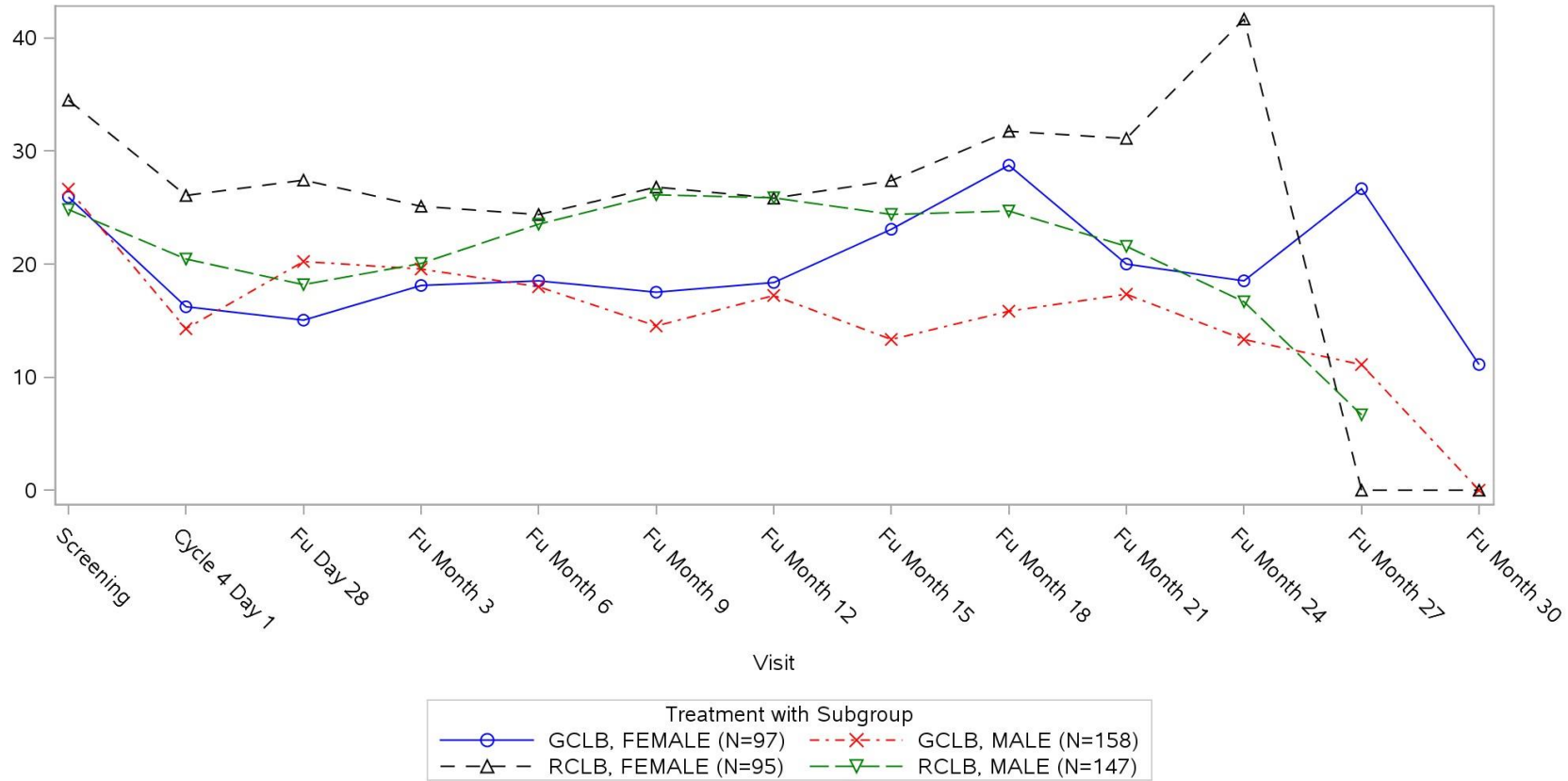
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04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Sex (N=497) Laboratory Test: Dyspnoea Scale



Clinical cut-off: 09MAY2013

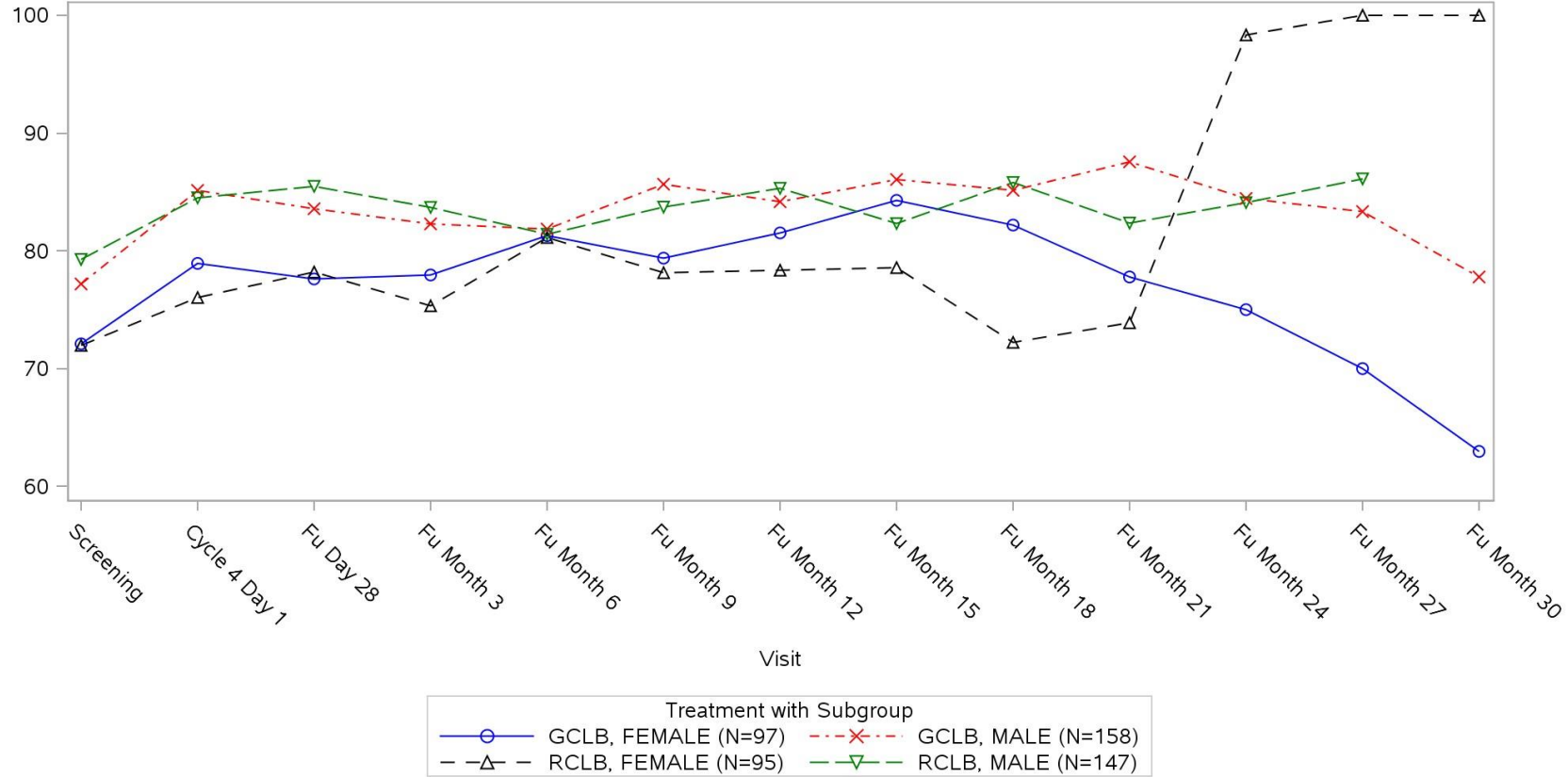
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04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Sex (N=497) Laboratory Test: Emotional Functioning Scale



Clinical cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/g_pro_mean.sas
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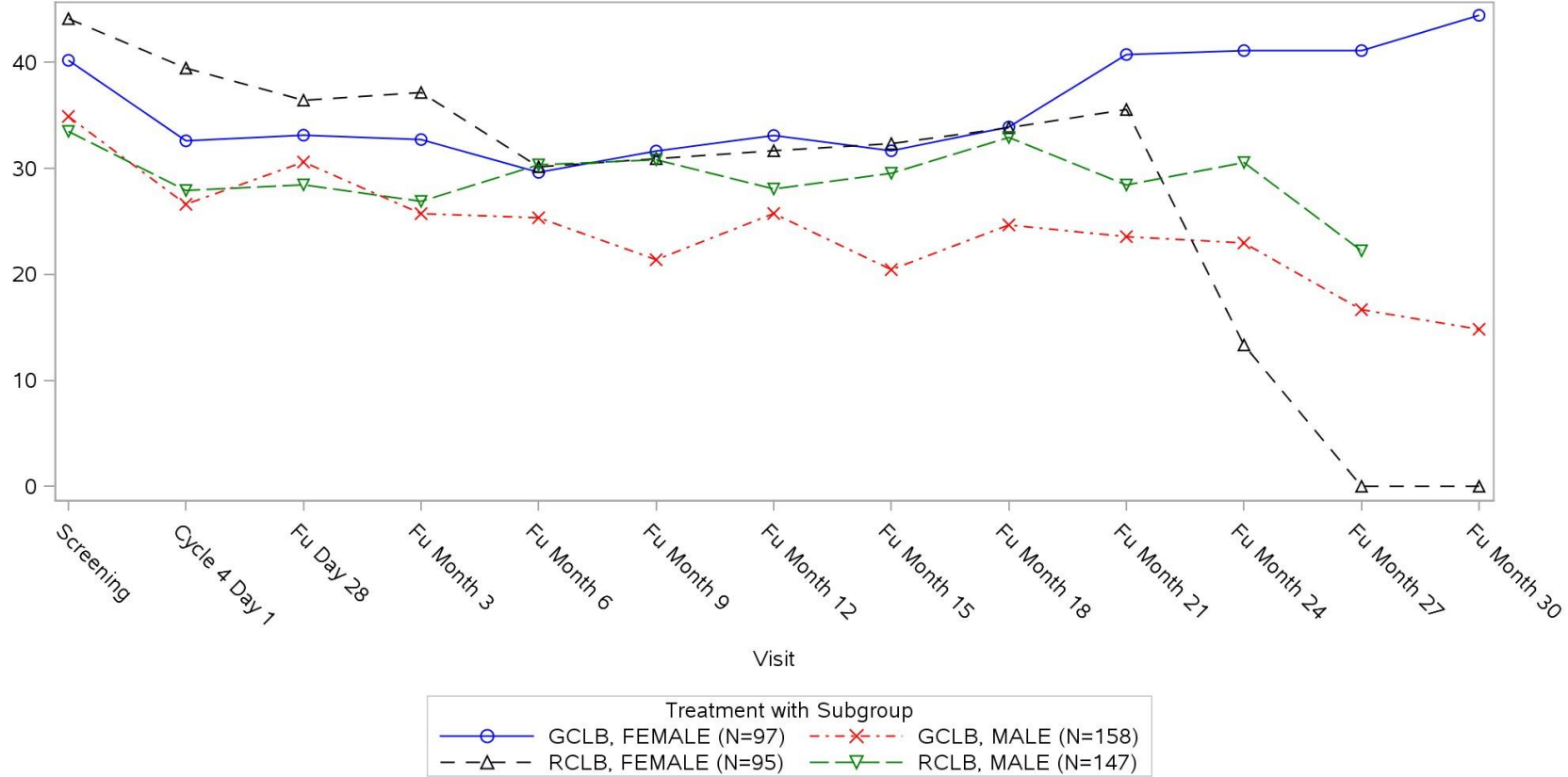
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Sex (N=497) Laboratory Test: Fatigue Scale



Clinical cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/g_pro_mean.sas
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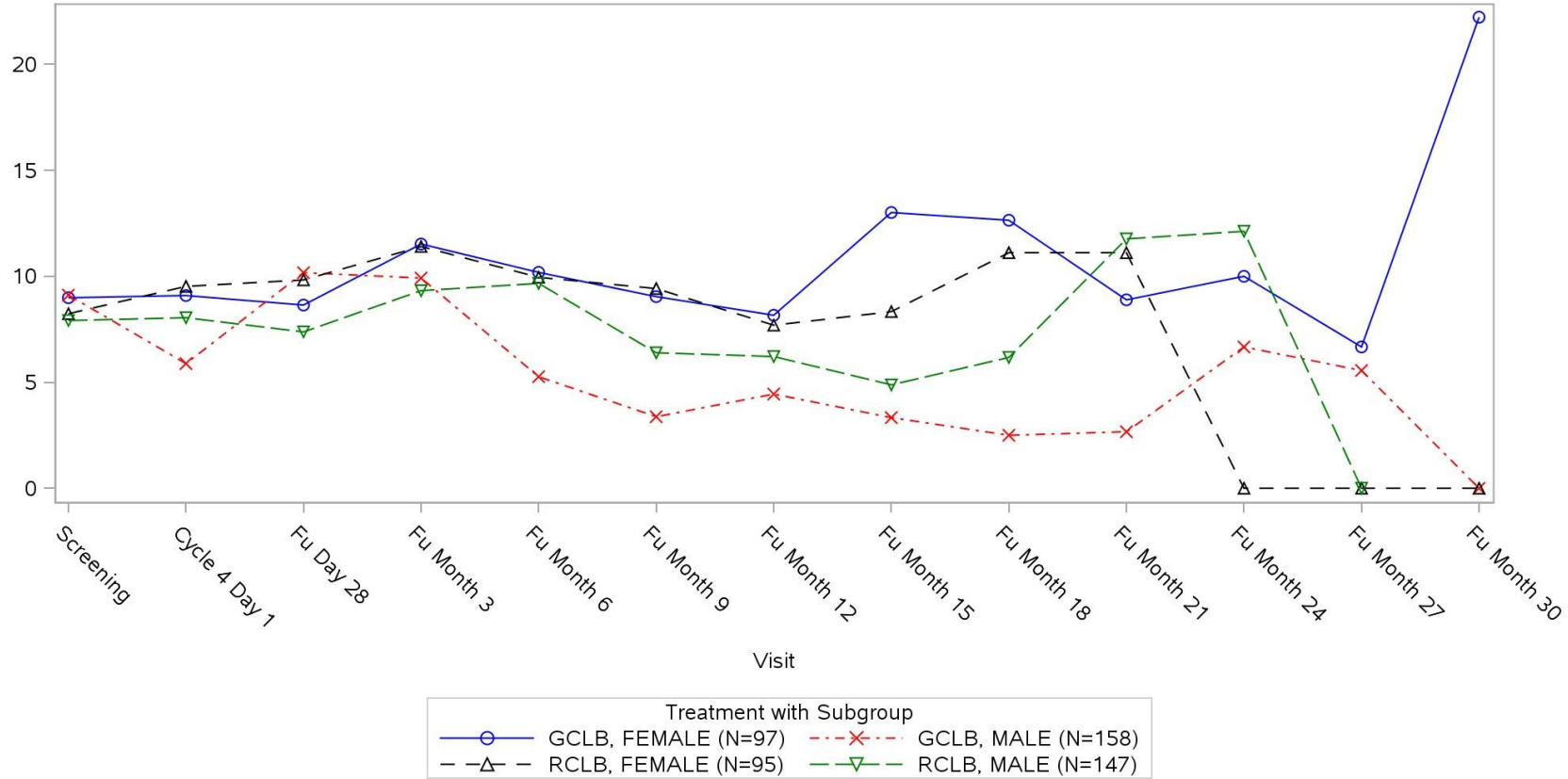
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Sex (N=497) Laboratory Test: Financial Difficulties Scale



Clinical cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/g_pro_mean.sas
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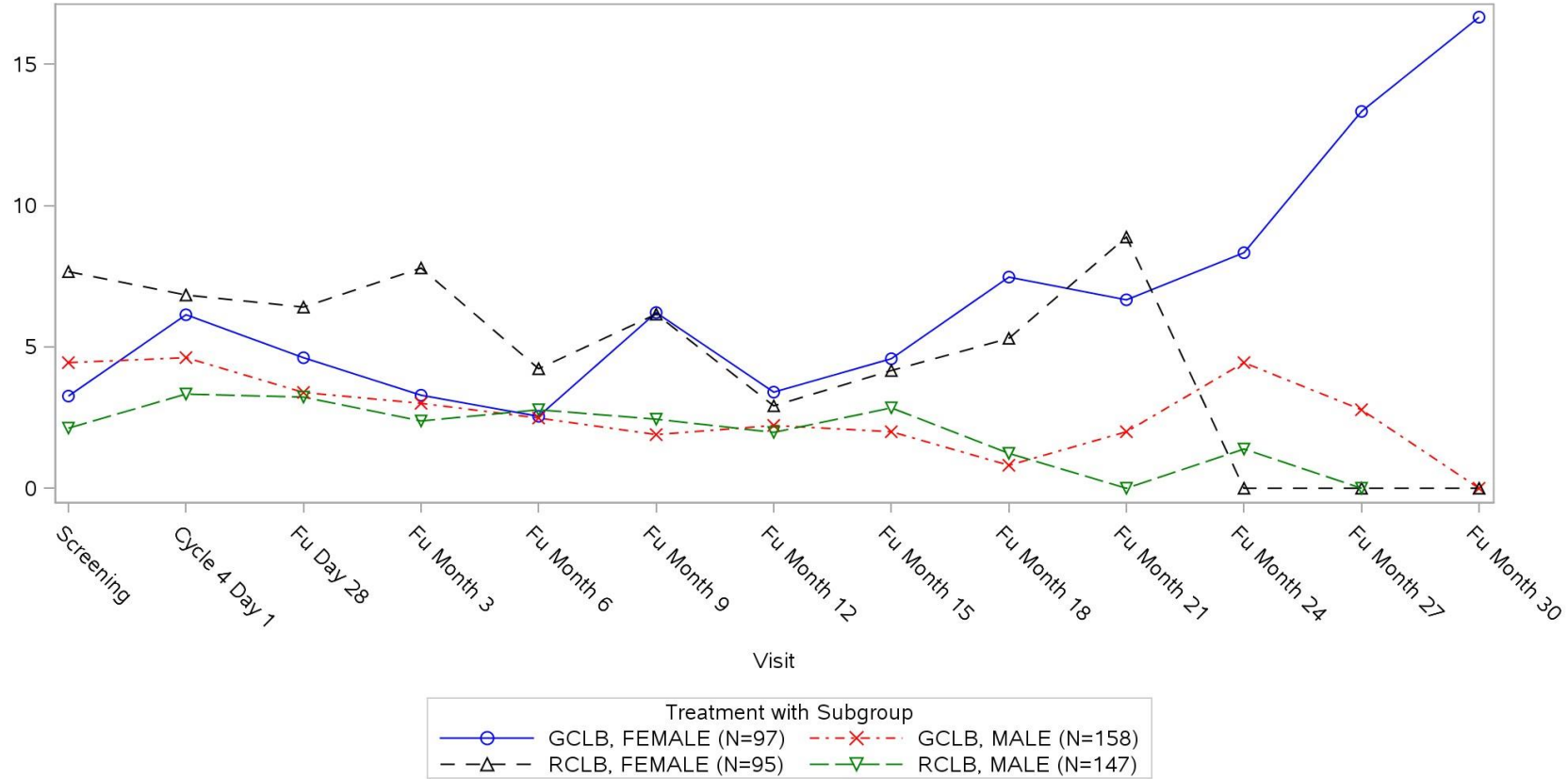
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Sex (N=497) Laboratory Test: Nausea And Vomiting Scale



Clinical cut-off: 09MAY2013

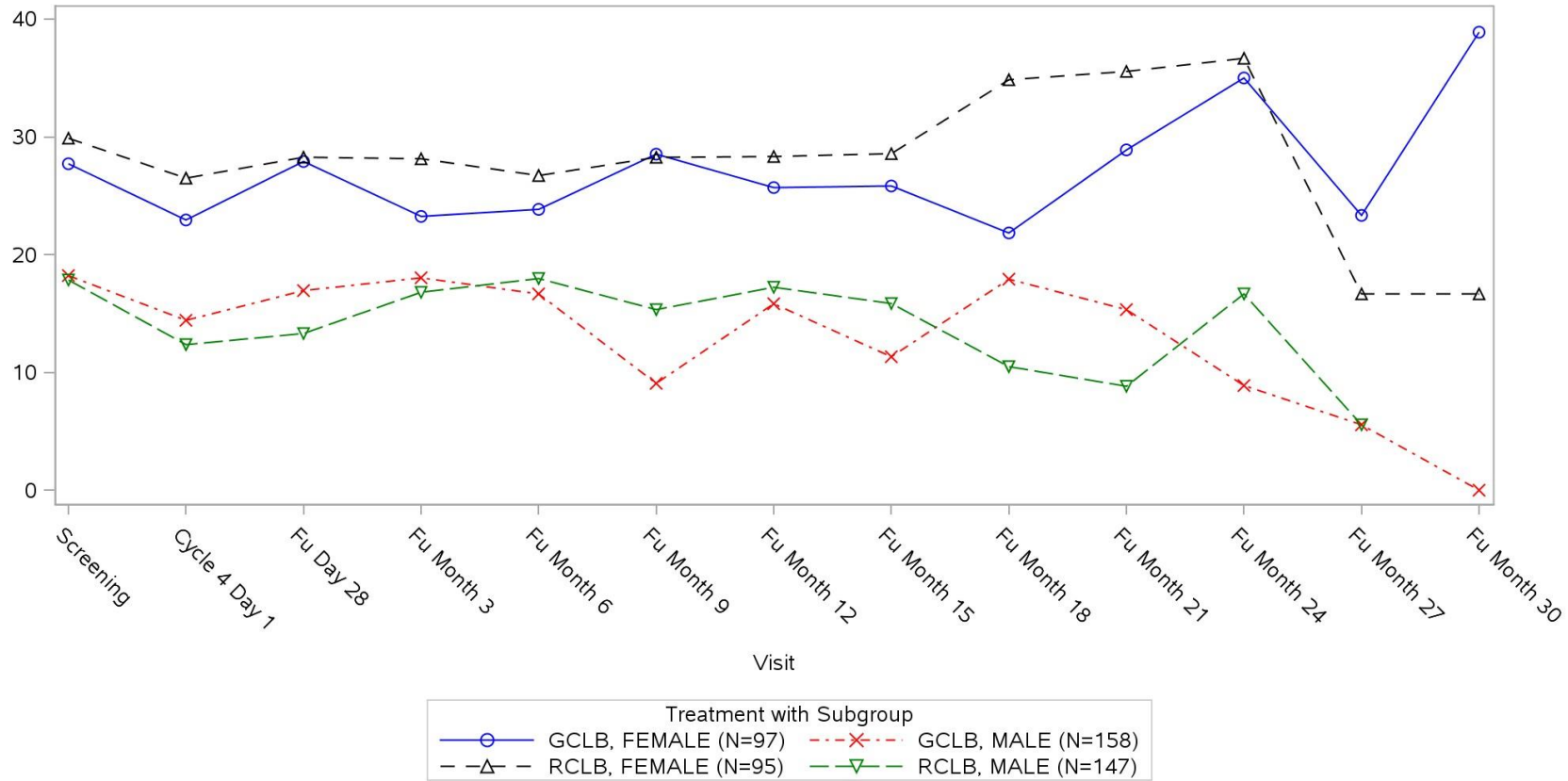
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 04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Sex (N=497) Laboratory Test: Pain Scale



Clinical cut-off: 09MAY2013

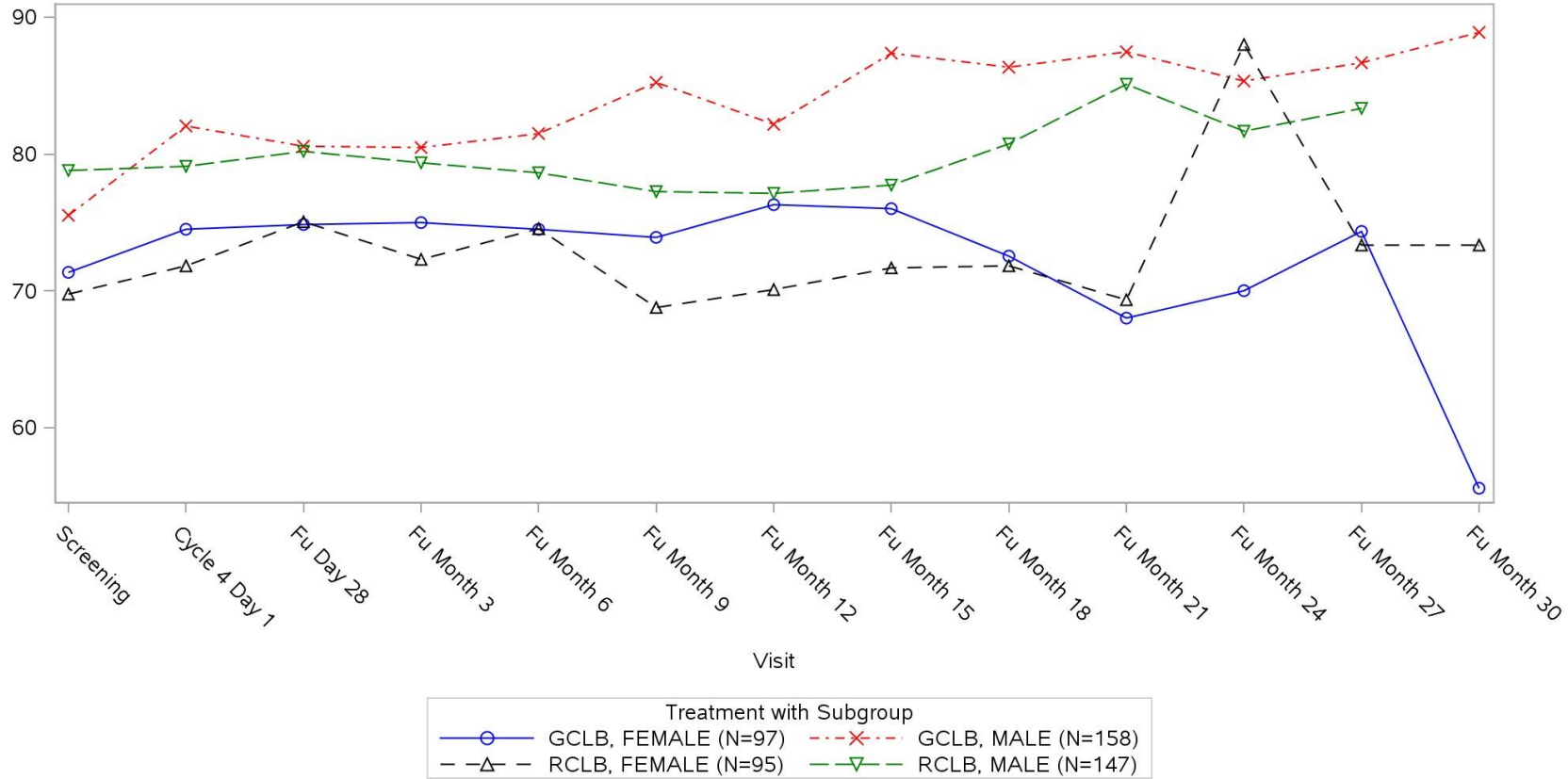
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04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Sex (N=497) Laboratory Test: Physical Functioning Scale



Clinical cut-off: 09MAY2013

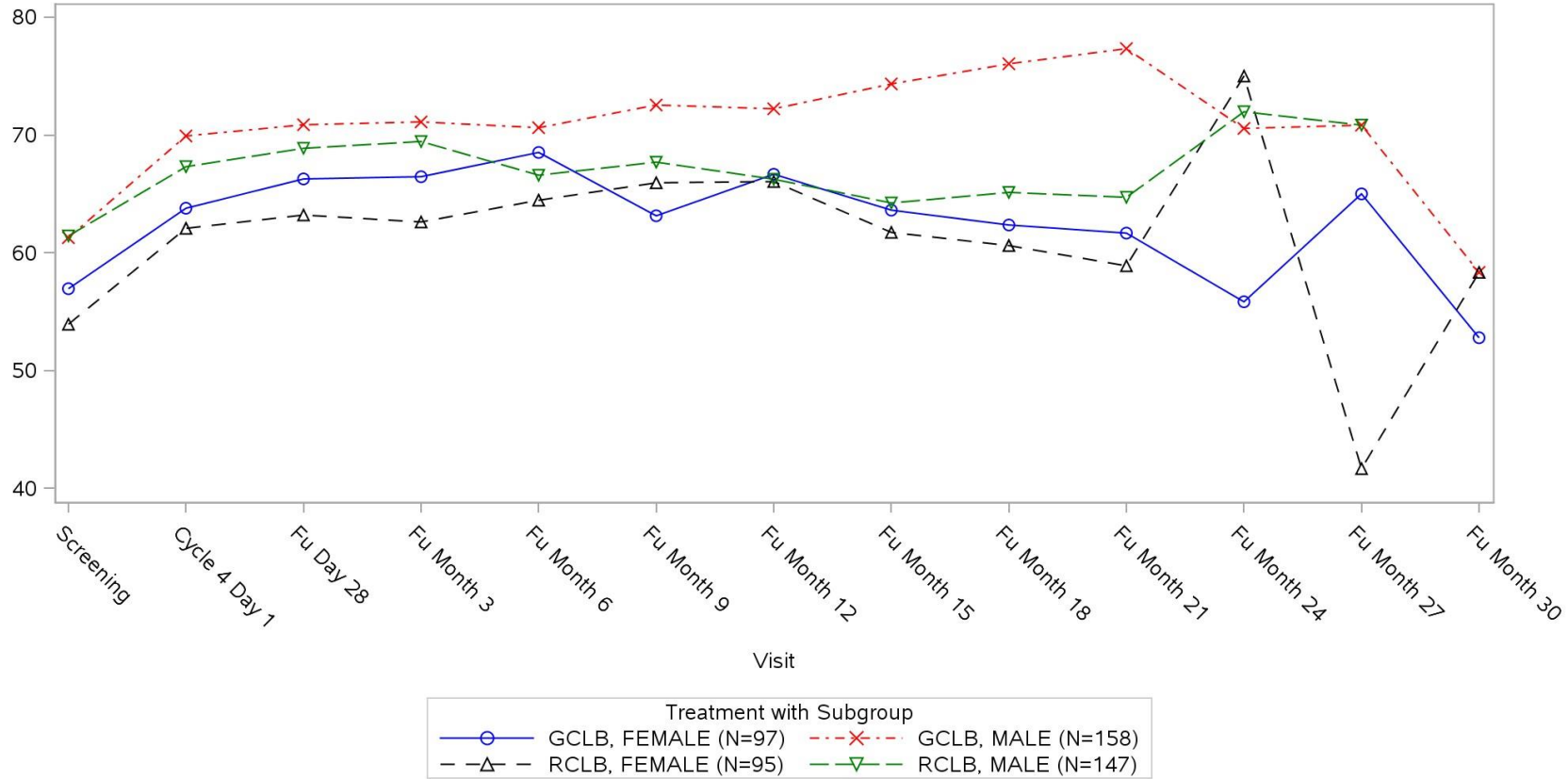
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 04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Sex (N=497) Laboratory Test: Global Health Status Scale



Clinical cut-off: 09MAY2013

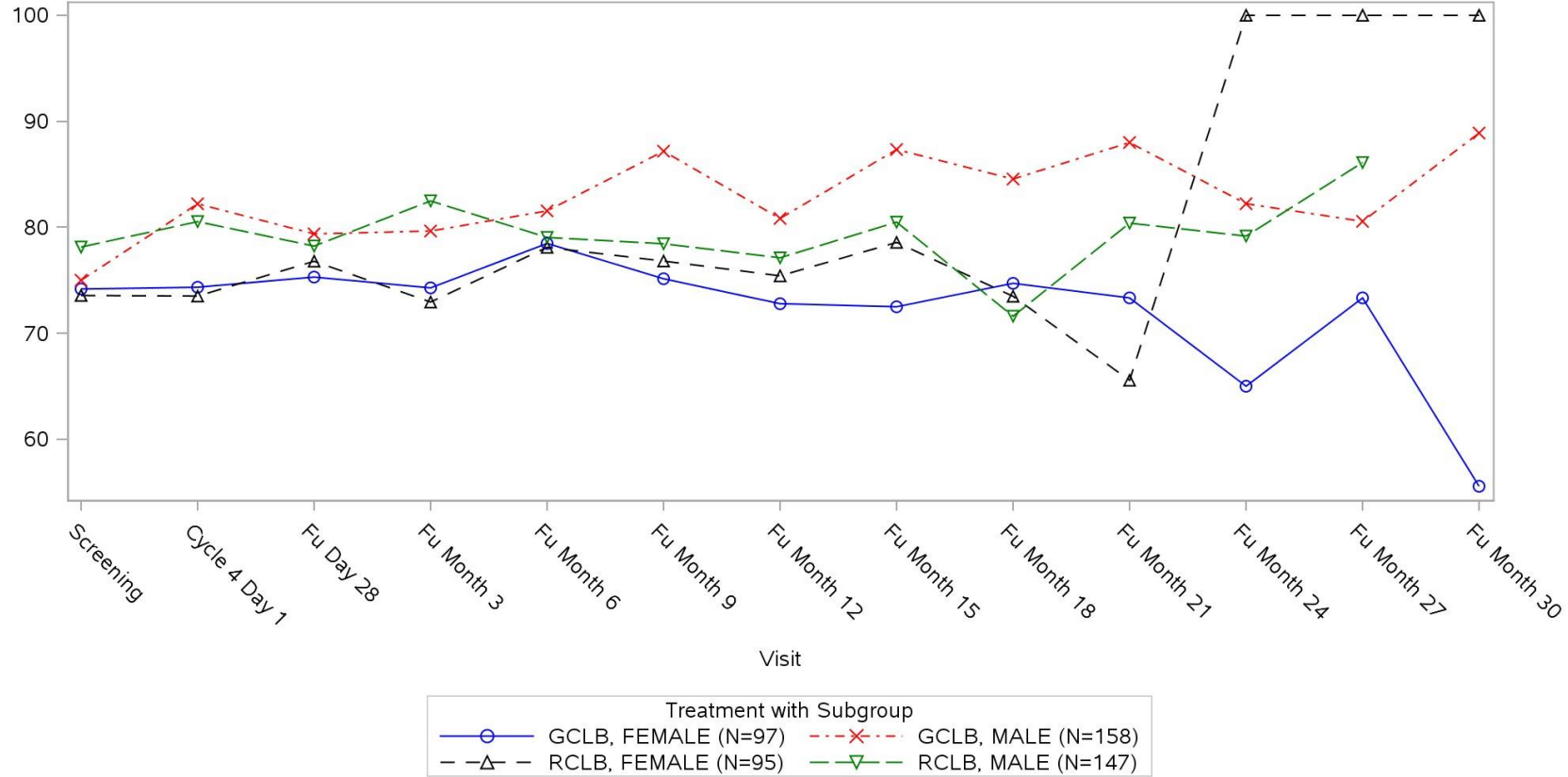
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04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Sex (N=497) Laboratory Test: Role Functioning Scale



Clinical cut-off: 09MAY2013

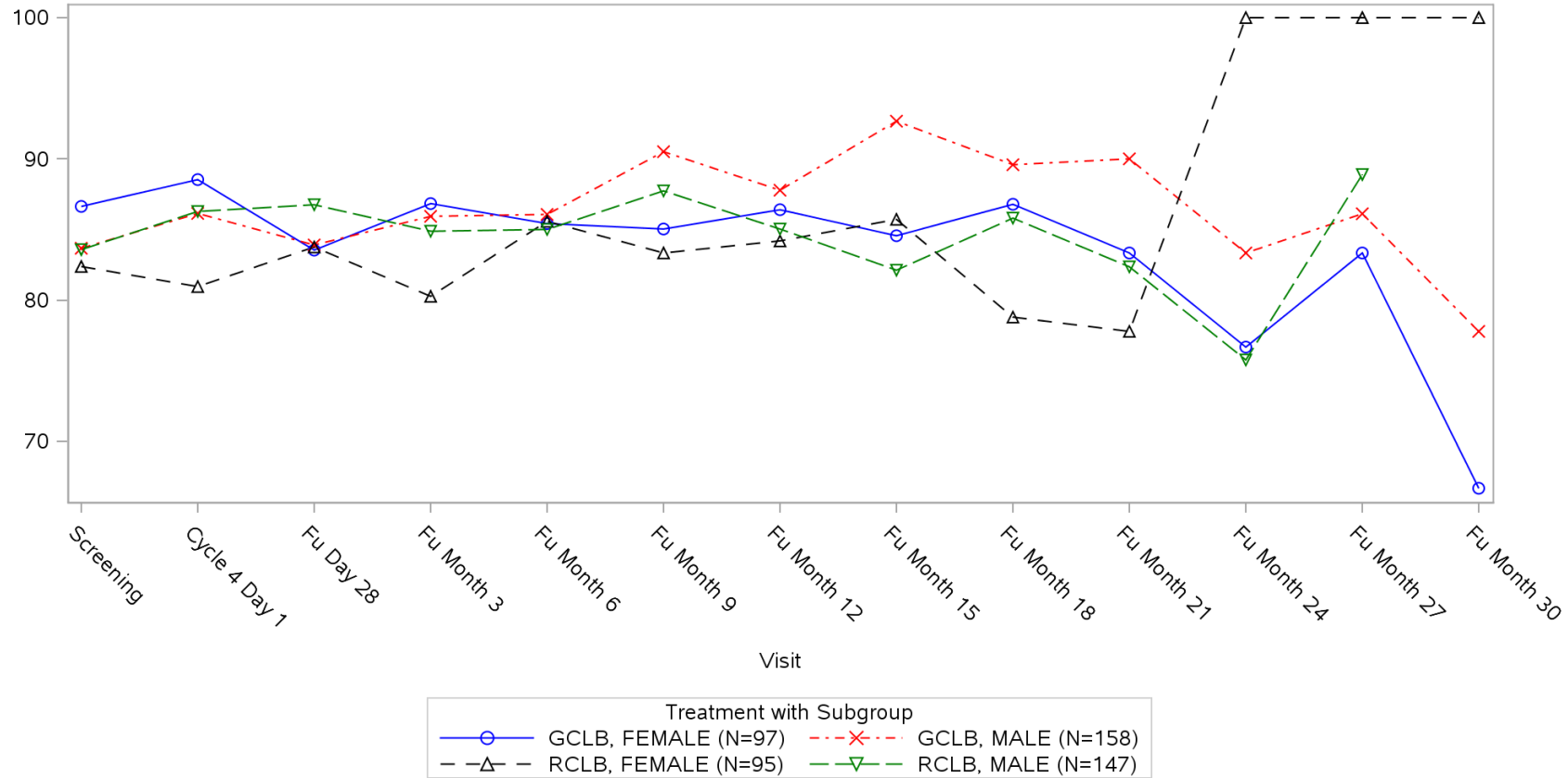
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 04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Sex (N=497) Laboratory Test: Social Functioning Scale



Clinical cut-off: 09MAY2013

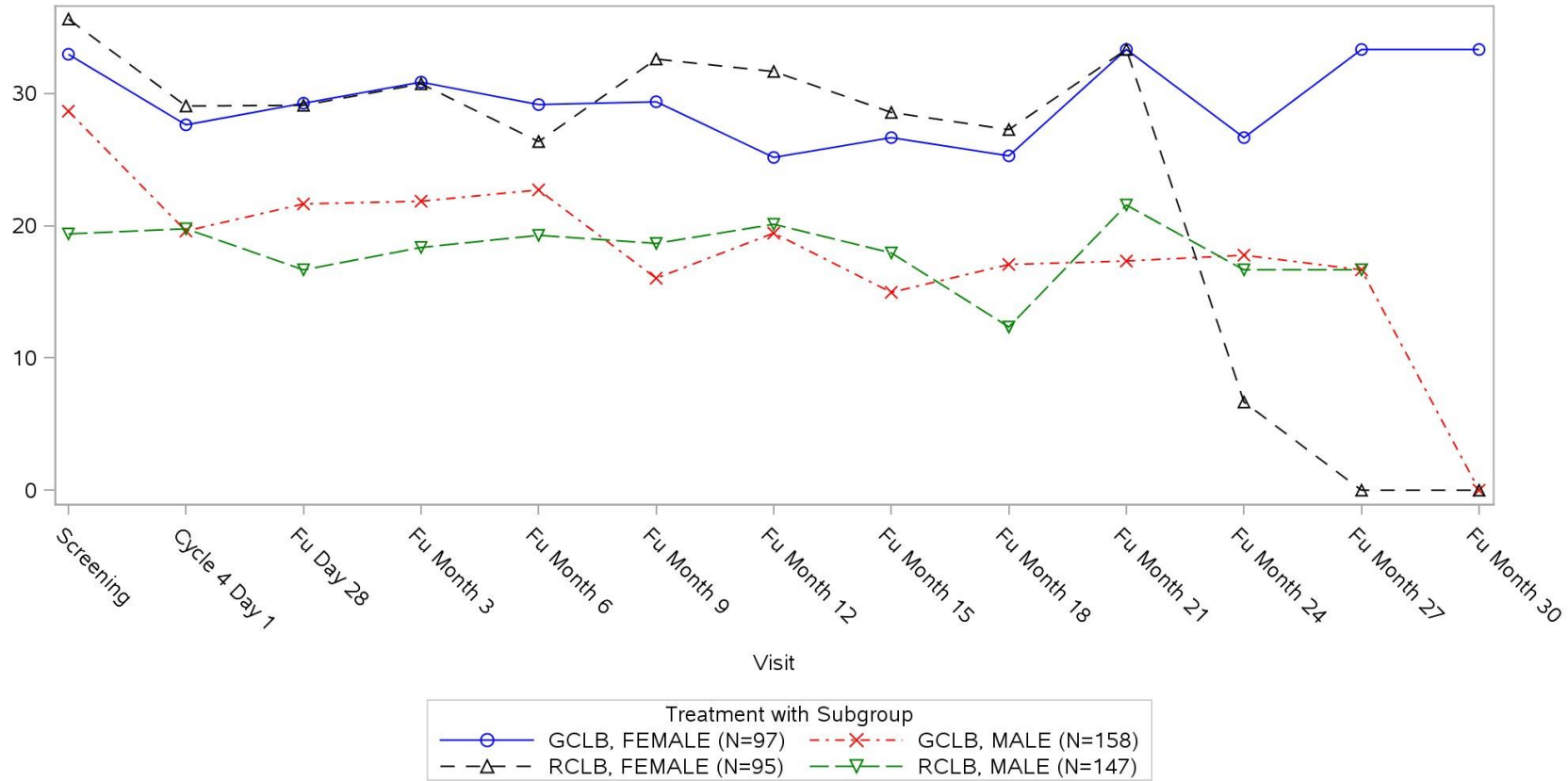
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04MAR2020 18:19

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 30

STUDY: CLL11(BO21004), Stage 2

Sex (N=497) Laboratory Test: Insomnia Scale



Clinical cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/g_pro_mean.sas
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16 (Anhang): Ergebnisse für EORTC QLQ-CLL16 – Mittelwerte pro Visite - Subgruppenanalysen aus RCT mit dem zu bewertenden Arzneimittel

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

MODEL: Unadjusted Analysis

STUDY: CLL11 (BO21004), Stage 2

Compliance/Mean

		GClb (N=255)						RC1b (N=242)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study ¹	%	with value ¹	%	Mean ²	SD(mean)	in study ¹	%	with value ¹	%	Mean ²	SD(mean)
All													
Screening	n/a	255	100,0	216	84,7	20,58	17,29	242	100,0	202	83,5	22,58	17,67
Cycle 4 Day 1	n/a	213	83,5	174	81,7	14,26	15,96	224	92,6	175	78,1	16,79	15,98
FU Day 28	n/a	230	90,2	184	80,0	14,22	15,64	225	93,0	183	81,3	16,09	16,82
FU Month 3	n/a	225	88,2	183	81,3	12,20	14,65	221	91,3	174	78,7	14,64	15,22
FU Month 6	n/a	207	81,2	171	82,6	11,34	13,81	192	79,3	147	76,6	14,63	16,68
FU Month 9	n/a	164	64,3	126	76,8	11,79	13,68	149	61,6	111	74,5	15,62	15,15
FU Month 12	n/a	125	49,0	100	80,0	12,25	14,46	117	48,3	92	78,6	17,33	16,72
FU Month 15	n/a	104	40,8	84	80,8	12,30	14,14	85	35,1	63	74,1	16,45	16,23
FU Month 18	n/a	79	31,0	61	77,2	13,21	15,21	60	24,8	45	75,0	16,42	18,14
FU Month 21	n/a	52	20,4	36	69,2	15,74	17,11	40	16,5	28	70,0	17,86	20,88
FU Month 24	n/a	32	12,5	21	65,6	13,76	17,00	18	7,4	14	77,8	8,33	10,34
FU Month 27	n/a	13	5,1	8	61,5	18,75	14,60	9	3,7	6	66,7	4,17	6,97
FU Month 30	n/a	7	2,7	4	57,1	18,75	14,23	1	0,4	1	100,0	0,00	NE
Gender													
Screening	Female	97	100,0	82	84,5	21,00	17,28	95	100,0	74	77,9	26,35	19,99
Cycle 4 Day 1	Female	84	86,6	67	79,8	18,24	19,91	88	92,6	67	76,1	21,27	18,47
FU Day 28	Female	90	92,8	75	83,3	16,67	17,49	91	95,8	70	76,9	20,71	19,18
FU Month 3	Female	88	90,7	73	83,0	14,84	16,51	87	91,6	63	72,4	18,65	16,71
FU Month 6	Female	84	86,6	64	76,2	13,76	15,56	77	81,1	56	72,7	17,71	21,38
FU Month 9	Female	70	72,2	52	74,3	14,64	16,90	61	64,2	39	63,9	20,16	19,68
FU Month 12	Female	56	57,7	45	80,4	14,38	17,79	47	49,5	34	72,3	18,06	18,03
FU Month 15	Female	47	48,5	37	78,7	16,67	15,21	33	34,7	24	72,7	20,02	18,68
FU Month 18	Female	34	35,1	25	73,5	19,22	18,56	26	27,4	19	73,1	22,37	21,35

FU Month 21	Female	21	21,6	11	52,4	25,00	22,05	17	17,9	12	70,6	22,92	19,82
FU Month 24	Female	12	12,4	6	50,0	27,31	24,43	6	6,3	3	50,0	13,89	17,35
FU Month 27	Female	6	6,2	2	33,3	33,33	11,79	2	2,1	1	50,0	0,00	NE
FU Month 30	Female	4	4,1	1	25,0	33,33	NE	1	1,1	1	100,0	0,00	NE
Screening	Male	158	100,0	134	84,8	20,32	17,35	147	100,0	128	87,1	20,40	15,85
Cycle 4 Day 1	Male	129	81,6	107	82,9	11,76	12,35	136	92,5	108	79,4	14,02	13,59
FU Day 28	Male	140	88,6	109	77,9	12,54	14,06	134	91,2	113	84,3	13,23	14,54
FU Month 3	Male	137	86,7	110	80,3	10,45	13,06	134	91,2	111	82,8	12,36	13,87
FU Month 6	Male	123	77,8	107	87,0	9,89	12,49	115	78,2	91	79,1	12,73	12,75
FU Month 9	Male	94	59,5	74	78,7	9,80	10,54	88	59,9	72	81,8	13,16	11,44
FU Month 12	Male	69	43,7	55	79,7	10,51	10,90	70	47,6	58	82,9	16,91	16,05
FU Month 15	Male	57	36,1	47	82,5	8,87	12,34	52	35,4	39	75,0	14,25	14,34
FU Month 18	Male	45	28,5	36	80,0	9,03	10,80	34	23,1	26	76,5	12,07	14,29
FU Month 21	Male	31	19,6	25	80,6	11,67	12,95	23	15,6	16	69,6	14,06	21,46
FU Month 24	Male	20	12,7	15	75,0	8,33	9,45	12	8,2	11	91,7	6,82	8,18
FU Month 27	Male	7	4,4	6	85,7	13,89	12,55	7	4,8	5	71,4	5,00	7,45
FU Month 30	Male	3	1,9	3	100,0	13,89	12,73	0	NE	0	NE	NE	NE
Age													
Screening	<75 years	130	100,0	102	78,5	18,25	15,79	120	100,0	91	75,8	22,07	17,29
Cycle 4 Day 1	<75 years	106	81,5	81	76,4	11,87	14,30	112	93,3	82	73,2	17,89	16,19
FU Day 28	<75 years	119	91,5	91	76,5	12,91	14,76	110	91,7	86	78,2	15,92	16,29
FU Month 3	<75 years	116	89,2	91	78,4	10,62	12,18	109	90,8	82	75,2	15,11	14,69
FU Month 6	<75 years	108	83,1	86	79,6	10,05	13,44	99	82,5	71	71,7	13,97	17,58
FU Month 9	<75 years	85	65,4	66	77,6	10,56	12,66	74	61,7	54	73,0	15,23	16,05
FU Month 12	<75 years	63	48,5	53	84,1	10,95	13,12	60	50,0	47	78,3	15,60	16,99
FU Month 15	<75 years	54	41,5	42	77,8	11,31	14,70	44	36,7	32	72,7	13,98	16,36
FU Month 18	<75 years	43	33,1	34	79,1	10,05	17,01	27	22,5	20	74,1	12,36	16,68
FU Month 21	<75 years	26	20,0	20	76,9	15,42	16,51	17	14,2	11	64,7	7,58	6,93
FU Month 24	<75 years	18	13,8	12	66,7	12,50	17,23	6	5,0	4	66,7	2,08	4,17
FU Month 27	<75 years	7	5,4	4	57,1	18,75	14,23	2	1,7	1	50,0	0,00	NE
FU Month 30	<75 years	4	3,1	2	50,0	20,83	5,89	0	NE	0	NE	NE	NE
Screening	>=75 years	125	100,0	114	91,2	22,66	18,35	122	100,0	111	91,0	23,00	18,04
Cycle 4 Day 1	>=75 years	107	85,6	93	86,9	16,34	17,08	112	91,8	93	83,0	15,83	15,82
FU Day 28	>=75 years	111	88,8	93	83,8	15,50	16,42	115	94,3	97	84,3	16,24	17,36
FU Month 3	>=75 years	109	87,2	92	84,4	13,77	16,66	112	91,8	92	82,1	14,22	15,75
FU Month 6	>=75 years	99	79,2	85	85,9	12,65	14,12	93	76,2	76	81,7	15,24	15,89
FU Month 9	>=75 years	79	63,2	60	75,9	13,15	14,71	75	61,5	57	76,0	15,98	14,38
FU Month 12	>=75 years	62	49,6	47	75,8	13,71	15,86	57	46,7	45	78,9	19,14	16,43
FU Month 15	>=75 years	50	40,0	42	84,0	13,29	13,66	41	33,6	31	75,6	19,00	15,96

FU Month 18	>=75 years	36	28,8	27	75,0	17,18	11,71	33	27,0	25	75,8	19,67	18,92
FU Month 21	>=75 years	26	20,8	16	61,5	16,15	18,38	23	18,9	17	73,9	24,51	24,20
FU Month 24	>=75 years	14	11,2	9	64,3	15,43	17,57	12	9,8	10	83,3	10,83	11,15
FU Month 27	>=75 years	6	4,8	4	66,7	18,75	17,18	7	5,7	5	71,4	5,00	7,45
FU Month 30	>=75 years	3	2,4	2	66,7	16,67	23,57	1	0,8	1	100,0	0,00	NE
Race													
Screening	Other	9	100,0	6	66,7	15,28	9,74	11	100,0	7	63,6	33,33	15,96
Cycle 4 Day 1	Other	7	77,8	4	57,1	10,42	4,17	10	90,9	6	60,0	19,44	10,09
FU Day 28	Other	8	88,9	5	62,5	15,00	10,87	10	90,9	7	70,0	13,10	17,91
FU Month 3	Other	8	88,9	4	50,0	12,50	4,81	10	90,9	6	60,0	16,67	13,94
FU Month 6	Other	8	88,9	4	50,0	2,08	4,17	8	72,7	6	75,0	9,72	12,27
FU Month 9	Other	4	44,4	3	75,0	13,89	4,81	5	45,5	4	80,0	18,75	18,48
FU Month 12	Other	3	33,3	2	66,7	12,50	5,89	4	36,4	4	100,0	16,67	11,79
FU Month 15	Other	2	22,2	1	50,0	0,00	NE	4	36,4	4	100,0	14,58	18,48
FU Month 18	Other	2	22,2	1	50,0	0,00	NE	2	18,2	2	100,0	4,17	5,89
FU Month 21	Other	2	22,2	1	50,0	0,00	NE	2	18,2	2	100,0	8,33	11,79
FU Month 24	Other	2	22,2	1	50,0	0,00	NE	0	NE	NE	NE	NE	NE
FU Month 27	Other	1	11,1			NE	NE	1	9,1			NE	NE
FU Month 30	Other	1	11,1			NE	NE	0	NE			NE	NE
Race													
Screening	White	246	100,0	210	85,4	20,73	17,45	231	100,0	195	84,4	22,19	17,64
Cycle 4 Day 1	White	206	83,7	170	82,5	14,35	16,13	214	92,6	169	79,0	16,70	16,16
FU Day 28	White	222	90,2	179	80,6	14,20	15,77	215	93,1	176	81,9	16,21	16,82
FU Month 3	White	217	88,2	179	82,5	12,20	14,80	211	91,3	168	79,6	14,57	15,30
FU Month 6	White	199	80,9	167	83,9	11,56	13,88	184	79,7	141	76,6	14,83	16,85
FU Month 9	White	160	65,0	123	76,9	11,74	13,83	144	62,3	107	74,3	15,50	15,10
FU Month 12	White	122	49,6	98	80,3	12,24	14,60	113	48,9	88	77,9	17,36	16,96
FU Month 15	White	102	41,5	83	81,4	12,45	14,16	81	35,1	59	72,8	16,57	16,24
FU Month 18	White	77	31,3	60	77,9	13,43	15,24	58	25,1	43	74,1	16,99	18,34
FU Month 21	White	50	20,3	35	70,0	16,19	17,14	38	16,5	26	68,4	18,59	21,38
FU Month 24	White	30	12,2	20	66,7	14,44	17,14	17	7,4	14	82,4	8,33	10,34
FU Month 27	White	12	4,9	8	66,7	18,75	14,60	8	3,5	6	75,0	4,17	6,97
FU Month 30	White	6	2,4	4	66,7	18,75	14,23	1	0,4	1	100,0	0,00	NE
Geographical Region													
Screening	Asia-Pacific	20	100,0	19	95,0	22,81	15,17	18	100,0	18	100,0	21,76	15,16
Cycle 4 Day 1	Asia-Pacific	15	75,0	14	93,3	14,29	11,98	16	88,9	15	93,8	16,11	9,16
FU Day 28	Asia-Pacific	18	90,0	18	100,0	18,52	13,57	18	100,0	16	88,9	16,67	15,21
FU Month 3	Asia-Pacific	18	90,0	16	88,9	14,06	14,18	18	100,0	15	83,3	14,44	9,69
FU Month 6	Asia-Pacific	16	80,0	14	87,5	22,62	24,55	17	94,4	14	82,4	10,71	9,49

FU Month 9	Asia-Pacific	14	70,0	12	85,7	15,97	8,30	13	72,2	10	76,9	14,17	6,86
FU Month 12	Asia-Pacific	10	50,0	8	80,0	15,63	11,30	10	55,6	10	100,0	16,67	7,86
FU Month 15	Asia-Pacific	8	40,0	6	75,0	15,28	17,81	9	50,0	9	100,0	18,21	18,27
FU Month 18	Asia-Pacific	6	30,0	4	66,7	4,17	4,81	6	33,3	6	100,0	13,43	9,53
FU Month 21	Asia-Pacific	5	25,0	3	60,0	2,78	4,81	4	22,2	4	100,0	10,42	7,98
FU Month 24	Asia-Pacific	3	15,0	2	66,7	4,17	5,89	1	5,6	0	NE	NE	NE
FU Month 27	Asia-Pacific	1	5,0			NE	NE	1	5,6			NE	NE
FU Month 30	Asia-Pacific	1	5,0			NE	NE	0	NE			NE	NE
Screening	Central and South America	3	100,0	3	100,0	13,89	12,73	2	100,0	2	100,0	20,83	17,68
Cycle 4 Day 1	Central and South America	3	100,0	3	100,0	2,78	4,81	2	100,0	2	100,0	16,67	0,00
FU Day 28	Central and South America	3	100,0	3	100,0	8,33	8,33	2	100,0	2	100,0	0,00	0,00
FU Month 3	Central and South America	3	100,0	3	100,0	5,56	9,62	2	100,0	2	100,0	0,00	0,00
FU Month 6	Central and South America	2	66,7	2	100,0	4,17	5,89	2	100,0	2	100,0	8,33	0,00
FU Month 9	Central and South America	2	66,7	2	100,0	4,17	5,89	1	50,0	1	100,0	16,67	NE
FU Month 12	Central and South America	2	66,7	2	100,0	4,17	5,89	1	50,0	1	100,0	25,00	NE
FU Month 15	Central and South America	1	33,3	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 18	Central and South America	1	33,3	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 21	Central and South America	1	33,3	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 24	Central and South America	1	33,3	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
Screening	North America	12	100,0	12	100,0	28,24	18,34	13	100,0	12	92,3	16,67	12,81
Cycle 4 Day 1	North America	9	75,0	9	100,0	21,30	23,24	12	92,3	12	100,0	12,27	10,08
FU Day 28	North America	11	91,7	11	100,0	18,94	21,76	13	100,0	13	100,0	9,62	7,49
FU Month 3	North America	11	91,7	11	100,0	21,21	20,54	12	92,3	12	100,0	11,11	12,97
FU Month 6	North America	11	91,7	10	90,9	16,67	17,57	11	84,6	11	100,0	15,15	15,73
FU Month 9	North America	8	66,7	8	100,0	21,88	30,19	9	69,2	9	100,0	15,74	11,37
FU Month 12	North America	8	66,7	7	87,5	17,86	23,29	7	53,8	7	100,0	17,46	10,96
FU Month 15	North America	6	50,0	6	100,0	12,50	8,74	6	46,2	5	83,3	23,33	10,87
FU Month 18	North America	4	33,3	4	100,0	20,83	10,76	3	23,1	3	100,0	22,22	17,35
FU Month 21	North America	3	25,0	2	66,7	8,33	11,79	1	7,7	1	100,0	41,67	NE

FU Month 24	North America	3	25,0	2	66,7	20,83	5,89	1	7,7	1	100,0	16,67	NE	
FU Month 27	North America	2	16,7	1	50,0	16,67		NE	1	7,7	1	100,0	16,67	NE
Screening	Other	45	100,0	17	37,8	24,51	18,04	44	100,0	16	36,4	27,60	19,18	
Cycle 4 Day 1	Other	37	82,2	14	37,8	19,64	11,61	40	90,9	14	35,0	17,86	12,60	
FU Day 28	Other	37	82,2	14	37,8	10,71	10,56	39	88,6	14	35,9	16,07	17,13	
FU Month 3	Other	38	84,4	15	39,5	10,56	10,67	38	86,4	14	36,8	17,26	16,17	
FU Month 6	Other	35	77,8	15	42,9	9,44	8,83	33	75,0	11	33,3	12,12	14,12	
FU Month 9	Other	26	57,8	12	46,2	12,50	7,54	24	54,5	8	33,3	22,92	20,29	
FU Month 12	Other	17	37,8	8	47,1	11,46	15,39	16	36,4	6	37,5	15,28	16,17	
FU Month 15	Other	12	26,7	4	33,3	10,42	10,49	9	20,5	3	33,3	8,33	8,33	
FU Month 18	Other	10	22,2	3	30,0	8,33	14,43	7	15,9	2	28,6	4,17	5,89	
FU Month 21	Other	7	15,6	2	28,6	25,00	0,00	4	9,1	0	NE	NE	NE	NE
FU Month 24	Other	6	13,3	1	16,7	25,00		NE	3	6,8	0	NE	NE	NE
FU Month 27	Other	4	8,9	1	25,0	25,00		NE	1	2,3	0	NE	NE	NE
FU Month 30	Other	2	4,4			NE	NE	0	NE				NE	NE
Screening	Western Europe	175	100,0	165	94,3	19,48	17,37	165	100,0	154	93,3	22,64	18,14	
Cycle 4 Day 1	Western Europe	149	85,1	134	89,9	13,47	16,16	154	93,3	132	85,7	17,17	17,43	
FU Day 28	Western Europe	161	92,0	138	85,7	13,77	15,85	153	92,7	138	90,2	16,87	17,59	
FU Month 3	Western Europe	155	88,6	138	89,0	11,59	14,52	151	91,5	131	86,8	14,93	15,89	
FU Month 6	Western Europe	143	81,7	130	90,9	10,04	11,88	129	78,2	109	84,5	15,44	17,89	
FU Month 9	Western Europe	114	65,1	92	80,7	10,45	12,53	102	61,8	83	81,4	15,06	15,79	
FU Month 12	Western Europe	88	50,3	75	85,2	11,67	13,95	83	50,3	68	81,9	17,48	18,43	
FU Month 15	Western Europe	77	44,0	67	87,0	12,31	14,60	61	37,0	46	75,4	15,88	16,71	
FU Month 18	Western Europe	58	33,1	49	84,5	13,89	15,96	44	26,7	34	77,3	17,16	19,78	
FU Month 21	Western Europe	36	20,6	28	77,8	17,56	18,19	31	18,8	23	74,2	18,12	22,14	
FU Month 24	Western Europe	19	10,9	15	78,9	14,26	19,10	13	7,9	13	100,0	7,69	10,46	
FU Month 27	Western Europe	6	3,4	6	100,0	18,06	17,01	6	3,6	5	83,3	1,67	3,73	
FU Month 30	Western Europe	4	2,3	4	100,0	18,75	14,23	1	0,6	1	100,0	0,00		NE
FCgamma receptor IIa														
Screening	131HH	58	100,0	46	79,3	23,37	18,06	76	100,0	60	78,9	22,41	17,02	
Cycle 4 Day 1	131HH	49	84,5	35	71,4	17,62	15,63	65	85,5	48	73,8	14,76	13,99	
FU Day 28	131HH	51	87,9	38	74,5	13,38	15,07	70	92,1	51	72,9	11,27	13,83	
FU Month 3	131HH	51	87,9	40	78,4	12,99	14,84	64	84,2	45	70,3	14,75	12,50	
FU Month 6	131HH	49	84,5	39	79,6	11,97	14,66	55	72,4	40	72,7	13,75	12,45	
FU Month 9	131HH	39	67,2	25	64,1	12,56	11,20	41	53,9	31	75,6	15,32	16,68	
FU Month 12	131HH	28	48,3	20	71,4	14,03	17,92	34	44,7	28	82,4	15,18	13,62	
FU Month 15	131HH	23	39,7	17	73,9	14,71	17,31	24	31,6	19	79,2	16,52	15,31	
FU Month 18	131HH	17	29,3	11	64,7	9,85	10,42	16	21,1	12	75,0	20,14	18,62	
FU Month 21	131HH	13	22,4	8	61,5	17,71	24,98	11	14,5	9	81,8	33,33	27,00	

FU Month 24	131HH	11	19,0	7	63,6	17,46	19,16	1	1,3	1	100,0	8,33	NE
FU Month 27	131HH	4	6,9	3	75,0	25,00	22,05	1	1,3	1	100,0	8,33	NE
FU Month 30	131HH	3	5,2	2	66,7	25,00	11,79	0	NE	0	NE	NE	NE
Screening	131HR	125	100,0	108	86,4	20,42	17,29	114	100,0	101	88,6	21,20	16,46
Cycle 4 Day 1	131HR	105	84,0	89	84,8	15,17	17,01	110	96,5	93	84,5	17,29	16,94
FU Day 28	131HR	116	92,8	97	83,6	15,26	16,14	105	92,1	92	87,6	17,24	17,10
FU Month 3	131HR	114	91,2	95	83,3	12,25	15,25	107	93,9	89	83,2	14,61	15,81
FU Month 6	131HR	104	83,2	86	82,7	11,89	13,83	95	83,3	76	80,0	14,04	17,39
FU Month 9	131HR	84	67,2	66	78,6	12,71	12,56	76	66,7	58	76,3	14,61	14,57
FU Month 12	131HR	64	51,2	54	84,4	12,86	13,21	57	50,0	46	80,7	16,55	17,16
FU Month 15	131HR	53	42,4	42	79,2	13,10	13,54	44	38,6	32	72,7	14,50	15,79
FU Month 18	131HR	43	34,4	34	79,1	14,87	15,95	32	28,1	25	78,1	11,89	15,14
FU Month 21	131HR	26	20,8	17	65,4	18,63	16,28	21	18,4	15	71,4	11,67	13,29
FU Month 24	131HR	12	9,6	8	66,7	11,46	9,90	12	10,5	10	83,3	9,17	12,08
FU Month 27	131HR	6	4,8	3	50,0	19,44	4,81	6	5,3	5	66,7	4,17	8,33
FU Month 30	131HR	3	2,4	1	33,3	25,00	NE	1	0,9	1	100,0	0,00	NE
Screening	131RR	49	100,0	41	83,7	19,44	16,71	33	100,0	28	84,8	22,92	20,24
Cycle 4 Day 1	131RR	40	81,6	33	82,5	9,85	14,20	31	93,9	24	77,4	19,33	17,46
FU Day 28	131RR	42	85,7	31	73,8	13,71	17,02	32	97,0	28	87,5	16,67	18,00
FU Month 3	131RR	39	79,6	31	79,5	11,56	14,22	32	97,0	28	87,5	11,61	15,27
FU Month 6	131RR	35	71,4	29	82,9	12,36	14,88	27	81,8	22	81,5	19,32	21,88
FU Month 9	131RR	24	49,0	20	83,3	12,50	21,54	19	57,6	16	84,2	18,23	17,00
FU Month 12	131RR	18	36,7	15	83,3	10,56	17,95	17	51,5	14	82,4	21,43	19,81
FU Month 15	131RR	16	32,7	14	87,5	10,12	14,68	11	33,3	9	81,8	22,22	21,25
FU Month 18	131RR	14	28,6	12	85,7	12,50	18,97	8	24,2	7	87,5	22,62	24,40
FU Month 21	131RR	8	16,3	6	75,0	13,89	11,39	5	15,2	4	80,0	6,25	7,98
FU Month 24	131RR	5	10,2	3	60,0	19,44	33,68	3	9,1	3	100,0	5,56	4,81
FU Month 27	131RR	2	4,1	1	50,0	0,00	NE	1	3,0	1	100,0	0,00	NE
FU Month 30	131RR	1	2,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
Screening	Missing	23	100,0	21	91,3	17,46	17,06	19	100,0	13	68,4	33,33	22,05
Cycle 4 Day 1	Missing	19	82,6	17	89,5	11,11	12,65	18	94,7	10	55,6	15,83	12,70
FU Day 28	Missing	21	91,3	18	85,7	11,27	11,76	18	94,7	12	66,7	26,39	19,08
FU Month 3	Missing	21	91,3	17	81,0	11,27	12,48	18	94,7	12	66,7	21,53	19,29
FU Month 6	Missing	19	82,6	17	89,5	5,39	8,30	15	78,9	9	60,0	12,04	12,58
FU Month 9	Missing	17	73,9	15	88,2	5,56	6,80	13	68,4	6	46,2	19,91	5,94
FU Month 12	Missing	15	65,2	11	73,3	8,33	7,45	9	47,4	4	44,4	27,08	20,83
FU Month 15	Missing	12	52,2	11	91,7	8,33	10,54	6	31,6	3	50,0	19,44	12,73
FU Month 18	Missing	5	21,7	4	80,0	10,42	7,98	4	21,1	1	25,0	41,67	NE
FU Month 21	Missing	5	21,7	5	100,0	5,00	7,45	3	15,8	0	NE	NE	NE

FU Month 24	Missing	4	17,4	3	75,0	5,56	9,62	2	10,5	0	NE	NE	NE
FU Month 27	Missing	1	4,3	1	100,0	16,67	NE	1	5,3	0	NE	NE	NE
FCgamma receptor IIIa													
Screening	158FF	103	100,0	92	89,3	18,75	15,73	83	100,0	72	86,7	23,03	17,83
Cycle 4 Day 1	158FF	89	86,4	74	83,1	14,11	15,53	78	94,0	64	82,1	18,53	16,09
FU Day 28	158FF	96	93,2	78	81,3	14,21	15,95	78	94,0	67	85,9	15,55	16,47
FU Month 3	158FF	94	91,3	76	80,9	12,61	14,56	78	94,0	65	83,3	12,18	15,17
FU Month 6	158FF	86	83,5	69	80,2	12,92	16,27	64	77,1	53	82,8	13,21	15,46
FU Month 9	158FF	71	68,9	56	78,9	12,75	16,71	47	56,6	41	87,2	15,24	15,01
FU Month 12	158FF	48	46,6	41	85,4	11,99	15,60	38	45,8	34	89,5	14,46	15,93
FU Month 15	158FF	37	35,9	31	83,8	11,29	14,68	30	36,1	23	76,7	14,13	14,74
FU Month 18	158FF	27	26,2	22	81,5	14,77	19,40	21	25,3	17	81,0	16,99	20,24
FU Month 21	158FF	16	15,5	15	93,8	18,89	14,25	9	10,8	8	88,9	9,38	15,06
FU Month 24	158FF	8	7,8	7	87,5	11,90	10,60	3	3,6	3	100,0	0,00	0,00
FU Month 27	158FF	5	4,9	4	80,0	8,33	9,62	1	1,2	1	100,0	0,00	NE
FU Month 30	158FF	3	2,9	3	100,0	13,89	12,73	0	NE	0	NE	NE	NE
Screening	158FV	119	100,0	98	82,4	21,80	18,85	109	100,0	90	82,6	21,88	18,66
Cycle 4 Day 1	158FV	99	83,2	80	80,8	14,13	17,31	100	91,7	77	77,0	17,35	16,59
FU Day 28	158FV	105	88,2	83	79,0	14,36	16,28	101	92,7	81	80,2	16,56	18,14
FU Month 3	158FV	101	84,9	84	83,2	11,90	15,67	97	89,0	75	77,3	15,07	15,88
FU Month 6	158FV	94	79,0	80	85,1	11,01	12,39	83	76,1	64	77,1	15,10	19,18
FU Month 9	158FV	71	59,7	53	74,6	11,90	11,56	65	59,6	46	70,8	15,46	15,26
FU Month 12	158FV	60	50,4	49	81,7	13,10	14,60	52	47,7	41	78,8	19,78	18,41
FU Month 15	158FV	52	43,7	41	78,8	13,41	13,42	36	33,0	29	80,6	19,92	19,02
FU Month 18	158FV	44	37,0	33	75,0	12,63	13,03	24	22,0	20	83,3	17,08	19,40
FU Month 21	158FV	28	23,5	14	50,0	16,07	22,28	18	16,5	14	77,8	23,21	25,14
FU Month 24	158FV	18	15,1	9	50,0	18,21	23,66	6	5,5	5	83,3	16,67	11,79
FU Month 27	158FV	6	5,0	2	33,3	33,33	11,79	2	1,8	1	50,0	0,00	NE
FU Month 30	158FV	4	3,4	1	25,0	33,33	NE	0	NE	0	NE	NE	NE
Screening	158VV	16	100,0	12	75,0	22,92	14,70	33	100,0	29	87,9	22,99	13,75
Cycle 4 Day 1	158VV	12	75,0	9	75,0	16,67	10,21	30	90,9	26	86,7	14,10	14,86
FU Day 28	158VV	14	87,5	11	78,6	12,88	12,56	30	90,9	26	86,7	13,25	13,34
FU Month 3	158VV	15	93,8	10	66,7	11,67	11,25	30	90,9	24	80,0	17,71	12,36
FU Month 6	158VV	14	87,5	11	78,6	9,09	8,70	30	90,9	21	70,0	16,27	12,49
FU Month 9	158VV	12	75,0	9	75,0	10,19	6,94	25	75,8	19	76,0	16,81	17,58
FU Month 12	158VV	8	50,0	5	62,5	11,67	9,50	20	60,6	16	80,0	15,10	11,06
FU Month 15	158VV	8	50,0	6	75,0	12,50	19,54	14	42,4	10	71,4	12,50	9,00
FU Month 18	158VV	4	25,0	3	75,0	12,96	11,56	11	33,3	8	72,7	13,54	9,90
FU Month 21	158VV	3	18,8	2	66,7	16,67	0,00	9	27,3	6	66,7	16,67	13,94

FU Month 24	158VV	2	12,5	2	100,0	12,50	5,89	7	21,2	6	85,7	5,56	6,80
FU Month 27	158VV	1	6,3	1	100,0	33,33	NE	5	15,2	4	80,0	6,25	7,98
FU Month 30	158VV	0	NE	0	NE	NE	NE	1	3,0	1	100,0	0,00	NE
Screening	Missing	17	100,0	14	82,4	22,02	18,38	17	100,0	11	64,7	24,24	19,53
Cycle 4 Day 1	Missing	13	76,5	11	84,6	14,14	13,80	16	94,1	8	50,0	6,25	7,39
FU Day 28	Missing	15	88,2	12	80,0	14,58	12,87	16	94,1	9	56,3	24,07	15,84
FU Month 3	Missing	15	88,2	13	86,7	12,18	11,59	16	94,1	10	62,5	20,00	15,81
FU Month 6	Missing	13	76,5	11	84,6	6,06	9,92	15	88,2	9	60,0	15,74	14,70
FU Month 9	Missing	10	58,8	8	80,0	6,25	7,39	12	70,6	5	41,7	15,56	6,39
FU Month 12	Missing	9	52,9	5	55,6	6,67	6,97	7	41,2	1	14,3	50,00	NE
FU Month 15	Missing	7	41,2	6	85,7	9,72	13,35	5	29,4	1	20,0	8,33	NE
FU Month 18	Missing	4	23,5	3	75,0	8,33	8,33	4	23,5	0	NE	NE	NE
FU Month 21	Missing	5	29,4	5	100,0	5,00	7,45	4	23,5	0	NE	NE	NE
FU Month 24	Missing	4	23,5	3	75,0	5,56	9,62	2	11,8	0	NE	NE	NE
FU Month 27	Missing	1	5,9	1	100,0	16,67	NE	1	5,9	0	NE	NE	NE
Binet Staging at baseline													
Screening	A	59	100,0	56	94,9	21,43	16,99	57	100,0	47	82,5	24,65	18,55
Cycle 4 Day 1	A	51	86,4	45	88,2	17,84	18,49	54	94,7	45	83,3	19,07	19,19
FU Day 28	A	58	98,3	51	87,9	16,50	17,12	54	94,7	45	83,3	19,81	20,04
FU Month 3	A	57	96,6	54	94,7	15,59	17,06	53	93,0	44	83,0	17,61	16,88
FU Month 6	A	56	94,9	47	83,9	13,95	15,80	45	78,9	36	80,0	18,06	21,59
FU Month 9	A	43	72,9	35	81,4	14,92	17,79	34	59,6	26	76,5	14,53	12,55
FU Month 12	A	36	61,0	32	88,9	15,19	18,84	24	42,1	18	75,0	21,14	20,03
FU Month 15	A	30	50,8	25	83,3	16,67	15,96	19	33,3	17	89,5	16,01	19,80
FU Month 18	A	22	37,3	15	68,2	11,67	13,66	16	28,1	14	87,5	20,04	20,04
FU Month 21	A	17	28,8	13	76,5	14,74	20,74	8	14,0	5	62,5	15,00	14,91
FU Month 24	A	10	16,9	6	60,0	13,43	21,04	5	8,8	4	80,0	14,58	12,50
FU Month 27	A	5	8,5	3	60,0	19,44	20,97	2	3,5	1	50,0	8,33	NE
FU Month 30	A	4	6,8	3	75,0	25,00	8,33	0	NE	0	NE	NE	NE
Screening	B	104	100,0	84	80,8	20,14	17,65	85	100,0	70	82,4	22,78	17,05
Cycle 4 Day 1	B	88	84,6	72	81,8	12,96	14,59	79	92,9	63	79,7	15,70	14,95
FU Day 28	B	91	87,5	70	76,9	13,33	16,82	79	92,9	63	79,7	13,76	14,98
FU Month 3	B	88	84,6	66	75,0	10,10	12,79	79	92,9	62	78,5	13,44	13,86
FU Month 6	B	80	76,9	68	85,0	9,31	12,43	70	82,4	52	74,3	15,22	17,05
FU Month 9	B	63	60,6	48	76,2	11,11	11,70	59	69,4	44	74,6	16,16	16,84
FU Month 12	B	47	45,2	34	72,3	11,27	13,12	46	54,1	37	80,4	16,37	14,33
FU Month 15	B	37	35,6	31	83,8	10,48	13,94	34	40,0	25	73,5	17,33	13,80
FU Month 18	B	31	29,8	25	80,6	14,89	17,95	22	25,9	17	77,3	12,75	15,06
FU Month 21	B	18	17,3	12	66,7	17,36	15,27	17	20,0	13	76,5	18,59	24,09

FU Month 24	B	11	10,6	8	72,7	16,67	19,42	8	9,4	7	87,5	7,14	10,12
FU Month 27	B	5	4,8	3	60,0	16,67	16,67	4	4,7	4	100,0	4,17	8,33
FU Month 30	B	2	1,9	1	50,0	0,00	NE	0	NE	0	NE	NE	NE
Screening	C	92	100,0	76	82,6	20,43	17,31	100	100,0	85	85,0	21,27	17,77
Cycle 4 Day 1	C	74	80,4	57	77,0	13,06	15,30	91	91,0	67	73,6	16,29	14,59
FU Day 28	C	81	88,0	63	77,8	13,36	12,84	92	92,0	75	81,5	15,81	16,00
FU Month 3	C	80	87,0	63	78,8	11,51	13,95	89	89,0	68	76,4	13,81	15,25
FU Month 6	C	71	77,2	56	78,9	11,61	13,45	77	77,0	59	76,6	12,01	12,21
FU Month 9	C	58	63,0	43	74,1	10,01	11,65	56	56,0	41	73,2	15,72	15,06
FU Month 12	C	42	45,7	34	81,0	10,46	10,46	47	47,0	37	78,7	16,44	17,40
FU Month 15	C	37	40,2	28	75,7	10,42	12,13	32	32,0	21	65,6	15,74	16,51
FU Month 18	C	26	28,3	21	80,8	12,30	13,08	22	22,0	14	63,6	17,26	20,01
FU Month 21	C	17	18,5	11	64,7	15,15	15,73	15	15,0	10	66,7	18,33	20,71
FU Month 24	C	11	12,0	7	63,6	10,71	11,50	5	5,0	3	60,0	2,78	4,81
FU Month 27	C	3	3,3	2	66,7	20,83	5,89	3	3,0	1	33,3	0,00	NE
FU Month 30	C	1	1,1	0	NE	NE	NE	1	1,0	1	100,0	0,00	NE
Total CIR score at baseline													
Screening	<=6	63	100,0	53	84,1	16,19	15,45	75	100,0	62	82,7	23,52	18,17
Cycle 4 Day 1	<=6	52	82,5	38	73,1	11,55	11,63	72	96,0	53	73,6	14,31	13,32
FU Day 28	<=6	56	88,9	45	80,4	13,52	13,10	72	96,0	53	73,6	12,95	15,71
FU Month 3	<=6	55	87,3	42	76,4	10,32	14,82	69	92,0	49	71,0	10,54	9,74
FU Month 6	<=6	52	82,5	43	82,7	9,63	10,66	60	80,0	45	75,0	11,48	10,99
FU Month 9	<=6	43	68,3	33	76,7	7,49	11,16	47	62,7	35	74,5	13,57	14,02
FU Month 12	<=6	35	55,6	27	77,1	10,19	10,16	34	45,3	27	79,4	12,96	14,12
FU Month 15	<=6	32	50,8	28	87,5	8,93	9,87	25	33,3	16	64,0	13,02	12,90
FU Month 18	<=6	23	36,5	19	82,6	12,13	12,08	19	25,3	14	73,7	14,29	20,26
FU Month 21	<=6	14	22,2	8	57,1	10,42	15,27	14	18,7	10	71,4	10,00	13,49
FU Month 24	<=6	8	12,7	7	87,5	15,48	21,21	7	9,3	6	85,7	4,17	4,56
FU Month 27	<=6	2	3,2	2	100,0	20,83	5,89	4	5,3	2	50,0	0,00	0,00
FU Month 30	<=6	0	NE	0	NE	NE	NE	1	1,3	1	100,0	0,00	NE
Screening	>6	192	100,0	163	84,9	22,00	17,66	167	100,0	140	83,8	22,16	17,49
Cycle 4 Day 1	>6	161	83,9	136	84,5	15,01	16,93	152	91,0	122	80,3	17,87	16,95
FU Day 28	>6	174	90,6	139	79,9	14,45	16,41	153	91,6	130	85,0	17,37	17,15
FU Month 3	>6	170	88,5	141	82,9	12,77	14,60	152	91,0	125	82,2	16,24	16,65
FU Month 6	>6	155	80,7	128	82,6	11,91	14,70	132	79,0	102	77,3	16,01	18,53
FU Month 9	>6	121	63,0	93	76,9	13,32	14,21	102	61,1	76	74,5	16,56	15,64
FU Month 12	>6	90	46,9	73	81,1	13,01	15,75	83	49,7	65	78,3	19,15	17,47
FU Month 15	>6	72	37,5	56	77,8	13,99	15,66	60	35,9	47	78,3	17,61	17,18
FU Month 18	>6	56	29,2	42	75,0	13,69	16,55	41	24,6	31	75,6	17,38	17,36

FU Month 21	>6	38	19,8	28	73,7	17,26	17,56	26	15,6	18	69,2	22,22	23,22
FU Month 24	>6	24	12,5	14	58,3	12,90	15,32	11	6,6	8	72,7	11,46	12,55
FU Month 27	>6	11	5,7	6	54,5	18,06	17,01	5	3,0	4	80,0	6,25	7,98
FU Month 30	>6	7	3,6	4	57,1	18,75	14,23	0	NE	0	NE	NE	NE
Calculated creatinine clearance cat. 2													
Screening	<70 ml/min	178	100,0	151	84,8	20,66	17,92	176	100,0	148	84,1	23,76	18,41
Cycle 4 Day 1	<70 ml/min	149	83,7	120	80,5	14,26	16,76	164	93,2	128	78,0	16,73	16,08
FU Day 28	<70 ml/min	162	91,0	132	81,5	14,65	16,22	166	94,3	132	79,5	15,55	15,87
FU Month 3	<70 ml/min	157	88,2	129	82,2	12,25	15,58	159	90,3	123	77,4	14,43	14,75
FU Month 6	<70 ml/min	144	80,9	121	84,0	10,93	12,89	139	79,0	105	75,5	14,52	17,45
FU Month 9	<70 ml/min	117	65,7	88	75,2	11,71	15,01	112	63,6	82	73,2	16,33	16,06
FU Month 12	<70 ml/min	92	51,7	72	78,3	11,77	14,50	87	49,4	68	78,2	16,58	16,63
FU Month 15	<70 ml/min	78	43,8	65	83,3	13,33	14,34	60	34,1	43	71,7	17,51	16,30
FU Month 18	<70 ml/min	59	33,1	46	78,0	14,07	14,64	43	24,4	32	74,4	17,97	19,18
FU Month 21	<70 ml/min	38	21,3	24	63,2	14,93	18,71	31	17,6	23	74,2	16,67	17,77
FU Month 24	<70 ml/min	24	13,5	16	66,7	15,45	19,06	13	7,4	9	69,2	8,33	11,02
FU Month 27	<70 ml/min	10	5,6	5	50,0	20,00	15,14	7	4,0	4	57,1	6,25	7,98
FU Month 30	<70 ml/min	5	2,8	2	40,0	16,67	23,57	1	0,6	1	100,0	0,00	NE
Screening	>=70 ml/min	77	100,0	65	84,4	20,38	15,87	66	100,0	54	81,8	19,34	15,14
Cycle 4 Day 1	>=70 ml/min	64	83,1	54	84,4	14,25	14,15	60	90,9	47	78,3	16,96	15,88
FU Day 28	>=70 ml/min	68	88,3	52	76,5	13,14	14,13	59	89,4	51	86,4	17,48	19,17
FU Month 3	>=70 ml/min	68	88,3	54	79,4	12,09	12,28	62	93,9	51	82,3	15,14	16,45
FU Month 6	>=70 ml/min	63	81,8	50	79,4	12,33	15,90	53	80,3	42	79,2	14,88	14,79
FU Month 9	>=70 ml/min	47	61,0	38	80,9	11,99	10,11	37	56,1	29	78,4	13,60	12,25
FU Month 12	>=70 ml/min	33	42,9	28	84,8	13,49	14,56	30	45,5	24	80,0	19,44	17,14
FU Month 15	>=70 ml/min	26	33,8	19	73,1	8,77	13,17	25	37,9	20	80,0	14,17	16,24
FU Month 18	>=70 ml/min	20	26,0	15	75,0	10,56	17,10	17	25,8	13	76,5	12,61	15,28
FU Month 21	>=70 ml/min	14	18,2	12	85,7	17,36	13,97	9	13,6	5	55,6	23,33	34,05
FU Month 24	>=70 ml/min	8	10,4	5	62,5	8,33	5,89	5	7,6	5	100,0	8,33	10,21
FU Month 27	>=70 ml/min	3	3,9	3	100,0	16,67	16,67	2	3,0	2	100,0	0,00	0,00
FU Month 30	>=70 ml/min	2	2,6	2	100,0	20,83	5,89	0	NE	0	NE	NE	NE
Beta2 microglobulin													
Screening	Missing	3	100,0	3	100,0	25,00	8,33	3	100,0	2	66,7	50,00	11,79
Cycle 4 Day 1	Missing	3	100,0	3	100,0	13,89	9,62	3	100,0	1	33,3	0,00	NE
FU Day 28	Missing	3	100,0	3	100,0	16,67	14,43	3	100,0	1	33,3	0,00	NE
FU Month 3	Missing	3	100,0	3	100,0	19,44	17,35	3	100,0	1	33,3	8,33	NE
FU Month 6	Missing	3	100,0	3	100,0	5,56	9,62	3	100,0	1	33,3	16,67	NE
FU Month 9	Missing	2	66,7	1	50,0	0,00	NE	3	100,0	1	33,3	16,67	NE

FU Month 12	Missing		133,3		1100,0	8,33		NE	266,7		0	NE	NE	NE
FU Month 15	Missing		133,3		1100,0	0,00		NE	266,7		0	NE	NE	NE
FU Month 18	Missing		133,3		1100,0	0,00		NE	266,7		0	NE	NE	NE
FU Month 21	Missing		133,3		1100,0	16,67		NE	266,7		0	NE	NE	NE
FU Month 24	Missing		133,3		1100,0	8,33		NE	133,3		0	NE	NE	NE
Screening	< 3.5 ug/mL	154	100,0	134	87,0	20,83	17,34	140	100,0	119	85,0	22,11	16,93	
Cycle 4 Day 1	< 3.5 ug/mL	127	82,5	108	85,0	16,02	18,16	129	92,1	101	78,3	17,52	16,81	
FU Day 28	< 3.5 ug/mL	137	89,0	116	84,7	14,30	15,53	132	94,3	109	82,6	18,07	18,36	
FU Month 3	< 3.5 ug/mL	134	87,0	117	87,3	12,92	15,14	130	92,9	103	79,2	16,24	15,40	
FU Month 6	< 3.5 ug/mL	128	83,1	108	84,4	11,63	14,52	120	85,7	97	80,8	15,29	17,17	
FU Month 9	< 3.5 ug/mL	104	67,5	82	78,8	11,96	12,19	98	70,0	76	77,6	16,89	16,81	
FU Month 12	< 3.5 ug/mL	78	50,6	65	83,3	12,44	15,08	75	53,6	62	82,7	18,86	17,97	
FU Month 15	< 3.5 ug/mL	65	42,2	54	83,1	12,96	14,63	60	42,9	47	78,3	16,73	16,26	
FU Month 18	< 3.5 ug/mL	46	29,9	36	78,3	14,27	17,16	43	30,7	33	76,7	17,34	19,22	
FU Month 21	< 3.5 ug/mL	30	19,5	20	66,7	16,25	20,14	27	19,3	20	74,1	16,67	22,78	
FU Month 24	< 3.5 ug/mL	19	12,3	14	73,7	12,90	15,66	12	8,6	10	83,3	7,50	9,98	
FU Month 27	< 3.5 ug/mL	10	6,5	7	70,0	21,43	13,49	7	5,0	4	57,1	2,08	4,17	
FU Month 30	< 3.5 ug/mL	5	3,2	3	60,0	19,44	17,35	1	0,7	1	100,0	0,00		NE
Screening	>= 3.5 ug/mL	98	100,0	79	80,6	19,97	17,55	99	100,0	81	81,8	22,60	18,47	
Cycle 4 Day 1	>= 3.5 ug/mL	83	84,7	63	75,9	11,24	11,12	92	92,9	73	79,3	16,02	14,82	
FU Day 28	>= 3.5 ug/mL	90	91,8	65	72,2	13,97	16,08	90	90,9	73	81,1	13,36	13,87	
FU Month 3	>= 3.5 ug/mL	88	89,8	63	71,6	10,54	13,61	88	88,9	70	79,5	12,38	14,86	
FU Month 6	>= 3.5 ug/mL	76	77,6	60	78,9	11,11	12,71	69	69,7	49	71,0	13,27	15,95	
FU Month 9	>= 3.5 ug/mL	58	59,2	43	74,1	11,76	16,34	48	48,5	34	70,8	12,75	10,51	
FU Month 12	>= 3.5 ug/mL	46	46,9	34	73,9	12,01	13,64	40	40,4	30	75,0	14,17	13,52	
FU Month 15	>= 3.5 ug/mL	38	38,8	29	76,3	11,49	13,44	23	23,2	16	69,6	15,63	16,63	
FU Month 18	>= 3.5 ug/mL	32	32,7	24	75,0	12,15	12,03	15	15,2	12	80,0	13,89	15,21	
FU Month 21	>= 3.5 ug/mL	21	21,4	15	71,4	15,00	13,44	11	11,1	8	72,7	20,83	16,06	
FU Month 24	>= 3.5 ug/mL	12	12,2	6	50,0	16,67	22,36	5	5,1	4	80,0	10,42	12,50	
FU Month 27	>= 3.5 ug/mL	3	3,1	1	33,3	0,00		NE	2,0	2	100,0	8,33	11,79	
FU Month 30	>= 3.5 ug/mL	2	2,0	1	50,0	16,67		NE	0	NE	0	NE	NE	NE
Immunoglobulin VH, cytogenetics 2														
Screening	12	45	100,0	39	86,7	19,44	16,92	44	100,0	40	90,9	24,38	17,94	
Cycle 4 Day 1	12	34	75,6	29	85,3	14,37	15,73	38	86,4	30	78,9	16,94	19,14	
FU Day 28	12	39	86,7	35	89,7	17,46	17,86	40	90,9	35	87,5	19,52	20,70	
FU Month 3	12	38	84,4	34	89,5	12,25	15,11	39	88,6	30	76,9	17,78	17,19	
FU Month 6	12	36	80,0	30	83,3	12,50	12,14	34	77,3	27	79,4	18,83	18,72	
FU Month 9	12	26	57,8	21	80,8	12,17	9,19	28	63,6	17	60,7	19,77	18,21	
FU Month 12	12	22	48,9	17	77,3	17,81	19,89	23	52,3	14	60,9	21,83	15,86	

FU Month 15	12	17	37,8	13	76,5	19,23	16,80	17	38,6	11	64,7	19,44	16,71
FU Month 18	12	15	33,3	11	73,3	10,61	9,92	13	29,5	8	61,5	17,71	15,06
FU Month 21	12	10	22,2	7	70,0	21,43	24,93	7	15,9	4	57,1	14,58	7,98
FU Month 24	12	8	17,8	5	62,5	21,11	21,39	6	13,6	5	83,3	13,33	15,14
FU Month 27	12	5	11,1	3	60,0	25,00	22,05	2	4,5	2	100,0	0,00	0,00
FU Month 30	12	4	8,9	2	50,0	16,67	23,57	1	2,3	1	100,0	0,00	NE
Screening	11q-	46	100,0	35	76,1	19,68	16,29	43	100,0	36	83,7	22,69	20,08
Cycle 4 Day 1	11q-	40	87,0	33	82,5	10,86	10,92	41	95,3	32	78,0	14,84	15,80
FU Day 28	11q-	42	91,3	29	69,0	11,78	13,64	39	90,7	32	82,1	15,36	17,72
FU Month 3	11q-	42	91,3	32	76,2	9,90	12,95	38	88,4	34	89,5	14,62	13,25
FU Month 6	11q-	38	82,6	31	81,6	9,95	9,72	32	74,4	26	81,3	14,42	19,52
FU Month 9	11q-	28	60,9	24	85,7	11,11	11,70	25	58,1	20	80,0	17,08	15,17
FU Month 12	11q-	20	43,5	17	85,0	10,29	10,84	18	41,9	16	88,9	24,83	21,09
FU Month 15	11q-	18	39,1	15	83,3	6,67	9,02	14	32,6	9	64,3	23,15	18,53
FU Month 18	11q-	15	32,6	11	73,3	8,33	10,54	8	18,6	6	75,0	20,83	27,26
FU Month 21	11q-	12	26,1	10	83,3	10,83	12,45	4	9,3	1	25,0	83,33	NE
FU Month 24	11q-	7	15,2	4	57,1	4,17	4,81	1	2,3	1	100,0	0,00	NE
FU Month 27	11q-	3	6,5	2	66,7	8,33	11,79	0	NE	0	NE	NE	NE
FU Month 30	11q-	3	6,5	2	66,7	20,83	5,89	0	NE	0	NE	NE	NE
Screening	13q-	79	100,0	68	86,1	17,12	15,75	75	100,0	57	76,0	21,00	16,21
Cycle 4 Day 1	13q-	67	84,8	51	76,1	15,09	18,59	68	90,7	50	73,5	18,28	14,36
FU Day 28	13q-	72	91,1	58	80,6	13,07	15,06	72	96,0	54	75,0	15,95	16,75
FU Month 3	13q-	73	92,4	60	82,2	13,80	16,07	69	92,0	49	71,0	15,31	15,81
FU Month 6	13q-	67	84,8	55	82,1	8,89	12,66	63	84,0	44	69,8	14,02	16,64
FU Month 9	13q-	56	70,9	44	78,6	11,49	17,40	52	69,3	38	73,1	16,01	16,48
FU Month 12	13q-	44	55,7	36	81,8	10,73	14,72	40	53,3	34	85,0	15,69	15,86
FU Month 15	13q-	38	48,1	32	84,2	12,24	14,66	29	38,7	23	79,3	15,94	16,84
FU Month 18	13q-	28	35,4	22	78,6	15,53	20,46	21	28,0	17	81,0	17,48	18,78
FU Month 21	13q-	16	20,3	12	75,0	15,97	14,85	16	21,3	12	75,0	15,97	15,67
FU Month 24	13q-	7	8,9	5	71,4	10,00	10,87	7	9,3	4	57,1	8,33	6,80
FU Month 27	13q-	2	2,5	1	50,0	16,67	NE	6	8,0	3	50,0	8,33	8,33
Screening	Norm. K.	65	100,0	57	87,7	26,61	18,80	58	100,0	50	86,2	25,67	18,35
Cycle 4 Day 1	Norm. K.	54	83,1	46	85,2	15,10	15,26	55	94,8	46	83,6	19,57	16,94
FU Day 28	Norm. K.	59	90,8	48	81,4	14,35	15,19	53	91,4	46	86,8	15,76	13,75
FU Month 3	Norm. K.	54	83,1	44	81,5	10,73	13,21	54	93,1	44	81,5	14,39	15,60
FU Month 6	Norm. K.	49	75,4	43	87,8	14,15	17,11	45	77,6	33	73,3	16,67	14,73
FU Month 9	Norm. K.	39	60,0	27	69,2	11,42	12,04	30	51,7	24	80,0	12,96	12,08
FU Month 12	Norm. K.	32	49,2	24	75,0	11,81	12,98	24	41,4	18	75,0	12,96	12,53
FU Month 15	Norm. K.	26	40,0	20	76,9	13,33	14,41	20	34,5	16	80,0	14,41	14,85

FU Month 18	Norm. K.	18	27,7	14	77,8	17,66	12,06	15	25,9	12	80,0	14,58	15,94
FU Month 21	Norm. K.	12	18,5	5	41,7	23,33	19,00	11	19,0	9	81,8	17,59	22,61
FU Month 24	Norm. K.	8	12,3	5	62,5	23,33	21,57	4	46,9	4	100,0	4,17	4,81
FU Month 27	Norm. K.	3	4,6	2	66,7	20,83	5,89	1	1,7	1	100,0	0,00	NE
Screening	Other Abn.	20	100,0	17	85,0	18,63	17,56	22	100,0	19	86,4	15,20	13,07
Cycle 4 Day 1	Other Abn.	18	90,0	15	83,3	16,11	19,02	22	100,0	17	77,3	8,33	8,84
FU Day 28	Other Abn.	18	90,0	14	77,8	15,48	18,16	21	95,5	16	76,2	11,46	14,23
FU Month 3	Other Abn.	18	90,0	13	72,2	15,38	15,90	21	95,5	17	81,0	7,84	11,59
FU Month 6	Other Abn.	17	85,0	12	70,6	13,19	17,93	18	81,8	17	94,4	5,88	8,72
FU Month 9	Other Abn.	15	75,0	10	66,7	15,00	13,49	14	63,6	12	85,7	11,34	11,39
FU Month 12	Other Abn.	7	35,0	6	85,7	12,96	8,55	12	54,5	10	83,3	12,50	17,24
FU Month 15	Other Abn.	5	25,0	4	80,0	6,25	7,98	5	22,7	4	80,0	4,17	4,81
FU Month 18	Other Abn.	3	15,0	3	100,0	2,78	4,81	3	13,6	2	66,7	0,00	0,00
FU Month 21	Other Abn.	2	10,0	2	100,0	0,00	0,00	2	9,1	2	100,0	4,17	5,89
FU Month 24	Other Abn.	2	10,0	2	100,0	0,00	0,00	0	NE	0	NE	NE	NE
Time from first diagnosis													
Screening	Missing	1	100,0	1	100,0	16,67	NE	0	NE	0	NE	NE	NE
Cycle 4 Day 1	Missing	1	100,0	1	100,0	8,33	NE	0	NE	0	NE	NE	NE
FU Day 28	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 3	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 6	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 9	Missing	1	100,0	1	100,0	8,33	NE	0	NE	0	NE	NE	NE
FU Month 12	Missing	1	100,0	1	100,0	8,33	NE	0	NE	0	NE	NE	NE
FU Month 15	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 18	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
Screening	13 - 24 months	41	100,0	31	75,6	23,57	20,16	31	100,0	30	96,8	19,17	15,19
Cycle 4 Day 1	13 - 24 months	35	85,4	28	80,0	15,58	20,54	30	96,8	26	86,7	15,38	14,47
FU Day 28	13 - 24 months	38	92,7	26	68,4	14,42	17,09	30	96,8	26	86,7	9,62	13,88
FU Month 3	13 - 24 months	36	87,8	28	77,8	13,00	19,11	30	96,8	25	83,3	12,56	10,94
FU Month 6	13 - 24 months	36	87,8	27	75,0	10,19	15,39	30	96,8	24	80,0	11,11	12,69
FU Month 9	13 - 24 months	32	78,0	22	68,8	7,95	8,32	21	67,7	17	81,0	9,80	8,95
FU Month 12	13 - 24 months	21	51,2	15	71,4	11,30	21,73	16	51,6	13	81,3	8,97	12,48
FU Month 15	13 - 24 months	19	46,3	15	78,9	10,56	17,95	16	51,6	8	50,0	8,33	9,96
FU Month 18	13 - 24 months	14	34,1	10	71,4	12,50	14,83	10	32,3	8	80,0	6,25	8,63
FU Month 21	13 - 24 months	11	26,8	7	63,6	21,43	24,93	6	19,4	4	66,7	6,25	7,98
FU Month 24	13 - 24 months	8	19,5	3	37,5	43,52	23,30	3	9,7	3	100,0	0,00	0,00
FU Month 27	13 - 24 months	5	12,2	3	60,0	25,00	22,05	2	6,5	2	100,0	0,00	0,00
FU Month 30	13 - 24 months	3	7,3	2	66,7	25,00	11,79	1	3,2	1	100,0	0,00	NE

Screening	<= 12 months	60	100,0	48	80,0	20,60	17,01	70	100,0	55	78,6	24,70	17,86
Cycle 4 Day 1	<= 12 months	48	80,0	35	72,9	14,76	19,18	60	85,7	44	73,3	18,06	16,76
FU Day 28	<= 12 months	54	90,0	39	72,2	16,45	16,50	62	88,6	47	75,8	20,57	19,18
FU Month 3	<= 12 months	53	88,3	38	71,7	11,18	13,46	59	84,3	44	74,6	15,53	16,23
FU Month 6	<= 12 months	46	76,7	35	76,1	13,57	14,59	47	67,1	32	68,1	14,06	16,04
FU Month 9	<= 12 months	35	58,3	27	77,1	12,86	12,64	37	52,9	27	73,0	14,71	12,98
FU Month 12	<= 12 months	27	45,0	21	77,8	15,61	13,19	29	41,4	24	82,8	19,44	17,49
FU Month 15	<= 12 months	22	36,7	16	72,7	14,06	13,17	17	24,3	15	88,2	15,00	13,80
FU Month 18	<= 12 months	16	26,7	10	62,5	11,67	11,25	13	18,6	11	84,6	15,15	14,82
FU Month 21	<= 12 months	9	15,0	5	55,6	5,00	7,45	7	10,0	5	71,4	31,67	32,49
FU Month 24	<= 12 months	6	10,0	3	50,0	8,33	14,43	2	2,9	0	NE	NE	NE
FU Month 27	<= 12 months	1	1,7				NE	NE	1	1,4		NE	NE
FU Month 30	<= 12 months	1	1,7				NE	NE	0	NE		NE	NE
Screening	>24 months	153	100,0	136	88,9	19,91	16,81	141	100,0	117	83,0	22,46	18,16
Cycle 4 Day 1	>24 months	129	84,3	110	85,3	13,81	13,56	134	95,0	105	78,4	16,61	16,11
FU Day 28	>24 months	137	89,5	118	86,1	13,56	15,09	133	94,3	110	82,7	15,71	15,94
FU Month 3	>24 months	135	88,2	116	85,9	12,45	13,92	132	93,6	105	79,5	14,76	15,73
FU Month 6	>24 months	124	81,0	108	87,1	11,01	13,20	115	81,6	91	79,1	15,75	17,81
FU Month 9	>24 months	96	62,7	76	79,2	12,57	15,22	91	64,5	67	73,6	17,45	16,86
FU Month 12	>24 months	76	49,7	63	82,9	11,42	12,90	72	51,1	55	76,4	18,38	16,92
FU Month 15	>24 months	62	40,5	52	83,9	12,50	13,46	52	36,9	40	76,9	18,61	17,71
FU Month 18	>24 months	48	31,4	40	83,3	14,10	16,43	37	26,2	26	70,3	20,09	20,55
FU Month 21	>24 months	32	20,9	24	75,0	16,32	15,44	27	19,1	19	70,4	16,67	18,00
FU Month 24	>24 months	18	11,8	15	83,3	8,89	9,16	13	9,2	11	84,6	10,61	10,60
FU Month 27	>24 months	7	4,6	5	71,4	15,00	9,13	6	4,3	4	66,7	6,25	7,98
FU Month 30	>24 months	3	2,0	2	66,7	12,50	17,68	0	NE	0	NE	NE	NE
High circulating tumor burden													
Screening	Missing	0	NE	0	NE	NE	NE	2	100,0	1	50,0	33,33	NE
Cycle 4 Day 1	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	0,00	NE
FU Day 28	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	16,67	NE
FU Month 3	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	25,00	NE
FU Month 6	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	8,33	NE
FU Month 9	Missing	0	NE			NE	NE	1	50,0			NE	NE
Screening	<25x10**9 cells/L	60	100,0	51	85,0	20,86	17,95	67	100,0	55	82,1	23,69	18,02
Cycle 4 Day 1	<25x10**9 cells/L	50	83,3	41	82,0	16,80	20,71	61	91,0	43	70,5	19,19	19,55
FU Day 28	<25x10**9 cells/L	56	93,3	44	78,6	16,60	17,55	61	91,0	46	75,4	16,30	18,75
FU Month 3	<25x10**9 cells/L	54	90,0	44	81,5	14,02	16,64	59	88,1	44	74,6	12,69	15,72
FU Month 6	<25x10**9 cells/L	50	83,3	41	82,0	17,07	17,87	51	76,1	38	74,5	12,50	18,56
FU Month 9	<25x10**9 cells/L	36	60,0	23	63,9	13,41	14,16	41	61,2	28	68,3	12,50	11,89

FU Month 12	<25x10**9 cells/L	29	48,3	23	79,3	16,18	17,48	34	50,7	23	67,6	19,20	18,88
FU Month 15	<25x10**9 cells/L	24	40,0	19	79,2	14,47	14,66	23	34,3	13	56,5	16,67	19,25
FU Month 18	<25x10**9 cells/L	20	33,3	17	85,0	8,33	8,84	19	28,4	13	68,4	12,18	20,30
FU Month 21	<25x10**9 cells/L	14	23,3	9	64,3	25,00	23,57	10	14,9	7	70,0	5,95	7,93
FU Month 24	<25x10**9 cells/L	8	13,3	4	50,0	20,14	26,39	6	9,0	5	83,3	6,67	10,87
FU Month 27	<25x10**9 cells/L	4	6,7	2	50,0	20,83	29,46	1	1,5	1	100,0	0,00	NE
FU Month 30	<25x10**9 cells/L	4	6,7	2	50,0	16,67	23,57	1	1,5	1	100,0	0,00	NE
Screening	>=25x10**9 cells/L	195	100,0	165	84,6	20,49	17,14	173	100,0	146	84,4	22,09	17,62
Cycle 4 Day 1	>=25x10**9 cells/L	163	83,6	133	81,6	13,47	14,18	162	93,6	131	80,9	16,14	14,63
FU Day 28	>=25x10**9 cells/L	174	89,2	140	80,5	13,47	14,98	163	94,2	136	83,4	16,01	16,25
FU Month 3	>=25x10**9 cells/L	171	87,7	139	81,3	11,63	13,98	161	93,1	129	80,1	15,22	15,09
FU Month 6	>=25x10**9 cells/L	157	80,5	130	82,8	9,53	11,76	140	80,9	108	77,1	15,43	16,06
FU Month 9	>=25x10**9 cells/L	128	65,6	103	80,5	11,43	13,62	107	61,8	83	77,6	16,67	16,03
FU Month 12	>=25x10**9 cells/L	96	49,2	77	80,2	11,08	13,34	83	48,0	69	83,1	16,71	16,04
FU Month 15	>=25x10**9 cells/L	80	41,0	65	81,3	11,67	14,04	62	35,8	50	80,6	16,39	15,58
FU Month 18	>=25x10**9 cells/L	59	30,3	44	74,6	15,09	16,76	41	23,7	32	78,0	18,14	17,22
FU Month 21	>=25x10**9 cells/L	38	19,5	27	71,1	12,65	13,55	30	17,3	21	70,0	21,83	22,43
FU Month 24	>=25x10**9 cells/L	24	12,3	17	70,8	12,25	14,77	12	6,9	9	75,0	9,26	10,58
FU Month 27	>=25x10**9 cells/L	9	4,6	6	66,7	18,06	11,08	8	4,6	5	62,5	5,00	7,45
FU Month 30	>=25x10**9 cells/L	3	1,5	2	66,7	20,83	5,89	0	NE	0	NE	NE	NE

¹ in study: number of subjects in study at respective visit; % based on baseline

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit

² mean: descriptive statistics - absolute values Clinical

cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/t_pro_mean.sas

Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/t_pro_mean_sg_EQCLL16_IT_label_09MAY2013_21004.xls 04MAR2020

17:21

POPULATION: Labelpopulation, Intent-to-Treat Patients
 ENDPOINT: EORTC QoL 16
 MODEL: Unadjusted Analysis
 STUDY: CLL11 (BO21004), Stage 2
 Compliance/Mean

Fatigue Scale

		GClb (N=255)						RC1b (N=242)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study ¹	%	with value ¹	%	Mean ²	SD(mean)	in study ¹	%	with value ¹	%	Mean ²	SD(mean)
All													
Screening	n/a	255	100,0	216	84,7	29,09	25,29	242	100,0	202	83,5	29,87	24,36
Cycle 4 Day 1	n/a	213	83,5	174	81,7	21,07	21,50	224	92,6	175	78,1	24,48	20,97
FU Day 28	n/a	230	90,2	183	79,6	23,59	25,15	225	93,0	183	81,3	22,59	22,17
FU Month 3	n/a	225	88,2	183	81,3	22,50	24,01	221	91,3	174	78,7	23,47	22,17
FU Month 6	n/a	207	81,2	171	82,6	21,64	22,43	192	79,3	148	77,1	25,23	24,24
FU Month 9	n/a	164	64,3	126	76,8	21,83	23,61	149	61,6	111	74,5	23,87	23,21
FU Month 12	n/a	125	49,0	101	80,8	24,92	25,67	117	48,3	92	78,6	23,91	24,37
FU Month 15	n/a	104	40,8	84	80,8	19,44	19,84	85	35,1	63	74,1	24,87	25,20
FU Month 18	n/a	79	31,0	62	78,5	23,12	24,40	60	24,8	45	75,0	28,52	29,22
FU Month 21	n/a	52	20,4	36	69,2	23,15	24,33	40	16,5	28	70,0	29,76	28,09
FU Month 24	n/a	32	12,5	21	65,6	25,40	24,51	18	7,4	14	77,8	17,86	23,99
FU Month 27	n/a	13	5,1	8	61,5	35,42	32,66	9	3,7	6	66,7	16,67	40,82
FU Month 30	n/a	7	2,7	4	57,1	29,17	28,46	1	0,4	1	100,0	16,67	NE
Gender													
Screening	Female	97	100,0	82	84,5	33,33	25,39	95	100,0	74	77,9	35,14	29,14
Cycle 4 Day 1	Female	84	86,6	67	79,8	25,37	23,09	88	92,6	67	76,1	31,59	23,23
FU Day 28	Female	90	92,8	75	83,3	24,89	23,15	91	95,8	70	76,9	24,05	25,79
FU Month 3	Female	88	90,7	73	83,0	25,57	25,17	87	91,6	63	72,4	29,37	24,45
FU Month 6	Female	84	86,6	64	76,2	25,78	23,56	77	81,1	56	72,7	26,49	23,52
FU Month 9	Female	70	72,2	52	74,3	26,60	25,62	61	64,2	39	63,9	28,63	23,24
FU Month 12	Female	56	57,7	45	80,4	27,78	26,59	47	49,5	34	72,3	29,90	28,66
FU Month 15	Female	47	48,5	37	78,7	23,42	19,82	33	34,7	24	72,7	26,39	28,20
FU Month 18	Female	34	35,1	25	73,5	26,67	23,07	26	27,4	19	73,1	35,96	33,91
FU Month 21	Female	21	21,6	11	52,4	34,85	30,23	17	17,9	12	70,6	38,89	33,58
FU Month 24	Female	12	12,4	6	50,0	41,67	22,97	6	6,3	3	50,0	5,56	9,62
FU Month 27	Female	6	6,2	2	33,3	66,67	47,14	2	2,1	1	50,0	0,00	NE
FU Month 30	Female	4	4,1	1	25,0	66,67	NE	1	1,1	1	100,0	16,67	NE

Screening	Male	158	100,0	134	84,8	26,49	24,97	147	100,0	128	87,1	26,82	20,62					
Cycle 4 Day 1	Male	129	81,6	107	82,9	18,38	20,08	136	92,5	108	79,4	20,06	18,19					
FU Day 28	Male	140	88,6	108	77,1	22,69	26,52	134	91,2	113	84,3	21,68	19,66					
FU Month 3	Male	137	86,7	110	80,3	20,45	23,10	134	91,2	111	82,8	20,12	20,12					
FU Month 6	Male	123	77,8	107	87,0	19,16	21,45	115	78,2		92	80,0	24,46	24,76				
FU Month 9	Male		94	59,5		74	78,7	18,47	21,65		88	59,9		72	81,8	21,30	22,93	
FU Month 12	Male		69	43,7		56	81,2	22,62	24,91		70	47,6		58	82,9	20,40	20,95	
FU Month 15	Male		57	36,1		47	82,5	16,31	19,50		52	35,4		39	75,0	23,93	23,51	
FU Month 18	Male		45	28,5		37	82,2	20,72	25,28		34	23,1		26	76,5	23,08	24,53	
FU Month 21	Male		31	19,6		25	80,6	18,00	19,79		23	15,6		16	69,6	22,92	21,84	
FU Month 24	Male		20	12,7		15	75,0	18,89	22,60		12	8,2		11	91,7	21,21	25,92	
FU Month 27	Male		7	4,4		6	85,7	25,00	22,97		7	4,8		5	71,4	20,00	44,72	
FU Month 30	Male		3	1,9		3	100,0	16,67	16,67		0	NE		0	NE	NE	NE	
Age																		
Screening	<75 years	130	100,0	102	78,5	28,10	27,25	120	100,0		91	75,8		26,01		22,39		
Cycle 4 Day 1	<75 years	106	81,5		81	76,4	19,34	20,66	112		93,3		82	73,2		21,34	20,16	
FU Day 28	<75 years	119	91,5		91	76,5	20,51	23,71	110		91,7		86	78,2		19,19	21,01	
FU Month 3	<75 years	116	89,2		91	78,4	20,33	23,01	109		90,8		82	75,2		19,31	20,53	
FU Month 6	<75 years	108	83,1		86	79,6	19,19	20,85		99	82,5		71	71,7		22,77	22,40	
FU Month 9	<75 years		85	65,4		66	77,6	19,70	22,05		74	61,7		54	73,0		21,30	20,84
FU Month 12	<75 years		63	48,5		53	84,1	22,96	22,46		60	50,0		47	78,3		22,70	22,90
FU Month 15	<75 years		54	41,5		42	77,8	19,84	19,56		44	36,7		32	72,7		20,31	23,08
FU Month 18	<75 years		43	33,1		34	79,1	20,59	23,59		27	22,5		20	74,1		25,83	28,34
FU Month 21	<75 years		26	20,0		20	76,9	26,67	22,56		17	14,2		11	64,7		22,73	25,03
FU Month 24	<75 years		18	13,8		12	66,7	25,00	21,90		6	5,0		4	66,7		16,67	19,25
FU Month 27	<75 years		7	5,4		4	57,1	33,33	23,57		2	1,7		1	50,0		0,00	NE
FU Month 30	<75 years		4	3,1		2	50,0	25,00	11,79		0	NE		0	NE		NE	NE
Age																		
Screening	>=75 years	125	100,0	114	91,2	29,97	23,48	122	100,0	111	91,0	33,03	25,52					
Cycle 4 Day 1	>=75 years	107	85,6		93	86,9	22,58	22,20	112		91,8		93	83,0		27,24	21,39	
FU Day 28	>=75 years	111	88,8		92	82,9	26,63	26,27	115		94,3		97	84,3		25,60	22,83	
FU Month 3	>=75 years	109	87,2		92	84,4	24,64	24,89	112		91,8		92	82,1		27,17	23,01	
FU Month 6	>=75 years		99	79,2		85	85,9	24,12	23,78		93	76,2		77	82,8		27,49	25,76
FU Month 9	>=75 years		79	63,2		60	75,9	24,17	25,20		75	61,5		57	76,0		26,32	25,19
FU Month 12	>=75 years		62	49,6		48	77,4	27,08	28,89		57	46,7		45	78,9		25,19	26,02
FU Month 15	>=75 years		50	40,0		42	84,0	19,05	20,35		41	33,6		31	75,6		29,57	26,77
FU Month 18	>=75 years		36	28,8		28	77,8	26,19	25,43		33	27,0		25	75,8		30,67	30,31
FU Month 21	>=75 years		26	20,8		16	61,5	18,75	26,44		23	18,9		17	73,9		34,31	29,74
FU Month 24	>=75 years		14	11,2		9	64,3	25,93	29,00		12	9,8		10	83,3		18,33	26,59
FU Month 27	>=75 years		6	4,8		4	66,7	37,50	43,83		7	5,7		5	71,4		20,00	44,72

FU Month 30	>=75 years	3	2,4	2	66,7	33,33	47,14	1	0,8	1	100,0	16,67	NE	
Race														
Screening	Other	9	100,0	6	66,7	27,78	17,21	11	100,0	7	63,6	35,71	22,42	
Cycle 4 Day 1	Other	7	77,8	4	57,1	16,67	19,25	10	90,9	6	60,0	19,44	16,39	
FU Day 28	Other	8	88,9	5	62,5	16,67	11,79	10	90,9	7	70,0	7,14	13,11	
FU Month 3	Other	8	88,9	4	50,0	25,00	21,52	10	90,9	6	60,0	16,67	10,54	
FU Month 6	Other	8	88,9	4	50,0	16,67	13,61	8	72,7	6	75,0	11,11	13,61	
FU Month 9	Other	4	44,4	3	75,0	11,11	9,62	5	45,5	4	80,0	25,00	21,52	
FU Month 12	Other	3	33,3	2	66,7	16,67	0,00	4	36,4	4	100,0	16,67	13,61	
FU Month 15	Other	2	22,2	1	50,0	16,67		NE	4	36,4	4	100,0	12,50	25,00
FU Month 18	Other	2	22,2	1	50,0	0,00		NE	2	18,2	2	100,0	16,67	23,57
FU Month 21	Other	2	22,2	1	50,0	0,00		NE	2	18,2	2	100,0	16,67	23,57
FU Month 24	Other	2	22,2	1	50,0	0,00		NE	1	9,1	0	NE	NE	NE
FU Month 27	Other	1	11,1				NE	NE	1	9,1			NE	NE
FU Month 30	Other	1	11,1				NE	NE	0	NE			NE	NE
Screening														
Screening	White	246	100,0	210	85,4	29,13	25,51	231	100,0	195	84,4	29,66	24,45	
Cycle 4 Day 1	White	206	83,7	170	82,5	21,18	21,59	214	92,6	169	79,0	24,65	21,14	
FU Day 28	White	222	90,2	178	80,2	23,78	25,41	215	93,1	176	81,9	23,20	22,25	
FU Month 3	White	217	88,2	179	82,5	22,44	24,11	211	91,3	168	79,6	23,71	22,45	
FU Month 6	White	199	80,9	167	83,9	21,76	22,61	184	79,7	142	77,2	25,82	24,44	
FU Month 9	White	160	65,0	123	76,9	22,09	23,81	144	62,3	107	74,3	23,83	23,36	
FU Month 12	White	122	49,6	99	81,1	25,08	25,90	113	48,9	88	77,9	24,24	24,75	
FU Month 15	White	102	41,5	83	81,4	19,48	19,96	81	35,1	59	72,8	25,71	25,20	
FU Month 18	White	77	31,3	61	79,2	23,50	24,41	58	25,1	43	74,1	29,07	29,57	
FU Month 21	White	50	20,3	35	70,0	23,81	24,35	38	16,5	26	68,4	30,77	28,55	
FU Month 24	White	30	12,2	20	66,7	26,67	24,42	17	7,4	14	82,4	17,86	23,99	
FU Month 27	White	12	4,9	8	66,7	35,42	32,66	8	3,5	6	75,0	16,67	40,82	
FU Month 30	White	6	2,4	4	66,7	29,17	28,46	1	0,4	1	100,0	16,67	NE	
Geographical Region														
Screening	Asia-Pacific	20	100,0	19	95,0	41,23	31,61	18	100,0	18	100,0	46,30	25,92	
Cycle 4 Day 1	Asia-Pacific	15	75,0	14	93,3	25,00	21,43	16	88,9	15	93,8	33,33	21,82	
FU Day 28	Asia-Pacific	18	90,0	18	100,0	28,70	30,14	18	100,0	16	88,9	25,00	28,54	
FU Month 3	Asia-Pacific	18	90,0	16	88,9	25,00	22,77	18	100,0	15	83,3	33,33	26,73	
FU Month 6	Asia-Pacific	16	80,0	14	87,5	28,57	32,31	17	94,4	14	82,4	32,14	29,57	
FU Month 9	Asia-Pacific	14	70,0	12	85,7	19,44	25,46	13	72,2	10	76,9	38,33	26,12	
FU Month 12	Asia-Pacific	10	50,0	8	80,0	20,83	14,77	10	55,6	10	100,0	35,00	32,82	
FU Month 15	Asia-Pacific	8	40,0	6	75,0	8,33	13,94	9	50,0	9	100,0	35,19	34,81	
FU Month 18	Asia-Pacific	6	30,0	4	66,7	0,00	0,00	6	33,3	6	100,0	38,89	25,09	

FU Month 21	Asia-Pacific	525,0	360,0	0,00	0,00	422,2	4100,0	37,50	34,36		
FU Month 24	Asia-Pacific	315,0	266,7	0,00	0,00	15,6	0	NE	NE	NE	
FU Month 27	Asia-Pacific	15,0		NE	NE	15,6			NE	NE	
FU Month 30	Asia-Pacific	15,0		NE	NE	0	NE		NE	NE	
Screening	Central and South America	3100,0	3100,0	27,78	9,62	2100,0	2100,0	33,33	23,57		
Cycle 4 Day 1	Central and South America	3100,0	3100,0	22,22	19,25	2100,0	2100,0	8,33	11,79		
FU Day 28	Central and South America	3100,0	3100,0	16,67	0,00	2100,0	2100,0	8,33	11,79		
FU Month 3	Central and South America	3100,0	3100,0	22,22	25,46	2100,0	2100,0	8,33	11,79		
FU Month 6	Central and South America	266,7	2100,0	25,00	11,79	2100,0	2100,0	16,67	0,00		
FU Month 9	Central and South America	266,7	2100,0	16,67	0,00	150,0	1100,0	0,00		NE	
FU Month 12	Central and South America	266,7	2100,0	16,67	0,00	150,0	1100,0	33,33		NE	
FU Month 15	Central and South America	133,3	1100,0	0,00		0	NE	0	NE	NE	NE
FU Month 18	Central and South America	133,3	1100,0	16,67		0	NE	0	NE	NE	NE
FU Month 21	Central and South America	133,3	1100,0	0,00		0	NE	0	NE	NE	NE
FU Month 24	Central and South America	133,3	1100,0	0,00		0	NE	0	NE	NE	NE
Screening	North America	12100,0	12100,0	48,61	27,94	13100,0	1292,3	34,72	25,08		
Cycle 4 Day 1	North America	975,0	9100,0	33,33	14,43	1292,3	12100,0	26,39	20,67		
FU Day 28	North America	1191,7	11100,0	24,24	21,56	13100,0	13100,0	25,64	18,78		
FU Month 3	North America	1191,7	11100,0	37,88	23,68	1292,3	12100,0	20,83	16,09		
FU Month 6	North America	1191,7	1090,9	31,67	30,88	1184,6	11100,0	33,33	25,82		
FU Month 9	North America	866,7	8100,0	33,33	29,55	969,2	9100,0	35,19	13,03		
FU Month 12	North America	866,7	787,5	33,33	33,33	753,8	7100,0	23,81	18,90		
FU Month 15	North America	650,0	6100,0	27,78	22,77	646,2	583,3	46,67	32,06		
FU Month 18	North America	433,3	4100,0	33,33	13,61	323,1	3100,0	44,44	34,69		
FU Month 21	North America	325,0	266,7	33,33	0,00	17,7	1100,0	33,33		NE	
FU Month 24	North America	325,0	266,7	50,00	23,57	17,7	1100,0	83,33		NE	
FU Month 27	North America	216,7	150,0	33,33		17,7	1100,0	100,00		NE	
Screening	Other	45100,0	1737,8	30,39	22,23	44100,0	1636,4	30,21	20,38		
Cycle 4 Day 1	Other	3782,2	1437,8	20,24	16,25	4090,9	1435,0	22,62	18,03		
FU Day 28	Other	3782,2	1437,8	17,86	15,28	3988,6	1435,9	19,05	20,52		
FU Month 3	Other	3884,4	1539,5	16,67	15,43	3886,4	1436,8	21,43	21,11		
FU Month 6	Other	3577,8	1542,9	22,22	12,06	3375,0	1133,3	30,30	22,13		
FU Month 9	Other	2657,8	1246,2	22,22	19,25	2454,5	833,3	22,92	26,63		
FU Month 12	Other	1737,8	847,1	27,08	21,71	1636,4	637,5	30,56	22,15		
FU Month 15	Other	1226,7	433,3	20,83	15,96	920,5	333,3	22,22	19,25		
FU Month 18	Other	1022,2	330,0	16,67	16,67	715,9	228,6	25,00	35,36		
FU Month 21	Other	715,6	228,6	33,33	0,00	49,1	0	NE	NE	NE	
FU Month 24	Other	613,3	116,7	33,33		36,8	0	NE	NE	NE	
FU Month 27	Other	48,9	125,0	33,33		12,3	0	NE	NE	NE	

FU Month 30	Other		24,4				NE	NE	0	NE			NE	NE
Screening	Western Europe	175	100,0	165	94,3	26,16	23,94	165	100,0	154	93,3	27,49	23,99	
Cycle 4 Day 1	Western Europe	149	85,1	134	89,9	19,90	22,34	154	93,3	132	85,7	23,74	21,21	
FU Day 28	Western Europe	161	92,0	137	85,1	23,60	25,85	153	92,7	138	90,2	22,58	22,04	
FU Month 3	Western Europe	155	88,6	138	89,0	21,62	24,70	151	91,5	131	86,8	23,03	22,21	
FU Month 6	Western Europe	143	81,7	130	90,9	20,00	21,41	129	78,2	110	85,3	23,18	23,69	
FU Month 9	Western Europe	114	65,1	92	80,7	21,20	23,71	102	61,8	83	81,4	21,29	22,74	
FU Month 12	Western Europe	88	50,3	76	86,4	24,56	26,73	83	50,3	68	81,9	21,57	23,76	
FU Month 15	Western Europe	77	44,0	67	87,0	19,90	20,15	61	37,0	46	75,4	20,65	21,43	
FU Month 18	Western Europe	58	33,1	50	86,2	24,67	25,70	44	26,7	34	77,3	25,49	29,65	
FU Month 21	Western Europe	36	20,6	28	77,8	25,00	25,86	31	18,8	23	74,2	28,26	28,17	
FU Month 24	Western Europe	19	10,9	15	78,9	26,67	24,23	13	7,9	13	100,0	12,82	15,45	
FU Month 27	Western Europe	6	3,4	6	100,0	36,11	38,61	6	3,6	5	83,3	0,00	0,00	
FU Month 30	Western Europe	4	2,3	4	100,0	29,17	28,46	1	0,6	1	100,0	16,67		NE
FCgamma receptor IIa														
Screening	131HH	58	100,0	46	79,3	32,61	27,21	76	100,0	60	78,9	28,06	25,21	
Cycle 4 Day 1	131HH	49	84,5	35	71,4	24,29	19,11	65	85,5	48	73,8	22,22	19,55	
FU Day 28	131HH	51	87,9	38	74,5	21,93	20,17	70	92,1	51	72,9	17,65	19,27	
FU Month 3	131HH	51	87,9	40	78,4	26,25	21,64	64	84,2	45	70,3	21,11	18,60	
FU Month 6	131HH	49	84,5	39	79,6	27,35	23,41	55	72,4	40	72,7	22,50	23,74	
FU Month 9	131HH	39	67,2	25	64,1	21,33	19,56	41	53,9	31	75,6	23,12	23,04	
FU Month 12	131HH	28	48,3	21	75,0	36,51	27,19	34	44,7	28	82,4	22,02	20,31	
FU Month 15	131HH	23	39,7	17	73,9	25,49	22,91	24	31,6	19	79,2	16,67	18,43	
FU Month 18	131HH	17	29,3	12	70,6	26,39	25,08	16	21,1	12	75,0	27,78	33,58	
FU Month 21	131HH	13	22,4	8	61,5	27,08	34,43	11	14,5	9	81,8	44,44	39,97	
FU Month 24	131HH	11	19,0	7	63,6	30,95	27,94	1	1,3	1	100,0	0,00		NE
FU Month 27	131HH	4	6,9	3	75,0	50,00	50,00	1	1,3	1	100,0	0,00		NE
FU Month 30	131HH	3	5,2	2	66,7	41,67	35,36	0	NE	0	NE	NE		NE
Screening	131HR	125	100,0	108	86,4	29,78	24,76	114	100,0	101	88,6	29,21	22,29	
Cycle 4 Day 1	131HR	105	84,0	89	84,8	23,03	23,23	110	96,5	93	84,5	24,01	21,06	
FU Day 28	131HR	116	92,8	96	82,8	27,60	29,00	105	92,1	92	87,6	24,46	22,30	
FU Month 3	131HR	114	91,2	95	83,3	21,75	25,16	107	93,9	89	83,2	24,16	24,10	
FU Month 6	131HR	104	83,2	86	82,7	20,35	20,99	95	83,3	77	81,1	27,27	25,21	
FU Month 9	131HR	84	67,2	66	78,6	25,51	26,35	76	66,7	58	76,3	22,70	23,92	
FU Month 12	131HR	64	51,2	54	84,4	22,84	25,76	57	50,0	46	80,7	25,00	26,93	
FU Month 15	131HR	53	42,4	42	79,2	20,63	19,06	44	38,6	32	72,7	26,56	26,39	
FU Month 18	131HR	43	34,4	34	79,1	25,49	24,70	32	28,1	25	78,1	25,33	24,59	
FU Month 21	131HR	26	20,8	17	65,4	29,41	22,46	21	18,4	15	71,4	25,56	17,67	
FU Month 24	131HR	12	9,6	8	66,7	29,17	23,15	12	10,5	10	83,3	21,67	26,12	

FU Month 27	131HR	64,8	350,0	38,89	9,62	65,3	466,7	25,00	50,00		
FU Month 30	131HR	32,4	133,3	33,33	NE	10,9	1100,0	16,67	NE		
Screening	131RR	49100,0	4183,7	26,83	25,79	33100,0	2884,8	26,79	23,72		
Cycle 4 Day 1	131RR	4081,6	3382,5	14,65	16,01	3193,9	2477,4	27,08	24,48		
FU Day 28	131RR	4285,7	3173,8	17,74	16,06	3297,0	2887,5	20,24	23,73		
FU Month 3	131RR	3979,6	3179,5	22,04	24,11	3297,0	2887,5	21,43	20,72		
FU Month 6	131RR	3571,4	2982,9	21,26	24,76	2781,8	2281,5	21,21	21,93		
FU Month 9	131RR	2449,0	2083,3	16,67	20,23	1957,6	1684,2	22,92	20,07		
FU Month 12	131RR	1836,7	1583,3	22,22	24,93	1751,5	1482,4	23,81	23,31		
FU Month 15	131RR	1632,7	1487,5	13,10	20,86	1133,3	981,8	22,22	18,63		
FU Month 18	131RR	1428,6	1285,7	19,44	25,46	824,2	787,5	33,33	34,69		
FU Month 21	131RR	816,3	675,0	11,11	13,61	515,2	480,0	12,50	15,96		
FU Month 24	131RR	510,2	360,0	11,11	19,25	39,1	3100,0	11,11	19,25		
FU Month 27	131RR	24,1	150,0	0,00	NE	13,0	1100,0	0,00	NE		
FU Month 30	131RR	12,0	1100,0	0,00	NE	0	NE	NE	NE		
Screening	Missing	23100,0	2191,3	22,22	22,57	19100,0	1368,4	50,00	30,43		
Cycle 4 Day 1	Missing	1982,6	1789,5	16,67	24,30	1894,7	1055,6	33,33	17,57		
FU Day 28	Missing	2191,3	1885,7	15,74	22,49	1894,7	1266,7	34,72	25,08		
FU Month 3	Missing	2191,3	1781,0	18,63	23,48	1894,7	1266,7	31,94	22,98		
FU Month 6	Missing	1982,6	1789,5	15,69	22,42	1578,9	960,0	29,63	24,69		
FU Month 9	Missing	1773,9	1588,2	13,33	19,11	1368,4	646,2	41,67	22,97		
FU Month 12	Missing	1565,2	1173,3	16,67	18,26	947,4	444,4	25,00	31,91		
FU Month 15	Missing	1252,2	1191,7	13,64	14,56	631,6	350,0	66,67	33,33		
FU Month 18	Missing	521,7	480,0	4,17	8,33	421,1	125,0	83,33	NE		
FU Month 21	Missing	521,7	5100,0	10,00	14,91	315,8	0	NE	NE		
FU Month 24	Missing	417,4	375,0	16,67	28,87	210,5	0	NE	NE		
FU Month 27	Missing	14,3	1100,0	16,67	NE	15,3	0	NE	NE		
FCgamma receptor IIIa											
Screening	158FF	103	100,0	9289,3	30,25	25,43	83100,0	7286,7	29,63	22,59	
Cycle 4 Day 1	158FF	8986,4	7483,1	20,05	21,54	7894,0	6482,1	23,70	21,58		
FU Day 28	158FF	9693,2	7881,3	23,93	25,28	7894,0	6785,9	19,65	19,66		
FU Month 3	158FF	9491,3	7680,9	20,83	25,11	7894,0	6583,3	18,72	16,80		
FU Month 6	158FF	8683,5	6980,2	20,77	24,98	6477,1	5382,8	19,81	20,94		
FU Month 9	158FF	7168,9	5678,9	22,92	25,34	4756,6	4187,2	23,58	21,40		
FU Month 12	158FF	4846,6	4185,4	23,98	27,40	3845,8	3489,5	19,61	17,63		
FU Month 15	158FF	3735,9	3183,8	19,35	22,40	3036,1	2376,7	21,74	24,84		
FU Month 18	158FF	2726,2	2281,5	24,24	25,58	2125,3	1781,0	27,45	29,43		
FU Month 21	158FF	1615,5	1593,8	22,22	23,29	910,8	888,9	25,00	33,33		
FU Month 24	158FF	87,8	787,5	23,81	25,20	33,6	3100,0	11,11	19,25		

FU Month 27	158FF	54,9	480,0	20,83	25,00	1	1,2	1	100,0	0,00	NE
FU Month 30	158FF	32,9	3100,0	16,67	16,67	0	NE	0	NE	NE	NE
Screening	158FV	119	100,0	9882,4	27,89	24,50	109	100,0	9082,6	29,81	24,03
Cycle 4 Day 1	158FV	99	83,2	8080,8	22,29	21,21	100	91,7	7777,0	25,54	21,56
FU Day 28	158FV	105	88,2	8278,1	23,37	23,11	101	92,7	8180,2	23,66	22,95
FU Month 3	158FV	101	84,9	8483,2	24,21	22,32	97	89,0	7577,3	25,78	23,62
FU Month 6	158FV	94	79,0	8085,1	22,50	19,68	83	76,1	6477,1	27,34	26,12
FU Month 9	158FV	71	59,7	5374,6	20,44	20,58	65	59,6	4670,8	24,28	22,96
FU Month 12	158FV	60	50,4	5083,3	25,33	25,03	52	47,7	4178,8	28,05	29,21
FU Month 15	158FV	52	43,7	4178,8	19,51	17,44	36	33,0	2980,6	29,31	28,05
FU Month 18	158FV	44	37,0	3477,3	23,53	24,66	24	22,0	2083,3	35,00	31,94
FU Month 21	158FV	28	23,5	1450,0	26,19	28,28	18	16,5	1477,8	38,10	27,29
FU Month 24	158FV	18	15,1	950,0	27,78	27,64	6	5,5	583,3	20,00	13,94
FU Month 27	158FV	6	5,0	233,3	66,67	47,14	2	1,8	150,0	0,00	NE
FU Month 30	158FV	4	3,4	125,0	66,67	NE	0	NE	0	NE	NE
Screening	158VV	16	100,0	1275,0	37,50	35,62	33	100,0	2987,9	27,01	24,16
Cycle 4 Day 1	158VV	12	75,0	975,0	16,67	18,63	30	90,9	2686,7	21,79	18,12
FU Day 28	158VV	14	87,5	1178,6	28,79	38,79	30	90,9	2686,7	21,15	22,39
FU Month 3	158VV	15	93,8	1066,7	21,67	30,48	30	90,9	2480,0	23,61	27,33
FU Month 6	158VV	14	87,5	1178,6	21,21	24,82	30	90,9	2273,3	27,27	24,96
FU Month 9	158VV	12	75,0	975,0	29,63	30,93	25	75,8	1976,0	21,93	27,25
FU Month 12	158VV	8	50,0	562,5	40,00	25,28	20	60,6	1680,0	19,79	20,38
FU Month 15	158VV	8	50,0	675,0	30,56	26,70	14	42,4	1071,4	18,33	16,57
FU Month 18	158VV	4	25,0	375,0	27,78	25,46	11	33,3	872,7	14,58	16,52
FU Month 21	158VV	3	18,8	266,7	41,67	11,79	9	27,3	666,7	16,67	18,26
FU Month 24	158VV	2	12,5	2100,0	33,33	0,00	7	21,2	685,7	19,44	34,02
FU Month 27	158VV	1	6,3	1100,0	50,00	NE	5	15,2	480,0	25,00	50,00
FU Month 30	158VV	0	NE	0	NE	NE	1	3,0	1100,0	16,67	NE
Screening	Missing	17	100,0	1482,4	22,62	19,18	17	100,0	1164,7	39,39	37,47
Cycle 4 Day 1	Missing	13	76,5	1184,6	22,73	27,15	16	94,1	850,0	29,17	21,36
FU Day 28	Missing	15	88,2	1280,0	18,06	25,08	16	94,1	956,3	38,89	27,64
FU Month 3	Missing	15	88,2	1386,7	21,79	24,89	16	94,1	1062,5	36,67	23,31
FU Month 6	Missing	13	76,5	1184,6	21,21	24,82	15	88,2	960,0	37,04	23,24
FU Month 9	Missing	10	58,8	880,0	14,58	22,60	12	70,6	541,7	30,00	29,81
FU Month 12	Missing	9	52,9	555,6	13,33	13,94	7	41,2	114,3	66,67	NE
FU Month 15	Missing	7	41,2	685,7	8,33	9,13	5	29,4	120,0	33,33	NE
FU Month 18	Missing	4	23,5	375,0	5,56	9,62	4	23,5	0	NE	NE
FU Month 21	Missing	5	29,4	5100,0	10,00	14,91	4	23,5	0	NE	NE
FU Month 24	Missing	4	23,5	375,0	16,67	28,87	2	11,8	0	NE	NE

FU Month 27	Missing		15,9		1100,0	16,67		NE		15,9		0		NE		NE		NE
Binet Staging at baseline																		
Screening	A		59100,0		5694,9	31,25	27,35		57100,0		4782,5	30,50		26,31				
Cycle 4 Day 1	A		5186,4		4588,2	22,59	20,77		5494,7		4583,3	31,11		24,26				
FU Day 28	A		5898,3		5187,9	25,16	25,25		5494,7		4583,3	28,89		26,69				
FU Month 3	A		5796,6		5494,7	27,16	27,15		5393,0		4483,0	29,92		27,27				
FU Month 6	A		5694,9		4783,9	25,53	24,29		4578,9		3680,0	34,26		32,11				
FU Month 9	A		4372,9		3581,4	27,14	26,53		3459,6		2676,5	31,41		28,02				
FU Month 12	A		3661,0		3288,9	27,60	29,52		2442,1		1875,0	34,26		29,96				
FU Month 15	A		3050,8		2583,3	17,33	19,53		1933,3		1789,5	25,49		29,53				
FU Month 18	A		2237,3		1568,2	22,22	20,57		1628,1		1487,5	35,71		31,93				
FU Month 21	A		1728,8		1376,5	19,23	27,93		814,0		562,5	23,33		22,36				
FU Month 24	A		1016,9		660,0	30,56	32,35		58,8		480,0	12,50		15,96				
FU Month 27	A		58,5		360,0	50,00	50,00		23,5		150,0	0,00						NE
FU Month 30	A		46,8		375,0	38,89	25,46		0	NE	0	NE		NE				NE
Screening																		
Screening	B	104	100,0		8480,8	26,79	21,80		85100,0		7082,4	30,95		25,11				
Cycle 4 Day 1	B		8884,6		7281,8	19,68	20,43		7992,9		6379,7	21,43		18,80				
FU Day 28	B		9187,5		7076,9	23,57	26,99		7992,9		6379,7	21,96		18,89				
FU Month 3	B		8884,6		6675,0	17,93	21,94		7992,9		6278,5	21,77		20,38				
FU Month 6	B		8076,9		6885,0	17,89	19,81		7082,4		5274,3	25,00		21,52				
FU Month 9	B		6360,6		4876,2	21,88	23,86		5969,4		4474,6	23,86		20,77				
FU Month 12	B		4745,2		3574,5	25,24	25,68		4654,1		3780,4	24,32		24,09				
FU Month 15	B		3735,6		3183,8	20,97	22,35		3440,0		2573,5	25,33		22,63				
FU Month 18	B		3129,8		2683,9	25,00	26,35		2225,9		1777,3	20,59		23,96				
FU Month 21	B		1817,3		1266,7	27,78	24,96		1720,0		1376,5	21,79		17,19				
FU Month 24	B		1110,6		872,7	20,83	24,80		89,4		787,5	19,05		31,07				
FU Month 27	B		54,8		360,0	22,22	25,46		44,7		4100,0	25,00		50,00				
FU Month 30	B		21,9		150,0	0,00		NE	0	NE	0	NE		NE				NE
Screening																		
Screening	C		92100,0		7682,6	30,04	27,35	100	100,0		8585,0	28,63		22,80				
Cycle 4 Day 1	C		7480,4		5777,0	21,64	23,56		9191,0		6773,6	22,89		19,86				
FU Day 28	C		8188,0		6276,5	22,31	23,17		9292,0		7581,5	19,33		21,23				
FU Month 3	C		8087,0		6378,8	23,28	22,71		8989,0		6876,4	20,83		19,40				
FU Month 6	C		7177,2		5678,9	22,92	23,48		7777,0		6077,9	20,00		19,36				
FU Month 9	C		5863,0		4374,1	17,44	20,23		5656,0		4173,2	19,11		21,59				
FU Month 12	C		4245,7		3481,0	22,06	21,99		4747,0		3778,7	18,47		20,33				
FU Month 15	C		3740,2		2875,7	19,64	17,60		3232,0		2165,6	23,81		25,59				
FU Month 18	C		2628,3		2180,8	21,43	25,35		2222,0		1463,6	30,95		31,93				
FU Month 21	C		1718,5		1164,7	22,73	20,10		1515,0		1066,7	43,33		37,84				
FU Month 24	C		1112,0		763,6	26,19	18,90		55,0		360,0	22,22		19,25				

FU Month 27	C		33,3		266,7	33,33	0,00		33,0		133,3	0,00		NE
FU Month 30	C		11,1		0	NE	NE	NE	11,0		1100,0	16,67		NE
Total CIR score at baseline														
Screening	<=6		63100,0		5384,1	27,67	22,87		75100,0		6282,7	30,65	23,41	
Cycle 4 Day 1	<=6		5282,5		3873,1	20,18	20,92		7296,0		5373,6	20,75	16,95	
FU Day 28	<=6		5688,9		4580,4	20,74	21,66		7296,0		5373,6	17,61	16,80	
FU Month 3	<=6		5587,3		4276,4	23,02	22,07		6992,0		4971,0	18,71	16,88	
FU Month 6	<=6		5282,5		4382,7	22,09	22,63		6080,0		4575,0	21,85	20,67	
FU Month 9	<=6		4368,3		3376,7	18,69	22,34		4762,7		3574,5	21,90	24,84	
FU Month 12	<=6		3555,6		2880,0	23,81	25,43		3445,3		2779,4	19,14	23,89	
FU Month 15	<=6		3250,8		2887,5	17,26	18,97		2533,3		1664,0	15,63	22,33	
FU Month 18	<=6		2336,5		2087,0	27,50	29,75		1925,3		1473,7	26,19	31,16	
FU Month 21	<=6		1422,2		857,1	22,92	23,46		1418,7		1071,4	30,00	30,23	
FU Month 24	<=6		812,7		787,5	21,43	20,89		79,3		685,7	13,89	16,39	
FU Month 27	<=6		23,2		2100,0	33,33	0,00		45,3		250,0	0,00	0,00	
FU Month 30	<=6		0	NE	0	NE	NE	NE	11,3		1100,0	16,67		NE
Screening >6														
Screening	>6		192100,0		16384,9	29,55	26,08		167100,0		14083,8	29,52	24,84	
Cycle 4 Day 1	>6		16183,9		13684,5	21,32	21,73		15291,0		12280,3	26,09	22,37	
FU Day 28	>6		17490,6		13879,3	24,52	26,19		15391,6		13085,0	24,62	23,77	
FU Month 3	>6		17088,5		14182,9	22,34	24,63		15291,0		12582,2	25,33	23,72	
FU Month 6	>6		15580,7		12882,6	21,48	22,44		13279,0		10378,0	26,70	25,60	
FU Month 9	>6		12163,0		9376,9	22,94	24,07		10261,1		7674,5	24,78	22,52	
FU Month 12	>6		9046,9		7381,1	25,34	25,93		8349,7		6578,3	25,90	24,48	
FU Month 15	>6		7237,5		5677,8	20,54	20,35		6035,9		4778,3	28,01	25,56	
FU Month 18	>6		5629,2		4275,0	21,03	21,48		4124,6		3175,6	29,57	28,77	
FU Month 21	>6		3819,8		2873,7	23,21	24,99		2615,6		1869,2	29,63	27,75	
FU Month 24	>6		2412,5		1458,3	27,38	26,64		116,6		872,7	20,83	29,21	
FU Month 27	>6		115,7		654,5	36,11	38,61		53,0		480,0	25,00	50,00	
FU Month 30	>6		73,6		457,1	29,17	28,46		0	NE	0	NE	NE	NE
Calculated creatinine clearance cat. 2														
Screening	<70 ml/min		178100,0		15184,8	30,68	25,10		176100,0		14884,1	31,19	25,74	
Cycle 4 Day 1	<70 ml/min		14983,7		12080,5	20,28	21,73		16493,2		12878,0	23,96	20,36	
FU Day 28	<70 ml/min		16291,0		13180,9	22,26	22,51		16694,3		13279,5	22,60	22,38	
FU Month 3	<70 ml/min		15788,2		12982,2	20,80	22,54		15990,3		12377,4	24,39	23,11	
FU Month 6	<70 ml/min		14480,9		12184,0	21,07	21,28		13979,0		10676,3	24,53	24,04	
FU Month 9	<70 ml/min		11765,7		8875,2	20,64	22,88		11263,6		8273,2	23,78	23,43	
FU Month 12	<70 ml/min		9251,7		7379,3	24,89	25,63		8749,4		6878,2	24,02	25,17	
FU Month 15	<70 ml/min		7843,8		6583,3	18,97	19,96		6034,1		4371,7	23,64	26,54	

FU Month 18	<70 ml/min	59	33,1	47	79,7	24,82	25,51	43	24,4	32	74,4	31,25	32,17
FU Month 21	<70 ml/min	38	21,3	24	63,2	22,22	24,90	31	17,6	23	74,2	31,88	29,69
FU Month 24	<70 ml/min	24	13,5	16	66,7	26,04	27,20	13	7,4	9	69,2	18,52	28,19
FU Month 27	<70 ml/min	10	5,6	5	50,0	36,67	38,01	7	4,0	4	57,1	25,00	50,00
FU Month 30	<70 ml/min	5	2,8	2	40,0	33,33	47,14	1	0,6	1	100,0	16,67	NE
Screening	>=70 ml/min	77	100,0	65	84,4	25,38	25,53	66	100,0	54	81,8	26,23	19,85
Cycle 4 Day 1	>=70 ml/min	64	83,1	54	84,4	22,84	21,06	60	90,9	47	78,3	25,89	22,74
FU Day 28	>=70 ml/min	68	88,3	52	76,5	26,92	30,81	59	89,4	51	86,4	22,55	21,81
FU Month 3	>=70 ml/min	68	88,3	54	79,4	26,54	26,99	62	93,9	51	82,3	21,24	19,74
FU Month 6	>=70 ml/min	63	81,8	50	79,4	23,00	25,17	53	80,3	42	79,2	26,98	24,95
FU Month 9	>=70 ml/min	47	61,0	38	80,9	24,56	25,33	37	56,1	29	78,4	24,14	22,97
FU Month 12	>=70 ml/min	33	42,9	28	84,8	25,00	26,25	30	45,5	24	80,0	23,61	22,48
FU Month 15	>=70 ml/min	26	33,8	19	73,1	21,05	19,91	25	37,9	20	80,0	27,50	22,47
FU Month 18	>=70 ml/min	20	26,0	15	75,0	17,78	20,38	17	25,8	13	76,5	21,79	19,70
FU Month 21	>=70 ml/min	14	18,2	12	85,7	25,00	24,10	9	13,6	5	55,6	20,00	18,26
FU Month 24	>=70 ml/min	8	10,4	5	62,5	23,33	14,91	5	7,6	5	100,0	16,67	16,67
FU Month 27	>=70 ml/min	3	3,9	3	100,0	33,33	28,87	2	3,0	2	100,0	0,00	0,00
FU Month 30	>=70 ml/min	2	2,6	2	100,0	25,00	11,79	0	NE	0	NE	NE	NE
Beta2 microglobulin													
Screening	Missing	3	100,0	3	100,0	33,33	0,00	3	100,0	2	66,7	83,33	23,57
Cycle 4 Day 1	Missing	3	100,0	3	100,0	16,67	16,67	3	100,0	1	33,3	33,33	NE
FU Day 28	Missing	3	100,0	3	100,0	16,67	16,67	3	100,0	1	33,3	0,00	NE
FU Month 3	Missing	3	100,0	3	100,0	22,22	19,25	3	100,0	1	33,3	33,33	NE
FU Month 6	Missing	3	100,0	3	100,0	11,11	9,62	3	100,0	1	33,3	33,33	NE
FU Month 9	Missing	2	66,7	1	50,0	33,33	NE	3	100,0	1	33,3	50,00	NE
FU Month 12	Missing	1	33,3	1	100,0	33,33	NE	2	66,7	0	NE	NE	NE
FU Month 15	Missing	1	33,3	1	100,0	33,33	NE	2	66,7	0	NE	NE	NE
FU Month 18	Missing	1	33,3	1	100,0	33,33	NE	2	66,7	0	NE	NE	NE
FU Month 21	Missing	1	33,3	1	100,0	33,33	NE	2	66,7	0	NE	NE	NE
FU Month 24	Missing	1	33,3	1	100,0	33,33	NE	1	33,3	0	NE	NE	NE
Screening	< 3.5 ug/mL	154	100,0	134	87,0	28,11	25,72	140	100,0	119	85,0	28,57	21,93
Cycle 4 Day 1	< 3.5 ug/mL	127	82,5	108	85,0	21,76	22,03	129	92,1	101	78,3	26,24	22,77
FU Day 28	< 3.5 ug/mL	137	89,0	116	84,7	22,27	23,25	132	94,3	109	82,6	24,31	22,63
FU Month 3	< 3.5 ug/mL	134	87,0	117	87,3	21,51	22,00	130	92,9	103	79,2	23,62	21,46
FU Month 6	< 3.5 ug/mL	128	83,1	108	84,4	22,84	22,04	120	85,7	98	81,7	26,87	25,51
FU Month 9	< 3.5 ug/mL	104	67,5	82	78,8	21,95	22,05	98	70,0	76	77,6	25,44	24,57
FU Month 12	< 3.5 ug/mL	78	50,6	66	84,6	26,01	26,82	75	53,6	62	82,7	25,27	26,09
FU Month 15	< 3.5 ug/mL	65	42,2	54	83,1	20,06	20,57	60	42,9	47	78,3	23,40	23,22
FU Month 18	< 3.5 ug/mL	46	29,9	37	80,4	23,87	24,39	43	30,7	33	76,7	28,79	29,25

FU Month 21	< 3.5 ug/mL	30	19,5	20	66,7	27,50	29,26	27	19,3	20	74,1	30,00	32,26
FU Month 24	< 3.5 ug/mL	19	12,3	14	73,7	29,76	27,09	12	8,6	10	83,3	10,00	14,05
FU Month 27	< 3.5 ug/mL	10	6,5	7	70,0	40,48	31,71	7	5,0	4	57,1	0,00	0,00
FU Month 30	< 3.5 ug/mL	5	3,2	3	60,0	33,33	33,33	1	0,7	1	100,0	16,67	NE
Screening	>= 3.5 ug/mL	98	100,0	79	80,6	30,59	25,10	99	100,0	81	81,8	30,45	26,46
Cycle 4 Day 1	>= 3.5 ug/mL	83	84,7	63	75,9	20,11	20,99	92	92,9	73	79,3	21,92	18,19
FU Day 28	>= 3.5 ug/mL	90	91,8	64	71,1	26,30	28,61	90	90,9	73	81,1	20,32	21,38
FU Month 3	>= 3.5 ug/mL	88	89,8	63	71,6	24,34	27,73	88	88,9	70	79,5	23,10	23,45
FU Month 6	>= 3.5 ug/mL	76	77,6	60	78,9	20,00	23,53	69	69,7	49	71,0	21,77	21,57
FU Month 9	>= 3.5 ug/mL	58	59,2	43	74,1	21,32	26,81	48	48,5	34	70,8	19,61	19,45
FU Month 12	>= 3.5 ug/mL	46	46,9	34	73,9	22,55	23,88	40	40,4	30	75,0	21,11	20,50
FU Month 15	>= 3.5 ug/mL	38	38,8	29	76,3	17,82	18,86	23	23,2	16	69,6	29,17	30,73
FU Month 18	>= 3.5 ug/mL	32	32,7	24	75,0	21,53	25,29	15	15,2	12	80,0	27,78	30,43
FU Month 21	>= 3.5 ug/mL	21	21,4	15	71,4	16,67	15,43	11	11,1	8	72,7	29,17	14,77
FU Month 24	>= 3.5 ug/mL	12	12,2	6	50,0	13,89	16,39		5,1	4	80,0	37,50	34,36
FU Month 27	>= 3.5 ug/mL	3	3,1	1	33,3	0,00	NE	2	2,0	2	100,0	50,00	70,71
FU Month 30	>= 3.5 ug/mL	2	2,0	1	50,0	16,67	NE	0	NE	0	NE	NE	NE
Immunoglobulin VH, cytogenetics 2													
Screening	12	45	100,0	39	86,7	32,48	24,47	44	100,0	40	90,9	29,17	23,80
Cycle 4 Day 1	12	34	75,6	29	85,3	23,56	19,17	38	86,4	30	78,9	20,00	18,26
FU Day 28	12	39	86,7	35	89,7	32,86	27,56	40	90,9	35	87,5	27,62	20,59
FU Month 3	12	38	84,4	34	89,5	22,55	22,43	39	88,6	30	76,9	21,11	19,54
FU Month 6	12	36	80,0	30	83,3	21,11	16,34	34	77,3	27	79,4	29,01	20,98
FU Month 9	12	26	57,8	21	80,8	22,22	26,53	28	63,6	17	60,7	28,43	19,33
FU Month 12	12	22	48,9	17	77,3	26,47	28,30	23	52,3	14	60,9	22,62	15,48
FU Month 15	12	17	37,8	13	76,5	24,36	21,10	17	38,6	11	64,7	30,30	20,84
FU Month 18	12	15	33,3	11	73,3	19,70	22,13	13	29,5	8	61,5	22,92	15,27
FU Month 21	12	10	22,2	7	70,0	33,33	33,33	7	15,9	4	57,1	20,83	15,96
FU Month 24	12	8	17,8	5	62,5	33,33	31,18	6	13,6	5	83,3	16,67	16,67
FU Month 27	12	5	11,1	3	60,0	50,00	50,00	2	4,5	2	100,0	0,00	0,00
FU Month 30	12	4	8,9	2	50,0	33,33	47,14	1	2,3	1	100,0	16,67	NE
Screening	11q-	46	100,0	35	76,1	25,24	21,53	43	100,0	36	83,7	23,61	20,07
Cycle 4 Day 1	11q-	40	87,0	33	82,5	13,64	18,84	41	95,3	32	78,0	20,83	17,45
FU Day 28	11q-	42	91,3	29	69,0	20,11	21,99	39	90,7	32	82,1	24,48	21,16
FU Month 3	11q-	42	91,3	32	76,2	16,15	19,62	38	88,4	34	89,5	22,55	22,43
FU Month 6	11q-	38	82,6	31	81,6	17,20	19,95	32	74,4	26	81,3	28,21	22,98
FU Month 9	11q-	28	60,9	24	85,7	20,14	20,84	25	58,1	20	80,0	26,67	19,79

FU Month 12	11q-	20	43,5	17	85,0	17,65	22,42	18	41,9	16	88,9	31,25	25,00
FU Month 15	11q-	18	39,1	15	83,3	14,44	19,79	14	32,6	9	64,3	27,78	20,41
FU Month 18	11q-	15	32,6	11	73,3	24,24	31,94	8	18,6	6	75,0	41,67	32,91
FU Month 21	11q-	12	26,1	10	83,3	16,67	19,25	4	9,3	1	25,0	33,33	NE
FU Month 24	11q-	7	15,2	4	57,1	8,33	16,67	1	2,3	1	100,0	0,00	NE
FU Month 27	11q-	3	6,5	2	66,7	25,00	35,36	0	NE	0	NE	NE	NE
FU Month 30	11q-	3	6,5	2	66,7	25,00	11,79	0	NE	0	NE	NE	NE
Screening	13q-	79	100,0	68	86,1	25,25	24,35	75	100,0	57	76,0	27,19	23,07
Cycle 4 Day 1	13q-	67	84,8	51	76,1	22,88	25,16	68	90,7	50	73,5	23,00	18,41
FU Day 28	13q-	72	91,1	58	80,6	16,67	21,40	72	96,0	54	75,0	17,90	20,69
FU Month 3	13q-	73	92,4	60	82,2	23,89	26,28	69	92,0	49	71,0	21,77	20,47
FU Month 6	13q-	67	84,8	55	82,1	21,52	22,61	63	84,0	44	69,8	21,97	27,32
FU Month 9	13q-	56	70,9	44	78,6	18,56	21,93	52	69,3	38	73,1	21,05	27,31
FU Month 12	13q-	44	55,7	37	84,1	25,68	25,03	40	53,3	34	85,0	23,04	26,28
FU Month 15	13q-	38	48,1	32	84,2	20,31	20,18	29	38,7	23	79,3	21,74	27,72
FU Month 18	13q-	28	35,4	23	82,1	26,09	25,54	21	28,0	17	81,0	28,43	28,73
FU Month 21	13q-	16	20,3	12	75,0	22,22	23,92	16	21,3	12	75,0	27,78	28,72
FU Month 24	13q-	7	8,9	5	71,4	36,67	24,72	7	9,3	4	57,1	29,17	39,38
FU Month 27	13q-	2	2,5	1	50,0	33,33	NE	6	8,0	3	50,0	33,33	57,74
Screening	Norm. K.	65	100,0	57	87,7	33,92	28,34	58	100,0	50	86,2	40,33	28,98
Cycle 4 Day 1	Norm. K.	54	83,1	46	85,2	23,91	20,38	55	94,8	46	83,6	32,61	25,81
FU Day 28	Norm. K.	59	90,8	47	79,7	26,95	24,71	53	91,4	46	86,8	24,28	24,52
FU Month 3	Norm. K.	54	83,1	44	81,5	25,38	23,70	54	93,1	44	81,5	29,17	26,44
FU Month 6	Norm. K.	49	75,4	43	87,8	26,36	27,75	45	77,6	34	75,6	26,96	25,63
FU Month 9	Norm. K.	39	60,0	27	69,2	27,16	27,40	30	51,7	24	80,0	25,00	23,57
FU Month 12	Norm. K.	32	49,2	24	75,0	29,17	30,00	24	41,4	18	75,0	19,44	26,97
FU Month 15	Norm. K.	26	40,0	20	76,9	20,83	20,14	20	34,5	16	80,0	28,13	28,36
FU Month 18	Norm. K.	18	27,7	14	77,8	22,62	20,26	15	25,9	12	80,0	30,56	36,12
FU Month 21	Norm. K.	12	18,5	5	41,7	30,00	24,72	11	19,0	9	81,8	40,74	33,45
FU Month 24	Norm. K.	8	12,3	5	62,5	30,00	18,26	4	6,9	4	100,0	12,50	15,96
FU Month 27	Norm. K.	3	4,6	2	66,7	25,00	11,79	1	1,7	1	100,0	0,00	NE
Screening	Other Abn.	20	100,0	17	85,0	28,43	26,20	22	100,0	19	86,4	23,68	15,03
Cycle 4 Day 1	Other Abn.	18	90,0	15	83,3	17,78	19,38	22	100,0	17	77,3	21,57	20,21
FU Day 28	Other Abn.	18	90,0	14	77,8	25,00	33,81	21	95,5	16	76,2	18,75	24,25
FU Month 3	Other Abn.	18	90,0	13	72,2	21,79	28,37	21	95,5	17	81,0	19,61	17,91
FU Month 6	Other Abn.	17	85,0	12	70,6	18,06	19,41	18	81,8	17	94,4	19,61	19,75
FU Month 9	Other Abn.	15	75,0	10	66,7	25,00	21,15	14	63,6	12	85,7	19,44	19,89
FU Month 12	Other Abn.	7	35,0	6	85,7	19,44	6,80	12	54,5	10	83,3	25,00	23,90
FU Month 15	Other Abn.	5	25,0	4	80,0	8,33	9,62	5	22,7	4	80,0	8,33	16,67

FU Month 18	Other Abn.	3	15,0	3	100,0	11,11	19,25	3	13,6	2	66,7	0,00	0,00
FU Month 21	Other Abn.	2	10,0	2	100,0	8,33	11,79	2	9,1	2	100,0	8,33	11,79
FU Month 24	Other Abn.	2	10,0	2	100,0	0,00	0,00	0	NE	0	NE	NE	NE
Time from first diagnosis													
Screening	Missing	1	100,0	1	100,0	33,33	NE	0	NE	0	NE	NE	NE
Cycle 4 Day 1	Missing	1	100,0	1	100,0	16,67	NE	0	NE	0	NE	NE	NE
FU Day 28	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 3	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 6	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 9	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 12	Missing	1	100,0	1	100,0	16,67	NE	0	NE	0	NE	NE	NE
FU Month 15	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 18	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
Screening	13 - 24 months	41	100,0	31	75,6	34,41	32,18	31	100,0	30	96,8	23,33	23,81
Cycle 4 Day 1	13 - 24 months	35	85,4	28	80,0	17,86	26,42	30	96,8	26	86,7	21,15	19,18
FU Day 28	13 - 24 months	38	92,7	26	68,4	23,08	18,90	30	96,8	26	86,7	14,10	15,41
FU Month 3	13 - 24 months	36	87,8	28	77,8	23,21	24,15	30	96,8	25	83,3	20,67	15,43
FU Month 6	13 - 24 months	36	87,8	27	75,0	15,43	22,13	30	96,8	24	80,0	21,53	23,30
FU Month 9	13 - 24 months	32	78,0	22	68,8	13,64	18,28	21	67,7	17	81,0	17,65	16,11
FU Month 12	13 - 24 months	21	51,2	15	71,4	22,22	31,29	16	51,6	13	81,3	12,82	13,87
FU Month 15	13 - 24 months	19	46,3	15	78,9	14,44	21,70	16	51,6	8	50,0	10,42	15,27
FU Month 18	13 - 24 months	14	34,1	10	71,4	21,67	24,91	10	32,3	8	80,0	16,67	17,82
FU Month 21	13 - 24 months	11	26,8	7	63,6	28,57	36,91	6	19,4	4	66,7	20,83	15,96
FU Month 24	13 - 24 months	8	19,5	3	37,5	50,00	28,87	3	9,7	3	100,0	0,00	0,00
FU Month 27	13 - 24 months	5	12,2	3	60,0	50,00	50,00	2	6,5	2	100,0	0,00	0,00
FU Month 30	13 - 24 months	3	7,3	2	66,7	41,67	35,36	1	3,2	2	100,0	16,67	NE
Screening	<= 12 months	60	100,0	48	80,0	27,08	23,48	70	100,0	55	78,6	30,00	21,85
Cycle 4 Day 1	<= 12 months	48	80,0	35	72,9	24,76	19,54	60	85,7	44	73,3	23,86	21,08
FU Day 28	<= 12 months	54	90,0	39	72,2	26,07	28,04	62	88,6	47	75,8	24,11	24,28
FU Month 3	<= 12 months	53	88,3	38	71,7	23,68	24,39	59	84,3	44	74,6	23,48	21,96
FU Month 6	<= 12 months	46	76,7	35	76,1	28,57	22,71	47	67,1	33	70,2	25,25	24,69
FU Month 9	<= 12 months	35	58,3	27	77,1	22,22	22,17	37	52,9	27	73,0	17,28	19,87
FU Month 12	<= 12 months	27	45,0	21	77,8	28,57	28,45	29	41,4	24	82,8	29,17	25,18
FU Month 15	<= 12 months	22	36,7	16	72,7	26,04	21,92	17	24,3	15	88,2	26,67	23,40
FU Month 18	<= 12 months	16	26,7	10	62,5	15,00	12,30	13	18,6	11	84,6	24,24	20,23
FU Month 21	<= 12 months	9	15,0	5	55,6	20,00	13,94	7	10,0	5	71,4	26,67	14,91
FU Month 24	<= 12 months	6	10,0	3	50,0	11,11	19,25	2	2,9	0	NE	NE	NE
FU Month 27	<= 12 months	1	1,7			NE	NE	1	1,4			NE	NE
FU Month 30	<= 12 months	1	1,7			NE	NE	0	NE			NE	NE

Screening	>24 months	153	100,0	136	88,9	28,55	24,25	141	100,0	117	83,0	31,48	25,50
Cycle 4 Day 1	>24 months	129	84,3	110	85,3	20,76	20,84	134	95,0	105	78,4	25,56	21,44
FU Day 28	>24 months	137	89,5	117	85,4	23,08	25,51	133	94,3	110	82,7	23,94	22,30
FU Month 3	>24 months	135	88,2	116	85,9	22,13	24,05	132	93,6	105	79,5	24,13	23,68
FU Month 6	>24 months	124	81,0	108	87,1	21,14	22,05	115	81,6	91	79,1	26,19	24,49
FU Month 9	>24 months	96	62,7	76	79,2	24,34	25,16	91	64,5	67	73,6	28,11	25,16
FU Month 12	>24 months	76	49,7	64	84,2	24,48	23,75	72	51,1	55	76,4	24,24	25,42
FU Month 15	>24 months	62	40,5	52	83,9	19,23	18,49	52	36,9	40	76,9	27,08	26,87
FU Month 18	>24 months	48	31,4	41	85,4	26,02	26,37	37	26,2	26	70,3	33,97	34,15
FU Month 21	>24 months	32	20,9	24	75,0	22,22	22,34	27	19,1	19	70,4	32,46	32,62
FU Month 24	>24 months	18	11,8	15	83,3	23,33	22,54	13	9,2	11	84,6	22,73	25,03
FU Month 27	>24 months	7	4,6	5	71,4	26,67	19,00	6	4,3	4	66,7	25,00	50,00
FU Month 30	>24 months	3	2,0	2	66,7	16,67	23,57	0	NE	0	NE	NE	NE
High circulating tumor burden													
Screening	Missing	0	NE	0	NE	NE	NE	2	100,0	1	50,0	0,00	NE
Cycle 4 Day 1	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	16,67	NE
FU Day 28	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	66,67	NE
FU Month 3	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	16,67	NE
FU Month 6	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	66,67	NE
FU Month 9	Missing	0	NE			NE	NE	1	50,0			NE	NE
Screening	<25x10**9 cells/L	60	100,0	51	85,0	30,39	27,63	67	100,0	55	82,1	31,52	22,61
Cycle 4 Day 1	<25x10**9 cells/L	50	83,3	41	82,0	25,61	22,70	61	91,0	43	70,5	22,87	18,91
FU Day 28	<25x10**9 cells/L	56	93,3	43	76,8	23,26	26,01	61	91,0	46	75,4	24,28	22,96
FU Month 3	<25x10**9 cells/L	54	90,0	44	81,5	23,86	21,98	59	88,1	44	74,6	20,08	19,88
FU Month 6	<25x10**9 cells/L	50	83,3	41	82,0	26,42	20,74	51	76,1	38	74,5	19,74	22,21
FU Month 9	<25x10**9 cells/L	36	60,0	23	63,9	22,46	22,25	41	61,2	28	68,3	16,07	16,66
FU Month 12	<25x10**9 cells/L	29	48,3	23	79,3	26,81	25,99	34	50,7	23	67,6	20,29	21,29
FU Month 15	<25x10**9 cells/L	24	40,0	19	79,2	23,68	17,84	23	34,3	13	56,5	21,79	20,84
FU Month 18	<25x10**9 cells/L	20	33,3	17	85,0	19,61	17,91	19	28,4	13	68,4	19,23	29,54
FU Month 21	<25x10**9 cells/L	14	23,3	9	64,3	27,78	30,05	10	14,9	7	70,0	19,05	15,00
FU Month 24	<25x10**9 cells/L	8	13,3	4	50,0	29,17	39,38	6	9,0	5	83,3	13,33	18,26
FU Month 27	<25x10**9 cells/L	4	6,7	2	50,0	50,00	70,71	1	1,5	1	100,0	0,00	NE
FU Month 30	<25x10**9 cells/L	4	6,7	2	50,0	33,33	47,14	1	1,5	1	100,0	16,67	NE
Screening	>=25x10**9 cells/L	195	100,0	165	84,6	28,69	24,60	173	100,0	146	84,4	29,45	24,99
Cycle 4 Day 1	>=25x10**9 cells/L	163	83,6	133	81,6	19,67	21,01	162	93,6	131	80,9	25,06	21,72
FU Day 28	>=25x10**9 cells/L	174	89,2	140	80,5	23,69	24,98	163	94,2	136	83,4	21,69	21,69
FU Month 3	>=25x10**9 cells/L	171	87,7	139	81,3	22,06	24,67	161	93,1	129	80,1	24,68	22,93
FU Month 6	>=25x10**9 cells/L	157	80,5	130	82,8	20,13	22,80	140	80,9	109	77,9	26,76	24,53

FU Month 9	>=25x10**9 cells/L	128	65,6	103	80,5	21,68	24,01	107	61,8	83	77,6	26,51	24,56
FU Month 12	>=25x10**9 cells/L	96	49,2	78	81,3	24,36	25,72	83	48,0	69	83,1	25,12	25,34
FU Month 15	>=25x10**9 cells/L	80	41,0	65	81,3	18,21	20,35	62	35,8	50	80,6	25,67	26,34
FU Month 18	>=25x10**9 cells/L	59	30,3	45	76,3	24,44	26,50	41	23,7	32	78,0	32,29	28,69
FU Month 21	>=25x10**9 cells/L	38	19,5	27	71,1	21,60	22,56	30	17,3	21	70,0	33,33	30,73
FU Month 24	>=25x10**9 cells/L	24	12,3	17	70,8	24,51	21,34	12	6,9	9	75,0	20,37	27,36
FU Month 27	>=25x10**9 cells/L	9	4,6	6	66,7	30,56	19,48	8	4,6	5	62,5	20,00	44,72
FU Month 30	>=25x10**9 cells/L	3	1,5	2	66,7	25,00	11,79	0	NE	0	NE	NE	NE

¹ in study: number of subjects in study at respective visit; % based on baseline

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit

² mean: descriptive statistics - absolute values Clinical

cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/t_pro_mean.sas

Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/t_pro_mean_sg_EQCLL16_IT_label_09MAY2013_21004.xls 04MAR2020

17:21

POPULATION: Labelpopulation, Intent-to-Treat Patients
 ENDPOINT: EORTC QoL 16
 MODEL: Unadjusted Analysis
 STUDY: CLL11 (BO21004), Stage 2
 Compliance/Mean

Future Health (Item 42)

		GClb (N=255)						RC1b (N=242)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study ¹	%	with value ¹	%	Mean ²	SD(mean)	in study ¹	%	with value ¹	%	Mean ²	SD(mean)
All													
Screening	n/a	255	100,0	212	83,1	48,11	31,99	242	100,0	201	83,1	46,10	32,79
Cycle 4 Day 1	n/a	213	83,5	173	81,2	27,75	30,30	224	92,6	173	77,2	34,87	31,09
FU Day 28	n/a	230	90,2	183	79,6	29,51	29,50	225	93,0	183	81,3	28,96	29,53
FU Month 3	n/a	225	88,2	182	80,9	28,39	29,83	221	91,3	173	78,3	28,90	28,07
FU Month 6	n/a	207	81,2	171	82,6	29,24	28,05	192	79,3	147	76,6	30,61	29,59
FU Month 9	n/a	164	64,3	123	75,0	25,20	28,42	149	61,6	109	73,2	27,22	26,90
FU Month 12	n/a	125	49,0	101	80,8	25,74	29,01	117	48,3	92	78,6	25,36	28,55
FU Month 15	n/a	104	40,8	84	80,8	18,25	22,79	85	35,1	63	74,1	29,10	30,23
FU Month 18	n/a	79	31,0	62	78,5	22,04	26,95	60	24,8	45	75,0	29,63	32,74
FU Month 21	n/a	52	20,4	36	69,2	19,44	21,64	40	16,5	28	70,0	28,57	26,78
FU Month 24	n/a	32	12,5	21	65,6	28,57	30,34	18	7,4	14	77,8	23,81	30,46
FU Month 27	n/a	13	5,1	8	61,5	25,00	23,57	9	3,7	6	66,7	5,56	13,61
FU Month 30	n/a	7	2,7	4	57,1	41,67	31,91	1	0,4	1	100,0	33,33	NE
Gender													
Screening	Female	97	100,0	78	80,4	53,85	31,43	95	100,0	74	77,9	54,95	31,42
Cycle 4 Day 1	Female	84	86,6	67	79,8	33,33	32,31	88	92,6	66	75,0	43,43	32,01
FU Day 28	Female	90	92,8	75	83,3	33,33	30,51	91	95,8	70	76,9	34,29	33,56
FU Month 3	Female	88	90,7	73	83,0	29,68	29,69	87	91,6	63	72,4	35,45	31,61
FU Month 6	Female	84	86,6	64	76,2	33,33	27,22	77	81,1	56	72,7	36,31	29,32
FU Month 9	Female	70	72,2	50	71,4	31,33	31,88	61	64,2	39	63,9	34,19	31,05
FU Month 12	Female	56	57,7	45	80,4	31,11	29,64	47	49,5	34	72,3	31,37	28,36
FU Month 15	Female	47	48,5	37	78,7	21,62	23,85	33	34,7	24	72,7	34,72	33,30
FU Month 18	Female	34	35,1	25	73,5	29,33	29,38	26	27,4	19	73,1	45,61	38,83
FU Month 21	Female	21	21,6	11	52,4	30,30	27,71	17	17,9	12	70,6	38,89	31,25
FU Month 24	Female	12	12,4	6	50,0	50,00	34,96	6	6,3	3	50,0	33,33	33,33
FU Month 27	Female	6	6,2	2	33,3	33,33	0,00	2	2,1	1	50,0	0,00	NE
FU Month 30	Female	4	4,1	1	25,0	33,33	NE	1	1,1	1	100,0	33,33	NE

Screening	Male	158	100,0	134	84,8	44,78	31,95	147	100,0	127	86,4	40,94	32,58
Cycle 4 Day 1	Male	129	81,6	106	82,2	24,21	28,56	136	92,5	107	78,7	29,60	29,43
FU Day 28	Male	140	88,6	108	77,1	26,85	28,63	134	91,2	113	84,3	25,66	26,36
FU Month 3	Male	137	86,7	109	79,6	27,52	30,04	134	91,2	110	82,1	25,15	25,22
FU Month 6	Male	123	77,8	107	87,0	26,79	28,39	115	78,2	91	79,1	27,11	29,36
FU Month 9	Male	94	59,5	73	77,7	21,00	25,16	88	59,9	70	79,5	23,33	23,64
FU Month 12	Male	69	43,7	56	81,2	21,43	28,02	70	47,6	58	82,9	21,84	28,31
FU Month 15	Male	57	36,1	47	82,5	15,60	21,82	52	35,4	39	75,0	25,64	28,06
FU Month 18	Male	45	28,5	37	82,2	17,12	24,37	34	23,1	26	76,5	17,95	21,56
FU Month 21	Male	31	19,6	25	80,6	14,67	16,89	23	15,6	16	69,6	20,83	20,64
FU Month 24	Male	20	12,7	15	75,0	20,00	24,56	12	8,2	11	91,7	21,21	30,81
FU Month 27	Male	7	4,4	6	85,7	22,22	27,22	7	4,8	5	71,4	6,67	14,91
FU Month 30	Male	3	1,9	3	100,0	44,44	38,49	0	NE	0	NE	NE	NE
Age													
Screening	<75 years	130	100,0	100	76,9	48,00	30,45	120	100,0	91	75,8	41,76	32,05
Cycle 4 Day 1	<75 years	106	81,5	80	75,5	27,08	27,61	112	93,3	80	71,4	32,92	31,15
FU Day 28	<75 years	119	91,5	91	76,5	29,67	27,42	110	91,7	86	78,2	27,91	29,31
FU Month 3	<75 years	116	89,2	90	77,6	28,15	27,78	109	90,8	81	74,3	29,22	29,53
FU Month 6	<75 years	108	83,1	86	79,6	29,07	25,97	99	82,5	71	71,7	29,58	28,48
FU Month 9	<75 years	85	65,4	64	75,3	22,40	25,93	74	61,7	54	73,0	28,40	25,42
FU Month 12	<75 years	63	48,5	53	84,1	23,90	27,25	60	50,0	47	78,3	21,28	29,01
FU Month 15	<75 years	54	41,5	42	77,8	19,84	22,16	44	36,7	32	72,7	26,04	27,74
FU Month 18	<75 years	43	33,1	34	79,1	20,59	24,64	27	22,5	20	74,1	30,00	32,26
FU Month 21	<75 years	26	20,0	20	76,9	16,67	17,10	17	14,2	11	64,7	21,21	26,97
FU Month 24	<75 years	18	13,8	12	66,7	27,78	27,83	6	5,0	4	66,7	16,67	33,33
FU Month 27	<75 years	7	5,4	4	57,1	33,33	27,22	2	1,7	1	50,0	0,00	NE
FU Month 30	<75 years	4	3,1	2	50,0	66,67	0,00	0	NE	0	NE	NE	NE
Screening	>=75 years	125	100,0	112	89,6	48,21	33,44	122	100,0	110	90,2	49,70	33,10
Cycle 4 Day 1	>=75 years	107	85,6	93	86,9	28,32	32,58	112	91,8	93	83,0	36,56	31,11
FU Day 28	>=75 years	111	88,8	92	82,9	29,35	31,58	115	94,3	97	84,3	29,90	29,85
FU Month 3	>=75 years	109	87,2	92	84,4	28,62	31,87	112	91,8	92	82,1	28,62	26,88
FU Month 6	>=75 years	99	79,2	85	85,9	29,41	30,17	93	76,2	76	81,7	31,58	30,74
FU Month 9	>=75 years	79	63,2	59	74,7	28,25	30,83	75	61,5	55	73,3	26,06	28,47
FU Month 12	>=75 years	62	49,6	48	77,4	27,78	31,01	57	46,7	45	78,9	29,63	27,73
FU Month 15	>=75 years	50	40,0	42	84,0	16,67	23,57	41	33,6	31	75,6	32,26	32,75
FU Month 18	>=75 years	36	28,8	28	77,8	23,81	29,89	33	27,0	25	75,8	29,33	33,77
FU Month 21	>=75 years	26	20,8	16	61,5	22,92	26,44	23	18,9	17	73,9	33,33	26,35
FU Month 24	>=75 years	14	11,2	9	64,3	29,63	35,14	12	9,8	10	83,3	26,67	30,63
FU Month 27	>=75 years	6	4,8	4	66,7	16,67	19,25	7	5,7	5	71,4	6,67	14,91

FU Month 30	>=75 years	3	2,4	2	66,7	16,67	23,57	1	0,8	1	100,0	33,33	NE
Race													
Screening	Other	9	100,0	6	66,7	33,33	21,08	11	100,0	7	63,6	28,57	23,00
Cycle 4 Day 1	Other	7	77,8	4	57,1	25,00	16,67	10	90,9	6	60,0	27,78	25,09
FU Day 28	Other	8	88,9	5	62,5	26,67	14,91	10	90,9	7	70,0	19,05	17,82
FU Month 3	Other	8	88,9	4	50,0	33,33	27,22	10	90,9	6	60,0	27,78	38,97
FU Month 6	Other	8	88,9	4	50,0	33,33	27,22	8	72,7	6	75,0	5,56	13,61
FU Month 9	Other	4	44,4	3	75,0	22,22	19,25	5	45,5	4	80,0	16,67	19,25
FU Month 12	Other	3	33,3	2	66,7	16,67	23,57	4	36,4	4	100,0	16,67	19,25
FU Month 15	Other	2	22,2	1	50,0	33,33	NE	4	36,4	4	100,0	16,67	19,25
FU Month 18	Other	2	22,2	1	50,0	0,00	NE	2	18,2	2	100,0	16,67	23,57
FU Month 21	Other	2	22,2	1	50,0	0,00	NE	2	18,2	2	100,0	33,33	47,14
FU Month 24	Other	2	22,2	1	50,0	0,00	NE	1	9,1	0	NE	NE	NE
FU Month 27	Other	1	11,1			NE	NE	1	9,1			NE	NE
FU Month 30	Other	1	11,1			NE	NE	0	NE			NE	NE
Screening													
Screening	White	246	100,0	206	83,7	48,54	32,18	231	100,0	194	84,0	46,74	32,95
Cycle 4 Day 1	White	206	83,7	169	82,0	27,81	30,58	214	92,6	167	78,0	35,13	31,32
FU Day 28	White	222	90,2	178	80,2	29,59	29,83	215	93,1	176	81,9	29,36	29,87
FU Month 3	White	217	88,2	178	82,0	28,28	29,95	211	91,3	167	79,1	28,94	27,76
FU Month 6	White	199	80,9	167	83,9	29,14	28,15	184	79,7	141	76,6	31,68	29,63
FU Month 9	White	160	65,0	120	75,0	25,28	28,66	144	62,3	105	72,9	27,62	27,13
FU Month 12	White	122	49,6	99	81,1	25,93	29,18	113	48,9	88	77,9	25,76	28,91
FU Month 15	White	102	41,5	83	81,4	18,07	22,87	81	35,1	59	72,8	29,94	30,76
FU Month 18	White	77	31,3	61	79,2	22,40	27,03	58	25,1	43	74,1	30,23	33,19
FU Month 21	White	50	20,3	35	70,0	20,00	21,69	38	16,5	26	68,4	28,21	26,15
FU Month 24	White	30	12,2	20	66,7	30,00	30,40	17	7,4	14	82,4	23,81	30,46
FU Month 27	White	12	4,9	8	66,7	25,00	23,57	8	3,5	6	75,0	5,56	13,61
FU Month 30	White	6	2,4	4	66,7	41,67	31,91	1	0,4	1	100,0	33,33	NE
Geographical Region													
Screening	Asia-Pacific	20	100,0	19	95,0	43,86	29,51	18	100,0	18	100,0	38,89	30,78
Cycle 4 Day 1	Asia-Pacific	15	75,0	14	93,3	21,43	16,57	16	88,9	15	93,8	28,89	27,79
FU Day 28	Asia-Pacific	18	90,0	18	100,0	33,33	32,34	18	100,0	16	88,9	27,08	21,84
FU Month 3	Asia-Pacific	18	90,0	16	88,9	29,17	29,50	18	100,0	15	83,3	35,56	29,46
FU Month 6	Asia-Pacific	16	80,0	14	87,5	35,71	35,72	17	94,4	14	82,4	35,71	35,72
FU Month 9	Asia-Pacific	14	70,0	12	85,7	19,44	22,29	13	72,2	10	76,9	30,00	33,15
FU Month 12	Asia-Pacific	10	50,0	8	80,0	16,67	17,82	10	55,6	10	100,0	20,00	23,31
FU Month 15	Asia-Pacific	8	40,0	6	75,0	16,67	18,26	9	50,0	9	100,0	40,74	32,39
FU Month 18	Asia-Pacific	6	30,0	4	66,7	0,00	0,00	6	33,3	6	100,0	33,33	21,08

FU Month 21	Asia-Pacific	5	25,0	3	60,0	11,11	19,25	4	22,2	4	100,0	33,33	27,22
FU Month 24	Asia-Pacific	3	15,0	2	66,7	16,67	23,57	1	5,6	0	NE	NE	NE
FU Month 27	Asia-Pacific	1	5,0			NE	NE	1	5,6			NE	NE
FU Month 30	Asia-Pacific	1	5,0			NE	NE	0	NE			NE	NE
Screening	Central and South America	3	100,0	3	100,0	33,33	33,33	2	100,0	2	100,0	33,33	0,00
Cycle 4 Day 1	Central and South America	3	100,0	3	100,0	11,11	19,25	2	100,0	2	100,0	16,67	23,57
FU Day 28	Central and South America	3	100,0	3	100,0	22,22	19,25	2	100,0	2	100,0	33,33	0,00
FU Month 3	Central and South America	3	100,0	3	100,0	33,33	0,00	2	100,0	2	100,0	0,00	0,00
FU Month 6	Central and South America	2	66,7	2	100,0	16,67	23,57	2	100,0	2	100,0	16,67	23,57
FU Month 9	Central and South America	2	66,7	2	100,0	16,67	23,57	1	50,0	1	100,0	0,00	NE
FU Month 12	Central and South America	2	66,7	2	100,0	16,67	23,57	1	50,0	1	100,0	33,33	NE
FU Month 15	Central and South America	1	33,3	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 18	Central and South America	1	33,3	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 21	Central and South America	1	33,3	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 24	Central and South America	1	33,3	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
Screening	North America	12	100,0	12	100,0	52,78	30,01	13	100,0	12	92,3	33,33	31,78
Cycle 4 Day 1	North America	9	75,0	9	100,0	25,93	32,39	12	92,3	12	100,0	22,22	21,71
FU Day 28	North America	11	91,7	11	100,0	21,21	22,47	13	100,0	13	100,0	20,51	28,99
FU Month 3	North America	11	91,7	11	100,0	18,18	27,34	12	92,3	12	100,0	22,22	16,41
FU Month 6	North America	11	91,7	10	90,9	36,67	29,19	11	84,6	11	100,0	24,24	21,56
FU Month 9	North America	8	66,7	8	100,0	29,17	37,53	9	69,2	9	100,0	22,22	16,67
FU Month 12	North America	8	66,7	7	87,5	19,05	17,82	7	53,8	7	100,0	14,29	17,82
FU Month 15	North America	6	50,0	6	100,0	11,11	17,21	6	46,2	5	83,3	20,00	18,26
FU Month 18	North America	4	33,3	4	100,0	8,33	16,67	3	23,1	3	100,0	22,22	19,25
FU Month 21	North America	3	25,0	2	66,7	33,33	0,00	1	7,7	1	100,0	33,33	NE
FU Month 24	North America	3	25,0	2	66,7	16,67	23,57	1	7,7	1	100,0	66,67	NE
FU Month 27	North America	2	16,7	1	50,0	0,00	NE	1	7,7	1	100,0	33,33	NE
Screening	Other	45	100,0	15	33,3	55,56	24,12	44	100,0	16	36,4	45,83	23,96
Cycle 4 Day 1	Other	37	82,2	14	37,8	30,95	24,33	40	90,9	14	35,0	45,24	30,96
FU Day 28	Other	37	82,2	14	37,8	33,33	18,49	39	88,6	14	35,9	28,57	34,24
FU Month 3	Other	38	84,4	15	39,5	31,11	19,79	38	86,4	13	34,2	23,08	31,58
FU Month 6	Other	35	77,8	15	42,9	42,22	19,79	33	75,0	11	33,3	18,18	22,92
FU Month 9	Other	26	57,8	12	46,2	27,78	19,25	24	54,5	8	33,3	25,00	29,55
FU Month 12	Other	17	37,8	8	47,1	29,17	33,03	16	36,4	6	37,5	33,33	21,08
FU Month 15	Other	12	26,7	4	33,3	8,33	16,67	9	20,5	3	33,3	11,11	19,25
FU Month 18	Other	10	22,2	3	30,0	22,22	19,25	7	15,9	2	28,6	16,67	23,57
FU Month 21	Other	7	15,6	2	28,6	16,67	23,57	4	9,1	0	NE	NE	NE
FU Month 24	Other	6	13,3	1	16,7	33,33	NE	3	6,8	0	NE	NE	NE
FU Month 27	Other	4	8,9	1	25,0	33,33	NE	1	2,3	0	NE	NE	NE

FU Month 30	Other		24,4			NE	NE	0	NE			NE	NE
Screening	Western Europe	175	100,0	163	93,1	47,85	33,13	165	100,0	153	92,7	48,15	33,96
Cycle 4 Day 1	Western Europe	149	85,1	133	89,3	28,57	32,08	154	93,3	130	84,4	35,90	32,05
FU Day 28	Western Europe	161	92,0	137	85,1	29,44	30,80	153	92,7	138	90,2	29,95	30,22
FU Month 3	Western Europe	155	88,6	137	88,4	28,71	31,36	151	91,5	131	86,8	29,77	28,42
FU Month 6	Western Europe	143	81,7	130	90,9	26,67	27,66	129	78,2	109	84,5	32,11	30,06
FU Month 9	Western Europe	114	65,1	89	78,1	25,47	29,74	102	61,8	81	79,4	27,98	27,11
FU Month 12	Western Europe	88	50,3	76	86,4	27,19	30,65	83	50,3	68	81,9	26,47	30,78
FU Month 15	Western Europe	77	44,0	67	87,0	19,90	23,97	61	37,0	46	75,4	28,99	31,12
FU Month 18	Western Europe	58	33,1	50	86,2	25,33	28,22	44	26,7	34	77,3	30,39	36,11
FU Month 21	Western Europe	36	20,6	28	77,8	20,24	22,84	31	18,8	23	74,2	27,54	27,80
FU Month 24	Western Europe	19	10,9	15	78,9	33,33	33,33	13	7,9	13	100,0	20,51	28,99
FU Month 27	Western Europe	6	3,4	6	100,0	27,78	25,09	6	3,6	5	83,3	0,00	0,00
FU Month 30	Western Europe	4	2,3	4	100,0	41,67	31,91	1	0,6	1	100,0	33,33	NE
FCgamma receptor IIa													
Screening	131HH	58	100,0	45	77,6	50,37	30,67	76	100,0	60	78,9	45,00	29,96
Cycle 4 Day 1	131HH	49	84,5	35	71,4	30,48	31,70	65	85,5	48	73,8	32,64	30,36
FU Day 28	131HH	51	87,9	37	72,5	33,33	27,22	70	92,1	51	72,9	25,49	28,74
FU Month 3	131HH	51	87,9	40	78,4	32,50	32,46	64	84,2	45	70,3	22,96	24,44
FU Month 6	131HH	49	84,5	39	79,6	33,33	30,59	55	72,4	40	72,7	30,00	28,04
FU Month 9	131HH	39	67,2	25	64,1	30,67	28,74	41	53,9	30	73,2	21,11	23,95
FU Month 12	131HH	28	48,3	21	75,0	41,27	36,37	34	44,7	28	82,4	22,62	25,75
FU Month 15	131HH	23	39,7	17	73,9	27,45	26,97	24	31,6	19	79,2	22,81	24,98
FU Month 18	131HH	17	29,3	12	70,6	27,78	27,83	16	21,1	12	75,0	22,22	29,59
FU Month 21	131HH	13	22,4	8	61,5	25,00	34,50	11	14,5	9	81,8	33,33	28,87
FU Month 24	131HH	11	19,0	7	63,6	42,86	37,09	1	1,3	1	100,0	0,00	NE
FU Month 27	131HH	4	6,9	3	75,0	22,22	19,25	1	1,3	1	100,0	0,00	NE
FU Month 30	131HH	3	5,2	2	66,7	50,00	23,57	0	NE	0	NE	NE	NE
Screening	131HR	125	100,0	106	84,8	45,91	32,68	114	100,0	100	87,7	45,67	35,35
Cycle 4 Day 1	131HR	105	84,0	88	83,8	28,79	30,40	110	96,5	91	82,7	38,46	31,40
FU Day 28	131HR	116	92,8	97	83,6	30,93	31,27	105	92,1	92	87,6	29,71	31,04
FU Month 3	131HR	114	91,2	95	83,3	28,07	29,30	107	93,9	88	82,2	28,79	28,67
FU Month 6	131HR	104	83,2	86	82,7	28,68	26,65	95	83,3	76	80,0	32,89	31,97
FU Month 9	131HR	84	67,2	64	76,2	25,52	27,69	76	66,7	57	75,0	29,82	28,65
FU Month 12	131HR	64	51,2	54	84,4	25,93	26,44	57	50,0	46	80,7	25,36	29,97
FU Month 15	131HR	53	42,4	42	79,2	16,67	23,57	44	38,6	32	72,7	30,21	30,95
FU Month 18	131HR	43	34,4	34	79,1	24,51	27,60	32	28,1	25	78,1	30,67	30,31
FU Month 21	131HR	26	20,8	17	65,4	21,57	16,42	21	18,4	15	71,4	31,11	26,63
FU Month 24	131HR	12	9,6	8	66,7	25,00	23,57	12	10,5	10	83,3	33,33	31,43

FU Month 27	131HR	6	4,8	3	50,0	33,33	33,33	6	5,3	4	66,7	8,33	16,67
FU Month 30	131HR	3	2,4	1	33,3	66,67	NE	1	0,9	1	100,0	33,33	NE
Screening	131RR	49	100,0	41	83,7	52,03	30,78	33	100,0	28	84,8	45,24	30,38
Cycle 4 Day 1	131RR	40	81,6	33	82,5	21,21	23,30	31	93,9	24	77,4	25,00	28,23
FU Day 28	131RR	42	85,7	31	73,8	22,58	23,39	32	97,0	28	87,5	29,76	29,17
FU Month 3	131RR	39	79,6	30	76,9	24,44	27,59	32	97,0	28	87,5	29,76	29,17
FU Month 6	131RR	35	71,4	29	82,9	26,44	25,79	27	81,8	22	81,5	28,79	27,78
FU Month 9	131RR	24	49,0	19	79,2	24,56	31,12	19	57,6	16	84,2	25,00	22,77
FU Month 12	131RR	18	36,7	15	83,3	15,56	21,33	17	51,5	14	82,4	23,81	24,21
FU Month 15	131RR	16	32,7	14	87,5	16,67	17,30	11	33,3	9	81,8	29,63	30,93
FU Month 18	131RR	14	28,6	12	85,7	11,11	21,71	8	24,2	7	87,5	42,86	46,00
FU Month 21	131RR	8	16,3	6	75,0	11,11	17,21	5	15,2	4	80,0	8,33	16,67
FU Month 24	131RR	5	10,2	3	60,0	33,33	33,33	3	9,1	3	100,0	0,00	0,00
FU Month 27	131RR	2	4,1	1	50,0	33,33	NE	1	3,0	1	100,0	0,00	NE
FU Month 30	131RR	1	2,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
Screening	Missing	23	100,0	20	87,0	46,67	34,88	19	100,0	13	68,4	56,41	31,58
Cycle 4 Day 1	Missing	19	82,6	17	89,5	29,41	38,88	18	94,7	10	55,6	36,67	36,68
FU Day 28	Missing	21	91,3	18	85,7	25,93	33,44	18	94,7	12	66,7	36,11	22,29
FU Month 3	Missing	21	91,3	17	81,0	27,45	31,70	18	94,7	12	66,7	50,00	26,59
FU Month 6	Missing	19	82,6	17	89,5	27,45	33,82	15	78,9	9	60,0	18,52	17,57
FU Month 9	Missing	17	73,9	15	88,2	15,56	27,79	13	68,4	6	46,2	38,89	32,77
FU Month 12	Missing	15	65,2	11	73,3	9,09	21,56	9	47,4	4	44,4	50,00	43,03
FU Month 15	Missing	12	52,2	11	91,7	12,12	16,82	6	31,6	3	50,0	55,56	50,92
FU Month 18	Missing	5	21,7	4	80,0	16,67	33,33	4	21,1	1	25,0	0,00	NE
FU Month 21	Missing	5	21,7	5	100,0	13,33	18,26	3	15,8	0	NE	NE	NE
FU Month 24	Missing	4	17,4	3	75,0	0,00	0,00	2	10,5	0	NE	NE	NE
FU Month 27	Missing	1	4,3	1	100,0	0,00	NE	1	5,3	0	NE	NE	NE
FCgamma receptor IIIa													
Screening	158FF	103	100,0	89	86,4	46,82	33,60	83	100,0	72	86,7	43,52	32,45
Cycle 4 Day 1	158FF	89	86,4	73	82,0	23,29	27,04	78	94,0	63	80,8	33,33	33,87
FU Day 28	158FF	96	93,2	78	81,3	26,50	29,11	78	94,0	67	85,9	26,87	30,28
FU Month 3	158FF	94	91,3	76	80,9	24,12	29,61	78	94,0	64	82,1	24,48	26,72
FU Month 6	158FF	86	83,5	69	80,2	27,05	29,86	64	77,1	53	82,8	26,42	30,91
FU Month 9	158FF	71	68,9	56	78,9	23,81	29,62	47	56,6	41	87,2	24,39	21,11
FU Month 12	158FF	48	46,6	41	85,4	21,95	29,45	38	45,8	34	89,5	19,61	24,78
FU Month 15	158FF	37	35,9	31	83,8	15,05	16,86	30	36,1	23	76,7	23,19	25,49
FU Month 18	158FF	27	26,2	22	81,5	18,18	26,68	21	25,3	17	81,0	29,41	35,12
FU Month 21	158FF	16	15,5	15	93,8	17,78	17,21	9	10,8	8	88,9	25,00	23,57
FU Month 24	158FF	8	7,8	7	87,5	28,57	23,00	3	3,6	3	100,0	33,33	33,33

FU Month 27	158FF		54,9		480,0	25,00	31,91		11,2		1100,0	0,00		NE
FU Month 30	158FF		32,9		3100,0	44,44	38,49		0	NE	0	NE	NE	NE
Screening	158FV	119	100,0		9882,4	48,64	30,71	109	100,0		8981,7	49,06	33,37	
Cycle 4 Day 1	158FV		9983,2		8080,8	29,58	30,92	100	91,7		7676,0	36,84	31,54	
FU Day 28	158FV	105	88,2		8278,1	31,71	29,12	101	92,7		8180,2	31,69	29,77	
FU Month 3	158FV	101	84,9		8382,2	30,92	29,35		9789,0		7577,3	31,11	29,68	
FU Month 6	158FV		9479,0		8085,1	30,42	24,99		8376,1		6477,1	34,38	29,68	
FU Month 9	158FV		7159,7		5171,8	26,80	24,96		6559,6		4569,2	29,63	30,34	
FU Month 12	158FV		6050,4		5083,3	31,33	28,89		5247,7		4178,8	29,27	30,00	
FU Month 15	158FV		5243,7		4178,8	20,33	24,58		3633,0		2980,6	34,48	32,71	
FU Month 18	158FV		4437,0		3477,3	24,51	27,60		2422,0		2083,3	36,67	34,03	
FU Month 21	158FV		2823,5		1450,0	21,43	28,06		1816,5		1477,8	35,71	30,56	
FU Month 24	158FV		1815,1		950,0	33,33	37,27		65,5		583,3	26,67	36,51	
FU Month 27	158FV		65,0		233,3	33,33	0,00		21,8		150,0	0,00		NE
FU Month 30	158FV		43,4		125,0	33,33		NE	0	NE	0	NE	NE	NE
Screening	158VV		16100,0		1275,0	44,44	25,95		33100,0		2987,9	40,23	30,05	
Cycle 4 Day 1	158VV		1275,0		975,0	25,93	32,39		3090,9		2686,7	34,62	24,00	
FU Day 28	158VV		1487,5		1178,6	30,30	31,46		3090,9		2686,7	20,51	26,79	
FU Month 3	158VV		1593,8		1066,7	33,33	31,43		3090,9		2480,0	26,39	24,04	
FU Month 6	158VV		1487,5		1178,6	24,24	30,15		3090,9		2170,0	26,98	24,99	
FU Month 9	158VV		1275,0		866,7	29,17	37,53		2575,8		1872,0	24,07	27,55	
FU Month 12	158VV		850,0		562,5	20,00	29,81		2060,6		1680,0	22,92	26,44	
FU Month 15	158VV		850,0		675,0	27,78	38,97		1442,4		1071,4	20,00	23,31	
FU Month 18	158VV		425,0		375,0	22,22	19,25		1133,3		872,7	12,50	17,25	
FU Month 21	158VV		318,8		266,7	33,33	0,00		927,3		666,7	16,67	18,26	
FU Month 24	158VV		212,5		2100,0	50,00	23,57		721,2		685,7	16,67	27,89	
FU Month 27	158VV		16,3		1100,0	33,33		NE	515,2		480,0	8,33	16,67	
FU Month 30	158VV		0	NE	0	NE	NE	NE	13,0		1100,0	33,33		NE
Screening	Missing	17	100,0		1376,5	56,41	36,98		17100,0		1164,7	54,55	37,34	
Cycle 4 Day 1	Missing	13	76,5		1184,6	45,45	40,20		1694,1		850,0	29,17	27,82	
FU Day 28	Missing	15	88,2		1280,0	33,33	34,82		1694,1		956,3	44,44	23,57	
FU Month 3	Missing	15	88,2		1386,7	33,33	33,33		1694,1		1062,5	46,67	28,11	
FU Month 6	Missing	13	76,5		1184,6	39,39	35,96		1588,2		960,0	37,04	30,93	
FU Month 9	Missing	10	58,8		880,0	20,83	35,36		1270,6		541,7	40,00	36,51	
FU Month 12	Missing	9	52,9		555,6	6,67	14,91		741,2		114,3	100,00		NE
FU Month 15	Missing	7	41,2		685,7	11,11	17,21		529,4		120,0	100,00		NE
FU Month 18	Missing	4	23,5		375,0	22,22	38,49		423,5		0	NE	NE	NE
FU Month 21	Missing	5	29,4		5100,0	13,33	18,26		423,5		0	NE	NE	NE
FU Month 24	Missing	4	23,5		375,0	0,00	0,00		211,8		0	NE	NE	NE

FU Month 27	Missing		15,9		1100,0	0,00		NE		15,9		0		NE		NE		NE
Binet Staging at baseline																		
Screening	A		59100,0		5593,2	48,48	33,83		57100,0		4680,7	52,17		35,59				
Cycle 4 Day 1	A		5186,4		4588,2	34,07	35,88		5494,7		4583,3	42,96		32,27				
FU Day 28	A		5898,3		5086,2	30,00	31,04		5494,7		4583,3	41,48		34,93				
FU Month 3	A		5796,6		5494,7	30,25	32,55		5393,0		4483,0	34,09		30,91				
FU Month 6	A		5694,9		4783,9	31,91	29,45		4578,9		3680,0	37,04		32,64				
FU Month 9	A		4372,9		3376,7	29,29	32,01		3459,6		2470,6	33,33		32,60				
FU Month 12	A		3661,0		3288,9	28,13	32,91		2442,1		1875,0	35,19		29,09				
FU Month 15	A		3050,8		2583,3	21,33	28,67		1933,3		1789,5	35,29		39,91				
FU Month 18	A		2237,3		1568,2	28,89	33,01		1628,1		1487,5	40,48		37,39				
FU Month 21	A		1728,8		1376,5	20,51	28,99		814,0		562,5	26,67		27,89				
FU Month 24	A		1016,9		660,0	38,89	38,97		58,8		480,0	16,67		33,33				
FU Month 27	A		58,5		360,0	33,33	33,33		23,5		150,0	0,00						NE
FU Month 30	A		46,8		375,0	55,56	19,25		0	NE	0	NE		NE				NE
Screening	B	104	100,0		8278,8	52,03	31,90		85100,0		7082,4	49,05		32,46				
Cycle 4 Day 1	B		8884,6		7281,8	26,85	27,77		7992,9		6379,7	35,98		30,70				
FU Day 28	B		9187,5		7076,9	30,48	30,95		7992,9		6379,7	22,22		27,44				
FU Month 3	B		8884,6		6573,9	31,79	29,13		7992,9		6177,2	28,96		28,20				
FU Month 6	B		8076,9		6885,0	26,47	25,47		7082,4		5274,3	28,85		28,79				
FU Month 9	B		6360,6		4774,6	26,24	30,25		5969,4		4474,6	27,27		26,19				
FU Month 12	B		4745,2		3574,5	25,71	28,11		4654,1		3780,4	24,32		27,94				
FU Month 15	B		3735,6		3183,8	17,20	22,56		3440,0		2573,5	29,33		27,76				
FU Month 18	B		3129,8		2683,9	25,64	27,17		2225,9		1777,3	27,45		29,43				
FU Month 21	B		1817,3		1266,7	13,89	17,16		1720,0		1376,5	20,51		21,68				
FU Month 24	B		1110,6		872,7	33,33	30,86		89,4		787,5	23,81		31,71				
FU Month 27	B		54,8		360,0	22,22	19,25		44,7		4100,0	8,33		16,67				
FU Month 30	B		21,9		150,0	0,00		NE	0	NE	0	NE		NE				NE
Screening	C		92100,0		7581,5	43,56	30,50	100	100,0		8585,0	40,39		30,90				
Cycle 4 Day 1	C		7480,4		5675,7	23,81	28,22		9191,0		6571,4	28,21		29,60				
FU Day 28	C		8188,0		6377,8	28,04	26,91		9292,0		7581,5	27,11		25,52				
FU Month 3	C		8087,0		6378,8	23,28	27,85		8989,0		6876,4	25,49		25,83				
FU Month 6	C		7177,2		5678,9	30,36	30,00		7777,0		5976,6	28,25		28,24				
FU Month 9	C		5863,0		4374,1	20,93	23,03		5656,0		4173,2	23,58		23,86				
FU Month 12	C		4245,7		3481,0	23,53	26,63		4747,0		3778,7	21,62		28,56				
FU Month 15	C		3740,2		2875,7	16,67	16,97		3232,0		2165,6	23,81		23,90				
FU Month 18	C		2628,3		2180,8	12,70	19,65		2222,0		1463,6	21,43		30,96				
FU Month 21	C		1718,5		1164,7	24,24	15,57		1515,0		1066,7	40,00		30,63				
FU Month 24	C		1112,0		763,6	14,29	17,82		55,0		360,0	33,33		33,33				

FU Month 27	C		33,3	266,7	16,67	23,57		33,0	133,3	0,00		NE	
FU Month 30	C		11,1	0	NE	NE	NE	11,0	1100,0	33,33		NE	
Total CIR score at baseline													
Screening	<=6	63	100,0	51	81,0	43,14	30,76	75	100,0	62	82,7	45,70	32,07
Cycle 4 Day 1	<=6	52	82,5	38	73,1	27,19	26,68	72	96,0	53	73,6	31,45	28,05
FU Day 28	<=6	56	88,9	45	80,4	28,89	28,07	72	96,0	53	73,6	25,79	25,85
FU Month 3	<=6	55	87,3	42	76,4	30,16	29,27	69	92,0	49	71,0	24,49	25,25
FU Month 6	<=6	52	82,5	43	82,7	28,68	27,78	60	80,0	45	75,0	30,37	29,15
FU Month 9	<=6	43	68,3	33	76,7	15,15	25,13	47	62,7	33	70,2	29,29	24,66
FU Month 12	<=6	35	55,6	28	80,0	27,38	31,50	34	45,3	27	79,4	29,63	29,72
FU Month 15	<=6	32	50,8	28	87,5	9,52	15,33	25	33,3	16	64,0	37,50	31,91
FU Month 18	<=6	23	36,5	20	87,0	23,33	28,82	19	25,3	14	73,7	30,95	35,72
FU Month 21	<=6	14	22,2	8	57,1	20,83	17,25	14	18,7	10	71,4	33,33	27,22
FU Month 24	<=6	8	12,7	7	87,5	19,05	26,23	7	9,3	6	85,7	22,22	27,22
FU Month 27	<=6	2	3,2	2	100,0	16,67	23,57	4	5,3	2	50,0	0,00	0,00
FU Month 30	<=6	0	NE	0	NE	NE	NE	1	1,3	1	100,0	33,33	NE
Screening >6													
Screening	>6	192	100,0	161	83,9	49,69	32,30	167	100,0	139	83,2	46,28	33,21
Cycle 4 Day 1	>6	161	83,9	135	83,9	27,90	31,33	152	91,0	120	78,9	36,39	32,34
FU Day 28	>6	174	90,6	138	79,3	29,71	30,05	153	91,6	130	85,0	30,26	30,91
FU Month 3	>6	170	88,5	140	82,4	27,86	30,08	152	91,0	124	81,6	30,65	29,01
FU Month 6	>6	155	80,7	128	82,6	29,43	28,25	132	79,0	102	77,3	30,72	29,92
FU Month 9	>6	121	63,0	90	74,4	28,89	28,79	102	61,1	76	74,5	26,32	27,92
FU Month 12	>6	90	46,9	73	81,1	25,11	28,21	83	49,7	65	78,3	23,59	28,09
FU Month 15	>6	72	37,5	56	77,8	22,62	24,71	60	35,9	47	78,3	26,24	29,44
FU Month 18	>6	56	29,2	42	75,0	21,43	26,36	41	24,6	31	75,6	29,03	31,90
FU Month 21	>6	38	19,8	28	73,7	19,05	23,00	26	15,6	18	69,2	25,93	26,95
FU Month 24	>6	24	12,5	14	58,3	33,33	32,03	11	6,6	8	72,7	25,00	34,50
FU Month 27	>6	11	5,7	6	54,5	27,78	25,09	5	3,0	4	80,0	8,33	16,67
FU Month 30	>6	7	3,6	4	57,1	41,67	31,91	0	NE	0	NE	NE	NE
Calculated creatinine clearance cat. 2													
Screening	<70 ml/min	178	100,0	147	82,6	48,98	32,01	176	100,0	148	84,1	47,07	31,81
Cycle 4 Day 1	<70 ml/min	149	83,7	119	79,9	26,61	29,62	164	93,2	128	78,0	36,20	31,31
FU Day 28	<70 ml/min	162	91,0	132	81,5	28,79	28,47	166	94,3	132	79,5	29,55	30,17
FU Month 3	<70 ml/min	157	88,2	129	82,2	26,87	29,19	159	90,3	123	77,4	30,62	27,85
FU Month 6	<70 ml/min	144	80,9	121	84,0	28,93	27,54	139	79,0	105	75,5	31,11	30,75
FU Month 9	<70 ml/min	117	65,7	87	74,4	22,61	28,53	112	63,6	80	71,4	28,75	27,94
FU Month 12	<70 ml/min	92	51,7	73	79,3	24,20	27,36	87	49,4	68	78,2	27,45	28,18
FU Month 15	<70 ml/min	78	43,8	65	83,3	15,90	21,33	60	34,1	43	71,7	32,56	31,28

FU Month 18	<70 ml/min	59	33,1	47	79,7	21,28	28,17	43	24,4	32	74,4	34,38	35,40
FU Month 21	<70 ml/min	38	21,3	24	63,2	19,44	23,91	31	17,6	23	74,2	31,88	27,48
FU Month 24	<70 ml/min	24	13,5	16	66,7	25,00	31,03	13	7,4	9	69,2	29,63	30,93
FU Month 27	<70 ml/min	10	5,6	5	50,0	20,00	18,26	7	4,0	4	57,1	8,33	16,67
FU Month 30	<70 ml/min	5	2,8	2	40,0	16,67	23,57	1	0,6	1	100,0	33,33	NE
Screening	>=70 ml/min	77	100,0	65	84,4	46,15	32,11	66	100,0	53	80,3	43,40	35,56
Cycle 4 Day 1	>=70 ml/min	64	83,1	54	84,4	30,25	31,90	60	90,9	45	75,0	31,11	30,48
FU Day 28	>=70 ml/min	68	88,3	51	75,0	31,37	32,26	59	89,4	51	86,4	27,45	28,05
FU Month 3	>=70 ml/min	68	88,3	53	77,9	32,08	31,33	62	93,9	50	80,6	24,67	28,42
FU Month 6	>=70 ml/min	63	81,8	50	79,4	30,00	29,55	53	80,3	42	79,2	29,37	26,75
FU Month 9	>=70 ml/min	47	61,0	36	76,6	31,48	27,54	37	56,1	29	78,4	22,99	23,74
FU Month 12	>=70 ml/min	33	42,9	28	84,8	29,76	33,13	30	45,5	24	80,0	19,44	29,35
FU Month 15	>=70 ml/min	26	33,8	19	73,1	26,32	26,24	25	37,9	20	80,0	21,67	27,09
FU Month 18	>=70 ml/min	20	26,0	15	75,0	24,44	23,46	17	25,8	13	76,5	17,95	22,01
FU Month 21	>=70 ml/min	14	18,2	12	85,7	19,44	17,16	9	13,6	5	55,6	13,33	18,26
FU Month 24	>=70 ml/min	8	10,4	5	62,5	40,00	27,89	5	7,6	5	100,0	13,33	29,81
FU Month 27	>=70 ml/min	3	3,9	3	100,0	33,33	33,33	2	3,0	2	100,0	0,00	0,00
FU Month 30	>=70 ml/min	2	2,6	2	100,0	66,67	0,00	0	NE	0	NE	NE	NE
Beta2 microglobulin													
Screening	Missing	3	100,0	3	100,0	44,44	50,92	3	100,0	2	66,7	83,33	23,57
Cycle 4 Day 1	Missing	3	100,0	3	100,0	33,33	33,33	3	100,0	1	33,3	66,67	NE
FU Day 28	Missing	3	100,0	3	100,0	33,33	33,33	3	100,0	1	33,3	33,33	NE
FU Month 3	Missing	3	100,0	3	100,0	33,33	33,33	3	100,0	1	33,3	33,33	NE
FU Month 6	Missing	3	100,0	3	100,0	0,00	0,00	3	100,0	1	33,3	33,33	NE
FU Month 9	Missing	2	66,7	1	50,0	0,00	NE	3	100,0	1	33,3	66,67	NE
FU Month 12	Missing	1	33,3	1	100,0	33,33	NE	2	66,7	0	NE	NE	NE
FU Month 15	Missing	1	33,3	1	100,0	33,33	NE	2	66,7	0	NE	NE	NE
FU Month 18	Missing	1	33,3	1	100,0	33,33	NE	2	66,7	0	NE	NE	NE
FU Month 21	Missing	1	33,3	1	100,0	33,33	NE	2	66,7	0	NE	NE	NE
FU Month 24	Missing	1	33,3	1	100,0	33,33	NE	1	33,3	0	NE	NE	NE
Screening	< 3.5 ug/mL	154	100,0	132	85,7	46,46	31,03	140	100,0	119	85,0	46,22	33,65
Cycle 4 Day 1	< 3.5 ug/mL	127	82,5	108	85,0	29,01	29,92	129	92,1	101	78,3	33,99	31,26
FU Day 28	< 3.5 ug/mL	137	89,0	115	83,9	27,83	28,93	132	94,3	109	82,6	26,91	28,50
FU Month 3	< 3.5 ug/mL	134	87,0	117	87,3	27,92	28,35	130	92,9	103	79,2	29,45	27,73
FU Month 6	< 3.5 ug/mL	128	83,1	108	84,4	28,70	26,75	120	85,7	97	80,8	31,62	29,80
FU Month 9	< 3.5 ug/mL	104	67,5	80	76,9	25,83	28,55	98	70,0	75	76,5	27,56	27,05
FU Month 12	< 3.5 ug/mL	78	50,6	66	84,6	29,29	31,22	75	53,6	62	82,7	25,81	30,43
FU Month 15	< 3.5 ug/mL	65	42,2	54	83,1	19,14	22,99	60	42,9	47	78,3	29,79	31,26
FU Month 18	< 3.5 ug/mL	46	29,9	37	80,4	23,42	28,18	43	30,7	33	76,7	32,32	33,83

FU Month 21	< 3.5 ug/mL	30	19,5	20	66,7	20,00	25,13	27	19,3	20	74,1	26,67	27,78
FU Month 24	< 3.5 ug/mL	19	12,3	14	73,7	28,57	34,24	12	8,6	10	83,3	13,33	23,31
FU Month 27	< 3.5 ug/mL	10	6,5	7	70,0	28,57	23,00	7	5,0	4	57,1	0,00	0,00
FU Month 30	< 3.5 ug/mL	5	3,2	3	60,0	33,33	33,33	1	0,7	1	100,0	33,33	NE
Screening	>= 3.5 ug/mL	98	100,0	77	78,6	51,08	33,15	99	100,0	80	80,8	45,00	31,42
Cycle 4 Day 1	>= 3.5 ug/mL	83	84,7	62	74,7	25,27	31,18	92	92,9	71	77,2	35,68	31,03
FU Day 28	>= 3.5 ug/mL	90	91,8	65	72,2	32,31	30,60	90	90,9	73	81,1	31,96	31,15
FU Month 3	>= 3.5 ug/mL	88	89,8	62	70,5	29,03	32,77	88	88,9	69	78,4	28,02	28,94
FU Month 6	>= 3.5 ug/mL	76	77,6	60	78,9	31,67	30,33	69	69,7	49	71,0	28,57	29,66
FU Month 9	>= 3.5 ug/mL	58	59,2	42	72,4	24,60	28,57	48	48,5	33	68,8	25,25	26,39
FU Month 12	>= 3.5 ug/mL	46	46,9	34	73,9	18,63	23,49	40	40,4	30	75,0	24,44	24,66
FU Month 15	>= 3.5 ug/mL	38	38,8	29	76,3	16,09	22,92	23	23,2	16	69,6	27,08	27,81
FU Month 18	>= 3.5 ug/mL	32	32,7	24	75,0	19,44	25,85	15	15,2	12	80,0	22,22	29,59
FU Month 21	>= 3.5 ug/mL	21	21,4	15	71,4	17,78	17,21	11	11,1	8	72,7	33,33	25,20
FU Month 24	>= 3.5 ug/mL	12	12,2	6	50,0	27,78	25,09		5,1	4	80,0	50,00	33,33
FU Month 27	>= 3.5 ug/mL	3	3,1	1	33,3	0,00	NE	2	2,0	2	100,0	16,67	23,57
FU Month 30	>= 3.5 ug/mL	2	2,0	1	50,0	66,67	NE	0	NE	0	NE	NE	NE
Immunoglobulin VH, cytogenetics 2													
Screening	12	45	100,0	38	84,4	48,25	27,62	44	100,0	40	90,9	46,67	33,59
Cycle 4 Day 1	12	34	75,6	29	85,3	32,18	32,71	38	86,4	29	76,3	32,18	33,90
FU Day 28	12	39	86,7	35	89,7	37,14	30,00	40	90,9	35	87,5	28,57	33,47
FU Month 3	12	38	84,4	34	89,5	37,25	34,59	39	88,6	30	76,9	27,78	34,00
FU Month 6	12	36	80,0	30	83,3	32,22	25,50	34	77,3	27	79,4	30,86	35,72
FU Month 9	12	26	57,8	20	76,9	35,00	27,52	28	63,6	17	60,7	33,33	28,87
FU Month 12	12	22	48,9	17	77,3	33,33	26,35	23	52,3	14	60,9	26,19	32,50
FU Month 15	12	17	37,8	13	76,5	20,51	21,68	17	38,6	11	64,7	30,30	27,71
FU Month 18	12	15	33,3	11	73,3	24,24	21,56	13	29,5	8	61,5	20,83	24,80
FU Month 21	12	10	22,2	7	70,0	33,33	33,33	7	15,9	4	57,1	16,67	19,25
FU Month 24	12	8	17,8	5	62,5	53,33	29,81	6	13,6	5	83,3	33,33	33,33
FU Month 27	12	5	11,1	3	60,0	33,33	0,00	2	4,5	2	100,0	0,00	0,00
FU Month 30	12	4	8,9	2	50,0	16,67	23,57	1	2,3	1	100,0	33,33	NE
Screening	11q-	46	100,0	34	73,9	37,25	26,92	43	100,0	35	81,4	44,76	32,28
Cycle 4 Day 1	11q-	40	87,0	33	82,5	20,20	24,92	41	95,3	32	78,0	36,46	28,54
FU Day 28	11q-	42	91,3	29	69,0	18,39	26,10	39	90,7	32	82,1	30,21	25,90
FU Month 3	11q-	42	91,3	32	76,2	22,92	26,01	38	88,4	34	89,5	26,47	24,31
FU Month 6	11q-	38	82,6	31	81,6	22,58	26,37	32	74,4	26	81,3	37,18	25,52
FU Month 9	11q-	28	60,9	23	82,1	23,19	29,19	25	58,1	20	80,0	25,00	23,88
FU Month 12	11q-	20	43,5	17	85,0	23,53	28,30	18	41,9	16	88,9	33,33	29,81
FU Month 15	11q-	18	39,1	15	83,3	11,11	20,57	14	32,6	9	64,3	22,22	16,67

FU Month 18	11q-	15	32,6	11	73,3	24,24	30,15	8	18,6	6	75,0	38,89	32,77
FU Month 21	11q-	12	26,1	10	83,3	16,67	17,57	4	9,3	1	25,0	33,33	NE
FU Month 24	11q-	7	15,2	4	57,1	25,00	31,91	1	2,3	1	100,0	0,00	NE
FU Month 27	11q-	3	6,5	2	66,7	33,33	47,14	0	NE	0	NE	NE	NE
FU Month 30	11q-	3	6,5	2	66,7	66,67	0,00	0	NE	0	NE	NE	NE
Screening	13q-	79	100,0	67	84,8	46,77	33,86	75	100,0	57	76,0	44,44	33,53
Cycle 4 Day 1	13q-	67	84,8	50	74,6	28,00	30,39	68	90,7	50	73,5	36,67	27,15
FU Day 28	13q-	72	91,1	58	80,6	26,44	27,04	72	96,0	54	75,0	24,69	26,84
FU Month 3	13q-	73	92,4	60	82,2	25,00	28,54	69	92,0	49	71,0	33,33	28,87
FU Month 6	13q-	67	84,8	55	82,1	27,27	26,52	63	84,0	44	69,8	29,55	28,04
FU Month 9	13q-	56	70,9	44	78,6	24,24	29,08	52	69,3	37	71,2	24,32	27,94
FU Month 12	13q-	44	55,7	37	84,1	26,13	29,54	40	53,3	34	85,0	21,57	25,80
FU Month 15	13q-	38	48,1	32	84,2	17,71	16,90	29	38,7	23	79,3	31,88	32,53
FU Month 18	13q-	28	35,4	23	82,1	20,29	27,96	21	28,0	17	81,0	35,29	36,27
FU Month 21	13q-	16	20,3	12	75,0	16,67	17,41	16	21,3	12	75,0	25,00	25,13
FU Month 24	13q-	7	8,9	5	71,4	13,33	18,26	7	9,3	4	57,1	16,67	33,33
FU Month 27	13q-	2	2,5	1	50,0	0,00	NE	6	8,0	3	50,0	11,11	19,25
Screening	Norm. K.	65	100,0	56	86,2	55,36	33,80	58	100,0	50	86,2	53,33	32,30
Cycle 4 Day 1	Norm. K.	54	83,1	46	85,2	28,99	31,90	55	94,8	45	81,8	38,52	34,78
FU Day 28	Norm. K.	59	90,8	47	79,7	33,33	31,85	53	91,4	46	86,8	35,51	32,51
FU Month 3	Norm. K.	54	83,1	43	79,6	29,46	29,29	54	93,1	43	79,6	30,23	28,00
FU Month 6	Norm. K.	49	75,4	43	87,8	35,66	33,65	45	77,6	33	73,3	34,34	31,72
FU Month 9	Norm. K.	39	60,0	26	66,7	19,23	26,95	30	51,7	24	80,0	29,17	28,34
FU Month 12	Norm. K.	32	49,2	24	75,0	22,22	32,10	24	41,4	18	75,0	25,93	29,27
FU Month 15	Norm. K.	26	40,0	20	76,9	18,33	27,52	20	34,5	16	80,0	29,17	31,91
FU Month 18	Norm. K.	18	27,7	14	77,8	23,81	30,46	15	25,9	12	80,0	25,00	35,18
FU Month 21	Norm. K.	12	18,5	5	41,7	20,00	18,26	11	19,0	9	81,8	40,74	32,39
FU Month 24	Norm. K.	8	12,3	5	62,5	33,33	33,33	4	6,9	4	100,0	25,00	31,91
FU Month 27	Norm. K.	3	4,6	2	66,7	16,67	23,57	1	1,7	1	100,0	0,00	NE
Screening	Other Abn.	20	100,0	17	85,0	50,98	33,58	22	100,0	19	86,4	33,33	29,40
Cycle 4 Day 1	Other Abn.	18	90,0	15	83,3	31,11	32,04	22	100,0	17	77,3	21,57	31,05
FU Day 28	Other Abn.	18	90,0	14	77,8	33,33	32,03	21	95,5	16	76,2	22,92	26,44
FU Month 3	Other Abn.	18	90,0	13	72,2	30,77	31,80	21	95,5	17	81,0	19,61	20,61
FU Month 6	Other Abn.	17	85,0	12	70,6	25,00	20,72	18	81,8	17	94,4	15,69	20,81
FU Month 9	Other Abn.	15	75,0	10	66,7	30,00	29,19	14	63,6	11	78,6	27,27	25,03
FU Month 12	Other Abn.	7	35,0	6	85,7	22,22	27,22	12	54,5	10	83,3	23,33	31,62
FU Month 15	Other Abn.	5	25,0	4	80,0	41,67	41,94	5	22,7	4	80,0	25,00	50,00
FU Month 18	Other Abn.	3	15,0	3	100,0	11,11	19,25	3	13,6	2	66,7	16,67	23,57
FU Month 21	Other Abn.	2	10,0	2	100,0	0,00	0,00	2	9,1	2	100,0	16,67	23,57

FU Month 24	Other Abn.	2	10,0	2	100,0	0,00	0,00	0	NE	0	NE	NE	NE
Time from first diagnosis													
Screening	Missing	1	100,0	1	100,0	33,33	NE	0	NE	0	NE	NE	NE
Cycle 4 Day 1	Missing	1	100,0	1	100,0	33,33	NE	0	NE	0	NE	NE	NE
FU Day 28	Missing	1	100,0	1	100,0	33,33	NE	0	NE	0	NE	NE	NE
FU Month 3	Missing	1	100,0	1	100,0	33,33	NE	0	NE	0	NE	NE	NE
FU Month 6	Missing	1	100,0	1	100,0	33,33	NE	0	NE	0	NE	NE	NE
FU Month 9	Missing	1	100,0	1	100,0	33,33	NE	0	NE	0	NE	NE	NE
FU Month 12	Missing	1	100,0	1	100,0	33,33	NE	0	NE	0	NE	NE	NE
FU Month 15	Missing	1	100,0	1	100,0	33,33	NE	0	NE	0	NE	NE	NE
FU Month 18	Missing	1	100,0	1	100,0	33,33	NE	0	NE	0	NE	NE	NE
Screening	13 - 24 months	41	100,0	31	75,6	59,14	31,87	31	100,0	30	96,8	43,33	30,51
Cycle 4 Day 1	13 - 24 months	35	85,4	28	80,0	38,10	35,96	30	96,8	26	86,7	30,77	24,81
FU Day 28	13 - 24 months	38	92,7	26	68,4	43,59	32,34	30	96,8	26	86,7	17,95	21,56
FU Month 3	13 - 24 months	36	87,8	28	77,8	33,33	31,43	30	96,8	25	83,3	22,67	23,01
FU Month 6	13 - 24 months	36	87,8	27	75,0	24,69	31,48	30	96,8	24	80,0	25,00	29,90
FU Month 9	13 - 24 months	32	78,0	22	68,8	24,24	31,17	21	67,7	17	81,0	15,69	20,81
FU Month 12	13 - 24 months	21	51,2	15	71,4	24,44	34,43	16	51,6	13	81,3	20,51	25,60
FU Month 15	13 - 24 months	19	46,3	15	78,9	15,56	30,52	16	51,6	8	50,0	8,33	15,43
FU Month 18	13 - 24 months	14	34,1	10	71,4	23,33	27,44	10	32,3	8	80,0	16,67	17,82
FU Month 21	13 - 24 months	11	26,8	7	63,6	28,57	35,63	6	19,4	4	66,7	25,00	16,67
FU Month 24	13 - 24 months	8	19,5	3	37,5	77,78	19,25	3	9,7	3	100,0	22,22	19,25
FU Month 27	13 - 24 months	5	12,2	3	60,0	22,22	19,25	2	6,5	2	100,0	0,00	0,00
FU Month 30	13 - 24 months	3	7,3	2	66,7	50,00	23,57	1	3,2	1	100,0	33,33	NE
Screening	<= 12 months	60	100,0	48	80,0	47,22	31,39	70	100,0	55	78,6	43,64	31,34
Cycle 4 Day 1	<= 12 months	48	80,0	34	70,8	27,45	26,55	60	85,7	43	71,7	38,76	31,65
FU Day 28	<= 12 months	54	90,0	39	72,2	32,48	28,08	62	88,6	47	75,8	34,04	32,96
FU Month 3	<= 12 months	53	88,3	38	71,7	31,58	30,95	59	84,3	44	74,6	32,58	32,54
FU Month 6	<= 12 months	46	76,7	35	76,1	34,29	28,57	47	67,1	32	68,1	31,25	32,72
FU Month 9	<= 12 months	35	58,3	27	77,1	27,16	27,79	37	52,9	27	73,0	19,75	24,91
FU Month 12	<= 12 months	27	45,0	21	77,8	28,57	30,34	29	41,4	24	82,8	23,61	30,26
FU Month 15	<= 12 months	22	36,7	16	72,7	27,08	25,00	17	24,3	15	88,2	31,11	23,46
FU Month 18	<= 12 months	16	26,7	10	62,5	16,67	23,57	13	18,6	11	84,6	21,21	22,47
FU Month 21	<= 12 months	9	15,0	5	55,6	13,33	18,26	7	10,0	5	71,4	33,33	23,57
FU Month 24	<= 12 months	6	10,0	3	50,0	11,11	19,25	2	2,9	0	NE	NE	NE
FU Month 27	<= 12 months	1	1,7			NE	NE	1	1,4			NE	NE
FU Month 30	<= 12 months	1	1,7			NE	NE	0	NE			NE	NE
Screening	>24 months	153	100,0	132	86,3	45,96	32,04	141	100,0	116	82,3	47,99	34,13

Cycle 4 Day 1	>24 months	129	84,3	110	85,3	25,15	29,67	134	95,0	104	77,6	34,29	32,33
FU Day 28	>24 months	137	89,5	117	85,4	25,36	28,58	133	94,3	110	82,7	29,39	29,17
FU Month 3	>24 months	135	88,2	115	85,2	26,09	29,21	132	93,6	104	78,8	28,85	27,11
FU Month 6	>24 months	124	81,0	108	87,1	28,70	27,14	115	81,6	91	79,1	31,87	28,51
FU Month 9	>24 months	96	62,7	73	76,0	24,66	28,34	91	64,5	65	71,4	33,33	27,64
FU Month 12	>24 months	76	49,7	64	84,2	25,00	27,86	72	51,1	55	76,4	27,27	28,75
FU Month 15	>24 months	62	40,5	52	83,9	16,03	19,23	52	36,9	40	76,9	32,50	33,32
FU Month 18	>24 months	48	31,4	41	85,4	22,76	28,32	37	26,2	26	70,3	37,18	38,10
FU Month 21	>24 months	32	20,9	24	75,0	18,06	16,97	27	19,1	19	70,4	28,07	29,94
FU Month 24	>24 months	18	11,8	15	83,3	22,22	24,12	13	9,2	11	84,6	24,24	33,63
FU Month 27	>24 months	7	4,6	5	71,4	26,67	27,89	6	4,3	4	66,7	8,33	16,67
FU Month 30	>24 months	3	2,0	2	66,7	33,33	47,14	0	NE	0	NE	NE	NE
High circulating tumor burden													
Screening	Missing	0	NE	0	NE	NE	NE	2	100,0	1	50,0	66,67	NE
Cycle 4 Day 1	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	0,00	NE
FU Day 28	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	33,33	NE
FU Month 3	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	66,67	NE
FU Month 6	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	0,00	NE
FU Month 9	Missing	0	NE			NE	NE	1	50,0			NE	NE
Screening													
Screening	<25x10**9 cells/L	60	100,0	50	83,3	47,33	35,05	67	100,0	55	82,1	46,06	31,09
Cycle 4 Day 1	<25x10**9 cells/L	50	83,3	41	82,0	26,83	30,02	61	91,0	43	70,5	34,88	31,67
FU Day 28	<25x10**9 cells/L	56	93,3	44	78,6	33,33	31,34	61	91,0	46	75,4	28,99	32,67
FU Month 3	<25x10**9 cells/L	54	90,0	43	79,6	31,78	30,82	59	88,1	44	74,6	25,76	26,77
FU Month 6	<25x10**9 cells/L	50	83,3	41	82,0	36,59	29,63	51	76,1	38	74,5	25,44	29,44
FU Month 9	<25x10**9 cells/L	36	60,0	23	63,9	27,54	25,92	41	61,2	28	68,3	21,43	22,62
FU Month 12	<25x10**9 cells/L	29	48,3	23	79,3	30,43	28,27	34	50,7	23	67,6	23,19	29,19
FU Month 15	<25x10**9 cells/L	24	40,0	19	79,2	28,07	27,81	23	34,3	13	56,5	15,38	17,30
FU Month 18	<25x10**9 cells/L	20	33,3	17	85,0	23,53	25,72	19	28,4	13	68,4	20,51	32,03
FU Month 21	<25x10**9 cells/L	14	23,3	9	64,3	25,93	32,39	10	14,9	7	70,0	23,81	25,20
FU Month 24	<25x10**9 cells/L	8	13,3	4	50,0	41,67	41,94	6	9,0	5	83,3	40,00	27,89
FU Month 27	<25x10**9 cells/L	4	6,7	2	50,0	33,33	0,00	1	1,5	1	100,0	0,00	NE
FU Month 30	<25x10**9 cells/L	4	6,7	2	50,0	16,67	23,57	1	1,5	1	100,0	33,33	NE
Screening													
Screening	>=25x10**9 cells/L	195	100,0	162	83,1	48,35	31,10	173	100,0	145	83,8	45,98	33,58
Cycle 4 Day 1	>=25x10**9 cells/L	163	83,6	132	81,0	28,03	30,50	162	93,6	129	79,6	35,14	30,99
FU Day 28	>=25x10**9 cells/L	174	89,2	139	79,9	28,30	28,91	163	94,2	136	83,4	28,92	28,63
FU Month 3	>=25x10**9 cells/L	171	87,7	139	81,3	27,34	29,56	161	93,1	128	79,5	29,69	28,44
FU Month 6	>=25x10**9 cells/L	157	80,5	130	82,8	26,92	27,25	140	80,9	108	77,1	32,72	29,53
FU Month 9	>=25x10**9 cells/L	128	65,6	100	78,1	24,67	29,06	107	61,8	81	75,7	29,22	28,08
FU Month 12	>=25x10**9 cells/L	96	49,2	78	81,3	24,36	29,26	83	48,0	69	83,1	26,09	28,51

FU Month 15	>=25x10**9 cells/L	80	41,0	65	81,3	15,38	20,48	62	35,8	50	80,6	32,67	31,94
FU Month 18	>=25x10**9 cells/L	59	30,3	45	76,3	21,48	27,67	41	23,7	32	78,0	33,33	32,79
FU Month 21	>=25x10**9 cells/L	38	19,5	27	71,1	17,28	16,97	30	17,3	21	70,0	30,16	27,70
FU Month 24	>=25x10**9 cells/L	24	12,3	17	70,8	25,49	27,71	12	6,9	9	75,0	14,81	29,40
FU Month 27	>=25x10**9 cells/L	9	4,6	6	66,7	22,22	27,22	8	4,6	5	62,5	6,67	14,91
FU Month 30	>=25x10**9 cells/L	3	1,5	2	66,7	66,67	0,00	0	NE	0	NE	NE	NE

¹ in study: number of subjects in study at respective visit; % based on baseline

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit

² mean: descriptive statistics - absolute values Clinical

cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/t_pro_mean.sas

Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/t_pro_mean_sg_EQCLL16_IT_label_09MAY2013_21004.xls 04MAR2020

17:21

POPULATION: Labelpopulation, Intent-to-Treat Patients
 ENDPOINT: EORTC QoL 16
 MODEL: Unadjusted Analysis
 STUDY: CLL11 (BO21004), Stage 2
 Compliance/Mean

Infection Scale

		GClb (N=255)						RC1b (N=242)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study ¹	%	with value ¹	%	Mean ²	SD(mean)	in study ¹	%	with value ¹	%	Mean ²	SD(mean)
All													
Screening	n/a	255	100,0	216	84,7	11,66	15,81	242	100,0	202	83,5	10,86	15,69
Cycle 4 Day 1	n/a	213	83,5	174	81,7	7,71	11,33	224	92,6	175	78,1	9,44	14,78
FU Day 28	n/a	230	90,2	184	80,0	9,75	16,30	225	93,0	183	81,3	10,93	14,18
FU Month 3	n/a	225	88,2	183	81,3	9,81	16,04	221	91,3	174	78,7	9,42	13,30
FU Month 6	n/a	207	81,2	171	82,6	10,14	15,88	192	79,3	146	76,0	9,11	13,37
FU Month 9	n/a	164	64,3	126	76,8	9,52	15,34	149	61,6	111	74,5	9,01	13,81
FU Month 12	n/a	125	49,0	101	80,8	11,47	18,44	117	48,3	91	77,8	8,97	11,87
FU Month 15	n/a	104	40,8	84	80,8	6,68	10,97	85	35,1	63	74,1	8,51	14,11
FU Month 18	n/a	79	31,0	62	78,5	10,53	17,11	60	24,8	45	75,0	8,15	12,24
FU Month 21	n/a	52	20,4	36	69,2	11,27	16,51	40	16,5	28	70,0	9,23	12,07
FU Month 24	n/a	32	12,5	21	65,6	6,75	13,34	18	7,4	14	77,8	6,55	11,87
FU Month 27	n/a	13	5,1	8	61,5	11,11	17,51	9	3,7	6	66,7	4,17	6,97
FU Month 30	n/a	7	2,7	4	57,1	6,25	7,98	1	0,4	1	100,0	0,00	NE
Gender													
Screening	Female	97	100,0	82	84,5	10,94	15,42	95	100,0	74	77,9	10,70	14,30
Cycle 4 Day 1	Female	84	86,6	67	79,8	9,20	11,53	88	92,6	67	76,1	11,48	16,01
FU Day 28	Female	90	92,8	75	83,3	9,26	14,01	91	95,8	70	76,9	12,14	14,17
FU Month 3	Female	88	90,7	73	83,0	6,62	10,93	87	91,6	63	72,4	10,45	15,62
FU Month 6	Female	84	86,6	64	76,2	9,38	13,49	77	81,1	55	71,4	9,49	14,06
FU Month 9	Female	70	72,2	52	74,3	9,62	15,95	61	64,2	39	63,9	8,55	12,31
FU Month 12	Female	56	57,7	45	80,4	10,00	15,95	47	49,5	33	70,2	7,32	10,98
FU Month 15	Female	47	48,5	37	78,7	5,71	7,91	33	34,7	24	72,7	6,60	13,00
FU Month 18	Female	34	35,1	25	73,5	7,67	11,26	26	27,4	19	73,1	10,09	13,77
FU Month 21	Female	21	21,6	11	52,4	18,18	22,30	17	17,9	12	70,6	7,64	12,03
FU Month 24	Female	12	12,4	6	50,0	5,56	6,80	6	6,3	3	50,0	2,78	4,81
FU Month 27	Female	6	6,2	2	33,3	29,17	29,46	2	2,1	1	50,0	0,00	NE
FU Month 30	Female	4	4,1	1	25,0	16,67	NE	1	1,1	1	100,0	0,00	NE

Screening	Male	158	100,0	134	84,8	12,11	16,09	147	100,0	128	87,1	10,96	16,49
Cycle 4 Day 1	Male	129	81,6	107	82,9	6,78	11,16	136	92,5	108	79,4	8,18	13,90
FU Day 28	Male	140	88,6	109	77,9	10,09	17,75	134	91,2	113	84,3	10,18	14,21
FU Month 3	Male	137	86,7	110	80,3	11,92	18,42	134	91,2	111	82,8	8,83	11,82
FU Month 6	Male	123	77,8	107	87,0	10,59	17,20	115	78,2	91	79,1	8,88	13,02
FU Month 9	Male	94	59,5	74	78,7	9,46	15,00	88	59,9	72	81,8	9,26	14,64
FU Month 12	Male	69	43,7	56	81,2	12,65	20,29	70	47,6	58	82,9	9,91	12,34
FU Month 15	Male	57	36,1	47	82,5	7,45	12,91	52	35,4	39	75,0	9,69	14,79
FU Month 18	Male	45	28,5	37	82,2	12,46	20,05	34	23,1	26	76,5	6,73	11,06
FU Month 21	Male	31	19,6	25	80,6	8,22	12,59	23	15,6	16	69,6	10,42	12,36
FU Month 24	Male	20	12,7	15	75,0	7,22	15,39	12	8,2	11	91,7	7,58	13,15
FU Month 27	Male	7	4,4	6	85,7	5,09	9,03	7	4,8	5	71,4	5,00	7,45
FU Month 30	Male	3	1,9	3	100,0	2,78	4,81	0	NE	0	NE	NE	NE
Age													
Screening	<75 years	130	100,0	102	78,5	13,32	17,16	120	100,0	91	75,8	10,53	14,53
Cycle 4 Day 1	<75 years	106	81,5	81	76,4	7,61	10,39	112	93,3	82	73,2	11,08	15,65
FU Day 28	<75 years	119	91,5	91	76,5	10,84	17,59	110	91,7	86	78,2	13,18	15,36
FU Month 3	<75 years	116	89,2	91	78,4	11,48	17,64	109	90,8	82	75,2	11,21	15,52
FU Month 6	<75 years	108	83,1	86	79,6	9,88	13,80	99	82,5	71	71,7	10,68	15,12
FU Month 9	<75 years	85	65,4	66	77,6	11,36	16,06	74	61,7	54	73,0	9,41	13,45
FU Month 12	<75 years	63	48,5	53	84,1	12,11	19,17	60	50,0	47	78,3	9,57	12,28
FU Month 15	<75 years	54	41,5	42	77,8	6,55	13,08	44	36,7	32	72,7	6,77	13,95
FU Month 18	<75 years	43	33,1	34	79,1	10,29	16,03	27	22,5	20	74,1	9,17	12,36
FU Month 21	<75 years	26	20,0	20	76,9	14,03	19,44	17	14,2	11	64,7	9,09	13,15
FU Month 24	<75 years	18	13,8	12	66,7	9,72	16,60	6	5,0	4	66,7	14,58	17,18
FU Month 27	<75 years	7	5,4	4	57,1	9,72	9,21	2	1,7	1	50,0	0,00	NE
FU Month 30	<75 years	4	3,1	2	50,0	4,17	5,89	0	NE	0	NE	NE	NE
Screening	>=75 years	125	100,0	114	91,2	10,19	14,41	122	100,0	111	91,0	11,14	16,64
Cycle 4 Day 1	>=75 years	107	85,6	93	86,9	7,80	12,15	112	91,8	93	83,0	8,00	13,90
FU Day 28	>=75 years	111	88,8	93	83,8	8,69	14,94	115	94,3	97	84,3	8,93	12,80
FU Month 3	>=75 years	109	87,2	92	84,4	8,15	14,19	112	91,8	92	82,1	7,82	10,79
FU Month 6	>=75 years	99	79,2	85	85,9	10,39	17,82	93	76,2	75	80,6	7,63	11,39
FU Month 9	>=75 years	79	63,2	60	75,9	7,50	14,37	75	61,5	57	76,0	8,63	14,26
FU Month 12	>=75 years	62	49,6	48	77,4	10,76	17,78	57	46,7	44	77,2	8,33	11,51
FU Month 15	>=75 years	50	40,0	42	84,0	6,81	8,51	41	33,6	31	75,6	10,30	14,28
FU Month 18	>=75 years	36	28,8	28	77,8	10,81	18,63	33	27,0	25	75,8	7,33	12,34
FU Month 21	>=75 years	26	20,8	16	61,5	7,81	11,57	23	18,9	17	73,9	9,31	11,74
FU Month 24	>=75 years	14	11,2	9	64,3	2,78	5,89	12	9,8	10	83,3	3,33	8,05
FU Month 27	>=75 years	6	4,8	4	66,7	12,50	25,00	7	5,7	5	71,4	5,00	7,45

FU Month 30	>=75 years	3	2,4	2	66,7	8,33	11,79	1	10,8	1	100,0	0,00	NE
Race													
Screening	Other	9	100,0	6	66,7	8,33	12,91	11	100,0	7	63,6	7,14	5,75
Cycle 4 Day 1	Other	7	77,8	4	57,1	16,67	22,57	10	90,9	6	60,0	18,06	24,39
FU Day 28	Other	8	88,9	5	62,5	16,67	16,67	10	90,9	7	70,0	10,71	11,50
FU Month 3	Other	8	88,9	4	50,0	14,58	23,94	10	90,9	6	60,0	16,67	21,08
FU Month 6	Other	8	88,9	4	50,0	12,50	19,84	8	72,7	6	75,0	2,78	4,30
FU Month 9	Other	4	44,4	3	75,0	19,44	26,79	5	45,5	4	80,0	6,25	4,17
FU Month 12	Other	3	33,3	2	66,7	20,83	29,46	4	36,4	4	100,0	6,25	7,98
FU Month 15	Other	2	22,2	1	50,0	0,00	NE	4	36,4	4	100,0	6,25	7,98
FU Month 18	Other	2	22,2	1	50,0	8,33	NE	2	18,2	2	100,0	25,00	11,79
FU Month 21	Other	2	22,2	1	50,0	8,33	NE	2	18,2	2	100,0	4,17	5,89
FU Month 24	Other	2	22,2	1	50,0	0,00	NE	1	9,1	0	NE	NE	NE
FU Month 27	Other	1	11,1			NE	NE	1	9,1			NE	NE
FU Month 30	Other	1	11,1			NE	NE	0	NE			NE	NE
Screening													
Screening	White	246	100,0	210	85,4	11,76	15,90	231	100,0	195	84,4	11,00	15,92
Cycle 4 Day 1	White	206	83,7	170	82,5	7,50	10,98	214	92,6	169	79,0	9,14	14,35
FU Day 28	White	222	90,2	179	80,6	9,56	16,29	215	93,1	176	81,9	10,94	14,31
FU Month 3	White	217	88,2	179	82,5	9,70	15,90	211	91,3	168	79,6	9,16	12,96
FU Month 6	White	199	80,9	167	83,9	10,08	15,84	184	79,7	140	76,1	9,38	13,57
FU Month 9	White	160	65,0	123	76,9	9,28	15,06	144	62,3	107	74,3	9,11	14,04
FU Month 12	White	122	49,6	99	81,1	11,28	18,34	113	48,9	87	77,0	9,10	12,03
FU Month 15	White	102	41,5	83	81,4	6,76	11,01	81	35,1	59	72,8	8,66	14,46
FU Month 18	White	77	31,3	61	79,2	10,56	17,25	58	25,1	43	74,1	7,36	11,81
FU Month 21	White	50	20,3	35	70,0	11,35	16,74	38	16,5	26	68,4	9,62	12,40
FU Month 24	White	30	12,2	20	66,7	7,08	13,59	17	7,4	14	82,4	6,55	11,87
FU Month 27	White	12	4,9	8	66,7	11,11	17,51	8	3,5	6	75,0	4,17	6,97
FU Month 30	White	6	2,4	4	66,7	6,25	7,98	1	0,4	1	100,0	0,00	NE
Geographical Region													
Screening	Asia-Pacific	20	100,0	19	95,0	9,21	14,14	18	100,0	18	100,0	4,63	5,87
Cycle 4 Day 1	Asia-Pacific	15	75,0	14	93,3	10,71	15,48	16	88,9	15	93,8	11,11	17,16
FU Day 28	Asia-Pacific	18	90,0	18	100,0	10,65	16,62	18	100,0	16	88,9	13,54	13,22
FU Month 3	Asia-Pacific	18	90,0	16	88,9	10,94	17,14	18	100,0	15	83,3	12,22	15,39
FU Month 6	Asia-Pacific	16	80,0	14	87,5	7,14	10,77	17	94,4	14	82,4	7,74	11,54
FU Month 9	Asia-Pacific	14	70,0	12	85,7	13,19	18,28	13	72,2	10	76,9	6,67	5,27
FU Month 12	Asia-Pacific	10	50,0	8	80,0	9,38	11,30	10	55,6	10	100,0	8,33	13,03
FU Month 15	Asia-Pacific	8	40,0	6	75,0	5,56	10,09	9	50,0	9	100,0	11,11	18,63
FU Month 18	Asia-Pacific	6	30,0	4	66,7	4,17	4,81	6	33,3	6	100,0	15,28	11,08

FU Month 21	Asia-Pacific	525,0	360,0	2,78	4,81	4	22,2	4	100,0	10,42	7,98
FU Month 24	Asia-Pacific	315,0	266,7	0,00	0,00	1	5,6	0	NE	NE	NE
FU Month 27	Asia-Pacific	15,0		NE	NE	1	5,6			NE	NE
FU Month 30	Asia-Pacific	15,0		NE	NE	0	NE			NE	NE
Screening	Central and South America	3100,0	3100,0	8,33	8,33	2	100,0	2	100,0	4,17	5,89
Cycle 4 Day 1	Central and South America	3100,0	3100,0	8,33	0,00	2	100,0	2	100,0	8,33	11,79
FU Day 28	Central and South America	3100,0	3100,0	16,67	22,05	2	100,0	2	100,0	8,33	11,79
FU Month 3	Central and South America	3100,0	3100,0	19,44	26,79	2	100,0	2	100,0	8,33	11,79
FU Month 6	Central and South America	266,7	2100,0	25,00	23,57	2	100,0	2	100,0	4,17	5,89
FU Month 9	Central and South America	266,7	2100,0	25,00	35,36	1	50,0	1	100,0	0,00	NE
FU Month 12	Central and South America	266,7	2100,0	20,83	29,46	1	50,0	1	100,0	0,00	NE
FU Month 15	Central and South America	133,3	1100,0	8,33	NE	0	NE	0	NE	NE	NE
FU Month 18	Central and South America	133,3	1100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 21	Central and South America	133,3	1100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 24	Central and South America	133,3	1100,0	0,00	NE	0	NE	0	NE	NE	NE
Screening	North America	12100,0	12100,0	11,11	16,41	13	100,0	12	92,3	5,09	4,56
Cycle 4 Day 1	North America	975,0	9100,0	3,70	6,05	12	92,3	12	100,0	4,17	5,62
FU Day 28	North America	1191,7	11100,0	3,03	5,62	13	100,0	13	100,0	7,05	5,74
FU Month 3	North America	1191,7	11100,0	4,55	10,11	12	92,3	12	100,0	9,03	6,61
FU Month 6	North America	1191,7	1090,9	5,00	11,25	11	84,6	11	100,0	4,55	5,73
FU Month 9	North America	866,7	8100,0	1,04	2,95	9	69,2	9	100,0	6,48	8,10
FU Month 12	North America	866,7	787,5	7,14	13,11	7	53,8	7	100,0	7,14	8,91
FU Month 15	North America	650,0	6100,0	9,72	13,35	6	46,2	5	83,3	8,33	5,89
FU Month 18	North America	433,3	4100,0	8,33	9,62	3	23,1	3	100,0	8,33	14,43
FU Month 21	North America	325,0	266,7	12,50	17,68	1	7,7	1	100,0	25,00	NE
FU Month 24	North America	325,0	266,7	20,83	29,46	1	7,7	1	100,0	25,00	NE
FU Month 27	North America	216,7	150,0	0,00	NE	1	7,7	1	100,0	16,67	NE
Screening	Other	45100,0	1737,8	17,16	13,00	44	100,0	16	36,4	17,19	19,12
Cycle 4 Day 1	Other	3782,2	1437,8	13,10	13,36	40	90,9	14	35,0	13,10	15,58
FU Day 28	Other	3782,2	1437,8	7,74	7,64	39	88,6	14	35,9	10,71	11,05
FU Month 3	Other	3884,4	1539,5	7,22	6,95	38	86,4	14	36,8	11,31	18,95
FU Month 6	Other	3577,8	1542,9	10,00	11,44	33	75,0	11	33,3	12,12	12,00
FU Month 9	Other	2657,8	1246,2	8,33	11,24	24	54,5	8	33,3	14,58	11,57
FU Month 12	Other	1737,8	847,1	9,38	17,50	16	36,4	6	37,5	6,94	6,27
FU Month 15	Other	1226,7	433,3	4,17	4,81	9	20,5	3	33,3	11,11	12,73
FU Month 18	Other	1022,2	330,0	2,78	4,81	7	15,9	2	28,6	4,17	5,89
FU Month 21	Other	715,6	228,6	16,67	11,79	4	9,1	0	NE	NE	NE
FU Month 24	Other	613,3	116,7	8,33	NE	3	6,8	0	NE	NE	NE
FU Month 27	Other	48,9	125,0	8,33	NE	1	2,3	0	NE	NE	NE

FU Month 30	Other	2	4,4			NE	NE	0	NE			NE	NE
Screening	Western Europe	175	100,0	165	94,3	11,48	16,32	165	100,0	154	93,3	11,47	16,42
Cycle 4 Day 1	Western Europe	149	85,1	134	89,9	7,09	10,89	154	93,3	132	85,7	9,36	15,06
FU Day 28	Western Europe	161	92,0	138	85,7	10,23	17,32	153	92,7	138	90,2	11,05	15,18
FU Month 3	Western Europe	155	88,6	138	89,0	10,17	16,78	151	91,5	131	86,8	8,95	12,95
FU Month 6	Western Europe	143	81,7	130	90,9	10,64	16,93	129	78,2	108	83,7	9,54	14,33
FU Month 9	Western Europe	114	65,1	92	80,7	9,60	15,48	102	61,8	83	81,4	9,14	15,16
FU Month 12	Western Europe	88	50,3	76	86,4	12,06	19,55	83	50,3	67	80,7	9,58	12,50
FU Month 15	Western Europe	77	44,0	67	87,0	6,63	11,30	61	37,0	46	75,4	7,85	14,14
FU Month 18	Western Europe	58	33,1	50	86,2	11,89	18,57	44	26,7	34	77,3	7,11	12,50
FU Month 21	Western Europe	36	20,6	28	77,8	12,10	17,86	31	18,8	23	74,2	8,33	12,56
FU Month 24	Western Europe	19	10,9	15	78,9	6,11	12,39	13	7,9	13	100,0	5,13	11,04
FU Month 27	Western Europe	6	3,4	6	100,0	13,43	19,91	6	3,6	5	83,3	1,67	3,73
FU Month 30	Western Europe	4	2,3	4	100,0	6,25	7,98	1	0,6	1	100,0	0,00	NE
FCgamma receptor IIa													
Screening	131HH	58	100,0	46	79,3	12,26	16,38	76	100,0	60	78,9	8,89	12,17
Cycle 4 Day 1	131HH	49	84,5	35	71,4	8,57	11,34	65	85,5	48	73,8	9,90	16,19
FU Day 28	131HH	51	87,9	38	74,5	11,18	16,24	70	92,1	51	72,9	8,99	9,84
FU Month 3	131HH	51	87,9	40	78,4	13,54	19,31	64	84,2	45	70,3	9,26	14,24
FU Month 6	131HH	49	84,5	39	79,6	12,54	20,95	55	72,4	40	72,7	6,46	13,14
FU Month 9	131HH	39	67,2	25	64,1	11,33	15,19	41	53,9	31	75,6	6,99	10,11
FU Month 12	131HH	28	48,3	21	75,0	14,29	20,94	34	44,7	28	82,4	9,52	13,74
FU Month 15	131HH	23	39,7	17	73,9	6,37	10,43	24	31,6	19	79,2	8,33	14,70
FU Month 18	131HH	17	29,3	12	70,6	15,51	23,10	16	21,1	12	75,0	9,72	12,22
FU Month 21	131HH	13	22,4	8	61,5	10,42	17,11	11	14,5	9	81,8	13,89	15,59
FU Month 24	131HH	11	19,0	7	63,6	13,10	15,85	1	1,3	1	100,0	0,00	NE
FU Month 27	131HH	4	6,9	3	75,0	24,07	25,05	1	1,3	1	100,0	8,33	NE
FU Month 30	131HH	3	5,2	2	66,7	12,50	5,89	0	NE	0	NE	NE	NE
Screening	131HR	125	100,0	108	86,4	10,03	13,27	114	100,0	101	88,6	11,17	15,91
Cycle 4 Day 1	131HR	105	84,0	89	84,8	8,52	12,11	110	96,5	93	84,5	8,54	14,21
FU Day 28	131HR	116	92,8	97	83,6	10,57	18,42	105	92,1	92	87,6	11,23	16,41
FU Month 3	131HR	114	91,2	95	83,3	8,07	14,25	107	93,9	89	83,2	8,96	12,53
FU Month 6	131HR	104	83,2	86	82,7	10,01	14,79	95	83,3	76	80,0	10,71	14,36
FU Month 9	131HR	84	67,2	66	78,6	10,73	16,59	76	66,7	58	76,3	9,77	14,40
FU Month 12	131HR	64	51,2	54	84,4	12,35	18,93	57	50,0	46	80,7	7,79	10,15
FU Month 15	131HR	53	42,4	42	79,2	7,01	9,39	44	38,6	32	72,7	7,38	11,63
FU Month 18	131HR	43	34,4	34	79,1	11,76	17,90	32	28,1	25	78,1	6,33	10,83
FU Month 21	131HR	26	20,8	17	65,4	15,52	19,67	21	18,4	15	71,4	8,33	10,45
FU Month 24	131HR	12	9,6	8	66,7	6,25	14,60	12	10,5	10	83,3	9,17	13,29

FU Month 27	131HR	64,8	350,0	5,56	4,81	65,3	466,7	4,17	8,33	
FU Month 30	131HR	32,4	133,3	0,00	NE	10,9	1100,0	0,00	NE	
Screening	131RR	49100,0	4183,7	13,28	15,00	33100,0	2884,8	14,29	19,88	
Cycle 4 Day 1	131RR	4081,6	3382,5	4,29	6,29	3193,9	2477,4	10,76	10,85	
FU Day 28	131RR	4285,7	3173,8	7,08	12,02	3297,0	2887,5	11,61	13,48	
FU Month 3	131RR	3979,6	3179,5	8,69	14,03	3297,0	2887,5	8,33	12,63	
FU Month 6	131RR	3571,4	2982,9	8,91	11,98	2781,8	2177,8	9,13	10,51	
FU Month 9	131RR	2449,0	2083,3	9,17	15,74	1957,6	1684,2	10,94	19,42	
FU Month 12	131RR	1836,7	1583,3	11,11	18,54	1751,5	1376,5	10,26	11,86	
FU Month 15	131RR	1632,7	1487,5	7,14	16,30	1133,3	981,8	14,81	21,56	
FU Month 18	131RR	1428,6	1285,7	3,47	5,57	824,2	787,5	9,52	16,96	
FU Month 21	131RR	816,3	675,0	1,39	3,40	515,2	480,0	2,08	4,17	
FU Month 24	131RR	510,2	360,0	0,00	0,00	39,1	3100,0	0,00	0,00	
FU Month 27	131RR	24,1	150,0	0,00	NE	13,0	1100,0	0,00	NE	
FU Month 30	131RR	12,0	1100,0	0,00	NE	0	NE	NE	NE	
Screening	Missing	23100,0	2191,3	15,61	25,56	19100,0	1368,4	10,26	18,68	
Cycle 4 Day 1	Missing	1982,6	1789,5	8,33	14,13	1894,7	1055,6	12,50	21,61	
FU Day 28	Missing	2191,3	1885,7	6,94	9,15	1894,7	1266,7	15,28	13,22	
FU Month 3	Missing	2191,3	1781,0	12,75	19,79	1894,7	1266,7	15,97	16,46	
FU Month 6	Missing	1982,6	1789,5	7,35	14,09	1578,9	960,0	7,41	11,37	
FU Month 9	Missing	1773,9	1588,2	1,67	3,45	1368,4	646,2	6,94	6,27	
FU Month 12	Missing	1565,2	1173,3	2,27	5,39	947,4	444,4	14,58	18,48	
FU Month 15	Missing	1252,2	1191,7	5,30	10,72	631,6	350,0	2,78	4,81	
FU Month 18	Missing	521,7	480,0	6,25	4,17	421,1	125,0	25,00	NE	
FU Month 21	Missing	521,7	5100,0	10,00	9,13	315,8	0	NE	NE	
FU Month 24	Missing	417,4	375,0	0,00	0,00	210,5	0	NE	NE	
FU Month 27	Missing	14,3	1100,0	0,00	NE	15,3	0	NE	NE	
FCgamma receptor IIIa										
Screening	158FF	103	100,0	9289,3	12,71	15,93	83100,0	7286,7	10,53	13,27
Cycle 4 Day 1	158FF	8986,4	7483,1	5,97	7,99	7894,0	6482,1	10,16	13,24	
FU Day 28	158FF	9693,2	7881,3	8,26	17,07	7894,0	6785,9	11,82	14,88	
FU Month 3	158FF	9491,3	7680,9	7,68	13,59	7894,0	6583,3	8,46	14,09	
FU Month 6	158FF	8683,5	6980,2	7,53	14,16	6477,1	5281,3	9,24	15,92	
FU Month 9	158FF	7168,9	5678,9	7,89	14,43	4756,6	4187,2	7,72	14,12	
FU Month 12	158FF	4846,6	4185,4	8,94	15,41	3845,8	3386,8	7,83	10,19	
FU Month 15	158FF	3735,9	3183,8	5,91	10,36	3036,1	2376,7	10,27	14,27	
FU Month 18	158FF	2726,2	2281,5	9,47	17,50	2125,3	1781,0	7,84	10,40	
FU Month 21	158FF	1615,5	1593,8	14,26	21,15	910,8	888,9	11,46	16,63	
FU Month 24	158FF	87,8	787,5	5,95	15,75	33,6	3100,0	8,33	14,43	

FU Month 27	158FF		54,9		480,0	2,08	4,17		1	1,2		1	100,0	0,00		NE
FU Month 30	158FF		32,9		3100,0	2,78	4,81		0	NE		0	NE		NE	NE
Screening	158FV	119	100,0		9882,4	11,11	14,41		109	100,0		90	82,6	10,77	17,36	
Cycle 4 Day 1	158FV		9983,2		8080,8	8,33	12,22		100	91,7		77	77,0	7,94	15,40	
FU Day 28	158FV	105	88,2		8379,0	9,64	13,86		101	92,7		81	80,2	8,85	13,07	
FU Month 3	158FV	101	84,9		8483,2	9,85	14,93		97	89,0		75	77,3	10,00	12,70	
FU Month 6	158FV		9479,0		8085,1	11,11	14,71		83	76,1		64	77,1	8,85	11,00	
FU Month 9	158FV		7159,7		5374,6	11,16	14,79		65	59,6		46	70,8	8,70	10,82	
FU Month 12	158FV		6050,4		5083,3	14,67	21,47		52	47,7		41	78,8	10,16	13,50	
FU Month 15	158FV		5243,7		4178,8	7,59	11,77		36	33,0		29	80,6	9,48	16,02	
FU Month 18	158FV		4437,0		3477,3	9,40	16,85		24	22,0		20	83,3	10,42	15,02	
FU Month 21	158FV		2823,5		1450,0	4,76	7,81		18	16,5		14	77,8	8,93	10,06	
FU Month 24	158FV		1815,1		950,0	8,33	13,82		6	5,5		5	83,3	0,00	0,00	
FU Month 27	158FV		65,0		233,3	29,17	29,46			21,8		1	50,0	0,00		NE
FU Month 30	158FV		43,4		125,0	16,67		NE	0	NE		0	NE		NE	NE
Screening	158VV		16100,0		1275,0	2,78	7,40		33	100,0		29	87,9	11,49	14,33	
Cycle 4 Day 1	158VV		1275,0		975,0	12,04	17,73		30	90,9		26	86,7	12,82	16,87	
FU Day 28	158VV		1487,5		1178,6	23,48	26,30		30	90,9		26	86,7	13,14	14,75	
FU Month 3	158VV		1593,8		1066,7	20,00	27,55		30	90,9		24	80,0	9,26	13,38	
FU Month 6	158VV		1487,5		1178,6	18,94	28,16		30	90,9		21	70,0	9,92	14,34	
FU Month 9	158VV		1275,0		975,0	17,59	25,15		25	75,8		19	76,0	11,40	17,83	
FU Month 12	158VV		850,0		562,5	8,33	11,79		20	60,6		16	80,0	8,33	11,39	
FU Month 15	158VV		850,0		675,0	5,56	6,80		14	42,4		10	71,4	2,50	4,03	
FU Month 18	158VV		425,0		375,0	33,33	14,43		11	33,3		8	72,7	3,13	6,20	
FU Month 21	158VV		318,8		266,7	37,50	5,89		9	27,3		6	66,7	6,94	11,08	
FU Month 24	158VV		212,5		2100,0	12,50	17,68		7	21,2		6	85,7	11,11	14,59	
FU Month 27	158VV		16,3		1100,0	22,22		NE	5	15,2		4	80,0	6,25	7,98	
FU Month 30	158VV		0	NE	0	NE	NE	NE	1	3,0		1	100,0	0,00		NE
Screening	Missing	17	100,0		1482,4	16,27	25,57		17	100,0		11	64,7	12,12	20,87	
Cycle 4 Day 1	Missing	13	76,5		1184,6	11,36	16,36		16	94,1		8	50,0	7,29	13,68	
FU Day 28	Missing	15	88,2		1280,0	7,64	10,33		16	94,1		9	56,3	16,67	16,14	
FU Month 3	Missing	15	88,2		1386,7	14,10	22,41		16	94,1		10	62,5	11,67	13,72	
FU Month 6	Missing	13	76,5		1184,6	10,61	16,70		15	88,2		9	60,0	8,33	12,50	
FU Month 9	Missing	10	58,8		880,0	1,04	2,95		12	70,6		5	41,7	13,33	20,92	
FU Month 12	Missing	9	52,9		555,6	3,33	7,45		7	41,2		1	14,3	8,33		NE
FU Month 15	Missing	7	41,2		685,7	5,56	13,61		5	29,4		1	20,0	0,00		NE
FU Month 18	Missing	4	23,5		375,0	8,33	0,00		4	23,5		0	NE	NE		NE
FU Month 21	Missing	5	29,4		5100,0	10,00	9,13		4	23,5		0	NE	NE		NE
FU Month 24	Missing	4	23,5		375,0	0,00	0,00		2	11,8		0	NE	NE		NE

FU Month 27	Missing		15,9	1100,0	0,00	NE	15,9	0	NE	NE	NE		
Binet Staging at baseline													
Screening	A	59	100,0	56	94,9	8,53	11,41	57	100,0	47	82,5	10,82	15,82
Cycle 4 Day 1	A	51	86,4	45	88,2	7,04	12,04	54	94,7	45	83,3	11,36	15,29
FU Day 28	A	58	98,3	51	87,9	7,68	15,17	54	94,7	45	83,3	11,67	16,13
FU Month 3	A	57	96,6	54	94,7	8,64	11,89	53	93,0	44	83,0	10,04	12,40
FU Month 6	A	56	94,9	47	83,9	7,27	11,21	45	78,9	36	80,0	10,57	15,31
FU Month 9	A	43	72,9	35	81,4	8,33	14,29	34	59,6	26	76,5	8,65	15,00
FU Month 12	A	36	61,0	32	88,9	8,33	14,97	24	42,1	18	75,0	6,94	10,00
FU Month 15	A	30	50,8	25	83,3	6,78	11,06	19	33,3	17	89,5	9,31	15,56
FU Month 18	A	22	37,3	15	68,2	12,22	21,10	16	28,1	14	87,5	9,52	13,42
FU Month 21	A	17	28,8	13	76,5	7,48	12,18	8	14,0	5	62,5	3,33	7,45
FU Month 24	A	10	16,9	6	60,0	1,39	3,40	5	8,8	4	80,0	0,00	0,00
FU Month 27	A	5	8,5	3	60,0	19,44	26,79	2	3,5	1	50,0	8,33	NE
FU Month 30	A	4	6,8	3	75,0	8,33	8,33	0	NE	0	NE	NE	NE
Screening	B	104	100,0	84	80,8	12,96	16,03	85	100,0	70	82,4	9,92	14,70
Cycle 4 Day 1	B	88	84,6	72	81,8	7,41	11,32	79	92,9	63	79,7	7,14	13,46
FU Day 28	B	91	87,5	70	76,9	8,85	14,46	79	92,9	63	79,7	9,52	11,48
FU Month 3	B	88	84,6	66	75,0	8,96	14,64	79	92,9	62	78,5	10,66	15,35
FU Month 6	B	80	76,9	68	85,0	9,80	16,10	70	82,4	51	72,9	8,66	13,01
FU Month 9	B	63	60,6	48	76,2	10,07	15,56	59	69,4	44	74,6	9,09	13,78
FU Month 12	B	47	45,2	35	74,5	15,24	21,34	46	54,1	36	78,3	10,88	13,19
FU Month 15	B	37	35,6	31	83,8	7,26	10,03	34	40,0	25	73,5	6,00	11,42
FU Month 18	B	31	29,8	26	83,9	11,97	18,22	22	25,9	17	77,3	5,88	12,42
FU Month 21	B	18	17,3	12	66,7	18,06	22,71	17	20,0	13	76,5	6,41	8,44
FU Month 24	B	11	10,6	8	72,7	15,63	18,60	8	9,4	7	87,5	8,33	14,43
FU Month 27	B	5	4,8	3	60,0	7,41	12,83	4	4,7	4	100,0	4,17	8,33
FU Month 30	B	2	1,9	1	50,0	0,00	NE	0	NE	0	NE	NE	NE
Screening	C	92	100,0	76	82,6	12,54	18,07	100	100,0	85	85,0	11,67	16,53
Cycle 4 Day 1	C	74	80,4	57	77,0	8,63	10,91	91	91,0	67	73,6	10,32	15,55
FU Day 28	C	81	88,0	63	77,8	12,43	18,81	92	92,0	75	81,5	11,67	15,07
FU Month 3	C	80	87,0	63	78,8	11,68	20,11	89	89,0	68	76,4	7,88	11,81
FU Month 6	C	71	77,2	56	78,9	12,95	18,53	77	77,0	59	76,6	8,62	12,57
FU Month 9	C	58	63,0	43	74,1	9,88	16,19	56	56,0	41	73,2	9,15	13,41
FU Month 12	C	42	45,7	34	81,0	10,54	18,04	47	47,0	37	78,7	8,11	11,37
FU Month 15	C	37	40,2	28	75,7	5,95	12,18	32	32,0	21	65,6	10,85	15,91
FU Month 18	C	26	28,3	21	80,8	7,54	12,33	22	22,0	14	63,6	9,52	11,26
FU Month 21	C	17	18,5	11	64,7	8,33	11,18	15	15,0	10	66,7	15,83	15,44
FU Month 24	C	11	12,0	7	63,6	1,19	3,15	5	5,0	3	60,0	11,11	12,73

FU Month 27	C		33,3		266,7	4,17	5,89		33,0		133,3	0,00	NE
FU Month 30	C		11,1		0	NE	NE	NE	11,0		1100,0	0,00	NE
Total CIR score at baseline													
Screening	<=6	63	100,0	53	84,1	8,65	11,09	75	100,0	62	82,7	11,83	15,58
Cycle 4 Day 1	<=6	52	82,5	38	73,1	6,14	10,38	72	96,0	53	73,6	9,49	13,87
FU Day 28	<=6	56	88,9	45	80,4	6,11	8,95	72	96,0	53	73,6	8,96	12,96
FU Month 3	<=6	55	87,3	42	76,4	8,73	14,72	69	92,0	49	71,0	7,48	11,19
FU Month 6	<=6	52	82,5	43	82,7	10,01	16,44	60	80,0	45	75,0	8,46	12,42
FU Month 9	<=6	43	68,3	33	76,7	4,80	8,08	47	62,7	35	74,5	9,52	15,14
FU Month 12	<=6	35	55,6	28	80,0	14,58	20,99	34	45,3	27	79,4	9,88	12,02
FU Month 15	<=6	32	50,8	28	87,5	5,46	9,73	25	33,3	16	64,0	6,77	13,68
FU Month 18	<=6	23	36,5	20	87,0	17,22	24,76	19	25,3	14	73,7	8,33	12,23
FU Month 21	<=6	14	22,2	8	57,1	6,25	8,63	14	18,7	10	71,4	11,67	14,80
FU Month 24	<=6	8	12,7	7	87,5	1,19	3,15	7	9,3	6	85,7	5,56	10,09
FU Month 27	<=6	2	3,2	2	100,0	4,17	5,89	4	5,3	2	50,0	0,00	0,00
FU Month 30	<=6	0	NE	0	NE	NE	NE	1	1,3	1	100,0	0,00	NE
Screening >6													
Screening	>6	192	100,0	163	84,9	12,64	16,98	167	100,0	140	83,8	10,44	15,78
Cycle 4 Day 1	>6	161	83,9	136	84,5	8,15	11,59	152	91,0	122	80,3	9,43	15,22
FU Day 28	>6	174	90,6	139	79,9	10,93	17,91	153	91,6	130	85,0	11,73	14,63
FU Month 3	>6	170	88,5	141	82,9	10,13	16,45	152	91,0	125	82,2	10,18	14,01
FU Month 6	>6	155	80,7	128	82,6	10,18	15,75	132	79,0	101	76,5	9,41	13,83
FU Month 9	>6	121	63,0	93	76,9	11,20	16,91	102	61,1	76	74,5	8,77	13,26
FU Month 12	>6	90	46,9	73	81,1	10,27	17,38	83	49,7	64	77,1	8,59	11,88
FU Month 15	>6	72	37,5	56	77,8	7,29	11,58	60	35,9	47	78,3	9,10	14,35
FU Month 18	>6	56	29,2	42	75,0	7,34	10,92	41	24,6	31	75,6	8,06	12,45
FU Month 21	>6	38	19,8	28	73,7	12,70	18,01	26	15,6	18	69,2	7,87	10,49
FU Month 24	>6	24	12,5	14	58,3	9,52	15,63	11	6,6	8	72,7	7,29	13,68
FU Month 27	>6	11	5,7	6	54,5	13,43	19,91	5	3,0	4	80,0	6,25	7,98
FU Month 30	>6	7	3,6	4	57,1	6,25	7,98	0	NE	0	NE	NE	NE
Calculated creatinine clearance cat. 2													
Screening	<70 ml/min	178	100,0	151	84,8	10,95	14,44	176	100,0	148	84,1	10,38	15,14
Cycle 4 Day 1	<70 ml/min	149	83,7	120	80,5	7,08	10,68	164	93,2	128	78,0	9,16	13,77
FU Day 28	<70 ml/min	162	91,0	132	81,5	8,04	14,21	166	94,3	132	79,5	9,72	12,53
FU Month 3	<70 ml/min	157	88,2	129	82,2	7,75	13,79	159	90,3	123	77,4	9,03	11,93
FU Month 6	<70 ml/min	144	80,9	121	84,0	9,16	14,97	139	79,0	104	74,8	7,91	12,49
FU Month 9	<70 ml/min	117	65,7	88	75,2	7,58	12,92	112	63,6	82	73,2	9,55	15,16
FU Month 12	<70 ml/min	92	51,7	73	79,3	11,64	18,62	87	49,4	67	77,0	8,33	11,05
FU Month 15	<70 ml/min	78	43,8	65	83,3	7,22	11,78	60	34,1	43	71,7	8,53	14,94

FU Month 18	<70 ml/min	59	33,1	47	79,7	10,34	18,05	43	24,4	32	74,4	9,11	12,41
FU Month 21	<70 ml/min	38	21,3	24	63,2	7,29	9,30	31	17,6	23	74,2	9,42	12,89
FU Month 24	<70 ml/min	24	13,5	16	66,7	7,29	14,23	13	7,4	9	69,2	6,48	10,85
FU Month 27	<70 ml/min	10	5,6	5	50,0	11,67	21,73	7	4,0	4	57,1	6,25	7,98
FU Month 30	<70 ml/min	5	2,8	2	40,0	8,33	11,79	1	0,6	1	100,0	0,00	NE
Screening	>=70 ml/min	77	100,0	65	84,4	13,33	18,62	66	100,0	54	81,8	12,19	17,19
Cycle 4 Day 1	>=70 ml/min	64	83,1	54	84,4	9,10	12,67	60	90,9	47	78,3	10,22	17,38
FU Day 28	>=70 ml/min	68	88,3	52	76,5	14,10	20,18	59	89,4	51	86,4	14,05	17,52
FU Month 3	>=70 ml/min	68	88,3	54	79,4	14,71	19,74	62	93,9	51	82,3	10,35	16,24
FU Month 6	>=70 ml/min	63	81,8	50	79,4	12,50	17,84	53	80,3	42	79,2	12,10	15,09
FU Month 9	>=70 ml/min	47	61,0	38	80,9	14,04	19,29	37	56,1	29	78,4	7,47	9,00
FU Month 12	>=70 ml/min	33	42,9	28	84,8	11,01	18,29	30	45,5	24	80,0	10,76	14,00
FU Month 15	>=70 ml/min	26	33,8	19	73,1	4,82	7,51	25	37,9	20	80,0	8,47	12,50
FU Month 18	>=70 ml/min	20	26,0	15	75,0	11,11	14,32	17	25,8	13	76,5	5,77	11,97
FU Month 21	>=70 ml/min	14	18,2	12	85,7	19,21	24,14	9	13,6	5	55,6	8,33	8,33
FU Month 24	>=70 ml/min	8	10,4	5	62,5	5,00	11,18	5	7,6	5	100,0	6,67	14,91
FU Month 27	>=70 ml/min	3	3,9	3	100,0	10,19	11,23	2	3,0	2	100,0	0,00	0,00
FU Month 30	>=70 ml/min	2	2,6	2	100,0	4,17	5,89	0	NE	0	NE	NE	NE
Beta2 microglobulin													
Screening	Missing	3	100,0	3	100,0	0,00	0,00	3	100,0	2	66,7	41,67	35,36
Cycle 4 Day 1	Missing	3	100,0	3	100,0	0,00	0,00	3	100,0	1	33,3	0,00	NE
FU Day 28	Missing	3	100,0	3	100,0	13,89	24,06	3	100,0	1	33,3	8,33	NE
FU Month 3	Missing	3	100,0	3	100,0	30,56	12,73	3	100,0	1	33,3	8,33	NE
FU Month 6	Missing	3	100,0	3	100,0	0,00	0,00	3	100,0	1	33,3	0,00	NE
FU Month 9	Missing	2	66,7	1	50,0	8,33	NE	3	100,0	1	33,3	0,00	NE
FU Month 12	Missing	1	33,3	1	100,0	0,00	NE	2	66,7	0	NE	NE	NE
FU Month 15	Missing	1	33,3	1	100,0	0,00	NE	2	66,7	0	NE	NE	NE
FU Month 18	Missing	1	33,3	1	100,0	16,67	NE	2	66,7	0	NE	NE	NE
FU Month 21	Missing	1	33,3	1	100,0	33,33	NE	2	66,7	0	NE	NE	NE
FU Month 24	Missing	1	33,3	1	100,0	0,00	NE	1	33,3	0	NE	NE	NE
Screening	< 3.5 ug/mL	154	100,0	134	87,0	11,44	16,44	140	100,0	119	85,0	11,37	16,15
Cycle 4 Day 1	< 3.5 ug/mL	127	82,5	108	85,0	7,95	11,47	129	92,1	101	78,3	10,89	15,16
FU Day 28	< 3.5 ug/mL	137	89,0	116	84,7	8,72	14,56	132	94,3	109	82,6	11,31	15,32
FU Month 3	< 3.5 ug/mL	134	87,0	117	87,3	8,78	14,59	130	92,9	103	79,2	8,14	11,63
FU Month 6	< 3.5 ug/mL	128	83,1	108	84,4	9,80	14,81	120	85,7	96	80,0	8,74	13,18
FU Month 9	< 3.5 ug/mL	104	67,5	82	78,8	8,94	13,78	98	70,0	76	77,6	10,64	15,31
FU Month 12	< 3.5 ug/mL	78	50,6	66	84,6	11,74	18,20	75	53,6	61	81,3	8,47	12,03
FU Month 15	< 3.5 ug/mL	65	42,2	54	83,1	7,30	11,46	60	42,9	47	78,3	9,63	15,86
FU Month 18	< 3.5 ug/mL	46	29,9	37	80,4	10,44	16,79	43	30,7	33	76,7	8,59	13,42

FU Month 21	< 3.5 ug/mL	30	19,5	20	66,7	13,61	19,85	27	19,3	20	74,1	6,67	10,33
FU Month 24	< 3.5 ug/mL	19	12,3	14	73,7	7,14	12,60	12	8,6	10	83,3	4,17	10,58
FU Month 27	< 3.5 ug/mL	10	6,5	7	70,0	12,70	18,28	7	5,0	4	57,1	2,08	4,17
FU Month 30	< 3.5 ug/mL	5	3,2	3	60,0	5,56	9,62	1	0,7	1	100,0	0,00	NE
Screening	>= 3.5 ug/mL	98	100,0	79	80,6	12,48	14,90	99	100,0	81	81,8	9,36	13,84
Cycle 4 Day 1	>= 3.5 ug/mL	83	84,7	63	75,9	7,67	11,33	92	92,9	73	79,3	7,57	14,18
FU Day 28	>= 3.5 ug/mL	90	91,8	65	72,2	11,41	18,84	90	90,9	73	81,1	10,39	12,48
FU Month 3	>= 3.5 ug/mL	88	89,8	63	71,6	10,71	18,11	88	88,9	70	79,5	11,31	15,41
FU Month 6	>= 3.5 ug/mL	76	77,6	60	78,9	11,25	17,95	69	69,7	49	71,0	10,03	13,92
FU Month 9	>= 3.5 ug/mL	58	59,2	43	74,1	10,66	18,21	48	48,5	34	70,8	5,64	9,11
FU Month 12	>= 3.5 ug/mL	46	46,9	34	73,9	11,27	19,34	40	40,4	30	75,0	10,00	11,66
FU Month 15	>= 3.5 ug/mL	38	38,8	29	76,3	5,75	10,23	23	23,2	16	69,6	5,21	5,99
FU Month 18	>= 3.5 ug/mL	32	32,7	24	75,0	10,42	18,27	15	15,2	12	80,0	6,94	8,58
FU Month 21	>= 3.5 ug/mL	21	21,4	15	71,4	6,67	9,02	11	11,1	8	72,7	15,63	14,39
FU Month 24	>= 3.5 ug/mL	12	12,2	6	50,0	6,94	17,01		5,1	4	80,0	12,50	14,43
FU Month 27	>= 3.5 ug/mL	3	3,1	1	33,3	0,00	NE	2	2,0	2	100,0	8,33	11,79
FU Month 30	>= 3.5 ug/mL	2	2,0	1	50,0	8,33	NE	0	NE	0	NE	NE	NE
Immunoglobulin VH, cytogenetics 2													
Screening	12	45	100,0	39	86,7	12,68	18,11	44	100,0	40	90,9	8,54	11,71
Cycle 4 Day 1	12	34	75,6	29	85,3	8,62	12,50	38	86,4	30	78,9	10,28	14,79
FU Day 28	12	39	86,7	35	89,7	12,14	18,00	40	90,9	35	87,5	9,76	14,64
FU Month 3	12	38	84,4	34	89,5	11,03	17,61	39	88,6	30	76,9	5,83	9,06
FU Month 6	12	36	80,0	30	83,3	11,11	15,06	34	77,3	27	79,4	9,88	13,28
FU Month 9	12	26	57,8	21	80,8	12,30	16,38	28	63,6	17	60,7	9,80	16,99
FU Month 12	12	22	48,9	17	77,3	13,24	18,41	23	52,3	14	60,9	10,12	13,15
FU Month 15	12	17	37,8	13	76,5	7,05	9,53	17	38,6	11	64,7	16,92	20,09
FU Month 18	12	15	33,3	11	73,3	6,82	12,81	13	29,5	8	61,5	10,42	14,60
FU Month 21	12	10	22,2	7	70,0	8,33	15,21	7	15,9	4	57,1	2,08	4,17
FU Month 24	12	8	17,8	5	62,5	6,67	10,87	6	13,6	5	83,3	1,67	3,73
FU Month 27	12	5	11,1	3	60,0	24,07	25,05	2	4,5	2	100,0	0,00	0,00
FU Month 30	12	4	8,9	2	50,0	8,33	11,79	1	2,3	1	100,0	0,00	NE
Screening	11q-	46	100,0	35	76,1	9,84	10,40	43	100,0	36	83,7	11,88	18,40
Cycle 4 Day 1	11q-	40	87,0	33	82,5	6,06	9,61	41	95,3	32	78,0	8,59	14,12
FU Day 28	11q-	42	91,3	29	69,0	9,48	17,78	39	90,7	32	82,1	13,02	13,21
FU Month 3	11q-	42	91,3	32	76,2	10,94	16,46	38	88,4	34	89,5	9,64	13,68
FU Month 6	11q-	38	82,6	31	81,6	7,80	14,74	32	74,4	26	81,3	9,94	11,31
FU Month 9	11q-	28	60,9	24	85,7	5,21	11,74	25	58,1	20	80,0	12,50	15,88

FU Month 12	11q-	20	43,5	17	85,0	12,25	18,89	18	41,9	16	88,9	15,10	14,97
FU Month 15	11q-	18	39,1	15	83,3	4,63	7,09	14	32,6	9	64,3	13,89	16,14
FU Month 18	11q-	15	32,6	11	73,3	11,36	17,98	8	18,6	6	75,0	15,28	20,69
FU Month 21	11q-	12	26,1	10	83,3	5,56	8,18	4	9,3	1	25,0	16,67	NE
FU Month 24	11q-	7	15,2	4	57,1	0,00	0,00	1	2,3	1	100,0	33,33	NE
FU Month 27	11q-	3	6,5	2	66,7	4,17	5,89	0	NE	0	NE	NE	NE
FU Month 30	11q-	3	6,5	2	66,7	4,17	5,89	0	NE	0	NE	NE	NE
Screening	13q-	79	100,0	68	86,1	10,25	13,14	75	100,0	57	76,0	10,67	15,33
Cycle 4 Day 1	13q-	67	84,8	51	76,1	6,54	10,58	68	90,7	50	73,5	12,11	18,90
FU Day 28	13q-	72	91,1	58	80,6	7,61	13,72	72	96,0	54	75,0	12,50	16,25
FU Month 3	13q-	73	92,4	60	82,2	8,47	14,43	69	92,0	49	71,0	9,86	15,74
FU Month 6	13q-	67	84,8	55	82,1	7,37	12,70	63	84,0	44	69,8	8,33	11,92
FU Month 9	13q-	56	70,9	44	78,6	7,20	9,94	52	69,3	38	73,1	8,33	11,94
FU Month 12	13q-	44	55,7	37	84,1	9,68	17,07	40	53,3	34	85,0	7,35	10,81
FU Month 15	13q-	38	48,1	32	84,2	7,29	14,16	29	38,7	23	79,3	3,99	6,59
FU Month 18	13q-	28	35,4	23	82,1	12,80	21,82	21	28,0	17	81,0	7,35	9,72
FU Month 21	13q-	16	20,3	12	75,0	20,14	22,60	16	21,3	12	75,0	9,72	13,22
FU Month 24	13q-	7	8,9	5	71,4	16,67	22,82	7	9,3	4	57,1	6,25	12,50
FU Month 27	13q-	2	2,5	1	50,0	0,00	NE	6	8,0	3	50,0	8,33	8,33
Screening	Norm. K.	65	100,0	57	87,7	13,45	19,14	58	100,0	50	86,2	14,50	18,66
Cycle 4 Day 1	Norm. K.	54	83,1	46	85,2	8,33	10,39	55	94,8	46	83,6	7,31	10,50
FU Day 28	Norm. K.	59	90,8	48	81,4	9,61	16,13	53	91,4	46	86,8	9,78	13,53
FU Month 3	Norm. K.	54	83,1	44	81,5	8,59	16,72	54	93,1	44	81,5	12,56	14,00
FU Month 6	Norm. K.	49	75,4	43	87,8	12,47	19,86	45	77,6	33	73,3	11,36	18,26
FU Month 9	Norm. K.	39	60,0	27	69,2	11,11	18,34	30	51,7	24	80,0	7,64	15,53
FU Month 12	Norm. K.	32	49,2	24	75,0	12,15	21,14	24	41,4	18	75,0	5,56	9,90
FU Month 15	Norm. K.	26	40,0	20	76,9	7,50	9,33	20	34,5	16	80,0	7,29	15,18
FU Month 18	Norm. K.	18	27,7	14	77,8	10,71	12,42	15	25,9	12	80,0	3,47	8,30
FU Month 21	Norm. K.	12	18,5	5	41,7	8,33	10,21	11	19,0	9	81,8	9,26	11,37
FU Month 24	Norm. K.	8	12,3	5	62,5	5,00	7,45	4	6,9	4	100,0	6,25	12,50
FU Month 27	Norm. K.	3	4,6	2	66,7	4,17	5,89	1	1,7	1	100,0	0,00	NE
Screening	Other Abn.	20	100,0	17	85,0	12,75	17,71	22	100,0	19	86,4	4,82	5,06
Cycle 4 Day 1	Other Abn.	18	90,0	15	83,3	11,67	16,90	22	100,0	17	77,3	7,52	12,14
FU Day 28	Other Abn.	18	90,0	14	77,8	13,69	19,78	21	95,5	16	76,2	7,29	8,54
FU Month 3	Other Abn.	18	90,0	13	72,2	14,10	16,80	21	95,5	17	81,0	5,88	6,43
FU Month 6	Other Abn.	17	85,0	12	70,6	18,06	16,22	18	81,8	16	88,9	3,99	6,95
FU Month 9	Other Abn.	15	75,0	10	66,7	20,00	25,52	14	63,6	12	85,7	6,94	5,98
FU Month 12	Other Abn.	7	35,0	6	85,7	12,50	19,54	12	54,5	9	75,0	9,26	8,78
FU Month 15	Other Abn.	5	25,0	4	80,0	4,17	8,33	5	22,7	4	80,0	4,17	8,33

FU Month 18	Other Abn.	3	15,0	3	100,0	2,78	4,81	3	13,6	2	66,7	12,50	5,89
FU Month 21	Other Abn.	2	10,0	2	100,0	4,17	5,89	2	9,1	2	100,0	16,67	23,57
FU Month 24	Other Abn.	2	10,0	2	100,0	0,00	0,00	0	NE	0	NE	NE	NE
Time from first diagnosis													
Screening	Missing	1	100,0	1	100,0	8,33	NE	0	NE	0	NE	NE	NE
Cycle 4 Day 1	Missing	1	100,0	1	100,0	8,33	NE	0	NE	0	NE	NE	NE
FU Day 28	Missing	1	100,0	1	100,0	8,33	NE	0	NE	0	NE	NE	NE
FU Month 3	Missing	1	100,0	1	100,0	8,33	NE	0	NE	0	NE	NE	NE
FU Month 6	Missing	1	100,0	1	100,0	8,33	NE	0	NE	0	NE	NE	NE
FU Month 9	Missing	1	100,0	1	100,0	8,33	NE	0	NE	0	NE	NE	NE
FU Month 12	Missing	1	100,0	1	100,0	8,33	NE	0	NE	0	NE	NE	NE
FU Month 15	Missing	1	100,0	1	100,0	8,33	NE	0	NE	0	NE	NE	NE
FU Month 18	Missing	1	100,0	1	100,0	8,33	NE	0	NE	0	NE	NE	NE
Screening	13 - 24 months	41	100,0	31	75,6	13,98	14,17	31	100,0	30	96,8	8,06	10,83
Cycle 4 Day 1	13 - 24 months	35	85,4	28	80,0	6,25	11,25	30	96,8	26	86,7	4,81	8,87
FU Day 28	13 - 24 months	38	92,7	26	68,4	11,54	15,82	30	96,8	26	86,7	5,45	11,29
FU Month 3	13 - 24 months	36	87,8	28	77,8	11,01	16,21	30	96,8	25	83,3	5,67	9,54
FU Month 6	13 - 24 months	36	87,8	27	75,0	11,73	16,87	30	96,8	24	80,0	4,75	7,44
FU Month 9	13 - 24 months	32	78,0	22	68,8	6,82	13,52	21	67,7	17	81,0	4,41	7,29
FU Month 12	13 - 24 months	21	51,2	15	71,4	10,56	17,95	16	51,6	13	81,3	3,85	5,50
FU Month 15	13 - 24 months	19	46,3	15	78,9	2,41	5,24	16	51,6	8	50,0	1,04	2,95
FU Month 18	13 - 24 months	14	34,1	10	71,4	10,83	13,64	10	32,3	8	80,0	4,17	6,30
FU Month 21	13 - 24 months	11	26,8	7	63,6	11,90	15,85	6	19,4	4	66,7	12,50	15,96
FU Month 24	13 - 24 months	8	19,5	3	37,5	11,11	12,73	3	9,7	3	100,0	2,78	4,81
FU Month 27	13 - 24 months	5	12,2	3	60,0	24,07	25,05	2	6,5	2	100,0	0,00	0,00
FU Month 30	13 - 24 months	3	7,3	2	66,7	12,50	5,89	1	3,2	1	100,0	0,00	NE
Screening	<= 12 months	60	100,0	48	80,0	13,02	14,58	70	100,0	55	78,6	10,45	16,37
Cycle 4 Day 1	<= 12 months	48	80,0	35	72,9	10,95	14,54	60	85,7	44	73,3	10,23	16,46
FU Day 28	<= 12 months	54	90,0	39	72,2	14,39	22,03	62	88,6	47	75,8	14,01	15,16
FU Month 3	<= 12 months	53	88,3	38	71,7	11,92	18,84	59	84,3	44	74,6	11,62	16,62
FU Month 6	<= 12 months	46	76,7	35	76,1	12,62	16,22	47	67,1	32	68,1	12,50	16,53
FU Month 9	<= 12 months	35	58,3	27	77,1	11,73	17,94	37	52,9	27	73,0	11,11	16,34
FU Month 12	<= 12 months	27	45,0	21	77,8	12,70	17,00	29	41,4	24	82,8	10,76	14,84
FU Month 15	<= 12 months	22	36,7	16	72,7	7,81	9,85	17	24,3	15	88,2	8,33	10,45
FU Month 18	<= 12 months	16	26,7	10	62,5	4,17	5,89	13	18,6	11	84,6	12,12	15,53
FU Month 21	<= 12 months	9	15,0	5	55,6	1,67	3,73	7	10,0	5	71,4	6,67	6,97
FU Month 24	<= 12 months	6	10,0	3	50,0	0,00	0,00	2	2,9	0	NE	NE	NE
FU Month 27	<= 12 months	1	1,7			NE	NE	1	1,4			NE	NE
FU Month 30	<= 12 months	1	1,7			NE	NE	0	NE			NE	NE

Screening	>24 months	153	100,0	136	88,9	10,68	16,63	141	100,0	117	83,0	11,78	16,42
Cycle 4 Day 1	>24 months	129	84,3	110	85,3	7,05	10,11	134	95,0	105	78,4	10,26	15,11
FU Day 28	>24 months	137	89,5	118	86,1	7,84	13,88	133	94,3	110	82,7	10,91	14,09
FU Month 3	>24 months	135	88,2	116	85,9	8,84	15,12	132	93,6	105	79,5	9,39	12,39
FU Month 6	>24 months	124	81,0	108	87,1	8,95	15,61	115	81,6	90	78,3	9,07	13,14
FU Month 9	>24 months	96	62,7	76	79,2	9,54	15,01	91	64,5	67	73,6	9,33	13,88
FU Month 12	>24 months	76	49,7	64	84,2	11,33	19,38	72	51,1	54	75,0	9,41	11,34
FU Month 15	>24 months	62	40,5	52	83,9	7,53	12,38	52	36,9	40	76,9	10,07	16,18
FU Month 18	>24 months	48	31,4	41	85,4	12,06	19,60	37	26,2	26	70,3	7,69	12,00
FU Month 21	>24 months	32	20,9	24	75,0	13,08	17,97	27	19,1	19	70,4	9,21	12,70
FU Month 24	>24 months	18	11,8	15	83,3	7,22	14,73	13	9,2	11	84,6	7,58	13,15
FU Month 27	>24 months	7	4,6	5	71,4	3,33	4,56	6	4,3	4	66,7	6,25	7,98
FU Month 30	>24 months	3	2,0	2	66,7	0,00	0,00	0	NE	0	NE	NE	NE
High circulating tumor burden													
Screening	Missing	0	NE	0	NE	NE	NE	2	100,0	1	50,0	0,00	NE
Cycle 4 Day 1	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	0,00	NE
FU Day 28	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	0,00	NE
FU Month 3	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	0,00	NE
FU Month 6	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	0,00	NE
FU Month 9	Missing	0	NE			NE	NE	1	50,0			NE	NE
Screening	<25x10**9 cells/L	60	100,0	51	85,0	12,25	14,94	67	100,0	55	82,1	11,06	17,05
Cycle 4 Day 1	<25x10**9 cells/L	50	83,3	41	82,0	7,11	9,04	61	91,0	43	70,5	9,43	14,46
FU Day 28	<25x10**9 cells/L	56	93,3	44	78,6	10,48	14,72	61	91,0	46	75,4	11,59	16,53
FU Month 3	<25x10**9 cells/L	54	90,0	44	81,5	9,66	14,14	59	88,1	44	74,6	9,28	13,48
FU Month 6	<25x10**9 cells/L	50	83,3	41	82,0	11,59	12,20	51	76,1	38	74,5	7,38	11,32
FU Month 9	<25x10**9 cells/L	36	60,0	23	63,9	13,41	16,04	41	61,2	28	68,3	7,14	12,57
FU Month 12	<25x10**9 cells/L	29	48,3	23	79,3	15,58	18,34	34	50,7	23	67,6	9,06	11,49
FU Month 15	<25x10**9 cells/L	24	40,0	19	79,2	9,65	15,03	23	34,3	13	56,5	11,54	15,04
FU Month 18	<25x10**9 cells/L	20	33,3	17	85,0	7,35	11,74	19	28,4	13	68,4	6,41	12,34
FU Month 21	<25x10**9 cells/L	14	23,3	9	64,3	8,33	8,33	10	14,9	7	70,0	10,71	15,75
FU Month 24	<25x10**9 cells/L	8	13,3	4	50,0	2,08	4,17	6	9,0	5	83,3	6,67	10,87
FU Month 27	<25x10**9 cells/L	4	6,7	2	50,0	25,00	35,36	1	1,5	1	100,0	0,00	NE
FU Month 30	<25x10**9 cells/L	4	6,7	2	50,0	8,33	11,79	1	1,5	1	100,0	0,00	NE
Screening	>=25x10**9 cells/L	195	100,0	165	84,6	11,48	16,11	173	100,0	146	84,4	10,86	15,24
Cycle 4 Day 1	>=25x10**9 cells/L	163	83,6	133	81,6	7,89	11,98	162	93,6	131	80,9	9,52	14,97
FU Day 28	>=25x10**9 cells/L	174	89,2	140	80,5	9,52	16,80	163	94,2	136	83,4	10,78	13,38
FU Month 3	>=25x10**9 cells/L	171	87,7	139	81,3	9,85	16,64	161	93,1	129	80,1	9,54	13,32
FU Month 6	>=25x10**9 cells/L	157	80,5	130	82,8	9,68	16,89	140	80,9	107	76,4	9,81	14,06

FU Month 9	>=25x10**9 cells/L	128	65,6	103	80,5	8,66	15,12	107	61,8	83	77,6	9,64	14,23
FU Month 12	>=25x10**9 cells/L	96	49,2	78	81,3	10,26	18,41	83	48,0	68	81,9	8,95	12,07
FU Month 15	>=25x10**9 cells/L	80	41,0	65	81,3	5,81	9,44	62	35,8	50	80,6	7,72	13,91
FU Month 18	>=25x10**9 cells/L	59	30,3	45	76,3	11,73	18,72	41	23,7	32	78,0	8,85	12,33
FU Month 21	>=25x10**9 cells/L	38	19,5	27	71,1	12,24	18,48	30	17,3	21	70,0	8,73	11,02
FU Month 24	>=25x10**9 cells/L	24	12,3	17	70,8	7,84	14,57	12	6,9	9	75,0	6,48	13,03
FU Month 27	>=25x10**9 cells/L	9	4,6	6	66,7	6,48	8,73	8	4,6	5	62,5	5,00	7,45
FU Month 30	>=25x10**9 cells/L	3	1,5	2	66,7	4,17	5,89	0	NE	0	NE	NE	NE

¹ in study: number of subjects in study at respective visit; % based on baseline

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit

² mean: descriptive statistics - absolute values Clinical

cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/t_pro_mean.sas

Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/t_pro_mean_sg_EQCLL16_IT_label_09MAY2013_21004.xls 04MAR2020

17:21

POPULATION: Labelpopulation, Intent-to-Treat Patients
 ENDPOINT: EORTC QoL 16
 MODEL: Unadjusted Analysis
 STUDY: CLL11 (BO21004), Stage 2
 Compliance/Mean

Social Problems (Item 41)

		GCLb (N=255)						RCLb (N=242)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study ¹	%	with value ¹	%	Mean ²	SD(mean)	in study ¹	%	with value ¹	%	Mean ²	SD(mean)
All													
Screening	n/a	255	100,0	213	83,5	23,32	31,12	242	100,0	199	82,2	24,96	32,60
Cycle 4 Day 1	n/a	213	83,5	173	81,2	20,81	29,04	224	92,6	174	77,7	21,07	26,15
FU Day 28	n/a	230	90,2	181	78,7	20,81	30,07	225	93,0	182	80,9	20,15	28,20
FU Month 3	n/a	225	88,2	178	79,1	17,98	27,01	221	91,3	173	78,3	19,27	29,22
FU Month 6	n/a	207	81,2	171	82,6	18,52	29,62	192	79,3	144	75,0	22,45	29,19
FU Month 9	n/a	164	64,3	126	76,8	17,20	29,13	149	61,6	108	72,5	16,98	27,15
FU Month 12	n/a	125	49,0	101	80,8	22,77	32,64	117	48,3	90	76,9	22,96	29,41
FU Month 15	n/a	104	40,8	81	77,9	16,87	27,95	85	35,1	62	72,9	21,51	30,24
FU Month 18	n/a	79	31,0	62	78,5	23,12	31,12	60	24,8	43	71,7	25,58	34,76
FU Month 21	n/a	52	20,4	36	69,2	16,67	27,02	40	16,5	28	70,0	29,76	31,87
FU Month 24	n/a	32	12,5	21	65,6	22,22	24,34	18	7,4	14	77,8	23,81	33,15
FU Month 27	n/a	13	5,1	8	61,5	12,50	17,25	9	3,7	6	66,7	16,67	27,89
FU Month 30	n/a	7	2,7	4	57,1	25,00	31,91	1	0,4	1	100,0	0,00	NE
Gender													
Screening	Female	97	100,0	80	82,5	28,75	33,01	95	100,0	74	77,9	31,98	35,94
Cycle 4 Day 1	Female	84	86,6	67	79,8	22,89	28,55	88	92,6	66	75,0	25,25	26,83
FU Day 28	Female	90	92,8	75	83,3	26,22	31,14	91	95,8	70	76,9	23,81	32,17
FU Month 3	Female	88	90,7	72	81,8	18,98	27,31	87	91,6	62	71,3	25,81	31,61
FU Month 6	Female	84	86,6	64	76,2	20,83	29,99	77	81,1	52	67,5	23,72	29,77
FU Month 9	Female	70	72,2	52	74,3	23,08	32,03	61	64,2	38	62,3	24,56	32,59
FU Month 12	Female	56	57,7	45	80,4	27,41	32,79	47	49,5	33	70,2	23,23	30,60
FU Month 15	Female	47	48,5	34	72,3	26,47	30,46	33	34,7	23	69,7	24,64	32,13
FU Month 18	Female	34	35,1	25	73,5	37,33	32,38	26	27,4	18	69,2	29,63	35,95
FU Month 21	Female	21	21,6	11	52,4	24,24	30,15	17	17,9	12	70,6	33,33	34,82
FU Month 24	Female	12	12,4	6	50,0	38,89	25,09	6	6,3	3	50,0	0,00	0,00
FU Month 27	Female	6	6,2	2	33,3	16,67	23,57	2	2,1	1	50,0	0,00	NE
FU Month 30	Female	4	4,1	1	25,0	33,33	NE	1	1,1	1	100,0	0,00	NE

Screening	Male	158	100,0	133	84,2	20,05	29,57	147	100,0	125	85,0	20,80	29,83
Cycle 4 Day 1	Male	129	81,6	106	82,2	19,50	29,41	136	92,5	108	79,4	18,52	25,51
FU Day 28	Male	140	88,6	106	75,7	16,98	28,82	134	91,2	112	83,6	17,86	25,28
FU Month 3	Male	137	86,7	106	77,4	17,30	26,92	134	91,2	111	82,8	15,62	27,27
FU Month 6	Male	123	77,8	107	87,0	17,13	29,45	115	78,2	92	80,0	21,74	29,00
FU Month 9	Male	94	59,5	74	78,7	13,06	26,36	88	59,9	70	79,5	12,86	22,91
FU Month 12	Male	69	43,7	56	81,2	19,05	32,32	70	47,6	57	81,4	22,81	28,98
FU Month 15	Male	57	36,1	47	82,5	9,93	23,99	52	35,4	39	75,0	19,66	29,34
FU Month 18	Male	45	28,5	37	82,2	13,51	26,60	34	23,1	25	73,5	22,67	34,32
FU Month 21	Male	31	19,6	25	80,6	13,33	25,46	23	15,6	16	69,6	27,08	30,35
FU Month 24	Male	20	12,7	15	75,0	15,56	21,33	12	8,2	11	91,7	30,30	34,82
FU Month 27	Male	7	4,4	6	85,7	11,11	17,21	7	4,8	5	71,4	20,00	29,81
FU Month 30	Male	3	1,9	3	100,0	22,22	38,49	0	NE	0	NE	NE	NE
Age													
Screening	<75 years	130	100,0	101	77,7	24,09	33,04	120	100,0	90	75,0	23,33	31,39
Cycle 4 Day 1	<75 years	106	81,5	81	76,4	18,93	29,79	112	93,3	81	72,3	19,34	25,75
FU Day 28	<75 years	119	91,5	91	76,5	19,41	29,84	110	91,7	86	78,2	20,16	28,14
FU Month 3	<75 years	116	89,2	91	78,4	18,68	27,76	109	90,8	82	75,2	19,51	30,52
FU Month 6	<75 years	108	83,1	86	79,6	15,12	24,87	99	82,5	69	69,7	19,32	28,24
FU Month 9	<75 years	85	65,4	66	77,6	14,65	28,12	74	61,7	54	73,0	15,43	24,84
FU Month 12	<75 years	63	48,5	53	84,1	21,38	33,39	60	50,0	46	76,7	20,29	30,21
FU Month 15	<75 years	54	41,5	41	75,9	21,14	33,96	44	36,7	31	70,5	13,98	25,49
FU Month 18	<75 years	43	33,1	34	79,1	22,55	31,48	27	22,5	19	70,4	24,56	36,59
FU Month 21	<75 years	26	20,0	20	76,9	20,00	29,42	17	14,2	11	64,7	18,18	31,14
FU Month 24	<75 years	18	13,8	12	66,7	25,00	25,13	6	5,0	4	66,7	8,33	16,67
FU Month 27	<75 years	7	5,4	4	57,1	16,67	19,25	2	1,7	1	50,0	0,00	NE
FU Month 30	<75 years	4	3,1	2	50,0	33,33	47,14	0	NE	0	NE	NE	NE
Screening	>=75 years	125	100,0	112	89,6	22,62	29,41	122	100,0	109	89,3	26,30	33,66
Cycle 4 Day 1	>=75 years	107	85,6	92	86,0	22,46	28,43	112	91,8	93	83,0	22,58	26,54
FU Day 28	>=75 years	111	88,8	90	81,1	22,22	30,39	115	94,3	96	83,5	20,14	28,40
FU Month 3	>=75 years	109	87,2	87	79,8	17,24	26,35	112	91,8	91	81,3	19,05	28,17
FU Month 6	>=75 years	99	79,2	85	85,9	21,96	33,55	93	76,2	75	80,6	25,33	29,93
FU Month 9	>=75 years	79	63,2	60	75,9	20,00	30,19	75	61,5	54	72,0	18,52	29,44
FU Month 12	>=75 years	62	49,6	48	77,4	24,31	32,06	57	46,7	44	77,2	25,76	28,63
FU Month 15	>=75 years	50	40,0	40	80,0	12,50	19,52	41	33,6	31	75,6	29,03	33,05
FU Month 18	>=75 years	36	28,8	28	77,8	23,81	31,24	33	27,0	24	72,7	26,39	34,02
FU Month 21	>=75 years	26	20,8	16	61,5	12,50	23,96	23	18,9	17	73,9	37,25	30,92
FU Month 24	>=75 years	14	11,2	9	64,3	18,52	24,22	12	9,8	10	83,3	30,00	36,68
FU Month 27	>=75 years	6	4,8	4	66,7	8,33	16,67	7	5,7	5	71,4	20,00	29,81

FU Month 30	>=75 years	3	2,4	2	66,7	16,67	23,57	1	0,8	1	100,0	0,00	NE
Race													
Screening	Other	9	100,0	6	66,7	0,00	0,00	11	100,0	6	54,5	33,33	29,81
Cycle 4 Day 1	Other	7	77,8	4	57,1	8,33	16,67	10	90,9	6	60,0	27,78	25,09
FU Day 28	Other	8	88,9	5	62,5	20,00	18,26	10	90,9	7	70,0	14,29	26,23
FU Month 3	Other	8	88,9	4	50,0	8,33	16,67	10	90,9	6	60,0	5,56	13,61
FU Month 6	Other	8	88,9	4	50,0	16,67	19,25	8	72,7	6	75,0	5,56	13,61
FU Month 9	Other	4	44,4	3	75,0	11,11	19,25	5	45,5	4	80,0	0,00	0,00
FU Month 12	Other	3	33,3	2	66,7	16,67	23,57	4	36,4	4	100,0	8,33	16,67
FU Month 15	Other	2	22,2	1	50,0	0,00	NE	4	36,4	4	100,0	25,00	31,91
FU Month 18	Other	2	22,2	1	50,0	0,00	NE	2	18,2	2	100,0	0,00	0,00
FU Month 21	Other	2	22,2	1	50,0	0,00	NE	2	18,2	2	100,0	16,67	23,57
FU Month 24	Other	2	22,2	1	50,0	0,00	NE	1	9,1	0	NE	NE	NE
FU Month 27	Other	1	11,1			NE	NE	1	9,1			NE	NE
FU Month 30	Other	1	11,1			NE	NE	0	NE			NE	NE
Screening													
Screening	White	246	100,0	207	84,1	23,99	31,31	231	100,0	193	83,5	24,70	32,72
Cycle 4 Day 1	White	206	83,7	169	82,0	21,10	29,24	214	92,6	168	78,5	20,83	26,23
FU Day 28	White	222	90,2	176	79,3	20,83	30,37	215	93,1	175	81,4	20,38	28,32
FU Month 3	White	217	88,2	174	80,2	18,20	27,19	211	91,3	167	79,1	19,76	29,53
FU Month 6	White	199	80,9	167	83,9	18,56	29,86	184	79,7	138	75,0	23,19	29,49
FU Month 9	White	160	65,0	123	76,9	17,34	29,37	144	62,3	104	72,2	17,63	27,46
FU Month 12	White	122	49,6	99	81,1	22,90	32,87	113	48,9	86	76,1	23,64	29,76
FU Month 15	White	102	41,5	80	78,4	17,08	28,06	81	35,1	58	71,6	21,26	30,40
FU Month 18	White	77	31,3	61	79,2	23,50	31,24	58	25,1	41	70,7	26,83	35,13
FU Month 21	White	50	20,3	35	70,0	17,14	27,26	38	16,5	26	68,4	30,77	32,56
FU Month 24	White	30	12,2	20	66,7	23,33	24,42	17	7,4	14	82,4	23,81	33,15
FU Month 27	White	12	4,9	8	66,7	12,50	17,25	8	3,5	6	75,0	16,67	27,89
FU Month 30	White	6	2,4	4	66,7	25,00	31,91	1	0,4	1	100,0	0,00	NE
Geographical Region													
Screening	Asia-Pacific	20	100,0	19	95,0	22,81	33,43	18	100,0	17	94,4	25,49	32,34
Cycle 4 Day 1	Asia-Pacific	15	75,0	14	93,3	21,43	30,96	16	88,9	15	93,8	15,56	24,77
FU Day 28	Asia-Pacific	18	90,0	18	100,0	25,93	31,43	18	100,0	16	88,9	14,58	20,97
FU Month 3	Asia-Pacific	18	90,0	16	88,9	16,67	32,20	18	100,0	15	83,3	8,89	15,26
FU Month 6	Asia-Pacific	16	80,0	14	87,5	28,57	36,65	17	94,4	14	82,4	28,57	41,05
FU Month 9	Asia-Pacific	14	70,0	12	85,7	5,56	19,25	13	72,2	10	76,9	23,33	35,31
FU Month 12	Asia-Pacific	10	50,0	8	80,0	8,33	23,57	10	55,6	10	100,0	26,67	30,63
FU Month 15	Asia-Pacific	8	40,0	6	75,0	0,00	0,00	9	50,0	9	100,0	25,93	36,43
FU Month 18	Asia-Pacific	6	30,0	4	66,7	0,00	0,00	6	33,3	6	100,0	22,22	34,43

FU Month 21	Asia-Pacific	525,0	360,0	0,00	0,00	422,2	4100,0	41,67	41,94		
FU Month 24	Asia-Pacific	315,0	266,7	0,00	0,00	15,6	0	NE	NE	NE	NE
FU Month 27	Asia-Pacific	15,0		NE	NE	15,6			NE	NE	NE
FU Month 30	Asia-Pacific	15,0		NE	NE	0	NE		NE	NE	NE
Screening	Central and South America	3100,0	3100,0	0,00	0,00	2100,0	2100,0	33,33	47,14		
Cycle 4 Day 1	Central and South America	3100,0	3100,0	0,00	0,00	2100,0	2100,0	16,67	23,57		
FU Day 28	Central and South America	3100,0	3100,0	0,00	0,00	2100,0	2100,0	0,00	0,00		
FU Month 3	Central and South America	3100,0	3100,0	11,11	19,25	2100,0	2100,0	0,00	0,00		
FU Month 6	Central and South America	266,7	2100,0	16,67	23,57	2100,0	2100,0	0,00	0,00		
FU Month 9	Central and South America	266,7	2100,0	16,67	23,57	150,0	1100,0	0,00		NE	NE
FU Month 12	Central and South America	266,7	2100,0	16,67	23,57	150,0	1100,0	33,33		NE	NE
FU Month 15	Central and South America	133,3	1100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 18	Central and South America	133,3	1100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 21	Central and South America	133,3	1100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 24	Central and South America	133,3	1100,0	0,00	NE	0	NE	0	NE	NE	NE
Screening	North America	12100,0	12100,0	33,33	40,20	13100,0	1292,3	13,89	22,29		
Cycle 4 Day 1	North America	975,0	9100,0	18,52	17,57	1292,3	12100,0	19,44	22,29		
FU Day 28	North America	1191,7	11100,0	18,18	31,14	13100,0	13100,0	17,95	29,24		
FU Month 3	North America	1191,7	981,8	18,52	17,57	1292,3	12100,0	13,89	17,16		
FU Month 6	North America	1191,7	1090,9	20,00	35,83	1184,6	11100,0	24,24	30,15		
FU Month 9	North America	866,7	8100,0	20,83	35,36	969,2	9100,0	11,11	23,57		
FU Month 12	North America	866,7	787,5	28,57	35,63	753,8	7100,0	19,05	26,23		
FU Month 15	North America	650,0	6100,0	0,00	0,00	646,2	583,3	20,00	29,81		
FU Month 18	North America	433,3	4100,0	8,33	16,67	323,1	3100,0	44,44	50,92		
FU Month 21	North America	325,0	266,7	0,00	0,00	17,7	1100,0	66,67		NE	NE
FU Month 24	North America	325,0	266,7	33,33	47,14	17,7	1100,0	100,00		NE	NE
FU Month 27	North America	216,7	150,0	0,00	NE	17,7	1100,0	66,67		NE	NE
Screening	Other	45100,0	1635,6	27,08	25,00	44100,0	1636,4	25,00	28,54		
Cycle 4 Day 1	Other	3782,2	1437,8	9,52	20,37	4090,9	1435,0	23,81	27,51		
FU Day 28	Other	3782,2	1437,8	2,38	8,91	3988,6	1435,9	9,52	15,63		
FU Month 3	Other	3884,4	1539,5	6,67	13,80	3886,4	1436,8	19,05	33,88		
FU Month 6	Other	3577,8	1542,9	6,67	13,80	3375,0	1030,3	16,67	23,57		
FU Month 9	Other	2657,8	1246,2	5,56	12,97	2454,5	833,3	12,50	17,25		
FU Month 12	Other	1737,8	847,1	12,50	35,36	1636,4	637,5	11,11	17,21		
FU Month 15	Other	1226,7	433,3	0,00	0,00	920,5	333,3	11,11	19,25		
FU Month 18	Other	1022,2	330,0	0,00	0,00	715,9	228,6	0,00	0,00		
FU Month 21	Other	715,6	228,6	0,00	0,00	49,1	0	NE	NE	NE	NE
FU Month 24	Other	613,3	116,7	0,00	NE	36,8	0	NE	NE	NE	NE
FU Month 27	Other	48,9	125,0	0,00	NE	12,3	0	NE	NE	NE	NE

FU Month 30	Other		24,4				NE	NE	0	NE			NE	NE
Screening	Western Europe	175	100,0	163	93,1	22,70	30,92	165	100,0	152	92,1	25,66	33,77	
Cycle 4 Day 1	Western Europe	149	85,1	133	89,3	22,56	30,30	154	93,3	131	85,1	21,63	26,77	
FU Day 28	Western Europe	161	92,0	135	83,9	22,72	30,92	153	92,7	137	89,5	22,38	29,73	
FU Month 3	Western Europe	155	88,6	135	87,1	19,51	28,03	151	91,5	130	86,1	21,28	30,78	
FU Month 6	Western Europe	143	81,7	130	90,9	18,72	29,64	129	78,2	107	82,9	22,43	28,14	
FU Month 9	Western Europe	114	65,1	92	80,7	19,93	30,88	102	61,8	80	78,4	17,50	27,55	
FU Month 12	Western Europe	88	50,3	76	86,4	25,00	33,17	83	50,3	66	79,5	23,74	30,81	
FU Month 15	Western Europe	77	44,0	64	83,1	21,35	29,91	61	37,0	45	73,8	21,48	30,28	
FU Month 18	Western Europe	58	33,1	50	86,2	28,00	32,55	44	26,7	32	72,7	26,04	34,64	
FU Month 21	Western Europe	36	20,6	28	77,8	21,43	28,99	31	18,8	23	74,2	26,09	30,08	
FU Month 24	Western Europe	19	10,9	15	78,9	26,67	22,54	13	7,9	13	100,0	17,95	25,88	
FU Month 27	Western Europe		63,4		6100,0	16,67	18,26		63,6		583,3	6,67	14,91	
FU Month 30	Western Europe	4	2,3	4	100,0	25,00	31,91		10,6	1	100,0	0,00		NE
FCgamma receptor IIa														
Screening	131HH	58	100,0	45	77,6	25,93	34,00	76	100,0	60	78,9	24,44	31,81	
Cycle 4 Day 1	131HH	49	84,5	34	69,4	26,47	26,94	65	85,5	48	73,8	18,06	24,75	
FU Day 28	131HH	51	87,9	38	74,5	19,30	27,54	70	92,1	51	72,9	18,95	29,25	
FU Month 3	131HH	51	87,9	38	74,5	17,54	24,18	64	84,2	45	70,3	17,04	27,18	
FU Month 6	131HH	49	84,5	39	79,6	26,50	32,61	55	72,4	38	69,1	22,81	29,11	
FU Month 9	131HH	39	67,2	25	64,1	17,33	25,68	41	53,9	31	75,6	13,98	26,91	
FU Month 12	131HH	28	48,3	21	75,0	28,57	33,81	34	44,7	28	82,4	23,81	28,48	
FU Month 15	131HH	23	39,7	16	69,6	14,58	20,97	24	31,6	19	79,2	19,30	30,05	
FU Month 18	131HH	17	29,3	12	70,6	22,22	21,71	16	21,1	11	68,8	30,30	37,87	
FU Month 21	131HH	13	22,4	8	61,5	12,50	24,80	11	14,5	9	81,8	40,74	40,06	
FU Month 24	131HH	11	19,0	7	63,6	28,57	23,00	1	1,3	1	100,0	33,33		NE
FU Month 27	131HH	4	6,9	3	75,0	22,22	19,25	1	1,3	1	100,0	33,33		NE
FU Month 30	131HH	3	5,2	2	66,7	16,67	23,57	0	NE	0	NE	NE		NE
Screening	131HR	125	100,0	107	85,6	25,23	31,34	114	100,0	99	86,8	24,92	32,42	
Cycle 4 Day 1	131HR	105	84,0	89	84,8	20,97	31,54	110	96,5	92	83,6	22,10	27,19	
FU Day 28	131HR	116	92,8	96	82,8	24,31	32,26	105	92,1	91	86,7	21,61	29,13	
FU Month 3	131HR	114	91,2	94	82,5	19,86	29,86	107	93,9	88	82,2	18,18	28,99	
FU Month 6	131HR	104	83,2	86	82,7	14,73	27,82	95	83,3	77	81,1	22,51	29,34	

FU Month 9	131HR	84	67,2	66	78,6	16,67	28,19	76	66,7	56	73,7	16,67	28,43	
FU Month 12	131HR	64	51,2	54	84,4	27,16	34,91	57	50,0	46	80,7	23,19	32,10	
FU Month 15	131HR	53	42,4	40	75,5	19,17	28,13	44	38,6	32	72,7	20,83	31,40	
FU Month 18	131HR	43	34,4	34	79,1	26,47	32,60	32	28,1	24	75,0	19,44	29,35	
FU Month 21	131HR	26	20,8	17	65,4	27,45	31,70	21	18,4	15	71,4	28,89	27,79	
FU Month 24	131HR	12	9,6	8	66,7	20,83	24,80	12	10,5	10	83,3	30,00	36,68	
FU Month 27	131HR	6	4,8	3	50,0	11,11	19,25		6	5,3	4	66,7	16,67	33,33
FU Month 30	131HR	3	2,4	1	33,3	66,67	NE	1	0,9	1	100,0	0,00	NE	
Screening	131RR	49	100,0	41	83,7	19,51	29,79	33	100,0	27	81,8	25,93	33,76	
Cycle 4 Day 1	131RR	40	81,6	33	82,5	13,13	21,95	31	93,9	24	77,4	19,44	23,91	
FU Day 28	131RR	42	85,7	30	71,4	14,44	25,80	32	97,0	28	87,5	17,86	26,42	
FU Month 3	131RR	39	79,6	30	76,9	16,67	24,37	32	97,0	28	87,5	25,00	35,86	
FU Month 6	131RR	35	71,4	29	82,9	18,39	30,32	27	81,8	20	74,1	23,33	32,62	
FU Month 9	131RR	24	49,0	20	83,3	18,33	36,63	19	57,6	15	78,9	24,44	26,63	
FU Month 12	131RR	18	36,7	15	83,3	8,89	26,63	17	51,5	12	70,6	25,00	25,13	
FU Month 15	131RR	16	32,7	14	87,5	19,05	38,60	11	33,3	8	72,7	25,00	29,55	
FU Month 18	131RR	14	28,6	12	85,7	22,22	38,49	8	24,2	7	87,5	28,57	40,50	
FU Month 21	131RR	8	16,3	6	75,0	0,00	0,00	5	15,2	4	80,0	8,33	16,67	
FU Month 24	131RR	5	10,2	3	60,0	22,22	38,49	3	9,1	3	100,0	0,00	0,00	
FU Month 27	131RR	2	4,1	1	50,0	0,00	NE	1	3,0	1	100,0	0,00	NE	
FU Month 30	131RR	1	2,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE	
Screening	Missing	23	100,0	20	87,0	15,00	25,31	19	100,0	13	68,4	25,64	38,86	
Cycle 4 Day 1	Missing	19	82,6	17	89,5	23,53	30,65	18	94,7	10	55,6	30,00	29,19	
FU Day 28	Missing	21	91,3	17	81,0	15,69	29,15	18	94,7	12	66,7	19,44	22,29	
FU Month 3	Missing	21	91,3	16	76,2	10,42	20,07	18	94,7	12	66,7	22,22	21,71	
FU Month 6	Missing	19	82,6	17	89,5	19,61	29,01	15	78,9	9	60,0	18,52	24,22	
FU Month 9	Missing	17	73,9	15	88,2	17,78	30,52	13	68,4	6	46,2	16,67	18,26	
FU Month 12	Missing	15	65,2	11	73,3	9,09	15,57	9	47,4	4	44,4	8,33	16,67	
FU Month 15	Missing	12	52,2	11	91,7	9,09	21,56	6	31,6	3	50,0	33,33	33,33	
FU Month 18	Missing	5	21,7	4	80,0	0,00	0,00	4	21,1	1	25,0	100,00	NE	
FU Month 21	Missing	5	21,7	5	100,0	6,67	14,91	3	15,8	0	NE	NE	NE	
FU Month 24	Missing	4	17,4	3	75,0	11,11	19,25	2	10,5	0	NE	NE	NE	
FU Month 27	Missing	1	4,3	1	100,0	0,00	NE	1	5,3	0	NE	NE	NE	
FCgamma receptor IIIa														
Screening	158FF	103	100,0	91	88,3	27,11	32,93	83	100,0	70	84,3	23,81	30,11	
Cycle 4 Day 1	158FF	89	86,4	73	82,0	21,00	31,67	78	94,0	63	80,8	20,63	26,39	
FU Day 28	158FF	96	93,2	78	81,3	19,66	31,52	78	94,0	67	85,9	20,40	27,80	
FU Month 3	158FF	94	91,3	75	79,8	16,00	26,49	78	94,0	65	83,3	20,00	30,51	
FU Month 6	158FF	86	83,5	69	80,2	17,39	30,58	64	77,1	51	79,7	20,92	27,46	

FU Month 9	158FF	71	68,9	56	78,9	18,45	32,36	47	56,6	40	85,1	16,67	28,24
FU Month 12	158FF	48	46,6	41	85,4	19,51	31,60	38	45,8	32	84,2	17,71	25,38
FU Month 15	158FF	37	35,9	30	81,1	17,78	33,60	30	36,1	23	76,7	17,39	29,93
FU Month 18	158FF	27	26,2	22	81,5	22,73	36,20	21	25,3	16	76,2	18,75	36,45
FU Month 21	158FF	16	15,5	15	93,8	13,33	27,60	9	10,8	8	88,9	29,17	27,82
FU Month 24	158FF	8	7,8	7	87,5	19,05	26,23	3	3,6	3	100,0	33,33	33,33
FU Month 27	158FF	5	4,9	4	80,0	8,33	16,67	1	1,2	1	100,0	0,00	NE
FU Month 30	158FF	3	2,9	3	100,0	22,22	38,49	0	NE	0	NE	NE	NE
Screening	158FV	119	100,0	97	81,5	19,24	27,99	109	100,0	90	82,6	27,04	34,58
Cycle 4 Day 1	158FV	99	83,2	80	80,8	20,83	27,24	100	91,7	77	77,0	19,91	27,18
FU Day 28	158FV	105	88,2	80	76,2	23,33	29,24	101	92,7	81	80,2	20,99	28,60
FU Month 3	158FV	101	84,9	80	79,2	22,50	28,94	97	89,0	74	76,3	18,47	29,27
FU Month 6	158FV	94	79,0	80	85,1	18,75	29,46	83	76,1	63	75,9	22,75	29,83
FU Month 9	158FV	71	59,7	53	74,6	15,72	25,82	65	59,6	45	69,2	20,00	29,64
FU Month 12	158FV	60	50,4	50	83,3	28,67	35,00	52	47,7	41	78,8	26,02	32,07
FU Month 15	158FV	52	43,7	39	75,0	17,09	25,21	36	33,0	28	77,8	25,00	33,49
FU Month 18	158FV	44	37,0	34	77,3	25,49	29,65	24	22,0	19	79,2	33,33	36,85
FU Month 21	158FV	28	23,5	14	50,0	23,81	30,46	18	16,5	14	77,8	30,95	38,04
FU Month 24	158FV	18	15,1	9	50,0	25,93	27,78	6	5,5	5	83,3	6,67	14,91
FU Month 27	158FV	6	5,0	2	33,3	16,67	23,57	2	1,8	1	50,0	0,00	NE
FU Month 30	158FV	4	3,4	1	25,0	33,33	NE	0	NE	0	NE	NE	NE
Screening	158VV	16	100,0	12	75,0	33,33	40,20	33	100,0	28	84,8	19,05	29,30
Cycle 4 Day 1	158VV	12	75,0	9	75,0	11,11	16,67	30	90,9	26	86,7	24,36	24,14
FU Day 28	158VV	14	87,5	11	78,6	12,12	22,47	30	90,9	25	83,3	17,33	30,61
FU Month 3	158VV	15	93,8	10	66,7	6,67	14,05	30	90,9	24	80,0	18,06	29,45
FU Month 6	158VV	14	87,5	11	78,6	15,15	22,92	30	90,9	21	70,0	22,22	30,43
FU Month 9	158VV	12	75,0	9	75,0	18,52	24,22	25	75,8	18	72,0	9,26	19,15
FU Month 12	158VV	8	50,0	5	62,5	13,33	18,26	20	60,6	16	80,0	27,08	30,35
FU Month 15	158VV	8	50,0	6	75,0	22,22	27,22	14	42,4	10	71,4	20,00	23,31
FU Month 18	158VV	4	25,0	3	75,0	22,22	19,25	11	33,3	8	72,7	20,83	24,80
FU Month 21	158VV	3	18,8	2	66,7	16,67	23,57	9	27,3	6	66,7	27,78	25,09
FU Month 24	158VV	2	12,5	2	100,0	33,33	0,00	7	21,2	6	85,7	33,33	42,16
FU Month 27	158VV	1	6,3	1	100,0	33,33	NE	5	15,2	4	80,0	25,00	31,91
FU Month 30	158VV	0	NE	0	NE	NE	NE	1	3,0	1	100,0	0,00	NE
Screening	Missing	17	100,0	13	76,5	17,95	29,24	17	100,0	11	64,7	30,30	40,70
Cycle 4 Day 1	Missing	13	76,5	11	84,6	27,27	32,72	16	94,1	8	50,0	25,00	23,57
FU Day 28	Missing	15	88,2	12	80,0	19,44	33,21	16	94,1	9	56,3	18,52	24,22
FU Month 3	Missing	15	88,2	13	86,7	10,26	21,01	16	94,1	10	62,5	23,33	22,50
FU Month 6	Missing	13	76,5	11	84,6	27,27	32,72	15	88,2	9	60,0	29,63	35,14

FU Month 9	Missing	10	58,8	8	80,0	16,67	35,63	12	70,6	5	41,7	20,00	18,26
FU Month 12	Missing	9	52,9	5	55,6	0,00	0,00	7	41,2	1	14,3	0,00	NE
FU Month 15	Missing	7	41,2	6	85,7	5,56	13,61	5	29,4	1	20,0	33,33	NE
FU Month 18	Missing	4	23,5	3	75,0	0,00	0,00	4	23,5	0	NE	NE	NE
FU Month 21	Missing	5	29,4	5	100,0	6,67	14,91	4	23,5	0	NE	NE	NE
FU Month 24	Missing	4	23,5	3	75,0	11,11	19,25	2	11,8	0	NE	NE	NE
FU Month 27	Missing	1	5,9	1	100,0	0,00	NE	1	5,9	0	NE	NE	NE
Binet Staging at baseline													
Screening	A	59	100,0	55	93,2	29,09	35,75	57	100,0	46	80,7	28,99	36,92
Cycle 4 Day 1	A	51	86,4	45	88,2	22,96	30,00	54	94,7	45	83,3	26,67	30,65
FU Day 28	A	58	98,3	51	87,9	24,84	32,55	54	94,7	44	81,5	32,58	33,32
FU Month 3	A	57	96,6	52	91,2	21,79	29,44	53	93,0	44	83,0	22,73	32,76
FU Month 6	A	56	94,9	47	83,9	26,24	34,71	45	78,9	35	77,8	24,76	30,62
FU Month 9	A	43	72,9	35	81,4	23,81	34,84	34	59,6	25	73,5	24,00	34,05
FU Month 12	A	36	61,0	32	88,9	27,08	38,28	24	42,1	18	75,0	25,93	29,27
FU Month 15	A	30	50,8	23	76,7	20,29	27,96	19	33,3	16	84,2	25,00	35,49
FU Month 18	A	22	37,3	15	68,2	33,33	35,63	16	28,1	13	81,3	35,90	39,58
FU Month 21	A	17	28,8	13	76,5	23,08	31,58	8	14,0	5	62,5	26,67	27,89
FU Month 24	A	10	16,9	6	60,0	27,78	25,09	5	8,8	4	80,0	25,00	31,91
FU Month 27	A	5	8,5	3	60,0	22,22	19,25	2	3,5	1	50,0	33,33	NE
FU Month 30	A	4	6,8	3	75,0	33,33	33,33	0	NE	0	NE	NE	NE
Screening													
Screening	B	104	100,0	83	79,8	20,08	26,00	85	100,0	69	81,2	23,67	30,30
Cycle 4 Day 1	B	88	84,6	72	81,8	16,67	23,74	79	92,9	63	79,7	20,11	24,35
FU Day 28	B	91	87,5	68	74,7	19,12	30,10	79	92,9	63	79,7	13,23	22,03
FU Month 3	B	88	84,6	63	71,6	17,46	25,30	79	92,9	61	77,2	18,03	27,60
FU Month 6	B	80	76,9	68	85,0	12,25	22,97	70	82,4	50	71,4	20,00	26,94
FU Month 9	B	63	60,6	48	76,2	13,89	26,48	59	69,4	42	71,2	15,87	22,38
FU Month 12	B	47	45,2	35	74,5	20,00	29,37	46	54,1	36	78,3	20,37	27,92
FU Month 15	B	37	35,6	31	83,8	19,35	30,76	34	40,0	25	73,5	18,67	25,60
FU Month 18	B	31	29,8	26	83,9	21,79	31,19	22	25,9	17	77,3	21,57	26,20
FU Month 21	B	18	17,3	12	66,7	11,11	21,71	17	20,0	13	76,5	25,64	27,74
FU Month 24	B	11	10,6	8	72,7	25,00	29,55	8	9,4	7	87,5	28,57	40,50
FU Month 27	B	5	4,8	3	60,0	11,11	19,25	4	4,7	4	100,0	16,67	33,33
FU Month 30	B	2	1,9	1	50,0	0,00	NE	0	NE	0	NE	NE	NE
Screening													
Screening	C	92	100,0	75	81,5	22,67	32,49	100	100,0	84	84,0	23,81	32,14
Cycle 4 Day 1	C	74	80,4	56	75,7	24,40	33,93	91	91,0	66	72,5	18,18	24,24
FU Day 28	C	81	88,0	62	76,5	19,35	28,02	92	92,0	75	81,5	18,67	27,53
FU Month 3	C	80	87,0	63	78,8	15,34	26,66	89	89,0	68	76,4	18,14	28,47
FU Month 6	C	71	77,2	56	78,9	19,64	30,99	77	77,0	59	76,6	23,16	30,48

FU Month 9	C	58	63,0	43	74,1	15,50	26,58	56	56,0	41	73,2	13,82	26,85
FU Month 12	C	42	45,7	34	81,0	21,57	30,58	47	47,0	36	76,6	24,07	31,48
FU Month 15	C	37	40,2	27	73,0	11,11	24,46	32	32,0	21	65,6	22,22	32,20
FU Month 18	C	26	28,3	21	80,8	17,46	27,12	22	22,0	13	59,1	20,51	39,76
FU Month 21	C	17	18,5	11	64,7	15,15	27,34	15	15,0	10	66,7	36,67	39,91
FU Month 24	C	11	12,0	7	63,6	14,29	17,82	5	5,0	3	60,0	11,11	19,25
FU Month 27	C	3	3,3	2	66,7	0,00	0,00	3	3,0	1	33,3	0,00	NE
FU Month 30	C	1	1,1	0	NE	NE	NE	1	1,0	1	100,0	0,00	NE

Total CIR score at baseline

Screening	<=6	63	100,0	53	84,1	22,01	31,99	75	100,0	60	80,0	32,78	35,52
Cycle 4 Day 1	<=6	52	82,5	38	73,1	21,05	25,02	72	96,0	53	73,6	16,98	24,13
FU Day 28	<=6	56	88,9	44	78,6	24,24	31,63	72	96,0	52	72,2	16,03	25,98
FU Month 3	<=6	55	87,3	40	72,7	20,00	31,85	69	92,0	49	71,0	10,20	22,78
FU Month 6	<=6	52	82,5	43	82,7	22,48	33,11	60	80,0	44	73,3	25,00	27,02
FU Month 9	<=6	43	68,3	33	76,7	20,20	33,27	47	62,7	34	72,3	14,71	26,20
FU Month 12	<=6	35	55,6	28	80,0	25,00	33,49	34	45,3	27	79,4	22,22	32,03
FU Month 15	<=6	32	50,8	25	78,1	17,33	29,06	25	33,3	16	64,0	25,00	33,33
FU Month 18	<=6	23	36,5	20	87,0	30,00	34,03	19	25,3	13	68,4	12,82	35,60
FU Month 21	<=6	14	22,2	8	57,1	29,17	33,03	14	18,7	10	71,4	33,33	27,22
FU Month 24	<=6	8	12,7	7	87,5	14,29	26,23	7	9,3	6	85,7	33,33	29,81
FU Month 27	<=6	2	3,2	2	100,0	0,00	0,00	4	5,3	2	50,0	0,00	0,00
FU Month 30	<=6	0	NE	0	NE	NE	NE	1	1,3	1	100,0	0,00	NE

Screening	>6	192	100,0	160	83,3	23,75	30,92	167	100,0	139	83,2	21,58	30,79
Cycle 4 Day 1	>6	161	83,9	135	83,9	20,74	30,16	152	91,0	121	79,6	22,87	26,89
FU Day 28	>6	174	90,6	137	78,7	19,71	29,58	153	91,6	130	85,0	21,79	28,97
FU Month 3	>6	170	88,5	138	81,2	17,39	25,54	152	91,0	124	81,6	22,85	30,76
FU Month 6	>6	155	80,7	128	82,6	17,19	28,37	132	79,0	100	75,8	21,33	30,16
FU Month 9	>6	121	63,0	93	76,9	16,13	27,63	102	61,1	74	72,5	18,02	27,69
FU Month 12	>6	90	46,9	73	81,1	21,92	32,50	83	49,7	63	75,9	23,28	28,48
FU Month 15	>6	72	37,5	56	77,8	16,67	27,71	60	35,9	46	76,7	20,29	29,38
FU Month 18	>6	56	29,2	42	75,0	19,84	29,50	41	24,6	30	73,2	31,11	37,07
FU Month 21	>6	38	19,8	28	73,7	13,10	24,58	26	15,6	18	69,2	27,78	34,77
FU Month 24	>6	24	12,5	14	58,3	26,19	23,31	11	6,6	8	72,7	16,67	35,63
FU Month 27	>6	11	5,7	6	54,5	16,67	18,26	5	3,0	4	80,0	25,00	31,91
FU Month 30	>6	7	3,6	4	57,1	25,00	31,91	0	NE	0	NE	NE	NE

Calculated creatinine clearance cat. 2

Screening	<70 ml/min	178	100,0	149	83,7	24,16	32,15	176	100,0	145	82,4	25,98	33,67
Cycle 4 Day 1	<70 ml/min	149	83,7	119	79,9	20,73	29,11	164	93,2	128	78,0	20,05	25,22

FU Day 28	<70 ml/min	162	91,0	129	79,6	21,71	30,52	166	94,3	131	78,9	19,34	27,72
FU Month 3	<70 ml/min	157	88,2	125	79,6	16,80	27,64	159	90,3	123	77,4	18,43	28,05
FU Month 6	<70 ml/min	144	80,9	121	84,0	18,18	30,12	139	79,0	103	74,1	22,01	28,98
FU Month 9	<70 ml/min	117	65,7	88	75,2	18,56	30,68	112	63,6	79	70,5	16,88	27,15
FU Month 12	<70 ml/min	92	51,7	73	79,3	21,00	31,18	87	49,4	67	77,0	24,38	29,35
FU Month 15	<70 ml/min	78	43,8	62	79,5	17,20	28,78	60	34,1	42	70,0	19,84	29,50
FU Month 18	<70 ml/min	59	33,1	47	79,7	24,11	31,62	43	24,4	31	72,1	27,96	35,59
FU Month 21	<70 ml/min	38	21,3	24	63,2	16,67	27,80	31	17,6	23	74,2	34,78	32,53
FU Month 24	<70 ml/min	24	13,5	16	66,7	20,83	26,87	13	7,4	9	69,2	33,33	37,27
FU Month 27	<70 ml/min	10	5,6	5	50,0	6,67	14,91	7	4,0	4	57,1	25,00	31,91
FU Month 30	<70 ml/min	5	2,8	2	40,0	16,67	23,57	1	0,6	1	100,0	0,00	NE
Screening	>=70 ml/min	77	100,0	64	83,1	21,35	28,71	66	100,0	54	81,8	22,22	29,67
Cycle 4 Day 1	>=70 ml/min	64	83,1	54	84,4	20,99	29,17	60	90,9	46	76,7	23,91	28,69
FU Day 28	>=70 ml/min	68	88,3	52	76,5	18,59	29,08	59	89,4	51	86,4	22,22	29,56
FU Month 3	>=70 ml/min	68	88,3	53	77,9	20,75	25,51	62	93,9	50	80,6	21,33	32,13
FU Month 6	>=70 ml/min	63	81,8	50	79,4	19,33	28,64	53	80,3	41	77,4	23,58	30,04
FU Month 9	>=70 ml/min	47	61,0	38	80,9	14,04	25,27	37	56,1	29	78,4	17,24	27,63
FU Month 12	>=70 ml/min	33	42,9	28	84,8	27,38	36,35	30	45,5	23	76,7	18,84	29,86
FU Month 15	>=70 ml/min	26	33,8	19	73,1	15,79	25,74	25	37,9	20	80,0	25,00	32,22
FU Month 18	>=70 ml/min	20	26,0	15	75,0	20,00	30,34	17	25,8	12	70,6	19,44	33,21
FU Month 21	>=70 ml/min	14	18,2	12	85,7	16,67	26,59	9	13,6	5	55,6	6,67	14,91
FU Month 24	>=70 ml/min	8	10,4	5	62,5	26,67	14,91	5	7,6	5	100,0	6,67	14,91
FU Month 27	>=70 ml/min	3	3,9	3	100,0	22,22	19,25	2	3,0	2	100,0	0,00	0,00
FU Month 30	>=70 ml/min	2	2,6	2	100,0	33,33	47,14	0	NE	0	NE	NE	NE
Beta2 microglobulin													
Screening	Missing	3	100,0	3	100,0	0,00	0,00	3	100,0	2	66,7	50,00	70,71
Cycle 4 Day 1	Missing	3	100,0	3	100,0	11,11	19,25	3	100,0	1	33,3	66,67	NE
FU Day 28	Missing	3	100,0	3	100,0	0,00	0,00	3	100,0	1	33,3	0,00	NE
FU Month 3	Missing	3	100,0	3	100,0	22,22	19,25	3	100,0	1	33,3	0,00	NE
FU Month 6	Missing	3	100,0	3	100,0	0,00	0,00	3	100,0	1	33,3	33,33	NE
FU Month 9	Missing	2	66,7	1	50,0	0,00	NE	3	100,0	1	33,3	33,33	NE
FU Month 12	Missing	1	33,3	1	100,0	0,00	NE	2	66,7	0	NE	NE	NE
FU Month 15	Missing	1	33,3	1	100,0	0,00	NE	2	66,7	0	NE	NE	NE
FU Month 18	Missing	1	33,3	1	100,0	33,33	NE	2	66,7	0	NE	NE	NE
FU Month 21	Missing	1	33,3	1	100,0	0,00	NE	2	66,7	0	NE	NE	NE
FU Month 24	Missing	1	33,3	1	100,0	33,33	NE	1	33,3	0	NE	NE	NE
Screening	< 3.5 ug/mL	154	100,0	131	85,1	25,95	30,74	140	100,0	117	83,6	27,07	32,44
Cycle 4 Day 1	< 3.5 ug/mL	127	82,5	108	85,0	20,68	27,99	129	92,1	101	78,3	20,79	26,60
FU Day 28	< 3.5 ug/mL	137	89,0	116	84,7	21,55	29,57	132	94,3	108	81,8	20,68	26,85

FU Month 3	< 3.5 ug/mL	134	87,0	114	85,1	17,84	27,04	130	92,9	102	78,5	17,97	26,81
FU Month 6	< 3.5 ug/mL	128	83,1	108	84,4	18,83	28,56	120	85,7	94	78,3	22,70	29,42
FU Month 9	< 3.5 ug/mL	104	67,5	82	78,8	19,92	29,56	98	70,0	74	75,5	18,47	28,74
FU Month 12	< 3.5 ug/mL	78	50,6	66	84,6	24,75	33,75	75	53,6	60	80,0	24,44	31,21
FU Month 15	< 3.5 ug/mL	65	42,2	51	78,5	15,69	26,96	60	42,9	46	76,7	23,19	32,10
FU Month 18	< 3.5 ug/mL	46	29,9	37	80,4	25,23	32,78	43	30,7	31	72,1	24,73	33,30
FU Month 21	< 3.5 ug/mL	30	19,5	20	66,7	21,67	31,11	27	19,3	20	74,1	30,00	34,03
FU Month 24	< 3.5 ug/mL	19	12,3	14	73,7	21,43	24,83	12	8,6	10	83,3	20,00	28,11
FU Month 27	< 3.5 ug/mL	10	6,5	7	70,0	14,29	17,82	7	5,0	4	57,1	8,33	16,67
FU Month 30	< 3.5 ug/mL	5	3,2	3	60,0	33,33	33,33	1	0,7	1	100,0	0,00	NE
Screening	>= 3.5 ug/mL	98	100,0	79	80,6	19,83	31,81	99	100,0	80	80,8	21,25	31,93
Cycle 4 Day 1	>= 3.5 ug/mL	83	84,7	62	74,7	21,51	31,42	92	92,9	72	78,3	20,83	25,29
FU Day 28	>= 3.5 ug/mL	90	91,8	62	68,9	20,43	31,57	90	90,9	73	81,1	19,63	30,35
FU Month 3	>= 3.5 ug/mL	88	89,8	61	69,3	18,03	27,60	88	88,9	70	79,5	21,43	32,62
FU Month 6	>= 3.5 ug/mL	76	77,6	60	78,9	18,89	32,11	69	69,7	49	71,0	21,77	29,31
FU Month 9	>= 3.5 ug/mL	58	59,2	43	74,1	12,40	28,19	48	48,5	33	68,8	13,13	23,48
FU Month 12	>= 3.5 ug/mL	46	46,9	34	73,9	19,61	30,83	40	40,4	30	75,0	20,00	25,67
FU Month 15	>= 3.5 ug/mL	38	38,8	29	76,3	19,54	30,23	23	23,2	16	69,6	16,67	24,34
FU Month 18	>= 3.5 ug/mL	32	32,7	24	75,0	19,44	29,35	15	15,2	12	80,0	27,78	39,78
FU Month 21	>= 3.5 ug/mL	21	21,4	15	71,4	11,11	20,57	11	11,1	8	72,7	29,17	27,82
FU Month 24	>= 3.5 ug/mL	12	12,2	6	50,0	22,22	27,22	5	5,1	4	80,0	33,33	47,14
FU Month 27	>= 3.5 ug/mL	3	3,1	1	33,3	0,00	NE	2	2,0	2	100,0	33,33	47,14
FU Month 30	>= 3.5 ug/mL	2	2,0	1	50,0	0,00	NE	0	NE	0	NE	NE	NE
Immunoglobulin VH, cytogenetics 2													
Screening	12	45	100,0	38	84,4	25,44	32,36	44	100,0	39	88,6	15,38	24,00
Cycle 4 Day 1	12	34	75,6	29	85,3	18,39	22,86	38	86,4	30	78,9	17,78	27,31
FU Day 28	12	39	86,7	34	87,2	28,43	30,85	40	90,9	35	87,5	20,95	25,67
FU Month 3	12	38	84,4	32	84,2	16,67	25,40	39	88,6	30	76,9	17,78	25,87
FU Month 6	12	36	80,0	30	83,3	15,56	28,68	34	77,3	27	79,4	17,28	21,42
FU Month 9	12	26	57,8	21	80,8	12,70	26,82	28	63,6	17	60,7	17,65	23,91
FU Month 12	12	22	48,9	17	77,3	17,65	29,15	23	52,3	13	56,5	17,95	17,30
FU Month 15	12	17	37,8	13	76,5	17,95	25,88	17	38,6	11	64,7	27,27	29,13
FU Month 18	12	15	33,3	11	73,3	18,18	17,41	13	29,5	8	61,5	4,17	11,79
FU Month 21	12	10	22,2	7	70,0	19,05	26,23	7	15,9	4	57,1	8,33	16,67
FU Month 24	12	8	17,8	5	62,5	33,33	23,57	6	13,6	5	83,3	0,00	0,00
FU Month 27	12	5	11,1	3	60,0	22,22	19,25	2	4,5	2	100,0	0,00	0,00
FU Month 30	12	4	8,9	2	50,0	16,67	23,57	1	2,3	1	100,0	0,00	NE
Screening	11q-	46	100,0	35	76,1	16,19	26,04	43	100,0	36	83,7	22,22	33,81
Cycle 4 Day 1	11q-	40	87,0	33	82,5	11,11	23,07	41	95,3	32	78,0	25,00	28,08

FU Day 28	11q-	42	91,3	29	69,0	22,99	35,75	39	90,7	32	82,1	25,00	32,79
FU Month 3	11q-	42	91,3	32	76,2	22,92	31,04	38	88,4	34	89,5	19,61	31,91
FU Month 6	11q-	38	82,6	31	81,6	15,05	28,33	32	74,4	25	78,1	24,00	24,57
FU Month 9	11q-	28	60,9	24	85,7	18,06	31,05	25	58,1	20	80,0	11,67	19,57
FU Month 12	11q-	20	43,5	17	85,0	27,45	39,50	18	41,9	16	88,9	22,92	29,11
FU Month 15	11q-	18	39,1	14	77,8	16,67	31,35	14	32,6	8	57,1	29,17	27,82
FU Month 18	11q-	15	32,6	11	73,3	24,24	39,70	8	18,6	5	62,5	40,00	43,46
FU Month 21	11q-	12	26,1	10	83,3	26,67	30,63	4	9,3	1	25,0	0,00	NE
FU Month 24	11q-	7	15,2	4	57,1	8,33	16,67	1	2,3	1	100,0	0,00	NE
FU Month 27	11q-	3	6,5	2	66,7	16,67	23,57	0	NE	0	NE	NE	NE
FU Month 30	11q-	3	6,5	2	66,7	33,33	47,14	0	NE	0	NE	NE	NE
Screening	13q-	79	100,0	66	83,5	19,70	30,93	75	100,0	56	74,7	27,98	32,89
Cycle 4 Day 1	13q-	67	84,8	51	76,1	22,88	30,18	68	90,7	50	73,5	16,00	23,56
FU Day 28	13q-	72	91,1	58	80,6	13,22	24,93	72	96,0	53	73,6	10,69	21,46
FU Month 3	13q-	73	92,4	57	78,1	11,11	23,00	69	92,0	49	71,0	17,01	28,16
FU Month 6	13q-	67	84,8	55	82,1	12,73	24,42	63	84,0	44	69,8	17,42	29,19
FU Month 9	13q-	56	70,9	44	78,6	15,15	30,03	52	69,3	36	69,2	16,67	31,37
FU Month 12	13q-	44	55,7	37	84,1	20,72	30,78	40	53,3	34	85,0	22,55	28,09
FU Month 15	13q-	38	48,1	31	81,6	17,20	29,65	29	38,7	23	79,3	17,39	28,19
FU Month 18	13q-	28	35,4	23	82,1	28,99	36,66	21	28,0	16	76,2	22,92	31,55
FU Month 21	13q-	16	20,3	12	75,0	5,56	19,25	16	21,3	12	75,0	30,56	26,43
FU Month 24	13q-	7	8,9	5	71,4	26,67	27,89	7	9,3	4	57,1	50,00	43,03
FU Month 27	13q-	2	2,5	1	50,0	0,00	NE	6	8,0	3	50,0	33,33	33,33
Screening	Norm. K.	65	100,0	57	87,7	29,24	32,78	58	100,0	50	86,2	34,67	36,24
Cycle 4 Day 1	Norm. K.	54	83,1	46	85,2	23,91	31,16	55	94,8	45	81,8	30,37	26,42
FU Day 28	Norm. K.	59	90,8	46	78,0	23,19	29,71	53	91,4	46	86,8	27,54	30,07
FU Month 3	Norm. K.	54	83,1	44	81,5	24,24	28,18	54	93,1	43	79,6	24,81	31,78
FU Month 6	Norm. K.	49	75,4	43	87,8	27,13	35,82	45	77,6	33	73,3	34,34	34,85
FU Month 9	Norm. K.	39	60,0	27	69,2	18,52	26,69	30	51,7	24	80,0	23,61	30,26
FU Month 12	Norm. K.	32	49,2	24	75,0	26,39	35,41	24	41,4	18	75,0	27,78	38,35
FU Month 15	Norm. K.	26	40,0	19	73,1	17,54	28,04	20	34,5	16	80,0	22,92	37,94
FU Month 18	Norm. K.	18	27,7	14	77,8	21,43	24,83	15	25,9	12	80,0	41,67	40,51
FU Month 21	Norm. K.	12	18,5	5	41,7	26,67	36,51	11	19,0	9	81,8	48,15	37,68
FU Month 24	Norm. K.	8	12,3	5	62,5	26,67	27,89	4	6,9	4	100,0	33,33	27,22
FU Month 27	Norm. K.	3	4,6	2	66,7	0,00	0,00	1	1,7	1	100,0	0,00	NE
Screening	Other Abn.	20	100,0	17	85,0	27,45	31,70	22	100,0	18	81,8	14,81	28,52
Cycle 4 Day 1	Other Abn.	18	90,0	14	77,8	30,95	38,04	22	100,0	17	77,3	9,80	19,60
FU Day 28	Other Abn.	18	90,0	14	77,8	21,43	33,61	21	95,5	16	76,2	18,75	32,13
FU Month 3	Other Abn.	18	90,0	13	72,2	17,95	29,24	21	95,5	17	81,0	13,73	26,51

FU Month 6	Other Abn.	17	85,0	12	70,6	30,56	26,43	18	81,8	15	83,3	17,78	30,52
FU Month 9	Other Abn.	15	75,0	10	66,7	30,00	33,15	14	63,6	11	78,6	12,12	22,47
FU Month 12	Other Abn.	7	35,0	6	85,7	22,22	27,22	12	54,5	9	75,0	22,22	33,33
FU Month 15	Other Abn.	5	25,0	4	80,0	8,33	16,67	5	22,7	4	80,0	8,33	16,67
FU Month 18	Other Abn.	3	15,0	3	100,0	0,00	0,00	3	13,6	2	66,7	0,00	0,00
FU Month 21	Other Abn.	2	10,0	2	100,0	0,00	0,00	2	9,1	2	100,0	0,00	0,00
FU Month 24	Other Abn.	2	10,0	2	100,0	0,00	0,00	0	NE	0	NE	NE	NE
Time from first diagnosis													
Screening	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
Cycle 4 Day 1	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Day 28	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 3	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 6	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 9	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 12	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 15	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
FU Month 18	Missing	1	100,0	1	100,0	0,00	NE	0	NE	0	NE	NE	NE
Screening	13 - 24 months	41	100,0	30	73,2	26,67	34,35	31	100,0	30	96,8	21,11	30,93
Cycle 4 Day 1	13 - 24 months	35	85,4	28	80,0	25,00	34,69	30	96,8	26	86,7	19,23	26,95
FU Day 28	13 - 24 months	38	92,7	26	68,4	25,64	33,08	30	96,8	26	86,7	8,97	20,13
FU Month 3	13 - 24 months	36	87,8	28	77,8	27,38	36,35	30	96,8	25	83,3	12,00	21,26
FU Month 6	13 - 24 months	36	87,8	27	75,0	13,58	29,61	30	96,8	23	76,7	14,49	24,26
FU Month 9	13 - 24 months	32	78,0	22	68,8	18,18	35,23	21	67,7	17	81,0	7,84	22,14
FU Month 12	13 - 24 months	21	51,2	15	71,4	22,22	34,88	16	51,6	13	81,3	12,82	21,68
FU Month 15	13 - 24 months	19	46,3	14	73,7	26,19	39,61	16	51,6	8	50,0	4,17	11,79
FU Month 18	13 - 24 months	14	34,1	10	71,4	30,00	39,91	10	32,3	7	70,0	4,76	12,60
FU Month 21	13 - 24 months	11	26,8	7	63,6	33,33	33,33	6	19,4	4	66,7	25,00	31,91
FU Month 24	13 - 24 months	8	19,5	3	37,5	55,56	19,25	3	9,7	3	100,0	22,22	38,49
FU Month 27	13 - 24 months	5	12,2	3	60,0	22,22	19,25	2	6,5	2	100,0	0,00	0,00
FU Month 30	13 - 24 months	3	7,3	2	66,7	16,67	23,57	1	3,2	1	100,0	0,00	NE
Screening	<= 12 months	60	100,0	48	80,0	21,53	31,88	70	100,0	54	77,1	18,52	26,44
Cycle 4 Day 1	<= 12 months	48	80,0	35	72,9	20,00	30,46	60	85,7	43	71,7	20,16	27,35
FU Day 28	<= 12 months	54	90,0	39	72,2	24,79	33,96	62	88,6	47	75,8	19,15	27,58
FU Month 3	<= 12 months	53	88,3	38	71,7	22,81	30,12	59	84,3	43	72,9	17,05	28,52
FU Month 6	<= 12 months	46	76,7	35	76,1	19,05	30,56	47	67,1	32	68,1	18,75	28,00
FU Month 9	<= 12 months	35	58,3	27	77,1	16,05	28,30	37	52,9	26	70,3	12,82	19,04
FU Month 12	<= 12 months	27	45,0	21	77,8	25,40	33,17	29	41,4	24	82,8	15,28	24,04
FU Month 15	<= 12 months	22	36,7	15	68,2	22,22	32,53	17	24,3	15	88,2	17,78	21,33
FU Month 18	<= 12 months	16	26,7	10	62,5	13,33	17,21	13	18,6	11	84,6	15,15	27,34

FU Month 21	<= 12 months	9	15,0	5	55,6	0,00	0,00	7	10,0	5	71,4	20,00	18,26
FU Month 24	<= 12 months	6	10,0	3	50,0	11,11	19,25	2	2,9	0	NE	NE	NE
FU Month 27	<= 12 months	1	1,7			NE	NE	1	1,4			NE	NE
FU Month 30	<= 12 months	1	1,7			NE	NE	0	NE			NE	NE
Screening	>24 months	153	100,0	134	87,6	23,38	30,32	141	100,0	115	81,6	28,99	35,19
Cycle 4 Day 1	>24 months	129	84,3	109	84,5	20,18	27,22	134	95,0	105	78,4	21,90	25,67
FU Day 28	>24 months	137	89,5	115	83,9	18,55	27,99	133	94,3	109	82,0	23,24	29,57
FU Month 3	>24 months	135	88,2	111	82,2	14,11	22,27	132	93,6	105	79,5	21,90	30,95
FU Month 6	>24 months	124	81,0	108	87,1	19,75	29,55	115	81,6	89	77,4	25,84	30,46
FU Month 9	>24 months	96	62,7	76	79,2	17,54	28,01	91	64,5	65	71,4	21,03	30,37
FU Month 12	>24 months	76	49,7	64	84,2	22,40	32,56	72	51,1	53	73,6	28,93	32,05
FU Month 15	>24 months	62	40,5	51	82,3	13,07	22,19	52	36,9	39	75,0	26,50	34,35
FU Month 18	>24 months	48	31,4	41	85,4	24,39	31,64	37	26,2	25	67,6	36,00	38,39
FU Month 21	>24 months	32	20,9	24	75,0	15,28	25,97	27	19,1	19	70,4	33,33	35,14
FU Month 24	>24 months	18	11,8	15	83,3	17,78	21,33	13	9,2	11	84,6	24,24	33,63
FU Month 27	>24 months	7	4,6	5	71,4	6,67	14,91	6	4,3	4	66,7	25,00	31,91
FU Month 30	>24 months	3	2,0	2	66,7	33,33	47,14	0	NE	0	NE	NE	NE
High circulating tumor burden													
Screening	Missing	0	NE	0	NE	NE	NE	2	100,0	1	50,0	0,00	NE
Cycle 4 Day 1	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	0,00	NE
FU Day 28	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	0,00	NE
FU Month 3	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	0,00	NE
FU Month 6	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	0,00	NE
FU Month 9	Missing	0	NE			NE	NE	1	50,0			NE	NE
Screening	<25x10**9 cells/L	60	100,0	50	83,3	26,67	30,86	67	100,0	53	79,1	27,04	33,37
Cycle 4 Day 1	<25x10**9 cells/L	50	83,3	41	82,0	20,33	28,75	61	91,0	43	70,5	25,58	28,95
FU Day 28	<25x10**9 cells/L	56	93,3	43	76,8	26,36	27,75	61	91,0	46	75,4	24,64	30,17
FU Month 3	<25x10**9 cells/L	54	90,0	43	79,6	24,81	27,31	59	88,1	43	72,9	19,38	28,39
FU Month 6	<25x10**9 cells/L	50	83,3	41	82,0	22,76	32,01	51	76,1	38	74,5	20,18	29,55
FU Month 9	<25x10**9 cells/L	36	60,0	23	63,9	14,49	22,08	41	61,2	27	65,9	14,81	28,24
FU Month 12	<25x10**9 cells/L	29	48,3	23	79,3	23,19	29,19	34	50,7	22	64,7	25,76	32,42
FU Month 15	<25x10**9 cells/L	24	40,0	19	79,2	12,28	19,91	23	34,3	12	52,2	22,22	35,77
FU Month 18	<25x10**9 cells/L	20	33,3	17	85,0	19,61	20,61	19	28,4	13	68,4	23,08	36,98
FU Month 21	<25x10**9 cells/L	14	23,3	9	64,3	18,52	29,40	10	14,9	7	70,0	23,81	25,20
FU Month 24	<25x10**9 cells/L	8	13,3	4	50,0	25,00	31,91	6	9,0	5	83,3	20,00	29,81
FU Month 27	<25x10**9 cells/L	4	6,7	2	50,0	16,67	23,57	1	1,5	1	100,0	0,00	NE
FU Month 30	<25x10**9 cells/L	4	6,7	2	50,0	16,67	23,57	1	1,5	1	100,0	0,00	NE
Screening	>=25x10**9 cells/L	195	100,0	163	83,6	22,29	31,22	173	100,0	145	83,8	24,37	32,45

Cycle 4 Day 1	>=25x10**9 cells/L	163	83,6	132	81,0	20,96	29,24	162	93,6	130	80,2	19,74	25,14
FU Day 28	>=25x10**9 cells/L	174	89,2	138	79,3	19,08	30,64	163	94,2	135	82,8	18,77	27,50
FU Month 3	>=25x10**9 cells/L	171	87,7	135	78,9	15,80	26,65	161	93,1	129	80,1	19,38	29,67
FU Month 6	>=25x10**9 cells/L	157	80,5	130	82,8	17,18	28,83	140	80,9	105	75,0	23,49	29,21
FU Month 9	>=25x10**9 cells/L	128	65,6	103	80,5	17,80	30,54	107	61,8	81	75,7	17,70	26,92
FU Month 12	>=25x10**9 cells/L	96	49,2	78	81,3	22,65	33,76	83	48,0	68	81,9	22,06	28,57
FU Month 15	>=25x10**9 cells/L	80	41,0	62	77,5	18,28	29,98	62	35,8	50	80,6	21,33	29,17
FU Month 18	>=25x10**9 cells/L	59	30,3	45	76,3	24,44	34,38	41	23,7	30	73,2	26,67	34,35
FU Month 21	>=25x10**9 cells/L	38	19,5	27	71,1	16,05	26,75	30	17,3	21	70,0	31,75	34,12
FU Month 24	>=25x10**9 cells/L	24	12,3	17	70,8	21,57	23,40	12	6,9	9	75,0	25,93	36,43
FU Month 27	>=25x10**9 cells/L	9	4,6	6	66,7	11,11	17,21	8	4,6	5	62,5	20,00	29,81
FU Month 30	>=25x10**9 cells/L	3	1,5	2	66,7	33,33	47,14	0	NE	0	NE	NE	NE

¹ in study: number of subjects in study at respective visit; % based on baseline

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit

² mean: descriptive statistics - absolute values Clinical

cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/t_pro_mean.sas

Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/output/t_pro_mean_sg_EQCLL16_IT_label_09MAY2013_21004.xls 04MAR2020

17:21

POPULATION: Labelpopulation, Intent-to-Treat Patients
 ENDPOINT: EORTC QoL 16
 MODEL: Unadjusted Analysis
 STUDY: CLL11 (BO21004), Stage 2
 Compliance/Mean

Treatment Side Effects Scale

		GClb (N=255)						RC1b (N=242)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study ¹	%	with value ¹	%	Mean ²	SD(mean)	in study ¹	%	with value ¹	%	Mean ²	SD(mean)
All													
Screening	n/a	255	100,0	216	84,7	18,93	17,15	242	100,0	202	83,5	17,48	15,68
Cycle 4 Day 1	n/a	213	83,5	174	81,7	15,31	15,56	224	92,6	175	78,1	15,25	13,85
FU Day 28	n/a	230	90,2	184	80,0	12,02	12,84	225	93,0	183	81,3	15,13	13,97
FU Month 3	n/a	225	88,2	183	81,3	12,13	14,54	221	91,3	174	78,7	13,49	13,32
FU Month 6	n/a	207	81,2	171	82,6	10,83	12,62	192	79,3	148	77,1	14,56	15,44
FU Month 9	n/a	164	64,3	126	76,8	10,54	10,44	149	61,6	111	74,5	13,36	14,05
FU Month 12	n/a	125	49,0	101	80,8	13,01	13,78	117	48,3	92	78,6	14,34	14,31
FU Month 15	n/a	104	40,8	84	80,8	13,56	12,90	85	35,1	63	74,1	16,14	13,95
FU Month 18	n/a	79	31,0	62	78,5	15,37	16,61	60	24,8	45	75,0	15,06	13,69
FU Month 21	n/a	52	20,4	36	69,2	13,19	12,01	40	16,5	28	70,0	13,69	13,84
FU Month 24	n/a	32	12,5	21	65,6	12,30	10,08	18	7,4	14	77,8	13,49	10,44
FU Month 27	n/a	13	5,1	8	61,5	14,58	10,68	9	3,7	6	66,7	11,11	12,55
FU Month 30	n/a	7	2,7	4	57,1	18,75	10,49	1	0,4	1	100,0	0,00	NE
Gender													
Screening	Female	97	100,0	82	84,5	21,27	19,36	95	100,0	74	77,9	21,88	18,18
Cycle 4 Day 1	Female	84	86,6	67	79,8	15,46	17,70	88	92,6	67	76,1	19,03	14,20
FU Day 28	Female	90	92,8	75	83,3	12,74	13,60	91	95,8	70	76,9	16,71	13,30
FU Month 3	Female	88	90,7	73	83,0	14,50	15,84	87	91,6	63	72,4	17,59	14,90
FU Month 6	Female	84	86,6	64	76,2	10,16	12,90	77	81,1	56	72,7	14,88	16,26
FU Month 9	Female	70	72,2	52	74,3	11,11	10,78	61	64,2	39	63,9	17,31	18,18
FU Month 12	Female	56	57,7	45	80,4	12,96	12,38	47	49,5	34	72,3	16,67	15,21
FU Month 15	Female	47	48,5	37	78,7	15,77	14,40	33	34,7	24	72,7	18,75	16,71
FU Month 18	Female	34	35,1	25	73,5	16,56	15,85	26	27,4	19	73,1	17,98	17,18
FU Month 21	Female	21	21,6	11	52,4	19,70	14,56	17	17,9	12	70,6	18,75	17,81
FU Month 24	Female	12	12,4	6	50,0	16,67	13,94	6	6,3	3	50,0	13,89	12,73
FU Month 27	Female	6	6,2	2	33,3	16,67	0,00	2	2,1	1	50,0	0,00	NE
FU Month 30	Female	4	4,1	1	25,0	8,33	NE	1	1,1	1	100,0	0,00	NE

Screening	Male	158	100,0	134	84,8	17,50	15,54	147	100,0	128	87,1	14,93	13,46								
Cycle 4 Day 1	Male	129	81,6	107	82,9	15,21	14,15	136	92,5	108	79,4	12,91	13,15								
FU Day 28	Male	140	88,6	109	77,9	11,52	12,32	134	91,2	113	84,3	14,16	14,34								
FU Month 3	Male	137	86,7	110	80,3	10,56	13,45	134	91,2	111	82,8	11,16	11,79								
FU Month 6	Male	123	77,8	107	87,0	11,24	12,50	115	78,2		92	80,0	14,37	15,01							
FU Month 9	Male		94	59,5		74	78,7		10,14		10,25		88	59,9		72	81,8		11,23		10,76
FU Month 12	Male		69	43,7		56	81,2		13,05		14,92		70	47,6		58	82,9		12,98		13,70
FU Month 15	Male		57	36,1		47	82,5		11,82		11,43		52	35,4		39	75,0		14,53		11,90
FU Month 18	Male		45	28,5		37	82,2		14,56		17,28		34	23,1		26	76,5		12,93		10,30
FU Month 21	Male		31	19,6		25	80,6		10,33		9,71		23	15,6		16	69,6		9,90		8,72
FU Month 24	Male		20	12,7		15	75,0		10,56		8,01		12	8,2		11	91,7		13,38		10,45
FU Month 27	Male		7	4,4		6	85,7		13,89		12,55		7	4,8		5	71,4		13,33		12,64
FU Month 30	Male		3	1,9		3	100,0		22,22		9,62		0	NE		0	NE		NE		NE
Age																					
Screening	<75 years	130	100,0	102	78,5	18,25	17,58	120	100,0		91	75,8	16,48	15,04							
Cycle 4 Day 1	<75 years	106	81,5		81	76,4	13,17	13,64	112	93,3	82	73,2	14,63	12,67							
FU Day 28	<75 years	119	91,5		91	76,5	10,78	11,85	110	91,7	86	78,2	13,53	12,24							
FU Month 3	<75 years	116	89,2		91	78,4	10,35	12,26	109	90,8	82	75,2	12,40	12,85							
FU Month 6	<75 years	108	83,1		86	79,6	10,01	11,58		99	82,5	71	71,7	12,09	12,89						
FU Month 9	<75 years		85	65,4		66	77,6	10,48	10,67		74	61,7	54	73,0	11,88	13,31					
FU Month 12	<75 years		63	48,5		53	84,1	13,05	14,66		60	50,0	47	78,3	12,94	14,52					
FU Month 15	<75 years		54	41,5		42	77,8	12,30	12,38		44	36,7	32	72,7	14,06	12,78					
FU Month 18	<75 years		43	33,1		34	79,1	12,01	12,34		27	22,5	20	74,1	10,83	11,18					
FU Month 21	<75 years		26	20,0		20	76,9	12,50	11,31		17	14,2	11	64,7	6,82	7,28					
FU Month 24	<75 years		18	13,8		12	66,7	12,50	9,06		6	5,0	4	66,7	8,33	6,80					
FU Month 27	<75 years		7	5,4		4	57,1	16,67	13,61		2	1,7	1	50,0	0,00		NE				
FU Month 30	<75 years		4	3,1		2	50,0	25,00	11,79		0	NE	0	NE		NE	NE				
Age																					
Screening	>=75 years	125	100,0	114	91,2	19,54	16,81	122	100,0	111	91,0	18,29	16,20								
Cycle 4 Day 1	>=75 years	107	85,6		93	86,9	17,17	16,92	112	91,8	93	83,0	15,80	14,86							
FU Day 28	>=75 years	111	88,8		93	83,8	13,23	13,69	115	94,3	97	84,3	16,55	15,27							
FU Month 3	>=75 years	109	87,2		92	84,4	13,89	16,36	112	91,8	92	82,1	14,46	13,73							
FU Month 6	>=75 years		99	79,2		85	85,9	11,67	13,62		93	76,2	77	82,8	16,85	17,24					
FU Month 9	>=75 years		79	63,2		60	75,9	10,60	10,27		75	61,5	57	76,0	14,77	14,69					
FU Month 12	>=75 years		62	49,6		48	77,4	12,96	12,88		57	46,7	45	78,9	15,80	14,10					
FU Month 15	>=75 years		50	40,0		42	84,0	14,81	13,42		41	33,6	31	75,6	18,28	14,97					
FU Month 18	>=75 years		36	28,8		28	77,8	19,44	20,14		33	27,0	25	75,8	18,44	14,76					
FU Month 21	>=75 years		26	20,8		16	61,5	14,06	13,17		23	18,9	17	73,9	18,14	15,38					
FU Month 24	>=75 years		14	11,2		9	64,3	12,04	11,87		12	9,8	10	83,3	15,56	11,20					
FU Month 27	>=75 years		6	4,8		4	66,7	12,50	8,33		7	5,7	5	71,4	13,33	12,64					

FU Month 30	>=75 years	3	2,4	2	66,7	12,50	5,89	1	0,8	1	100,0	0,00	NE
Race													
Screening	Other	9	100,0	6	66,7	20,37	8,55	11	100,0	7	63,6	38,10	21,97
Cycle 4 Day 1	Other	7	77,8	4	57,1	6,25	4,17	10	90,9	6	60,0	23,61	15,29
FU Day 28	Other	8	88,9	5	62,5	13,33	15,14	10	90,9	7	70,0	16,67	8,33
FU Month 3	Other	8	88,9	4	50,0	6,25	4,17	10	90,9	6	60,0	19,44	14,59
FU Month 6	Other	8	88,9	4	50,0	8,33	6,80	8	72,7	6	75,0	9,72	9,74
FU Month 9	Other	4	44,4	3	75,0	13,89	12,73	5	45,5	4	80,0	12,50	15,96
FU Month 12	Other	3	33,3	2	66,7	8,33	11,79	4	36,4	4	100,0	6,25	4,17
FU Month 15	Other	2	22,2	1	50,0	33,33	NE	4	36,4	4	100,0	10,42	10,49
FU Month 18	Other	2	22,2	1	50,0	8,33	NE	2	18,2	2	100,0	4,17	5,89
FU Month 21	Other	2	22,2	1	50,0	8,33	NE	2	18,2	2	100,0	8,33	11,79
FU Month 24	Other	2	22,2	1	50,0	8,33	NE	1	9,1	0	NE	NE	NE
FU Month 27	Other	1	11,1			NE	NE	1	9,1			NE	NE
FU Month 30	Other	1	11,1			NE	NE	0	NE			NE	NE
Screening													
Screening	White	246	100,0	210	85,4	18,89	17,34	231	100,0	195	84,4	16,74	14,96
Cycle 4 Day 1	White	206	83,7	170	82,5	15,52	15,67	214	92,6	169	79,0	14,96	13,75
FU Day 28	White	222	90,2	179	80,6	11,98	12,82	215	93,1	176	81,9	15,07	14,16
FU Month 3	White	217	88,2	179	82,5	12,26	14,66	211	91,3	168	79,6	13,28	13,27
FU Month 6	White	199	80,9	167	83,9	10,89	12,74	184	79,7	142	77,2	14,77	15,63
FU Month 9	White	160	65,0	123	76,9	10,46	10,43	144	62,3	107	74,3	13,40	14,05
FU Month 12	White	122	49,6	99	81,1	13,10	13,85	113	48,9	88	77,9	14,71	14,51
FU Month 15	White	102	41,5	83	81,4	13,32	12,79	81	35,1	59	72,8	16,53	14,14
FU Month 18	White	77	31,3	61	79,2	15,48	16,72	58	25,1	43	74,1	15,57	13,77
FU Month 21	White	50	20,3	35	70,0	13,33	12,16	38	16,5	26	68,4	14,10	14,10
FU Month 24	White	30	12,2	20	66,7	12,50	10,30	17	7,4	14	82,4	13,49	10,44
FU Month 27	White	12	4,9	8	66,7	14,58	10,68	8	3,5	6	75,0	11,11	12,55
FU Month 30	White	6	2,4	4	66,7	18,75	10,49	1	0,4	1	100,0	0,00	NE
Geographical Region													
Screening	Asia-Pacific	20	100,0	19	95,0	17,11	12,50	18	100,0	18	100,0	24,54	21,10
Cycle 4 Day 1	Asia-Pacific	15	75,0	14	93,3	14,88	11,87	16	88,9	15	93,8	18,33	14,84
FU Day 28	Asia-Pacific	18	90,0	18	100,0	14,35	13,65	18	100,0	16	88,9	16,15	13,43
FU Month 3	Asia-Pacific	18	90,0	16	88,9	11,46	14,87	18	100,0	15	83,3	17,22	13,90
FU Month 6	Asia-Pacific	16	80,0	14	87,5	12,30	11,92	17	94,4	14	82,4	15,08	21,09
FU Month 9	Asia-Pacific	14	70,0	12	85,7	10,42	10,13	13	72,2	10	76,9	15,83	16,41
FU Month 12	Asia-Pacific	10	50,0	8	80,0	8,33	7,72	10	55,6	10	100,0	13,33	15,81
FU Month 15	Asia-Pacific	8	40,0	6	75,0	16,67	13,94	9	50,0	9	100,0	15,74	14,70
FU Month 18	Asia-Pacific	6	30,0	4	66,7	4,17	4,81	6	33,3	6	100,0	15,28	14,35

FU Month 21	Asia-Pacific	525,0	360,0	5,56	4,81	422,2	4100,0	10,42	7,98		
FU Month 24	Asia-Pacific	315,0	266,7	4,17	5,89	15,6	0	NE	NE	NE	
FU Month 27	Asia-Pacific	15,0		NE	NE	15,6			NE	NE	
FU Month 30	Asia-Pacific	15,0		NE	NE	0	NE		NE	NE	
Screening	Central and South America	3100,0	3100,0	19,44	4,81	2100,0	2100,0	33,33	0,00		
Cycle 4 Day 1	Central and South America	3100,0	3100,0	8,33	8,33	2100,0	2100,0	20,83	5,89		
FU Day 28	Central and South America	3100,0	3100,0	5,56	4,81	2100,0	2100,0	20,83	5,89		
FU Month 3	Central and South America	3100,0	3100,0	8,33	0,00	2100,0	2100,0	8,33	11,79		
FU Month 6	Central and South America	266,7	2100,0	12,50	5,89	2100,0	2100,0	12,50	5,89		
FU Month 9	Central and South America	266,7	2100,0	8,33	11,79	150,0	1100,0	16,67		NE	
FU Month 12	Central and South America	266,7	2100,0	16,67	0,00	150,0	1100,0	41,67		NE	
FU Month 15	Central and South America	133,3	1100,0	8,33	NE	0	NE	0	NE	NE	NE
FU Month 18	Central and South America	133,3	1100,0	8,33	NE	0	NE	0	NE	NE	NE
FU Month 21	Central and South America	133,3	1100,0	8,33	NE	0	NE	0	NE	NE	NE
FU Month 24	Central and South America	133,3	1100,0	8,33	NE	0	NE	0	NE	NE	NE
Screening	North America	12100,0	12100,0	21,76	14,64	13100,0	1292,3	11,81	11,49		
Cycle 4 Day 1	North America	975,0	9100,0	18,52	18,06	1292,3	12100,0	10,65	12,36		
FU Day 28	North America	1191,7	11100,0	11,36	9,33	13100,0	13100,0	12,82	11,59		
FU Month 3	North America	1191,7	11100,0	19,19	16,27	1292,3	12100,0	8,33	6,15		
FU Month 6	North America	1191,7	1090,9	15,83	12,08	1184,6	11100,0	15,15	11,68		
FU Month 9	North America	866,7	8100,0	19,79	13,32	969,2	9100,0	10,19	10,02		
FU Month 12	North America	866,7	787,5	14,29	9,27	753,8	7100,0	9,52	14,77		
FU Month 15	North America	650,0	6100,0	14,81	11,87	646,2	583,3	21,67	4,56		
FU Month 18	North America	433,3	4100,0	14,58	7,98	323,1	3100,0	11,11	12,73		
FU Month 21	North America	325,0	266,7	8,33	0,00	17,7	1100,0	25,00		NE	
FU Month 24	North America	325,0	266,7	16,67	0,00	17,7	1100,0	33,33		NE	
FU Month 27	North America	216,7	150,0	16,67	NE	17,7	1100,0	25,00		NE	
Screening	Other	45100,0	1737,8	24,67	21,69	44100,0	1636,4	20,31	18,50		
Cycle 4 Day 1	Other	3782,2	1437,8	15,08	12,74	4090,9	1435,0	14,88	14,31		
FU Day 28	Other	3782,2	1437,8	7,14	9,16	3988,6	1435,9	14,29	13,25		
FU Month 3	Other	3884,4	1539,5	6,67	6,45	3886,4	1436,8	14,88	19,11		
FU Month 6	Other	3577,8	1542,9	5,00	6,90	3375,0	1133,3	12,12	13,62		
FU Month 9	Other	2657,8	1246,2	8,33	10,05	2454,5	833,3	17,71	20,62		
FU Month 12	Other	1737,8	847,1	12,50	22,71	1636,4	637,5	13,89	10,09		
FU Month 15	Other	1226,7	433,3	6,25	4,17	920,5	333,3	19,44	12,73		
FU Month 18	Other	1022,2	330,0	11,11	12,73	715,9	228,6	12,50	5,89		
FU Month 21	Other	715,6	228,6	8,33	0,00	49,1	0	NE	NE	NE	
FU Month 24	Other	613,3	116,7	16,67	NE	36,8	0	NE	NE	NE	
FU Month 27	Other	48,9	125,0	16,67	NE	12,3	0	NE	NE	NE	

FU Month 30	Other	2	4,4				NE	NE	0	NE			NE	NE
Screening	Western Europe	175	100,0	165	94,3	18,33	17,41	165	100,0	154	93,3	16,59	14,74	
Cycle 4 Day 1	Western Europe	149	85,1	134	89,9	15,32	16,22	154	93,3	132	85,7	15,28	13,94	
FU Day 28	Western Europe	161	92,0	138	85,7	12,40	13,35	153	92,7	138	90,2	15,24	14,48	
FU Month 3	Western Europe	155	88,6	138	89,0	12,32	15,01	151	91,5	131	86,8	13,46	13,04	
FU Month 6	Western Europe	143	81,7	130	90,9	10,94	13,19	129	78,2	110	85,3	14,72	15,42	
FU Month 9	Western Europe	114	65,1	92	80,7	10,08	10,08	102	61,8	83	81,4	12,95	13,60	
FU Month 12	Western Europe	88	50,3	76	86,4	13,34	13,77	83	50,3	68	81,9	14,62	14,27	
FU Month 15	Western Europe	77	44,0	67	87,0	13,68	13,35	61	37,0	46	75,4	15,40	14,70	
FU Month 18	Western Europe	58	33,1	50	86,2	16,72	17,81	44	26,7	34	77,3	15,52	14,35	
FU Month 21	Western Europe	36	20,6	28	77,8	14,88	13,10	31	18,8	23	74,2	13,77	14,78	
FU Month 24	Western Europe	19	10,9	15	78,9	12,78	11,30	13	7,9	13	100,0	11,97	9,10	
FU Month 27	Western Europe	6	3,4	6	100,0	13,89	12,55	6	3,6	5	83,3	8,33	11,79	
FU Month 30	Western Europe	4	2,3	4	100,0	18,75	10,49	1	0,6	1	100,0	0,00		NE
FCgamma receptor IIa														
Screening	131HH	58	100,0	46	79,3	19,20	19,40	76	100,0	60	78,9	15,79	12,50	
Cycle 4 Day 1	131HH	49	84,5	35	71,4	15,95	18,01	65	85,5	48	73,8	15,63	12,35	
FU Day 28	131HH	51	87,9	38	74,5	14,62	16,30	70	92,1	51	72,9	12,58	11,23	
FU Month 3	131HH	51	87,9	40	78,4	14,17	16,26	64	84,2	45	70,3	14,26	12,26	
FU Month 6	131HH	49	84,5	39	79,6	10,97	13,83	55	72,4	40	72,7	13,40	12,18	
FU Month 9	131HH	39	67,2	25	64,1	13,00	9,03	41	53,9	31	75,6	13,71	16,60	
FU Month 12	131HH	28	48,3	21	75,0	18,92	14,82	34	44,7	28	82,4	12,00	14,58	
FU Month 15	131HH	23	39,7	17	73,9	16,18	16,26	24	31,6	19	79,2	13,16	10,14	
FU Month 18	131HH	17	29,3	12	70,6	20,60	25,05	16	21,1	12	75,0	20,14	17,21	
FU Month 21	131HH	13	22,4	8	61,5	16,67	17,25	11	14,5	9	81,8	23,15	15,47	
FU Month 24	131HH	11	19,0	7	63,6	14,29	11,50	1	1,3	1	100,0	8,33		NE
FU Month 27	131HH	4	6,9	3	75,0	16,67	16,67	1	1,3	1	100,0	25,00		NE
FU Month 30	131HH	3	5,2	2	66,7	12,50	5,89	0	NE	0	NE	NE		NE
Screening	131HR	125	100,0	108	86,4	18,70	16,39	114	100,0	101	88,6	17,66	16,43	
Cycle 4 Day 1	131HR	105	84,0	89	84,8	15,70	16,48	110	96,5	93	84,5	15,62	15,78	
FU Day 28	131HR	116	92,8	97	83,6	12,34	12,61	105	92,1	92	87,6	16,52	16,39	
FU Month 3	131HR	114	91,2	95	83,3	11,78	15,12	107	93,9	89	83,2	13,92	14,89	
FU Month 6	131HR	104	83,2	86	82,7	10,08	11,44	95	83,3	77	81,1	16,49	18,46	
FU Month 9	131HR	84	67,2	66	78,6	10,27	10,82	76	66,7	58	76,3	13,36	14,30	
FU Month 12	131HR	64	51,2	54	84,4	12,81	14,72	57	50,0	46	80,7	16,12	15,36	
FU Month 15	131HR	53	42,4	42	79,2	13,03	11,60	44	38,6	32	72,7	17,71	16,63	
FU Month 18	131HR	43	34,4	34	79,1	14,87	14,23	32	28,1	25	78,1	13,44	13,14	
FU Month 21	131HR	26	20,8	17	65,4	10,78	11,32	21	18,4	15	71,4	8,89	9,69	
FU Month 24	131HR	12	9,6	8	66,7	11,46	7,63	12	10,5	10	83,3	15,56	11,20	

FU Month 27	131HR	64,8	350,0	16,67	0,00	65,3	466,7	10,42	12,50		
FU Month 30	131HR	32,4	133,3	33,33	NE	10,9	1100,0	0,00	NE		
Screening	131RR	49100,0	4183,7	22,22	18,79	33100,0	2884,8	17,56	16,41		
Cycle 4 Day 1	131RR	4081,6	3382,5	14,23	11,64	3193,9	2477,4	11,46	9,46		
FU Day 28	131RR	4285,7	3173,8	9,77	10,56	3297,0	2887,5	13,39	9,44		
FU Month 3	131RR	3979,6	3179,5	12,37	13,07	3297,0	2887,5	10,12	8,89		
FU Month 6	131RR	3571,4	2982,9	14,08	15,76	2781,8	2281,5	11,36	10,14		
FU Month 9	131RR	2449,0	2083,3	11,25	11,56	1957,6	1684,2	13,54	9,07		
FU Month 12	131RR	1836,7	1583,3	9,44	8,83	1751,5	1482,4	13,69	10,13		
FU Month 15	131RR	1632,7	1487,5	12,50	12,12	1133,3	981,8	17,59	12,80		
FU Month 18	131RR	1428,6	1285,7	12,50	15,28	824,2	787,5	13,10	8,13		
FU Month 21	131RR	816,3	675,0	16,67	7,45	515,2	480,0	10,42	15,77		
FU Month 24	131RR	510,2	360,0	13,89	17,35	391,1	3100,0	8,33	8,33		
FU Month 27	131RR	24,1	150,0	0,00	NE	13,0	1100,0	0,00	NE		
FU Month 30	131RR	12,0	1100,0	16,67	NE	0	NE	NE	NE		
Screening	Missing	23100,0	2191,3	13,10	10,55	19100,0	1368,4	23,72	20,93		
Cycle 4 Day 1	Missing	1982,6	1789,5	14,05	12,63	1894,7	1055,6	19,17	8,83		
FU Day 28	Missing	2191,3	1885,7	8,64	8,02	1894,7	1266,7	19,44	11,96		
FU Month 3	Missing	2191,3	1781,0	8,82	8,57	1894,7	1266,7	15,28	13,69		
FU Month 6	Missing	1982,6	1789,5	8,82	9,07	1578,9	960,0	11,11	8,33		
FU Month 9	Missing	1773,9	1588,2	6,67	9,02	1368,4	646,2	11,11	10,09		
FU Month 12	Missing	1565,2	1173,3	7,58	8,70	947,4	444,4	12,50	14,43		
FU Month 15	Missing	1252,2	1191,7	12,88	14,12	631,6	350,0	13,89	4,81		
FU Month 18	Missing	521,7	480,0	12,50	8,33	421,1	125,0	8,33	NE		
FU Month 21	Missing	521,7	5100,0	11,67	9,50	315,8	0	NE	NE		
FU Month 24	Missing	417,4	375,0	8,33	8,33	210,5	0	NE	NE		
FU Month 27	Missing	14,3	1100,0	16,67	NE	15,3	0	NE	NE		
FCgamma receptor IIIa											
Screening	158FF	103	100,0	9289,3	18,03	15,30	83100,0	7286,7	17,55	16,59	
Cycle 4 Day 1	158FF	8986,4	7483,1	14,45	13,65	7894,0	6482,1	14,19	14,37		
FU Day 28	158FF	9693,2	7881,3	9,83	11,14	7894,0	6785,9	14,18	14,21		
FU Month 3	158FF	9491,3	7680,9	11,07	13,50	7894,0	6583,3	11,92	12,67		
FU Month 6	158FF	8683,5	6980,2	10,14	12,69	6477,1	5382,8	13,68	14,44		
FU Month 9	158FF	7168,9	5678,9	9,42	10,55	4756,6	4187,2	12,80	13,71		
FU Month 12	158FF	4846,6	4185,4	10,37	11,30	3845,8	3489,5	11,27	10,44		
FU Month 15	158FF	3735,9	3183,8	12,10	13,92	3036,1	2376,7	15,22	13,21		
FU Month 18	158FF	2726,2	2281,5	12,50	13,79	2125,3	1781,0	13,24	16,15		
FU Month 21	158FF	1615,5	1593,8	12,22	11,73	910,8	888,9	8,33	17,82		
FU Month 24	158FF	87,8	787,5	9,52	10,12	33,6	3100,0	2,78	4,81		

FU Month 27	158FF		54,9		480,0	8,33	9,62		1	1,2		1	100,0	0,00		NE
FU Month 30	158FF		32,9		3100,0	22,22	9,62		0	NE		0	NE		NE	NE
Screening	158FV	119	100,0		9882,4	19,90	19,42		109	100,0		90	82,6	16,88	15,85	
Cycle 4 Day 1	158FV		9983,2		8080,8	15,69	17,92		100	91,7		77	77,0	15,69	13,24	
FU Day 28	158FV	105	88,2		8379,0	14,12	14,47		101	92,7		81	80,2	15,47	14,20	
FU Month 3	158FV	101	84,9		8483,2	13,62	16,31		97	89,0		75	77,3	12,78	14,58	
FU Month 6	158FV		9479,0		8085,1	11,49	13,23		83	76,1		64	77,1	12,85	16,16	
FU Month 9	158FV		7159,7		5374,6	12,26	10,79		65	59,6		46	70,8	13,04	14,02	
FU Month 12	158FV		6050,4		5083,3	14,94	15,28		52	47,7		41	78,8	15,92	17,63	
FU Month 15	158FV		5243,7		4178,8	13,96	12,08		36	33,0		29	80,6	18,10	15,76	
FU Month 18	158FV		4437,0		3477,3	18,22	18,62		24	22,0		20	83,3	17,50	13,76	
FU Month 21	158FV		2823,5		1450,0	13,69	13,32		18	16,5		14	77,8	16,67	13,48	
FU Month 24	158FV		1815,1		950,0	15,74	11,37		6	5,5		5	83,3	18,33	6,97	
FU Month 27	158FV		65,0		233,3	16,67	0,00		2	1,8		1	50,0	16,67		NE
FU Month 30	158FV		43,4		125,0	8,33		NE	0	NE		0	NE		NE	NE
Screening	158VV		16100,0		1275,0	21,53	17,93		33	100,0		29	87,9	18,58	13,45	
Cycle 4 Day 1	158VV		1275,0		975,0	13,89	12,50		30	90,9		26	86,7	16,77	16,11	
FU Day 28	158VV		1487,5		1178,6	14,39	12,96		30	90,9		26	86,7	15,71	13,40	
FU Month 3	158VV		1593,8		1066,7	9,17	12,70		30	90,9		24	80,0	17,94	10,26	
FU Month 6	158VV		1487,5		1178,6	12,12	12,00		30	90,9		22	73,3	20,83	14,26	
FU Month 9	158VV		1275,0		975,0	12,96	8,45		25	75,8		19	76,0	15,35	16,73	
FU Month 12	158VV		850,0		562,5	18,33	18,07		20	60,6		16	80,0	15,63	10,92	
FU Month 15	158VV		850,0		675,0	16,67	12,91		14	42,4		10	71,4	12,50	10,58	
FU Month 18	158VV		425,0		375,0	11,11	19,25		11	33,3		8	72,7	12,85	6,11	
FU Month 21	158VV		318,8		266,7	20,83	17,68		9	27,3		6	66,7	13,89	6,80	
FU Month 24	158VV		212,5		2100,0	12,50	5,89		7	21,2		6	85,7	14,81	11,87	
FU Month 27	158VV		16,3		1100,0	33,33		NE	5	15,2		4	80,0	12,50	14,43	
FU Month 30	158VV		0	NE	0	NE		NE	1	3,0		1	100,0	0,00		NE
Screening	Missing	17	100,0		1482,4	15,87	10,42		17	100,0		11	64,7	18,94	15,41	
Cycle 4 Day 1	Missing	13	76,5		1184,6	19,44	11,85		16	94,1		8	50,0	14,58	7,39	
FU Day 28	Missing	15	88,2		1280,0	9,49	8,90		16	94,1		9	56,3	17,59	13,47	
FU Month 3	Missing	15	88,2		1386,7	10,90	8,60		16	94,1		10	62,5	18,33	12,30	
FU Month 6	Missing	13	76,5		1184,6	9,09	8,70		15	88,2		9	60,0	16,67	17,18	
FU Month 9	Missing	10	58,8		880,0	4,17	6,30		12	70,6		5	41,7	13,33	7,45	
FU Month 12	Missing		952,9		555,6	10,00	10,87		7	41,2		1	14,3	33,33		NE
FU Month 15	Missing		741,2		685,7	15,28	15,29		5	29,4		1	20,0	16,67		NE
FU Month 18	Missing		423,5		375,0	8,33	0,00		4	23,5		0	NE			NE
FU Month 21	Missing		529,4		5100,0	11,67	9,50		4	23,5		0	NE			NE
FU Month 24	Missing		423,5		375,0	8,33	8,33		2	11,8		0	NE			NE

FU Month 27	Missing		15,9	1100,0	16,67	NE	15,9	0	NE	NE	NE		
Binet Staging at baseline													
Screening	A	59	100,0	56	94,9	17,31	17,73	57	100,0	47	82,5	18,20	17,27
Cycle 4 Day 1	A	51	86,4	45	88,2	16,48	18,68	54	94,7	45	83,3	14,32	14,70
FU Day 28	A	58	98,3	51	87,9	13,40	15,28	54	94,7	45	83,3	14,94	14,35
FU Month 3	A	57	96,6	54	94,7	13,63	16,23	53	93,0	44	83,0	14,02	14,90
FU Month 6	A	56	94,9	47	83,9	10,34	11,58	45	78,9	36	80,0	16,90	18,63
FU Month 9	A	43	72,9	35	81,4	10,24	11,09	34	59,6	26	76,5	10,90	15,59
FU Month 12	A	36	61,0	32	88,9	13,02	12,86	24	42,1	18	75,0	15,28	14,08
FU Month 15	A	30	50,8	25	83,3	11,56	11,42	19	33,3	17	89,5	17,16	17,30
FU Month 18	A	22	37,3	15	68,2	10,37	15,30	16	28,1	14	87,5	18,65	11,71
FU Month 21	A	17	28,8	13	76,5	11,54	12,97	8	14,0	5	62,5	18,33	12,36
FU Month 24	A	10	16,9	6	60,0	8,33	12,91	5	8,8	4	80,0	18,06	7,35
FU Month 27	A	5	8,5	3	60,0	11,11	9,62	2	3,5	1	50,0	25,00	NE
FU Month 30	A	4	6,8	3	75,0	19,44	12,73	0	NE	0	NE	NE	NE
Screening	B	104	100,0	84	80,8	21,23	18,83	85	100,0	70	82,4	16,39	13,44
Cycle 4 Day 1	B	88	84,6	72	81,8	12,85	13,21	79	92,9	63	79,7	14,02	11,77
FU Day 28	B	91	87,5	70	76,9	11,31	12,13	79	92,9	63	79,7	13,45	12,52
FU Month 3	B	88	84,6	66	75,0	10,35	11,79	79	92,9	62	78,5	13,84	13,15
FU Month 6	B	80	76,9	68	85,0	11,40	13,27	70	82,4	52	74,3	15,22	12,65
FU Month 9	B	63	60,6	48	76,2	10,76	11,14	59	69,4	44	74,6	14,20	13,40
FU Month 12	B	47	45,2	35	74,5	14,44	15,87	46	54,1	37	80,4	14,71	14,73
FU Month 15	B	37	35,6	31	83,8	13,71	14,20	34	40,0	25	73,5	15,33	10,94
FU Month 18	B	31	29,8	26	83,9	18,48	19,36	22	25,9	17	77,3	13,24	11,81
FU Month 21	B	18	17,3	12	66,7	17,36	13,04	17	20,0	13	76,5	9,62	11,71
FU Month 24	B	11	10,6	8	72,7	13,54	9,90	8	9,4	7	87,5	14,29	12,47
FU Month 27	B	5	4,8	3	60,0	16,67	16,67	4	4,7	4	100,0	10,42	12,50
FU Month 30	B	2	1,9	1	50,0	16,67	NE	0	NE	0	NE	NE	NE
Screening	C	92	100,0	76	82,6	17,58	14,50	100	100,0	85	85,0	17,97	16,59
Cycle 4 Day 1	C	74	80,4	57	77,0	17,50	15,47	91	91,0	67	73,6	17,04	15,04
FU Day 28	C	81	88,0	63	77,8	11,68	11,49	92	92,0	75	81,5	16,67	14,88
FU Month 3	C	80	87,0	63	78,8	12,70	15,62	89	89,0	68	76,4	12,83	12,55
FU Month 6	C	71	77,2	56	78,9	10,57	12,86	60	77,9	47	77,9	12,59	15,57
FU Month 9	C	58	63,0	43	74,1	10,53	9,28	56	56,0	41	73,2	14,02	13,87
FU Month 12	C	42	45,7	34	81,0	11,52	12,48	47	47,0	37	78,7	13,51	14,35
FU Month 15	C	37	40,2	28	75,7	15,18	12,84	32	32,0	21	65,6	16,27	14,78
FU Month 18	C	26	28,3	21	80,8	15,08	13,34	22	22,0	14	63,6	13,69	17,48
FU Month 21	C	17	18,5	11	64,7	10,61	9,20	15	15,0	10	66,7	16,67	16,67
FU Month 24	C	11	12,0	7	63,6	14,29	7,93	5	5,0	3	60,0	5,56	4,81

FU Month 27	C		33,3		266,7	16,67	0,00		33,0		133,3	0,00		NE
FU Month 30	C		11,1		0	NE	NE	NE	11,0		1100,0	0,00		NE
Total CIR score at baseline														
Screening	<=6		63100,0		5384,1	17,61	17,01		75100,0		6282,7	19,44		18,77
Cycle 4 Day 1	<=6		5282,5		3873,1	13,60	13,20		7296,0		5373,6	12,74		13,34
FU Day 28	<=6		5688,9		4580,4	13,77	12,81		7296,0		5373,6	12,89		13,92
FU Month 3	<=6		5587,3		4276,4	11,11	14,10		6992,0		4971,0	10,20		12,06
FU Month 6	<=6		5282,5		4382,7	11,56	14,28		6080,0		4575,0	14,14		16,60
FU Month 9	<=6		4368,3		3376,7	7,83	9,30		4762,7		3574,5	12,38		12,36
FU Month 12	<=6		3555,6		2880,0	13,29	17,06		3445,3		2779,4	12,14		13,52
FU Month 15	<=6		3250,8		2887,5	11,61	12,07		2533,3		1664,0	10,42		9,38
FU Month 18	<=6		2336,5		2087,0	16,11	20,68		1925,3		1473,7	13,89		18,33
FU Month 21	<=6		1422,2		857,1	7,29	9,38		1418,7		1071,4	14,17		16,69
FU Month 24	<=6		812,7		787,5	14,29	11,50		79,3		685,7	10,65		9,37
FU Month 27	<=6		23,2		2100,0	16,67	0,00		45,3		250,0	8,33		11,79
FU Month 30	<=6		0	NE	0	NE	NE	NE	11,3		1100,0	0,00		NE
Screening >6														
Screening	>6		192100,0		16384,9	19,36	17,22		167100,0		14083,8	16,61		14,08
Cycle 4 Day 1	>6		16183,9		13684,5	15,79	16,17		15291,0		12280,3	16,35		13,97
FU Day 28	>6		17490,6		13979,9	11,45	12,84		15391,6		13085,0	16,05		13,94
FU Month 3	>6		17088,5		14182,9	12,43	14,70		15291,0		12582,2	14,78		13,62
FU Month 6	>6		15580,7		12882,6	10,59	12,07		13279,0		10378,0	14,75		14,99
FU Month 9	>6		12163,0		9376,9	11,50	10,70		10261,1		7674,5	13,82		14,82
FU Month 12	>6		9046,9		7381,1	12,90	12,43		8349,7		6578,3	15,26		14,63
FU Month 15	>6		7237,5		5677,8	14,53	13,28		6035,9		4778,3	18,09		14,78
FU Month 18	>6		5629,2		4275,0	15,01	14,56		4124,6		3175,6	15,59		11,33
FU Month 21	>6		3819,8		2873,7	14,88	12,29		2615,6		1869,2	13,43		12,50
FU Month 24	>6		2412,5		1458,3	11,31	9,59		116,6		872,7	15,63		11,30
FU Month 27	>6		115,7		654,5	13,89	12,55		53,0		480,0	12,50		14,43
FU Month 30	>6		73,6		457,1	18,75	10,49		0	NE	0	NE	NE	NE
Calculated creatinine clearance cat. 2														
Screening	<70 ml/min		178100,0		15184,8	19,17	17,09		176100,0		14884,1	18,37		15,97
Cycle 4 Day 1	<70 ml/min		14983,7		12080,5	15,65	16,00		16493,2		12878,0	14,67		12,09
FU Day 28	<70 ml/min		16291,0		13281,5	11,72	12,60		16694,3		13279,5	14,88		13,84
FU Month 3	<70 ml/min		15788,2		12982,2	12,49	15,78		15990,3		12377,4	14,07		13,36
FU Month 6	<70 ml/min		14480,9		12184,0	10,70	12,97		13979,0		10676,3	13,89		15,82
FU Month 9	<70 ml/min		11765,7		8875,2	9,97	10,33		11263,6		8273,2	13,72		14,37
FU Month 12	<70 ml/min		9251,7		7379,3	12,63	12,98		8749,4		6878,2	14,99		14,99
FU Month 15	<70 ml/min		7843,8		6583,3	14,06	13,38		6034,1		4371,7	15,50		13,56

FU Month 18	<70 ml/min	59	33,1	47	79,7	16,55	17,76	43	24,4	32	74,4	15,45	15,10
FU Month 21	<70 ml/min	38	21,3	24	63,2	10,76	11,91	31	17,6	23	74,2	13,77	14,99
FU Month 24	<70 ml/min	24	13,5	16	66,7	13,54	10,92	13	7,4	9	69,2	12,65	12,28
FU Month 27	<70 ml/min	10	5,6	5	50,0	13,33	7,45	7	4,0	4	57,1	12,50	14,43
FU Month 30	<70 ml/min	5	2,8	2	40,0	12,50	5,89	1	0,6	1	100,0	0,00	NE
Screening	>=70 ml/min	77	100,0	65	84,4	18,38	17,41	66	100,0	54	81,8	15,02	14,72
Cycle 4 Day 1	>=70 ml/min	64	83,1	54	84,4	14,56	14,68	60	90,9	47	78,3	16,84	17,85
FU Day 28	>=70 ml/min	68	88,3	52	76,5	12,77	13,51	59	89,4	51	86,4	15,80	14,43
FU Month 3	>=70 ml/min	68	88,3	54	79,4	11,27	11,12	62	93,9	51	82,3	12,09	13,26
FU Month 6	>=70 ml/min	63	81,8	50	79,4	11,17	11,86	53	80,3	42	79,2	16,27	14,49
FU Month 9	>=70 ml/min	47	61,0	38	80,9	11,84	10,72	37	56,1	29	78,4	12,36	13,29
FU Month 12	>=70 ml/min	33	42,9	28	84,8	13,99	15,88	30	45,5	24	80,0	12,50	12,29
FU Month 15	>=70 ml/min	26	33,8	19	73,1	11,84	11,22	25	37,9	20	80,0	17,50	15,03
FU Month 18	>=70 ml/min	20	26,0	15	75,0	11,67	12,12	17	25,8	13	76,5	14,10	9,85
FU Month 21	>=70 ml/min	14	18,2	12	85,7	18,06	11,14	9	13,6	5	55,6	13,33	7,45
FU Month 24	>=70 ml/min	8	10,4	5	62,5	8,33	5,89	5	7,6	5	100,0	15,00	6,97
FU Month 27	>=70 ml/min	3	3,9	3	100,0	16,67	16,67	2	3,0	2	100,0	8,33	11,79
FU Month 30	>=70 ml/min	2	2,6	2	100,0	25,00	11,79	0	NE	0	NE	NE	NE
Beta2 microglobulin													
Screening	Missing	3	100,0	3	100,0	16,67	8,33	3	100,0	2	66,7	33,33	11,79
Cycle 4 Day 1	Missing	3	100,0	3	100,0	11,11	4,81	3	100,0	1	33,3	16,67	NE
FU Day 28	Missing	3	100,0	3	100,0	13,89	12,73	3	100,0	1	33,3	0,00	NE
FU Month 3	Missing	3	100,0	3	100,0	8,33	8,33	3	100,0	1	33,3	16,67	NE
FU Month 6	Missing	3	100,0	3	100,0	8,33	14,43	3	100,0	1	33,3	8,33	NE
FU Month 9	Missing	2	66,7	1	50,0	16,67	NE	3	100,0	1	33,3	25,00	NE
FU Month 12	Missing	1	33,3	1	100,0	0,00	NE	2	66,7	0	NE	NE	NE
FU Month 15	Missing	1	33,3	1	100,0	0,00	NE	2	66,7	0	NE	NE	NE
FU Month 18	Missing	1	33,3	1	100,0	0,00	NE	2	66,7	0	NE	NE	NE
FU Month 21	Missing	1	33,3	1	100,0	8,33	NE	2	66,7	0	NE	NE	NE
FU Month 24	Missing	1	33,3	1	100,0	16,67	NE	1	33,3	0	NE	NE	NE
Screening	< 3.5 ug/mL	154	100,0	134	87,0	18,68	17,23	140	100,0	119	85,0	16,43	15,20
Cycle 4 Day 1	< 3.5 ug/mL	127	82,5	108	85,0	15,56	16,90	129	92,1	101	78,3	16,94	15,42
FU Day 28	< 3.5 ug/mL	137	89,0	116	84,7	12,33	12,73	132	94,3	109	82,6	14,78	12,81
FU Month 3	< 3.5 ug/mL	134	87,0	117	87,3	13,56	14,47	130	92,9	103	79,2	12,68	11,52
FU Month 6	< 3.5 ug/mL	128	83,1	108	84,4	11,93	13,23	120	85,7	98	81,7	14,40	13,46
FU Month 9	< 3.5 ug/mL	104	67,5	82	78,8	11,31	10,82	98	70,0	76	77,6	13,93	13,90
FU Month 12	< 3.5 ug/mL	78	50,6	66	84,6	14,35	14,75	75	53,6	62	82,7	15,64	14,73
FU Month 15	< 3.5 ug/mL	65	42,2	54	83,1	16,00	13,69	60	42,9	47	78,3	16,67	12,77
FU Month 18	< 3.5 ug/mL	46	29,9	37	80,4	15,84	18,61	43	30,7	33	76,7	15,74	14,21

FU Month 21	< 3.5 ug/mL	30	19,5	20	66,7	15,83	13,22	27	19,3	20	74,1	13,33	14,66
FU Month 24	< 3.5 ug/mL	19	12,3	14	73,7	10,71	9,49	12	8,6	10	83,3	12,22	8,61
FU Month 27	< 3.5 ug/mL	10	6,5	7	70,0	16,67	9,62	7	5,0	4	57,1	10,42	12,50
FU Month 30	< 3.5 ug/mL	5	3,2	3	60,0	19,44	12,73	1	0,7	1	100,0	0,00	NE
Screening	>= 3.5 ug/mL	98	100,0	79	80,6	19,44	17,38	99	100,0	81	81,8	18,62	16,31
Cycle 4 Day 1	>= 3.5 ug/mL	83	84,7	63	75,9	15,08	13,46	92	92,9	73	79,3	12,90	11,11
FU Day 28	>= 3.5 ug/mL	90	91,8	65	72,2	11,37	13,20	90	90,9	73	81,1	15,87	15,60
FU Month 3	>= 3.5 ug/mL	88	89,8	63	71,6	9,66	14,68	88	88,9	70	79,5	14,64	15,70
FU Month 6	>= 3.5 ug/mL	76	77,6	60	78,9	8,98	11,35	69	69,7	49	71,0	15,02	19,05
FU Month 9	>= 3.5 ug/mL	58	59,2	43	74,1	8,91	9,69	48	48,5	34	70,8	11,76	14,52
FU Month 12	>= 3.5 ug/mL	46	46,9	34	73,9	10,78	11,52	40	40,4	30	75,0	11,67	13,24
FU Month 15	>= 3.5 ug/mL	38	38,8	29	76,3	9,48	10,14	23	23,2	16	69,6	14,58	17,35
FU Month 18	>= 3.5 ug/mL	32	32,7	24	75,0	15,28	13,38	15	15,2	12	80,0	13,19	12,54
FU Month 21	>= 3.5 ug/mL	21	21,4	15	71,4	10,00	10,06	11	11,1	8	72,7	14,58	12,40
FU Month 24	>= 3.5 ug/mL	12	12,2	6	50,0	15,28	12,27	5	5,1	4	80,0	16,67	15,21
FU Month 27	>= 3.5 ug/mL	3	3,1	1	33,3	0,00	NE	2	2,0	2	100,0	12,50	17,68
FU Month 30	>= 3.5 ug/mL	2	2,0	1	50,0	16,67	NE	0	NE	0	NE	NE	NE
Immunoglobulin VH, cytogenetics 2													
Screening	12	45	100,0	39	86,7	19,23	17,10	44	100,0	40	90,9	18,82	17,80
Cycle 4 Day 1	12	34	75,6	29	85,3	15,71	16,97	38	86,4	30	78,9	18,33	16,44
FU Day 28	12	39	86,7	35	89,7	15,63	16,80	40	90,9	35	87,5	16,83	16,69
FU Month 3	12	38	84,4	34	89,5	12,01	14,82	39	88,6	30	76,9	13,06	14,46
FU Month 6	12	36	80,0	30	83,3	9,72	8,78	34	77,3	27	79,4	18,11	20,11
FU Month 9	12	26	57,8	21	80,8	9,13	9,83	28	63,6	17	60,7	13,73	12,48
FU Month 12	12	22	48,9	17	77,3	13,73	12,13	23	52,3	14	60,9	14,88	9,90
FU Month 15	12	17	37,8	13	76,5	16,03	11,00	17	38,6	11	64,7	18,94	15,41
FU Month 18	12	15	33,3	11	73,3	15,91	12,05	13	29,5	8	61,5	13,54	7,63
FU Month 21	12	10	22,2	7	70,0	20,24	17,25	7	15,9	4	57,1	4,17	4,81
FU Month 24	12	8	17,8	5	62,5	15,00	13,69	6	13,6	5	83,3	13,33	11,18
FU Month 27	12	5	11,1	3	60,0	16,67	16,67	2	4,5	2	100,0	0,00	0,00
FU Month 30	12	4	8,9	2	50,0	12,50	5,89	1	2,3	1	100,0	0,00	NE
Screening	11q-	46	100,0	35	76,1	16,03	14,05	43	100,0	36	83,7	17,28	14,79
Cycle 4 Day 1	11q-	40	87,0	33	82,5	14,39	15,21	41	95,3	32	78,0	14,06	13,12
FU Day 28	11q-	42	91,3	29	69,0	11,30	12,64	39	90,7	32	82,1	17,10	10,52
FU Month 3	11q-	42	91,3	32	76,2	11,20	14,60	38	88,4	34	89,5	13,97	10,99
FU Month 6	11q-	38	82,6	31	81,6	12,63	15,19	32	74,4	26	81,3	14,42	11,92
FU Month 9	11q-	28	60,9	24	85,7	8,33	10,43	25	58,1	20	80,0	13,33	15,39
FU Month 12	11q-	20	43,5	17	85,0	11,76	16,68	18	41,9	16	88,9	15,10	17,27

FU Month 15	11q-	18	39,1	15	83,3	7,22	8,83	14	32,6	9	64,3	17,59	12,80
FU Month 18	11q-	15	32,6	11	73,3	8,33	11,18	8	18,6	6	75,0	12,50	12,64
FU Month 21	11q-	12	26,1	10	83,3	8,33	8,78	4	9,3	1	25,0	25,00	NE
FU Month 24	11q-	7	15,2	4	57,1	6,25	7,98	1	2,3	1	100,0	16,67	NE
FU Month 27	11q-	3	6,5	2	66,7	8,33	11,79	0	NE	0	NE	NE	NE
FU Month 30	11q-	3	6,5	2	66,7	25,00	11,79	0	NE	0	NE	NE	NE
Screening	13q-	79	100,0	68	86,1	16,91	15,99	75	100,0	57	76,0	17,06	15,52
Cycle 4 Day 1	13q-	67	84,8	51	76,1	15,85	15,39	68	90,7	50	73,5	15,39	13,69
FU Day 28	13q-	72	91,1	58	80,6	9,82	10,01	72	96,0	54	75,0	15,28	14,27
FU Month 3	13q-	73	92,4	60	82,2	14,07	17,20	69	92,0	49	71,0	14,46	14,71
FU Month 6	13q-	67	84,8	55	82,1	9,04	11,08	63	84,0	44	69,8	11,55	13,83
FU Month 9	13q-	56	70,9	44	78,6	13,13	11,12	52	69,3	38	73,1	13,82	16,81
FU Month 12	13q-	44	55,7	37	84,1	13,21	13,99	40	53,3	34	85,0	15,44	15,37
FU Month 15	13q-	38	48,1	32	84,2	14,76	13,62	29	38,7	23	79,3	15,22	15,42
FU Month 18	13q-	28	35,4	23	82,1	16,55	20,73	21	28,0	17	81,0	16,83	17,11
FU Month 21	13q-	16	20,3	12	75,0	15,28	11,14	16	21,3	12	75,0	13,89	14,79
FU Month 24	13q-	7	8,9	5	71,4	11,67	7,45	7	9,3	4	57,1	15,97	14,76
FU Month 27	13q-	2	2,5	1	50,0	16,67	NE	6	8,0	3	50,0	16,67	14,43
Screening	Norm. K.	65	100,0	57	87,7	24,76	20,20	58	100,0	50	86,2	18,33	16,06
Cycle 4 Day 1	Norm. K.	54	83,1	46	85,2	15,04	13,94	55	94,8	46	83,6	14,86	13,37
FU Day 28	Norm. K.	59	90,8	48	81,4	13,19	12,78	53	91,4	46	86,8	12,50	14,03
FU Month 3	Norm. K.	54	83,1	44	81,5	11,55	11,81	54	93,1	44	81,5	14,71	13,98
FU Month 6	Norm. K.	49	75,4	43	87,8	12,73	14,76	45	77,6	34	75,6	19,12	16,35
FU Month 9	Norm. K.	39	60,0	27	69,2	9,88	9,54	30	51,7	24	80,0	14,93	11,52
FU Month 12	Norm. K.	32	49,2	24	75,0	13,54	14,08	24	41,4	18	75,0	12,65	14,04
FU Month 15	Norm. K.	26	40,0	20	76,9	15,42	14,38	20	34,5	16	80,0	17,19	12,72
FU Month 18	Norm. K.	18	27,7	14	77,8	19,44	16,38	15	25,9	12	80,0	15,97	13,97
FU Month 21	Norm. K.	12	18,5	5	41,7	11,67	9,50	11	19,0	9	81,8	18,52	14,89
FU Month 24	Norm. K.	8	12,3	5	62,5	18,33	9,13	4	6,9	4	100,0	10,42	7,98
FU Month 27	Norm. K.	3	4,6	2	66,7	16,67	0,00	1	1,7	1	100,0	16,67	NE
Screening	Other Abn.	20	100,0	17	85,0	12,75	11,83	22	100,0	19	86,4	14,04	12,75
Cycle 4 Day 1	Other Abn.	18	90,0	15	83,3	15,56	20,38	22	100,0	17	77,3	12,75	12,54
FU Day 28	Other Abn.	18	90,0	14	77,8	9,52	11,72	21	95,5	16	76,2	14,58	12,73
FU Month 3	Other Abn.	18	90,0	13	72,2	7,69	7,19	21	95,5	17	81,0	7,35	8,27
FU Month 6	Other Abn.	17	85,0	12	70,6	10,42	12,37	18	81,8	17	94,4	7,84	10,40
FU Month 9	Other Abn.	15	75,0	10	66,7	9,17	10,72	14	63,6	12	85,7	8,33	8,70
FU Month 12	Other Abn.	7	35,0	6	85,7	11,11	10,09	12	54,5	10	83,3	11,67	13,15
FU Month 15	Other Abn.	5	25,0	4	80,0	10,42	15,77	5	22,7	4	80,0	6,25	7,98
FU Month 18	Other Abn.	3	15,0	3	100,0	11,11	12,73	3	13,6	2	66,7	8,33	0,00

FU Month 21	Other Abn.	2	10,0	2	100,0	4,17	5,89	2	9,1	2	100,0	4,17	5,89
FU Month 24	Other Abn.	2	10,0	2	100,0	4,17	5,89	0	NE	0	NE	NE	NE
Time from first diagnosis													
Screening	Missing	1	100,0	1	100,0	8,33	NE	0	NE	0	NE	NE	NE
Cycle 4 Day 1	Missing	1	100,0	1	100,0	16,67	NE	0	NE	0	NE	NE	NE
FU Day 28	Missing	1	100,0	1	100,0	8,33	NE	0	NE	0	NE	NE	NE
FU Month 3	Missing	1	100,0	1	100,0	8,33	NE	0	NE	0	NE	NE	NE
FU Month 6	Missing	1	100,0	1	100,0	8,33	NE	0	NE	0	NE	NE	NE
FU Month 9	Missing	1	100,0	1	100,0	8,33	NE	0	NE	0	NE	NE	NE
FU Month 12	Missing	1	100,0	1	100,0	8,33	NE	0	NE	0	NE	NE	NE
FU Month 15	Missing	1	100,0	1	100,0	16,67	NE	0	NE	0	NE	NE	NE
FU Month 18	Missing	1	100,0	1	100,0	8,33	NE	0	NE	0	NE	NE	NE
Screening	13 - 24 months	41	100,0	31	75,6	19,09	19,04	31	100,0	30	96,8	14,35	12,49
Cycle 4 Day 1	13 - 24 months	35	85,4	28	80,0	13,39	18,19	30	96,8	26	86,7	13,57	13,93
FU Day 28	13 - 24 months	38	92,7	26	68,4	15,28	15,28	30	96,8	26	86,7	9,94	11,31
FU Month 3	13 - 24 months	36	87,8	28	77,8	13,39	20,46	30	96,8	25	83,3	9,33	10,57
FU Month 6	13 - 24 months	36	87,8	27	75,0	7,41	9,62	30	96,8	24	80,0	9,03	14,52
FU Month 9	13 - 24 months	32	78,0	22	68,8	8,33	10,60	21	67,7	17	81,0	6,86	8,45
FU Month 12	13 - 24 months	21	51,2	15	71,4	11,67	13,29	16	51,6	13	81,3	5,77	7,89
FU Month 15	13 - 24 months	19	46,3	15	78,9	9,44	14,39	16	51,6	8	50,0	10,42	14,60
FU Month 18	13 - 24 months	14	34,1	10	71,4	16,67	18,00	10	32,3	8	80,0	6,25	5,89
FU Month 21	13 - 24 months	11	26,8	7	63,6	19,05	18,46	6	19,4	4	66,7	4,17	4,81
FU Month 24	13 - 24 months	8	19,5	3	37,5	25,00	14,43	3	9,7	3	100,0	0,00	0,00
FU Month 27	13 - 24 months	5	12,2	3	60,0	16,67	16,67	2	6,5	2	100,0	0,00	0,00
FU Month 30	13 - 24 months	3	7,3	2	66,7	12,50	5,89	1	3,2	1	100,0	0,00	NE
Screening	<= 12 months	60	100,0	48	80,0	19,79	19,00	70	100,0	55	78,6	22,68	17,77
Cycle 4 Day 1	<= 12 months	48	80,0	35	72,9	18,10	18,17	60	85,7	44	73,3	17,80	17,01
FU Day 28	<= 12 months	54	90,0	39	72,2	11,97	12,06	62	88,6	47	75,8	19,09	16,64
FU Month 3	<= 12 months	53	88,3	38	71,7	13,82	14,92	59	84,3	44	74,6	18,88	14,95
FU Month 6	<= 12 months	46	76,7	35	76,1	14,68	15,88	47	67,1	33	70,2	17,00	18,73
FU Month 9	<= 12 months	35	58,3	27	77,1	11,11	10,84	37	52,9	27	73,0	16,36	15,93
FU Month 12	<= 12 months	27	45,0	21	77,8	17,06	16,13	29	41,4	24	82,8	18,06	16,61
FU Month 15	<= 12 months	22	36,7	16	72,7	16,15	13,43	17	24,3	15	88,2	19,44	12,47
FU Month 18	<= 12 months	16	26,7	10	62,5	13,33	8,05	13	18,6	11	84,6	15,15	11,07
FU Month 21	<= 12 months	9	15,0	5	55,6	13,33	4,56	7	10,0	5	71,4	18,33	12,36
FU Month 24	<= 12 months	6	10,0	3	50,0	16,67	8,33	2	2,9	0	NE	NE	NE
FU Month 27	<= 12 months	1	1,7			NE	NE	1	1,4			NE	NE
FU Month 30	<= 12 months	1	1,7			NE	NE	0	NE			NE	NE

Screening	>24 months	153	100,0	136	88,9	18,67	16,15	141	100,0	117	83,0	15,84	14,90
Cycle 4 Day 1	>24 months	129	84,3	110	85,3	14,90	14,00	134	95,0	105	78,4	14,60	12,27
FU Day 28	>24 months	137	89,5	118	86,1	11,35	12,56	133	94,3	110	82,7	14,67	12,90
FU Month 3	>24 months	135	88,2	116	85,9	11,30	12,75	132	93,6	105	79,5	12,22	12,61
FU Month 6	>24 months	124	81,0	108	87,1	10,47	11,94	115	81,6	91	79,1	15,14	14,15
FU Month 9	>24 months	96	62,7	76	79,2	11,00	10,38	91	64,5	67	73,6	13,81	14,03
FU Month 12	>24 months	76	49,7	64	84,2	12,07	13,12	72	51,1	55	76,4	14,75	13,77
FU Month 15	>24 months	62	40,5	52	83,9	13,89	12,39	52	36,9	40	76,9	16,04	14,30
FU Month 18	>24 months	48	31,4	41	85,4	15,72	18,18	37	26,2	26	70,3	17,74	15,46
FU Month 21	>24 months	32	20,9	24	75,0	11,46	10,66	27	19,1	19	70,4	14,47	14,92
FU Month 24	>24 months	18	11,8	15	83,3	8,89	7,36	13	9,2	11	84,6	17,17	8,50
FU Month 27	>24 months	7	4,6	5	71,4	13,33	7,45	6	4,3	4	66,7	16,67	11,79
FU Month 30	>24 months	3	2,0	2	66,7	25,00	11,79	0	NE	0	NE	NE	NE
High circulating tumor burden													
Screening	Missing	0	NE	0	NE	NE	NE	2	100,0	1	50,0	8,33	NE
Cycle 4 Day 1	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	16,67	NE
FU Day 28	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	8,33	NE
FU Month 3	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	8,33	NE
FU Month 6	Missing	0	NE	0	NE	NE	NE	1	50,0	1	100,0	8,33	NE
FU Month 9	Missing	0	NE			NE	NE	1	50,0			NE	NE
Screening	<25x10**9 cells/L	60	100,0	51	85,0	18,41	19,53	67	100,0	55	82,1	18,74	16,46
Cycle 4 Day 1	<25x10**9 cells/L	50	83,3	41	82,0	17,82	19,00	61	91,0	43	70,5	15,89	14,64
FU Day 28	<25x10**9 cells/L	56	93,3	44	78,6	13,83	15,15	61	91,0	46	75,4	15,76	14,51
FU Month 3	<25x10**9 cells/L	54	90,0	44	81,5	16,10	17,46	59	88,1	44	74,6	14,39	13,25
FU Month 6	<25x10**9 cells/L	50	83,3	41	82,0	14,50	13,95	51	76,1	38	74,5	14,04	14,25
FU Month 9	<25x10**9 cells/L	36	60,0	23	63,9	8,70	8,51	41	61,2	28	68,3	12,20	10,26
FU Month 12	<25x10**9 cells/L	29	48,3	23	79,3	15,22	11,14	34	50,7	23	67,6	13,41	15,44
FU Month 15	<25x10**9 cells/L	24	40,0	19	79,2	15,35	11,87	23	34,3	13	56,5	18,59	12,34
FU Month 18	<25x10**9 cells/L	20	33,3	17	85,0	15,20	10,31	19	28,4	13	68,4	12,82	7,31
FU Month 21	<25x10**9 cells/L	14	23,3	9	64,3	16,67	15,02	10	14,9	7	70,0	10,71	12,47
FU Month 24	<25x10**9 cells/L	8	13,3	4	50,0	16,67	15,21	6	9,0	5	83,3	10,00	10,87
FU Month 27	<25x10**9 cells/L	4	6,7	2	50,0	8,33	11,79	1	1,5	1	100,0	0,00	NE
FU Month 30	<25x10**9 cells/L	4	6,7	2	50,0	12,50	5,89	1	1,5	1	100,0	0,00	NE
Screening	>=25x10**9 cells/L	195	100,0	165	84,6	19,09	16,40	173	100,0	146	84,4	17,07	15,44
Cycle 4 Day 1	>=25x10**9 cells/L	163	83,6	133	81,6	14,54	14,34	162	93,6	131	80,9	15,03	13,68
FU Day 28	>=25x10**9 cells/L	174	89,2	140	80,5	11,45	12,03	163	94,2	136	83,4	14,97	13,88
FU Month 3	>=25x10**9 cells/L	171	87,7	139	81,3	10,87	13,31	161	93,1	129	80,1	13,22	13,43
FU Month 6	>=25x10**9 cells/L	157	80,5	130	82,8	9,68	12,00	140	80,9	109	77,9	14,81	15,95
FU Month 9	>=25x10**9 cells/L	128	65,6	103	80,5	10,95	10,82	107	61,8	83	77,6	13,76	15,15

FU Month 12	>=25x10**9 cells/L	96	49,2	78	81,3	12,36	14,46	83	48,0	69	83,1	14,65	14,02
FU Month 15	>=25x10**9 cells/L	80	41,0	65	81,3	13,03	13,22	62	35,8	50	80,6	15,50	14,39
FU Month 18	>=25x10**9 cells/L	59	30,3	45	76,3	15,43	18,54	41	23,7	32	78,0	15,97	15,57
FU Month 21	>=25x10**9 cells/L	38	19,5	27	71,1	12,04	10,92	30	17,3	21	70,0	14,68	14,41
FU Month 24	>=25x10**9 cells/L	24	12,3	17	70,8	11,27	8,81	12	6,9	9	75,0	15,43	10,31
FU Month 27	>=25x10**9 cells/L	9	4,6	6	66,7	16,67	10,54	8	4,6	5	62,5	13,33	12,64
FU Month 30	>=25x10**9 cells/L	3	1,5	2	66,7	25,00	11,79	0	NE	0	NE	NE	NE

¹ in study: number of subjects in study at respective visit; % based on baseline

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit

² mean: descriptive statistics - absolute values Clinical

cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/t_pro_mean.sas

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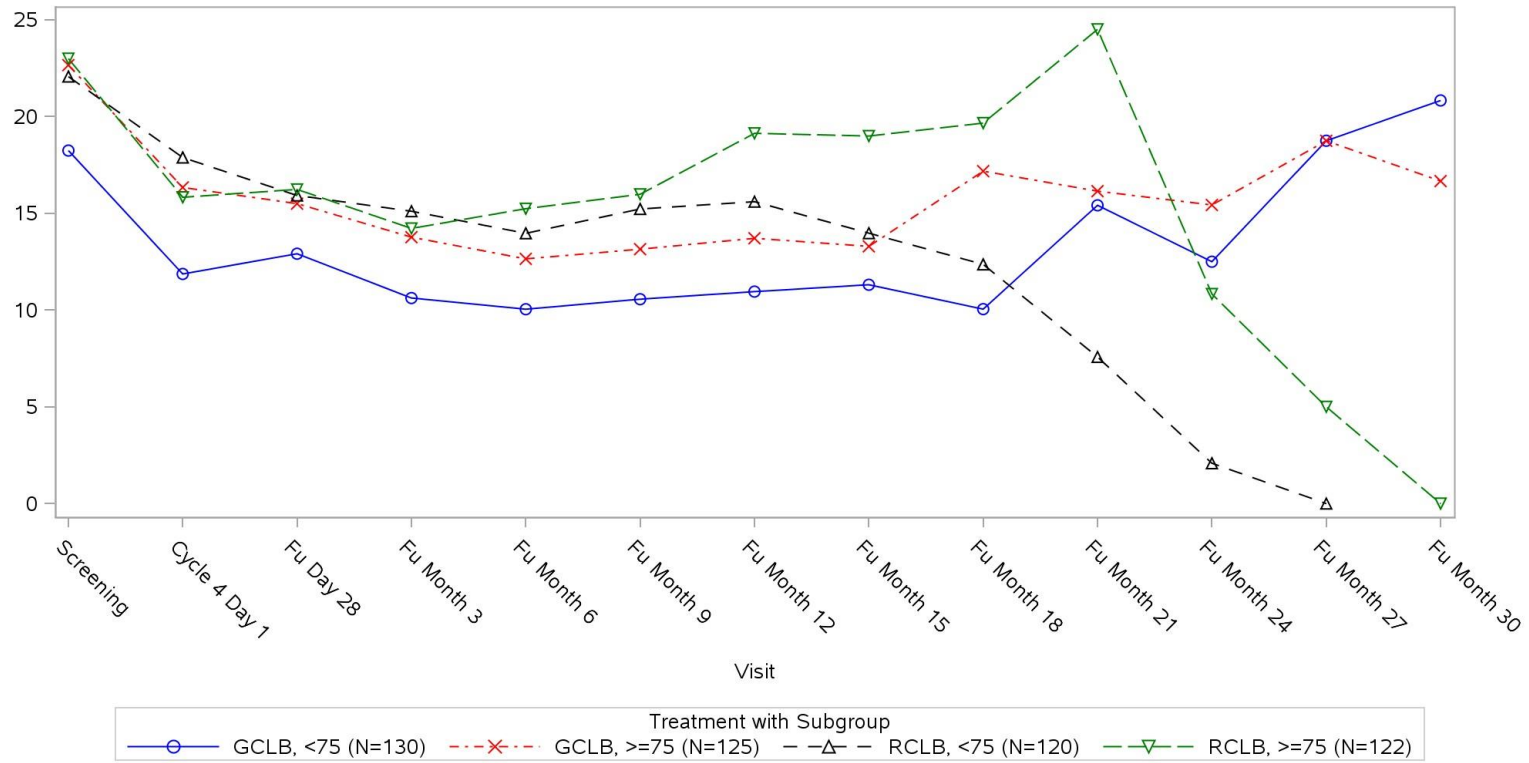
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

Age (N=497) Laboratory Test: Disease Effects Scale



Clinical cut-off: 09MAY2013

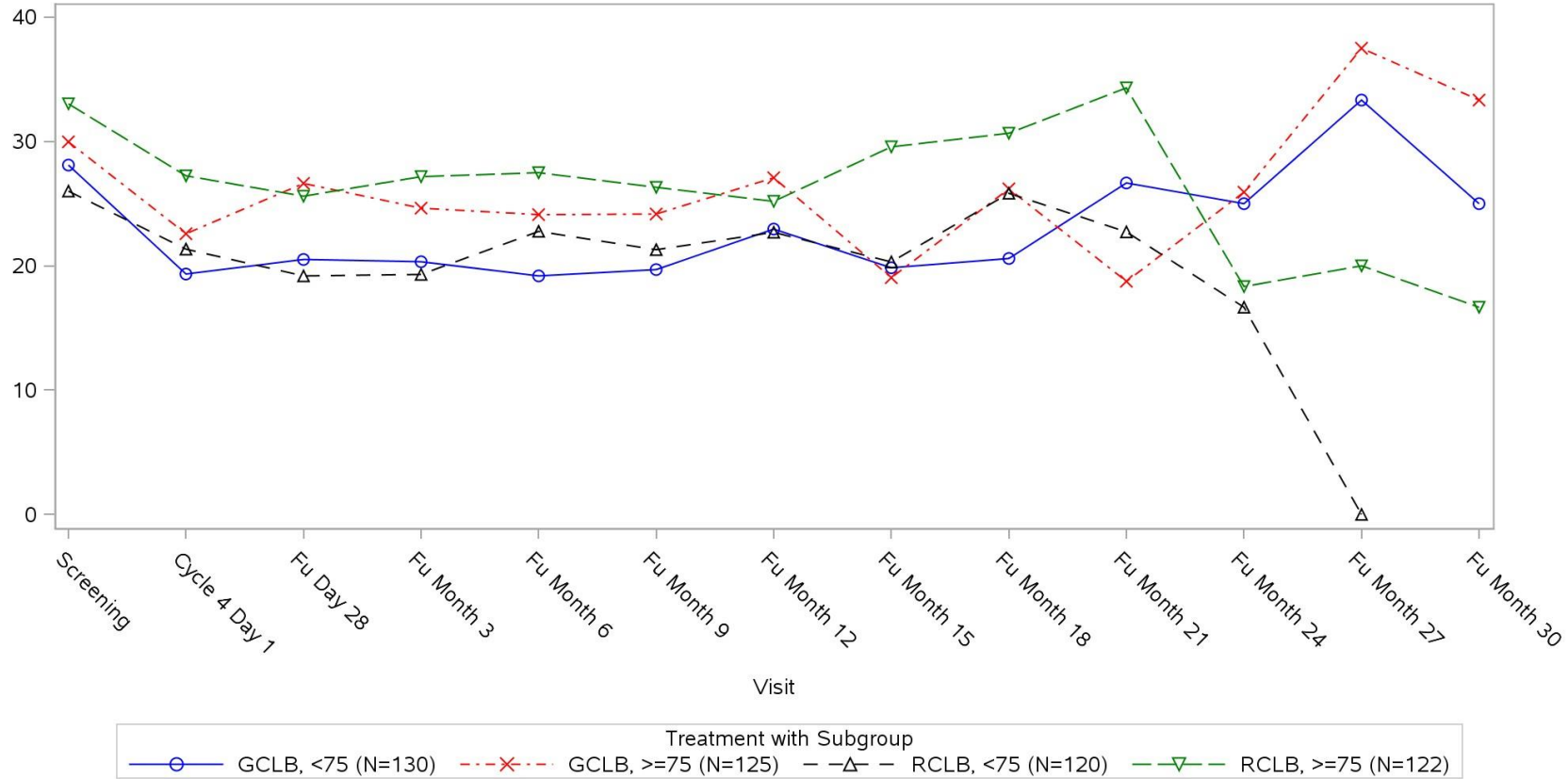
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 04MAR2020 19:13

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

Age (N=497) Laboratory Test: Fatigue Scale



Clinical cut-off: 09MAY2013

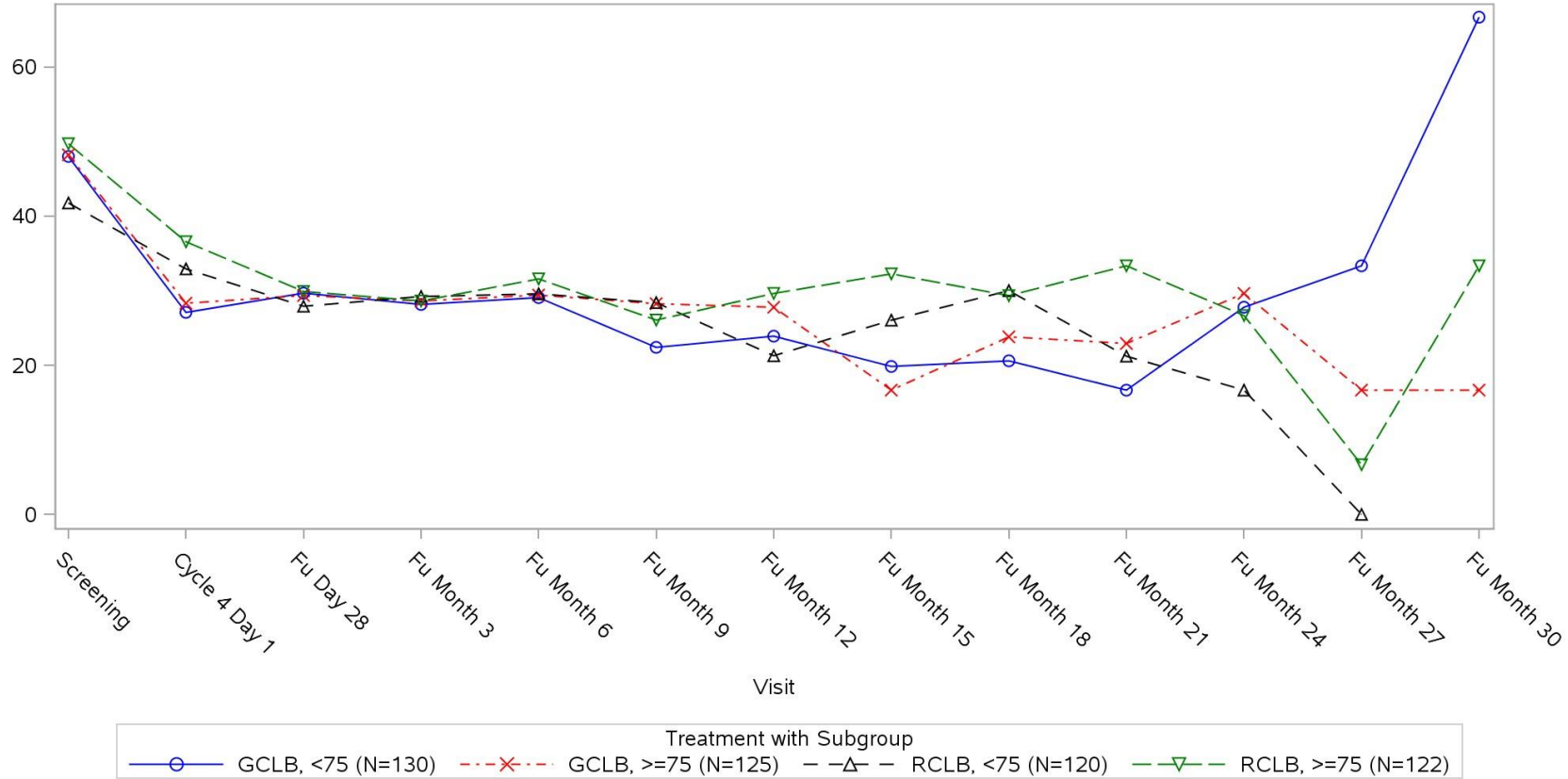
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04MAR2020 19:13

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

Age (N=497) Laboratory Test: Future Health



Clinical cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/g_pro_mean.sas
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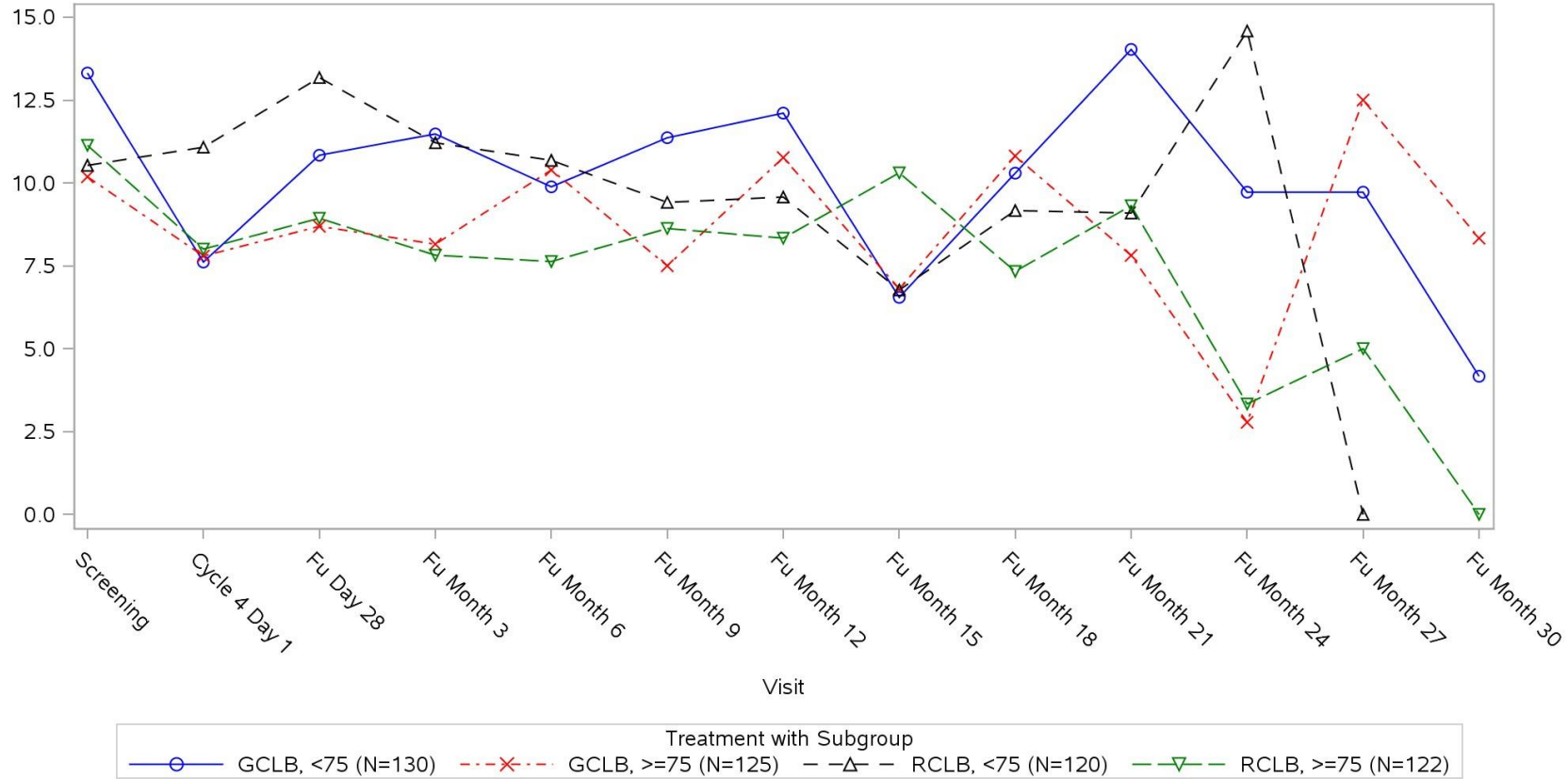
Page 3 of 78

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

Age (N=497) Laboratory Test: Infection Scale



Clinical cut-off: 09MAY2013

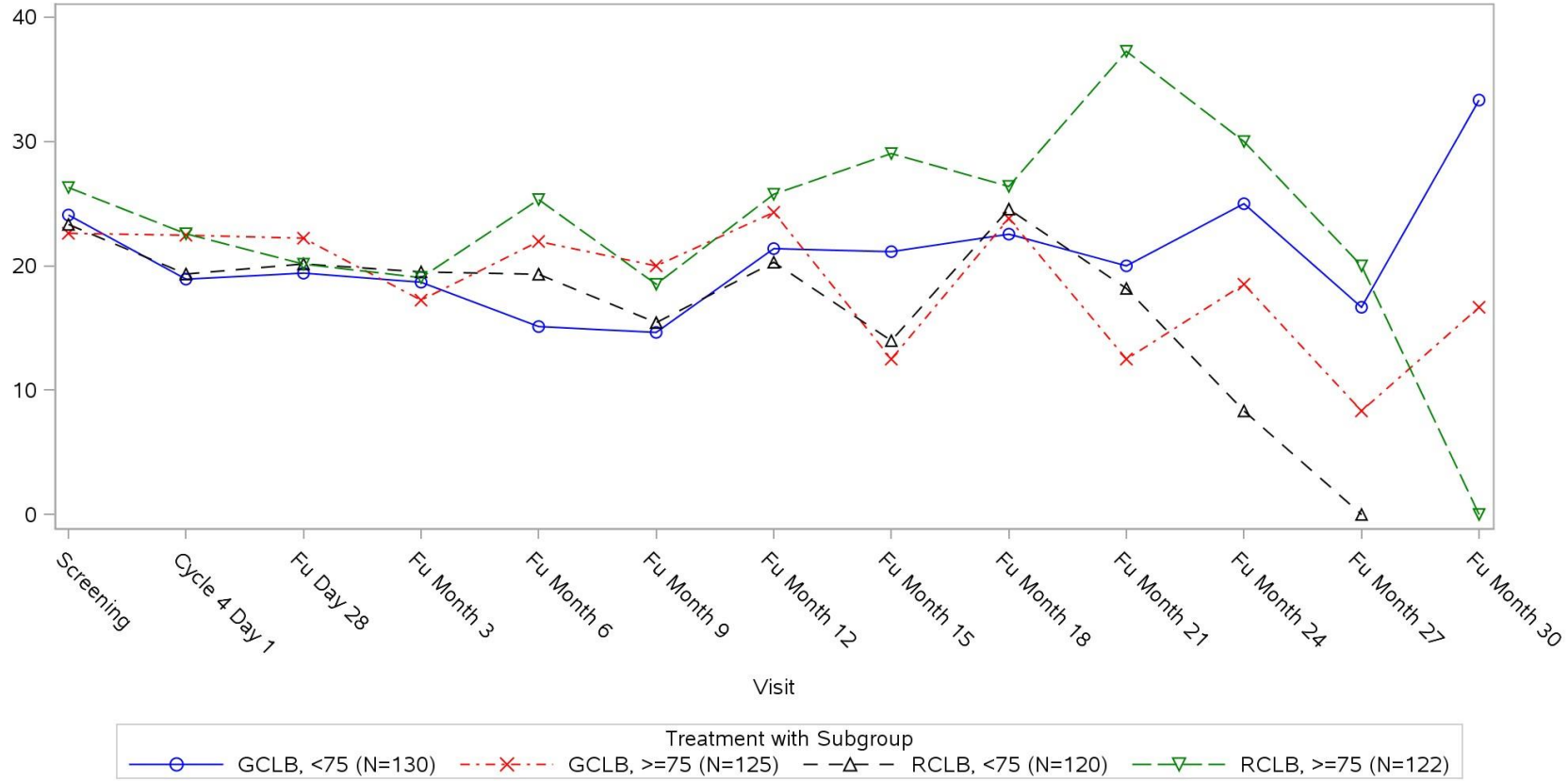
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04MAR2020 19:13

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

Age (N=497) Laboratory Test: Social Problems



Clinical cut-off: 09MAY2013

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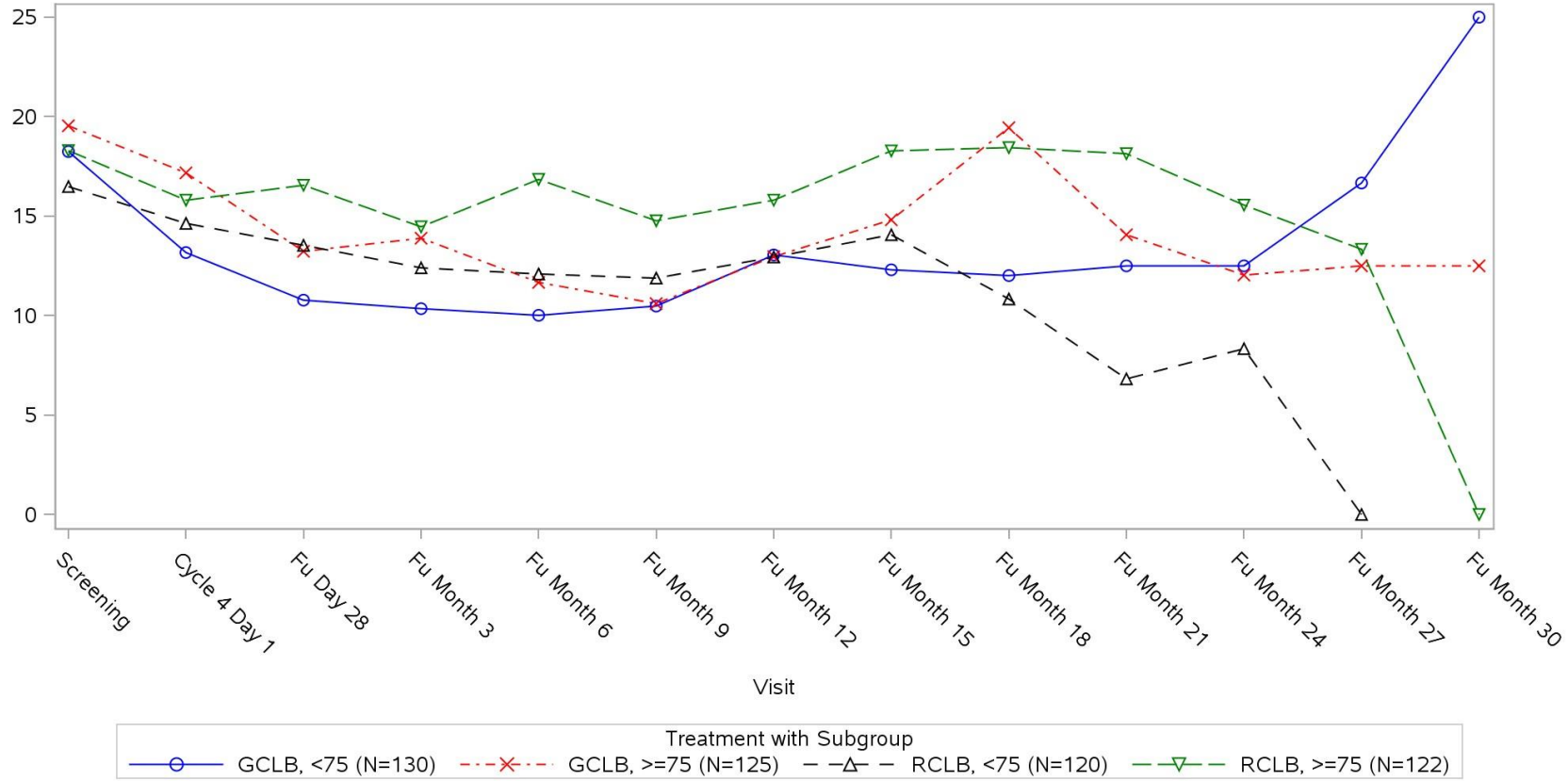
Page 5 of 78

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

Age (N=497) Laboratory Test: Treatment Side Effects Scale



Clinical cut-off: 09MAY2013

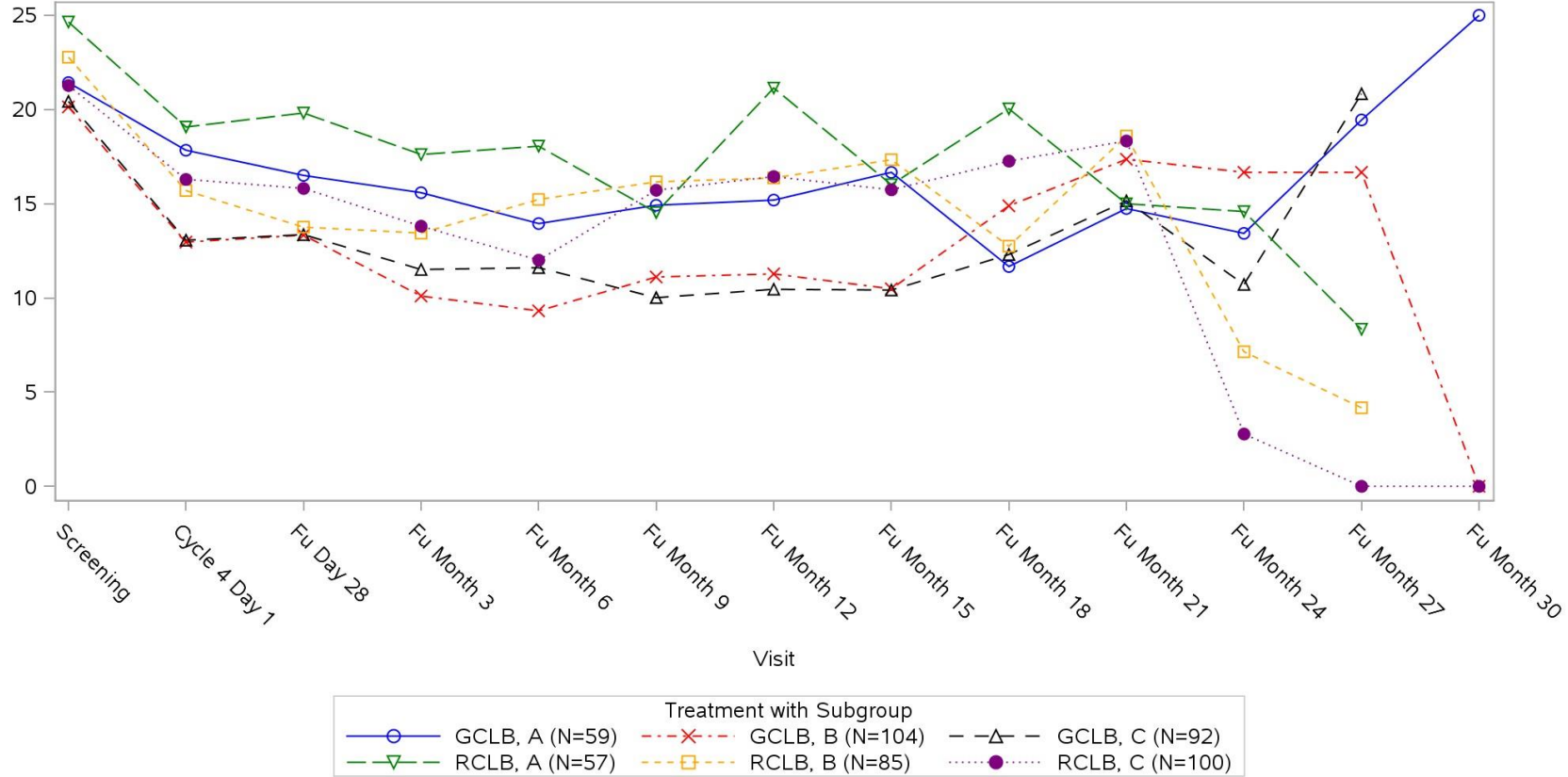
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

Binet Staging at baseline (N=497) Laboratory Test: Disease Effects Scale



Clinical cut-off: 09MAY2013

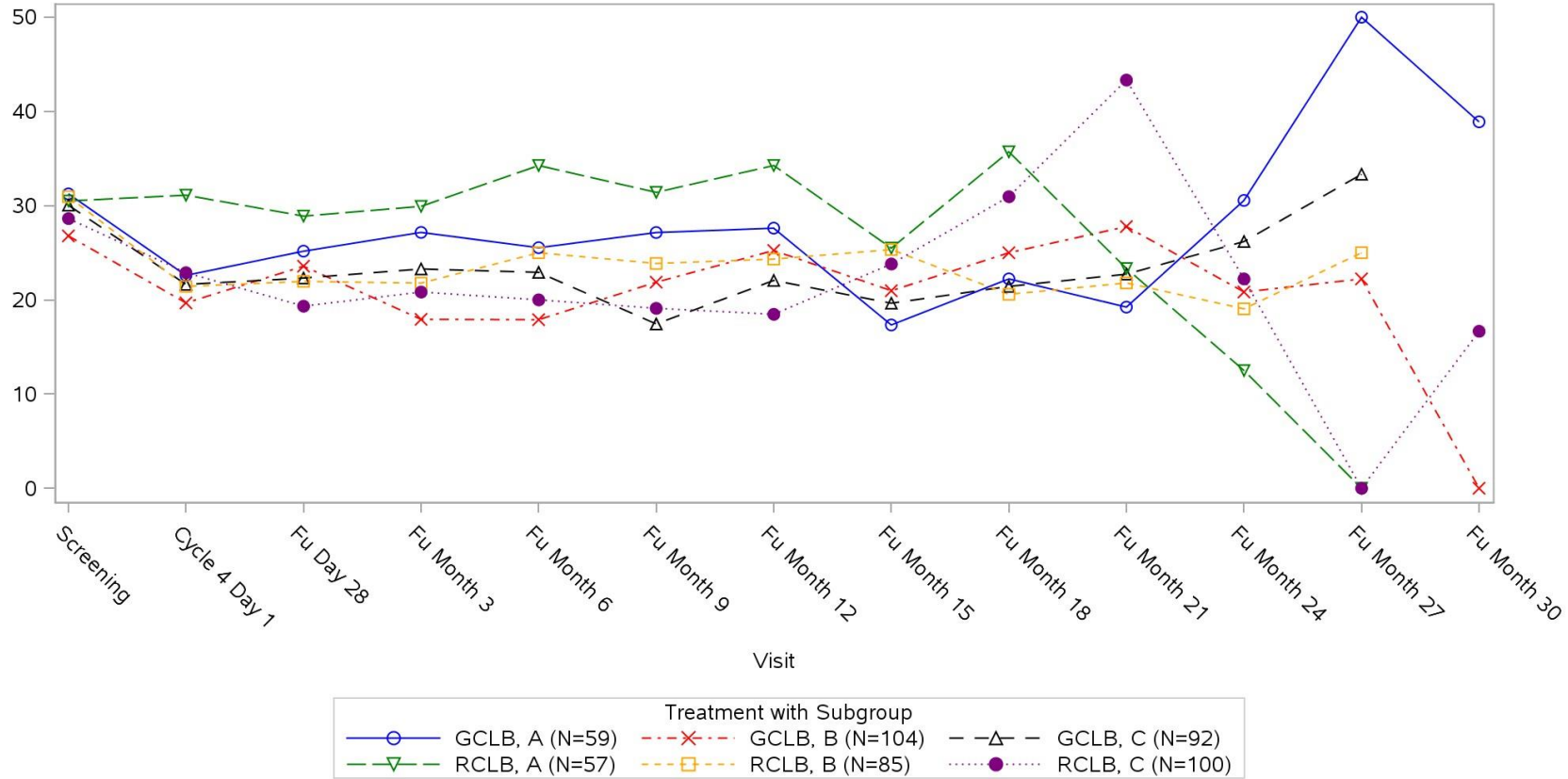
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

Binet Staging at baseline (N=497) Laboratory Test: Fatigue Scale



Clinical cut-off: 09MAY2013

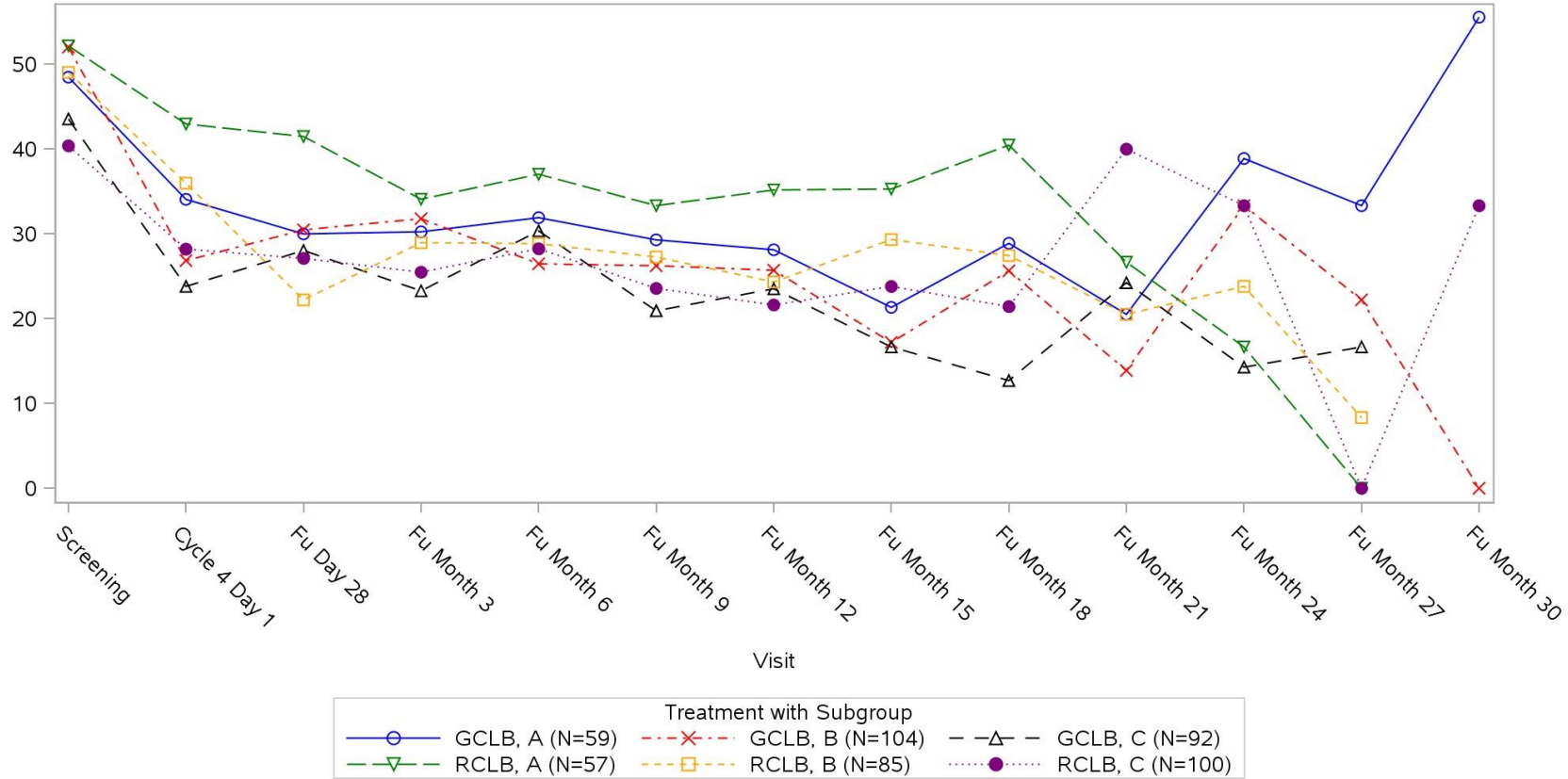
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 04MAR2020 19:13

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

Binet Staging at baseline (N=497) Laboratory Test: Future Health



Clinical cut-off: 09MAY2013

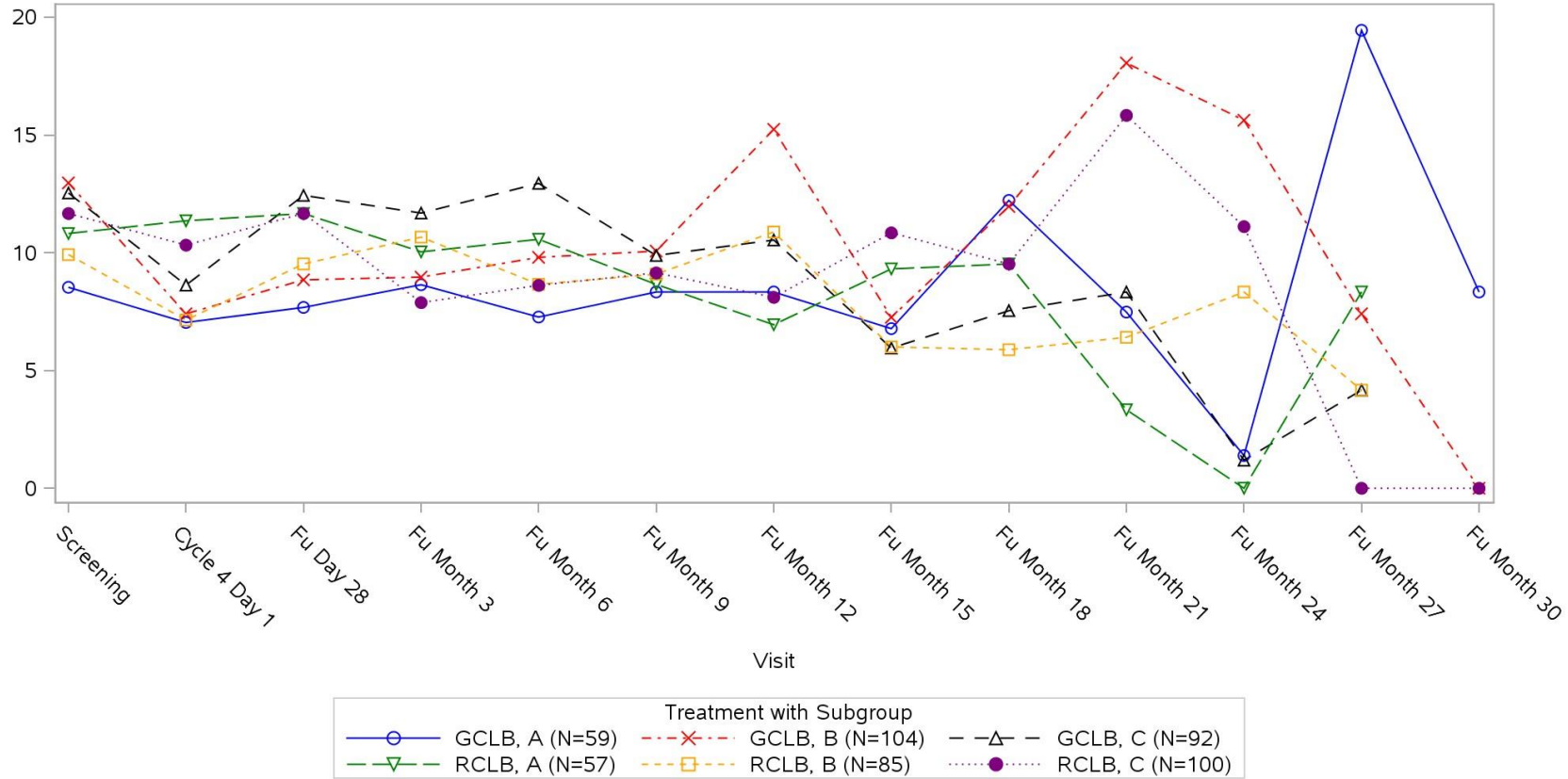
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 04MAR2020 19:13

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

Binet Staging at baseline (N=497) Laboratory Test: Infection Scale



Clinical cut-off: 09MAY2013

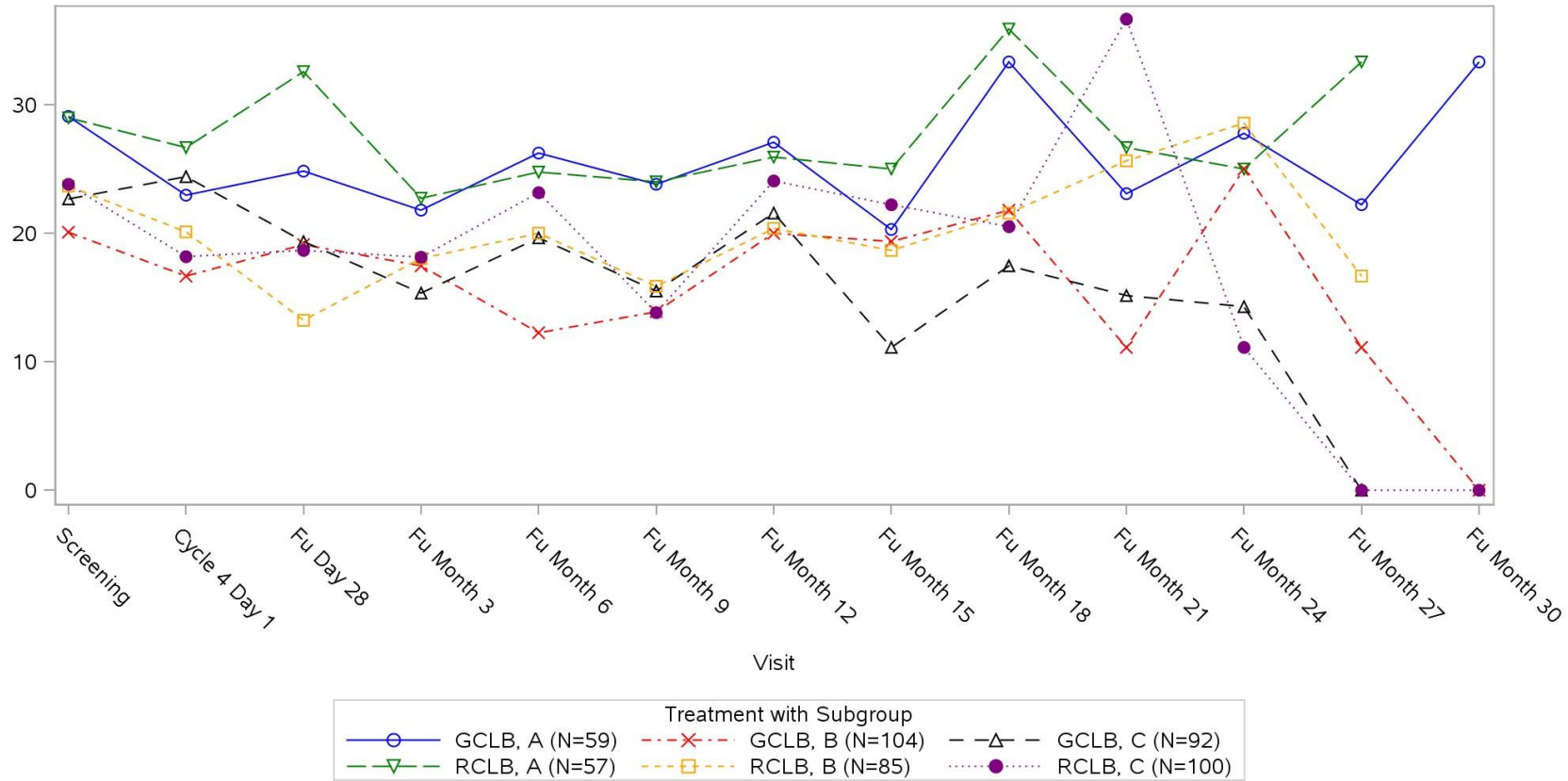
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

Binet Staging at baseline (N=497) Laboratory Test: Social Problems



Clinical cut-off: 09MAY2013

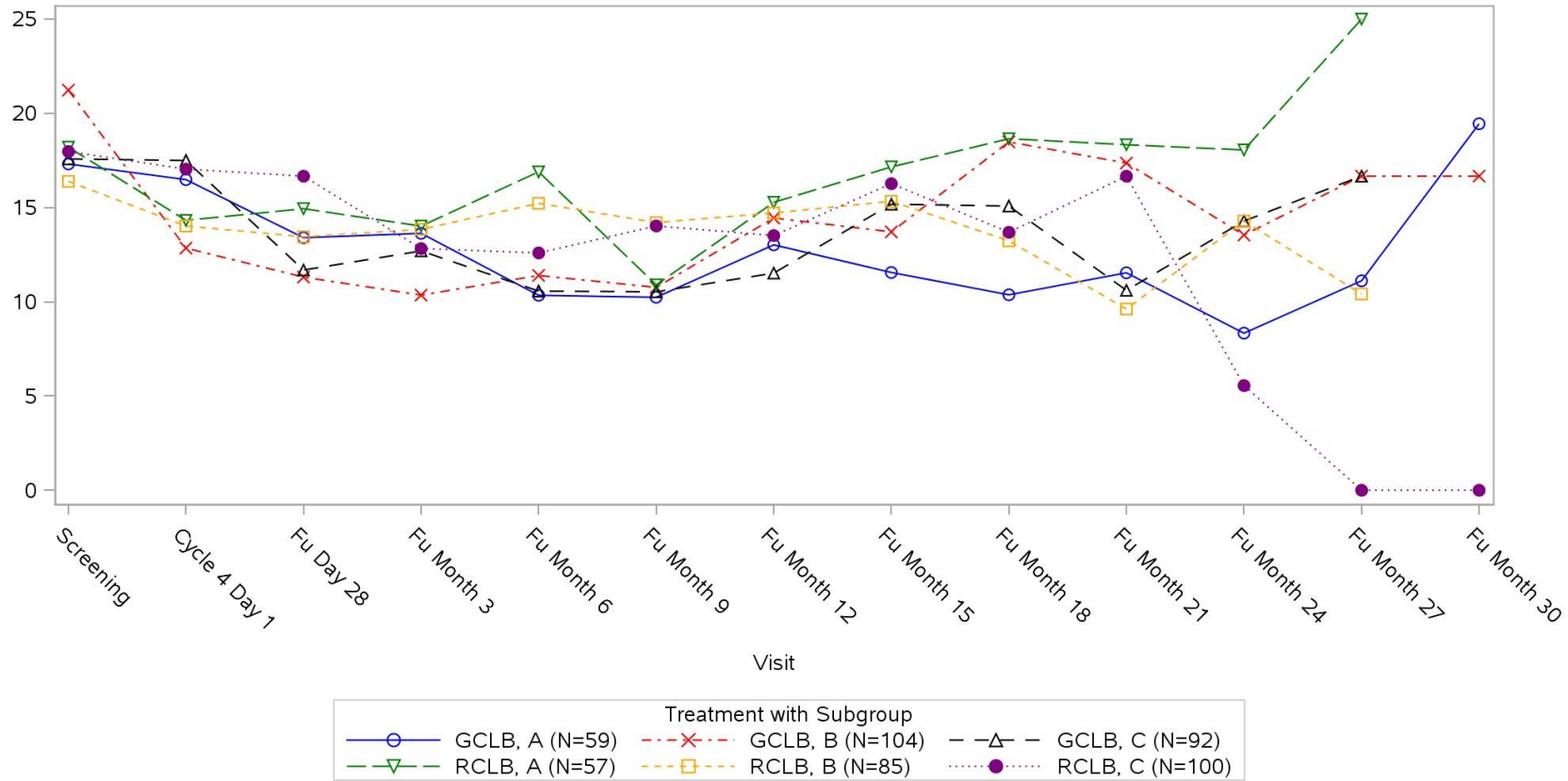
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

Binet Staging at baseline (N=497) Laboratory Test: Treatment Side Effects Scale



Clinical cut-off: 09MAY2013

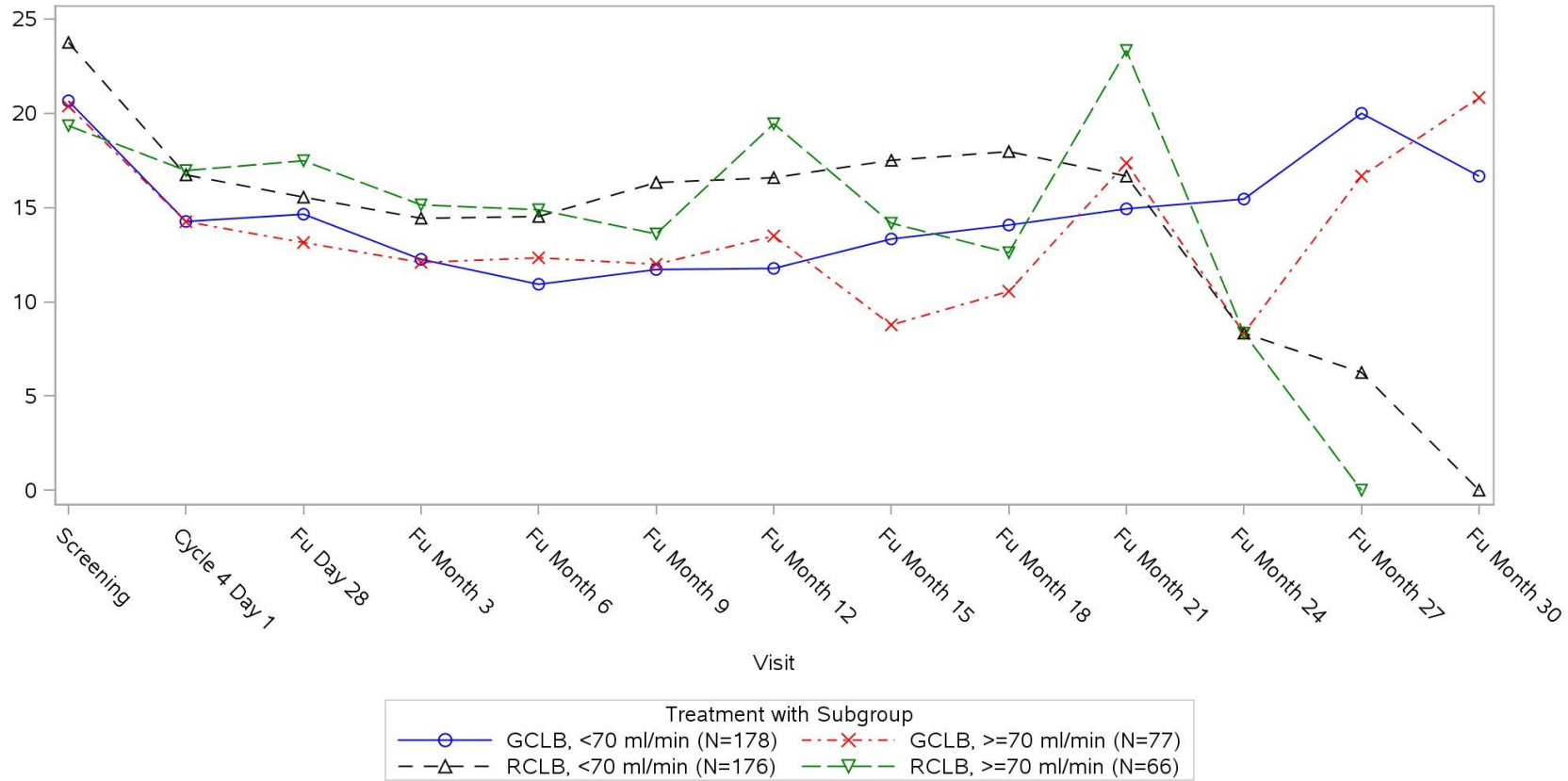
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04MAR2020 19:13

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

Calculated creatinine clearance cat. 2 (N=497) Laboratory Test: Disease Effects Scale



Clinical cut-off: 09MAY2013

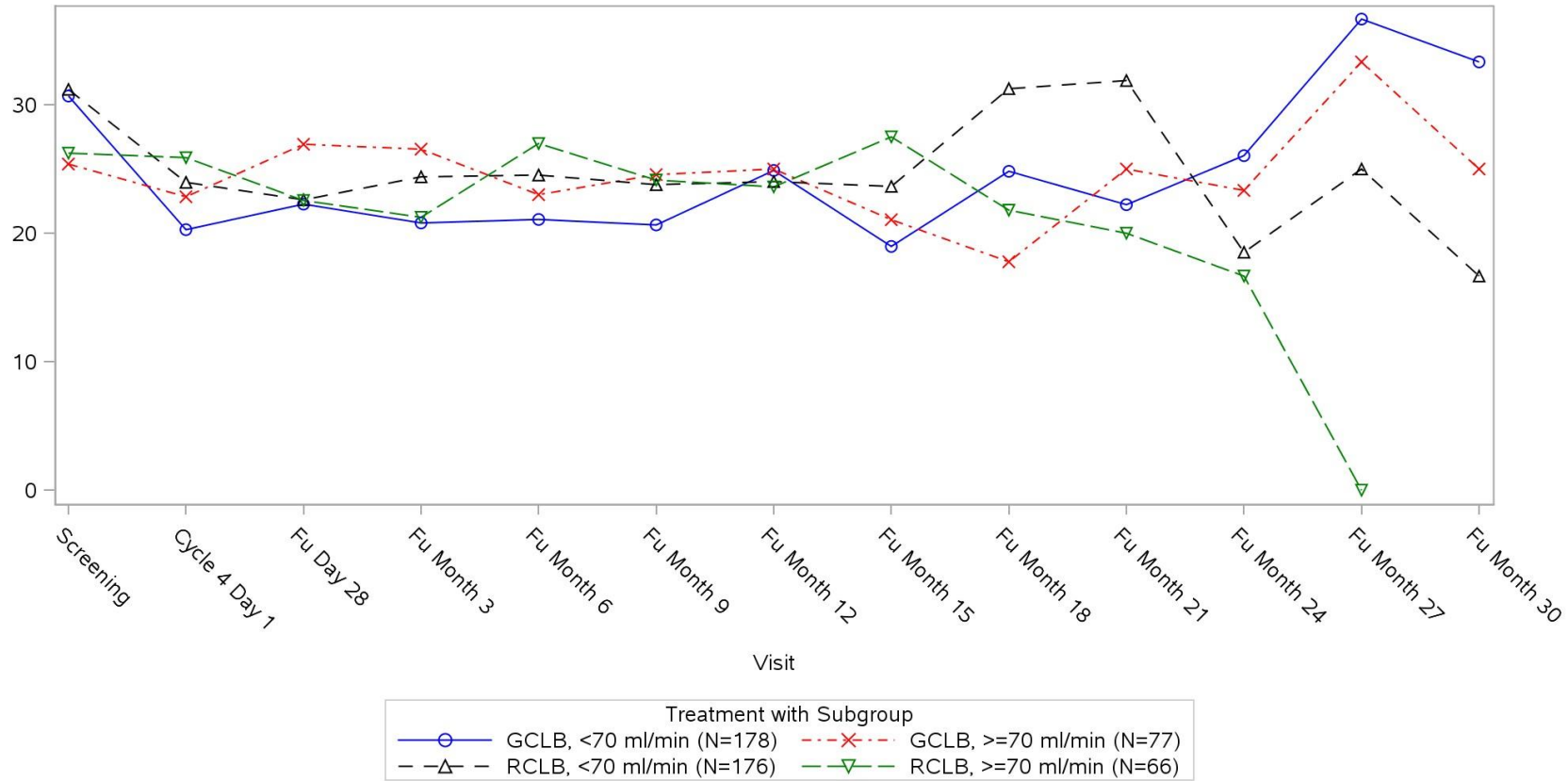
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04MAR2020 19:13

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

Calculated creatinine clearance cat. 2 (N=497) Laboratory Test: Fatigue Scale



Clinical cut-off: 09MAY2013

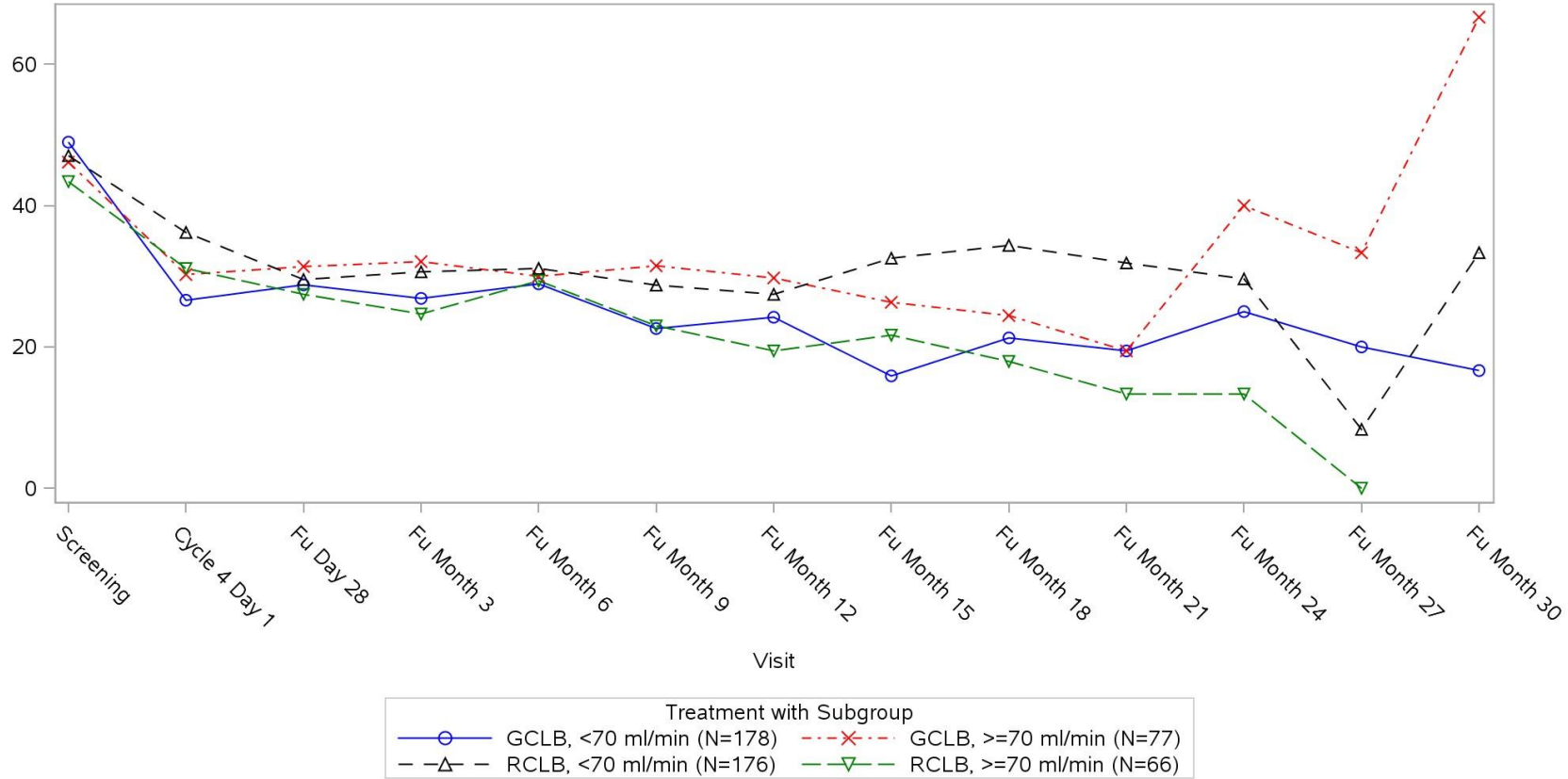
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

Calculated creatinine clearance cat. 2 (N=497) Laboratory Test: Future Health



Clinical cut-off: 09MAY2013

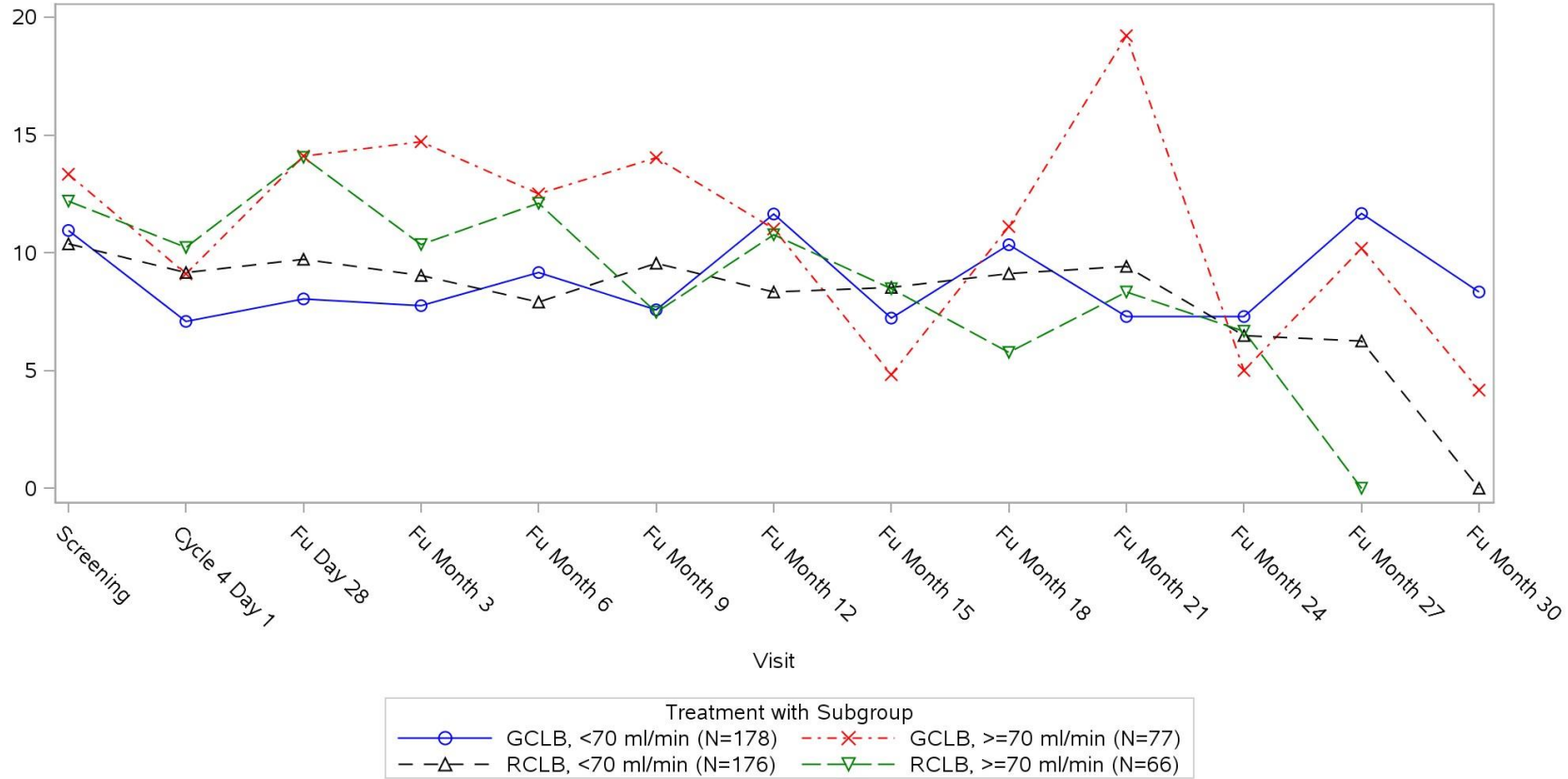
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04MAR2020 19:13

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

Calculated creatinine clearance cat. 2 (N=497) Laboratory Test: Infection Scale



Clinical cut-off: 09MAY2013

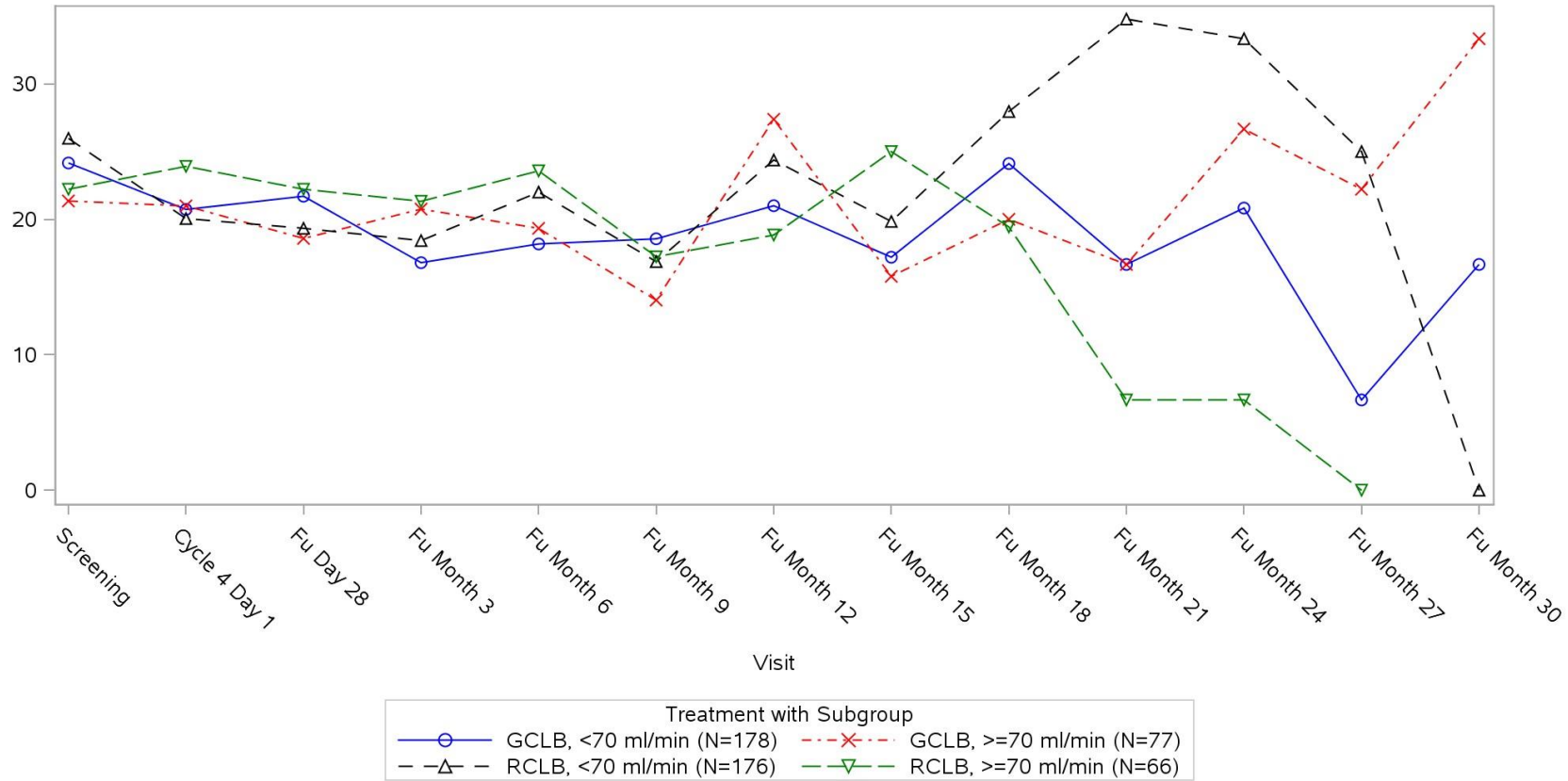
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04MAR2020 19:13

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

Calculated creatinine clearance cat. 2 (N=497) Laboratory Test: Social Problems



Clinical cut-off: 09MAY2013

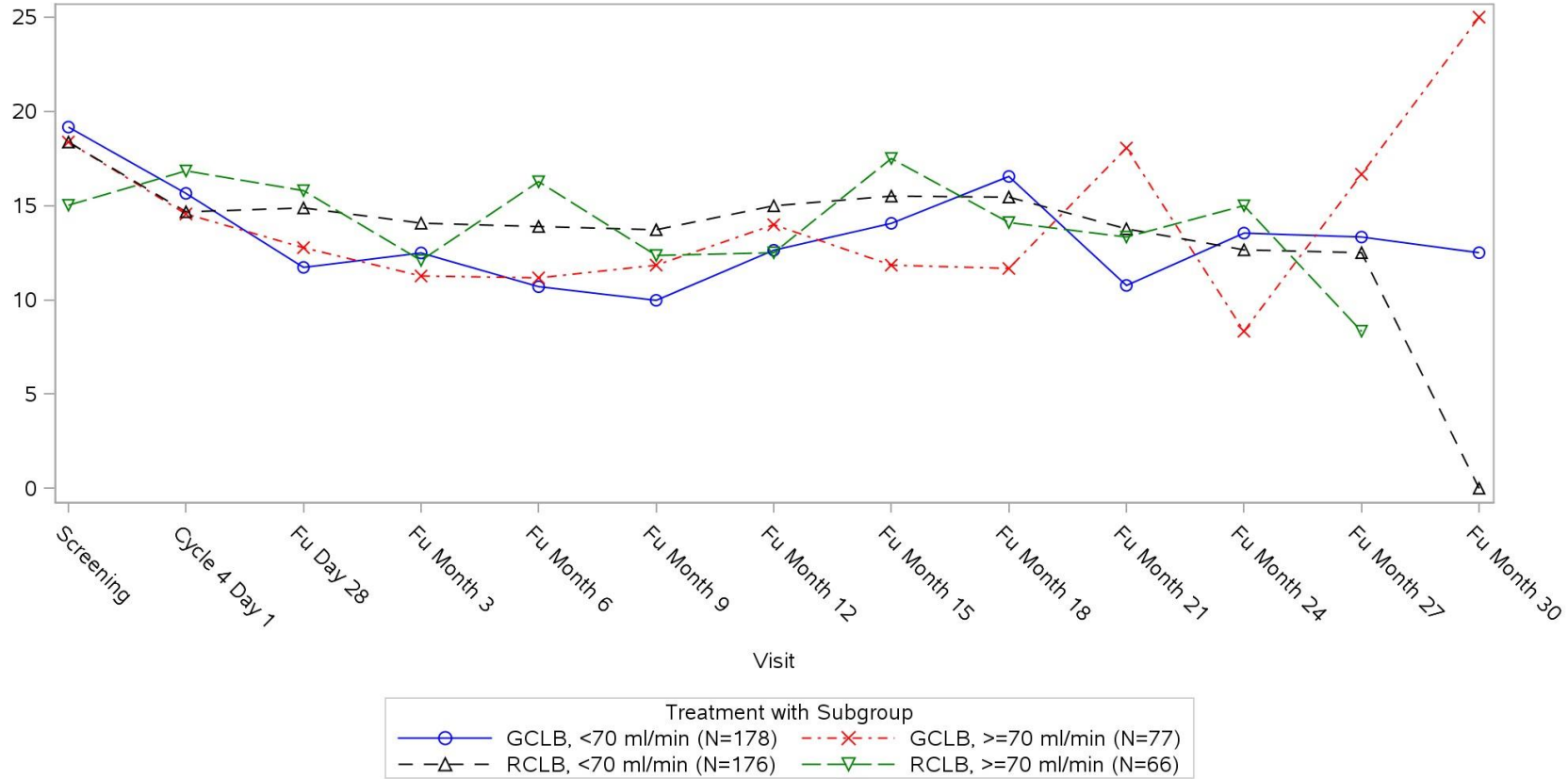
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

Calculated creatinine clearance cat. 2 (N=497) Laboratory Test: Treatment Side Effects Scale



Clinical cut-off: 09MAY2013

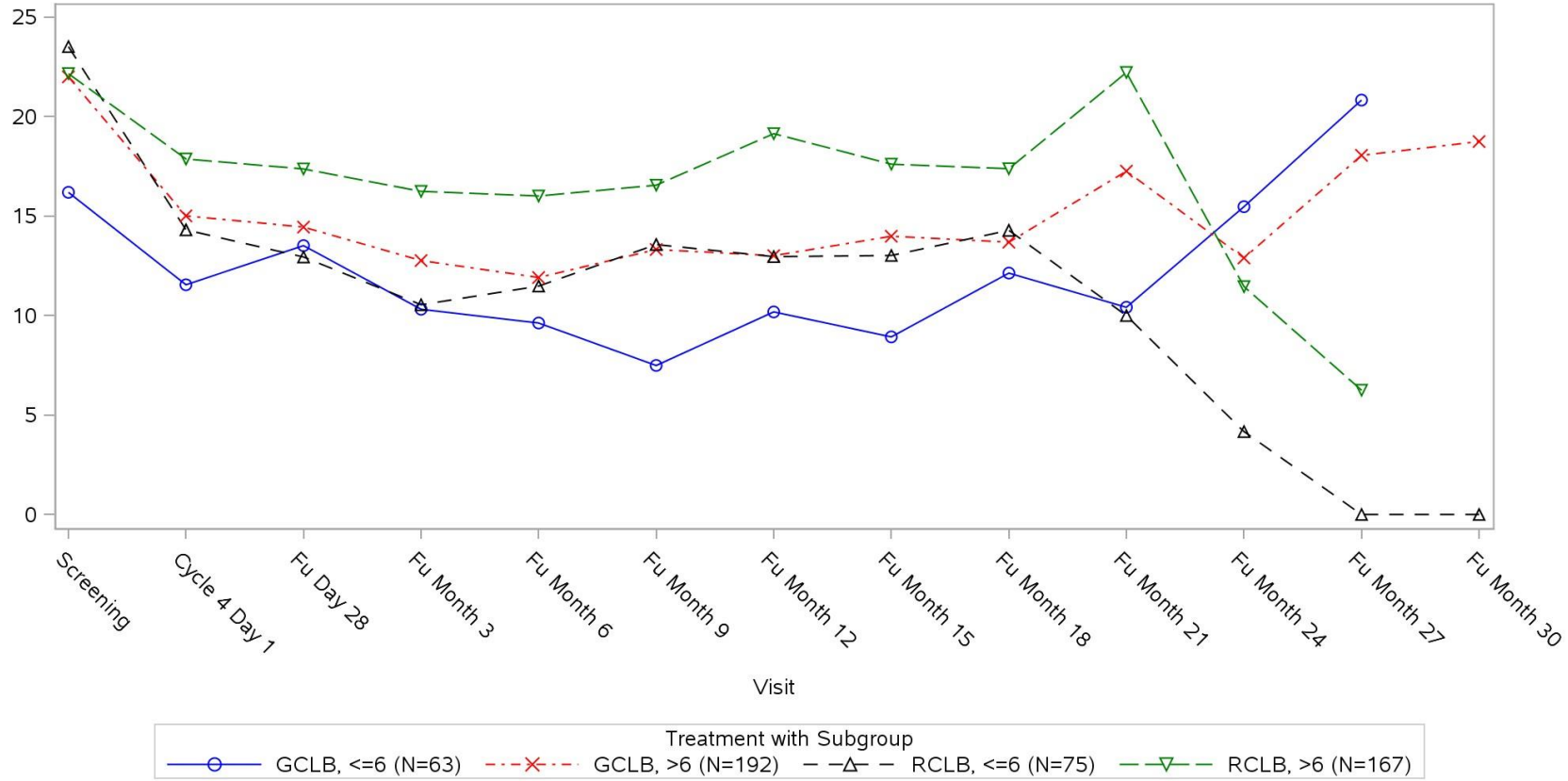
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04MAR2020 19:13

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

Total CIR score at baseline (N=497) Laboratory Test: Disease Effects Scale



Clinical cut-off: 09MAY2013

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSR_stage2/qa/program/g_pro_mean.sas
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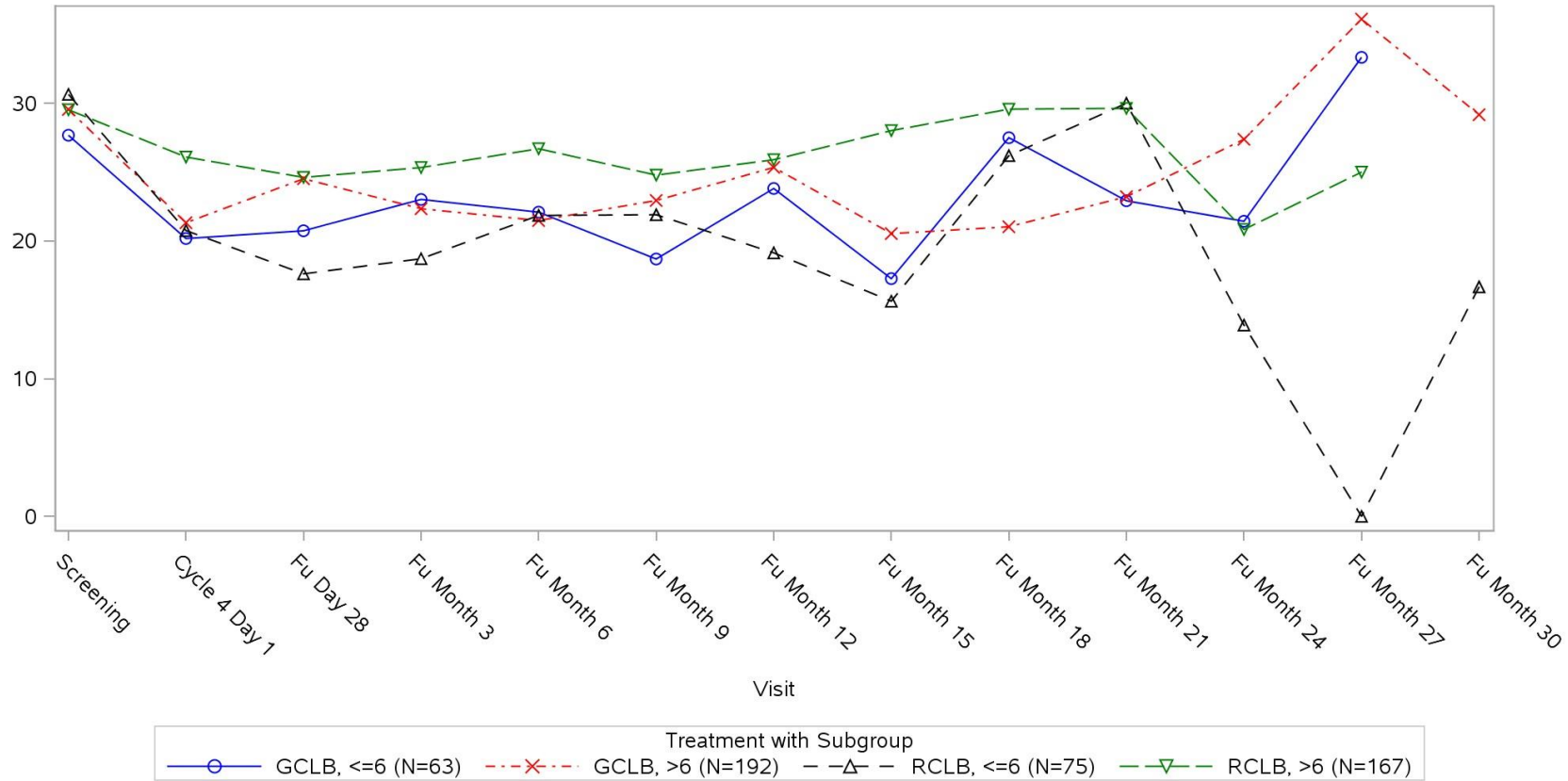
Page 19 of 78

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

Total CIR score at baseline (N=497) Laboratory Test: Fatigue Scale



Clinical cut-off: 09MAY2013

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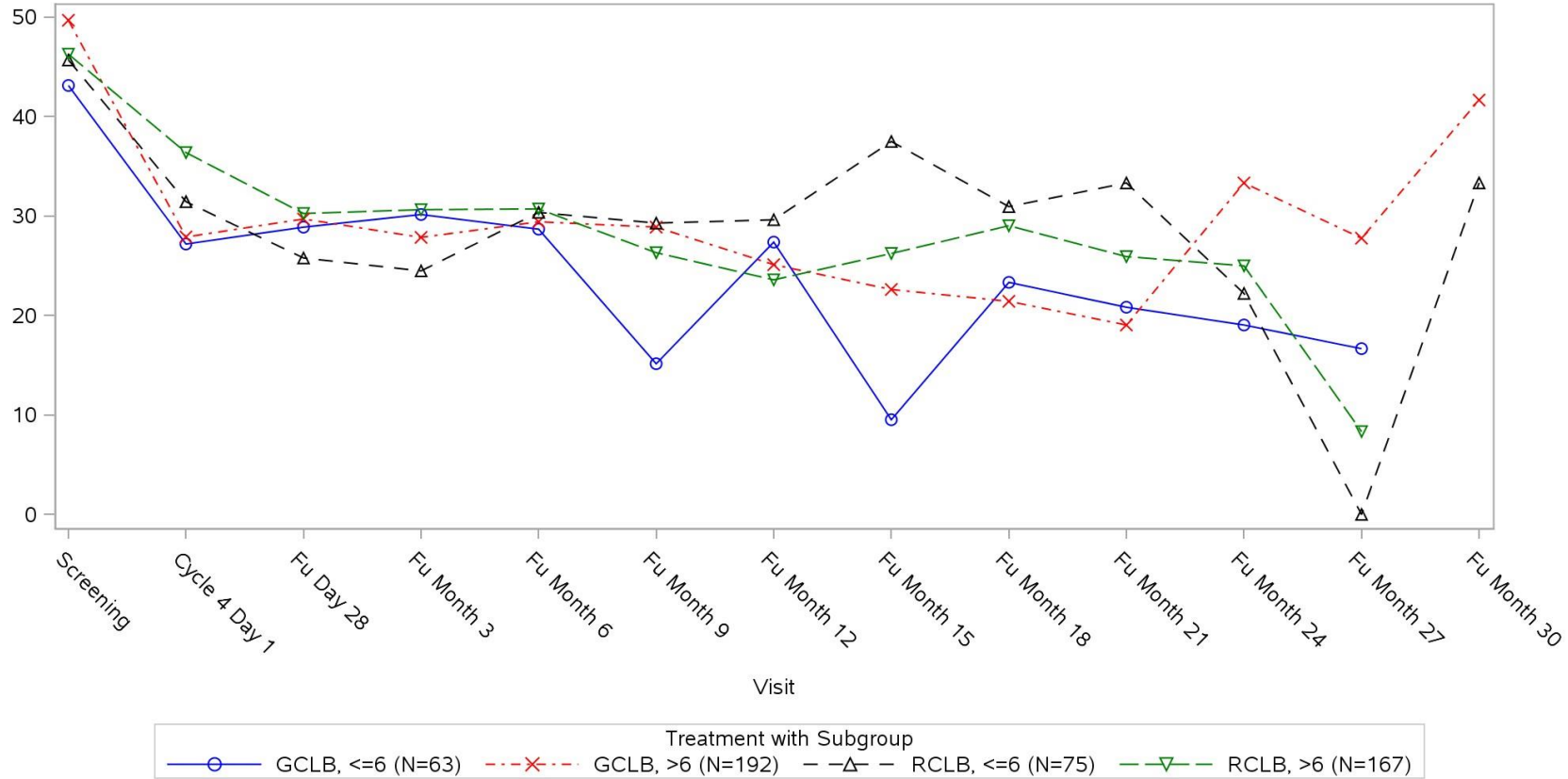
Page 20 of 78

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

Total CIR score at baseline (N=497) Laboratory Test: Future Health



Clinical cut-off: 09MAY2013

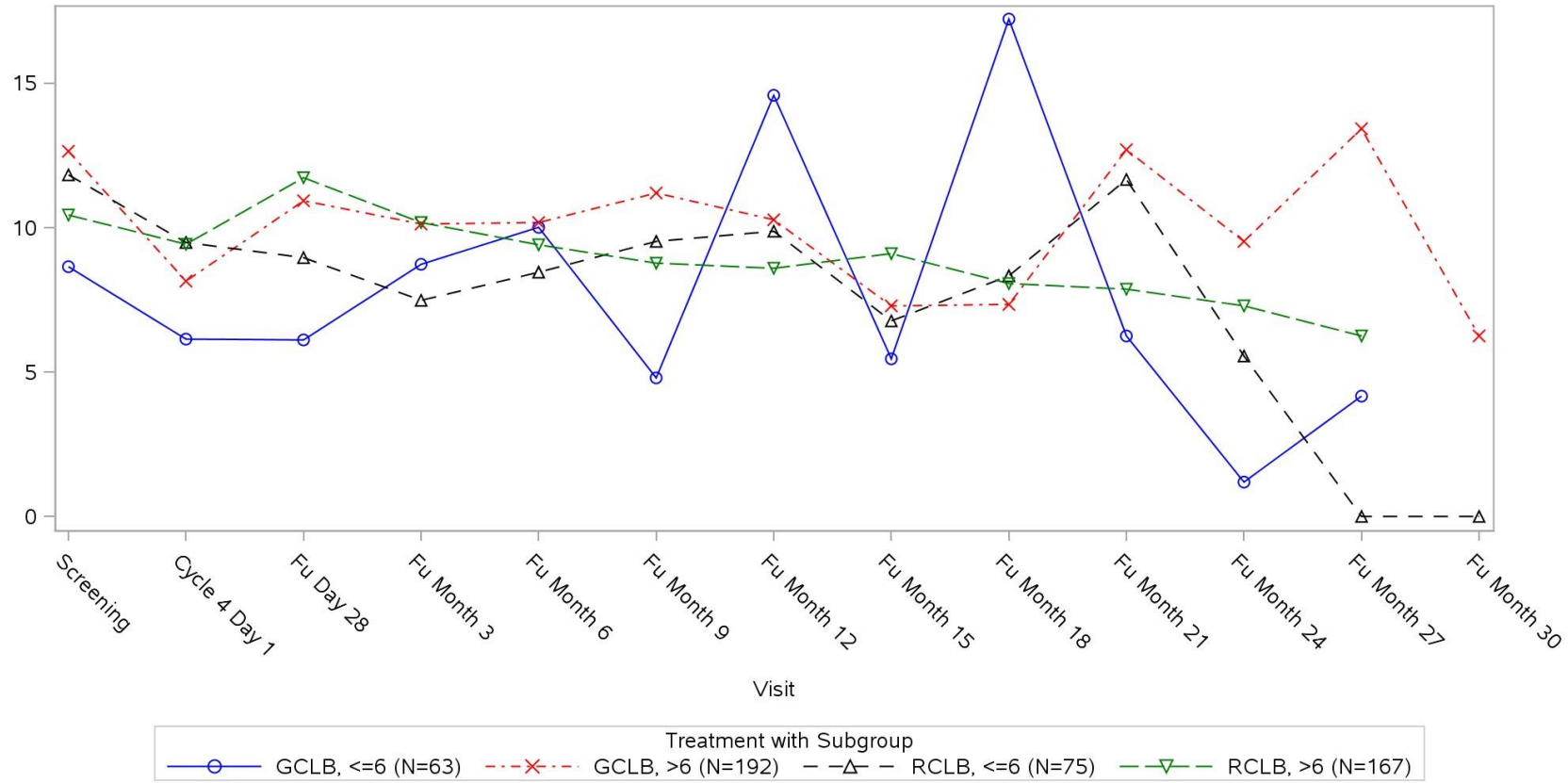
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

Total CIR score at baseline (N=497) Laboratory Test: Infection Scale



Clinical cut-off: 09MAY2013

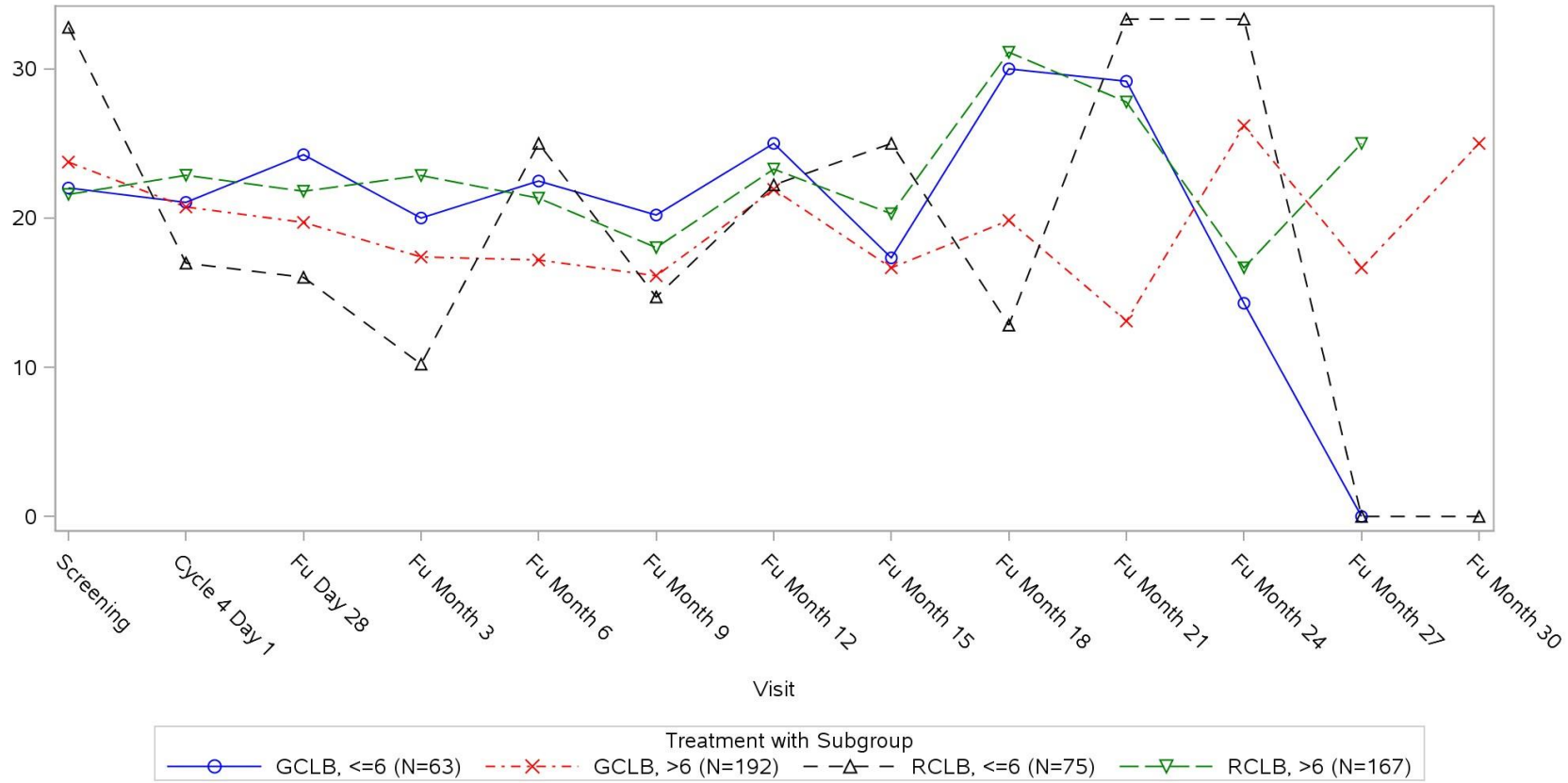
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

Total CIR score at baseline (N=497) Laboratory Test: Social Problems



Clinical cut-off: 09MAY2013

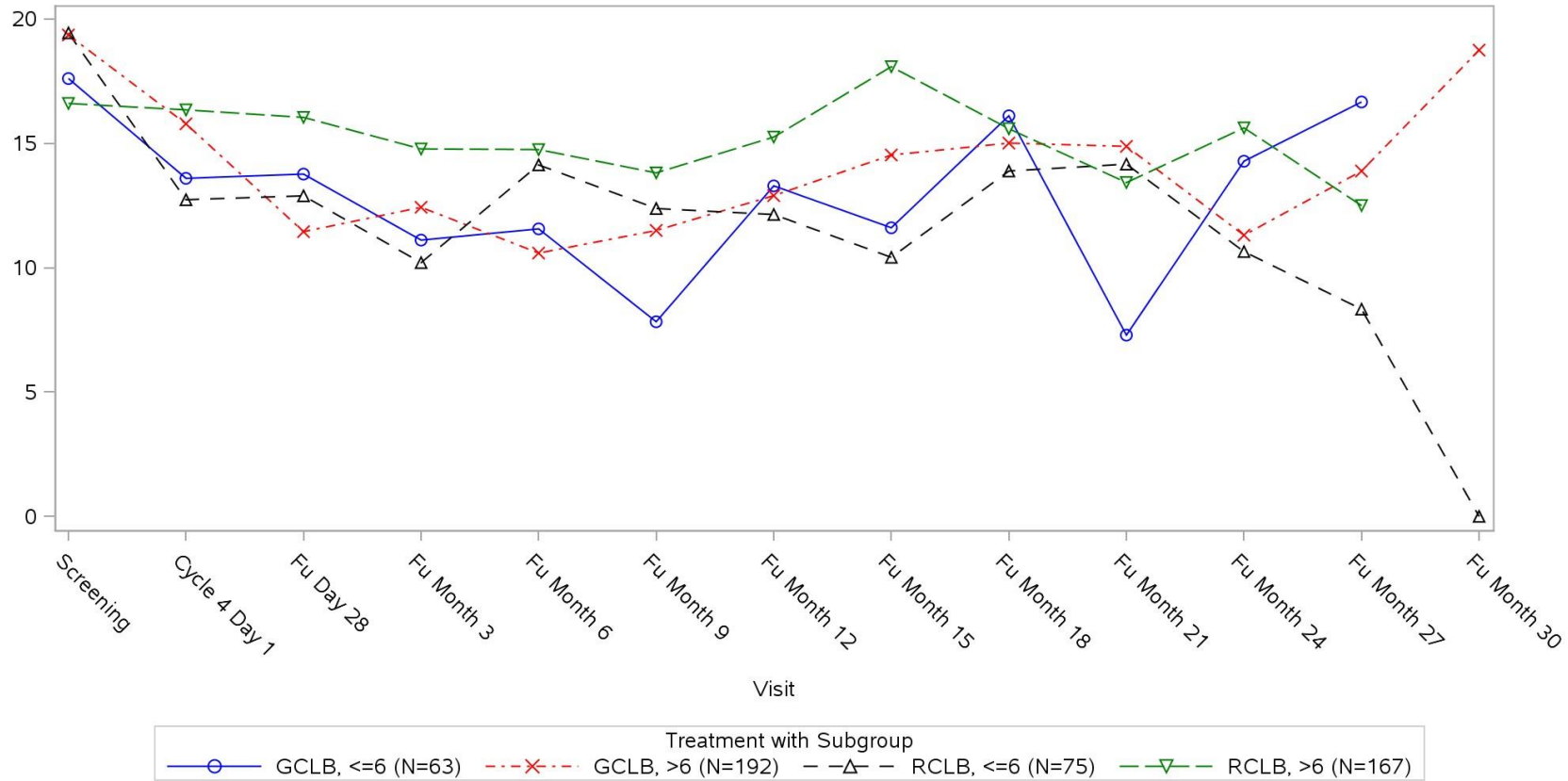
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

Total CIR score at baseline (N=497) Laboratory Test: Treatment Side Effects Scale



Clinical cut-off: 09MAY2013

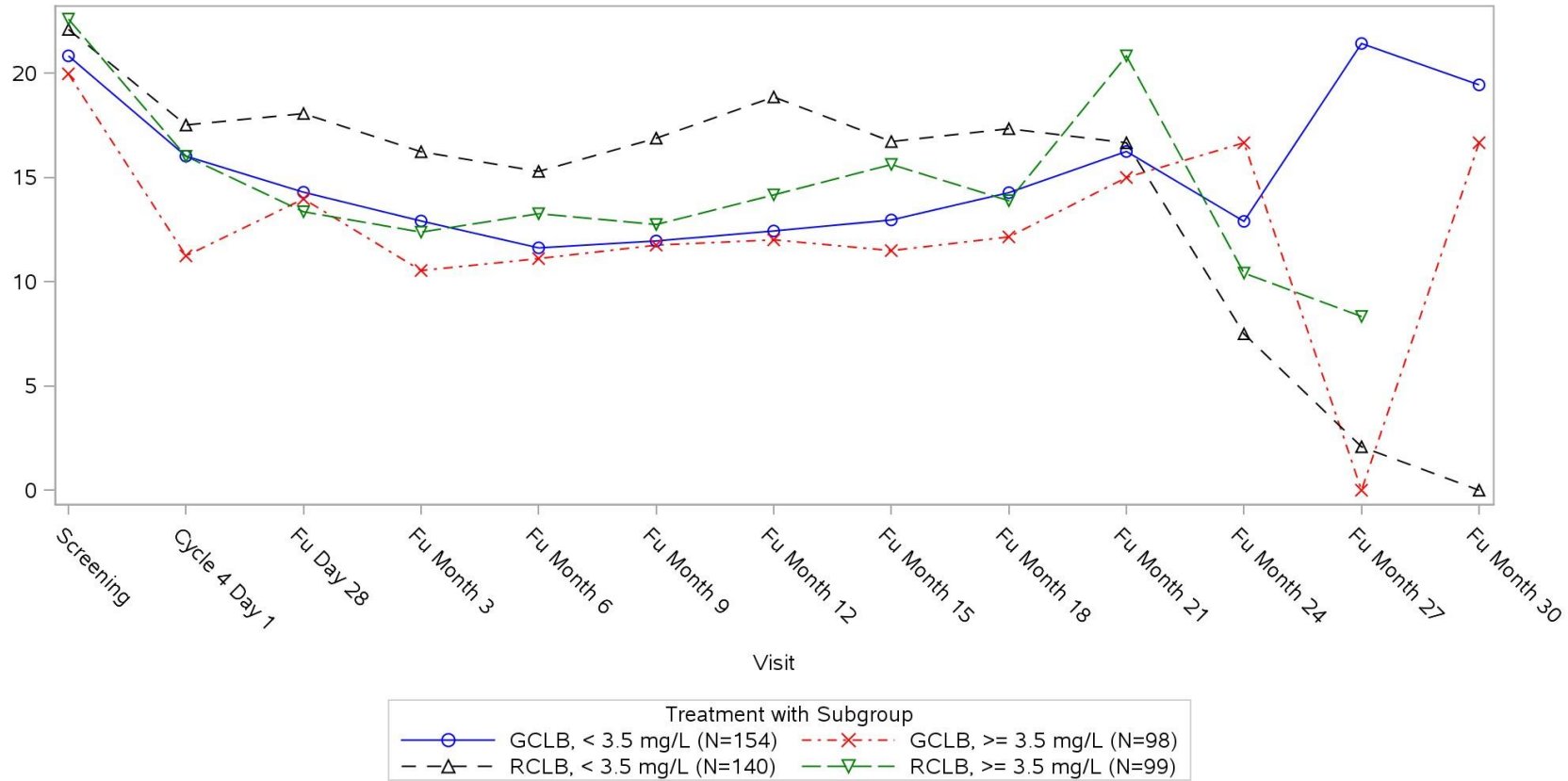
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 04MAR2020 19:13

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

Beta2 microglobulin (N=491) Laboratory Test: Disease Effects Scale



Clinical cut-off: 09MAY2013

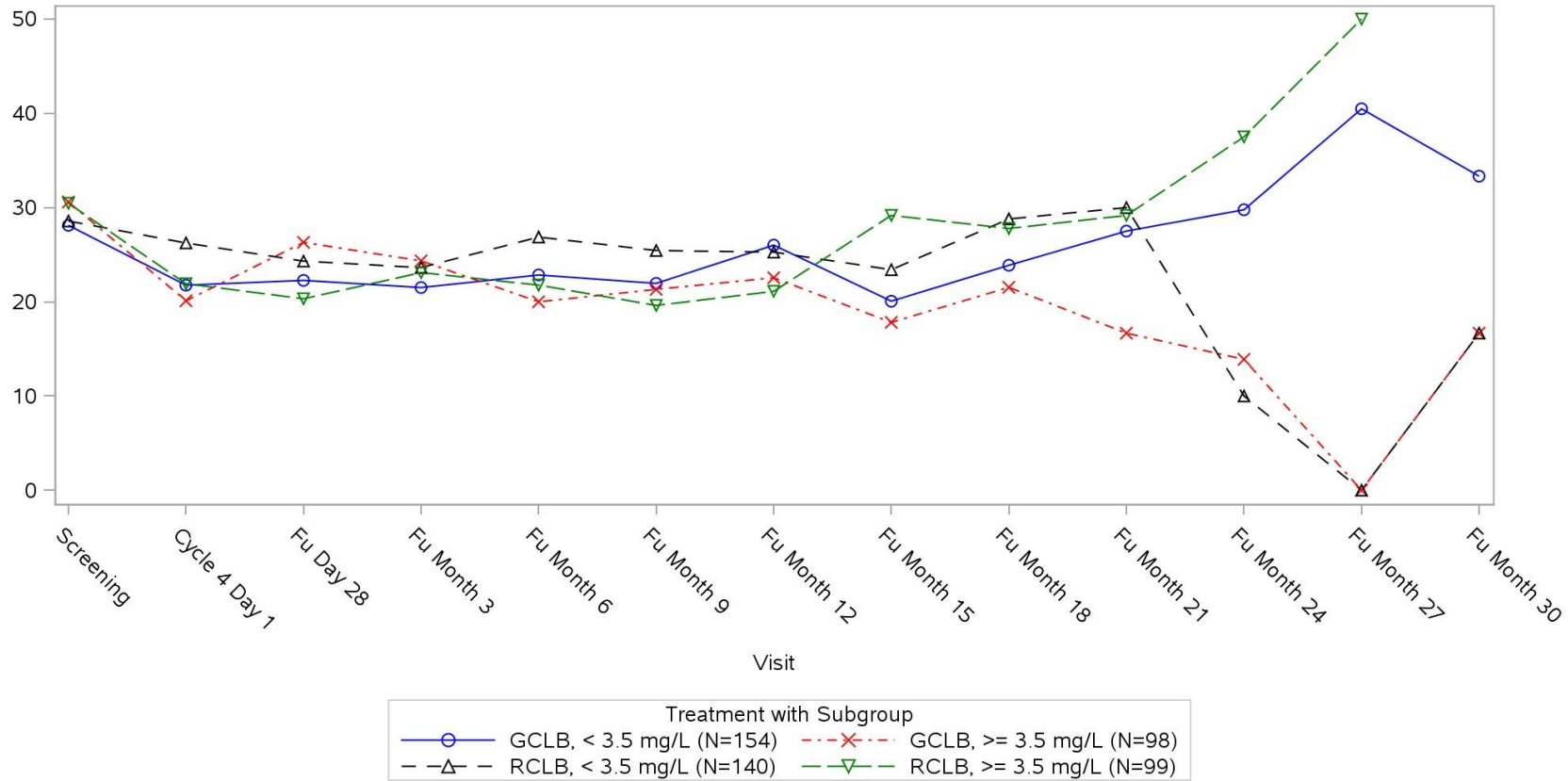
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

Beta2 microglobulin (N=491) Laboratory Test: Fatigue Scale



Clinical cut-off: 09MAY2013

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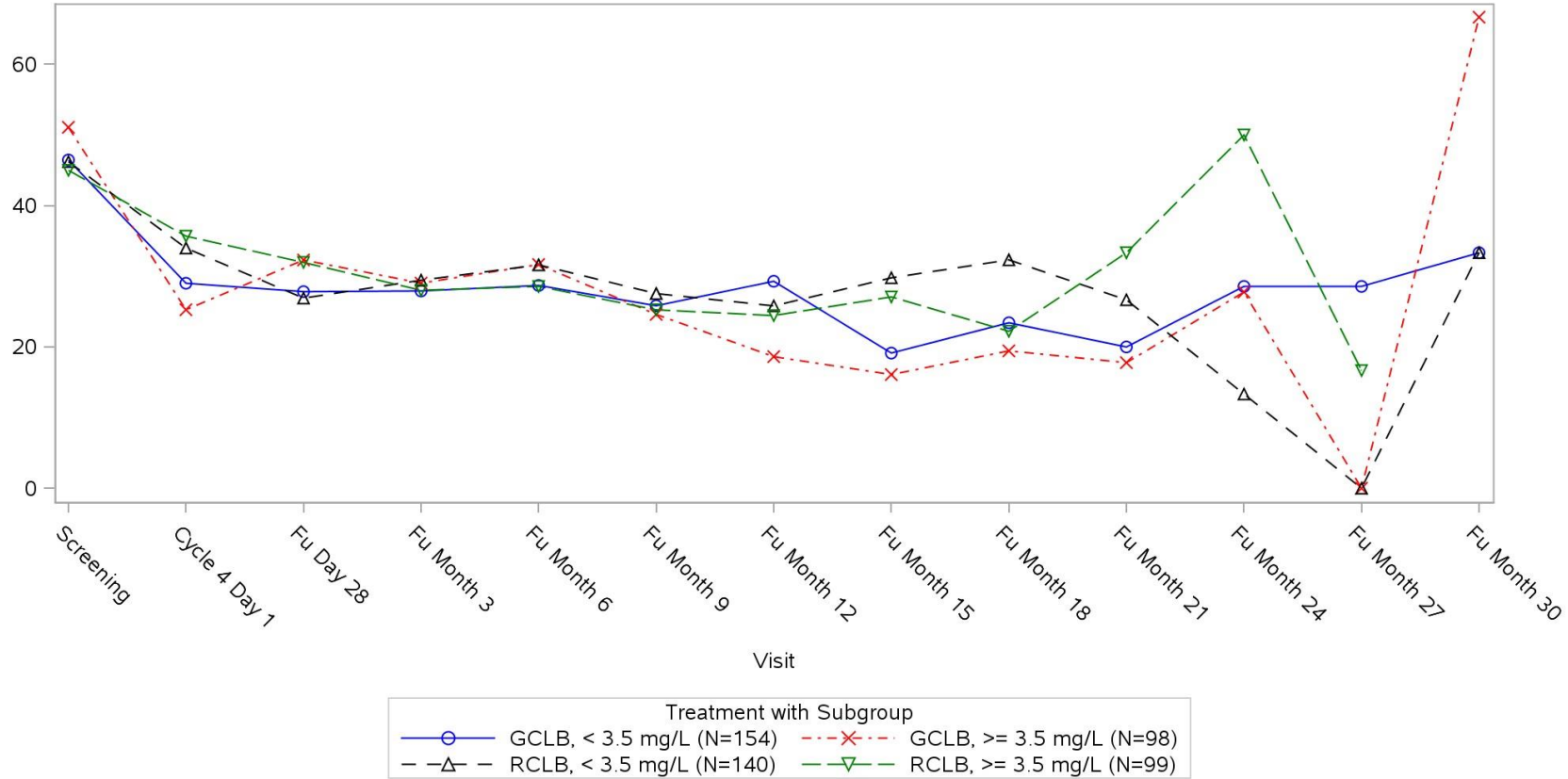
Page 26 of 78

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

Beta2 microglobulin (N=491) Laboratory Test: Future Health



Clinical cut-off: 09MAY2013

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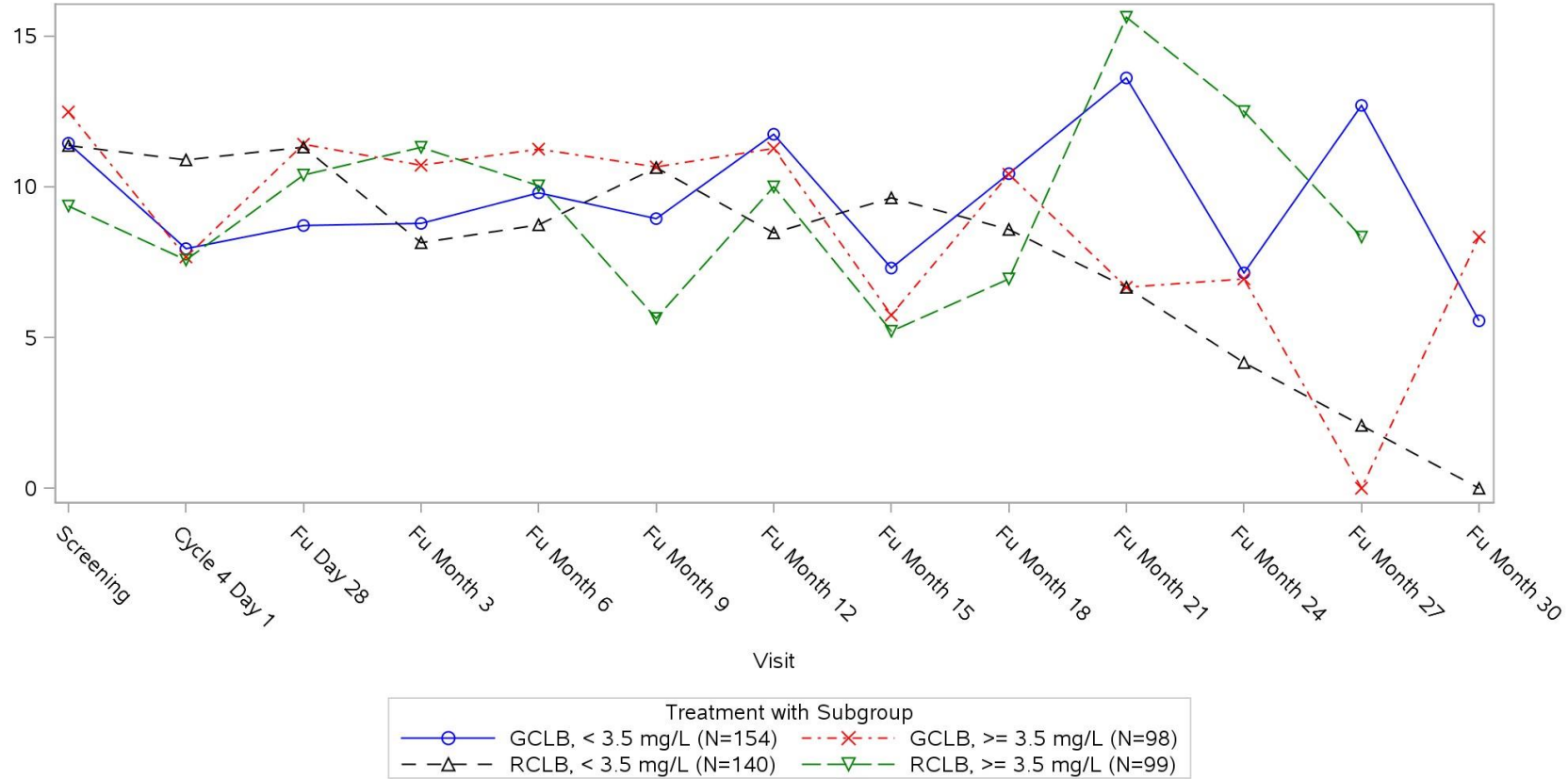
Page 27 of 78

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

Beta2 microglobulin (N=491) Laboratory Test: Infection Scale



Clinical cut-off: 09MAY2013

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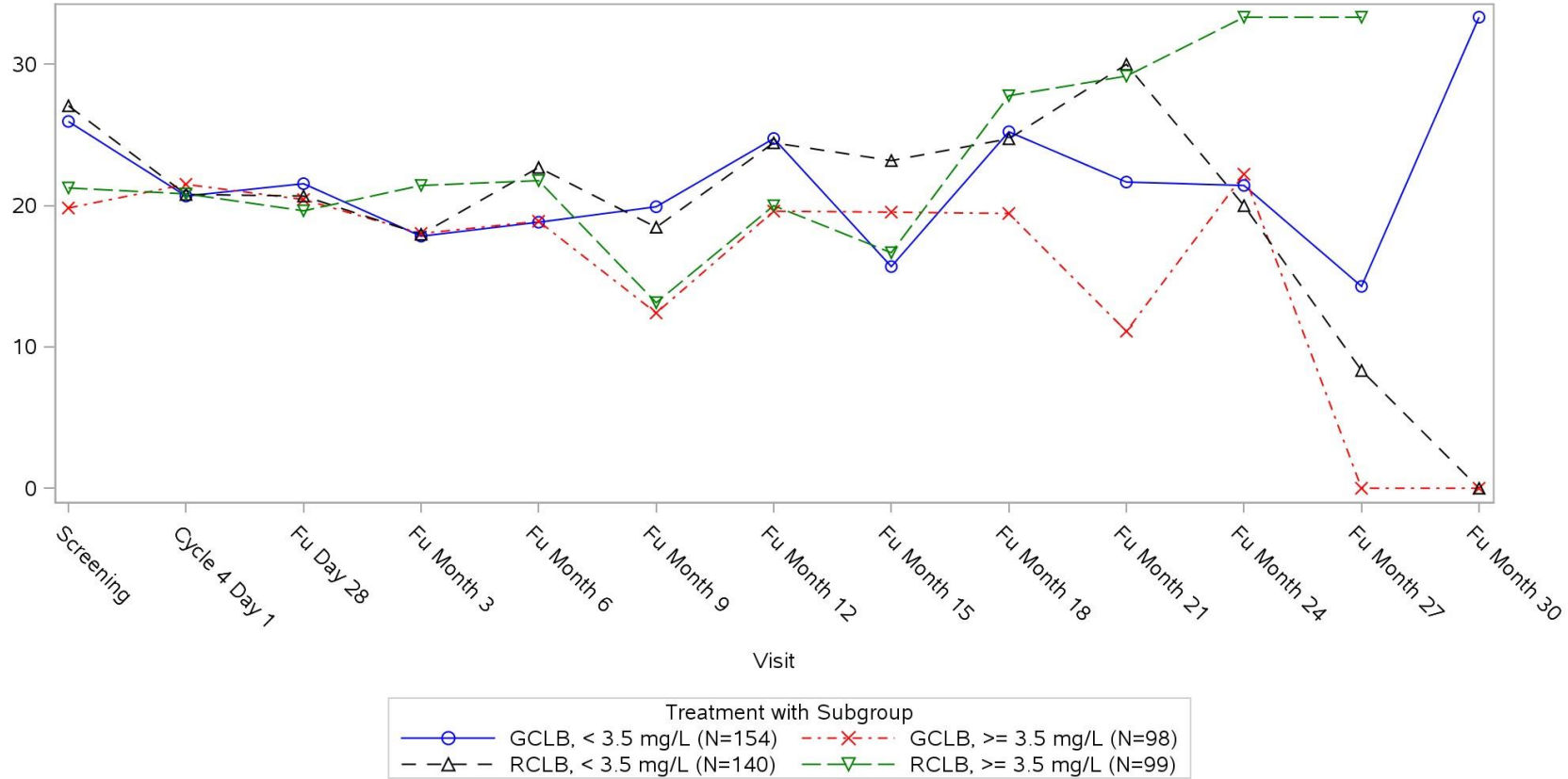
Page 28 of 78

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

Beta2 microglobulin (N=491) Laboratory Test: Social Problems



Clinical cut-off: 09MAY2013

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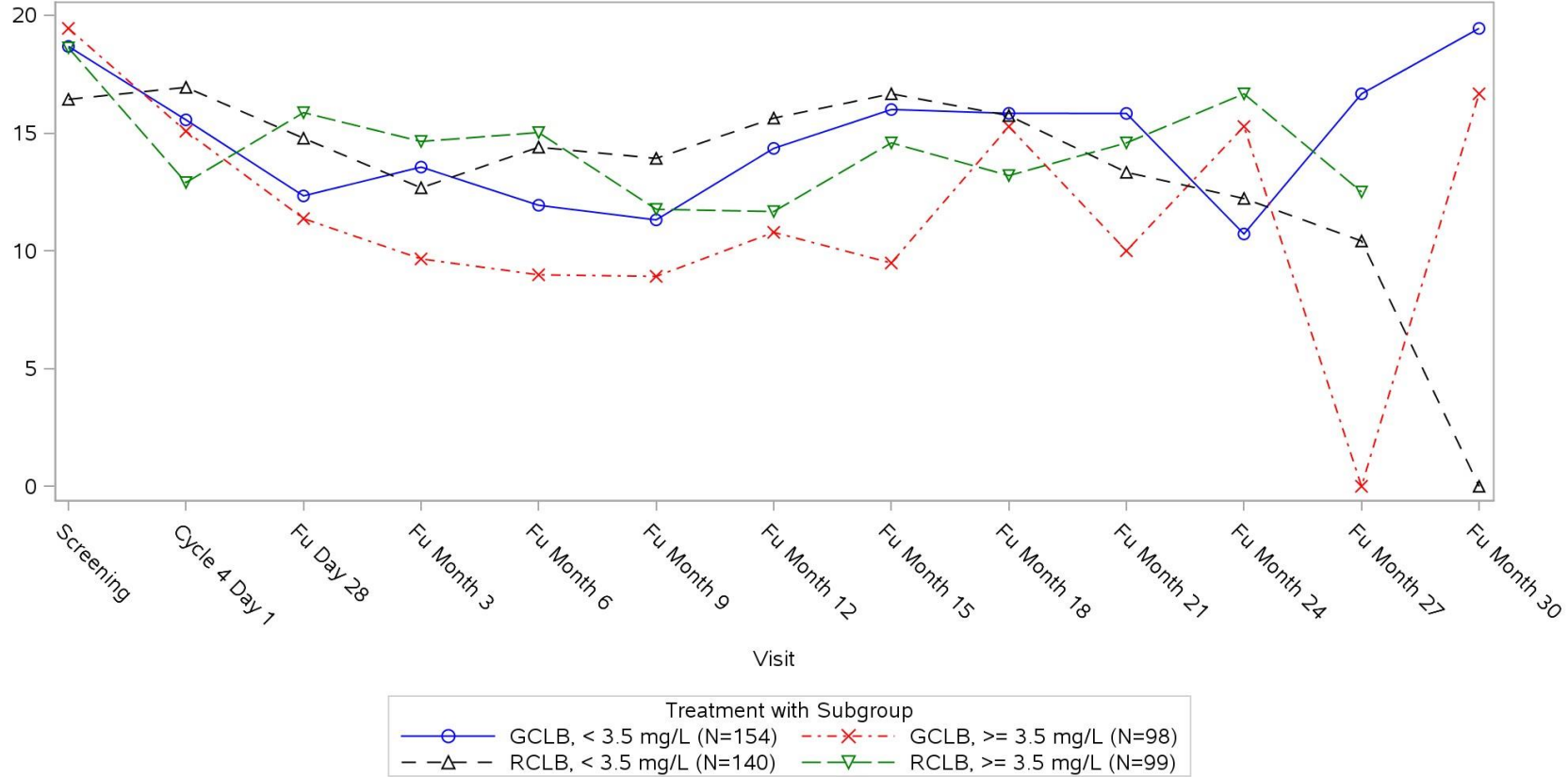
Page 29 of 78

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

Beta2 microglobulin (N=491) Laboratory Test: Treatment Side Effects Scale



Clinical cut-off: 09MAY2013

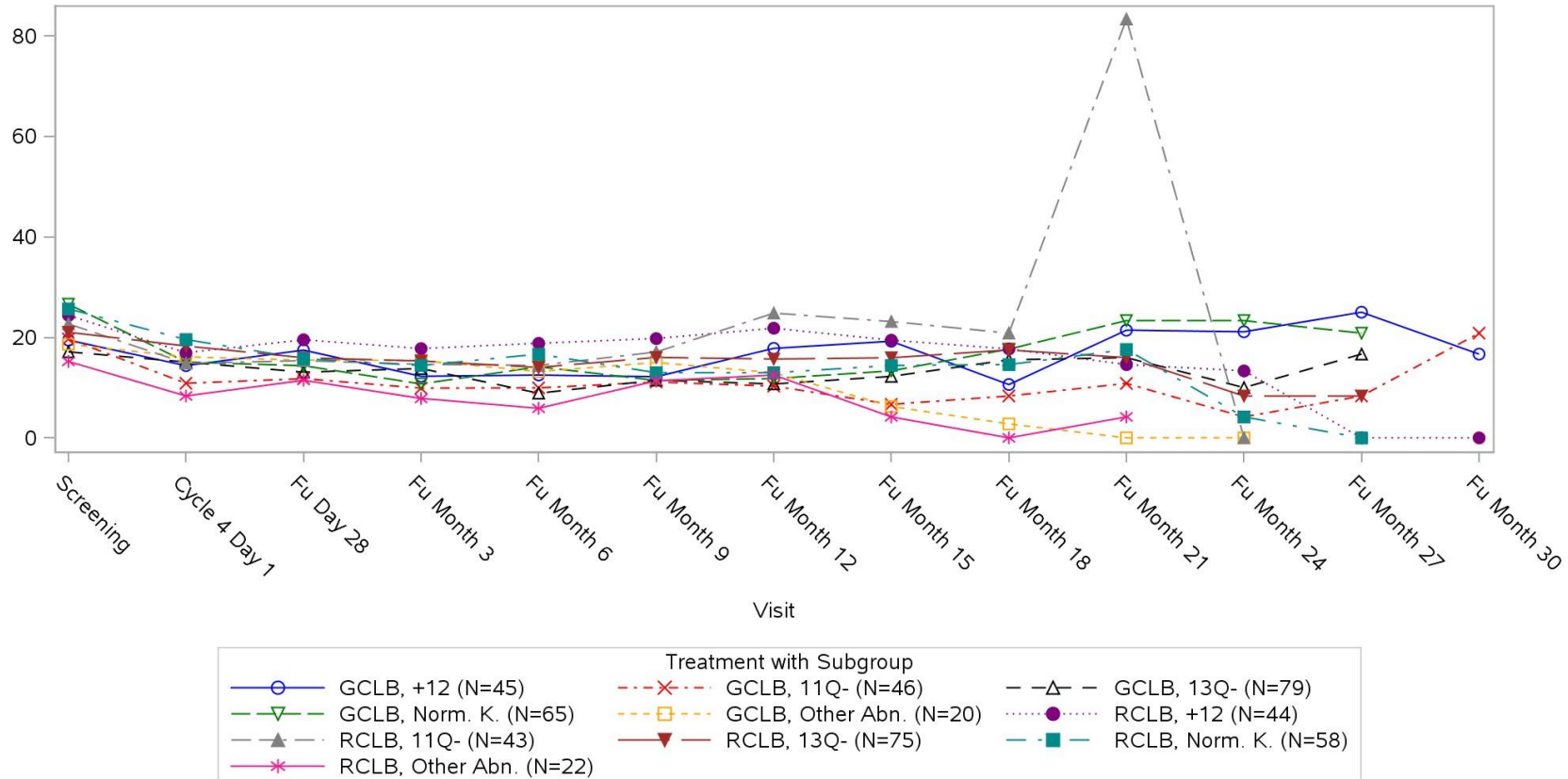
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

Immunoglobulin VH, cytogenetics 2 (N=497) Laboratory Test: Disease Effects Scale



Clinical cut-off: 09MAY2013

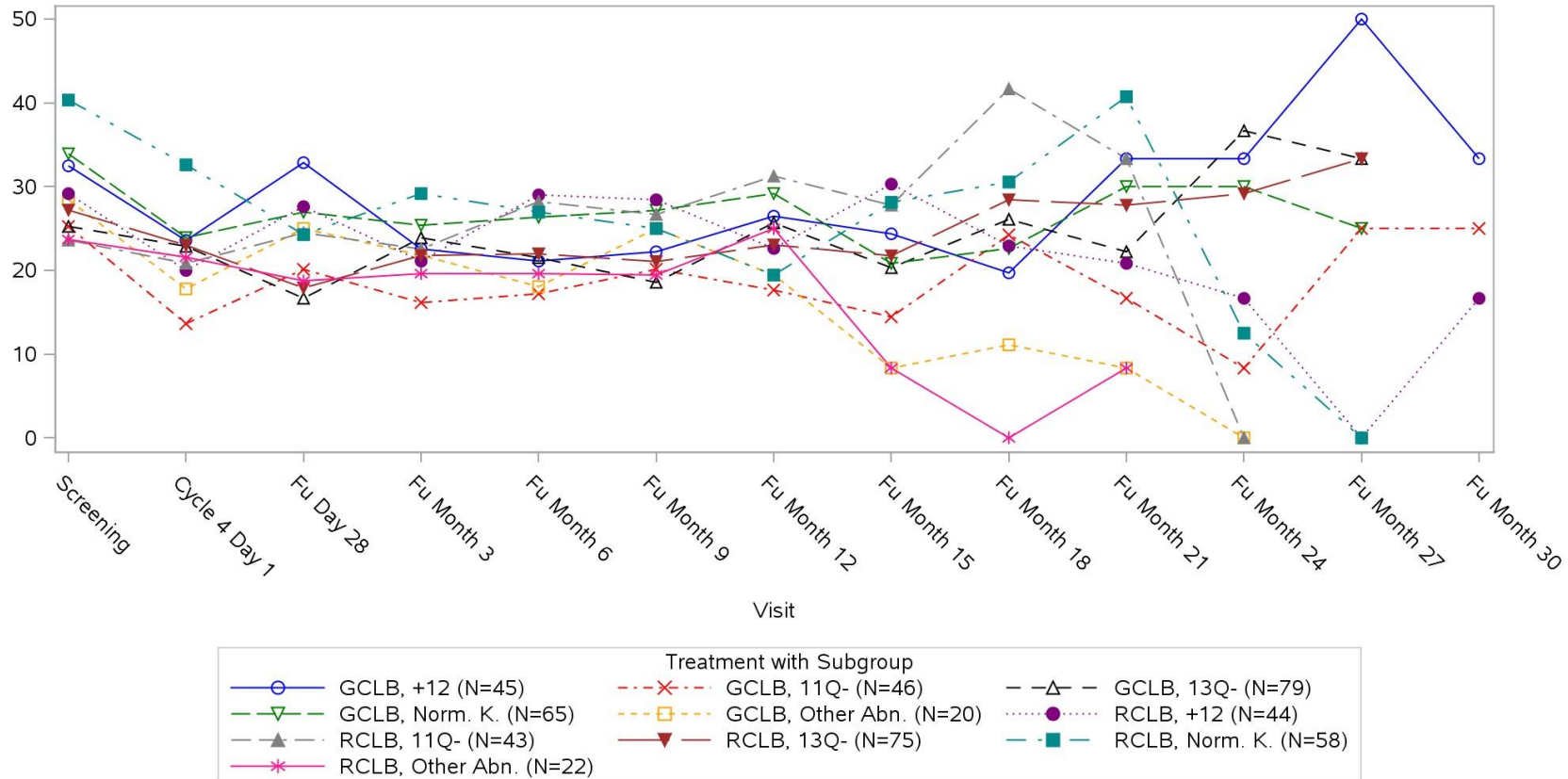
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

Immunogloblin VH, cytogenetics 2 (N=497) Laboratory Test: Fatigue Scale



Clinical cut-off: 09MAY2013

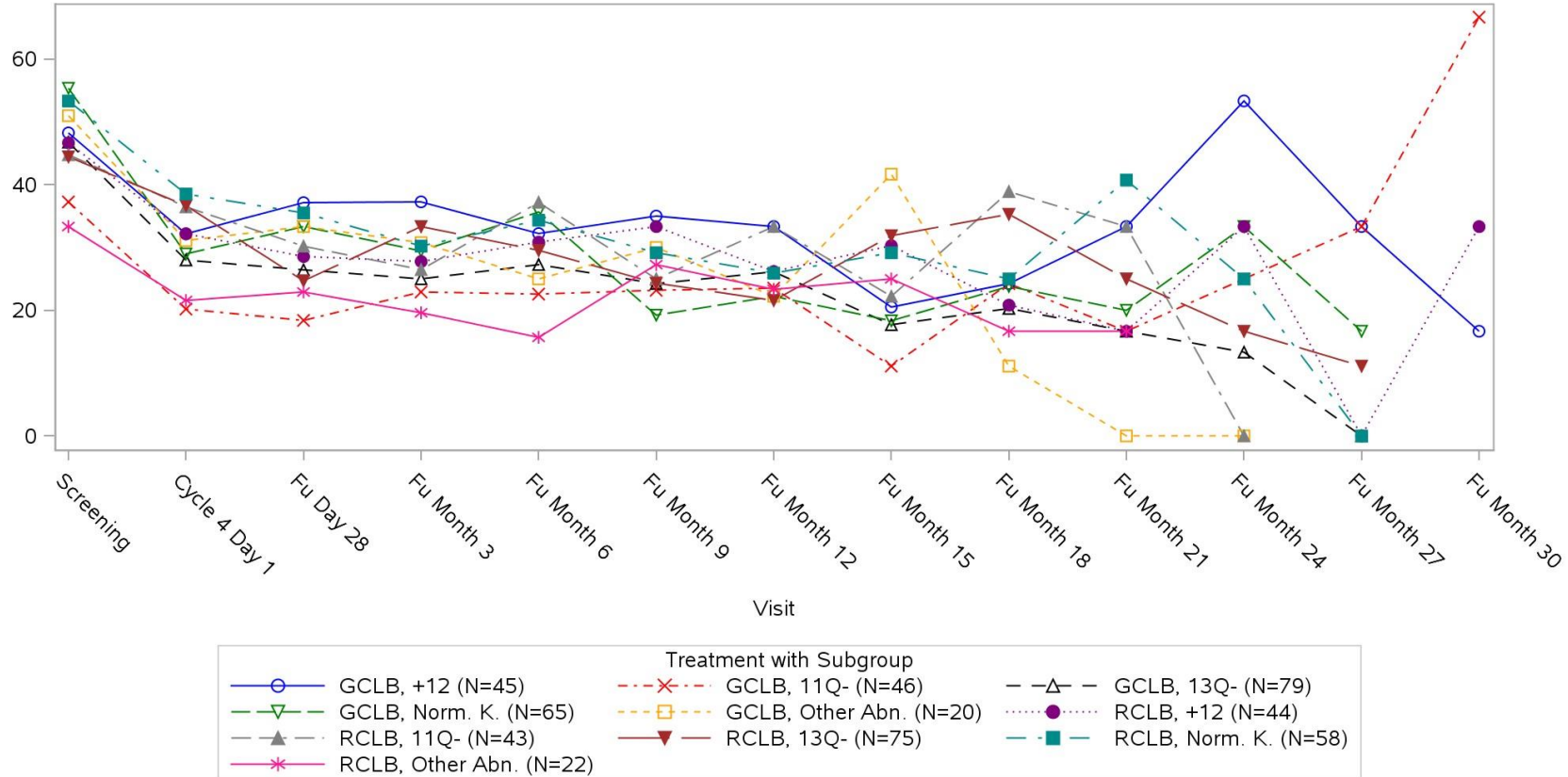
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

Immunoglobulin VH, cytogenetics 2 (N=497) Laboratory Test: Future Health



Clinical cut-off: 09MAY2013

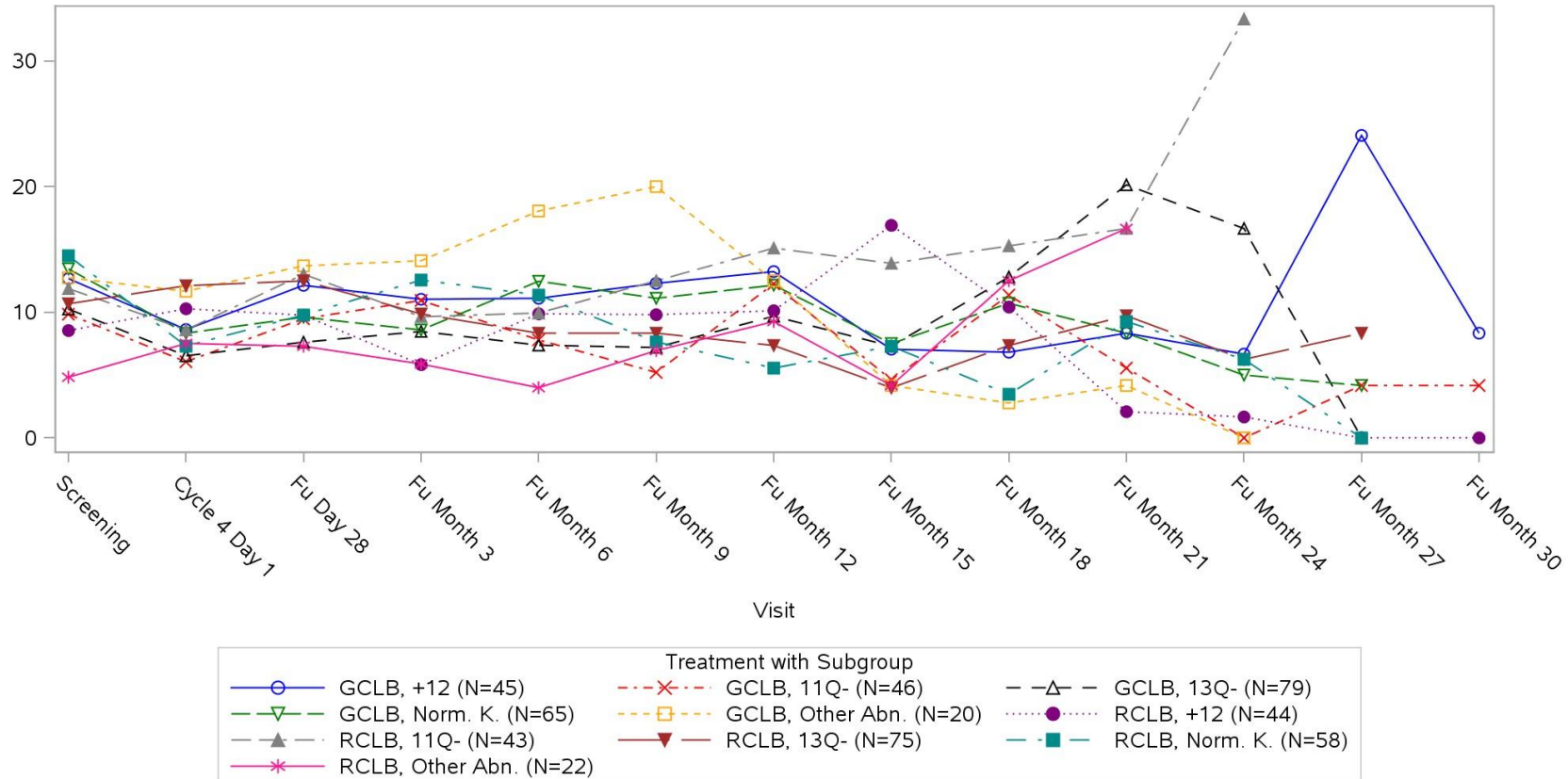
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

Immunoglobulin VH, cytogenetics 2 (N=497) Laboratory Test: Infection Scale



Clinical cut-off: 09MAY2013

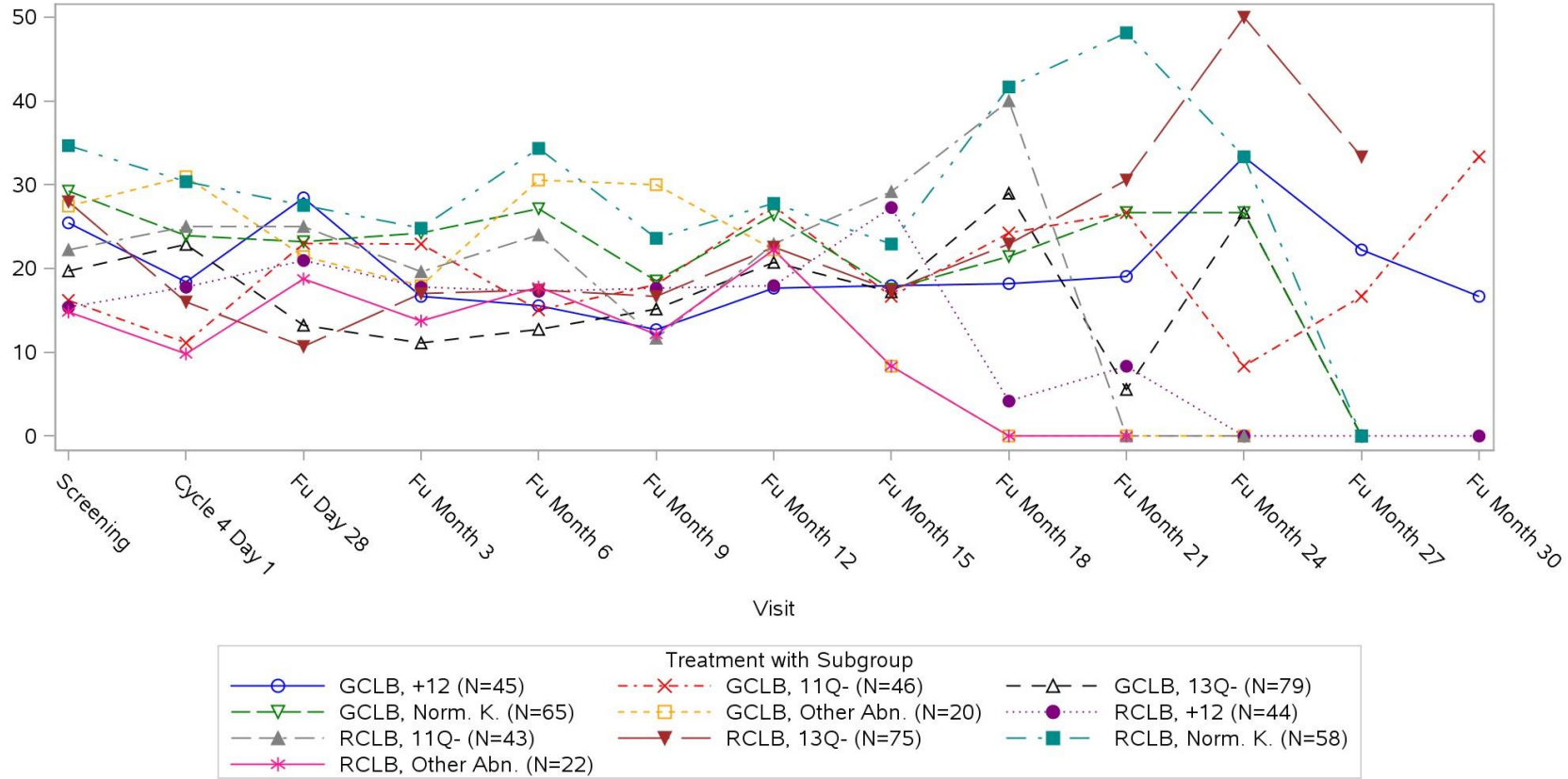
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

Immunogloblin VH, cytogenetics 2 (N=497) Laboratory Test: Social Problems



Clinical cut-off: 09MAY2013

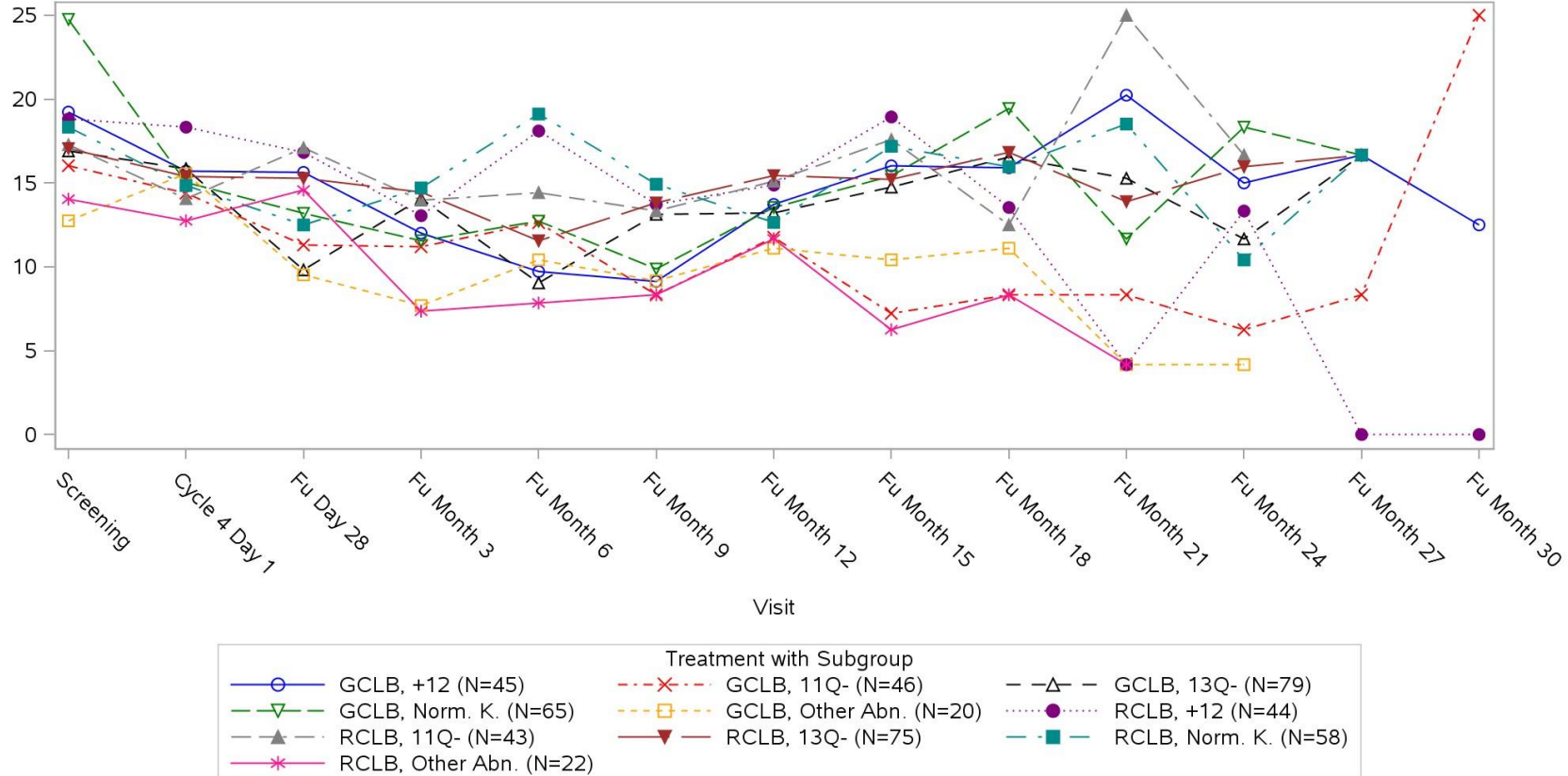
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

Immunoglobulin VH, cytogenetics 2 (N=497) Laboratory Test: Treatment Side Effects Scale



Clinical cut-off: 09MAY2013

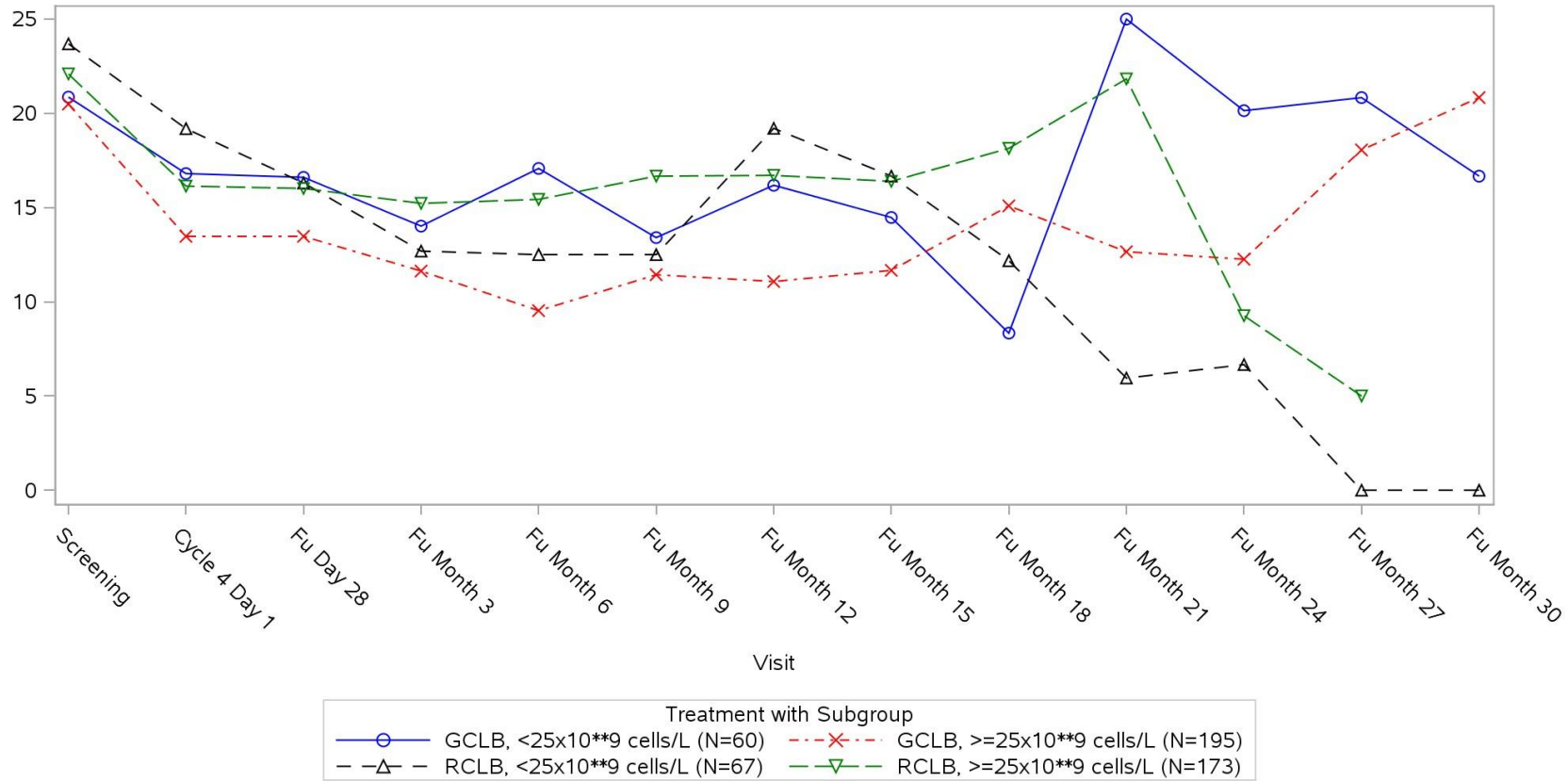
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

High circulating tumor burden (N=495) Laboratory Test: Disease Effects Scale



Clinical cut-off: 09MAY2013

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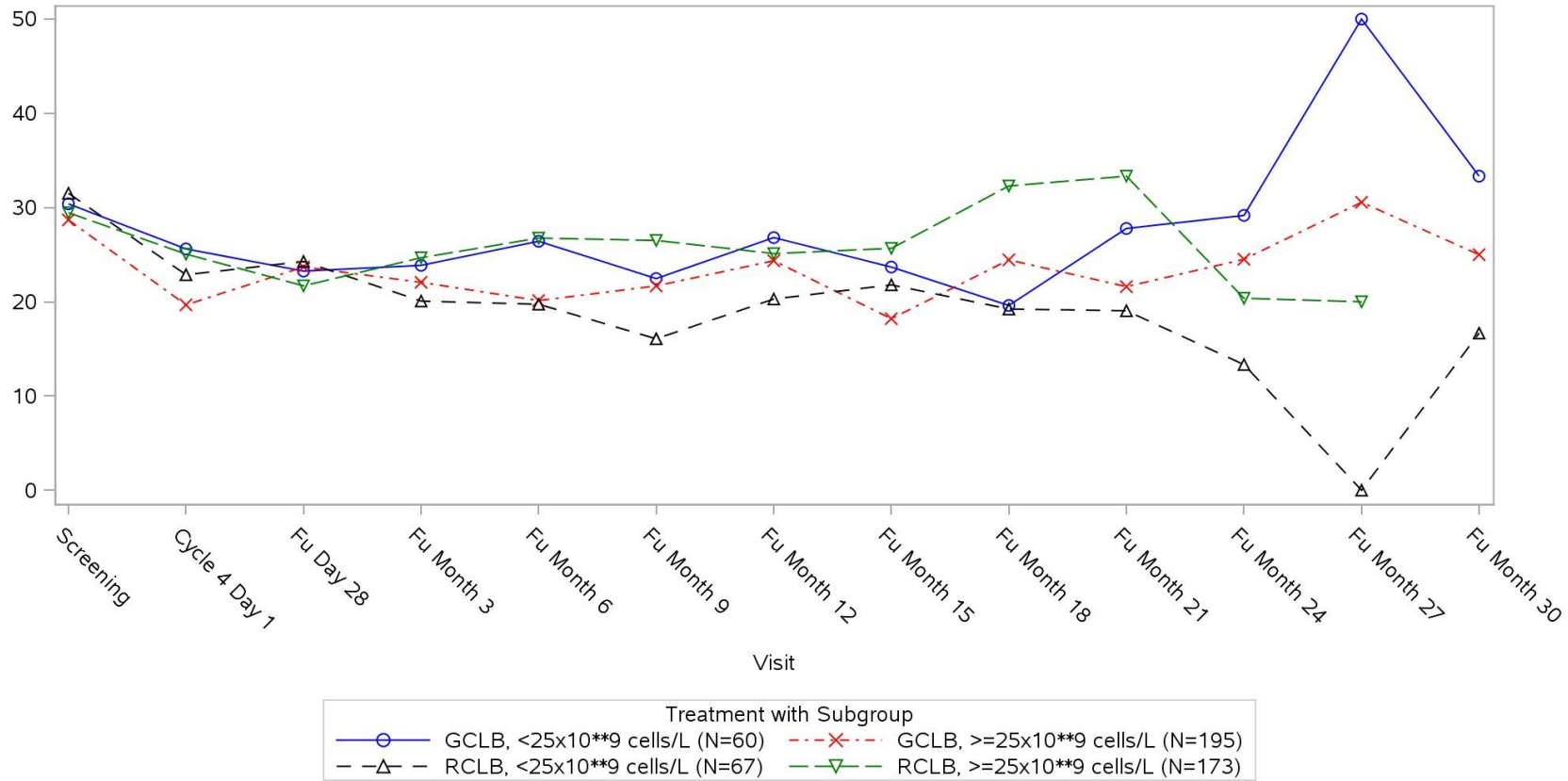
Page 37 of 78

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

High circulating tumor burden (N=495) Laboratory Test: Fatigue Scale



Clinical cut-off: 09MAY2013

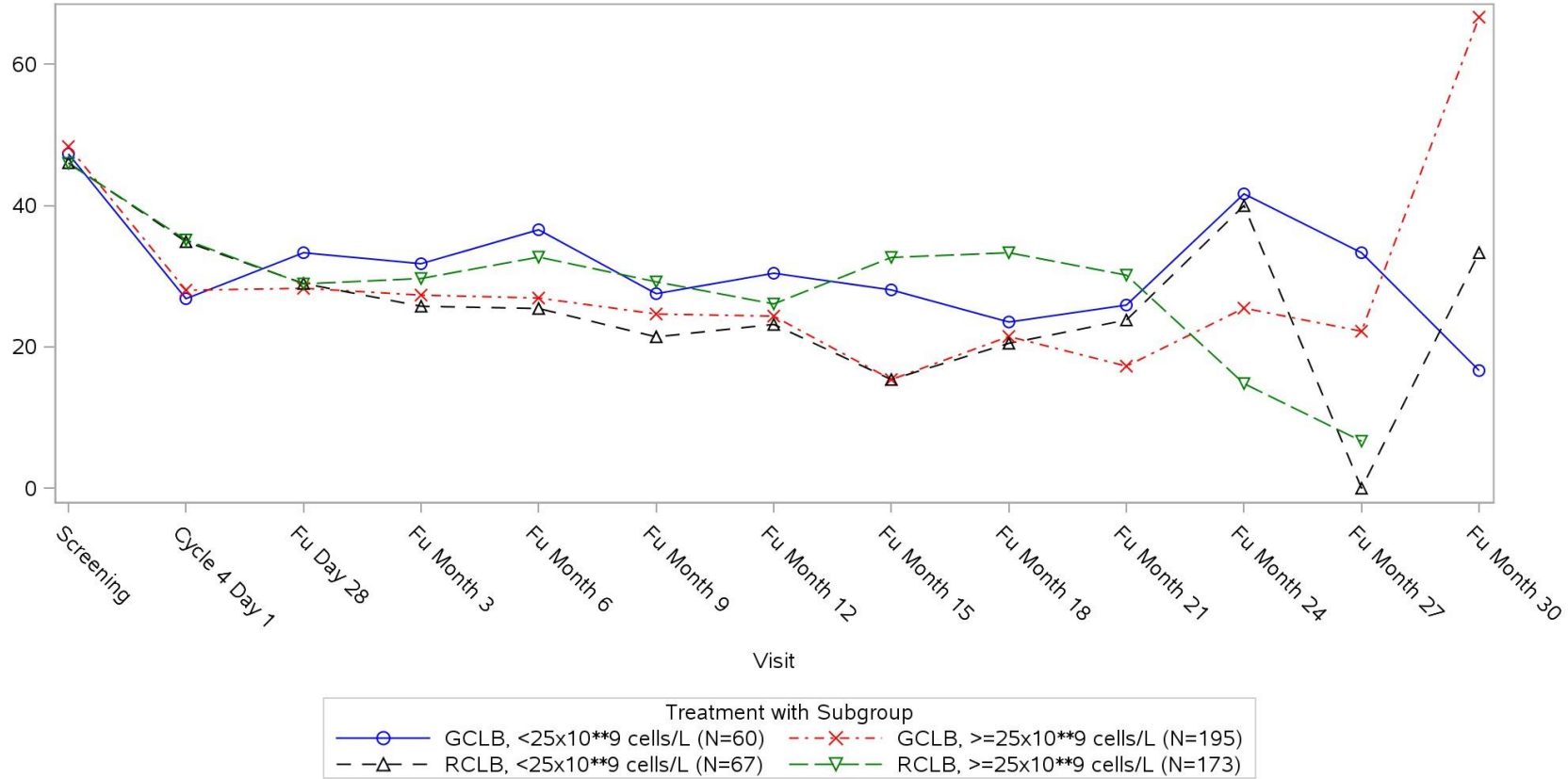
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

High circulating tumor burden (N=495) Laboratory Test: Future Health



Clinical cut-off: 09MAY2013

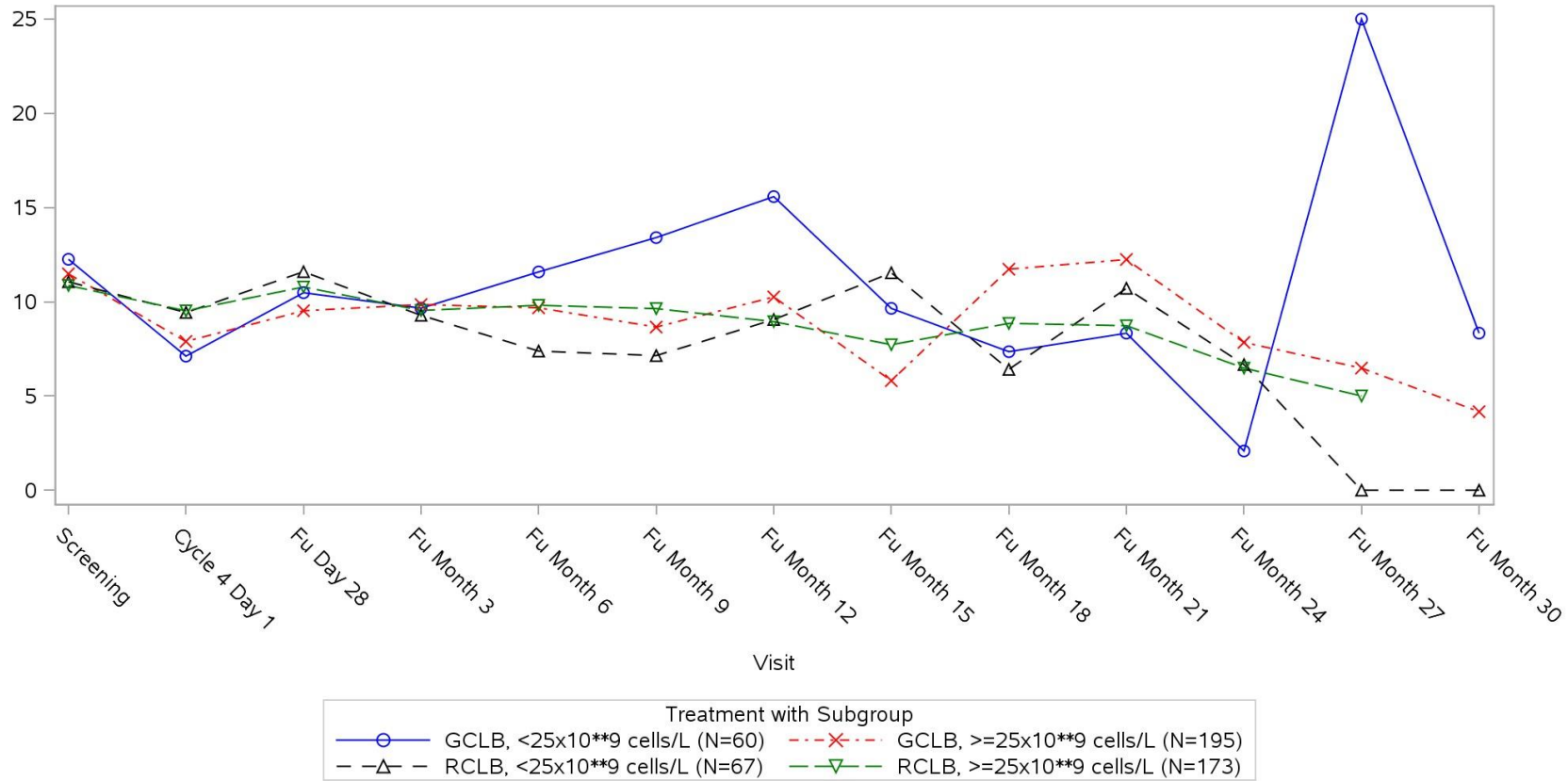
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

High circulating tumor burden (N=495) Laboratory Test: Infection Scale



Clinical cut-off: 09MAY2013

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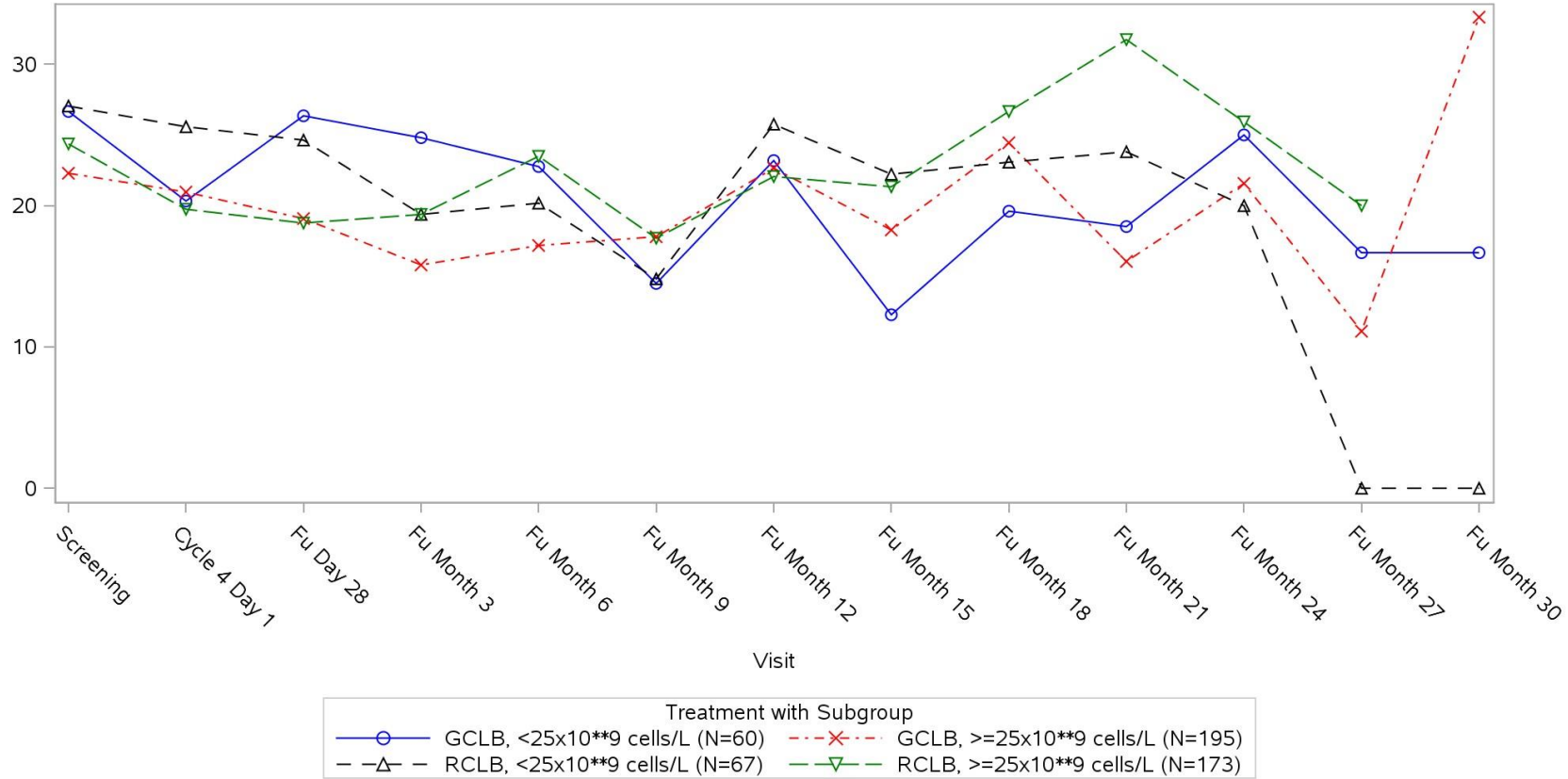
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

High circulating tumor burden (N=495) Laboratory Test: Social Problems



Clinical cut-off: 09MAY2013

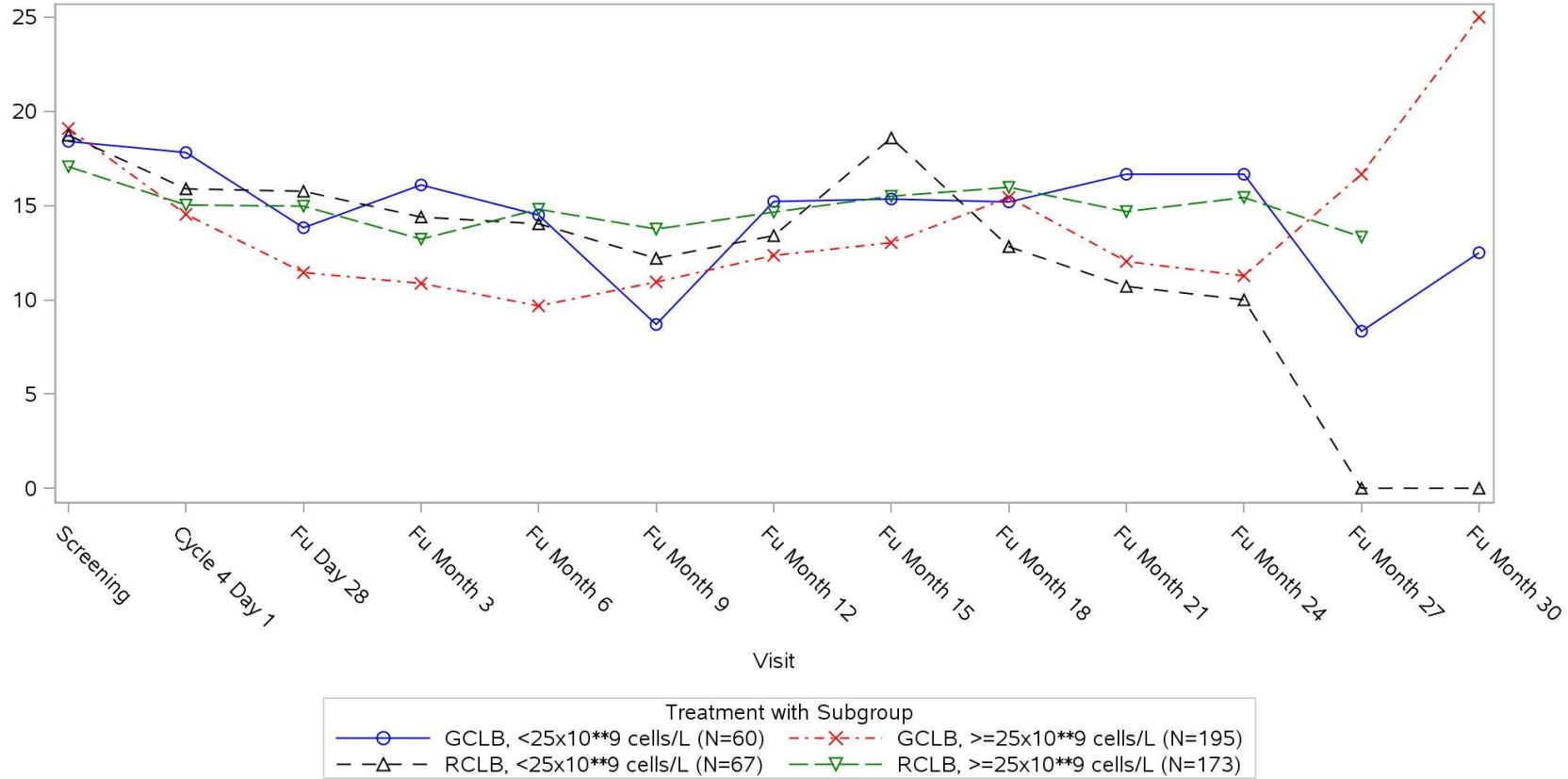
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

High circulating tumor burden (N=495) Laboratory Test: Treatment Side Effects Scale



Clinical cut-off: 09MAY2013

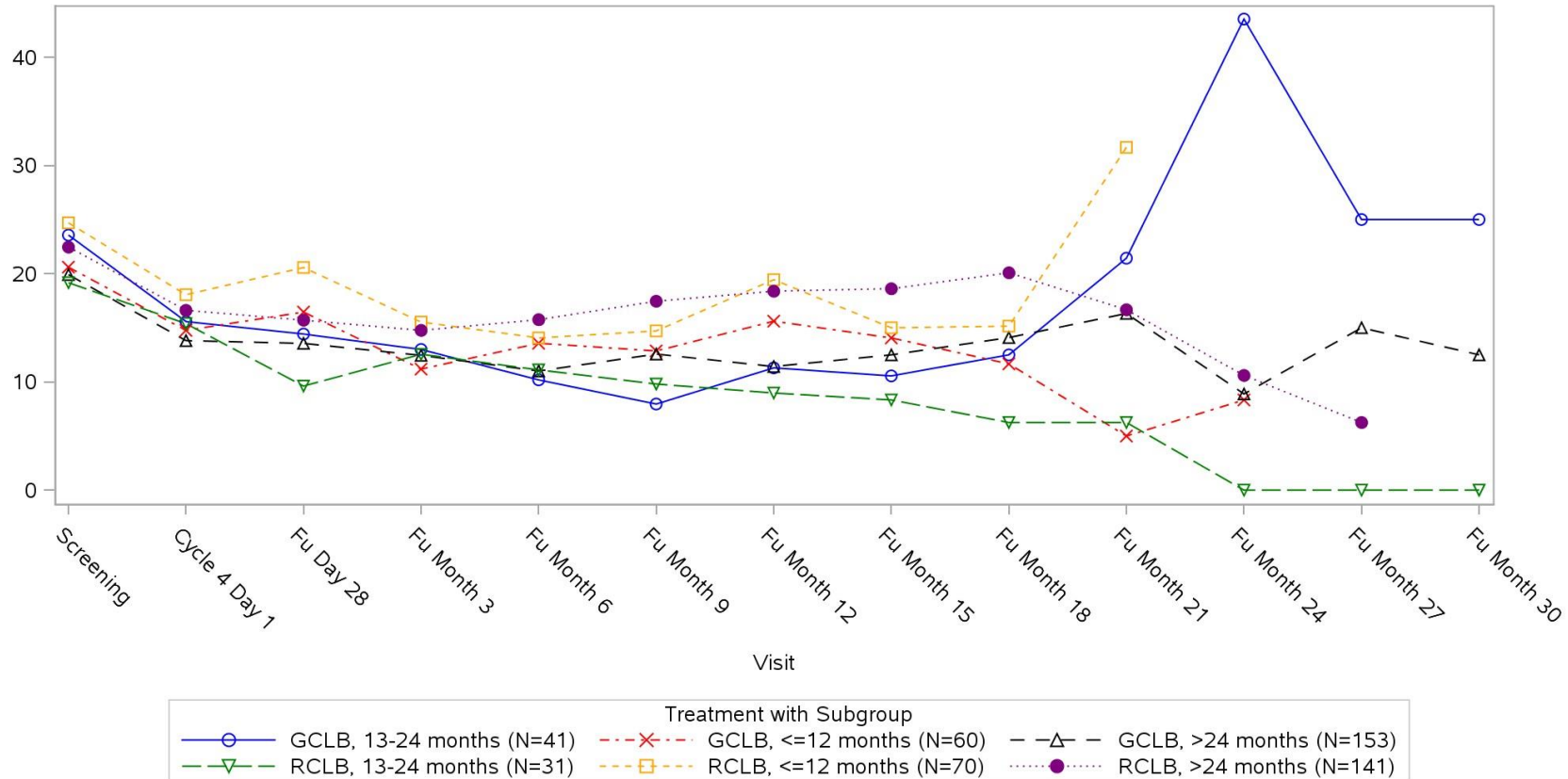
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

Time from first diagnosis (N=496) Laboratory Test: Disease Effects Scale



Clinical cut-off: 09MAY2013

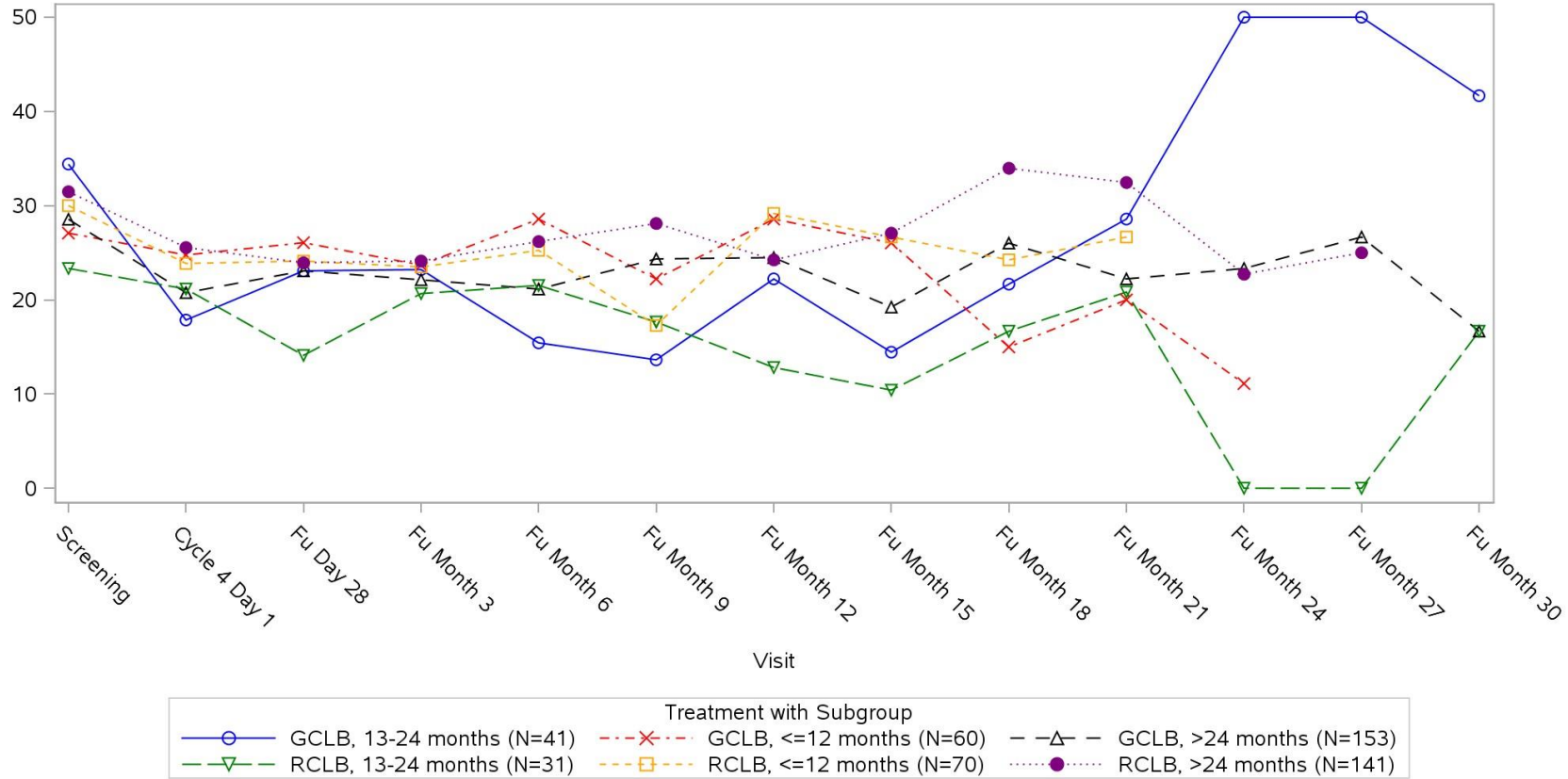
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

Time from first diagnosis (N=496) Laboratory Test: Fatigue Scale



Clinical cut-off: 09MAY2013

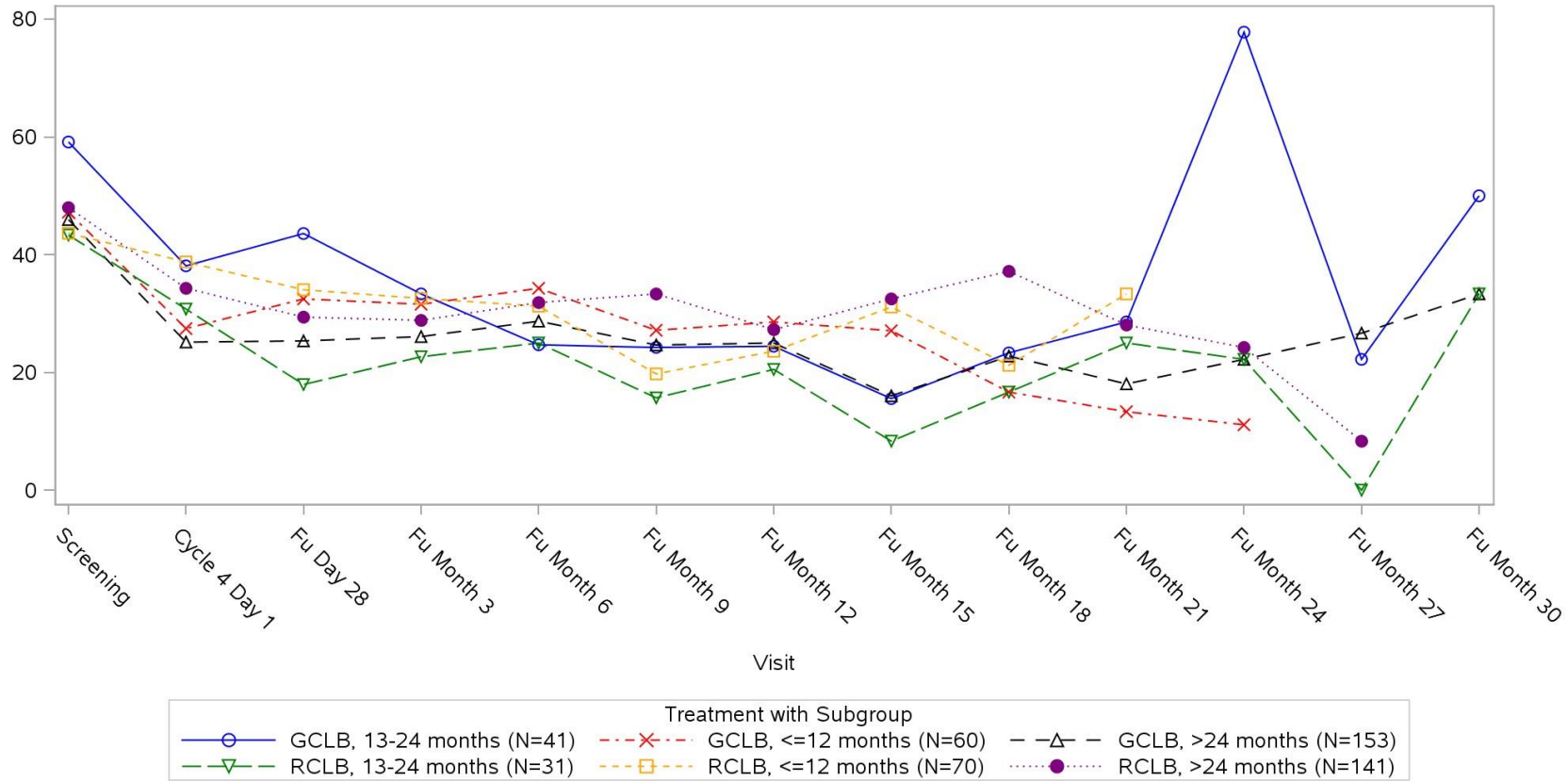
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

Time from first diagnosis (N=496) Laboratory Test: Future Health



Clinical cut-off: 09MAY2013

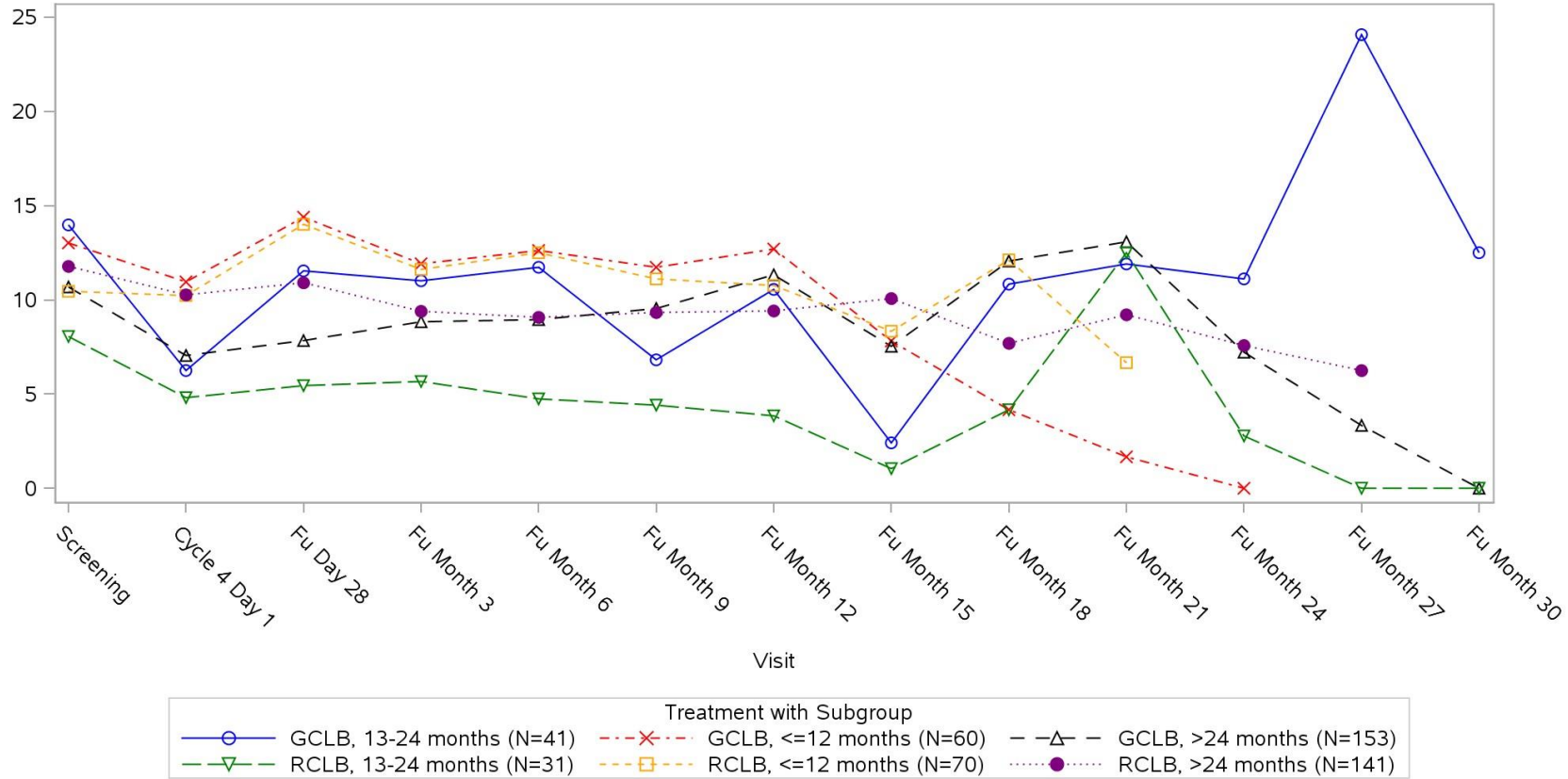
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

Time from first diagnosis (N=496) Laboratory Test: Infection Scale



Clinical cut-off: 09MAY2013

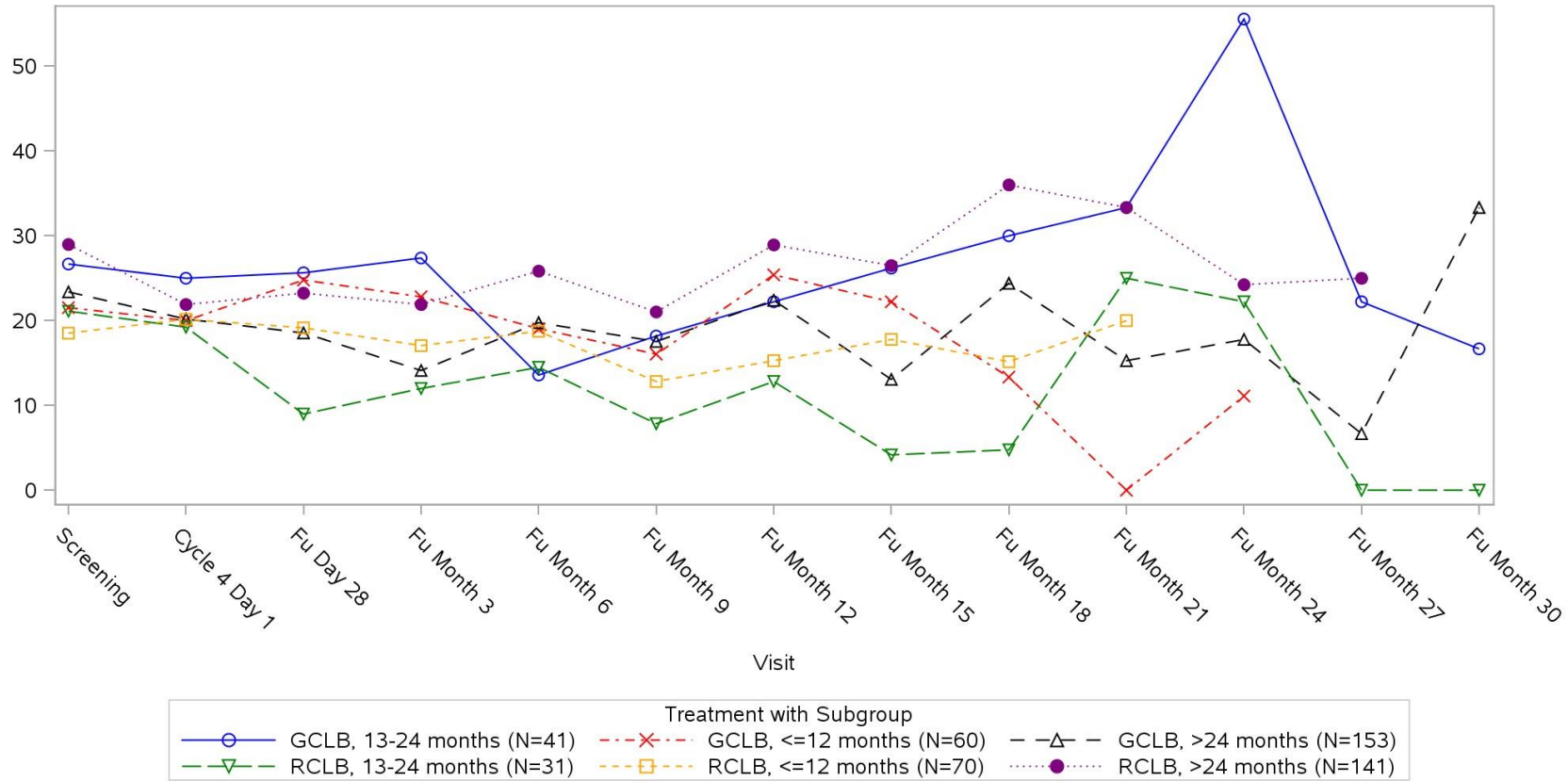
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

Time from first diagnosis (N=496) Laboratory Test: Social Problems



Clinical cut-off: 09MAY2013

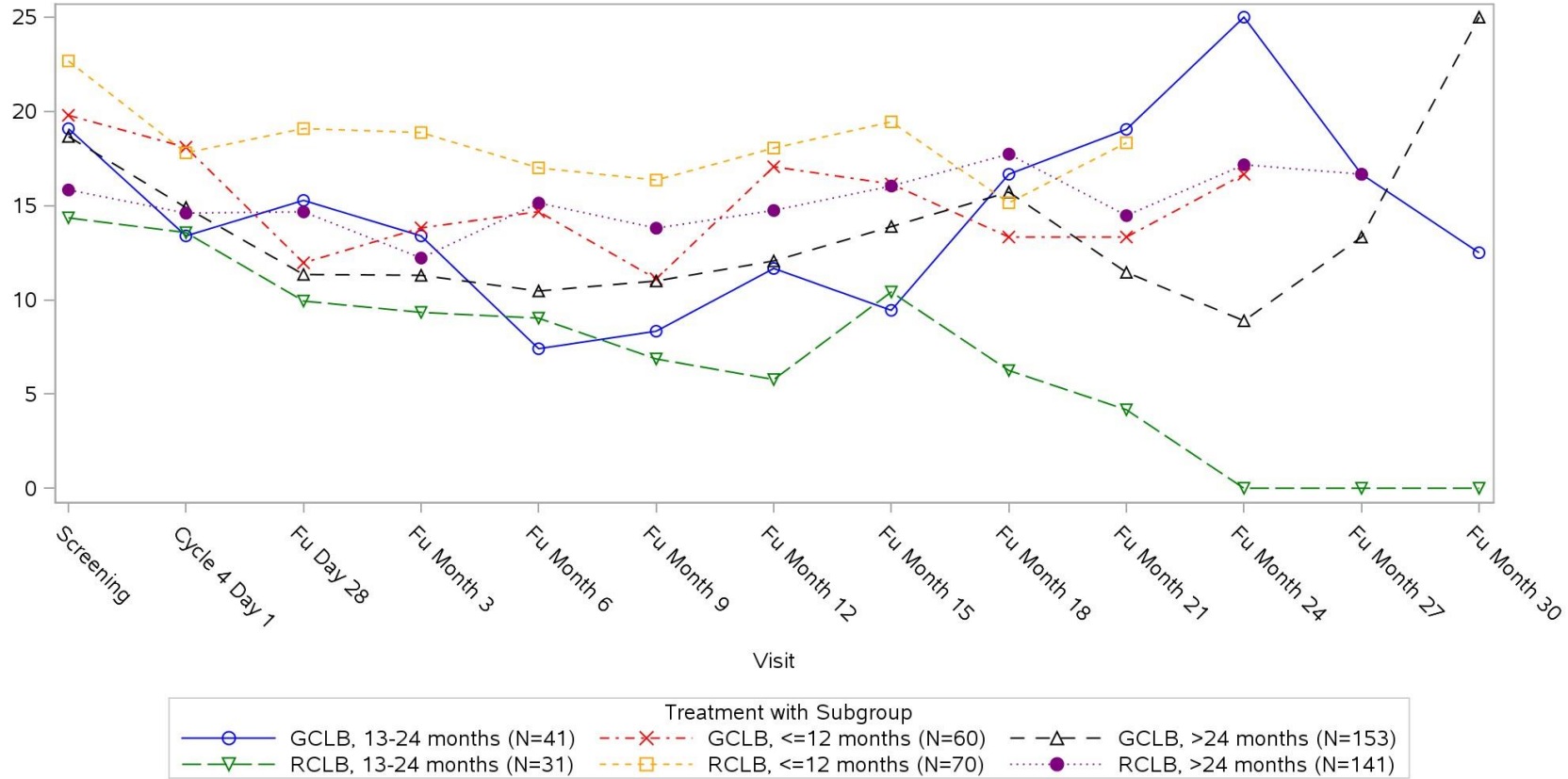
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

Time from first diagnosis (N=496) Laboratory Test: Treatment Side Effects Scale



Clinical cut-off: 09MAY2013

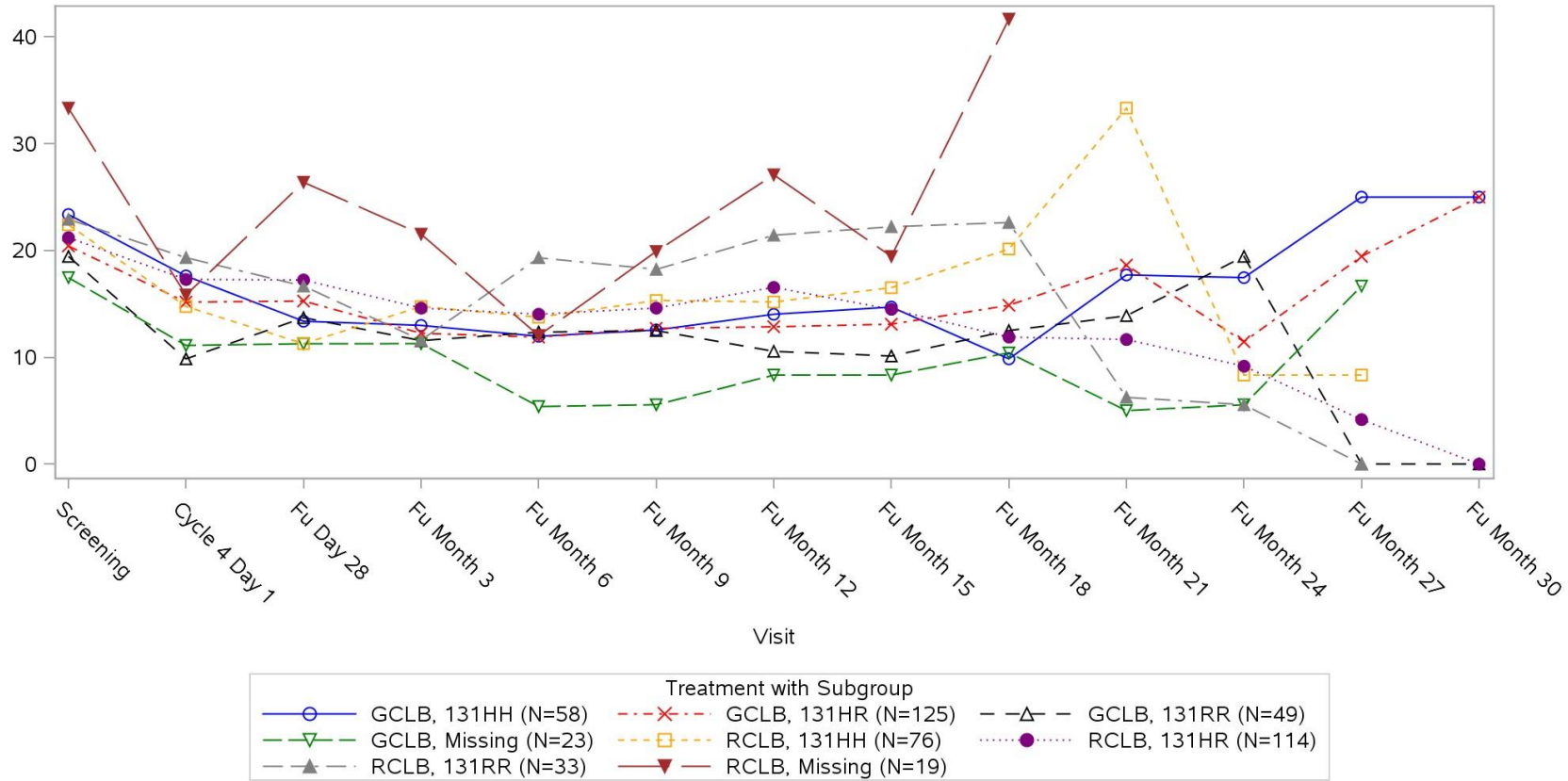
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

FCgamma receptor IIa (N=497) Laboratory Test: Disease Effects Scale



Clinical cut-off: 09MAY2013

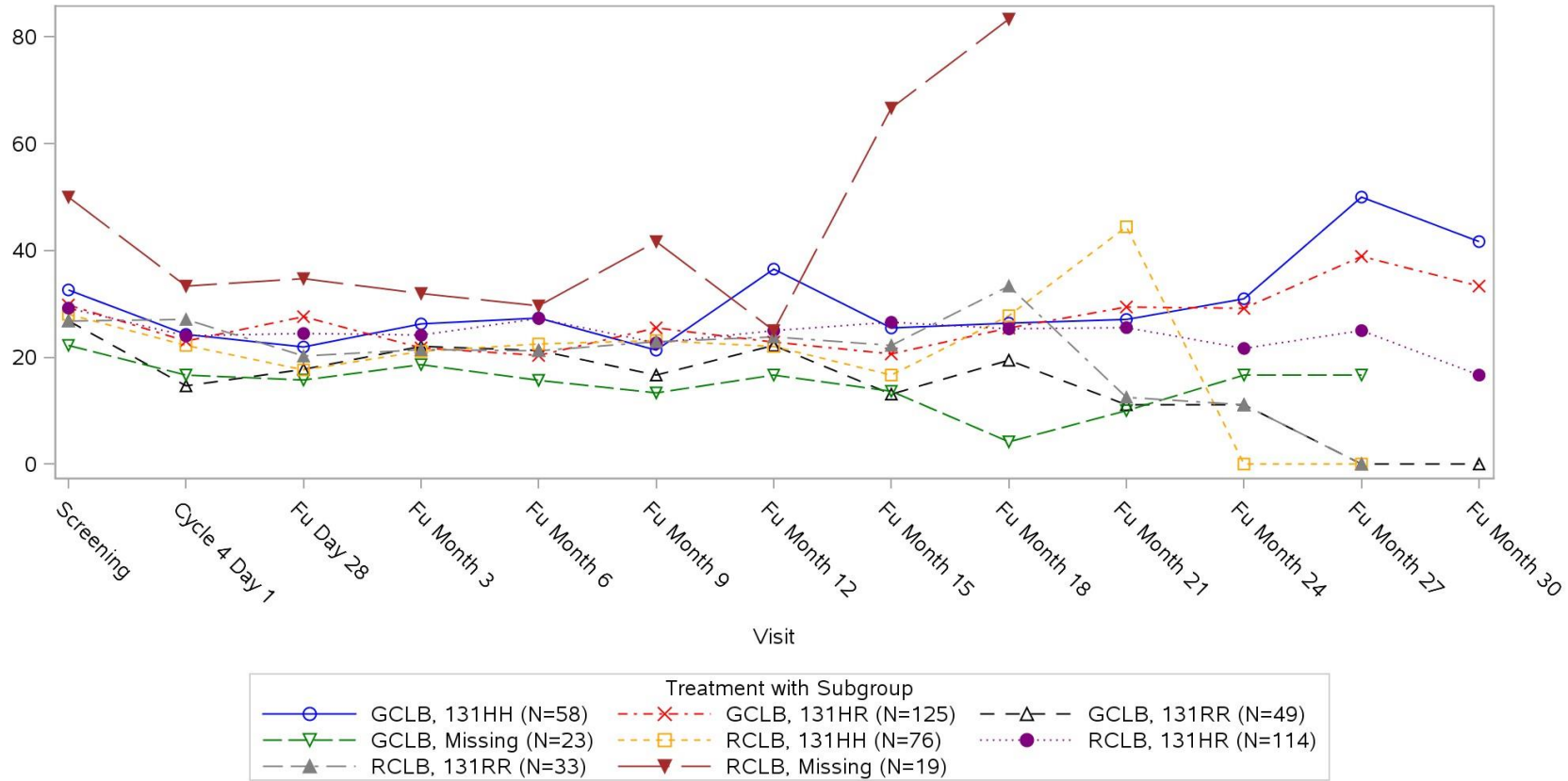
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

FCgamma receptor IIa (N=497) Laboratory Test: Fatigue Scale



Clinical cut-off: 09MAY2013

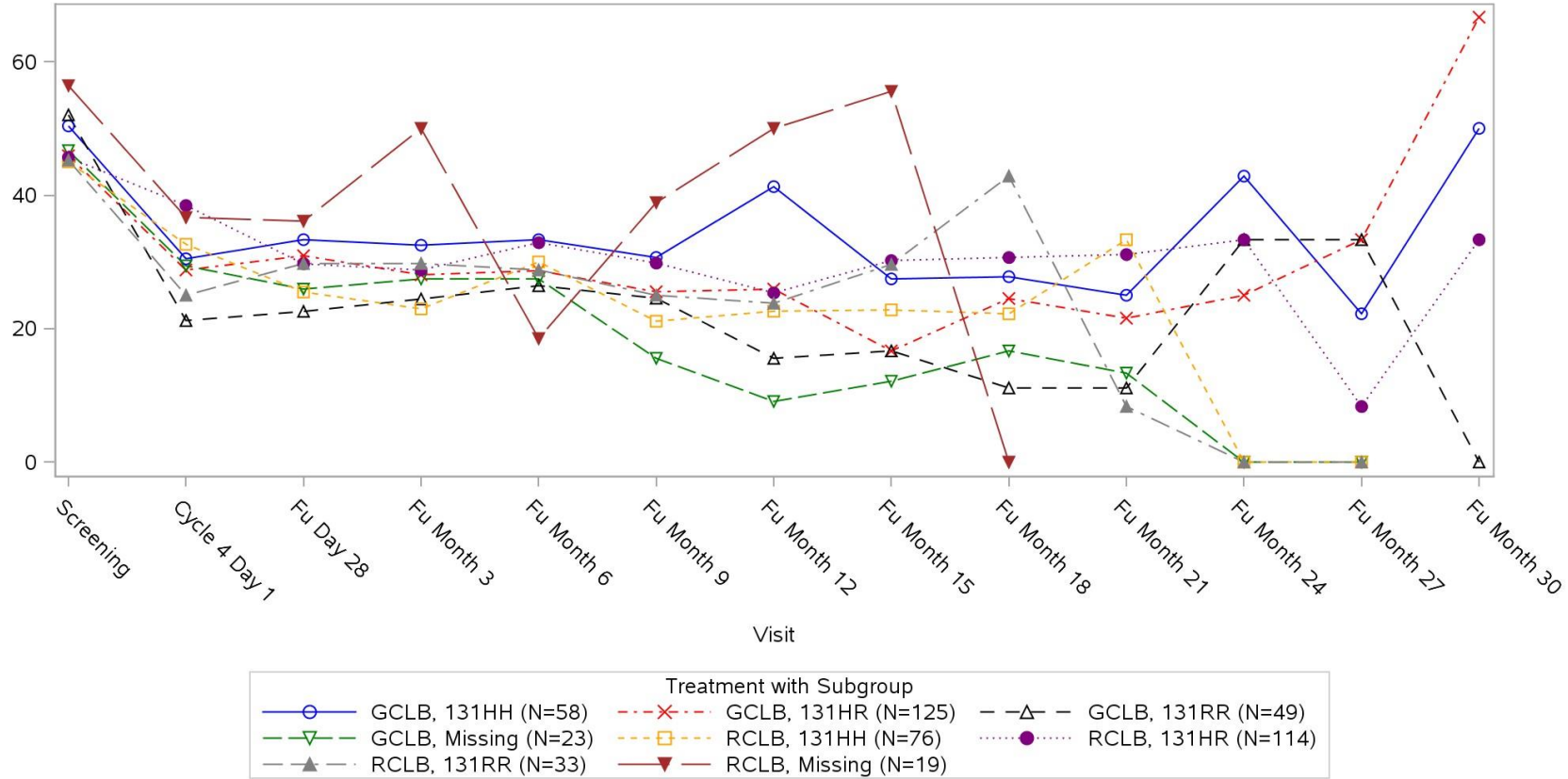
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

FCgamma receptor IIa (N=497) Laboratory Test: Future Health



Clinical cut-off: 09MAY2013

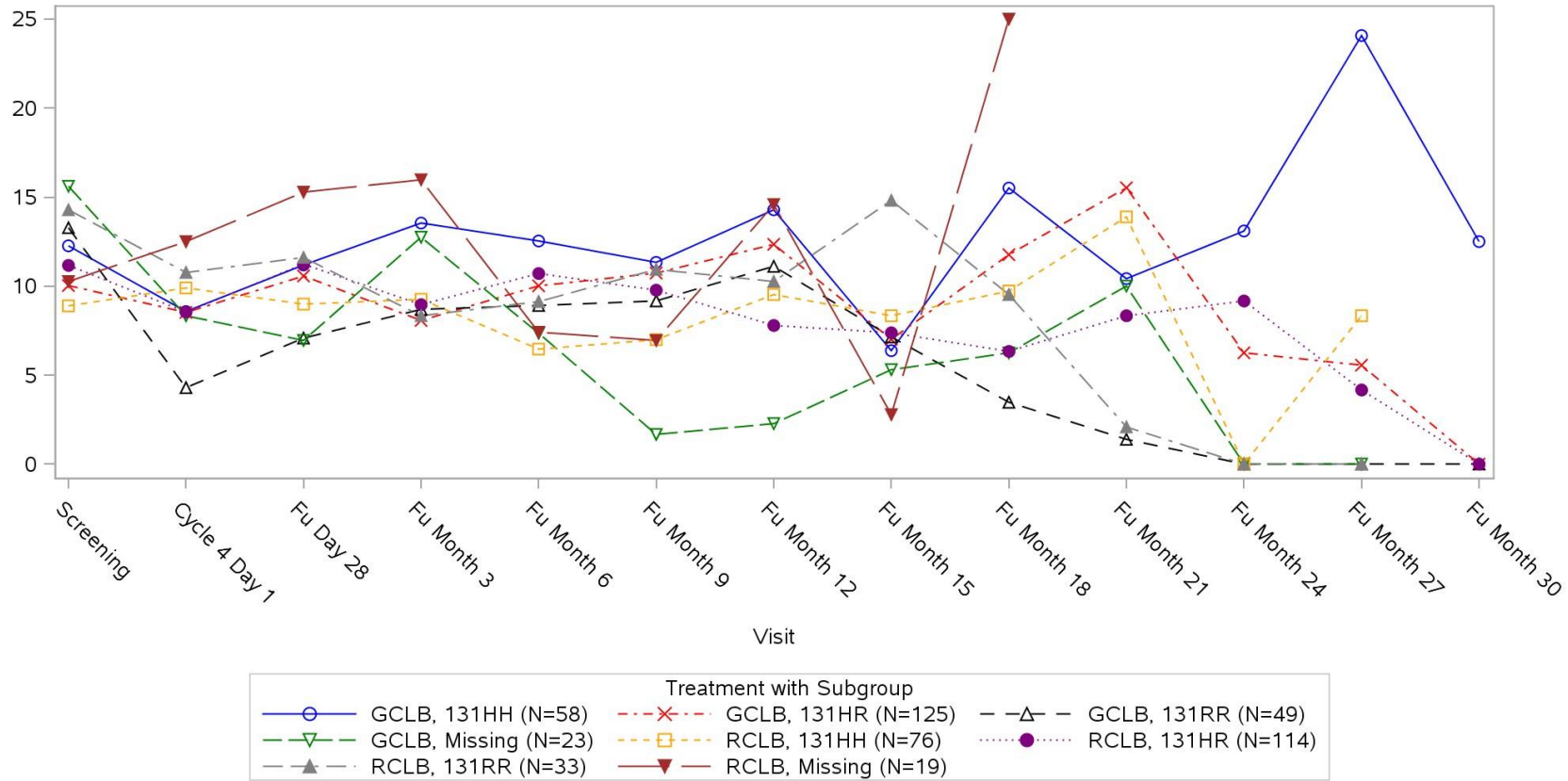
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

FCgamma receptor IIa (N=497) Laboratory Test: Infection Scale



Clinical cut-off: 09MAY2013

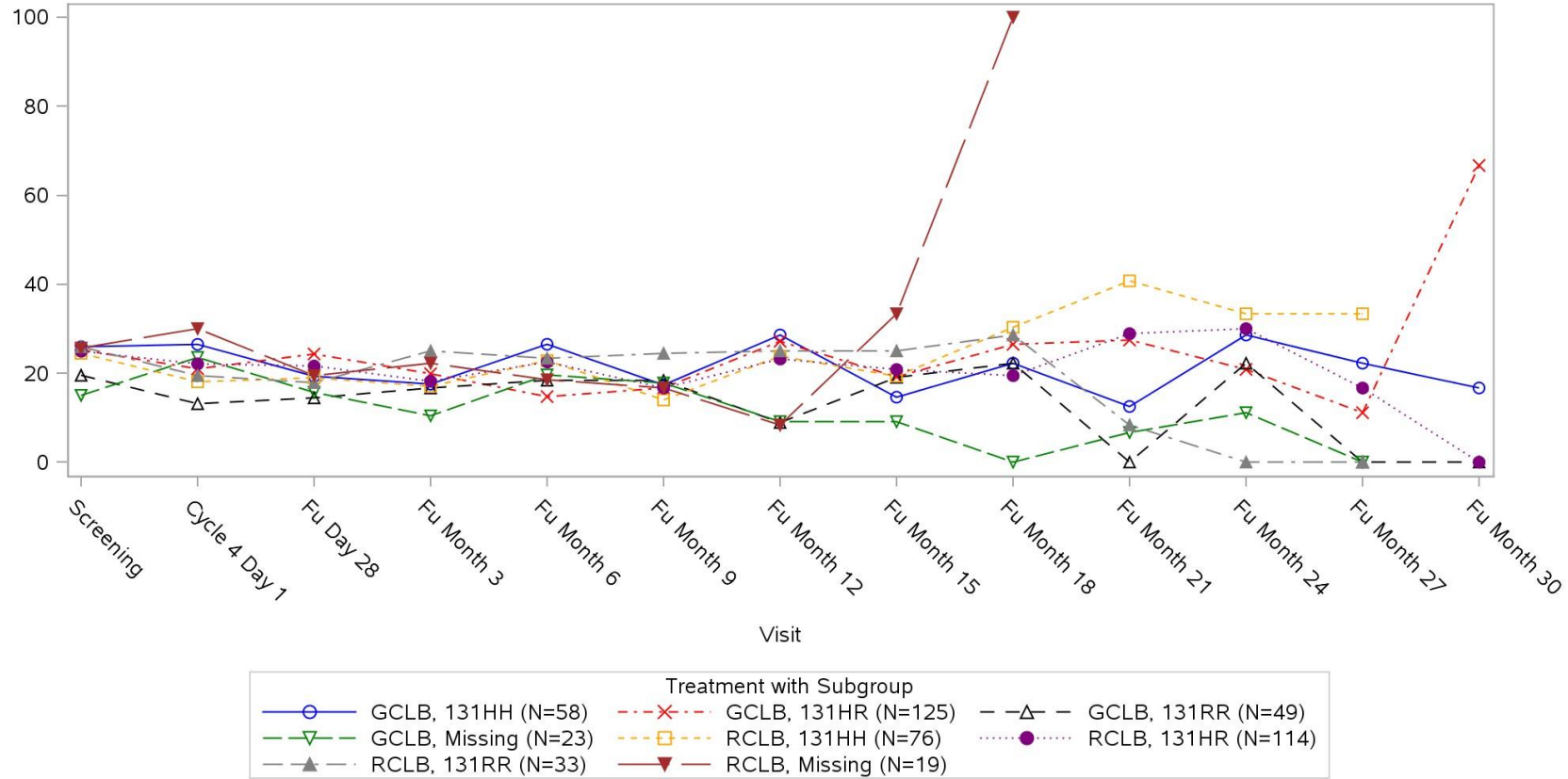
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

FCgamma receptor IIa (N=497) Laboratory Test: Social Problems



Clinical cut-off: 09MAY2013

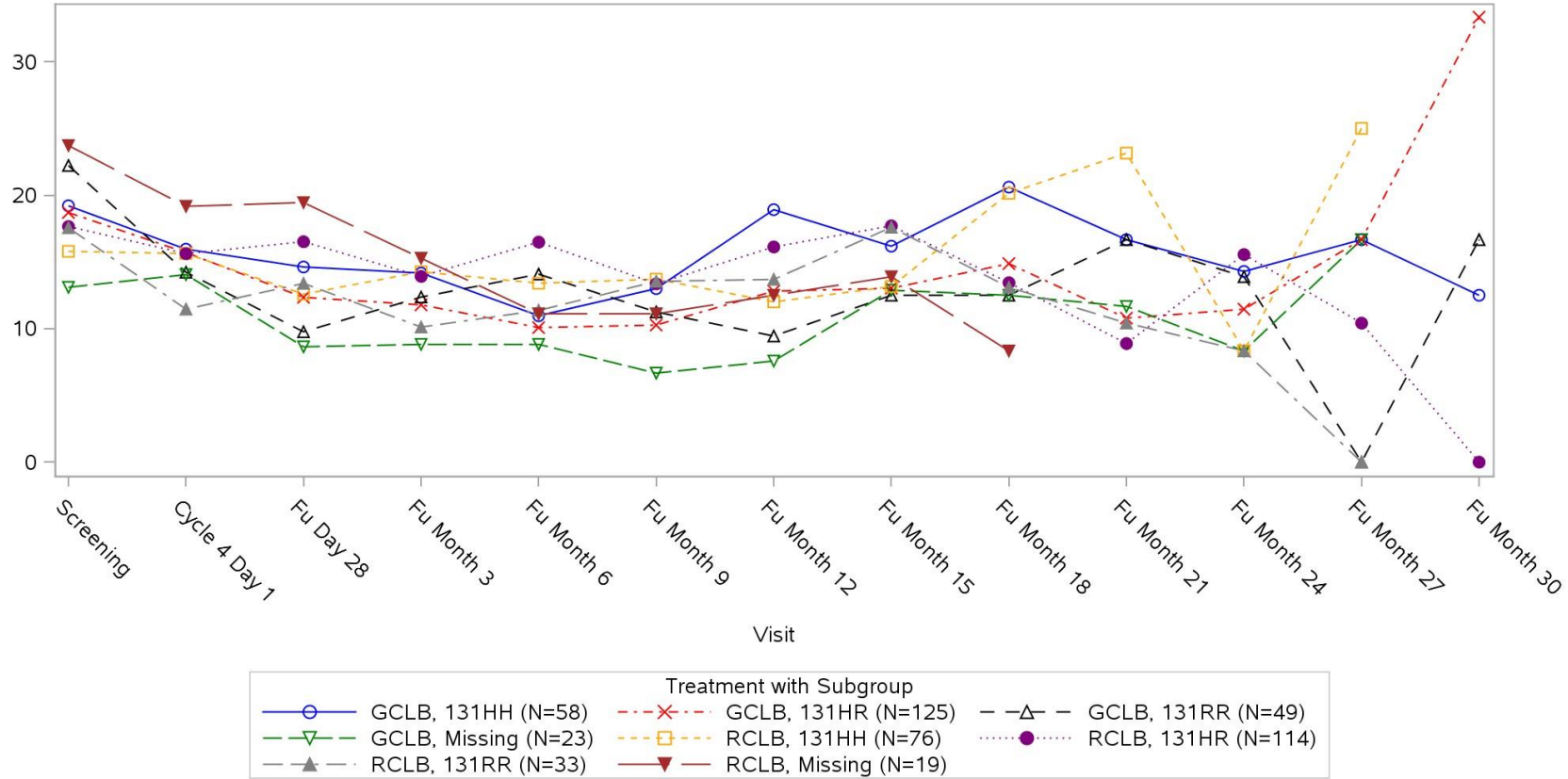
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

FCgamma receptor IIa (N=497) Laboratory Test: Treatment Side Effects Scale



Clinical cut-off: 09MAY2013

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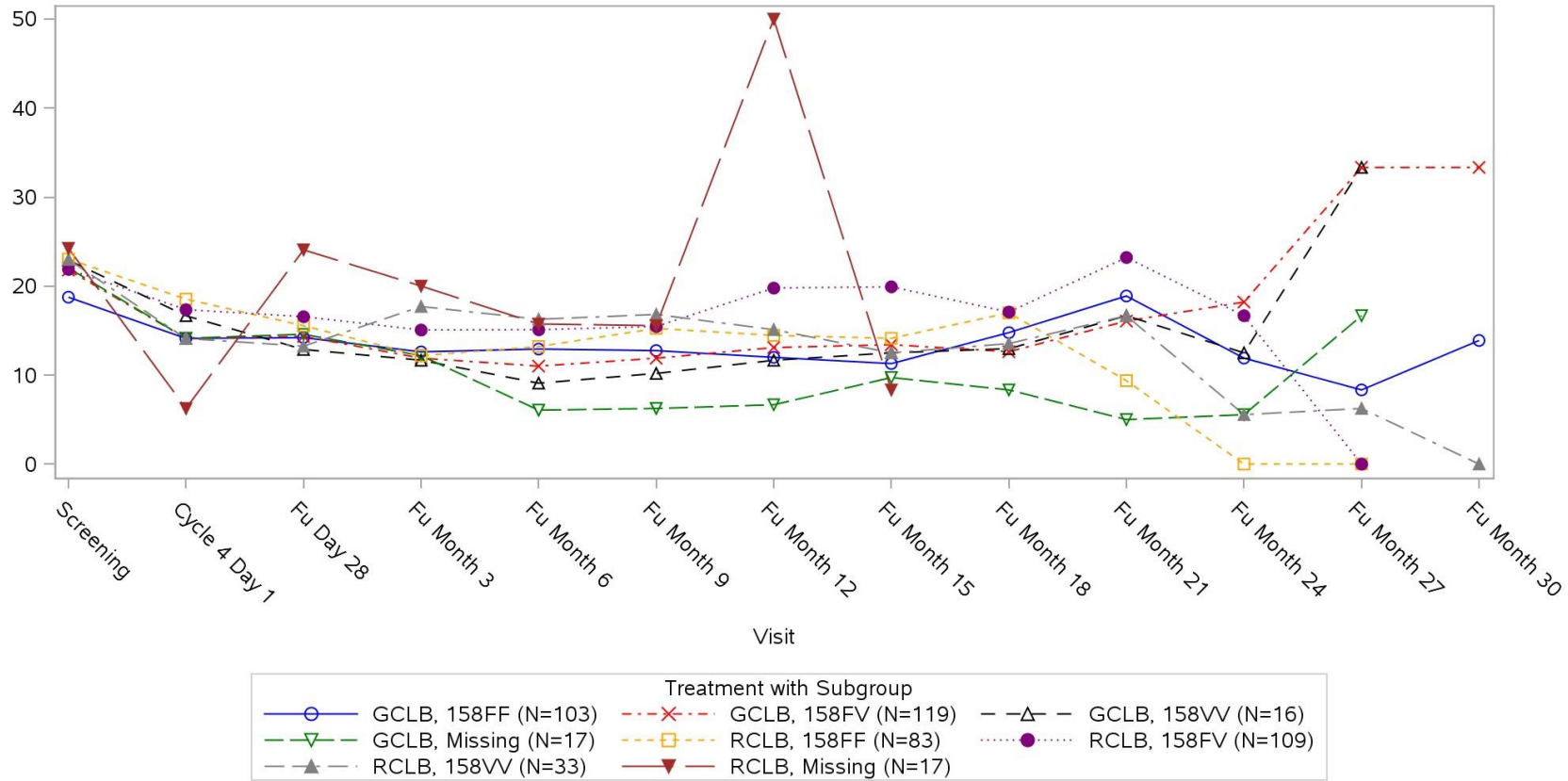
Page 54 of 78

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

FCgamma receptor IIIa (N=497) Laboratory Test: Disease Effects Scale



Clinical cut-off: 09MAY2013

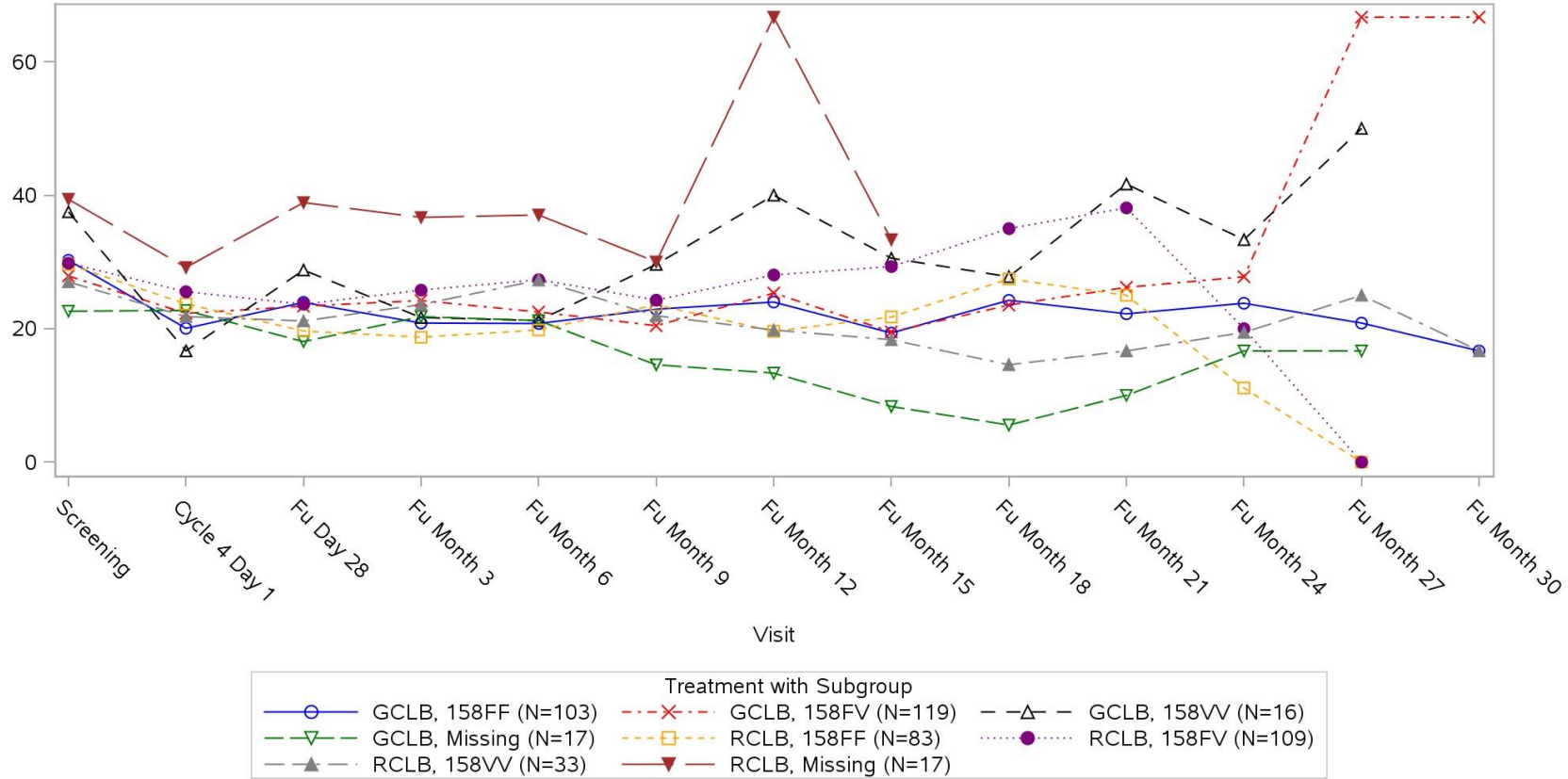
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 04MAR2020 19:13

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

FCgamma receptor IIIa (N=497) Laboratory Test: Fatigue Scale



Clinical cut-off: 09MAY2013

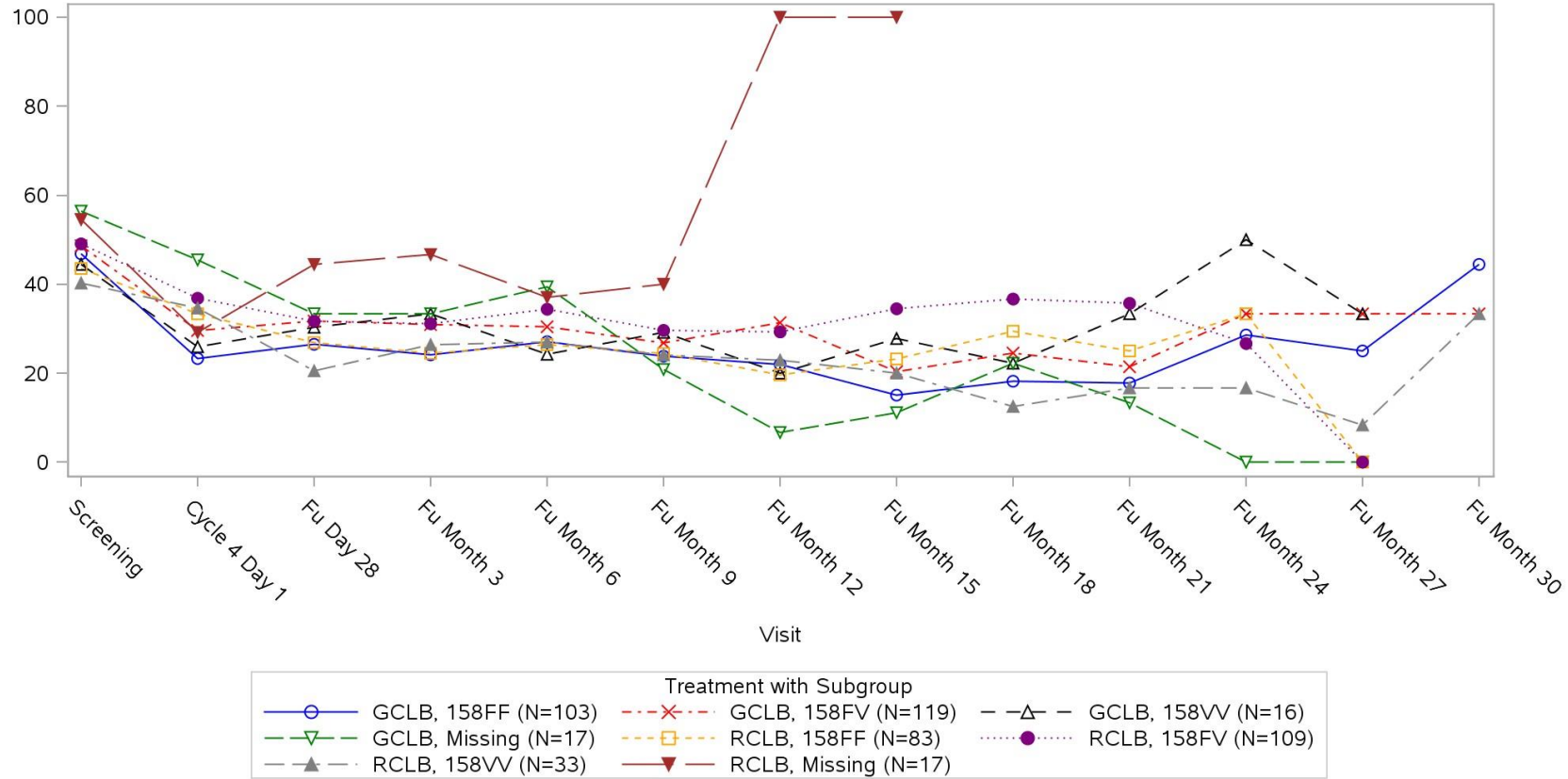
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

FCgamma receptor IIIa (N=497) Laboratory Test: Future Health



Clinical cut-off: 09MAY2013

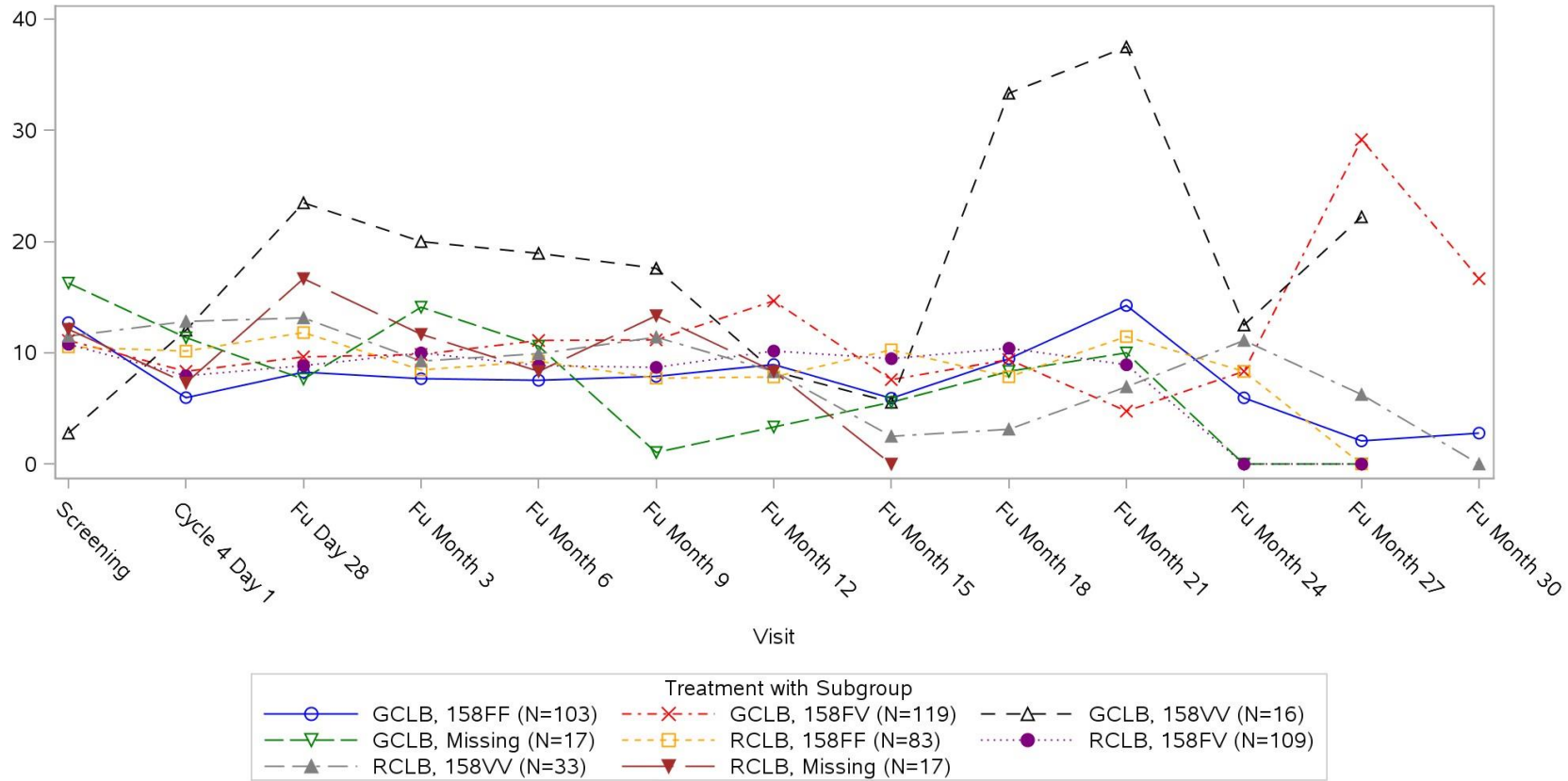
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

FCgamma receptor IIIa (N=497) Laboratory Test: Infection Scale



Clinical cut-off: 09MAY2013

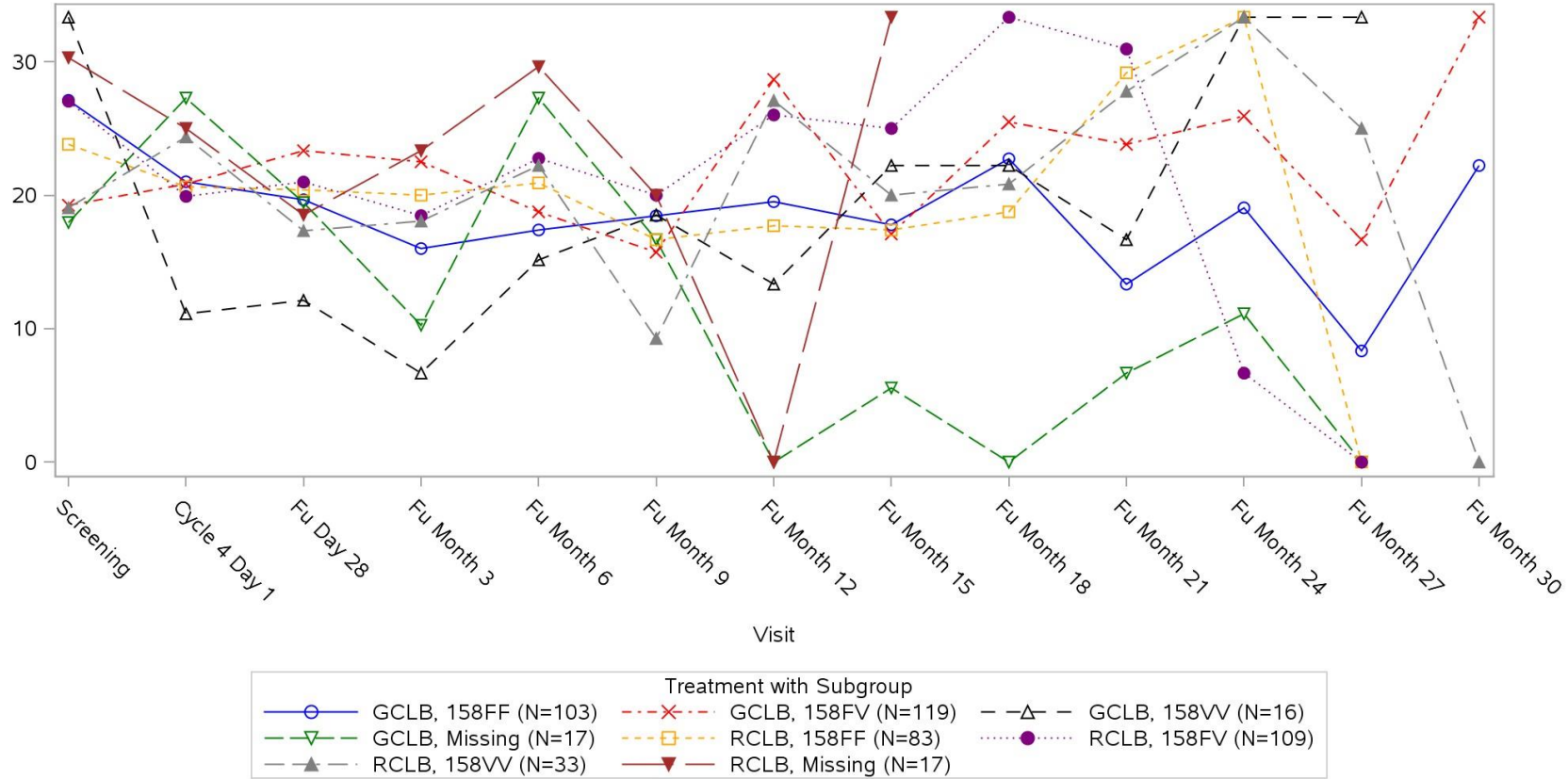
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

FCgamma receptor IIIa (N=497) Laboratory Test: Social Problems



Clinical cut-off: 09MAY2013

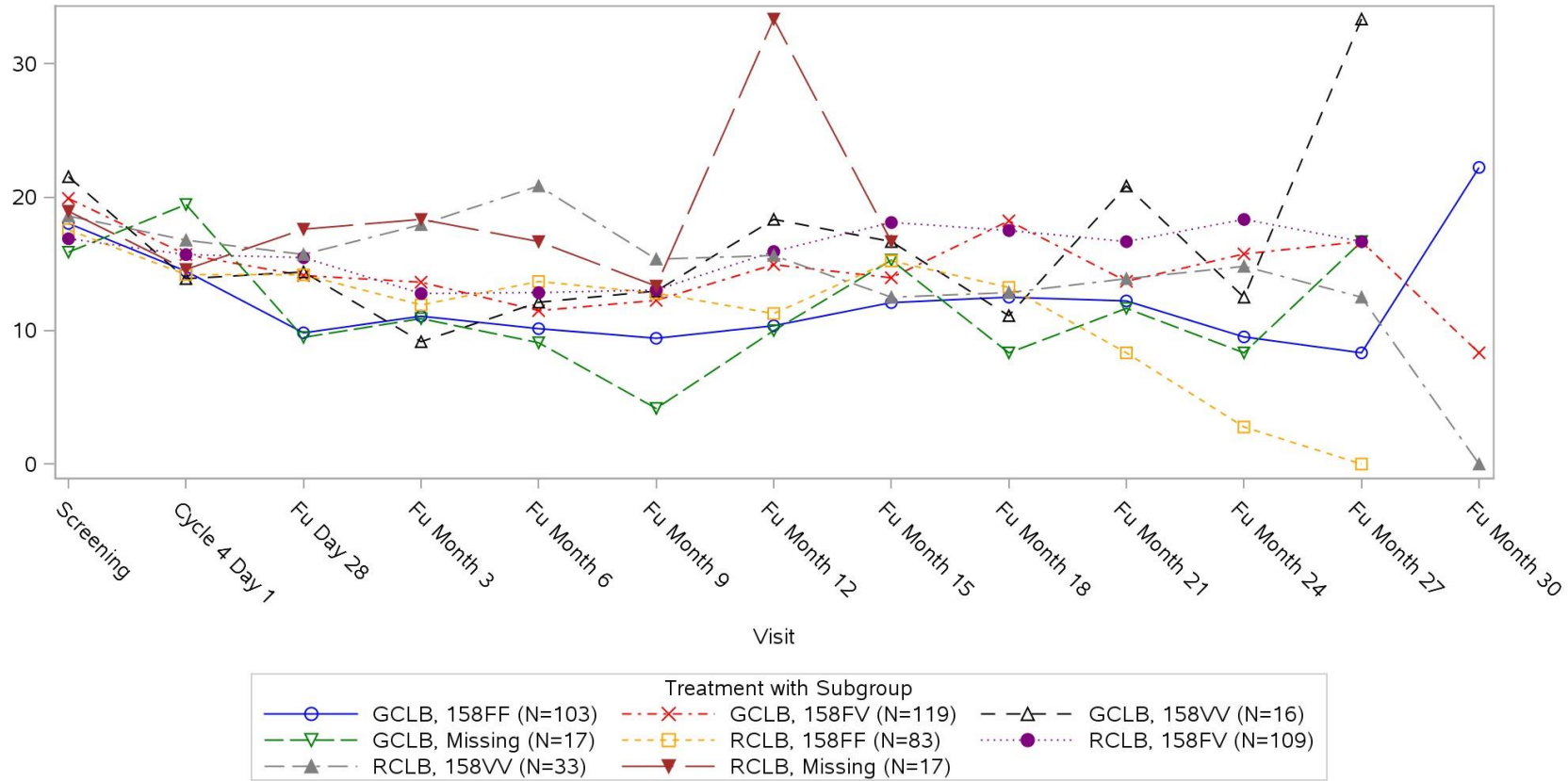
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

FCgamma receptor IIIa (N=497) Laboratory Test: Treatment Side Effects Scale



Clinical cut-off: 09MAY2013

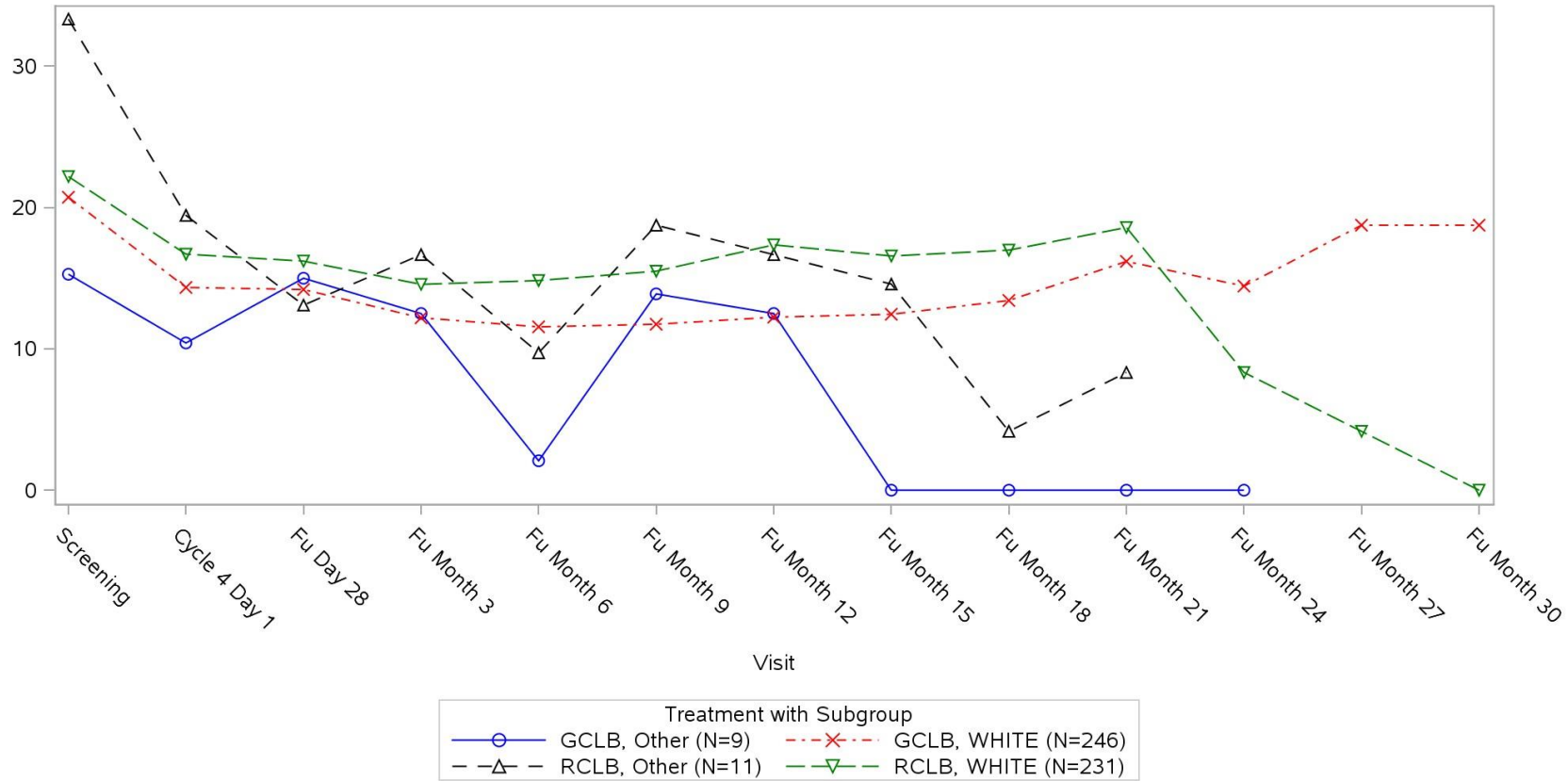
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

Race/ethnicity (N=497) Laboratory Test: Disease Effects Scale



Clinical cut-off: 09MAY2013

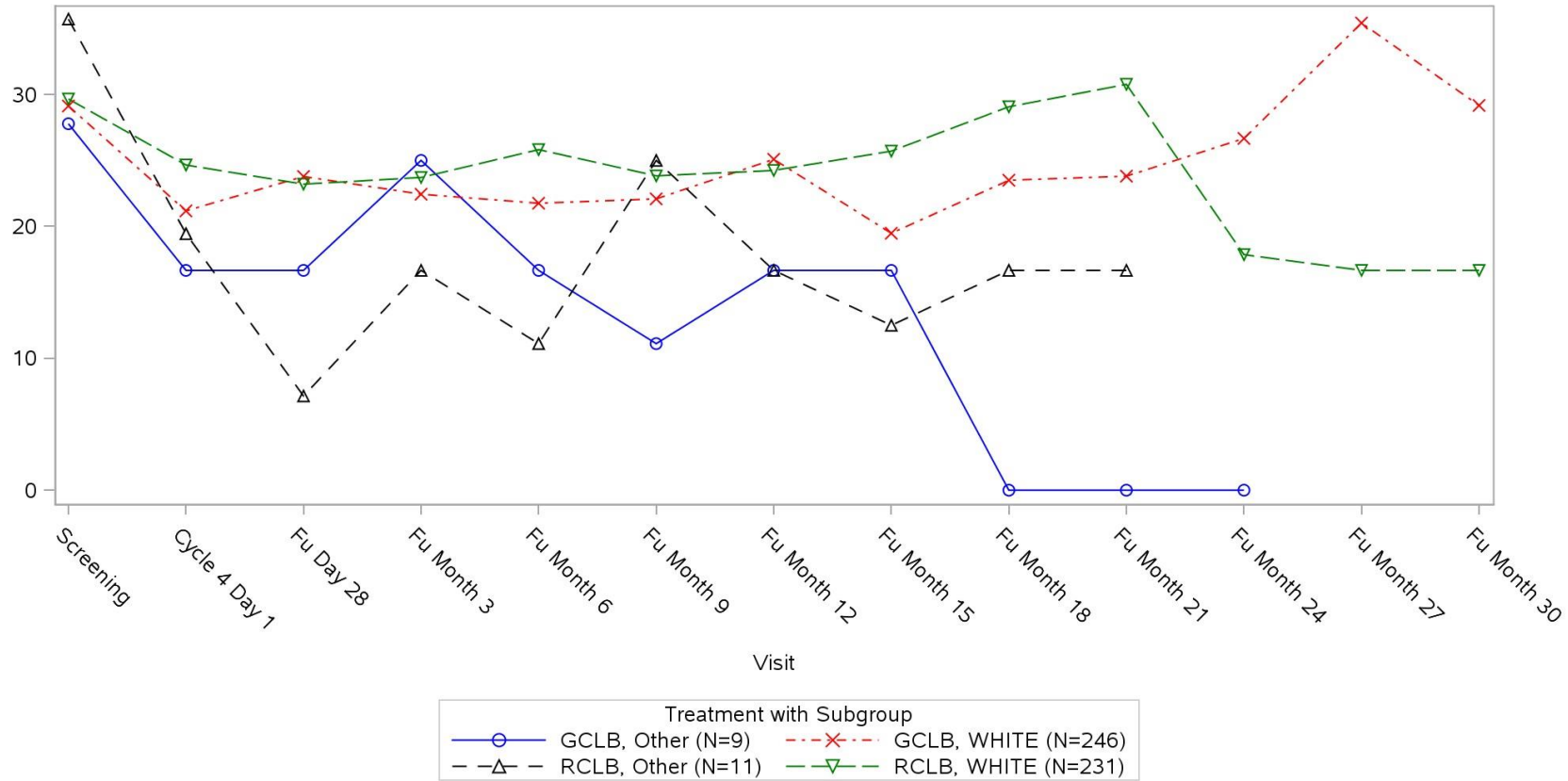
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

Race/ethnicity (N=497) Laboratory Test: Fatigue Scale



Clinical cut-off: 09MAY2013

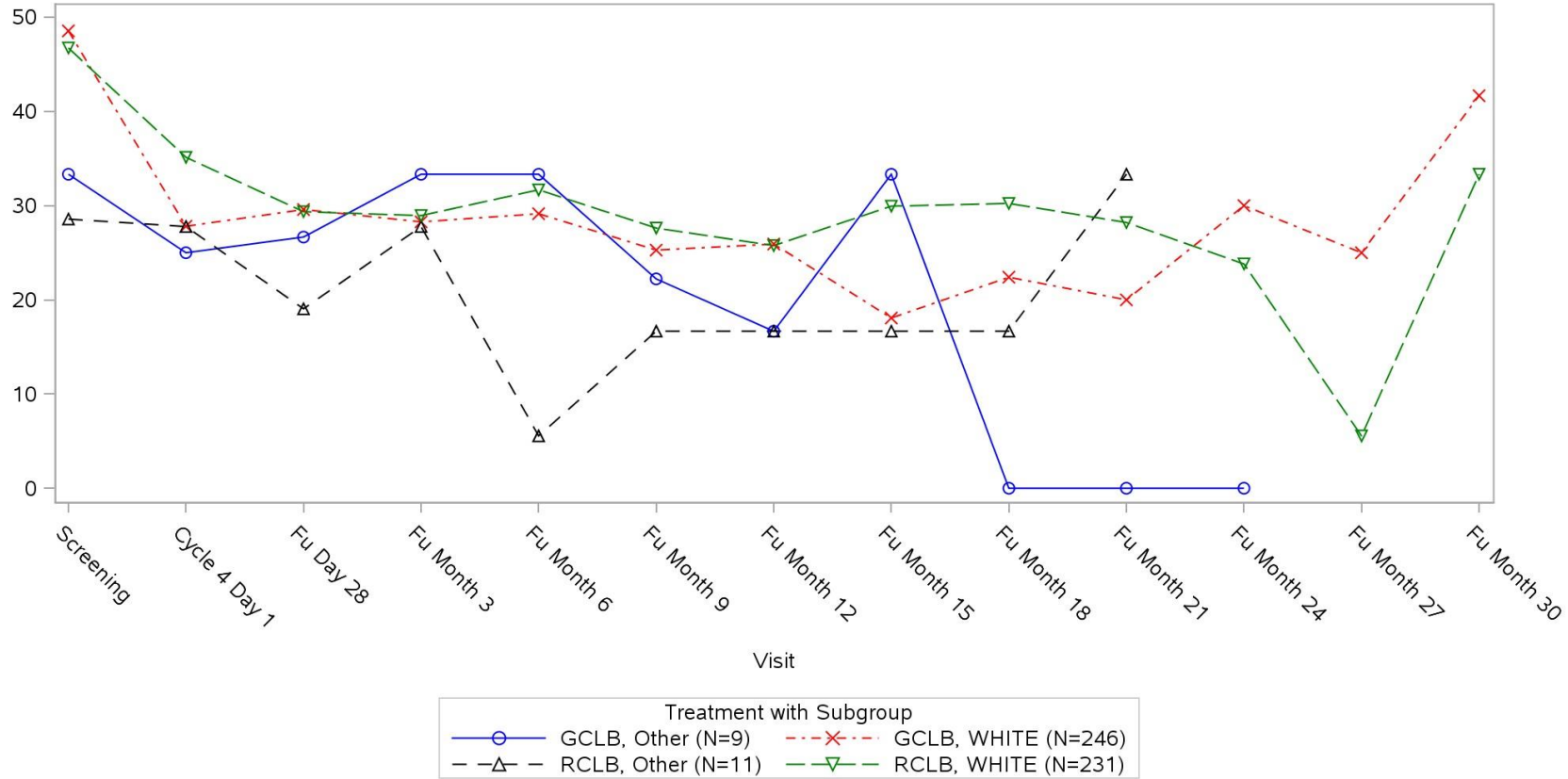
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

Race/ethnicity (N=497) Laboratory Test: Future Health



Clinical cut-off: 09MAY2013

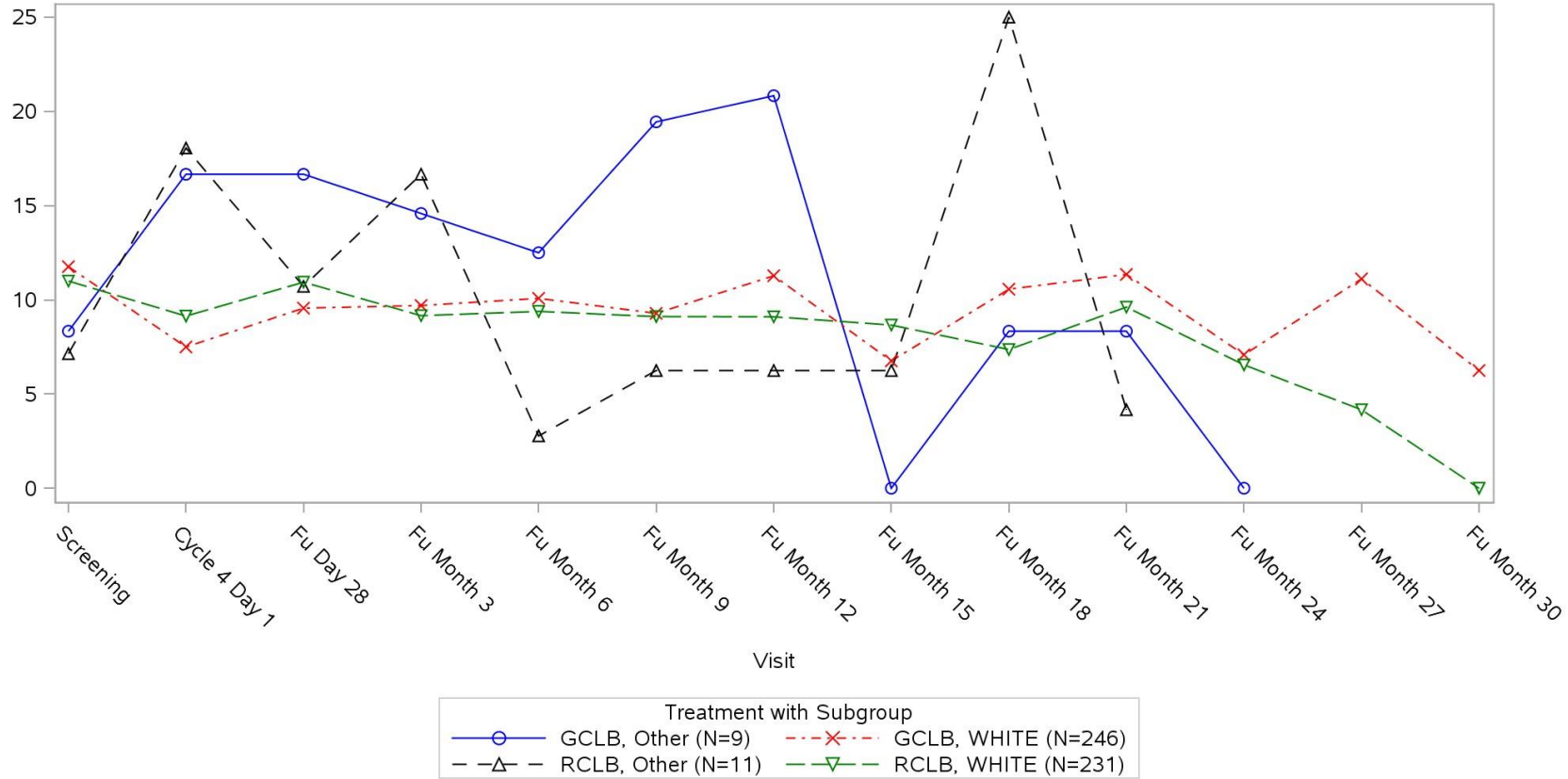
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

Race/ethnicity (N=497) Laboratory Test: Infection Scale



Clinical cut-off: 09MAY2013

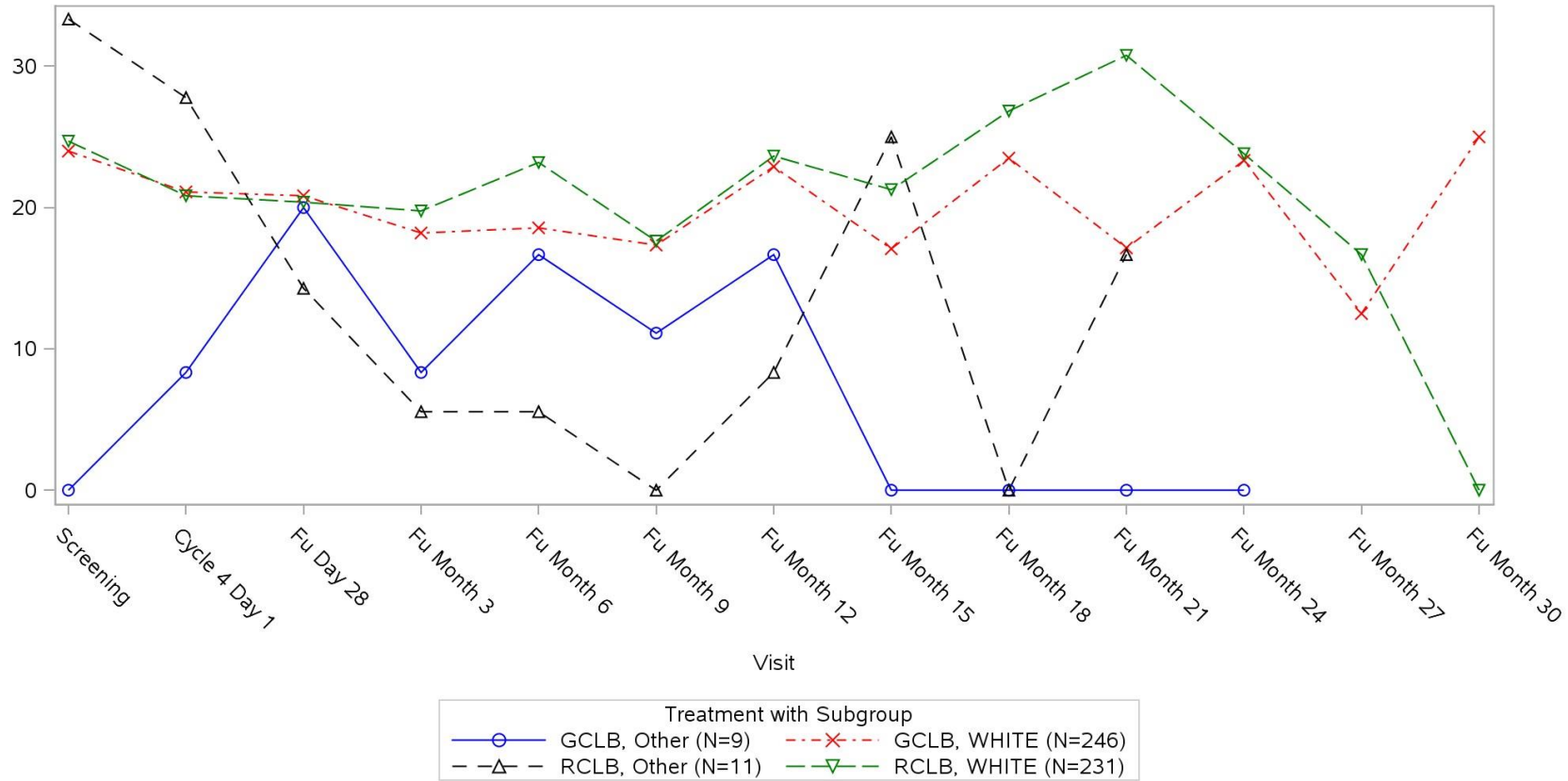
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

Race/ethnicity (N=497) Laboratory Test: Social Problems



Clinical cut-off: 09MAY2013

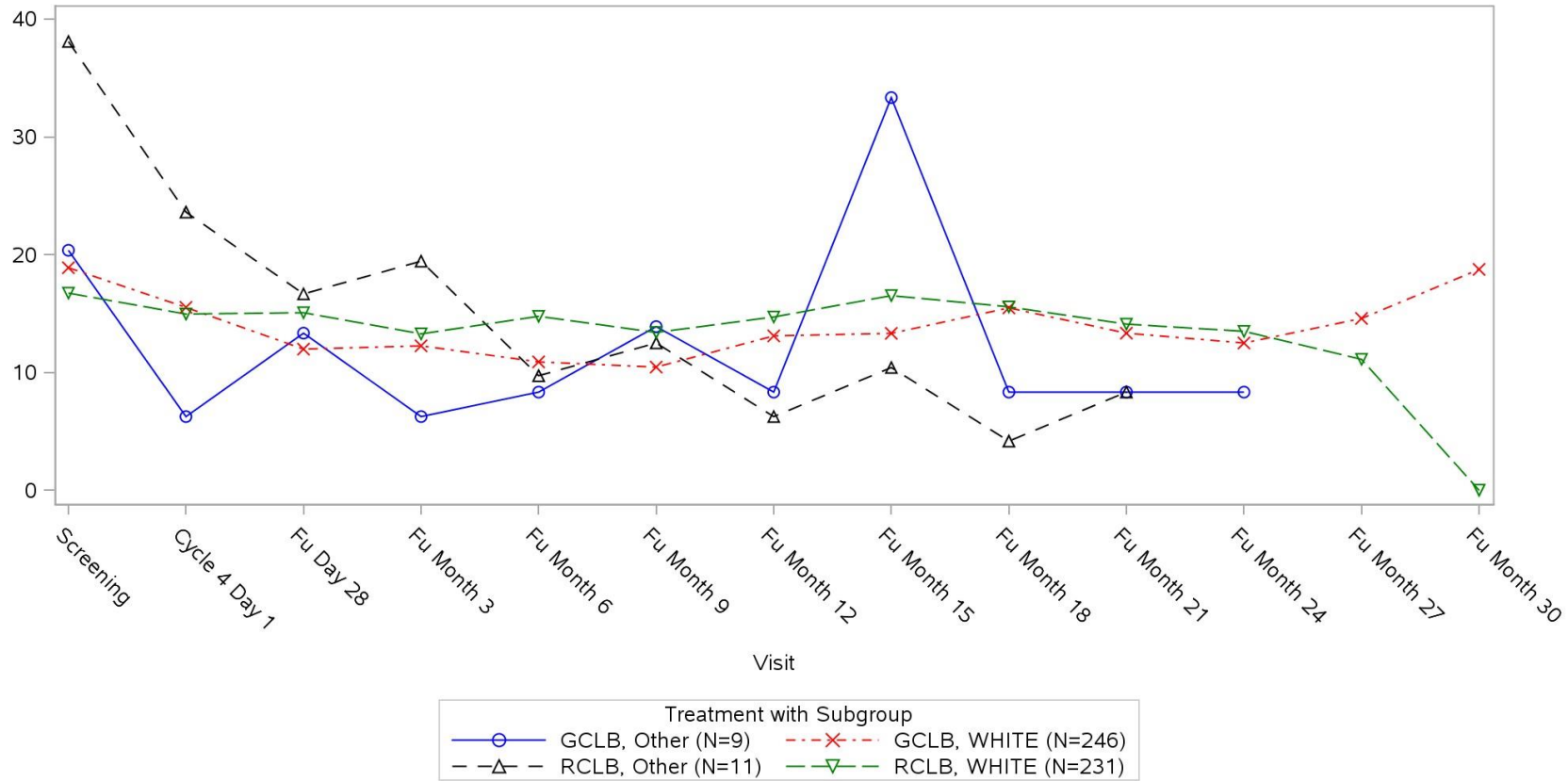
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

Race/ethnicity (N=497) Laboratory Test: Treatment Side Effects Scale



Clinical cut-off: 09MAY2013

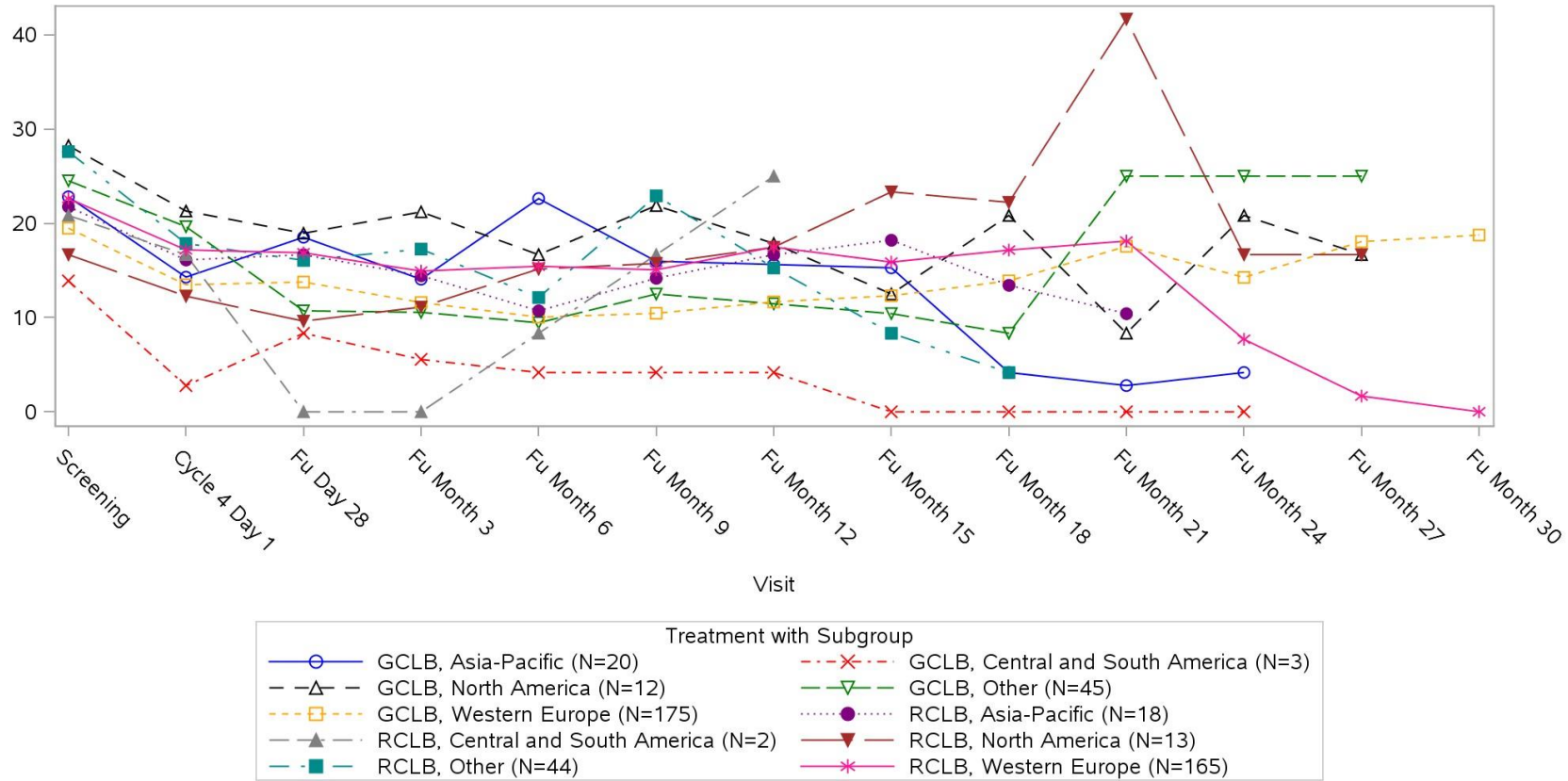
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

Geographic Region (N=497) Laboratory Test: Disease Effects Scale



Clinical cut-off: 09MAY2013

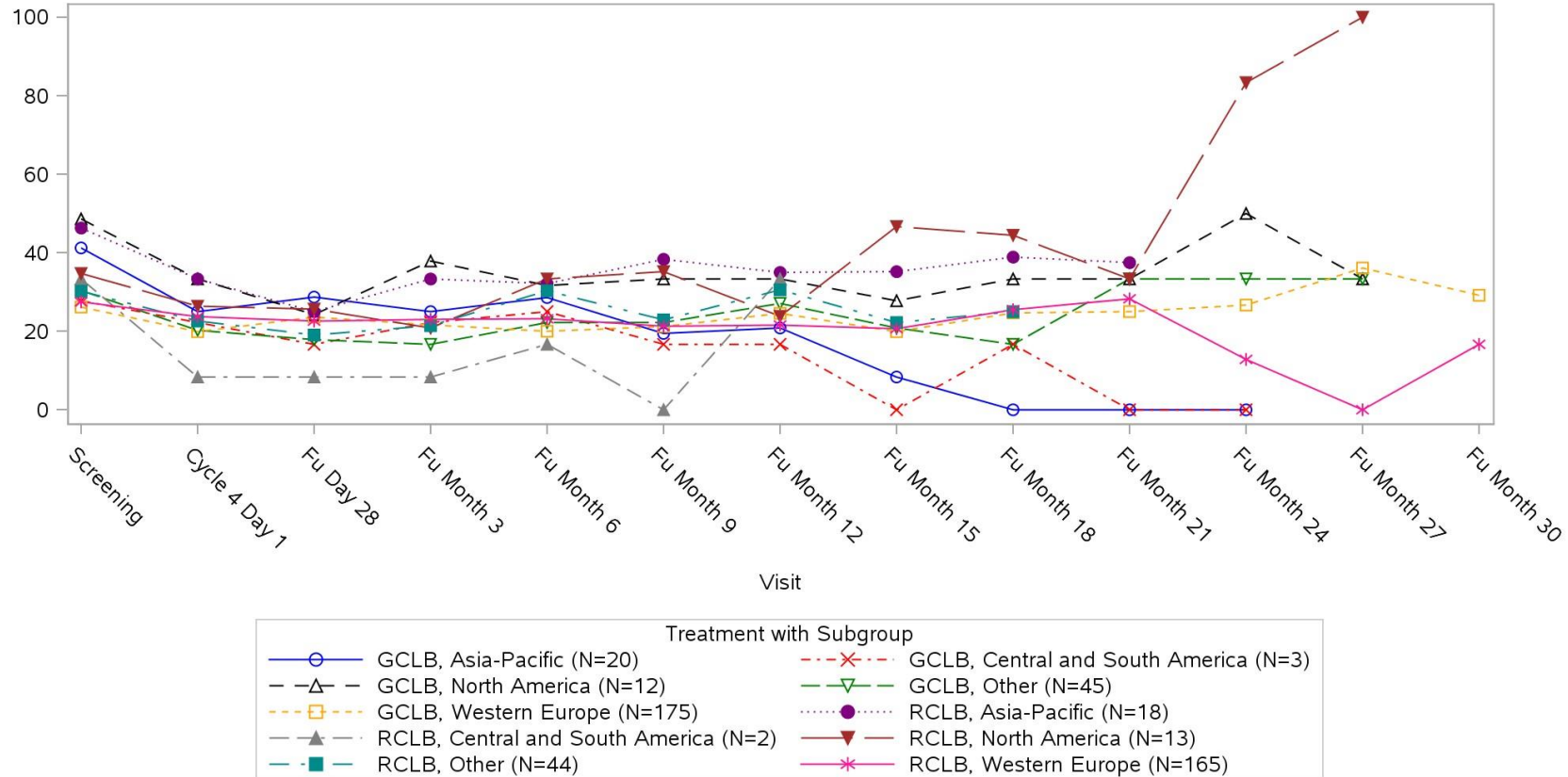
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

Geographic Region (N=497) Laboratory Test: Fatigue Scale



Clinical cut-off: 09MAY2013

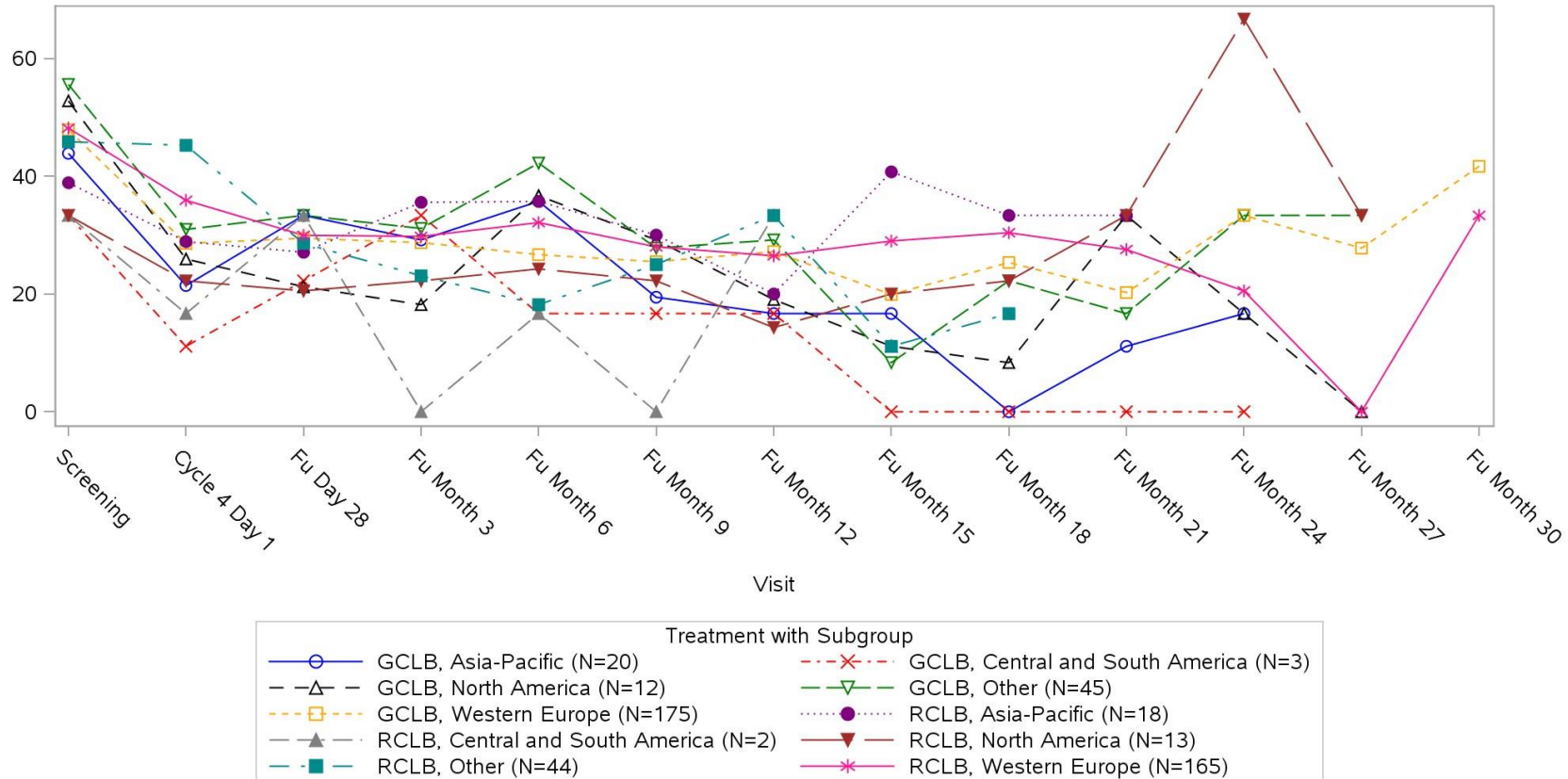
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

Geographic Region (N=497) Laboratory Test: Future Health



Clinical cut-off: 09MAY2013

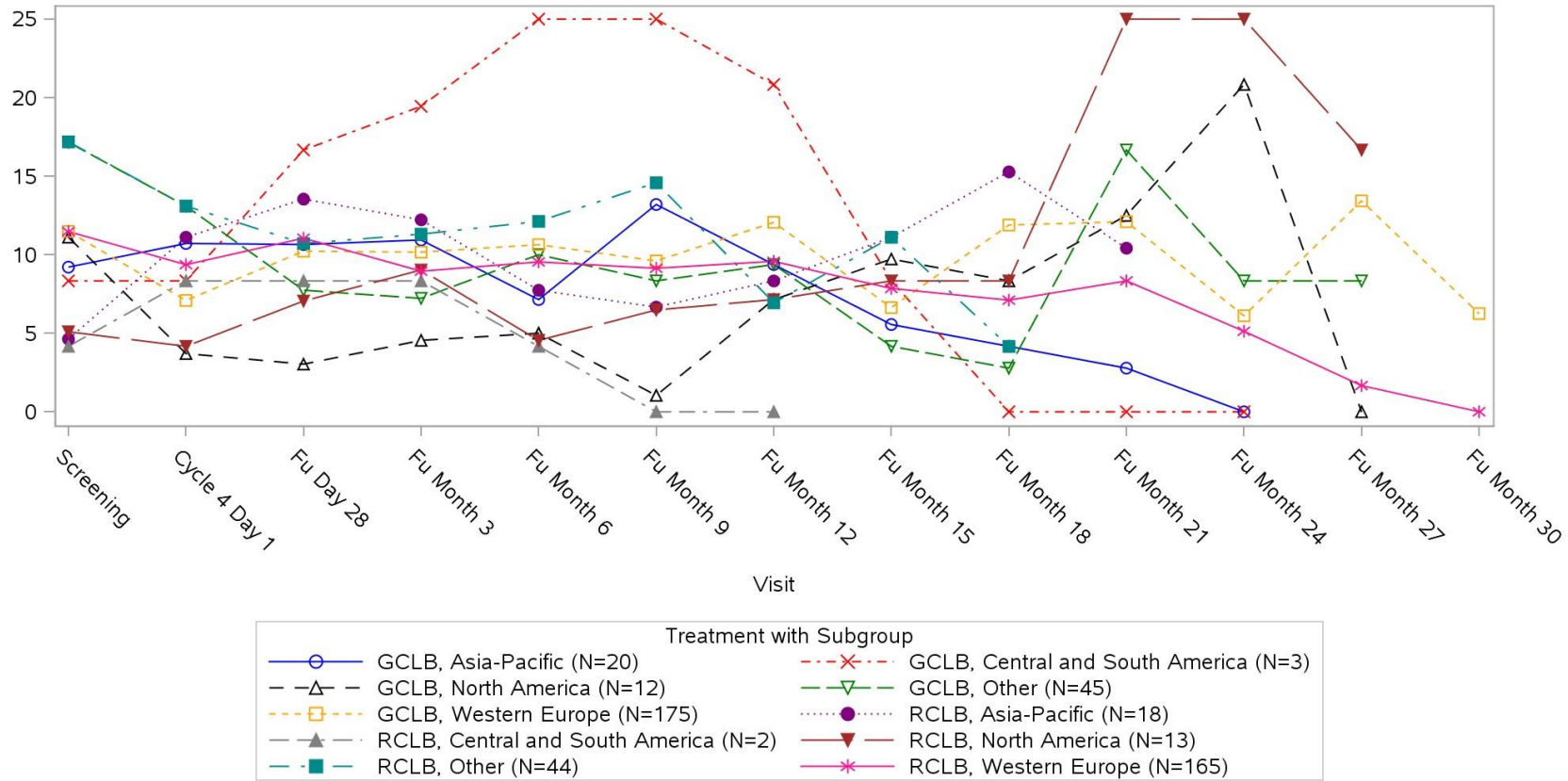
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

Geographic Region (N=497) Laboratory Test: Infection Scale



Clinical cut-off: 09MAY2013

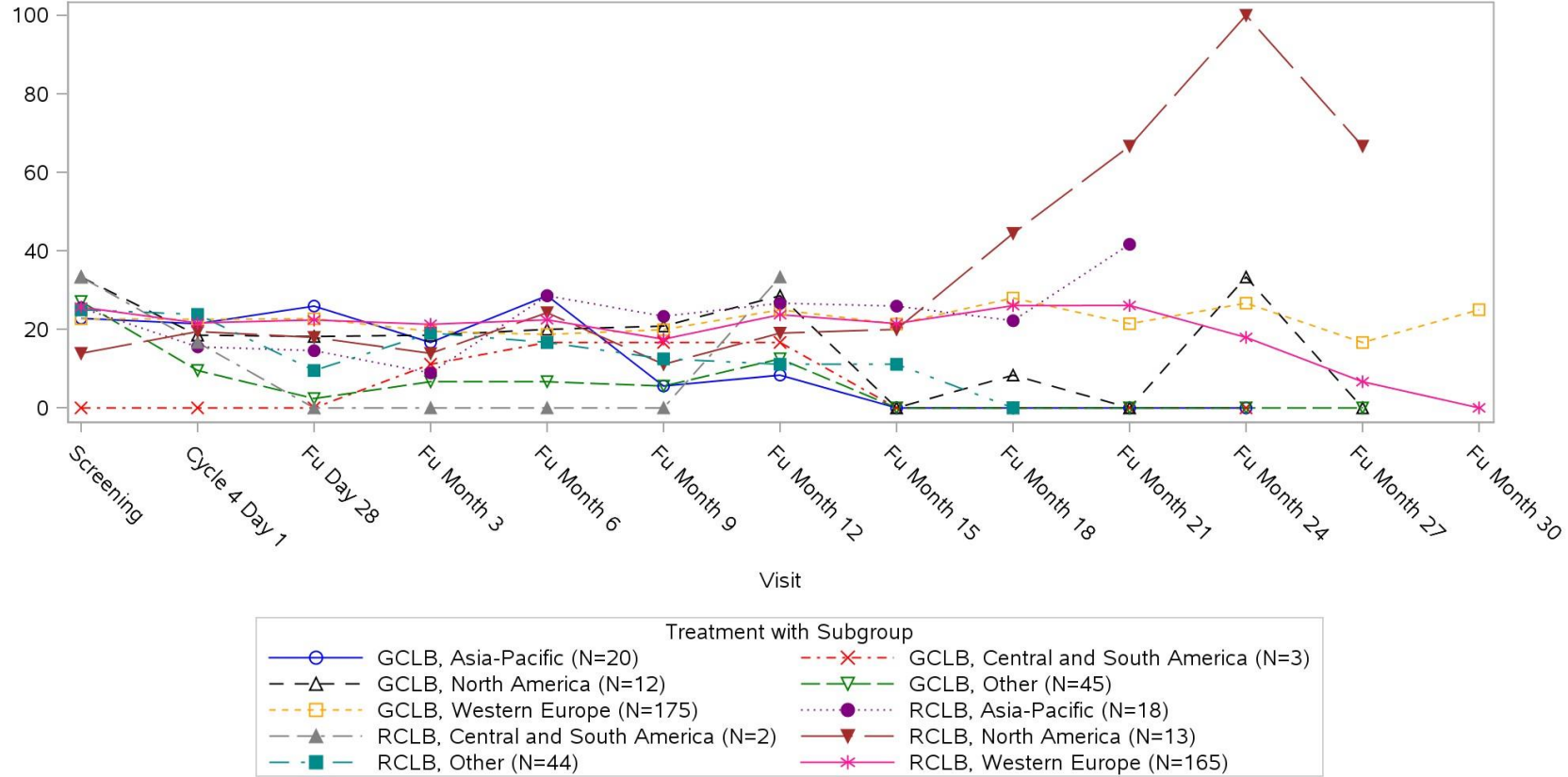
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 04MAR2020 19:13

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

Geographic Region (N=497) Laboratory Test: Social Problems



Clinical cut-off: 09MAY2013

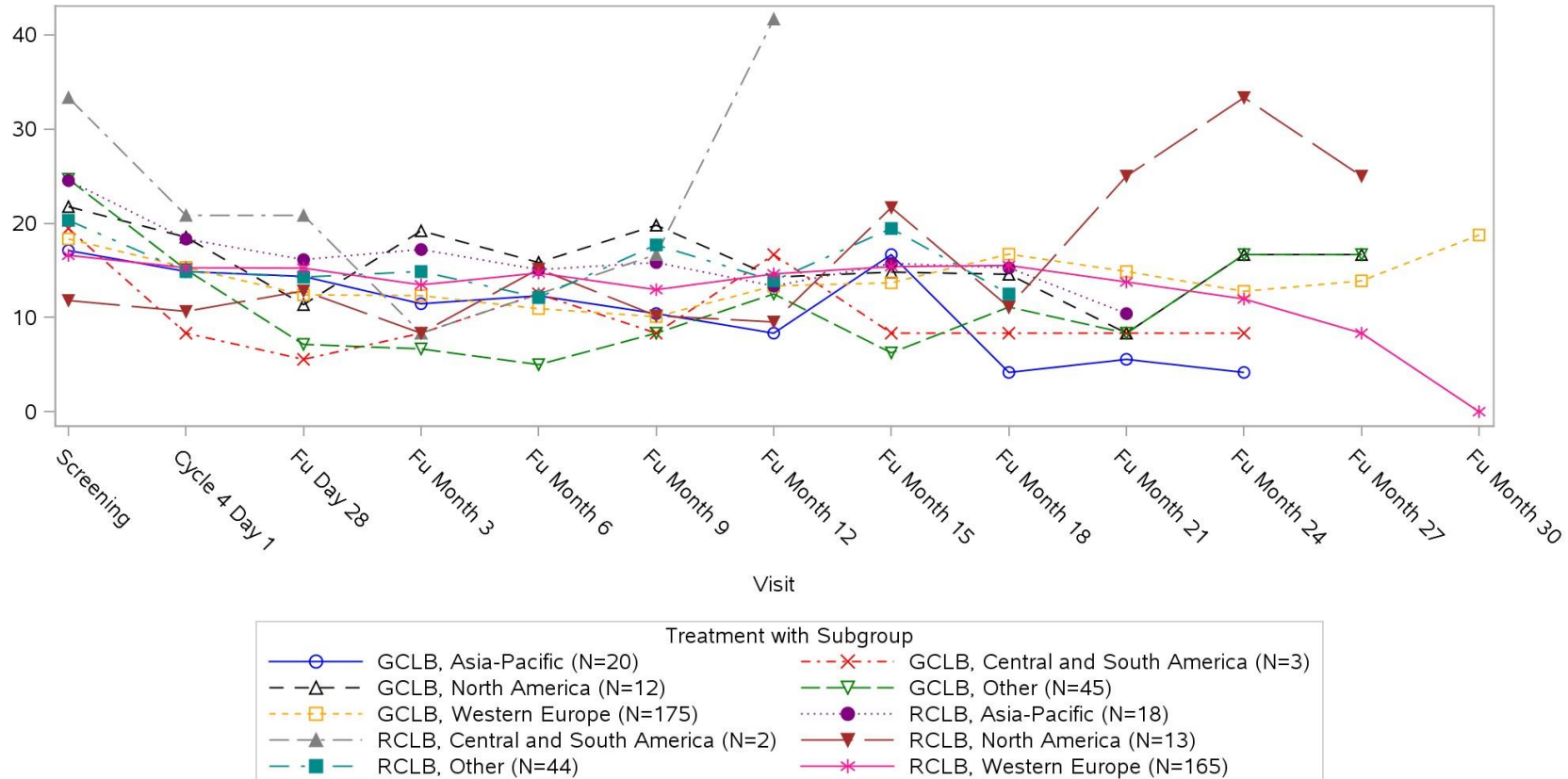
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

Geographic Region (N=497) Laboratory Test: Treatment Side Effects Scale



Clinical cut-off: 09MAY2013

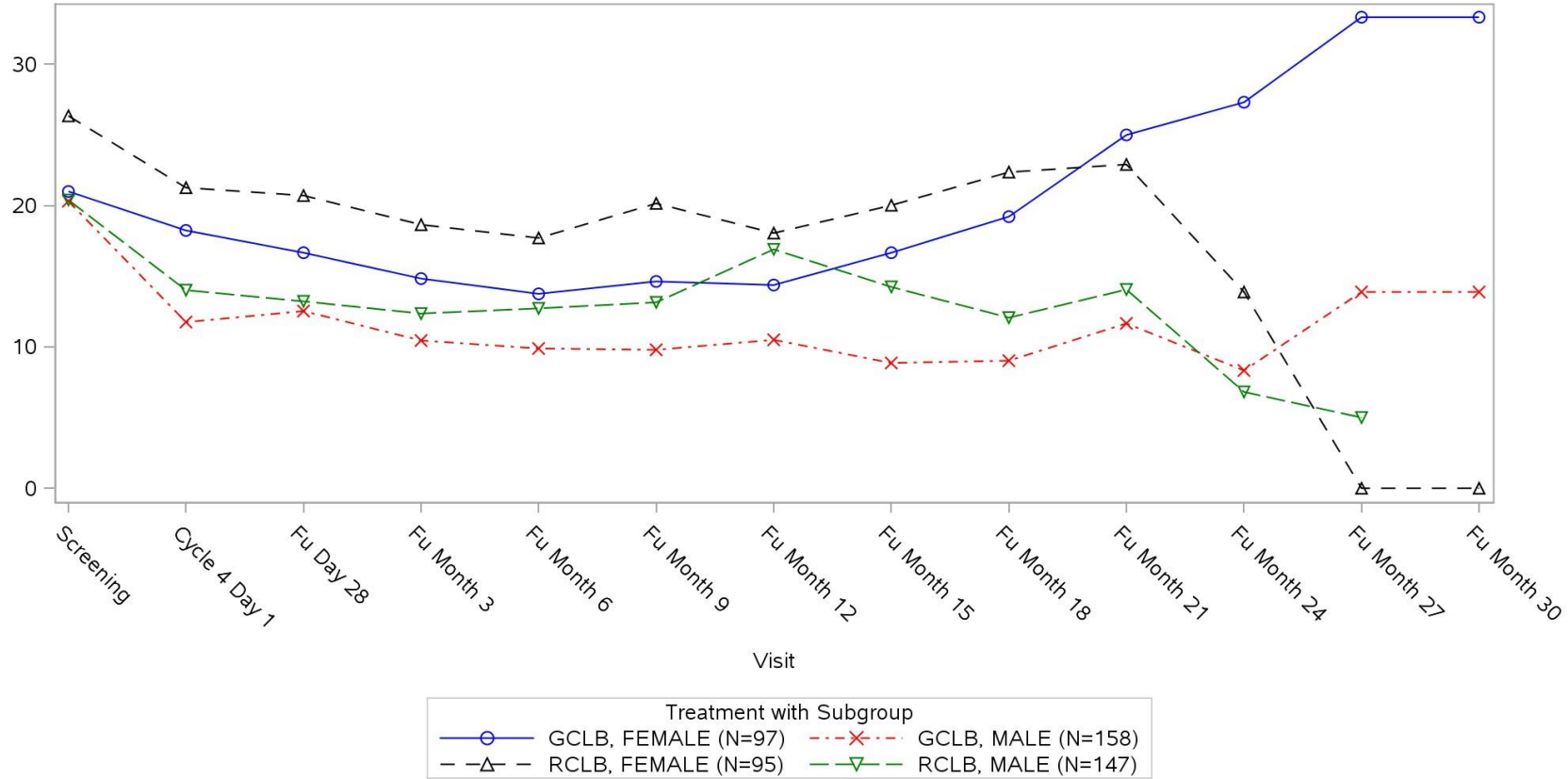
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

Sex (N=497) Laboratory Test: Disease Effects Scale



Clinical cut-off: 09MAY2013

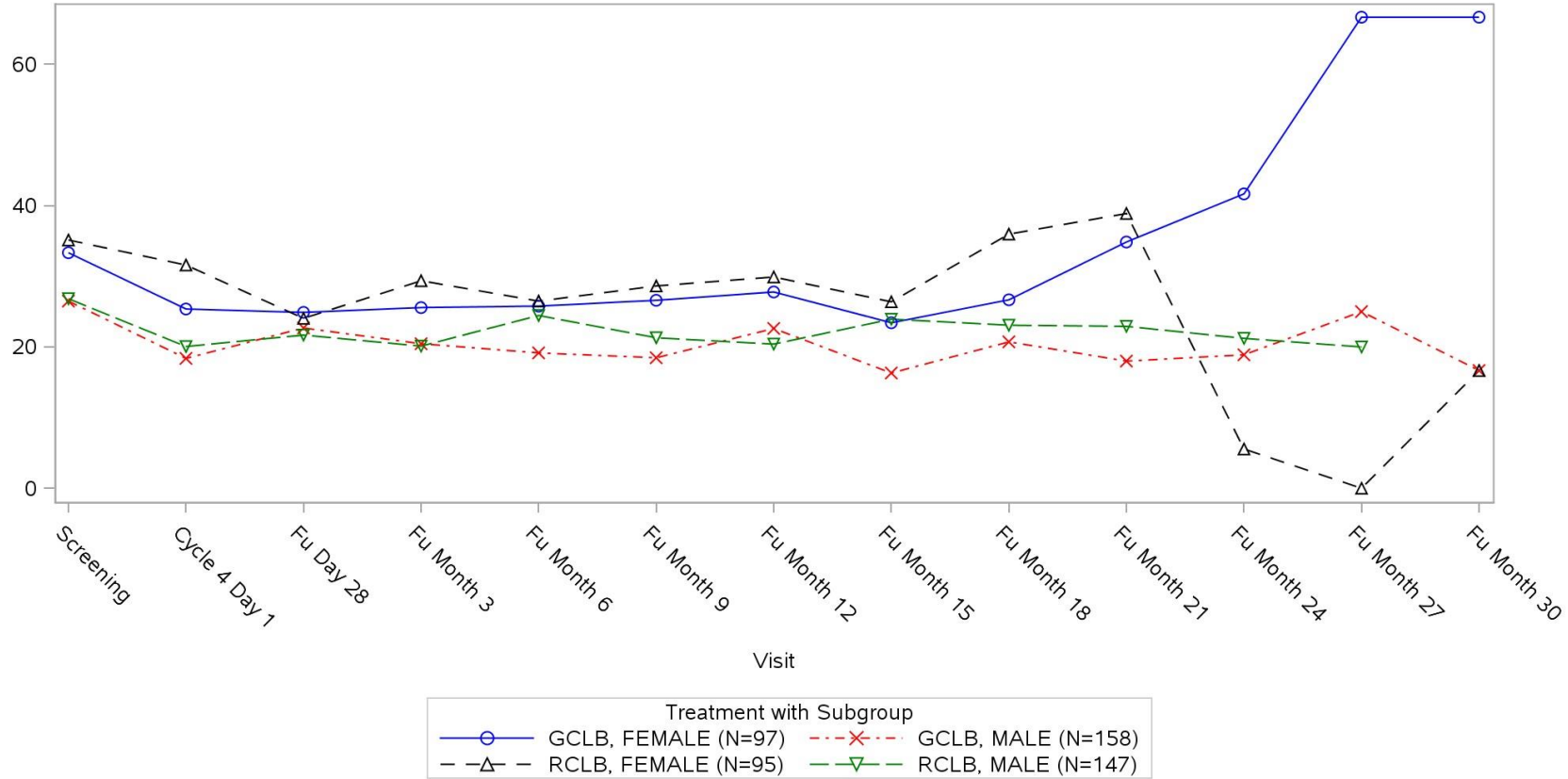
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 04MAR2020 19:13

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

Sex (N=497) Laboratory Test: Fatigue Scale



Clinical cut-off: 09MAY2013

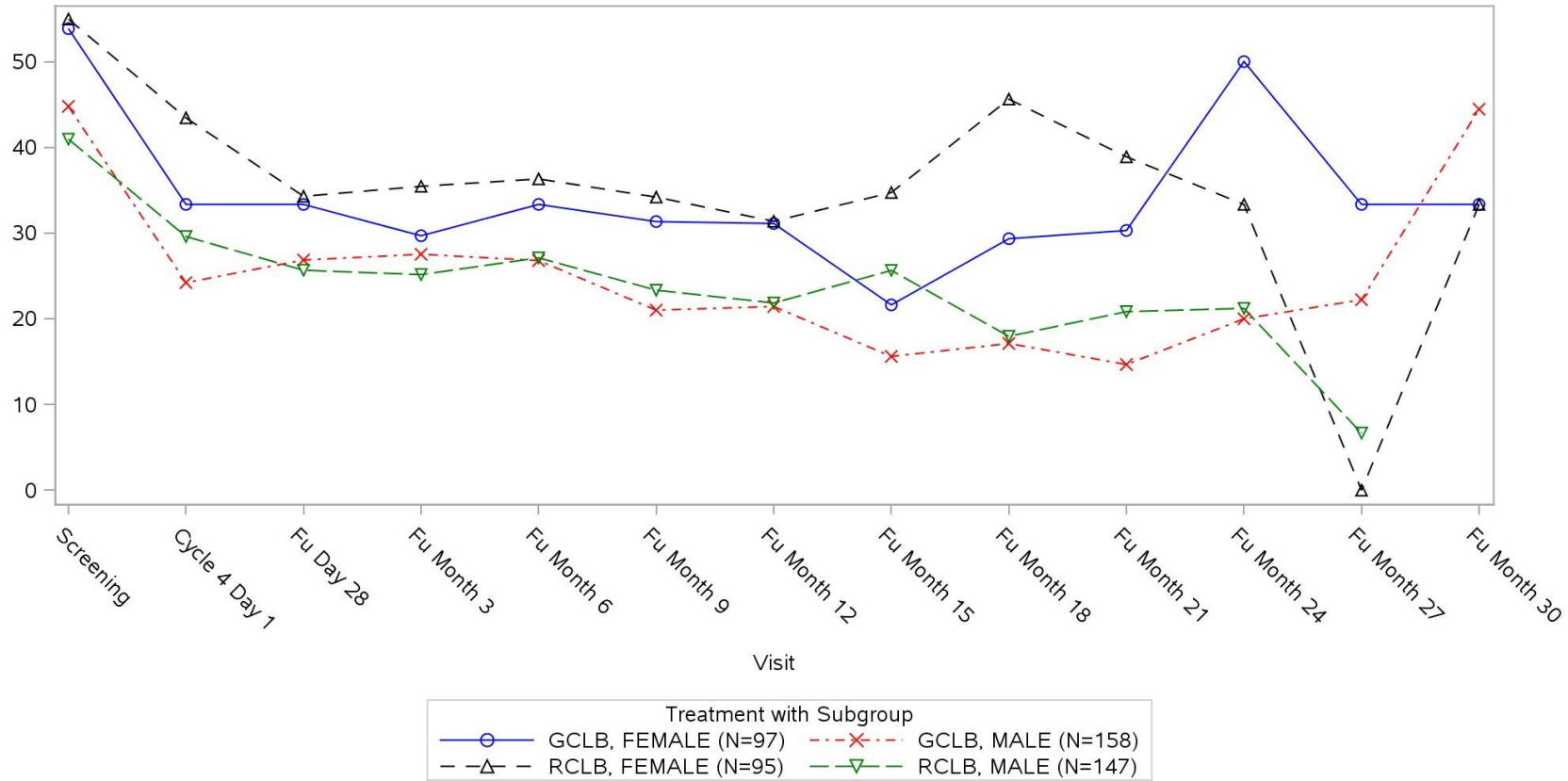
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04MAR2020 19:13

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

Sex (N=497) Laboratory Test: Future Health



Clinical cut-off: 09MAY2013

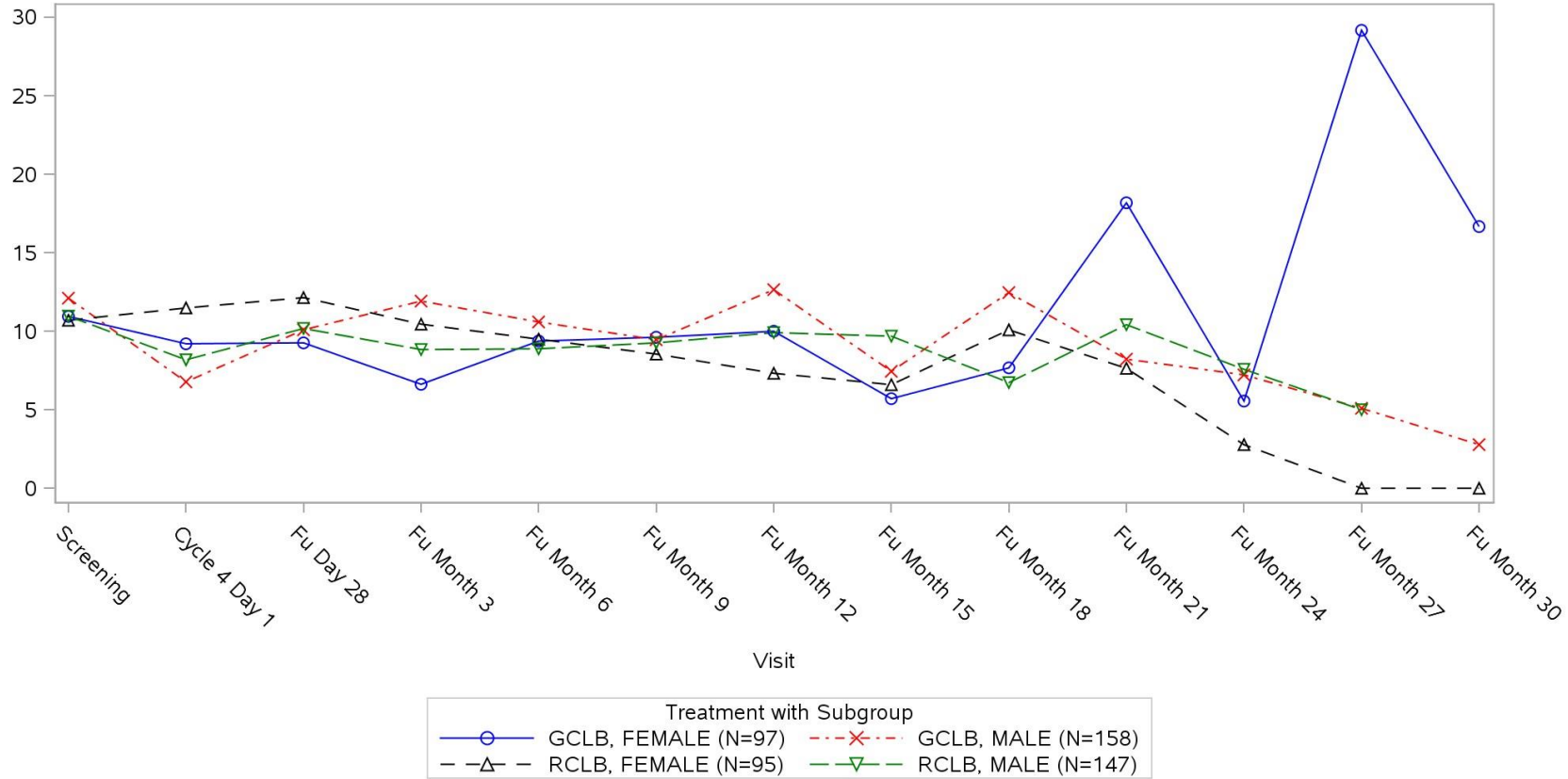
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

Sex (N=497) Laboratory Test: Infection Scale



Clinical cut-off: 09MAY2013

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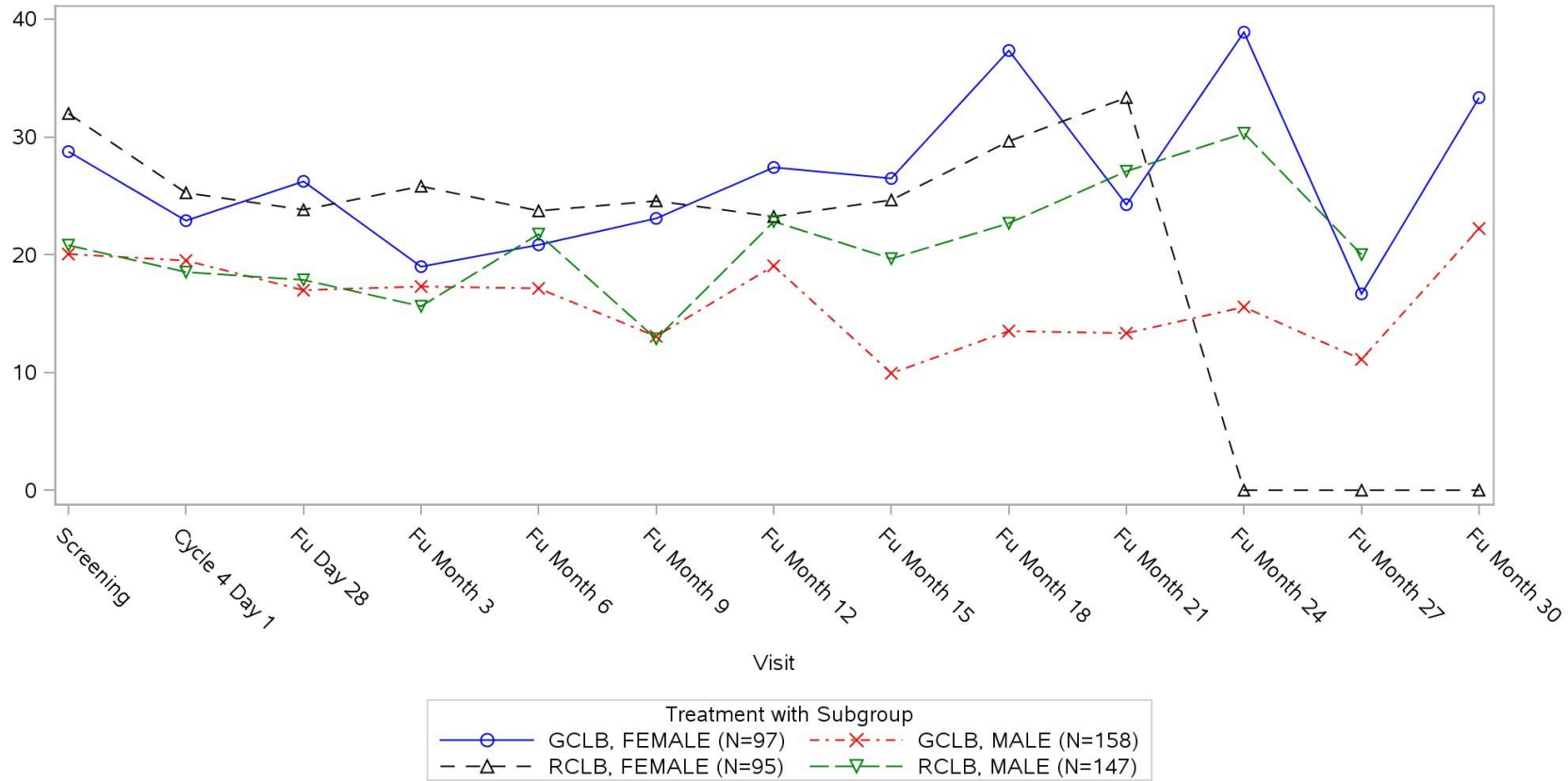
Page 76 of 78

POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

Sex (N=497) Laboratory Test: Social Problems



Clinical cut-off: 09MAY2013

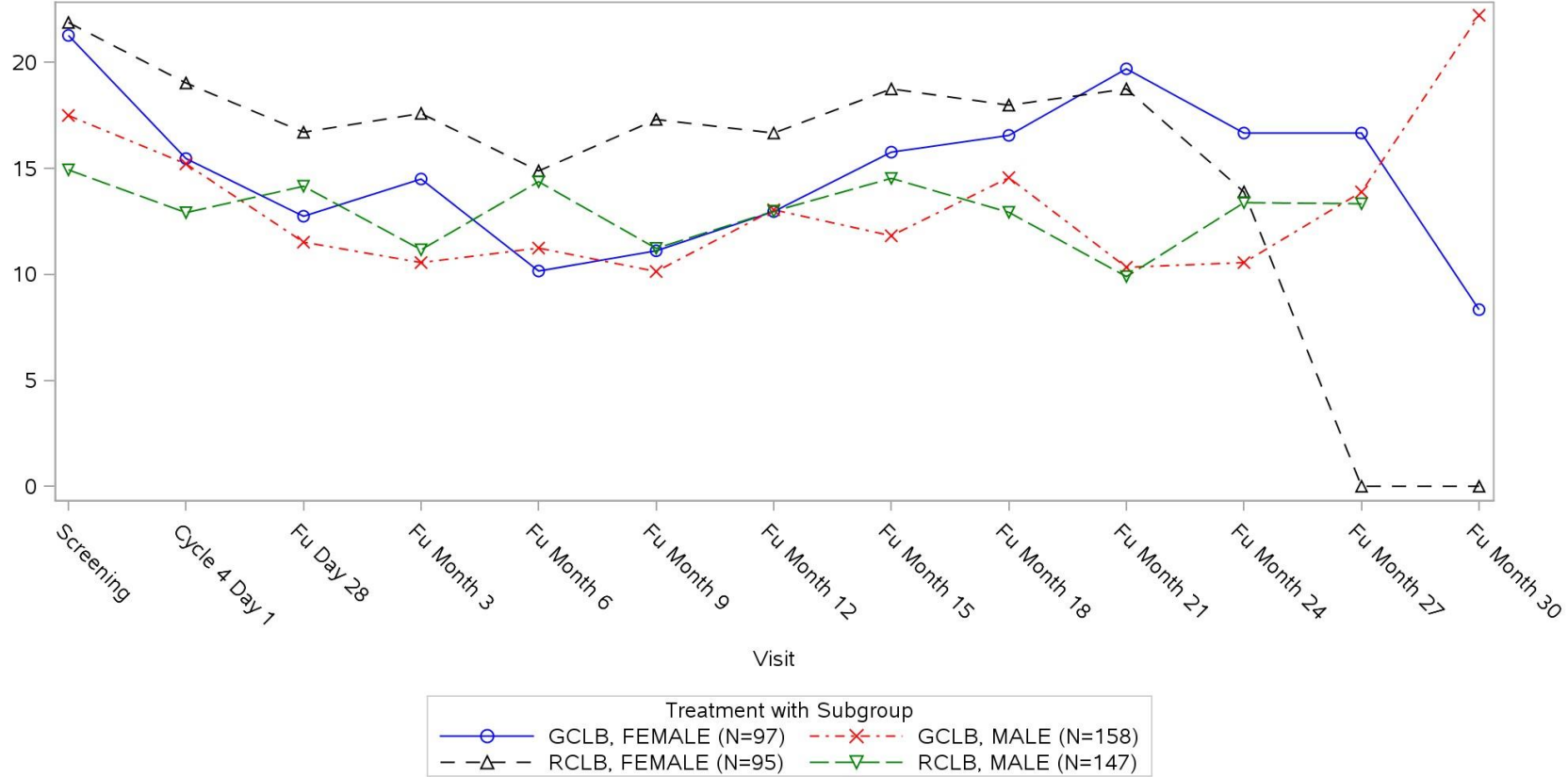
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POPULATION: Labelpopulation, Intent-to-Treat Patients

ENDPOINT: EORTC QoL 16

STUDY: CLL11(BO21004), Stage 2

Sex (N=497) Laboratory Test: Treatment Side Effects Scale



Clinical cut-off: 09MAY2013

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04MAR2020 19:13

Anhang 4-G3: Generelle Verträglichkeit

17 (Anhang): Ergebnisse für Patienten mit UE aus RCT mit dem zu bewertenden Arzneimittel - Subgruppenanalysen

POPULATION: Safety Evaluable Patients
 ENDPOINT: Any AEs
 MODEL: Unstratified Analysis STUDY:
 CLL11 (8021004), Final
 Dichotomous Analysis by Subgroups (Safety)

Name	Level	SC1b (N=336)				SC1b (N=321)				SC1b vs. SC1b																		
		Patients		Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference			Relative Risk					Relative Risk								
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CI	95% Upper CI	Absolute Risk	Convergence Reason	95% Lower CI	95% Upper CI	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI	
All	n/a	336	100,0	316	94,0	321	100,0	290	90,3	0,69	Convergence criterion (GCONV+E-8) satisfied.	0,94	0,03	0,037	Algorithm converged.	-0,004	0,078	1,04	Algorithm converged.	0,00	0,09	0,0784		0,96	Algorithm converged.	0,92	1,00	
Gender	Male	205	61,0	193	93,7	199	62,0	183	92,0	0,29	Convergence criterion (GCONV+E-8) satisfied.	0,60	0,76	0,017	Algorithm converged.	-0,033	0,067	1,02	Algorithm converged.	0,96	0,08	0,5094	0,2256	0,98	Algorithm converged.	0,93	1,04	
	Female	131	39,0	124	94,7	122	38,0	107	87,3	0,48	Convergence criterion (GCONV+E-8) satisfied.	0,98	0,32	0,070	Algorithm converged.	0,000	0,139	1,08	Algorithm converged.	1,00	0,17	0,0550		0,93	Algorithm converged.	0,86	1,00	
Age	<75 years	180	53,6	164	91,1	187	58,3	161	86,1	0,66	Convergence criterion (GCONV+E-8) satisfied.	0,86	0,20	0,050	Algorithm converged.	-0,015	0,115	1,06	Algorithm converged.	0,98	0,14	0,1310	0,3031	0,94	Algorithm converged.	0,88	1,02	
	≥75 years	156	46,4	152	97,4	134	41,7	129	96,3	1,47	Convergence criterion (GCONV+E-8) satisfied.	0,39	0,60	0,012	Algorithm converged.	-0,029	0,052	1,01	Algorithm converged.	0,97	0,06	0,5733		0,99	Algorithm converged.	0,95	1,03	
Geographical Region	North America	16	4,8	16	100,0	13	4,0	13	100,0																			
	Central and South America	11	3,3	11	100,0	6	1,9	6	100,0																			
	Western Europe	208	61,9	205	98,6	193	60,1	190	98,4	1,08	Convergence criterion (GCONV+E-8) satisfied.	0,22	0,41	0,001	Algorithm converged.	-0,023	0,025	1,00	Algorithm converged.	0,98	0,03	0,9265		1,00	Algorithm converged.	0,98	1,02	
	Asia-Pacific	23	6,8	23	100,0	22	6,9	22	100,0																			
	Other	78	23,2	63	78,2	87	27,1	58	67,8	1,70	Convergence criterion (GCONV+E-8) satisfied.	0,84	0,43	0,104	Algorithm converged.	-0,030	0,238	1,15	Algorithm converged.	0,96	0,19	0,1336		0,87	Algorithm converged.	0,72	1,04	
Binet Staging at Baseline	I	75	22,3	73	97,3	72	22,4	64	88,9	0,56	Convergence criterion (GCONV+E-8) satisfied.	0,93	0,27	0,084	Algorithm converged.	0,003	0,166	1,10	Algorithm converged.	1,00	0,20	0,0477	0,3478	0,91	Algorithm converged.	0,83	1,00	
	II	143	42,6	129	89,5	132	41,1	114	86,4	0,35	Convergence criterion (GCONV+E-8) satisfied.	0,65	0,80	0,031	Algorithm converged.	-0,046	0,109	1,04	Algorithm converged.	0,95	0,13	0,4254		0,96	Algorithm converged.	0,88	1,05	
	III	118	35,1	113	97,5	117	36,4	112	95,7	1,71	Convergence criterion (GCONV+E-8) satisfied.	0,40	0,33	0,017	Algorithm converged.	-0,029	0,064	1,02	Algorithm converged.	0,97	0,07	0,4653		0,98	Algorithm converged.	0,94	1,03	

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable. Clinical cut-off:
 100CT2017

Program: root/clinical_studies/R05072759/CDPT7159/8021004/data_analysis/ACE_CSRFinal/qe/program/t_a_wm_sas
 Output: root/clinical_studies/R05072759/CDPT7159/8021004/data_analysis/ACE_CSRFinal/qe/output/t_a_wm_sq_AAB_SR_100CT2017_21004.xls 090CT2019 0:27

18 (Anhang): Ergebnisse für Patienten mit SUE aus RCT mit dem zu bewertenden Arzneimittel - Subgruppenanalysen

POPULATION: Safety Evaluable Patients
 ENDPOINT: Any SAEs
 MODEL: Unstratified Analysis STUDY:
 CLL11 (N021004), Final
 Dichotomous Analysis by Subgroups (Safety)

Name	Level	GC1b (N=236)				GC1b (N=921)				GC1b vs. GC1b																	
		Patients		Events		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk				Relative Risk							
		n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CI	95% Upper CI	Absolute Risk	Convergence Reason	95% Lower CI	95% Upper CI	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI	
All	n/a	336	100,0	150	44,6	321	100,0	124	38,6	0,28	Convergence criterion (GCONV+E=8) satisfied.	0,94	0,75	0,060	Algorithm converged.	-0,015	0,135	1,16	Algorithm converged.	0,96	0,79	0,1196		0,87	Algorithm converged.	0,72	0,04
Gender	Male	205	61,0	101	49,3	199	62,0	79	39,7	1,48	Convergence criterion (GCONV+E=8) satisfied.	0,99	0,19	0,096	Algorithm converged.	-0,001	0,192	1,24	Algorithm converged.	1,00	0,55	0,0549	0,3099	0,81	Algorithm converged.	0,65	1,00
	Female	131	39,0	49	37,4	122	38,0	45	36,8	1,02	Convergence criterion (GCONV+E=8) satisfied.	0,61	0,70	0,005	Algorithm converged.	-0,114	0,124	1,01	Algorithm converged.	0,74	0,40	0,9319		0,99	Algorithm converged.	0,72	0,16
Age	<75 years	180	53,6	67	37,2	187	58,3	59	31,6	1,29	Convergence criterion (GCONV+E=8) satisfied.	0,84	0,98	0,057	Algorithm converged.	-0,040	0,154	1,18	Algorithm converged.	0,89	0,57	0,2537	0,6950	0,85	Algorithm converged.	0,64	0,13
	≥75 years	156	46,4	83	53,2	134	41,7	65	48,5	1,21	Convergence criterion (GCONV+E=8) satisfied.	0,76	0,92	0,047	Algorithm converged.	-0,068	0,162	1,10	Algorithm converged.	0,87	0,38	0,4273		0,91	Algorithm converged.	0,73	0,15
Geographical Region	North America	16	4,8	7	43,8	13	4,0	4	30,8	1,75	Convergence criterion (GCONV+E=8) satisfied.	0,38	0,14	0,130	Algorithm converged.	-0,220	0,479	1,42	Algorithm converged.	0,53	0,81	0,4844		0,70	Algorithm converged.	0,26	0,89
	Central and South America	11	3,3	5	45,5	6	1,9				Quasi-complete separation if data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.				WARNING: Negative of Hessian not positive definite.						WARNING: Negative of Hessian not positive definite.		
	Western Europe	208	61,9	108	51,9	193	60,1	89	46,1	1,26	Convergence criterion (GCONV+E=8) satisfied.	0,85	0,87	0,058	Algorithm converged.	-0,040	0,156	1,13	Algorithm converged.	0,92	0,38	0,2471		0,89	Algorithm converged.	0,73	0,09
Asia-Pacific	Asia-Pacific	23	6,8	13	56,5	22	6,9	12	54,5	1,08	Convergence criterion (GCONV+E=8) satisfied.	0,33	0,51	0,020	Algorithm converged.	-0,271	0,310	1,04	Algorithm converged.	0,61	0,75	0,8940		0,97	Algorithm converged.	0,57	0,63
	Other	78	23,2	17	21,8	87	27,1	19	21,8	1,00	Convergence criterion (GCONV+E=8) satisfied.	0,48	0,09	0,000	Algorithm converged.	-0,127	0,126	1,00	Algorithm converged.	0,56	0,78	0,9945		1,00	Algorithm converged.	0,56	0,79
Binet Staging at Baseline	A	75	22,3	35	46,7	72	22,4	30	41,7	1,22	Convergence criterion (GCONV+E=8) satisfied.	0,64	0,35	0,050	Algorithm converged.	-0,110	0,210	1,12	Algorithm converged.	0,78	0,61	0,5428	0,9699	0,89	Algorithm converged.	0,62	0,29
	B	143	42,6	54	37,8	132	41,1	43	32,6	1,26	Convergence criterion (GCONV+E=8) satisfied.	0,76	0,06	0,052	Algorithm converged.	-0,061	0,165	1,16	Algorithm converged.	0,84	0,60	0,3704		0,86	Algorithm converged.	0,62	0,19
	C	118	35,1	61	51,7	117	36,4	51	43,6	1,38	Convergence criterion (GCONV+E=8) satisfied.	0,83	0,31	0,081	Algorithm converged.	-0,046	0,208	1,19	Algorithm converged.	0,91	0,55	0,2158		0,84	Algorithm converged.	0,64	0,10

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable. Clinical cut-off: 100CR2017

Program: root/clinical_studies/R05072759/CDPP7159/N021004/data_analysis/ACE_CSRFinal/qa/program/t_s_ae.sas
 Output: root/clinical_studies/R05072759/CDPP7159/N021004/data_analysis/ACE_CSRFinal/qa/output/t_s_ae_sg_ASAE_8E_100CR2017_21004.xls 09OCT2019 1:07

19 (Anhang): Ergebnisse für Patienten mit Behandlungsabbruch wegen UE aus RCT mit dem zu bewertenden Arzneimittel - Subgruppenanalysen

POPULATION: Safety Evaluable Patients
 ENDPOINT: AEs leading to treatment discontinuation MODEL:
 Unstratified Analysis
 STUDY: CLL11 (R021004), Final
 Dichotomous Analysis by Subgroups (Safety)

Name	Level	GC1b (N=236)				GC1b (N=921)				GC1b vs. GC1b																	
		Patients		Events		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk				Relative Risk							
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	336	100,0	67	19,9	321	100,0	47	14,6	0,45	Convergence criterion (GCONV+E=8) satisfied.	0,96	2,19	0,053	Algorithm converged.	-0,005	0,111	1,36	Algorithm converged.	0,97	0,91	0,0751		0,73	Algorithm converged.	0,52	1,03
Gender	Male	205	61,0	37	18,0	199	62,0	29	14,6	0,29	Convergence criterion (GCONV+E=8) satisfied.	0,76	2,20	0,035	Algorithm converged.	-0,037	0,107	1,24	Algorithm converged.	0,79	0,93	0,3464	0,5213	0,81	Algorithm converged.	0,52	1,26
	Female	131	39,0	30	22,9	122	38,0	18	14,8	0,72	Convergence criterion (GCONV+E=8) satisfied.	0,90	3,27	0,081	Algorithm converged.	-0,014	0,177	1,55	Algorithm converged.	0,91	0,64	0,1038		0,64	Algorithm converged.	0,38	1,09
Age	<75 years	180	53,6	30	16,7	187	58,3	20	10,7	0,67	Convergence criterion (GCONV+E=8) satisfied.	0,91	3,07	0,060	Algorithm converged.	-0,010	0,130	1,56	Algorithm converged.	0,92	0,64	0,0993	0,4223	0,64	Algorithm converged.	0,38	1,09
	≥75 years	156	46,4	37	23,7	134	41,7	27	20,1	0,23	Convergence criterion (GCONV+E=8) satisfied.	0,70	2,16	0,036	Algorithm converged.	-0,060	0,131	1,18	Algorithm converged.	0,76	0,83	0,4667		0,85	Algorithm converged.	0,55	1,32
Geographical Region	North America	16	4,8	3	11,3	13	4,0	2	15,4	0,50	Convergence criterion (GCONV+E=8) satisfied.	0,40	15,75	0,159	Algorithm converged.	-0,141	0,459	2,03	Algorithm converged.	0,47	0,81	0,3439	0,3609	0,49	Algorithm converged.	0,11	2,14
	Central and South America	11	3,3	2	18,2	6	6,9				Quasi-complete separation if data points detected.				ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
	Western Europe	208	61,9	44	21,2	193	60,1	37	19,2	0,13	Convergence criterion (GCONV+E=8) satisfied.	0,69	1,84	0,020	Algorithm converged.	-0,059	0,098	1,10	Algorithm converged.	0,75	0,63	0,6216		0,91	Algorithm converged.	0,61	1,34
	Asia-Pacific	23	6,8	6	26,1	22	6,9	2	9,1	0,53	Convergence criterion (GCONV+E=8) satisfied.	0,63	19,83	0,170	Algorithm converged.	-0,046	0,386	2,87	Algorithm converged.	0,65	0,73	0,1655		0,35	Algorithm converged.	0,08	1,55
Other	78	23,2	10	12,8	87	27,1	6	6,9	0,99	Convergence criterion (GCONV+E=8) satisfied.	0,69	5,74	0,059	Algorithm converged.	-0,032	0,151	1,86	Algorithm converged.	0,71	0,88	0,2079		0,54	Algorithm converged.	0,20	1,41	
Binet Staging at Baseline	A	75	22,3	14	18,7	72	22,4	8	11,1	0,84	Convergence criterion (GCONV+E=8) satisfied.	0,72	4,69	0,076	Algorithm converged.	-0,039	0,190	1,68	Algorithm converged.	0,75	0,76	0,2072	0,8572	0,60	Algorithm converged.	0,27	1,33
	B	143	42,6	23	16,7	132	41,1	19	11,4	0,34	Convergence criterion (GCONV+E=8) satisfied.	0,66	2,73	0,033	Algorithm converged.	-0,046	0,113	1,29	Algorithm converged.	0,70	0,40	0,4168		0,77	Algorithm converged.	0,42	1,44
	C	118	35,1	32	27,1	117	36,4	24	20,5	0,44	Convergence criterion (GCONV+E=8) satisfied.	0,79	2,64	0,066	Algorithm converged.	-0,043	0,175	1,32	Algorithm converged.	0,83	0,10	0,2377		0,76	Algorithm converged.	0,48	1,20

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable. Clinical cut-off:
 100CR2017

Program: root/clinical_studies/R05072759/CDP7159/R021004/data_analysis/ACE_CSRFinal/qa/program/t_s_ae.sas
 Output: root/clinical_studies/R05072759/CDP7159/R021004/data_analysis/ACE_CSRFinal/qa/output/t_s_ae_sg_AE1DIS_8E_100CR2017_21004.xls 09OCT2019 0:49

20 (Anhang): Ergebnisse für Patienten mit nicht schweren UE (Grad 1 und Grad 2) aus RCT mit dem zu bewertenden Arzneimittel - Subgruppenanalysen

POPULATION: Safety Evaluable Patients
 ENDPOINT: AEs Grade 1-2
 MODEL: Unstratified Analysis STUDY:
 CLL11 (R021004), Final
 Dichotomous Analysis by Subgroups (Safety)

Name	Level	GC1b (N=236)				GC1b (N=921)				GC1b vs. GC1b																	
		Patients		Events		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk				Relative Risk							
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CI	95% Upper CI	Absolute Risk	Convergence Reason	95% Lower CI	95% Upper CI	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI
All	n/a	336	100,0	75	22,3	321	100,0	99	30,8	0,64	Convergence criterion (GCONV+E=8) satisfied.	0,45	0,91	-0,085	Algorithm converged.	-0,153	-0,018	0,72	Algorithm converged.	0,56	0,94	0,0141		1,38	Algorithm converged.	1,07	1,79
Gender	Male	205	61,0	43	21,0	199	62,0	59	29,6	0,63	Convergence criterion (GCONV+E=8) satisfied.	0,40	0,99	-0,087	Algorithm converged.	-0,171	-0,002	0,71	Algorithm converged.	0,50	1,00	0,0468	0,8458	1,41	Algorithm converged.	1,00	1,99
	Female	131	39,0	32	24,4	122	38,0	40	32,8	0,66	Convergence criterion (GCONV+E=8) satisfied.	0,38	1,15	-0,084	Algorithm converged.	-0,195	0,028	0,75	Algorithm converged.	0,50	1,10	0,1432		1,34	Algorithm converged.	0,91	1,99
Age	<75 years	180	53,6	39	21,7	187	58,3	61	32,6	0,57	Convergence criterion (GCONV+E=8) satisfied.	0,36	0,91	-0,110	Algorithm converged.	-0,200	-0,019	0,66	Algorithm converged.	0,47	0,94	0,0204	0,4465	1,51	Algorithm converged.	1,07	2,13
	≥75 years	156	46,4	36	23,1	134	41,7	38	28,4	0,76	Convergence criterion (GCONV+E=8) satisfied.	0,45	1,29	-0,053	Algorithm converged.	-0,154	0,048	0,81	Algorithm converged.	0,55	1,21	0,3041		1,23	Algorithm converged.	0,83	1,82
Geographical Region	North America	16	4,8	2	12,5	13	4,0	5	38,5	0,23	Convergence criterion (GCONV+E=8) satisfied.	0,04	1,46	-0,260	Algorithm converged.	-0,570	0,051	0,33	Algorithm converged.	0,07	1,41	0,1333	0,1534	0,08	Algorithm converged.	0,71	13,35
	Central and South America	11	3,3	1	9,1	6	1,9	4	66,7	0,05	Convergence criterion (GCONV+E=8) satisfied.	0,01	0,72	-0,576	Algorithm converged.	-0,989	-0,162	0,14	Algorithm converged.	0,02	0,96	0,0455		7,33	Algorithm converged.	1,04	81,67
	Western Europe	208	61,9	47	22,6	193	60,1	60	31,1	0,65	Convergence criterion (GCONV+E=8) satisfied.	0,41	1,01	-0,085	Algorithm converged.	-0,171	0,002	0,73	Algorithm converged.	0,52	1,01	0,0564		1,38	Algorithm converged.	0,99	1,91
	Asia-Pacific	53	15,8	11	20,8	47	14,3	15	22,7	0,72	Convergence criterion (GCONV+E=8) satisfied.	0,16	3,11	-0,053	Algorithm converged.	-0,287	0,180	0,77	Algorithm converged.	0,24	2,48	0,6561		1,31	Algorithm converged.	0,40	4,24
Binet Staging at Baseline	A	75	22,3	18	25,3	72	22,4	22	30,6	0,77	Convergence criterion (GCONV+E=8) satisfied.	0,37	1,59	-0,052	Algorithm converged.	-0,197	0,093	0,83	Algorithm converged.	0,49	1,40	0,4814	0,2955	1,21	Algorithm converged.	0,72	2,03
	B	143	42,6	41	28,7	132	41,1	47	35,6	0,73	Convergence criterion (GCONV+E=8) satisfied.	0,44	1,21	-0,069	Algorithm converged.	-0,180	0,041	0,81	Algorithm converged.	0,57	1,14	0,2193		1,24	Algorithm converged.	0,88	1,75
C		118	35,1	15	12,7	117	36,4	30	25,6	0,42	Convergence criterion (GCONV+E=8) satisfied.	0,21	0,84	-0,129	Algorithm converged.	-0,229	-0,030	0,50	Algorithm converged.	0,28	0,87	0,0149		1,02	Algorithm converged.	1,15	3,55

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable. Clinical cut-off:
 10OCT2017

Program: root/clinical_studies/R05072759/CDPT7159/R021004/data_analysis/ACR_CSRFinal/qe/program/t_a_se.sas
 Output: root/clinical_studies/R05072759/CDPT7159/R021004/data_analysis/ACR_CSRFinal/qe/output/t_a_se_sq_ARG12_SE_10OCT2017_21004.xls 09OCT2019
 0:31

21 (Anhang): Ergebnisse für Patienten mit schweren UE (Grad ≥ 3) aus RCT mit dem zu bewertenden Arzneimittel - Subgruppenanalysen

POPULATION: Safety Evaluable Patients
 ENDPOINT: AEs Grade ≥ 3
 MODEL: Unstratified Analysis STUDY:
 CLL11 (N021004), Final
 Dichotomous Analysis by Subgroups (Safety)

Name	Level	GC1b (N=236)				GC1b (N=921)				GC1b vs. GC1b																	
		Patients		Events		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk				Relative Risk							
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CI	95% Upper CI	Absolute Risk	Convergence Reason	95% Lower CI	95% Upper CI	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI
All	n/a	336	100,0	243	71,7	321	100,0	191	59,5	0,73	Convergence criterion (GCONV+E=8) satisfied.	1,25	0,39	0,122	Algorithm converged.	0,050	0,194	1,21	Algorithm converged.	0,08	0,35	0,0011		0,83	Algorithm converged.	0,74	0,93
Gender	Male	205	61,0	149	72,7	199	62,0	124	62,3	0,61	Convergence criterion (GCONV+E=8) satisfied.	1,06	0,45	0,104	Algorithm converged.	0,013	0,195	1,17	Algorithm converged.	0,02	0,34	0,0274	0,4482	0,86	Algorithm converged.	0,75	0,98
	Female	131	39,0	92	70,2	122	38,0	67	54,9	0,94	Convergence criterion (GCONV+E=8) satisfied.	1,15	0,25	0,153	Algorithm converged.	0,035	0,271	1,28	Algorithm converged.	0,05	0,56	0,0138		0,78	Algorithm converged.	0,64	0,95
Age	<75 years	180	53,6	124	69,4	187	58,3	100	53,5	0,98	Convergence criterion (GCONV+E=8) satisfied.	1,29	0,03	0,160	Algorithm converged.	0,062	0,258	1,30	Algorithm converged.	0,10	0,53	0,0019	0,1328	0,77	Algorithm converged.	0,65	0,91
	≥75 years	156	46,4	119	74,4	134	41,7	91	67,9	0,37	Convergence criterion (GCONV+E=8) satisfied.	0,82	0,28	0,064	Algorithm converged.	+0,040	0,169	1,09	Algorithm converged.	0,94	0,27	0,2310		0,91	Algorithm converged.	0,79	1,06
Geographical Region	North America	16	4,8	14	87,5	13	4,0	8	61,5	0,37	Convergence criterion (GCONV+E=8) satisfied.	0,68	0,98	0,260	Algorithm converged.	-0,051	0,570	1,42	Algorithm converged.	0,89	0,27	0,1404	0,2030	0,70	Algorithm converged.	0,44	1,12
	Central and South America	11	3,3	10	90,9	6	0,9	2	33,3	0,00	Convergence criterion (GCONV+E=8) satisfied.	1,39	287,60	0,576	Algorithm converged.	0,162	0,989	2,73	Algorithm converged.	0,87	0,59	0,0864		0,37	Algorithm converged.	0,12	1,15
	Western Europe	208	61,9	158	76,0	193	60,1	130	67,4	0,53	Convergence criterion (GCONV+E=8) satisfied.	0,99	0,37	0,086	Algorithm converged.	-0,002	0,174	1,13	Algorithm converged.	0,00	0,28	0,0583		0,89	Algorithm converged.	0,78	1,00
	Asia-Pacific	53	15,8	49	92,6	22	6,9	17	77,3	0,40	Convergence criterion (GCONV+E=8) satisfied.	0,32	6,07	0,053	Algorithm converged.	-0,180	0,287	1,07	Algorithm converged.	0,80	0,43	0,6564		0,94	Algorithm converged.	0,70	1,26
Other	78	23,2	40	51,3	87	27,1	34	39,1	0,64	Convergence criterion (GCONV+E=8) satisfied.	0,88	0,05	0,122	Algorithm converged.	-0,029	0,273	1,31	Algorithm converged.	0,93	0,84	0,1173		0,76	Algorithm converged.	0,54	1,07	
Binet Staging at Baseline	A	75	22,3	54	72,0	72	22,4	42	58,3	0,84	Convergence criterion (GCONV+E=8) satisfied.	0,82	0,66	0,137	Algorithm converged.	-0,016	0,289	1,23	Algorithm converged.	0,97	0,57	0,0868	0,9834	0,81	Algorithm converged.	0,64	1,03
	B	143	42,6	87	60,8	132	41,1	67	50,8	0,51	Convergence criterion (GCONV+E=8) satisfied.	0,93	0,43	0,101	Algorithm converged.	-0,016	0,218	1,20	Algorithm converged.	0,97	0,48	0,0961		0,83	Algorithm converged.	0,67	1,03
	C	118	35,1	100	84,7	117	36,4	82	70,1	0,37	Convergence criterion (GCONV+E=8) satisfied.	1,25	0,49	0,147	Algorithm converged.	0,041	0,252	1,21	Algorithm converged.	0,05	0,39	0,0083		0,83	Algorithm converged.	0,72	0,95

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable. Clinical cut-off:
 10OCT2017

Program: root/clinical_studies/R05072759/CDPT7159/R021004/data_analysis/ACR_CSRFinal/qe/program/t_a_se.sas
 Output: root/clinical_studies/R05072759/CDPT7159/R021004/data_analysis/ACR_CSRFinal/qe/output/t_a_se_sq_AEG345_SE_10OCT2017_21004.xls 09OCT2019 0:44

22 (Anhang): Ergebnisse für Patienten mit UE Grad 1 aus RCT mit dem zu bewertenden Arzneimittel - Subgruppenanalysen

POPULATION: Safety Evaluable Patients
 ENDPOINT: AEs Grade 10
 MODEL: Unstratified Analysis
 STUDY: CLL11 (R021004), Final
 Dichotomous Analysis by Subgroups (Safety)

Name	Level	R1b (N=336)				R01b (N=321)				G01b vs. R1b										R01b vs. G01b							
		Patients		Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference		Relative Risk				Relative Risk									
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CI	95% Upper CI	Absolute Risk	Convergence Reason	95% Lower CI	95% Upper CI	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI
All	n/a	336	100,0	23	7,4	321	100,0	34	10,6	0,68	Convergence criterion (GCONV1E-8) satisfied.	0,40	1,17	-0,032	Algorithm converged.	-0,075	0,012	0,70	Algorithm converged.	0,43	1,15	0,1605		1,42	Algorithm converged.	0,87	2,33
Gender	Male	305	91,0	17	5,3	299	92,0	19	6,3	0,86	Convergence criterion (GCONV1E-8) satisfied.	0,43	1,70	-0,013	Algorithm converged.	-0,068	0,043	0,87	Algorithm converged.	0,47	1,62	0,6583	0,2838	1,15	Algorithm converged.	0,62	2,15
	Female	131	39,0	6	4,6	122	38,0	15	12,3	0,46	Convergence criterion (GCONV1E-8) satisfied.	0,19	1,14	-0,062	Algorithm converged.	-0,133	0,009	0,50	Algorithm converged.	0,22	1,13	0,0952		2,01	Algorithm converged.	0,89	4,58
Age	<75 years	180	53,6	10	5,6	187	58,3	21	11,2	0,46	Convergence criterion (GCONV1E-8) satisfied.	0,21	1,02	-0,057	Algorithm converged.	-0,113	0,000	0,49	Algorithm converged.	0,24	1,02	0,0570	0,1732	1,02	Algorithm converged.	0,98	4,17
	≥75 years	156	46,4	13	8,6	134	41,7	13	9,7	0,99	Convergence criterion (GCONV1E-8) satisfied.	0,45	2,16	-0,001	Algorithm converged.	-0,069	0,067	0,99	Algorithm converged.	0,49	2,01	0,9803		1,01	Algorithm converged.	0,50	2,04
Geographical Region	North America	16	4,8			13	4,0	2	15,4		Quasi-complete separation * of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.				Algorithm converged.	0,00	NE	0,9999	0,0580	>999,99	Algorithm converged.	0,00	NE
	Central and South America	11	3,3			6	1,9	3	50,0		Quasi-complete separation * of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.				WARNING: Negative of Hessian not positive definite.						WARNING: Negative of Hessian not positive definite.		
	Western Europe	208	61,9	18	8,7	193	60,1	15	7,8	0,87	Convergence criterion (GCONV1E-8) satisfied.	0,44	1,71	-0,012	Algorithm converged.	-0,069	0,045	0,88	Algorithm converged.	0,48	1,62	0,6808		1,14	Algorithm converged.	0,62	2,10
Asia-Pacific		23	6,8	1	4,3	22	6,9	1	4,5	0,95	Convergence criterion (GCONV1E-8) satisfied.	0,06	16,27	-0,002	Algorithm converged.	-0,122	0,119	0,96	Algorithm converged.	0,06	1,47	0,9743		1,05	Algorithm converged.	0,07	15,70
	Other	78	23,2	6	7,7	87	27,1	8	10,3	0,72	Convergence criterion (GCONV1E-8) satisfied.	0,24	1,13	-0,027	Algorithm converged.	-0,114	0,061	0,74	Algorithm converged.	0,28	1,09	0,5562		1,34	Algorithm converged.	0,50	3,61
Binet Staging at Baseline	I	75	22,3	6	8,0	72	22,4	8	11,1	0,70	Convergence criterion (GCONV1E-8) satisfied.	0,23	1,11	-0,031	Algorithm converged.	-0,126	0,064	0,72	Algorithm converged.	0,26	1,07	0,5229	0,8064	1,39	Algorithm converged.	0,51	3,81
	II	143	42,6	13	10,5	132	41,1	18	13,6	0,74	Convergence criterion (GCONV1E-8) satisfied.	0,36	1,54	-0,031	Algorithm converged.	-0,109	0,046	0,77	Algorithm converged.	0,40	1,46	0,4239		1,30	Algorithm converged.	0,68	2,47
	III	118	35,1	4	3,4	117	36,4	8	6,8	0,48	Convergence criterion (GCONV1E-8) satisfied.	0,14	1,63	-0,034	Algorithm converged.	-0,091	0,022	0,50	Algorithm converged.	0,15	1,60	0,2409		1,02	Algorithm converged.	0,62	0,52

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable. Clinical cut-off: 100CT2017

Program: root/clinical_studies/R05072759/CDPT7159/R021004/data_analysis/ACE_CSRFinal/qs/program/t_s_ag_sas
 Output: root/clinical_studies/R05072759/CDPT7159/R021004/data_analysis/ACE_CSRFinal/qs/output/t_s_ag_sq_AE1_3E_100CT2017_21004.xls 09OCT2019 0:29

23 (Anhang): Ergebnisse für Patienten mit UE Grad 2 aus RCT mit dem zu bewertenden Arzneimittel - Subgruppenanalysen

POPULATION: Safety Evaluable Patients
 ENDPOINT: AEs Grade 11
 MODEL: Unstratified Analysis
 STUDY: CLL11 (B021004), Final
 Dichotomous Analysis by Subgroups (Safety)

Name	Level	R01b (N=336)				R01b (N=321)				R01b vs. R01c																	
		Patients		Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference		Relative Risk		Relative Risk		Interaction Test									
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CI	95% Upper CI	Absolute Risk	Convergence Reason	95% Lower CI	95% Upper CI	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI
All	n/a	336	100,0	50	14,9	321	100,0	65	20,2	0,69	Convergence criterion (GCONV1E=8) satisfied.	0,46	1,03	-0,054	Algorithm converged.	-0,112	0,004	0,73	Algorithm converged.	0,53	1,03	0,0719		1,36	Algorithm converged.	0,97	1,90
Gender	Male	205	61,0	26	12,7	199	62,0	40	20,1	0,58	Convergence criterion (GCONV1E=8) satisfied.	0,34	0,99	-0,074	Algorithm converged.	-0,146	-0,002	0,63	Algorithm converged.	0,40	0,99	0,0466	0,3124	1,58	Algorithm converged.	1,01	2,49
	Female	131	39,0	24	18,3	122	38,0	25	20,5	0,87	Convergence criterion (GCONV1E=8) satisfied.	0,47	1,62	-0,022	Algorithm converged.	-0,119	0,076	0,89	Algorithm converged.	0,54	1,48	0,6625		1,12	Algorithm converged.	0,68	1,85
Age	<75 years	180	53,6	29	16,1	187	58,3	40	21,4	0,71	Convergence criterion (GCONV1E=8) satisfied.	0,42	1,20	-0,053	Algorithm converged.	-0,132	0,027	0,75	Algorithm converged.	0,49	1,16	0,1985	0,9023	1,33	Algorithm converged.	0,86	2,05
	>=75 years	156	46,4	21	13,5	134	41,7	25	18,7	0,68	Convergence criterion (GCONV1E=8) satisfied.	0,36	1,28	-0,052	Algorithm converged.	-0,137	0,033	0,72	Algorithm converged.	0,42	1,23	0,2294		1,39	Algorithm converged.	0,81	2,36
Geographical Region	North America	16	4,8	2	12,5	13	4,0	3	23,1	0,48	Convergence criterion (GCONV1E=8) satisfied.	0,07	3,40	-0,106	Algorithm converged.	-0,386	0,175	0,54	Algorithm converged.	0,11	2,77	0,4617	0,8052	1,85	Algorithm converged.	0,36	8,45
	Central and South America	11	3,3	1	9,1	6	1,9	1	16,7	0,50	Convergence criterion (GCONV1E=8) satisfied.	0,03	6,77	-0,076	Algorithm converged.	-0,419	0,267	0,55	Algorithm converged.	0,04	7,25	0,4461		1,83	Algorithm converged.	0,14	24,37
	Western Europe	208	61,9	29	13,9	193	60,1	41	21,2	0,60	Convergence criterion (GCONV1E=8) satisfied.	0,36	1,01	-0,073	Algorithm converged.	-0,147	0,001	0,66	Algorithm converged.	0,43	1,01	0,0568		1,52	Algorithm converged.	0,99	2,35
	Asia-Pacific	23	6,8	3	13,0	22	6,9	4	18,2	0,68	Convergence criterion (GCONV1E=8) satisfied.	0,13	3,43	-0,051	Algorithm converged.	-0,263	0,161	0,72	Algorithm converged.	0,18	2,85	0,6367		1,39	Algorithm converged.	0,35	5,53
	Other	78	23,2	13	19,2	87	27,1	16	18,4	1,06	Convergence criterion (GCONV1E=8) satisfied.	0,48	2,31	0,008	Algorithm converged.	-0,111	0,128	1,05	Algorithm converged.	0,55	1,97	0,8903		0,96	Algorithm converged.	0,51	1,80
Binet Staging at Baseline	A	75	22,3	13	17,3	72	22,4	14	19,4	0,87	Convergence criterion (GCONV1E=8) satisfied.	0,38	2,00	-0,021	Algorithm converged.	-0,146	0,104	0,89	Algorithm converged.	0,45	1,76	0,7412	0,3848	1,12	Algorithm converged.	0,57	2,22
	B	143	42,6	28	19,2	132	41,1	28	22,0	0,79	Convergence criterion (GCONV1E=8) satisfied.	0,44	1,43	-0,038	Algorithm converged.	-0,133	0,057	0,83	Algorithm converged.	0,52	1,33	0,4335		1,21	Algorithm converged.	0,75	1,94
	C	118	35,1	13	10,3	117	36,4	22	18,8	0,44	Convergence criterion (GCONV1E=8) satisfied.	0,20	0,96	-0,095	Algorithm converged.	-0,183	-0,007	0,50	Algorithm converged.	0,25	0,98	0,0422		0,92	Algorithm converged.	1,02	3,97

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable. Clinical cut-off: 100CT2017

Program: root/clinical_studies/R05072759/CDPT7159/B021004/data_analysis/ACE_CSRFinal/qa/program/t_s_ae.sas
 Output: root/clinical_studies/R05072759/CDPT7159/B021004/data_analysis/ACE_CSRFinal/qa/output/t_s_ae_sg_AEG2_SE_100CT2017_21004.xls 09OCT2019 0:33

24 (Anhang): Ergebnisse für Patienten mit UE Grad 3 aus RCT mit dem zu bewertenden Arzneimittel - Subgruppenanalysen

POPULATION: Safety Evaluable Patients
 ENDPOINT: AEs Grade 3
 MODEL: Unstratified Analysis STUDY:
 CLL11 (N021004), Final
 Dichotomous Analysis by Subgroups (Safety)

Name	Level	GClb (N=236)				GClb (N=221)				GClb vs. GClb																
		Patients		Events		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference		Relative Risk				Interaction Test		Relative Risk						
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL
All	n/a	336	100,0	123	36,0	321	100,0	108	33,6	0,11			0,024	Algorithm converged.	-0,049	0,097	1,07	Algorithm converged.	0,87	0,32	0,5249		0,93	Algorithm converged.	0,76	0,15
Gender	Male	205	61,0	73	35,6	199	62,0	65	32,7	0,14			0,029	Algorithm converged.	-0,063	0,122	1,09	Algorithm converged.	0,83	0,43	0,5329	0,8272	0,92	Algorithm converged.	0,70	0,20
	Female	131	39,0	48	36,6	122	38,0	43	35,2	0,06			0,014	Algorithm converged.	-0,104	0,132	1,04	Algorithm converged.	0,75	0,45	0,8173		0,96	Algorithm converged.	0,69	0,14
Age	<75 years	180	53,6	63	35,0	187	58,3	66	35,3	0,99			-0,003	Algorithm converged.	-0,101	0,095	0,99	Algorithm converged.	0,75	0,31	0,9530	0,4087	0,01	Algorithm converged.	0,76	0,33
	≥75 years	156	46,4	58	37,2	134	41,7	42	31,3	0,30			0,058	Algorithm converged.	-0,051	0,168	1,19	Algorithm converged.	0,86	0,64	0,3003		0,84	Algorithm converged.	0,61	0,16
Geographical Region	North America	16	4,8	10	22,5	13	4,0	4	30,8	0,75			0,317	Algorithm converged.	-0,028	0,663	2,03	Algorithm converged.	0,83	0,99	0,1225	0,0523	0,49	Algorithm converged.	0,20	0,21
	Central and South America	11	3,3	3	27,3	6	9,9	1	16,7	0,87			0,106	Algorithm converged.	-0,292	0,504	1,64	Algorithm converged.	0,21	0,49	0,6349		0,61	Algorithm converged.	0,08	0,67
	Western Europe	208	61,9	80	38,5	193	60,1	71	36,8	0,07			0,017	Algorithm converged.	-0,078	0,112	1,05	Algorithm converged.	0,81	0,35	0,7298		0,96	Algorithm converged.	0,74	0,23
	Asia-Pacific	23	6,9	4	17,4	22	6,9	11	50,0	0,21			-0,326	Algorithm converged.	-0,586	-0,066	0,35	Algorithm converged.	0,13	0,93	0,0354		0,87	Algorithm converged.	1,07	7,69
Binet Staging at Baseline	A	75	22,3	31	41,3	72	22,4	24	33,3	0,41			0,080	Algorithm converged.	-0,076	0,236	1,24	Algorithm converged.	0,81	0,89	0,3195	0,7178	0,81	Algorithm converged.	0,53	0,23
	B	143	42,6	49	34,3	132	41,1	43	32,6	0,08			0,017	Algorithm converged.	-0,095	0,128	1,05	Algorithm converged.	0,75	0,47	0,7668		0,95	Algorithm converged.	0,68	0,33
C	118	35,1	43	34,7	117	36,4	41	35,0	0,99			-0,003	Algorithm converged.	-0,125	0,119	0,99	Algorithm converged.	0,70	0,41	0,9619		1,01	Algorithm converged.	0,71	0,43	

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable. Clinical cut-off:
 10OCT2017

Program: root/clinical_studies/R05072759/CDPT7159/R021004/data_analysis/ACR_CSRFinal/qe/program/t_a_se.sas
 Output: root/clinical_studies/R05072759/CDPT7159/R021004/data_analysis/ACR_CSRFinal/qe/output/t_a_se_sq_ARG3_BR_10OCT2017_21004.xls 09OCT2017 0:35

25 (Anhang): Ergebnisse für Patienten mit UE Grad 4 aus RCT mit dem zu bewertenden Arzneimittel - Subgruppenanalysen

POPULATION: Safety Evaluable Patients
 ENDPOINT: AEs Grade 4 MODEL: Unstratified Analysis
 STUDY: CLL11(B021004), Final
 Dichotomous Analysis by Subgroups (Safety)

Name	Level	GClb (N=336)		RClb (N=321)				GClb vs. RClb																			
		Patients	Event	Patients	Patients with Event	Odds Ratio	Absolute Risk Difference	Relative Risk			Relative Risk																
		n	%	n	%	n	%	Odds Ratio	95% Lower CI	95% Upper CI	Absolute Risk	Convergence Reason	95% Lower CI	95% Upper CI	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI	p-Value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI			
All	n/a	336	100,0	37	28,9	321	100,0	52	16,2	0,10	Convergence criterion (GCONV+E-8) satisfied.	1,44	0,07	0,127	Algorithm converged.	0,064	0,190	1,78	Algorithm converged.	0,132	0,41	0,0002		0,56	Algorithm converged.	0,42	0,76
Gender	Male	205	61,0	59	28,8	199	62,0	37	18,6	0,177	Convergence criterion (GCONV+E-8) satisfied.	1,11	0,82	0,102	Algorithm converged.	0,020	0,184	1,55	Algorithm converged.	0,08	0,22	0,0179	0,1990	0,65	Algorithm converged.	0,45	0,93
	Female	131	39,0	38	29,0	122	38,0	15	12,3	0,91	Convergence criterion (GCONV+E-8) satisfied.	1,51	0,63	0,167	Algorithm converged.	0,070	0,264	2,36	Algorithm converged.	0,37	4,07	0,0020		0,42	Algorithm converged.	0,25	0,73
Age	<75 years	180	53,6	52	28,9	187	38,3	22	11,8	0,105	Convergence criterion (GCONV+E-8) satisfied.	1,76	0,28	0,171	Algorithm converged.	0,091	0,252	2,46	Algorithm converged.	0,56	0,87	0,0001	0,0355	0,41	Algorithm converged.	0,26	0,64
	≥75 years	156	46,4	45	28,8	134	41,7	30	22,4	1,41	Convergence criterion (GCONV+E-8) satisfied.	0,82	0,40	0,065	Algorithm converged.	-0,036	0,165	1,29	Algorithm converged.	0,86	0,92	0,2145		0,78	Algorithm converged.	0,52	1,16
Geographical Region	North America	16	4,8	3	18,8	13	4,0	2	15,4	0,27	Convergence criterion (GCONV+E-8) satisfied.	0,18	0,02	0,034	Algorithm converged.	-0,240	0,308	1,22	Algorithm converged.	0,24	0,24	0,8123	0,5102	0,82	Algorithm converged.	0,16	0,20
	Central and South America	11	3,3	7	63,6	6	19,9	1	16,7	0,75	Convergence criterion (GCONV+E-8) satisfied.	0,74	0,03	0,470	Algorithm converged.	0,058	0,882	3,82	Algorithm converged.	0,60	24,14	0,1545		0,26	Algorithm converged.	0,04	1,66
	Western Europe	208	61,9	59	28,4	193	60,1	35	18,1	0,179	Convergence criterion (GCONV+E-8) satisfied.	1,11	0,87	0,102	Algorithm converged.	0,020	0,184	1,56	Algorithm converged.	0,08	0,26	0,0176		0,64	Algorithm converged.	0,44	0,93
	Asia-Pacific	23	6,8	15	65,2	22	6,9	5	22,7	0,37	Convergence criterion (GCONV+E-8) satisfied.	1,71	0,76	0,425	Algorithm converged.	0,163	0,687	2,87	Algorithm converged.	0,26	0,56	0,0124		0,35	Algorithm converged.	0,15	0,80
	Other	78	23,2	13	16,7	87	27,1	9	10,3	0,73	Convergence criterion (GCONV+E-8) satisfied.	0,70	0,31	0,063	Algorithm converged.	-0,041	0,168	1,61	Algorithm converged.	0,73	0,56	0,2385		0,62	Algorithm converged.	0,28	1,37
Binet Staging at Baseline	A	75	22,3	21	28,0	72	22,4	7	9,7	0,61	Convergence criterion (GCONV+E-8) satisfied.	1,43	0,14	0,183	Algorithm converged.	0,060	0,305	2,88	Algorithm converged.	0,30	0,36	0,0088	0,3945	0,35	Algorithm converged.	0,16	0,77
	B	143	42,6	30	21,0	132	41,1	17	12,9	0,80	Convergence criterion (GCONV+E-8) satisfied.	0,94	0,44	0,081	Algorithm converged.	-0,007	0,169	1,63	Algorithm converged.	0,94	0,81	0,0798		0,61	Algorithm converged.	0,36	1,06
	C	118	35,1	46	39,0	117	36,4	28	23,9	0,203	Convergence criterion (GCONV+E-8) satisfied.	1,16	0,57	0,151	Algorithm converged.	0,033	0,268	1,63	Algorithm converged.	0,10	0,42	0,0152		0,61	Algorithm converged.	0,41	0,91

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable. Clinical cut-off: 100CT2017

Program: root/clinical_studies/R05072759/CDP7159/B021004/data_analysis/ACE_CSRFinal/qa/program/t_s_se.sas
 Output: root/clinical_studies/R05072759/CDP7159/B021004/data_analysis/ACE_CSRFinal/qa/output/t_s_se_sg_AE04_RR_100CT2017_21004.xls 09OCT2019 0:46

26 (Anhang): Ergebnisse für Patienten mit UE Grad 5 aus RCT mit dem zu bewertenden Arzneimittel - Subgruppenanalysen

POPULATION: Safety Evaluable Patients
 ENDPOINT: AEs Grade 5 (AEs leading to death) MODEL:
 Unstratified Analysis
 STUDY: CLL11 (B021004), Final
 Dichotomous Analysis by Subgroups (Safety)

Name	Level	GClb (N=336)				RClb (N=321)				GClb vs. RClb																	
		Patients		Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk				Relative Risk							
		n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CI	95% Upper CI	Absolute Risk	Convergence Reason	95% Lower CI	95% Upper CI	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI	
All	n/a	336	100,0	236,8	70,8	321	100,0	31	9,7	0,69			-0,028	Algorithm converged.	-0,070	0,014	0,71	Algorithm converged.	0,42	0,19	0,1922		1,41	Algorithm converged.	0,64	0,37	
Gender	Male	205	61,0	170,3	83,1	199	62,0	22	11,1	0,73			-0,028	Algorithm converged.	-0,085	0,030	0,75	Algorithm converged.	0,41	0,37	0,3493	0,7506	1,33	Algorithm converged.	0,73	0,43	
	Female	131	39,0	66,5	50,8	122	38,0	9	7,4	0,60			-0,028	Algorithm converged.	-0,087	0,031	0,62	Algorithm converged.	0,23	0,69	0,3517		1,61	Algorithm converged.	0,59	0,39	
Age	<75 years	180	53,6	105,6	58,7	187	58,3	12	6,4	0,86			-0,009	Algorithm converged.	-0,057	0,040	0,87	Algorithm converged.	0,38	0,95	0,7284	0,4710	1,16	Algorithm converged.	0,51	0,61	
	>=75 years	156	46,4	131,2	84,1	134	41,7	19	14,2	0,55			-0,058	Algorithm converged.	-0,132	0,015	0,59	Algorithm converged.	0,30	0,14	0,1181		1,70	Algorithm converged.	0,87	0,31	
Geographical Region	North America	16	4,8	16,3	101,9	13	4,0	2	15,4	0,37			-0,091	Algorithm converged.	-0,321	0,138	0,41	Algorithm converged.	0,04	0,00	0,4400		1,46	Algorithm converged.	0,25	0,21	
	Central and South America	11	3,3						0,9																		
	Western Europe	208	61,9	139,1	66,8	193	60,1	24	12,4	0,71			-0,033	Algorithm converged.	-0,094	0,028	0,73	Algorithm converged.	0,42	0,30	0,2881		1,36	Algorithm converged.	0,77	0,41	
Asia-Pacific	23	6,8			22	6,9	1	4,3					ERROR: Error in computing the link function, its derivatives, or the variance function.														
Other	78	23,2	32,8	42,1	87	27,1	4	4,6	0,83			-0,008	Algorithm converged.	-0,069	0,054	0,84	Algorithm converged.	0,19	0,62	0,8113		1,20	Algorithm converged.	0,28	0,18		
Binet Staging at baseline	I	75	22,3	32,7	43,5	72	22,4	11	15,3	0,15			-0,126	Algorithm converged.	-0,217	-0,035	0,17	Algorithm converged.	0,04	0,76	0,0201	0,0442	5,73	Algorithm converged.	1,32	0,96	
	II	143	42,6	85,6	59,9	132	41,1	7	5,3	1,06			0,003	Algorithm converged.	-0,051	0,057	1,05	Algorithm converged.	0,39	0,83	0,9154		0,95	Algorithm converged.	0,35	0,54	
	III	118	35,1	131,0	111,0	117	36,4	13	11,1	0,99			-0,001	Algorithm converged.	-0,081	0,079	0,99	Algorithm converged.	0,48	0,05	0,9816		1,01	Algorithm converged.	0,49	0,08	

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable. Clinical cut-off:
 100CT2017

Program: root/clinical_studies/R05072759/CDPT7159/B021004/data_analysis/ACE_CSRFinal/qa/program/t_s_ae.sas
 Output: root/clinical_studies/R05072759/CDPT7159/B021004/data_analysis/ACE_CSRFinal/qa/output/t_s_ae_sg_AEG5_SE_100CT2017_21004.xls 09OCT2019 0:48

Anhang 4-G4: Spezifische Verträglichkeit: Unerwünschte Ereignisse von besonderem Interesse (AESI)

Für die AESI Hepatitis B (HBV) Reaktivierung, verlängerte Neutropenie und spät einsetzende Neutropenie liegen weder Informationen zum Zeitpunkt des Ereignisses vor, noch dazu, ob es sich jeweils um ein schwere oder schwerwiegendes Ereignis handelt. Für diese AESI werden daher keine Tabellen nach SUE und UE Grad ≥ 3 dargestellt.

27 (Anhang): Ergebnisse für Akute Thrombozytopenie nach UE, SUE, UE Grad ≥ 3 aus RCT mit dem zu bewertenden Arzneimittel

POPULATION: Safety Evaluable Patients
 POINT: Acute Thrombocytopenia
 MODEL: Unstratified Analysis
 STUDY: CLL1 (B021004), Final

Population Analysis by subgroup (stratify)		sClb (N=336)				sClb (N=321)				sClb vs. sClb																
		Patients		Patients		Patients		Patients		Odds Ratio					Absolute Risk Difference					Relative Risk						
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Rela Elve Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	s/a	336	100,0	321	100,0	30,9	9,5	1,31	16,19	0,032				Algorithm converged.	0,009	0,056	4,46	Algorithm converged.	0,29	15,37	0,0179		0,22	Algorithm converged.	0,07	0,77
Gender	Male	205	61,0	199	62,0					Quasi-complete separation of data points detected.				ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			NE	Algorithm converged.	NE	NE	NE	0,0053	NE	Algorithm converged.	NE	NE
	Female	131	39,0	122	38,0	32,5	9,9	0,93	4,70	-0,002				Algorithm converged.	-0,039	0,036	0,93	Algorithm converged.	0,19	4,53	0,9207		1,07	Algorithm converged.	0,22	5,22
Age	<75 years	280	83,6	277	86,3	10,5	3,5			Convergence criterion (GCONV=1E-8) satisfied.	1,07	69,86	0,039	Algorithm converged.	0,007	0,071	8,31	Algorithm converged.	0,05	65,78	0,0448	0,3634	0,12	Algorithm converged.	0,02	0,95
	>=75 years	156	46,4	144	44,7	21,5	6,6			Convergence criterion (GCONV=1E-8) satisfied.	0,52	13,30	0,024	Algorithm converged.	-0,013	0,060	2,58	Algorithm converged.	0,53	12,56	0,2414		0,39	Algorithm converged.	0,08	1,89
Geographical Region	North America	16	4,8	13	4,0																					
	Central and South America	11	3,3	6	1,9					Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
	Western Europe	208	61,9	193	60,1	31,6	9,5			Convergence criterion (GCONV=1E-8) satisfied.	0,97	12,87	0,037	Algorithm converged.	0,002	0,072	3,40	Algorithm converged.	0,96	12,01	0,0571		0,29	Algorithm converged.	0,08	1,04
	Asia-Pacific	23	6,8	22	6,9					Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 5,2811994485 is greater than the limit of 0,0001. The convergence is questionable.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
	Other	78	23,2	67	20,7					Quasi-complete separation of data points detected.				ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Binet Staging at baseline	A	75	22,3	72	22,4	22,8	6,8			Convergence criterion (GCONV=1E-8) satisfied.	0,47	13,32	0,039	Algorithm converged.	-0,029	0,107	2,40	Algorithm converged.	0,48	11,98	0,2858	0,5384	0,42	Algorithm converged.	0,08	1,08
	B	143	42,6	132	41,1					Quasi-complete separation of data points detected.				ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
	C	118	35,1	117	36,4	10,9	3,3			Convergence criterion (GCONV=1E-8) satisfied.	1,04	68,54	0,059	Algorithm converged.	0,011	0,108	7,93	Algorithm converged.	0,01	62,43	0,0401		0,13	Algorithm converged.	0,02	0,99

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable. Clinical cut-off: 100CT2017

Program: root/clinical_studies/R05072759/CDPT7159/B021004/data_analysis/ACE_CSRFinal/qa/program/t_s_ae.sas
 Output: root/clinical_studies/R05072759/CDPT7159/B021004/data_analysis/ACE_CSRFinal/qa/output/t_s_ae_sq_AEPIATHROM_SE_100CT2017_21004.xls 09OCT2019 0:50

POPULATION: Safety Evaluable Patients
 ENDPOINT: Acute Thrombocytopenia Serious
 MODEL: Unstratified Analysis
 STUDY: CLL11 (B021004) - Final
 Dichotomous Analysis by Subgroups (Safety)

Name	Level	G1b (N=336)				G2b (N=321)				G1b vs. G2b																		
		Patients		Patients		Patients		Patients		Odds Ratio					Absolute Risk Difference					Relative Risk								
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	
All	G/A	336	100,0	157,3	321	100,0				Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.				NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE	
Gender	Male	205	61,0		189	59,0												NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE	
	Female	131	39,0		132	41,0				Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.				NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE	
Age	<75 years	180	53,6		187	58,3				Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.				NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE	
	≥75 years	156	46,4		134	41,7																						
Geographical Region	North America	16	4,8		13	4,0																						
	Central and South America	11	3,3																									
	Western Europe	208	61,9		193	60,1				Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.				NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE	
	Asia-Pacific	53	15,8		52	16,2																						
	Other	78	23,2		67	20,9																						
Binet Staging at baseline	A	75	22,3		72	22,4				Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 12.388004663 is greater than the limit of 0.0001. The convergence is questionable.				NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE	
	B	143	42,6		132	41,1																						
	C	118	35,1		117	36,4																						

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable. Clinical cut-off: 100CT2017

Program: root/clinical_studies/B05072759/CDPT159/B021004/data_analysis/ACE_CSRFinal/qe/program/t_s_ee.sas
 Output: root/clinical_studies/B05072759/CDPT159/B021004/data_analysis/ACE_CSRFinal/qe/output/t_s_ee_sq_ARFIATHROMS_SE_100CT2017_21004.xls 09OCT2019 1:24

POPULATION: Safety Evaluable Patients
 ENDPOINT: Acute Thrombocytopenia Grade >= 3
 MODEL: Unstratified Analysis
 STUDY: CLL11 (BOZ1004) - Final
 Dichotomous Analysis by Subgroups (Safety)

Name	Level	OC1b (N=336)				OC1b (N=321)				OC1b vs. OC1b																
		Patients		Patients		Patients		Patients		Odds Ratio			Absolute Risk Difference			Relative Risk					OC1b vs. OC1b Relative Risk					
		n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% Upper CL	Absolute Risk	95% Lower CL	95% Upper CL	95% CI	Convergence Reason	95% Lower CL	95% Upper CL	P-value (Wald)	Interaction Test P-value (likelihood ratio)	Relative Risk	95% Lower CL	95% Upper CL		
All	5/5	336	100.0	13	3.9	321	100.0	20.6	6.42	1.44	0.67	0.032	0.010	0.055	6.21	Algorithm converged.	0.41	0.30	0.0156		0.16		Algorithm converged.	0.04	0.71	
Gender	Male	205	61.0	10	4.9	199	62.0									ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE		NE	0.0225	NE		Algorithm converged.	NE	NE	
	Female	131	39.0	3	2.3	122	38.0	21.6	6.41	0.23	3.56	0.007	-0.028	0.041	1.40	Algorithm converged.	0.24	0.22	0.7116		0.72		Algorithm converged.	0.12	1.21	
Age	<75 years	180	53.6	8	4.4	187	58.3									ERROR: Error in computing the link function, its derivatives, or the variance function.	NE		NE	0.0495	NE		Algorithm converged.	NE	NE	
	≥75 years	156	46.4	5	3.2	134	41.7	21.5	6.19	0.42	11.45	0.017	-0.017	0.052	1.15	Algorithm converged.	0.42	0.89	0.3562		0.47		Algorithm converged.	0.09	2.36	
Geographical Region	North America	16	4.8			13	4.0																			
	Central and South America	1	0.3			1	0.1									ERROR: Error in computing the link function, its derivatives, or the variance function.	NE		NE		NE		Algorithm converged.	NE	NE	
	Western Europe	208	61.9	10	4.8	193	60.1	23.0	4.82	1.04	22.30	0.038	0.005	0.070	1.64	Algorithm converged.	0.03	0.91	0.0457		0.22		Algorithm converged.	0.05	0.97	
Asia-Pacific		23	6.8	1	0.3	22	6.9									WARNING: The relative Hessian convergence criterion of 5.2811994485 is greater than the limit of 0.0001. The convergence is questionable.	NE		NE		NE		Algorithm converged.	NE	NE	
	Other	78	23.2	1	0.3	87	27.1									ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE		NE		NE		Algorithm converged.	NE	NE	
Binet Staging at baseline	A	75	22.3	5	6.7	72	22.4	12.4	5.07	0.58	14.52	0.053	-0.010	0.135	1.80	Algorithm converged.	0.57	0.09	0.1475	0.8431	0.01		Algorithm converged.	0.02	1.71	
	B	143	42.6	1	0.7	132	41.1									ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE		NE		NE		Algorithm converged.	NE	NE	
	C	118	35.1	7	5.9	117	36.4	10.9	7.31	0.89	20.41	0.051	0.005	0.097	0.94	Algorithm converged.	0.87	0.54	0.0679		0.14		Algorithm converged.	0.02	1.15	

Test for interaction based on RR (Log-binomial regression)

* indicates convergence problem. Result is uninterpretable. Clinical cut-off: 10OCT2017

Program: root/clinical_studies/RO5072759/CDPT159/BOZ1004/data_analysis/ACE_CSRFinal/qc/program/t_s_oe.sas

Output: root/clinical_studies/RO5072759/CDPT159/BOZ1004/data_analysis/ACE_CSRFinal/qc/output/t_s_oe_sq_ARFIATHROM3_SE_10OCT2017_21004.xls 09OCT2019 1:16

28 (Anhang): Ergebnisse für Infektionen nach UE, SUE, UE Grad ≥ 3 aus RCT mit dem zu bewertenden Arzneimittel

POPULATION: Safety Evaluable Patients
 ENDPOINT: Infections
 MODEL: Unstratified Analysis STUDY: CLL11 (BO21004), Final
 Dichotomous Analysis by Subgroups (Safety)

Name	Level	GClb (N=336)				RClb (N=321)				Odds Ratio	Convergence Reason	GClb vs. RClb				RClb vs. GClb											
		Patients	n	%	with Event	Patients	n	%	with Event			Odds Ratio	95% Lower CL	95% Upper CL	Absolute Risk Difference	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	
All	n/a	336	100,0	130	38,7	321	100,0	122	38,0	1,03	Convergence criterion (GCONV=1E-8) satisfied.	1,75	1,41	2,007	Algorithm converged.	-0,068	0,081	1,02	Algorithm converged.	0,84	1,24	0,8569	Interaction Test p-value (likelihood ratio)	0,98	Algorithm converged.	0,81	1,19
Gender	Male	205	61,0	82	40,0	199	62,0	85	42,7	0,89	Convergence criterion (GCONV=1E-8) satisfied.	0,60	1,33	-0,027	Algorithm converged.	-0,123	0,069	0,94	Algorithm converged.	0,74	1,18	0,5798	0,2333	0,07	Algorithm converged.	0,85	1,35
	Female	131	39,0	48	36,6	122	38,0	37	30,3	1,33	Convergence criterion (GCONV=1E-8) satisfied.	0,79	1,25	1,063	Algorithm converged.	-0,053	0,179	1,21	Algorithm converged.	0,85	1,72	0,2907		0,83	Algorithm converged.	0,58	1,18
Age	<75 years	180	53,6	68	37,8	187	58,3	68	36,4	1,06	Convergence criterion (GCONV=1E-8) satisfied.	1,70	1,62	1,014	Algorithm converged.	-0,085	0,113	1,04	Algorithm converged.	0,80	1,36	0,7791	3,7931	0,96	Algorithm converged.	0,74	1,26
	≥75 years	156	46,4	62	39,7	134	41,7	54	40,3	0,98	Convergence criterion (GCONV=1E-8) satisfied.	0,61	1,57	-0,006	Algorithm converged.	-0,119	0,108	0,99	Algorithm converged.	0,74	1,31	0,9234		1,01	Algorithm converged.	0,76	1,34
Geographical Region	North America	16	4,8	10	62,5	13	4,0	7	53,8	1,43	Convergence criterion (GCONV=1E-8) satisfied.	1,32	5,32	1,087	Algorithm converged.	-0,274	0,447	1,16	Algorithm converged.	0,62	5,18	0,6431	5,7030	0,86	Algorithm converged.	0,46	1,62
	Central and South America	11	3,3	7	63,6	6	1,9	2	33,3	1,50	Convergence criterion (GCONV=1E-8) satisfied.	0,43	28,44	1,303	Algorithm converged.	-0,169	0,775	1,91	Algorithm converged.	0,57	6,44	0,2975		0,52	Algorithm converged.	0,16	1,77
	Western Europe	208	61,9	84	40,4	193	60,1	79	40,9	0,98	Convergence criterion (GCONV=1E-8) satisfied.	0,66	1,46	-0,005	Algorithm converged.	-0,102	0,091	0,99	Algorithm converged.	0,78	1,25	0,9111		1,01	Algorithm converged.	0,80	1,28
	Asia-Pacific	23	6,8	12	52,2	22	6,9	11	50,0	1,09	Convergence criterion (GCONV=1E-8) satisfied.	0,34	1,51	1,022	Algorithm converged.	-0,270	0,214	1,04	Algorithm converged.	0,59	1,85	0,8841		0,96	Algorithm converged.	0,54	1,70
	Other	78	23,2	17	21,8	87	27,1	23	26,4	0,78	Convergence criterion (GCONV=1E-8) satisfied.	0,38	1,59	-0,046	Algorithm converged.	-0,177	0,084	0,82	Algorithm converged.	0,48	1,43	0,4893		1,21	Algorithm converged.	0,70	2,10
Binet Staging at Baseline	A	75	22,3	35	46,7	72	22,4	29	40,3	1,30	Convergence criterion (GCONV=1E-8) satisfied.	0,67	1,49	1,054	Algorithm converged.	-0,096	0,224	1,18	Algorithm converged.	0,80	1,68	0,4367	0,2207	0,86	Algorithm converged.	0,60	1,25
	B	143	42,6	62	29,4	132	41,1	68	36,4	0,73	Convergence criterion (GCONV=1E-8) satisfied.	1,44	1,21	-0,070	Algorithm converged.	-0,181	0,041	0,81	Algorithm converged.	0,57	1,13	0,2181		1,24	Algorithm converged.	0,88	1,74
	C	118	35,1	53	44,9	117	36,4	45	38,5	1,30	Convergence criterion (GCONV=1E-8) satisfied.	0,78	1,19	1,065	Algorithm converged.	-0,061	0,190	1,17	Algorithm converged.	0,86	1,58	0,3174		0,86	Algorithm converged.	0,63	1,16

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable. Clinical cut-off: 100CT2017

Program: root/clinical_studies/RO5072759/CDPT159/BO21004/data_analysis/ACE_CSRFinal/qa/program/t_s_se.sas
 Output: root/clinical_studies/RO5072759/CDPT159/BO21004/data_analysis/ACE_CSRFinal/qa/output/t_s_se_seg_AEPIINFECC_SE_100CT2017_21004.xls 09OCT2019 0:54

POPULATION: Safety Evaluable Patients
 ENDPOINT: Infections Serious
 MODEL: Unstratified Analysis
 STUDY: CLL11 (BO21004), Final
 Dichotomous Analysis by Subgroups (Safety)

Name	Level	GClb (N=336)				RClb (N=321)				Odds Ratio	Convergence Reason	Absolute Risk Difference				Convergence Reason	Relative Risk				Interaction Test p-value (likelihood ratio)	Relative Risk	RClb vs. GClb Relative Risk				
		Patients		with Event		Patients		with Event				95% Lower CL	95% Upper CL	Absolute Risk	95% Lower CL		95% Upper CL	Relative Risk	95% Lower CL	95% Upper CL			p-value (Wald)	95% Lower CL	95% Upper CL		
		n	%	n	%	n	%	n	%																		
All	n/a	336	100,0	83	12,8	321	100,0	67	14,6	0,86	Convergence criterion (GCONV=1E-8) satisfied.	0,55	0,34	-0,018	Algorithm converged.	-0,071	0,034	0,87	Algorithm converged.	0,60	0,28	0,4923		0,14	Algorithm converged.	0,78	0,68
Gender	Male	205	61,0	32	15,6	199	62,0	30	15,1	0,04	Convergence criterion (GCONV=1E-8) satisfied.	0,61	0,79	0,005	Algorithm converged.	-0,065	0,076	1,04	Algorithm converged.	0,65	0,64	0,8816	0,2083	0,97	Algorithm converged.	0,61	0,53
	Female	131	39,0	11	8,4	122	38,0	17	13,9	0,57	Convergence criterion (GCONV=1E-8) satisfied.	0,25	0,26	-0,055	Algorithm converged.	-0,133	0,022	0,60	Algorithm converged.	0,29	0,23	0,1663		0,66	Algorithm converged.	0,81	0,40
Age	<75 years	180	53,6	19	10,6	187	58,3	23	12,3	0,84	Convergence criterion (GCONV=1E-8) satisfied.	0,44	0,60	-0,017	Algorithm converged.	-0,082	0,048	0,86	Algorithm converged.	0,48	0,52	0,6004	0,9982	0,17	Algorithm converged.	0,66	0,06
	≥75 years	156	46,4	24	15,4	134	41,7	24	17,9	0,83	Convergence criterion (GCONV=1E-8) satisfied.	0,45	0,55	-0,025	Algorithm converged.	-0,111	0,061	0,86	Algorithm converged.	0,51	0,44	0,5641		0,16	Algorithm converged.	0,69	0,95
Geographical Region	North America	16	4,8		38,8	13	4,0		17,7	0,77	Convergence criterion (GCONV=1E-8) satisfied.	0,25	0,38	0,111	Algorithm converged.	-0,129	0,350	2,44	Algorithm converged.	0,29	0,75	0,4148	0,3214	0,41	Algorithm converged.	0,05	0,49
	Central and South America	11	3,3		28,2	6	1,9				Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 1.1519208752 is greater than the limit of 0.0001. The convergence is questionable.				Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
	Western Europe	208	61,9	32	15,4	193	60,1	34	17,6	0,85	Convergence criterion (GCONV=1E-8) satisfied.	0,50	0,44	-0,022	Algorithm converged.	-0,095	0,050	0,87	Algorithm converged.	0,56	0,36	0,5473		0,15	Algorithm converged.	0,74	0,78
	Asia-Pacific	23	6,8		28,7	22	6,9		32,7	0,32	Convergence criterion (GCONV=1E-8) satisfied.	0,06	0,88	-0,140	Algorithm converged.	-0,350	0,068	0,38	Algorithm converged.	0,08	0,77	0,2191		0,61	Algorithm converged.	0,56	0,10
	Other	78	23,2		45,1	67	20,9		28,0	0,62	Convergence criterion (GCONV=1E-8) satisfied.	0,17	0,20	-0,029	Algorithm converged.	-0,104	0,046	0,64	Algorithm converged.	0,19	0,09	0,4581		0,57	Algorithm converged.	0,48	0,16
Binet Staging at Baseline	A	75	22,3		79,3	72	22,4		15,3	0,57	Convergence criterion (GCONV=1E-8) satisfied.	0,21	0,57	-0,059	Algorithm converged.	-0,185	0,047	0,61	Algorithm converged.	0,25	0,49	0,2782	0,6019	0,64	Algorithm converged.	0,67	0,99
	B	143	42,6		10,5	132	41,1		16	0,85	Convergence criterion (GCONV=1E-8) satisfied.	0,40	0,79	-0,016	Algorithm converged.	-0,091	0,059	0,87	Algorithm converged.	0,45	0,68	0,6693		0,16	Algorithm converged.	0,60	0,24
	C	118	35,1		17,8	117	36,4		17,1	0,05	Convergence criterion (GCONV=1E-8) satisfied.	0,54	0,06	0,007	Algorithm converged.	-0,090	0,104	1,04	Algorithm converged.	0,60	0,82	0,8872		0,96	Algorithm converged.	0,55	0,68

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable. Clinical cut-off:
 100CT2017

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSRFinal/qa/program/t_s_ae.sas
 Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSRFinal/qa/output/t_s_ae_sg_ABPINFEC_SE_100CT2017_21004.xls 09OCT2019 0:54

POPULATION: Safety Evaluable Patients
 ENDPOINT: Infections Grade >= 3
 MODEL: Unstratified Analysis
 STUDY: CLL11 (R021004), Final
 Dichotomous Analysis by Subgroups (Safety)

Name	Level	GClb (N=336)				GClb (N=321)				Odds Ratio	Convergence Reason	Absolute Risk Difference			Convergence Reason	Relative Risk				GClb vs. GClb								
		Patients	with	Patients	with Event	Patients	with	Patients	with Event			95% Lower CI	95% Upper CI	Absolute Risk		95% Lower CI	95% Upper CI	Relative Risk	95% Lower CI	95% Upper CI	p-value (Weight)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI		
All	n/a	336	100,0	81	24,2	321	100,0	46	14,3	0,83	Convergence criterion (GCONV=1E-8) satisfied.	0,53	0,31	-0,021	Algorithm converged.	-0,073	0,031	0,85	Algorithm converged.	0,58	0,26	0,4218	0,17	Algorithm converged.	0,79	1,74		
Gender	Male	205	61,0	29	14,1	199	62,0	32	16,1	0,86	Convergence criterion (GCONV=1E-8) satisfied.	0,50	0,48	-0,019	Algorithm converged.	-0,089	0,051	0,88	Algorithm converged.	0,55	0,40	0,5876	0,8256	0,14	Algorithm converged.	0,72	1,81	
	Female	131	39,0	52	39,2	122	38,0	14	11,5	0,78	Convergence criterion (GCONV=1E-8) satisfied.	0,34	0,76	-0,023	Algorithm converged.	-0,098	0,052	0,80	Algorithm converged.	0,38	0,66	0,5455	0,25	Algorithm converged.	0,60	2,60		
Age	<75 years	180	53,6	21	11,7	187	58,3	23	12,3	0,94	Convergence criterion (GCONV=1E-8) satisfied.	0,50	0,77	-0,006	Algorithm converged.	-0,073	0,060	0,95	Algorithm converged.	0,54	0,65	0,8520	0,5500	0,05	Algorithm converged.	0,61	1,84	
	≥75 years	156	46,4	60	38,8	134	41,7	23	17,2	0,71	Convergence criterion (GCONV=1E-8) satisfied.	0,37	0,36	-0,043	Algorithm converged.	-0,126	0,039	0,75	Algorithm converged.	0,43	0,30	0,3011	0,34	Algorithm converged.	0,77	2,33		
Geographical Region	North America	16	4,8		425,0	13	4,0		17,7	4,00	Convergence criterion (GCONV=1E-8) satisfied.	0,39	41,21	0,173	Algorithm converged.	-0,084	0,430	0,25	Algorithm converged.	0,41	25,64	0,2634	0,2201	0,31	Algorithm converged.	0,04	2,43	
	Central and South America	11	3,3		28,2		0,9				quasi-complete separation of data points detected.				ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	
	Western Europe	208	61,9	29	13,9	193	60,1	33	17,1	0,79	Convergence criterion (GCONV=1E-8) satisfied.	0,46	0,35	-0,032	Algorithm converged.	-0,103	0,039	0,82	Algorithm converged.	0,52	0,29	0,3834	0,23	Algorithm converged.	0,78	1,94		
	Asia-Pacific	23	6,8		28,7	22	6,9		22,7	0,32	Convergence criterion (GCONV=1E-8) satisfied.	0,06	0,88	-0,140	Algorithm converged.	-0,350	0,069	0,38	Algorithm converged.	0,08	0,77	0,2191	0,61	Algorithm converged.	0,56	12,10		
	Other	78	23,2		45,1	67	20,9		21,0	0,62	Convergence criterion (GCONV=1E-8) satisfied.	0,17	0,20	-0,029	Algorithm converged.	-0,104	0,046	0,64	Algorithm converged.	0,19	0,09	0,4581	0,57	Algorithm converged.	0,48	5,16		
Binet Staging at Baseline	A	75	22,3		79,3	72	22,4		11	15,3	0,57	Convergence criterion (GCONV=1E-8) satisfied.	0,21	0,57	-0,059	Algorithm converged.	-0,165	0,047	0,61	Algorithm converged.	0,25	0,49	0,2782	0,5910	0,64	Algorithm converged.	0,67	3,99
	B	143	42,6		9,8	132	41,1		16	12,1	0,75	Convergence criterion (GCONV=1E-8) satisfied.	0,37	0,68	-0,023	Algorithm converged.	-0,097	0,051	0,81	Algorithm converged.	0,41	0,59	0,5365	0,24	Algorithm converged.	0,63	2,44	
	C	118	35,1		16,9	117	36,4		29	16,2	0,05	Convergence criterion (GCONV=1E-8) satisfied.	0,53	0,09	0,007	Algorithm converged.	-0,088	0,102	0,04	Algorithm converged.	0,59	0,85	0,8837	0,96	Algorithm converged.	0,54	1,70	

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable. Clinical cut-off: 100CT2017

Program: root/clinical_studies/R05072759/CDPT7159/R021004/data_analysis/ACE_CSRFinal/qe/program/t_s_ae.sas
 Output: root/clinical_studies/R05072759/CDPT7159/R021004/data_analysis/ACE_CSRFinal/qe/output/t_s_ae_ag_ABPINFEC_SE_100CT2017_21004.xls 09OCT2019 0:54

29 (Anhang): Ergebnisse für Infusionsbedingte Reaktionen (IRR) nach UE, SUE, UE Grad ≥ 3 aus RCT mit dem zu bewertenden Arzneimittel

POPULATION: Safety Evaluable Patients
 ENDPOINT: Infusion Related Reaction
 MODEL: Unstratified Analysis
 STUDY: CLL11(B021004) Final
 Dichotomous Analysis by Subgroups (Safety)

Name	Level	GC1b (N=336)				GC1b (N=321)				Odds Ratio			GC1b vs. GC1b				GC1b vs. GC1b															
		Patients	n	%	95% Lower CL	Patients	n	%	95% Lower CL	Odds Ratio	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	95% Lower CL	95% Upper CL	P-value (Wald)	Interaction Test P-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL							
All	g/a	336	100,0	222	66,1	321	100,0	121	37,7	0,22			Convergence criterion (GCQNV+1E-8) satisfied.	0,24	0,43	0,284		Algorithm converged.	0,210	0,357	0,75		Algorithm converged.	0,49	0,06	<0,001		0,57		Algorithm converged.	0,49	0,67
Gender	Male	208	61,0	139	67,8	199	62,0	77	38,7	0,34			Convergence criterion (GCQNV+1E-8) satisfied.	0,22	0,02	0,291		Algorithm converged.	0,198	0,386	0,75		Algorithm converged.	0,44	0,14	<0,001	0,9883	0,57		Algorithm converged.	0,47	0,70
	Female	131	39,0	83	63,4	122	38,0	44	36,1	0,07			Convergence criterion (GCQNV+1E-8) satisfied.	1,84	0,12	0,273		Algorithm converged.	0,154	0,392	0,76		Algorithm converged.	0,34	0,30	<0,001		0,57		Algorithm converged.	0,43	0,75
Age	<75 years	180	53,6	113	62,8	187	58,3	66	35,3	0,09			Convergence criterion (GCQNV+1E-8) satisfied.	0,02	0,73	0,275		Algorithm converged.	0,176	0,373	0,78		Algorithm converged.	0,42	0,23	<0,001	0,7880	0,56		Algorithm converged.	0,45	0,70
	≥75 years	156	46,4	109	69,9	134	41,7	55	41,0	0,33			Convergence criterion (GCQNV+1E-8) satisfied.	2,05	0,41	0,288		Algorithm converged.	0,178	0,398	0,70		Algorithm converged.	0,36	0,14	<0,001		0,59		Algorithm converged.	0,47	0,74
Geographical Region	North America	6	1,8	0	0,0	13	4,0	0	0,0	0,33			Convergence criterion (GCQNV+1E-8) satisfied.	0,26	0,83	0,058		Algorithm converged.	-0,271	0,386	1,08		Algorithm converged.	0,68	1,72	0,7329	0,1943	0,92		Algorithm converged.	0,58	0,86
	Central and South America	1	0,3	0	0,0	4,5	1,4	0	0,0	0,20			Convergence criterion (GCQNV+1E-8) satisfied.	0,16	0,80	0,045		Algorithm converged.	-0,451	0,542	1,09		Algorithm converged.	0,42	0,86	0,8597		0,92		Algorithm converged.	0,35	0,41
	Western Europe	208	61,9	155	74,5	193	60,1	79	40,9	0,22			Convergence criterion (GCQNV+1E-8) satisfied.	2,76	0,45	0,336		Algorithm converged.	0,245	0,427	1,82		Algorithm converged.	0,51	0,20	<0,001		0,55		Algorithm converged.	0,46	0,66
	Asia-Pacific	23	6,8	14	60,9	22	6,9	11	50,0	1,56			Convergence criterion (GCQNV+1E-8) satisfied.	0,48	0,08	0,109		Algorithm converged.	-0,180	0,398	0,22		Algorithm converged.	0,72	0,07	0,4678		0,82		Algorithm converged.	0,48	1,40
	Other	78	23,2	35	44,9	87	27,1	19	21,8	0,91			Convergence criterion (GCQNV+1E-8) satisfied.	1,48	0,73	0,230		Algorithm converged.	0,090	0,371	0,05		Algorithm converged.	0,29	0,28	0,0025		0,49		Algorithm converged.	0,30	0,78
Binet Staging at baseline	A	75	22,3	50	66,7	72	22,4	25	34,7	0,76			Convergence criterion (GCQNV+1E-8) satisfied.	1,90	0,44	0,319		Algorithm converged.	0,166	0,473	0,92		Algorithm converged.	0,35	0,74	0,0003	0,8425	0,52		Algorithm converged.	0,37	0,74
	B	13	3,6	8	61,5	12	3,1	0	0,0	0,60			Convergence criterion (GCQNV+1E-8) satisfied.	1,59	0,24	0,233		Algorithm converged.	0,118	0,347	1,68		Algorithm converged.	0,28	0,22	0,0002		0,59		Algorithm converged.	0,45	0,78
	C	118	35,1	90	76,3	117	36,4	51	43,6	0,16			Convergence criterion (GCQNV+1E-8) satisfied.	2,38	0,28	0,327		Algorithm converged.	0,209	0,445	0,75		Algorithm converged.	0,39	0,20	<0,001		0,57		Algorithm converged.	0,45	0,72

Test for interaction based on RR (Log-binomial regression)

* indicates convergence problem. Result is uninterpretable. Clinical cut-off: 100CT2017

Program: root/clinical_studies/R05072759/CDPT7159/B021004/data_analysis/ACE_CSRFinal/qa/program/t_s_ag_sas

Output: root/clinical_studies/R05072759/CDPT7159/B021004/data_analysis/ACE_CSRFinal/qa/output/t_s_ag_sq_ARPIRR_SE_100CT2017_21004.xls 09OCT2019 0:55

POPULATION: Safety Evaluable Patients
 ENDPOINT: Infection Related AEs Serious
 MODEL: Unstratified Analysis
 STUDY: CLL11 (R021004) - Final
 Dichotomous Analysis by Subgroups (Safety)

Name	Level	OC1b (N=136)				OC1b (N=221)				OC1b vs. OC1b				OC1b vs. OC1b														
		Patients		Patients		Patients		Patients		Odds Ratio				Absolute Risk Difference				Relative Risk										
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	Interaction Test p-value (Likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL		
All	p/a	336	100,0	34	10,1	321	100,0	52,6	7,11	Convergence criterion (GCONV=1E-8) satisfied.	2,75	18,43	0,086	Algorithm converged.	0,051	0,121	0,50	Algorithm converged.	0,57	16,40	<0,0001	0,15	Algorithm converged.	0,06	0,39			
Gender	Male	205	61,0	22	10,7	189	82,0	42,0	6,86	Convergence criterion (GCONV=1E-8) satisfied.	1,98	17,33	0,087	Algorithm converged.	0,041	0,134	0,54	Algorithm converged.	1,87	15,22	0,0017	0,5014	0,19	Algorithm converged.	0,07	0,53		
	Female	131	39,0	12	9,2	122	89,0	10,8	12,20	Convergence criterion (GCONV=1E-8) satisfied.	0,56	05,32	0,083	Algorithm converged.	0,031	0,135	11,18	Algorithm converged.	1,48	84,67	0,0195	0,09	Algorithm converged.	0,01	0,68			
Age	<75 years	180	53,6	20	11,1	167	88,3	21,1	11,56	Convergence criterion (GCONV=1E-8) satisfied.	2,66	50,23	0,100	Algorithm converged.	0,052	0,149	10,39	Algorithm converged.	2,46	43,81	0,0014	0,3173	0,10	Algorithm converged.	0,02	0,41		
	≥75 years	156	46,4	14	9,0	134	81,7	30,2	4,31	Convergence criterion (GCONV=1E-8) satisfied.	1,21	15,32	0,067	Algorithm converged.	0,016	0,119	4,01	Algorithm converged.	1,18	13,65	0,0264	0,25	Algorithm converged.	0,07	0,85			
Geographical Region	North America	6	1,8			18,8	13	8,0		Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.				NE	Algorithm converged.		NE	NE	NE	Algorithm converged.		NE		
	Central and South America	11	3,3			10,1	6,9			Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.				NE	Algorithm converged.		NE	NE	NE	Algorithm converged.		NE		
	Western Europe	208	61,9	24	11,5	193	80,1	52,6	4,90	Convergence criterion (GCONV=1E-8) satisfied.	1,83	13,13	0,089	Algorithm converged.	0,041	0,138	4,45	Algorithm converged.	1,73	11,44	0,0019	0,22	Algorithm converged.	0,09	0,58			
	Asia-Pacific	23	6,8			4,7,4	22	6,9		Quasi-complete separation of data points detected.				ERROR: The mean parameter is either invalid or at a limit of its range for some observations.				NE	Algorithm converged.		NE	NE	NE	Algorithm converged.		NE		
Other	78	23,2			2,2,6	87	27,1			Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 0,0172758121 is greater than the limit of 0,0001. The convergence is questionable.				NE	Algorithm converged.		NE	NE	NE	Algorithm converged.		NE		
Binet Staging at baseline	A	75	22,3			8,0,7	72	22,4		Quasi-complete separation of data points detected.				ERROR: The mean parameter is either invalid or at a limit of its range for some observations.				NE	Algorithm converged.		NE	NE	NE	0,1592	NE	Algorithm converged.		NE
	B	143	42,6	12	8,4	132	41,1	10,8	12,00	Convergence criterion (GCONV=1E-8) satisfied.	1,54	33,62	0,076	Algorithm converged.	0,029	0,124	11,08	Algorithm converged.	1,46	84,02	0,0200	0,09	Algorithm converged.	0,01	0,68			
	C	118	35,1	14	11,9	117	36,4	40,4	3,80	Convergence criterion (GCONV=1E-8) satisfied.	1,21	11,92	0,084	Algorithm converged.	0,017	0,151	3,47	Algorithm converged.	1,18	10,23	0,0241	0,29	Algorithm converged.	0,10	0,85			

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable. Clinical cut-off: 10OCT2017

Program: root/clinical_studies/R05072759/CDPT7159/R021004/data_analysis/ACE_CSRFinal/qe/program/t_s_se.sas
 Output: root/clinical_studies/R05072759/CDPT7159/R021004/data_analysis/ACE_CSRFinal/qe/output/t_s_se_sq_ARFIFRRS_SE_10OCT2017_21004.xls 09OCT2019 1:26

POPULATION: Safety Evaluable Patients
 ENDPOINT: Infusion Related AEs Grade >= 3
 MODEL: Unstratified Analysis
 STUDY: CLL11 (R021004) - Final
 Dichotomous Analysis by Subgroups (Safety)

Name	Level	OCb (N=136)					RCb (N=221)					OCb vs. RCb															
		Patients		Patients		Odds Ratio	Patients		Patients		Odds Ratio			Absolute Risk Difference			Relative Risk				RCb vs. OCb						
		n	%	n	%		95% Lower CL	95% Upper CL	Absolute Risk	95% Lower CL	95% Upper CL	Relative Risk	95% Lower CL	95% Upper CL	P-value (Wald)	Interaction Test P-value (Likelihood ratio)	Relative Risk	95% Lower CL	95% Upper CL								
All	n/a	336	100.0	66	19.6	321	100.0	13	4.0	2.79	Convergence criterion (GCONV=1E-8) satisfied.	2.13	10.73	0.156	Algorithm converged.	0.108	0.204	1.85	Algorithm converged.	2.73	3.62	<.0001		0.21	Algorithm converged.	0.12	0.37
Gender	Male	205	61.0	41	20.0	189	92.0	10	5.0	4.72	Convergence criterion (GCONV=1E-8) satisfied.	2.29	9.73	0.150	Algorithm converged.	0.087	0.212	3.98	Algorithm converged.	2.05	7.72	<.0001	0.3094	0.25	Algorithm converged.	0.13	0.49
	Female	131	39.0	25	19.1	122	89.0	3	2.5	0.35	Convergence criterion (GCONV=1E-8) satisfied.	2.75	31.87	0.166	Algorithm converged.	0.094	0.239	7.76	Algorithm converged.	2.40	25.05	0.0006		0.19	Algorithm converged.	0.04	0.42
Age	<75 years	180	53.6	38	21.1	187	98.3	5	2.7	0.74	Convergence criterion (GCONV=1E-8) satisfied.	3.74	25.38	0.184	Algorithm converged.	0.120	0.248	7.90	Algorithm converged.	3.18	19.61	<.0001	0.1028	0.13	Algorithm converged.	0.05	0.31
	≥75 years	156	46.4	28	17.9	134	85.7	8	6.0	0.44	Convergence criterion (GCONV=1E-8) satisfied.	1.51	7.85	0.120	Algorithm converged.	0.047	0.192	5.01	Algorithm converged.	1.42	6.37	0.0041		0.33	Algorithm converged.	0.16	0.70
Geographical Region	North America	16	4.8	7	43.8	13	8.0	1	7.7	0.33	Convergence criterion (GCONV=1E-8) satisfied.	0.97	80.03	0.361	Algorithm converged.	0.078	0.644	8.69	Algorithm converged.	0.80	10.51	0.0827		0.18	Algorithm converged.	0.02	1.25
	Central and South America	1	0.3	1	10.0	1	100.0	0	0.0	0.00	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE/NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
	Western Europe	208	61.9	46	22.1	193	92.1	11	5.7	4.70	Convergence criterion (GCONV=1E-8) satisfied.	2.35	9.38	0.164	Algorithm converged.	0.099	0.229	3.88	Algorithm converged.	2.07	7.27	<.0001		0.26	Algorithm converged.	0.14	0.48
	Asia-Pacific	23	6.8	5	21.7	22	95.7	6	6.9	0.44	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE/NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Binet Staging at baseline	A	75	22.3	17	22.7	72	94.7	2	2.8	10.76	Convergence criterion (GCONV=1E-8) satisfied.	5.28	46.24	0.199	Algorithm converged.	0.097	0.301	8.16	Algorithm converged.	1.95	34.06	0.0040	0.4045	0.12	Algorithm converged.	0.03	0.51
	B	143	42.6	18	12.6	132	91.1	3	2.3	6.19	Convergence criterion (GCONV=1E-8) satisfied.	1.78	21.54	0.103	Algorithm converged.	0.043	0.163	5.54	Algorithm converged.	1.67	18.37	0.0051		0.18	Algorithm converged.	0.05	0.69
C		118	35.1	31	26.3	117	98.4	8	6.8	4.85	Convergence criterion (GCONV=1E-8) satisfied.	5.12	31.10	0.194	Algorithm converged.	0.103	0.286	8.84	Algorithm converged.	1.84	8.00	0.0003		0.26	Algorithm converged.	0.12	0.54

Test for interaction based on RR (Log-binomial regression)

* indicates convergence problem. Result is uninterpretable. Clinical cut-off: 100CT2017

Program: root/clinical_studies/R05072759/CDPT7159/R021004/data_analysis/ACE_CSRFinal/qc/program/t_s_se.sas

Output: root/clinical_studies/R05072759/CDPT7159/R021004/data_analysis/ACE_CSRFinal/qc/output/t_s_se_ARPIIR3_SE_100CT2017_21004.xls 09OCT2019 1:18

30 (Anhang): Ergebnisse für Neutropenie nach UE, SUE, UE Grad ≥ 3 aus RCT mit dem zu bewertenden Arzneimittel

POPULATION: Safety Evaluable Patients
 ENDPOINT: Neutropenia
 MODEL: Unstratified Analysis
 STUDY: CLL11 (R021004), Final
 Dichotomous Analysis by Subgroups (Safety)

Name	Level	SC1b (N=336)				SC1b (N=323)				Odds Ratio				Absolute Risk Difference				Relative Risk				SC1b vs. SC1b			
		Patients	n	%	with Event	Patients	n	%	with Event	Odds Ratio	95% Lower CI	95% Upper CI	Absolute Risk	95% Lower CI	95% Upper CI	Relative Risk	95% Lower CI	95% Upper CI	p-value (Wald)	Interaction Test p-value (Likelihood ratio)	Relative Risk	95% Lower CI	95% Upper CI		
All	n/a	336	100,0	142	42,3	321	100,0	107	33,3	1,46			0,07	0,01	0,089										
										Convergence criterion (GCONV=1E-8) satisfied.						Algorithm converged.									
Gender	Male	305	91,0	86	28,0	299	92,0	70	23,2	1,33			0,89	0,99	0,068										
	Female	131	39,0	56	42,7	122	93,0	37	30,3	1,72			1,02	2,88	0,124										
Age	<75 years	180	53,6	69	38,3	187	58,3	60	32,1	1,32			0,86	2,02	0,062										
	>=75 years	156	46,4	73	46,8	134	86,0	47	35,1	1,63			1,01	2,62	0,117										
Geographical Region	North America	16	4,8	5	31,3	13	8,0	3	18,5	0,73			0,16	3,39	-0,072										
	Central and South America	11	3,3	7	63,6	6	54,5	1	16,7	3,75			0,74	103,80	0,470										
	Western Europe	208	61,9	93	44,7	193	60,1	68	35,2	1,49			0,99	2,22	0,095										
	Asia-Pacific	33	9,8	12	36,4	32	9,7	11	30,0	1,09			0,34	3,51	0,022										
	Other	78	23,2	25	32,1	87	27,1	22	25,3	1,39			0,71	2,75	0,068										
Binet Staging at baseline	A	75	22,3	27	36,0	72	22,4	18	25,0	1,69			0,83	3,44	0,110										
	B	143	42,6	46	32,2	132	41,1	38	28,8	1,17			0,70	1,96	0,034										
	C	118	35,1	69	58,5	117	36,4	51	43,6	1,82			1,09	3,06	0,149										

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable. Clinical cut-off: 100CT2017

Program: root/clinical_studies/R05072759/CDPF7159/R021004/data_analysis/ACE_CSRFinal/qa/program/t_s_se.sas
 Output: root/clinical_studies/R05072759/CDPF7159/R021004/data_analysis/ACE_CSRFinal/qa/output/t_s_se_sg_ARPINEU_SR_100CT2017_21004.xls 09OCT2019 1:00

POPULATION: Safety Evaluable Patients
 ENDPOINT: Neurotoxicia Serious
 MODEL: Unstratified Analysis
 STUDY: CL11 (N021004) - Final
 Dichotomous Analysis by Subgroups (Safety)

Name	Level	RC1b (N=336)				RC1b (N=321)				GC1b vs. RC1b										RC1b vs. GC1b									
		Patients		Patients		Patients		Patients		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk				
		n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	P-value (Wald)	Interaction Test P-value (Likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL			
All	n/s	336	100,0	4,2	321	100,0	2,8	2,92				0,35	10,36	0,006	Algorithm converged.	-0,009	1,020	1,91	Algorithm converged.	0,35	10,36	0,4528		0,52	Algorithm converged.	0,10	0,84		
Gender	Male	205	61,0	3,1	199	62,0	1,5	1,95				0,18	21,69	0,005	Algorithm converged.	-0,012	0,021	1,94	Algorithm converged.	0,18	21,24	0,5868	0,9808	0,52	Algorithm converged.	0,05	0,64		
	Female	131	39,0	2,5	122	38,0	1,8	1,88				0,17	20,95	0,007	Algorithm converged.	-0,019	0,033	1,86	Algorithm converged.	0,17	20,28	0,6097		0,54	Algorithm converged.	0,05	0,85		
Age	<75 years	180	53,6	1,6	187	58,3	1,5	1,04				0,06	16,74	0,000	Algorithm converged.	-0,015	0,015	1,04	Algorithm converged.	0,07	16,48	0,9784	0,6151	0,96	Algorithm converged.	0,06	15,27		
	≥75 years	156	46,4	3,9	134	41,7	1,7	2,61				0,27	25,37	0,012	Algorithm converged.	-0,014	0,038	2,58	Algorithm converged.	0,27	24,48	0,4099		0,39	Algorithm converged.	0,04	0,69		
Geographical Region	North America	18	4,8		13	4,0																							
	Central and South America	11	3,3		6	1,9																							
	Western Europe	208	61,9	4,9	193	60,1	1,5	3,76				0,42	33,98	0,014	Algorithm converged.	-0,007	0,035	3,71	Algorithm converged.	0,42	32,92	0,2389		0,27	Algorithm converged.	0,03	0,39		
	Asia-Pacific	23	6,8		22	6,9	1,5																						
	Other	78	23,2		67	21,1																							
Binet Staging at baseline	A	75	22,3	1,3	72	22,4																							
	B	143	42,6		132	41,1																							
	C	118	35,1	2,5	117	36,4	1,9	3,03				0,31	29,51	0,017	Algorithm converged.	-0,016	0,050	2,97	Algorithm converged.	0,31	28,18	0,3420		0,34	Algorithm converged.	0,04	0,19		

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable. Clinical cut-off: 100CT2017

Program: root/clinical_studies/R05072759/CDPT7159/R021004/data_analysis/ACE_CSRFinal/ga/program/t_s_ag.sas
 Output: root/clinical_studies/R05072759/CDPT7159/R021004/data_analysis/ACE_CSRFinal/ga/output/t_s_ag_ag_AEPINBU_SE_100CT2017_21004.xls 09OCT2019 1:00

POPULATION: Safety Evaluable Patients
 ENDPOINT: Neutropenia Grade >= 3
 MODEL: Unstratified Analysis
 STUDY: CLL11 (B021004), Final
 Dichotomous Analysis by Subgroups (Safety)

Name	Level	GC1b (N=336)				GC1b (N=321)				GC1b vs. R01b																	
		Patients		Patients		Patients		Patients		Odds Ratio					Absolute Risk Difference					Relative Risk							
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	P-value (Wald)	Interaction Test P-value (Likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	p/a	336	100,0	111	33,0	321	100,0	92	28,7	1,23	Convergence criterion (GCONV=1E-8) satisfied.	0,88	1,71	0,044	Algorithm converged.	-0,027	0,114	0,15	Algorithm converged.	0,92	0,45	0,2263		0,87	Algorithm converged.	0,69	0,99
Gender	Male	205	61,0	67	32,7	199	62,0	58	29,1	1,18	Convergence criterion (GCONV=1E-8) satisfied.	0,77	1,80	0,035	Algorithm converged.	-0,055	0,125	0,12	Algorithm converged.	0,84	1,50	0,4427	0,7656	0,89	Algorithm converged.	0,67	0,19
	Female	131	39,0	44	33,6	122	38,0	34	27,9	1,31	Convergence criterion (GCONV=1E-8) satisfied.	0,77	2,24	0,057	Algorithm converged.	-0,056	0,171	0,21	Algorithm converged.	0,83	0,75	0,3273		0,83	Algorithm converged.	0,57	0,21
Age	<75 years	180	53,6	52	28,9	187	58,3	57	25,1	1,21	Convergence criterion (GCONV=1E-8) satisfied.	0,76	1,92	0,038	Algorithm converged.	-0,053	0,128	0,15	Algorithm converged.	0,82	1,61	0,4183	0,9307	0,87	Algorithm converged.	0,62	0,22
	≥75 years	156	46,4	59	37,8	134	41,7	45	33,6	1,20	Convergence criterion (GCONV=1E-8) satisfied.	0,74	1,95	0,042	Algorithm converged.	-0,068	0,153	0,13	Algorithm converged.	0,82	0,54	0,4549		0,89	Algorithm converged.	0,65	0,21
Geographical Region	North America	16	4,8		425,0	13	0,0		538,5	0,51	Convergence criterion (GCONV=1E-8) satisfied.	0,11	2,62	-0,135	Algorithm converged.	-0,474	1,204	0,65	Algorithm converged.	1,22	1,94	0,4195	0,3847	1,54	Algorithm converged.	0,52	0,59
	Central and South America	11	3,3		763,6	6	1,9		116,7	0,75	Convergence criterion (GCONV=1E-8) satisfied.	0,74	103,80	0,470	Algorithm converged.	0,058	0,882	0,82	Algorithm converged.	0,60	24,14	0,1545		0,26	Algorithm converged.	0,04	0,66
	Western Europe	208	61,9	73	35,1	193	60,1	60	31,1	1,20	Convergence criterion (GCONV=1E-8) satisfied.	0,79	1,82	0,040	Algorithm converged.	-0,052	0,132	0,13	Algorithm converged.	0,85	1,49	0,3956		0,89	Algorithm converged.	0,67	0,17
	Asia-Pacific	23	6,8	10	43,5	22	6,9	10	45,5	0,92	Convergence criterion (GCONV=1E-8) satisfied.	0,28	2,99	-0,020	Algorithm converged.	-0,310	0,271	0,96	Algorithm converged.	0,50	0,84	0,8939		0,05	Algorithm converged.	0,54	0,01
Other	78	23,2	17	21,8	87	27,1	16	18,4	0,24	Convergence criterion (GCONV=1E-8) satisfied.	0,58	2,65	0,034	Algorithm converged.	-0,089	0,157	0,19	Algorithm converged.	0,64	0,18	0,5856		0,84	Algorithm converged.	0,46	0,55	
Binet Staging at baseline	A	75	22,3	19	25,3	72	22,4	16	22,2	1,19	Convergence criterion (GCONV=1E-8) satisfied.	0,55	2,54	0,031	Algorithm converged.	-0,106	0,169	0,14	Algorithm converged.	0,64	0,04	0,6585	0,9441	0,88	Algorithm converged.	0,49	0,57
	B	143	42,6	36	25,2	132	41,1	30	22,7	1,14	Convergence criterion (GCONV=1E-8) satisfied.	0,66	1,99	0,024	Algorithm converged.	-0,076	0,125	0,11	Algorithm converged.	0,73	1,69	0,6354		0,90	Algorithm converged.	0,59	0,38
	C	118	35,1	56	47,5	117	36,4	16	13,3	1,39	Convergence criterion (GCONV=1E-8) satisfied.	0,83	2,34	0,081	Algorithm converged.	-0,045	0,208	0,21	Algorithm converged.	0,90	0,62	0,2104		0,83	Algorithm converged.	0,62	0,11

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable. Clinical cut-off: 10OCT2017

Program: root/clinical_studies/R05072759/CDPT7159/B021004/data_analysis/ACE_CSRFinal/ga/program/t_s_se.mas
 Output: root/clinical_studies/R05072759/CDPT7159/B021004/data_analysis/ACE_CSRFinal/ga/output/t_s_se_ag_ABPINBU_SE_10OCT2017_21004.xls 09OCT2019 1:00

31 (Anhang): Ergebnisse für Progressive multifokale Leukenzephalopathie nach UE, SUE, UE Grad ≥ 3 aus RCT mit dem zu bewertenden Arzneimittel

POPULATION: Safety Evaluable Patients
 ENDPOINT: Progressive multifocal leukoencephalopathy
 MODEL: Unstratified Analysis
 STUDY: CLL11 (N021004)_Final
 Dichotomous Analysis by Subgroups (Safety)

Name	Level	GC1b (N=336)				GC1b (N=321)				GC1b vs. GC1b							GC1b vs. GC1b																
		Patients		Patients		Patients		Patients		Odds Ratio			Absolute Risk Difference				Relative Risk				Relative Risk												
		n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	P-value (Wald)	Interaction Test P-value (Likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL							
All	n/s	316	100,0	1	0,3	321	100,0	3	0,9	0,32	0,03	0,06	<0,006	Convergence criterion (GCONV=1E-8) satisfied.	0,03	0,06	<0,006	Algorithm converged.	-0,018	0,006	0,32	Algorithm converged.	0,03	0,05	0,3206		0,14	Algorithm converged.	0,33	0,03			
Gender	Male	295	81,0	1	0,5	199	62,0	1	0,5	0,97	0,06	15,62	<0,000	Convergence criterion (GCONV=1E-8) satisfied.	0,06	15,62	<0,000	Algorithm converged.	-0,014	0,016	0,97	Algorithm converged.	0,06	15,41	0,9832	0,1828	1,03	Algorithm converged.	0,06	16,36			
	Female	31	9,0			122	38,0							Quasi-complete separation of data points detected.					WARNING: The relative Hessian convergence criterion of 11,926181054 is greater than the limit of 0.0001. The convergence is questionable.				<0,0	1	Algorithm converged.	0,00	NE	0,9999	>999,99	Algorithm converged.	0,00	NE	
Age	<75 years	180	53,6			187	58,3							Quasi-complete separation of data points detected.					ERROR: Error in computing the link function, its derivatives, or the variance function.				<0,0	1	Algorithm converged.	0,00	NE	0,9999	0,4421	>999,99	Algorithm converged.	0,00	NE
	≥75 years	156	46,4	1	0,6	134	41,7	2	0,5	0,43	0,04	4,75	<0,009	Convergence criterion (GCONV=1E-8) satisfied.	0,04	4,75	<0,009	Algorithm converged.	-0,033	0,016	0,43	Algorithm converged.	0,04	4,68	0,4881		0,33	Algorithm converged.	0,21	25,39			
Geographical Region	North America	16	4,8			33	10,0																										
	Central and South America	1	0,3																														
	Western Europe	208	61,9	1	0,5	193	60,1	2	0,6	0,46	0,04	5,13	<0,006	Convergence criterion (GCONV=1E-8) satisfied.	0,04	5,13	<0,006	Algorithm converged.	-0,023	0,012	0,46	Algorithm converged.	0,04	5,08	0,5292		0,16	Algorithm converged.	0,20	23,58			
Asia-Pacific	Asia-Pacific	33	9,8			32	9,9							Quasi-complete separation of data points detected.					ERROR: Error in computing the link function, its derivatives, or the variance function.				<0,0	1	Algorithm converged.	0,00	NE	1,0000	>999,99	Algorithm converged.	0,00	NE	
	Other	78	23,2			87	27,1																										
Binet Strains at baseline	A	75	22,3			72	22,4							Quasi-complete separation of data points detected.					WARNING: The relative Hessian convergence criterion of 5,9257523469 is greater than the limit of 0.0001. The convergence is questionable.				<0,0	1	Algorithm converged.	0,00	NE	0,9999	>999,99	Algorithm converged.	0,00	NE	
	B	143	42,6	1	0,7	132	41,1							Quasi-complete separation of data points detected.					ERROR: The mean parameter is either invalid or at a limit of its range for some observations.				NE		Algorithm converged.	NE	NE	NE	NE	Algorithm converged.	NE	NE	
	C	118	35,1			117	36,4																										

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable. Clinical cut-off: 100CT2017

Program: root/clinical_studies/R05072759/CDPT7159/N021004/data_analysis/ACE_CSRFinal/ga/program/t_e_se.sas
 Output: root/clinical_studies/R05072759/CDPT7159/N021004/data_analysis/ACE_CSRFinal/ga/output/t_e_se_sq_ARPRMLR_SE_100CT2017_21004.xls 09OCT2019 1:06

POPULATION: Safety Evaluable Patients
 ENDPOINT: Progressive multifocal leukoencephalopathy Serious
 MODEL: Unstratified Analysis
 STUDY: CLL11(BO21004) , Final
 Dichotomous Analysis by Subgroups (Safety)

Name	Level	GC1b (N=336)				GC1b (N=321)				GC1b vs. GC1b				GC1b vs. GC1b				GC1b vs. GC1b												
		Patients		Patients		Patients		Patients		Odds Ratio		Absolute Risk Difference		Relative Risk		Relative Risk		Relative Risk		Relative Risk										
		n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% Upper CL	Absolute Risk	95% Lower CL	95% Upper CL	Relative Risk	95% Lower CL	95% Upper CL	P-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	95% Lower CL	95% Upper CL							
All	n/s	336	100,0	10,3	321	100,0	10,3	0,96		Convergence criterion (GCONV=1E-8) satisfied.	0,06	15,33	0,008		Algorithm converged.	-0,009	0,008	0,96		Algorithm converged.	0,06	15,21	0,9742		0,05		Algorithm converged.	0,07	16,66	
Gender	Male	205	61,0	10,5	199	62,0				Quasi-complete separation of data points detected.					WARNING: Negative of Hessian not positive definite.	NE				NE	0,930	NE			Algorithm converged.	NE	NE	NE	NE	
	Female	131	39,0		122	38,0	10,8			Quasi-complete separation of data points detected.					WARNING: The relative Hessian convergence criterion of 19,055174806 is greater than the limit of 0.0001. The convergence is questionable.	<0,0	1			Algorithm converged.	1,00	NE	0,9999	>999,99		Algorithm converged.	0,00	NE		
Age	<75 years	180	53,6		187	58,3														1,0000										
	≥75 years	156	46,4	10,6	134	41,7	10,7	0,86		Convergence criterion (GCONV=1E-8) satisfied.	0,05	13,85	<0,001		Algorithm converged.	-0,020	0,018	0,86		Algorithm converged.	0,05	13,60	0,9141		1,16		Algorithm converged.	0,07	18,43	
Saparabical Region	North America	0,6	0,8		1,0	0,0																								
	Central and South America	0,1	0,3		0,1	0,9																								
	Western Europe	208	61,9	10,5	193	60,1	10,5	0,93		Convergence criterion (GCONV=1E-8) satisfied.	0,06	14,93	0,000		Algorithm converged.	-0,014	0,013	0,93		Algorithm converged.	0,06	14,73	0,9577		1,08		Algorithm converged.	0,07	17,11	
	Asia-Pacific	0,3	0,8		0,2	0,9																								
	Other	0,6	1,2		0,7	2,1																								
Binet Staging at baseline	A	75	22,3		72	22,4	10,4			Quasi-complete separation of data points detected.					ERROR: Error in computing the link function, its derivatives, or the variance function.	<0,0	1			Algorithm converged.	0,00	NE	1,0000	>999,99		Algorithm converged.	0,00	NE		
	B	143	42,6	10,7	132	41,1				Quasi-complete separation of data points detected.					ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE				Algorithm converged.	NE	NE	NE	NE		Algorithm converged.	NE	NE		
	C	118	35,1		117	36,4																								

Test for interaction based on RR (Log-binomial regression)

* indicates convergence problem. Result is uninterpretable. Clinical cut-off: 10OCT2017

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSRFinal/qe/program/t_s_se.sas

Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSRFinal/qe/output/t_s_se_sq_ARFRMLSE_10OCT2017_21004.xls 09OCT2019 1:30

POPULATION: Safety Evaluable Patients
 ENDPOINT: Progressive multifocal leukoencephalopathy Grade >= 3
 MODEL: Unstratified Analysis
 STUDY: C1111 (R021004) - Final
 Dichotomous Analysis by Subgroups (Safety)

Name	Level	GC1b (N=936)				GC1b (N=921)				Odds Ratio				GC1b vs. GC1b				GC1b vs. GC1b											
		Patients		Patients		Patients		Patients		Absolute Risk Difference		Relative Risk		Relative Risk		Relative Risk		Relative Risk											
		n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CI	95% Upper CI	Absolute Risk	95% Lower CI	95% Upper CI	Relative Risk	95% Lower CI	95% Upper CI	Relative Risk	95% Lower CI	95% Upper CI								
All	5/5	336	100,0	1	0,3	321	100,0	3	0,9	0,32	Convergence criterion (GCCNV+1E-8) satisfied.	0,03	0,06	-0,006	Algorithm converged.	-0,018	0,006	0,32	Algorithm converged.	0,03	0,05	0,3206	Interaction Test: p-value (likelihood ratio)	0,14	Algorithm converged.	0,33	0,03		
Gender	Male	265	61,0	1	0,5	199	52,0	1	0,5	0,97	Convergence criterion (GCCNV+1E-8) satisfied.	0,06	0,15	0,000	Algorithm converged.	-0,014	0,014	0,97	Algorithm converged.	0,06	0,15	0,9832	0,1828	0,03	Algorithm converged.	0,06	0,16		
	Female	33	39,0			122	38,0	2	1,6		Quasi-complete separation of data points detected.							<0,0	Algorithm converged.	0,00	NE	0,9999	>999,99	Algorithm converged.	0,00	NE			
Age	<75 years	180	53,6			187	58,3	1	0,5		Quasi-complete separation of data points detected.							<0,0	Algorithm converged.	0,00	NE	0,9999	0,4421	>999,99	Algorithm converged.	0,00	NE		
	≥75 years	156	46,4	1	0,6	134	41,7	2	1,5	0,43	Convergence criterion (GCCNV+1E-8) satisfied.	0,04	0,15	-0,009	Algorithm converged.	-0,033	0,016	0,43	Algorithm converged.	0,04	0,16	0,4881		0,33	Algorithm converged.	0,21	0,25		
Geographical Region	North America	16	4,8			13	4,0																						
	Central and South America	11	3,3			6	1,9																						
	Western Europe	208	61,9	1	0,5	193	60,1	1	0,0	0,46	Convergence criterion (GCCNV+1E-8) satisfied.	0,04	0,13	-0,006	Algorithm converged.	-0,023	0,012	0,46	Algorithm converged.	0,04	0,08	0,5292		2,16	Algorithm converged.	0,20	0,18		
	Asia-Pacific	23	6,8			22	6,9			14,5	Quasi-complete separation of data points detected.							<0,0	Algorithm converged.	0,00	NE	1,0000	>999,99	Algorithm converged.	0,00	NE			
Other	78	23,2			87	27,1																							
Biomarkers at baseline	A	75	22,3			72	22,4	1	0,2		Quasi-complete separation of data points detected.							<0,0	Algorithm converged.	0,00	NE	0,9999	>999,99	Algorithm converged.	0,00	NE			
	B	143	42,6	1	0,7	132	41,1				Quasi-complete separation of data points detected.																		
	C	118	35,1			117	36,4																						

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable. Clinical cut-off: 100CT2017

Program: root/clinical_studies/R05072759/CDPT1159/R021004/data_analysis/ACE_CSRFinal/qc/program/t_s_ee.sas
 Output: root/clinical_studies/R05072759/CDPT1159/R021004/data_analysis/ACE_CSRFinal/qc/output/t_s_ee_sq_ARFRMLR3_SE_100CT2017_21004.xls 09OCT2019 1:22

32 (Anhang): Ergebnisse für Thrombozytopenie nach UE, SUE, UE Grad ≥ 3 aus RCT mit dem zu bewertenden Arzneimittel

POPULATION: Safety Evaluable Patients
 ENDPOINT: Thrombocytopenia
 MODEL: Unstratified Analysis
 STUDY: C1111 (BO21004) - Final
 Dichotomous Analysis by Subgroups (Safety)

Name	Level	R11b (N=136)				R01b (N=321)				Odds Ratio				R01b vs. R11b Absolute Risk Difference				Relative Risk				R01b vs. R01b Relative Risk					
		n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% Upper CL	Absolute Risk	95% Lower CL	95% Upper CL	Relative Risk	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	95% Lower CL	95% Upper CL				
All	n/a	316	100,0	54	16,1	321	100,0	52	6,9	2,60	Convergence criterion (GCONV=1E-8) satisfied.	1,54	4,39	0,092	Algorithm converged.	0,044	0,140	0,34	Algorithm converged.	1,46	1,76	0,0004	0,43	Algorithm converged.	0,27	0,68	
Gender	Male	205	61,0	33	16,1	199	62,0	12	6,0	0,99	Convergence criterion (GCONV=1E-8) satisfied.	1,50	5,97	0,101	Algorithm converged.	0,040	0,161	0,67	Algorithm converged.	1,42	1,02	0,0023	0,5226	0,37	Algorithm converged.	0,20	0,70
	Female	111	39,0	21	16,0	122	38,0	10	8,2	0,14	Convergence criterion (GCONV=1E-8) satisfied.	0,56	0,78	0,078	Algorithm converged.	-0,001	0,158	1,96	Algorithm converged.	1,96	1,98	0,0646	0,51	Algorithm converged.	0,25	0,74	
Age	<75 years	180	63,6	26	14,4	187	58,3	10	5,3	0,99	Convergence criterion (GCONV=1E-8) satisfied.	1,40	6,39	0,091	Algorithm converged.	0,030	0,152	2,70	Algorithm converged.	1,34	1,44	0,0054	0,5356	0,37	Algorithm converged.	0,18	0,75
	≥75 years	136	36,4	28	17,0	134	41,7	12	9,0	0,22	Convergence criterion (GCONV=1E-8) satisfied.	0,68	0,57	0,090	Algorithm converged.	0,013	0,167	0,00	Algorithm converged.	1,06	0,78	0,0320	0,50	Algorithm converged.	0,26	0,94	
Geographical Region	North America	16	4,8	1	6,3	13	4,0	1	7,7	0,80	Convergence criterion (GCONV=1E-8) satisfied.	0,05	14,16	-0,014	Algorithm converged.	-0,202	0,173	0,81	Algorithm converged.	0,06	11,77	0,8790	0,1680	1,23	Algorithm converged.	0,08	17,83
	Central and South America	11	3,3	2	18,2	6	1,9	1	16,7	1,11	Convergence criterion (GCONV=1E-8) satisfied.	0,08	15,53	0,015	Algorithm converged.	-0,360	0,390	1,09	Algorithm converged.	0,12	0,70	0,9378	0,92	Algorithm converged.	0,10	0,15	
	Western Europe	208	61,9	37	17,8	193	60,1	13	6,7	0,00	Convergence criterion (GCONV=1E-8) satisfied.	1,54	5,83	0,111	Algorithm converged.	0,048	0,173	0,64	Algorithm converged.	1,45	1,82	0,0015	0,38	Algorithm converged.	0,21	0,69	
	Asia-Pacific	33	9,8	6	16,1	32	9,9	6	27,3	0,94	Convergence criterion (GCONV=1E-8) satisfied.	0,25	0,53	-0,012	Algorithm converged.	-0,270	0,247	0,96	Algorithm converged.	0,36	0,52	0,9284	1,05	Algorithm converged.	0,40	0,75	
	Other	78	23,2	8	10,3	87	27,1	11	11,1	0,83	Convergence criterion (GCONV=1E-8) satisfied.	1,20	10,44	0,091	Algorithm converged.	0,020	0,162	0,92	Algorithm converged.	1,14	09,75	0,0370	0,11	Algorithm converged.	0,01	0,88	
Binet Staging at baseline	A	75	22,3	11	14,7	72	22,4	5	6,9	0,30	Convergence criterion (GCONV=1E-8) satisfied.	0,76	7,00	0,077	Algorithm converged.	-0,022	0,177	0,11	Algorithm converged.	0,77	0,78	0,1454	0,9642	0,47	Algorithm converged.	0,17	1,30
	B	143	42,6	11	7,7	132	41,1	4	3,0	0,67	Convergence criterion (GCONV=1E-8) satisfied.	0,83	0,59	0,047	Algorithm converged.	-0,006	0,099	0,54	Algorithm converged.	0,83	1,78	0,1030	0,39	Algorithm converged.	0,13	0,21	
	C	118	35,1	32	27,1	117	36,4	13	11,1	0,98	Convergence criterion (GCONV=1E-8) satisfied.	1,47	0,02	0,160	Algorithm converged.	0,062	0,258	0,44	Algorithm converged.	1,35	1,41	0,0031	0,41	Algorithm converged.	0,23	0,74	

Test for interaction based on RR (Log-binomial regression)

* indicates convergence problem. Result is uninterpretable. Clinical cut-off: 10OCT2017

Program: root/clinical_studies/RO5072759/CDPT1159/BO21004/data_analysis/ACE_CSRFinal/qa/program/t_s_se.sas
 Output: root/clinical_studies/RO5072759/CDPT1159/BO21004/data_analysis/ACE_CSRFinal/qa/output/t_s_se_sq_ABPITHRM_SE_10OCT2017_21004.xls 09OCT2019 1:03

POPULATION: Safety Evaluable Patients
 ENDPOINT: Thrombocytopenia Serious
 MODEL: Unstratified Analysis
 STUDY: CLL11 (BO21004) - Final
 Dichotomous Analysis by Subgroups (Safety)

Name	Level	GC1b (N=336)				GC1b (N=321)				GC1b vs. GC1b																		
		Patients		Patients		Patients		Patients		Odds Ratio					Absolute Risk Difference					Relative Risk								
		n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	P-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL		
All	Overall	336	100.0	4	1.2	321	100.0	10.3	3.86			0.43	34.68	0.009	Algorithm converged.	-0.004	0.022	3.82	Algorithm converged.	0.43	34.01	0.2294		0.26	Algorithm converged.	0.03	0.33	
Gender	Male	205	61.0	3	1.5	199	62.0	10.5	2.94			0.10	28.50	0.010	Convergence criterion (GCONV=1E-9) satisfied.	-0.010	0.028	2.91	Algorithm converged.	0.31	27.76	0.3528	0.4839	0.34	Algorithm converged.	0.04	0.27	
	Female	131	39.0	1	0.8	122	38.0								Quasi-complete separation of data points detected.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	
Age	<75 years	180	53.6	2	1.1	187	58.3								Quasi-complete separation of data points detected.			NE	Algorithm converged.	NE	NE	NE	0.2455	NE	Algorithm converged.	NE	NE	
	≥75 years	156	46.4	2	1.3	134	41.7	10.7	5.73			0.15	19.26	0.005	Convergence criterion (GCONV=1E-9) satisfied.	-0.018	0.028	1.72	Algorithm converged.	0.16	18.74	0.6571		0.58	Algorithm converged.	0.05	0.35	
Geographical Region	North America	16	4.8			13	4.0																					
	Central and South America	11	3.3																									
	Western Europe	208	61.9	3	1.4	193	60.1	10.5	2.81			0.29	27.24	0.009	Convergence criterion (GCONV=1E-9) satisfied.	-0.010	0.028	2.78	Algorithm converged.	0.29	26.53	0.3735		0.36	Algorithm converged.	0.04	0.32	
	Asia-Pacific	33	9.8	1	0.3	22	6.9								Quasi-complete separation of data points detected.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE	
	Other	28	8.2			27	8.1																					
Binet Staging at baseline	A	75	22.3	1	1.3	72	22.4								Quasi-complete separation of data points detected.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE	
	B	163	48.6			132	41.1																					
	C	118	35.1	3	2.5	117	36.4	10.9	3.03			0.31	29.51	0.017	Convergence criterion (GCONV=1E-9) satisfied.	-0.016	0.050	2.97	Algorithm converged.	0.31	28.18	0.3420		0.34	Algorithm converged.	0.04	0.19	

Test for interaction based on RR (Log-binomial regression)

* indicates convergence problem. Result is uninterpretable. Clinical cut-off: 10OCT2017

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSRFinal/qa/program/t_s_ae.sas

Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSRFinal/qa/output/t_s_ae_sq_ARPTHRMS_SE_10OCT2017_21004.xls 09OCT2019 1:27

POPULATION: Safety Evaluable Patients
 ENDPOINT: Thrombocytopenia Grade >= 3
 MODEL: Unstratified Analysis
 STUDY: CLL11 (R021004) - Final
 Dichotomous Analysis by Subgroups (Safety)

Name	Level	OC1b (N=136)				OC1b (N=221)				OC1b vs. OC1b				OC1b vs. OC1b													
		Patients		Patients		Patients		Patients		Odds Ratio		Absolute Risk Difference		Relative Risk		Relative Risk											
		n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% Upper CL	Absolute Risk	95% Lower CL	95% Upper CL	Relative Risk	95% Lower CL	95% Upper CL									
All	n/a	336	100.0	39	11.6	321	100.0	11	3.4	0.70	Convergence criterion (GCONV=1E-8) satisfied.	1.86	0.36	0.082	Algorithm converged.	0.042	0.121	0.39	Algorithm converged.	1.77	0.50	0.0002	0.30	Algorithm converged.	0.15	0.57	
Gender	Male	205	61.0	26	12.7	189	82.0	6	3.0	1.67	Convergence criterion (GCONV=1E-8) satisfied.	1.88	11.62	0.097	Algorithm converged.	0.045	0.148	0.21	Algorithm converged.	1.77	10.00	0.0011	0.4168	0.24	Algorithm converged.	0.10	0.57
	Female	131	39.0	13	9.9	122	89.0	5	4.1	2.58	Convergence criterion (GCONV=1E-8) satisfied.	0.89	0.46	0.058	Algorithm converged.	-0.004	0.120	0.42	Algorithm converged.	0.89	0.59	0.0835	0.41	Algorithm converged.	0.15	0.12	
Age	<75 years	180	53.6	19	10.6	167	88.3	3	1.6	7.24	Convergence criterion (GCONV=1E-8) satisfied.	2.10	24.91	0.090	Algorithm converged.	0.041	0.138	0.58	Algorithm converged.	1.98	21.85	0.0021	0.1089	0.15	Algorithm converged.	0.05	0.50
	≥75 years	156	46.4	20	12.8	134	81.7	8	5.0	0.32	Convergence criterion (GCONV=1E-8) satisfied.	0.99	0.45	0.069	Algorithm converged.	0.002	0.135	0.15	Algorithm converged.	0.98	0.72	0.0569	0.47	Algorithm converged.	0.21	0.02	
Geographical Region	North America	6	1.8	1	16.3	13	5.0				Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.				NE	Algorithm converged.	NE	NE	NE	NE	Algorithm converged.	NE	NE
	Central and South America	11	3.3	2	18.2	6	1.9				Quasi-complete separation of data points detected.				ERROR: The mean parameter is either invalid or at a limit of its range for some observations.				NE	Algorithm converged.	NE	NE	NE	NE	Algorithm converged.	NE	NE
	Western Europe	208	61.9	23	11.1	193	80.1	9	4.7	2.54	Convergence criterion (GCONV=1E-8) satisfied.	1.15	0.64	0.064	Algorithm converged.	0.012	0.116	0.37	Algorithm converged.	1.13	0.00	0.0232	0.42	Algorithm converged.	0.20	0.89	
	Asia-Pacific	23	6.8	3	21.7	22	6.9	2	0.1	0.78	Convergence criterion (GCONV=1E-8) satisfied.	0.48	16.13	0.126	Algorithm converged.	-0.081	0.333	0.38	Algorithm converged.	0.52	11.07	0.2647	0.42	Algorithm converged.	0.09	0.94	
Other	78	23.2	8	10.3	87	27.1				Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.				NE	Algorithm converged.	NE	NE	NE	NE	Algorithm converged.	NE	NE	
Binet Staging at baseline	A	75	22.3	8	10.7	72	22.4	1	1.4	8.48	Convergence criterion (GCONV=1E-8) satisfied.	1.03	09.59	0.093	Algorithm converged.	0.018	0.168	0.68	Algorithm converged.	1.99	19.87	0.0517	0.6179	0.13	Algorithm converged.	0.02	0.02
	B	143	42.6	8	5.6	132	41.1	2	1.5	3.85	Convergence criterion (GCONV=1E-8) satisfied.	0.80	18.48	0.041	Algorithm converged.	-0.002	0.084	0.69	Algorithm converged.	0.80	17.07	0.0945	0.27	Algorithm converged.	0.06	1.25	
	C	118	35.1	23	19.5	117	36.4	8	6.8	0.30	Convergence criterion (GCONV=1E-8) satisfied.	1.41	0.72	0.127	Algorithm converged.	0.042	0.211	0.85	Algorithm converged.	1.33	0.11	0.0071	0.35	Algorithm converged.	0.16	0.75	

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable. Clinical cut-off: 10OCT2017

Program: root/clinical_studies/R05072759/CDPT159/R021004/data_analysis/ACE_CSRFinal/qe/program/t_s_ae.sas
 Output: root/clinical_studies/R05072759/CDPT159/R021004/data_analysis/ACE_CSRFinal/qe/output/t_s_ae_sq_ARFITHROM3_SE_10OCT2017_21004.xls 09OCT2019 1:20

33 (Anhang): Ergebnisse für Tumorlyse-Syndrom (TLS) nach UE, SUE, UE Grad ≥ 3 aus RCT mit dem zu bewertenden Arzneimittel

POPULATION: Safety Evaluable Patients
 ENDPOINT: Tumor Lysis Syndrome
 MODEL: Unstratified Analysis
 STUDY: CLL11 (R021004), Final
 Dichotomous Analysis by Subgroups (Safety)

Name	Level	GC1b (N=336)				GC1b (N=321)				GC1b vs. GC1b																	
		Patients		Events		Patients		Events		Odds Ratio					Absolute Risk Difference					Relative Risk							
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CI	95% Upper CI	Absolute Risk	Convergence Reason	95% Lower CI	95% Upper CI	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI
All	n/a	336	100,0	15	4,5	321	100,0				Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.				Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Gender	Male	205	61,0	13	6,3	189	82,0				Quasi-complete separation of data points detected.				ERROR: The mean parameter is either invalid or at a limit of its range for some observations.				Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
	Female	131	39,0	2	1,5	122	88,0				Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 10,94302222 is greater than the limit of 0.0001. The convergence is questionable.				Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Age	<75 years	180	53,6	7	3,9	187	88,3				Quasi-complete separation of data points detected.				ERROR: The mean parameter is either invalid or at a limit of its range for some observations.				Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
	≥75 years	156	46,4	8	5,1	134	81,7				Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 4,213783558 is greater than the limit of 0.0001. The convergence is questionable.				Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Geographical Region	North America	16	4,8	1	6,3	13	4,0				Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.				Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
	Central and South America	1	0,3	1	100,0	1	0,3				Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.				Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
	Western Europe	208	61,9	12	5,8	193	80,1				Quasi-complete separation of data points detected.				ERROR: The mean parameter is either invalid or at a limit of its range for some observations.				Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
	Asia-Pacific	23	6,8	2	8,7	22	9,9				Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.				Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Binet Staging at baseline	0	76	22,3	3	4,0	72	82,4				Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 3,631977941 is greater than the limit of 0.0001. The convergence is questionable.				Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
	1	143	42,6	7	4,9	132	81,1				Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 4,6792126674 is greater than the limit of 0.0001. The convergence is questionable.				Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
	2	118	35,1	5	4,2	117	96,4				Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.				Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE

Test for interaction based on RR (Log-binomial regression)

* indicates convergence problem. Result is uninterpretable. Clinical cut-off: 100CT2017

Program: root/clinical_studies/R05072759/CDPT7159/R021004/data_analysis/ACT_CSRFinal/qe/program/t_a_se.as

Output: root/clinical_studies/R05072759/CDPT7159/R021004/data_analysis/ACT_CSRFinal/qe/output/t_a_se_ARPTL0_SE_100CT2017_21004.xls 09OCT2019 1:04

POPULATION: Safety Evaluable Patients
 ENDPOINT: Tumor Lysis Syndrome Serious
 MODEL: Unstratified Analysis
 STUDY: CLL11 (R021004) - Final
 Dichotomous Analysis by Subgroups (Safety)

Name	Level	GC1b (N=336)				GC1b (N=321)				GC1b vs. GC1b																		
		Patients		Patients		Patients		Patients		Odds Ratio					Absolute Risk Difference					Relative Risk								
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	P-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	
All	p/s	336	100,0	321	100,0																							
Gender	Male	205	61,0	199	62,0																							
	Female	131	39,0	122	38,0																							
Age	<75 years	180	53,6	187	58,3																							
	≥75 years	156	46,4	134	41,7																							
Geographical Region	North America	16	4,8	13	4,0																							
	Central and South America	11	3,3	6	1,9																							
	Western Europe	208	61,9	193	60,1																							
	Asia-Pacific	23	6,8	22	6,9																							
	Other	78	23,2	87	27,1																							
Binet Staging at baseline	a	75	22,3	72	22,4																							
	b	143	42,6	132	41,1																							
	c	118	35,1	117	36,4																							

Test for interaction based on RR (Log-binomial regression)

* indicates convergence problem. Result is uninterpretable. Clinical cut-off: 10OCT2017

Program: root/clinical_studies/R05072759/CDPT159/BO21004/data_analysis/ACE_CSRFinal/qa/program/t_se.sas
 Output: root/clinical_studies/R05072759/CDPT159/BO21004/data_analysis/ACE_CSRFinal/qa/output/t_se_sq_ARFITLSS_SE_10OCT2017_21004.xls 09OCT2019 1:28

POPULATION: Safety Evaluable Patients
 ENDPOINT: Tumor Lysis Syndrome Grade >= 3
 MODEL: Unstratified Analysis
 STUDY: CLL11 (N021004), Final
 Dichotomous Analysis by Subgroups (Safety)

Name	Level	OC1b (N=136)				OC1b (N=221)				OC1b vs. OC1b					OC1b vs. OC1b													
		Patients		Patients		Patients		Patients		Odds Ratio					Absolute Risk Difference					Relative Risk								
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	
All	n/a	336	100,0	72,1	321	100,0				Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.				NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE	
Gender	Male	205	61,0	52,4	189	82,0				Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.				NE	Algorithm converged.	NE	NE	NE	0,0000	NE	Algorithm converged.	NE	NE	
	Female	131	39,0	21,5	122	88,0				Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 10,94302222 is greater than the limit of 0,0001. The convergence is questionable.				NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE	
Age	<75 years	180	53,6	52,8	187	88,3				Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.				NE	Algorithm converged.	NE	NE	NE	0,0000	NE	Algorithm converged.	NE	NE	
	≥75 years	156	46,4	21,3	134	81,7				Quasi-complete separation of data points detected.				ERROR: The mean parameter is either invalid or at a limit of its range for some observations.				NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE	
Geographical Region	North America	6	1,8	12,3	13	6,0				Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.				NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE	
	Central and South America	11	3,3	13,1	61,9					Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.				NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE	
	Western Europe	108	31,9	52,4	193	80,1				Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.				NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE	
	Asia-Pacific	31	9,2	22	9,9																							
	Other	78	23,2		87	37,1																						
Binet Staging at baseline	A	75	22,3	11,3	72	32,6				Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 12,388004663 is greater than the limit of 0,0001. The convergence is questionable.				NE	Algorithm converged.	NE	NE	NE	0,0000	NE	Algorithm converged.	NE	NE	
	B	143	42,6	32,1	132	61,1				Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.				NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE	
	C	118	35,1	32,5	117	56,4				Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 8,0833541543 is greater than the limit of 0,0001. The convergence is questionable.				NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable. Clinical cut-off: 100CT2017

Program: root/clinical_studies/R05072759/CDPT7159/R021004/data_analysis/ACE_CSRFinal/qe/program/t_a_se.sas
 Output: root/clinical_studies/R05072759/CDPT7159/R021004/data_analysis/ACE_CSRFinal/qe/output/t_a_se_090CT2017_21004.xls 090CT2019 1:21

34 (Anhang): Ergebnisse für Kardiale Ereignisse nach UE, SUE, UE Grad ≥ 3 aus RCT mit dem zu bewertenden Arzneimittel

POPULATION: Safety Evaluable Patients
 ENDPOINT: Cardiac Events MODEL: Unstratified
 Analysis STUDY: CL11 (R021004), Final
 Dichotomous Analysis by Subgroups (Safety)

Name	Label	GC1b (N=336)				GC1b (N=321)				Odds Ratio					Absolute Risk Difference					Relative Risk					Interaction Test			Relative Risk		
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio	Convergence Reason	PSS Lower CI	PSS Upper CI	Absolute Risk	Convergence Reason	PSS Lower CI	PSS Upper CI	Relative Risk	Convergence Reason	PSS Lower CI	PSS Upper CI	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	PSS Lower CI	PSS Upper CI			
		n	%	n	%	n	%	n	%																					
All	U/a	336	100,0	50	14,9	321	100,0	32	10,0	1,58	Convergence criterion (G2CONV+1B=8) satisfied.	0,98	0,53	0,049	Algorithm converged.	-0,001	0,059	0,49	Algorithm converged.	0,98	0,26	0,0594	0,67	Algorithm converged.	0,44	1,02				
Gender	Male	305	90,8	31	10,2	299	93,1	21	7,0	0,51	Convergence criterion (G2CONV+1B=8) satisfied.	0,84	0,33	0,046	Algorithm converged.	-0,019	0,111	0,43	Algorithm converged.	0,85	0,41	0,1738	0,7945	0,70	Algorithm converged.	0,42	1,17			
	Female	31	9,2	19	61,3	22	70,1	11	50,0	0,71	Convergence criterion (G2CONV+1B=8) satisfied.	0,78	0,76	0,055	Algorithm converged.	-0,024	0,134	0,61	Algorithm converged.	0,80	0,24	0,1835	0,62	Algorithm converged.	0,31	1,25				
Age	<75 years	180	53,6	18	10,0	187	58,3	22	11,8	0,83	Convergence criterion (G2CONV+1B=8) satisfied.	0,43	0,61	-0,018	Algorithm converged.	-0,081	0,046	0,85	Algorithm converged.	0,47	0,53	0,5882	0,0076	1,18	Algorithm converged.	0,63	0,12			
	≥75 years	156	46,4	32	20,5	134	41,7	10	7,4	0,20	Convergence criterion (G2CONV+1B=8) satisfied.	1,51	0,79	0,131	Algorithm converged.	0,053	0,208	0,75	Algorithm converged.	1,40	0,38	0,0032	0,36	Algorithm converged.	0,19	0,71				
Geographical Region	North America	16	4,8	4	25,0	13	4,0	3	19,2	0,81	Convergence criterion (G2CONV+1B=8) satisfied.	0,28	0,07	0,086	Algorithm converged.	-0,193	0,185	0,62	Algorithm converged.	0,31	0,52	0,5144	0,2318	0,62	Algorithm converged.	0,13	0,81			
	Central and South America	11	3,3	1	9,1	9	2,8	0	0,0		Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.				NR											
	Western Europe	308	91,9	30	10,0	293	91,5	23	7,8	0,25	Convergence criterion (G2CONV+1B=8) satisfied.	0,70	0,23	0,025	Algorithm converged.	-0,041	0,091	0,21	Algorithm converged.	0,73	0,01	0,4403	0,83	Algorithm converged.	0,30	0,37				
Asia-Pacific	Asia-Pacific	23	6,8	3	13,0	22	6,9	1	4,5	1,20	Convergence criterion (G2CONV+1B=8) satisfied.	1,26	0,25	0,302	Algorithm converged.	0,089	0,516	0,65	Algorithm converged.	1,04	0,26	0,0456	0,13	Algorithm converged.	0,02	0,96				
	Other	78	23,2	7	9,0	70	21,8	7	10,0	0,31	Convergence criterion (G2CONV+1B=8) satisfied.	0,43	0,15	0,023	Algorithm converged.	-0,062	0,104	0,30	Algorithm converged.	0,46	0,71	0,6219	0,77	Algorithm converged.	0,27	0,19				
Event Staging at baseline	A	75	22,3	14	18,7	72	22,4	8	11,1	0,84	Convergence criterion (G2CONV+1B=8) satisfied.	0,72	0,69	0,076	Algorithm converged.	-0,039	0,190	0,68	Algorithm converged.	0,75	0,76	0,2072	0,1442	0,60	Algorithm converged.	0,27	0,33			
	B	143	42,6	13	9,1	132	41,1	14	10,6	0,84	Convergence criterion (G2CONV+1B=8) satisfied.	0,38	0,87	-0,015	Algorithm converged.	-0,086	0,055	0,86	Algorithm converged.	0,42	0,76	0,6734	0,17	Algorithm converged.	0,57	0,39				
	C	118	35,1	23	19,5	117	36,4	10	8,5	0,59	Convergence criterion (G2CONV+1B=8) satisfied.	1,17	0,72	0,109	Algorithm converged.	0,022	0,197	0,28	Algorithm converged.	1,14	0,58	0,0204	0,44	Algorithm converged.	0,22	0,88				

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable. Clinical cut-off: 10007207

Program: root/clinical_studies/R05072759/CDPT1159/R021004/data_analysis/ACE_CBRFinal/qv/program/c_4_w_008
 Output: root/clinical_studies/R05072759/CDPT1159/R021004/data_analysis/ACE_CBRFinal/qv/output/c_4_w_008_R05072759_010072017_21004.w 090CT2019 0:51

POPULATION: Safety Evaluable Patients
 ENDPOINT: Cardiac Events Various
 MODEL: Unstratified Analysis
 STUDY: c1311(8021004): Final
 Dichotomous Analysis by Subgroups (Safety)

Name	Level	OC1b (N=716)				OC1b (N=721)				Odds Ratio				Absolute Risk Difference				Relative Risk				OC1b vs. OC1b					
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio	Convergence Reason	95% Lower CI	95% Upper CI	Absolute Risk	Convergence Reason	95% Lower CI	95% Upper CI	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI
		n	%	n	%	n	%	n	%																		
All	r/a	336	100.0	13	3.9	321	100.0	14	4.4	0.88	Convergence criterion (GCONV=1E-8) satisfied.	0.41	0.51	-0.005	Algorithm converged.	-0.035	0.025	0.89	Algorithm converged.	0.42	0.86	0.7508	0.13	Algorithm converged.	0.54	0.36	
Gender	Male	205	51.0	11	5.4	199	52.0	10	6.0	0.88	Convergence criterion (GCONV=1E-8) satisfied.	0.38	0.55	-0.007	Algorithm converged.	-0.032	0.039	0.89	Algorithm converged.	0.40	0.97	0.7734	0.3661	0.12	Algorithm converged.	0.51	0.49
	Female	131	39.0	2	1.5	122	39.0	4	1.6	0.93	Convergence criterion (GCONV=1E-8) satisfied.	0.13	0.71	0.001	Algorithm converged.	-0.039	0.030	0.93	Algorithm converged.	0.13	0.51	0.9428	0.07	Algorithm converged.	0.15	0.50	
Age	<75 years	180	53.6	4	2.2	187	58.3	8	4.3	0.51	Convergence criterion (GCONV=1E-8) satisfied.	0.15	0.72	-0.021	Algorithm converged.	-0.057	0.016	0.52	Algorithm converged.	0.16	0.69	0.2777	0.2426	0.93	Algorithm converged.	0.59	0.28
	≥75 years	156	46.4	9	5.8	134	41.7	6	4.5	1.31	Convergence criterion (GCONV=1E-8) satisfied.	0.45	0.77	0.013	Algorithm converged.	-0.038	0.064	1.29	Algorithm converged.	0.47	0.53	0.6218	0.78	Algorithm converged.	0.28	0.12	
Geographical Region	North America	16	4.8		13	4.0		1	7.7		Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.	0.01			Algorithm converged.	0.00	NE1.0000		1999.99		Algorithm converged.	0.00	NE
	Central and South America	1	0.3		1	0.3		0			Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.	NE		NE	Algorithm converged.	NE	NE	NE	NE		Algorithm converged.	NE	NE
	Western Europe	208	61.9	11	5.3	193	60.1	8	4.1	1.29	Convergence criterion (GCONV=1E-8) satisfied.	0.51	0.28	0.011	Algorithm converged.	-0.030	0.053	1.28	Algorithm converged.	0.52	0.10	0.5914	0.78	Algorithm converged.	0.32	0.91	
	Asia-Pacific	23	6.8	1	4.3	22	6.9				Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.	NE			Algorithm converged.	NE	NE	NE	NE		Algorithm converged.	NE	NE
Other	78	23.2		17	21.1		1	5.7		Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 4.030642134 is greater than the limit of 0.001. The convergence is questionable.	0.01			Algorithm converged.	0.00	NE0.9999		1999.99		Algorithm converged.	0.00	NE	
Time Staging at Baseline	1	76	22.3		72	22.4		4	4.2		Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.	0.01			Algorithm converged.	0.00	NE0.9999	0.0752	1999.99		Algorithm converged.	0.00	NE
	2	143	42.6	1	3.1	132	41.1	1	4.5	0.74	Convergence criterion (GCONV=1E-8) satisfied.	0.23	0.55	-0.010	Algorithm converged.	-0.037	0.036	0.77	Algorithm converged.	0.24	0.46	0.6584	0.30	Algorithm converged.	0.41	0.16	
	3	118	35.1	8	6.8	117	35.4	5	4.3	0.62	Convergence criterion (GCONV=1E-8) satisfied.	0.52	0.13	0.025	Algorithm converged.	-0.033	0.083	0.59	Algorithm converged.	0.53	0.71	0.4056	0.63	Algorithm converged.	0.21	0.87	

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable. Clinical cut-off:
 1000000

Program: root/clinical_studies/R05072759/CDPT159/8021004/data_analysis/ACE_CSRFinal/qv/program/c_4_w_sas
 Output: root/clinical_studies/R05072759/CDPT159/8021004/data_analysis/ACE_CSRFinal/qv/output/c_4_w_sas_8021004_11004.w19 090CT2019: 0:51

POPULATION: Safety Evaluable Patients
 ENDPOINT: Cardiac Events Grade 2-3
 MODEL: Unstratified Analysis
 STUDY: C111(B021004)_Final
 Dichotomous Analysis by Subgroups (Safety)

Name	Level	C111 (N=716)				C111 (N=721)				C111 vs. C112										C111 vs. C113								
		Patients		Patients With Event		Patients		Patients With Event		Odds Ratio		Absolute Risk Difference						Relative Risk				Relative Risk						
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Maid)	Interaction Test p-value (Likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	
All	2/a	336	100.0	12	3.6	321	100.0	12	3.7	0.95	Convergence criterion (GCONV+1E-8) satisfied.	0.42	0.15	-0.002	Algorithm converged.	-0.030	0.027	0.96	Algorithm converged.	0.44	0.10	0.9093	1.05		Algorithm converged.	0.48	0.30	
Gender	3/a	205	51.0	10	4.9	199	52.0	10	5.0	0.97	Convergence criterion (GCONV+1E-8) satisfied.	0.39	0.38	-0.001	Algorithm converged.	-0.044	0.041	0.97	Algorithm converged.	0.41	0.28	0.9457	0.995	1.03	Algorithm converged.	0.44	0.42	
	3/b	121	29.9	0	1.3	122	32.9	0	1.8	0.91	Convergence criterion (GCONV+1E-8) satisfied.	0.13	0.71	-0.001	Algorithm converged.	-0.032	0.010	0.93	Algorithm converged.	0.13	0.51	0.9422	0.07		Algorithm converged.	0.15	0.50	
Age	4/a	380	93.6	0	2.8	377	98.3	0	4.3	0.64	Convergence criterion (GCONV+1E-8) satisfied.	0.21	0.39	-0.015	Algorithm converged.	-0.053	0.023	0.65	Algorithm converged.	0.22	0.55	0.4410	0.3058	1.54	Algorithm converged.	0.31	0.62	
	4/b	156	46.4	7	4.5	134	41.7	4	3.0	0.53	Convergence criterion (GCONV+1E-8) satisfied.	0.44	0.33	-0.015	Algorithm converged.	-0.028	0.058	0.50	Algorithm converged.	0.45	0.02	0.5078	0.67		Algorithm converged.	0.20	0.22	
Geographical Region	5/a	16	4.8	1	6.3	13	4.0	1	7.7	0.80	Convergence criterion (GCONV+1E-8) satisfied.	0.05	0.16	-0.014	Algorithm converged.	-0.202	0.173	0.81	Algorithm converged.	0.06	0.177	0.8790	1.23		Algorithm converged.	0.08	0.83	
	5/b	11	3.3	1	9.1	9	2.9				Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.				Algorithm converged.	NR	NR	NR	NR		Algorithm converged.	NR	NR	
	5/c	208	51.9	0	4.3	193	50.1	0	3.3	1.41	Convergence criterion (GCONV+1E-8) satisfied.	0.49	0.04	0.012	Algorithm converged.	-0.025	0.049	0.39	Algorithm converged.	0.50	0.84	0.5029	0.72		Algorithm converged.	0.26	1.98	
	5/d	21	6.8	1	4.3	22	6.9				Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.				Algorithm converged.	NR	NR	NR	NR		Algorithm converged.	NR	NR	
	5/e	78	23.2			87	27.1	0	5.7		Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 4.000602154 is greater than the limit of 0.0001. The convergence is questionable.				Algorithm converged.	0.01		NR	0.9999	0.9999	Algorithm converged.	0.00	NR	
Site Staging at Baseline	6/a	75	22.3			72	22.4	1	4.2		Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.				Algorithm converged.	0.00		NR	0.9999	0.0289	0.9999	Algorithm converged.	0.00	NR
	6/b	143	42.6	0	2.1	132	41.1	0	3.8	0.54	Convergence criterion (GCONV+1E-8) satisfied.	0.13	0.32	-0.017	Algorithm converged.	-0.057	0.023	0.55	Algorithm converged.	0.13	0.27	0.4120	1.81		Algorithm converged.	0.44	0.41	
	6/c	118	35.1	1	7.6	117	35.4	4	3.0	0.33	Convergence criterion (GCONV+1E-8) satisfied.	0.70	0.80	0.042	Algorithm converged.	-0.016	0.100	0.23	Algorithm converged.	0.71	0.04	0.1713	0.45		Algorithm converged.	0.14	0.42	

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable. Clinical cut-off: 100CT2017

Program: root/clinical_studies/R05072759/CDPT1159/B021004/data_analysis/ACE_CSRFinal/ga/program/t_s_aa.sas
 Output: root/clinical_studies/R05072759/CDPT1159/B021004/data_analysis/ACE_CSRFinal/ga/output/t_s_aa_sq_ARPICARD_0E_100CT2017_21004.xls 090CT2019 0:51

35 (Anhang): Ergebnisse für Zweitneoplasie / Zweitmalignom nach UE, SUE, UE Grad ≥ 3 aus RCT mit dem zu bewertenden Arzneimittel

POPULATION: Safety Evaluable Patients
 ENDPOINT: Second malignancies
 MODEL: Unstratified Analysis
 STUDY: CLL11 (R021004), Final
 Dichotomous Analysis by Subgroups (Safety)

Name	Level	OC1b (N=336)				OC1b (N=321)				Odds Ratio			OC1b vs. OC1b			Relative Risk				OC1b vs. OC1b									
		Patients		Events		Patients		Events		Odds Ratio	95% Lower CI	95% Upper CI	Absolute Risk	Convergence Reason	95% Lower CI	95% Upper CI	Relative Risk	95% Lower CI	95% Upper CI	p-value (Wald)	Interaction Test P-value (Likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI				
All	n/s	316	100,0	37	11,0	321	100,0	33	10,3	1,08			Convergence criterion (GCONV=1E-8) satisfied.	0,66	1,77	0,007	Algorithm converged.	-0,040	1,054	1,07	Algorithm converged.	1,69	1,67	0,7614	0,93	Algorithm converged.	0,60	1,45	
Gender	Male	208	61,0	27	13,2	189	59,0	21	10,6	1,29			Convergence criterion (GCONV=1E-8) satisfied.	0,70	1,36	0,026	Algorithm converged.	-0,037	0,089	1,25	Algorithm converged.	0,73	1,13	0,4176	0,3329	0,80	Algorithm converged.	0,47	1,37
	Female	131	39,0	10	7,6	132	39,0	12	9,8	0,76			Convergence criterion (GCONV=1E-8) satisfied.	0,31	1,82	<0,022	Algorithm converged.	-0,092	0,048	0,78	Algorithm converged.	0,35	1,73	0,5357	1,29	Algorithm converged.	0,58	0,87	
Age	<75 years	180	53,6	17	9,4	187	58,3	13	7,0	1,40			Convergence criterion (GCONV=1E-8) satisfied.	0,66	1,96	0,025	Algorithm converged.	-0,031	0,081	1,36	Algorithm converged.	0,68	1,72	0,3858	0,3170	0,74	Algorithm converged.	0,37	1,47
	≥75 years	156	46,4	20	12,8	134	41,7	20	14,9	0,94			Convergence criterion (GCONV=1E-8) satisfied.	0,43	1,63	<0,021	Algorithm converged.	-0,101	0,059	0,86	Algorithm converged.	0,48	1,53	0,6045	1,16	Algorithm converged.	0,65	0,97	
Geographical Region	North America	6	1,8			13	4,0		17,7				Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.			<0,0	Algorithm converged.	1,00	NE	1,0000	>999,99	Algorithm converged.	0,00	NE	
	Central and South America	11	3,3		218,2	61,9							Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 1.1519208752 is greater than the limit of 0.0001. The convergence is questionable.			NE	Algorithm converged.	NE	NE	NE	NE	Algorithm converged.	NE	NE	
	Western Europe	208	61,9	26	12,5	193	60,1	25	13,0	0,96			Convergence criterion (GCONV=1E-8) satisfied.	0,53	1,73	-0,005	Algorithm converged.	-0,070	0,061	0,97	Algorithm converged.	0,58	1,61	0,8917	1,04	Algorithm converged.	0,62	1,73	
Asia-Pacific	23	6,8		321,7	6,9		418,2	1,25				Convergence criterion (GCONV=1E-8) satisfied.	0,29	6,43	0,036	Algorithm converged.	-0,198	0,262	1,20	Algorithm converged.	0,37	0,88	0,7662	0,84	Algorithm converged.	0,26	0,72		
Other	78	23,2		45,1	87	27,1		33,4	1,51			Convergence criterion (GCONV=1E-8) satisfied.	0,33	6,98	0,017	Algorithm converged.	-0,045	0,079	1,49	Algorithm converged.	0,34	6,44	0,5955	0,67	Algorithm converged.	0,16	0,91		
Biomarkers at baseline	+	75	23,3	12	16,0	72	22,4		811,1	1,52			Convergence criterion (GCONV=1E-8) satisfied.	0,58	0,98	0,049	Algorithm converged.	-0,061	0,159	1,44	Algorithm converged.	0,63	0,32	0,3915	0,6373	0,69	Algorithm converged.	0,30	1,60
	=	143	42,6	15	10,5	132	41,1	13	9,8	1,07			Convergence criterion (GCONV=1E-8) satisfied.	0,49	1,35	0,006	Algorithm converged.	-0,065	0,078	1,07	Algorithm converged.	0,53	1,15	0,8606	0,94	Algorithm converged.	0,46	1,20	
	-	118	35,1	10	8,5	117	36,4	12	10,3	0,81			Convergence criterion (GCONV=1E-8) satisfied.	0,34	1,96	<0,018	Algorithm converged.	-0,092	0,057	0,83	Algorithm converged.	0,37	1,84	0,6398	1,21	Algorithm converged.	0,54	0,69	

Test for interaction based on RR (Log-binomial regression)

* indicates convergence problem. Result is uninterpretable. Clinical cut-off: 100CT2017

Program: root/clinical_studies/R05072759/CDPT159/R021004/data_analysis/ACE_CSRFinal/qa/program/t_s_ag_sas
 Output: root/clinical_studies/R05072759/CDPT159/R021004/data_analysis/ACE_CSRFinal/qa/output/t_s_ag_AEPFINAL_SE_100CT2017_21004.xls 090CT2019 22:48

POPULATION: Safety Evaluable Patients
 PROXY: Scaled malignancy Series
 MODEL: Unstratified Analysis
 STUDY: CLL11 (BO21004) - Final
 Dichotomous Analysis by Subgroups (Safety)

Name	Level	OC1b (N=336)				OC1b (N=321)				OC1b vs. OC1b																
		Patients		Patients		Patients		Patients		Odds Ratio					Absolute Risk Difference					Relative Risk						
		n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	P-value (Wald)	Interaction Test P-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	o/a	336	100.0	35	10.4	321	100.0	32	10.0	1.05	0.63	1.74	0.004	Algorithm converged.	-0.042	0.051	1.04	Algorithm converged.	0.66	1.65	0.8496		0.86	Algorithm converged.	0.61	1.51
Gender	Male	205	61.0	25	12.2	199	62.0	21	10.6	1.18	0.64	2.18	0.016	Algorithm converged.	-0.045	0.078	1.16	Algorithm converged.	0.67	1.00	0.6039	0.5356	0.87	Algorithm converged.	0.50	1.49
	Female	131	39.0	10	7.6	122	38.0	11	9.0	0.83	0.34	2.04	-0.014	Algorithm converged.	-0.082	0.054	0.85	Algorithm converged.	0.37	1.92	0.6907		1.18	Algorithm converged.	0.52	2.68
Age	<75 years	180	53.6	15	8.3	187	58.3	13	7.0	1.22	0.56	2.63	0.014	Algorithm converged.	-0.041	0.068	1.20	Algorithm converged.	0.59	1.45	0.6188	0.5488	0.83	Algorithm converged.	0.41	1.70
	≥75 years	156	46.4	20	12.8	134	41.7	19	14.2	0.89	0.45	1.75	-0.014	Algorithm converged.	-0.093	0.065	0.90	Algorithm converged.	0.50	1.62	0.7353		1.11	Algorithm converged.	0.62	1.98
Geographical Region	North America	16	4.8			13	4.0		17.7					ERROR: Error in computing the link function, its derivatives, or the variance function.			<0.0	Algorithm converged.	0.00	NE	1.0000		>999.99	Algorithm converged.	0.00	NE
	Central and South America	11	3.3	2	18.2		61.9							WARNING: The relative Hessian convergence criterion of 1.1519208752 is greater than the limit of 0.0001. The convergence is questionable.			NE	Algorithm converged.		NE	NE		NE	Algorithm converged.		NE
	Western Europe	208	61.9	25	12.0	193	60.1	24	12.4	0.96	0.53	1.75	-0.006	Algorithm converged.	-0.068	0.060	0.97	Algorithm converged.	0.57	1.63	0.8889		1.03	Algorithm converged.	0.61	1.75
	Asia-Pacific	23	6.8	3	21.7	22	6.9		418.2	1.25	0.29	5.43	0.036	Algorithm converged.	-0.198	0.269	1.20	Algorithm converged.	0.37	3.88	0.7662		0.84	Algorithm converged.	0.26	2.72
	Other	78	23.2	3	3.8	87	27.1		33.4	1.12	0.22	5.72	0.004	Algorithm converged.	-0.053	0.061	1.12	Algorithm converged.	0.23	5.37	0.8916		0.90	Algorithm converged.	0.19	4.31
Binet Staging at baseline	A	75	22.3	12	16.0	72	22.4		111.1	1.52	0.58	3.98	0.049	Algorithm converged.	-0.061	0.159	1.44	Algorithm converged.	0.63	3.32	0.3915	0.6292	0.69	Algorithm converged.	0.30	1.60
	B	143	42.6	13	9.1	132	41.1		12	1.00	0.44	2.28	0.000	Algorithm converged.	-0.068	0.068	1.00	Algorithm converged.	0.47	2.11	1.0000		1.00	Algorithm converged.	0.47	2.11
	C	118	35.1	10	8.5	117	36.4		12	10.3	0.34	1.96	-0.018	Algorithm converged.	-0.092	0.057	0.83	Algorithm converged.	0.37	1.84	0.6398		1.21	Algorithm converged.	0.54	2.69

Test for interaction based on RR (Log-binomial regression)

* indicates convergence problem. Result is uninterpretable. Clinical cut-off: 10OCT2017

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSRFinal/ga/program/t_a_se sas
 Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSRFinal/ga/output/t_a_se_sq_ARFINAL_SE_10OCT2017_21004.xls 09OCT2019 14:33

POPULATION: Safety Evaluable Patients
 ENDPOINT: Second malignancies Grade >= 3
 MODEL: Unstratified Analysis
 STUDY: CLL11 (BO21004) , Final
 Dichotomous Analysis by Subgroups (Safety)

Name	Level	GC1b (N=336)				GC1b (N=321)				GC1b vs. GC1b					GC1b vs. GC1b										
		Patients		Patients		Patients		Patients		Odds Ratio					Relative Risk										
		n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	95% Lower CL	95% Upper CL	Intersection Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	
All	p/s	336	100,0	24	7,1	321	100,0	26	8,1	0,97	0,49	1,55	-0,010	Algorithm converged.	-0,050	0,031	0,88	0,52	1,50	0,6441	1,13	Algorithm converged.	0,67	1,93	
Gender	Male	205	61,0	16	7,8	199	62,0	18	9,0	0,85	0,42	1,72	-0,012	Algorithm converged.	-0,067	0,042	0,86	0,45	1,64	0,6538	0,8962	1,16	Algorithm converged.	0,61	0,21
	Female	131	39,0	8	6,1	122	38,0	8	6,6	0,93	0,34	0,55	-0,005	Algorithm converged.	-0,065	0,056	0,93	0,36	1,40	0,8831	1,07	Algorithm converged.	0,42	0,77	
Age	<75 years	180	53,6	10	5,6	187	58,3	10	5,3	1,04	0,42	0,56	0,002	Algorithm converged.	-0,044	0,049	1,04	0,44	1,44	0,9301	0,5605	0,96	Algorithm converged.	0,41	0,26
	>=75 years	156	46,4	14	9,0	134	41,7	16	11,9	0,73	0,34	1,55	-0,030	Algorithm converged.	-0,101	0,041	0,75	0,38	1,48	0,4099	1,33	Algorithm converged.	0,67	0,62	
Geographical Region	North America	16	4,8			13	4,0		17,7					ERROR: Error in computing the link function, its derivatives, or the variance function.			<0,0	0,00	NE	1,0000	0,6067	>999,99	Algorithm converged.	0,00	NE
	Central and South America	1	0,3			1	0,3		0,9					ERROR: the mean parameter is either invalid or at a limit of its range for some observations.			NE	NE	NE	NE	NE	NE	NE	NE	NE
	Western Europe	208	61,9	19	9,1	193	60,1	19	9,8	0,92	0,47	1,80	-0,007	Algorithm converged.	-0,065	0,050	0,93	0,51	1,70	0,8084	1,08	Algorithm converged.	0,59	1,97	
	Asia-Pacific	23	6,8	2	0,7	22	6,9		3,3,6	0,60	0,09	0,01	-0,049	Algorithm converged.	-0,233	0,135	0,64	0,12	1,46	0,6020	1,57	Algorithm converged.	0,29	0,51	
	Other	78	23,2	2	0,6	87	27,1		3,3,4	0,74	0,12	1,53	-0,009	Algorithm converged.	-0,061	0,043	0,74	0,13	1,33	0,7419	1,34	Algorithm converged.	0,23	0,84	
Binet Staging at baseline	A	75	22,3	8	10,7	72	22,4		8,11,1	0,96	0,34	0,70	-0,004	Algorithm converged.	-0,105	0,096	0,96	0,38	1,42	0,9311	0,9536	1,04	Algorithm converged.	0,41	0,63
	B	143	42,6	8	5,6	132	41,1		8,6,1	0,92	0,33	0,52	-0,005	Algorithm converged.	-0,060	0,051	0,92	0,36	1,39	0,8690	1,08	Algorithm converged.	0,42	0,80	
	C	118	35,1	8	6,8	117	36,4		10	0,78	0,30	0,05	-0,018	Algorithm converged.	-0,086	0,050	0,79	0,32	1,94	0,6115	1,26	Algorithm converged.	0,52	0,88	

Test for interaction based on RR (Log-binomial regression)

* indicates convergence problem. Result is uninterpretable. Clinical cut-off: 100CT2017

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSRFinal/qe/program/t_s_qe.sas

Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSRFinal/qe/output/t_s_qe_ARFINAL3_SE_100CT2017_21004.xls 09OCT2019 22:51

36 (Anhang): Ergebnisse für Neoplasien nach UE, SUE, UE Grad ≥ 3 aus RCT mit dem zu bewertenden Arzneimittel

POPULATION: Safety Evaluable Patients
 ENDPOINT: Neoplasm
 MODEL: Unstratified Analysis STUDY:
 CLL11 (B021004), Final
 Dichotomous Analysis by Subgroups (Safety)

Name	Level	GClb (N=336)				GClb (N=321)				GClb vs. GClb					GClb vs. GClb												
		n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CI	95% Upper CI	Absolute Risk	Convergence Reason	95% Lower CI	95% Upper CI	Relative Risk	95% Lower CI	95% Upper CI	Interaction test p-value (likelihood ratio)	Relative Risk	95% Lower CI	95% Upper CI				
All	n/a	336	100.0	41	12.2	321	100.0	40	12.5	0.98	Convergence criterion (GCONV=1E-8) satisfied.	0.61	1.55	-0.003	Algorithm converged.	-0.053	0.048	0.98	Algorithm converged.	0.65	1.47	0.9197	1.02	Algorithm converged.	0.68	1.54	
Gender	Male	205	61.0	30	14.6	199	62.0	28	14.1	1.05	Convergence criterion (GCONV=1E-8) satisfied.	0.60	1.83	0.006	Algorithm converged.	-0.063	0.074	1.04	Algorithm converged.	0.65	1.68	0.8717	0.6718	0.96	Algorithm converged.	0.60	1.55
	Female	131	39.0	11	8.4	122	38.0	12	9.8	0.84	Convergence criterion (GCONV=1E-8) satisfied.	0.36	1.98	-0.014	Algorithm converged.	-0.085	0.057	0.85	Algorithm converged.	0.39	1.86	0.6910	1.17	Algorithm converged.	0.54	2.56	
Age	<75 years	180	53.6	17	9.4	187	58.3	16	8.6	1.11	Convergence criterion (GCONV=1E-8) satisfied.	0.54	2.28	0.009	Algorithm converged.	-0.050	0.067	1.10	Algorithm converged.	0.58	2.12	0.7663	0.5543	0.91	Algorithm converged.	0.47	1.74
	≥75 years	156	46.4	24	15.4	134	41.7	24	17.9	0.83	Convergence criterion (GCONV=1E-8) satisfied.	0.45	1.55	-0.025	Algorithm converged.	-0.111	0.061	0.86	Algorithm converged.	0.51	1.44	0.5641	1.16	Algorithm converged.	0.69	1.95	
Geographical Region	North America	16	4.8			13	4.0		215.4		Quasi-complete separation of data points detected.							<0.0	Algorithm converged.	0.00	NE	0.9999	>999.99	Algorithm converged.	0.00	NE	
	Central and South America	11	3.3			218.2	61.9				Quasi-complete separation of data points detected.							NE	Algorithm converged.		NE	NE	NE	Algorithm converged.		NE	
	Western Europe	208	61.9	31	14.9	193	60.1	30	15.5	0.95	Convergence criterion (GCONV=1E-8) satisfied.	0.55	1.64	-0.006	Algorithm converged.	-0.077	0.064	0.96	Algorithm converged.	0.60	1.52	0.8584	1.04	Algorithm converged.	0.66	1.66	
	Asia-Pacific	23	6.8			521.7	22	6.9	418.2	1.25	Convergence criterion (GCONV=1E-8) satisfied.	0.29	5.43	0.036	Algorithm converged.	-0.198	0.269	1.20	Algorithm converged.	0.37	3.88	0.7662	0.84	Algorithm converged.	0.26	2.72	
	Other	78	23.2			33.8	87	27.1	44.6	0.83	Convergence criterion (GCONV=1E-8) satisfied.	0.18	3.83	-0.008	Algorithm converged.	-0.069	0.054	0.84	Algorithm converged.	0.19	3.62	0.8113	1.20	Algorithm converged.	0.28	3.18	
Binet Staging at baseline	A	75	22.3	12	16.0	72	22.4	10	13.9	1.18	Convergence criterion (GCONV=1E-8) satisfied.	0.48	2.93	0.021	Algorithm converged.	-0.094	0.136	1.15	Algorithm converged.	0.53	2.50	0.7203	0.6216	0.87	Algorithm converged.	0.40	1.88
	B	143	42.6	18	12.6	132	41.1	15	11.4	1.12	Convergence criterion (GCONV=1E-8) satisfied.	0.54	2.33	0.012	Algorithm converged.	-0.064	0.089	1.11	Algorithm converged.	0.58	2.11	0.7552	0.90	Algorithm converged.	0.47	1.72	
	C	118	35.1	11	9.3	117	36.4	15	12.8	0.70	Convergence criterion (GCONV=1E-8) satisfied.	0.31	1.59	-0.035	Algorithm converged.	-0.115	0.045	0.73	Algorithm converged.	0.35	1.52	0.3953	1.38	Algorithm converged.	0.66	2.87	

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable. Clinical cut-off: 10OCT2017

Program: root/clinical_studies/R05072759/CDPT7159/B021004/data_analysis/ACR_CSRFinal/ga/program/t_s_ag_se.sas
 Output: root/clinical_studies/R05072759/CDPT7159/B021004/data_analysis/ACR_CSRFinal/ga/output/t_s_ag_ag_ABPINNO_SR_10OCT2017_21004.xls 09OCT2019 0:59

POPULATION: Safety Evaluable Patients
 ENDPOINT: Neoplasm Serious
 MODEL: Unstratified Analysis
 STUDY: CLL11(R021004), Final
 Dichotomous Analysis by Subgroups (Safety)

Name	Level	OC1b (N=336)				OC1b (N=321)				OC1b vs. OC1b					OC1b vs. OC1b										
		Patients		Patients		Patients		Patients		Odds Ratio		Absolute Risk Difference			Relative Risk			Relative Risk							
		n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	95% Lower CL	95% Upper CL	P-value (Wald)	Interaction Test P-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	336	100.0	40	11.9	321	100.0	38	11.8	1.01	0.62	1.61	0.001	Convergence criterion (GCONV=1E-8) satisfied.	-0.049	0.050	1.01	0.66	1.53	0.9789		0.99	Algorithm converged.	0.66	1.51
Gender	Male	205	61.0	29	14.1	199	62.0	27	13.6	1.05	0.60	1.85	0.006	Convergence criterion (GCONV=1E-8) satisfied.	-0.062	0.073	1.04	0.64	1.70	0.8664	0.8129	0.96	Algorithm converged.	0.59	1.56
	Female	131	39.0	11	8.4	122	38.0	11	9.0	0.92	0.39	2.22	-0.006	Convergence criterion (GCONV=1E-8) satisfied.	-0.076	0.063	0.93	0.42	2.07	0.8613		1.07	Algorithm converged.	0.48	2.39
Age	<75 years	180	53.6	16	8.9	187	58.3	16	8.6	1.04	0.50	2.15	0.003	Convergence criterion (GCONV=1E-8) satisfied.	-0.054	0.061	1.04	0.54	2.01	0.9101	0.8117	0.96	Algorithm converged.	0.50	1.87
	≥75 years	156	46.4	24	15.4	134	41.7	22	16.4	0.93	0.49	1.74	-0.010	Convergence criterion (GCONV=1E-8) satisfied.	-0.095	0.074	0.94	0.55	1.59	0.8102		1.07	Algorithm converged.	0.63	1.81
Geographical Region	North America	16	4.8			13	4.0			215.4				Quasi-complete separation of data points detected.											
	Central and South America	11	3.3			218.2				61.9				Quasi-complete separation of data points detected.											
	Western Europe	208	61.9	30	14.4	193	60.1	28	14.5	0.99	0.57	1.73	-0.001	Convergence criterion (GCONV=1E-8) satisfied.	-0.070	0.068	0.99	0.62	1.60	0.9808		1.01	Algorithm converged.	0.62	1.62
	Asia-Pacific	23	6.8			521.7				2.25	0.29	5.43	0.036	Convergence criterion (GCONV=1E-8) satisfied.	-0.198	0.269	1.20	0.37	3.88	0.7662		0.84	Algorithm converged.	0.26	2.72
	Other	78	23.2			39.8	12.4			0.83	0.18	3.83	-0.008	Convergence criterion (GCONV=1E-8) satisfied.	-0.069	0.054	0.84	0.19	3.62	0.8113		1.20	Algorithm converged.	0.28	5.18
Binet Staging at baseline	A	75	22.3	12	16.0	72	22.4	10	13.9	1.18	0.48	2.93	0.021	Convergence criterion (GCONV=1E-8) satisfied.	-0.094	0.136	1.15	0.53	2.50	0.7203	0.5611	0.87	Algorithm converged.	0.40	1.88
	B	143	42.6	17	11.9	132	41.1	13	9.8	1.24	0.58	2.65	0.020	Convergence criterion (GCONV=1E-8) satisfied.	-0.053	0.094	1.21	0.61	2.39	0.5887		0.83	Algorithm converged.	0.42	1.64
	C	118	35.1	11	9.3	117	36.4	15	12.8	0.70	0.31	1.59	-0.035	Convergence criterion (GCONV=1E-8) satisfied.	-0.115	0.045	0.73	0.35	1.52	0.3953		1.38	Algorithm converged.	0.66	2.87

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable. Clinical cut-off: 100CT2017

Program: root/clinical_studies/R05072759/CMPT7159/R021004/data_analysis/ACR_CSRFinal/ga/program/t_s_as_sas
 Output: root/clinical_studies/R05072759/CMPT7159/R021004/data_analysis/ACR_CSRFinal/ga/output/t_s_as_sg_AFPINNO_SR_100CT2017_21004.xls 090CT2019 0:59

POPULATION: Safety Evaluable Patients
 ENDPOINT: Neoplasm Grade >= 3
 MODEL: Unstratified Analysis
 STUDY: CLL11(R021004), Final
 Dichotomous Analysis by Subgroups (Safety)

Name	Level	GClb (N=336)				GClb (N=321)				GClb vs. GClb																
		Patients		Patients		Patients		Patients		Odds Ratio					Absolute Risk Difference					Relative Risk						
		n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% Upper CL	Absolute Risk	95% Lower CL	95% Upper CL	Relative Risk	95% Lower CL	95% Upper CL	P-value (Wald)	Interaction Test P-value (likelihood ratio)	Relative Risk	95% Lower CL	95% Upper CL			
All	n/a	336	100.0	28	8.3	321	100.0	31	9.7	0.85	0.50	1.45	-0.012	Algorithm converged.	-0.057	0.031	0.86	Algorithm converged.	0.53	1.41	0.5533	1.16	Algorithm converged.	0.71	0.89	
Gender	Male	205	61.0	19	9.3	189	62.0	23	11.6	0.78	0.41	1.48	-0.023	Algorithm converged.	-0.082	0.037	0.80	Algorithm converged.	0.45	1.43	0.4521	0.6287	1.25	Algorithm converged.	0.70	0.22
	Female	131	39.0	9	6.9	122	38.0	8	6.6	1.05	0.39	2.82	0.003	Algorithm converged.	-0.059	0.065	1.05	Algorithm converged.	0.42	2.63	0.9209	0.95	Algorithm converged.	0.38	0.39	
Age	<75 years	180	53.6	11	6.1	187	58.3	13	7.0	0.87	0.38	2.00	-0.008	Algorithm converged.	-0.059	0.042	0.88	Algorithm converged.	0.40	1.91	0.7449	0.8743	1.14	Algorithm converged.	0.52	0.47
	≥75 years	156	46.4	17	10.9	134	41.7	18	13.4	0.79	0.39	1.60	-0.025	Algorithm converged.	-0.101	0.050	0.81	Algorithm converged.	0.44	1.51	0.5094	1.23	Algorithm converged.	0.66	0.29	
Geographical Region	North America	16	4.8			13	4.0		2	6.4				Quasi-complete separation of data points detected.			<0.0	Algorithm converged.	0.00	NE	0.9999	>999.99	Algorithm converged.	0.00	NE	
	Central and South America	11	3.3			19	6.1							Quasi-complete separation of data points detected.			NE	Algorithm converged.	NE	NE	NE	NE	Algorithm converged.	NE	NE	
	Western Europe	208	61.9	23	11.1	193	60.1	22	11.4	0.97	0.52	1.80	-0.003	Algorithm converged.	-0.065	0.058	0.97	Algorithm converged.	0.56	1.68	0.9139	1.03	Algorithm converged.	0.59	0.79	
	Asia-Pacific	23	6.8	2	0.7	22	6.9		3	13.6	0.60		-0.049	Algorithm converged.	-0.233	0.135	0.64	Algorithm converged.	0.12	3.46	0.6020	1.57	Algorithm converged.	0.29	0.51	
	Other	78	23.2	2	2.6	87	27.1		4	4.6	0.55		-0.020	Algorithm converged.	-0.077	0.036	0.56	Algorithm converged.	0.11	2.96	0.4930	1.79	Algorithm converged.	0.34	0.52	
Binet Staging at baseline	A	75	22.3	8	10.7	72	22.4		9	12.5	0.84		-0.018	Algorithm converged.	-0.122	0.085	0.85	Algorithm converged.	0.35	2.09	0.7286	0.5021	1.17	Algorithm converged.	0.48	0.87
	B	143	42.6	12	8.4	132	41.1		9	6.8	1.25		0.016	Algorithm converged.	-0.047	0.078	1.23	Algorithm converged.	0.54	2.83	0.6244	0.81	Algorithm converged.	0.35	0.87	
	C	118	35.1	8	6.8	117	36.4		13	11.1	0.58		-0.043	Algorithm converged.	-0.116	0.029	0.61	Algorithm converged.	0.26	1.42	0.2506	1.64	Algorithm converged.	0.71	0.81	

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable. Clinical cut-off: 100CT2017

Program: root/clinical_studies/R05072759/CPPT7159/R021004/data_analysis/ACR_CSRFinal/ga/program/t_s_ae.sas
 Output: root/clinical_studies/R05072759/CPPT7159/R021004/data_analysis/ACR_CSRFinal/ga/output/t_s_ae_sg_RFPINB3_100CT2017_21004.xls 09OCT2019 0:59

37 (Anhang): Ergebnisse für Hepatitis-B (HBV) Reaktivierung nach UE aus RCT mit dem zu bewertenden Arzneimittel

POPULATION: Safety Evaluable Patients
 ENDPOINT: Hepatitis B reactivation (based on laboratory values)
 MODEL: Unstratified Analysis
 STUDY: CL111(BO21004)_Final
 Dichotomous Analysis by Subgroups (Safety)

Name	Level	GC1b (N=336)				GC1b (N=321)				GC1b vs. GC1b																		
		Patients		Patients		Patients		Patients		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk			
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CI	95% Upper CI	Absolute Risk	Convergence Reason	95% Lower CI	95% Upper CI	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI	p-value (95% CI)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI	
All	n/s	336	100,0			321	100,0			1,0,3	Quasi-complete separation of data points detected.				ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			<0.0	1	Algorithm converged.	0,00	NE	0,9999		>999,99	Algorithm converged.	0,00	NE
Gender	Male	205	61,0			199	62,0																					
	Female	131	39,0			122	38,0				Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 19.055176906 is greater than the limit of 0.0001. The convergence is questionable.			<0.0	1	Algorithm converged.	0,00	NE	0,9999		>999,99	Algorithm converged.	0,00	NE
Age	<75 years	180	53,6			187	58,3			10,5	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.			<0.0	1	Algorithm converged.	0,00	NE	0,9999		>999,99	Algorithm converged.	0,00	NE
	≥75 years	156	46,4			134	41,7																					
Geographical Region	North America	16	4,8			13	4,0																					
	Central and South America	11	3,3																									
	Western Europe	208	61,9			193	60,1			10,5	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.			<0.0	1	Algorithm converged.	0,00	NE	0,0000		>999,99	Algorithm converged.	0,00	NE
	Asia-Pacific	53	15,8			52	16,2																					
Other	78	23,2			87	27,1																						
Hinet Staining at baseline	A	75	22,3			72	22,4																					
	B	143	42,6			132	41,1			10,8	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 20.199376503 is greater than the limit of 0.0001. The convergence is questionable.			<0.0	1	Algorithm converged.	0,00	NE	0,9999		>999,99	Algorithm converged.	0,00	NE
	C	118	35,1			117	36,4																					

Hepatitis B DNA positive is considered HBV-DNA ≥ 100 IU/mL. Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable. Clinical cut-off: 100CT2017

Program: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSRFinal/qa/program/t_a_se.sas
 Output: root/clinical_studies/RO5072759/CDPT7159/BO21004/data_analysis/ACE_CSRFinal/qa/output/t_a_se_sq_ARPIREP_SE_100CT2017_21004.xls 090CT2019 0:53

38 (Anhang): Ergebnisse für Spät einsetzende Neutropenie nach UE aus RCT mit dem zu bewertenden Arzneimittel

POPULATION: Safety Evaluable Patients
 ENDPOINT: Late Onset Neutropenia
 MODEL: Unstratified Analysis
 STUDY: CLL11(B021004)_Final
 Dichotomous Analysis by Subgroups (Safety)

Name	Level	Gc1b (N=336)				Gc1b (N=321)				Gc1b vs. Gc1b					Gc1b vs. Gc1b								
		Patients		Patients		Patients		Patients		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk				
		n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% Upper CL	Absolute Risk	95% Lower CL	95% Upper CL	Relative Risk	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	95% Lower CL	95% Upper CL
All	n/a	336	100,0	321	100,0	336	100,0	321	100,0	1,22	0,77	1,95	0,022	-0,028	0,072	1,19	0,79	1,80	0,3970	0,84	0,84	0,56	1,26
Gender	Male	205	61,0	194	60,4	205	61,0	194	60,4	0,85	0,48	1,50	-0,019	-0,086	0,048	0,87	0,53	1,42	0,5801	0,239	1,15	0,70	1,88
	Female	131	39,0	127	39,6	131	39,0	127	39,6	0,79	1,13	0,89	0,088	0,015	0,161	0,53	1,10	0,80	0,0287	0,40	0,40	0,17	0,91
Age	<75 years	180	53,6	178	55,4	180	53,6	178	55,4	0,88	0,45	1,71	-0,012	-0,075	0,051	0,89	0,49	1,62	0,7026	0,1922	1,12	0,62	2,04
	≥75 years	156	46,4	143	44,6	156	46,4	143	44,6	0,66	0,84	0,27	0,061	-0,019	0,141	1,55	0,86	0,78	0,1460	0,65	0,65	0,36	1,16
Geographical Region	North America	16	4,8	12	3,7	16	4,8	12	3,7	1,71	0,14	21,33	0,048	-0,169	0,265	1,62	0,17	15,99	0,6772	0,5244	0,62	0,06	6,05
	Central and South America	1	0,3	1	0,3	1	0,3	1	0,3	0,11	0,08	15,53	0,015	-0,360	0,390	1,08	0,12	0,70	0,9378	0,92	0,92	0,10	0,15
	Western Europe	308	91,9	293	91,3	308	91,9	293	91,3	0,54	0,86	0,78	0,050	-0,016	0,116	1,46	0,87	0,43	0,1479	0,69	0,69	0,41	1,14
	Asia-Pacific	23	6,8	22	6,8	23	6,8	22	6,8	0,29	0,03	1,00	-0,093	-0,259	0,073	0,32	0,04	0,84	0,3055	0,14	0,14	0,35	27,92
Other	78	23,2	76	23,7	78	23,2	76	23,7	0,76	0,27	0,10	-0,025	-0,117	0,067	0,78	0,31	1,85	0,5965	0,28	0,28	0,51	0,20	
Binet Staging at baseline	A	75	22,3	72	22,4	75	22,3	72	22,4	0,21	0,31	0,71	0,011	-0,066	0,088	1,20	0,34	1,29	0,7792	0,7857	0,83	0,23	2,88
	B	143	42,6	132	41,1	143	42,6	132	41,1	1,49	0,71	0,13	0,041	-0,035	0,118	1,42	0,74	0,74	0,2954	0,70	0,70	0,37	1,16
	C	118	35,1	117	36,4	118	35,1	117	36,4	0,05	0,53	0,09	0,007	-0,088	0,102	1,04	0,59	1,85	0,8837	0,96	0,96	0,54	0,70

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable. Clinical cut-off: 10OCT2017

Program: root/clinical_studies/R05072759/CDPT7159/B021004/data_analysis/ACE_CSRFinal/qa/program/t_s_ae.sas
 Output: root/clinical_studies/R05072759/CDPT7159/B021004/data_analysis/ACE_CSRFinal/qa/output/t_s_ae_sg_ARFILLONBU_SE_10OCT2017_21004.xls 09OCT2019 22:47

39 (Anhang): Ergebnisse für Verlängerte Neutropenie nach UE aus RCT mit dem zu bewertenden Arzneimittel

POPULATION: Safety Evaluable Patients
 ENDPOINT: Prolonged Neutropenia
 MODEL: Unstratified Analysis
 STUDY: CLL11 (R021004) - Final
 Dichotomous Analysis by Subgroups (Safety)

Name	Level	GC1b (N=336)				GC1b (N=321)				Odds Ratio		GC1b vs. GC1b					GC1b vs. GC1b										
		Patients		Patients		Patients		Patients		Odds Ratio	Convergence Reason	Absolute Risk Difference			Relative Risk		Relative Risk			Relative Risk							
		n	%	n	%	n	%	n	%			95% Lower CL	95% Upper CL	Absolute Risk	95% Lower CL	95% Upper CL	Relative Risk	95% Lower CL	95% Upper CL	P-value (Wald)	Interaction Test P-value (likelihood ratio)	Relative Risk	95% Lower CL	95% Upper CL			
All	n/a	336	100,0	315	97,5	321	100,0	30	9,3	0,47	Convergence criterion (GCONV=1E-8) satisfied.	0,16	1,39	-0,016	Algorithm converged.	-0,039	0,007	0,48	Algorithm converged.	0,17	1,38	0,1729		2,09	Algorithm converged.	0,72	6,06
Gender	Male	205	61,0	210	63,0	199	62,0	7	3,5	0,27	Convergence criterion (GCONV=1E-8) satisfied.	0,06	0,32	-0,025	Algorithm converged.	-0,054	0,003	0,28	Algorithm converged.	0,06	1,32	0,1070	0,2762	1,61	Algorithm converged.	0,76	17,15
	Female	131	39,0	105	32,3	122	38,0	3	2,5	0,93	Convergence criterion (GCONV=1E-8) satisfied.	0,18	1,70	-0,002	Algorithm converged.	-0,039	0,036	0,93	Algorithm converged.	0,19	1,53	0,9297		1,07	Algorithm converged.	0,22	8,22
Age	<75 years	180	53,6	171	51,7	187	58,3	3	1,6	1,04	Convergence criterion (GCONV=1E-8) satisfied.	0,21	0,22	0,001	Algorithm converged.	-0,025	0,027	1,04	Algorithm converged.	0,21	1,08	0,9624	0,1942	0,96	Algorithm converged.	0,20	0,71
	≥75 years	156	46,4	144	44,3	134	41,7	7	5,2	0,24	Convergence criterion (GCONV=1E-8) satisfied.	0,05	1,15	-0,039	Algorithm converged.	-0,081	0,002	0,25	Algorithm converged.	0,05	1,16	0,0765		4,07	Algorithm converged.	0,86	19,28
Geographical Region	North America	16	4,8	13	4,0	17	5,3	1	3,0	0,12	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.			<0,0	Algorithm converged.	0,00	NE	1,0000	0,4414	>999,99	Algorithm converged.	0,00	NE
	Central and South America	1	0,3	1	0,3	1	0,3	0	0,0	0,00	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
	Western Europe	208	61,9	210	63,0	193	60,1	7	3,6	0,26	Convergence criterion (GCONV=1E-8) satisfied.	0,05	1,26	-0,027	Algorithm converged.	-0,056	0,003	0,27	Algorithm converged.	0,06	1,26	0,0951		3,77	Algorithm converged.	0,79	17,94
	Asia-Pacific	23	6,8	22	6,8	22	6,9	1	4,5	0,95	Convergence criterion (GCONV=1E-8) satisfied.	0,06	16,27	-0,002	Algorithm converged.	-0,122	0,118	0,96	Algorithm converged.	0,06	14,37	0,9743		1,05	Algorithm converged.	0,07	15,70
	Other	78	23,2	77	23,5	87	27,1	1	1,1	1,12	Convergence criterion (GCONV=1E-8) satisfied.	0,07	18,16	0,001	Algorithm converged.	-0,032	0,035	1,12	Algorithm converged.	0,07	17,53	0,9381		0,90	Algorithm converged.	0,06	14,09
Binet Staging at baseline	A	75	22,3	72	22,4	72	22,4	0	0,0	0,00	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 10,388004663 is greater than the limit of 0,0001. The convergence is questionable.			NE	Algorithm converged.	NE	NE	NE	0,0904	NE	Algorithm converged.	NE	NE
	B	143	42,6	132	41,1	132	41,1	3	2,3	0,82	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 9,559294631 is greater than the limit of 0,0001. The convergence is questionable.			<0,0	Algorithm converged.	0,00	NE	0,9999	>999,99	NE	Algorithm converged.	0,00	NE
	C	118	35,1	117	36,4	117	36,4	7	6,0	0,55	Convergence criterion (GCONV=1E-8) satisfied.	0,16	1,94	-0,026	Algorithm converged.	-0,080	0,028	0,57	Algorithm converged.	0,17	1,88	0,3541		1,76	Algorithm converged.	0,53	6,87

Test for interaction based on RR (Log-binomial regression)

* indicates convergence problem. Result is uninterpretable. Clinical cut-off: 100CT2017

Program: root/clinical_studies/R05072759/CDPT7159/R021004/data_analysis/ACE_CSRFinal/qa/program/t_ae_sas

Output: root/clinical_studies/R05072759/CDPT7159/R021004/data_analysis/ACE_CSRFinal/qa/output/t_ae_sq_ARPINHEU_SE_100CT2017_21004.xls 090CT2019 1:02

Anhang 4-G5: Spezifische Verträglichkeit: UE nach SOC/PT

SOC/PT ohne aufgetretene Ereignisse werden im Folgendem nicht dargestellt.

40 (Anhang): Ergebnisse für UE bei ≥ 10 % der Patienten in einem Studienarm nach SOC/PT aus RCT mit dem zu bewertenden Arzneimittel

POPULATION: Safety Evaluable Patients
 ENDPOINT: Any AEs
 MODEL: Unstratified Analysis STUDY: CLL11 (R021004), Final
 Dichotomous Analysis by Subgroups (Safety)

MedDRA System Organ Class	MedDRA Preferred Term	G1b (N=336)				G1b (N=321)				G1b vs. G1b					G1b vs. G1b												
		Level	n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% Upper CL	Absolute Risk Difference	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ALL	3/a	336	100,0	167	49,7	321	100,0	133	41,4	1,40			0,083	Algorithm converged.	0,007	0,159	1,20	Algorithm converged.	0,01	0,42	0,0346		0,83	Algorithm converged.	0,70	0,99
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANEMIA	3/a	336	100,0	36	10,7	321	100,0	36	11,2	0,95			-0,005	Algorithm converged.	-0,053	0,043	0,96	Algorithm converged.	0,62	0,48	0,8373		1,05	Algorithm converged.	0,68	1,62
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	3/a	336	100,0	129	38,4	321	100,0	104	32,4	1,30			0,060	Algorithm converged.	-0,013	0,133	1,19	Algorithm converged.	0,96	0,46	0,1099		0,84	Algorithm converged.	0,69	1,04
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	3/a	336	100,0	48	14,3	321	100,0	21	6,5	2,38			0,077	Algorithm converged.	0,031	0,124	2,18	Algorithm converged.	1,34	0,56	0,0018		0,46	Algorithm converged.	0,28	0,75
GASTROINTESTINAL DISORDERS	ALL	3/a	336	100,0	120	35,7	321	100,0	108	33,6	1,10			0,021	Algorithm converged.	-0,052	0,093	1,06	Algorithm converged.	0,86	0,31	0,5778		0,94	Algorithm converged.	0,76	1,16
GASTROINTESTINAL DISORDERS	DIARRHOEA	3/a	336	100,0	34	10,1	321	100,0	24	7,5	1,39			0,026	Algorithm converged.	-0,017	0,070	1,35	Algorithm converged.	0,82	0,23	0,2352		0,74	Algorithm converged.	0,45	1,22
GASTROINTESTINAL DISORDERS	NAUSEA	3/a	336	100,0	40	11,9	321	100,0	42	13,1	0,90			-0,012	Algorithm converged.	-0,062	0,039	0,91	Algorithm converged.	0,61	0,36	0,6477		1,10	Algorithm converged.	0,73	1,65
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ALL	3/a	336	100,0	98	29,2	321	100,0	104	32,4	0,86			-0,032	Algorithm converged.	-0,103	0,038	1,90	Algorithm converged.	0,72	0,13	0,3697		1,11	Algorithm converged.	0,88	1,40
INFECTIONS AND INFESTATIONS	ALL	3/a	336	100,0	130	38,7	321	100,0	122	38,0	1,03			0,007	Algorithm converged.	-0,068	0,081	1,02	Algorithm converged.	0,84	0,24	0,8569		0,98	Algorithm converged.	0,81	1,19
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	3/a	336	100,0	132	39,0	321	100,0	129	40,2	0,92			0,289	Algorithm converged.	0,216	0,362	1,72	Algorithm converged.	1,48	0,00	<0,001		0,58	Algorithm converged.	0,50	0,68
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	3/a	336	100,0	222	66,1	321	100,0	121	37,7	1,22			0,284	Algorithm converged.	0,210	0,357	1,75	Algorithm converged.	1,49	0,06	<0,001		0,57	Algorithm converged.	0,49	0,67
INVESTIGATIONS	ALL	3/a	336	100,0	36	10,1	321	100,0	25	7,8	1,33			0,023	Algorithm converged.	-0,020	0,067	1,30	Algorithm converged.	0,79	0,13	0,2981		0,77	Algorithm converged.	0,47	1,26
METABOLISM AND NUTRITION DISORDERS	ALL	3/a	336	100,0	82	24,5	321	100,0	26	8,1	2,57			0,104	Algorithm converged.	0,052	0,155	2,28	Algorithm converged.	1,48	0,51	0,0002		0,44	Algorithm converged.	0,29	0,68
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	ALL	3/a	336	100,0	62	18,5	321	100,0	48	15,0	1,29			0,035	Algorithm converged.	-0,022	0,092	1,23	Algorithm converged.	0,87	0,74	0,2314		0,81	Algorithm converged.	0,57	1,14
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	ALL	3/a	336	100,0	41	12,2	321	100,0	40	12,5	0,98			-0,003	Algorithm converged.	-0,053	0,048	0,98	Algorithm converged.	0,65	0,47	0,9197		1,02	Algorithm converged.	0,68	1,54
NERVOUS SYSTEM DISORDERS	ALL	3/a	336	100,0	61	18,2	321	100,0	52	16,2	1,15			0,020	Algorithm converged.	-0,038	0,077	1,12	Algorithm converged.	0,80	0,57	0,5072		0,89	Algorithm converged.	0,64	1,25
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	ALL	3/a	336	100,0	64	19,0	321	100,0	56	17,4	1,11			0,016	Algorithm converged.	-0,043	0,075	1,09	Algorithm converged.	0,79	0,51	0,5955		0,92	Algorithm converged.	0,66	1,27
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ALL	3/a	336	100,0	52	15,5	321	100,0	50	15,6	0,99			-0,001	Algorithm converged.	-0,056	0,054	0,99	Algorithm converged.	0,70	0,42	0,9717		1,01	Algorithm converged.	0,70	1,44
VASCULAR DISORDERS	ALL	3/a	336	100,0	35	10,4	321	100,0	29	9,0	1,17			0,014	Algorithm converged.	-0,031	0,059	1,15	Algorithm converged.	0,72	0,84	0,5508		0,87	Algorithm converged.	0,54	1,38

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable. Clinical cut-off: 100CT2017

Program: root/clinical_studies/R05072759/CDPT7159/R021004/data_analysis/ACE_CSRFinal/qe/program/t_s_ae_soc.sas
 Output: root/clinical_studies/R05072759/CDPT7159/R021004/data_analysis/ACE_CSRFinal/qe/output/t_s_ae_soc_sg_80C01_AAR_SE_100CT2017_21004.xls 090CT2019 10:48

41 (Anhang): Ergebnisse für UE bei ≥ 10 % der Patienten in einem Studienarm nach SOC/PT und mit statistisch signifikantem Ergebnis für die Gesamtpopulation nach Subgruppen aus RCT mit dem zu bewertenden Arzneimittel

POPULATION: Safety Evaluable Patients
 ENDPOINT: Any AE
 MODEL: Unstratified Analysis STUDY: CLL11(N021004), Final
 Dichotomous Analysis by Subgroups (Safety)

MedSRA System Organ Class	MedSRA Preferred Term	Level	SOC (n=336)						SOC vs. SOC						SOC vs. SOC													
			Patients		Patients		Patients		Odds Ratio		Absolute Risk Difference		Relative Risk		Relative Risk		Relative Risk											
			n	%	n	%	n	%	95% Lower CL	95% Upper CL	Absolute Risk	95% Lower CL	95% Upper CL	Relative Risk	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (Likelihood ratio)	Relative Risk	95% Lower CL	95% Upper CL							
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ALL	Male	205	81	39	48,3	199	82	84	42,2	1,28	Convergence criterion (GCOMV18-8) satisfied.	0,86	1,89	0,061	Algorithm converged.	-0,036	0,138	1,14	Algorithm converged.	0,92	1,42	0,2211	0,4902000000000000	0,87	Algorithm converged.	0,7	1,08
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	Male	205	81	146	71,2	199	82	80	40,2	0,68	Convergence criterion (GCOMV18-8) satisfied.	0,43	0,97	0,01	Algorithm converged.	0,218	0,402	1,77	Algorithm converged.	1,46	2,14	<0,001	0,6163999999999999	0,56	Algorithm converged.	0,47	0,68
METABOLISM AND NUTRITION DISORDERS	ALL	Male	205	81	41	20	199	82	18	9,5	0,37	Convergence criterion (GCOMV18-8) satisfied.	1,32	4,25	0,105	Algorithm converged.	0,036	0,173	0,69	Algorithm converged.	0,26	0,48	0,0043	0,5533000000000001	0,48	Algorithm converged.	0,29	0,79
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Male	205	81	28	13,7	199	82	11	5,5	0,74	Convergence criterion (GCOMV18-8) satisfied.	1,91	0,99	0,081	Algorithm converged.	0,025	0,138	2,47	Algorithm converged.	0,26	0,83	0,0081	0,5729999999999999	0,4	Algorithm converged.	0,21	0,79
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	Male	205	81	139	67,8	199	82	77	38,7	0,34	Convergence criterion (GCOMV18-8) satisfied.	2,22	5,02	0,291	Algorithm converged.	0,198	0,384	1,75	Algorithm converged.	0,44	0,74	<0,001	0,9882999999999999	0,57	Algorithm converged.	0,47	0,7
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ALL	Female	131	39	48	36,9	122	38	49	40,2	1,61	Convergence criterion (GCOMV18-8) satisfied.	0,98	2,65	0,117	Algorithm converged.	-0,005	0,239	1,29	Algorithm converged.	0,98	1,7	0,0647		0,77	Algorithm converged.	0,59	1,02
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	Female	131	39	86	65,6	122	38	49	40,2	2,65	Convergence criterion (GCOMV18-8) satisfied.	1,71	4,75	0,255	Algorithm converged.	0,136	0,374	1,63	Algorithm converged.	1,27	2,1	0,0001		0,61	Algorithm converged.	0,48	0,78
METABOLISM AND NUTRITION DISORDERS	ALL	Female	131	39	21	16	122	38	7	5,7	0,14	Convergence criterion (GCOMV18-8) satisfied.	1,28	7,67	0,103	Algorithm converged.	0,028	0,178	0,79	Algorithm converged.	0,23	0,34	0,014		0,36	Algorithm converged.	0,16	0,81
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Female	131	39	20	15,3	122	38	0	0,2	0,02	Convergence criterion (GCOMV18-8) satisfied.	0,9	4,51	0,071	Algorithm converged.	-0,008	0,145	1,86	Algorithm converged.	0,91	1,82	0,0895		0,54	Algorithm converged.	0,26	1,1
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	Female	131	39	83	63,4	122	38	44	36,1	0,07	Convergence criterion (GCOMV18-8) satisfied.	1,84	5,12	0,273	Algorithm converged.	0,154	0,392	1,76	Algorithm converged.	1,34	2,3	<0,001		0,57	Algorithm converged.	0,43	0,75
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ALL	>75 years	180	53,6	79	43,9	187	56,3	72	38,3	1,23	Convergence criterion (GCOMV18-8) satisfied.	0,82	1,89	0,054	Algorithm converged.	-0,047	0,154	1,14	Algorithm converged.	0,89	1,46	0,2952	0,6264999999999999	0,88	Algorithm converged.	0,69	1,12
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	>75 years	180	53,6	118	65,6	187	56,3	88	46,4	0,33	Convergence criterion (GCOMV18-8) satisfied.	0,17	0,11	0,292	Algorithm converged.	0,194	0,39	1,8	Algorithm converged.	1,45	2,24	0,0001	0,4506	0,55	Algorithm converged.	0,45	0,69
METABOLISM AND NUTRITION DISORDERS	ALL	>75 years	180	53,6	30	16,7	187	56,3	13	6,9	0,29	Convergence criterion (GCOMV18-8) satisfied.	1,19	4,43	0,086	Algorithm converged.	0,02	0,153	0,68	Algorithm converged.	0,16	0,33	0,0143	0,6771000000000000	0,48	Algorithm converged.	0,27	0,86
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	>75 years	180	53,6	24	13,3	187	56,3	9	4,8	0,04	Convergence criterion (GCOMV18-8) satisfied.	1,37	6,74	0,085	Algorithm converged.	0,027	0,144	0,77	Algorithm converged.	0,32	0,8	0,0068	0,34	0,36	Algorithm converged.	0,17	0,76
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	>75 years	180	53,6	113	62,8	187	56,3	66	35,3	0,09	Convergence criterion (GCOMV18-8) satisfied.	0,02	0,73	0,078	Algorithm converged.	0,176	0,373	1,78	Algorithm converged.	1,42	2,23	<0,001	0,7880000000000003	0,56	Algorithm converged.	0,48	0,7
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ALL	>75 years	156	46,4	38	24,3	134	41,7	41	26,5	1,55	Convergence criterion (GCOMV18-8) satisfied.	0,97	2,46	0,109	Algorithm converged.	-0,008	0,224	1,24	Algorithm converged.	0,98	1,56	0,0688		0,81	Algorithm converged.	0,64	1,02
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	>75 years	156	46,4	114	73,1	134	41,7	61	45,5	0,25	Convergence criterion (GCOMV18-8) satisfied.	1,99	5,31	0,276	Algorithm converged.	0,166	0,385	1,61	Algorithm converged.	1,3	1,98	0,0001		0,62	Algorithm converged.	0,51	0,77
METABOLISM AND NUTRITION DISORDERS	ALL	>75 years	156	46,4	12	7,7	134	41,7	11	8,2	0,80	Convergence criterion (GCOMV18-8) satisfied.	1,99	0,98	0,123	Algorithm converged.	0,044	0,202	2,3	Algorithm converged.	0,31	0,76	0,0034		0,4	Algorithm converged.	0,21	0,76
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	>75 years	156	46,4	24	15,4	134	41,7	12	9	1,85	Convergence criterion (GCOMV18-8) satisfied.	0,89	3,86	0,064	Algorithm converged.	-0,01	0,139	1,72	Algorithm converged.	0,89	1,3	0,1045		0,58	Algorithm converged.	0,3	1,12
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	>75 years	156	46,4	109	69,9	134	41,7	65	48,1	0,33	Convergence criterion (GCOMV18-8) satisfied.	2,05	5,41	0,288	Algorithm converged.	0,178	0,398	1,7	Algorithm converged.	1,36	2,14	<0,001		0,59	Algorithm converged.	0,47	0,74
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ALL	North America	16	4,8	7	43,8	13	8	3	18,5	1,24	Convergence criterion (GCOMV18-8) satisfied.	0,28	0,53	0,053	Algorithm converged.	-0,306	0,412	1,14	Algorithm converged.	0,47	0,75	0,7752	0,65	0,88	Algorithm converged.	0,36	0,13
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	North America	16	4,8	13	81,3	13	8	10	76,9	1,3	Convergence criterion (GCOMV18-8) satisfied.	0,21	0,87	0,043	Algorithm converged.	-0,255	0,342	1,06	Algorithm converged.	0,72	1,34	0,7775	0,1539000000000001	0,95	Algorithm converged.	0,65	1,38
METABOLISM AND NUTRITION DISORDERS	ALL	North America	16	4,8	3	18,8	13	8	3	23,1	0,77	Convergence criterion (GCOMV18-8) satisfied.	0,13	4,65	-0,043	Algorithm converged.	-0,342	0,255	0,81	Algorithm converged.	0,2	0,37	0,7749	0,6543999999999999	1,23	Algorithm converged.	0,3	0,11
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	North America	16	4,8	1	6,3	13	8	1	7,7	0,8	Convergence criterion (GCOMV18-8) satisfied.	0,05	14,16	-0,014	Algorithm converged.	-0,202	0,173	0,81	Algorithm converged.	0,06	1,77	0,879	0,0981000000000000	1,23	Algorithm converged.	0,08	17,83
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	North America	16	4,8	12	75	13	8	9	69,2	1,33	Convergence criterion (GCOMV18-8) satisfied.	0,26	0,83	0,058	Algorithm converged.	-0,271	0,366	1,08	Algorithm converged.	0,68	0,72	0,7329	0,1943	0,92	Algorithm converged.	0,58	1,46
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ALL	Ind South	11	3,3	8	72,7	6	5,9	2	18,3	0,33	Convergence criterion (GCOMV18-8) satisfied.	0,62	45,99	0,194	Algorithm converged.	-0,066	0,854	0,18	Algorithm converged.	0,67	0,16	0,1981		0,46	Algorithm converged.	0,14	1,5
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	Ind South	11	3,3	6	54,5	6	5,9	1	9,1	1,2	Convergence criterion (GCOMV18-8) satisfied.	0,16	0,9	0,045	Algorithm converged.	-0,451	0,542	1,09	Algorithm converged.	0,42	0,86	0,8597		0,92	Algorithm converged.	0,35	0,41
METABOLISM AND NUTRITION DISORDERS	ALL	Ind South	11	3,3	2	18,2	6	5,9	1	16,7	1,11	Convergence criterion (GCOMV18-8) satisfied.	0,08	15,33	0,015	Algorithm converged.	-0,36	0,39	1,09	Algorithm converged.	0,12	0,7	0,9378		0,92	Algorithm converged.	0,1	0,15
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Ind South	11	3,3	1	9,1	6	5,9	1	16,7	0,5	Convergence criterion (GCOMV18-8) satisfied.	0,03	0,77	-0,078	Algorithm converged.	-0,418	0,267	0,55	Algorithm converged.	0,04	1,25	0,6461		1,83	Algorithm converged.	0,14	0,47
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	Ind South	11	3,3	6	54,5	6	5,9	1	9,1	1,2	Convergence criterion (GCOMV18-8) satisfied.	0,16	0,9	0,045	Algorithm converged.	-0,451	0,542	1,09	Algorithm converged.	0,42	0,86	0,8597		0,92	Algorithm converged.	0,35	0,41

BLOOD AND LYMPHATIC SYSTEM DISORDERS	ALL	Western Europe	208	31,9	108	11,9	193	30,1	81	83	1,43	Convergence criterion (GCOMV+1E-8) satisfied.	2,97	2,12	1,089	Algorithm converged.	3,008	2,187	1,221	Algorithm converged.	2,98	1,49	1,0765	Algorithm converged.	2,81	Algorithm converged.	2,87	1,02
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	Western Europe	208	81,9	157	75,5	193	80,1	86	84,6	3,83	Convergence criterion (GCOMV+1E-8) satisfied.	2,5	5,86	2,309	Algorithm converged.	2,218	2,401	1,69	Algorithm converged.	1,42	2,02	1,0001	Algorithm converged.	2,59	Algorithm converged.	2,5	2,7
METABOLISM AND NUTRITION DISORDERS	ALL	Western Europe	208	31,9	12	20,2	193	30,1	16	2,3	2,8	Convergence criterion (GCOMV+1E-8) satisfied.	1,52	2,17	1,119	Algorithm converged.	1,552	2,188	2,44	Algorithm converged.	1,42	2,19	1,0013	Algorithm converged.	2,41	Algorithm converged.	2,24	2,71
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Western Europe	208	81,9	13	25,9	193	80,1	12	6,2	2,84	Convergence criterion (GCOMV+1E-8) satisfied.	1,42	5,69	2,096	Algorithm converged.	2,536	2,157	2,55	Algorithm converged.	1,36	2,8	2,0036	Algorithm converged.	2,39	Algorithm converged.	2,21	2,74
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	Western Europe	208	31,9	155	74,1	193	30,1	79	85,9	4,22	Convergence criterion (GCOMV+1E-8) satisfied.	2,78	6,45	2,136	Algorithm converged.	2,245	2,427	1,82	Algorithm converged.	1,51	2,2	1,0001	Algorithm converged.	2,55	Algorithm converged.	2,46	2,66
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ALL	Asia-Pacific	13	2,8	15	25,2	12	2,9	15	88,2	0,88	Convergence criterion (GCOMV+1E-8) satisfied.	2,25	3,03	-0,03	Algorithm converged.	2,305	2,246	2,96	Algorithm converged.	1,63	1,45	1,8329	Algorithm converged.	1,05	Algorithm converged.	2,69	1,58

INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	Asia-Pacific	33	3,8	37	33,3	32	3,9	1	30	2,81	Convergence criterion (GCOMV1E=8) satisfied.	0,81	0,9	0,239	Algorithm converged.	-0,036	0,315	1,48	Algorithm converged.	0,91	0,4	0,1129	0,68	Algorithm converged.	0,42	0,1		
METABOLISM AND NUTRITION DISORDERS	ALL	Asia-Pacific	23	6,8	3	23	22	6,9	1	4,5	1,15	Convergence criterion (GCOMV1E=8) satisfied.	0,3	32,85	0,085	Algorithm converged.	-0,078	0,248	0,87	Algorithm converged.	0,32	25,55	0,3447	0,35	Algorithm converged.	0,04	0,1		
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Asia-Pacific	33	3,8	3	31,3	32	3,9	3	27,3	0,74	Convergence criterion (GCOMV1E=8) satisfied.	0,19	0,9	-0,055	Algorithm converged.	-0,306	0,196	0,8	Algorithm converged.	0,28	0,24	0,467	1,25	Algorithm converged.	0,45	0,52		
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	Asia-Pacific	23	6,8	34	20,9	22	6,9	11	30	1,56	Convergence criterion (GCOMV1E=8) satisfied.	0,48	0,08	0,109	Algorithm converged.	-0,18	0,398	1,22	Algorithm converged.	0,72	0,07	0,4678	0,82	Algorithm converged.	0,48	0,4		
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ALL	Other	78	23,2	39	37,2	37	27,1	28	32,2	1,23	Convergence criterion (GCOMV1E=8) satisfied.	0,66	0,37	0,05	Algorithm converged.	-0,095	0,195	1,16	Algorithm converged.	0,76	1,76	0,0006	0,87	Algorithm converged.	0,57	0,32		
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	Other	78	23,2	39	35	37	27,1	39	31,8	0,58	Convergence criterion (GCOMV1E=8) satisfied.	0,82	0,03	0,282	Algorithm converged.	0,141	0,422	0,20	Algorithm converged.	0,45	0,61	0,0004	0,44	Algorithm converged.	0,28	0,69		
METABOLISM AND NUTRITION DISORDERS	ALL	Other	78	23,2	32	15,4	37	27,1	3	5,7	0,98	Convergence criterion (GCOMV1E=8) satisfied.	1	8,89	0,096	Algorithm converged.	0,003	0,19	0,68	Algorithm converged.	0,99	0,26	0,053	0,37	Algorithm converged.	0,14	0,01		
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Other	78	23,2	8	10,3	37	27,1	3	1,1	0,83	Convergence criterion (GCOMV1E=8) satisfied.	0,2	30,44	0,091	Algorithm converged.	0,02	0,162	0,90	Algorithm converged.	0,14	33,75	0,037	0,11	Algorithm converged.	0,01	0,88		
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	Other	78	23,2	35	46,9	37	27,1	33	21,8	0,91	Convergence criterion (GCOMV1E=8) satisfied.	1,48	5,73	1,23	Algorithm converged.	0,09	0,371	0,05	Algorithm converged.	0,29	0,28	0,0025	0,49	Algorithm converged.	0,3	0,78		
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ALL	1	75	22,3	35	16,7	32	22,4	22	30,6	1,99	Convergence criterion (GCOMV1E=8) satisfied.	1,01	0,91	1,161	Algorithm converged.	0,006	0,316	1,53	Algorithm converged.	1	0,33	0,0503	0,3397	0,65	Algorithm converged.	0,43	1	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	1	75	22,3	33	10,7	32	22,4	27	37,5	4,02	Convergence criterion (GCOMV1E=8) satisfied.	0,02	8	0,332	Algorithm converged.	0,18	0,484	1,88	Algorithm converged.	0,35	2,63	0,0002	0,7561999999999999	0,53	Algorithm converged.	0,38	0,74	
METABOLISM AND NUTRITION DISORDERS	ALL	1	75	22,3	32	18	32	22,4	10	13,9	0,18	Convergence criterion (GCOMV1E=8) satisfied.	0,48	0,99	0,021	Algorithm converged.	-0,094	0,166	1,16	Algorithm converged.	0,53	0,3	0,7203	1	0,8290000000000000	0,87	Algorithm converged.	0,4	0,88
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	1	75	22,3	3	12	32	22,4	1	6,9	1,83	Convergence criterion (GCOMV1E=8) satisfied.	0,58	0,74	0,051	Algorithm converged.	-0,044	0,145	1,73	Algorithm converged.	0,61	0,31	0,3046	0,8660999999999999	0,58	Algorithm converged.	0,2	0,64	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	1	75	22,3	30	36,7	32	22,4	23	34,7	0,78	Convergence criterion (GCOMV1E=8) satisfied.	1,9	0,44	0,319	Algorithm converged.	0,166	0,473	1,92	Algorithm converged.	0,35	0,74	0,0003	0,8425000000000000	0,52	Algorithm converged.	0,37	0,74	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ALL	1	43	22,6	20	18,3	32	31,1	31	31,1	1,30	Convergence criterion (GCOMV1E=8) satisfied.	0,84	0,29	0,074	Algorithm converged.	-0,038	0,186	1,24	Algorithm converged.	0,89	1,72	0,2016	0,81	Algorithm converged.	0,58	1,12		
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	3	43	22,6	37	30,8	32	31,1	46	34,8	0,9	Convergence criterion (GCOMV1E=8) satisfied.	1,78	4,74	0,26	Algorithm converged.	0,146	0,374	1,75	Algorithm converged.	0,34	2,28	0,0001	0,57	Algorithm converged.	0,44	0,75		
METABOLISM AND NUTRITION DISORDERS	ALL	3	43	22,6	22	13,1	32	31,1	9	6,8	0,48	Convergence criterion (GCOMV1E=8) satisfied.	1,1	0,66	0,086	Algorithm converged.	0,013	0,159	0,26	Algorithm converged.	0,08	0,72	0,0308	0,44	Algorithm converged.	0,21	0,93		
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	3	43	22,6	31	7,2	32	31,1	4	9	0,67	Convergence criterion (GCOMV1E=8) satisfied.	0,83	0,59	0,047	Algorithm converged.	-0,006	0,099	0,54	Algorithm converged.	0,83	0,78	0,103	0,39	Algorithm converged.	0,13	0,21		
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	3	43	22,6	32	17,3	32	31,1	35	34,1	0,6	Convergence criterion (GCOMV1E=8) satisfied.	0,58	0,24	0,231	Algorithm converged.	0,118	0,367	1,68	Algorithm converged.	0,28	0,22	0,0002	0,59	Algorithm converged.	0,45	0,78		
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ALL	1	118	35,1	37	33,3	37	36,4	70	39,8	1,25	Convergence criterion (GCOMV1E=8) satisfied.	0,74	0,14	0,054	Algorithm converged.	-0,065	0,178	1,09	Algorithm converged.	0,89	0,33	0,3513	0,92	Algorithm converged.	0,75	1,12		
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	1	118	35,1	32	17	36,4	36	47,9	5,85	Convergence criterion (GCOMV1E=8) satisfied.	0,19	6,79	1,301	Algorithm converged.	0,184	0,418	1,63	Algorithm converged.	0,32	0,01	0,0001	0,61	Algorithm converged.	0,5	0,76			
METABOLISM AND NUTRITION DISORDERS	ALL	1	118	35,1	38	23,7	37	36,4	7	6	4,89	Convergence criterion (GCOMV1E=8) satisfied.	0,04	13,71	0,177	Algorithm converged.	0,089	0,265	1,97	Algorithm converged.	1,8	0,72	0,0006	0,25	Algorithm converged.	0,11	0,55		
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	1	118	35,1	38	33,7	37	36,4	3	10,3	0,72	Convergence criterion (GCOMV1E=8) satisfied.	0,33	0,66	0,135	Algorithm converged.	0,04	0,229	0,31	Algorithm converged.	0,24	0,43	0,0086	0,43	Algorithm converged.	0,23	0,81		
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	1	118	35,1	30	16,3	37	36,4	21	13,6	1,16	Convergence criterion (GCOMV1E=8) satisfied.	0,38	0,28	0,127	Algorithm converged.	0,205	0,445	1,75	Algorithm converged.	0,35	0,2	0,0001	0,57	Algorithm converged.	0,45	0,72		

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable.
 Clinical out-off: 10002017

Program: root/clinical_studies/R05072759/CDPT1159/B021004/data_analysis/ACE_CRFfinal/qa/program/t_ae_soc_sas
 Output: root/clinical_studies/R05072759/CDPT1159/B021004/data_analysis/ACE_CRFfinal/qa/output/t_ae_soc_ag_S0C01_AAR_SE_10002017_21004.xls
 09CC2219 10:48

42 (Anhang): Ergebnisse für SUE bei $\geq 5\%$ der Patienten in einem Studienarm nach SOC/PT aus RCT mit dem zu bewertenden Arzneimittel

POPULATION: Safety Evaluable Patients
 ENDPOINT: Any SAE
 MODEL: Unstratified Analysis
 STUDY: CLL11 (B021004), Final
 Dichotomous Analysis by Subgroups (Safety)

MedDRA System Organ Class	MedDRA Preferred Term	Level	SC1b (n=336)				SC1b (n=321)				Odds Ratio	Absolute Risk Difference				Relative Risk				SC1b vs. SC1c									
			Patients		Events		Patients		Events			95% Lower CI	95% Upper CI	Absolute Risk	Convergence Reason	95% Lower CI	95% Upper CI	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI		
			n	%	n	%	n	%	n	%																			
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ALL	n/a	336	100,0	20	6	321	100,0	12	3,7	5,63	(GCONV=1E-8) satisfied.	0,78	0,39	0,022	Algorithm converged.	0,01	0,055	1,59			Algorithm converged.	0,79	0,2	0,1922	0,63	Algorithm converged.	0,31	0,26
INFECTIONS AND INFESTATIONS	ALL	n/a	336	100,0	43	12,8	321	100,0	17	5,3	0,86	(GCONV=1E-8) satisfied.	0,55	0,34	0,018	Algorithm converged.	0,07	0,034	0,87			Algorithm converged.	0,6	0,28	0,4923	0,14	Algorithm converged.	0,78	0,68
INFECTIONS AND INFESTATIONS	PNEUMONIA	n/a	336	100,0	14	4,2	321	100,0	5	1,6	0,69	(GCONV=1E-8) satisfied.	0,34	0,4	0,018	Algorithm converged.	0,05	0,016	0,70			Algorithm converged.	0,36	0,38	0,3067	0,42	Algorithm converged.	0,72	0,78
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	n/a	336	100,0	45	13,4	321	100,0	15	4,7	1,15	(GCONV=1E-8) satisfied.	0,72	0,78	0,087	Algorithm converged.	0,044	0,130	0,87			Algorithm converged.	0,63	0,04	0,0003	0,35	Algorithm converged.	0,20	0,61
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	n/a	336	100,0	14	4,1	321	100,0	5	1,6	1,11	(GCONV=1E-8) satisfied.	0,75	0,43	0,086	Algorithm converged.	0,051	0,121	0,50			Algorithm converged.	0,57	0,4	0,0001	0,15	Algorithm converged.	0,06	0,39
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL. CYSTS AND POLYPS)	ALL	n/a	336	100,0	40	11,9	321	100,0	18	5,6	0,01	(GCONV=1E-8) satisfied.	0,63	0,61	0,001	Algorithm converged.	0,05	0,050	0,01			Algorithm converged.	0,66	0,53	0,9789	0,99	Algorithm converged.	0,66	0,61

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 30002019
 Program: root/clinical studies/R05072759/CDP7395/G001297/data analysis/ACE CS Output: root/clinical studies/R05072759/CDP7395/G001297/data analysis/ACE CSR 07OCT2019 11:13

43 (Anhang): Ergebnisse für SUE bei ≥ 5 % der Patienten in einem Studienarm nach SOC/PT und mit statistisch signifikantem Ergebnis für die Gesamtpopulation nach Subgruppen aus RCT mit dem zu bewertenden Arzneimittel

POPULATION: Safety Evaluable Patients
 ENDPOINT: Any SAEs
 MODEL: Unstratified Analysis
 STUDY: CLL11(B021004). Final
 Dichotomous Analysis by Subgroups (Safety)

All

MedDRA System Organ Class	MedDRA Preferred Term	Level	SOC (N=336)						SOC vs. SOC						SOC vs. SOC														
			Patients			Patients			Dds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk											
			n	%	CI	n	%	CI	Ratio	Lower	Upper	Risk	Lower	Upper	Relative	Lower	Upper	Relative	Lower	Upper									
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	Male	205	31	19	14,1	199	32	10	3	1,11	(GCONV+1E-8) satisfied.	1,47	0,98	2,051	Algorithm converged.	0,035	0,148	2,82	Algorithm converged.	1,41	0,62	0,0034	0,8234	0,36	Algorithm converged.	0,18	0,71	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	Male	205	31	12	10,7	199	32	4	5	1,86	(GCONV+1E-8) satisfied.	1,98	0,73	3,087	Algorithm converged.	0,041	0,134	3,34	Algorithm converged.	1,87	0,22	0,0017	0,9999	0,19	Algorithm converged.	0,07	0,53	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	Female	131	19	18	12,2	122	18	0	1,1	1,26	(GCONV+1E-8) satisfied.	1,15	0,38	3,081	Algorithm converged.	0,015	0,147	1,98	Algorithm converged.	1,13	0,89	0,0278		0,34	Algorithm converged.	0,13	0,89	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	Female	131	19	12	9,2	122	18	1	3,8	12,2	(GCONV+1E-8) satisfied.	1,56	0,52	3,083	Algorithm converged.	0,031	0,135	11,18	Algorithm converged.	1,48	0,67	0,0195		0,09	Algorithm converged.	0,01	0,68	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	<75 years	180	33,6	19	13,9	187	39,3	4	5,1	1,38	(GCONV+1E-8) satisfied.	1,51	0,66	3,117	Algorithm converged.	0,063	0,172	1,49	Algorithm converged.	1,31	0,29	0,0004	0,99999	0,15	Algorithm converged.	0,05	0,43	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	<75 years	180	33,6	10	11,1	187	39,3	2	5,1	11,94	(GCONV+1E-8) satisfied.	2,66	0,023	5,1	Algorithm converged.	0,052	0,149	10,39	Algorithm converged.	2,46	0,81	0,0014	0,00000	0,0003	Algorithm converged.	0,02	0,41	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	>=75 years	156	46,4	19	12,8	134	41,7	11	5,2	1,64	(GCONV+1E-8) satisfied.	0,76	0,57	0,046	Algorithm converged.	-0,02	0,116	1,56	Algorithm converged.	0,78	0,14	0,011		0,64	Algorithm converged.	0,32	1,29	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	>=75 years	156	46,4	14	9	134	41,7	3	5,2	1,31	(GCONV+1E-8) satisfied.	1,21	0,52	0,067	Algorithm converged.	0,016	0,119	1,01	Algorithm converged.	1,18	0,69	0,0264		0,25	Algorithm converged.	0,07	0,85	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	North America	16	4,8	3	18,8	13	4				Separation of data points detected.				In computing the link				NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	North America	16	4,8	3	18,8	13	4				Separation of data points detected.				In computing the link				NE	NE	NE	NE	NE	NE	NE	NE	NE	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	and South	11	3,3	1	9,1	8	1,9				Separation of data points detected.				In computing the link				NE	NE	NE	NE	NE	NE	NE	NE	NE	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	and South	11	3,3	1	9,1	8	1,9				Separation of data points detected.				In computing the link				NE	NE	NE	NE	NE	NE	NE	NE	NE	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	Western Europe	208	31,9	13	19,3	201	33	7,7	1,07	(GCONV+1E-8) satisfied.	1,03	0,13	0,062	Algorithm converged.	0,005	0,12	1,93	Algorithm converged.	1,02	0,63	0,0419		0,52	Algorithm converged.	0,28	0,98		
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	Western Europe	208	31,9	14	11,5	193	30,1	0	3,6	1,9	(GCONV+1E-8) satisfied.	1,83	0,13	0,089	Algorithm converged.	0,041	0,138	1,45	Algorithm converged.	1,73	0,44	0,0019		0,22	Algorithm converged.	0,09	0,58	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	Asia-Pacific	13	4,8	8	19,1	12	6,9	1	4,5	13,5	(GCONV+1E-8) satisfied.	1,54	0,86	0,346	Algorithm converged.	0,128	0,363	0,61	Algorithm converged.	1,19	0,45	0,0332		0,12	Algorithm converged.	0,02	0,84	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	Asia-Pacific	13	4,8	4	17,4	12	6,9				Separation of data points detected.				Mean parameter is				NE	NE	NE	NE	NE	NE	NE	NE	NE	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	Other	78	23,2	8	14	67	27,1	1	1,1	1,89	(GCONV+1E-8) satisfied.	0,67	0,157	0,053	Algorithm converged.	-0,01	0,111	0,59	Algorithm converged.	0,67	0,7	0,113		0,18	Algorithm converged.	0,02	1,5	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	Other	78	23,2	1	0,6	67	27,1				Separation of data points detected.				Relative Russian				NE	NE	NE	NE	NE	NE	NE	NE	NE	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	A	75	22,3	12	12	22,4	1	1,4	1,68	(GCONV+1E-8) satisfied.	1,19	0,47	0,106	Algorithm converged.	0,028	0,184	0,64	Algorithm converged.	1,12	0,48	0,0383	0,2114	0,12	Algorithm converged.	0,02	0,89		
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	A	75	22,3	8	10,7	12	12,4				Separation of data points detected.				Mean parameter is				NE	NE	NE	NE	NE	NE	NE	NE	NE	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	B	143	42,6	17	11,9	132	41,1	4	3	1,02	(GCONV+1E-8) satisfied.	1,41	0,19	0,089	Algorithm converged.	0,028	0,149	1,92	Algorithm converged.	1,35	0,36	0,0117		0,20	Algorithm converged.	0,09	0,74	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	B	143	42,6	12	8,4	132	41,1	1	3,8	12	(GCONV+1E-8) satisfied.	1,54	0,62	0,076	Algorithm converged.	0,029	0,124	11,08	Algorithm converged.	1,46	0,42	0,02		0,09	Algorithm converged.	0,01	0,68	

INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	C	18	15,1	19	16,1	17	16,4	10	1,5	1,05	(GCONV=1E-8) satisfied.	1,91	1,63	1,076	Algorithm converged.	-0,01	0,159	1,88	Algorithm converged.	0,92	1,88	0,2855	0,53	Algorithm converged.	0,26	1,09
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	C	18	15,1	14	11,9	17	16,4	4	1,4	1,8	(GCONV=1E-8) satisfied.	1,21	11,92	0,084	Algorithm converged.	0,017	0,151	1,47	Algorithm converged.	1,18	10,23	0,0241	0,29	Algorithm converged.	0,1	0,85

Test for interaction based on RR (Log-Binomial regression)
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 30NOV2018
 Program: root/clinical studies/RO5072759/CDPT7395/G001297/data analysis/ACE CS Output: root/clinical studies/RO5072759/CDPT7395/G001297/data analysis/ACE CSR 07OCT2019 11:13

44 (Anhang): Ergebnisse für UE Grad ≥ 3 bei $\geq 5\%$ der Patienten in einem Studienarm nach SOC/PT aus RCT mit dem zu bewertenden Arzneimittel

POPULATION: Safety Evaluable Patients
 ENDPOINT: AEs Grade ≥ 3
 MODEL: Unstratified Analysis
 STUDY: CLL11(B021004), Final
 Dichotomous Analysis by Subgroups (Safety)

All

MedDRA System Organ Class	MedDRA Preferred Term	Level	SOC1 (N=336)				SOC2 (N=321)				SOC1 vs. SOC2																	
			Patients		Patients with		Patients		Patients with		Odds Ratio					Absolute Risk Difference					Relative Risk							
			n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CI	95% Upper CI	Absolute Risk	Convergence Reason	95% Lower CI	95% Upper CI	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ALL	N/A	336	100,0	143	42,6	321	100,0	112	34,9	2,38	Convergence criterion (GCONV=1E-8) satisfied.	1,01	1,90	0,177	Algorithm converged.	0,002	0,151	1,22	Algorithm converged.	1,00	1,48	0,0451		0,82	Algorithm converged.	0,68	1,00
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	N/A	336	100,0	111	33,0	321	100,0	92	28,7	1,23	Convergence criterion (GCONV=1E-8) satisfied.	0,88	1,71	0,144	Algorithm converged.	-0,027	0,114	1,15	Algorithm converged.	0,92	1,45	0,2263		0,87	Algorithm converged.	0,69	1,09
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	N/A	336	100,0	35	10,4	321	100,0	11	3,4	3,28	Convergence criterion (GCONV=1E-8) satisfied.	1,63	8,57	0,170	Algorithm converged.	0,032	0,108	1,04	Algorithm converged.	1,57	8,88	0,0010		0,33	Algorithm converged.	0,17	0,64
INFECTIONS AND INFESTATIONS	ALL	N/A	336	100,0	41	12,2	321	100,0	46	14,3	0,83	Convergence criterion (GCONV=1E-8) satisfied.	0,53	1,31	-0,021	Algorithm converged.	-0,073	0,031	0,88	Algorithm converged.	0,58	1,06	0,4218		1,17	Algorithm converged.	0,79	1,74
INFECTIONS AND INFESTATIONS	PNEUMONIA	N/A	336	100,0	13	3,9	321	100,0	9	2,8	0,64	Convergence criterion (GCONV=1E-8) satisfied.	0,31	1,32	-0,020	Algorithm converged.	-0,054	0,013	0,65	Algorithm converged.	0,33	1,10	0,2263		0,53	Algorithm converged.	0,77	1,05
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	N/A	336	100,0	77	22,9	321	100,0	22	6,9	0,04	Convergence criterion (GCONV=1E-8) satisfied.	2,44	6,67	0,161	Algorithm converged.	0,108	0,213	1,34	Algorithm converged.	2,14	6,24	<0,0001		0,30	Algorithm converged.	0,19	0,47
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	N/A	336	100,0	68	20,2	321	100,0	13	4,0	0,01	Convergence criterion (GCONV=1E-8) satisfied.	3,25	11,12	0,162	Algorithm converged.	0,114	0,210	0,00	Algorithm converged.	2,82	8,87	<0,0001		0,20	Algorithm converged.	0,11	0,35
METABOLISM AND NUTRITION DISORDERS	ALL	N/A	336	100,0	12	3,5	321	100,0	1	0,3	4,43	Convergence criterion (GCONV=1E-8) satisfied.	1,66	11,84	0,150	Algorithm converged.	0,020	0,080	1,20	Algorithm converged.	1,61	8,97	0,0033		0,24	Algorithm converged.	0,09	0,62
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL. CYSTS AND POLYPS)	ALL	N/A	336	100,0	10	3,0	321	100,0	11	3,4	0,85	Convergence criterion (GCONV=1E-8) satisfied.	0,50	1,45	-0,013	Algorithm converged.	-0,057	0,031	0,86	Algorithm converged.	0,53	1,41	0,5833		1,16	Algorithm converged.	0,71	1,60

Test for interaction based on RR (log-binomial regression)
 * indicates convergence problem. Result is uninterpretable. Clinical cut-off: 100CT2017
 Program: root/clinical_studies/R05072759/CDPT7159/B021004/data_analysis/A Output: root/clinical_studies/R05072759/CDPT7159/B021004/data_analysis/AC_05OCT2019_11:05

45 (Anhang): Ergebnisse für UE Grad ≥ 3 bei $\geq 5\%$ der Patienten in einem Studienarm nach SOC/PT und mit statistisch signifikantem Ergebnis für die Gesamtpopulation nach Subgruppen aus RCT mit dem zu bewertenden Arzneimittel

POPULATION: Safety Evaluable Patients
 ENDPOINT: AE Grade ≥ 3
 MODEL: Unstratified Analysis
 STUDY: C111 (NCT0104), Final
 Dichotomous Analysis by Subgroups (Safety)

MedDRA System Organ Class	MedDRA Preferred Term	Level	SOC (N=336)				SOC (N=32)				SOC vs. SOC																								
			Patients		Patients with		Patients		Patients with		Odds Ratio					Absolute Risk Difference					Relative Risk														
			n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CI	95% Upper CI	Absolute Risk	95% Lower CI	95% Upper CI	Relative Risk	95% Lower CI	95% Upper CI	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	95% Lower CI	95% Upper CI											
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ALL	Male	205	61	88	42,9	9,9	82	71	35,7	0,36	Convergence criterion (GCONV(I=8)) satisfied.	0,91	0,02	0,072	Algorithm converged.	-0,022	0,167	1,2	Algorithm converged.	0,94	1,54	0,138	0,8570000000000004	0,83	Algorithm converged.	0,65	1,06							
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	Male	205	61	49	23,9	9,9	82	19	7,9	0,85	Convergence criterion (GCONV(I=8)) satisfied.	1,08	0,14	0,164	Algorithm converged.	0,095	0,233	1,17	Algorithm converged.	0,84	0,47	0,0001	0,7406000000000004	0,32	Algorithm converged.	0,18	0,54							
METABOLISM AND NUTRITION DISORDERS	ALL	Male	205	61	12	5,9	9,9	82	4	2	0,03	Convergence criterion (GCONV(I=8)) satisfied.	0,96	0,56	0,038	Algorithm converged.	0,001	0,076	0,91	Algorithm converged.	0,96	0,88	0,0602	0,28989999999999999	0,34	Algorithm converged.	0,11	0,05							
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Male	205	61	12	10,7	9,9	82	6	3	0,87	Convergence criterion (GCONV(I=8)) satisfied.	0,53	0,78	0,077	Algorithm converged.	0,029	0,126	0,56	Algorithm converged.	0,47	0,50	0,0048	0,57299999999999999	0,28	Algorithm converged.	0,10	0,68							
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	Male	205	61	41	21	9,9	82	10	3	0,02	Convergence criterion (GCONV(I=8)) satisfied.	2,44	0,3	0,16	Algorithm converged.	0,096	0,223	1,07	Algorithm converged.	0,16	0,98	0,0001	0,34589999999999999	0,24	Algorithm converged.	0,12	0,46							
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ALL	Female	131	39	35	42	12	18	61	31,6	0,43	Convergence criterion (GCONV(I=8)) satisfied.	0,86	0,38	0,084	Algorithm converged.	-0,038	0,203	1,25	Algorithm converged.	0,91	0,72	0,1735		0,8	Algorithm converged.	0,58	1,1							
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	Female	131	39	38	21,4	12	38	7	2,7	0,47	Convergence criterion (GCONV(I=8)) satisfied.	1,87	0,66	0,156	Algorithm converged.	0,075	0,238	1,73	Algorithm converged.	0,69	0,21	0,0011		0,27	Algorithm converged.	0,12	0,58							
METABOLISM AND NUTRITION DISORDERS	ALL	Female	131	39	10	7,6	12	38	1	0,8	0,99	Convergence criterion (GCONV(I=8)) satisfied.	1,25	0,24	0,058	Algorithm converged.	0,02	0,116	0,31	Algorithm converged.	0,21	0,68	0,0321		0,11	Algorithm converged.	0,01	0,83							
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Female	131	39	13	9,9	12	38	5	0,1	0,58	Convergence criterion (GCONV(I=8)) satisfied.	0,89	0,46	0,058	Algorithm converged.	-0,094	0,12	0,42	Algorithm converged.	0,89	0,99	0,9835		0,41	Algorithm converged.	0,15	1,12							
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	Female	131	39	15	19,1	12	38	3	2,2	0,35	Convergence criterion (GCONV(I=8)) satisfied.	0,75	0,87	0,166	Algorithm converged.	0,094	0,239	0,76	Algorithm converged.	0,4	0,05	0,0006		0,13	Algorithm converged.	0,04	0,42							
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ALL	>75 years	180	33,6	87	37,2	8,7	88,3	8	11	0,32	Convergence criterion (GCONV(I=8)) satisfied.	0,86	0,03	0,062	Algorithm converged.	-0,035	0,159	1,2	Algorithm converged.	0,9	1,6	0,211	0,9704000000000004	0,83	Algorithm converged.	0,63	1,11							
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	>75 years	180	33,6	13	23,9	8,7	88,3	7	0,7	0,07	Convergence criterion (GCONV(I=8)) satisfied.	1,52	0,49	0,201	Algorithm converged.	0,133	0,269	0,38	Algorithm converged.	0,35	0,81	0,0001	0,01129999999999999	0,16	Algorithm converged.	0,07	0,34							
METABOLISM AND NUTRITION DISORDERS	ALL	>75 years	180	33,6	13	7,2	8,7	88,3	4	2,1	0,56	Convergence criterion (GCONV(I=8)) satisfied.	1,14	0,13	0,051	Algorithm converged.	0,008	0,094	0,38	Algorithm converged.	0,12	0,16	0,0304	0,4603000000000004	0,3	Algorithm converged.	0,1	0,89							
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	>75 years	180	33,6	17	9,4	8,7	88,3	3	0,6	0,4	Convergence criterion (GCONV(I=8)) satisfied.	1,84	0,22	0,078	Algorithm converged.	0,032	0,125	0,89	Algorithm converged.	0,76	0,975	0,0041	0,1154	0,17	Algorithm converged.	0,05	0,97							
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	>75 years	180	33,6	19	21,7	8,7	88,3	5	2,7	0,07	Convergence criterion (GCONV(I=8)) satisfied.	1,87	0,2	0,19	Algorithm converged.	0,125	0,254	0,1	Algorithm converged.	0,27	0,1	0,0001	0,1051	0,12	Algorithm converged.	0,05	0,31							
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ALL	>75 years	156	46,4	76	48,7	13,4	41,7	24	80,3	0,41	Convergence criterion (GCONV(I=8)) satisfied.	0,88	0,24	0,084	Algorithm converged.	-0,03	0,198	1,21	Algorithm converged.	0,93	1,57	0,155		0,83	Algorithm converged.	0,64	1,07							
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	>75 years	156	46,4	14	21,8	13,4	41,7	15	11,2	0,21	Convergence criterion (GCONV(I=8)) satisfied.	0,15	0,37	0,106	Algorithm converged.	0,022	0,19	0,95	Algorithm converged.	0,11	0,42	0,0201		0,51	Algorithm converged.	0,29	0,9							
METABOLISM AND NUTRITION DISORDERS	ALL	>75 years	156	46,4	3	0,8	13,4	41,7	0	0,7	0,14	Convergence criterion (GCONV(I=8)) satisfied.	1,02	0,1	0,05	Algorithm converged.	0,011	0,09	0,73	Algorithm converged.	0,99	0,04	0,0509		0,13	Algorithm converged.	0,02	0,01							
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	>75 years	156	46,4	18	11,5	13,4	41,7	3	0,05	0,05	Convergence criterion (GCONV(I=8)) satisfied.	1,86	0,89	0,056	Algorithm converged.	-0,003	0,12	1,93	Algorithm converged.	0,87	0,3	0,1065		0,52	Algorithm converged.	0,23	1,15							
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	>75 years	156	46,4	29	18,6	13,4	41,7	8	0,6	0,6	Convergence criterion (GCONV(I=8)) satisfied.	1,58	0,17	0,126	Algorithm converged.	0,053	0,199	0,11	Algorithm converged.	0,47	0,58	0,0029		0,32	Algorithm converged.	0,15	0,68							
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ALL	North America	16	1,8	3	15,3	3	4	3	18,5	0,73	Convergence criterion (GCONV(I=8)) satisfied.	1,16	0,39	0,072	Algorithm converged.	-0,421	0,276	0,81	Algorithm converged.	0,3	0,21	0,6842	0,8282000000000005	1,23	Algorithm converged.	0,45	1,35							
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	North America	16	1,8	7	43,8	3	4	1	7,7	0,33	Convergence criterion (GCONV(I=8)) satisfied.	0,97	0,03	0,361	Algorithm converged.	0,078	0,644	0,69	Algorithm converged.	0,8	0,51	0,0827	1,4284	0,18	Algorithm converged.	0,02	1,25							
METABOLISM AND NUTRITION DISORDERS	ALL	North America	16	1,8	1	6,3	3	4				ERROR: Error in computing the link function, its derivative, or the variance function. Data-complete requirement of data points detected.										Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION		75	32.3	37	32.7	32	32.4	2	2.8	0.26		Convergence criterion (CONV+1E-8) satisfied	5.28	16.24	5.139		Algorithm converged.	0.097	5.301	5.16		Algorithm converged.	0.95	18.06	5.004	2.6118999999 1899998	5.12		Algorithm converged.	0.01	0.51
													Convergence criterion (CONV+1E-8) satisfied	5.89	2.84	5.107		Algorithm converged.	1	0.214	1.44		Algorithm converged.	0.49	0.1	5.0558	5.69		Algorithm converged.	0.48	1.01	
BLOOD AND LYMPHATIC SYSTEM DISORDERS		11	143	32.6	30	33	31.1	32	25.2	0.88			Convergence criterion (CONV+1E-8) satisfied	5.89	2.84	5.107		Algorithm converged.	1	0.214	1.44		Algorithm converged.	0.49	0.1	5.0558	5.69		Algorithm converged.	0.48	1.01	

INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	3	143	12.6	21	16.1	12	11.1	1	0.8	0.87		Convergence criterion (GCONV1E=8) satisfied	0.79	13.22	0.173		Algorithm converged	0.055	0.191	0.25		Algorithm converged	0.46	10.85	0.0075		0.24		Algorithm converged	0.09	0.6
METABOLISM AND NUTRITION DISORDERS	ALL	3	143	12.6	7	6.9	12	11.1	2	0.5	0.34		Convergence criterion (GCONV1E=8) satisfied	0.68	16.39	0.034		Algorithm converged	-0.007	0.075	0.23		Algorithm converged	0.68	15.28	0.139		0.31		Algorithm converged	0.07	0.66
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	3	143	12.6	3	0.6	12	11.1	0	0.1	0.85		Convergence criterion (GCONV1E=8) satisfied	0.8	18.48	0.041		Algorithm converged	-0.002	0.084	0.69		Algorithm converged	0.9	13.07	0.0465		0.27		Algorithm converged	0.06	0.25
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	3	143	12.6	18	12.6	12	11.1	0	0.1	0.19		Convergence criterion (GCONV1E=8) satisfied	0.78	11.84	0.163		Algorithm converged	0.043	0.149	0.34		Algorithm converged	0.87	18.87	0.0501		0.18		Algorithm converged	0.06	0.6
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ALL	3	118	15.1	27	16.8	13	16.4	0	0.1	0.17		Convergence criterion (GCONV1E=8) satisfied	0.7	1.95	0.038		Algorithm converged	-0.080	0.166	0.07		Algorithm converged	0.85	0.35	0.56		0.03		Algorithm converged	0.74	0.18
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	3	118	15.1	18	10.6	13	16.4	1	0.2	0.23		Convergence criterion (GCONV1E=8) satisfied	0.63	0.39	0.185		Algorithm converged	0.084	0.287	0.55		Algorithm converged	0.85	0.47	0.0011		0.39		Algorithm converged	0.22	0.63
METABOLISM AND NUTRITION DISORDERS	ALL	3	118	15.1	10	9.5	13	16.4	1	0.3	10.74		Convergence criterion (GCONV1E=8) satisfied	0.35	85.31	0.076		Algorithm converged	0.023	0.129	0.92		Algorithm converged	0.29	76.23	0.0275		0.1		Algorithm converged	0.01	0.78
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	3	118	15.1	10	16.9	13	16.4	0	0.8	0.78		Convergence criterion (GCONV1E=8) satisfied	0.17	0.8	0.101		Algorithm converged	0.019	0.183	0.48		Algorithm converged	0.14	0.4	0.0224		0.4		Algorithm converged	0.19	0.88
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	3	118	15.1	11	8.8	13	16.4	1	0.8	0.39		Convergence criterion (GCONV1E=8) satisfied	0.32	12.04	0.211		Algorithm converged	0.118	0.304	0.09		Algorithm converged	0.97	0.48	0.0002		0.24		Algorithm converged	0.12	0.51

Test for interaction based on RR (Log-Binomial regression)
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 100T2017

Program: root/clinical studies/R05072759/CDPT7159/BO21004/data analysis/ACE CSRFinal
 Output: root/clinical studies/R05072759/CDPT7159/BO21004/data analysis/ACE CSRFinal/
 08OCT2019 11:05

46 (Anhang): Ergebnisse für Abbruchgründe (UE) nach SOC aus RCT mit dem zu bewertenden Arzneimittel

POPULATION: Safety Evaluable Patients

ENDPOINT: AEs leading to treatment discontinuation MODEL:

Unstratified Analysis

STUDY: CLL11(BO21004), Final

Dichotomous Analysis by Subgroups (Safety)

		GC1b (N=336)	RC1b (N=321)
MedDRA System Organ Class	MedDRA Preferred Term	Patients with events n (%)	Patients with events n (%) ²
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	25 (7,4)	3 (0,9)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ALL	23 (6,8)	25 (7,8)
INFECTIONS AND INFESTATIONS	ALL	3 (0,9)	6 (1,9)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	ALL	3 (0,9)	4 (1,2)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	ALL	3 (0,9)	1 (0,3)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ALL	3 (0,9)	3 (0,9)
GASTROINTESTINAL DISORDERS	ALL	2 (0,6)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ALL	2 (0,6)	1 (0,3)
INVESTIGATIONS	ALL	2 (0,6)	1 (0,3)
NERVOUS SYSTEM DISORDERS	ALL	2 (0,6)	2 (0,6)
HEPATOBIILIARY DISORDERS	ALL	1 (0,3)	1 (0,3)
IMMUNE SYSTEM DISORDERS	ALL	1 (0,3)	1 (0,3)
METABOLISM AND NUTRITION DISORDERS	ALL	1 (0,3)	0 (0,0)
PSYCHIATRIC DISORDERS	ALL	1 (0,3)	1 (0,3)
RENAL AND URINARY DISORDERS	ALL	0 (0,0)	1 (0,3)

47 (Anhang): Ergebnisse für Abbruchgründe (UE) nach SOC/PT aus RCT mit dem zu bewertenden Arzneimittel

POPULATION: Safety Evaluable Patients

ENDPOINT: AEs leading to treatment discontinuation

MODEL: Unstratified Analysis

STUDY: CLL11(BO21004), Final

Dichotomous Analysis by Subgroups (Safety)

		GC1b (N=336)	RC1b (N=321)
MedDRA System Organ Class	MedDRA Preferred Term	Patients with events n (%)	Patients with events n (%) ²
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	25 (7,4)	3 (0,9)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	15 (4,5)	19 (5,9)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	4 (1,2)	3 (0,9)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	2 (0,6)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	2 (0,6)	1 (0,3)
INFECTIONS AND INFESTATIONS	PNEUMONIA	2 (0,6)	3 (0,9)
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	2 (0,6)	1 (0,3)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	IMMUNE THROMBOCYTOPENIC PURPURA	1 (0,3)	0 (0,0)
GASTROINTESTINAL DISORDERS	ENTEROCOLITIS	1 (0,3)	0 (0,0)
GASTROINTESTINAL DISORDERS	PANCREATITIS ACUTE	1 (0,3)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PERFORMANCE STATUS DECREASED	1 (0,3)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	1 (0,3)	0 (0,0)
HEPATOBIILIARY DISORDERS	HYPERTRANSAMINASAEMIA	1 (0,3)	0 (0,0)
IMMUNE SYSTEM DISORDERS	ANAPHYLACTIC REACTION	1 (0,3)	0 (0,0)
INFECTIONS AND INFESTATIONS	PULMONARY SEPSIS	1 (0,3)	0 (0,0)
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	1 (0,3)	0 (0,0)
METABOLISM AND NUTRITION DISORDERS	TUMOUR LYSIS SYNDROME	1 (0,3)	0 (0,0)

NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	COLON CANCER	1 (0,3)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	PLASMA CELL MYELOMA	1 (0,3)	0 (0,0)

NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	SQUAMOUS CELL CARCINOMA OF LUNG	1 (0,3)	0 (0,0)
NERVOUS SYSTEM DISORDERS	CENTRAL NERVOUS SYSTEM HAEMORRHAGE	1 (0,3)	0 (0,0)
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	1 (0,3)	0 (0,0)
PSYCHIATRIC DISORDERS	DELIRIUM	1 (0,3)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	1 (0,3)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PNEUMONITIS	1 (0,3)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY ALVEOLAR HAEMORRHAGE	1 (0,3)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DERMATITIS ALLERGIC	1 (0,3)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	1 (0,3)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH MACULO-PAPULAR	1 (0,3)	1 (0,3)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	CYTOPENIA	0 (0,0)	1 (0,3)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	0 (0,0)	1 (0,3)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	0 (0,0)	1 (0,3)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ASTHENIA	0 (0,0)	1 (0,3)
HEPATOBIILIARY DISORDERS	HEPATOCELLULAR INJURY	0 (0,0)	1 (0,3)
IMMUNE SYSTEM DISORDERS	HYPERSENSITIVITY	0 (0,0)	1 (0,3)
INFECTIONS AND INFESTATIONS	BRONCHITIS	0 (0,0)	2 (0,6)
INFECTIONS AND INFESTATIONS	HERPES SIMPLEX	0 (0,0)	1 (0,3)
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	0 (0,0)	1 (0,3)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	ADENOCARCINOMA	0 (0,0)	1 (0,3)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	LUNG NEOPLASM MALIGNANT	0 (0,0)	1 (0,3)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	METASTATIC SQUAMOUS CELL CARCINOMA	0 (0,0)	1 (0,3)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	OROPHARYNGEAL CANCER	0 (0,0)	1 (0,3)
NERVOUS SYSTEM DISORDERS	DEPRESSED LEVEL OF CONSCIOUSNESS	0 (0,0)	1 (0,3)
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	0 (0,0)	1 (0,3)
PSYCHIATRIC DISORDERS	MANIA	0 (0,0)	1 (0,3)
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	0 (0,0)	1 (0,3)

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	0 (0,0)	1 (0,3)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRUG ERUPTION	0 (0,0)	1 (0,3)

SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	0 (0,0)	1 (0,3)
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48 (Anhang): Ergebnisse für Abbruchgründe (UE) nach SOC/PT nach Subgruppen aus RCT mit dem zu bewertenden Arzneimittel

POPULATION: Safety Evaluable Patients
 ENDPOINT: AEs leading to treatment discontinuation
 MODEL: Unstratified Analysis
 STUDY: CLL11(BO21004), Final
 Dichotomous Analysis by Subgroups (Safety)

				GClb (N=336)	RClb (N=321)
MedDRA System Organ Class	MedDRA Preferred Term	Level		Patients with events n (%)	Patients with events n (%) ²
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ALL	Female	sex	13 (9,9)	11 (9,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ALL	Male	sex	10 (4,9)	14 (7,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Female	sex	0 (0,0)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Male	sex	2 (1,0)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	CYTOPENIA	Female	sex	0 (0,0)	1 (0,8)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	CYTOPENIA	Male	sex	0 (0,0)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	IMMUNE THROMBOCYTOPENIC PURPURA	Female	sex	1 (0,8)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	IMMUNE THROMBOCYTOPENIC PURPURA	Male	sex	0 (0,0)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Female	sex	0 (0,0)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Male	sex	2 (1,0)	1 (0,5)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	Female	sex	0 (0,0)	1 (0,8)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	Male	sex	0 (0,0)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Female	sex	11 (8,4)	8 (6,6)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Male	sex	4 (2,0)	11 (5,5)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	Female	sex	0 (0,0)	0 (0,0)

BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	Male	sex	0 (0,0)	1 (0,5)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Female	sex	2 (1,5)	1 (0,8)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Male	sex	2 (1,0)	2 (1,0)
GASTROINTESTINAL DISORDERS	ALL	Female	sex	1 (0,8)	0 (0,0)
GASTROINTESTINAL DISORDERS	ALL	Male	sex	1 (0,5)	0 (0,0)
GASTROINTESTINAL DISORDERS	ENTEROCOLITIS	Female	sex	1 (0,8)	0 (0,0)
GASTROINTESTINAL DISORDERS	ENTEROCOLITIS	Male	sex	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	PANCREATITIS ACUTE	Female	sex	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	PANCREATITIS ACUTE	Male	sex	1 (0,5)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ALL	Female	sex	1 (0,8)	1 (0,8)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ALL	Male	sex	1 (0,5)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ASTHENIA	Female	sex	0 (0,0)	1 (0,8)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ASTHENIA	Male	sex	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PERFORMANCE STATUS DECREASED	Female	sex	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PERFORMANCE STATUS DECREASED	Male	sex	1 (0,5)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	Female	sex	1 (0,8)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	Male	sex	0 (0,0)	0 (0,0)
HEPATOBIILIARY DISORDERS	ALL	Female	sex	1 (0,8)	1 (0,8)
HEPATOBIILIARY DISORDERS	ALL	Male	sex	0 (0,0)	0 (0,0)
HEPATOBIILIARY DISORDERS	HEPATOCELLULAR INJURY	Female	sex	0 (0,0)	1 (0,8)
HEPATOBIILIARY DISORDERS	HEPATOCELLULAR INJURY	Male	sex	0 (0,0)	0 (0,0)
HEPATOBIILIARY DISORDERS	HYPERTRANSAMINASAEMIA	Female	sex	1 (0,8)	0 (0,0)
HEPATOBIILIARY DISORDERS	HYPERTRANSAMINASAEMIA	Male	sex	0 (0,0)	0 (0,0)
IMMUNE SYSTEM DISORDERS	ALL	Female	sex	0 (0,0)	1 (0,8)
IMMUNE SYSTEM DISORDERS	ALL	Male	sex	1 (0,5)	0 (0,0)
IMMUNE SYSTEM DISORDERS	ANAPHYLACTIC REACTION	Female	sex	0 (0,0)	0 (0,0)
IMMUNE SYSTEM DISORDERS	ANAPHYLACTIC REACTION	Male	sex	1 (0,5)	0 (0,0)

IMMUNE SYSTEM DISORDERS	HYPERSENSITIVITY	Female	sex	0 (0,0)	1 (0,8)
IMMUNE SYSTEM DISORDERS	HYPERSENSITIVITY	Male	sex	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	ALL	Female	sex	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	ALL	Male	sex	3 (1,5)	6 (3,0)
INFECTIONS AND INFESTATIONS	BRONCHITIS	Female	sex	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	BRONCHITIS	Male	sex	0 (0,0)	2 (1,0)
INFECTIONS AND INFESTATIONS	HERPES SIMPLEX	Female	sex	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	HERPES SIMPLEX	Male	sex	0 (0,0)	1 (0,5)
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	Female	sex	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	Male	sex	0 (0,0)	1 (0,5)
INFECTIONS AND INFESTATIONS	PNEUMONIA	Female	sex	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	PNEUMONIA	Male	sex	2 (1,0)	3 (1,5)
INFECTIONS AND INFESTATIONS	PULMONARY SEPSIS	Female	sex	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	PULMONARY SEPSIS	Male	sex	1 (0,5)	0 (0,0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	Female	sex	10 (7,6)	2 (1,6)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	Male	sex	15 (7,3)	1 (0,5)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	Female	sex	10 (7,6)	2 (1,6)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	Male	sex	15 (7,3)	1 (0,5)
INVESTIGATIONS	ALL	Female	sex	0 (0,0)	1 (0,8)
INVESTIGATIONS	ALL	Male	sex	2 (1,0)	0 (0,0)
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Female	sex	0 (0,0)	0 (0,0)
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Male	sex	1 (0,5)	0 (0,0)
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Female	sex	0 (0,0)	1 (0,8)
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Male	sex	2 (1,0)	0 (0,0)
METABOLISM AND NUTRITION DISORDERS	ALL	Female	sex	0 (0,0)	0 (0,0)
METABOLISM AND NUTRITION DISORDERS	ALL	Male	sex	1 (0,5)	0 (0,0)
METABOLISM AND NUTRITION DISORDERS	TUMOUR LYSIS SYNDROME	Female	sex	0 (0,0)	0 (0,0)
METABOLISM AND NUTRITION DISORDERS	TUMOUR LYSIS SYNDROME	Male	sex	1 (0,5)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	ALL	Female	sex	1 (0,8)	0 (0,0)

NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	ALL	Male	sex	2 (1,0)	4 (2,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	ADENOCARCINOMA	Female	sex	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	ADENOCARCINOMA	Male	sex	0 (0,0)	1 (0,5)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	COLON CANCER	Female	sex	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	COLON CANCER	Male	sex	1 (0,5)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	LUNG NEOPLASM MALIGNANT	Female	sex	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	LUNG NEOPLASM MALIGNANT	Male	sex	0 (0,0)	1 (0,5)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	METASTATIC SQUAMOUS CELL CARCINOMA	Female	sex	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	METASTATIC SQUAMOUS CELL CARCINOMA	Male	sex	0 (0,0)	1 (0,5)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	OROPHARYNGEAL CANCER	Female	sex	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	OROPHARYNGEAL CANCER	Male	sex	0 (0,0)	1 (0,5)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	PLASMA CELL MYELOMA	Female	sex	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	PLASMA CELL MYELOMA	Male	sex	1 (0,5)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	SQUAMOUS CELL CARCINOMA OF LUNG	Female	sex	1 (0,8)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	SQUAMOUS CELL CARCINOMA OF LUNG	Male	sex	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	ALL	Female	sex	1 (0,8)	1 (0,8)
NERVOUS SYSTEM DISORDERS	ALL	Male	sex	1 (0,5)	1 (0,5)
NERVOUS SYSTEM DISORDERS	CENTRAL NERVOUS SYSTEM HAEMORRHAGE	Female	sex	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	CENTRAL NERVOUS SYSTEM HAEMORRHAGE	Male	sex	1 (0,5)	0 (0,0)
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	Female	sex	1 (0,8)	0 (0,0)

NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	Male	sex	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	DEPRESSED LEVEL OF CONSCIOUSNESS	Female	sex	0 (0,0)	1 (0,8)
NERVOUS SYSTEM DISORDERS	DEPRESSED LEVEL OF CONSCIOUSNESS	Male	sex	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	Female	sex	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	Male	sex	0 (0,0)	1 (0,5)
PSYCHIATRIC DISORDERS	ALL	Female	sex	1 (0,8)	0 (0,0)
PSYCHIATRIC DISORDERS	ALL	Male	sex	0 (0,0)	1 (0,5)
PSYCHIATRIC DISORDERS	DELIRIUM	Female	sex	1 (0,8)	0 (0,0)
PSYCHIATRIC DISORDERS	DELIRIUM	Male	sex	0 (0,0)	0 (0,0)
PSYCHIATRIC DISORDERS	MANIA	Female	sex	0 (0,0)	0 (0,0)
PSYCHIATRIC DISORDERS	MANIA	Male	sex	0 (0,0)	1 (0,5)
RENAL AND URINARY DISORDERS	ALL	Female	sex	0 (0,0)	1 (0,8)
RENAL AND URINARY DISORDERS	ALL	Male	sex	0 (0,0)	0 (0,0)
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	Female	sex	0 (0,0)	1 (0,8)
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	Male	sex	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	ALL	Female	sex	2 (1,5)	1 (0,8)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	ALL	Male	sex	1 (0,5)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	Female	sex	0 (0,0)	1 (0,8)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	Male	sex	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	Female	sex	1 (0,8)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	Male	sex	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PNEUMONITIS	Female	sex	1 (0,8)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PNEUMONITIS	Male	sex	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY ALVEOLAR HAEMORRHAGE	Female	sex	0 (0,0)	0 (0,0)

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY ALVEOLAR HAEMORRHAGE	Male	sex	1 (0,5)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ALL	Female	sex	1 (0,8)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ALL	Male	sex	2 (1,0)	3 (1,5)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DERMATITIS ALLERGIC	Female	sex	0 (0,0)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DERMATITIS ALLERGIC	Male	sex	1 (0,5)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRUG ERUPTION	Female	sex	0 (0,0)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRUG ERUPTION	Male	sex	0 (0,0)	1 (0,5)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	Female	sex	1 (0,8)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	Male	sex	0 (0,0)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	Female	sex	0 (0,0)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	Male	sex	0 (0,0)	1 (0,5)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH MACULO-PAPULAR	Female	sex	0 (0,0)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH MACULO-PAPULAR	Male	sex	1 (0,5)	1 (0,5)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ALL	<75 years	agecat3	9 (5,0)	11 (5,9)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ALL	>=75 years	agecat3	14 (9,0)	14 (10,4)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	<75 years	agecat3	0 (0,0)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	>=75 years	agecat3	2 (1,3)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	CYTOPENIA	<75 years	agecat3	0 (0,0)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	CYTOPENIA	>=75 years	agecat3	0 (0,0)	1 (0,7)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	IMMUNE THROMBOCYTOPENIC PURPURA	<75 years	agecat3	1 (0,6)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	IMMUNE THROMBOCYTOPENIC PURPURA	>=75 years	agecat3	0 (0,0)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	<75 years	agecat3	1 (0,6)	1 (0,5)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	>=75 years	agecat3	1 (0,6)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	<75 years	agecat3	0 (0,0)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	>=75 years	agecat3	0 (0,0)	1 (0,7)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	<75 years	agecat3	6 (3,3)	9 (4,8)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	>=75 years	agecat3	9 (5,8)	10 (7,5)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	<75 years	agecat3	0 (0,0)	1 (0,5)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	>=75 years	agecat3	0 (0,0)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	<75 years	agecat3	1 (0,6)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	>=75 years	agecat3	3 (1,9)	3 (2,2)

GASTROINTESTINAL DISORDERS	ALL	<75 years	agecat3	1 (0,6)	0 (0,0)
GASTROINTESTINAL DISORDERS	ALL	>=75 years	agecat3	1 (0,6)	0 (0,0)
GASTROINTESTINAL DISORDERS	ENTEROCOLITIS	<75 years	agecat3	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	ENTEROCOLITIS	>=75 years	agecat3	1 (0,6)	0 (0,0)
GASTROINTESTINAL DISORDERS	PANCREATITIS ACUTE	<75 years	agecat3	1 (0,6)	0 (0,0)
GASTROINTESTINAL DISORDERS	PANCREATITIS ACUTE	>=75 years	agecat3	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ALL	<75 years	agecat3	1 (0,6)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ALL	>=75 years	agecat3	1 (0,6)	1 (0,7)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ASTHENIA	<75 years	agecat3	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ASTHENIA	>=75 years	agecat3	0 (0,0)	1 (0,7)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PERFORMANCE STATUS DECREASED	<75 years	agecat3	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PERFORMANCE STATUS DECREASED	>=75 years	agecat3	1 (0,6)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	<75 years	agecat3	1 (0,6)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	>=75 years	agecat3	0 (0,0)	0 (0,0)
HEPATOBIILIARY DISORDERS	ALL	<75 years	agecat3	1 (0,6)	0 (0,0)
HEPATOBIILIARY DISORDERS	ALL	>=75 years	agecat3	0 (0,0)	1 (0,7)
HEPATOBIILIARY DISORDERS	HEPATOCELLULAR INJURY	<75 years	agecat3	0 (0,0)	0 (0,0)
HEPATOBIILIARY DISORDERS	HEPATOCELLULAR INJURY	>=75 years	agecat3	0 (0,0)	1 (0,7)
HEPATOBIILIARY DISORDERS	HYPERTRANSAMINASAEMIA	<75 years	agecat3	1 (0,6)	0 (0,0)
HEPATOBIILIARY DISORDERS	HYPERTRANSAMINASAEMIA	>=75 years	agecat3	0 (0,0)	0 (0,0)
IMMUNE SYSTEM DISORDERS	ALL	<75 years	agecat3	1 (0,6)	0 (0,0)
IMMUNE SYSTEM DISORDERS	ALL	>=75 years	agecat3	0 (0,0)	1 (0,7)
IMMUNE SYSTEM DISORDERS	ANAPHYLACTIC REACTION	<75 years	agecat3	1 (0,6)	0 (0,0)
IMMUNE SYSTEM DISORDERS	ANAPHYLACTIC REACTION	>=75 years	agecat3	0 (0,0)	0 (0,0)
IMMUNE SYSTEM DISORDERS	HYPERSENSITIVITY	<75 years	agecat3	0 (0,0)	0 (0,0)
IMMUNE SYSTEM DISORDERS	HYPERSENSITIVITY	>=75 years	agecat3	0 (0,0)	1 (0,7)
INFECTIIONS AND INFESTATIONS	ALL	<75 years	agecat3	0 (0,0)	5 (2,7)

INFECTIONS AND INFESTATIONS	ALL	>=75 years	agecat3	3 (1,9)	1 (0,7)
INFECTIONS AND INFESTATIONS	BRONCHITIS	<75 years	agecat3	0 (0,0)	1 (0,5)
INFECTIONS AND INFESTATIONS	BRONCHITIS	>=75 years	agecat3	0 (0,0)	1 (0,7)
INFECTIONS AND INFESTATIONS	HERPES SIMPLEX	<75 years	agecat3	0 (0,0)	1 (0,5)
INFECTIONS AND INFESTATIONS	HERPES SIMPLEX	>=75 years	agecat3	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	<75 years	agecat3	0 (0,0)	1 (0,5)
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	>=75 years	agecat3	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	PNEUMONIA	<75 years	agecat3	0 (0,0)	3 (1,6)
INFECTIONS AND INFESTATIONS	PNEUMONIA	>=75 years	agecat3	2 (1,3)	0 (0,0)
INFECTIONS AND INFESTATIONS	PULMONARY SEPSIS	<75 years	agecat3	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	PULMONARY SEPSIS	>=75 years	agecat3	1 (0,6)	0 (0,0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	<75 years	agecat3	13 (7,2)	1 (0,5)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	>=75 years	agecat3	12 (7,7)	2 (1,5)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	<75 years	agecat3	13 (7,2)	1 (0,5)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	>=75 years	agecat3	12 (7,7)	2 (1,5)
INVESTIGATIONS	ALL	<75 years	agecat3	1 (0,6)	0 (0,0)
INVESTIGATIONS	ALL	>=75 years	agecat3	1 (0,6)	1 (0,7)
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	<75 years	agecat3	1 (0,6)	0 (0,0)
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	>=75 years	agecat3	0 (0,0)	0 (0,0)
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	<75 years	agecat3	1 (0,6)	0 (0,0)
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	>=75 years	agecat3	1 (0,6)	1 (0,7)
METABOLISM AND NUTRITION DISORDERS	ALL	<75 years	agecat3	1 (0,6)	0 (0,0)
METABOLISM AND NUTRITION DISORDERS	ALL	>=75 years	agecat3	0 (0,0)	0 (0,0)
METABOLISM AND NUTRITION DISORDERS	TUMOUR LYSIS SYNDROME	<75 years	agecat3	1 (0,6)	0 (0,0)
METABOLISM AND NUTRITION DISORDERS	TUMOUR LYSIS SYNDROME	>=75 years	agecat3	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	ALL	<75 years	agecat3	1 (0,6)	2 (1,1)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	ALL	>=75 years	agecat3	2 (1,3)	2 (1,5)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	ADENOCARCINOMA	<75 years	agecat3	0 (0,0)	0 (0,0)

NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	ADENOCARCINOMA	>=75 years	agecat3	0 (0,0)	1 (0,7)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	COLON CANCER	<75 years	agecat3	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	COLON CANCER	>=75 years	agecat3	1 (0,6)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	LUNG NEOPLASM MALIGNANT	<75 years	agecat3	0 (0,0)	1 (0,5)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	LUNG NEOPLASM MALIGNANT	>=75 years	agecat3	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	METASTATIC SQUAMOUS CELL CARCINOMA	<75 years	agecat3	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	METASTATIC SQUAMOUS CELL CARCINOMA	>=75 years	agecat3	0 (0,0)	1 (0,7)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	OROPHARYNGEAL CANCER	<75 years	agecat3	0 (0,0)	1 (0,5)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	OROPHARYNGEAL CANCER	>=75 years	agecat3	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	PLASMA CELL MYELOMA	<75 years	agecat3	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	PLASMA CELL MYELOMA	>=75 years	agecat3	1 (0,6)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	SQUAMOUS CELL CARCINOMA OF LUNG	<75 years	agecat3	1 (0,6)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	SQUAMOUS CELL CARCINOMA OF LUNG	>=75 years	agecat3	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	ALL	<75 years	agecat3	1 (0,6)	2 (1,1)
NERVOUS SYSTEM DISORDERS	ALL	>=75 years	agecat3	1 (0,6)	0 (0,0)
NERVOUS SYSTEM DISORDERS	CENTRAL NERVOUS SYSTEM HAEMORRHAGE	<75 years	agecat3	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	CENTRAL NERVOUS SYSTEM HAEMORRHAGE	>=75 years	agecat3	1 (0,6)	0 (0,0)
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	<75 years	agecat3	1 (0,6)	0 (0,0)
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	>=75 years	agecat3	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	DEPRESSED LEVEL OF CONSCIOUSNESS	<75 years	agecat3	0 (0,0)	1 (0,5)

NERVOUS SYSTEM DISORDERS	DEPRESSED LEVEL OF CONSCIOUSNESS	>=75 years	agecat3	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	<75 years	agecat3	0 (0,0)	1 (0,5)
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	>=75 years	agecat3	0 (0,0)	0 (0,0)
PSYCHIATRIC DISORDERS	ALL	<75 years	agecat3	0 (0,0)	1 (0,5)
PSYCHIATRIC DISORDERS	ALL	>=75 years	agecat3	1 (0,6)	0 (0,0)
PSYCHIATRIC DISORDERS	DELIRIUM	<75 years	agecat3	0 (0,0)	0 (0,0)
PSYCHIATRIC DISORDERS	DELIRIUM	>=75 years	agecat3	1 (0,6)	0 (0,0)
PSYCHIATRIC DISORDERS	MANIA	<75 years	agecat3	0 (0,0)	1 (0,5)
PSYCHIATRIC DISORDERS	MANIA	>=75 years	agecat3	0 (0,0)	0 (0,0)
RENAL AND URINARY DISORDERS	ALL	<75 years	agecat3	0 (0,0)	0 (0,0)
RENAL AND URINARY DISORDERS	ALL	>=75 years	agecat3	0 (0,0)	1 (0,7)
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	<75 years	agecat3	0 (0,0)	0 (0,0)
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	>=75 years	agecat3	0 (0,0)	1 (0,7)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	ALL	<75 years	agecat3	1 (0,6)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	ALL	>=75 years	agecat3	2 (1,3)	1 (0,7)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	<75 years	agecat3	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	>=75 years	agecat3	0 (0,0)	1 (0,7)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	<75 years	agecat3	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	>=75 years	agecat3	1 (0,6)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PNEUMONITIS	<75 years	agecat3	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PNEUMONITIS	>=75 years	agecat3	1 (0,6)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY ALVEOLAR HAEMORRHAGE	<75 years	agecat3	1 (0,6)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY ALVEOLAR HAEMORRHAGE	>=75 years	agecat3	0 (0,0)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ALL	<75 years	agecat3	2 (1,1)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ALL	>=75 years	agecat3	1 (0,6)	3 (2,2)

SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DERMATITIS ALLERGIC	<75 years	agecat3	1 (0,6)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DERMATITIS ALLERGIC	>=75 years	agecat3	0 (0,0)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRUG ERUPTION	<75 years	agecat3	0 (0,0)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRUG ERUPTION	>=75 years	agecat3	0 (0,0)	1 (0,7)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	<75 years	agecat3	0 (0,0)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	>=75 years	agecat3	1 (0,6)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	<75 years	agecat3	0 (0,0)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	>=75 years	agecat3	0 (0,0)	1 (0,7)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH MACULO-PAPULAR	<75 years	agecat3	1 (0,6)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH MACULO-PAPULAR	>=75 years	agecat3	0 (0,0)	1 (0,7)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ALL	Asia-Pacific	reg1	2 (8,7)	1 (4,5)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ALL	Central and South America	reg1	1 (9,1)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ALL	North America	reg1	1 (6,3)	1 (7,7)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ALL	Other	reg1	3 (3,8)	2 (2,3)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ALL	Western Europe	reg1	16 (7,7)	21 (10,9)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Asia-Pacific	reg1	1 (4,3)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Central and South America	reg1	0 (0,0)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	North America	reg1	0 (0,0)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Other	reg1	0 (0,0)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Western Europe	reg1	1 (0,5)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	CYTOPENIA	Asia-Pacific	reg1	0 (0,0)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	CYTOPENIA	Central and South America	reg1	0 (0,0)	0 (0,0)

BLOOD AND LYMPHATIC SYSTEM DISORDERS	CYTOPENIA	North America	reg1	0 (0,0)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	CYTOPENIA	Other	reg1	0 (0,0)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	CYTOPENIA	Western Europe	reg1	0 (0,0)	1 (0,5)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	IMMUNE THROMBOCYTOPENIC PURPURA	Asia-Pacific	reg1	0 (0,0)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	IMMUNE THROMBOCYTOPENIC PURPURA	Central and South America	reg1	0 (0,0)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	IMMUNE THROMBOCYTOPENIC PURPURA	North America	reg1	0 (0,0)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	IMMUNE THROMBOCYTOPENIC PURPURA	Other	reg1	0 (0,0)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	IMMUNE THROMBOCYTOPENIC PURPURA	Western Europe	reg1	1 (0,5)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Asia-Pacific	reg1	0 (0,0)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Central and South America	reg1	0 (0,0)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	North America	reg1	0 (0,0)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Other	reg1	0 (0,0)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Western Europe	reg1	2 (1,0)	1 (0,5)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	Asia-Pacific	reg1	0 (0,0)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	Central and South America	reg1	0 (0,0)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	North America	reg1	0 (0,0)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	Other	reg1	0 (0,0)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	Western Europe	reg1	0 (0,0)	1 (0,5)

BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Asia-Pacific	reg1	0 (0,0)	1 (4,5)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Central and South America	reg1	1 (9,1)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	North America	reg1	0 (0,0)	1 (7,7)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Other	reg1	3 (3,8)	2 (2,3)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Western Europe	reg1	11 (5,3)	15 (7,8)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	Asia-Pacific	reg1	0 (0,0)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	Central and South America	reg1	0 (0,0)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	North America	reg1	0 (0,0)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	Other	reg1	0 (0,0)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	Western Europe	reg1	0 (0,0)	1 (0,5)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Asia-Pacific	reg1	1 (4,3)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Central and South America	reg1	0 (0,0)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	North America	reg1	1 (6,3)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Other	reg1	1 (1,3)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Western Europe	reg1	1 (0,5)	3 (1,6)
GASTROINTESTINAL DISORDERS	ALL	Asia-Pacific	reg1	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	ALL	Central and South America	reg1	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	ALL	North America	reg1	0 (0,0)	0 (0,0)

GASTROINTESTINAL DISORDERS	ALL	Other	reg1	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	ALL	Western Europe	reg1	2 (1,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	ENTEROCOLITIS	Asia-Pacific	reg1	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	ENTEROCOLITIS	Central and South America	reg1	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	ENTEROCOLITIS	North America	reg1	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	ENTEROCOLITIS	Other	reg1	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	ENTEROCOLITIS	Western Europe	reg1	1 (0,5)	0 (0,0)
GASTROINTESTINAL DISORDERS	PANCREATITIS ACUTE	Asia-Pacific	reg1	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	PANCREATITIS ACUTE	Central and South America	reg1	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	PANCREATITIS ACUTE	North America	reg1	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	PANCREATITIS ACUTE	Other	reg1	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	PANCREATITIS ACUTE	Western Europe	reg1	1 (0,5)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ALL	Asia-Pacific	reg1	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ALL	Central and South America	reg1	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ALL	North America	reg1	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ALL	Other	reg1	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ALL	Western Europe	reg1	2 (1,0)	1 (0,5)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ASTHENIA	Asia-Pacific	reg1	0 (0,0)	0 (0,0)

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ASTHENIA	Central and South America	reg1	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ASTHENIA	North America	reg1	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ASTHENIA	Other	reg1	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ASTHENIA	Western Europe	reg1	0 (0,0)	1 (0,5)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PERFORMANCE STATUS DECREASED	Asia-Pacific	reg1	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PERFORMANCE STATUS DECREASED	Central and South America	reg1	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PERFORMANCE STATUS DECREASED	North America	reg1	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PERFORMANCE STATUS DECREASED	Other	reg1	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PERFORMANCE STATUS DECREASED	Western Europe	reg1	1 (0,5)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	Asia-Pacific	reg1	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	Central and South America	reg1	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	North America	reg1	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	Other	reg1	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	Western Europe	reg1	1 (0,5)	0 (0,0)
HEPATOBIILIARY DISORDERS	ALL	Asia-Pacific	reg1	0 (0,0)	0 (0,0)
HEPATOBIILIARY DISORDERS	ALL	Central and South America	reg1	0 (0,0)	0 (0,0)

HEPATOBIILIARY DISORDERS	ALL	North America	reg1	0 (0,0)	0 (0,0)
HEPATOBIILIARY DISORDERS	ALL	Other	reg1	1 (1,3)	0 (0,0)
HEPATOBIILIARY DISORDERS	ALL	Western Europe	reg1	0 (0,0)	1 (0,5)
HEPATOBIILIARY DISORDERS	HEPATOCELLULAR INJURY	Asia-Pacific	reg1	0 (0,0)	0 (0,0)
HEPATOBIILIARY DISORDERS	HEPATOCELLULAR INJURY	Central and South America	reg1	0 (0,0)	0 (0,0)
HEPATOBIILIARY DISORDERS	HEPATOCELLULAR INJURY	North America	reg1	0 (0,0)	0 (0,0)
HEPATOBIILIARY DISORDERS	HEPATOCELLULAR INJURY	Other	reg1	0 (0,0)	0 (0,0)
HEPATOBIILIARY DISORDERS	HEPATOCELLULAR INJURY	Western Europe	reg1	0 (0,0)	1 (0,5)
HEPATOBIILIARY DISORDERS	HYPERTRANSAMINASAEMIA	Asia-Pacific	reg1	0 (0,0)	0 (0,0)
HEPATOBIILIARY DISORDERS	HYPERTRANSAMINASAEMIA	Central and South America	reg1	0 (0,0)	0 (0,0)
HEPATOBIILIARY DISORDERS	HYPERTRANSAMINASAEMIA	North America	reg1	0 (0,0)	0 (0,0)
HEPATOBIILIARY DISORDERS	HYPERTRANSAMINASAEMIA	Other	reg1	1 (1,3)	0 (0,0)
HEPATOBIILIARY DISORDERS	HYPERTRANSAMINASAEMIA	Western Europe	reg1	0 (0,0)	0 (0,0)
IMMUNE SYSTEM DISORDERS	ALL	Asia-Pacific	reg1	0 (0,0)	0 (0,0)
IMMUNE SYSTEM DISORDERS	ALL	Central and South America	reg1	0 (0,0)	0 (0,0)
IMMUNE SYSTEM DISORDERS	ALL	North America	reg1	0 (0,0)	0 (0,0)
IMMUNE SYSTEM DISORDERS	ALL	Other	reg1	0 (0,0)	1 (1,1)
IMMUNE SYSTEM DISORDERS	ALL	Western Europe	reg1	1 (0,5)	0 (0,0)
IMMUNE SYSTEM DISORDERS	ANAPHYLACTIC REACTION	Asia-Pacific	reg1	0 (0,0)	0 (0,0)

IMMUNE SYSTEM DISORDERS	ANAPHYLACTIC REACTION	Central and South America	reg1	0 (0,0)	0 (0,0)
IMMUNE SYSTEM DISORDERS	ANAPHYLACTIC REACTION	North America	reg1	0 (0,0)	0 (0,0)
IMMUNE SYSTEM DISORDERS	ANAPHYLACTIC REACTION	Other	reg1	0 (0,0)	0 (0,0)
IMMUNE SYSTEM DISORDERS	ANAPHYLACTIC REACTION	Western Europe	reg1	1 (0,5)	0 (0,0)
IMMUNE SYSTEM DISORDERS	HYPERSENSITIVITY	Asia-Pacific	reg1	0 (0,0)	0 (0,0)
IMMUNE SYSTEM DISORDERS	HYPERSENSITIVITY	Central and South America	reg1	0 (0,0)	0 (0,0)
IMMUNE SYSTEM DISORDERS	HYPERSENSITIVITY	North America	reg1	0 (0,0)	0 (0,0)
IMMUNE SYSTEM DISORDERS	HYPERSENSITIVITY	Other	reg1	0 (0,0)	1 (1,1)
IMMUNE SYSTEM DISORDERS	HYPERSENSITIVITY	Western Europe	reg1	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	ALL	Asia-Pacific	reg1	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	ALL	Central and South America	reg1	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	ALL	North America	reg1	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	ALL	Other	reg1	0 (0,0)	1 (1,1)
INFECTIONS AND INFESTATIONS	ALL	Western Europe	reg1	3 (1,4)	5 (2,6)
INFECTIONS AND INFESTATIONS	BRONCHITIS	Asia-Pacific	reg1	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	BRONCHITIS	Central and South America	reg1	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	BRONCHITIS	North America	reg1	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	BRONCHITIS	Other	reg1	0 (0,0)	0 (0,0)

INFECTIONS AND INFESTATIONS	BRONCHITIS	Western Europe	reg1	0 (0,0)	2 (1,0)
INFECTIONS AND INFESTATIONS	HERPES SIMPLEX	Asia-Pacific	reg1	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	HERPES SIMPLEX	Central and South America	reg1	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	HERPES SIMPLEX	North America	reg1	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	HERPES SIMPLEX	Other	reg1	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	HERPES SIMPLEX	Western Europe	reg1	0 (0,0)	1 (0,5)
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	Asia-Pacific	reg1	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	Central and South America	reg1	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	North America	reg1	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	Other	reg1	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	Western Europe	reg1	0 (0,0)	1 (0,5)
INFECTIONS AND INFESTATIONS	PNEUMONIA	Asia-Pacific	reg1	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	PNEUMONIA	Central and South America	reg1	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	PNEUMONIA	North America	reg1	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	PNEUMONIA	Other	reg1	0 (0,0)	1 (1,1)
INFECTIONS AND INFESTATIONS	PNEUMONIA	Western Europe	reg1	2 (1,0)	2 (1,0)
INFECTIONS AND INFESTATIONS	PULMONARY SEPSIS	Asia-Pacific	reg1	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	PULMONARY SEPSIS	Central and South America	reg1	0 (0,0)	0 (0,0)

INFECTIONS AND INFESTATIONS	PULMONARY SEPSIS	North America	reg1	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	PULMONARY SEPSIS	Other	reg1	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	PULMONARY SEPSIS	Western Europe	reg1	1 (0,5)	0 (0,0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	Asia-Pacific	reg1	3 (13,0)	1 (4,5)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	Central and South America	reg1	1 (9,1)	0 (0,0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	North America	reg1	1 (6,3)	0 (0,0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	Other	reg1	4 (5,1)	0 (0,0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	Western Europe	reg1	16 (7,7)	2 (1,0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	Asia-Pacific	reg1	3 (13,0)	1 (4,5)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	Central and South America	reg1	1 (9,1)	0 (0,0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	North America	reg1	1 (6,3)	0 (0,0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	Other	reg1	4 (5,1)	0 (0,0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	Western Europe	reg1	16 (7,7)	2 (1,0)
INVESTIGATIONS	ALL	Asia-Pacific	reg1	0 (0,0)	0 (0,0)
INVESTIGATIONS	ALL	Central and South America	reg1	0 (0,0)	0 (0,0)
INVESTIGATIONS	ALL	North America	reg1	0 (0,0)	0 (0,0)
INVESTIGATIONS	ALL	Other	reg1	0 (0,0)	0 (0,0)
INVESTIGATIONS	ALL	Western Europe	reg1	2 (1,0)	1 (0,5)

INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Asia-Pacific	reg1	0 (0,0)	0 (0,0)
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Central and South America	reg1	0 (0,0)	0 (0,0)
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	North America	reg1	0 (0,0)	0 (0,0)
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Other	reg1	0 (0,0)	0 (0,0)
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Western Europe	reg1	1 (0,5)	0 (0,0)
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Asia-Pacific	reg1	0 (0,0)	0 (0,0)
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Central and South America	reg1	0 (0,0)	0 (0,0)
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	North America	reg1	0 (0,0)	0 (0,0)
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Other	reg1	0 (0,0)	0 (0,0)
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Western Europe	reg1	2 (1,0)	1 (0,5)
METABOLISM AND NUTRITION DISORDERS	ALL	Asia-Pacific	reg1	0 (0,0)	0 (0,0)
METABOLISM AND NUTRITION DISORDERS	ALL	Central and South America	reg1	0 (0,0)	0 (0,0)
METABOLISM AND NUTRITION DISORDERS	ALL	North America	reg1	1 (6,3)	0 (0,0)
METABOLISM AND NUTRITION DISORDERS	ALL	Other	reg1	0 (0,0)	0 (0,0)
METABOLISM AND NUTRITION DISORDERS	ALL	Western Europe	reg1	0 (0,0)	0 (0,0)
METABOLISM AND NUTRITION DISORDERS	TUMOUR LYSIS SYNDROME	Asia-Pacific	reg1	0 (0,0)	0 (0,0)
METABOLISM AND NUTRITION DISORDERS	TUMOUR LYSIS SYNDROME	Central and South America	reg1	0 (0,0)	0 (0,0)
METABOLISM AND NUTRITION DISORDERS	TUMOUR LYSIS SYNDROME	North America	reg1	1 (6,3)	0 (0,0)

METABOLISM AND NUTRITION DISORDERS	TUMOUR LYSIS SYNDROME	Other	reg1	0 (0,0)	0 (0,0)
METABOLISM AND NUTRITION DISORDERS	TUMOUR LYSIS SYNDROME	Western Europe	reg1	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	ALL	Asia-Pacific	reg1	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	ALL	Central and South America	reg1	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	ALL	North America	reg1	0 (0,0)	1 (7,7)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	ALL	Other	reg1	0 (0,0)	1 (1,1)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	ALL	Western Europe	reg1	3 (1,4)	2 (1,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	ADENOCARCINOMA	Asia-Pacific	reg1	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	ADENOCARCINOMA	Central and South America	reg1	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	ADENOCARCINOMA	North America	reg1	0 (0,0)	1 (7,7)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	ADENOCARCINOMA	Other	reg1	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	ADENOCARCINOMA	Western Europe	reg1	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	COLON CANCER	Asia-Pacific	reg1	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	COLON CANCER	Central and South America	reg1	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	COLON CANCER	North America	reg1	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	COLON CANCER	Other	reg1	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	COLON CANCER	Western Europe	reg1	1 (0,5)	0 (0,0)

NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	LUNG NEOPLASM MALIGNANT	Asia-Pacific	reg1	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	LUNG NEOPLASM MALIGNANT	Central and South America	reg1	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	LUNG NEOPLASM MALIGNANT	North America	reg1	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	LUNG NEOPLASM MALIGNANT	Other	reg1	0 (0,0)	1 (1,1)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	LUNG NEOPLASM MALIGNANT	Western Europe	reg1	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	METASTATIC SQUAMOUS CELL CARCINOMA	Asia-Pacific	reg1	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	METASTATIC SQUAMOUS CELL CARCINOMA	Central and South America	reg1	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	METASTATIC SQUAMOUS CELL CARCINOMA	North America	reg1	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	METASTATIC SQUAMOUS CELL CARCINOMA	Other	reg1	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	METASTATIC SQUAMOUS CELL CARCINOMA	Western Europe	reg1	0 (0,0)	1 (0,5)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	OROPHARYNGEAL CANCER	Asia-Pacific	reg1	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	OROPHARYNGEAL CANCER	Central and South America	reg1	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	OROPHARYNGEAL CANCER	North America	reg1	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	OROPHARYNGEAL CANCER	Other	reg1	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	OROPHARYNGEAL CANCER	Western Europe	reg1	0 (0,0)	1 (0,5)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	PLASMA CELL MYELOMA	Asia-Pacific	reg1	0 (0,0)	0 (0,0)

NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	PLASMA CELL MYELOMA	Central and South America	reg1	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	PLASMA CELL MYELOMA	North America	reg1	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	PLASMA CELL MYELOMA	Other	reg1	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	PLASMA CELL MYELOMA	Western Europe	reg1	1 (0,5)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	SQUAMOUS CELL CARCINOMA OF LUNG	Asia-Pacific	reg1	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	SQUAMOUS CELL CARCINOMA OF LUNG	Central and South America	reg1	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	SQUAMOUS CELL CARCINOMA OF LUNG	North America	reg1	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	SQUAMOUS CELL CARCINOMA OF LUNG	Other	reg1	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	SQUAMOUS CELL CARCINOMA OF LUNG	Western Europe	reg1	1 (0,5)	0 (0,0)
NERVOUS SYSTEM DISORDERS	ALL	Asia-Pacific	reg1	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	ALL	Central and South America	reg1	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	ALL	North America	reg1	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	ALL	Other	reg1	0 (0,0)	1 (1,1)
NERVOUS SYSTEM DISORDERS	ALL	Western Europe	reg1	2 (1,0)	1 (0,5)
NERVOUS SYSTEM DISORDERS	CENTRAL NERVOUS SYSTEM HAEMORRHAGE	Asia-Pacific	reg1	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	CENTRAL NERVOUS SYSTEM HAEMORRHAGE	Central and South America	reg1	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	CENTRAL NERVOUS SYSTEM HAEMORRHAGE	North America	reg1	0 (0,0)	0 (0,0)

NERVOUS SYSTEM DISORDERS	CENTRAL NERVOUS SYSTEM HAEMORRHAGE	Other	reg1	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	CENTRAL NERVOUS SYSTEM HAEMORRHAGE	Western Europe	reg1	1 (0,5)	0 (0,0)
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	Asia- Pacific	reg1	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	Central and South America	reg1	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	North America	reg1	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	Other	reg1	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	Western Europe	reg1	1 (0,5)	0 (0,0)
NERVOUS SYSTEM DISORDERS	DEPRESSED LEVEL OF CONSCIOUSNESS	Asia- Pacific	reg1	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	DEPRESSED LEVEL OF CONSCIOUSNESS	Central and South America	reg1	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	DEPRESSED LEVEL OF CONSCIOUSNESS	North America	reg1	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	DEPRESSED LEVEL OF CONSCIOUSNESS	Other	reg1	0 (0,0)	1 (1,1)
NERVOUS SYSTEM DISORDERS	DEPRESSED LEVEL OF CONSCIOUSNESS	Western Europe	reg1	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	Asia- Pacific	reg1	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	Central and South America	reg1	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	North America	reg1	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	Other	reg1	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	Western Europe	reg1	0 (0,0)	1 (0,5)
PSYCHIATRIC DISORDERS	ALL	Asia- Pacific	reg1	1 (4,3)	0 (0,0)

PSYCHIATRIC DISORDERS	ALL	Central and South America	reg1	0 (0,0)	0 (0,0)
PSYCHIATRIC DISORDERS	ALL	North America	reg1	0 (0,0)	0 (0,0)
PSYCHIATRIC DISORDERS	ALL	Other	reg1	0 (0,0)	0 (0,0)
PSYCHIATRIC DISORDERS	ALL	Western Europe	reg1	0 (0,0)	1 (0,5)
PSYCHIATRIC DISORDERS	DELIRIUM	Asia-Pacific	reg1	1 (4,3)	0 (0,0)
PSYCHIATRIC DISORDERS	DELIRIUM	Central and South America	reg1	0 (0,0)	0 (0,0)
PSYCHIATRIC DISORDERS	DELIRIUM	North America	reg1	0 (0,0)	0 (0,0)
PSYCHIATRIC DISORDERS	DELIRIUM	Other	reg1	0 (0,0)	0 (0,0)
PSYCHIATRIC DISORDERS	DELIRIUM	Western Europe	reg1	0 (0,0)	0 (0,0)
PSYCHIATRIC DISORDERS	MANIA	Asia-Pacific	reg1	0 (0,0)	0 (0,0)
PSYCHIATRIC DISORDERS	MANIA	Central and South America	reg1	0 (0,0)	0 (0,0)
PSYCHIATRIC DISORDERS	MANIA	North America	reg1	0 (0,0)	0 (0,0)
PSYCHIATRIC DISORDERS	MANIA	Other	reg1	0 (0,0)	0 (0,0)
PSYCHIATRIC DISORDERS	MANIA	Western Europe	reg1	0 (0,0)	1 (0,5)
RENAL AND URINARY DISORDERS	ALL	Asia-Pacific	reg1	0 (0,0)	0 (0,0)
RENAL AND URINARY DISORDERS	ALL	Central and South America	reg1	0 (0,0)	0 (0,0)
RENAL AND URINARY DISORDERS	ALL	North America	reg1	0 (0,0)	0 (0,0)
RENAL AND URINARY DISORDERS	ALL	Other	reg1	0 (0,0)	1 (1,1)

RENAL AND URINARY DISORDERS	ALL	Western Europe	reg1	0 (0,0)	0 (0,0)
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	Asia-Pacific	reg1	0 (0,0)	0 (0,0)
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	Central and South America	reg1	0 (0,0)	0 (0,0)
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	North America	reg1	0 (0,0)	0 (0,0)
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	Other	reg1	0 (0,0)	1 (1,1)
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	Western Europe	reg1	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	ALL	Asia-Pacific	reg1	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	ALL	Central and South America	reg1	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	ALL	North America	reg1	1 (6,3)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	ALL	Other	reg1	1 (1,3)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	ALL	Western Europe	reg1	1 (0,5)	1 (0,5)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	Asia-Pacific	reg1	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	Central and South America	reg1	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	North America	reg1	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	Other	reg1	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	Western Europe	reg1	0 (0,0)	1 (0,5)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	Asia-Pacific	reg1	0 (0,0)	0 (0,0)

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	Central and South America	reg1	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	North America	reg1	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	Other	reg1	1 (1,3)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	Western Europe	reg1	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PNEUMONITIS	Asia-Pacific	reg1	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PNEUMONITIS	Central and South America	reg1	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PNEUMONITIS	North America	reg1	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PNEUMONITIS	Other	reg1	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PNEUMONITIS	Western Europe	reg1	1 (0,5)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY ALVEOLAR HAEMORRHAGE	Asia-Pacific	reg1	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY ALVEOLAR HAEMORRHAGE	Central and South America	reg1	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY ALVEOLAR HAEMORRHAGE	North America	reg1	1 (6,3)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY ALVEOLAR HAEMORRHAGE	Other	reg1	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY ALVEOLAR HAEMORRHAGE	Western Europe	reg1	0 (0,0)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ALL	Asia-Pacific	reg1	0 (0,0)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ALL	Central and South America	reg1	0 (0,0)	0 (0,0)

SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ALL	North America	reg1	1 (6,3)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ALL	Other	reg1	1 (1,3)	2 (2,3)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ALL	Western Europe	reg1	1 (0,5)	1 (0,5)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DERMATITIS ALLERGIC	Asia-Pacific	reg1	0 (0,0)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DERMATITIS ALLERGIC	Central and South America	reg1	0 (0,0)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DERMATITIS ALLERGIC	North America	reg1	0 (0,0)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DERMATITIS ALLERGIC	Other	reg1	1 (1,3)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DERMATITIS ALLERGIC	Western Europe	reg1	0 (0,0)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRUG ERUPTION	Asia-Pacific	reg1	0 (0,0)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRUG ERUPTION	Central and South America	reg1	0 (0,0)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRUG ERUPTION	North America	reg1	0 (0,0)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRUG ERUPTION	Other	reg1	0 (0,0)	1 (1,1)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRUG ERUPTION	Western Europe	reg1	0 (0,0)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	Asia-Pacific	reg1	0 (0,0)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	Central and South America	reg1	0 (0,0)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	North America	reg1	0 (0,0)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	Other	reg1	0 (0,0)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	Western Europe	reg1	1 (0,5)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	Asia-Pacific	reg1	0 (0,0)	0 (0,0)

SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	Central and South America	reg1	0 (0,0)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	North America	reg1	0 (0,0)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	Other	reg1	0 (0,0)	1 (1,1)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	Western Europe	reg1	0 (0,0)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH MACULO-PAPULAR	Asia-Pacific	reg1	0 (0,0)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH MACULO-PAPULAR	Central and South America	reg1	0 (0,0)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH MACULO-PAPULAR	North America	reg1	1 (6,3)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH MACULO-PAPULAR	Other	reg1	0 (0,0)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH MACULO-PAPULAR	Western Europe	reg1	0 (0,0)	1 (0,5)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ALL	A	bl_binet	3 (4,0)	3 (4,2)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ALL	B	bl_binet	5 (3,5)	8 (6,1)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ALL	C	bl_binet	15 (12,7)	14 (12,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	A	bl_binet	1 (1,3)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	B	bl_binet	1 (0,7)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	C	bl_binet	0 (0,0)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	CYTOPENIA	A	bl_binet	0 (0,0)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	CYTOPENIA	B	bl_binet	0 (0,0)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	CYTOPENIA	C	bl_binet	0 (0,0)	1 (0,9)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	IMMUNE THROMBOCYTOPENIC PURPURA	A	bl_binet	1 (1,3)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	IMMUNE THROMBOCYTOPENIC PURPURA	B	bl_binet	0 (0,0)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	IMMUNE THROMBOCYTOPENIC PURPURA	C	bl_binet	0 (0,0)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	A	bl_binet	0 (0,0)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	B	bl_binet	0 (0,0)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	C	bl_binet	2 (1,7)	1 (0,9)

BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	A	bl_binet	0 (0,0)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	B	bl_binet	0 (0,0)	1 (0,8)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	C	bl_binet	0 (0,0)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	A	bl_binet	0 (0,0)	2 (2,8)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	B	bl_binet	4 (2,8)	7 (5,3)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	C	bl_binet	11 (9,3)	10 (8,5)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	A	bl_binet	0 (0,0)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	B	bl_binet	0 (0,0)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	C	bl_binet	0 (0,0)	1 (0,9)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	A	bl_binet	1 (1,3)	1 (1,4)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	B	bl_binet	0 (0,0)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	C	bl_binet	3 (2,5)	2 (1,7)
GASTROINTESTINAL DISORDERS	ALL	A	bl_binet	1 (1,3)	0 (0,0)
GASTROINTESTINAL DISORDERS	ALL	B	bl_binet	1 (0,7)	0 (0,0)
GASTROINTESTINAL DISORDERS	ALL	C	bl_binet	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	ENTEROCOLITIS	A	bl_binet	1 (1,3)	0 (0,0)
GASTROINTESTINAL DISORDERS	ENTEROCOLITIS	B	bl_binet	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	ENTEROCOLITIS	C	bl_binet	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	PANCREATITIS ACUTE	A	bl_binet	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	PANCREATITIS ACUTE	B	bl_binet	1 (0,7)	0 (0,0)
GASTROINTESTINAL DISORDERS	PANCREATITIS ACUTE	C	bl_binet	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ALL	A	bl_binet	0 (0,0)	1 (1,4)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ALL	B	bl_binet	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ALL	C	bl_binet	2 (1,7)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ASTHENIA	A	bl_binet	0 (0,0)	1 (1,4)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ASTHENIA	B	bl_binet	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ASTHENIA	C	bl_binet	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PERFORMANCE STATUS DECREASED	A	bl_binet	0 (0,0)	0 (0,0)

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PERFORMANCE STATUS DECREASED	B	bl_binet	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PERFORMANCE STATUS DECREASED	C	bl_binet	1 (0,8)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	A	bl_binet	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	B	bl_binet	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	C	bl_binet	1 (0,8)	0 (0,0)
HEPATOBIILIARY DISORDERS	ALL	A	bl_binet	0 (0,0)	0 (0,0)
HEPATOBIILIARY DISORDERS	ALL	B	bl_binet	0 (0,0)	1 (0,8)
HEPATOBIILIARY DISORDERS	ALL	C	bl_binet	1 (0,8)	0 (0,0)
HEPATOBIILIARY DISORDERS	HEPATOCELLULAR INJURY	A	bl_binet	0 (0,0)	0 (0,0)
HEPATOBIILIARY DISORDERS	HEPATOCELLULAR INJURY	B	bl_binet	0 (0,0)	1 (0,8)
HEPATOBIILIARY DISORDERS	HEPATOCELLULAR INJURY	C	bl_binet	0 (0,0)	0 (0,0)
HEPATOBIILIARY DISORDERS	HYPERTANSAMINASAEMIA	A	bl_binet	0 (0,0)	0 (0,0)
HEPATOBIILIARY DISORDERS	HYPERTANSAMINASAEMIA	B	bl_binet	0 (0,0)	0 (0,0)
HEPATOBIILIARY DISORDERS	HYPERTANSAMINASAEMIA	C	bl_binet	1 (0,8)	0 (0,0)
IMMUNE SYSTEM DISORDERS	ALL	A	bl_binet	0 (0,0)	1 (1,4)
IMMUNE SYSTEM DISORDERS	ALL	B	bl_binet	1 (0,7)	0 (0,0)
IMMUNE SYSTEM DISORDERS	ALL	C	bl_binet	0 (0,0)	0 (0,0)
IMMUNE SYSTEM DISORDERS	ANAPHYLACTIC REACTION	A	bl_binet	0 (0,0)	0 (0,0)
IMMUNE SYSTEM DISORDERS	ANAPHYLACTIC REACTION	B	bl_binet	1 (0,7)	0 (0,0)
IMMUNE SYSTEM DISORDERS	ANAPHYLACTIC REACTION	C	bl_binet	0 (0,0)	0 (0,0)
IMMUNE SYSTEM DISORDERS	HYPERSENSITIVITY	A	bl_binet	0 (0,0)	1 (1,4)
IMMUNE SYSTEM DISORDERS	HYPERSENSITIVITY	B	bl_binet	0 (0,0)	0 (0,0)
IMMUNE SYSTEM DISORDERS	HYPERSENSITIVITY	C	bl_binet	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	ALL	A	bl_binet	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	ALL	B	bl_binet	1 (0,7)	3 (2,3)
INFECTIONS AND INFESTATIONS	ALL	C	bl_binet	2 (1,7)	3 (2,6)
INFECTIONS AND INFESTATIONS	BRONCHITIS	A	bl_binet	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	BRONCHITIS	B	bl_binet	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	BRONCHITIS	C	bl_binet	0 (0,0)	2 (1,7)

INFECTIONS AND INFESTATIONS	HERPES SIMPLEX	A	bl_binet	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	HERPES SIMPLEX	B	bl_binet	0 (0,0)	1 (0,8)
INFECTIONS AND INFESTATIONS	HERPES SIMPLEX	C	bl_binet	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	A	bl_binet	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	B	bl_binet	0 (0,0)	1 (0,8)
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	C	bl_binet	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	PNEUMONIA	A	bl_binet	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	PNEUMONIA	B	bl_binet	1 (0,7)	2 (1,5)
INFECTIONS AND INFESTATIONS	PNEUMONIA	C	bl_binet	1 (0,8)	1 (0,9)
INFECTIONS AND INFESTATIONS	PULMONARY SEPSIS	A	bl_binet	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	PULMONARY SEPSIS	B	bl_binet	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	PULMONARY SEPSIS	C	bl_binet	1 (0,8)	0 (0,0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	A	bl_binet	8 (10,7)	0 (0,0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	B	bl_binet	7 (4,9)	1 (0,8)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	C	bl_binet	10 (8,5)	2 (1,7)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	A	bl_binet	8 (10,7)	0 (0,0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	B	bl_binet	7 (4,9)	1 (0,8)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	C	bl_binet	10 (8,5)	2 (1,7)
INVESTIGATIONS	ALL	A	bl_binet	1 (1,3)	0 (0,0)
INVESTIGATIONS	ALL	B	bl_binet	0 (0,0)	0 (0,0)
INVESTIGATIONS	ALL	C	bl_binet	1 (0,8)	1 (0,9)
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	A	bl_binet	1 (1,3)	0 (0,0)
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	B	bl_binet	0 (0,0)	0 (0,0)
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	C	bl_binet	0 (0,0)	0 (0,0)
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	A	bl_binet	1 (1,3)	0 (0,0)
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	B	bl_binet	0 (0,0)	0 (0,0)
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	C	bl_binet	1 (0,8)	1 (0,9)
METABOLISM AND NUTRITION DISORDERS	ALL	A	bl_binet	0 (0,0)	0 (0,0)
METABOLISM AND NUTRITION DISORDERS	ALL	B	bl_binet	0 (0,0)	0 (0,0)

METABOLISM AND NUTRITION DISORDERS	ALL	C	bl_binet	1 (0,8)	0 (0,0)
METABOLISM AND NUTRITION DISORDERS	TUMOUR LYSIS SYNDROME	A	bl_binet	0 (0,0)	0 (0,0)
METABOLISM AND NUTRITION DISORDERS	TUMOUR LYSIS SYNDROME	B	bl_binet	0 (0,0)	0 (0,0)
METABOLISM AND NUTRITION DISORDERS	TUMOUR LYSIS SYNDROME	C	bl_binet	1 (0,8)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	ALL	A	bl_binet	0 (0,0)	1 (1,4)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	ALL	B	bl_binet	3 (2,1)	1 (0,8)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	ALL	C	bl_binet	0 (0,0)	2 (1,7)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	ADENOCARCINOMA	A	bl_binet	0 (0,0)	1 (1,4)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	ADENOCARCINOMA	B	bl_binet	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	ADENOCARCINOMA	C	bl_binet	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	COLON CANCER	A	bl_binet	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	COLON CANCER	B	bl_binet	1 (0,7)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	COLON CANCER	C	bl_binet	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	LUNG NEOPLASM MALIGNANT	A	bl_binet	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	LUNG NEOPLASM MALIGNANT	B	bl_binet	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	LUNG NEOPLASM MALIGNANT	C	bl_binet	0 (0,0)	1 (0,9)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	METASTATIC SQUAMOUS CELL CARCINOMA	A	bl_binet	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	METASTATIC SQUAMOUS CELL CARCINOMA	B	bl_binet	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	METASTATIC SQUAMOUS CELL CARCINOMA	C	bl_binet	0 (0,0)	1 (0,9)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	OROPHARYNGEAL CANCER	A	bl_binet	0 (0,0)	0 (0,0)

NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	OROPHARYNGEAL CANCER	B	bl_binet	0 (0,0)	1 (0,8)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	OROPHARYNGEAL CANCER	C	bl_binet	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	PLASMA CELL MYELOMA	A	bl_binet	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	PLASMA CELL MYELOMA	B	bl_binet	1 (0,7)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	PLASMA CELL MYELOMA	C	bl_binet	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	SQUAMOUS CELL CARCINOMA OF LUNG	A	bl_binet	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	SQUAMOUS CELL CARCINOMA OF LUNG	B	bl_binet	1 (0,7)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	SQUAMOUS CELL CARCINOMA OF LUNG	C	bl_binet	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	ALL	A	bl_binet	1 (1,3)	0 (0,0)
NERVOUS SYSTEM DISORDERS	ALL	B	bl_binet	1 (0,7)	1 (0,8)
NERVOUS SYSTEM DISORDERS	ALL	C	bl_binet	0 (0,0)	1 (0,9)
NERVOUS SYSTEM DISORDERS	CENTRAL NERVOUS SYSTEM HAEMORRHAGE	A	bl_binet	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	CENTRAL NERVOUS SYSTEM HAEMORRHAGE	B	bl_binet	1 (0,7)	0 (0,0)
NERVOUS SYSTEM DISORDERS	CENTRAL NERVOUS SYSTEM HAEMORRHAGE	C	bl_binet	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	A	bl_binet	1 (1,3)	0 (0,0)
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	B	bl_binet	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	C	bl_binet	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	DEPRESSED LEVEL OF CONSCIOUSNESS	A	bl_binet	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	DEPRESSED LEVEL OF CONSCIOUSNESS	B	bl_binet	0 (0,0)	1 (0,8)
NERVOUS SYSTEM DISORDERS	DEPRESSED LEVEL OF CONSCIOUSNESS	C	bl_binet	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	A	bl_binet	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	B	bl_binet	0 (0,0)	0 (0,0)

NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	C	bl_binet	0 (0,0)	1 (0,9)
PSYCHIATRIC DISORDERS	ALL	A	bl_binet	0 (0,0)	0 (0,0)
PSYCHIATRIC DISORDERS	ALL	B	bl_binet	0 (0,0)	0 (0,0)
PSYCHIATRIC DISORDERS	ALL	C	bl_binet	1 (0,8)	1 (0,9)
PSYCHIATRIC DISORDERS	DELIRIUM	A	bl_binet	0 (0,0)	0 (0,0)
PSYCHIATRIC DISORDERS	DELIRIUM	B	bl_binet	0 (0,0)	0 (0,0)
PSYCHIATRIC DISORDERS	DELIRIUM	C	bl_binet	1 (0,8)	0 (0,0)
PSYCHIATRIC DISORDERS	MANIA	A	bl_binet	0 (0,0)	0 (0,0)
PSYCHIATRIC DISORDERS	MANIA	B	bl_binet	0 (0,0)	0 (0,0)
PSYCHIATRIC DISORDERS	MANIA	C	bl_binet	0 (0,0)	1 (0,9)
RENAL AND URINARY DISORDERS	ALL	A	bl_binet	0 (0,0)	1 (1,4)
RENAL AND URINARY DISORDERS	ALL	B	bl_binet	0 (0,0)	0 (0,0)
RENAL AND URINARY DISORDERS	ALL	C	bl_binet	0 (0,0)	0 (0,0)
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	A	bl_binet	0 (0,0)	1 (1,4)
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	B	bl_binet	0 (0,0)	0 (0,0)
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	C	bl_binet	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	ALL	A	bl_binet	1 (1,3)	1 (1,4)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	ALL	B	bl_binet	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	ALL	C	bl_binet	2 (1,7)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	A	bl_binet	0 (0,0)	1 (1,4)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	B	bl_binet	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	C	bl_binet	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	A	bl_binet	1 (1,3)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	B	bl_binet	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	C	bl_binet	0 (0,0)	0 (0,0)

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PNEUMONITIS	A	bl_binet	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PNEUMONITIS	B	bl_binet	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PNEUMONITIS	C	bl_binet	1 (0,8)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY ALVEOLAR HAEMORRHAGE	A	bl_binet	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY ALVEOLAR HAEMORRHAGE	B	bl_binet	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY ALVEOLAR HAEMORRHAGE	C	bl_binet	1 (0,8)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ALL	A	bl_binet	0 (0,0)	1 (1,4)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ALL	B	bl_binet	3 (2,1)	1 (0,8)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ALL	C	bl_binet	0 (0,0)	1 (0,9)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DERMATITIS ALLERGIC	A	bl_binet	0 (0,0)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DERMATITIS ALLERGIC	B	bl_binet	1 (0,7)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DERMATITIS ALLERGIC	C	bl_binet	0 (0,0)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRUG ERUPTION	A	bl_binet	0 (0,0)	1 (1,4)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRUG ERUPTION	B	bl_binet	0 (0,0)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRUG ERUPTION	C	bl_binet	0 (0,0)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	A	bl_binet	0 (0,0)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	B	bl_binet	1 (0,7)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	C	bl_binet	0 (0,0)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	A	bl_binet	0 (0,0)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	B	bl_binet	0 (0,0)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	C	bl_binet	0 (0,0)	1 (0,9)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH MACULO-PAPULAR	A	bl_binet	0 (0,0)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH MACULO-PAPULAR	B	bl_binet	1 (0,7)	1 (0,8)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH MACULO-PAPULAR	C	bl_binet	0 (0,0)	0 (0,0)