

Supplementary Online Content

Rafii MS, Sol O, Mobley WC, et al. Safety, tolerability, and immunogenicity of the ACI-24 vaccine in adults with Down syndrome: a phase 1b randomized clinical trial. *JAMA Neurol.* Published online May 9, 2022. doi:10.1001/jamaneurol.2022.0983

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This supplementary material has been provided by the authors to give readers additional information about their work.

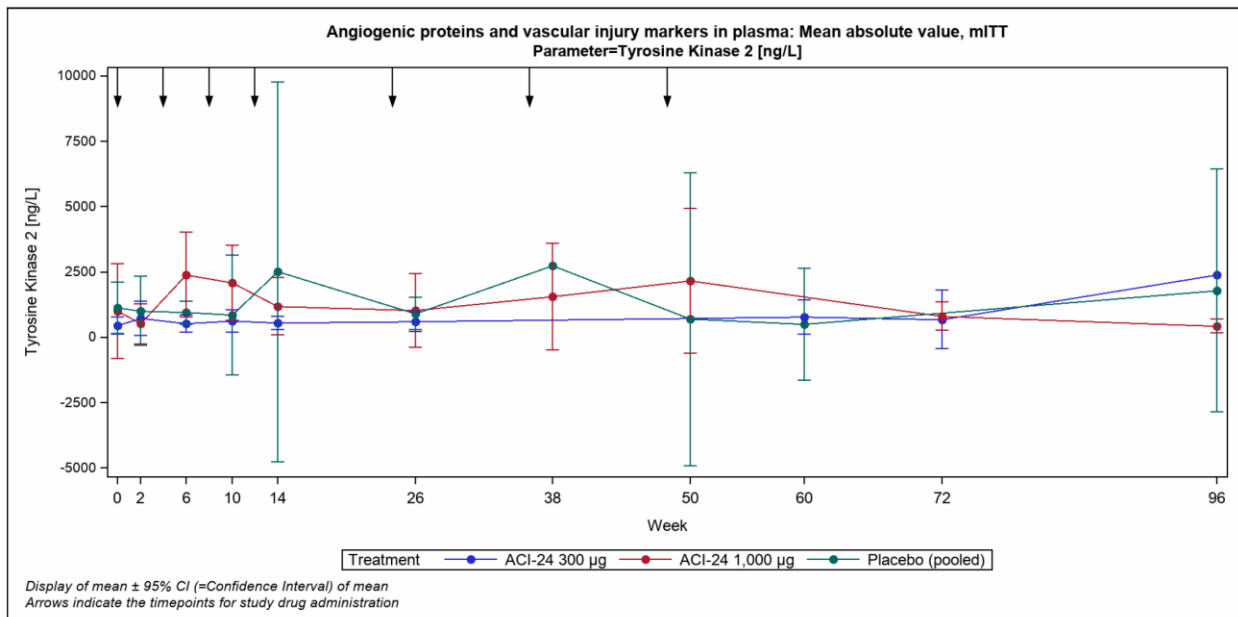
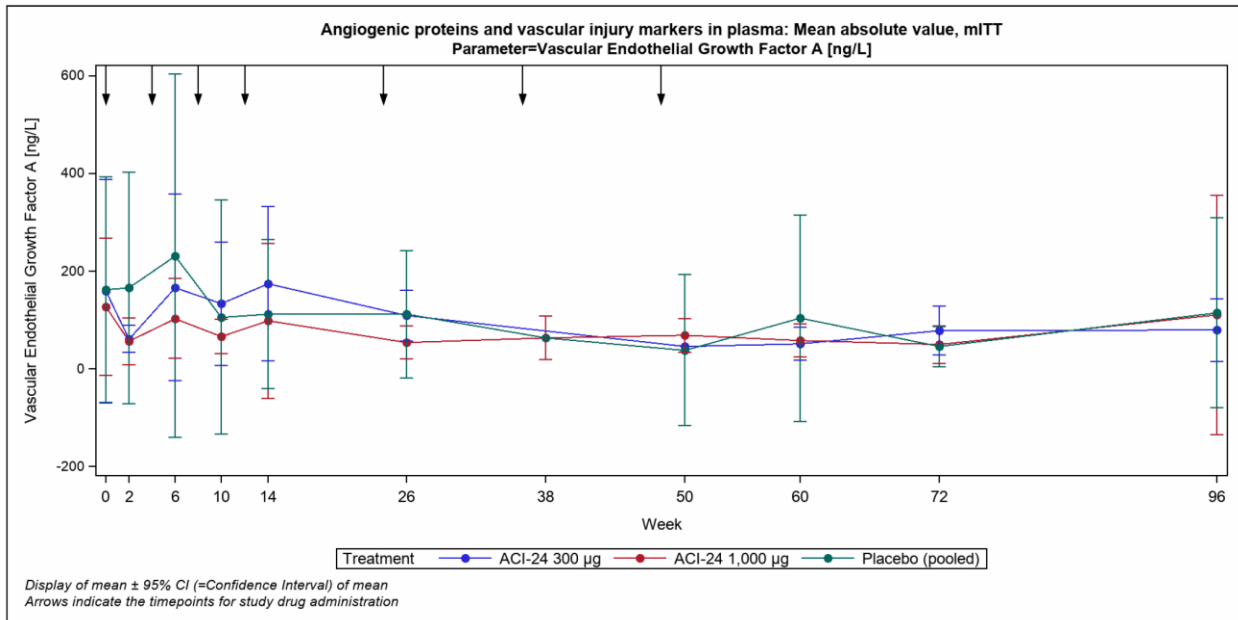
eTable. Columbia–Suicide Severity Rating Scale (C-SSRS)

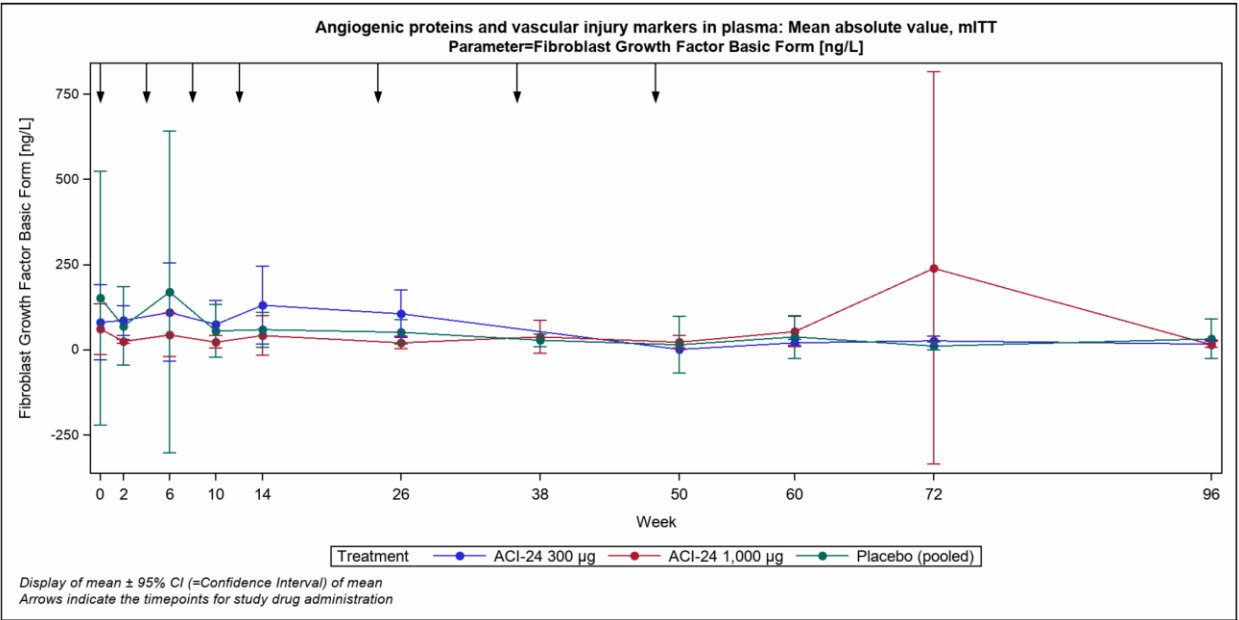
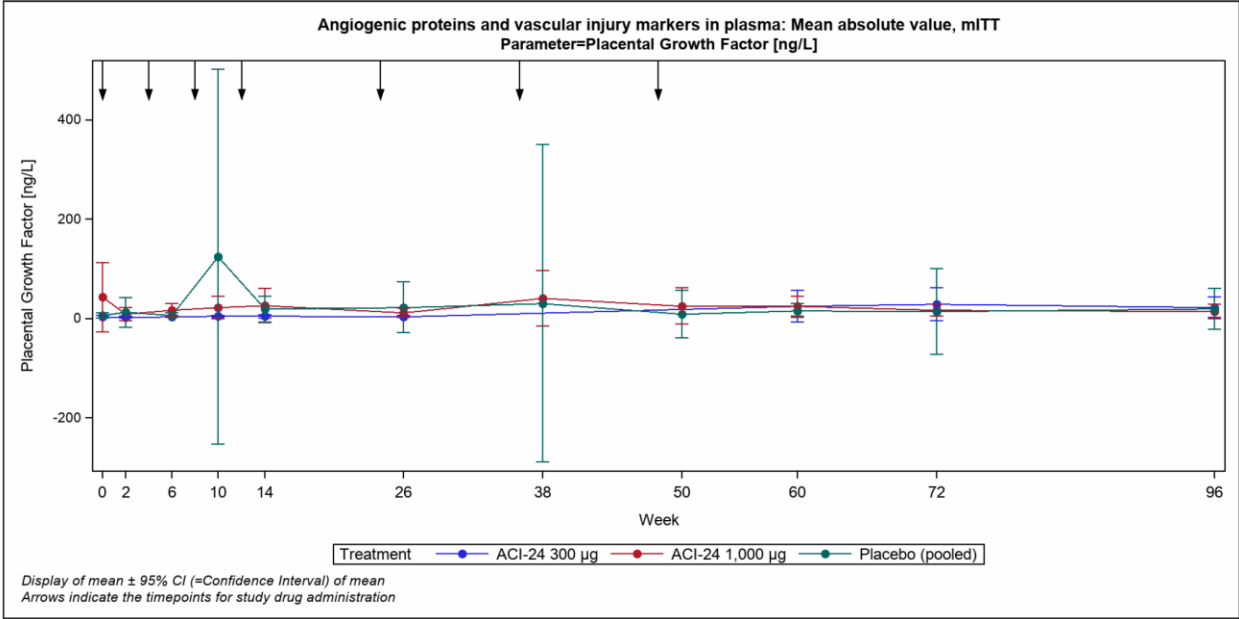
Appendix

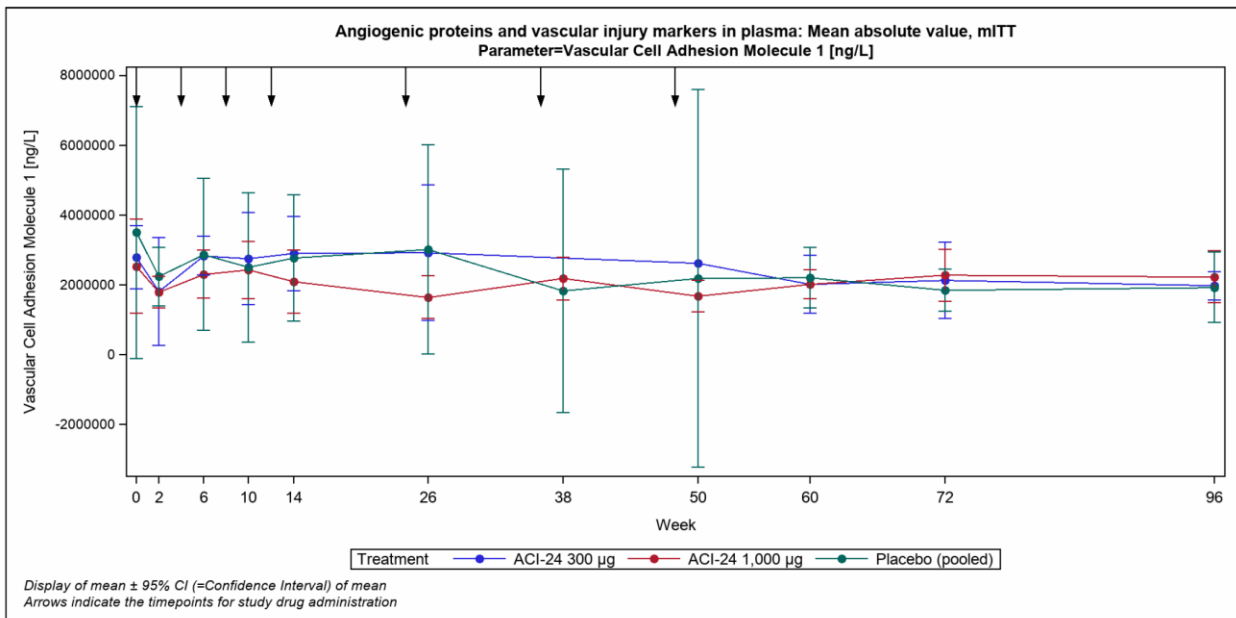
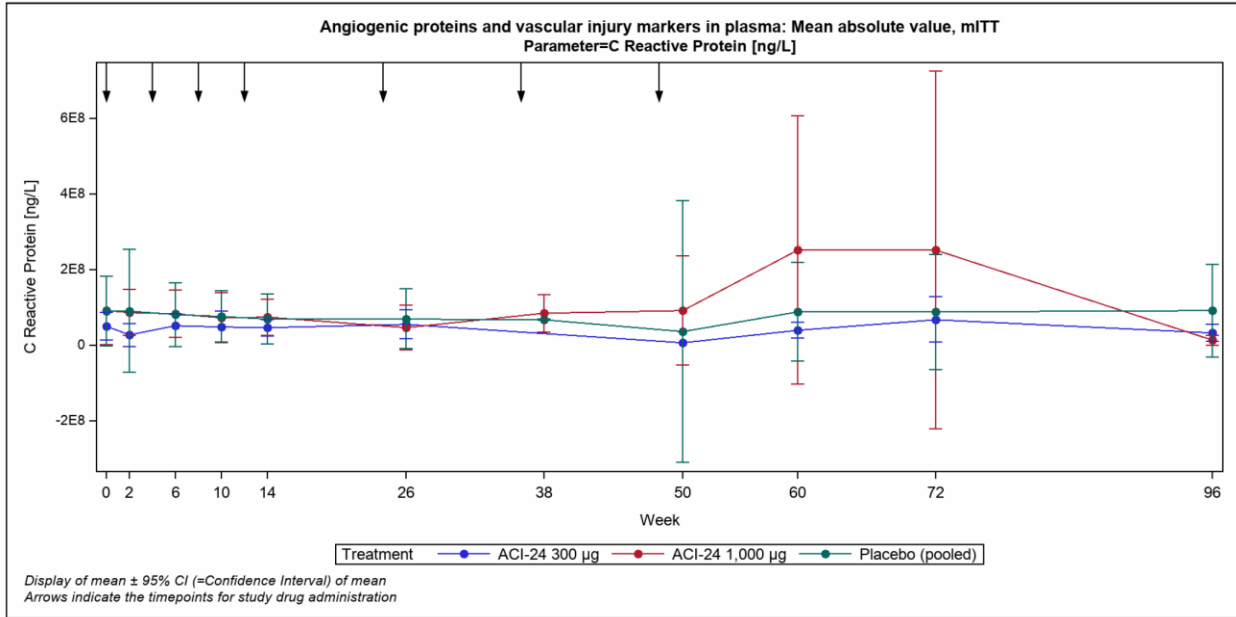
Suicidal ideation/ behavior			Descriptive statistics					
Suicidal ideation/ behavior: General questions, SAF			ACI-24 300 µg (N=6)	ACI-24 1,000 µg (N=6)	Placebo coh1 (N=2)	Placebo coh2 (N=2)	Total (N=16)	
Result								
Wish to die/sleep & Never wake up	Screening	no	6 (100.0%)	6 (100.0%)	2 (100.0%)	2 (100.0%)	16 (100.0%)	
		yes	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	
	Visit 1 (week 0)	no	6 (100.0%)	6 (100.0%)	2 (100.0%)	2 (100.0%)	16 (100.0%)	
		yes	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	
	Visit 17 (week 50)	no	6 (100.0%)	6 (100.0%)	2 (100.0%)	2 (100.0%)	16 (100.0%)	
		yes	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	
	Visit 21 (week 96)	no	6 (100.0%)	4 (100.0%)	2 (100.0%)	2 (100.0%)	14 (100.0%)	
		yes	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	
	Attempted Suicide	Screening	no	6 (100.0%)	6 (100.0%)	2 (100.0%)	2 (100.0%)	16 (100.0%)
			yes	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Visit 1 (week 0)	no	6 (100.0%)	6 (100.0%)	2 (100.0%)	2 (100.0%)	16 (100.0%)
			yes	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Visit 17 (week 50)		no	6 (100.0%)	6 (100.0%)	2 (100.0%)	2 (100.0%)	16 (100.0%)	
		yes	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	
Visit 21 (week 96)		no	6 (100.0%)	4 (100.0%)	2 (100.0%)	2 (100.0%)	14 (100.0%)	
		yes	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	
Harmed Himself/Herself		Screening	no	6 (100.0%)	5 (83.3%)	2 (100.0%)	2 (100.0%)	15 (93.8%)
			yes	0 (0.0%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	1 (6.3%)
		Visit 1 (week 0)	no	6 (100.0%)	5 (83.3%)	2 (100.0%)	2 (100.0%)	15 (93.8%)
			yes	0 (0.0%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	1 (6.3%)
	Visit 17 (week 50)	no	6 (100.0%)	6 (100.0%)	2 (100.0%)	2 (100.0%)	16 (100.0%)	
		yes	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	
	Visit 21 (week 96)	no	6 (100.0%)	4 (100.0%)	2 (100.0%)	2 (100.0%)	14 (100.0%)	
		yes	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	
	Self-Injurious Behaviour	Screening	no	6 (100.0%)	5 (83.3%)	2 (100.0%)	2 (100.0%)	15 (93.8%)
			yes	0 (0.0%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	1 (6.3%)
		Visit 1 (week 0)	no	6 (100.0%)	5 (83.3%)	2 (100.0%)	2 (100.0%)	15 (93.8%)
			yes	0 (0.0%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	1 (6.3%)
Visit 17 (week 50)		no	6 (100.0%)	6 (100.0%)	2 (100.0%)	2 (100.0%)	16 (100.0%)	
		yes	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	
Visit 21 (week 96)		no	6 (100.0%)	4 (100.0%)	2 (100.0%)	2 (100.0%)	14 (100.0%)	
		yes	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	

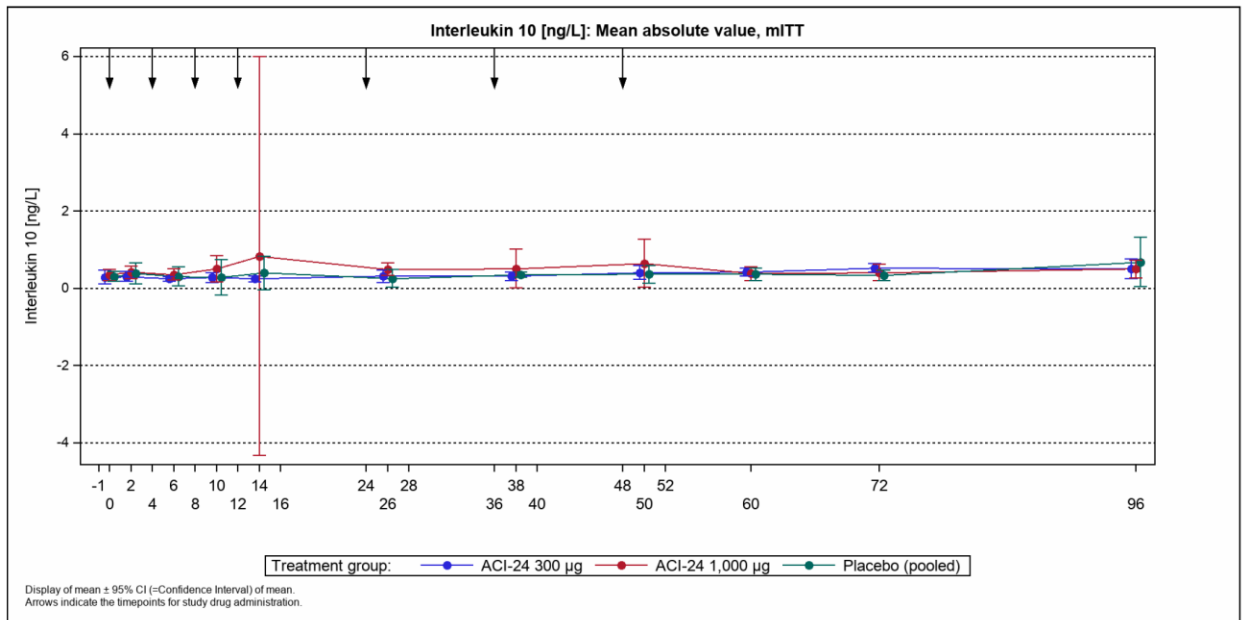
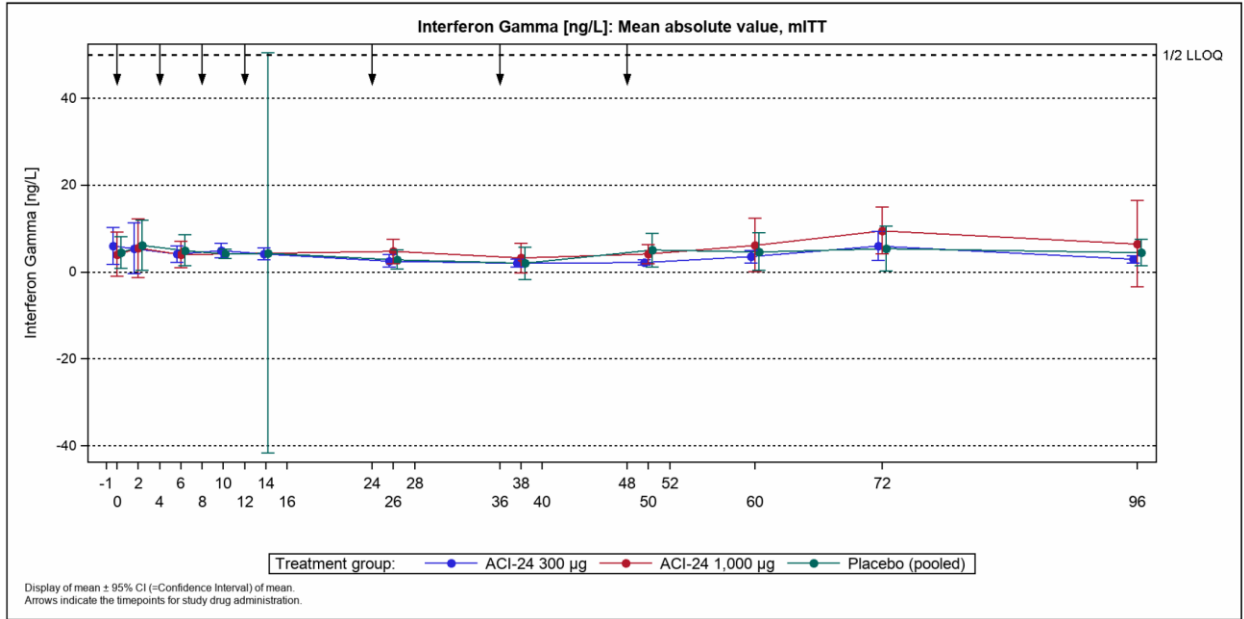
			ACI-24 300 µg (N=0)	ACI-24 1,000 µg (N=1)	Placebo coh1 (N=0)	Placebo coh2 (N=0)	Total (N=1)
Wish to be Dead	Screening	no	0 (0.0%)	1 (100.0%)	0 (0.0%)	0 (0.0%)	1 (100.0%)
		yes	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Visit 1 (week 0)	no	0 (0.0%)	1 (100.0%)	0 (0.0%)	0 (0.0%)	1 (100.0%)
		yes	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Non-Specific Suicidal Thought	Screening	no	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		yes	0 (0.0%)	1 (100.0%)	0 (0.0%)	0 (0.0%)	1 (100.0%)
	Visit 1 (week 0)	no	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		yes	0 (0.0%)	1 (100.0%)	0 (0.0%)	0 (0.0%)	1 (100.0%)
Suicidal Ideation-No Intent	Screening	no	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		yes	0 (0.0%)	1 (100.0%)	0 (0.0%)	0 (0.0%)	1 (100.0%)
	Visit 1 (week 0)	no	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		yes	0 (0.0%)	1 (100.0%)	0 (0.0%)	0 (0.0%)	1 (100.0%)
Ideation With Intent, No Plan	Screening	no	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		yes	0 (0.0%)	1 (100.0%)	0 (0.0%)	0 (0.0%)	1 (100.0%)
	Visit 1 (week 0)	no	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		yes	0 (0.0%)	1 (100.0%)	0 (0.0%)	0 (0.0%)	1 (100.0%)

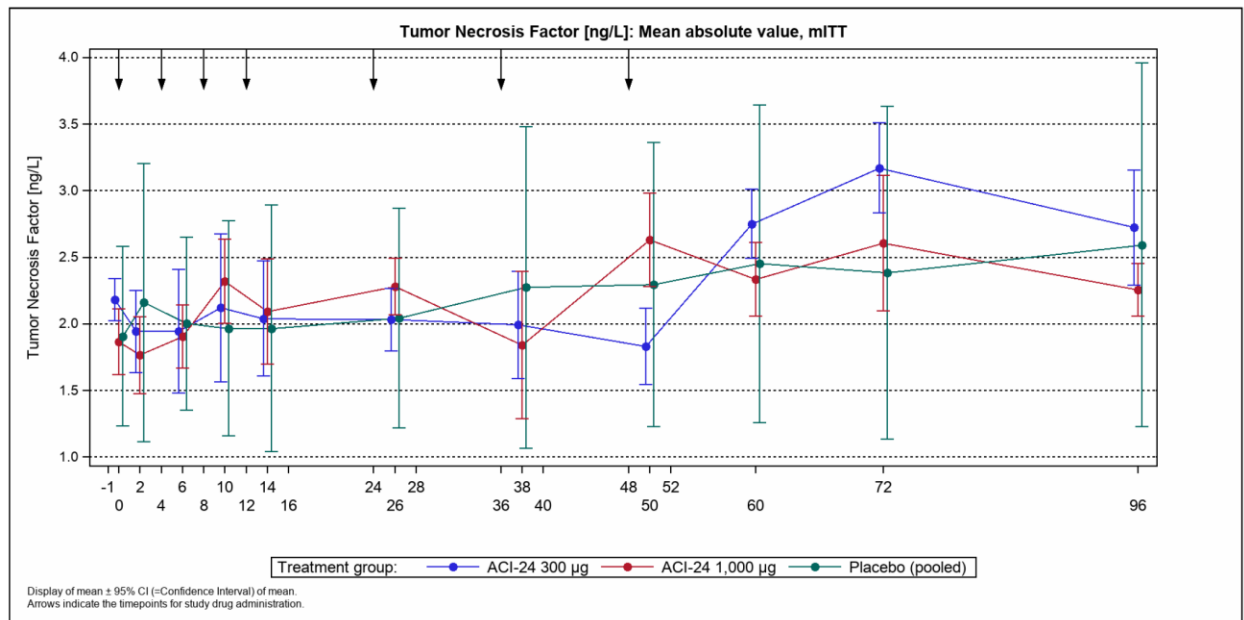
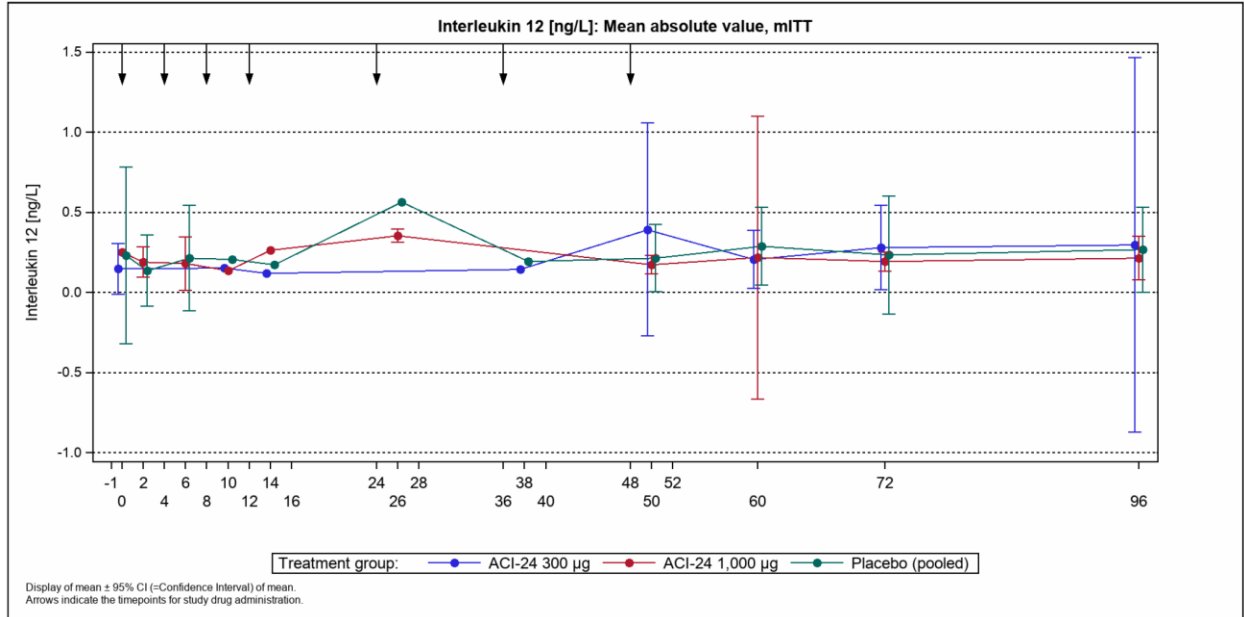
eFigure 1. Angiogenic Markers



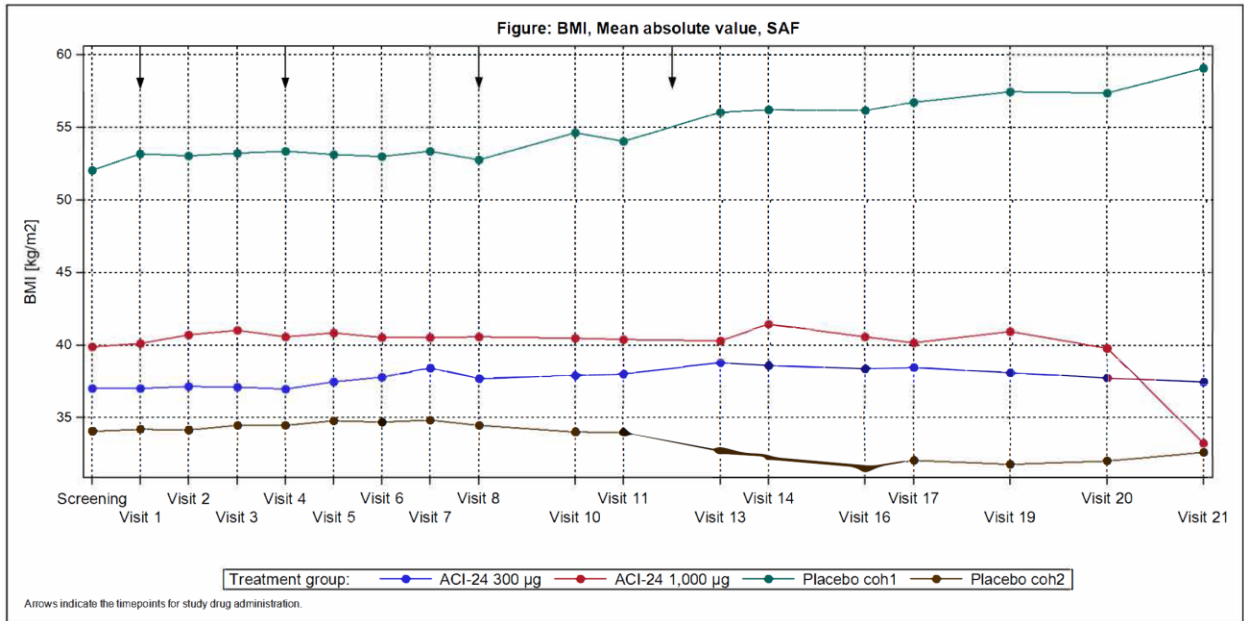




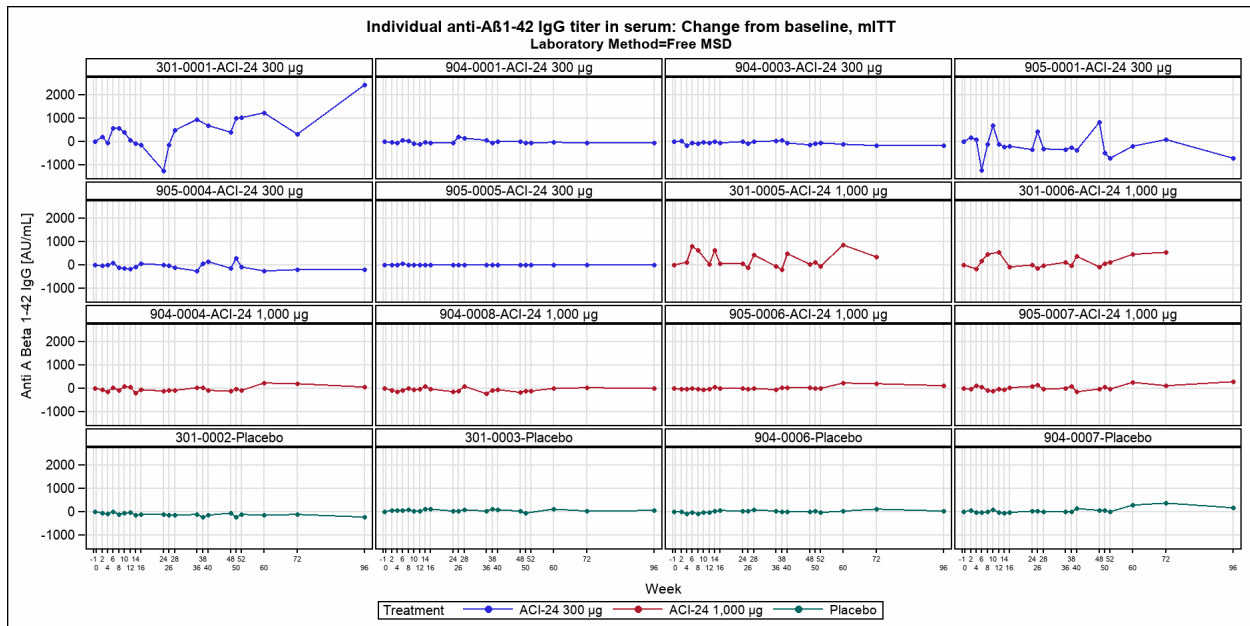




eFigure 2. Body Mass Index

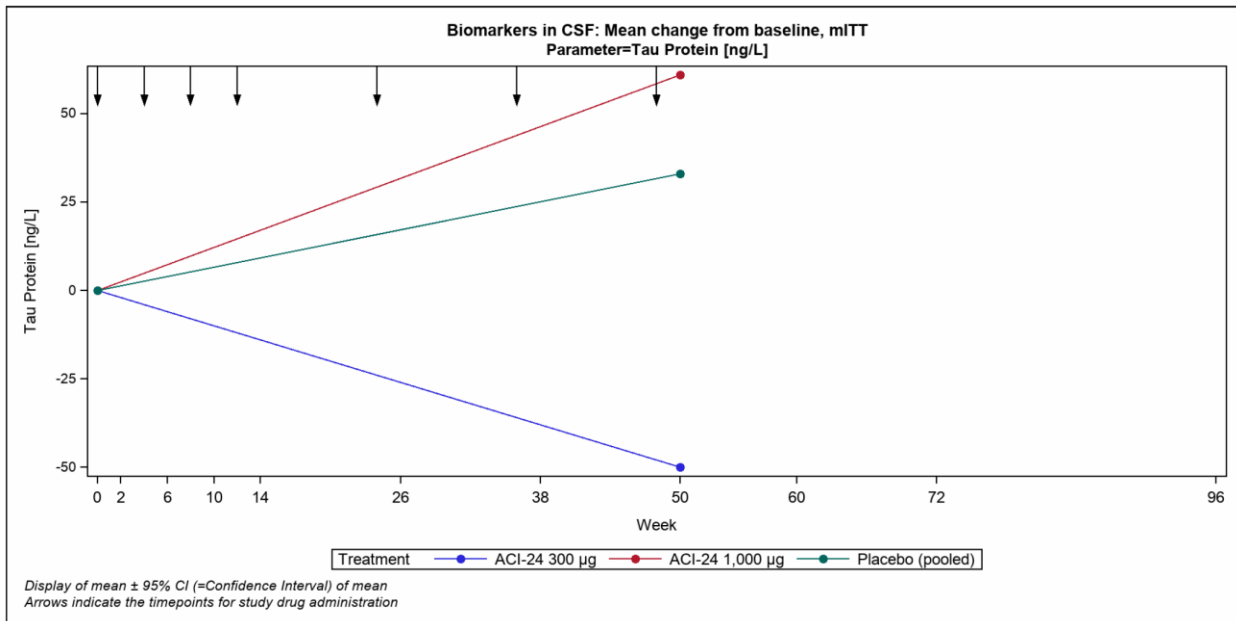
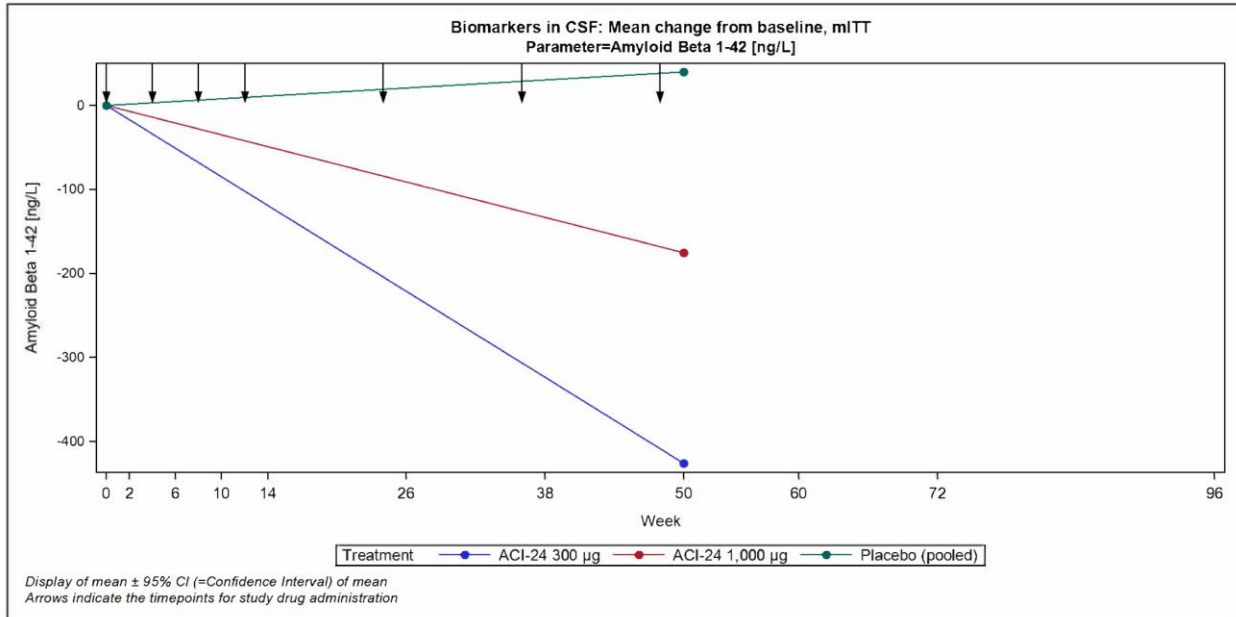


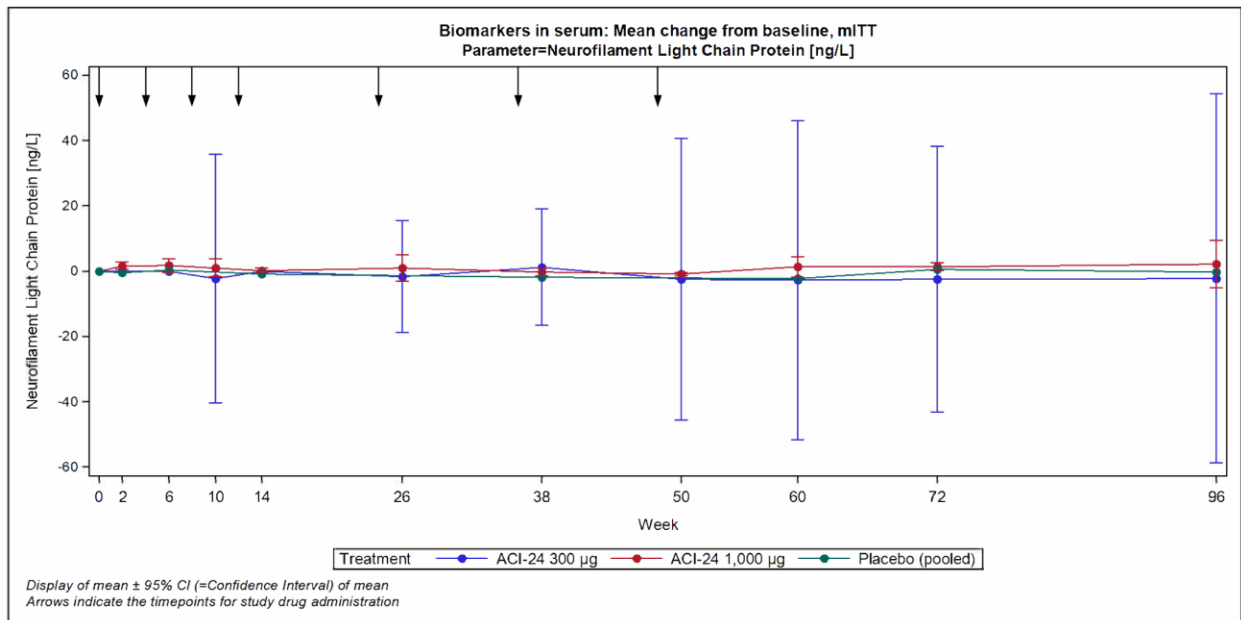
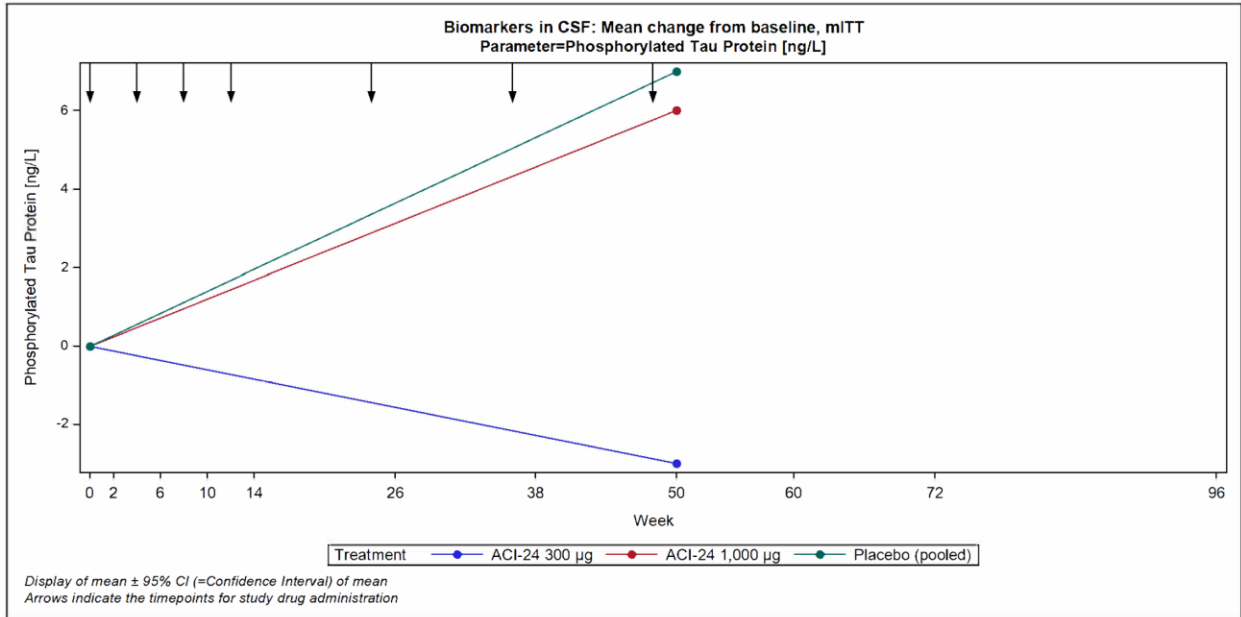
eFigure 3. Anti–Amyloid- β 1-42 Immunoglobulin G Titer in Serum Using the Meso Scale Discovery Free Assay: Change From Baseline in Modified Intention-to-Treat Population per Individual Participant

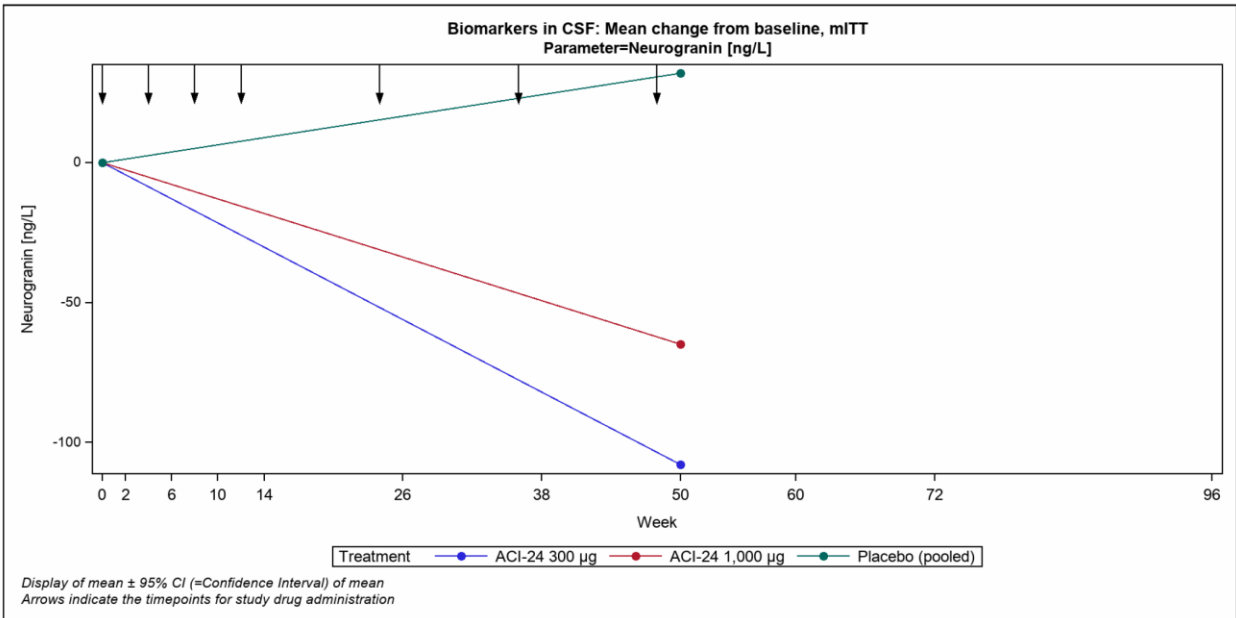
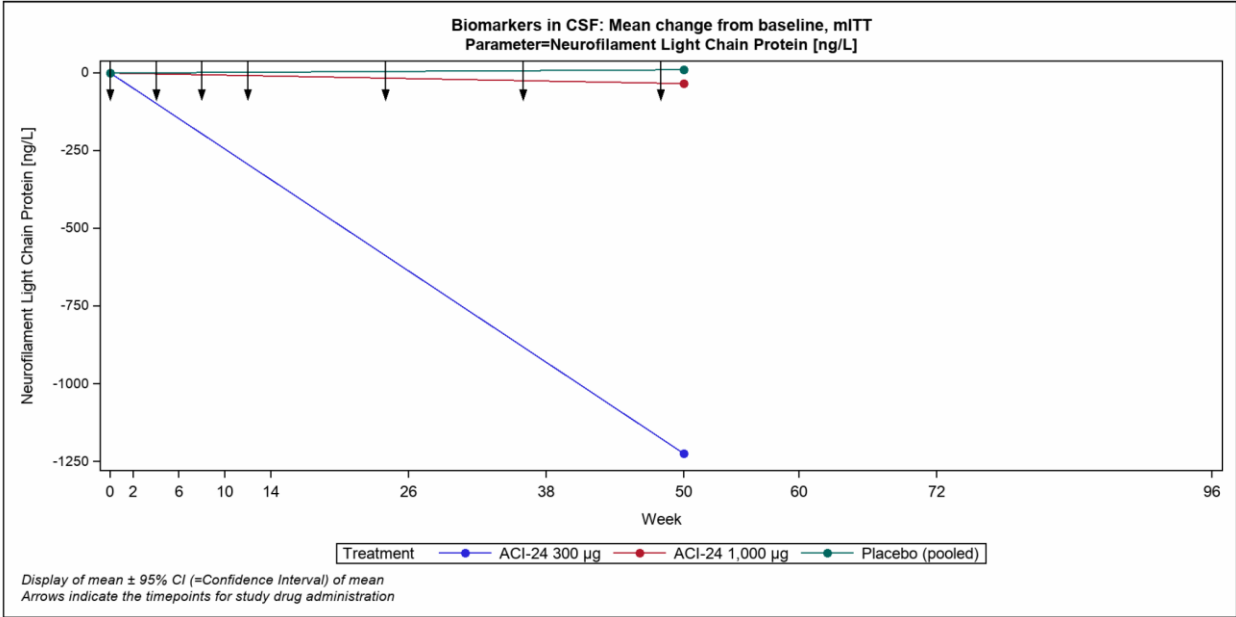


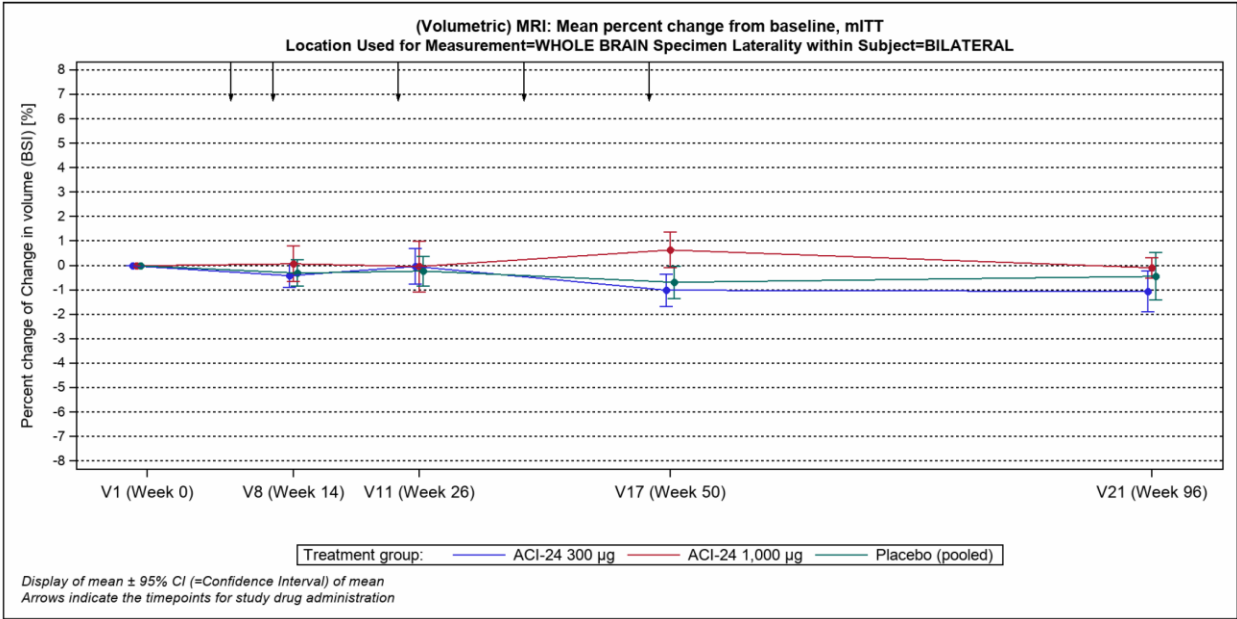
Abbreviations: A β ₁₋₄₂=amyloid beta 1-42; AU=arbitrary units; IgG=immunoglobulin G; mITT=modified Intent-to-Treat; mL=milliliters; MSD=Meso Scale Discovery assay platform

eFigure 4. Alzheimer Disease Biomarkers









eFigure 5. Cognitive Measures

