

Table 14.2.1.1.12.1

Summary of Binding Antibody Levels Specific to SARS-CoV-2 Spike Protein by ELISA
Per-Protocol Set for SARS-CoV-2-specific bAb

Antibody: VAC65 Spike IgG Antibody (AU/mL) (LLOQ: 1, ULOQ: 2052) ADIS.PARAMCD=V65IGGS, LLOQ=ADIS.ISLLOQ, ULOQ=ADIS.ULOQ

Timepoint Data Category Statistic	N where ADSL.PPBABFL=Y and ADSL.TRT01PN in (1, 2, 3)		Overall mRNA-1273			
	Placebo (N=XXX)	ADSL.TRT01PN=1 50 µg (N=XXX)	ADSL.TRT01PN=2 100 µg (N=XXX)	ADSL.TRT01PN=3	Total (N=XXX)	
Baseline						
n[1]	xxx	xxx	xxx	xxx	xxx	
GM Level	xx.x	xx.x	xx.x	xx.x	xx.x	
95% CI [2]	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	
Median	xx.x	xx.x	xx.x	xx.x	xx.x	
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	
Baseline Summary of ADIS.AVAL where ADIS.ABLFL=Y and ADIS.ANL01FL=Y and ADIS.PARAMCD = V65IGGS						

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Timepoint Data Category Statistic	Overall			
	Placebo (N=XXX)	50 µg (N=XXX)	100 µg (N=XXX)	Total (N=XXX)
Day XX	Day XX Summary of ADIS.AVAL where ADIS.AVISIT = 'DAY XX' and ADIS.ANL01FL=Y and PARAMCD = V65IGGS			
n[3]		x	xxx	xxx
GM Level		xx	xx.xx	xx.xx
95% CI [2]	xx.xx, xx.xx	xx.xx, xx.xx	xx.xx, xx.xx	xx.xx, xx.xx
Median	xx.xx	xx.xx	xx.xx	xx.xx
Min, Max	xx.x, xxx.x	xx.x, xxx.x	xx.x, xxx.x	xx.x, xxx.x
GM Fold-Rise	xx.xx	xx.xx	xx.xx	xx.xx
95% CI [2]	xxx.xx, xxx.xx	xxx.xx, xxx.xx	xxx.xx, xxx.xx	xxx.xx, xxx.xx
Seroconversion [4]				
n[5] (%)	ADIS.CRIT4FL = Y xxx(xx.x)	xxx(xx.x)	xxx(xx.x)	xxx(xx.x)
95% CI [6]	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Seroresponse [7]				
n[5] (%)	ADIS.CRIT5FL = Y xxx(xx.x)	xxx(xx.x)	xxx(xx.x)	xxx(xx.x)
95% CI [6]	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
>=2-fold Increase from Baseline [8]				
n[5] (%)	ADIS.CRIT1FL = Y xxx(xx.x)	xxx(xx.x)	xxx(xx.x)	xxx(xx.x)
95% CI [6]	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x

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		Overall			
		mRNA-1273			
Timepoint		Placebo	50 µg	100 µg	Total
Data Category		(N=XXX)	(N=XXX)	(N=XXX)	(N=XXX)
Statistic					
>=3-fold Increase	ADIS.CRIT2FL = Y				
from Baseline [8]					
n[5] (%)		xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
95% CI [6]		xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
>=4-fold Increase					
from Baseline [8]					
n[5] (%)	ADIS.CRIT3FL = Y	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
95% CI [6]		xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x

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