COVID-19 Correlates of Risk Analysis Report

COVID-19 Prevention Network (CoVPN) Biostatistics Team

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Chapter 1

Summary Tables

Table 1. Demographic and Clinical Characteristics at Baseline in the baseline SARS-CoV-2 negative per-protocol cohort

Characteristics	Vaccine (N = 914)	Placebo (N = 163)	Total (N = 1077)
Age			
Age $\geq$ 65	482 (52.7%)	83 (50.9%)	565 (52.5%)
Age $<$ 65	432 (47.3%)	80 (49.1%)	512 (47.5%)
Mean (Range)	58.6 (18.0, 85.0)	59.0 (18.0, 85.0)	58.7 (18.0, 85.0)
BMI			
Mean $\pm$ SD	30.1 $\pm$ 7.0	29.6 $\pm$ 7.2	30.0 $\pm$ 7.0
Sex			
Female	519 (56.8%)	87 (53.4%)	606 (56.3%)
Male	395 (43.2%)	76 (46.6%)	471 (43.7%)
Race			
White Non-Hispanic	362 (43.8%)	67 (44.7%)	429 (43.9%)
Black or African American	195 (23.6%)	39 (26.0%)	234 (24.0%)
Asian	67 (8.1%)	12 (8.0%)	79 (8.1%)
American Indian or Alaska Native	13 (1.6%)	5 (3.3%)	18 (1.8%)
Native Hawaiian or Other Pacific Islander	17 (2.1%)	1 (0.7%)	18 (1.8%)
Multiracial	52 (6.3%)	8 (5.3%)	60 (6.1%)
Other	34 (4.1%)	4 (2.7%)	38 (3.9%)
Not reported and unknown	87 (10.5%)	14 (9.3%)	101 (10.3%)
Communities of Color	420 (53.7%)	73 (52.1%)	493 (53.5%)
Hispanic or Latino ethnicity			
Hispanic or Latino	136 (14.9%)	20 (12.3%)	156 (14.5%)
Not Hispanic or Latino	690 (75.5%)	130 (79.8%)	820 (76.1%)
Not reported and unknown	88 (9.6%)	13 (8.0%)	101 (9.4%)

(continued)

Characteristics	Vaccine (N = 914)	Placebo (N = 163)	Total (N = 1077)
Risk for Severe Covid-19			
At-risk	469 (51.3%)	84 (51.5%)	553 (51.3%)
Not at-risk	445 (48.7%)	79 (48.5%)	524 (48.7%)

This table summarises the random subcohort, which was randomly sampled from the per-protocol individuals without a COVID failure event ¡ 7 days post Day 57. The sampling was stratified by the key baseline covariates: assigned treatment arm, baseline SARS-CoV-2 status (defined by serostatus and possibly also NAAT and/or RNA PCR testing), any additional important demographic factors such as the randomization strata (e.g., defined by age and/or co-morbidities).

Table 2. Demographic and Clinical Characteristics at Baseline in the baseline SARS-CoV-2 positive per-protocol cohort

Characteristics	Vaccine (N = 274)	Placebo (N = 270)	Total (N = 544)
Age			
Age $\geq$ 65	128 (46.7%)	123 (45.6%)	251 (46.1%)
Age $<$ 65	146 (53.3%)	147 (54.4%)	293 (53.9%)
Mean (Range)	56.0 (18.0, 85.0)	55.8 (18.0, 85.0)	55.9 (18.0, 85.0)
BMI			
Mean $\pm$ SD	30.7 $\pm$ 6.8	30.1 $\pm$ 7.2	30.4 $\pm$ 7.0
Sex			
Female	153 (55.8%)	155 (57.4%)	308 (56.6%)
Male	121 (44.2%)	115 (42.6%)	236 (43.4%)
Race			
White Non-Hispanic	125 (49.8%)	121 (49.0%)	246 (49.4%)
Black or African American	52 (20.7%)	60 (24.3%)	112 (22.5%)
Asian	24 (9.6%)	13 (5.3%)	37 (7.4%)
American Indian or Alaska Native	6 (2.4%)	4 (1.6%)	10 (2.0%)
Native Hawaiian or Other Pacific Islander	5 (2.0%)	1 (0.4%)	6 (1.2%)
Multiracial	12 (4.8%)	19 (7.7%)	31 (6.2%)
Other	7 (2.8%)	5 (2.0%)	12 (2.4%)
Not reported and unknown	20 (8.0%)	24 (9.7%)	44 (8.8%)
Communities of Color	120 (49.0%)	111 (47.8%)	231 (48.4%)
Hispanic or Latino ethnicity			
Hispanic or Latino	35 (12.8%)	38 (14.1%)	73 (13.4%)
Not Hispanic or Latino	217 (79.2%)	214 (79.3%)	431 (79.2%)
Not reported and unknown	22 (8.0%)	18 (6.7%)	40 (7.4%)
Risk for Severe Covid-19			
At-risk	125 (45.6%)	123 (45.6%)	248 (45.6%)
Not at-risk	149 (54.4%)	147 (54.4%)	296 (54.4%)

This table summarises the random subcohort, which was randomly sampled from the per-protocol individuals without a COVID failure event ¡ 7 days post Day 57. The sampling was stratified by the key baseline covariates: assigned treatment arm, baseline SARS-CoV-2 status (defined by serostatus and possibly also NAAT and/or RNA PCR testing), any additional important demographic factors such as the randomization strata (e.g., defined by age and/or co-morbidities).

Table 3. Antibody levels in the baseline SARS-CoV-2 negative per-protocol cohort (vaccine recipients)

		Baseline SARS-CoV-2 Negative Vaccine Recipients							
		Cases*			Non-Cases/Control			Comparison	
Visit	Marker	N	Resp rate	GMT/GMC	N	Resp rate	GMT/GMC	Resp Rate Difference	GMTR/GMCR
Day 29	Anti N IgG (IU/ml)	11	64.1/64.1 = 100.0% (100.0%, 100.0%)	9163 (3359, 24998)	903	13230.9/13230.9 = 100.0% (100.0%, 100.0%)	23718 (20083, 28010)	0% (0%, 0%)	0.39 (0.14, 1.07)
Day 29	Anti RBD IgG (IU/ml)	11	64.1/64.1 = 100.0% (100.0%, 100.0%)	9820 (4734, 20366)	903	13230.9/13230.9 = 100.0% (100.0%, 100.0%)	23105 (20011, 26677)	0% (0%, 0%)	0.43 (0.20, 0.89)
Day 29	Anti Spike IgG (IU/ml)	11	64.1/64.1 = 100.0% (100.0%, 100.0%)	12852 (7097, 23271)	903	13230.9/13230.9 = 100.0% (100.0%, 100.0%)	41328 (37060, 46086)	0% (0%, 0%)	0.31 (0.17, 0.57)
Day 29	Pseudovirus-nAb ID50	11	56.7/64.1 = 90.9% (46.3%, 99.1%)	37 (16, 86)	903	11676.4/13230.9 = 88.3% (84.8%, 91.1%)	107 (91, 126)	2.6% (-42.1%, 11.6%)	0.35 (0.15, 0.82)
Day 29	Pseudovirus-nAb ID80	11	56.1/64.1 = 81.8% (42.0%, 96.5%)	103 (30, 351)	903	12465.5/13230.9 = 94.2% (91.6%, 96.1%)	190 (161, 223)	-12.4% (-52.3%, 2.6%)	0.54 (0.16, 1.87)
Day 57	Anti N IgG (IU/ml)	11	64.1/64.1 = 100.0% (100.0%, 100.0%)	110124 (35353, 343038)	903	13230.9/13230.9 = 100.0% (100.0%, 100.0%)	327744 (269226, 398981)	0% (0%, 0%)	0.34 (0.11, 1.06)
Day 57	Anti RBD IgG (IU/ml)	11	64.1/64.1 = 100.0% (100.0%, 100.0%)	334195 (161041, 693528)	903	13230.9/13230.9 = 100.0% (100.0%, 100.0%)	974227 (829937, 1143602)	0% (0%, 0%)	0.34 (0.16, 0.72)
Day 57	Anti Spike IgG (IU/ml)	11	64.1/64.1 = 100.0% (100.0%, 100.0%)	240794 (105801, 548023)	903	13230.9/13230.9 = 100.0% (100.0%, 100.0%)	2116905 (1856215, 2414208)	0% (0%, 0%)	0.11 (0.05, 0.26)
Day 57	Pseudovirus-nAb ID50	11	64.1/64.1 = 100.0% (100.0%, 100.0%)	188 (73, 487)	903	13095.3/13230.9 = 99.0% (98.0%, 99.5%)	1517 (1244, 1850)	1% (0.5%, 2%)	0.12 (0.05, 0.33)
Day 57	Pseudovirus-nAb ID80	11	64.1/64.1 = 100.0% (100.0%, 100.0%)	350 (165, 740)	903	13110.7/13230.9 = 99.1% (97.1%, 99.7%)	2249 (1829, 2766)	0.9% (0.3%, 2.9%)	0.16 (0.07, 0.34)

*Cases are baseline negative per-protocol vaccine recipients with the symptomatic infection COVID-19 primary endpoint diagnosed starting 7 days after the Day 57 study visit. Non-cases/Controls are baseline negative per-protocol vaccine recipients sampled into the random subcohort with no evidence of SARS-CoV-2 infection up to the time of data cut.

Table 4. Antibody levels in the baseline SARS-CoV-2 positive per-protocol cohort (vaccine recipients)

		Baseline SARS-CoV-2 Positive Vaccine Recipients							
		Cases*			Non-Cases/Control			Comparison	
Visit	Marker	N	Resp rate	GMT/GMC	N	Resp rate	GMT/GMC	Resp Rate Difference	GMTR/GMCR
Day 29	Anti N IgG (IU/ml)	2	17.2/17.2 = 100.0%	130813 (3444, 4969160)	272	1414.8/1414.8 = 100.0% (100.0%, 100.0%)	43029 (32995, 56114)	0%	3.04 (0.08, 116.61)
Day 29	Anti RBD IgG (IU/ml)	2	17.2/17.2 = 100.0%	153444 (6865, 3429945)	272	1414.8/1414.8 = 100.0% (100.0%, 100.0%)	35885 (27859, 46223)	0%	4.28 (0.19, 96.57)
Day 29	Anti Spike IgG (IU/ml)	2	17.2/17.2 = 100.0%	104737 (14230, 770889)	272	1414.8/1414.8 = 100.0% (100.0%, 100.0%)	80297 (65042, 99128)	0%	1.30 (0.18, 9.71)
Day 29	Pseudovirus-nAb ID50	2	17.2/17.2 = 100.0%	323 (71, 1472)	272	1365.9/1414.8 = 96.5% (91.4%, 98.6%)	185 (141, 244)	3.5%	1.74 (0.37, 8.13)
Day 29	Pseudovirus-nAb ID80	2	17.2/17.2 = 100.0%	481 (4, 60966)	272	1390.1/1414.8 = 98.2% (93.6%, 99.5%)	428 (320, 573)	1.8%	1.12 (0.01, 143.66)
Day 57	Anti N IgG (IU/ml)	2	17.2/17.2 = 100.0%	2440779 (43120, 138159231)	272	1414.8/1414.8 = 100.0% (100.0%, 100.0%)	985914 (697182, 1394221)	0%	2.48 (0.04, 142.23)
Day 57	Anti RBD IgG (IU/ml)	2	17.2/17.2 = 100.0%	2749023 (61314, 123253076)	272	1414.8/1414.8 = 100.0% (100.0%, 100.0%)	2328268 (1802226, 3007855)	0%	1.18 (0.03, 53.40)
Day 57	Anti Spike IgG (IU/ml)	2	17.2/17.2 = 100.0%	3627856 (538606, 24435925)	272	1414.8/1414.8 = 100.0% (100.0%, 100.0%)	5409865 (4378235, 6684574)	0%	0.67 (0.10, 4.57)
Day 57	Pseudovirus-nAb ID50	2	17.2/17.2 = 100.0%	1829 (160, 20945)	272	1414.8/1414.8 = 100.0% (100.0%, 100.0%)	5816 (3934, 8599)	0%	0.31 (0.03, 3.72)
Day 57	Pseudovirus-nAb ID80	2	17.2/17.2 = 100.0%	5772 (290, 114704)	272	1414.8/1414.8 = 100.0% (100.0%, 100.0%)	7960 (5601, 11311)	0%	0.73 (0.04, 14.71)

*Cases are baseline positive per-protocol vaccine recipients with the symptomatic infection COVID-19 primary endpoint diagnosed starting 7 days after the Day 57 study visit. Non-cases/Controls are baseline negative per-protocol vaccine recipients sampled into the random subcohort with no evidence of SARS-CoV-2 infection up to the time of data cut.

Table 5. Antibody levels in the baseline SARS-CoV-2 positive per-protocol cohort (placebo recipients)

		Baseline SARS-CoV-2 Positive Placebo Recipients							
		Cases*			Non-Cases/Control			Comparison	
Visit	Marker	N	Resp rate	GMT/GMC	N	Resp rate	GMT/GMC	Resp Rate Difference	GMTR/GMCR
Day 29	Anti N IgG (IU/ml)	2	4/4 = 100.0%	44658 (376, 5310188)	268	1353/1353 = 100.0% (100.0%, 100.0%)	12485 (9430, 16531)	0%	3.58 (0.03, 428.83)
Day 29	Anti RBD IgG (IU/ml)	2	4/4 = 100.0%	42959 (6946, 265696)	268	1353/1353 = 100.0% (100.0%, 100.0%)	12824 (10117, 16255)	0%	3.35 (0.53, 21.04)
Day 29	Anti Spike IgG (IU/ml)	2	4/4 = 100.0%	37021 (6048, 226609)	268	1353/1353 = 100.0% (100.0%, 100.0%)	18162 (15129, 21803)	0%	2.04 (0.33, 12.59)
Day 29	Pseudovirus-nAb ID50	2	1.6/4 = 50.0%	93 (0, 28176)	268	1138.2/1353 = 84.1% (76.9%, 89.4%)	51 (40, 66)	-34.1%	1.80 (0.01, 550.47)
Day 29	Pseudovirus-nAb ID80	2	4/4 = 100.0%	372 (107, 1290)	268	1254.5/1353 = 92.7% (86.8%, 96.1%)	129 (98, 169)	7.3%	2.89 (0.81, 10.32)
Day 57	Anti N IgG (IU/ml)	2	4/4 = 100.0%	652604 (78974, 5392810)	268	1353/1353 = 100.0% (100.0%, 100.0%)	129537 (92255, 181885)	0%	5.04 (0.59, 42.78)
Day 57	Anti RBD IgG (IU/ml)	2	4/4 = 100.0%	2348281 (194513, 28349939)	268	1353/1353 = 100.0% (100.0%, 100.0%)	380897 (298347, 486288)	0%	6.17 (0.50, 75.32)
Day 57	Anti Spike IgG (IU/ml)	2	4/4 = 100.0%	767715 (603034, 977368)	268	1353/1353 = 100.0% (100.0%, 100.0%)	676673 (530979, 862343)	0%	1.13 (0.81, 1.60)
Day 57	Pseudovirus-nAb ID50	2	4/4 = 100.0%	1515 (18, 129242)	268	1297.7/1353 = 95.9% (90.6%, 98.3%)	565 (408, 782)	4.1%	2.68 (0.03, 231.59)
Day 57	Pseudovirus-nAb ID80	2	4/4 = 100.0%	6066 (474, 77675)	268	1326.1/1353 = 98.0% (93.2%, 99.4%)	1319 (934, 1864)	2%	4.60 (0.35, 60.26)

*Cases are baseline negative per-protocol vaccine recipients with the symptomatic infection COVID-19 primary endpoint diagnosed starting 7 days after the Day 57 study visit. Non-cases/Controls are baseline negative per-protocol vaccine recipients sampled into the random subcohort with no evidence of SARS-CoV-2 infection up to the time of data cut.

Chapter 2

Graphical Description of Antibody Marker Data

2.1 Boxplots

2.1.1 Baseline seronegative

Figure 2.1: (Mock data) Boxplots of D57 Ab markers: baseline negative vaccine arm.

2.1.2 Baseline seropositive

2.2 Weighted RCDF plots

Figure 2.2: (Mock data) Boxplots of D57 fold-rise over D1 Ab markers: baseline negative vaccine arm.

2.2.1 Baseline seronegative

2.2.2 Baseline seropositive

2.3 Weighted RCDF plots showing threshold correlate concentration for overall vaccine efficacy

2.3.1 Baseline seronegative

2.4 Spaghetti plots

2.5 Violin and line plots

Figure 2.3: (Mock data) Boxplots of D29 Ab markers: baseline negative vaccine arm.

Figure 2.4: (Mock data) Boxplots of D29 fold-rise over D1 Ab markers: baseline negative vaccine arm.

Figure 2.5: (Mock data) Boxplots of D57 Ab markers: baseline positive vaccine arm.

Figure 2.6: (Mock data) Boxplots of D57 fold-rise over D1 Ab markers: baseline positive vaccine arm.

Figure 2.7: (Mock data) Boxplots of D29 Ab markers: baseline positive vaccine arm.

Figure 2.8: (Mock data) Boxplots of D29 fold-rise over D1 Ab markers: baseline positive vaccine arm.

Figure 2.9: (Mock data) RCDF plots for D57 Ab markers: baseline negative by treatment arm.

Figure 2.10: (Mock data) RCDF plots for D57 fold-rise over D1 Ab markers: baseline negative by treatment arm.

Figure 2.11: (Mock data) RCDF plots for D29 Ab markers: baseline negative by treatment arm.

Figure 2.12: (Mock data) RCDF plots for D29 fold-rise over D1 Ab markers: baseline negative by treatment arm.

Figure 2.13: (Mock data) RCDF plots for D57 Ab markers: baseline positive by treatment arm.

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Figure 2.15: (Mock data) RCDF plots for D29 Ab markers: baseline positive by treatment arm.

Figure 2.16: (Mock data) RCDF plots for D29 fold-rise over D1 Ab markers: baseline positive by treatment arm.

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Figure 2.18: (Mock data) Marker RCDF of D57 anti-RBD binding Ab: baseline negative vaccine arm

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Figure 2.21: (Mock data) Spaghetti Plots of Marker Trajectory: baseline negative vaccine arm

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Figure 2.24: (Mock data) lineplots of Binding Antibody to Spike: baseline negative vaccine arm (2 timepoints)

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Figure 2.31: (Mock data) violinplots of Binding Antibody to Spike: baseline negative placebo arm (2 timepoints)

Figure 2.32: (Mock data) violinplots of Binding Antibody to Spike: baseline negative vaccine arm (2 timepoints)

Figure 2.33: (Mock data) violinplots of Binding Antibody to RBD: baseline negative placebo arm (2 timepoints)

Figure 2.34: (Mock data) violinplots of Binding Antibody to RBD: baseline negative vaccine arm (2 timepoints)

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Figure 2.36: (Mock data) violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm (2 timepoints)

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Figure 2.44: (Mock data) lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm (3 timepoints)

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Figure 2.48: (Mock data) violinplots of Binding Antibody to Spike: baseline negative vaccine arm (3 timepoints)

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Figure 2.50: (Mock data) violinplots of Binding Antibody to RBD: baseline negative vaccine arm (3 timepoints)

Figure 2.51: (Mock data) violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm (3 timepoints)

Figure 2.52: (Mock data) violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm (3 timepoints)

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Figure 2.54: (Mock data) violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm (3 timepoints)

Figure 2.55: (Mock data) lineplots of Binding Antibody to Spike: baseline negative placebo arm by age (2 timepoints)

Figure 2.56: (Mock data) lineplots of Binding Antibody to Spike: baseline negative vaccine arm by age (2 timepoints)

Figure 2.57: (Mock data) lineplots of Binding Antibody to RBD: baseline negative placebo arm by age (2 timepoints)

Figure 2.58: (Mock data) lineplots of Binding Antibody to RBD: baseline negative vaccine arm by age (2 timepoints)

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Figure 2.66: (Mock data) violinplots of Binding Antibody to RBD: baseline negative vaccine arm by age (2 timepoints)

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Figure 2.68: (Mock data) violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by age (2 timepoints)

Figure 2.69: (Mock data) violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by age (2 timepoints)

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Figure 2.149: (Mock data) violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by age and risk condition (3 timepoints)

Figure 2.150: (Mock data) violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by age and risk condition (3 timepoints)

Figure 2.151: (Mock data) lineplots of Binding Antibody to Spike: baseline negative placebo arm by sex assigned at birth (2 timepoints)

Figure 2.152: (Mock data) lineplots of Binding Antibody to Spike: baseline negative vaccine arm by sex assigned at birth (2 timepoints)

Figure 2.153: (Mock data) lineplots of Binding Antibody to RBD: baseline negative placebo arm by sex assigned at birth (2 timepoints)

Figure 2.154: (Mock data) lineplots of Binding Antibody to RBD: baseline negative vaccine arm by sex assigned at birth (2 timepoints)

Figure 2.155: (Mock data) lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by sex assigned at birth (2 timepoints)

Figure 2.156: (Mock data) lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by sex assigned at birth (2 timepoints)

Figure 2.157: (Mock data) lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by sex assigned at birth (2 timepoints)

Figure 2.158: (Mock data) lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by sex assigned at birth (2 timepoints)

Figure 2.159: (Mock data) violinplots of Binding Antibody to Spike: baseline negative placebo arm by sex assigned at birth (2 timepoints)

Figure 2.160: (Mock data) violinplots of Binding Antibody to Spike: baseline negative vaccine arm by sex assigned at birth (2 timepoints)

Figure 2.161: (Mock data) violinplots of Binding Antibody to RBD: baseline negative placebo arm by sex assigned at birth (2 timepoints)

Figure 2.162: (Mock data) violinplots of Binding Antibody to RBD: baseline negative vaccine arm by sex assigned at birth (2 timepoints)

Figure 2.163: (Mock data) violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by sex assigned at birth (2 timepoints)

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Figure 2.167: (Mock data) lineplots of Binding Antibody to Spike: baseline negative placebo arm by sex assigned at birth (3 timepoints)

Figure 2.168: (Mock data) lineplots of Binding Antibody to Spike: baseline negative vaccine arm by sex assigned at birth (3 timepoints)

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Figure 2.171: (Mock data) lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by sex assigned at birth (3 timepoints)

Figure 2.172: (Mock data) lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by sex assigned at birth (3 timepoints)

Figure 2.173: (Mock data) lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by sex assigned at birth (3 timepoints)

Figure 2.174: (Mock data) lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by sex assigned at birth (3 timepoints)

Figure 2.175: (Mock data) violinplots of Binding Antibody to Spike: baseline negative placebo arm by sex assigned at birth (3 timepoints)

Figure 2.176: (Mock data) violinplots of Binding Antibody to Spike: baseline negative vaccine arm by sex assigned at birth (3 timepoints)

Figure 2.177: (Mock data) violinplots of Binding Antibody to RBD: baseline negative placebo arm by sex assigned at birth (3 timepoints)

Figure 2.178: (Mock data) violinplots of Binding Antibody to RBD: baseline negative vaccine arm by sex assigned at birth (3 timepoints)

Figure 2.179: (Mock data) violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by sex assigned at birth (3 timepoints)

Figure 2.180: (Mock data) violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by sex assigned at birth (3 timepoints)

Figure 2.181: (Mock data) violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by sex assigned at birth (3 timepoints)

Figure 2.182: (Mock data) violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by sex assigned at birth (3 timepoints)

Figure 2.183: (Mock data) lineplots of Binding Antibody to Spike: baseline negative placebo arm by race and ethnic group (2 timepoints)

Figure 2.184: (Mock data) lineplots of Binding Antibody to Spike: baseline negative vaccine arm by race and ethnic group (2 timepoints)

Figure 2.185: (Mock data) lineplots of Binding Antibody to RBD: baseline negative placebo arm by race and ethnic group (2 timepoints)

Figure 2.186: (Mock data) lineplots of Binding Antibody to RBD: baseline negative vaccine arm by race and ethnic group (2 timepoints)

Figure 2.187: (Mock data) lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by race and ethnic group (2 timepoints)

Figure 2.188: (Mock data) lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by race and ethnic group (2 timepoints)

Figure 2.189: (Mock data) lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by race and ethnic group (2 timepoints)

Figure 2.190: (Mock data) lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by race and ethnic group (2 timepoints)

Figure 2.191: (Mock data) violinplots of Binding Antibody to Spike: baseline negative placebo arm by race and ethnic group (2 timepoints)

Figure 2.192: (Mock data) violinplots of Binding Antibody to Spike: baseline negative vaccine arm by race and ethnic group (2 timepoints)

Figure 2.193: (Mock data) violinplots of Binding Antibody to RBD: baseline negative placebo arm by race and ethnic group (2 timepoints)

Figure 2.194: (Mock data) violinplots of Binding Antibody to RBD: baseline negative vaccine arm by race and ethnic group (2 timepoints)

Figure 2.195: (Mock data) violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by race and ethnic group (2 timepoints)

Figure 2.196: (Mock data) violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by race and ethnic group (2 timepoints)

Figure 2.197: (Mock data) violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by race and ethnic group (2 timepoints)

Figure 2.198: (Mock data) violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by race and ethnic group (2 timepoints)

Figure 2.199: (Mock data) lineplots of Binding Antibody to Spike: baseline negative placebo arm by race and ethnic group (3 timepoints)

Figure 2.200: (Mock data) lineplots of Binding Antibody to Spike: baseline negative vaccine arm by race and ethnic group (3 timepoints)

Figure 2.201: (Mock data) lineplots of Binding Antibody to RBD: baseline negative placebo arm by race and ethnic group (3 timepoints)

Figure 2.202: (Mock data) lineplots of Binding Antibody to RBD: baseline negative vaccine arm by race and ethnic group (3 timepoints)

Figure 2.203: (Mock data) lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by race and ethnic group (3 timepoints)

Figure 2.204: (Mock data) lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by race and ethnic group (3 timepoints)

Figure 2.205: (Mock data) lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by race and ethnic group (3 timepoints)

Figure 2.206: (Mock data) lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by race and ethnic group (3 timepoints)

Figure 2.207: (Mock data) violinplots of Binding Antibody to Spike: baseline negative placebo arm by race and ethnic group (3 timepoints)

Figure 2.208: (Mock data) violinplots of Binding Antibody to Spike: baseline negative vaccine arm by race and ethnic group (3 timepoints)

Figure 2.209: (Mock data) violinplots of Binding Antibody to RBD: baseline negative placebo arm by race and ethnic group (3 timepoints)

Figure 2.210: (Mock data) violinplots of Binding Antibody to RBD: baseline negative vaccine arm by race and ethnic group (3 timepoints)

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Figure 2.212: (Mock data) violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by race and ethnic group (3 timepoints)

Figure 2.213: (Mock data) violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by race and ethnic group (3 timepoints)

Figure 2.214: (Mock data) violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by race and ethnic group (3 timepoints)

Figure 2.215: (Mock data) lineplots of Binding Antibody to Spike: baseline negative placebo arm by dichotomous classification of race and ethnic group (2 timepoints)

Figure 2.216: (Mock data) lineplots of Binding Antibody to Spike: baseline negative vaccine arm by dichotomous classification of race and ethnic group (2 timepoints)

Figure 2.217: (Mock data) lineplots of Binding Antibody to RBD: baseline negative placebo arm by dichotomous classification of race and ethnic group (2 timepoints)

Figure 2.218: (Mock data) lineplots of Binding Antibody to RBD: baseline negative vaccine arm by dichotomous classification of race and ethnic group (2 timepoints)

Figure 2.219: (Mock data) lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by dichotomous classification of race and ethnic group (2 timepoints)

Figure 2.220: (Mock data) lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by dichotomous classification of race and ethnic group (2 timepoints)

Figure 2.221: (Mock data) lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by dichotomous classification of race and ethnic group (2 timepoints)

Figure 2.222: (Mock data) lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by dichotomous classification of race and ethnic group (2 timepoints)

Figure 2.223: (Mock data) violinplots of Binding Antibody to Spike: baseline negative placebo arm by dichotomous classification of race and ethnic group (2 timepoints)

Figure 2.224: (Mock data) violinplots of Binding Antibody to Spike: baseline negative vaccine arm by dichotomous classification of race and ethnic group (2 timepoints)

Figure 2.225: (Mock data) violinplots of Binding Antibody to RBD: baseline negative placebo arm by dichotomous classification of race and ethnic group (2 timepoints)

Figure 2.226: (Mock data) violinplots of Binding Antibody to RBD: baseline negative vaccine arm by dichotomous classification of race and ethnic group (2 timepoints)

Figure 2.227: (Mock data) violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by dichotomous classification of race and ethnic group (2 timepoints)

Figure 2.228: (Mock data) violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by dichotomous classification of race and ethnic group (2 timepoints)

Figure 2.229: (Mock data) violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by dichotomous classification of race and ethnic group (2 timepoints)

Figure 2.230: (Mock data) violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by dichotomous classification of race and ethnic group (2 timepoints)

Figure 2.231: (Mock data) lineplots of Binding Antibody to Spike: baseline negative placebo arm by dichotomous classification of race and ethnic group (3 timepoints)

Figure 2.232: (Mock data) lineplots of Binding Antibody to Spike: baseline negative vaccine arm by dichotomous classification of race and ethnic group (3 timepoints)

Figure 2.233: (Mock data) lineplots of Binding Antibody to RBD: baseline negative placebo arm by dichotomous classification of race and ethnic group (3 timepoints)

Figure 2.234: (Mock data) lineplots of Binding Antibody to RBD: baseline negative vaccine arm by dichotomous classification of race and ethnic group (3 timepoints)

Figure 2.235: (Mock data) lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by dichotomous classification of race and ethnic group (3 timepoints)

Figure 2.236: (Mock data) lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by dichotomous classification of race and ethnic group (3 timepoints)

Figure 2.237: (Mock data) lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by dichotomous classification of race and ethnic group (3 timepoints)

Figure 2.238: (Mock data) lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by dichotomous classification of race and ethnic group (3 timepoints)

Figure 2.239: (Mock data) violinplots of Binding Antibody to Spike: baseline negative placebo arm by dichotomous classification of race and ethnic group (3 timepoints)

Figure 2.240: (Mock data) violinplots of Binding Antibody to Spike: baseline negative vaccine arm by dichotomous classification of race and ethnic group (3 timepoints)

Figure 2.241: (Mock data) violinplots of Binding Antibody to RBD: baseline negative placebo arm by dichotomous classification of race and ethnic group (3 timepoints)

Figure 2.242: (Mock data) violinplots of Binding Antibody to RBD: baseline negative vaccine arm by dichotomous classification of race and ethnic group (3 timepoints)

Figure 2.243: (Mock data) violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by dichotomous classification of race and ethnic group (3 timepoints)

Figure 2.244: (Mock data) violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by dichotomous classification of race and ethnic group (3 timepoints)

Figure 2.245: (Mock data) violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by dichotomous classification of race and ethnic group (3 timepoints)

Figure 2.246: (Mock data) violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by dichotomous classification of race and ethnic group (3 timepoints)

Figure 2.247: (Mock data) scatterplots of Binding Antibody to Spike: baseline negative vaccine arm at day 1

Figure 2.248: (Mock data) scatterplots of Binding Antibody to Spike: baseline negative vaccine arm at day 29

Figure 2.249: (Mock data) scatterplots of Binding Antibody to Spike: baseline negative vaccine arm at day 57

Figure 2.250: (Mock data) scatterplots of Binding Antibody to RBD: baseline negative vaccine arm at day 1

Figure 2.251: (Mock data) scatterplots of Binding Antibody to RBD: baseline negative vaccine arm at day 29

Figure 2.252: (Mock data) scatterplots of Binding Antibody to RBD: baseline negative vaccine arm at day 57

Figure 2.253: (Mock data) scatterplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm at day 1

Figure 2.254: (Mock data) scatterplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm at day 29

Figure 2.255: (Mock data) scatterplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm at day 57

Figure 2.256: (Mock data) scatterplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm at day 1

Figure 2.257: (Mock data) scatterplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm at day 29

Figure 2.258: (Mock data) scatterplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm at day 57

Figure 2.259: (Mock data) scatterplots of Binding Antibody to Spike: by arm at day 1

Figure 2.260: (Mock data) scatterplots of Binding Antibody to Spike: by arm at day 29

Figure 2.261: (Mock data) scatterplots of Binding Antibody to Spike: by arm at day 57

Figure 2.262: (Mock data) scatterplots of Binding Antibody to RBD: by arm at day 1

Figure 2.263: (Mock data) scatterplots of Binding Antibody to RBD: by arm at day 29

Figure 2.264: (Mock data) scatterplots of Binding Antibody to RBD: by arm at day 57

Figure 2.265: (Mock data) scatterplots of Pseudovirus Neutralization ID50: by arm at day 1

Figure 2.266: (Mock data) scatterplots of Pseudovirus Neutralization ID50: by arm at day 29

Figure 2.267: (Mock data) scatterplots of Pseudovirus Neutralization ID50: by arm at day 57

Figure 2.268: (Mock data) scatterplots of Pseudovirus Neutralization ID80: by arm at day 1

Figure 2.269: (Mock data) scatterplots of Pseudovirus Neutralization ID80: by arm at day 29

Figure 2.270: (Mock data) scatterplots of Pseudovirus Neutralization ID80: by arm at day 57

Chapter 3

Day 57 Univariate CoR: Cox Models of Risk

The main regression model is the Cox proportional hazards model. All plots are made with Cox models fit unless specified otherwise.

3.1 Hazard ratios

Inference for Day 57 antibody marker covariate-adjusted correlates of risk of COVID in the vaccine group: Hazard ratios per 10-fold increment in the marker*

Mock Immunologic Marker	No. cases / No. at-risk**	HR per 10-fold incr. Pt. Est.	95% CI	P-value (2-sided)	q-value	FWER
Spike IgG (IU/ml)	70/13,295	0.10	(0.06-0.15)	<0.001	<0.001	<0.001
RBD IgG (IU/ml)	70/13,295	0.27	(0.20-0.37)	<0.001	<0.001	<0.001
PsV-nAb ID50	70/13,295	0.30	(0.23-0.40)	<0.001	<0.001	<0.001
PsV-nAb ID80	70/13,295	0.49	(0.37-0.63)	<0.001	<0.001	<0.001

*Baseline covariates adjusted for: age in years, at risk or not, community of color or not . Average follow-up time 172 days, maximum follow-up time 185 days.
**No. at-risk = number of per-protocol baseline negative vaccine recipients at-risk for COVID; no. cases = number of this cohort with an observed COVID endpoints starting 7 days post Day 57 visit.

Inference for Day 57 antibody marker covariate-adjusted correlates of risk of COVID in the vaccine group: Hazard ratios for Middle vs. Upper tertile vs. Lower tertile*

Mock Immunologic Marker	Tertile	No. cases / No. at-risk**	Attack rate	Haz. Ratio Pt. Est.	Haz. Ratio 95% CI	P-value (2-sided)	Overall P-value***	Overall q-value	Overall FWER
Spike IgG (IU/ml)	Lower	58/4,434	0.0131	1	N/A	N/A	<0.001	<0.001	<0.001
	Middle	11/4,436	0.0025	0.10	(0.05-0.19)	<0.001			
	Upper	1/4,424	0.0002	0.00	(0.00-0.03)	<0.001			
RBD IgG (IU/ml)	Lower	38/4,459	0.0085	1	N/A	N/A	<0.001	<0.001	<0.001
	Middle	27/4,397	0.0061	0.40	(0.23-0.69)	0.001			
	Upper	5/4,439	0.0011	0.05	(0.02-0.12)	<0.001			
PsV-nAb ID50	Lower	45/4,457	0.0101	1	N/A	N/A	<0.001	<0.001	<0.001
	Middle	21/4,364	0.0048	0.31	(0.17-0.56)	<0.001			
	Upper	5/4,475	0.0011	0.05	(0.02-0.12)	<0.001			
PsV-nAb ID80	Lower	35/4,443	0.0079	1	N/A	N/A	<0.001	<0.001	<0.001
	Middle	25/4,419	0.0057	0.46	(0.26-0.83)	0.010			
	Upper	10/4,433	0.0023	0.15	(0.07-0.33)	<0.001			
Placebo		719/13,359	0.0538						

*Baseline covariates adjusted for: age in years, at risk or not, community of color or not . Average follow-up time 172 days, maximum follow-up time 185 days. Cutpoints: Spike IgG (IU/ml) [6.03, 6.67), RBD IgG (IU/ml) [5.65, 6.39), PsV-nAb ID50 [2.74, 3.56), PsV-nAb ID80 [2.9, 3.83).
**No. at-risk = number of per-protocol baseline negative vaccine recipients at-risk for COVID at 7 days post Day 57 visit; no. cases = number of this cohort with an observed COVID endpoints.
***Generalized Wald-test p-value of the null hypothesis that the hazard rate is constant across the Lower, Middle, and Upper tertile groups.

Figure 3.1: Forest plots of hazard ratios per 10-fold increase in the marker among baseline seronegative vaccine recipients and subgroups with 95% point-wise confidence intervals.

Figure 3.2: Forest plots of hazard ratios per 10-fold increase in the Day 57 binding Ab to spike markers among baseline seronegative vaccine recipients (top row) and eight subpopulations (row 2-9) with 95% point-wise confidence intervals.

Figure 3.3: Forest plots of hazard ratios per 10-fold increase in the Day 57 binding Ab to RBD markers among baseline seronegative vaccine recipients (top row) and eight subpopulations (row 2-9) with 95% point-wise confidence intervals.

Figure 3.4: Forest plots of hazard ratios per 10-fold increase in the Day 57 pseudo neut ID50 markers among baseline seronegative vaccine recipients (top row) and eight subpopulations (row 2-9) with 95% point-wise confidence intervals.

Figure 3.5: Forest plots of hazard ratios per 10-fold increase in the Day 57 pseudo neut ID80 markers among baseline seronegative vaccine recipients (top row) and eight subpopulations (row 2-9) with 95% point-wise confidence intervals.

3.2 Marginalized risk and controlled vaccine efficacy plots

Figure 3.6: Marginalized cumulative risk by Day 174 as functions of Day 57 markers (=s) among baseline seronegative vaccine recipients with 95% bootstrap point-wise confidence bands. The horizontal lines indicate the overall cumulative risk of the placebo and vaccine arms by Day 174 and its 95% point-wise confidence interval. Histograms of the immunological markers in the vaccine arm are overlaid. lod: lower limit of detection.

Figure 3.7: Marginalized cumulative risk by Day 174 as functions of Day 57 markers above a threshold ($\geq s$) among baseline seronegative vaccine recipients with 95% bootstrap point-wise confidence bands (at least 5 cases are required). The horizontal lines indicate the overall cumulative risk of the vaccine arm by Day 174 and its 95% point-wise confidence interval. Histograms of the immunological markers in the vaccine arm are overlaid. lod: lower limit of detection.

Figure 3.8: Controlled VE with sensitivity analysis as functions of Day 57 markers (=s) among baseline seronegative vaccine recipients with 95% bootstrap point-wise confidence bands. Histograms of the immunological markers in the vaccine arm are overlaid. lod: lower limit of detection.

Figure 3.9: Marginalized cumulative incidence rate curves for trichotomized Day 57 markers among baseline seronegative vaccine recipients. The gray line is the overall cumulative incidence rate curve in the placebo arm.

Chapter 4

Day 29 Univariate CoR: Cox Models of Risk

The main regression model is the Cox proportional hazards model. All plots are made with Cox models fit unless specified otherwise.

4.1 Hazard ratios

Inference for Day 29 antibody marker covariate-adjusted correlates of risk of COVID in the vaccine group: Hazard ratios per 10-fold increment in the marker*

Mock Immunologic Marker	No. cases / No. at-risk**	HR per 10-fold incr. Pt. Est.	95% CI	P-value (2-sided)	q-value	FWER
Spike IgG (IU/ml)	81/13,315	0.09	(0.05-0.16)	<0.001	<0.001	<0.001
RBD IgG (IU/ml)	81/13,315	0.29	(0.20-0.42)	<0.001	<0.001	<0.001
PsV-nAb ID50	81/13,315	0.38	(0.28-0.51)	<0.001	<0.001	<0.001
PsV-nAb ID80	81/13,315	0.59	(0.43-0.81)	0.001	<0.001	<0.001

*Baseline covariates adjusted for: age in years, at risk or not, community of color or not . Average follow-up time 200 days, maximum follow-up time 213 days.
**No. at-risk = number of per-protocol baseline negative vaccine recipients at-risk for COVID; no. cases = number of this cohort with an observed COVID endpoints starting 7 days post Day 29 visit.

Inference for Day 29 antibody marker covariate-adjusted correlates of risk of COVID in the vaccine group: Hazard ratios for Middle vs. Upper tertile vs. Lower tertile*

Mock Immunologic Marker	Tertile	No. cases / No. at-risk**	Attack rate	Haz. Ratio Pt. Est.	Haz. Ratio 95% CI	P-value (2-sided)	Overall P-value***	Overall q-value	Overall FWER
Spike IgG (IU/ml)	Lower	49/4,460	0.0110	1	N/A	N/A	<0.001	<0.001	<0.001
	Middle	21/4,406	0.0048	0.24	(0.13-0.43)	<0.001			
	Upper	11/4,449	0.0025	0.06	(0.03-0.14)	<0.001			
RBD IgG (IU/ml)	Lower	40/4,461	0.0090	1	N/A	N/A	<0.001	<0.001	<0.001
	Middle	21/4,412	0.0048	0.38	(0.22-0.68)	0.001			
	Upper	20/4,442	0.0045	0.19	(0.10-0.35)	<0.001			
PsV-nAb ID50	Lower	40/4,441	0.0090	1	N/A	N/A	<0.001	<0.001	<0.001
	Middle	30/4,429	0.0068	0.54	(0.32-0.92)	0.022			
	Upper	10/4,445	0.0022	0.14	(0.07-0.29)	<0.001			
PsV-nAb ID80	Lower	29/4,440	0.0065	1	N/A	N/A	0.075		
	Middle	28/4,434	0.0063	0.76	(0.43-1.35)	0.349			
	Upper	24/4,441	0.0054	0.50	(0.27-0.91)	0.023			
Placebo		828/13,380	0.0619						

*Baseline covariates adjusted for: age in years, at risk or not, community of color or not . Average follow-up time 200 days, maximum follow-up time 213 days. Cutpoints: Spike IgG (IU/ml) [4.35, 4.87), RBD IgG (IU/ml) [4.05, 4.64), PsV-nAb ID50 [1.67, 2.39), PsV-nAb ID80 [1.92, 2.61).
**No. at-risk = number of per-protocol baseline negative vaccine recipients at-risk for COVID at 7 days post Day 29 visit; no. cases = number of this cohort with an observed COVID endpoints.
***Generalized Wald-test p-value of the null hypothesis that the hazard rate is constant across the Lower, Middle, and Upper tertile groups.

Figure 4.1: Forest plots of hazard ratios per 10-fold increase in the marker among baseline seronegative vaccine recipients and subgroups with 95% point-wise confidence intervals.

Figure 4.2: Forest plots of hazard ratios per 10-fold increase in the Day 29 binding Ab to spike markers among baseline seronegative vaccine recipients (top row) and eight subpopulations (row 2-9) with 95% point-wise confidence intervals.

Figure 4.3: Forest plots of hazard ratios per 10-fold increase in the Day 29 binding Ab to RBD markers among baseline seronegative vaccine recipients (top row) and eight subpopulations (row 2-9) with 95% point-wise confidence intervals.

Figure 4.4: Forest plots of hazard ratios per 10-fold increase in the Day 29 pseudo neut ID50 markers among baseline seronegative vaccine recipients (top row) and eight subpopulations (row 2-9) with 95% point-wise confidence intervals.

Figure 4.5: Forest plots of hazard ratios per 10-fold increase in the Day 29 pseudo neut ID80 markers among baseline seronegative vaccine recipients (top row) and eight subpopulations (row 2-9) with 95% point-wise confidence intervals.

4.2 Marginalized risk and controlled vaccine efficacy plots

Figure 4.6: Marginalized cumulative risk by Day 202 as functions of Day 29 markers (=s) among baseline seronegative vaccine recipients with 95% bootstrap point-wise confidence bands. The horizontal lines indicate the overall cumulative risk of the placebo and vaccine arms by Day 202 and its 95% point-wise confidence interval. Histograms of the immunological markers in the vaccine arm are overlaid. lod: lower limit of detection.

Figure 4.7: Marginalized cumulative risk by Day 202 as functions of Day 29 markers above a threshold ($\geq s$) among baseline seronegative vaccine recipients with 95% bootstrap point-wise confidence bands (at least 5 cases are required). The horizontal lines indicate the overall cumulative risk of the vaccine arm by Day 202 and its 95% point-wise confidence interval. Histograms of the immunological markers in the vaccine arm are overlaid. lod: lower limit of detection.

Figure 4.8: Controlled VE with sensitivity analysis as functions of Day 29 markers (=s) among baseline seronegative vaccine recipients with 95% bootstrap point-wise confidence bands. Histograms of the immunological markers in the vaccine arm are overlaid. lod: lower limit of detection.

Figure 4.9: Marginalized cumulative incidence rate curves for trichotomized Day 29 markers among baseline seronegative vaccine recipients. The gray line is the overall cumulative incidence rate curve in the placebo arm.

Chapter 5

Univariate CoR: Nonparametric Threshold Modeling

An extension of the unadjusted nonparametric threshold-searching approach developed in Donovan, Hudgens, and Gilbert (2019), the covariate-adjusted TMLE-based approach developed by van der Laan, Zhang, Gilbert (submitted) is used to estimate the so-called threshold-response function $E_X[E[Y|S \geq s, X, A = 1]|A = 1]$ for a range of thresholds s.Here, X is a set of baseline characteristics, $A = 1$ represents the vaccine group, S is the biomarker/immune-response/correlate of interest, and Y is the indicator of COVID disease before some time point t_f. This parameter can be viewed as a causal/covariate-adjusted version of the parameter $P(Y = 1|S \geq s, A = 1)$. Intuitively, the threshold-response at a given threshold is the expected probability of obtaining COVID disease if one experiences a marker/immune-response value above that threshold. The threshold-response function is estimated for each of the four Day 57 antibody markers, in each case adjusting for the baseline covariates: baseline risk score, high risk indicator, and underrepresented minority status. A parametric learner, selected via cross-validation, is used for the covariate adjustment. A number of plots and tables are reported:

1. A plot and table with risk estimates and point-wise 95% confidence intervals
2. A plot and table with risk estimates and simultaneous 95% confidence bands
3. Monotone-corrected versions of 1 and 2.

A reverse cumulative distribution function curve estimated by the IPW NPMLE of the marker values is superimposed on the threshold-response plots and a dashed red line is added to mark the threshold value after which no more events are observed.

5.1 Plots and Tables with estimates and pointwise confidence interval for Day 57

5.1.1 Day 57 Spike protein binding antibody

Figure 5.1: Adjusted threshold-response function for a range of thresholds of the Day 57 Spike protein binding antibody levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

Table of risk estimates for a range of thresholds of Day 57 Spike protein binding antibody levels with pointwise 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
4.536	$3.44 * 10^4$	0.00480	0.00353	0.00608
5.413	$2.59 * 10^5$	0.00271	0.00173	0.00369
5.797	$6.27 * 10^5$	0.00172	0.00090	0.00255
6.165	$1.46 * 10^6$	0.00115	0.00040	0.00191
6.405	$2.54 * 10^6$	0.00079	0.00008	0.00150
6.622	$4.19 * 10^6$	0.00022	0.00000	0.00066
6.820	$6.61 * 10^6$	0.00028	0.00000	0.00087
7.127	$1.34 * 10^7$	0.00000	0.00000	NA
7.409	$2.56 * 10^7$	0.00000	0.00000	NA
8.244	$1.75 * 10^8$	0.00000	0.00000	NA

5.1.2 Day 57 RBD binding antibody

Figure 5.2: Adjusted threshold-response function for a range of thresholds of the Day 57 RBD binding antibody levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

Table of risk estimates for a range of thresholds of Day 57 RBD binding antibody levels with pointwise 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
4.062	$1.15 * 10^4$	0.00489	0.00360	0.00619
5.085	$1.22 * 10^5$	0.00406	0.00282	0.00529
5.507	$3.21 * 10^5$	0.00377	0.00247	0.00507
5.839	$6.90 * 10^5$	0.00288	0.00162	0.00414
6.048	$1.12 * 10^6$	0.00238	0.00113	0.00364
6.257	$1.81 * 10^6$	0.00159	0.00043	0.00275
6.499	$3.16 * 10^6$	0.00131	0.00007	0.00255
6.847	$7.03 * 10^6$	0.00043	0.00000	0.00134
7.181	$1.52 * 10^7$	0.00087	0.00000	0.00279
8.239	$1.73 * 10^8$	0.00000	0.00000	NA

5.1.3 Day 57 Pseudo virus-neutralizing antibody (50% titer)

Figure 5.3: Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (50% titer) levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

Table of risk estimates for a range of thresholds of Day 57 Pseudo virus-neutralizing antibody (50% titer) levels with pointwise 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
0.699	$5.00 * 10^0$	0.00508	0.00376	0.00639
2.033	$1.08 * 10^2$	0.00391	0.00270	0.00513
2.447	$2.80 * 10^2$	0.00347	0.00223	0.00471
2.913	$8.18 * 10^2$	0.00265	0.00145	0.00385
3.196	$1.57 * 10^3$	0.00234	0.00109	0.00358
3.464	$2.91 * 10^3$	0.00115	0.00021	0.00209
3.736	$5.45 * 10^3$	0.00134	0.00012	0.00256
4.123	$1.33 * 10^4$	0.00000	0.00000	NA
4.629	$4.26 * 10^4$	0.00000	0.00000	NA
5.730	$5.37 * 10^5$	0.00000	0.00000	NA

5.1.4 Day 57 Pseudo virus-neutralizing antibody (80% titer)

Figure 5.4: Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (80% titer) levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

Table of risk estimates for a range of thresholds of Day 57 Pseudo virus-neutralizing antibody (80% titer) levels with pointwise 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
1.289	$1.95 * 10^1$	0.00514	0.00381	0.00647
2.368	$2.33 * 10^2$	0.00469	0.00334	0.00605
2.755	$5.69 * 10^2$	0.00428	0.00290	0.00565
3.104	$1.27 * 10^3$	0.00350	0.00213	0.00488
3.373	$2.36 * 10^3$	0.00310	0.00169	0.00452
3.624	$4.21 * 10^3$	0.00301	0.00143	0.00459
3.909	$8.11 * 10^3$	0.00244	0.00085	0.00404
4.259	$1.82 * 10^4$	0.00206	0.00013	0.00399
4.676	$4.74 * 10^4$	0.00246	0.00000	0.00557
5.796	$6.25 * 10^5$	0.00000	0.00000	NA

5.2 Plots and Tables with estimates and pointwise confidence intervals for Day 29

5.2.1 Day 29 Spike protein antibody

Figure 5.5: Adjusted threshold-response function for a range of thresholds of the Day 29 Spike protein antibody levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

Table of risk estimates for a range of thresholds of Day 29 Spike protein antibody levels with pointwise 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
3.202	$1.59 * 10^3$	0.00567	0.00427	0.00707
3.926	$8.43 * 10^3$	0.00476	0.00341	0.00611
4.187	$1.54 * 10^4$	0.00459	0.00317	0.00601
4.478	$3.01 * 10^4$	0.00355	0.00216	0.00495
4.658	$4.55 * 10^4$	0.00278	0.00138	0.00418
4.841	$6.93 * 10^4$	0.00231	0.00084	0.00378
5.022	$1.05 * 10^5$	0.00175	0.00025	0.00326
5.310	$2.04 * 10^5$	0.00147	0.00000	0.00353
5.523	$3.33 * 10^5$	0.00132	0.00000	0.00393
6.259	$1.82 * 10^6$	0.00000	0.00000	NA

5.2.2 Day 29 RBD binding antibody

Figure 5.6: Adjusted threshold-response function for a range of thresholds of the Day 29 RBD binding antibody levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

Table of risk estimates for a range of thresholds of Day 29 RBD binding antibody levels with pointwise 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
2.882	$7.62 * 10^2$	0.00576	0.00434	0.00717
3.628	$4.25 * 10^3$	0.00523	0.00379	0.00666
3.889	$7.74 * 10^3$	0.00459	0.00316	0.00602
4.180	$1.51 * 10^4$	0.00434	0.00278	0.00589
4.395	$2.48 * 10^4$	0.00487	0.00299	0.00674
4.603	$4.01 * 10^4$	0.00403	0.00205	0.00601
4.826	$6.70 * 10^4$	0.00385	0.00168	0.00603
5.105	$1.27 * 10^5$	0.00096	0.00000	0.00239
5.422	$2.64 * 10^5$	0.00097	0.00000	0.00298
6.197	$1.57 * 10^6$	0.00000	0.00000	NA

5.2.3 Day 29 Pseudo virus-neutralizing antibody (50% titer)

Figure 5.7: Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (50% titer) levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

Table of risk estimates for a range of thresholds of Day 29 Pseudo virus-neutralizing antibody (50% titer) levels with pointwise 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
0.699	$5.00 * 10^0$	0.00585	0.00442	0.00727
1.363	$2.31 * 10^1$	0.00469	0.00330	0.00609
1.628	$4.25 * 10^1$	0.00468	0.00319	0.00617
1.848	$7.05 * 10^1$	0.00451	0.00290	0.00612
2.078	$1.20 * 10^2$	0.00399	0.00233	0.00565
2.293	$1.96 * 10^2$	0.00337	0.00167	0.00506
2.537	$3.44 * 10^2$	0.00143	0.00016	0.00270
2.791	$6.18 * 10^2$	0.00091	0.00000	0.00217
3.109	$1.29 * 10^3$	0.00197	0.00000	0.00479
4.080	$1.20 * 10^4$	0.00000	0.00000	NA

5.2.4 Day 29 Pseudo virus-neutralizing antibody (80% titer)

Figure 5.8: Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (80% titer) levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

Table of risk estimates for a range of thresholds of Day 29 Pseudo virus-neutralizing antibody (80% titer) levels with pointwise 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
0.699	$5.00 * 10^0$	0.00585	0.00442	0.00727
1.525	$3.35 * 10^1$	0.00535	0.00387	0.00682
1.840	$6.92 * 10^1$	0.00580	0.00412	0.00747
2.049	$1.12 * 10^2$	0.00553	0.00378	0.00729
2.276	$1.89 * 10^2$	0.00540	0.00348	0.00732
2.583	$3.83 * 10^2$	0.00479	0.00269	0.00690
2.785	$6.10 * 10^2$	0.00559	0.00288	0.00830
3.039	$1.09 * 10^3$	0.00332	0.00080	0.00584
3.351	$2.24 * 10^3$	0.00160	0.00000	0.00398
4.285	$1.93 * 10^4$	0.00000	0.00000	NA

5.3 Plots and Tables with estimates and pointwise confidence interval for Day 57 (monotone-corrected)

5.3.1 Day 57 Spike protein binding antibody

Figure 5.9: Adjusted threshold-response function for a range of thresholds of the Day 57 Spike protein binding antibody levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table of monotone-corrected risk estimates for a range of thresholds of Day 57 Spike protein binding antibody levels with pointwise 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
4.536	$3.44 * 10^4$	0.00480	0.00353	0.00608
5.413	$2.59 * 10^5$	0.00271	0.00173	0.00369
5.797	$6.27 * 10^5$	0.00172	0.00090	0.00255
6.165	$1.46 * 10^6$	0.00115	0.00040	0.00191
6.405	$2.54 * 10^6$	0.00083	0.00012	0.00153
6.622	$4.19 * 10^6$	0.00024	0.00000	0.00069
6.820	$6.61 * 10^6$	0.00024	0.00000	0.00083
7.127	$1.34 * 10^7$	0.00000	0.00000	NA
7.409	$2.56 * 10^7$	0.00000	0.00000	NA
8.244	$1.75 * 10^8$	0.00000	0.00000	NA

5.3.2 Day 57 RBD binding antibody

Figure 5.10: Adjusted threshold-response function for a range of thresholds of the Day 57 RBD binding antibody levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table of monotone-corrected risk estimates for a range of thresholds of Day 57 RBD binding antibody levels with pointwise 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
4.062	$1.15 * 10^4$	0.00489	0.00360	0.00619
5.085	$1.22 * 10^5$	0.00407	0.00283	0.00531
5.507	$3.21 * 10^5$	0.00377	0.00247	0.00507
5.839	$6.90 * 10^5$	0.00288	0.00162	0.00414
6.048	$1.12 * 10^6$	0.00238	0.00113	0.00364
6.257	$1.81 * 10^6$	0.00159	0.00043	0.00275
6.499	$3.16 * 10^6$	0.00124	0.00001	0.00248
6.847	$7.03 * 10^6$	0.00065	0.00000	0.00156
7.181	$1.52 * 10^7$	0.00065	0.00000	0.00256
8.239	$1.73 * 10^8$	0.00000	0.00000	NA

5.3.3 Day 57 Pseudo virus-neutralizing antibody (50% titer)

Figure 5.11: Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (50% titer) levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table of monotone-corrected risk estimates for a range of thresholds of Day 57 Pseudo virus-neutralizing antibody (50% titer) levels with pointwise 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
0.699	$5.00 * 10^0$	0.00508	0.00376	0.00639
2.033	$1.08 * 10^2$	0.00391	0.00270	0.00513
2.447	$2.80 * 10^2$	0.00347	0.00223	0.00471
2.913	$8.18 * 10^2$	0.00272	0.00152	0.00392
3.196	$1.57 * 10^3$	0.00234	0.00109	0.00358
3.464	$2.91 * 10^3$	0.00127	0.00033	0.00221
3.736	$5.45 * 10^3$	0.00127	0.00005	0.00249
4.123	$1.33 * 10^4$	0.00000	0.00000	NA
4.629	$4.26 * 10^4$	0.00000	0.00000	NA
5.730	$5.37 * 10^5$	0.00000	0.00000	NA

5.3.4 Day 57 Pseudo virus-neutralizing antibody (80% titer)

Figure 5.12: Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (80% titer) levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table of monotone-corrected risk estimates for a range of thresholds of Day 57 Pseudo virus-neutralizing antibody (80% titer) levels with pointwise 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
1.289	$1.95 * 10^1$	0.00514	0.00381	0.00647
2.368	$2.33 * 10^2$	0.00469	0.00334	0.00605
2.755	$5.69 * 10^2$	0.00428	0.00290	0.00565
3.104	$1.27 * 10^3$	0.00350	0.00213	0.00488
3.373	$2.36 * 10^3$	0.00310	0.00169	0.00451
3.624	$4.21 * 10^3$	0.00294	0.00136	0.00452
3.909	$8.11 * 10^3$	0.00247	0.00088	0.00407
4.259	$1.82 * 10^4$	0.00206	0.00013	0.00399
4.676	$4.74 * 10^4$	0.00206	0.00000	0.00517
5.796	$6.25 * 10^5$	0.00000	0.00000	NA

5.4 Plots and Tables with estimates and pointwise confidence intervals for Day 29 (monotone-corrected)

5.4.1 Day 29 Spike protein antibody

Figure 5.13: Adjusted threshold-response function for a range of thresholds of the Day 29 Spike protein antibody levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table of monotone-corrected risk estimates for a range of thresholds of Day 29 Spike protein antibody levels with pointwise 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
3.202	$1.59 * 10^3$	0.00567	0.00427	0.00707
3.926	$8.43 * 10^3$	0.00476	0.00341	0.00611
4.187	$1.54 * 10^4$	0.00459	0.00317	0.00601
4.478	$3.01 * 10^4$	0.00355	0.00216	0.00495
4.658	$4.55 * 10^4$	0.00278	0.00138	0.00418
4.841	$6.93 * 10^4$	0.00231	0.00084	0.00378
5.022	$1.05 * 10^5$	0.00175	0.00025	0.00326
5.310	$2.04 * 10^5$	0.00173	0.00000	0.00379
5.523	$3.33 * 10^5$	0.00173	0.00000	0.00434
6.259	$1.82 * 10^6$	0.00000	0.00000	NA

5.4.2 Day 29 RBD binding antibody

Figure 5.14: Adjusted threshold-response function for a range of thresholds of the Day 29 RBD binding antibody levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table of monotone-corrected risk estimates for a range of thresholds of Day 29 RBD binding antibody levels with pointwise 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
2.882	$7.62 * 10^2$	0.00576	0.00434	0.00717
3.628	$4.25 * 10^3$	0.00523	0.00379	0.00666
3.889	$7.74 * 10^3$	0.00459	0.00316	0.00602
4.180	$1.51 * 10^4$	0.00452	0.00297	0.00607
4.395	$2.48 * 10^4$	0.00452	0.00264	0.00640
4.603	$4.01 * 10^4$	0.00405	0.00207	0.00603
4.826	$6.70 * 10^4$	0.00385	0.00168	0.00603
5.105	$1.27 * 10^5$	0.00110	0.00000	0.00254
5.422	$2.64 * 10^5$	0.00110	0.00000	0.00312
6.197	$1.57 * 10^6$	0.00000	0.00000	NA

5.4.3 Day 29 Pseudo virus-neutralizing antibody (50% titer)

Figure 5.15: Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (50% titer) levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table of monotone-corrected risk estimates for a range of thresholds of Day 29 Pseudo virus-neutralizing antibody (50% titer) levels with pointwise 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
0.699	$5.00 * 10^0$	0.00585	0.00442	0.00727
1.363	$2.31 * 10^1$	0.00470	0.00330	0.00609
1.628	$4.25 * 10^1$	0.00468	0.00319	0.00617
1.848	$7.05 * 10^1$	0.00446	0.00284	0.00607
2.078	$1.20 * 10^2$	0.00409	0.00243	0.00575
2.293	$1.96 * 10^2$	0.00337	0.00167	0.00506
2.537	$3.44 * 10^2$	0.00164	0.00037	0.00291
2.791	$6.18 * 10^2$	0.00164	0.00039	0.00290
3.109	$1.29 * 10^3$	0.00164	0.00000	0.00446
4.080	$1.20 * 10^4$	0.00000	0.00000	NA

5.4.4 Day 29 Pseudo virus-neutralizing antibody (80% titer)

Figure 5.16: Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (80% titer) levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table of monotone-corrected risk estimates for a range of thresholds of Day 29 Pseudo virus-neutralizing antibody (80% titer) levels with pointwise 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
0.699	$5.00 * 10^0$	0.00585	0.00442	0.00727
1.525	$3.35 * 10^1$	0.00553	0.00405	0.00701
1.840	$6.92 * 10^1$	0.00553	0.00385	0.00721
2.049	$1.12 * 10^2$	0.00545	0.00370	0.00721
2.276	$1.89 * 10^2$	0.00534	0.00342	0.00727
2.583	$3.83 * 10^2$	0.00515	0.00304	0.00726
2.785	$6.10 * 10^2$	0.00515	0.00244	0.00786
3.039	$1.09 * 10^3$	0.00344	0.00092	0.00596
3.351	$2.24 * 10^3$	0.00219	0.00000	0.00457
4.285	$1.93 * 10^4$	0.00000	0.00000	NA

5.5 Plots and Tables with estimates and simultaneous confidence bands for Day 57

5.5.1 Day 57 Spike protein binding antibody

Figure 5.17: Adjusted threshold-response function for a range of thresholds of the Day 57 Spike protein binding antibody levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

Table of risk estimates for a range of thresholds of Day 57 Spike protein binding antibody levels with simultaneous 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
4.536	$3.44 * 10^4$	0.00480	0.00289	0.00671
5.413	$2.59 * 10^5$	0.00271	0.00125	0.00418
5.797	$6.27 * 10^5$	0.00172	0.00049	0.00296
6.165	$1.46 * 10^6$	0.00115	0.00002	0.00228
6.405	$2.54 * 10^6$	0.00079	0.00000	0.00185
6.622	$4.19 * 10^6$	0.00022	0.00000	0.00088
6.820	$6.61 * 10^6$	0.00028	0.00000	0.00116
7.127	$1.34 * 10^7$	0.00000	0.00000	NA
7.409	$2.56 * 10^7$	0.00000	0.00000	NA
8.244	$1.75 * 10^8$	0.00000	0.00000	NA

5.5.2 Day 57 RBD binding antibody

Figure 5.18: Adjusted threshold-response function for a range of thresholds of the Day 57 RBD binding antibody levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

Table of risk estimates for a range of thresholds of Day 57 RBD binding antibody levels with simultaneous 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
4.062	$1.15 * 10^4$	0.00489	0.00302	0.00677
5.085	$1.22 * 10^5$	0.00406	0.00226	0.00585
5.507	$3.21 * 10^5$	0.00377	0.00189	0.00565
5.839	$6.90 * 10^5$	0.00288	0.00106	0.00470
6.048	$1.12 * 10^6$	0.00238	0.00057	0.00420
6.257	$1.81 * 10^6$	0.00159	0.00000	0.00327
6.499	$3.16 * 10^6$	0.00131	0.00000	0.00310
6.847	$7.03 * 10^6$	0.00043	0.00000	0.00175
7.181	$1.52 * 10^7$	0.00087	0.00000	0.00364
8.239	$1.73 * 10^8$	0.00000	0.00000	NA

5.5.3 Day 57 Pseudo virus-neutralizing antibody (50% titer)

Figure 5.19: Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (50% titer) levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

Table of risk estimates for a range of thresholds of Day 57 Pseudo virus-neutralizing antibody (50% titer) levels with simultaneous 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
0.699	$5.00 * 10^0$	0.00508	0.00314	0.00701
2.033	$1.08 * 10^2$	0.00391	0.00213	0.00570
2.447	$2.80 * 10^2$	0.00347	0.00165	0.00529
2.913	$8.18 * 10^2$	0.00265	0.00089	0.00442
3.196	$1.57 * 10^3$	0.00234	0.00051	0.00417
3.464	$2.91 * 10^3$	0.00115	0.00000	0.00254
3.736	$5.45 * 10^3$	0.00134	0.00000	0.00313
4.123	$1.33 * 10^4$	0.00000	0.00000	NA
4.629	$4.26 * 10^4$	0.00000	0.00000	NA
5.730	$5.37 * 10^5$	0.00000	0.00000	NA

5.5.4 Day 57 Pseudo virus-neutralizing antibody (80% titer)

Figure 5.20: Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (80% titer) levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

Table of risk estimates for a range of thresholds of Day 57 Pseudo virus-neutralizing antibody (80% titer) levels with simultaneous 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
1.289	$1.95 * 10^1$	0.00514	0.00322	0.00706
2.368	$2.33 * 10^2$	0.00469	0.00273	0.00665
2.755	$5.69 * 10^2$	0.00428	0.00229	0.00627
3.104	$1.27 * 10^3$	0.00350	0.00151	0.00550
3.373	$2.36 * 10^3$	0.00310	0.00106	0.00515
3.624	$4.21 * 10^3$	0.00301	0.00073	0.00530
3.909	$8.11 * 10^3$	0.00244	0.00014	0.00475
4.259	$1.82 * 10^4$	0.00206	0.00000	0.00486
4.676	$4.74 * 10^4$	0.00246	0.00000	0.00696
5.796	$6.25 * 10^5$	0.00000	0.00000	NA

5.6 Plots and Tables with estimates and simultaneous confidence bands for Day 29

5.6.1 Day 29 Spike protein antibody

Figure 5.21: Adjusted threshold-response function for a range of thresholds of the Day 29 Spike protein antibody levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

Table of risk estimates for a range of thresholds of Day 29 Spike protein antibody levels with simultaneous 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
3.202	$1.59 * 10^3$	0.00567	0.00365	0.00770
3.926	$8.43 * 10^3$	0.00476	0.00280	0.00672
4.187	$1.54 * 10^4$	0.00459	0.00254	0.00665
4.478	$3.01 * 10^4$	0.00355	0.00153	0.00557
4.658	$4.55 * 10^4$	0.00278	0.00076	0.00481
4.841	$6.93 * 10^4$	0.00231	0.00018	0.00443
5.022	$1.05 * 10^5$	0.00175	0.00000	0.00394
5.310	$2.04 * 10^5$	0.00147	0.00000	0.00446
5.523	$3.33 * 10^5$	0.00132	0.00000	0.00511
6.259	$1.82 * 10^6$	0.00000	0.00000	NA

5.6.2 Day 29 RBD binding antibody

Figure 5.22: Adjusted threshold-response function for a range of thresholds of the Day 29 RBD binding antibody levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

Table of risk estimates for a range of thresholds of Day 29 RBD binding antibody levels with simultaneous 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
2.882	$7.62 * 10^2$	0.00576	0.00374	0.00777
3.628	$4.25 * 10^3$	0.00523	0.00318	0.00727
3.889	$7.74 * 10^3$	0.00459	0.00255	0.00663
4.180	$1.51 * 10^4$	0.00434	0.00212	0.00655
4.395	$2.48 * 10^4$	0.00487	0.00219	0.00755
4.603	$4.01 * 10^4$	0.00403	0.00121	0.00686
4.826	$6.70 * 10^4$	0.00385	0.00075	0.00696
5.105	$1.27 * 10^5$	0.00096	0.00000	0.00301
5.422	$2.64 * 10^5$	0.00097	0.00000	0.00384
6.197	$1.57 * 10^6$	0.00000	0.00000	NA

5.6.3 Day 29 Pseudo virus-neutralizing antibody (50% titer)

Figure 5.23: Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (50% titer) levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

Table of risk estimates for a range of thresholds of Day 29 Pseudo virus-neutralizing antibody (50% titer) levels with simultaneous 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
0.699	$5.00 * 10^0$	0.00585	0.00382	0.00788
1.363	$2.31 * 10^1$	0.00469	0.00271	0.00667
1.628	$4.25 * 10^1$	0.00468	0.00256	0.00681
1.848	$7.05 * 10^1$	0.00451	0.00221	0.00680
2.078	$1.20 * 10^2$	0.00399	0.00163	0.00635
2.293	$1.96 * 10^2$	0.00337	0.00095	0.00578
2.537	$3.44 * 10^2$	0.00143	0.00000	0.00323
2.791	$6.18 * 10^2$	0.00091	0.00000	0.00270
3.109	$1.29 * 10^3$	0.00197	0.00000	0.00598
4.080	$1.20 * 10^4$	0.00000	0.00000	NA

5.6.4 Day 29 Pseudo virus-neutralizing antibody (80% titer)

Figure 5.24: Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (80% titer) levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

Table of risk estimates for a range of thresholds of Day 29 Pseudo virus-neutralizing antibody (80% titer) levels with simultaneous 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
0.699	$5.00 * 10^0$	0.00585	0.00382	0.00788
1.525	$3.35 * 10^1$	0.00535	0.00324	0.00745
1.840	$6.92 * 10^1$	0.00580	0.00340	0.00819
2.049	$1.12 * 10^2$	0.00553	0.00303	0.00804
2.276	$1.89 * 10^2$	0.00540	0.00266	0.00814
2.583	$3.83 * 10^2$	0.00479	0.00179	0.00780
2.785	$6.10 * 10^2$	0.00559	0.00173	0.00946
3.039	$1.09 * 10^3$	0.00332	0.00000	0.00691
3.351	$2.24 * 10^3$	0.00160	0.00000	0.00499
4.285	$1.93 * 10^4$	0.00000	0.00000	NA

5.7 Plots and Tables with estimates and pointwise confidence interval for Day 57 (monotone-corrected)

5.7.1 Day 57 Spike protein binding antibody

Figure 5.25: Adjusted threshold-response function for a range of thresholds of the Day 57 Spike protein binding antibody levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table of monotone-corrected risk estimates for a range of thresholds of Day 57 Spike protein binding antibody levels with simultaneous 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
4.536	$3.44 * 10^4$	0.00480	0.00289	0.00671
5.413	$2.59 * 10^5$	0.00271	0.00125	0.00418
5.797	$6.27 * 10^5$	0.00172	0.00049	0.00296
6.165	$1.46 * 10^6$	0.00115	0.00002	0.00228
6.405	$2.54 * 10^6$	0.00083	0.00000	0.00189
6.622	$4.19 * 10^6$	0.00024	0.00000	0.00091
6.820	$6.61 * 10^6$	0.00024	0.00000	0.00112
7.127	$1.34 * 10^7$	0.00000	0.00000	NA
7.409	$2.56 * 10^7$	0.00000	0.00000	NA
8.244	$1.75 * 10^8$	0.00000	0.00000	NA

5.7.2 Day 57 RBD binding antibody

Figure 5.26: Adjusted threshold-response function for a range of thresholds of the Day 57 RBD binding antibody levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table of monotone-corrected risk estimates for a range of thresholds of Day 57 RBD binding antibody levels with simultaneous 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
4.062	$1.15 * 10^4$	0.00489	0.00302	0.00677
5.085	$1.22 * 10^5$	0.00407	0.00228	0.00586
5.507	$3.21 * 10^5$	0.00377	0.00189	0.00565
5.839	$6.90 * 10^5$	0.00288	0.00106	0.00470
6.048	$1.12 * 10^6$	0.00238	0.00057	0.00420
6.257	$1.81 * 10^6$	0.00159	0.00000	0.00327
6.499	$3.16 * 10^6$	0.00124	0.00000	0.00303
6.847	$7.03 * 10^6$	0.00065	0.00000	0.00196
7.181	$1.52 * 10^7$	0.00065	0.00000	0.00342
8.239	$1.73 * 10^8$	0.00000	0.00000	NA

5.7.3 Day 57 Pseudo virus-neutralizing antibody (50% titer)

Figure 5.27: Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (50% titer) levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table of monotone-corrected risk estimates for a range of thresholds of Day 57 Pseudo virus-neutralizing antibody (50% titer) levels with simultaneous 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
0.699	$5.00 * 10^0$	0.00508	0.00314	0.00701
2.033	$1.08 * 10^2$	0.00391	0.00213	0.00570
2.447	$2.80 * 10^2$	0.00347	0.00165	0.00529
2.913	$8.18 * 10^2$	0.00272	0.00095	0.00448
3.196	$1.57 * 10^3$	0.00234	0.00051	0.00417
3.464	$2.91 * 10^3$	0.00127	0.00000	0.00265
3.736	$5.45 * 10^3$	0.00127	0.00000	0.00306
4.123	$1.33 * 10^4$	0.00000	0.00000	NA
4.629	$4.26 * 10^4$	0.00000	0.00000	NA
5.730	$5.37 * 10^5$	0.00000	0.00000	NA

5.7.4 Day 57 Pseudo virus-neutralizing antibody (80% titer)

Figure 5.28: Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (80% titer) levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table of monotone-corrected risk estimates for a range of thresholds of Day 57 Pseudo virus-neutralizing antibody (80% titer) levels with simultaneous 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
1.289	$1.95 * 10^1$	0.00514	0.00322	0.00706
2.368	$2.33 * 10^2$	0.00469	0.00273	0.00665
2.755	$5.69 * 10^2$	0.00428	0.00229	0.00627
3.104	$1.27 * 10^3$	0.00350	0.00151	0.00550
3.373	$2.36 * 10^3$	0.00310	0.00106	0.00514
3.624	$4.21 * 10^3$	0.00294	0.00065	0.00522
3.909	$8.11 * 10^3$	0.00247	0.00017	0.00478
4.259	$1.82 * 10^4$	0.00206	0.00000	0.00486
4.676	$4.74 * 10^4$	0.00206	0.00000	0.00656
5.796	$6.25 * 10^5$	0.00000	0.00000	NA

5.8 Plots and Tables with estimates and pointwise confidence intervals for Day 29 (monotone-corrected)

5.8.1 Day 29 Spike protein antibody

Figure 5.29: Adjusted threshold-response function for a range of thresholds of the Day 29 Spike protein antibody levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table of monotone-corrected risk estimates for a range of thresholds of Day 29 Spike protein antibody levels with simultaneous 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
3.202	$1.59 * 10^3$	0.00567	0.00365	0.00770
3.926	$8.43 * 10^3$	0.00476	0.00280	0.00672
4.187	$1.54 * 10^4$	0.00459	0.00253	0.00664
4.478	$3.01 * 10^4$	0.00355	0.00153	0.00557
4.658	$4.55 * 10^4$	0.00278	0.00076	0.00481
4.841	$6.93 * 10^4$	0.00231	0.00018	0.00443
5.022	$1.05 * 10^5$	0.00175	0.00000	0.00394
5.310	$2.04 * 10^5$	0.00173	0.00000	0.00472
5.523	$3.33 * 10^5$	0.00173	0.00000	0.00551
6.259	$1.82 * 10^6$	0.00000	0.00000	NA

5.8.2 Day 29 RBD binding antibody

Figure 5.30: Adjusted threshold-response function for a range of thresholds of the Day 29 RBD binding antibody levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table of monotone-corrected risk estimates for a range of thresholds of Day 29 RBD binding antibody levels with simultaneous 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
2.882	$7.62 * 10^2$	0.00576	0.00374	0.00777
3.628	$4.25 * 10^3$	0.00523	0.00318	0.00727
3.889	$7.74 * 10^3$	0.00459	0.00255	0.00663
4.180	$1.51 * 10^4$	0.00452	0.00230	0.00674
4.395	$2.48 * 10^4$	0.00452	0.00184	0.00720
4.603	$4.01 * 10^4$	0.00405	0.00122	0.00688
4.826	$6.70 * 10^4$	0.00385	0.00075	0.00696
5.105	$1.27 * 10^5$	0.00110	0.00000	0.00315
5.422	$2.64 * 10^5$	0.00110	0.00000	0.00398
6.197	$1.57 * 10^6$	0.00000	0.00000	NA

5.8.3 Day 29 Pseudo virus-neutralizing antibody (50% titer)

Figure 5.31: Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (50% titer) levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table of monotone-corrected risk estimates for a range of thresholds of Day 29 Pseudo virus-neutralizing antibody (50% titer) levels with simultaneous 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
0.699	$5.00 * 10^0$	0.00585	0.00382	0.00788
1.363	$2.31 * 10^1$	0.00470	0.00271	0.00668
1.628	$4.25 * 10^1$	0.00468	0.00256	0.00680
1.848	$7.05 * 10^1$	0.00446	0.00216	0.00675
2.078	$1.20 * 10^2$	0.00409	0.00173	0.00645
2.293	$1.96 * 10^2$	0.00337	0.00095	0.00578
2.537	$3.44 * 10^2$	0.00164	0.00000	0.00344
2.791	$6.18 * 10^2$	0.00164	0.00000	0.00343
3.109	$1.29 * 10^3$	0.00164	0.00000	0.00565
4.080	$1.20 * 10^4$	0.00000	0.00000	NA

5.8.4 Day 29 Pseudo virus-neutralizing antibody (80% titer)

Figure 5.32: Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (80% titer) levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table of monotone-corrected risk estimates for a range of thresholds of Day 29 Pseudo virus-neutralizing antibody (80% titer) levels with simultaneous 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
0.699	$5.00 * 10^0$	0.00585	0.00382	0.00788
1.525	$3.35 * 10^1$	0.00553	0.00342	0.00763
1.840	$6.92 * 10^1$	0.00553	0.00314	0.00792
2.049	$1.12 * 10^2$	0.00545	0.00295	0.00796
2.276	$1.89 * 10^2$	0.00534	0.00260	0.00809
2.583	$3.83 * 10^2$	0.00515	0.00215	0.00816
2.785	$6.10 * 10^2$	0.00515	0.00129	0.00901
3.039	$1.09 * 10^3$	0.00344	0.00000	0.00704
3.351	$2.24 * 10^3$	0.00219	0.00000	0.00558
4.285	$1.93 * 10^4$	0.00000	0.00000	NA