# COVID-19 Baseline Risk Score Analysis Report $$_{\rm MockCOVE\ Study}$$

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#### Chapter 1

#### **Disclaimers**

- The data presented in the analysis originated from the Moderna Sponsored mRNA-1273-P301 clinical study and are provided to NIAID in accordance with Clinical Trial Agreement between the parties. The study was funded in part by BARDA under Government Contract No. 75A50120C00034
- The preliminary immunogenicity data presented here do not reflect the Sponsors statistical analysis plan and therefore should not be interpreted as a protocol defined read-out of the clinical study.
- These data are not to be disclosed without written permission of Moderna.



### Chapter 2

Baseline Risk Score (Proxy for SARS-CoV-2 Exposure)

Table 2.1: Variables considered for risk score analysis.

Variable.Name	Definition	Total.missing.values	Comments
MinorityInd	Baseline covariate underrepresented minority status (1=minority,	0/13336 (0.0%)	NA
EthnicityHispanic	0=non-minority) Indicator ethnicity = Hispanic (0 =	0/13336 (0.0%)	NA
EthnicityNotreported	Non-Hispanic) Indicator ethnicity = Not reported (0 =	0/13336 (0.0%)	NA
EthnicityUnknown	Non-Hispanic) Indicator ethnicity = Unknown (0 =	0/13336 (0.0%)	NA
Black	Non-Hispanic) Indicator race = Black $(0 = White)$	0/13336 (0.0%)	NA
Asian	Indicator race $=$ Asian $(0 = White)$	0/13336 (0.0%)	NA
NatAmer	Indicator race = American Indian or Alaska Native (0 = White)	0/13336 (0.0%)	NA
PacIsl	Indicator race = Native Hawaiian or Other Pacific Islander (0 = White)	0/13336 (0.0%)	NA
Multiracial	Indicator race = Multiracial (0 = White)	0/13336 (0.0%)	NA
Other	Indicator race = Other (0 = White)	0/13336 (0.0%)	NA
Notreported	Indicator race = Not reported (0 = White)	0/13336 (0.0%)	NA
Unknown	Indicator race = unknown (0 = White)	0/13336 (0.0%)	NA
HighRiskInd	Baseline covariate high risk pre-existing condition (1=yes, 0=no)	0/13336 (0.0%)	NA
Sex	Sex assigned at birth (1=female, 0=male)	0/13336 (0.0%)	NA
Age	Age at enrollment in years, between 18 and 85	0/13336 (0.0%)	NA
BMI	BMI at enrollment (kg/m <sup>2</sup> )	0/13336 (0.0%)	NA

Table 2.2: All learner-screen combinations (28 in total) used as input to the Superlearner.

Learner	Screen*
SL.mean	all
SL.glm	all glmnet univar_logistic_pval highcor_random

#### Note:

\*Screen details:

all: includes all variables

glmnet: includes variables with non-zero coefficients in the standard implementation of SL.glmnet that optimizes the lasso tuning parameter via cross-validation

univar\_logistic\_pval: Wald test 2-sided p-value in a logistic regression model  $<0.10\,$ 

high cor\_random: if pairs of quantitative variables with Spearman rank correlation > 0.90, select one of the variables at random



Figure 2.1: Cross-validated AUC (95% CI) of algorithms for predicting COVID-19 disease status starting 7 days after Day 57.



Figure 2.2: CV-estimated predicted probabilities of COVID-19 disease 7 days after Day 57 by case/control status for top 2 learners, SuperLearner and Discrete  $^{\rm CT}$ 



Figure 2.3: ROC curves based off CV-estimated predicted probabilities for the top 2 learners, Superlearner and Discrete SL.

Table 2.3: Weights assigned by Superlearner.

Learner	Screen	Weight
SL.glm	screen_all	0.590
SL.glm	screen_glmnet	0.376
SL.mean	screen_all	0.034
SL.glm	screen_univariate_logistic_pval	0.000
SL.glm	screen_highcor_random	0.000



Screen Weight Predictors Coefficient Odds.Ratio Learner 0.59 SL.glm  $screen\_all$ (Intercept) -2.7670.063 SL.glm $screen\_all$ 0.59 MinorityInd-0.015 0.985 SL.glm EthnicityHispanic -0.013 0.987 screen\_all SL.glm0.0461.048  $screen\_all$ EthnicityNotreported SL.glm 0.59 EthnicityUnknown -0.072 0.931 screen\_all SL.glm screen\_all 0.59 Black -0.024 0.977 SL.glm $screen\_all$ 0.59 Asian 0.0571.058 0.007 SL.glmscreen\_all 0.59 NatAmer1.007 SL.glm $screen\_all$ 0.59 PacIsl -0.025 0.975 0.59 -0.052 SL.glm  $screen\_all$ Multiracial 0.95 $screen\_all$ Other SL.glm 0.590.0551.056  $_{\mathrm{SL.glm}}$  $screen\_all$ 0.59 Notreported 0.0051.005 SL.glm screen all 0.59 Unknown 0.01 1.01 HighRiskInd SL.glm $screen\_all$ 0.59 -0.019 0.981SL.glm screen\_all 0.59-0.006 0.994 $_{\mathrm{SL.glm}}$ 0.59 0.8242.279 screen\_all Age SL.glm $screen\_all$ 0.59BMI -0.045 0.956 ${\tt screen\_glmnet}$ 0.376 0.063 SL.glm (Intercept) -2.7670.048 SL.glmscreen\_glmnet 0.376EthnicityNotreported 1.049 SL.glm 0.376 EthnicityUnknown -0.071 0.932 screen glmnet SL.glm $screen\_glmnet$ 0.376Black -0.0350.966 SL.glm 0.376 0.05 1.051 screen glmnet Asian Multiracial -0.064 0.938 SL.glm0.376 screen\_glmnet SL.glmscreen\_glmnet 0.376Other 0.0481.049 SL.glm 0.8242.279  $screen\_glmnet$ 0.376Age SL.glmscreen\_glmnet 0.376 $_{\mathrm{BMI}}$ -0.0450.956SL.glm  $screen\_glmnet$ 0.376 (Intercept) -2.767 0.063 0.048 SL.glm $screen\_glmnet$ 0.376  ${\bf EthnicityNot reported}$ 1.049 SL.glm 0.376 EthnicityUnknown -0.071 0.932 screen\_glmnet -0.035 SL.glm 0.376 Black 0.966 screen\_glmnet SL.glmscreen\_glmnet 0.376Asian 0.051.051 SL.glmMultiracial -0.064 0.938  $screen\_glmnet$ 0.376 0.048SL.glm $screen\_glmnet$ 0.376 Other 1.049 SL.glmscreen\_glmnet 0.3760.824 2.279 Age 0.956 SL.glm  $screen\_glmnet$ 0.376  $_{\rm BMI}$ -0.045

Table 2.4: Predictors in learners assigned weight > 0.0 by Superlearner.



Figure 2.4: Superlearner predicted probabilities of COVID-19 disease in vaccinees 7 days after Day 57 by case/control status.



Figure 2.5: ROC curve based off Superlearner predicted probabilities in vaccinees.

#### Chapter 3

## **Appendix**

- This report was built from the CoVPN/correlates\_reporting repository with commit hash 9f175c1bff6ceed1368c491743af9c7ef744cca5. A diff of the changes introduced by that commit may be viewed at https://github.com/CoVPN/correlates\_reporting/commit/9f175c1bff6ceed1368c491743af9c7ef744cca5
- The sha256 hash sum of the raw input file, "COVID\_VEtrial\_practicedata\_primarystage1.csv": 83d0f55d1745ffd42be124d8f9ec9a9903abcc13cd22f95e537542a08b41300a
- The sha256 hash sum of the processed file, "moderna\_mock\_data\_processed.csv": 28964ce20cfcd70a621aff9df412c42b1178d5e749e0f49ddd79fbff2dc7c90a