# Verification Plan for Immunogenicity Plots

March 04, 2021

Project directory: `correlates_reporting/immuno_graphical`

Specifications: `correlates_reporting/immuno_graphical/verification/graphical_specifications.md`

Other Background Information: N/A

**Verification Sign-Off**

| Role | Name | Signature | Date |
|---|---|---|---|
| Manager | Dr. Peter Gilbert | | |
| Programmer | Dr. David Benkeser | | |
| Programmer | Nima Hejazi | | |
| Programmer | Chenchen Yu | | |
| Specifier/Programmer | Kendric Li | | |
| Tester | Di Lu | | |

## Verification Procedure

Verification for the immunogenicity plots generated in support of the CoVPN correlates reporting will be based on a risked based approach. Risk of a plot is determined by importance: whether it will be used to drive decision making. Plots that are determined to have high importance, thus high risk, will go through independent double programming. If a plot is decided to have low risk, it will be verified via code review, not through independent double programming. A plot will be verified by someone other than the original programmer (the tester).

For independent double programming, the tester will independently generate the same the data set based on the plot's specification. They will then visually compare the values presented in the original plot against the ones generated by the verification code. Any statistical calculations (mean, median, percentiles, etc.) will either be verified by comparing them to a verified statistical table, or they will be generated independently.

For code review, the tester will review the programmers code directly from the code folder. The review will consist of checking the programming logic of the code for consistency with the specifications, verifying the assumptions in the source data. The tester will confirm that the code does not produce errors or unexpected warnings, check the output for nonsensical or unexpected results, and finally review the output headers, footers and formatting for consistency.

The plots targeted for independent double programming include:

- Plot 1.3; Pair plots of D57 Ab markers: baseline negative vaccine arm (pairs_Day57_Markers_BaselineNeg_vaccine_ar
- Plot 1.24; RCDF plots for D57 Ab markers: by baseline status for the vaccine arm (Marker_Rcdf_Day57_trt_vaccine_b
- Plot 1.32; Boxplots of D57 Ab markers: baseline negative vaccine + placebo arms (boxplots_Day57_x_trt_BaselineNeg_mock.png)
- Plot 1.47; Spaghetti plots of Ab markers over time: baseline negative vaccine + placebo arm (Spaghetti_plot_BaselineNeg_mock.png)

Mock data used in the verification can be found in the `COVIDcorr` R package, available at https://github.com/CoVPN/correlates_mockdata. Any use of this code outside of the mock data is not guaranteed and is subject to additional verification.

**Verification Assignments**

The verification results will be contained in `verification_results.pdf`, where the results of the independent verification will be reported. It will contain a table that lists the Plot, the original source code filename, the verification code filename, the results of the visual comparison, and the date the testing is completed.