

# Verification Plan for Immunogenicity Plots

February 01, 2021

Project directory: `correlates_reporting/immuno_graphical`

Specifications:

Other Background Information: N/A

## Verification Sign-Off

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

## Verification Procedure

Verification for the immunogenicity plots generated in support of the CoVPN correlates reporting will be based on a risk 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; Plot title
- Plot 3; Plot title
- Plot 45; Plot title

Mock data used in the verification can be found in the `COVIDcorr` R package, available at [https://github.com/CoVPN/correlates\\_mockdata](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.