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Poster presentation

P16-19. Statistical design and analysis of the CAVD-VIMC Elispot transfer study 001

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Background

Following the success of the CAVD-VIMC ELISpot comparison study, the CAVD-VIMC ELISpot Assay Transfer study was designed to evaluate the transfer of the ELISpot assay SOP from IAVI CL to NVITAL using the same set of 150 samples. Assay results for the parent SOP (IAVI) from the comparison study will be used to compare to those for the transferred SOP (NVITAL). The co-primary objectives are to ensure that the response rates are equivalent and the positivity calls are concordant. Concordance of response magnitudes among the dynamic range of positive responders is evaluated in the secondary objectives.

Methods

To allow for resource-saving, a pre-specified interim analysis at n = 75 was designed for the study. Simulation studies incorporating past data demonstrated satisfactory statistical power and justified the appropriate sample sizes for both the interim and final analyses.

Results

The primary equivalence criteria on response rates and positivity calls were both met in the interim analysis. The 95% C.I. on the difference in response rates is contained in the pre-specified equivalence margin of [-15%, 15%] (i.e. (-2.8%, 2.8%) for CMV and (-1.6%, 13.0%) for FEC responses), and the lower bound of the 95% confidence interval on the proportion of positivity concordance is greater than the pre-specified margin of 70% (i.e. 94.7% for CMV and 82.1% for FEC responses). Preliminary investigation of the secondary objectives suggests that Elispot readers are contributing to differences in raw spot counts; concordance of response magnitudes improves when plates from experiments performed at NVITAL were read at IAVI. If accepted, both the interim and final study results will be presented.

Conclusion

The transfer study continued to the testing of the remaining samples. The interim analysis allowed for an early look of futility and helped to identify sources of any possible differences between the parent and the transferred SOP.