IMMUNOGENICITY ASSAY DEVELOPMENT, VALIDATION & TRANSFER IN A VACCINE CANDIDATE CLINICAL TRIAL

INTRODUCTION / OVERVIEW

Vaccine development is a long, complex process, requiring evaluation for safety, immunogenicity, and protective efficacy. With this complexity, many factors can impact the probability of licensure and ultimate public health impact.

A large global pharmaceutical company, with a promising new vaccine candidate, partnered with Eurofins Clinical Trial Solutions to perform immunogenicity testing as part of their clinical trial development. The sponsor's goal in developing the vaccine is to create widespread immunity to protect against infection, morbidity, and potential mortality. This objective can be compared to the historical efforts used to control polio, smallpox, HPV, or measles.

SITUATION / CHALLENGE

The sponsor initially recruited Eurofins Clinical Trial Solutions for rapid transfer of an ELISpot assay, before recognizing the value and efficiency of being able to rely on their broad technical expertise as a single provider for all assay optimization, validation and transfer requirements of the trial. Consequently, the success of the first project was soon followed by an expanded request for combined development and transfer for a Neutralizing Antibody (NAb) assay. Ultimately, Eurofins Clinical Trial Solutions was asked to develop, validate and perform multiple biomarker assays including ELISpot and NAb, with a qPCR assay added later as an endpoint.

SOLUTION

ELISpot Assay:

The ELISpot assay enables assessment of study subjects' adaptive immunity induced by the sponsor's vaccine candidate through quantification of the T cell responses. Combining the results of the ELISpot assay with the NAb assay enables a broad spectrum interpretation of overall immunity induced by the vaccine.

The developed ELISpot assay was performed in tandem at the sponsor's site and at Eurofins Clinical Trial Solutions, with the same PBMC sample panel. The results of this study demonstrated an excellent level of analytical concordance between the two sites, and therefore confidence that the assay was performing well. In addition, assay optimization by the Eurofins Clinical Trial Solutions R&D team improved throughput, maximized signal robustness, improved precision and enhanced analytical specificity of the assay.

Neutralizing Antibody Assay (NAb)

This is a cell-based assay for determining the presence and relative titer of human virus-specific neutralizing antibodies in subjects' serum following investigational treatment with the vaccine. Increases in virus-specific neutralization titer response demonstrates the study subject is producing a positive immune response to the vaccination.

The resulting fully developed and optimized assay was validated following FDA immunogenicity guidance criteria and transitioned to Eurofins Clinical Trial Solutions' clinical lab environment for high throughput testing of trial samples.

qPCR Assay

The purpose of this assay in the study was to assess for a viral infection and therefore determine vaccine efficacy.

Eurofins Clinical Trial Solutions performed four validations as part of the project (virus in matrix 1, virus in matrix 2, human cellular gene in matrix 1, and human cellular gene in matrix 2). In addition to this Eurofins Viracor BioPharma developed assay, another assay was also developed to assess qPCR assay specificity.

CASE STUDY

Immunogenicity Assay Development, Validation & Transfer in a Vaccine Candidate Clinical Trial

OUTCOME

- Acceptance criteria for the assay(s) were created in pre-validation, submitted to and approved by CBER without change or comment.
- Several specific areas of our expertise were called upon to enable the Eurofins Clinical Trial Solutions team to deliver on this project for the sponsor:

1. Our PCR expertise was needed to optimize and validate the quantitative viral detection and PCR specificity assays, as well as troubleshooting specific obstacles during nucleic acid extraction.
2. Our equipment allowed high through-put of samples, which was of high importance for the timely processing of the high number of samples expected in this study.
3. Our expertise in cell culture and ELISpot assay techniques proved invaluable to optimization and validation of a sensitive, robust, precise and specific ELISpot assay method.
4. Leveraging our excellent project management with Eurofins Clinical Trial Solutions' scientific expertise and openness to collaboration allowed timelines to exceed sponsor expectations.

- Our commitment to quality, technical precision, maintenance of critical cell lines and serum samples allowed Eurofins Clinical Trial Solutions to optimize, validate, and deliver multiple precise, robust and sensitive assays for the sponsor's trial.

Eurofins Clinical Trial Solutions is an integrated arm of Eurofins, offering complex/esoteric testing for clinical research. For more than 40 years, Eurofins Clinical Trial Solutions has been dedicated to helping clients by providing high quality, accurate results across multiple phases of drug development. Offering our partners broad experience in molecular infectious disease testing, immune response monitoring, vaccine safety/efficacy assessment, allergy and hypersensitivity testing.

Eurofins Clinical Trial Solutions is passionate about delivering value to our clients by providing timely, actionable information — never losing sight of the connection between the testing we perform and the goals of your study.

Contact us today to discover how the Eurofins Clinical Trial Solutions team can make the difference in your projects.

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