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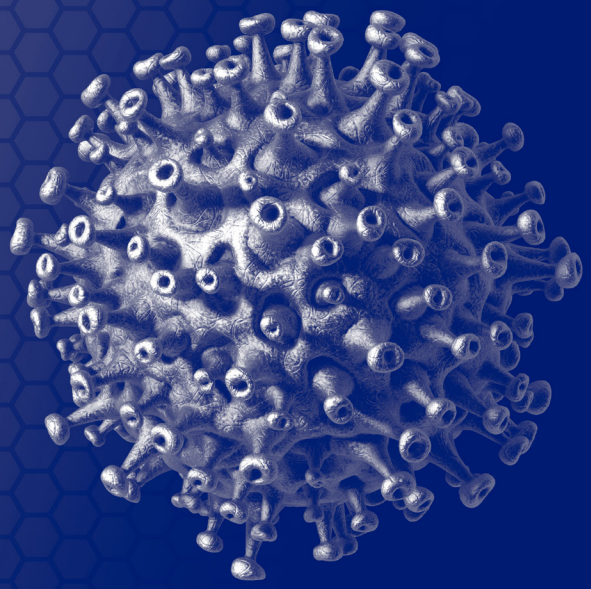

Assay development, validation & testing for an mRNA-1273 COVID-19 Vaccine Clinical Trial

INTRODUCTION / OVERVIEW

Vaccine development has historically been a long, complex process, requiring evaluation for immunogenicity, safety and protective efficacy. With this complexity, many factors can affect the probability of licensure and ultimate public health impact. However, with the recent emergence of a novel coronavirus, and the subsequent pandemic, research began on the first vaccine development efforts leveraging an mRNA vaccine platform. This new platform offered the advantages of both efficiency and flexibility in immunogen design, which proved critical for developing a therapeutic that could provide protective immunity in the face of the SARS COVID-19 outbreak, for which much of the world was unprepared.

SITUATION / CHALLENGE

As a leading provider of assay development and testing services for clinical development of vaccines and anti-virals, Eurofins Clinical Trial Solutions has supported multiple clinical trials for vaccine manufacturers. So, when Moderna was gearing up for clinical studies of their mRNA-1273 COVID-19 vaccine candidate, developed in collaboration with the Vaccine Research Center at the National Institute of Allergy and Infectious Diseases (NIAID), they reached out to Eurofins Clinical Trial Solutions to provide quantitative polymerase chain reaction (qPCR) assay development, validation, and testing. Eurofins Clinical Trial Solutions was already gearing up to enter the fight against the COVID-19 pandemic with the launch of their new Coronavirus (COVID-19) SARS-CoV-2 RT-PCR test. A qPCR assay that the US Food and Drug Administration (FDA) would later show to have the highest sensitivity of any they evaluated.

mRNA-1273 COVID-19 Vaccine Development

SOLUTION

In support of the Moderna mRNA-1273 vaccine clinical trial (COVE Study), Eurofins Clinical Trial Solutions quickly validated the assay, and carried out pivotal RT-qPCR testing for both the Phase II and Phase III portions of the clinical trial to assess the safety and efficacy of the Moderna vaccine candidate against novel coronavirus infection.

After validating a sensitive and robust qPCR assay for Moderna's clinical study, that was bridged to their EUA assay, the Eurofins Clinical Trial Solutions laboratory team performed over 2,000 Phase II tests, and more than 85,000 tests (on NP swab and saliva samples) to support their >30,000 subject Phase III trial.

The SARS-CoV-2 specific RT-qPCR assay was used to detect SARS-CoV-2 RNA in upper respiratory (nasal/nasopharyngeal wash and swab) and bronchoalveolar lavage (BAL) samples. This assay, provided qualitative detection of SARS-CoV-2 virus RNA in specimens collected from individuals in the trial. The SARS-CoV-2 RT-qPCR assay was also used for quantitative detection of viral RNA in both nasopharyngeal swabs and saliva samples to assess viral load.

Eurofins Clinical Trial Solutions also performed a spike-gene sequencing assay (SARS-CoV-2 S gene NGS assay) and a Whole Genome Sequencing Assay (WGS) on nasal swabs to assess SARS-CoV2 variants in the study population.

In addition to the SARS-CoV-2 testing, Eurofins Clinical Trial Solutions provided qualitative detection and differentiation of respiratory pathogens for 20 different viral and bacterial respiratory organisms associated with respiratory tract infection.

Lastly, as a function of the ongoing pandemic, Eurofins and Moderna overcame some of the most extreme logistical and inventory challenges a clinical trial can experience, to deliver consistent high-quality results in a timely manner.

OUTCOME

Eurofins Clinical Trial Solutions' contribution was essential to the successful completion of the COVE study trial, and ultimately the Emergency Use Authorization (EUA) by the U.S. FDA of the mRNA-1273 vaccine candidate for the prevention of COVID-19 on December 18, 2020; with subsequent approvals by regulatory agencies around the globe.

The RT-qPCR assay designed by Eurofins Clinical Trial Solutions, has also now been utilized world-wide to provide >20 million COVID-19 infection results.

In an era where therapy and vaccine efficacy are threatened by variants, Eurofins Clinical Trial Solutions continues to battle the global health threat by providing immunity testing and whole genome sequencing of SARS-COV-2.

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- 40 years of Scientific Experience
- Trusted Laboratory Partner
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- Over 3,000 validated assays

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

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Lit No. EBPS-VE-US-ADCS-10/2024
Printed in the USA.