Emmes

SARS-CoV-2 Pandemic Case Study

Vaccine Study Marked by Urgency and Complexity: Success Achieved with Experience, Flexibility and Dedication

Virtually every clinical trial involves meeting aggressive timelines. Few, however, have the urgency and broad impact of those testing vaccines for the SARS-CoV-2 virus in the middle of the pandemic. When a U.S. government division needed help in managing a platform trial to test additional doses of vaccine candidates from three manufacturers, they relied on Emmes. We collaborated with protocol development, specimen tracking, patient safety monitoring, data analyses and report preparation – all with an appropriate appreciation for the gravity of the situation. Public health policy decisions and the health of the nation were hanging in the balance.

Date Published: 06/15/2023 | Emmes- SARS-CoV-2 Pandemic- V:01

Case Study

The Challenge: Keeping Pace with the Pandemic

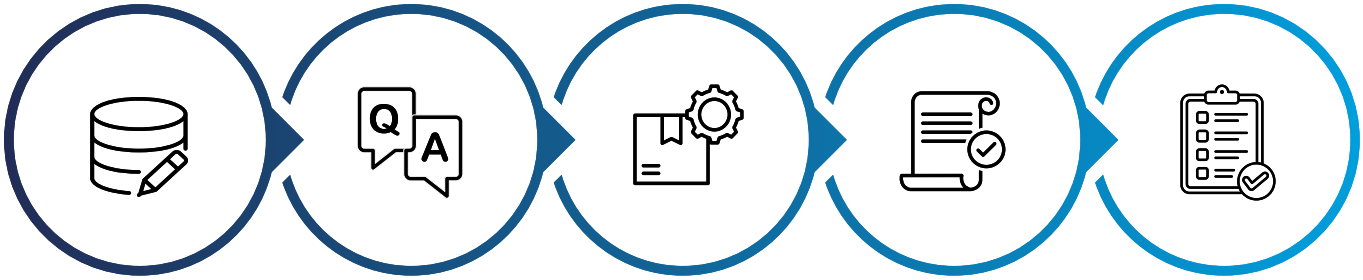
The study was undertaken to give the US Food and Drug Administration (FDA) the additional information it needed from a non-manufacturer to make decisions on booster vaccines as quickly as possible – even as the SARS-CoV-2 virus was mutating.

Meeting this need for rapid answers challenged Emmes to deploy the study in record time as well as to manage the study data in a way that gave the requesting government entity feedback on a rolling basis.

Emmes needed to complete protocol development and have its clinical trial management system up and running in a matter of weeks. It also needed to be able to track the disposition of hundreds of thousands of samples drawn from approximately 1,500 trial participants. The specimens would be collected at 24 sites across the country, then sent to a central repository before being shipped to seven labs for processing.

Because new variants of the virus were emerging over the course of the study (which is still ongoing and in the follow-up phase), Emmes' systems had to accommodate a series of protocol amendments seamlessly.

And, in order to support the decision-making process, the reporting requirements were extraordinary in their volume, speed, and frequency, calling upon Emmes' statistical programmers to be flexible, innovative, and efficient.



Information changing as the virus was mutating

Need for rapid answers

Logistical hurdled due to sample volumes

Seamless protocol amendments£

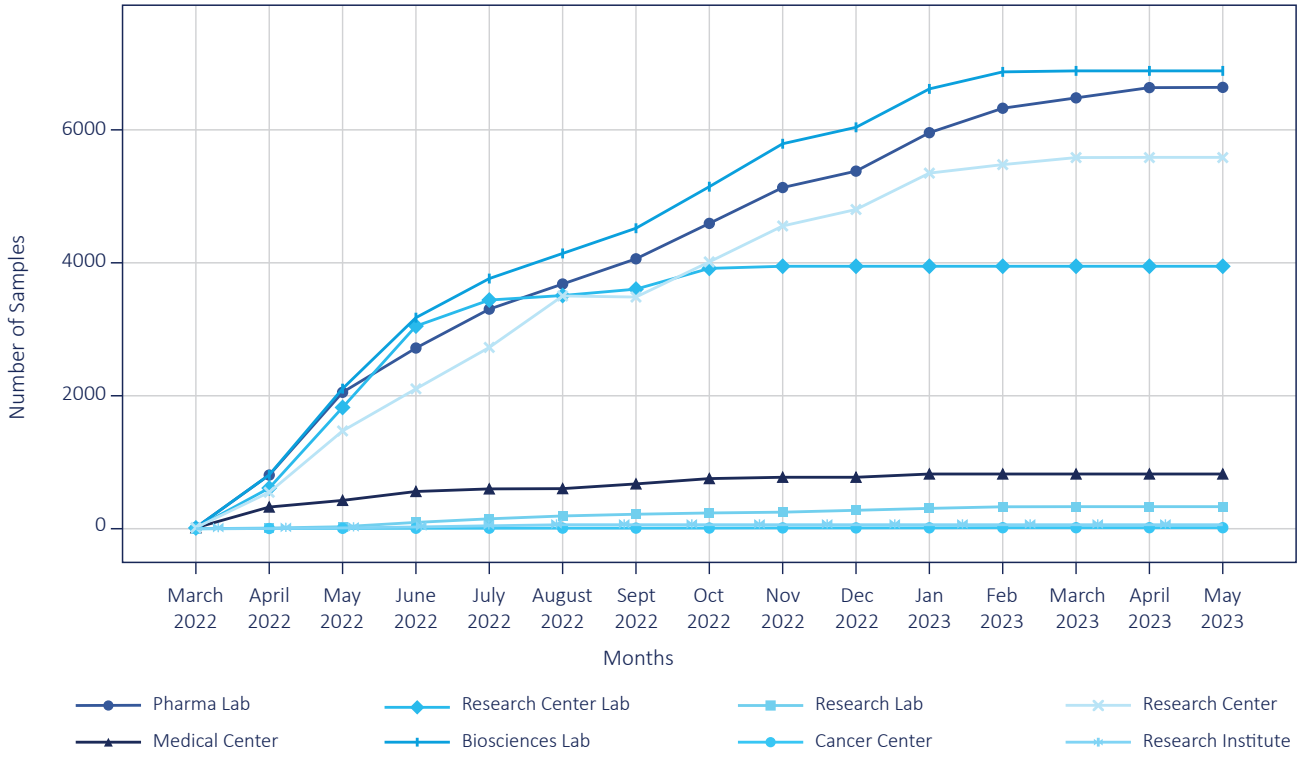
High volume reporting requirements

The Solution: An Integrated, Data Management and Capture Platform

To set up the clinical trial's data management system quickly, the data management and statistical team were also able to draw upon existing templates within Advantage eClinical and follow standardized processes from their work on prior vaccine studies to design the reports that were needed to disseminate the results. Additionally case report forms and the system were designed to be flexible enough to accept large amounts of data from multiple labs in varying formats and to allow easy updates to the randomization plan and treatment table to accommodate protocol changes as the trial was adapted to the changing circumstances of the pandemic. The statistical team was in turn able to create tables, figures and listings such as box plots and Kaplan-Meier curves for easy consumption.

To accurately track the location and status of every aliquot of every blood draw amounting to approximately 323,000 specimens to date, Emmes used its proprietary software, GlobalTrace. To prevent any delays in processing samples, the Emmes team proactively monitored subject visit schedules and encouraged sites to enter specimens into the system and ship them promptly to the central repository.

Clinical Trial Specimens Tracked using Emmes GlobalTrace



The Graph represents the number of specimens sent from the Central Repository to the Assay Laboratories and tracked using the Emmes GlobalTrace specimen management system during the course of the clinical trial. The Emmes data management and statistical team accessed the integrated GlobalTrace and Advantage eClinical data to track and process samples, proactively monitor participant activities, and generate immunogenicity reports from the analyzed samples.

The Results: Timely Answers for Government Decision Makers

The goal of the study was to provide policy makers at the FDA with the information needed to defend against the existing SARS-CoV-2 virus and emerging variants. Thanks to Emmes being able to deploy the study within eight weeks from the protocol concept to the first subject's first visit, the Sponsor was able to begin research with remarkable speed and with out any delays as the trial unfolded. Within a few months, the Sponsor was able to provide the FDA with the data it needed to make informed recommendations on booster vaccinations.

To satisfy the need for early and ongoing feedback, Emmes analyzed the data and produced an extraordinary number of reports as the trial progressed which allowed for regular insights as the pandemic evolved. Emmes biostatisticians also prepared manuscripts and letters to the editor that have been accepted for publication in several peer-reviewed journals and are being presented in various scientific forums.

Through a team effort, unwavering dedication, and a profound sense of commitment to helping manage the pandemic, we delivered just what the government Sponsor needed to provide the FDA with time-sensitive data. Subsequently, confident of our ability to meet even the most challenging study goals, the government Sponsor returned to us with two additional studies that had been assigned to other contract research organizations (CROs) that needed to be rescued.

8

8 different labs performing testing

8

Start up in 8 weeks

Publications

1 manuscript and 2 letters to the editor have been accepted for publication

323,000+

323,000+ specimens and counting

60+

Over 60 reports and counting

For additional information on our Data Management , please visit
https://www.emmes.com/vaccines-and-Infectious-diseases

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