CASE STUDY: Improving Clinical Trials With Innovative Solutions

BACKGROUND

Accelerating timelines for clinical trials has long been a top priority for drug developers. This is especially true for large, multi-site clinical trials where even with painstaking planning and design, it is easy for timelines to stretch, budgets to expand, and issues with data management to surface. But what solutions can be employed to avoid these problems and improve clinical trials?

This case study details how the central lab of one contract research organization (CRO) used innovative solutions to accelerate a large-scale clinical trial during the COVID-19 pandemic. Timelines absolutely could not be expanded, and sample collection, management, and analysis needed to be meticulous, though millions of samples would be collected. The result was the fast and successful completion of a monumental Phase III COVID-19 vaccine study that had a major positive impact on public health.

CHALLENGE: RAPID COMPLETION OF PHASE III COVID-19 VACCINE STUDY

In May 2020, during the height of the pandemic, PPD partnered with a drug company that was aiming to bring a much-needed COVID-19 vaccine to market very quickly. The drug company had targeted June 2020 for the kickoff of its Phase III clinical trial, creating a compressed start-up timeline of just six weeks.

The size and breadth of this trial was unprecedented. Approximately 30,000 patients needed to be enrolled over the course of this study. The study design included the collection of samples at six scheduled time points, four of which would happen within the first seven months of the study. At least 25 samples would be collected at each patient visit. In addition, investigators anticipated patients might need several sick visits over and above scheduled visits.

This equated to the collection of approximately 4.5 million samples, coming from nearly 100 different clinical sites. About three million of those samples would come within the first seven months of the study. Despite the incredible volume and speed, PPD would need to ensure every sample was tracked, recorded, and analyzed with the utmost care and detail.

Jennifer Markarian
Contributing Editor
Pharmaceutical Technology

Olivia Aspite
Executive Director, Global Lab Operations
PPD®, part of Thermo Fisher Scientific

Bryan Neth
Associate Director, Information Technology
Manager of Business Analytics
PPD®, part of Thermo Fisher Scientific

EMPLOYING STRATEGIC SOLUTIONS

To accommodate for challenges associated with analyzing such a large volume of samples in a short time period, the sponsor quickly reviewed its staffing, organized teams in the laboratory, and ensured all relevant materials were available. Organization-wide planning meetings were held weekly to discuss challenges and ensure the successful completion of action items.

A major issue considered was dedicated storage space for the millions of samples that would be collected for this study. PPD quickly identified some in-house storage space and initiated a collaboration with a third-party biorepository for overflow storage.

To keep track of the many samples quickly coming through the laboratory and storage areas, several proprietary technology solutions were employed, including those intended for use at clinical sites for sample tracking.

A critical piece of this endeavor was a multi-pronged deployment of PPD's Preclarus portals and central lab database. These tools ensured PPD had a full sample chain of custody for all 4.5 million samples traveling from the sites to the lab.

Included in this approach:

- The Preclarus investigator site portal and mobile app were set up at all clinical trial sites. The electronic requisitioning automatically logged samples from the point of collection, at the patient's bedside, to initiate the full visibility of samples at the start of their journey.
- A third-party lab portal was used in case referential labs were needed, thereby allowing that data to flow back into the system.
- A companion sponsor portal gave the sponsor the ability to see information about samples in real-time.

Electronic requisition and shipment tracking allowed PPD to track samples and give the sponsor and PPD teams full visibility of samples at any time.

FIGURE 1: Virtual Biorepository landing page-case study data.

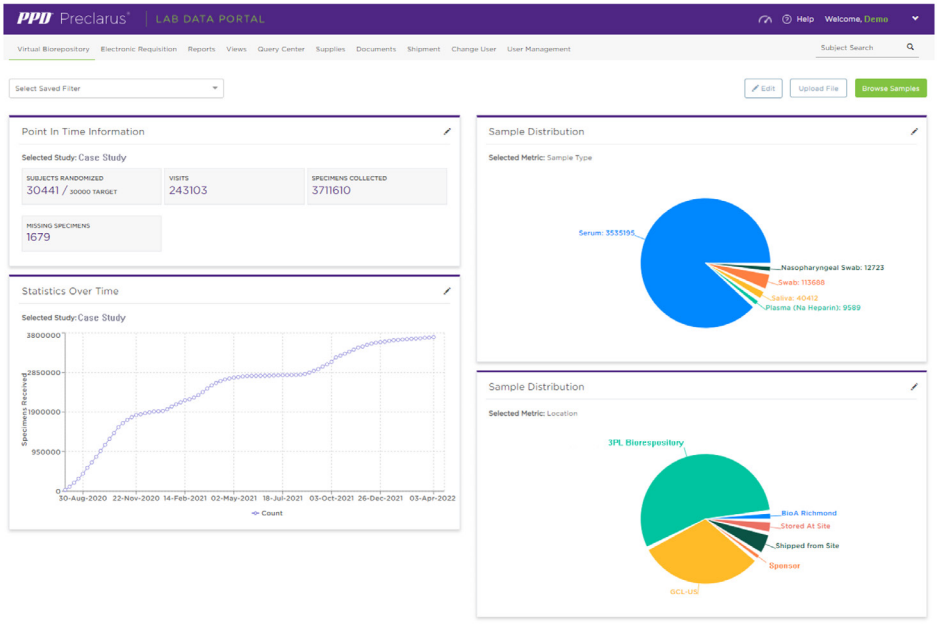

FIGURE 2: Outcome.

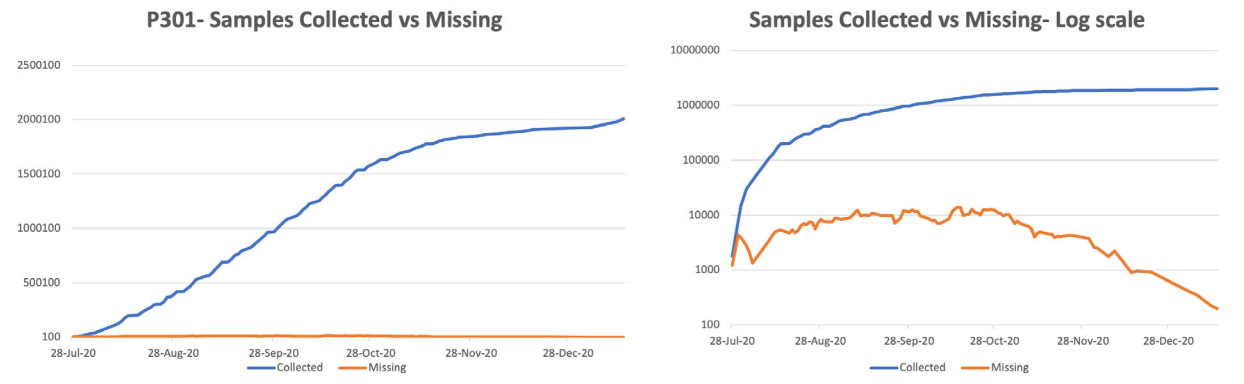

FIGURE 1 highlights a screenshot from PPD's virtual buyer repository landing page. The repository gave the sponsor and PPD teams insight into study data, regardless of where the samples were at any given time. The top left side of **FIGURE 1** reveals the number of samples collected and high-level metrics. The right-hand side shows a breakdown of the samples, their locations, the various associated sample types, and a trend of that collection. All this information was available for the sponsor to view in real-time.

RESULTS AND CONCLUSION

PPD tracked the number of samples that were received versus the number of missing samples daily. As a result of PPD's strategy and tools, less than 0.01% of all samples collected and sent to PPD's site throughout the first six months of the study were considered missing (**FIGURE 2**).

This is a significant achievement, especially given the size of this study and the speed at which it was executed. Moreover, with PPD's meticulous handling of the samples, all samples can now be used for further testing and development.