Rapid Study Activation and Enhanced Sample Management for COVID-19 Studies

SUMMARY

PPD® Laboratory Services central lab achieved study startup in less than two weeks and implemented a process utilizing innovative web-based data solutions to enhance oversight for critical COVID-19 studies sponsored by a large pharmaceutical client.

OBJECTIVES

- Complete setup of a new clinical trial database and deliver kits on-site within two weeks to meet accelerated timelines
- Provide enhanced sample chain of custody and a formalized oversight process to safeguard irreplaceable samples

study setup and enhanced sample oversight FOR A LARGE PHARMA CLIENT IN **<10 business days**

BACKGROUND

The COVID-19 pandemic has created unprecedented challenges for pharmaceutical companies operating clinical trials. As a result, these organizations are prioritizing rapid startup of their clinical trials for vaccines and therapeutics that prevent or treat the coronavirus. Due to the pandemic nature of the disease and the associated mortality/morbidity, there is an urgent need to identify therapies that improve patient outcomes and reduce the burden on health care systems globally.

CHALLENGES

PPD Laboratory Services central lab typically achieves database setup in 25 business days and is well known for database quality and integrity.[1,2] For this program, our team needed to find innovative ways to further streamline the study startup process while maintaining high-quality standards.

STRATEGY

In order to accelerate startup beyond already aggressive timelines, the central lab activated its global rapid implementation team (GRIT). The GRIT approach is used to meet the most challenging startup targets, while simultaneously ensuring quality. The GRIT approach is supported by an experienced, highly skilled project management team that applies a flexible and innovative approach to finalize central lab specifications and build the customized, program-specific database. Keys to success include:

- Beginning to build the central lab specifications utilizing draft protocols
- Initiating the customized database build utilizing the draft central lab specifications
- Early activation of the database through the Preclarus® investigator site portal to support initial kit delivery sooner

To enhance sample chain of custody and establish a formalized oversight process, the central lab project management team implemented and mandated the use of electronic lab requisition (eReq), a web-based sample accessioning tool available in the Preclarus investigator site portal, for the program.

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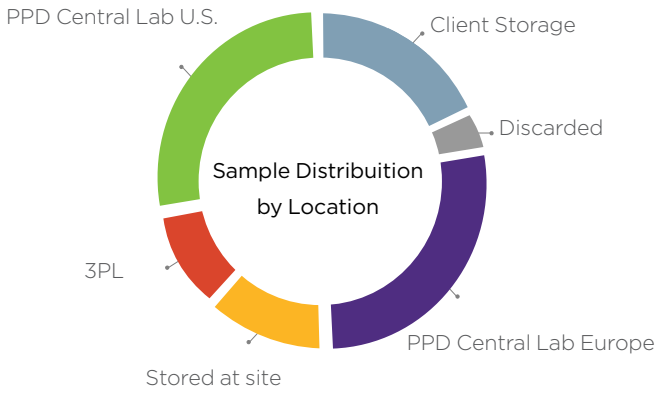
The eReq is used to connect patient/specimen information and the bar code, providing data visibility and strengthening chain of custody. Together, the central lab and PPD clinical teams disseminated instructional materials including job aids, YouTube videos and web-based training to drive compliance. The implementation of eReq and the investigator site portal for the study leveraged the tool's virtual biorepository and shipping functionality, making it possible to account for all COVID-19 positive samples at any time (see figure 1).

Key successes include:

- Utilizing eReq functionality to identify all COVID-19 positive samples immediately
- Tracking compliance of eReq functionality among sites multiple times per week
- Swiftly highlighting challenges and risks, removing potential roadblocks
- Arranging shipments using the Preclarus investigator site portal to plan for receipt of COVID-19 samples, protecting irreplaceable samples and ensuring employee safety

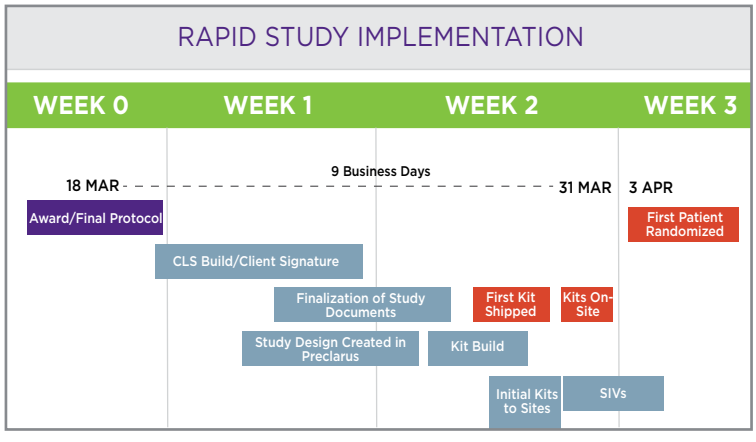
FIGURE 1. VIRTUAL BIOREPOSITORY

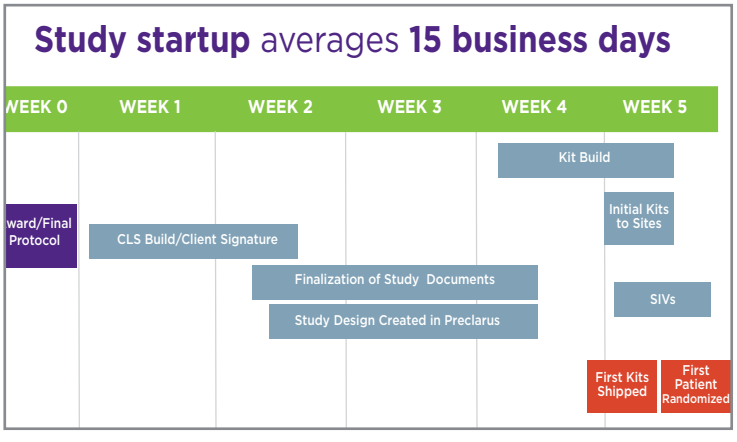


RESULTS

Quality study setup was achieved in nine business days and eReq was implemented across 73 sites for three separate studies in the COVID-19 therapeutic program. This allowed for rapid study initiation and patient enrollment for these time-critical studies (see figure 2). In addition, the enhanced sample management oversight processes implemented ensured that all samples could be accounted for and compliance with eReq requirements remained high, reducing risk of lost or misplaced samples and any risk to PPD staff upon sample receipt.

FIGURE 2. STUDY STARTUP TIMELINES





1. ISR Reports, Central Lab Market Dynamics and Service Provider Benchmarking, 2014.
2. ISR Reports, Central Lab Market Dynamics and Outsourcing Performance , 2016 and 2019.

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