



July 2020

Innovative Solutions to Enhance Specimen Chain of Custody

Executive Summary

The complexity of today's clinical trials often demands hundreds of sites, dozens of countries and varied needs for laboratory testing. PPD[®] Laboratories leverages a sophisticated single, global database called the Preclarus[®] central lab database that provides cutting-edge sample tracking technology. We have a robust suite of specimen tracking tools available to meet site lab shipment needs, resolve data discrepancies quickly and enhance chain of custody in all specimen shipping situations.

Award Winning Solutions: The Preclarus investigator site portal from PPD Laboratories' central lab is a web-based app designed to help pharmaceutical development sites manage PPD Laboratories interactions from start to finish. The portal automates and streamlines routine tasks, reduces data discrepancies by up to 67% and delivers cleaner data faster. [Learn more about the CenterWatch Top 100 Innovators award.](#)

Preclarus Central Lab Database

The unique web-based architecture of the Preclarus central lab database eliminates all steps involved in configuring multiple regional databases, as it only needs to be set up one time. Quality control (QC) and verification are performed once on the single instance of the global database. This results in higher quality and faster study startup compared to traditional multi-instance databases utilized by most CRO labs.

The Preclarus central lab database receives study data from sources across the global network through web-based portals and apps. This data is automatically QC'd as it enters into the single global database. As the trial progresses, data and results can be immediately provided on demand through sponsor and site portals. The Preclarus lab data portal and investigator site portal can provide visibility into sample status and test results regardless of the region the site is in, PPD lab location or third-party lab (3PL) that performed the testing.

Data from 3PLs is integrated into the database in one of two ways. PPD's bioanalytical, biomarker and vaccine sciences labs, and NeoGenomics have direct access so data and results are automatically consolidated. Other 3PLs are provided with a purpose-built 3PL portal where receipt of specimens can be recorded and test results uploaded.

Preclarus Investigator Site Portal

The Preclarus investigator site portal is a direct connection between PPD Laboratories' central lab and clinical trial sites, specifically designed to simplify clinical

trial management for site coordinators and investigators. The reports and tools within the portal streamline every process, including adding patients to the trial, ordering specimen collection kits, reviewing lab results, managing patients and critical values and registering and shipping samples to PPD. The investigator site portal also provides on-site biorepository tools to help manage samples and track them to their final destinations. Key functionality within the portal includes:

- **Patient/subject registration:** Study-specific patient/subject data is scanned or entered directly into the portal. Data is checked in real-time against the central lab database so that errors can be immediately corrected.
- **Electronic Lab Requisition (eReq):** eReq is an online specimen submission functionality that eliminates the need for a paper requisition by enabling study coordinators/investigators to scan to log samples into the Preclarus central lab database at the time of collection. Once the connection has been made between the sample/patient information and the bar code on the tube/vial/container, the data is immediately available to PPD Laboratories and select 3PLs. Electronic requisition strengthens the chain of custody by giving sites and PPD Laboratories full visibility to all specimens in real time from the point of collection.



Integrating lab
and clinical data
Real-time for
10+ years

- **Specimen management and shipping:** The investigator portal has several tools to help track specimens and organize/schedule shipments. These tools help the site monitor the progress of shipments to PPD labs or 3PLs.

- **Access to results:** As test results are released from the lab, they are immediately visible in the portal and on the companion mobile app. Graphing and trending tools are also available. The mobile app enables total portability of information for the site monitor/coordinator and the investigator.

- **Online collection kit ordering:** Preclarus notifies the site when to order kits based on an active site inventory, ensuring the right kit is used for each visit and the right sample is being collected. Feedback is immediate in the case of errors so that corrections can be made while the patient is still in the clinic.

The Preclarus investigator site portal was introduced in 2015. There are currently more than 23,000 sites actively using the portal. Use of the portal and eReq reduces the occurrence of errors up to 67%. Historically, about 85% of all errors are related to the paper requisition process as opposed to the online process. With eReq, requisition-related errors per sample are reduced by more than 55%. In addition, the time to resolve errors with the portal is more than 60% faster (<1 day vs. 2.3 days without the portal).



67%
Reduction in
queries/visit

Figure 1. Comparison of top ten errors encountered in recent PPD central lab trials and resulting decrease in errors with use of eReq throughout the Preclarus investigator site portal

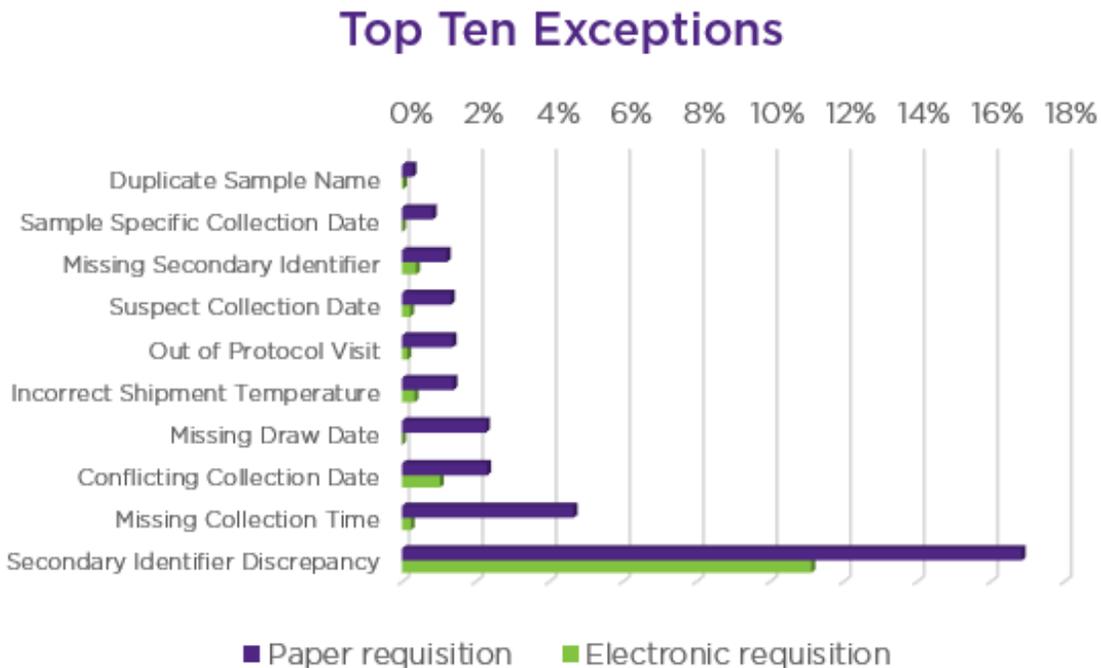
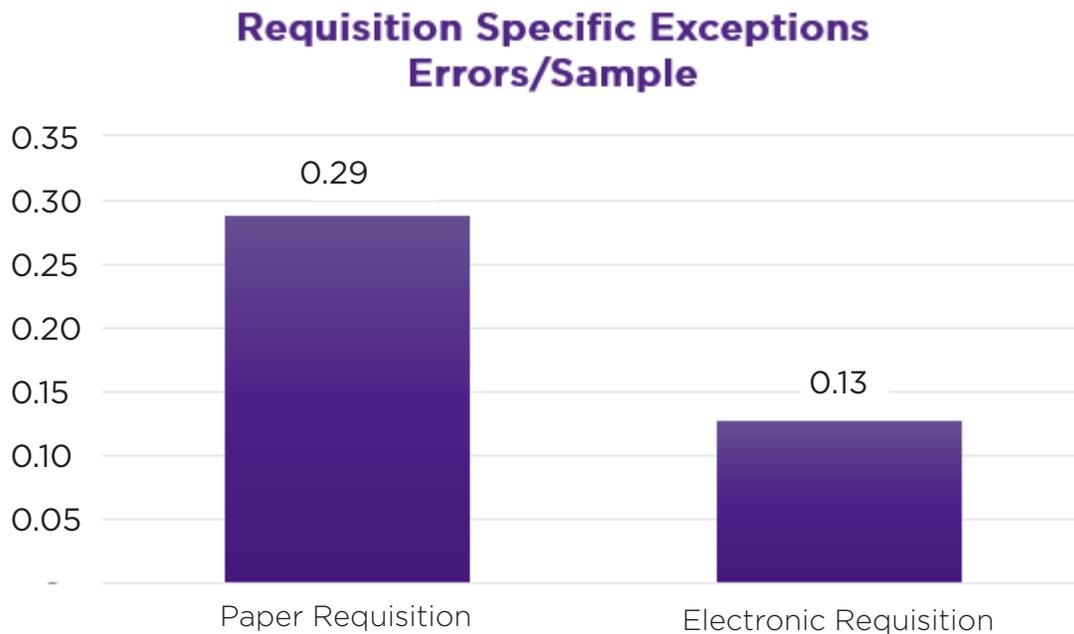


Figure 2. Reduction in requisition-related errors with the use of eReq via the Preclarus investigator site portal



Enhanced Specimen Chain of Custody

Sites use the Preclarus investigator site portal's online patient registration and eReq for access to their PPD central lab trials. Once specimens are logged into the portal by scanning the barcode on the pre-labeled specimen container, the data is immediately visible to PPD Laboratories central lab and other labs directly connected to the central lab database. The progress of the specimen stays up to date in the investigator site portal as the sample is shipped to, and received by, the central lab. The site uses the portal's shipping tool to create a specimen shipping list and capture the air waybill number for the shipment. The air waybill number becomes part of the record enabling shipment tracking by the site or the project team and maintaining the chain of custody.

Preclarus Lab Data Portal

The Preclarus lab data portal is a secure access point for customers/study sponsors to oversee their PPD central lab trial performance and analyze lab results. The

Preclarus lab data portal provides:

- Secure customer access to real-time, studywide data 24/7
- Ability to visualize, organize, search and manage lab data from a centralized access point
- A virtual biorepository with real-time visibility to specimen storage location and specimen chain of custody
- On-demand, customized sample history reporting and tracking of samples across customer, site and PPD lab locations and 3PLs

The electronic sample requisition and tracking tools within the Preclarus lab data portal create a virtual biorepository for unsurpassed visibility to specimen location and documented chain of custody. Specimen history and chain of custody reports document the proper handling of trial specimens, ensure data integrity and improve the amount of usable data. Online specimen accessioning creates a virtual biorepository and provides visibility to specimen whereabouts across client, investigator and any PPD lab location and select 3PLs.

Preclarus third party lab portal: The Preclarus third party lab portal strengthens chain of custody for samples shipped directly to the 3PL. The portal gives the 3PL direct visibility to samples that are in transit to their lab. In addition, the portal allows the 3PL to see what tests are being ordered on each sample to facilitate scheduling and improve turnaround time. These capabilities are 21CFR part 11 compliant.

Preclarus lab data portal: The business analytics team is also working on a software update for the lab data portal that will expand the functionality of the virtual biorepository tools. The new functionality will give customers/study sponsors the ability to upload information about samples stored at their facility or other off-site storage centers. This data will be searchable and custom reporting capabilities will be available to help organize and manage samples. This functionality will be especially helpful for locating samples that fit specific criteria for future studies, (e.g., trials for newly identified biomarkers, intended use expansion trials, etc.)

The update will also expand the functionality for informed consent status so stored information becomes part of the database. This will enable detailed visualizations of the data within the system and facilitate keeping informed consent documentation current.



Conclusion

PPD Laboratories' central lab has a proven ability to track samples and reduce errors through innovative web-based applications. When used together, these Preclarus lab solutions create a fully documented chain of custody for clinical trial specimens.

The Preclarus central lab database creates a single global database to enable real-time access to sample data and test results.

The Preclarus investigator site portal and companion mobile app streamline clinical trial management for busy site coordinators and investigators. When specimens are shipped to or through PPD Laboratories, chain of custody is established at the time of specimen collection.

The Preclarus third party lab portal connects 3PLs to PPD Laboratories' central lab database and allows 3PLs to log specimens into the system when they arrive and upload test results.

The Preclarus lab data portal puts studywide lab data in the hands of the customer/sponsor study team in real time so that decisions about their studies can be made quickly and with confidence.

PPD Laboratories' award winning Preclarus lab solutions continue to grow and evolve to meet the changing needs of today's complex clinical trials. Our solutions are designed to streamline every step of the drug development process for customers, sites, investigators, project managers, 3PLs and our own PPD laboratory scientists.

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For more information, please contact us at

Americas +1 859 781 8877

EMEA +32 2 275 2127 ext. 4300

APAC +65 6594 6210

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