WHITE PAPER

June 2021

# **PPD Laboratories' Preclarus Lab Solutions:** A Comprehensive Suite of Portals, Dashboards and Innovative Tools to Enhance Your Clinical Trial

## Executive Summary

Preclarus® is PPD's award-winning comprehensive clinical data portfolio solution that consolidates and presents data from multiple sources. It delivers data on dashboards that offer interactive visualizations and analytics to identify trends and enable the user to drill down to detailed information. Within the broader Preclarus umbrella, PPD® Laboratories offers the Preclarus Lab Solutions. For our laboratories, Preclarus is more than just a suite of databases, portals and dashboards — it is an invaluable solution to maximize the utilization of time and resources of your study while ensuring its quality. Our proprietary global database, which utilizes interactive web portals and a first-of-its kind mobile app, provides customers, investigators and project teams secure access to clean, laboratory data to enable faster, more-informed decisions.

## **Preclarus central lab database:** The heart of our central lab, providing integrated data to project teams to make informed decisions

The Preclarus central lab database is PPD Laboratories' proprietary enterprise and information management system purposefully designed to manage every aspect of a central lab clinical trial. The web-based architecture eliminates all steps involved in configuring (and later reconciling) multiple regional databases. It only needs to be set up one time, and 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.

**PPD Laboratories'**
on average, achieves study startup in
**24** business days, **75%** faster
than the industry standard

### Access to integrated lab and study data

The central lab database receives study data from sources across the global network through web-based portals and apps that are automatically QC'd as the data enters the single global database. For trials that use both PPD laboratory and clinical development services, real-time study data can be provided on demand through PPD's clinical trial management system and proprietary interface to the central lab database. In addition to real-time study data from PPD Laboratories' central lab, combined laboratory and clinical data can be accessed by project teams through Preclarus. This provides teams and customers transparent, real-time access to all clinical trial operations and patient data, which can be viewed through interactive dashboards that provide insightful data visualizations. Access to this data and information helps our customers make better decisions faster.

### Data reconciliation

More than 70% of data submitted for a new drug

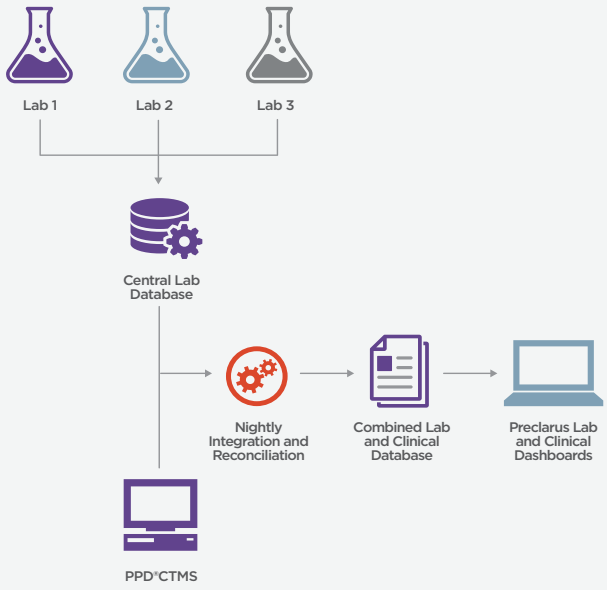
Integrating lab and clinical data
**Real-time for**
**10+ years**

application (NDA) come from the laboratory. At no time is the central lab database more valuable than at the end of the trial when all data have been collected. Without Preclarus, data sets from individual lab locations must be standardized before they can be combined, an expensive and time-consuming task. Patient and lab data are collected separately throughout the course of a trial. Data from clinical trial sites, which consist of patient demographics and clinical measurements from patient visits, are captured on case report forms (CRFs), while central laboratory data, which consists of results of sample analyses (e.g., blood, urine), must be transferred to the CRO and integrated with CRF data. The two data sets then must be reconciled to eliminate discrepancies, errors and omissions. Before the database is closed at the end of the study, reconciliation of all integrated data must be reconfirmed. To merge the two data sets, transfers must take place at set intervals; in most cases weekly or monthly. Each transfer requires two to six hours of preparation before transfer, and an additional two to four hours to merge the data upon receipt of the transfer. When data are collected separately, CRF data may not be updated and reconciled with laboratory result data until the end of the study. End-of-study reconciliation of the data sets for each patient over the full duration of the study can take up to several weeks. This is frequently the cause of significant delays in database lock.

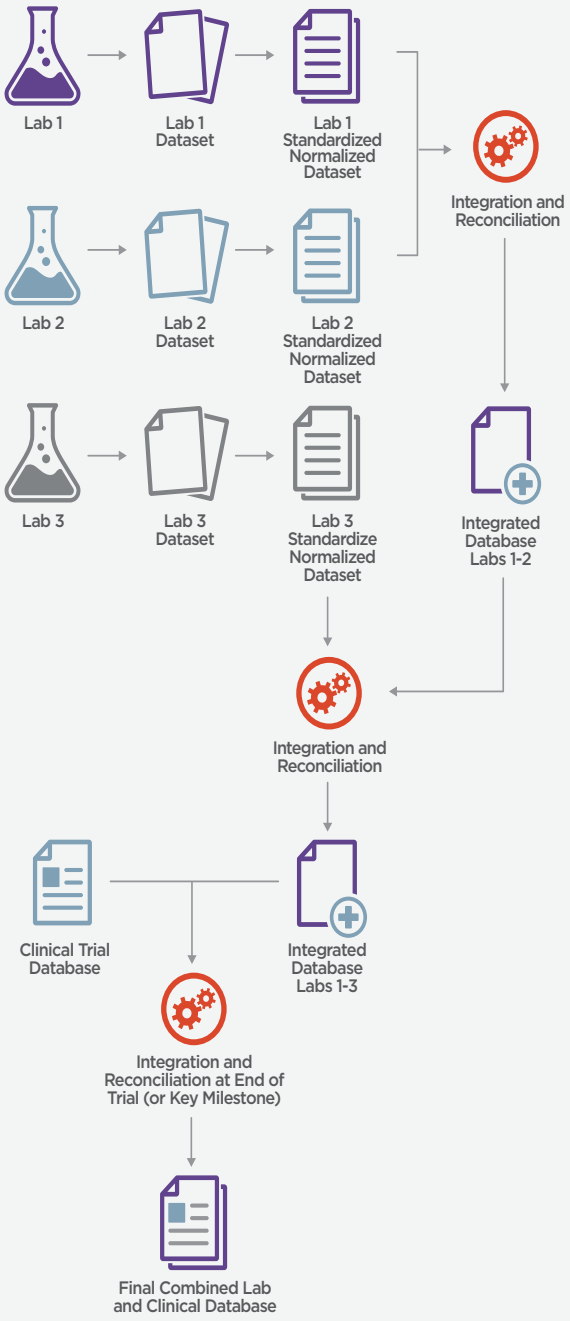
With the Preclarus central lab database interfaced to PPD's clinical trial management system, data standardization and reconciliation happen automatically, eliminating the need to merge and harmonize data from different systems and saving hundreds of hours at the end of the trial. This eliminates the labor-intensive process of data transfer, which requires up to 100 hours (about

four days), and it also eliminates the four- to eight-hour hour total transfer time, which typically saves from 100 to 200 work hours over the life of a trial. The potential for transfer format errors is eliminated as well. The cost savings achieved are estimated at tens of thousands of dollars for an individual study. However, the less quantifiable – and more significantly measured – is the reduction of risk to study closure achieved because of reduced cycle time and elimination of transfer/ reconciliation cycles on the critical path to database lock.

## Data Integration With Preclarus




## Data Integration Without Preclarus



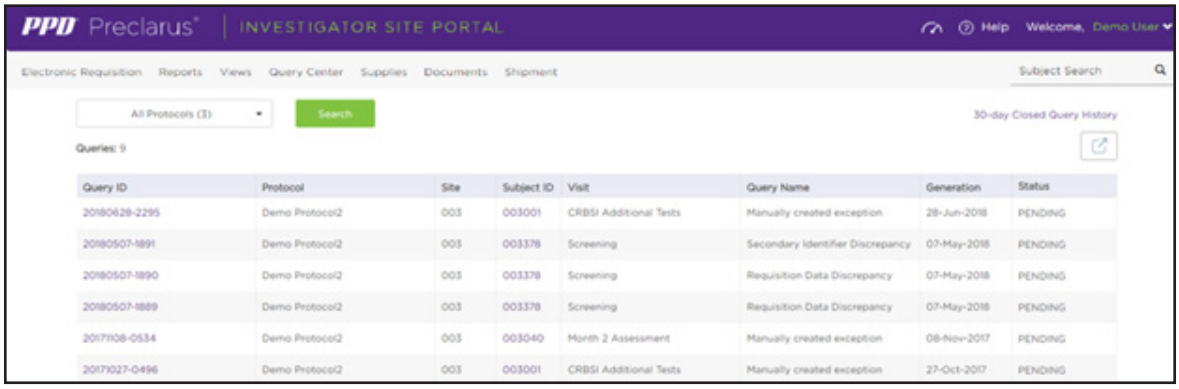
## **Preclarus investigator site portal:** Streamlining clinical trial management for busy site coordinators and investigators

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**.**

**In 2021, 98% of our studies are using the Preclarus investigator site portal**

The investigator site portal provides several tools to streamline the management of PPD Laboratories' clinical trials. Subject registration tools allow investigators to scan and directly enter study-specific patient/subject registration into the portal. The data are checked in real time against the data housed in the central lab database, so errors can be immediately corrected, eliminating costly error reconciliation at the end of the trial. Available in the investigator site portal are advanced specimen tracking tools to aid investigators in tracing specimens and organizing/scheduling specimen shipments, as well as monitoring the progress of these shipments to PPD facilities or third-party labs (3PLs). In addition to scheduling and organizing shipments, the investigator site portal notifies sites when to reorder kits based on active site inventory, ensuring the right kit is used for each visit and the right sample is being collected.

Real-time data is one of the main benefits of the Preclarus suite of lab solutions, which is the case for the investigator site portal. Access to test results are immediately available to view in the investigator site portal and its companion mobile app. The mobile app enables site monitors, coordinators and investigators to have all the functionality of the portal on their smartphone or tablet. Graphing and trending tools also are available. Specimen chain of custody is of paramount importance to any clinical trial. The electronic lab requisition (eReq) in the investigator site portal is an online specimen submission functionality that eliminates the need for a paper requisition by enabling study coordinators/investigators to scan and 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 are immediately available to PPD Laboratories, the study team and select 3PLs. Electronic requisition strengthens the chain of custody by giving sites, study teams and PPD Laboratories full visibility to all specimens in real time from the point of



**67%**
Reduction in queries/visit

collection. Use of the portal and eReq reduces the occurrence of sample registration errors by 67%. Historically, about 85% of all errors are related to the paper requisition 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 (less than one day vs. 2.3 days without the portal).

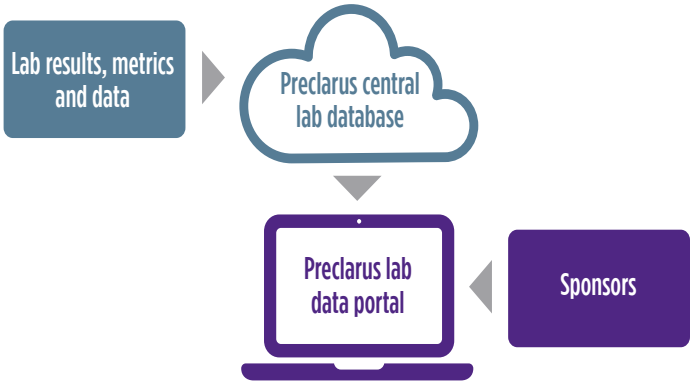
## PRECLARUS INVESTIGATOR SITE PORTAL IN ACTION

**"I underestimated how awesome bar codes would be; I was dreading the process change but now I wish I could apply this to other protocols. The Preclarus system catches potential errors when entering visit information and scanning specimens, avoiding costly mistakes. The batch shipment feature is my favorite, specifically scanning the group of tubes and having them linked to the preprinted shipping label automatically. The documentation generated by Preclarus makes it easy and convenient to locate sample information. Preclarus has spoiled me."**

**Administrator, Clinical and Translational Research Center**

## **Preclarus lab data portal:** The secure access point for laboratory data, metrics and clinical trial information for customers

In addition to the central lab database and the investigator site portal, the Preclarus lab data portal puts studywide lab data in the hands of the customer study team in real time so decisions about their studies can be made quickly and with confidence. Similar to the investigator site portal, it is the secure access point for study customers where they can search, visualize and manage the real-time laboratory data related to their study that is collected and stored in the Preclarus central lab database.

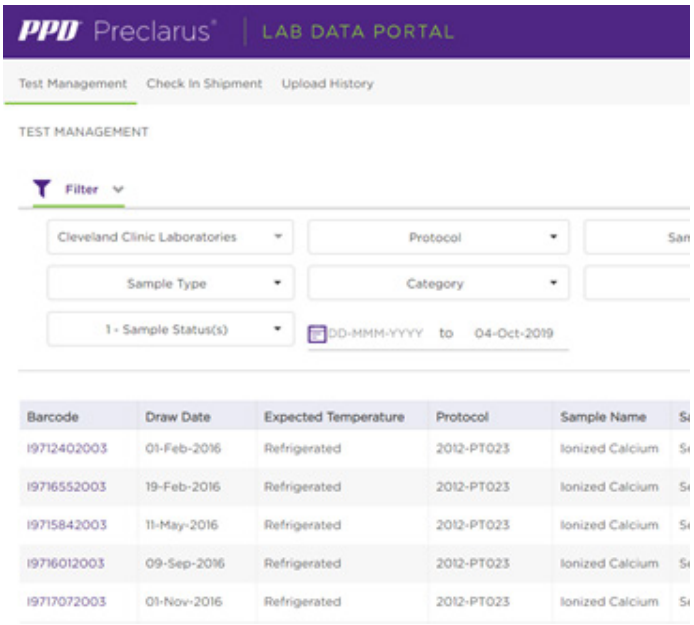



The Preclarus lab data portal includes a virtual biorepository and provides complete chain of custody for all study specimens. The lab data portal provides real-time visibility to specimen storage location, whether that is the customer's facility, the investigator site, a PPD lab or certain 3PLs.

## **Preclarus 3PL portal:** Streamlining routine study activities for third-party/partner laboratories

Preclarus lab solutions include a secure access point for 3PL or partner laboratories similar to the investigator site portal and the lab data portal. The Preclarus 3PL portal streamlines routine study activities and provides ease of use for chain of custody and lab result updates.

The 3PL portal provides the ability to filter samples that are assigned to the 3PL for testing, to upload results directly into the Preclarus central lab database, to update the chain of custody on 3PL samples they have received and allow users to search for samples throughout the portal.




## **Preclarus project management dashboard:** Access to nearly every element of your clinical trial

The PM dashboard is a tool for PPD Laboratories' central lab project managers to monitor the non-data aspect of customer studies quickly and easily. Tracking and reporting include missing samples, kit utilization rate, spend rate, patient enrollment and site performance. Project managers are essential to a clinical trial's success. The dashboard enables them to manage collection kit inventory and missing samples, along with other critical elements of a central lab program. These powerful studywide tracking and trending tools provide a succinct view of how a study is progressing and enable more efficient, proactive and strategic communication between a PM and customer/customer team members.

The PM dashboard enables a **proactive approach** so exceptions and queries can be prevented.

## Future enhancments to Preclarus

Through feedback gathered by listening to our clinical partners in the field, we are continuing to improve the Preclarus lab data portal. Our upcoming enhancements will help improve the end-user experience through: significant reduction of kit waste by accepting bar codes from outside kit vendors; the ability to view and sign a daily site (results) report directly from your device; and enhanced patient safety reporting.

PPD®

For more information, please contact us at

| | |
|---|---|
| Americas | +1 859 781 8877 |
| EMEA | +32 2 275 2127 ext. 4300 |
| APAC | +65 6594 6210 |

ppd.com/our-solutions/ppd-laboratories

twitter.com/PPDCRO

facebook.com/PPDCRO

youtube.com/PPDCRO

linkedin.com/showcase/ppd-laboratories