Accelerating Clinical Trials and Reducing Human Error Through Innovative Data Solutions

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Central laboratories have traditionally used regional databases to collect data during clinical trials. This approach creates some significant problems, however, that could ultimately lead to elongated timelines and additional costs for sponsors. An optimized model seeks to address these challenges with a single-source global database.

ENHANCING CLINICAL TRIAL SUPPORT IN THE CENTRAL LAB

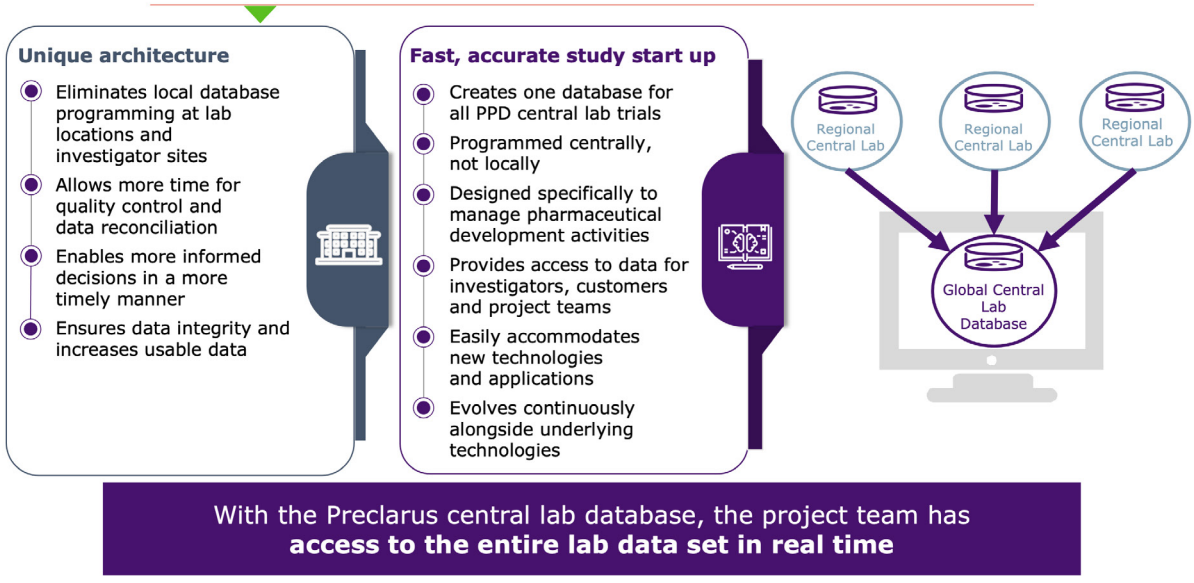
Using regional databases to collect data from various sites often creates inefficiencies. Laboratories must set up and validate each database individually, which is time consuming and stretches resources. Moreover, nightly data merges and reconciliation cycles are needed to create a single global data transmission, which causes unnecessary delays and blind spots for seeing data in real-time.

This inefficient model also has strong potential for human error. One cannot guarantee each database is set up with the exact same specifications.

To address these challenges and accelerate clinical trial processes, one contract research organization (CRO) built a proprietary single-source global database (Preclarus®, PPD Laboratory services' central lab database) with a unique architecture that integrates data from all labs involved in a study (**FIGURE 1**). Designed specifically for managing pharmaceutical development activities, the system is programmed centrally, as opposed to individually, ensuring the same specifications are implemented for all regional labs. This frees up time for quality control and data reconciliation.

This solution provides other important advantages as well. This proprietary single-source database integrates with internal bioanalytical, biomarker, and vaccines labs as well as those of third-party laboratories. This data exchange allows the system to interface all laboratory data daily, with automated data reconciliation against the clinical database.

FIGURE 1: Integrated study management with Preclarus® Central lab database.



This approach pays dividends in time savings. The CRO can reconcile queries within 2–3 days versus 2–3 weeks for an average cycle. With a near real-time reconciliation process, data corrections occur well before study milestones and clean data are delivered on time.

Moreover, since data do not need to be merged and harmonized individually, global data sets are readily available for investigator sites and project teams. This means sponsors can use innovative reporting and analytical technologies that allow project and clinical teams to monitor study-wide data in real time. Ultimately, this improves data quality, allows for immediate data reporting, accelerates decision-making, and leads to cost savings.

INTEGRATED DATABASE APPROACH OFFERS BENEFITS TO SITES

The single-source database system also provides advantages for sites. The proprietary database has an investigator site portal and a mobile application that connect directly with the central lab, enabling sites to easily register new subjects. Sites also benefit from streamlined inventory management. Each site has a "virtual closet," where inventory of kits used, expiry dates, and more are housed. Users can view and respond to queries here as well.

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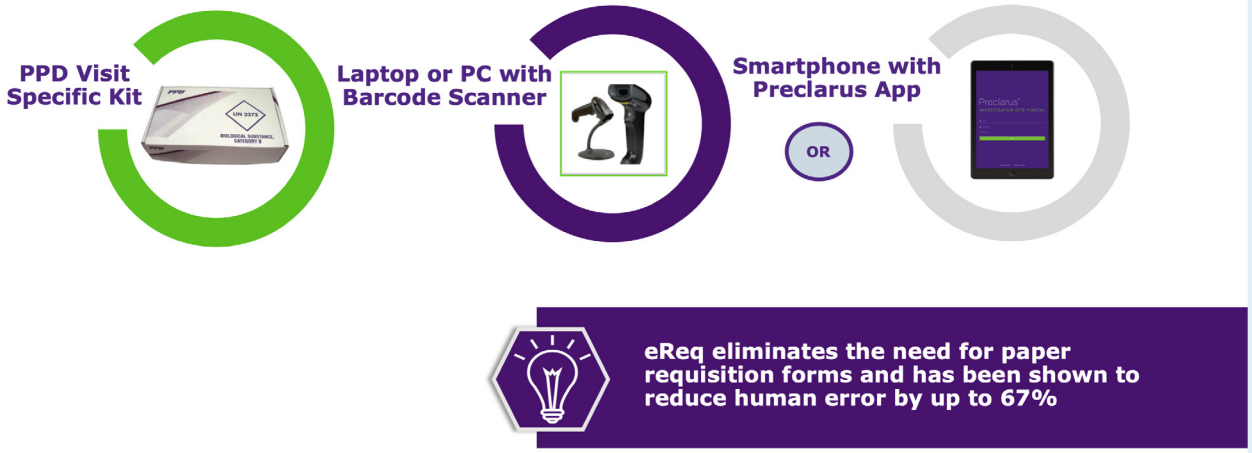
Moreover, the electronic lab requisition (eReq) provides sites a means for straightforward online specimen registration and full visibility into sample chain of custody from the time of specimen collection (**FIGURE 2**). Lab kits used with this system have pre-barcoded sample collection containers that are

FIGURE 2: Electronic lab requisition (eReq) for straightforward submission and full visibility.



scanned into the portal at time of collection, eliminating the need for paper requisition forms. The database immediately crosschecks this scan with any previous subject demographics and protocol visit requirements, to look for discrepancies. All information is linked to the barcode when the specimen is taken. Thus, the potential for data gaps and discrepancies is dramatically reduced over what is typically seen with paper requisition forms. eReq has helped reduce inquiries that investigator sites need to resolve by 67%.

This process saves time at the lab as well. When samples arrive at the central lab for testing, they are immediately recognized and available for testing.

DATA SOLUTIONS ON THE HORIZON

CROs are continuing to build innovative solutions to further accelerate clinical trials. The integrated database solution discussed here provides an incredible opportunity for improving data quality and visibility in multiple ways, cutting costs, accelerating timelines, and providing advantages for sites. Technology to incorporate a portal that aims to improve patient recruitment, retention, readiness, and diversity of patient populations is currently being investigated. With advances such as these, the future is bright for innovative data solutions to improve clinical trials.