White paper

Central lab

How can a central lab deliver essential lab data and optimize study timelines?

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In this Xtalks Spotlight, Chris Clendening, SVP, PPD™ Laboratory Services, discussed the importance of robust central lab solutions that offer an integrated, flexible, one-stop solution for the collection, management and analysis of lab and study data in the clinical trial ecosystem.

A central lab is a specialized facility that offers centralized services including laboratory tests and analyses for clinical studies and clinical care. These labs play a crucial role in ensuring standardization, accuracy and reliability of data across multiple study sites. Central labs ensure consistency in test methodologies, equipment and reporting standards, which is vital for the integrity of clinical trials.

Accurate and reliable lab data play a crucial role in any clinical trial. Real-time access to clean data can drive higher operational efficiencies and assist clinicians and sites in making more informed decisions for patients. Strategic tools and systems that effectively manage all aspects of clinical trials help to enable informed decision-making, drive site excellence and address challenges.

In today's digital age, the enormous amount of data generated in clinical studies necessitates the need for powerful, dynamic digital tools that provide data integration in real time from which insights can be garnered to help inform clinical decisions. Modern central lab solutions often integrate advanced technologies like Laboratory Information Management Systems (LIMS), Electronic Data Capture (EDC) and other digital tools to streamline processes and ensure seamless data flow. They also handle logistical aspects like sample collection, transportation and storage, adhering to stringent regulatory standards.

In this Xtalks Spotlight feature, Chris Clendening, senior vice president of Central Lab at PPD, the clinical research business of Thermo Fisher Scientific, spoke about the importance of robust central lab solutions that offer an integrated, flexible, one-stop solution for the collection, management and analysis of lab and study data in the clinical trial ecosystem.

Clendening spoke about the company's Preclarus™ Lab Solutions, a cutting-edge data and analytics platform that offers real-time access to study and lab data with transparent reporting and analytic capabilities to facilitate critical clinical decision-making and solutions to challenges that drug developers face. It includes a proprietary web-based enterprise and information management system for the central lab to provide a fast and accurate study startup, as well as data visualizations and interactive reporting tools to turn data into actionable intelligence.

Lab data challenges that drug developers face today

Laboratory data management presents several challenges that can have significant implications for data quality, research outcomes and patient care.

In the central lab industry today, some of the major challenges include the acquisition and integration of lab data in real time. Specifically, while lab test data has been the focus for most central labs, there's a lack of operational data, explains Clendening. The processes do not simply involve receiving a sample, testing it and producing a result, he says. *"There's an entire ecosystem in the central lab and in a clinical trial that you need to be aware of," he says. "All of those pieces in the ecosystem present their own challenges and obstacles to overcome."*

This ecosystem involves many moving parts, including a central database, managing the ordering of test kits, shipping kits to sites, kits being translated into samples, tracking samples as they're sent back to the lab, sample analysis, results reporting and analysis and sharing data with clinicians. This is difficult to do from a complete data perspective if there isn't visibility of the moving pieces in real time. And even if this operational data is effectively captured, it becomes key to surfacing and analyzing it to create efficiencies that save time and money.

Clendening says perhaps the hardest part for a lot of clients *"is being able to visualize what's going on within their study in real time. It has kind of been a black box until you develop tools that allow for that."* This necessitates a system that shows every step of the process, which includes tracking from the staple chain of custody, presenting outstanding queries, kits and supplies used, etc.

Moreover, particularly in the post-COVID-19 era, clinical trial complexity continues to increase across the industry, which includes how trials are designed. Therefore, Clendening says, you *"need to have systems that are flexible enough that allow you to pivot, still do everything that you need to do, but produce it in a faster, more efficient way."*

PPD laboratory services' lab data solution: Preclarus

Managing the lifecycle of laboratory data, from collection to archiving or disposal, while ensuring it remains useful and accessible, is a complex task.

Clendening explains how around 13 years ago, the company's central lab team recognized that day-to-day tactical operational data was lacking across the industry. This led to a focus on developing the right tools that went beyond just testing and delivering data. Instead, they built a tool that encompasses all of the moving parts of a clinical trial and that surfaces actionable data from those pieces.

This also included the need for a single global database. This is critical for multi-center trials that are often conducted around the world, from the US to the European Union (EU) to the Asia-Pacific (APAC) region. While they operate in the same way and face similar challenges, it is important to have visibility to all of them simultaneously, explains Clendening.

Preclarus acts as a single global database to provide that visibility, enabling study teams to access what is happening within a study all at one time, in real time. This makes processes seamless as you don't have to deal with several databases that may need to be integrated. Instead, there is one database that you're logging into, programming it, data is surfaced and it's ready to go all in one fell swoop, says Clendening. Importantly, a single database allows for the setup speed to be much faster.

Study database setup is also faster because Preclarus is a web-based application, which makes its usability and application broad and user friendly, as it doesn't require programming by a specialized data or IT team. Protocols are simply transferred into the database through a series of modules in the web-based application and include self-editing as you go along. And as a single global database, it can be programmed from anywhere in the world that you have web access.

Industry challenges: Managing the clinical trial ecosystem

The development of Preclarus was guided by the identification of key industry challenges and the creation of solutions to them within a single platform. Some of the features and solutions that Preclarus offers include:

Sample Chain of Custody

The sample chain of custody is an important challenge in the industry. Tracking samples from the point of collection through the entire life cycle can be a challenge. This includes collecting details such as information about the airway courier bill, the different modes of transport involved in getting the sample to a lab and identifying the type of lab i.e., central versus non-central lab. It is therefore critical to be able to track the chain of custody through the entire journey. Preclarus tracks the chain of custody of millions of samples in real time.

Real-Time Error Checking

Identifying and correcting errors is also a key challenge. Clendening says Preclarus was designed to help people avoid making mistakes at the point of inception by having real-time error checking. Being well acquainted with the types of errors that happen, he says the goal with Preclarus was to integrate real-time error checking that would help guide the site or the person entering information to get it right the first time. This can include something as simple as inputting correct dates to more complex data measures and processes.

Meeting Study Timelines

From a speed and timeline standpoint, cleaning up data after errors have been propagated downstream (i.e., from a central lab to third-party labs, biorepositories, etc.) can be complicated, tedious and time-consuming. Preclarus' real-time error checking can prevent issues as the data is continuously monitored and cleaned. The result is clean, error-free data at interim and final database locks, which can help adherence to timelines. This is especially significant when studies have hundreds or thousands of patients and visits, as one small error can become a major setback, explains Clendening.

Additionally, since Preclarus is a single global database that only has to be programmed once, this decreases the amount of time it takes to program it. As it is web-based, developers or data managers do not have to be involved in setting up the database, which can reduce setup times.

Flexibility

In the clinical trial industry, there is a multitude of different studies, disease states and timelines among other elements. Clendening explains that in designing Preclarus, having the ability to deal with different and changing components simultaneously within the system was key to its design. Functionality is also a crucial need, which is what the design team is continually investing its efforts in, i.e., to create more functionality in the system.

Client-Centered Usability

"Our conversations with clients and sites give us feedback and we take all of that information to continually improve the system," says Clendening. The product is therefore ever-evolving as new information and needs surface.

"We're taking that same mindset that you see out there with successful technology firms and others doing real-time development to make sure that your product is staying fresh and solving the most important problems that you're coming up against," explains Clendening.

Lab data collection and data quality

As a holistic tool that encompasses and captures the entire clinical trial ecosystem, Preclarus endeavors to provide data on every measure and element in a trial. This includes principal data that is sent to investigators in a timely manner so that they can make important clinical decisions for their patients.

Querying

Surfacing query information from and between users is important. For example, if mistakes are made, the information is not only sent back to the site but also to a client (Sponsor) or a clinical research organization (CRO) partner that is involved to ask about the errors and see how they can be rectified.

The goal with errors and other issues is prevention, not just correction, explains Clendening. The tool is assistive: it takes user feedback to see how particular mistakes can be prevented from happening again, which can include better educating users on how to prevent errors.

Data and tracking of supplies such as kits, including how they can be ordered, is also information that is housed within Preclarus. It has query engines that allow users to locate supplies for purchasing and other activities, much like an online shopping tool. An agent is also available to help resolve issues. Importantly,

the platform's data mining is powerful and monitors operational issues including errors. In the end, the goal is to deliver clean, actionable data to help clinicians implement more robust monitoring plans.

Data Quality

With more powerful data query capabilities comes higher data quality. Clendening says that through studies conducted involving thousands of sites and millions of samples to compare the use of Preclarus with older methodologies, such as paper-based methods, they found a 66 percent reduction in overall query rate with Preclarus. Clendening shared that one of their clients also did their own analysis and found an 80 percent decrease in queries with Preclarus versus traditional paper methods.

Additionally, there was also a decrease in the number of lost samples, which was achieved by establishing a robust chain of custody aided by the tool. This includes having a running list of samples, including samples in storage that are not in any active mode of transport or processing.

User adoption

Clendening says the response to Preclarus has been *"overwhelmingly positive."* The tool has significant value and relevance in the current clinical trials landscape, especially in the context of pre- and post-COVID-19 environments.

Before COVID-19, a lot of clients were used to "the way they were already doing things, married to the paper documentation, which made it tough to try and move the needle," he says.

However, post-COVID-19, with changes in trial procedures and a general reliance on different technologies to enable remote work due to the pandemic, there was a significant fundamental shift where people became much more open to electronic processes, he says. *"The pandemic really propagated the usage of the tool beyond our expectations. And sites love it because they don't have any paper, they're getting rid of it and they have fewer queries, which saves a lot of time."*

Digital tools for an evolving clinical trial landscape

With Preclarus, Clendening says the team has never stopped development work. There is a long list of things the company wants to do with it based on user/site requests for specific additional functionalities.

"The big focus we have is that we want to become the central lab of choice for sites," says Clendening. He says the goal is to give them the entire toolset that they need to help manage their clinical trial and to make it highly efficient, flexible and easy to use.

Another important aspect is to bring focus to the patient side to facilitate a near patient experience. This is particularly key in today's landscape of increased decentralized and hybrid trials where the trial, or at least some of its components, are brought to the patient and their personal spaces like their home. Clendening shared that they are looking to provide patient-focused solutions shortly.

Business-to-business communication is another important aspect, says Clendening. This means finding effective and innovative ways to integrate with clients and other labs. *"We have this great system, so how do we expand the ecosystem to make it larger? We want to have a larger footprint that is all-encompassing so it's a one-stop shop."*

Managing the lifecycle of laboratory data and tools, from collection to archiving/disposal and delivery of actionable data to clinical trial investigators and sites, is a difficult task. The rapid evolution of technology in data management and analysis means laboratories can leverage technological tools to continually adapt and upgrade their systems, most fundamentally from paper to electronic databases, and effectively deliver trial components from sites to a patient's home.

A comprehensive data solution that consolidates and standardizes data from multiple sources can provide study teams with real-time access to all clinical trial operations, which can improve operational efficiencies resulting in improved study timelines, outcomes and ultimately, patient care.

This article was created in collaboration with PPD Laboratory Services and the Xtalks editorial team.

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