

Preclarus

Enable faster insights to improve clinical trial efficiency and quality

Clarity, understanding and confidence

Every clinical trial has moments when decisive action is needed to set the course for a critical next step, determining not only the future of your product, but also the level of impact for the patients you serve. It's in these moments that you need the clarity, understanding and confidence that only the right data delivered at the right time can provide—data that offers more, translating into actionable intelligence for faster insight. The Preclarus™ central lab database is the ideal solution, transforming and organizing your data in ways that offer better clarity and understanding every step of the way, giving you the confidence you need to make the right decisions.

Preclarus. Data driven. People powered.



Bring the bigger picture into clearer focus

Preclarus is the PPD™ clinical research business of Thermo Fisher Scientific's award-winning comprehensive clinical data portfolio solution that consolidates and standardizes data from multiple sources. It is also the people, the process and the organization behind the data.

By clearly portraying the bigger picture, Preclarus gives you an unprecedented view into clinical trial data and operations. With real-time access to trial, patient and laboratory information, data presented on dashboards that offer interactive visualizations and sophisticated analytics that enable innovative research approaches, Preclarus drives informed decision-making and facilitates efficiency.

Preclarus is revolutionizing the drug development process—delivering you the information you need, when you need it. The result? Your product gets to market faster and impacts the lives of patients sooner.

Real time that works on your time

Clarity and control

Preclarus puts the power of real-time data in your hands, giving you access to the clinical trial data you need. Once the data is standardized, it is compiled into a data warehouse from multiple sources:

- Electronic data capture (EDC) patient data and metrics
- Interactive voice and Web response system (IVRS /IWRS)
- Clinical trial management system (CTMS)
- PPD™ Laboratory services Central Lab database
- Our preferred third-party vendors

Take advantage of a NEW personalized approach to data

Preclarus' comprehensive data packages deliver solutions that provide the information you're looking for, at exactly the right time.

As the engine that drives early recognition of trends and risks, Preclarus clears that path for more immediate, effective decisions and actions that improve study quality and efficiency and optimize clinical evaluation.

Key benefits include:

- Greater transparency for data and operations
- · Faster decisions
- Enhanced data quality





Dig deeper and discover more

Unleash the power of Preclarus dashboards

Preclarus dashboards let you rapidly explore and share data to generate deeper understanding and better guide the research process. The dashboards provide cross-functional, holistic views of study status, actions and communications. These dynamic views enable fuller insight by revealing study milestones and performance relative to study goals and timelines. Business logic is embedded in the dashboards to expose essential criteria that support better decisions to improve study success.

Dashboards enhance:

- Collaboration and transparency with multifunction insights and cross-department metrics
- Detailed analysis through real-time views for study teams and clients, who can drill down into single data-point details
- Speed and efficiency by reducing hours spent consolidating data, freeing study managers to focus on decision-making and immediate action
- Corporate experience by leveraging our clinical trial history for data-supported proposal development
- Global site selection by identifying sites based on actual experience data*

*Access to data may vary

Dashboards enhance the interactive visualizations of operational and patient data. Users have the ability to filter and mark selected data points to leverage details through:

- Cross-functional visibility to improve study startup, enrollment, monitoring and data collection
- Real-time access to patient safety data, allowing study teams to continually assess study data and adapt monitoring decisions
- Highlights key performance indicators, manages metrics and measures service delivery against commitments
- Focused searches to monitor patient safety, recruitment and investigator site activity

Better decisions enable bigger impact

Move your product to market more confidently

The expanded access to data that Preclarus provides drives clinical research innovations to improve data quality, potentially reduce time and cost and increase the likelihood of conducting a successful trial. As evolving technology gives rise to more sophisticated analytics and intelligence capabilities, Preclarus will continue to grow and adapt to fit your needs—driving innovation even further.

Our commitment to fostering new and disruptive ideas across the clinical development process and the solutions Preclarus offers can help you optimize your development process and propel your product toward the market with confidence.



Connect with adaptive and intelligent monitoring

Preclarus' real-time data solutions and dynamic analytics facilitate our adaptive and intelligent monitoring approach—a major shift to technologydriven monitoring practices that improves operational efficiency and data quality.

Using Preclarus, we leverage industry-leading people, processes and technology to offer more effective solutions that allow clinical teams to:

- Identify and detect anomalies in data using Preclarus' dynamic analytic dashboards
- View site health assessments and analyze key risk indicators (KRI) at each study site
- Perform root cause analyses of variances to prompt remote and on-site monitoring visits, during which changes can be implemented to mitigate risks before problems arise
- Focus on working with study sites to assess processes, anticipate problems and enact improvements to address potential safety issues and avoid potential errors and delays
- Reduce the frequency of on-site visits and the level of source data verification (SDV) while maintaining close, quality oversight of clinical trial sites

Increase agility with adaptive trial design

Adaptive trial design provides a significant opportunity to improve success rates across the drug development continuum. With Preclarus, we provide the robust real-time data acquisition, aggregation, cleaning and analysis capabilities necessary for successful execution of adaptive trial designs.

With more insightful interim analysis and real-time data delivery, Preclarus benefits studies employing adaptive trials designs through:

- Faster insights that enable cost saving decisions
- Better early development decisions on dose and frequency
- Critical information to stop trials earlier for ineffective or unsafe drugs to increase

Move forward with mobile health

Mobile devices are reshaping the health care landscape, evolving rapidly to address the full spectrum of health evaluation and care delivery through monitoring and reporting patient metrics, guiding and tracking lifestyle interventions, and prompting patient compliance and adherence with medication reminders and reinforcements.

We continue to expand Preclarus' capabilities to harness mobile health innovations for new clinical research models, including access to:

- External data sources, including electronic medical and health records, disease databases, industry data sources and collaborations
- Devices and sensors, such as wearable devices and mobile apps
- Adherence and compliance technologies
- Predictive analytics and modeling and simulation capabilities

Simplify studies with PPD Laboratory services' single global database

For studies utilizing PPD Laboratory services Central Lab, Preclarus combines our ability to deliver data in real-time with a proprietary, global database and interactive Web portal to provide project teams with secure access to clean, study-wide lab data.

Preclarus maximizes the time and resources of your study, while ensuring its quality through:

- Simplified processes at every step from study definition to study closeout
- Increased time for quality control while achieving industry-leading setup and closeout time lines
- Merged and harmonized data
- Real-time, study-wide data monitoring through dashboard tools
- Rapid resolution of inquiries and real-time reporting to improve quality and speed decision making



The people behind the data

While Preclarus is the data solution that enables us to lead innovation in clinical research and deliver unprecedented access to data, the driving force behind it is our people. They not only help power Preclarus, but also consistently work to further advance its effectiveness and set you on a more successful path to market.

By closely integrating with client teams, we work directly with you to find solutions and implement strategies that drive critical decisions. A new role, the cross-functional data liaison (CDL), was created specifically to use Preclarus dashboards to identify actionable trends that may indicate risks. By working closely with the project manager and study team, the CDL drives data-driven decisions and, when necessary, escalates corrective and preventative action plans to client teams.

This type of strategic collaboration, coupled with the range of expertise and viewpoints offered by team members during the process, contributes to the development of more profound insights, more effective problem-solving and more operational efficiency.

Our global team of scientific, medical and strategic experts is dedicated to empowering you realize the full potential and value of your product with excellence, efficiency and results.