

Preclarus™ Overview

PPD delivers real-time data and analysis to power improved clinical trial quality and efficiency. Preclarus, our preengineered, comprehensive clinical data portfolio solution consolidates and standardizes data from multiple sources, giving cross-functional teams transparent, real-time access to all clinical trial data, as well as interactive reporting capabilities. These capabilities allow clients to address issues quickly and efficiently in order to make faster strategic and tactical decisions about their studies.

Preclarus is more than a technology—it's the process, people and organization behind the data.

Data Visualizations to Increase Insight

Preclarus compiles both patient and metric data from electronic data capture (EDC), clinical trial management system (CTMS), interactive voice or Web response system (IVRS/ IWRS), central labs and third-party vendors into a data warehouse, where it can be viewed through interactive dashboards that provide unique visual representations.

- The dashboards offer interactive visualizations of operational and patient data, giving PPD and our clients the ability to identify trends and drill down for more detailed information.
- The user is able to filter and mark specific data points and view the details behind the visualizations through the interactive dashboards.

The visualizations facilitate analysis and identification of trends in both patient and operational data, enabling informed decision-making at the earliest possible time points.

Know Sooner, Act Faster

When clients utilize Preclarus, they are provided end-to-end support that lead to timeline and cost efficiencies, as well as improved quality. In addition to interactive dashboards for data visualizations, PPD's real-time data and analysis solution offers benefits such as:

- Improved PPD CDISC-based standards around EDC data collection and statistical analysis reporting
- Global biostatistical technology infrastructure for consistent use of analytical tools and processes from all PPD resources
- The PPD cross-functional data liaison (CDL)
- A combination of in-house and on-site monitors

PPD also provides clients the foundation to further exploit real-time data and analytics to provide predictive power to our management and oversight of clinical development programs. Through this access to operations and patient data, study teams now are able to adapt monitoring decisions based on data quality to enable risk-based monitoring approaches. Real-time access to study data also supports adaptive trial designs that lead to a better informed risk identification and mitigation process, accelerated operations, better execution and more informed decision-making for our clients.

Driving the Future of Clinical Trials

As PPD expands Preclarus with more historical data and additional data connectivity capabilities, we will provide clients with the tools for better, faster decisions.

- Using accumulating data, historical evidence and statistical models and simulations, we are developing enhanced site activation and patient enrollment modeling techniques. That approach can be extended to provide other advancements, such as predictive analytics on study durations for event-driven trials or for predicted clinical supply needs across sites.
- The same data sources provide additional information required to measure and track key-risk indicators, driving earlier identification of risk

and issue resolution, mitigating data quality or timeline departures, and focusing costly monitoring (travel and visits) on the data points or sites that most require attention.

- Our ongoing investment in business process management technology and skill sets will come together with defined and automated work flows to ensure the power of analytics drives efficient intervention and action. We will ensure the right information is being made available to the right people or the right systems in order to drive the right next steps.