

Accelerated Patient Data Access with the Preclarus® Patient Data Dashboard

Dynamic Visualizations of Near Real-time Data in One Convenient Dashboard Improve patient safety with actionable intelligence.

Monitoring patient safety throughout the course of your study is possible with a better, clearer view of data that has been standardized and consolidated from multiple sources. Clinical study teams—including medical reviewers, clinical reviewers, biostatisticians and those in data analytics and data management—use the Preclarus® patient data dashboard to perform detailed, near real-time analysis of accumulating subject data.

Near real-time, consolidated data

The data in the Preclarus patient data dashboard is sourced from in the study data tabulation model (SDTM) format, which includes data from electronic data capture/ collection (EDC), interactive voice response system (IVRS), central lab database and other third-party vendors. Data is typically refreshed with the medical review cycle on the study. Filters offer a variety of options, such as the ability to view only data that has changed since the last data refresh.

FDA guidance regarding clinical trial data

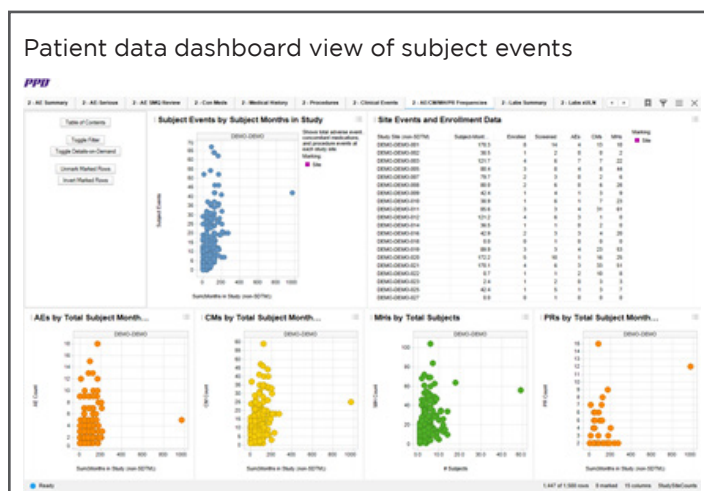
Per guidance from the U.S. Food and Drug Administration (FDA), submitting clinical trial data using the SDTM format developed by the Clinical Data Interchange Standards Consortium (CDISC) will expedite the regulatory review cycle. PPD has completed more than 500 studies in SDTM format.

Enabling faster insights to improve clinical trial efficiency and quality

Greater timeline and cost efficiencies

- Frees study managers to focus on decision-making and immediate action by reducing time spent consolidating data

- Interact with and evaluate the data more immediately, without having to rely on others to provide that information
- Export data and visualizations



Actionable intelligence for faster insight and decision-making

- Assess study data to adapt monitoring decisions
- Evaluate safety profiles across a project and identify data trends
- View and investigate trends using displays for both summary-level information and individual subject-level information
- Drill down to subject-level data, looking at it both by subject and event count

Improved safety and efficacy monitoring

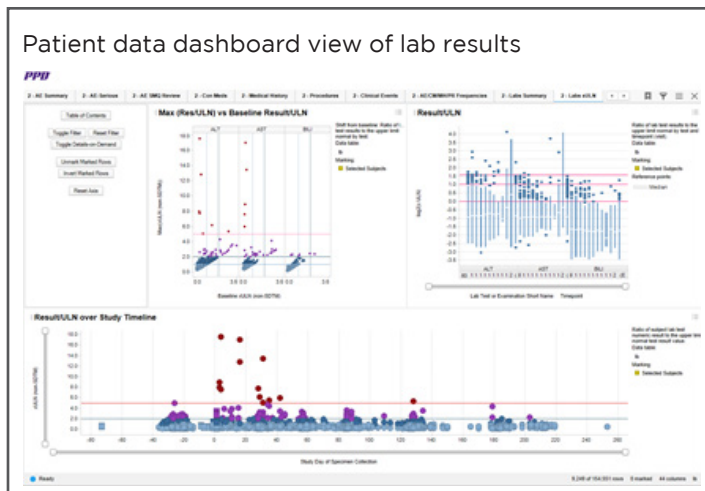
- Monitor patient safety through quick, focused reviews of data
- Evaluate details from medications to procedures to

lab reports to vital signs; no need to pull multiple data sets to see a specific patient's data

- See a complete, current summary of adverse events and the number of occurrences throughout your study, including severe adverse events displayed by body system and organ class
- Access efficacy visualizations for specific therapeutic areas such as oncology (disease response, tumor identification and tumor results) and cardiology (clinical events, death details and questionnaires)* in addition to safety data

* PPD continues to add additional therapeutic area visualizations into the dashboard as CDISC/CFast release new therapeutic area users guides.

Patient data dashboard view of lab results



For more information or to request a demo, please visit www.preclarus.com\moment.