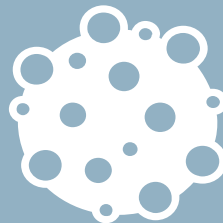




Global Reach



Speed & Delivery



Therapeutic Knowledge



Creative Solutions

Industry Trends, Advancement and Innovation in Clinical Trials

PPD[®]



Preclarus®: Patient Data Dashboards

Payal Pallavi
PPD, Inc

HELPING DELIVER LIFE
CHANGING THERAPIES

PPD®

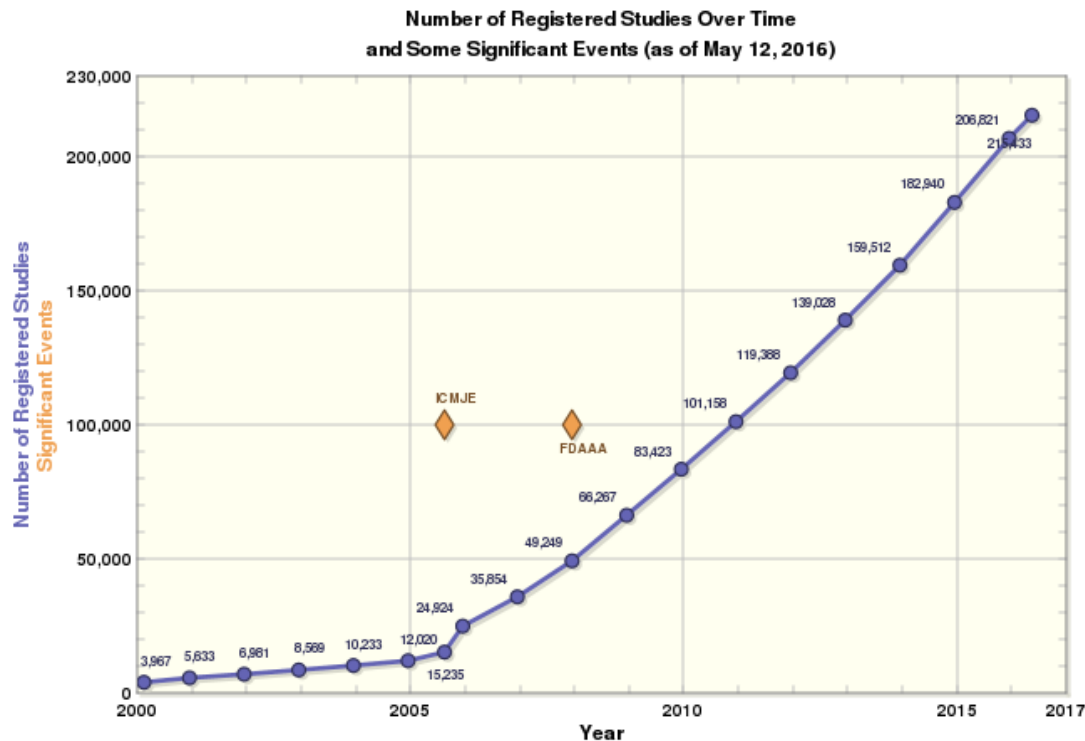
Agenda Slide

- 1 Need to Innovate
- 2 Data Visualization: The game changer
- 3 Filling the Gaps: What is and what could be
- 4 Preclarus Patient Data Dashboard: Salient features
- 5 Preclarus Patient Data Dashboard: A quick tour
- 6 The Road Ahead.....

Need to innovate



Need for Innovation



Source: <https://ClinicalTrials.gov>

Data Visualization & Dashboards

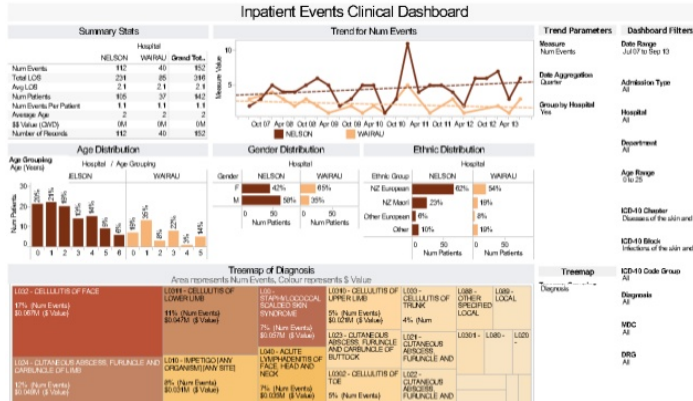
A game changer

Data Visualization & Dashboards

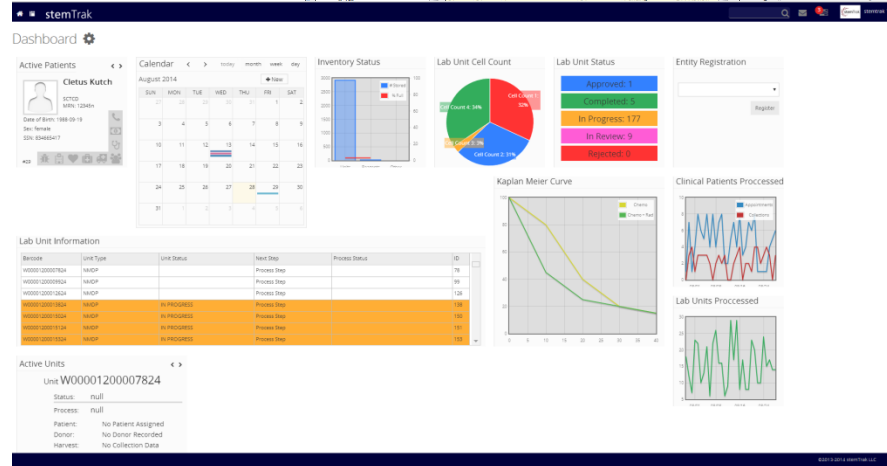
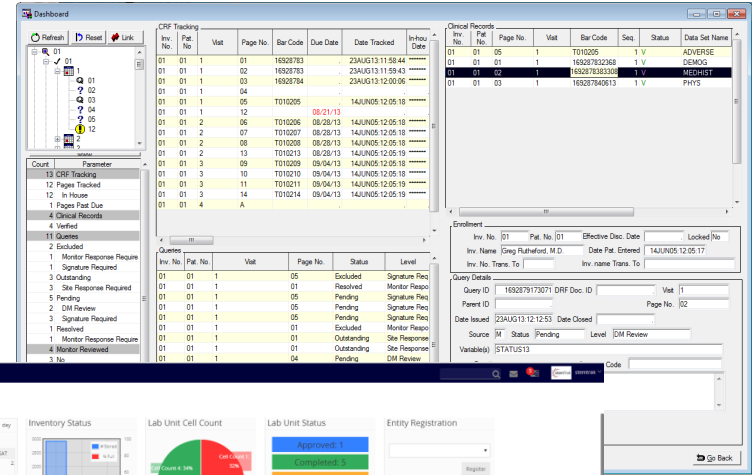
A game changer

- ❖ Data visualization is the presentation of data in a pictorial or graphical format.
 - Enables decision makers to see analytics presented visually
 - Easy to grasp difficult concepts or identify new patterns
 - Interactive visualization – using technology to drill down into charts, interactively changing what data you see and how it's processed.
- ❖ Data dashboard is a user interface that, organizes and presents information in a way that is easy to read

A piece of the pie



Clinical Overview: % of Total Num Events and sum of \$8 Value (CNY). Color shows sum of \$8 Value (CNY). The marks are labeled by Clinical Grouping, % of Total Num Events and sum of \$8 Value (CNY). The data is filtered on Date Range: Hospital, MISC, Primary Diagnosis, DRG, Hospital, ICD-10 Chapter, Health Specialty, ICD-10 Code Group, ICD-10 Block, Diagnosis, Age Range, Admission Type and In Date Range. The Date Range filter spans from Jul 1 to Sep 13. The Hospital filter spans from 10/10/10 to 10/10/13. The Primary Diagnosis filter spans from 10/10/10 to 10/10/13. The DRG filter spans from 10/10/10 to 10/10/13. The Health Specialty filter spans from 10/10/10 to 10/10/13. The ICD-10 Chapter filter spans from 10/10/10 to 10/10/13. The ICD-10 Code Group filter spans from 10/10/10 to 10/10/13. The ICD-10 Block filter spans from 10/10/10 to 10/10/13. The Diagnosis filter spans from 10/10/10 to 10/10/13. The Age Range filter spans from 10/10/10 to 10/10/13. The Admission Type filter spans from 10/10/10 to 10/10/13. The In Date Range filter spans from 10/10/10 to 10/10/13.



The Gaps: What is and What could be



HELPING DELIVER LIFE-CHANGING THERAPIES

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Need for Speed



Manage costs and implementation



Easy to scale up, easy to automate.



Gain critical insights faster



Enable efficient, proactive decisions



Understanding the Data

What you see is just the Tip of the Iceberg



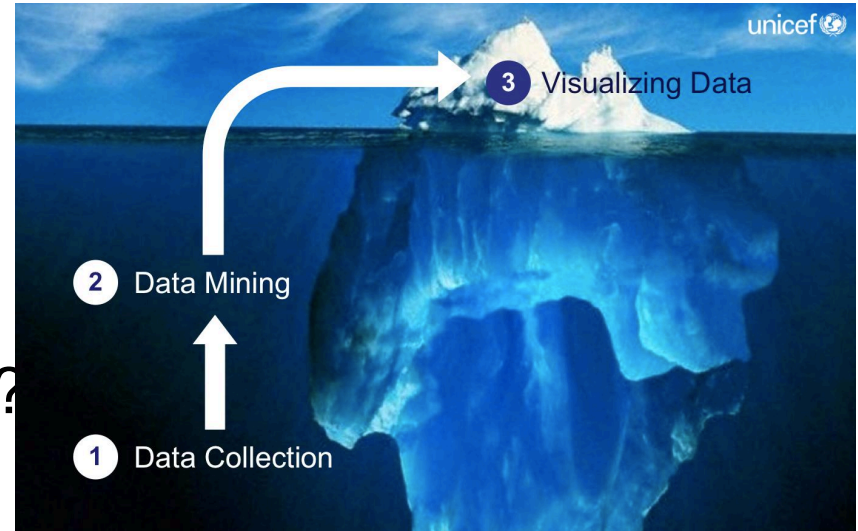
Where it does it come from?



Where it does it go?
Domains



What are we looking for?



Addressing Data Quality....Early.



Decision making suffers due to poor quality



Good data quality saves time



Data quality issues get expensive if addressed late



Spotting the Outliers



Spot the outliers: at a glance



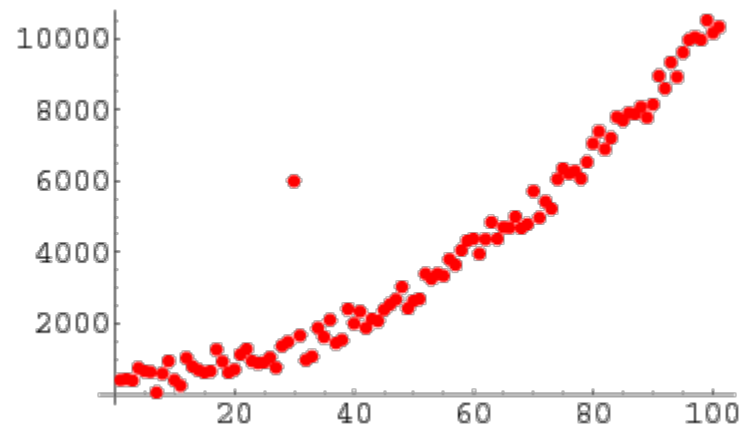
Address critical issues before it is too late



Traceability: at your finger tips



Optimize patient safety



Big Data: Small Insight



Add insight to complex data



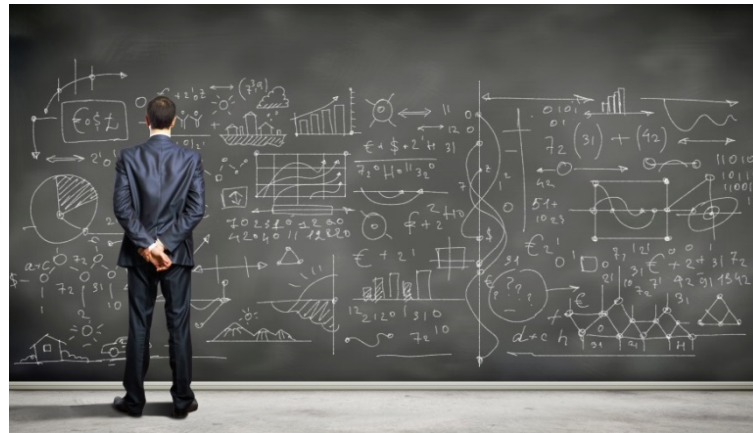
Data has meaning only in context



Think dynamic; Think interactive

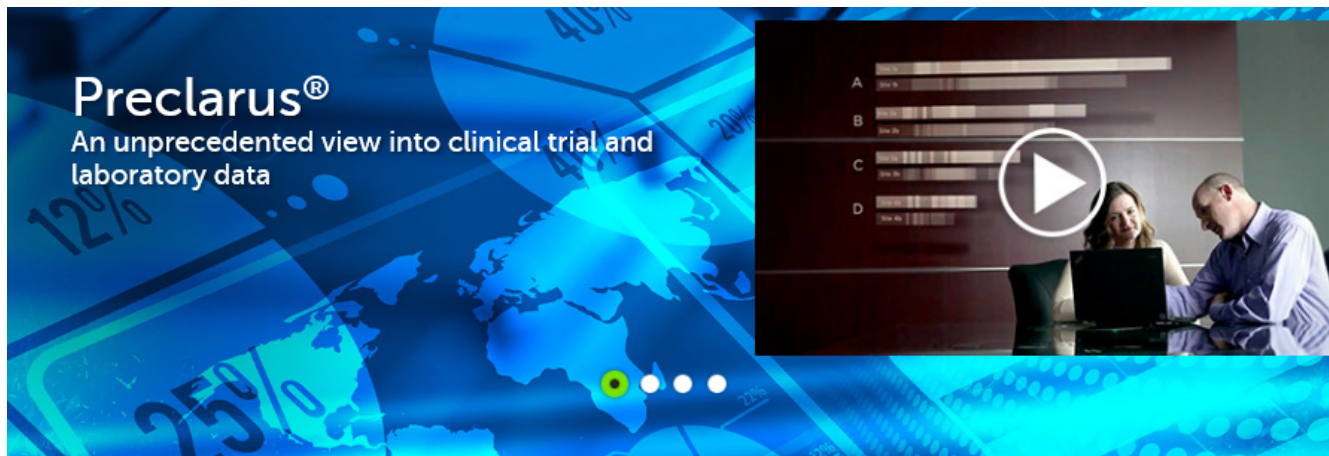


Cluster data into higher level views



Data analysis isn't about graphics and visualizations; it's about telling a story.

Can Preclarus fill these gaps?



Preclarus®
An unprecedented view into clinical trial and laboratory data

The banner features a blue background with a world map, various percentage figures (12%, 25%, 40%, 20%), and a DNA helix. A video player is embedded on the right side, showing two people working on a laptop with a play button overlay.



Real-time Data

The icon depicts a line graph with four data points connected by lines, set against a background of a laboratory or office setting.



Dynamic Visualization

The icon shows a vertical rectangular frame containing a stylized bar chart and a pie chart, representing data visualization.

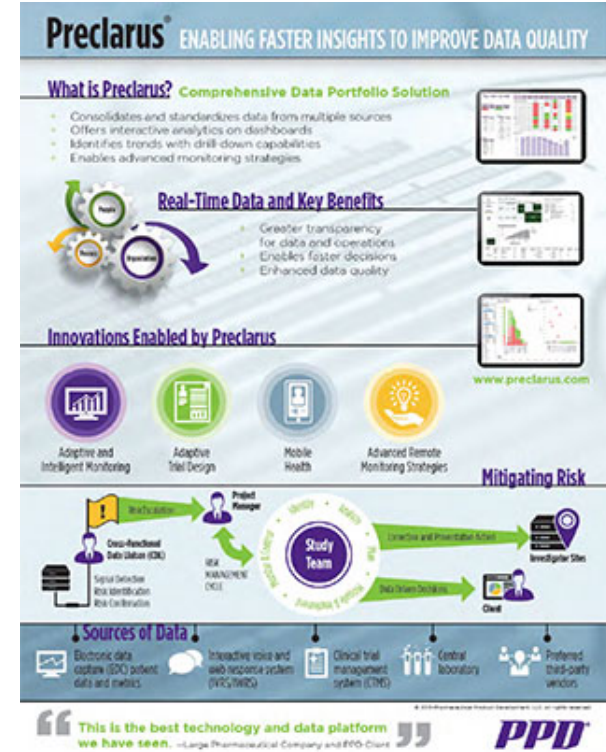


Innovations

The icon is a white lightbulb inside a circle, symbolizing ideas and innovation.

Patient Data Dashboard: Salient Features

- Real Time Data: The Power of Now.
- Integration of Data from Multiple Sources: EDC, CTMS, Central Labs, IVRS, preferred 3rd party vendors
- Better Transparency
- Dig Deeper: Discover more
- Cross-functional Visibility
- Focused searches to monitor patient safety, recruitment and site activity



Preclarus Patient Data Dashboard: A Quick Tour



In the context of SDTM

- Data Creation
- Data Cleaning
- SDTM Mapping



DYNAMIC
VISUALIZATION

Preclarus Data Dashboard: Study Overview

- The Dashboard is split into three sections:
 - ❖ Study Overview
 - ❖ Designed to look at high level general study information
 - ❖ Clinical Data at Study Level
 - ❖ Allows one to explore summary data at study level
 - ❖ Clinical Data at Subject Level
 - ❖ Allows one to specifically look at different data for selected patients

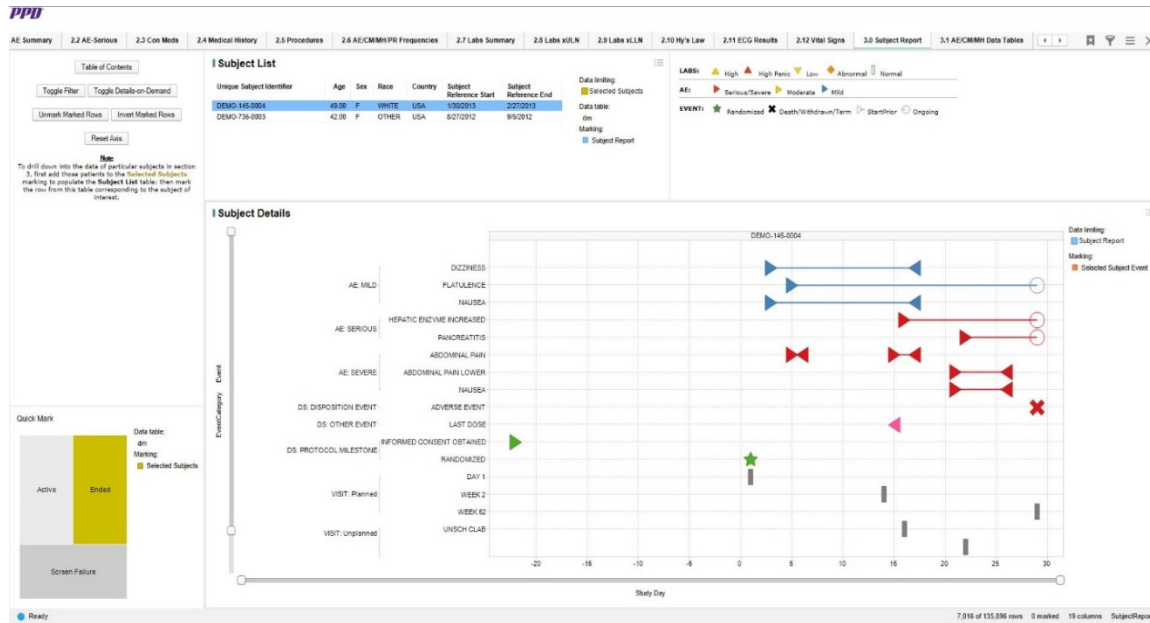
Preclarus Dashboards: AE/CM/MH/PR Frequencies

PPD



- Plots of combined and individual AE, CM and PR events/interventions for each site, by the sum total of subject months in Study
- MHs by Total Subjects: plots the total number of MHs for each site, by the total number of subjects
- Site Events and Enrollment Data

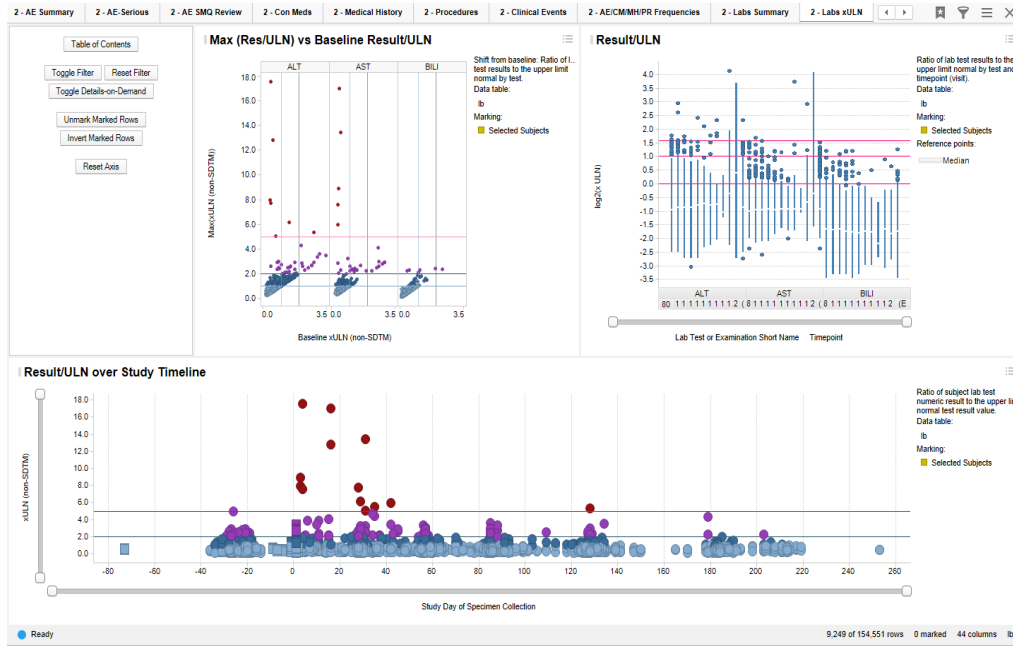
Preclarus Dashboards: Subject Details



- View subject details for an event
- Toggle filter to add/remove Event Types of interest
- View an event in detail
- Zoom in on data points of interest
- Reset axis

Preclarus Dashboards: Laboratory Results

PPD



- Enables visualization of lab data in near real time due to better integration of vendor data and seamless automation of data into dashboards.
- View lab details for selected subjects/outliers
- Use filters to view data by different criteria

Preclarus Dashboards: Therapeutic Areas

PPD



- PPD continues to invest in enhancements to the dashboard
- Focusing on specific visualizations for newer therapeutic areas in accordance with CDISC/CFAST release of TA standards
 - Cardiology, Oncology, and Ophthalmology currently included

The Road Ahead.....

+ **Adaptive** Trial Design

- + With more insightful interim analysis and real-time data delivery, Preclarus benefits studies employing adaptive trials designs through:
 - + Better early development decisions on dose and frequency
 - + Critical information to stop trials earlier for ineffective or unsafe drugs to increase safety and improve patient experience

+ **Integration** to more external data sources including disease databases and wearable devices

+ **Predictive** analysis, modeling and simulation capabilities

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