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Clinical Data Explorer: Transforming Clinical Data into Actionable Insights

Karma Tarap, Oriana Esposito, Maheshkumar Sagabhau Umbarkar, Ramnath Balasaheb Dhadage and Tamara T. Martin, Bristol Myers Squibb

ABSTRACT

Early Development operates in a dynamic, high-stakes space where rapid, data-informed decisions are essential. With a “go fast, kill fast” approach, innovative study designs, continuous data monitoring, and dose optimization strategies drive efficient decision-making. Clinical Data Explorer (CDEx) is a near real-time (NRT) platform providing aggregated clinical and biomarker data through a self-guided, customizable interface. Designed for BMS OneClinical teams and other users, CDEx enables rapid visualization and statistical analysis of safety and efficacy trends, guiding data-driven decisions for dose escalations and expansions. The foundation of CDEx was built utilizing an R-shiny opensource package, Teal, created by Roche. CDEx integrates SDTM and ADaM lite data, ensuring consistent updates with automated refreshed of SDTM. Key benefits of CDEx include: Rapid access to clinical data for faster, informed decision-making. Real-time identification of safety and efficacy trends, optimizing dose selection. Cross-functional collaboration, driving continuous improvements to meet evolving clinical needs. This session will showcase how CDEx enhances data exploration and accelerates critical decisions, ultimately improving patient outcomes.

INTRODUCTION

The field of Early Development in clinical trials is characterized by rapid, high-stakes decision-making where speed and accuracy are paramount. With a “go fast, kill fast” approach, clinical teams face the challenge of processing vast amounts of data quickly while ensuring that decisions made are well-informed and optimal. In this environment, innovative study designs, continuous data monitoring, and dose optimization strategies are crucial. The ability to quickly identify trends in data and make informed decisions is essential for the success of clinical trials and, ultimately, for improving patient outcomes.

One tool that has emerged within BMS as a key enabler in this space is Clinical Data Explorer (CDEx), a near real-time (NRT) platform developed to aggregate clinical and biomarker data. By offering a self-guided, customizable interface, CDEx allows clinical teams to visualize and analyze data swiftly, supporting more efficient and accurate decision-making processes such as dose escalations and expansions. The platform facilitates a more streamlined approach to clinical statistical data analysis, empowering teams to respond to evolving trial needs with agility.

CDEx is built on the foundation of Roche’s open-source Teal framework, developed using R-shiny (Roche. (n.d.).). This framework allows CDEx to be both scalable and adaptable, making it a highly valuable resource for the OneClinical teams and other users within the organization.

OBJECTIVE

The primary objective of CDEx is to provide rapid access to aggregated clinical and biomarker data through a self-guided platform. This platform enables users to explore, visualize, and analyze data, which is essential for identifying safety and efficacy trends that can drive faster and more informed decisions during clinical trials.

Key Capabilities of CDEX:

Capability 1. Real-time data exploration

CDEx offers interactive visualizations that allow clinical teams to engage with live data and extract meaningful insights instantaneously. This is a continuation of the body of the paper—after an unordered list.

Capability 2. Safety and Efficacy Trend Identification

By providing aggregated data visualizations, CDEx enables users to track important safety

and efficacy metrics over time, which is critical for making decisions on dose adjustments.

Capability 3. Support for dose optimization

The platform provides the necessary tools to assess the impact of different treatment doses and escalate or expand doses accordingly based on real-time data.

CDEx is an essential tool, where clinical data must be analyzed and acted upon quickly to make crucial decisions that could impact the trajectory of a study.

CDEX WORKFLOW AND TEAM STRUCTURE

The development and maintenance of CDEx follow a systematic workflow designed to ensure that the platform is always up to date, efficient, and aligned with the needs of clinical teams.

CDEX Workflow:

Step 1. SDTM Mapping and Conversion

The process begins with mapping and converting SDTM (Study Data Tabulation Model) data to a standardized format suitable for analysis.

Step 2. Study & Requirement Prioritization

Based on project timelines and clinical needs, the team prioritizes the studies that will be loaded into CDEx.

Step 3. SDTM Mapping and Conversion

CDEx programmers build the studies based on the available SDTM data, integrating other sources as required.process begins with mapping and converting SDTM (Study Data Tabulation Model) data to a standardized format suitable for analysis.

Step 4. Deployment, Review, and Quality Control (QC):

Once the studies are built, they are deployed to the platform. At this stage, thorough QC by CDEx developers and Clinical and Statistical Programming SMEs, ensures the integrity and accuracy of the data.

Step 5. User Acceptance Testing (UAT) and Follow-Up(s)

A critical step in the workflow, UAT allows clinical teams to verify that the platform meets their needs before full deployment.

Step 6. Ongoing Updates and Re-deployment

The platform is continuously updated with new data and features to ensure it evolves in line with the demands of clinical trials.

Step 7. Clinical Training and Requests

Clinical SMEs (Subject Matter Experts) are trained to use CDEx, and they serve as the liaison between clinical teams and the CDEx team to provide ongoing feedback and requests for new functionalities.

Step 8. Governance and Continuous Improvement

Regular governance meetings ensure that the platform remains aligned with the clinical team's needs and that any required improvements are prioritized.

CURRENT CAPABILITIES AND SCOPE

CDEx provides a range of capabilities that support clinical teams in their decision-making processes. Its core functionality revolves around providing self-service, interactive visualizations of clinical and biomarker data.

Most Current Capabilities:

i. **Interactive Data Visualizations**

CDEx supports the exploration of SDTM and ADaM lite data through various interactive visualizations, allowing users to create customized views of the data. These include visualizations of safety and efficacy metrics, as well as biomarkers data.

ii. **Real-time Data Updates**

CDEx is capable of refreshing data at any time based on the source data availability, ensuring that clinical teams have access to the most current data.

iii. **Adverse Event and Safety Data**

The platform includes interactive tools for analyzing adverse events (AEs), and other safety parameters (i.e. Lab tests, ECGs, Vital Signs) which are a critical aspect of clinical trials. Clinical teams can use CDEx to assess the number and severity of adverse events across multiple treatments or doses and monitor safety trends.

iv. **Efficacy Data**

The platform includes visualizations that allow users to track the efficacy across different treatments and doses and identify any trends in treatment effectiveness. CDEx also allows for disease specific customizations.

v. **Comprehensive Data Listings and Variable Browser**

Users can easily access and explore detailed data listings and use the variable browser to examine key clinical variables, such as adverse events, lab tests, ECG results, and vital signs.

DETAILED FUNCTIONALITIES AND BENEFITS

CDEx allows clinical teams to explore and analyze various types of clinical data using a wide range of visualizations.

Key Functionalities and Associated Benefits:

i. **Data Table**

Allows users to review a listings of clinical data across different domains and organize the information for detailed analysis.

ii. **Variable Browser**

Offers univariate descriptive analysis for each variable within the domain datasets. This tab helps users visualize continuous variables through:

a. Horizontal Boxplots

b. Density Plots

iii. **Study Population**

Provides a critical overview of patient characteristics and study populations.

a. **Demographics**: Offers detailed demographic statistics by treatments, country, regions, and etc.

b. **Disposition Table**: Displays a summary of the patient disposition (e.g., randomized, treated, discontinued).

c. **Death Table:** Displays a death summary of the patients.

d. **Demographic Oneway Anova Analysis**: Analyzes the demographic data across different treatment groups.

iv. **Adverse Event Analysis**

CDEx provides several interactive visualizations for analyzing adverse events such has various summaries found below. Each subtab provides customizable filters, such as treatment variable selection and event grading, to tailor the data view according to specific needs.

a. **Adverse Event Summary**: This table summarizes the number and percentage of patients who experienced AEs, allowing for easy comparison across different treatment groups, including those leading to drug withdrawal.

b. **TEAE (Treatment-Emergent Adverse Events)**: The platform helps clinical teams track AEs that emerge during the course of treatment, helping to identify any potential safety concerns early. Visualizations display the number of patients who experienced AE by grade, as well as the most common TEAE across treatment groups in a stacked bar chart.

c. **Adverse Event Onset**: Visualizes the onset distribution of AEs by their severity grade.

v. Exposure Data

Provides detailed information about participant exposure to the investigational product. By providing real-time insights into exposure, this helps clinical teams monitor the consistency of treatment administration across the study population.

a. **Exposure Summary**: This provides an overview of patient exposure to treatments across different arms, allowing clinical teams to evaluate treatment consistency and dosing patterns.

b. **Status**: Displays the current status of the exposure data.

c. **Exposure Swimmer Plot**: This plot visualizes the time to event for patients, making it easier to compare the exposure across treatments.

vi. **Laboratory Data**

CDEx also supports detailed visualizations of laboratory results, including:

a. **Summary Statistics**: Provides a summary table of laboratory data, allowing users to select treatment variables, endpoints, and summary variables for customized views.

b. **Individual Waterfall Plot**: Displays the mean or median values of laboratory parameters for individual patients across treatment arms, with customization options for post-baseline changes and specific patient selections.

c. **Shift Plot**: Compares changes in lab values between treatments from baseline to the end of the study, including options to show linear regression and scatter plots.

d. **Individual Linechart Plot**: Visualizes individual data points over time for different treatment arms, with customization options for facets and the number of columns.

e. **Mean with Error Bars – By Treatment**: Displays the average laboratory values for each treatment group, along with error bars to show variability.

f. **Box Plot**: Provides a visual summary of lab values across treatment groups by study visit.

g. **Oneway Anova Analysis**: Analyzes the differences between treatment groups using Oneway Anova plots, with customization options for data points and axis values.

By automating the generation of these visualizations, CDEx reduces the manual effort required by clinical teams, allowing them to focus on analysis and decision-making.

CROSS-FUNCTIONAL COLLABORATION AND GOVERNANCE

The success of CDEx depends on the collaboration between various functional teams, including clinical scientists, statisticians, statistical programmers, and the CDEx development team. Regular cross-functional meetings help ensure alignment on policies, principles, and platform development.

Key Governance Activities:

i. **Review and Alignment of Cross-Functional Policies**
Allows users to review clinical data across different domains and organize the information for detailed analysis.

ii. **Continuous Improvement**
Feedback from clinical scientists and other stakeholders is gathered and incorporated into the platform to enhance its functionality.

iii. **New Functionalities and Visualization Requests**

Clinical SMEs collect feedback from their respective teams, which is reviewed to identify any additional functionality or visualizations needed for future releases.

By engaging all relevant stakeholders, CDEx ensures that the platform continues to evolve in line with the needs of clinical teams.

NEXT STEPS AND FUTURE ENHANCEMENTS

As CDEx continues to mature, there are several key areas of focus for future enhancements:

i. **New Data Visualizations**
Allows users to review clinical data across different domains and organize the information for detailed analysis.

ii. **Integration of AI and Advanced Analytics**
Feedback from clinical scientists and other stakeholders is gathered and incorporated into the platform to enhance its functionality.

iii. **Broader Rollout**

CDEx will continue to be expanded to new therapeutic areas, including Late Development, with a focus on integrating learnings from pilot studies and refining the deployment process.

CONCLUSION

Clinical Data Explorer (CDEx) is a transformative platform that supports clinical teams in making faster, data-driven decisions in the early stages of clinical trials. By providing near real-time statistical data analysis and visualizations, CDEx accelerates the decision-making process, enabling teams to optimize doses, track safety and efficacy trends, and ultimately improve patient outcomes. As the platform continues to evolve, its integration with advanced technologies and its ongoing development will ensure it remains a vital resource for clinical scientists, empowering them to navigate the complexities of clinical trials with greater efficiency and accuracy.

REFERENCES

Roche. (n.d.). *teal: Modular framework for interactive exploration of data summaries* (R package version 0.13.0). https://github.com/insightsengineering/teal

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CDEx Developers:
Manish Bhagchandani

Shekhar Chalwadi
Nandukrishnan H
Hitesh Juneja
Maheshwarn Muthiah
Akshata Salian
Dineshkumar Subbu

Core CDEx SME Team (Non-Authored):
Silvia Mosulen Machuca
Mohan Mandava
Yun Shen

Early Development Build Team:
Sadhna Mishra
Akshay Nethikar
Bharath Pakeer

Additional Contributor:
John Gerks

CONTACT INFORMATION

Your comments and questions are valued and encouraged. Contact the author at:

Karma Tarap, Assoc Dir, Innovation Lead - Analysis Standards & Innovation
Karma.Tarap@bms.com

Oriana Esposito, Sr. Dir, Early Clinical Scientist Hematology Therapeutic Lead - Early Clinical Science HOCT
Oriana.Esposito@bms.com

Maheshkumar Umbarkar, Senior Manager, Programming - Open Source Innovation
maheshkumar.umbarkar@bms.com

Ramnath Balasaheb Bhadage, Open Source Innovation
RamnathBalasaheb.Dhadage@bms.com

Tamara Martin, Senior Manager, Statistical Programming
Tamara.Martin@bms.com