

In the Studio



Welcome to Medidata's
In the Studio
Newsletter!

Since our last newsletter, the first **Innovation Studio** virtual gathering occurred on July 18th. Topics included a Clinical Data Studio overview, Oncology (RECIST 1.1) Dashboard user feedback, and input on new features coming in December 2024 - Audit Trail Review and Integrated Data Quality Plan.

Join us on October 18th for our next Innovation Studio - [Register here.](#)

What is Data Connect and how can I use it effectively?

In the world of increasing variety, velocity, and volume of data in clinical trials, along with silos of working groups across different study stages, life science companies are overwhelmed with data operation complexity and unscalable overhead. Our mission is to reduce the complexity and overhead of managing, consuming, and utilizing data to drive actionable insights. We provide a single source of truth and empower users with best-in-class capabilities that are fit for purpose.

Clinical Data Studio currently consists of three main components: Data Surveillance, RBQM, and Data Connect. Data Connect is a one-stop solution for data ingestion, standardization, and transformation capabilities. It enables easy data ingestion with automated validation checks and unit conversions, making datasets ready for review and analysis with a no/low-code drag-and-drop interface.

Improve data consistency with simplified source management

- Various industry data source connections and support industry-standard data formats that allow the user to bring in any data or study metadata that is relevant to your clinical trial
- Centralized management of data transfer agreements which provide automated validation/monitoring at the time of data ingestion
- Data catalog provides a single source of validated truth across various stages and source systems that can be activated for different use cases without the need to make extra copies of the data assets so they stay in sync
- Robust version control system captures configuration history and changes across the life cycle of a data asset

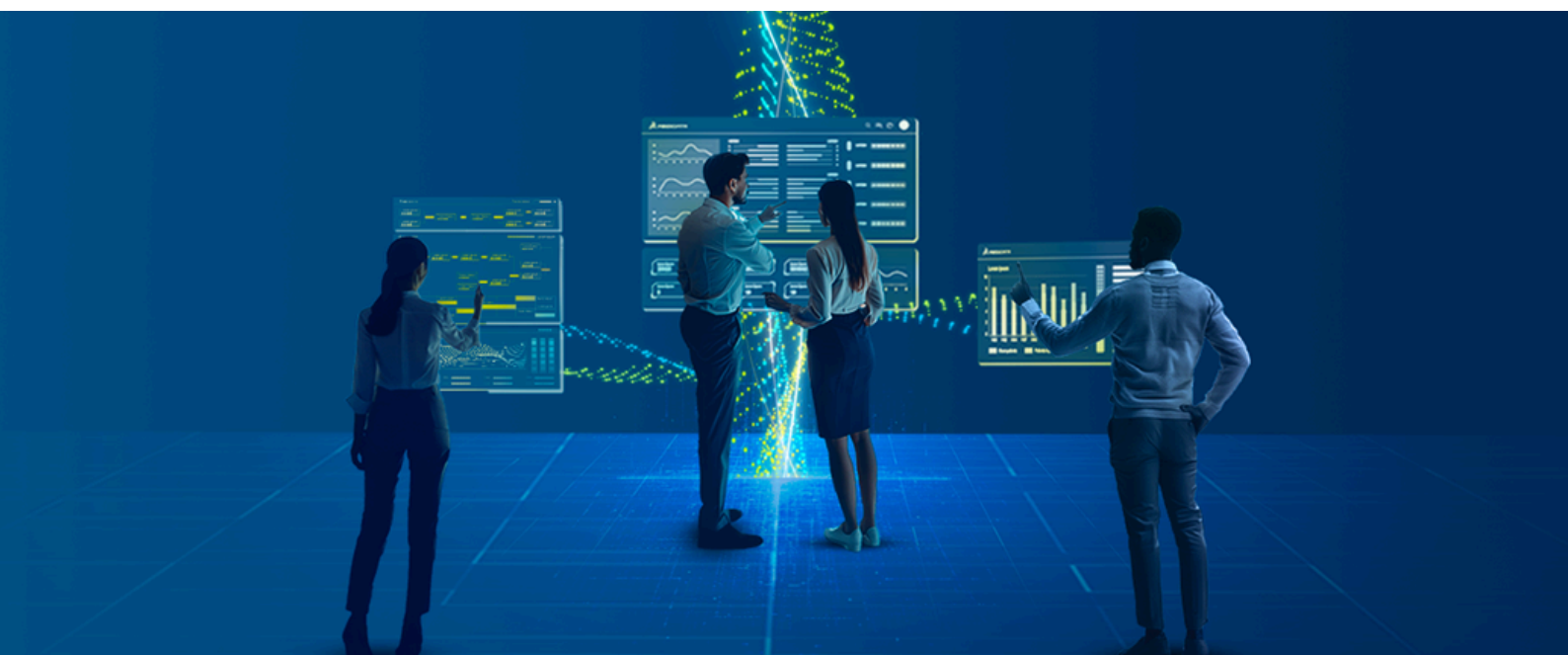
Accelerate insight and standard data asset generation while reducing technical training/onboarding requirements

- No-code configuration with intuitive mapping and transformation user interface that covers 80-90% of common data operations
- Data standard templates across a wide range of industry standards (e.g., SDTM) with the ability to create customizations to help you generate any fit-for-purpose data product
- Real-time view and validation to provide instant feedback on conformance with expected standard/result

Increase collaboration across teams to support multi-faceted workflow

- Comprehensive data lineage highlights the data asset health, how data assets are constructed, and where data assets are being used, which minimizes unintentional breaking changes and time to troubleshoot
- Variety of industry-standard data export/sharing connectors and file formats to enable use-case-specific downstream systems (i.e., Statistical Computing Environment, visualization, etc) to provide ultimate flexibility for workflow orchestration from a single source of truth

With Data Connect (part of Medidata Clinical Data Studio), users have a complete data ingestion, standardization, and transformation experience, embedded with automation and AI, for all data (Medidata and non-Medidata sourced).



In the Studio With...



We've included Medidata's Clinical Data Studio in our clinical trial management platform given its ability to break down data silos and seamlessly integrate into our current software stack, while maintaining quality and integrity across all data sources. Having a suite of technology solutions capable of processing diverse clinical and patient data types provides increased efficiencies without sacrificing quality or needing additional resources."

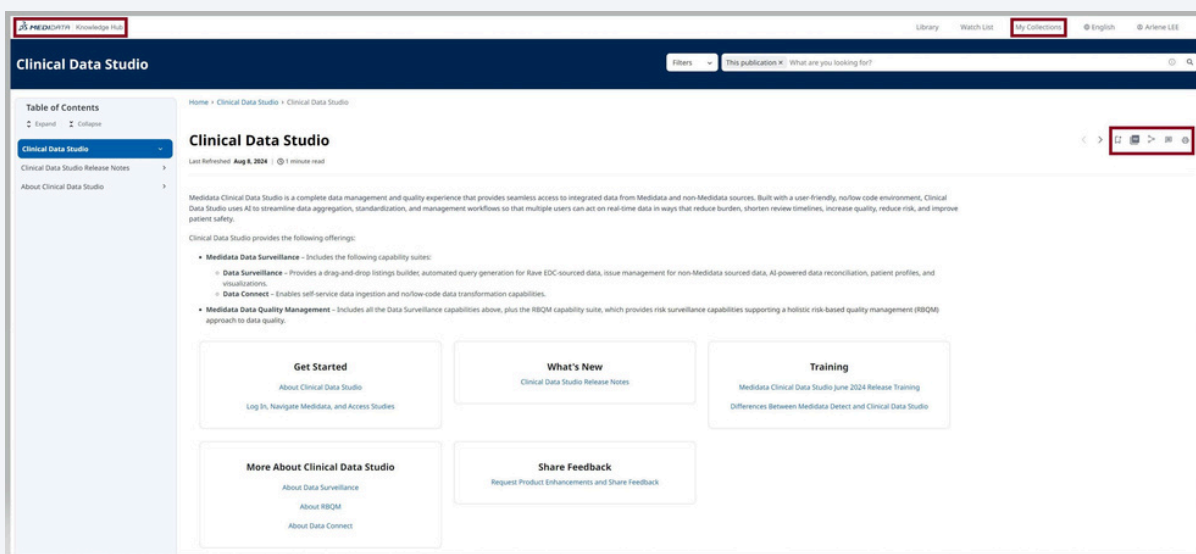
Shobha Dhadda, Ph.D. Chief Clinical Science & Operations Officer Eisai, Inc

Did You Know?

Unpacking the Black Box (Medidata Knowledge Hub)

The term "black box" originates from engineering and aviation, where it refers to devices that record data and cannot be easily accessed or understood without specialized knowledge. In the context of knowledge and information, it describes the process by which data is transformed into insights and decisions. At Medidata, ensuring that users of our systems have access to detailed information around the operation and development of our products is important. As such, Medidata developed the **Medidata Knowledge Hub** which includes details on all product families and can be found [HERE](#).

The **Clinical Data Studio Knowledge Hub** provides product release information as well as user assistance such as high-level product/capability information, how-to instructions, best practices, workflows, algorithm logic, interactive instructional videos, training resources, and guidance on how to provide product design feedback to Medidata. Users are advised to bookmark the following link: [Clinical Data Studio Knowledge Hub](#)



Useful Information:

- From the Clinical Data Studio home page, navigate to the 'More About Clinical Data Studio' links to access details about each specific module (About Data Surveillance, About RBQM, About Data Connect)
- Click on the Medidata | Knowledge Hub icon at the upper right hand side of the page to navigate back to the Medidata Home Page

Icons on the upper right hand of the page include the following functionality (from left to right):

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Industry News

ACRO and TransCelerate BioPharma, Inc co-developed a tool that explains control strategies, as laid out in ICH E6(R3). Control strategies can help avoid unnecessary risks, reduce the impact of risks that do occur, and increase the likelihood of detecting a risk quickly, should a risk occur during the course of a clinical trial. Medidata was happy to be a part of this continued, industry collaboration!

[Control Strategies and Good Clinical Practice ICH E6 \(R3\)](#)

Coming Soon - September 2024!

Clinical Data Studio – Data Surveillance and RBQM

- Vendor Query Feedback: Third party vendors can receive and respond to reconciliation queries directly via notification center
- Patient Profiles: Ability to view New and Changed data functionality added and visibility of critical data flags (defined in the Risk Management module)
- Clean Patient Tracker: Ability to upload a missing pages report
- Listings and Data Sets: Locked Patient, Site, Country columns for easier viewing when scrolling and added unique Record ID
- Risk Level Notifications: Risk Review Due Soon and Risk Review Overdue notifications
- Cross Client Division Templates: Import or Export KRI, QTL and Listings templates across client divisions

Clinical Data Studio – Data Connect

- Imports: Addition of FTPS connection for ingested files
- Dataset and Transformations: Enhanced live validation and dataset version consolidation
- Exports: Allow outputs of Dataset-JSON 1.1

Complete product release details are located here:

[Clinical Data Studio Release Newsletters](#)

Next major Clinical Data Studio release is coming December 2024 and will include the following...

- New Protocol Deviation Module
- New Cross Study Metrics
- New Integrated Data Quality Plan
- Addition of SDV counts to the Clean Patient Tracker
- Plus much more!

In the News

Eisai Selects **Medidata's Clinical Data Studio** to Enhance and Modernize Clinical Trial Efficiency and Patient Experience.

[Read Now](#)

Upcoming Events | Connect with Us!

SCDM | Sep 29 - Oct 2 | Boston
ACDM RBQM Symposium | Oct 7 - 8 | Brussels
SCOPE Europe | Oct 29 - 30 | Barcelona

The Latest from Medidata!

5 Strategies to Dramatically Improve Clinical Data Quality

How to Solve Data Quality Oversight Challenges to Improve Processes for All Data Stakeholders.

[Read our latest eBook today!](#)



Read our latest blog posts

- [Evolution of AI in Healthcare and Clinical Research](#)
- [AI in Clinical Data Management: What Does it Do, and How Does It Work](#)
- [Transforming the Clinical Research Experience](#)
- [Demystifying AI-Powered Data Quality: Unveiling the Mechanics](#)

YOU ARE INVITED!! Join our October 18th Innovation Studio

This virtual, interactive session will bring together Clinical Data Studio users and experts to learn from each other and gain practical insights on how to maximize your use of the tool. Join us to share your thoughts and help shape future enhancements.

Click on the registration link to learn more and register for the meeting. The agenda will be sent prior to the event.

October 18th, 2024

11:00AM - 1:30PM EST

[Register Here](#)

Medidata NEXT New York

November 13 - 14

[Register Today!](#)