

# In the Studio



Welcome to the second edition of Medidata's **In the Studio** Newsletter!

We've created this easy-to-read content to highlight industry news and information, to provide our users with helpful tips and to share information regarding upcoming events that may be of interest. We hope that you enjoy reading Volume 2.

## Introducing Medidata Clinical Data Studio

Unlocking Your Data's Full Potential

### Streamlining Data Quality Management

High-quality data delivery is a cornerstone of study conduct, protecting medical integrity and patient safety throughout the trial. It's also not a one-person job. Multiple functional areas coordinate distinct yet interdependent activities to ensure data is complete, reliable, and analysis-ready. Inefficiencies in these processes increase operational costs and delay the data insights needed for clinical decision-making.

As the universe of data acquisition sources continues to expand, the universe of data management tools actually needs to shrink, so that different users can act on diverse data brought together in ways that lower overhead, shorten cycle times, increase data quality, manage risk, and ensure patient safety. This is why Medidata developed Clinical Data Studio.

### All Data. Together.

Today, clinical data is acquired in all shapes and sizes from multiple vendors and is typically stored in siloed databases. These data are rarely analysis-ready in their raw forms, requiring organizations to rely on complex programming and expensive systems to harmonize disparate data before it can be reviewed. The industry has long needed a more efficient way to standardize these streams upfront, regardless of their origin, so that all data stakeholders have a contemporaneous view of integrated data.

Clinical Data Studio includes a new self-service ingestion and transformation experience that allows users to easily aggregate and standardize data from different sources, vendors, and formats for downstream review and analysis. Built with a low-code/no-code design, even non-technical users can transform, convert, and derive complex datasets with ease, facilitating faster analysis.

## Faster Time to Data Insights

Good data requires timely data, which is why Clinical Data Studio is built on a next-generation architecture with streaming data pipelines. Rather than providing data in batches, which can lead to inconsistencies in how different users see their data, delivery streams offer the lowest latency possible, enabling faster and parallel workflows. Whether that data is being used by data managers for review and reconciliation, medical monitors for safety review, central monitors for risk oversight, or extracted by biostatisticians for analysis, everyone sees the same contemporaneous data across varied use cases.

Those use cases are powered by the capabilities formerly known as Medidata Detect, now fully integrated within the Clinical Data Studio experience. We will continue to release additional use cases as part of our robust roadmap, including the application of Generative AI for audit trail review, a new protocol deviation module and enhanced patient profiles to name a few.

## A New Experience

When you log into Clinical Data Studio, you'll experience an updated homepage and navigation, including new tabs and enhanced personalization. Our goal is to provide your teams with the most complete, consistent, and intuitive data quality and management experience, from ingestion and standardization to data surveillance and risk and safety oversight, so that you can manage more complex trials with lower overhead and faster insights.



## NEW Medidata Clinical Data Studio - June Release!

*While the look and feel of the new enhanced global navigation will be different, users will retain all of their current capabilities PLUS the addition of new Data Connect functionality.*

**Data Connect** - new streamlined Ingestion, Transformation including unit conversions, and Extraction capabilities

**Data Surveillance and RBQM** (previously Detect) - enhancements include two new AI Data Reconciliation reports for CTCAE v5, the ability to surface critical variables identified in the risk assessment module in other areas such as data sets and listings, and the ability to view new and changed data in listings.

### More features and enhancements to Clinical Data Studio - Coming 2H2024!

- Audit Trail Review powered by Gen AI
- Protocol Deviation Module
- Third Party Vendor (TPV) interface enhancements utilizing Notification Center
- Clean Patient Tracker enhancements (including TSDV data and Missing Pages)
- Use of non-Medidata EDC in Clinical Data Studio (select EDC platforms only)
- Integrated Quality and Data Review Plan

## Resources

Complete Clinical Data Studio Release Details here:

[Medidata Clinical Data Studio Release Newsletters](#)

Clinical Data Studio June 2024 - Customer Awareness Webinar (CAW) Recording:

[CAW Demo June 2024](#)

Find all prior Medidata Detect Release Newsletters here:

[Medidata Detect Release Newsletters](#)

## Did You Know?

**Did you know** the Medidata Notification Center is integrated with Detect (Clinical Data Studio) to help deliver notifications to users. Refresh notifications are sent through email, and also made available in the Medidata Notification Center and are available for scheduled and manual refreshes for Quality Tolerance Limits (QTL), Key Risk Indicators (KRI), and Centralized Statistical Monitoring (CSM). Manual refreshes become available once the notification is sent, and scheduled refreshes appear after 7:00 a.m. EST on the day the refresh is requested. In addition, if a QTL on your study breaches the predefined data quality threshold or is considered an excursion, then you receive a notification in the Notification Center that at least one QTL has a status of Out of Range or Excursion. Additional notification templates will be added by end of the year as part of Risk Management, Third Party Vendor communication and Patient Profiles.

**Did you know** that users can provide feedback directly to the Medidata Product Team on the User Interface (UI)? In Detect, the Lightbulb icon (lower right hand side of screen) is being retired with the launch of Clinical Data Studio. Beginning June 26, users can use the Feedback icon (upper right hand side of the screen) to provide feedback and enhancement requests. *Note: if you have technical issues however, please do not submit those details in this manner - reach out to the Medidata Help Desk as per usual process.*



We want to hear from you!

Email Address

Sponsor or CRO Name

What is your department?

Module

Feedback or Enhancement Requests

May we contact you for additional feedback?  
☐ Yes  
☐ No

Submit Cancel

## YOU ARE INVITED!! Join our Innovation Studios throughout 2024

These virtual, interactive sessions 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 links to learn more and register for each meeting. Agendas will be sent prior to the event.

**July 19th, 2024**  
**11:00AM - 1:30PM EST**  
[Register Here](#)

**October 18th, 2024**  
**11:00AM - 1:30PM EST**  
[Register Here](#)

### In the News

**Medidata Launches Clinical Data Studio**, Leveraging AI to Modernize the Data Experience in Clinical Trials. [Read now](#)

### Awards

**Citeline Awards 2024**  
 Best Sponsor Facing Technology Winner



### Upcoming Events | Connect with Us!

**ACDM AI Symposium**  
 Jun 24 - 25th, 2024  
 Basel, Switzerland

## The Latest from Medidata!

**Empowering Transformation Through Technology:** From Clinical Data Management to Clinical Data Science. Read our [latest paper](#) today!



**RBQM: The Connective Tissue for Data Quality - 7 Ways the Human Body Inspires Better Data Quality in Clinical Trials.** Read our [latest eBook](#) today!



**Medidata NEXT New York | November 13 - 14 | [Register Today!](#)**