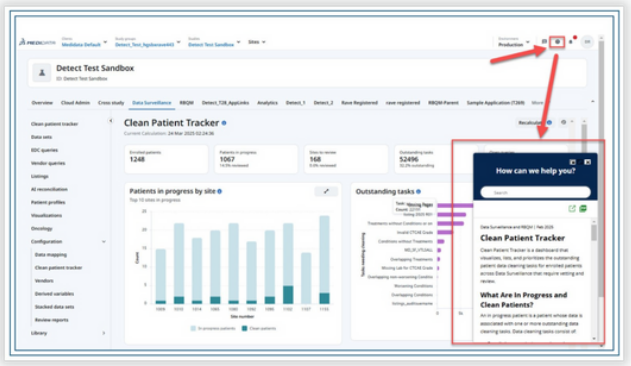
Did You Know

Did you know… that you can now access and view page-level Help directly in CDS?

The improved User Assistance Experience is easy to access directly from CDS.

- Click the Help icon ? in the Toolbar and then click Help on This Page.
- User assistance related to the page you are working on pops up on the screen.
- You do not need to leave CDS to get user assistance!
- Note that all other in-app user assistance continues to be available via the ⓘ next to the name.

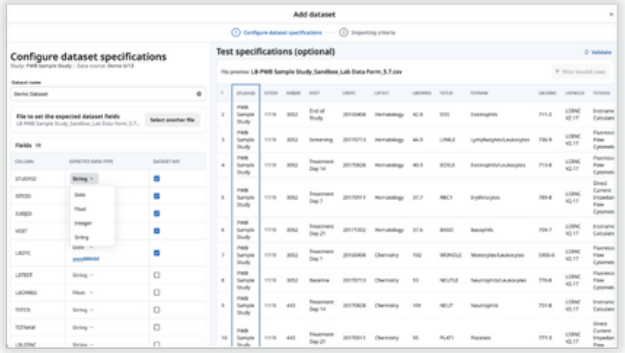


Did you know… that users can perform end-to-end vendor reconciliation with EDC data within Clinical Data Studio (CDS)?

Data Managers (DM) frequently reconcile third-party vendor (TPV) data with the clinical trial database while cleaning trial data. Ensuring alignment with any duplicated data in both systems is crucial for successful backend integration when creating SDTM datasets for regulatory submission. Typically, clinical programmers create listings (e.g., using SAS) and send them to Data Managers for review. However, CDS streamlines TPV reconciliation by handling everything from ingesting third-party vendor data to creating necessary transformations, generating reconciliation listings, and querying and posting them directly into Rave EDC. If a vendor query arises, a detailed notification can be sent to the vendor for review and response. CDS offers a complete, end-to-end TPV data reconciliation solution that eliminates the need for manual trackers and constant emails.

Bringing External Data In
— Data Connect Imports

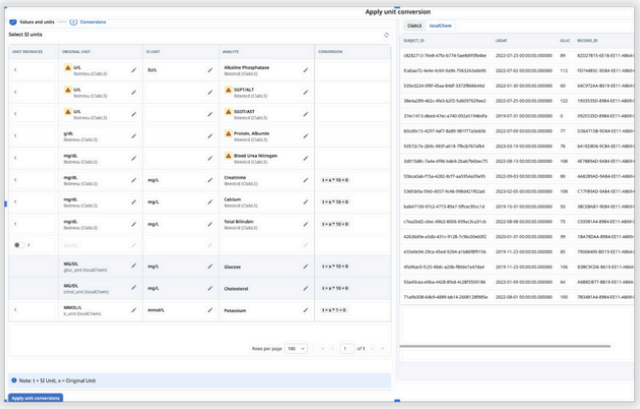
The first step is to ingest third-party vendor data into the platform using CDS Data Connect Imports, which supports automated data feeds from secure sources such as sFTP, S3, and FTPS. Once the external data is ingested, the next step is configuring your dataset specifications using your DTA import criteria in the system. Users can track incoming data transmissions and will see exactly what came in and when, along with status notices of whether there are any errors or unregistered values for the dataset. Once the dataset is imported and data flows, you can access CDS Data Connect Transformations for Unit Standardization.



KNOWLEDGE HUB - IMPORTS

Standardizing with Unit Mapping

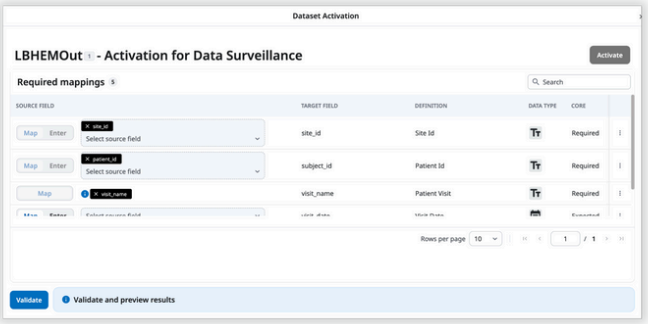
Some data files may need to go through a standardization process. Unit Conversions, a part of the Transformations feature, enables you to automatically leverage our Quantities, Units, Dimensions, and Types (QUDT) industry library to identify relevant source and target units and analytes. Laboratories often report the same tests using different units (i.e., mg/dL vs. mmol/L), and to review this data easily, it may be necessary to standardize outputs to SI units, for example. If this standardization is needed, it can be performed within Transformations, creating a derived dataset for upstream use in CDS. Data transformations such as unions and pivots are also available within Data Connect.



KNOWLEDGE HUB - TRANSFORMATIONS

Activate Your Transformed Dataset

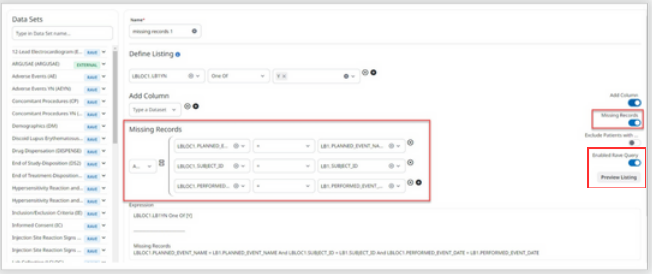
Once the data is standardized, the new dataset will be activated - essentially telling the system, “This is ready for use in Data Surveillance or RBQM”. Activation isn’t just a switch, it’s an assurance that your dataset is aligned with your internal standards and ready to be referenced across tools and workflows. Following successful activation, the TPV dataset will now exist inside the Data Sets tab of CDS Data Surveillance and will be ready for use.



KNOWLEDGE HUB - TRANSFORMATIONS

Constructing the Listing

Go to the Listings page on the Data Surveillance tab and select Create Listing. Once you give it a name, you can begin creating your listings utilizing details from your pre-defined specifications document. The Listings module is flexible, allowing users to generate many listings with easy drag-and-drop functionality. For this example, let’s list missing records to reconcile your lab data with the EDC. Start by defining listing and select the data that enables you to know a result was collected, typically a yes/no selection or observation point.

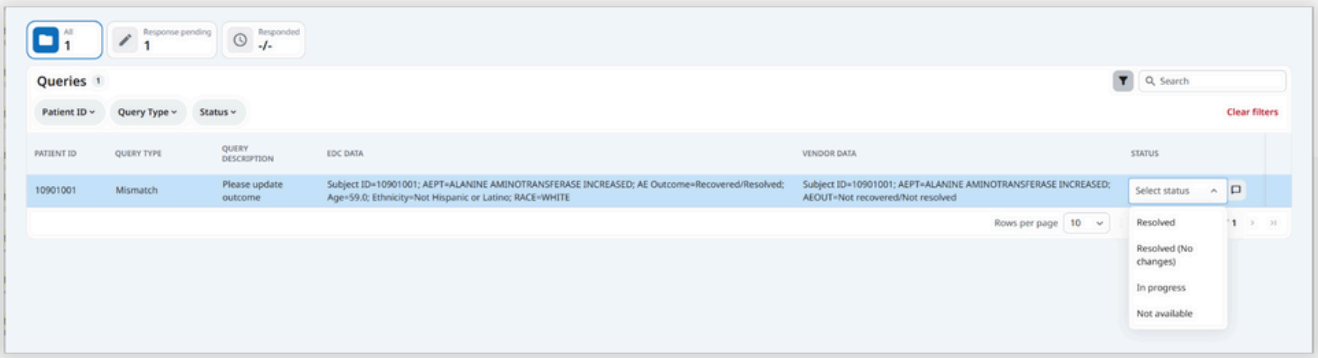


KNOWLEDGE HUB - LISTINGS

Then, activate the Missing Records button by toggling it, and the Missing Records section shows beneath the Definite Listing column. In the Missing Records section, you can build conditional expressions defining the source target datasets and the external datasets that you want the data listing to search, compare, and report on. Here, you would typically relate the visit name, the date, and any collection-specific details that define a record or collection. Note that you do not need to relate the patient ID between the two datasets because the system does this automatically. Once the logic has been reviewed and accepted, the user can set up the option to issue queries directly into Rave EDC by toggling the Enabled Rave Query button and saving. The listing is now activated and ready for use. Lastly, counts of unreviewed records at the patient level from the listings selected can be tracked in the CDS Clean Patient Tracker.

Integrated Vendor Queries

Once the site responds to the Rave query and the Data Manager realizes that the vendor needs to resolve the issue, it's time to create Vendor Queries in CDS. This communication between the DM and TPV is generally completed via manual tracker with the details specified and then uploaded to the appropriate sFTP site for pickup by the vendor, which is then returned to the DM the same way. CDS has automated this process by allowing Vendor Queries to be created from within the system and sending issues directly to the vendor via Medidata's Notification Center. The vendor will not have access to the study data or CDS; however, they will receive a system-generated email with a link to a detailed tracker that will be accessible via Notification Center, allowing comments to be entered along with a status. The vendor will send their responses back to CDS, and the DM can view the details within CDS and submit additional queries as needed.



Clinical Data Studio's end-to-end third-party vendor reconciliation capabilities provide a one-stop shop to enhance quality, save time, and allow real-time viewing of the statuses of all queries (EDC and Vendor).

CREATE, VIEW, DELETE, AND SUBMIT VENDOR QUERIES

RESPOND TO QUERIES AS A VENDOR

Release Info

We are excited to announce that the **April release of (CDS) Data Connect -** is now available!

Imports

The use of DateTime format is now allowed for all external data, making importing data more seamless. The list of date formats is also now standardized across all Data Connect applications.

Datasets

Data Connect now centralizes and reconciles any issues surfaced across the platform and centralizes datasets and activation statuses. This update allows users to view the end-to-end status of a dataset, from import to transformation to export, in a single location and drill into details.

Transformations

Along with improved navigation and expansion of Snowflake's direct data sharing eligibility, enhancements were made to just-in-time data querying performance to improve data retrieval speed and minimize application timeout for large datasets and complex transformations. The system can now automatically map visit names in a derived or external dataset to visit names in the EDC system based on an exact match. This applies to scheduled and unscheduled visits and will reduce user error and the burden of activating a dataset for data surveillance. Lastly, users can now edit previously created derived datasets within Data Connect, allowing the addition of the raw or source variables that are now available.

Additional Release details can be found at:

[CDS Data Connect - April Release Newsletter]
[CDS Data Connect - April Customer Awareness Webinar (recording)]

Industry News

TransCelerate BioPharma, in collaboration with the Association of Clinical Research Organizations (ACRO), has released tools and resources to support clinical trial stakeholders in implementing the updated ICH E6(R3) Good Clinical Practice (GCP) guidelines. Issued by the ICH in January 2025, the revised guidelines prioritize flexibility, operational efficiency, and data quality in executing clinical trials. In preparation for these updates, TransCelerate convened a group of industry experts to analyze the guidance and create practical tools aligned with six key focus areas:

- Risk proportionality
- Monitoring
- Trial design
- Investigators
- Risk management (in collaboration with ACRO)
- Data governance (in partnership with ACRO)

All tools are available free of charge to foster global advancement in clinical trial practices.

[ICH E6 Asset Library - TransCelerate]
[Navigating ICH E6(R3): Tools & Resources for Understanding Changes and Supporting Adoption (Webinar)]

Coming Soon — Clinical Data Studio May Release!

Enhancements across Data Surveillance, RBQM, and Data Connect will be available by the end of May!

Data Refresh Time

Data Refresh Time will be shortened, allowing users to see updated data from Rave and activated data from Data Connect between 12-18 hours in Data Surveillance and RBQM. This will allow data review globally and in a timely manner.

Clean Patient Tracker (CPT)

Exciting news – you asked for it, and we are delivering on improvements to the Clean Patient Tracker! CPT will be able to handle up to 25 listings, and for studies utilizing Medidata Rave, Patient Form statuses such as Incomplete, Requires Review, Locked, Frozen, Signed, and Non-Conformant will be available for view and tracking.

Listings

We've made some powerful advancements to listings that will improve efficiencies! Soon, you can copy listings between different Client and Study Groups, Study Environments, and even within the same study. To make it easier to process all listings during a review cycle, a handy refresh button will update all of your listings at once. We are also adding the option to query Rave variables directly from the derived dataset, allowing for more adaptability in creating desired reviews. Lastly, downloading listings as Excel files with comments is also on track.

AI Reconciliation

Our latest updates will bring new features to AI Reconciliation, including a modernized user interface. Additionally, AI Reconciliation reports will soon be able to utilize externally coded data, allowing for more flexibility for non-Rave coder studies. Users can also submit queries for Rave variables, such as the AE term, from within a derived dataset created within Data Connect. Lastly, users can download the reports in Excel format, including comments aligned with the records on which they were created. *Note: CSV export will no longer be supported.*

Audit Trail Review (ATR)

New features will be added to make our AI-powered Audit Trail Review more intuitive and efficient. A notable addition is the display of the actual SQL queries executed in the background, providing transparency and enabling users to verify the accuracy of the data retrieval process. Published dataset names will be available in Chat, thus easily allowing users to access published dataset names directly for quicker reference. Furthermore, the system will support more natural language date filtering, such as "Give me audits for the past month". User-based filtering will also be introduced, enabling the isolation of audits performed by specific individuals; for example, filter audit results by user using the format *First Initial.Last Name (e.g., J. Smith).*

Note: *Users will also be able to query audits from edit checks by asking for "system user." These updates will make it easier than ever to review and analyze your audit trail data as required by regulatory agencies.*

Patient Profiles

Patient Profiles will be updated with new changes to optimize your workflow and enhance data oversight. Users can copy patient profiles across different Client Divisions, duplicate them within the same study, or even transfer them to another study's environment. This feature simplifies managing patient data across multiple studies and divisions. Additionally, all comments will be downloadable into a single file for editing or deletion. Users can also edit or delete their comments within the system. A new audit trail log will track comment updates, including who made the changes, when they were made, and what the changes were, along with Patient/Site/Country details and design name, thereby enhancing transparency and accountability.

Oncology (RECIST 1.1) Dashboard

The RECIST 1.1 algorithm will be updated to broaden its applicability to various database study designs and enhance calculations for edge cases. These improvements make tracking RECIST data more adaptable and precise.

Risk Management

We are making tracking changes to the risk details page easier. Users will be able to see risk statuses. In addition, users can track changes to risk statuses as they are reviewed by others or automatically updated by the system based on review dates.

Data Connect Datasets

Users can upgrade previously created and activated datasets to enable Rave direct query. Dataset version selection will also be available.

Additional May release details can be found at:

[Clinical Data Studio (Data Surveillance/RBQM) May Release Newsletter]
[Clinical Data Studio (Data Connect) May Release Newsletter]

Here is a sneak peek of what's coming in the second half 2025!

As requested, more functionality around **Visualizations** will be made available later this year, including additional graphs, new calculations (numeric aggregations such as min, max, average, and mode), and a new data grid that surfaces the underlying data details from the graph to the user. All data and graphs will be exportable!

A new integrated, **Automated Signals Report** is being developed to enhance data quality oversight by consolidating findings from various analyses (manual and system-created) into a single, streamlined view. This feature will allow the user to assign signals, promote to an issue, create actions, and add comments, significantly reducing time and effort around centralized monitoring and study oversight activities.

Resource Center

Blog Post:
The 5Es of Operationalizing AI in Clinical Data Management

Blog Post:
The New Era of Audit Trail Review in Clinical Research

Upcoming Events

Webinar

Risk-Based Quality Management (RBQM):
The Connective Tissue for Clinical Data Quality.

April 30 | 10:00am EDT | 15:00 BST | 16:00 CEST

REGISTER HERE