# In the Studio

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

We've created this easy-to-read content to highlight industry news and information, to provide Detect users with helpful tips and to share information regarding upcoming events that may be of interest. We hope that you enjoy reading Volume 1.

## Detect User Survey Results

Thank you to everyone who provided feedback on our Detect Customer User Survey sent out in February. We appreciate the time spent providing feedback and will continue to implement new features and enhancements. Below are some highlights of the responses received.

### What do you like about Detect?

- Patient profiles provide a quick overview
- Easy to create listings (drag and drop functionality is useful and also ability to issue batch queries directly into Rave EDC)
- Ability to see all data sources (including those external to Rave EDC) in one system
- Identify trends easily at sites and study; easy user interface

**Reminder**
Users can provide feature requests or enhancements via the Detect UI using the light bulb icon on the lower right-hand corner of the screens. We welcome your ideas!

### What improvements would you like to see?

**Ingestor improvements**
New self-service ingestion experience with enhanced capabilities will be available with Clinical Data Studio at the end of June

**More frequent data refreshes**
Currently every 24hrs; on the roadmap to increase frequency in the second half of 2024

**Visualization capabilities in data reviewer**
Self-serve visualizations available end of April

**Combine datasets with subsets (i.e., Vital Signs different timepoints are in separate datasets)**
Ability to create stacked data sets available end of April

## Oncology Dashboards/Visualizations and Why They Are Important

Oncology dashboards and visualizations are tools used to organize and present complex oncology-related data in a visually comprehensible format. These tools serve important purposes in oncology clinical trials by providing study personnel (such as Medical Monitors, Data Managers, Clinical Operations and Safety staff) with real-time access to patient data, including tumor burden, response to therapy, and adverse events to facilitate data-driven decision-making and ensure regulatory compliance.

How can Medidata Detect help with this task? With the upcoming April 2024 Detect software release, study teams will have the capability to view key RECIST 1.1 data in a visually appealing format. Study personnel (such as Medical Monitors) will be able to monitor disease response (tumor burden) to study drugs via waterfall plots or spaghetti plots.

Waterfall plots provide a visual representation of individual patient responses to treatment, typically measured as changes in tumor burden from baseline. Each bar on the waterfall plot represents a single patient, with bars extending upwards or downwards to indicate tumor growth or shrinkage, respectively. Medical monitors use waterfall plots to assess treatment efficacy, identify outliers or exceptional responders, and guide decisions regarding treatment continuation or trial endpoints.

To assess an individual patient's tumor response trajectory over time, a spaghetti plot can be viewed in Detect, thereby allowing medical monitors to assess the overall effectiveness of the investigational therapy. They can identify patients who are responding well to treatment, those who are experiencing disease progression, and those who may be candidates for additional interventions or modifications to their treatment regimen. This information helps inform decisions regarding treatment efficacy and patient management strategies.

For the initial release of the new Detect Oncology Dashboard, the user will be notified of any discrepancy between the *reported* Overall Disease Response (in Rave EDC data) versus the *calculated* Overall Disease Response generated by our algorithm.

In addition to these oncology-specific visualizations provided in the new Oncology Dashboard, ad hoc visualizations of any Rave EDC or external vendor data ingested into Detect may be generated with the new Self-Serve Visualizations module. Study teams will be able to plot data in the following formats: line graphs, bar charts, and donut charts. Want to view key Adverse Events of special interest graphically by patient, site, or study? With this new tool, they can be easily generated.

Visualization of key data in oncology clinical trials enables clinical trial teams to actively track trial progress, evaluate treatment efficacy and safety, identify potential issues or trends, and make data-driven decisions to ensure the integrity and success of these trials.

## Industry News

**ICH E6 (R3) - Draft version 19May2023**
The International Council for Harmonisation (ICH) of Technical Requirements for Pharmaceuticals for Human Use is in the process of updating the Good Clinical Practice (GCP) E6 guidance and released the latest draft in May 2023.

To aid in understanding the changes coming, TransCelerate and the Association of Clinical Research Organizations (ACRO) collaborated to release a new infographic that highlights the key changes to risk management in ICH E6 (R3) between Version 2 and 3. Learn more and check out the new infographic: **https://lnkd.in/gGC-fJtR**

**Audit trail review (ATR)** is now described in three regulatory guidance documents: the **MHRA GxP Data Integrity Guidance from March 2018**, the **EMA Guideline on computerised systems and electronic data in clinical trials from March 2023** and in the draft **ICH E6 (R3) guidance, released in May 2023**.

In clinical research, ATR is performed to verify the accuracy, reliability, and authenticity of the clinical trial data. This expectation that ATR is proactively planned and documented is clearly outlined in the regulatory guidelines and is to be executed during the conduct of a clinical trial. The specific details of 'how' to perform these reviews is dependent upon the technology being utilized and the study design and can be quite complex for those performing the reviews.

For customers using Detect, audit trail data is utilized in several system KRIs. Additional audit trail data review capabilities powered by GenAI will be available later this year.

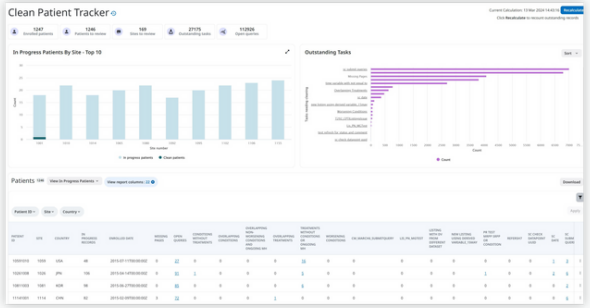
## Did You Know?

**Did you know** that Detect includes a Clean Patient Tracker (CPT)?

A clean patient tracker is a tool designed to systematically monitor and manage patient data throughout the trial process. It streamlines the management of patient data, enhances trial efficiency, and supports the generation of reliable clinical evidence for evaluating investigational treatments. Development of additional Detect CPT capabilities will continue throughout 2024.

**Helpful Tips**

- For the most up-to-date counts, refresh individual listings on the Data Listings page and refresh the AI Data Reconciliation page, and then click Recalculate in Clean Patient Tracker.
- To track data listings in the CPT, go to Data Reviewer > Data Listings > Select Data Listings to activate in CPT using the toggle button under Track.
- Open Queries tab — Here you can view a detailed, consolidated list of all open and answered queries raised against patient data in your study and also go directly into a patient's eCRFs in Rave EDC by clicking on the hyperlinked Patient ID.




**Check out upcoming Detect software release information along with other recent releases!**
Key enhancements and new features are listed below.

**Coming Soon — April 2024!**

- **NEW** Self Serve Visualizations
- **NEW** Oncology Analytics (RECIST 1.1)
- **NEW** Third Party Vendor communication
- **NEW** Stacked Data Sets
- Data Reviewer enhancements
- Risk Management enhancements

**Resources**
Find all of the Medidata Detect Release Newsletters here:

**FIND HERE**

**Sneak Peak**
Coming end of June 2024!

**MEDIDATA CLINICAL DATA STUDIO**

## Awards

**ACDM Awards 2024**
Innovation in the Management of Clinical Data
**Award Finalist**

**Citeline Awards 2024**
Best Sponsor Facing Technology
**Award Finalist**

## Upcoming Events | Connect with Us!

**SCDM EMEA**
April, 17-19, 2024
Warsaw, Poland

**Speaking Session**
**"**Transforming Trials with RBQM as the Connective Tissue for Data Quality"

**Featuring**

**Olgica Klindworth**
VP, Data Quality and Risk Management Solutions, **Medidata**

**Genevieve Nadeau**
Head of RBQM & Clinical Operations, **Orion**

**Elena Zaffaroni**
Sr Director, Clinical Risk Management, **ICON**

**Miguel Valenzuela**
Associate Director Clin Ops RBQM+, **Alnylam**

**DIA** | June 16 - 20, 2024 | San Diego, CA

## The Latest from Medidata!

**A (R)evolutionary Path for Data Managers.** The guide to driving data quality across the "5 Vs" of clinical data. Read our latest e-book today!


## Medidata's NEXT City Series — Register Today!

**San Francisco** | May 1, 2024
**Basel** | May 15, 2024
**Boston** | May 21, 2024

## Join our Innovation Studios throughout 2024

These virtual, interactive sessions will bring together Detect 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 to learn more and register for each meeting. Agendas will be sent 3 weeks prior to the event.

**May 3, 2024**
11:00AM - 1:30PM EST

**July 19, 2024**
11:00AM - 1:30PM EST

**October 18, 2024**
11:00AM - 1:30PM EST

## In the Studio with...

We've used a lot of different systems when it comes to risk-based management tool. I see Detect as something much, much more. We all have challenges with the big conglomerates statistical software that we must use, which is a burden to a pocketbook for many organizations. We're going to be able to shift things that we typically have done in statistical analysis software to do it within Detect."

**Mike Mendoza**
Executive Director, eClinical Technology Strategy & Biometrics **TFS HealthScience**
From NEXT NT