In the Studio

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

Please enjoy our final *In the Studio* newsletter of 2024!

As the year comes to a close, we want to take a moment to express our heartfelt gratitude for your trust and partnership. Your support has been the cornerstone of our success, and we are truly honored to have had the opportunity to work with you.

This year brought new opportunities and some challenges but together we achieved remarkable milestones. Your collaboration and feedback have been invaluable, driving us to continually improve and deliver better solutions.

As we look ahead to the new year, we remain committed to supporting your goals. We are excited about the opportunities the future holds and look forward to continuing this journey with you.

Wishing you and your loved ones a joyous holiday season and a prosperous New Year!

Navigating the Growing Complexity of Clinical Trials: The Role of Audit Trail Reviews

Clinical trials have undoubtedly grown in complexity, driven by advancements in adaptive trial designs, increased protocol amendments, and a heightened focus on rare disease research. Consequently, there has been an exponential rise in the volume of data.

Ensuring data quality today requires reconsidering and expanding patient data monitoring approaches including focusing on metadata and the value it can bring in identification of data interactions, unusual data acquisition patterns, flagging frequent or excessive changes, etc.

What is an Audit Trail
Most modern systems/software have integrated tracking of audit trails.

Audit trails are chronological records that log changes or actions related to data, capturing:

- Who has access to and interacted with data
- What action was taken - added, deleted, changed, queried, etc.
- When the change was made
- Why data was changed
- System integration statuses and failures, etc.

Regulatory Requirements for Audit Trail Review (ATR) in our industry

When computerized systems are used to capture, process, report, store, or archive raw data electronically, their design must support the retention of audit trails. These requirements are specified in regulatory documents such as the FDA's 21 CFR Part 11 and its guidance on Electronic Source Data in Clinical Investigations. Similar mandates are also embedded in regulations from global health authorities, underscoring the universal importance of maintaining data integrity and traceability.

The importance of reviewing system-generated audit trail data is emphasized in several key regulatory guidance documents, including the MHRA GxP Data Integrity Guidance (March 2018), the EMA Guideline on Computerised Systems and Electronic Data in Clinical Trials (March 2023), and the draft ICH E6 (R3) guidance (May 2023). These documents collectively emphasize the critical role of audit trail review in ensuring data validity and compliance in clinical research; in addition to SCDM's position paper (Audit Trail Review: A Key Tool to Ensure Data Integrity - an Industry Position Paper April 2021).

While there is not enough clarity in industry on how to operationalize audit trail review (frequency, scope, etc.), it is clear that regulators are urging us to consider ATR as an important data quality oversight concept and apply a risk based approach when planning implementation on a given trial. ATR is not meant to be a forensic activity, but scope appropriate to the risk level on a given trial.

Challenges in ATR Implementation

Despite its benefits, ATR implementation face challenges, including:

- Data Volume: Ability to access and extract audit trail data from all relevant systems.
- Lack of Standardization: Inconsistent formats across systems hinder uniform audit review
- Time-Consuming Reviews: Manual processes are labor-intensive preventing frequent and targeted reviews.
- Expertise Gaps: No standards or prior knowledge.

Introducing Audit Trail Review within Medidata's Clinical Data Studio

Audit trail data has historically been utilized within Clinical Data Studio as a key component in several system Key Risk Indicators (KRIs). Understanding the need to support a more comprehensive and scalable approach for metadata access and review, we have added a new capability within Clinical Data Studio supported by Generative AI technology. This new feature allows users to access and format large audit trail data sets from Rave EDC within minutes.

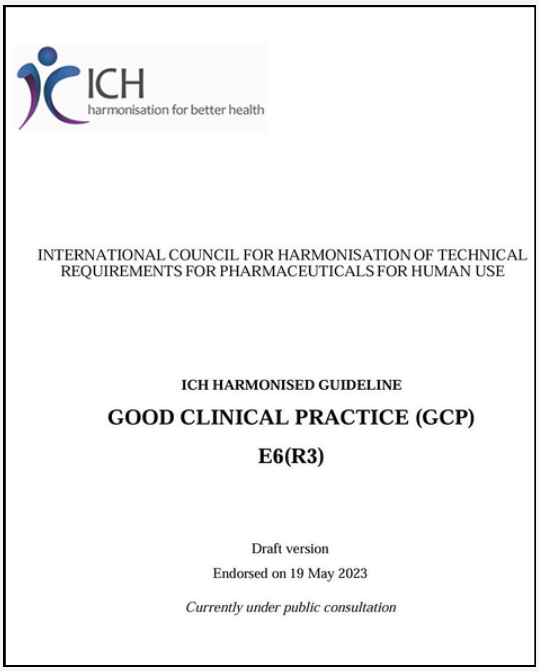
Through an easy-to-use chat function, you can easily create and save a prompt to generate a view of the audit trail data that you are interested in and then interrogate this data asynchronously, or leverage this generated data set within Clinical Data Studio's data, including listings, KRIs, and anomaly detection…just like any other data set. This allows users to examine data ad hoc and/or add templated approach for a scheduled/frequent review e.g., sites with most data changes via KRIs, data with changes and no queries via listings, data changes and queries related to critical data, unusual patterns in eCOA data via anomaly detection, etc. To learn more please visit Medidata's Knowledge Hub (Audit Trail Review).

In today's clinical trial environment, advanced ATR tools are indispensable. Generative AI, coupled with a risk-based quality management approach, is paving the way for improved data oversight. Integrating these technologies into workflows enhances efficiency, ensures compliance and better data quality oversight.

Did You Know?

ICH E6 (R3) [draft] builds upon the key principles outlined in E6 (R2), refining them to be more flexible, adoptable, and aligned with the overarching goal of encouraging a risk-proportionate approach to ensure data quality while supporting ongoing innovation. Acknowledging the impracticality of perfect data and flawless clinical trials, E6 (R3) advocates for a risk-based approach to clinical study management that prioritizes safety and efficiency over unattainable perfection. This framework promotes innovation, flexibility, and a data-focused mindset. By recognizing the inevitability of errors and fostering cross-team collaboration, E6 (R3) advances the ultimate objective of improving patient outcomes.

These principles align seamlessly with the goals that we built Clinical Data Studio (CDS) around. Our approach to CDS development, embraces a high level of flexibility, recognizing that ensuring data quality is not a one-size-fits-all process. There are multiple ways to safeguard patient safety and data integrity while implementing a risk-based approach within CDS e.g. by supporting critical thinking approach, focusing on critical factors identified during the initial risk assessment that can be then followed/monitored throughout the trial by all stakeholders, promoting transparency and better collaboration. CDS leverages an ongoing innovation, including AI-driven automation, with adequate level of validation to drive better, faster and more reliable outcomes.



Learn More

Clinical Data Studio - December Release is Now Available!

Clinical Data Studio – Data Surveillance and RBQM

- Cross Study Analytics Dashboard
- Integrated Data Quality Plan (IDQP)
- Audit Trail Review (ATR) powered by Gen AI
- Protocol Deviation Module
- Risk Management Enhancements
- Patient Profile Enhancements
- Clean Patient Tracker Enhancements

Clinical Data Studio – Data Connect

- Ingestion of Third Party EDC data from data files
- Ingestion of Veeva Vault EDC data via direct connect integration
- Data Profiling capabilities
- Enriched View/Unit Conversion Enhancements
- Field Transformation Enhancements
- Reusing SDTM configurations across studies
- SDTM Pinnacle 21 agency validation direct integration

Complete product release details are located here:
Clinical Data Studio Release Newsletters

Sneak peek! Clinical Data Studio updates coming throughout 2025 will include the following...

- New Centralized Monitoring Dashboard
- Enhancements to Cross Study Analytics, Patient Profiles, Clean Patient Tracker, AI Reconcilation, Self-Service Visualizations, Oncology Analytics...plus much more!

In the News

Clinical Data Studio wins **Best In Show** at SCOPE EMEA!

Upcoming Events | Connect with Us!

SCOPE | Orlando | February 3-6
ACDM | Prague | March 2-4
NEXT London | London | March 20

The Latest from Medidata!

Clinical Leader Webinar:
5 Strategies to Dramatically Improve Clinical Data Quality

SCDM Webinar:
The '5Es" of Operationalizing AI in Clinical Data Management

Read our latest blog posts

- The Essential 5 Es for Operationalizing AI in Clinical Data Management
- The Role of Source Data Verification (SDV) and Source Data Review (SDR) in Driving Clinical Trial Data Quality
- Generative AI in Clinical Development

Highlighted Presentations at SCOPE in February 2025

Advancements and Challenges in Clinical Trial Data Quality Control: A Roadmap for Audit Trail Analysis
Speakers: Charles Johnson, CSL Behring | Simon Walsh, J&J Innovative Medicines | Kevin Stephenson MS, Karyopharm Therapeutics | Olgica Klindworth, Medidata

In Pursuit of Adoption: Risk-Based Quality Management and ICH E6 R3
Speakers: Arlene Lee, Medidata | Nicole Stansbury, Premier Research | Madeleine Whitehead, Roche Products Ltd.

For more information on Clinical Data Studio, please visit: **CDS Knowledge Hub**