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5 STRATEGIES TO DRAMATICALLY IMPROVE CLINICAL DATA QUALITY

HOW TO SOLVE DATA QUALITY OVERSIGHT
CHALLENGES TO IMPROVE PROCESSES
FOR ALL DATA STAKEHOLDERS

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INTRODUCTION

TRANSFORMING CLINICAL DATA QUALITY OVERSIGHT

Clinical research professionals across all quality oversight functions face inefficient review processes.

Data management and risk-based quality management (RBQM), clinical operations, and IT teams need access to the same error-free, low-latency data to achieve their goals - to shorten operational timelines, increase data quality, reduce risk, or improve patient safety.

However, the data and technology landscape is changing, increasing the complexity of data quality oversight. Incumbent processes are struggling to keep data moving. With a shift to broad ecosystems of patient data, teams face an explosion of data points beyond the EDC, stored in fragmented, disconnected systems.

In this period of transition, teams need to know:

- How to manage source data verification (SDV) for expanding data sources
- How to improve quality oversight workflows to prevent bottlenecks and delays in decision-making
- How to deploy automation, integration, and AI to drive efficiencies

These are the big questions addressed in this eBook, which delivers 5 smart strategies to transform data quality oversight workflows for next-generation clinical trials.

MORE DATA. MORE COMPLEXITY.

27% in endpoints[1] **10%** in trial complexity[2] Only **57%** of Sponsors and CROs have adopted RBQM[3]

Imaging · eCOA · EDC · Sensors · EMR/EHR · Labs · RWD

Sources:
1. Getz K, Smith Z, Kravet M. Protocol Design and Performance Benchmarks by Phase and by Oncology and Rare Disease Subgroups.
2. Markey, N., Howitt, B., El-Mansouri, I. et al. Clinical trials are becoming more complex: a machine learning analysis of data from over 16,000 trials. Sci Rep 14, 3514 (2024).
3. Scope Of Industry Risk-Based Quality Management (RBQM) Adoption Revealed. News release. April 2, 2024. Accessed April 4, 2024. https://cluepoints.com/scope-of-industry-risk-based-quality-management-rbqm-adoption-revealed/)

CENTRALIZE DATA ACCESS

Centralization is the foundation for driving efficiency in data quality oversight. By integrating a trial's total data sources and presenting data in actionable review formats, all stakeholders can act on findings, removing delays and bottlenecks.
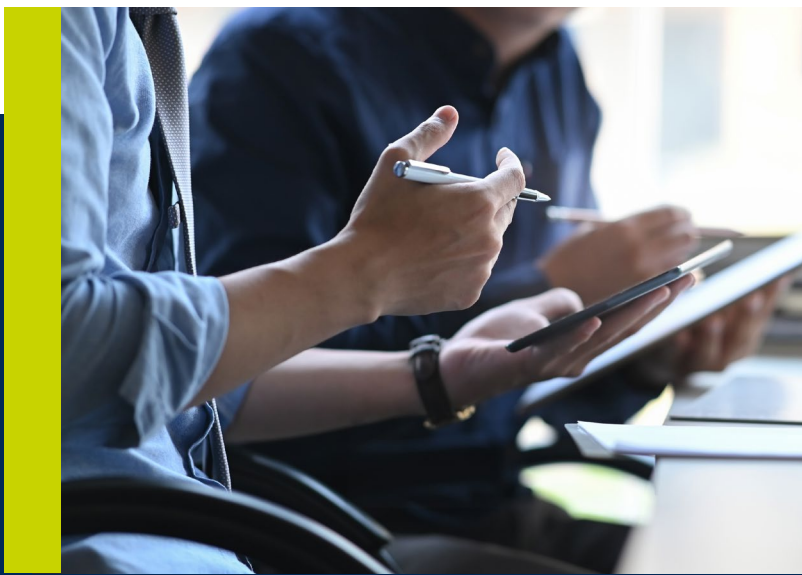
When centralizing data access, considerations include:

Platform versus point solution
Evaluate which approach future-proofs teams and business activities as technology, such as AI integration, transforms operational workflows.

Ease of use and customization
Assess how easily teams process or configure data review tools using self-service interfaces, powered by low-code, no-code design.

Speed of data delivery
Make sure latency is minimal. Data delivery is fit for purpose when the timescale matches the analysis, speeding up decision-making.

Interoperable systems
Check systems are agnostic and talk to each other so data flows unhindered between sources.

Data visualizations
Adopt a solution with multiple ways of representing data for stakeholders and use cases.

START THE RBQM JOURNEY

Organizations must adapt to the challenges of voluminous data and new trial designs and technologies. The solution is to shift to a risk-proportionate approach to data quality oversight.

By moving from volume (checking every data point) to value (the most important protocol data and processes to protect), an RBQM approach shortens trial timelines, reduces overall costs, and improves trial outcomes.
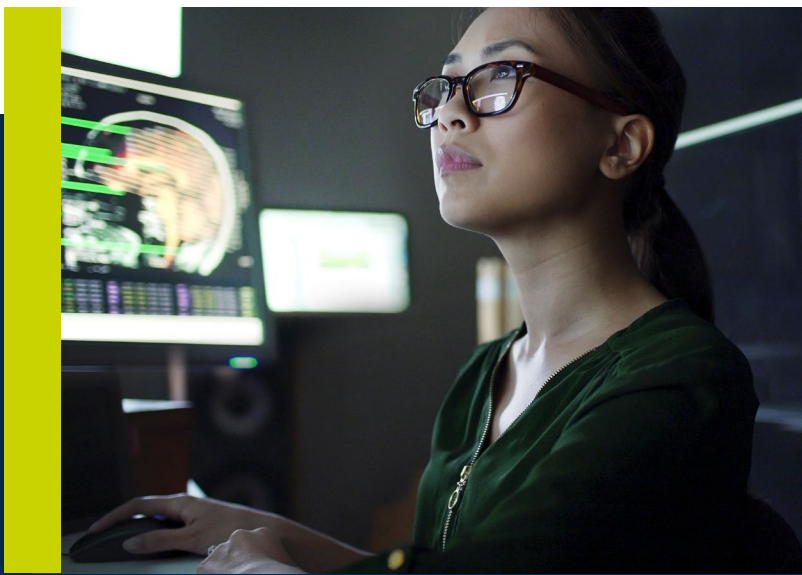
Working towards RBQM maturity

The journey to comprehensive RBQM involves these steps:

Reducing SDV
Adopt a risk-based approach targeting SDV on critical data and high risk-areas.

Central monitoring
Deploy a framework for proactive oversight. Set key risk indicators (KRIs) and quality tolerance limits (QTLs) through a central monitoring system that flags data quality risks.

Statistical analysis
Use ML-powered analysis to check for data inconsistencies, anomalies, and unusual associations, like duplicate patients, potential data fabrication, and weekend and holiday visits.

5 ways to succeed with RBQM:

1. Be data-driven and cross-functional

2. Apply RBQM beyond monitoring

3. Draw insights from accessible statistics

4. Deploy for trials of every size

5. Build data confidence with smart analytics

INCREASE EFFICIENCY WITH AUTOMATION

Clinical trial data quality oversight is complex. Automation and integration technology for repetitive, manual tasks allow teams to focus on higher-value tasks.

Data quality use cases suited to automation and integration include:

Connecting data review systems
Integrating all systems involved in a data review - from the EDC to a clinical data review system to spreadsheets - prevents laborious switching, or 'swivel chair management.'

Managing trial queries
Using interfaces for query management saves time by sending multiple queries into the EDC with one click, replacing time-consuming single-query workflows.

Configuring data listings
Equipping teams with drag-and-drop systems to map and configure listings to their specs removes programming delays and reduces managed service costs.
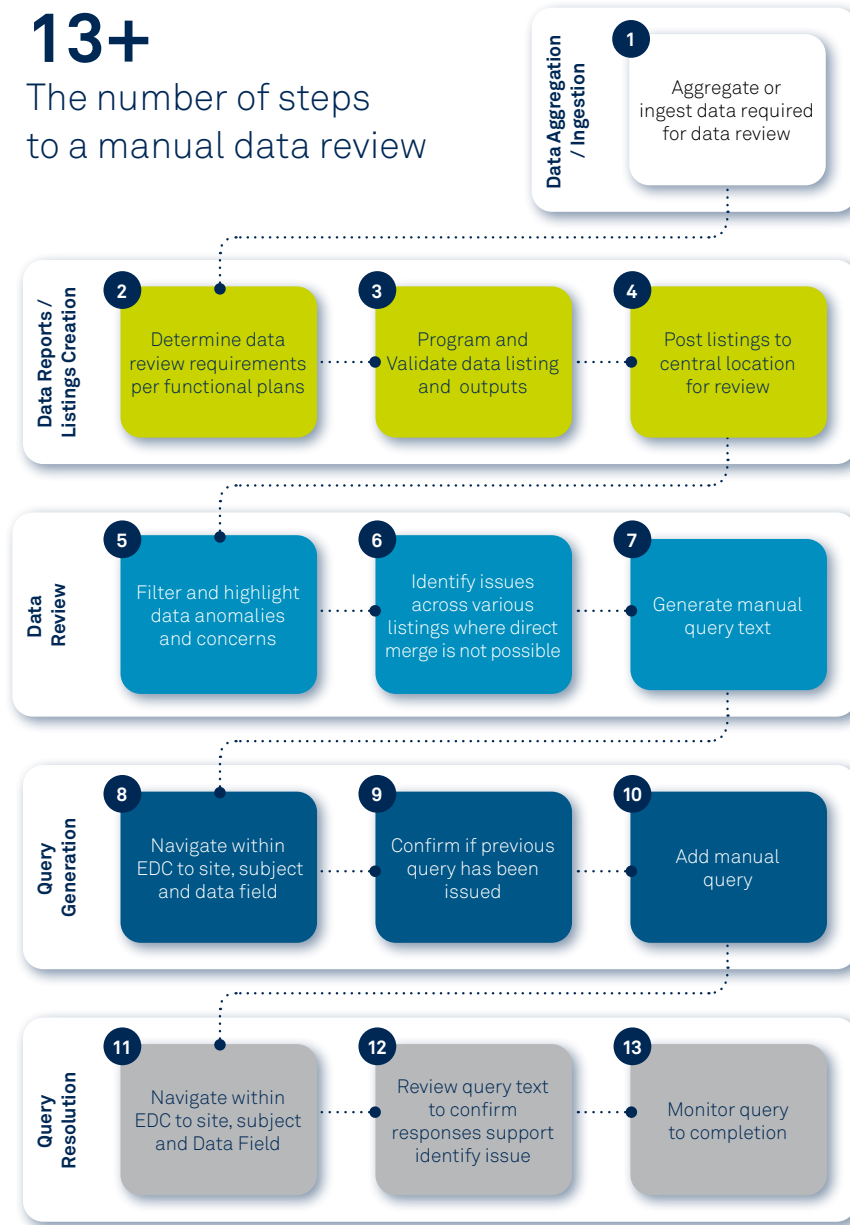
Setting up new studies
Reusing listing templates or patient profile designs and automatically applying them to new studies decreases set-up time.

Automating notifications
Setting up systems with automated notifications, such as when data is changed, improves productivity and task focus.

13+
The number of steps to a manual data review

Data Aggregation / Ingestion

1. Aggregate or ingest data required for data review

Data Reports / Listings Creation

2. Determine data review requirements per functional plans
3. Program and Validate data listing and outputs
4. Post listings to central location for review

Data Review

5. Filter and highlight data anomalies and concerns
6. Identify issues across various listings where direct merge is not possible
7. Generate manual query text

Query Generation

8. Navigate within EDC to site, subject and data field
9. Confirm if previous query has been issued
10. Add manual query

Query Resolution

11. Navigate within EDC to site, subject and Data Field
12. Review query text to confirm responses support identify issue
13. Monitor query to completion

Source: Medidata

STRATEGY 4:

OPERATIONALIZE AI

AI is valuable when embedded in teams' daily data quality workflows, assisting with complex, labor-intensive tasks.

AI as a virtual assistant

Use case 1:
Data reconciliation and consistency checks
AI data reconciliation assists users in reviewing adverse events, concomitant medications, and medical history datasets for consistency.

The tool assesses and ranks complex associations between datasets and includes human-in-the-loop feedback to improve subsequent iterations.

Use case 2:
Audit trail review
This generative AI solution addresses a historic challenge in the industry: analyzing large volumes of changes made to data during a trial. Smart prompts and a chat function assist users in finding trends in audit trail data.

Evaluate AI with the 5 'Es'

Before operationalizing AI, use this checklist to assess user experience and ROI:

Essential:
Does the workflow need AI or simple automation?

Efficient:
Will AI enhance workflow integration, create measurable ROI and, reduce user burden?

Explainable:
Does the AI model's decision-making logic reassure users?

Ethical:
Is the AI system designed to prevent bias and ensure fairness?

Enjoyable:
Can users' feedback fine-tune output to reduce false positives?

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STRATEGY 5:

SIMPLIFY PROCESSES

The final strategy for democratizing access for all stakeholders to low-latency, accurate data is simplification - streamlining how data is aggregated, integrated, and delivered.

Many organizations struggle with technology stacks with too many systems or insufficient interoperability.

This challenge is what Medidata simplifies so data teams can achieve their goals.

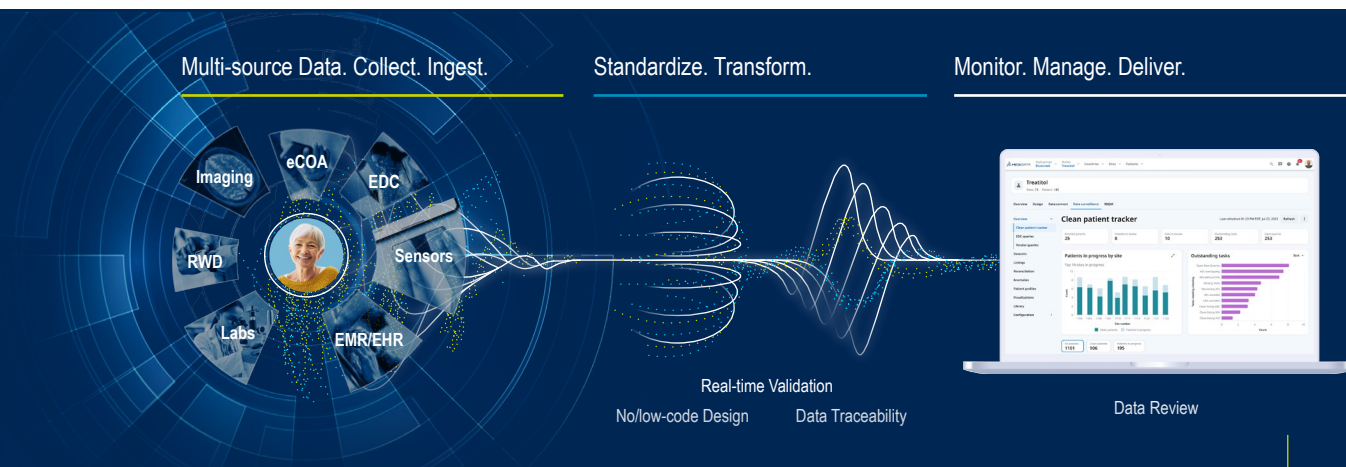## Solving complexity in data quality oversight

Medidata Clinical Data Studio is a solution that integrates, monitors, and delivers data from complex data ecosystems in simple and scalable ways.

The technology manages all your data sources, end-to-end, in one place, and streamlines the delivery of that data to multiple data stakeholders.

Benefits of Medidata Clinical Data Studio include:

- Agnostic to data acquisition tools
- Standardize all data for a total patient view
- Semi-automated data transfer management
- No code/low code programming to create complex datasets
- Centralized capabilities for data review, RBQM, safety oversight, etc.
- AI-driven analysis streamlining complex data review activities

Medidata Clinical Data Studio

Multi-source Data. Collect. Ingest.   Standardize. Transform.   Monitor. Manage. Deliver.

Imaging | eCOA | EDC | RWD | Sensors | Labs | EMR/EHR

Real-time Validation

No/low-code Design   Data Traceability

Data Review

CONCLUSION

Transitioning to fit-for-purpose workflows for clinical data quality oversight is achievable.

Giving all data stakeholders holistic oversight to make faster decisions and protect trial integrity begins with data centralization.

With a collaborative data review framework, teams can shift to a risk-based and dynamic RBQM framework.

Automation and integration are suited to many data quality oversight use cases, saving time and reducing user burden.

AI applied to data quality workflows offers new potential for reaching goals more efficiently and with deeper analytical insight.

Medidata supports organizations in these areas with solutions integrating fragmented, disconnected systems that dramatically improve data stakeholders' processes.

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Discover more about Medidata Clinical Data Studio by clicking <u>here.</u>

Medidata, a Dassault Systèmes company, is leading the digital transformation of life sciences.

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