DCRI **RISK-BASED MONITORING**

Minimizing Risk, Improving Quality

WHO WE ARE

The Duke Clinical Research Institute (DCRI), the world's largest academic clinical research organization and part of the Duke University School of Medicine, is known for conducting groundbreaking multinational clinical trials, managing major national patient registries, and performing landmark outcomes research.

DATA-DRIVEN TRIAL MANAGEMENT

Risk-based Monitoring (RBM) as part of trial design and management supports a targeted analysis-based monitoring effort designed to proactively minimize risk and improve quality.

EVOLUTION OF MONITORING

Paper-based
On-site Monitoring
- Review of data
- 100% SDV
- Monthly site visits

Computer-based
Centralized Monitoring
- Remote data review
- Targeted SDV
- Targeted site visits

Risk-based
Continuous and Centralized Remote Data Analysis
- Site management
- Site training trigger
- SDV trigger
- On-site visit trigger

The FDA recommends a quality risk management approach to clinical trial design and conduct, and the new ICH E6 (R2) GCP Revision requires a risk quality management approach to clinical trials.

The Clinical Trials Transformation Initiative, in which the DCRI is a proactive and leading participant, has also generated recommendations and guidance on the implementation of RBM.

At the DCRI, we embed our RBM efforts in a centralized Data-Driven Trial Management (DDTM) process. DDTM impacts many different facets of clinical trial design, implementation, and management. This approach requires collaboration among multiple groups and is based on a constant and accurate stream of data with remote, complex analytics to identify risks. This data stream then informs decisions regarding the frequency and nature of site monitoring.

What Sets Us Apart

The key to optimal RBM and the best outcomes (quality, reliable data, safety, efficiency, and economy) is thoughtful statistical design, data monitoring, and analysis.

The DCRI offers world-leading statistical and analytical expertise for optimal outcomes thus benefiting all clinical trial stakeholders.

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Find out more about RBM at the DCRI.

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WHY THE DCRI FOR RBM?

Use of advanced statistical methods and highly experienced statisticians and analysts increases the potential value and outcome of the DDTM approach.

Benefits include:

- Continuous and centralized remote data analysis allows for rapid and precise decisions on trial management and intervention on a site-by-site basis.
  - Problems identified quickly allowing for fast corrective actions.
  - Monitoring resources conserved and focused where risks are greater and intervention is necessary.
- Operational improvements:
  - Reports of improved satisfaction among investigators when working on DDTM trials than with conventional trials.
  - Action item closure rates significantly higher.
  - Source Data Verification (SDV) backlog significantly reduced.
  - Potential to reduce costs by avoidance of unnecessary site monitoring visits.
- Compliance with emerging clinical trial requirements and regulations.
- More efficient trials without compromising patient safety or data quality.

Though comprehensive and multifaceted, DCRI's approach is based on simple, objective, and pragmatic project management principles with data quality as a foundation to planning and execution.

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