Theme:
Capabilities | Collaboration | Change on the way to Clinical Data Science

SCDM Live
India conference

2nd - 3rd December 2022
Radisson Blu Hotel, Bengaluru
RBQM – Solution Building Blocks

01
Data Fabric: Digital Trial Foundation

02
Proactive Data Quality & Risk Management

03
Holistic Data Surveillance & Operational Oversight

04
Traceability & Reproducibility of Trial Results

Future-proof, Scalable, & Flexible Approach
Data Fabric Foundation

Key Goals:

- **Data Unification & Standardization** – Minimal effort for Programming resources to unify & flexibility to standardize.
- **Socialize Data** – Comprehensive Single Source of Truth across all relevant stakeholders
- **Focus on High-value Tasks** - Time back to data managers & analysts to focus on high-value tasks instead of data wrangling & curating

Data Landscape & RBQM Solution Need:

Challenges

- VOLUME
- VELOCITY
- VERACITY

Solutions

- Cloud
- Data Lake / Virtualization
- Standardization
**Key Goals:**

- **Real Time, Targeted Patient Safety & Data Quality Reviews** – Review targeted risks, threatening the integrity of ‘Critical to Quality’.

- **Focus on key study based risks** - Reuse of Risk repository with associated mitigation and measure (KRI/QTL) thus focusing on study specific factors.

- **Surveying Data** – No longer managing data, but surveying, understanding & protecting data

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**Critical to Quality Planning:**

1. **Define critical data and processes** to subject safety and data quality

2. **Create a Risk Plan along with different mitigation strategy**, identifying relevant risks and key risk indicators (KRI/QTL) that could impact subject safety and/or data quality

3. **Determine thresholds and triggers** ensuring they’re relevant, measurable, easy to monitor, auditable, and comparable

4. **Develop study monitoring plans** and adjust based on issues and risks that arise throughout the study

5. **Monitor data quality** through continuous review of data

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**Challenges**

- **Threshold Conundrum**
- **Risk Fatigue**
- **Silo'ed Review**

**Solutions**

- **ML Driven Risk Prioritization**
- **Library**
- **Integrated Review Platform**
Data Surveillance & Study Oversight

Key Goals:

• **Actionable Insight** – Story telling Visualizations & Predictive Analytics with AI/ML.

• **Expediate Decision-making** – 360° dashboard view of data/risk reviews, assigned actions, and data discrepancy, pending prioritized activities, resource & timeline view.

• **Data Access & Autonomy** – Sponsor to view near real-time selected raw & standardized data.

Analytics for RBQM:

![Diagram showing various dashboards and analytics for RBQM](image)

Challenges

- Reuse Of Metrics
- Data Fatigue
- Error of Omission (False Negative)

Solutions

- OOTB Standard Metrics & Analytics
- Focused, Predictive Analytics
- Integrated Statistical Workbench
**Traceability & Reproducibility**

**Key Goals:**

- **End-to-End review register** – Traceability of reviews. Plan → Manifest → Review → Action → Closure (Risk, Data, Medical)

- **Cohesive story for Audits/Compliance** – Point in time traceability of any reviews with associated data.

- **Document for Submission** – Easy system generated documents for TMF & submission.

**Challenges**

- Point Solution
- Lack of Automation
- Fragmented Documentation

**Solutions**

- Stacked Platform
- Cross-Functional Review (auto generated documents)
**RBQM Implementation Considerations**

**People**
- Train and retrain staff so they understand the RBQM strategy and follow a predefined process.
- Develop new communication methods between monitor and site staff.

**Process**
- Update processes and SOPs to identify key risks early in the clinical trial and develop a plan to address them.
- Take into account revenue model is going to change with a shift from being paid on visits to being paid on outcomes.

**Technology**
- Incorporate effective integration of disparate data sources and formats that enable efficient, remote monitoring.
- Develop relevant analytics to enable rapid identification of outliers and trends in large volumes of data.

**Goal:** Increased monitoring efficiency **without compromising subject safety or data quality**, while encouraging improved and more efficient approaches to clinical trial design, conduct, oversight, recording and reporting.
ICH E6 R2 Toolset

Clinical Trial Risk Management Toolset*

Risk Management
- Risk Identification
- Risk Assessment
- Risk Categorization
- Risk Control
- Quality Tolerance Limits (QTLs)
- Key Risk Indicators (KRI)
- Risk Library

Issue Management
- Issue Identification
- Issue Categorization
- Issue Assessment
- Issue Escalation
- Issue Remediation

Site & Central Monitoring and Analytics
- Portfolio to Trial Reporting**
- Risk and Issue Management Output
- Data Visualization
- Predictive Risk Identification
- Automated Escalation
- Centralized Risk Monitoring
- Trending Reports

Foundational Functionalities
- Consolidated Data (e.g., Database / Lake)
- Workflow

* ICH E6 R2 and CFR Part 11 compliant toolset
** Therapeutic area, Asset / Compound, Indication, Protocol / Study, Country, and Site