Society for Clinical Data Management
DATA DRIVEN

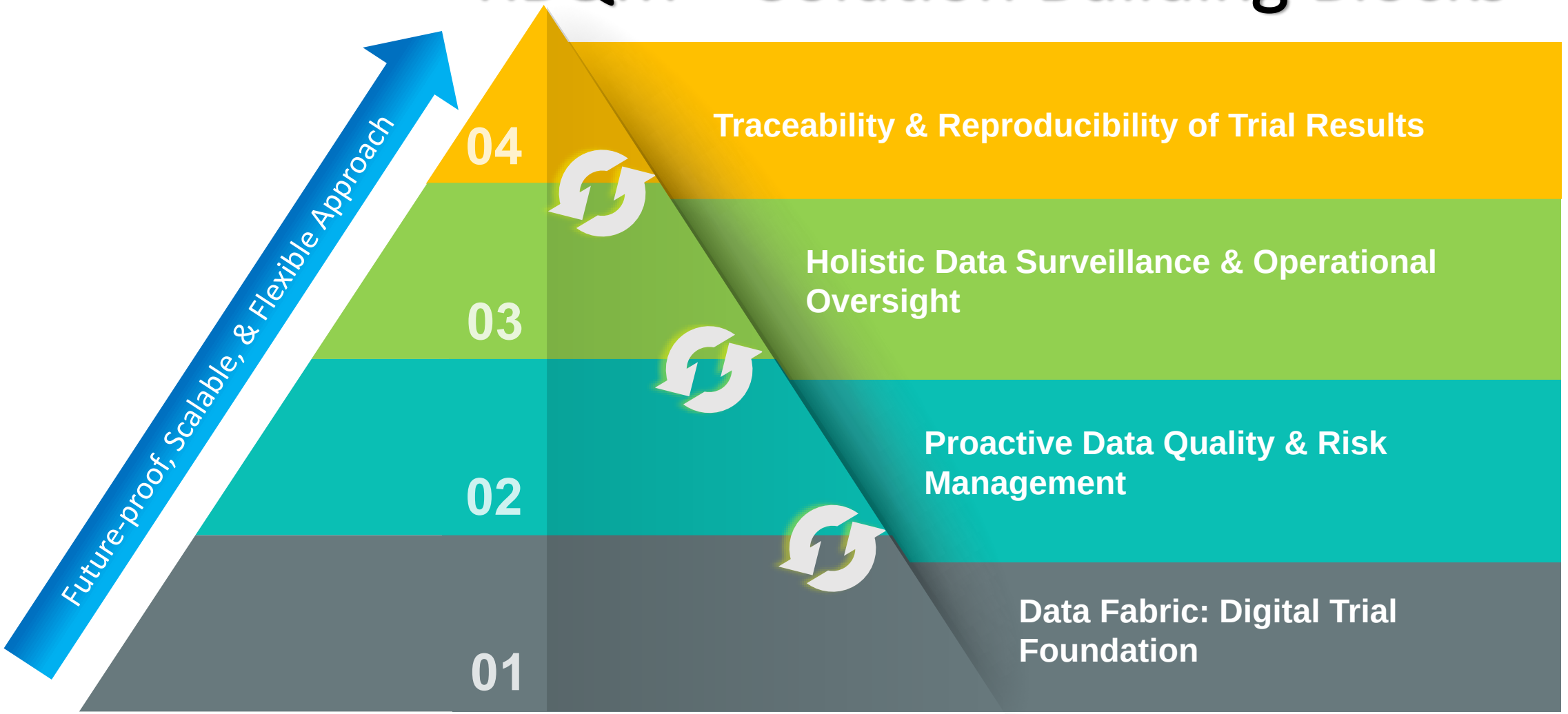
Theme:
Capabilities | Collaboration |
Change on the way to Clinical Data Science

SCDM Live

India conference

2nd - 3rd December 2022
Radisson Blu Hotel, Bengaluru

RBQM – Solution Building Blocks

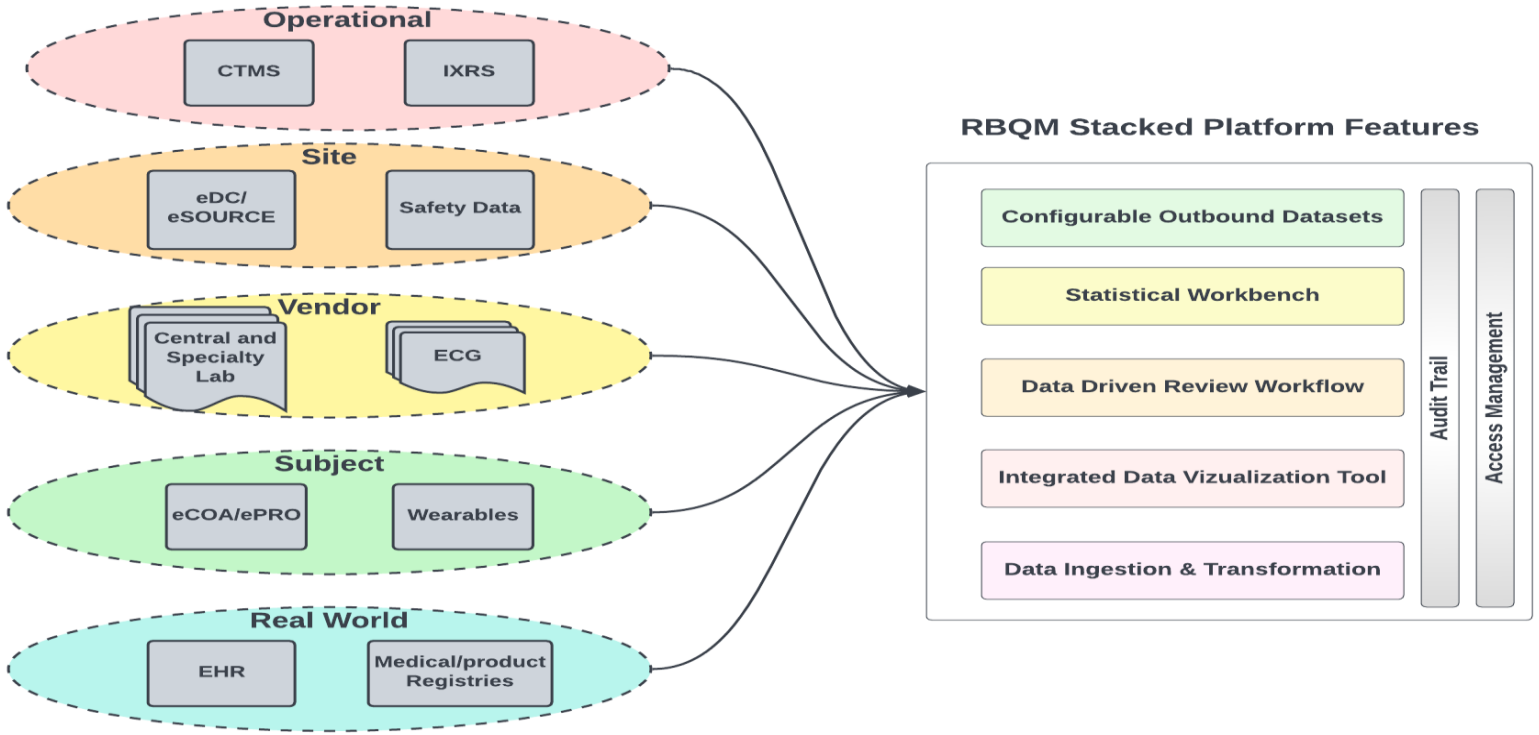


Data Fabric Foundation

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

Data Quality & Risk Management

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 (KRIs/QTLs) thus focusing on study specific factors.
- **Surveying Data** – No longer managing data, but surveying, understanding & protecting data

Critical to Quality Planning:

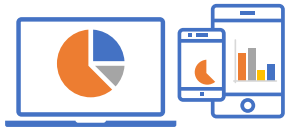
1. **Define critical data and processes** to subject safety and data quality

2. **Create a Risk Plan along with different mitigation strategy**, identifying relevant risks and key risk indicators (KRIs) 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

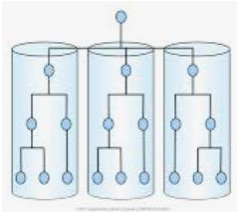
4. **Develop study monitoring plans** and adjust based on issues and risks that arise throughout the study

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



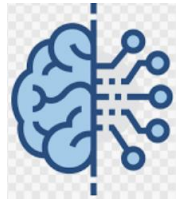
Challenges

Risk Fatigue

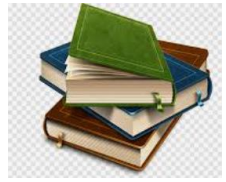


Silo'ed Review

Solutions



ML Driven Risk Prioritization



Library

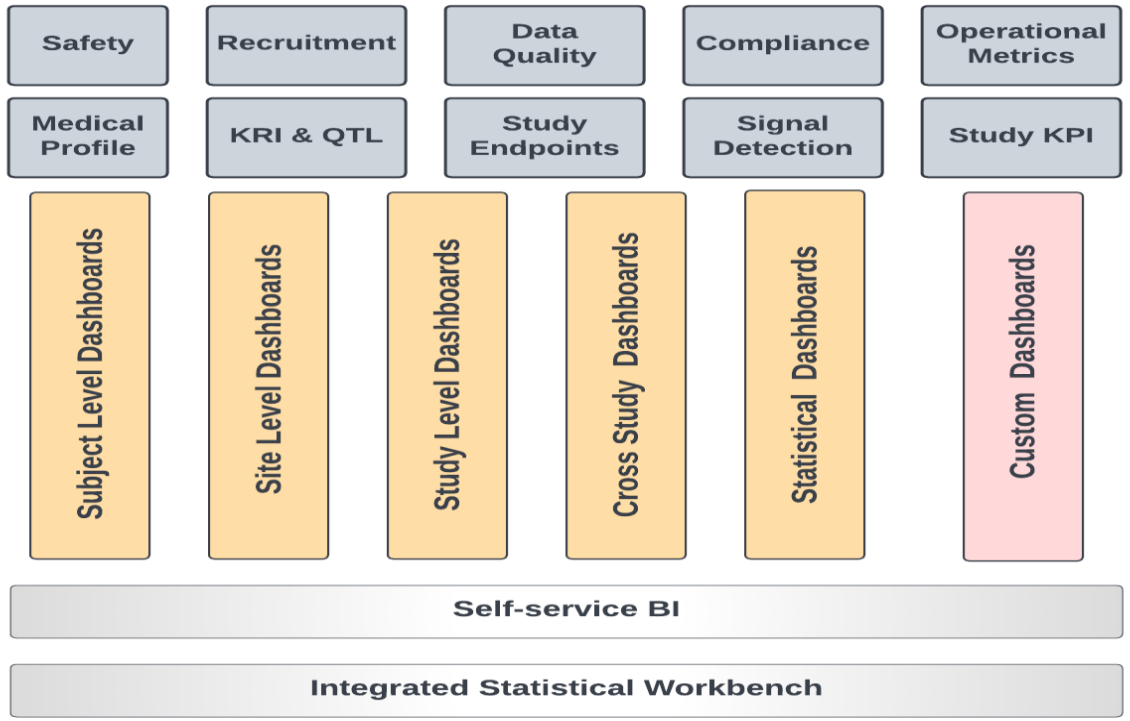
Integrated Review Platform

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:



Challenges

Reuse Of Metrics

Data Fatigue

Error of Omission
(False Negative)

Solutions

OOTB Standard Metrics & Analytics

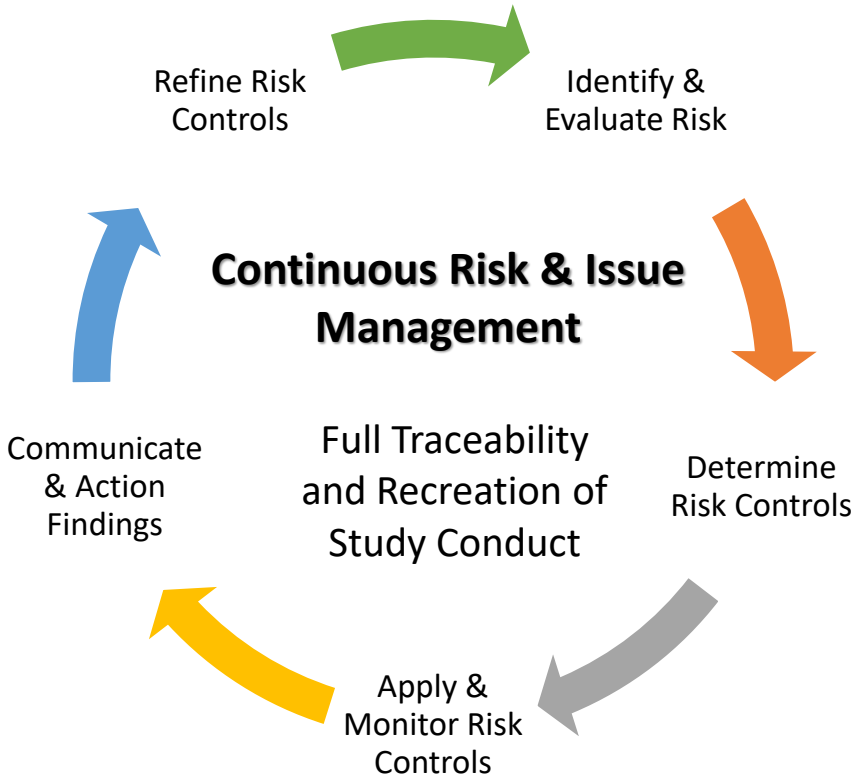
Focused, Predictive Analytics

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.



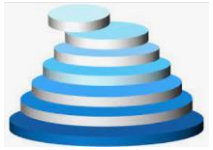
Challenges

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