Risk-Based Monitoring (RBM) and Technology Strategies
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Risk-Based Monitoring (RBM) and Technology Strategies

Embracing Risk-Based Monitoring (RBM) in Clinical Trials
Learning Objectives

Upon embracing a paradigm shift to a more targeted, centralized, and risk-based approach to monitoring, participants should be able to:

- Analyze ways to improve resource efficiency
- Differentiate methods of increasing quality of trial conduct and data collected
- Prescribe techniques to maintain or reduce study timelines
- Apply technology to reduce overall study costs
- Identify approaches to focus on Key Risk Indicators (KRIs) and risk analysis
Considerations for Risk-Based Monitoring

- Does your present Electronic Data Capture system have ability to track data to be verified?
- How are you determining study-level risk?
- How are your risk tools integrated, and who performs maintenance on these tools?
- Who mediates the decisions for risk mitigation?
- Technology must go hand-in-hand with Business Processes evolution and Change Management
- Collaboration among all areas is key to success
Key Drivers for RBM through technology

Only 2.4% of critical data is queried on average

Quality focus
- Site and data
- Increasing safety

Advance technology to streamline drug development
- Getting more drugs to market to help patients

R&D pipeline
- Reducing risk for financial investment
- 10 to 40% cost savings needed over the next 3 to 5 years
  - Travel cost
  - Resource cost
  - Site time
RBM Industry Investments

CROs and sponsors investing millions to implement RSDV
- Standardizing data and processes
- Creating KRI’s
  - Operational focused (TransCelerate)
  - Infancy in what is working and what is not.
- Introducing new business process and change management
  - Business Intelligence (BI) tools
  - Integrating systems and data – platform approach

New focus
- Focus on data quality algorithms, not just operational data
- Business process management tools

Future focus – Getting smarter with the data
- Artificial intelligence
Industry Initiatives

Regulatory drivers
  • FDA, MHRA, EMA
    • Guidance document on eSource Data Collection
    • Oversight of Clinical Investigation – A Risk-Based Approach to Monitoring

Clinical Trials Transformation Initiative (CTTI)
  • Quality by design (QbD)

TransCelerate
  • Building QbD into trials
  • Early and ongoing risk assessment
  • Focus on critical processes
  • Use of risk indicators through trial
Risk-Based Monitoring Stages

• **Planning**
  – Identify, plan, and prioritize risk of studying the investigational product.
  – Identify *the risk factors* unique to the investigational product, the program and the protocol.

• **Design**
  – Define protocol eligibility criteria, efficacy, and safety risk factors during design; for inclusion in the eCRF edit build, as well as define key protocol deviations anticipated for study.

• **Execution:**
  – Clear direction in the oversight and monitoring of parameters leading up to study endpoints, integrated study level monitoring plan, clear direction on evaluating fraud.
    *Comprehensive risk assessment that focuses on individual site risk factors*
    *Set each site up for success by defining a focused risk mitigation strategy*

• **Analysis:**
  – Clear definition of data measurement and reporting, defined elements of statistical analysis of protocol endpoints, safety, etc.

• **Disclosure**
  – Publish outcome data, bringing all the above together in the clinical study report (CSR).
An Approach to Risk-Based Monitoring
Multi-System Solution supports all 5 stages of RBM
RBM Support – CTMS, Analytics (CDA), & EDC

**RACT Assessment - CTMS**
- Support Risk Assessment Categorization Tool (RACT) features from TransCelerate
- Use of ‘Assessments’ feature in Siebel
- Assessment template applied at various levels

**Key Risk Indicators - CDA**
- TransCelerate Key Risk Indicators added to CDA data model
- Out of the box dashboards at the Study and Study-Site level

**Partial SDV Support – CTMS/EDC**
- Identify critical visits and pages
- Set partial SDV strategy at various levels
- Define criteria for SDV based on subject statuses/events
- Import SDV rules from InForm

**Training Planning & Tracking for Sites - CTMS**
- Define Training Topics & Plans
- Track Training at Various Levels

**Issue Management – CTMS**
- Record RBM Mitigations and actions
Utilize Oracle systems to identify operational risks in conjunction with CluePoints central statistical monitoring capabilities for clinical/patient data
RBM Use Case
Study Planning through Study Disclosure
CTMS: RACT Assessment
Study Planning

Standard out of the box template for RACT using Siebel Assessments

Available at the Program, Protocol, Region, & Site levels

Follows TransCelerate RACT standard, with capabilities for customer specific additions or modifications
CTMS: Partial SDV – Study, Regions & Sites

Study Setup

Define Visits and Specific CRF Pages for Monitoring

Setup Critical Visits & Pages for all subjects.
When building the SVT, critical pages and visits can be defined for SDV.

SDR items can be added as an activity for each visit or at a patient level.

SDR items can be required or not required.
CTMS: SDR at the Subject level

Study Setup

For a CRA, the SDR items appear as activities to be completed for that subject visit.

This example shows multiple documents in a single SDR activity.
CTMS SDV Screenshot: Partial SDV Setup

Study Setup & Execution

Define SDV % at the Protocol or Region or Site

Integrate SDV rules from an external EDC system (ex: InForm)

Modify based on site risks during study execution
Based on the SDV setup – Subject AAA was targeted for SDV as the initial subject at the site. Subject FFF was targeted based on the 50% auto-selection rate.
Out of the box dashboards at the Study and Study-Site level.

Aligned with TransCelerate Key Risk Indicators.
CTMS: RBM Issue Management

Study Execution

Serves as a master source of RBM issues and actions.

Issues recorded in site management as follow-up items with RBM Mitigation type.

Entered directly by CRAs, linked from CDA or external systems (ex: CluePoints).
CDA: RBM Issue Management
Study Analysis & Disclosure

RBM Issues and actions pulled from CTMS into CDA dashboard.

Easily exportable for reporting for auditors or regulatory authorities.
RBM Summary

- Risk-based monitoring is still young
- Regulatory agency are key supporter
- Investments in RBM will continue, standardization is key
- Key Stages- Planning, Design, Execution, Analysis, and Disclosure
- Process and change management investments
- New and changing roles
- Real time and historical data access is key
- Platform approach is required
- Integration between operational and clinical study data for RBM provides a more comprehensive approach
Questions

Thank you

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