Data Preparation & Publishing Best Practices for a Successful RBM Implementation

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Sreekanth Gudapati, Director, Technical Services
Agenda

• Introduction & Definitions
• Data Flow
• Data Preparation
• Analytics
• User Actions
• Questions ?
• References
Disclaimer

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Introduction & Definitions

• **Risk Based Monitoring (RBM)**¹

The proactive method of clinical trial monitoring called risk-based monitoring (RBM) is an adaptive approach that directs monitoring focus and activities to the evolving areas of greatest need which have the most potential to impact patient safety and data quality.

• **Key Risk Indicator (KRI)**²

A metric to quantify risk associated specific to any activity.

• **Data Preparation**

The process of parsing the data from different sources, normalizing and transforming into structures required.

• **Publishing**

Posting the normalized data into charts/graphs and listings, for review and action from the end user.
Data Flow

**DATA INGESTION**

**SOURCE DATA**
- EDC
- CTMS
- ePRO
- Safety
- Real World Evidence

**STAGE THE DATA**
- EDC
- CTMS
- ePRO
- Safety
- Real World Evidence

**TRANSFORM**
- Visualize
- Risk-Based Monitoring
- Review
- Assign Actions
- Follow Up

**DATA AGGREGATION**

**VISUALIZE AND TAKE ACTION**
Data Preparation

Data Ingestion

Collect all the data from different data sources and load it into the database or file system, for aggregation and normalization.

Complex clinical trials mean more complex data structures. A few common challenges with Data Ingestion are:

1. Access to real time data
2. Disparate data sources & formats
3. Unexpected changes in structure and incorrect file transmission
4. Self Service
Data Preparation: Data Ingestion

1. Access to real time data: Integrate using web service call with EDC / Mobile data
Data Preparation: Data Ingestion

2. Disparate Data Sources & Formats: Build connectors and flexibility to consume different data sources.
   – Delimited Files
   – SAS datasets (sas7bdat, xpt)
   – Excel
   – xml
Data Preparation: Data Ingestion

3. Unexpected changes in structure and incorrect file transmission: Reconcile with the previously processed files for metadata

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<th>Variable Count</th>
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File: lb.sas7bdat
## Data Preparation: Data Ingestion

### 4. Self Service

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**Active Import for eCS-ONCODEMO Rave Biostats Import**

- **Status:** Ready To Integrate
- **Created By:** sgdapati
- **Created Date:** 15 Feb 2019 10:11:00

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</tbody>
</table>
Data Preparation: Data Ingestion

Example:

• To identify the sites that have patients who are behind on ePRO completion for more than two assessment periods.

Data Sources Integrated:

a. Rave clinical data through web service
b. ePRO data through SFTP
c. Static file from user
Data Preparation: Aggregation

Data Aggregation

The step to summarize and process data through any statistical or algorithmic approaches can be done using any robust ETL tool. Here are a few common challenges and the processes that worked for different implementations.

1. Modularization: Break down the code into reusable components to gain efficiencies
   • Quality
   • Development time
   • Maintenance
Data Preparation: Aggregation

Example:

- **Study X**
  - Rave Clinical ODM Operational
  - Standardize for Scoring

- **Study Y**
  - Trail Master Clinical Exp
  - Query Management Reports
  - Standardize for Scoring

Query Aging weighted average

Other Functions:
- KRI_HighLabVariance
- KRI_DataEntry
- KRI_RatebySubject
- KRI_Zscore
- KRI_LowVariability...

[Diagram showing risk-based monitoring, review, assign actions, and follow up]
Data Preparation: Aggregation

2. Automation & Self Service: Every data integration should be tightly integrated with transformation to keep output as up to date as source.
   - Nightly batch refresh
   - On-demand self service
Publishing & User Action

Publishing

The interactive presentation of data in charts, graphs, and listings. Irrespective of the methods used for risk calculation, here are few key practices that help adoption:

• Simple and intuitive
• Visualization using a unified data model
• Interactive
• User connection with data
Publishing & User Action

Risk Overview

Risk Level Site Summary 5 4 2 6 Total Sites: 17 Total Actions: 30 □ 14 Past Due Actions

Map of the United States with markers indicating various cities, including Seattle, Vancouver, Los Angeles, San Francisco, New York, and others. Cities are color-coded to indicate risk levels.
## Publishing & User Action

### Site level detail

<table>
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<tr>
<th>Indicator</th>
<th>Score</th>
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<tr>
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<tr>
<td>Drug Related Blood Pressure Events</td>
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<tr>
<td>Renal Safety Data</td>
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<tr>
<td>Treatment Emergent Adverse Events</td>
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</tr>
<tr>
<td>Hemococoncentration data (indirect method)</td>
<td>2.00</td>
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<tr>
<td>Plasma Volume Results (direct method)</td>
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<tr>
<td>Enrollment of diabetic patients</td>
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<tr>
<td>Missing data per visit per patient diary</td>
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</tbody>
</table>
Publishing & User Action

Unified data model – Lab Visualization
Publishing & User Action

Unified data model – Lab Visualization
Publishing & User Action

Unified data model – Patient Profile
Publishing & User Action

User Actions

- Assign for action
- Analyze data for additional information
- Follow-up action
- Snooze a KRI
- Acknowledge & suspend
Questions?

Session AR05 – Thank You

Contact Details:

Sreekanth Gudapati
Director, Technical Services
sgudapati@eclinicalsol.com
References

1. TransCelerate – RBM Interactive Guide
2. A Risk Based approach for to Monitoring - FDA