Commissioning MDR System: Next-generation of standards implementation

Abhinav Jain, Ephicacy Consulting Group, USA
CDISC Landscape

Commissioning a MDR System: Next-generation of standards implementation
Challenges with Standards Implementation

• Standards are implemented in silos.
• Data definitions vary from study to study
• Data definitions in different data models are not linked
• Spreadsheets are used for metadata management
• Manual processes for content management, change control, versioning and distribution of metadata
• Inconsistent implementation of standards between organization teams
• For large organizations having investigational drugs in various therapeutic areas, maintaining global and therapeutic area standards is an enormous task
• With version releases in the standards, organizations struggle with maintaining multiple versions of the standard
Commissioning a MDR System: Next-generation of standards implementation
MDR System

- Metadata Repository (MDR)
  Centralized metadata governance platform

- Cloud-based application with
  Interactive Graphic User Interface (GUI)

- Inventory of metadata components for data artifact: forms, fields, domains, variables, mapping algorithms, controlled terminology, codelists

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MDR Architecture

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Features of MDR System

- Hierarchical Metadata Management
- Role Based Access
- Interconnected Data Models
- Version Control and Audit trail
- Impact Analysis
- Generate Study Artifacts
- Integrated Workflows
- Integration with external systems
- Change Control System
- Metadata Quality Control

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Collection Metadata Management with MDR

- Metadata management in organization EDC configuration (Rave, OC)
- Metadata components from eCRF like forms, fields, data and unit dictionaries
- Standards codelist and codelist terms consistently used across all trials
- Grab and Go approach to Study EDC specification generation
- Study DM team designs the study EDC specification using Global and TA-level collection Standards
- Specification generated by MDR system can be plugged into EDC system
- Maintains the version history of study EDC specifications
- Study teams can request updates/enhancements to the standard items via change request system
- Study-level items are adjudicated to enrich the standards metadata to be available for future studies

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Study Collection Metadata with MDR System

<table>
<thead>
<tr>
<th>MDR Forms Metadata</th>
<th>Study needs:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adverse Events</td>
<td>Adverse Events</td>
</tr>
<tr>
<td>Demographics</td>
<td>Demographics</td>
</tr>
<tr>
<td>Disposition</td>
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</tr>
<tr>
<td>Vital Sign</td>
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<tr>
<td>Dose Administration</td>
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<tr>
<td>SF-36</td>
<td>Tumor Assessment</td>
</tr>
<tr>
<td>Visual Analog Scale</td>
<td>Physical Examination</td>
</tr>
</tbody>
</table>

Study specification

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Tumor Assessment

Physical Examination

Metadata Enrichment

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Management of SDTM Metadata with MDR System

- Inventory of all SDTM metadata components: Domain, Variable, ValueLevel, WhereClause, Methods, Comments, Codelists (Cterms)
- Preserves the mapping relationship between source EDC fields with target SDTM variables
- Eliminates the excel spreadsheets for managing SDTM specification
- Ensures implementation of consistent coding values and derivation rules
- Generates draft study specification by comparing the study EDC specification with EDC-SDTM mappings
- Workflow based creation, review and approval of study specifications
- Maintains the version history of study specifications
- Integration with Pinnacle21 for SDTM Validation
## Metadata Driver Transformation

<table>
<thead>
<tr>
<th>EDC Form</th>
<th>EDC Field</th>
<th>Mapping Relationship</th>
<th>Target SDTM Domain</th>
<th>Target SDTM Variable</th>
</tr>
</thead>
<tbody>
<tr>
<td>DM_V01</td>
<td>RACE</td>
<td>COPY</td>
<td>DM</td>
<td>RACE</td>
</tr>
<tr>
<td>DM_V01</td>
<td>BRTHDTC YY, BRTHDTC MM, BRTHDTC DD</td>
<td>DATE_TRANSFORM</td>
<td>DM</td>
<td>BRTHDTC</td>
</tr>
</tbody>
</table>

- Based upon the study forms and fields list of target SDTM domains and variables.
- Confirmation if a optional SDTM variables is required for the study.
- Confirmation if all the collected fields are mapped
- Auto-generated SDTM Programs. Generation of SDTM artifacts like SDTM Specs, Define.xml
10 Reasons to commission MDR System

- Centralized management of standards and study metadata
- Substantial Reduction in DB-built time
- Reusability and automation of DM, SDTM and ADaM Processes
- Captures data models metadata with mapping relationships
- Metadata driven transformation
- Consistent Implementation of Business Rules
- Improved operations by advanced Comparison and Collaboration tools
- Content management
- Quality control of metadata
- Significant improvement in the data handling capabilities of the organization
Questions?