Agenda

- Creation of a Data Standards Library
- CDISC Compliance: Challenges & Considerations
- Conclusion
Agenda

Creation of a Data Standards Library

CDISC Compliance: Challenges & Considerations

Conclusion
Data Standards Solution Overview

An integrated solution with six components:

- Data Standards Library Management
- Study Specification
- Study Metadata
- Study Validation
- Issue Management
- Administration
Data Standards Solution Overview

DATA COLLECTION AREA
- EDC
- DBA
- CRO

DATA MANAGEMENT AREA
- DATA STANDARDS LIBRARY
  - DM
  - ISSUE Reports
- STUDY SPECIFICATION
- STUDY METADATA REPOSITORY
  - ISSUE Reports
- COMPARISON
- DEFINE.XML
- STUDY SDTM DATA & METADATA

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Library Management

DATA COLLECTION AREA
- EDC
- DBA
- CRO

DATA MANAGEMENT AREA
- DATA STANDARDS LIBRARY
- STUDY SPECIFICATION
- STUDY METADATA REPOSITORY
- DATA & METADATA SPECIFICATION
- RAW DATA & METADATA SPECIFICATION
- STUDY SDTM DATA & METADATA
- DEFINE.XML

Data Standards Library Management

Validation

Comparison

Issue Reports

DM

EDC

CRO

DBA

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Study Validation – Issue Management

DATA COLLECTION AREA

DATA MANAGEMENT AREA

STUDY METADATA

STUDY SPECIFICATION

STUDY METADATA REPOSITORY

DATA STANDARDS LIBRARY

ISSUE Management

Study Validation

VALIDATION

ISSUE Reports

ISSUE Reports

EDC DBA

CRO

RAW DATA & METADATA SPECIFICATION

STUDY SDTM DATA & METADATA

DEFINE.XML

COMPARISON

Study Validation – Issue Management

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Three main areas

1. Metadata Creation
2. Metadata Loading
3. Updates in Library Management Module

Challenges related to CDISC-Compliance
1. Creation of Metadata

Challenges

- Alignment of vision of different team players
- Divergent viewpoints on the requirements, priorities and understanding of standards
- Development of EDC System independent standard CRFs
1. Creation of Metadata

Considerations

- Streamlined vision
- Define objectives and processes
- Agree/Enforce DS Library design principles
2. Loading of Metadata

Challenges

• Although BDLS-defined validation rules are available in the Library Management (LM) module, CDISC validation rules are not available at this level.
• Risk of loading non-CDISC compliant metadata into Data Standards (DS) Library.
2. Loading of Metadata

**Considerations**

- Set of external QC tools to check for compliance between the metadata created and:
  - CDISC CDASH UG
  - CDISC SDTM IG
  - Controlled Terminology
3. Updates in Data Standards Library

- No CDISC validation rules available at the LM module level
- Non-CDISC-compliant library objects could be created when working in the Data Standards Library in the LM Module
3. Updates in Data Standards Library

Considerations

- eSHARE API Integration
- CDISC eSHARE DS Library in LM
- Reporting Tool in LM

Managed within Library Module
- Library Compliance Report comparing Company standards to CDISC standards
- Auto-generate change requests with impact report

Synchronize CDISC metadata

Automatically connect to SHARE
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When creating a Data Standards Library

Alignment team vision:
- Define objectives and processes
- Agree/Enforce DS Library design principles

Implementation of CDISC validation rules and sponsor-specific business rules

Implement a CDISC eSHARE DS Library that allows
- Promoting CDISC compliant metadata to repository
- Generating CDISC compliant study specifications
- Compare study data to sponsor-specific DS Library
- Compare study data to a specific standard version in the CDISC eSHARE DS Library
Data Standards Extended Solution
Benefits of a CDISC compliant Data Standards Library

- **Eliminate data inconsistencies, improves quality** and ensures full CDISC (CDASH/SDTM/ADaM) compliance resulting in a reference for internal stakeholders.

- Drive the streamlining of internal processes and ensures **Regulatory compliance**.

- Allow **traceability** of data, more data trustworthiness and **tighter data governance**.

- Can be **automated** by integrating in a fully automated platform, the CDISC **Data Standards Library solution** of Business and Decision Life Sciences (CDmation).

- Reduce timelines, allows fewer resources and produces ‘**ready for submission**’ data.

- Enable control and **cooperation** with partners and vendors.
Thank you for your attention.
Vienna, Austria, 12 OCT 2015