Oracle Health Sciences
Streamlining SDTM with CDASH input

Mike Collinson
Life Sciences Architect
Oracle Health Sciences Consulting (HSC)

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Streamlining SDTM with CDASH input

Agenda

• Clinical Regulatory Background
• Conversion to SDTM
• Central Designer / InForm CDASH Study
• DMW QuickStart
  – CDASH Support
  – SDTM Libraries
  – Review Model and Traceability
  – Libraries and Templates
  – Data Extract
  – Data Visualization
Clinical Regulatory Background

FDA Binding Guidance on SDTM Submissions

- Submission Guidance
  - FDA SDTM Submissions: 2017
    - Paper and non-eCTD submissions will no longer be accepted
  - PMDA SDTM Submissions: 2016
- FDA Submission Gateway
  - 80% of trials in SDTM in 2015
- FDA Data Standards Catalog
  - Catalogues evolving support for CDISC Standards
Conversion to SDTM

Adoption Trends for CDISC standards (2004-2014)

Source: Tufts research on “Industry Adoption of eClinical Solutions and CDISC Standards”
Conversion to SDTM

Oracle’s strategic approach using Data Management Workbench (DMW)

• Oracle has created a platform for reducing the time from EDC and External data to SDTM/ADaM/Analysis Datasets.

• Transformations and validation checks are automated as fresh data arrives.

• Traceability from source to deliverable is maintained at the level of the single data point.

• Study components (transformations, edit checks) are reused as linked objects, making them easy to track and maintain.

• HSC can accelerate study set up based on CDASH forms using eShare derived transformations included in a Study Template.
Conversion to SDTM
Oracle Data Management Workbench (DMW) data processing
Central Designer / InForm QuickStart CDASH Study

Simplify EDC set up using CDASH forms

• Simplify study set up with Central Designer CDASH Library
• CDASH v1.1 support
• English and Japanese forms
Central Designer / InForm QuickStart CDASH Study
DMW connects directly to the EDC data

DMW inherits
- Clinical data
- Metadata
- Operational data
from the CDASH study automatically
DMW QuickStart SDTM Libraries
Change controlled Libraries for all versions

- Control SDTM versions with Libraries easily loaded from zip files
- Transformations created from eShare cdash-2-sdtm-map.xls
- Facilitate submissions in CDISC SDTM
- Deliver data to downstream systems
DMW QuickStart Review Model and Traceability
Complete Data Model designed for Data Management

• Designed for specifically for Data Management
• Pre-built mapping from CDASH
  – Supports DM Review with InForm
  – Default Listings show queries
  – TMS Medical Dictionary coding
• Single point of change
• Traceability is maintained from CDASH > Review > SDTM
DMW QuickStart Libraries and Templates

Simplify and speed Study Set Up

• Study and Template objects based on pre-existing Therapeutic Area Libraries
• Template Study provided to simplify study set up
• Includes Review and SDTM
• Can reduce study set up time to around 30 minutes
DMW QuickStart Data Flow

EDC, Coding Integration, DMW Data Models, Transformations, GVA Schema and Data Extract

Data Load:
- Clinical
- Metadata
- Operational
- Queries

Visualization Adapter:
- Data Extract
- Visualization Tools
InForm objects created and installed in a single step

Data Models, TMS coding and Transformations created almost instantly from Study Template

GVA Schema created when Template data models are installed
DMW QuickStart Data Extract

Instant data delivery to downstream systems

- GVA Business Areas for direct connection to Review and SDTM data
  - JReview
  - Spotfire
  - SAS
- SAS xpt file generation for SDTM
  - Scheduled / On Demand
  - Files placed on sFTP for secure download
DMW QuickStart Data Visualization

Data Visualization in Business Intelligence tools

- Direct Integration with OBIEE
- Data is updated automatically using DMW triggered execution
DMW QuickStart Data Visualization

Data Visualization in Business Intelligence tools

• Direct Integration with OBIEE
• Data is updated automatically using DMW triggered execution
Oracle Health Sciences Services have completed a set of standards based accelerators to aid CDASH and SDTM Adoption

1. CDASH Input
2. Review Model
3. SDTM Models
4. Libraries & Template
5. Data Extract / Visualization
6. Security