SDTM AND ADaM: HANDS-ON SOLUTIONS

CDISC French Speaking User Group
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Process Improvements

WHEN YOU NEED TO BE SURE
OUTLINE

- SDTM and ADaM: Standards review
- A central Metadata Repository
- ADaM implementation: Strategies
- Conclusion
CDISC: STANDARDS REVIEW

- CDISC end-to-end!
  - CDASH identifies the (e)CRF data collection fields
  - SDTM defines a standard structure for study data tabulations
  - ADaM specifies the fundamental principles for the creation of analysis datasets
STUDY DATA TABULATION MODEL (SDTM) & ANALYSIS DATA MODEL (ADaM)

- SDTM and ADaM: Hands-on solutions
  - Focus on submission standards: SDTM, ADaM, (define.xml)
  - Hands-on solutions for daily work:
    - Manage a spectrum of SDTM implementations
    - ADaM best build upon SDTM, not on ‘raw’ data
SDTM & ADaM AT SGS

- Data Management
  - SDTM datasets at (and before) database lock with associated metadata

- Statistics
  - Statistical analysis on SDTM datasets
  - ADaM datasets with associated metadata
STUDY DATA TABULATION MODEL (SDTM): WHAT’S NEW, WHAT’S COMING?

**Today**
- Implementation Guide v3.1.2, 12-NOV-2008
- Amendment 1 to SDTM 1.2 (IG 3.1.2), 14-DEC-2011
- Alzheimer’s Disease v1.0, 30-NOV-2010
- + CRTDD v1.0.0, 09-FEB-2005

**Coming up**
- Non-Subject Data Supplement, draft 17-JUN-2011
- Device Supplement, draft 24-JAN-2012
- Virology draft domains, draft AUG-2011
- Development program for 55 therapeutic area standards in 5 years [CDISC strategic goals & themes]
# FDA Study Data Standards Catalog

<table>
<thead>
<tr>
<th>Data Standard Type</th>
<th>Governing Organization</th>
<th>Standard</th>
<th>Version</th>
<th>Implementation Guide</th>
<th>FDA Component</th>
<th>Date Support Begins*</th>
<th>Date Support Ends**</th>
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### Version 1.0; Effective 13-JUN-2011
SGS maintains 16 SDTM models!

- Multiple SDTM versions
- Multiple sponsors
  - Custom controlled terminology
  - Custom domains
  - Custom variable implementations
- Multiple implementations per sponsor per SDTM version
SDTMs: THE CHALLENGE, AN EXAMPLE

- SDS team TC: 15-Jul-2011
  - Holter data in Interventions domain

**Example A) Mockups of Revised Proposal**

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- Holter data in Findings domain

**Example B) Mockups of Original Proposal**

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2011-01-01 T08:10
2011-01-01 T10:08
SDTM AND ADaM INTERFACING: THE CHALLENGE

- SDTM concepts are standard, details are not
- Due to:
  - Missing therapeutic area standards
  - Missing controlled terminology items
  - Flexible SDTM variables
    - Permissible variables
    - Flexible variable length
      » based on used codelist values (SDTM Amendment 1)
      » only few variables lengths are fixed (e.g. --TESTCD, --TEST, --PARMCD, --PARM, QNAM, QLABEL, ARMCD)

16 SDTMs to 16 ADaMs?
Add a new dimension to your trials
  • Use Metadata from the start

Pull the CRF forms for all your trials out of a metadata repository into the (e)CRF design tool
SDTM SPECTRUM MANAGEMENT: THE SOLUTION

- Add a new dimension to your trials
  - Use Metadata during the trial
    - Verify **consistency** of your trials
    - Use the metadata repository to **update** the protocol amendments
    - Store the trial metadata in the metadata repository for **future reference**
SDTM SPECTRUM MANAGEMENT: THE SOLUTION

- Add a new dimension to your trials
  - Use Metadata till the end
    - Sponsor SDTM IGs with update option copied from fixed SGS SDTM IGs
    - Use the trial metadata in the metadata repository to generate SDTM datasets

Metadata Repository

SGS: SDTM 1.1
SGS: SDTM 1.2

XXX: SDTM 1.1 (v1)
XXX: SDTM 1.1 (v2)
XXX: SDTM 1.2 (v1)
YYY: SDTM 1.2 (v1)
YYY: SDTM 1.2 (v2)
SDTM SPECTRUM MANAGEMENT: THE SOLUTION

- Add a new dimension to your trials
  - Share Metadata across standards and teams
  - ... and bring the SDTM spectrum closer to ADaM

![Diagram showing SDTM and ADaM connections through Metadata Repository]
METADATA REPOSITORY: WHAT’S IN THE BOX?

- CDISC metadata
  - SDTM version
  - SDTM metadata
  - ...  

- Study characteristics
  - Therapeutic area
  - Clinical phase
  - Trial design characteristics
  - ...  

- Project metadata
  - Study timelines
  - Key Performance Indicators
  - ...
OUTLINE – ADaM 2.1

- Introduction
- SDTM and ADaM implementation: Strategies
- Linear method
- Conclusion
ADaM 2.1 – INTRODUCTION

- Excel file → SAS datasets
  - codelist.sas7bdat
  - domlist.sas7bdat
  - varlist.sas7bdat

- Analysis Dataset Metadata – domlist.sas7bdat
- Analysis Variable Metadata – varlist.sas7bdat

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<td>+ Length (SAS environment)</td>
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<td>+ Position in observation (SAS environment)</td>
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- ADaM V2.1: Analysis Results Metadata (not required)
ADaM 2.1 – INTRODUCTION

- CDISC Analysis Data Model V2.1
  - Fundamental principles
    - Traceability
  - Practical considerations
    - Maintain the values and attributes of SDTM variables

- CDISC ADaM implementation guide V1.0
  - General variable naming convention
Any ADaM variable whose name is the same as an SDTM variable must be a copy of the SDTM variable, and its label, meaning, and values must not be modified.
ADaM 2.1 – INTRODUCTION

- Traceability
- Flexible
- Delivery of consistent analysis datasets
- Easy to use (Excel file)
- Easy to maintain (Excel file)
OUTLINE – ADaM 2.1

- Introduction
- SDTM and ADaM implementation: Strategies
- Linear method
- Conclusion
STRATEGIES FOR IMPLEMENTING SDTM AND ADaM STANDARDS: SUSAN KENNY – MICHAEL LITZSINGER

- Parallel method
  
  DBMS Extract ← SDTM Domains ← Analysis Datasets

- Retrospective method
  
  DBMS Extract → Analysis Datasets → SDTM Domains

- Linear method
  
  DBMS Extract → SDTM Domains → Analysis Datasets

- Hybrid method
  
  DBMS Extract → SDTM Draft Domains → Analysis Datasets → SDTM Final Domains
STRATEGIES FOR IMPLEMENTING SDTM AND ADaM STANDARDS: SUSAN KENNY – MICHAEL LITZSINGER

- Linear method
  - Traceability
  - CDISC SDTM/ADaM Pilot Project
  - Recommended

  DBMS Extract → SDTM Domains → Analysis Datasets

- Hybrid method
  - Traceability
  - Amendment 1 SDTM V1.2 and SDTM IG V3.1.2
  - Future?!?

  DBMS Extract → SDTM Draft Domains → Analysis Datasets → SDTM Final Domains
OUTLINE – ADaM 2.1

- Introduction
- SDTM and ADaM implementation: Strategies
- Linear method
- Conclusion
Step 1
### Linear Method – Step 1

CDISC SDTM Implementation Guide

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Any ADaM variable whose name is the same as an SDTM variable must be a copy of the SDTM variable, and its label, meaning, and values must not be modified.
**LINEAR METHOD – STEP 1**
**CHALLENGE: FLEXIBLE VARIABLE LENGTH**

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LINEAR METHOD – STEP 1
CHALLENGE: FLEXIBLE VARIABLE LENGTH

- CDISC SDTM IG
  - Version 5 SAS transport file format: max. 200 characters
  - -- TESTCD and QNAM: max. 8 characters
  - -- TEST and QLABEL: max. 40 characters

- Example: DM.RACE: $41, $50, and $200

- Amendment 1 to SDTM V1.2 and SDTM IGV3.1.2
  - Version 5 SAS transport file format: max. 200 characters
  - ! only if necessary!
LINEAR METHOD – STEP 1
CHALLENGE: FLEXIBLE VARIABLE LENGTH

- Traceability
- Flexible
- Delivery of consistent analysis datasets
- Easy to use
- Easy to maintain
LINEAR METHOD – STEP 1
SOLUTION: [SDTM] ↔ %ADAM(DS_ = )

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LINEAR METHOD – STEP 1
CHALLENGE: PERMISSIBLE VARIABLES

Example: LB.LBSCAT

Solution: \([\text{sdtm}] \leftrightarrow \%\text{ADAM}(\text{ds}_\_ = )\)

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Step 2
LINEAR METHOD – STEP 2
SUPP--

- **QNAME**  → variable name
- **QLABEL**  → variable label
- **QVAL**    → variable type
- **QVAL**    → variable length

* e.g. SUPPDM SDTM dataset
* e.g. ADSL ADaM dataset
LINEAR METHOD – STEP 2
CHALLENGE: FLEXIBLE CODE LIST

- **QLABEL is different for the same QNAM**
  - Example
    - ELIGCONF Subject Still Eligible
    - ELIGCONF Still Fulfill Eligibility Criteria

- **QLABEL format**
  - Example
    - RANDNO RANDOMIZATION NUMBER
    - RANDNO Randomization Number

- **QLABEL changes during the course of a study**
  - Example
    - ELIGIBLE **Subject** Eligible For Dosing
    - ELIGIBLE **Subject** Eligible For Dosing
LINEAR METHOD – STEP 2
SOLUTION: [SUPP] ↔ %ADAM(DS_=

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<tbody>
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<td>VARIABLE NAME</td>
<td>VARIABLE LABEL</td>
<td>VARIABLE TYPE</td>
<td>LENGTH</td>
<td>DISPLAY FORMAT</td>
<td>CODELIST / CONTROLLED TERMS</td>
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Step 3
LINEAR METHOD – STEP 3
CHALLENGE: 16 SDTM → 16 ADAM?!!
SDTM Column Resizing: Background and Industry Testing Results – Warfield and Chhatre

Research: CDISC Submission Dataset Sizes

Data Collection

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<th></th>
<th>N</th>
<th>Minimum</th>
<th>Maximum</th>
<th>Range</th>
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LINEAR METHOD – STEP 3
CHALLENGE: 16 SDTM $\rightarrow$ 16 ADaM?!?
LINEAR METHOD – STEP 3
SOLUTION: 1 CENTRAL MODEL + SPONSOR SPECIFIC ADD-ONS

1. Convert Excel file to SAS datasets (by ADaM administrator)
2. Combine central model and sponsor specific add-on (by study programmer)
LINEAR METHOD – STEP 3
SOLUTION: 1 CENTRAL MODEL + SPONSOR SPECIFIC ADD-ONS

- Traceability
- Flexible
- Delivery of consistent analysis datasets
- Easy to use
- Easy to maintain
Step 4
LINEAR METHOD – STEP 4
CHALLENGE: SDTM MODEL NO. 1, 2, 3 ... ?

SDTM

ADaM

?
LINEAR METHOD – STEP 4
SOLUTION: CENTRAL METADATA REPOSITORY

- CDISC metadata
  - SDTM version
  - SDTM metadata
  - ...

- Study characteristics
  - Therapeutic area
  - Clinical phase
  - Trial design characteristics
  - ...

- Project metadata
  - Study timelines
  - Key Performance Indicators
  - ...

Step 5
LINEAR METHOD – STEP 5
CHALLENGE: FUTURE

- **SDTM**
  - Device Supplement, draft 24-JAN-2012
  - Virology draft domains, draft AUG-2011
  - Development program for 55 therapeutic area standards in 5 years

- **ADaM**
  - BDS for Time-to-Event Analysis, draft 05-JAN-2011
  - Data Structure for Adverse Event Analysis, draft 02-FEB-2011

- **Coming up**
  - ???
OUTLINE – ADaM 2.1

- Introduction
- SDTM and ADaM implementation: Strategies
- Linear method
- Conclusion
SDTM AND ADaM: HANDS-ON SOLUTIONS

CONCLUSION

- Linear method:
  - Recommended
  - Challenging

- Solution:
  - SDTM: Central metadata repository
  - ADaM: Automatization, e.g. [sdtm], [supp] …

Study metadata differences are handled efficiently
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