SDTM 3.1.3 / 3.1.4 Overview
Devices User's Guide

January 11, 2013

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Overview

- ➤ SDTM IG 3.1.3 / SDTM 1.3

- ➤ SDTM IG 3.1.4 DRAFT
  - ➤ SDTMIG-MD 1.0 touched on throughout
    - ➤ Device Identifiers (DI)
    - ➤ Device In-Use (DU)
    - ➤ Device Exposure (DX)
    - ➤ Device Events (DE)
    - ➤ Device Tracking and Disposition (DT)
    - ➤ Device-Subject Relationships (DR)
    - ➤ Device Properties (DO)

- ➤ Concluding Thoughts

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Note of Thanks

Dan Godoy & Barrie Nelson (SDS Team Co-Leaders)

➤ Provided material & insight

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SDTM IG 3.1.3 / SDTM 1.3

Dude, Where's My Update?

3.1.3

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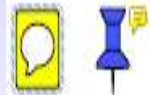
SDTM IG 3.1.3 / SDTM 1.3

Not your typical update

- ➢ Annotated SDTM IG 3.1.2 rather than full document update
- ➢ Sticky Notes
- ➢ Pins linking to annotations
- ➢ Text markups

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SDTM IG 3.1.3 / SDTM 1.3

➢ **Reasons behind this**
   ➢ Limited resources
   ➢ Limited time

➢ **What to expect with 3.1.4**
   ➢ Modular PDF sections to better support
      ➢ Printing
      ➢ Updating

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SDTM IG 3.1.3 / SDTM 1.3 - Contents

Amendment 1 to SDTM 1.2 & SDTMIG 3.1.2

- Demography updates
  - Actual Arm
  - Dates of First/Last Study Treatment, Informed Consent, End of Participation
  - Date of Death and Death Flag

- Adverse Event updates
  - Coding variables promoted out of SuppQual to parent record

- New Section 4.1.2.9 - Variable Lengths
  - Keep 'em short

- Appendix C5: Standard SuppQual Name Codes updates
  - Removal of Coding Variables

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SDTM IG 3.1.3 / SDTM 1.3 - Contents

Revised Trial Summary domain

- ➢ Trial Summary Updated

- ➢ Null Flavor Enumeration introduced
    - ➢ Return of CDM concept
    - ➢ Why Missing

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SDTM IG 3.1.3 / SDTM 1.3 - Contents

➢ New Section 2.7
  ➢ SDTM Variables allowed in SDTMIG
    ➢ SEND (non-clinical study) interactions

➢ New Sections 6.3.11 & 6.3.12
  ➢ 6.3.11 Oncology Domains - TU and TR
  ➢ 6.3.12 Disease Response - RS
    ➢ Presented as an oncology use case

➢ Errata Corrections
  ➢ Typos
  ➢ Corrections
  ➢ Deletions

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SDTM IG 3.1.3 / SDTM 1.3 - Contents

Not Called Out

- Use of EPOCH, ELEMENT, and ETCD for every subject-level observation per CDER Common Data Standards Issues Document

- SDTM Model already accommodates this

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SDTM IG 3.1.4 DRAFT

3.1.4

By Peter Jackson??

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SDTM IG 3.1.4 DRAFT

➢ Batch 1
  ➢ Released for review middle of 2012
  ➢ Easily digestible

➢ Batch 2
  ➢ Released for review end of 2012
  ➢ Lots of content, lots of implications

➢ Batch 3
  ➢ Coming soon (2013)
  ➢ Wrap-up?

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SDTM IG 3.1.4 DRAFT – Batch 1

Exposure Domains

- ➢ Clarifications
  - ➢ EX recognized as derived
  - ➢ Dose amounts in protocol-specified units

- ➢ Standard Representations
  - ➢ New Domain: EC (Exposure as Collected)
  - ➢ New Conventions (e.g., --OCCUR/--REASND, Scheduled vs. Performed)
  - ➢ New Variables (e.g., --METHOD, --FAST)
  - ➢ Proposed Deprecations (EXVAMT / EXVAMTU)

- ➢ Deferred Issues
  - ➢ Delayed/Interrupted Dosing

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SDTM IG 3.1.4 DRAFT – Batch 1

Exposure Domains (cont.)

- ➤ Interacts with Device Domains

- ➤ For example, per SDTMIG-MD (Medical Device) 1.0:

  In cases where a device/drug combination is being studied, the device exposure data would generally be submitted in DX and the drug exposure data would generally be submitted in EX, but each sponsor should confer with the appropriate regulatory authorities to determine the right datasets.

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SDTM IG 3.1.4 DRAFT – Batch 1

Immunogenicity Domains

> - IS (Immunogenicity Specimen Assessment)

> - SR (Skin Response)
>   > - FA-based model
>   > - Uses --OBJ variable

> - Inconsistent with EC/EX proposal, has EXMETHOD in SUPPEX

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SDTM IG 3.1.4 DRAFT – Batch 1

Reproductive Details (RD)

> All reproduction details captured in a study related to the subject

> Examples
>> Pregnancy
>> Menopause status
>> Birth control method
>> Childbearing potential

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SDTM IG 3.1.4 Batch 2

Package Contents:

➢ New Domain Documentation:
- ➢ CV   Cardiovascular Physiology
- ➢ DD   Death Details
- ➢ MI   Microscopic Findings
- ➢ MO   Morphology
- ➢ PR   Procedures
- ➢ SS   Subject Status
- ➢ TD   Trial Disease Assessment

➢ SDS Team Proposal Documents:
- ➢ Alternative Method of submitting Supplemental Qualifier Variables

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SDTM IG 3.1.4 Batch 2

Cardiovascular Physiology (CV)

➤ Designed to report data on cardiovascular physiological findings which include information relating to the heart, blood vessels, and circulation, such as:
  ➤ Ischemic myocardium percentage
  ➤ Stenosis
  ➤ New York Heart Association class.

➤ Holds the results/findings of a cardiovascular diagnostic procedure
  ➤ Information about the conduct of the procedure(s) is submitted in the Procedure Domain (PR)
  ➤ Data describing structural measurements of the heart should be reported in the Morphology Domain (MO)

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SDTM IG 3.1.4 Batch 2

Death Details (DD)

➢ Supplemental data that are typically collected when a death occurs, such as the official cause of death

➢ Does not replace existing data such as the SAE details in AE

➢ Does not introduce a new requirement to collect information that is not already indicated as Good Clinical Practice or defined in regulatory guidelines

➢ It provides a consistent dataset for the submission of information that previously did not have a clearly defined home

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SDTM IG 3.1.4 Batch 2

Microscopic Findings (MI)

➢ Captures all Microscopic Findings information related to the subject in a Findings domain.

➢ Reflects details of histopathologic examinations which are the microscopic study of characteristic tissue abnormalities by employing various histochemical and immunohistochemical stains.

➢ For example, histologic type, histologic grade, stage, diagnosis, and slide stain results from pathology/histopathology examination are MI findings

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SDTM IG 3.1.4 Batch 2

Morphology (MO)

- ➢ Macroscopic results that are seen by the naked eye or observed via procedures such as imaging modalities, endoscopy, or other technologies
  - ➢ Examples: size, shape, color, and abnormalities of body parts or specimens.

- ➢ The Morphology domain is used for all macroscopic findings in human clinical trials . . . except in the context of Oncology
  - ➢ MO is concerned with general findings, and not necessarily the time-course or growth pattern of a specific clinical anomaly

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SDTM IG 3.1.4 Batch 2

Morphology (MO) cont.

- ➢ Information about the procedure may or may not be collected. If collected, a corresponding PR domain may be created with appropriate linkage variables and the use of RELREC

- ➢ Can also interact with Device Domains
  - ➢ e.g., MRI settings

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SDTM IG 3.1.4 Batch 2

Procedures (PR)

➢ It reflects collected details describing a subject's therapeutic and diagnostic procedures, such as:

  ➢ disease screening (e.g., mammogram, pap smear)
  ➢ endoscopic examinations (e.g., arthroscopy, colonoscopy)
  ➢ diagnostic tests (e.g., amniocentesis, biopsy)
  ➢ therapeutic procedures (e.g., ablation therapy, catheterization)
  ➢ surgical procedures (e.g., curative surgery)

➢ Measurements obtained from procedures are to be represented in their respective Findings domain(s)

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SDTM IG 3.1.4 Batch 2

Procedures (PR) cont.

➢ Can interact or overlap with Device Domains

  ➢ For MRI Imaging
   ➢ Result (e.g., Brain Volume) in MO
   ➢ Is MRI captured in PR or Device domain?
   ➢ Or neither (MOMETHOD=MRI)?

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SDTM IG 3.1.4 Batch 2

Subject Status (SS)

➢ Subject Status is for data relating to general subject characteristics which are evaluated periodically to determine if they have changed
  ➢ For example: repeated survival questions where mortality is assessed many times during an ongoing study follow-up period

➢ Subject Status does not contain details about the circumstances of a subject's status
  ➢ The response to the status assessment may trigger collection of additional details, but those details are to be stored in appropriate separate domains

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SDTM IG 3.1.4 Batch 2

Trial Disease Assessment (TD)

➢ An addition to the trial design model

➢ For use when disease assessments occur on a fixed schedule (e.g., Oncology)

➢ Provides information on the disease assessment schedule for comparison with actual occurrence of efficacy assessments to measure compliance

➢ FDA has standard programs (panels) which rely on the TD domain to evaluate possible 'assessment time bias' for efficacy assessments, in particular, for studies with progression-free survival endpoints

➢ Existing Trial Design domains do not convey the detail required, but future enhancements to the TDM may incorporate these requirements

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SDTM IG 3.1.4 Batch 2

Alternative Method of submitting SuppQual

➢ The SDTM Supplemental Qualifiers structure is a method for representing non-standard variables (NSVs) in a standard way within the SDTM.

➢ The current format for representing NSVs is as separate SUPP-- datasets that are associated with the corresponding "parent" dataset

➢ Proposal is to place NSVs onto the parent record (like coding variables were moved in AE).

➢ Identifies the conditions under which this practice would be permitted.

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SDTM IG 3.1.4 Batch 3

Batch 3!

➢ SDTM – Study Data Tabulation Model v1.4

➢ AP UG – Associated Persons UG

➢ LA – Lesion Attributes

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Concluding Thoughts

SDTM IG 3.1.3/3.1.4

- ➢ Microscopic and Morphology vs. Cardiovascular
  - ➢ MI/MO capture broad range of data
  - ➢ CV is a targeted body system

- ➢ Multiple pathways for mapping depending on level of detail
  - ➢ e.g., PR or no PR with Imaging results in MO

- ➢ SDTM version releases
  - ➢ 1 to 2 a year
  - ➢ Complexity increasing at rapid pace compared to prior versions
  - ➢ Implications on governance

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Concluding Thoughts

SDTM IG 3.1.3/3.1.4

> ➢ FDA Adoption
>> ➢ FDA publish on the Data Standards Website which versions of standards are being accepted
>>> ➢ http://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm
>>> ➢ Identifies 3.1.1 and 3.1.2
>>> ➢ 3.1.3?
>>
>> ➢ Domains may be published by CDISC as provisional
>>> ➢ Can be used, but with the understanding that it may still change up until the point of the next SDTM release
>>
>> ➢ Possible that any domains published as part of a new version that conform to an accepted version could be used in a submission (only after discussion with FDA Review Division)

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Concluding Thoughts

SDTM IG 3.1.3/3.1.4

- ➢ What does the version mean?

  - ➢ SDTMIG 3.1.4/SDTM 1.4

  - ➢ SDTM IG MD 1.0

  - ➢ Theraputic Area releases

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Questions?

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Thank you.

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