SDTMIG 3.3: New domains, new benefits

Nick De Donder
A brief history

ROI² return on investment through return on information
Provisional vs Final

Provisional use means that the standard has been published for initial use, and is dependent upon completion of other standards

- The SDTM Model
- Controlled Terminology (codelists referenced in the SDTMIG are published)
- Conformance Rules
- Metadata in SHARE
- Educational learning objectives
Grandfathered Standards

SDTMIG v3.3 is grandfathered such that it will be published as Final (as opposed to Provisional) even though the SDS team is still working on the associated conformance rules

- Any standard that has already passed public review will be eligible for final publication in 2018

- Any standard that has already passed cross-team internal review and been approved by SRC or GGG to proceed to public review
  - Will be eligible for Provisional publication in 2018

Publication guidelines:

- Still must be handed over to the publication team by cut-off date
- Will be prioritized according to specific criteria
SDTMIG v3.3

Release Date: 20 Nov 2018

Version 3.3 of the Study Data Tabulation Model Implementation Guide for Human Clinical Trials (SDTMIG) is available in HTML format, which can be viewed in a browser.

Please log in or create an account to access the link to the Standard.

HTML Format

This release is published in HTML format, which expedites delivery of the standard and is viewable in any standard browser. HTML format allows users to search for keywords within the page, and bookmark the information in a browser. Implementers can also print the page, or export the information into other formats (e.g., PDF). To save a copy of the HTML publication on your desktop to access the document offline, press CTRL-S (PC) or COMMAND-S (Mac) on your keyboard.

Enhancements, Key Additions and Revisions

SDTMIG v3.3 provides the following enhancements, key additions and revisions to prior versions:

- Revised Disposition (DS) assumptions to facilitate greater clarity
- Introduction of morphology/physiology domains to support specific body systems
- New Functional Tests (FT) domain supporting QRS supplements
- Expanded Disease Response and Clin Classification (RS) domain to include QRS clinical classification content
- New class of Study References (e.g., Non-host Organism Identifiers)
- Many new examples, revisions, and corrections across domains
- New variables and assumptions for Demographics (DM)
- Associations to supplemental implementation guides (e.g., SDTMIG-PGx, SDTMIG-MD)
- Significant revisions to microbiology domains
- Additional new supporting domains (e.g., MI, TM, SM)
- Greater guidance on managing text strings that are more than 200 characters
New Variables

- Included in previous SDTM versions
  - Changes from SDTM V1.4 to SDTM V1.5
  - Changes from SDTM V1.5 to SDTM V1.6
  - Changes from SDTM V1.6 to SDTM V1.7

- See back-up slides
New Domains

Special Purpose
- Comments (CO)
- Demographics (DM)
- Subject Elements (SE)
- Subject Visits (SV)
- Subject Disease Milestones (SM)

Relationships
- Related Records (RELREC)
- Supplemental Qualifiers (SUPP--)

Trial Design
- Trial Arms (TA)
- Trial Elements (TE)
- Trial Visits (TV)
- Trial Disease Assessments (TD)
- Trial Inclusion/Exclusion Criteria (TI)
- Trial Summary (TS)
- Trial Disease Milestones (TM)
New Domains

Interventions
- Concomitant Medications (CM)
- Exposure (EX)
- Exposure as Collected (EC)
- Procedures (PR)
- Substance Use (SU)
- Procedure Agents (AG)
- Meal Data (ML)

Events
- Adverse Events (AE)
- Clinical Events (CE)
- Disposition (DS)
- Protocol Deviations (DV)
- Healthcare Encounters (HO)
- Medical History (MH)

Findings About Events or Interventions
- Findings About (FA)
- Skin Response (SR)
New Domains

Findings
- Drug Accountability (DA)
- Death Details (DD)
- ECG Test Results (EG)
- Inclusion/Exclusion Criteria Not Met (IE)
- Immunogenicity Specimen Assessments (IS)
- Laboratory Test Findings (LB)
- Microbiology Specimen (MB)
- Microbiology Susceptibility (MS)
- Microscopic Findings (MI)

Findings
- Pharmacokinetic Concentrations (PC)
- Pharmacokinetic Parameters (PP)
- Physical Examination (PE)
- Questionnaires (QS)
- Subject Characteristics (SC)
- Subject Status (SC)
- Tumor Identification (TU)
- Tumor Results (TR)
- Disease Response (RS)
- Vital Signs (VS)

Findings
- Morphology (MO)
- Reproductive System Findings (RP)
- Cardiovascular System Findings (CV)
- Musculoskeletal System Findings (MK)
- Nervous System Findings (NV)
- Ophthalmic Examinations (OE)
- Respiratory System Findings (RE)
- Urinary System Findings (UR)
SDTMIG History

What’s New

Deep Dive

Q&A
**TM – Trial Disease Milestones**

**Description:** This domain is used to describe Disease Milestones, which are observations or activities anticipated to occur in the course of the disease under study, and which trigger the collection of data

**Origin:** TAUG Diabetes (V1.0 Provisional 2014-08-01)

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<td>Initial diagnosis of diabetes, the first time a physician told the subject they had diabetes</td>
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<td>Hypoglycemic Event, the occurrence of a glucose level below (threshold level)</td>
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**SM – Subject Disease Milestones**

*Description:* This domain is designed to record the timing, for each subject, of Disease Milestones that have been defined in the Trial Disease Milestones (TM) dataset

*Origin: TAUG Diabetes (V1.0 Provisional 2014-08-01)*

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ML – Meal Data

Description: The Meal Data domain model reflects collected details describing a subject’s food product consumption.

Origin: TAUG Diabetes (V1.0 Provisional 2014-08-01)

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AG – Procedure Agents

**Description:** A domain for the agents administered to the subject as part of a procedure or assessment, as opposed to drugs, medications, and therapies administered with therapeutic intent.

**Origin:** TAUG Asthma (V1.0 Provisional 2013-11-26)

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<td>Y</td>
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<td>Y</td>
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# RE – Respiratory System Findings

**Description:** A domain for morphological and physiological findings related to the respiratory system, including the organs that are involved in breathing, such as the nose, throat, larynx, trachea, bronchi, and lungs

**Origin:** TAUG Asthma (V1.0 Provisional 2013-11-26)

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Back-up Slides

https://wiki.cdisc.org/display/SDTMIG33/Revision+History
https://www.cdisc.org/standards/in-development
https://wiki.cdisc.org/display/GGG/Standards+Development+Timeline
Changes from SDTM v1.4 to SDTM v1.5

Table 2.2.1: Interventions:
- **USCHFL Unscheduled Flag**

Table 2.2.2: Events:
- **USCHFL Unscheduled Flag**

Table 2.2.3: Findings:
- **ORREF Reference Result in Original Units**
- **STREFC Reference Result in Standard Format**
- **STREFN Numeric Reference Result in Std Units**
- **IMPLBL Implantation Site Label**
- **CHRON Chronicity of Finding**
- **DISTR Distribution Pattern of Finding**
- **LOBXFL Last Observation Before Exposure Flag**
- **USCHFL Unscheduled Flag**
- **RENUM Repetition Number**

Unique for SEND, should not be used in SDTMIG
Changes from SDTM v1.4 to SDTM v1.5

Table 2.2.4: Identifiers for All Classes:
- APID Associated Persons Identifier
- FETUSID Fetus Identifier
- FOCID Focus of Study Specific Interest
- --RECID Invariant Record Identifier

Table 2.2.5: Timing Variables for All Classes:
- --NOMDY Nominal Study Day for Tabulations
- --NOMLBL Label for Nominal Study Day
- MIDS Disease Milestone Instance Name
- RELMIDS Temporal Relation to Milestone Instance
- MIDSDTC Disease Milestone Instance Date/Time

Table 2.2.10: Subject Disease Milestones (new table)
Table 2.2.11: Domain-Specific Variables for the General Observation Class (new table)
Table 3.5.2: Trial Disease Milestones (new table)
Changes from SDTM v1.5 to SDTM v1.6

Variable Changes:

Table 2.2.2: Interventions – Topic and Qualifier Variables Changed the Roles:

- **PSTRG** – Pharmaceutical Strength from Variable Qualifier to Record Qualifier
- **PSTRGU** – Variable Qualifier of **PSTRG** from Variable Qualifier to Variable Qualifier of **PSTRG**

Variable Additions:

Table 2.2.3: Findings – Topic and Qualifier Variables

- **RESLOC** – Result Location of Finding
Changes from SDTM v1.5 to SDTM v1.6

Table 2.2.5: Timing Variables for All Classes
- **RPHASE** – Repro Phase
- **RPPLLDY** – Planned Repro Phase Day of Observation
- **RPPLSTDY** – Planned Repro Phase Day of Obs Start
- **RPPLENDY** – Planned Repro Phase Day of Obs End
- **RPDY** – Actual Repro Phase Day of Observation
- **RPSTDY** – Actual Repro Phase Day of Obs Start
- **RPENDY** – Actual Repro Phase Day of Obs End

Table 2.2.6: Demographics
- **RPATHCD** – Planned Repro Path Code

Dataset Additions:
- **Table 2.2.11: Subject Repro Stages (new table)**
- **Table 3.1.5: Trial Repro Stages (new table)**
- **Table 3.1.6: Trial Repro Paths (new table)**
Changes from SDTM v1.6 to SDTM v1.7

Variable Additions:

Table 2.2.1: Interventions - Topic and Qualifier Variables
- RSDISC - Reason for Treatment Discontinuation

Table 2.2.6: Demographics
- ARMNRS - Reason Arm and/or Actual Arm is Null
- ACTARMUD - Description of Unplanned Actual Arm

Table 2.2.7: Comments
- COEVALID - Evaluator Identifier
- CODY - Study Day of Comment
Changes from SDTM v1.6 to SDTM v1.7

Table 2.2.12: Domain-Specific Variables for General Observation Class Domains

- MHEVDTYP - Medical History Event Date Type
- MSAGENT - Agent Name
- MSCONC - Agent Concentration
- MSCONCU - Agent Concentration Units

Dataset Additions:

- Table 4.1.5: Device-Subject Relationships Dataset
- Table 5.1.1: Device Identifiers Dataset
- Table 5.1.2: Non-Host Organism Identifiers Dataset
## CV – Cardiovascular System Findings

**Description:** A domain for morphological and physiological findings related to the cardiovascular system, including the heart, blood vessels, and lymphatic vessels

**Origin:** TAUG Cardiovascular Disease (V1.0 Draft 2014-04-07)

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## MK – Musculoskeletal System Findings

**Description:** A domain for morphological and physiological findings related to the system of muscles, tendons, ligaments, bones, joints, and associated tissues

**Origin:** TAUG Duchenne Muscular Dystrophy (V1.0 Provisional 2017-09-25)

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# NV – Nervous System Findings

**Description:** A domain for physiological and morphological findings related to the nervous system based on neurological examinations or procedures, involving the brain, spinal cord, the cranial and spinal nerves, autonomic ganglia, and plexuses

**Origin:** TAUG Alzheimer (V2.0 Final 2013-12-16)

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OE – Ophthalmic Examinations

**Description:** The OE domain is for findings related to tests that measure a person's ocular health and visual status, to detect abnormalities in the components of the visual system, and to determine how well the person can see.

**Origin:** TAUG Multiple Sclerosis (V1.0 Provisional 2014-05-02)

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**Interpretation:**
- NORMAL
- ABNORMAL
- RED SPOT VISIBLE
- CONJUNCTIVA
- MULTIPLE

**Footnote:**
ROI² return on investment through return on information
**UR – Urinary System Findings**

**Description:** A domain for morphological and physiological findings related to the urinary tract, including the organs involved in the creation and excretion of urine, such as the kidneys, ureters, bladder, and urethra

**Origin:** TAUG Polycystic Kidney Disease (V1.0 Provisional 2013-02-26)

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ROI² return on investment through return on information