Paper DS10

What's New in the SDTMIG v3.4 and the SDTM v2.0

Sumanth Goud Bheemagani, Merck & Co. Inc, North Wales, PA.
Bhanoji Duppada, Vita Data Sciences, Waltham, MA.

ABSTRACT

The SDTMIG v3.4 and the SDTM v2.0 were released in July 2022. These versions have been published as HTML documents, rather than the typical PDF's of the past. While the SDTMIG v3.2 which was published in 2013 contained 398 pages and SDTMIG v3.4 would be more than 400 pages if formatted properly and printed to a PDF. Several new domains, new concepts have been added and several domains that had undergone public review in 2014 were subsequently combined with existing domains. The Disease Milestones concept, introduced for the TAUG-Diabetes in 2014, is now included in the latest version of the SDTMIG. A new Section '9' includes Study References with added models for Device Identifiers and Non-host Organism Identifiers. Three versions of the SDTM have been published since the release of v1.4 with the SDTMIG v3.2. These have added not only new variables for general-observation-class domains but also have added new tables including those for as domain-specific variables, SEND reproductive stages and study references. The primary focus of this paper is to demonstrate the changes in SDTMIG v3.4 from SDTMIG v3.2 and to discuss the SDTM versions published in between these two IGs. When relevant, changes in v3.4 from the batches that went out for public comment will be noted. Changes to the SDTM will be discussed first, followed by changes to the SDTMIG, in approximate order of their appearance in the IG.

INTRODUCTION

CDISC has been providing an accepted standard for the submission of tabulation data in the form of SDTM and SDTMIG since 2004. The first versions that became part of the FDA's Study Data Specifications were SDTM v.1.0 and SDTMIG v3.1. Prior to SDTM/SDTMIG, the CDISC Submission Data Standards (SDS) Team has created precursor documents known as Submission Data Standards, which includes 1.x. and 2.x versions of the team's standards-development efforts. The figure below shows the relationship between versions of SDTM and SDTM-based implementation guides since the publication of SDTMIG v3.2 in 2013. In order to ensure the alignment of new domains and concepts in each SDTM-based implementation guide (IG) with the SDTM at the time of publication, a new version of the SDTM is released with each IG. In many cases, more than one IG may be associated with a version of the SDTM. The figure shows that two versions of the SDTM were released in between version 3.2 and 3.3 of the SDTMIG, and SDTM v2.0 with SDTMIG v3.2. This paper will first look at the changes that occurred in Versions 1.5 through 1.7 of the SDTM.

SDTM Version	Year	SDTMIG Version	Number of Domains*
1.0	2004	3.1	23
1.1	2005	3.1.1	30
1.2	2008	3.1.2	32
1.3	2012	3.1.3	32
1.4	2013	3.2	46
1.5	2016	N/A**	
1.6	2017	N/A***	
1.7	2018	3.3	61
2.0	2021	3.4	63

* *Includes all special-purpose, general-observation-class domains, and study references*
** *Created for the SENDIG v3.1*
*** *Created for the SENDIG-DART v1.1*

After the publication of the SDTMIG v3.2 in 2013, the SDS Team had decided that it would be better to release updated material for public review in batches rather than all at once. This was expected to be easier for the Team to manage, and to be easier for public review. Updates that would have been included in the SDTMIG v3.4 were planned to be released in three batches. Batches 1 and 2 had completed public review by the end of 2014. Batch 3 had been scheduled for some time in Q2 of 2015. What was expected to be in the final version of SDTMIG v3.2 was presented by this author then (4). The Public Review period for Batch 3 occurred in August/September of 2016.The SDS Team received additional comments from FDA in March 2017, which took time to resolve. Handover for publication took place in November 2021, and v3.4 was published in July of 2022.

ADDITIONS AND CHANGES TO THE SDTM

There have been a number of changes to the SDTM from Version 1.4, issued with SDTMIG v3.2, through SDTM v2.0, issued with SDTMIG v3.4. These are summarized in the text and tables below. The new tables will be presented first, followed by the new variables.

NEW SDTM TABLES

Version 1.5

SDTM Version 1.5 saw the addition of two tables for Disease Milestones (Subject Disease Milestones and Trial Disease Milestones), a concept that will be discussed later in this paper, and a table for Domain-Specific variables, shown below. They are shown with their two-letter domain codes. This was initially Table 2.2.11 was changed to Table 2.2.12 in v1.6. This table shows a limited set of variables approved for use in only in a single domain. The scope of these variables may change in future versions of the SDTM, based upon SDTMIG implementation needs.

Variable Name	Variable Label
MHEVDTYP	Medical History Event Date Type
EXMETHOD	Method of Administration
EGBEATNO	ECG Beat Number
ICIMPLBL	Implantation Site Label
MSAGENT	Agent Name
MSCONC	Agent Concentration
MSCONCU	Agent Concentration Units

Version 1.6

Version 1.6 primarily added new tables that were limited to supporting the SEND Implementation Guide for Developmental and Reproductive Toxicology (SENDIG-DART). These included Subject Repro Stages, Trial Repro Stages, and Trial Repro Paths.

Version 1.7

Changes to v1.7 included the following:

- Table numbers changed. All v1.6 and earlier table numbers have a ".1" added.
- Study Reference Section 5 was added, and Associated Persons modeling was moved to Section 6.

Additions in v1.7 included the Device-Subject Relationships (DR, Table 4.1.5.1) the Device Identifiers (DI, Table 5.1.1.1) datasets, both previously only in the SDTMIG for Medical Devices (SDTMIG-MD) Also added was the Non- Host Organism Identifiers Dataset (Table 5.1.2.1).

Version 2.0

Changes to v2.0 included the following:

- Section numbers for the General Observation Classes was moved to Section 3.1.1, The Interventions Observation Class, Section 3.1.2, The Events Observation Class, and Section 3.1.3, The Findings Observation Class.
- A Study-Level Data Section 5 was added, and Associated Persons modeling was moved to Section 4.
- A Datasets for Representing Relationships Data Section 6 was added.

Additions in v2.0 included Changes to Structures of Tables and All tables have been updated to include the following columns. Variable Name, Variable Label, Type, Format, Role, Variable Qualified.

NEW SDTM VARIABLES

Since the publication of SDTM v2.0, new variables have been added to the SDTM. These are shown by version in the following tables. Many, however, are not intended for use in human clinical trials. These are shown with a single asterisk (*). Others are accompanied by a statement that have not been evaluated for use in human clinical trials and must therefore be used with extreme caution. These are identified with a double asterisk (**).

SDTM Version 1.5

There are the variables in the list below that can be used in human clinical trials.

SDTM Table	Variable Name	Variable Label
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 *
	--REPNUM	Repetition Number
Table 2.2.4 Identifiers	APID	Associated Persons Identifier
	FETUSID	Fetus Identifier *
	FOCID	Focus of Study Specific Interest
	--RECID	Invariant Record Identifier

Table 2.2.5 Timing Variables	--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

* Not intended for use in human clinical trials.

** Not evaluated for use in human clinical trials and must therefore be used with extreme caution.

SDTM Version 1.6

In this version of the SDTM, only the variable NHOID is intended for use in human clinical trials. It's used to represent a sponsor-defined, intuitive name of the non-host organism being tested. Further details of the taxonomic classification are represented in the Non-host Organism Identifiers (OI) dataset (SDTM Table 5.1.2, SDTMIG Table 9.2). NHOID should be populated only with values representing what's known about the identity of the organism before the results of any tests are determined. It should never be used as a qualifier of any result.

SDTM Table	Variable Name	Variable Label
Table 2.2.3 Findings	--RESLOC	Result Location of Finding*
Table 2.2.4 Identifiers	NHOID	Non-Host Organism Identifier
Table 2.2.5 Timing Variables	RPHASE	Repro Phase *
	RPPLDY	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 *

* *Not intended for use in human clinical trials.*

SDTM Version 1.7

The additions to v1.7 included two new variables for the Demographics dataset and will be discussed under the following section on Additions and Changes to the SDTMIG. The other three additions are self-explanatory.

SDTM Table	Variable Name	Variable Label
Table 2.2.1.1 Interventions	--RSDISC	Reason for Treatment Discontinuation
Table 2.2.6.1 Demographics	ARMNRS	Reason Arm and/or Actual Arm is Null
	ACTARMUD	Description of Unplanned Actual Arm
Table 2.2.7.1 Comments	COEVALID	Evaluator Identifier
	CODY	Study Day of Comment

SDTM Version 2.0

The additions to v2.0 included new variable. The special-purpose Subject Visits (SV) domain remains a special-purpose domain, but additional variables have been added to address the effect of an epidemic or pandemic on visits and Changes to the SDTMIG. Other new variables are added as shown in the table below/The other additions of new variable is added as per below table

SDTM Table	Variable Name	Variable Label
Table 3.1.1 Interventions Observation Class	-- REASOC	Reason for Occur Value
	--CNTMOD	Contact Mode
	--EPCHGI	Epi/Pandemic Change Indicator
Table 3.1.1 Events Observation Class	-- REASOC	Reason for Occur Value
	--CNTMOD	Contact Mode
	--EPCHGI	Epi/Pandemic Change Indicator
	--RLPRT	Rel of AE to Device-Related Procedure
	--RLPRC	Rel of AE to Non-Dev-Rel Study Activity
Table 3.1.3 Findings Observation Class	--SBMRKS	Sublineage Marker String
	--CELSTA	Cell State
	--CSMRKS	Cell State Marker String
	--CNTMOD	Contact Mode
	--EPCHGI	Epi/Pandemic Related Change Indicator
Table 3.2.3.3 Subject Visits	SVPRESP	Pre-Specified
	SVOCCUR	Occurrence
	SVREASOC	Reason for Occur Value
	SVCNTMOD	Contact Mode
	SVEPCHGI	Epi/Pandemic Related Change Indicator
Table 3.1.5 Timing Variables for All Classes	--PTFL	Point in Time Flag
	--PDUR	Planned Duration

ADDITIONS AND CHANGES TO THE SDTMIG

UPDATES TO SECTIONS 1 (INTRODUCTION) AND 2 (FUNDAMENTALS OF THE SDTM)

- A new section (Section 1.4.1, How to Read a Domain Specification) provides clear descriptions of the columns in the domain specifications, and how these relate to the metadata described in the SDTM.
- Section 2.5, the table listing all the domains in v3.2 and previous versions was removed, as it was considered redundant.
- While not foremost in the minds of most sponsors, the policy on domain versioning was added in the new Section 2.5. Starting with SDTMIG v3.4, any new domain will be Version 1.0. An existing version that has changed since the last published version of the SDTMIG will be up-versioned. Note that some domains in SDTMIG v3.4 are domain versions 3.2 (unchanged) and others are v3.4 (up-versioned).

UPDATES TO SECTION 4, ASSUMPTIONS FOR DOMAIN MODELS

Section 4.5.3.2 Text Values Greater than 200

Clarified section on text values greater than 200 characters, and added a new table, a condensation of which is shown below.

General Observation Class & Supplemental Qualifier Variables	CO.COVAL and TS.TSVAL	TI.IETEST and IE.IETEST
The first 200 characters should be represented in the variable. Each additional 200 characters should be represented as a record in a SUPP-- dataset.	The first 200 characters should be represented in COVAL or TSVAL. Each additional 200 characters should be represented in COVAL1 (or TSVAL1) to COVALn (or TSVALn).	Put meaningful text in IETEST and describe the full text in the study metadata.
When splitting a text string, text should be split between words to improve readability.		Not applicable.
The value for QLABEL should be the original domain variable label.	The variable labels for COVAL1 to COVALn should be "Comment". The Variable labels for TSVAL1 to TSVALn should be "Parameter Value".	Not applicable.

Section 4.1.3.1 Added Guidance on Populating the Epoch Variable

The text in Section 4.1.3.1 can be summarized as follows:

- Sponsors should not impute EPOCH values.
- The EPOCH value should be null if it's not possible to determine the EPOCH of an observation.
- Methods for assigning EPOCH values can be described in the Define-XML document.
- Since EPOCH is a study-design construct, it is not applicable to observations prior to study start.
- EPOCH values may be determined as follows:

Most Findings	--DTC
Specimen Collection with End Dates	--ENDTC may be more appropriate
Events and Interventions	--STDTC

Section 4.1.5 Updated Guidance on Permissible Variables.

The following key points were added:

- Domain assumptions that say a variable is "generally not used" don't prohibit use of the variable.
- If a study includes a data item that would be represented in a Permissible variable, then that variable must be included in the SDTM dataset, even if null. Indicate no data were available for that variable in the Define-XML document.
- If a study did not include a data item that would be represented in a Permissible variable, then that variable should not be included in the SDTM dataset and should not be declared in the Define-XML document.

Section 4.4.7 Values for Relative Timing Variables, --STRF and --ENRF

The advice in various versions of the SDTMIG for the values used for Relative Timing Variables has varied. For some unknown reason, the text in v3.2 was changed to allow the two additional values (COINCIDENT and ONGOING) that were added to the code list to support the use of --STRTPT and --ENRTPT to be used for --STRF and --ENRF. This was never the intention, so in v3.4 (Section 4.4.7) this was corrected and reverted back to the original values. A comparison of allowable values is shown in the following table.

Version	Allowable Values for –STRF and --ENRF
Versions 3.1.2 and 3.1.3	BEFORE, DURING, DURING/AFTER, AFTER, and U
Version 3.2	BEFORE, DURING, DURING/AFTER, AFTER, COINCIDENT, ONGOING, and U
Version 3.4	BEFORE, DURING, DURING/AFTER, AFTER, and U

NEW DOMAINS IN SECTIONS 5-9

These are the new domains were added in the latest version 2.0 that can be used in human clinical trials.

Section	Domain Type	Domain Name and Code
5	Special Purpose	Subject Milestones (SM)
6.1	Interventions	Meal Data (ML)
		Procedure Agents (AG)
		Protocol Deviations (DV)
6.3	Findings	Functional Tests (FT)
		Generic Morphology/Physiology Specification
		Musculoskeletal Findings (MK)
		Nervous System Findings (NV)
		Ophthalmic Examinations (OE)
		Respiratory System Findings (RE)
		Cardiovascular System Findings (CV)
		Urinary System Findings (UR)
		Ophthalmic Examinations (OE)
		Biospecimen Findings (BS)
		Immunogenicity Specimen Assessments (IS)
		Laboratory Test Results (LB)
		Microscopic Findings (MI)
		Disease Response and Clin Classification (RS)
		Cell Phenotype Findings (CP)
7	Trial Design	Trial Milestones (TM)
8	Relationships	Related Subjects (RELSUB)
		Related Specimens (RELSPEC)
9	Study References	Device Identifiers (DI)
		Non-host Organism Identifiers (OI)

CHANGES TO DEMOGRAPHICS

Removal of Population Flags

In a major change from previous versions of the SDTMIG, an assumption in the DM domain of v3.4 states that the Population Flags (COMPLT, FULLSET, ITT, PPROT, and SAFETY) should not be included in SDTM data. Values for these in the SUPPDM dataset often came from ADaM datasets, and as was the case with –BLFL would violate the traceability principle that all data in ADaM datasets must be traceable back to the SDTM datasets.

In addition to the change in the DM assumption, the corresponding example in Section 8 was removed, as were the QNAMs from Appendix C2. This change came slowly, again as a joint effort of the SDS and ADaM Teams over many years.

Population of ARMCD/ARM for Screen Failures and Subjects Not Assigned

Text in v3.2 stated that ARMCD (ARM) should be SCRNFAIL (Screen Failure) and NOTASSGN (Not Assigned). In v3.4, this changed, largely as a result of text in the FDA Study Data Technical Conformance Guide that states the following:

> *"Screen failures, when provided, should be included as a record in DM with the ARM, ARMCD, ACTARM, and ACTARMCD field left blank. For subjects who are randomized into a treatment group but not treated, the planned arm variables (ARM and ARMCD) should be populated, but actual treatment arm variables (ACTARM and ACTARMCD) should be left blank."*

Since the ARM and ARMCD values will not be populated in these two cases, the information that subjects were screen failures or not assigned will be represented in two new Expected variables added to v3.4. These are summarized below.

ARMNRS	Reason Arm and/or Actual Arm is Null	The reason that Arm variables (ARM and ARMCD) and/or actual Arm variables (ACTARM and ACTARMCD) are null.
ACTARMUD	Description of Unplanned Actual Arm	A description of actual treatment for a subject who did not receive treatment described in one of the planned trial Arms.

CHANGES IN THE FINDINGS GENERAL OBSERVATION CLASS

Approach to Morphology and Physiology

There are a number of changes in v3.4 that will affect the submission of morphology and physiology data. Prior to the publication of v3.2, there was considerable discussion by the SDS Team around the modeling philosophy of this type of data. There were at least three team-wide polls that revolved around grouping vs. splitting data by body system. At the time when v3.2 was published, it was decided that morphology findings

would be represented in the MO domain, and physiology findings would be in separate body-system-based domains. Since then, there were a number of TAUGs in which separating morphology and physiology endpoints became difficult. After additional discussion, it was decided that it would be easier if morphology data was also separated by body system. The SDTMIG v3.2 contains additional implementation advice around the use of the MO domain, which will be deprecated in a future version of the SDTMIG.

New body-system domains, intended for both morphology and physiology data, appearing in v3.4 include the following:

- Cardiovascular System Findings
- Musculoskeletal System Findings
- Nervous System Findings
- Ophthalmic Examinations
- Respiratory System Findings
- Urinary System Findings

These are grouped together in v3.4 with the Reproductive Findings domain that was published in v3.2. Preceding these domains in the IG is a new section called Generic Morphology/Physiology Specification that shows Required and Expected variables common to all morphology physiology domains. Although not stated in the text, it can be inferred that this would be a base for the creation of any custom (not yet modeled) body-system-based morphology/physiology domain.

Findings Domains with Expanded Scope

Two domains that were in v3.2 had their scope expanded in v3.4. The Disease Response (RS) domain was expanded to include data that would have been in submitted in the Clinical Classifications (CC) domain and was renamed Disease Response and Clin Classification. The CC domain that was part of the Batch 2 Public Review was not implemented.

The scope of the TU and TR domains has been broadened to include other types of lesions, rather than being limited to tumors. The domain names have been updated to include "Tumor/Lesion" to reflect the broadened usage. The documentation mentions the very broad definition of "lesion", which "can be almost any abnormal change involving any tissue or organ, usually due to disease or injury." Text and examples have been updated to include examples for Cardiovascular Lesions data and the representation of cysts for the Polycystic Kidney Disease.

Questionnaires, Rating, and Scales

For v3.4, it was decided by the SDS QRS Sub-team that data previously represented in the QS domain should be split into three domains to more adequately represent the data that was collected. Many instruments and assessments that had been categorized as questionnaires were not (since some had no questions). The categories of data included the following:

- QS – True questionnaire data (questions with responses)
- FT – Functional Tests (the subject is asked to perform a task and is evaluated
- RS – Response and Clinical Classifications (subject and objective assessments of a subject's status. More details on the last two categories are provided in the New Domains section of this document.

Changes in Representing Baseline Flags

In previous versions of the SDTMIG, the variable –BLFL was used for representing baseline values. Its use, however, had two major disadvantages: 1) it was sponsor defined, and 2) it was sometimes populated with baseline values from the ADaM datasets. The latter, of course, resulted in a violation of the fundamental traceability principle that all data in the ADaM datasets must be traceable back to the SDTM datasets.

To address these issues, the SDS and ADaM Teams proposed a new variable, --LOBXFL (Last Observation Before Exposure Flag). This proposal was actually developed prior to the publication of SDTMIG v3.2 but getting approval from all the necessary parties went slowly. Success was achieved in time for v3.4. The new variable is defined as the last non-missing value prior to RFXSTDTC. This solves the two problems associated with –BLFL described above.

--LOBXFL has a Core value of Expected in the domains that have baseline values. In domains where --BLFL was present and Expected in v3.2, its Core value has been changed to Permissible in v3.4. Section 4.5.9 was added to explain the use of the new variable, showing a comparison between --LOBXFL, --BLFL, and the ADaM variable ABLFL.

CHANGES IN THE EVENTS GENERAL OBSERVATION CLASS

Assumptions in the Disposition Domain

Some of the assumptions in v3.2 and previous version were too restrictive, and sponsors ended up not following them. An example was that EPOCH should not be populated when DSCAT = "PROTOCOL MILESTONE".

Following this prevented a sponsor from accurately representing multiple informed consents, which are Protocol Milestones. In 3.3, this restriction was removed. Version 3.3 expanded the assumptions to include the use of DSSCAT to distinguish between study treatment and study participation. Many sponsors had been including both types of events, and now there's a standard way to do so.

ADDITION OF SECTION 9, STUDY REFERENCES

A Study Reference section (Section 9) was added in v3.4. It includes the following datasets, the first two of which are also present in the SDTM v2.0.

- Device Identifiers (DI). This was previously published in the SDTMIG-MD as a Special-Purpose domain in v1.0 and as a Study Reference in v1.1.
- The Non-host Organism Identifiers (OI). This domain is essentially a lookup table, created to provides further taxonomic classification

data for the NHOID variable in the Findings general observation class. Since parameters of interest may vary by the type of organism (e.g., viruses, bacteria, fungi), sponsors can include as many as needed for clear identification.

- Pharmacogenomic/Genetic Biomarker Identifiers (PB). PB was first Introduced as part of the SDTMIG-PGx v1.0 as a Special-Purpose domain. It serves as a reference to associate observed genetic mutations with medical conclusions (e.g. disease diagnosis, drug resistance.

HIGHLIGHTS OF NEW DOMAINS

Almost all of the domains described below came about as the result of the development of Therapeutic-Area User Guides (TAUGs). Domains are arranged alphabetically by domain name (and not domain code).

Cardiovascular System Findings (CV)

This is a physiology Findings domain which was developed as part of the Therapeutic Area User Guide for Cardiovascular Disease (TAUG-CV). Cited examples of assessments submitted in this domain include coronary artery dominance, ischemic myocardium percentage, coronary artery dissection grade, and degree of stenosis. CV follows the traditional Findings data structure and contains no new variables. Considerable controlled terminology for cardiac endpoints has been developed by CDISC.

Functional Tests (FT)

As noted above, the functional-test data is under the QRS umbrella. This domain is intended for named tests that evaluate a subject's functional capacity. Included are tests for mobility, dexterity, and cognitive ability.

Characteristics of functional tests:

- They have documented methods for administration, analysis and require a subject to perform specific activities that are evaluated and recorded.
- They are an objective measurement of the performance of the task by the subject in a specific instance. Most often, they are quantitative measurements.
- As with questionnaires in QS, they may be documented in the public domain or be owned by a copyright holder. Examples of functional tests include the 25-Foot Walk Test, the 9-Hole Peg Test, and the Rey Auditory Verbal Learning Test (AVLT).

The modeling of the FT domain is consistent with that for questionnaires represented in the QS domain. Functional tests for which CDISC Controlled Terminology exists can be found at cdisc.org.

Meals (ML)

This domain debuted in the Diabetes TAUG. It is used for the submission of meal data. Because this is an Interventions domain, the focus is on the type and timing of ingested meals. Data about meal amounts and composition would need to be submitted in either TS (if the same for all subjects) or in a Findings About domain if unique to each subject.

Nervous System Findings (NV)

This domain was first introduced as part of the TAUG for Multiple Sclerosis. It is a physiology domain intended for the representation of results from active neurological processes. Some evaluations may occur as the results of a procedure. If the information about the procedure is important, it can be represented in the PR domain. One example of data that would be included in this domain is glucose metabolism by various regions of the brain, assessed by using radiotracers and PET scans. Another is the Visual Evoked Potential (VEP) which assesses a subject's response to a visual stimulus via an EEG. The modeling of this data does not differ from that of most Findings domains, and no new variables were needed.

Respiratory System Findings (RE)

The Respiratory Systems Findings domain was first created for the Asthma TAUG. It is used for data related to 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. Examples of data collected in this domain include forced expiratory volume in one second (FEV1) and forced vital capacity (FVC). This domain introduced the concept of a reference value, as opposed to a reference range defined by the pairs -- ORNRLO and --ORNRHI, and by --STNRLO and STNRHI. This is because FEV1 (forced expiratory volume in 1 second), FVC (forced vital capacity), and the FEV1/FVC ratio have reference values (not ranges) that are based upon age, race, sex, and height. Three reference value variables were created: --ORREF (Reference Result in Original Units), --STREFC (Reference Result in Standard Format), and --STREFN (Numeric Reference Result in Std. Units). These were added to SDTM v1.5, as noted previously.

Morphology Findings (MO)

Section 6.3.6 of SDTM-IG 3.4 includes an update on the decommissioning of the MO domain, including the history of the decision-making that led to the update. There is guidance for updating mapping of data that you may have been using the MO domain for the SDTM-IG defines body-system domains that should be used instead of the MO domain such as:

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

These domains were introduced in the previous version of the SDTM Implementation Guide: SDTM-IG 3.3. Although SDTM-IG 3.3 states, "For

data prepared using a version of the SDTMIG that includes both the MO domain and body system-based physiology/morphology domains, morphology findings may be represented in either the MO domain or in a body system-based physiology/morphology domain," we recommend simply moving to the appropriate body system domains now and leaving the MO domain behind.

CONCLUSIONS

The development of SDTM-based standards is occurring at a relatively rapid rate. This paper has presented a summary of the new domains, new concepts, and new variables that have been developed for SDTMIG v3.4 and the SDTM versions created since v1.4. Nine new general-observation class domains have been added since SDTMIG v3.2. Seventeen new variables have been added for use in SDTMIG domains. The Disease Milestones concept resulted in the creation of three new Timing variables and two new domains to more clearly represent event-driven observations of interest.

REFERENCES

- CDISC SDTM IG : https://www.cdisc.org/standards/foundational/sdtmig.
- CDISC SDTM IG v3.4. Available at: https://www.cdisc.org/system/files/members/standard/foundational/SDTMIG%20v3.4-FINAL_2022-0721.pdf

CONTACT INFORMATION

Your comments and questions are valued and encouraged. Contact the authors at:

Sumanth Goud Bheemagani
Merck & Co., Inc. USA
351 N Sumneytown Pike,
Upper Gwynedd, North Wales, PA 19454
Work Email: Sumanth.goud.bheemagani@merck.com

Bhanoji Duppada
Vita Clinical Solutions,
281 Winter St, suite# 100
Waltham, MA, 02451
Work Email: bduppada@softworldinc.com