CDISC Public Webinar – Standards Updates SDTM1.7/SDTMIG3.3

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Agenda

- Updates of SDTM in history version since SDTM1.4
- Updates of SDTMIG3.3 from SDTMIG3.2
- Key considerations of SDTM1.7/SDTMIG3.3
- Q&A

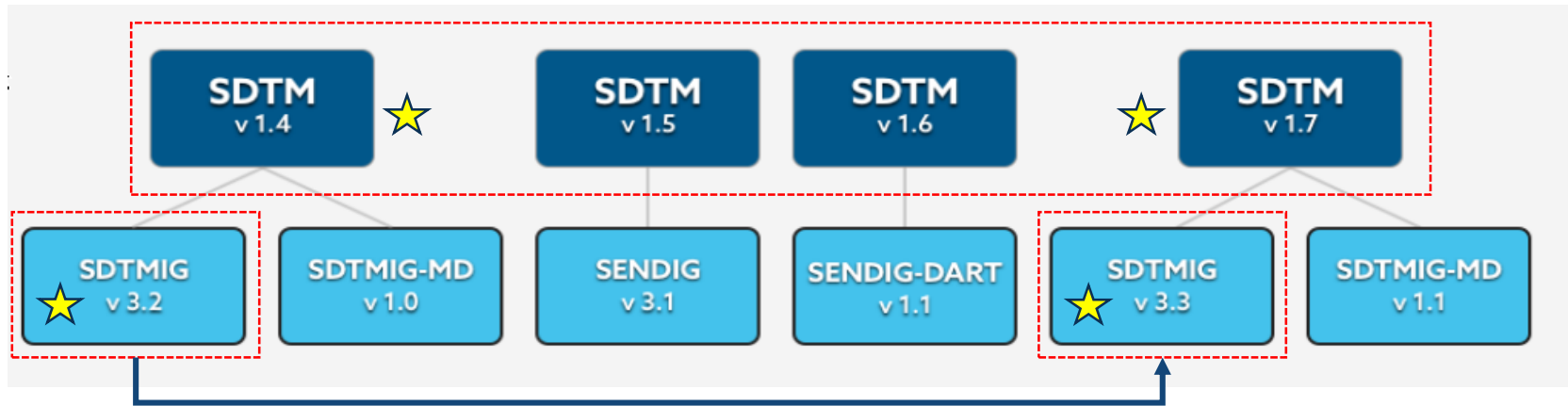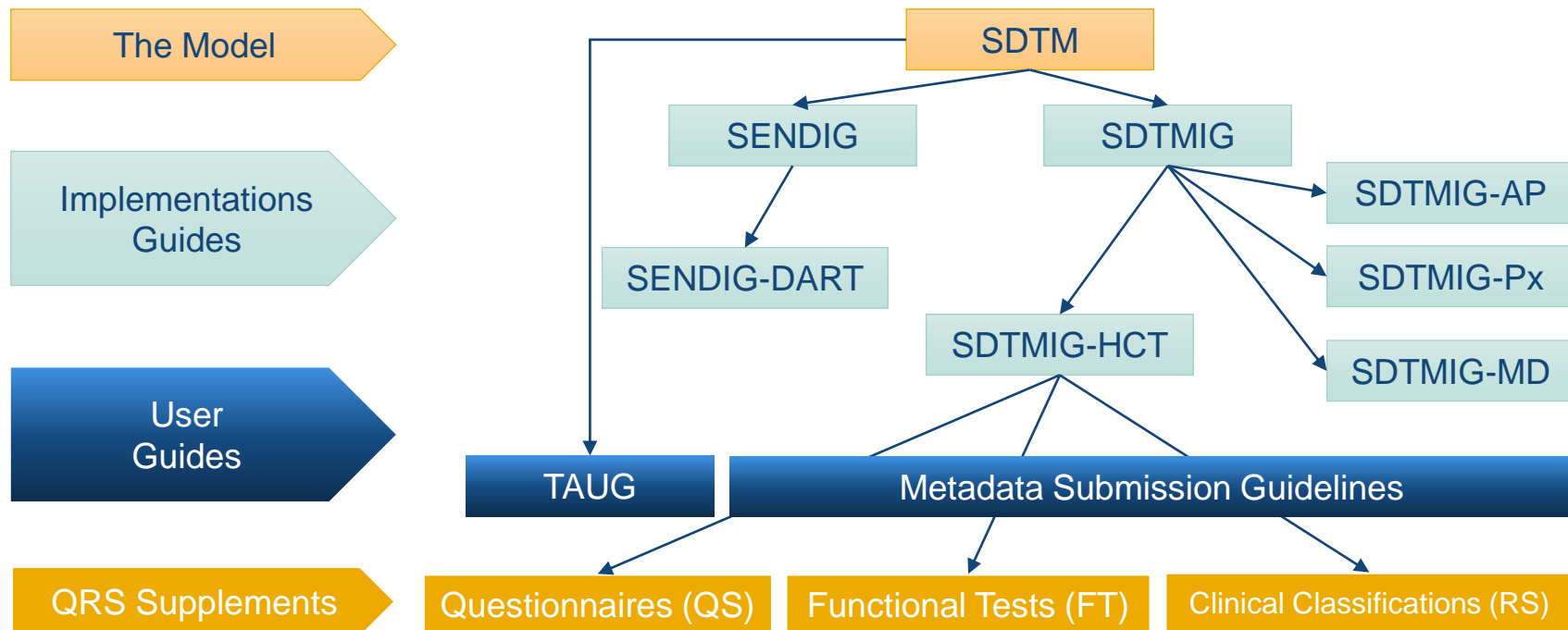# History Versions of SDTM/SDTMIG Standards

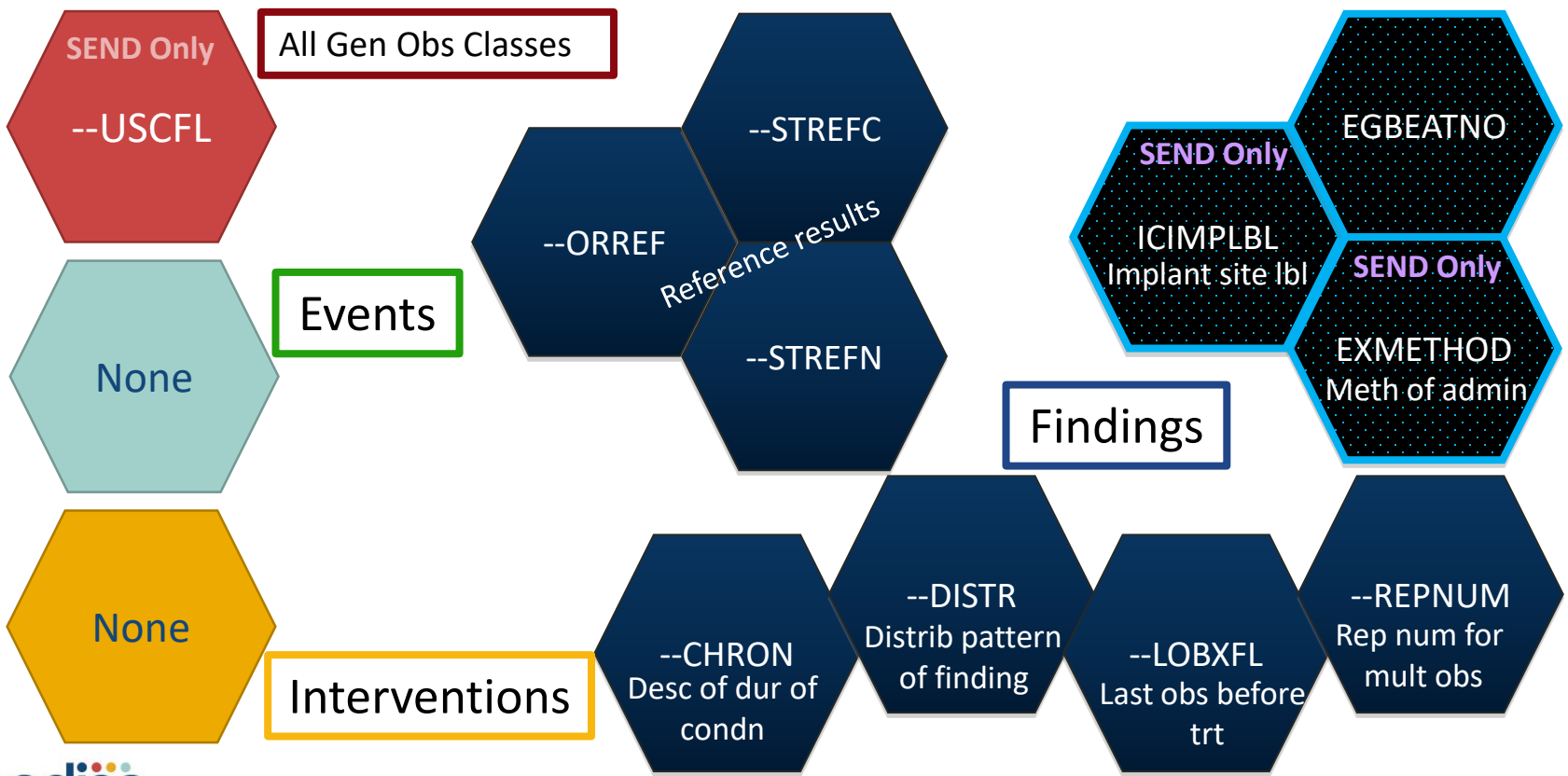# Relationships between SDTM, IGs and TAUGs

Major Updates between History Versions of SDTM
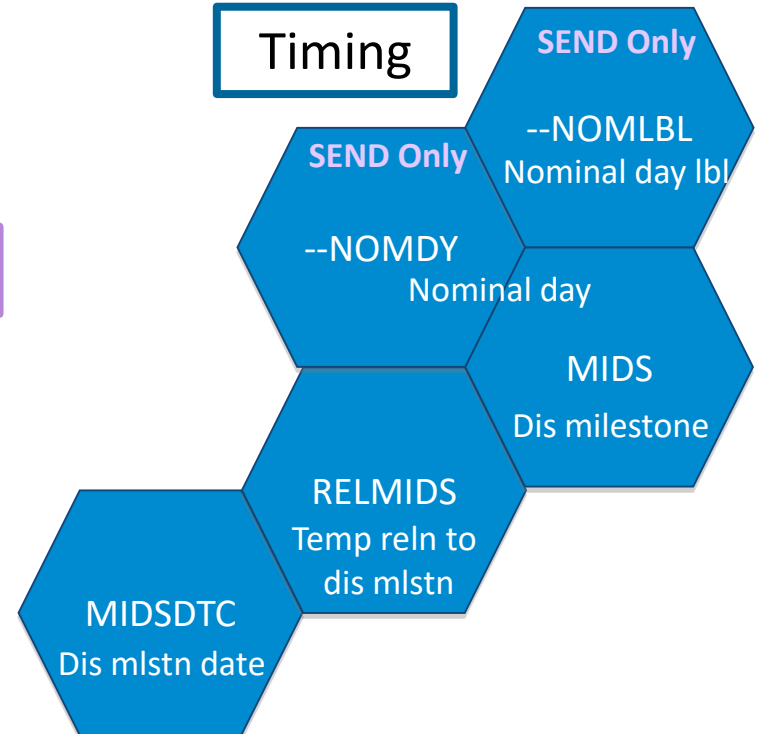
SDTM Version 1.5

- Introduces the concept of domain specific variables.

- Introduce new tables to relay data about disease milestones

- Contains a few newly added variables to address TAUG needs

- Contains newly added variables to support SEND that will not be used in human clinical trials.

- Only SENDIG v3.1 was specifically developed based on this version SDTM.

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New Variables in SDTM v1.5

Domain-Specific Variables

SEND Only
--USCFL

All Gen Obs Classes

Events

None

Interventions

None

--ORREF

--STREFC

Reference results

--STREFN

Findings

--CHRON
Desc of dur of condn

--DISTR
Distrib pattern of finding

--LOBXFL
Last obs before trt

--REPNUM
Rep num for mult obs

SEND Only

ICIMPLBL
Implant site lbl

EGBEATNO

SEND Only

EXMETHOD
Meth of admin

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New Variables in SDTM v1.5

APID
Assoc Pers

SEND Only

FETUSID

Identifiers

FOCID
Focus of Int

--RECID
Invariant rec ID

Timing

SEND Only

--NOMLBL
Nominal day lbl

SEND Only

--NOMDY
Nominal day

MIDS
Dis milestone

RELMIDS
Temp reln to dis mlstn

MIDSDTC
Dis mlstn date

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Major Updates between History Versions of SDTM

SDTM Version 1.6

- Start to use HTML webpage instead of PDF document.

- Supports the SENDIG-DART v1.1

- Includes additional variables related to developmental and reproductive toxicology (DART) animal studies.

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New Variables in SDTM v1.6
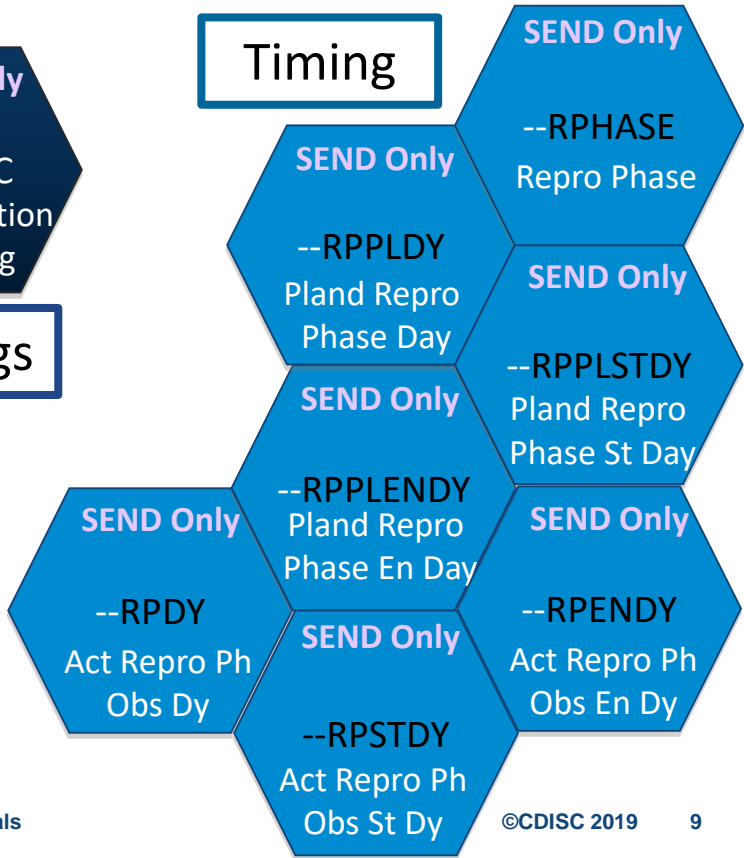
Demographics

SEND Only

--RPATHCD

SEND Only

--RESLOC
Result location
of finding

Findings

Timing

SEND Only

--RPHASE
Repro Phase

SEND Only

--RPPLDY
Pland Repro
Phase Day

SEND Only

--RPPLSTDY
Pland Repro
Phase St Day

SEND Only

--RPPLENDY
Pland Repro
Phase En Day

SEND Only

--RPDY
Act Repro Ph
Obs Dy

SEND Only

--RPSTDY
Act Repro Ph
Obs St Dy

SEND Only

--RPENDY
Act Repro Ph
Obs En Dy

None

Events

None

Interventions

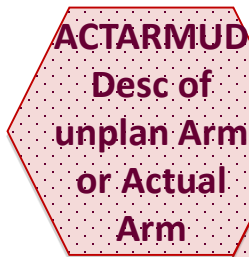# Major Updates between History Versions of SDTM

SDTM Version 1.7

- Added the Role column to the TDM Datasets and Relationship Datasets.
- Dataset additions:
  - Device-Subject Relationships Dataset
  - Device Identifiers Dataset
  - Non-Host Organism Identifiers Dataset
- Domain-specific variables additions

- Each implementation guide specifies the version of the SDTM that it is associated with.
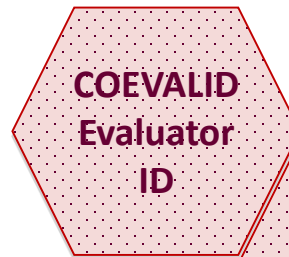
New Variables in SDTM v1.7

MHEVDTYP
MH Event Date Type

Events Domain-Specific Variables

ACTARMUD
Desc of unplan Arm or Actual Arm

ARMNRS
Reas Arm or Actual Arm is null

Demographics

COEVALID
Evaluator ID

CODY
Study day of comment

Comments

Interventions

--RSDISC
Reas for discount.

Findings Domain-Specific Variables

MSCONCU
Agent Concentr Unit

MSCONC
Agent Concentr

MSAGENT
Agent Name

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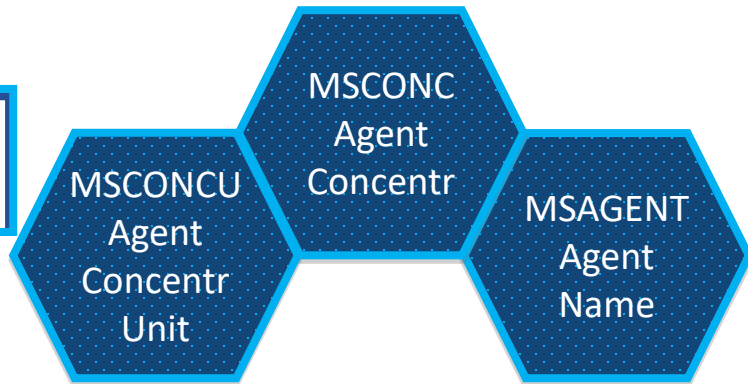
Domain-Specific Variables for the General Observation Classes

Table 2.2.12.1 Domain-Specific Variables for General Observation Class Domains

Observation Class	Domain	Variable Name	Variable Label	Type	Role	Description	Position
Events	MH	MHEVDTYP	Medical History Event Date Type	Char	Variable Qualifier of MHSTDTC and/or MHENDTC	Specifies the aspect of the medical condition or event by which MHSTDTC and/or the MHENDTC is defined. Examples: "DIAGNOSIS", "SYMPTOMS", "RELAPSE", "INFECTION".	After MHDECOD
Interventions	EX	EXMETHOD	Method of Administration	Char	Record Qualifier	Method of administration of the treatment. Not to be used with human clinical trials.	After EXLOC
Findings	EG	EGBEATNO	ECG Beat Number	Num	Variable Qualifier of EGORRES	A sequence number that identifies the beat within an ECG.	After EGPOS
Findings	IC	ICIMPLBL	Implantation Site Label	Char	Record Qualifier	Label or identifier that describes the location or position of a fetal implantation site in the uterus (or uterine horn) when classifying implantations during a uterine examination in a reproductive toxicology study. Not to be used with human clinical trials.	After ICSTRESC
Findings	MS	MSAGENT	Agent Name	Char	Record Qualifier	The name of the drug or other material for which resistance is tested. The agent may be used for in vitro testing or may be used in tests for genetic markers or in direct phenotypic drug-sensitivity testing.	After MSTEST
Findings	MS	MSCONC	Agent Concentration	Num	Variable Qualifier of MSAGENT	The amount of drug or other material listed in MSAGENT per unit volume or weight. Used when the agent is part of the pre-specified test. Not to be used when the concentration is a result of a test such as minimal inhibitory concentration, IC50, or EC50.	After MSAGENT
Findings	MS	MSCONCU	Agent Concentration Units	Char	Variable Qualifier of MSCONC	Unit of measure for MSCONC.	After MSCONC

Notable Changes between SDTM v1.4 and 1.7

NEW! Concept

Domain-Specific Variables

- Selected variables added to be used only in specific gen obs domains, e.g., MHEVDTYP

NEW! Content

Representing Relationships

- RELSUB: relating subjects to subjects (e.g., mother/infant)
- DR: relating subjects to devices

NEW! Content

Trial Design

- Subject Disease Milestones
- Trial Disease Milestones

NEW! Section

Study References

- Datasets that construct objects needed for a study
- Ex. device identifiers (SPDEVID), non-host organism identifiers (NHOID)

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Major Changes from Previous Version SDTMIG3.2

- Preparation of the SDTMIG in the CDISC wiki environment, with HTML format.
- New domains for existing models/sections
  - Special purpose domains: Subject Disease Milestones (SM)
  - Interventions domains: Meal Data (ML), Procedure Agents (AG)
  - Findings domains: Functional Tests (FT)
  - Trial design datasets: Trial Disease Milestones (TM)
- Newly added models/sections
  - Body system-based domains (Morphology/Physiology Domains):
    - Cardiovascular System Findings (CV)
    - Musculoskeletal System Findings (MK)
    - Nervous System Findings (NV)
    - Ophthalmic Examinations (OE)
    - Respiratory System Findings (RE)
    - Urinary System Findings (UR)
  - Study references:
    - Device Identifiers (DI)
    - Non-host Organism Identifiers (OI)

Domain Additions and *Changes* by Class: SDTM IG v3.3

Interventions	Events	Findings	Special Purpose	Trial Design	Study References
Procedure Agents (AG)	N/A	Morphology (MO)	Subject Disease Milestones (SM)	Subject Disease Milestones (TM)	Non-Host Organism ID (OI)
Meal Data (ML)		Cardiovascular (CV)			*Device Identifiers (DI) (moved)*
		Musculoskeletal (MK)			
		Nervous (NV)			
		Ophthalmic (OE)			
		Respiratory (RE)			
		Urinary (UR)			
		Functional Tests (FT)			

Respiratory System Findings (RE)

- A physiology findings domain, one of several domains used to represent tests/examinations that assess functioning of a particular body system

- Developed as part of the Asthma TA project

- Examples show pulmonary function tests

- Controlled terminology for test names has been approved; additional test names may be requested

- Introduces 3 new variables for a single reference value (REORREF, RESTREFN, RESTREFC), units themselves are in REORRESU and RESTRESU, as for the normal range variables

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Functional Tests (FT)

- A findings domain used to represent tests/examinations that are task-based evaluations that provide an assessment of the subject's mobility, dexterity, or cognitive ability

- They are not subjective assessments of how the subject generally performs a task. Rather they are an objective measurement of the performance of the task by the subject in a specific instance

- Examples include the 25-foot Walk Test and the 6 Minute Walk Test

- Developed as part of the Multiple Sclerosis TA project

- Introduces 1 new variable (Repetition Number --REPNUM)

Domain-Related Changes (V3.3)

RS/CC/QRS
- Expanded scope of RS domain to include clinical classifications as well as oncology disease response.
- RS moved from old Oncology grouping to Questionnaires, Ratings, and Scales grouping.

TU/TR
- Scope of TU and TR domains was expanded to include lesions in addition to tumors.

MB/NHOID
- Now handles tests for all types of microorganisms, not just bacteria.
- NHOID created to allow construction of meaningful identifiers.

Domain-Related Changes (V3.3)

DM
- Revised assumption to say that supplemental qualifiers for population flags should not be used.

DS
- Defined use of Disposition Events for both study participation disposition and study treatment disposition.
- Representing multiple informed consents in DS

PE
- Domain limited to data collected in a traditional physical examination of the body
- Included reference to CDASH advice on physical examination data.

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Additional Items (V3.3)

Baseline values
- New section, describing the new --LOBXFL variable and contrasting it with the old --BLFL variable and the ADaM variable ABLFL.

Conformance
- Variable labels removed from conformance

Epoch
- Describes period of time based on Arms/Elements in Trial Arms (TA) dataset
- Assigning from data on CRF is preferable to imputing
- If data not collected, if Epoch is not clear, should be left null
- For data prior to subject participation, Epoch should be null
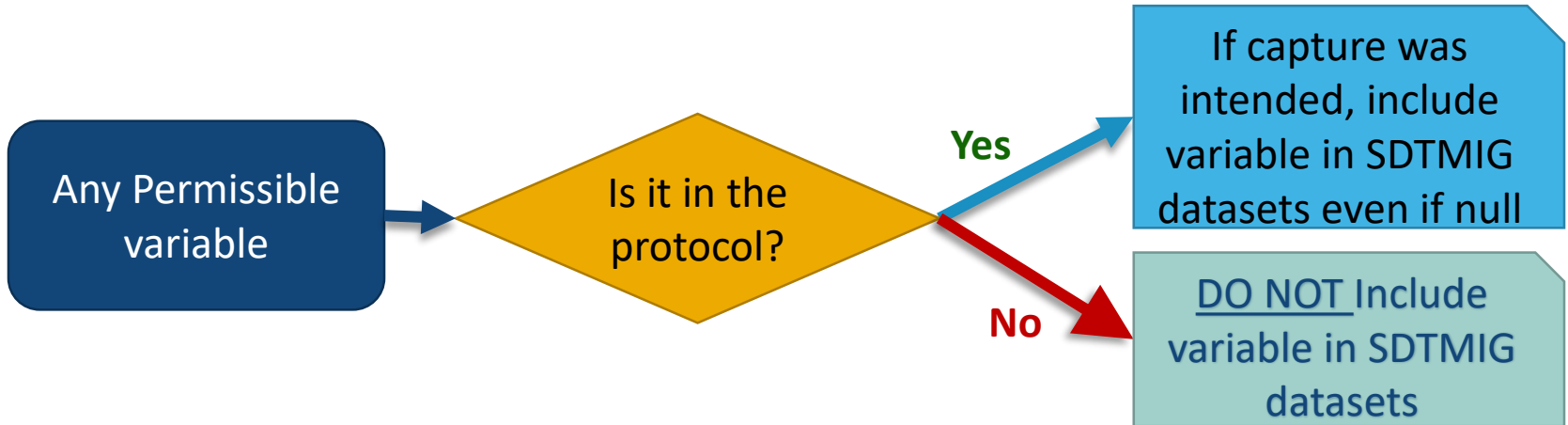
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New Functionality: Multiple CT Lists for One Variable

DS Domain (example)

DSDECOD	Standardized Disposition Term	Char	(NCOMPLT)	Synonym Qualifier	Controlled terminology for the name of disposition event or protocol milestone. Examples of protocol milestones: INFORMED CONSENT OBTAINED, RANDOMIZED	Req

DSDECOD	Standardized Disposition Term	Char	(NCOMPLT) (PROTMLST)	Synonym Qualifier	Controlled terminology for the name of disposition event or protocol milestone. Examples of protocol milestones: "INFORMED CONSENT OBTAINED", "RANDOMIZED". There are separate codelists used for DSDECOD where the choice depends on the value of DSCAT. Codelist "NCOMPLT" is used for disposition events and codelist "PROTMLST" is used for protocol milestones. The variable may be subject to controlled terminology for other events.	Req

Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value	CDISC Synonym(s)
C114118		Yes	Protocol Milestone	PROTMLST	Protocol Milestone
C132447	C114118		Protocol Milestone	ELIGIBILITY CRITERIA MET	
C16735	C114118		Protocol Milestone	INFORMED CONSENT OBTAINED	

Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value	CDISC Synonym(s)
C66727		Yes	Completion/Reason for Non-Completion	NCOMPLT	Completion/Reason for Non-Completion
C41331	C66727		Completion/Reason for Non-Completion	ADVERSE EVENT	
C25250	C66727		Completion/Reason for Non-Completion	COMPLETED	

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Permissible Variables (v3.3)

```
Any Permissible     ──►   Is it in the   ── Yes ──►   If capture was
variable                  protocol?                   intended, include
                                                      variable in SDTMIG
                                                      datasets even if null

                                   ── No ──►   DO NOT Include
                                               variable in SDTMIG
                                               datasets
```

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Planned and Actual Arm (v3.2)

Planned Arm: **<u>required</u>** for all subjects (ARM, ARMCD)

- No planned arm = NOT ASSIGNED
- Screen Failure = SCREEN FAILURE

Actual Arm: **<u>required</u>** for all subjects (ACTARM, ACTARMCD)

- Not treated = NOT TREATED

Planned and Actual Arm (v3.3)

Planned Arm: expected for all subjects (ARM, ARMCD)

Actual Arm: expected for all subjects (ACTARM, ACTARMCD)

Reason why Planned and/or Actual Arm is null (ARMNRS)

- Screen Failure
- Not Assigned

Unplanned Actual Arm: expected for all subjects (ACTARMUD)

SDTM Model to SDTMIG Correspondence

- The Global Governance Team made a decision that a version of the SDTM will be published with any new release of an SDTM-based implementation guide:
    - SDTMIG
    - SENDIG
    - SDTM-PGx
    - SDTM-AP
    - SDTMIG-MD
- This will ensure alignment of new domains and concepts in each IGs with the SDTM at the time of publication.
-

How do I Access the Latest Controlled Terminology?

- https://www.cdisc.org/standards/terminology

- https://www.cancer.gov/research/resources/terminology/cdisc

- https://evs.nci.nih.gov/ftp1/CDISC/

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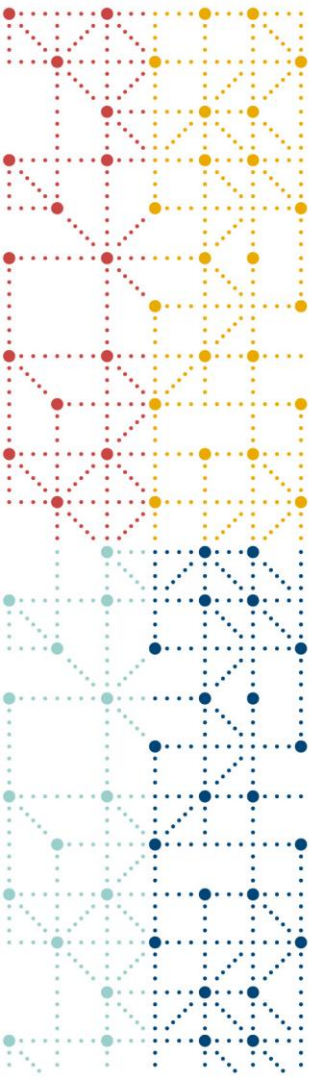
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