



## SDTM 1.5 DRAFT WHAT'S NEW?

15-Sep-2015, 21<sup>st</sup> German CDISC User Network Meeting  
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# WHEN & WHAT

- **Roadmap**

- SDTM 1.5 draft for public review released on 13-Jul-2015
- Public review comments were due on 24-Aug-2015
- Target date is Q3/2015

Source: 2015 CDISC Technical Plan dated 10-Jun-2015

- **New in SDTM 1.5**

- New domains (TM, SM)
- New variables
- Domain specific variables

👉 Only additions, nothing deprecated

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# NEW DOMAINS

- **TM: Trial Disease Milestones [Trial Design]**
  - Describes Disease Milestones for the trial
  - Disease Milestones are observations or activities  
...expected to occur in the course of the disease under study, and  
...timing is of interest for the study
  - Examples: Diagnosis; hypoglycemic events in diabetes
- **SM: Subject Disease Milestones [Special Purpose Domain]**
  - Used to record timing of Disease Milestones defined in TM for each subject
  - Milestones can be referenced in other domains to specify temporal relationships (see New Variables)

# NEW VARIABLES

- **Identifiers for all classes**

- APID Associated Persons Identifier

- FETUSID Fetus Identifier

- For prenatal evaluations*

- FOCID Focus of Study Specific Interest

- Focus of study-specific interest as called out in the protocol for which a measurement, test, or examination was performed*

- --RECID Invariant Record Identifier

- Unique identifier for a record that remains invariant even if content is modified*

- **Variable for all General Observation classes**

- --USCHFL Unscheduled Flag

- Indicates whether the timing of a performed test or observation was unscheduled (Y or null)*

- From Description of USCHFL*

- "Not to be used with human clinical trials." - ??*

- "This variable would not be needed when information on planned assessments is provided, such as when the Trial Visits (TV) and Subject Visits (SV) domains are used." - ??*

# NEW VARIABLES

- **Timing Variables for all classes**

- --NOMDY      Nominal Study Day for Tabulations

- --NOMLBL     Label for Nominal Study Day

- For grouping records for observations that may be scheduled to occur on different days into a single study day (e.g., output on a tabulation report). Not to be used with human clinical trials.*

- MIDS            Disease Milestone Instance Name

- RELMIDS       Temporal Relation to Milestone Instance

- MIDSDTC       Disease Milestone Instance Date/Time

- Instance of a Disease Milestone Type (MIDSTYPE); temporal relationship with the Disease Milestone; start date/time of the Disease Milestone.*

# NEW VARIABLES

- **Events Observation Class**

- --EVAL            Evaluator
- --EVALID        Evaluator Identifier

*Like QEVAL in SUPP--*

- --ACPTFL        Accepted Record Flag

*Flags records considered to be the accepted evaluation if more than one assessor evaluated.  
Not an analysis flag.*

- **Interventions Observation Class**

...No new class-specific variables

# NEW VARIABLES

## • Findings Observation Class

- --NSPCES      Non-Host Organism Species  
*Biological classification for a non-host organism*
- --ORREF      Reference Result in Original Units
- --STREFC      Reference Result in Standard Format
- --STREFN      Numeric Reference Result in Std Units  
*Reference value for the result or finding (e.g. value from predicted normal value in spirometry tests)*
- --IMPLBL      Implantation Site Label  
*For reproductive toxicology studies: location/position of a fetal implantation site in the uterus*
- --CHRON      Chronicity of Finding  
*Duration characterization of a bio. process resulting in finding (e.g. CHRONIC, ACUTE)*
- --DISTR      Distribution Pattern of Finding  
*e.g., FOCAL, MULTIFOCAL, DIFFUSE, FOCAL MULTIFOCAL*
- --LOBXFL      Last Observation Before Exposure Flag
- --REPNUM      Repetition Number

# NEW VARIABLES

- **Domain-Specific Variables**

- New concept in SDTM 1.5
- Variables that are for use only in a specific domain
  
- SDTMIG
  - ECG Test Results: EGBEATNO ECG Beat Number
  - Medical History: MHEVTYP      Medical History Event Type
  
- SDTMIG-PGx
  - Pharmacogenomics Biomarker: PBGENRI Genetic Region of Interest
  - Pharmacogenomics/Genetics Findings: PFGENTYP, PFNSTRN, PFGENLI, PFGENTRG, PFGENLOC, PFGENSR, PFRSNUM, PFALLELC, PFMUTYP
  - Pharmacogenomics/Genetics Methods and Supporting Information: PGGENRI, PGGENTYP, PGNSTRN



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*THANK YOU*