



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

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DISCLAIMERS

- The opinions in this presentation are those of the presenter and may not necessarily reflect the views of CDISC.
- All the examples displayed as 'Table no. x' are taken from SDTM_v3.4 and SDTM_v3.2

- **SDTMIG 3.4 Introduction**
- **SDTMIG Major updates**
 - Domain level updates
 - Variable level updates
- **Recommendations**
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WHAT'S NEW IN THE SDTMIG v3.4 AND THE SDTM v2.0

- In November 2021, the SDTMIG 3.4 and SDTM 2.0 were released.
- Since 2004, CDISC has provided an accepted standard for the submission of tabulation data in the form of SDTM and SDTMIG.
- A large amount of information, as well as new tables, including those for domains specific variables has been updated to the most recent version of SDTM.
- It includes a summary of new domains, concepts and variables.
- SDTM IG v3.4 includes the addition of new domains.

MAJOR UPDATES IN SDTM IG 3.4 – DOMAIN LEVEL UPDATES

- 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)

MAJOR UPDATES IN SDTM IG 3.4 – DOMAIN LEVEL UPDATES (Cont)

There are several updates in the SDTM IG Version 3.4, and this presentation has identified major categories of updates that we will be focusing on:

Section 9

Device Identifiers (DI)

Nonhost Organism Identifiers (OI)

Subject Disease Milestones (SM)

Trial Disease Milestones (TM)

Related Specimens
(RELSPEC)

Cardiovascular System Findings
(CV)

Procedure Agents (AG)

Biospecimen Findings (BS)

Musculoskeletal System Findings
(MK)

Urinary System Findings (UR)

Nervous System Findings (NV)

Functional Tests (FT)

Ophthalmic Examinations (OE)

Phenotype Findings (CP)

Respiratory System Findings (RE)

Biospecimen Event (BE)

Genomic Findings (GF)

Meal Data (ML)

New SDTM Domains

NEW INTERVENTION DOMAIN -ML

- Food-Effect Studies
- Alternatively, recording food taken may be useful for understanding the causes of hypoglycemic events for diabetic subjects.
- Inclusion in Interventions Domains
- The structure of this domain is one record per food product.
- ML should record fluid or food intake only in the ML.SDTM datasets.
- Information already recorded on the EC/EX, CM, SU or AG domains should not be repeated in ML.

The below example illustrates how the ML domain might be used in a food effect industry

Meal in Day 1

Category: BREAKFAST

Food and Fluid Intake Record

Is Breakfast given?

☒ Yes

☐ No

Start Date/Time: End Date/Time:

Percentage meal consumed: 0% 10 to 50% 100%

Figure 1: Example annotated meal record CRF page

NEW INTERVENTION DOMAIN – ML (Cont)

- The associated SDTM dataset is presented in (Table No. 4).
- Some early phase studies may also need to distinguish between LOW FAT and HIGH FAT meals.

Table No. 1

ROW	USUBJID	MLSEQ	MLTRT	MLPRESP	MLOCCUR	MLDOSTXT
1	001	1	BREAKFAST	Y	Y	1-50%
2	001	2	LUNCH	Y	Y	50-100%
3	001	3	DINNER	Y	Y	1-50%
ROW	VISITNUM	VISIT	MLSTDTC	MLENDTC	MLSTDY	MLENDY
1 (cont.)	30001	DAY 1	2019-05-01T08:20	2019-05-01T08:40	1	1
2 (cont.)	30001	DAY 1	2019-05-01T12:20	2019-05-01T12:45	1	1

MAJOR UPDATES IN SDTM IG 3.4 – VARIABLE LEVEL UPDATES

- New variables have been added into some existing domains (see Table No. 1).

Table No. 2

NEW VARIABLES	LABEL	DOMAIN
ARMNRS	Reason Arm and/or Actual Arm is Null	DM
ACTARMUD	Description of Unplanned Actual Arm	DM
SPDEVID	Sponsor Device Identifier	EG
EGBEATNO	ECG Beat Number	EG
EGREPNUM	Repetition Number	EG
CMADJ	Reason for Dose Adjustment	CM
CMRSDISC	Reason the Intervention Was Discontinued	CM
MHEVDTP	Medical History Event Date Type	MH
FOCID	Focus of Study-Specific Interest	MB
--LOBXFL	Last Observation Before Exposure Flag	All Findings domains

NEW VARIABLES	LABEL	DOMAIN
TAETORD	Planned Order of Element within Arm	All Findings and Events domains
SVPRESP	Prespecified	SV
SVOCCUR	Occurrence	SV
SVREASOC	Reason for Occur Value	SV
SVCNTMOD	Contact Mode	SV
SVEPCHGI	Epi/Pandemic Related Change Indicator	SV
--REASOC	Reason for Occur Value	SV
--CLSIG	Clinically Significant Collected	SV

VARIABLE LEVEL UPDATES- DM

Table No. 3

VARIABLE NAME	VARIABLE LABEL	TYPE	ROLE	CDISC NOTES	CORE
ARMNRS	Reason Arm and/or Actual Arm is Null	Char	Record Qualifier	▪ A coded reason that Arm variables (ARM and ARMCD) and/or actual Arm variables (ACTARM and ACTARMCD) are null. ▪ Examples: "SCREEN FAILURE", "NOT ASSIGNED", "ASSIGNED, NOT TREATED", "UNPLANNED TREATMENT". ▪ It is assumed that if the Arm and actual Arm variables are null, the same reason applies to both Arm and actual Arm.	Exp
ACTARM UD	Description of Unplanned Actual Arm	Char	Record Qualifier	A description of actual treatment for a subject who did not receive treatment described in one of the planned trial Arms.	Exp

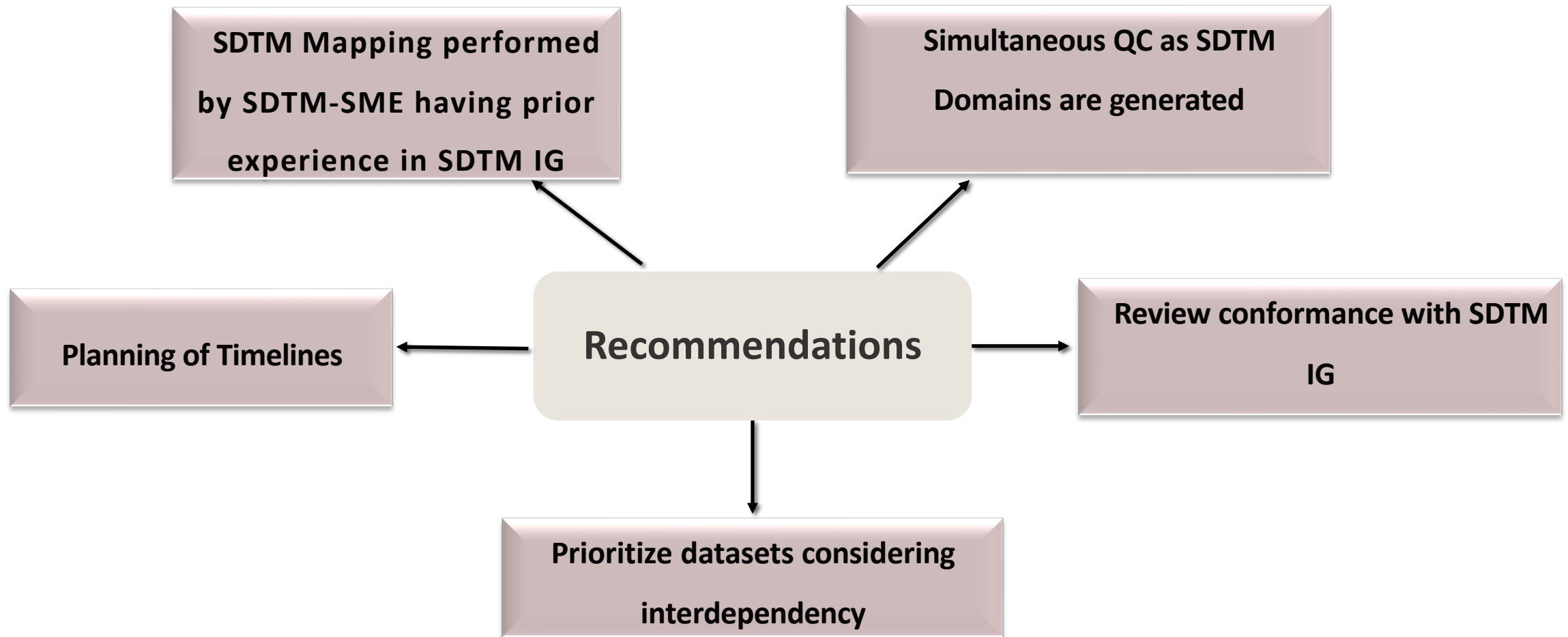
VARIABLE LEVEL UPDATES- EG

- The ECG Test Results (EG) domain is used to document all ECG findings.
- Sometimes the protocol specifies that the ECG will be measured multiple times for a subject at the same visit/time point, for example the ECG may be measured in triplicate.

Table No. 4

ROW	USUBJID	EGSEQ	EGTEST	EGORRES	EGORRESU	EGREPNUM	EGDTC
1	001	1	PR Interval, Aggregate	162	msec	1	2019-02- 26T07:06
2	001	2	PR Interval, Aggregate	165	msec	2	2019-02- 26T07:08
3	001	3	PR Interval, Aggregate	167	msec	3	2019-02- 26T07:10

RECOMMENDATIONS



REFERENCES

1. CDISC SDTM IG : <https://www.cdisc.org/standards/foundational/sdtmig>
2. SDTM IG v 3.4 Available at
https://www.cdisc.org/system/files/members/standard/foundational/SDTMIG%20v3.4-FINAL_2022-0721.pdf

QUESTIONS



THANK YOU