




**CDISC 2019 Europe Interchange**  
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# Handling Multiple Enrollments and Screenings Subjects in SDTM: Are We There Yet?

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## Agenda

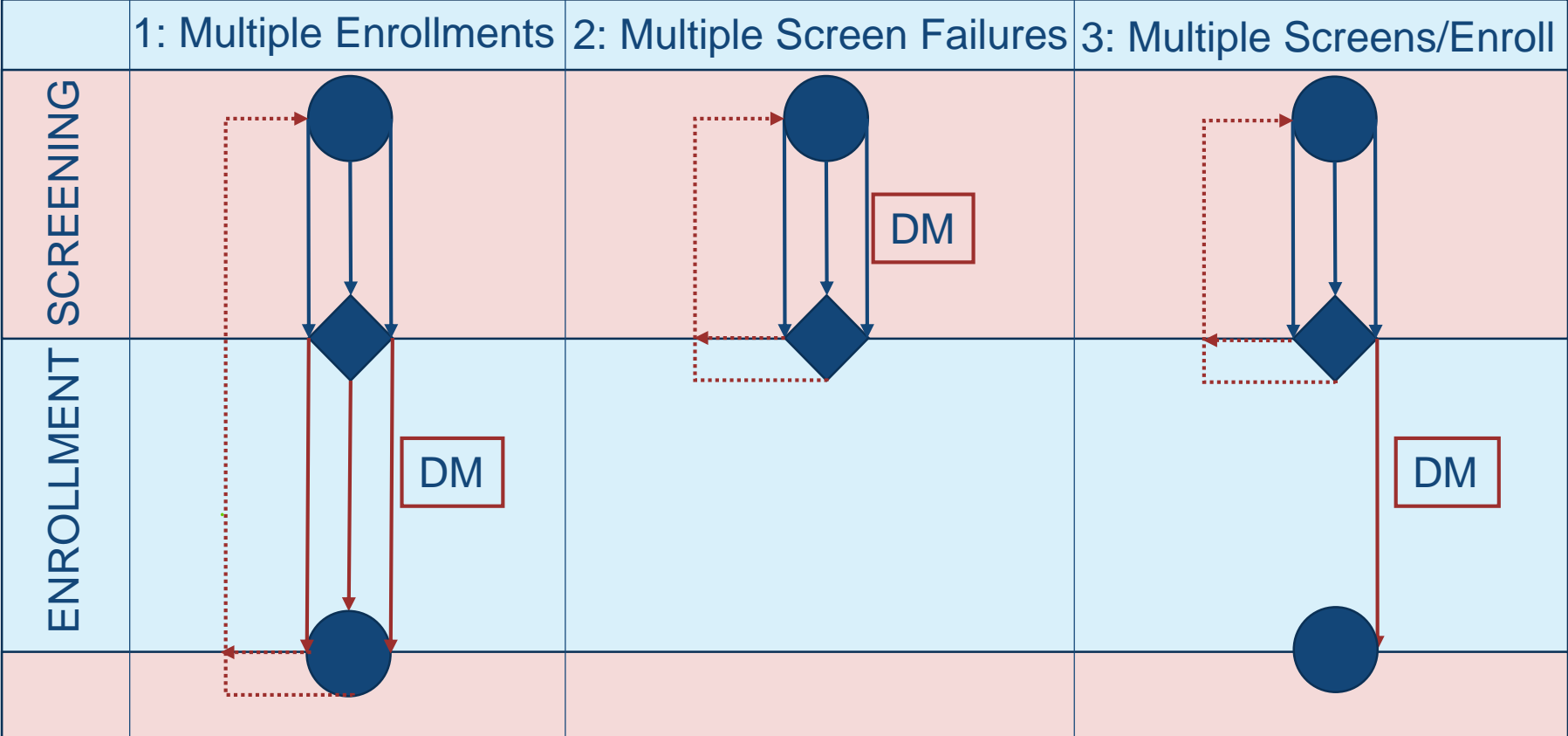
1. FDA Technical Conformance Guide 4.2
  1. Selecting Custom DM Domain Variables
  2. Custom DM Examples
  3. Implementation Considerations
2. SDS Multiple Subject Instances (MSI) Team
3. Open Questions



# FDA Position on Multiple Enrollments and Screenings

- In October 2018 the FDA Technical Conformance Guide (TCG) V4.2 section 4.1.1.3 SDTM Domain Specifications DM Domain (Demographics) added the text:
  - *For subjects with multiple enrollments within a single study, the primary enrollment should be submitted in DM. Additional enrollments should be included in a custom domain with a similar structure to DM. Clarifying statements in the RG would be helpful.*
  - *For subjects with multiple screenings and no subsequent enrollment, include the primary screening in DM with additional screenings in a custom domain with a structure similar to DM.*
  - *For subjects with multiple screenings and subsequent enrollment, include the enrollment in DM with screenings in a custom domain with a structure similar to DM.*
- No implementation examples were provided.

# Multiple Subject Enrollment and Screening Graphic





*“...a custom domain with a similar structure to DM”*

### **SDTMIG 3.3 section 2.6 Creating a New Domain**

*... a custom domain, which must be based on one of the three SDTM general observation classes*

- Creating a custom domain based on a Special Purpose domain is not in agreement with the SDTMIG

### **SDTMIG 3.3 section 2.6.1**

*Confirm that none of the existing published domains will fit the need.*

- The DM domain fits the need however only one record is allowed

### **SDTMIG 3.3 DM Assumption 2.**

*only one DM record should be submitted for the subject. The Supplemental Qualifiers dataset may be used if appropriate to provide additional information*

- FDA TCG 4.2 requests us not to use SUPPDM for this information

## 2.6.2 Check <https://wiki.cdisc.org/x/s4lv> for a proposed domain (checked 2019-04-25)

### ▼ List of Draft Domains

- › Cardiovascular System Findings (CV)
- › Disease Response and Clin Classification (RS)
- › ECG QT Correction Model Data (QT)
- › ECG Test Results (EG)
- › Environmental and Social Factors (ER)
- › Meal Data (ML)
- › Microbiology Domains - MB and MS
- › Musculoskeletal System Findings (MK)
- › Nervous System Findings (NV)
- › Ophthalmic Examinations (OE)
- › Non-host Organism Identifiers (OI)
- › Procedure Agents (AG)
- › Respiratory System Findings (RE)
- › Subject Disease Milestones (SM)
- › Trial Disease Milestones (TM)
- Tumor/Lesion Domains - TU and TR
- › Urinary System Findings (UR)
- › Gastrointestinal System Findings (GI)
- › Product Accountability (DA)

### ▼ SDTM Draft Domains Under Construction

- › Common Metadata for Physiology Morphology Domains
- › Site Summary (SI)
- › Subject Biomarkers (SB)
- › Whole-Body System (WB)
- › Trial Test Lookup
- › Ophthalmic Examinations (OE)
- › Pharmacogenomics/Genetics Findings (PF)
- › Biospecimen Events (BE)
- › Biospecimen Findings (BS)
- › PGx Biomarker and Subject Biomarker Domains - PB and SB
- › Pharmacogenomics/Genetics Methods and Supporting Information (PG)
- › Related Specimens (RELSPEC)
- › Trial Time Points (TT)





## 2.6.3 Selecting Custom DM Domain Variables

- 2.6.3.a Identifier Variables
  - STUDYID, DOMAIN, USUBJID, --SEQ
- 2.6.3.b Topic Variables
  - SUBJID
- 2.6.3.c Qualifier Variables
  - RFSTDTC, RFENDTC, RFXSTDTC, RFXENDTC, RFICDTC, RFPENDTC
  - DTHDTC, DTHFL
  - SITEID, INVID, INVNAM
  - BRTHDTC, AGE, AGEU
  - SEX, RACE, ETHNIC
  - ARMCD, ARM, ACTARMCD, ACTARM, ARMNRS, ACTARMUD
  - COUNTRY

## 2.6.3.c Qualifier Variables: Reference Period Variables

- The reference period variables will be needed for multiple enrollment subjects.
- For screening failure and rescreening subjects only the RFICDTC and RFPENDTC will be needed.

Variable Name	Variable Label	SDTMIG 3.3 DM	Custom DM Domain		
			1: Multiple Enrollments	2: Multiple Screening Failure	3: Multiple Screening Enrollment
RFSTDTC	Subject Reference Start Date/Time	Exp	Exp	Perm	Perm
RFENDTC	Subject Reference End Date/Time	Exp	Exp	Perm	Perm
RFXSTDTC	Date/Time of First Study Treatment	Exp	Exp	Perm	Perm
RFXENDTC	Date/Time of Last Study Treatment	Exp	Exp	Perm	Perm
RFICDTC	Date/Time of Informed Consent	Exp	Exp	Exp	Exp
RFPENDTC	Date/Time of End of Participation	Exp	Exp	Exp	Exp

## 2.6.3.c Qualifier Variables: Death, Site Identifiers

- Death information could be better centralized in the parent DM records and not duplicated in the custom DM domain

Variable Name	Variable Label	SDTM IG 3.3 DM	Custom DM
DTHDTC	Date/Time of Death	Exp	Perm
DTHFL	Subject Death Flag	Exp	Perm

- Site, investigator and country should be submitted if collected on the CRF or if there is a change. If not collected it could be not submitted.

Variable Name	Variable Label	SDTM IG 3.3 DM	Custom DM
SITEID	Study Site Identifier	Req	Perm
INVID	Investigator Identifier	Perm	Perm
INVNAM	Investigator Name	Perm	Perm
COUNTRY	Country	Req	Perm

## 2.6.3.c Qualifier Variables: Collected/Assigned/Derived

- **SDTMIG 3.3 section 3.2.2.7 Conformance**
- *Including all collected and relevant derived data in one of the standard domains, special-purpose datasets, or general-observation-class structures*

### FDA TCG 4.2 Section 4.1.4.1 General Considerations: SDTM/SEND/ADaM

*For the purposes of SDTM and SEND submissions, all Required, Expected, and Permissible variables that were collected, plus any variables that are used to compute derivations, should be submitted.*

ABC123	Subject: 01001	Site is explicitly collected on CRF	ABC123	Subject: 01001
Demographics			Demographics	Site: ____
Birth Year	----	Site assigned to the site staff through user account access	Birth Year	----
Age	--		Age	--
Sex	<input type="radio"/> Male <input type="radio"/> Female		Sex	<input type="radio"/> Male <input type="radio"/> Female

## 2.6.3.c Qualifier Variables: Date of Birth and Age

- If date of birth, age and age unit are collected they should be submitted.

Variable Name	Variable Label	SDTMIG 3.3 DM	Custom DM
BRTHDTC	Date/Time of Birth	Perm	Perm
AGE	Age	Exp	Perm
AGEU	Age Units	Exp	Perm

- Collecting the complete Date of Birth can be considered patient identifying and may have restrictions around it (e.g. collecting Birth Year only in European countries).
- Collecting multiple ages and collection dates (Custom DMDTC) could narrow down or reveal the date of birth.

USUBJID	BRTHDTC	AGE	AGEU	Custom DMDTC	Custom DMDY
01001	1982	36	Year	2019-04-21	-2
01001	1982	37	Year	2019-04-22	-1



## 2.6.3.c Qualifier Variables: Sex, Race and Ethnicity

- If SEX, RACE and ETHNIC are collected they should be submitted.
- If they are not collected I would recommend not duplicating them from the parent DM domain.

Variable Name	Variable Label	SDTMIG 3.3 DM	Custom DM
SEX	Sex	Req	Perm
RACE	Race	Exp	Perm
ETHNIC	Ethnicity	Perm	Perm

## 2.6.3.c Qualifier Variables: Arm Information

- For Custom DM Domain Type 1: Multiple Enrollments I would recommend submitting all arm related information.
- For Custom DM Domain's related to multiple screenings (failures) only the ARMNRS and ACTARMUD would be expected.

Variable Name	Variable Label	SDTMIG 3.3 DM	Custom DM Domain		
			1: Multiple Enrollments	2: Multiple Screening Failure	3: Multiple Screening /Enroll
ARMCD	Planned Arm Code	Exp	Exp	Perm	Perm
ARM	Description of Planned Arm	Exp	Exp	Perm	Perm
ACTARMCD	Actual Arm Code	Exp	Exp	Perm	Perm
ACTARM	Description of Actual Arm	Exp	Exp	Perm	Perm
ARMNRS	Reason Arm and/or Actual Arm is Null	Exp	Exp	Exp	Exp
ACTARMUD	Description of Unplanned Actual Arm	Exp	Exp	Perm	Perm

## 2.6.3.d Timing Variables

- If the sponsor does not use a unique SUBJID per subject screening instance Custom DM --DTC and --DY may be useful in separate different screening instances.

Variable Name	Variable Label	SDTM IG 3.3 DM	Custom DM
DMDTC	Date/Time of Collection	Perm	Perm
DMDY	Study Day of Collection	Perm	Perm

## 2.6.3.e Determine the Domain Code

- SDTMIG 3.3 section 4.1.6 Additional Guidance on Dataset Naming
  - *domain codes beginning with the letters X, Y, or Z have been reserved for the creation of custom domains.*
- There is an informal convention where the X-, Y-, or Z- domain abbreviations are used for the Interventions, Events and Findings respectively.
- There are no reserved letters for custom Special Purpose domains (or Trial Design/Relationship) since this was not planned in the IG.

Class	Domain Code
Interventions	X
Events	Y
Findings	Z

Datasets	Domain Code
Special Purpose	W?
Trial Design	V?
Relationship	U?

## 2.6.3.e Determine the Domain Code

- If the sponsor chooses to create a custom domain starting with W- then WD would make sense.
- The original Multiple Subject Instances (MSI) team proposed a draft domain name which was submitted to the FDA.
- I am not able to communicate the name without official CDISC approval.
- The current core MSI team is also discussing a new name of DC (Demographics as Collected).

Domain Code	Domain Name
WD	Custom Demographics Domain
XD, YD, or ZD	Custom Demographics Domain
DC	Demographics as Collected



# My Opinion on Custom DM Domain Variables

Variable Name	STUDYID	DOMAIN	USUBJID	DCSEQ	SUBJID	RFSTDTC	RFENDTC	RFXSTDTC	RFXENDTC	RFICDTC
<b>SDTMIG 3.3 DM</b>	Req	Req	Req		Req	Exp	Exp	Exp	Exp	Exp
<b>1: Multiple Enrollments</b>	Req	Req	Req	Req	Req	Exp	Exp	Exp	Exp	Exp
<b>2: Multiple Screening Failure</b>	Req	Req	Req	Req	Req	Perm	Perm	Perm	Perm	Exp
<b>3: Multiple Screening/Enroll</b>	Req	Req	Req	Req	Req	Perm	Perm	Perm	Perm	Exp

RFPENDTC	DTHDTC	DTHFL	SITEID	INVID	INVNAM	BRTHDTC	AGE	AGEU	SEX	RACE	ETHNIC	ARMCD	ARM
Exp	Exp	Exp	Req	Perm	Perm	Perm	Exp	Exp	Req	Exp	Perm	Exp	Exp
Exp	Perm	Perm	Perm	Perm	Perm	Perm	Perm	Perm	Perm	Perm	Perm	Exp	Exp
Exp	Perm	Perm	Perm	Perm	Perm	Perm	Perm	Perm	Perm	Perm	Perm	Perm	Perm
Exp	Perm	Perm	Perm	Perm	Perm	Perm	Perm	Perm	Perm	Perm	Perm	Perm	Perm

ACTARMCD	ACTARM	ARMNRS	ACTARMUD	COUNTRY	DCDTC	DCDY
Exp	Exp	Exp	Exp	Req	Perm	Perm
Exp	Exp	Exp	Exp	Perm	Perm	Perm
Perm	Perm	Exp	Perm	Perm	Perm	Perm
Perm	Perm	Exp	Perm	Perm	Perm	Perm

# 1: Multiple Enrollments

STUDYID	DOMAIN	USUBJID		SUBJID	RFSTDTC	RFENDTC	RFXSTDTC	RFXENDTC	RFICDTC	RFPENDTC
CB-1	DM	CB-1-01001		1001	2019-01-01	2019-01-15	2019-01-01	2019-01-15	2019-01-01	2019-01-22
STUDYID	DOMAIN	USUBJID	DCSEQ	SUBJID	RFSTDTC	RFENDTC	RFXSTDTC	RFXENDTC	RFICDTC	RFPENDTC
CB-1	DC	CB-1-01001	1	1007	2019-02-27	2019-03-13	2019-02-27	2019-03-13	2019-02-27	2019-03-20
CB-1	DC	CB-1-01001	2	1015	2019-04-25	2019-05-09	2019-04-25	2019-05-09	2019-04-25	2019-05-16

SITEID	INVTNAM	BRTHDTC	AGE	AGEU	SEX	RACE	ETHNIC	ARMCD	ARM	ACTARMCD	ACTARM
1	SCHMIDT	1982	36	YEARS	M	WHITE	NOT HISPANIC OR LATINO	A	Drug A	A	Drug A
SITEID	INVTNAM	BRTHDTC	AGE	AGEU	SEX	RACE	ETHNIC	ARMCD	ARM	ACTARMCD	ACTARM
1	SCHMIDT	1982	36	YEARS	M	WHITE	NOT HISPANIC OR LATINO	C	Drug C	C	Drug C
1	SCHMIDT	1982	37	YEARS	M	WHITE	NOT HISPANIC OR LATINO	E	Drug E	E	Drug E

ARMNRS	ACTARMUD	COUNTRY	DMDTC	DMDY
		DEU	2019-01-01	1
ARMNRS	ACTARMUD	COUNTRY	DCDTC	DCDY
		DEU	2019-02-27	58
		DEU	2019-04-25	115

## 2: Multiple Screening Failure

STUDYID	DOMAIN	USUBJID		SUBJID	RFSTDTC	RFENDTC	RFXSTDTC	RFXENDTC	RFICDTC	RFPENDTC
CB-1	DM	CB-1-01001		1001					2019-01-01	2019-01-01
STUDYID	DOMAIN	USUBJID	DCSEQ	SUBJID	RFSTDTC	RFENDTC	RFXSTDTC	RFXENDTC	RFICDTC	RFPENDTC
CB-1	DC	CB-1-01001	1	1007					2019-01-02	2019-01-02
CB-1	DC	CB-1-01001	2	1015					2019-01-03	2019-01-03

SITEID	INVTNAM	BRTHDTC	AGE	AGEU	SEX	RACE	ETHNIC	ARMCD	ARM	ACTARMCD	ACTARM
1	SCHMIDT	1982	36	YEARS	M	WHITE	NOT HISPANIC OR LATINO				
SITEID	INVTNAM	BRTHDTC	AGE	AGEU	SEX	RACE	ETHNIC	ARMCD	ARM	ACTARMCD	ACTARM
1	SCHMIDT	1982	36	YEARS	M	WHITE	NOT HISPANIC OR LATINO				
1	SCHMIDT	1982	36	YEARS	M	WHITE	NOT HISPANIC OR LATINO				

ARMNRS	ACTARMUD	COUNTRY	DMDTC	DMDY
SCREEN FAILURE		DEU	2019-01-01	
ARMNRS	ACTARMUD	COUNTRY	DCDTC	DCDY
SCREEN FAILURE		DEU	2019-01-02	
SCREEN FAILURE		DEU	2019-01-03	

### 3: Multiple Screening and Subsequent Enrollment

STUDYID	DOMAIN	USUBJID		SUBJID	RFSTDTC	RFENDTC	RFXSTDTC	RFXENDTC	RFICDTC	RFPENDTC
CB-1	DM	CB-1-01015		1015	2019-01-03	2019-01-17	2019-01-03	2019-01-17	2019-01-03	2019-01-24
STUDYID	DOMAIN	USUBJID	DCSEQ	SUBJID	RFSTDTC	RFENDTC	RFXSTDTC	RFXENDTC	RFICDTC	RFPENDTC
CB-1	DC	CB-1-01015	1	1001					2019-01-01	2019-01-01
CB-1	DC	CB-1-01015	2	1007					2019-01-02	2019-01-02

SITEID	INVNAM	BIRTHDTC	AGE	AGEU	SEX	RACE	ETHNIC	ARMCD	ARM	ACTARMCD	ACTARM
1	SCHMIDT	1982	36	YEARS	M	WHITE	NOT HISPANIC OR LATINO	E	Drug E	E	Drug E
SITEID	INVNAM	BIRTHDTC	AGE	AGEU	SEX	RACE	ETHNIC	ARMCD	ARM	ACTARMCD	ACTARM
1	SCHMIDT	1982	36	YEARS	M	WHITE	NOT HISPANIC OR LATINO				
1	SCHMIDT	1982	36	YEARS	M	WHITE	NOT HISPANIC OR LATINO				

ARMNRS	ACTARMUD	COUNTRY	DMDTC	DMDY
		DEU	2019-01-03	1
ARMNRS	ACTARMUD	COUNTRY	DCDTC	DCDY
SCREEN FAILURE		DEU	2019-01-01	-2
SCREEN FAILURE		DEU	2019-01-02	-1

USUBJID	DSTERM	DSSTDTC	DSDY
CB-1-01015	INFORMED CONSENT OBTAINED	2019-01-01	-2
CB-1-01015	INFORMED CONSENT OBTAINED	2019-01-02	-1
CB-1-01015	INFORMED CONSENT OBTAINED	2019-01-03	1

**SDTMIG 3.3 DM Assumption 10.c** In the event that there are multiple informed consents, this [DM.RFICDTC] will be the date of the first one.

### 3: Multiple Screening and Subsequent Enrollment

STUDYID	DOMAIN	USUBJID		SUBJID	RFSTDTC	RFENDTC	RFXSTDTC	RFXENDTC	RFICDTC	RFPENDTC
CB-1	DM	CB-1-01015		1015	2019-01-03	2019-01-17	2019-01-03	2019-01-17	2019-01-01	2019-01-24
STUDYID	DOMAIN	USUBJID	DCSEQ	SUBJID	RFSTDTC	RFENDTC	RFXSTDTC	RFXENDTC	RFICDTC	RFPENDTC
CB-1	DC	CB-1-01015	1	1001					2019-01-01	2019-01-01
CB-1	DC	CB-1-01015	2	1007					2019-01-02	2019-01-02

SITEID	INVNAM	BIRTHDTC	AGE	AGEU	SEX	RACE	ETHNIC	ARMCD	ARM	ACTARMCD	ACTARM
1	SCHMIDT	1982	36	YEARS	M	WHITE	NOT HISPANIC OR LATINO	E	Drug E	E	Drug E
SITEID	INVNAM	BIRTHDTC	AGE	AGEU	SEX	RACE	ETHNIC	ARMCD	ARM	ACTARMCD	ACTARM
1	SCHMIDT	1982	36	YEARS	M	WHITE	NOT HISPANIC OR LATINO				
1	SCHMIDT	1982	36	YEARS	M	WHITE	NOT HISPANIC OR LATINO				

ARMNRS	ACTARMUD	COUNTRY	DMDTC	DMDY
		DEU	2019-01-03	1
ARMNRS	ACTARMUD	COUNTRY	DCDTC	DCDY
SCREEN FAILURE		DEU	2019-01-01	-2
SCREEN FAILURE		DEU	2019-01-02	-1

USUBJID	DSTERM	DSSTDTC	DSDY
CB-1-01015	INFORMED CONSENT OBTAINED	2019-01-01	-2
CB-1-01015	INFORMED CONSENT OBTAINED	2019-01-02	-1
CB-1-01015	INFORMED CONSENT OBTAINED	2019-01-03	1

**SDTMIG 3.3 DM Assumption 10.c** In the event that there are multiple informed consents, this [DM.RFICDTC] will be the date of the first one.



# EC/EX and DM/DC

- Is the DM a summary domain or a subject instance domain?
- From my understanding of the FDA TCG the DM domain is a subject instance.
- The original MSI team had DM as a summary record similar to EC/EX.
  - All MSI recorded in DC, then primary selected
  - If no MSI DC is not required
  - DM provides a summary (conventions needed)
    - How to manage summary DM SUBJID ~MULTIPLE?

# Linking MSI to GOC Domains

- If a VS assessment is carried out on an MSI it can be differentiated by the VSDY variables e.g.

STUDYID	DOMAIN	USUBJID	VSTESTCD	VSTEST	VSORRES	VSORRESU	VSDTC	VSDY
CB-1	VS	CB-1-01015	HEIGHT	Height	175	cm	2019-01-02	-1
CB-1	VS	CB-1-01015	HEIGHT	Height	175	cm	2019-01-03	1

- If VSDTC is incomplete the VSDY will be missing more explicit linking could be done with a supplement variable or by using a --LNKID variable.

STUDYID	DOMAIN	USUBJID	VSLNKID	VSTESTCD	VSTEST	VSORRES	VSORRESU	VSDTC	VSDY
CB-1	VS	CB-1-01015	1001	HEIGHT	Height	175	cm	2019-01	
CB-1	VS	CB-1-01015	1007	HEIGHT	Height	175	cm	2019-01-02	-1

- Possible issues in oncology domains if --LNKID/--LNKGRP is in use already.
- The SDS MSI team is evaluating updating SDTM to allow SUBJID and possibly DCSEQ as an **Identifiers for All Classes**. This is to be determined.

# Unique SUBJID?

- FDA TCG 4.2 section 4.1.1.2 SDTM General Considerations

*Subject Identifier (SUBJID) The SUBJID is an ID of the entity (i.e., person) that participates in a trial. If the same subject is screened more than once in a trial, then the subject's SUBJID should be different.*

- Some companies do not assign a subject a new SUBJID if they are a rescreening subject.

# CDASH and MSI

- Collect the SUBJID and demographics data on the primary screening
- For rescreening only collect a new SUBJID and DMDTC
- If this could be collected in the same subject eCRF it would reduce mapping between subjects in EDC systems.

<b>STUDYID</b>	ABC123	<b>SUBJID</b>	Subject: 01001
<b>DOMAIN</b>	Demographics		
<b>DSNEXT</b>	Will the subject rescreen?	<input type="radio"/> Yes	<input type="radio"/> No
<b>SUBJID</b>	What is the subject identifier? _____		
<b>DMDAT/DCDAT</b>	Collection Date	__ / __ / __	__ / __ / __

# Primary vs First?

adjective

1. of chief importance; principal.

"the government's primary aim is to see significant reductions in unemployment"

*synonyms:* main, chief, key, prime, central, principal, foremost, first, most important, predominant, paramount, overriding, major, ruling, dominant, master, supreme, cardinal, pre-eminent, ultimate; *informal* number-one

"the police believe that crime detection is their primary role"

2. earliest in time or order.

"the primary stage of their political education"

*synonyms:* original, earliest, initial, beginning, first; More

## CDISC ADaM Implementation Guide Version 1.1

Population flags are required by ADaM. Table 3.2.3 describes ADaM population flags, though the list is not meant to be all-inclusive. See Section [3.5](#) for details on the differences between SDTM- and ADaM-defined population flags.

**Table 3.2.3 ADSL Population Indicator Variables**

Variable Name	Variable Label	Type	Codelist/ Controlled Terms	Core	CDISC Notes
FASFL	Full Analysis Set Population Flag	Char	Y, N	Cond	These flags identify whether or not the subject is included in the specified population. A minimum of one subject-level population flag variable is required in ADSL. Not all of the indicators listed here need to be included in ADSL. As stated in Section <a href="#">3.1.4</a> , Item 2, only those indicators corresponding to populations defined in the statistical analysis plan or populations used as a basis for analysis need be included in ADSL. This list of flags is not meant to be all-inclusive. Additional population flags may be added. The values of subject-level population flags cannot be blank. If a flag is used, the corresponding numeric version (*FN, where 0=no and 1=yes) of the population flag can also be included. Please also refer to Section <a href="#">3.1.4</a> .
SAFFL	Safety Population Flag	Char	Y, N	Cond	
ITTFLL	Intent-To-Treat Population Flag	Char	Y, N	Cond	
PPROTFL	Per-Protocol Population Flag	Char	Y, N	Cond	
COMPLFL	Completers Population Flag	Char	Y, N	Cond	
RANDFL	Randomized Population Flag	Char	Y, N	Cond	
ENRFL	Enrolled Population Flag	Char	Y, N	Cond	



# Submission Data Standards (SDS) Multiple Subject Instances (MSI) Team

- The SDS Multiple Subject Instances (MSI) team prepared 3 options for representing multiple enrollment and screening subjects for FDA review and input.
- 1 of the 3 options was the basis of the FDA TCG 4.2 text, with some modification
- The MSI team is working on integrating the that proposal into SDTM.
- A draft domain proposal will be made public when in a pre-final state.
- It is planned to have it in SDTM IG 3.4 or 3.5 depending on comments.
- The MSI team plans to provide further updates at the CDISC US Interchange

# MSI Team Members

- Weekly meeting to define the domain.
- Expand the core team to include more beginning-to-end CDISC volunteers for further feedback once a complete initial review is provided.

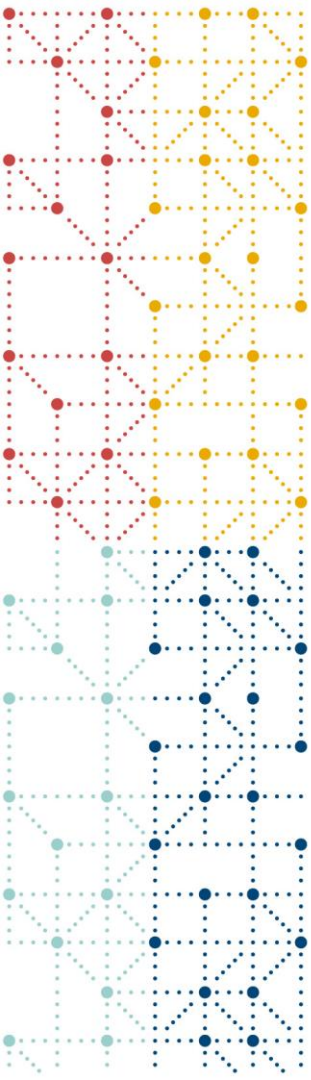
Current Core Team			
Name	Affiliation	Position	Email
Tom Guinter	Independent	Team Lead	guinter@ptd.net
Janet Reich	Amgen	SDS Lead	jroich@amgen.com
Carlo Radovsky	etera solutions		carlo.radovsky@eterasolutions.com
Éanna Kiely	ClinBuild		eanna.kiely@clinbuild.com

# Open Questions

- Does this also apply to PMDA submissions or do they require the sponsor to submit data still in accordance with the SDTMIG
- Subjects changing sites? DC domain or SUPPDM?
- Conventions for derived variables and datasets (eg, EPOCH, DY, SE, SV) for multiple enrollments and screenings.

STUDYID	DOMAIN	USUBJID	VSLNKID	VSTESTCD	VSTEST	VSORRES	VSORRESU	EPOCH	VSDTC	VSDY
CB-1	VS	CB-1-01015	1001	HEIGHT	Height	175	cm	SCREENING 1	2019-01-01	-2
CB-1	VS	CB-1-01015	1007	HEIGHT	Height	175	cm	SCREENING 2	2019-01-02	-1
CB-1	VS	CB-1-01015	1015	HEIGHT	Height	175	cm	SCREENING 3	2019-01-03	1





# Thank You!

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**cdisc**