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SDTMIG v4.0: Are You Ready For It?

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Kristin Kelly is a Senior Principal CDISC Consultant at Pinnacle 21 by Certara. Kristin has nearly 20 years of experience working in the pharmaceutical industry primarily focused on clinical data standards. She spends her days supporting customers implementing Pinnacle 21's MDR and Foundational offerings. Kristin is involved with the CDISC SDS team as the former Team Lead, various sub-teams within SDS, Global Governance Group (GGG), the SDTM Team, the SEND Core Team as well as several Phuse Working Groups. Kristin has also contributed to several FDA projects for both clinical and nonclinical. She is a regular presenter at conferences including the CDISC Interchange, PharmaSUG and PhUSE.

Background

SDTMIG v4.0

- Considered to be a major release due to changing structures and content
 - MSI, SUPP to NSV, metadata restructuring
- Scoping began in 2020

SDTM v3.0

- Also supports the upcoming SENDIG v4.0
- Addition of Variable Groups and Variable Relationships

Conformance Rules v3.0



What's New in SDTM v3.0?

- New Domains
- New Variables
- Variable Definitions, Groups, and Relationships

New Domains

Class	Domain	Domain Label	Definition	Notes
Special-purpose	DC	Demographics for Multiple Participations	Domain similar to Demographics (DM) to capture data for each participation in studies that allow subjects to re-screen or re-enroll in the same study.	Can contain more than one record per subject.
Study Reference	RELDEV	Related Devices Dataset	RELDEV is a relationship table that allows devices and their components to be related to each.	Supports upcoming SDTMIG-MD v2.0
Relationship	NS--	Non-standard Variables Dataset	Non-standard variables in a horizontal format.	Replaces SUPPQUAL

New Variables

Class	Variable Name	Variable Label	Root Variable Definition	Usage Restrictions
Interventions	--TRTCD	Standardized Intervention Code	A standardized or dictionary-derived short sequence of characters used to represent the intervention.	
Events	--CLASI	Classification of Protocol Deviation	A classification of protocol deviations based on the potential impact to the completeness, accuracy, and/or reliability of the study data, or to a subject's rights, safety, or well-being. (ICH E3 Q&As (R1))	DV domain only
Findings	--RSCNT	Result Count	The number of occurrences of a result.	EG domain only
Findings	--CBRFL	Conditionally Branched Item Flag	An indication that this instance of an item within a QRS instrument was conditionally branched. An item is conditionally branched when the instrument does not solicit a response from the respondent based on a given condition, although for certain instruments, the instrument may provide a result for the item. Allowed value: Y	QS, FT, RS (clinical classification use case) only
Special-purpose	AGERLO	Age Range Lower Limit	A numeric representation of the lowest possible value for the age of the subject at a specific point in time defined for the trial. Replaces AGETXT.	DM and DC only
Special-purpose	AGERHI	Age Range Upper Limit	A numeric representation of the highest possible value for the age of the subject at a specific point in time defined for the trial. Replaces AGETXT.	DM and DC only
Special-purpose	CRACE	Collected Race	A classification of race as specified by the sponsor in the data collection field.	DM and DC only
Special-purpose	CETHNIC	Collected Ethnicity	A classification of ethnicity as specified by the sponsor in the data collection field.	DM and DC only
Relationship	IDVARVLN	Identifying Variable Numeric Value	The numeric value of the variable named in IDVAR used to identify related records.	

Variable Definitions, Groups, and Relationships

- All variables now have a 'Root Variable Definition'
 - Consistent definitions across SDTM v3.0 and SDTMIG v4.0
- 'Variable Groups' defined to group variables based on their purpose

Variable Group	Variable Name	Variable Group Definition
Result Value	--ORRES	A group of variables used to represent the result value.
	--STRESC	
	--STRESN	

- 'Variable Groups' column added to all specification tables in the SDTM and SDTMIG

Variable Definitions, Groups, and Relationships

- Variable Relationships tables introduced and included after specification tables in the SDTM and SDTMIG

Subject Root Variable	Subject Root Variable Label	Linking Phrase	Predicate Term	Object Root Variable	Object Root Variable Label
--TEST	Name of Measurement, Test or Exam	decodes the value in	DECODES	--TESTCD	Short Name of Measurement, Test, or Exam
--TESTCD	Short Name of Measurement, Test, or Exam	is the code for the value in	IS_DECODED_BY	--TEST	Name of Measurement, Test or Exam

- A row in the table can be read by concatenating the subject variable, the linking phrase and the object variable



What's New in SDTMIG v4.0?

- Reorganization/Re-write of Sections 1 – 4
- Metadata Restructuring
- --BLFL Removal
- Protocol Deviations (DV) Updates
- Event Adjudication (EA)
- Gastrointestinal Findings (GI)
- Multiple Subject Instances
- SUPPQUAL (SUPP--) to NSV (NS--)

Reorganization/Re-write of Sections 1 – 4

- These sections contain assumptions that apply to all domains
- Sections 1 – 4 were reorganized and updated for further clarity
- These sections were largely untouched in previous versions
- Many conformance rules are based on content
- Much of the general content also in domain sections has been removed and moved to these sections to avoid duplication

- 1 Introduction
- ▼ 2 Fundamentals of the SDTM
 - 2.1 Datasets and Domains
 - 2.2 Root Variables in SDTMIG
 - 2.3 Representation of Variable Relationships
 - 2.4 Subject-level Datasets
 - 2.5 Trial-level Datasets
 - 2.6 How to Determine Where Data Belong in SDTM-Compliant Data Tabulation
- ▼ 3 Conformance
 - 3.1 Conformance Scope and References
 - 3.2 Data to be Included in SDTM Datasets for Human Clinical Trials
 - 3.3 SDTM Variables Developed for Nonclinical Trials
 - 3.4 Conformance Rules Catalog
- ▼ 4 Assumptions for Domain Models
 - 4.1 Preparing Datasets and Dataset Metadata
 - 4.2 Variable Metadata
 - 4.3 Populating Variables
 - 4.4 Assumptions for Identifiers
 - 4.5 Actual and Relative Time Assumptions
 - 4.6 Qualifier Variables Included in Multiple General Observation Classes
 - 4.7 Assumptions for Events and Interventions
 - 4.8 Assumptions for Findings
 - 4.9 Coding and Controlled Terminology Assumptions

Metadata Restructuring

- SDTMIG v3.4

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format ¹	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	MH	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
MHSEQ	Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
MHGRPID	Group ID	Char		Identifier	Used to tie together a block of related records in a single domain for a subject.	Perm
MHREFID	Reference ID	Char		Identifier	Internal or external medical history identifier.	Perm
MHSPID	Sponsor-Defined Identifier	Char		Identifier	Sponsor-defined reference number. May be preprinted on the CRF as an explicit line identifier or defined in the sponsor's operational database. Example: Line number on a Medical History CRF page.	Perm
MHTERM	Reported Term for the Medical History	Char		Topic	Verbatim or preprinted CRF term for the medical condition or event.	Req

Metadata Restructuring

- SDTMIG v4.0

#	Variable Name	Variable Label	Type	Codelist	Allowed Controlled Terms	Format	Role	Variable Group	Root Variable C-code	Root Variable Definition	Notes	Examples	Core
1	STUDYID	Study Identifier	Char				Identifier	Study	C83082	A sequence of characters used to identify or name the study.			Req
2	DOMAIN	Domain Abbreviation	Char	(DOMAIN)	MH		Identifier	Domain	C49558	An abbreviation for a collection of observations, with a topic-specific commonality.	See Datasets and Domains .		Req
3	USUBJID	Unique Subject Identifier	Char				Identifier	Observation Subject	C69256	A sequence of characters used to uniquely identify a subject across all studies for all applications or submissions involving the product.	See Use of "Subject" and USUBJID and SUBJID.		Req
4	SUBJID	Subject Identifier for the Participation	Char				Identifier	Observation Subject		A sequence of characters used to uniquely identify a subject's participation in a study.	See USUBJID and SUBJID .		Perm
5	MHSEQ	Sequence Number	Num				Identifier	Record	C70710	A number used in combination with the identifier of the subject of the observation to uniquely identify a record within a domain.	See Record Identifiers .		Req
6	MHGRPID	Group ID	Char				Identifier	Record Group	C170996	A sequence of characters used to uniquely identify related records for a subject or pool within a domain, or related parameters in trial design and study reference datasets.	See Relating Groups of Records Within a Domain Using the --GRPID Variable and Category Variables (--CAT and --SCAT) and Identifiers that Group Records .		Perm
7	MHREFID	Reference ID	Char				Identifier	Observation Subject	C82531	A sequence of characters used to uniquely identify a source of information.	See --REFID .	Internal or external medical history identifier.	Perm
8	MHSPID	Sponsor-Defined Identifier	Char				Identifier	Record	C82530	A sponsor-defined sequence of characters used to identify an instance of an observation.	See Record Identifiers .		Perm
9	MHTERM	Reported Term for the Medical History	Char				Topic	Event Name	C82571	The collected name for an event observation.			Req

Removal of Baseline Flag (--BLFL)

Baseline Flag (--BLFL) was deprecated in SDTMIG v3.3 and Last Observation Before Exposure (--LOBXFL) was added

- Core in v3.3 and v3.4:
 - --BLFL was changed from 'Expected' to 'Permissible'
 - --LOBXFL was added as 'Expected'

--BLFL has been removed from all tables in the SDTM v3.0 / SDTMIG v4.0

WHAT THIS MEANS:

- --BLFL is no longer supported
- Can no longer be used as a parent variable in SDTM

Event Adjudication (EA)

- Adjudication is a committee's blinded evaluation of specific endpoints/events in a clinical trial
- EA is a Findings About structured domain where EAOBJ is populated with the event being adjudicated

USUBJID	EASEQ	EATESTCD	EATEST	EAOBJ	EASTRESC	EAEVAL	EAEVALID	EAACPTFL	EADTC
01-001	1	OCCUR	Occurrence Indicator	ACUTE CORONARY SYNDROME	Y	ADJUDICATOR	ADJUDICATOR 1		2021-06-30
01-001	2	EVTTYPE	Event Type	ACUTE CORONARY SYNDROME	Acute myocardial infarction	ADJUDICATOR	ADJUDICATOR 1		2021-06-30
01-001	3	EVSTDTC	Start Date/Time of Event	ACUTE CORONARY SYNDROME	2021-06-21	ADJUDICATOR	ADJUDICATOR 1		2021-06-30
01-001	4	OCCUR	Occurrence Indicator	ACUTE CORONARY SYNDROME	Y	ADJUDICATOR	ADJUDICATOR 2	Y	2021-06-30
01-001	5	EVTTYPE	Event Type	ACUTE CORONARY SYNDROME	Acute myocardial infarction	ADJUDICATOR	ADJUDICATOR 2	Y	2021-06-30
01-001	6	EVSTDTC	Start Date/Time of Event	ACUTE CORONARY SYNDROME	2021-06-21	ADJUDICATOR	ADJUDICATOR 2	Y	2021-06-30

- This domain should contain findings about the adjudication process itself. Data collected about the event or diagnostic findings that support the events data should still reside in the appropriate domain.

Protocol Deviations (DV) Update

DV was updated to support new regulatory guidance including ICH E6 R3

Classification of Protocol Deviation (DVCLASI) domain-specific variable added to provide a standardized way for submitting the investigator-determined classification of a protocol deviation

- Sponsors typically hijack DVCAT or DVSCAT to store this information when it is not appropriate for this purpose

Term pairs vary across regulatory documents and sponsors: MAJOR/MINOR, IMPORTANT/NON-IMPORTANT, CRITICAL/NONCRITICAL

- No CDISC CT for DVCLASI has been created at this time
- DVDECOD and DVCAT CT is in development

Protocol Deviations (DV) Update

STUDYID	DOMAIN	USUBJID	DVSEQ	DVTERM	DVDECOD	DVCAT	DVCLASI	EPOCH	DVSTDTC
ABC123	DV	123101	1	IVRS PROCESS DEVIATION - NO DOSE CALL PERFORMED.	TREATMENT DEVIATION	STUDY INTERVENTION	NON- IMPORTANT	TREATMENT	2003-09-21
ABC123	DV	123103	1	DRUG XXX ADMINISTERED DURING STUDY TREATMENT PERIOD	EXCLUDED CONCOMITANT MEDICATION	PROHIBITED CONCOMITANT INTERVENTION	IMPORTANT	TREATMENT	2003-10-30
ABC123	DV	123103	2	VISIT 3 DOSE <15 MG	TREATMENT DEVIATION	STUDY INTERVENTION	IMPORTANT	TREATMENT	2003-10-30
ABC123	DV	123104	1	TOOK ASPIRIN	PROHIBITED MEDS	PROHIBITED CONCOMITANT INTERVENTION	IMPORTANT	TREATMENT	2003-11-30

Gastrointestinal System Findings (GI)

- Gastrointestinal System Findings (GI) domain is used to represent results and findings related to the gastrointestinal system, including the esophagus, stomach, small and large intestine, anus, liver, biliary tract and pancreas

USUBJID	GISEQ	GITESTCD	GITEST	GIORRES	GIORRESU	GISTRESC	GISTRESN	GISTRESU
6002	1	PAREAULC	Percent Area Covered By Ulcers	11.2	%	11.2	11.2	%

GILOC	GIMETHOD	VISITNUM	VISIT	GIDTC	GIDY
STOMACH WALL	ENDOSCOPY	1	SCREENING	2016-04-18	-10

- CDISC CT codelists for GI tests, responses and units

Multiple Subject Instances (MSI)

It has become more common for a study design to allow subjects to participate more than once in the same study

FDA Study Data Technical Conformance Guide (sdTCG) provides some details for submitting data for multiple enrollments

In a nutshell:

- Subjects screened and/or enrolled more than once, SUBJID should be different for each participation
- The same USUBJID per subject should be assigned within the study and across the application
- Data collected for each participation should be submitted in a custom domain similar to DM
- DM should still contain one record per subject and should be the primary enrollment
- SUBJID should be included in all other subject-level domains to differentiate records across participations

Demographics for Multiple Participations (DC)

Demographics for Multiple Participations (DC) domain developed to represent subject data for each participation

- DM domain still contains one record per subject considered to be the 'primary enrollment'

DC is structured similar to DM with the main difference being the addition of DCSEQ

- DCSEQ is needed because it will contain more than one record per subject

Subjects are assigned one USUBJID but SUBJID must be different for each participation

Derivation of Study Day variables (--DY, --ENDY, --STDY) is still based on RFSTDTC in DM

- DCDY is not permitted to be added since DM is essentially derivative of DC

SUBJID can now be added to subject-level domains to differentiate records for each participation

If the study design does not allow for multiple enrollments, DC and addition of SUBJID to domains is not permitted

Multiple Subject Instances (MSI) Example

dc.xpt

STUDYID	DOMAIN	USUBJID	SUBJID	DCSEQ	RFSTDTC	RFENDTC	RFXSTDTC	RFXENDTC	RFICDTC	RFPENDTC
ABC123	DC	ABC12301001	1001	1	2006-01-14	2006-01-28	2006-01-14	2006-01-28	2006-01-05	2006-02-25
ABC123	DC	ABC12301002	1002	1	2006-01-12	2006-01-26	2006-01-12	2006-01-26	2006-01-04	2006-02-23
ABC123	DC	ABC12301003	1003	1	2006-01-08	2006-01-20	2006-01-08	2006-01-20	2006-01-02	2006-02-17
ABC123	DC	ABC12301004	1004	1					2005-09-13	2005-09-21
ABC123	DC	ABC12301004	1004B	2					2005-11-14	2005-11-16
ABC123	DC	ABC12301004	1004C	3	2006-01-16	2006-02-01	2006-01-16	2006-02-01	2006-01-07	2006-03-02

BIRTHDT	AGE	AGEU	SEX	RACE	ETHNIC	ARMCD	ARM	ACTARMCD	ACTARM	ARMNRS
1948-12-13	57	YEARS	M	WHITE	HISPANIC OR LATINO	A	Drug A	A	Drug A	
1955-03-22	50	YEARS	M	WHITE	NOT HISPANIC OR LATINO	P	Placebo	P	Placebo	
1938-01-19	67	YEARS	F	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	P	Placebo	P	Placebo	
1941-07-02			M	ASIAN	NOT HISPANIC OR LATINO					SCREEN FAILURE
										SCREEN FAILURE
	64	YEARS				A	Drug A	A	Drug A	

Multiple Subject Instances (MSI) Example

dm.xpt

STUDYID	DOMAIN	USUBJID	SUBJID	RFSTDTC	RFENDTC	RFXSTDTC	RFXENDTC	RFICDTC	RFPENDTC
ABC123	DM	ABC12301001	1001	2006-01-14	2006-01-28	2006-01-14	2006-01-28	2006-01-05	2006-02-25
ABC123	DM	ABC12301002	1002	2006-01-12	2006-01-26	2006-01-12	2006-01-26	2006-01-04	2006-02-23
ABC123	DM	ABC12301003	1003	2006-01-08	2006-01-20	2006-01-08	2006-01-20	2006-01-02	2006-02-17
ABC123	DM	ABC12301004	1004C	2006-01-16	2006-02-01	2006-01-16	2006-02-01	2006-01-07	2006-03-02

BRTHDTC	AGE	AGEU	SEX	RACE	ETHNIC	ARMCD	ARM	ACTARMCD	ACTARM	ARMNRS
1948-12-13	57	YEARS	M	WHITE	HISPANIC OR LATINO	A	Drug A	A	Drug A	
1955-03-22	50	YEARS	M	WHITE	NOT HISPANIC OR LATINO	P	Placebo	P	Placebo	
1938-01-19	67	YEARS	F	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	P	Placebo	P	Placebo	
1941-07-02	64	YEARS	M	ASIAN	NOT HISPANIC OR LATINO	A	Drug A	A	Drug A	

Multiple Subject Instances (MSI) Example

ds.xpt

STUDYID	DOMAIN	USUBJID	SUBJID	DSSEQ	DSTERM	DSDECOD	DSCAT	EPOCH	DSSTDTC
ABC123	DS	ABC12301004	1004	1	INFORMED CONSENT OBTAINED	INFORMED CONSENT OBTAINED	PROTOCOL MILESTONE	SCREENING	2005-09-13
ABC123	DS	ABC12301004	1004	2	SCREEN FAILURE	SCREEN FAILURE	DISPOSITION EVENT	SCREENING	2005-09-21
ABC123	DS	ABC12301004	1004B	3	INFORMED CONSENT OBTAINED	INFORMED CONSENT OBTAINED	PROTOCOL MILESTONE	SCREENING	2005-11-14
ABC123	DS	ABC12301004	1004B	4	SCREEN FAILURE	SCREEN FAILURE	DISPOSITION EVENT	SCREENING	2005-11-16
ABC123	DS	ABC12301004	1004C	5	INFORMED CONSENT OBTAINED	INFORMED CONSENT OBTAINED	PROTOCOL MILESTONE	SCREENING	2006-01-07
ABC123	DS	ABC12301004	1004C	6	COMPLETED	COMPLETED	DISPOSITION EVENT	SCREENING	2006-01-16
ABC123	DS	ABC12301004	1004C	7	COMPLETED	COMPLETED	DISPOSITION EVENT	TREATMENT	2006-02-01
ABC123	DS	ABC12301004	1004C	8	COMPLETED	COMPLETED	DISPOSITION EVENT	FOLLOW-UP	2006-03-02

Additional DM (and DC) Updates

RACE and ETHNIC variables no longer have assigned codelists

- In earlier SDTMIGs, the codelists were following FDA requirements (US-focused)
- Assumption has been added directing to use terminology defined by the data recipient, e.g. FDA, PMDA, NMPA, EMEA

CDASH variables, CRACE and CETHNIC, added to SDTM

- Both variables have extensive, extensible codelists in CDISC CT

RACE, ETHNIC, CRACE, and CETHNIC are all 'Permissible' variables

AGERLO and AGERHI added to SDTM

- Replaces AGEXTX
- Can be used when a subject's exact age is not known or collected

SUPPQUAL to NSV (NS--)

The vertical structure of SUPPQUAL is being replaced by horizontal-structured datasets for Non-standard variables (NSV)

SUPP– datasets need to be transposed before they can be joined back onto the parent dataset. NS– datasets do not.

Per the SDTM, NSVs cannot be added to parent domains. NSVs will still be separate datasets and not included in the parent domain

Naming of NSV datasets is similar to SUPP--, where the 2 hyphens in NS– are replaced with the domain code of the parent domain, e.g. NS– dataset for AE is named 'NSAE'

STUDYID, RDOMAIN, USUBJID, IDVAR variables that link back to the parent are the same in NSV datasets

IDVARVAL (a character type variable) will be replaced by IDVARVLN (a numeric type variable)

- There is now an assumption that IDVAR/IDVARVLN must be –SEQ from the parent domain except for NSDM

NSV datatypes can now be defined as either character or numeric versus only allowing character type for SUPPQUAL.QVAL

- For NSV, the corresponding metadata should be clearly enumerated in the define.xml

SUPPQUAL Example

ho.xpt

STUDYID	DOMAIN	USUBJID	HOSEQ	HOTERM	HOSTDTC	HOENDTC
1999001	HO	1001	1	HOSPITAL STAY	2004-01-05	2004-01-12
1999001	HO	1001	2	HOSPITAL STAY	2004-01-23	2004-02-07
1999001	HO	1002	1	HOSPITAL STAY	2004-01-21	2004-01-22

suppho.xpt

STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG	QEVAL
1999001	HO	1001	HOSEQ	1	HOAERPFL	AE Reported This Episode	Y	CRF	
1999001	HO	1001	HOSEQ	1	HOMEDSFL	Meds Prescribed	Y	CRF	
1999001	HO	1001	HOSEQ	1	HOPROCFL	Procedures Performed	Y	CRF	
1999001	HO	1001	HOSEQ	1	HONAM	Provider Name	GENERAL HOSP	CRF	
1999001	HO	1001	HOSEQ	1	HOSPUTY	Specialized Unit Type	ICU	CRF	
1999001	HO	1001	HOSEQ	1	HOSPUFL	Any Time in Spec. Unit	Y	CRF	
1999001	HO	1001	HOSEQ	1	HORLCNDF	Visit Related to Study Med Cond.	Y	CRF	
1999001	HO	1001	HOSEQ	2	HOAERPFL	AE Reported This Episode	Y	CRF	
1999001	HO	1001	HOSEQ	2	HOMEDSFL	Meds Prescribed	Y	CRF	
1999001	HO	1001	HOSEQ	2	HOPROCFL	Procedures Performed	N	CRF	
1999001	HO	1001	HOSEQ	2	HONAM	Provider Name	UNIV HOSP	CRF	
1999001	HO	1001	HOSEQ	2	HOSPUTY	Specialized Unit Type	CCU	CRF	
1999001	HO	1001	HOSEQ	2	HOSPUFL	Any Time in Spec. Unit	Y	CRF	
1999001	HO	1001	HOSEQ	2	HORLCNDF	Visit Related to Study Med Cond.	Y	CRF	
1999001	HO	1002	HOSEQ	1	HOAERPFL	AE Reported This Episode	Y	CRF	
1999001	HO	1002	HOSEQ	1	HOMEDSFL	Meds Prescribed	N	CRF	
1999001	HO	1002	HOSEQ	1	HOPROCFL	Procedures Performed	Y	CRF	
1999001	HO	1002	HOSEQ	1	HONAM	Provider Name	ST. MARY'S	CRF	
1999001	HO	1002	HOSEQ	1	HOSPUTY	Specialized Unit Type	ICU	CRF	
1999001	HO	1002	HOSEQ	1	HOSPUFL	Any Time in Spec. Unit	N	CRF	
1999001	HO	1002	HOSEQ	1	HORLCNDF	Visit Related to Study Med Cond.	Y	CRF	

NSV Example

ho.xpt

STUDYID	DOMAIN	USUBJID	HOSEQ	HOTERM	HOSTDTC	HOENDTC
1999001	HO	1001	1	HOSPITAL STAY	2004-01-05	2004-01-12
1999001	HO	1001	2	HOSPITAL STAY	2004-01-23	2004-02-07
1999001	HO	1002	1	HOSPITAL STAY	2004-01-21	2004-01-22

nsho.xpt

STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVLN	HOAERPFL	HOMEDSFL	HOPROCFL	HONAM	HOSPUTY	HOSPUFL	HORLCNDF
1999001	HO	1001	HOSEQ	1	Y	Y	Y	GENERAL HOSP	ICU	Y	Y
1999001	HO	1001	HOSEQ	2	Y	Y	N	UNIV HOSP	CCU	Y	Y
1999001	HO	1002	HOSEQ	1	Y	N	Y	ST. MARY'S	ICU	N	Y

NSV Metadata

Variable	Label	Type	Codelist	Role
HOAERPFL	AE Reported This Episode	Char	(NY)	Non-Standard Qualifier
HOMEDSFL	Meds Prescribed	Char	(NY)	Non-Standard Qualifier
HOPROCFL	Procedures Performed	Char	(NY)	Non-Standard Qualifier
HONAM	Provider Name	Char		Non-Standard Qualifier
HOSPUTY	Specialized Unit Type	Char		Non-Standard Qualifier
HOSPUFL	Any Time in Spec. Unit	Char	(NY)	Non-Standard Qualifier
HORLCNDF	Visit Related to Study Med Cond.	Char	(NY)	Non-Standard Qualifier

Are We There Yet?.....

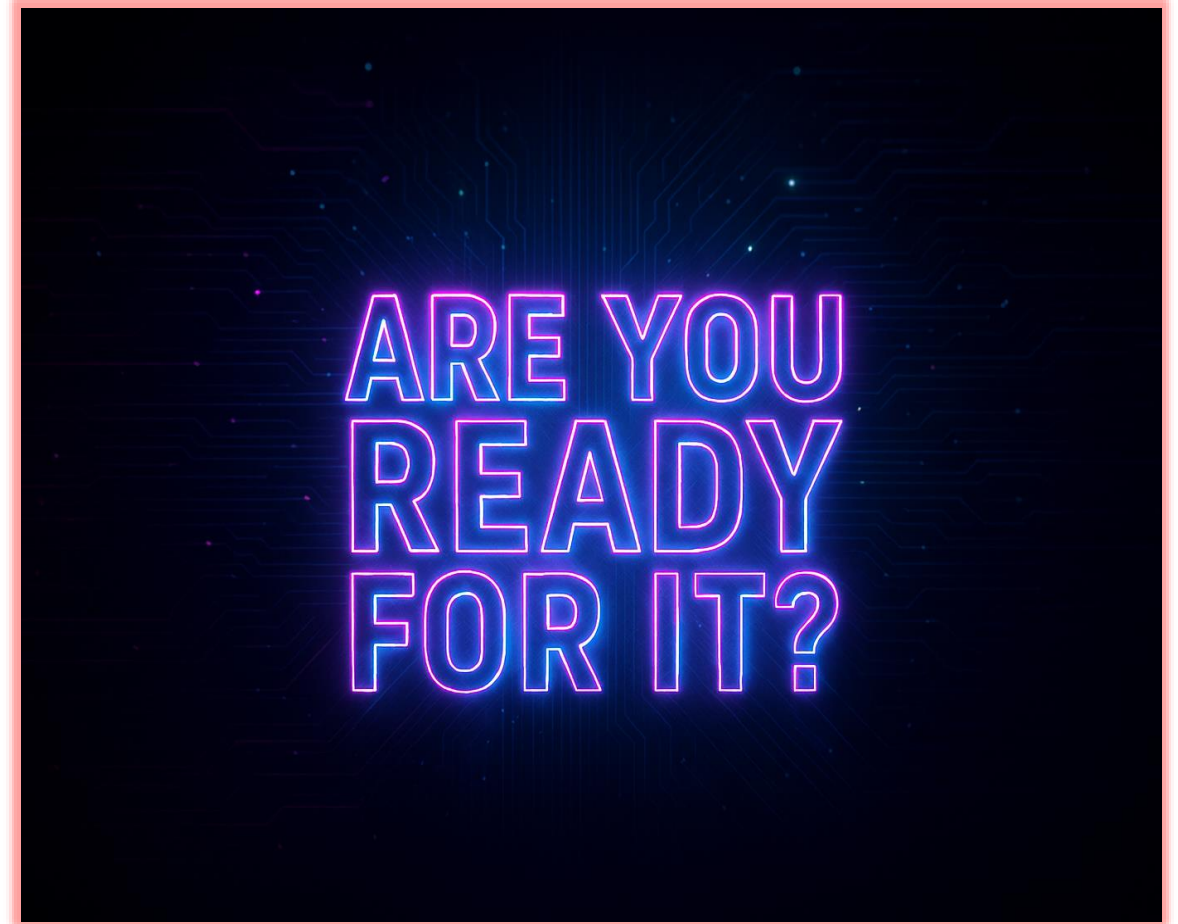
EXPANDED SCOPE FOR SDTMIG V4.0



- Because standards development will pause after SDTMIG v4.0, there will be additional scope
- Expanded scope includes the following:
 - SDTMIG-Associated Persons (SDTMIG-AP) v2.0
 - Laboratory Results for Conventional Units (LC) domain
 - Splitting Disease Response and Clinical Classification (RS) into RS (Disease Response) and CC (Clinical Classifications) domains
 - Additional Morphology/Physiology domains – AU, ED, HM, IG

Summary

- SDTMIG v4.0 is considered a major release with the debut of MSI, SUPP to NSV, metadata restructuring and significant revision of general content
- Transitioning into this new phase will require planning, updates to internal processes, and time for teams to adapt
- As the last major SDTMIG before CDISC shifts toward Biomedical Concepts, v4.0 closes one door and confidently opens the next, inviting sponsors to step forward through it
- So now the question becomes....





Thank You!

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