NEW DOMAINS IN SDTM IG V3.3 BATCH 3

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NEW DOMAINS IN SDTM IG V3.3 BATCH 3

- Findings
- Urinary System Findings (UR)
- Nervous System Findings (NV) *
- Cardiovascular System Findings (CV) *
- Ophthalmic Examinations (OE) *
- Respiratory System Findings (RE) *
- Musculoskeletal System Findings (MK) *
- ECG QT Correction Model Data (QT)

* Revised after review in Batch 1 or Batch 2

The SDS team decided to have body system-based domains cover both morphology and physiology findings, and to deprecate Morphology (MO) in a future version of SDTM IG.

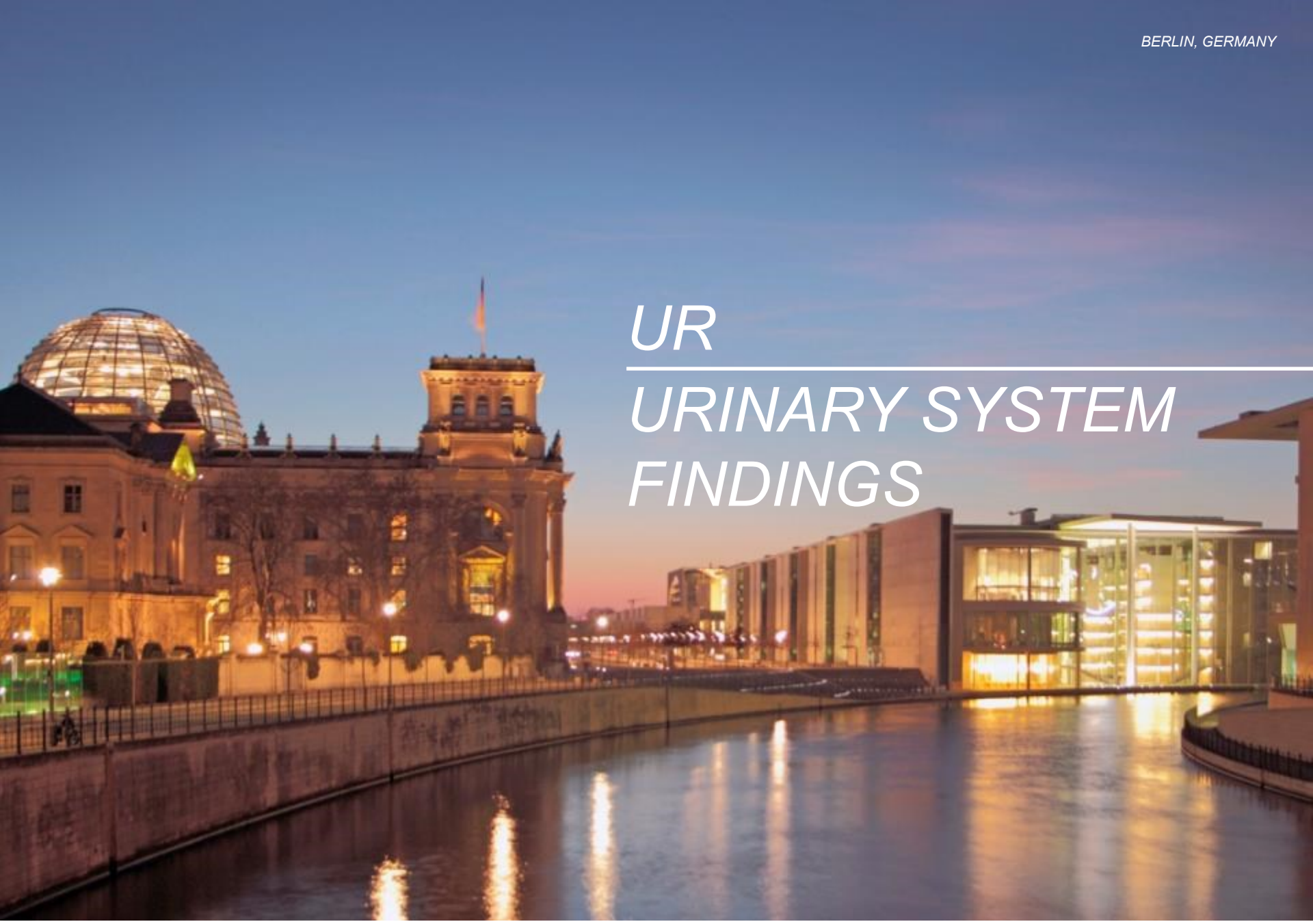
NEW DOMAINS IN SDTM IG V3.3 BATCH 3

- Disease Milestones (update)
  - Disease Milestones and Disease Milestones Timing Variables
- Interventions
  - Meal Data (ML)
- Events
  - Environmental Risk Factors (ER)
- Study Reference
  - Non-host Organism Identifiers (OI)
- Relationship
  - Related Subjects (RELSUB)

NEW DOMAINS IN SDTM IG V3.3 BATCH 3

ANJTE SIMON

- Findings
- **Urinary System Findings (UR)**
- **Nervous System Findings (NV) ***
- Cardiovascular System Findings (CV) *
- Respiratory System Findings (RE) *
- Ophthalmic Examinations (OE) *
- Musculoskeletal System Findings (MK)
- ECG QT Correction Model Data (QT)



UR
URINARY SYSTEM FINDINGS

UR - URINARY SYSTEM FINDINGS

- Findings domain for morphological and physiological findings related to the urinary tract
- First review; Not part of a TAUG
- Domain definition is in SDTM DOMAIN CT from 2016-06-24 but has been modified by inserting "morphological and" before "physiological findings."
- URTEST, URTESTCD are not in SDTM CT 2016-06-24
- The usual identifiers, timing variables, and variables for Findings Observation Class
- Not-so-common:
  - URTSTDTL (Measurement, Test or Examination Detail)
  - URRESCAT (Result Category)
  - URSPCUFL (Specimen Usability for the Test)
- Two new variables: URLOBXFL, URRESTRG (see next slide)

UR - URINARY SYSTEM FINDINGS

- **New SDTM 1.5 Variable: URLOBXFL (Last Observation Before Exposure Flag)**

URLOBXFL	Last Observation Before Exposure Flag	Char	(NY)	Record Qualifier	SDTM V1.5 Operationally-derived indicator used to identify the last non-missing value prior to RFXSTDTC. The value should be "Y" or null.	Exp

URBLFL is retained for backward compatibility

- **New Variable: URRESTRG (Pre-Specified Result Targeted by Test)**
  - Approved by the SDTM Governance Committee but is not included in SDTM v1.5

URRESTRG	Pre-Specified Result Targeted by Test	Char		Variable Qualifier	NEW Describes the result targeted by the test identified in URTESTCD. Used when the measurement, test, or examination indicates the presence or absence of a pre-specified result value. The value of URORRES should indicate whether the pre-specified result value was found to be present, not present, or not determined.	Perm

UR - URINARY SYSTEM FINDINGS

- **Example with URRESTRG**

	STUDYID	DOMAIN	USUBJID	URSEQ	URTESTCD	URTEST	URRESTRG
1	ABC	UR	ABC-001-011	1	TRGEXM	Targeted Examination	Hematoma
2	ABC	UR	ABC-001-011	2	TRGEXM	Targeted Examination	Surgical Damage

	URORRES	URORRESU	*URSTRES**	URLOC	URLAT	URDIR	URMETHOD	URDTC
1	ABSENT		…	KIDNEY			CT SCAN	2016-03-30
2	PRESENT		…	KIDNEY, CORTEX	LEFT	SUPERIOR	CT SCAN	2016-03-30

- Row 1: If a hematoma had been present, the variable URLOC (with URDIR as necessary) would have specified where within the kidney.
- Row 2: Shows that surgical damage was noted in the superior portion of the kidney cortex. Note that in SDTM, there is no way to clearly distinguish between the use of --LOC as a qualifier of --TEST vs. as a qualifier of results, as it is used here.

UR draft domain for review in CDISC Wiki http://wiki.cdisc.org/pages/viewpage.action?pageId=31311120

NV
NERVOUS SYSTEM FINDINGS

NV – NERVOUS SYSTEM FINDINGS

- Findings domain for morphological and physiological findings related to the nervous system
- Public as part of the Multiple Sclerosis 1.0 and Alzheimer's Disease 1.0 Provisional TAUGs
  - Changes from definition in TAUG: Removed NVPOS, NVXFN, NVNAM,
    Added NVLNKGRP, NVBLFL, NVEVALID, TAETORD, EPOCH + new SDTM 1.5 variables
- Was reviewed in SDTM IG 3.3 Batch 2. Updated to include both morphology and physiology results
- Domain definition is in SDTM DOMAIN CT from 2016-06-24 but has been modified by inserting "morphological and" before "physiological findings."
- Codelists NVTEST(CD) (Nervous System Physiology Test) are in SDTM CT 2016-06-24
- Use of new SDTM 1.5 variables:
  NVLOBXFL (Last Observation Before Exposure Flag),
  FOCID (Focus of Study-Specific Interest)

NV – NERVOUS SYSTEM FINDINGS

- New SDTM 1.5 Variable: NVLOBXFL (Last Observation Before Exposure Flag)

NVLOBXFL	Last Observation Before Exposure Flag	Char	(NY)	Record Qualifier	SDTM V1.5 Operationally-derived indicator used to identify the last non-missing value prior to RFXSTDTC. The value should be "Y" or null.	Perm

NVBLFL is retained for backward compatibility

- New SDTM 1.5 Variable: FOCID (Focus of Study-Specific Interest)

FOCID	Focus of Study-Specific Interest	Char		Identifier	Identification of a focus of study-specific interest on or within a subject or specimen as called out in the protocol for which a measurement, test, or examination was performed, such as a drug application site, e.g., "Injection site 1", "Biopsy site 1", "Treated site 1", or a more specific focus, e.g., "OD" (right eye) or "Upper left quadrant of the back". The value in this variable should have inherent semantic meaning.	Perm

NV draft domain for review in CDISC Wiki http://wiki.cdisc.org/pages/viewpage.action?pageId=29111254

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CV
CARDIOVASCULAR SYSTEM FINDINGS

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CARDIOVASCULAR SYSTEM FINDINGS – CV DOMAIN

- **Findings Domain**
- **Codelists:** CVTESTCD, CVTEST
- Designed to report data on cardiovascular physiology and morphology findings including information relating to heart, blood vessels, and circulation
  - Stenosis – narrowing bloodvessels and valves
  - New York Heart Association Class (NYHA) – Classifies the extent of heart failure
  - Ischemic myocardium percentage

Row	STUDYID	DOMAIN	USUBJID	CVSEQ	CVTESTCD	CVTEST	CVORRES	CVSTRESC	CVDTC
1	ABC	CV	ABC-123	1	NYHACLS	New York Heart Association Class	I	I	2010-05-16
2	ABC	CV	ABC-123	2	NYHACLS	New York Heart Association Class	II	II	2010-05-31
3	ABC	CV	ABC-123	3	KILLIPCL	Killip Class	II	II	2010-06-12
4	ABC	CV	ABC-123	4	NYHACLS	New York Heart Association Class	II	II	2010-06-22
5	ABC	CV	ABC-123	5	KILLIPCL	Killip Class	II	II	2010-06-24
6	ABC	CV	ABC-123	6	NYHACLS	New York Heart Association Class	I	I	2010-07-06
7	ABC	CV	ABC-123	7	KILLIPCL	Killip Class	II	II	2010-08-03
8	ABC	CV	ABC-124	1	CCSGRDS	Canadian CV Society Grading Scale	1	1	2011-01-02
9	ABC	CV	ABC-125	1	CCSGRDS	Canadian CV Society Grading Scale	2	2	2011-03-03

CV – UPDATE

- **New variable CVRESTRG:**
  - Permissible variable, not yet in SDTM v1.5
  - Used if a result is pre-specified on the CRF: describes result targeted by test identified in CVTESTCD
  - Used in combination with –TESTCD/--TEST
  - CVORRES should indicate if the result was present or not („Y“ or „N“)

CVRESTRG	Pre-Specified Result Targeted by Test	Char		Variable Qualifier	NEW Describes the result or examination indicates the presenc indicate whether the pre-specified res

CVTESTCD	CVTEST	CVRESTRG	CVORRES		
ADISCCLS	Aortic Dissection Classification	STANFORD CLASS A	Y		

CV – UPDATE

- **New SDTM v1.5 variable --LOBXFL:**
  - Expected derived variable CVLOBXFL added, was not present in Batch 1
  - „Last Observation Before Exposure Flag / Operationally-derived indicator used to identify the last non-missing value prior to RFXSTDTC“ (date/time of first study treatment)
  - Included in SDTM v1.5 as --LOBXFL
  - Proposal to transition from BLFL to a new variable LOBXFL which will not conflict with ADaM baselines
  - Value should be „Y“ or null
  - The description of –BLFL (Baseline Flag) will be modified in SDTM v1.6

				Qualifier	directionality. Examples: ANTER
CVMETHOD	Method of Test or Examination	Char	(METHOD)	Record Qualifier	Method used to create the result
CVLOBXFL	Last Observation Before Exposure Flag	Char	(NY)	Record Qualifier	SDTM V1.5 Operationally-der non-missing value prior to RFXST
CVBLFL	Baseline Flag	Char	(NY)	Record Qualifier	Indicator used to identify a baseli
CVDRVFL	Derived Flag	Char	(NY)	Record	Used to indicate a derived record

RE
RESPIRATORY SYSTEM FINDINGS

RESPIRATORY SYSTEM FINDINGS – RE DOMAIN

- **Findings Domain**

- This domain is used to represent the results/findings of a respiratory diagnostic procedure, such as spirometry. Information about the conduct of the procedure(s), if collected, should be submitted in the Procedures (PR) domain

- **Codelists**: RETESTCD, RETEST

RELNKGRP	Link Group	Char		Identifier	Identifier
RETESTCD	Test or Examination Short Name	Char		Topic	Short na from a ve start with undersc
RETEST	Name of Measurement, Test or Examination	Char		Synonym Qualifier	Verbatim be longe
RECAT	Category	Char		Grouping	Used to

RE – UPDATE

- **New SDTM v1.5 variables --ORREF and --STREFN**
  - Variables were already present in Batch 1, however, variables now added to SDTM v1.5
  - Added because pulmonary function test results are compared to a single predicted normal value rather than to a normal range

REORREF	Reference Result in Original Units	Char		Variable Qualifier	SDTM V1.5 Reference result for continuous measurements in original units. Should be collected only for continuous results.
RESTRESC	Result or Finding in Standard Format	Char		Result Qualifier	Contains the result value for all findings, copied or derived from REORRES in a standard format or in standard units. RESTRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in RESTRESN.
RESTRESN	Numeric Result/Finding in Standard Units	Num		Result Qualifier	Used for continuous or numeric results or findings in standard format; copied in numeric format from RESTRESC. RESTRESN should store all numeric test results or findings.
RESTRESU	Standard Units	Char	(UNIT)	Variable Qualifier	Standardized unit used for RESTRESC, RESTRESN and RESTREFN.
RESTREFN	Numeric Reference Result in Std Units	Num		Variable Qualifier	SDTM V1.5 Reference result for continuous measurements in standard units. Should be populated only for continuous results.

re.xpt

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	RESEQ	RETESTCD	RETEST	REORRES	REORRESU	REORREF	...	VISITNUM	VISIT	REDTC
1	XYZ	RE	XYZ-001-001	ABC001	1	FEV1	Forced Expiratory Volume in 1 Second	2.73	L	3.37		2	VISIT 2	2013-06-30
2	XYZ	RE	XYZ-001-001	ABC001	2	FVC	Forced Vital Capacity	3.91	L	3.86		2	VISIT 2	2013-06-30
3	XYZ	RE	XYZ-001-001	ABC001	3	FEV1PP	Percent Predicted FEV1	81	%			2	VISIT 2	2013-06-30
4	XYZ	RE	XYZ-001-001	ABC001	4	FVCPP	Precent Predicted FVC	101.3	%			2	VISIT 2	2013-06-30
5	XYZ	RE	XYZ-001-001	DEF999	5	PEF	Peak Expiratory Flow	6.11	L/s	7.33		4	VISIT 4	2013-07-17

RE – UPDATE

- **New SDTM v1.5 variable --REPNUM**
  - --REPNUM included in SDTM v1.5
  - REREPNUM added, REIRESFL removed

re.xpt

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	RESEQ	RETESTCD	RETEST	REORRES	REORRESU	RESTRESN	RESTRESU	REREPNUM	VISITNUM	VISIT	REDTC
1	XYZ	RE	XYZ-001-001	ABC001	1	FEV1	Forced Expiratory Volume in 1 Second	1.94	L	1.94	L	1	2	VISIT 2	2013-04-23
2	XYZ	RE	XYZ-001-001	ABC001	2	FEV1	Forced Expiratory Volume in 1 Second	1.88	L	1.88	L	2	2	VISIT 2	2013-04-23
3	XYZ	RE	XYZ-001-001	ABC001	3	FEV1	Forced Expiratory Volume in 1 Second	1.88	L	1.88	L	3	2	VISIT 2	2013-04-23
4	XYZ	RE	XYZ-001-001	ABC001	4	FEV1	Forced Expiratory Volume in 1 Second	1.57	L	1.57	L	4	2	VISIT 2	2013-04-23

REBLFL	Baseline Flag	Char	(NY)	Record Qualifier	Indicator used
REDRVFL	Derived Flag	Char	(NY)	Record Qualifier	Used to indica records, or tha of records that null, with RES
REEVAL	Evaluator	Char	(EVAL)	Record Qualifier	Role of the per by a person or RADIOLOGIST
REEVALID	Evaluator Identifier	Char	(MEDEVAL)	Variable Qualifier	Used to disting RADIOLOGIST
REREPNUM	Repetition Number	Num		Record Qualifier	SDTM V1.5 test. The level measurements
VISITNUM	Visit Number	Num		Timing	Clinical encou

REEVAL	Evaluator	Char	*
REIRESFL	Inadequate Results Flag	Char	(NY)
VISITNUM	Visit Number	Num	

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL
1	XYZ	RE	XYZ-001-001	EGSEQ	1	BRESFL	Best Result Flag	Y
2	XYZ	RE	XYZ-001-001	EGSEQ	4	IRESFL	Inadequate Results Flag	Y

OE
OPHTHALMIC EXAMINATIONS

OPHTHALMIC EXAMINATIONS – OE DOMAIN

- **Findings Domain**
- Tests that measure a person's ocular health and visual status to detect abnormalities and to determine how well the person can see
- **Codelists**: OETESTCD, OETEST, OEFOCUS

OE – UPDATE

- **Includes also morphology and physiology results**
- **New SDTM v1.5 variable FOCID, --REPNUM, --LOBXFL**
  - FOCID = Focus of Study-Specific interest, was already present in Batch 2
    - Codelist: OEFOCUS
  - OEREPNUM = Repetition Number, was already present in Batch 2
  - OELOBXFL added as an expected variable, was not present in Batch 2

FOCID	Focus of Study-Specific Interest	Char	(OEFOCUS)	Identifier	SDTM V1.5 Identification of a focus of stu in the protocol for which a measurement, test Ophthalmic studies, used as a key identifying Assumption 2.
OELOBXFL	Last Observation Before Exposure Flag	Char	(NY)	Record Qualifier	SDTM V1.5 Operationally-derived ir The value should be "Y" or null.
OEREPNUM	Repetition Number	Num		Record Qualifier	SDTM V1.5 The incide level of granularity can var blood pressure or multiple

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- **Musculoskeletal System Findings (MK)**
- **ECG QT Correction Model Data (QT)**

MK
MUSCULOSKELETAL SYSTEM FINDINGS

MK – MUSCULOSKELETAL SYSTEM FINDINGS (FINDINGS)

- appeared alongside the TAUG-RA
- For current public review to be found here: http://wiki.cdisc.org/pages/viewpage.action?pageId=30674939
- One record per finding/ per location/ per time point/ per visit/ per subject
- **Intended for:** morphological and physiological findings related to the system of muscles, tendons, ligaments, bones, joints and associated tissues (e.g. swollen/tender joint count, limb movement, strength/grip measurements)
- **Not intended for**: oncology data related to the musculoskeletal system (e.g. bone lesions -> should go to TU, TR, RS

MK – MUSCULOSKELETAL SYSTEM FINDINGS (FINDINGS)

- **required variables**: STUDYID, DOMAIN, USUBJID, MKSEQ, MKTESTCD (Examples: TNDRIND, SWLLIND, SGJSNSCR), MKTEST (Examples: SWOLLEN/TENDER JOINT ASSESSMENT)

- --BLFL is retained for backward compatibility.

- any Identifier, Timing or Qualifier variables may be added

- the following Qualifiers would generally **not** be used: --MODIFY, --BODSYS,--LOINC, --TOX, --TOXGR, --FAST, --ORNRLO, --ORNRHI, --STNRLO, --STNRHI, --ORREF, --STREFC, --STREFN

QT

ECG QT CORRECTION MODEL DATA

QT – ECG QT CORRECTION MODEL DATA (FINDINGS)

- Public review as part of the TAUG-QT (Version 1.0 Provisional of the QT Studies Therapeutic Area Data Standard, released 2014-12-8).
- For public review to be found here: http://wiki.cdisc.org/pages/viewpage.action?pageId=29923747
- describes correction methods, formulas, and coefficients
- One record per finding or result/ per subject
- **Intended for:** :
  - An EG dataset exists which contains QTc values, and
  - The QT corrections were performed by a vendor, rather than the sponsor, and
  - The QT corrections are derived from data collected in the study (i.e. are not historical)
  - The coefficients used for the QT corrections are other than Bazett's or Fridericia's.
- **Not Intended for:** when any of the above not apply

QT – ECG QT CORRECTION MODEL DATA (FINDINGS)

- **required variables:** STUDYID, DOMAIN, USUBJID, QTSEQ, QTTESTCD, QTTEST
- QTGRPID holds the EGTESTCD value for the record in EG to which it applies
- Timing variable should **not** be included (relates to all the data for a population or subject)
- the following Qualifiers would generally **not** be used: --POS, --BODSYS, --ORRESU, --ORNLO, --ORNHI, --STRESU, --STNRLO, --STNRHI, --STNRC, --NRIND, --SPEC, --ANTREG, --SPCCND, --SPCUFL, --LOC, --LAT, --DIR, --PORTOT, --CSTATE, --FAST, --EVAL, --EVALID, --ACPTFL, --TOX, --TOXGR, --SEV, --DTHREL, --LLOQ, --ULOQ

QT – ECG QT CORRECTION MODEL DATA - EXAMPLE

eg.xpt

Row	DOMAIN	USUBJID	EGSEQ	EGCAT	EGTESTCD	EGTEST	EGORRES	EGORRESU	...
1	EG	P384QT204_001	1	INTERVAL	QTCIAG1	QTCI Interval, Aggregate 1	345	msec	...
2	EG	P384QT204_001	2	INTERVAL	QTCIAG2	QTCI Interval, Aggregate 2	350	msec	...
3	EG	P384QT204_001	3	INTERVAL	QTCNAG	QTCN Interval, Aggregate	353	msec	...

qt.xpt

Row	DOMAIN	USUBJID	QTSEQ	QTGRPID	QTTESTCD	QTTEST	QTORRES	...
1	QT	P384QT204_001	1	QTCIAG1	QTCDESC	QT Correction Method Description	PARABOLIC LOG/LOG	...
2	QT	P384QT204_001	2	QTCIAG1	QTCFORM	QT Correction Formula	QTC=QT/(RR^A)	...
3	QT	P384QT204_001	3	QTCIAG1	QTCCOEFA	QT Correction Coefficient A	0.432	...
4	QT	P384QT204_001	4	QTCIAG2	QTCDESC	QT Correction Method Description	LINEAR	...
5	QT	P384QT204_001	5	QTCIAG2	QTCFORM	QT Correction Formula	QTC=QT+(A*(1-RR))	...
6	QT	P384QT204_001	6	QTCIAG2	QTCCOEFA	QT Correction Coefficient A	0.154	...
7	QT	P384QT204_001	7	QTCNAG	QTCDESC	QT Correction Method Description	RAUTAHARJU COR	...
8	QT	P384QT204_001	8	QTCNAG	QTCFORM	QT Correction Formula	QTC=QT+A-(B*(e^(C^HR))	...
9	QT	P384QT204_001	9	QTCNAG	QTCCOEFA	QT Correction Coefficient A	0.2425	...
10	QT	P384QT204_001	10	QTCNAG	QTCCOEFB	QT Correction Coefficient B	0.434	...
11	QT	P384QT204_001	11	QTCNAG	QTCCOEFC	QT Correction Coefficient C	-0.0097	...

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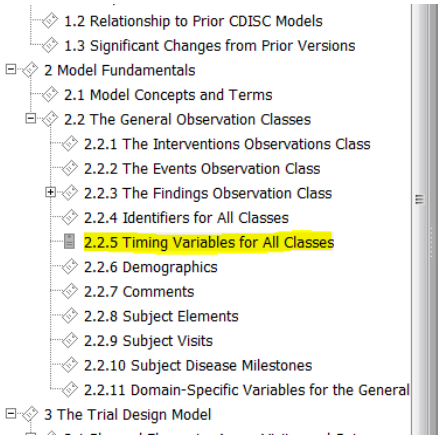
PETRA REIN

- Disease Milestones (update)
  - Disease Milestones and Disease Milestones Timing Variables
- Interventions
  - Meal Data (ML)
- Events
  - Environmental Risk Factors (ER)
- Study Reference
  - Non-host Organism Identifiers (OI)
- Relationship
  - Related Subjects (RELSUB)

TIMING VARIABLES
DISEASE MILESTONES

DISEASE MILESTONES AND DISEASE MILESTONES TIMING VARIABLES

- For current public review to be found here:
  http://wiki.cdisc.org/display/SDTMIGBAT/Disease+Milestones+and+Disease+Milestones+Timing+Variables
- Related information for SM and TM in SDTMIG 3.3 Batch 2
- New variables MIDS, RELMIDS, MIDSDTC in SDTM 1.5 (within new SEND package)



	Time Point		defined reference time point defined by variable --ENTPT.
--ENTPT	End Reference Time Point	Char	Description or date/time in ISO 8601 or other character format of the sponsor-defined reference point referred to by --ENRTPT. Examples: "2003-12-25" or "VISIT 2".
MIDS	Disease Milestone Instance Name	Char	The name of a specific instance of a Disease Milestone Type (MIDSTYPE) described in the Trial Disease Milestones dataset (See Section 3.5). This should be unique within a subject. Used only in conjunction with RELMIDS and MIDSDTC.
RELMIDS	Temporal Relation to Milestone Instance	Char	The temporal relationship of the observation to the Disease Milestone Instance Name in MIDS. Examples: IMMEDIATELY BEFORE, AT TIME OF, AFTER.
MIDSDTC	Disease Milestone Instance Date/Time	Char	The start date/time of the Disease Milestone Instance Name in MIDS, in ISO8601 format.
--STINT	Planned Start of Assessment Interval	Char	The start of a planned evaluation or assessment interval in ISO 8601 character format relative to the Time Point Reference (--TPTREF).*

DISEASE MILESTONES AND DISEASE MILESTONES TIMING VARIABLES

- For disease milestone itself:
  - MIDS populated, but RELMIDS and MIDSDTC will not be populated;
  - usual timing variables to be used to derive dates and study days in the SM domain.

- For related records to disease milestone:
  - Observations in conjunction with Disease Milestone use MIDS, RELMIDS and MIDSDTC to describe the timing of the observation.

ML
MEAL DATA

ML – MEAL DATA (INTERVENTION CLASS)

- First published (Version 1.0 Provisional of the Diabetes Therapeutic Area User Guide (TAUG-Diabetes), released 2014-09-11, p.165), not reviewed
- For current public review to be found here: http://wiki.cdisc.org/pages/viewpage.action?pageId=29109919
- New definition: „The Meal Data domain model reflects collected details describing a subject's food product consumption." – Not yet available in current CT from 2016-06-24
- Removed variables: MLMODIFY, MLDECOD, MLINDC, MLDOSTOT, MLDOSRGM, MLROUTE, MLSTRF, MLENRF, MLSTRTPT, MLSTTPT, MLENRTPT, MLENTPT
- Added variables: MLDTC, MLDY, MLTPT, MLTPTNUM, MLELTM, MLTPTREF, MLRFTDTC, MIDS, RELMIDS, MIDSDTC
- Required variables: STUDYID, DOMAIN, USUBJID, MLSEQ, MLTRT
- Any additional Timing variable or Interventions Qualifiers to be added

CONTINUING: ML – MEAL DATA
ML – EXAMPLE

- Intended for: - *FOOD PRE-DEFINED IN PROTOCOL*
  - *FED AND FAST STUDIES*
  - *ANY NUTRITIONAL INTAKE*
- Not intended for: - *PRODUCTS KEPT IN SUBSTANCE USE (SU)*

CRF

Type	Occurrence		If yes, Date
Wild mushrooms	**X Yes**	No	2015 DEC 24
Ackee fruit	Yes	**X No**	
Cycad seeds	Yes	**X No**	

Type			If Nutritional Drink, volume (ounces)	Start Date	Start Time	Event ID
X Snack	Nutritional drink	Meal		2015 Jun 03	14:15	CE001
Snack	**X Nutritional drink**	Meal	8 oz	2015 Sep 03	8:30	CE002
Snack	Nutritional drink	**X Meal**		2015 Dec 31	19:00	CE003

ML

Row	STUDYID	DOMAIN	USUBJID	MLSEQ	MLTRT	MLCAT	MLPRESP	MLOCCUR	MLDOSE	MLDOSU	MLSTDTC	MLENDTC	MLEVLINT	RELMIDS	MIDS	MIDSDTC
1	XYZ	ML	XYZ-001-001	1	SNACK	HYPOGLYCEMIA EVALUATION	Y	Y			2015-06-03T14:15			LAST MEAL PRIOR TO	HYPO1	2015-06-03T19:20
2	XYZ	ML	XYZ-001-001	2	NUTRITIONAL DRINK	HYPOGLYCEMIA EVALUATION	Y	Y	8	oz	2015-09-03T08:30			LAST MEAL PRIOR TO	HYPO2	2015-09-03T17:00
3	XYZ	ML	XYZ-001-001	3	MEAL	HYPOGLYCEMIA EVALUATION	Y	Y			2015-12-31T19:00			LAST MEAL PRIOR TO	HYPO3	2016-01-01T10:30
4	XYZ	ML	XYZ-001-001	4	WILD MUSHROOMS	DILI EVALUATION	Y	Y			2015-12-24		-P1W			
5	XYZ	ML	XYZ-001-001	5	ACKEE FRUIT	DILI EVALUATION	Y	N					-P1W			
6	XYZ	ML	XYZ-001-001	6	CYCAD SEEDS	DILI EVALUATION	Y	N					-P1W			

ER
ENVIRONMENTAL RISK FACTORS

ER – ENVIRONMENTAL RISK FACTORS (EVENTS)

- Public review (Version 2.0 of the Tuberculosis Therapeutic Area User Guide (TAUG-TB), released 2016-02-26, p.15) http://wiki.cdisc.org/display/PUB/Draft+Standards+of+Interest+to+TAUG-TB
- For current public review to be found here: http://wiki.cdisc.org/pages/viewpage.action?pageId=29918868
- Domain is only draft and domain name is not yet available in current CT from 2016-06-24
- Removed variables: ERMODIFY, ERDECOD, ERBODSYS, ERBDSYCD, ERSTINT, ERENINT
- Added variables: TAETORD, ERSTRF, ERENRF
- Required variables: STUDYID, DOMAIN, USUBJID, ERTERM (even ERSEQ is perm)
- Any Identifier/Timing variables, or Events class Qualifier may be added excluding: --SER, --ACN, --ACNOTH, --REL, --RELNST, --OUT, --SCAN, --SCONG, --SDISAB, --SDTH, --SHOSP, -- SLIFE, -- SOD, -- SMIE

CONTINUING: ER – ENVIRONMENTAL RISK FACTORS

ER – EXAMPLE

- .Intended for:
  - *INFECTIOUS DISEASES* + *KNOWN EXPOSURES TO INFECTED PERSONS OR ANIMALS* + *POTENTIAL EXPOSURES VIA ENVIRONMENTAL CIRCUMSTANCES* + *HIGH-RISK BEHAVIORS*
  - NON-*INFECTIOUS DISEASES* + *PARTICIPATION IN CONTACT SPORTS* + *EXPOSURE TO PESTICIDES* + *HAZARDOUS MATERIALS, …*
- Not intended for:
  - *RISK FACTORS NOT DIRECTLY ASSOCIATED WITH EXPOSURE TO ENVIRONMENTAL FACTORS*

STUDYID	DOMAIN	USUBJID	ERSEQ	ERTERM	ERCAT	ERPRESP	EROCCUR	ERDTC	ERSTDTC	ERENDTC
CLN-03	ER	ABC-01-201	1	Percutaneous or mucous membrane exposure to blood or body fluids	EVD RISK FACTORS	Y	N	2015-03-10	2015-03-05	2015-03-05
CLN-03	ER	ABC-01-201	2	Direct skin contact	EVD RISK FACTORS	Y	N	2015-03-10	2015-03-05	2015-03-05
CLN-03	ER	ABC-01-201	3	Processing blood or body fluids of confirmed EVD patient	EVD RISK FACTORS	Y	Y	2015-03-10		
CLN-03	ER	ABC-01-201	4	Direct contact with dead body	EVD RISK FACTORS	Y	N	2015-03-10		
CLN-03	ER	ABC-01-201	5	Direct handling of bats	EVD RISK FACTORS	Y	Y	2015-03-10	2015-03-05	2015-03-05

OI
NON-HOST ORGANISM IDENTIFIERS

*OI – NON-HOST ORGANISM IDENTIFIERS (**STUDY REFERENCE**)*

- To establish study-specific terminology used in subject data.
  - Identifiers for devices
  - Identifiers for non-host organisms
  - Identifiers for pharmacogenomic/genetic biomarkers
- Planned: new Section 9 in SDTMIG; referencing SDTM Section 4
- The needs for these **identifiers** have been met by three datasets:
  - Device Identifiers (**DI**); introduced in SDTMIG for Medical Devices (**SDTMIG-MD**) as special-purpose domain / reclassified as Study Reference Dataset; identifiers established by means of the DI domain are used to populate *SPDEVID*, an identifier variable which may be included **in any general observation** class domain.
  - Phamacogenomic/Genetic Biomarkers (**PB**); introduced in SDTMIG Pharmacogenomics / Genetics (**SDMIG-PGx**) as special-purpose domain / reclassified as Study Reference Dataset. These *identifiers* are used **only in certain domains** described in the SDTMIG-PGx.
  - Non-host Organism Identifiers (**OI**); introduced as **draft domain** in the Therapeutic Area Data Standards User Guide for Virology (**TAUG-Virology**); incorporated into the new SDTMIG 3.3 Batch 3.

OI – NON-HOST ORGANISM IDENTIFIERS (STUDY REFERENCE)

- Public in Version 2.0 of the Virology Therapeutic Area User Guide (TAUG-Virology v2.0), released 2015-09-30 **Virology (Viral Resistance) Therapeutic Area User Guide v2** **http://www.cdisc.org/search/site/virology**
- For current public review to be found here: http://wiki.cdisc.org/pages/viewpage.action?pageId=33587591
- Any additional Timing variable or Interventions Qualifiers to be added

- Intended for:
  - *FOR STORING THE LEVELS OF TAXONOMIC NOMENCLATURE OF MICROBES OR PARASITES* + *EXPERIMENTALLY DETERMINED* + *PREVIOUSLY KNOWN AS IN THE CASE OF LAB STRAINS USED AS REFERENCE*
  - *VIRUSES*
  - *PATHOGENS OR PARASITES*
  - *NON-PATHOGENIC ORGANISMS* + *NORMAL INTESTINAL FLORA, …*
- Not intended for/to:
  - *HOST SPECIES IDENTIFICATION (E.G. IN ANIMAL STUDIES)*
  - *REPRESENT OTHER, NON-TAXONOMY CHARACTERISTICS OF NON-HOST SPECIES SUCH AS DRUG SUSCEPTIBILITY, GROWTH RATES, ETC.*

CONTINUING: OI – NON-HOST ORGANISM IDENTIFIERS

OI – EXAMPLE

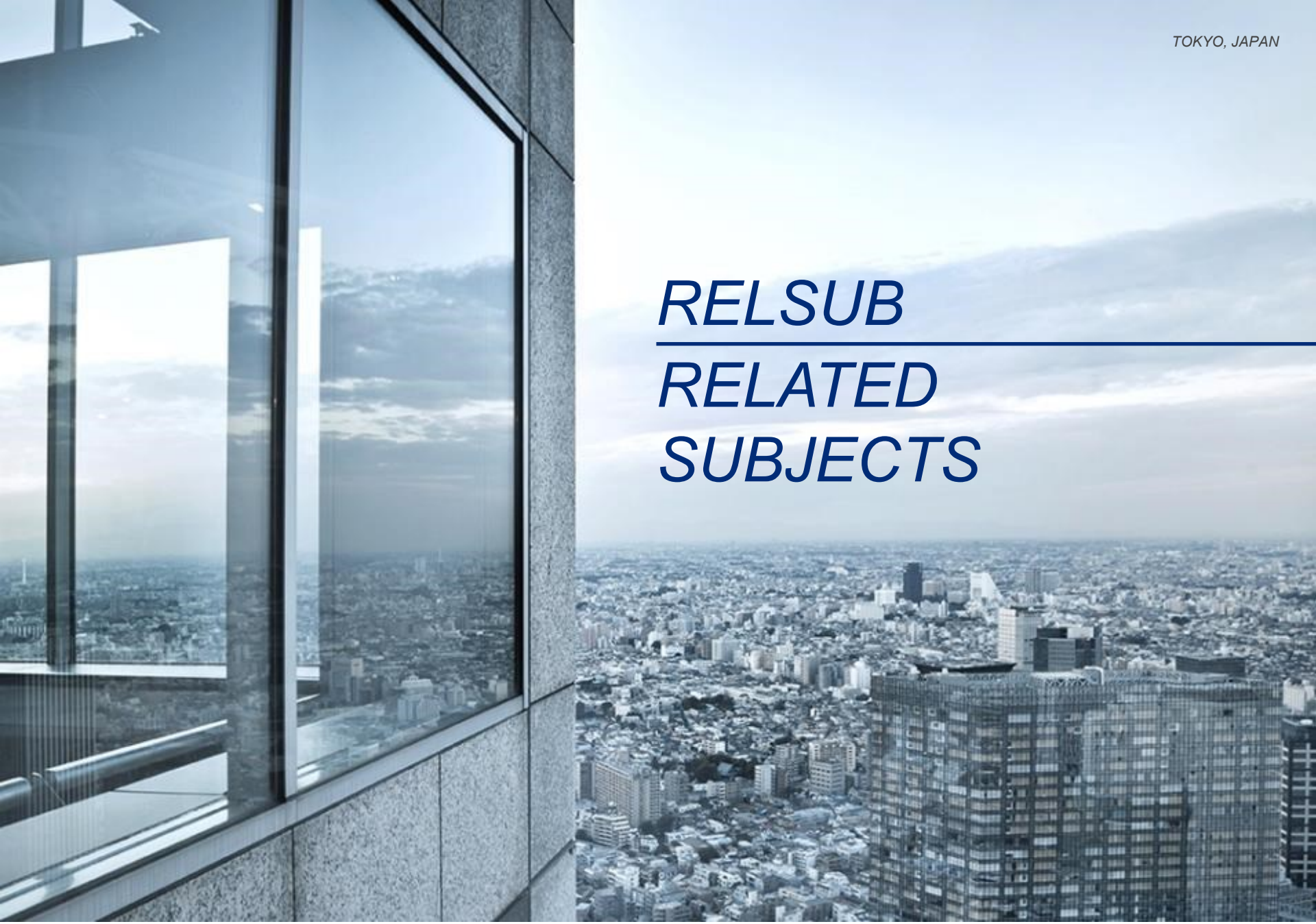
- All variables required
- Variables not listed in the OI domain table above should not be used in OI data sets.
- NHOID is:
  - Sponsor defined
  - Unique
  - With intuitive name
  - To be used in any domain where observations about these organisms are being represented

ms.xpt

Row	STUDYID	DOMAIN	USUBJID	MSSEQ	MSGRPID	NHOID	MSNSPCES	MSTESTCD	MSTEST
1	COINF1	MS	COINF1-01	1	1	HIV1MC	IUMA MMUNODEFICIENCY VIRUS 1	IC50S	IC50 Subject Result
2	COINF1	MS	COINF1-01	2	1	HIV1MB	IUMAN IMMUN FICIENCY VIRUS 1	IC50R	IC50 Reference Control Result
3	COINF1	MS	COINF1-01	3	1				
4	COINF1	MS	COINF1-01	4	2	HCV1a	H		
5	COINF1	MS	COINF1-01	5	2	HCV1a-H77	H		
6	COINF1	MS	COINF1-01	6	2				
7	COINF1	MS	COINF1-02	1	1	HIV1M/N	IUMAN IM		
8	COINF1	MS	COINF1-02	2	1	HIV1MB	IUMAN IM		
9	COINF1	MS	COINF1-02	3	1				
10	COINF1	MS	COINF1-02	4	2	HCV1a/b	H		
11	COINF1	MS	COINF1-02	5	2	HCV1a-H77	H		
12	COINF1	MS	COINF1-02	6	2				

oi.xpt

Row	STUDYID	DOM	NHOID	OISEQ	OIPARMCD	OIPARM	OIVAL
1	STUDY123	OI	HIV1MC	1	SPCIES	Species	HIV-1
2	STUDY123	OI	HIV1MC	2	GROUP	Group	M
3	STUDY123	OI	HIV1MC	3	SUBTYP	Subtype	C
4	STUDY123	OI	HIV1MB	1	SPCIES	Species	HIV-1
5	STUDY123	OI	HIV1MB	2	GROUP	Group	M
6	STUDY123	OI	HIV1MB	3	SUBTYP	Subtype	B
7	STUDY123	OI	HCV1a	1	SPCIES	Species	HCV
8	STUDY123	OI	HCV1a	2	GENTYP	Genotype	1
9	STUDY123	OI	HCV1a	3	SUBTYP	Subtype	a
10	STUDY123	OI	HCV1a-H77	1	SPCIES	Species	HCV
11	STUDY123	OI	HCV1a-H77	2	GENTYP	Genotype	1
12	STUDY123	OI	HCV1a-H77	3	SUBTYP	Subtype	a
13	STUDY123	OI	HCV1a-H77	4	ISOLATE	Isolate	H77
14	STUDY123	OI	HIV1M/N	1	SPCIES	Species	HIV-1
15	STUDY123	OI	HIV1M/N	2	GROUP	Group	M/N
16	STUDY123	OI	HCV1a/b	1	SPCIES	Species	HCV
17	STUDY123	OI	HCV1a/b	2	GENTYP	Genotype	1
18	STUDY123	OI	HCV1a/b	3	SUBTYP	Subtype	a/b



RELSUB RELATED SUBJECTS

RELSUB – RELATED SUBJECTS (RELATIONSHIP)

- Introduced in SDTM v1.4 (p.33, Section 4.1.4), but not been included in any version of SDTMIG.
- For current public review to be found here: http://wiki.cdisc.org/pages/viewpage.action?pageId=32806797
- Domain definition is not yet in current CT from 2016-06-24
- Variables required: STUDYID, RSUBJID, SREL; USUBJID is expected
- POOLID (permissible) developed for non-clinical studies => if POOLID submitted, POOLDEF relationship domain must be submitted
- RSUBJID must be a USUBJID value present in the DM domain. RSUBJID must be populated in every record.
- CT RELSUB for variable SREL already exists in version 2016-06-24; NCI code: C100130 http://evs.nci.nih.gov/ftp1/CDISC/SDTM/SDTM%20Terminology.html#top

CONTINUING: RELSUB – RELATED SUBJECTS

RELSUB – EXAMPLE

- Intended for: - *RELATIONSHIPS BETWEEN STUDY SUBJECTS, BOTH OF WHOM ARE STUDY SUBJECTS*
- Not intended for: - *RELATIONSHIP BETWEEN A STUDY SUBJECT AND PERSON WHO IS NOT A STUDY SUBJECT (APRELSUB TO BE USED)*

dm.xpt

Row	STUDYID	DOMAIN	USUBJID	BRTHDTC	AGE	AGEU	SEX
1	HEM021	DM	HEM021-001	1941-05-16	60	YEARS	F
2	HEM021	DM	HEM021-002	1965-04-12	35	YEARS	M
3	HEM021	DM	HEM021-003	1965-04-12	35	YEARS	M

relsub.xpt

Row	STUDYID	USUBJID	RSUBJID	SREL
1	HEM021	HEM021-001	HEM021-002	MOTHER, BIOLOGICAL
2	HEM021	HEM021-001	HEM021-003	MOTHER, BIOLOGICAL
3	HEM021	HEM021-002	HEM021-001	CHILD, BIOLOGICAL
4	HEM021	HEM021-002	HEM021-003	TWIN, DIZOGOTIC
5	HEM021	HEM021-003	HEM021-001	CHILD, BIOLOGICAL
6	HEM021	HEM021-003	HEM021-002	TWIN, DIZOGOTIC

THANK YOU

