SDTMIG 3.3: New domains, new benefits

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Agenda

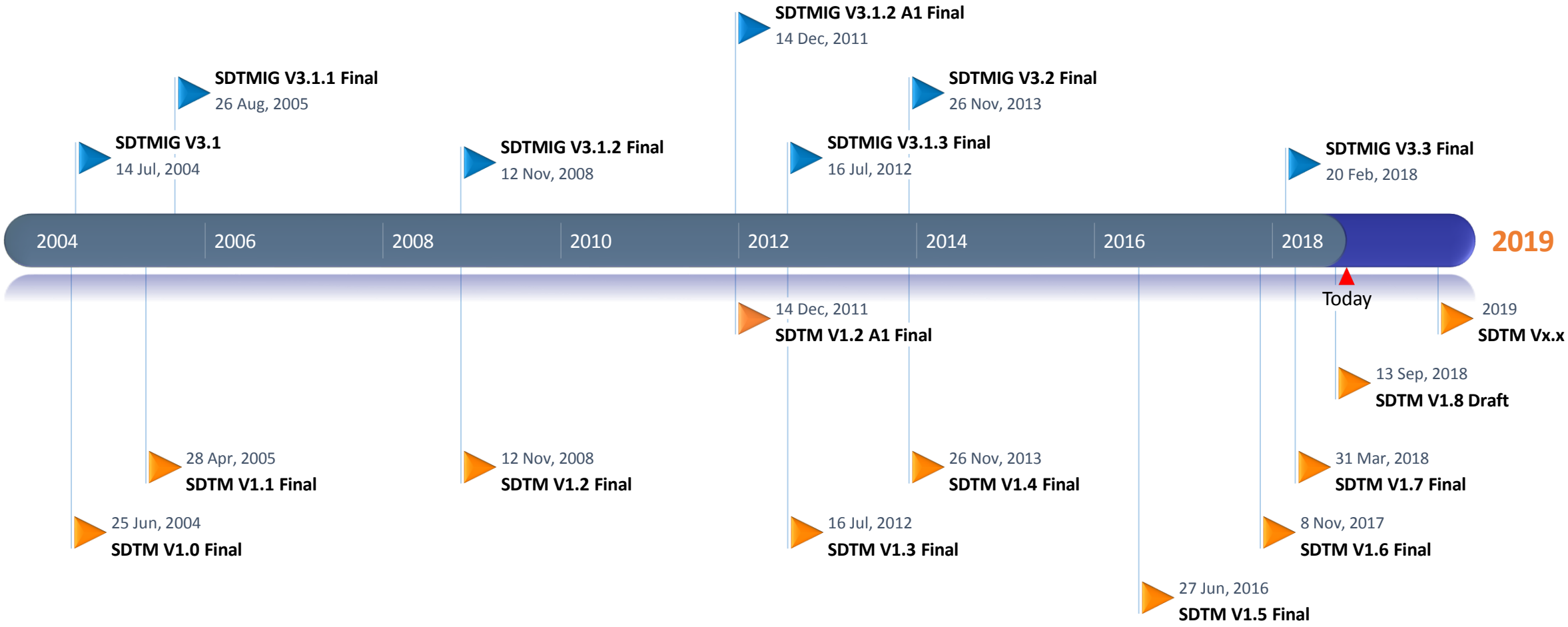
SDTMIG History

What's New

Deep Dive

Q&A

A brief history



Provisional vs Final

- ***Provisional use means that the standard has been published for initial use, and is dependent upon completion of other standards***
  - *The SDTM Model*
  - *Controlled Terminology (codelists referenced in the SDTMIG are published)*
  - *Conformance Rules*
  - *Metadata in SHARE*
  - *Educational learning objectives*

Grandfathered Standards

- ***SDTMIG v3.3 is grandfathered such that it will be published as Final (as opposed to Provisional) even though the SDS team is still working on the associated conformance rules***
  - ***Any standard that has already passed public review will be eligible for final publication in 2018***
  - ***Any standard that has already passed cross-team internal review and been approved by SRC or GGG to proceed to public review***
    - Will be eligible for **Provisional** publication in 2018
  - ***Publication guidelines:***
    - Still must be handed over to the publication team by cut-off date
    - Will be prioritized according to specific criteria

Current status

SDTMIG v3.3

3.3 Release Date: 20 Nov 2018

Version 3.3 of the Study Data Tabulation Model Implementation Guide for Human Clinical Trials (SDTMIG) is available in HTML format, which can be viewed in a browser.

Please log in or create an account to access the link to the Standard.

HTML Format

This release is published in HTML format, which expedites delivery of the standard and is viewable in any standard browser. HTML format allows users to search for keywords within the page, and bookmark the information in a browser. Implementers can also print the page, or export the information into other formats (e.g., PDF). To save a copy of the HTML publication on your desktop to access the document offline, press CTRL-S (PC) or COMMAND-S (Mac) on your keyboard.

Enhancements, Key Additions and Revisions

SDTMIG v3.3 provides the following enhancements, key additions and revisions to prior versions:

- Revised Disposition (DS) assumptions to facilitate greater clarity
- Introduction of morphology/physiology domains to support specific body systems
- New Functional Tests (FT) domain supporting QRS supplements
- Expanded Disease Response and Clin Classification (RS) domain to include QRS clinical classification content
- New class of Study References (e.g., Non-host Organism Identifiers)
- Many new examples, revisions, and corrections across domains
- New variables and assumptions for Demographics (DM)
- Associations to supplemental implementation guides (e.g., SDTMIG-PGx, SDTMIG-MD)
- Significant revisions to microbiology domains
- Additional new supporting domains (e.g., ML, TM, SM)
- Greater guidance on managing text strings that are more than 200 characters

Agenda

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Deep Dive

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New Variables

- *Included in previous SDTM versions*
  - *Changes from SDTM V1.4 to SDTM V1.5*
  - *Changes from SDTM V1.5 to SDTM V1.6*
  - *Changes from SDTM V1.6 to SDTM V1.7*
- *See back-up slides*

New Domains

Special Purpose

- Comments (CO)
- Demographics (DM)
- Subject Elements (SE)
- Subject Visits (SV)

- Subject Disease Milestones (SM)

Relationships

- Related Records (RELREC)
- Supplemental Qualifiers (SUPP--)

Trial Design

- Trial Arms (TA)
- Trial Elements (TE)
- Trial Visits (TV)
- Trial Disease Assessments (TD)
- Trial Inclusion/Exclusion Criteria (TI)
- Trial Summary (TS)

- Trial Disease Milestones (TM)

New Domains

Interventions

- Concomitant Medications (CM)
- Exposure (EX)
- Exposure as Collected (EC)
- Procedures (PR)
- Substance Use (SU)

- Procedure Agents (AG)
- Meal Data (ML)

Events

- Adverse Events (AE)
- Clinical Events (CE)
- Disposition (DS)
- Protocol Deviations (DV)
- Healtcare Encounters (HO)
- Medical History (MH)

Findings About Events or Interventions

- Findings About (FA)
- Skin Response (SR)

New Domains

Findings

- Drug Accountability (DA)
- Death Details (DD)
- ECG Test Results (EG)
- Inclusion/Exclusion Criteria Not Met (IE)
- Immunogenicity Specimen Assessments (IS)
- Laboratory Test Findings (LB)
- Microbiology Specimen (MB)
- Microbiology Susceptibility (MS)
- Microscopic Findings (MI)

Findings

- Pharmacokinetic Concentrations (PC)
- Pharmacokinetic Parameters (PP)
- Physical Examination (PE)
- Questionnaires (QS)
- Subject Characteristics (SC)
- Subject Status (SC)
- Tumor Identification (TU)
- Tumor Results (TR)
- Disease Response (RS)
- Vital Signs (VS)

Findings

- Morphology (MO)
- Reproductive System Findings (RP)
- Cardiovascular System Findings (CV)
- Musculoskeletal System Findings (MK)
- Nervous System Findings (NV)
- Ophthalmic Examinations (OE)
- Respiratory System Findings (RE)
- Urinary System Findings (UR)

Agenda

SDTMIG History

What's New

Deep Dive

Q&A

TM – Trial Disease Milestones

- ***Description:*** ***This domain is used to describe Disease Milestones, which are observations or activities anticipated to occur in the course of the disease under study, and which trigger the collection of data***

- ***Origin:*** ***TAUG Diabetes (V1.0 Provisional 2014-08-01)***

Row	STUDYID	DOMAIN	MIDSTYPE	TMDEF	TMRPT
1	XYZ	TM	DIAGNOSIS	Initial diagnosis of diabetes, the first time a physician told the subject they had diabetes	N
2	XYZ	TM	HYPOGLYCEMIC EVENT	Hypoglycemic Event, the occurrence of a glucose level below (threshold level)	Y

SM – Subject Disease Milestones

- *Description: This domain is designed to record the timing, for each subject, of Disease Milestones that have been defined in the Trial Disease Milestones (TM) dataset*

- *Origin: TAUG Diabetes (V1.0 Provisional 2014-08-01)*

Row	STUDYID	DOMAIN	USUBJID	SMSEQ	MIDS	MIDSTYPE	SMSTDTC	SMENDTC	SMSTDY	SMENDY
1	XYZ	SM	001	1	DIAG	DIAGNOSIS	2005-10			
2	XYZ	SM	001	2	HYPO1	HYPOGLYCEMIC EVENT	2013-09-01T11:00		25	
3	XYZ	SM	001	3	HYPO2	HYPOGLYCEMIC EVENT	2013-09-24T8:48		50	
4	XYZ	SM	002	1	DIAG	DIAGNOSIS	2010-05-15		-1046	

ML – Meal Data

- *Description: The Meal Data domain model reflects collected details describing a subject's food product consumption*

- *Origin: TAUG Diabetes (V1.0 Provisional 2014-08-01)*

Row	STUDYID	DOMAIN	USUBJID	MLSEQ	MLTRT	MLCAT	MLPRESP	MLOCCUR	MLDOSE	MLDOSU	MLSTDTC	MLENDTC	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

AG – Procedure Agents

- ***Description:*** ***A domain for the agents administered to the subject as part of a procedure or assessment, as opposed to drugs, medications, and therapies administered with therapeutic intent***

- ***Origin:*** ***TAUG Asthma (V1.0 Provisional 2013-11-26)***

Row	STUDYID	DOMAIN	USUBJID	AGSEQ	AGTRT	AGPRESP	AGOCCUR	AGDOSE	AGDOSU	AGROUTE	VISIT	AGENDTC
1	XYZ	AG	XYZ-001-001	1	SALINE	Y	Y	0	SQ-u/mL	RESPIRATORY (INHALATION)	SCREENING	2010-11-07T10:56:00
2	XYZ	AG	XYZ-001-001	2	GRASS	Y	Y	250	SQ-u/mL	RESPIRATORY (INHALATION)	SCREENING	2010-11-07T11:19:00
3	XYZ	AG	XYZ-001-001	3	GRASS	Y	Y	1000	SQ-u/mL	RESPIRATORY (INHALATION)	SCREENING	2010-11-07T11:43:00
4	XYZ	AG	XYZ-001-001	4	GRASS	Y	Y	2000	SQ-u/mL	RESPIRATORY (INHALATION)	SCREENING	2010-11-07T12:06:00

RE – Respiratory System Findings

- *Description: A domain for morphological and physiological findings related to the respiratory system, including the organs that are involved in breathing, such as the nose, throat, larynx, trachea, bronchi, and lungs*
- *Origin: TAUG Asthma (V1.0 Provisional 2013-11-26)*

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	Percent Predicted Forced Vital Capacity	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

Agenda

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What's New

Deep Dive

Q&A

ROI²
return on investment
through
return on information

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Back-up Slides

https://wiki.cdisc.org/display/SDTMIG33/Revision+History

https://www.cdisc.org/standards/in-development

https://wiki.cdisc.org/display/GGG/Standards+Development+Timeline

Changes from SDTM v1.4 to SDTM v1.5

Table 2.2.1: Interventions:

- ***--USCHFL Unscheduled Flag*** Unique for SEND, should not be used in SDTMIG

Table 2.2.2: Events:

- ***--USCHFL Unscheduled Flag***

Table 2.2.3: Findings:

- ***--ORREF Reference Result in Original Units***
- ***--STREFC Reference Result in Standard Format***
- ***--STREFN Numeric Reference Result in Std Units***
- ***--IMPLBL Implantation Site Label***
- ***--CHRON Chronicity of Finding***
- ***--DISTR Distribution Pattern of Finding***
- ***--LOBXFL Last Observation Before Exposure Flag***
- ***--USCHFL Unscheduled Flag***
- ***--REPNUM Repetition Number***

Changes from SDTM v1.4 to SDTM v1.5

Table 2.2.4: Identifiers for All Classes:

- *APID Associated Persons Identifier*
- *FETUSID Fetus Identifier*
- *FOCID Focus of Study Specific Interest*
- *--RECID Invariant Record Identifier*

Table 2.2.5: Timing Variables for All Classes:

- *--NOMDY Nominal Study Day for Tabulations*
- *--NOMLBL Label for Nominal Study Day*
- *MIDS Disease Milestone Instance Name*
- *RELMIDS Temporal Relation to Milestone Instance*
- *MIDSDTC Disease Milestone Instance Date/Time*

Table 2.2.10: Subject Disease Milestones (new table)

Table 2.2.11: Domain-Specific Variables for the General Observation Class (new table)

Table 3.5.2: Trial Disease Milestones (new table)

Changes from SDTM v1.5 to SDTM v1.6

Variable Changes:

Table 2.2.2: Interventions – Topic and Qualifier Variables Changed the Roles:

- ***--PSTRG – Pharmaceutical Strength from Variable Qualifier to Record Qualifier***
- ***--PSTRGU – Variable Qualifier of --PSTRG from Variable Qualifier to Variable Qualifier of --PSTRG***

Variable Additions:

Table 2.2.3: Findings – Topic and Qualifier Variables

- ***--RESLOC – Result Location of Finding***

Changes from SDTM v1.5 to SDTM v1.6

Table 2.2.5: Timing Variables for All Classes

- ***RPHASE – Repro Phase***
- ***RPPLDY – Planned Repro Phase Day of Observation***
- ***RPPLSTDY – Planned Repro Phase Day of Obs Start***
- ***RPPLENDY – Planned Repro Phase Day of Obs End***
- ***--RPDY – Actual Repro Phase Day of Observation***
- ***--RPSTDY – Actual Repro Phase Day of Obs Start***
- ***--RPENDY – Actual Repro Phase Day of Obs End***

Table 2.2.6: Demographics

- ***RPATHCD – Planned Repro Path Code***

Dataset Additions:

Table 2.2.11: Subject Repro Stages (new table)

Table 3.1.5: Trial Repro Stages (new table)

Table 3.1.6: Trial Repro Paths (new table)

Changes from SDTM v1.6 to SDTM v1.7

Variable Additions:

Table 2.2.1: Interventions - Topic and Qualifier Variables

- ***--RSDISC - Reason for Treatment Discontinuation***

Table 2.2.6: Demographics

- ***ARMNRS - Reason Arm and/or Actual Arm is Null***
- ***ACTARMUD - Description of Unplanned Actual Arm***

Table 2.2.7: Comments

- ***COEVALID - Evaluator Identifier***
- ***CODY - Study Day of Comment***

Changes from SDTM v1.6 to SDTM v1.7

Table 2.2.12: Domain-Specific Variables for General Observation Class Domains

- ***MHEVDTYP - Medical History Event Date Type***
- ***MSAGENT - Agent Name***
- ***MSCONC - Agent Concentration***
- ***MSCONCU - Agent Concentration Units***

Dataset Additions:

Table 4.1.5: Device-Subject Relationships Dataset

Table 5.1.1: Device Identifiers Dataset

Table 5.1.2: Non-Host Organism Identifiers Dataset

CV – Cardiovascular System Findings

- *Description: A domain for morphological and physiological findings related to the cardiovascular system, including the heart, blood vessels, and lymphatic vessels*

- *Origin: TAUG Cardiovascular Disease (V1.0 Draft 2014-04-07)*

Row	STUDYID	DOMAIN	USUBJID	CVSEQ	CVGRPID	CVTESTCD	CVTEST	CVORRES	CVSTRESC	CVLOC	CVMETHOD	VISITNUM	VISIT	CVDTC
1	ABC123	CV	002-2004	1	2	ANEURIND	Aneurysm Indicator	Y	Y	THORACIC AORTA	TRANSTHORACIC ECHOCARDIOGRAPHY	2	BASELINE	2015-06-09T14:20
2	ABC123	CV	002-2004	2	2	DISECIND	Dissection Indicator	Y	Y	THORACIC AORTA	TRANSTHORACIC ECHOCARDIOGRAPHY	2	BASELINE	2015-06-09T14:20
3	ABC123	CV	002-2004	3	2	STANFADC	Stanford AoD Classification	CLASS A	CLASS A	THORACIC AORTA	TRANSTHORACIC ECHOCARDIOGRAPHY	2	BASELINE	2015-06-09T14:20
4	ABC123	CV	002-2004	4		ANEURIND	Aneurysm Indicator	N	N	SUPRARENAL AORTA	TRANSTHORACIC ECHOCARDIOGRAPHY	2	BASELINE	2015-06-09T14:20
5	ABC123	CV	002-2004	5		ANEURIND	Aneurysm Indicator	N	N	INFRARENAL AORTA	TRANSTHORACIC ECHOCARDIOGRAPHY	2	BASELINE	2015-06-09T14:20

MK – Musculoskeletal System Findings

- *Description: A domain for morphological and physiological findings related to the system of muscles, tendons, ligaments, bones, joints, and associated tissues*

- *Origin: TAUG Duchenne Muscular Dystrophy (V1.0 Provisional 2017-09-25)*

Row	STUDYID	DOMAIN	USUBJID	MKSEQ	MKTESTCD	MKTEST	MKORRES	MKSTRESC	MKSTRESN	MKLOC	MKLAT	MKMETHOD	VISITNUM	VISIT	MKDTC
1	DEF	MK	DEF-138	1	TNDRIND	Tenderness Indicator	Y	Y		TEMPOROMANDIBULAR JOINT	RIGHT	PHYSICAL EXAMINATION	2	WEEK 4	2012-09-30
2	DEF	MK	DEF-138	2	SWLLIND	Swollen Indicator	Y	Y		TEMPOROMANDIBULAR JOINT	RIGHT	PHYSICAL EXAMINATION	2	WEEK 4	2012-09-30
3	DEF	MK	DEF-138	3	TNDRIND	Tenderness Indicator	N	N		TEMPOROMANDIBULAR JOINT	LEFT	PHYSICAL EXAMINATION	2	WEEK 4	2012-09-30
4	DEF	MK	DEF-138	4	SWLLIND	Swollen Indicator	N	N		TEMPOROMANDIBULAR JOINT	LEFT	PHYSICAL EXAMINATION	2	WEEK 4	2012-09-30

NV – Nervous System Findings

- *Description: A domain for physiological and morphological findings related to the nervous system based on neurological examinations or procedures, involving the brain, spinal cord, the cranial and spinal nerves, autonomic ganglia, and plexuses*
- *Origin: TAUG Alzheimer (V2.0 Final 2013-12-16)*

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	NVSEQ	NVREFID	NVLNKID	NVTESTCD	NVTEST	NVORRES	NVORRESU	NVLOC	NVDIR	NVMETHOD	VISITNUM	NVDTC
1	ABC123	NV	AD01-101	22	1	1236	03	SUVR	Standard Uptake Value Ratio	0.95	RATIO	PRECUNEUS		PET/CT SCAN	1	2012-05-22
2	ABC123	NV	AD01-101	22	2	1236	03	SUVR	Standard Uptake Value Ratio	1.17	RATIO	CINGULATE CORTEX	POSTERIOR	PET/CT SCAN	1	2012-05-22
3	ABC123	NV	AD01-102	22	1	1237	04	SUVR	Standard Uptake Value Ratio	1.21	RATIO	PRECUNEUS		PET/CT SCAN	1	2012-05-22
4	ABC123	NV	AD01-102	22	2	1237	04	SUVR	Standard Uptake Value Ratio	1.78	RATIO	CINGULATE CORTEX	POSTERIOR	PET/CT SCAN	1	2012-05-22
5	ABC123	NV	AD01-103	44	1	1238	05	SUVR	Standard Uptake Value Ratio	1.52	RATIO	PRECUNEUS		FDGPET	1	2012-05-22
6	ABC123	NV	AD01-103	44	2	1238	05	SUVR	Standard Uptake Value Ratio	1.63	RATIO	CINGULATE CORTEX	POSTERIOR	FDGPET	1	2012-05-22

OE – Ophthalmic Examinations

- ***Description:*** ***The OE domain is for findings related to tests that measure a person's ocular health and visual status, to detect abnormalities in the components of the visual system, and to determine how well the person can see***

- ***Origin:*** ***TAUG Multiple Sclerosis (V1.0 Provisional 2014-05-02)***

Row	STUDYID	DOMAIN	USUBJID	FOCID	OESEQ	OETESTCD	OETEST	OEORRES	OESTRESC	OELOC	OELAT	OEDIR	OEMETHOD	OEEVAL	VISITNUM	VISIT	OEDTC
1	XXX	OE	XXX-450-110	OS	1	INTP	Interpretation	NORMAL	NORMAL	LENS	LEFT		SLIT LAMP	INVESTIGATOR	1	SCREENING	2012-03-20
2	XXX	OE	XXX-450-110	OD	2	INTP	Interpretation	ABNORMAL	ABNORMAL	LENS	RIGHT		SLIT LAMP	INVESTIGATOR	1	SCREENING	2012-03-20
3	XXX	OE	XXX-450-110	OD	3	OEEXAM	Ophthalmic Examination	RED SPOT VISIBLE	RED SPOT VISIBLE	CONJUNCTIVA	RIGHT	MULTIPLE	SLIT LAMP	INVESTIGATOR	1	SCREENING	2012-03-20

UR – Urinary System Findings

- ***Description:*** ***A domain for morphological and physiological findings related to the urinary tract, including the organs involved in the creation and excretion of urine, such as the kidneys, ureters, bladder, and urethra***
- ***Origin:*** ***TAUG Polycystic Kidney Disease (V1.0 Provisional 2013-02-26)***

Row	STUDYID	DOMAIN	USUBJID	URSEQ	URTESTCD	URTEST	URORRES	URORRESU	URSTRESC	URSTRESN	URSTRESU	URLOC	URLAT	URDIR	URMETHOD	URDTC
1	ABC	UR	ABC-001-011	1	LENGTH	Length	12.6	cm	126	126	mm	KIDNEY	LEFT		CT SCAN	2016-03-30
2	ABC	UR	ABC-001-011	2	COUNT	Count	2		2	2		RENAL ARTERY	LEFT		CT SCAN	2016-03-30
3	ABC	UR	ABC-001-011	3	COUNT	Count	1		1	1		RENAL VEIN	LEFT		CT SCAN	2016-03-30
4	ABC	UR	ABC-001-011	4	HEMAIND	Hematoma Indicator	ABSENT		ABSENT			KIDNEY			CT SCAN	2016-03-30
5	ABC	UR	ABC-001-011	5	SGDMGIND	Surgical Damage Indicator	PRESENT		PRESENT			KIDNEY, CORTEX	LEFT	SUPERIOR	CT SCAN	2016-03-30