



INTEGO
GROUP

DS05: Implementation of SDTM IG v.3.3 for Neurological Therapeutic Area



Amsterdam 2019





PART I.

Introduction



Contents

- 1) TAUGs
- 2) SDTMIG v.3.3
- 3) Mapping of rawdata
- 4) Comparison
- 5) Examples



PART II.

TAUG. SDTMIG

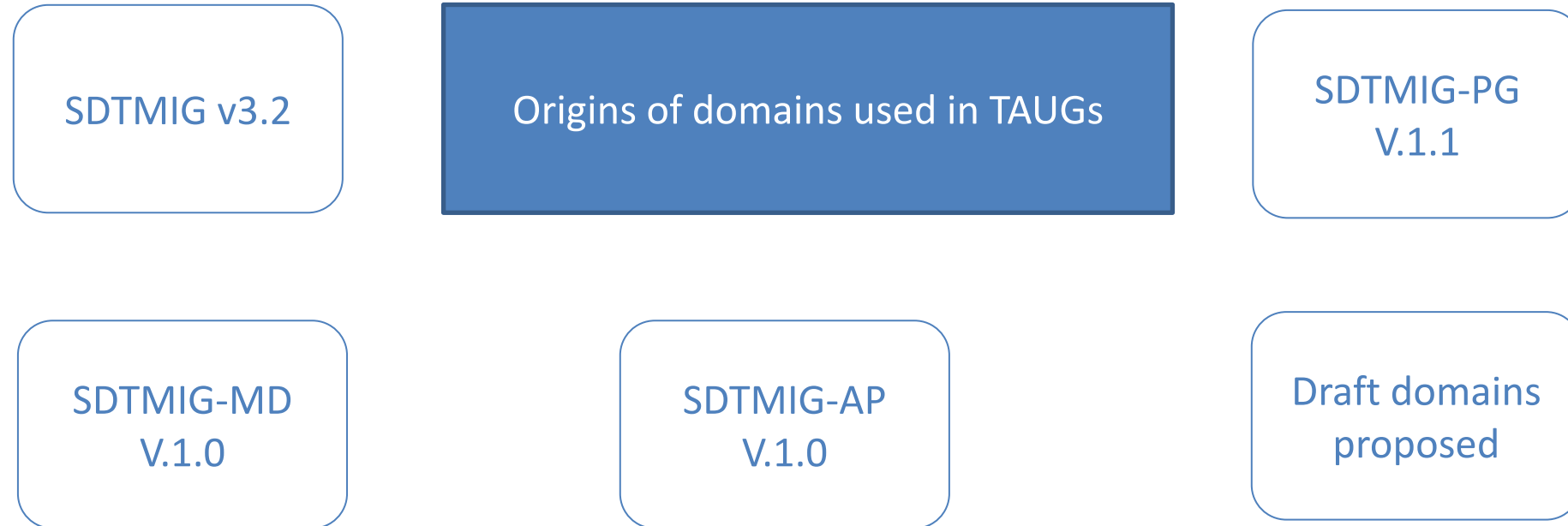


#	TAUGs	Based on	Date and Version	SDTM version	SDTMIG
1	Therapeutic Area User Guide for Parkinson's Disease NEUROLOGY	This is the provisional Parkinson's disease user guide for Human Clinical Trials corresponding to the CDISC Study Data Tabulation Model. It is based on the CDISC Submission Data Standards and domain models but includes draft domains slated for a future release of the SDTM Implementation Guide. · This work was funded by National Institute of Neurological Diseases and Stroke (NINDS), funded under a subcontract with KAI Research, Inc., via NINDS contract N01-NS-7-2372.	2012-12-18 v1.0 - Provisional	-	-
2	Therapeutic Area Data Standards User Guide for Alzheimer's Disease and Mild Cognitive Impairment NEUROLOGY	CFAST Alzheimer's Development Team • This document corresponds to the SDTM v1.4 and SDTMIG v3.2.	2013-12-16 2.0 TAUG-Alzheimer's v2.0	1.4	3.2
3	Therapeutic Area Data Standards User Guide for Multiple Sclerosis NEUROLOGY	Multiple Sclerosis Outcome Assessments Consortium and the CFAST Multiple Sclerosis Development Team • This document corresponds to the SDTM v1.4 and SDTMIG v3.2.	2014-05-02 Provisional Multiple Sclerosis User Guide v1.0 release	1.4	3.2
4	Therapeutic Area Data Standards User Guide for Traumatic Brain Injury NEUROLOGY	This document is based on SDTM v1.4 and SDTMIG v3.2, and on CDASH v1.1 and CDASHUG v1.0. • This document is based on SDTM v1.4 and SDTMIG v3.2, and on CDASH v1.1 and CDASHUG v1.0.	2015-12-02 Version 1.0 for provisional use	1.4	3.2
5	Therapeutic Area User Guide for Huntington's Disease NEUROLOGY	CFAST Huntington's Disease Standards Team • This document is based on SDTM v1.5, SDTMIG v3.2, SDTMIG-PGx v1.0, and SDTMIG-MD v1.0 (provisional).	2018-10-01 1.0 Provisional	1.5	3.2



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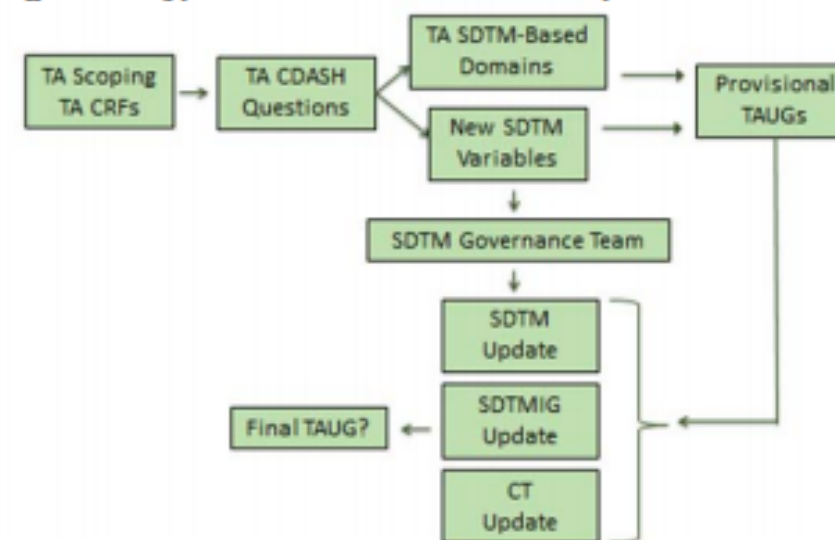


How to use TAUG?

- 1) Define TA
- 2) Rawdata mapped into any existing SDTMs
- 3) Any TAUG
- 4) Any CT

EXAMPLE from TAUG != REQUIREMENT

Figure 1. Typical TA Standards-Development Process



#	Year	TAUGs	TAUGs in Neurology
1	2012	1	1
2	2013	3	1
3	2014	3	1
4	2015	5	1
5	2016	9	
6	2017	5	
7	2018	4	1
8	2019	5	
9	2020	6+	

#	SDTM	PD	AD	HD	MS	TBI	Total	Comments
1	DI	+	+	+	+	+	5	
2	DU	+	+	+	+	+	5	
3	MO	+	+		+	+	4	Is decommissioning
4	*DO	+	+	+		+	4	SDTMIG-MD
5	MH		+		+	+	3	
6	PR		+	+		+	3	
7	NV		+	+	+		3	
8	BS	+	+	+			3	
9	LB		+	+			2	
10	AG		+	+			2	
11	CE	+			+		2	
12	OE				+	+	2	
13	FA				+	+	2	
14	BE		+	+			2	

AD	PD	MS	TBI	HD
Cognitive Impairments	Tremor	Depression	Loss of Consciousness	Irritability
Speech Problems	Walking Impairment	Pain	Memory Loss	Depression
Depression	Gait Impairment	Numbness/Tingling	Speech Problems	Pain
Sleeping Changes	Spacticity	Sexual Dysfunction	Confusion	Fatigue
Gait Slowed	Pain	Fatigue	Dizziness/Vertigo	Sleeping Problems
Dizziness/Vertigo	Depression	Spacticity	Blurry Vision	Walking Impairment
Swallowing (Advanced Stages)	Bowel/Bladder Problems	Lower And Upper Extremity Impairments	Tinnitus	Upper And Lower Extremity Impairments
Pain	Fatigue	Walking Impairment	Sleeping Impaired	Dizziness/Vertigo
	Sleeping Impaired	Bowel/Bladder Problems	Changes in Behavior and/or Mood	Cognitive Impairments
	Dizziness/Vertigo	Dizziness/Vertigo		Speech Problems
	Cognitive Impairments	Cognitive Impairments		
	Speech Problems			

New domains, pt.1

SPECIAL PURPOSE DOMAINS

1) SM

New domains, pt.1

SPECIAL PURPOSE DOMAINS

1) SM

INTERVENTIONS

1) AG

2) ML

New domains, pt.1

SPECIAL PURPOSE DOMAINS

1) SM

INTERVENTIONS

1) AG

2) ML

STUDY REFERENCES SECTION

1) DI

2) OI

3) PB

New domains, pt.1

SPECIAL PURPOSE DOMAINS

1) SM

STUDY REFERENCES SECTION

1) DI

2) OI

3) PB

INTERVENTIONS

1) AG

2) ML

TRIAL DOMAINS

1) TM

New domains, pt.1

SPECIAL PURPOSE DOMAINS

1) SM

STUDY REFERENCES SECTION

1) DI

2) OI

3) PB

INTERVENTIONS

1) AG

2) ML

TRIAL DOMAINS

1) TM

FINDINGS

1) FT

New domains, pt.1

SPECIAL PURPOSE DOMAINS

1) SM

STUDY REFERENCES SECTION

1) DI

2) OI

3) PB

INTERVENTIONS

1) AG

2) ML

TRIAL DOMAINS

1) TM

FINDINGS

1) FT

ag.xpt

Row	STUDYID	DOMAIN	USUBJID	AGSEQ	AGTRT	AGPRES	AGOCUR	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

ag.xpt

Row	STUDYID	DOMAIN	USUBJID	AGSEQ	AGTRT	AGPRES	AGOCUR	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

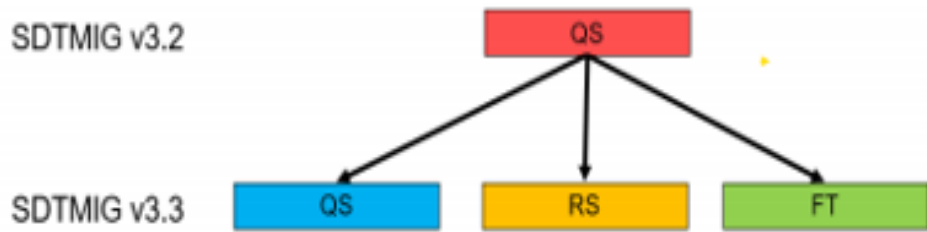
STUDYID	DOMAIN	SPDEVID	DISEQ	DIPARMCD	DIPARM	DIVAL
AB1001	DI	20000	1	MANUF	Manufacturer	Manufacturer
AB1001	DI	20000	2	MODEL	Model	ABC123
AB1001	DI	20000	3	PACK	Pack Number	20000
AB1001	DI	20000	4	SERIAL	Serial Number	A745631
AB1001	DI	20000	5	TYPE	Type of Device	TBD
AB1001	DI	20001	1	MANUF	Manufacturer	Manufacturer
AB1001	DI	20001	2	MODEL	Model	ABC123
AB1001	DI	20001	3	PACK	Pack Number	20001
AB1001	DI	20001	4	SERIAL	Serial Number	A852746
AB1001	DI	20001	5	TYPE	Type of Device	TBD

ag.xpt

Row	STUDYID	DOMAIN	USUBJID	AGSEQ	AGTRT	AGPRES	AGOCUR	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

STUDYID	DOMAIN	SPDEVID	DISEQ	DIPARMCD	DIPARM	DIVAL
AB1001	DI	20000	1	MANUF	Manufacturer	Manufacturer
AB1001	DI	20000	2	MODEL	Model	ABC123
AB1001	DI	20000	3	PACK	Pack Number	20000
AB1001	DI	20000	4	SERIAL	Serial Number	A745631
AB1001	DI	20000	5	TYPE	Type of Device	TBD
AB1001	DI	20001	1	MANUF	Manufacturer	Manufacturer
AB1001	DI	20001	2	MODEL	Model	ABC123
AB1001	DI	20001	3	PACK	Pack Number	20001
AB1001	DI	20001	4	SERIAL	Serial Number	A852746
AB1001	DI	20001	5	TYPE	Type of Device	TBD

ROW	STUDYID	PBSEQ	PBMRKRID	PBMRKR	PBGENRI	PBGENTYP	PBDRUG	PBSTMT
1	ABC-1234	1	C463A	c.463C>A	SLCO1B1	DNA	XStatin	Reduced Transporter Activity
2	ABC-1234	2	A388G	c.388A>G	SLCO1B1	DNA	XStatin	Reduced Transporter Activity
3	ABC-1234	3	T521C	c.521T>C	SLCO1B1	DNA	XStatin	Increased Transporter Activity



Row	STUDYID	DOMAIN	USUBJID	FTSEQ	FTTESTCD	FTTEST	FTCAT	FTORRES	FTORRESU	FTSTRESC	FTSTRESN	FTSTRESU	FTLOBXFL	VISITNUM	FTDTC
1	STUDYX	FT	P0001	1	FYD01001	FYD01-Time	FORTY YARD DASH	5.2	sec	5.2	5.2	sec	Y	1	2012-11-16
2	STUDYX	FT	P0001	2	FYD01001	FYD01-Time	FORTY YARD DASH	5	sec	5	5	sec		2	2012-11-23
3	STUDYX	FT	P0001	3	FYD01001	FYD01-Time	FORTY YARD DASH	4.9	sec	4.9	4.9	sec		3	2012-11-30

New domains, pt.2, Morphology/Physiology

SPECIAL PURPOSE DOMAINS

- 1) Cardiovascular System Findings (CV)
- 2) Musculoskeletal System Findings (MK)
- 3) Nervous System Findings (NV)
- 4) Ophthalmic Examinations (OE)
- 5) Respiratory System Findings (RE)
- 6) Urinary System Findings (UI)

New domains, pt.2, Morphology/Physiology

SPECIAL PURPOSE DOMAINS

- 1) Cardiovascular System Findings (CV)
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- 5) Respiratory System Findings (RE)
- 6) Urinary System Findings (UI)

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	NVSEQ	NVREFID	NVLNKID	NVTESTCD	NVTEST	NVORRES	NVORRESU	NVSTRESC	NVSTRESN	NVSTRESU	NVLOC	NVDIR
1	ABC123	NV	AD01-101	22	1	1236	03	SUVR	Standard Uptake Value Ratio	.95	RATIO	.95	.95	RATIO	PRECUNEUS	
2	ABC123	NV	AD01-101	22	2	1236	03	SUVR	Standard Uptake Value Ratio	1.17	RATIO	1.17		RATIO	CINGULATE CORTEX	POSTERIOR
3	ABC123	NV	AD01-102	22	1	1237	04	SUVR	Standard Uptake Value Ratio	1.21	RATIO	1.21	1.21	RATIO	PRECUNEUS	
4	ABC123	NV	AD01-102	22	2	1237	04	SUVR	Standard Uptake Value Ratio	1.78	RATIO	1.78	1.78	RATIO	CINGULATE CORTEX	POSTERIOR
5	ABC123	NV	AD01-103	44	1	1238	05	SUVR	Standard Uptake Value Ratio	1.52	RATIO	1.52	1.52	RATIO	PRECUNEUS	
6	ABC123	NV	AD01-103	44	2	1238	05	SUVR	Standard Uptake Value Ratio	1.63	RATIO	1.63	1.63	RATIO	CINGULATE CORTEX	POSTERIOR

Row	STUDYID	DOMAIN	USUBJID	FOCID	OSEQ	OELNKID	OETESTCD	OETEST	OERRES	OERRESU	OESTRESC	OESTRESN	OESTRESU	OELC	OELAT	OEMETHOD
1	XYZ	OE	XYZ-100-001	OS	1		EDEMA	Edema	PRESENT		PRESENT			MACULA	LEFT	OPHTHALMOSCOPY
2	XYZ	OE	XYZ-100-001	OD	2		EDEMA	Edema	ABSENT		ABSENT			MACULA	RIGHT	OPHTHALMOSCOPY
3	XYZ	OE	XYZ-100-001	OS	3	1	EDEMA	Edema	PRESENT		PRESENT			MACULA	LEFT	OPTICAL COHERENCE TOMOGRAPHY
4	XYZ	OE	XYZ-100-001	OD	4	2	EDEMA	Edema	ABSENT		ABSENT			MACULA	RIGHT	OPTICAL COHERENCE TOMOGRAPHY
5	XYZ	OE	XYZ-100-001	OS	5	1	THICK	Thickness	1030	um	1030	1030	um	MACULA	LEFT	OPTICAL COHERENCE TOMOGRAPHY
6	XYZ	OE	XYZ-100-001	OD	6	2	THICK	Thickness	1005	um	1005	1005	um	MACULA	RIGHT	OPTICAL COHERENCE TOMOGRAPHY

MO=Morphology

MI=Microscopic

BS=Bio-Specimen

CE=Clinical Event

Neuropathology

Page 1 of 7

[Study Name/ID pre-filled]

Site Name: _____

Subject ID: _____

BRAIN TISSUE AND POST MORTEM CSF

8. Is banked frozen brain tissue accessible?

☐ Yes ☐ No ☐ Unknown

BSORRES for BSTEMESTCD=ACCESSBL

BSSPEC=TISSUE

QNAM=BSSPCFRM

BSLOC=BRAIN

9. Is formalin-fixed brain tissue accessible?

☐ Yes ☐ No ☐ Unknown

BSORRES for BSTEMESTCD= ACCESSBL

BSSPEC=TISSUE

QNAM=BSSPCFRM

BSLOC=BRAIN

10. Are paraffin-embedded blocks of brain tissue accessible?

☐ Yes ☐ No ☐ Unknown

BSORRES for BSTEMESTCD= ACCESSBL

BSSPEC=TISSUE

QNAM=BSSPCFRM

BSLOC=BRAIN

BSLOC=BRAIN

MACROSCOPIC ASPECTS

14. Brain weight

Record brain

MOORRES for MOTESTCD=WEIGHT

MOORRESU

MOLOC=BRAIN

MOLAT

weight: _____ (grams)

What hemisphere of brain was evaluated? ☐ Left ☐ Right ☐ Both ☐ N/A

14a. Type of tissue weighed

MOSPEC=TISSUE

QNAM=SPCFRM in SUPPMO

☐ Whole fresh brain ☐ Whole fixed brain ☐ Fixed hemibrain (calculated whole brain weight) ☐ Unknown

MOORRES for MOTESTCD=HYDROCPH

MOLOC=BRAIN

MOLAT

15. Hydrocephalus

☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Not assessed ☐ Unknown

Start date of relapse symptoms	CESTDTC	
End date of relapse symptoms	CEENDTC	
Recovery from relapse	None	☐
SUPPCE.QVAL where QNAM=RECOVER	Partial	☐
	Complete	☐

Recovery from relapse 0=None 1=Partial 2=Complete	Hospitalization 0=No 1=Yes	Steroid used 0=No 1=Yes	Confirmed relapse 0=No 1=Yes	Severity 1=Mild 2=Moderate 3=Severe	Affects daily activities 0=No 1=Yes
Start date of relapse symptoms CESTDTC	End date of relapse symptoms CEENDTC	Recovery from relapse 0 1 2 ☐ ☐ ☐	Hospitalization 0 1 ☐ ☐	CESHOSP	
CEOUTOR in SUPPCE					



PART III.

Conclusion



PROS:

- Clearly defined rules and codelists
- Consistency
- Principles
- TA

CONS:

- Duplicated information
- Specific domains
(important/not important)
- Updates
- No validation



THANK YOU FOR ATTENTION😊





QUESTIONS?





THANK YOU

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