



2nd eHS Workshop, CC-IN2P3
14th October 2015, Lyon,



eTR!KS



efpia*



CDISC tranSMART master tree via tranSMART clinical study tree.

Work Package Number: WP3&WP4

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AGENDA:

- ✓ Goal
- ✓ Input, output
- ✓ Achievements
- ✓ Proposition of planned activities 2015-2016
- ✓ Resource and/or material needs to be addressed.
When? How?



eTRIKS tranSMART goals

- tranSMART Standards Master Ontology Tree (TM-SMOT) designed based on the SDTM model.
- SDTM IMI clinical study data mapped via the MT-SMOT and going on the tranSMART tree CDISC standard model
- CDASH IMI Clinical data mapped via the MT-SMOT and going on the tranSMART three CDISC standard model



eTRIKS tranSMART tree procedures

Operational side

to define variable, term, data label, validation test

Development side

to design template forms (e.g. TM-SMOT)

to define business rules (e.g. split data, annotation tranSMART language)

to test the mapping/upload processes

(e.g. a kettle job "create_clinical_data.kjb")

Strategic side

what are we doing, new capability, planning, validation



Operational side

The study package – An overview – Challenge MT

SDTM model use case



eSHARE Downloads



eSHARE Catalog: 2015-09-29

This catalog provides a listing of the eSHARE content available for download as of the above date. Users must access this content through eSHARE using their account on the CDISC web site.

<http://cdisc.org/eshare-downloads>

CDASH

Date Posted	Content	Version	Type	Download File
2014-06-02	CDASH	1.1	Metadata	• ODM v1.1 • CSV • Excel
2014-06-02	CDASH + CT	1.1 + 2013-12	Bundle	• ODM • Excel
2014-06-02	CDASH	1.1	Document	• PDF
2014-06-02	CDASH UG	1.1	Document	• PDF

CDISC sources

SDTM metadata version

Date Posted	Content	Version	Type	Download Files
SDTM 1.5 (IG 3.3)				
2015-07-14	SDTM IG Diff	3.3 (Draft) - 3.2	For Review	• Excel
2015-07-14	SDTM (IG)	1.5 (3.3) (Draft)	For Review	• Excel

SDTMIG version

CDISC SDTM Implementation Guide (Version 3.1.3)



Study Data Tabulation Model Implementation Guide: Human Clinical Trials

Prepared by the CDISC Submission Data Standards Team

Notes to Readers

- This is the implementation guide for the CDISC Submission Data Standards Team.
- The address of any variable in the present document is the address of the corresponding variable in the CDISC Submission Data Standards Team.
- This implementation guide complies with version 3.1.3 (3.1.3) of the CDISC Submission Data Standards Team and its derivatives.

Date	Version	Summary of Changes
2012-07-19	3.1.3 Final	Final version of the implementation guide for the CDISC Submission Data Standards Team. This version includes the following updates: • The address of any variable in the present document is the address of the corresponding variable in the CDISC Submission Data Standards Team. • The incorporation of the content previously published in the CDISC Implementation Guide for the CDISC Submission Data Standards Team. • Changes to the CDISC Submission Data Standards Team logo. • Deleted extraneous updates. • Updated the CDISC Submission Data Standards Team logo.
2012-07-22	3.1.3 Draft	Final version of the implementation guide for the CDISC Submission Data Standards Team. This version includes the following updates: • The address of any variable in the present document is the address of the corresponding variable in the CDISC Submission Data Standards Team. • The incorporation of the content previously published in the CDISC Implementation Guide for the CDISC Submission Data Standards Team. • Deleted extraneous updates. • Updated the CDISC Submission Data Standards Team logo.
2012-08-28	3.1.3 Final	Final version of the implementation guide for the CDISC Submission Data Standards Team. This version includes the following updates: • The address of any variable in the present document is the address of the corresponding variable in the CDISC Submission Data Standards Team. • The incorporation of the content previously published in the CDISC Implementation Guide for the CDISC Submission Data Standards Team. • Deleted extraneous updates. • Updated the CDISC Submission Data Standards Team logo.
2012-07-14	3.1	Final version of the implementation guide for the CDISC Submission Data Standards Team. This version includes the following updates: • The address of any variable in the present document is the address of the corresponding variable in the CDISC Submission Data Standards Team. • The incorporation of the content previously published in the CDISC Implementation Guide for the CDISC Submission Data Standards Team. • Deleted extraneous updates. • Updated the CDISC Submission Data Standards Team logo.

Note: Please see Appendix F for Representations and Variations, Limitations of Liability, and Disclaimers.

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SDTM model version



Study Data Tabulation Model Version 1.4

Prepared by the CDISC Submission Data Standards Team

Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value	CDISC Synonym(s)	CDISC Definition	NCI Preferred Term
C66767		No	Action Taken with Study Treatment	ACT	Action Taken with Study Treatment	Action Taken with Study Treatment	CDISC SDTM Action Taken with Study Treatment Terminology
C49503	C66767		Action Taken with Study Treatment	DOSE INCREASED		An indication that a medication schedule was modified by addition, either by changing the frequency, strength or amount. (NCI)	Dose Increased
C49504	C66767		Action Taken with Study Treatment	DOSE NOT CHANGED		An indication that a medication schedule was maintained. (NCI)	Dose Not Changed
C49505	C66767		Action Taken with Study Treatment	DOSE REDUCED		An indication that a medication schedule was modified by subtraction, either by changing the frequency, strength or amount. (NCI)	Dose Reduced
C49501	C66767		Action Taken with Study Treatment	DRUG INTERRUPTED		An indication that a medication schedule was modified by temporarily terminating a prescribed regimen of medication. (NCI)	Drug Interrupted
C49502	C66767		Action Taken with Study Treatment	DRUG WITHDRAWN		An indication that a medication schedule was modified through termination of a prescribed regimen of medication. (NCI)	Drug Withdrawn
C48860	C66767		Action Taken with Study Treatment	NOT APPLICABLE	NA; Not Applicable	Determination of a value is not relevant in the current context. (NCI)	Not Applicable
C17998	C66767		Action Taken with Study Treatment	UNKNOWN	U; Unknown	Not known, not observed, not recorded, or refused. (NCI)	Unknown
C66768		No	Outcome of Event	OUT	Outcome of Event	A condition or event that is attributed to the adverse event and is the result or conclusion of the adverse event. (NCI)	CDISC SDTM Adverse Event Outcome Terminology
C48275	C66768		Outcome of Event	FATAL	Grade 5; 5; FATAL	The termination of life as a result of an adverse event. (NCI)	Death Related to Adverse Event

Control terminology version

Clinical Study SDTM files

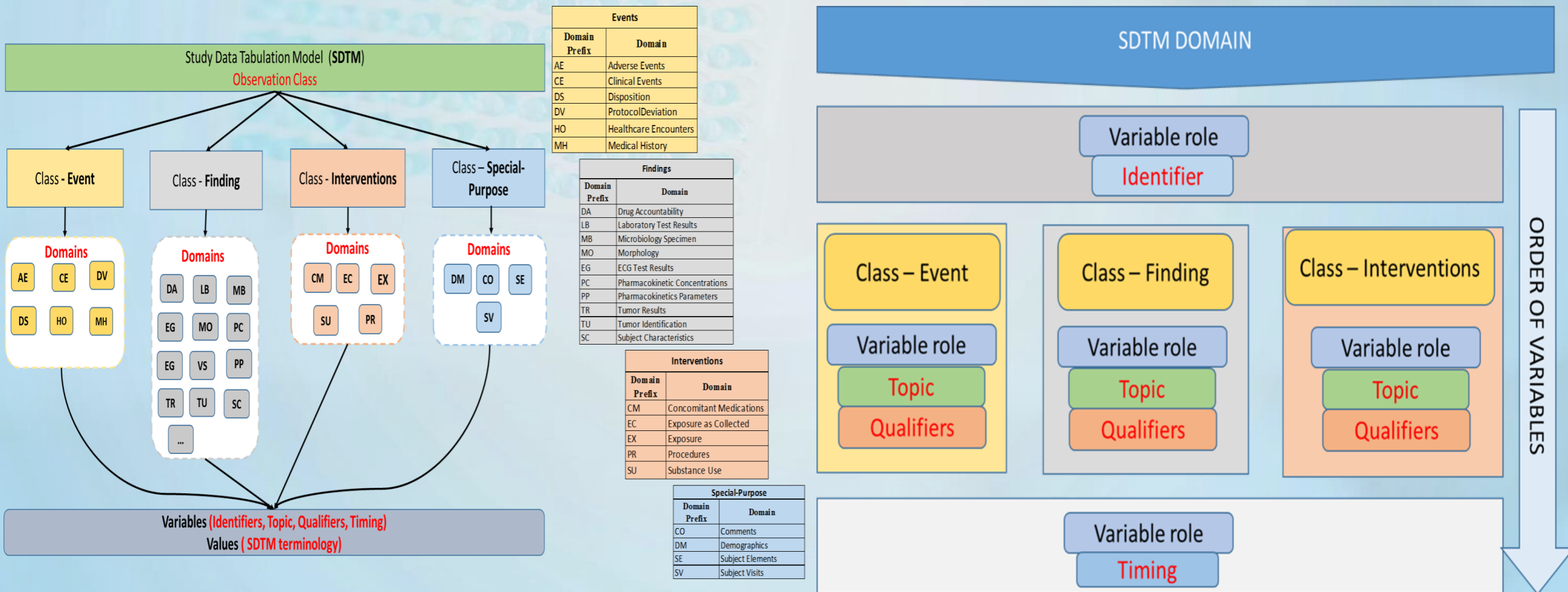
eTRIKS project sources

Alignment across SDTM domains:

- One version SDTM IG per study/side
- One version SDTM model per study /side
- One version Control terminology per study /side
- One version SDTM metadata per study/side
- One version SDTM Clinical study metadata
- ETL directory of the transSMART

<http://www.cdisc.org>

<https://github.com/transmart/tranSMART-ETL/tree/master/Postgres/GPL%201.0/Kettle/Kettle-ETL>





TM-SMOT template

tranSMART ontology

CDISC ontology

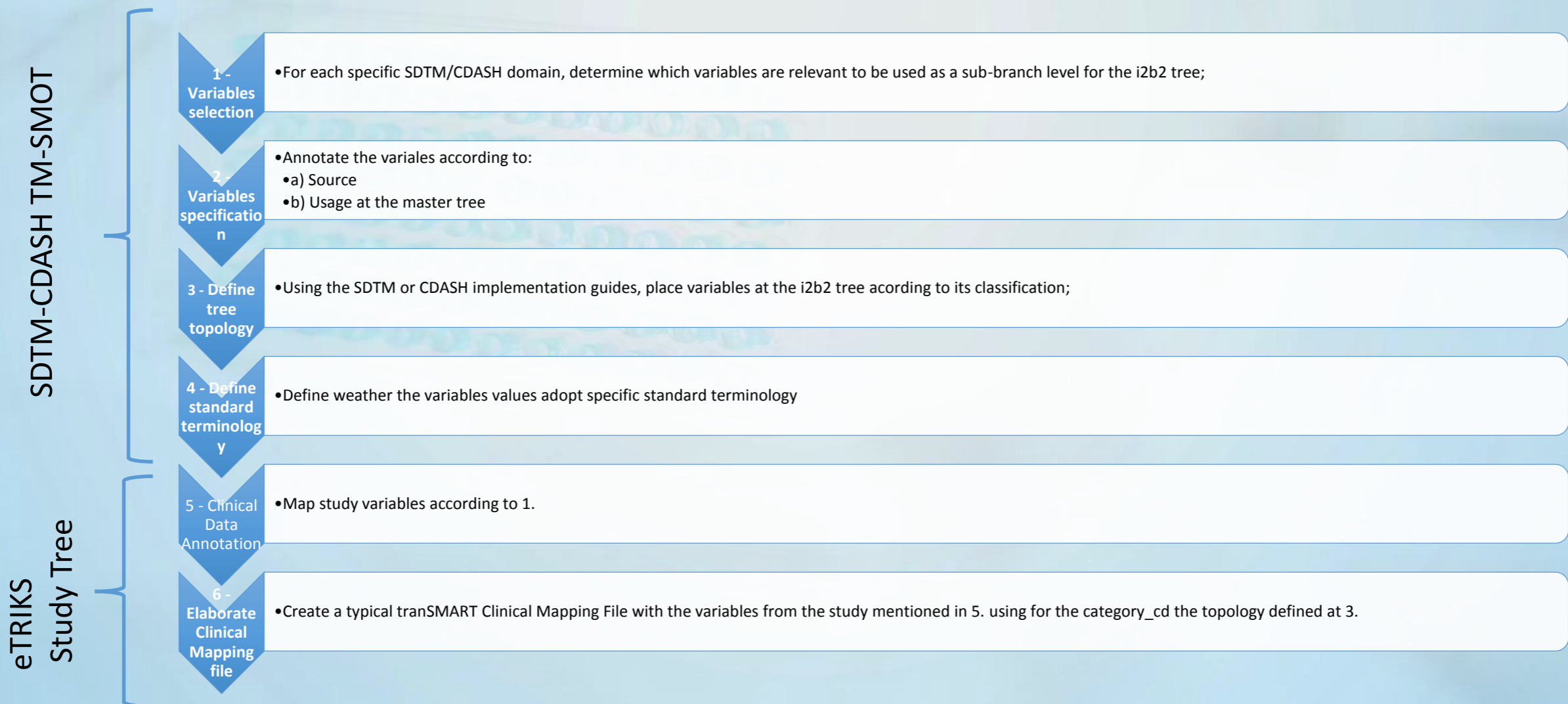
Seq. For Order	Observation Class	Domain Prefix	Domain	Variable Name	Variable Label	Type	Controlled Terms or Format	Role	Core	Seq. For Order	Variable name (control_vocal_code)	Variable label (data_label)	Usage at MasterTree	category_cd
1	Findings About	SR	Skin_Response_(SR)	STUDYID	Study Identifier	Char		Identifier	Req	1	STUDYID	Study Identifier	OMIT	
2	Findings About	SR	Skin_Response_(SR)	DOMAIN	Domain Abbreviation	Char	SR	Identifier	Req	2	DOMAIN	Domain Abbreviation	OMIT	
3	Findings About	SR	Skin_Response_(SR)	USUBJID	Unique Subject Identifier	Char		Identifier	Req	3	USUBJID	Unique Subject Identifier(SUBJ_ID)	SUBJ_ID	
4	Findings About	SR	Skin_Response_(SR)	SRSEQ	Sequence Number	Num		Identifier	Req	4	SRSEQ	Sequence Number	OMIT	
						Char		Identifier	Perm	5	SRGRPID	Group ID	Level of sub-branch	TA-Asthma+Findings-About_Class_Domains+Skin_Response_(SR)+Identifier
						Char		Identifier	Perm	6	SRREFID	Reference ID	OMIT	
7	Findings About	SR	Skin_Response_(SR)	SRSPID	Sponsor-Defined Identifier	Char		Identifier	Perm	7	SRSPID	Sponsor-Defined Identifier	Level of sub-branch	TA-Asthma+Findings-About_Class_Domains
8	Findings About	SR	Skin_Response_(SR)	SRTESTCD	Skin Response Test or Exam Short Name	Char		Topic	Req	8	SRTESTCD	Skin Response Test or Exam Short Name	Level of sub-branch	TA-Asthma+Findings-About_Class_Domains
9	Findings About	SR	Skin_Response_(SR)	SRTEST	Skin Response Test or Examination Name	Char		Synonym Qualifier	Req	9	SRTEST	Skin Response Test or Examination Name	Level of sub-branch	TA-Asthma+Findings-About_Class_Domains
10	Findings About	SR	Skin_Response_(SR)	SROBJ	Object of the Observation	Char		Record Qualifier	Req	10	SROBJ	Object of the Observation	Level of sub-branch	TA-Asthma+Findings-About_Class_Domains
11	Findings About	SR	Skin_Response_(SR)	SRCAT	Category for Test	Char		Grouping Qualifier	Perm	11	SRCAT	Category for Test	Level of sub-branch	TA-Asthma+Findings-About_Class_Domains
12	Findings About	SR	Skin_Response_(SR)	SRSCAT	Subcategory for Test	Char		Grouping Qualifier	Perm	12	SRSCAT	Subcategory for Test	Level of sub-branch	TA-Asthma+Findings-About_Class_Domains
13	Findings About	SR	Skin_Response_(SR)	SRORRES	Results or Findings in Original Units	Char		Result Qualifier	Exp	13	SRORRES	Results or Findings in Original Units	OMIT	
14	Findings About	SR	Skin_Response_(SR)	SRORRESU	Original Units	Char	UNIT	Variable Qualifier	Exp	14	SRORRESU	Original Units	OMIT	
15	Findings About	SR	Skin_Response_(SR)	SRORRESU	Original Units	Char		Variable Qualifier	Exp	15	SRORRESU	Original Units	OMIT	

The business rules (a few of)

- ❖ The define the variables which will be included in the Level of sub branch based on the SDTM role
- ❖ The rules for splitting dataset in sub datasets, for annotation, for conversion....
- ❖ To lunch job for upload data into tranSMART...
- ❖ I2b2 workflow design ...



The annotation-mapping/upload processes i2b2 tree workflow





Achievements:

tranSMART Standards Master Ontology Tree (TM-SMOT) ready for

A. SDTMIG 3.2 -TM-SMOT: CDISC01 TM-SMOT

B. TAUG Asthma v1.0 - TM-SMOT :

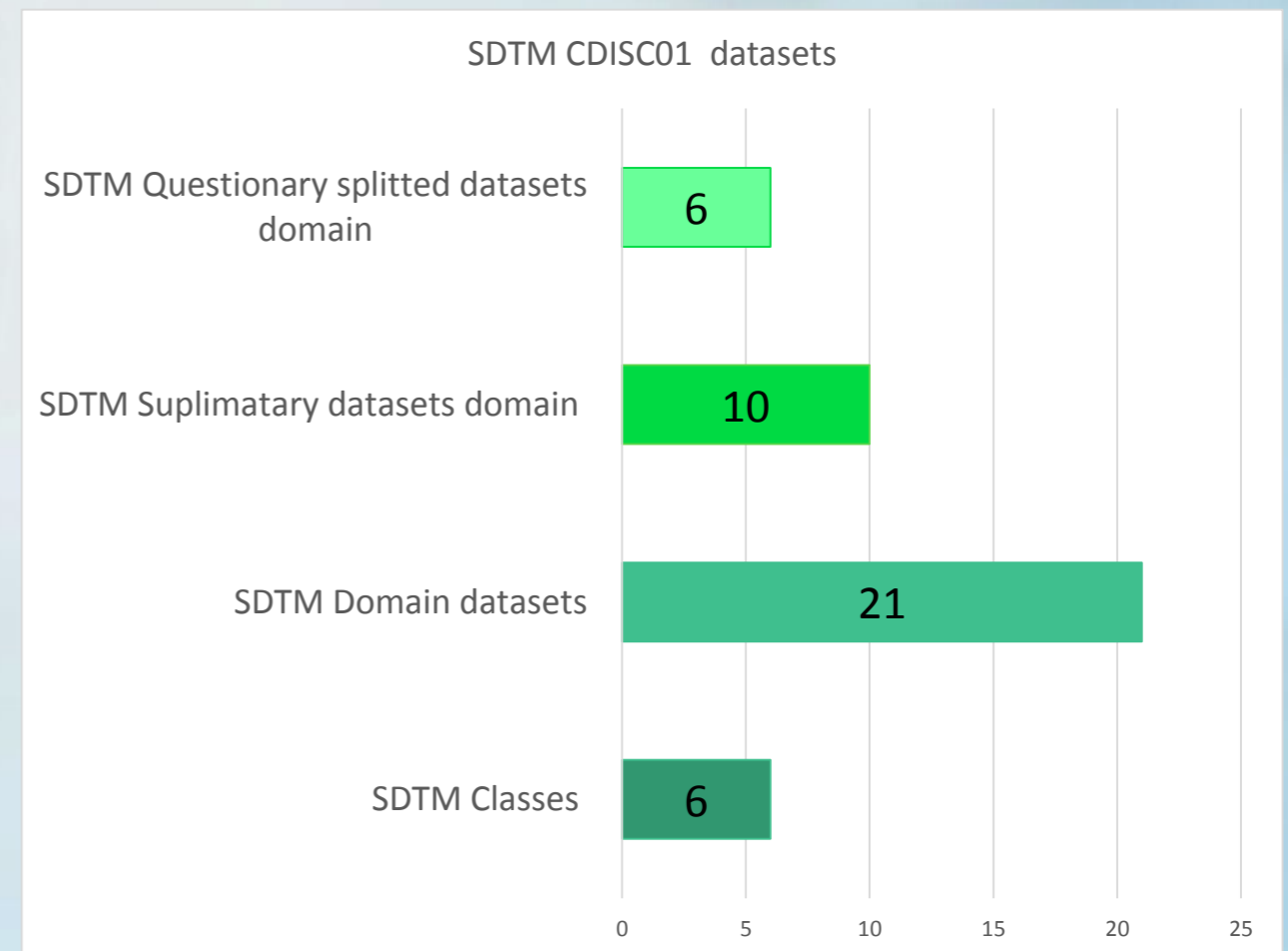
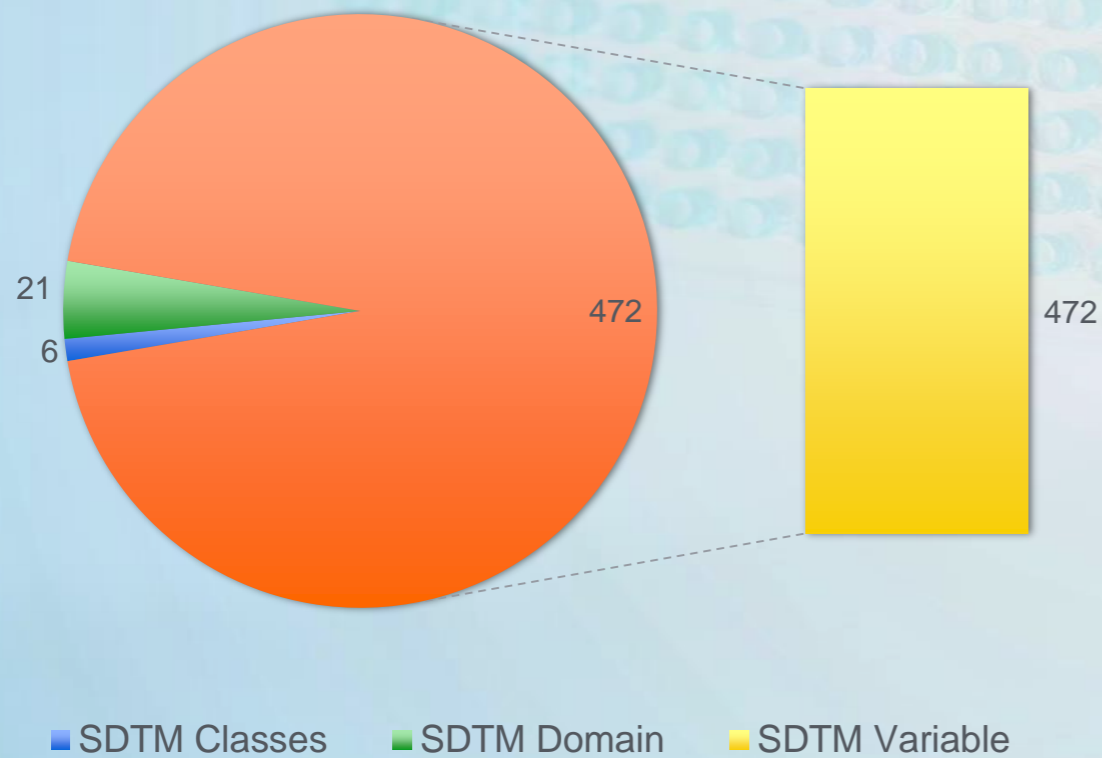
- sdtm-ta-asthma-med-devices-TM-SMOT
- sdtm-ta-asthma-routine-TM-SMOT
- sdtm-ta-asthma-taug-TM-SMOT

A. Clinical Study SDTM CDISC01 files

5. Special-Purpose	
Domain Prefix	Domain
DM	Demographics_(DM)
SE	Subject_Elements_(SE)
SV	Subject_Visits_(SV)
6. General Observational Classes	
6.1 Interventions	
Domain Prefix	Domain
CM	Concomitant_Medications_(CM)
EX	Exposure_(EX)
6.2 Events	
Domain Prefix	Domain
AE	Adverse_Events_(AE)
DS	Disposition_(DS)
MH	Medical_History_(MH)
6.3 Findings	
Domain Prefix	Domain
DA	Drug_Accountability_(DA)
EG	ECG_Test_Results_(EG)
IE	Inclusion_Exclusion_Criteria_Not_Met_(IE)
LB	Laboratory_Test_Results_(LB)
PE	Physical_Examination_(PE)
QSCG	Questionnaire_(QS)
QSCS	Questionnaire_(QS)
QSMM	Questionnaire_(QS)
VS	Vital_Signs_(VS)
SC	Subject_Characteristics_(SC)
7. Trial Design	
Domain Prefix	Domain
TA	Trial_Arms_(TA)
TE	Trial_Elements_(TE)
TI	Trial_Inclusion_Exclusion_Criteria_(TI)
TS	Trial_Summary_Information_(TS)
TV	Trial_Visits_(TV)
8. Relationship	
Domain Prefix	Domain
SUPPDM	Supplemental_Qualifiers_SUPPDM
SUPPCM	Supplemental_Qualifiers_SUPPCM
SUPPEX	Supplemental_Qualifiers_SUPPEX
SUPPAE	Supplemental_Qualifiers_SUPPAE
SUPPEG	Supplemental_Qualifiers_SUPPEG
SUPPLB	Supplemental_Qualifiers_SUPPLB
SUPPQS_CG	Supplemental_Qualifiers_SUPPQS_CG
SUPPPQS_CS	Supplemental_Qualifiers_SUPPQS_CS
SUPPQS_MM	Supplemental_Qualifiers_SUPPQS_MM
SUPPVS	Supplemental_Qualifiers_SUPPVS



A. SDTM TM-SMOT CDISC01 use case




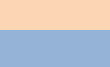




TranSMART A. CDISC01 Tree Clinical Data

SDTM Study Identifier	
CDISC01	SDTM Class
	5. Special-Purpose
	SDTM Domains
	Demographics_(DM)
	Subject_Elements_(SE)
	Subject_Visits_(SV)
	SDTM Domains
	6.1 Interventions
	Concomitant_Medications_(CM)
	Exposure_(EX)
	SDTM Domains
	6.2 Events
	Adverse_Events_(AE)
	Disposition_(DS)
	Medical_History_(MH)
	SDTM Domains
	6.3 Findings
	Drug_Accountability_(DA)
	ECG_Test_Results_(EG)
	Inclusion_Exclusion_Criteria_Not_Met_(IE)
	Laboratory_Test_Results_(LB)
	Physical_Examination_(PE)
	Questionnaire_(QS)
	Questionnaire_(QS)
	Questionnaire_(QS)
	Vital_Signs_(VS)
	Subject_Characteristics_(SC)
	SDTM Domains
	6.4 Finding about
	7. Trial Design
	SDTM Domains
	Trial_Arms_(TA)
	Trial_Elements_(TE)
	Trial_Inclusion_Exclusion_Criteria_(TI)
	Trial_Summary_Information_(TS)
	Trial_Visits_(TV)
	SDTM Domains
	8. Relationship
	Supplemental_Qualifiers_SUPPDM
	Supplemental_Qualifiers_SUPPCM
	Supplemental_Qualifiers_SUPPEX
	Supplemental_Qualifiers_SUPPAE
	Supplemental_Qualifiers_SUPPEG
	Supplemental_Qualifiers_SUPPLB
	Supplemental_Qualifiers_SUPPQS_CG
	Supplemental_Qualifiers_SUPPQS_CS
	Supplemental_Qualifiers_SUPPQS_MM

LEGEND

	FOLDER
	Study Identifier
	Observation Class
	Domain

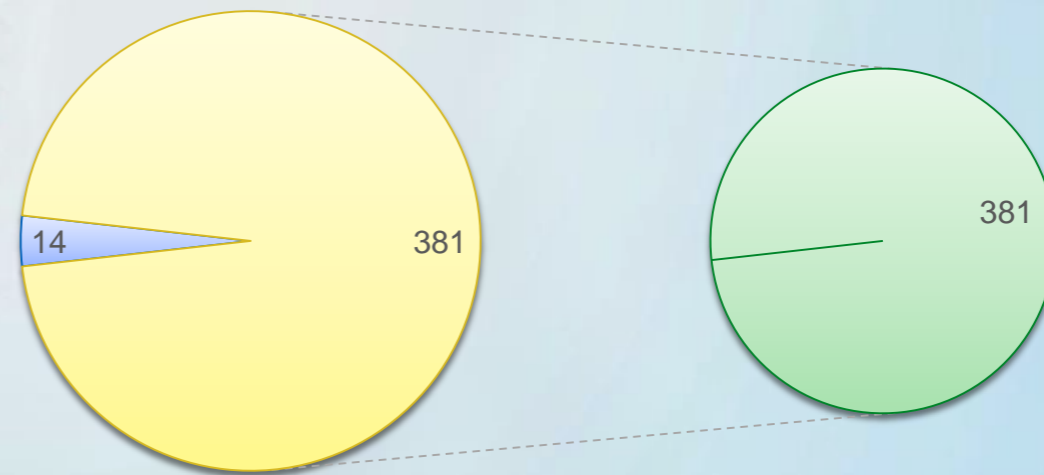


B. SDTM TM-SMOT TAUG-Asthma use case

B. Clinical Study SDTM TA-Asthma files

Domains from SDTMIG v3.2 TA-Asthma v1.0	
Special propose	
DM	Demographic
Interventions domains	
AG	Procedure Agents
CM	Concomitant Medications
Events domains	
AE	Adverse Events
HO	Healthcare Encounters
MH	Medical History
Findings domains	
LB	Laboratory Test Results
RE	Respiratory System Findings
Findings About Interventions and Events domains	
FAMH	Finding about Medical History
FAAE	Finding about Adverse Events
FAHO	Finding about Healthcare Encounters
SR	Skin Response

Domains from SDTMIG-MD	
Medical Devices domains	
DI	Device Identifier
DU	Device-in-Use



□ SDTM Domains □ SDTM variables



❑ CDISC newsletter:

<http://content.yudu.com/web/2htg1/0A2hthm/Q3-2015/html/index.html?refUrl=http%3A%2F%2Fwww.cdisc.org%2Fnewsletter>

❑ The tranSMART Standard Tree User Guide document is under development

❖ Next steps:

- 2015

- ✓ To finish the TM-SMOT annotation for all other SDTMIG 3.2 domains
- ✓ To review TM-SMOT
- ✓ tranSMART user guide v1.0 ready for review
- ✓ To test TM-SMOT model using IMI study dataset (e.g. UBIOPRED SDTM datasets)

- 2016

- ✓ To start the development of CDASH TM-SMOT
- ✓ To start preparing Training Material (webinar) CDISC TM Tree
- ✓ To start the development of PGx TM-SMOT



- ✓ Resource and/or material needs to be addressed.
When? How?
 - To use eTRIKS resources
 - IMI study data for testing and validation



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