

PhUSE Single-Day Event

SDTM - Insights and Future

Gary Walker
Bangalore - 22nd August, 2015



Sponsors

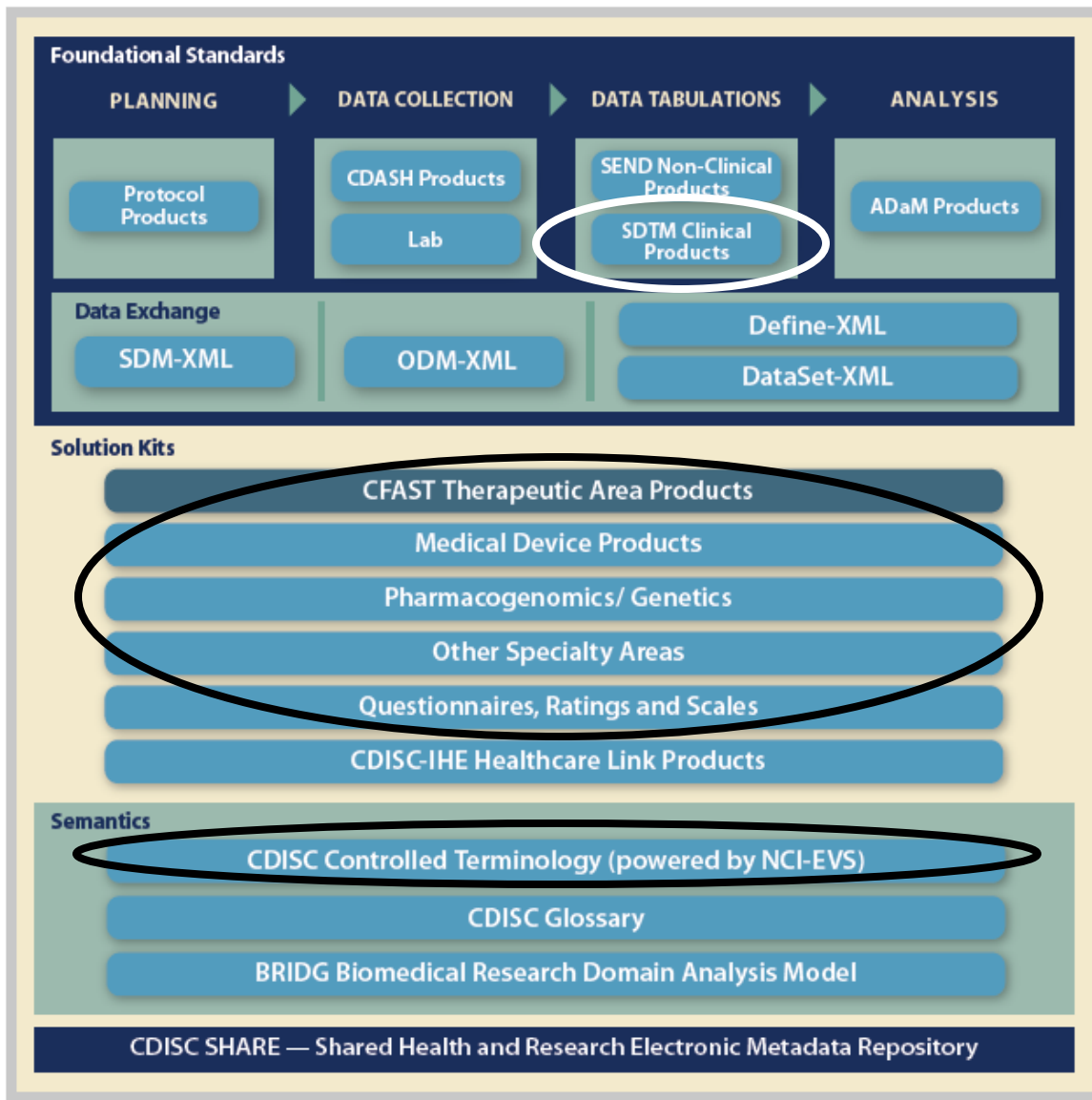


Agenda

Time	Presentation
8.00 - 8.45	Welcome Refreshments & Registration
8.45 - 9.00	Welcome & Introduction
9.00 - 10.00	Overview of SDTM/SDTM-IG and Related CDISC Standards, including Common Mistakes Made
10.00 - 10.30	Tips and Tricks to Ensure Common Sense is Used while Mapping Data
10.30 - 11.00	Morning Break
11.00 - 12.30	Trial Design
12.30 - 1.30	Lunch
1.30 - 2.00	Mapping Relations such as RELREC
2.00 - 2.30	PhUSE SDRG (Study Data Reviewer's Guide) and OpenCDISC Results: Documentation
2.30 - 2.45	Afternoon Break
2.45 - 4.00	The Next Steps of CDISC/SDTM/Therapeutic Area User Guides and what is the Vision Going Forward



Overview of SDTM/SDTM-IG and Related CDISC Standards, including Common Mistakes Made



SDTM
SDTMIG
SDTMIG-AP
SDTM Medical Devices

TAUGs

Controlled Terminology
QRS
(formerly COA
formerly QS)



SDTM general observation class domains and allowed variables

SDTM Observation Class
(from model)

SDTM domains'
variable order (from model)

SDTM-IG Domain examples*

Findings
Domains
(test/result)

Events
Domains
("things that happen")

Interventions
Domains
(something causing
physiological affect)

Identifier variables (allowed from SDTM 2.2.4)	Topic and <u>qualifier</u> <u>variables</u> (allowed from SDTM 2.2.3)	Timing variables (allowed from SDTM 2.2.5)
	Topic and <u>qualifier</u> <u>variables</u> (allowed from SDTM 2.2.2)	
	Topic and <u>qualifier</u> <u>variables</u> (allowed from SDTM 2.2.1)	

VS (Vital Signs)

LB (Lab Test Results)

EG (ECG Test Results)

DS (Disposition)

AE (Adverse Events)

MH (Medical History)

EX (Exposure)

CM (Con Meds)

SU (Substance Use)

*Two-character domain codes are used for dataset file names and as a prefix for many variables.



Understanding the SDTM Associated Persons IG

Trial Design Data

TE
(Trial Elements)

TA
(Trial Arms)

TV
(Trial Visits)

TD
(Trial Disease Assessments)

TI
(Trial Inclusion/
Exclusion
Criteria)

TS
(Trial Summary
Information)

Special Purpose Domains

SE (Subject Elements)

SV (Subject Visits)

CO
(Comments)

DM (Demographics **)

Subject Data

General Observation Class Domains (Standard Variables) (Non-Standard Variables)

VS (Vital Signs)

LB (Lab Results)

EG (ECG Results)

FA-- (Findings about...)

AE (Adverse Events)

MH (Medical History)

DS (Disposition**)

EX (Exposure**)

CM (Con Meds)

SU (Substance Use)

SUPPLB

SUPPEG

SUPPFA--

SUPPAE

SUPPEX

SUPPCM

RELREC

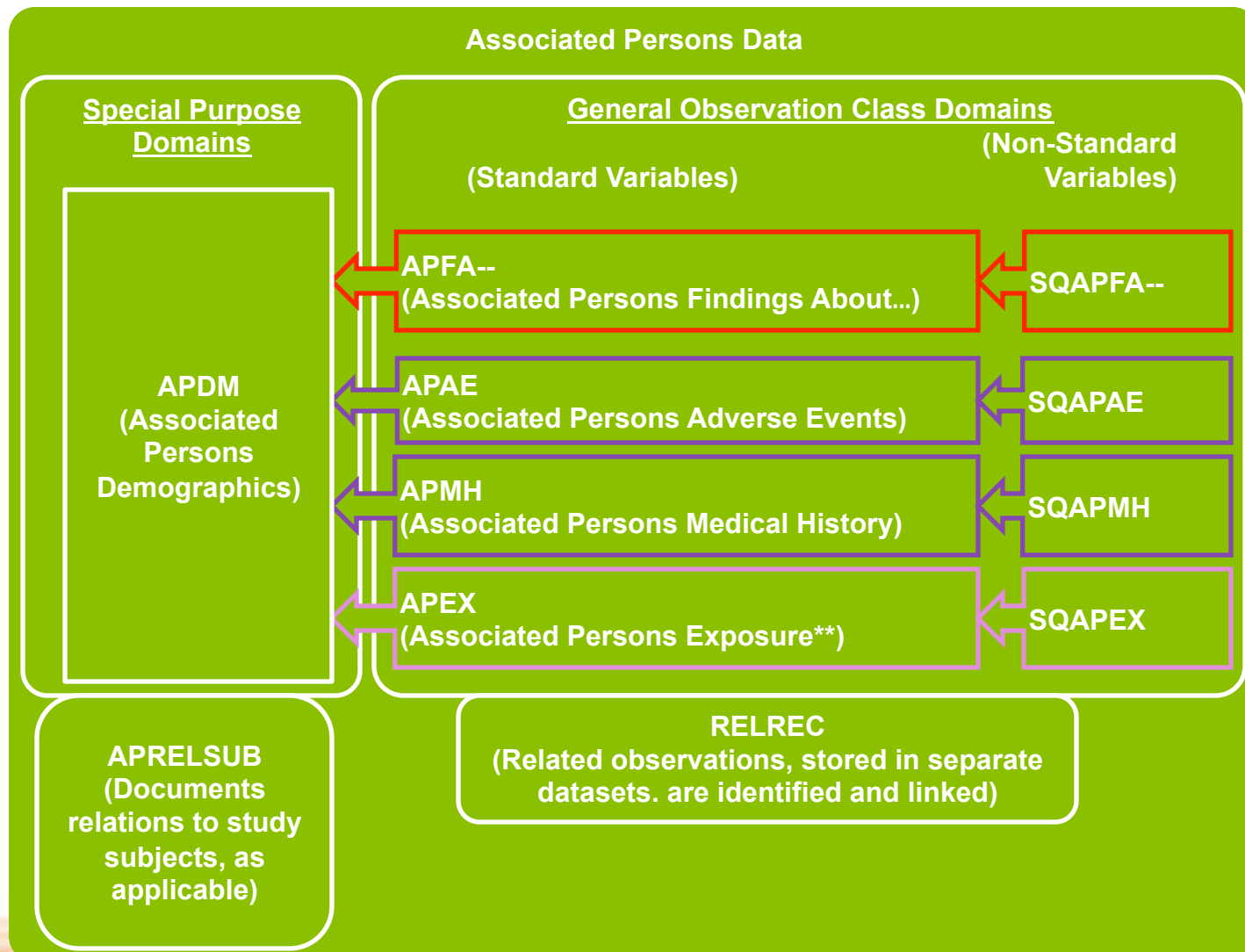
(Related observations, stored in separate datasets. are identified and linked),

Associated Persons Data

Mimics Subject Data structure, but used for data about persons who are not subject in the trial, but whose data is useful for the study, such as parents, siblings, device operator who experiences an Adverse Event with the device.



SDTM Associated Persons domains structure



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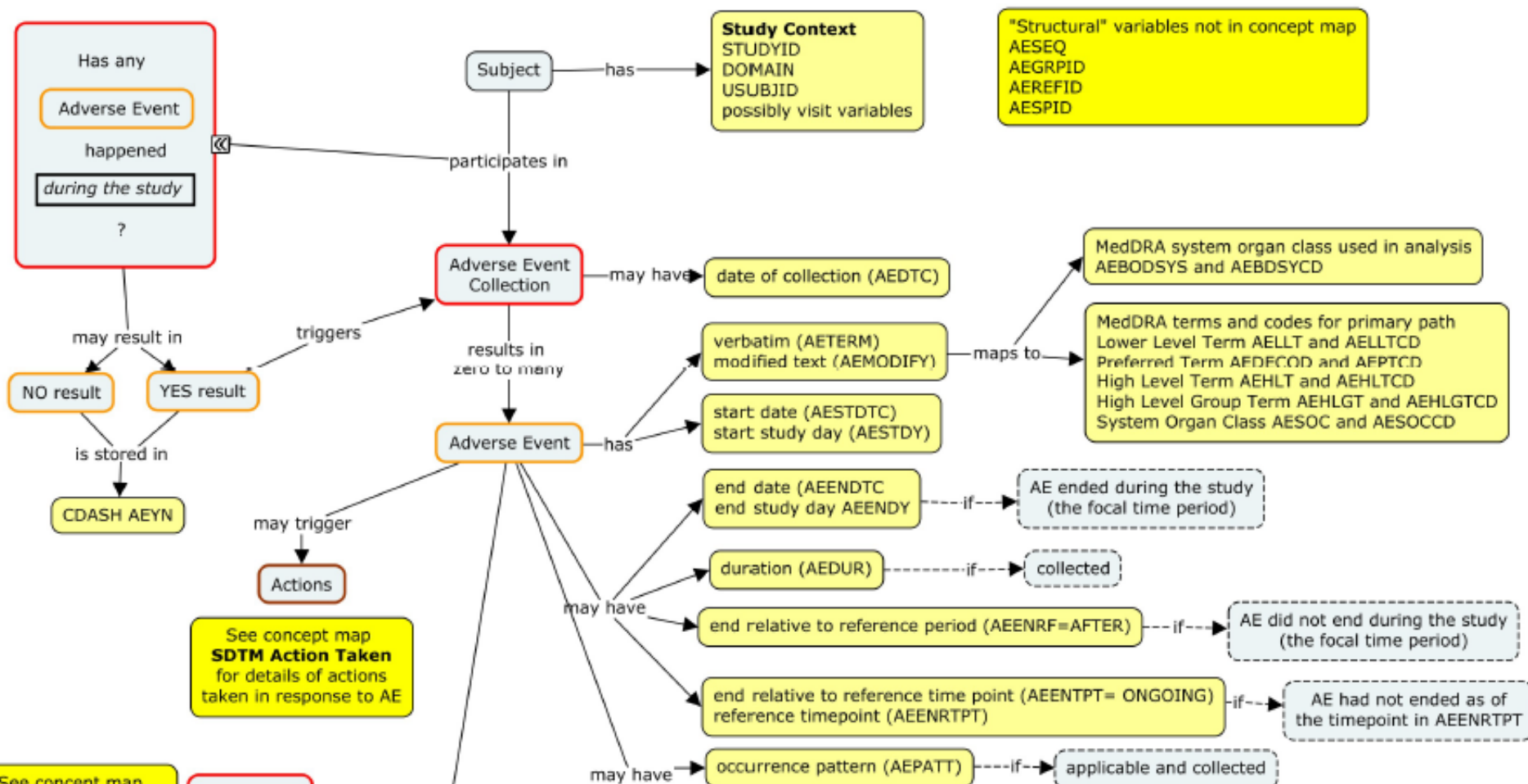


Mapping data

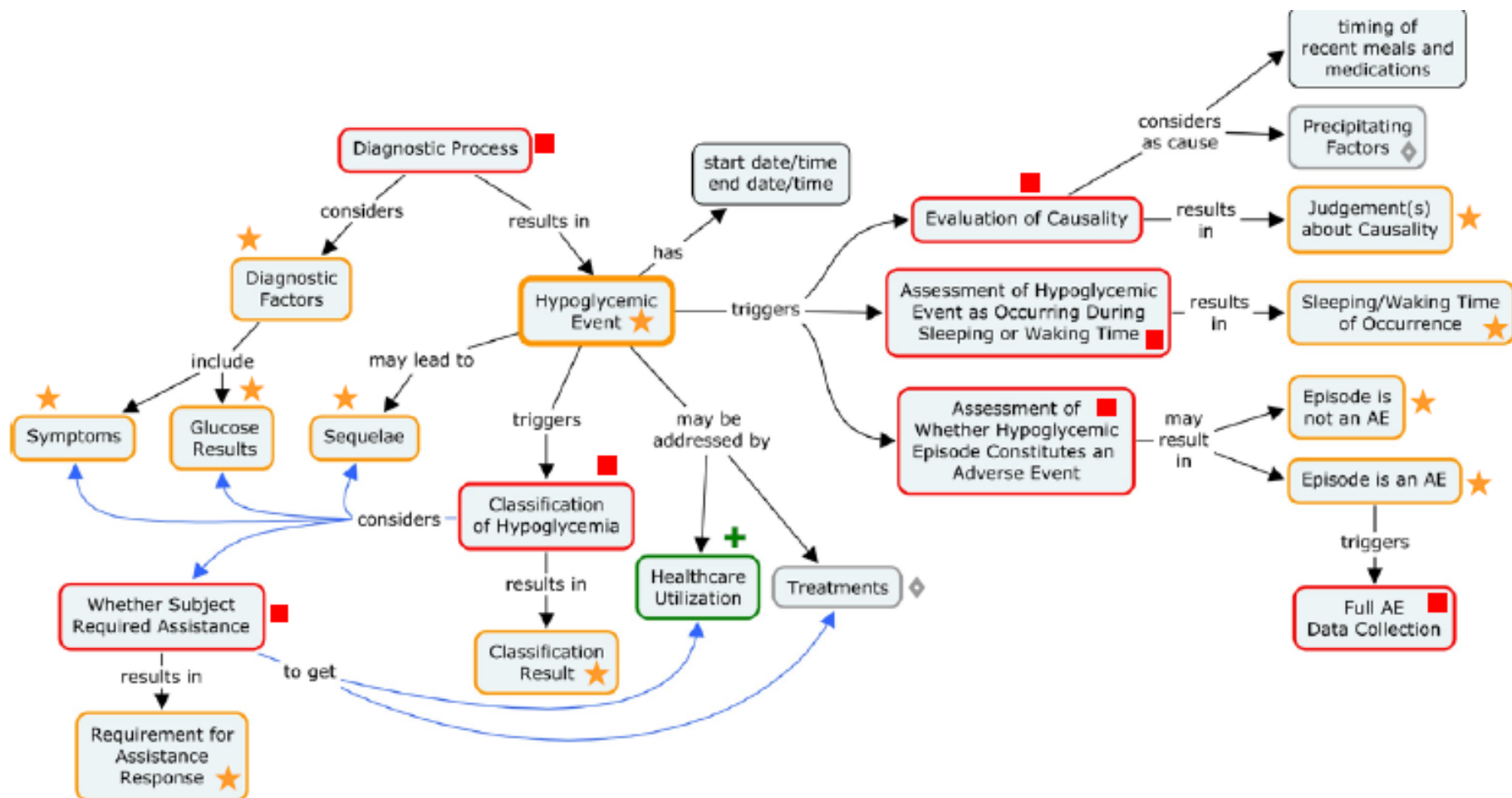
- Use Protocol, and CRF to identify "source" for variables (concept)
- Use CDISC standards to look for appropriate destination for data
 - SDTM/SDTM-IG
 - Controlled Terminology
 - TAUGs
 - Concept Maps - Formalized diagramming of concepts



Example Concept map for AE domain



Complex concepts detailed in TAUGs



Concept Map 7: Hypoglycemic Event



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Trial Design



- Time and events plan (TE/TA, TV, TD)
 - Trial Disease Milestones (TM)
Proposed in SDTM 1.5
- Study requirements TI
- Study characteristics TS
 - SDTM-IG Appendix C1



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Captured Relationships: Discussion points

- Most SDTM-IG examples use --SEQ or --GRPID as the RELREC IDVAR (Identifying Variable).
- (Note that IDVAR can be any "Identifying Variable" and is not limited to "Identifier" variables.)
- Relationships captured in Clinical Data Management Systems rely on CDMS-specific targets (e.g., record identifier). --SEQ does not exist outside of final SDTM structure (Surrogate Key).
- In CDASH, --SPID = line or record identifier associated with the data. --SPID as defined by CDASH is a useful RELREC target variable (IDVAR) for building and storing relationship information in CDMS that gets passed forward into SDTM



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Study Data Reviewers Guide (SDRG)

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Therapeutic Area User Guides (TAUGs)



Program Overview – July 2015 Approved Therapeutic Area Standards Projects



Therapeutic Area	Coordinating Organization/PM	Stage 0 Scoping	Stage 1 Concept Modeling	Stage 2 Standards Development	Stage 3a Internal Review	*Stage 3b Public Review	*Stage 3c **Projected Publication
Traumatic Brain Injury v1	CDISC Rhonda Facile	Dec	Jan	Feb	July	Sept	2015
Breast Cancer v1	TCB John Owen	Aug	Dec	Jan	July	Sept	2015
COPD v1	TCB John Glover	Aug	Dec	Apr	Aug	Oct	2015
ADaM Supplement to Diabetes v1	TCB Rachael Zirkle	NA	NA	Jan	July	Sept	2015
Virology v2	C-Path Laura Butte	Mar	Apr	May	July	Aug	2015
Diabetic Kidney Disease v1	TCB Rachael Zirkle	May	July	Sept			Q116
Tuberculosis v2	C-Path Laura Butte	Apr	Jun	Aug	Oct		Q116
Rheumatoid Arthritis v1	TCB Trisha Simpson	Jun	July				Q116
CV Imaging v1	CDISC/DCRI Amy Palmer	Apr	July	Aug			Q216
Prostate Cancer v1	CDISC John Owen	July	Oct				Q216
Major Depressive Disorder	CDISC Amy Palmer						Q316

Key | Stage completed | Stage ongoing | All months reflect when stage is, or is projected to be, completed.

*The Stage3b concludes at the end of the 30-day review period and Stage 3c concludes when all tasks have been completed and the standard is publicly available.
** Specific projected publication dates to be added to the notes section at the conclusion of Stage 3b.

