PhUSE Single-Day Event
SDTM - Insights and Future

Gary Walker
Bangalore - 22nd August, 2015

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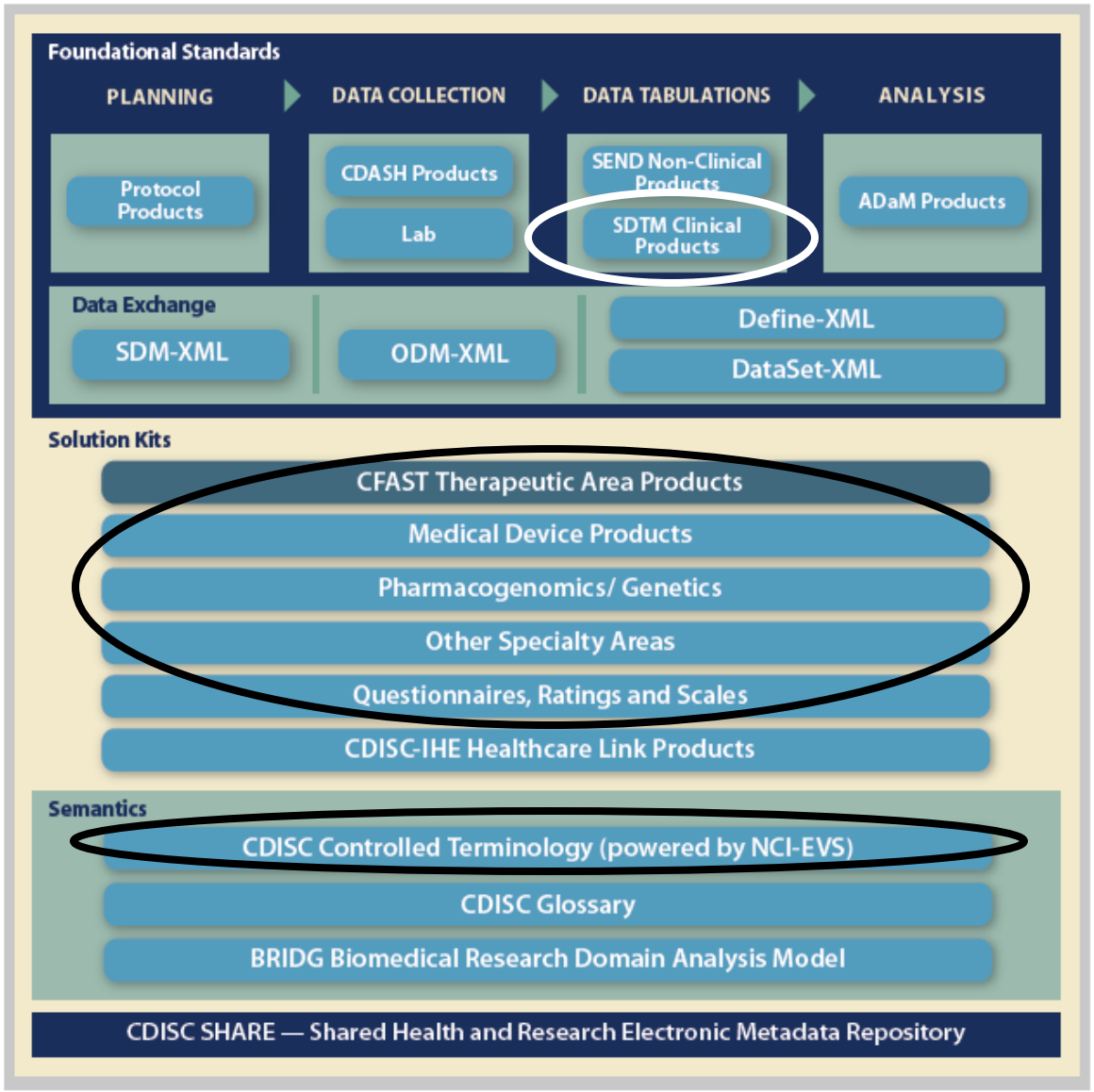
Agenda

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

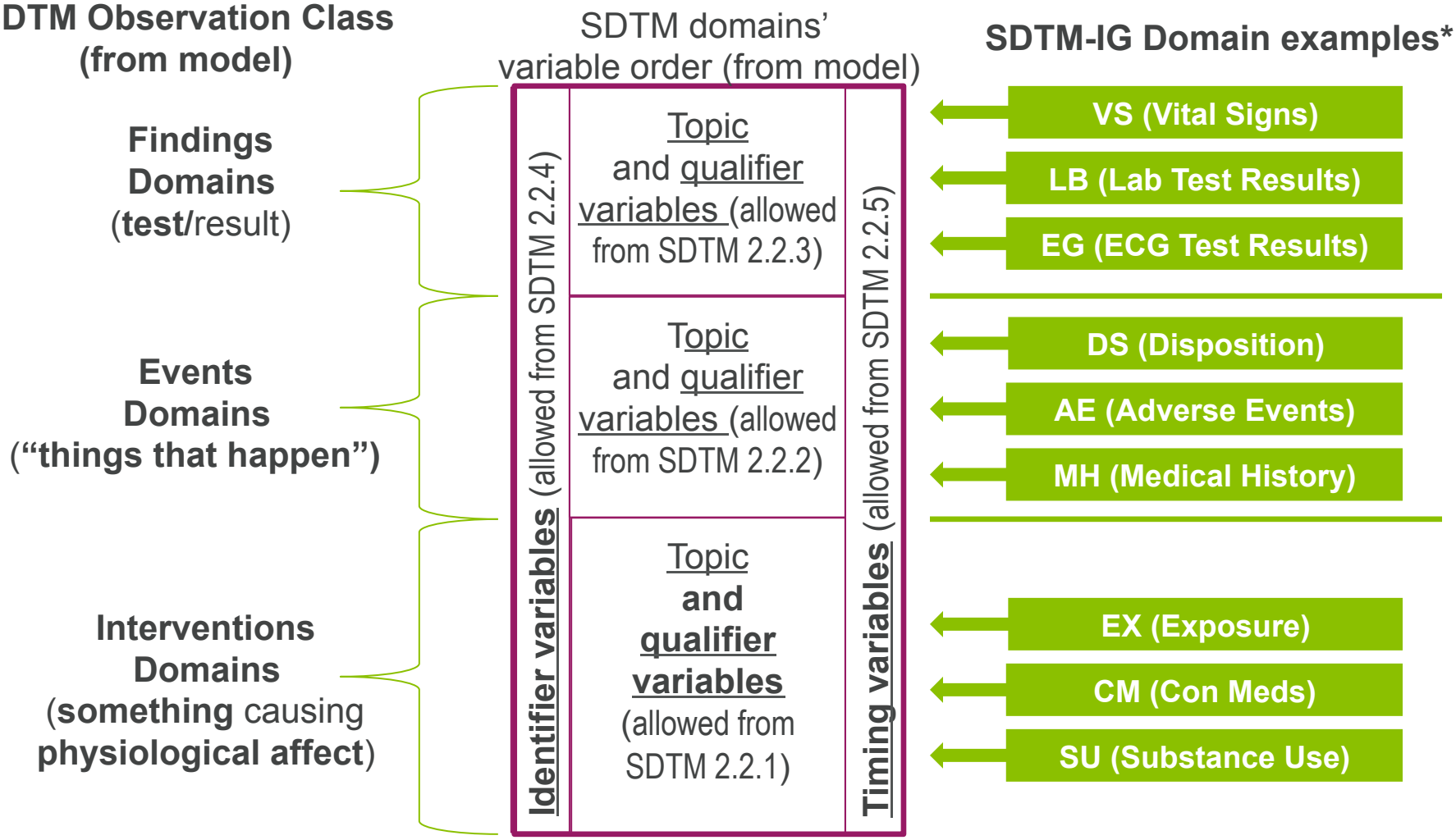


SDTM
SDTMIG
SDTMIG-AP
SDTM Medical Devices

TAUGs

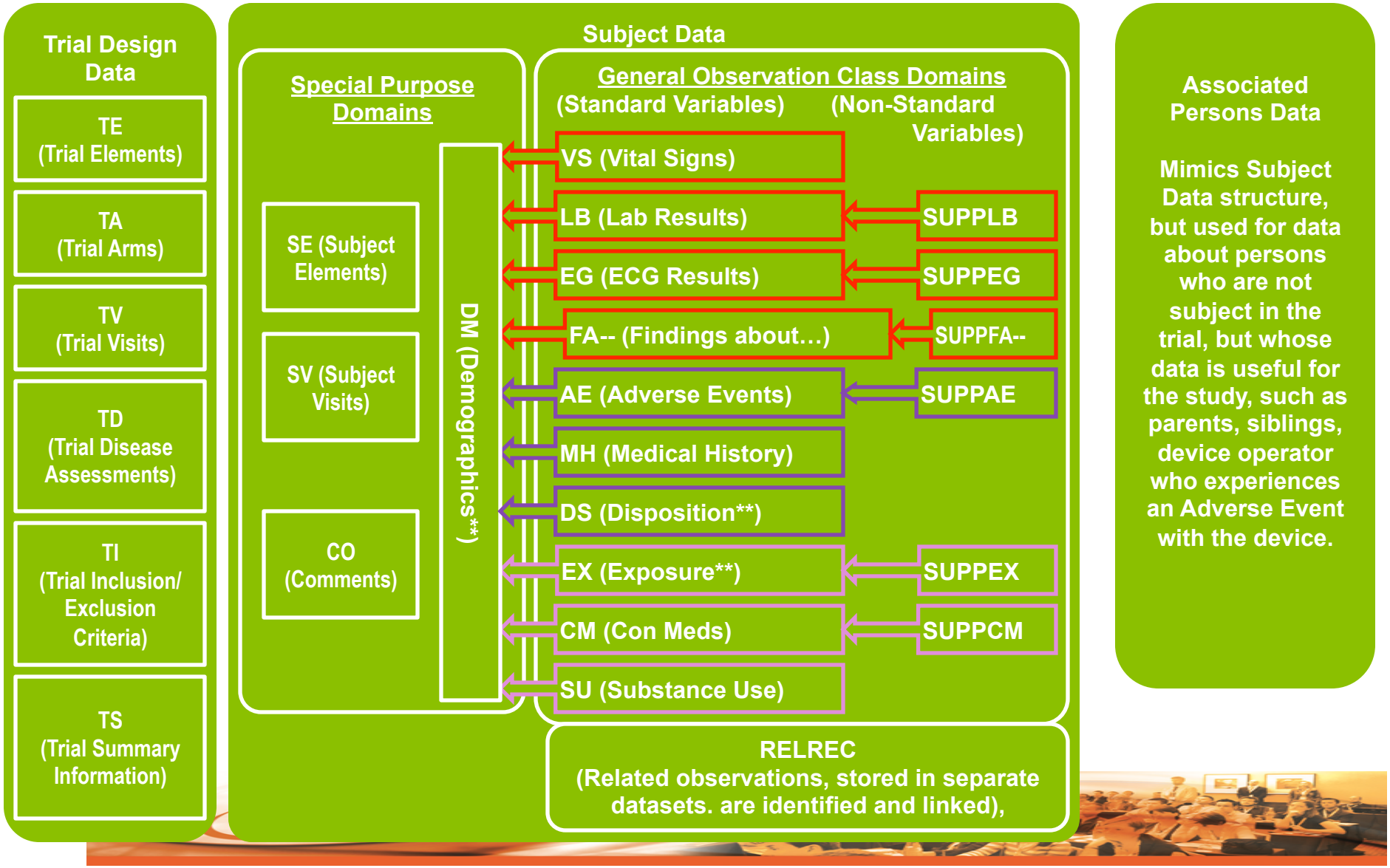
Controlled Terminology
QRS
(formerly COA
formerly QS)

SDTM general observation class domains and allowed variables

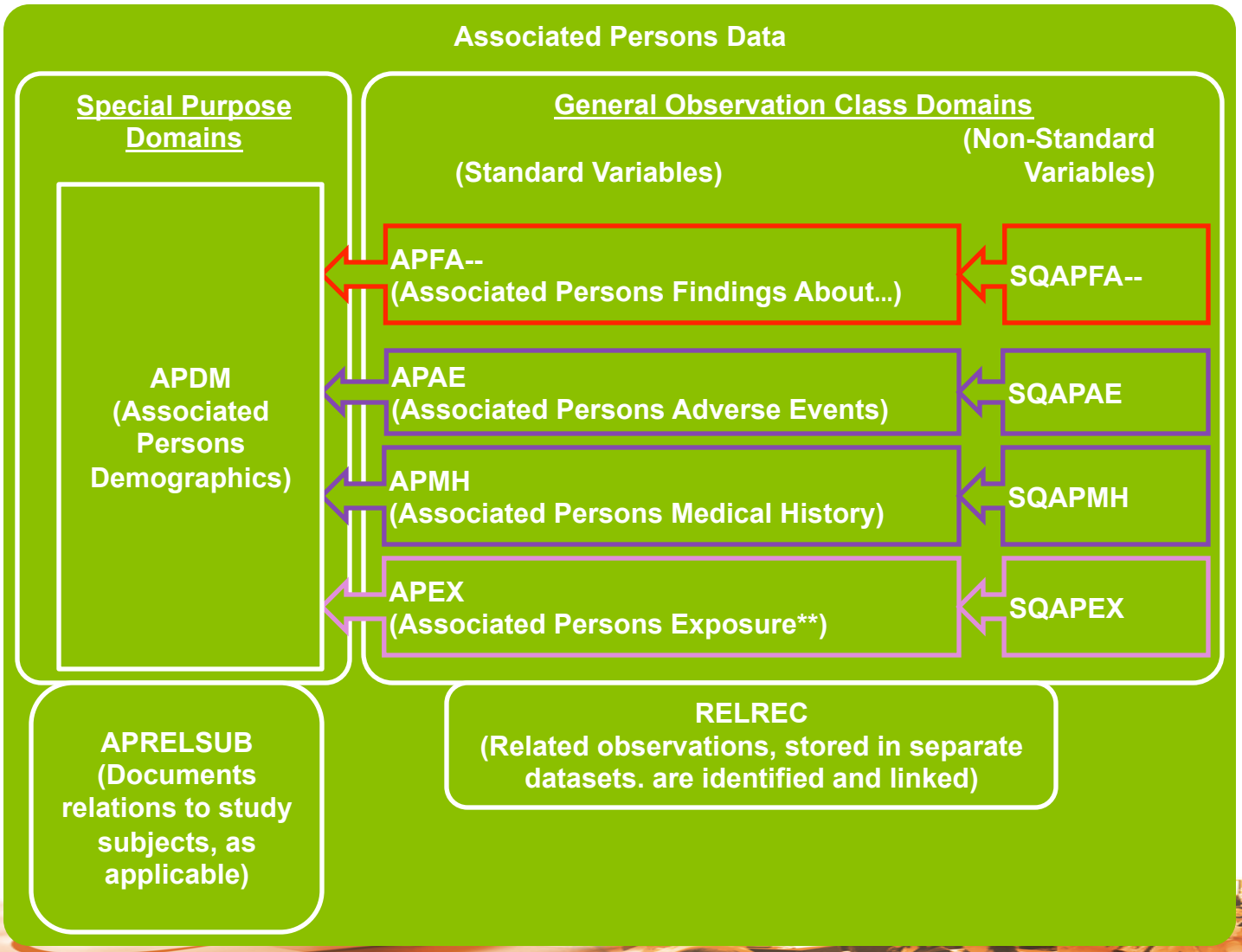


*Two-character domain codes are used for dataset file names and as a prefix for many variables.

Understanding the SDTM Associated Persons IG



SDTM Associated Persons domains structure



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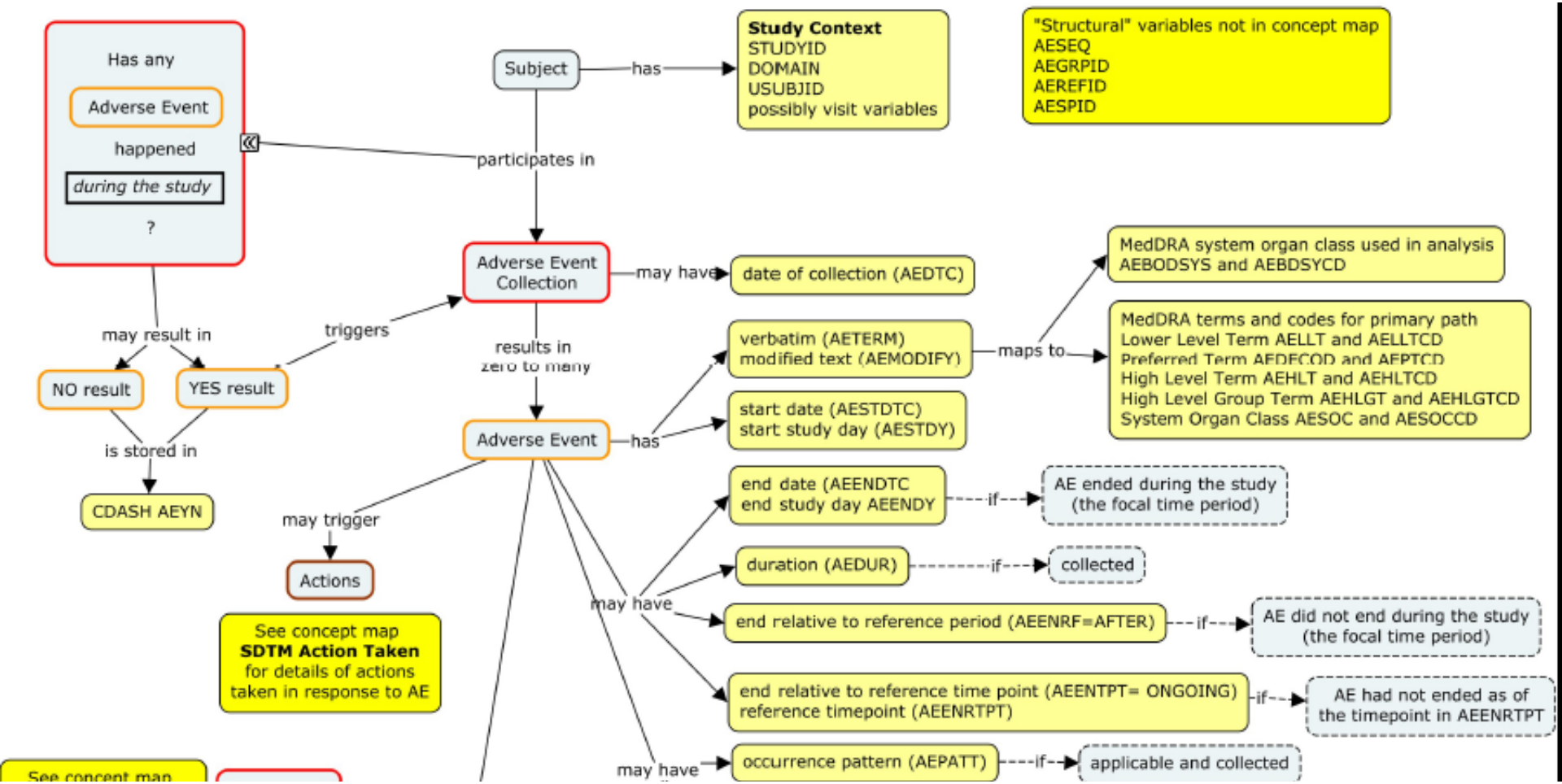
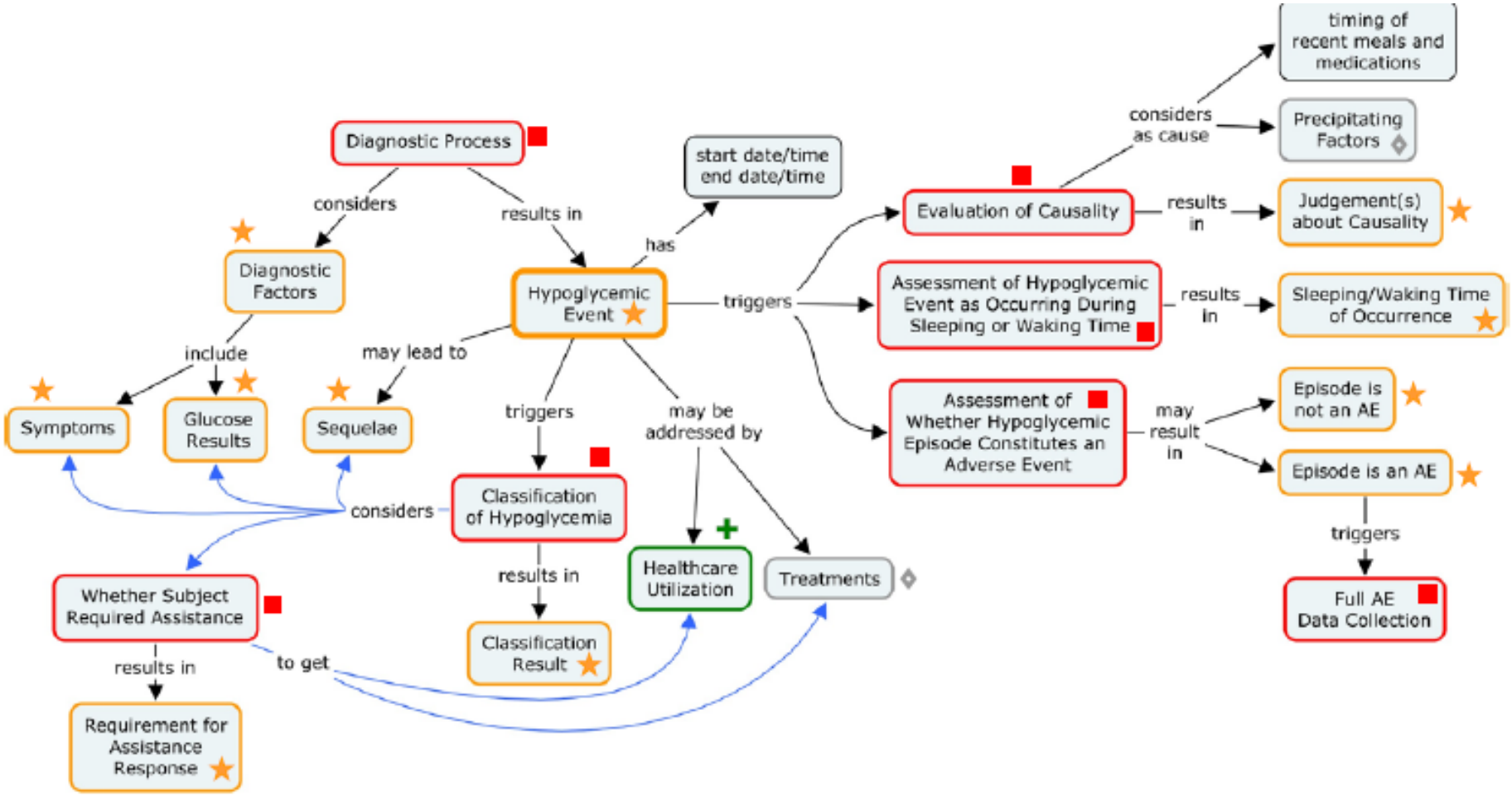
Mapping data

- 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 diagraming 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 publically available.
** Specific projected publication dates to be added to the notes section at the conclusion of Stage 3b.