

UNTANGLING THE SUBJECT ELEMENTS DOMAIN

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Paper DS10

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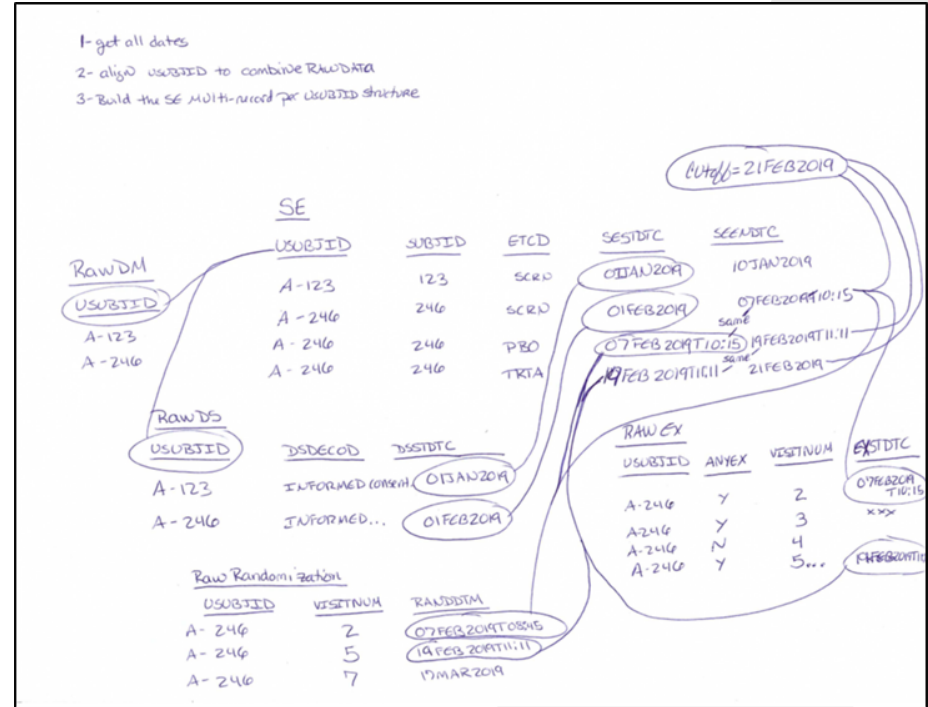
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Public

Untangling the Subject Elements Domain

- ▶ Subject Elements (SE)
- ▶ Mapping flows
- ▶ Unique SE flow
- ▶ Construction
- ▶ Cautions and Considerations

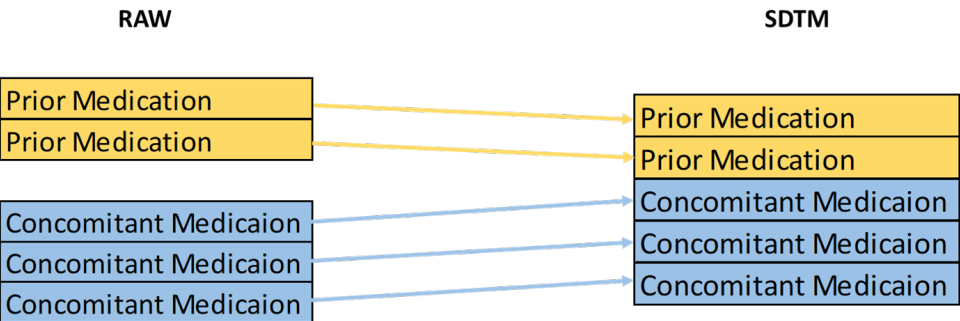


Subject Elements (SE)

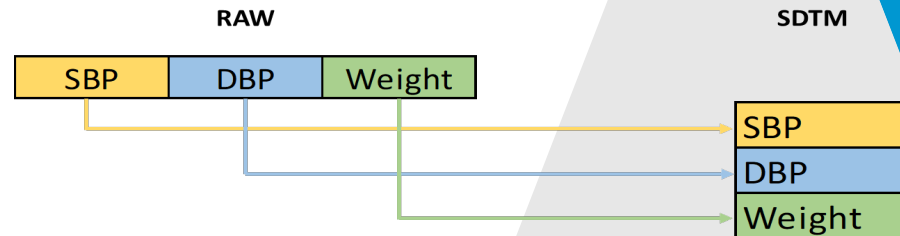
STUDYID	DOMAIN	USUBJID	SESEQ	ETCD	ELEMENT	SESTDTC	SEENDTC	TAETORD	EPOCH	SEUPDES
ABC	SE	ABC-1	1	SCREEN	Screening	2019-02-01	2019-02-21	1	SCREENING	
ABC	SE	ABC-1	2	TRT1	Treatment 1	2019-02-21	2019-03-17	2	OPEN LABEL TREATMENT	
ABC	SE	ABC-1	3	TRT2	Treatment 2	2019-03-17	2019-03-29	3	BLINDED TREATMENT	
ABC	SE	ABC-1	4	FOLLOWUP	Follow-up	2019-03-29	2019-04-28	4	FOLLOW-UP	
ABC	SE	ABC-2	1	SCREEN	Screening	2019-01-23	2019-02-07	1	SCREENING	

Common Mapping Flows

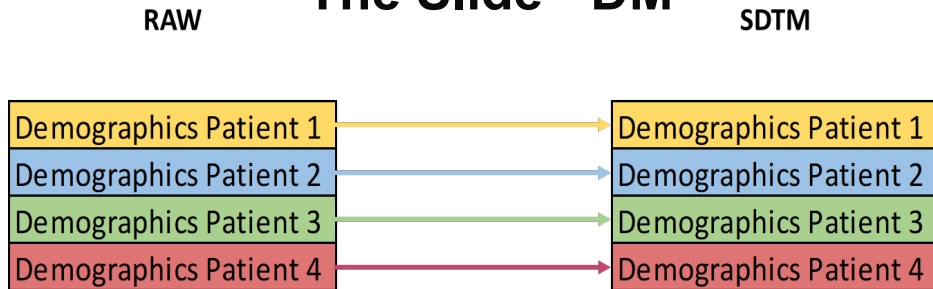
The Stack - CM



The Flip - VS



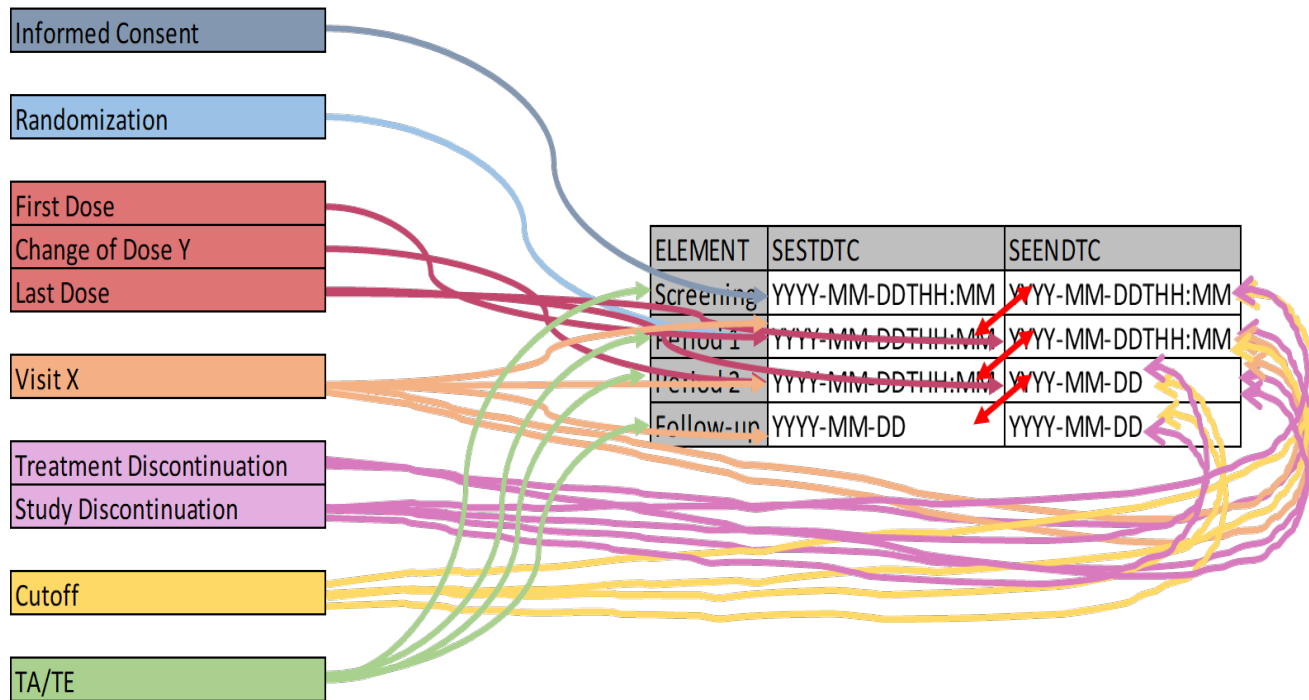
The Slide - DM



The Tangle - SE

RAW

SDTM



- ▶ Multiple data sources
- ▶ Building SE with TDM
- ▶ Derivation of Element Dates
- ▶ Algorithm Complexities

Multiple Data Sources

- ▶ TDM – Trial Arms (TA), Trial Elements (TE)
- ▶ SDTM – DM.ARM
- ▶ Other dates
 - Informed consent
 - Randomization date(s)
 - Dose dates – first, last, change
 - Visit dates
 - Visit driven assessment dates
 - Disposition – treatment/study
 - Cutoff

Building SE Structure with References to TDM

- ▶ No parallel raw structure
- ▶ Build Rows
 - DM.USUBJID -> DM.ARM
 - TA.ARM -> TA.ELEMENT
- ▶ Date Rules
 - TE.ELEMENT -> TE.TESTRL, TE.TEENRL, TE.TEDUR
 - Identify actual rows

Derivation of Element Dates

► Rules

- TE.TESTRL, TE.TEENRL, TE.TEDUR

► Derivations

- Multiple source dates per SESTDTC/SEENDTC
- Multiple SESTDTC/SEENDTC per source date

► SEENDTC vs next SESTDTC

- Last element definition

Algorithm Complexities

- ▶ Minimum/Maximum
- ▶ Partial dates
- ▶ Date vs date/time
- ▶ Multiple sources for similar values
 - Last EX.EXSTDTC/EXENTDC
 - DS.DSSTDTC where DS.DSSCAT=TREATMENT
- ▶ Derivation intricacies
 - max(LAST_TRT, STUDY_DC, CUTOFF)
 - max(LAST_TRT, STUDY_DC), else CUTOFF
 - STUDY_DC, else max(LAST_TRT, CUTOFF)

SE Construction

► Pre-work

- TDM defined

► Construction

- Build rows
- Derive date values

SE Construction - Rows

- ▶ TDM defined
- ▶ Define rows per subject

- DM.USUBJID → DM.ARM

- TA.ARM → TA.ELEMENT

- TA.ELEMENT → SE.ELEMENT

STUDYID	DOMAIN	USUBJID	ARMCD	ARM
ABC	DM	ABC-1	ARMA	TREATMENT ARM A
ABC	DM	ABC-2	ARMB	TREATMENT ARM B

STUDYID	DOMAIN	ARMCD	ARM	TAETORD	ETCD	ELEMENT
ABC	TA	ARMA	TREATMENT ARM A	1	SCREEN	Screening
ABC	TA	ARMA	TREATMENT ARM A	2	TRT1	Treatment 1
ABC	TA	ARMA	TREATMENT ARM A	3	TRT2	Treatment 2
ABC	TA	ARMA	TREATMENT ARM A	4	FOLLOWUP	Follow-up
ABC	TA	ARMB	TREATMENT ARM B	1	SCREEN	Screening
ABC	TA	ARMB	TREATMENT ARM B	2	TRT3	Treatment 3

USUBJID	SESEQ	ETCD	ELEMENT	SESTDTC	SEENDTC	TAETORD	EPOCH
ABC-1	1	SCREEN	Screening			1	SCREENING
ABC-1	2	TRT1	Treatment 1			2	OPEN LABEL TREATMENT
ABC-1	3	TRT2	Treatment 2			3	BLINDED TREATMENT
ABC-1	4	FOLLOWUP	Follow-up			4	FOLLOW-UP

SE Construction – Date Values

- ▶ TE – identify source data points
- ▶ Data sources
- ▶ TE – algorithms
- ▶ Assign SESTDTC/SEENDTC
- ▶ Keep applicable ELEMENT rows

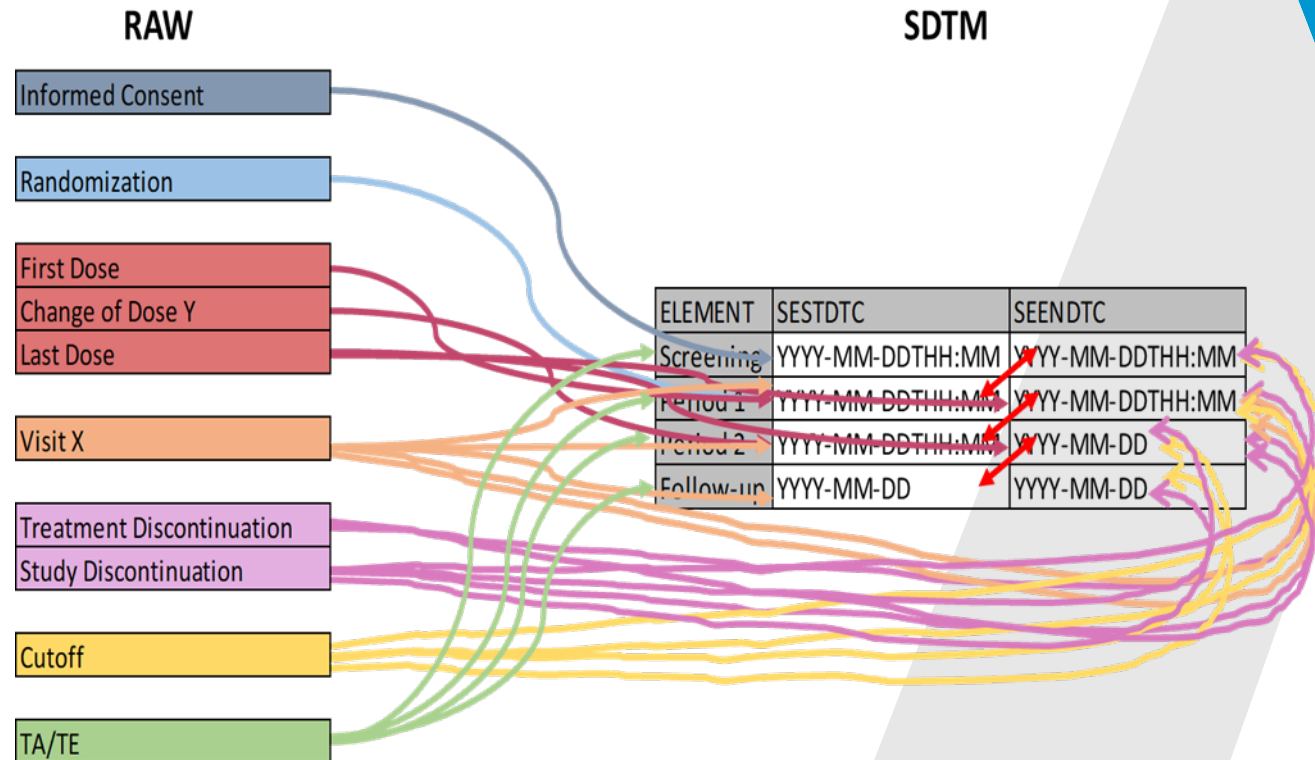
STUDYID	DOMAIN	ETCD	ELEMENT	TESTRL	TEENRL	TEDUR
ABC	TE	SCREEN	Screening	Informed consent	2 weeks after element start	P14D
ABC	TE	TRT1	Treatment 1	First dose of Treatment 1	4 weeks after element start	P28D
ABC	TE	TRT2	Treatment 2	First dose of Treatment 2	4 weeks after element start	P28D
ABC	TE	FOLLOWUP	Follow-up	Last dose	4 weeks after element start	P28D

Cautions and Considerations

- ▶ Subject identifier
- ▶ Partial dates
- ▶ Time presence
- ▶ Date/time format
- ▶ Multiple sources
- ▶ Derivation intricacies

Summary

- Build rows
- Derive dates



Questions?

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