cdisc

2023
KOREA
INTERCHANGE
SEOUL | 11-14 DECEMBER

Considerations in converting study data and lesson learned from our experiences

Presented by Mia Kim, Clinical Data Team Manager
Clinical Data Team, DATA TEAMz Inc.

Meet the Speaker

Mia Kim

Title: Clinical Data Team Manager

Organization: DATA TEAMz Inc.

Mia Kim, who has been working in the field of clinical data management for 13 years, majored in nursing at Yonsei University and started working in clinical data management at the local CRO in Korea. Inspired and influenced by her team leader and colleagues she worked with at the time, she became interested in data management.

She has also experience in clinical data management work at Asan Medical Center and served as head of the data quality innovation team and head of the data management team at a full service local CRO. Currently, she is working as a clinical data team manager at DATA TEAMz Inc., a company specializing in clinical data management, to bring new perspectives and technologies to data management work to make data science a reality. She is interested in energizing people and increasing job satisfaction for data managers and loves thinking about the future of data management as it evolves in response to a changing environment.

Disclaimer and Disclosures

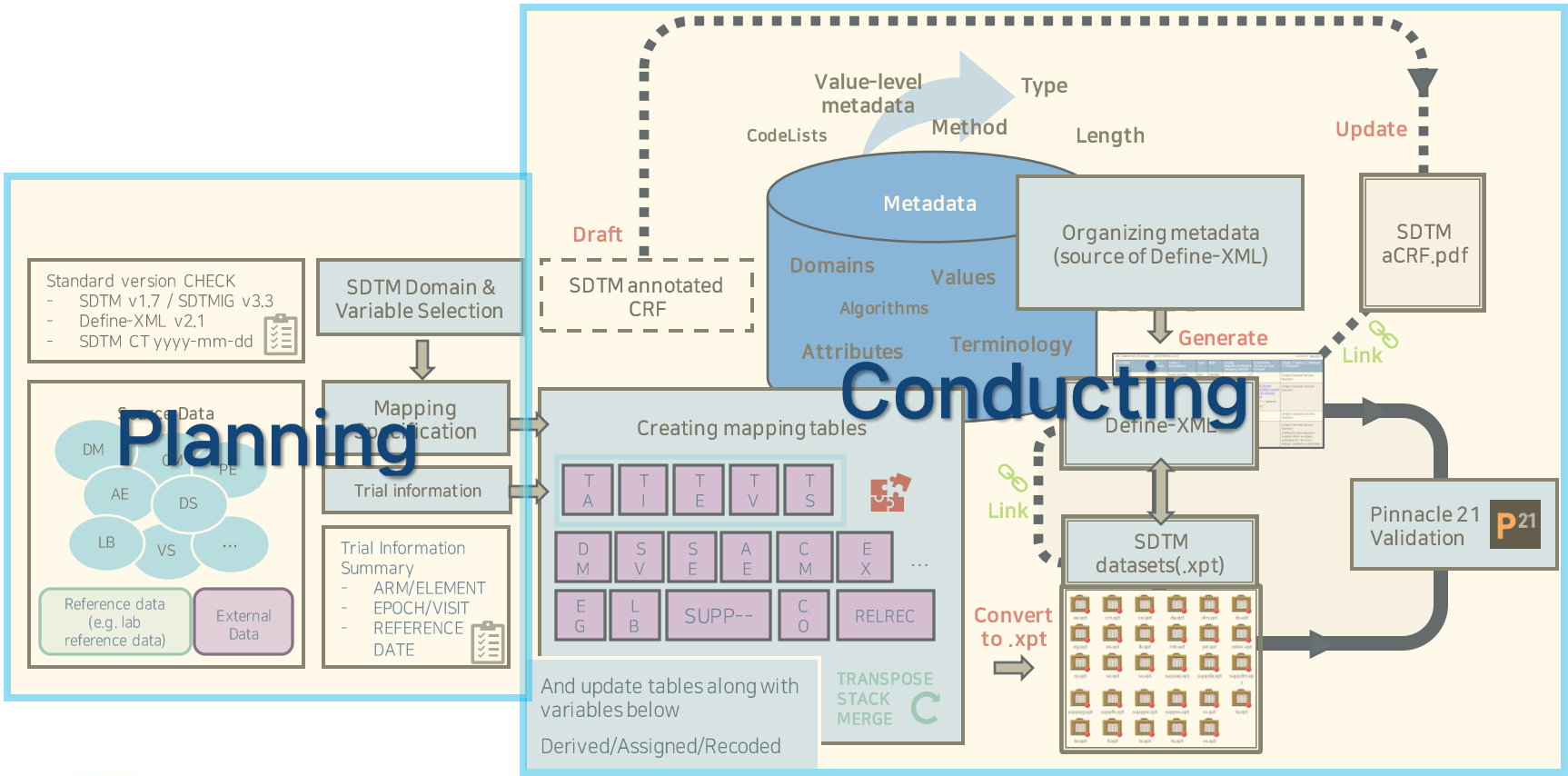
- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*

Agenda

1. Considerations in converting study data and the cases you may encounter when you are in early stage of work
2. Lesson learned from our experiences

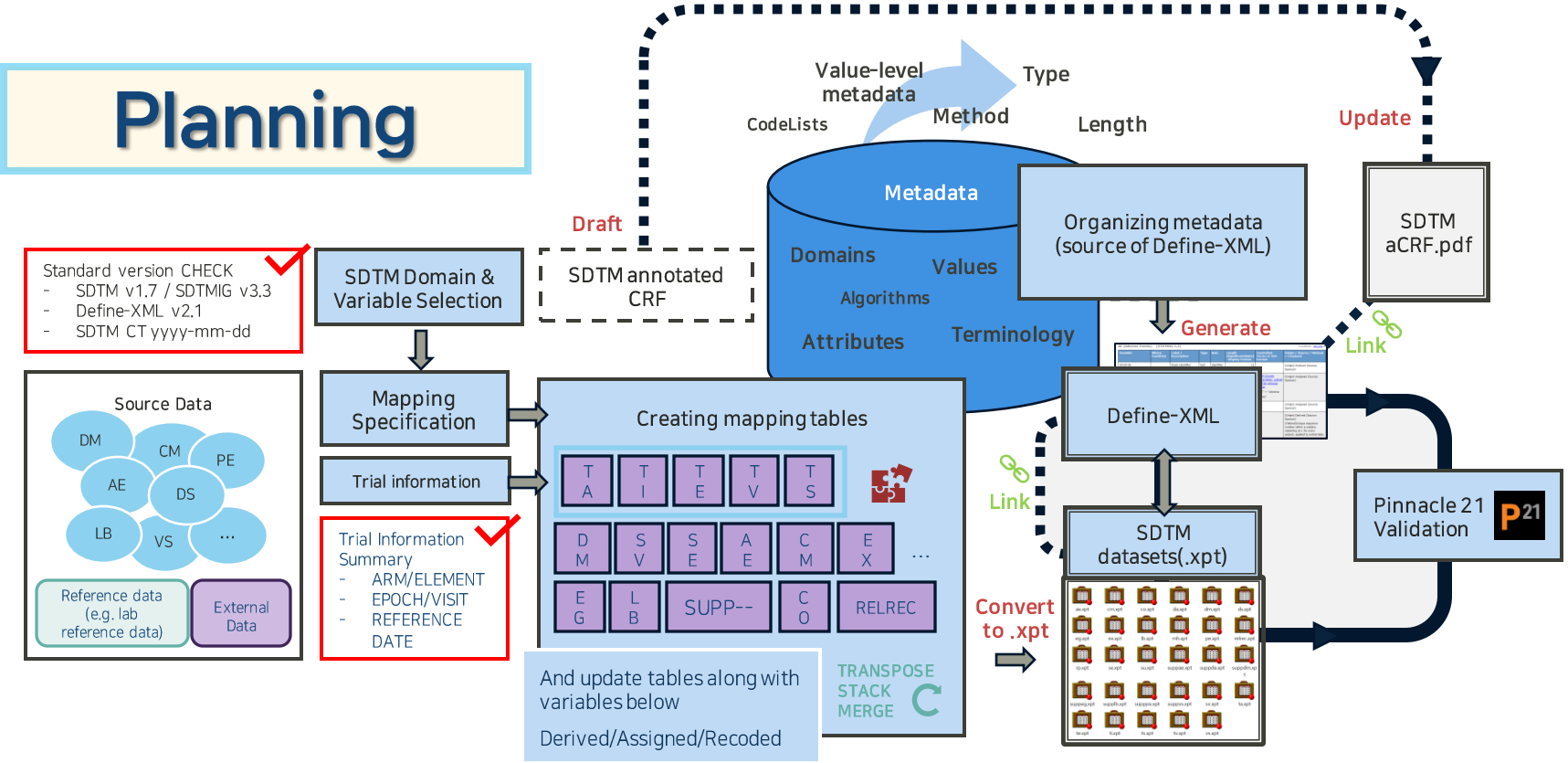
Considerations in converting study data and the cases you may encounter when you are in early stage of work

Data Conversion Process



Data Conversion Process

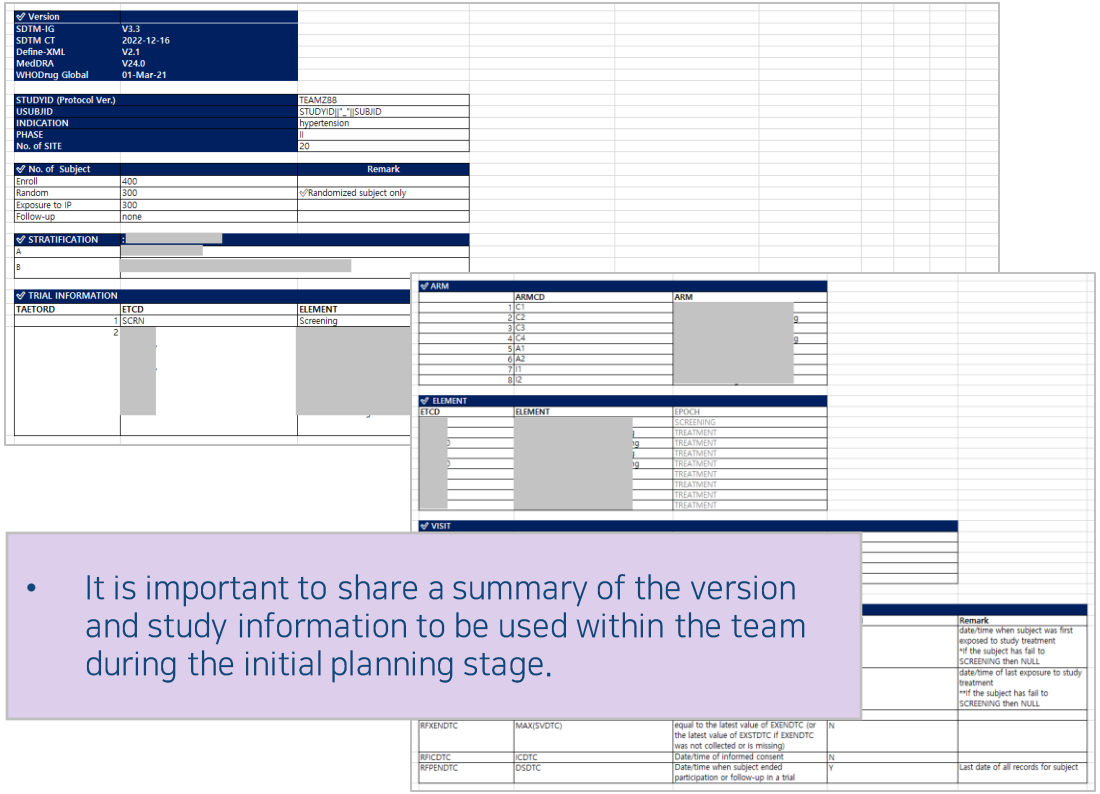
Planning



Data Conversion Process

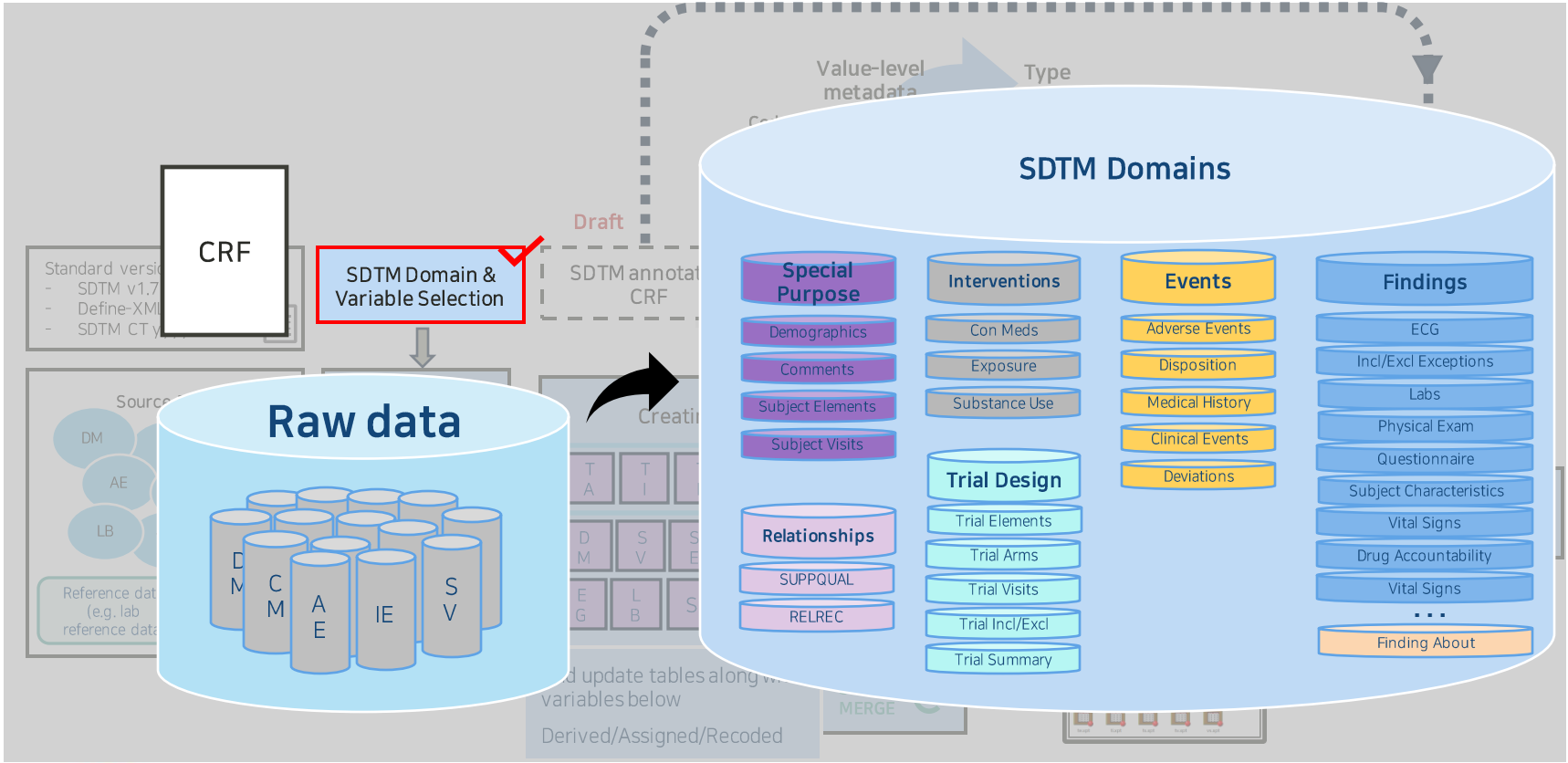
Standard version CHECK
- SDTM v1.7 / SDTMIG v3.3
- Define-XML v2.1
- SDTM CT yyyy-mm-dd

Trial Information Summary
- ARM/ELEMENT
- EPOCH/VISIT
- REFERENCE DATE



- It is important to share a summary of the version and study information to be used within the team during the initial planning stage.

Data Conversion Process



Data Conversion Process

SDTM Domain & Variable Selection

Value-level metadata

Type

Method

Length

CodeLists

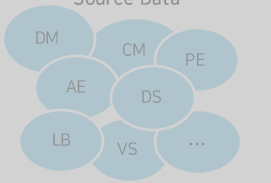
Update

Metadata

Mapping Specification

Standard version CHECK
- SDTM v1.7 / SDTMIG v3.3
- Define-XML v2.1
- SDTM CT yyyy-mm-dd

Source Data



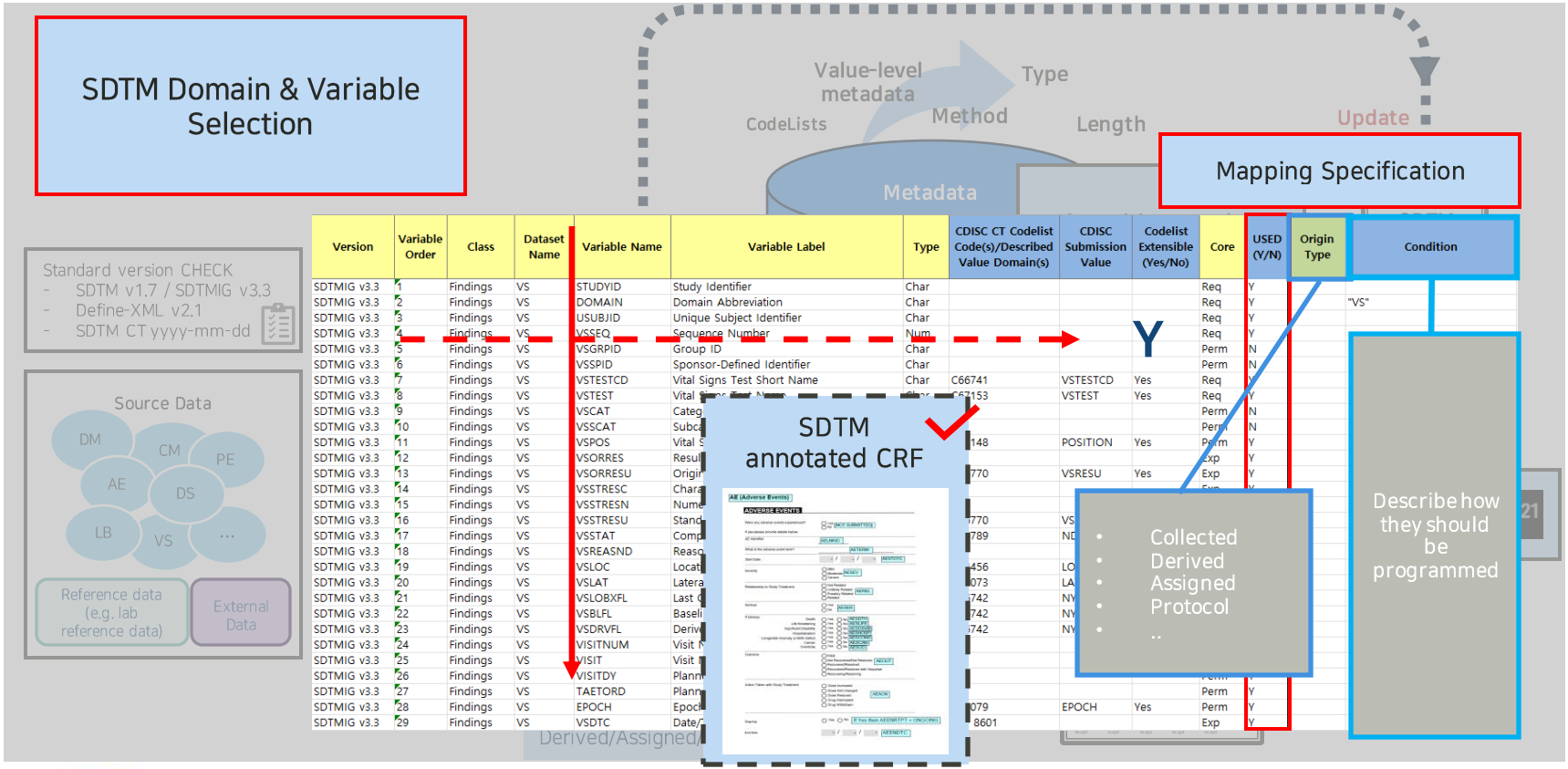
Reference data (e.g. lab reference data)

External Data

Version	Variable Order	Class	Dataset Name	Variable Name	Variable Label	Type	CDISC CT Codelist Code(s)/Described Value Domain(s)	CDISC Submission Value	Codelist Extensible (Yes/No)	Core	USED (Y/N)	Origin Type	Condition
SDTMIG v3.3	1	Findings	VS	STUDYID	Study Identifier	Char				Req	Y		
SDTMIG v3.3	2	Findings	VS	DOMAIN	Domain Abbreviation	Char				Req	Y		"VS"
SDTMIG v3.3	3	Findings	VS	USUBJID	Unique Subject Identifier	Char				Req	Y		
SDTMIG v3.3	4	Findings	VS	VSSEQ	Sequence Number	Num				Req	Y		
SDTMIG v3.3	5	Findings	VS	VSGRPID	Group ID	Char				Perm	N		
SDTMIG v3.3	6	Findings	VS	VSSPID	Sponsor-Defined Identifier	Char				Perm	N		
SDTMIG v3.3	7	Findings	VS	VSTESTCD	Vital Signs Test Short Name	Char	C66741	VSTESTCD	Yes	Req	Y		
SDTMIG v3.3	8	Findings	VS	VSTEST	Vital Signs Test Name	Char	C67153	VSTEST	Yes	Req	Y		
SDTMIG v3.3	9	Findings	VS	VSCAT	Category for Vital Signs	Char				Perm	N		
SDTMIG v3.3	10	Findings	VS	VSSCAT	Subcategory for Vital Signs	Char				Perm	N		
SDTMIG v3.3	11	Findings	VS	VSPOS	Vital Signs Position of Subject	Char	C71148	POSITION	Yes	Perm	Y		
SDTMIG v3.3	12	Findings	VS	VSORRES	Result or Finding in Original Units	Char				Exp	Y		
SDTMIG v3.3	13	Findings	VS	VSORRESU	Original Units	Char	C66770	VSRESU	Yes	Exp	Y		
SDTMIG v3.3	14	Findings	VS	VSSTRESC	Character Result/Finding in Std Format	Char				Exp	Y		
SDTMIG v3.3	15	Findings	VS	VSSTRESN	Numeric Result/Finding in Standard Units	Num				Exp	Y		
SDTMIG v3.3	16	Findings	VS	VSSTRESU	Standard Units	Char	C66770	VSRESU	Yes	Exp	Y		
SDTMIG v3.3	17	Findings	VS	VSSTAT	Completion Status	Char	C66789	ND	No	Perm	Y		
SDTMIG v3.3	18	Findings	VS	VSREASND	Reason Not Performed	Char				Perm	N		
SDTMIG v3.3	19	Findings	VS	VSLOC	Location of Vital Signs Measurement	Char	C74456	LOC	Yes	Perm	Y		
SDTMIG v3.3	20	Findings	VS	VSLAT	Laterality	Char	C99073	LAT	Yes	Perm	Y		
SDTMIG v3.3	21	Findings	VS	VSLOBXFL	Last Observation Before Exposure Flag	Char	C66742	NY	No	Exp	Y		
SDTMIG v3.3	22	Findings	VS	VSBLFL	Baseline Flag	Char	C66742	NY	No	Perm	N		
SDTMIG v3.3	23	Findings	VS	VSDRVFL	Derived Flag	Char	C66742	NY	No	Perm	Y		
SDTMIG v3.3	24	Findings	VS	VISITNUM	Visit Number	Num				Exp	Y		
SDTMIG v3.3	25	Findings	VS	VISIT	Visit Name	Char				Perm	Y		
SDTMIG v3.3	26	Findings	VS	VISITDY	Planned Study Day of Visit	Num				Perm	Y		
SDTMIG v3.3	27	Findings	VS	TAETORD	Planned Order of Element within Arm	Num				Perm	Y		
SDTMIG v3.3	28	Findings	VS	EPOCH	Epoch	Char	C99079	EPOCH	Yes	Perm	Y		
SDTMIG v3.3	29	Findings	VS	VSDTC	Date/Time of Measurements	Char	ISO 8601			Exp	Y		

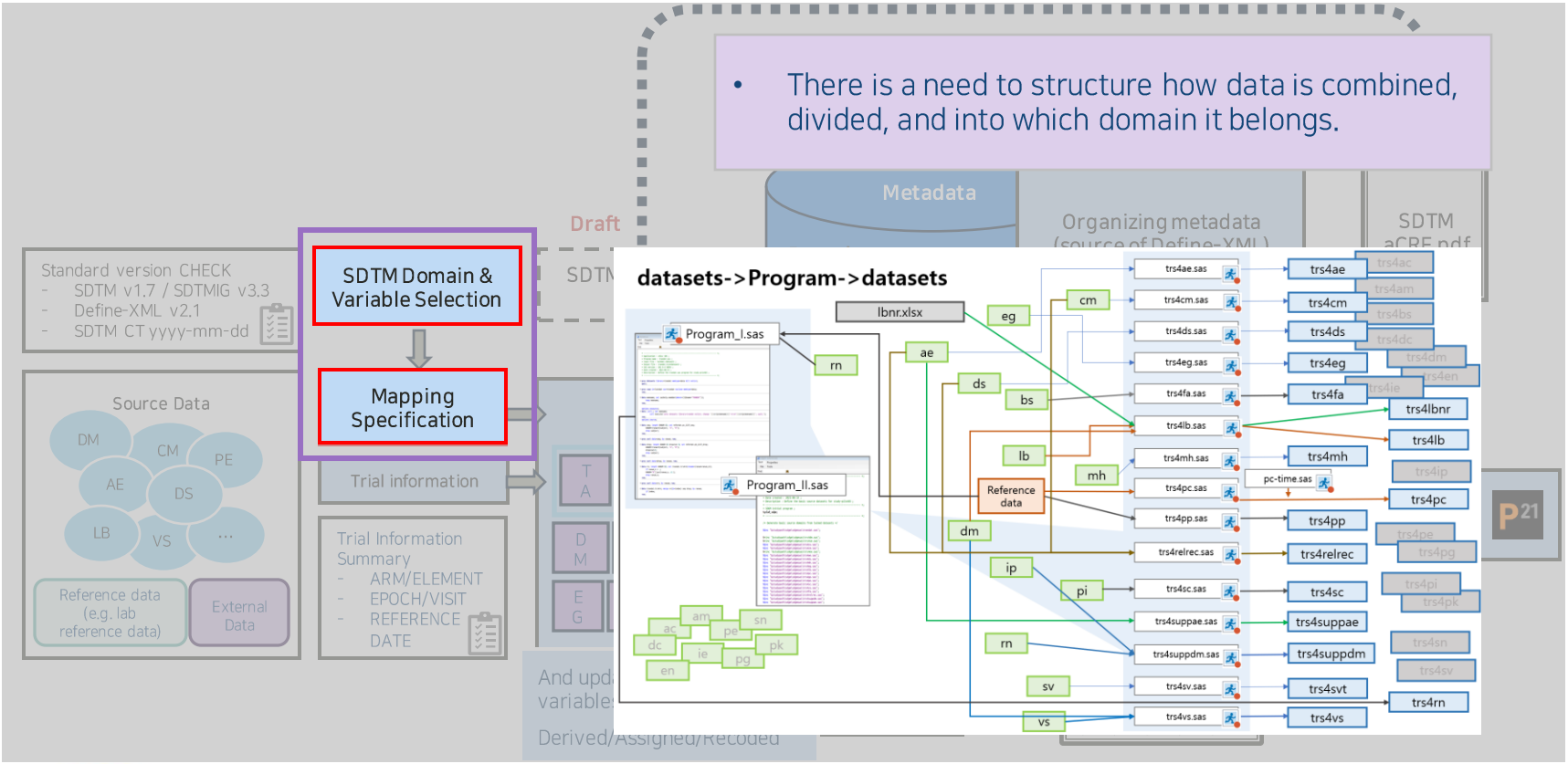
Derived/Assigned/Recoded

Data Conversion Process

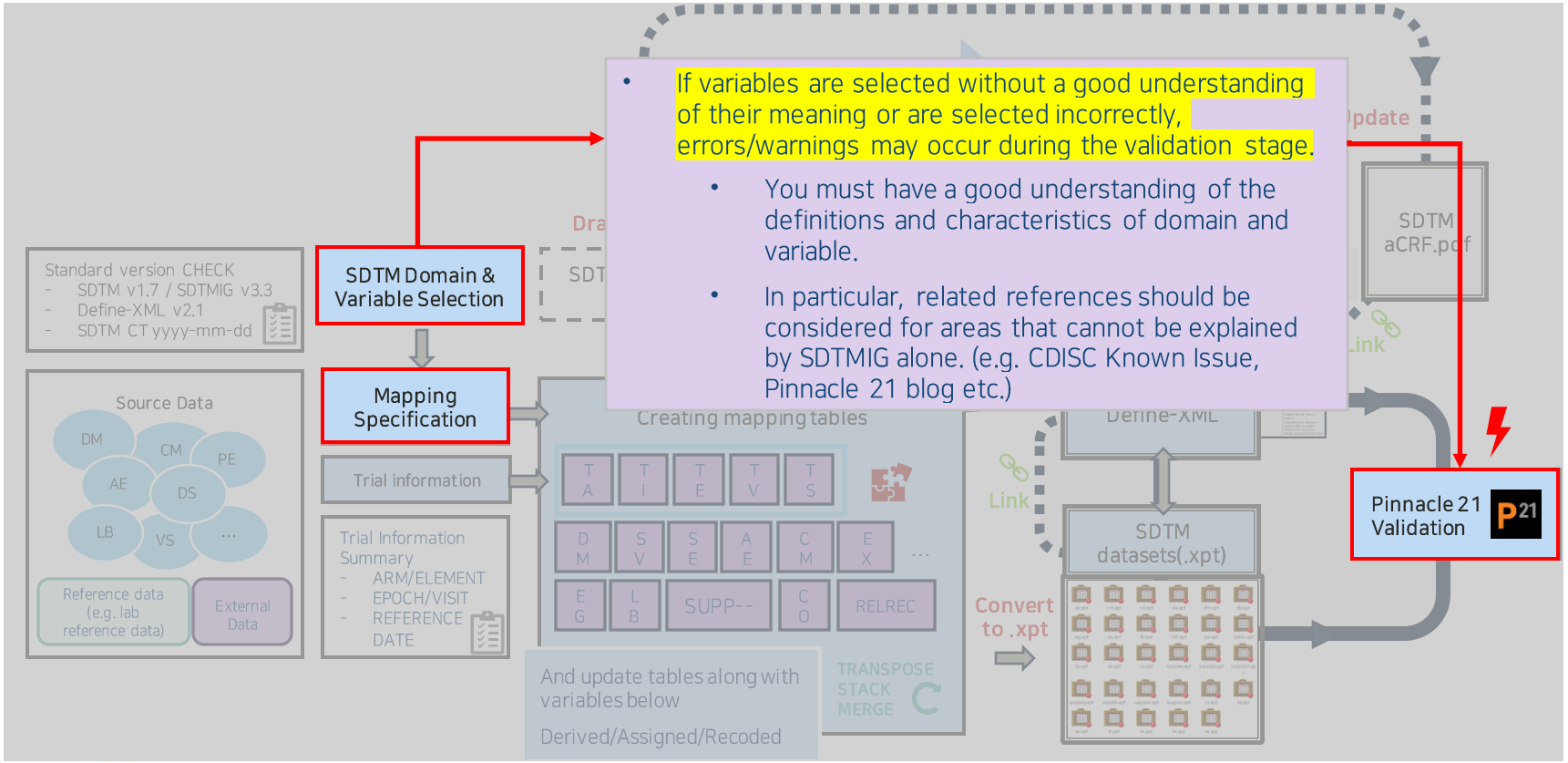


Data Conversion Process

- There is a need to structure how data is combined, divided, and into which domain it belongs.



Data Conversion Process



Case I.

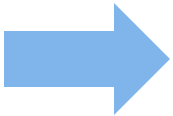
Unexpected value in IDVAR/IDVARVAL

Core
- Required
- Expected
- Permissible

When creating the SUPPDM dataset, the IDVAR and IDVARVAL variables were included because their core were Expected, but an error occurred in the validation report for this part.

SDTMIG v3.3

Class	Dataset Name	Variable Name	Variable Label	Type	Core
Relationship	SUPPQUAL	IDVAR	Identifying Variable	Char	Exp
Relationship	SUPPQUAL	IDVARVAL	Identifying Variable Value	Char	Exp



Pinnacle 21 Validator Report

Issue Summary

Source	Pinnacle 21 ID	Message
SUPPDM		
	SD1051	Unexpected value for IDVAR/IDVARVAL

Case I.

Unexpected value in IDVAR/IDVARVAL

8.4.1 Supplemental Qualifiers – SUPP-- Datasets [SDTMIG v3.3]

A record in a SUPP-- dataset relates back to its parent record(s) via the key identified by the STUDYID, RDOMAIN, USUBJID, and IDVAR/IDVARVAL variables. An exception is SUPP-- dataset records that are related to Demographics (DM) records, where both IDVAR and IDVARVAL will be null because the key variables STUDYID, RDOMAIN, and USUBJID are sufficient to identify the unique parent record in DM (DM has one record per USUBJID).

Exceptionally, in the SUPP-dataset for DM, STUDYID, RDOMAIN, and USUBJID are key variables, so IDVAR and IDVARVAL are null.

Solution: When creating a SUPP– dataset relating information to the DM domain, keep IDVAR and IDVARVAL blank!

Case II.
Missing DSDTC, when DSDY is presented

- DSDTC stands for collection date for disposition event. However, since this information is not confirmed in the original data, we decided not to include the DSDTC variable in the DS dataset.
- DSDY is a variable calculated as an integer day based on DSDTC. Since DSDTC is not collected, DSDY is all Null, but since the core is Expected, it must be included in the DS dataset.

SDTMIG v3.3

Class	Dataset Name	Variable Name	Variable Label	Type	Core
Events	DS	DSDTC	Date/Time of Collection	Char	Perm
Events	DS	DSSTDTC	Start Date/Time of Disposition Event	Char	Exp
	DS	DSDY	Study Day of Collection	Num	Exp

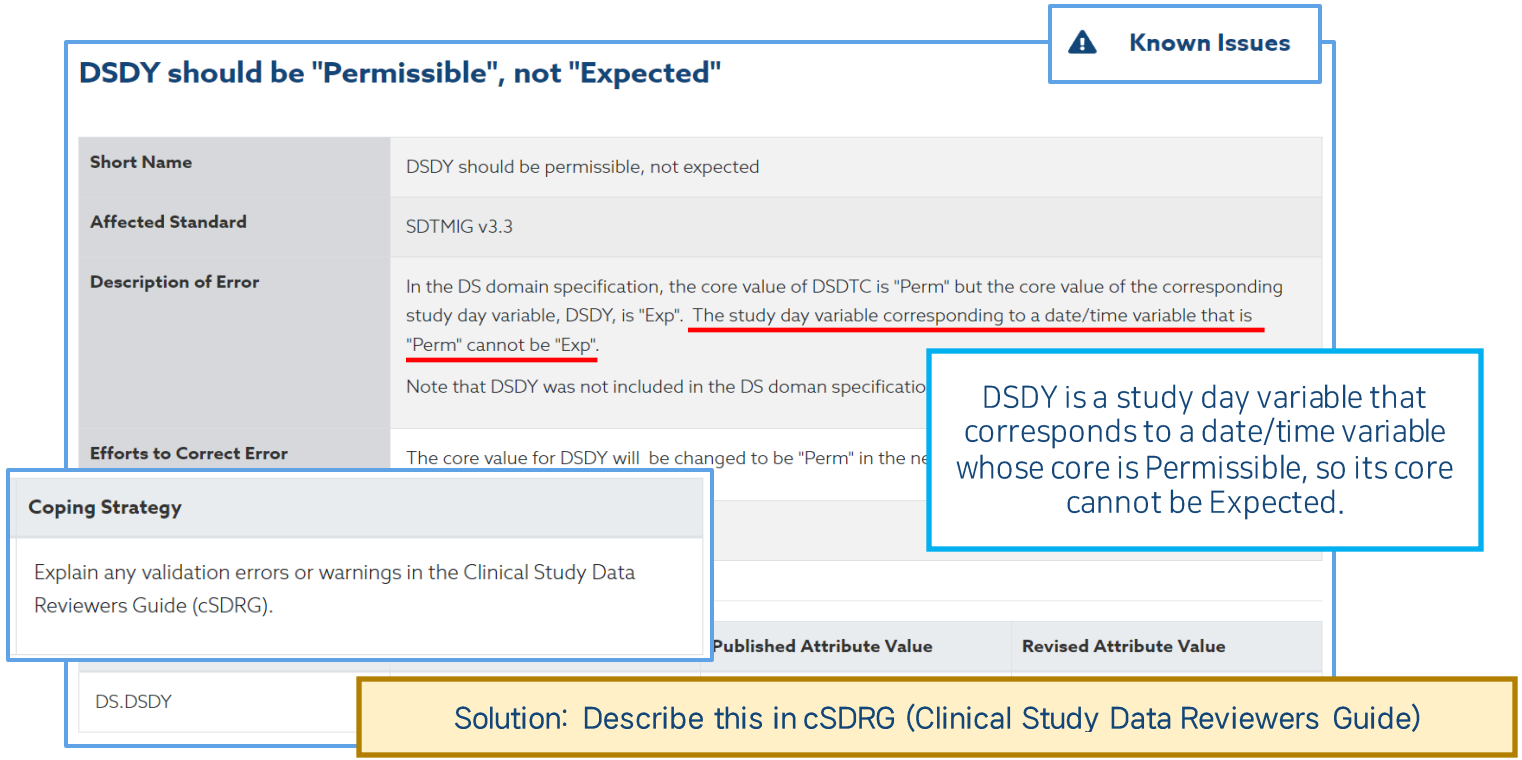
Pinnacle 21 Validator Report

Issue Summary

Source	Pinnacle 21 ID	Message
DS		
	SD2270	Missing DSDTC variable, when DSDY variable is present

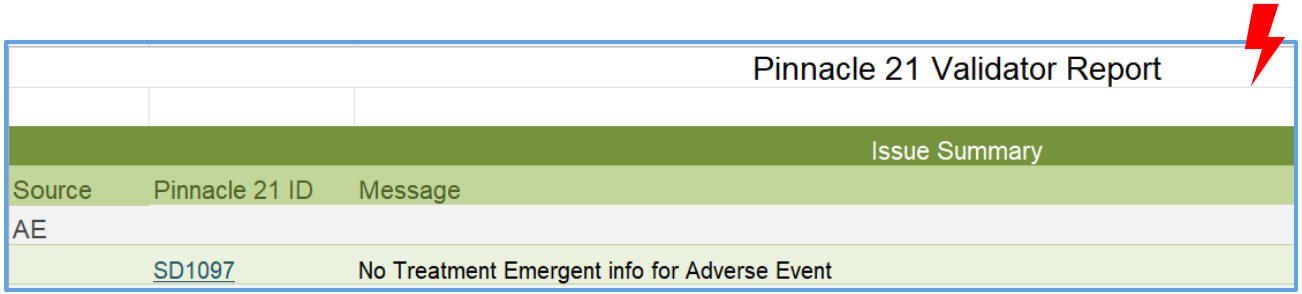
Case II.

Missing DSDTC, when DSDY is presented



Case III.

Treatment Emergent Adverse Event(TEAE) flag?



Pinnacle 21 Validator Report

Issue Summary

Source	Pinnacle 21 ID	Message
AE		
	SD1097	No Treatment Emergent info for Adverse Event

- Among the variables in the AE domain, there is no variable that can display information about Treatment Emergent.
- Additionally, there is no guideline in SDTMIG that states that it is mandatory to include whether the AE is a treatment emergent.

Case III.

Treatment Emergent Adverse Event(TEAE) flag?

Inquiries and answers on the forum board of the Pinnacle 21 website

Hello,

There is an error in AE domain: No Treatment Emergent info for Adverse Event.

The description of rule 1097 states, it should be included in SUPPAE. But there is no imputation done at sdtm level, so how can one create emergent flag?

J Jozef on March 24, 2017

No Treatment Emergent info for Adverse Event

There SHOULD not be any imputed data in SDTM, but the sad reality is different ...
This is a requirement added by the FDA on top of what CDISC has as requirements.
According to the CDISC principles, "treatment emergent flags" should only appear in ADaM, but the FDA also wants it in SDTM.

Ref. https://www.pinnacle21.com/forum/no-treatment-emergent-info-adverse-event

Case III.

Treatment Emergent Adverse Event(TEAE) flag?

FDA Validator rules v1.6

FDA Validator Rule ID	Publisher	Publisher ID	FDA Validator Rule Message
SD1321	FDA	FDAB001	No Treatment Emergent info for Adverse Event (missing SUPPAE)

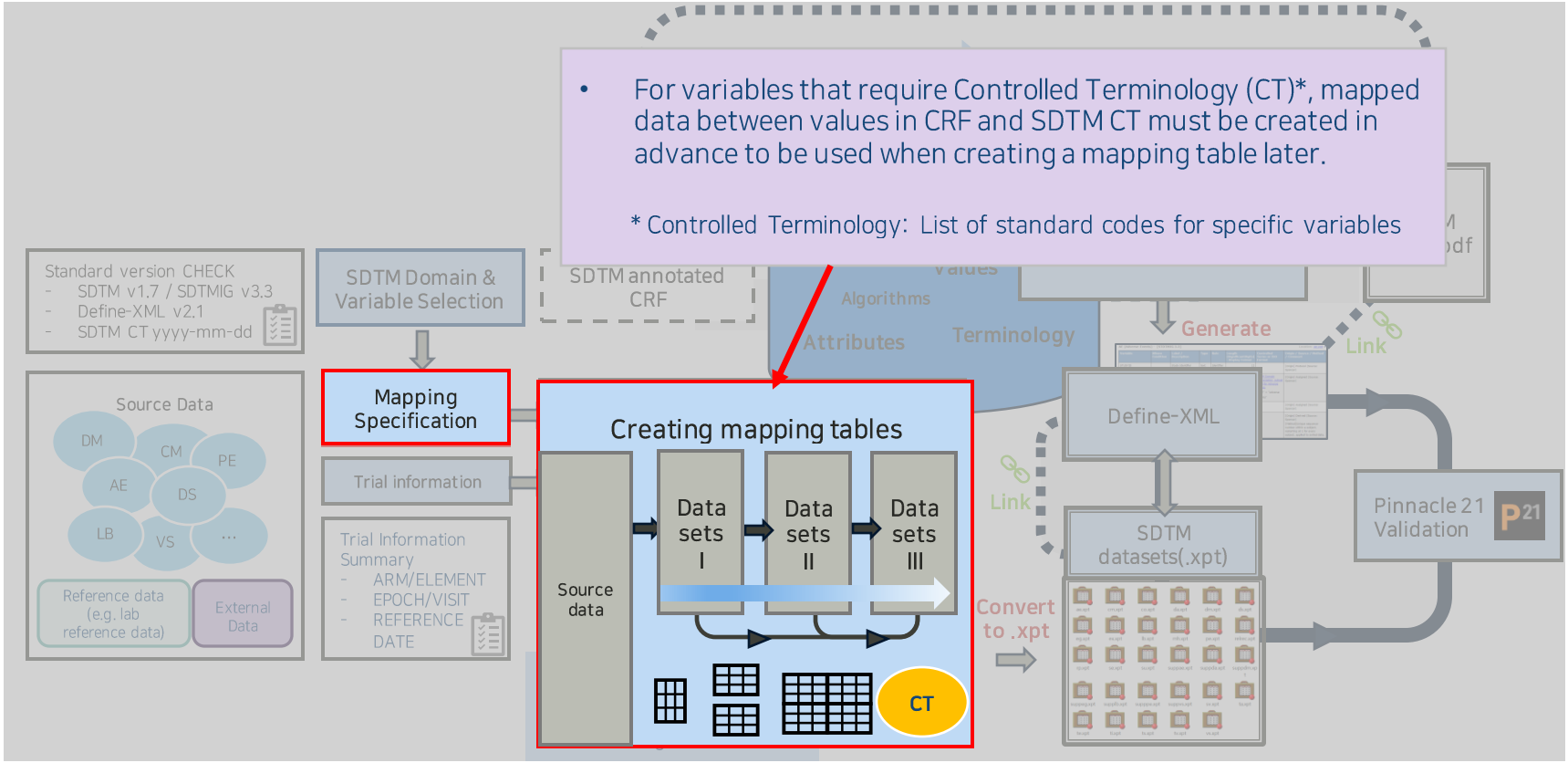
FDA Validator Rule Description
A treatment-emergent flag should be included in SUPPAE according to the FDA business rule that states, 'A treatment-emergent flag should be submitted.'

Although it is not included in the SDTM principles, a treatment-emergent flag must be included in the SUPPAE as specified in FDA business rules.

Version 1.5 finalized June 2019

FDA Business Rule ID	FDA Business Rule
FDAB001	A treatment-emergent flag should be submitted.

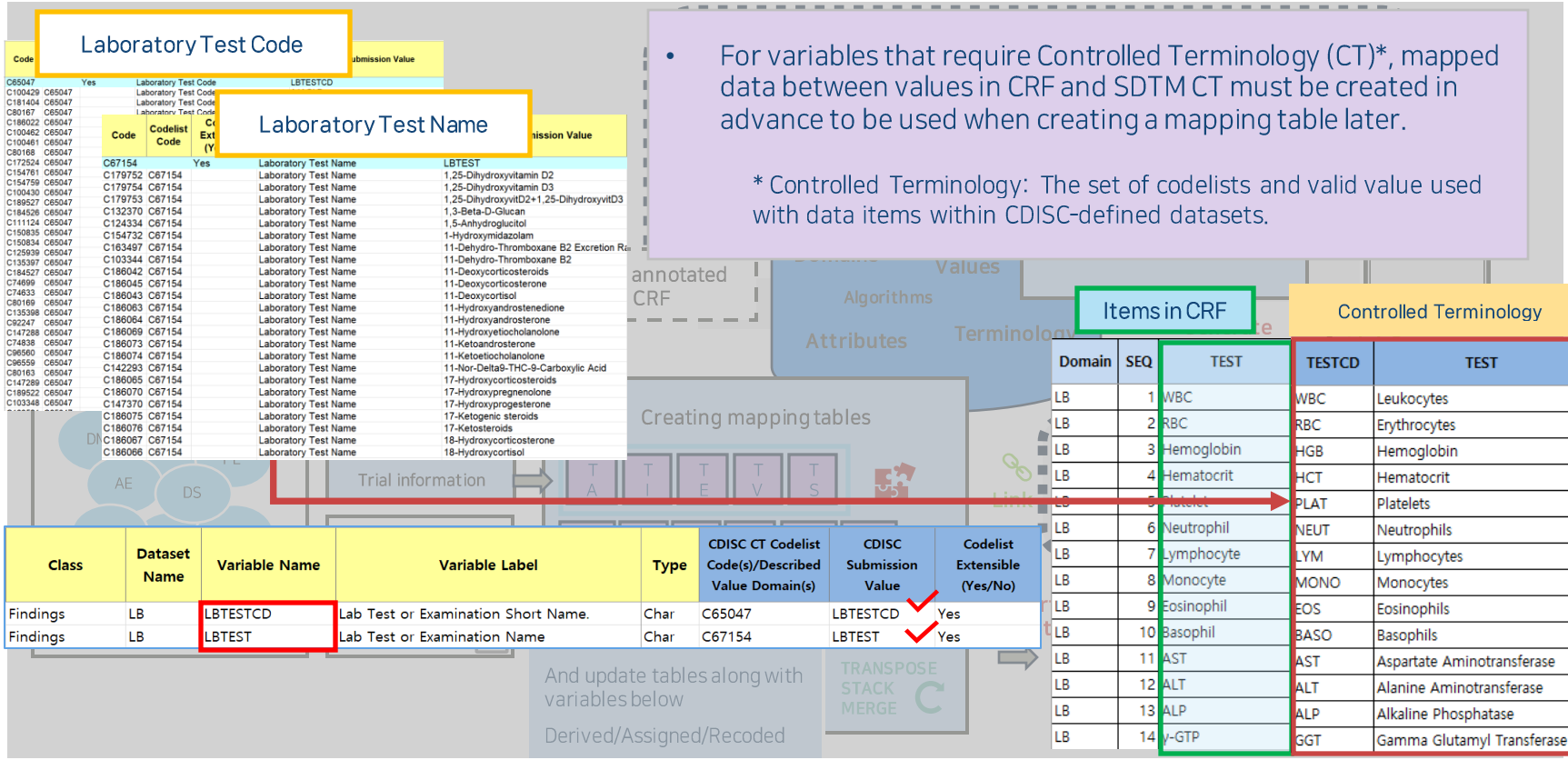
Data Conversion Process



Data Conversion Process

- For variables that require Controlled Terminology (CT)*, mapped data between values in CRF and SDTM CT must be created in advance to be used when creating a mapping table later.

  * Controlled Terminology: The set of codelists and valid value used with data items within CDISC-defined datasets.



Code	Codelist Code	Codelist Extensible (Yes/No)	Submission Value	
C67154		Yes	Laboratory Test Name	LBTEST
C179752	C67154		Laboratory Test Name	1,25-Dihydroxyvitamin D2
C179754	C67154		Laboratory Test Name	1,25-Dihydroxyvitamin D3
C179753	C67154		Laboratory Test Name	1,25-DihydroxyvitD2+1,25-DihydroxyvitD3
C132370	C67154		Laboratory Test Name	1,3-Beta-D-Glucan
C124334	C67154		Laboratory Test Name	1,5-Anhydroglucitol
C154732	C67154		Laboratory Test Name	1-Hydroxymidazolam
C163497	C67154		Laboratory Test Name	11-Dehydro-Thromboxane B2 Excretion Ra
C103344	C67154		Laboratory Test Name	11-Dehydro-Thromboxane B2
C186042	C67154		Laboratory Test Name	11-Deoxycorticosteroids
C186045	C67154		Laboratory Test Name	11-Deoxycorticosterone
C186043	C67154		Laboratory Test Name	11-Deoxycortisol
C186063	C67154		Laboratory Test Name	11-Hydroxyandrostenedione
C186064	C67154		Laboratory Test Name	11-Hydroxyandrosterone
C186069	C67154		Laboratory Test Name	11-Hydroxyetiocholanolone
C186073	C67154		Laboratory Test Name	11-Ketoandrosterone
C186074	C67154		Laboratory Test Name	11-Ketoetiocholanolone
C142293	C67154		Laboratory Test Name	11-Nor-Delta9-THC-9-Carboxylic Acid
C186065	C67154		Laboratory Test Name	17-Hydroxycorticosteroids
C186070	C67154		Laboratory Test Name	17-Hydroxypregnenolone
C147370	C67154		Laboratory Test Name	17-Hydroxyprogesterone
C186075	C67154		Laboratory Test Name	17-Ketogenic steroids
C186076	C67154		Laboratory Test Name	17-Ketosteroids
C186067	C67154		Laboratory Test Name	18-Hydroxycorticosterone
C186066	C67154		Laboratory Test Name	18-Hydroxycortisol

Class	Dataset Name	Variable Name	Variable Label	Type	CDISC CT Codelist Code(s)/Described Value Domain(s)	CDISC Submission Value	Codelist Extensible (Yes/No)
Findings	LB	LBTESTCD	Lab Test or Examination Short Name.	Char	C65047	LBTESTCD	Yes
Findings	LB	LBTEST	Lab Test or Examination Name	Char	C67154	LBTEST	Yes

Items in CRF

Domain	SEQ	TEST
LB	1	WBC
LB	2	RBC
LB	3	Hemoglobin
LB	4	Hematocrit
LB	5	Platelet
LB	6	Neutrophil
LB	7	Lymphocyte
LB	8	Monocyte
LB	9	Eosinophil
LB	10	Basophil
LB	11	AST
LB	12	ALT
LB	13	ALP
LB	14	γ-GTP

Controlled Terminology

TESTCD	TEST
WBC	Leukocytes
RBC	Erythrocytes
HGB	Hemoglobin
HCT	Hematocrit
PLAT	Platelets
NEUT	Neutrophils
LYM	Lymphocytes
MONO	Monocytes
EOS	Eosinophils
BASO	Basophils
AST	Aspartate Aminotransferase
ALT	Alanine Aminotransferase
ALP	Alkaline Phosphatase
GGT	Gamma Glutamyl Transferase

The importance of accurate CT mapping

There may be simple mappings such as gender (Male - M, Female - F),

but In the case of temperature measurement area,

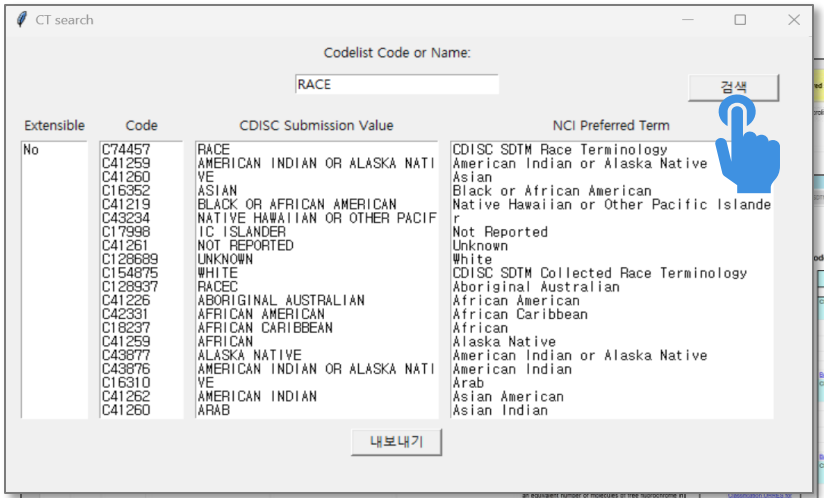
TYMPANIC MEMBRANE

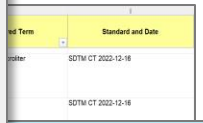
Among the dosage forms, tablets vary as follows.

- → TABLET
- → TABLET, FILM COATED
- → TABLET, CHEWABLE
- → TABLET, EXTENDED RELEASE
- → TABLET, MULTILAYER
- → TABLET, ORALLY DISINTEGRATING …

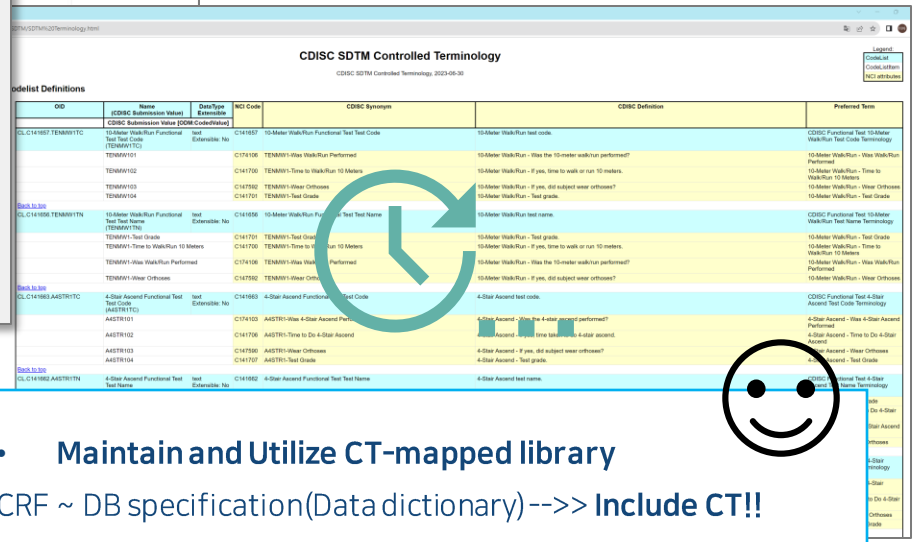
Since the code classification criteria can be very detailed or broad depending on the nature of the item, finding the correct terminology and reflecting it in the data to prevent data from being distorted or lost during the mapping process can lead to improved quality of results.

CT mapping takes more time than you think





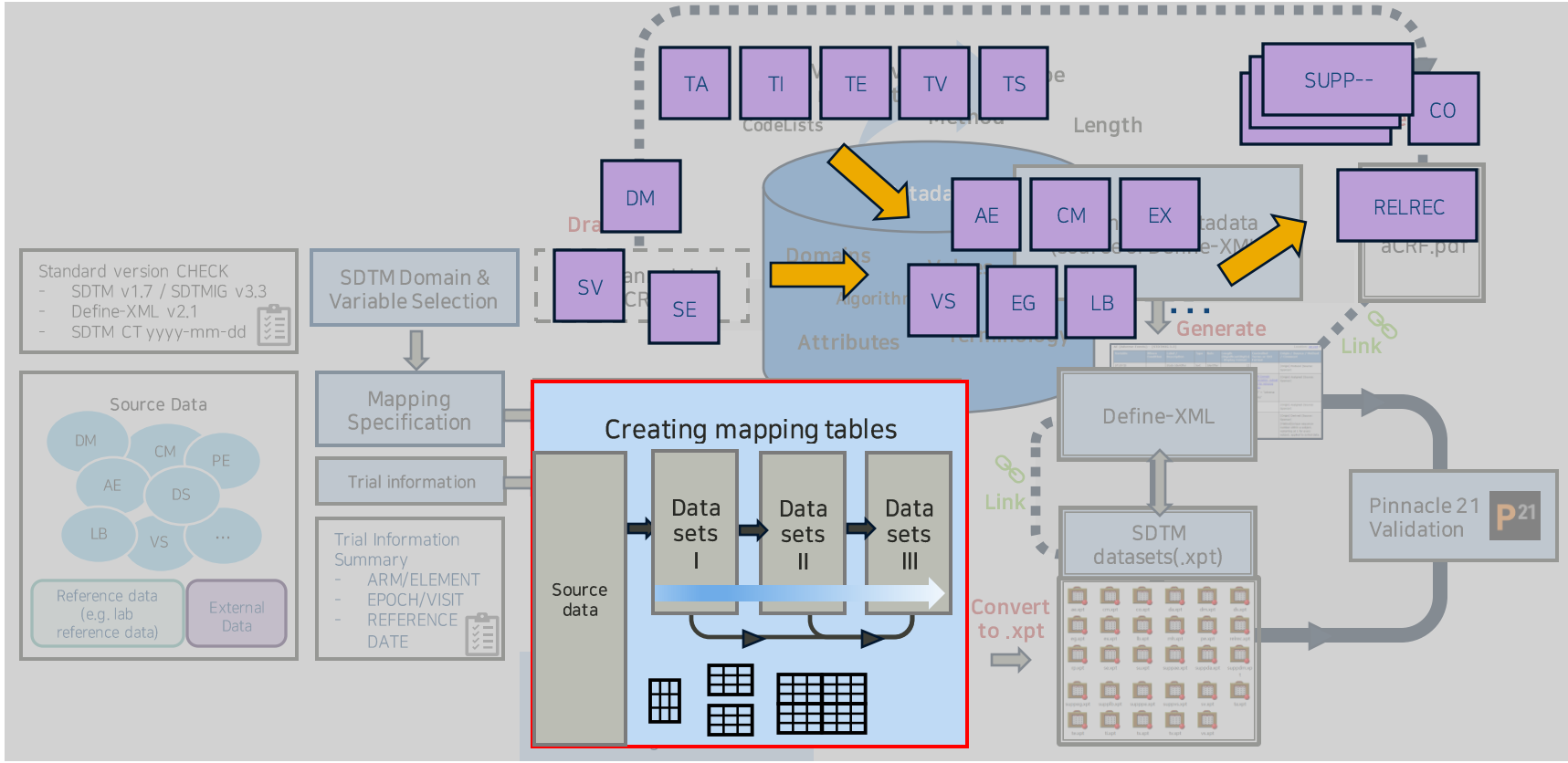
SDTM Terminology Website



- **Maintain and Utilize CT-mapped library**

CRF ~ DB specification(Data dictionary) -->>> **Include CT!!**

Data Conversion Process



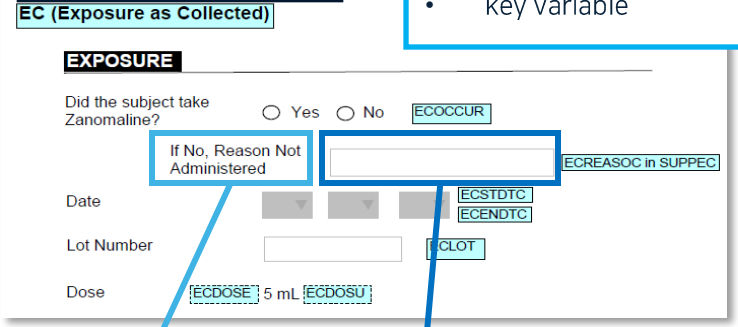
Consider connectivity between tables

- The order of creating tables
- key variable

EC domain

Domain Abbreviation	Unique Subject Identifier	Sponsor Device Identifier	Sequence Number	Name of Treatment	Pre-Specified	Occurrence
EC	CDISC009	DEV0009	122	PLACEBO	Y	N
EC	CDISC009	DEV0009	123	PLACEBO	Y	N
EC	CDISC009	DEV0009	124	PLACEBO	Y	N
EC	CDISC009	DEV0009	125	PLACEBO	Y	N
EC	CDISC009	DEV0009	126	PLACEBO	Y	N
EC	CDISC009	DEV0009	127	PLACEBO	Y	N
EC	CDISC009	DEV0009	128	PLACEBO	Y	N
EC	CDISC009	DEV0009	129	PLACEBO	Y	Y
EC	CDISC009	DEV0009	130	PLACEBO	Y	Y
EC	CDISC009	DEV0009	131	PLACEBO	Y	Y
EC	CDISC009	DEV0009	132	PLACEBO	Y	Y
EC	CDISC009	DEV0009	133	PLACEBO	Y	Y
EC	CDISC009	DEV0009	134	PLACEBO	Y	Y

EC page (aCRF)



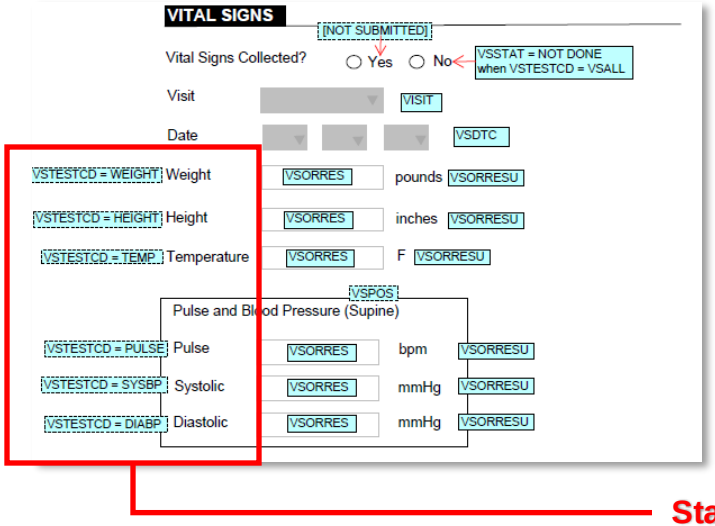
SUPPEC domain

Related Domain Abbreviation	Unique Subject Identifier	Identifying Variable	Identifying Variable Value	Qualifier Variable Name	Qualifier Variable Label	Data Value
EC	CDISC009	ECSEQ	122	ECREAS	Reason for Occur Value	INVESTIGATOR DECISION
EC	CDISC009	ECSEQ	123	ECREAS	Reason for Occur Value	INVESTIGATOR DECISION
EC	CDISC009	ECSEQ	124	ECREAS	Reason for Occur Value	INVESTIGATOR DECISION
EC	CDISC009	ECSEQ	125	ECREAS	Reason for Occur Value	INVESTIGATOR DECISION
EC	CDISC009	ECSEQ	126	ECREAS	Reason for Occur Value	INVESTIGATOR DECISION
EC	CDISC009	ECSEQ	127	ECREAS	Reason for Occur Value	INVESTIGATOR DECISION
EC	CDISC009	ECSEQ	128	ECREAS	Reason for Occur Value	INVESTIGATOR DECISION

Consider how the table structure changes

TEMP	PULSE	SYSBP	DIABP
97.4	51	137	71

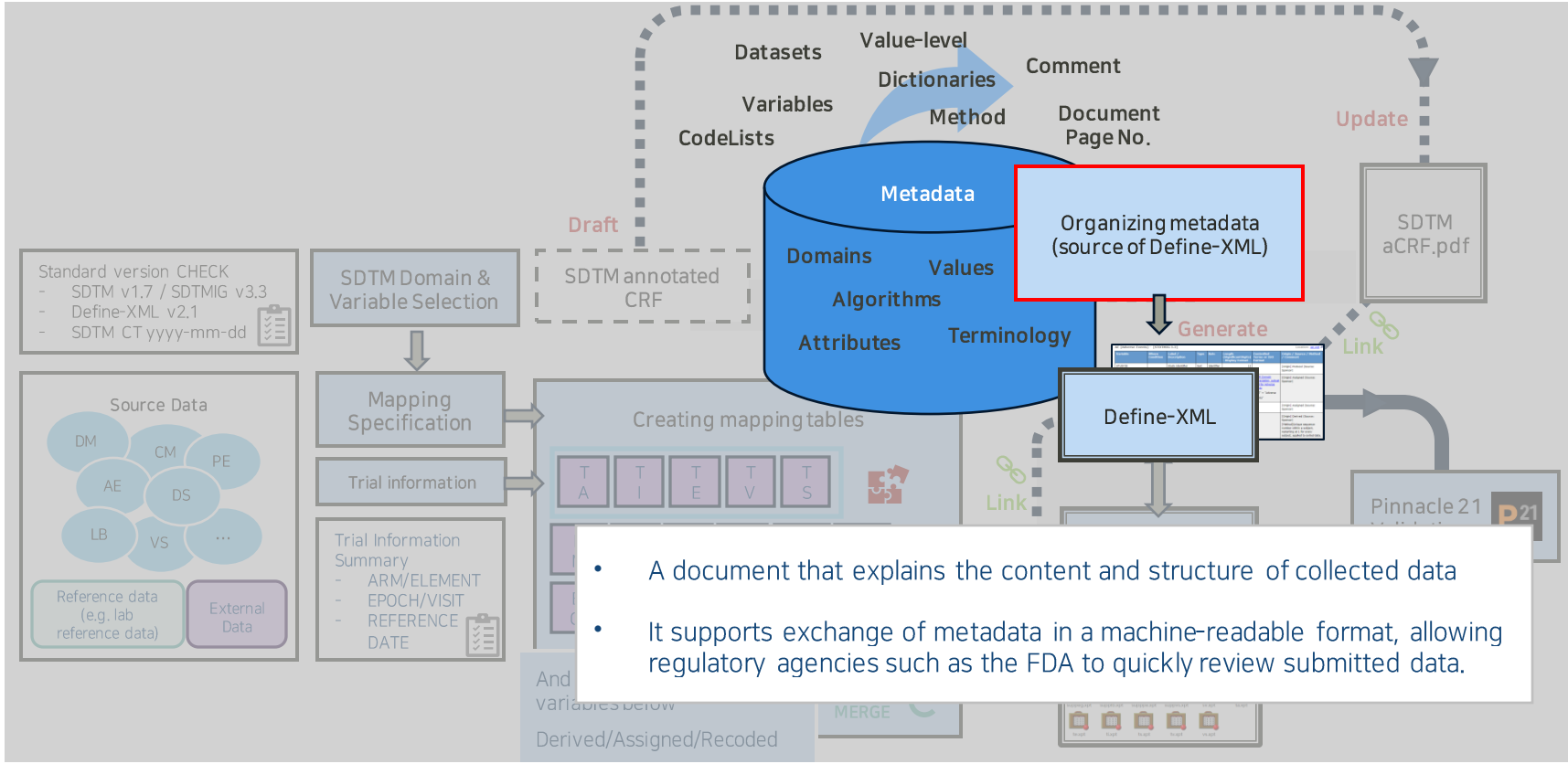
VSTESTCD	VSORRES
TEMP	97.4
PULSE	51
SYSBP	137
DIABP	71



Unique Subject Identifier	Sequence Number	Vital Signs Test Short Name	Vital Signs Test Name	Vital Signs Position of Subject	Result or Finding in Original Units	Original Units
CDISC00	1	DIABP	Diastolic Blood Pressure	STANDIN	71	mmHg
CDISC00	15	HEIGHT	Height		71,5	in
CDISC00	16	PULSE	Pulse Rate	STANDIN	51	beats/min
CDISC00	30	SYSBP	Systolic Blood Pressure	STANDIN	137	mmHg
CDISC00	44	TEMP	Temperature		97,4	F
CDISC00	52	WEIGHT	Weight		173,5	LB
CDISC00	2	DIABP	Diastolic Blood Pressure	STANDIN	71	mmHg
CDISC00	17	PULSE	Pulse Rate	STANDIN	50	beats/min
CDISC00	31	SYSBP	Systolic Blood Pressure	STANDIN	137	mmHg
CDISC00	45	TEMP	Temperature		97,2	F
CDISC00	3	DIABP	Diastolic Blood Pressure	STANDIN	83	mmHg
CDISC00	18	PULSE	Pulse Rate	STANDIN	50	beats/min
CDISC00	32	SYSBP	Systolic Blood Pressure	STANDIN	130	mmHg
CDISC00	46	TEMP	Temperature		98,0	F

Stack!

Data Conversion Process



- A document that explains the content and structure of collected data
- It supports exchange of metadata in a machine-readable format, allowing regulatory agencies such as the FDA to quickly review submitted data.

Define-XML

Machine-readable format

```
</ItemDef>
<ItemDef OID="IT.EX.DOMAIN" Name="DOMAIN" DataType="text" Length="2" SASFieldName="DOMAIN">
  <Description>
    <TranslatedText xml:lang="en">Domain Abbreviation</TranslatedText>
  </Description>
  <CodeListRef CodeListOID="CL.EX.DOMAIN"/>
  <def:Origin Type="Assigned" Source="Sponsor"/>
</ItemDef>
<ItemDef OID="IT.EX.EXDOSE" Name="EXDOSE" DataType="integer" Length="2"
  <Description>
    <TranslatedText xml:lang="en">Dose per Administration</TranslatedTe
  </Description>
  <def:Origin Type="Derived" Source="Sponsor"/>
</ItemDef>
<ItemDef OID="IT.EX.EXDOSFRM" Name="EXDOSFRM" DataType="text" Length="7
  <Description>
    <TranslatedText xml:lang="en">Dose Form</TranslatedText>
  </Description>
  <CodeListRef CodeListOID="CL.FRM"/>
  <def:Origin Type="Predecessor" Source="Sponsor">
    <Description>
      <TranslatedText xml:lang="en">EC.ECDOSFRM</TranslatedText>
    </Description>
    <def:DocumentRef leafID="LF.acrf">
      <def:PDFPageRef PageRefs="20" Type="PhysicalRef"/>
    </def:DocumentRef>
  </def:Origin>
</ItemDef>
<ItemDef OID="IT.EX.EXDOSU" Name="EXDOSU" DataType="text" Length="2" SA
  <Description>
    <TranslatedText xml:lang="en">Dose Units</TranslatedText>
  </Description>
  <def:Origin Type="Derived" Source="Sponsor"/>
</ItemDef>
<ItemDef OID="IT.EX.EXENDTC" Name="EXENDTC" DataType="date" SASFieldNam
  <Description>
    <TranslatedText xml:lang="en">End Date/Time of Treatment</Translate
  </Description>
  <def:Origin Type="Predecessor" Source="Sponsor">
```

Style sheet applied

CDISC01_1

- Annotated CRF
- Supplemental Documents
- Standards
- Datasets
- Controlled Terminology
- Methods

Expand all VLM

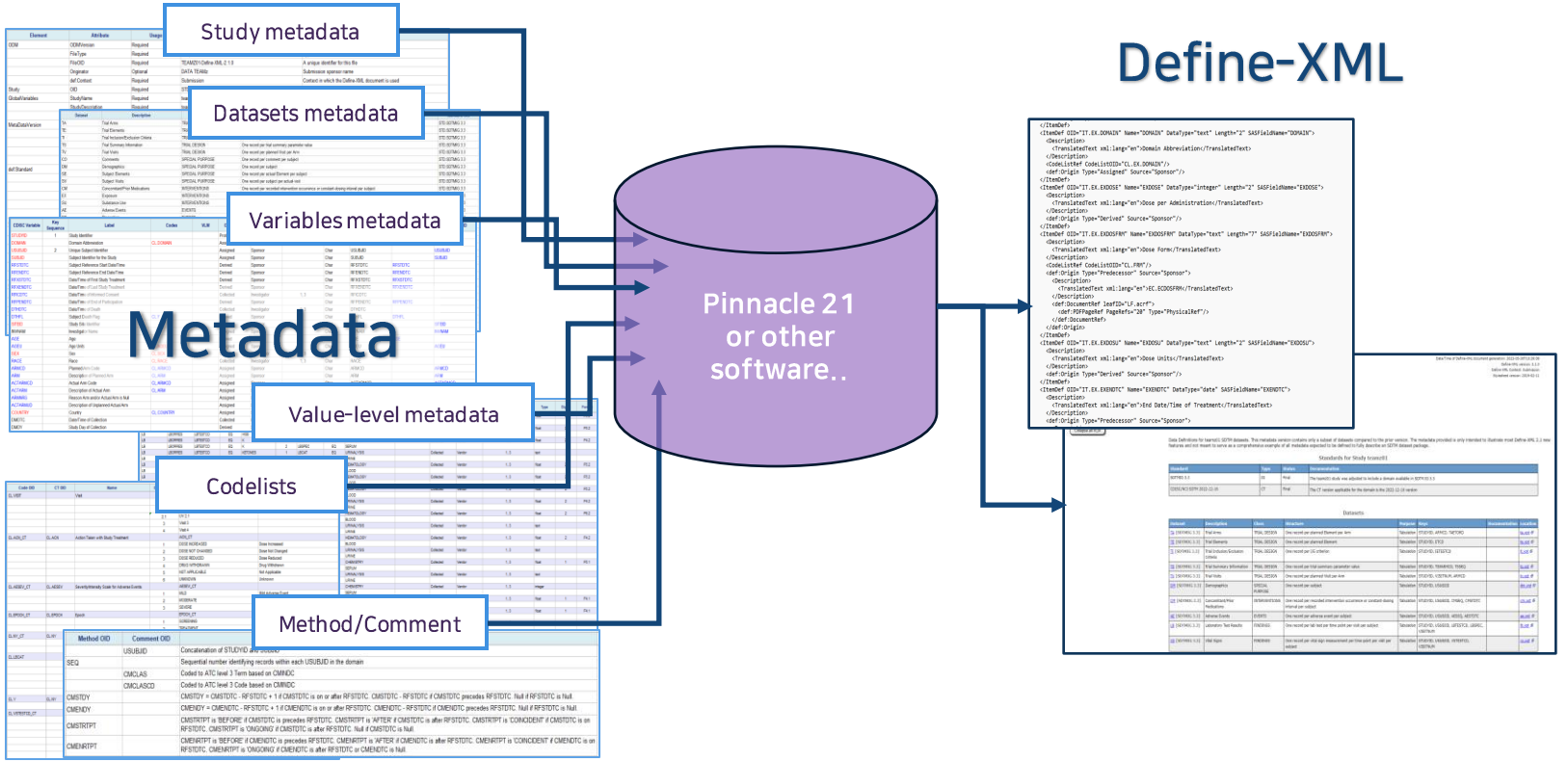
Collapse all VLM

EX (Exposure) - [SDTMIG 3.1.2]

Location: ex.xpt

Variable	Label / Description	Type	Length or Display Format	Controlled Terms or ISO Format	Origin / Source / Method / Comment
STUDYID	Study Identifier	text	7		Protocol (Source: Sponsor)
DOMAIN	Domain Abbreviation	text	2	Domain Abbreviation (EX) • "EX" = "Exposure"	Assigned (Source: Sponsor)
USUBJID	Unique Subject Identifier	text	14		Derived (Source: Sponsor) Concatenation of STUDYID and SUBJID
EXSEQ	Sequence Number	integer	1		Derived (Source: Sponsor) Sequential number identifying records within each USUBJID in the domain.
EXTRT	Name of Actual Treatment	text	20	Treatment • "Miracle Drug" • "Placebo"	Derived (Source: Sponsor) Derived from ARM, ARMCD
EXDOSE	Dose per Administration	integer	2		Derived (Source: Sponsor) If ARMCD=WONDER10 then EXDOSE = Number of Tablets per Day (QVAL where QNAM=SMNO) * 10. If ARMCD=WONDER20 then EXDOSE = Number of Tablets per Day (QVAL where QNAM=SMNO) * 20. If ARMCD=PLACEBO then EXDOSE = 0.
EXDOSU	Dose Units	text	2		Derived (Source: Sponsor) Derived from ARM, ARMCD - equal to mg
EXDOSFRM	Dose Form	text	7	Pharmaceutical Dosage Form • "TABLET" = "tab"	Predecessor (Source: Sponsor) EC.ECDOSFRM Annotated CRF [20]
EXSTDTC	Start Date/Time of Treatment	date		ISO 8601	Predecessor (Source: Sponsor) EC.ECSTDTC Annotated CRF [20]

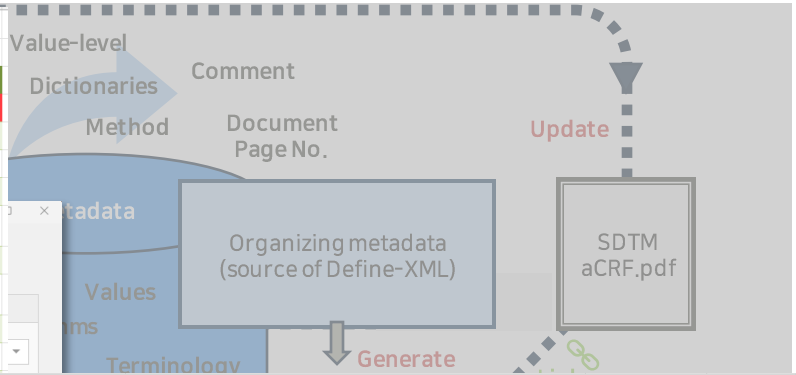
Define-XML


Study metadata
Datasets metadata
Variables metadata
Metadata
Value-level metadata
Codelists
Method/Comment
Pinnacle 21 or other software..
Define-XML

Data Conversion Process

Pinnacle 21 Validator Report

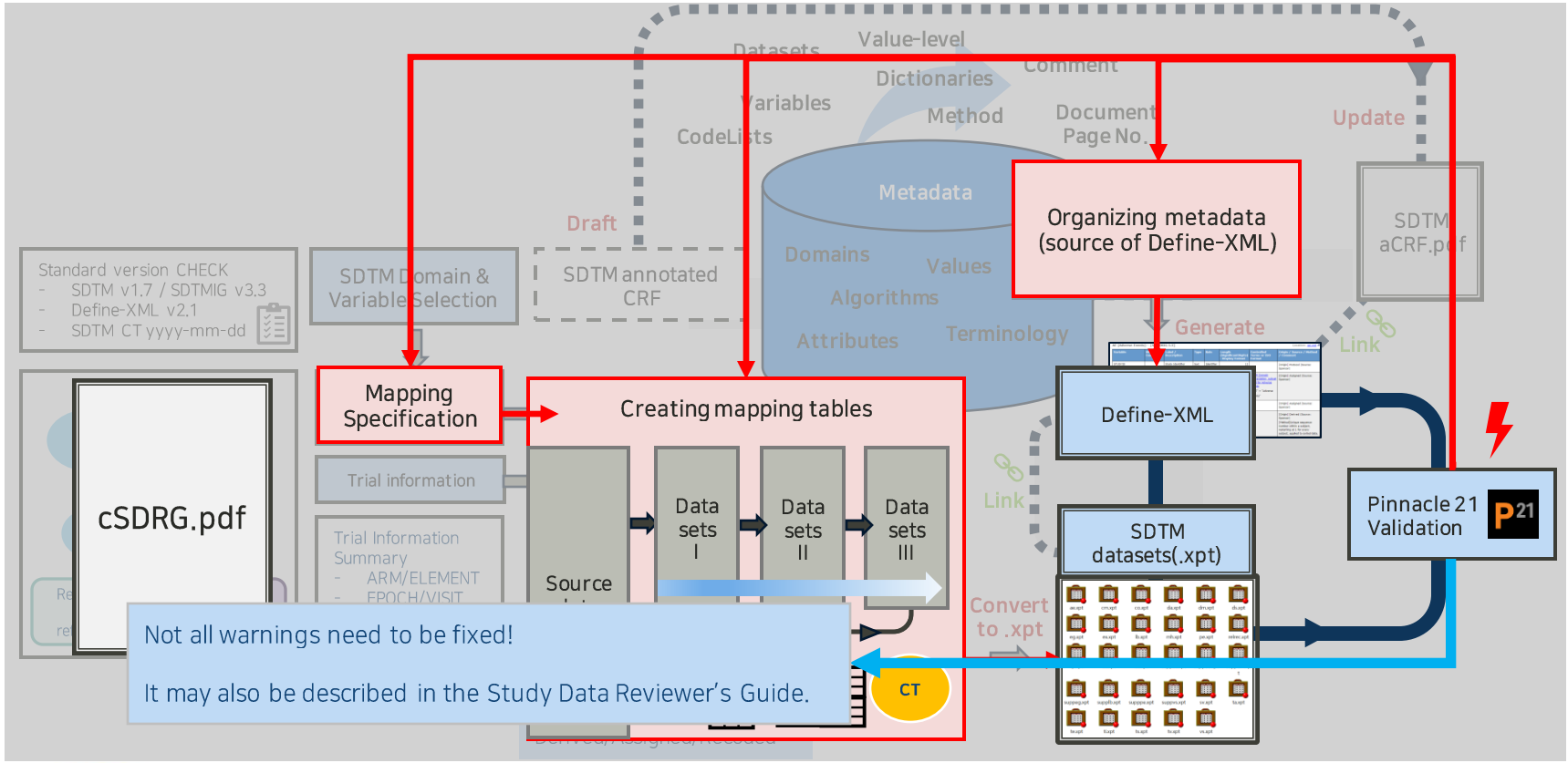
Processed Sources					
Domain	Label	Class	Source	Records	Rejects
GLOBAL	Global Metadata	--	--	0	0
AE	Adverse Events	EVENTS	ae.xpt	115	0
CM	Concomitant/Prior Medications	INTERVENTIONS	cm.xpt	1030	0
CO	Comments	SPECIAL PURPOSE	co.xpt	788	0
DA	Drug Accountability	FINDINGS	da.xpt	16108	0
DM	Demographics	SPECIAL PURPOSE	dm.xpt	413	0
DS	Disposition	EVENTS	ds.xpt	1652	0
EG	ECG Test Results	FINDINGS	eg.xpt	828	0
EX	Exposure	INTERVENTIONS	ex.xpt	1652	0
LB	Laboratory Test Results	FINDINGS	lb.xpt	37204	0
MH	Medical History	EVENTS	mh.xpt	1019	0
PE	Physical Examination	FINDINGS	pe.xpt	1466	0
RELREC	Related Records	RELATIONSHIP	relrec.xpt	442	0
RP	Reproductive System Findings	FINDINGS	rp.xpt	554	0
SE	Subject Elements	SPECIAL PURPOSE	se.xpt	826	0
SU	Substance Use	INTERVENTIONS	su.xpt	826	0
SUPPAE	Supplemental Qualifiers for AE	--	suppae.xpt	115	0
SUPPDA	Supplemental Qualifiers for DA	--	suppda.xpt	3220	0
SUPPDM	Supplemental Qualifiers for DM	--	suppdm.xpt	826	0
SUPPEG	Supplemental Qualifiers for EG	--	suppeg.xpt	308	0
SUPPLB	Supplemental Qualifiers for LB	--	supplb.xpt	3900	0
SUPPPE	Supplemental Qualifiers for PE	--	supppe.xpt	34	0
SUPPVS	Supplemental Qualifiers for VS	--	suppvs.xpt	413	0



Pinnacle 21 Validator Report

Issue Summary				
Source	Pinnacle 21 ID	Message	Severity	Found
DS				
	SD2270	Missing DSDTC variable, when DSDY variable is present		1
EG				
	SD1023	VISIT/VISITNUM values do not match TV domain data		2
EX				
	SD1078	Permissible variable with missing value for all records		1
PE				
	SD0065	USUBJID/VISIT/VISITNUM values do not match SV domain data		2
	SD1023	VISIT/VISITNUM values do not match TV domain data		2
SU				
	SD1076	Model permissible variable added into standard domain		1
SUPPAE				
	CT2002	QEVAL value not found in 'Evaluator' extensible codelist		115
	SD0077	Invalid referenced record		1

Data Conversion Process



Lesson learned from our experiences

4-important things

Understanding the Definitions correctly

And huge Resources..

Starting with a pilot project

Experience SDTM project
Face challenges as many as you can

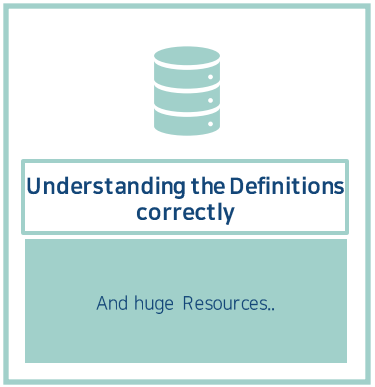
Utilizing technologies

Use software for repetitive and time-consuming tasks

Library and Knowledge repository

Maintain inhouse library
Update and Share Knowledge
Learn from others' experiences

4-important things



- CDISC
  - SDTM
  - SDTMIG, SDTMIG-MD, AP
  - SDTM-MSG
  - Conformance Rules
  - Define-XML specification..
- Regulatory agencies
  - Study Data Technical Conformance Guide
  - Study Data Standard Catalog
  - Business Rules, Validator Rules..
- Others
  - PHUSE WGs documents
    - cSDRG, SDSP packages..
  - PharmaSUG papers
  - Pinnacle 21 resources
    - Validation rules per engines, Blog, Community forum

The requirements of the CDISC standard and the requirements of the regulatory agency exist separately and must be reflected when composing submission data to ensure that both are satisfied.

4-important things

Understanding the Definitions correctly

And huge Resources..

Starting with a pilot project

Experience SDTM project
Face challenges as many as you can

Utilizing technologies

Use software for repetitive and time-consuming tasks

Library and Knowledge repository

Maintain inhouse library
Update and Share Knowledge
Learn from others' experiences

- If you practice with actual data, you will become more familiar with the theory and it will be easier to understand how to use it.
- In the early stages of work, you can conduct practice by creating dummy data as a virtual study model.
  - Regular group meeting -> Sharing & discussion of results created by each person
  - Share questions or data processing skills during the table creation process.

4-important things

Understanding the Definitions correctly

And huge Resources..

Starting with a pilot project

Experience SDTM project
Face challenges as many as you can

Utilizing technologies

Use software for repetitive and time-consuming tasks

Library and Knowledge repository

Maintain inhouse library
Update and Share Knowledge
Learn from others' experiences

- Proper use of technology and software improves efficiency compared to doing it manually. This can simplify repetitive, complex tasks and save time.
- Especially if you are new to SDTM work, applying standardization-related software to your procedures can help you quickly establish SDTM work processes.
- Sponsors can use vendors that provide SDTM conversion services.

4-important things

Understanding the Definitions correctly

And huge Resources..

Starting with a pilot project

Experience SDTM project
Face challenges as many as you can

Utilizing technologies

Use software for repetitive and time-consuming tasks

Library and Knowledge repository

Maintain inhouse library
Update and Share Knowledge
Learn from others' experiences

- Utilizing the library enables efficient work progress while maintaining the quality of results.
- It is helpful to accumulate and manage various questions raised and new information learned while performing work.
- Accumulate and manage a Q&A log containing various inquiries regarding the entire SDTM tasks.
- For resolved content, specify an answer to the questions with references, or establish a provisional internal guidelines for parts for which no reference was found.
- It is also helpful to explore relevant experiences and share them within the team.

On a final note..

- When looking for various examples or solutions to the numerous questions encountered while performing SDTM dataset conversion work, it was difficult to find shared data in Korea.
- In comparison, many questions about standardization work were being actively discussed on websites in other countries.
- I hope that standardization work will be activated in Korea as well, that many experienced people and experts in this field will be trained, and that an environment will be created where various practical cases can be shared and discussed actively.

Thank you !

makim@datateamz.co.kr