

Accelerating Beyond Excel:

Mapping Specifications in
an Intelligent Web-based GUI

PHUSE EU Connect 2021



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Disclaimer

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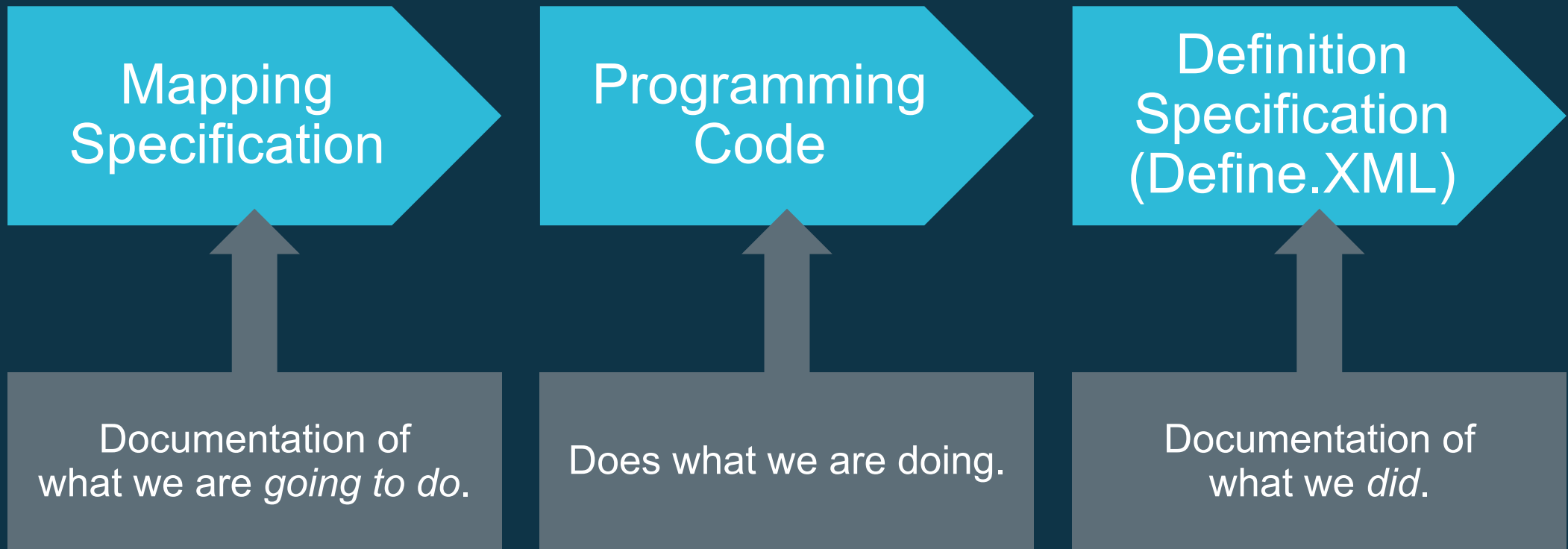
Agenda

- Background: Specification Documents
- Excel as the Tool of “Choice”
- Alternative Approach
- Benefits
- Discussion
- Summary and Questions

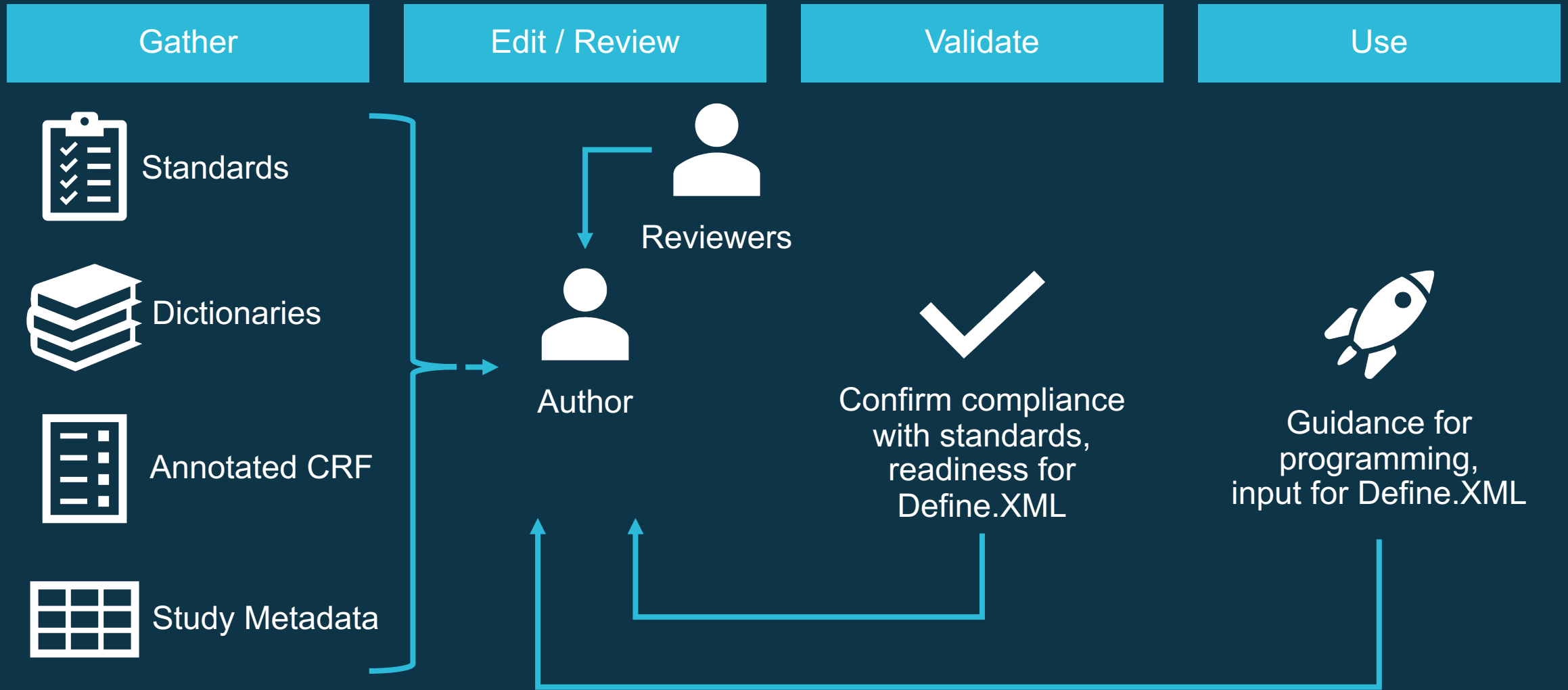


Background: Specification Documents

Specifications in Context



Creating Specifications



Excel: Tool of “Choice”

Good Old Excel

“

The most dangerous phrase
in the language is

‘we’ve always done it this way.’

”

- Grace Hopper

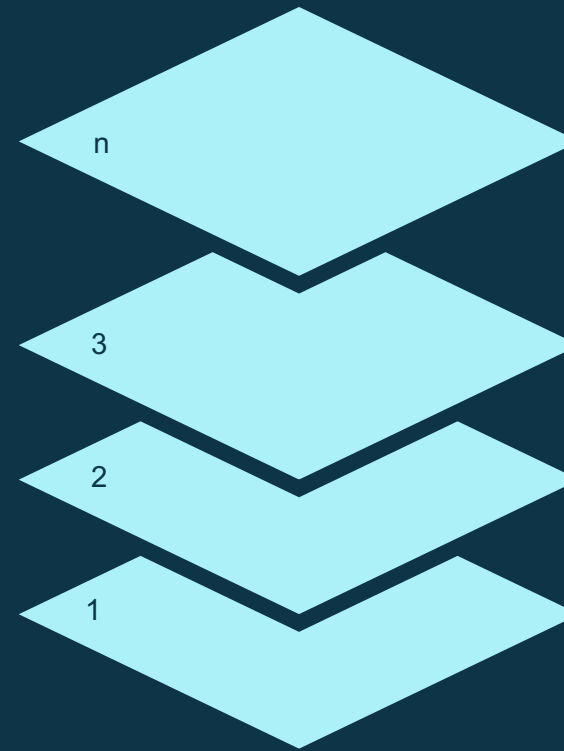
Benefits of Excel

- Ease of Use
 - Familiar product
 - Basic operations are simple and intuitive
- Features for editing and formatting
 - Copy and paste, auto fill
 - Formulas
- Extensible with macros and VBA



Limitations to Address

- Version control



Limitations to Address

- Version control
- Collaboration



Limitations to Address

- Version control
- Collaboration
- Related data



Limitations to Address

- Version control
- Collaboration
- Related data
- Duplicated effort



Limitations to Address

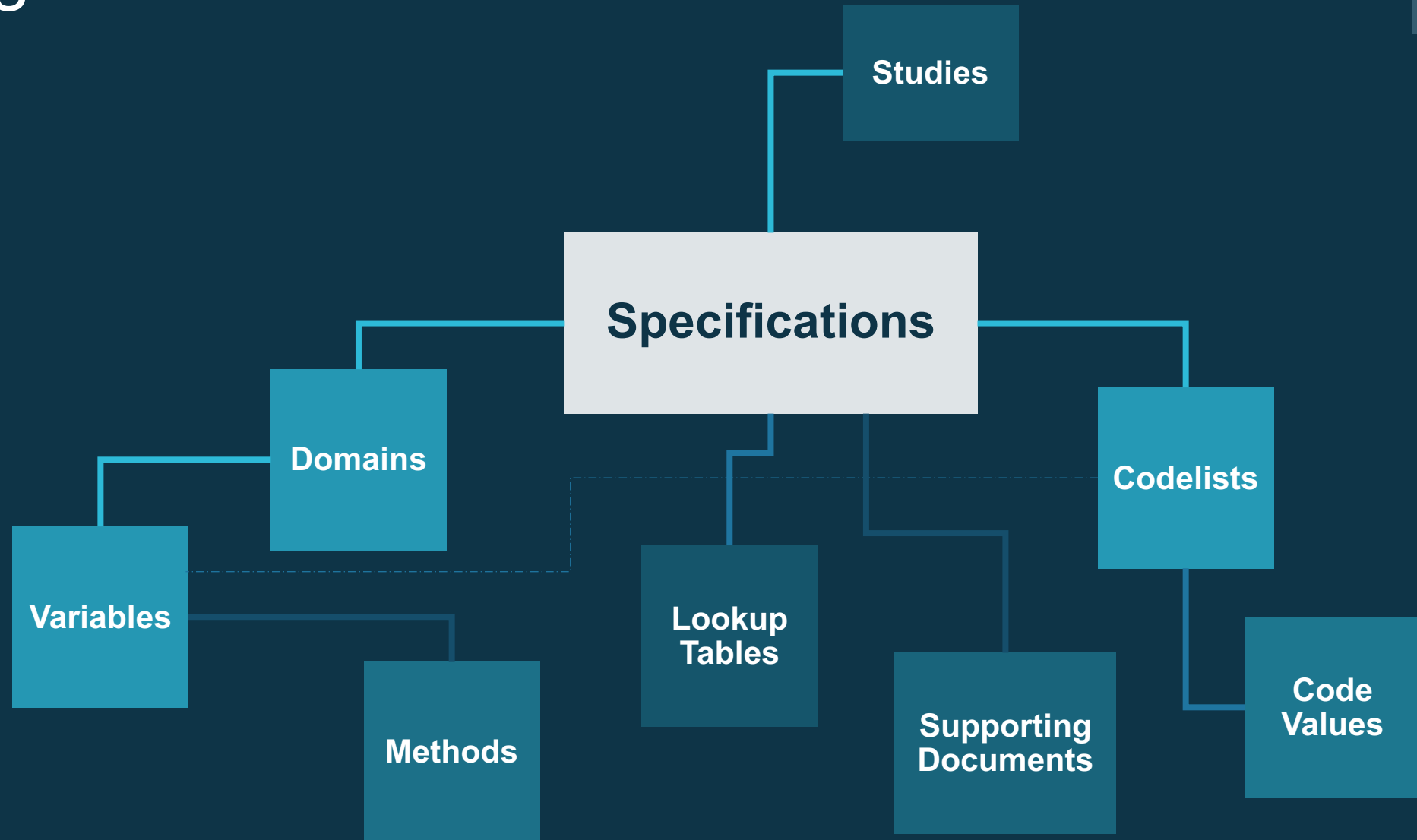
- Version control
- Collaboration
- Related data
- Duplicated effort



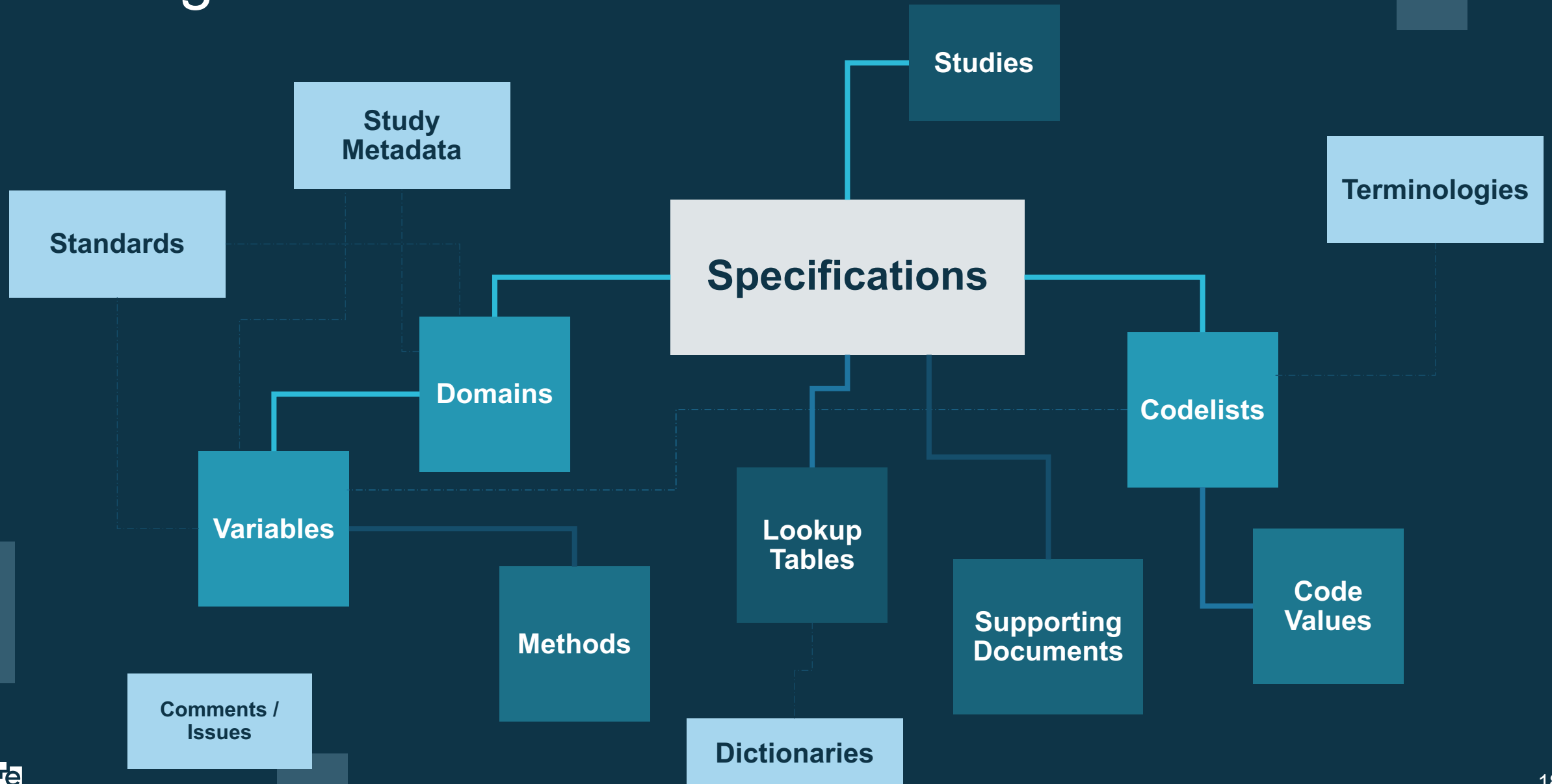
Alternative Approach

Storage: Relational Database

Storage: Related Tables



Storage: Related Tables



Design Considerations

- Versioning of Objects
- Standard Agnostic
- Logging and Audit Trail
- Security

Front End: Web Application

View All Specifications

Name	
	MyStudy-1001-SDTM_Specs - draft.xlsx
	MyStudy-1001-SDTM_Specs 2021-01-31 draft.xlsx
	MyStudy-1001-SDTM_Specs 2021-01-31 for review - nlj comments.xlsx
	MyStudy-1001-SDTM_Specs 2021-01-31 for review.xlsx
	MyStudy-1001-SDTM_Specs 2021-02-15 - review comments.xlsx
	MyStudy-1001-SDTM_Specs 2021-02-15.xlsx
	MyStudy-1001-SDTM_Specs final - update 2021-02-22 DO NOT USE.xlsx
	MyStudy-1001-SDTM_Specs final - update 2021-02-22.xlsx
	MyStudy-1001-SDTM_Specs final final.xlsx
	MyStudy-1001-SDTM_Specs final.xlsx
	MyStudy-1001-SDTM_Specs old.xlsx
	MyStudy-1001-SDTM_Specs.xlsx

View All Specifications

Specifications7

Domains

Codelists



☒	Name	Description	Type	Study	Active	Version	Version Name	Status	Requires Domain Approval	Approved Version	Last Approved Date	Notes
☐	Exception Listing		Mapping	Z-study	☒	1		In Development	☐			
☐	Exceptions Specification	specification for exception listings	ExceptionListing	Demo-001	☒	3		In Development	☐	2	12 Jan 2021 12:20:35	
☐	SDTM Datasets - Achilles		Mapping	Z-study	☒	1		In Development	☐			
☒	SDTM Mapping Specs		Mapping	Demo-001	☒	5		In Development	☒	4	21 May 2021 11:17:13	Updates following review
☐	SDTM Specs		Mapping	eCS-DS-003	☒	1		In Development	☒			
☐	test	test mapping spec	Mapping	Demo-005	☒	3		Submitted For Review	☐	2	13 Jan 2021 16:04:58	additional updates require
☐	Test Specifications	Mapping specs	Mapping	eCS-ONCODEMO	☒	1		In Development	☐			

Version History

Specification Versions for SDTM Mapping Specs

Version

Version Name

Approved Date

Approved By

Version Notes

4

Protocol Amendment 2

21 May 2021 11:17:13

NJOHNSON

updates to spec following protocol changes

3

more updates

21 May 2021 11:16:26

NJOHNSON

additional updates to specification

2

updated specs

18 Jan 2021 12:35:23

NJOHNSON

updates following initial development

1

18 Jan 2021 12:34:38

NJOHNSON

Details

Standard

SDTM

Standard Version

3.2

Controlled Terminology

2020.03.27

Event Dictionary

Drug Dictionary

Therapeutic Area

Requires Domain Approval

true

Current Version (v 5)

Close

Selecting Domains

	A	B	C	D	E	F	G	H	I	J	K	L	M	O	
	Seq. For Order	Domain Prefix	Variable Name	Variable Label	Origin (Specify the appropriate Origin)	Key Sequence	Role	Type	Length	Significant Digit Column	Format	Code List	aCRF Page # (if Origin = CRF)	Core	
1															
2	1	LB	STUDYID	Study Identifier	Protocol	1	Identifier	Char	12					Req	STUDYID =
3	2	LB	DOMAIN	Domain Abbreviation	Assigned		Identifier	Char	2			DOMAIN		Req	LB
4	3	LB	USUBJID	Unique Subject Identifier	Assigned	2	Identifier	Char	23					Req	DM.USUBJ
5	4	LB	LBSEQ	Sequence Number	Derived		Identifier	Num	8					Req	Ascending i are sorted in LBDTC, LB
6	5	LB	LBSPID	Sponsor-Defined Identifier	Assigned		Identifier	Char	18					Perm	When sourc Else LBSPID RECORDP
7	6	LB	LBTESTCD	Lab Test or Examination Short Name	CRF	4	Topic	Char	8			LBTESTCD	56	Req	See criteria
8	7	LB	LBTEST	Lab Test or Examination Name	CRF		Synonym Qualifier	Char	39				56	Req	See criteria
9	8	LB	LBCAT	Category for Lab Test	CRF	3	Grouping Qualifier	Char	14				27, 56	Exp	See criteria
10	9	LB	LBORRES	Result or Finding in Original Units	CRF	8	Result Qualifier	Char	9				56	Exp	LBORRES
11	10	LB	LBORRESU	Original Units	CRF		Variable Qualifier	Char	7				56	Exp	LBORRESU
12	11	LB	LBORNRL	Reference Range Lower Limit in Orig Unit	Assigned		Variable Qualifier	Char	5					Exp	LBORNRL
13	12	LB	LBORNRI	Reference Range Upper Limit in Orig Unit	Assigned		Variable Qualifier	Char	5					Exp	LBORNRI

Import Domains from Standard

> ADAM

> CDASH

> Custom

▼ SDTM

3.1.2

3.1.3

3.2

3.3

☒	Name	Description	Class
☐	AG	Procedure Agents	Interventions
☐	CE	Clinical Events	Events
☒	CM	Concomitant Meds	Interventions
☐	CO	Comments	Special-Purpose
☐	CV	Cardiovascular System Findings	Findings
☒	DA	Drug Accountability	Findings
☐	DD	Death Diagnosis	Findings
☒	DM	Demographics	Special-Purpose
☒	DS	Disposition	Events
☐	DV	Protocol Deviations	Events
☐	EC	Exposure as Collected	Interventions
☒	EG	Electrocardiogram	Findings
☐	FA	Findings About Events or Interventions	Findings
☐	FT	Functional Tests	Findings
☐	HO	Healthcare Encounters	Events
☐	IE	Inclusion/Exclusion	Findings
☐	IS	Immunogenicity Specimen Assessments	Findings
☒	LB	Laboratory Data	Findings
☐	MB	Microbiology	Findings
☒	MH	Medical History	Events
☐	MI	Microscopic Findings	Findings
☐	MK	Musculoskeletal Findings, Connective and Soft Tissue ...	Findings
☐	ML	Meal Data	Interventions
☐	MO	Morphology Findings	Findings
☐	MS	Microbiology Susceptibility	Findings
☐	NV	Nervous System Findings	Findings
☐	OE	Ophthalmic Examinations	Findings
☐	OI	Object Identifier	Study Reference
☐	PC	Pharmacokinetic Concentration	Findings
☐	PE	Physical Exam	Findings

Cancel

Import

Variable List

Variable List 40														Codelists		+    			
Specifications: SDTM Specs (v 1) > Domains: AE > Variables														Standard: SDTM 3.2 CodeList: 2020.11.06				Save	
	Sequence	Target Variable Name	Variable Label	Origin	Supporting Document	Origin Metadata	Key Sequence	Role	Type	Length	Required	Code List Name	Mapping Notes						
1	1	STUDYID	Study Identifier	Protocol			1	Identifier	Char	12	Req		DM.STUDYID						
2	2	DOMAIN	Domain Abbreviation	Assigned				Identifier	Char	2	Req	DOMAIN	AE						
3	3	USUBJID	Unique Subject Identifier	Assigned			2	Identifier	Char	23	Req		DM.USUBJID						
4	4	AESEQ	Sequence Number	Derived				Identifier	Num	8	Req		Ascending integer, starting at 1, unique within DM.STUDYID and DM.USUBJID when records are sorted in the following order: STUDYID, USUBJID, AEDECOD, AESTDTC, AESPID						
5	7	AESPID	Sponsor-Defined Identifier	Derived			5	Identifier	Char	12	Perm		AESPID = 'AE1' concatenated with raw AE1.RECORDID and raw AE1.RECORDPOSITION, separated with -.						
6	8	AETERM	Reported Term for the Adverse Event	CRF		90 91 92 93 9		Topic	Char	94	Req		AETERM = raw.AE1.AETERM						
7	10	AELLT	Lowest Level Term	Assigned				Variable Qualifier	Char	49	Exp	MedDRA	AELLT = raw.AE1.AETERM_LLT						
8	11	AELLTCD	Lowest Level Term Code	Assigned				Variable Qualifier	Num	8	Exp	MedDRA	AELLTCD = raw.AE1.AETERM_LLT_CODE						
9	12	AEDECOD	Dictionary-Derived Term	Assigned			3	Synonym Qualifier	Char	40	Req	MedDRA	AEDECOD = raw.AE1.AETERM_PT						
10	13	AEPTCD	Preferred Term Code	Assigned				Variable Qualifier	Num	8	Exp	MedDRA	AEPTCD = raw.AE1.AETERM_PT_CODE						
11	14	AEHLT	High Level Term	Assigned				Variable Qualifier	Char	63	Exp	MedDRA	AEHLT = raw.AE1.AETERM_HLT						
12	15	AEHLTCD	High Level Term Code	Assigned				Variable Qualifier	Num	8	Exp	MedDRA	AEHLTCD = raw.AE1.AETERM_HLT_CODE						
13	16	AEHLGT	High Level Group Term	Assigned				Variable Qualifier	Char	60	Exp	MedDRA	AEHLGT = raw.AE1.AETERM_HLGT						
14	17	AEHLGTC	High Level Group Term Code	Assigned				Variable Qualifier	Num	8	Exp	MedDRA	AEHLGTC = raw.AE1.AETERM_HLGT_CODE						
15	18	AECAT	Category for Adverse Event	CRF		90 91 92 93 9		Grouping Qualifier	Char	33	Perm		AECAT = 'ADVERSE EVENT OF SPECIAL INTEREST' when raw.AE1.AEOSI_CV = Y						
16	19	AESCAT	Subcategory for Adverse Event	CRF		90 91 92 93 9		Grouping Qualifier	Char	79	Perm		AESCAT = (uppercase) raw.AE1.AEOSISP						
17	21	AEBODSYS	Body System or Organ Class	Assigned				Record Qualifier	Char	52	Exp	MedDRA	AEBODSYS = AESOC						
18	22	AEBDSYCD	Body System or Organ Class Code	Assigned				Variable Qualifier	Num	8	Exp	MedDRA	AEBDSYCD = AESOCCD						
19	23	AESOC	Primary System Organ Class	Assigned				Variable Qualifier	Char	52	Exp	MedDRA	AESOC = raw.AE1.AETERM_SOC						
20	24	AESOCCD	Primary System Organ Class Code	Assigned				Variable Qualifier	Num	8	Exp	MedDRA	AESOCCD = raw.AE1.AETERM_SOC_CODE						
21	26	AESEV	Severity/Intensity	CRF		90 91 92 93 9		Record Qualifier	Char	8	Perm	AESEV	AESEV = raw.AE1.AESEV_CV Note: When raw.AE1.AESEV_CV = LIFE THREATENING or DEATH, AESEV = SEVERE. Map the actual values to SUPPAE as QNAM = AESEV2.						
22	27	AESER	Serious Event	CRF		90 91 92 93 9		Record Qualifier	Char	1	Exp	NY	AESER = raw.AE1.AESER_CV						
23	28	AEACN	Action Taken with Study Treatment	CRF		90 91 92 93 9		Record Qualifier	Char	16	Exp	ACN	AEACN = raw.AE1.AEACN_CV						
24	30	AEREL	Causality	CRF		90 91 92 93 9		Record Qualifier	Char	11	Exp		AEREL = raw.AE1.AEREL_CV						
25	32	AEPATT	Pattern of Adverse Event	CRF		90 91 92 93 9		Record Qualifier	Char	12	Perm		AEPATT = raw.AE1.AEPATT_CV						

Variable List

Controlled Entry

up Term	Assigned	▼	▼
up Term Co	Assigned	▼	▼
lverse Eve	CRF	▼	▼
r Adverse	Assigned		▼
r Organ Cl	Collected		▼
r Organ Cl	CRF	✓	▼
n Organ Cl	eDT		▼
n Organ Cl	Derived		▼
ity	Not Available		▼
	Predecessor		
	Protocol		▼
ith Study 1	CRF	▼	▼
	CRF	▼	▼
E	CRF		

Variable List

Dynamic Links to Codelists

h ▼	8	Exp ▼	MedDRA	AEBDSYCD = AESOCCD
r ▼	52	Exp ▼	MedDRA	AESOC = raw.AE1.AETERM_SOC
h ▼	8	Exp ▼	MedDRA	AESOCCD = raw.AE1.AETERM_SOC_CODE
r ▼	8	Perm ▼	AESEV	AESEV = raw.AE1.AESEV_CV Note: When raw.AE1.AESEV_CV = LIFE THREATENING actual values to
r ▼	1	Exp ▼	NY	
r ▼	16	Exp ▼	ACN	
r ▼	11	Exp ▼		
r ▼	12	Perm ▼		
r ▼	26	Perm ▼	OUT	AEOUT = the value of raw.AE1.AEOUT_CV
r ▼	1	Perm ▼	NY	When raw.AE1.AESCON = 1, AESCONG = 'Y' Else when raw.AE1.AESCON = 0, AESCONG = 'N' Note: Assign when AESER = 'Y'

View Codelist
Select Codelist
Remove Codelist
Delete Row

Variable List

Dynamic Links to Codelists

Codelists

Standard: SDTM 3.2 |

Mapping Notes

HLGT = raw.AE1.AETERM_HLGT

HLGTCD = raw.AE1.AETERM_H

CAT = 'ADVERSE EVENT OF SPE

en raw.AE1.AEOSL_CV = Y

SCAT = (uppercase) raw.AE1.AE

BODSYS = AESOC

BDSYCD = AESOCCD

SOC = raw.AE1.AETERM_SOC

SOCCD = raw.AE1.AETERM_SO

SEV = raw.AE1.AESEV_CV

te: When raw.AE1.AESEV_CV =

DEATH, AESEV = SEVERE. Map

PPAE as QNAM = AESEV2.

SER = raw AE1.AESER_CV

ACN = raw.AE1.AEACN_CV

REL = raw.AE1.AEREL_CV

PATT = raw.AE1.AEPATT_CV

OUT = the value of raw.AE1.AE

pecs (v 1) > Domains:

et Variable... Variable Label

GT High Level Gro

GTCD High Level Gro

T Category for Ad

AT Subcategory fo

OSYS Body System o

SYCD Body System o

C Primary System

CCD Primary System

/ Severity/Intens

R Serious Event

N Action Taken w

C Causality

TT Pattern of Adve

T Outcome of Ad

ONG Congenital Anomaly or Bi CRF

Codelist: AESEV

Edit Codelist X

Name: AESEV

Display Name: Severity/Intensity Scale for Adverse Events

Description: A scale that defines the degree or state of disease existing in a patient as a result of the occurrence of an adverse event. (NCI)

Type: Enumerated

Extensible: false

CDISC Code: C66769

External Reference:

Codelist Values 3

Edit Values

Sequence	Code Value	Decode	Description
	MILD	Mild Adverse Event	A type of adverse event that is usually...
	MODERATE	Moderate Adverse Event	A type of adverse event that is usually...
	SEVERE	Severe Adverse Event	A type of adverse event that interrupt...

90 91 92 93 9

Record Qualifier

Char

1

Perm

NY

When raw.AE1.AESCON = 1, AESC

Else when raw.AE1.AESCON = 0, A

Note: Assign when AESER = 'Y'

Details Panels

Details Panels: Domain

Domains 22

Variables Codelists

DM

Specifications: [SDTM Specs](#) (v 1) > Domains
Standard: [SDTM v.3.2](#) | CT: 2020.11.06

☐	Domain Name	Description	Sort Order	Active	Version	Status	Last Modified
☐	AE	Adverse Events	STUDYID, USUBJID, AEDECOD, AESTDTC,...	☒	1	In Development	18/11/2020
☐	CM	Concomitant Meds	STUDYID, USUBJID, CMTRT, CMSTDTC	☒	1	In Development	17/11/2020
☐	DA	Drug Accountability	STUDYID, USUBJID, DASPID, DATESTCD, ...	☒	1	In Development	17/11/2020
☒	DM	Demographics	STUDYID, USUBJID	☒	1	In Development	17/11/2020
☐	DS	Disposition	STUDYID, USUBJID, DSSPID, DSDECOD, D...	☒	1	In Development	17/11/2020
☐	DV	Protocol Deviations	STUDYID, USUBJID, DVDECOD, DVSTDTC	☒	1	In Development	17/11/2020
☐	EG	Electrocardiogram	STUDYID, USUBJID, EGTESTCD, EGDTC	☒	1	In Development	17/11/2020
☐	EX	Exposure		☒	1	In Development	17/11/2020
☐	FA	Findings About Events or Interventions		☒	1	In Development	17/11/2020
☐	IE	Inclusion/Exclusion Criteria Not Met		☒	1	In Development	17/11/2020
☐	LB	Laboratory Data		☒	1	In Development	17/11/2020
☐	MH	Medical History		☒	1	In Development	17/11/2020
☐	PE	Physical Exam		☒	1	In Development	17/11/2020
☐	QS	Questionnaires		☒	1	In Development	17/11/2020
☐	RP	Reproductive System Findings		☒	1	In Development	17/11/2020
☐	SV	Subject Visits		☒	1	In Development	17/11/2020
☐	TA	Trial Arms		☒	1	In Development	17/11/2020
☐	TE	Trial Elements		☒	1	In Development	17/11/2020
☐	TI	Trial Inclusion/Exclusion Criteria		☒	1	In Development	17/11/2020
☐	TS	Trial Summary	STUDYID, TSPARMCD, TSSEQ	☒	1	In Development	17/11/2020
☐	TV	Trial Visits	STUDYID, VISITNUM, VISITDY	☒	1	In Development	17/11/2020

Name

DM

Description

Demographics

Is Repeating

No

Record Description

Is Reference Data

No

Parent Domain

Class

Special-Purpose

Purpose

Source Table

Source Logic

Supporting Document

Supporting Document Pages

Active

Yes

Version

1

> Variables 27

Go to Variables

< Codelists 6

Go to Codelists

Codelist Name	Display Name	CDISC Code
AGEU	Age Unit	C66781
DOMAIN	SDTM Domain Abbreviation	C66734
ETHNIC	Ethnic Group	C66790
NY	No Yes Response	C66742
RACE	Race	C74457
SEX	Sex	C66731

Details Panels: Codelist

Codelists 43

Values

Domains

Specifications: SDTM Specs (v 1) > Codelists

Standard: SDTM v.3.2 | CT: 2020.11.06

☒	Name	DisplayName	Description	Type
☐	LAT	Laterality	CDISC terminology for anatomical location or specimen fu...	Enumerated
☐	LBSTRESC	Laboratory Test Standard Character Result	Terminology relevant to the standardized results, in charac...	Enumerated
☐	LBTEST	Laboratory Test Name	Terminology used for laboratory test names of the CDISC ...	Enumerated
☐	LBTESTCD	Laboratory Test Code	Terminology used for laboratory test codes of the CDISC S...	Enumerated
☐	LOC	Anatomical Location	Terminology codelist used for anatomical location within ...	Enumerated
☐	METHOD	Method	Method is any technique or procedure (an action) that det...	Enumerated
☐	NCOMPLT	Completion/Reason for Non-Completion	The status of the subject's completion of the study or a se...	Enumerated
☐	ND	Not Done	Indicates a task, process or examination that has either no...	Enumerated
☐	NRIND	Reference Range Indicator	A description of the results relative to the normal or expec...	Enumerated
☒	NY	No Yes Response	A term that is used to indicate a question with permissible...	Enumerated
☐	OUT	Outcome of Event	A condition or event that is attributed to the adverse event ...	Enumerated
☐	POSITION	Position	Terminology codelist used with Body Position within CDISC.	Enumerated
☐	QSCAT	Category of Questionnaire	A grouping of observations within the Questionnaires dom...	Enumerated
☐	RACE	Race	Terminology codelist used to identify the race of an individ...	Enumerated
☐	ROUTE	Route of Administration Response	A terminology codelist relevant to the course by which a s...	Enumerated
☐	RPTEST	Reproductive System Findings Test Name	A terminology codelist for the physiological test names rel...	Enumerated
☐	RPTESTCD	Reproductive System Findings Test Code	A terminology codelist for the physiological test codes rel...	Enumerated
☐	SEX	Sex	The assemblage of physical properties or qualities by whi...	Enumerated
☐	SPECCOND	Specimen Condition	The physical state or quality of a biological specimen.	Enumerated
☐	SPECTYPE	Specimen Type	The name and description of a biological specimen.	Enumerated
☐	STENRF	Relation to Reference Period	The relative relationship of a timepoint to a reference time...	Enumerated
☐	TSPARM	Trial Summary Parameter Test Name	The test name for an individual characteristic of a clinical ...	Enumerated

NY

Name

NY

Display Name

No Yes Response

Description

A term that is used to indicate a question with permissible values of yes/no/unknown/not applicable.

Type

Enumerated

External References

CDISC Code

C66742

Extensible

No

Version

1

Created

17 May 2021 14:35:03

Created By

njohnson

Last Changed

17 May 2021 14:35:03

Last Changed By

njohnson

> Codelist Values 4

Go to Values

Variables 25

Domain	Name	Label	Origin
DM	DTHFL	Subject Death Flag	Derived
EX	EXFAST	Fasting Status	
AE	AESER	Serious Event	CRF
AE	AESCONG	Congenital Anomaly or Birth Defect	CRF
AE	AESDISAB	Persist or Signif Disability/Incapacity	CRF
AE	AESDTH	Results in Death	CRF
AE	AESHOSP	Requires or Prolongs Hospitalization	CRF
AE	AESLIFE	Is Life Threatening	CRF
AE	AESMIE	Other Medically Important Serious Event	CRF
AE	AECONTRT	Concomitant or Additional Trtmnt Given	CRF

Comments and Issues

Create Issue

Type

Specification

Study

eCS-DS-003

Specification Name

SDTM Specs

Specification Version

1

Priority

Moderate

Assign To

User

Data Central Reviewer Role

* User

Nathan Johnson (NJOHNSON) [njohnson@ec]

* Due By

5/22/2021, 2:02 PM

* Issue Text

Definition of AE.AESTDY is unclear

☒ Send Notification Email

Cancel

Save

Benefits

Benefits of Web Application

Single Study

- Accelerated development
- Real-time data validation
- Collaboration
- Traceability and transparency

Benefits of This Approach

Across Studies

- Efficiency
- Searchability
- Consistency

Discussion

Future Development

- Increased automation
- Integration with programming environment
- Enhanced validation, Pinnacle 21 integration

Discussion

- Worth the investment?
- Learning new tools
- Acceleration of trials

Questions?



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Thank you

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