WITH STANDARDS – UNLOCK THE POWER OF DATA

cdisc

2022
EUROPE
INTERCHANGE
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CDASH at Scale

Éanna Kiely
Head, Clinical Data Standards, UCB
CDISC Consultant, ClinBuild

Meet the Speaker

Éanna Kiely

Titles: Head, Clinical Data Standards / CDISC Consultant

Organizations: UCB / ClinBuild

Éanna Kiely is the Head of Clinical Data Standards in UCB where he leads a team creating CDASH and SDTM standards supporting study build, SDTM reporting and End to End standards.

He is a CDISC Consultant through ClinBuild where he provides CDISC standardization services and trainings.

He is a CDASH instructor and author on CDASHIG 2.0 and Model 1.0 and SDTM IG 3.3 and 3.4. He is a member and lead of multiple CDISC project teams

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

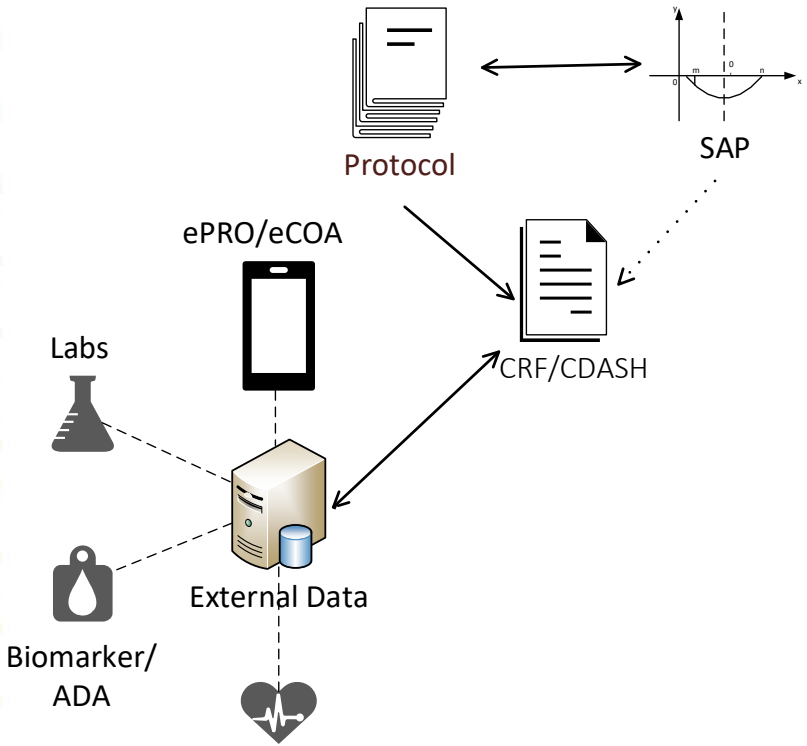
1. (E2E) Standards From The Start
2. CDASH Variable Naming Conventions (VNCs)
3. Reducing Variation Between Fields
4. Creating New CDASH Variable & Field Conventions

Clinical Data's Journey

- Clinical Data's journey begins with the CRF
- The protocol and SAP define the data to be collected on the CRF

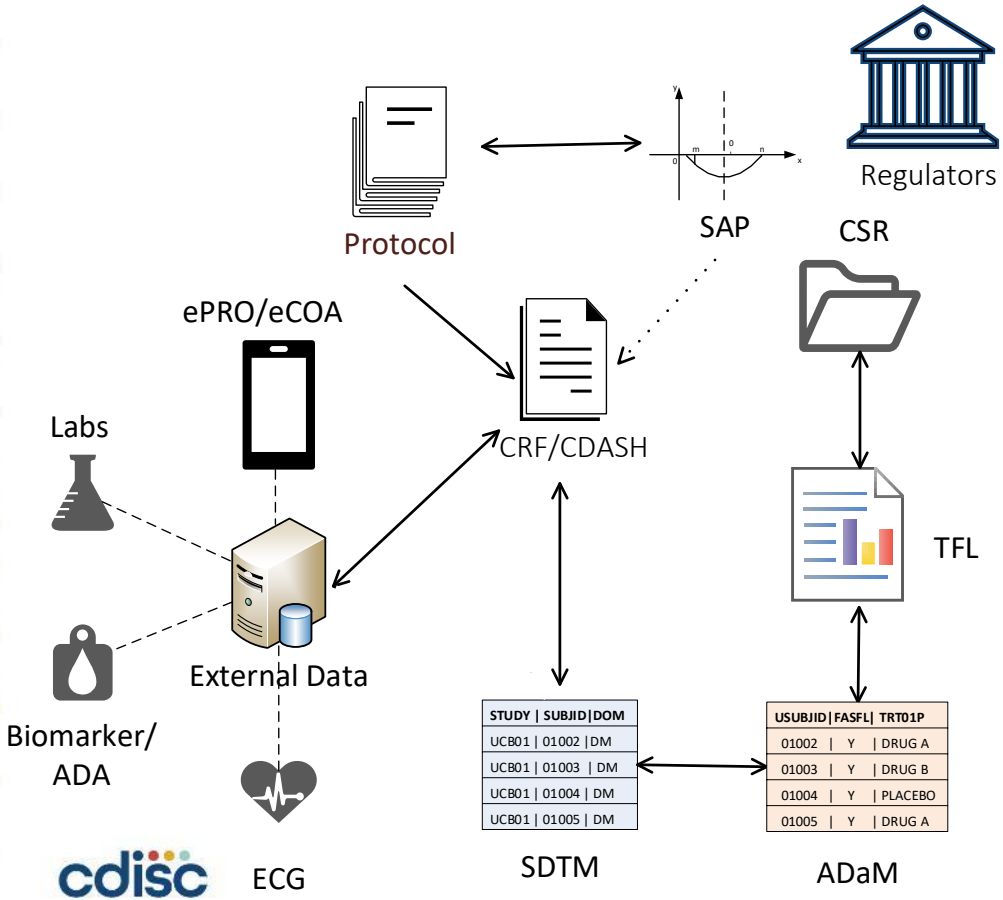
CRF/CDASH

Clinical Data's Journey – Multimodal



- The protocol and SAP define the data to be collected on the CRF
- CRFs have more modes of data collection than EDC systems including:
  - External data
  - Mobile devices
  - Wearables
- eSource systems:
  - Direct Data Capture (DDC)
  - APIs to EHR
- are changing the assumptions of clinical data collection.

Clinical Data's Journey – End to End (E2E)



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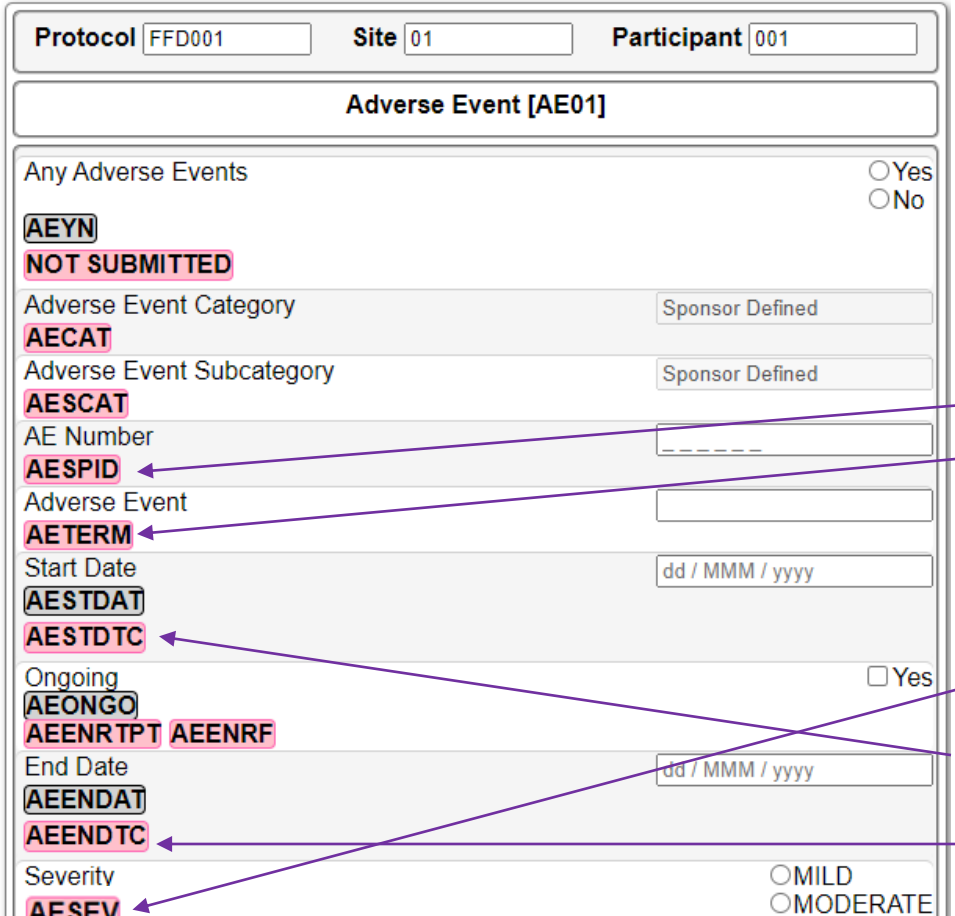
- CRFs have more modes of data collection than EDC systems including:
  - External data
  - Mobile devices
  - Wearables
- eSource systems:
  - Direct Data Capture (DDC)
  - APIs to EHR
- are changing the assumptions of clinical data collection.
- Often CRFs do not have robust standards in place from the start

(E2E) Standards from the Start

CDASH Supports Data Collection

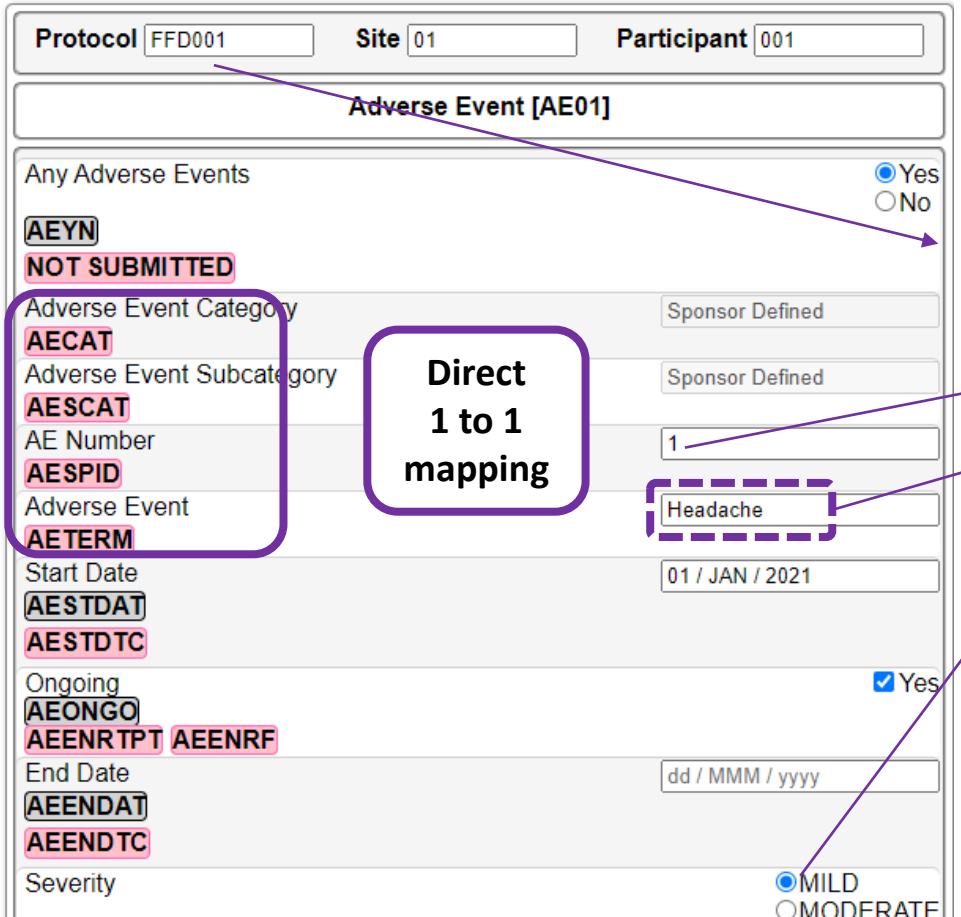
- CDASH (Clinical Data Acquisition Standards Harmonization) is the CDISC standard for collecting clinical data.
- It provides a standard set of variables and fields for creating CRFs (Case Report Forms) and a model to create new standard CRF variables and fields.
- CDASH variables map to SDTM by design.

Adverse Event CRF **CDASH** and **SDTM** Annotations



Variable Name	Variable Label	Type	Controlled Terms	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	AE	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
AESEQ	Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
AESPID	Sponsor-Defined Identifier	Char		Identifier	Sponsor-defined identifier. It may be preprinted on the CRF.	Perm
AETERM	Reported Term for the Adverse Event	Char		Topic	Verbatim name of the event.	Req
AECAT	Category for Adverse Event	Char	*	Grouping Qualifier	Used to define a category of related records. Example: "BLEEDING", "NEUROPSYCHIATRIC".	Perm
AESCAT	Subcategory for Adverse Event	Char	*	Grouping Qualifier	A further categorization of adverse event. Example: "NEUROLOGIC".	Perm
AESEV	Severity/Intensity	Char	(AESEV)	Record Qualifier	The severity or intensity of the event. Examples: "MILD", "MODERATE", "SEVERE".	Perm
AESTDTC	Start Date/Time of Adverse Event	Char	ISO 8601	Timing	Start date/time of the adverse event represented in ISO 8601 character format.	Exp
AEENDTC	End Date/Time of Adverse Event	Char	ISO 8601	Timing	End date/time of the adverse event represented in ISO 8601 character format.	Exp

Adverse Event CRF **CDASH** and **SDTM** Annotations

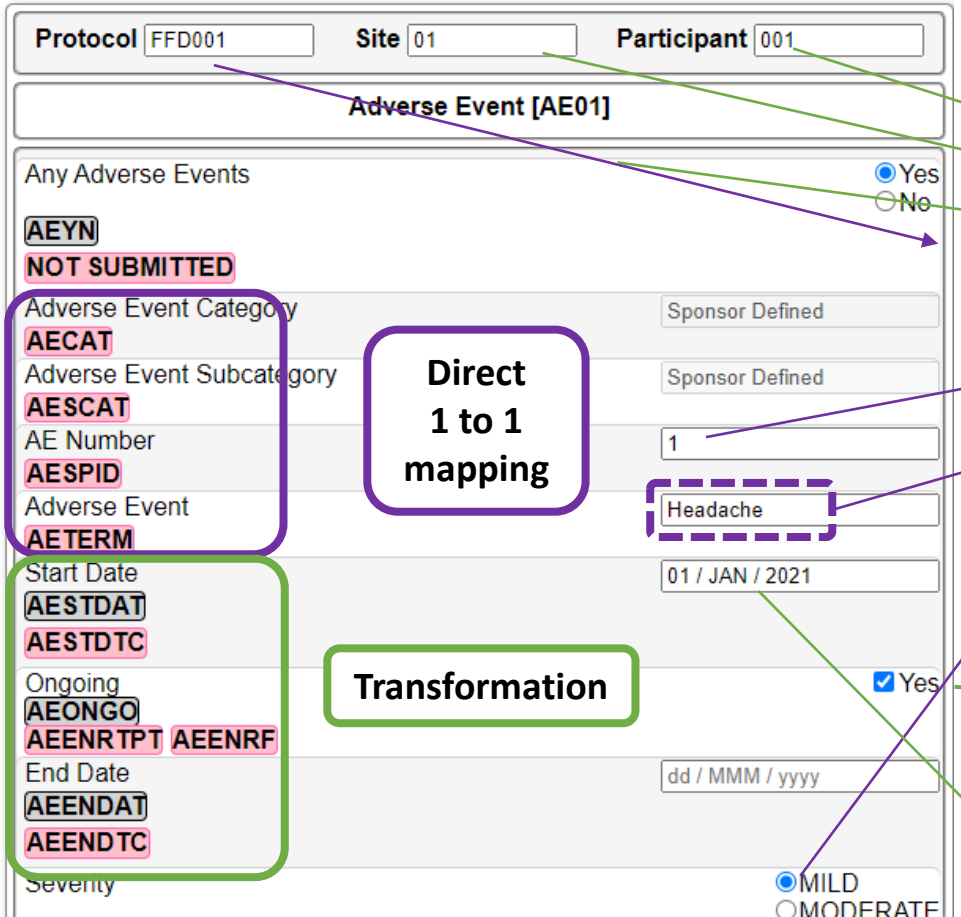


Study Identifier	Domain Abbreviation	Unique Subject Identifier	Sequence Number	Sponsor-Defined Identifier	Reported Term for the Adverse Event
STUDYID	**DOMAIN**	**USUBJID**	**AESEQ**	**AESPID**	**AETERM**
FFD001	AE	FFD001-01-001	1	1	HEADACHE

Severity/Intensity	Serious Event	Action Taken with Study Treatment	Causality	Outcome of Adverse Event
AESEV	**AESER**	**AEACN**	**AEREL**	**AEOUT**
MILD	N	DOSE NOT CHANGED	NOT RELATED	RECOVERING / RESOLVING

Start Date/Time of Adverse Event	End Date/Time of Adverse Event	End Relative to Reference Time Point	End Reference Time Point
AESTDTC	**AEENDTC**	**AEENRTPT**	**AEENTPT**
2020-12-31		AFTER	VISIT 1

Adverse Event CRF **CDASH** and **SDTM** Annotations



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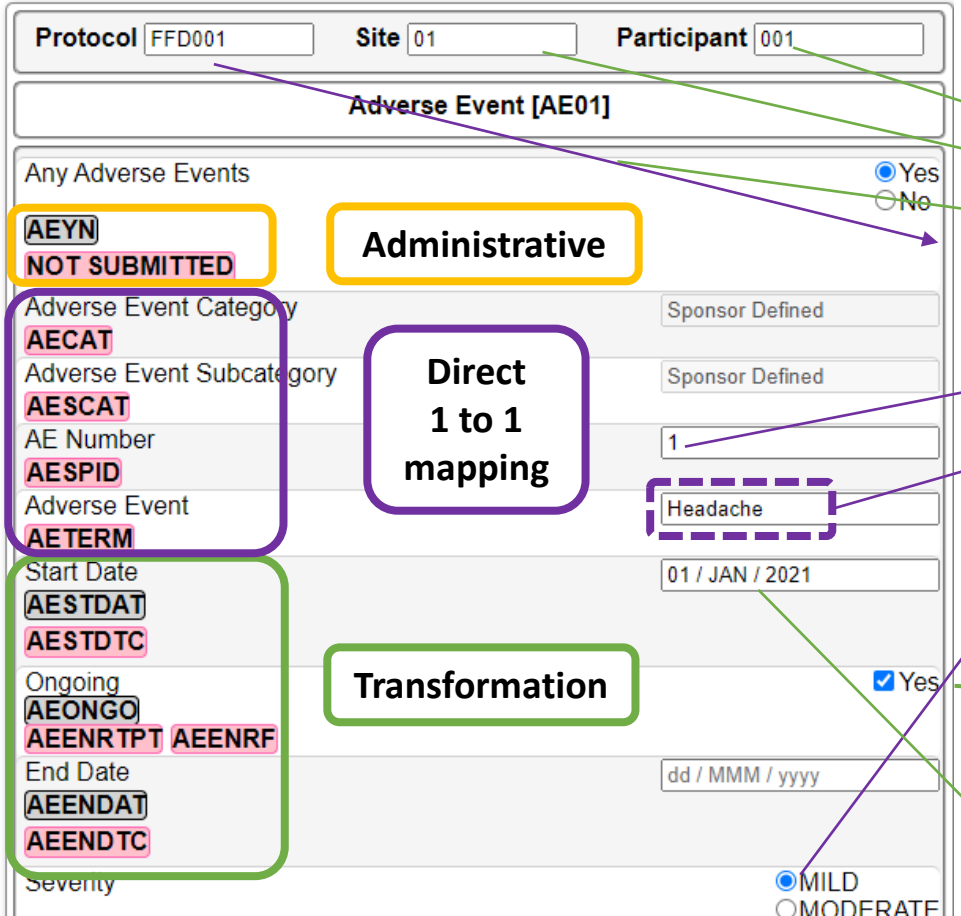
Start Date/Time of Adverse Event	End Date/Time of Adverse Event	End Relative to Reference Time Point	End Reference Time Point
AESTDTC	**AEENDTC**	**AEENRTPT**	**AEENTPT**
2021-01-31		AFTER	VISIT 1

Adverse Event CRF **CDASH** and **SDTM** Annotations



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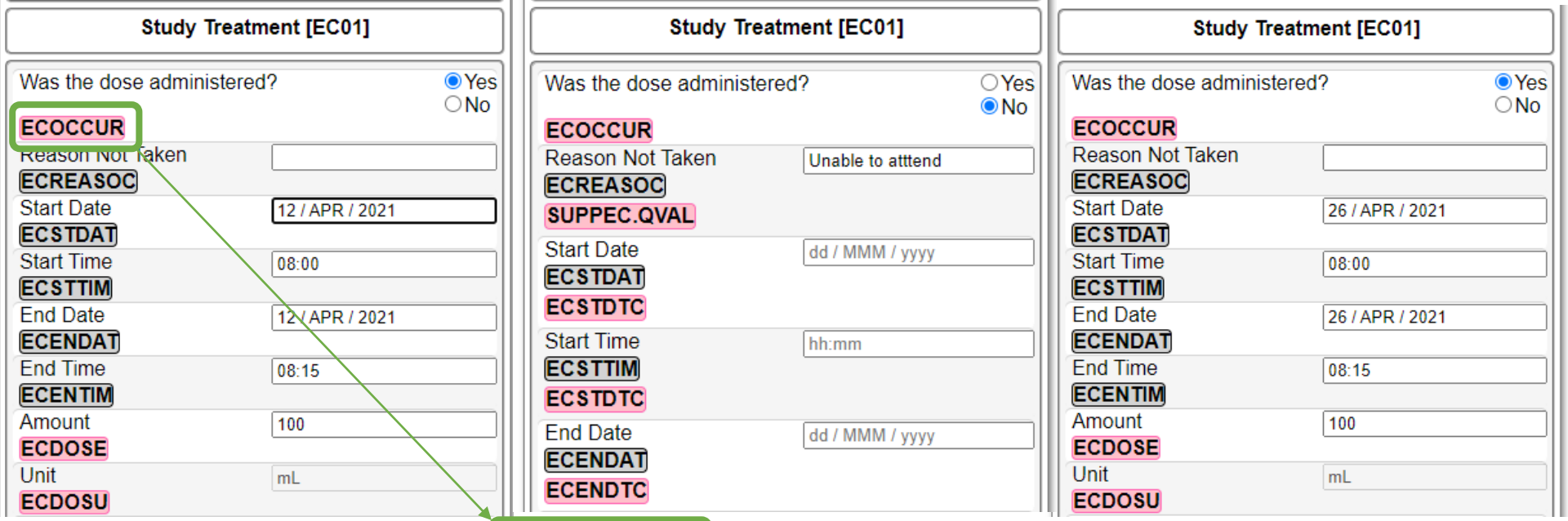
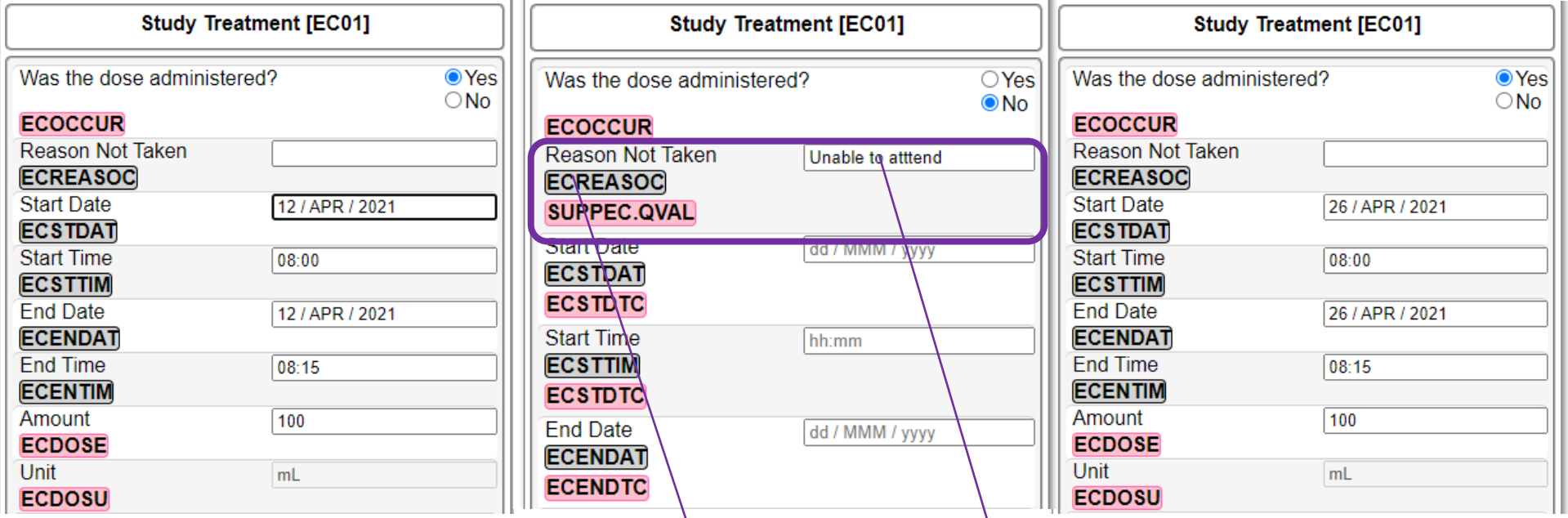
2020-12-31		AFTER	VISIT 1



STUDYID	DOMAIN	USUBJID	ECSEQ	ECTRT	ECPRESP	ECOCCUR	ECDOSE	ECDOSU	VISITNUM	VISIT	ECSTDTC	ECENDTC	ECSTDY	ECENDY
FFD001	EC	FFD001-01-001	1	MASKED	Y	Y	100	mL	1	VISIT 1	2021-04-12T08:00	2021-04-12T08:15	1	1
FFD001	EC	FFD001-01-001	2	MASKED	Y	N			2	VISIT 2	2021-04-19	2021-04-19	8	8
FFD001	EC	FFD001-01-001	3	MASKED	Y	Y	100	mL	3	VISIT 3	2021-04-26T08:00	2021-04-26T08:15	15	15

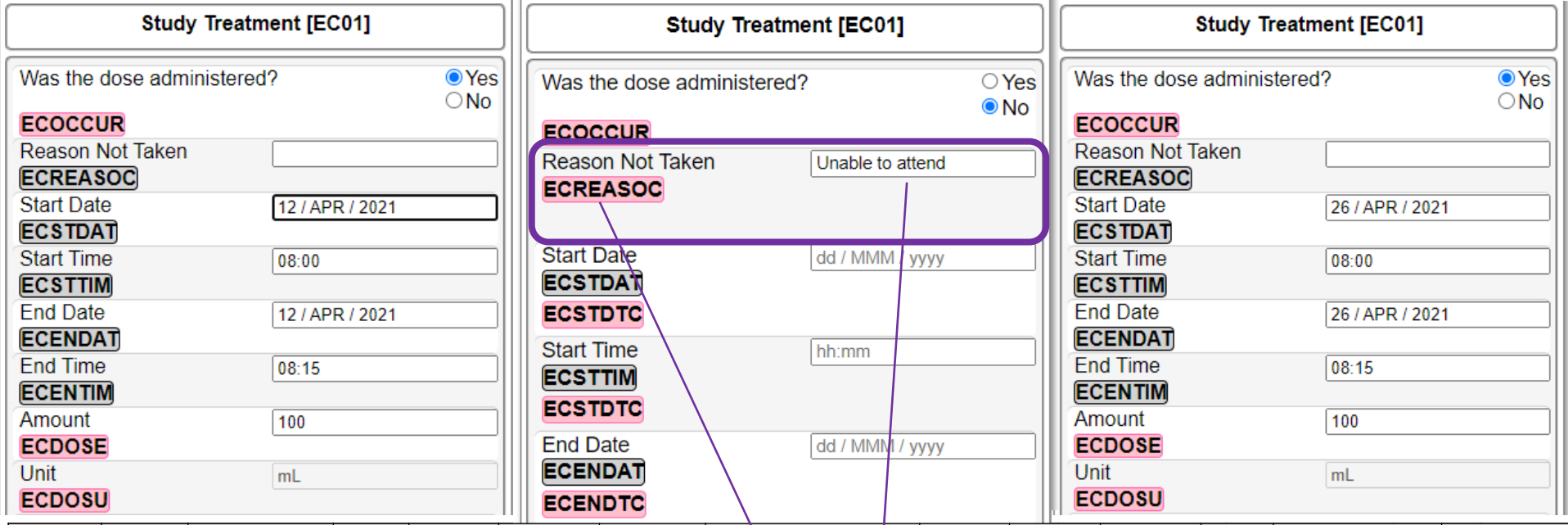
CDASH manages basic transformations of --OCCUR to --OCCUR --PRESP and more complex...



STUDYID	DOMAIN	USUBJID	ECSEQ	ECTRT	ECPRESP	ECOCCUR	ECDOSE	ECDOSU	VISITNUM	VISIT	ECSTDTC	ECENDTC	ECSTDY	ECENDY
FFD001	EC	FFD001-01-001	1	MASKED	Y	Y	100	mL	1	VISIT 1	2021-04-12T08:00	2021-04-12T08:15	1	1
FFD001	EC	FFD001-01-001	2	MASKED	Y	N			2	VISIT 2	2021-04-19	2021-04-19	8	8
FFD001	EC	FFD001-01-001	3	MASKED	Y	Y	100	mL	3	VISIT 3	2021-04-26T08:00	2021-04-26T08:15	15	15

STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG	QEVAL
FFD001	EC	FFD001-01-001	ECSEQ	2	ECREASOC	Reason for Occur Value	UNABLE TO ATTTEND	CRF	

ECREASOC is a supplemental variable in SDTMIG 3.2/3.3

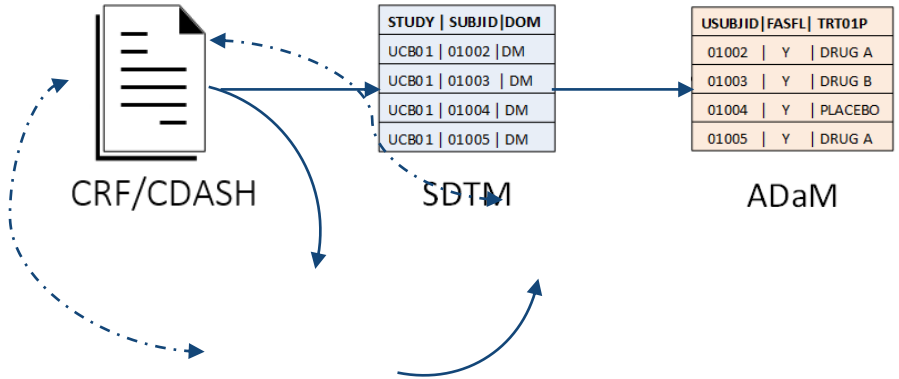


STUDYID	DOMAIN	USUBJID	ECSEQ	ECTRT	ECPRESP	ECOCCUR	ECREASOC	ECDOSE	ECDOSU	VISITNUM	VISIT	ECSTDTC	ECENDTC
FFD001	EC	FFD001-01-001	1	MASKED	Y	Y	UNABLE TO ATTTEND	100	mL	1	VISIT 1	2021-04-12T08:00	2021-04-12T08
FFD001	EC	FFD001-01-001	2	MASKED	Y	N				2	VISIT 2	2021-04-19	2021-04-19
FFD001	EC	FFD001-01-001	3	MASKED	Y	Y		100	mL	3	VISIT 3	2021-04-26T08:00	2021-04-26T08

... but in the parent domain in SDTMIG 3.4
which does not have an impact the CDASH variable

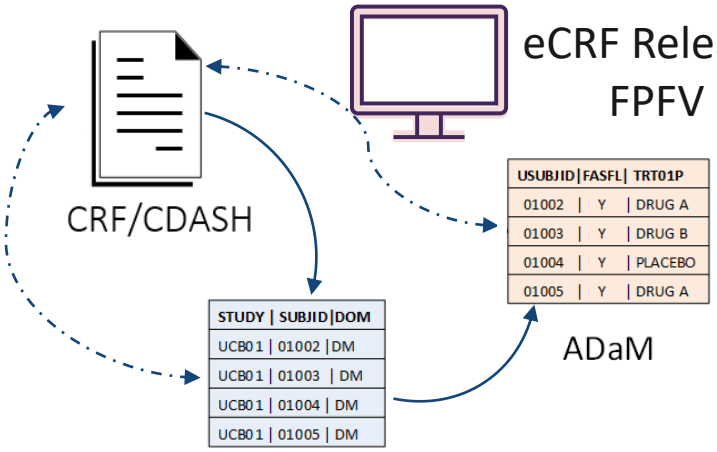
(E2E) Standards from the Start

- By moving the SDTM mapping to the CRF creation phase with CDASH potential mapping challenges with missed variables Required/Expected/Permissible) and incorrect CDISC terminology can be reduced



(E2E) Standards from the Start – Challenges

- By moving the SDTM mapping to the CRF creation phase with CDASH potential mapping challenges with missed variables Required/Expected/Permissible) and incorrect CDISC terminology can be reduced



1 By moving the SDTM mapping further upstream in the process the amount of resources needs to increase and the time taken to deliver eCRFs increases.

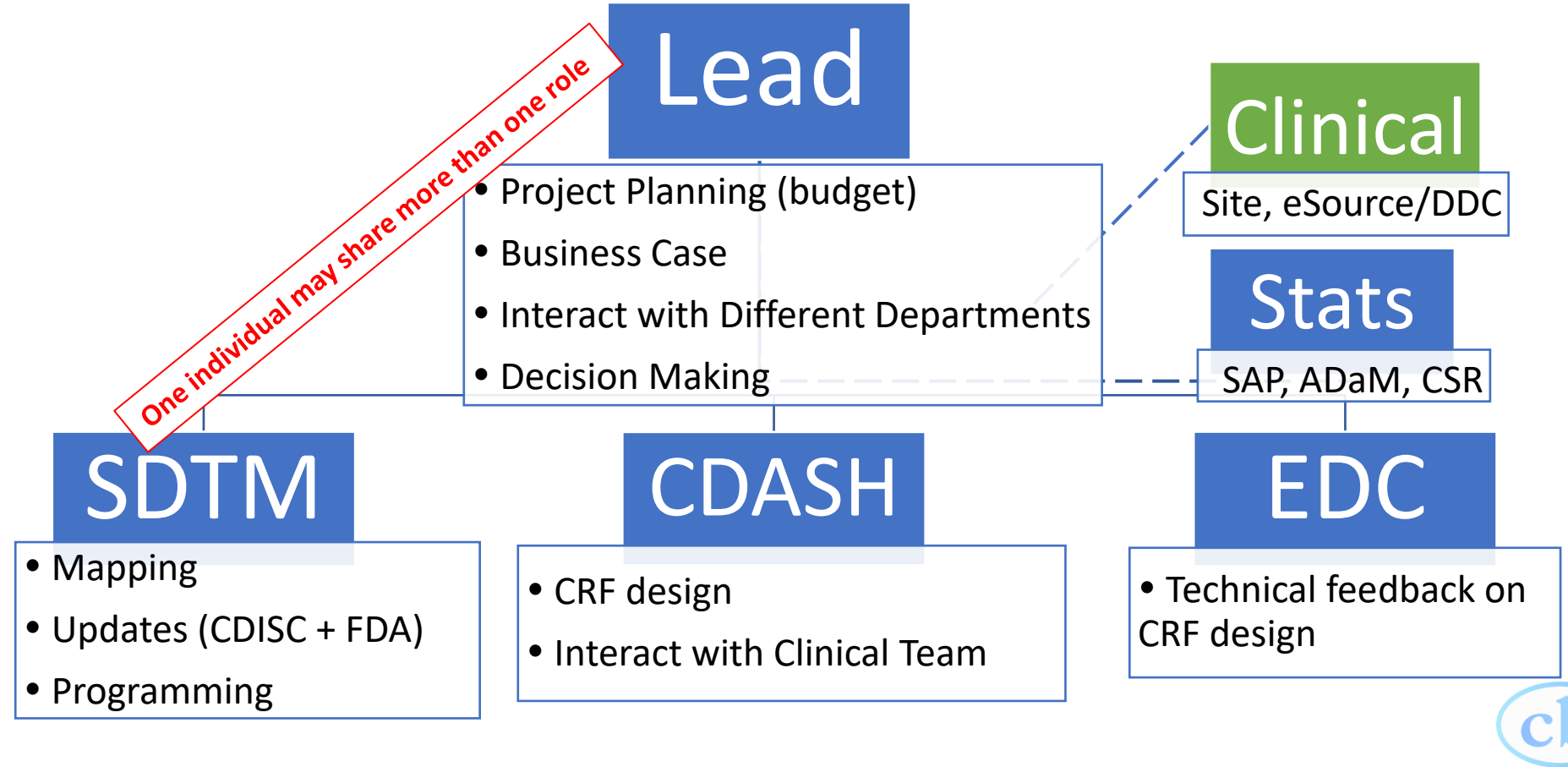
3 CDM and EDC will need to be trained on CDASH/SDTM

3 Standards are an important part of clinical research

2 If the CDASH team and SDTM team do not align on SDTM mapping conventions double work can be done

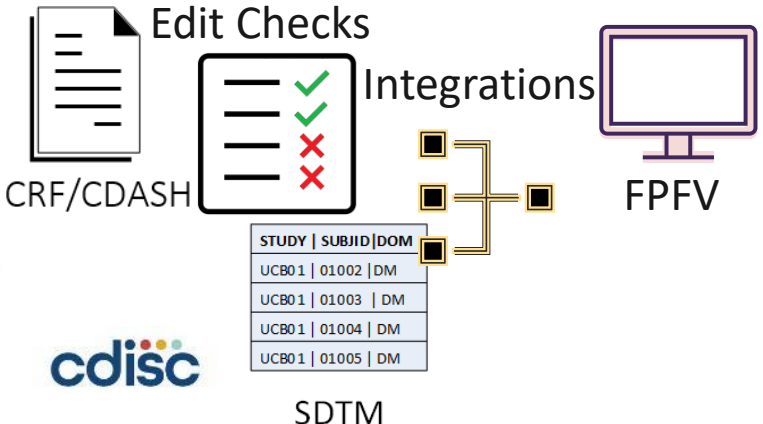
2 Better alignment through a (E2E) Standards Team

CDASH/CDM Standards Team Competencies



CDASH Challenge 1: SDTM Complexity

- The Clinical Data Management (CDM) and EDC build team are expected to do map CDASH CRFs in line with SDTM.
- Some SDTM mappings can be complex and may require input and support from the SDTM standards team and ADaM team.
- The CDM and EDC team also have to spec, program and validate edit checks and work on (multiple) integrations which all require variables to be defined upfront.

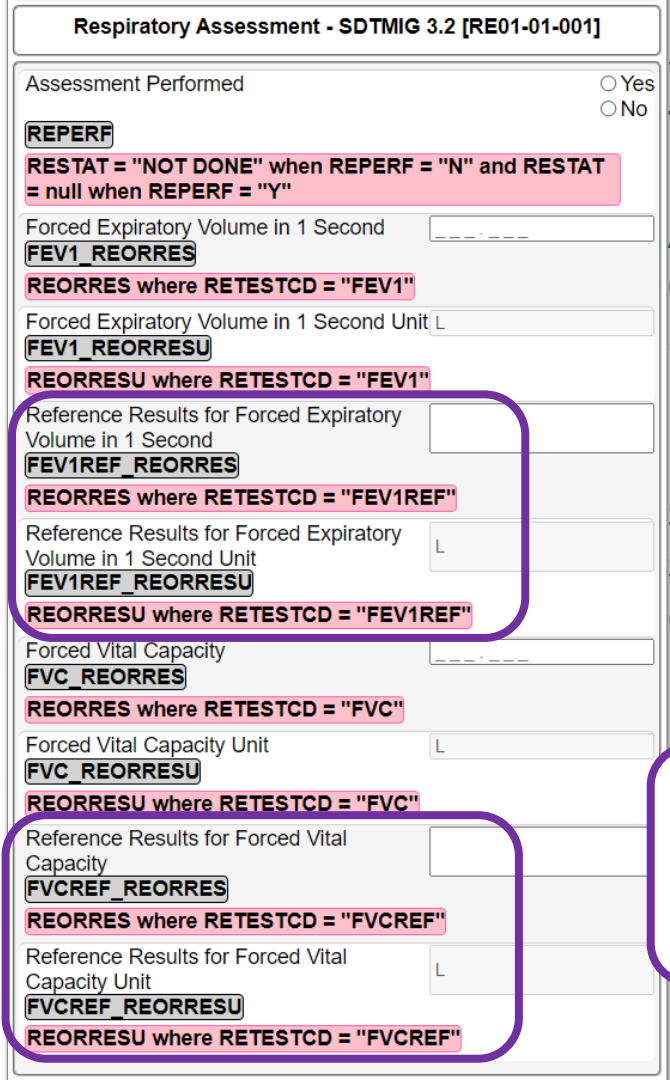


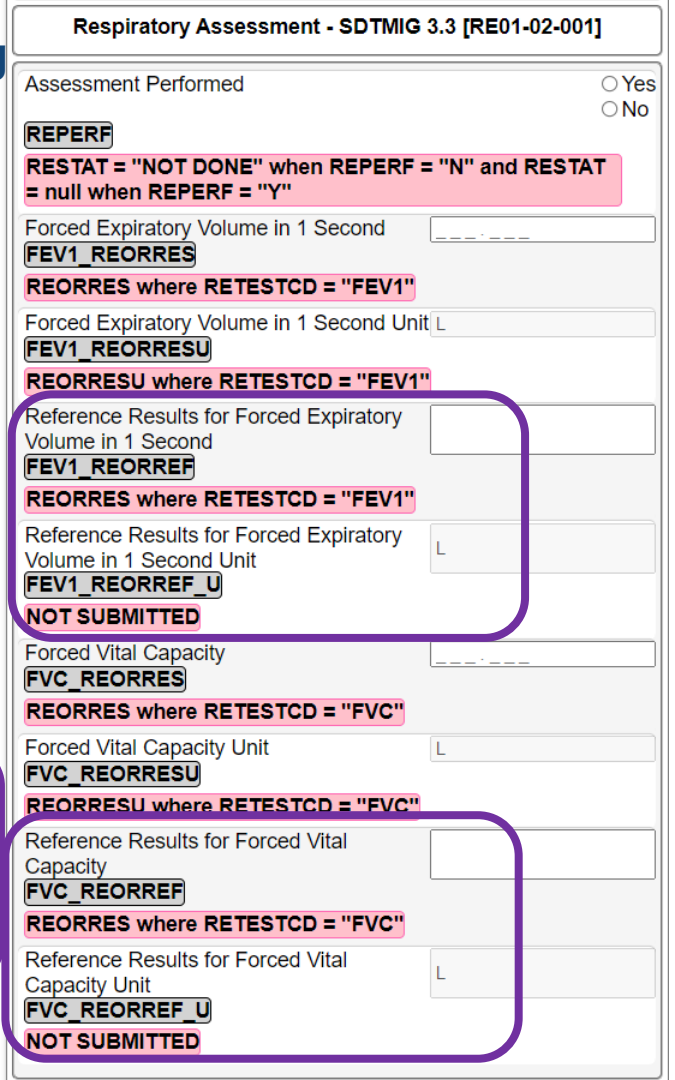
SDTMIG 3.3 Upversioning

The Reference Results for Respiratory (Continuous) Assessments has a dedicated variable in SDTMIG 3.3.

In SDTMIG 3.2 this could have been used in a supplemental variable or a sponsor could have collected it in a new RETESTCD

RETESTCD = “FEV1REF” now REORREF / Reference Result in Original Units





CDASH Challenge 1: SDTM Complexity – Fix it Later

- The Clinical Data Management (CDM) and EDC build team are expected to do map CDASH CRFs in line with SDTM.
- Some SDTM mappings can be complex and may require input and support from the SDTM standards team and ADaM team.
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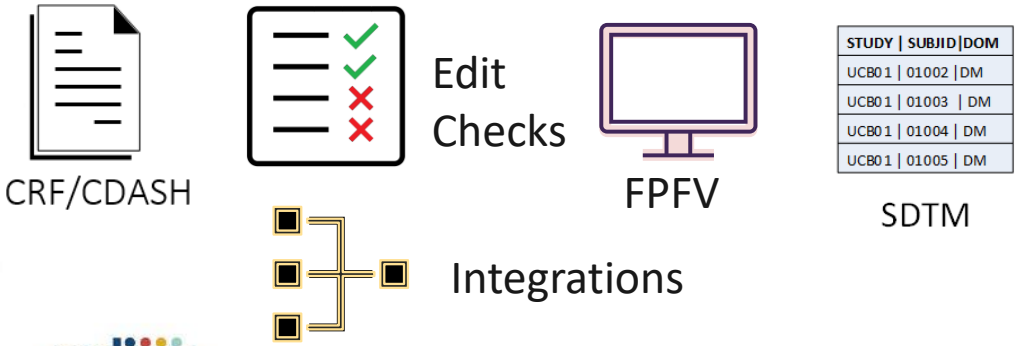


SDTM mapping issues from the CDASH CRFs can be fixed further downfield and added to an updated version of the CRF standard.

CDASH Variable Naming Conventions (VNCs)

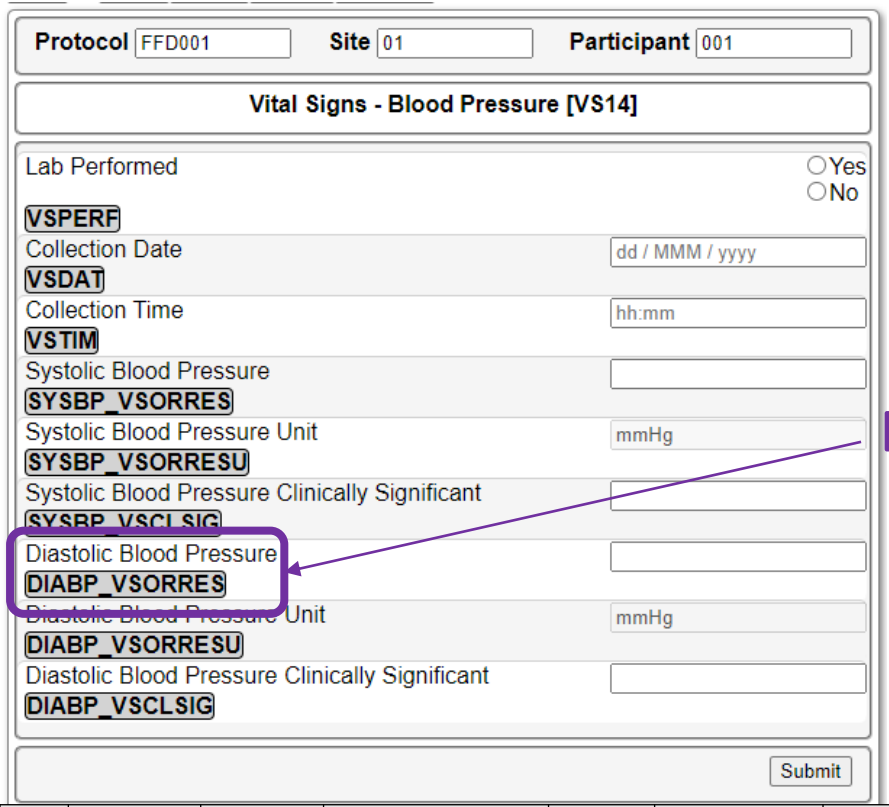
CDASHIG 2.x Variable Naming Convention

- CDASHIG 2.0 introduced a defined convention for variables
- <Topic>_<Domain><RootVariable>

CDISC Submission Value	CDISC Synonym(s)	NCI Preferred Term
VSTESTCD	Vital Signs Test Code	CDISC SDTM Vital Sign
HEIGHT	Height	Height

CDASH Variable	Question Text	Prompt
HEIGHT_VSORRES	What was the result of the height measurement	Height

- This supports the creation and identification of unique clinical data elements
  - on a CRF
  - in a study
  - across a standards library, an organization
  - across clinical research
- Adopting and adhering to a Variable Naming Conventions (VNC) early supports standards at scale



DIABP_VSORRES

	Study Identifier	Domain Abbreviation	Unique Subject Identifier	Sequence Number	Vital Signs Test Short Name	Vital Signs Test Name	Result or Finding in Original Units	Original Units	Visit Name	Repetition Number	Date/Time of Meas
Row	**STUDYID**	**DOMAIN**	**USUBJID**	**VSSEQ**	**VSTESTCD**	**VSTEST**	**VSORRES**	**VSORRESU**	**VISIT**	**VSREPNUM**	**VSDTC**
1	FFD001	VS	FFD001-01-001	1	SYSBP	Systolic Blood Pressure	120	mmHg	VISIT 1		2021-10-06T
2	FFD001	VS	FFD001-01-001	2	DIABP	Diastolic Blood Pressure	90	mmHg	VISIT 1		2021-10-06T

CDASHIG 2.x Variable Naming Convention

<Topic>_<Domain><RootVariable>

CDISC Submission Value	CDISC Synonym(s)	NCI Preferred Term
VSTESTCD	Vital Signs Test Code	CDISC SDTM Vital Sign
HEIGHT	Height	Height

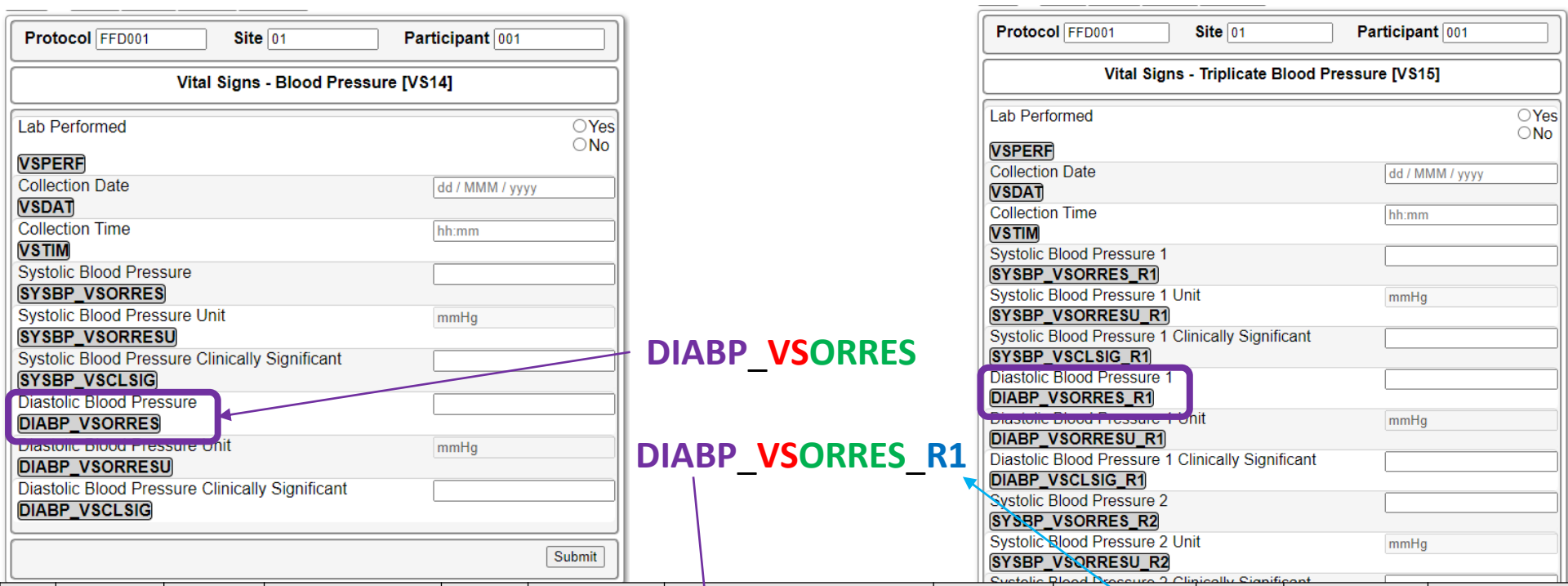
CDASH Variable	Question Text	Prompt
HEIGHT_VSORRES	What was the result of the height measurement	Height

<Topic>_<Domain><RootVariable>_<Appended>

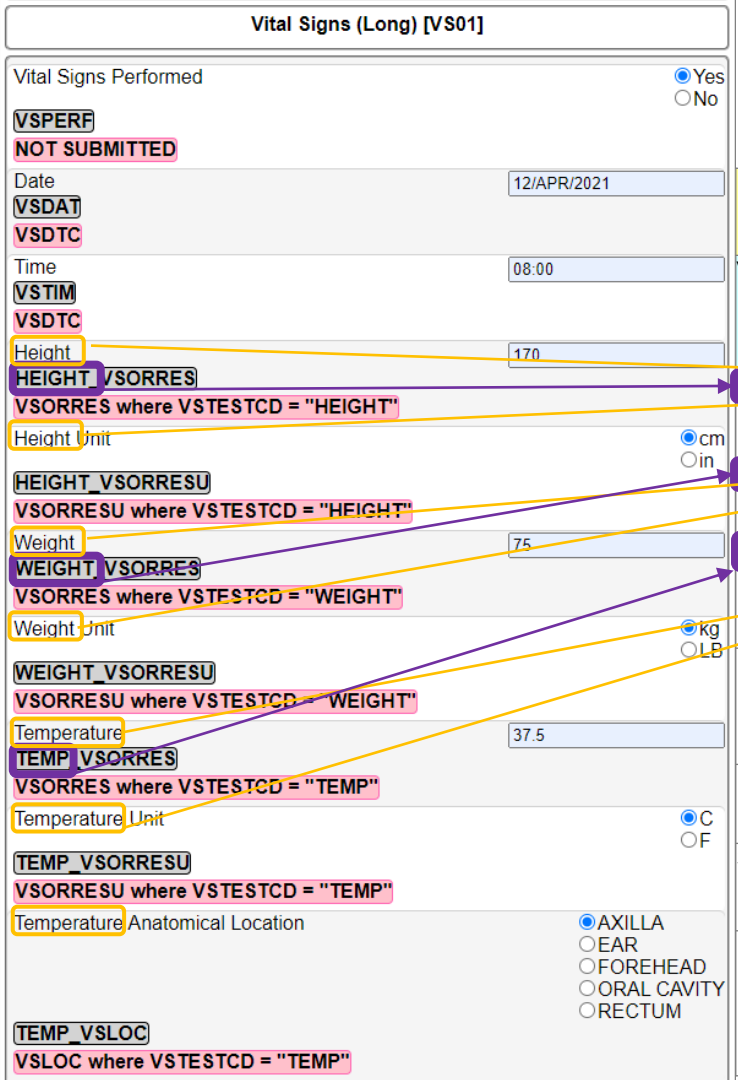
Taken in triplicate

CDISC Submission Value	CDISC Synonym(s)	NCI Preferred Term
VSTESTCD	Vital Signs Test Code	CDISC SDTM Vital Sign
DIABP	Diastolic Blood Pressure	Diastolic Blood Pressure

CDASH Variable	Question Text	Prompt
DIABP_VSORRES_R1	What was the result of the first systolic blood pressure measurement?	Diastolic Blood Pressure 1
DIABP_VSORRES_R2	What was the result of the second systolic blood pressure measurement?	Diastolic Blood Pressure 2
DIABP_VSORRES_R3	What was the result of the third systolic blood pressure measurement?	Diastolic Blood Pressure 3

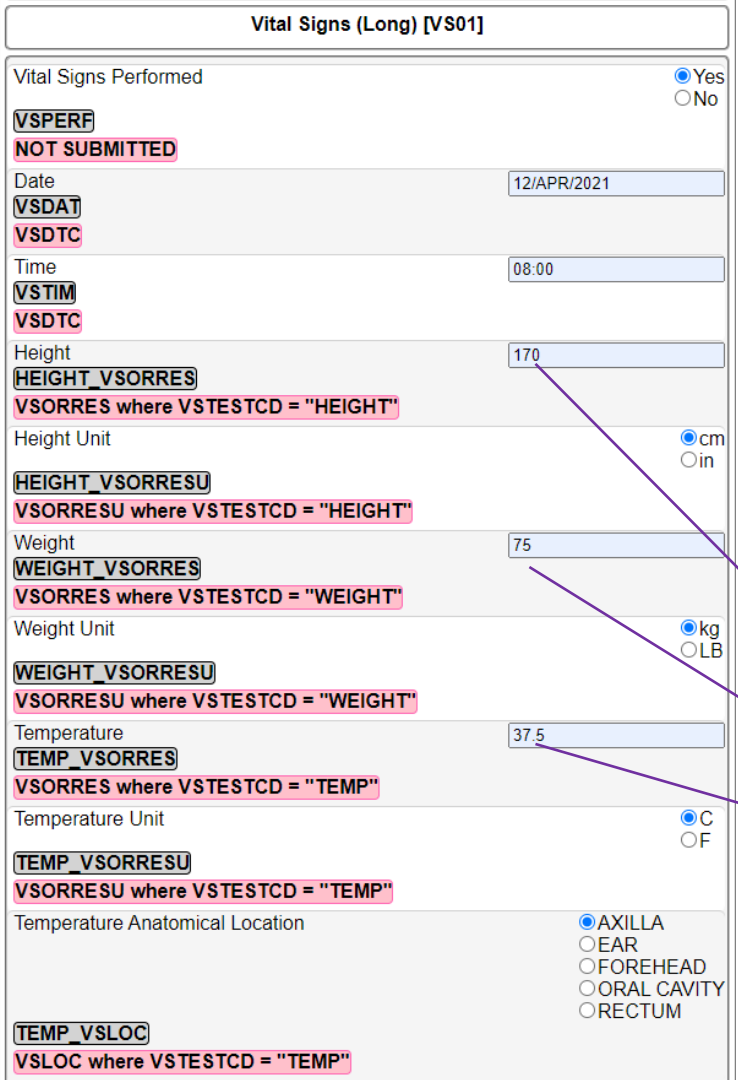


Row	STUDYID	DOMAIN	USUBJID	VSSEQ	VSTESTCD	VSTEST	VSORRES	VSORRESU	VISIT	VSREPNUM	VSDTC
1	FFD001	VS	FFD001-01-001	1	SYSBP	Systolic Blood Pressure	120	mmHg	VISIT 1		2021-10-06T
2	FFD001	VS	FFD001-01-001	2	DIABP	Diastolic Blood Pressure	90	mmHg	VISIT 1		2021-10-06T
3	FFD001	VS	FFD001-01-001	3	SYSBP	Systolic Blood Pressure	120	mmHg	VISIT 2	1	2021-10-07T
4	FFD001	VS	FFD001-01-001	4	DIABP	Diastolic Blood Pressure	90	mmHg	VISIT 2	1	2021-10-07T
5	FFD001	VS	FFD001-01-001	5	SYSBP	Systolic Blood Pressure	120	mmHg	VISIT 2	2	2021-10-07T
6	FFD001	VS	FFD001-01-001	6	DIABP	Diastolic Blood Pressure	90	mmHg	VISIT 2	2	2021-10-07T
7	FFD001	VS	FFD001-01-001	7	SYSBP	Systolic Blood Pressure	120	mmHg	VISIT 2	3	2021-10-07T



CDASH Variable Naming Conventions

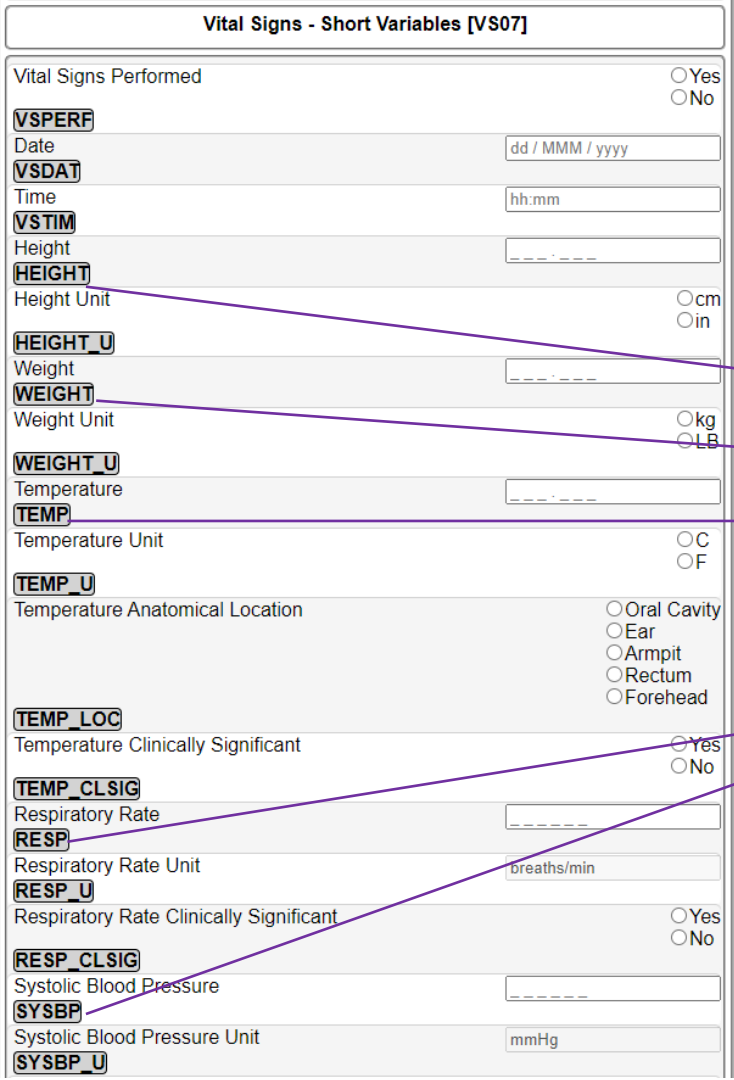
CDISC Submission Value	CDISC Synonym(s)	CDISC Definition	NCI Preferred Term
VSTESTCD	Vital Signs Test Code	The test code given to the test that analyzes a particular set of vital signs including temperature, respiratory rate, heart rate, and blood pressure.	CDISC SDTM Vital Sign Test Code Terminology
HEIGHT	Height	The vertical measurement or distance from the base to the top of an object; the vertical dimension of extension. (NCI)	Height
WEIGHT	Weight	The vertical force exerted by a mass as a result of gravity. (NCI)	Weight
TEMP	Body Temperature; Temperature	A measurement of the temperature of the body.	Body Temperature
RESP	Respiratory Rate	The rate of breathing (inhalation and exhalation) measured within a unit time, usually expressed as breaths per minute. (NCI)	Respiratory Rate
DIABP	Diastolic Blood Pressure	The minimum blood pressure in the systemic arterial circulation during the cardiac cycle.	Diastolic Blood Pressure
SYSBP	Systolic Blood Pressure	The maximum blood pressure in the systemic arterial circulation during the cardiac cycle.	Systolic Blood Pressure
PULSE	Pulse Rate	The rate of the pulse as observed in an artery, expressed as beats per minute. It can be measured at several anatomical sites, including the wrist, neck, temple, groin, behind the knees, or on top of the foot. (NCI)	Pulse Rate



CDISC Submission Value	CDISC Synonym(s)
VSTESTCD	Vital Signs Test Code
HEIGHT	Height
WEIGHT	Weight
TEMP	Body Temperature; Temperature
RESP	Respiratory Rate
DIABP	Diastolic Blood Pressure
SYSBP	Systolic Blood Pressure
PULSE	Pulse Rate

Row	STUDYID	DOMAIN	USUBJID	VSSEQ	VSTESTCD	VSTEST
1	FFD001	VS	FFD001-01-001	1	HEIGHT	Height
2	FFD001	VS	FFD001-01-001	2	WEIGHT	Weight
3	FFD001	VS	FFD001-01-001	3	TEMP	Temperature
4	FFD001	VS	FFD001-01-001	4	SYSBP	Systolic Blood Pressure
5	FFD001	VS	FFD001-01-001	5	DIABP	Diastolic Blood Pressure
6	FFD001	VS	FFD001-01-001	6	RESP	Respiratory Rate
7	FFD001	VS	FFD001-01-001	7	PULSE	Pulse

Row	VSPOS	VSORRES	VSORRESU	VSLOC	VSLAT	VSDTC
1		170	cm			2021-04-12T08:00
2		75	kg			2021-04-12T08:00
3		37.5	C	AXILLA		2021-04-12T08:00
4	SUPINE	60	breaths/min	BRACHIAL ARTERY	LEFT	2021-04-12T08:00
5	SUPINE	120	mmHg	BRACHIAL ARTERY	LEFT	2021-04-12T08:00
6		90	mmHg			2021-04-12T08:00
7		60	beats/min	RADIAL ARTERY	LEFT	2021-04-12T08:00



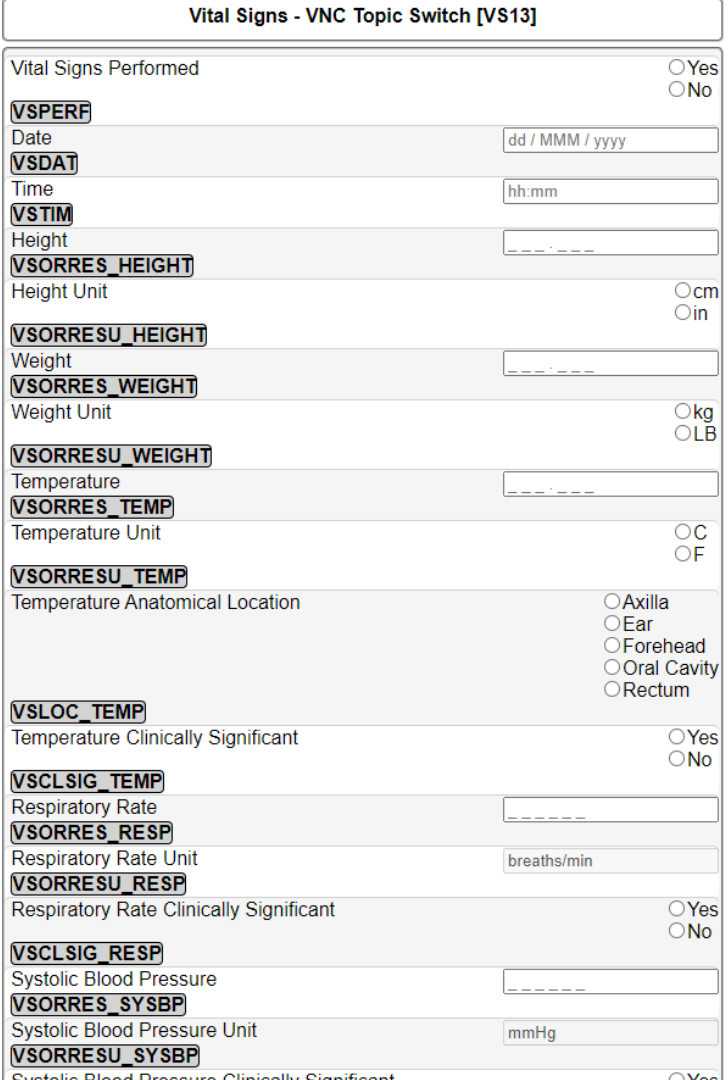
Shorten Variables

Not Recommend - very concise

- If data is not expected to be submitted to SDTM it could be a quicker approach.

Row	STUDYID	DOMAIN	USUBJID	VSSEQ	VSTESTCD	VSTEST
1	FFD001	VS	FFD001-01-001	1	HEIGHT	Height
2	FFD001	VS	FFD001-01-001	2	WEIGHT	Weight
3	FFD001	VS	FFD001-01-001	3	TEMP	Temperature
4	FFD001	VS	FFD001-01-001	4	SYSBP	Systolic Blood Pressure
5	FFD001	VS	FFD001-01-001	5	DIABP	Diastolic Blood Pressure
6	FFD001	VS	FFD001-01-001	6	RESP	Respiratory Rate
7	FFD001	VS	FFD001-01-001	7	PULSE	Pulse

Row	VSPOS	VSORRES	VSORRESU	VSLOC	VSLAT	VSDTC
1		170	cm			2021-04-12T08:00
2		75	kg			2021-04-12T08:00
3		37.5	C	AXILLA		2021-04-12T08:00
4	SUPINE	60	breaths/min	BRACHIAL ARTERY	LEFT	2021-04-12T08:00
5	SUPINE	120	mmHg	BRACHIAL ARTERY	LEFT	2021-04-12T08:00
6		90	mmHg			2021-04-12T08:00
7		60	beats/min	RADIAL ARTERY	LEFT	2021-04-12T08:00



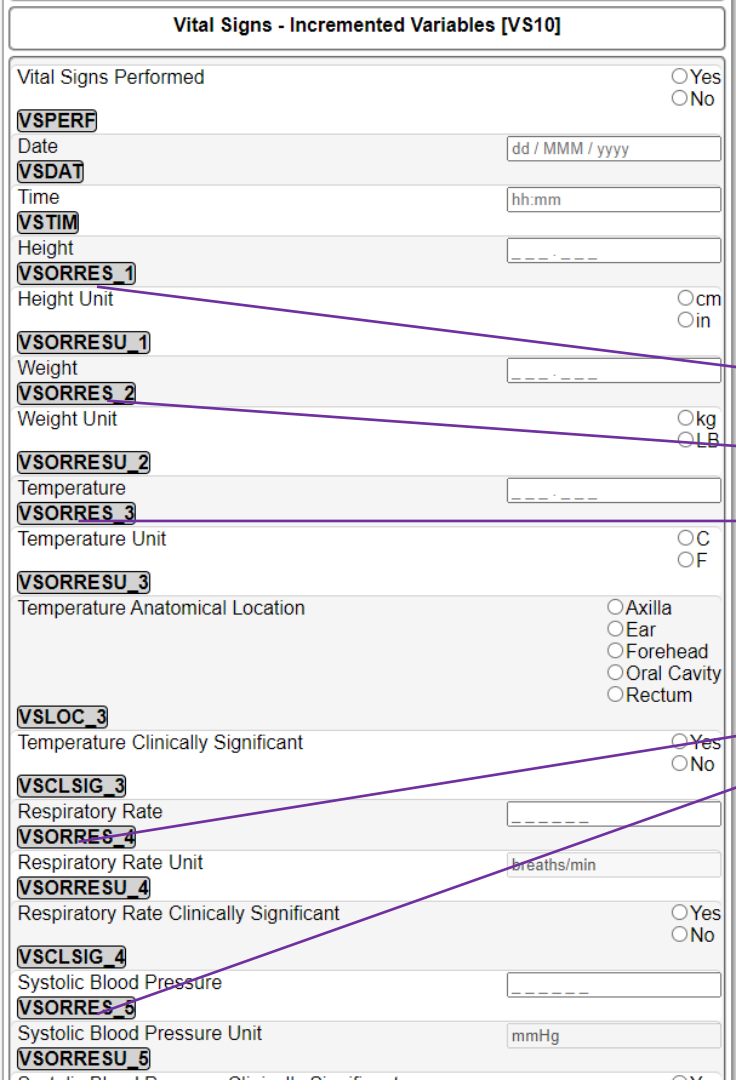
Reversed CDASH Variable Naming Conventions - Fine…

<Domain><RootVariable>_<Topic>

vs

<Topic>_<Domain><RootVariable>

- A number of sponsors are activity creating CDASH standards using VNCs that have the Topic information after the domain and root variable.
- This is not in line with the CDASHIG recommendations but is still a good approach to creating unique variables.

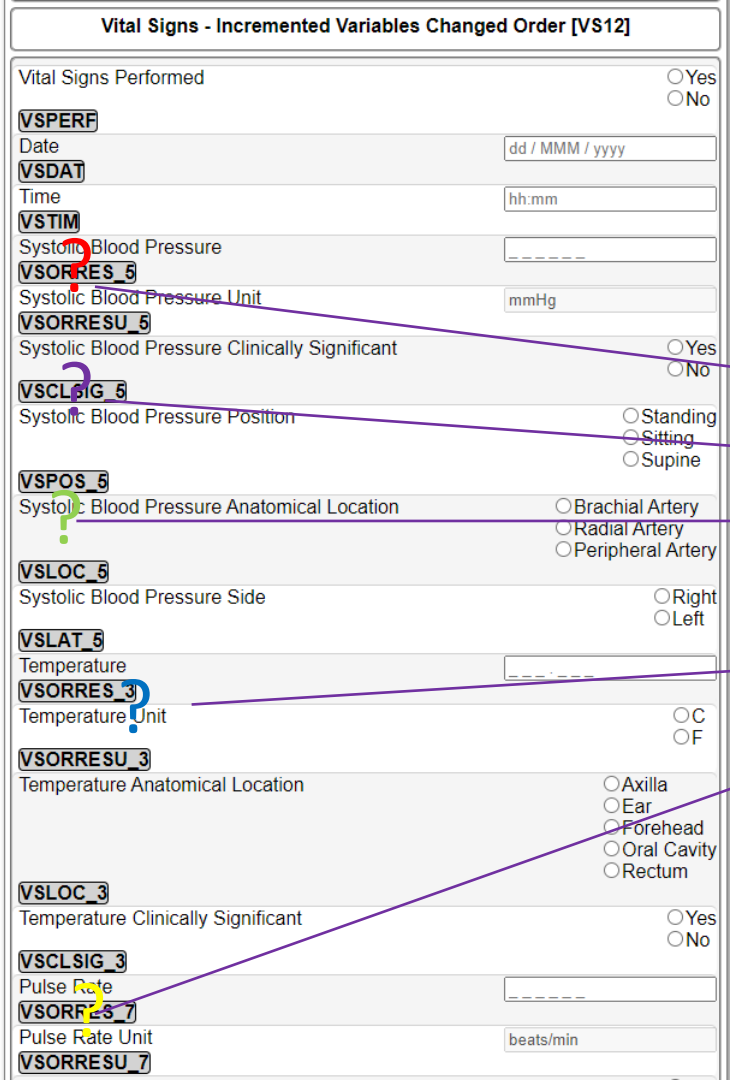


Incremented Variables

Not Recommend - Very Fast

- Quicker to create difficult to reuse
- Can be difficult to map to SDTM

Row	STUDYID	DOMAIN	USUBJID	VSSEQ	VSTESTCD	VSTEST
1	FFD001	VS	FFD001-01-001	1	HEIGHT	Height
2	FFD001	VS	FFD001-01-001	2	WEIGHT	Weight
3	FFD001	VS	FFD001-01-001	3	TEMP	Temperature
4	FFD001	VS	FFD001-01-001	4	SYSBP	Systolic Blood Pressure
5	FFD001	VS	FFD001-01-001	5	DIABP	Diastolic Blood Pressure
6	FFD001	VS	FFD001-01-001	6	RESP	Respiratory Rate
7	FFD001	VS	FFD001-01-001	7	PULSE	Pulse

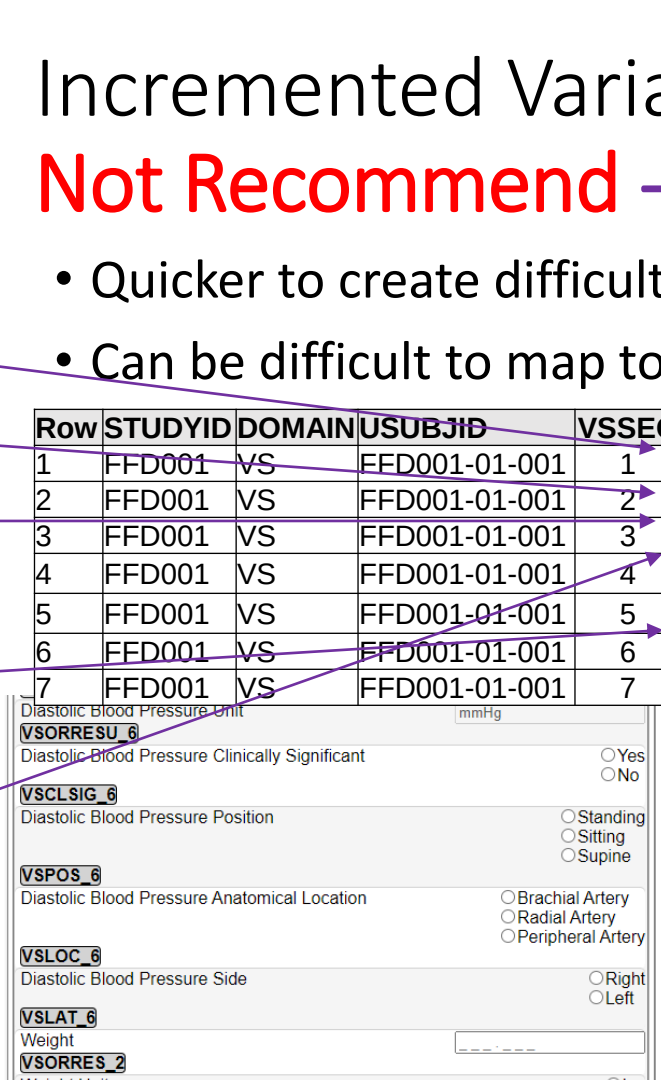


Incremented Variables

Not Recommend - Limited Reuse

- Quicker to create difficult to reuse
- Can be difficult to map to SDTM

Row	STUDYID	DOMAIN	USUBJID	VSSEQ	VSTESTCD	VSTEST
1	FFD001	VS	FFD001-01-001	1	HEIGHT	Height
2	FFD001	VS	FFD001-01-001	2	WEIGHT	Weight
3	FFD001	VS	FFD001-01-001	3	TEMP	Temperature
4	FFD001	VS	FFD001-01-001	4	SYSBP	Systolic Blood Pressure
5	FFD001	VS	FFD001-01-001	5	DIABP	Diastolic Blood Pressure
6	FFD001	VS	FFD001-01-001	6	RESP	Respiratory Rate
7	FFD001	VS	FFD001-01-001	7	PULSE	Pulse



CDASHIG 2.2 ~2021-09-28

- Proposes a standard approach for variable naming conventions :

CDASHIG 2.2 section 2.3.1

<Topic Variable values > _<*Qualifier(s)*>_<SDTMIG Target>. Sponsors may define their own conventions for creating denormalized CDASH variable names.

Examples:

- DIABP_VSORRES where DIABP is the value for VSTESTCD (topic variable) and VSORRES is the SDTMIG target
- DIABP_ARM _RIGHT_VSORRES where DIABP is the value for VSTESTCD (topic variable): ARM and RIGHT are values of the SDTM Qualifier variables VSLOC and VSLAT; VSORRES is the SDTMIG target
- DEPRESSION_MHOCCUR where DEPRESSION is the value of MHTERM (topic variable): MHOCCUR is the SDTMIG target

✘ **This Presentation**

<Topic>_<Domain><RootVariable>_<Appended>

<Topic>_<Appended>_<Domain><RootVariable>

✓ **CDASH**

Please follow the CDASH conventions to remain internationally standard

Reducing Variation Between Fields

Understanding Variable and Field Conventions

CRF	Variable	Field
Vital Signs (DILI)	VSBPDIAD	Diastolic blood pressure:
Vital Signs (DILI)	VSBPSYSD	Systolic blood pressure:
Vital Signs (Log)	BPDIA	Diastolic Blood Pressure
Vital Signs (Log)	BPSYS	Systolic Blood Pressure
Vital Signs (Safety)	VSBPDIA	Diastolic blood pressure:
Vital Signs (Safety)	VSBPSYS	Systolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPDIO1	Diastolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPSYO1	Systolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPDIO2	Diastolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPSYO2	Systolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPDIO3	Diastolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPSYO3	Systolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPDIO4	Diastolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPSYO4	Systolic blood pressure:

How many field conventions?

Understanding Variable and Field Conventions

CRF	Variable	Field
Vital Signs (DILI)	VSBPDIAD	Diastolic blood pressure:
Vital Signs (DILI)	VSBPSYSD	Systolic blood pressure:
Vital Signs (Log)	BPDIA	Diastolic Blood Pressure
Vital Signs (Log)	BPSYS	Systolic Blood Pressure
Vital Signs (Safety)	VSBPDIA	Diastolic blood pressure:
Vital Signs (Safety)	VSBPSYS	Systolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPDIO1	Diastolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPSYO1	Systolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPDIO2	Diastolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPSYO2	Systolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPDIO3	Diastolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPSYO3	Systolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPDIO4	Diastolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPSYO4	Systolic blood pressure:

Understanding Variable and Field Conventions

CRF	Variable	Field
Vital Signs (DILI)	VSBPDIAD	Diastolic blood pressure:
Vital Signs (DILI)	VSBPSYSD	Systolic blood pressure:
Vital Signs (Log)	BPDIA	Diastolic Blood Pressure
Vital Signs (Log)	BPSYS	Systolic Blood Pressure
Vital Signs (Safety)	VSBPDIA	Diastolic blood pressure:
Vital Signs (Safety)	VSBPSYS	Systolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPDIO1	Diastolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPSYO1	Systolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPDIO2	Diastolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPSYO2	Systolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPDIO3	Diastolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPSYO3	Systolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPDIO4	Diastolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPSYO4	Systolic blood pressure:

Diastolic blood pressure:
Systolic blood pressure:

Diastolic Blood Pressure
Systolic Blood Pressure

1) Sentence vs Title case
2) Semicolon

Check CDASH Model and IG

Minor formatting difference

Understanding Variable and Field Conventions

CRF	Variable	Field
Vital Signs (DILI)	VSBPDIAD	Diastolic blood pressure:
Vital Signs (DILI)	VSBPSYSD	Systolic blood pressure:
Vital Signs (Log)	BPDIA	Diastolic Blood Pressure
Vital Signs (Log)	BPSYS	Systolic Blood Pressure
Vital Signs (Safety)	VSBPDIA	Diastolic blood pressure:
Vital Signs (Safety)	VSBPSYS	Systolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPDIO1	Diastolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPSYO1	Systolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPDIO2	Diastolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPSYO2	Systolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPDIO3	Diastolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPSYO3	Systolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPDIO4	Diastolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPSYO4	Systolic blood pressure:

Diastolic blood pressure:
Systolic blood pressure:

Diastolic Blood Pressure
Systolic Blood Pressure

1) Sentence vs Title case
2) Semicolon

Check CDASH Model and IG

CDISC Submission Value	CDISC Synonym(s)
VSTESTCD	Vital Signs Test Code
DIABP	Diastolic Blood Pressure
SYSBP	Systolic Blood Pressure

Choose one convention

CDASH	Variable	Prompt
Model	--ORRES	([Result/Amount] of) [value from --TEST]
IG	VSORRES	[VSTEST] (Result)
Metadata	DIABP_VSORRES	Diastolic Blood Pressure

Understanding Variable and Field Conventions

CRF	Variable	Field
Vital Signs (DILI)	VSBPDIAD	Diastolic blood pressure:
Vital Signs (DILI)	VSBPSYSD	Systolic blood pressure:
Vital Signs (Log)	BPDIA	Diastolic Blood Pressure
Vital Signs (Log)	BPSYS	Systolic Blood Pressure
Vital Signs (Safety)	VSBPDIA	Diastolic blood pressure:
Vital Signs (Safety)	VSBPSYS	Systolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPDIO1	Diastolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPSYO1	Systolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPDIO2	Diastolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPSYO2	Systolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPDIO3	Diastolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPSYO3	Systolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPDIO4	Diastolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPSYO4	Systolic blood pressure:

DIABP_VSORRES_fsc Diastolic blood pressure:
SYSBP_VSORRES_fsc Systolic blood pressure:

DIABP_VSORRES Diastolic Blood Pressure
SYSBP_VSORRES Systolic Blood Pressure

1) Sentence vs Title case
2) Semicolon

Check CDASH Model and IG

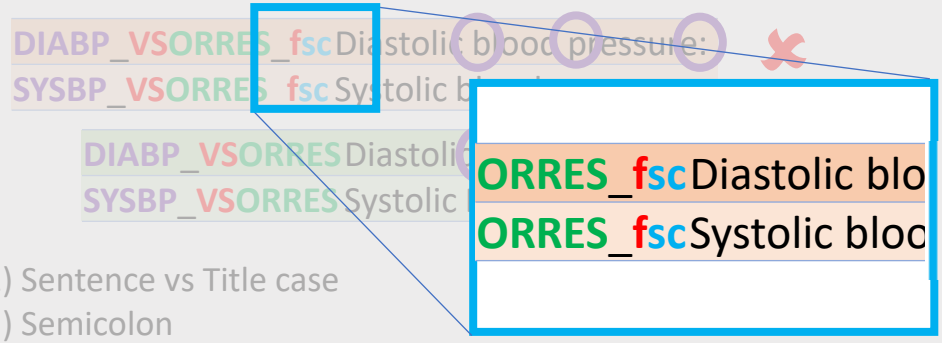
CDISC Submission Value	CDISC Synonym(s)
VSTESTCD	Vital Signs Test Code
DIABP	Diastolic Blood Pressure
SYSBP	Systolic Blood Pressure

Choose one convention

CDASH	Variable	Prompt
Model	--ORRES	([Result/Amount] of) [value from --TEST]
IG	VSORRES	[VSTEST] (Result)
Metadata	DIABP_VSORRES	Diastolic Blood Pressure

Understanding Variable and Field Conventions

CRF	Variable	Field
Vital Signs (DILI)	VSBPDIAD	Diastolic blood pressure:
Vital Signs (DILI)	VSBPSYSD	Systolic blood pressure:
Vital Signs (Log)	BPDIA	Diastolic Blood Pressure
Vital Signs (Log)	BPSYS	Systolic Blood Pressure
Vital Signs (Safety)	VSBPDIA	Diastolic blood pressure:
Vital Signs (Safety)	VSBPSYS	Systolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPDIO1	Diastolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPSYO1	Systolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPDIO2	Diastolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPSYO2	Systolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPDIO3	Diastolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPSYO3	Systolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPDIO4	Diastolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPSYO4	Systolic blood pressure:



1) Sentence vs Title case
2) Semicolon

Check CDASH Model and IG

CDISC Submission Value	CDISC Synonym(s)
VSTESTCD	Vital Signs Test Code
DIABP	Diastolic Blood Pressure
SYSBP	Systolic Blood Pressure

	Variable	Prompt
	-ORRES	([Result/Amount] of) [value from --TEST]
	SORRES	[VSTEST] (Result)
Metadata	DIABP_VSORRES	Diastolic Blood Pressure

Depending on your system's ability to manage unique variable

Remove Variations Between Fields

- If a request has been received to create **Bold,** *Italics or* ***Bold Italics*** look to push back on these through an established governance process.
- They could require additional variables to be created without adding additional value

Reduce Variability

DIABP_VSORRES_fsc Diastolic blood pressure: ✗

DIABP_VSORRES_f? Diastolic blood **pressure**: ✗

DIABP_VSORRES_fbsc Diastolic blood pressure:

DIABP_VSORRES_f? Diastolic blood *pressure*: ✗

DIABP_VSORRES_fisc Diastolic blood pressure:

DIABP_VSORRES_f? Diastolic blood ***pressure***: ✗

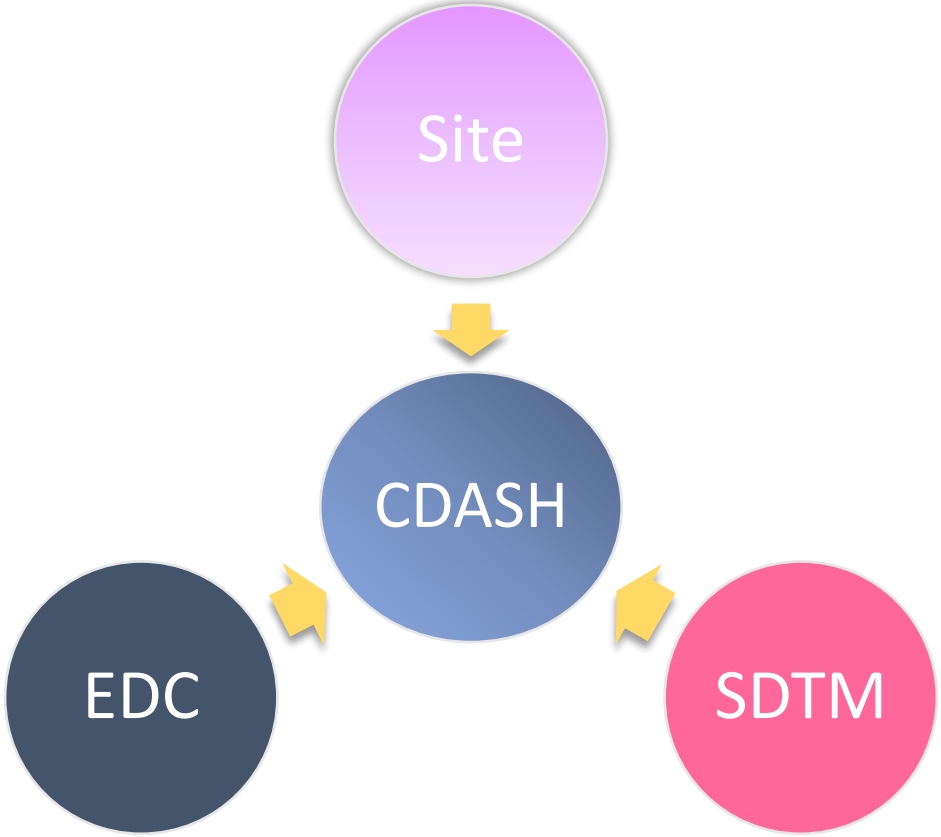
DIABP_VSORRES_fbisc Diastolic blood pressure:

DIABP_VSORRES Diastolic Blood Pressure ✓

If a QRS instrument has formatting retain it

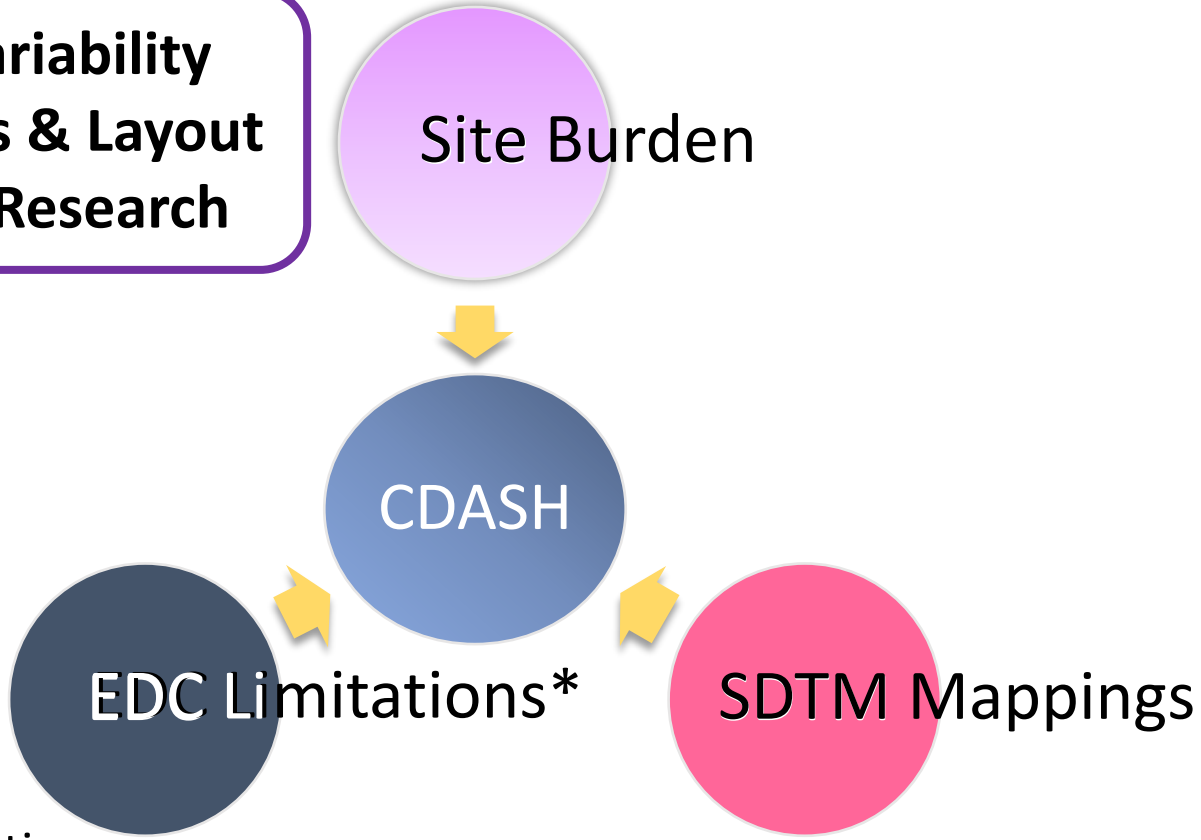
✓ **e.g. <QRS-TESTCD>_<QRS><ORRES>**

The 3 Forces on CDASH Conformance



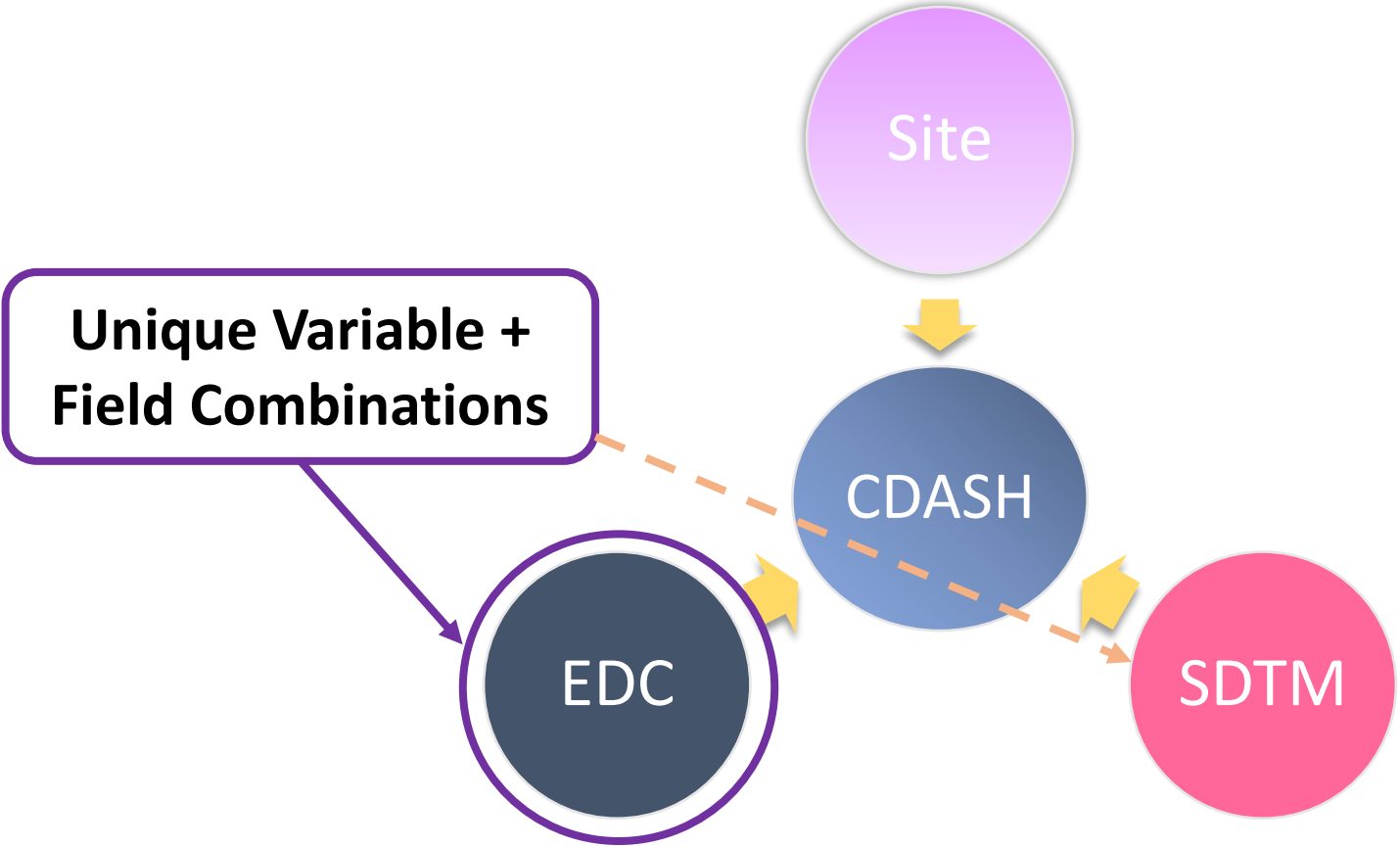
The 3 Forces on CDASH Conformance

Reduce CRF Variability
Consistent Fields & Layout
Across Clinical Research

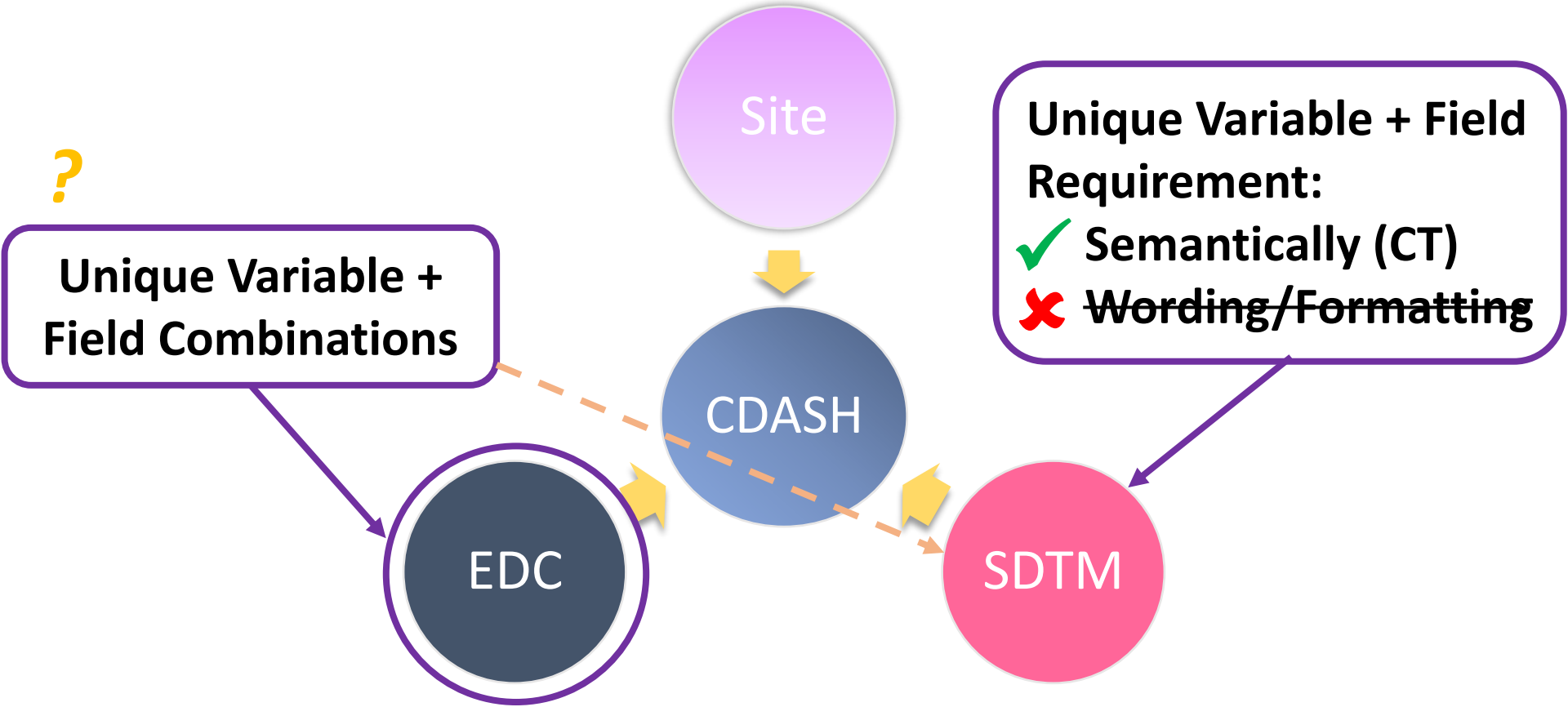


*Consider MDR Limitations

The 3 Forces on CDASH Conformance



The 3 Forces on CDASH Conformance



Understanding Variable and Field Conventions

<Topic>_<Domain><RootVariable>_<Appended>

CRF	Variable	Field
Vital Signs (DILI)	VSBPDIAD	Diastolic blood pressure:
Vital Signs (DILI)	VSBPSYSD	Systolic blood pressure:
Vital Signs (Log)	BPDIA	Diastolic Blood Pressure
Vital Signs (Log)	BPSYS	Systolic Blood Pressure
Vital Signs (Safety)	VSBPDIA	Diastolic blood pressure:
Vital Signs (Safety)	VSBPSYS	Systolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPDIO1	Diastolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPSYO1	Systolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPDIO2	Diastolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPSYO2	Systolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPDIO3	Diastolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPSYO3	Systolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPDIO4	Diastolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPSYO4	Systolic blood pressure:

Convention	Variable	Description
	VSBPDIAD	
	VSBPSYSD	
	BPDIA	
	BPSYS	
	VSBPDIA	
	VSBPSYS	
	VSBPDIO1	
	VSBPSYO1	
	VSBPDIO2	
	VSBPSYO2	
	VSBPDIO3	
	VSBPSYO3	
	VSBPDIO4	
	VSBPSYO4	

How many variable conventions?

Understanding Variable and Field Conventions

<Topic>_<Domain><RootVariable>_<Appended>

CRF	Variable	Field
Vital Signs (DILI)	VSBPDIAD	Diastolic blood pressure:
Vital Signs (DILI)	VSBPSYSD	Systolic blood pressure:
Vital Signs (Log)	BPDIA	Diastolic Blood Pressure
Vital Signs (Log)	BPSYS	Systolic Blood Pressure
Vital Signs (Safety)	VSBPDIA	Diastolic blood pressure:
Vital Signs (Safety)	VSBPSYS	Systolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPDIO1	Diastolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPSYO1	Systolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPDIO2	Diastolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPSYO2	Systolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPDIO3	Diastolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPSYO3	Systolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPDIO4	Diastolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPSYO4	Systolic blood pressure:

Convention	Variable	Description
1	VSBPDIAD	
1	VSBPSYSD	
2	BPDIA	
2	BPSYS	
3	VSBPDIA	
3	VSBPSYS	
4	VSBPDIO1	
4	VSBPSYO1	
4	VSBPDIO2	
4	VSBPSYO2	
4	VSBPDIO3	
4	VSBPSYO3	
4	VSBPDIO4	
4	VSBPSYO4	

Understanding Variable and Field Conventions

<Topic>_<Domain><RootVariable>_<Appended>

CRF	Variable	Field
Vital Signs (DILI)	VSBPDIAD	Diastolic blood pressure:
Vital Signs (DILI)	VSBPSYSD	Systolic blood pressure:
Vital Signs (Log)	BPDIA	Diastolic Blood Pressure
Vital Signs (Log)	BPSYS	Systolic Blood Pressure
Vital Signs (Safety)	VSBPDIA	Diastolic blood pressure:
Vital Signs (Safety)	VSBPSYS	Systolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPDIO1	Diastolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPSYO1	Systolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPDIO2	Diastolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPSYO2	Systolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPDIO3	Diastolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPSYO3	Systolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPDIO4	Diastolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPSYO4	Systolic blood pressure:

Convention	Variable	Description
1	VSBPDIAD	<Domain><Group><Topic><CRF> 2-2-3-1 (8)
1	VSBPSYSD	<Domain><Group><Topic><CRF> 2-2-3-1 (8)
2	BPDIA	<Group><Topic> 2-3 (5)
2	BPSYS	<Group><Topic> 2-3 (5)
3	VSBPDIA	<Domain><Group><Topic> 2-2-3 (7)
3	VSBPSYS	<Domain><Group><Topic> 2-2-3 (7)
4	VSBPDIO1 or VSBPDIO1	<Domain><Group><Topic><Appended> or <Domain><Group><Topic><Unique> - 2-2-2-2 (8)
4	VSBPSYO1	<Domain><Group><Topic><Appended> 2-2-2-2 (8)
4	VSBPDIO2	<Domain><Group><Topic><Appended> 2-2-2-2 (8)
4	VSBPSYO2	<Domain><Group><Topic><Appended> 2-2-2-2 (8)
4	VSBPDIO3	<Domain><Group><Topic><Appended> 2-2-2-2 (8)
4	VSBPSYO3	<Domain><Group><Topic><Appended> 2-2-2-2 (8)
4	VSBPDIO4	<Domain><Group><Topic><Appended> 2-2-2-2 (8)
4	VSBPSYO4	<Domain><Group><Topic><Appended> 2-2-2-2 (8)

Choose one convention

Preferably an international standard

CDISC Submission Value
VSTESTCD
DIABP
SYSBP

Vital Signs – for Orthostatic Reaction

Participant rests for 2 minutes then lies supine. Blood pressure and pulse rate are measured after 1 minute and after 5 minutes post supine.

CRF	Variable	Field
Vital Signs – for Orthostatic Reaction	VSBPDIO1	Diastolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPSYO1	Systolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPDIO2	Diastolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPSYO2	Systolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPDIO3	Diastolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPSYO3	Systolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPDIO4	Diastolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPSYO4	Systolic blood pressure:

Participant stands. Blood pressure and pulse rate are measured after 1 minute and after 3 minutes post standing.

A series of measurements is taken in different positions

This is not a repetition of the same measurement e.g.

CDASH Variable	Prompt
DIABP_VSORRES_R1	Diastolic Blood Pressure 1
DIABP_VSORRES_R2	Diastolic Blood Pressure 2
DIABP_VSORRES_R3	Diastolic Blood Pressure 3

Royal College of Physicians

Procedure for measuring lying and standing BP

- Use a manual sphyg if possible.
- Lie down 5 minutes. Take BP 1.
- Stand up. Take BP 2 in 1st min.
- After 3 minutes, take BP 3.

Continued opposite >>>

A positive result is:

- A drop in systolic BP of 20mmHg or more.
- A drop to below 90mmHg on standing.
- A drop in diastolic BP of 10mmHg with symptoms.

For further info, visit
rcplondon.ac.uk/falls/bp

Vital Signs – for Orthostatic Reaction

Participant rests for 2 minutes then lies supine. Blood pressure and pulse rate are measured after 1 minute and after 5 minutes post supine.

Measurement 1: VSMEASO1

Position: VSPOSO1

Actual time (24h clock/HH:MM): VSTIMO1

Systolic blood pressure: VSBPSYO1

Diastolic blood pressure: VSBPDIO1

Pulse rate: VSPULSO1

CRF	Variable	Field
Vital Signs – for Orthostatic Reaction	VSBPDIO1	Diastolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPSYO1	Systolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPDIO2	Diastolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPSYO2	Systolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPDIO3	Diastolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPSYO3	Systolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPDIO4	Diastolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPSYO4	Systolic blood pressure:

Measurement 3: VSMEASO3

Position: VSPOSO3

Actual time (24h clock/HH:MM): VSTIMO3

Systolic blood pressure: VSBPSYO3

Diastolic blood pressure: VSBPDIO3

Participant stands. Blood pressure and pulse rate are measured after 1 minute and after 3 minutes post standing.

Measurement 2: VSMEASO2

Position: VSPOSO2

Pulse rate: VSPULSO2

Measurement 4: VSMEASO4

Position: VSPOSO4

h clock/HH:MM): VSTIMO4

pressure: VSBPSYO4

pressure: VSBPDIO4

Pulse rate: VSPULSO4

<Topic>_<Domain><RootVariable>_<Appended>

Create unique field variable combinations

CDASH Variable	Prompt
DIABP_VSORRES_SUPINE_TPT1	Diastolic Blood Pressure Supine 1 Minute
DIABP_VSORRES_SUPINE_TPT5	Diastolic Blood Pressure Supine 5 Minutes
DIABP_VSORRES_STANDING_TPT1	Diastolic Blood Pressure Standing 1 Minute
DIABP_VSORRES_STANDING_TPT3	Diastolic Blood Pressure Standing 3 Minutes

Vital Signs – for Orthostatic Reaction

Participant rests for 2 minutes then lies supine. Blood pressure and pulse rate are measured after 1 minute and after 5 minutes post supine.

Measurement 1: VSMEASO1

Position: VSPOSO1

Actual time (24h clock/HH:MM): VSTIMO1

Systolic blood pressure: VSBPSYO1

Diastolic blood pressure: VSBPDIO1

Pulse rate: VSPULSO1

CRF	Variable	Field
Vital Signs – for Orthostatic Reaction	VSBPDIO1	Diastolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPSYO1	Systolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPDIO2	Diastolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPSYO2	Systolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPDIO3	Diastolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPSYO3	Systolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPDIO4	Diastolic blood pressure:
Vital Signs – for Orthostatic Reaction	VSBPSYO4	Systolic blood pressure:

Measurement 3: VSMEASO3

Position: VSPOSO3

Actual time (24h clock/HH:MM): VSTIMO3

Systolic blood pressure: VSBPSYO3

Diastolic blood pressure: VSBPDIO3

Participant stands. Blood pressure and pulse rate are measured after 1 minute and after 3 minutes post standing.

Measurement 2: VSMEASO2

Position: VSPOSO2

Actual time (24h clock/HH:MM): VSTIMO2

Pulse rate: VSPULSO2

Measurement 4: VSMEASO4

Position: VSPOSO4

h clock/HH:MM): VSTIMO4

pressure: VSBPSYO4

pressure: VSBPDIO4

Pulse rate: VSPULSO4

CDASHIG 2.2

<Topic>_<Appended>_<Domain><RootVariable>

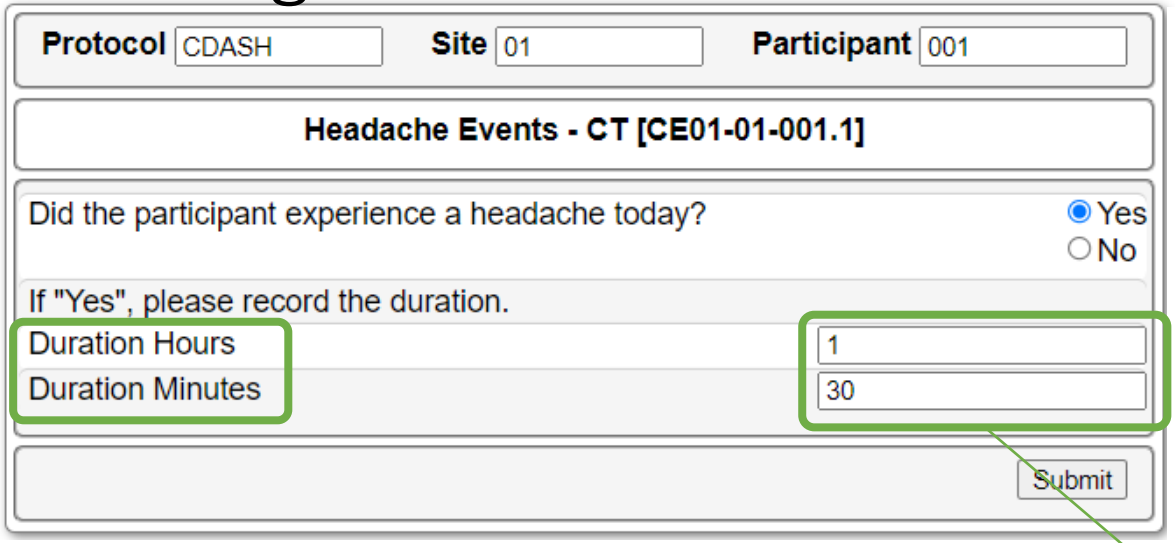
CDASH Variable	Prompt
DIABP_SUPINE_TPT1_VSORRES	Diastolic Blood Pressure Supine 1 Minute
DIABP_SUPINE_TPT5_VSORRES	Diastolic Blood Pressure Supine 5 Minutes
DIABP_STANDING_TPT1_VSORRES	Diastolic Blood Pressure Standing 1 Minute
DIABP_STANDING_TPT3_VSORRES	Diastolic Blood Pressure Standing 3 Minutes

Creating New CDASH Variable & Field Conventions

Generating New CDASH Variable and Field Conventions

- If a new variable or field (type) is encountered a standards task/role/team should be available to assess it and create a consistent convention for it.
- This standards group should meet a regular cadence so standards tasks can be sent for review.
- Prioritization should be incorporated into the process
  - This can be supported by a standards requests ticketing system.
- If the standards assessment is taking too long or not possible in a timely manner the study/eCRF build team should be empowered to make independent decisions which can be later elevated to the standards level or reassessed.

Creating New CDASH Variables Conventions



- In CDASH --CDUR (Collected Duration) is used since --DUR is in ISO 8601 format
- There is not a 1:1 mapping a --"C" / "Collected" variable is used
- It is not specific to units

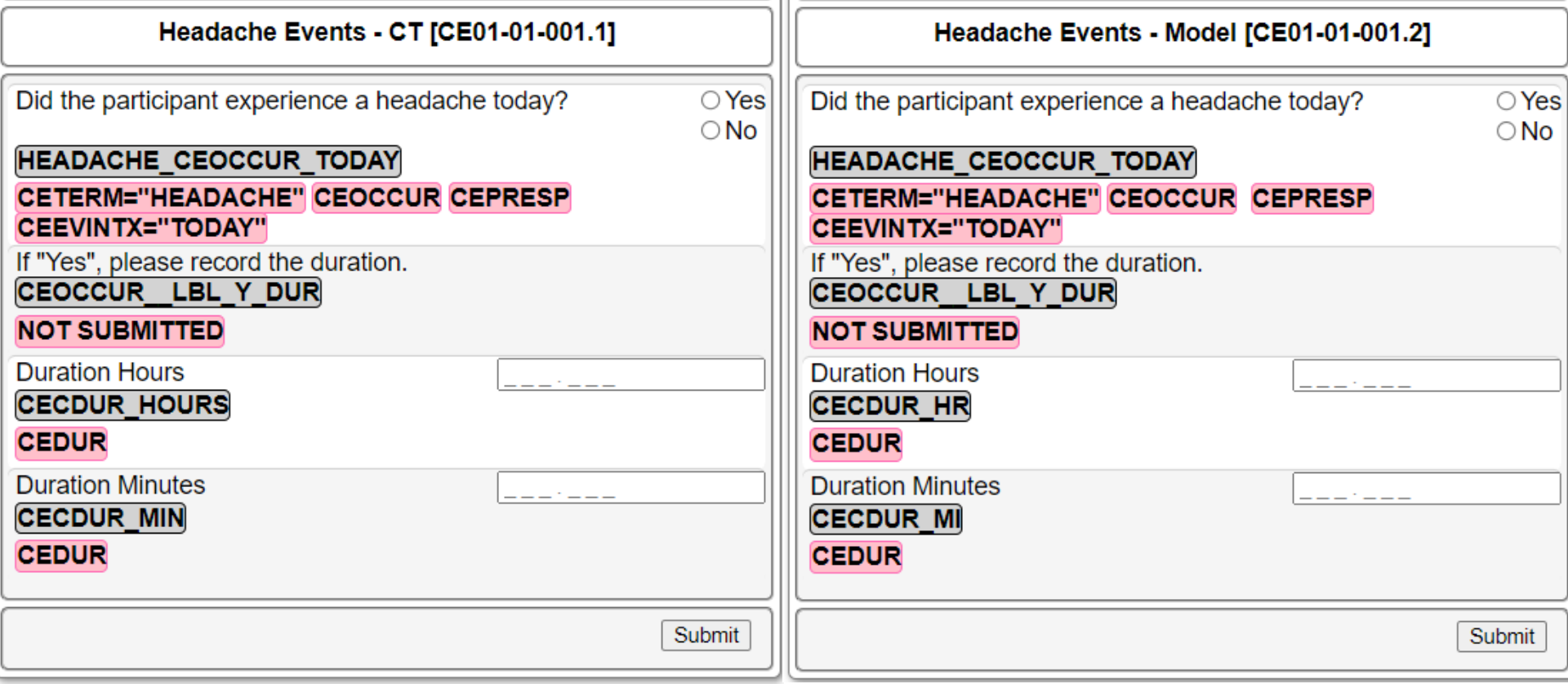
- Choose appropriate variable components e.g. CDISC Controlled Terminology (CT) or CDASH Model or SDTM e.g. Non-standard Variable Registry Fragments

Study Identifier	Domain Abbreviation	Unique Subject Identifier	Sequence Number	Reported Term for the Clinical Event	Clinical Event Pre-specified	Clinical Event Occurrence	Completion Status	Duration of Clinical Event	Evaluation Interval Text
STUDYID	DOMAIN	USUBJID	CESEQ	CETERM	CEPRESP	CEOCCUR	CESTAT	CEDUR	CEEVINTX
BIOS01	CE	CDASH-01-001	1	HEADACHE	Y	Y		PT1H30M	TODAY

Variable Fragments from the CT & Model

CDISC Submission Value	CDISC Synonym(s)	CDISC Definition	NCI Preferred Term
UNIT	Unit	Terminology codelist used for units within CDISC.	CDISC SDTM Unit of Measure Terminology
HOURS	Hours; h; hr	A unit of measurement of time equal to 60 minutes.	Hour
min	Minute	A unit of measurement of time equal to 60 seconds.	Minute

Observation Class	Domain	Order Number	CDASH Variable	CDASH Variable Label	DRAFT CDASH Definition	Question Text	Prompt
Timing	N/A	20	–STTIM	Observation Start Time	Start time of an observation.	What [is/was] the ([intended/planned/actual]) ([event/intervention]) ([MHEVDTYP]/start/admission) time?	([Intended/Planned/Actual]) ([MHEVDTYP]/Start/Admission) Time
Timing	N/A	21	–STHR	Observation Start Hour	Start hour of an observation.	What [is/was] the ([intended/planned/actual]) ([event/intervention]) ([MHEVDTYP]/start/admission) hour?	([Intended/Planned/Actual]) ([MHEVDTYP]/Start/Admission) Hour
Timing	N/A	22	–STMI	Observation Start Minute	Start minute of an observation.	What [is/was] the ([intended/planned/actual]) ([event/intervention]) ([MHEVDTYP]/start/admission) minute?	([Intended/Planned/Actual]) ([MHEVDTYP]/Start/Admission) Minute
Timing	N/A	23	–STSS	Observation Start Second	Start second of an observation.	What [is/was] the ([intended/planned/actual]) ([event/intervention]) ([MHEVDTYP]/start/admission) second?	([Intended/Planned/Actual]) ([MHEVDTYP]/Start/Admission) Second



- Having an evaluation or governance process in place to support decision making.
- Documenting and rolling out any decisions.
- Making decisions quickly, if necessary, to support FPFV eCRF release

CDASH Supports Data Collection

- CDASH (Clinical Data Acquisition Standards Harmonization) is the CDISC standard for collecting clinical data.
- It provides a standard set of variables and fields for creating CRFs (Case Report Forms) and a model to create new standard CRF variables and fields.
- CDASH variables map to SDTM by design.
- If CDASH is used by an organization it's CRFs become more consistent. It becomes easier for investigators and site staff to understand and enter data on the standard CDASH CRFs. This can contribute to improved data quality and timeliness.
- It easier for teams (internal/external) to develop and review CDASH CRFs.
- If CDASH is used across the entire clinical research community, sites will be entering data in CRFs designed to the same field format, layout and best practices. Reducing the variability between different organizations' CRFs.

Thank you!

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CDASHIG 2.2

Model 1.2

CDASH SAE Supplement v2.0

Any Questions?

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CDASHIG 2.2

Model 1.2

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