

LPO Webinar Series: CDASH Conformance

Session 2

CDASH Conformance Rules for Naming EDC Variables

CDASH Conformance Rules Webinar Series

- CDASH Conformance Rules describe how to “conform” to the CDASH standard in such a way that the “harmonization” with SDTM is maintained
- This Webinar Series will cover each conformance rule, with examples of which rules are “built in” to the NCI GLIB ALS and how they have been addressed

5 CONFORMANCE TO THE CDASH STANDARD

5.1 Conformance Rules

Session	Topic Covered
1	Introduction to how CDASH is harmonized with SDTM at the Model and IG level
2	Conformance Rule: Use Variable Naming Conventions that make it easy to create SDTM datasets
3	Conformance Rule: Use the required SDTM controlled terminology to collect data
4	Conformance Rule: Use the published Question Text or Prompt to ask the questions on the CRF
5	Conformance Rule: Follow the Core Designations Conformance Rule: Follow CDASH Best Practices

Review: Purpose of CDASH

Standardized Case Report
Forms that meet FDA preference

- To **implement SDTM prior to data collection** (reference FDA Technical Conformance Guide) for traceability
- CDASH is *Harmonized with SDTM and SDTMIG*

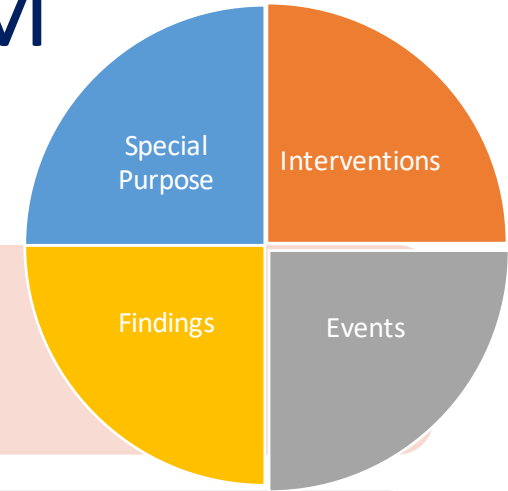
More efficiency creating
submission datasets (tabulations
and analysis) and
documentation (TLFs in the CSR)

- AVOID legacy data conversion - very time consuming / costly / error-prone
- Achieve higher quality datasets, faster

Save time setting up new studies

- Most data collection can be standardized across all studies
- Associated programming (edit checks, data transfers/loads, derivations, ETL) can also be standardized

How CDASH is Harmonized with SDTM



Same overall structure

- general observation classes, special purpose domains

Covered in
Session 1

Same domain topics and
naming conventions (DM =
DM, AE=AE)

- However, CDASH does not put restrictions on how to organize questions
- Multiple domain questions can be on the same data collection form (DM, VS)
- Multiple data collection forms can all be about the same topic (VS at each visit)

Mostly the same variables

- Same meaning (definitions are important) ensured through QText/Prompt
- A few differences to meet data collection needs DAT/TIM vs DTC, Findings class with multiple TESTs)
- Additional variables (e.g., common non-standard concepts, edit checks)

Same terminology

Will be covered in Session 3

- Same meaning (definitions)
- Can display synonyms (user friendly) but should store the CDISC Submission Value to avoid transformations
- Use --TESTCD terminology to construct EDC variable names / --TEST for prompts

CDASH Variable Naming Conformance Rule

CDASHIG V2.0

Variable Names: The CDASHIG variable naming conventions should be used in the operational database, using a consistent syntax that includes the root variable name and/or controlled terminology, and any other standardized concepts that are needed to support efficient mapping of the collected value to SDTM datasets. The goals are to have beginning-to-end traceability of the variable name from the data capture system to the SDTM datasets, and to support automating electronic data capture (EDC) setup and downstream processes.

- a. It is recognized that particularly in an EDC system, the variable name of a data collection field, as well as the name in the underlying database, may have various "system" components that become part of the item's identifier. EDC systems, prior to exporting data in a defined format, may require the variable name to include such database "references" as the EDC page name, the item "group" name, or perhaps a combination.
 - b. In cases where the data collection is done in a denormalized way, appropriate CDISC controlled terminology must be used when it is available. For example, when collecting Vital Signs results in a denormalized eCRF, the variable names can be created by using terms from the Vital Signs Test Code codelist. For example, Temperature result can be collected in a variable called TEMP or TEMP_VSORRES, Systolic Blood Pressure result, can be collected in a variable called SYSBP or SYSBP_VSORRES. When a particular system's constraints limit the variable name to 8 characters, a similar, consistent implementation that preserves either the normalized root variable (e.g., ORRES) or the controlled terminology (e.g., --TESTCD value) should be implemented.
 - c. Whereas all CDASHIG defined variable names are 8 characters or less to accommodate SDTM limits on variable names, QNAMs, and --TESTCDs, the maximum length of a variable name that may be implemented is determined by the data management system used, not by CDASH.
6. **Data Values and Format:** Because an SDTM data programmer should be able to assume that data in an SDTMIG variable is SDTMIG compliant, the data output by the operational database into an SDTMIG variable ideally requires no additional processing. Minimal processing (e.g., changing case) is still conformant. This helps to ensure a quality deliverable, even if the SDTM data programmer is unfamiliar with data capture practices.

Draft CDASHIG V2.2

5. **CDASHIG variable naming conventions should be used in the operational database.** Use a consistent syntax that includes the root variable name and/or controlled terminology, and any other standardized concepts that are needed to support efficient mapping of the collected value to SDTM datasets. The goals are to have beginning-to-end traceability of the variable name from the data capture system to the SDTM datasets, and to support automating electronic data capture (EDC) set-up and downstream processes.
- a. It is recognized that (particularly in an EDC system) the variable name of a data collection field, as well as the name in the underlying database, may have various "system" components that become part of the item's identifier. EDC systems, prior to exporting data in a defined format, may require the variable name to include such database "references" as the EDC page name, the item "group" name, or perhaps a combination.
 - b. In cases where the data collection is done in a denormalized way, appropriate CDISC CT must be used when it is available.
 - i. For example, when collecting vital signs results in a denormalized eCRF, the variable names can be created by using terms from the Vital Signs Test Code codelist. For example, temperature result can be collected in a variable called TEMP or TEMP_VSORRES; systolic blood pressure result can be collected in a variable called SYSBP or SYSBP_VSORRES. When a particular system's constraints limit the variable name to 8 characters, a similar, consistent implementation that preserves either the normalized root variable (e.g., ORRES) or the controlled terminology (e.g., --TESTCD value) should be implemented.
 - ii. Other variable patterns that intentionally connect the data collection variable to the target SDTMIG variable are also acceptable. For example, targetDataset_targetVariable[optionalTopic] is acceptable. Examples of this pattern include DM_AGE, DM_AGEU, VS_VSORRES_TEMP, VS_VSORRESU_TEMP, SUPPAE_QVAL_AEDIS.
 - c. Whereas all CDASHIG defined variable names are 8 characters or fewer to accommodate SDTM limits on variable names, QNAMs, and --TESTCDs, the maximum length of a variable name that may be implemented is determined by the data management system used, not by CDASH.
 - d. When collecting data in a horizontal manner, to facilitate transformation to SDTM datasets, when possible it is recommended to create denormalized CDASH variables in the data collection system by incorporating the SDTMIG variable name target and/or the controlled terminology (e.g., --TESTCD) as part of the CDASH variable names. The domain-level metadata labeled as "Horizontal-Generic" in the Implementation Options column of the CDASHIG metadata tables are examples of how to implement this. There is no conformance requirement implied by these examples.
6. **Data output by the operational database into an SDTMIG variable should require no additional processing if the CDASHIG and SDTMIG variable names are the same.** An SDTM data programmer should be able to assume that data in an SDTMIG variable is SDTMIG-compliant. Minimal processing (e.g., changing case) does not effect conformance. This helps to ensure a quality deliverable, even if the programmer is unfamiliar with data capture practices.

CDASH Conformance Rules

CDASH Conformance Rule	Rationale	How This is Reflected in NCI GLIB ALS
<p>Use Variable Naming Conventions that</p> <ul style="list-style-type: none"> • Use <u>consistent</u> syntax • Use published variables (+ CT) • Provide clear traceability to SDTM • Support automation (i.e., creating SDTMs) 	<p>Foundational purpose of CDASH is to implement SDTM before we collect the data.</p> <p>CDASH also has to accommodate data entry needs (like splitting date and time into two fields) using standard collection variables</p>	<p>FieldOIDs are linked to SDTM</p> <ul style="list-style-type: none"> • Directly link the collected value to the associated SDTM dataset and variable • Standard syntax (pattern) allows us to write standard SDTM programs (near automation)
<p>Use the re... to collect</p>	<p>ng as the</p>	<p>DataDictionary and DataDictionaryEntries match required SDTM Controlled Terminology</p> <ul style="list-style-type: none"> • CodedData uses value required for submission data • UserDataString uses same or synonymous value
<p>Follow the Core Designations</p>	<p>Reflects the minimum set of questions needed to get a meaningful record</p>	<p>Requirements not indicated in ALS. Must reference CDASHIG for this information</p>
<p>Use the published Question Text or Prompt to ask the questions on the CRF</p>	<p>Ensure the question means the same thing as the target SDTM variable</p>	<p>PreText uses the flexible Question Text published in CDASHIG. Apply flexibility rules as needed</p>
<p>Follow CDASH Best Practices</p>	<p>Widely vetted clinical data management practices</p>	<p>Not indicated in ALS. Must reference CDASHIG for this information</p>

Related Rule #6- SDTM Programming should be able to expect that if a value is sent to them in a valid SDTM variable, then it should be the **right value for that variable i.e., the value should not require "transformation"**

CDASH and SDTM Variables

Domain	CDASHIG Variable	Question Text	Prompt	Data Type	CDASHIG Core	SDTMIG Target	Controlled Terminology Codelist Name
DM	BRTHDAT	What is the subject's date of birth?	Birth Date	Char	R/C	BRTHDTC	N/A
DM	SEX	What is the sex of the subject?	Sex	Char	R/C	SEX	(SEX)
DM	ETHNIC	Do you consider yourself Hispanic/Latino or not Hispanic/Latino?	Ethnicity	Char	O	ETHNIC	(ETHNIC)
DM	RACE	Which of the following five racial designations best describes you? (More than one choice is acceptable.)				RACE	(RACE)

Many CDASH variables exactly match the SDTM variable because the values they collect can directly populate the SDTM variable without any transformation.

Other variables collect values that must be "transformed" before they can populate the SDTM variable, so they have a different - but **standard** -variable name.
 E.g., Use --DAT and --TIM variables to collect dates and times. These will be transformed to --DTC variables in SDTM (ISO 8601)

CDASH Conformance Rule

Use Standardized Variable Names *that will help you get to SDTM datasets efficiently and with traceability*

Standardizing variable names supports efficient programming processes and reusability (e.g., edit check programs)

Standardizing variable naming **patterns** supports near-automation of transforming to SDTM data

Published as FieldOIDs in the NCI GLIB ALS and the NCI Standard Forms ALS use this pattern (chosen by the LPOs/ Implementation Committee):

Normalized version:

targetDataset_targetVariable

Denormalized version:

targetDataset_targetVariable_(predefinedValue)
(e.g., --TESTCD, QNAM, --TRT, --TERM)

Version 2.012: SAS Matrix
Form: Demography **Demographics (DM)**
Generated On: 11 Feb 2020 22:42:29

FORM_OID PID3302204_V1_0

Target Dataset:
e.g., DM, AE, SUPPAE

==

Target Variable:
e.g., ETHNIC, AETERM, QVAL

Patient Initials (LFM)

Patient's Date of Birth **DM_BRTHDAT**

Ethnicity **DM_ETHNIC**

Hispanic or Latino
Not Hispanic or Latino
Not Reported
Unknown

Gender of a Person **DM_SEX**

Female Gender
Male Gender
Unknown

Deconstructing FieldOIDs into SDTM domains

Version 2.012: SAS Matrix

Form: Demography

Demographics (DM)

Generated On: 11 Feb 2020 22:42:29

targetDataset_targetVariable

DM_BRTHDAT

DM_ETHNIC

DM_SEX

dm.xpt

STUDYID	DOMAIN	USUBJID	SUBJID	RFSTDTM	RFENDTM	RFXSTDTM	RFXENDTM	RFICDTM	RFPENDTM	SITEID	INVTNAM	BRTHDTM	AGE	AGEU	SEX	RACE	ETHNIC	ARM
ABC123	DM	ABC12301001	01001	2006-01-12	2006-03-10	2006-01-12	2006-03-10	2006-01-03	2006-04-01	01	JOHNSON, M	1948-12-13	57	YEARS	M	WHITE	HISPANIC OR LATINO	A
ABC123	DM	ABC12301002	01002	2006-01-15	2006-02-28	2006-01-15	2006-02-28	2006-01-04	2006-03-26	01	JOHNSON, M	1955-03-22	50	YEARS	M	WHITE	NOT HISPANIC OR LATINO	P
ABC123	DM	ABC12301003	01003	2006-01-16	2006-03-19	2006-01-16	2006-03-19	2006-01-02	2006-03-19	01	JOHNSON, M	1938-01-19	68	YEARS	F	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	P
ABC123	DM	ABC12301004	01004					2006-01-07	2006-01-08	01	JOHNSON, M	1941-07-02			M	ASIAN	NOT HISPANIC OR LATINO	
ABC123	DM	ABC12302001	02001	2006-02-02	2006-03-31	2006-02-02	2006-03-31	2006-01-15	2006-04-12	02	GONZALEZ, E	1950-06-23	55	YEARS	F	AMERICAN INDIAN OR ALASKA NATIVE	NOT HISPANIC OR LATINO	P
ABC123	DM	ABC12302002	02002	2006-02-03	2006-04-05	2006-02-03	2006-04-05	2006-01-10	2006-04-25	02	GONZALEZ, E	1956-05-05	49	YEARS	F	NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDERS	NOT HISPANIC OR LATINO	A

Gender of a Person

- Female Gender
- Male Gender
- Unknown

Deconstructing FieldOIDs into SDTM domains

Version 2.012: SAS Matrix

Form: Demography

Demographics (DM)

Generated On: 11 Feb 2020 22:42:29

FORM_OID

targetDataset_targetVariable

Patient Initials (LFM)

Patient's Date of Birth

DM_BRTHDAT

Ethnicity

DM_ETHNIC

Gender of a Person

DM_SEX

Female Gender

Male Gender

Unknown

dm.xpt

STUDYID	DOMAIN	USUBJID	SUBJID	RFSTDTC	RFENDTC	RFXSTDTC	RFXENDTC	RFICDTC	RFPENDTC	SITEID	INVNAM	BRTHDTC	AGE	AGEU	SEX	RACE	ETHNIC	ARM
ABC123	DM	ABC12301001	01001	2006-01-12	2006-03-10	2006-01-12	2006-03-10	2006-01-03	2006-04-01	01	JOHNSON, M	1948-12-13	57	YEARS	M	WHITE	HISPANIC OR LATINO	A
ABC123	DM	ABC12301002	01002	2006-01-15	2006-02-28	2006-01-15	2006-02-28	2006-01-04	2006-03-26	01	JOHNSON, M	1955-03-22	50	YEARS	M	WHITE	NOT HISPANIC OR LATINO	P
ABC123	DM	ABC12301003	01003	2006-01-16	2006-03-19	2006-01-16	2006-03-19	2006-01-02	2006-03-19	01	JOHNSON, M	1938-01-19	68	YEARS	F	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	P
ABC123	DM	ABC12301004	01004					2006-01-07	2006-01-08	01	JOHNSON, M	1941-07-02			M	ASIAN	NOT HISPANIC OR LATINO	
ABC123	DM	ABC12302001	02001	2006-02-02	2006-03-31	2006-02-02	2006-03-31	2006-01-15	2006-04-12	02	GONZALEZ, E	1950-06-23	55	YEARS	F	AMERICAN INDIAN OR ALASKA NATIVE	NOT HISPANIC OR LATINO	P
ABC123	DM	ABC12302002	02002	2006-02-03	2006-04-05	2006-02-03	2006-04-05	2006-01-10	2006-04-25	02	GONZALEZ, E	1956-05-05	49	YEARS	F	NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDERS	NOT HISPANIC OR LATINO	A

Deconstructing FieldOIDs into SDTM domains

Version 2.012: SAS Matrix

Form: Demography

Demographics (DM)

Generated On: 11 Feb 2020 22:42:29

FORM_OID

targetDataset_targetVariable

Patient Initials (LFM)

Patient's Date of Birth

DM_BRTHDAT

Ethnicity

DM_ETHNIC

Gender of a Person

DM_SEX

Female Gender

Male Gender

Unknown

dm.xpt

STUDYID	DOMAIN	USUBJID	SUBJID	RFSTDTC	RFENDTC	RFXSTDTC	RFXENDTC	RFICDTC	RFPENDTC	SITEID	INVNAM	BRTHDTC	AGE	AGEU	SEX	RACE	ETHNIC	ARM
ABC123	DM	ABC12301001	01001	2006-01-12	2006-03-10	2006-01-12	2006-03-10	2006-01-03	2006-04-01	01	JOHNSON, M	1948-12-13	57	YEARS	M	WHITE	HISPANIC OR LATINO	A
ABC123	DM	ABC12301002	01002	2006-01-15	2006-02-28	2006-01-15	2006-02-28	2006-01-04	2006-03-26	01	JOHNSON, M	1955-03-22	50	YEARS	M	WHITE	NOT HISPANIC OR LATINO	P
ABC123	DM	ABC12301003	01003	2006-01-16	2006-03-19	2006-01-16	2006-03-19	2006-01-02	2006-03-27	01	JOHNSON, M	1938-01-19	68	YEARS	F	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	P
ABC123	DM	ABC12301004	01004					2006-01-07	2006-01-08	01	JOHNSON, M	1941-07-02			M	ASIAN	NOT HISPANIC OR LATINO	
ABC123	DM	ABC12302001	02001	2006-02-02	2006-03-31	2006-02-02	2006-03-31	2006-01-15	2006-04-12	02	GONZALEZ, E	1950-06-23	55	YEARS	F	AMERICAN INDIAN OR ALASKA NATIVE	NOT HISPANIC OR LATINO	P
ABC123	DM	ABC12302002	02002	2006-02-03	2006-04-05	2006-02-03	2006-04-05	2006-01-10	2006-04-25	02	GONZALEZ, E	1956-05-05	49	YEARS	F	NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDERS	NOT HISPANIC OR LATINO	A

Deconstructing FieldOIDs into SDTM domains

Version 2.012: SAS Matrix
 Form: Demography **Demographics (DM)**
 Generated On: 11 Feb 2020 22:42:29

FORM_OID

targetDataset_targetVariable

Patient Initials (LFM)

Patient's Date of Birth

DM_BRTHDAT

Ethnicity

DM_ETHNIC

Gender of a Person

DM_SEX

Female Gender
 Male Gender
 Unknown

dm.xpt

STUDYID	DOMAIN	USUBJID	SUBJID	RFSTDTC	RFENDTC	RFXSTDTC	RFXENDTC	RFICDTC	RFPENDTC	SITEID	INVNAM	BRTHDTC	AGE	AGEU	SEX	RACE	ETHNIC	ARM
ABC123	DM	ABC12301001	01001	2006-01-12	2006-03-10	2006-01-12	2006-03-10	2006-01-03	2006-04-01	01	JOHNSON, M	1948-12-13	57	YEARS	M	WHITE	HISPANIC OR LATINO	A
ABC123	DM	ABC12301002	01002	2006-01-15	2006-02-28	2006-01-15	2006-02-28	2006-01-04	2006-03-26	01	JOHNSON, M	1955-03-22	50	YEARS	M	WHITE	NOT HISPANIC OR LATINO	P
ABC123	DM	ABC12301003	01003	2006-01-16	2006-03-19	2006-01-16	2006-03-19			2							NOT HISPANIC OR LATINO	P
ABC123	DM	ABC12301004	01004														NOT HISPANIC OR LATINO	P
ABC123	DM	ABC12302001	02001	2006-02-02	2006-03-31	2006-02-02	2006-03-31			2							NOT HISPANIC OR LATINO	P
ABC123	DM	ABC12302002	02002	2006-02-03	2006-04-05	2006-02-03	2006-04-05	2006-01-10	2006-04-25	02	GONZALEZ, E	1956-05-05	49	YEARS	F	NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDERS	NOT HISPANIC OR LATINO	A

CDASH --DAT variables are concatenated with CDASH --TIM variables (if any) and re-formatted as ISO 8601 YYYY-MM-DDTHH:MM:SS to populate the target SDTM --DTC variable

Conformant Variables can be Normalized or De-Normalized

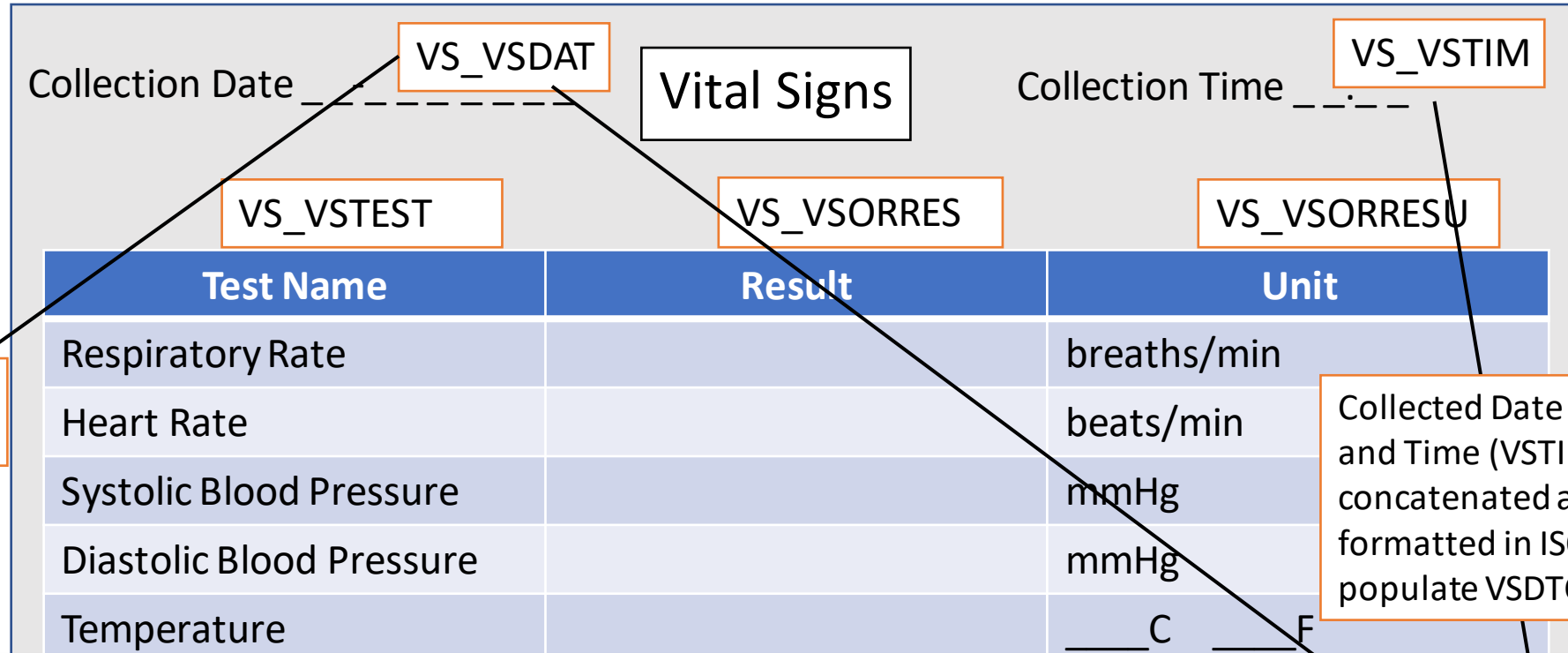
Constructing **FINDINGS Class** Data Collection Fields and (**NORMALIZED**) variables using CDASHIG and Controlled Terminology Normalized Variables (VS_VSTEST, VS_VSORRES, VS_VSORRESU) are used to create repeating log forms.

Use pattern: targetDataset_targetVariable

to create CDASH Conformant variables (e.g., VS_VSDAT, VS_VSTIM, VS_VSTEST, VS_VSORRES, VS_VSORRESU)

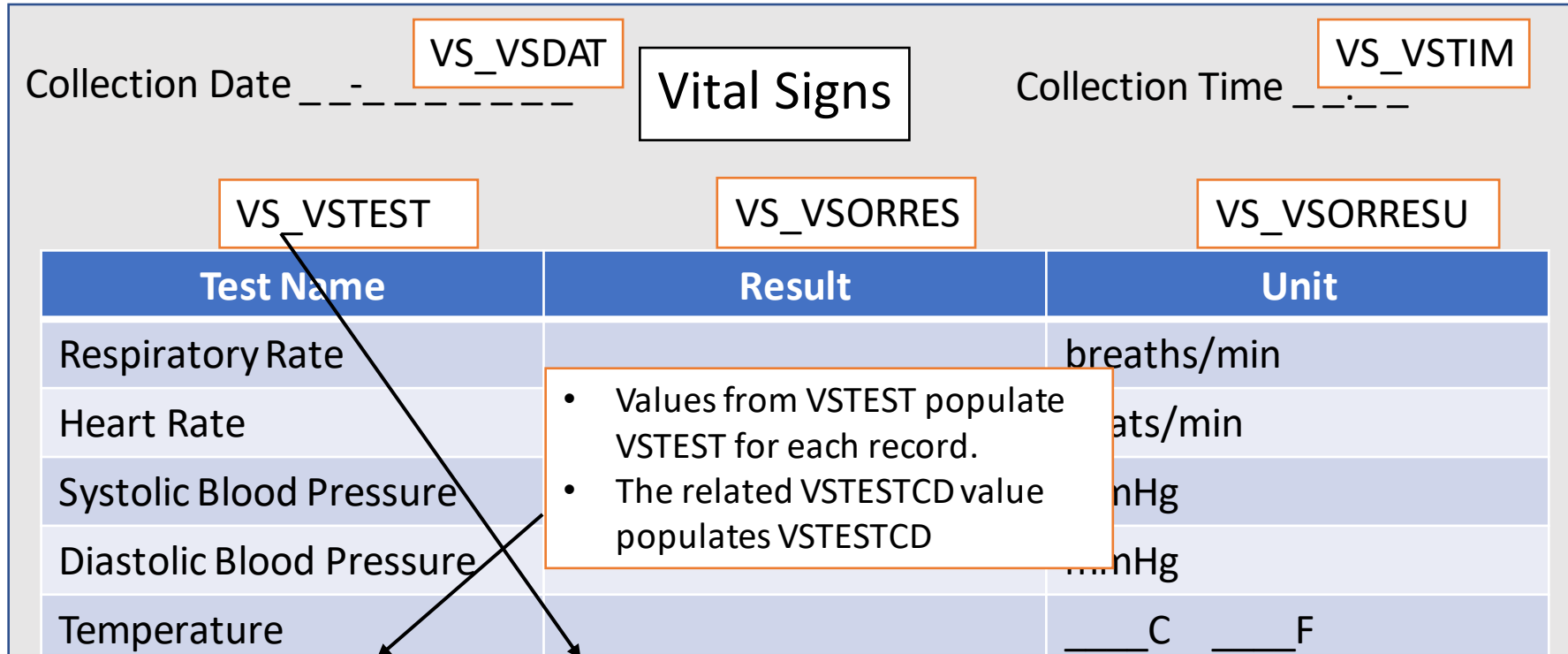
Collection Date ____-____-____	VS_VSDAT	Vital Signs	Collection Time ____:____	VS_VSTIM
VS_VSTEST	VS_VSORRES		VS_VSORRESU	
Test Name	Result	Unit		
Respiratory Rate		breaths/min		
Heart Rate		beats/min		
Systolic Blood Pressure		mmHg		
Diastolic Blood Pressure		mmHg		
Temperature		____C ____F		
BMI				

Mapping CDASHIG **normalized** data to SDTMIG domains



STUDYID	DOMAIN	USUBJID	VSSEQ	VSTESTCD	VSTEST	VSORRES	VSORRESU	VSDTC
ABC	VS	ABC-001-001	1	SYSBP	Systolic Blood Pressure	154	mmHg	2018-06-19T08:45
ABC	VS	ABC-001-001	2	DIABP	Diastolic Blood Pressure	44	mmHg	2018-06-19T08:45
ABC	VS	ABC-001-001	3	HR	Heart Rate	72	beats/min	2018-06-19
ABC	VS	ABC-001-001	4	TEMP	Temperature	34.7	C	2018-06-19T08:45
ABC	VS	ABC-001-001	5	RESP	Respiratory Rate	16	breaths/min	2018-06-19T09:00
ABC	VS	ABC-001-001	6	BMI	Body Mass Index	28		2018-06-19

Mapping CDASHIG **normalized** data to SDTMIG domains



vs.xpt

STUDYID	DOMAIN	USUBJID	VSSEQ	VSTESTCD	VSTEST	VSORRES	VSORRESU	VSDAT
ABC	VS	ABC-001-001	1	SYSBP	Systolic Blood Pressure	154	mmHg	2018-06-19T08:45
ABC	VS	ABC-001-001	2	DIABP	Diastolic Blood Pressure	44	mmHg	2018-06-19T08:45
ABC	VS	ABC-001-001	3	HR	Heart Rate	72	beats/min	2018-06-19
ABC	VS	ABC-001-001	4	TEMP	Temperature	34.7	C	2018-06-19T08:45
ABC	VS	ABC-001-001	5	RESP	Respiratory Rate	16	breaths/min	2018-06-19T09:00
ABC	VS	ABC-001-001	6	BMI	Body Mass Index	28		2018-06-19

Mapping CDASHIG **normalized** data to SDTMIG domains

Collection Date ____-____-____ **VS_VSDAT** **Vital Signs** Collection Time ____:____:____ **VS_VSTIM**

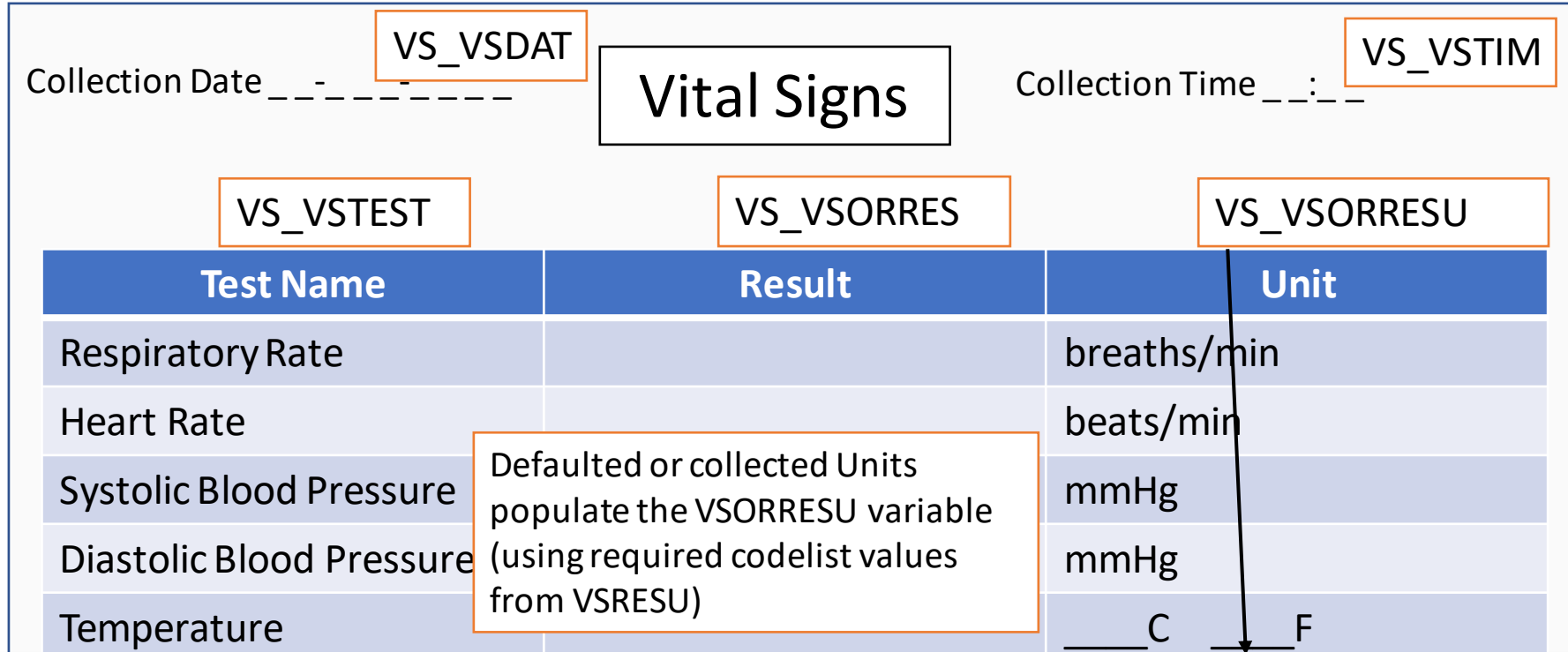
VS_VSTEST	VS_VSORRES	VS_VSORRESU
Test Name	Result	Unit
Respiratory Rate	16	
Heart Rate	72	
Systolic Blood Pressure	154	mmHg
Diastolic Blood Pressure	44	mmHg
Temperature	34.7	<u> </u> X <u> </u> C <u> </u> F

The collected (original) result populates VSORRES

vs.xpt

STUDYID	DOMAIN	USUBJID	VSSEQ	VSTESTCD	VSTEST	VSORRES	VSORRESU	VSDAT
ABC	VS	ABC-001-001	1	SYSBP	Systolic Blood Pressure	154	mmHg	2018-06-19T08:45
ABC	VS	ABC-001-001	2	DIABP	Diastolic Blood Pressure	44	mmHg	2018-06-19T08:45
ABC	VS	ABC-001-001	3	HR	Heart Rate	72	beats/min	2018-06-19
ABC	VS	ABC-001-001	4	TEMP	Temperature	34.7	C	2018-06-19T08:45
ABC	VS	ABC-001-001	5	RESP	Respiratory Rate	16	breaths/min	2018-06-19T09:00

Mapping CDASHIG **normalized** data to SDTMIG domains



vs.xpt

STUDYID	DOMAIN	USUBJID	VSSEQ	VSTESTCD	VSTEST	VSORRES	VSORRESU	VSDAT
ABC	VS	ABC-001-001	1	SYSBP	Systolic Blood Pressure	154	mmHg	2018-06-19T08:45
ABC	VS	ABC-001-001	2	DIABP	Diastolic Blood Pressure	44	mmHg	2018-06-19T08:45
ABC	VS	ABC-001-001	3	HR	Heart Rate	72	beats/min	2018-06-19
ABC	VS	ABC-001-001	4	TEMP	Temperature	34.7	C	2018-06-19T08:45
ABC	VS	ABC-001-001	5	RESP	Respiratory Rate	16	breaths/min	2018-06-19T09:00
ABC	VS	ABC-001-001	6	BMI	Body Mass Index	28		2018-06-19

Conformance Variables can be Normalized or De-normalized

Constructing **Findings Class** Data Collection Fields and (**denormalized**) variables using CDASHIG and Controlled Terminology
Use when you DO NOT want to use a log form to collect Findings Class data

FIND the Questions you need

Create the denormalized variable name

DDTEST codelist is required in the CDASHIG Domain for the DDTEST variable

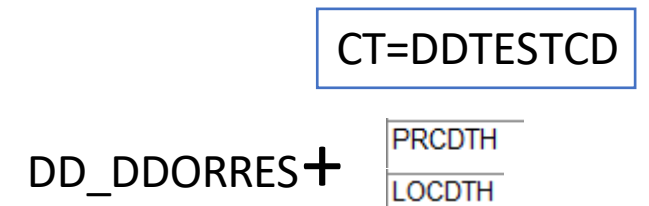
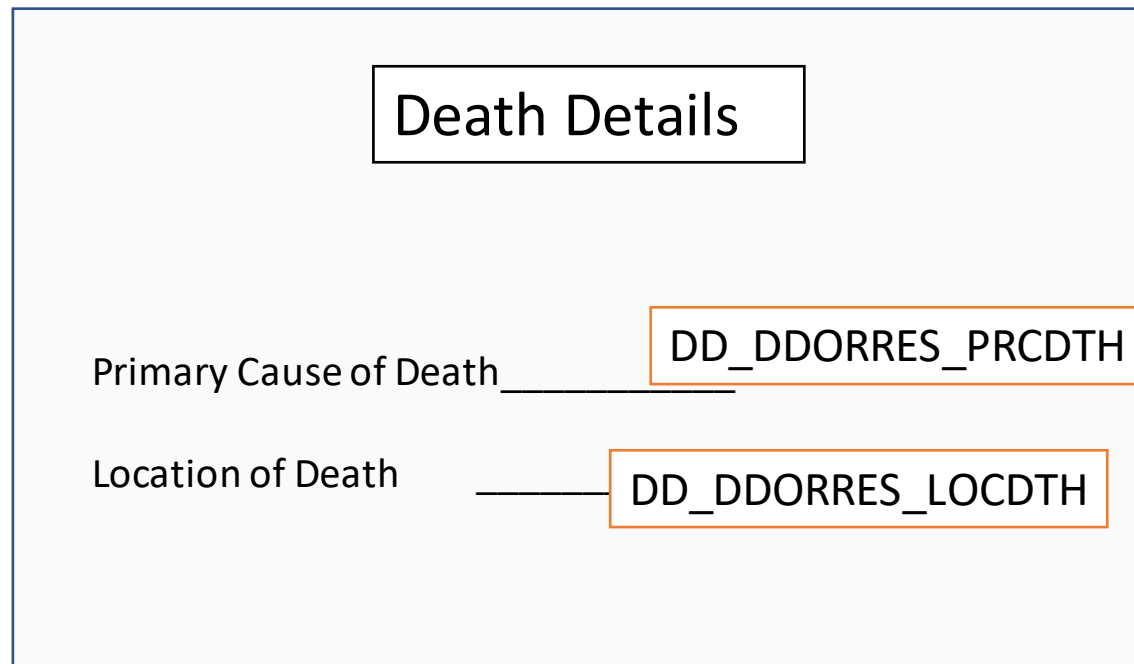
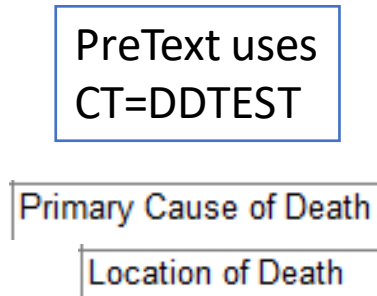
=

Use the DDTEST terminology to create a conformant Prompt

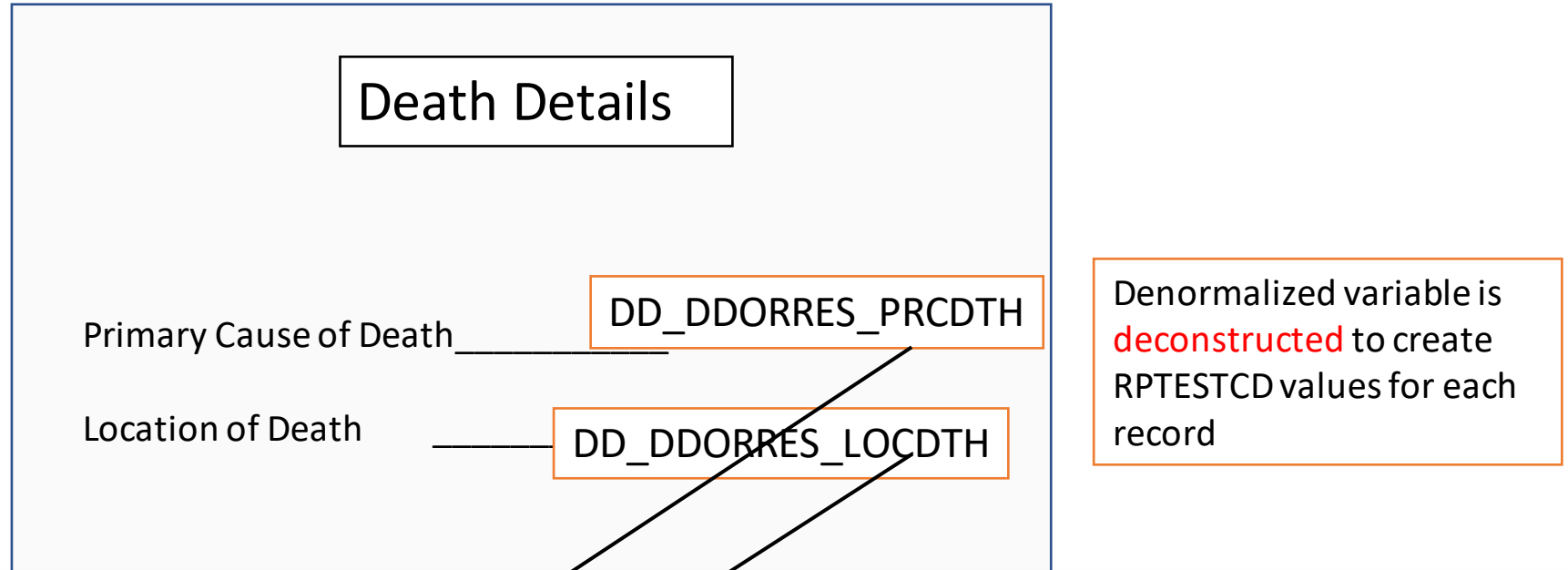
CDASH variable (e.g., DD_DDORRES)

+

Values from the DDTESTCD codelist

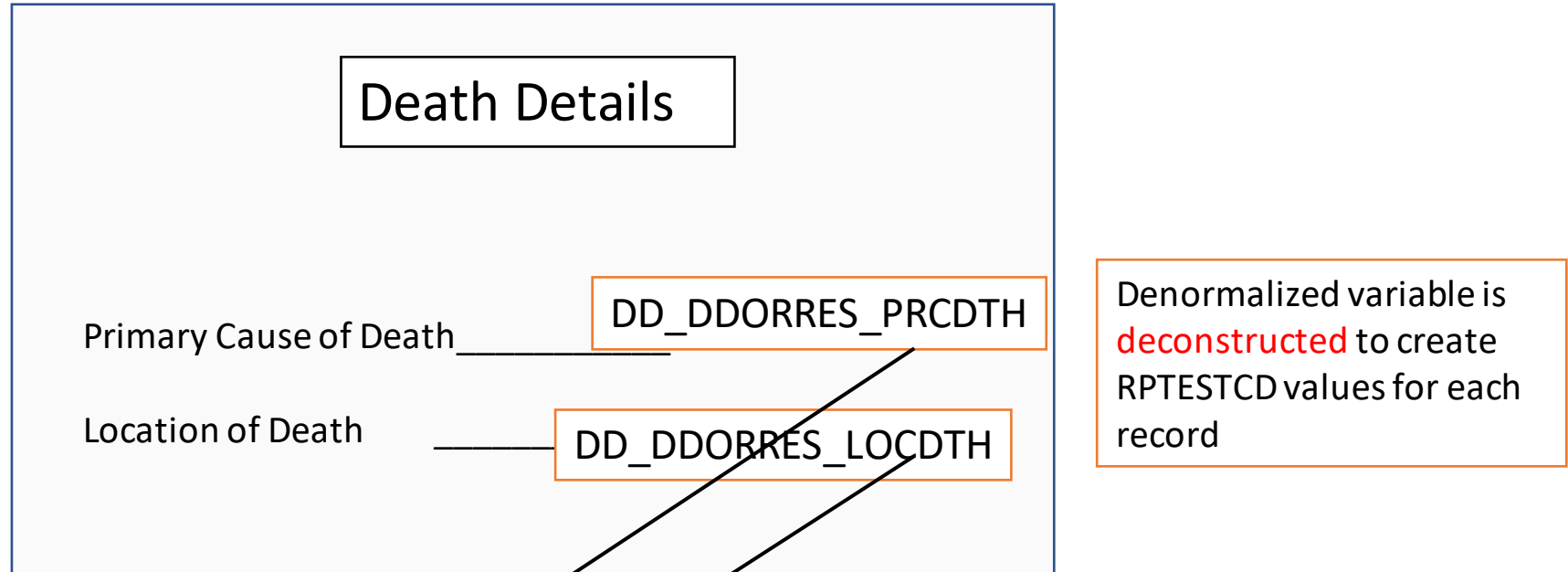


Mapping CDASHIG **de-normalized** data to SDTMIG domains



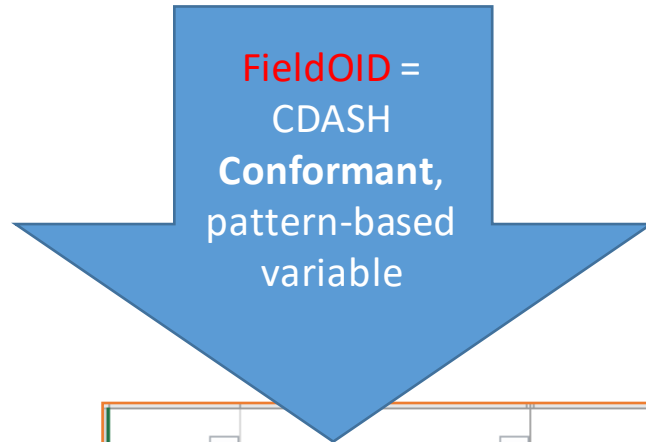
STUDYID	DOMAIN	USUBJID	DDSEQ	DDTESTCD	DDTEST	DDORRES
ABC	DD	ABC-001-001	1	PRCDTH	Primary Cause of Death	HEART FAILURE
ABC	DD	ABC-001-001	2	LOCDTH	Location of Death	ICU
ABC	DD	ABC-001-003	1	PRCDTH	Primary Cause of Death	METASTATIC LIVER CANCER
ABC	DD	ABC-001-003	2	LOCDTH	Location of Death	HOME HOSPICE

Mapping CDASHIG **de-normalized** data to SDTMIG domains



STUDYID	DOMAIN	USUBJID	DDSEQ	DDTESTCD	DDTEST	DDORRES
ABC	DD	ABC-001-001	1	PRCDTH	Primary Cause of Death	HEART FAILURE
ABC	DD	ABC-001-001	2	LOCDTH	Location of Death	ICU
ABC	DD	ABC-001-003	1	PRCDTH	Primary Cause of Death	METASTATIC LIVER CANCER
ABC	DD	ABC-001-003	2	LOCDTH	Location of Death	HOME HOSPICE

CDASH-Conformant normalized variables in the NCI GLIB ALS



targetDataset_targetVariable

FormOID	FieldOID	DataDictionaryName	PreText
CM	CM_CMYN	CDISC_SDTM_YES_PID6343337_V1_0F	Were any (concomitant) [medication(s)/treatment(s)/therap(ies)] taken?
CM	CM_CMSPID		[Line Number/CM Number]
CM	CM_CMTRT		What was the (concomitant) [medication/treatment/therapy] (name/term)?
CM	CM_CMOCCUR	CDISC_SDTM_YES_PID6343337_V1_0F	Did the subject take [pre-specified (concomitant) medication/treatment/therapy/dose]?; Has the subject taken [pre-specified (concomitant) medication/treatment/therapy/dose]?
CM	CM_CMINGRD		What were the active ingredients?
CM	CM_CMINDC		For what indication, was the (concomitant) [medication/treatment/therapy] taken?

CDASH-Conformant variables in the NCI GLIB ALS

targetDataset_targetVariable_[--TESTCD]

FormOID	FieldOID	VariableOID	DataDictionaryName	PreText
VS	VS_VSORRES_DIABP	VS_VSORRES_DIABP		What was the result of the diastolic blood pressure measurement?
VS	VS_VSORRESU_DIABP	VS_VSORRESU_DIABP	CDISC_SDTCM_UNIT_PID6401717_V1_0F	What was the unit of the diastolic blood pressure measurement?
VS	VS_VSORRES_HR	VS_VSORRES_HR		What was the result of the heart rate measurement?
VS	VS_VSORRESU_HR	VS_VSORRESU_HR	CDISC_SDTCM_UNIT_PID6401717_V1_0F	What was the unit of the heart rate measurement?
VS	VS_VSORRES_RESP	VS_VSORRES_RESP		What was the result of the respiratory rate measurement?
VS	VS_VSORRESU_RESP	VS_VSORRESU_RESP	CDISC_SDTCM_UNIT_PID6401717_V1_0F	What was the unit of the respiratory rate measurement?
VS	VS_VSORRES_SYSBP	VS_VSORRES_SYSBP		What was the result of the systolic blood pressure measurement?
VS	VS_VSORRESU_SYSBP	VS_VSORRESU_SYSBP	CDISC_SDTCM_UNIT_PID6401717_V1_0F	What was the unit of the systolic blood pressure measurement?
VS	VS_VSORRES_TEMP	VS_VSORRES_TEMP		What was the result of the temperature measurement?
VS	VS_VSORRESU_TEMP	VS_VSORRESU_TEMP	CDISC_SDTCM_UNIT_PID6401717_V1_0F	What was the unit of the temperature measurement?

Values collected in these fields will map into the SDTM:
 Target dataset (e.g., VS), populating the Target Variable (e.g., VSORRES, VSORRESU) where the VSTESTCD is [VSTESTCD] (e.g., DIABP, SYSBP, HR, RESP, TEMP)

CDASH-Conformant variables in the NCI Standard Forms ALS

targetDataset_targetVariable_[QNAM]

FormOID	FieldOID	PreText
CTSU_STEP_INFORMATION	SUPPDM_QVAL_TRTINV	Treating Investigator
CTSU_STEP_INFORMATION	SUPPDM_QVAL_REGNAM	Site Registrar
CTSU_STEP_INFORMATION	SUPPDM_QVAL_CGRPNAM	Crediting Group
CTSU_PATIENT_INFORMATION	SUPPMH_QVAL_MHDSXCD	Disease Code
CTSU_PATIENT_INFORMATION	SUPPMH_QVAL_MHDSX	Disease Name
CTSU_RAND	SUPPMH_QVAL_MHDSXCD	Disease Code
CTSU_RANDBLINDED	SUPPMH_QVAL_MHDSXCD	Disease Code
CTSU_AE	SUPPAE_QVAL_CYCLNUM	* Course/Cycle #
CTSU_AE	SUPPAE_QVAL_CYCENDAT	Reporting period end date * Start date of <u>this course/cycle</u>
CTSU_AE	SUPPAE_QVAL_CYCSTDAT	* Start date of <u>first course/cycle</u>
CTSU_AE	SUPPAE_QVAL_FCYSTDAT	* Adverse event term (CTCAE v5.0)

Values collected in these fields will map into the SDTM: Target dataset (e.g., SUPPDM), populating the Target Variable (QVAL) where the QNAM is [QNAM] (e.g., TRTINV, REGNAM)

Session 2 Summary

- CDASH Conformance Rule covered in this session is to use EDC variables that
 - Use CDASH or SDTM variable names plus associated controlled terminology
 - Have a **consistent syntax** / pattern (NCI implementation uses: `targetDataset_targetVariable[_predefinedValue]`)
 - Make it easy to transform the collected data to the required SDTM variables
- CDASH Variables are harmonized with SDTM variables
 - Same **meaning** of collected data (definitions are important) ensured through QText/Prompt
 - A few CDASH variables are different to meet data collection needs (e.g., DAT/TIM vs DTC, denormalized Findings class variables for individual tests)
 - Additional CDASH variables (e.g., common non-standard concepts, edit checks)
- NCI GLIB ALS FieldOIDs conform to this CDASH rule

Q&A