Microsoft

CDISC360

Art of the Possible Initial Concepts

San Diego Interchange

Welcome to the Clinical Study Definition System

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What is CDISC 360?

CDISC 360 is an ambitious new project geared toward innovating clinical data standards to ensure they remain valuable and relevant into the future. CDISC 360 aims to support standards-based, metadata-driven automation across the end-to-end clinical research data lifecycle and represents a significant next step toward realizing an increased return on investment in standards implementation that our stakeholders expect – substantially improved efficiency, consistency, and re-usability.

We are inviting your organization to join us in this important project by getting involved. CDISC values the input and collaboration of our members; we want to ensure your needs and expectations are taken into account so that the project achieves results that are supported and endorsed by our community.

CDISC 360 seeks to implement standards as linked metadata with a conceptual foundation providing the additional semantics needed to support metadata driven-automation across the end-to-end clinical research data lifecycle.

The Opportunity

The CDISC foundational standards define research data and metadata structures, but writing these standards as documents has yielded more text than metadata. Gaps in standards metadata limit automation opportunities. The inherent flexibility provided by the standards supports a broad range of implementations, but that flexibility also allows for inconsistencies that make scaling automation difficult. The lack of a conceptual foundation for the standards further contributes to these inconsistencies. The relationships that would be expressed by these concepts remain largely implicit in the current versions of the standards.

CDISC 360 seeks to implement standards as linked metadata with a conceptual foundation providing the additional semantics needed to support metadata driven-automation across the end-to-end clinical research data lifecycle. New software tools will consume this new metadata to ease standards implementations while increasing data processing efficiencies.

CDISC 360 will demonstrate the feasibility of standards-based metadata-driven automation as a start towards realizing the primary benefits expected of the CDISC standards: substantially improved efficiency, consistency, and re-usability across the clinical research

Objectives

CDISC 360 will develop proof-of-concept enhancements to the CDISC standards metadata as well as related proof-of-concept software to confirm that the enhanced standards can be used to automate preparation of study specification metadata and end-to-end study data processing.

The focal point of this project is concept-based modeling. CDISC will not deliver software to industry as an outcome of CDISC 360. However, during the project, an enhanced set of API prototypes will be developed to demonstrate that the concept-based metadata can be accessed in order to implement metadata-driven automation.

Scope

CDISC 360 will implement end-to-end standards-based metadata-driven automated processing by conducting three use cases, demonstrated by implementing portions of the CDISC Type 1 Diabetes TAUG.

Metadata / Data Processing Use Cases

Use Case 1: Create end-to-start specification – Demonstrate the ability to produce a standards-based, machine-readable specification for the data and analysis artifacts to be created in the study.

Use Case 2: Generate start-to-end metadata - Demonstrate the ability to generate study-specific artifacts given the standards specification from Use Case 1.

Use Case 3: Transform data start-to-end - Demonstrate the ability to process data and execute data transformations given the study specification from Use Case 2.

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laurasantos@mdemail.com

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Laura Santos
Welcome to CDISC360

Create a new study definition

360 Participation Continues to Grow

Participation has grown through the summer. Currently, 67 individuals from 29 member companies are contributing actively to the project, across six workstreams. With this large number of participants working remotely across the globe, effective online collaboration tools are key to project success. As previously reported, project participant Microsoft, is providing its Azure product as a cloud collaboration platform. At this point, the platform instance has been configured and access has been provided to all project participants. A subset of participants is currently installing the software tools to build and run the scripts to execute the project use cases; these participants have already begun to build and run initial scripts!

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There will be many opportunities to learn about CDISC 360 at the 2019 US Interchange. The Project will be the focus of the second Opening Plenary and include presentations by CDISC Board Members Dave Evans and Chris Decker, CDISC VP, Data Science Dr. Sam Hume, and me. Sam's presentation will include a demo of the progress made on the 360 Project to date. Next, a breakout session titled "CDISC 360 Use Cases - Industry Perspectives" will include a presentation on each of the three 360 Project use cases, delivered by the individual workstream leads. Finally, a post-conference CDISC 360 workshop will be held on Friday 18 October.

360 Looking Ahead

Following the US Interchange, CDISC 360 will enter its second six-month phase with several agile sprints planned until the 2020 Europe Interchange in Berlin. The workstream teams expect to build upon their knowledge gained in the early sprints, identify reasonable targets for the second six-month phase, and work down their respective agile sprint backlogs defined for those targets, all toward a more mature development of standard concepts and of execution of the three use cases. A more feature-rich demo will be planned for the 2020 Europe Interchange. A CDISC 360 web page on the CDISC web site is also planned for this period. If you are an employee of a CDISC Member organization and interested in participating in CDISC 360, please send a message to info@cdisc.org.

1 Disease Category

2 Disease Area

3 Study Focus

4 Domains

5 Concepts

6 Data Collection

7 Confirmation

Select a disease area category

Therapeutic Area (TA) Standards extend the Foundational Standards to represent data that pertains to specific disease areas. TA Standards include disease-specific metadata, examples and guidance on implementing CDISC standards for a variety of uses, including global regulatory submission.

Autoimmune	Cardiovascular	Endocrine
Gastrointestinal	Infectious	Mental Health
Neurology	Oncology	Rare Diseases
Respiratory	Treatments	Other

Back

Continue

1 Disease Category
✓ Endocrine

2 Disease Area

3 Study Focus

4 Domains

5 Concepts

6 Data Collection

7 Confirmation

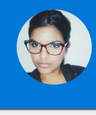
Select a disease area

Therapeutic Area (TA) Standards extend the Foundational Standards to represent data that pertains to specific disease areas. TA Standards include disease-specific metadata, examples and guidance on implementing CDISC standards for a variety of uses, including global regulatory submission.

- Acute Kidney Injury
- Diabetes - Type 1
- Diabetes - Type 2
- Diabetic Kidney Disease
- Dyslipidemia
- Kidney Transplant
- Polycystic Kidney Disease

Back

Continue



1 Disease Category
✓ Endocrine

2 Disease Area
✓ Diabetes - Type 2

3 Study Focus

4 Domains

5 Concepts

6 Data Collection

7 Confirmation

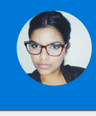
Select a study focus

Safety

Efficacy

Back

Continue



1 Disease Category
✓ Endocrine

2 Disease Area
✓ Diabetes - Type 2

3 Study Focus
✓ Safety

4 Domains

5 Concepts

6 Data Collection

7 Confirmation

Select from safety domains

Drug Accountability

A findings domain that contains the accountability of study drug, such as information on the receipt, dispensing, return, and packaging.

ECG Results

A findings domain that contains ECG data, including position of the subject, method of evaluation, all cycle measurements and all findings..

Exposure

An interventions domain that contains the details of a subject's exposure to protocol-specified study treatment. Study treatment may be any...

Inclusion/Exclusion

A findings domain that contains those criteria that cause the subject to be in violation of the inclusion/exclusion criteria.

LabTest Results

A findings domain that contains laboratory test data such as hematology, clinical chemistry and urinalysis. This domain does not include microbiology ...

Microscopic Findings

A findings domain that contains histopathology findings and microscopic evaluations.

Morphology

A findings domain relevant to the science of the form and structure of an organism or of its parts.

Physical Examination

A findings domain that contains findings observed during a physical examination where the body is evaluated by inspection, palpation, percussion, and...

Questionnaires

A findings domain that contains data for named, stand-alone instruments designed to provide an assessment of a concept. Questionnaires have a defined...

Subject Characteristics

A findings domain that contains subject-related data not collected in other domains.

Vital Signs

A findings domain that contains measurements including but not limited to blood pressure, temperature, respiration, body surface area, body mass index...

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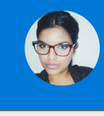
Continue



1 Disease Category
✓ Endocrine

2 Disease Area
✓ Diabetes - Type 2

3 Study Focus
✓ Safety

4 Domains
✓ Vital Signs

5 Concepts

6 Data Collection

7 Confirmation

Please select vital signs concepts

Height

The vertical measurement or distance from the base to the top of an object; the vertical dimension of extension.

Weight

The vertical force exerted by a mass as a result of gravity.

Heart rate

The number of heartbeats per unit of time, usually expressed as beats per minute.

Temperature

The property of a body or region of space that determines whether or not there will be a net flow of heat into it or out of it from a neighboring body or region and...

Blood Pressure

The pressure of the circulating blood against the walls of the blood vessels.

Respiratory Rate

The rate of breathing (inhalation and exhalation) measured within in a unit time, usually expressed as breaths per minute.

Oxygen Saturation

A measurement of the oxygen-hemoglobin saturation of a volume of blood.

Hip Circumference

The distance around an individual's pelvic area or hips.

Body Fat Measurement

A measurement of the total fat mass within the subject's body.

Body Frame Size

The categorization of a person's body frame into small, medium and large based on the measurement of wrist circumference or the breadth of the elbow.

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Continue

1 Disease Category
✓ Endocrine

2 Disease Area
✓ Diabetes - Type 2

3 Study Focus
✓ Safety

4 Domains
✓ Vital Signs

5 Concepts

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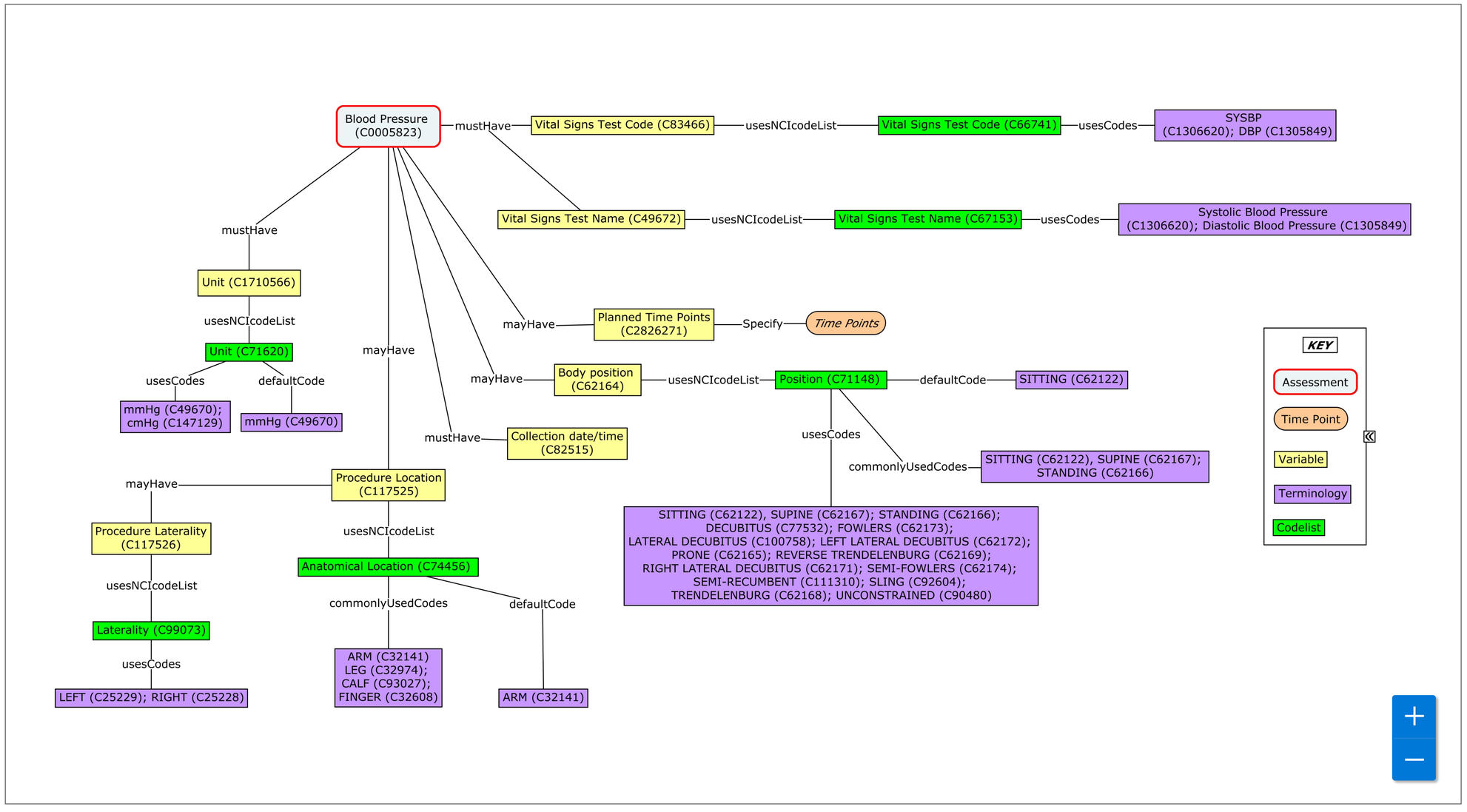
Blood Pressure

Concept Map



1 Disease Category
✓ Endocrine

2 Disease Area
✓ Diabetes - Type 2

3 Study Focus
✓ Safety

4 Domains
✓ Vital Signs

5 Concepts
✓ Height
✓ Weight
✓ Heart Rate
✓ Temperature
✓ Blood Pressure

6 Data Collection

7 Confirmation

Would you like to measure Blood Pressure and Heart Rate at multiple time points?

Yes

No

Back

Continue

1 Disease Category
✓ Endocrine

2 Disease Area
✓ Diabetes - Type 2

3 Study Focus
✓ Safety

4 Domains
✓ Vital Signs

5 Concepts
✓ Height
✓ Weight
✓ Heart Rate
✓ Temperature
✓ Blood Pressure

6 Data Collection

7 Confirmation

Would you like to measure Blood Pressure and Heart Rate at multiple time points?

Yes

No

Select time points

- [x] 5 minutes pre-dose
- [x] 30 minutes post-dose
- [ ] 1 hour post-dose
- [ ] 2 hour post-dose
- [ ] 4 hour post-dose
- [ ] 8 hour post-dose

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Continue

1 Disease Category
✓ Endocrine

2 Disease Area
✓ Diabetes - Type 2

3 Study Focus
✓ Safety

4 Domains
✓ Vital Signs

5 Concepts
✓ Height
✓ Weight
✓ Heart Rate
✓ Temperature
✓ Blood Pressure

6 Data Collection

7 Confirmation

Would you like to collect Vital Signs body position(s)?

Yes

No

Back

Continue

1 Disease Category
✓ Endocrine

2 Disease Area
✓ Diabetes - Type 2

3 Study Focus
✓ Safety

4 Domains
✓ Vital Signs

5 Concepts
✓ Height
✓ Weight
✓ Heart Rate
✓ Temperature
✓ Blood Pressure

6 Data Collection

7 Confirmation

Would you like to collect Vital Signs body position(s)?

Yes

No

Select body positions

- ○ Sitting
- ◉ Sitting, Standing, Supine

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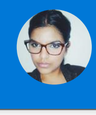
Continue



1 Disease Category
- ✓ Endocrine

2 Disease Area
- ✓ Diabetes - Type 2

3 Study Focus
- ✓ Safety

4 Domains
- ✓ Vital Signs

5 Concepts
- ✓ Height
- ✓ Weight
- ✓ Heart Rate
- ✓ Temperature
- ✓ Blood Pressure

6 Data Collection
- ✓ 5 minutes pre-dose
- ✓ 30 minutes post-dose

7 Confirmation

Let's recap your study definition selections and prepare to assign

Standard Disease Area

✓ Diabetes - Type 2 Edit

Study Focus

✓ Safety Edit

Domains

✓ Vital Signs Edit

Concepts

✓ Height Edit
✓ Weight Edit
✓ Heart Rate Edit
✓ Temperature Edit
✓ Blood Pressure Edit

Data Collection Options

✓ 5 minutes pre-dose Edit
✓ 30 minutes post-dose Edit

Back

Prepare

Diabetes - Type 2

1 Standard Disease Area
✓ Diabetes - Type 2

2 Study Type
✓ Safety

3 Domains
✓ Vital Signs

4 Concepts
✓ Blood Pressure

5 Data Collection Options
✓ Multiple BP time points
✓ Multiple BP body positions

6 Confirmation

Let's recap your study definition selections and prepare to assign

Standard Disease Area
✓ Diabetes - Type 2 Edit

Edit

Edit

Edit

Edit

Prepare

Study definition was prepared successfully

Study definition information

Study definition name

Height, weight, heart rate, temperature, and pre- and post-dose blood pressure measurements

Asssign Data Manager

Rebecca Kim

Cancel

Submit

Welcome to the Clinical Study Build System

Login

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Rebecca Kim
Welcome to CDISC360

View Study Definitions Dashboard

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Not started
STUDY DEFINITIONS

1

In progress
STUDY DEFINITIONS

2

Completed
STUDY DEFINITIONS

2

Study Definitions
BY CREATOR

Name	Standard Disease Area	Creator
Height, weight, heart rate, temperature, and pre- and post-dose blood pressure measurements	Diabetes - Type 2	Santos, Laura
Serum creatinine, change from baseline	Acute Kidney Injury	Garcia, Mary
Frequency Listing of Treatment Emergent Adverse Events	Acute Kidney Injury	Dominguez, Teri
Number of and Reasons for Early Discontinuations from Study	Dyslipidemia	Robinson, Linda
Demographics	Polycystic Kidney Disease	Santos, Laura

Height, weight, heart rate, temperature, and pre- and post-dose blood pressure measurements

Generate eCRF | Generate define.xml

Let's recap your study definition selections

Standard Disease Area

✓ Diabetes - Type 2 Edit

Study Focus

✓ Safety Edit

Domains

✓ Vital Signs Edit

Concepts

✓ Height Edit
✓ Weight Edit
✓ Heart Rate Edit
✓ Temperature Edit
✓ Blood Pressure Edit

Data Collection Options

✓ 5 minutes pre-dose Edit
✓ 30 minutes post-dose Edit

Which CDASH version is needed?

- ○ Version 1.1
- ◉ Version 2.0

Which Terminology version is needed?

- ○ 2019-09-03
- ◉ 2019-06-06
- ○ 2019-03-01
- ○ 2018-11-20

Which ODM version is needed?

- ○ Version 1.3.1
- ◉ Version 1.3.2

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Continue

ODM successfully created

Ok

Height, weight, heart rate, temperature, and pre- and post-dose blood pressure measurements

View eCRF

Generate define.xml

Let's recap your study definition selections

Standard Disease Area

✓ Diabetes - Type 2 Edit

Study Focus

✓ Safety Edit

Domains

✓ Vital Signs Edit

Concepts

✓ Height Edit
✓ Weight Edit
✓ Heart Rate Edit
✓ Temperature Edit
✓ Blood Pressure Edit

Data Collection Options

✓ 5 minutes pre-dose Edit
✓ 30 minutes post-dose Edit

Define.xml was successfully generated

Ok

Height, weight, heart rate, temperature, and pre- and post-dose blood pressure measurements

View eCRF | View define.xml

Let's recap your study definition selections

Standard Disease Area

✓ Diabetes - Type 2 Edit

Study Focus

✓ Safety Edit

Domains

✓ Vital Signs Edit

Concepts

✓ Height Edit
✓ Weight Edit
✓ Heart Rate Edit
✓ Temperature Edit
✓ Blood Pressure Edit

Data Collection Options

✓ 5 minutes pre-dose Edit
✓ 30 minutes post-dose Edit

cdisc Protocol CDISC 360	Site Number	Subject Number

Vital Signs (Timepoint)	
What was the date of the vital signs measurement? (DD-MMM-YYYY)	
What was the time of the vital signs measurement? (24 hour clock)	
Were vital signs performed?	[Y] Yes [N] No Reason Not Performed
What was the result of the weight measurement?	kg LB
What was the result of the height measurement?	cm in
What was the result of the temperature measurement?	C F

Vital Signs (Timepoint)

What is the planned time point for this vital signs measurement?	What was the position of the subject during the measurement?	What was the result of the systolic blood pressure measurement?	What was the result of the diastolic blood pressure measurement?	What was the result of the heart rate measurement?
5 min pre-dose	Sitting Standing Supine	mmHg inHg	mmHg inHg	beats/min
30 min post-dose	Sitting Standing Supine	mmHg inHg	mmHg inHg	beats/min

Define.xml

VS (Vital Signs) - [SDTMIG 3.2]

Variable	Where Condition	Label / Description	Type	Length or Display Format	Controlled Terms or ISO Format	Origin / Source / Method / Comment
STUDYID		Unique identifier for a study.	text	40		
DOMAIN		Two-character abbreviation for the domain.	text	2		
USUBJID		Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	text	40		
VSSEQ		Sequence Number given to ensure uniqueness of subject records within a domain. May be any valid number.	integer	4		
VSTESTCD		Short name of the measurement, test, or examination described in VSTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in VSTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g."1TEST"). VSTESTCD cannot contain characters other than letters, numbers, or underscores. Examples: SYSBP, DIABP, BMI.	text	8	Vital Signs Test Code [6 Terms]	
VSTEST		Verbatim name of the test or examination used to obtain the measurement or finding. The value in VSTEST cannot be longer than 40 characters. Examples: Systolic Blood Pressure, Diastolic Blood Pressure, Body Mass Index.	text	40	Vital Signs Test Name [6 Terms]	
VSORRES VLM		Result of the vital signs measurement as originally received or collected.	text	30		
	VSTESTCD = "TEMP"	VSORRES for Temperature	float	4		
	VSTESTCD = "HEIGHT"	VSORRES for Height	float	5		
	VSTESTCD = "DIABP"	VSORRES for Diastolic Blood Pressure	integer	3		
	VSTESTCD = "SYSBP"	VSORRES for Systolic Blood Pressure	integer	3		
	VSTESTCD = "WEIGHT"	VSORRES for Weight	float	6		
	VSTESTCD = "HR"	VSORRES for Heart Rate	integer	3		
VSORRESU VLM		Original units in which the data were collected. The unit for VSORRES. Examples: IN, LB, BEATS/MIN.	text	20		
	VSTESTCD = "TEMP"	VSORRESU for Temperature	text		Units for Vital Signs Results Temperature • "C" • "F"	

Not started
STUDY BUILDS

1

In progress
STUDY BUILDS

1

Completed
STUDY BUILDS

3

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