6 Domain Models Based on the General Observation Classes

6.3 Findings

Vital Signs (VS)

VS – Description/Overview for Vital Signs Domain Model

Measurements including but not limited to blood pressure, temperature, respiration, body surface area, BMI, height and weight.

VS – Specification for Vital Signs Domain Model

vs.xpt, Vital Signs — Findings, Version 3.2. One record per vital sign measurement per time point per visit per subject, Tabulation

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	VS	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
VSSEQ	Sequence Number	Num		Identifier	Sequence Number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
VSGRPID	Group ID	Char		Identifier	Used to tie together a block of related records in a single domain for a subject.	Perm
VSSPID	Sponsor-Defined Identifier	Char		Identifier	Sponsor-defined reference number. Perhaps pre-printed on the CRF as an explicit line identifier or defined in the sponsor's operational database.	Perm
VSTESTCD	Vital Signs Test Short Name	Char	(VSTESTCD)	Topic	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.	Req

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Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
VSTEST	Vital Signs Test Name	Char	(VSTEST)	Synonym Qualifier	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.	Req
VSCAT	Category for Vital Signs	Char	*	Grouping Qualifier	Used to define a category of related records.	Perm
VSSCAT	Subcategory for Vital Signs	Char	*	Grouping Qualifier	A further categorization of a measurement or examination.	Perm
VSPOS	Vital Signs Position of Subject	Char	(POSITION)	Record Qualifier	Position of the subject during a measurement or examination. Examples: SUPINE, STANDING, SITTING.	Perm
VSORRES	Result or Finding in Original Units	Char		Result Qualifier	Result of the vital signs measurement as originally received or collected.	Exp
VSORRESU	Original Units	Char	(VSRESU)	Variable Qualifier	Original units in which the data were collected. The unit for VSORRES. Examples: IN, LB, BEATS/MIN.	Exp
VSSTRESC	Character Result/Finding in Std Format	Char		Result Qualifier	Contains the result value for all findings, copied or derived from VSORRES in a standard format or standard units. VSSTRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in VSSTRESN. For example, if a test has results "NONE", "NEG", and "NEGATIVE" in VSORRES and these results effectively have the same meaning, they could be represented in standard format in VSSTRESC as "NEGATIVE".	Exp
VSSTRESN	Numeric Result/Finding in Standard Units	Num		Result Qualifier	Used for continuous or numeric results or findings in standard format; copied in numeric format from VSSTRESC. VSSTRESN should store all numeric test results or findings.	Exp
VSSTRESU	Standard Units	Char	(VSRESU)	Variable Qualifier	Standardized unit used for VSSTRESC and VSSTRESN.	Exp
VSSTAT	Completion Status	Char	(ND)	Record Qualifier	Used to indicate that a vital sign measurement was not done. Should be null if a result exists in VSORRES.	Perm
VSREASND	Reason Not Performed	Char		Record Qualifier	Describes why a measurement or test was not performed. Examples: BROKEN EQUIPMENT or SUBJECT REFUSED. Used in conjunction with VSSTAT when value is NOT DONE.	Perm
VSLOC	Location of Vital Signs Measurement	Char	(LOC)	Record Qualifier	Location relevant to the collection of Vital Signs measurement. Example: ARM for blood pressure.	Perm
VSLAT	Laterality	Char	(LAT)	Result Qualifier	Qualifier for anatomical location or specimen further detailing laterality. Examples: RIGHT, LEFT, BILATERAL	Perm
VSBLFL	Baseline Flag	Char	(NY)	Record Qualifier	Indicator used to identify a baseline value. The value should be "Y" or null.	Exp
VSDRVFL	Derived Flag	Char	(NY)	Record Qualifier	Used to indicate a derived record. The value should be Y or null. Records which represent the average of other records or which do not come from the CRF are examples of records that would be derived for the submission datasets. If VSDRVFL=Y, then VSORRES may be null, with VSSTRESC and (if numeric) VSSTRESN having the derived value.	Perm

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Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
VISITNUM	Visit Number	Num		Timing	1. Clinical encounter number. 2. Numeric version of VISIT, used for sorting.	Exp
VISIT	Visit Name	Char		Timing	1. Protocol-defined description of clinical encounter. 2. May be used in addition to VISITNUM and/or VISITDY.	Perm
VISITDY	Planned Study Day of Visit	Num		Timing	Planned study day of the visit based upon RFSTDTC in Demographics.	Perm
VSDTC	Date/Time of Measurements	Char	ISO 8601	Timing		Exp
VSDY	Study Day of Vital Signs	Num		Timing	1. Study day of vital signs measurements, measured as integer days. 2. Algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in Demographics.	Perm
VSTPT	Planned Time Point Name	Char		Timing	1. Text Description of time when measurement should be taken. 2. This may be represented as an elapsed time relative to a fixed reference point, such as time of last dose. See VSTPTNUM and VSTPTREF. Examples: Start, 5 min post.	Perm
VSTPTNUM	Planned Time Point Number	Num		Timing	Numerical version of VSTPT to aid in sorting.	Perm
VSELTM	Planned Elapsed Time from Time Point Ref	Char	ISO 8601	Timing	Planned Elapsed time (in ISO 8601) relative to a planned fixed reference (VSTPTREF). This variable is useful where there are repetitive measures. Not a clock time or a date time variable. Represented as an ISO 8601 Duration. Examples: "-PT15M" to represent the period of 15 minutes prior to the reference point indicated by VSTPTREF, or "PT8H" to represent the period of 8 hours after the reference point indicated by VSTPTREF.	Perm
VSTPTREF	Time Point Reference	Char		Timing	Name of the fixed reference point referred to by VSELTM, VSTPTNUM, and VSTPT. Examples: PREVIOUS DOSE, PREVIOUS MEAL.	Perm
VSRFTDTC	Date/Time of Reference Time Point	Char	ISO 8601	Timing	Date/time of the reference time point, LBTPTREF.	Perm

* Indicates variable may be subject to controlled terminology, (Parenthesis indicates CDISC/NCI codelist code value)

VS – Assumptions for Vital Signs Domain Model

1. VS Definition: CRF data that captures measurements such as blood pressure, height, weight, pulse, and body temperature, or derived data such as body mass index.

2. In cases where the LOINC dictionary is used for Vital Sign tests, the permissible variable VSLOINC could be used. The sponsor is expected to provide the dictionary name and version used to map the terms utilizing the define.xml external codelist attributes

3. If a reference range is available for a vital signs test, the variables VSORNRLO, VSORNRHI, VSNRIND from the Findings observation class may be added to the domain. VSORNRLO and VSORNRHI would represent the reference range, and VSNRIND would be used to indicate where a result falls in respect to the reference range (examples: HIGH, LOW). Clinical significance would be represented as described in *Section 4: 4.1.5.5, Clinical Significance for Findings Observation Class Data* as a record in SUPPVS with a QNAM of VSCLSIG.

4. The following Qualifiers would not generally be used in VS: --BODSYS, --XFN, --SPEC, --SPCCND, --FAST, --TOX, --TOXGR.

VS – Examples for Vital Signs Domain Model

The example below shows one subject with two visits, Baseline and Visit 2, including examples of both collected and derived baseline measurements.

Rows 1, 2, 4, 5, 8, 9: VSTPT and VSTPTNUM are populated since more than one measurement was taken at this visit.

Rows 3, 6: Show an example of a derived value that was not considered to be an original result. In this case the sponsor derived the value in a different variable in the operational database. VSTPT and VSTPTNUM are not populated for these derived records.

Rows 8, 9: Show two temperatures taken at the baseline visit. Row 9 has a "Y" in the VSBLFL to indicate it was used as the baseline measurement.

Row 14: Shows a value collected in one unit, but converted to selected standard unit.

Row 15: Shows the proper use of the --STAT variable to indicate "NOT DONE" where a reason was collected when a test was not done.

Row	STUDYID	DOMAIN	USUBJID	VSSEQ	VSTESTCD	VSTEST	VSPOS	VSORRES	VSORRESU	VSSTRESC	VSSTRESN	VSSTRESU
1	ABC	VS	ABC-001-001	1	SYSBP	Systolic Blood Pressure	SITTING	154	mmHg	154	154	mmHg
2	ABC	VS	ABC-001-001	2	SYSBP	Systolic Blood Pressure	SITTING	152	mmHg	152	152	mmHg
3	ABC	VS	ABC-001-001	3	SYSBP	Systolic Blood Pressure	SITTING			153	153	mmHg
4	ABC	VS	ABC-001-001	4	DIABP	Diastolic Blood Pressure	SITTING	44	mmHg	44	44	mmHg
5	ABC	VS	ABC-001-001	5	DIABP	Diastolic Blood Pressure	SITTING	48	mmHg	48	48	mmHg
6	ABC	VS	ABC-001-001	6	DIABP	Diastolic Blood Pressure	SITTING			46	46	mmHg
7	ABC	VS	ABC-001-001	7	PULSE	Pulse Rate	SITTING	72	BEATS/MIN	72	72	BEATS/MIN
8	ABC	VS	ABC-001-001	8	TEMP	Temperature		34.7	C	34.7	34.7	C
9	ABC	VS	ABC-001-001	9	TEMP	Temperature		36.2	C	36.2	36.2	C
10	ABC	VS	ABC-001-001	10	WEIGHT	Weight	STANDING	90.5	kg	90.5	90.5	kg
11	ABC	VS	ABC-001-001	11	HEIGHT	Height	STANDING	157	cm	157	157	cm
12	ABC	VS	ABC-001-001	12	SYSBP	Systolic Blood Pressure	SITTING	95	mmHg	95	95	mmHg
13	ABC	VS	ABC-001-001	13	DIABP	Diastolic Blood Pressure	SITTING	44	mmHg	44	44	mmHg
14	ABC	VS	ABC-001-001	14	TEMP	Temperature		97.16	F	36.2	36.2	C
15	ABC	VS	ABC-001-001	15	WEIGHT	Weight						

Row	VSSTAT	VSREASND	VSLOC	VSLAT	VSBLFL	VSDRVFL	VISITNUM	VISIT	VISITDY	VSDTC	VSDY	VSTPT	VSTPTNUM
1 (cont)			ARM	LEFT			1	BASELINE	1	1999-06-19T08:45	1	BASELINE 1	1
2 (cont)			ARM	LEFT			1	BASELINE	1	1999-06-19T09:00	1	BASELINE 2	2
3 (cont)			ARM	LEFT	Y	Y	1	BASELINE	1	1999-06-19	1		
4 (cont)			ARM	LEFT			1	BASELINE	1	1999-06-19T08:45	1	BASELINE 1	1
5 (cont)			ARM	LEFT	Y	Y	1	BASELINE	1	1999-06-19T09:00	1	BASELINE 2	2
6 (cont)			ARM	LEFT	Y	Y	1	BASELINE	1	1999-06-19	1		
7 (cont)			ARM	LEFT	Y		1	BASELINE	1	1999-06-19	1		
8 (cont)			MOUTH				1	BASELINE	1	1999-06-19T08:45	1	BASELINE 1	1
9 (cont)			MOUTH		Y		1	BASELINE	1	1999-06-19T09:00	1	BASELINE 2	2
10 (cont)					Y		1	BASELINE	1	1999-06-19	1		
11 (cont)					Y		1	BASELINE	1	1999-06-19	1		
12 (cont)			ARM	LEFT			2	VISIT 2	33	1999-07-21	35		
13 (cont)			ARM	LEFT			2	VISIT 2	33	1999-07-21	35		
14 (cont)			MOUTH				2	VISIT 2	33	1999-07-21	35		
15 (cont)	NOT DONE	Subject refused	MOUTH				2	VISIT 2	33	1999-07-21	35		