Note: Section 6.3 - RE Domain underwent public review as part of SDTMIG 3.3 Batch 1 toward the end of 2013. The date in the footer of this copy reflects the most recent updates made since then.

6 Domain Models Based on the General Observation Classes

6.3 Findings

Respiratory System Findings (RE)

RE – Description/Overview for Respiratory System Findings Domain Model

A domain for physiological findings related to the respiratory system, including the organs that are involved in breathing such as the nose, throat, larynx, trachea, bronchi and lungs.

The Respiratory System Findings domain is a draft domain at the time of this publication. Note also that REORREF, RESTREFN, and REIRESFL are new variables. REORREF and RESTREFN are needed because pulmonary function test results are compared to a single predicted normal value rather than to a normal range. The idea of a single reference result was introduced in the Virology User Guide. REIRESFL indicates that the result may be problematic. A flag indicating the presence of such problems rather than a variable with a value describing the problem was chosen because a test with a questionable result often has multiple problems.

RE – Specification for Respiratory System Findings Domain Model

re.xpt, Respiratory Physiology — Findings, Version 3.x.x. One record per finding or result 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	RE	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
SPDEVID	Sponsor Device Identifier	Char		Identifier	Sponsor-defined identifier for a device	Perm
RESEQ	Sequence Number	Num		Identifier	Sequence Number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
REGRPID	Group ID	Char		Identifier	Used to tie together a block of related records in a single domain for a subject.	Perm
REREFID	Reference ID	Char		Identifier	Internal or external procedure identifier.	Perm

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
RESPID	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. Example: Line number from the procedure or test page.	Perm
RETESTCD	Test or Examination Short Name	Char	(RETESTCD)	Topic	Short name of the measurement, test, or examination described in RETEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in RETESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST"). RETESTCD cannot contain characters other than letters, numbers, or underscores. Examples: FEV1, FVC	Req
RETEST	Test or Examination Name	Char	(RETEST)	Synonym Qualifier	Verbatim name of the test or examination used to obtain the measurement or finding. The value in RETEST cannot be longer than 40 characters. Examples: Forced Expiratory Volume in 1 Second, Forced Vital Capacity	Req
RECAT	Category for Test	Char	*	Grouping Qualifier	Used to categorize observations across subjects.	Perm
RESCAT	Subcategory for Test	Char	*	Grouping Qualifier	A further categorization.	Perm
REPOS	Position of Subject	Char	(POSITION)	Record Qualifier	Position of the subject during a measurement or examination. Examples: SUPINE, STANDING, SITTING.	Perm
REORRES	Result or Finding in Original Units	Char		Result Qualifier	Result of the procedure measurement or finding as originally received or collected.	Exp
REORRESU	Original Units	Char	(UNIT)	Variable Qualifier	Original units in which the data were collected. The unit for REORRES and REORREF.	Perm
REORREF	Reference Result in Original Units	Char		Variable Qualifier	Reference result for continuous measurements in original units. Should be populated only for continuous results.	Perm
RESTRESC	Character Result/Finding in Std Format	Char	*	Result Qualifier	Contains the result value for all findings, copied or derived from REORRES in a standard format or standard units. RESTRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in RESTRESN.	Exp
RESTRESN	Numeric Result/Finding in Std Format	Num		Result Qualifier	Used for continuous or numeric results or findings in standard format; copied in numeric format from RESTRESC. RESTRESN should store all numeric test results or findings.	Perm
RESTRESU	Standard Units	Char	(UNIT)	Variable Qualifier	Standardized unit used for RESTRESC, RESTRESN and RESTREFN.	Perm
RESTREFN	Reference Result in Standard Units	Num		Variable Qualifier	Reference result for continuous measurements in standard units. Should be populated only for continuous results.	Perm
RESTAT	Completion Status	Char	(ND)	Record Qualifier	Used to indicate that a test was not done or a measurement was not taken. Should be null if a result exists in REORRES.	Perm
REREASND	Reason Test Not Performed	Char		Record Qualifier	Describes why a measurement or test was not performed. Examples: BROKEN EQUIPMENT or SUBJECT REFUSED. Used in conjunction with RESTAT when value is NOT DONE.	Perm

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
RELOC	Location Used for Measurement	Char	(LOC)	Record Qualifier	Location relevant to the collection of the measurement. Example: 'LUNG', 'BRONCHUS'	Perm
RELAT	Laterality	Char	(LAT)	Record Qualifier	Side of the body used to collect measurement. Examples: RIGHT, LEFT, BILATERAL, UNILATERAL	Perm
REDIR	Directionality	Char	(DIR)	Record Qualifier	Directionality to indicate where on the body the collection was taken. Examples: PROXIMAL, DISTAL, ANTERIOR	Perm
REMETHOD	Method of Test or Examination	Char	(METHOD)	Record Qualifier	Method used to create the result.	Perm
REBLFL	Baseline Flag	Char	(NY)	Record Qualifier	Indicator used to identify a baseline value. The value should be "Y" or null.	Exp
REDRVFL	Derived Flag	Char	(NY)	Record Qualifier	Used to indicate a derived record. The value should be Y or null. Records that represent the average of other records, or that do not come from the CRF, or are not as originally collected or received are examples of records that would be derived for the submission datasets. If REDRVFL=Y, then REORRES could be null, with RESTRESC, and (if numeric) RESTRESN having the derived value.	Perm
REEVAL	Evaluator	Char	*	Record Qualifier	Role of the person who provided the evaluation. Used only for results that are subjective (e.g., assigned by a person or a group). Should be null for records that contain collected or derived data. Examples: INVESTIGATOR, ADJUDICATION COMMITTEE.	Perm
REIRESFL	Inadequate Results Flag	Char	(NY)	Record Qualifier	Used to indicate that a result is not considered acceptable/adequate according to the assessment protocol. The value should be Y or null. If additional qualification of the result is collected then this could be recorded in a Supplemental Qualifier variable.	Perm
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
REDTC	Date/Time of Test	Char		Timing	Date/Time of procedure or test.	Exp
REDY	Study Day of Test	Num	ISO 8601	Timing	1. Study day of the procedure or test, measured as integer days. 2. Algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in Demographics.	Perm
RETPT	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 RETPTNUM and RETPTREF. Examples: Start, 5 min post.	Perm
RETPTNUM	Planned Time Point Number	Num		Timing	Numerical version of RETPT to aid in sorting.	Perm
REELTM	Planned Elapsed Time from Time Point Ref	Char	ISO 8601	Timing	Planned elapsed time (in ISO 8601) relative to a fixed time point reference (RETPTREF). Not a clock time or a date time variable. Represented as an ISO	Perm

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
					8601 duration. Examples: "-PT15M" to represent the period of 15 minutes prior to the reference point indicated by RETPTREF, or "PT8H" to represent the period of 8 hours after the reference point indicated by RETPTREF.	
RETPTREF	Time Point Reference	Char		Timing	Name of the fixed reference point referred to by REELTM, RETPTNUM, and RETPT. Examples: PREVIOUS DOSE, PREVIOUS MEAL.	Perm
RERFTDTC	Date/Time of Reference Time Point	Char	ISO 8601	Timing	Date/time of the reference time point, RETPTREF.	Perm

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

RE – Assumptions for Respiratory System Findings Domain Model

1. RE Definition: This domain has been designed to store data on respiratory physiological findings that include information relating to the lungs and airways, including the nose, throat, larynx, thrachea, and bronchi, such as forced expiratory volume in one second (FEV1) and forced vital capacity (FVC).
2. This domain holds the results/findings of a respiratory diagnostic procedure. Information about the conduct of the procedure(s), if collected, should be submitted in the Procedures (PR) domain. Data describing structural measurements or assessments of the lungs should be reported in the Morphology (MO) domain.
3. SPDEVID provides a consistent variable for linking data across Device domains, independent of the level of granularity by which a device might be identified by a sponsor in a study. SPDEVID is a mechanism for aggregating any number of identifiers into one, allowing for a consistent structure for identifying all devices. SPDEVID is a surrogate identifier that represents all the characteristics of a device in the Study Device Identifier (DI) domain, and is also a simple, short identifier that can appear in each dataset.

RE – Examples for Respiratory System Findings Domain Model

Example 1

This example shows results from several spirometry tests using either a spirometer or a peak flow meter where only the best result is available.
The Device Identifiers (DI) domain contains the total set of characteristics necessary for device identification, and the Device Properties (DO) domain contains information important for submission but that are not part of the device identifier.

Because the original and standardized units of measure are identical in this example, RESTRESC, RESTRESN, RESTRESU, and RESTREFN are not shown. Instead, an ellipsis marks their place in the dataset.

Rows 1-2: Show the data in original units of measure in REORRES for the best result for spirometry tests with the predicted values in REORREF.
Rows 3-4: Show the data in original units of measure in REORRES of percent predicted tests as output by the spirometer device. REORREF is null as there are no reference results for percent predicted tests.
Row 5: Shows the data in original units of measure in REORRES for the peak flow test with the predicted values in REORREF.

re.xpt

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	RESEQ	RETESTCD	RETEST	REORRES	REORRESU	REORREF	...	VISITNUM	VISIT	REDTC
1	XYZ	RE	XYZ-001-001	ABC001	1	FEV1	Forced Expiratory Volume in 1 Second	2.73	L	3.37	...	2	VISIT 2	2013-06-30
2	XYZ	RE	XYZ-001-001	ABC001	2	FVC	Forced Vital Capacity	3.91	L	3.86	...	2	VISIT 2	2013-06-30
3	XYZ	RE	XYZ-001-001	ABC001	3	FEV1PP	Percent Predicted FEV1	81	%		...	2	VISIT 2	2013-06-30
4	XYZ	RE	XYZ-001-001	ABC001	4	FVCPP	Percent Predicted FVC	101.3	%		...	2	VISIT 2	2013-06-30
5	XYZ	RE	XYZ-001-001	DEF999	5	PEF	Peak Expiratory Flow	6.11	L/s	7.33	...	4	VISIT 4	2013-07-17

Rows 1-2:   Show the device type that was used to perform for the pulmonary function tests

di.xpt

Row	STUDYID	DOMAIN	SPDEVID	DISEQ	DIPARMCD	DIPARM	DIVAL
1	XYZ	DI	ABC001	1	TYPE	Device Type	SPIROMETER
2	XYZ	DI	DEF999	1	TYPE	Device Type	PEAK FLOW METER

Row 1:   Displays the record the reference equation used by the spirometer device.
Row 2:   Displays the record the reference equation used by the peak flow meter device.

du.xpt

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	DUSEQ	DUTESTCD	DUTEST	DUORRES
1	XYZ	DU		ABC001	1	SPIREFEQ	Spirometric Reference Equation	NATIONAL HEALTH NUTRITION EXAMINATION SURVEY (NHANES) III
2	XYZ	DU		DEF999	1	SPIREFEQ	Spirometric Reference Equation	NATIONAL HEALTH NUTRITION EXAMINATION SURVEY (NHANES) III

Example 2

This example shows results from several spirometry tests using a spirometer where both the best result and individual results are available. The best result has been flagged using a supplemental qualifier.

Because the original and standardized units of measure are identical in this example, RESTRESC, RESTRESN, and RESTRESU are not shown. Instead, an ellipsis marks their place in the dataset.

Rows 1-3:   Show the data in original and standardized units of individual test results for FEV1 as measured by spirometry. The absence of a flag in REIRESFL indicates that the data were adequate.
Row 4:   Shows the data in original and standardized units of an individual test result for FEV1 as measured by spirometry. The presence of a flag in REIRESFL indicates that the data were inadequate. SUPPRE.xpt contains two reasons why this was the case.
Row 5:   Shows the data in original and standardized units of the best test result for FEV1 as measured by spirometry.

re.xpt

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	RESEQ	RETESTCD	RETEST	REORRES	REORRESU	...	REIRESFL	VISITNUM	VISIT	REDTC
1	XYZ	RE	XYZ-001-001	ABC001	1	FEV1	Forced Expiratory Volume in 1 Second	1.94	L	...		2	VISIT 2	2013-04-23
2	XYZ	RE	XYZ-001-001	ABC001	2	FEV1	Forced Expiratory Volume in 1 Second	1.88	L	...		2	VISIT 2	2013-04-23
3	XYZ	RE	XYZ-001-001	ABC001	3	FEV1	Forced Expiratory Volume in 1 Second	1.88	L	...		2	VISIT 2	2013-04-23
4	XYZ	RE	XYZ-001-001	ABC001	4	FEV1	Forced Expiratory Volume in 1 Second	1.57	L	...	Y	2	VISIT 2	2013-04-23

Row 1: Shows that the record in the RE dataset with RESEQ value of 1 has a supplemental qualifier indicating that this is the best result.

Rows 2-3: Show that the record in the RE dataset with RESEQ value of 4 has supplemental qualifier records providing the reasons the result collected was inadequate. Those reasons were that coughing was detected and that the repeatability was unacceptable.

suppre.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG	QEVAL
1	XYZ	RE	XYZ-001-001	RESEQ	1	REBRESFL	Best Result Flag	Y	CRF	
2	XYZ	RE	XYZ-001-001	RESEQ	4	REIRREA1	Inadequate Result Reason 1	COUGHING WAS DETECTED IN THE FIRST PART OF THE EXPIRATION	CRF	
3	XYZ	RE	XYZ-001-001	RESEQ	4	REIRREA2	Inadequate Result Reason 2	FEV1 REPEATABILITY IS UNACCEPTABLE	CRF	

Row 1: Shows the device type that was used to perform for the pulmonary function tests

di.xpt

Row	STUDYID	DOMAIN	SPDEVID	DISEQ	DIPARMCD	DIPARM	DIVAL
1	XYZ	DI	ABC001	1	TYPE	Device Type	SPIROMETER

Row 1: Displays the record the reference equation used by the spirometer device.

du.xpt

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	DUSEQ	DUTESTCD	DUTEST	DUORRES
1	XYZ	DU		ABC001	1	SPIREFEQ	Spirometric Reference Equation	NATIONAL HEALTH NUTRITION EXAMINATION SURVEY (NHANES) III