

QUESTIONNAIRE SDTM – FINDINGS CLASS

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01 Example from FINDINGS class

QS SDTM METADATA

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	QS	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
QSSSEQ	Sequence Number	Num		Identifier	Sequence Number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
QSGRPID	Group ID	Char		Identifier	Used to tie together a block of related records in a single domain for a subject.	Perm
QSSPID	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: Question number on a questionnaire.	Perm
QSTESTCD	Question Short Name	Char	(QSTESTCD)	Topic	Topic variable for QS. Short name for the value in QSTEST, which can be used as a column name when converting the dataset from a vertical format to a horizontal format. The value in QSTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g. "1TEST"). QSTESTCD cannot contain characters other than letters, numbers, or underscores. See QS Terminology Spreadsheet for specific text for QSTESTCD. Examples: ADCCMD01, BPR0103	Req

QS SDTM METADATA

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
<u>QSTEST</u>	Question Name	Char	(QSTEST)	Synonym Qualifier	Verbatim name of the question or group of questions used to obtain the measurement or finding. The value in QSTEST cannot be longer than 40 characters. See QS Terminology Spreadsheet for specific text for QSTEST. Example: Fist, BPR01 - Emotional Withdrawal	Req
QSCAT	Cat	Char	(CAT)	Grouping Qualifier	Used to define a category of related records that will be meaningful to the Reviewer. See QS Terminology Spreadsheet for specific text for QSCAT. Examples: ADAS-COG, MDS-UPDRS.	Req
QSSCAT	Sub	Char	(SCAT)	Grouping Qualifier	A further categorization of the questions within the category. Examples: MENTAL HEALTH DOMAIN, DEPRESSION DOMAIN, WORD RECALL.	Perm
<u>QSORRES</u>	Finding in Original Units	Char	(QSORRES)	Result Qualifier	Finding as originally received or collected (e.g. RARELY, SOMETIMES). When sponsors apply codelist to indicate the code values are statistically meaningful standardized scores, which are defined by sponsors or by valid methodologies such as SF36 questionnaires, QSORRES will contain the decode format, and QSSSTRESN and QSSSTRESN may contain the standardized code values or scores.	Exp
QSORRESU	Original Units	Char	(UNIT)	Variable Qualifier	Original units in which the data were collected. The unit for QSORRES, such as minutes or seconds or the units associated with a visual analog scale.	Perm
<u>QSSSTRESN</u>	Character Result/Finding in Standard Format	Char	(QSSSTRESN)	Result Qualifier	Contains the finding for all questions or sub-scores, copied or derived from QSORRES in a standard format or standard units. QSSSTRESN should store all findings in character format; if findings are numeric, they should also be stored in numeric format in QSSSTRESN. If question scores are derived from the original finding, then the standard format is the score. Examples: 0, 1. When sponsors apply codelist to indicate the code values are statistically meaningful standardized scores, which are defined by sponsors or by valid methodologies such as SF36 questionnaires, QSORRES will contain the decode format, and QSSSTRESN and QSSSTRESN may contain the standardized code values or scores.	Exp
<u>QSSSTRESN</u>	Numeric Finding in Standard Units	Num	(QSSSTRESN)	Result Qualifier	Used for continuous or numeric findings in standard format; copied in numeric format from QSSSTRESN. QSSSTRESN should store all numeric results or findings.	Perm
QSSSTRESU	Standard Units	Char	(UNIT)	Variable Qualifier	Standardized unit used for QSSSTRESN or QSSSTRESN.	Perm
QSSTAT		Char	(ND)	Record Qualifier	Used to indicate a questionnaire or response to a questionnaire was not done. Should be null if a result exists in QSORRES.	Perm
QSREASND		Char	(ND)	Record Qualifier	Describes why a question was not answered. Used in conjunction with QSSTAT when value is NOT DONE. Example: SUBJECT REFUSED.	Perm
<u>QSBFL</u>	Baseline Flag	Char	(NY)	Record Qualifier	Indicator used to identify a baseline value. The value should be "Y" or null.	Exp

Verbatim name for Question

Results captured on CRF page

Coded results in Character Format (if any coding required)

QSSSTRESN=coded values in Numeric Format

Baseline Flag

QS SDTM METADATA

Variable Name				CDISC Notes	Core
QSTEST	Q	MOBILITY	For each heading, please Select the ONE Option from Dropdown list provided that best describes your health TODAY I have no problems in walking about <input checked="" type="radio"/> 2 I have slight problems in walking about <input type="radio"/> I have moderate problems in walking about <input type="radio"/> I have severe problems in walking about <input type="radio"/> I am unable to walk about <input type="radio"/>	Full name of the question or group of questions used to obtain the assessment or finding. The value in QSTEST cannot be longer than 40 characters. See Terminology Spreadsheet for specific text for QSTEST. Example: First, - Emotional Withdrawal	Req
QSCAT	C			Define a category of related records that will be meaningful to the user. See QS Terminology Spreadsheet for specific text for QSCAT. Examples: ADAS-COG, MDS-UPDRS.	Req
QSSCAT	S	SELF-CARE	I have no problems washing or dressing myself <input checked="" type="radio"/> 3 I have slight problems washing or dressing myself <input type="radio"/> I have moderate problems washing or dressing myself <input type="radio"/> I have severe problems washing or dressing myself <input type="radio"/> I am unable to wash or dress myself <input type="radio"/>	Enter categorization of the questions within the category. Examples: MENTAL HEALTH DOMAIN, DEPRESSION DOMAIN, WORD RECALL	Perm
QSORRES	F			As originally received or collected (e.g. RARELY, SOMETIMES). When applying codelist to indicate the code values are statistically meaningful standardized scores, which are defined by sponsors or by valid methodologies such as SF36 questionnaires, QSORRES will contain the format, and QSSTRESC and QSSTRESN may contain the standardized values or scores.	Exp
QSORRESU	O			The unit for QSORRES, such as a visual analog scale.	Perm
QSSTRESC	C	USUAL ACTIVITIES	I have no problems doing my usual activities <input checked="" type="radio"/> 4 I have slight problems doing my usual activities <input type="radio"/> I have moderate problems doing my usual activities <input type="radio"/> I have severe problems doing my usual activities <input type="radio"/> I am unable to do my usual <input type="radio"/>	When the standard format is the score. Examples: 0, 1. When sponsors apply to indicate the code values are statistically meaningful standardized scores, are defined by sponsors or by valid methodologies such as SF36 questionnaires, QSORRES will contain the decode format, and QSSTRESC and QSSTRESN may contain the standardized code values or scores.	Exp
QSSTRESN	N			Used for continuous or numeric findings in standard format; copied in numeric format from QSSTRESC. QSSTRESN should store all numeric results or findings.	Perm
QSSTRESU	S			Standardized unit used for QSSTRESC or QSSTRESN.	Perm
QSSTAT	S			Used to indicate a questionnaire or response to a questionnaire was not done. Should be null if a result exists in QSORRES.	Perm
QSREASND	S			Describes why a question was not answered. Used in conjunction with QSSTAT when value is NOT DONE. Example: SUBJECT REFUSED.	Perm
QSBLFL	S			Indicator used to identify a baseline value. The value should be "Y" or null.	Exp

QSSTRESN=coded values in Numeric Format

Baseline Flag

QSSTRESC=coded values in Character Format

QS SDTM METADATA

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
QSDRVFL	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 questionnaire sub-scores that do not come from the CRF are examples of records that would be derived for the submission datasets. If QSDRVFL=Y, then QSORRES may be null with QSTRESC and (if numeric) QSTRESN having the derived value.	Perm
QSEVAL	Evaluator	Char	(EVAL)	Record Qualifier	Role of the person who provided the evaluation. Examples: STUDY SUBJECT, CAREGIVER, INVESTIGATOR.	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
QSDTC	Date/Time of Finding	Char	ISO 8601	Timing	Date of questionnaire.	Exp
QSDY	Study Day of Finding	Num		Timing	1. Study day of finding collection, measured as integer days. 2. Algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in Demographics.	Perm
QSTPT	Planned Time Point Name	Char		Timing	1. Text Description of time when questionnaire should be administered. 2. This may be represented as an elapsed time relative to a fixed reference point, such as time of last dose. See QSTPTNUM and QSTPTREF.	Perm
QSTPTNUM	Planned Time Point Number	Num		Timing	Numerical version of QSTPT to aid in sorting.	Perm
QSELTM	Planned Elapsed Time from Time Point Ref	Char	ISO 8601	Timing	Planned Elapsed time (in ISO 8601) relative to a planned fixed reference (QSTPTREF). 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 QSTPTREF, or "PT8H" to represent the period of 8 hours after the reference point indicated by QSTPTREF.	Perm
QSTPTREF	Time Point Reference	Char		Timing	Name of the fixed reference point referred to by QSELTM, QSTPTNUM, and QSTPT. Examples: PREVIOUS DOSE, PREVIOUS MEAL.	Perm
QSRFDTDC	Date/Time of Reference Time Point	Char	ISO 8601	Timing	Date/time of the reference time point, LBTPREF.	Perm
QSEVLINT	Evaluation Interval	Char	ISO 8601	Timing	Evaluation Interval associated with a QSTEST question represented in ISO 8601 character format. Example: "-P2Y" to represent an interval of 2 years in the question "Have you experienced any episodes in the past 2 years?"	Perm

Data Snapshot of QS SDTM

Row	STUDYID	DOMAIN	USUBJID	QSSSEQ	QSTESTCD	QSTEST	QSCAT	QSORRES
1	STUDYX	QS	P0001	1	HAMD101	HAMD1-Depressed Mood	HAMD 17	Absent
2	STUDYX	QS	P0001	2	HAMD102	HAMD1-Feelings of Guilt	HAMD 17	Self reproach, feels he/she has let people down
3	STUDYX	QS	P0001	3	HAMD103	HAMD1-Suicide	HAMD 17	Ideas or gestures suicide
4	STUDYX	QS	P0001	4	HAMD104	HAMD1-Insomnia Early - Early Night	HAMD 17	No difficulty falling asleep
5	STUDYX	QS	P0001	5	HAMD105	HAMD1-Insomnia Middle - Middle Night	HAMD 17	No difficulty
6	STUDYX	QS	P0001	6	HAMD106	HAMD1-Insomnia Early Hours -Morning	HAMD 17	No difficulty
7	STUDYX	QS	P0001	7	HAMD107	HAMD1-Work and Activities	HAMD 17	No difficulty
8	STUDYX	QS	P0001	8	HAMD108	HAMD1-Retardation	HAMD 17	Complete stupor
9	STUDYX	QS	P0001	9	HAMD109	HAMD1-Agitation	HAMD 17	Fidgetiness
10	STUDYX	QS	P0001	10	HAMD110	HAMD1-Anxiety Psychic	HAMD 17	No difficulty
11	STUDYX	QS	P0001	11	HAMD111	HAMD1-Anxiety Somatic	HAMD 17	Moderate
12	STUDYX	QS	P0001	12	HAMD112	HAMD1-Somatic Symptoms GI	HAMD 17	None
13	STUDYX	QS	P0001	13	HAMD113	HAMD1-General Somatic Symptoms	HAMD 17	None
14	STUDYX	QS	P0001	14	HAMD114	HAMD1-Genital Symptoms	HAMD 17	Mild
15	STUDYX	QS	P0001	15	HAMD115	HAMD1-Hypochondriasis	HAMD 17	Not present
16	STUDYX	QS	P0001	16	HAMD116A	HAMD1-Loss of WT According to Patient	HAMD 17	Definite (according to patient) weight loss
17	STUDYX	QS	P0001	17	HAMD116B	HAMD1-Loss of WT According to WK Meas	HAMD 17	Greater than 2 lb weight loss in week
18	STUDYX	QS	P0001	18	HAMD117	HAMD1-Insight	HAMD 17	Denies being ill at all
19	STUDYX	QS	P0001	19	HAMD118	HAMD1-Total Score	HAMD 17	18

Row	QSSSTRESC	QSSSTRESN	QSBFL	QSDRVFL	VISITNUM	QSDTC	QSEVAL	QSEVLINT
1 (cont)	0	0	Y		1	2012-08-11	INVESTIGATOR	-P1W
2 (cont)	1	1	Y		1	2012-08-11	INVESTIGATOR	-P1W
3 (cont)	3	3	Y		1	2012-08-11	INVESTIGATOR	-P1W
4 (cont)	0	0	Y		1	2012-08-11	INVESTIGATOR	-P1W
5 (cont)	0	0	Y		1	2012-08-11	INVESTIGATOR	-P1W
6 (cont)	0	0	Y		1	2012-08-11	INVESTIGATOR	-P1W
7 (cont)	0	0	Y		1	2012-08-11	INVESTIGATOR	-P1W
8 (cont)	4	4	Y		1	2012-08-11	INVESTIGATOR	-P1W
9 (cont)	1	1	Y		1	2012-08-11	INVESTIGATOR	-P1W
10 (cont)	0	0	Y		1	2012-08-11	INVESTIGATOR	-P1W

Row	QSSSTRESC	QSSSTRESN	QSBFL	QSDRVFL	VISITNUM	QSDTC	QSEVAL	QSEVLINT
11 (cont)	2	2	Y		1	2012-08-11	INVESTIGATOR	-P1W
12 (cont)	0	0	Y		1	2012-08-11	INVESTIGATOR	-P1W
13 (cont)	0	0	Y		1	2012-08-11	INVESTIGATOR	-P1W
14 (cont)	1	1	Y		1	2012-08-11	INVESTIGATOR	-P1W
15 (cont)	0	0	Y		1	2012-08-11	INVESTIGATOR	-P1W
16 (cont)	2	2	Y		1	2012-08-11	INVESTIGATOR	-P1W
17 (cont)	2	2	Y		1	2012-08-11	INVESTIGATOR	-P1W
18 (cont)	2	2	Y		1	2012-08-11	INVESTIGATOR	-P1W
19 (cont)	18	18	Y	Y	1	2012-08-11	INVESTIGATOR	-P1W

flag indicates that the record is derived

Thank You