Understanding RELREC and Supplemental Qualifier

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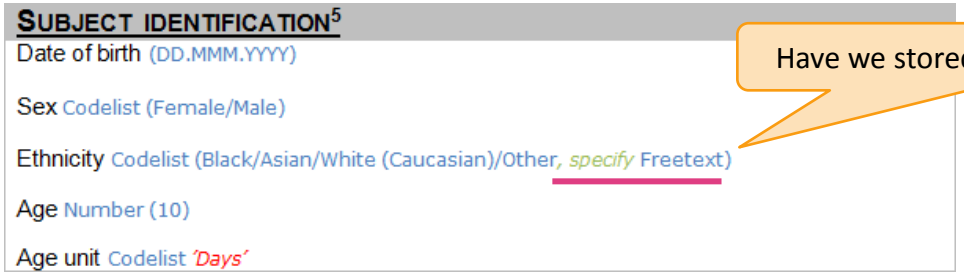
Agenda

01 Understand Supplemental qualifiers

02 Understand Relationship Records Dataset

Understanding SUPPLEMENTAL QUALIFIER



Check your IG to see which Variable can store this data

I want to create a new variable to store this variable, as I do not find a variable in Demographic SDTM, Can I?

Supplemental Qualifier

- You can not add New Variables in the SDTM dataset
- Non standard data can be stored in the Supplemental Qualifiers special purpose dataset
- Supplemental Qualifiers data will be presented as SUPP–
- -- being the domain name for which you are creating SUPP data
- E.g SUPPDM, SUPPAE etc

SDTM IG : Section 8

8 REPRESENTING RELATIONSHIPS AND DATA

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Structure of SUPP-- dataset

Variable	Variable Label	Type	Controlled Terms, Codelist or Format	CDISC Notes	Core
STUDYID	Study Identifier	Char		Study Identifier of the Parent record(s).	Req
RDOMAIN	Related Domain Abbreviation	Char	DOMAIN	Two-character abbreviation for the domain of the parent record(s).	Req
USUBJID	Unique Subject Identifier	Char		Unique Subject Identifier of the Parent record(s).	Req
IDVAR	Identifying Variable	Char	*	Identifying variable in the dataset that identifies the related record(s). Examples: --SEQ, --GRPID.	Exp
IDVARVAL	Identifying Variable Value	Char		Value of identifying variable of the parent record(s).	Exp
QNAM	Qualifier Variable Name	Char	*	The short name of the Qualifier variable, which is used as a column name in a domain view with data from the parent domain. The value in QNAM cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST"). QNAM cannot contain characters other than letters, numbers, or underscores. This will often be the column name in the sponsor's operational dataset.	Req

Value stored in QNAM is the name of new variable that user wants to create

Structure of SUPP-- dataset

Variable	Variable Label	T	CDISC Notes	Core
QLABEL	Qualifier Variable Label	Cha	This is the long name or label associated with QNAM. The value in QLABEL cannot be longer than 40 characters. This will often be the column label in the sponsor's original dataset.	Req
QVAL	Dat		Result of, response to, or value associated with QNAM. A value for this column is required; no records can be in SUPP-- with a null value for QVAL.	Req
QORIG	Orig		Since QVAL can represent a mixture of collected (on a CRF), derived, or assigned items, QORIG is used to indicate the origin of this data. Examples include CRF, ASSIGNED, or DERIVED. See ***Section 4: 4.1.1.8, Origin Metadata***.	Req
QEVAL	E		Used only for results that are subjective (e.g., assigned by a person or a group). Should be null for records that contain objectively collected or derived data. Some examples include ADJUDICATION COMMITTEE, STATISTICIAN, DATABASE ADMINISTRATOR, CLINICAL COORDINATOR, etc.	Exp

User defined label for the new variable

Value of the new variable, in this example it will be the free text that use eneters on CRF

Source or Origin of the information

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

Example of MULTIPLE RACE

Race	Check all that apply
American Indian or Alaska Native	☐
Asian	☐
Black or African American	☐
Native Hawaiian or Other Pacific Islander	☐
White	☐
Other, Specify: _____	☐

Additional information will be included in the Supplemental Qualifiers dataset

Row 1 (DM) and
Row 1 (SUPPDM): Subject 001 checked "Other, Specify:" and entered "Brazilian" as race.
Row 2 (DM) and
Rows 2, 3, 4, 5 (SUPPDM): Subject 002 checked three races, including an "Other, Specify" value. The three values are reported in SUPPDM using QNAM values RACE1 - RACE3. The specified information describing other race for is submitted in the same manner as subject 001.
Row 3 (DM): Subject 003 refused to provide information on race.
Row 4 (DM): Subject 004 checked "Asian" as their only race.

If multiple races are collected then the value of RACE should be "MULTIPLE"

dm.xpt

Row	STUDYID	DOMAIN	USUBJID	RACE
1	ABC	DM	001	OTHER
2	ABC	DM	002	MULTIPLE
3	ABC	DM	003	
4	ABC	DM	004	ASIAN

Controlled Terminology for RACE should be used in both DM and SUPPDM

suppdm.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL		
1	ABC	DM	001			RACEOTH	Race, Other	BRAZILIAN		
2	ABC	DM	002			RACE1	Race 1	BLACK OR AFRICAN AMERI	CRF	
3	ABC	DM	002			RACE2	Race 2	AMERICAN INDIAN OR ALASKA NATIVE	CRF	
4	ABC	DM	002			RACE3	Race 3	OTHER	CRF	
5	ABC	DM	002			RACEOTH	Race, Other	ABORIGINE	CRF	

SUPPDM Data Snapshot

STUDYID	USUBJID	RDOMAIN	QNAM	QLABEL	QVAL	QORIG
XXXX	XXX-002-004	DM	RACEOTH	Race, Other Specifys	BRAZILIAN	CRF

RELREC DATASET

- The Related Records (RELREC) domain is a Special-Purpose Relationship domain in the SDTM
- It is used to identify relationships between records in two (or more) domains.
- The RELREC domain can be used to describe relationships between
  - records for a subject
  - relationships between different domains
- In RELREC, a relationship is constructed by adding a record to RELREC for each record to be related and by assigning a unique character identifier value for that relationship.

RELREC METADATA

Variable	Variable Label	Type	Controlled Terms, Codelist or Format	CDISC Notes	Core
STUDYID	Study Identifier	Char		Unique identifier for a study	Req
RDOMAIN	Related Domain Abbreviation	Char	DOMAIN	Two-character abbreviation for the domain of the parent record(s)	Req
USUBJID	Unique Subject Identifier	Char		Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Exp
IDVAR	Identifying Variable	Char	*	Name of the identifying variable in the general-observation-class dataset that identifies the related record(s). Examples include --SEQ and --GRPID.	Req
IDVARVAL	Identifying Variable Value	Char		Value of identifying variable described in IDVAR. If --SEQ is the variable being used to describe this record, then the value of --SEQ would be entered here.	Exp
RELTYPE	Relationship Type	Char	ONE, MANY	Identifies the hierarchical level of the records in the relationship. Values should be either ONE or MANY. Used only when identifying a relationship between datasets (as described in Section 8.3).	Exp
RELID	Relationship Identifier	Char		Unique value within USUBJID that identifies the relationship. All records for the same USUBJID that have the same RELID are considered "related/associated." RELID can be any value the sponsor chooses, and is only meaningful within the RELREC dataset to identify the related/associated Domain records.	Req

CASE 1 : RECORDS FOR ONE SUBJECT

- Used for records based on CRF collected information (Not applicable for derived records)
- Single record can be related by using a unique record identifier variable like XXSEQ in IDVAR
- Group records for a patient can be related using a grouping variable XXGRPID in IDVAR
- RELID must be same for all related records within each subject

RELREC for relationship in Records

Record in DS Domain

STUDYID	DOMAIN	USUBJID	DSSEQ	DSTERM	DSDECODE	DSCAT	EPOCH	DSDTC
XYZ999	DS	Xyz999-1000-1001	001	Heart Failure	DEATH	DISPOSITION EVENT	TREATMENT	2017-10-10

Record in AE Domain

STUDYID	DOMAIN	USUBJID	AESEQ	AETERM	AEDECODE	AEBOBSYS	AESER	AESTDH	AESTDTC	AEENDTC
XYZ999	AE	Xyz999-1000-1001	002	Heart Failure	HEART FAILURE	CARDIOVASCULAR SYSTEM DISORDER	Y	Y	2017-10-10	2017-10-10

Record in RELREC domain

STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
XYZ999	DS	Xyz999-1000-1001	DSSEQ	001	ONE	1
XYZ999	AE	Xyz999-1000-1001	AESEQ	002	ONE	1

For this patient record with DSSEQ=1 is related with AESEQ=2; RELID=1 indicates both are related

CASE 2 : RELATING MORE THAN ONE DATASET

- Include single record for each dataset
- This record should have the key(s) of the dataset that can be used to relate
- USUBJID is not required , as relation is set between two datasets and not for a single patient
- IDVARVAL is not populated because the relationship exists for all values of IDVAR within a subject

RELREC for relationship between two Datasets

Mapping this information in CE, as this is a Clinical event and not AE as per study CRF

Migraine Symptoms Diary	
Migraine Reference Number	xx
When did the migraine start	DD-MMM-YYYY HH:MM
Answer the following 5 Minutes BEFORE Dosing	
Severity of Migraine	○ Mild ○ Moderate ○ Severe
Associated Symptoms: Sensitivity to light Sensitivity to sound Nausea Aura	 ○ No ○ Yes ○ No ○ Yes ○ No ○ Yes ○ No ○ Yes
Answer the following 30 Minutes AFTER Dosing	
Severity of Migraine	○ Mild ○ Moderate ○ Severe
Associated Symptoms: Sensitivity to light Sensitivity to sound Nausea Aura	 ○ No ○ Yes ○ No ○ Yes ○ No ○ Yes ○ No ○ Yes
Answer the following 90 Minutes AFTER Dosing	
Severity of Migraine	○ Mild ○ Moderate ○ Severe
Associated Symptoms: Sensitivity to light Sensitivity to sound Nausea Aura	 ○ No ○ Yes ○ No ○ Yes ○ No ○ Yes ○ No ○ Yes

ce.xpt

Row	STUDYID	DOMAIN	USUBJID	CESEQ	CESPID	CETERM	CEDECOD	CESTDTC
1	ABC	CE	ABC-123	1	90567	Migraine	Migraine	2007-05-16T10:30

RELREC for relationship between two Datasets

Row	STUDYID	DOMAIN	USUBJID	FASEQ	FASPID	FATESTCD	FATEST	FAOBJ	FACAT	FAORRES	FASTRESC
1	ABC	FA	ABC-123	1	90567	SEV	Severity/Intensity	Migraine	MIGRAINE SYMPTOMS	SEVERE	SEVERE
2	ABC	FA	ABC-123	2	90567	OCCUR	Occurrence	Sensitivity To Light	MIGRAINE SYMPTOMS	Y	Y
3	ABC	FA	ABC-123	3	90567	OCCUR	Occurrence	Sensitivity To Sound	MIGRAINE SYMPTOMS	N	N
4	ABC	FA	ABC-123	4	90567	OCCUR	Occurrence	Nausea	MIGRAINE SYMPTOMS	Y	Y
5	ABC	FA	ABC-123	6	90567	OCCUR	Occurrence	Aura	MIGRAINE SYMPTOMS	Y	Y
6	ABC	FA	ABC-123	7	90567	SEV	Severity/Intensity	Migraine	MIGRAINE SYMPTOMS	MODERATE	MODERATE
7	ABC	FA	ABC-123	8	90567	OCCUR	Occurrence	Sensitivity To Light	MIGRAINE SYMPTOMS	Y	Y
8	ABC	FA	ABC-123	9	90567	OCCUR	Occurrence	Sensitivity To Sound	MIGRAINE SYMPTOMS	N	N
9	ABC	FA	ABC-123	10	90567	OCCUR	Occurrence	Nausea	MIGRAINE SYMPTOMS	N	N
10	ABC	FA	ABC-123	12	90567	OCCUR	Occurrence	Aura	MIGRAINE SYMPTOMS	Y	Y
11	ABC	FA	ABC-123	13	90567	SEV	Severity/Intensity	Migraine	MIGRAINE SYMPTOMS	MILD	MILD
12	ABC	FA	ABC-123	14	90567	OCCUR	Occurrence	Sensitivity To Light	MIGRAINE SYMPTOMS	N	N
13	ABC	FA	ABC-123	15	90567	OCCUR	Occurrence	Sensitivity To Sound	MIGRAINE SYMPTOMS	N	N
14	ABC	FA	ABC-123	16	90567	OCCUR	Occurrence	Nausea	MIGRAINE SYMPTOMS	N	N
15	ABC	FA	ABC-123	18	90567	OCCUR	Occurrence	Aura	MIGRAINE SYMPTOMS	N	N

Row	FADTC	FATPT	FAELTM	FATPTREF
1 (cont)	2007-05-16	5M PRE-DOSE	-PT5M	DOSING
2 (cont)	2007-05-16	5M PRE-DOSE	-PT5M	DOSING
3 (cont)	2007-05-16	5M PRE-DOSE	-PT5M	DOSING
4 (cont)	2007-05-16	5M PRE-DOSE	-PT5M	DOSING
5 (cont)	2007-05-16	5M PRE-DOSE	-PT5M	DOSING
6 (cont)	2007-05-16	30M POST-DOSE	PT30M	DOSING
7 (cont)	2007-05-16	30M POST-DOSE	PT30M	DOSING
8 (cont)	2007-05-16	30M POST-DOSE	PT30M	DOSING
9 (cont)	2007-05-16	30M POST-DOSE	PT30M	DOSING
10 (cont)	2007-05-16	30M POST-DOSE	PT30M	DOSING
11 (cont)	2007-05-16	90M POST-DOSE	PT90M	DOSING
12 (cont)	2007-05-16	90M POST-DOSE	PT90M	DOSING
13 (cont)	2007-05-16	90M POST-DOSE	PT90M	DOSING
14 (cont)	2007-05-16	90M POST-DOSE	PT90M	DOSING
15 (cont)	2007-05-16	90M POST-DOSE	PT90M	DOSING

Migraine Symptoms Diary	
Migraine Reference Number	xx
When did the migraine start	DD-MMM-YYYY HH:MM
Answer the following **5 Minutes BEFORE Dosing**	
Severity of Migraine	○ Mild ○ Moderate ○ Severe
Associated Symptoms: Sensitivity to light Sensitivity to sound Nausea Aura	 ○ No ○ Yes ○ No ○ Yes ○ No ○ Yes ○ No ○ Yes
Answer the following **30 Minutes AFTER Dosing**	
Severity of Migraine	○ Mild ○ Moderate ○ Severe
Associated Symptoms: Sensitivity to light Sensitivity to sound Nausea Aura	 ○ No ○ Yes ○ No ○ Yes ○ No ○ Yes ○ No ○ Yes
Answer the following **90 Minutes AFTER Dosing**	
Severity of Migraine	○ Mild ○ Moderate ○ Severe
Associated Symptoms: Sensitivity to light Sensitivity to sound Nausea Aura	 ○ No ○ Yes ○ No ○ Yes ○ No ○ Yes ○ No ○ Yes

Mapping this information in FA, as this is finding more about a Clinical event

RELREC for relationship between two Datasets (Contd…)

relrec.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
1	ABC	CE		CESPID		ONE	1
2	ABC	FA		FASPID		MANY	1

Relationship between two datasets CE and FA based on earlier example

RECAP Points

- The RELREC is important that it can **identify relationships** between records in two (or more) domains
- Relationship represented in RELREC is collected relationships, either by explicit references or check boxes on the Case Report Form (CRF) and **this relationship can only be mapped to RELREC**
- **SEQ i**s used to be the **IDVAR to merge/join** records between datasets when relating records for a subject while **GRPID playing the same role when relating across datasets**

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