



An introduction of SDTM domain RELREC

David Shang May24, 2013

Outline

- What is Related Records (RELREC) dataset
- Standard RELREC dataset
- Relate records for one subject in RELREC
- Relate SDTM datasets in RELREC
- Summary

An asymptomatic episode is defined as an episode without symptoms of hypoglycemia, but with a fingerstick glucose level ≤ 70 mg/dL

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graph TD; A[An asymptomatic episode is defined as an episode without symptoms of hypoglycemia, but with a fingerstick glucose level ≤70 mg/dL] --> B[1. Episode with/without symptoms of hypoglycemia is mapped into CF domain<br/>2. Episode fingerstick glucose value is mapped into LB domain]; B --> C[Using RLEREC to link together and then define what is asymptomatic episode];
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1. Episode with/without symptoms of hypoglycemia is mapped into CF domain
2. Episode fingerstick glucose value is mapped into LB domain

Using RLEREC to link together and then define what is asymptomatic episode

Five types of relationship in SDTM

- relationship between a group of records for a given subject within same dataset
 - CMGRPID
 - **relationship between independent records for a subject**
 - **a concomitant medication to treat adverse event**
 - **relationship between two datasets where records of one dataset is related to records in another dataset**
 - **MS (microbiology specimen) related with MB (microbiology susceptibility)**
 - Relationship between non-standard variables and its parent domain
 - SUPPQUAL (supplemental qualifiers) domain
 - relationship between a comment in the CO (comment) domain and parent record(s) in other datasets
 - comment recorded in association with an adverse event
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- RELREC

What is RELREC domain?

- The Related Record (RELREC) dataset is used to describe
 - relationship between records for a subject
 - relationship between datasets
- Relationship is defined by adding a record to RELREC for each record to be related and by assigning a unique character identifier value for the relationship

Standard RELREC dataset

Variable	Description
STUDYID	Study Identifier
RDOMAIN	Two-character abbreviation domain code of the record in the relationship
USUBJID	Unique Subject Identifier
IDVAR	Unique Record Identifier
IDVARVAL	Value of corresponding IDVAR
<u>RELTYPE</u>	Relationship Type. Value should be either ONE or MANY. Used only when identifying a relationship between datasets
<u>RELID</u>	Relationship Identifier

STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
ABC101	AE	123456	AESEQ	5		1
ABC101	CM	123456	CMSEQ	1		1
ABC101	CM	123456	CMSEQ	2		1
ABC101	LB	123456	LBSEQ	3		1
ABC101	LB	123456	LBSEQ	4		1

Relate records for one subject in RELREC

- Used for collected relationship
(not post hoc determinations)
- Single record can be related by using a unique-record-identifier variable such as AESEQ in IDVAR
- Group records can be related by using grouping variable such as LBGRPID in IDVAR
- If relation is constructed, RELID must be identical for all related records within each subject

Example 1:

Table 1: Record in DS domain

STUDYID	DOMAIN	USUBJID	DSSEQ	DSTERM	DSDECODE	DSCAT	EPOCH	DSDTC
ABC123	DS	123101	1	Heart Failure	DEATH	DISPOSITION EVENT	TREATMENT PHASE	2010-03-10

Table 2: Record in AE domain

STUDYID	DOMAIN	USUBJID	AESEQ	AETERM	AEDECODE	AEBODYSIS	AESER	AESTDH	AESTDTC	AEENDTC
ABC123	AE	123101	2	Heart Failure	HEART FAILURE	CARDIOVASCULAR SYSTEM	Y	Y	2010-03-10	2010-03-10

Example 1:

Table 3: Records in RELREC

STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
ABC123	DS	123101	DSSEQ	1		1
ABC123	AE	123101	AESEQ	2		1

For subject 123101, the disposition record (DSSEQ = 1) is related to AE record (AESEQ = 2). These two records are assigned with RELID = 1

Example 2:

Background: The hypoglycemia (CAH) form collects both clinical findings and lab result of finger glucose and these two information are mapped to CF and LB domain respectively.

- Table 1: Raw CAH data pre-mapped

USUBJID	VISITNM	DT_ASSESSMENT	DT_EPISODE	TM_EPISODE	REQUIRE_MED_ATTENTION	GLUCOSE	GLUCOSE_UNIT
000010	CAH/FSG	9/14/2010	2/4/2010	11:05	N	160	mg/dL

Example 2:

Table 2: Record in CF domain

USUBJID	DOMA IN	CFGRPID	CFSEQ	VISIT	CFDTC	CFTEST	CFORRES
000010	CF	CAH	22	V8 week 34	2010-9-14	Receive Medical Attention for Symptoms	N

Table 3: Record in LB domain

USUBJID	DOMA IN	LBGRPID	LBSEQ	LBDTC	LBTEST	LBORRES	LBORRESU
000010	LB	CAH	29	2010-09-14T11:05	Glucose	160	mg/dL

Table 4: Record showed in RELREC

RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
CF	000010	CFSEQ	22		A
LB	000010	LBSEQ	29		A

Through RELREC, we can then combine the relevant LB and CF record together which will facilitate to create the ADaM dataset.

Example 3:

Table 1:

STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
EFC1234	AE	123456	AESEQ	5		1
<i>EFC1234</i>	<i>CM</i>	<i>123456</i>	<i>CMSEQ</i>	<i>11</i>		<i>1</i>
<i>EFC1234</i>	<i>CM</i>	<i>123456</i>	<i>CMSEQ</i>	<i>12</i>		<i>1</i>

Table 2:

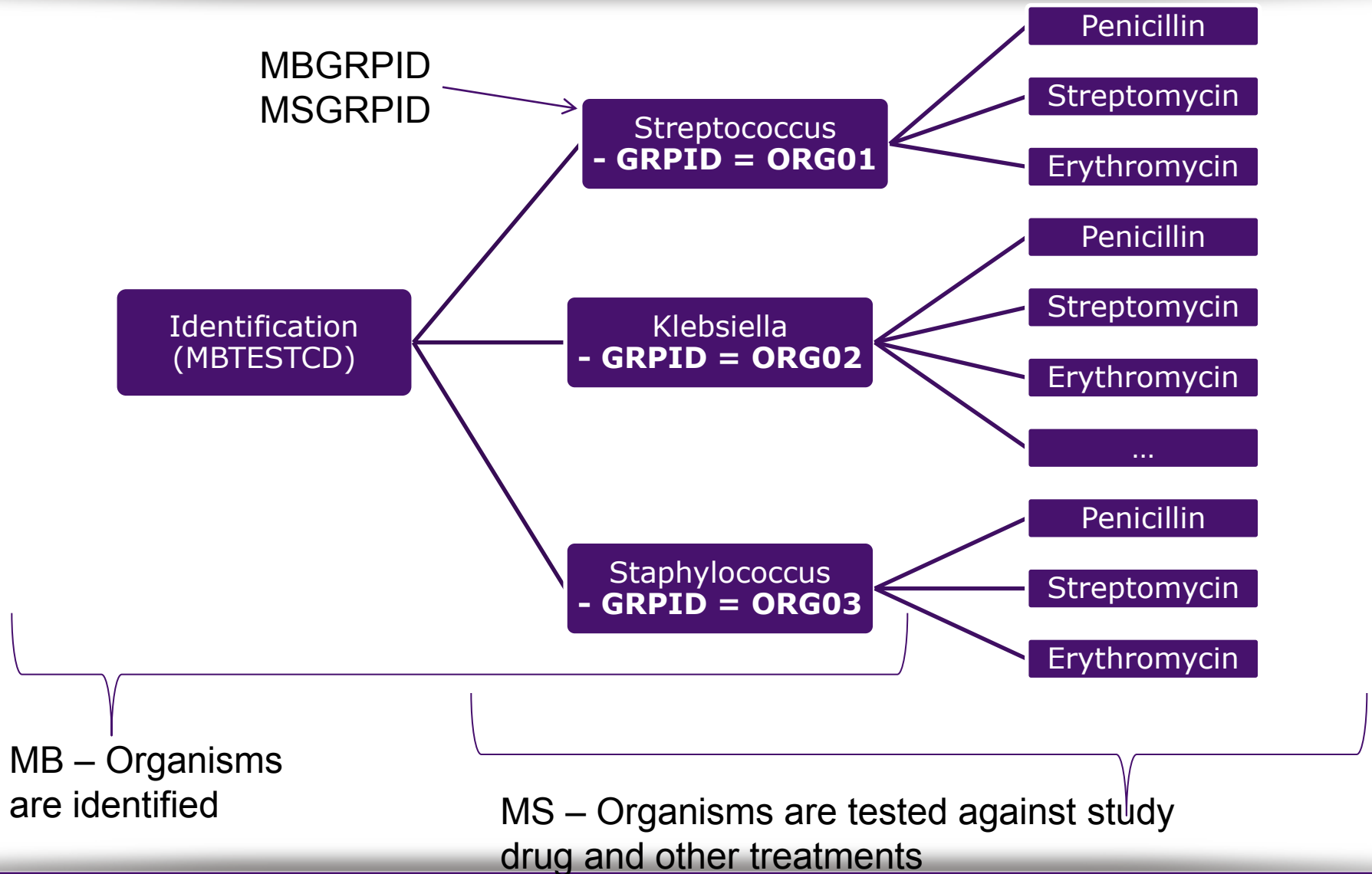
STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
EFC1234	AE	123456	AESEQ	5		1
<i>EFC1234</i>	<i>CM</i>	<i>123456</i>	<i>CMGRPID</i>	<i>COMBO1</i>		<i>1</i>

- In table 1, the two CM records (CMSEQ=11&12) are linked with AE (AESEQ=5)
- In table 2, CM have been grouped in the CM dataset by assigning a CMGRPID with 'COMBO1'
- This allows the elimination of a record in RELREC dataset

Relate SDTM datasets in RELREC

- The relationship within datasets is defined by including a single record for each related dataset that identifies the keys of the dataset that can be used to relate the respective records
- RELTYPE is required. Values should be either ONE or MANY
- USUBJID is not populated because the relationship exists for all subjects
- IDVARVAL is not populated because the relationship exists for all values of IDVAR within a subject

Example 4:



Example 4:

Table 1: Microbiology Specimen (MB) Dataset

STUDYID	DOMAIN	USUBJID	MBGRPID	MBTESTCD	MBORRES
EFC1234	MB	123456	ORG02	ORGANISM	Klebsiella Pneumoniae
EFC1234	MB	123456	ORG01	ORGANISM	Strptococcus Pneumoniae

Table 2: Microbiology Susceptibility (MS) Dataset

STUDYID	DOMAIN	USUBJID	MSGRPID	MSTEST	MSORRES
EFC1234	MS	123456	ORG02	Amoxicillin	0.25 mcg/mL
EFC1234	MS	123456	ORG02	Clavulanic Acid	0.1 mcg/mL
EFC1234	MS	123456	ORG02	Erythromycin	0.5 mcg/mL

Example 4:

Table 3: Records in RELREC

STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
EFC1234	MB		MBGRPID		ONE	A
EFC1234	MS		MSGRPID		MANY	A

Now the MB can be linked to MS by each organism within each subject.

Summary

- 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 is 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

Thanks for your attention!

Contact me with
junjie.shang@ppdi.com