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RELREC - SDTM Programmer's Bermuda Triangle

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ABSTRACT

The CDISC Study Data Tabulation Model (SDTM) provides framework for organizing and converting clinical trial data into standard formats. This supports easy interpretation and maintaining consistency across trials. Sometimes, it becomes vital to establish relationship between records/datasets in SDTM to facilitate linking process at the time of conversion. Logic of relationship is either identified by profile/outliers in data (ex: PC and PP) or by identifying the data link between domains to examine associated information from individual domains collectively (ex: TU, TR and RS).

Related Records (RELREC) - Special Purpose Relationship Domain - can capture these explicit and inexplicit relationship(s) to aid further in-depth exploration of data collected during trials. Often, perceived as a challenging zone, this beauty is yet to be explored to its maximum potential.

This paper details the process to standardize relationships within and between SDTM domains by using the concept of Group Identifier (--GRPID - a variable used to link a block of related records within a subject in a domain), distinct requirements for assigning RELID, appropriate usage of RELTYPE and best variables to be considered for populating IDVAR in the following scenarios:

i. The relationship between an intervention and its findings related to the efficacy endpoints of the clinical study

ii. The relationship and control of event record over intervention, exposure and disposition of the subject involved in the trial

iii. The relationship between oncology specific domains and

iv. The relationship between pharmacokinetics domains

INTRODUCTION

The Clinical Data Interchange Standards Consortium (CDISC) is a non-profit organization, started in 2000, to develop global and platform-independent standards for clinical trial data, to improve its data quality and to accelerate the product development. It has established standards to support the acquisition, exchange, submission and archive of clinical research data and metadata.

The CDISC Study Data Tabulation Model (SDTM) provides framework for organizing and converting clinical trial data into standard formats. It is usually described as the study source data i.e. contents and structure of data collected during a clinical trial. SDTM provides a standardized platform-independent mechanism for representing all the essential information collected in clinical trial with intent to easily interpret, understand, and navigate. The purpose of SDTM is to provide regulatory authority reviewers a clear description of the structure, attributes and contents of each dataset and variables submitted as part of a product application.

In some circumstances, during data conversion to SDTM standards, it becomes vital to establish relationship between records/datasets in SDTM to achieve the standard. The logic of these relationship is either identified by profile/outliers in data (ex: PC and PP) or by identifying the data link between domains to examine associated information from individual domains collectively (ex: TU, TR and RS).

The CDISC SDTM provides several ways to relate records within and between SDTM domains. Records within a domain can be related by assigning them the same value for --GRPID. The --GRPID supports the relationships within and between domains by being an ideal identifying variable(IDVAR) in RELREC. The RELREC dataset can be used to relate multiple records in multiple domains. The types of relationships that can be established using SDTM are:

- Record to record relationship
  - --GRPID

- Dataset to dataset relationship (using RELREC)
  - PR to FA
  - AE to CM, EX and DS
  - TU, TR, RS and PR
  - PC and PP

RECORD TO RECORD RELATIONSHIP

--GRPID

One of the optional grouping identifier in CDISC SDTM is --GRPID and it can be used across all domains of SDTM. The --GRPID variable can be used to establish a relationship between a set of observations which bear similarities within a subject in a dataset i.e., the value of --GRPID can be used to subset the observations within an USUBJID. For instance, when the severity changes for an AE that occurred in a subject in a study, the AEs collected can be grouped using AEGRPID. This example is shown in Table 1 below.

Row	STUDYID	DOMAIN	USUBJID	AEGREFID	AETERM	AESEV
1	ABC123	123101	1		NAUSEA	MODERATE
2	ABC123	123101	2	1	VOMITING	MILD
3	ABC123	123101	3	1	VOMITING	SEVERE
4	ABC123	123101	4	1	VOMITING	MILD
5	ABC123	123101	5	2	DIARRHEA	SEVERE
6	ABC123	123101	6	2	DIARRHEA	MODERATE

Table 1. AE dataset showing the --GRPID

The --GRPID has no inherent meaning across the subjects/domains in the study. All observations in the same domain with the same --GRPID value are a group of records within an USUBJID. The --GRPID can be assigned in a logical and sequential manner, during/after data collection. It does not have any restriction with respect to controlled terminology of the SDTM. The grouping variable comes in handy when relating peer records of the data collected. It also allows repeated events/assessments to be grouped logically for analysis. For example, grouping retests done on a few parameters in the LB domain allows for separate analyses of these tests.

Another example can be provided in the TU domain, where the TUGRPID can be used to identify the 'parent' tumor of split tumors and the 'parents' of merged tumors as shown in the sample TU dataset shown in Table 2 below.

DOMAIN	USUBJID	TUGRPID	TULNKID	TUTESTCD	TUTEST	TUORRES
TU	40004		T04	TUMIDENT	Tumor Identification	TARGET
TU	40004		NT01	TUMIDENT	Tumor Identification	NON-TARGET
TU	40004	T04	T04.1	TUSPLIT	Tumor Split	TARGET
TU	40004	T04	T04.2	TUSPLIT	Tumor Split	TARGET
TU	40004	T02/T03	T02/T03	TUMERGE	Tumor Merged	TARGET
TU	40004		NEW01	TUMIDENT	Tumor Identification	NEW

Table 2. TU dataset showing --GRPID

DATASET TO DATASET RELATIONSHIP

RELREC

The RELREC domain defines a relationship between independent records in separate domains to capture its consistency (dependencies between variables) and referential integrity (dependencies across domains). The RELREC records identify the related domains, define the variables that identify the related records, specify the relationship type, and give each relationship a unique identifier.

Basic structure of RELREC

The following variables are present in the RELREC domain

STUDYID, RDOMAIN, USUBJID, IDVAR, IDVARVAL, RELTYPE, and RELID

The key variables in the RELREC domain are:

STUDYID, RDOMAIN, USUBJID, IDVAR, IDVARVAL, and RELID

Definition of the variables in RELREC

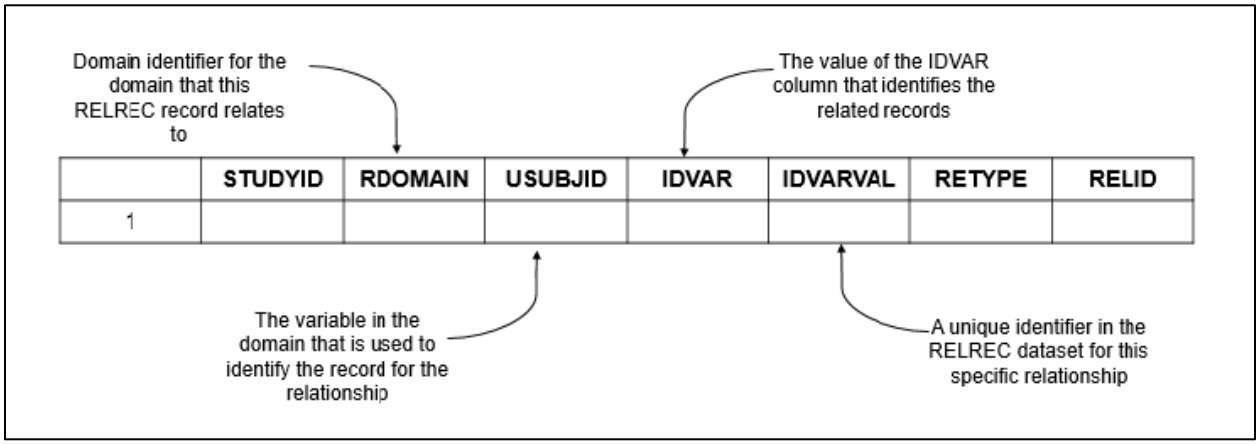

Figure 1. Definition of variables

In RELREC, a relationship is created by adding a record to RELREC for each record to be related and by assigning a unique character identifier value for that relationship. Each record in the RELREC domain contains keys that identify a record (or group of records) and the relationship identifier stored in the RELID variable. The value of RELID must be identical for all related records within each USUBJID.

For each relationship, there are always two records required in the RELREC dataset– one for each domain in the relationship, with each record containing a value pointing to the domain and the record that is part of the relationship.

Identifying Relationships in RELREC – 2-way Approach

The relationships in RELREC can be identified in two ways – Prospective and retrospective.

Prospective Way:

- Identify all combinations (typically pairs) of domains which could logically generate RELREC records
- Trim this list down in consultation with the study statistician, safety physician and clinical scientist.

Retrospective Way:

- RELREC records are created based on the data collected through CRF to prove a certain scientific rationale/ inputs from biostatistician/clinical scientist
- Review of the prospective list to avoid mundane reporting into the CSR.

Type of relationships in RELREC

Explicit

These are collected relationships, either by explicit references or check boxes on the CRF. The classic example for this type of relationship is the link between AE and CM records.

Inexplicit

These are relationships established between variables from the same CRF pages mapped to different SDTM domains to comply with the SDTM IG. Although different information is mapped to different domains, the relationship that is established in RELREC shows that they are related – both come from the same CRF page at the same assessment. The example which will depict this relationship are records from events linked to finding domains.

Usage of RELTYPE

The RELTYPE variable is populated only in circumstances when two entire datasets are fully related. The variable RELTYPE identifies the type of relationship between the datasets. The permissible values for populating RELTYPE – ONE and MANY. The information defines how to merge/join the data, and what would be the outcome of the merge/join.

The subject information like USUBJID will not be provided when RELTYPE is populated, as it implies that entire datasets are linked to get complete information. The possible combinations are:

ONE and ONE

This combination indicates that there is no hierarchical relationship between the datasets and the records in the datasets. Only one record from each dataset will potentially have the same value of the IDVAR within USUBJID.

ONE and MANY

This combination indicates that there is a hierarchical (parent/child) relationship between the datasets. One record within USUBJID in the dataset identified by RELID will potentially have the same value of the IDVAR with many (one or more) records in the dataset identified by RELID.

MANY and MANY

This combination is unusual and challenging to manage in a merge/join.

Assigning RELID

The RELREC dataset has a unique variable named RELID (Relationship Identifier), which is identical for all related records. The value of RELID can be customized by the programmer. It will be ideal to set a meaningful value to RELID allowing the traceability of the related records.

The best practice of creating RELIDs is to use the related domain abbreviations as the first four characters of the RELID and adding a sequential number to it if more than one relationship exists. For instance, the RELID for the records linked between AE and CM will be AECM001, AECM002, and so on. The sequential number can be created as a part of programming after the records are linked in the initial stages.

The number suffixed to the RELID can be numbered sequentially, or it can have digit level values like 1, 10, 100, and so on for better clarity. The suffix can also be a roman numeral like I, II, III, IV, V, X and so on. It is left to the proficient SDTM programmer's to showcase a unique way of numbering.

The below SAS code is the sample for creating RELID programmatically:

```
data ae_cm;
    merge ae (in=a) cm (in = b);
    by usubjid aeid;
    if a and b;
run;
```

```
proc sort data = ae_cm out= ae_cm_;
    by usubjid aeid;
run;
data seq_cm;
    set ae_cm_;
    by usubjid aeid;
    if first.usubjid then seq = 1;
     else seq+1;
     RELID = compress('AECM'||put(seq,best.));
run;
```

CASE STUDIES

INTERVENTION RECORD RELATED TO FINDINGS RECORDS

PR related to FA

An oncology study which considers the prior radio therapy for checking medical condition of all subjects participating in the clinical trial. The eCRF page captures the following:

1. Location of the radiotherapy
2. Start and end of radiotherapy
3. Type of radiotherapy
4. The patient's best response for that radiotherapy
5. Further chemotherapy taken
6. If progression occurred

DOMAIN	USUBJID	PRSEQ	PRSPID	PRTRT	PRSTDTC	VISIT	PRPRESP
PR	9999-1212	1	DAY2-018	RADIO THERAPY	2012-08-22	DAY2	Y

Table 3. SDTM.PR dataset

DOMAIN	USUBJID	FASEQ	FASPID	FAOBJ	FATEST	FASTRESC	VISIT	FAPRESP
FA	9999-1212	1	DAY2-018	RADIO THERAPY	Progression	Y	DAY2	Y
FA	9999-1212	2	DAY5-010	RADIO THERAPY	Best Response	STABLE DISEASE	DAY5	Y

Table 4. SDTM.FA dataset

As per SDTMIG, the points 1-3 can be standardized under PR domain as it is about therapeutic and diagnostic procedures. The points 4-6 are questions related to response or progressions, which are significant for analysis in an oncology study. Therefore, for better utilization of the data, it is captured in FA.

To perform further analysis, it is important to know the best response corresponding to each PR record. So, a dataset-level relationship between PR and FA is established.

IDVAR:

The inexplicit relationship between the PR and FA can be established using the –SPID. The value of SPID will be populated with a database generated unique identifier for each iteration of this form with which we can relate the PR and FA records. IDVARVAL will not be populated with the value of –SPID as the relationship exists for all the values of IDVARVAL.

RELTYPE:

In this case study, all the subjects participating in the trial are undergoing the prior radio therapy. Therefore, RELTYPE will be populated. This combination of records indicates that there is a hierarchical (parent/child) relationship between the datasets which would mean a 'One to Many' relationship.

RELID:

A single value of RELID establishes the complete relationship in this scenario. The ideal RELID will be the summation of the domain abbreviations, i.e., PRFA.

STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
XYZ-8888	PR		PRSPID		ONE	PRFA
XYZ-8888	FA		FASPID		MANY	PRFA

Table 5. RELREC dataset linking PR to FA

The below SAS code is the mockup for creating the RELREC dataset for this example:

```
DATA relrec;
     INFILE DATALINES;
     length   RDOMAIN $2 IDVAR $8 RELTYPE $4 RELID $3;
     INPUT RDOMAIN $ IDVAR $ RELTYPE $ RELID $;
     DATALINES;
         PR PRSPID ONE PRFA
         FA FASPID MANY PRFA
   ;
run;
```

EVENT RECORD RELATED TO INTERVENTION RECORDS (CM & EX) AND DISPOSITION OF THE SUBJECT

AE related to CM, EX and DS

A clinical study is conducted for assessing the safety and efficacy of the study drug administrated. The following are captured in eCRF

a) Concomitant Medication Page

b) Start Date

Prior/Concomitant Medications and Treatments (CONMED) – Repeating Form (CONMED)											
#	Sequence No.	Medication Name	Taken Prior to Study?	Anti Tumour Therapy	Start Date	Dose	Dose Unit	Route	Frequency	Reason for taking Medication	Ongoing
1											

The '**Reason for Medication**' collects the reason for the concomitant medication administration. Usually, concomitant medications are administrated to treat the adverse events observed during a study. The concomitant medications may have substantial efficacy implications on the study drug. For this purpose,

the relationships are established between AE and CM records, concentrating on serious adverse events(SAEs).

c) Disposition Page

End of Study:	
End of Study*:	
Completion or Discontinuation Date	
Completion or Discontinuation Time	
Status	COMPLETED|COMPLETED ADVERSE EVENT|ADVERSE EVENT LOST TO FOLLOW UP|LOST TO FOLLOW UP WITHDRAWAL BY SUBJECT|WITHDRAWAL BY SUBJECT STUDY TERMINATED BY SPONSOR|STUDY TERMINATED BY SPONSOR PHYSICIAN DECISION|PHYSICIAN DECISION PROTOCOL VIOLATION|PROTOCOL VIOLATION DEATH|DEATH OTHER|OTHER [completion reason for non completion]

The protocol may have a series of checks for certain non-compliances at every visit. Thus, certain AEs can make a subject non-compliant and result in termination from the study. Since an AE is the main cause of termination, it is beneficial to relate it to the disposition data.

d) Exposure Page

Exposure:	
Exposure*:	
Start Date and Time	datetime
End Date and Time	datetime
Dose	float
Lot Number	text
Treatment Name	text
Adjusted	N|No Y|Yes [No Yes Response]
Reason Adjusted	text

During a trial, the study drug dose is adjusted for various reasons, including impact of multiple lab test values, duration of administration or investigator decision. The dose is also adjusted after the occurrence of an AE. Establishing this relationship shows the effect of the AE on the exposure of the study drug. Prolonged/Serious AEs may lead to discontinuation of the study drug also. Tables 6, 7, 8 and 9 show sample data in the AE, CM, DS and EX domains.

DOMAIN	USUBJID	AESEQ	AESPID	AETERM
AE	12345	20	15	ACUTE VIRAL NASOPHARYNGITIS

Table 6. SDTM.AE dataset

DOMAIN	USUBJID	CMSEQ	CMSPID	CMTRT	CMINDC
CM	12345	10	2	AVAMYS	AE

Table 7. SDTM.CM dataset

DOMAIN	USUBJID	DSSEQ	DSTERM	DSDECOD	DSSCAT
DS	12345	5	AE: ACUTE VIRAL NASOPHARYNGITIS	ADVERSE EVENT	END OF STUDY

Table 8. SDTM.DS dataset

DOMAIN	USUBJID	EXSEQ	EXTRT	EXDOSE	EXADJ
EX	12345	4	XYZ	20	
EX	12345	5	XYZ	10	ADVERSE EVENT
EX	12345	6	XYZ	0	

Table 9. SDTM.EX dataset

IDVAR:

The explicit relationship between AE intervention records and disposition records can be established using --SEQ as the IDVAR, when there is a one to one record mapping relationship. The --GRPID variable can also be used when a group of AEs form a similar relationship. The usage of --GRPID will lessen the iteration of review. Care has to be taken when considering --GRPID variable. It should be employed for similar relationships only. The --SPID variable can also be considered as the IDVAR, as the information is collected in the CRF. The value of the IDVAR should be ideally used as IDVARVAL for better traceability and referential integrity.

RELTYPE:

The RELTYPE will be not populated in this case, as it's a subject level relationship. It will be left BLANK in the final RELREC dataset.

RELID:

The RELID will be the domain abbreviations followed by a sequential number.

Table 10 shows the RELREC dataset created for this example linking AE, CM, DS and EX datasets.

STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
ABC-999	AE	12345	AESPID	15		AECM1
ABC-999	AE	12345	AESEQ	5		AEDS1
ABC-999	AE	12345	AESEQ	5		AEEX1
ABC-999	CM	12345	CMSPID	21		AECM1
ABC-999	DS	12345	DSSEQ	10		AEDS1
ABC-999	EX	12345	EXSEQ	23		AEEX1

Table 10. RELREC dataset linking AE, CM, DS and EX

ONCOLOGY DOMAINS RELATIONSHIP

TR, TU and RS

The domains, TU and TR are intended to represent data collected in oncology trials where tumors or lymph nodes are identified at baseline visits and then repeatedly measured or assessed at subsequent time points to support assessment criteria such as RECIST (solid tumors), Cheson2 (e.g. lymphoma), or, Hallek3(3) (chronic lymphocytic leukemia). The results of these measurements and assessments are used in the evaluation of the disease response.

Response data is one of the key efficacy measurements for oncology trials. It is collected in RS domain with the assessment criteria terminology. There are generally two types of efficacy analysis for oncology trials that require response endpoint data: response analysis and time-to-event analysis. By adopting these

standard structures, the data from independent vendors can be collaborated efficiently and the standardized data can be utilized directly for analysis.

IDVAR:

The three oncology domains mentioned above are closely associated to form a complete package of disease response data. The --LNKID/--LNKGRP variable provides a unique code for each identified tumor, and for each response and associated tumor measurements/assessments. This helps build a comprehensive relationship between the three oncology domains to ensure their organic integrity. --LNKID is more like a point to point linkage, whereas, --LNKGRP link the records having RSTEST= "Overall Response" in the RS to TR as a one to many linkages.

RELTYPE:

The RELTYPE will be not populated when it's a subject level relationship. In this oncology study example, all the subjects are considered to have this relationship. Therefore, the RELTYPE is populated.

RELID:

The RELID will be the domain abbreviations followed by a sequential number/roman numeral.

The RELREC dataset for this example is shown in Table 11.

STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
ABC12345	TU		TULNKID		ONE	TUTR-I
ABC12345	TR		TRLNKID		MANY	TUTR-I
ABC12345	TR		TRLNKGRP		MANY	TRRS-II
ABC12345	RS		RSLNKGRP		ONE	TRRS-II
ABC12345	PR		PRREFID		ONE	PRTU-I
ABC12345	TU		TUREFID		MANY	PRTU-I
ABC12345	PR		PRLNKGRP		MANY	PRRS-III
ABC12345	RS		RSLNKGRP		ONE	PRRS-III

Table 11. Oncology domains linked among themselves and with PR which captures the Procedure methods

The mock SAS code for deriving the relationships mentioned above:

```
****Creating TU & TR rel data*****;
proc sort data= sdtm.tr out=tr;
    by usubjid trlnkid;
run;
proc sort data= sdtm.tu out=tu;
    by usubjid tulnkid;
run;
proc sql;
    create table in1_2 as select * from tu a inner join (select * from tr)
as tr
    on a.usubjid = tr.usubjid and a.tulnkid = tr.trlnkid;
quit;
proc sort data = in1_2 out = in1_2_;
    by usubjid lnkid;
run;
data rel_tr_tu;
    set in1_2_;
    by usubjid lnkid;

    seq+1;
    if first.usubjid then seq = 1;
```

```
    RELID = compress("TUTR"||put(seq,best.));
run;
/*APPENDING TR TO TU*/
data tr_tu_fin;
    set rel_tr_tu (in=a)
        rel_tr_tu (in=b);
    if b then do;
        idvar = 'TRLNKID';
        idvarval = trlnkid;
        rdomain = 'TR';
    end;
run;
```

PHARMACOKINETICS DOMAINS RELATIONSHIP

PC and PP

Pharmacokinetics can be defined as the study of the time course of drug absorption, distribution, metabolism, and excretion. Clinical pharmacokinetics is the application of pharmacokinetic principles to the safe and effective therapeutic management of drugs under development in an individual patient.

The PC domain captures the pharmacokinetics data as the concentration of the drug/metabolites in blood/plasma and/or urine sample collected at various timepoints in the trial. The time-concentration profiles are analyzed for the pharmacokinetic characteristics of the drug and related analytes.

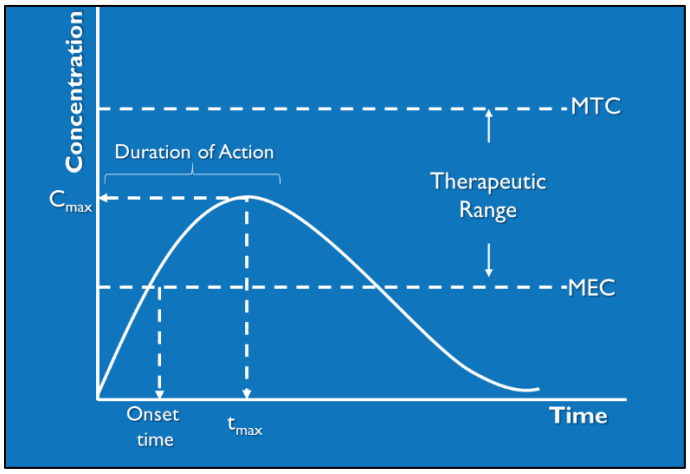

Figure 2. Time Concentration Profile

Thus, the PC domain ultimately forms the basis of the pharmacokinetic analysis used to derive multiple pharmacokinetic parameters for each individual Pharmacokinetic (PK) profile (such as C_{max}, t_{max}, AUC, half-life, etc.), which are subsequently submitted in the Pharmacokinetic Parameter (PP) domain. Each record in PP contains a value that is calculated based on a profile in the PC domain.

IDVAR:

The explicit relationship between PC and PP can be best described using the –GRPID. The PCGRPID will link all the records in the PC domain to be utilized in the calculation of certain PK parameters. The PPGRPID will be the linking of records within the PP domain which depends on a similar set of records in PC domain.

RELTYPE:

The RELTYPE will be left blank in this case, as it's a subject level relationship.

RELID:

The RELID can be the domain abbreviations followed by a sequential number. It can also be a combination of the domain abbreviations with suffixed alphabets for better clarity.

Table 12 shows the RELREC dataset for the linked pharmacokinetics domains.

STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
XYZ123	PC	XYZ123-001	PCGRPID	DY1-DRGX		PCPP-I
XYZ123	PP	XYZ123-001	PPGRPID	DY1-DRGX		PCPP-I
XYZ123	PC	XYZ123-001	PCGRPID	DY11-DRGX		PCPP-II
XYZ123	PP	XYZ123-001	PPGRPID	DY11-DRGX		PCPP-II

Table 11. Pharmacokinetic domains linked among themselves

CONCLUSION

The RELREC domain provides a flexible method to link data points. RELREC creation can be a herculean task, considering the whirlpool of intertwining data relationships one needs to keep in mind while programming. It is easy to lose track of the end objective while working on RELREC especially when the data relationships are highly complex. That's why I chose to term it as a 'Bermuda Triangle', where the whirlpool of data keeps getting interesting and intertwining more and more that, one can lose track easily. RELREC can be used to establish relationships: between records of a subjects and between different SDTM domains. An additional review of the relationships established will be a good practice, so that unwanted/mismatched relationships with mundane value can be avoided in the CSR.

This paper is an attempt to help programmers with a sequence of considerations for deriving the key variables in RELREC domain through repetitive probable scenarios where the relationships needed to be established in a clinical trial.

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RECOMMENDED READING

Study Data Tabulation Model Implementation Guide: Human Clinical Trials, Version 3.2, CDISC Submission Data Standards Team (November 26, 2013).

Study Data Tabulation Model, Version 1.4, CDISC Submission Data Standards Team (November 26, 2013)

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