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Trial Sets in Human Clinical Trials

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ABSTRACT

The Trial Sets domain specification has been included in the Study Data Tabulation Model (SDTM) since Version 1.3, published in 2012; however, the only implementation guide in which it appears is the SEND ((Standard for the Exchange of Nonclinical Data) Implementation Guide (SENDIG). The Trial Sets dataset (TX) was created to allow the subsetting of subjects within an Arm (treatment path) as well as facilitating the "grouping" multiple Arms together. A Trial Set represents the most granular subdivision of all the experimental factors, treatment factors, inherent characteristics, and distinct sponsor designations as specified in the design of the study.

Within a nonclinical trial, each animal is assigned to a Set in addition to an Arm. The Set Code (SETCD) variable is Required in the SEND DM dataset. While there is no such requirement for the SDTMIG DM dataset, Trial Sets has potential uses in human clinical trials, particularly when the randomization or the study design is based on factors other than treatment (e.g., subjects who have undergone previous heart surgery vs. those who have not). This paper will provide an introduction to Trial Sets as it's used in nonclinical studies as well as examples of how this dataset could be used in human clinical trials.

INTRODUCTION

SEND BACKGROUND

The SENDIG describes the format for the submission of nonclinical tabulation data from general toxicology, pharmacology, and carcinogenicity, studies to regulatory agencies. Version 3.0 was published in 2011, and Version 3.1 was published in 2016, and is based upon Version 1.5 of the SDTM. Details regarding the history, as well as basics of the SENDIG have been published previously (1). How the SENDIG compares to the SDTMIG was the subject of a previous paper (2).

TRIAL SETS RATIONALE AND OVERVIEW

Trial Sets was expressly created for the SENDIG. The Trial Sets dataset provides a mechanism for representing two aspects of a study's design: 1) the subdivision of individual Arms, and 2) the "grouping" of multiple Arms. Examples of these two cases follow.

1) Subsetting within an Arm. Some animals within the same sequence of Elements may be predesignated at the time of randomization for toxicokinetic (TK) sampling. In small animals such as rats and mice, these are often a satellite group. Due to the potential trauma from blood sampling, data from these animals are usually not analyzed with data from the main group. There are other scenarios when animals within an Arm may be divided into groups, such as when animals receive different diets or are housed differently.

2) Grouping of Arms. Nonclinical studies may include "recovery" animals in one or more treatment groups. In such studies, after a period of dosing (e.g., a Treatment Epoch, often 28 days or more), designated animals are sacrificed, while others are maintained with the study treatment suspended (e.g., a Recovery Epoch). While these latter animals will be in a different Arm from those who were sacrificed at the end of the study-treatment period, the data for the Treatment Epoch in both Arms will usually be combined for many analyses.

A Trial Set represents the most granular subdivision of all the experimental factors, treatment factors, inherent characteristics, and distinct sponsor designations as specified in the design of the study. It does so by allowing as many rows per Set as there are parameters of interest. In order to represent these, Trial

Sets was modeled following the structure of Trial Summary, with parameters and values. The TX domain specification is shown Table 1.

Table 1. Trial Sets Domain Specification

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	TX	Identifier	Two-character abbreviation for the domain.	Req
SETCD	Set Code	Char		Identifier	Short name of the Trial Set.	Req
SET	Set Description	Char		Synonym Qualifier	Long description of a specific Trial Set, as defined by the sponsor.	Req
TXSEQ	Sequence Number	Num		Identifier	Unique number for this record within this dataset.	Req
TXPARMCD	Trial Set Parameter Short Name	Char	(STSPRMCD)	Topic	Short character value for the Trial Set parameter described in TXPARM.	Req
TXPARM	Trial Set Parameter	Char	(STSPRM)	Synonym Qualifier	Term for the Trial Set parameter.	Req
TXVAL	Trial Set Parameter Value	Char		Result Qualifier	Value of the Trial Set parameter.	Req

Table 2 shows example of Trial Set parameters and parameter codes, with some of the most common ones shown in bold type. It should be noted that the parameters represent pre-randomization criteria. In other words, they are part of the experimental design. Since SEND has no corresponding concept of analysis datasets (i.e., ADaM), having these parameters in the tabulation datasets is important in the analysis of nonclinical studies.

Table 1. Trial Sets Example Parameters

- Arm Code
- **Control** Type
- Basal Diet
- Environmental Temperature
- Feeding Regimen
- **Group Label**
- Housing Type Housing Humidity
- Light Cycle
- Planned Number of Male Subjects
- Planned Number of Female Subjects
- Planned Number of Subjects
- **Set Label**
- **Sponsor-Defined Group Code**
- Strain/Substrain
- Drinking Water
- Water Delivery
- **Dose Level**
- **Dose Units**

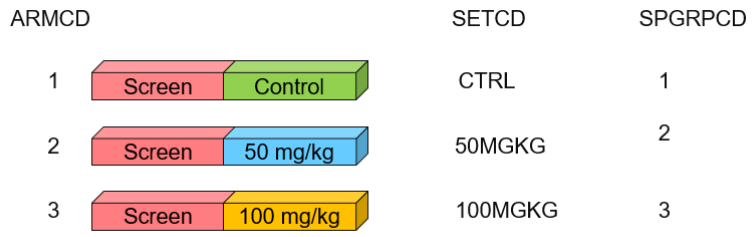
TRIAL SETS IN NONCLINICAL STUDIES

This section will show examples of the implementation of Trial Sets in three common types of nonclinical studies. Additional examples can be found in the SENDIG (3). These examples will show how Trial Sets works, and will help facilitate the understanding of how its use can be applied to human clinical trials.

EXAMPLE 1

The example shows a three-Arm 28-day study with two dose levels (50 and 100 mg/kg) of Drug A plus a control, as shown in Figure 1. The sequence of Elements in each Arm is shown, as are the corresponding values for ARMCD, SETCD (Set Code), and SPGRPID (Sponsor-Defined Group Code), which are all sponsor defined). Since there was no subdivision of Arms in this study, each Arm consists of only one Set. The corresponding Trial Elements and Trial Arms datasets can be found in Appendix A. Some of the more important parameters are shown in the Trial Sets tx.xpt example below the figure.

Figure 1. Design of Study in Example 1



tx.xpt

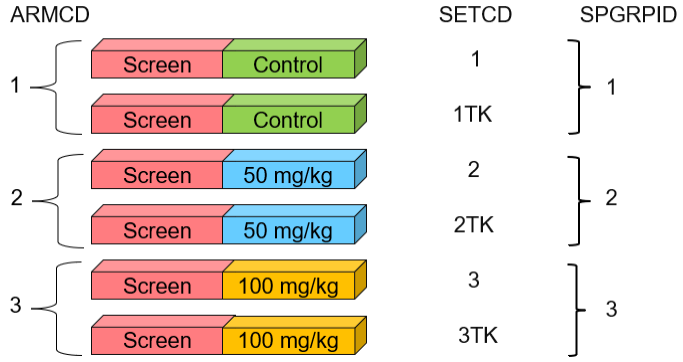
STUDYID	DOMAIN	SETCD	SET	TXSEQ	TXPARMCD	TXPARM	TXVAL
ABC-001	TX	CTRL	Control	1	ARMCD	Arm Code	1
ABC-001	TX	CTRL	Control	2	SPGRPCD	Sponsor-Defined Group Code	1
ABC-001	TX	CTRL	Control	3	TCNTRL	Control Type	Vehicle
ABC-001	TX	CTRL	Control	4	GRPLBL	Group Label	Group 1, Control
ABC-001	TX	CTRL	Control	5	TRTDOS	Dose Level	0
ABC-001	TX	CTRL	Control	6	TRTDOSU	Dose Units	mg/kg
ABC-001	TX	50MGKG	50 mg/kg Drug A	7	ARMCD	Arm Code	2
ABC-001	TX	50MGKG	50 mg/kg Drug A	8	SPGRPCD	Sponsor-Defined Group Code	2
ABC-001	TX	50MGKG	50 mg/kg Drug A	9	GRPLBL	Group Label	Group 2, 50 mg/kg Drug A
ABC-001	TX	50MGKG	50 mg/kg Drug A	10	TRTDOS	Dose Level	50
ABC-001	TX	50MGKG	50 mg/kg Drug A	11	TRTDOSU	Dose Units	mg/kg
ABC-001	TX	100MGKG	100 mg/kg Drug A	12	ARMCD	Arm Code	3
ABC-001	TX	100MGKG	100 mg/kg Drug A	13	SPGRPCD	Sponsor-Defined Group Code	3
ABC-001	TX	100MGKG	100 mg/kg Drug A	14	GRPLBL	Group Label	Group 3, 100 mg/kg Drug A
ABC-001	TX	100MGKG	100 mg/kg Drug A	15	TRTDOS	Dose Level	100
ABC-001	TX	100MGKG	100 mg/kg Drug A	16	TRTDOSU	Dose Units	mg/kg

EXAMPLE 2

This example shows a 28-day study similar to that above in Figure 1. It uses the same dose levels (50 and 100 mg/kg) of Drug A plus a control, but in this study, each Arm had a subset of animals that were predesignated as toxicokinetic animals, and these were planned to be analyzed separately from the main group. Thus, each Arm would be divided into two Sets. The design is reflected in Figure 2. The number of Elements and Arms does not change, but the number of Sets now doubles.

As in Example 1, the sequence of Elements in each Arm is shown, as are the corresponding values for ARMCD, SETCD, and SPGRPID (Sponsor-Defined Group Code). The Trial Elements and Trial Arms datasets would be the same as those in Example 1, while the Trial Sets dataset would become larger with the addition of three more Sets as well as the parameter, TKDESC (Toxicokinetic Description), as shown below the figure. Records for the parameters of Control Type, Dose Level, and Dose Units are the same as those in Example 1, and have been omitted to save space here. The full example can be found in Appendix A.

Figure 2. Design of Study in Example 2



tx.xpt

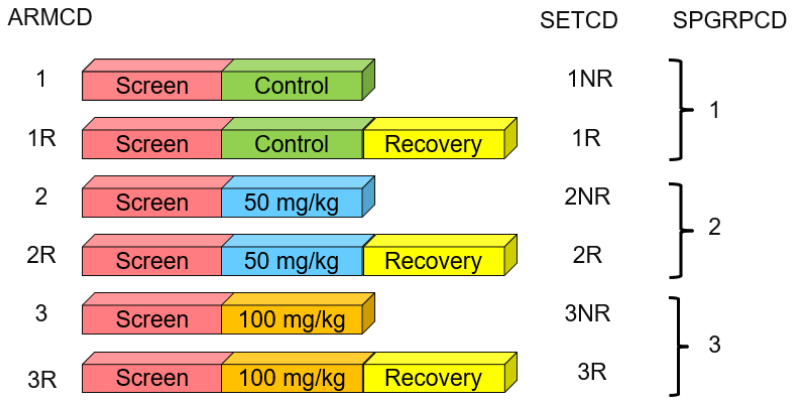
STUDYID	DOMAIN	SETCD	SET	TXSEQ	TXPARMCD	TXPARM	TXVAL
ABC-002	TX	CTRL	Control, Non-TK	1	ARMCD	Arm Code	1
ABC-002	TX	CTRL	Control, Non-TK	2	SPGRPCD	Sponsor-Defined Group Code	1
ABC-002	TX	CTRL	Control, Non-TK	4	GRPLBL	Group Label	Group 1, Control
ABC-002	TX	CTRL	Control, Non-TK	7	TKDESC	Toxicokinetic Description	NON-TK
ABC-002	TX	CTRLTK	Control, TK	8	ARMCD	Arm Code	1
ABC-002	TX	CTRLTK	Control, TK	9	SPGRPCD	Sponsor-Defined Group Code	1
ABC-002	TX	CTRLTK	Control, TK	11	GRPLBL	Group Label	Group 1, Control
ABC-002	TX	CTRLTK	Control, TK	14	TKDESC	Toxicokinetic Description	TK
ABC-002	TX	50MGKG	50 mg/kg Drug A, Non-TK	15	ARMCD	Arm Code	2
ABC-002	TX	50MGKG	50 mg/kg Drug A, Non-TK	16	SPGRPCD	Sponsor-Defined Group Code	2
ABC-002	TX	50MGKG	50 mg/kg Drug A, Non-TK	17	GRPLBL	Group Label	Group 2, 50 mg/kg Drug A
ABC-002	TX	50MGKG	50 mg/kg Drug	20	TKDESC	Toxicokinetic	NON-TK

			A, Non-TK			Description	
ABC-002	TX	50MGKGTK	50 mg/kg Drug A, TK	21	ARMCD	Arm Code	2
ABC-002	TX	50MGKGTK	50 mg/kg Drug A	22	SPGRPCD	Sponsor-Defined Group Code	2
ABC-002	TX	50MGKGTK	50 mg/kg Drug A	23	GRPLBL	Group Label	Group 2, 50 mg/kg Drug A
ABC-002	TX	50MGKGTK	50 mg/kg Drug A	26	TKDESC	Toxicokinetic Description	TK
ABC-002	TX	100MGKG	100 mg/kg Drug A, Non-TK	27	ARMCD	Arm Code	3
ABC-002	TX	100MGKG	100 mg/kg Drug A, Non-TK	28	SPGRPCD	Sponsor-Defined Group Code	3
ABC-002	TX	100MGKG	100 mg/kg Drug A, Non-TK	29	GRPLBL	Group Label	Group 3, 100 mg/kg Drug A
ABC-002	TX	100MGKG	100 mg/kg Drug A, Non-TK	32	TKDESC	Toxicokinetic Description	NON-TK
ABC-002	TX	100MGKGTK	100 mg/kg Drug A, TK	33	ARMCD	Arm Code	3
ABC-002	TX	100MGKGTK	100 mg/kg Drug A, TK	34	SPGRPCD	Sponsor-Defined Group Code	3
ABC-002	TX	100MGKGTK	100 mg/kg Drug A, TK	35	GRPLBL	Group Label	Group 3, 100 mg/kg Drug A
ABC-002	TX	100MGKGTK	100 mg/kg Drug A, TK	38	TKDESC	Toxicokinetic Description	TK

EXAMPLE 3

This example shows a 28-day study similar to those above in Examples 1 and 2. It uses the same dose levels (50 and 100 mg/kg) of Drug A plus a control, but in this study, a Recovery Element was added for each of the dose groups. This results in a doubling of the number of Arms, as shown in Figure 3. The use of the same Sponsor-Defined Group Code (SPGRPCD) in Trial Sets allows for animals from different Arms receiving the same dose level (i.e., 1NR and 1R, 2NR and 2R, and 3NR and 3R) to be grouped together for any necessary analyses. To save space here, the Trial Sets dataset for this study is shown in Appendix A.

Figure 3. Design of Study in Example 3



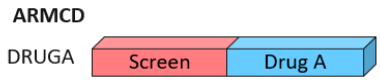
TRIAL SETS IN HUMAN CLINICAL TRIALS

The preceding sections have shown how Trial Sets (TX) is used in nonclinical studies. Human clinical trials may also have experimental variables of interest that are determined prior to randomization. While ADaM can accommodate the analysis of such groupings within and across Arms, Trial Sets allows this distinction to be made in the tabulation datasets. Two potential use cases for TX in human clinical trials are shown in the following examples..

EXAMPLE 1

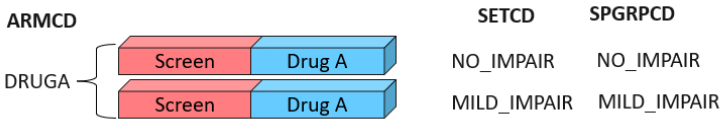
The first example is a trial in which the sponsor will be comparing the safety and efficacy of Drug A in subjects who have mild renal impairment compared to subjects who do not. Establishing this as part of the design and assigning a Set Code (SETCD) to each subject in DM will facilitate making comparisons between the two types of subjects. Without Trial Sets, this study design would have looked like that in Figure 4.

Figure 4. Design of Study in Clinical Example 1 Without Trial Sets



With the use of Trial Sets, the design becomes what is shown in Figure 5.

Figure 5. Design of Study in Clinical Example 1 With Trial Sets:



It can be seen that either way, the number of Elements and Arms is the same. Some key parameters for Trial Sets are shown the table below.

tx.xpt

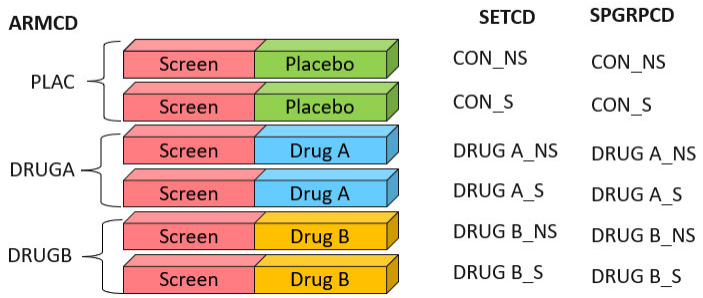
STUDYID	DOMAIN	SETCD	SET	TXSEQ	TXPARMCD	TXPARM	TXVAL
ABC-004	TX	NO-IMPAIR	No Renal Impairment	1	ARMCD	Arm Code	DRUGA
ABC-004	TX	NO-IMPAIR	No Renal Impairment	2	GRPLBL	Group Label	No Impairment
ABC-004	TX	NO-IMPAIR	No Renal Impairment	3	SPGRPCD	Sponsor-Defined Group Code	NO_IMPAIR
ABC-004	TX	NO-IMPAIR	No Renal Impairment	4	TRTDOS	Dose Level	400
ABC-004	TX	NO-IMPAIR	No Renal Impairment	5	TRTDOSU	Dose Units	mg
ABC-004	TX	NO-IMPAIR	No Renal Impairment	6	POPTYPE	Population Type	No Renal Impairment

ABC-004	TX	MILD_IMPAIR	Mild Impairment	7	ARMCD	Arm Code	DRUGA
ABC-004	TX	MILD_IMPAIR	Mild Impairment	8	GRPLBL	Group Label	Drug A, NS
ABC-004	TX	MILD_IMPAIR	Mild Impairment	9	SPGRPCD	Sponsor-Defined Group Code	MILD_IMPAIR
ABC-004	TX	MILD_IMPAIR	Mild Impairment	10	TRTDOS	Dose Level	400
ABC-004	TX	MILD_IMPAIR	Mild Impairment	11	TRTDOSU	Dose Units	mg
ABC-004	TX	MILD_IMPAIR	Mild Impairment	12	POPTYPE	Population Type	Mild Renal Impairment

EXAMPLE 2

The second example consists of a study in which Drug A and Drug B are being compared to a placebo in smokers and non-smokers. Including the smoking status as part of the design and prior to randomization will help ensure that smokers and non-smokers will be equally distributed across the three Arms. The design tresults in six Sets, and is shown in Figure 6. In this design, there is really no need to group Arms using SPGRPID, so the values for smoking and non-smoking Sets and Set Codes can be different.

Figure 6. Design of Study in Clinical Example 2 With Trial Sets



The records in Trial Sets for just the Drug A Arms are shown in the following dataset example.

tx.xpt

STUDYID	DOMAIN	SETCD	SET	TXSEQ	TXPARMCD	TXPARM	TXVAL
TDM10	TX	DRUG A_NS	Drug A Non-Smokers	1	ARMCD	Arm Code	DRUGA
TDM10	TX	DRUG A_NS	Drug A Non-Smokers	2	GRPLBL	Group Label	Drug A, Non
TDM10	TX	DRUG A_NS	Drug A Non-Smokers	3	SPGRPCD	Sponsor-Defined Group Code	DRUG A_NS
TDM10	TX	DRUG A_NS	Drug A Non-Smokers	4	TRTDOS	Dose Level	200
TDM10	TX	DRUG A_NS	Drug A Non-Smokers	5	TRTDOSU	Dose Units	mg
TDM10	TX	DRUG A_NS	Drug A Non-Smokers	6	POPTYPE	Population Type	Non-Smokers
TDM10	TX	DRUG	Drug A	7	ARMCD	Arm Code	DRUGA

		A_S	Smokers				
TDM10	TX	DRUG A_S	Drug A Smokers	8	GRPLBL	Group Label	Drug A, Smokers
TDM10	TX	DRUG A_S	Drug A Smokers	9	SPGRPCD	Sponsor-Defined Group Code	DRUG A_S
TDM10	TX	DRUG A_S	Drug A Smokers	10	TRTDOS	Dose Level	200
TDM10	TX	DRUG A_S	Drug A Smokers	11	TRTDOSU	Dose Units	mg
TDM10	TX	DRUG A_S	Drug A Smokers	12	POPTYPE	Population Type	Smokers

CONCLUSIONS

- Trial Sets is modeled in the SDTM and the SENDIG, but not in the SDTMIG.
- Likewise, the SETCD variable is modeled in Demographics in the SDTM and the SENDIG, but not in the SDTMIG.
- TX Allows for the subdivision of Arms, using different parameters.
- TX Allows for multiple Arms to be “grouped” together (using the TXPARMCD of SPGRPCD).
- The analysis of data in non-clinical studies is based on the SEND datasets, so being able to group animals within and across Arms in the tabulation data is important.
- Trial Sets could be applied to human clinical trials in cases where there are pre-randomization criteria.
- The use of Trial Sets might be more appropriate in early-phase human studies where subjects are recruited for specific characteristics.

REFERENCES

1. Wood, F., and Kramer, L. (2011) SEND History and Basics. PharmaSUG Proceedings, May 2011. http://www.lexjansen.com/pharmasug/2011/CD/PharmaSUG-2011-CD14.pdf.
2. Wood, F. (2016). SEND History, Basics, and Comparisons with Clinical Data. PharmaSUG Proceedings, May 2016. http://www.pharmasug.org/proceedings/2016/SS/PharmaSUG-2016-SS13.pdf.
3. Standard for the Exchange of Nonclinical Data, Version 3.1 (2016). Published by CDISC. https://www.cdisc.org/standards/foundational/send.

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CONTACT INFORMATION

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APPENDIX A

TRIAL DESIGN DATASETS FROM EXAMPLES

EXAMPLE 1, TRIAL ARMS AND TRIAL ELEMENTS

te.xpt

STUDYID	DOMAIN	ETCD	ELEMENT	TESTRL	TEENRL	TEDUR
ABC-001	TE	SCRN	Screen	Start of Pretreatment	1 week after start of Element	P7D
ABC-001	TE	CTRL	Control	First day of dosing with Control	28 days after start of Element	P28D
ABC-001	TE	50MGKG	50 mg/kg Drug A, once daily	First day of dosing with 50 mg/kg Drug A	28 days after start of Element	P28D
ABC-001	TE	100MGKG	100 mg/kg Drug A, once daily	First day of dosing with 100 mg/kg Drug A	28 days after start of Element	P28D

ta.xpt

STUDYID	DOMAIN	ARMCD	ARM	TAETORD	ETCD	ELEMENT	TABRANCH	EPOCH
ABC-001	TA	1	Control	1	SCRN	Screen		SCREEN
ABC-001	TA	1	Control	2	CTRL	Vehicle Control		TREATMENT
ABC-001	TA	2	50 mg/kg	1	SCRN	Screen		SCREEN
ABC-001	TA	2	50 mg/kg	2	50MGKG	50 mg/kg Drug A		TREATMENT
ABC-001	TA	3	100 mg/kg	1	SCRN	Screen		SCREEN
ABC-001	TA	3	100 mg/kg	2	100MGKG	100 mg/kg Drug A		TREATMENT

EXAMPLE 2, TRIAL SETS

STUDYID	DOMAIN	SETCD	SET	TXSEQ	TXPARMCD	TXPARM	TXVAL
ABC-002	TX	CTRL	Control, Non-TK	1	ARMCD	Arm Code	1
ABC-002	TX	CTRL	Control, Non-TK	2	SPGRPCD	Sponsor-Defined Group Code	1
ABC-002	TX	CTRL	Control, Non-TK	3	TCNTRL	Control Type	Vehicle
ABC-002	TX	CTRL	Control, Non-TK	4	GRPLBL	Group Label	Group 1, Control
ABC-002	TX	CTRL	Control, Non-TK	5	TRTDOS	Dose Level	0
ABC-002	TX	CTRL	Control, Non-TK	6	TRTDOSU	Dose Units	mg/kg
ABC-002	TX	CTRL	Control, Non-TK	7	TKDESC	Toxicokinetic Description	NON-TK
ABC-002	TX	CTRLTK	Control, TK	8	ARMCD	Arm Code	1
ABC-002	TX	CTRLTK	Control, TK	9	SPGRPCD	Sponsor-Defined Group Code	1
ABC-002	TX	CTRLTK	Control, TK	10	TCNTRL	Control Type	Vehicle
ABC-002	TX	CTRLTK	Control, TK	11	GRPLBL	Group Label	Group 1, Control
ABC-002	TX	CTRLTK	Control, TK	12	TRTDOS	Dose Level	0
ABC-002	TX	CTRLTK	Control, TK	13	TRTDOSU	Dose Units	mg/kg
ABC-002	TX	CTRLTK	Control, TK	14	TKDESC	Toxicokinetic Description	TK
ABC-002	TX	50MGKG	50 mg/kg Drug A, Non-TK	15	ARMCD	Arm Code	2
ABC-002	TX	50MGKG	50 mg/kg Drug A, Non-TK	16	SPGRPCD	Sponsor-Defined Group Code	2
ABC-002	TX	50MGKG	50 mg/kg Drug A, Non-TK	17	GRPLBL	Group Label	Group 2, 50 mg/kg Drug A
ABC-002	TX	50MGKG	50 mg/kg Drug A, Non-TK	18	TRTDOS	Dose Level	50
ABC-002	TX	50MGKG	50 mg/kg Drug A, Non-TK	19	TRTDOSU	Dose Units	mg/kg
ABC-002	TX	50MGKG	50 mg/kg Drug A, Non-TK	20	TKDESC	Toxicokinetic Description	NON-TK
ABC-002	TX	50MGKGTK	50 mg/kg Drug A, TK	21	ARMCD	Arm Code	2
ABC-002	TX	50MGKGTK	50 mg/kg Drug A	22	SPGRPCD	Sponsor-Defined Group Code	2
ABC-002	TX	50MGKGTK	50 mg/kg Drug A	23	GRPLBL	Group Label	Group 2, 50 mg/kg

							Drug A
ABC-002	TX	50MGKGTK	50 mg/kg Drug A	24	TRTDOS	Dose Level	50
ABC-002	TX	50MGKGTK	50 mg/kg Drug A	25	TRTDOSU	Dose Units	mg/kg
ABC-002	TX	50MGKGTK	50 mg/kg Drug A	26	TKDESC	Toxicokinetic Description	TK
ABC-002	TX	100MGKG	100 mg/kg Drug A, Non-TK	27	ARMCD	Arm Code	3
ABC-002	TX	100MGKG	100 mg/kg Drug A, Non-TK	28	SPGRPCD	Sponsor-Defined Group Code	3
ABC-002	TX	100MGKG	100 mg/kg Drug A, Non-TK	29	GRPLBL	Group Label	Group 3, 100 mg/kg Drug A
ABC-002	TX	100MGKG	100 mg/kg Drug A, Non-TK	30	TRTDOS	Dose Level	100
ABC-002	TX	100MGKG	100 mg/kg Drug A, Non-TK	31	TRTDOSU	Dose Units	mg/kg
ABC-002	TX	100MGKG	100 mg/kg Drug A, Non-TK	32	TKDESC	Toxicokinetic Description	NON-TK
ABC-002	TX	100MGKGTK	100 mg/kg Drug A, TK	33	ARMCD	Arm Code	3
ABC-002	TX	100MGKGTK	100 mg/kg Drug A, TK	34	SPGRPCD	Sponsor-Defined Group Code	3
ABC-002	TX	100MGKGTK	100 mg/kg Drug A, TK	35	GRPLBL	Group Label	Group 3, 100 mg/kg Drug A
ABC-002	TX	100MGKGTK	100 mg/kg Drug A, TK	36	TRTDOS	Dose Level	100
ABC-002	TX	100MGKGTK	100 mg/kg Drug A, TK	37	TRTDOSU	Dose Units	mg/kg
ABC-002	TX	100MGKGTK	100 mg/kg Drug A, TK	38	TKDESC	Toxicokinetic Description	TK

EXAMPLE 3, TRIAL SETS

STUDYID	DOMAIN	SETCD	SET	TXSEQ	TXPARMCD	TXPARM	TXVAL
ABC-003	TX	CTRL	Control, No Recovery	1	ARMCD	Arm Code	1
ABC-003	TX	CTRL	Control, No Recovery	2	SPGRPCD	Sponsor-Defined Group Code	1
ABC-003	TX	CTRL	Control, No Recovery	3	TCNTRL	Control Type	Vehicle
ABC-003	TX	CTRL	Control, No Recovery	4	GRPLBL	Group Label	Group 1, Control
ABC-003	TX	CTRL	Control, No Recovery	5	TRTDOS	Dose Level	0
ABC-003	TX	CTRL	Control, No Recovery	6	TRTDOSU	Dose Units	mg/kg
ABC-003	TX	CTRLTK	Control, Recovery	8	ARMCD	Arm Code	1R
ABC-003	TX	CTRLTK	Control, Recovery	9	SPGRPCD	Sponsor-Defined Group Code	1
ABC-003	TX	CTRLTK	Control, Recovery	10	TCNTRL	Control Type	Vehicle
ABC-003	TX	CTRLTK	Control, Recovery	11	GRPLBL	Group Label	Group 1, Control
ABC-003	TX	CTRLTK	Control, Recovery	12	TRTDOS	Dose Level	0
ABC-003	TX	CTRLTK	Control, Recovery	13	TRTDOSU	Dose Units	mg/kg
ABC-003	TX	50MGKG	50 mg/kg Drug A, No Recovery	15	ARMCD	Arm Code	2
ABC-003	TX	50MGKG	50 mg/kg Drug A, No Recovery	16	SPGRPCD	Sponsor-Defined Group Code	2
ABC-003	TX	50MGKG	50 mg/kg Drug A, No Recovery	17	GRPLBL	Group Label	Group 2, 50 mg/kg Drug A
ABC-003	TX	50MGKG	50 mg/kg Drug A, No Recovery	18	TRTDOS	Dose Level	50
ABC-003	TX	50MGKG	50 mg/kg Drug A, No Recovery	19	TRTDOSU	Dose Units	mg/kg
ABC-003	TX	50MGKGTK	50 mg/kg Drug A, Recovery	21	ARMCD	Arm Code	2R
ABC-003	TX	50MGKGTK	50 mg/kg Drug A	22	SPGRPCD	Sponsor-Defined Group Code	2
ABC-003	TX	50MGKGTK	50 mg/kg Drug A	23	GRPLBL	Group Label	Group 2, 50 mg/kg Drug A
ABC-003	TX	50MGKGTK	50 mg/kg Drug A	24	TRTDOS	Dose Level	50
ABC-003	TX	50MGKGTK	50 mg/kg Drug A	25	TRTDOSU	Dose Units	mg/kg

ABC-003	TX	100MGKG	100 mg/kg Drug A, No Recovery	27	ARMCD	Arm Code	3
ABC-003	TX	100MGKG	100 mg/kg Drug A, No Recovery	28	SPGRPCD	Sponsor-Defined Group Code	3
ABC-003	TX	100MGKG	100 mg/kg Drug A, No Recovery	29	GRPLBL	Group Label	Group 3, 100 mg/kg Drug A
ABC-003	TX	100MGKG	100 mg/kg Drug A, No Recovery	30	TRTDOS	Dose Level	100
ABC-003	TX	100MGKG	100 mg/kg Drug A, No Recovery	31	TRTDOSU	Dose Units	mg/kg
ABC-003	TX	100MGKGTK	100 mg/kg Drug A, Recovery	33	ARMCD	Arm Code	3R
ABC-003	TX	100MGKGTK	100 mg/kg Drug A, Recovery	34	SPGRPCD	Sponsor-Defined Group Code	3
ABC-003	TX	100MGKGTK	100 mg/kg Drug A, Recovery	35	GRPLBL	Group Label	Group 3, 100 mg/kg Drug A
ABC-003	TX	100MGKGTK	100 mg/kg Drug A, Recovery	36	TRTDOS	Dose Level	100
ABC-003	TX	100MGKGTK	100 mg/kg Drug A, Recovery	37	TRTDOSU	Dose Units	mg/kg