Trial Sets in Human Clinical Trials

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Agenda

- Trial Sets (TX)
  - Introduction to Trial Sets in SEND
  - Nonclinical Trial Set Examples
  - Human Clinical Trial Set Rationale and Examples
  - Points to Consider
  - Conclusions
- Proposed Allocation to Treatment
- Proposed (AT)Trial Lookup (TL)
- Overall Conclusions

What are Trial Sets?

- The Trial Sets (TX) table is part of the Trial Design Model in the SDTM and SENDIG
- TX is required in SEND submissions, and the variable, SETCD, is required in the SEND DM domain.
- Trial Sets Domain Definition:
  - "Provides the list of distinct sets of subjects having different experimental factors, treatment factors, inherent characteristics, or distinct sponsor designations as specified in the trial design."
- TX represents pre-randomization criteria.
- The SENDIG lists a minimum set of parameters that should be included.

Trial Sets Specification

7.4.1 Trial Sets – TX

tx.xpt, Trial Sets - Trial Design. One record per Trial Set parameter per Trial Set, Tabulation.

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. The same element may occur more than once within an Arm. Maximum 8 characters. This represents the Trial Set for which parameters are being submitted.	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. (This sequence should be unique within the entire dataset because there is no USUBJID.)	Req
TXPARMCD	Trial Set Parameter Short Name	Char	(STSPRMCD)	Topic	Short character value for the Trial Set parameter described in TXPARM. Maximum 8 characters.	Req
TXPARM	Trial Set Parameter	Char	(STSPRM)	Synonym Qualifier	Term for the Trial Set parameter. Maximum 40 characters.	Req
TXVAL	Trial Set Parameter Value	Char		Result Qualifier	Value of the Trial Set parameter (e.g., Fed ad libitum or Restricted Feeding when TXPARM is FEEDREG). Some parameters may be subject to controlled terminology. See the Controlled Terms, Codelist, or Format column in Section 7.4.2 that lists all defined Trial Set parameters.	Req

Trial Sets Relationship to Trial Arms

- TX Allows for the subdivision of Arms, using different parameters.
- TX Allows for multiple Arms to be “grouped” together (using the TXPARMCD of SPGRPCD)
- There should be no planned parameters of interest that could further subdivide a Trial Set.
- Each subject must be assigned to one and only one Trial Set in DM.

Example Trial Set Parameters

- Arm Code
- Bedding Change
- Bedding
- **Control Type**
- Basal Diet
- Environmental Temperature
- Feeding Regimen
- **Group Label**
- Housing Group
- Housing Type
- Housing Humidity
- Housing Humidity Units
- Light Cycle
- Planned Number of Male Subjects
- Planned Number of Subjects
- **Set Label**
- **Sponsor-Defined Group Code**
- Test Subject Supplier Site
- Test Subject Supplier
- Strain/Substrain
- Toxicokinetic Description
- Drinking Water
- Water Delivery
- **Dose Level**
- **Dose Units**

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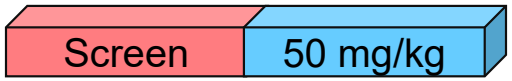
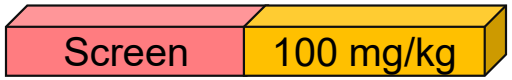
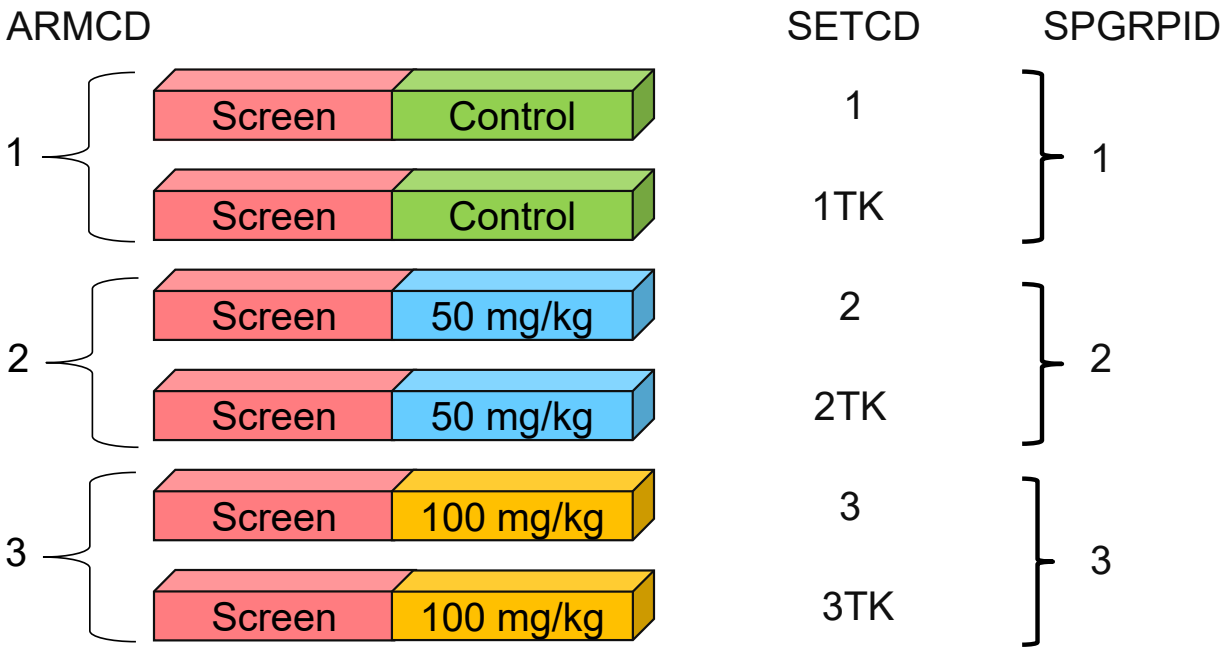
Nonclinical TX Example 1: 3 Arms and 3 Sets

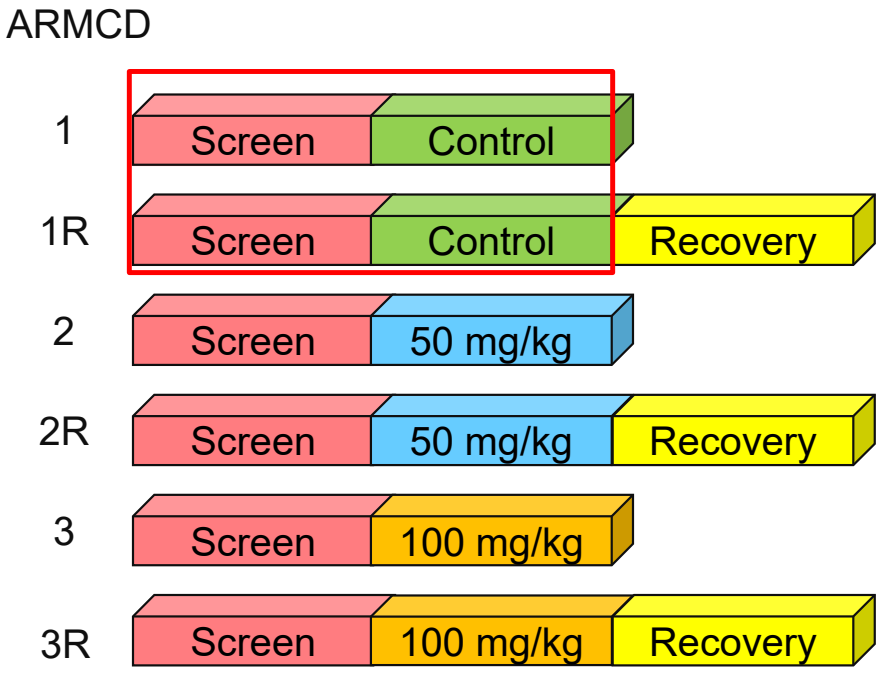
ARMCD		SETCD	SPGRPCD
1		CTRL	1
2		50MGKG	2
3		100MGKG	3

- Even if there is no subdivision of Arms, TX is required, and SETCD in DM is required

Nonclinical TX Example 2:
3 Arms and 6 Sets Based on Toxicokinetic Groups



Nonclinical TX Example 3:
6 Arms and 6 Sets Based on Recovery (1)



SPGRPCD allows for animals from different Arms to be grouped together for some analyses.

Nonclinical TX Example 3:
6 Arms and 6 Sets Based on Recovery (2)

STUDYID	DOMAIN	SETCD	SET	TXSEQ	TXPARMCD	TXPARM	TXVAL
ABC123	TX	INR	Control, No Recovery	1	GRPLBL	Group Label	Control
ABC123	TX	INR	Control, No Recovery	2	SPGRPCD	Sponsor-Defined Group Code	1
ABC123	TX	INR	Control, No Recovery	3	RECSAC	Recovery Period	P0D
ABC123	TX	1R	Control, Recovery	4	GRPLBL	Group Label	Control
ABC123	TX	1R	Control, Recovery	5	SPGRPCD	Sponsor-Defined Group Code	1
ABC123	TX	1R	Control, Recovery	6	POPTYPE	Recovery Period	P28D
ABC123	TX	2NR	50 mg/kg, No Recovery	7	GRPLBL	Group Label	Low Dose
ABC123	TX	2NR	50 mg/kg, No Recovery	8	SPGRPCD	Sponsor-Defined Group Code	2
ABC123	TX	2NR	50 mg/kg, No Recovery	9	POPTYPE	Recovery Period	P0D
ABC123	TX	2R	50 mg/kg, Recovery	10	GRPLBL	Group Label	Low Dose
ABC123	TX	2R	50 mg/kg, Recovery	11	SPGRPCD	Sponsor-Defined Group Code	2
ABC123	TX	2R	50 mg/kg, Recovery	12	POPTYPE	Recovery Period	P28D
ABC123	TX	3NR	100 mg/kg, No Recovery	13	GRPLBL	Group Label	High Dose
ABC123	TX	3NR	100 mg/kg, No Recovery	14	SPGRPCD	Sponsor-Defined Group Code	3
ABC123	TX	3NR	100 mg/kg, No Recovery	15	POPTYPE	Recovery Period	P0D
ABC123	TX	3R	100 mg/kg, Recovery	16	GRPLBL	Group Label	High Dose
ABC123	TX	3R	100 mg/kg, Recovery	17	SPGRPCD	Sponsor-Defined Group Code	3
ABC123	TX	3R	100 mg/kg, Recovery	18	POPTYPE	Recovery Period	P28D

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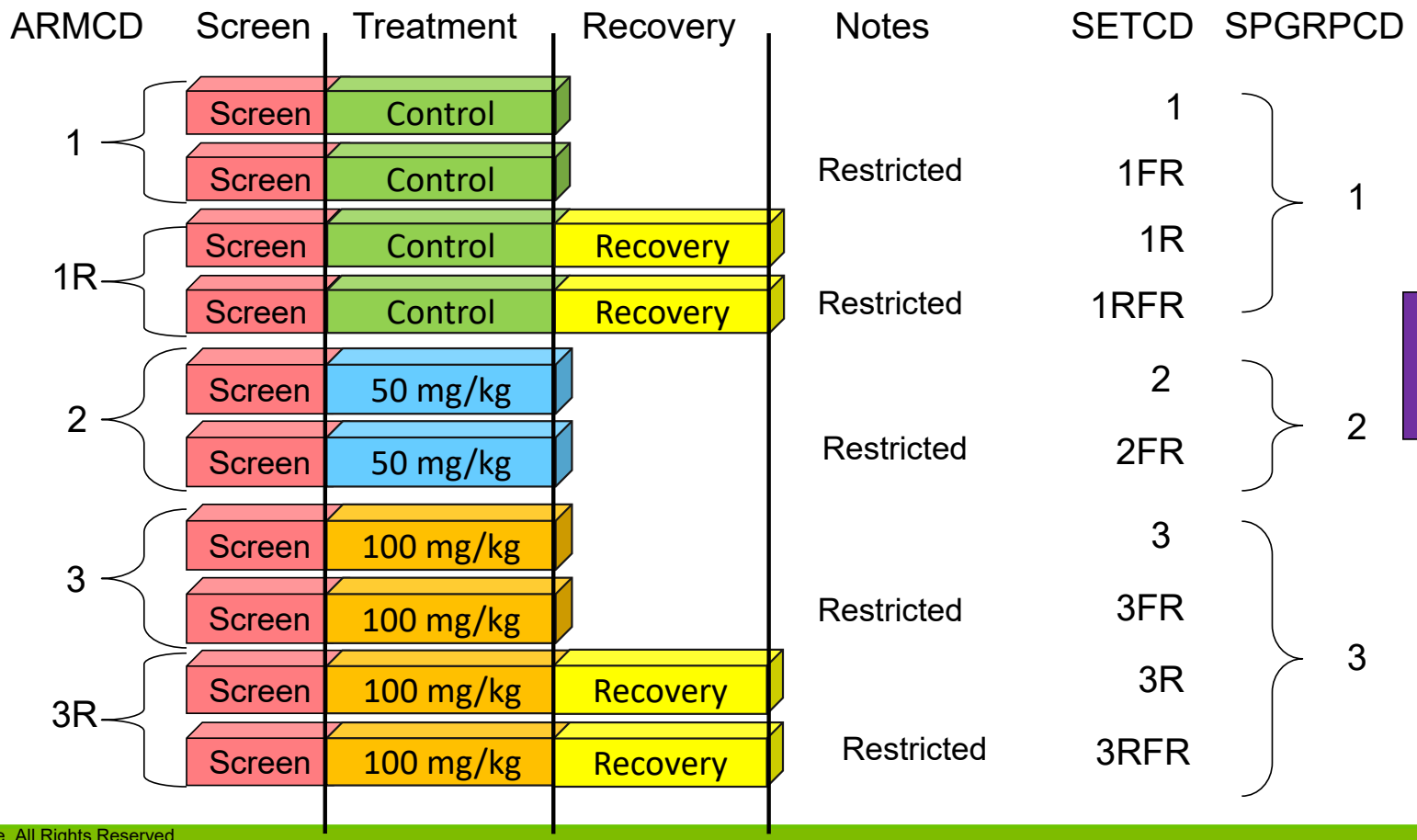
Nonclinical TX Example 4:
Arms Split by Recovery and Food Restriction



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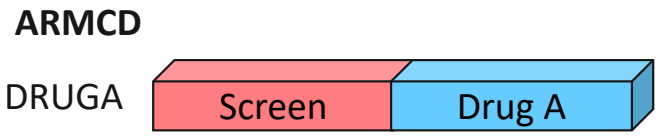
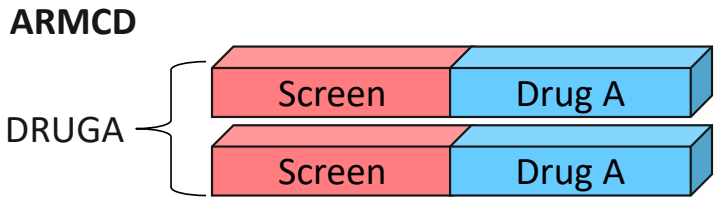
Why Trial Sets for Human Clinical Trials?

- Human clinical trials may have experimental factors, treatment factors, or inherent characteristics", determined prior to randomization (part of the design) that might be of interest.
- 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.

Clinical Example 1: Renal Impairment





SETCD	SPGRPCD
NO_IMPAIR	NO_IMPAIR
MILD_IMPAIR	MILD_IMPAIR

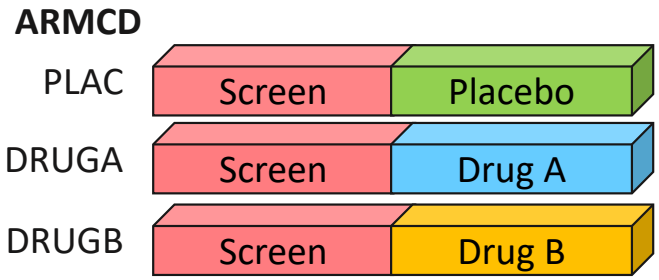
TX Dataset for Renal Impairment Study

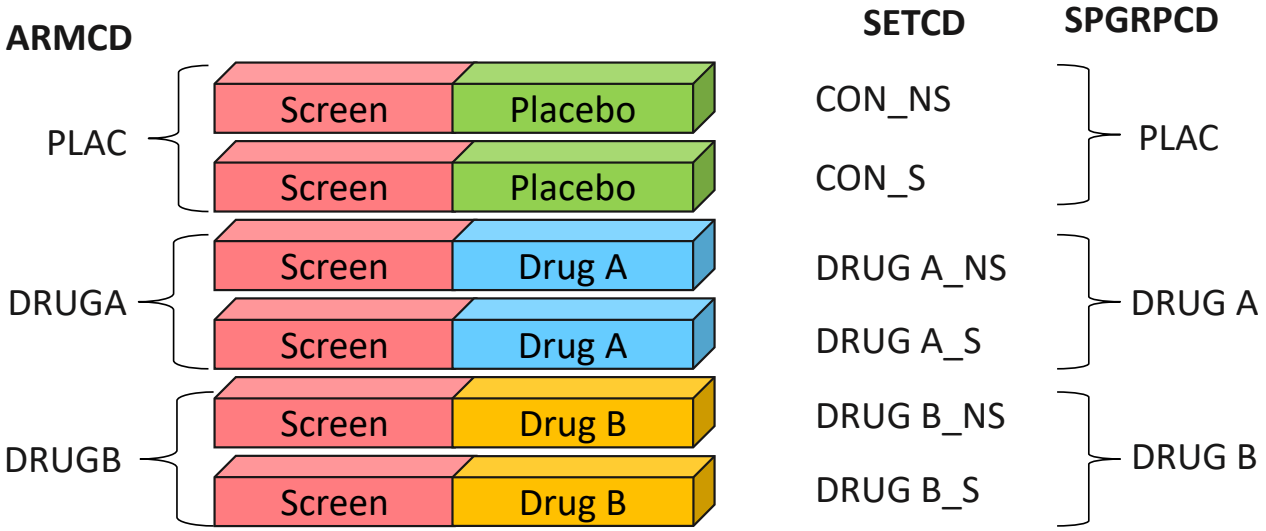
STUDYID	DOMAIN	SETCD	SET	TXSEQ	TXPARMCD	TXPARM	TXVAL
TDM11	TX	NO-IMPAIR	No Renal Impairment	1	ARMCD	Arm Code	DRUGA
TDM11	TX	NO-IMPAIR	No Renal Impairment	2	GRPLBL	Group Label	No Impairment
TDM11	TX	NO-IMPAIR	No Renal Impairment	3	SPGRPCD	Sponsor-Defined Group Code	NO_IMPAIR
TDM11	TX	NO-IMPAIR	No Renal Impairment	4	TRTDOS	Dose Level	400
TDM11	TX	NO-IMPAIR	No Renal Impairment	5	TRTDOSU	Dose Units	mg
TDM11	TX	NO-IMPAIR	No Renal Impairment	6	POPTYPE	Population Type	No Renal Impairment
TDM11	TX	MILD_IMPAIR	Mild Impairment	7	ARMCD	Arm Code	DRUGA
TDM11	TX	MILD_IMPAIR	Mild Impairment	8	GRPLBL	Group Label	Drug A, NS
TDM11	TX	MILD_IMPAIR	Mild Impairment	9	SPGRPCD	Sponsor-Defined Group Code	MILD_IMPAIR
TDM11	TX	MILD_IMPAIR	Mild Impairment	10	TRTDOS	Dose Level	400
TDM11	TX	MILD_IMPAIR	Mild Impairment	11	TRTDOSU	Dose Units	mg
TDM11	TX	MILD_IMPAIR	Mild Impairment	12	POPTYPE	Population Type	No Renal Impairment

TX Dataset for Renal Impairment Study (Condensed)

STUDYID	DOMAIN	SETCD	SET	TXSEQ	TXPARMCD	TXPARM	TXVAL
TDM11	TX	NO-IMPAIR	No Renal Impairment	2	GRPLBL	Group Label	No Impairment
TDM11	TX	NO-IMPAIR	No Renal Impairment	3	SPGRPCD	Sponsor-Defined Group Code	NO_IMPAIR
TDM11	TX	NO-IMPAIR	No Renal Impairment	6	POPTYPE	Population Type	No Renal Impairment
TDM11	TX	MILD_IMPAIR	Mild Impairment	8	GRPLBL	Group Label	Drug A, NS
TDM11	TX	MILD_IMPAIR	Mild Impairment	9	SPGRPCD	Sponsor-Defined Group Code	MILD_IMPAIR
TDM11	TX	MILD_IMPAIR	Mild Impairment	12	POPTYPE	Population Type	No Renal Impairment

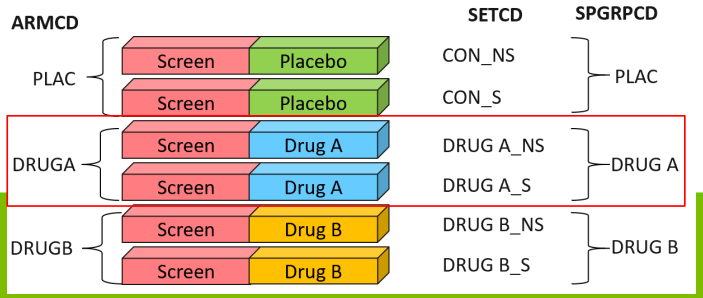
Clinical Example 2: Smoker/Non-Smoker Study





TX Dataset for Smoker/Non-Smoker Study: Records for the Two Drug A Sets

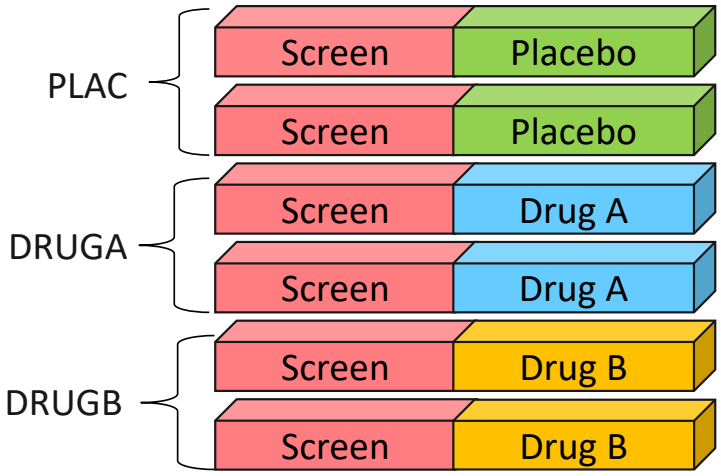
STUDYID	DOMAIN	SETCD	SET	TXSEQ	TXPARMCD	TXPARM	TXVAL
TDM10	TX	DRUG A_NS	Drug A Non-Smokers	1	ARMCD	Arm Code	DRUGA
TDM10	TX	DRUG A_NS	Drug A Non-Smokers	2	GRPLBL	Group Label	Drug A, Non
TDM10	TX	DRUG A_NS	Drug A Non-Smokers	3	SPGRPCD	Sponsor-Defined Group Code	DRUG A
TDM10	TX	DRUG A_NS	Drug A Non-Smokers	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 A_S	Drug A Smokers	7	ARMCD	Arm Code	DRUGA
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
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



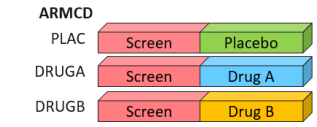
TX Dataset for Smoker/Non-Smoker Study: Records for the Two Drug A Sets (Condensed)

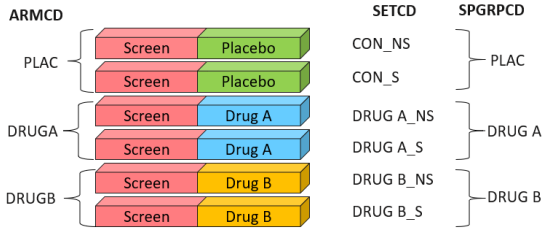
STUDYID	DOMAIN	SETCD	SET	TXSEQ	TXPARMCD	TXPARM	TXVAL
TDM10	TX	DRUG A_NS	Drug A Non-Smokers	2	GRPLBL	Group Label	Drug A, Non
TDM10	TX	DRUG A_NS	Drug A Non-Smokers	6	POPTYPE	Population Type	Non-Smokers
TDM10	TX	DRUG A_S	Drug A Smokers	8	GRPLBL	Group Label	Drug A, Smokers
TDM10	TX	DRUG A_S	Drug A Smokers	12	POPTYPE	Population Type	Smokers

Clinical Example 2:
Smoker/Non-Smoker Study, Alternate SPGRPCD Codes



SETCD	SPGRPCD
CON_NS	CON_NS
CON_S	CON_S
DRUG A_NS	DRUG A_NS
DRUG A_S	DRUG A_S
DRUG B_NS	DRUG B_NS
DRUG B_S	DRUG B_S





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Points to Consider

- SEND does not use ADaM datasets.
- The analysis of data in non-clinical studies is based on SEND datasets, so grouping of animals within and across Arms in the tabulation data is important.
- For clinical trials, grouping of subjects can be performed in ADaM datasets.
- The use of Trial Sets might be more appropriate in early phase human studies where subjects are recruited for specific characteristics.

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)
- There should be no planned parameters of interest that could further subdivide a Trial Set.

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Proposed Allocation to Treatment (AT) Domain

- Special-Purpose domain
- Used in conjunction with DM
- Used when the subject is not the experimental unit being treated or evaluated, but dosing sites are
- Potential use when a subject is in two Arms at the same time
- Use cases have included animals with multiple dose sites, with each dose site receiving a different treatment. Example: One eye is being treated with Drug A and the other Drug B.

Allocation to Treatment (AT) Domain Specification (Proposed)

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Core
USUBJID	Unique Subject Identifier	Char		Exp
STUDYID	Study Identifier	Char		Req
DOMAIN	Domain Abbreviation	Char	AT	Req
FOCID	Focus of Study-Specific Interest	Char		Req
RFXSTDTC	Date/Time of First Study Treatment	Char	ISO 8601	Exp
RFXENDTC	Date/Time of Last Study Treatment	Char	ISO 8601	Exp
ARMCD	Planned Arm Code	Char		Req
ARM	Description of Planned Arm	Char		Perm
SETCD	Set Code	Char		Req

The FOCID Variable

- Added in SDTM v1.7 and SDTMIG v3.3
- An Identifier variable that has no domain prefix.
- Describes a focus of specific interest (e.g., body location) the same way across all domains
  - Example: the right eye might be treated (data in EX) and then evaluated, with results in OE.
- Implementations outside of OE will likely use protocol-defined terminology.
- The Findings variables --LOC (e.g., EYE) and --LAT (e.g., RIGHT), and to a lesser extent, --DIR, and --PORTOT may also be used.

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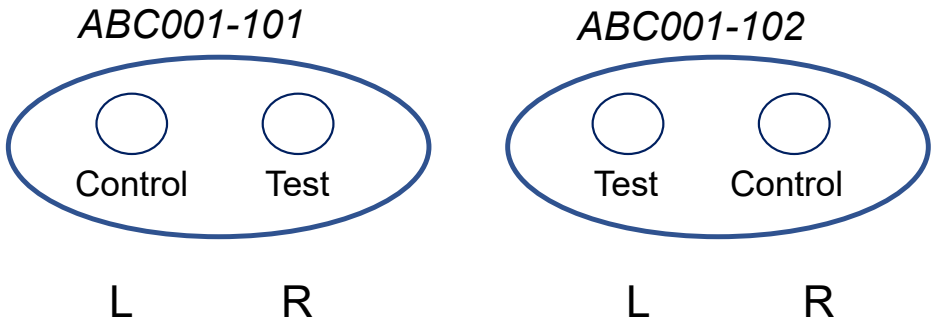
Allocation to Treatment Example: DM and AT



dm.xpt

Row	STUDYID	DOMAIN	USUBJID	SUBJID	AGETXT	AGEU	SEX	SPECIES	STRAIN
1	ABC001	DM	ABC001-101	101	4-6	WEEKS	M	RAT	FISCHER 344
2	ABC001	DM	ABC001-102	102	4-6	WEEKS	M	RAT	FISCHER 344

at.xpt

Row	STUDYID	DOMAIN	USUBJID	FOCID	RFXSTDTC	RFXENDTC	ARMCD	SETCD
1	ABC001	AT	ABC001-101	LEFT EYE	2014-07-01	2014-07-01	1	1
2	ABC001	AT	ABC001-101	RIGHT EYE	2014-07-01	2014-07-01	2	2
3	ABC001	AT	ABC001-102	LEFT EYE	2014-07-01	2014-07-01	2	2
4	ABC001	AT	ABC001-102	RIGHT EYE	2014-07-01	2014-07-01	1	1

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Allocation to Treatment Example: TA and TX

ta.xpt

STUDYID	DOMAIN	ARMCD	ARM	TAETORD	ETCD	ELEMENT	EPOCH
ABC001	TA	CTRL	Control	1	SCRN	Screen	Screen
ABC001	TA	CTRL	Control	2	CTRL	Control	Treatment
ABC001	TA	CPDX	Compound X	1	SCRN	Screen	Screen
ABC001	TA	CPDX	Compound X	2	TRT	Compound X	Treatment

tx.xpt

STUDYID	DOMAIN	SETCD	SET	TXSEQ	TXPARMCD	TXPARM	TXVAL
ABC001	TX	CTRL	Control	1	ARMCD	Arm Code	CTRL
ABC001	TX	CTRL	Control	2	SPGRPCD	Sponsor-Defined Group Code	1
ABC001	TX	CTRL	Control	3	GRPLBL	Group Label	Control
ABC001	TX	CTRL	Control	4	TRTDOS	Dose Level	1
ABC001	TX	CTRL	Control	5	TRTDOSU	Dose Units	mL/dose
ABC001	TX	CTRL	Control	6	TCNTRL	Control Type	Vehicle Control
ABC001	TX	CPDX	Compound X	7	ARMCD	Arm Code	CPDX
ABC001	TX	CPDX	Compound X	8	SPGRPCD	Sponsor-Defined Group Code	2
ABC001	TX	CPDX	Compound X	9	GRPLBL	Group Label	Compound X
ABC001	TX	CPDX	Compound X	10	TRTDOS	Dose Level	1
ABC001	TX	CPDX	Compound X	11	TRTDOSU	Dose Units	mL/dose
ABC001	TX	CPDX	Compound X	12	TRT	Investigation Therapy or Treatment	Compound X
ABC001	TX	CPDX	Compound X	13	TRTCONC	Treatment Concentration	1 mg/mL

AT Pros and Cons

Pros

- Maintains a one record per subject structure in DM
- Allows for the separation of true demographic data from study participation data
- Could be applied to multiple enrollments

Cons

- It’s new and different
- Could be applied to multiple enrollments

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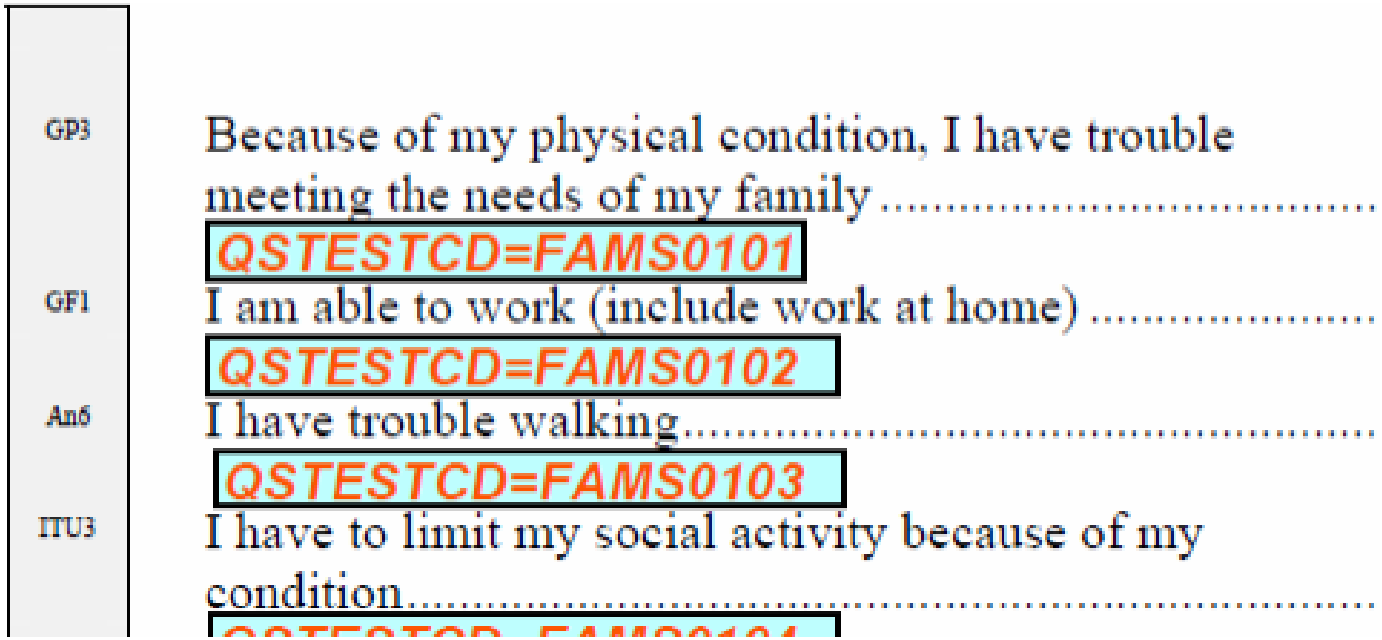
Trial Lookup (TL) Overview

- Proposed domain for data/metadata at a higher level than the subject
  - --CAT level
  - --SCAT level
  - --TESTCD level
- Would eliminate the need for data that's the same for all subjects to be in SUPP-- datasets

Trial Lookup (TL) Domain Specification (Proposed)

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	CDISC Notes	Core
STUDYID	Study Identifier	Char		Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	TL	Two-character abbreviation for the domain.	Req
RDOMAIN	Related Domain Abbreviation	Char		Two-character abbreviation for the domain containing the data being qualified.	Req
TLSEQ	Sequence Number	Num		Sequence number given to ensure uniqueness within a dataset. Allows inclusion of multiple records for the same TLPARMCD/TLVRVALn/TLVARn combination.	Req
TLGRPID	Group ID	Char		Used to tie together a group of related records.	Perm
TLVAR1	Identifying Variable 1	Char		Name of the first identifying variable in the related domain that identifies the record(s) being qualified.	Exp
TLVRVAL1	Identifying Variable Value 1	Char		Value of the first identifying variable TLVAR1 in the related domain that identifies the record(s) being qualified.	Exp
TLVAR2	Identifying Variable 2	Char		Name of the second identifying variable in the related domain that identifies the record(s) being qualified.	Perm
TLVRVAL2	Identifying Variable Value 2	Char		Value of the second identifying variable TLVAR2 in the related domain that identifies the record(s) being qualified.	Perm
TLVAR3	Identifying Variable 3	Char		Name of the third identifying variable in the related domain that identifies the record(s) being qualified.	Perm
TLVRVAL3	Identifying Variable Value 3	Char		Value of the third identifying variable TLVAR3 in the related domain that identifies the record(s) being qualified.	Perm
TLPARMCD	Trial Lookup Parameter Short Name	Char	TLPARMCD	Short name for the Trial Lookup Parameter TLPARM. TLPARMCD is limited to 8 characters and does not have special character restrictions.	Req
TLPARM	Trial Lookup Parameter	Char	TLPARM	Term for the Trial Lookup Parameter. The value in TLPARM cannot be longer than 40 characters.	Req
TLVAL	Trial Lookup Parameter Value	Char	*	Value of the Trial Lookup Parameter TLPARM.	Req
TLVALCD	Parameter Value Code	Char	*	This is the code of the term in TLVAL. The length of this variable can be longer than 8 to accommodate the length of the external terminology.	Perm
TLVCDREF	Name of the Reference Terminology	Char		The name of the Reference Terminology from which TLVALCD is taken.	Perm
TLVCDVER	Version of the Reference Terminology	Char		The version number of the Reference Terminology, if applicable.	Perm

Trial Lookup (TL) Example (1)



From https://wiki.cdisc.org/pages/viewpage.action?pageId=51088498

Trial Lookup (TL) Example (2)

qs.xpt

STUDYID	DOMAIN	USUBJID	QSSEQ	QSTESTCD	QSTEST	QSCAT	QSORRES	QSSTRESC	QSSTRESN	QSPUBCD
12345	QS	1031154	1	FAMS0101	FAMS01-Trouble Meeting Needs of Family	FAMS	Somewhat	2	2	GP3
12345	QS	1031154	2	FAMS0102	FAMS02-I Am Able to Work	FAMS	A little bit	1	1	GF1
12345	QS	1071001	1	FAMS0101	FAMS01-Trouble Meeting Needs of Family	FAMS	A little bit	1	1	GP3
12345	QS	1071001	2	FAMS0102	FAMS02-I Am Able to Work	FAMS	Quite a bit	3	3	GF1
12345	QS	1031235	1	FAMS0101	FAMS01-Trouble Meeting Needs of Family	FAMS	Somewhat	2	2	GP3
12345	QS	1031235	2	FAMS0102	FAMS02-I Am Able to Work	FAMS	A little bit	1	1	GF1
12345	QS	1071050	1	FAMS0101	FAMS01-Trouble Meeting Needs of Family	FAMS	A little bit	1	1	GP3
12345	QS	1071050	2	FAMS0102	FAMS02-I Am Able to Work	FAMS	Quite a bit	3	3	GF1

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Trial Lookup (TL) Example (3): SUPPQS vs. TL

suppqs.xpt

STUDYID	DOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL
12345	QS	1031154	QSTESTCD	FAMS0101	QSPUBCD	Publisher-Defined Question Code	GP3
12345	QS	1031154	QSTESTCD	FAMS0102	QSPUBCD	Publisher-Defined Question Code	GF1
12345	QS	1071001	QSTESTCD	FAMS0101	QSPUBCD	Publisher-Defined Question Code	GP3
12345	QS	1071001	QSTESTCD	FAMS0102	QSPUBCD	Publisher-Defined Question Code	GF1
12345	QS	1031235	QSTESTCD	FAMS0101	QSPUBCD	Publisher-Defined Question Code	GP3
12345	QS	1031235	QSTESTCD	FAMS0102	QSPUBCD	Publisher-Defined Question Code	GF1
12345	QS	1071050	QSTESTCD	FAMS0101	QSPUBCD	Publisher-Defined Question Code	GP3
12345	QS	1071050	QSTESTCD	FAMS0102	QSPUBCD	Publisher-Defined Question Code	GF1

tl.xpt

STUDYID	DOMAIN	RDOMAIN	TLSEQ	TLVAR1	TLVRVAL1	TLPARMCD	TLPARM	TLVAL
12345	TL	QS	1	QSTESTCD	FAMS0101	PUBCD	Publisher-Defined Question Code	GP3
12345	TL	QS	1	QSTESTCD	FAMS0102	PUBCD	Publisher-Defined Question Code	GF1

Modified from https://wiki.cdisc.org/pages/viewpage.action?pageId=51088498

Trial Lookup (TL) Example (4)

tl.xpt

RDOMAIN	TLVAR1	TLVRVAL1	TLVAR2	TLVRVAL2	TLVAR3	TLVRVAL3	CDISCSYN	TLSEQ	TLGRPID	TLPARMCD	TLPARM	TLVAL
QS	QSCAT	FAMS	QSTESTCD	QSALL			FAMS01	1	A	QSSTRESN	Finding Numeric	0
QS	QSCAT	FAMS	QSTESTCD	QSALL			FAMS01	2	B	QSSTRESN	Finding Numeric	1
QS	QSCAT	FAMS	QSTESTCD	QSALL			FAMS01	3	C	QSSTRESN	Finding Numeric	2
QS	QSCAT	FAMS	QSTESTCD	QSALL			FAMS01	4	D	QSSTRESN	Finding Numeric	3
QS	QSCAT	FAMS	QSTESTCD	QSALL			FAMS01	5	E	QSSTRESN	Finding Numeric	4
QS	QSCAT	FAMS	QSTESTCD	QSALL			FAMS01	1	A	QSORRES	Finding in Text	Not at all
QS	QSCAT	FAMS	QSTESTCD	QSALL			FAMS01	2	B	QSORRES	Finding in Text	A little bit
QS	QSCAT	FAMS	QSTESTCD	QSALL			FAMS01	3	C	QSORRES	Finding in Text	Somewhat
QS	QSCAT	FAMS	QSTESTCD	QSALL			FAMS01	4	D	QSORRES	Finding in Text	Quite a bit
QS	QSCAT	FAMS	QSTESTCD	QSALL			FAMS01	5	E	QSORRES	Finding in Text	Very much

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SEND Use Cases for TL

1. Tissue Collection List
2. Tissue Fixation Method
3. Anticoagulant for blood collection
4. Sample processing information
5. Startle test frequency, amplitude, and duration
6. Rotorod speed
7. Procedural ERG Data
8. Duration of Fasting
9. Terminal body weight pre- or post-exsanguination
10. Historical control data - each lab has its own unique set of historical control data
11. Methods for immunophenotyping
12. Procedure information that could be used from study to study
13. Data not in the data management system
14. Cut-off points for ADA, Flow cytometry, --LLOQ

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Alternatives to TL

- Define-XML
  - Many people feel that the data shown here in TL examples could be represented in this file.
  - In data warehouses, the file may not be readily available, and comparing something such as VAS scale lengths might be beneficial to see in the data.
- Trial Summary
  - Some people feel that this data could be represented in TS.
  - TL was created to prevent TS from getting too big.

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Overall Conclusions

- Trial Sets is modeled in the SDTM and the SENDIG
- Trial Sets allows for the the subdivision or grouping of Arms
- Trial Sets could be applied to human clinical trials in cases where there are pre-randomization criteria
- The Allocation to Treatment domain could be useful when a subject is in more than one Arm at any given time.
- The Trial Lookup table allows for the representation of data that applies to all subjects in a structure that is more efficient than SUPP-- datasets.

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