Trial Design Domains

From Protocol to Analysis

-> Implementation Example

Content

- List of Requirements
- Study Design of Example
- Implementation
  - TS
  - TI
  - TV
  - TE
  - TA
- Effects on other Domains

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List of Requirements

- SDTM IG Version 3.1.2
- SDTM Terminology
- Study Protocol
- Specification Templates for TS, TI, TE, TA and TV (Excel Workbooks)
- Template for TrialDesign.xls (Excel Workbook with Worksheets for TS, TI, TE, TA and TV)
- Open CDISC Validator (SDTM Configuration Version 3.1.2)

Study Design of Example

- This study will be a randomised, double-blind, placebo-controlled, multicenter, clinical trial comparing 2 dosage regimens of TRT_X (44 mcg tiw and ow) in a 1:1:1 randomisation of patients with a single demyelinating event, who are at high risk of converting to a diagnosis of MS. When subjects reach CDMS (Clinically Definite MS) they will be re-titrated to open-label treatment with TRT_X 44 mcg tiw. The duration of study treatment will be a total 24 months from randomisation.
- (Subjects who have not converted to CDMS at 24 months will be offered the possibility to receive an optional additional 1-year open-label treatment period with TRT_X 44 mcg tiw.)

Implementation Example

- TS

Implementation Example: TS

- SDTM IG - 7.6 Trial Summary Information
  - TSPARMCD / TSPARM: see Appendix C3 in SDTM IG
  - For TSVAL Controlled Terminology needed.

ts.xpt, Trial Summary — Trial Design, Version 3.1.2.One record per trial summary parameter value

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	TS	Identifier	Two-character abbreviation for the domain.	Req
TSSEQ	Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness within a dataset. Allows inclusion of multiple records for the same TSPARMCD, and can be used to join related records.	Req
TSGRPID	Group ID	Char		Identifier	Used to tie together a group of related records	Perm
TSPARMCD	Trial Summary Parameter Short Name	Char	TSPARMCD	Topic	TSPARMCD (the companion to TSPARM) is limited to 8 characters and does not have special character restrictions. These values should be short for ease of use in programming, but it is not expected that TSPARMCD will need to serve as variable names. Examples: AGEMIN, AGEMAX	Req
TSPARM	Trial Summary Parameter	Char	TSPARM	Synonym Qualifier	Term for the Trial Summary Parameter. The value in TSPARM cannot be longer than 40 characters. Examples Planned Minimum Age of Subjects, Planned Maximum Age of Subjects	Req
TSVAL	Parameter Value	Char	*	Result Qualifier	Value of TSPARM. Example: "ASTHMA" when TSPARM value is "Trial Indication". TSVAL cannot be null – a value is required for the record to be valid. Text over 200 characters can be added to additional columns TSVAL1-TSVALn.	Req

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

Implementation Example: TS

- ✓ Complete Specification <TS-Trial Summary.xls>

Microsoft Excel - TS-Trial Summary

File Edit View Insert Format Tools Data Window Help

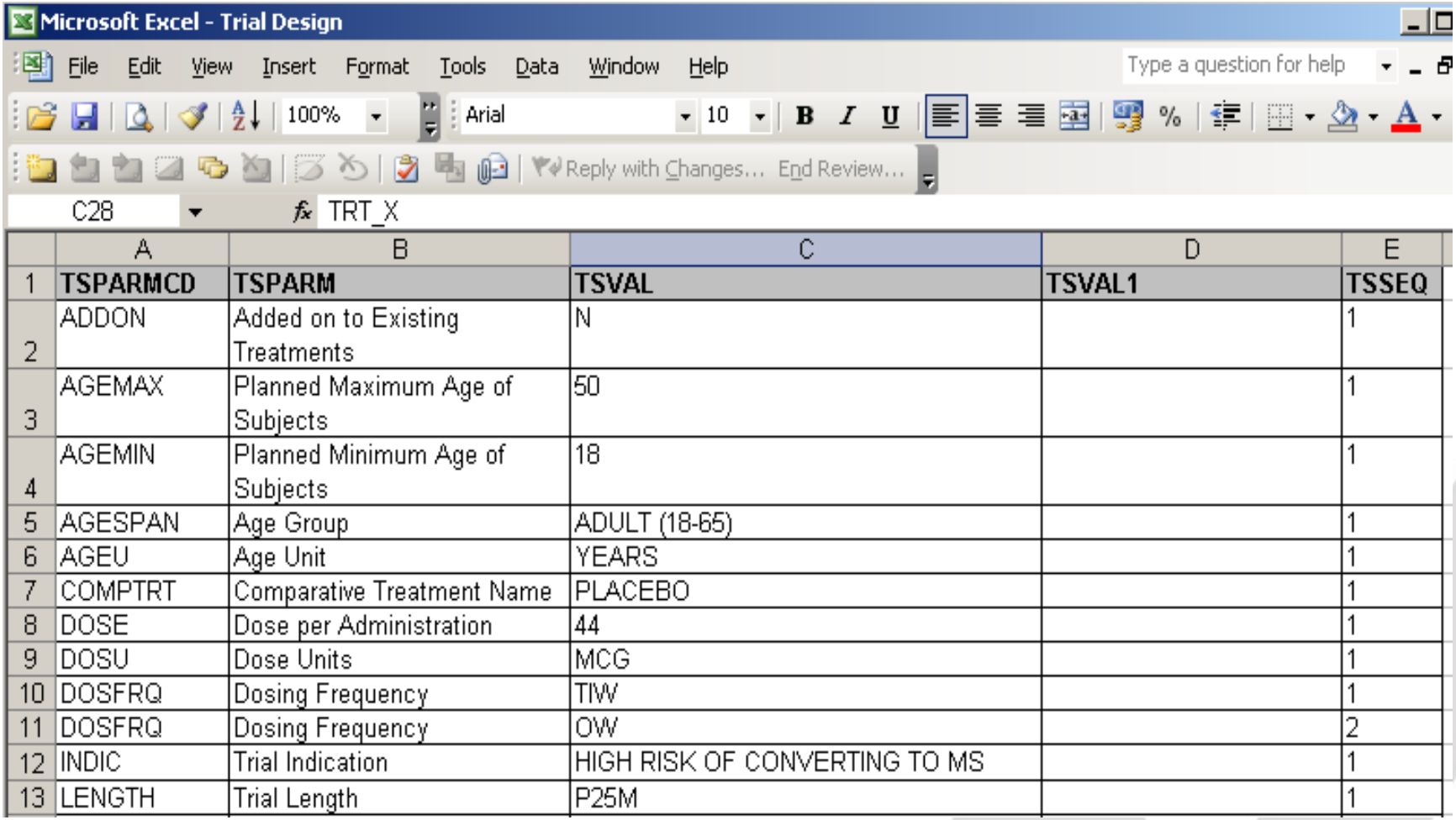
J6 Derived

	A	C	E	F	G	H	I	J	K	L	M
1	Seq. For Order	Domain Prefix	Variable	Label	Type	Length	Controlled Terms or Format	Origin	Role	Comments (define.xml)	Mapping Info (source => SDTM)
3	1	TS	STUDYID	Study Identifier	Char	5		Assigned	Identifier	STUDYID = "nnnnn"	STUDYID = "nnnnn"
4	2	TS	DOMAIN	Domain Abbreviation	Char	2	DOMAIN	Assigned	Identifier	DOMAIN = "TS"	DOMAIN = "TS"
5	3	TS	TSSEQ	Sequence Number	Num	8		Derived	Identifier	Sequence No. to ensure uniqueness within a dataset for a TSPARM	
6	4	TS	TSPARMCD	Trial Summary Parameter Short Name	Char	8		Derived	Topic	Short name for the Parameter described in TSPARM	See <Trial Design.xls (TS)>
7	5	TS	TSPARM	Trial Summary Parameter	Char	40		Derived	Synonym Qualifier	Term for the Trial Summary Parameter	See <Trial Design.xls (TS)>
8	6	TS	TSVAL	Parameter Value	Char	200		Derived	Result Qualifier	Derived from Information of Study Protocol	See <Trial Design.xls (TS)>
9	7	TS	TSVAL1	Parameter Value	Char	200		Derived	Result Qualifier	Continuing text for parameter value (TSVAL) if original information has more than 200 characters	See <Trial Design.xls (TS)> (see SDTM Ig 3.1.2, page 249)
10											

s_ts

Implementation Example: TS

- ✓ Complete <TrialDesign.xls (TS)> using Study Protocol



	A	B	C	D	E
1	**TSPARMCD**	**TSPARM**	**TSVAL**	**TSVAL1**	**TSSEQ**
2	ADDON	Added on to Existing Treatments	N		1
3	AGEMAX	Planned Maximum Age of Subjects	50		1
4	AGEMIN	Planned Minimum Age of Subjects	18		1
5	AGESPAN	Age Group	ADULT (18-65)		1
6	AGEU	Age Unit	YEARS		1
7	COMPTRT	Comparative Treatment Name	PLACEBO		1
8	DOSE	Dose per Administration	44		1
9	DOSU	Dose Units	MCG		1
10	DOSFRQ	Dosing Frequency	TIW		1
11	DOSFRQ	Dosing Frequency	OW		2
12	INDIC	Trial Indication	HIGH RISK OF CONVERTING TO MS		1
13	LENGTH	Trial Length	P25M		1

Implementation Example: TS

14	OBJPRIM	Trial Primary Objective	TO EVALUATE THE EFFECT OF TRT_X 44 MCG TIW AND ONCE A WEEK (OW) VERSUS PLACEBO ON THE "TIME TO CONVERSION TO MCDONALD MS" IN SUBJECTS WITH A FIRST CLINICAL DEMYELINATING EVENT AT HIGH RISK	OF CONVERTING TO MS.	1
15	OBJSEC	Trial Secondary Objective	TO EVALUATE THE EFFECT OF TRT_X 44 MCG (TIW AND OW) VERSUS PLACEBO ON THE "TIME TO CONVERSION TO CDMS" IN SUBJECTS WITH A FIRST CLINICAL DEMYELINATING EVENT AT HIGH RISK		1
16	PLANSUB	Planned Number of Subjects	530		1
17	RANDOM	Trial is Randomized	Y		1
18	ROUTE	Route of Administration	SUBCUTANEOUS		1
19	SEXPOP	Sex of Participants	BOTH		1
20	SPONSOR	Sponsoring Organization	PHARMA XY		1
21	STOPRULE	Study Stop Rules	NONE		1
22	TBLIND	Trial Blinding Schema	DOUBLE BLIND		1
23	TCNTRL	Control Type	PLACEBO		1
24	TDIGRP	Diagnosis Group	SUBJECTS WITH A SINGLE CLINICAL DEMYELINATING EVENT AT HIGH RISK OF CONVERTING TO MS		1
25	TINDTP	Trial Indication Type	TREATMENT		1

Implementation Example: TS

26	TITLE	Trial Title	A PHASE III, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, MULTICENTRE CLINICAL TRIAL OF TRT_X (44 MCG TIW AND 44 MCG OW) IN SUBJECTS AT HIGH RISK OF CONVERTING TO MULTIPLE SCLEROSIS		1
27	TPHASE	Trial Phase Classification	Phase III Trial		1
28	TRT	Reported Name of Test Product	TRT_X		1
29	TTYPE	Trial Type	EFFICACY		1
30	TTYPE	Trial Type	SAFETY		2

TV TA TE TS

Implementation Example

- TI

Implementation Example: TI

- SDTM IG - 7.5 Trial Inclusion/Exclusion Criteria
  - For IECAT Controlled Terminology needed.

ti.xpt, Trial Inclusion/Exclusion Criteria — Trial Design, Version 3.1.2.One record per I/E criterion

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	TI	Identifier	Two-character abbreviation for the domain.	Req
IETESTCD	Incl/Excl Criterion Short Name	Char	*	Topic	Short name IETEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in IETESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST"). IETESTCD cannot contain characters other than letters, numbers, or underscores. The prefix "IE" is used to ensure consistency with the IE domain.	Req
IETEST	Inclusion/Exclusion Criterion	Char	*	Synonym Qualifier	Full text of the inclusion or exclusion criterion. The prefix "IE" is used to ensure consistency with the IE domain.	Req
IECAT	Inclusion/Exclusion Category	Char	(IECAT)	Grouping Qualifier	Used for categorization of the inclusion or exclusion criteria.	Req
IESCAT	Inclusion/Exclusion Subcategory	Char	*	Grouping Qualifier	A further categorization of the exception criterion. Can be used to distinguish criteria for a sub-study or for to categorize as a major or minor exceptions. Examples: MAJOR, MINOR.	Perm
TIRL	Inclusion/Exclusion Criterion Rule	Char		Rule	Rule that expresses the criterion in computer-executable form (see assumption 4 below).	Perm
TIVERS	Protocol Criteria Versions	Char		Record Qualifier	The number of this version of the Inclusion/Exclusion criteria. May be omitted if there is only one version.	Perm

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

Implementation Example: TI

- ✓ Complete Specification <TI-Trial InclusionExclusion Criteria.xls>

Microsoft Excel - TI-Trial InclusionExclusion Criteria

File Edit View Insert Format Tools Data Window Help — Type a question for help

Times New Roman 10 — 75% — Reply with Changes... End Review...

C8 fx TI

	C	E	F	G	H	I	J	K	L	M
1	Domain Prefix	Variable	Label	Type	Length	Controlled Terms or Format	Origin	Role	Comments (define.xml)	Mapping Info (Source data => SDTM)
3	TI	STUDYID	Study Identifier	Char	5		Assigned	Identifier	STUDYID = "nnnnn"	STUDYID = "nnnnn"
4	TI	DOMAIN	Domain Abbreviation	Char	2	DOMAIN	Assigned	Identifier	DOMAIN = "TI"	DOMAIN = "TI"
5	TI	IETESTCD	Incl/Excl Criterion Short Name	Char	8		Assigned	Topic		Select data from INCTXT: concatenate 'INCL' and variable INC (2 digits are mandatory, for one-digit number a preceding 0 has to be added); select data from EXCTXT: concatenate 'EXCL' and variable EXC (2 digits are mandatory, for one-digit number a preceding 0 has to be added) For OCT Informed Consent: For data from OCTIC use IETESTCD=EXCL01O and IETESTCD=EXCL02O
	TI	IETEST	Inclusion/Exclusion Criterion	Char	200		CRF Pages 122, 123, 124, 126	Synonym Qualifier		Inclusion criteria: If IETESTCD = "INCL02" to "INCL06": IETEST = INCTXT.INCAXT If IETESTCD = "INCL01": IETEST = "Subject with single, first clinical event suggestive of MS within 60 days prior to SD1. Event must be a new neurol. abnormality present for at least 24 hours" if IETESTCD = "INCL07": IETEST = "Females neither pregnant nor breast-feeding, nor attempt to conceive. They must use a highly effective method of contraception"

Implementation Example: TI

6										Exclusion criteria: If IETESTCD = ("EXCL01" to "EXL10") or ("EXCL12" to "EXCL18) or ("EXCL20" to "EXCL24"): IETEST=EXCTXT.EXCAXT if IETESTCD = "EXCL11": IETEST = "Subject suffers from major medical or psychiatric illness that in the opinion of the investigator creates undue risk to the subject or could affect compliance with the study protocol" if IETESTCD = "EXCL19": IETEST = "Subject has received any immunomodulatory or immunosuppressive therapy at any time prior to SD1 from pre-defined list provided in study protocol" OCT Informed Consent: If IETESTCD = EXCL01O: IETEST= "Subject has co-morbid ocular condition not related to MS (ascertained by a detailed history and examination)" IF IETESTCD = EXCL02O: IETEST= "Subject has severe myopia superior to 5 diopters"
7	TI	IECAT	Inclusion/Exclusion Category	Char	10	IECAT	CRF Pages 122, 123, 126	Grouping Qualifier	Category: "INCLUSION" or "EXCLUSION"	If UPCASE(CAT)='I' then IECAT='INCLUSION' else if UPCASE(CAT)='E' then IECAT='EXCLUSION'
8	TI	IESCAT	Inclusion/Exclusion Subcategory	Char	15		CRF Page 126	Grouping Qualifier		For OCT Informed Consent: IESCAT = "OCT SUBSTUDY"
9	TI	TIRL	Inclusion/Exclusion Criterion Rule	Char			Derived	Rule		Not needed
10	TI	TIVERS	Protocol Criteria Versions	Char			Assigned	Record Qualifier		Not needed

s_ti

ACCOVION

Implementation Example: TI

- For this example SAS-datasets with In- and Exclusion Criterias are available
- <TrialDesign.xls (TI)> not needed

Implementation Example

- TV

Implementation Example: TV

- ✓ SDTM IG - 7.4 Trial Visits

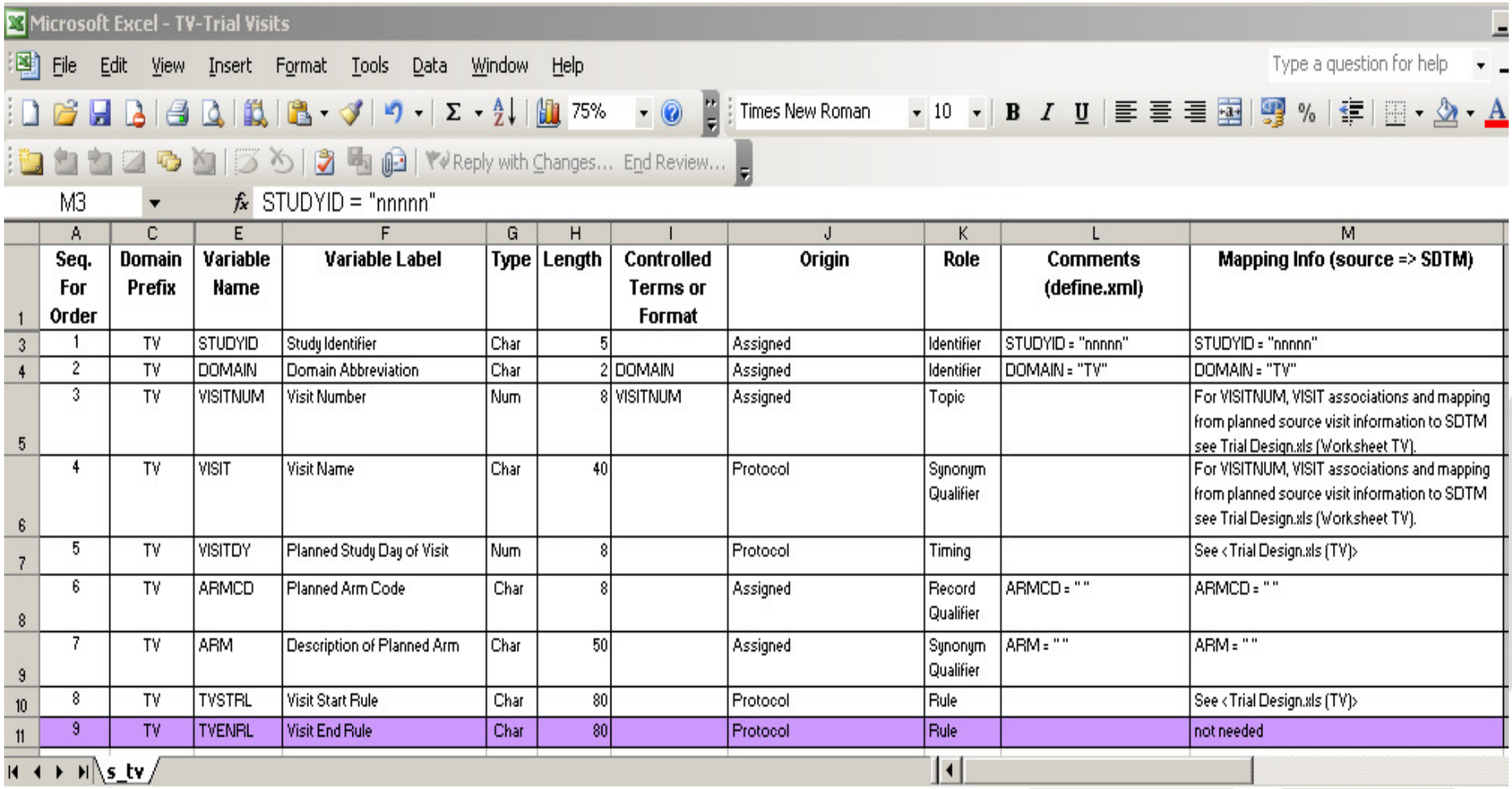
tv.xpt, Trial Visits — Trial Design, Version 3.1.2. One record per planned Visit per Arm

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	TV	Identifier	Two-character abbreviation for the domain	Req
VISITNUM	Visit Number	Num		Topic	1. Clinical encounter number 2. Numeric version of VISIT, used for sorting.	Req
VISIT	Visit Name	Char		Synonym Qualifier	1. Protocol-defined description of clinical encounter. 2. May be used in addition to VISITNUM and/or VISITDY as a text description of the clinical encounter.	Perm
VISITDY	Planned Study Day of Visit	Num		Timing	1. Planned study day of VISIT. 2. Due to its sequential nature, used for sorting.	Perm
ARMCD	Planned Arm Code	Char	*	Record Qualifier	1.ARMCD is limited to 20 characters and does not have special character restrictions. The maximum length of ARMCD is longer than for other "short" variables to accommodate the kind of values that are likely to be needed for crossover trials. For example, if ARMCD values for a seven-period crossover were constructed using two-character abbreviations for each treatment and separating hyphens, the length of ARMCD values would be 20. 2. If the timing of Visits for a trial does not depend on which ARM a subject is in, then ARMCD should be null.	Exp
ARM	Description of Planned Arm	Char	*	Synonym Qualifier	1. Name given to an Arm or Treatment Group. 2. If the timing of Visits for a trial does not depend on which Arm a subject is in, then Arm should be left blank.	Perm
TVSTRL	Visit Start Rule	Char		Rule	Rule describing when the Visit starts, in relation to the sequence of Elements.	Req
TVENRL	Visit End Rule	Char		Rule	Rule describing when the Visit ends, in relation to the sequence of Elements.	Perm

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

Implementation Example: TV

- ✓ Complete specification <TV-Trial Visits.xls>



Microsoft Excel - TV-Trial Visits

File Edit View Insert Format Tools Data Window Help

Type a question for help

Times New Roman 10 75%

Reply with Changes... End Review...

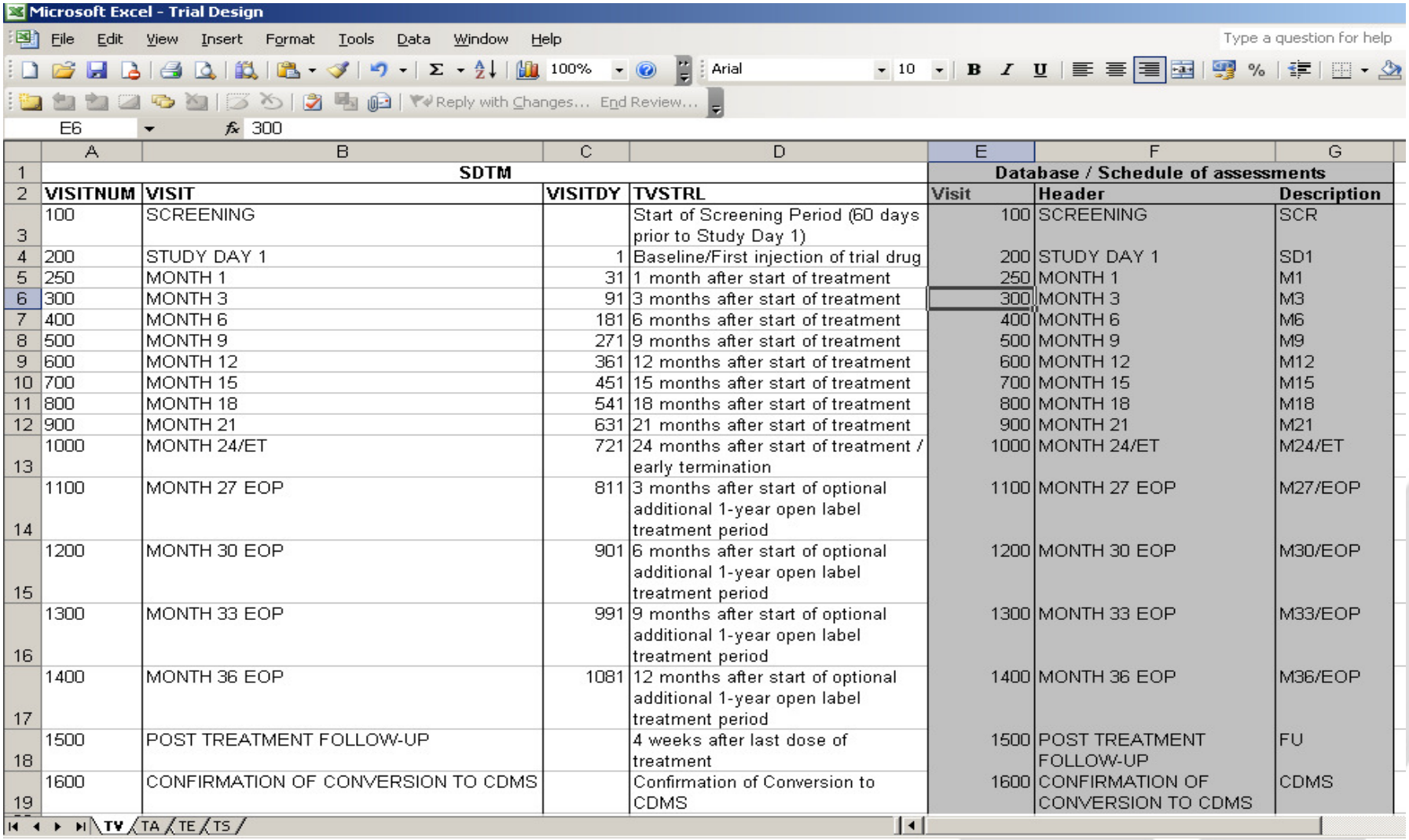
M3 STUDYID = "nnnnn"

	A	C	E	F	G	H	I	J	K	L	M
1	Seq. For Order	Domain Prefix	Variable Name	Variable Label	Type	Length	Controlled Terms or Format	Origin	Role	Comments (define.xml)	Mapping Info (source => SDTM)
3	1	TV	STUDYID	Study Identifier	Char	5		Assigned	Identifier	STUDYID = "nnnnn"	STUDYID = "nnnnn"
4	2	TV	DOMAIN	Domain Abbreviation	Char	2	DOMAIN	Assigned	Identifier	DOMAIN = "TV"	DOMAIN = "TV"
5	3	TV	VISITNUM	Visit Number	Num	8	VISITNUM	Assigned	Topic		For VISITNUM, VISIT associations and mapping from planned source visit information to SDTM see Trial Design.xls (Worksheet TV).
6	4	TV	VISIT	Visit Name	Char	40		Protocol	Synonym Qualifier		For VISITNUM, VISIT associations and mapping from planned source visit information to SDTM see Trial Design.xls (Worksheet TV).
7	5	TV	VISITDY	Planned Study Day of Visit	Num	8		Protocol	Timing		See <Trial Design.xls (TV)>
8	6	TV	ARMCD	Planned Arm Code	Char	8		Assigned	Record Qualifier	ARMCD = " "	ARMCD = " "
9	7	TV	ARM	Description of Planned Arm	Char	50		Assigned	Synonym Qualifier	ARM = " "	ARM = " "
10	8	TV	TVSTRL	Visit Start Rule	Char	80		Protocol	Rule		See <Trial Design.xls (TV)>
11	9	TV	TVENRL	Visit End Rule	Char	80		Protocol	Rule		not needed

s_tv

Implementation Example: TV

✓ Complete <TrialDesign.xls (TV)>



	A	B	C	D	E	F	G
1	SDTM				Database / Schedule of assessments		
2	VISITNUM	VISIT	VISITDY	TVSTRL	Visit	Header	Description
3	100	SCREENING		Start of Screening Period (60 days prior to Study Day 1)	100	SCREENING	SCR
4	200	STUDY DAY 1	1	Baseline/First injection of trial drug	200	STUDY DAY 1	SD1
5	250	MONTH 1	31	1 month after start of treatment	250	MONTH 1	M1
6	300	MONTH 3	91	3 months after start of treatment	300	MONTH 3	M3
7	400	MONTH 6	181	6 months after start of treatment	400	MONTH 6	M6
8	500	MONTH 9	271	9 months after start of treatment	500	MONTH 9	M9
9	600	MONTH 12	361	12 months after start of treatment	600	MONTH 12	M12
10	700	MONTH 15	451	15 months after start of treatment	700	MONTH 15	M15
11	800	MONTH 18	541	18 months after start of treatment	800	MONTH 18	M18
12	900	MONTH 21	631	21 months after start of treatment	900	MONTH 21	M21
13	1000	MONTH 24/ET	721	24 months after start of treatment / early termination	1000	MONTH 24/ET	M24/ET
14	1100	MONTH 27 EOP	811	3 months after start of optional additional 1-year open label treatment period	1100	MONTH 27 EOP	M27/EOP
15	1200	MONTH 30 EOP	901	6 months after start of optional additional 1-year open label treatment period	1200	MONTH 30 EOP	M30/EOP
16	1300	MONTH 33 EOP	991	9 months after start of optional additional 1-year open label treatment period	1300	MONTH 33 EOP	M33/EOP
17	1400	MONTH 36 EOP	1081	12 months after start of optional additional 1-year open label treatment period	1400	MONTH 36 EOP	M36/EOP
18	1500	POST TREATMENT FOLLOW-UP		4 weeks after last dose of treatment	1500	POST TREATMENT FOLLOW-UP	FU
19	1600	CONFIRMATION OF CONVERSION TO CDMS		Confirmation of Conversion to CDMS	1600	CONFIRMATION OF CONVERSION TO CDMS	CDMS

Implementation Example

- TE

Implementation Example: TE

- SDTM IG - 7.3 Trial Elements

te.xpt, Trial Elements — Trial Design, Version 3.1.2 One record per planned Element

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	TE	Identifier	Two-character abbreviation for the domain.	Req
ETCD	Element Code	Char	*	Topic	ETCD (the companion to ELEMENT) is limited to 8 characters and does not have special character restrictions. These values should be short for ease of use in programming, but it is not expected that ETCD will need to serve as a variable name.	Req
ELEMENT	Description of Element	Char	*	Synonym Qualifier	The name of the Element.	Req
TESTRL	Rule for Start of Element	Char		Rule	Expresses rule for beginning Element.	Req
TEENRL	Rule for End of Element	Char		Rule	Expresses rule for ending Element. Either TEENRL or TEDUR must be present for each Element.	Perm
TEDUR	Planned Duration of Element	Char	ISO 8601	Timing	Planned Duration of Element in ISO 8601 format. Used when the rule for ending the Element is applied after a fixed duration.	Perm

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

Implementation Example: TE

- ✓ Complete specification <TE-Trial Elements.xls>

Microsoft Excel - TE-Trial Elements

File Edit View Insert Format Tools Data Window Help

L3 STUDYID = "nnnnn"

	A	C	E	F	G	H	I	J	K	L	M
1	Seq. For Order	Domain Prefix	Variable Name	Variable Label	Type	Length	Controlled Terms or Format	Origin	Role	Comments (define.xml)	Mapping Info (source => SDTM)
3	1	TE	STUDYID	Study Identifier	Char	5		Assigned	Identifier	STUDYID = "nnnnn"	STUDYID = "nnnnn"
4	2	TE	DOMAIN	Domain Abbreviation	Char	2	DOMAIN	Assigned	Identifier	DOMAIN = "TE"	DOMAIN = "TE"
5	3	TE	ETCD	Element Code	Char	8	ETCD	Assigned	Topic		See <Trial Design.xls (TE)>
6	4	TE	ELEMENT	Description of Element	Char	45	ELEMENT	Protocol	Synonym Qualifier		See <Trial Design.xls (TE)>
7	5	TE	TESTRL	Rule for Start of Element	Char	80		Protocol	Rule		See <Trial Design.xls (TE)>
8	6	TE	TEENRL	Rule for End of Element	Char	80		Protocol	Rule		See <Trial Design.xls (TE)>
9	7	TE	TEDUR	Planned Duration of Element	Char	10	ISO 8601	Protocol	Timing		not needed

s_te

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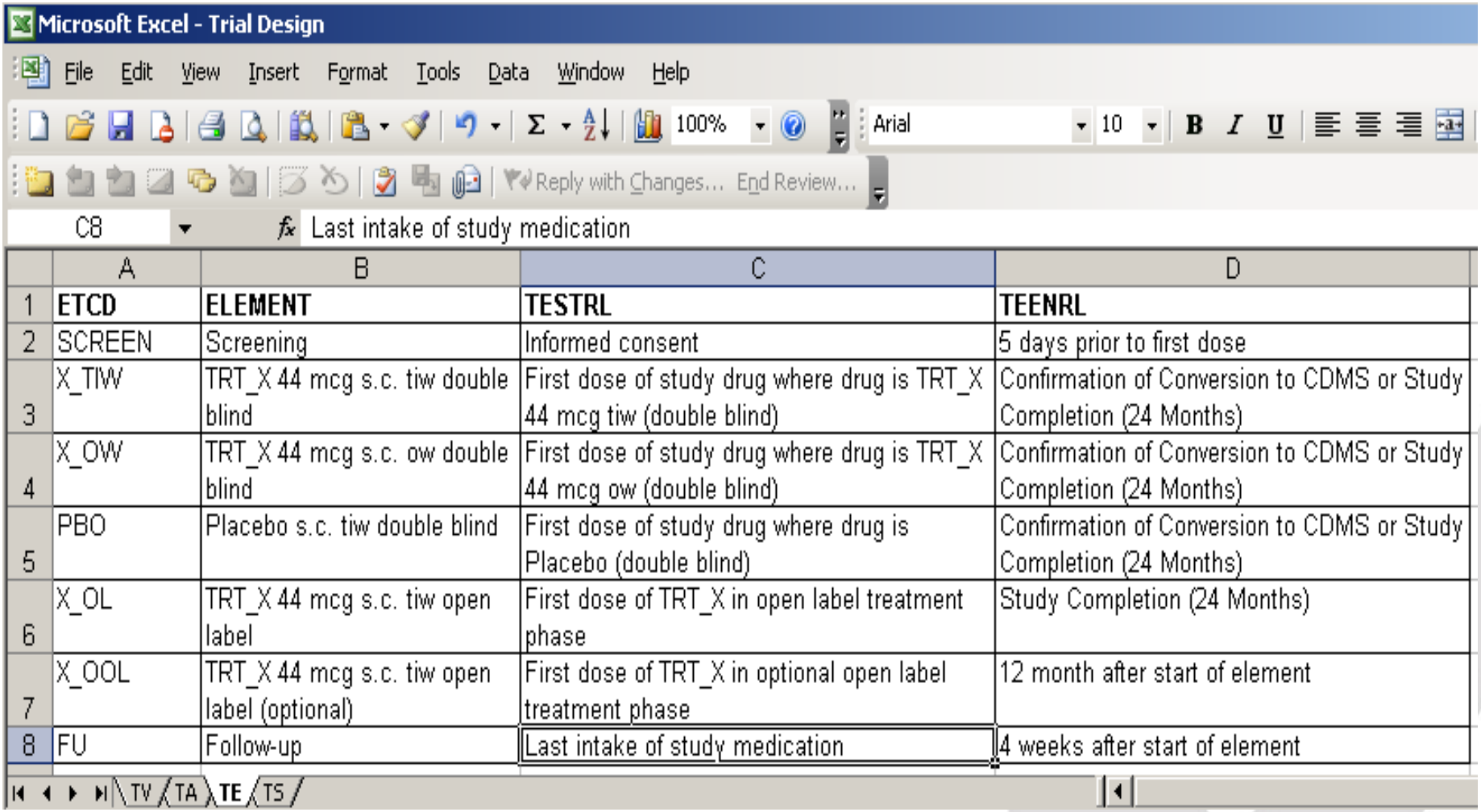
Implementation Example: TE

✓ Complete <TrialDesign.xls (TE)>



	A	B	C	D
1	**ETCD**	**ELEMENT**	**TESTRL**	**TEENRL**
2	SCREEN	Screening	Informed consent	5 days prior to first dose
3	X_TIW	TRT_X 44 mcg s.c. tiw double blind	First dose of study drug where drug is TRT_X 44 mcg tiw (double blind)	Confirmation of Conversion to CDMS or Study Completion (24 Months)
4	X_OW	TRT_X 44 mcg s.c. ow double blind	First dose of study drug where drug is TRT_X 44 mcg ow (double blind)	Confirmation of Conversion to CDMS or Study Completion (24 Months)
5	PBO	Placebo s.c. tiw double blind	First dose of study drug where drug is Placebo (double blind)	Confirmation of Conversion to CDMS or Study Completion (24 Months)
6	X_OL	TRT_X 44 mcg s.c. tiw open label	First dose of TRT_X in open label treatment phase	Study Completion (24 Months)
7	X_OOL	TRT_X 44 mcg s.c. tiw open label (optional)	First dose of TRT_X in optional open label treatment phase	12 month after start of element
8	FU	Follow-up	Last intake of study medication	4 weeks after start of element

Implementation Example

- TA

Implementation Example: TA

- SDTM IG – 7.2 Trial Arms

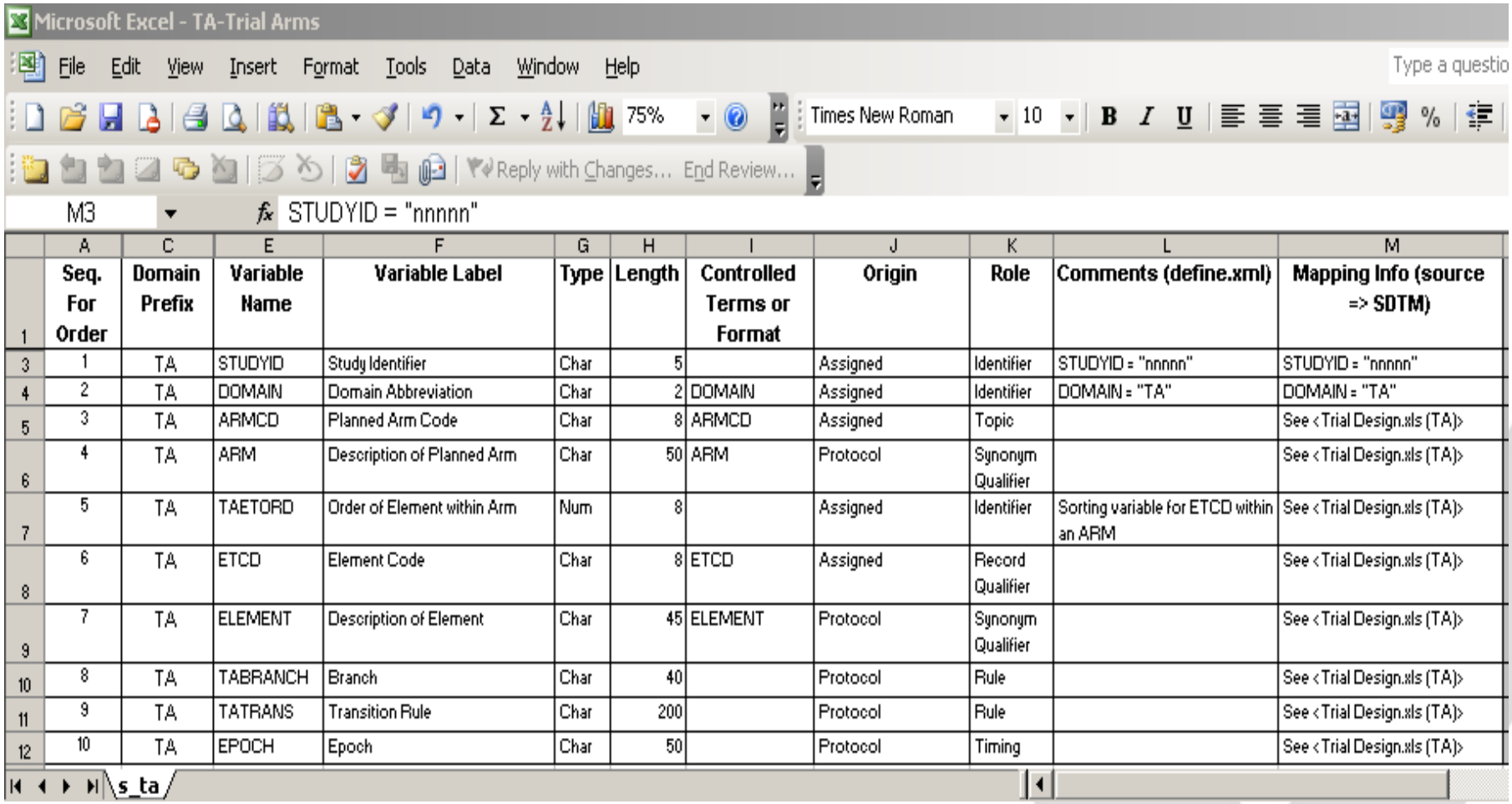
ta.xpt, Trial Arms — Trial Design, Version 3.1.2. One record per planned Element per Arm

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	TA	Identifier	Two-character abbreviation for the domain.	Req
ARMCD	Planned Arm Code	Char	*	Topic	ARMCD is limited to 20 characters and does not have special character restrictions. The maximum length of ARMCD is longer than that for other "short" variables to accommodate the kind of values that are likely to be needed for crossover trials. For example, if ARMCD values for a seven-period crossover were constructed using two-character abbreviations for each treatment and separating hyphens, the length of ARMCD values would be 20.	Req
ARM	Description of Planned Arm	Char	*	Synonym Qualifier	Name given to an Arm or treatment group.	Req
TAETORD	Order of Element within Arm	Num		Identifier	Number that gives the order of the Element within the Arm.	Req
ETCD	Element Code	Char	*	Record Qualifier	ETCD (the companion to ELEMENT) is limited to 8 characters and does not have special character restrictions. These values should be short for ease of use in programming, but it is not expected that ETCD will need to serve as a variable name.	Req
ELEMENT	Description of Element	Char	*	Synonym Qualifier	The name of the Element. The same Element may occur more than once within an Arm.	Perm
TABRANCH	Branch	Char		Rule	Condition subject met, at a "branch" in the trial design at the end of this Element, to be included in this Arm; (e.g., randomization to DRUG X).	Exp
TATRANS	Transition Rule	Char		Rule	If the trial design allows a subject to transition to an Element other than the next Element in sequence, then the conditions for transitioning to those other Elements, and the alternative Element sequences, are specified in this rule (e.g., Responders go to washout).	Exp
EPOCH	Epoch	Char	*	Timing	Name of the Trial Epoch with which this Element of the Arm is associated.	Req

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

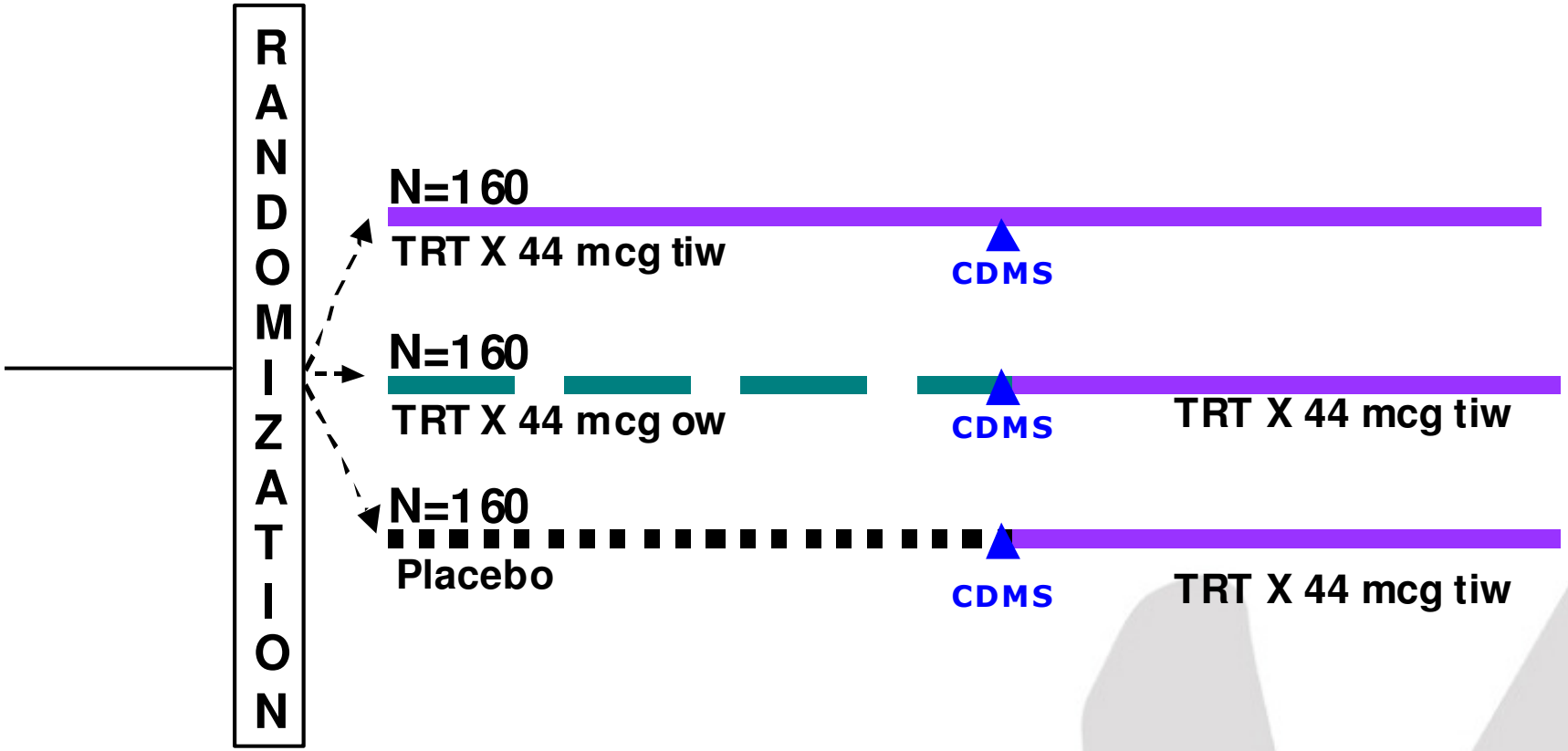
Implementation Example: TA

- ✓ Complete Specification <TA-Trial Arms.xls>



	A	C	E	F	G	H	I	J	K	L	M
1	Seq. For Order	Domain Prefix	Variable Name	Variable Label	Type	Length	Controlled Terms or Format	Origin	Role	Comments (define.xml)	Mapping Info (source => SDTM)
3	1	TA	STUDYID	Study Identifier	Char	5		Assigned	Identifier	STUDYID = "nnnnn"	STUDYID = "nnnnn"
4	2	TA	DOMAIN	Domain Abbreviation	Char	2	DOMAIN	Assigned	Identifier	DOMAIN = "TA"	DOMAIN = "TA"
5	3	TA	ARMCD	Planned Arm Code	Char	8	ARMCD	Assigned	Topic		See <Trial Design.xls (TA)>
6	4	TA	ARM	Description of Planned Arm	Char	50	ARM	Protocol	Synonym Qualifier		See <Trial Design.xls (TA)>
7	5	TA	TAETORD	Order of Element within Arm	Num	8		Assigned	Identifier	Sorting variable for ETCD within an ARM	See <Trial Design.xls (TA)>
8	6	TA	ETCD	Element Code	Char	8	ETCD	Assigned	Record Qualifier		See <Trial Design.xls (TA)>
9	7	TA	ELEMENT	Description of Element	Char	45	ELEMENT	Protocol	Synonym Qualifier		See <Trial Design.xls (TA)>
10	8	TA	TABRANCH	Branch	Char	40		Protocol	Rule		See <Trial Design.xls (TA)>
11	9	TA	TATRANS	Transition Rule	Char	200		Protocol	Rule		See <Trial Design.xls (TA)>
12	10	TA	EPOCH	Epoch	Char	50		Protocol	Timing		See <Trial Design.xls (TA)>

Study Design of Example



Implementation Example: TA

- ✓ Complete <TrialDesign.xls (TA)>

Microsoft Excel - Trial Design

File Edit View Insert Format Tools Data Window Help

B14 | Placeho - TRT_X 44 mcg s.c. tiw OL

	A	B	C	D	E	F	G	H
1	**ARMCD**	**ARM**	**TAETORD**	**ETCD**	**ELEMENT**	**TABRANCH**	**TATRANS**	**EPOCH**
2	X_TIW/OL	TRT_X 44 mcg s.c. tiw DB - TRT_X 44 mcg s.c. tiw OL	1	SCREEN	Screening	Randomization to TRT_X 44 mcg tiw		Screening
3	X_TIW/OL	TRT_X 44 mcg s.c. tiw DB - TRT_X 44 mcg s.c. tiw OL	2	X_TIW	TRT_X 44 mcg s.c. tiw double blind		If conversion to CDMS confirmed, go to Open Label Treatment (up to 24 Month) Epoch. If no conversion to CDMS, go to Open Label Treatment (Month 25 - 36) Epoch	Double Blind Treatment
4	X_TIW/OL	TRT_X 44 mcg s.c. tiw DB - TRT_X 44 mcg s.c. tiw OL	3	X_OL	TRT_X 44 mcg s.c. tiw open label		If no conv. to CDMS and no participation in the double-blind 3-year extension study optional add. Open Label Treatment (Month 25 - 36) is possible; if subject doesn't participate go to Follow-up Epoch	Open Label Treatment: up to 24 Month
5	X_TIW/OL	TRT_X 44 mcg s.c. tiw DB - TRT_X 44 mcg s.c. tiw OL	4	X_OOL	TRT_X 44 mcg s.c. tiw open label (optional)			Open Label Treatment: Month 25 - 36 (optional)
6	X_TIW/OL	TRT_X 44 mcg s.c. tiw DB - TRT_X 44 mcg s.c. tiw OL	5	FU	Follow-up			Follow-up

Implementation Example: TA

7	X_OW/OL	TRT_X 44 mcg s.c. ow DB - TRT_X 44 mcg s.c. tiw OL	1	SCREEN	Screening	Randomization to TRT_X 44 mcg ow		Screening
8	X_OW/OL	TRT_X 44 mcg s.c. ow DB - TRT_X 44 mcg s.c. tiw OL	2	X_OW	TRT_X 44 mcg s.c. ow double blind		If conversion to CDMS confirmed, go to Open Label Treatment (up to 24 Month) Epoch. If no conversion to CDMS, go to Open Label Treatment (Month 25 - 36) Epoch	Double Blind Treatment
9	X_OW/OL	TRT_X 44 mcg s.c. ow DB - TRT_X 44 mcg s.c. tiw OL	3	X_OL	TRT_X 44 mcg s.c. tiw open label		If no conv. to CDMS and no participation in the double-blind 3-year extension study optional add. Open Label Treatment (Month 25 - 36) is possible; if subject doesn't participate go to Follow-up Epoch	Open Label Treatment: up to 24 Month
10	X_OW/OL	TRT_X 44 mcg s.c. ow DB - TRT_X 44 mcg s.c. tiw OL	4	X_OOL	TRT_X 44 mcg s.c. tiw open label (optional)			Open Label Treatment: Month 25 - 36 (optional)
11	X_OW/OL	TRT_X 44 mcg s.c. ow DB - TRT_X 44 mcg s.c. tiw OL	5	FU	Follow-up			Follow-up

Implementation Example: TA

12	PBO_X/OL	Placebo - TRT_X 44 mcg s.c. tiw OL	1	SCREEN	Screening	Randomization to Placebo s.c. tiw		Screening
13	PBO_X/OL	Placebo - TRT_X 44 mcg s.c. tiw OL	2	PBO	Placebo s.c. tiw double blind		If conversion to CDMS confirmed, go to Open Label Treatment (up to 24 Month) Epoch. If no conversion to CDMS, go to Open Label Treatment (Month 25 - 36) Epoch	Double Blind Treatment
14	PBO_X/OL	Placebo - TRT_X 44 mcg s.c. tiw OL	3	X_OL	TRT_X 44 mcg s.c. tiw open label		If no conv. to CDMS and no participation in the double-blind 3-year extension study optional add. Open Label Treatment (Month 25 - 36) is possible; if subject doesn't participate go to Follow-up Epoch	Open Label Treatment: up to 24 Month
15	PBO_X/OL	Placebo - TRT_X 44 mcg s.c. tiw OL	4	X_OOL	TRT_X 44 mcg s.c. tiw open label (optional)			Open Label Treatment: Month 25 - 36 (optional)
16	PBO_X/OL	Placebo - TRT_X 44 mcg s.c. tiw OL	5	FU	Follow-up			Follow-up

TV TA TE TS

ACCOVION

Effects on other Domains (OpenCDISC Validator)

- TI:
  - IE (IETESTCD, IETEST, IECAT – all required)
- TE:
  - TA, SE (ETCD (req.), ELEMENT)
- TV:
  - SV (VISITNUM (req.), VISIT, VISITDY)
- TA:
  - DM (ARMCD, ARM – all required)
  - CO (TAETORD)
  - SE, SV, CM, EX, SU, AE, DS, MH, DV, CE, EG, IE, LB, PE, QS, SC, VS, DA, MB, MS, PC, PP, FA (EPOCH, TAETORD)

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