



SI06-Trial Summary SDTM Domain Made Easy for Regulatory Submissions

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What is a Trial Summary Domain?

- The Trial Summary (TS) dataset allows the sponsor to submit a summary of the trial in a structured format
- Each record contains the value of a parameter or characteristic of the trial.
- It is used to record basic information about the study such as trial phase, protocol title, and trial objectives.
- It contains both planned and actual aspects of the trial, such as the number of subjects, and study start/end dates.

Regulatory submission requirements

- Trial summary domains are one of the most overlooked datasets for submissions
- There are different rules regarding trial summary domains depending on the type of application and whether the study is clinical or nonclinical.
- Fortunately, the FDA has provided multiple guidelines to aid Sponsors in determining the requirements for their specific programs. Among these are a list of technical rejection criteria and a self-check worksheet
- Trial summary domains must be submitted for all nonclinical studies that fall within the required SEND study types, but they are only required for clinical studies if other “.xpt” data are submitted.

Studies and Timelines for Trial Summary Domains

Study Type	Study Start Date	Application Type	Criteria to Follow (CDER)
Nonclinical	Prior to or on December 17, 2016	NDA, BLA, ANDA	Simplified TS domain required
	Prior to or on December 17, 2017	Commercial IND	Simplified TS domain required
	After December 17, 2016	NDA, BLA, ANDA	Full TS domain required
	After December 17, 2017	Commercial IND	Full TS domain required
Clinical	Prior to or on December 17, 2016	NDA, BLA, ANDA	Simplified TS domain required if other ".xpt" datasets submitted
	Prior to or on December 17, 2017	Commercial IND	None
	After December 17, 2016	NDA, BLA, ANDA	Full TS domain required
	After December 17, 2017	Commercial IND	None

Trial Summary Specification

TS – Specification

ts.xpt, Trial Summary Information — Trial Design, Version 3.2. One record per trial summary parameter value, Tabulation.

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format ¹	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.	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 can only be null when TSVALNF is populated. Text over 200 characters can be added to additional columns TSVAL1-TSVALn. See Assumption 8.	Exp
TSVALNF	Parameter Null Flavor	Char	ISO 21090 NullFlavor enumeration	Result Qualifier	Null flavor for the value of TSPARM, to be populated if and only if TSVAL is null.	Perm
TSVALCD	Parameter Value Code	Char	*	Result Qualifier	This is the code of the term in TSVAL. For example, "6CW7F3G59X" is the code for Gabapentin; "C49488" is the code for Y. The length of this variable can be longer than 8 to accommodate the length of the external terminology.	Exp
TSVCDREF	Name of the Reference Terminology	Char		Result Qualifier	The name of the Reference Terminology from which TSVALCD is taken. For example; CDISC, SNOMED, ISO 8601.	Exp
TSVCDVER	Version of the Reference Terminology	Char		Result Qualifier	The version number of the Reference Terminology, if applicable.	Exp

¹ In this column, * indicates the variable may be subject to controlled terminology, and CDISC/NCI codelist code values are enclosed in (parenthesis).

- **Required:** STUDYID, DOMAIN, TSSEQ, TSPARMCD, TSPARM
- **Expected:** TSVAL, TSVALCD, TSVCDREF, TSVCDVER
- **Permissible:** TSGRPID, TSVALNF

FDA Technical Conformance Guide – TS Parameters

➤ Trial Summary (TS) Parameters for Submission – Clinical

FDA Desired - Clinical	TSPARMCD	TSPARM	FDA Notes
Y	ACTSUB	Actual Number of Subjects	
Y	ADAPT	Adaptive Design	
Y	ADDON	Added on to Existing Treatments	
Y	AGEMAX	Planned Maximum Age of Subjects	
Y	AGEMIN	Planned Minimum Age of Subjects	
Y	COMPTRT	Comparative Treatment Name	
Conditional	CRMDUR	Confirmed Response Minimum Duration	If applicable.
Conditional	CTAUG	CDISC Therapeutic Area User Guide	If applicable, the value should be the exact listing as in section 5.2 of the Technical Conformance Guide. Use as many rows as needed.
Conditional	CURTRT	Current Therapy or Treatment	Where ADDON = 'Y'. Use as many rows as needed.
Y	DCUTDESC	Data Cutoff Description	GRPID relates DCUTDTC to DCUTDESC.
Y	DCUTDTC	Data Cutoff Date	GRPID relates DCUTDTC to DCUTDESC.
Conditional	EGBLIND	ECG Reading Blinded	For QT submissions.
Conditional	EGCTMON	ECG Continuous Monitoring	For QT submissions.
Conditional	EGLEADPR	ECG Planned Primary Lead	For QT submissions.
Conditional	EGLEADSM	ECG Used Same Lead	For QT submissions.
Conditional	EGRDMETH	ECG Read Method	For QT submissions.
Conditional	EGREPLBL	ECG Replicates at Baseline	For QT submissions.
Conditional	EGREPLTR	ECG Replicates On-Treatment	For QT submissions.

FDA Technical Conformance Guide – TS Parameters

➤ Trial Summary (TS) Parameters for Submission – Non-Clinical

FDA Desired - Nonclinical	TSPARMCD	TSPARM	FDA Notes
See Notes	AGE	Age	Age of subjects planned for the study population as an integer. Either AGE or AGETXT should be populated (not both). If the planned age is a range, then use AGETXT
See Notes	AGETXT	Age Text	Age of subjects planned for the study population expressed as a range. Either AGE or AGETXT should be populated (not both). If an age integer value is available, populate the AGE variable instead
Y	AGEU	Age Unit	
Conditional	ASOCSTDY	Associated Study	If applicable.
Y	DOSDUR	Dosing Duration	
Y	DOSENDTC	End Date/Time of Dose Interval	
Y	DOSSTDTC	Start Date/Time of Dose Interval	
Y	EXPENDTC	Experimental End Date	
Y	EXPSTDTC	Experimental Start Date	
Y	GLPFL	GLP Flag	
Y	GLPTYP	Good Laboratory Practice Type	
Conditional	INTSAC	Time to Interim Sacrifice	Include when the study has an interim sacrifice
Y	PCLASS	Pharmacologic Class	We recognize that pharmacologic class can change throughout the drug development timeline. Refer to the FDA Established Pharmacologic Class (EPC) Text Phrase Document (https://www.fda.gov/media/144963/download).

FDA Technical Conformance Guide – TS Parameters

- The term “Conditional” means a parameter might not be relevant to a trial or study design.
- If the TS Parameter is relevant to the study design and is listed as “Conditional” in the TCG, it should be included in the dataset submitted to the FDA
- For complete list of TS parameters, please visit <https://www.fda.gov/media/153632/download>

Mapping TS Parameters

TSPARMCD	TSPARM	TSVAL	TSVALNF	TSVALCD	TSVCDREF	TSVCDVER
ADAPT	Adaptive Design	N		C49487	CDISC	2020-11-06
ADDON	Added on to Existing Treatments	N		C49487	CDISC	2020-11-06
DMCIND	Data Monitoring Committee Indicator	N		C49487	CDISC	2020-11-06
DOSFRQ	Dosing Frequency	ONCE		C64576	CDISC	2020-11-06
DOSU	Dose Units	mg/kg		C67401	CDISC	2020-11-06
HLTSUBJI	Healthy Subject Indicator	Y		C49488	CDISC	2020-11-06
INTMODEL	Intervention Model	PARALLEL		C82639	CDISC	2020-11-06
INTTYPE	Intervention Type	DRUG		C1909	CDISC	2020-11-06
PDSTIND	Pediatric Study Indicator	N		C49487	CDISC	2020-11-06
PDPSTIND	Pediatric Postmarket Study Indicator	N		C49487	CDISC	2020-11-06
PIPIND	Pediatric Investigation Plan Indicator	N		C49487	CDISC	2020-11-06
RANDOM	Trial is Randomized	Y		C49488	CDISC	2020-11-06
RDIND	Rare Disease Indicator	N		C49487	CDISC	2020-11-06
ROUTE	Route of Administration	INTRAVENOUS		C38276	CDISC	2020-11-06
SEXPOP	Sex of Participants	BOTH		C49636	CDISC	2020-11-06
SSTDYIND	Substudy Planned Indicator	N		C49487	CDISC	2020-11-06
STYPE	Study Type	INTERVENTIONAL		C98388	CDISC	2020-11-06
TBLIND	Trial Blinding Schema	DOUBLE BLIND		C15228	CDISC	2020-11-06
TCNTRL	Control Type	PLACEBO		C49648	CDISC	2020-11-06
TINDTP	Trial Intent Type	TREATMENT		C49656	CDISC	2020-11-06
TPHASE	Trial Phase Classification	PHASE I TRIAL		C15600	CDISC	2020-11-06
TTYE	Trial Type	SAFETY		C49667	CDISC	2020-11-06
TTYE	Trial Type	TOLERABILITY		C98791	CDISC	2020-11-06
TTYE	Trial Type	PHARMACOKINETIC		C49663	CDISC	2020-11-06

- Create a TS parameter template based on the required, conditionally required parameters for a study
- Map the parameters for which the parameter values can be mapped from CDISC SDTM Controlled Terminology document

Link: <https://datascience.cancer.gov/resources/cancer-vocabulary/cdisc-terminology>

Mapping TS Parameters

TSPARMCD	TSPARM	TSVAL	TSVALNF	TSVALCD	TSVCDREF	TSVCDVER
AGEMAX	Planned Maximum Age of Subjects	P55Y			ISO 8601	
AGEMIN	Planned Minimum Age of Subjects	P18Y			ISO 8601	
DCUTDTC	Data Cutoff Date	2021-05-11			ISO 8601	
LENGTH	Trial Length	P148D			ISO 8601	
PLNTRDUR	Planned Trial Duration	P148D			ISO 8601	
SENDTC	Study End Date	2021-04-08			ISO 8601	
SSTDTC	Study Start Date	2020-09-28			ISO 8601	
TRGFUDUR	Target Follow-Up Duration	P115D			ISO 8601	

- Map the parameters for which the parameter values are based on ISO 8601 reference terminology
- For this set of parameters, TSVALCD, TSVCDVER will be missing.

Mapping TS Parameters

TSPARMCD ▾	TSPARM ▾	TSVAL ▾	TSVALNF ▾	TSVALCD ▾	TSVCDREF ▾	TSVCDVER ▾
FCNTRY	Planned Country of Investigational Sites	USA		USA	ISO 3166	
MNFCNTRY	Country of Manufacture	USA		USA	ISO 3166	

- Map the parameters for which the parameter values are based on ISO 3166 reference terminology

TSPARMCD ▾	TSPARM ▾	TSVAL ▾	TSVALNF ▾	TSVALCD ▾	TSVCDREF ▾	TSVCDVER ▾
REGID	Registry Identifier	NCT123456789		NCT123456789	ClinicalTrials.GOV	

- Map the registry identifier parameter value by referencing www.clinicaltrials.gov

TSPARMCD ▾	TSPARM ▾	TSVAL ▾	TSVALNF ▾	TSVALCD ▾	TSVCDREF ▾	TSVCDVER ▾
SPONSOR	Clinical Study Sponsor	Pharmaco		123456789	DUNS	

- Map the Clinical Study Sponsor parameter value by referencing <https://www.dnb.com/duns-number/lookup.html>

Mapping TS Parameters

TSPARMCD ▾	TSPARM ▾	TSVAL ▾	TSVALNF ▾	TSVALCD ▾	TSVCDREF ▾	TSVCDVER ▾
PCLAS	Pharmacologic Class	Antipsychotic Agent		N0000178316	MED-RT	2020-11-02

- Map the Pharmacologic Class parameter value by referencing <https://evs.nci.nih.gov/ftp1/MED-RT/MEDRT.txt>

TSPARMCD ▾	TSPARM ▾	TSVAL ▾	TSVALNF ▾	TSVALCD ▾	TSVCDREF ▾	TSVCDVER ▾
INDIC	Trial Disease/Condition Indication	Tonic-Clonic Epilepsy (Disorder)		24700007	SNOMED	2020-09-01
TDIGRP	Diagnosis Group	Neurofibromatosis Syndrome (Disorder)		19133005	SNOMED	2020-09-01

- Map the Trial Disease/Condition Indication and Diagnosis Group parameter values by referencing <https://browser.ihtsdotools.org/?perspective=full&conceptId1=724760003&edition=MAIN/2022-03-31&release=&languages=en>

Mapping TS Parameters

TSPARMCD ▾	TSPARM ▾	TSVAL ▾	TSVALNF ▾	TSVALCD ▾	TSVCDREF ▾	TSVCDVER ▾
CURTRT	Current Therapy or Treatment	Phenytoin		6158TKW0C5	UNII	2020-08-18
TRT	Investigational Therapy or Treatment	Gabapentin		6CW7F3G59X	UNII	2020-08-18

- Map the Current Therapy or Treatment and Investigational Therapy or Treatment parameter values by referencing <https://precision.fda.gov/uniisearch>

Some Key Points To Remember

- TS domain should be developed closer to database lock or end of a study
- TS domain should reference the same version of CDISC SDTM CT used for programming of all other domains
- Latest available versions of other external dictionaries such as SNOMED, MED-RT, UNII etc. should be referenced
- TSVALCD is unique for each TSVAL
- TSVALNF should be populated only when TSVAL is blank and should follow the ISO 21090 null flavor terminology

References

- <https://www.pharmasug.org/proceedings/2016/DS/PharmaSUG-2016-DS11.pdf>
- <https://www.nuventra.com/resources/blog/regulatory-data-standards-considerations/>
- <https://www.fda.gov/industry/fda-data-standards-advisory-board/study-data-standards-resources>

CONTACT INFORMATION

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