

A “How-to Guide” for Trial Summary 3.1.3

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Agenda

- ✓ CDISC SDTM **Trial Summary** domain (**TS**) – General introduction
- ✓ What's new for **Trial Summary** in SDTM IG 3.1.3 (SDTM 1.3)
- ✓ How & where to find the information for **TS** requested in SDTM IG 3.1.3

Trial Summary – general introduction

- ✓ Trial Summary is used to record basic information about the trial, such as trial phase, protocol title and design objectives
 - The Trial Summary Information Domain (TS) contains one record for each trial summary characteristic
 - This is not subject-level data

Row	STUDYID	DOMAIN	TSSEQ	TSGRPID	TSPARMCD	TSPARM	TSVAL	TSVALNF	TSVALCD	TSVCDREF	TSVCDVER
1	XYZ	TS	1		ADDON	Added on to Existing Treatments	Y		C49488	CDISC	2011-06-10
2	XYZ	TS	1		AGEMAX	Planned Maximum Age of Subjects	P70Y			ISO 8601	
3	XYZ	TS	1		AGEMIN	Planned Minimum Age of Subjects	P18M			ISO 8601	
4	XYZ	TS	1		LENGTH	Planned Trial Length	P3M			ISO 8601	
5	XYZ	TS	1		PLANSUB	Planned Number of Subjects	300				
6	XYZ	TS	1		RANDOM	Trial is Randomized	Y		C49488	CDISC	2011-06-10
7	XYZ	TS	1		SEXPOP	Sex of Participants	BOTH		C49636	CDISC	2011-06-10
8	XYZ	TS	1		STOPRULE	Study Stop Rules	INTERIM ANALYSIS FOR FUTILITY				
9	XYZ	TS	1		TBLIND	Trial Blinding Schema	DOUBLE BLIND		C15228	CDISC	2011-06-10
10	XYZ	TS	1		TCNTRL	Control Type	PLACEBO		C49648	CDISC	2011-06-10
11	XYZ	TS	1		TDIGRP	Diagnosis Group	Neurofibromatosis Syndrome (Disorder)		19133005	SNOMED	
12	XYZ	TS	1		TINDTP	Trial Indication Type	TREATMENT		C49656	CDISC	2011-06-10

example from SDTM IG 3.1.3 section 7.6.3

What's new for Trial Summary in SDTM IG 3.1.3

Row	STUDYID	DOMAIN	TSSEQ	TSPARMCD	TSPARM	TSVAL
1	ABC	TS	1	AGEMIN	Planned Minimum Age of Subjects	18 P18Y
2	ABC	TS	1	AGEMAX	Planned Maximum Age of Subjects	64 P64Y
3	ABC	TS	1	AGEU	Age Unit	YEARS
4	ABC	TS	1	COMPTRT	Comparative Treatment Name	PLACEBO
5	ABC	TS	1	DESIGN	Description of Trial Design	Parallel
6	ABC	TS	1	INDIC	Trial Indication	Tonic-Clonic Epilepsy (Disorder)
7	ABC	TS	1	LENGTH	Trial Length	P14W
8	ABC	TS	1	PLANSUB	Planned Number of Subjects	500
9	ABC	TS	1	PLANEVAL	Planned Number of Evaluable Subjects	470
10	ABC	TS	1	SEXPOP	Sex of Participants	BOTH
11	ABC	TS	1	RANDOM	Trial is Randomized	Y
12	ABC	TS	1	TBLIND	Trial Blinding Schema	DOUBLE BLIND
13	ABC	TS	1	TCNTRL	Type of Control	PLACEBO

Structure in
SDTM IG 3.1.2

Extended list of parameters

SDTM IG 3.1.2

✓ Recommended minimum set:

- TITLE, INDIC, TCNTRL, RANDOM, TRT, COMPTRT (when applicable), **AGESPAN**, AGEMIN, AGEMAX, **AGEU**, SEXPOP, PLANSUB, OBJPRIM, OBJSEC

✓ Optional:

- ADDON, DOSE, DOSFRQ, DOSU, LENGTH, ROUTE, SPONSOR, STOPRULE, TBLIND, TDIGRP, TINDTP, TPHASE

from SDTM IG 3.1.2 section 7.6.2

SDTM IG 3.1.3

✓ Required:

- ADDON, AGEMIN, AGEMAX, LENGTH, PLANSUB, RANDOM, SEXPOP, STOPRULE, TBLIND, TCNTRL, TITLE, TPHASE, TTYPE, OBJPRIM, SPONSOR, REGID, OUTMSPRI, FCNTRY, ADAPT, DCUTDTC, DCUTDESC, NARMS, STYPE, SSTDTC, SENDTC, ACTSUB, HLTSUBJI

✓ Conditionally required:

- TDIGRP, TINDTP, CURTRT, TRT, RANDQT, PCLAS, INTMODEL, INTTYPE

✓ If applicable:

- OBJSEC, COMPTRT, INDIC, STRATFCT, OUTMSSEC, OUTMSEXP, SDMDUR, CRMDUR

from SDTM IG 3.1.3 Appendix C3

Changes from SDTM IG 3.1.2 to 3.1.3

- ✓ Additional variables
 - Code list variables
 - Null flavor
- ✓ Higher demand for controlled terminology

TSPARMCD	TSPARM	TSVAL (Codelist Name or Format)	Record with this Parameter	Notes
ADDON	Added on to Existing Treatments	No Yes Response	Required	
AGEMAX	Planned Maximum Age of Subjects	ISO 8601	Required	If there is no maximum age, TSVALNF = PINF
AGEMIN	Planned Minimum Age of Subjects	ISO 8601	Required	If there is no minimum age, populate TSVAL with P0Y
LENGTH	Planned Trial Length	ISO 8601	Required	
PLANSUB	Planned Number of Subjects	number	Required	
RANDOM	Trial is Randomized	No Yes Response	Required	
SEXPOP	Sex of Participants	Sex of Participants	Required	
STOPRULE	Study Stop Rules	text	Required	Protocol-specified stopping rule. If there is no stopping rule record "NONE" in this field.
TBLIND	Trial Blinding Schema	Trial Blinding Schema	Required	
TCNTRL	Control Type	Control Type	Required	

from SDTM IG 3.1.3 Appendix C3

New: Code List Variables

- ✓ Variables TSVALCD, TSVCDREF, TSVCDVER
 - TSVALCD – Code of parameter value
 - TSVCDREF – Name of reference terminology
 - TSVCDVER – Version of the reference terminology
 - Should be filled for all parameters where controlled terminology is required
 - Examples are given in the SDTM IG 3.1.3, e.g.

TSPARMCD	TSPARM	TSVAL	TSVALNF	TSVALCD	TSVCDREF	TSVCDVER
RANDOM	Trial is Randomized	Y		C49488	CDISC	2013-12-20

New: Null Flavor Variable

✓ Variable TSVALNF (fill TSVCDREF with ISO 21090)

- To be filled, if no value for TSVAL is available
- Uses ISO 21090 null flavor terminology, e.g.

→ **NI** – No information

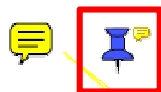
→ **PINF** – Positive infinity, e.g.

→ **UNK** – Unknown

→ **NA** – Not applicable

TSPARMCD	TSPARM	TSVAL	TSVALNF	TSVALCD	TSVCDREF	TSVCDVER
AGEMAX	Planned Maximum Age of Subjects		PINF		ISO 21090	

Complete list available in SDTM IG 3.1.3 section 7.6.4






CDISC

18.06.2012 06:23:45

SDTMIG 3.1.3 contains a new Section, 7.6.4 USE OF NULL FLAVOR ENUMERATION. The new section has been inserted into this document as an attachment.

[Click on the attachment icon to open the document.]

The attached document describes how the new TSVALNF variable is used. The new variable TSVALNF is based on the idea of a "null flavor" as embodied in the ISO 21090 standard, "Health Informatics – Harmonized data

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November 12, 2008

Higher Demand for Controlled Terminology

- ✓ Very few parameters without controlled terminology:
 - Text from study protocol:
 - TITLE, OBJPRIM, OBJSEC, OUTMSPRI, OUTMSSEC, OUTMSEXP, STOPRULE, DCUTDESC
 - Numbers:
 - PLANSUB, ACTSUB, NARMS, RANDQT
 - Variable names:
 - STRATFCT
- ✓ Everything else is 'controlled'.

How & where to find the information for TS requested in SDTM IG 3.1.3

- ✓ ISO 8601 & ISO 3166-1 alpha-3
- ✓ CDISC controlled terminology
- ✓ Some of the code lists named in the SDTM IG might not be easy to access or even unavailable, e.g.
 - UNII, SRS Preferred Substance Name
 - NDF-RT
 - DUNS
 - SNOMED

Example usage of CDISC CT

✓ Source:

<http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/cdisc>

CDISC's **Study Data Tabulation Model (SDTM)** is an international standard for clinical research data, and is approved by the FDA as a standard electronic submission format. NCI EVS maintains and distributes SDTM controlled terminology as part of NCI Thesaurus. More information is available at CDISC's [SDTM Web page](#). SDTM terminology is available for direct download from the [CDISC SDTM directory](#) on an NCI File Transfer Protocol (FTP) site in [Excel](#), [text](#), [odm.xml](#), [pdf](#), [html](#) and [OWL/RDF](#) formats.

TSPARMCD	TSPARM		TSVAL (Codelist Name or Format)		Record with this Parameter Required	Notes
RANDOM	Trial is Randomized		No Yes Response			
1	Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value	CDISC Synonym(s)
	C66742		No	No Yes Response	NY	No Yes Response
5626	C49487	C66742		No Yes Response	N	No
5627	C48660	C66742		No Yes Response	NA	NA; Not Applicable
5628	C17998	C66742		No Yes Response	U	U; Unknown
5629	C49488	C66742		No Yes Response	Y	Yes
5630	C49488	C66742		No Yes Response	Y	Yes

TSPARMCD	TSPARM	TSVAL	TSVALNF	TSVALCD	TSVCDREF	TSVCDVER
RANDOM	Trial is Randomized	Y		C49488	CDISC	2014-03-28

List of controlled terms from ISO & CDISC CT

✓ ISO 8601

- Dates & duration for: AGEMAX, AGEMIN, LENGTH, DCUTDTC, SSTDTC, SENDTC, SDMDUR, CRMDUR

✓ ISO 3166-1 alpha-3

- Country codes for FCNTRY

✓ No Yes Response

✓ Sex of Participants

✓ Trial Blinding Schema

✓ Control Type

✓ Trial Indication Type

✓ Trial Phase

✓ Trial Type

✓ Intervention Model

✓ Study Type

✓ Intervention Type

UNII, SRS Preferred Substance Name

✓ FDA Substance Registration System –
Unique Ingredient Identifier

- To be used for:
 - TRT – Investigational Therapy or Treatment
 - CURTRT – Current Therapy or Treatment
 - COMPTRT – Comparative Treatment Name

✓ Source:

<http://fdasis.nlm.nih.gov/srs/>

- Use **UNII** for TSVALCD
- Use **Preferred Substance Name** for TSVAL

UNII, SRS Preferred Substance Name

U.S. Food and Drug Administration
 Protecting and Promoting Your Health

United States
National Library of Medicine
 National Institutes of Health

Substance Registration System - Unique Ingredient Identifier (UNII)

[Home](#) > [Search Results](#)

Search
Substance Registration System

☒ By Name ☐ By UNII

[Go back to previous page.](#)

Search Results

Preferred Substance Name: METFORMIN [\[show more names\]](#)

UNII: 9100L32L2N

Formula: C₄H₁₁N₅

InChIKey: XZWYZXLPXDOLR-UFEEFAOYSA-N

Resources

- [ChemIDplus](#)
- [DrugPortal](#)
- [NCI Thesaurus](#)

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 National Institutes of Health, Health & Human Services
 Freedom of Information Act
 Last updated: Apr 2014

TSPARMCD	TSPARM	TSVAL	TSVALNF	TSVALCD	TSVCDREF	TSVCDVER
TRT	Investigational Therapy or Treatment	METFORMIN		9100L32L2N	UNII	

NDF-RT

✓ Veterans Affairs National Drug File Reference Terminology

- To be used for
 - PCLAS - Pharmacological Class

✓ Source:

<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm162549.htm> :

Downloadable ZIP file [“FDA Pharmacologic Classes”](#)

- also contains UNII

NDF-RT

1	Active Moiety Name	Active Moiety UNII	FDA Text Phrase	NDF-RT Concept	NDF-RT NUI
8485	metformin	9100L32L2N	biguanide	Biguanide [EPC]	N0000175565
8486	metformin	9100L32L2N		Biguanides [Chemical/Ingredient]	N0000007698
8487	methadone	UC6VBE7V1Z	opioid agonist	Opioid Agonist [EPC]	N0000175690
8488	methadone	UC6VBE7V1Z		Full Opioid Agonists [MoA]	N0000175684
8489	methimazole	554Z48XN5E	thyroid hormone synthesis inhibitor	Thyroid Hormone Synthesis Inhibitor [EPC]	N0000175918
8490	methimazole	554Z48XN5E		Thyroid Hormone Synthesis Inhibitors [MoA]	N0000175917

TSPARMCD	TSPARM	TSVAL	TSVALNF	TSVALCD	TSVCDREF	TSVCDVER
PCLAS	Pharmacological Class of Investigational Therapy	Biguanide		N0000175565	NDF-RT	

DUNS

- ✓ Data Universal Numbering System
by Dun and Bradstreet
 - To be used for:
 - SPONSOR – Clinical Study Sponsor
- ✓ Source:
 - https://www.upik.de/de/upik_suche.cgi (German)
 - https://www.upik.de/en/upik_suche.cgi (English)

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[When is a D-U-N-S® Number considered as non-active?](#)

[When are there no hits?](#)

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[UPIK® Basics](#)



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DUNS

UPIK®-Search hit list

To access the detailed information, you have to click on the company name.

L	MERCK Kommanditgesellschaft auf Aktien	Industriepark Höchst	Branch	Frankfurt am Main
L	Merck G.m.b.H.	Höfestr. 3	Headquarters	Isernhagen
L	Gerline Merck	Dachauer Str. 85	Single location	Markt Indersdorf
L	MERCK Kommanditgesellschaft auf Aktien	Mainzer Str. 41	Branch	Gernsheim
L	Merck Wohnungs- und Grundstücksverwaltungsgesellschaft mbH	Frankfurter Str. 250	Single location	Darmstadt
L	MERCK Kommanditgesellschaft auf Aktien	Wernher-von-Braun-Straße 9	Branch	Eppelheim
L	MERCK Kommanditgesellschaft auf Aktien	Frankfurter Str. 250	Headquarters	Darmstadt
L	Jasmin Merck	Am Abhang 9	Single location	Hamburg
L	H.J. Merck & Co. GmbH	Hasenhöhe 40B	Single location	Hamburg
L	Josef Witt GmbH	Schillerstr. 4-12	Headquarters	Weiden i.d.OPf. (Weiden i.d.OPf.)
L	Gabrielle Merck	Hamburger Str. 29	Single location	Landau in der Pfalz
L	Julia Merck	Südstr. 4	Single location	Sendenhorst
L	Oliver Merck	Alpenstr. 68	Single location	Gröbenzell
L	Josef Witt Beteiligungs-Verwaltungsgesellschaft International mbH	Schillerstr. 4-12	Headquarters	Weiden i.d.OPf. (Weiden i.d.OPf.)
L	Dr.med. Waldemar Merck	Marktstätte 11	Single location	Konstanz
L	Katharina Merck Cordula Rohmoser	Winterbachstr. 13	Single location	Frankfurt am Main
L	Yvonne Merck	Rigaer Str. 66	Single location	Berlin

UPIK® Record - L

L	Registered company name	MERCK Kommanditgesellschaft auf Aktien
	Non-registered name or business unit	
L	D-U-N-S® Number	342249299
L	Registered address	Frankfurter Str. 250
L	Post code	64293
L	City	Darmstadt
	Country	Germany
W	Country code	269
	Post office box number	
	Post office box town	
L	Telephone number	06151720
W	Fax number	06151722000
W	Name primary executive	Rolf Krebs
W	Activity (SIC)	2834

TSPARMCD	TSPARM	TSVAL	TSVALNF	TSVALCD	TSVCDREF	TSVCDVER
SPONSOR	Clinical Study Sponsor	MERCK Kommanditgesellschaft auf Aktien		342249299	DUNS	

SNOMED

- ✓ Systematized Nomenclature of Medicine
 - To be used for
 - INDIC – Trial Indication
 - TDIGRP – Diagnosis Group
- ✓ Problem: Not licensed in many companies, especially outside of the U.S.
- ✓ Proposal: Use terms as described in protocol

TSPARMCD	TSPARM	TSVAL	TSVALNF	TSVALCD	TSVCDREF	TSVCDVER
INDIC	Trial Indication	Tonic-Clonic Epilepsy (Disorder)			SNOMED	
TDIGRP	Diagnosis Group	Subjects with type 2 diabetes mellitus			SNOMED	

REGID: CT.GOV / EUDRACT

✓ CT.GOV Source:
<http://www.clinicaltrials.gov/>

A Safety/Efficacy Study of Intra-coronary Tenecteplase During Balloon Angioplasty to Treat Heart Attacks (ICE T-TIMI 49)

This study has been completed.

Sponsor:

C. Michael Gibson, MS, MD

Collaborator:

Genentech

Information provided by (Responsible Party):

C. Michael Gibson, MS, MD, Brigham and Women's Hospital

ClinicalTrials.gov Identifier:

NCT00604695

First received: January 7, 2008

Last updated: August 6, 2012

Last verified: August 2012

[History of Changes](#)

TSPARMCD	TSPARM	TSVAL	TSVALNF	TSVALCD	TSVCDREF	TSVCDVER
REGID	Registry Identifier	NCT00604695		NCT00604695	CT.GOV	
REGID	Registry Identifier	XYZ1234		XYZ1234	EUDRACT	

✓ EudraCT number often found in protocol

Questions?



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