



A “How-to Guide” for Trial Summary



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

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 3.2, e.g.

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

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 3.2 section 7.4, page 360

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 3.2

- 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> or on eSHARE **Study Data Tabulation Model (SDTM)**

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](#).

- 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.



Microsoft Excel - SDTM Terminology.xls [Read-Only] [Compatibility Mode]

	A	B	C	D	E	F
	Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value	CDISC Synonym(s)
1	C66742		No	No Yes Response	NY	No Yes Response
5626	C49487	C66742		No Yes Response	N	No
5628	C48660	C66742		No Yes Response	NA	NA; Not Applicable
5629	C17998	C66742		No Yes Response	U	U; Unknown
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

METFORMIN

Go

Go back to previous page.

Search Results

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

UNII: 9100L32L2N

Formula: C4H11N5

InChIKey: XZWYZXLPXDOLR-UFEEFAOYSA-N

Resources

- ▶ [i ChemIDplus](#)
- ▶ [i DrugPortal](#)
- ▶ [i 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:

https://ncit.nci.nih.gov/ncitbrowser/pages/multiple_search.jsf?nav_type=terminologies

- Click on:

NDF-RT: National Drug File Reference Terminology Public Inferred Edition (July2016)

NDF-RT

Version: July2016 (Release date: 2016-07-05-08:00)

Search



Contains Exact Match Begins With

Name Code Property Relationship

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Biguanide [EPC] (Code N0000175565)

Terms & Properties

Synonym Details

Relationships

Mappings

View All

Terms & Properties

label: Biguanide [EPC]

Display Name: Biguanide

National Drug File - Reference Terminology Code: N0000175565

NCI Metathesaurus Link: C3537187 [\(see NCI Metathesaurus info\)](#)

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?](#)

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[UPIK® Basics](#)

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	Gerfine 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	06 51720
W	Fax number	06 51722000
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

➤ Source:

https://ncit.nci.nih.gov/ncitbrowser/pages/multiple_search.jsf?nav_type=terminologies

- Click on:

[SNOMED CT: Systematized Nomenclature of Medicine-Clinical Terms \(2015_09_01\)](#)

SNOMED

SNOMED CT

Version: 2015_09_01 (Release date: 2015-09-01-08:00)

Tonic-Clonic Epilepsy (Disorder)

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Tonic-clonic epilepsy (Code 352818000)

Terms & Properties

Synonym Details

Relationships

Mappings

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Terms & Properties

SNOMED Clinical Terms Code: 352818000

TSPARMCD	TSPARM	TSVAL	TSVALNF	TSVALCD	TSVCDREF	TSVCDVER
INDIC	Trial Indication	Tonic-clonic epilepsy		352818000	SNOMED	
TDIGRP	Diagnosis Group	Type 2 diabetes mellitus		44054006	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

References

- <http://www.lexjansen.com/pharmasug/2016/DS/PharmaSUG-2016-DS02.pdf>



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