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

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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.

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<tr>
<th>TSPARMCD</th>
<th>TSPARM</th>
<th>TSVAL</th>
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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

- 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](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.


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**Microsoft Excel - SDTM Terminology.xlsx**

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**Example:**

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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:
  - Use UNII for TSVALCD
  - Use Preferred Substance Name for TSVAL
## UNII, SRS Preferred Substance Name

### Search Results

- **Prefered Substance Name**: METFORMIN
- **UNII**: 9100L32L2N
- **Formula**: C4H11N5
- **InChIKey**: XZWyZzLpxDolr-UHFFFAOYSA-N

### Resources
- ChemIDplus
- DrugPortal
- NCI Thesaurus

### Table

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<th>TSPARM</th>
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Veterans Affairs National Drug File Reference Terminology

To be used for

PCLAS - Pharmacological Class

Source:


Click on:

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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)
UPIK® - Unique Partner Identification Key

Access information about 235,811,265 companies worldwide – instantly and cost-free. Thanks to the D&B D-U-N-S® Number, all companies are clearly identified and associated data are correctly classified.

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D&B D-U-N-S® Number
Select country

Display business partner information

If you don't know the D&B D-U-N-S® Number of the company you're seeking, please enter the name and address of the company into the fields below.

Company
Address
Zip Code
City
Country

Find

For more accurate search results, please complete as many fields as possible. A maximum of 100 results will be displayed for each query.

* These fields must be completed to conduct a search
To access the detailed information, you have to click on the company name.

L. MERCK Kommanditgesellschaft auf Aktien
  Branch: Frankfurt am Main
  Headquarter: Darmstadt

L. Jasmin Merck
L. H. J. Merck & Co. GmbH
L. Josef Witt GmbH
L. Gabriele Merck
L. Julia Merck
L. Oliver Merck
L. Josef Witt Beteiligungs-Verwaltungsgesellschaft International mbH
L. Dr. med. Waldemar Merck
L. Katharina Merck Cordula Rohmoser
L. Yvonne Merck

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Systematized Nomenclature of Medicine

To be used for
- INDIC – Trial Indication
- TDIGRP – Diagnosis Group

Source:

Click on:
SNOMED CT: Systematized Nomenclature of Medicine-Clinical Terms (2015_09_01)
Tonic-clonic epilepsy (Code 352818000)

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REGID: CT.GOV / EUDRACT


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

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EudraCT number often found in protocol
References

Nicola Tambascia
A “How-to Guide” for Trial Summary
Phone: +49 6196 7709 283
ntambascia@clinipace.com
clinipace.com