



# *SDTM TAUGS OVERVIEW OF CURRENT DEVELOPMENT*

13 September 2016, 23<sup>rd</sup> German CDISC User Network Meeting Berlin  
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**PAREXEL.**  
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# AGENDA

## *SDTM THERAPEUTIC AREA USER GUIDES*

Status as of September 2016

- Released TAUGs
- TAUGs in public review
- Project Status

# CURRENTLY RELEASED TAUGS

- Alzheimer's Disease v2.0 Provisional (2013-12-16)
- Asthma v1.0 Provisional (2013-11-26)
- Breast Cancer v1.0 Provisional (2016-05-16)
- COPD v1.0 Provisional (2016-01-22)
- Cardiovascular v1.0 Provisional (2014-10-17)
- Diabetes v1.0 Provisional (2014-08-01)
- Dyslipidemia v1.0 Provisional (2015-06-02)
- Chronic Hepatitis C Virus Infection v1.0 Provisional (2015-04-25)
- Influenza v1.0 Provisional (2014-11-25)
- Multiple Sclerosis v1.0 Provisional (2014-05-02)
- Polycystic Kidney Disease (PKD) v1.0 Provisional (2013-02-26)
- Pain v1.0 Provisional (2012-08-07)
- Parkinson's Disease v1.0 Provisional (2012-12-18)
- QT Studies v1.0 Provisional (2014-12-08)
- Schizophrenia v1.0 Provisional (2015-05-26)
- Traumatic Brain Injury (TBI) v1.0 Provisional (2015-12-02)
- Tuberculosis v2.0 Provisional (2016-02-19)
- Virology v2.0 Provisional (2015-09-30)

A CDISC provisional release is defined as a proposed standard that has completed a public review within the CDISC user community and is available for initial use; but subject to modification for some component parts still in process. Any revisions to the draft or provisional domains and their publication status will be updated as needed in future versions of the TAUG.

- The FDA supports Therapeutic Area Data Elements for 5 therapeutic areas

FDA Conformance Guide (Version 3.1, July 2016) section 5:

## 5. Therapeutic Area Standards

### 5.1 General

CDISC Therapeutic Area (TA) standards are comprised of existing data elements, but may introduce new data elements (e.g. domains, variables, terminologies). These data elements are components of current CDISC implementation guides or will be integrated into future implementation guides. CDISC publishes a user guide for each therapeutic area use case which describes the most common data elements for clinical studies (<http://www.cdisc.org/therapeutic>).

### 5.2 Supported Therapeutic Areas

Generally, when a data standard is released for public use by the SDO, it is not supported by FDA and is not listed in the FDA Data Standards Catalog. FDA performs acceptance testing to determine its ability to support new TA data elements.<sup>32</sup> The CDISC data elements associated with following therapeutic areas are supported by FDA:

#### 5.2.1 Chronic Hepatitis C

#### 5.2.2 Dyslipidemia

#### 5.2.3 Diabetes

#### 5.2.4 QT Studies

#### 5.2.5 Tuberculosis

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# TAUGS IN PUBLIC REVIEW

- **The following TAUG drafts are available for public review**
- [Asthma v1.1](#)
- [Influenza v1.1](#)
- [Pain v1.1](#)
- [Schizophrenia v1.1](#)
- [Virology v2.1](#)

**Comments due 30 September 2016**

# CHANGES IN TAUGS CURRENTLY UNDER REVIEW

- **General and organizational updates in all TAUGs under review, e.g.**
    - Errata corrected
    - Terminology updated to conform to current standards
    - Adapted to CDISC Wiki environment
    - Organizational updates and modeling changes, e.g. section 1 re-organized
    - Concept maps updated to conform to current practice
    - "Known Issues" updated
  - **Non-Standard Variables (NSV) Proposal**
    - Examples updated to follow the suggestions of the NSV proposal, i.e. representing additional information in variables in the parent domain instead of SUPP--  
<http://wiki.cdisc.org/display/PUB/Alternative+Representation+of+Non-Standard+Variables>
- ... And domain specific changes

# CFAST PROJECT STATUS – AS OF JULY 2016



## Program Overview – July 2016



Therapeutic Area	Charter Approved	Check of Concepts Completed	Posted for Internal Review	Posted for Public Review	Projected Publication
<a href="#"><u>Rheumatoid Arthritis v1</u></a>	Jun 15	Oct 15	Jan	May	Q3 2016
<a href="#"><u>CV Imaging v1</u></a>	May 15	Jul 15	Dec 15	May	Q3 2016
<a href="#"><u>Diabetic Kidney Disease v1</u></a>	May 15	Aug 15	Jan	Jul	Q3 2016
<a href="#"><u>Ebola v1*</u></a>	Sep 15	Mar	Mar	Jul	Q3 2016
<a href="#"><u>Kidney Transplant v1</u></a>	Jan	Mar	Apr	Jul	Q3 2016
<a href="#"><u>Prostate Cancer v1</u></a>	Nov 15	Mar	Jul	Aug	Q3 2016
<a href="#"><u>Major Depressive Disorder v1**</u></a>	Dec 15	Feb	May	Jul	Q3 2016
<a href="#"><u>Vaccines v1*</u></a>	Q4 14	Oct 15	Jul		Q4 2016
<a href="#"><u>Malaria v1*</u></a>	Oct 15	Jul	Jul	Aug	Q4 2016
<a href="#"><u>Nutritional Standards v1*</u></a>	Mar 15	Q316			Q4 2016
<a href="#"><u>Coronary Heart Disease – TCM v1*</u></a>	Apr	Q316			Q4 2016
<a href="#"><u>Acupuncture – TCM v1*</u></a>	Apr	Q316			Q1 2017
<a href="#"><u>Colorectal Cancer v1</u></a>	May	Jul			Q4 2016
<b>Duchenne Muscular Dystrophy</b>	Sep				Q4 2017

Key |   Stage completed |   Stage ongoing | All months reflect when stage is, or is projected to be, completed

\*Project duration dependent on volunteer resourcing

\*\*General Anxiety Disorder and Bipolar Disorder pending resource availability

<http://www.cdisc.org/system/files/all/standard/CFAST-TA-Project-Status.pdf>

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*THANK YOU*