SDTM TAUGS
OVERVIEW OF
CURRENT
DEVELOPMENT

13 September 2016, 23rd German CDISC User Network Meeting Berlin
Antje Simon
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. 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
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

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

**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

THANK YOU