

CDISC News



Setting the
Global Standard
for Clinical Data

**CLINICAL DATA INTERCHANGE
STANDARDS CONSORTIUM**

Leverkusen, 26 February 2013

CDISC News

- Updated Version of SDTM/ADaM Pilot Submission Package - Jan 2013
(member's only: <http://www.cdisc.org/content1037>)
- SDTM, QS, CDASH, SEND Controlled Terminology Updates – Dec 2012
(<http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/cdisc>)
- Medical Device Supplement to Study Data Tabulation Model v.1.0 – Dec 2012
(<http://www.cdisc.org/sdtm>)
- Overview of Recently Posted Updates
(http://www.cdisc.org/stuff/contentmgr/files/0/6497cf2280bc974792a8803e973d1dee/files/standards_updates_11_feb_2013_final.pdf)

New Standard	Link	Date Posted
Table for All Therapeutic Area Standards	http://www.cdisc.org/therapeutic	Posted in January 2013
Table for All Questionnaires	http://www.cdisc.org/content2909	Posted in January 2013
Updated Version of SDTM/ADaM Pilot	http://www.cdisc.org/content1037	Posted in January 2013

CDISC Therapeutic Area Standards

Therapeutic Area	Current State	Key Date
<u>Alzheimer's Disease v1</u>	Final	September 30, 2011
Cardiovascular Disease	In Development	---
<u>Pain v1</u>	Provisional	August 7, 2012
<u>Parkinson's Disease</u>	Provisional	December 18, 2012
<u>Polycystic Kidney Disease</u>	Review Closed	November 30, 2012
<u>Tuberculosis v1</u>	Provisional	June 29, 2012
<u>Virology</u>	Provisional	December 6, 2012

CDISC Questionnaire Supplement

Questionnaire	Version	Short Name (QSCAT)	Permission	Release Date
<u>Alzheimer's Disease Assessment Scale - Cognitive (ADAS-Cog)</u>	V1.0	ADAS-COG	Granted	January 26, 2012
<u>Brief Pain Inventory-Interference Scale - Short Form (BPI-I)</u>	V1.0	BPI SHORT FORM	Granted	
<u>Brief Pain Inventory-Interference Scale (BPI-I)</u>	V1.0	BPI	Granted	August 7, 2012
<u>Brief Psychiatric Rating Scale-Anchored (BPRS-A)</u>	V1.0	BPRS-A	Public Domain	January 29, 2013
<u>Clinical Global Impression (CGI)</u>	V1.0	CGI	Public Domain	August 7, 2012
<u>Columbia Suicide Severity Rating Scale - Baseline (CSSRS-BSL)</u>	V1.0	C-SSRS BASELINE	Granted	August 7, 2012
<u>Columbia Suicide Severity Rating Scale - Baseline (CSSRS-BSL)</u>	V1.1	C-SSRS BASELINE	Granted	February 06, 2013
<u>Columbia-Suicide Severity Rating Scale Since Last Visit (C-SSRS SINCE LAST VISIT)</u>	V1.0	C-SSRS SINCE LAST VISIT	Granted	February 06, 2013
<u>Current Opioid Misuse Measure (COMM)</u>	V1.0	COMM	Granted	August 7, 2012
<u>Euroqol (European Quality of Life) Five Dimension three level scale (EQ-5D-3L)</u>	V1.0	EQ-5D-3L	Not Permitted	August 7, 2012

... further questionnaires

CDISC Standards Webinars

2013 Schedule, Agenda, Registration Details available at:

<http://www.cdisc.org/webinars>

Slides and taped versions of previous webinars available at member's only area

Next Webinar: Thursday, 14 March 2013, 11:00 AM - 12:30 PM EST

Topic:

Learning Health System – Essential Standards to Enable Learning (ESTEL)

Agenda Details:

Overview of proposed use cases from breakout groups at CDISC Learning Health System Meeting in Austin, TX. Participants come from backgrounds in government, education, and private sector.

Topics to be discussed on webinar will be published in the coming days.

Upcoming Events:

FDA/PhUSE Computational Science Symposium (CSS)



18-19 March in Silver Spring, MD

The aim of the FDA/PhUSE annual Computational Science Symposium (CSS) is to provide updates on collaborations with project groups to improve standards, tools and processes across regulatory review and computational science.

Visit the PhUSE website for details on the individual working groups (http://www.phuse.eu/WorkingGroup_OverviewCSS.aspx)

Upcoming events: CDISC Interchange Europe

CDISC Interchange Europe
22-26 April 2013

Location:

Dolce Bad Nauheim
Elvis-Presley-Platz 1
61231 Bad Nauheim
Germany



PRELIMINARY PROGRAM

Conference 24-25 April 2013
Training 22, 23 & 26 April 2013

Other News

- **Update to FDA Study Data Standards Webpage (22-Feb-2013)**
 - The changes to the Study Data Standards web page (<http://www.fda.gov/ForIndustry/DataStandards/StudyDataStandards/default.htm>) acknowledge CBER/CDER/CDRH-approved support for the voluntary submission of human study data using CDISC **SDTM I.G. v3.1.3**.
 - It also acknowledges the ongoing support for **define.xml v.1.0**
- **New online CDISC training modules are in development and coming soon**