

CDISC News



Setting the
Global Standard
for Clinical Data

**CLINICAL DATA INTERCHANGE
STANDARDS CONSORTIUM**

Eschborn, 18 February 2014

CDISC News

- SDTM 1.4, SDTMIG 3.2, SDTMIG-AP 1.0 - Dec 2013
(<http://www.cdisc.org/sdtm>)
- SDTM, QS, CDASH, SEND Controlled Terminology Updates – Dec 2013
(<http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/cdisc>)
- CDASH Serious Adverse Event Supplement 1.0 - Dec 2013
(<http://www.cdisc.org/cdash>)
- TAUG Asthma 1.0, TAUG Alzheimer's 2.0 - Q4 2013
(<http://www.cdisc.org/therapeutic>)
- Draft SDS-XML - already discussed in the morning session

CDISC Standards Webinars

2014 Schedule, Agenda, Registration Details available at:

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

Next Webinar: Thursday, 20 Feb 2014, 11:00 AM - 12:30 PM EST

Agenda:

- SDTM Pharmacogenomics IG v1.1
- What to expect from SHARE R1 and R2

Upcoming events: CDISC Interchange Europe

CDISC Interchange Europe
07-11 April 2014

Location:

Eurosites George V
28, Avenue George V | 75008
Paris, France

PRELIMINARY PROGRAM

Conference 09-10 April 2014
Training 07, 08 & 11 April 2014



Other Upcoming Events

- **CDISC All Team INTRACHange**
Feb. 25-27, 2014 at the Silver Spring Civic Center in Silver Spring, MD, USA
- **FDA/PhUSE Computational Science Symposium (CSS)**
Mar.16-18, 2014 at the Silver Spring Civic Center in Silver Spring, MD, USA

Other News

FDA Guidance on Standardized Study Data for Electronic Submissions
(<http://www.cdisc.org/fda-guidance-on-standardized-study-data->)

Drafts published for 90 day review period (06-Feb-2014)

- **FDA-2014-D-0092 -**
[Study Data Technical Conformance Guide and Data Standards Catalog](#)
- **FDA-2012-D-0097 -**
[Guidance on Electronic Submissions: Standardized Study Data](#)
- **FDA-2014-D-0085 -**
[Guidance on Submissions in Electronic Format--Submissions under the Federal Food, Drug, and Cosmetic Act](#)