CDISC News

CDISC℠

Setting the
Global Standard
for Clinical Data

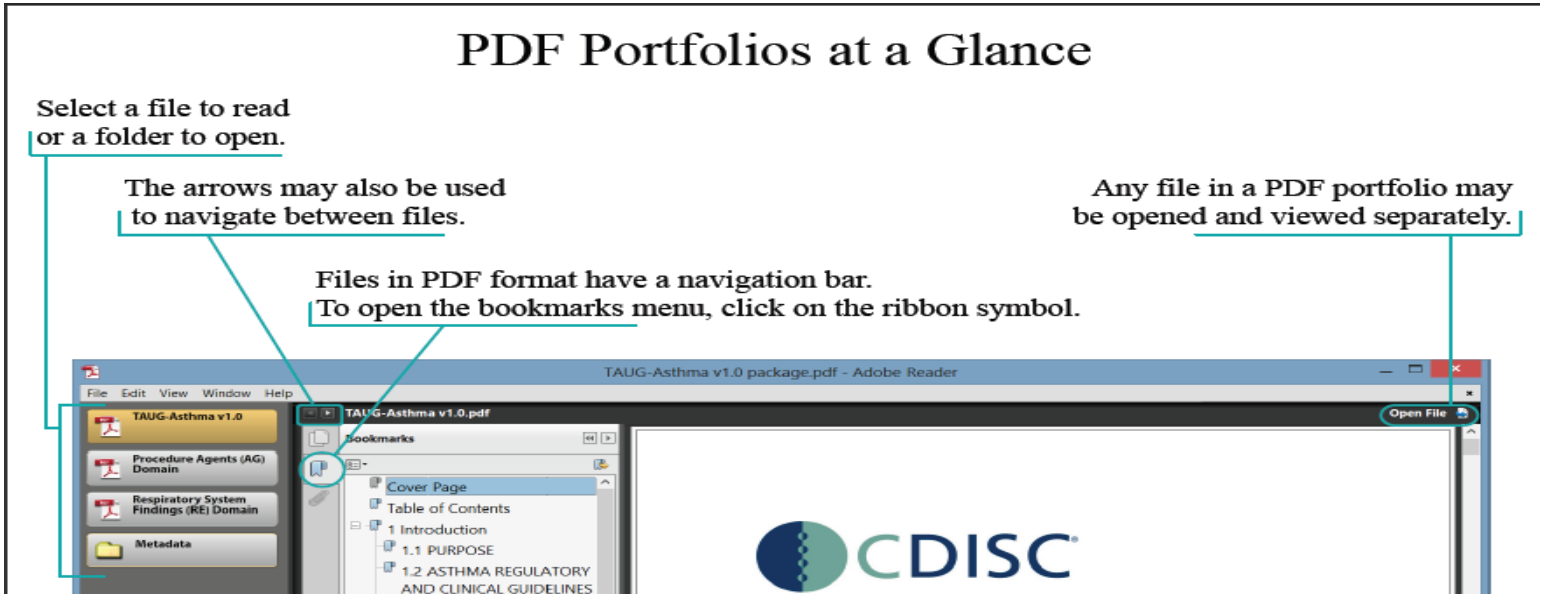
CLINICAL DATA INTERCHANGE
STANDARDS CONSORTIUM

Berlin, 24 September 2013

CDISC News

- **Asthma Therapeutic Area Data Standard User Guide v 1.0 (TAUG-Asthma) Now Available for Public Review**
  - Comments Due 18 October 2013
  - Details: http://www.cdisc.org/therapeutic

  - New Format: PDF Portfolio (search within individual file or portfolio)



CDISC Therapeutic Area Standards Status

CFAST Program Overview

Therapeutic Area Standards Under Development

	Coordinating Organization(s)	Stage 0	Stage 1	Stage 2	Stage 3a	Stage 3b	Stage 3c
	Project Manager	Scoping & Input	Concept Modeling	Standards Development	Internal Review	Public Review	Publication
Alzheimer's V1.1	CPATH/CDISC Jon Neville	Jan	Mar	Jun	*Jul*	*Sep*	*Q313*
Asthma V1	CDISC Rhonda Facile	Jan	Mar	Jun	Jul	*Sep*	*Q413*
Cardiovascular Endpoints V1	CDISC/DCRI Amy Palmer	Jun	*Jul*	*Aug*			*Q114*
Multiple Sclerosis V1	CPATH/CDISC Bess Leroy	May	*Aug*	*Jul*			*Q114*
Diabetes V1	TCB/CDISC Rachael Zirkle	Mar	*Jun*	Aug	*Sep*		*Q114*
QT Studies V1	TCB/CDISC John Owen	*Jul*	*Sep*				*Q214*
Traumatic Brain Injury V1	CDISC TBD	*Sep*					*Q214*
Hepatitis C V1	TBD	*Sep*					*Q314*
Schizophrenia V1	CDISC/DCRI Amy Palmer	*Oct*					*Q314*
Oncology	TBD	*Oct*					

Project Status: Stage ongoing Stage completed *Italics = Projected*

Reference: http://www.cdisc.org/stuff/contentmgr/files/0/2356ae38ac190ab8ca4ae0b222392b37/misc/cfast_ta_project_status_for_website_4_.pdf

SHARE - Latest News

- SOA Software's Semantic Manager product chosen as SHARE technology platform (20-Jun-2013)
  - Externally hosted computing environment

- Functionality
  - Global electronic repository for developing, integrating and accessing CDISC metadata standards
  - Help users find, understand and use rich metadata and CTs relevant to clinical studies more efficiently and consistently

- Access to **full** set of SHARE features will likely involve nominal costs to licensed trained and qualified users

- Follow YouTube video on CDISC SHARE (http://www.youtube.com/watch?v=gCyVdvgVpY8&feature=youtu.be)
- SHARE will be launched at the CDISC US Interchange

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 or as YouTube videos

Next Webinar: Thursday, 10 October 2013, 11:00 AM - 12:30 PM EST

Agenda and links coming soon!

Other News

– **Update to FDA Study Data Standards Catalog**
(http://www.fda.gov/ForIndustry/DataStandards/StudyDataStandards/default.htm)

1.5 Download a catalog of FDA-supported Study Data Standards for offline viewing (XLS) (Updated September 2013)

- Please read the instructions on using the Data Standards Catalog

An error has been identified in the Instructions for the Study Data Standards Catalog related to MedDRA versioning. This document is under review and will be republished as soon as possible

Data Standard Type	Governing Organization	Standard	Version	Implementation Guide	FDA Component	Date Support Begins*	Date Support Ends**	Use
Exchange and Analysis Standard	CDISC	define.xml	2.0		CBER, CDER, CDRH	2013-8-07		Study data definition specification
	CDISC	define.xml	1.0		CBER, CDER, CDRH	Ongoing		Study data definition specification
	CDISC	SDTM	SDTM 1.3	3.1.3	CBER, CDER, CDRH	2012-12-01		Human study tabulation data
	CDISC	SDTM	SDTM 1.2	3.1.2 Amendment 1	CBER, CDER, CDRH	2013-08-07		Human study tabulation data. Amendment 1 has been incorporated into version 3.1.3
	CDISC	SDTM	SDTM 1.2	3.1.2	CBER, CDER, CDRH	2009-10-30		Human study tabulation data
	CDISC	SDTM	SDTM 1.1	3.1.1	CBER, CDER, CDRH	Ongoing	2015-01-28	Human study tabulation data. Do not use for studies initiated after 2011-06-13.
	CDISC	SEND	SDTM 1.2	3.0	CDER	2011-06-13		General toxicology and carcinogenicity study tabulation data
	CDISC	ADaM	2.1	1.0	CBER, CDER, CDRH	Ongoing		Human study data analysis datasets

Other News

- **FDA Position Statement**
  see http://www.fda.gov/ForIndustry/DataStandards/StudyDataStandards/ucm368613.htm

Study Data Standards for Regulatory Submissions
Position Statement

FDA recognizes the investment made by sponsors over the past decade to develop the expertise and infrastructure to utilize Clinical Data Interchange Standards Consortium (CDISC)[1] standards for study data. The submission of standardized study data enhances a reviewer's ability to more fully understand and characterize the efficacy and safety of a medical product.

The Prescription Drug User Fee Act (PDUFA V)[2] Performance Goals state that FDA will develop guidance for industry on the use of CDISC data standards for the electronic submission of study data in applications. **In the near future, FDA will publish guidance that will require study data in conformance to CDISC standards.[3]**

FDA envisions a semantically interoperable and sustainable submission environment that serves both regulated clinical research and health care. To this end, FDA will continue to research and evaluate, with its stakeholders, potential new approaches to current and emerging data standards. FDA does not foresee the replacement of CDISC standards for study data and will not implement new approaches without public input on the cost and utility of those approaches.

September 13, 2013

Other News

OpenCDISC Validator 1.4.1 released (12-Sep-2013)

- Support for latest ADaM v1.2 Validation Checks
- Validation of QS Controlled Terminology
- Enhanced Excel report with the versions of Validator, MedDRA, CDISC CT
- Refined SDTM, SEND, and ADaM rule messages and descriptions
- Various bug fixes and minor enhancements

Details at http://www.opencdisc.org/

Upcoming Events:
PhUSE - Annual Conference 2013

Date: 13th - 16th October 2013

Visit the PhUSE website for further details:
http://www.phuse.eu/annual-conference.aspx

Upcoming events: CDISC Interchanges

- **CDISC International Interchange in Bethesda, MD on 4-8 November 2013**
- **CDISC Japan Interchange in Tokyo on 3-6 December 2013**
- **CDISC European Interchange in Paris, France 7-11 April 2014**