

2012-2021 FDA/PHUSE Collaboration -- All of You Are Making a Difference

Steve Wilson, DrPH (Biostatistics)
Senior Staff Fellow
FDA/CDER/OTS/OB/AIS



FDA Disclaimer

This presentation reflects the views of the author and should not be construed to represent the views or policies of the U.S. Food and Drug Administration



The FDA Mission and Our Collaboration

- The Food and Drug Administration is **responsible for protecting the public health** by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation.
- FDA is responsible for **advancing the public health by helping to speed innovations that make medical products more effective, safer, and more affordable and by helping the public get the accurate, science-based information they need to use medical products and foods to maintain and improve their health.**

Collaboration

- Goals: Identifying needs, prioritizing, listening, observing, assessing and evaluating The Data
- System Objectives: Facilitating communication and understanding within and across groups of participants and organizations
- Purpose: Establishing mechanisms and processes so that individuals work together to achieve well-defined/ beneficial deliverables.
- Importance – Bringing people and organizations together to learn and to solve problems and to make a difference.

Some Historical Background



- NDA Rewrite (1987)
- PDUFA (1992)
- Submission Management and Review Tracking (SMART) Program (1994)
- FDAMA (1997)
- 21 CFR Part 11 (1997)
- Providing Regulatory Submissions in Electronic Format — NDAs (1998)
- Critical Path Initiative (2004)
- Critical Path Institute (2005)
- Office of Translational Sciences (2006)
- Office of Computational Science

DIA/FDA CDER/CBER Computational Science Annual Meeting (2010-2011)



DIA/FDA CDER/CBER Computational Science Annual Meeting

March 22-23, 2010
Bethesda North Marriott, Bethesda, MD, USA



PROGRAM CO-CHAIRPERSONS

Charles Cooper, MD
Medical Officer, Office of Translational Sciences, CDER, FDA
Stephen E. Wilson, DrPH, CAPT, USPHS
Director, Division of Biometrics III, CDER, FDA

PROGRAM COMMITTEE

B. Sue Bell, PhD
Director, CDER Computational Science Center
CDER, FDA
Gary M. Gensinger, MBA
Deputy Director, Office of Business Process Support
CDER, FDA

Ted Guo, PhD
Mathematical Statistician, Division of Biometrics II
CDER, FDA

Ghanshyam Gupta, PhD
Chief, Therapeutics Evaluation Branch
Office of Biostatistics and Epidemiology
CDER, FDA

Tarek A. Hammad, MD, PhD, MSc, MS
Associate Director of Epidemiology, Division of
Epidemiology, Office of Surveillance and Epidemiology
CDER, FDA

Edward Helton, PhD
Associate Director, Center for Biomedical Informatics
and Information Technology
National Cancer Institute, NIH

Robert Powell, PharmD
Scientific Advisor, Roche Shanghai

John Speakman
Associate Director
Center for Bioinformatics and Information Technology

Norman Stockbridge, MD, PhD
Director, Division of Cardiovascular and Renal Products
CDER, FDA

Ram Tiwari, PhD
Associate Director for Statistical Science and Policy
CDER, FDA

Christoffer Wenzel Tornøe, PhD
PharmacoMetrics Team Leader, CDER, FDA

Worldwide Headquarters
Drug Information Association, Inc.
800 Enterprise Road, Suite 200
Horsesham, PA 19044, USA

Regional Offices
Basel, Switzerland Tokyo, Japan Mumbai, India Beijing, China

FDA Forum to Promote Progress in Computational Science from Regulatory and Product Development Perspectives

One of the most important and unrecognized issues contributing to drug development and regulatory productivity and quality is the ability to acquire, store, analyze, share and report information needed to make the most informed and rapid decisions in pharmaceutical companies, contract research organizations, and international regulatory agencies. This meeting will review progress on topics such as data standards, best practices-driven analytical tool development, business processes driving information systems development, and user experience/evaluation of current tools.

Highlights

- Breakout Sessions:
 - Nonclinical preapproval
 - Clinical preapproval
 - Postmarket safety
 - Product quality
 - Data quality
- Formation of ongoing Working Groups to address computational science issues and solutions from the Breakout Sessions
- Poster Presentations
- Interactive Exhibit Hall
- Software Showcase and Demonstrations: SDTM Validation Tool Demo- please refer to the Exhibitor Summary to identify which companies are participating in this demonstration

continued

Co-sponsored by



Due Date for Poster Abstract Submissions EXTENDED TO FEB. 14, 2011

See page 8 for submission guidelines.

DIA/FDA CDER/CBER Computational Science Annual Meeting

March 14-15, 2011
Sheraton National Hotel | Arlington, VA, USA



PROGRAM CHAIRPERSONS

Charles Cooper, MD
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Director, Division of Biometrics III, CDER, FDA

PROGRAM COMMITTEE

Tarek A. Hammad, MD, PhD, MSc, MS
Associate Director of Epidemiology, Division of Epidemiology,
Office of Surveillance and Epidemiology, CDER, FDA

Jingyao Kou, PhD

Mathematical Statistician (Biomed), Vaccine Evaluation
Branch, CDER, FDA

Patricia Koussis, RN, CMRP
Coordinator, CDER Computational Science Center, FDA

Timothy Krupp, PhD
Toxicologist, Office of Oncology Drug Products, CDER, FDA

Amy Kelly, MHA/CPA, CQA, PMP
Associate Director of Epidemiology, Division of Epidemiology,
Office of Surveillance and Epidemiology, CDER, FDA

Susan McCune, MD
Deputy Director, Office of Translational Sciences, CDER, FDA

Thomas Moreno
Project Management Officer, Division of Scientific
Investigations, CDER, FDA

Armando Oliva, PhD
Senior Biomedical Informatics Advisor
CDER Computational Science Center

Lillian Rosario, PhD
Associate Director, Office of the Chief Scientist
Office of the Commissioner

WHO SHOULD ATTEND

- Physicians, biostatisticians, epidemiologists, clinical pharmacologists, and other drug development and review scientists
- Professionals involved in data management, programming, information management, and software tool design who work in environments where drugs and biological products are studied, developed, and regulated
- Pharmaceutical industry professionals (nonclinical, pre-market, post-market development, IT)
- Contract research organizations
- Government organizations (FDA, NIH)
- Information management and bioinformatics companies
- Academia
- Toxicologists

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Review Progress on Data Standards, Comparative Effectiveness Research, and Tools that Support Analysis and Collaboration.

One of the most important and unrecognized issues contributing to drug development and regulatory productivity and quality is the ability to acquire, store, analyze, share, and report information needed to make the most informed and rapid decisions. This annual meeting will have an FDA-centric focus on the current needs and implementation plans to help the broader community both align and share knowledge/tools to advance Computational Science.

FEATURED TOPICS

Regulatory submissions

- Share quality metrics and case studies regarding data submission quality
- Discuss, recommend and evaluate process and tools designed to assure adequate data quality supporting a successful review

Tool development and evaluation

- Discuss the need and propose specifications for new tools
- Provide a forum for new tools to be introduced

Impact

- Promote regulatory data submissions using standardized data
- Promote development of a bioinformatics FDA platform enabling electronic regulatory review of routine submissions and emerging safety and product quality concerns
- Promote the ability to learn from prior knowledge and apply this learning to improving the quality and productivity of both product development and regulation

SPECIAL BREAKOUT SESSIONS

In addition to the featured meeting topics, breakout sessions will drill down and explore the requirements, standards, tools, and activities needed to support specific aspects of drug development. These breakout sessions will form the foundation for working groups that can collaborate to discuss issues on and find solutions to challenges in:

- Clinical Data
- Comparative Effectiveness Research
- Post-market Data
- Community Repository of Program Code
- Electronic Case Report Forms and Data Standards
- Nonclinical Data

EXHIBIT OPPORTUNITY AVAILABLE

Contact **Jeff Korn**, Exhibits Associate | Phone +125.442.6184
Fax +125.293.5924 | email: Jeff.Korn@diahome.org

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FDA/PHUSE CSS (2012 – 2021)



Two DIA/FDA Computational Science Meetings

“Meetings - 1.0”



- Clinical Data Submission Standards and Tools
- Terminology Standards
- Data Quality Assurance
- Chemistry and Manufacturing
- Post-Market Safety
- Community Repository of Program Code
- NCI CaBIG
- eCRFs
- Non-Clinical Data Submission Standards and Tools
- Janus
- Comparative Effectiveness Research
- HL7

FDA/PHUSE CSS

“Meetings - 2.0”



- A different kind of conference: A Collaborative Workgroup Symposium
- Organizing Committee: Broadly defined 6 working groups to continue the work
- Much bigger than these workgroups
- Looking to start and **support collaborative workgroups that will continue until all of the work is done.**
- Technical “Stakeholder Workgroups” – but we are asking you to move beyond “your stake” ... act as knowledgeable professionals seeking solutions
- Work Products, timelines, next steps



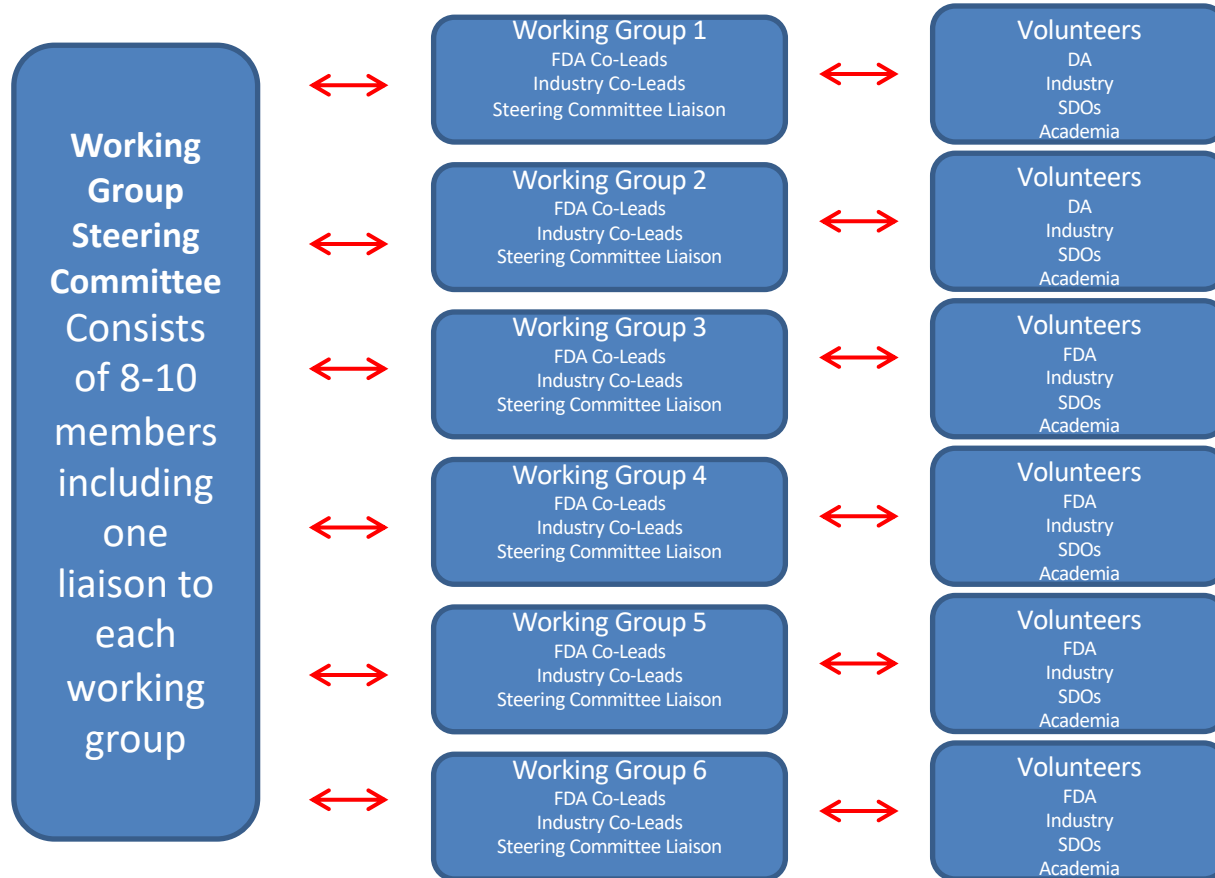
2012 CSS Original Purpose

The FDA wishes to establish collaborative working groups to address current challenges related to the access and review of data to support product development. These groups will work on possible solutions and practical implementations with the goal of helping the broader community align and share experiences to advance computational science.

Tom Sawyer & The Fence



2012 FDA/PHUSE CSS: Working Group Structure



Pre-2012 FDA/PHUSE CSS: Assignments



- The March 2012 Computational Science Meeting is a starting point
 - We want to maintain the working groups
- Each working group needs to develop a short list of key topics by 7 March 2012 to be shared with meeting attendees to help the attendees select a working group within which they will participate
- Each working group should beginning to plan to identify ways to communicate and share their work (e.g., white paper, lesson learned, best practices)
- We will be developing a Wiki to serve as a means to share information in a managed fashion(e.g., who can post information)

2012 CSS: The Six Original Working Groups



- Working Group 1: Data Validation and Quality Assessment
- Working Group 2: Reducing Risk Within the Inspection Site
- Working Group 3: Challenges of Integrating and Converting Data Across Studies
- Working Group 4: Standards Implementation Issues With the Clinical Data Interchange Standards Consortium Data Models
- Working Group 5: Development of Standard Scripts for Analysis and Programming
- Working Group 6: ``Non-Clinical Road-Map'' and Impacts on Implementation

2012 CSS Working Group 4

Standards Implementation Issues with the CDISC Data Models – Original Members



- **FDA**
 - Helena Sviglin
- **Industry**
 - Joanna Koft
 - John Brega
 - Liz Leahy
 - Scott Bahlavooni

Developing a Transparent Collaborative Tool for WGs: The PHUSE Wiki



Page
Navigation trail: Annual Conference > CSS Working Groups > PHUSE Wiki

Read View source View history Search

PHUSE Wiki

Welcome to the Wiki

Currently 605 users are helping to **Share, Contribute and Advance** clinical informatics.

All content on this wiki is non-binding. All content expresses opinions of users and not necessarily that of their employer nor PHUSE. See our [Disclaimers](#) page.

What is this place?

The PHUSE Wiki is an PHUSE @FDA/Industry collaboration to provide a medium to share information specifically relating to clinical trial informatics. The wiki has three main goals:

- To support the Computational Science Symposium (CSS) Working Groups by creating an online collaboration environment.
- To support the sharing of statistical and informatics software code (SAS, R etc).
- To serve as a medium to share information related to software programming and processes for pharmaceutical, biotech, CRO, medical device and health care programmers.

What can I do here?

Well that depends who you are. If you are an **CSS Working Group member** you can [click here](#) to access your specific working group. If you are **authoring a wiki for the Brussels Conference** you can [click here](#). Otherwise, if you have something to share, enter the title of your page into the box at the right. If you are looking for something, use the search at the top right of this page.

Start by **creating a User account**. In order to keep this Wiki transparent for all users it would be great if you could use your **real name as your user name**. Note that you also need to create a User account if you are a PHUSE member. **Your PHUSE login details do not work here**. It might also be good to familiarize yourself with the **wiki language**. After that, you are welcome to add, edit, read, and discuss anything in this wiki. If you have questions, please contact us @ . Interested, but don't know which topic to tackle? Check out the **Wanted** pages. Make someone's day by answering their question.

Recent Changes

17 March 2014

- [diff](#) | [hist](#) ... WGS Project 07: 04:54 ... (+214) ... [Dirk Spruck](#) ([talk](#)) ([contribs](#)) ([Planned Presentation](#))

10 March 2014

- [diff](#) | [hist](#) ... [Metadata Definition Project: 2011](#) ... (+1) ... [Mitarasica](#) ([talk](#)) ([contribs](#))
- [diff](#) | [hist](#) ... [Metadata Definition Project: 2010](#) ... (+8) ... [Mitarasica](#) ([talk](#)) ([contribs](#))
- [diff](#) | [hist](#) ... [Metadata Definition Project: 2009](#) ... (+9) ... [Mitarasica](#) ([talk](#)) ([contribs](#))
- [upload log](#): 20:07 ... [Mitarasica](#) ([talk](#)) ([contribs](#)) uploaded "File:ST project MDO 2014-03-12.pptx"
- [diff](#) | [hist](#) ... [Metadata Definition Project: 20:04](#) ... (+221) ... [Mitarasica](#) ([talk](#)) ([contribs](#))
- [upload log](#): 20:02 ... [Mitarasica](#) ([talk](#)) ([contribs](#)) uploaded "File:ST MDO v1.0 2014-03-12 final.docx"

Add a new wiki page

☐ option

News

Most Popular Pages

Computational Science Symposium
March 16th - 18th 2014
[View Spring CSS Content](#) [View Spring Program](#) [View CSS](#)

CSS News

- March 11, 2014: Final draft PK White Paper is available for review
- February 7, 2014: Two Draft White Papers on Standard Analyses open for review
- December 8, 2013: CSS Working Group initiates best practices document with recommendation for Data Sizing
- December 8, 2013: White Paper on Central Tendency TPI finalized
- December 8, 2013: CSS 2014 will feature first Scriptathon ever

CSS Deliverables

- Data Sizing Best Practices Recommendation

White Paper on Central Tendency TPI finalized

Recent changes on active CSS Projects:

- WGS Project 02
- WGS Project 04
- WGS Project 05
- WGS Project 06

Home
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New Pages
Popular Pages

Projects
CSS Working Groups
Annual Conference
Therapeutic Areas
Good Programming Practice
QSPI

PHUSE Wiki Help
Toolbox

What links here
Related changes
Special pages
Printable version
Permanent link

Before the 2012 FDA/PHUSE CSS ...

Identifying Issues -- A Sample



2. MOD-020: High Adding "analysis-like" content to SDTM skews the intent of the tabulation model and presents traceability challenges.

- The addition of “analysis-like” variables to SDTM is resulting in a circular conversion process. CDMS data converted to SDTM datasets → Create derived analysis datasets using SAP → derived content from analysis datasets is recycled back into SDTM datasets to make complete.

3. MOD-030: High The SDTM IG does not adequately describe the Exposure domain.

- EX Assumption 1c provides five different methods for creating/deriving EX.
- SDTM IG examples are insufficient for industry implementation.

4. MOD-040: High CDISC models do not provide a method for adequately describing the content of supplemental qualifiers or the Findings About (FA) domain.

- “Forward traceability” – CDISC models should enable the documentation of the content of supplemental qualifiers and FA such that CDER can easily identify key content from those sources that were used in an analysis.
- If this cannot be done within model, the Data Guide may be a viable alternative.



During the FDA/PHUSE CSS Working Group 4 Projects / Work Products

- Data Guide
- Information not to include in SDTM for submissions
- Use Cases
- Challenges Industry Faces with Implementing Standards

The PHUSE CSS SDRG

The State of Data Reviewer Guides *

** For this presentation a Reviewer Guide refers to the document in the m4 or m5 (not m1) in eCTD*

Helena Sviglin, MPH
Office of Computational Science, CDER, FDA
March 2016

SDRG (the clinical one)

- PhUSE/FDA collaboration started in 2012
- FDA folks invested heavily in development by providing content and leadership
- V1.1 released at PhUSE CSS in March 2013
- In the Technical Conformance Guide in January 2014
- V1.2 released in January 2015
- 80 FR 43779 Intent to Review in July 2015
- We reviewed and considered each one carefully

The FDA/PHUSE CSS Collaboration -- Flying Many, Many Planes While Building Them



https://www.youtube.com/watch?v=S_dgWI83cTM



“Socializing” the Deliverables



STUDY DATA TECHNICAL CONFORMANCE GUIDE

Technical Specifications Document

This Document is incorporated by reference into the following
Guidance Document(s):

**Guidance for Industry Providing Regulatory Submissions in Electronic
Format – Standardized Study Data**

For questions regarding this technical specifications document, contact CDER at
cdcr-edata@fda.hhs.gov or CBER at cber-edata@fda.hhs.gov

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

August 2021

2.2.1 SDRG for Clinical Data

An SDRG for clinical data should be named cSDRG (the prefix ‘c’ designates ‘clinical’) and the document should be named ‘csdrg’ and provided as a PDF file upon submission (csdrg.pdf).

...

14. A specific template for a Study Data Reviewer’s Guide for clinical studies is not specified. However, an example can be found at <https://www.phuse.eu/css-deliverables>. The PhUSE nSDRG template has been reviewed by FDA and published in the Federal Register ...

Do collaborations work to advance regulatory science? (BIMO) Bio-research Data Reviewers Guide



Dashboard / ... / Optimizing the Use of Data Standards

(BIMO) Bio-research Monitoring Data Reviewers Guide

Created by: last modified by Paula on Sep 16, 2021



Project Scope

Develop a Data Reviewer's Guide Template (referenced in the Technical Conformance Guide) and associated documents to allow up-front communications regarding the sponsors interpretation of the Bio-research Monitoring Technical Conformance Guide. Initially, the scope will include the development of the template and then expand to cover the full suite of documents. The current CDORG and ADRG templates will be considered to avoid unnecessary duplication of content. Therefore, revision of these templates are not in scope.

Project Leads	Email
Julie Maynard	jmaynard1@tsj.org
Sopan Kathi	sopan.kathi@cs.com
Paula Rowley (Phuse Project Assistant)	paula@phuse.global
Objectives & Deliverables	Timelines
Kick Off Project	Apr-2021
Template & Completion Guidelines	Oct-2021
Examples	Dec-2021

Current results Q22021

Team have split into 3 sub-teams to work on assigned sections of the BIMO Reviewer's Guide (Template, Completion Guidelines and Examples).
Completed Sub-Team Draft Template Sections.
Assigned sections to be merged as one final draft Template for full team review.
Final draft template to be completed by 31st August.

Project Members	Organisation
Aakya Zaidi	Gilead
Ashly Shelke	Pfizer
Amie Sagady	Takeda
Achra Monchaux	Sanofi
Avinash Reddi Rathi	GSK
Barbara Lockley	Industry
Bhanu Kannan	FDA
Bei Yu	FDA
Cara Affero	FDA
Cecily Michelsky	Teva Pharmaceuticals
Chunying Yin	Janssen Research & Development
Cynthia Clappinger	FDA
David Potoma	Pfizer
Dmitry Golubovsky	Teva Pharmaceuticals
Harini Kunduru	DSI
Karen Bleich	FDA
Kathryn Knudsen	BI Lilly
Ke Wang	BMS
Kiran Kunderapu	Merck
Kristy Wall	GSK
Jack Field	AstraZeneca
Lin Yuan	Astellas

Project Members	Organisation
Lisa Zhou	Janssen Research & Development
Maggie Lo	Lung Biotechnology PBC
Michael Johnson	FDA
Meng Li	AstraZeneca
Nancy Bauer	Boehringer Ingelheim
Nigel Montgomery	Roche
Phil Liu	AstraZeneca
Phyllis Smetana	UCB
Sai Ma	Bayer
Sathesh Avary	PPD
Santosh Kumar Lingala	Gilead
Shrestam Shengar	Covance
Srinivasan Ramasubramanian	Abbvie
Stanley Au	FDA
Stanley Brill	Janssen Research & Development
Steve Fitzpatrick	Novartis
Steven Clark	Astellas
Todd Rider	BMS
Yan (Joy) Shen	Pfizer

Problem Statement

FDA drafted the initial Bio-research Monitoring Technical Conformance Guide in December 2017, with an updated version published in July 2020 (<https://www.fda.gov/media/5001/download>). The guide provides specifications for preparing and submitting the following components in electronic format that are used by FDA for planning of Bio-research Monitoring (BIMO) inspections.

- Clinical Study-Level Information.
- Subject-Level Data Link Listings by Clinical Site.
- Summary-Level Clinical Site Dataset (SiteData.spt).
- NDA, BLA, and supplemental submissions to FDA require BIMO as a critical part of the electronic application.

There is currently a lack of clarity as each sponsor will have defined their own approach to the generation of this content, especially where there is a need to interpret the Technical Conformance Guide.

Problem Impact

This need for interpretation leads to inconsistencies between Sponsors when submitting this content to the agency. Potentially, this results in the need for Sponsors to provide additional clarification to the agency subsequent to the submission of the content.

The FDA/PHUSE CSS -- 10 Years of Collaboration

Supported by an Independent, Non-Profit, Global Community of Data & Project Management Professionals



The screenshot shows the PHUSE website interface. At the top is a teal navigation bar with the PHUSE logo, a search icon, and links for EVENTS, COMMUNICATIONS, WORKING GROUPS, EDUCATION, COMMUNITY, and EVENTS CALENDAR. Below the navigation bar is a large graphic of a globe with icons representing data and people. To the left of the globe is the text "The Global Healthcare Data Science Community" and a subtitle "Sharing ideas, tools and standards around data, statistical and reporting technologies". Below this is a grid of six cards, each with an icon, a title, a brief description, and a button.

PHUSE Open Data Repository
The PHUSE platform will help individual users to acquire new skills to improve their job prospects.
[Learn more](#)

About PHUSE
New to PHUSE? Find out more about who we are and what we do, and get involved!
[Find Out More](#)

Deliverables
View the Working Group deliverables including white papers, references and regulatory referenced documents.
[Search the Deliverables](#)

Job Vacancies
If you are looking for a new opportunity or want to advertise a vacancy, use our jobs board.
[Find Opportunities](#)

Volunteer with PHUSE
Actively participate in the Working Groups, join an event committee, present at an event or try your hand at writing an article!
[Join Us](#)

PHUSE Archive
Access PHUSE materials from previous Connects, Single Day Events, Webinars and publications.
[Search the Archive](#)



Documentation: The PHUSE Archive



Home / Communications / PHUSE Archive

PHUSE Archive

All materials from PHUSE Events (e.g. Connect conferences, SDEs) can be found in this section of the website. Using the filters will allow you to narrow down your search of our vast archive. In the interest of sharing knowledge, this section is open to everyone.

Please note – we are currently working on moving across 15 years-worth of content into the new archive. This transition will be completed shortly and all information from previous years will be accessible. If you need anything in particular, please contact communications@phuse.global who will be happy to help in the meantime.

Event Type	Year	Region	City
CSS	Select	Select	Enter
Educational Category			
Select	Title	Company	sviglin
Co-Author	Key Words		

Clear Filter

Search

Show/hide columns

Event	Year	Region	City	Title	Author	Company	Co-author	Keywords	Links
CSS	2018	US	Silver Spring	PP35: What's Rules Got to Do With It?	Helena Sviglin	FDA		PP35: Poster Presentation	POS_PP35.pdf
CSS	2016	US	Silver Spring	The State of the Data Reviewer's Guide	Helena Sviglin	FDA			PBE_04.pdf
CSS	2015	US	Silver Spring	PP17: Beyond Submission: Business Rules in Legacy Data Conversion for better CTR Integration	Helena Sviglin	FDA	Eileen Navarro	PP17: Poster Presentation	POS_PP17.pdf
CSS	2015	US	Silver Spring	PP18: Implementing the SDRG: Reflections from the Reviewer Community	Helena Sviglin	FDA/CDER/OTS	Eileen Navarro	PP18: Poster Presentation	POS_PP18.pdf
CSS	2013	US	Silver Spring	PP13: JANUS CTR Data and Cross Study Analysis at FDA	Helena Sviglin	FDA	Iffat Chowdhury	PP13: Poster Presentation	POS_PP13.pdf



PHUSE EU/US Connect



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PHUSE EU Connect 2021

Overview

By joining the EU Connect, you are far more than an attendee; you are an integral cog in the PHUSE Community, driving forward innovation and developing the future of life sciences.

The Connect creates a space for global professionals from across the industry to unite, explore and train through its trademark inspirational content and networking opportunities.

As a transition back to physical events, the EU Connect will be a hybrid event, with Monday and Tuesday taking place in person in London, UK (limited capacity) and Thursday and Friday remaining virtual.

To enhance the audience experience, a selection of speakers will join PHUSE in London to present in person to both the live audience and virtual attendees as part of the daily broadcast. All sessions will also be available to watch on-demand on the PHUSE Engagement Hub.

If you wish to attend in person, you are required to purchase an upgraded Hybrid ticket, see the [registration page](#) for more information. PHUSE have reserved a hotel for attendees, further details will be issued shortly.

For information about the available [sponsorship opportunities](#), contact events@phuse.global.

OVERVIEW

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PHUSE/FDA INNOVATION CHALLENGE

PHUSE US Connect 2022

Overview

The long-awaited return of in-person PHUSE events is fast approaching.

The importance of face-to-face networking is undeniable – you connect on a higher level and facilitate meaningful relationships. In-person events allow you to immerse yourself for a few days in all aspects of the event experience, the content on offer, socialising and even sightseeing. Join us in Atlanta at the US Connect 2022, 13-16 February to do just that.

PHUSE's agile approach meant we could digitally transform our events and make a successful transition to the virtual world. Continuing to be flexible is the key to moving forward. Our in-person event experience has been re-designed from top to bottom and is more creative and adaptable than ever.

Create opportunities, expand your circles, reinvigorate your passions, and surround yourself with experts. Connect events are a hub for fuelling innovation and this four-day experience will fundamentally shift the way you increase your knowledge.

Organizational Collaboration



CDISC/PhUSE MOU

The screenshot shows a web page with a light blue and white background featuring a subtle circuit pattern. At the top, the title "CDISC/PhUSE MOU" is displayed in large blue letters. Below it is a navigation bar with links: NEWSLETTER SIGNUP, MAKE A GIFT, CDISC CERTIFICATION, CDISC PORTAL, BECOME A MEMBER, and MEMBER | USER LOGIN. The CDISC logo, with the tagline "Strength Through Collaboration", is on the left, and a search bar with social media icons (Facebook, LinkedIn, Twitter, YouTube) is on the right. A secondary navigation bar includes links for ABOUT, STANDARDS, COLLABORATIONS, RESOURCES, NEWS/PUBLICATIONS, EDUCATION, EVENTS, and MEMBERSHIP. The main content area features the headline "CDISC and PhUSE Announce Signed Partnership in Support of Ongoing Collaboration" with a date of February 19, 2015. It includes contact information for both organizations: CDISC Contact (Andrea Vadakin, +1.316.558.0160, avadakin@cdisc.org) and PhUSE Contact (Sascha Ahrweiler, +49.179.4613496, sascha.ahrweiler@phuse.eu). A "News Archive" sidebar lists years from 2015 to 2009 with article counts. A "Follow CDISC Today" section contains social media icons. The bottom paragraph details the MOU's purpose, mentioning the development of global data standards and collaborative projects like the PhUSE Computational Science Symposium (CSS) Working Group. The footer of the page features the PhUSE logo.

NEWSLETTER SIGNUP MAKE A GIFT CDISC CERTIFICATION CDISC PORTAL BECOME A MEMBER MEMBER | USER LOGIN

CDISC Strength Through Collaboration

ABOUT STANDARDS COLLABORATIONS RESOURCES NEWS/PUBLICATIONS EDUCATION EVENTS MEMBERSHIP

CDISC and PhUSE Announce Signed Partnership in Support of Ongoing Collaboration

February 19, 2015

CDISC

CDISC Contact:
Andrea Vadakin
+1.316.558.0160
avadakin@cdisc.org

phuse

PhUSE Contact:
Sascha Ahrweiler
+49.179.4613496
sascha.ahrweiler@phuse.eu

News Archive

- 2015 (3)
- 2014 (14)
- 2013 (12)
- 2012 (13)
- 2011 (12)
- 2010 (11)
- 2009 (5)

Follow CDISC Today

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Austin, TX - 19 February 2015 - The Clinical Data Interchange Standards Consortium (CDISC), and the Pharmaceutical Users Software Exchange (PhUSE) announced today the signing of a Memorandum of Understanding (MOU), strengthening the partnership for the benefit of stakeholders conducting regulated clinical research and product development.

The CDISC-PhUSE MOU furthers the mission of each organization collectively with (1) CDISC focusing on development of global, platform-independent data standards; and (2) PhUSE focusing on the implementation and use of CDISC standards. The two organizations will combine efforts and seek to collaborate on key initiatives such as the PhUSE Computational Science Symposium (CSS) Working Group projects, many of which already directly involve the testing and implementation of CDISC standards. The Working Groups are a collaborative effort between PhUSE, the FDA, industry and the CDISC community. In addition to these projects, CDISC and PhUSE will cooperate on joint marketing and communications activities, particularly around CDISC Interchanges and PhUSE annual events.





FDA/PHUSE Regulatory Science Collaboration: Making A Difference



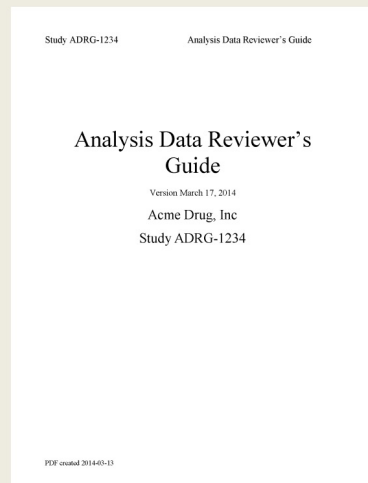
The Analysis Data Reviewer's Guide (ADRG)

Presented on behalf of PhUSE Working Group 4:

Ben Vali (FDA), Mina Hohlen (FDA), Steve Wilson (FDA)

Susan Kenny (Amgen), Gail Stoner (J&J), Linda Collins (PharmaStat), Chris Price (Roche), Jennifer Montello (J&J), Nancy Friedland (IBM) and Team

- ❖ To complement the Submission Data Reviewer's Guide (SDRG), the PhUSE Working Group 4 developed an Analysis Data Reviewer's Guide (ADRG) Template to provide information pertaining to the analysis datasets that supplements the information found in the define.xml. This reviewer's guide would be included in Module 5 of the eCTD with the study's analysis datasets.
- ❖ This poster presents the ADRG Template with description of the type of information (in blue) that would be provided in each section. Text in black is required.
- ❖ The ADRG is nearing completion and the Working Group is in the process of gathering comments from industry reviewers.



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Analysis Data Reviewer's Guide	
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One of Us ...

“Susan had a long career as a statistician and worked to pave the way for safer treatments and medications in the United States.”

Susan Kenny

1957 - 2021



<https://www.legacy.com/us/obituaries/newsobserver/name/susan-kenny-obituary?pid=199387312>

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Susan Kenny

July 19, 1957 - July 2, 2021

Durham, North Carolina - Susan Kenny, age 63 passed peacefully on July 2, 2021 from cancer. Susan (Sue) spent her final years travelling and spending precious time with her husband Kevin and the friends and family that she held dear. Susan was born on July 19th, 1957 in Wichita, Kansas to Wey Dennis Kenny and Agnes Lievens Kenny. Susan grew up alongside her four sisters: Kathy Arenz (Milwaukee, WI), Mary Adair (Kansas City, MO), Pat Kenny (deceased), and Joan Kenny (Lawrence, KS). Susan had an early passion for academics; earning a high school diploma from Kapaun Mt. Carmel Catholic High School, an undergraduate degree from Kansas State, a masters of ecology from the University of Illinois, and a PhD in statistics from the University of Oklahoma. Susan had a long career as a statistician and worked to pave the way for safer treatments and medications in the United States.



So ... Who's In for the 2021 CSS?
Continue to be You ... to
Collaborate, to Think, to Do ...
to **Make a Difference!**

**Tom Sawyer says, "THANK YOU
FOR ALL OF OF THESE YEARS OF
WHITE PAINT AND SWEAT!!!"**



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