



Computational Science Symposium

March 15th–17th 2015

Silver Spring Civic Center | Silver Spring, Maryland, USA



The PhUSE CSS Collaboration – Getting Involved and Getting it Done: A Regulatory Perspective

–

Steve Wilson, Dr.PH, CAPT., USPHS Director,
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Disclaimer

This speech reflects the views of the speaker and should not be construed to represent FDA's views or policies

Topics

- This is a Conversation, A Relationship
- Learning About Collaboration
- Current Working Groups
- A Small, Selective Sample of Projects: Old and New
- Meanwhile ... Back at the FDA
- CDISC and PhUSE
- Challenges/Progress
- Looking for Motivation

This Is A Conversation, A Relationship

- Some History
- A Note Concerning Tom Sawyer
- Last Year
 - “Pre-Competitive Collaboration”
 - CSS and Meetings 2.0
 - “Socializing Deliverables” Tony Hower, Emerging Technologies Working Group

Some History

DIA/FDA CDER/CBER Computational Science Annual Meeting

March 22-23, 2010

Bethesda North Marriott, Bethesda, MD, USA



PROGRAM CO-CHAIRPERSONS

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Worldwide Headquarters

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800 Enterprise Road, Suite 200
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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



Learning About Collaboration

- Organization
 - Steering Committee
 - CSS Planning Committee
 - Leadership Teams
 - Projects
- Connecting with the FDA
- Technology – Wiki, Tcons, Document Sharing
- The CSS

2015 CSS-Optimizing Data Standards WG Agenda

		T&DF 2	T&DF 2	T&DF 1.5	BP 2	BP 2	BP/SDSP 1	SDSP 3	Exp 2	Exp 3
Hours Allocated		Legacy Data Conversion Plan Template	Integration Traceability	Analysis Data Process Flow	VISITNUM & EPOCH Paper	Lab Units & USUBJID Papers	SDSP Test Unit Plan	SDSP Template & Cover Letter	eSHARE TAUG	FDA Guidance
Monday	1100-1130	INTRODUCTIONS, PROJECT OVERVIEW, CONFERENCE EXPECTATIONS								
	1130-1200									
	1200-1230									
	1230-1300	LUNCH								0.5
	1300-1330									0.5
	1330-1400		0.5		0.5				0.5	
	1400-1430		0.5		0.5				0.5	
	1430-1500		0.5					0.5		
	1500-1530		0.5					0.5		
	1530-1600	0.5					0.5	0.5		
	1600-1630	0.5					0.5	0.5		
Tuesday	0830-0900					0.5				0.5
	0900-0930					0.5			0.5	0.5
	0930-1000					0.5			0.5	0.5
	1000-1030					0.5		0.5		0.5
	1030-1100			0.5				0.5		
	1100-1130	0.5		0.5	0.5					
	1130-1200	0.5		0.5	0.5					
	1200-1230	LUNCH								
	1230-1300									
	1300-1330	WRAP-UP, ACCOMPLISHMENTS, AND NEXT STEPS								
	1330-1400									

Current Working Groups

- Optimizing the Use of Data Standards
- Development of Standard Scripts for Analysis and Programming
- Non-Clinical Road-map and Impacts on Implementation
- Semantic Technology
- Emerging Trends and Technologies

A Small, Selective Sample of Projects: Old and New

- Representing Clinical Program Design in RDF
 - Impressive Sequel, Keeping it New
- PhUSE Data Transparency Working Group
 - Recognizing a Need
- My New Camera & the SEND Implementation Forum
 - Creating a Product, Becoming “Essential”

Representing Clinical Program Design in RDF

Representing Clinical Program Design in RDF

Project Overview

Develop an RDF information model to capture, retain, reuse and share the design of clinical programs:

- Design inputs such as claims, target product profile, development plans etc.
- Design elements such as objectives, endpoints, treatments, patient population, etc.
- Options being considered for each design decision
- Rationale for each design decision, including related information, guidance, best practice
- Trial and program prototypes and options

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- 1 Project Overview
- 2 Project Leads
- 3 Project Updates
- 4 Objectives and Timelines
- 5 Project Activities
- 6 Meeting Minutes
- 7 Archived Content

Project Leads

Name	Role	Organization	E-mail
Laszlo Vasko	Project Co-Lead	Astra Zeneca	Laszlo.Vasko@astrazeneca.com
Mary Banach	Project Co-Lead	ER Squared	mbanach@er2inc.com
Frederik Malfait	Project Manager	IMOS Consulting	frederik.malfait@roche.com

Project Updates

Join us at the 2015 CSS for the project kickoff!

Objectives and Timelines

Objective	Timeline
Project Kickoff	2015 CSS
Collect Requirements for a Clinical Program Design information model	Jun 2015
Create a draft RDF model for the representation of a Clinical Program Design	Sept 2015
Review and evaluate model, investigate options for a CDISC standard	Oct 2015/Nov 2015

PhUSE Working Group: Data Transparency

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Data Transparency

In 2013, the European Medical Agency (EMA) released a draft policy on the publication and access to de-identified clinical-trial data for a 3 month public consultation. A PhUSE working group provided consolidated industry comments on behalf of the PhUSE membership.

The EMA have now internally agreed the framework of the policy focusing on CSRs and the approach to raw-level patient data will continue to be discussed. Ahead of this guidance and forthcoming EU law, many pharmaceutical companies have already started to prepare their own de-identified data to deal with research requests.

In 2014, 2 of the EU PhUSE Single Day Events have been focused around data transparency. It has become apparent during these 2 meetings that there is not an industry specific standard on what rules to use when de-identifying data.

Realising the impact that this will have on our industry and in line with the PhUSE strategy to act as the industry voice to regulatory agencies, the PhUSE Board recently agreed to set up a working group that will drive an industry set of de-identified rules that are based on the CDISC SDTM data model.

Collaboration on this is open to all PhUSE members, but we will limit each company to one person to control the size of the group and to ensure a wide industry view. There will also be a special session at this year's October conference in London on Sunday 12. between 3-5pm.

This working group will focus in the first place to define de-identification standards in terms of rules to apply, rational and impact on data utility for quasi and direct identifiers in SDTM 3.2. A final draft will be sent for public review in Q1 2014.

A group was formed in July with representatives from Pharmaceuticals, CROs, Academia and Software companies that now consists of 3 subteams working on the different SDTM domains and variables:

Working Group Lead: Jean-Marc Ferran (Qualiance), PhUSE Special Projects Director

Special Purpose: Sarah Nolan (Liverpool University & Cochran) Gary Chen (Shire) Carl Herremans (MSD) Beate Hientzch (Accovion) Adel Salem (Novo Nordisk) Khaled El Emam (Privacy Analytics) Vinitha Arumugam & Patricia Coyle (GSK)

Events & Interventions: Kelly Mewes (Roche) Boris Grimm (Boehringer Ingelheim) Shafi Chowdury (Shafi Consultancy) Nancy Freidland (IBM) Cathal Gallagher (d-Wise) Anup Patel (GSK) Sarvesh Singh (ICON) Thijs van den Hoven (Astellas)

Findings Sherry Meeh (J&J) Lauren Shinaberry (BDLS) Kim Musgrave (Amgen) Gene Lightfoot (SAS) Per-Arne Stahl (AstraZeneca) Nate Freimark (Theorem) Jennifer Chin (EISAI) Kristin Kelly (Accenture) Joanna Koft (Biogen Idec) Jacques Lanoue (Novartis)

The views published on this page does not represent the participants' companies ones.



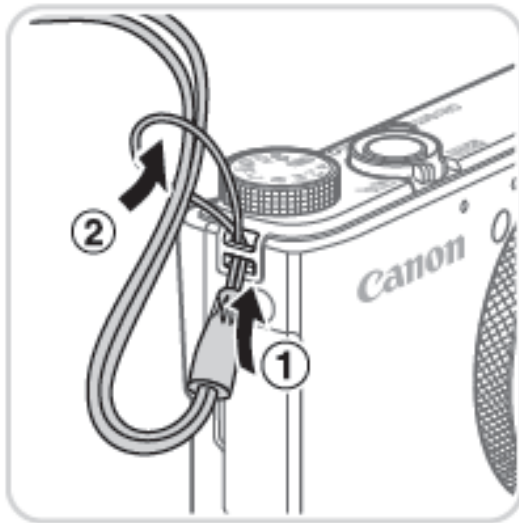
My New Camera

Canon PowerShot S110

Initial Preparations

Prepare for shooting as follows.

Attaching the Strap



Attach the strap.

- Thread the end of the strap through the strap hole (①), and then pull the other end of the strap through the loop on the threaded end (②).

The YouTube Solution

The video player shows a black screen with the title 'Canon PowerShot S110: Attach Wrist Strap' in large blue text. Below the title is the URL 'http://idiotusescanons110.blogspot.com'. The video progress bar is at 0:01 / 3:20. The video title 'Canon PowerShot S110- How to Attach Wrist Strap' is displayed below the player, along with the channel name 'kemas tham', a 'Subscribe' button, and a view count of 11,103.

**Canon PowerShot S110:
Attach Wrist Strap**

<http://idiotusescanons110.blogspot.com>

0:01 / 3:20

Canon PowerShot S110- How to Attach Wrist Strap

kemas tham

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SEND Implementation Forum

http://www.phusewiki.org/wiki/index.php?title=SEND_Implementation_Forum

SEND Implementation Forum

This page is a discussion forum for SEND implementation.

[<< Go to the SEND Implementation Wiki Landing Page](#)

See also:

- [SEND Implementation Wiki](#)
- [Usage Guidelines](#)
- [DISQUS FAQ](#)
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- 2 Forum

Basics

Please see the [Usage Guidelines](#) for basic guidelines on usage of the forum.

Please see the [DISQUS FAQ](#) for basics on how to get started - e.g., how to start commenting, tips, and troubleshooting.

Forum

105 Comments PhUSE Wiki

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Join the discussion...



BDAWG · 4 days ago

Hello,

I currently have a study which involves 2 test articles, where there is a period of just one test article being dosed, moving onto a period where both test articles are being dosed at the same time but with different dose levels.

For the Trial Sets, what would need to be stated for the Dose Level (TRTDOS) and Dose Units (TRTDOSU)? As the SEND guidelines only specify for dose levels that vary over time, where a semi-colon can be used, but as this is going from one test article being dosed onto 2 test articles dosed at varying levels, it wouldn't be clear if we used a semi-colon.

Meanwhile, ... Back at the FDA

Lilliam, Peter, Steven, Armando -- Impressively Handled

- Lawyers, PhUSE Deliverables, SDRG, Federal Register Announcement
- PhUSE FDA Participants Support Group – Crystal Allard
- Office of Biostatistics, Statistical Policy Council, Data Review Committee ... Please Say “Hello”
- Therapeutic Area Standards User Guides
- Global Attention – PMDA, EMA
- Wiki

OB/SPC Data Review Committee

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1. OB/SPC Data Review Committee Charter and Membership

[Data Review Committee Team](#)

OB/SPC Data Review Committee Charter and Membership

October 10, 2014

The OBSPC DRC (Office of Biostatistics Statistical Policy Committee Data Review Committee) will be chaired by  [Stephen E. Wilson](#). Its initial charge is to:

1. Describe and assess OB practice for the receipt and handling of review data and evaluate compliance with existing CDER policies.
2. Develop necessary OB-wide Standard Operating Procedures (SOPs) and guidelines for the regulatory review of data for INDs, NDAs, ANDAs and BLAs, (e.g., quality validation of an applicant's analysis datasets and the statistical review of efficacy and safety results).
3. Collaborate with internal data standards organizations (e.g., OSP / DST, Data Standards Program Board, CSC Board, OND Data Standards Division Leads WG,), CDER Offices, Centers and the FDA Commissioner's Office.
4. Liaise with outside organizations and activities (e.g., CDISC, PhUSE, PharmaSUG, TransCelerate, CPath Institute, CFAST, DIA, HL7, SCDM and ASA) to influence and improve the development of data collection, standardization and submission processes of the data needed for OB review.
5. Develop external communication plans for data policies, as they are approved by the SPC. (External communication, here, refers to data requests made to sponsors/applicants and presentations and manuscripts intended for professional audiences).
6. Coordinate with the OB Training Committee to provide periodic reassessment of OB training needs pertaining to OB/Center SOPs/guidelines, health care informatics and data standards.



Therapeutic Area Users Guides



Program Overview – February 2015 Approved Therapeutic Area Standards Projects



Therapeutic Area	Coordinating Organizations/ Project Manager	Proposal Approval Date	Stage 0 Scoping & Planning	Stage 1 Concept Modeling	Stage 2 Standards Development	Stage 3a Internal Review	*Stage 3b Public Review	**Stage 3c Projected Publication
Traumatic Brain Injury v1	CDISC Rhonda Facile	Oct 13	Dec	Jan	Feb	Mar		Q315
Chronic Hepatitis C Virus v1	TCB John Owen	Nov 13	Feb	Apr	Jul	Nov	Jan	Q115
Schizophrenia v1	CDISC/DCRI Amy Palmer	Nov 13	May	Jul	Aug	Dec	Mar	Q215
Breast Cancer v1	TCB John Owen	Nov 13	Aug	Dec	Jan	Mar	May	Q315
Dyslipidemia v1	TCB John Glover	Dec 13	May	Sept	Dec	Feb	Apr	Q215
COPD v1	TCB John Glover	Nov 13	Aug	Dec	Feb	Apr		Q315
ADA-M Supplement to Diabetes v1	TCB Rachael Zirkle	NA	NA	NA	Jan	Mar		Q215
Diabetic Kidney Disease v1	TCB Rachael Zirkle	May 14	Feb	Mar				Q116
Tuberculosis v2	C-Path Laura Butte	Dec 14	Mar	Apr				Q116
Rheumatoid Arthritis v1	TCB Trisha Simpson	Jul 13	Feb					Q116
CV Imaging v1	CDISC/DCRI Amy Palmer	Dec 13						

Key: Stage completed | Stage ongoing | All months reflect when stage is, or is projected to be, completed.

February 6, 2015

*The Stage 3b concludes at the end of the 30-day review period and Stage 3c concludes when all tasks have been completed and the standard is publicly available.
** Specific projected publication dates to be added to the notes section at the conclusion of Stage 3b.

Meanwhile, ... Back at the FDA

- New Attitudes
- Filing and 21st Century Review
- New seriousness concerning data
- “Due Data Diligence”
- “Data Partner”
- New Position Created – Lead Medical Officer, Associate Director for Informatics, OND/IO

CDISC and PhUSE

- MOU
- Mutual Recognition ... Making it Real
- Going Global
- And so much more ...

CDISC/PhUSE MOU

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 *Strength Through Collaboration*

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CDISC and PhUSE Announce Signed Partnership in Support of Ongoing Collaboration

February 19, 2015



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News Archive

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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.



Examining Our Relationship: Challenges/Progress

- Volunteer / Co-Lead /Staying Involved
- Getting the Right Projects
- Transparency/”Optics”
- Recognition/Appreciation
- FDA Involvement – Disclaimer & “Liaison”
- Wiki and “Agile Communication”
- Testing and “Socialization of Deliverables”

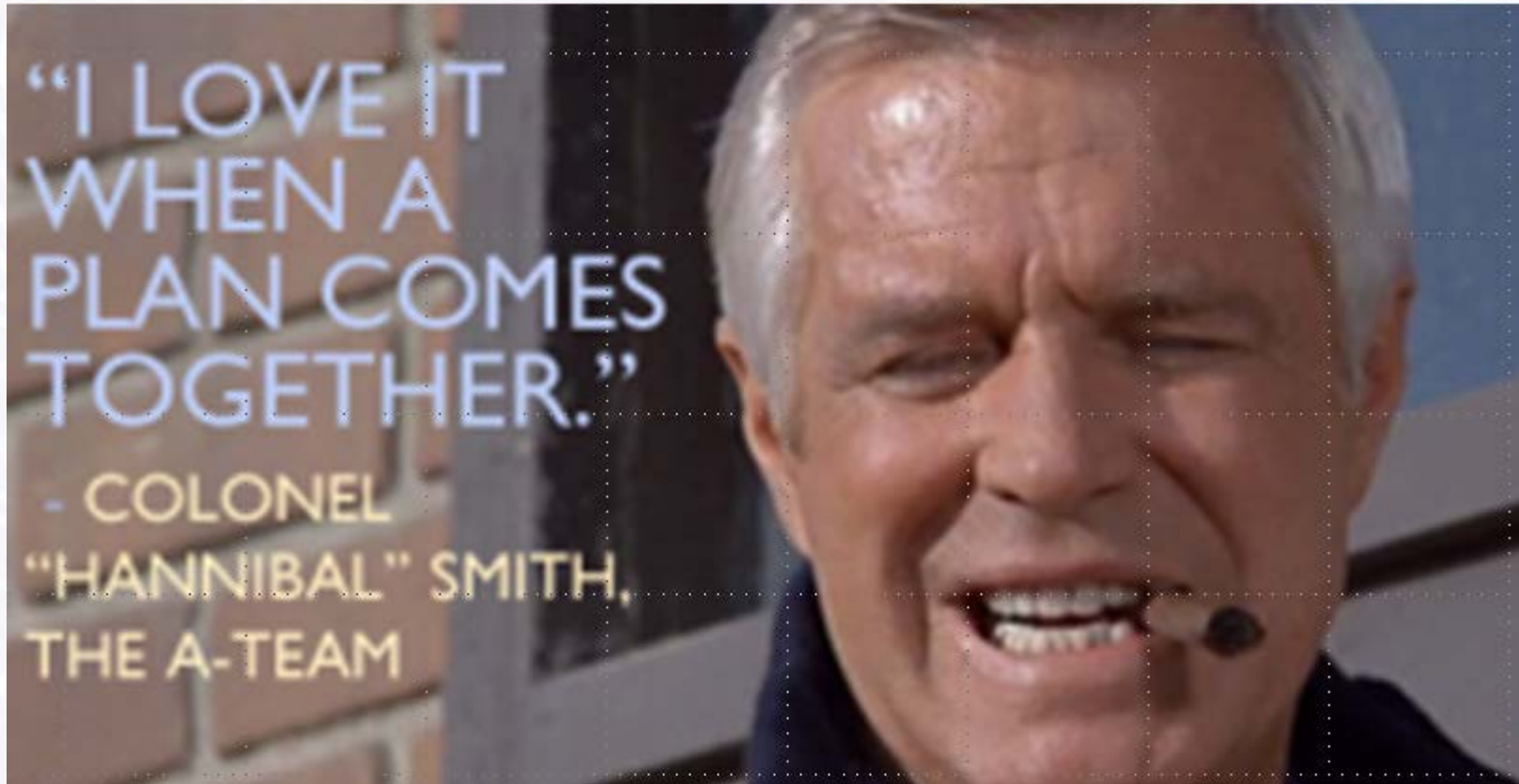
Looking for Motivation



The 2015 PhUSE CSS ... We Are Here ... So ... Where Are Those Next New Projects?

- “Curating” Clinical Data?
- ADaM Analysis Results Metadata 1.0 for Review?
- Using Therapeutic Area Standards in Developing Protocols and SAPs?
- ...
- What’s in Your Head/Heart/Gut?

Looking for Motivation





Give Yourself A Group Hug



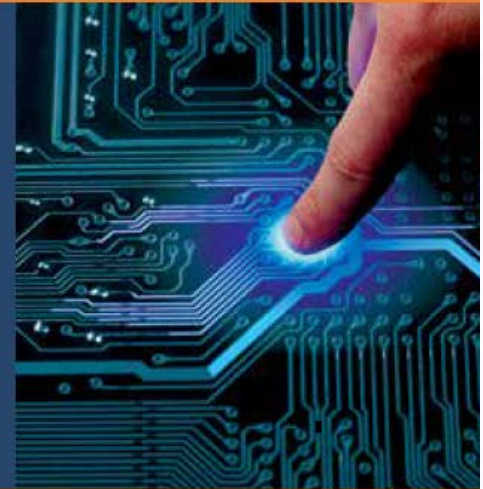
... And Let's Get Started..



Computational Science Symposium

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**Collaboration to Advance Computational Science
Across Regulatory Review and Product Development**



Thank You From Me, Tom and a Grateful World

