

The Big Value of Collaboration Through the Global Activities of PhUSE

ACRONET

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Agenda

- What's about PhUSE
- Computational Science Symposium 2014
- PhUSE CSS Working Group
 - Standard Script
 - Semantic Technology

What is PhUSE ?

Pharmaceutical Users Software Exchange

- PhUSE is an Independent, Not-for-profit Organization
- Data Managers, Biostatisticians, Statistical Programmers and eClinical IT professionals

History

2004 Stephen Bamford started looking at the opportunities available for the training of Pharmaceutical Programmers and have often felt that there should be a European forum where we can get together to share ideas, thoughts, concerns and ask questions about the future direction of the industry.

History

- 2005 The first conference held in Heidelberg, Germany. 270+ attendees from 12 countries joined.
- 2006 First EU single day events, Journal introduced, Society born with 502 members

History

- 2010 First US single day events
- 2012 FDA/PhUSE Computational Science Symposium
- 2013 First India and China single day events
- 2014 First Japan Single Day Event

Structure

The PhUSE Board Members

Click on the links below to view the other PhUSE board members and their roles.

<u>Operations Director</u> John Salter	<u>Finance Director</u> John Hirst	<u>US Events Director</u> Ed Jones	<u>FDA Liaison Director</u> Chris Decker
<u>Technical Director</u> Dirk Spruck	<u>US Membership Director</u> Frank Senk	<u>Strategic Partnerships Director</u> Christian Mueller	<u>EU Events Director</u> Stephen Bamford
<u>Asia Events Director</u> Ajay Sathe	<u>Communications Director</u> Sascha Ahrweiler	<u>EU Membership Director</u> Yvonne Moores	<u>Special Projects Directors</u> Adrienne Bonwick & Jean-Marc Ferran

Picture from PhUSE Website: <http://www.phuse.eu/PhUSE-Board.aspx>

Members

Global Top 5

US 1310

India 599

UK 531

Switzerland 239

Germany 166

Asian Top 5

India 599

China 66

➡ Japan 22

Korea 3

Singapore 2

Conference

- Annual Conference
- Computer Science Symposium
- Single Day Event

CSS Working Group

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

Deliverables

- Good Programming Practice Guidance
- White Paper: Analyses and Displays Associated with Measures of Central Tendency
- White Paper: Analyses and Displays Associated with Demographics, Disposition, and Medications in Phase 2-4 Clinical Trials and Integrated Summary Documents
- White Paper: Analyses and Displays Associated to Non-Compartmental Pharmacokinetics – with a Focus on Clinical Trials
- Reviewers Guides: Study Data Reviewer's (SDRG) Guide Work Package
- Reviewers Guides: Analysis Data Reviewer's (ADRG) Guide Work Package
- Semantic Technology Primer

Computational Science Symposium 2014

Silver Spring Civic Center



Agenda

Speaker Presentations

Monday, March 17th

To listen to Monday's presentations [click here](#)

Fulfilling the Promise of Information Technology

- Taha A. Kass-Hout, M.D., M.S., FDA Chief Health Informatics Officer

TransCelerate Biopharma: Pre-Competitive Collaboration in Clinical Trials

- David Jordan, TransCelerate Biopharma

FDA Standards Strategy: Where are We and Where are We Going?

- Ron Fitzmartin, Ph.D., Office of Strategic Programs, CDER, FDA

CSC Update: A Demonstration of JumpStart, the New FDA Platform of Tools and Processes for Product Review - Lilliam Rosario, PhD., Director, Computational Science Center, CDER, FDA

Innovation through Collaboration: Why the CSS Working Groups are Important to FDA

- Steve Wilson, DrPH, CAPT., USPHS Director, Division of Biometrics III, CDER, FDA

Agenda

Summary of Working Group Progress

- *Optimizing Data Standards Working Group*
- *Emerging Technologies Working Group*
- *Standard Scripts Working Group*
- *Non-Clinical Working Group*

What you want to Know - An Open Discussion of Data Standards Implementation

- *FDA Expert Panel*

Script-athon

CSS Script-athon

The 2014 PhUSE Computational Sciences Symposium will feature the first ever "Script-athon".

This hands-on opportunity will jump-start the Standard Scripts Working Group code repository. The Script-athon participants will collaborate to create standard scripts using various code languages like SAS and R. Output of the Script-athon will be put on the PhUSE Code Repository and will be publically accessible for regulatory reviewers and Clinical Data Scientists across the industry. Targets will be selected from the first finalized White Paper on Central Tendency (full paper can be found [here](#)).

When and How?

The group will meet during the conference and on Monday from 6pm to midnight they will bang through some code to fill the PhUSE code repository.

While we expect participants to bring solid programming skills and a good experience, the technical requirements are minimal. Participants will need a laptop with a browser (Chrome, Safari, or Firefox only). That's it. Participants will access and work on three cloud based programming environments:

- The Google-hosted code repository will hold the targets (ie. annotated mock tables and graphs from the White Paper) and the source datasets (ie. CDISC ADaM pilot datasets) and finally the scripts
- The R server (hosted by Mike Carniello - courtesy of RStudio and free Amazon Web Services: <http://rstudio.carniello.org>) will enable coding in R
- The SAS server (hosted by SAS Institute) will enable coding in SAS.

The Script-athon participants will execute 100% of their work within the cloud server, accessing programs and data sources.

Picture from PhUSE Website: http://www.phuse.eu/Script-athon_CSS.aspx

Questions?



Photo by Marco Bellucci