



Pharmaceutical Users Software Exchange (PhUSE)



Mission

Be the Life Science industry's premier society for creating & sharing ideas, implementing tools & standards around data, and exploring statistical & reporting technologies.

Share – Contribute – Advance



Core Values

- Independent
- Promote professional excellence
- Open and Inclusive
- Collaborate and share knowledge

- Idea was born in 2004 because Europe needed a forum for sharing
- First conference held in Heidelberg – over 270 attendees from 12 countries
- Have held conferences across Europe and grown to 400-500 attendees
- Journal introduced in 2008
- Single Day events began in 2009



More then a conference...

PhUSE is an organization that provides a variety of networking opportunities

- Annual Conference/Single day events
- Monthly Mailshot/Newsletter quarterly/Blog
- Wiki in collaboration with various groups

PhUSE provides a unique experience

- Vendor neutral
- Events emphasize interaction and discussion
- Collaboration with FDA



PhUSE in Numbers

8 conferences **2,345** have attended a PhUSE Conference

10 SDEs this year Over **2,000** members

Events on **4** continents

35 past SDEs

Over 600 people attended SDEs last year

621 conference presentations to date



FDA/PhUSE Collaboration



FDA/PhUSE Collaboration

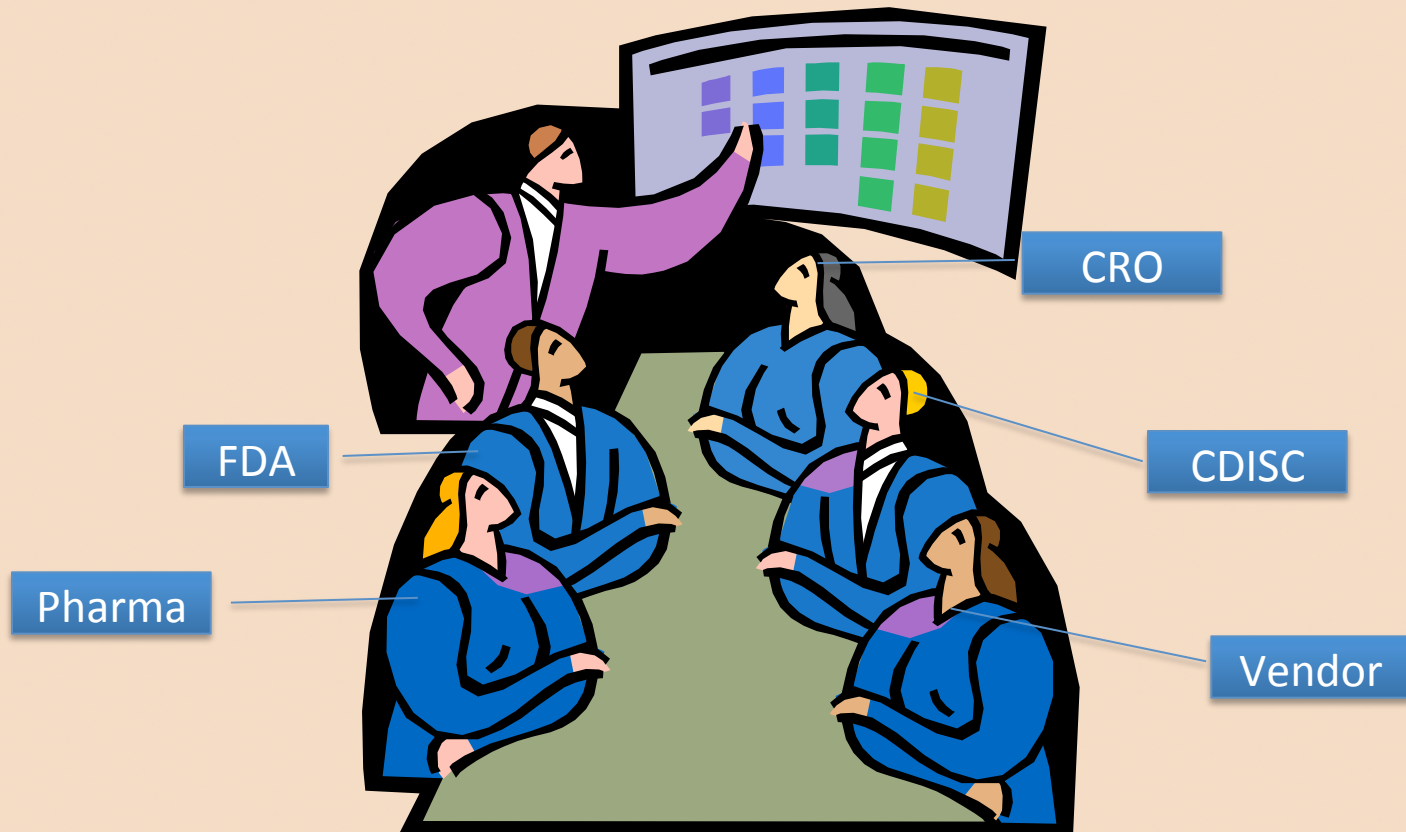


FDA
Proclamation



We the Masses
Yearning for
Answers

Paradigm Shift





Meetings 2.0

- A different kind of event
- Collaborative working meeting
- Initially defined working groups focused on general topics with projects
- Work does not stop when people go home – Continue the collaboration
- Work Products, timelines, next steps



CSS Working Groups

- Improving Data Quality – focused on the process of validation and assessing data quality
 - Project: SDTM Validation Rules
- Optimizing the Use of Data Standards – work on issue and close gap in the implementation of standards
 - Study Data and Analysis Reviewer's Guide
 - Pilot for Medical Device Data
 - Evaluation of Traceability
 - Evaluation of SDTM Elements



CSS Working Group

- Standard Scripts for Analysis and Reporting – work towards standards analyses and building a open shared code repository
 - Implementation of an open code repository
 - Development of white papers around standard analyses
- Non-Clinical Roadmap and Implementation – improve the processes and standards around Non-Clinical Data
- Emerging Technologies – new working group trying to evaluating how newer technologies/methods could be applied to improve the process



Get Involved

- Check out the PhUSE Wiki for working group and project updates
 - www.phusewiki.org
- Email and working group lead or sign up for a mailing list
 - http://www.phusewiki.org/wiki/index.php?title=Listbox_Instructions

Only works if people contribute!



Upcoming Events



Brussels2013

Patient Centricity

Radisson Blu Royal Hotel, Brussels, Belgium

October 13th - 16th

Patient Centricity

Patients at the heart of the
conference



#PhUSE13



Conference Topic

Patient Centricity

Call for
Paper
closes
April 30th

What Oncology makes special
Patient Centric Papers Dirty Data in Patient Reported Outcomes Accelerating Clinical
Development

Innovation through
Standardization

Global Collaboration

PhUSE has been a Patient Centric Conference for
many years

Inspiring keynotes

Prof. Lord Winston Charles Sabine

Health Outcomes and Epidemiology
Streams

Our higher goal is to make Patients lives better...





Single Day Events

Europe:

- Copenhagen, Frankfurt, Beerse, Basel

US:

- Boston, MA – *Model Based Drug Development*
- Canton, MI – *Transparency in Clinical Research*
- San Francisco, CA – *Implementation of R in the Drug Development Process*
- TBD

Other:

- India, Hyderabad
- China, Shanghai



Help shape the industry

Present at the conference

Contribute to the Wiki

PhUSE
News

Blog
Article

SDE

Regional
Contacts



Thank you!

- Can't do this without volunteers
- Raleigh SDE Coordinators
 - Susan Kenny
 - Gustav Bernard
 - Karen Pieper
- SDE Committee
 - Ed jones
 - Cathy Bezek
 - Phuong Dang
 - Ian Fleming



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