PhUSE Activities Worldwide - 2017 US CSS Report

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Disclaimer

- The opinions and information in this presentation are those of the author, and do not represent the views, practices and/or policies of the Eli Lilly Japan K.K.

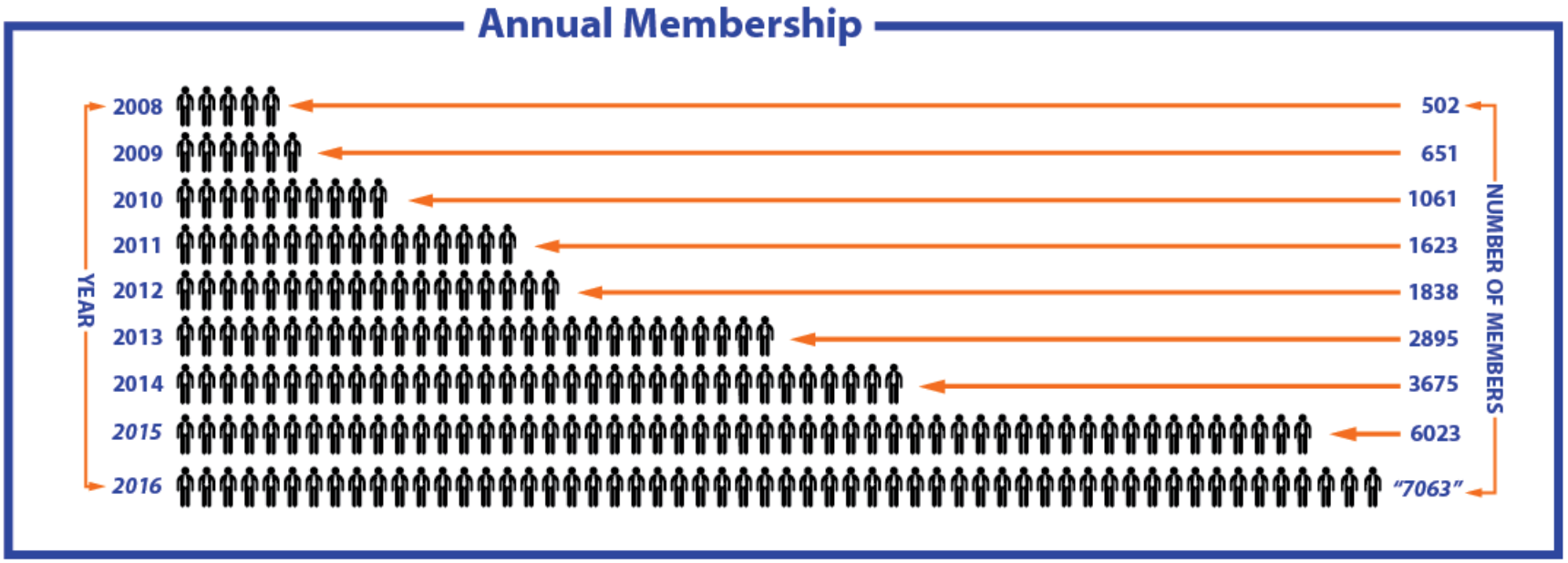
Agenda

- What is PhUSE? What is CSS?
- US CSS 2017 at a Glance
  - Keynote Presentations
  - Working Group Activities
  - Poster Session
- CS Working Group
- Summary

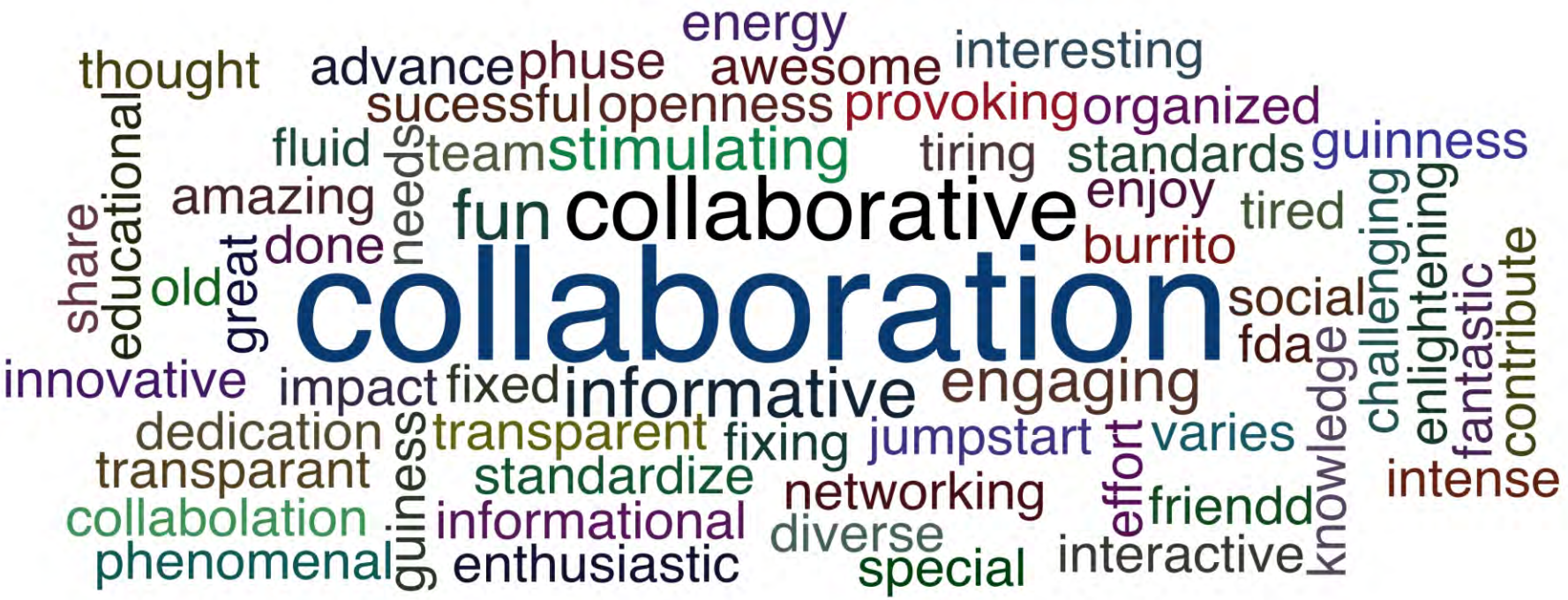
What is PhUSE?

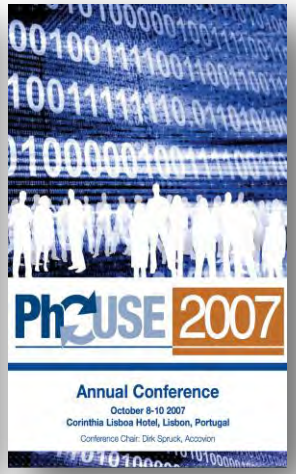
- Established 2005
- More than 7000 members worldwide
- Focus on “Implementation” of standards, technologies in regulatory/industry
- Organizing events such as Annual Conference (EU), Computational Science Symposium (US and EU) and Single Day Events (Worldwide)
- Working Group activities

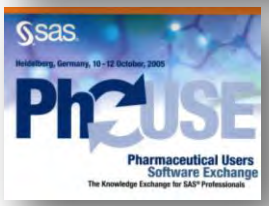
PhUSE is the World's Largest Biometrics Society



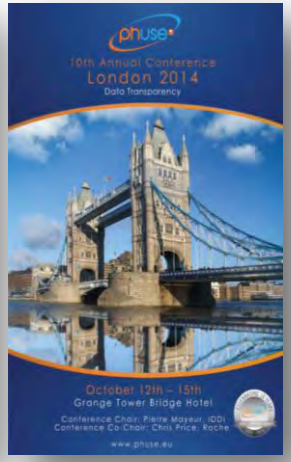
Words to describe the 5th PhUSE CSS (March 2016)

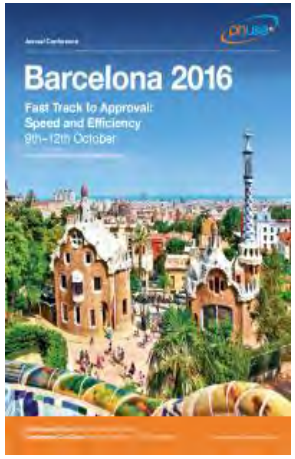


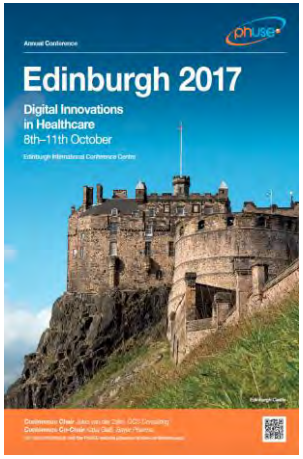




PhUSE Annual Conferences
2005 – 2017



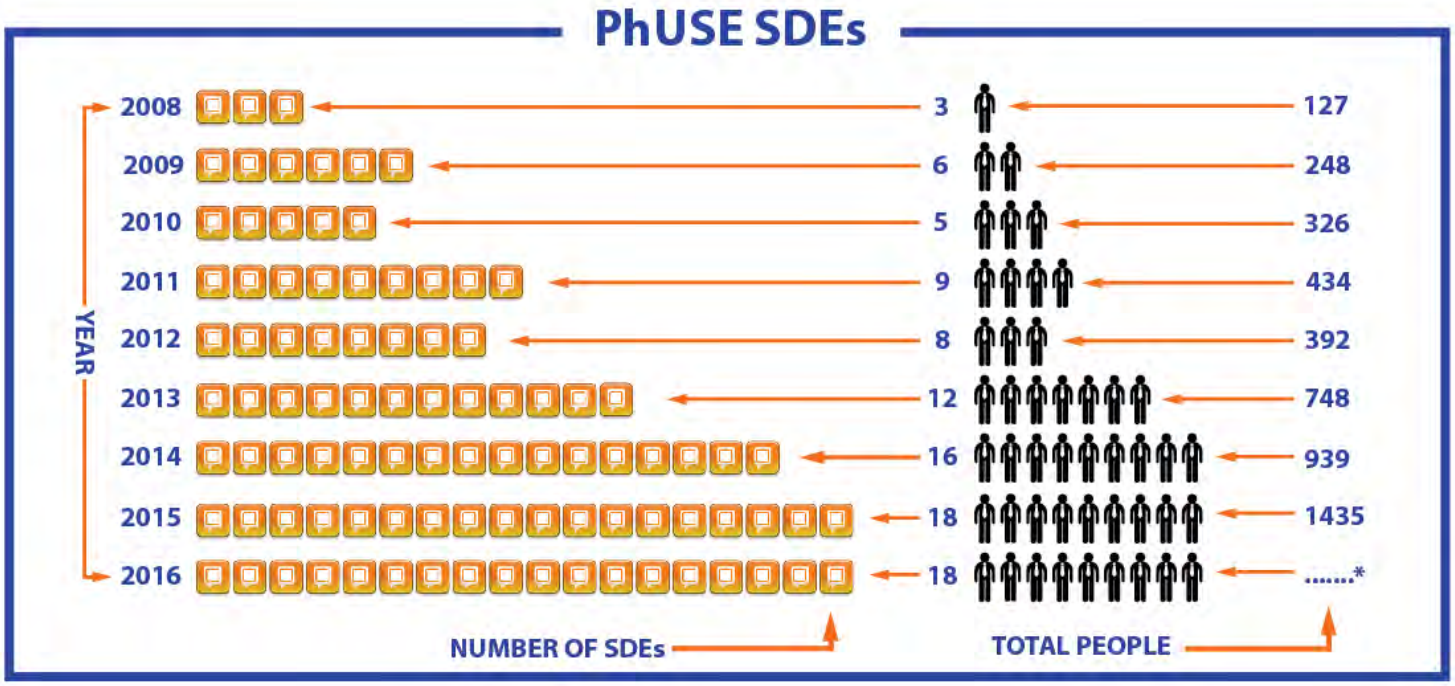




Share
Contribute
Advance

Single Day Events

2017
Celebrating 100 SDEs Across the Globe



2017 – 21 Global SDEs

USA

- Foster City, CA
- Boston, MA
- Raritan, NJ
- North Chicago, IL
- Whippany, NJ
- Chapel Hill, NC

Europe

- Netherlands
- Germany
- Switzerland
- UK
- Denmark
- France
- Belgium

Asia

India

- Dehli
- Bangalore
- Hyderabad
- Mumbai

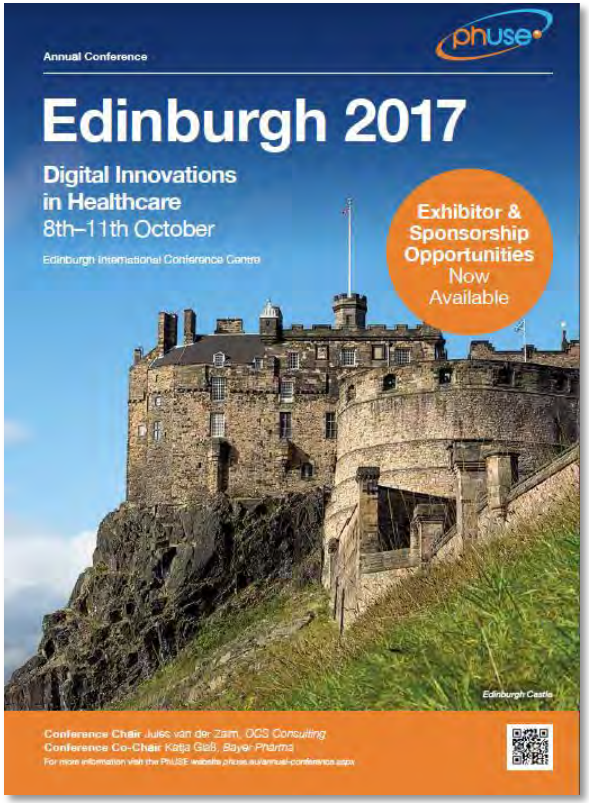
China

- Beijing, China
- Shanghai, China

Japan

- Tokyo, Japan - April
- Tokyo, Japan – August

PhUSE 2017 Conferences



What's New for 2018

PhUSE are excited to announce
we will be introducing a
US Annual Conference in 2018.

Join us in Raleigh, North Carolina,
June 3rd – 6th 2018 !

What is CSS?

- Computational Science Symposium
- In the US, since 2012
  - EU CSS initiated since 2016
- Working Group Breakout Sessions + Keynote presentations
- Co-sponsored by PhUSE and FDA

CSS Day 1 (Sunday Mar19)

- Working Group Opening Session
  - Linked Data and Graph Databases
  - Optimizing the Use of Data Standards
  - Standard Analyses and Code Sharing


A CRO Like No Other
USA
UK


Thank You!
Thank You!
Computational Science
Working Groups

CSS Day 2 (Monday Mar20)

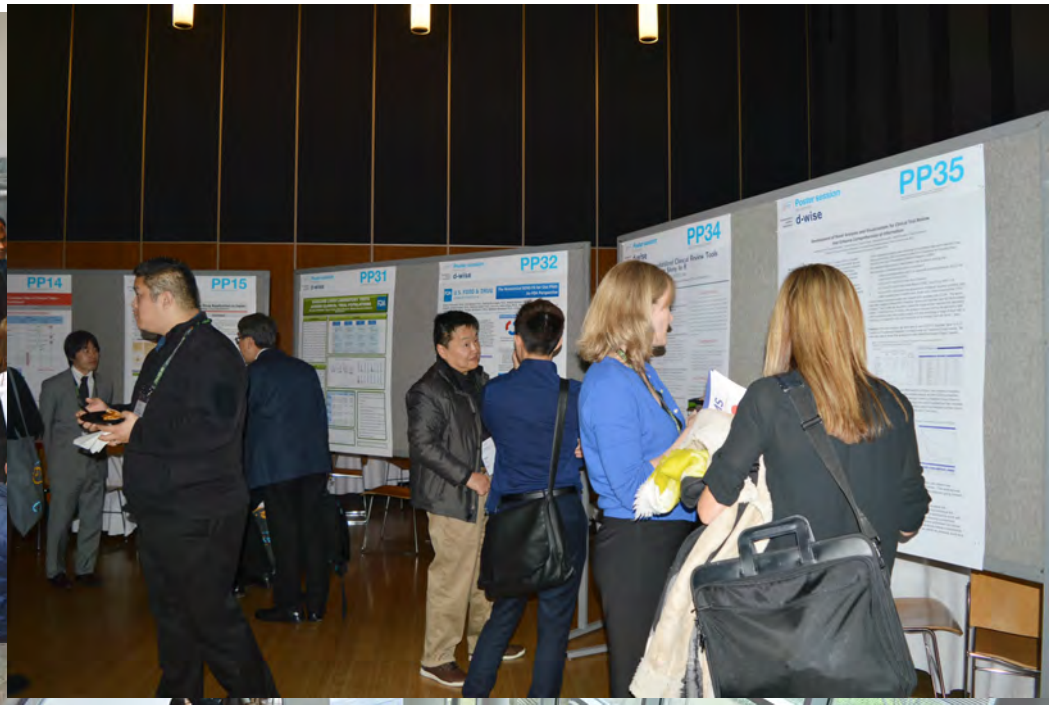
- **Introduction** – *Crystal Allard, FDA/CDER*

  Visualization of Nonclinical Standardized Data and the Fit for Use Pilot – *Elaine Thompson, FDA/CDER*

  How Analysis Tools are Used for the NDA/BLA Clinical Review – *Mary Doi, FDA/CDER & Vaishali Popat, FDA/CDER*

  From CDISC to PhUSE to Approval – A Statistical Reviewer's Experience and Thoughts
  Steve Wilson, Huanyu Chen
  – Steve Wilson, CDER/FDA & Huanyu (Jade) Chen, FDA/CDER


PP22
PP17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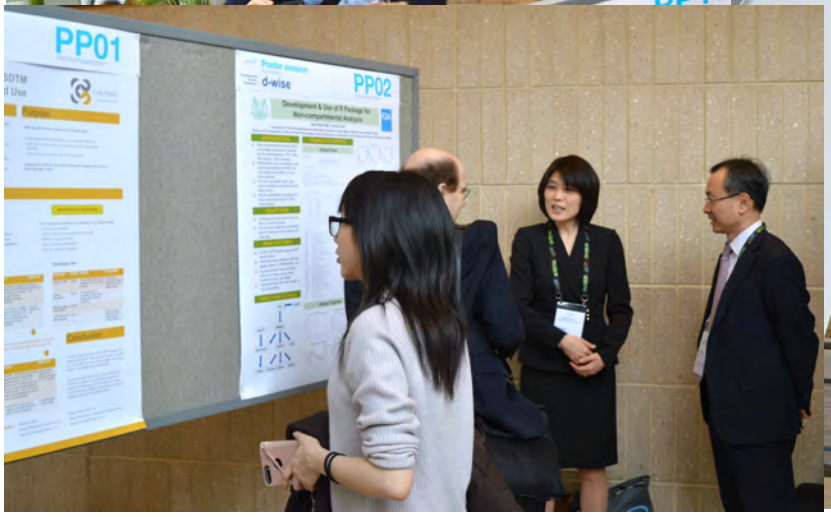
d-wise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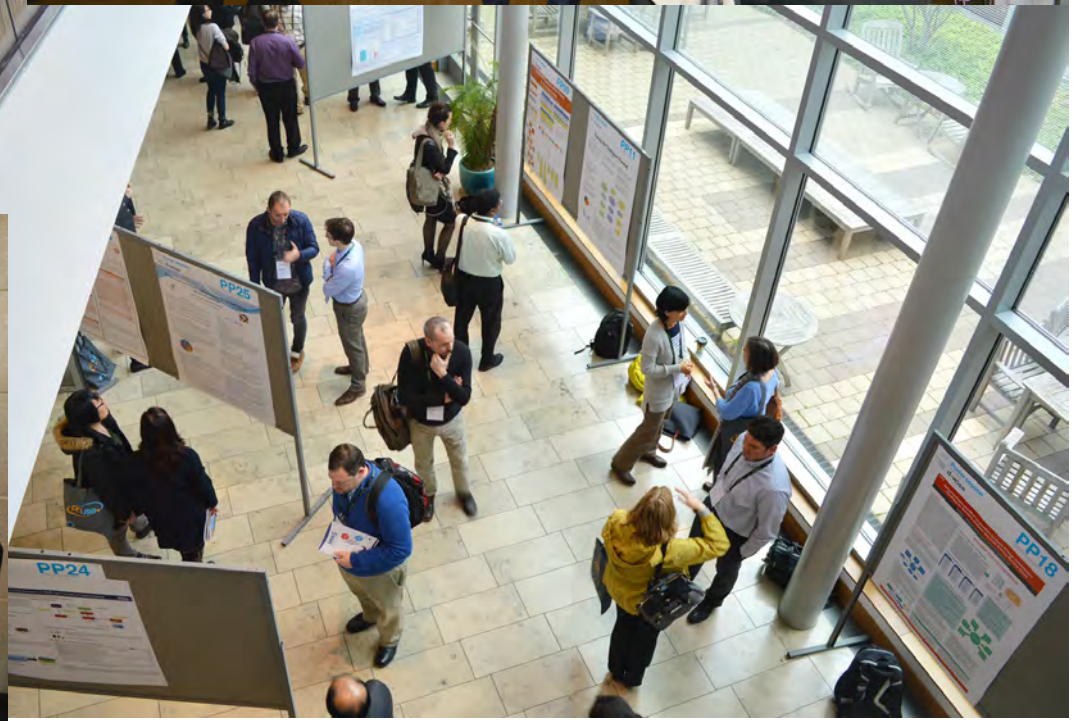
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PP18

CSS Day 3 (Tuesday Mar21)

- **WG Breakout Sessions (Continued)**
  8.30am - 12pm
- **Industry and Regulatory Panel:**
  Impact of the Guidance on Submissions
  2.30pm - 3.30pm
- **Poster Awards and Closing Remarks**
  Summary of the two days, a review of the WG achievements and best poster awards.

Congratulations!!! One of the poster award went to -
Electronic Study Data Submission for New Drug Application in Japan
Ken Sakushima, PMDA, Hiroshi Sakaguchi, PMDA & TJ Chen FDA/CDER/OSP

CSS Working Groups

PhUSE Working Groups Overview

PhUSE CS Working Groups:

Nonclinical Topics

Sue DeHaven
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Formed in 2012.

To improve nonclinical assessments and regulatory science by identifying key needs and challenges and establishing an innovative framework for addressing them in a collaborative manner.

The focus is on using informatics approaches and standards for delivering ideas and solutions to nonclinical data challenges.

Current Active Projects:

- Nonclinical Study Data Reviewers Guide
- SEND Implementation User Group
- Application of SEND Data for Analysis
- Investigating Endpoint Modeling
- Industry SEND Progress Survey
- Test Submission Forum Group
- Nonclinical Scripts Assessment Project
- Data Consistency: SEND Datasets and the Study Report
- Visualisation of group related differences in Histopathology Data

Patty Brundage
patricia.brundage@fda.hhs.gov

PhUSE CS Working Groups:

Standard Analyses & Code Sharing

Formed in 2012.

To leverage crowd-sourcing to improve the content and implementation of analyses for medical research, leading to better data interpretations and increased efficiency in the clinical drug development and review processes. The goal is to establish and maintain a publicly available repository for storing program code to be used as analytical tools for medical research.

Where gaps exist, develop recommendations and code for analyses and displays in areas that could benefit from crowd-sourcing.

Current Active Projects:

- Script Discovery & Acquisition
- Repository Content & Delivery
- Repository Governance & Infrastructure
- Communication, Promotion & Education
- Analysis & Display White Papers
- Test Dataset Factory

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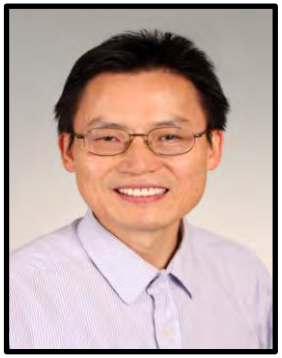

Hanming Tu
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PhUSE CS Working Groups:

Optimizing the Use of Data Standards

Formed in 2012.

The development and adoption of data standards over the last decade has shown significant promise in improving efficient delivery of data to support drug product and device submissions as well as the review process. However, there have also been gaps, issues and challenges in the interpretation and use of data standards.

This working group will identify and work to close specific gaps that prevent FDA and industry from optimizing the use of data standards.

Current Active Projects:

- Study Data Standardisation Plan (SDSP)
- Best Practices for Metadata define.xml vs. Reviewers Guide
- Define v2.0 Implementation & Style Sheet Recommendations
- Data Reviewers Guide in XML
- Legacy Data Conversion Plan & Report
- SDTM / ADaM FAQ Implementation
- Impact on Regulatory Guidance on CDISC Implementation
- Best Practices on Data Collection

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Susan Kenny
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PhUSE CS Working Groups:

Linked Data and Graph Databases

Formed in 2012.

This workgroup will investigate how W3C semantic standards can support the clinical and nonclinical trial data life cycle from protocol to submission including the representation of CDISC Foundational Standards in RDF, modeling analysis results, and representing a protocol in RDF.

Current Active Projects:

- CDD Ontology
- SDTM Data as RDF
- Representing Clinical Program Design in RDF

Scott Bahlavooni
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Tim Williams
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PhUSE CS Working Groups:

Emerging Trends & Technologies

Formed in 2012.

New challenges in regulatory science and drug, biologic, and device development provide new opportunities for recognising and leveraging new or emerging technologies and computational tools or underutilised existing technologies.

This Working Group provides a forum for determining interest in specific computational science topics, tools, technologies, and approaches and is an open and transparent forum for sharing pre-competitive means of applying new technologies.

The objective is to create well-defined collaborative projects that will describe, prioritize, assess, and assist advancement of these opportunities.

Current Active Projects:

- Cloud Adoption in the Life Sciences Industry
- Educating for the Future
- Data Visualisation for Clinical Data
- Evaluation of Alternative Transport Formats
- Evaluating the USE of FHIR in Clinical Research

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Ian Fleming
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PhUSE Future Forum Working Groups:

Process

Formed in 2016.

To define optimal processes to enable new ways of working and increase collaboration. Identify where clinical programmers can take a lead and add value.

Current Active Projects:

- **Evaluation of Data Processes in Other Industries**
  Some processes in the Pharma Industry are lengthy and take a long time to change. We will explore how other industries, both regulated and non-regulated, process their data, and update their process as data and requirements change in their industries.

- **Professional Development – Roles and Collaboration**
  It is important to ensure that the role of a clinical data scientist stays relevant and continues to evolve from primarily a programming role, to the current status providing more input into requirements, to the future, where hopefully we will lead different tasks. Key to all this is ensuring the resource is available and has the relevant skills.

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Shafi Chowdhury
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PhUSE Future Forum Working Groups:

Interoperability & Technology

Formed in 2016.

Lead the definition of open source standards and best practices that enable data, computing technology and software interoperability and usage with new health technologies and look to produce a White Paper

Purpose

- Advancing clinical data science by providing visibility and understanding of the challenges in the areas of interoperability and technology of health data.
- Creating a directional focus and an impetus in support of innovative projects that benefit the industry and advance towards a better future.

Scope

- Studying and advancing the capability of technology and practices enabling the bidirectional flow of data and information.
- To include the entire flow from patient recruitment to clinical trial, to data collection, data analysis and regulatory submission.

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Nalin Gupta
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PhUSE Data Metrics & KPI Reporting Working Group:

Formed in 2016.

The PhUSE Board endorsed a new project to categorize, standardize and collate reporting metrics. The project aim is to have a cross-industry working party that covers all global regions and company types (large pharma to biotech as well as CROs). This Working Group has split into three sub-teams:

Submissions

Defining metrics related to the clinical data contained in clinical drug submissions.

Working Group Co-Leads:
Beate.hientzsch@analytical-software.de

Alassane.doumbia@bayer.com

Study

Defining the metrics related to clinical study report data and processes.

Working Group Co-Leads:
Caroline.gray@inventivhealth.com

Polina.kuznetsova-nguyen@norvartis.com

Definitions & Ground Rules

To define the terminology and boundaries for the collection of clinical data as well as agreeing the ground rules to ensure correct procedures are applied and data security and confidentiality is maintained.

Working Group Co-Leads:
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PhUSE Working Groups:

Data Transparency

Formed in July 2014.

The PhUSE Data Transparency Working Group began working on a de-identification standard for SDTM.

This standard was published in May 2015 and has since then been referenced in a number of publications including the EMA Policy 0070 CSR Anonymization External Guidance.

The Working Group is now enhancing this first deliverable to also address ADaM and work in parallel on clarifying a number of aspects of EMA Policy 0070 from a practical standpoint.

Current Active Projects:

- Policy 0070 Interpretation
- SDTM De-Identification Standards
- ADaM De-Identification Standards

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Working Groups

Newsletter articles

Wiki input

Document Review


phuse
The premier community for people working in the biometric area
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www.phusewiki.org

Resources and Archives

- US CSS 2017
  - Presentations & Posters
    (Audio etc. are for member's only)

- PhUSE Archive
  - Webinar http://www.phuse.eu/webinars
  - Past CSSs http://www.phuse.eu/arc-css
  - Single Day Events http://www.phuse.eu/arc-sde

Question?