PhUSE Single Day Events

Delhi SDE

17th March 2018

PhUSE Single Day Events

Delhi SDE

Jayapandian N

17th March 2018

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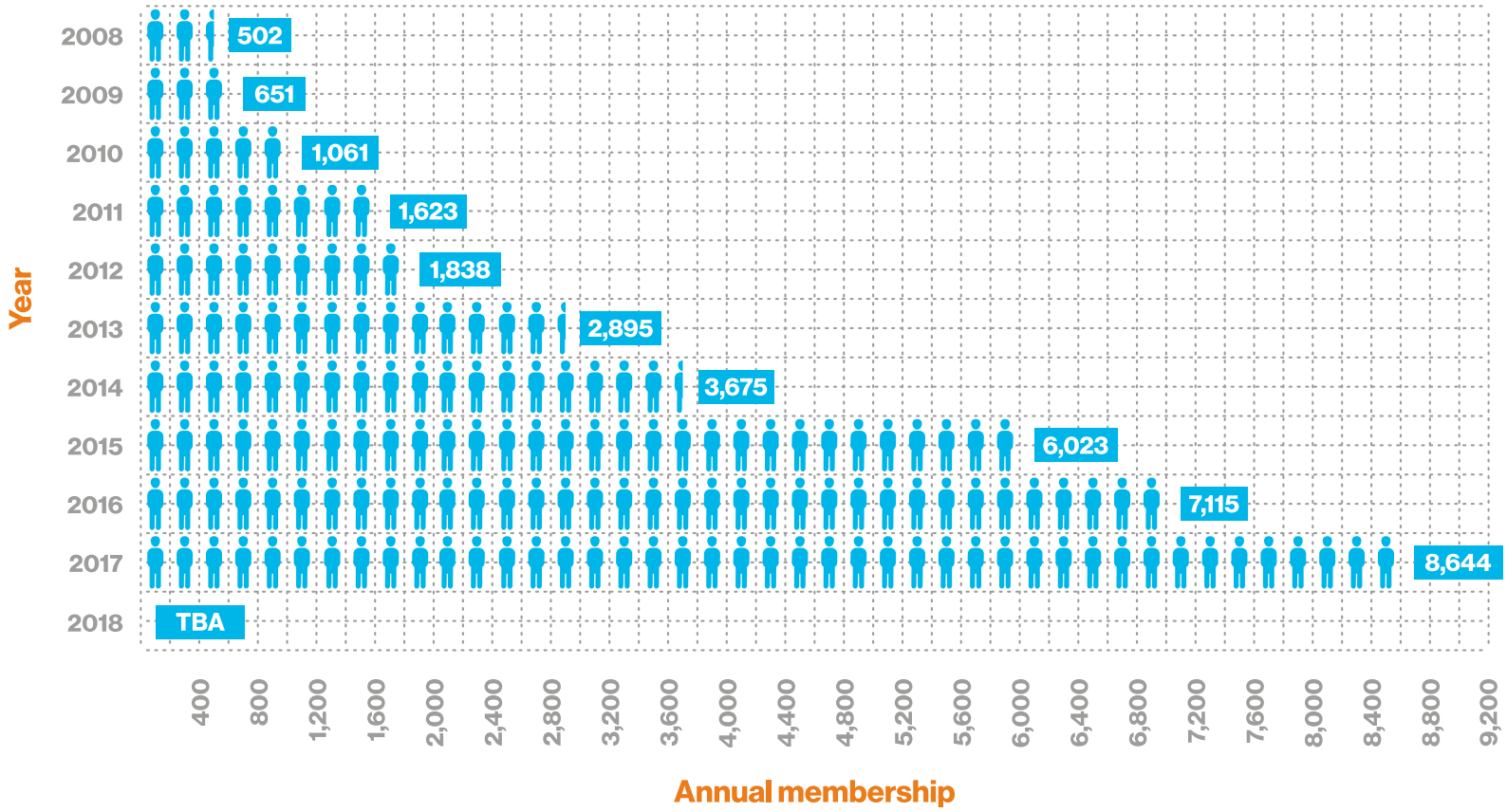
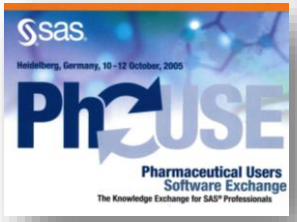
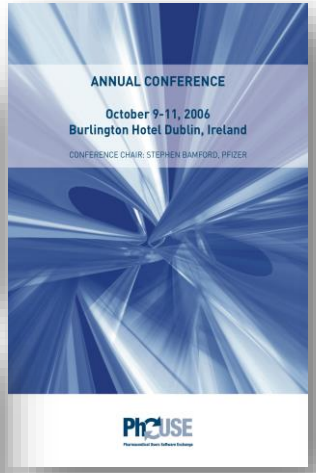
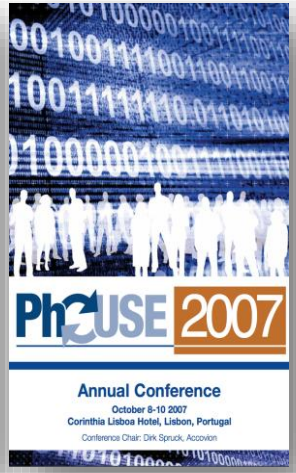
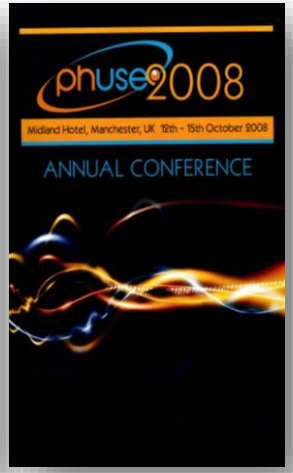


** Figures not final*


sas
Heidelberg, Germany, 10 - 12 October, 2005
PhUSE
Pharmaceutical Users Software Exchange
The Knowledge Exchange for SAS® Professionals


ANNUAL CONFERENCE
October 9-11, 2006
Burlington Hotel Dublin, Ireland
CONFERENCE CHAIR: STEPHEN BAMFORD, PFIZER
PhUSE


PhUSE 2007
Annual Conference
October 8-10 2007
Corinthia Lisboa Hotel, Lisbon, Portugal
Conference Chair: Dirk Spruck, Accovion


phuse 2008
Midland Hotel, Manchester, UK 12th - 15th October 2008
ANNUAL CONFERENCE

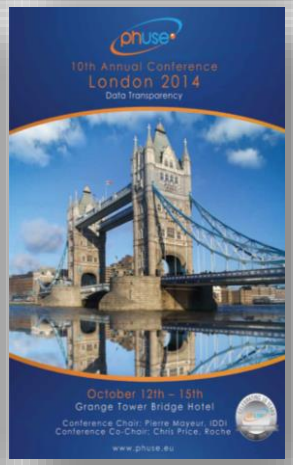

phuse 2009
Accelerating Clinical Development
ANNUAL CONFERENCE


phuse 2010
Berlin
INNOVATION DRIVEN BY TECHNOLOGY
Annual Conference
Radisson Blu Hotel, Berlin, Germany
18th - 20th October 2010


phuse
Brighton 2011
OPEN STANDARDS AND GLOBAL COLLABORATION
SUPPORTING
genesis research trust
Annual Conference
Hilton Metropole, Brighton
9th – 12th October 2011


phuse
Budapest 2012
CONFERENCE 2.0:
FROM ATTENDING TO COLLABORATING
Annual Conference
Budapest Marriott Hotel
14th - 17th October 2012


phuse
Brussels2013
Patient Centricity
Annual Conference
Radisson Blu Royal Hotel, Brussels, Belgium
October 13th-16th


phuse
10th Annual Conference
London 2014
Data Transparency
October 12th - 15th
Grange Tower Bridge Hotel
www.phuse.eu


phuse
Vienna 2015
Clinical Data Science
From Data to Knowledge
October 11th - 14th


phuse
Barcelona 2016
Fast Track to Approval:
Speed and Efficiency
9th–12th October


Edinburgh
2017

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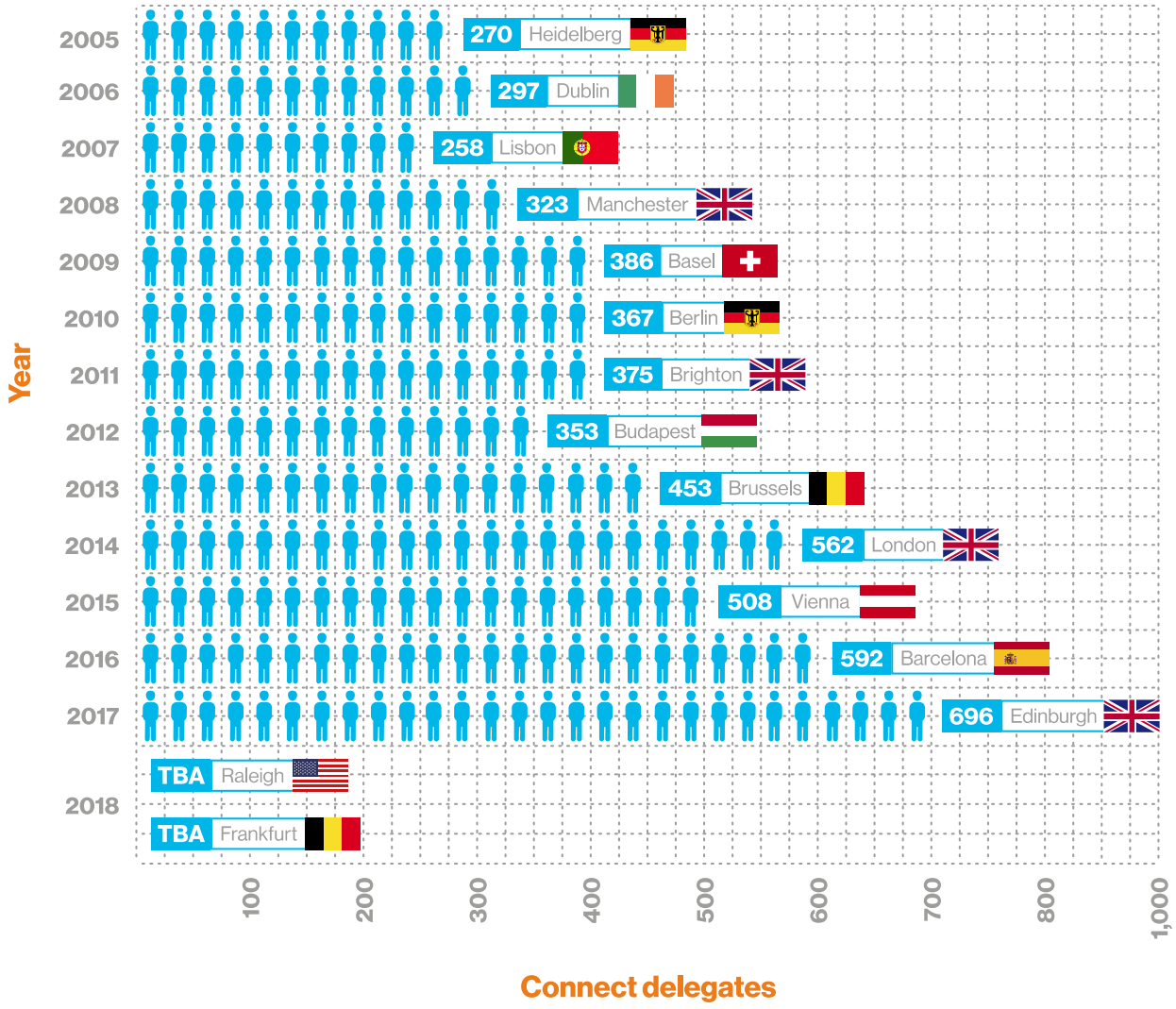
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696 Edinburgh
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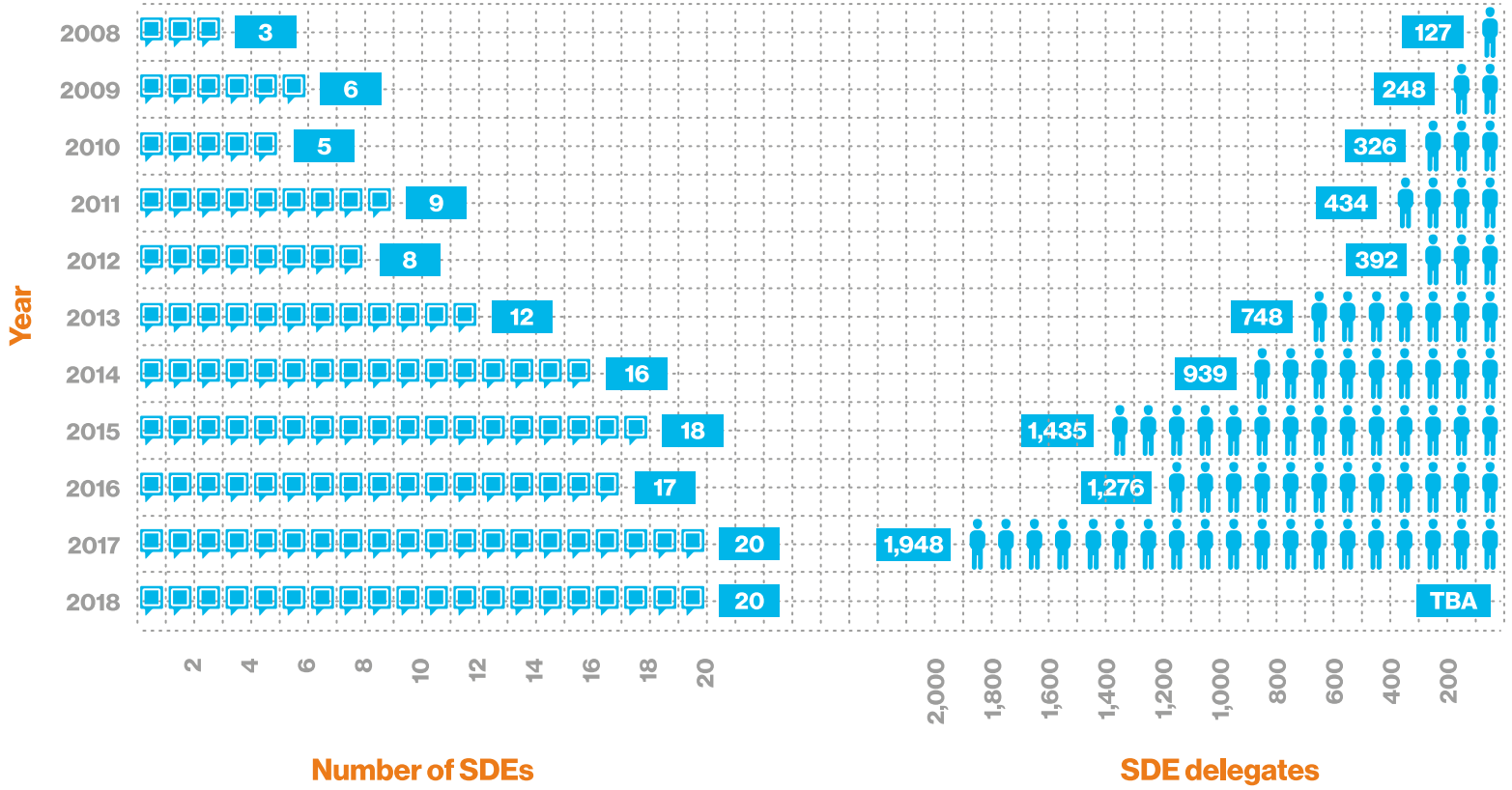
Connect delegates

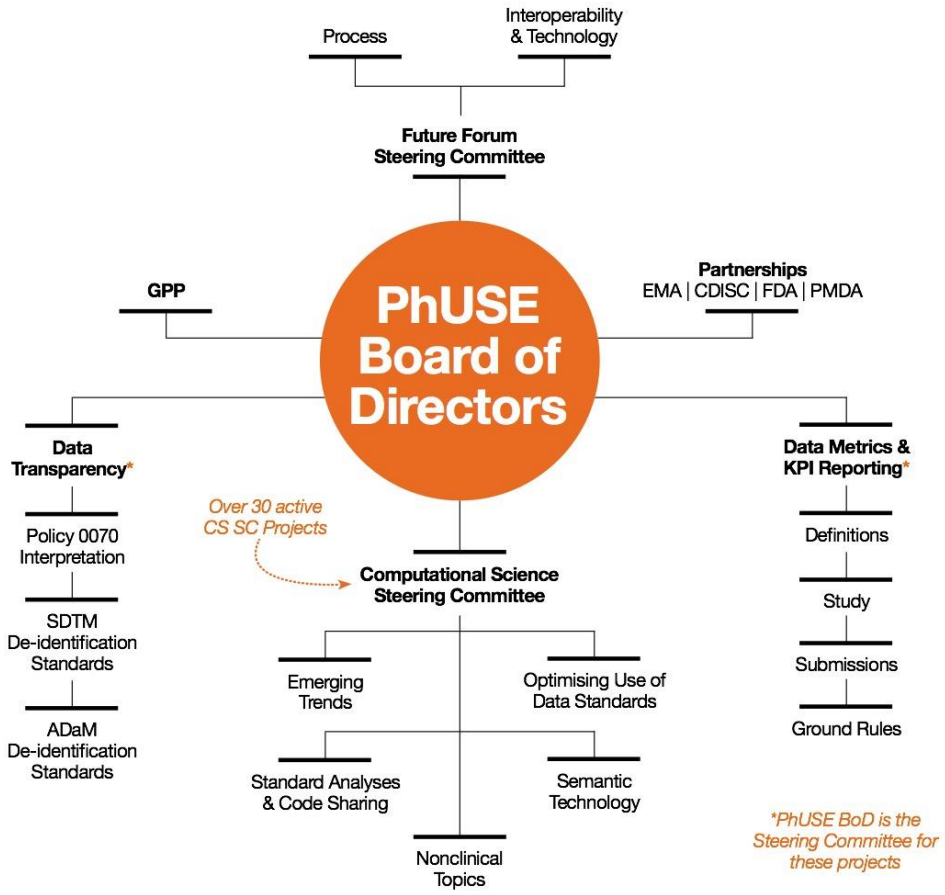
20% of PhUSE Members Attend a Single Day Event



PhUSE 2018 Dates

SDE	Date	Theme
Bengaluru	12 May 2018	Real World Evidence Study and use of Analytics and visualization
Hyderabad	14 Jul 2018	Life cycle of a drug – Stats and programmers standpoint. Safety and efficacy end points in breakthrough therapies
Chennai	13 Oct 2018	Converting High volume Data Challenge to relevant clinical data insight
Full details and event dates can be found on the PhUSE website		

Working Groups are the fastest growing part of PhUSE and are our way of gaining traction with our core partners.



PhUSE CS Final Deliverables Catalog

The PhUSE CS Working Groups bring together academia, industry, technology providers and regulatory agencies including the FDA to collaborate on projects to address unmet computational science needs. This catalog provides a single point of reference for content developed by the CS Working Group projects.

Deliverables

Preliminary recommendations for Traceability using Define-XML Version 2.0: 15-DEC-13: The Define-XML 2.0 Specifications, "Metadata Submission Guidelines" (MSG) V1 and the "ADaM Implementation Guide" V1 documents, describe metadata for SDTM, Analysis Data Sets (ADS) [*1] and Analysis Results. The Define-XML specification document is expected to handle the technical implementation of what is described in less technical terms in implementation guidelines documents; however, it must be recognized that the Define-XML 2.0 Specifications document is reflecting the current version of the Metadata requirements, while the implementation guidelines are not updated yet.

Traceability: Current State Analysis. Version 1.0: 21-AUG-13: Addresses the challenges of integrating and converting data across studies. To define traceability considerations and best practices for study level and integrated dataset conversion for a variety of different data flow scenarios.

Analysis Data Reviewer's (ADRG) Version 1.1: 01-NOV-16: The ADRG provides FDA Reviewers an orientation to the submitted analysis data in a consistent and usable format. The ADRG Work Package includes a ADRG Completion Guidelines, ADRG Template, and examples. *This document is referenced in the FDA Study Data Technical Conformance Guide release, March 2015 - click here to view.*

Study Data Reviewer's (SDRG) Version 1.2: 01-NOV-16: The SDRG provides FDA Reviewers with additional context for SDTM datasets received as part of a regulatory submission. The SDRG Work Package includes a SDRG Completion Guidelines, SDRG Template, and example SDRGs. *This document is referenced in the FDA Study Data Technical Conformance Guide release, March 2015 - click here to view.*

Standardizing Data within the Inspection Site Selection Process Final Version: 26-MAY-16: "Guidance for Industry: Providing submissions in electronic format.

CDISC Foundational Standards in RDF Final Version: 30-AUG-15: CDISC has officially taken this on

Metadata Definitions Document Version 1.0: 15-JULY-14: This document contains definitions and example usage for commonly used terms relating to metadata and master data management.

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CONNECT SHARE ADVANCE

EU 2018

The Clinical Data Science Conference

4th–7th November
KAP Europa
Frankfurt, Germany

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US 2018

The Computational Science Symposium

March 4th–6th
Silver Spring Civic Center
Silver Spring, Maryland, USA

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US 2018

The Clinical Data Science Conference

June 3rd–6th
Raleigh Convention Center
Raleigh, NC, USA

phuse.eu

PhUSE CS Working Groups:

Nonclinical Topics

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

Sue DeHaven
susan.dehaven@sanofi.com

Bob Dorsam
robert.dorsam@fda.hhs.gov

PhUSE CS Working Groups:

Standard Analyses & Code Sharing

Formed in 2012.

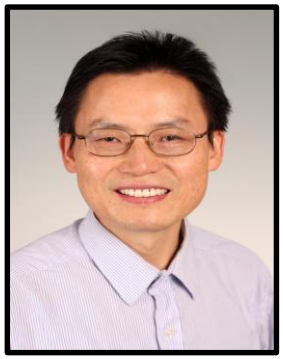
To leverage crowd-sourcing to improve the content and implementation of analyses for medical research, leading to better data interpretations and increased efficiency in the clinical drug development and review processes. The goal is to establish and maintain a publicly available repository for storing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

Mary Nilsson
nilsson_mary_e@lilly.com



Hanming Tu
hanming.h.tu@accenture.com

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)
- Standardising Data within the Inspection Site Selection Process
- Standards Implementation Nuances (by version)
- 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

Jane Lozano
Lozano_Jane_a@lilly.com

Dhananjay Chhatre
dhananjay.Chhatre@gilead.com

PhUSE CS Working Groups:

Semantic Technology

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:

- Representing Regulatory Guidance in RDF
- Representing Clinical Program Design for RDF
- Analysis Results and Metadata
- Use Cases for Linked Data
- Representing CDISC Protocol Representation Model in RDF

Scott Bahlavooni
scott.bahlavooni@phuse.eu

Tim Williams
tim.williams@ucb.com

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
- Statistical Computing Environments
- Data Visualisation for Clinical Data
- Evaluation of Alternative Transport Formats

Geoff Low
Geoff.low@phuse.eu

Ian Fleming
Ian.Fleming@d-wise.com

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.

Chris Price
chris.price.cp1@roche.com

Shafi Chowdhury
shafi@shaficonsultancy.com

PhUSE Future Forum Working Groups:

Interoperability & Technology

Paul Vervuren
Paul.vervuren@danone.com

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.

Nalin Gupta
nalin@gcesolutions.com

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:
Hanming.h.tu@accenture.com
Yvonne.moores@phuse.eu
Avinashreddy.pati@astellas.com

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.

Jean-Marc Ferran
Jean-Marc.ferran@phuse.eu

- Working Groups
- Newsletter Articles
- Wiki Input
- Committee Members
- Document Review

Personalized Medicine: Statistical and Programming Challenges

Precision medicine is an emerging approach for disease treatment and prevention that takes into account individual variability in genes, environment and lifestyle for each person. It is a key topic in clinical trials in today's and tomorrow's world. Leading large pharma companies are coming up with ways to discover and develop medicines to foster disease prevention and come out with better outcomes for patients. From a data analysis standpoint, it is new for many of us in terms of data captured, its volume and analyzing it.

Agenda:

Agenda

Time	Title and Speaker
08:30–09:00	**Registration**
09:00–09:45	**Welcome and Overview of PhUSE** Sarvesh Singh, *PhUSE APAC Director*
09:45–10:15	**Personalized Medicine: Statistical and Programming Challenges and Standards** Sravan Nagi Reddy, *PPD*
10:15–10:45	**'One Size Fits All!' for Precisioned/Personalized Drugs – Thought Journey** Divya Gunasekar, *Novo Nordisk*
10:45–11:15	**Personalized Medicine: Randomization Challenges in Adaptive Trial Designs** Shrutimita Pokhariyal, *GCE Solutions*
11:15–11:30	**Morning break**
11:30–12:15	**Personalized Medicine: Clinical Trial Design Considerations and Statistical Aspects** Apoorva Singh, *Quanticate*
12:15–13:00	**Machine Learning Techniques to Personalize Medicine** Vinodh Kumar Katikala, *GSK*
13:00–14:00	**Lunch and networking**
14:00–14:45	**Personalized Medicine: Promises and Challenges** Pritish Dash & Gaurab Chakraborty, *Chiltern*
14:45–15:30	**Genomically Driven Cancer Trials: An Evolution of Personalized Medicine** Kameshwari Peri, *Syneos Health*
15:30–16:15	**Semi-parametric Bayesian Model for Personalized Medicine** Ayan Das Gupta, *Novartis*
16:15–16:30	**Afternoon break**
16:30–17:45	**Digital Disruption: A Boon or Curse for Personalized Medicine and Q&A** Mayank Anand, *Syneos Health*, Gaurab Chakraborty, *Chiltern* & Arjun Roy, *AB Sciences*
17:45–18:00	**Wrap-up and closing remarks** Sarvesh Singh, *PhUSE APAC Director*

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