

100

Single Day Events

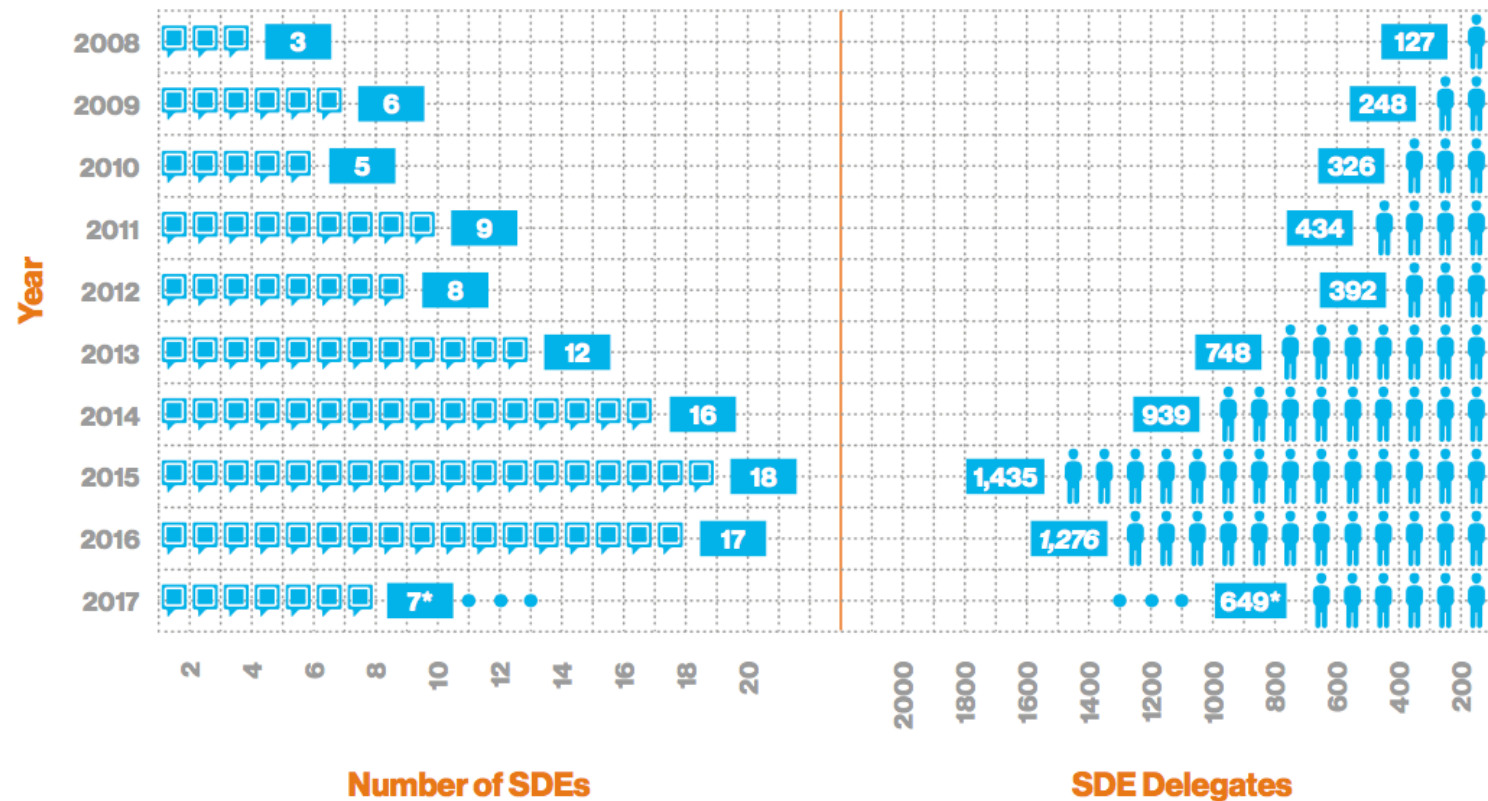




CELEBRATING

SINGLE DAY EVENTS

Member feedback in 2012, 2014 and 2016 all showed that PhUSE Single Day Events are the highest rated benefit of being a PhUSE member – almost 20% of PhUSE Members attend 1 SDE per year.



* Figures not final



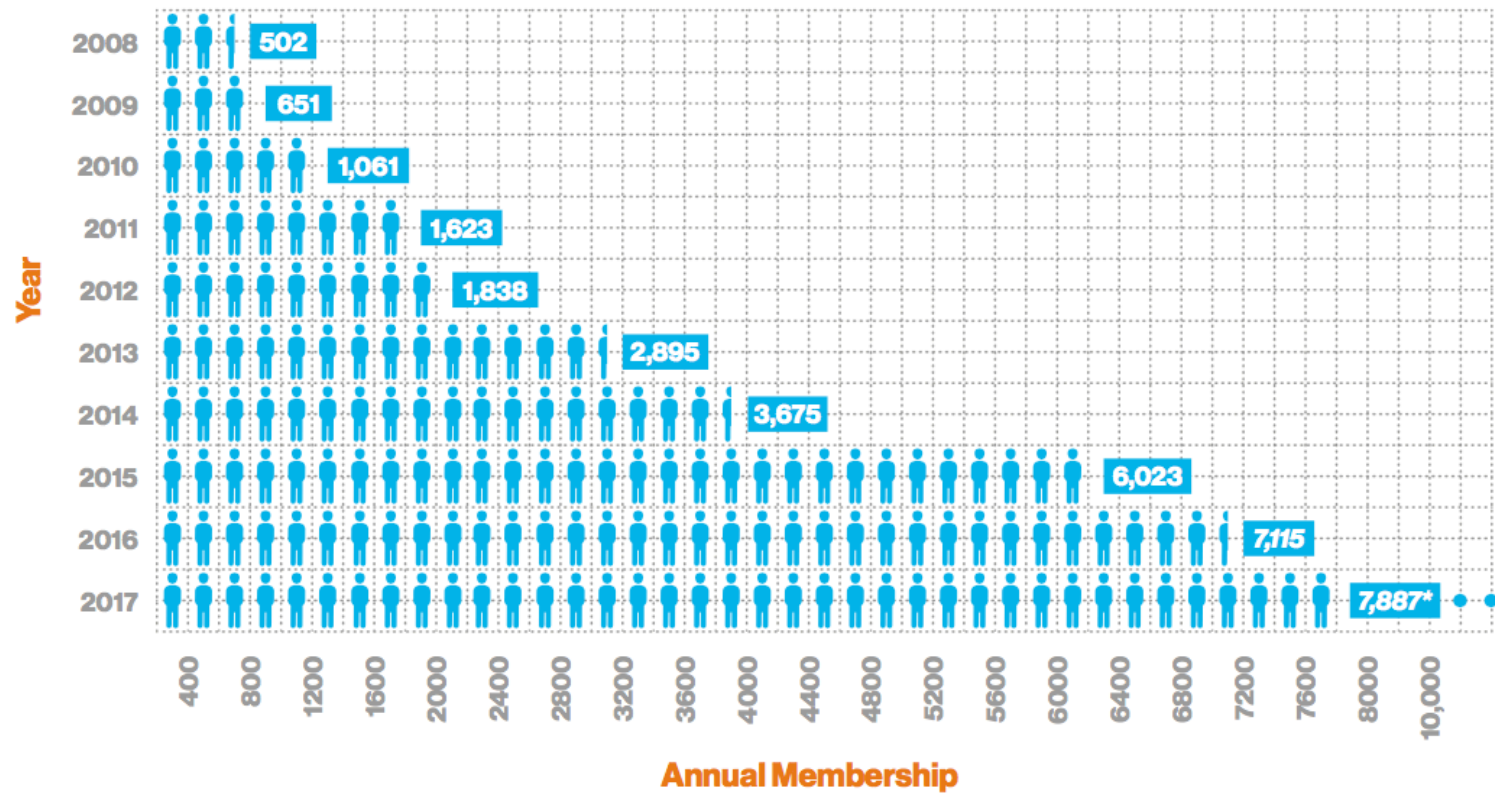








PhUSE has grown to be the World's Largest (healthcare related) Biometrics Society with a true global reach. This helps PhUSE become a representative voice for comment and feedback.



* Figures not final



We are resource constrained. We need an easy way to focus our time in a way that best suits our members and to show value-add.

Tier 1 Relationships

Core



Tier 2 Relationships

Transactional



“

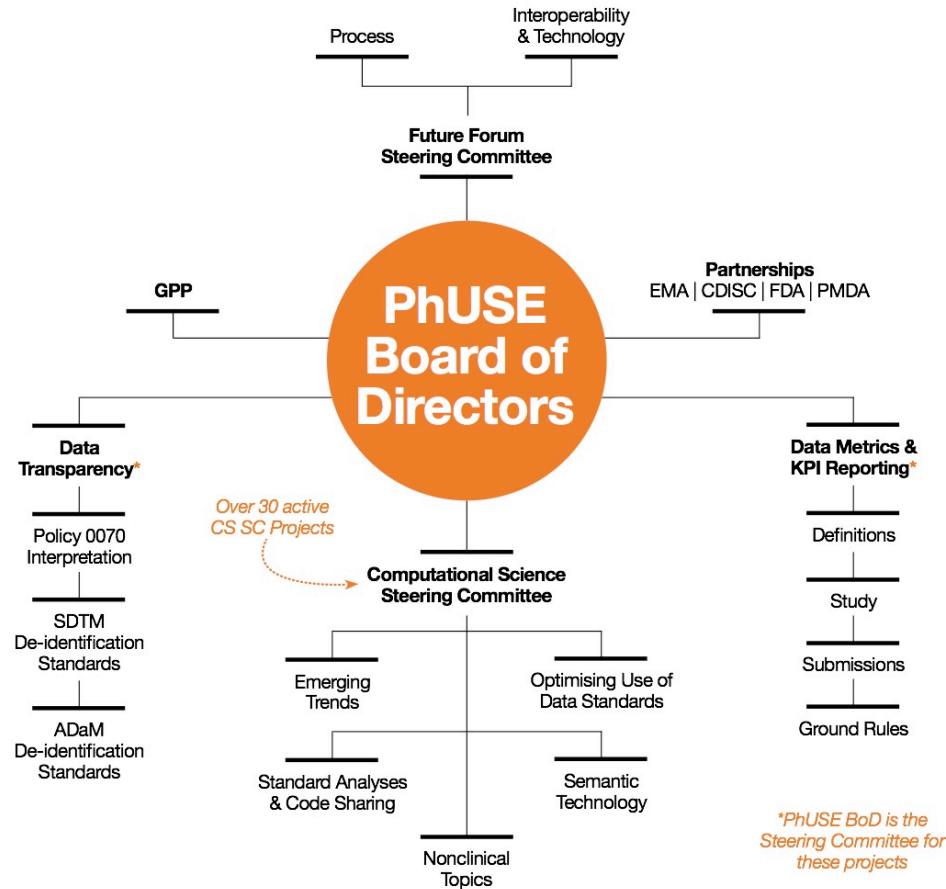
CDISC needs PhUSE to succeed

”

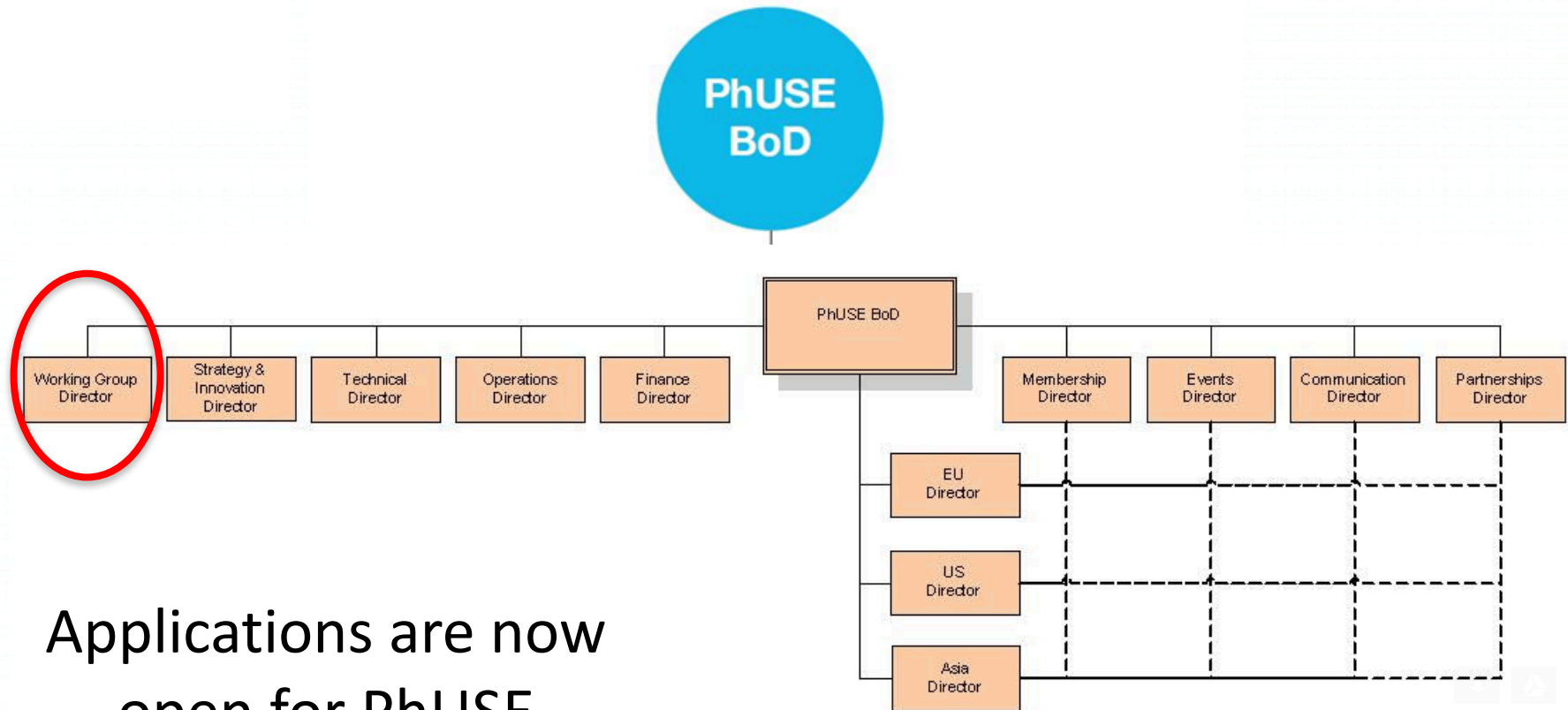
David R. Bobbitt,
President & CEO of CDISC
London 2017



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



The PhUSE Board has always adapted to meet the needs of our membership and partnerships



Applications are now
open for PhUSE
Working Group Director
position.

PhUSE EU CSS



Computational Science Symposium

19th–20th June 2017

Grange Tower Bridge Hotel, London



**The 2nd
European
Symposium**

Computational Science Symposium

19th–20th June 2017

Grange Tower Bridge Hotel, London



Data Transparency

Nonclinical Workgroup

PhUSE Future Forum Interoperability & Technology

Emerging Trends & Technologies (FHIR Project)

Standard Analyses & Code Sharing

Optimizing the Use of Data Standards: SDTM / ADaM Implementation FAQs

Reimagining Clinical Data Beginning with SDTM



Future Forum

The Vision of Clinical Data Science

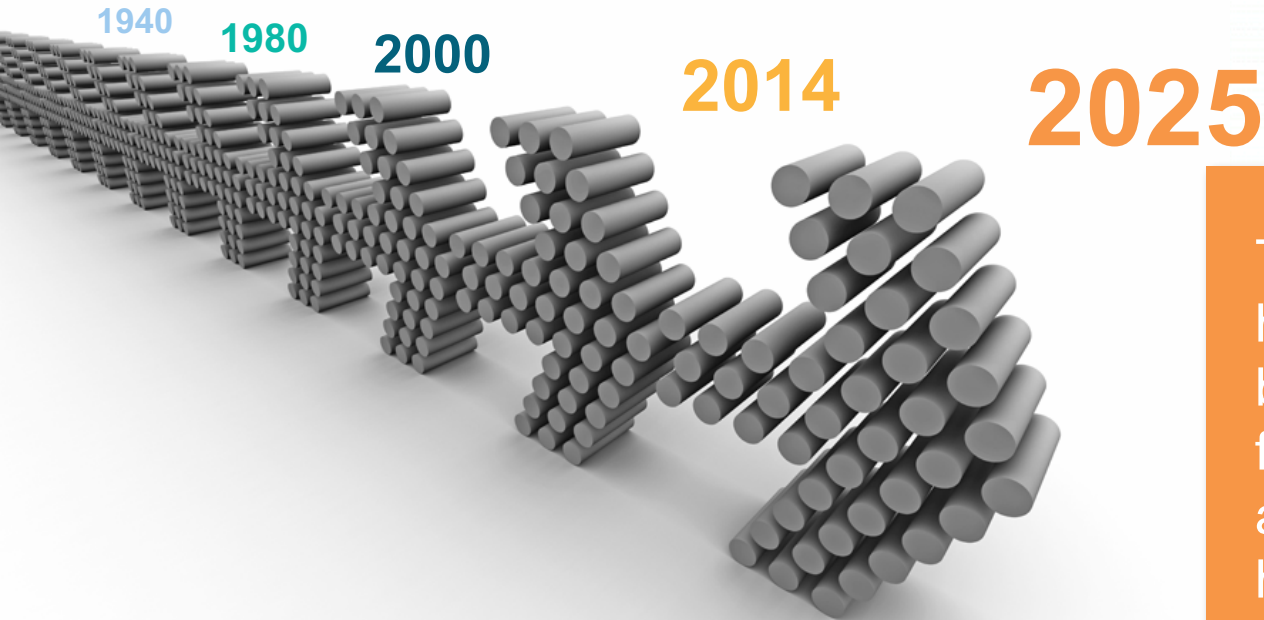
Where will we be in 2025?



A word cloud of various terms related to clinical data science, arranged in a circular pattern. The words are in different colors (orange, blue, white) and sizes. The most prominent words are 'eSource' and 'FOR'. Other words include 'Insourcing', 'Patient Monitoring', 'Wearable', 'Adaptive', 'Globalisation', 'Resource', 'and Talent', 'Life Cycle', 'Patient Engagement', 'Health Outcomes', 'In-life Trials', 'Off-shoring', 'Real Life Data', 'Statistical Computing Environments', 'Personalised Tx', 'Approvals', 'Conditional', 'Sophisticated Trials', 'Collaborative R&D Models', 'Increased Risk Averseness', 'Open Source Tools', 'Wearable', 'Adaptive', 'Globalisation', 'Resource', 'and Talent', 'Life Cycle', 'Patient Engagement', 'Health Outcomes', 'In-life Trials', 'Off-shoring', 'Real Life Data', 'Statistical Computing Environments', 'Personalised Tx', 'Approvals', 'Conditional', 'Sophisticated Trials', 'Collaborative R&D Models', 'Increased Risk Averseness', 'Open Source Tools'.

eSource
FOR
Insourcing
Patient Monitoring
Wearable
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Life Cycle
Patient Engagement
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Open Source Tools

Rethink today for tomorrow

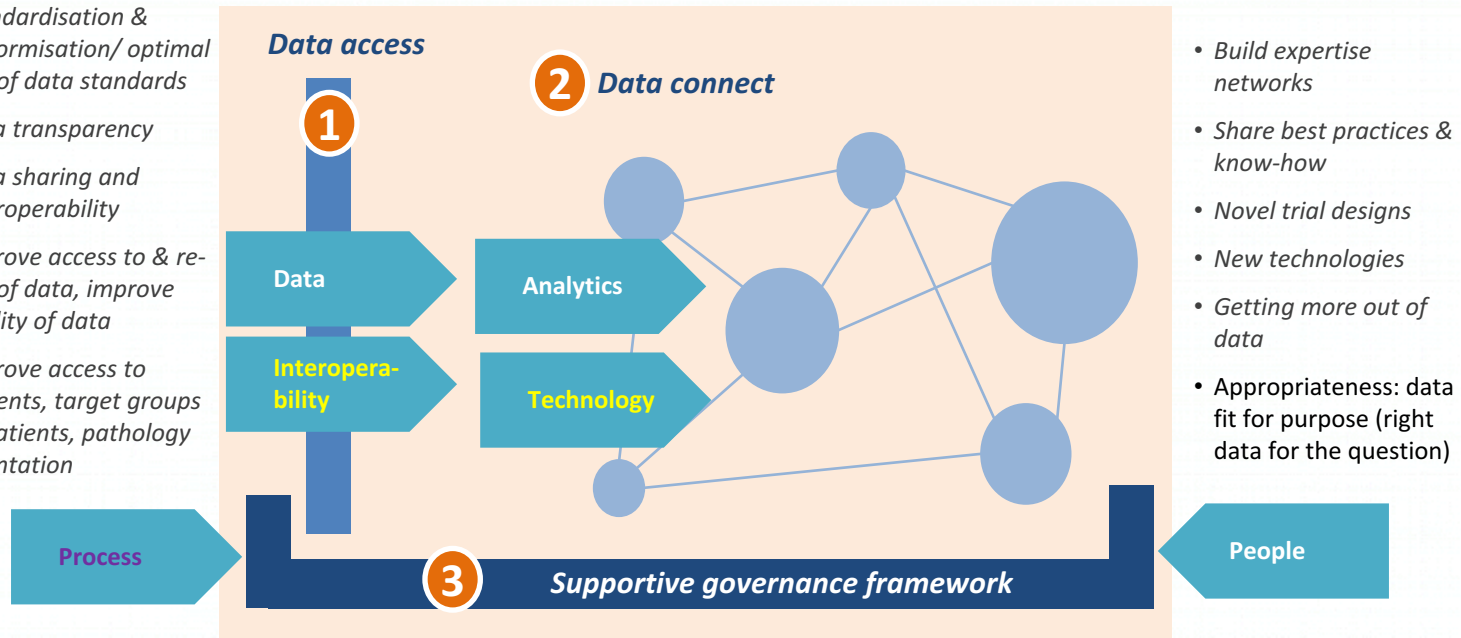


Tomorrow's healthcare system will be connected and focused on outcomes and actionable healthcare data, incentivizing prevention and cure

PhUSE will enable adaptability and flexibility that will bring more value

STRATEGIC INITIATIVES

- Standardisation & uniformisation/ optimal use of data standards
- Data transparency
- Data sharing and interoperability
- Improve access to & re-use of data, improve quality of data
- Improve access to patients, target groups of patients, pathology orientation



- Build expertise networks
- Share best practices & know-how
- Novel trial designs
- New technologies
- Getting more out of data
- Appropriateness: data fit for purpose (right data for the question)

- Collaborative business models
- Facilitate access to innovative therapeutic solutions
- Provide supportive incentives for innovation
- Interdisciplinary & multidisciplinary approaches

Annual Conference



Edinburgh 2017

Digital Innovations in Healthcare
8th–11th October

Edinburgh International Conference Centre

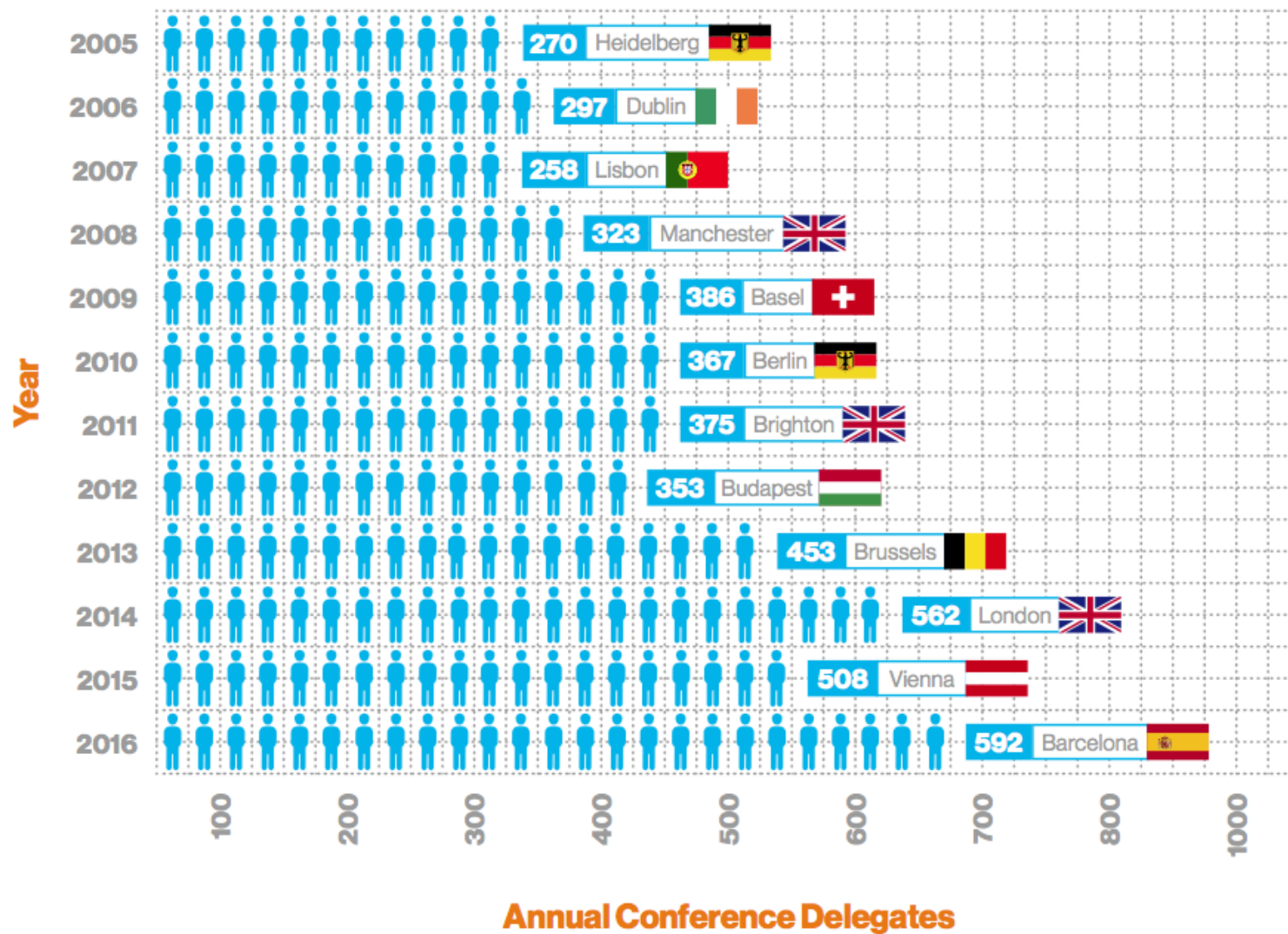


Edinburgh Castle

Conference Chair Jules van der Zalm, *OCS Consulting*

Conference Co-Chair Katja Glaß, *Bayer Pharma*

For more information visit the PhUSE website phuse.eu/annual-conference.aspx





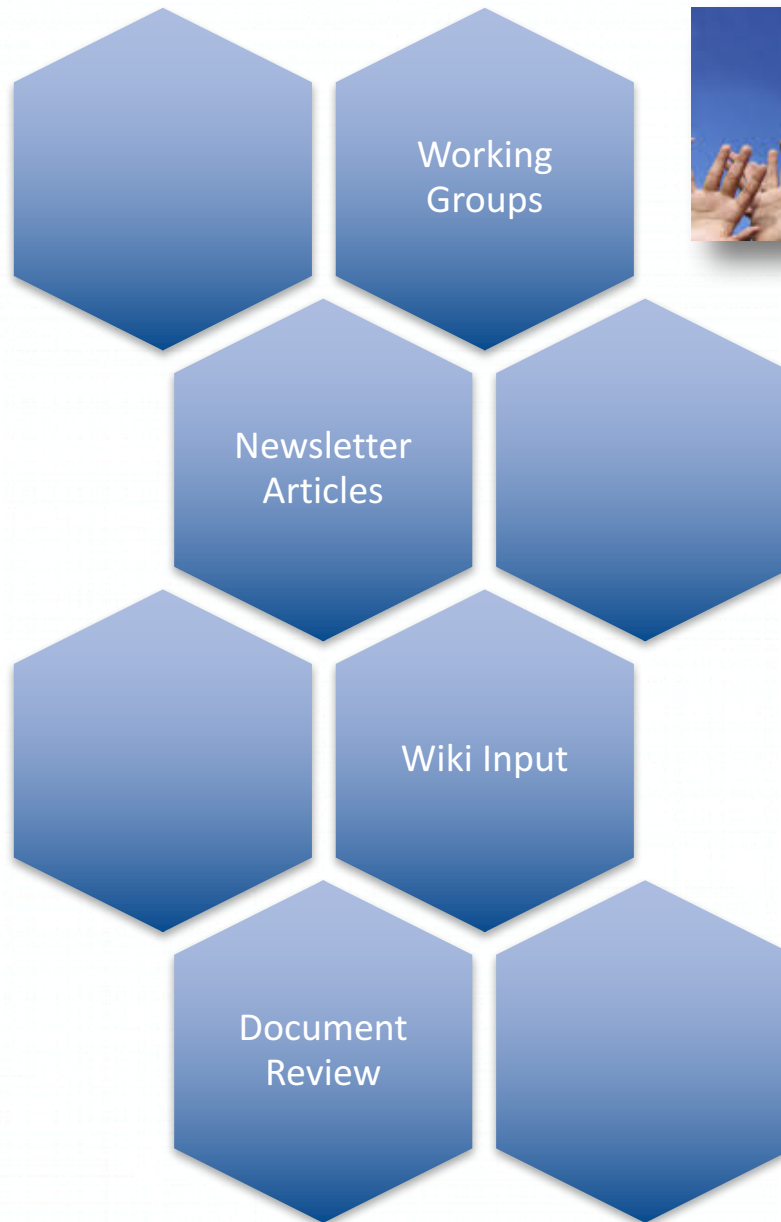
US 2018

The Clinical Data Science Conference

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



phuse.eu



WE NEED YOU !





The premier community for people working in the biometric area



@PhUSETwitta



PhUSE



www.phusewiki.org

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



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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.

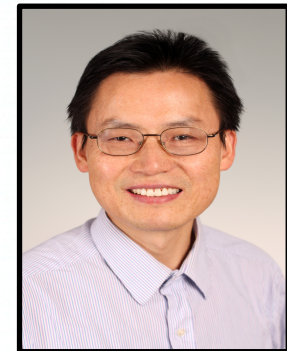
Current Active Projects:

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



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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



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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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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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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:

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Study

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

Working Group Co-Leads:

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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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