

PhUSE Computational Science Working Groups

Solutions Through Collaboration
2017 Computational Science Symposium

PhUSE

Mission:

Provide a platform for creating and sharing ideas, implementing tools and standards around data, and exploring innovative methods and technologies



**Computational Science
Working Groups**



Paradigm Shift



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Computational Science Collaboration

Mission:

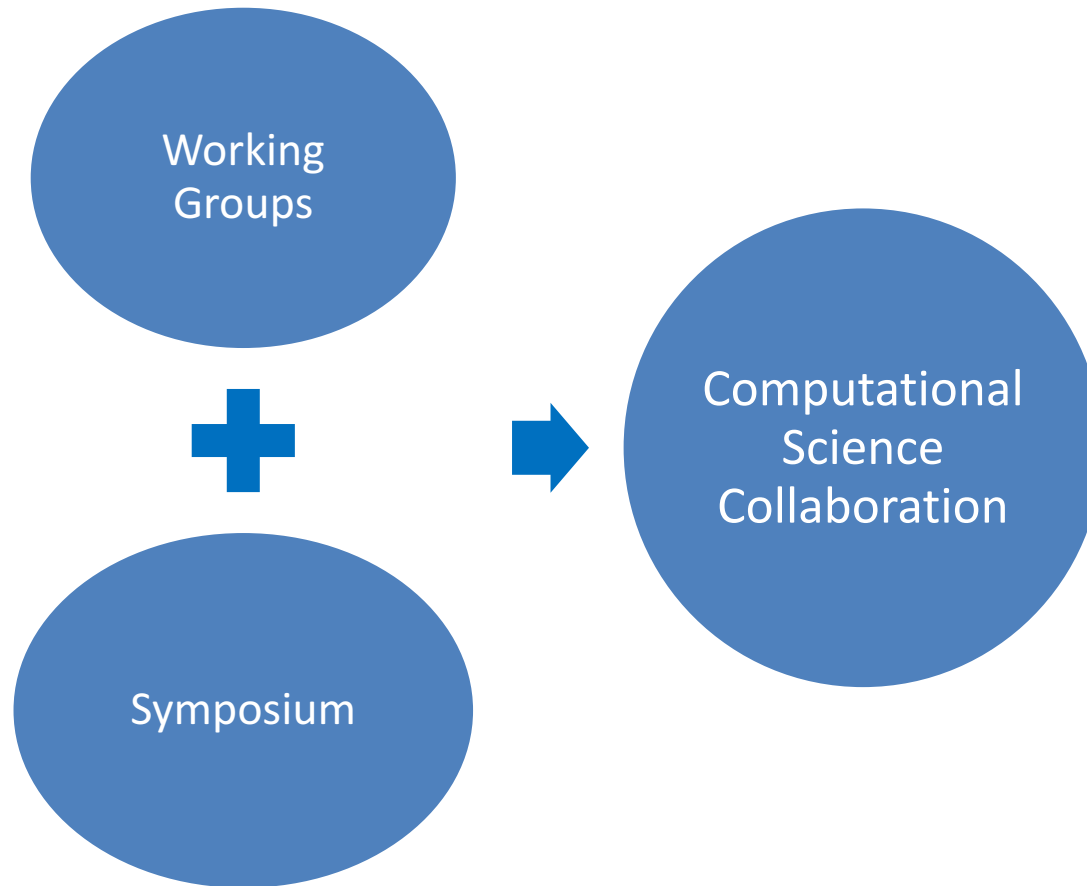
To provide an open, transparent, and collaborative forum in a non-competitive environment in which Academia, Regulators, Industry, and Technology providers can address computational science needs in support of product development and regulatory review, ultimately bringing safe and effective products to those who need them.



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CS Collaboration Framework



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CS Working Groups



Over 30
active
projects



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Working Group Objectives

Nonclinical Topics: Improve nonclinical assessments and regulatory science by identifying key needs and challenges in the field and then establishing an innovative framework for addressing them in a collaborative manner.

Optimizing the Use of Data Standards: Identify specific gaps that prevent FDA and industry from optimizing the use of data standards by collaborating to close these gaps.

Linked Data & Graph Databases: Investigate how formal semantic standards can support the clinical and non-clinical trial data life cycle from protocol to submission.



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Working Group Objectives

Standard Analyses & Code Sharing: Establish a platform for the collaborative development of program code to be used as analytical tools for clinical trial research, reporting, and analysis.

Emerging Trends & Technologies: Provide a form identifying new opportunities for recognizing and leveraging new or emerging technologies and computational tools or under-utilized existing technologies.



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CS Steering Committee

- Ensures Working Groups and projects are aligned with the CS Collaboration Mission
- Supports the planning and execution of the US-CSS and EU-CC
- Approves new projects and Working Group Deliverables
- Collaborates with other organizations (e.g. CDISC, DIA, ASA, etc.)



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New Projects in 2017

- **Evaluating the Use of FHIR in Clinical Studies**
Emerging Trends & Technologies
- **Educating for the Future**
Emerging Trends and Technologies
- **Clinical Development Design Ontology**
Linked Data & Graph Databases
- **Best Practices for Data Collection Instructions**
Optimizing the Use of Data Standards



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2017 CSS Agenda

Sunday	
16:00 - 17:00	On-site registration
17:00 - 19:00	Opening Session: Welcome and Working Group Overview
19:30 - 21:00	Workshop: Introduction to Linked Data & Graph Databases (Arrive AS SOON AS POSSIBLE...19:01 , please!)
Monday	
08:30 – 10:30	<ul style="list-style-type: none">• CDER Reviewers: Insight into Review & Analysis• Introduction: <i>Crystal Allard</i>• Visualization of Nonclinical Standardized Data and the Fit for Use Pilot: <i>Elaine Thompson</i>• How analysis tools are used for the NDA/BLA review: <i>Mary Doi</i>• From CDISC to PhUSE to approval. A statistical reviewers experience and thoughts: <i>Steve Wilson</i>



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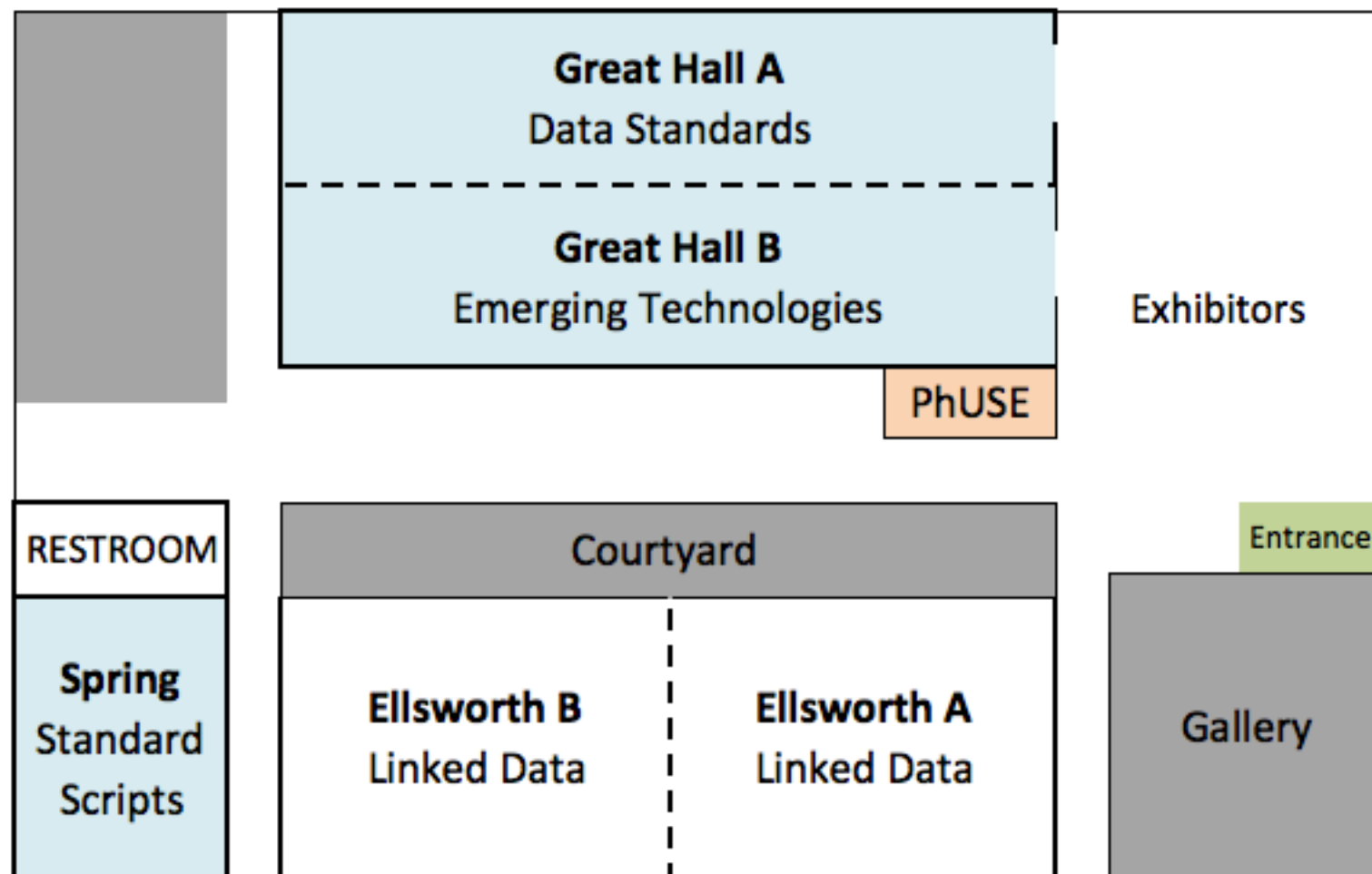


Monday	
10:30 - 11:00	<i>Break & Networking</i>
11:00 - 12:00	Working Group Breakout session
12:00 - 13:00	<i>Lunch & Networking</i>
13:00 - 16:30	Working Group Breakout session
17:00 - 18:30	Poster Session
18:00 - 19:30	Workshop: Code Sharing Utilizing GitHub
Tuesday	
08:30 - 12:00	Working Group Breakouts
12:00 - 13:00	<i>Lunch & Networking</i>
13:00 - 14:00	Working Group Breakout Wrap up session
14:00 - 14:30	<i>Break & Networking</i>
14:30 - 15:30	Industry Panel: Impact of the Guidance on Submissions
15:30 - 16:00	Poster Awards and Closing Remarks

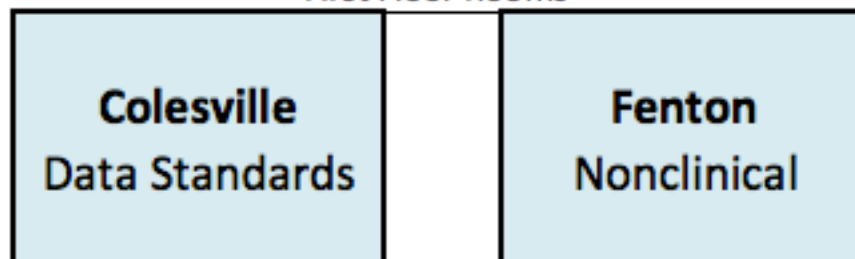


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First Floor Rooms



CS Collaboration Activities

Conferences:

- US-CSS (You're here!)
- EU-CSS, London: 19th – 20th June 2017
- CSS Discussion Club, PhUSE Annual Conference: Edinburgh: 8th – 11th Oct 2017

Resources:

- PhUSE CS Working Groups: [Overview of the groups](#)
- PhUSE Deliverables Under Review: [Draft work packages](#)
- PhUSE CS Deliverables: [Finalized work packages](#)
- PhUSE New Projects: [Call for volunteers & leaders](#)



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Get Involved and Make a Difference

We Want
YOU
To Volunteer!



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Let's Innovate

- *Great leaders are almost always great simplifiers, who can cut through argument, debate and doubt, and offer a solution everybody can understand – Colin Powell*
- *There is no innovation and creativity without failure. Period. – Brene Brown*
- *Real change never occurs from the top on down, [but] always from the bottom up. – Bernie Sanders*



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**The premier community for people
working in the biometric area**



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