

PhUSE Computational Science Working Groups

Solutions Through Collaboration

What is PhUSE?

Pharmaceutical Users Software Exchange

Mission:

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



Paradigm Shift

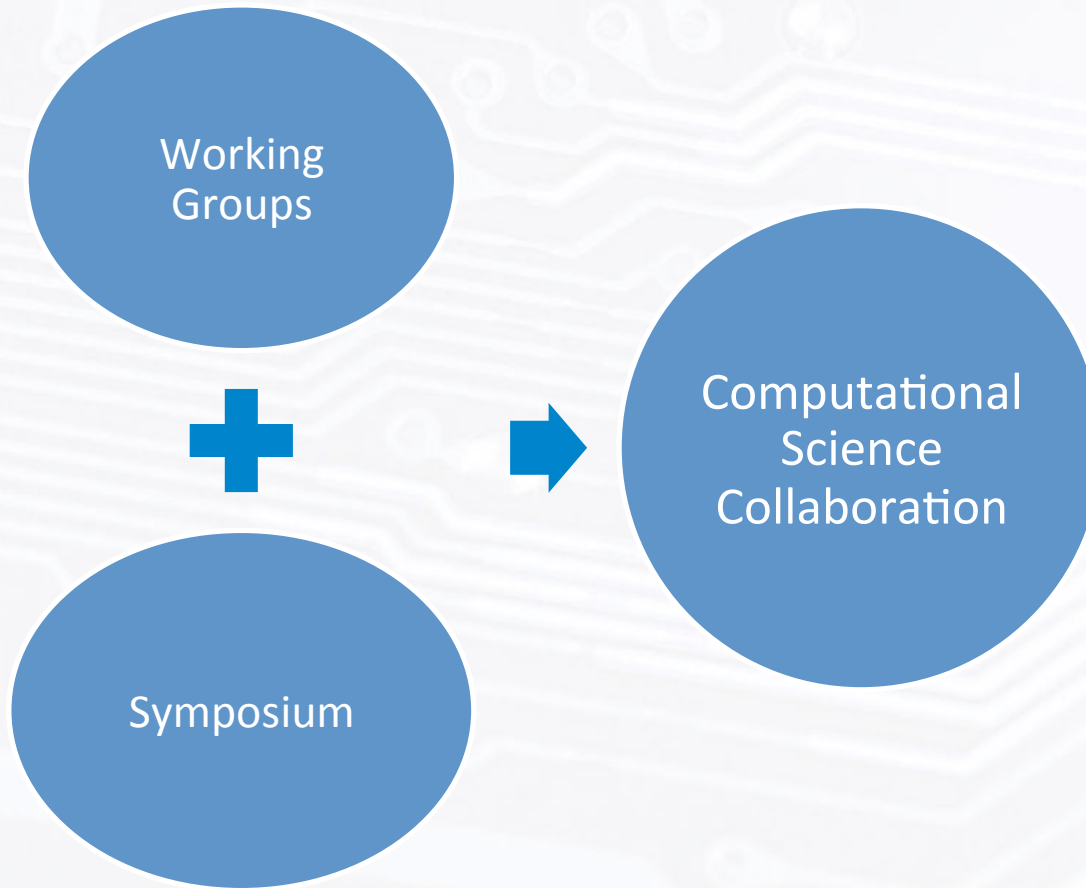


Computational Science Collaboration

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.*

CS Collaboration Framework



Computational Science Symposium

- In 2012, PhUSE and the FDA collaborated to execute a different type of meeting, a “working meeting” to address unmet computational science needs

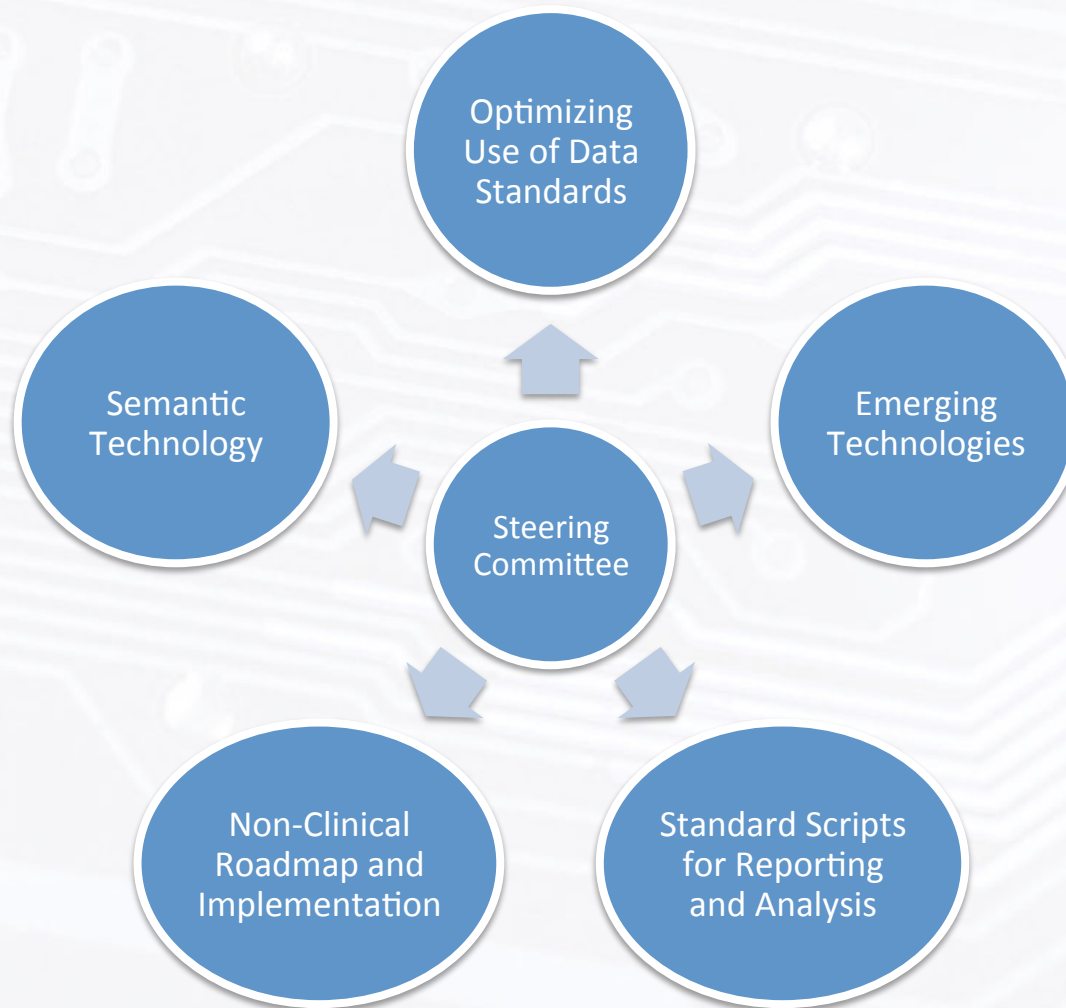
CSS Focus:

- Working Group Projects meet and continue their work from the previous “CSS fiscal year”
- Serves as an incubator for new Working Group projects
- Provides updates to the CS Collaboration community on FDA activities and CS Working Group activities

Quotes from the 2015 CSS

- *“One of the best meetings I've been to - actually informative and productive in the same meeting”*
- *“Having FDA analysts & medical reviewers present their experience was invaluable...”*
- *“This meeting brings decision makers from the FDA, CDISC, and Industry with the goal of creating useful materials for our industry. What more can you ask for?”*

CS Working Groups



CS Working Group Objectives

- **Non-Clinical WG:** 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 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
- **Semantic Technology:** Investigate how formal semantic standards can support the clinical and non-clinical trial data life cycle from protocol to submission

CS Working Group Objectives

- **Standard Scripts WG:** 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 WG:** Provide a forum identifying new opportunities for recognizing and leveraging new or emerging technologies and computational tools or under-utilized existing technologies.

New CS Working Group Projects

Non-Clinical Working Group:

- [Investigating Endpoint Modeling: Biomarkers, ADA data, and Immunophenotyping](#)
- [Visualization of Group Related Differences in Histopathology Data](#)
- [Application of SEND for Analysis](#)

Semantic Technology Working Group:

- [Representing a Clinical Program Design in RDF](#)

Emerging Trends & Technologies WG:

- [Experiences with Statistical Computing Environments](#)
- Data Visualizations

New CS Working Group Projects

Optimizing the Use of Data Standards:

- Test Unit Plan
- Legacy Data Conversion Plan Template
- Integrated Data Reviewer's Guide
- Best Practice for Timing and Implementation of SDTM Trial Design Datasets
- Best Practices for SDTM define.xml vs. SDRG
- Identification of Discrepancies between the FDA Guidance and Standards/Industry Practices
- Guidance Readiness Checklist
- Template for Communications with the FDA

CS Collaboration Activities

- **Computational Science Symposium:** Annual working meeting
 - March 2016 in Silver Spring, MD: <http://www.phuse.eu/css.aspx>
 - European CSS...coming in 2016!
- **PhUSE CS Dashboard:** Overview of active projects
 - <http://www.phuse.eu/CSS-dashboard.aspx>
- **PhUSE Catalog of WG Deliverables:** Finalized work packages
 - <http://www.phuse.eu/CSS-deliverables.aspx>
- **PhUSE WG Deliverables Under Review:** Draft work packages available for public review
 - <http://www.phuse.eu/cs-deliverables-under-review.aspx>

Get Involved and Join the Collaboration

- **Need more information?** Visit the PhUSE Wiki more detailed working group and project information
 - http://www.phusewiki.org/wiki/index.php?title=CSS_Working_Groups
- **Ready to join?** Email Working Group Leads or join a Working Group Mailing List
 - http://www.phusewiki.org/wiki/index.php?title=Listbox_Instructions
- **Have an idea?** Submit a new project request today!
 - http://www.phuse.eu/Call_for_NewProjectsCSS.aspx
- **Join our Technical Team**
 - Wiki support
 - Collaboration tool support
 - Distribution list/emails
 - Contact css@phuse.eu to help