

# PhUSE US Connect 2018

Paper PP01

## PhUSE Working Groups - Now & Next

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### ABSTRACT

Since PhUSE working groups started with the FDA and PhUSE Computational Science Symposium (CSS) in 2012 the number of working groups and project has grown rapidly, incorporating diverse areas such as the Future Forum and KPIs. To support this growth two Working Groups Directors were appointed to the PhUSE Board to ensure that the working groups continue in their mission to provide an open and transparent collaborative framework in a non-competitive environment to share and discuss topics relating to clinical data science. A new structure for PhUSE working groups was announced at the CSS in March to help drive the strategy and coordination. This will ensure that the PhUSE working groups will continue to make important contributions in the coming years.

### INTRODUCTION

Since the first Computation Science Symposium (CSS) in 2012, PhUSE Working Groups have expanded to cover 4 different frameworks, has run over 75 projects, and produced over 35 deliverables. The PhUSE Working Groups have definitely been a success but to continue operating efficiently the PhUSE Board of Directors recognized in 2017 that this was an area that would benefit from dedicated support. In January 2018, Chris Price and Scott Bahlavooni joined the PhUSE Board of Directors as PhUSE Working Group Directors with the remit is to ensure Working Group activities:

- Reflect the PhUSE mission and align with industry and regulatory objectives.
- Operate efficiently, transparently, and effectively
- Maintain appropriate visibility across industry, regulators, and other strategic partners

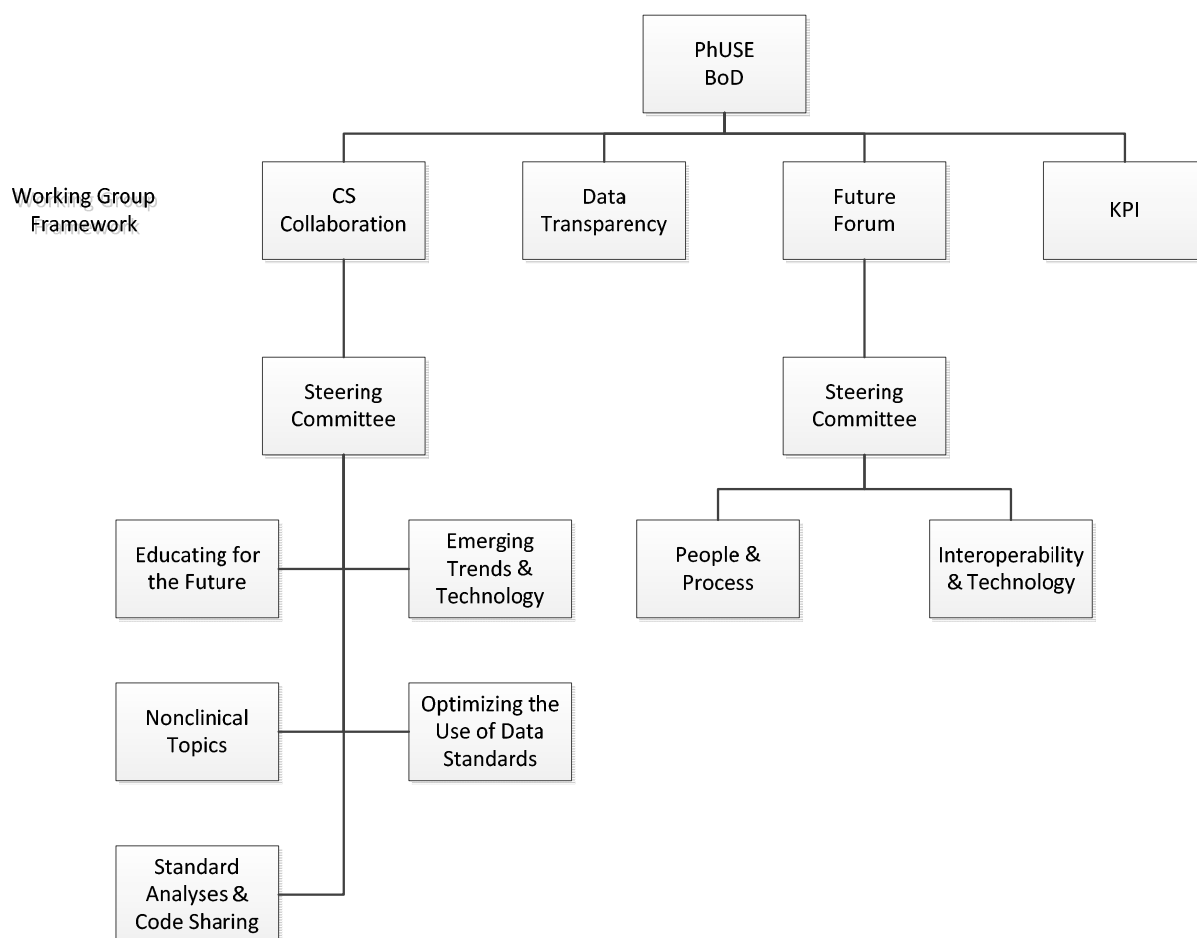
Additionally, we will build upon the amazing previous efforts and continue to foster and cultivate partnerships with key industry and regulatory entities like FDA, PMDA, EMA, CDISC, and HL-7. Finally, we liaise with the PhUSE Board of Directors to ensure alignment between the PhUSE Working Groups and other PhUSE activities.

After examining the current state of the Working Groups, we noted synergies and similarities existed across the four Working Group frameworks. We identified opportunities to maximize the efforts of our volunteers as well as improve transparency and collaboration. Moving forward you will find all of the PhUSE Working Groups under one framework. This will allow the Working Groups to maximize the efforts of our volunteers without compromising the culture and collaboration that has made the PhUSE Working Groups a success.

### CURRENT STATE

The current structure of PhUSE working groups consists of the Computational Science (CS) Collaboration, the Data Transparency Working Group, the Future Forum and KPI Working Group each with each responsible for a combination of working groups and projects. Both the CS Collaboration and Future Forum are supported by their own independent steering committees.

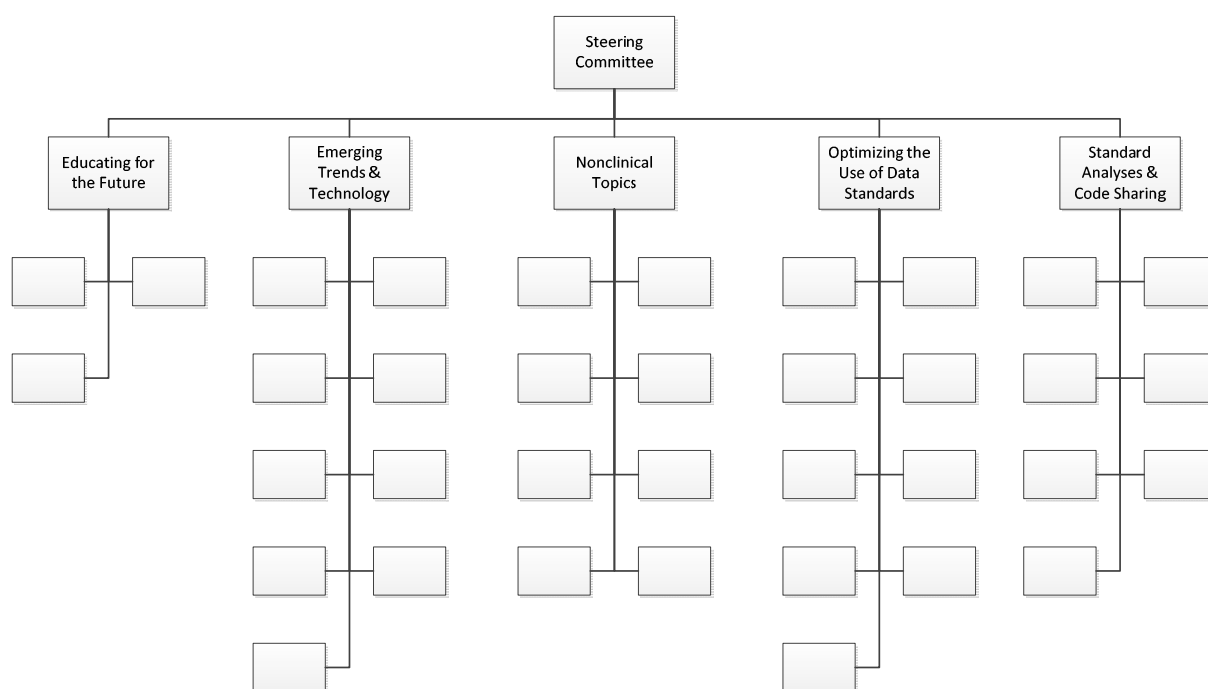
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The CS collaboration is responsible for the majority of ongoing PhUSE Working Group activities with 5 different working groups and (at the time of writing) 36 ongoing projects. The working groups in the CS Collaboration cover a wide ranging set of topics:

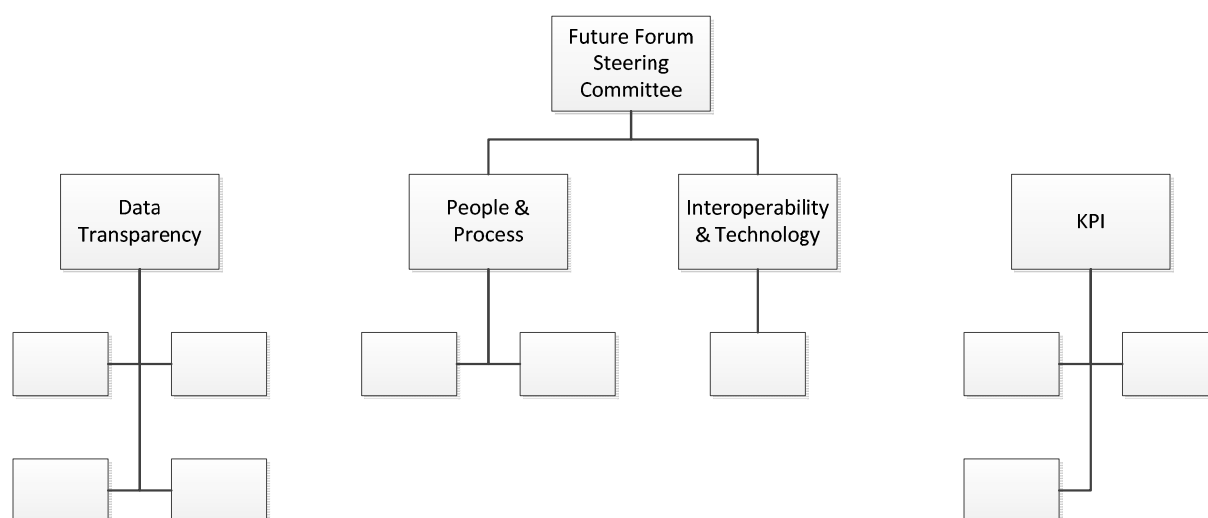
- **Optimizing the Use of Data Standards** - The mission of the Optimizing the Use of Data Standards Working Group is to identify specific gaps that prevent the FDA and industry from optimizing the use of data standards, and collaborate to close these gaps.
- **Nonclinical Topics** - The mission of the Nonclinical Topics Working Group is to 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.
- **Standard Analyses & Code Sharing** - The mission of the Standard Analyses & Code Sharing Working Group is to establish a platform for the collaborative development of white papers and program code to be used as analytical tools for clinical trial research, reporting and analysis.
- **Emerging Trends & Technologies** - The mission of the Emerging Trends & Technologies Working Group is to provide a forum for identifying new opportunities for recognizing and leveraging new or emerging technologies and computational tools or under-utilized existing technologies.
- **Educating for the Future** - The mission of the Educating for the Future Working Group is to develop frameworks by which to educate the PhUSE community at large. The frameworks will be designed to educate the community on the importance of topics where we feel we have gaps, the details of the topics themselves, and how they can be used to drive innovation in the industry.

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The Data Transparency Working Group was initially address the challenge of how to effectively respond to researchers requesting access to data across sponsors. A combination of the difference of company's data models and de-identification techniques may make the analyses cumbersome and error-prone. The working group has collaborated to define a set of rules built around the CDISC SDTM standards to provide the industry with a consistent approach to data de-identification and increase consistency across anonymized datasets. Subsequently this working group has grown to support a wider body of work as the topic has grown in importance for both regulators and industry.

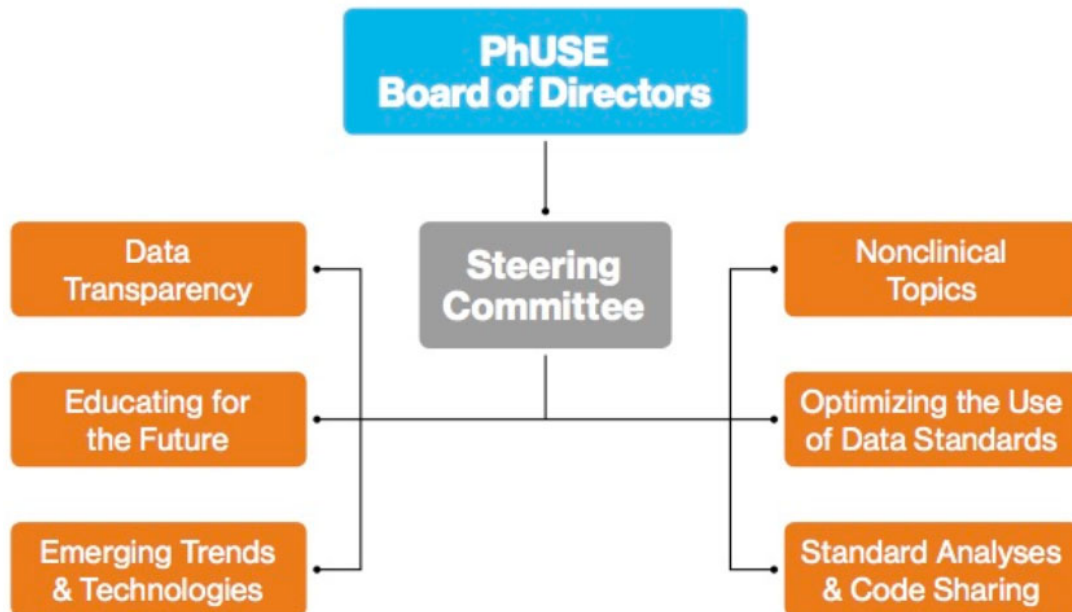
The Future Forum was created to explore the vision and, in turn, develop the key themes for the future of clinical development and data science. It is a key initiative to share – contribute and advance towards the future together. It is framework of key topics that are defining the future of clinical development and data science, in the next 10 years to come. These working groups have focused so far on areas relating to people and process and interoperability and technology. Lastly the KPI working group has been working to establish a set of common Data Reporting Metrics which are more detailed than industry wide metrics, therefore, allowing a greater level of granularity in our project reporting, and business process management.



## FUTURE STATE

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As we addressed the goal to maximize the efforts of our volunteers as well as improve transparency and collaboration we noted synergies and similarities existed across the four Working Group frameworks. By bringing all working groups together under a single framework we hope to help support the working groups in operating efficiently, transparently, and effectively. The Working Group Directors provide a direct link for the Working Group Steering Committee to the PhUSE Board. The Steering Committee includes all working group leads, representatives from our key regulatory and industry partners, and a small number of industry representatives.

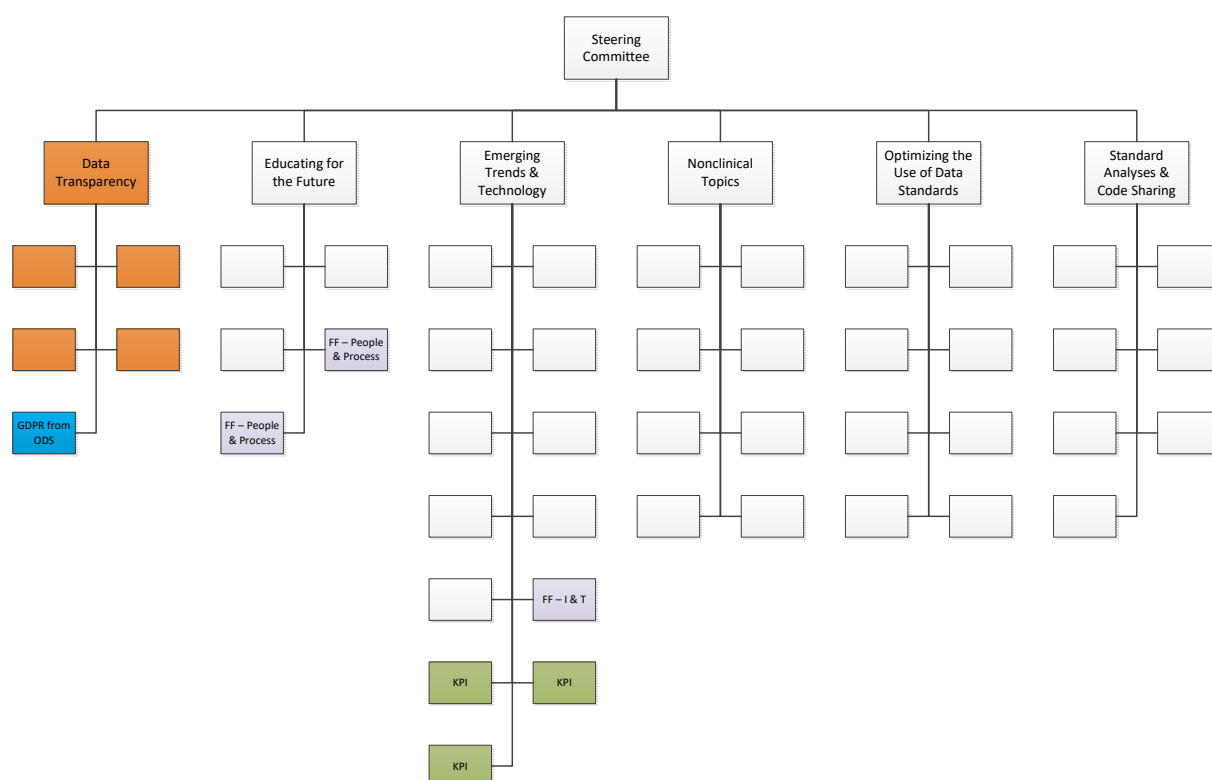


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Moving forward there will be six PhUSE Working Groups representing the current key computational science topics. All are responsible for driving forward projects that seek to resolve current challenges as well as those taking a more strategic view of the future meeting the goals of both the previous CS Collaboration and Future Forum working group structures. As part of this new structure a number of projects have a new home.

- Future Forum - Interoperability and Technology will be part of the Emerging Trends & Technology Working Group
- GDPR will be part of the Data Transparency Working Group
- Future Forum - People and Process projects will be part of the Educating for the Future Working Group
- The KPI projects will be part of the Emerging trends & Technology Working Group

While we envisage this structure will support our current needs we will work with the steering committee to continue to adapt this structure as new projects are proposed as well as to react to new opportunities in computational science.



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### ROLES AND RESPONSIBILITIES

The Working Group Directors responsibilities include:

- Coordinating the Working Group activities of PhUSE and ensuring that deliverables progress the industry knowledge base.
- Forming and maintaining strategic and technical relationships with similar organisations (e.g. CDISC, HL7) so that deliverables are fully aligned across initiatives.
- Forming and maintaining relationships with regulatory agencies (e.g. FDA, EMA and PMDA).
- Work closely with the PhUSE Office and other relevant parties to ensure effective organisation of the communication around the deliverables from all PhUSE Working Groups.
- Enable cross-sharing of ideas, resources and methods across all Working Groups.
- Establish infrastructure and operational processes which involves collaboration from all contributors in the decision-making and project development processes
- Work with the Communications Director, Steering Committee, Working Groups and Project Teams to provide outward bound information about the Working Group

The Working Group Steering Committee responsibilities are:

- Support ongoing collaborative working groups and project teams throughout the year
- Check with Working Group leads on a regular basis to ensure projects are aligned, moving forward, and have resources
- Encourage and facilitate cross working group collaboration
- Make the determination as to the appropriate Working Group for proposed projects
- Ensure working groups have tools/processes to effectively communicate
- Provide a framework for handoffs between project and appropriate organizations (e.g. FDA, SDOs) if applicable
- Communicate information to the working group and project leads on a regular basis which could include processes, information about other projects, or upcoming activities
- Accept and facilitate review of all project deliverables and new project requests

Working Group Leads responsibilities are:

- Responsible for all projects within their Working Group, working to ensure the success of each Project.
- Provide a single point of contact for Project Teams, and manage communications to and from the Steering Committee.
- Propose new projects to the steering committee
- Assure a well-defined, manageable project scope, capable of being accomplished within a predetermined time frame
- Provide an avenue of communication between the Steering Committee and the Project Leads to allow all Project teams to be informed of Project related information in a timely and appropriate manner
- Work with Project Leads to understand any project issues that may affect the success of the project and raise those issues to the Steering Committee for further discussion if needed.
- Work with PhUSE office (and steering committee) to seek volunteers for projects

Project Team responsibilities include:

- Responsible for the overall success of the project and for delivering project results within a timely manner.
- Manage all Project Team activities
- Organize and manage meetings
- Set expectations for the team
- Manage project tasks
- Provide adequate communication
- Ensure Project Team deliverables are provided in a timely manner
- Create well reviewed and vetted deliverables
- Ensure cross-functional input and subject matter expertise

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### CONCLUSION

Building on the current success of the working groups we feel the new structure that will continue to support the working group mission to provide an open, transparent, and collaborative forum in a non-competitive environment in which Regulators, Life Science Companies, Technology Providers, SDOs, and Academia can address unmet computational science needs impacting product development and regulatory review as to improve human health. The working groups are not a rigid structure and we will continue working with the steering committee to take an agile approach so that we can continue to address new business challenges.

The success of the Working Groups is driven by the volunteers who commit their time and energy to making this a reality. We encourage all PhUSE members to get involved in working groups as project members or project leads to continue the excellent work of the working group. If you would like to join an existing project or have an idea for a new project, then please get in touch.

### CONTACT INFORMATION

Your comments and questions are valued and encouraged. Contact the authors at:

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