PhUSE Working Groups Charter

Purpose

The purpose of this document is to define the operating guidelines for the Pharmaceutical Users Software Exchange (PhUSE) Working Groups. These include all existing Working Groups and any other Working Groups established at the discretion of the Working Groups Director(s).

Mission

The mission of the PhUSE Working Groups is to provide an open and transparent collaborative framework in a non-competitive environment allowing (but not limited to) industry, researchers, standards organizations, and regulatory agencies to share and discuss topics and solutions relating to the advancement of computational science in medical research, ultimately bringing safe and effective medical products to those who need them.

Goals

1. To facilitate discussions among regulatory agencies, industry, and other stakeholders that inform and improve computational science to support product development and review.
2. To bring together experts in specific areas to collaborate on computational science, describe best practices in challenging areas, and propose methods for addressing knowledge gaps.
3. To support ongoing collaborative Working and Project Groups throughout the year by aligning Working Group objectives, reviewing Project requests and deliverables, and providing direction for Project issues and gaps.
4. To support open and transparent participation in all activities of the PhUSE Working Groups.
5. To support an annual public conference where collaborators and interested individuals come together to summarize and share work accomplished to date, and plan for future efforts.
6. To establish an infrastructure and operational processes with the following components:

a. Transparent processes that promote exchange of ideas
b. Help gather input from all primary stakeholders, e.g. regulatory agencies, industry, academics, standard development organizations (SDOs)
c. Create an open and efficient method for submitting potential projects and providing an objective evaluation and approval process for proposed projects
d. Provide a framework for handoff of deliverables between Project Teams and appropriate organizations, using formal processes as defined by the receiving organizations.

Working Groups and Project Teams

Structure

- PhUSE collaborations are organized into a number of Working Groups, with each Working Group having a broad topic area. PhUSE may initiate collaborations that fall outside of the Working Groups. These will be supervised by a PhUSE Director.
- A PhUSE Director will represent the Working Groups on the PhUSE Board of Directors and will be responsible for chairing the Working Groups Steering Committee.
- The Working Groups Steering Committee oversees the entirety of the PhUSE Working Groups at a strategic and tactical level.
- Each Working Group will have specific projects designed to achieve a set of specific objectives.
- Working Groups include volunteers from major stakeholders including, but not limited to, academia, the pharmaceutical industry, biologics industry, device industry, contract research organizations, core laboratory organizations, technology vendors, SDOs, other industry bodies, and interested regulatory agencies.
- All Working Group members are encouraged to join PhUSE, but participation is open to all who want to contribute.
- Each Working Group is led by a team designed to provide oversight for all Projects within that Working Group, ensuring that Projects are aligned with the overall goals of PhUSE, that objectives are being met in a timely manner, and that support is provided for Project Leads.
- Each Project has one or more Leads responsible for leading the project, scheduling meetings, working with the Project Team to meet objectives, and providing updates to the Working Group Leads and Steering Committee.

PhUSE Computational Science Symposiums (CSSes)

Computational Science Symposiums bring together academia, regulators, industry and technology providers to address computational science needs in support of regulatory review, and ultimately bring safe and effective products to those who need them. The focus of a Computational Science Symposium is to continue the work initiated at the previous meetings, by bringing together contributors to explore emerging technologies, and establish collaborative Working Groups to address current challenges related to the access and review of data, to support product development

Organizational Guidelines

- The Working Groups Steering Committee will consist of:
    - PhUSE Working Groups Director(s) – Chair
    - Two industry representatives (the Leads or designates) from each Working Group
    - Four industry at-large members appointed by the Steering Committee
        - To be elected by the Steering Committee by a simple majority for a term of two years
        - Two industry at-large members will be elected each year, with a term commencing in January
        - Nominations will be sought from the PhUSE membership
        - There is no limit to the number of terms an industry at-large member can serve
    - 3-5 non-voting FDA Advisors to the Steering Committee, including at least one from each of CDER, CBER, and CDER OCS FDA.
- Facilitated by the PhUSE Office.
- Meetings will be held monthly, with additional meetings scheduled as required.
- Guests may be invited to facilitate discussions as required.
- Decision-making will be on a consensus basis. In the event of conflicting opinions, the PhUSE Working Groups Director(s) will be accountable for the final decision.

Guiding Principles

The PhUSE Working Groups intend to follow a set of guiding principles in the work of Working Groups and Project Teams which will include the following:
- Minimize bureaucracy: "Use as little governance as possible but no less"
- Minimize intervention: Push decisions down to the lowest responsible levels
- Leverage existing work where possible, and clearly define boundaries and links to other existing standards; develop only when needed
- Define a manageable scope to fit a predetermined time frame
- Meeting materials and agendas to be provided in advance of meetings
- Strive to adjust scope and ensure sufficient resources before extending the time schedule for each Project
- Ensure that Project and Working Group objectives are relevant to all participating parties
- Consistently define all concepts. Reuse, don't recreate
- Ensure that all Projects are defined to deliver value to all participating collaborators
- All Projects should be aligned with the PhUSE and Working Groups mission, and provide sufficient value to ensure this is the best use of volunteers' time
- Ensure all Projects define a deliverable(s)
- Projects will not provide a deliverable that will involve regulatory agency policy or give the perception of impacting regulatory policy
- Project deliverable reviews are focused on ensuring that the content is aligned with the PhUSE Working Groups mission, and do not seek to represent the views of other organizations or regulatory agencies unless these are publically available
- Each Project will have at least two Co-Leads and sufficient participating members to ensure success

- Outputs from the Working Groups can be used by all. Users are encouraged to feedback any comments or enhancements to the Working Group Leads to benefit the wider community.

Representation from the FDA

FDA centers follow individual, similar processes for engaging with external collaborators. The participation of the CDER/FDA will be guided by "Manual of Policies and Procedures (MAPP) 4100.2, entitled "CDER Staff Participation in Public Private Partnerships and Consortia". MAPP 4100.2 establishes a process for CDER staff to obtain clearance for participation in these activities, and to obtain appropriate assurances regarding CDER's terms and conditions for engagement from external organizations with which they engage. The MAPP also defines responsibilities for CDER PPP Liaisons who are engaged with a PPP or consortium convened by an external organization to support scientific projects.

Participation of CBER/FDA staff will be guided by its standard operating policies and procedures (SOPP #8125) entitled "CBER Employee Participation in Public-Private Partnerships and Consortia". The SOPP establishes a process for CBER employees to obtain clearance for participation in PPPs, and for CBER to obtain appropriate assurances from the external conveners or coordinators regarding CBER's terms and conditions for engagement in PPPs. The SOPP defines the roles and responsibilities of the PPP Liaison, as well as reporting of PPP activities.

The FDA will appoint liaisons to the Steering Committee and, as needed, to the other Working Groups and Projects within those groups. Such liaisons will not have any fiduciary roles in the collaboration and will be non-voting.

Representation from Vendors

The official participation by vendors (as opposed to individuals) in Working Group Projects can be supported. Working Group Projects must ensure that no inference can be made indicating PhUSE's support of a particular vendor or product. Where official vendor participation occurs, this project may additionally be supported by a PhUSE Working Groups Director.

Representation from Other Organizations

Participants in PhUSE Working Groups are expected to act in the interest of PhUSE. Where individuals are representing their own organization, then their participation will be governed by a Memorandum of Understanding between PhUSE and the organization. A Memorandum of Understanding will be signed by the PhUSE Working Groups Director(s) on behalf of the PhUSE Board of Directors.

Roles and Responsibilities

Working Groups Director(s)

- Coordinate the Working Group activities of PhUSE, and ensure deliverables progress the industry knowledge base.
- Form and maintain strategic and technical relationships with similar organizations (e.g. CDISC, HL7) so that deliverables are fully aligned across initiatives.
- Form and maintain relationships with regulatory agencies (e.g. the FDA, EMA and PMDA).
- Work closely with the PhUSE Office and other relevant parties, to ensure effective organization 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 activities.
- Appoint the Working Group Leads on the identification of a vacancy. For existing Working Groups, this should be following an open and transparent application process.
- Act as final decision-maker for any issues relating to the Working Groups Steering Committee.

Working Groups Steering Committee

- 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.
- Escalation path for any issues with Working Group or Project activities.
- Ensure Working Groups have the tools/processes to effectively communicate.
- Provide a framework for handoffs between Project and appropriate organizations (e.g. the FDA, SDOs) if applicable.
- Provide recommendations and approve the introduction of new Working Groups.
- Communicate information to the Working Group and Project Leads on a regular basis which could include processes, information about other projects, or upcoming activities.
- Facilitate the review and approve all Project deliverables and New Project Requests.

Industry At-large Steering Committee Member(s)

- Support and identify opportunities for cross-Working Group collaboration.
- Support and facilitate the review and approval of all Project deliverables and New Project Requests.
- Propose new Projects to the Steering Committee.
- Support the socialization of all Working Group deliverables.

Working Group Lead(s)

- 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 timeframe.
- Assure the goals of the Project are attainable through a partnership within the context of the Working Groups.
- Assure the Project has leadership and sufficient participating members to ensure success.
- 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 and the PhUSE Office to understand any Project issues that may affect the success of the Project by committing to attend regular Working Group meetings of the Working Group Leads and Project Leads.
- Proactively decline PhUSE meetings when conflicts occur.
- Raise any issues to the Steering Committee for further discussion if needed.
- Review and bring all Project deliverables to the attention of the Steering Committee for approval prior to deliverables being published in the public domain.
- Work with the PhUSE Office (and Steering Committee) to seek volunteers for Projects.
- Support the socialization of all Working Group deliverables.

Project Team Lead(s)

- Responsible for the overall success of the Project and for delivering Project results within a timely manner.
- Commit to attend regular Working Group meetings of the Working Group Leads and Project Leads.
- Proactively decline PhUSE meetings when conflicts occur.

- Work with the PhUSE Office to manage all Project Team activities:
    - Manage meetings
    - Set expectations for the team
    - Manage and track Project tasks
    - Provide adequate communications.
- Ensure Project Team deliverables are provided in a timely manner:
    - Create well-reviewed and vetted deliverables
    - Ensure cross-functional input and subject matter expertise
    - Provide strategy for overcoming obstacles.
- Support the socialization of project deliverables.