



PHUSE Working Groups

Charter

Purpose

The purpose of this document is to define the operating guidelines for the 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 for industry, researchers, standards organisations 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 healthcare data science to support product development and review.
2. To bring together experts in specific areas to collaborate on healthcare data science, describe best practices in challenging areas and propose methods for addressing knowledge gaps.
3. To align Working Groups objectives, review New Project Requests and deliverables, and provide direction for Project issues and gaps.
4. To support open and transparent participation in all PHUSE Working Groups activities.
5. To establish an infrastructure and operational processes with the following components:
 - a. Transparent processes that promote exchange of ideas.
 - b. Gather input from all primary stakeholders, e.g. regulatory agencies, industry, academics, standard development organisations (SDOs).
 - c. Manage an open and efficient method for submitting potential Projects and provide an objective evaluation and approval process for proposed Projects.
 - d. Provide a framework for handoff of deliverables between Project teams and appropriate organisations, using formal processes as defined by the receiving organisations.

Working Groups and Project Teams

Structure

- PHUSE Projects are organised into Working Groups, with each Working Group having a broad topic area. PHUSE may initiate Projects that fall outside of the Working Groups. These will be supervised by a PHUSE Director.
- The PHUSE Working Groups Director will represent the Working Groups on the PHUSE Board of Directors. They will be responsible for chairing both the Working Groups Leadership Committee and the Working Groups Operations Committee.
- The Working Groups Leadership Committee oversees the entirety of the PHUSE Working Groups at a strategic level.
- The Working Groups Operations Committee oversees the entirety of the PHUSE Working Groups at an implementation and delivery level.
- Each Working Group has specific Projects designed to achieve a set of specific objectives.
- Working Groups include volunteers from major stakeholders such as academia, the pharmaceutical industry, the biologics industry, the device industry, contract research organisations, core laboratory organisations, technology vendors, SDOs, other industry bodies, and interested regulatory agencies.
- Participation is open to all, in accordance with the [PHUSE Code of Conduct](#).
- Each Working Group is led by a team who provide oversight for all Projects within that Working Group, ensuring 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 a team of Leads responsible for scheduling meetings, working with the Project team to meet objectives, and providing updates to the Working Groups Leads.

Organisational Guidelines

- Working Groups Leadership Committee
 - Membership will consist of:
 - PHUSE Working Groups Director – Chair
 - New Project Proposals Review and Development Lead
 - Ongoing & Final Deliverables Lead
 - Working Groups Events Lead
 - Members are requested to commit to the role for at least 24 months
 - Nominations will be sought from the PHUSE Community (priority will be given to those nominated by PHUSE Supporters)
 - There is no limit to how long a member of the committee can serve
 - The committee is facilitated by the PHUSE Office
 - Meetings are held bi-monthly, with additional meetings scheduled as required
 - Guests (including Working Groups Leads) may be invited to facilitate discussions
 - Decision-making will be on a consensus basis. In the event of conflicting opinions, the PHUSE Working Groups Director will be accountable for the final decision
- Working Groups Operations Committee
 - Membership will consist of:
 - PHUSE Working Groups Director – Chair
 - All Working Groups Leads
 - All members of the Working Groups Leadership Committee
 - 3–5 non-voting FDA advisors to the Working Groups Leadership Operations Committee, including at least one representative from CDER, CBER and CDER OCS FDA
 - Industry members are requested to commit to the role for at least 24 months
 - The committee is facilitated by the PHUSE Office
 - Meetings are held monthly, with additional meetings scheduled as required
 - Guests may be invited to facilitate discussions.
 - Decision-making will be on a consensus basis. In the event of conflicting opinions, the PHUSE Working Groups Director will be accountable for the final decision.

Working Groups and Project Teams

Guiding Principles

The PHUSE Working Groups and Project Teams follow a set of guiding principles:

- Minimise bureaucracy: “Use as little governance as possible but no less.”
- Minimise intervention: Push decisions down to the lowest responsible levels.
- Leverage work where possible and clearly define boundaries and links to other standards; develop only when needed.
- Define a manageable scope to fit a predetermined time frame.
- Provide meeting materials and agendas in advance of meetings.
- Strive to adjust the scope and ensure sufficient resources before extending the schedule for each Project.
- Ensure Project and Working Groups objectives are relevant to all participating parties.
- Consistently define all concepts. Reuse – don’t recreate.
- Ensure all Projects are defined to deliver value to 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). For some Projects, this may be facilitating discussion forums.
- Projects will not develop a deliverable that gives the perception of either speaking on behalf of or having influence on regulatory agencies.
- Project deliverable reviews are focused on ensuring the content and quality are aligned with the PHUSE Working Groups mission and do not seek to represent the views of other organisations or regulatory agencies. (Note that referencing publicly available material is supported.)
- Each Project will have at least two Co-Leads and sufficient participating active members.
- Project status will be monitored monthly by the Working Groups Leads and quarterly by the Working Groups Leadership Committee.
- Outputs from the Working Groups can be used by all. Users are encouraged to feed back any comments or enhancements to the Working Groups Leads to benefit the wider community.
- Recognise (with their permission) those who make meaningful contributions to the PHUSE deliverables.
- Active contribution from all involved: Memberships lists will be managed in consultation with the Project Leads and the Project members to ensure only those taking an active role (e.g. discussing, writing, reviewing) are included.

Working Groups and Project Teams

Representation from the FDA

FDA centres follow individual, similar processes for engaging with external collaborators. CDER/FDA participation will be guided by the [Manual of Policies and Procedures \(MAPP\) 4100.2, titled '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 appropriate assurances regarding CDER's terms and conditions for engagement from external organisations. It also defines responsibilities for CDER PPP Liaisons, who are engaged with a PPP or consortium convened by an external organisation to support scientific projects.

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

The FDA will appoint liaisons as needed to the Working Groups and the Projects. The liaisons will not have any fiduciary roles in the collaboration and will be non-voting.

Representation from Vendors

The Working Groups Projects support official vendor participation (as opposed to individuals who happen to work for vendors). Working Groups Projects must ensure there are no inferences of PHUSE supporting a particular vendor or product. Projects with official vendor participation may be supported by a PHUSE Director.

Representation from other organisations

PHUSE Working Groups are expected to act in the interest of the PHUSE Community, with the goal of reaching a consensus deliverable. Where individuals are formally representing an organisation (e.g. a standards development organisation, another professional society), then their participation will be governed by a memorandum of understanding between PHUSE and the organisation. The memorandum of understanding will be co-authored with the partner organisation and signed by the PHUSE Operations Director on behalf of the PHUSE Board of Directors.

Working Groups and Project Teams

Working Groups Leadership Committee

- Provide strategic guidance to the Working Groups and Project Teams.
- Encourage and facilitate cross-Working Group collaboration.
- Act as an escalation path for any issues with Working Groups or Project activities.
- Ensure Working Groups have the tools/processes to communicate.
- Provide recommendations and approve new Working Groups.
- Facilitate the review of and approve all Project deliverables and New Project Requests.
- Support the socialisation of all Working Groups deliverables.
- Provide a framework for handoffs between Projects and appropriate organisations (e.g. the FDA, SDOs) if applicable.

Working Groups Operations Committee

- Support the Working Groups and Project Teams.
- Act as a forum for individual Working Groups to share current highlights, challenges and opportunities with the leadership community to encourage and facilitate cross-Working Group collaboration.
- Act as a forum for discussing processes, information about other Projects, or upcoming activities which can be shared with the Project Leads and the wider Working Group community
- Act as a forum for planning Working Groups participation in PHUSE events.
- Support the socialisation of all Working Groups deliverables.