

PHUSE TERMS OF REFERENCE

WORKING GROUPS DIRECTOR

1. POSITION DESCRIPTION

To be the link between all PHUSE Working Groups and the PHUSE Board of Directors to ensure that all Working Groups are working in the most efficient manner and that the PHUSE community is fully aware of all the activities from across all Working Groups.

2. OVERALL APPROACH

- 2.1 The PHUSE Working Groups Director will be the primary contact for PHUSE Working Group activities. Support will be provided by a Leadership Team and Leads appointed for each of the PHUSE Working Groups. The PHUSE Office will also assist the Working Groups Director.
- 2.2 The Working Groups Director will be responsible for approving new project and deliverables and for determining and tracking the status of each of the Working Groups projects. In this capacity, the Working Groups Director will chair a Working Group Operations Committee consisting of the Working Group Leads, other industry representatives and liaisons appointed by Regulatory Authorities.

3. SCOPE

- 3.1 Coordinate the Working Groups activities of PHUSE and ensure deliverables progress the industry knowledge base.
- 3.2 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.
- 3.3 Form and maintain strategic and technical relationships with similar organisations (e.g. CDISC, HL7) and Regulatory Agencies (e.g. FDA, EMA and PMDA).
- 3.4 Work closely with PHUSE collaborative partners to ensure that they are appraised of Working Groups activities and can support and influence these where applicable as well as drive new collaboration opportunities.
- 3.5 Work closely with PHUSE Community Director to ensure that PHUSE Supporters are appraised of Working Groups activities and can support and influence these where applicable as well as to identify to new opportunities.
- 3.6 Enable cross-sharing of ideas, resources and methods across all Working Groups.
- 3.7 Chair the PHUSE Working Groups Leadership and Operations Committees.
- 3.8 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.
- 3.9 Identify key contacts within the industry who can help to catalyse and implement initiatives.

- 3.10 Work with the Education, Open Source Technologies, and Communications Directors, Working Groups Committees, Working Groups and Project Teams to provide outward bound information about the Working Group activities.
- 3.11 Review relevant draft regulatory guidelines and collating the comments and producing a final set of PHUSE comments.
- 3.12 For areas of major interest, the Committee will form expert groups. to discuss with the aim of forming an industry consensus.

4. MEETINGS

- 4.1 Hold an Operations Committee meeting at least every two months.
- 4.2 The Committee must keep records of its activities through the taking of minutes.
- 4.3 Participate in 2 one-day annual PHUSE BoD meetings (preferably face-to-face) usually organised at the back of one major PHUSE event in the EU and one major PHUSE event in the US. Typically, one day following the EU Connect and US Connect.

5. REPORTING

- 5.1 Prepare a written report of activities, recommendations and/or discussion items for consideration at each meeting of the Board of Directors (twice a year). This report may be based on (draft) minutes and/or any other appropriate supporting material.
- 5.2 Prepare a summary presented ahead of monthly Board Calls (ten times per year).
- 5.3 Prepare a quarterly report for PHUSE Supporters and the wider community.

6. DECISION MAKING AUTHORITY

- 6.1 The Director is free to act within the remit without further approval from the Board of Directors unless the decision involves budgets above £1,000 that would require BoD approval.
- 6.2 Major or strategic recommendations of the Committee are subject to the approval of the Board of Directors.

7. FINANCIALS

The Director can claim expenses for incidental costs in discharging their duties (e.g. travel, subsistence) within the allocated budget agreed at the beginning of each calendar year.