



Health Level Seven International (HL7)

and

PHUSE

Statement of Understanding (SOU)

THIS STATEMENT OF UNDERSTANDING ("SOU"), is made by the Health Level Seven International (HL7) with its principal place of business located at 3300 Washtenaw Avenue, Suite 227 Ann Arbor, Michigan 48104-4261, and PHUSE, with its principal place of business located at Kent Innovation Centre, Millennium Way, Kent, CT10 2QQ England UK. Both Parties may hereinafter be referred to as "Party" or "Parties".

This agreement is effective 1 September 2020 through 31 September 2023 and may be extended and/or amended with mutual agreement or terminated early by either party according to Section 7.0 Termination.

Statement of Purpose

HL7 has as its mission the goal of providing reliable standards for the exchange, management and integration of data that support clinical patient care and the management, delivery and evaluation of healthcare services. HL7 encourages the creation of flexible, cost-effective approaches, standards, guidelines, methodologies, and related services for the interoperability of healthcare information systems. HL7 provides a forum for the effective and efficient communication between the constituents of the healthcare community as represented by its membership: an international community of healthcare organizations, vendors and developers of healthcare information systems, consultants and systems integrators, and related public and private healthcare service agencies.

PHUSE is an independent, not-for-profit organisation run by volunteers. A society with a membership exceeding 9,750, across more than 40 countries worldwide, PHUSE has become the industry voice to regulatory agencies and standards organisations such as the FDA, EMA & CDISC. We act as a global platform for the discussion of topics encompassing the work of data managers, biostatisticians, clinical data scientists and eClinical IT professionals.

1.0 Introduction

- 1.1 Parties may establish similar meeting schedules. Parties are also encouraged to work with other standards organizations toward harmonization.
- 1.2 Official joint meetings between Parties may be scheduled where such meetings serve a common purpose.
- 1.3 The parties to this SOU shall each appoint a liaison for interactions between the parties. It is not required, that each liaison hold joint membership in Parties. See section 10.0 Contacts at Time of Signing.
- 1.4 Such projects as might be jointly undertaken by Parties will be clearly defined and delineated by a joint project proposal which, if approved by both parties, must include a succinct description of the proposed project and estimate of time required.

2.0 Rights Granted

- 2.1 Members of PHUSE, while encouraged to participate in HL7 Work Groups, may not seek leadership positions within HL7 unless they also hold HL7 membership. In turn, HL7 members, while encouraged to participate in PHUSE's Work Groups, may not seek leadership positions within PHUSE's Work Groups unless they also hold PHUSE membership.

3.0 Fees and Payments

- 3.1 No monies shall be exchanged between Parties as a result of this SOU.
- 3.2 Members of either organization are encouraged to attend the events of the other. Fees shall be the responsibility of the individual.

4.0 Obligations

- 4.1 Parties expressly agree:
 - a. That ownership rights to HL7 trademarks or standards or PHUSE trademark or standards are neither extended nor transferred; and
 - b. That there shall be no exchange of mailing lists or general membership information; and
 - c. That they will comply with all provisions of this SOU.

5.0 Joint Work Product Copyright

- 5.1 Joint work documents and other productions are intellectual property of, and held under joint copyright of Parties.
- 5.2 Parties reserve the right to publish the jointly developed work for the benefit of their members. All publications of the joint work product, or parts thereof, shall include the joint copyright statement and any and all logos or identifying graphics as agreed in the initial issuance.

5.3 Members of either Parties may copy and use the work or any part thereof in connection with the business purposes of the member. Members of either Parties may not reproduce or redistribute the joint work products except as permitted in the respective membership agreement.

5.4 Joint work products must be made freely available to all members and non-members alike in front of any established firewalls.

6.0 Warranties

6.1 Parties make no express or implied warranties other than those that may be contained in or appended to this SOU.

7.0 Termination

7.1 Either Parties may terminate this SOU upon 30 days written notice.

7.2 In the event of such termination all registrations for Parties sponsored events recorded prior to the termination date shall be honored.

8.0 Term

8.1 This SOU shall have a three-year term, renewable upon expiry by written agreement for subsequent three-year terms.

9.0 Miscellaneous

9.1 This SOU constitutes the entire agreement and complete understanding of the relationship between Parties.

9.2 Parties may propose alterations to this SOU in writing upon appropriate action of their respective governing body. The receiving party shall be afforded sixty (60) days to adopt any proposal for change and/or amendment to this SOU and shall acknowledge such acceptance in writing to the submitting party. In the event such proposals are deemed unacceptable and cannot be resolved through negotiation, either party may execute the Termination provisions afforded above.

10.0 Contacts at Time of Signing

10.1 *Strategic relationship* HL7 Wayne Kubick wkubick@HL7.org and PHUSE Lisa Brooks lisa.brooks@phuse.eu.

10.2 Knowledge Base/Coordinating content: Andrea Ribick Andrea@HL7.org ;and PHUSE communications@phuse.eu.

11.0 Authorized Signatures:

For PHUSE

Signature: *Lisa K Brooks*

Name: Lisa Brooks, Collaborations Director

Date: October 24, 2020

For HL7

Signature: *Charles Jaffe MD*

Name: Charles Jaffe MD PhD, CEO

Date: October 20, 2020