

Statement of Understanding (SOU)

Defining the relationship between:

Health Level Seven International
3300 Washtenaw Avenue, Suite 227
Ann Arbor, Michigan 48104-4261

Hereinafter identified as HL7

AND

Observational Health Data Sciences and Informatics (OHDSI)
OHDSI Coordinating Center
Columbia University
622 W 168th St
New York, NY 10032

Hereinafter identified as OHDSI

This SOU shall have an effective date of: March 1, 2024

Statement of Purpose

HL7 and OHDSI agree to foster collaboration between relevant work groups to advance the integration of HL7 FHIR and OHDSI OMOP CDM.

Health Level Seven® International (HL7) is an ANSI-accredited, not-for-profit standards developing organization with the mission of empowering global health interoperability. With affiliates in over 30 countries, HL7's global membership envisions a world in which everyone can securely access and use the right data when and where they need it. Widely implemented by vendor and health care systems, and required by governing bodies around the world, HL7 standards deliver solutions for health information technology, including HL7® Fast health care Interoperability Resources (FHIR®), Version 2 (V2) and Clinical Document Architecture (CDA®).

OHDSI is a multi-stakeholder, interdisciplinary collaborative to bring out the value of health data through large-scale analytics. Their international network of researchers and observational health databases improve decision-making in both health and healthcare. Research in the network is based on the Observational Medical Outcomes Partnership (OMOP) Common Data Model (CDM), enabling federated analytics amongst collaborators.

This SOU defines the objectives regarding the relationship between HL7 and OHDSI. Potential areas for collaboration between the parties are outline in Appendix I of this document.

1.0 Collaboration Guidelines

1.1 A structured 3-year plan that includes milestones and goals for integrating HL7 FHIR and the OHDSI OMOP CDM shall be developed within 3 months of the effective date of this SOU to guide the collaboration.

1.2 OHDSI may establish meeting schedules similar to HL7, and in addition may establish meetings with other Associates when convenient. OHDSI is also encouraged to work with other standards organizations toward further harmonization.

1.3 Official joint meetings between the OHDSI and HL7 may be scheduled where such meetings serve a common purpose and are convenient to the HL7 meeting agenda.

1.4 The parties to this SOU shall each appoint a liaison for interactions between the parties for the purpose of harmonized standards development. It is expected, although not required, that each liaison hold joint membership in HL7 and OHDSI.

1.5 Such projects as might be jointly undertaken by HL7 and OHDSI 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, an estimate of time required and resources expected to be committed by each party.

2.0 Rights Granted

2.1 The HL7 Working Group Meeting (WGM) and the equivalent OHDSI Work Group may be convened and conducted as a joint meeting of the two organizations.

2.2 Such joint meetings, when conducted, shall at all times adhere to the rules of the host organization. When voting within the joint meeting context to propose changes to the standard, or to conduct other business specific to either HL7 or OHDSI, the relevant procedures of the respective organization shall be enforced.

2.3 Members of OHDSI, 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 OHDSI's Working Groups, may not seek leadership positions within OHDSI's Work Groups unless they also hold OHDSI membership.

3.0 Fees and Payments

3.1 No monies shall be exchanged between HL7 and OHDSI as a result of this SOU.

4.0 Obligations

4.1 HL7 and OHDSI expressly agree:

- a. That ownership rights to HL7 trademarks or standards or OHDSI's trademarks 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 produced under this SOU are intellectual property of, and held under joint copyright of, HL7 and OHDSI.

5.2 Both HL7 and OHDSI 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 Both HL7 and OHDSI agree that all document and productions produced on this SOU shall be licensed free of charge.

6.0 Warranties

6.1 HL7 and OHDSI 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 HL7 or OHDSI may terminate this SOU upon 30 days written notice.

8.0 Term

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

9.0 Miscellaneous

9.1 This SOU constitutes the entire agreement and complete understanding of the relationship between HL7 and OHDSI.

9.2 HL7 or OHDSI 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.

Authorized Signatures:

For
HL7 INTERNATIONAL

A handwritten signature in black ink, appearing to read "Charles Jaffe" with a stylized flourish at the end.

Signed:

Charles Jaffe, MD PhD
Chief Executive Officer

For
OHDSI

A handwritten signature in black ink, appearing to read "George Hripcsak" in a cursive style.

Signed:

George Hripcsak
Director of the Coordinating Center

Appendix I

Areas for Collaboration

1. Development of a formal balloted and approved Implementation Guide (IG) that describes definitive integration between FHIR resources and profiles and the OMOP data model.