

PROJECT COLLABORATION AGREEMENT

between

the **World Health Organization**

20, Avenue Appia

1211 Geneva 27

Switzerland

(hereinafter referred to as “WHO”)

on the one side

and

Health Level Seven International

3300 Washtenaw Avenue

Suite 227

Ann Arbor, Michigan 48104-4261

United States of America

(hereinafter referred to as “HL7”)

on the other side

WHEREAS WHO works worldwide to promote health, keep the world safe, and serve the vulnerable by enabling preparedness, surveillance and response to global health issues and crises, preparing standards to diagnostic and therapeutic guidance, algorithms for treatment, prevention and all aspects of health management, forms for recording and reporting health-related data, and health-related classifications and terminologies, which are mandated under national and international law (e.g. the International Health Regulations stipulate mandatory use of ICD latest version).

WHEREAS HL7 develops technical interoperability standards that empower global health data interoperability, and

WHEREAS both parties agree that a coordinated collaboration can advance interoperability for the improvement of global health, WHO and HL7 enter into this formal Collaboration Agreement.

1. The Project

1.1 WHO and HL7 shall collaborate on the project(s) as described in Annex 1 attached hereto (hereinafter referred to as the “Projects”), which forms an integral part of this Agreement. The activities to be carried out by each party under the Project(s) are also described in Annex 1.

1.2 WHO and HL7 shall each appoint business and technical liaisons for interactions between the parties. The number of liaisons will vary depending on the project. The appointed liaisons will meet on a regular basis as required for coordinating joint projects and sharing information regarding activities of

mutual interest and be responsible for establishing necessary liaisons with groups within each other's respective organisations.

- 1.3 The implementation of Project activities by a party is subject to that party's regulations, rules, and administrative practices.

2. Funding

- 2.1 Each party hereto shall be fully responsible for the funding of its activities under this Agreement, except as may otherwise expressly be agreed in this Agreement or in any sub-agreement thereto. The implementation of each Project activity is subject to the availability of sufficient human and financial resources.

- 2.2 Any fund-raising for the Project will be decided jointly by the parties and will be directed to governments, non-profit organisations, and foundations. Any fund-raising from commercial entities or their foundations, or organisations funded mainly from commercial sources, shall be decided jointly by the parties and will be made in accordance with the regulations, rules and administrative practices of the parties in order to avoid any real or perceived conflict of interest.

- 2.3 Each party shall administer the funds handled by it in accordance with its financial regulations, rules, and administrative practices. The accounts shall be subject to audit in accordance with the party's audit rules and procedures and a copy of the report of the external auditor shall be sent to the other party, if so requested, as soon as it becomes available.

- 2.4 Any transfer of funds between the parties shall be made under an appropriate separate agreement, to be negotiated in good faith between the parties.

3. Copyright/Publications

3.1 Pre-existing Intellectual Property Rights

- 3.1.1 This Agreement shall not assign or otherwise transfer any Intellectual Property Rights of either Party:

- (a) existing as at the Effective date; or
- (b) creating during the Term of this Agreement, other than as set out in Annex 1.

- 3.1.2 For the avoidance of doubt, any intellectual property, including copyright, related to the development of WHO SMART Guidelines content will be vested to WHO.

- 3.1.3 For the avoidance of doubt, any intellectual property including trademark and copyright related to the development of HL7® FHIR® standard will be vested to HL7.

3.2 New Intellectual Property Rights

- 3.2.1 Publications foreseen to be prepared collaboratively under the Project are listed in Annex 1. The parties may prepare additional publications, unforeseen at the conclusion of this Agreement, subject to the provisions here below. The intellectual property and copyright of work products listed in Annex 1 and other outputs collaboratively developed by WHO and HL7 will be agreed at the outset of each project.
- 3.2.3 For work products declared to be vested in WHO, WHO shall be the lead publishing party and will publish all work products in accordance with WHO's publishing policies¹. For the sake of clarity, work products and outputs shall be published under Creative Commons attribution 3.0 International Organization License (CC BY 3.0 IGO)² and/or an open-source license, as appropriate and as determined by WHO. WHO shall serve as copyright administrator and will act as the contact for third parties with regard to requests to reproduce or make use of the publications, or portions thereof, for commercial purposes in any form or medium in all languages. WHO herewith grants HL7 a perpetual and irrevocable, non-exclusive, world-wide, royalty-free, sub-licensable license to use such jointly prepared work, or parts thereof, for public health purposes.
- 3.2.4 For work products declared to be vested in HL7, HL7 shall be the lead publishing party and will publish all work products in accordance with HL7's publishing policies. HL7 will publish specifications based on the HL7® FHIR® standard under the Creative Commons "No Rights Reserved" (CC0) license. HL7 will publish software using an open-source license as appropriate and as determined by HL7, typically either Apache License, Version 2.0 or the MIT License.
- 3.3 For the avoidance of doubt, WHO and HL7 shall both retain ownership of any intellectual property developed independently of the joint work products and other collaboratively developed outputs.
- 3.4 Copyright of any work prepared by one of the parties, on its own, under this Project shall be vested in that party, who may publish the work provided that the other party has been given the opportunity to comment on the work and any references to that other party before publication, which comments shall be given due consideration by the publishing party.
- 3.5 Sale, licensing or otherwise making available collaborative work products for profit is not permitted.
- 3.6 The collaboration of the parties shall be duly acknowledged in any publication resulting from the Project unless a party does not wish to be associated with the publication. The wording of the acknowledgement shall be agreed between the parties.

¹ WHO Policy on Open Access (<https://www.who.int/about/policies/publishing/open-access>)

² Creative Commons — Attribution 3.0 IGO — CC BY 3.0 IGO
(<https://creativecommons.org/licenses/by/3.0/igo/>)

- 3.7 No publication from the Project shall contain commercial advertising or be used for the promotion of any commercial product or service.
4. Web site
- 4.1 The parties shall decide jointly on any dissemination of Project information over the Internet. The parties shall not create a separate web site for this purpose, except by mutual agreement, but any information shall be disseminated through one or both parties' existing web site(s).
5. Use of Logo and Promotional Activities
- 5.1 A party may not use the logo of the other party unless that party has given its prior approval in writing.
- 5.2 Without the prior written consent of the other party, neither party shall, in any statement or material of an advertising or promotional nature, refer to the relationship of the parties under this Agreement.
6. Relationship and Responsibility of the Parties
- 6.1 Nothing in this Agreement shall be construed as creating a relationship of joint venturers, partners, employer/employee, or agent between the parties. Neither party shall have the authority to make any statements, representations, or commitments of any kind, or to take any action which shall be binding on the other party, except as may be explicitly provided for in this Agreement or authorized in writing by the other party.
- 6.2 Each party shall be solely responsible for the way it carries out its part of the collaborative activities under this Agreement. Thus, a party shall not be responsible for any loss, accident, damage, or injury suffered or caused by the other party, or that other party's staff or sub-contractors, in connection with, or because of, the collaboration under the Project.
7. Notices

All notices to be given under this Agreement must be in writing and sent to the address or email address of the intended recipient set out hereinafter or to any other address or email address which the intended recipient may designate by notice given in accordance with this Article. Any notice may be delivered personally or sent by first class pre-paid registered mail or by email, and it will be deemed to have been served: if by hand, when delivered; if by first class registered mail, 48 hours after posting; and if by email when the sender receives verification from his email system that the email has been opened by the intended recipient.

If to WHO: World Health Organization
Attention: Jeremy Farrar
20, Avenue Appia

CH-1211 Geneva 27
Switzerland
Tel.: +41 22 791 5800
Email: farrarj@who.int
With CC: Alain Labrique (labriquea@who.int) and
Fatima Serhan (serhanfa@who.int)

If to HL7: Health Level Seven International
Attention : Charles Jaffe, MD, PhD
3300 Washtenaw Avenue
Suite 227
Ann Arbor, MI 48104-4261
Tel: +1 734 677 7777
Email: CJaffe@HL7.org

8. Zero tolerance for sexual exploitation and abuse, sexual harassment and other types of abusive conduct

WHO has zero tolerance towards sexual exploitation and abuse, sexual harassment and other types of abusive conduct. In this regard, and without limiting any other provisions contained herein, each Party warrants that it shall: (i) take all reasonable and appropriate measures to prevent sexual exploitation or abuse as described in the WHO Policy on Sexual exploitation and Abuse Prevention and Response and/or sexual harassment and other types of abusive conduct as described in the WHO Policy on Preventing and Addressing Abusive Conduct by any of its employees and any other persons engaged by it to perform any services under the Memorandum of Understanding (MoU), and, in the case of the other Party, (ii) promptly report to WHO and respond to, in accordance with the terms of the respective Policies, any actual or suspected violations of either Policy of which the other Party becomes aware.

9. Duration, Termination and Modification

- 9.1 This Agreement shall be valid for an initial period of five years, commencing 1 July 2023 and ending 1 July 2028, unless terminated earlier by either party by giving three months' notice in writing to the other party. The parties may agree in writing to extend this Agreement for subsequent periods of two years.
- 9.2 In the event of termination of this Agreement, the parties shall take the necessary steps to ensure that the activities carried out under the Agreement are brought to a prompt and orderly conclusion, and they shall wind up their obligations hereunder.
- 9.3 Further, in case of breach of Article 9, WHO may terminate this MoU immediately upon written notice to the other Party.
- 9.4 This Agreement may be modified by mutual consent of the parties as expressed in writing.

10. Privileges and Immunities

Nothing contained herein shall be construed as a waiver of any of the privileges and immunities enjoyed by WHO under national or international law, and/or as submitting WHO to any national court jurisdiction.

11. Settlement of Disputes

Any dispute relating to the interpretation or application of this Agreement shall, unless amicably settled, be subject to conciliation. In the event of failure of the latter, the dispute shall be settled by arbitration. The arbitration shall be conducted in accordance with the modalities to be agreed upon by the parties or, in the absence of agreement, in accordance with the UNCITRAL Arbitration Rules. The parties shall accept the arbitral award as final.

Agreed and signed on behalf of the
World Health Organization



Jeremy Farrar, MD, PhD

Chief Scientist

23 June 2023

Date

Agreed and signed on behalf of
Health Level Seven International



Charles Jaffe, MD, PhD

Chief Executive Officer

June 23, 2023

Date

Support implementation of the Global strategy on digital health 2020 - 2025 with interoperability standards

Background: As countries increasingly adopt digital technologies for health service delivery and health systems strengthening, there is an increased need for guidance from WHO for interoperability standards adoption and the ability to translate WHO clinical, public health and data guidance into these digital systems, as outlined in the WHO Global strategy on digital health 2020 – 2025. Because of this, WHO has established the SMART Guidelines — Standards-based, Machine-readable, Adaptive, Requirements-based, and Testable — approach that transform the guideline adaptation and implementation process to preserve fidelity and accelerate uptake of evidence-based guidelines in digital systems using interoperability standards.

The proposed engagement will advance the WHO General Programme of Work (GPW) across multiple outputs including: 1.1.1. Countries enabled to provide high quality, people-centered health services, based on PHC strategies and comprehensive essential service packages; and 4.1.1. Countries enabled to strengthen health information and data systems, including at the subnational level, and to use this information to inform policy-making.

The WHO Global strategy on digital health 2020 – 2025 outlines four (4) strategic objectives, with a number of proposed actions for the WHO Secretariat across all objectives that are intended to be supported through WHO’s collaboration with Health Level Seven International (HL7) in the use of the HL7 FHIR standard, as follows:

Strategic objective 1: Promote global collaboration and advance the transfer of knowledge on digital health.

- Promote digital health collaborations and partnership models within and across organizations on the use of software global goods, open-standards, and common digital health architecture.

Strategic objective 2: Advance the implementation of national digital health Strategies.

- Advocate digital health architectural blueprints or road maps, adoption and use of open-source standards and reuse of shared assets or services and systems including interoperability standards.
- Facilitate the use of organizations involved in standards development and partner agencies to advance the use of appropriate standards to ensure interoperability between systems and across domains.

Strategic objective 3: Strengthen governance for digital health at global, regional and national levels.

- Promote exchange of best practices, good governance, infrastructure architecture, programme management, and use of standards to promote interoperability for digital health.

- Develop a guideline on global interoperability standards for digital health.

Strategic objective 4: Advocate people-centred health systems that are enabled by digital health.

- Develop global minimum standards for electronic health records.
- Provide support to countries to enable countries meeting global minimum standards for electronic patient health records.

Objectives of the proposed engagement:

1. Strengthen implementation of the WHO Global strategy on digital health 2020-2025 at country level and build capacity to support the adoption and appropriate use of interoperability standards in Member States in an equitable manner.
2. Increase access to WHO's guidance and recommendations through developing interoperability specifications that are applicable globally and suited for local adaptation.
3. Support the use of WHO Family of international classifications and terminologies (WHO-FIC) in the HL7 FHIR community.
4. Make available the technical infrastructure (e.g. sandbox testing environment) and documentation to support interoperability.

Roles:

WHO will be responsible for:

- Leading the normative standard for health content and the SMART guideline development process
- Coordinating and identifying needs of the global health community and sharing needs gap with HL7 as and when appropriate
- Reviewing all outputs of the activities conducted ensuring alignment with WHO's policies and procedures before use and publication
- WHO reserves the right to accept or decline inputs and feedback in relation to activities conducted under this MoU from HL7 as WHO deems appropriate
- Ensure correct representation of WHO-FIC classifications and terminologies within HL7.

Health Level Seven International (HL7) will be responsible for:

- Providing technical inputs and recommendations to WHO that may inform WHO when developing WHO SMART Guidelines
- Providing technical input on the developing training materials and tools in line with WHO's recommendations to strengthen implementation the adoption of interoperability standards, as and when appropriate, at country level as agreed with national authorities
- Creating the technical mechanisms for FHIR-based standards (including those developed by WHO) to be translated into the six official languages of the United Nations (Arabic, Chinese, English, French, Russian and Spanish) and assisting with the translation process as needed
- Enabling the proper representation of the WHO Family of international classifications and terminologies (WHO-FIC) in the HL7 FHIR terminology structures in line with WHO guidance for correctness and their use in particular for data input. This includes working with WHO to help the global community to adopt WHO classifications seamlessly, including the development of specific

guidance and tooling for using WHO-FIC terminology combined with HL7 Standards. For use-cases which require ICD-11 coding the use of the ICD-11 API and derived tooling are strongly recommended.

Expected outcomes:

HL7 FHIR enabled SMART Guidelines with multilingual support across all UN languages made available to the public at no cost compliant with WHO standards.

Budget and Timeline: The engagement will begin on 1 July 2023 and end on 1 July 2028. No exchange of funds will occur as part of this engagement.