

VULCAN MEMBERSHIP STATEMENT OF UNDERSTANDING

This Membership Statement of Understanding (the “SOU”) is entered into effective as of XXX (the “Effective Date”) by and between [organizational name] with its office at [organization address],[organization short name] and Health Level Seven International (HL7) with its principal offices at 3300 Washtenaw Avenue, Suite 227, Ann Arbor, MI 48104.

PURPOSE STATEMENT

This SOU will create formal commitment between [organizational name] “Vulcan Member” and HL7 with regard to Vulcan. It is agreed that it would be mutually beneficial to work collaboratively to accelerate the translational and clinical research community’s use of the HL7 FHIR® standard through a coordinated HL7 project called, “Vulcan”. HL7 and Vulcan Member have identified certain areas of mutual interest, as further described below. Vulcan is an initiative (“Initiative”) led by the Steering Committee. For the avoidance of doubt, Vulcan is not a separate legal entity and the Steering Committee is not a formal Board of Directors.

US Federal Government entities participate in the work of the Vulcan Accelerator project, as described in Section 6.

The goals of the Vulcan Accelerator project are to:

- *Bridge Existing Gaps: Work to close gaps between clinical care and clinical research to improve patient lives, decrease costs and improve efficiency.*
- *Strategically Connect Industry Collaborations: Coordinate strategy between stakeholders and leverage existing work within HL7 and other groups.*
- *Maximize Collective Resources: leverage shared community and resources to be able to communicate the return on investment and return on value that a unified network could realize to various parties and provide comprehensive recommendations to global regulators.*
- *Deliver Integrated Tools and Solutions: Develop necessary FHIR Research Resources to maturity. Accelerator program will handle identified and prioritized use cases for secondary use of EHR data that meet interested parties needs and goals.*

Recognizing that complementary efforts are underway to create and extend comprehensive standards in the healthcare community, HL7 enters into formal SOU relationships with Vulcan Member to further these goals. Many different and independent entities share the same goals to advance, nationally and internationally, the acceptance and usage of the HL7 Fast Healthcare Interoperable Resource (HL7 FHIR®) standards within healthcare. Vulcan is an Initiative that addresses the needs of the clinical research communities by leveraging the HL7 FHIR platform and the contribution of Vulcan members. Vulcan members would include, but are not limited to standards development organizations, industry associations and consortiums, technology vendors, electronic health record vendors, research academia, government agencies, patients and other groups that share the vision to develop and deploy solutions that will result in more effective and widely accepted standards. Participation in Vulcan by any government agency does not mean that any Vulcan work product or standard will be mandated by law or regulation.

HL7 is a not-for-profit, ANSI-accredited standards developing organization dedicated to providing a comprehensive framework and related standards for the exchange, integration, sharing and retrieval of electronic health information that supports clinical practice and the management, delivery and evaluation of

health services to meet the triple aim. HL7 is supported by more than 1,600 members from over 50 countries, including 500+ corporate members representing healthcare providers, government stakeholders, payers, pharmaceutical companies, vendors/suppliers, and consulting firms.

Each Vulcan Member agrees that Vulcan will explore various solutions including but not limited to (*and where needed, include extensions and/or revisions*):

1. Base Standards (FHIR),
2. Implementation Guide standards, and
3. Reference Implementations, connectathons and pilot projects to guide the development and deployment of interoperable solutions on a national scale.

NOW, THEREFORE, the parties hereto each, in consideration of the mutual rights and obligations set out herein, hereby agree as follows:

DEFINITIONS

For the purposes of this SOU:

(a) “Convener” is the entity representing and supporting Vulcan and its members to HL7 in order to enable Vulcan’s participation in the Accelerator Program. This role is filled by one of the organizations represented on Steering Committee on a rotating bases according to the membership year, appointment of which is agreed to by the Steering Committee.

(b) “Founding Member” are those organizations that helped to initiate and formally establish the Vulcan Accelerator.

(c) “Vulcan Member” are those organizations that have joined Vulcan through a formal acceptance of the Vulcan Statement of Understanding (this SOU) and have paid an annual membership fee (if applicable).

(d) “Steering Committee” is a governing body elected by Vulcan Members from key stakeholder groups such as government agencies, research sites, standards development organizations, pharma and/or patients. The Steering Committee shall prioritize Vulcan activities; approve projects; approve Vulcan contracts (subject to HL7 approval); monitor progress; and report status to the Vulcan members. The Vulcan Steering Committee shall reserve a representative seat(s) on the Steering Committee for HL7.

(e) “Contracted Resources” means the individual or organizations identified and approved by the Steering Committee to help organize and/or support, on an outsourced or contracted basis, the projects approved by the Steering Committee.

(f) “Contributions” means any work or content that is submitted to Vulcan by any Vulcan Member for inclusion in a Vulcan Document.

(g) “Documents” means copies of working documents, drafts and final work product, including standards, implementation guides, reference implementations and supporting collateral, within the agreed upon collaboration tools and web sites.

1.0 VULCAN MEMBER & HL7 UNDERSTANDING

- 1.1 The Vulcan Steering Committee will elect on a case-by-case basis projects, project outputs, deliverables and artifacts to bring into the HL7 standards development process. This collaboration will proceed on a project by project basis upon the determination that any particular project could benefit the broader industry through an HL7 standard, which will be validated and balloted through HL7.
- 1.2 Vulcan will follow HL7/ANSI process for all artifacts for introduction into the HL7 standards development process. Artifacts from such projects shall at all times adhere to the rules of HL7 relating to creation, balloting and publication of HL7 standard artifacts.
- 1.3 HL7 and Vulcan will work to coordinate meeting schedules leveraging HL7 activities and may establish independent meeting locations and schedules.
- 1.4 HL7 and Vulcan Member will share information, documents, tools and site access within the defined areas of mutual interest and to cooperate under professional standards of business practice, as described in this Agreement. The goal of Vulcan is to provide open, available artifacts for public use. All public information, documents, contributions, tools and site access will be shared across Vulcan and the implementation community. HL7 and Vulcan Member will work with their own internal staff to ensure that no confidential, proprietary information or business practices are shared as part of project work. To the extent the participating parties share member protected health information as defined by HIPAA and any other applicable privacy regulations, all appropriate legal agreements will be put into place before that type of information is shared. No financial data is to be shared, and all parties will follow and comply with all state and Federal Antitrust rules and laws. The parties therefore seek to define specific roles and responsibilities to ensure the success of Vulcan as defined through this SOU.
- 1.5 Vulcan has a defined governance model for setting strategic direction, establishing priorities and to support structured decision making. The Vulcan Governance Model is available for review on the Vulcan Confluence site ([Vulcan Governance Model](#)).
- 1.6 HL7 will provide to Vulcan baseline project infrastructure and limited marketing support as defined in Exhibit A. HL7 will also provide selected mutually agreeable optional services as approved by the Steering Committee. HL7 will provide a schedule of known administrative services to the Steering Committee for each year. Steering Committee and HL7 will work together to mutually align on the scope of services and associated fees for Vulcan.
- 1.7 Vulcan Member will contribute membership fees and/or in-kind support for Vulcan as defined by the Vulcan Membership Model which is available for review on the Vulcan Confluence site ([Vulcan Membership Model](#)).

2.0 RIGHTS GRANTED

- 2.1 All Documents, and Intellectual Property Rights created by and under Vulcan shall be available to the public with no required fees. Implementation guides and other artifacts from Contributions that are balloted under the rules of HL7 shall become HL7 intellectual property and subject to HL7's intellectual property regulations. To be clear, however, HL7 must apply its IP regulations to any relevant Vulcan document or work in such a way as to ensure the document or work will be freely available for use by the public and Vulcan Members.
- 2.2 Vulcan Member agrees that it will make a Contribution of content to Vulcan only if Vulcan Member has sufficient rights in the Contribution to allow Vulcan, HL7, and other Vulcan Members to freely and properly

exercise the license rights conveyed in Section 2.3. Conversely, Vulcan Member agrees that it will not make any Contribution of content to Vulcan if Vulcan, HL7, other Vulcan Members, or members of the public would infringe a third-party's intellectual property rights in the Contributed content by using, reproducing, or publicly presenting any Vulcan Document.

- 2.3 To ensure that Vulcan will be able to provide its Documents freely to the public, Vulcan Member agrees that it hereby provides to Vulcan, HL7, and all other Vulcan Members a royalty-free, non-exclusive, sub-licensable, perpetual, and worldwide license to any Contribution that Vulcan Member may make to Vulcan.

3.0 MEMBERSHIP FEES & IN-KIND CONTRIBUTIONS

- 3.1 Vulcan Member shall contribute in-kind hours and / or pay membership fees designated for support of the Vulcan Initiative. Detailed descriptions of in-kind contributions and membership fees can be found in the Vulcan Membership Model which is available for review on the Vulcan Confluence site ([Vulcan Membership Model](#)).
- 3.2 As applicable, Vulcan Program Management Office, in conjunction with HL7 shall notify Vulcan Member of subsequent years membership fees within 60 days of the end of the membership year.
- 3.3 Membership in Vulcan is year-to-year and Vulcan Member can renew annually. Vulcan reserves the right to ensure that Member is meeting in-kind contribution targets and / or membership fees in order to maintain Vulcan membership.
- 3.4 As applicable, Vulcan will invoice Vulcan Member upon execution of initial SOU for a Vulcan Member's first year of membership in Vulcan, prorated to the end of the current year (June 30). In subsequent years, Vulcan will invoice in advance of July 1st. The invoice will be due within 60 days of receipt by Vulcan Member. Subject to the Steering Committee decision on financial management services, HL7 (if the Optional Services is elected as defined in Exhibit A) or another Vulcan Member on behalf of Vulcan will invoice and collect payment of the membership fees.
- 3.5

4.0 VULCAN BUDGET AND EXPENSES FOR HL7 SERVICES

- 4.1 The Steering Committee will approve the budget and in-kind contributions necessary to operate Vulcan for each annual term. HL7 Executive Committee will work with the Steering Committee to establish fee and payment schedules for HL7's administrative and professional services.
- 4.2 The funds will be disbursed by HL7, as directed by the Steering Committee or another Vulcan Member on behalf of Vulcan, primarily to fund Contracted Resources for project management, project oversight for specific use case driven projects, and HL7 Services approved in writing in Exhibit A. Steering Committee Members will disclose any conflicts of interest associated with Contracted Resources.
- 4.3 The Initial Convener Fee to cover the Baseline Package services in the first membership year of Vulcan is \$25,000 for HL7 services in Exhibit A and has been paid by TransCelerate BioPharma Inc. as the Convener in the first membership year of Vulcan ending June 30, 2021. The responsibility to pay HL7 for the Baseline Package services, in the form of an Annual Maintenance Fee, after the first membership year will shift to the Vulcan Members collectively.
- 4.4 The Maintenance Fee for the Baseline Package services provided by HL7 to Vulcan is set by the HL7 Executive

Committee each year.

- 4.5 The Steering Committee will approve any other Optional Services from HL7, as part of the Vulcan budget. Optional Services and associated fees are found in Exhibit A.
- 4.6 Should HL7 contract with subject matter experts on behalf of Vulcan, the Financial Administrative Services listed in Exhibit A shall be required rather than optional.

5.0 VULCAN AND VULCAN MEMBER OBLIGATIONS

5.1 HL7 and Vulcan Member expressly agree:

- a. There shall be no rights to HL7 trademarks, copyrights, or standards or Vulcan Member trademarks, copyrights, or standards. Except for the transfer of rights embodied in the license provision in Section 2.3 and the commitment by HL7 and Vulcan to make available freely to the public all standards and artifacts developed through Vulcan, no rights are extended or transferred by this SOU or participation in Vulcan.
- b. Any standards or artifacts created by HL7 as a result of the Vulcan project will be freely available for copying and use by the public, including any Vulcan Member.
- c. HL7 shall own the trademark to the Vulcan logo, the use of which shall be authorized by the Vulcan Steering Committee.
- d. There shall be no exchange of mailing lists or general membership information in Vulcan or by Vulcan Member, with the exception of the HL7-created listserv(s) for the Vulcan project. These listservs shall be used to schedule and announce Vulcan project conference calls, ensuring their transparency to the HL7 community. Vulcan shall provide HL7 with an initial list of names/emails to be subscribed to these listservs.
- e. Vulcan Member will comply with all [HL7 Codes of Conduct](#) (posted on the HL7 website).
- f. Vulcan Member will comply with all HL7 communication requirements and instructions regarding use of HL7 trademarks.
- g. Vulcan Member will actively participate in HL7 work groups and projects directly related to the business topics being addressed by the Vulcan Project.
- h. HL7 and Vulcan Member will comply with all provisions of this SOU.

5.2 Vulcan Member acknowledges that Vulcan, through Convener and in partnership with its Steering Committee, shall adhere to the following principles:

- a. Acknowledge that Vulcan has the following aspirational membership goal: 50% of the organizations participating in the Vulcan project will maintain HL7 organizational membership in good standing.
- b. Provide a program plan to HL7 that includes projects, timelines, and plans for balloting and life cycle support of artifacts.
- c. Provide an HL7 Project Scope Summary form acceptable to HL7 that describes each Vulcan Project artifact that will be submitted for ballot using the HL7 process and a description of a governance model, lead participants and ongoing maintenance and support plans.

- d. Submit those FHIR-based artifacts produced under the FHIR Accelerator Program that will be balloted under the HL7 process. HL7 recognizes that not all of the implementation guides that the Vulcan Project will work on will become an HL7 balloted standard.

6.0 U.S. FEDERAL AGENCY PARTICIPATION

- 6.1 U.S. Federal agencies share the goals of the Vulcan Accelerator and may participate in providing scientific advice as part of the Vulcan Accelerator work subject to the availability of personnel, resources, and funds. U.S. Federal agencies agree in principle and support the stated understanding, rights and obligations as described in this agreement. U.S. Federal agencies are not bound by the terms of this SOU and will not participate in financial or contractual direction setting or decision making, nor pay membership or other fees associated with this agreement.

Work products that are substantially developed by U.S. Federal agencies shall not be bound by trademark, brand, slogan, and copyright usage policies.

Either party may terminate this agreement with 60 days written notice.

7.0 WARRANTY

- 7.1 HL7 and Vulcan Member make no express or implied warranties other than those that may be contained in or appended to this SOU.

8.0 TERMINATION

- 8.1 Each of HL7 and Vulcan Member may terminate this SOU upon 60 days written notice.
- 8.2 Vulcan Member will not receive refunds for SOU termination, provided that if Steering Committee disbands Vulcan due to HL7's termination of this SOU and/or Vulcan, any remaining funds will be distributed proportionally, based on membership fees paid by members during the same membership year in which Vulcan is disbanded.
- 8.3 HL7 and Vulcan Member agree in the event of any controversy or claim arising out of or relating to this SOU, or a breach thereof, the parties hereto shall first attempt to settle the dispute through mediation.

9.0 TERM

- 9.1 Each membership year is from July 1 through June 30. The SOU will automatically renew year to year unless either party provides 30 days written notice before the end of the membership year, subject to payment of membership fees, if applicable.

10.0 MISCELLANEOUS

- 10.1 This SOU constitutes the entire agreement and complete understanding of the relationship between HL7 and Vulcan Member.
- 10.2 This SOU can only be amended in writing executed by HL7 and Vulcan Member and only if the amendment is approved by both the Vulcan Steering Committee and an affirmative vote of two-thirds of the Vulcan Members then in good standing. It is expected that any amendment to this SOU will be incorporated into the SOUs between HL7 and other Vulcan Members as well.
- 10.3 Additional collaborations around projects, joint meetings, promotion, educational and marketing activities can be amended to this SOU as opportunities arise.

- 10.4 Vulcan Member may participate in HL7 standards discussions at HL7 workgroups but must be an active member of HL7, in good standing, or pay the current non-member voting fee to vote and participate in proposed standards balloting process.
- 10.5 Vulcan Member and HL7 will discuss and mutually agree to trademark, brand, slogan, and copyright usage policies.
- 10.6 HL7 and Vulcan Member agree that Vulcan is an intended non-party beneficiary of this Agreement and that Vulcan, acting through its Steering Committee, may enforce this Agreement against either Party as if Vulcan were itself a party to this Agreement.
- 10.7 Vulcan public communications shall be coordinated through HL7.

Authorized Signatures:

For HL7 INTERNATIONAL	For [organizational name]
Signed: 	Signed: _____
Charles Jaffe, MD, PhD Chief Executive Officer	[Organization Signatory] Title

Exhibit A: HL7 Services

HL7 will provide the following services as the “Baseline Package” with payment of the Initial Convener Fee or Annual Maintenance Fee.

For the avoidance of doubt, the Baseline Package will be provided by HL7 to Vulcan and, except for the first membership year, will be paid by either Vulcan through the Vulcan project budget or any subsequent Convener willing to pay the Annual Maintenance Fee.

- a. Non-exclusive right to use the HL7 FHIR Accelerator mark (the “Mark”) in connection with its website and other marketing collateral for the purpose of identifying the Vulcan Project as a FHIR Accelerator Member.
- b. Once voted on and accepted by the sponsoring HL7 workgroup, HL7 will make every reasonable effort to facilitate project development and approvals through the HL7 process. HL7 will provide up to four (4) hours per month of navigator/concierge support to facilitate the processing of Vulcan balloted artifacts within the HL7 process. Unused monthly hours do not accrue.
- c. Presentation and/or demonstration opportunities at HL7’s booth at HIMSS each year during the term of this SOU
- d. Access, on par with other FHIR Accelerator Members, to a set of HL7-standard collaboration tools, which include:
 - 1. Shared project workspace/website space on Confluence
 - 2. Issue tracker project on JIRA
 - 3. Individual group chat stream on Zulip – chat.fhir.org
 - 4. Access to an HL7 GitHub repository for source code
 - 5. Conference calling/screensharing: FreeConferenceCall.com

The foregoing access shall be subject to the terms and conditions (as they may be amended from time to time) of each respective tool. For the avoidance of doubt, if the Vulcan Project members do not agree to and comply with a given tool’s terms and conditions, then that Vulcan member it is not authorized to access or use such tool.

- g. Ability to post content for FHIR Implementation Guides on Registry.fhir.org and build.fhir.org accelerator as an HL7 project according to HL7 project and product procedures.
- h. Listing on HL7 website as a HL7 FHIR Accelerator Project on par with other FHIR Accelerator Members.
- i. Recognition in HL7 newsletters, press releases, website, conferences, etc. on par with other FHIR Accelerator Members.
- j. Advance notice of all HL7-sponsored and affiliated events (e.g., connectathons, DevDays, HIMSS demos, FHIR Application Roundtable events, etc.)