



November 22, 2019

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National Institutes of Health  
Department of Health and Human Services (HHS)  
9000 Rockville Pike  
Bethesda, MD 20857

Submitted electronically to: <https://datascience.nih.gov/fhir-rfi-submission>

Re: Request for Information (RFI): Use of the Health Level Seven International (HL7®) Fast Healthcare Interoperability Resources (FHIR®) for Capturing and Sharing Clinical Data for Research Purposes

Dear Dr. Seto:

Health Level Seven (HL7®) International welcomes the opportunity to submit comments on the *Request for Information (RFI): Use of the Health Level Seven International (HL7®) Fast Healthcare Interoperability Resources (FHIR®) for Capturing and Sharing Clinical Data for Research Purposes*.

HL7 is the global authority on healthcare interoperability and a critical leader and driver in the standards arena. The products of our organization provide the underpinnings for connected, patient-centered health care and an information highway for precision medicine. HL7 is a not-for-profit, ANSI-accredited standards developing organization dedicated to providing a comprehensive framework and related interoperability standards, including of course, the rapidly evolving Fast Healthcare Interoperability Resources (HL7 FHIR®), the Consolidated Clinical Document Architecture (C-CDA®), and the widely used V2 messaging standards. HL7 has more than 1,600 members from over 50 countries, including 500+ corporate members representing healthcare consumers, providers, government stakeholders, payers, pharmaceutical companies, vendors/suppliers, and consulting firms.

As the home of FHIR, HL7 greatly appreciates NIH's timely efforts to:

- Collect information about how the FHIR standard could be used by NIH funded researchers to capture and integrate patient- and population-level data from clinical information systems for research purposes;
- Illuminate how to use FHIR as a common structure for sharing research data;

- Better understand researchers' experiences using FHIR, the extent to which researchers plan or do not plan to use FHIR, what tools may be needed to effectively use FHIR; and
- Identify the need for research regarding standards development, and opportunities and challenges with using FHIR.

We provide our comments on the applicability and implications of HL7 standards and other RFI issues below. Importantly, HL7 emphasizes our willingness to work in partnership with NIH and other appropriate federal partners on issues and key use cases at the intersection of FHIR and clinical information systems used for research purposes assuming the needed technical, financial and other appropriate resources are made available. HL7's FHIR Accelerator Program is a viable avenue for collaboration and advancement on the many questions relevant to FHIR and clinical information systems used for research purposes. For example, of direct relevance to this RFI is a proposed HL7 Accelerator Project focused on the use of FHIR in regulated and translational research. HL7 would be happy to discuss this opportunity with you. More information about HL7 Accelerator Programs is available at: <https://www.hl7.org/about/fhir-accelerator/>.

In addition to our leadership and Policy Advisory Committee, HL7 Work Groups contributing to these comments include:

- Community-Based Care and Privacy (CBCP); and
- Security.

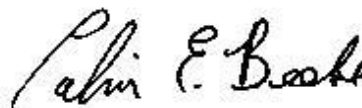
HL7 stands ready to support NIH in using FHIR for capturing and sharing clinical data for research purposes. It is a critical area of growth and capability our organization, the FHIR suite and family of standards and better health in America.

Should you have any questions about our attached comments, please contact Charles Jaffe, MD, PhD, Chief Executive Officer of Health Level Seven International at [cjaffe@HL7.org](mailto:cjaffe@HL7.org) or 734-677-7777. We look forward to continuing this discussion and offer our assistance to NIH.

Sincerely,



Charles Jaffe, MD, PhD  
Chief Executive Officer  
Health Level Seven International



Calvin Beebe  
Board of Directors, Chair  
Health Level Seven International

## Detailed HL7 Comments on NIH RFI: Use of HL7 FHIR for Capturing and Sharing Clinical Data for Research Purposes

The NIH seeks input in eight distinct areas as part of this RFI. HL7 comments on relevant questions are below.

### **Question #1: The application of the FHIR standard to research data, considering: anticipated challenges and opportunities.**

Overall, we emphasize the important research opportunities for granular data access that FHIR provides. FHIR's overall features and capabilities are rapidly expanding and it is therefore essential that NIH, potential users and other relevant parties have a balanced view of maturity and timelines for specific use and implementation approaches. We specifically highlight that the FHIR Bulk Data specification has been published, extensively tested by the FHIR Community and is ready for use in use cases including research. HL7 would be happy to provide such insights in real-time discussions to assist in assessing readiness for intended purposes. HL7 welcomes the participation of NIH and its stakeholders in the continuing development of FHIR, as outlined below.

We note that effective data re-use for research requires sufficient metadata for researchers to evaluate the appropriateness of each data instance. We suggest that NIH work with HL7 to identify the necessary metadata and engage with appropriate federal agencies, including FDA and ONC with its work on the USCDI and similar initiatives, to promote consistent definitions, data capture, and communication for those involved with research initiatives. Collaboration between key public and private sector players, such as professional societies focused on research, is also vital here to encourage collaboration across stakeholders.

### **Question #4: Additional routes by which NIH can encourage the development and use of FHIR for research purposes.**

NIH can encourage the development and use of FHIR for research purposes by prioritizing use of FHIR in applicable research solicitations and grant scoring. To support such a focus, NIH will need to develop a deeper understanding of FHIR as well as educational resources for applicants. HL7 can be a source, partner, home, hub, and catalyst for such work. HL7 emphasizes our willingness to work in partnership with NIH and other appropriate federal partners on issues and key use cases at the intersection of FHIR and clinical information systems used for research purposes, assuming the needed technical, financial and other appropriate resources are made available. HL7's FHIR Accelerator Program is also a viable avenue for collaboration and advancement on the many questions relevant to FHIR and clinical information systems used for research purposes. For example, of direct relevance to this RFI is a proposed HL7 Accelerator Project focused on the use of FHIR in regulated and translational research. HL7 would be happy to discuss this with you. More information about HL7 Accelerator Programs is available at: <https://www.hl7.org/about/fhir-accelerator/>.

In order to illuminate an impactful, expeditious path for HL7 to assist and collaborate with NIH in achieving the priorities outlined in this RFI, HL7 is willing to outline relevant tools, resources and expert knowledge our organization possesses and can provide to accomplish NIH's highlighted objectives with available funding.

HL7/NIH collaboration to accelerate health innovation with FHIR and clinical research could potentially include:

- Leveraging additional NIH subject matter expertise, and NIH financial support, for these efforts;
- Ongoing HL7 facilitation and project management/coordination;
- Increasing NIH participation in and support of HL7 Connectathons to accelerate and mature relevant standards and specifications;

- NIH and HL7 convening germane stakeholders and providing leadership to enable broader access to FHIR and all relevant information resources and facilitation across all the stakeholders;
- NIH expanding the scope of HL7 Accelerator projects by contributing human and financial resources;
- Use case and implementation guide development, pilot tests and evaluation of pilots, including those that can provide feedback to refine relevant implementation guides. Conformity assessment mechanisms and education will also be needed.
- It would be helpful for NIH to facilitate participation of more clinical researchers in the standards development process overall.

HL7 applauds NIH in advancing the use of the FHIR specification in the emerging NIDDK Multiple Chronic Conditions (MCC) eCare Plan project that will develop and test an open-source SMART on FHIR-based eCare plan application and develop a supporting FHIR Implementation Guide through the HL7 process. HL7 believes existing FHIR CarePlan related resources can readily be used to facilitate the transfer of patient care plan data and support the use and aggregation of the data for Patient-Centered Outcomes Research.

**Question #5: Ethical, privacy, and security considerations when using FHIR to share research data.**

HL7 notes it has developed [Research Security Labels](#), which would enhance the ability to control access and research purposes for which FHIR-based research data are used. These labels can be used to convey choices made by study subjects in their HIPAA Authorizations for Research Disclosures and for Informed Consent. HL7 has also developed Research Purpose of Use codes, which can be used to label data. These codes are based on the restrictions regarding the type of research for which access to research repositories is granted, which are now handled manually. They were developed in concert with the Global Alliance for Genomic Health (GA4GH) to align with the GA4GH Consent Codes. Our HL7 privacy and security experts are available to review research security labels in-depth with NIH.

**Question #6: Tools that would assist NIH funded researchers in advancing identified opportunities using FHIR.**

Regarding the question of tools that would assist NIH funded researchers in advancing identified opportunities using FHIR, HL7 points to the utility of:

- FHIR Implementation Guides applicable to the research project. A dynamic listing of FHIR implementation guides is at <https://registry.fhir.org/>. Our HL7 experts are also available to discuss any more specific issues with you.
- Apps and modules that could connect EHRs and other data sources using SMART on FHIR [\[http://www.hl7.org/fhir/smart-app-launch/\]](http://www.hl7.org/fhir/smart-app-launch/);
- Exploring how the US Core Implementation Guide can give clinical researchers a starter set of information they need and be designed for helpful, effective consumption. More information and resources on the US Core Implementation Guide can be found at: <https://www.hl7.org/fhir/us/core/>; and
- Access to the rapidly expanding and dynamic FHIR Community of experts, along with a rich set of open source tools and code for working with FHIR.

**Question #8: Any other topic which may be relevant for NIH to consider in encouraging the use of the FHIR standard for research and to facilitate the interoperability of research data.**

One powerful way NIH could encourage the use of the FHIR standard for research and facilitate the interoperability of research data with healthcare is to create a common boiler-plate language on use of FHIR in capturing and sharing clinical data for research purposes, to be included in all future relevant federal NIH proposals and requirements. NIH could also directly sponsor connectathons, hackathons, demonstrations and competitions to encourage development of research-focused apps and tools based on FHIR.