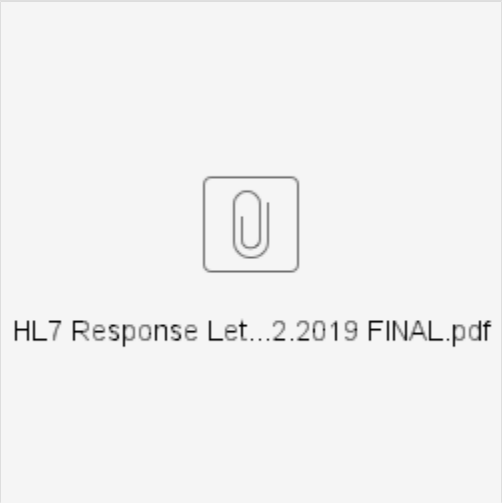
NIH RFI: HL7 FHIR Interoperability Resources for Capturing and Sharing Clinical Data for Research Purposes

HL7 Policy Advisory Committee submitted comments



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

Notice Number: NOT-OD-19-150

Key Dates
Release Date: September 24, 2019
Response Date: November 23, 2019

Related Announcements

NOT-OD-19-122
NOT-OD-19-127
NOT-OD-19-014
NOT-OD-18-134

Issued by
National Institutes of Health (NIH)

Purpose

This Request for Information (RFI) is to solicit public input on how the Health Level Seven International (HL7®) Fast Healthcare Interoperability Resources (FHIR®) standard[1] could be used to capture, integrate, and exchange clinical data for research purposes and to enhance capabilities to share research data.

Background

Once research is approved and compliant with human subjects protections, use of FHIR can accelerate the use of clinical data for research. FHIR is a standardized way of transmitting health data from one health information system to another through an application programming interface (API). Use of a standard such as FHIR could accelerate the use of clinical data for research. In addition, FHIR provides a way to structure data generated from research in a manner that fosters interoperability and interchange of both research and clinical data. FHIR benefits from relative ease of implementation, availability of open source implementation tools, considerable industry support, and an American National Standards Institute (ANSI) consensus development process. It is also compatible with analytic resources used in biomedical research, such as R and Python.

Several Federal health agencies are promoting the use of FHIR in electronic health record (EHR) systems. The 21st Century Cures Act requires that a health information technology (IT) developer or entity "allow health information… to be accessed, exchanged, and used without special effort through the use of application programming interfaces (APIs)… including providing access to all data elements of a patient's electronic health record." [2] To implement this provision, the Department of Health and Human Services, Office of the National Coordinator for Health Information Technology (ONC) has proposed a new rule to support seamless and secure access, exchange, and use of electronic health information. [3] Specifically, the proposed rule calls on the health care industry to adopt standardized APIs by using the FHIR standard to share patient data.

Concurrently, the Centers for Medicare & Medicaid Services (CMS) released a proposed rule with requirements for Medicaid, the Children's Health Insurance Program, Medicare Advantage plans, and Qualified Health Plans in the federally-facilitated Exchanges to provide enrollees with immediate electronic access to medical claims and other health information electronically by 2020 by adopting and implementing openly published APIs. [4] CMS would also require these health care providers and plans to implement open data sharing technologies that are consistent with the FHIR standard in ONC's notice of proposed rulemaking (NPRM). Both the ONC and CMS NPRMs also support the use of specific content and vocabulary standards to achieve interoperability.

FHIR is already broadly used in health care. As of mid-April 2019, approximately one third of health IT developers certified under the 2015 Edition [5] of ONC's Health IT Certification Program published that they are using a FHIR API [6] . It is estimated that approximately 96% of hospitals and 74% of clinicians have EHR systems with some FHIR API capabilities. In addition, federal agencies are using FHIR to exchange data. For example, CMS developed the BlueButton 2.0 FHIR API to enable exchange of claims data with software applications [7] . Payors, including CMS, and providers are working together to automate data sharing using FHIR under the Da Vinci Project [8] . The broader IT sector has also begun adopting FHIR, for example, to enable individuals to import their health records from providers' EHR systems or to support the uploading of data to cloud-based services. Pharmaceutical companies are active in FHIR development efforts [9] , including to use FHIR to integrate clinical trial management with EHRs [10] .

The respective interoperability goals of the NPRMs issued by ONC and CMS align with and facilitate many of the objectives asserted in the NIH Strategic Plan for Data Science [11] , as well as NIH's long-term policy goals for data management and sharing [12] . Additionally, in its 2017-2027 Strategic Plan, [13] NLM proposes technical and scientific advances to ensure that research data are Findable, Accessible, Interoperable and Re-usable (FAIR). [14] As with all NIH-funded or supported research involving human participants, and as is currently the expectation in using FHIR, investigators must obtain participant consent and following applicable national, tribal, and state laws and regulations, as well as relevant institutional policies, for the protection of human subjects.

On July 30, 2019, NIH issued a notice (NOT-OD-19-122) to encourage NIH-funded investigators to explore the use of FHIR to capture, integrate, and exchange clinical data for research purposes and to enhance capabilities to share research data. In addition, NIH issued a notice (NOT-OD-19-127) to small business communities that announces NIH's special interest in supporting applications that use FHIR in the development of health IT products and services.

Information Requested

NIH is requesting input on 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 and to use it as common structure for sharing research data. In particular, NIH would like to 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, the need for research regarding standards development, and opportunities and challenges with using FHIR. The NIH seeks comments on any or all of the following topics:

1. The application of the FHIR standard to research data, considering:
    a. Anticipated challenges
    b. Anticipated opportunities
2. Current experiences of researchers using FHIR, including where researchers are depositing their data once FHIR-enabled, and extent to which researchers plan or do not plan to use FHIR
3. Current experiences of researchers not using FHIR and reasons for not using it
4. Additional routes by which NIH can encourage the development and use of FHIR for research purposes
5. Ethical, privacy, and security considerations when using FHIR to share research data
6. Tools that would assist NIH funded researchers in advancing identified opportunities using FHIR
7. Ways NIH can stimulate research into FHIR-related standards development
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

Submitting a Response

Comments should be submitted electronically to the following webpage: https://datascience.nih.gov/fhir-rfi-submission

This RFI is for planning purposes only and should not be construed as a policy, solicitation for applications, or as an obligation on the part of the Government to provide support for any ideas identified in response to it. Please note that the Government will not pay for the preparation of any information submitted or for its use of that information.

Responses may be compiled and shared publicly in an unedited version after the close of the comment period. Please do not include any proprietary, classified, confidential, or sensitive information in your response. The Government reserves the right to use any non-proprietary technical information in summaries of the state of the science, and any resultant solicitation(s). The NIH may use information gathered by this RFI to inform development of future guidance and policy directions.

We look forward to your input and hope you will share this RFI with your colleagues.

Inquiries

Please direct all inquiries to:

Belinda Seto, PhD
Office of Data Science Strategy
National Institutes of Health
Email: FHIRRFI@nih.gov

References

1 https://www.hl7.org/fhir/overview.html

[2] Section 4002(D)(iv) of the 21st Century Cures Act (P.L. 114 – 255)

[3] https://www.federalregister.gov/documents/2019/03/04/2019-02224/21st-century-cures-act-interoperability-information-blocking-and-the-onc-health-it-certification

[4] https://www.federalregister.gov/documents/2019/03/04/2019-02200/medicare-and-medicaid-programs-patient-protection-and-affordable-care-act-interoperability-and

[5] https://www.healthit.gov/topic/certification-ehrs/2015-edition

[6] https://chpl.healthit.gov/#/search

[7] https://bluebutton.cms.gov/

[8] http://www.hl7.org/about/davinci/

[9] https://transceleratebiopharmainc.com/esource-connectathon-challenge-recap/

[10] https://www.healthleadersmedia.com/innovation/ochsner-and-pfizer-constructing-digital-superhighway-clinical-trials

[11] https://datascience.nih.gov/news/nih-releases-strategic-plan-data-science

[12] https://osp.od.nih.gov/scientific-sharing/nih-data-management-and-sharing-activities-related-to-public-access-and-open-science/

[13] https://www.nlm.nih.gov/pubs/plan/lrp17/NLM_StrategicReport2017_2027.html

[14] https://www.force11.org/group/fairgroup/fairprinciples