



November 21, 2019

Dr. Susan Gregurick

Associate Director for Data Science (ADDS)

Director of the NIH Office of Data Science Strategy (ODSS)

Notice Number: NOT-OD-19-150

Submitted electronically to FHIRRFI@nih.gov and via form at <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

Dr. Gregurick:

The American Medical Informatics Association (AMIA) appreciates the opportunity to provide input on this Request for Information (RFI) on the use of the Health Level Seven International (HL7) Fast Healthcare Interoperability Resources (FHIR) for capturing and sharing clinical data for research purposes.

Informatics is the science of how to use data, information, and knowledge to improve human health and the delivery of health care services. AMIA is the professional home for more than 5,500 informatics professionals, representing frontline clinicians, researchers, public health experts, and educators who bring meaning to data, manage information, and generate new knowledge across the research and healthcare enterprise. AMIA members advance health and wellness by implementing and evaluating informatics interventions, innovations, and public policy across settings and patient populations, adding to our collective understanding of health in the 21st century through peer-reviewed journals and scientific meetings.

AMIA is encouraged by NIH efforts to understand how FHIR-based clinical data may be used for research, and we anticipate that the characteristics and capabilities of FHIR will enable rapid advancement towards the goal of maximizing the use of EHR-based clinical data for a wide variety of research.¹ In time, we anticipate that FHIR will also be a great enabler of research by representing consents/permissions and questionnaires electronically,² as well as help facilitate learning health systems by integrating interoperable knowledge assets back into care delivery workflows.³ Given the

¹ In the context of this response, research refers primarily to the kind of research funded by the NIH. However, health services and patient-centered outcomes research, as well as various types of public health research and post-market surveillance funded by other federal entities also stand to benefit greatly by FHIR. [Flat FHIR or Bulk Data Access](#) may help provide better access to clinical data for research.

² Such as the [Research Consent Directive](#) and [Questionnaire Resource](#),

³ Such as clinical research evidence and clinical practice guidelines, e.g. [EBMonFHIR](#)

November 21, 2019

direction of ONC and CMS rulemaking,^{4,5} and the standards development infrastructure established and maintained by HL7,⁶ it is likely that FHIR will become the standard for exchange of most common categories of clinical data over the next two to three years.⁷ However, we note that this vision for the use of FHIR is distant and in need of federal support.

Today, most clinical data used for research is extracted from EHRs, transformed, and then made available for research. The variable implementation of EHRs and the idiosyncratic mappings of clinical data within EHRs have a cascading effect on data quality for research and this challenge will not be obviated by FHIR. Different EHR developers are using different versions of FHIR and even within the same version of FHIR, there may be varying degrees of consistency and constraints applied to the same FHIR Resource across implementations. Until there is more uniformity in how EHRs generate clinical data using FHIR, those data will need a high degree of additional, potentially manual, curation, and data quality will remain a central constraint to fully appreciate FHIR's capacity to be used for research. The current version of FHIR allows extraction of data for a single patient at one time. A large number of research use cases call for analyzing data from a larger population of patients. A new set of capabilities in FHIR, referred to by HL7 as "bulk FHIR," is currently being developed, but has not reached the standard stage. Adoption of "bulk FHIR" by the vendor community is essential to fulfilling the promise of FHIR as a way to democratize clinical data for research. Finally, there are also a host of technical, policy, and operational challenges to the widespread use of FHIR for research (see comments [in the attached table](#) for more discussion on challenges and opportunities).

Despite these current limitations, it is imperative that NIH take a position of leadership to coordinate research and development (R&D) efforts for using FHIR for funded research. **AMIA strongly recommends the NIH devote substantial resources to develop a strategy and a framework for FHIR R&D to maximize the utility and secondary use of EHR data for research and to encourage the development of clinical informatics innovations aimed at improving care.** By working through the established standards maturity model progressions and balloting processes of HL7, this strategy and framework for FHIR R&D should result in FHIR Resources, FHIR Profiles, FHIR Implementation Guides (IGs), to facilitate a broad range of research using clinical data. AMIA recommends the NIH focus on three categories of activity, including the use of FHIR to:

1. Facilitate access to clinical data for research, such as by supporting development of bulk access to clinical data;
2. Enable clinical research using FHIR, such as refinement of the Consent Resource and development of Privacy Labels; and
3. Translate clinical evidence back into practice, such as efforts to use FHIR for clinical guidelines.

⁴ ONC Proposed Rule (available [here](#)) would require 15 categories and 50+ data elements currently part of the Common Clinical Data Set to be encoded using FHIR standards by all certified EHRs

⁵ CMS Proposed Rule (available [here](#)) would require certain claims data to be available via API

⁶ HL7 is the SDO responsible for development and stewardship of FHIR and the associated implementation guides. It also manages the FHIR Accelerator program, with details available here: <http://www.hl7.org/about/fhir-accelerator/>

⁷ Proposed rules by ONC and CMS would require the use of FHIR by both certified EHRs and the providers who use them by 2022.

November 21, 2019

AMIA recommends the NIH execute this strategy by directly funding FHIR R&D through grants; indirectly through special emphasis notices and project requirements that favor / prioritize projects that will use FHIR; and by educating the research community and help represent the research community in activities supported by ONC, HL7, and other SDOs with interest in FHIR.

Directly fund FHIR R&D

AMIA recommends the NIH continue efforts to fund, develop, and improve FHIR standards through various means. For example, the NIH could support research communities through grants to find consensus on domain or disease specific data elements. These efforts should result in development of specified FHIR Profiles to reduce overall variation for specific kinds of research and improve the availability of clinical data for population management, clinical decision support, quality measurement, and other use cases. Such convening could also fund development of a common Research Profile specification to avoid having to implement many different APIs to suit the desires of study sponsors. Additionally, the NIH should fund R&D to promote the capture of data in FHIR, rather than post-hoc mapping, which can introduce error and lead to the loss of granularity and nuance. Specifically, R&D should focus on what approaches to capturing clinical data in FHIR will better ensure data accuracy and facilitate reproducibility. Finally, the NIH could support the mapping of data elements in the NLM Common Data Element (CDE) portal⁸ into FHIR. It is likely that this exercise can stimulate research communities to better define CDEs and create a process to determine where new FHIR Resources and Profiles are needed. The NIH could also take a lead role in refining the existing Consent Resource⁹ and Security Labels.¹⁰ These will be foundational to facilitate research using FHIR.

The above notwithstanding, we note that the NIH must be cognizant of the need to harmonize with existing Common Data Models (CDMs). Extraordinary resources have been deployed for several widely adopted CDMs. Each have somewhat differing research applications across CDMs, such as OHDSI OMOP, PCORnet, i2b2 ACT/SHRINE, and Sentinel, among others. The NIH should directly fund efforts to understand how FHIR may complement these CDMs, where appropriate. In addition, we note that “bulk FHIR” can be deployed instead of the tradition methodology for extracting the data from the EHRs, transforming the process to the modern API-based approach and improving data availability for research, while enhancing data quality. We recommend direct funding to investigate how FHIR can and should be used within the context of these research networks and data models.

Indirectly fund FHIR R&D

Beyond direct funding, AMIA recommends the NIH indirectly support and encourage FHIR R&D through special emphasis notices and through project evaluation guidelines. For example, NIH-funded projects could be encouraged, or even required, to provide their open datasets mapped to

⁸ <https://www.nlm.nih.gov/cde/index.html>

⁹ ONC has issued a grant to help refine the [Consent Resource](#). More information [here](#).

¹⁰ Security Labels enable more data to flow as they enable policy fragments to accompany the resource data. Available here: <https://www.hl7.org/fhir/security-labels.html>

November 21, 2019

FHIR as part of the emphasis on FAIR data in the Data Science Strategy. The NIH could coordinate with other federal partners, such as the CDC or the FDA as they accept EHR data in support of public health surveillance and device/drug applications, to encourage standards adoption. A preference of NIH funding could be to have researchers identify which FHIR profiles they will be using for their projects, for example. Such promotion could be part of the forthcoming Data Management and Sharing Policy.

Educate and help represent the research community in ONC, HL7, and other SDO activities

Given the size and reach of the NIH, it could be a prominent stakeholder to educate the research community on the benefits and known limitations of FHIR. It could be useful for NIH to sponsor the development of an informative document that lays out high-priority use cases for research and identifies FHIR capabilities that could be used to support those use cases. Informative documents are a part of the HL7 portfolio of standard artifacts, so there is already a standard process to create and publish such informative documents within HL7. In addition to HL7, the NIH could coordinate with CDISC to define scope and strategy to ensure that data elements which are being used in regulatory reporting have appropriate FHIR representations. Finally, the NIH should dedicate experts to work with ONC to encourage and/or support further capabilities for certified EHRs, such as the capability for bulk data export.

We hope our comments are helpful as you gather more information in this important area and as we advance towards the shared goal of maximizing EHRs for research. Should you have questions about these comments or require additional information, please contact Jeffery Smith, Vice President of Public Policy at jsmith@amia.org or (301) 657-1291. You may also reach out directly to our members who assisted in this response below. We look forward to continued partnership and dialogue.

Sincerely



Douglas B. Fridsma, MD, PhD, FACP, FACMI
President and CEO
AMIA

November 21, 2019

We wish to acknowledge the following AMIA Member Respondents:

Tom Caruso, PhD, MBA, PMP T.P. Caruso & Associates	Thomson Kuhn American College of Physicians
Arjun Chatterjee, MD, MS, FACP, FCCP, FAASM Wake Forest University School of Medicine	Russell Leftwich, MD InterSystems
Christopher Chute, MD, DrPH Johns Hopkins University	Sameer Malhotra, MD, MA Weill Cornell Medicine
Catherine Craven, PhD, MA, MLS, FAMIA Mount Sinai Health System	Ben Orwoll, MD, MS, FAAP Oregon Health & Science University
Guilherme Del Fiol, MD, PhD University of Utah	John Osborne, PhD University of Alabama at Birmingham
David Dorr, MD Oregon Health & Science University	Matvey Palchuk, MD, MS, FAMIA TriNetX, Inc.
Dan Fort, PhD, MPH Ochsner Health System	Vasiliki Rahimzadeh, PhD Stanford University
Harry Hochheiser, PhD University of Pittsburgh	Rachel Richesson, PhD Duke University
	Jessica Tenenbaum, PhD Duke University

Enclosed: AMIA Response to NIH RFI on FHIR

November 21, 2019

Preface to RFI Response

In 2016, AMIA convened a group of members who were expert in health data standards and interoperability to develop Principles and Positions describing the desired characteristics of data standards for care and research.¹¹ Among these are that such data are “modular and substitutable, have clear boundaries for use and application, with specifications for automated access, use, and integration;” that they “leverage existing information technology stacks, such as the Internet Protocol Suite;” that they are “simple, parsimonious, and include documentation that is complete, comprehensible, readily available, and contemporaneous.” FHIR is a more granular data standard, which is comprised of building blocks that leverage RESTful protocols, consistent with the modern web architecture. This allows specific clinical data elements to be shared via application programming interfaces (APIs), rather than the entire Consolidated Clinical Document Architecture (C-CDA) via Simple Mail Transfer Protocol (SMTP).

In addition to these desiderata, these Principles and Positions also articulated the importance of governance, testing, and multi-stakeholder standards development. “To ensure the consistency and comparability of biomedical and clinical data, health IT standards must have coordinated development, open participation, and transparent governance,” the principles note with corresponding positions of support for “The development and management of health IT standards as a public good, operated in a nonprofit, non-proprietary basis, with low barriers to review, reference, or use,” and a standards development process that “incorporates implementation experience and feedback loops from real-world settings...” Finally, we note that health IT systems should be tested for both conformance to the standard and interoperability of the standard, which entails testing both the sending of data using a specific standard(s) as well as receipt of data using the same standard(s), and testing adherence to Postel’s Principle. Through a combination of processes and governance principles, FHIR has been adopted more widely and more quickly than previous efforts. This is due to the processes established by HL7 and due to the iterative development and testing cycle that occurs between standards developers, health IT developers, and health IT implementors.

Today, nearly every hospital and physician office has a certified EHR, which presents the research enterprise with a first-in-history opportunity to leverage real-world data from real-world patients. Compared to the latent opportunities our digital transformation to EHRs presents, experience to-date in using EHRs for research has been limited. EHR data is inconsistently structured, difficult to access, and of varying quality for research purposes. Progress to improve EHR data and EHR-derived research data has been hindered by (1) legacy data standards that are inconsistently implemented and insufficiently granular and (2) rigid information models that are complex to manage and require specialized clinical workflows to answer limited research questions. However, the widespread adoption of FHIR may present us with an opportunity to improve this infrastructure at the point of data collection.

¹¹ Health IT Data Standards & Interoperability Policy Principles: <https://www.amia.org/sites/default/files/2018-2019-AMIA-Health-Informatics-Policy-Priorities.pdf#page=14>

November 21, 2019

FHIR is a more granular, parsimonious, substitutable, and modular data standard with which to conduct research. It enables easier query of specific data elements within a patient record, rather than the entire record, and leverages RESTful protocols that enable the use of application programming interfaces, or APIs, to access data in real-time. The quality of data generated using FHIR is also improved given better implementation guides with less ambiguous, better standardized syntax and better terminology bindings to improve semantics.

Despite our enthusiasm for FHIR, the benefits of FHIR for research remain largely theoretical. In the future when all EHRs are certified to send and receive common clinical data represented as FHIR Resources and Profiles, we believe there will be tremendous benefit to both regulated and observational research and – eventually – the learning health system. Of immediate concern, however, is that of implementation variability and idiosyncratic mappings by EHRs, which have a cascading effect on data quality for research. Today, different EHR developers are using different versions of FHIR and within the same version of FHIR, there may be varying degrees of consistency and constraint applied to the same FHIR Resource across implementations. Lastly, FHIR today is incapable of efficiently delivering the data on a population of patients – data can only be obtained one patient at a time. Until there is more uniformity in how EHRs generate clinical data using FHIR, those data will need a high degree of additional, potentially manual, curation.

Below, we provide feedback to the NIH questions as developed over several weeks in October and early November 2019. More than 30 AMIA members participated in the develop of this response from more than a dozen organizations, representing clinical, academic, research, and industry viewpoints.

November 21, 2019

NIH Question	AMIA Member Response(s)
<p>The application of the FHIR standard to research data, considering:</p> <ul style="list-style-type: none"> ● Anticipated challenges ● Anticipated opportunities <p>AMIA members identified several opportunities and challenges with using FHIR. Generally, there is mixed experience in having support for EHR-based research from EHR developers and local EHR implementations have varying architectures and do not support all available FHIR Resources (or the latest versions of FHIR). There is also concern about the current inability to retrieve data from many patients at once (i.e. bulk data access).</p> <p>AMIA members also identified a great deal of opportunity with more widespread and normalized use of FHIR for clinical data. They noted that several FHIR characteristics, such as the use of RESTful transport, and use of Implementation Guides with better terminology binding make the standard more usable and therefore more implementable. They view FHIR is a substantial improvement over prior HL7 messaging standards v2 and v3, but it's not</p>	<ul style="list-style-type: none"> ● Challenge: Technical/database/architectural - using FHIR to move one patient's chart around is fine. Doing so for all patients in an institution will result in a significant performance impact on transactional systems that underlie the EHR. They are not designed for these types of queries. This means that the implementation of bulk FHIR by vendors will not be trivial. Another major reason it will be slow is that vendors will not be tremendously willing without regulatory requirements. ● Challenge: The FHIR security model (to the extent it is being developed by HL7 and others in the FHIR community) is not capable of providing consistent protections for discrete data elements ● Challenge: Limitations in discrete data in EHR and potential requirement to build data capture tools in EHR for API reporting purposes ● Challenge: Current architecture requires serial calls to different resources to perform the equivalent of a JOIN statement with filtering and processing done on the client side. Therefore, even very restricted data questions (i.e. observations from a specific encounter) expose a great deal of information (all encounters for that patient). ● Challenge: some of the current EHR FHIR implementations adopt an all-or-nothing security approach. A client application that is authenticated against a FHIR server/API will have access to all FHIR resources supported by the API, for any timeframe, and from any patient in the EHR.

November 21, 2019

<p>just the standard itself, it is the approachability of the standard and the capacity to test applications iteratively.</p> <p>Additional opportunities for FHIR include enabling interoperability of data that is not in the EHR, such as from social determinants of health and Internet of Things devices, structured data capture from both clinicians and patients, and making clinical trials/protocols more computable.</p>	<ul style="list-style-type: none"> ○ Addition here: many FHIR servers use Oauth2 for authentication/authorization processes - the number of currently supported contexts/roles is too limited to provider granular access control ● Challenge: current FHIR implementations do not impose constraints on the volume of data potentially returned by queries submitted by a client application (e.g., a client can request all lab results from a patient), which can result in significant load on the transactional FHIR server. ● Challenge: FHIR does not solve semantic interoperability. Different vendors are supporting different versions of FHIR and the core FHIR standard is still being changed at a fast pace. Second, there is wide variability in the FHIR resources that each vendor supports. Third, since most attributes within resources are optional, there is wide variability in the resource attributes that are supported. The same is true for FHIR queries. Fourth, support for standard terminologies is mostly loosely defined. FHIR profiles are being developed to address these issues, but there is rising concern about the proliferation of profiles, which could lead to even more variability in terms of levels of FHIR support across FHIR implementations. ● Challenge: New FHIR profiles need to be created for ‘omics data. Different types of ‘omics data will require different profiles to be interoperable with laboratories that are generating these datasets for patients and in pre-clinical setting. ● Challenge: More tooling in necessary to use FHIR. For example, mapping FHIR to OMOP to support use of OMOP based tools for observational studies.
--	--

November 21, 2019

	<ul style="list-style-type: none"> ● Challenge: Availability of the EHRs FHIR support for commercial purposes through their application/approval models (e.g., Epic’s App Orchard). ● Challenge: Of the about 150 FHIR Resources that currently exist, more than 100 are still in relatively immature state. This includes resources such as the FHIR Evidence resource (EBM) and FHIR Library resource. ● Opportunity: replace ETL with API. Significantly less effort and, therefore, more <i>implementable</i>. ● Opportunity: improvement on HL7v2 in both syntax (less ambiguous, better standardized structures) and semantics (better terminology bindings) ● Opportunity: Improved efficiency and accuracy in data capture and reporting to sponsors replacing manual data entry methods. ● Opportunity: Construct of standards and open source reference implementations to lessen vendor dependency and vendor data lock in. ● Opportunity: despite the non-trivial challenges above, FHIR is based on a foundation of widely adopted standards (e.g., REST Web services) and provides an initial common ground that is much simpler and easier to implement than previous approaches based on HL7 v2 and v3. Additionally, workforce of skilled developers/analysts who are able to work with standardized/REST APIs is large and can be drawn from worldwide pool through telework. ● Opportunity: there are excellent publicly available and vendor-specific sandbox resources, including sandbox FHIR servers, with lots of sample FHIR data and tools that allow developers to easily create FHIR data. This makes it a lot
--	--

November 21, 2019

	<p>easier to teach FHIR and for developers to develop/test their applications.</p> <ul style="list-style-type: none"> ● Opportunity: FHIR resources, in parallel with US Core Implementation Guide, can provide a basis for a canonical form for interoperability. This matters to research as one could then support scalable federated query. ● Opportunity: Creating Bots that use FHIR to explore health records for research opportunities without threat to privacy or security of the data, since the Bot would be looking for and reporting on trends not specific data. Bots could also be used to determine the quality of data across a research network, notifying researchers where data quality needs to be addressed. Consider as an example a Bot looking at particular data elements – for example sex - to determine patterns being used for the coding of this element, and to help a research network standardize around that code set for that data element. Bots could work across multiple health systems with the health system approving their use with their data, and on the types of data that can be used by the Bots. Bot reports would be provided back to the health systems, and health systems could potentially get financially rewarded for allowing Bots to access them, or health systems may only be allowed into a clinical research study if they allow specific Bots to check the quality of that health system’s data.
<p>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.</p> <p>See direct quotes in next cell.</p>	<ul style="list-style-type: none"> ● “We are currently implementing FHIR API Epic EHR to REDCap, working through HIPAA concerns and also heavy lift of mapping data elements between EHR and each REDCap research project. Have already been asked by a sponsor to implement another FHIR API for one specific research study. I’m concerned that sponsors will develop their own or will require use of an API and we will eventually have many different APIs installed and having to be maintained/supported all essentially doing the same thing.” ● “Currently implementing FHIR to support clinical data transfer for clinical trials. Largest concern is data governance / working within current limitations

November 21, 2019

	<p>to only query specific data elements for specific encounters while acknowledging client has access to all data on each authorized patient.”</p> <ul style="list-style-type: none"> ● “We are extracting FHIR data in bulk for hundreds of thousands of patients to identify those who meet family history-based criteria for hereditary cancers. We had to develop FHIR adaptors over our EHR's proprietary APIs for FHIR resources that were not natively supported, such as FamilyHealthHistory. We also had to deploy these adaptors at two academic medical centers that serve as study sites. This may become a common pattern until EHR support for FHIR becomes more comprehensive and consistent across vendors. We also had to create infrastructure to be able to pull FHIR data in bulk.” ● “We have REDCap FHIR in production. Yes, privacy approval was challenging, but with the proper implementation, I don’t foresee many privacy challenges as what you can get via FHIR is directly tied to your EHR rights.”
<p>Current experiences of researchers not using FHIR and reasons for not using it.</p>	<ul style="list-style-type: none"> ● Use case mismatch - current FHIR supports one patient at-a-time data extraction. Researchers need data on multiple patients - bulk FHIR, which has its own issues. This use case is very demanding and complex. Alternatively, one can pull patients one at a time using a list with current version of FHIR, but at a population level, using a list with FHIR is not feasible. ● Some healthcare institutions not familiar with FHIR in the context of research, but rather only applications where data is needed for a single patient. ● Organizations are now using FHIR for pushing out data, but not receiving data. There are research data that would make sense to push to EHRs (e.g. whether a patient is on a study or had a safety event or some study data to share to EHR), but health care organizations are generally not prepared to receive this data. We thus Need policies around it and guidance for where and how it should be labeled and added.

November 21, 2019

<p>Additional routes by which NIH can encourage the development and use of FHIR for research purposes.</p>	<ul style="list-style-type: none"> ● Continue efforts to fund/develop/improve standards. NIH could support research communities through meeting grants to reduce variation and come to consensus on domain or disease specific data elements, including those already specified within major existing Common Data Models (CDM), which have been optimized for somewhat different research uses, with resulting differing levels of granularity for different elements. These activities would be strengthened by having disease experts thinking about population management, CDS, quality measurement, and other use cases for relevant FHIR resources. ● NIH could support the mapping of data elements in the NLM CDE browser into FHIR. Some can be straight forward, but it is likely that this exercise can stimulate research communities to better define the CDEs. NIH-funded projects could be encouraged or even required to provide their open datasets mapped to FHIR. ● Encourage capturing data to official standards. Along with improving standards, promote the need to capture data directly to these standards in the primary systems, rather than post-hoc mapping; this is fraught with error and loses granularity and nuance. ● Encourage development of a standard research FHIR profile, so as to avoid having to implement many different APIs to suit the desires of study sponsors ● Population of reference HAPI FHIR implementation with real de-identified data sets, including text documents, for testing purposes and clinical/biological shared tasks in NLP, ML, and other areas. Perhaps collaboration with MIMIC data set folks. ● Encourage and/or support further development of bulk FHIR data export approach that addresses several of the challenges listed above. Coordinate with
--	---

November 21, 2019

	<p>ongoing efforts and research projects currently funded by ONC to investigate bulk FHIR data export.</p> <ul style="list-style-type: none"> • Coordinate with CDISC to define scope and strategy to ensure that data elements which are being used in regulatory reporting have appropriate FHIR representations. Secondary users should also be able to find these representations. • Fund and support the development of tools that can create FHIR datasets and consume them for analysis. • An important barrier to using FHIR for research is educating researchers about the capabilities of FHIR that could be relevant for research. It could be useful for NIH to sponsor the development of an informative document that lays out high-priority use cases for research and identifies FHIR capabilities that could be used to support those use cases. Informative documents are a part of the HL7 portfolio of standard artifacts, so there is already a standard process to create and publish such informative documents within HL7. • NIH should support the development and accessibility of FHIR sandboxes to foster development of FHIR for research. • Promote the development of tools and standards that will simplify the development of clinical decision support rules, and other extensions that might use FHIR to add functionality to the EMR. Support efforts such as CDS Hooks and other approaches that will enable integration of FHIR-based apps into clinical workflows.
<p>Ethical, privacy, and security considerations when using FHIR to share research data.</p>	<ul style="list-style-type: none"> • Challenge: Patient privacy - Current FHIR specs do not include de-identification capabilities. Will FHIR client have to implement de-identification features? Each implementation has its own local assumptions about what it

November 21, 2019

	<p>means to de-identify. What criteria and/or conditions must be met for data re-identification to be permissible?</p> <ul style="list-style-type: none"> ● Challenge: Ensuring proper tracking of disclosures related to use of data over time and disease course for research purposes under HIPAA. This is especially key for data capture involving children, who may have to be re-consented at the age of maturity. ● Technically difficult to achieve sufficiently granular control over certain data elements. FHIR standard currently does not address this. ● Must ensure proper tracking of data disclosures per HIPAA. ● FHIR is designed to make access and transfer of all data on an authorized patient extremely easy. For studies which intersect production EHRs, reasonable access restrictions rely on the good faith of the client in <i>not</i> simply querying everything.
<p>Tools that would assist NIH funded researchers in advancing identified opportunities using FHIR.</p>	<ul style="list-style-type: none"> ● Financially support, and thus guide cooperation, with the existing NIH-funded CD2H efforts to curate an index of such “identified opportunities,” e.g. demo servers, educational materials, existing proof-of-concept projects, new calls for funding, language by which to discuss the FHIR-for-Research efforts with CTSA PIs, and other internal decision-makers, who may or may not be conversant with FHIR and Common Data Model (CDM) topics. This will serve change management and sustainability. NIH can also work with the CD2H effort to create educational webinars/videos and other materials to help with needed education for change management and sustainability within the research community. Educational materials should include information about what it is <i>not</i> used for and some use cases people may <i>think</i> it will solve, but is not the best choice.

November 21, 2019

<p>Ways NIH can stimulate research into FHIR-related standards development.</p>	<ul style="list-style-type: none"> • NIH should continue to fund FHIR-related standards. The NIH-funded CD2H initiative is already pursuing FHIR as a potential Common Data Model for research, perhaps a canonical one, with Hopkins and UNC being two major loci of initial data modeling work. NIH has stayed away from backing standards, according to NCATS, but ultimately, for interoperability and data exchange, including for research, we cannot have unlimited “railroad gauges.” We don’t necessarily want it to supplant the existing CDM, which are used in specific platforms for specific purposes, e.g. PCORI, OMOP, TriNetX, and Sentinel, but we may need one FHIR-for-Research CDM to unite them all, which meshes with the larger effort/push to use the FHIR interoperability standard for interoperability for APIs, by CMS, ONC, and industry. NIH can use its influence and funding weight to guide cooperative efforts to build a true FHIR-for-Research shared CDM, rather 37 local versions of an ostensible “CDM.” • NIH could also require or promote de-identified FHIR data deposition for grant holders and/or import “publicly” available clinical data sets that are hard to get into FHIR with the appropriate authorization mechanisms. • NIH should identify types of data that are high-priority for research and support the community to develop tools to help extract high-priority data into research data models, such as OMOP and PCORnet.
<p>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.</p>	<ul style="list-style-type: none"> • Launch shared clinical tasks/challenges where data access and authorization all take place through FHIR to allow developers to familiarize themselves with the API • It is worth noting that there are different types of research that have different data needs: observational (with emphasis on re-using EHR data and linkage to other data sources), and interventional, which requires randomization, safety checks, and data adherence. The latter might produce data that should

November 21, 2019

	<p>eventually be written to the EHR and there are different needs for that. A subtype of the interventional research could be implementation science approaches to research and pragmatic research embedded in health systems. A third type of research – development of clinical informatics tools – will rely on the use of FHIR to access data from the EMR, analyze this data, develop novel presentations of this data, and possibly write data back to the EMR. These efforts will need infrastructure that supports this integration in the EMR and related workflows.</p> <ul style="list-style-type: none"> • Regardless of how we describe the scope of research, there are many overlapping issues such as managing informed consent, data use agreements, data security, privacy, etc. • Data quality is not inherently part of, or addressed by, the FHIR standard. Data quality thus remains an issue. • Convincing people to use a new tool will also be a challenge. • FHIR could be used to do n-of-1 studies, given significantly long longitudinal data on one patient, but best practices and broader acceptance of the validity of n-of-1 studies need to be created for n-of-1 studies for this type of opportunity to develop. • NIH should coordinate across various government stakeholders, in particular FDA, as it accepts EHR data in support of device applications. This would encourage standards adoption.
--	--