EHRA
HIMSS ELECTRONIC HEALTH RECORD ASSOCIATION

350 North Orleans Street, Suite S10000
Chicago, IL 60654

@EHRAssociation | ehra.org

December 21, 2022

The Honorable Dr. Arati Prabhakar
Director
Office of Science and Technology Policy
Executive Office of the President
Washington, DC 20500

Dear Director Prabhakar,

On behalf of the 30 member companies of the HIMSS Electronic Health Record (EHR) Association, we are pleased to offer our comments to the White House Office of Science and Technology Policy (OSTP) Request for Information (RFI) on *Data Collection for Emergency Clinical Trials and Interoperability Pilot.*

As a national trade association of EHR developers, Association member companies serve the vast majority of hospital, post-acute, specialty-specific, and ambulatory healthcare providers using EHRs and other health IT across the United States. Together, we work to improve the quality and efficiency of care through the adoption and use of innovative, interoperable, and secure health information technology.

While we acknowledge the great potential to utilize proposed tools and technologies to build an emergency clinical trial data collection infrastructure that could be used beyond emergency clinical trials, much effort is required to build the necessary implementation guidance and gain operational experience for rapid deployment. We urge OSTP to engage all critical stakeholders, particularly providers and their health IT suppliers, to address the complexities from the start.

The tools have promise but have not all been built for these use cases. We must not underestimate what it will take to establish a fully deployed infrastructure. An analogous effort around electronic prior authorization took two to three years to establish initial implementation guides, and initial implementations are only just starting for a limited scope of interactions, not yet the comparable full breadth of interactions. The experiences gained in those efforts can and should be taken advantage of, including other FHIR accelerator efforts, to optimize the reuse of common patterns and approaches.

We appreciate the opportunity to provide more detailed feedback as follows. The EHR Association and our individual members look forward to collaborating with you as this initiative unfolds.

Sincerely,

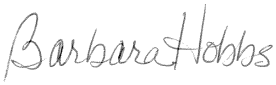
Hans J. Buitendijk
Chair, EHR Association
Cerner Corporation

David J. Bucciferro
Vice Chair, EHR Association
Foothold Technology

HIMSS EHR Association Executive Committee

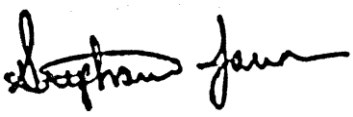
Pamela Chapman
Experity

William J. Hayes, M.D., M.B.A.
CPSI



Barbara Hobbs
MEDITECH, Inc.

Cherie Holmes-Henry
NextGen Healthcare



Stephanie Jamison
Greenway Health

Sasha TerMaat
Epic

Question 1: United States Core Data for Interoperability (USCDI)

The USCDI and USCDI+ extensions provide a useful framework to determine data for which FHIR-based support is available – or soon to be available, noting that when a USCDI version is published the actual FHIR-based implementation guidance necessary to support that USCDI version would not be available for another nine to twelve months. As USCDI versions, along with their supporting FHIR implementation guide standards, are included in either ONC's SVAP or certification rules, health IT developers focus on subsequent adoption and deployment. When included in updated certification rules, all certified health IT would aim to adopt that version, while they may or may not do so for versions referenced in SVAP. Therefore, the FHIR US Core version supporting the USCDI version referenced in certification rules would be the best indicator of data one can expect to be available through FHIR-based APIs in certified health IT once the adoption of that certification rule is mandated.

For example, as of January 1, 2023, it is reasonable to expect that all software certified to the 21st Century Cures Act Update to the 2015 Certification Rules (Cures Act Final Rule) supports the data required in FHIR US Core, at a minimum. For interoperability purposes, adherence to FHIR US Core is a more specific and relevant gauge than USCDI, as USCDI is only a set of concepts and vocabulary, not a standard on how to access and exchange that data. Only a standard such as FHIR or CDA C-CDA or v2 would provide that level of guidance.

The EHR Association suggests that the focus should be on identifying gaps in FHIR US Core to support the clinical trials for which uncurated data directly from the health IT source can be of value.

Question 2: HL7 FHIR APIs

The FHIR-based APIs being deployed in certified health IT, including individual data element and bulk data access, have the opportunity to support a wide range of data requests to inform clinical trials. FHIR-based APIs deployed for certification typically include QuestionnaireResponse as specified in FHIR US Core, even though USCDI v1, v2, or v3 do not include data using that resource. However, Questionnaire is not yet part of FHIR US Core, thus not as likely to be widely available across certified health IT. However, these tools would provide appropriate capabilities to access critical data more dynamically in support of clinical trials.

We should clarify that these APIs access the data as documented and do not distinguish between additional data or subsets of the data having been curated to ensure it is suited to clinical trials that have special data requirements. The data quality would be more aligned with what is suitable for real-world data-based research. The FHIR Questionnaire, QuestionnaireResponse, and Clinical Quality Language (CQL) would enable combining the ability to gather relevant data through automated processes where possible while allowing for further data collection through manual workflows. This could be facilitated through the source health IT or FHIR-based Apps that can orchestrate such automated and manual data collection using SMART Apps for user interactions as needed. HL7 FHIR Accelerators such as Vulcan (specifically focused on research and clinical trials), Da Vinci (focused on provider-payer interactions), as well as CDC's eCR Now, MedMorph, and NHSNlink initiatives demonstrate the direction and capabilities that can be pursued using FHIR-based technologies integrated into and/or connected with data sources that support FHIR US Core based APIs as a minimum.

FHIR US Core-based APIs are now widely deployed as part of certified HIT, while automated ingestion of FHIR Questionnaires and CQL translation into user interactions and automated data capture is starting to emerge, particularly among FHIR-based Apps.

Question 3: SMART on FHIR APIs

SMART on FHIR tools enable add-on solutions providing additional user-focused data collection for clinical trials where the source health IT may otherwise not (yet) collect such data, and support for these tools can connect to certified health IT. However, the source health IT would have to support both FHIR US Core and SMART to take advantage of those capabilities, thus still having some level of health IT capabilities. As referenced above, the type of App typically required would not solely be a SMART App but have other capabilities as well to orchestrate the clinical trial data requests.

Question 4: Clinical Decision Support (CDS) Hooks

CDS Hooks could be considered to streamline the initiation of data collection and sharing upon certain actions – including placing certain types of orders, documenting a qualifying condition, and other triggers that either potentially qualify the patient for a clinical trial or indicate the need for certain data collection for a patient within a clinical trial. It is critical to understand the workflows of interest in which such triggers occur and the type of interactions to consider depending on the variety of health IT that would be relevant. One cannot assume that all provider workflows and data are managed by a singular health IT solution, such as an EHR, as relevant data and triggers may be distributed across multiple systems.

Any FHIR-based implementation guides must clearly recognize the variety of health IT configurations that are reasonably expected to be deployed and thus needed to participate in the full workflow, starting with triggers and interactions relevant to the clinical trial at hand.

Initial CDS Hooks are starting to deploy across various health IT, although they are not addressed through certification criteria in the ONC's 21st Century Cures Update final rule.

Question 5: Operationalizing protocols of varying complexity

When considering FHIR-based tools and the types of studies for which they may be best suited, the key consideration may not be complexity, but volume. The challenge of the necessary data collection for a clinical trial often lies in the conditions of qualifying patients and specific data rather than the volume of data.

FHIR bulk data focuses on more efficient sharing of large data sets whether the data set was a result of simple data requirements or complex data requirements involving intricate conditions on qualifying data. The FHIR Questionnaire and CQL capabilities focus on the ability to convey simple data sets (FHIR Questionnaire) or more complex yet rigorously defined data sets (CQL).

As indicated in our response to Question 2, the automated ingestion of FHIR Questionnaire and CQL resulting in the automated collection of data through user interactions and/or FHIR API or native services are still emerging.

Question 6: Consent, deidentification, return of results

Where data needs to be shared in a de-identified format because sufficient authority and/or consent is not available to share identifiable data, the tools considered within this RFI can still be utilized. De-identification can start at the source, or in central/intermediary repositories that are authorized to manage identifiable data.

The primary challenge, however, is maintaining a complete patient record where clinical trials depend on aggregating data about the same patient across different source health IT, across different and distinct organizations that do not share a common enterprise master patient index (EMPI). Various techniques and technologies are available to utilize tokens or other privacy-preserving record linkages, but one must assess the risk of re-identification and how that risk can be managed.

Ensuring appropriate re-sharing/use of data for subsequent studies could be captured and conveyed using FHIR's Security Labeling capabilities. The challenges are not as much in the FHIR standards and sharing technologies, but rather in the upfront process of obtaining such patient consent and defining the scope and duration of such consent. Where data is being shared in de-identified form, any desired future changes to their consent would effectively be impossible,

whether expanding or contracting. This further emphasizes the need for great clarity and transparency when the patient is asked to consent to particular reuse of the data.

Where the data can be used in an identifiable form, such adjustments to its use could be managed, but the necessary standards and infrastructure to assert the most current patient consent directives relevant to their study would have to be established. One could consider the approaches being pursued by the San Diego LEAP project that is further advancing the use of patient-centric consent repositories that could incorporate consent relative to clinical trials as well, minimizing the places where a patient would have to maintain their various consent directives.

The ability to return data to study sites and participants could be enabled using FHIR-based technologies as well, including the emerging pub/sub capabilities that can be established at the time of joining a clinical trial.

Question 7: User interface and experience

It will be critical that any data collected for a clinical trial, particularly an emergency clinical trial when clinicians already are under great pressure, does not interfere or unduly add to a clinician's documentation burden. This will require significant consideration, as the EHR is the source of most clinical data.

Manual data collection must be minimized, if not eliminated, and should certainly not duplicate efforts when the data is readily available through automated means. Therefore, the clinical trial should be designed based on data already being documented, to the extent possible. This will enable maximum opportunities to automatically trigger the collection of relevant data and share it in identifiable, de-identifiable, or aggregate form.

We recognize that not all trials can rely on already available data and that clinicians are often willing and committed to performing the extra data collection. Well-defined use of FHIR-based tools has the opportunity to target the ideal users to collect the least amount of data, where the use of FHIR-based Apps (including SMART on FHIR Apps) can be made available with limited or no development efforts by the source health IT developer, assuming the health IT has minimally required FHIR based capabilities (particularly FHIR US Core based APIs and CDS Hooks).

To the extent that data remains identifiable, missing data could be collected and re-associated with the patient later.

Question 8: Capturing data elements required for clinical trial protocols

Considering the various analogous use cases that are starting to emerge, the anticipated flow would start with CDS Hooks invoking interactions with the research organization for the clinical trial at hand based on a patient cohort and/or defined patient characteristics. This is followed by a sharing of the FHIR Questionnaire identifying the relevant data of interest, either using specific questions to populate a form and/or CQL to specify the data of interest. Either the source health IT or a FHIR-based App will ingest that Questionnaire to then determine what data can be automatically gathered using individual FHIR US Core-based APIs or a bulk data export approach rather than requiring user interactions through a form of sorts.

Any workflow can be orchestrated to address missing data requiring follow-up, while then packaging data for sharing with the research organization. Depending on the extent to which the source health IT can translate FHIR Questionnaires or CQL into automated data collection or user interaction will determine the need for a FHIR-based App to be introduced to augment the source health IT.

Tools translating FHIR Questionnaire and CQL in automated data collection and/or user interactions are very much in the early days of development and utilization, although FHIR-based Apps in particular are starting to take advantage of this functionality utilizing FHIR-based APIs to collect the data automatically and interact with users using SMART on FHIR Apps for any data that otherwise could not be obtained.

We suggest that it is premature to consider regulatory requirements of FHIR-based capabilities at their current maturity level, including operational use for this type of use case. Rather, the availability of a comprehensive implementation guide is essential to start to progress a clear understanding of what is relevant and needed across all anticipated components of this infrastructure, including the multiple health IT present in the various provider organizations. Once sufficiently mature, with a clear understanding of the different roles that various health IT take on in the workflows can regulations, such as certification programs, effectively identify necessary and critical capabilities for applicable health IT, provider organizations, and research organizations.

Question 9: TEFCA and QHINs

TEF QHINs have the unique opportunity to identify where the patient has data and collect data across those locations. To the extent that clinical trials require access to a patient's data across multiple sources, TEF QHINs would provide a clear avenue to collect such data. Where the data of interest for a given patient is not distributed across different providers, TEF can still provide the legal and governance framework to ease connections with the provider of interest as well as using the clinical trial use case as one of the FHIR-based use cases in a TEF QHIN facilitated (but not brokered) FHIR-based interaction with the provider. This would reduce the number of

data-sharing agreements and interaction approaches to one agreement and one approach at a national level.

To the extent that the authority to access the data is under a public health authority, that Exchange Purpose could be used. This further emphasizes the need to align the techniques used in research and defined Exchange Purposes (including Public Health, Payment, Treatment, and Health Care Operations) to be consistent. Not all emergency clinical trials can or should be considered a Public Health Purpose, as explicit patient consent is required for participation where identifiable data is to be used. When unidentifiable or aggregated data is used, that may reduce these requirements, but raises privacy and ethical questions as to whether patients wish their data to be used in that manner beyond Treatment.

Question 11: Pilot or demonstration project

We suggest pilot activities should be explored in close collaboration with an HL7 FHIR Accelerator, such as Vulcan, to ensure continuous alignment in developing the necessary implementation guidance based on ongoing experience gained during connectathons and real-world pilots. It is critical that all relevant stakeholders have the opportunity to be engaged from the start and involve researchers, providers, and health IT suppliers at a minimum.

Question 12: Specific commercial capabilities

Given the nature of the EHR Association as a national trade association of EHR developers, we cannot directly respond to this question though individual member companies may provide further insights into their capabilities.

Generally, EHRs do provide a valuable source of relevant data when the data as documented can provide critical insights to clinical trials not requiring rigorous, trial-specific data collection. The use of FHIR-based apps connected to EHRs supporting FHIR and SMART can currently enable relevant incremental data collection. Advances are also being made such that EHRs over time could ingest data requests and potentially gather any additional data natively. The latter would vary by respective EHR developers as to the extent to which they do so or rely on FHIR-based apps to enable those capabilities more tightly integrated into their workflows.