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July 13, 2016

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852
Submitted electronically to: http://www.regulations.gov

Re: Request for Comments on *Use of Electronic Health Record Data in Clinical Investigations - Guidance for Industry*
Docket ID: FDA-2016-D-1224

Health Level Seven (HL7) International welcomes the opportunity to submit comments regarding the referenced draft guidance document posted by FDA in May 2016 under Docket ID FDA-2016-D-1224.

HL7 is a not-for-profit, ANSI-accredited standards developing organization dedicated to providing a comprehensive framework and related health data interoperability standards, including Fast Healthcare Interoperability Resources (FHIR) and Consolidated Clinical Document Architecture (C-CDA). HL7 has also produced standards currently used by FDA such as Structured Product Labelling (SPL) and Individual Case Safety Report (ICSR). HL7 is comprised of 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.

In general, HL7 applauds the FDA for encouraging use of EHRs in clinical research. We also believe that FDA's well-recognized global leadership in regulatory science and continuing efforts to improve the research process should set a precedent for better utilizing healthcare data to improve the safety and efficacy of therapeutic products for the betterment of patients not just in the USA, but also worldwide.

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** or 734-677-7777. We look forward to continuing this discussion and offer our assistance to FDA as it continues to make progress in improving its ability to use healthcare data to support its mission to protect the public health.

Sincerely,

Charles Jaffe, MD, PhD
Chief Executive Officer

Patricia Van Dyke
Board of Directors, Chair

HL7 Comments on *Use of Electronic Health Record Data in Clinical Investigations - Guidance for Industry*

HL7 strongly endorses the agency's goals to facilitate the use of EHR data in clinical investigations, and to promote the interoperability of EHRs and electronic systems supporting the clinical investigation. HL7 believes that its "Fast Healthcare Interoperability Resources" (www.hl7.org/fhir) standard provides an unprecedented platform for achieving these goals.

The HL7 FHIR standard has been positively viewed by ONC for providing an Application Programming Interface (API) in numerous communications, including the *2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications.*

It is anticipated that such a FHIR interface, which has been undergoing extensive evaluation and testing by Project Argonaut, a collaboration of 89 participants from government, providers and technology vendors, will be supported by most major EHR vendors in the USA within two years. A FHIR-based API can thus make it possible for research sponsors and regulators to gain consistent access to electronic health records for a variety of research-oriented and pharmacovigilance activities.

HL7 also believes that support for a FHIR-based API will improve the quality, validity, reliability and integrity of data from EHRs, making it more suitable for use for secondary research.

In addition to sourcing data in research databases, a FHIR API also offers the promise of providing a window into the patient record, which can be utilized as a powerful resource to FDA medical reviewers exploring the safety of individual patients enrolled in clinical trials. This can provide additional relevant contextual data that may not have been specified for collection in the clinical trial protocol, thus improving the reviewer's ability to understand safety events in more detail than ever before.

Comments on specific sections of the guidance document are provided below.

Lines 118-125: In addition to reducing transcription errors and providing more accurate and complete data, interoperability between EHR and EDC systems will also lessen the effort of sites by reducing duplicate data entry, and greatly improve traceability to source, by reducing the number of processing steps between data origination and clinical databases representation.

Lines 133-134: Use of a standard FHIR API by all US certified EHR systems would greatly facilitate and simplify the effort of pre-populating EDC systems from multiple sites and EHR systems.

Lines 148-155: The FDA should consider whether adopting some of the same clinical data standards used by ONC will reduce transformations from healthcare data to research databases, with the potential to further improve traceability, quality and efficiency in research.

Line 165: It is important to recognize that the definition of data elements described here and in footnote 19 often consist of a set of data variables (such as name, value, units and other attributes) with varying data types and often with associated controlled terminologies. The FHIR standard, based on a core set of resources, is especially appropriate for representing such data.

Lines 188-197: The HL7 Consolidated CDA standard is already specified by ONC as part of EHR certification requirements. The ONC has also expressed strong support for a FHIR API, which can be used to represent clinical data as documents, messages and services, to be added within two years.

Lines 236-240: Use of a FHIR API can provide a simplified standard means of extracting data from EHRs and importing such data into EDC systems.

Lines 257-261: Since FHIR supports updates as well as read transactions, it should be possible for EDC systems to message the EHR of potential data discrepancies that may need to be updated in the EHR, to ensure consistency of data across systems. The standard FHIR extract used to pre-populate CRFs can be rerun prior to database lock to verify no additional changes have been made to the EHR record and that the source and clinical representation remain in synch. Such an extract could be retained by the site as a permanent audit trail record.

Lines 285-288: FHIR will include a standard method for managing consent, which will include consent by patients for data access, procedures and other purposes, that can be utilized for research as well. The SMART on FHIR initiative already uses a patient-driven consent model based on the OAuth2 and OpenID Connect framework.

Lines 303-310: As noted above, a FHIR API can allow FDA reviewers to directly access the EHR record for clinical study subjects, to improve ability to conduct remote site inspections of patient records as well as allow medical reviewers to drill down into the detailed EHR record for a subject.