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Food and Drug Administration
Division of Dockets Management (HFA-305)
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Use of Electronic Health Record Data in Clinical Investigations; Draft Guidance for Industry; Availability (Docket No. FDA-2016-D-1224)

The Association of American Medical Colleges ("AAMC"), a not-for-profit association representing all 145 accredited U.S. medical schools, nearly 400 major teaching hospitals and health systems and more than 80 academic societies, appreciates the opportunity to submit comments on the *Draft Guidance on the Use of Electronic Health Record Data in Clinical Investigations*, released on May 17, 2016 by the Food and Drug Administration ("FDA"). Through the AAMC's member institutions and organizations, the AAMC represents nearly 160,000 faculty members, 83,000 medical students, 115,000 resident physicians, and thousands of graduate students and post-doctoral trainees.

The AAMC commends the FDA on the development of guidance surrounding the use of electronic health record (EHR) data in clinical investigations and agrees that EHRs have the potential to "improve patient safety, data accuracy, and clinical trial efficacy when data from these systems are used in clinical investigations." Many of AAMC's members have helped to pioneer the development and use of EHR technology and are committed to providing quality care using these systems. The Association is supportive of developing frameworks and processes to increase the use of EHR data in clinical investigations, but urges the FDA to revisit specific aspects of the guidance as recommended in our comments.

Interoperability of Data Systems

The AAMC recognizes the benefits surrounding the exchange of electronic patient data in clinical investigations and agrees with the FDA that the interoperability of data systems, such as an electronic data capture (EDC) system, can benefit the clinical investigation, patients, and other healthcare providers. Whether EHR and EDC systems within clinical sites are fully interoperable is often not within the control of the sponsor, clinical investigator, or even the health care organizations that maintain the EHR. Missing from the FDA's discussion of challenges to the interoperability of these systems is the recognition that most EHR systems are not created or configured by the health care organizations. The capabilities and limitations on interoperability are most often a function of the commercial organizations that develop, customize, and sell EHR systems. The challenges are multiplied in the case of multi-site clinical investigations, where likelihood that more than one EHR system is interoperable with a single EDC system is remote.

The AAMC is concerned that the draft guidance focuses too heavily on the responsibility of sponsors and clinical investigators to use interoperable systems without a discussion of how software developers and vendors outside of the direct employ of health care organizations should be expected to assist in achieving this goal. **The AAMC supports the FDA's encouragement for interoperability of EHR and EDC systems to improve research data as well as clinical care, and urges the FDA to recognize that the goal of interoperability relies heavily on the external developers and vendors creating EHR and EDC systems.**

The draft guidance lacks sufficient detail on the expectations for the integration and transfer of EHR data across multiple clinical investigation sites which may require the development of specific data standards or processes. Additional guidance on the respective roles and responsibilities of the sponsors, clinical investigators, and the entities that control the EHRs at each site could be clarified.

Best Practices for the Use of EHR Data in Clinical Investigations

AAMC has supported the development of the ONC voluntary certification program for health IT and appreciates the FDA's guidance on an internal assessment of whether EHRs not certified by ONC are sufficient to inform FDA's regulatory responsibilities. One aspect missing from the draft guidance is how FDA will assess or review a sponsor's decision that a non-ONC certified system adequately implements the broadly-defined internal security safeguards, and at what point in the process of submitting data to the FDA the sufficiency of that system would be considered.

In reference to the fundamental elements of data quality, the draft guidance indicates that "sponsors should ensure that the EHRs they use and the processes and policies for their use provide electronic source data that are attributable, legible, contemporaneous, original, and accurate (ALCOA)" but only discusses how a sponsor would assess the accuracy of the data from electronic sources. **The FDA should consider providing specific guidance on all elements within "ALCOA" to ensure sponsors clearly understand how to assess those recommended elements of data quality.**

Informed Consent

The AAMC commends the FDA in its development of informed consent guidelines for the use of electronic health records in clinical investigations and supported the FDA's July 2014 *Informed Consent Information Sheet, Draft Guidance for IRBs, Clinical Investigators, and Sponsors*. In the AAMC's response to the draft guidance on informed consent, the Association urged the FDA "to consider [the] guidance document an opportunity to reinforce that a document capturing required elements of informed consent is only a component of the ethical obligation to ensure that research subjects have meaningful awareness of what their participation in a clinical trial means to them."[1]

Given the highly sensitive nature of patient data, the AAMC strongly recommends that the FDA work with experts and the patient community to identify the most ethically appropriate informed consent process for the use of EHR data gathered during the course of a clinical investigation. Promising example approaches include the Point of Care Research process utilized by the Department of Veterans Affairs.[2]

[1] AAMC Comment Letter, September 15, 2014 (available at https://www.aamc.org/download/404310/data/aamccommentsonfdasdraftguidanceoninformedconsent.pdf).
[2] http://www.research.va.gov/services/csrd/point-of-care.cfm

Related to interoperability, the AAMC agrees with the FDA that the parties granted access to the research and clinical care data should be described in the informed consent and the reasonable and foreseeable risks (e.g., risk of data breach) and benefits should be clearly communicated.

In closing, we recognize that there are many challenges related to the storage, transmission, and use of EHR patient data in clinical investigations and applaud the FDA in its efforts to modernize and streamline clinical investigations by gathering stakeholder feedback. The AAMC appreciates the opportunity to comment on this important issue.

If you have any questions concerning these comments, please feel free to contact Heather Pierce, Senior Director for Science Policy and Regulatory Counsel at hpierce@aamc.org or (202) 478-9926.

Sincerely,

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