21 C.F.R. Part 11 and Epic

All Applications

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21 CFR Part 11 and EHRs

In the past, it was unclear whether 21 CFR Part 11 applied to EHRs. As a result of this lack of clear guidance from the FDA, Epic provided a robust compliance guide detailing how our software could support an organization's overall 21 CFR Part 11 compliance efforts.

Some data directly relevant to clinical trials and clinical research may be documented in Epic and become a source of data to support research. In September 2013, the FDA released a Guidance for Industry on Electronic Source Data in Clinical Investigations: (http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM328691.pdf)

This guidance provided much needed clarification around the FDA's perspective on the use of EHRs as a type of source data system. In recognizing the important role of EHRs as part of a more efficient overall process, Part IV of the guidance states the following:

> **IV. USE AND DESCRIPTION OF COMPUTERIZED SYSTEMS IN CLINICAL INVESTIGATIONS**
>
> Adequate controls should be in place to ensure confidence in the reliability, quality, and integrity of the electronic source data. The determination of whether a computer system used in a clinical investigation is suitable for its intended purpose might not be under the control of the clinical investigator(s) or sponsor (e.g., EHRs). The performance standards for these computer systems may be regulated by other authorities[22] and under the control of, for example, healthcare providers or institutions. FDA does not intend to assess the compliance of EHRs with part 11.

On line 23 it is clarified that the **"FDA does not intend to assess compliance of EHRs with part 11."** On lines 21 and 22, the guidance states that "The performance standards for these computer systems may be regulated by other authorities" and then defers to 45 CFR Part 170 which is the foundation on which ONC has built EHR certification requirements for Meaningful Use.

The FDA released another Guidance for Industry on the Use of Electronic Health Record Data in Clinical Investigations in July 2018: (https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM501068.pdf).

In this guidance (page 7) the FDA reiterated that "Under the ONC Health IT Certification Program, certified EHR technology would be in compliance with applicable provisions under 45 CFR part 170. EHR technology with certified capabilities generally has clear advantages, because many of the certification requirements are aimed toward ensuring interoperable data sharing and enabling processes to keep electronic data confidential and secure. In particular, all EHR technology certified under the ONC Health IT Certification Program is required to meet certain privacy and security protection requirements for an individual's health information (see 45 CFR 170.314(d)(1) through (8) and 45 CFR 170.315(d)(1) through (11)). FDA encourages the use of such certified EHR systems together with appropriate policies and procedures for their use."

Epic Certification to ONC Criteria

Epic has historically been one of the first EHR developers to have ambulatory and inpatient software applications certified against industry standard criteria. For current certification information, see: http://www.epic.com/docs/mucertification.pdf