FDA Guidance on Use of Electronic Health Record Data in Clinical Investigations

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As electronic health record systems (EHR Systems) become the norm at trial sites, clinical trial sponsors – particularly those using electronic data capture (EDC) systems – should take note of FDA's recent guidance on theUse of Electronic Health Record Data in Clinical Investigations(July 18, 2018). As part of FDA's effort to modernize and streamline clinical trials, the guidance aims to facilitate the use of EHR data in clinical trials, and to promote the interoperability of EHR and EDC systems.

No Part 11:

FDA reiterates that it does not intend to assess compliance of site EHR systems with 21 CFR Part 11. However, for FDA to accept data from a clinical trial, FDA needs the ability to verify the quality and integrity of the data during an inspection.

Impact on Clinical Trial Agreements

Per the guidance, Sponsor should:

1. Determine whether the site's EHR system is certified per 45 Part 170 by the Office of the National Coordination for Health Information Technology (ONC) at the Department of Health and Human Services. If it is not, then the guidance includes standards that Sponsor should review the EHR system against. A lack of ONC certification is not an automatic out, but sponsors need to confirm that adequate controls are in place to ensure the confidentiality, integrity and security of data.
2. Validate the interoperability of the EHR system and quality management plan should address this. For example, you should be confident that your software updates do not affect the integrity or security of the EHR data transmitted to your EDC system. You should also periodically validate a subset of the extracted data.
3. Address EHRs in the ICF on several fronts, such as informing the subject which entities may access the subject's EHR relating to the study and explaining that FDA may inspect records in the EHR and does not guarantee confidentiality.
4. List, in your data management plan, the EHR systems used by each site, including the manufacturer, model number, version number and whether it is ONC certified. You should also address decertification of the EHR system during the study.
5. Ensure that appropriate policies and processes are in place to ensure the confidentiality, security and integrity of the data in the EHR system.
6. Consider whether use of interoperable EHR and EDC systems could unblind the treatment allocation.
7. Keep in mind that, in addition to accessing EHR records that pertain to the study (either original or certified copies), FDA may review the EHR audit trail information during an inspection. Addressing the items listed above will help ensure that the FDA has a good experience during the inspection. As you know, and as the guidance reiterates,

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FDA's acceptance of study data for decision-making purposes depends on its ability to verify the quality and integrity of the data during its inspections.

Outside of Guidance Scope:

As FDA expresses increasing levels of interest in real world evidence, it is interesting that the guidance does not apply to data collected for registries or natural history studies. The guidance also does not apply to EHR data used to evaluate the feasibility of trial design, as a study recruitment tool for clinical investigations, or in postmarketing observational pharmacoepidemiologic studies that assess adverse events and risks associated with drug exposure or those that are designed to test prespecified hypotheses for such studies.

The FDA guidance is available here.

If you have any questions or would like more information about these developing issues, please contact the following:

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