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FDA issues guidance on use of EHR data in clinical research

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Many hospitals and health systems conduct sponsored clinical research at their facilities, and clinical trial agreements typically require that sponsors and clinical investigators have access to certain data regarding the research activities and results. When access is given via the institution's electronic health record (EHR) system, the FDA's newly released guidance, "Use of Electronic Health Record Data in Clinical Investigations," may apply.

The FDA guidance encourages the use of EHRs in most situations and provides four factors to consider when EHRs are utilized:

1. Deciding whether and how to use EHRs as a data source

- Many types of data can be combined, aggregated and analyzed.
- Researchers can access real-time data for post-trial follow-up on patients to assess long-term safety and effectiveness of medical products.
- If the study design is blinded, consideration should be given to whether using an EHR may unblind the treatment allocation.

2. Using EHR systems that are interoperable with electronic data capture systems

- Interoperability is key to simplifying data collection (and improving accuracy) by permitting transmission of relevant data without the risk of errors that come with manual transcription of paper records.
- Sponsors and clinical investigators are encouraged to work with entities whose EHRs are interoperable but should ensure they have a full understanding of data flow and visibility to allow for a clear description in the informed consent of the parties granted access to the patient's data.

3. Ensuring the quality and integrity of EHR data collected and used as electronic source data

- Sponsors and clinical investigators should confirm that EHR software updates do not affect data integrity and security.
- Periodically, subsets of data should be checked with source data for accuracy, consistency and completeness.

4. Ensuring that the use of EHR data collected and used as electronic source data meets FDA inspection, recordkeeping and record retention requirements

- All paper and electronic source documents and records must be maintained in compliance with applicable law.
- ONC-certified EHRs are recommended.
- Sponsors and clinical investigators must be able to demonstrate that:
    - Each electronic data element is associated with a data originator (specific EHR).
    - All modifications or corrections to data have identifiers for the date, time, data originator and the reason for the change. Modified/corrected data should not obscure previous entries.