Source Data Capture from Electronic Health Records: Using Standardized Clinical Research Data

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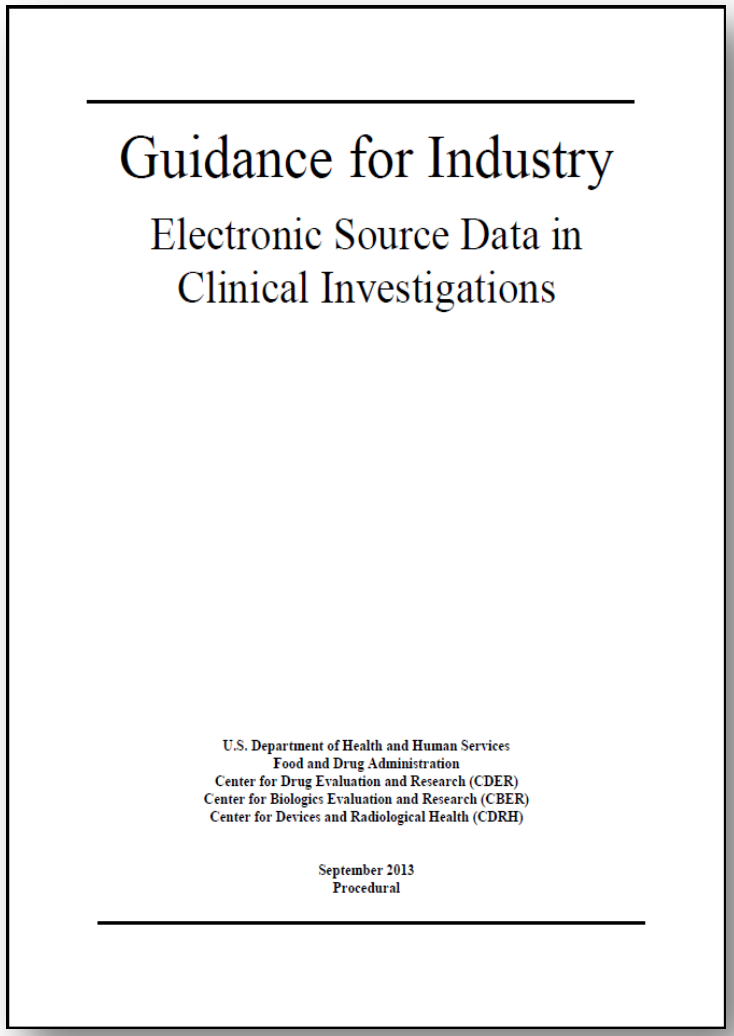
Topics

- Background
  - eSource Guidance
  - Benefits
  - Key Points
- Goals: Support Demonstration Projects
- Federal Register (FR) Notice
- EHR End-to-End Single Point Data Capture
- Questions to Stakeholders
- Q & A

Background



Guidance for Industry

Electronic Source Data in Clinical Investigations

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Devices and Radiological Health (CDRH)

September 2013
Procedural

"…promotes capturing source data in electronic form…,"

[assists] *"in ensuring the reliability, quality, integrity, and traceability of electronic source data."*

http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM328691.pdf

- Eliminate duplication of data
- Reduce transcription errors
- Timely source data
- Facilitate remote data monitoring
- More accurate and complete data
- Traceable end-to-end data flow

Guidance for Industry Electronic Source Data Capture in Clinical Investigations, 2013, page 3.

KEY POINTS

- 45 CFR part 170 regulates Health IT systems.
- 21 CFR part 11 regulates clinical research systems (e.g., EDC).
- Leverage technology to implement the eSource guidance.
- FDA wants to see direct use of EHRs for clinical research in regulatory submissions.

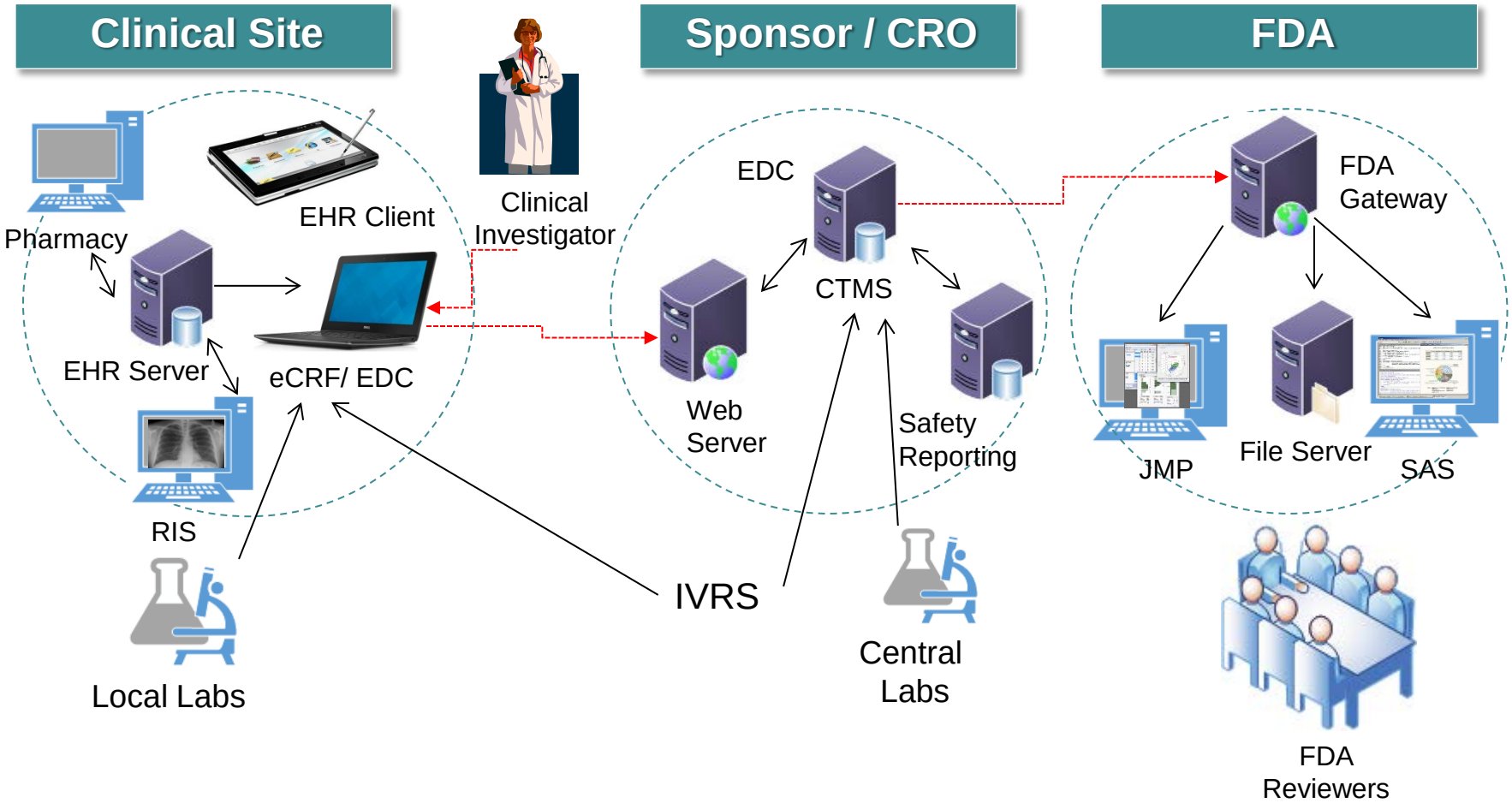
- **Issued Federal Register (FR) Notice 26 June 2015**
- **Focus: Support Demonstration Projects**
  - Test the capability and evaluate performance of using an end-to-end EHR-to-EDC single-point data capture approach.
  - Leverage established data and implementation standards in a regulated clinical research environment.

EHR End-to-End Single Point Data Capture

Federal Register (FR) Notice: Source Data Capture from EHRs: Using Standardized Clinical Research Data

- Requesting comments, proposed approaches, interest in participating in the demonstration projects
- FR notice will provide questions to stakeholders
- Your response to the docket is greatly appreciated.

EHR End-to-End Single Point Data Capture



EHR End-to-End Single Point Data Capture Demonstration Projects

- Assess and report value and challenges of the EHR-to-EDC single-point capture of source data in a clinical research environment
- Streamline clinical research at the source
  - Improve clinical trial design and execution
  - Speed the cycle of clinical research
  - Get medicines to market faster

Questions to Stakeholders

Questions

1. What other potential benefits to stakeholders can be achieved through the use of a standards-based technology solution focusing on EHR and EDC integration?
2. What are the challenges to the implementation of a standards-based technology solution focusing on EHR and EDC integration?
3. What are the gaps between the data collected in a healthcare setting by EHRs vs. clinical research data required for regulated drug development?

Questions

4. Are there any perceived regulatory obstacles to the implementation of a standards-based technology solution focusing on EHR and EDC integration (Examples include: Source data verification, remote monitoring, 21CFR Part11, patient privacy, access control and confidentiality safeguards)? If yes, what approach(es) would you recommend to overcome these obstacles?
5. Are there any obstacles to the implementation of a standards-based technology solution focusing on EHR and EDC integration?
6. What standards-based solutions may exist?

Q & A

Please submit your questions to: CDERSBIA@fda.hhs.gov

Link to the FR Notice:
(http://www.gpo.gov/fdsys/pkg/FR-2015-06-26/html/2015-15644.htm)

Thanks

Glossary

Glossary of Terms

Clinical Trial Management System (CTMS): Used to manage critical functions of the research site such as patient recruitment, study tracking, financial accounting, scheduling, reporting and more.

Electronic Case Report Forms (eCRFs): The eSource guidance refers to the Electronic Data Capture (EDC) systems as Electronic Case Report Forms (eCRFs).

Electronic Data Capture (EDC) : Designed to collect and manage clinical research data in an electronic format.

Electronic Health Record (EHR): A repository of a patient's health care information, in computer processable form (ISO Definition).

Electronic Patient Reported Outcomes (ePRO): A measurement based on a report that comes directly from the patient (i.e., study subject) about the status of a patient's health condition without amendment or interpretation of the patient's response by a clinician or anyone else in electronic form.

Glossary of Terms

Health Information Technology: the area of IT involving the design, development, creation, use and maintenance of information systems for the healthcare industry. (Health IT) allows comprehensive management of medical information and its secure exchange between health care consumers and providers, e.g. Electronic Health Records (EHR), pharmacy and health claims.

Interactive Voice/Web Response System (IVRS/IWRS): a technology that allows a computer to interact with humans through the use of voice and telephone touch-tone keypad.

Office of the National Coordinator for Health Information Technology: the forefront of the administration's health IT efforts and is a resource to the entire health system to support the adoption of health information technology and the promotion of nationwide health information exchange to improve health care. ONC is organizationally located within the Office of the Secretary for the U.S. Department of Health and Human Services (HHS)

Radiology Information System (RIS): A database used by radiology departments in conjunction with a hospital's EHR and information systems to store, analyze and distribute medical images.