Promoting eSource Data Capture in Regulated Clinical Research

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Disclaimer

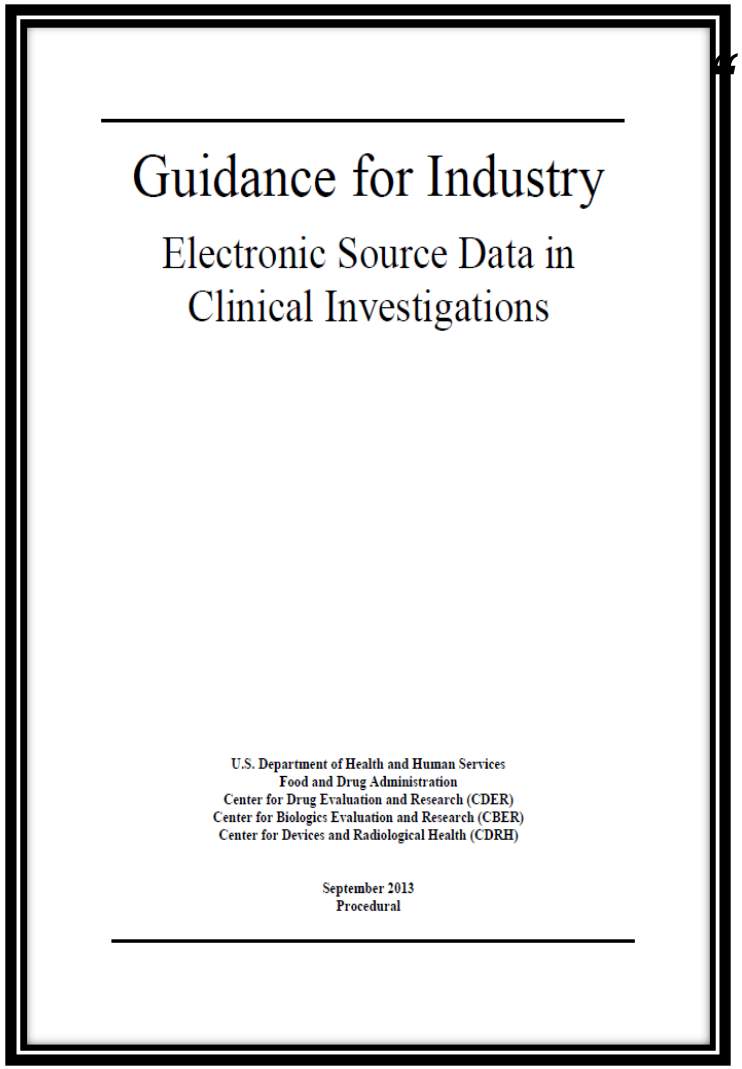
The views and opinions presented here represent those of the speaker and should not be considered to represent advice or guidance on behalf of the Food and Drug Administration.


THE BIG
PICTURE
NEXT EXIT

"Actually, we defined the quality of a pharmaceutical product a long time ago: fitness for use. It delivers the properties described on the label and is not contaminated."

"Data quality in general needs industry's attention"

--J. Woodcock, 2/14/2014



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

THE SOURCE Needs to be:

- Attributable
- Legible
- Contemporaneous
- Original
- Accurate

Selected Study Sponsor Concerns*

- EDC systems are not built to communicate with clinical sites' EHR systems.
- What is the expectation of source data verification with direct EHR to EDC?
- Should monitors and auditors have access EHRs to review source?

* FDA Webinar, January 2014

Selected Study Sponsor Concerns*

- Sites frequently refuse access to EHRs
- Should EHRs be part 11 compliant?
- Explain electronic certified records?
- What documentation should be available at the site?

* FDA Webinar, January 2014

KEY POINTS

- 45 CFR part 170 regulates EHRs.
- 21 CFR part 11 regulates clinical systems (e.g., EDC).
- Leverage technology to implement the eSource guidance.
- eSource facilitates data quality.

FDA wants to see direct use of EHRs for regulated clinical research.