

eSource Regulatory View

What are we waiting for?



46th Annual Meeting
Washington, DC - 2010

Moderator:

Ed Seguire

Commentary:

John Helfgott, FDA



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- What has the FDA already stated about eSource?
- In addition to ePRO, are there other acceptable eSource technologies?
- How do I inform the agency my study will use eSource?
- What requirements apply to eSource data and documents?

FDA Guidance on Computerized Systems (May 2007)

“Because the **source data** are necessary for the reconstruction and evaluation of the study . . . this guidance is intended to assist in ensuring confidence in the reliability, quality, and integrity of **electronic source data and source documentation**” (page 1)

“**Electronic source data and source documentation** must meet the same fundamental elements of data quality (e.g., *attributable, legible, contemporaneous, original, and accurate*) that are expected of paper records” (page 2)

FDA Guidance on Computerized Systems (May 2007)

“**Study protocol** should identify each step at which a computerized system will be used to create, modify, maintain, archive, retrieve, or transmit **source data**.” (page 3)

“When original observations are entered directly into a computerized system, the **electronic record** is the **source document**. . .The clinical investigator must retain records required. . .This requirement applies to the retention of the original source document, or a copy of the source document.” (page 4)

Limited Access, Audit Trails, Date/Time Stamps (page 4,5)

FDA Guidance on ePRO (Dec 2009)

“Use of ePRO instruments may pose a problem if direct **control over source data** is maintained by the sponsor or the CRO and not by the clinical investigator. We consider the investigator to have met his or her responsibility when the **investigator retains the ability to control and provide access** to the records that serve as the electronic source documentation **for the purpose of an FDA inspection.**”



Department of Health and Human Services

Public Health Service
Food and Drug Administration
Silver Spring, MD 20993

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ref: 10-HFD-45-11-02

Thomas Gazda, M.D.
4383 N. 75th Street
Scottsdale, Arizona 85251

Dear Dr. Gazda:

Between January 20 and February 6, 2009, Ms. Tonia Sawyer, representing the Food and Drug Administration (FDA), conducted an investigation and met with Dr. (b)(6), current Meadowbrook Research, Inc. clinical staff member; and Ms. Pamela Larson, President and CEO of Meadowbrook Research, Inc., to review your conduct of a clinical investigation (b)(4) of the investigational drug (b)(4) performed for (b)(4).

EMEA Reflections on Source Docs (Oct 2007)

“Source data and raw data have traditionally been paper documents. Many requirements and expectations have been developed in this context. The principles underlying these expectations and requirements are **largely applicable to electronic media, but their practical application will be different.** In addition, some of the physical attributes of paper records require rethinking in the context of electronic media.”

- FDA has already “APPROVED” eSource
- FDA has already stated criteria for use
- FDA has already clarified requirements for technology vendors
- FDA has already defined responsibilities for investigators and sponsors
- FDA has already explained acceptable use