**FDA’s Draft Guidance for Industry on Electronic Source Documentation in Clinical Investigations**

Event #11208 • February 28, 2011

11:00 AM-12:30 PM ET  9:00 AM-10:30 AM MT
10:00 AM-11:30 AM CT  8:00 AM-9:30 AM PT

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FDA’s Draft Guidance for Industry on Electronic Source Documentation in Clinical Investigations, issued in early January 2011, is part of FDA’s Critical Path Initiative to streamline clinical investigations, moving away from paper case report forms to the use of a wholly electronic environment for recording clinical trial data. To encourage and support industry in recording their clinical trial data in electronic format, FDA issued a draft guidance for industry on electronic source documentation in clinical investigations. Representatives from the eSource Guidance Working Group and Dr. Sacks will provide an overview of practices recommended by the guidance on capturing, using, and archiving electronic data in FDA-regulated clinical investigations, which will help ensure that electronic source data are accurate, legible, original, attributable, and contemporaneously entered, and meet the regulatory requirements for record-keeping and record retention. Dr. Sacks and the panel will answer questions about the draft guidance.

**LEARNING OBJECTIVES**

At the conclusion of this webinar, participants should be able to:

- Recognize terminology of electronic source data, source documents, and basic data elements
- Describe how to create, modify, transmit, and archive electronic source data
- Explain investigator responsibilities regarding reviewing and archiving data
- Discuss how to preserve data integrity

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MODERATOR
LEONARD SACKS, MD
Acting Director, Office of Critical Path Programs
Office of the Chief Scientist
FDA

PANEL
LESLEY K. BALL, MD, CAPT, USPHS
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MATHEW THOMAS, MD
Health Science Administrator
Office of the Commissioner, FDA

STEPHEN E. WILSON, DrPH, CAPT, USPHS
Director, Division of Biometrics III, CDER, FDA

WHO SHOULD ATTEND
Professionals involved in:
- Clinical data management
- Quality control and quality assurance
- Document management
- Clinical research and development
- GCP
- Information management
- Information technology/eBusiness
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Technical Requirements for Audience Members

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<td>&quot;Sun Java 5 or above, libstdc++ 6.0, GNOME/KDE windowing system&quot;</td>
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Internet Connection Speed
56k or faster

Display
800x600 pixel resolution or greater (1024x768 pixels recommended)

To test your system compatibility, click on the link below.
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CONTACT INFORMATION: Questions about this Webinar? Contact Benjamin Zaitz at the DIA office in Horsham, PA by telephone +1.215.293.5803, fax +1.215.442.6199, or email Benjamin.Zaitz@diahome.org.

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