FDA's Draft Guidance for Industry on Electronic Source Documentation in Clinical Investigations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
10:00 AM-11:30 AM CT
9:00 AM-10:30 AM MT
8:00 AM-9:30 AM PT

MODERATOR

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

PANEL

LESLIE K. BALL, MD, CAPT, USPHS
Director, Division of Scientific Investigations
Office of Compliance, CDER, FDA

JONATHAN HELFGOTT
Consumer Safety Officer, CDRH, FDA

BHANU KANNAN
Consumer Safety Officer, CBER, FDA

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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FDA's *Draft Guidance for Industry on Electronic Source Documentation in Clinical Investigations*, issued in early January 2011, is part of FDA's Critical Path Initiative to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 trail 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 To encourage and support industry in recording their clinical trial data in electronic format, FDA issued a draft guidance for industry on electronic source documentation in clinical investigations.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 Sacks and the panel will answer questions about the draft guidance.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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WebEx OS and Browser Support

	Windows	Mac OS X	Linux
Operating Systems	2000, XP, 2003, 32-bit Vista, 64-bit Vista (not including Remote Access and Productivity Tools), 32-bit Windows 7, 64-bit Windows 7 (not including Remote Access and Productivity Tools)	10.4, 10.5, 10.6	"Ubuntu 9.04, Red Hat 5, Open SuSE 11.1, Fedora 11"
Minimum System Requirements			
Processor	Intel or AMD	PowerPC or Intel	Intel or AMD
JavaScript	JavaScript and cookies enabled	JavaScript and cookies enabled	JavaScript and cookies enabled
Other	Active X enabled (unblocked for IE is recommended)	Apple Java 5 or above	"Sun Java 5 or above, libstdc++ 6.0, GNOME/KDE windowing system"
Browsers (Recommended browsers are shown in bold)			
Internet Explorer	6, **7, 8**		
Mozilla			1.7
Firefox	2/**3/3.5**	2/**3/3.5**	2/**3/3.5**
Safari		**4-Mar**	
Chrome	**3**		

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- Building, maintaining, and facilitating trusted relationships with and among individuals and organizations that drive and share DIA values and mandates; and
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WEBINAR

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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