Taking the "Risk" Out of Risk-based Monitoring

July 31

11:00 AM-12:30 PM EDT
10:00-11:30 AM CDT
9:00-10:30 AM MDT
8:00-9:30 AM PDT

MODERATOR AND PRESENTER

DARLENE PANZITTA
President and Founder
DSP Clinical Research

PRESENTERS

GUY BOLTON
Director of Clinical Operations
Ferring Pharmaceuticals

ANN MEEKER-O'CONNELL, MS, CCEP
Office of Policy, Office of the Commissioner
FDA

WHO SHOULD ATTEND

Professionals involved in:

- Clinical Research
- Clinical Safety/Pharmacovigilance

Worldwide Headquarters
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Regional Offices
Basel, Switzerland Tokyo, Japan Mumbai, India Beijing, China

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The pharmaceutical research industry is abuzz with the idea of risk-based monitoring. Very few companies have implemented risk-based monitoring into their clinical trials, as many sponsors and CROs feel that risk-based monitoring is too risky. They know that the traditional way of monitoring trials with 100% source document verification on a routine 4-8 week monitoring frequency is expensive, but it feels safe. It's the way they've always run their trials, and it's the way they can confidently show the FDA they are appropriately overseeing their studies.

This webinar will examine the *FDA Guidance for Industry Oversight of Clinical Investigations — A Risk-Based Approach to Monitoring, August 2011*, from the regulatory, sponsor and CRO viewpoints and discuss how the Guidance can improve risk-based monitoring and therefore overall clinical trial management.

We will look closely into the guidance document to see there is no "risk" in risk-based monitoring. It clearly provides the fundamentals in how to approach and organize monitoring plans in a way to better achieve protocol compliance, patient safety, and ensure date integrity for our critical data endpoints.

We'll also look at potential procedures in a risk-based monitoring plan, such as the use of an EDC System and centralized monitoring; subject safety risk assessments; identification of critical study data points; and, methods for ongoing evaluation of site performance.

LEARNING OBJECTIVES

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

- Discuss how to determine when a clinical research study requires, and how to develop a common sense risk-based monitoring plan.
- Describe potential procedures in a risk-based monitoring plan
- Explain the *Guidance for Industry Oversight of Clinical Investigations — A Risk-Based Approach to Monitoring, August 2011*, and determine if there is no "risk" in risk-based monitoring.

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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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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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