Research Dynamics Consulting Group
April 2012 Newsletter

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Greetings!

We hope you have been as busy as we have been! In the April 2012 newsletter, you'll find an announcement about some new webinar trainings, information about SOP templates, Lorraine's latest Ahead of the Curve blog post, and some recent FDA news.

Webinar Announcements

Coming May 17th and 18th

Since our webinars earlier this month were so successful, we are scheduling two more for mid May.

Draft Guidance for Industry Oversight of Clinical Investigations - A Risk Based Approach to Monitoring - Thursday May 17th 2012

Perfect For:
Sponsors | Monitors | Clinical Research Associates
Project Managers | GCP Auditors | Regulatory Personnel

Summary:
This new draft guidance, that was released last summer, replaces the 1988 Monitoring guidance. FDA has updated its monitoring guidance with some of the current monitoring practices, especially those using EDC systems. FDA has retained some existing practices and proposed some "radical" (some say) changes. The guidance proposes that each Sponsor develop a specific monitoring plan for each study based on the study risk and that includes both on-site and "centralized" (or "remote") monitoring.

CLICK HERE for more information and to sign up!

Monitoring in the 21st Century: What the Investigative Site Needs to Know - Friday May 18th 2012

Perfect For:
Clinical Research Investigators / Coordinators / Associates
Monitors | Project Managers | GCP Auditors | Sponsors

Summary:
This webinar discusses how FDA's new draft guidance on Risk-Based Monitoring will affect Investigators and Coordinators' daily study activities as well as when the monitor is performing monitoring activities.

CLICK HERE for more information and to sign up!

Standard Operating Proceedures

FDA expecting more standard processes at sites

SOP Templates

FDA's recent guidance documents are noting increased need for standardized procedures and processes at sites.

Investigator site SOPs provide standard procedures for site staff as well as a training tool for new coordinators and other site staff. Standard procedures help to establish and maintain quality for daily site activities.

Last year, Applied Clinical Trials **published an article** about the importance of SOPs - how a site that maintains and operates under SOPs demonstrates it has a commitment to research, and the effects that can have internally as well as assisting in the site selection process.

Our SOP Template Kit is a great tool and will provide a "quick start" on developing your own custom SOPs. And if you don't require the complete set, you can now purchase individual SOPs to add to your site's SOPs!

Ahead of the Curve

Re-engineering and Integration of Clinical Trial processes for Efficiency and Cost-reduction

Over the past 25 years I have been involved in implementing technology (EDC, CTMS, etc) in Clinical Trials and in revising processes for efficiency and cost-reduction. In one instance I was able to save the Sponsor $750,000 on one large trial by using technology more effectively and re-engineering the process.

The technology has greatly advanced over the years but the process for re-engineering is still effective. I have been involved in clinical trial process re-engineering for over 25 years so you can imagine the different changes in technology that I have seen and implemented. This blog will discuss the implementation of one type of technology... EDC.

In the past, re-engineering efforts involved processes within one department, such as Clinical Operations or Data Management. One of the recent changes in process re-engineering is the integration of clinical trial processes ACROSS departments for further efficiency and cost-reduction...

To read the rest of Ahead of the Curve, visit our blog!

FDA News

March 2012: Final Guidance "Guidance for Industry and FDA Staff FDA Acceptance of Foreign Clinical Studies Not Conducted Under an IND: Frequently Asked Questions".

This guidance document is intended to clarify for sponsors and applicants how they can demonstrate compliance with the requirements of 21 CFR 312.120 which requires the protection of human subjects enrolled in non-IND foreign clinical studies as well as the quality and integrity of the resulting data.

This guidance provides recommendations for the submission of information, whether in an IND or application for marketing approval for a drug or biological drug product, to demonstrate that a non-IND foreign clinical study was conducted in accordance with GCP.

GUIDANCE DOCUMENT

Thanks for reading, and please don't hesitate to give a call or email with feedback!

Alex Shortt
Research Dynamics Consulting Group
1250 Pittsford Victor Road
Pittsford NY 14534
585-381-1350 x246
ashortt@resdyncg.com