Research Dynamics Consulting Group
March 2012 Newsletter

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Featured Product

SOP TEMPLATE KIT

Our SOPs are now available as a full kit, or for individual purchase **Click Here** to learn more and to order!

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Greetings!

Spring is in the air for parts of the country! We've got a new blog post up, taking a look into monitoring time. Check out what Research Dynamics has been up to this past month:

NEW WEBINAR TRAINING

GCP Webinar Program Update

Our GCP Training Webinars are now available for individual students, student groups or as subscriptions for larger organizations such as IRBs, Hospitals, or Academic Medical Centers. There are 4 courses available:

- Basic GCP and Human Subject Protection Course - 8 hours (Four 2-hour webinars)
- Refresher GCP Course - 4 hours (Two 2-hour webinars)
- Advanced GCP Course - 4 hours (Two 2-hour webinars)
- Principal Investigator Training: Roles and Responsibilities (One 2-hour webinar)

These GCP courses are unique because they are available at your desk AND they are conducted with a LIVE with an expert Instructor. For more information, click on one of the courses above or contact:

Alex Shortt
585-381-1350 x246
ashortt@resdyncg.com

INDUSTRY NEWS

LOTS of FDA News

Reminder on Informed Consents: Although FDA's updated Informed Consent Regulations (21 CFR part 50) became effective on March 7, 2011, FDA has stated that this requirement will be enforced for informed consent documents and processes for trials that are initiated on or after **March 7, 2012.** This new update requires that informed consent documents contain a statement that the results of the trial will be listed on www.clinicaltrials.gov See below. Don't forget to add to all new trial consent forms!

"Sec. 50.25 Elements of informed consent.
(c) When seeking informed consent for applicable clinical trials, as defined in 42 U.S.C. 282(j)(1)(A), the following statement shall be provided to each clinical trial subject in informed consent documents and processes. This will notify the clinical trial subject that clinical trial information has been or will be submitted for inclusion in the clinical trial registry databank under paragraph (j) of section 402 of the Public Health Service Act. The statement is: "A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."

During February FDA has issued (Feb 2012) 3 draft guidance documents to provide information to those companies developing Biosimilars.
1. Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009. (link)
2. Quality Considerations in Demonstrating Biosimilarity to a Reference Protein Product (link)
3. Scientific Considerations in Demonstrating Biosimilarity to a Reference Product (link)

DRAFT guidance on "Providing Regulatory Submissions in Electronic Format Standardized Study Data" during February 2012 (link)
This guidance document is intended to assist sponsors and applicants making regulatory submissions to FDA in electronic format. This guidance establishes FDA's recommendation that study data are submitted in a standardized electronic format. This guidance applies to submissions of clinical and nonclinical study data within INDs, NDAs, ANDAs, IDEs, BLAs, 510(k)s, and PMAs, to CDER, CBER, and CDRH.

Final Guidance for "IRBs, Clinical Investigators and Sponsors. IRB Continuing Review after Clinical Investigations Approval" Feb. 2012 (link)

This guidance is intended to assist IRBs in carrying out their continuing review responsibility under 21 CFR 56.108(a) and 56.109(f) by providing recommendations regarding the criteria, process, and frequency of continuing review to assure the protection of the rights and welfare of human subjects enrolled in clinical investigations. This guidance should also help clinical investigators and sponsors better understand their responsibilities related to continuing review. This document supersedes the Information Sheet, Continuing Review After Study Approval (September 1998, Office of Health Affairs, FDA).

Draft Guidance on "FDA Acceptance of Foreign Clinical Studies Not Conducted Under an IND FAQs" (link)

This guidance document is intended to clarify for sponsors and applicants how they can demonstrate compliance with the requirements of 21 CFR 312.120. It 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.

AHEAD OF THE CURVE...

Maximizing EDC

Lorraine Ellis

Research Dynamics integrated the use of EDC over 7 years ago! We re-engineered our monitoring and site management processes to generate efficiency and improve data quality. Our processes were also modified to improve the oversight of the Investigator site activities and enhance compliance at the Investigator Site.

With its release of its new draft monitoring guidance (Risk-based Approach to Monitoring, August 2011), FDA is now encouraging a variety of monitoring approaches to monitoring the quality of Investigator conduct and data collection. FDA is specifically encouraging greater use of centralized monitoring methods!

We have been using "centralized" monitoring for over 7 years! Now that FDA is supporting centralized monitoring, many CROs will state that they perform centralized monitoring and plan risk-based monitoring processes. Few, if any, will have the length of experience and the re-engineered processes that we have. We have also conducted trials with these efficient processes with 6 different EDC systems so we can modify our processes to work with any system or your system.

With FDA's new recommendations for monitoring, new types of monitoring plans must be considered and written. The plan should be based on a risk assessment that considers the factors and parameters of the study and should focus the monitoring activities on those procedures and data that are critical to the reliability and results of the study. Our experience in writing and implementing these plans has resulted in studies that are more efficient and have improved data quality.

For an example of how our centralized monitoring processes saved time and money in a trial, please read our case study.

For more information on FDA's new recommendations on Monitoring please see the draft guidance.

Regards,

Lorraine

Thanks for reading, and please contact us with any question or comments you might have!

Sincerely,

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