Research Dynamics Consulting Group Newsletter

December 2011

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Featured Product: SOP Template Kit for the Investigator Site

Our SOPs are now available for **individual purchase** or as a full kit!

Improve regulatory compliance

Enhance staff performance

Reduce supervisory and management time

Standardize training and research practices

Investigator Registration

Click here to access our Investigator Registration form

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Greetings!

As the year comes to a close, we think about New Year Resolutions and the changes we will institute next year. We have several end-of year activities to complete as I am sure you do as well. We are planning to review our successes and challenges and act on lessons learned for next year. We will conduct our annual review of our processes and procedures and prepare and implement improved procedures for next year. We will also develop our training plans for new and current employees for skill development and to learn new GCP items.

As you complete your year-end activities, perhaps one of the items or information below can help you complete your activities.

Don't forget to check **our blog** regularly for news and comment!

Happy Holidays and a peaceful New Year!

Lorraine

THOUGHTS FROM LORRAINE

Several interesting news items within the industry this year have had a significant effect on clinical trials.

- Early approval program and its oversight works! Although Avastin was able to be approved for breast cancer through the accelerated approval program, it did not live up to its promise and FDA has reversed their approval decision for the breast cancer indication. Although a disappointing outcome, it is encouraging to see that the accelerated approval program does provide treatments to patients earlier AND that it also has the oversight to ensure there are clinical trial data to support the early approval.
- Devices face new approval pathways. FDA continues to overhaul the 510K and medical device approval programs requiring stricter requirements for devices, some including new clinical trials, and a more transparent review and approval process. Two new draft guidance documents are noted below.
- New technologies and treatments are reaching the market. The first cord blood product, Hemacord, was approved by FDA this month providing life-saving treatments for patients.
- Monitoring processes will be different and risk-based. A new draft Monitoring guidance document was released by FDA that will significantly change how Sponsors and monitors view the monitoring process. Once finalized, we expect more efficient monitoring plans that are based more on risk than "usual" procedures.
- Technology continues to change clinical trial procedures. Roles and responsibilities for monitors and data managers continue to be variable as the industry more readily adopts EDC and re-engineers its processes.

After more than 30 years in clinical trials, I can't wait to see what happens next year!

SOPs: 26 INDIVIDUAL SOPs NOW AVAILABLE FOR PURCHASE

Complete Template Kit Still Available

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!

FDA NEWS

Noteworthy Avastin Decision

FDA has decided to revoke the agency's approval of the breast cancer indication for Avastin (bevacizumab) after determining that the drug has not shown to be safe and effective for that indication. Avastin will remain on the market for other indications

Link: FDA Commissioner Announces Avastin Decision

New Draft Guidance Documents

FDA continues to issue new draft guidance documents for medical devices as it revises the 510k and IDE programs. Here are 2 new guidance documents:

Draft Guidance for Industry and Food and Drug Administration Staff - Investigational Device Exemptions (IDE) for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human (FIH) Studies

This Document discusses early stage development of medical devices and new approaches towards early feasibility studies that would resolve final design issues before the large pivotal clinical trial.

Draft Guidance for Industry, Clinical Investigators, Institutional Review Boards, and Food and Drug Administration Staff - FDA Decisions for Investigational Device Exemption (IDE) Clinical Investigations

The Second Guidance Document describes FDA's process for approving application for the conduct of medical device clinical trials.

WHITE PAPER: NOW AVAILABLE

"Integrating Trial Data Process Across Functional Areas Using EDC Technology"

The white paper describes how to implement the use of EDC systems across clinical, data management, biostatistics and the Investigator sites to maximize the benefits of the latest EDC systems. Available in our **White Papers** section on our website!

DECEMBER 9th WEBINAR - INVESTIGATOR RESPONSIBILITIES

Stay Up-To-Date on FDA's Expectations of Investigator Activities - Webinar for Investigators, Coordinators, Monitors, and Sponsors!

Investigator responsibilities have evolved over the years to more exacting standards and details. FDA recently released a new guidance that modified some of the earlier guidance. This seminar will provide details on such topics as Investigator Supervision, trial planning, and delegation and protecting subjects.

This class is great for Investigators, Coordinators, Monitors, and Sponsors, and is a fantastic way to supplement your training and stay up-to-date, and all at a great price - just $99! This 1 hour class will be lead by Lorraine Ellis, who has over 30 years clinical research experience and is the author of several books, articles and other clinical research materials.

Click to learn more and sign up

Thanks for reading our update. Please feel free to contact us with any questions or comments!

Sincerely,

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