Research Dynamics Consulting Group Newsletter

October 2011

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Featured Product: SOP Template Kit for the Investigator Site

More comprehensive, with new easy to understand text, and sample job descriptions.

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

Join Our List

Join Our Mailing List!

Greetings!

The new draft monitoring guidance continues to be discussed throughout the industry. Be sure to see linkedin groups and website blogs about this new guidance. Every monitoring group will need to evaluate the implications of this guidance on their clinical trials. Our September blog adds our comments on the guidance. **Be sure to read it!**

Our webinar this month is a repeat of a popular one - Investigator Responsibilities. We have revised our webinars to be more concise to fit into a lunch hour, since we are all so busy - read more about this below.

We will be publishing a new White Paper on EDC on our site at the beginning of November... watch for it!

Have a great month,

Lorraine

NEW FORMAT WEBINARS

"Lunch Group" Webinars - More Concise and a Better Price!

After speaking with folks who have joined our webinar training groups, we found the number one suggestion was that we cut down the time of our webinars from 1.5 hours to 1 hour. And with that, we've dropped the price too!

Our new **1 hour "Lunch Group" Webinars** will run from 12pm - 1pm Eastern time and are **now just $99**. Many folks have in-house training programs, but these webinars are a crucial add-on to make sure you and your staff are as up-to-date as possible with recent FDA Guidance and changes.

The next webinar on the schedule will be covering **Investigator Responsibilities**. This course will teach you how the latest FDA information affects your daily clinical trial activities. You may need to change what you currently do to continue to be compliant. This webinar is scheduled for Friday November 11th at 12:00pm Eastern time.

Click here to read more about this webinar and to sign up!

LATEST FDA NEWS:

CDRH continues to provide documents from the Plan of Action announced earlier this year. We still have yet to see the "510(k) Paradigm Guidance" that was planned for September delivery to provide greater clarity for clinical trial data requirements for these products.

Be sure to read this new medical device draft guidance:

Draft Guidance for Industry, Clinical Investigators, and Food and Drug Administration Staff - Design Considerations for Pivotal Clinical Investigations for Medical Devices

Follow us on twitter

RDCG - Now Tweeting!

Follow us and check in, we'll be sharing links and insight on all the lastest industry news and notes!

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

Sincerely,

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