December 2013 Newsletter

Greetings from Lorraine.

As another year nears the end, it is a chance to review the year's activities and plan for next year. We at Research Dynamics review our clinical trial activities with a view to continuous improvement and improving our processes.

Have you reviewed your processes and SOPs recently? Most organizations review them on an annual basis. Are they up-to-date with your actual procedures and current FDA GCP guidance and regulations? Do you need updated procedures?

As I conduct GCP audits during the year, I still see outdated SOPs that are not up-to-date with current actual procedures or GCP requirements. I also find that many of the organizations do not have SOP training on a regular basis or for new hires.

Inadequate training and training records are also common findings from my audits. GCP training should be completed on a regular basis, usually annually, especially if FDA has issued new guidance documents or regulations. Be sure to update your GCP training materials with the most current GCP requirements before each class.

Be sure to train your staff in your SOPs and procedures. The best way to ensure repeatable quality results in each trial is to have standard procedures that the entire team can follow. Finally, as you review the year that is completing, make plans for next year's projects: Update or revise SOPs, prepare new training sessions, review processes for continuous improvement, and find new ways to conduct trials.

I hope everyone enjoys their Holidays and has a great New Year!

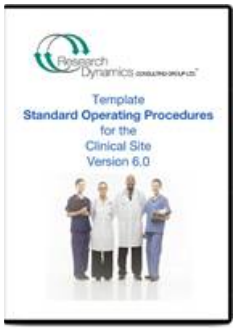
-Lorraine

SOP template Sale

END OF THE YEAR SALE 10% off until December 31st

Investigator SOP Templates 10% Off

As 2013 comes to an end, we are offering 10% off from now through December 31st on our SOP Template Kit.



Having up-to-date SOPs is extremely important and helps to ensure a quality and consistency for all your projects throughout your year.

Also check out our training books. They are a great way to help improve GCP compliance and help increase productivity and the overall quality of your work!

Sponsors!... we also provide custom SOPs for your clinical trial activities. Contact Gail Kalbach using the information below.

To order, get discount at checkout through paypal payment or contact Gail (gkalbach@resdyncg.com) or 585-381-1350 x228.

Learn More - Research Dynamics products site

FDA News

FDA has issued some new guidance documents:

Guidance for Industry: Oversight of Clinical Investigations - A Risk-Based Approach to Monitoring [.pdf] FINAL

This guidance assists sponsors of clinical trials in developing risk-based monitoring strategies and plans for studies of drugs, biologics and devices. This guidance provides information to enhance human subject protection and the quality of clinical trial data by focusing sponsor oversight on the most important aspects of study conduct.

Sponsors can use a variety of approaches to fulfill their monitoring responsibilities. The guidance describes strategies for monitoring activities for a risk-based approach focusing on critical study parameters and using combination of monitoring activities. One of the newer strategies is to use centralized monitoring to a greater degree when appropriate.

Guidance for Industry: Codevelopment of Two or More New Investigational Drugs for Use in Combination [.pdf]

This guidance is intended to assist sponsors in the codevelopment of two or more new drugs that have not been previously developed for any indication to be used in combination to treat a disease or condition.

Guidance for Industry: Electronic Source Data in Clinical Investigations [.pdf]

This guidance provides recommendations to sponsors, CROs, Investigators, and others involved in the capture, review, and retention of electronic source data in FDA-regulated investigations.

The guidance discusses identification and specification of source data originators, creation of data element identifiers to facilitate examination of the audit trail bysponsors, FDA, and other authorized parties. It discusses ways to capture source data into the eCRF using either manual or electronic methods, and clinical investigator(s) responsibilities with respect to electronic source data, and use and description of computerized systems in clinical investigations.

Check out our new website

We have just launched our re-designed website. It is easier to read and find information. It is located at www.resdyncg.com.

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For a competitive bid on your next project, **Email Lorraine Ellis** with your RFP.

Gail Kalbach
585.381.1350 x228
gkalbach@resdyncg.com

Thanks for reading, and we look forward to hearing from you!

Please forward to a colleague who might be interested or send us their email address and we will add them to our mailing list.

Give us a call today!

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