July 2014 Newsletter

From Lorraine's Desk

Hope you are having a great summer! It's a great time of year for outdoor activities and vacations.

Unfortunately there is no vacation from GCP compliance. Every trial, all the time, must meet GCP requirements. This month we have several activities highlighting trial document compliance and ways to keep your documents accurate, complete and in compliance.

- I will be providing a free webinar this month with Bio-Optronics on "Maintaining Regulatory Compliance with Trial Documents" that you will want to attend.
- Our blog will be discussing trial documents and their importance to the quality of your clinical trial.

Enjoy your summer, relaxed schedules and vacations!

SOP Summer Sale

10% off Investigator SOP Templates until August 15, 2014

Have you updated or reviewed your SOPs lately?
There have been some changes in the conduct of clinical trials that may modify your procedures:

- Has risk-based monitoring changed the way your site is monitored or the way you process clinical trial data?
- Has the increased use of EDC affected your data collection or data recording processes?
- Has the guidance for increased supervision of staff by the PI changed your training methods, or communication procedures?
- Have your source documentation methods changed through EHR (electronic health records) or Sponsor use of electronic records?

If so, we recommend you review your SOPs and modify them to match your actual processes.

Sponsors, we have SOPs for you too!

We provide Custom SOPs for your clinical trial activities since every Sponsor has specific requirements and corporate policies for their processes.

We also can audit your SOPs for gap analysis or review them to determine needs for updates.

To order, get discount at checkout through paypal payment or contact Gail Kalbach (gkalbach@resdyncg.com) or 585-381-1350 ext 228.

Learn More - Research Dynamics products site

FREE Webinar on Essential Clinical Trial Documents

Lorraine will be providing a free webinar on: "Maintaining Regulatory Compliance with Trial Documents" on Thursday July 17, 2014 at 3:00 pm EDT. For more information and to sign up, go to https://www2.gotomeeting.com/register/375050658

Our latest Blog - Essential Documents

According to ICH E-6 Guidelines, "Essential Documents are those documents that individually and collectively permit evaluation of the conduct of a trial and the quality of the data produced. These documents serve to demonstrate the compliance of the investigator, sponsor, and monitor with the standards of GCP and with all applicable regulatory requirements".

In other words, these trial documents provide a reference on how the trial was conducted and whether it was in compliance with GCP requirements. In addition, it validates the quality and integrity of the data collected and recorded during the trial.....**Read more on our blog**

Check out our website located at www.resdyncg.com.

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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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