Research Dynamics Consulting Group

November Newsletter: Training

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For a competitive bid on your next project, **email Lorraine Ellis** with your RFP!

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Greetings!

As this year ends, it completes 30 years in clinical research for me. When I started as a monitor, there were very few Study Coordinators and monitoring was much less rigorous. Most PI's completed all the paperwork and case report forms. Monitors carried back mounds of corrected paper CRFs. As I review the 3 decades, I see improvements as well as increasing complexity in the conduct of clinical trials.

Some of the improvements over the years:

- No more carrying many pounds of CRFs back to the Sponsor!
- Remote monitoring allows for cleaner data and less costly monitoring.
- Some Investigator sites have become more proficient with more consistent results.
- Faster FDA approvals for therapeutic advances.

Some of the changes that have increased the complexity and difficulty of conducting clinical trials that result in product approvals:

- Protocols have increased in complexity.
- More procedures are expected per protocol.
- CRFs are collecting more data than ever.
- Higher expectations of compliance.
- Monitoring has become more complex requiring more experienced monitors.
- Collection of safety and adverse event data has increased.

Overall most of the changes in clinical research have resulted in better clinical trials.

So, to continue your work in clinical research for the next decades, keep informed of new GCP requirements, and changes in standards, and keep your clinical research skills and knowledge current. You never know what will be the next change in clinical research and you need to be ready for it.

- Lorraine

Spotlight on Research Dynamics GCP Training Webinars

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
- **Refresher GCP Course** - 4 hours
- **Advanced GCP Course** - 4 hours
- **Principal Investigator Training: Roles and Responsibilities** - 2 hours

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:

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Spotlight on our Training Course - Clinical Quality Assurance and Audit Conduct

This course provides information on Clinical Quality Assurance and practical techniques and procedures for conducting CQA audits. Developing and implementing CAPA plans after the audit are also discussed.

Our trainers are active auditors so we have up-to-date information, examples, and experience to share with you during the course. In the past month we have conducted audits in oncology and medical devices. For more information, please click below!

For more information on the Clinical Quality Assurance and Audit Conduct course, click here!

New Blog Post on Clinical Research Training

How do you know when you or your staff needs additional training to conduct or monitor clinical trials properly?

- Are they new to clinical trials or new to your organization?
- Have they had training in ALL the basic and necessary topics relevant to clinical trials?
- Do they need special topics training to perform their job more effectively?
- Do they need special expertise, skills or knowledge to perform their clinical trial responsibilities?
- When they perform their clinical trial responsibilities, are the results inconsistent or of poor quality?

Click Here to continue reading!

Great reviews of Research Dynamics' Webinar Training Programs

Here's some real feedback from one of our recent webinars:

"My training with Research Dynamics Consulting Group far exceeded my expectations! The training was extremely thorough, but also allowed for quality Q & A sessions with Lorraine. I especially enjoyed hearing about the real life scenarios that can occur in clinical research and the importance of detailed records and communication!!"
-Clinical Research Professional, 2012

"I honestly did not expect to hear much that I had not heard in the past, but was surprised at some of the material, and I learned several things I did not know."
-Clinical Research Professional, 2012

For more information about our GCP Webinars, click here!

We'd love to hear from you! Call or email with your comments, or reach out to us on Twitter!

Sincerely,

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