Research Dynamics CONSULTING GROUP LTD™

*April 2013 Newsletter*
*Site Monitoring*

# Greetings from Lorraine.

After 30 years of involvement in monitoring, I have seen many changes. When I started monitoring in the early 80's, the PI did most of the work including completing paper CRFs and regulatory documents and had sporadic assistance from other office staff. There was no official CRC position and office staff filled in. Everyone was working part-time on studies after completing their "regular" office job. Monitors dragged home reams of paper CRFs after a monitoring visit but studies and data review were easier since protocols were about 10-15 pages long and not as complex as they are now.

Shift to 2013 when CRCs are now formal professionals that are certified. CRCs complete most of the eCRFs and documents and the PI works on the clinical parts of the protocol. Monitors can review eCRFS from the office and there are no paper CRFs (in most cases) to take back to the office. Protocols and trials are more complex and CRCs and monitors need more time to work on them.

The August 2011 FDA draft guidance on monitoring has started many people discussing monitoring methodologies. Technological advances have affecting monitoring practices by bringing more monitoring "in-house", so to speak. Both these events should trigger a radical change to the way we currently monitor. The challenge is.... Is everyone ready for a foundational change in monitoring? **See my blog this month for more**

## New Blog:
Site Monitoring

Clinical site monitoring is a common term in clinical research but, after a review of many CRO websites, oversight of many monitors, and experience working with many different Sponsors; it appears that there are many definitions of monitoring and "adequate" monitoring. The practice of monitoring ranges in intensity, procedures, emphasis, and scope across all the entities. This variability is not surprising considering that... **Keep Reading**

## FDA News
FDA has issued some new final and draft guidance documents:

### Proposed Rule: Human Subject Protection; Acceptance of Data from Clinical Studies for Medical Devices (.pdf)

FDA is proposing to amend its regulations on acceptance of data from clinical studies for medical devices. The proposal will require that clinical studies conducted outside the United States be conducted in accordance with GCP, which includes obtaining and documenting IRB review and approval and obtaining informed consent from study subjects. This proposed rule will also amend the IDE and 510(k) regulations to address the requirements for FDA acceptance of data from USA clinical studies so that there is consistency in FDA requirements for acceptance of clinical data, whatever the application or submission type.
**Comments are due by May 28, 2013.**

### Financial Disclosure by Clinical Investigators (.pdf)

This guidance is a revision of the guidance dated March 20, 2001. This is the final version of the updated guidance. It was prepared to assist clinical investigators, industry, and FDA staff in complying with the financial disclosure regulations 21 CFR part 54.

### Humanitarian Use Device (HUD) Designations (.pdf)

This guidance document is the final version and intended to assist applicants in the preparation and submission of Humanitarian Use Device (HUD) designation requests to FDA. It is also designed to assist FDA reviewers in their evaluation and analysis of HUD designation requests.
This guidance addresses only HUD requests, which are the first step in seeking marketing approval of a HUD. This guidance does not address the second step in this marketing approval process-namely, the submission of a Humanitarian Device Exemption (HDE) application to FDA.

## April ACRP Meeting Sale
10% Off our SOP Template Kit, GCP Guide, and CRA/CRC Reference Books

We are happy to offer 10% off your order of our SOP Template Kit, GCP Guide, and CRA/CRC Reference Books during the month of April to coincide with ACRP 2013. **Please visit our website** to learn more about these products and to place your order.

## Preparing and Updating SOPs - Free Webinar

To assist in your review and preparation of SOPs to conduct quality research, Lorraine Ellis will be hosting a free webinar on designing, revising, and preparing SOPs at the investigator site. This webinar will be held on May 1st from 12 - 1pm EST. **Sign up today.**

**Alex Shortt**
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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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