June 2013 Newsletter
Document Management

Greetings from Lorraine.

This month we are focusing on Document Management and SOP preparation.

Whether you are a Sponsor, IRB, or Investigator Site, there are many regulatory and trial documents to manage during a clinical trial. There are also many steps in the processing of each document that need to be completed and tracked. How does an organization keep track of the documents and their status?

Some use Word tables or Excel spreadsheets. There are limitations to these methods including limited search capabilities, and potential for loss of data as different people access the spreadsheet.

Some use relational databases such as Access which is a slight improvement as it has better search capabilities.

What is really needed is a process to manage the documents (eg SOPs) and a system for managing the documents and the data about the documents (eg, document status, expiration date, etc).

I have audited Sponsors and Investigator Sites and am surprised how many organizations do not have a hard copy filing system, or some type of tracking system, or even a SOP to govern document management. Since FDA inspections consist of reviewing all types of documentation, it makes sense to have a procedure (SOP) and system (database) to manage the clinical trial documentation.

We use a CTMS system to manage all our clinical trial documentation. It has saved us time and assisted in maintaining GCP compliance in many trials. I will provide more information on this procedure next month.

For this month, we have two opportunities for assistance in managing your documents. Our Blog discusses using a system for document management. For SOP assistance, we are offering a new Webinar on "SOP design and preparation"

Have a great summer month!

-Lorraine

New Webinar Announcement:
SOP Design and Preparation

Last month, Research Dynamics offered a webinar on the Importance of SOPs. The demand for this webinar was overwhelming and we had to add a second webinar which filled up quickly! Feedback was great, and a lot of people asked if we would present another webinar that went into more depth on designing and preparing SOPs.

We listened to you, and are happy to announce that we will be holding a new webinar on July 12th called "**SOP Design and Preparation**". Some details:

This 2 hour webinar will provide instruction on how to design the procedures and document them in practical SOPs that will provide your organization will greater consistency and higher quality results. Once the SOPs are written and implemented, your organization will have a standard method for day to day clinical trial procedures that will improve your quality and provide more compliant results.

Procedural design will include how to create step-by-step directions from your clinical trial processes. Discussions on implementation, training and maintenance will also be included.

Case studies and examples of SOPs will be discussed.

This webinar will be presented on **July 12th** from **11:30am - 1:30pm Eastern time**, and we are offering it at a summer sale price of $99!

CLICK HERE TO REGISTER!

New Blog:
Document Management

*We have a guest blogger this month, **Chartfield Bliss** from **Bio-Optronics**. He has some great ideas for handling the volumes of clinical research documents that every Site, Sponsor and IRB manages for each clinical trial. Research Dynamics uses our CTMS system to organize, track, manage, and inventory our clinical research documents. It is one of the easiest ways to track documents during a clinical trial.*

"FDA audits can be one of the most terrifying and stressful events that a clinical research organization may encounter. Audits can quickly sneak up on the unsuspecting research organization. A staggering 77% of all FDA warning letters are..." **Keep Reading**

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

Draft Guidance: Charging for Investigational Drugs Under an IND - Q&As

This draft guidance is intended to provide information for industry, researchers, and physicians about the implementation of FDA's regulation on charging for investigational drugs under an Investigational New Drug Application (IND) (21 CFR 312.8), which went into effect on October 13, 2009. It includes information concerning charging for investigational drugs made available under expanded access programs.

Draft Guidance: Expanded Access to Investigational Drugs for Treatment Use - Q&As

This draft guidance is intended to provide information for industry, researchers, physicians, and patients about the implementation of FDA's regulations on expanded access to investigational drugs for treatment use under an investigational new drug application (IND) (21 CFR part 312, subpart I), which went into effect on October 13, 2009.

Molecular Diagnostic Instruments with Combined Functions DRAFT April 2013

FDA's current thinking on regulation of molecular diagnostic instruments that are intended for use as a device and for other non-device functions. It provides advice on the type of information that should be provided in a premarket submission for a molecular diagnostic instrument that measures or characterizes nucleic acid analytes and has combined functions. In this document, "combined functions" refer to instruments that serve as a component of an FDA-cleared or approved IVD system but can also be configured by the user for other test purposes, such as basic research.

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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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