



The Past Year in Articles

Throughout the years, Kit Howard has published many articles both in trade journals and in K-News as well as her personal blog. We at Kestrel thought that a catalogue of her articles of the past year might be a good way to let our newer readers know what we at Kestrel are about. Past issues of K-News and K-Blog can be found at www.kestrelconsultants.com

K-News:

- August 2009, [FDA on Quality and Risk in Clinical Trials](#), At the DIA's 2009 Annual Meeting, Dr. Leslie Ball, Director of the Division of Scientific Investigations at FDA's Center for Drug Evaluation and Research (CDER), delivered a great presentation on the FDA's views on data quality and risk in clinical trials.
- September 2009, [The Line of Control](#), An interesting article on where we, as members of industry, see ourselves in our own departments as well as our role in projects. This article helps readers to understand the reason behind the perception and gives steps to help alleviate feelings of powerlessness.
- December 2009, [ISO Updates Medical Device GCP](#), The International Standards Organization (ISO) issued the final draft of ISO 14155.2, "Clinical Investigation of Medical Devices for Human Subjects – Good Clinical Practice." This revision combines two prior documents (ISO 14155-1:2003 and ISO 14155-

2:2003) covering general research requirements and clinical investigation plans, respectively and the differences between each version of the document.

Did You Know?

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Standards Management 101

If you have decided to adopt clinical data standards, you know that standards promise cost and efficiency improvements. But what you might not know is that standards management requires a specialized and dedicated knowledge set that does not exist in other functional areas. Kestrel has developed the Standards Management 101 education series to address just that. Our in-depth 7-part course teaches you the range of skills necessary for ongoing development, management, maintenance, tracking and retirement of standards in today's increasingly streamlined industry.

Standards Management 101 Session Titles

Part 1: An Introduction to Standards

Part 2: Standards Development

Part 3: Standardization and Flexibility

Part 4: Governance

Part 5: Managing Standards

Part 6: Standards in Contracted Clinical Environment

Part 7: When Standards Collide

*The Last Year in Articles cont.**(Continued from page 1)*

- January 2010, [FDA Guidance on DILI, New Data Requirements for all Trials](#), The FDA issued a *new final guidance defining clinical trial design, data and analysis requirements* for drug-induced liver injury, or DILI, cases *in all drug and biologic agent clinical trials*. This article highlights some critical aspects of the guidance.
- March 2010, [EDC Help Text Or No EDC Help Text, That is the Question](#), There is debate today about whether or not EDC applications should contain completion instructions and/or help texts associated with individual fields or eCRFs. This article goes into the pros and cons and the reasons behind them.

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Employment Opportunities

From time to time, Kestrel receives emails for employment opportunities and we have decided that it would be a great idea to pass them onto our colleagues. If you can't benefit from this, but you know of someone who would, please pass it along.

Position: **Senior CDM**, Location: **Southern US**, This is a contract-to-hire position where we will pay for temporary housing expenses during the contract portion of the project. Contact: **Colin Dittus**, Dir, Contract Staffing, Life Sciences Division, Klein Hersh International, 2300 Computer Avenue Suite C-15 Willow Grove, PA 19090, 215-830-9211 Ext. 117 cdittus@kleinhersh.com, www.kleinhersh.com

Position: **Senior Biostatistician**, Location: **Rockaway, NJ**, Reporting to the Director of Biostatistics and Statistical Programming, The Senior Biostatistician; researches, designs and executes statistical activities in clinical trials from protocol conception and development to final study report as well as data driven analyses, regulatory responses, and data mining. Contact: **Elise Wilkins**, WILKINS 231 North Avenue West, Suite 149, Westfield, NJ 07090, 908-301-0536 elisewilkins@elisewilkins.com, <http://www.elisewilkins.com>

Position: **Data Manager**, Location: **Rockaway, NJ**, Data Manager to manage clinical studies as a DM lead. Ability to work and operate independently within a tight deadline environment as well as with teams. High degree of creativity, latitude and attention to detail required. Familiarity with all applicable regulations including; CFR, GCP, and ICH Guidelines. Works with involved parties to assure that DMM is prepared according to company SOP's and in compliance with companies data standards. Coordinates, leads and performs clinical data management activities for assigned studies in accordance with companies SOP's and policies and practices. Contact: **Elise Wilkins**, WILKINS 231 North Avenue West, Suite 149, Westfield, NJ 07090, 908-301-0536 elisewilkins@elisewilkins.com, <http://www.elisewilkins.com>

Consultant's Corner

Kestrel is pleased to bring a new feature to K-news, the Consultant's Corner. In every issue, we will highlight members of our consulting community by listing their company's name, contact information and specialty. The goal is to present our readers with a resource to utilize if and when a consultant's expertise is needed.

Name: Richard McLain, MS
 Company: PFP Statistical Consulting, LLC
 Email: richard.mclain@ameritech.net
 Phone: 734-266-0100
 Services: STATISTICAL SUPPORT: Over 20 years experience working for a large pharmaceutical company. Providing support with study design, sample size calculation, protocol development, statistical analysis plans, interim analyses, DSMB reports and final analyses.



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- April 2010, [FDA Takes up Standards Again](#), An in-depth article on the FDA jointly hosted "Computational Science Annual Meeting," a conference to explore how advanced scientific computing tools can help the agency become more efficient.
- May 2010 K-news, [CDASH v1.1 & Review of the User Guide](#), This article briefly describes the history of CDASH, the documents that were out for review, the process for submitting comments, and provides some guidance on reviewing the documents.
- June 2010 K-News, [Ten Myths About standards](#) talks about the ten most common misconceptions that people have when it comes to clinical data standards.



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Do you...

Manage the Risks in Cleaning Your Data?

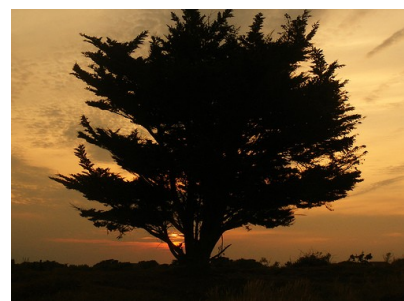
Order Kestrel's prerecorded 2-part webinar, *Risk Assessment in Cleaning Clinical Data*, for the tools you need to optimize your data cleaning.



Fun Pharma Facts

Did you know?

Paclitaxel has become one of the most effective drugs used in the treatment of breast and ovarian cancers. It was first found in 1970 when the US National Cancer Institute tested plants held in various collections. Paclitaxel was found in an extract that had been made from the bark and needles of the Pacific yew. Taxol (the trade marked drug) is now made from the needles of the English yew. Research continues into the compounds obtained from the yew and their role in treating cancers.



Yams belong to the botanical group dioscorea, which contain a range of steroids and alkaloids. The most significant steroid obtained from yams was diosgenin in the 1940s by Russell Marker, who found he could synthesize testosterone and progesterone from it. By 1951 the first chemical to be used as an oral contraceptive had been made and clinical trials began which led to "The Pill" being available in the 1960s.

Thanks to www.corsinet.com for the above trivia.

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Consultant's Corner Cont.

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 Services: consulting and auditing services in the areas of clinical data management, electronic data capture (EDC), e-clinical, data repositories, and outsourcing



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K-Blog

Here are some K-Blog highlights over the past year:

- Monday, December 7, 2009, [Complexities in Reporting SAEs: What do the Regs Really Say?](#) “If a patient is randomized to the study but never receives study drug, must site staff report serious adverse events (SAEs) for this patient?” I think the answer is probably “it depends”! As with most aspects of clinical research, deciding what to collect and to report requires understanding the risks associated with the different choices. Go to www.kestrelconsultants.com for the full entry.
- Sunday, October 18, 2009, [Structuring Clinical Data: AE Seriousness Fields](#), Even in a world with data standards, clinical data can be structured in different ways and still be standards-compliant. This is especially true when the standards define what to collect, but not how, or when, or in what combination. This article takes one example, the serious adverse event (SAE) fields, and explores several designs and the circumstances in which they could be appropriate.

If the above articles are of interest to you, please go to

www.kestrelconsultants.com for all of our past K-News and K-Blog articles, as well as links to some of Kit’s articles that have appeared in trade journals.

Fan Forum!

In case you don’t hear it enough- your K-news is great! Thanks for sharing, Christine

Christine Lys, M.S.
Director Business Development

Merge eClinical

Do You Know

Clinical Data Design Best Practices?

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Best Practices in Designing Clinical Data

Then You Will.