



Eligibility Criteria: 1; Enrollment: 0!

It is common knowledge that a substantial proportion of trials fail to complete on time, and a big factor is slow enrollment. Lasagna's Law states (roughly) that a given site has lots of eligible patients, most of whom disappear as soon as the protocol is signed, only to reappear as soon as enrollment is done. Its severity is inversely proportional to the number and restrictiveness of the eligibility criteria.



To improve this, it helps to know why criteria are set. Some define the condition under study, and others exclude subjects who may be at increased risk for AEs. Still others define analysis populations. Each is usually based on literature references, the company's prior experience, and/or expectations of regulatory requirements. Regardless, this doesn't always tell us *why* the criteria exist. Why an upper age of 65? Is it because it's the upper end of the range for menopause? An arbitrary age after which increased health issues are likely to appear? A regulatory expectation? If the last, why is it set there? Knowing why could allow criteria to be adjusted and perhaps make recruitment a little easier.

One approach is to document the reason for each criterion very clearly, including a specific rationale, why it is included, the evidence supporting it, and why parameters were set as they were. Here are two examples from a first-in-humans study:

Inclusion: Male and female subjects between the ages of 18 and 45 years, inclusive. ECG 4 weeks prior to the screening visit	Sex: There are no reasons to exclude either sex Age: 18 is the age of consent; 45 is the lower limit of the average age of onset of menopause (citation) ECG: this ensures no active cardiovascular conditions (<i>note: this states that it must be 28 days prior, or it's a deviation—better to be more flexible—within 4 weeks, or 3 to 5 weeks</i>)
Exclusion: Supine blood pressure at screening above 140/90 mmHg.	Animal models indicate possible hypertensive effects; excluding hypertensive subjects reduces the risk of these AEs. 140/90 is the standard definition of hypertension (citation)

New K-Blog Rant!

Why do so many companies still use the same inefficient and ineffective clinical trials processes that were discredited 15 years ago?! It seems as though our industry hasn't moved forward at all. Every other industry has. Why not us? The latest K-Blog points the finger at some likely culprits. Check it out and add your comments!



They Like It!!

"I attended *Creating new Domains in CDASH* ... and it was great! I have attended similar courses given by other companies, but this one definitely stood out because it made a technical topic easily understandable for non-technical people, but still kept the attention of the technical people... Kit Howard presented the topic well and it was clear she fully understands it. We will definitely be looking to Kestrel Consultants for more offerings!"

Michelle Meany,
Standards Chair,
Schering Plough

Kestrel's June Webinars on Quality and Standards

Kestrel's June data quality webinars focus on improving data quality by examining aggregated data, and by using a collaborative approach to defining and understanding data quality. Our standards webinar this month is an introduction to CDASH. Our webinars are divided into data quality and data standards tracks, and although courses can be taken individually, each track is designed to provide an integrated view of the topic. Please visit the Education and Training page on [our website](#) to see the complete set of courses and to register.

Beyond Pregnant Males: Finding Systemic Errors, Bias and Fraud in Clinical Data **Monday June 15, 11:00—12:30 pm EDT**

There is evidence that much data cleaning today does little to increase data quality, in that data being "clean" or "dirty" rarely changes the outcome of the study. Worse, it usually misses bias and fraud, which are a much greater risk to the trial conclusions. This webinar:

- Examines different methods for assessing data quality
- Includes methods for
 - looking for patterns in aggregated data
 - comparing data across subjects, sites and time
- Discusses interpretations when unexpected patterns emerge
- Reviews a selection of case histories
- Targets non-statisticians who wish to implement tools that do not require specialized software or statistical knowledge.



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Kit Howard is Presenting at the 2009 DIA Annual Meeting



Kestrel's Kit Howard will be both a speaker and a session chair at the DIA Annual Meeting in San Diego this year. She is chairing **a session on reducing data queries** in clinical trials. She is presenting the first talk, which focuses on the collaborative techniques discussed in How to Stop Drowning in Queries Part 1. She will be followed by Jonathan Andrus, from BioClinica, who will present on ways to use EDC to reduce the number of queries by paying attention to quality requirements throughout the EDC lifecycle. This building checks into the data capture environment, but Jonathan also will discuss other techniques that look at data quality more broadly. The third presenter will be Melissa Binz, from Wyeth, who will look at defining where queries come from, and how cross-functional data standards can be applied to reduce the number of queries. It promises to be a very interesting and innovative talk.

Kit is also **presenting on strategic approaches to evaluating and implementing data standards**. Every major organizational change requires thinking strategically about whether to do it and, if so, how to approach it. There are some special considerations when applying this to standards however. These include items such as determining the current state of standards in the organization, learning what standards are available externally that may make the process easier (including, but is not at all limited to, CDISC). Companies must decide what the standards scope should be, from only core data to all data, or only data capture and database structure to protocol through submission. Each decision has implications for both the cost/benefit analysis and the future value of the standards. This talk provides a very high-level overview of many of these factors, and some insight into the impact that some can have. For those who will not be attending DIA, if there is sufficient interest in the topic, it could be turned into a 90 minute webinar and added to Kestrel's line-up. Let us know what you think! Email us at inquiries@kestrelconsultants.com.

June Kestrel Webinars (cont.)

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New Education Web Page

Watch for our new education and training page that will be easier to navigate and to use. It will launch later this month! Please check it out and let us know what you think!

Introduction to CDASH Standards Wednesday June 17, 11:00—12:30 pm EDT

This webinar offers an overview of the structure, content and terminology of the standard and how it fits into the research process. It is a good foundation for "Getting from Here to There" and "Creating New Domains in CDASH." It includes:

- A brief history of the project
- A discussion of each data domain
- Key design decisions
- The links between CDASH to SDTM
- The business case for CDASH implementation.

How to Stop Drowning in Queries, Part 1: A Collaborative Approach to Reducing Queries and Increasing Quality Wednesday June 29, 9:00—10:30 am EDT

Some believe that the number of data queries in a study reflects the quality of the data - the more queries, the worse the quality. It really measures how well the investigative site followed the sponsor's data quality rules, but sites rarely know or understand those rules. This webinar:

- Defines "quality" in alignment with the Institutes of Medicine reports
- Demonstrates why our current approach to data cleaning sets the sites up for failure
- Presents a practical method for dramatically reducing data queries by ensuring a cross-functional understanding of study-specific "data quality" definitions
- Outlines how to ensure that all quality requirements are defined in a common language, not "computerese"
- Provides additional tips for helping the sites to generate high quality data

Please visit the Education and Training page on our website to register: www.kestrelconsultants.com.

