



## The Line of Control

Everyone feels powerless at some point. Sometimes it's a result of an act of nature, sometimes the behavior of others, and especially sometimes at work. In clinical trial operations, I sometimes think we practice it.

I once participated in an exercise during a cross-functional team-building course. We had to line up, from the most powerful to the least powerful. We weren't allowed to stand next to each other, and we had to self-select – it was about how powerful we felt, not how others perceived us. Every single person in the group tried to put themselves in the back half of the line, from the data managers to the statisticians, even the department managers. Each function truly saw itself at the bottom of the totem pole.



(Continued on page 2)



## Special Deal on "Mapping Your CRFs to CDASH"!

The audio conference "Mapping Your CRFs to CDASH," being offered in collaboration with [FXTrans](#) tomorrow at 11:30 am EDT, is an abbreviated version of Kestrel's webinar of the same name. This course will give you a set of tools and knowledge you'll need to map your own core CRFs to CDASH. It reviews the elements of SDTM (the submission standards) that impact CDASH, and walks through the process of comparing a CRF to CDASH, documenting the similarities and differences, and deciding on the result.

**Kestrel usually charges \$275 for our webinars, but with this special deal, you can attend for only \$200! Use coupon code KAP20090730 at check-out.**

**Date / Time:** Tuesday, September 15th, 2009 / 11:30 am—12:30 pm EDT

**Format:** Audio Conference

### What You Will Learn:

- An overview of SDTM
- The relationship between SDTM and CDASH
- How to evaluate your CRF vs CDASH for content, structure, intent and controlled terminology

**Who Will Benefit:** Anyone responsible for migrating from current CRF/database structures to CDASH.

### What You Will Get:

- The full slide deck covered in the presentation
- A tool to guide you in your mapping and documentation
- 60 minutes of presentation and Q&A
- An opportunity to ask questions of Kit Howard, an expert in CDASH
- A certificate of completion (upon request)
- A quiz to test your knowledge of the course material

**Fee:** \$200

**Registration:** Please register on the [FXTrans](#) website, and use coupon code KAP20090730 at checkout



## Upcoming Courses

**Coming up soon - Mark your calendar!**

### Data Quality Series

- Stop Drowning in Queries Part 1: Mon Oct 12, 11:00 am - 12:30 pm EDT
- Stop Drowning in Queries Part 3: Mon Oct 26, 11:00 am - 12:30 pm EDT

### Standards Series

- Creating New Domains in CDASH: Mon Sep 21, 9:30 am - 10:30 pm EDT
- Standards, Standards, Everywhere!: Wed Sep 23, 11:00 - 12:30 am EDT
- Introduction to CDASH: Wed Oct 14, 2:00 - 3:30 pm EDT

Click [here](#) for more information and registration details!

## The Line of Control (cont.)

(Continued from page 1)

This illustrated the degree of dysfunction in the department. Everyone felt that the others, and especially management, did not understand, respect or value them or their work. The saddest part was all the time we spent arguing about who really was the most powerless.

The situation is self-perpetuating. The more people distrust each other, the less they respect or trust others' work, encouraging each department to recheck what they get (e.g., CDM redoing all quality checks that CRAs "should" have caught). Each department interacts just enough to get work done, and optimize their processes only within their silos, even at the risk of working at cross-purposes.

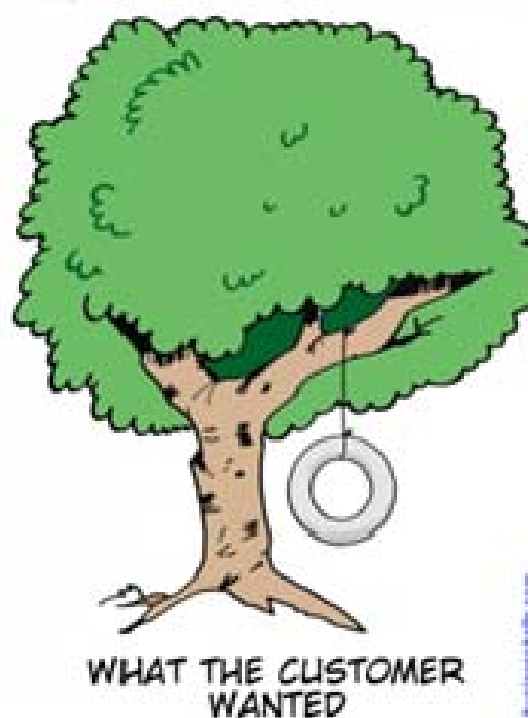


These problems can't be fixed overnight, but they can be fixed. Departments must learn what the others do, recognize the value of each process, and learn to work collaboratively. The usual fix, putting everyone through team-building, can be valuable, but it won't fix the process problems. Here are a few suggestions.



- Place ownership of the data where it's used. CDM usually "owns" the data, in that they create the mechanisms for capturing, storing and cleaning the data. CDM does not generate or use the data, nor design the study questions the data will answer. Ownership should rest with the data's users, namely the clinicians, statisticians and medical writers.

- Bring departments together to learn each others' data requirements and processes. It's easiest to do this on a domain-by-domain basis (e.g., first AEs, then demography, etc.). This is a great way to clarify different and conflicting expectations, and challenge "we always did it that way" practices.
- Perform a Lean Thinking exercise to identify waste points within *and between* departments.
- Reward those who come up with innovative ideas for improving relations and processes.
- Honestly discuss how good is good enough – do you really have to clean all data points to the same degree? Are there sampling methods to eliminate 100% source data verification? Can you make program code handle unexpected values?
- Understand the balance between standards and scientific need, and recognize that if a standard needs to be bent once, it will probably be needed again, so document the variation and make it available to future teams.



None of this is easy or quick, but getting into the predicament wasn't either. The first step must be to recognize that something is broken, and then decide to change. With the mounting pressures to do things faster, better and cheaper, there is no longer a choice. Each organization will have to empower itself, and the only effective way to do this is through collaboration. The alternative is to fail, and that empowers no one.

"Quality is not an act, it is a habit."

- Aristotle, Greek Philosopher

Please visit our corporate website at [www.kestrelconsultants.com](http://www.kestrelconsultants.com) for information about our other services, including consulting on standards development and implementation, data quality, clinical data management projects, and data and process audits.