



FDA on Quality and Risk in Clinical Trials

At the DIA annual meeting this year, 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. She affirmed the agency's commitment to risk management in defining data quality, asserting that eliminating all errors is neither practical nor cost-effective, and that a better approach is to manage the risks that such errors might pose. This clearly reflects the agency's transition from a "gotcha" mentality of pouncing on every mistake to a more collaborative approach.



As Dr. Ball described it, data that are "fit for their intended use" have both high quality and high integrity**. The studies also must focus on clinically relevant endpoints that support the FDA's regulatory safety and efficacy decisions. The simplest and most effective way to achieve this is to build quality into the data rather than try to inspect it in.

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DID YOU KNOW?

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Special Deal on Intro to CDASH!

Upcoming Courses

Coming up soon - Mark your calendar!

Data Quality Series

- *Stop Drowning in Queries Part 1: Mon Aug 10, 2 - 3:30 pm EDT*

- *Stop Drowning in Queries Part 3: Mon Aug 24, 9 - 10:30 am EDT*

Standards Series

- *Clinical Data Capture Standards for Regulatory Submission Trials: Tue Aug 18, 11:30 am - 12:30 pm EDT (see info on the right)*

- *Mapping Current Data Structures to CDASH: Wed Aug 26, 9 - 10:30 am EDT*

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

"Clinical Data Capture Standards for Regulatory Submission Trials" is an abbreviated version of Kestrel's popular course "Introduction to CDISC CDASH Data Capture Standards" that provides an overview of the data capture standards developed by the CDISC CDASH team. These standards provide predefined CRF modules for 16 core data types, eliminating much of the repetitive discussions that take so long in CRF development meetings.

Kestrel has teamed up with [FXTrans](#) to offer this shorter version that covers the same material as the full length course, but in less depth. It's a great opportunity for those who have been putting off attending, or those who don't need as much detail. It's also a chance to experience one of Kestrel's courses at a great price.

Date / Time: Tuesday, August 18th, 2009 / 11:30 am—12:30 pm EDT

Format: Audio Conference

What You Will Learn:

- A brief history of the project
- A discussion of each data domain, including key decisions and suggestions for implementation
- The types of fields in CDASH and how to use them
- The links between CDASH to SDTM

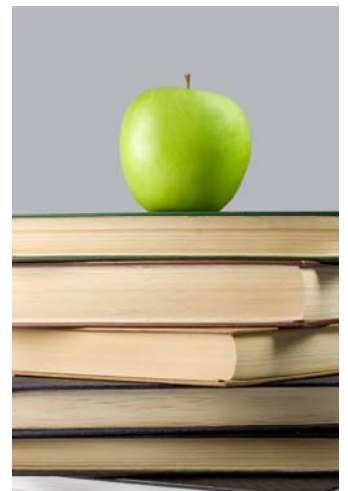
Who Will Benefit: Anyone who designs or uses CRFs in industry or academic clinical trials

What You Will Get:

- The full slide deck covered in the presentation
- 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



CDASH Updates (cont.)

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With the goal no longer being perfect data, risk management should be used to focus available resources on the biggest threats to subject safety and trial conclusions. The first step is to design electronic and human systems that minimize the possibility of error. Dr. Ball provided several examples, including:

- Simplify protocol and outcomes assessed
- Standardize systems and formats where possible
- Use validated instruments/definitions
- Write down all procedures (SOPs). Use checklists
- Minimize amendments and cross-check each with the CRFs and consent form
- Think very carefully about unblinding procedures
- Require training and test it
- Have a disaster plan
- Do beta-testing /dry-runs
- Monitor and correct errors in real time



The second element is to recognize that the regulations allow sponsors to use their judgment to prioritize the areas in which to focus their efforts. As examples, she lists:

- Protocol design (superiority, inferiority, adaptive designs)
- Study monitoring
- Record keeping, case histories
- Data analysis plan



Risk management also includes:

- Developing an integrated framework***
- Protocol design, Site selection and training, Data and Safety Monitoring Plan, Data Management Plan, Quality Assurance Plan, Data Analysis Plan
- Using information technology to detect data irregularities
- Addressing the human factors in systems, including
- Decreasing the number of times data are handled
- Using quality management system approaches to design better clinical trial monitoring
- Having single points of accountability, including appropriate management of outsourcing

In our view, it is heartening to see the agency taking such a clear position defining data quality more holistically, embracing quality management system principles, and supporting using judgment in deciding "how good is good enough". This should encourage industry to pursue these approaches, and abandon the endless and futile quest for perfection.

* The slides are available on the DIA's conference website for meeting attendees. They may be posted on the FDA website at some point, and may be available directly from Dr. Ball at leslie.ball@fda.hhs.gov

** "Quality" is defined using ALCOA, i.e., Attributable, Legible, Contemporaneous, Original and Accurate.

"Integrity" is defined as being "trustworthy," i.e., the 3 C's, or Credible, Consistent and Corroborated.

*** Those who are interested in more about this topic, please explore the material on Data Lifecycle Plans (DLPs) on [Kestrel's corporate website](#). DLPs provide a framework and set of tools that support and facilitate exactly this kind of integration.

"Quality has to be caused, not controlled."

- Philip Crosby

Please visit our corporate website at www.kestrelconsultants.com for information about our other services, including consulting on standards development and implementation, clinical data management projects, and data and process audits.