

Kit Howard, CCDM, CRCP  
Biography, March 2010

Kit Howard is the founder and owner of Kestrel Consultants. She has 25 years of pharmaceutical industry experience in basic research through clinical development, including positions in the lab, preclinical, clinical data management, programming, contracts & outsourcing, and most extensively in clinical data standardization. She specializes in clinical data standardization and data quality, and provides consulting and education & training services to pharma, biotech and medical device companies.

Kit is a CDISC CDASH Registered Solutions Provider, a member of CDISC's data capture standards (CDASH) management team and co-leads the CDISC Medical Devices Standards team. Kit serves on the Editorial Board for the Society for Clinical Data Management, and frequently speaks on data standardization and quality.

Kit received her BA in Biology from Franklin and Marshall College and her MS from the University of Michigan's School of Public Health in *Clinical Research Design and Statistical Analysis*. Her professional accreditations include SCDM's *Certified Clinical Data Manager* (CCDM<sup>®</sup>) and MAGI's *Clinical Research Contracts Professional* (CRCP).



## Consulting, Auditing and Training Services in Data Management, Data Standards and Data Quality

*Kit Howard, MS, CCDM, CRCP, is Kestrel's principal consultant, and is a multi-faceted professional with 25 years of experience in many aspects of pharmaceutical drug development. She has an excellent grasp of the entire drug development process, particularly with respect to the scientific / operational interface in clinical development. She specializes in data management, data standards and data quality processes for biopharmaceutical, device and academic research organizations. Kit leads Kestrel's network of consultants in providing services for their varied clientele.*

### Recent Consulting Accomplishments:

- Assessed a major pediatrics research hospital for data management practices across 17 therapeutically-aligned research divisions, and developed short, medium and long range plans to bring them into compliance with US regulations and Good Clinical Data Management Practices. *(Kestrel network project)*
- Evaluated client standards and recommended changes to achieve CDASH compatibility and SDTM mappability; resulted in significant study development streamlining
- Audited academic data center to determine readiness for pharma company partnership; resulted in successful contract bid
- Developed strategy, cost analysis, EDC selection and implementation plan for transitioning data management in-house for a small devices company
- Subject matter expert for Data Lifecycle Plan® customization and implementation for major Pharma company
- Developed and regularly present full suite of training sessions covering data standards and data quality

### Consulting

Kestrel makes process evaluation and change as efficient and high quality as possible, allowing organizations to refocus on their core business.

- Clinical data standards evaluation, strategy, development, implementation and training, including CDISC's CDASH
- Standards implementation utilizing Kestrel's Data Lifecycle Plans® (DLPs)  
DLPs are sponsor-defined, CDISC-compliant, cross-functional standards that capture all data requirements from both clinical and operations groups. *(Kestrel network project)*
- Data management evaluation and process development and implementation, including data management department and center design
- Data quality systems design and development
- Process and SOP strategy, definition, documentation and development

### Auditing & Evaluations

Audits can focus on general processes or individual studies.

- Data audits
- Process, SOP and documentation audits
- Data management audits
- Data standards implementation and compliance audits

*Kestrel Consultants, Inc.*

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## Training

Kit Howard designed, developed and presents Kestrel's current suite of webinars.

- Data Standards
  - Standards Management 101: A 7-Part Introduction to Clinical Data Standards
  - Standards, Standards, Everywhere! A Survey of Standards and How They Can Help You
- Data Quality
  - Best Practices in Designing Clinical Data
  - Reducing Data Queries in Clinical Trials: A Collaborative Approach Improving Data Quality
  - Reducing Data Queries in Clinical Trials: Using Aggregate Data Checks to Find Bias and Fraud
  - Applying Risk Management in Cleaning Clinical Data
  - Database Audits Today

## Publications

- Numerous articles on data standards, quality and related topics published in Society for Clinical Data Management's Data Basics, Journal of Clinical Research Best Practices, World Pharma Network and PharmaVoice.
- Presentations at Drug Information Association's Annual meeting and CDM Annual meeting, SCDM Fall Conference, Northwestern University's Clinical Education Conference, and MAGI.

## Client Testimonials

*"I attended the "Creating new Domains in CDASH" webinar as part of a group registration at my company 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. Group consensus was all felt less intimidated about working with CDASH and had good direction about where to start. 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, GCDM Manager, Standards Chairperson, Schering-Plough Research Institute*

*"At Wyeth we have taken on a large project to standardize data collection, analysis and reporting across all of our therapeutic specialty areas. Kit Howard's experience and input has been invaluable in helping us to focus on the things that matter most and in organizing our efforts in a coherent way. The guidance she has provided around design, implementation and training issues definitely has given us a leg up on completing this very challenging project."*

*Dr. Mike Poole, Wyeth Research*

*"We receive exceptional service and quality products from Kestrel and recommend it to those interested in developing customized clinical research education and training for their institution. Kestrel provides knowledgeable, dependable and timely assistance to Northwestern University across a variety of projects in clinical research."*

*Thomas Schnitzer, MD, PhD, Northwestern University Feinberg School of Medicine, and Mary Sullivan, Northwestern Center for Clinical Research*

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