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Next Steps for CDASH Data Capture Standards

On 3 October 2008, CDISC's CDASH team released Version 1.0 of the [CDASH standard](#). It contains recommendations for the data to be captured for 16 core data domains and 2 common identifier ones. While this represented a massive effort on the part of over 200 volunteers and Rhonda Facile, the team leader, the initial standard was just the first deliverable.

CDISC for Medical Devices is coming up next! A joint CDASH/SDTM team has been tasked with identifying new domains and also modifications to existing domains to support device data collection and submission. We are looking for volunteers with devices expertise to help out, and are also looking for representative sets of device case report forms to identify differences from the current domain definitions. Please consider helping out in this next big step, and please forward this info to anyone you think may be interested.

The **CDASH users' guide** is in progress. While the original CDASH standard contains much more information than the original SDTM data model, the team will provide more implementation sug-

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New Webinars on Data Standards and Quality

Kestrel has launched a new set of educational webinars to provide robust training for colleagues involved in clinical data standards and in data quality. Existing training on these topics tends to be fragmented and presented once at a conference, and then is effectively lost. Kestrel's curricula will continue to evolve and expand until they contain robust comprehensive materials on data standards and on data quality that address all the facets of these two complex and evolving fields. All webinars are 90 minutes long, and the seminar is one full day.

The first set of courses in clinical data quality consists of 4 offerings.

Introduction to CDASH Standards: this webinar provides a basic overview of the CDASH standards document, along with some project history and some insight into the rationale for some of the data structure decisions.

Standards, Standards, Everywhere!: this webinar examines the definition of "standards," explores the myriad standards available for developing safety and efficacy clinical trials data, and provides information and recommendations on using them.

Creating New Domains in CDASH: CDASH provides standards for the most common domains, as well as common identifiers and dates. SDTM has examples for a few more domains, but most clinical trials will collect additional data. This webinar shows how to model a new domain in CDASH that will address data capture needs, conform to CDISC standards expectations, and be SDTM-compliant.

Implementing CDASH Standards: This full day face to face seminar provides a more in-depth review of the CDASH standard, and provides hands-on interactive exercises in mapping an existing domain to CDASH, and creating a new CDASH-compliant one. Both benefits and drawbacks of the model's flexibility are explored.

The curriculum in data quality currently contains three webinars.

How to Stop Drowning in Queries Part 1: A Collaborative Approach to Reducing Queries and Increasing Quality: defining, generating, addressing and documenting data queries typically take a lot of resources and are often on the critical path for closing the database. This webinar examines the reasons behind these activities and defines a practical solution to reduce the number of data queries. This solution works whether or not CROs are used, and results in overall higher quality data for significantly less effort.

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K-Blog Tackles Touchy Topics

K-Blog is Kestrel's forum for ranting about things that don't make sense, or have to change, or both. Written by Kit Howard, they discuss topics that many hesitate to take on, including whether data management can be a "non-core-competency," if the absence of evidence is evidence of absence, our moral responsibility to fix drug development, looking at our world from a different perspective, and whether the Washington Monument was built by aliens. [Visit](#) and contribute your comments.



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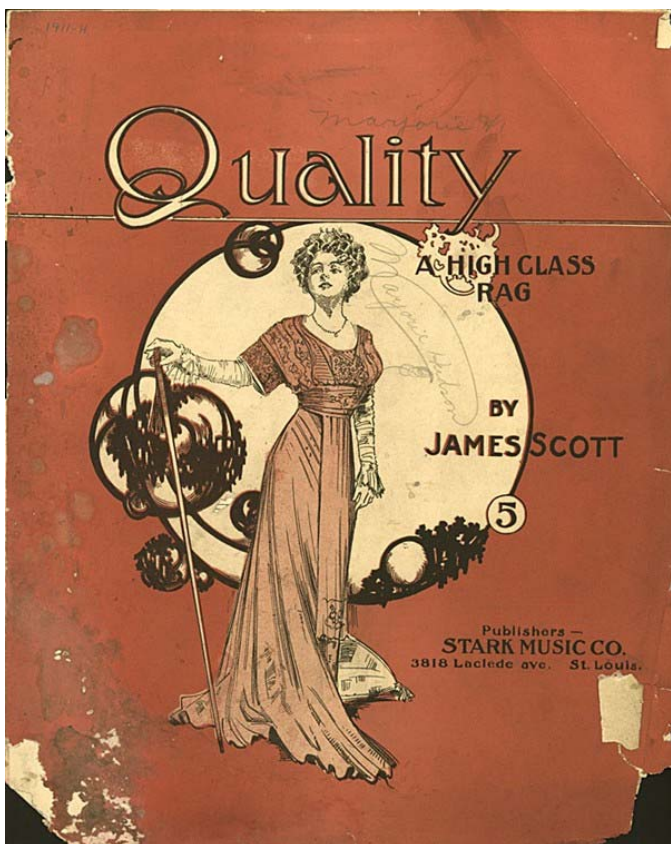
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FDA Policy on Standards Participation

On the FDA's guidance home page, there are [links](#) for policies from the Commissioner's Office. One is the FDA's policy on participation in standards development groups. It covers several aspects of standards, and says that, unless mandated by regulation, standards are voluntary. That said, chances are that following them will ease and shorten your submission review...

CDASH Updates (cont.)



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gestions in the users' guide. There will also be a couple of implementation examples for each domain, an ODM (data transmission model) example, and some more information on the rationales behind many of the decisions. The guide will also contain the lists of fields that were deemed unnecessary for data capture for each domain, along with the rationale for excluding them.

The **Operational Data Model (ODM)** is an XML-based model for transporting CRF-type data between organizations. Because of the way it is structured, a new model must be built for each type of data to be transferred. Once built, however, it can be extensively reused. The CDASH ODM model will allow companies to transfer data between each other easily, for example, a central lab transferring study data to a sponsor. It can be used to structure data transfers between sponsors and CROs, and even to build EDC applications fairly automatically if a compatible EDC package is used. ODM is a CDISC standard.

Communication and education are critical for any project to succeed. The CDASH team is focused on developing and providing outreach and educational opportunities. We present at meetings, publish articles, teach tutorials associated with conferences, and generally work to get the word out. If you know of meetings

where you think attendees would benefit from a presentation on CDASH, please email Rhonda Facile, at rfacile@cdisc.org.

Finally, standards must work in the real world. **If you are implementing CDASH**, please send information about your experiences to Rhonda at the above email address, or to Kit Howard, at Kit@KestrelConsultants.com. We are very interested in feedback, both to improve the standard and to know where additional published information would be helpful. Please help us make the standards work well for us all.

New Kestrel Webinars (cont.)

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How to Stop Drowning in Queries Part 2: Using Risk Assessment to Decide What Data to Clean. The FDA has recognized that trying to deliver "perfect" data is neither cost-effective nor feasible, and is starting to embrace a risk-based approach to data quality. Based in part on work by the Data Quality Research Institute, this webinar challenges the idea that all data should be cleaned equally. Using a two-tiered approach to defining risk, it provides concrete tools for assessing risk levels and for determining exactly what data should be cleaned and to what extent.

Beyond Pregnant Males: Finding Systemic Errors, Bias and Fraud in Clinical Data: There is evidence that most data cleaning does little to increase data quality. Worse, it usually does not identify potential bias and fraud that are much more likely to jeopardize trial conclusions. This webinar examines different types of data cleaning, looking at the impact of "within-subject" cleaning vs "across-subject" cleaning on data validity, and provides a practical approach for ensuring that systemic issues are surfaced in time to be remedied.

Please visit the Education and Training page on KestrelConsultants.com for more information and to register.

Journal of Clinical Research Best Practices

Dr. Norman Goldfarb heads an interesting group named [First Clinical Research](#). These brave souls from investigational sites and sponsors recognized that the negotiations around clinical trials agreements (CTA) and site budgets took a tremendous amount of time, and rarely resulting in changes of any real significance. In the interests of getting trials started more efficiently, and helping to speed treatments to patients, they formed a group named MAGI and developed standard templates for both the CTA and the budget. These went through extensive review, and are now available for free to anyone who registers on the MAGI website.

This is a perfect illustration of Dr. Goldfarb himself. A man with little patience for the administrative absurdities inherent in any complex process, he also edits the monthly Journal of Clinical Research Best Practices. This on-line free journal publishes articles that share efficient approaches to site processes, contracting, and budgeting, review books, discuss elements of GCP, illuminate various aspects of biostatistics and data, and surface topics of particular current interest. They even have their own stock index and cartoons!

The journal has a circulation of well over 60,000, and is unfailingly informative, interesting, relevant and dedicated to improving the quality and efficiency of clinical trials. Consider attending the [MAGI conference](#), coming up in Miami 31May-3June. It's well worth the effort.



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