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Suggest a project!

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DQRI Board of Directors Changes

The Board of Directors for the DQRI was formed in July 2003. Consistent with the organization's commitment to re-researching issues of clinical data quality wherever they arise, the Board is comprised of representatives from industry, academia and the government, thus providing a balance of views in any discussion. The Board members are:

- Kaye H. Fendt, MS, Scientific Director and

Head

- David Christiansen, DrPH, Board Member
- Imogene McCanless Grimes, PhD, Board Member
- Kay Obenshain, Board Member
- Jennifer Powell, Board Member
- William A. Sollecito, DrPH, Board Member

The Institute's FDA liaison is Dr. Steve Wilson, Deputy Division Director for the Division of Biostatistics. Biographies for the Board

members are available on the DQRI website. Recently the composition of the board changed slightly. Jennifer Powell joined the Board, and brings with her a wealth of knowledge and experience in the business aspects of running and funding non-profit organizations. In addition, Kay Obenshain will soon be moving on to other opportunities, and we thank her for her contributions and wish her the best in her new position. ➔

Project Updates

The heart of DQRI is the projects. Each of these is outlined on the DQRI website, and below are summaries of current progress.

Risks in Software Validation

On 29 September 2004, the FDA issued a revision to the guidance titled Draft Guidance for Industry: Computerized Systems Used in Clinical Trials. On January 1, 2005, in response to a call for public input from the FDA, DQRI submitted a commentary on this draft FDA guidance.

The comments suggest a defined risk process based on the work of the validation team. Other comments are included. A copy of the comments can be downloaded from the DQRI web site.

The team continues to work on a risk model that would provide a level of software validation appropriate to the risk of the system. A white paper is being written to describe the model.

The team's members are Sue Carroll (leader), Anthony Costello and Don Hopkins. Sue Carroll presented an Update on DQRI Risk Team at the ASQ World



Many thanks to

Sue Carroll
Alec Vardy
Mike Koza

for their leadership roles in DQRI projects.

DQRI at Meetings

In alignment with its commitment to sharing information, DQRI will be presenting at additional meetings in 2005:

Drug Information Association, Annual Meeting, 28Jun2005, Washington DC. The DQRI is chairing a session examining current state of clinical data quality research. In 1999, the Institutes of Medicine chaired a roundtable discussion that resulting in a publication outlining the state of data quality at that time. It also laid out a direction for future action. Since that time, little formal activity has occurred on this topic. The DIA session, entitled "Advancing Data Quality in the 21st Century, will provide different perspectives on what should happen now. Speakers will include Dr. Janet Woodcock, Director, CDER, who will speak on the FDA's interest in clearly defined quality measures. Dr.


Paul Miles, Director of Quality for the American Board of Pediatrics, will address the need for the application of data quality principles to the field of academic and medical practice-based research. Kaye Fendt, Scientific Director for DQRI, will wrap up with some comments on industry's perspective on this topic, and will outline a research agenda for progressing this field over the next five years.

Drug Information Association, Computer Validation and IT Conference, September 2005, Williamsburg, VA.

Sue Carroll will be presenting a session titled 'Using Risk Assessment to Justify Validation Decisions', based on work being done by the DQRI software validation project. The session is designed to provide practical tools for the application of risk

assessment to software projects.

Society for Clinical Data Management, Fall Conference, October 2005, San Diego, CA. DQRI will be represented by two papers at this meeting.

- Kaye Fendt, in collaboration with Meredith Nahm from the Duke Clinical Research Institute, will present a paper outlining centralized vs distributed data management approaches, and discusses literature survey results focusing on the variability in data quality based on each approach.
- In addition, Alec Vardy will be presenting a summary of the results to date of the Database Audit project. It is anticipated that results from the first two subteams will be available, as well as a detailed description of the steps necessary to complete the project. 

Project Update (cont.)

Continued from page 1

Conference on Quality and Improvement in Seattle, WA on May 18, 2005.

A Critical Examination of Database Audits

This team, facilitated by Alec Vardy, has completed a general discussion and overview of the topic of database audits, and defined the parameters of the processes to be examined. The team has achieved its first objective, which was to determine if there was value in examining the practice of database audits, and if there are circumstances where audits should indeed be performed. The conclusion was that there is

sufficient variation in practice to warrant continuing, and that there are times when the audit is an appropriate quality step. The team then identified four key subjects that need further definition. Two subteams have been formed to begin to address the first two topics. The first subteam, headed by Alec Vardy, is working on cementing the definition of what is the 'correct data value' against which a database audit should be performed. The second subteam, headed by Mike Koza, is defining the common steps in the data capture processes, identifying where manual interventions happen, and assessing potential impact on data quality. When these tasks have

been completed, two additional teams will be created to determine the process variations that would reasonably call for database audits to be performed, and design statistically robust mechanisms for performing them.

The team's currently active members include Alec Vardy (leader), Michelle Shuman, Debbie Stein-Kurz, Jonathan Andrus, Mike Koza, Donna Strauss, Reza Rostami, Nancy Milliken, Carol Tranfaglia and Janice Kulp. Others also participate on a periodic basis.

Logistical support is provided by Kit Howard.



Database Audit and Quality References

As part of its research into existing practice, the Database Audits team compiled a list of references that pertain to its project. The references were drawn from on-line searches, SCDM's Good Clinical Data Management Practices, an existing list compiled by Duke Clinical Research Institute. Many thanks to all who contributed to this resource.

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“It is quality rather than quantity that matters.”*★



Data Quality Research Institute

P. O. Box 9124
Chapel Hill, NC 27515

Phone: 919-417-3540
Email: info@dqri.org
Website: www.dqri.org

Quality Matters

Editor: Kit Howard, MS,
Associate Director DQRI
Contact: QM@dqri.org



Advancing the Quality of Clinical Data.

The **Data Quality Research Institute (DQRI)** is a non-profit organization that provides an international scientific forum for academia, healthcare providers, industry, government and other stakeholders to research and develop the science of quality as it applies to clinical research data.

DQRI is run through an Operating Board drawn from industry, academia, regulatory agencies and support services. The Institute also has been assigned an FDA liaison, Dr. Steve Wilson.

DQRI Projects Seek Funding

In addition to DQRI's on-going activities, there are a number of projects that are seeking funding. These include:

- Assessing and improving data quality in patient data repositories
- Developing statistical tools for defining and measuring data quality
- Data quality assessment in pediatric process improvement projects
- Defining the nomenclature of data quality

Any organization interested in the results of any of these initiatives and willing to provide funding is urged to contact DQRI. In addition, DQRI is always open to proposals for quality projects that are in alignment with its goals. ➔

* *Lucius Annaeus Seneca 5BC-65AD, Roman tragedian, philosopher, and counselor to Nero, Epistles.*



Regulatory Compliance Workshop Group



2005 International Clinical Research WORKSHOP

A Complete Step-by-Step Guide to

Essential SOPs, Required Documentation and Regulatory Requirements for Clinical Research

This 2-day International WORKSHOP is aimed at all those working to GCP in North America and Europe. This WORKSHOP will take attendees step-by-step through what SOPs and documentation you SHOULD have, what the regulators DEMAND you have and HOW to generate compliant documentation that meet both regulatory and organizational requirements.

Expert speakers will cover topics including:

- Regulatory requirements and guidelines governing SOPs - GCP, FDA, ICH, and HIPAA
- Critical components of SOPs - details to include and how to design, write and implement SOPs
- What SOPs you need for clinical research
- Quality control, validation and revision of SOPs
- Regulatory audits for clinical research sites
- SOPs for clinical research sites, SOPs pertaining to FDA inspections, SOPs for Clinical Affairs and Clinical Compliance Departments
- How to best maintain compliant SOPs
- What happens when SOPs are not compliant?
- SOPs for large vs. small organizations
- Developing a hierarchy and company wide policies and SOPs
- How to work with SOPs of an outsourced vendor
- Process design vs. writing SOPs
- SOPs vs. procedural documents
- Training on SOPs
- Creating and using metrics programs for SOPs and procedural documents
- How to best deal with audits and inspections

Limited to 40 Attendees

Includes interactive WORKSHOPS that will use **real examples** explaining how to generate compliant SOPs and documentation.

WORKSHOP A - SOPs for the Preparation of a Clinical Protocol Synopsis and a Clinical Protocol
WORKSHOP B - Designing CRFs and Generating SOPs for CRF Design
WORKSHOP C - Structured Approach to Building a Procedural Document System
WORKSHOP D - An Interactive "Mock Audit"

Supporting Publication



Supporting Organizations



Tuesday, 19th & Wednesday, 20th July 2005
Marriott Key Bridge Hotel, Virginia, USA

Visit our website: www.rcwg.org