Title: CDISC Medical Device Standard - Your Change to Preview this New CDISC Standard

Date: AUGUST 18, 2011

TIME: 10:00 AM CDT, 11:00 AM EDT (DURATION 1.5 HOURS)

Intended Audience:

This webinar is aimed at professionals involved in research and development of devices in 510K (Class II and Class III) development. It will be of interest to individuals whose functions include the following: data managers, database and statistical programmers, those involved in submission of data to the FDA, and regulatory managers receiving Class II and Class III device submissions.

Topic description:

This webinar is intended bring attendees up to date on the work of the CDISC Devices Team. It will provide a brief summary of the project background and accomplishments, orient attendees to the draft domains, the underlying data models, and how these domains fit in with other CDISC standards. The primary emphasis will be on the seven proposed SDTM-based device domains that will be posted for open public review on the CDISC website. A panel made up of Device Team members will then answer questions.

What you’ll learn (objectives):

At the conclusion of this webinar, participants should:

Know more about the CDISC Device Team and have a general understanding project goals and deliverables. (Basic)

- Have a general understanding of how the proposed device domains have been developed and their expected uses. (basic)
- Understand how to access, review, and submit comments on the draft device domains that have been presented. (Basic)

Level: (Basic, Intermediate, Advanced)
Presenter Bios:

**Name:** Rhonda Facile  
**Organization:** NCI-EVS  
**Title:** CDISC SHARE and CDASH Project Director

Bio: Rhonda Facile has over 20 years of clinical research experience including monitoring, project management, clinical outsourcing and planning, SOP development and regulatory affairs. She has participated in global process reengineering efforts in the biopharmaceutical industry as well as CRF standardization earlier in her career. She has worked for a global CRO, a global pharmaceutical company and most recently for a biotech company. She has been employed in the U.S. and in Europe prior to joining CDISC. Rhonda is CDASH Program Director, a project that seeks to standardize basic CRF data elements and is responsible for the CDASH-ODM project and a new project that seeks to identify the basic device collection data elements. In addition Rhonda manages the CDISC Share project, a project that seeks to develop a global, accessible, electronic library, which through advanced technology, enables precise and standardized data element definitions that can be used within applications and across studies to improve biomedical research and its link with healthcare.

Ms. Facile has presented at numerous conferences and webinars for the DIA, SCDM, CDISC and others. Rhonda is a member of the DIA, SCDM, ACRP, and the Swedish Academy of Pharmaceutical Science (Apotekarsocieteten).

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**Name:** Kit Howard  
**Organization:** Kestrel Consultants  
**Title:** Founder and Owner

**Bio:** Kit Howard is the founder and owner of Kestrel Consultants. She has over 25 years of experience in the biopharmaceutical industry and specializes in clinical data management, standardization and data quality. She provides consulting, education & auditing services to pharma, biotech and medical device companies, and academic medical centers.

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

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**Name:** Carey Smoak  
**Organization:** Pharma SUG  
**Title:** Senior Manager, SAS Programming
Bio: Carey has more than 25 years’ experience using SAS. He has a master’s degree in public health and currently works for Roche Molecular Systems as a senior manager of SAS programming. He is the co-leader of the CDISC Device team. Carey has presented papers at PharmaSUG, SAS Global Forum, the Bay Area SAS Users Group, the Bay Area CDISC Implementation Network, and other venues.

Name: Fred Wood
Organization: Octagon Research Solutions
Title: Vice President, Data Standards Consulting

Bio: Fred is currently Vice President, Data Standards Consulting at Octagon Research Solutions. Fred is one of the principal contributors to the SDTM, and was the primary editor for v3.1.2 of the SDTM Implementation Guide. He is the team lead for the CDISC SDS Team, and a founding team member. Fred has also had a leadership role on the SEND Team since its inception in 2002. He has been on many other CDISC teams since 1999.

Prior to joining Octagon, Fred was the Global Data Standards Manager for Procter & Gamble Pharmaceuticals. Prior to this, he was a toxicologist supporting Rx and OTC and Rx health care. Fred holds M.S. and Ph.D. degrees in Biochemistry from the University of Massachusetts.