CDISC International Interchange – Highlights

For those of you who have registered for the **CDISC International Interchange**, which will take place in **Baltimore 10-14 October**, following are some of the highlights you can expect. [For those of you who have not registered, although online registration has closed, you can still register in person at the event!]

**The complete program** can be accessed here http://www.cdisc.org/interchange?a=2437#2437

Opening remarks by Dr. Frank Rockhold (Chair of the CDISC Board of Directors and Senior Vice President, Drug Development Sciences, Medicines Development at GlaxoSmithKline), will launch the event. A robust program was organized by the Program Committee to focus on “Standards for the Patient”. The presentations and interactive panel discussions will bring you fresh information on new topics including transforming the clinical research process, eSource, and the value that standards play in enabling the meaningful use of clinical data for research and other purposes. These will complement the traditional topics on case studies and implementation experiences with respect to the CDISC standards. Highlights follow.

- **Keynote speakers:** Dr. ShaAvhree Buckman, Director of the Office of Translational Sciences (OTS), Center for Drug Evaluation and Research (CDER), U.S. Food and Drug Administration, on Thursday afternoon (13 October), **Dr. Greg Koski**, Senior Scientist at the Institute for Health Policy and Associate Professor of Anesthesia, Massachusetts General Hospital, Harvard Medical School on Thursday morning (13 October) and **Dr. Charles Friedman**, Professor and Director of the health informatics program in the Schools of Information and Public Health at the University of Michigan on Wednesday morning (12 October).

- **FDA Panelists for Thursday afternoon:** Amy Malla (CBER), Dr. Armando Oliva (CDER), Dr. Chuck Cooper (CDER), Doug Warfield (CDER), Gary Gensinger (CDER), Helena Sviglin (CDER), Mary Ann Slack (CDER), Paul Okwesili (CDER), Dr. Sean Kassim (CDER/OSI), Dhananjay Chhatre (CDER/OBI), Dr. ShaAvhree Buckman (CDER)
• And, for Platinum Members, there will be an FDA Town Hall on Tuesday (11 October) from 4-5:30 pm with FDA participants: Amy Malla (CBER), Dr. Armando Oliva (CDER), Catherine Jansto (CDER), Dr. Chuck Cooper (CDER), Helena Sviglin (CDER), Mary Ann Slack (CDER), and Terrie Reed (CDRH)

• Session 8 on Thursday, will be focused on the use of EHR in Clinical Research and will have a panel of regulatory and industry experts. In advance of this session, the chair, presenter and panelists would love to get any questions you might have. Please feel free to forward any questions for this session to the session chair in advance: jonathan.andrus@bioclinica.com

• CDISC Authorized Educational Courses will run Monday, Tuesday, and Friday. Courses include SDTM Theory & Application, ODM Implementation, LAB Implementation, ADaM Implementation, Controlled Terminology and Protocol Representation.

• Colloquia on Standards for 6 Therapeutic Areas will take place on Tuesday (TB, Virology (Hep C/Hep B/HIV), Pain) and Friday (Oncology, Diabetes, Imaging)

• Also new this year: Theme-based Roundtable Discussions, kindly organized by Peter Schaefer of the Interchange Program Committee. A description follows.

When going to lunch during the CDISC International Interchange conference on Wednesday, 12 October, you should be prepared to have a discussion with fellow colleagues about more than the latest baseball or football scores. The Program Committee has organized Lunch Table Discussions for a structured open table exchange between conference participants. At each table, a facilitator will try to keep the discussion on topic and will take notes that will be shared with the CDISC community later. The discussion tables will be clearly marked with topics covering more or less all relevant standards and topics, including CDASH, SEND, SDTM, ADaM, ODM/define, Terminology. Questions to address could include implementation challenges, risks / benefits of a specific standard and the impact on your organization's efficiency. Of course, all ideas about the future directions of the standard are very welcome. No additional registration is required to participate in the discussion – just pick your table and talk. (If you do not want to participate, there will still be tables where sports can be discussed!) However, the Program Committee is really hoping that this informal setting will help to strengthen contacts within the CDISC community and will spark further discussions throughout the conference. Many of you who participated in last year’s discussion round tables found these events a very interesting and valuable part of the conference and we hope that this new format can provide the same or more value. Certainly, success depends on your participation! Look for further details in your information package at the event.