Announcing the CDISC International Interchange – 24-26 October 2012
Baltimore, MD

“Accelerating Therapies Through Standards”

The 2012 International Interchange will be a new format this year, with a focus on launching the Coalition For Accelerating Standards and Therapies (CFAST). Based upon a partnership between CDISC and the Critical Path Institute, CFAST is an initiative to accelerate clinical research and medical product development by creating and maintaining data standards, tools and methods for conducting research in therapeutic areas that are important to public health.

Per the FDA website, “FDA, CDISC and the Critical Path Institute [C-Path] are collaborating on efforts to support development of therapeutic area standards. […] We encourage stakeholders to engage in and, where possible, support these data standardization efforts.” The Interchange will be an excellent venue for everyone to become engaged, if they have not already found a way to do so. The development of standards in disease/therapeutic areas will require not only data managers and statisticians, who were indispensable in the development of CDISC Foundational Standards, but now also clinicians, program managers, patients and patient advocacy groups, academics and anyone interested in streamlining the path to new therapies.

- Day 1 of the Interchange program will be designed to appeal to anyone and everyone – technical or clinical.
- Day 2 will be devoted to more technical topics, including an FDA Panel and introductions to SHARE and BRIDG and how they will support CFAST.
- Day 3 will be a day for cross-team meetings.
Highlights of the program for Day 1 (24 October):

The Interchange Keynote will be delivered by Dr. Janet Woodcock, FDA/CDER

Dr. Janet Woodcock is the Director of the Center for Drug Evaluation and Research (CDER) at FDA. She previously served as FDA Deputy Commissioner and Chief Medical Officer. She introduced FDA’s “Critical Path” Initiative, which is designed to improve the scientific basis for medical product development.

• **Session 2:** Stakeholder Perspectives on Disease Area Standards – Patients, Biopharma, CROs, HHS, NIH, FDA
• **Session 3:** Experiences - Lessons Learned from the initial Disease Area Standards, working with CDISC and C-Path: Alzheimer’s Disease (CAMD), Tuberculosis (Gates Foundation and CPTR), Polycystic Kidney Disease (Tufts University and the Polycystic Kidney Disease Foundation, Parkinson’s Disease (NINDS), Pain (Rochester University and FDA), Virology (FDA)
• **Session 4:** Where Should we be Going? - OneMind, CEO Roundtable on Cancer, Tuberculosis (Gates Foundation), CIMI, SHARP and SHARE
• **Session 5:** New Processes – What is CFAST and What Can it Be?

In addition, we will have CDISC Educational Courses on Monday and Tuesday, 22 and 23 October. These courses will include: Global Approach to Accelerating Medical Research, Healthcare Link, SDTM, ADaM, ODM, Controlled Terminology and Deep Dive BRIDG.

Please see the following link: (http://www.cdisc.org/interchange?a=2438#2438) for further information such as opportunities for sponsorships, exhibits and registration. Registration will open very soon. Stay tuned to our website!