Why Should I Attend the CDISC 2012 Interchange?

Q: As a long-time attendee of CDISC Interchanges, why should I attend the 2012 CDISC International Interchange? What is so special about this year’s event?

A: This year is an especially exciting year to attend the annual CDISC International Interchange, our flagship event. This Interchange marks the launch of CFAST, the Coalition For Accelerating Standards and Therapies, and initiative of CDISC and the Critical Path Institute (C-Path). In honor of this occasion, we have invited experts from across the clinical research and healthcare arenas to present on how standards can accelerate the development of new therapies for specific diseases. Attendees will gain a crucial understanding of the lessons learned in therapeutic area standards development and how these will apply to the CDISC Foundational Standards and their role with respect to the new processes that CDISC will apply to the development of therapeutic area-specific standards and implementation guides (especially to address the recent PDUFA V requirements for FDA and Industry).

If your company or client is in any way involved or interested in drug development for specific disease areas, you should not miss the International Interchange. Don’t end up behind the curve on these groundbreaking standards development areas and processes. Gain an edge through information sharing on lessons learned and best practices in the implementation experiences of your peers. Register for all three days of the CDISC 2012 International Interchange today!

Q: What’s in the program for current CDISC implementers?

The 2012 Interchange will continue to hold sessions relevant to our core base – the current users of CDISC standards. Our Wednesday program will close with a review of the many standards projects recently completed and in progress, and a discussion of our technical roadmap to address future standards development needs, both for our foundational standards and our new therapeutic area projects. Our Thursday session will include detailed updates from the FDA on their use of CDISC standards, and how they are working to identify ways to promote implementation and improve use of CDISC at FDA. There will also be an interactive Q&A discussion session featuring FDA speakers and CDISC leaders where you’ll be able to have your questions addressed.

Probably the most important reason for long-term CDISC participants to attend is the opportunity to meet with FDA, team leaders and members, and other CDISC adopters. Posters will describe key updates from each team, and allow new attendees to meet active participants. This year’s networking reception will showcase the many available solutions from CDISC solution providers, many of whom will be exhibiting features relevant to CDISC SHARE, as well as other tools and solutions that capitalize on CDISC standards.
Finally, our Friday session will be a CDISC Intra-change, where active and prospective team members can meet with each other to discuss key topics and learn more about standards development plans for the coming year. This year’s Intra-change will focus primarily on topics involving harmonization across teams, and especially on how the new therapeutic area projects will affect the ongoing needs of teams, as well as allowing teams to work on issues relevant to specific standards. Topics will be posted in advance of the meeting so people can sign-up for specific topics of interest.

**Q: What about newcomers to CDISC?**

The CDISC Interchange is the single best opportunity to learn about CDISC and our standards. Anyone interested in medical research will want to learn about our new CFAST initiative to develop therapeutic area standards. But anyone with an interest in improving clinical development and data quality will want to attend to learn from training classes and presentations and to dialogue with kindred spirits involved in clinical research.

**Q: Why should I come early to attend CDISC courses on Monday and Tuesday?**

Did you know that CDISC offers courses that have been developed by CDISC team members and that all of our instructors are qualified using the same rigorous criteria? Instructors and course material developers have to have a specific level of experience with the standard they are teaching, so that you can be sure you are receiving authoritative, up-to-the-minute information in our courses.

For some people, the convenience of combining the travel expenses for both educational courses and a conference is also an important consideration.

**Q: Who are some of the speakers who will be participating?**

Attendees of the CFAST launch at the CDISC 2012 International Interchange will have the opportunity to hear presentations and participate in panel discussions with an unprecedented number of experts across industry, governmental and non-governmental organizations:

**Government:**

- **Dr. Janet Woodcock**, Director of the Center for Drug Evaluation and Research, FDA will discuss how CFAST will improve FDA reviews
- **Dr. Ron Fitzmartin**, Senior Advisor for the Center for Drug Evaluation and Research, FDA
- **Dr. Chuck Cooper** of the Office of Translational Sciences at the Center for Drug Evaluation and Research, FDA
Dr. Steven Hirschfeld, Associate Director for Clinical Research at the National Institute of Child Health & Human Development and the National Institutes of Health
Margaret Haber, Co-Director, Enterprise Vocabulary Services at the National Cancer Institute
And others invited

Industry:

Peter Loupos, Partners in Patient Health, U.S. Corporate Affairs at Sanofi
Sue Dubman, Senior Director, R&D IS, Strategy, Standards and Architecture at Genzyme – Sanofi and a volunteer for the Michael J. Fox Foundation
Jane Diefenbach, Standards Implementation & Integrated Safety Consultant at PharmaStat
Dr. Pierre-Yves Lastic – CDISC Chair-elect and participant in the TB Alliance

Organizations and Initiatives:

Ann Martin, Principal Scientific Officer with the European Innovative Medicines Initiative (a public-private partnership between the European Commission and EFPIA) will discuss how CDISC standards will support IMI knowledge
Dr. Douglas Peddicord, Executive Director of the Association of Clinical Research Organizations (ACRO)
Dr. Meredith Nahm, Associate Director for Clinical and Translational Research Informatics at Duke University
John Dwyer, representing US Against Alzheimer's
Dr. Magali Haas, Chief Science and Technology Officer for One Mind for Research
Dr. Charles Hugh-Jones, Vice President, Medical Affairs North America, Oncology, Hematology & Solid Organ Transplant at Sanofi representing DataSphere, a biopharmaceutical initiative to share oncology data
Dr. Dave Jordan, Abbott, representing the Hever Initiative
Nora Belcher, Executive Director at the Texas e-Health Alliance

Q: Who will be representing the FDA at Thursday's CDISC Standards at FDA Session and Roundtable Discussion?

Dr. Steve Wilson, CDER, discussing statistical review, ADaM and CSS Workgroup progress
Dr. Chuck Cooper, CDER, discussing clinical review and CSS Workgroup progress
Amy Malla, CBER, discussing use of SDTM and ADaM and the FDA’s Clinical Trials Repository
Dr. Lauren Mihalcek, CDER, discussing use of SEND at FDA
A speaker from CDRH discussing CDISC Device Standards
Dr. Ron Fitzmartin, Senior Advisor, CDER, discussing future plans for standards.
Q: OK, I’m in. So what do I need to do?

Register now at http://www.cdisc.org/interchange?a=2438#2438. If you register for the conference on Wednesday and Thursday, you can attend Friday at no charge.

We hope to see you in Baltimore!