January 2011 eNewsletter

Newsletters are posted as they are released, so check regularly for the latest edition.

Welcome to the first newsletter of 2011.

This month we look forward to our forthcoming events, news about Membership and some exciting developments. We would also like to thank you for your on-going support throughout 2010 (whether through membership, team participation, speaking at our events or any other contribution) and we look forward to you joining us on our journey through 2011. Thank you!

If you have any comments or would like to contribute an article to the CDISC Newsletter, please contact AJ de Montjoie.

CDISC Interchanges: News

Interchange Europe: 11 - 15 April 2011, Brussels, Belgium

The European Interchange is forging ahead and the E3C have completed their programme which is now posted on the website and registration is open! The E3C are pleased to welcome, Ilias Iakovidis, Deputy Head of Unit, ICT for Health, DG Information Society and Media at European Commission, as the Keynote Speaker. Once again they have organised a fantastic evening event and this year attendees will be lucky enough to enjoying drinks and dinner at the Belgium Comic Strip Center. The Round Table Discussion Groups which were so successful last year will also be available in 2011, running in parallel to the main sessions. Don’t forget to book your hotel room, full details on the event webpage.

Interchange Japan: 12 - 15 July 2011, Tokyo, Japan

The J3C have also announced their dates for the Interchange in Japan and they will be posting their call for abstracts soon. Keep an eye on the website for more details.

Remember that all our Interchanges have a full program of CDISC training.

CDASH Version 1.1 Now Available for Download

CDASH is a standardized core dataset for clinical research that has been demonstrated to significantly decrease study start-up time and will streamline the production of SDTM downstream (i.e. reduce legacy data conversion costs and resources). As many of you may have seen, the CDASH team has now published CDASH V. 1.1. This new version builds upon the foundation established in the earlier version and takes a significant step towards seamless interoperability between CDISC and other international standards. You can read a summary of the changes and information on the next steps from the CDASH team here. The CDASH User Guide should be available to our members soon!

Public Review & Comment Periods

There are a number of documents that are open for public review at this time. CDISC and the other organizations involved appreciate and value your input on these public reviews. Full details of all open reviews & comment periods can be found here. Or you can find them posted on the homepage.
**CDISC Membership Levels are Changing**

CDISC is simplifying the membership structure and improving the benefits packages. You can read all the details here [8].

**Official Translation of CDISC Standards into Japanese**

At the October 2010 CDISC Interchange in Baltimore, CDISC representatives from Japan and the U.S. met with Ms. Masako Yamada, from Translational Research Informatics Center (TRI) [9] at the Foundation of Biomedical Research and Innovation (FBRI), a non-profit organization in Japan. TRI has translated the CDISC Glossary and is interested in translating the CDISC standards to make them more widely available for Japanese researchers. A Memorandum of Understanding was signed in early January 2011 between CDISC and FBRI to proceed with the translation of CDISC Standards into Japanese. Please see the Blog for more detail [10].

**Signing of the CDISC China Advisory Council (CCAC) Charter**

On 16 July 2010 a meeting was held in Beijing, China, attended by 21 local clinical research leaders from worldwide biopharmaceutical companies, CROs, FDA, NCI and 2 representatives from CDISC headquarters. It resulted in the formation of the CDISC China Advisory Council (CCAC) with Claire Tan (Quintiles Transnational) as Chair and Bruce Xue (Johnson & Johnson) as Assist. Chair. Under Claire’s leadership, a Steering Committee was formed in September with a select group of professionals who have proven experience in industry and academic environments as well as involvement in communication with SFDA/CDE for the advancement of China drug development. The CCAC has now developed a charter, describing their objectives and how they will interface with the CDISC China Coordinating Committee (C3C) that was initiated in 2008 and is based in Shanghai. CCAC is set up to act as an independent advocacy in connecting with professional and academic groups as well as the Chinese government agencies who have interests in the development of CDISC standards in China. Looking ahead, CCAC and C3C will help CDISC in promoting clinical research standards in China.

**New in the Members' Area** [11]

The latest ADaM validation checks are now posted in the members' area [12]. The ADaM team would welcome your feedback. In addition, the Round Table Discussion Groups’ Feedback from the North American Interchange [13] is posted.

**News about the ASTER Project and RFD**

Read two articles about the success of the ASTER project in enabling physicians to easily submit adverse reports to the FDA [14], using the Retrieve form for Data Capture Profile developed by CDISC and IHE.

**New CDISC Journal**

CDISC's Journal has been delayed, however we anticipate an informative first edition. We are still offering opportunities for people to advertise in the Journal. If you would like to contribute an article to our next journal or find out more details of the advertising opportunities, please contact AJ de Montjoie [1].

**User Network/Group Meetings**

A number of user network meetings are taking place in the next few months:

- **German User Network Meeting - 14 February 2011** [19]
- **CDISC Japan User Group (CJUG) - 18 March 2011** [16]
- **English Speaking User Group Teleconference - 22 March 2011** [15]
- **Delaware Valley User Network Meeting - 29 March 2011** [15]
Don't forget that there are materials from many of the User Groups posted on the CDISC Portals.  

Publications from Our Media Partners

CDISC has worked with Touch Briefings for a number of years now and they have continued to support us in many aspects of our work through advertising our events and compiling CDISC related articles. You can read their latest publications here.

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