CALL FOR ABSTRACTS

The Japan Interchange Programme Committee is now accepting abstracts for presentations for the 2010 CDISC Japan Interchange to be held in Tokyo on the 20th – 21st July 2010.

Several sessions are planned with presentations lasting between 20 and 30 minutes. Abstracts for presentations in the following areas are welcome:

**Regulatory submissions**
Experience with electronic submissions; preparation time, agency understanding & questions; FDA data submissions: content: SDTM & ADAM & define.xml, Transport: future transition from SAS transport files to HL7 V3 messages

**Integration of standards & processes**
Embedding CDISC standards (e.g. SDTM, terminology, CDASH) in your R&D process; harmonizing the processes from start to finish

**Safety data and CDISC**
Clinical trial AE and SAE data and spontaneous SAE data and regulatory reporting requirements (e.g. how CDASH and SDTM accommodate the ICH-E2B needs; impact of FDA’s Sentinel initiatives)

**EHR and CDISC**
Use of EHR data in clinical trials and safety monitoring, data exchange, data validation, and regulatory requirements (e.g. Case studies; Initiatives and pilots; EHR data used for regulatory submissions; EHR data used for patient recruitment, protocol feasibility; HL7 data standard)

**Vendor Applications and Tools**
Applications and tools for data migration, data integration, compliance check with CDISC models, define.xml setup etc. Demonstration of data integration using CDISC models (up to end-to-end integration), e.g. EDC forms, ePRO, central lab, ECG, device data.

**Other topics around CDISC Standards**
Feel free to submit your experience with one of the models or standards, its implementation or implementation planning

**ABSTRACT SUBMISSION**
The deadline for submission of abstracts is the end of Friday, 21st May 2010.

Abstracts should be 2 or 3 paragraphs in length, formatted in Microsoft Word and sent, via email, to swilliams@cdisc.org. Abstracts must include the name of the author/presenter, company name and contact details consisting of postal address, phone number, fax number and email address.

**CONFERENCE FORMAT**
The main conference will commence on Tuesday, 20th July and run through to the end of Wednesday, 21st July. Additional sessions will take place on Thursday, 22nd July and on Friday, 23rd July. These sessions will consist of official CDISC training courses.

WE LOOK FORWARD TO YOUR CONTRIBUTION!