



## 2010 CDISC Japan Interchange

Toshi Center Hotel, Tokyo  
Tuesday-Wednesday, 20<sup>th</sup> -21<sup>st</sup> July 2010

### 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 20<sup>th</sup> – 21<sup>st</sup> 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, 21<sup>st</sup> May 2010.**

Abstracts should be 2 or 3 paragraphs in length, formatted in Microsoft Word and sent, via email, to [swilliams@cdisc.org](mailto: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, 20<sup>th</sup> July** and run through to the end of **Wednesday, 21<sup>st</sup> July**. Additional sessions will take place on Thursday, 22<sup>nd</sup> July and on Friday, 23<sup>rd</sup> July. These sessions will consist of official CDISC training courses.

**WE LOOK FORWARD TO YOUR CONTRIBUTION!**