CDISC Japan Interchange

“Committed to a Brighter Future for Regulated Research”

3-6 December 2013
UDX Conference & Theater
Tokyo, Japan
TUESDAY, 3 December 2013

09:00 - 17:00  SDTM Theory & Application Course (Day 1 of a 2 day course)
Instructor: Peter Van Reusel, Business & Decision Life Sciences

WEDNESDAY, 4 December 2013

09:00 - 17:00  SDTM Theory & Application Course (Day 2 of a 2 day course)
Instructor: Peter Van Reusel, Business & Decision Life Sciences

09:00 - 17:00  ADaM Implementation Course
Instructor: Monika Kawohl, Accovion GmbH

“The Prescription Drug User Fee Act (PDUFA V) Performance Goals state that FDA will develop guidance for industry on the use of CDISC data standards for the electronic submission of study data in applications. In the near future, FDA will publish guidance that will require study data in conformance to CDISC standards.”

-FDA Position Statement, 17 September 2013

“In this regard, your member companies are kindly requested to provide electronic clinical study data to PMDA so that the Agency may test the feasibility of the system [...] PMDA will need data that meet the following three criteria for this feasibility test: [...] 2) data amassed and summarized according to the CDISC standards...”

-PMDA Request for Electronic Clinical Study Data for Pilot Project, 2 September 2013
CDISC Interchange Conference

THURSDAY, 5 December 2013

08:45 - 09:00  Exhibition Booth Set-Up
09:00 - 18:00  Exhibition Open
09:00 - 17:00  Conference Registration
09:15 - 10:25  Session 1: Opening Plenary & Keynote
   Session Chair: Ken Toyoda, J3C Chair
   Welcome to the CDISC Interchange Japan 2013
   Ken Toyoda, J3C Chair
   Welcome to the CDISC Interchange Japan 2013
   Rebecca Kush, CDISC President & CEO
   Keynote Presentation
   Taisuke Hojo, Senior Executive Director, PMDA
   Keynote Presentation - EHRs and Clinical Research
   Mihoko Okada, President, Japan Association for Medical Informatics

10:25 - 10:55  Coffee Break

10:55 - 12:25  Session 2: CDISC Global Update
   Session Chair: Kiyoteru Takenouchi, J3C
   The State of the CDISC Union
   Rebecca Kush, CDISC President & CEO
   CDISC SHARE and the Technical Roadmap
   Wayne Kubick, CDISC Chief Technology Officer
   CDISC Vision
   Pierre-Yves Lastic, Chair-Elect, CDISC Board of Directors

12:25 - 13:45  Lunch Break

13:45 - 14:45  Session 3: CDISC Regional Update
   Session Chair: Hidetoshi Misawa, J3C Vice-Chair
   CDISC in Japan
   Ken Toyoda, J3C Chair
   CDISC in China
   Yazhong Deng, C3C
   CDISC in Asia-Pacific
   Kiyoteru Takenouchi, J3C
   CDISC in Europe
   Peter Van Reusel, E3C Chair

The CDISC Vision:
Informing Patient Care and Safety through Higher Quality Medical Research

CDISC is the global language for clinical research data.
14:45 - 15:35  Session 4: CDISC Experiences and Approaches in the Pharmaceutical Industry  
Session Chair: Satoru Tsuchiya, J3C  
Working in a Global Team for CDISC Standards Development - Throughout the Experience from Asthma TA Standards Development  
Miho Hashio, GlaxoSmithKline  
Simple Tool for Creating ADaM Define.xml for Statisticians in Pharmaceutical Companies using SAS and HTML Application with Excel Metadata File  
Yohei Takanami, Takeda  

15:35 - 16:05  Coffee Break  

16:05 - 17:45  Session 5: CDISC Experiences and Approaches in Academia, CRO & IT Vendor  
Session Chair: Masahiko Onodera, J3C  
UMIN INDICE Lower Level Data Communication Protocol (LLDCP) for CDISC ODM  
Yoshiteru Chiba, J3C, UMIN Center  
Clinical Research in Academia  
Shoji Tokunaga, Kyushu University  
Getting the most out of CDASH and SDTM: Automating the Specification and Validation Process  
Peter Van Reusel, E3C, Business & Decision Life Sciences  
Feasibility Study on Applying CDISC SDTM to Post Marketing Surveillance  
Kunihito Ebi, Fujitsu  

18:00 - 20:00  NETWORKING RECEPTION

FRIDAY, 6 December 2013

09:00 - 15:30  Exhibition Open  
09:00 - 12:30  Conference Registration  
09:15 - 10:30  Session 6: Lessons Learned from CDISC Implementation in Japan  
Session Chair: Yoshiteru Chiba, J3C  
CJUG Activities: CDASH  
Masayuki Ikeda, CJUG, CAC  
Lessons Learned from CJUG-SDTM Activities  
Hajime Shimizu, CJUG, Takeda  
Implementation of ADaM and Optimization of Statistical Analysis Process  
Taku Sakaue, CJUG, Chugai Clinical Research Center  
CJUG Activities: SEND  
Yoshinori Fujimura, CJUG, Fujitsu  

10:30 - 11:00  Coffee Break
11:00 - 12:30  Session 7: Implications from FDA and EMA Regulations

Session Chair: Michiyo Mori, J3C

- Experience of FDA Submission with CDISC
  Akiko Okamoto, Janssen Pharma
- Regulatory Submissions of Global Joint Development Project Based on CDISC Standards
  Yumiko Asami, Daiichi Sankyo
- EMA Data Transparency Initiative
  Pierre-Yves Lastic, Chair-Elect, CDISC Board of Directors

12:30 - 13:45  Lunch Break

13:45 - 15:00  Session 8: eData Submission and CDISC Implementation in Japan: Challenges in Implementing CDISC for eData Submission

Session Chairs: Satoru Tsuchiya, J3C, and Yoshio Tsukada, J3C

- Advanced Workflow of Review and Consultation in PMDA
  Yuki Ando, J3C, Senior Scientist for Biostatistics, PMDA
- Challenges from Pharmaceutical Industry’s Aspect
  Hironori Sakai, JPMA, Mitsubishi Tanabe Pharma
- Challenges from CRO’s Aspect
  Koji Iwamoto, J3C, JCROA, CAC Exicare

15:00 - 15:30  Coffee Break

15:30 - 16:50  Session 9: Panel Discussion

Session Chairs: Satoru Tsuchiya, J3C, and Yoshio Tsukada, J3C

Panelists:
Yuki Ando, Senior Scientist for Biostatistics, PMDA
Taku Watanabe, IT Expert, Office of Review Management, PMDA
Hironori Sakai, JPMA
Akiko Okamoto, PhRMA
Yumiko Sami, CJUG
Koji Iwamoto, J3C, JCROA

16:50 - 17:00  Closing Remarks

Hidetoshi Misawa, J3C Vice-Chair

SAVE THE DATE!

CDISC Europe Interchange 2014
7-11 April 2014
Paris, France

CDISC Asia-Pacific Interchange 2014
Details to be Announced
### CONFERENCE AT-A-GLANCE

**TUESDAY, 3 December 2013**

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"Wherever technically possible, analysable, de-identified raw CT data should be made available for downloading in the format in which they were analysed by the applicant, submitted and evaluated. For the time being, this can be according to CDISC or other appropriate standard. In future, CDISC shall be the required standard, in line with future guidance from the Agency."

-Section 4.2, EMA Publication and Access to Clinical Trial Data