

A collaborative event to share
progress, implementation
experiences, and strategic ideas
on worldwide data interchange
standards for medical research.



**PROGRAM
INTERCHANGE
Japan**

20 - 23 July 2010

Toshi Center Hotel

Tokyo

Japan

Dear All,

On behalf of the Japan CDISC Coordinating Committee (J3C), I would like to thank you for your contributions to the 2010 CDISC Japan Interchange on July 20-23 at Toshi Center hotel in Tokyo.

At the main conference on Tuesday-Wednesday July 20-21, you can learn the most up to date status of the CDISC standards and initiatives, including: CDSIC SHARE, FDA's data standards implementation plan for regulatory submissions and regional activities from Rebecca Kush, CDISC President & CEO, CDISC experts and chairpersons of the Regional CDISC Coordinating Committees.

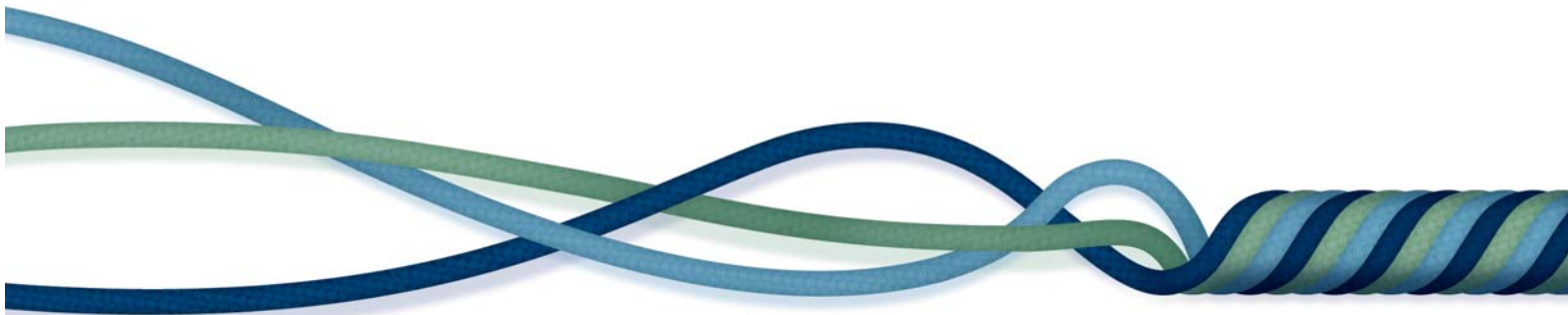
CDISC official training courses will take place on Thursday-Friday July 22-23. In addition to SDTM, ADaM and CDASH courses, Protocol Representation course which is a first time in Japan is also available this year.

As you may know, CDISC is not just for regulatory submission standards, but it is also effective and useful standards in the clinical trial processes whether US, Europe, Japan or anywhere. We believe this is a crucial opportunity to update your knowledge and skills on the CDISC for the further steps.

We are pleased to share the recent topics on CDISC standards with you at the Japan Interchange.

With kind regards,

Yoshio Tsukada
Chairperson of Japan CDISC Coordinating Committee



Strength *through collaboration.*

CDISC INTERCHANGE, JAPAN 2010

CONFERENCE-AT-A-GLANCE

TUESDAY 20 JULY

09:00 - 17:00	Registration
09:30 - 10:30	Session 1: Welcome & Keynote
10:30 - 11:00	Coffee
11:00 - 12:30	Session 2: CDISC Regional Update
12:30 - 13:30	Lunch
13:30 - 15:00	Session 3: CDISC Standards Update
15:00 - 15:30	Coffee
15:30 - 17:00	Session 4: Integration of Standards and Processes
18:00 - 20:00	Evening Reception

WEDNESDAY 21 JULY

09:00 - 10:45	Session 5: Safety Data & CDISC
10:45 - 11:15	Coffee
11:15 - 12:45	Session 6: CDISC - Current Practice & Future in Japan
12:45 - 13:45	Lunch
13:45 - 15:15	Session 7: CDISC More in Japan
15:15 - 15:45	Coffee
15:45 - 16:45	Session 8: Vendor Applications & Tools
16:45 - 17:00	Session 9: Closing Address

THURSDAY 22 JULY

09:00 - 17:00	SDTM v3.1.2 Training: Application and Theory
09:00 - 17:00	ADaM Training: An Implementation Course
09:00 - 12:30	CDASH Training: An Introduction
13:30 - 17:00	Protocol Representation Training: An Introduction

FRIDAY 23 JULY

09:00 - 17:00	SDTM v3.1.2 Training: Application and Theory (Continued)
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CDISC INTERCHANGE JAPAN SESSION DETAILS

TUESDAY 20 JULY 2010

Interchange Conference, Cosmos Hall, 3rd Floor

(Japanese - English simultaneous interpretation is available)

09:00 - 17:00

Registration

09:30 - 17:00

Exhibition Open (6th Floor)

09:30 - 10:30

Session 1: Welcome & Keynote

Chair: Yoshio Tsukada, Chair of the Japanese CDISC Coordinating Committee

- **Welcome to the 2010 CDISC Interchange in Japan**
Yoshio Tsukada, Chair of the Japanese CDISC Coordinating Committee
- **State of the CDISC Union**
Rebecca Kush, CDISC President and CEO
- **Keynote Speech**
Key Factors for Development of Clinical Research in Japan – Potential of Introduction of National ID System (To be confirmed)
Shinichi Nozaki, Counselor Office of Health and Welfare for Director-General for Policy Planning and Evaluation, MHLW
- **Keynote Speech**
Recent trends of Clinical Trials and Clinical Researches – Interim review of the “new 5 yearly clinical trial activation plan”
Yuta Nakaya, Office of Clinical Trial Promotion, Research and Development Division, Health Policy Bureau, MHLW

10:30 - 11:00

Coffee

11:00 - 12:30

Session 2: CDISC Regional Update

Chair: Hiroshi Azuma, Vice Chair of the Japanese CDISC Coordinating Committee

- **CDISC Europe Update**
Pierre-Yves Lastic, Chair of the European CDISC Coordinating Committee
- **CDISC Korea Update**
Sukil Kim, Chair of the Korean CDISC Coordinating Committee
- **CDISC Japan Update**
Kiyoteru Takenouchi, Past Chair of the Japanese CDISC Coordinating Committee

12:30 - 13:30

Lunch

13:30 - 15:00

Session 3: CDISC Standards Update

Chair: Kiyoteru Takenouchi, Past Chair of the Japanese CDISC Coordinating Committee

- **CDISC Standards: Current and Future**
Rebecca Kush, CDISC President and CEO
- **CDISC SHARE: The CDISC Metadata Repository**
Gary Walker, Quintiles
- **Integrating Business Processes between Healthcare and Research**
Landen Bain, CDISC Liaison to Healthcare

15:00 - 15:30

Coffee

15:30 - 17:00

Session 4: Integration of Standards and Processes

Chair: Motohide Nishi, Vice Chair, Japanese CDISC Coordinating Committee

- **Disease-specific Data Standards: Case Studies in TB, Cardiology and Neurology**
Bron Kisler, CDISC Senior Director of Terminology
- **Define.XML –It's Not just for Submissions Any More**
Joel Hoffman, Phase Forward
- **Introduction about our activities on diffusion and implementation of CDISC standards in Translational Research Informatics Center**
Kotone Matsuyama, TRI Center

18:00 - 20:00

CDISC Evening Reception

WEDNESDAY 21 JULY 2010

Interchange Conference, Cosmos Hall, 3rd Floor

(Japanese - English simultaneous interpretation is available)

09:00 - 17:00

Exhibition Open (6th Floor)

09:00 - 10:45

Session 5: Safety Data & CDISC

Chair: Yutaka Sugihara, Japanese CDISC Coordinating Committee

- **Using CDASH data collection forms for automated SAE reporting**
Andrew Newbigging, Medidata Solutions Worldwide
- **Doing more with SDTM – Safety Signal Detection on Clinical Trial Data**
Robbert P. van Manen, Phase Forward
- **E2B Under the Umbrella of HL7 and BRIDG: Looking to the future of data integrations between Pharmacovigilance (E2B) and Clinical Trial Management**
Joerge Dillert, Phase Forward Europe
- **MIHARI Project – PMDA's Pharmacovigilance project with information out of Japan's HIS**
Michio Kimura, Hamamatsu University School of Medicine, Ayumi Endo, Pharmaceuticals and Medical Devices Agency

10:45 - 11:15

Coffee

11:15 - 12:45

Session 6: CDISC Current Practice & Future in Japan

Chair: Toshiaki Ogawa, Japanese CDISC Coordinating Committee

- **Neotor Project: A real academic clinical trial using CDISC ODM-based EDC**
Takahiro Kiuchi, UMIN Center
- **Remoted-SDV using electronic regional medical network system**
Akimasa Yamatani, National Hospital Organization Kanazawa Medical Center
- **Industry Effort for Implementation of CDISC in Japan**
Yoshiko Terui, JPMA

12:45 - 13:45

Lunch

13:45 - 15:15

Session 7: CDISC More in Japan

Chair: Hisao Iizuka, Japanese CDISC Coordinating Committee

- **Activities on CJUG CDASH**
Kazuki Furuno, CJUG CDASH Team
- **CJUG Activities on SDTM implementation team**
Yoshiteru Chiba, CJUG SDTM team, UMIN Center
- **Activities on CJUG ADaM**
Hiroki Takagi, CJUG ADaM Team, Sanofi-Aventis

15:15 - 15:45

Coffee

15:45 - 16:45

Session 8: Vendor Applications and Tools

Chair: Kenji Nagaya, Japanese CDISC Coordinating Committee

- **Cloud based Clinical Trial Management Systems (CTMS)**
Chris Merriam-Leith, Transgenic Software
- **Simplifying trial data extraction with CDISC ODM as web service interface**
Herve Ouambo Fotso, Phase Forward Europe

16:45 - 17:00

**Session 9:
Closing Address**

Hiroshi Azuma, Vice Chair of the Japanese CDISC Coordinating Committee

THURSDAY 22 JULY 2010

(CDISC Official Training Courses, 7th floor)

09:00 - 17:00

Training: SDTM v 3.1.2: Application & Theory
(Room #703)
Gary Walker, Quintiles

The SDTM (Study Data Tabulation Model) v3.1.2 is a specification in the FDA eCTD Guidance as the model for submitting clinical and preclinical data to the FDA.

This two-day course consists of:

- A detailed review of SDTM concepts, SDTM domain models, and relationship tables
- A discussion of common implementation issues, and exercises including CRF-annotations
- Creation of SDTM datasets that reinforce attendees' understanding of the SDTM and the SDTM Implementation Guide

09:00 - 17:00

Training: ADaM Implementation
(Room #707)

Florence Somers, Business & Decision Life Sciences

This course discusses the purpose of analysis datasets, the basic principles of the ADaM data standard, how ADaM fits in the CDISC framework, and the relationship between ADaM and SDTM. Attendees will learn specifics about the subject-level analysis data model and how to start to apply the ADaM standards right now.

09:00 - 12:30

Training: CDASH: An Introduction

(Room #705)

Rebecca Kush, CDISC President & CEO, Bron Kisler, Senior Director Terminology

This half-day course will provide attendees with an overview of the CDASH and Terminology projects as well as covering history and philosophy. This course will provide the information needed to facilitate access, implementation and use of these important standards.

13:30 - 17:00

Training: Protocol Representation: An Introduction

(Room #705)

Rebecca Kush, CDISC President & CEO, Bron Kisler, Senior Director Terminology

This is the first time the Protocol Representation course has been offered in Japan. The objective of the Protocol Representation model is publication of a standard, machine-readable model for protocol representation that will enable interchange of this data among systems and stakeholders. This half-day course will describe the first release of the Protocol Representation Standard, which includes Clinical Trial Registry, Trial Design, and Eligibility Criteria.

FRIDAY 23 JULY 2010

(CDISC Official Training Course, 7th floor)

09:00 - 17:00

Training (Continued): SDTM v3.1.2: Application & Theory

(Room #703)

Corporate Benefactors

