Dear All,

On behalf of 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 updated status of 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 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

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 break
11:00 - 12:30 **Session 2: CDISC Regional Update**
12:30 - 13:30 Lunch break
13:30 - 15:00 **Session 3: CDISC Standards Update**
15:00 - 15:30 Coffee break
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 and CDISC**
10:45 - 11:15 Coffee break
11:15 - 12:45 **Session 6: CDISC – Current Practice & Future in Japan**
12:45 - 13:45 Lunch break
13:45 - 15:15 **Session 7: CDISC More in Japan**
15:15 - 15:45 Coffee break
15:45 - 16:45 **Session 8: Vendor Applications and Tools**
16:45 - 17:00 **Closing Address**

THURSDAY, 22 JULY

09:00 - 17:00 **SDTM Training**
09:00 - 17:00 **ADaM Training**
09:00 - 12:30 **CDASH Training**
13:30 - 17:00 **Protocol Representation Training**

FRIDAY, 23 JULY

09:00 - 17:00 **SDTM Training (Cont)**

CDISC JAPAN INTERCHANGE 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 - 17:30 Exhibition Open (6th Floor)

09:30 - 10:30 **Session 1:**
Welcome & Keynote
Chair: Yoshio Tsukada / J3C Chair

- **Welcome to the 2010 CDISC Japan Interchange**
  Yoshio Tsukada / J3C Chair
- **State of the CDISC Union**
  Rebecca Kush / CDISC President & CEO
- **Keynote Speech**
  Key Factors for Development of Clinical Research in Japan – Potential of Introduction of National ID System (* Under Discussion) -
  Shinichi Nozaki / Counselor Office of Health and Welfare for Director-General for Policy Planning and Evaluation, MHLW
- **Keynote Speech**
  Recent trend of Clinical Trials and Clinical Researches – Interim review of "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 break

11:00 - 12:30 **Session 2:**
CDISC Regional Update
Chair: Hiroshi Azuma / J3C Vice Chair

- **CDISC Europe**
  Pierre-Yves Lastic / E3C Chair
- **CDISC Korea**
  Sukil Kim / K3C Chair
- **CDISC Japan**
  Kiyoteru Takenouchi / J3C Past Chair

12:30 - 13:30 Lunch break

13:30 - 15:00 **Session 3:**
CDISC Standards Update
Chair: Kiyoteru Takenouchi / J3C Past Chair

- **CDISC Standards: Current & Future**
  Rebecca Kush / CDISC President & CEO
- **CDISC SHARE: The CDISC metadata repository**
  Gary Walker / Quintiles
- **Integrating Business Processes between Healthcare and Research**
  Landen Bain / CDISC

15:00 - 15:30 Coffee break

15:30 - 17:00 **Session 4:**
Integration of Standards and Processes
Chair: Motohide Nishi / J3C

- **Disease-specific Data Standards: Case Studies in TB, Cardiology and Neurology**
  Bron Kisler / CDISC Director
- **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 **Evening Reception**

WEDNESDAY, 21 JULY 2010

(Interchange Conference, Cosmos hall, 3rd Floor)
(Japanese-English simultaneous interpretation is available)

09:00 - 17:00 **Exhibition Open**

09:00 - 10:45 **Session 5:**
Safety Data and CDISC
Chair: Yutaka Sugihara / J3C

- **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 break

11:15 - 12:45 **Session 6:**
CDISC - Current Practice & Future in Japan
Chair: Toshiaki Ogawa / J3C

- **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 break

13:45 - 15:15 **Session 7:**
CDISC More in Japan
Chair: Hisao Iizuka / J3C

- **Activities on CJUG CDASH**
  Kazuki Furuno / CJUG CDASH Team, Mochida
- **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 break

15:45 - 16:45 **Session 8:**
Vendor Applications and Tools
Chair: Kenji Nagaya / J3C

- **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 **Closing Address**
Hiroshi Azuma / J3C Vice Chair

THURSDAY, 22 JULY 2010

(CDISC Official Training Courses, 7th Floor)

09:00 - 17:00 SDTM Training: SDTM v3.1.2 Implementation Course
(Room #703)
Instructor: 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 ADaM Training: An Implementation Course
(Room #704)
Instructor: Florence Somers / Business & Decision Life Sciences
The course discusses the purpose of analysis datasets, the basic principles and implementation of the ADaM, and the relationship 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 CDASH Training: An Introduction Course
(Room #705)
Instructor: Bron Kisler / CDISC Director, Rebecca Kush / CDISC President & CEO
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 Protocol Representation Training: An Introduction Course
(Room #705)
Instructor: Rebecca Kush / CDISC President & CEO, Bron Kisler / CDISC Director
This is the first time of Protocol Representation course 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 Courses, 7th Floor)

09:00 - 17:00 SDTM Training: SDTM v3.1.2 Implementation Course (Continued)
(Room #703)

The second day of two-day course.