



2010年6月28日

関係各位 殿

2010 CDISC Japan Interchangeのご案内（最終）

拝啓

時下、益々ご清祥の事とお慶び申し上げます。

平素よりCDISCの活動に関しましては格別のご高配を賜りまして厚く御礼申し上げます。

さて、先般ご案内致しました「2010 CDISC Japan Interchange」のプログラムが確定致しましたので、改めてご案内申し上げます。

今年は前半の2日間にカンファレンスを、後半の2日間にトレーニングコースを設定致しました。カンファレンスでは、CDISC創設者のRebecca Kushさんの他、米国CDISC本部よりCDISCの各標準の専門家、またヨーロッパと韓国の各地域のCDISC Coordinating Committeeを代表する方々にも来日頂き、CDISC SHAREを含むCDISC標準の最新状況、規制当局のCDISCへの対応動向、ならびに各地域でのCDISCへの取り組み等について幅広くご紹介を頂きます。

CDISC公式トレーニングコースでは、SDTM、ADaM、CDASHの各コースに加え、今回初めて、Protocol Representationのコースも開設しております。各標準の一層の理解と実際の導入に有益なトレーニングになるものと存じます。

なお、カンファレンスでは英語 日本語の同時通訳を、またトレーニングコースではJ3Cメンバーによるサポートを予定しております。

また、カンファレンスに事前登録して参加された方には、ご希望により会場にて「CDISC Primer」(CDISC入門書、"Introducing the CDISC Standards, New Efficiencies for Medical Research")の日本語翻訳版を無料にて贈呈する予定です。

時節柄ご多忙の事とは存じますが、国内においてCDISCの詳細に触れることのできる年に一度の機会ですので、万障お繰り合わせの上ご参加下さいますよう重ねてご案内申し上げます。

敬具

Japan CDISC Coordinating Committee (J3C)

Chair 塚田 良雄



記

日 時：2010年7月20日（火）より7月23日（金）までの4日間

（7月20、21日はカンファレンス、7月22、23日はトレーニング）

会 場：都市センターホテル（カンファレンス、トレーニングとも同会場です）

〒102-0093 東京都千代田区平河町 2-4-1

Tel 03-3265-8211

<http://www.toshicenter.co.jp>

参加申込み方法：下記の CDISC ホームページから原則的にオンラインでの参加申込みとなります。

<http://www.cdisc.org/interchange> から 「Online Registration」へお進み下さい。

参加申し込み期限：2010年7月9日（金）を予定

カンファレンス及びトレーニングコースのいずれも、定員になり次第、受付を締め切らせて頂きますので、参加をご希望の方は、なるべく早く登録されることをお勧め致します。

参加費：下記の CDISC membership 区分によりカンファレンス及びトレーニングへの参加費が異なります。懇親会へ参加の方は、参加費はカンファレンス参加費に含まれておりますが、事前登録が必要となります。

1. Corporate Benefactor：CDISC コーポレートベネファクター会社の方
2. Corporate Sponsor /Gov't/Academic/Non-Profit：CDISC コーポレートスポンサー会社の方、政府関係、学術機関、病院、非営利団体関係の方
3. Corporate Member：CDISC コーポレートメンバー会社の方
4. Associate Member：CDISC アソシエートメンバー会社の方
5. Non-Member：非会員の方

参加費はすべて米ドル立てで、米国 CDISC 本部への事前支払となります。

支払方法はクレジットカードによる引き落としか、銀行口座への振込みとなります。

銀行口座への振込みの場合は Shirley Williams (Executive VP, Finance and Administration)

swilliams@cdisc.org までご連絡下さい。なお、銀行口座への振込みの場合、手数料が必要となりますので、ご注意ください。

参加をキャンセルされた場合には、お支払頂いた参加費はクレジット口座あるいは銀行口座に返金されます。銀行口座への返金の場合は Shirley Williams (Executive VP, Finance and Administration) swilliams@cdisc.org までご連絡下さい。なお、7月16日（金）を過ぎますと参加費の返金はできませんので、ご了承下さい。



最終プログラム及び参加費に関しては添付ファイルをご参照下さい。

内容や参加に関してのお問い合わせは e-mail にて下記宛にお願い致します。

J3C : 坂下 総亮

e-mail アドレス : cdiscsaka@yahoo.co.jp

あるいは

CDISC : Shirley Williams

e-mail アドレス : swilliams@cdisc.org

以上



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 Kislner / 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 Kislner / 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.