

2009年6月吉日

関係各位 殿

## The 5th CDISC Japan Interchange の最終案内

拝啓

時下、益々ご清祥の段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「The 5th CDISC Japan Interchange」のプログラムが確定いたしましたので、改めてご案内申し上げます。

今回のカンファレンスでは、CDISC 設立者の Rebecca Kush さんの他、CDASH Project Leader の Rhonda Facile さん、CDISC Director の Chris Tolk さん等にも来日頂き、CDASH プロジェクト及びアメリカ、ヨーロッパおよび中国での活動状況等、CDISC の最新動向につきまして幅広くご紹介頂くことを予定しております。

トレーニングコースでは、昨年に引き続き SDTM のトレーニングコースを、また、今回初めて ADaM、Healthcare Link ならびに CDASH のトレーニングコースも予定しております。

時節柄ご多忙の事とは存じますが、万障お繰り合わせの上ご参加下さいますようお願い申し上げます。

敬具

CDISC 日本グループ  
代表 竹之内 喜代輝

### 記

日 時：2009年7月14日（火）より7月17日（金）までの4日間

（7月14、15日はトレーニング、7月16、17日はカンファレンス）

会 場：あいおい損保新宿ホール（カンファレンス）

〒151-0053 東京都渋谷区代々木 3-25-3

Tel 03-5371-5000

<http://www.jeef.or.jp/new-old/map.html>

都市センターホテル（トレーニング）

〒102-0093 東京都千代田区平河町 2-4-1

Tel 03-3265-8211

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

参加申込み方法：（CDISC ホームページからのオンラインでの参加申込みとなります。）

CDISC ホームページ <http://www.cdisc.org/> ⇒ EVENTS

<http://www.cdisc.org/events/index.html> ⇒ 2009 CDISC Japan Interchange

参加申し込み期限：2009年7月3日（金曜日）

参加申し込み期限を設けておりますが、カンファレンスおよ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いただきますので、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いたします。

参加費：下記の区分によりトレーニング及びカンファレンスへの参加費用が異なります。なお、懇親会参加費はカンファレンスへの参加費用に含まれております。

1. Corporate Benefactor/Govt/Academic/Non-Profit : CDISC コーポレートベネファクタ一会社の方、政府関係、非営利団体、大学・病院関係の方
2. Corporate Sponsor : CDISC コーポレートスポンサー会社の方
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 本部への事前振り込みとなります。

振込み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。

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、クレジット口座に返金されます。銀行口座への振込みの場合は Shirley Williams, VP of Finance and Administration [swilliams@cdisc.org](mailto:swilliams@cdisc.org) までご連絡下さい。

なお、7月7日を過ぎますと参加費の返金はできませんので、ご了承をお願いします。

プログラムおよび参加費に関しては添付ファイルをご参照ください。

内容や参加に関するお問い合わせは 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](mailto:cdiscsaka@yahoo.co.jp)

あるいは

CDISC : Shirley Williams

e-mail アドレス : [swilliams@cdisc.org](mailto:swilliams@cdisc.org)

以上

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



**PROGRAM  
INTERCHANGE  
Japan**

**14 - 17 July 2009**

**Aioi Sonpo Shinjuku Hall**

**& Toshi Center Hotel**

**Tokyo**

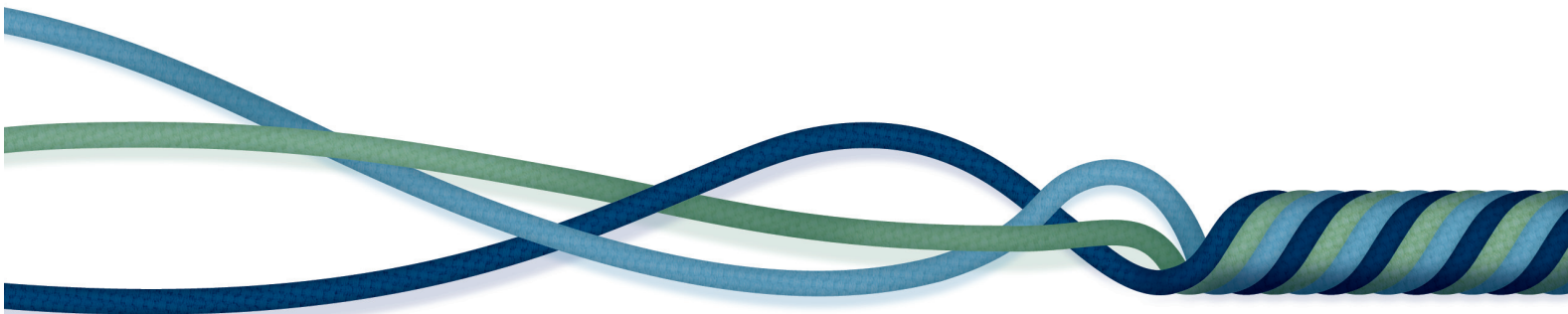
**Japan**

**Save the Date  
CDISC Interchanges in 2009**

**China  
Beijing  
28 - 31 October 2009**



**North America  
Marriott Baltimore Waterfront Hotel  
Baltimore, Maryland, USA  
9 - 13 November 2009**



**Strength** *through collaboration.*

# CDISC INTERCHANGE, JAPAN 2009

## CONFERENCE-AT-A-GLANCE

### TUESDAY 14 JULY

- 09:00 - 17:00 SDTM Training: Application and Theory
- 09:00 - 17:00 ADaM Training: An Implementation Course

### WEDNESDAY 15 JULY

- 09:00 - 17:00 SDTM Training: Application and Theory (Continued)  
*\*\*New CDISC Course\*\**
- 09:00 - 15:00 Healthcare Link Training: An Introduction
- 09:00 - 12:00 CDASH & Terminology Training: An Introduction
- 13:30 - 16:30 CDASH & Terminology Training: An Introduction

### THURSDAY 16 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 Present and Future
- 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: From Protocol & CRF/eCRF to Submission
- 18:00 - 20:00 CDISC Reception

### FRIDAY 17 JULY

- 09:00 - 10:30 Session 5: EHRs & CDISC
- 10:30 - 11:00 Coffee
- 11:00 - 12:30 Session 6: CDISC 'Apply' and 'Do' in Japan
- 12:30 - 13:30 Lunch
- 13:30 - 15:00 Session 7: CDISC More
- 15:00 - 15:30 Coffee
- 15:30 - 16:45 Session 8: CDISC 'End-to-End'
- 16:45 - 17:00 Session 9: Closing Address

# CDISC INTERCHANGE JAPAN SESSION DETAILS

TUESDAY 14 JULY 2009

## *Training will take place at the Toshi Center Hotel*

2-4-1, Hirakawa-cho, Chiyoda-ku, Tokyo 102-0093

Tel. +81 (0)3-3265-8211

(English) <http://www.toshicenter.co.jp/e/index.html>

(Japanese) <http://www.toshicenter.co.jp>

09:00 - 17:00

**Registration**

09:00 - 17:00

**Training: SDTM Application & Theory**

(Toshi Centre Hotel, Room #703)

*Chris Tolk, CDISC Director of Terminology*

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

This class 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**

*(First time on offer in Japan)*

(Toshi Center Hotel, Room #707)

*Sandra Minjoe, Genentech*

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.

12:30 - 13:30

Lunch

WEDNESDAY 15 JULY 2009

09:00 - 17:00

**Registration**

09:00 - 17:00

**Training (Continued): SDTM Application & Theory**

(Toshi Centre Hotel, Room #703)

09:00 - 12:00

**Training: CDASH and Terminology: An Introduction (morning course)** *(First time on offer in Japan)*

(Toshi Centre Hotel, Room #707)

*Rhonda Facile, CDISC Director of CDASH Project*

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.

09:00 - 15:00

**Training: Healthcare Link: An Introduction**

**\*\*NEW CDISC COURSE\*\***

**(Toshi Centre Hotel, Room #704)**

*Rebecca Kush, CDISC President & Dan Levy, Outcome Sciences*

CDISC has several initiatives underway that support the link between medical research and healthcare. This course will include an introduction to the basics of the CDISC Healthcare Link initiative, including the following:

- CDISC interactions with health informatics standards organizations such as HL7 and ISO TC 215
- The Biomedical Research Integrated Domain Group (BRIDG) model
- Activities of CDISC with FDA and EMEA around recommendations for eSource and standards
- Scenarios for the use of electronic health records for clinical research
- The RFD (Retrieve Form for Data Capture), an IHE (Integrating the Healthcare Enterprise) integration profile in use now to support various EHR-research related use cases

12:30 - 13:30

Lunch

13:30 - 16:30

**Training: CDASH and Terminology: An Introduction (afternoon course)**

*(First time on offer in Japan)*

**(Toshi Centre Hotel, Room #707)**

*Rhonda Facile, CDISC Director of CDASH Project*

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.

**THURSDAY 16 JULY 2009**

**Conference at the Aioi Sonpo Shinjuku Hall**

*25-3, Yoyogi 3-chome, Shibuya-ku, Tokyo 151-0053*

*Tel. +81 (0)3-5371-5000*

*(Japanese only) <http://www.jeef.or.jp/new-old/map.html>*

*(Japanese-English simultaneous interpretation available)*

09:00 - 10:30

**Exhibit Booth Setup**

09:00 - 17:00

**Registration**

09:30 - 17:00

**Exhibition Open**

09:30 - 10:30

**Session 1: Welcome & Keynote**

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

- **Welcome to the 5th CDISC Interchange in Japan**  
*Chair: Kiyoteru Takenouchi, Chair of the Japanese CDISC Coordinating Committee*
- **Keynote Speech 1**  
**“New Five Yearly Clinical Trial Activation Plan”: Achievements and Challenges**  
*Satoshi Mano, Office of Clinical Trial Promotion, Research and Development Division, Health Policy Bureau, MHLW*
- **Keynote Speech 2**

**Challenge to Develop a New Activity for Introducing Electronic Health Information to Pharmacovigilance in PMDA**

*Ayumi Endo, Surveillance and Analysis Division, Office of Safety, Pharmaceuticals and Medical Devices Agency*

10:30 - 11:00

Coffee

11:00 - 12:30

**Session 2: CDISC Present and Future**

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

- **CDISC Worldwide**  
*Rebecca Kush, CDISC President*
- **CDISC Europe Update**  
*Ann-Sofie Bergström, European CDISC Coordinating Committee*
- **CDISC China Update**  
*Simon Wang, Chair of the China CDISC Coordinating Committee*
- **Implementing CDISC When You Already Have Standards**  
*Sandra Minjoe, Genentech*

12:30 - 13:30

Lunch

13:30 - 15:00

**Session 3: CDISC Standards Update**

*Chair: Hiroshi Azuma, Japanese CDISC Coordinating Committee*

- **CDASH Overview and CDISC Shared Semantics Repository Update**  
*Rhonda Facile, CDISC Director CDASH Project*
- **An Update on SDTM and Terminology**  
*Chris Tolk, CDISC Director of Terminology*
- **An Overview of Global Safety Initiatives and their Relationship to CDISC Standards**  
*Wayne Kubick, Phase Forward Lincoln Safety Group*

15:00 - 15:30

Coffee

15:30 - 17:00

**Session 4: From Protocol & CRF/eCRF to Submission**

*Chair: Masahiro Yokokawa, Vice Chair, Japanese CDISC Coordinating Committee*

- **The CDISC Protocol Representation Model**  
*Chris Tolk, CDISC Director of Terminology*
- **Building an eCRF CDASH Library – A Case Study**  
*Rob Nichols, Phase Forward*
- **Electronic Case Report Form (e-CRF) System for Easy Transformation into the CDISC SDTM Format**  
*Inyoung Choi, The Catholic University of Korea*

18:00 - 20:00

**CDISC Evening Reception**

**Restaurant Ginza Lion**

**Tokyo Metropolitan Assembly Hall, 1F**

8-1, Nishishinjuku 2-chome, Shinjuku-ku, Tokyo 163-8001

Tel. +81 (0)3-5908-4334

(Japanese only) <http://r.gnavi.co.jp/g008260/>

**FRIDAY 17 JULY 2009**

09:00 - 15:30

**Exhibition Open**



09:00 - 10:30

**Session 5: EHRs & CDISC**

*Chair: Hiroyuki Nishimoto, Japanese CDISC Coordinating Committee*

- **EHRs for Clinical Research**  
*Rebecca Kush, CDISC President*
- **IHE RFD used for Patient Registries**  
*Dan Levy, Outcome Sciences*
- **IHE RFD Connection Test (Adverse Event Reporting) with Ministry Project SS-MIX, at HL7 Kyoto Working Group Meetings**  
*Michio Kimura, Hamamatsu University School of Medicine*

10:30 - 11:00

Coffee

11:00 - 12:30

**Session 6: CDISC 'Apply' and 'Do' in Japan**

*Chair: Yutaka Sugihara, Japanese CDISC Coordinating Committee*

- **MHLW CDISC Grant Project in Japan (Update)**  
*Takahiro Kiuchi, The University of Tokyo*
- **SDTM Conversion of Japanese Data**  
*Jagruthi Kasuganti, TAKE Solutions*
- **SDTM Conversion and Matters Require Attention of Legacy Data**  
*Hideaki Ogawa, CMIC*
- **JCG Activities on ADaM 2008**  
*Yoshiyuki Shibasaki, Quintiles Transnational Japan & Masao Shinoya, The Institute of Japanese Union of Scientists and Engineers*

12:30 - 13:30

Lunch

13:30 - 15:00

**Session 7: CDISC More**

*Chair: Motohide Nishi, Japanese CDISC Coordinating Committee*

- **The Janus Clinical Trial Data Repository – What is it and how can it benefit you?**  
*Douglas Del Prete, IBM Global Industry Solutions*
- **Integration of Electronic Data Capture (EDC) and Interactive Voice Response (IVR) randomization systems using ODM, vendor expansions and web services**  
*Andrew Newbigging, Medidata Solutions*
- **JPMA's Efforts to Facilitate CDISC in Japanese Industry**  
*Osamu Komiyama, Vice Chair, Biostatistics & Data Management Subcommittee, JPMA*

15:00 - 15:30

Coffee

15:30 - 16:45

**Session 8: CDISC 'End-to-End'**

*Chair: Toru Morimoto, Japanese CDISC Coordinating Committee*

- **End To End Processing – A CDISC ODM metadata-driven approach to accelerate CRF design and database set-up**  
*Claus Lindenau, XClinical*
- **Overview of the WebSDM Submission Validation and Review Tool**  
*Wayne Kubick, Phase Forward Lincoln Safety Group*
- **Approach to CDISC with System Engineer's Point of View – What has been affected within our engineering field?**  
*Goro Asahina, Mebix*

16:45 - 17:00

**Session 9:**  
**Closing Address**

15:30 - 17:00

**Exhibit Booth Breakdown**

## Corporate Benefactors



## Registration fee for 2009 CDISC Japan Interchange

*\*\*Note: All amounts are in US Dollars*

### Tuesday & Wednesday, 14-15 July 2009

	Non Member	Associate Member	Corporate Member	Corporate Sponsor	Corporate Benefactor Gov't/Academic/Non-Profit
<b>ADaM Implementation Course</b> <sup>1), 2)</sup> 09:00-17:00 Tuesday Only	\$ 900.00	\$ 675.00	\$ 585.00	\$ 405.00	\$ 225.00
<b>SDTM Implementation Course</b> <sup>1), 2)</sup> 09:00-17:00 Tuesday & Wednesday	\$ 1,800.00	\$ 1,350.00	\$ 1,170.00	\$ 810.00	\$ 450.00

### Wednesday, 15 July 2009

<b>Health Care Link Implementation Course</b> <sup>1), 2)</sup> 09:00-17:00	\$ 900.00	\$ 675.00	\$ 585.00	\$ 405.00	\$ 225.00
<b>CDASH Implementation (Morning) Course</b> <sup>1), 2), 3)</sup> 09:00-12:00	\$ 450.00	\$ 337.50	\$ 292.50	\$ 202.50	\$ 112.50
<b>CDASH Implementation (Afternoon) Course</b> <sup>1), 2), 3)</sup> 13:30-16:30	\$ 450.00	\$ 337.50	\$ 292.50	\$ 202.50	\$ 112.50

### Thursday & Friday, 16-17 July 2009

<b>Interchange Conference</b> <sup>4)</sup> 09:30-17:00 Thursday 09:00-17:00 Friday	\$ 600.00	\$ 450.00	\$ 390.00	\$ 270.00	\$ 150.00
---	-----------	-----------	-----------	-----------	-----------

### Thursday, 16 July 2009

<b>Evening Reception</b> <sup>5)</sup> 18:00-20:00	Free with Interchange Conference Pass Required				
---	--	--	--	--	--

**Note 1) :** Training courses will be held at Toshi Center Hotel 7F

**Note 2) :** Japanese colleagues will support the training course

**Note 3) :** The same course twice, Half-day training course

**Note 4) :** English-Japanese simultaneous interpretation is available

**Note 5) :** Evening Reception takes place at a restaurant nearby Aioi Sonpo Shinjuku Hall

Clinical Data Interchange Standards Consortium, Inc.

15907 Two Rivers Cove  
Austin, Texas 78717 USA  
512-341-9885