The CDISC vision is to inform patient care & safety through higher quality medical research.
J3C Update

J3C Vice Chair
Yoshiteru Chiba
15-NOV-2017
TOC

1. History of J3C
2. Achievements of J3C
   1. CDISC Interchange Japan/Workshop
   2. CDISC training in Japan/Japanese instructors development
   3. Translation coordinating
   4. Public relation
   5. Collaborating with CJUG
   6. Support for organizing TA Workshop
3. Introduce CJUG
4. Introduce AMED
History of J3C
CDISC Japan Events

- **2005 CDISC Japan Interchange**
  June 8-10 (Main Conference: June 10)

- **2006 CDISC Japan Interchange**
  July 11-13 (Main Conference: July 13)

- **2007 CDISC Japan Interchange**
  May 14-16 (Main Conference: May 16)

- **2008 CDISC Japan Interchange**
  June 3-6 (Main Conference: June 5-6)

- **2009 CDISC Japan Interchange**
  July 14-17 (Main Conference: July 16-17)

- **2010 CDISC Japan Interchange**
  July 20-23 (Main Conference: July 20-21)

- **2011 CDISC Japan Training Courses**
  Nov 14-16 (LDC Workshop & SDTM)

- **2012 CDISC Japan Interchange**
  July 10-13 (Main Conference: July 12-13)

- **2013 CDISC Japan Interchange**
  December 3-6 (Main Conference: Dec 5-6)

- **2014 CDISC Japan Training Courses**
  May 19-21 (CDASH & SDTM)

- **2014 CDISC Japan/AP Interchange**
  July 28-August 1 (Main Conference: Jul 31-Aug 1)
<table>
<thead>
<tr>
<th>Year</th>
<th>time</th>
<th>Conference</th>
<th>Training</th>
<th>Reception</th>
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<td>Tokyo Opera City</td>
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## CDISC Official Training Courses

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<th>Year</th>
<th>SDTM</th>
<th>ODM/LAB</th>
<th>Intro CDISC</th>
<th>ADaM</th>
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<th>HC Link</th>
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<th>LDC</th>
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<th>Terminology</th>
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CDISC Japan Interchange Attendees

J3C Update
# J3C Members

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<thead>
<tr>
<th>Sector</th>
<th>Name</th>
<th>Title &amp; Organization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Academia</td>
<td>Yoshiteru Chiba</td>
<td>University Hospital Medical Information Network (UMIN) Center (J3C Vice Chair)</td>
</tr>
<tr>
<td>Academia</td>
<td>Dr. Shiro Hinotsu</td>
<td>Professor, Okayama University Hospital and Center for Innovative Clinical Medicine</td>
</tr>
<tr>
<td>Academia</td>
<td>Dr. Toshiki Saito</td>
<td>Director, Department of Regenerative Medicine, NHO Nagoya Medical Center.</td>
</tr>
<tr>
<td>Academia</td>
<td>Dr. Takuhiro Yamaguchi</td>
<td>Professor and Director, Division of Biostatistics, Tohoku University Graduate School of Medicine and Clinical Research Data Center, Tohoku University Hospital</td>
</tr>
<tr>
<td>Academia</td>
<td>Dr. Hideto Yokoi</td>
<td>Professor of Department of Medical Informatics, Director of Clinical Research Support Center, Kagawa University Hospital</td>
</tr>
<tr>
<td>CRO</td>
<td>Yuya Ikeda</td>
<td>Manager, Data Management Department, Data Science Division, Development Business, Headquarters, EPS Corporation</td>
</tr>
<tr>
<td>CRO</td>
<td>Koji Iwamoto</td>
<td>Executive Officer, Vice President, BTO Division II &amp; Drug Discovery Information Department Director, CAC Croit Corporation</td>
</tr>
<tr>
<td>Sector</td>
<td>Name</td>
<td>Title &amp; Organization</td>
</tr>
<tr>
<td>-----------------</td>
<td>--------------------------</td>
<td>-----------------------------------------------------------------------------------------------------------------------------------------------------</td>
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<tr>
<td><strong>Pharma</strong></td>
<td>Naoto Awaji</td>
<td>Group Manager Clinical System and Process management Group Clinical Operation Dept., Chugai Pharmaceutical Co., Ltd.</td>
</tr>
<tr>
<td></td>
<td>Hidetoshi Misawa</td>
<td>Senior Manager, Clinical Data Integration and Operations, Biometrics and Data Management, Pfizer Japan (J3C Chair)</td>
</tr>
<tr>
<td></td>
<td>Satoru Tsuchiya</td>
<td>Senior Director, Data Science, Sumitomo Dainippon Pharma, Co., Ltd.</td>
</tr>
<tr>
<td></td>
<td>Katsuhiko Yoshimoto</td>
<td>Manager, Biostatistics &amp; Data Management Dept., Clinical Development Div., Nippon Shinyaku Co., Ltd.</td>
</tr>
<tr>
<td><strong>Service Providers</strong></td>
<td>Yoshinori Fujimura</td>
<td>Senior Manager, LIFE SCIENCE SOLUTIONS DIVISION MANUFACTURING &amp; DISTRIBUTION INDUSTRY SYSTEM B.U., FUJITSU LIMITED</td>
</tr>
<tr>
<td><strong>Service Providers</strong></td>
<td>Takako Nozaki</td>
<td>Lead Product Manager, Product Management, Medidata Solutions Worldwide (J3C Vice Chair)</td>
</tr>
<tr>
<td><strong>Regulatory Agency</strong></td>
<td>Dr. Yuki Ando</td>
<td>Senior Scientist for Biostatistics, Advanced Review with Electronic Data Promotion Group Pharmaceuticals and Medical Devices Agency</td>
</tr>
<tr>
<td><strong>(BOD)</strong></td>
<td>Dr. Hiromichi Shirasawa</td>
<td>Vice President and Executive Officer, Head of Japan Development, MSD K.K (Member of CDISC Board of Directors)</td>
</tr>
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J3C Recent Achievements

Interchange/Workshops
Public Training/Instructor Development
Coordination in Translation of Standards
Communications & Public Relations
Promotion of CDISC in Academia
<table>
<thead>
<tr>
<th>Committee Name</th>
<th>Members</th>
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<tbody>
<tr>
<td>Interchange Program</td>
<td>Awaji, Ikeda, Tsuchiya, Ando, Hinotsu, Yamaguchi, Saito, Misawa</td>
</tr>
<tr>
<td>Interchange/Workshop Operations</td>
<td>Nozaki, Matsumi, Chiba, Misawa (Others as needed)</td>
</tr>
<tr>
<td>Training/Instructor Development</td>
<td>Chiba, Iwamoto, Fujimura, E&amp;T Team</td>
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<tr>
<td>TA Workshop Program</td>
<td>Hinotsu, Yokoi, Yamaguchi, Saito, Ando, Misawa</td>
</tr>
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<td>SHARE Workshop Program</td>
<td>Misawa, Chiba</td>
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<td>Translation Coordination</td>
<td>Chiba, Saito, Misawa</td>
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<tr>
<td>Public Relations</td>
<td>Tsuchiya, Ikeda, Yoshimoto</td>
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<td>TA Standards</td>
<td>Ando, Misawa (others like CJUG as needed)</td>
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<tr>
<td>Healthcare Link</td>
<td>Chiba, Yokoi, Saito</td>
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</tbody>
</table>

**Chair**
- Misawa

**Vice Chair**
- Chiba, Nozaki
Interchange/Workshops
# of Japan Interchange Attendees
(Training, Workshop, Interchange)

- **2013**: 169
- **2014**: 240
- **2015**: 237
- **2016**: 344

**PMDA’s Announcement**
regarding CDISC Submission

**CDISC Symposium**

**TA Symposium**
PMDA’s CDISC Submission Requirements
Effective in Oct.
# of Japan Interchange Attendees 2017

<table>
<thead>
<tr>
<th>Name</th>
<th>Registered</th>
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<td>SHARE Workshop</td>
<td>24</td>
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<tr>
<td>Therapeutic Area Standards Workshop</td>
<td>92</td>
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<tr>
<td><strong>Main Interchange Conference</strong></td>
<td>159</td>
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<td>Training Courses</td>
<td>49</td>
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<td><strong>Total</strong></td>
<td><strong>324</strong></td>
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2017 CDISC Japan Interchange Program

2017 CDISC Japan Interchange

“Innovation through CDISC Standards to Advance Medical Breakthroughs”

14 - 15 June 2017
University of Tokyo
Ito International Research Center
Tokyo, Japan
2017 CDISC Japan Interchange Program

KEYNOTE SPEAKER
Takashi Moritoyo, M.D., Ph.D.
Project Professor & Director, Department of Clinical Research Governance, The University of Tokyo Hospital, Secretary General, National University Hospital Clinical Research Promotion Initiative

Dr. Moritoyo is Project Professor & Director of the Department of Clinical Research Governance, the University of Tokyo Hospital as well as Expert Advisor, Office of New Drug II, Pharmaceuticals and Medical Devices Agency. He received his M.D. and Ph.D. from the Faculty of Medicine, Kagoshima University, and studied as a Postdoctoral Associate in the Department of Microbiology, University of Minnesota for three years. He was an Associate Professor and the Deputy Head of the Clinical Therapeutic Research Center, Ehime University Hospital from 2003 to 2010. He then became Deputy Review Director of the Office of New Drug II and II, PMDA, from 2010 to 2012. He was Project Associate Professor, Unit for Early and Exploratory Clinical Development and Head of the Phase 1 unit at the University of Tokyo Hospital from 2012 to 2015. He began his current position in 2015. Also beginning in 2015, Dr. Moritoyo became Secretary General at the National University Hospital Clinical Research Promotion Initiative. He is a principal investigator of a project termed “Regulatory science research on therapeutic area standards for the development of drugs in Japan,” supported by the Japan Agency for Medical Research and Development.

REGULATORY & CDISC SPEAKERS

- Dr. Yuki Ando, PMDA
- Hiroshi Sakaguchi, PMDA
- Chikako Ishige, PMCA
- Dr. Ron Fitzmartin, FDA-CDER
- David Bobbitt, CDISC
- Dr. Lauren Becnel, CDISC
- Rhonda Fassie, CDISC
- Khi Howard, CDISC
- Sam Hume, CDISC
- Dr. Diane Wold, CDISC
# 2017 CDISC Japan Interchange Program

## Conference Schedule

### Wednesday 14 June

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
<th>Location</th>
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<td>09:00 - 10:00</td>
<td>EXHIBITION BOOTH SET-UP</td>
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<td>10:00 - 20:00</td>
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<td>09:30 - 17:00</td>
<td>CONFERENCE REGISTRATION</td>
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### 09:00 - 10:30
**Session Chair:** Takako Nozaki, JSC Vice-Chair

- **Opening Remarks & Introducing David Bobbitt, CDISC President and CEO**
- **Hideto Oh Mowa, JSC Chair, and David Bobbitt, CDISC President and CEO**
- **Keynote: Regulatory Science Research on Therapeutic Area Standards for the Development of Drugs in Japan**
  - Dr. Takashi Moritaya, Director and Project Professor, Department of Clinical Research Governance, University of Tokyo Hospital
- **CDISC Standards In 2017 and Forward**
  - Phoenda Facile, CDISC VP, Standards Development
  - Dr. Diane Wold, CDISC Sr. Director, Standards Development and Modeling

### 10:30 - 11:00
**COFFEE BREAK**

### 11:00 - 12:05
**Session Chair:** Koji Iwamoto, JSC

**SHARE 2.0**
- Dr. Lauren Bechelor, CDISC VP, Strategy and Innovation

**Update on CDISC Education in Japan**
- Kit Howard, CDISC Director, Education

**CDASH and SDTM: Why Do We Need Both Standards?**
- Kit Howard, CDISC Director, Education

### 12:05 - 13:35
**LUNCH BREAK**

### 13:35 - 18:05
**Session Chair:** Shiro Hinatsu, JSC

**PMDA Update**
- **Current Status of Electronic Data Submission in PMDA**
  - Dr. Yuki Ando, PMDA
- **Experiences Receiving and Using Electronic Data in PMDA**
  - Chikako Iwige, PMDA
- **Implementation of Therapeutic Area Standards in Japan**
  - Hitoshi Sakaguchi, PMDA
- Q&A with PMDA Representatives
2017 CDISC Japan Interchange Program
2017 CDISC Japan Interchange Program
Public Training/Instructor Development
### Public Training Courses in 2016 & 2017

#### 2016

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<th>JAN</th>
<th>FEB</th>
<th>MAR</th>
<th>APR</th>
<th>MAY</th>
<th>JUN</th>
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<th>AUG</th>
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#### 2017

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<th>OCT</th>
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<th>DEC</th>
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<tr>
<td>SDTM (3/13-14)</td>
<td>CDASH (3/15)</td>
<td>Define (3/15)</td>
<td>ADaM P (3/16)</td>
<td>ADaM T (3/17)</td>
<td>SDTM (6/8-9)</td>
<td>CDASH (6/5)</td>
<td>Define (6/6)</td>
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<td>SDTM (9/11-12)</td>
<td>CDASH (9/13)</td>
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Japanese Instructors Authorization

- Total 10* Japanese instructors authorized
  - *One authorized for SDTM as well as Define/ODM
  - 1 left the instructor team
- 3 new SDTM instructor candidates started training early 2017
Translation Coordination
Contribution to COP007-Translation

- Detailed review comments provided from J3C to Draft Operation Procedures for Translation in August
- Further discussion followed between Rhonda, Andrea and J3C in September
- Most of the comments taken into the final COP
Coordination of SDTM/SDTM IG Translation

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<th>CDISC Standards/Materials</th>
<th>JPN Version 1.0</th>
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<tbody>
<tr>
<td>SDTM IG v3.2</td>
<td>Translation Project Plan (Final)</td>
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1. Purpose & Scope

The purpose of this document is to describe a plan for the translation coordination mentioned below which intend to translate a CDISC standard in accordance with CDISC-COP-007 CDISC Translation Project Plan (Final) dated October 2015.

The scope of this document includes the parties, the object of translation, quality control, timelines, publication, funding and referenced materials. A detailed description of the translated material (e.g. style, layout) is out of the scope of this document, which will be documented separately.

2. Participating Parties

The participating parties in this plan will be the National Hospital Organization Nagoya Medical Center, the Translational Research Informatics Center (Foundation for Biomedical Research and Innovation) and the CDISC Japan User Group SDTM Team (hereinafter called “Translation Parties”).

Excellent example of collaboration among Nagoya Medical Center, TRI, CJUG and J3C
Japanese SDTM v1.4 & ADaM IG v1.0 Authorized

SDTM v1.4 と ADaMIG v1.0 が日本語に翻訳されました。CDISC は翻訳を行ってくださった名古屋医療センター、日本の CDISCユーザーグループ (CJUG) および先端医療振興財団 臨床研究情報センターに大変感謝しております。これらの文書は COP-007 に順守して作成されました。

CDISC is pleased to announce SDTM 1.4 and ADaMIG 1.0 have been translated to Japanese. We are very grateful to the Nagoya Medical Center, CDISC Japanese User Group (CJUG), and Translational Research Institute (TRI) for their assistance in providing the translations. These documents were created in compliance with COP-007.

Downloads:

- SDTM v1.4_JPN_v1.0.pdf
- ADaMIG v1.0_JPN_v1.0.pdf

These are the first translated versions of CDISC standards authorized according to COP007.
## Coordination in Translation

<table>
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<tr>
<th>CDISC Standards</th>
<th>Version</th>
<th>Translator</th>
<th>Note</th>
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<td>SDTM Implementation Guide</td>
<td>3.2</td>
<td>NMC*</td>
<td>NMC and CJUG SDTM Team have agreed that the SDTM Team preform peer review. A translation project plan agreed among the parties.</td>
</tr>
<tr>
<td>ADaM</td>
<td>2.1</td>
<td>NMC*</td>
<td>NMC and CJUG ADaM Team have agreed that the ADaM Team preform peer review. A translation project plan to be created.</td>
</tr>
<tr>
<td>CDASH Implementation Guide</td>
<td>2.0</td>
<td>TRI**</td>
<td>TRI and CJUG CDASH Team have agreed that CJUG CDASH Team preform peer review.</td>
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*NMC: Nagoya Medical Center  
**TRI: Translational Research Informatics Center

Just examples to show excellent collaboration being developed among research organizations and CJUG Teams.
Public Review Process Established

CDISC Operational Procedure CDISC-COP-007
CDISC Translations

### Revision History

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<th>Revision</th>
<th>Description</th>
<th>Author</th>
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<td>July 2015</td>
<td>0.1</td>
<td>Initial Draft</td>
<td>Andrea Vadakin and Rebecca Kush</td>
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<tr>
<td>September 2015</td>
<td>0.2</td>
<td>Comments from 3Cs</td>
<td>Andrea Vadakin</td>
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</table>

- Following internal review, the translated document will be posted to the CDISC website for an open, 30-day **public review** period, to be coordinated by the local 3C.

- The 3C will submit the final draft of the translated document to either the regional regulatory authority that has agreed to assist with this process, or CDISC Operations, who will make a final recommendation regarding authorization. The regulatory authority and CDISC Operations have a 30-60 day window before making a final recommendation. Depending upon the number of reviewers involved, this window may include an open **public review** period.

Public Review process established via real authorization
Public review schedule of SDTM IG

- Briefing GoToWebinar held 15-Sep
- Using JIRA(Comment tracker)

<table>
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<th>End</th>
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<td>5</td>
<td>2-Feb-18</td>
<td>9-Mar-18</td>
<td>35</td>
</tr>
<tr>
<td>6</td>
<td>9-Mar-18</td>
<td>13-Apr-18</td>
<td>35</td>
</tr>
<tr>
<td>7</td>
<td>13-Apr-18</td>
<td>18-May-18</td>
<td>35</td>
</tr>
</tbody>
</table>
Japanese version of SDTM IG 3.2

CDISC SDTM Implementation Guide (Version 3.2)

1. はじめに

1.1 Purpose

This document comprises the CDISC Version 3.2 (V3.2) Study Data Tabulation Model Implementation Guide for Human Clinical Trials (SDTMIG) and format of standard clinical trial tabulation datasets submitted to a regulatory authority such as the Study Data Tabulation Model Implementation Guide for Human Clinical Trials (SDTMIG).

SDTMIG は、CDISC 試験データ表形式モデル（SDTM）の最新バージョン（http://www.jisc民国 apocalypse に申請される臨床研究データを表現するための一般概念モデルが SDTM に記載される
SDTMに基づく標準の表形式データセットを作成するための具体的なドメインモデル
The SDTMIG should be used in close concert with the current version of the CDISC Study Data Tabulation Model Implementation Guide for Human Clinical Trials (SDTMIG) and the general conceptual model for representing clinical study data that is submitted to regulatory domain models, assumptions, business rules, and examples for preparing standard tabulation data.
Login for Issue Tracker (JIRA) and Webinar

Welcome to Issue Tracker (JIRA)

You must log in to access this page.
If you think this message is wrong, please contact your JIRA administrators.

Username
Password
Remember my login on this computer

Not a member? Sign up for an account.

Log In
Can't access your account?

CDISC Webinar Organizer (cdiscwebinar@cdisc.org) から次のウェビナーのパネリストとして招待されています。

CDISC Public Webinar - Japanese SDMIG v 3.2 Public Review and JIRA Demonstration
Communications & Public Relations
J3C WEB Page in Japanese available

- New Website using WIKI
- Timely updated by J3C with write access
- CJUG deliverables being posted

J3Cからのお知らせ

本日本語ページは、J3C (Japan CDISC Coordinating Committee) による情報を掲載しております。
日本国内で行われるCDISCに関するイベントや、日本語の資料を公開しております。

J3Cニュース

イベント、トレーニング情報

3/23-28 Mar 2016・・・CDISC公式トレーニング（SDTM, ADaM, CDASH, ODM, XML（Define））
詳細な申し込み方法はこちらをご覧ください。（http://cdisc.org/public-training-tokyo-japan）
すべて日本語でのトレーニングを予定しております。

J3C/CJUG作成資料

作成者 Yuya Ikeda, 最終変更日 1/6/2016

★ J3C、あるいはCJUGで作成した資料を掲載しています。ご活用ください。

<table>
<thead>
<tr>
<th>CJUG資料</th>
<th>説明（日本語 &amp; 英語）</th>
<th>制作時期</th>
</tr>
</thead>
</table>

CJUG (CDISC Japan User Group)

CDISCユーザーネットワークは、アメリカ、ヨーロッパ、アジアなどでそれぞれ設立されている組織です。

CJUG (CDISC Japan User Group) は、日本のCDISCユーザーネットワークであり、2002年に設立されました。

規制当局、製薬企業、CRO、アカデミア、ITベンダーなどのメンバーがCDISC標準のワーキンググループに参加し、
日本でのCDISC標準の普及へ向け活動しています。
Japanese Announcement via email

Japanese email communications distributed via many channels (e.g. JPMA, CJUG, Academia Organizations, CROs)

関係者各位

「2017 CDISC Japan Interchange」のご案内（第二報）

2017年5月吉日

関係者各位

「2017 TA ワークショップ」のご案内（第二報）

Japan CDISC Coordinating Committee

2017年5月吉日

拝啓

時下ますますご清栄のこととお喜び申し上げます。

今般、2017 CDISC Japan Interchange Conference に先立ち、疾患領域別データ標準（TA: Therapeutic Area Standards）に関するワークショップを開催する運びとなりました。
J3C-CJUG meeting

• Quarterly between J3C CJUG(CDISC Japan User Group) meeting

• Collaboration and supports
  – Interchange/training operation supports
    • Include online presentation supports
  – Development of Japanese version documents
    • Internal review
    • Public review
Support for organizing TA Workshop hosted by CDISC
<table>
<thead>
<tr>
<th>Presentation Title</th>
<th>Speaker</th>
<th>Title &amp; Organization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Therapeutic Area Standards Update</td>
<td>Ms. Rhonda Facile Dr. Diane Wold</td>
<td>CDISC</td>
</tr>
<tr>
<td>Approach of AMED to promote CDISC into academia</td>
<td>Mr. Yasunori Yoshida</td>
<td>AMED</td>
</tr>
<tr>
<td>Perspective of Therapeutic Area Standards in Kidney Disease</td>
<td>Dr. Masaomi Nangaku</td>
<td>The University of Tokyo Graduate School of Medicine, Division of Nephrology and Endocrinology</td>
</tr>
<tr>
<td>Development Outline of SEAMAT (Standard Export datA forMAT by Japanese Circulation Society)</td>
<td>Dr. Kazuya Takehana</td>
<td>Department of Medicine II, Division of Cardiology Kansai Medical University</td>
</tr>
<tr>
<td>Gap between medical information systems and standardized regulation - Problems for CDISC, SS-MIX2, and SEAMAT application in NCVC</td>
<td>Dr. Kunihiro Nishimura</td>
<td>Center for Cerebral and Cardiovascular Disease Information, National Cerebral and Cardiovascular Center</td>
</tr>
<tr>
<td>Standardization of clinical data in rheumatoid arthritis</td>
<td>Dr. Tsuneyo Mimori</td>
<td>Department of Rheumatology and Clinical Immunology, Graduate School of Medicine, Kyoto University</td>
</tr>
</tbody>
</table>

**First time to have Speakers working in Real Japanese Academia Organizations**
<table>
<thead>
<tr>
<th>Presentation Title</th>
<th>Speaker</th>
<th>Title &amp; Organization</th>
</tr>
</thead>
<tbody>
<tr>
<td>PMDA’s approach to utilizing Therapeutic Area Standards</td>
<td>Mr. Hiroshi Sakaguchi</td>
<td>PMDA</td>
</tr>
<tr>
<td>Value of CDISC standards in the academia and use cases</td>
<td>Dr. Toshiki Saito*</td>
<td>Department of Regenerative Medicine, NHO Nagoya Medical Center.</td>
</tr>
<tr>
<td>Prospects and challenges in use of TA standards – from the views of clinical research and medical informatics</td>
<td>Dr. Hideto Yokoi*</td>
<td>Department of Medical Informatics, Director of Clinical Research Support Center, Kagawa University Hospital</td>
</tr>
<tr>
<td>Prospects and challenges in use of TA standards – from the views of clinical research design and quality control</td>
<td>Dr. Takuhiro Yamaguchi*</td>
<td>Division of Biostatistics, Tohoku University Graduate School of Medicine and Clinical Research Data Center, Tohoku University Hospital</td>
</tr>
</tbody>
</table>

*: J3C Members

Significant contribution made by “academia” J3C members to organize this event
# Academia Sessions in 2017 JPN Conference

<table>
<thead>
<tr>
<th>15:35 - 17:40</th>
<th>Session Chair: Yoshinori Fujimura, J3C</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Session 4: Update from Japanese Academia and Use Cases for CDISC Standards &amp; Technology</strong></td>
<td></td>
</tr>
<tr>
<td>Reports on the Application of the CDISC Standards in NHO Nagoya Medical Center</td>
<td>Dr. Toshiki Saito, National Hospital Organization, Nagoya Medical Center</td>
</tr>
<tr>
<td>Experiences from the PMDA Pilot Project for Utilization of Electronic Data in an Academic Setting</td>
<td>Dr. Takuhiro Yamaguchi, Tohoku University</td>
</tr>
<tr>
<td>TBD</td>
<td>Dr. Shizuko Takahara, Innovative Clinical Research Center, Kanazawa University</td>
</tr>
<tr>
<td>Define2Validate - An Implementation of Dataset-XML Validator with R</td>
<td>Dr. Masafumi Okada, University Hospital Medical Information Network (UMIN) Center</td>
</tr>
<tr>
<td>Current Status Update on the WHODrug B3/C3 Formats and CDISC SDTM Compliance</td>
<td>Damon Fahimi, Uppsala Monitoring Centre</td>
</tr>
<tr>
<td>Introducing Metadata Repository Implementation Practices</td>
<td>Kunihito Ebi, Fujitsu</td>
</tr>
<tr>
<td>Good Validation Practice</td>
<td>Sergiy Sirichenko, Pinnacle 21</td>
</tr>
</tbody>
</table>
Involvement J3C in a AMED-initiated research

From “Call for Proposal - AMED 2016 Research Project for Clinical Research/Study Promotion”

2. Research that contribute development of infrastructure to enhance quality of clinical research etc.

2-1. Research for conversion of medical information standardized with SS-MIX format into CDISC

<Purpose>
By converting electronic medical information and/or electronic health record standardized with SS-MIX format adopted at medical institutes etc into CDISC format, to aim at establishment of methodology to contribute to conduct of clinical research effectively utilizing electronic medical information and/or electronic health and to efficient operation on NDA submission

<Adoptable Condition>
To take into consideration the discussion about electronic data submission of clinical study in CDISC compliant format that PMDA is promoting and other CDISC-related topics. Tie with CDISC’s related projects, closely exchanging information with PMDA and J3C.

* This English is provided by Hidetoshi Misawa just for reference purposes only. In the event of any inconsistency between the Japanese original and the English translation, the former shall prevail.
CDISC Japan User Group Updates

Presented by Yoshiteru Chiba
Leader, CDISC Japan User Group
15-16NOV2017
Contents

• CDISC and CJUG History in Japan
• CDISC Japan User Group System
• Numbers of CJUG member
• CJUG team
  ▪ ADaM
  ▪ CDASH
  ▪ PR
  ▪ SDS
  ▪ SDTM
  ▪ SEND
• Information
CDISC and CJUG History in Japan

2002

May

Inauguration

Nov

J3C formed

2003

Jan

CJUG (JCG) formed

2004

Jun

1st Japan Interchange

2005

Jul

2nd Japan Interchange

Jun

1st Japan Interchange

2006

Dec

2nd CJUG Workshop

Dec

3rd CJUG Workshop

2007

May

3rd Japan Interchange

2011

Nov

JP Training Courses

Jun

8th CJUG Workshop

2015

Jun

10th Japan Interchange

Mar

12th CJUG Workshop

2016

Jun

11th Japan Interchange

Mar

13th CJUG Workshop
CDISC Japan User Group System (2017-05-10)
Numbers of CJUG member (CJUG team / Business area) (n= 348, 2017-05-10)

- **Total**: 348
- **Drug (Pharma)**: 155
- **CRO**: 96
- **Labo**: 8
- **Academia**: 39
- **Others**: 10
- **SDTM**: 171
- **CDASH**: 38
- **ADaM**: 62
- **SEND**: 45
- **PR**: 19
- **SDS**: 11
CJUG team

- ADaM
- CDASH
- PR
- SDS
- SDTM
- SEND
CJUG team

- ADaM
- CDASH
- PR
- SDS
- SDTM
- SEND
CJUG ADaM Team Office (Since Oct. 2017)

ADaM team Leader
• Yumiko Asami

ADaM mtg coordinator (full-member mtg, TL mtg, CJUG mtg)
• Akira Kurisu

CJUG across-team WS pgm committee
• Masahiro Yoshizaki
• Kunika Kikumori

Membership
• Tomotaro Shiraishi

ADaM & stat analysis advisory group
• Taku Sakaue
• Youhei Takanami
• Yoshiumi Ouchi

Liaison & Partnership
• Yoshiumi Ouchi

Global communication
• Shinichi Hotta (Minutes)
• Ayako Noda (Events)
• Youhei Takanami (Events)
• Masato Suzuki (Others)

ADaM Education
• Masataka Sano
• Kota Ono

Sub-team leaders
• (see later pages)
Sub team: Oct.2016-Sep.2017 (1-year term)

7 projects Completed!!!

1. Investigating ADaM related guidance and manuscripts
2. Therapeutic standards
3. Utility tools for ADaM and analysis
4. e-Data submission to PMDA
5. ADaM and analysis for clinical pharmacology
6. Commonly used ADaM examples
7. ADaM and e-Data submission of complicated statistical methods

7 **projects started**

1. e-Data submission to PMDA (Y.Takanami)
2. Statistical analysis plan for ADaM dataset creation (Y.Ouchi)
3. Utility tools for ADaM (T.Sakaue)
4. Quality management for ADaM (T.Sakaue)
5. ADaM and analysis for clinical pharmacology (Y.Furukawa)
6. Translation of ADaM-related documents (M.Sano & K.Ono)
7. ADSL (K.Kikumori)
Japanese translation of CDISC ADaM IG v.1.0 in adherence to CDISC Operating Procedure 007

- Applicants should conform to the CDISC ADaM document and the ADaM IG for PMDA submissions.
- ADaM document and IG are written in English and include many technical terms and wording for statistics analysis.
  - "word-for-word" translation of the documents without deep expertise in statistics may lead to misunderstanding or misconception for non-English-speaking readers.

CJUG ADaM created
- Japanese translation of CDISC ADaM IG v. 1.0 with due consideration for statistics and analysis.
- Translation plan in adherence with COP-007 to ensure the quality of the translation.

Published on https://www.cdisc.org/standards/foundational/japanese

Will be presented later
CJUG team

- ADaM
- CDASH
- PR
- SDS
- SDTM
- SEND
CJUG CDASH Team

• 37 members, as of May 2017
• Most members are from pharmaceutical company and CRO. Some members are from LAB and academia, and one overseas member is in the team.
• Team is following

CJUG CDASH Team: Charter

“We are the team which can be…”

- Recognized as a group of the first contact for CDASH standards by Japan regulatory, academia and any other groups/organizations

- A provider of information/procedures/practices for CDASH implementation/handling to any activities within Japan industry/academia/regulatory

- A primary contact to CDASH groups in other country and a part of user group network on global
CDASH Sub-team Activities in 2017

Sub team structure: 6 sub-team

- 5 sub-teams have been organized before 2017. These are continuing their discussion in 2017.
- 1 sub-team is newly organized in 2017.

<table>
<thead>
<tr>
<th>Team target</th>
<th>Proposer</th>
<th>Lead</th>
</tr>
</thead>
<tbody>
<tr>
<td>Create CRF library with CDASH</td>
<td>M Okada</td>
<td>S Ueno</td>
</tr>
<tr>
<td>Investigate needs and advantages for using CDASH</td>
<td>Y Takahashi</td>
<td>K Uchida</td>
</tr>
<tr>
<td>QA station &amp; CDASH Web exercise</td>
<td>S Tanaka</td>
<td>M Okada</td>
</tr>
<tr>
<td>Instruction for CDASH</td>
<td>Y Takahashi</td>
<td>H Tanaka</td>
</tr>
<tr>
<td>V2.0 translation in Japanese</td>
<td>M Imasho</td>
<td>S Ueno</td>
</tr>
<tr>
<td>CRF Sample in conformity with CDASH</td>
<td>H Kato</td>
<td>S Ueno</td>
</tr>
</tbody>
</table>
Focus of our activities in 2017

◆ CDASH team has made some results in 2016, which are collaboration with other groups outside of CJUG.
  ▪ Join a meeting with ACRP
  ▪ Join CRC Arikata-Kaigi
  ▪ Join Annual Meeting of Japanese Society of Clinical Pharmacology and Therapeutics

✓ We are open to get together for discussing CDISC future with other groups/teams in industry/academia/ regulatory!

◆ We really look forward to see CDASH V2.0. Followings are ready to start once we get V2.0 announcement.
  ▪ CDASH V2.0 translation in Japanese
  ▪ Instruction for CDASH,
  ▪ CDASH Web exercise for CDASH V2.0
CJUG team

- ADaM
- CDASH
- PR
- SDS
- SDTM
- SEND
CJUG PR Team

- 20 members (May 2017)
- Formed on 2006 as “eSDI Team”
- Based in Osaka
- Consists of:
  - Pharmaceutical company
  - CRO
  - IT vendor
  - Academia
Topics in CJUG PR

- eSDI team
- BRIDG team
- PR team

- eCT: eClinical Trial
- eSDI: eSource Data Interchange
- BRIDG: Biomedical Research Integrated Domain Group Model
- Domain Analysis Model?
- PRM: Protocol Representation Model
- CSHARE: CDISC Shared Health and Clinical Research Electronic Library
- RDF: Resource Description Framework
- TDM: Trial Design Model
- SDM: Study Design Model
- Semantic Interoperability?
- Seamless?

- Osaka Area
- EDC
- Healthcar e-Link

- 2006
- 2007
- 2008
- 2009
- 2010
- 2011
- 2012
- 2013
- 2014
- 2015
- 2016

- Seamless?
- Semantic Interoperability?
PR Team Activities in 2017

Topic of PR Team

- Investigating data interchange (REDCap - SDTM)
- Reference Tool for SDTM Conformance Rules (by RDF)
- Investigating global trends of data standards
- CTR-XML
CJUG team

- ADaM
- CDASH
- PR
- SDS
- SDTM
- SEND
CJUG-SDS team

- CJUG-SDS
  (CDISC Japan User Group – Submission Data Standards)
- Since 2014
CJUG-SDS team

1) Open Innovation:

1-1) To classify **Pinnacle 21 rules** related to PMDA

- To make “Data Validation” more efficient, according to progress “Data Cleaning”.
- Type A) To be checked just now even during data cleaning.
  (ex. An issue related to SDTM specification)
- Type B) To be checked when data were collected almost.
  (It may be resolved at that time)

1-2) To make **an educational materials** about CDISC standard

- Contents : the outline and all guidelines related CDISC by PMDA at 2017.
- Subject : Beginner (an unexperienced person for CDISC standard)
- Objects : Decreasing work for making educational materials

1-3) (Plan to) collaborate with other CJUG team.

2) Discussion: Teach me about X.  (X=an issue)

Scope: all issues related CDISC in member’s business area.
Method: F2F after members exchange their opinions on email.
1) Open Innovation:

1-1) To classify **Pinnacle 21 rules** related to PMDA
CJUG team

- ADaM
- CDASH
- PR
- SDS
- SDTM
- SEND
## Objectives of SDTM Team

### Beginner

**Acquiring experience of the SDTM implementation and deepen understanding**

- Create SDTM Dataset via test trial
- A series of work (from planning Clinical Protocol to create SDTM) will be carried out.

### Experienced

**Consideration of Know-how in the SDTM implementation**

- Examining some problems which may occur through developing SDTM and method to solve them.
- Announce achievement on SDTM team meeting.
- Publication deliverables (CDISC Portal)

### Presentations

**Collect up-to-date information about CDISC**

- Information about e-Submission at FDA/EMA
- Information about CDISC essential standard, Therapeutic Area Standard, and more
### SDTM activity summary（2017~）

<table>
<thead>
<tr>
<th>Ongoing Theme</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Trial</td>
<td>Assess the brain function improvement effect of menthol</td>
</tr>
<tr>
<td>SDTM QC</td>
<td>Consideration of the Tips of SDTM QC</td>
</tr>
<tr>
<td>PMDA FAQ</td>
<td>Extraction of a seductive matter in PMDA-FAQ</td>
</tr>
<tr>
<td>Arm/Epoch/Visit</td>
<td>Adequate setting of Time-Point variable in Japanese trial</td>
</tr>
<tr>
<td>Custom Domains</td>
<td>Examine to categorize Custom Domain</td>
</tr>
<tr>
<td>SDTM AREKORE USER ASSOCIATION</td>
<td>Discuss and find the best solution for SDTM implementation in Japan.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Guest lecture</th>
<th>Lecturer</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report on PhUSE EU CSS</td>
<td>Yoshiko Kitagawa (ONO Pharma UK)</td>
<td>Jul-2017</td>
</tr>
<tr>
<td>CDISC Oncology and CDISC SHARE</td>
<td>John Owen (CDISC)</td>
<td></td>
</tr>
<tr>
<td>Life of a CRC</td>
<td>Yuko Yokoi (Kanazawa University Hospital)</td>
<td></td>
</tr>
<tr>
<td>CDISC Evolution</td>
<td>Nicole Harmon (CDISC)</td>
<td>Sep-2017</td>
</tr>
<tr>
<td>eClinical Solution Market Trends</td>
<td>Wolf (OmniComm)</td>
<td></td>
</tr>
<tr>
<td>SHARE 2.0 and Other CDISC Innovation</td>
<td>Lauren Becnel (CDISC)</td>
<td>Oct-2017</td>
</tr>
<tr>
<td>Risk Based Monitoring</td>
<td>Francois Torche (CluePoints)</td>
<td></td>
</tr>
<tr>
<td>Case of Electronic Study Data Submission</td>
<td>Yoshihisa Mizuno (astellas)</td>
<td>Nov-2017</td>
</tr>
<tr>
<td>An update on WHODrug with a focus on the new B3/C3 formats and WHODrug Global</td>
<td>Damon Fahimi (UMC) Carin Ellene (UMC)</td>
<td></td>
</tr>
</tbody>
</table>
Activity policy
doing SDTM AREKORE USER ASSOCIATION

【Primary】
To collect questions related to SDTM implementation from AREKORE members, and to discuss with them in the team to find the best solution.
(Developing our knowledge through discussion comes first, and as a result of discussion, we will reach solution)

【Secondary】
To introduce the contents of the discussions and our opinion/view to other CJUG SDTM members.

【Exploratory】
To ask opinions of CJUG overseas members, if we cannot find an answer to questions or reach an agreement within a team.
CJUG team

- ADaM
- CDASH
- PR
- SDS
- SDTM
- SEND
SEND Status Update

• Current version: SEND IG v3.0
  ▪ Single-dose general toxicology
  ▪ Repeat-dose general toxicology
  ▪ Carcinogenicity

• Next version: SEND IG v3.1
  ▪ Adds domains
    CV: CARDIOVASCULAR TEST RESULTS
    RE: RESPIRATORY TEST RESULTS
  ▪ Adds Variable Name
    EGTPT(EG), VSTPT(VS)
SEND Status Update

• New standard: SEND IG-DART v1.0
  - DART (Developmental and Reproductive Toxicology) Embryo Fetal Development study
  - Uncorrespondence Fertility and Early Embryonic Development study Pre-and Postnatal Development study
SEND Team Activity

• Started in 2004

• Meeting: Monthly at Tokyo (F2F+WebEX)
Information
Information

- **CJUG HP**

- **Apply for an admission:**

- **Contact:**
  [CJUG-OFFICE@umin.ac.jp](mailto:CJUG-OFFICE@umin.ac.jp)
Introduce of AMED
AMED: A New System for Medical R&D in Japan

**Headquarters for Healthcare Policy (HHP)**
- develop a comprehensive plan for the promotion of medical R&D
- integrate medical R&D budget requests of relevant ministries
- make strategic decisions on the allocation of promotional adjustment funds

**Ministries**
- Advise on Nomination of President and Auditor
- Advise on Mid-to-Long Term Targets
- Comprehensive adjustment of budget request

**Japan Agency for Medical Research and Development (AMED)**
- Handle Nomination and Dismissal of AMED President and Auditor
- Present Mid-to-Long Term Targets
- Allocate Subsidy Operating Expense

**Funding**
- Provides a unified point of contact for funding and for application procedures.
- Provides support from basic research to practical use.

**Institutes/Researchers**

Support of AMED for academia utilizing CDISC

- promotion of conforming to CDISC at a planning stage of clinical trials
- joint sponsorship of training and/or webinar for conforming to CDISC
- incorporation of opinions to CDISC Advisory Council

PMDA: Pharmaceuticals and Medical Devices Agency

AMED: Japan Agency for Medical Research and Development
Conclusion

• Mutual collaboration would be truly appreciated.
• Thank you!

Contact: CDISC-J3C@umin.ac.jp