

# CDISC関連情報の紹介

2014年12月4日

製薬協 データサイエンス部会

タスクフォース2

# CDISC関連情報の調査方法

## 1. HP公開資料

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1. CDISC HPに掲載されている資料
  - A) 制限なく誰でもアクセスできるもの
  - B) CDISCメンバー会社だけがアクセス可能なもの
2. FDA HPに掲載されている資料
  - <http://www.fda.gov/ForIndustry/DataStandards/StudyDataStandards/default.htm>
3. PMDA HPに掲載されている資料
  - <http://www.pmda.go.jp/operations/shonin/info/iyaku/jisedai.html>
4. その他の資料
  - CDISC eNewsletter (毎月)、CDISCからのメール案内
  - PhUSE (ヒューズ)、SAS Forum等のSAS関連の学会論文
    - <http://www.phuse.eu/>
    - [http://www.sas.com/ja\\_jp/usergroups.html](http://www.sas.com/ja_jp/usergroups.html)
    - <http://lexjansen.com/>

# CDISC関連情報の調査方法

## 2. 会合と関連情報

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- CDISC Interchange、CDISC公式トレーニング
  - 資料は参加者のみの使用に限定
- CDISC Webinar
  - 月1-2回程度実施(時間は日本の夜)
  - 非メンバー会社でも参加できる会と、メンバー会社のみ参加できる会
  - アーカイブされた資料は、メンバー会社のみアクセス可能
- その他、DIA、PhUSE、製薬協、SAS主催の会合等

# CDISC公式イベント予定

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- CDISC公式トレーニング
  - Learn CDISC from CDISC!
  - 2014年12月10-12日: SDTM、ADaM
    - SDTMは一部を日本人トレーナーによる日本語で実施
  - 2015年3月: SDTM、CDASH、CT (予定)
  - 2015年6月: SDTM、ADaM、CDASH、CT、XML (予定)
- CDISC Japan Interchange
  - 2015/6/25-26
  - UDX秋葉原Conference Center & Theater

# CDISC ホームページ

<http://www.cdisc.org/>



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**CDISC** *Strength Through Collaboration*

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### 2014 CDISC International Interchange

*"Embracing a Changing Landscape: Standards to Connect Research and Patient Care"*

Bethesda, MD  
10-14 November 2014  
Bethesda North Marriott Hotel & Conference Center

**Global Diamond Sponsor:**  
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**Conference Highlights:**  
eSHARE Experience  
Examples of Using CDISC Standards from the Start  
Real World Standards Implementation Case Studies  
High-Level Regulatory Speakers & Panel Discussion  
Best Practices in Use of the Foundational Standards  
Updates on Therapeutic Area Standards Development  
CDISC Standards Development Team Meetings  
Major Update on CDISC Standards Adoption  
New Sessions on Safety Monitoring Devices & New Approaches to Research

**Available Courses:**  
BRIDG Deep Dive  
ODM Implementation  
SDTM Theory & Application  
SEND Implementation  
Controlled Terminology Dataset XML  
CDISC Healthcare Link Define-XML  
ADAM Implementation  
CDASH Implementation  
SDTM for Medical Devices

**Distinguished Speakers:**  
Keynote: General Peter Chianelli, One Mind  
Keynote: Dr. Laura Esserman, UC San Francisco  
Keynote: Dr. Eileen Navarra, FDA-CDER  
Dr. Mayumi Shikano, PMDA  
Dr. Ron Fitzmartin, FDA-CDER  
Kenneth A. Getz, Tufts University  
Ben Yall, FDA-CDER  
Dr. Martha Bramfield, Critical Path Institute  
Dr. Rob Dicco, GlaxoSmithKline  
Dr. David Hardison, Deloitte  
Dr. Rebecca Rush, CDISC President  
Wayne Kubick, CDISC CTO

#### What's New

**CDASH Version 2.0 Needs Your Input!**

**New Draft SDTMIG Version 3.3 Batch 2 Now Available for Public Review - Comments due December 10, 2014**

**CDISC Standards to Facilitate Ebola Research!**

**New Draft SENDIG Version 3.1 (Standard for Exchange of Nonclinical Data Implementation Guide) Now Available for Public Review - Comments due 04 December 2014**

#### News

**CDISC October eNewsletter Available Here.**

**CDISC Press Release: CDISC 2014 Business Case Highlights Significant Time and Cost Savings through Use of CDISC Standards in Medical Research Studies**

**\*Sign-up for the CDISC monthly newsletter here\***

**Collaboration at Global CDISC Events**

#### New: Quick Start Guide

**Quick Start Guide Now Available for Anyone Seeking Information about CDISC!**

#### CDISC eSHARE Downloads

**eSHARE Downloads Now Available for Platinum Members!**

*If your organization is a Platinum member, please sign in with your organization's email address.*

#### Create a CDISC Online Account

Instructions on how to create a CDISC account to download standards and access the Members' Area.

#### Volunteer for CDISC

# CDISC 日本語ページ

