



# CDISC Overview

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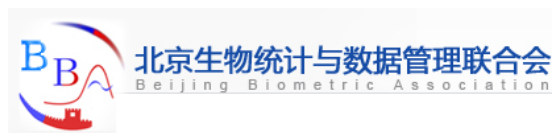
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# What CDISC Stands for?

- ▶ Clinical Data Interchange Standards Consortium
- ▶ Non-profit Organization
  - The CDISC mission is to develop and support global, platform-independent **data standards** that enable information system **interoperability** to improve medical research and related areas of healthcare.
- ▶ Global Data Standards
  - **acquisition, exchange, submission and archive**

# CDISC History

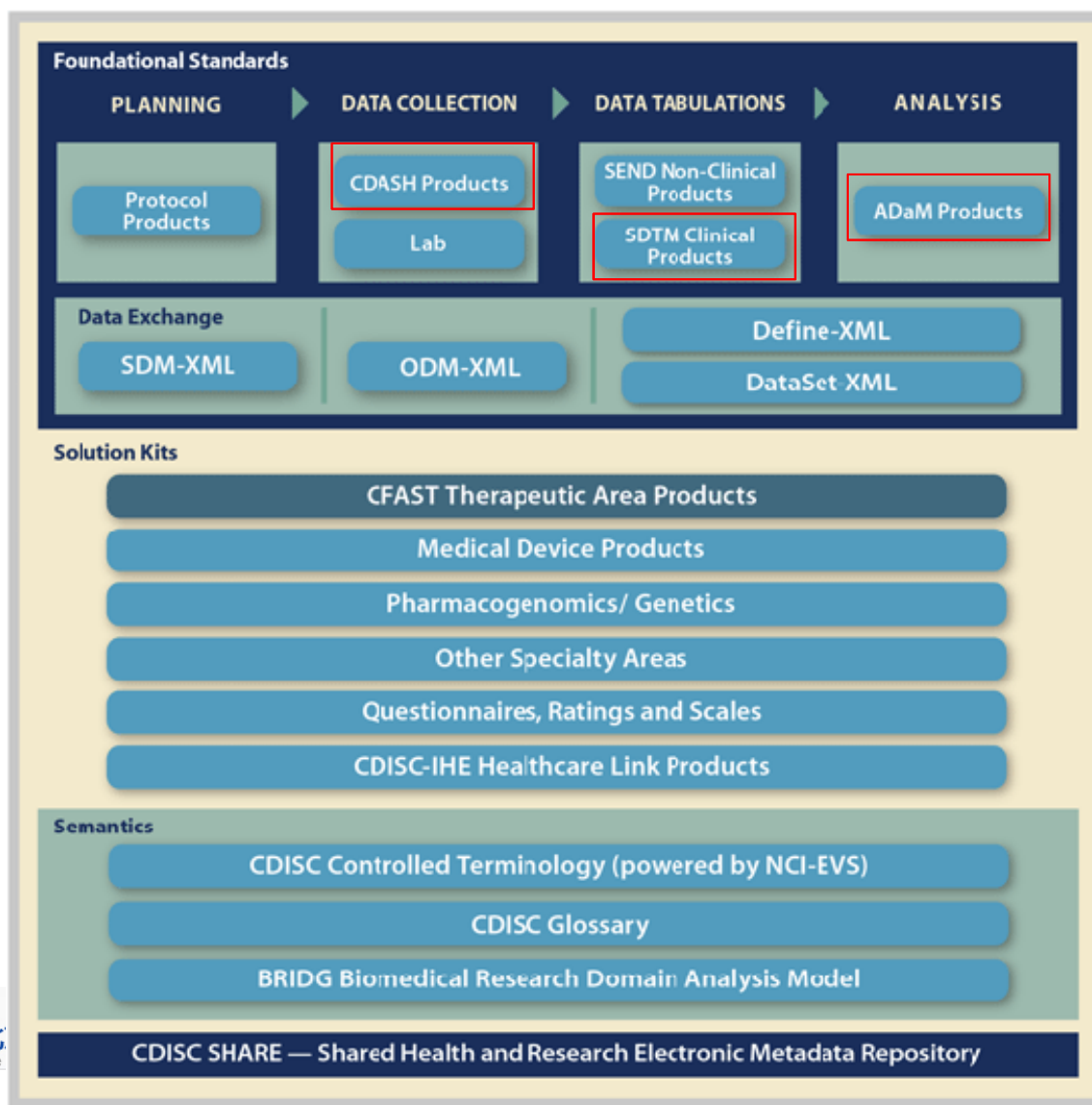
- initiated as a volunteer organization in 1997
- non-profit organization in February 2000
- >385 CDISC member organization
- Active CDISC Coordinating Committee in each region
  - E3C, J3C, C3C, K3C

[www.cdisc.org](http://www.cdisc.org)

# CDISC map



# Standards & Implementations



# CDSIC in Regulatory Submission

## ▶ FDA

- *Mandatory from Dec2016.*  
--FDA Guidance (Dec2014): *Provide Submissions in Electronic Format – Standardized Study Data*

## ▶ PMDA

- 1Oct2016 - 31Mar2020

## ▶ China

- TBD

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# CDISC History in China

- Sandy Lei (JJPRD) introduced CDISC to China in Nov 2007
- First CDISC half-day educational event was provided by Rebecca Kush (CDISC President and CEO) and Sandy Lei in Jun 2008 in Shanghai
- **China CDISC Coordinating Committee (C3C)** was initiated in Jun 2008
- The first CDISC Interchange China was held in Oct 2008 in Shanghai at Fudan University
- Shanghai and Beijing **CDISC User Groups** were organized and held their first events in the end of 2008
- CDISC public trainings in each year
  - 2016: Oct Beijing & Shanghai
- Quarterly seminar

# Organizations

- **China CDISC Coordinating Committee (C3C)**

中国**CDISC**协调委员会

*Focus on event coordination and strategic planning for CDISC operations*

- **CDISC China User Groups**

中国用户组

*Focus on the experience sharing and problem solving of CDISC standards between users*

# C3C Members

- C3C is a group of volunteers, who support CDISC global for regional activities
- The current C3C members include
  - Zibao Zhang (PPD) – Chair
  - Victor Wu (迪时咨询Data Science Express) – Vice Chair
  - John Wang (Johnson & Johnson) – Vice Chair
  - Stanley Wei (Novartis)
  - Linda Wang (Novartis)
  - Pamela Chen (MacroStat)
  - Simon Wang (Roche)
  - Yazhong Deng (Covance)
  - Wejun Bao (SAS JMP)
  - Ruiling Peng (医普科诺Improve-Quality)
  - Lily Zhao (Parexel)
  - Billy Xin (Johnson & Johnson)
  - Yanhong Li (MSD)
  - Zehuai Wen (Guangdong Hospital of TCM)

# CDISC China User Groups

- Beijing User Group: Chaired by Victor Wu (2008)
- Shanghai User Group: Chaired by Pamela Chen (2008)
- Guangzhou User Group: Chaired by Zehuai Wen (2013)



Beijing

Shanghai

Guangzhou

# China CDISC Coordinating Committee 中国CDISC协调委员会（C3C）

- ▶ Coordinating CDISC activities in China
- ▶ 协调**CDISC**在中国的活动
- ▶ **CDISC standards documents translation and review**
- ▶ **CDISC标准翻译和审阅**

# 中国CDE临床试验数据标准化专项工作 — 指导组

## China CDE Specific Work on Clinical Data Standardization — Steering Committee

### ► Responsibilities 指导组的职责

- 促进、指导和规划国内临床试验数据标准的统一工作。

### ► Members 指导组的成员

- CDE staff, CDISC standards Experts, data management professionals, statistician, clinical/medical experts
- CDE人员、CDISC标准专家、数据管理专家、统计专家、临床专家。

### ► Working Scope 工作内容

- 部署工作、讨论问题、规划进度、讨论共识度、审阅工作组提交的专题标准，及采取措施（即“发布”或“不发布”），药审中心在指导组审核发布的基础上，根据情况实行进一步监管要求：推荐使用还是强制使用。

# CDE临床试验数据标准化专项工作 —专题工作组

China CDE Specific Work on Clinical Data Standardization  
— Working Group

- ▶ CDASH/SDTM/ADaM/CT/TCM/ODM & Define.xml
- ▶ **Responsibilities**主要任务
  - Plan 制定工作计划和时间表
  - Translation and localization, come to industry consensus through discussion 汉化和本土化，开展业界讨论达成共识
  - Feasibility assessment 可行性研究
  - Training and promotion 培训和应用推广
- ▶ **Member** 工作组成员
  - Lead 组长
  - Member成员：
    - Experts, regulatory reviewers, and volunteers 由专家、审评员和志愿者组成
- ▶ **Welcome to join the working group!**
- ▶ 欢迎所有有志于临床试验数据标准化的同行参加!

Ask





# Thank You 谢谢!



**Strength** *through collaboration.*

[www.cdisc.org](http://www.cdisc.org)

[www.cdiscChina.org](http://www.cdiscChina.org)

[www.datascie.com](http://www.datascie.com)

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