Introduction to China
CDISC Coordinating Committee (C3C)

February 2014
Outline

- Regulatory history of study data in China
- CDISC application and history in China
- China CDISC coordinating committee (C3C)
- Future working plan of C3C
Regulatory of Clinical Data in China

Prior to 1999

1992 to 1999
GCP started

1999
Chinese GCP released

2003
Amended GCP

2005
Statistical principles for clinical trials
Structure and content of clinical study reports

2007
Drug registration regulation
Submit study data (data accuracy and reliability)

2010
Draft guidance on clinical data management release

2011
CDE reorganization
Established Office of Biostatistics

2012
Draft guidance on clinical data management release

2013
SFDA changed to CFDA

June: Established China Clinical Trial Data Standard Steering Committee (CTDS-SC)

July: Issued China Clinical Data Plan (CCDP)

August: Formed several working groups (CTDS-WG)

2012
Jan: organized Expert Consultation Meeting on Data Management Practice and Data Standards

May: Issued Technical Guideline for Clinical Trial Data Management

Jun- Oct: (based on presentations from Dr. Huang)

1. To standardize submission data format
2. To establish a steering committee on data management and data standards, and several working groups including submission data standards

Source: based on slides from Dr. Qin Huang, Office of Biostatistics, CDE, SFDA
China Clinical Data Plan (CCDP)

- China Clinical Data Plan published by CDE/CFDA in July 2013
  
  
  - Issue good clinical data management practice guidelines
  - Build website for clinical trials registration and disclosure
  - Develop China clinical data standards
  - Draft submission data requirements guideline
  - Conduct clinical data quality evaluation
  - Build clinical data repository
China Clinical Trial Data Standard (CTDS)

- Established China CTDS Steering Committee in June 2013
  

- Kicked off Work Groups of Data Standard in August 2013
  1) CDASH
  2) SDTM
  3) ADaM
  4) CT - Controlled Terminology
  5) TCM - Traditional Chinese Medicine
  6) ODM/Define.XML (currently as C3C team)
Overview - CDISC development in China

**Nov**: Sandy Lei (JJPRD) introduced CDISC

**2007**

**Jun**: half-day education from Rebecca Kush and Sandy Lei in Shanghai

**China CDISC Coordinating Committee (C3C) was initiated**

**Oct**: first CDISC Interchange China held at Fudan university

**Dec**: CDISC User Groups Beijing and Shanghai organized and held the first events

**2008**

**Apr**: Public Trainings in Beijing

**2009**

**Nov**: Public training in Beijing and Shanghai

**C-STAR initiate**

**2010**

**Nov**: Public training in Beijing and Shanghai

**2011**

**2012**

**2013**

**2014**

**May**: Translation for public review

**Aug**: multiple working groups setup

**Aug/Oct**: TCM WG set and workshop held

**Oct**: CDISC Public Trainings in Beijing and Shanghai

**2007-2014**

**Present CDISC data standards in multiple local conferences (SFDA Consultation meeting, SFDA workshop, DIA CDM Annual Workshop etc)**
China CDISC Coordinating Committee (C3C)

- Founded in 2008
- A group of volunteers, who support CDISC global for regional activities per the x3C Charter

Main responsibilities:
- Facilitate and coordinate **CDISC activities in China**
- Translate CDISC standards into Chinese
- Communicate with **China CDFA/CDE**
- Provide **feedback and issues** in China to CDISC
- Organize **China Interchange, public trainings and seminars**
Organizations Development

- Establish CDISC user groups
  - Beijing, Shanghai and Guangzhou

- Formed CDISC China Advisory Council (CCAC)
  - Promote and advocate the use of CDISC to the regulators and investigators

 Victor Wu, 2008
 Pamela Chen, 2008
 Zehuai Wen, 2013
C3C, UGs/Teams Contacts

- The active C3C members
  - Zibao Zhang (PPD) – Chair
  - zibao.zhang@ppdi.com
  - Victor Wu (Covance) – Vice Chair
  - John Wang (J&J) – Vice Chair
  - Simon Wang (Roche) – Past Chair
  - Stanley Wei (Novartis)
  - Pamela Chen (MacroStat)
  - Linda Wang (Novartis)
  - Yazhong Deng (Covance)
  - Billy Xin (Parexel)
  - Wenjun Bao (SAS/JMP)
  - Ruiling Peng (NNIT)
  - Lily Zhao (Parexel)
  - Yanhong Li (MerckSerono)
  - Zehuai Wen (GZUCM)

- CDISC Regional User Groups
  - Beijing: Victor Wu
    - victor.wu@covance.com
  - Shanghai: Pamela Chen
    - pamela.chen@macrostat.com
  - Guangzhou: Zehuai Wen
    - wenzh@gzucm.edu.cn

- C3C Standard Teams*
  - 6 groups with CDE (see next slide)
  - Glossary (TBD*)
  - Protocol/SDM (TBD*)
  - Lab (TBD*)
  - BRIDG (TBD*)
  - *welcome to join us via
    cdiscChina@cdisc.org
China Clinical Trial Data Standard (CTDS) Committee and Working Groups Contacts

- **China CTDS Steering Committee leadership**
  - Chair: Dr. Qin Huang (CFDA/CDE)
  - Vice Chair: Prof. Chen Yao (Peking University)
  - Vice Chair: Dr. Zibao Zhang (PPD)

- **China CTDS Working Groups**
  - CDASH: Lily Zhao  lily.zhao@parexel.com
  - SDTM: John Wang  Jwang19@its.jnj.com
  - ADaM: Victor Wu  victor.wu@covance.com
  - CT: Yanhong Li  Yanhong.Li@merckgroup.com
  - TCM: Billy Xin  Billy.Xin@parexel.com
  - ODM/define.XML  rulp@nnit.com

*volunteers are welcome!
CDISC Standards Translation

CDISC Standards Translation And Review (C-STAR)

- Project Lead: Zibao Zhang
- Co-Leaders: Stanley Wei, Victor Wu et al (2-4 leads for each standard)
- ~ 50 volunteers from > 20 organizations
- The original translations by Absolute Systems Clinical Data Co., Ltd.
- C-STAR members reviewed, revised, and reconciled the wordings across the documents
- Initiated from CDASH, SDTM, and ADaM
- Goal: to take the lead in future translation and to build C3C working groups for development and promotion of CDISC standards in China

Current Updates:
- CDASH, SDTM, ADaM final to be released in Q4 2013
- ODM / CT / Glossary Draft in Q4
Educations

- To schedule public trainings (e.g. CDASH/SDTM/ADaM)
  - [http://www.cdisc.org/public-courses](http://www.cdisc.org/public-courses)

- “Train the trainer” Program
  - Initiated in 2011-2012
  - Five (5) candidates are identified to train
    - Batch 1: CDASH/SDTM/ADaM
      - 2 certified CDISC trainers for each standard (1 BJ 1 SH)
    - Batch 2: CT/ODM/define.XML (in 2014?)

- Regular Seminars
  - Half day each quarter since 2014
# Educations

## Certified Training Courses in China

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<th>Year</th>
<th>Intro to CDISC</th>
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*Private training for a global pharma China R&D Center*

# Both public and private training
Connections and Collaborations

Connections

- CFDA/CDE
  - Public trainings
  - China CTDS SC/WG
- DIA China
  - Annual meeting
  - Workshops: QSF, DM training
- PharmaSUG/PhUSE
- DMCN/CDMC
- HL7 China (Healthcare IT groups) – under planning
- Universities/institutes – under planning

Collaborations

- Working Groups (CDE)
- Conference Sessions (DIA, PhUSE, PharmaSUG etc)
  - Trainings/webinars (DIA DM, DMCN/CDMC) – under planning
- Co-develop courses (Universities) – under planning
Future working plan

C-STAR Project and Support to CDE

TCM Data Standard – to follow TA data standard

Schedule more public trainings

Connections and Collaborations
CDISC Interchange China 2008
CDISC Interchange China 2010

Panel Discussion

- Topics for brainstorming...
  - How to promote CDISC standards in China?
  - How to adopt CDISC standards in your company (any successful cases)
- How about A3C (AS-CCC)?
- Chinese version of CDISC standards (e.g., SDTM)?
CDISC Interchange AP 2013 in Singapore