

--Current status, challenge and solution of data submission in China --中国数据递交的现状、挑战与解决之道

Victor Wu

CDISC Authorized SDTM Instructor
Vice Chair, China CDISC Coordinating
Committee
Chief Consultant
Vice President, Data Science Department,
Beijing Data Science Express Consulting Co., Ltd

吴崇胜

CDISC 认证SDTM讲师
CDISC中国协调委员会副主席
首席咨询师
数据科学中心 副总裁
北京迪时咨询有限公司

www.datascie.com
victor2050wu@hotmail.com

TOC

- ▶ Current status
- ▶ Challenges
- ▶ Solutions

Current Status

- Why standards?
- Why CDISC?
- Where we are?

World without Standardization



Data without Standardization

► Demographics

Study#3 – axd222.xpt

USUBID	SEX
00011	0
00012	1
00013	1
00014	0
00015	1

Study#1 – demog.xpt

SUBJID	SEX
0001	M
0002	F
0003	F
0004	M
0005	F

Study#3 – dmghp.xpt

PTID	GENDER
0001	1
0002	1
0003	2
0004	2
0005	1

More Data, More Headaches?

- Where is data needed?
- What dose it mean?!
- The data was coded in different way, pool them?!



What's data standards about?

- ▶ A standard way to **organize** and **format** study data

dm.xml

STUDYID	DOMAIN	USUBJID	SUBJID	AGE	AGEU	SEX	RACE
CDE01	DM	CDE01-701-1015	1015	63	YEARS	F	WHITE
CDE01	DM	CDE01-701-1023	1023	64	YEARS	M	WHITE
CDE01	DM	CDE01-701-1033	1033	74	YEARS	M	WHITE
CDE01	DM	CDE01-701-1047	1047	85	YEARS	F	WHITE
CDE01	DM	CDE01-701-1097	1097	68	YEARS	M	WHITE
CDE01	DM	CDE01-701-1111	1111	81	YEARS	F	ASIAN
CDE01	DM	CDE01-701-1115	1115	84	YEARS	M	WHITE
CDE01	DM	CDE01-701-1118	1118	52	YEARS	M	WHITE
CDE01	DM	CDE01-701-1130	1130	84	YEARS	M	BLACK OR AFRICAN AMERICAN

Standardized vs Non-standardized

- Dataset level
 - Name
 - Description
 - Structure
 - Allowed Variables
- Variable level
 - Name
 - Label
 - Type
 - Format
- Value level
 - Controlled Terminology

Predictable
vs
Unpredictable

Why CDISC?

- ▶ To build China data submission standards, or
 - ▶ To use the prepared CDISC standards?
- √ And the final agreement is to use CDISC standards, to keep consistent with global.

Where we are?

► 2013

- June: Steering Committee, China CDE Specific Work on Clinical Data Standardization 指导组
- August: 5 Working Groups, China CDE Specific Work on Clinical Data Standardization 工作组

► 2014年-2016

- CDASH, SDTM, ADaM, CT, ODM document Translation
- Quarterly Seminar on CDISC

► 2016 目标:

- 完成“中国临床试验数据递交要求”草案
 - 包括技术依从性指南

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!

TOC

- ▶ Current status
- ▶ Challenges
- ▶ Solutions

Challenges - Technically

- ▶ language issue such as CT;
- ▶ date format;
- ▶ people;
- ▶ Traditional Chinese Medicine

Challenges - Capability

– Capability of Implementation in local companies:

- lack of knowledge and
- Lack of experience



Challenges - Policy

► Policy from regulatory agency

- Clear voice?



TOC

- ▶ Current status
- ▶ Challenges
- ▶ Solutions

Solutions - Policy

- ▶ **Regulatory need to be more aggressive:**
 - ▶ Japan is a good example
- ▶ Once statistical review become routine practice, there will be immediate needs

Sooner or Later!
It is coming!

Solutions - Technically

- ▶ Working Group is working on data submission proposal and China implementation guide
 - language issue such as CT: Translated Core CT
 - date format: YYYY-MM-DD or MMDDDDYYYY
 - People: RACEOR?
 - Traditional Chinese Medicine: New/Custom Domain
- ▶ C3C will organize trainings on it

Solutions - Capability

► Company level:

- to realize the importance of data standards, which will improve quality and efficiency, not just meet regulatory needs

► Staff:

- Hire the experience person and provide training
- CDISC Public training

► Turn to external experts:

- to leverage knowledge and experience, to simplify implementation through process, templates and tools

Ask



Thank You 谢谢!



Strength *through collaboration.*

www.cdisc.org

www.cdiscChina.org

www.datascie.com

victor2050wu@hotmail.com