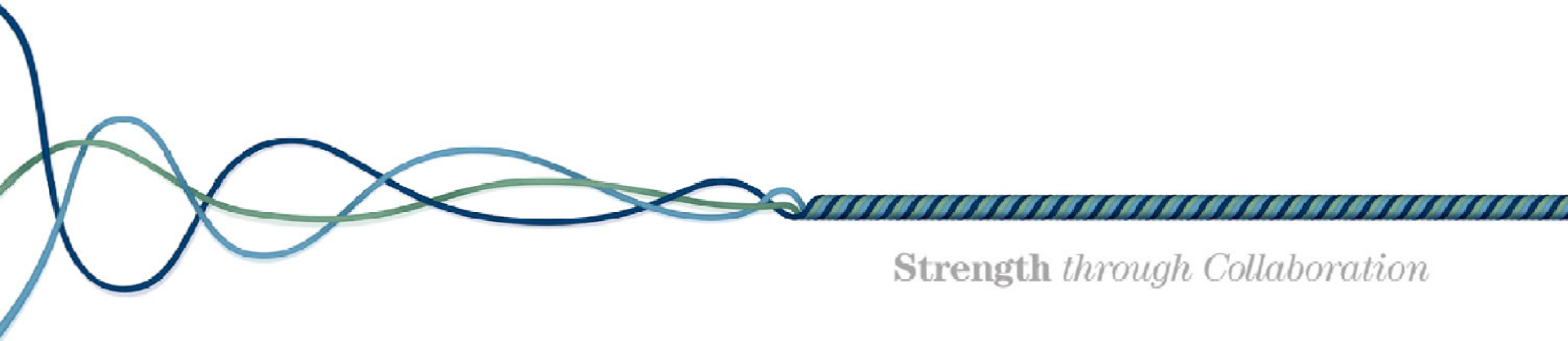


Introduction to C3C

Presented by Simon Wang (C3C, Roche)

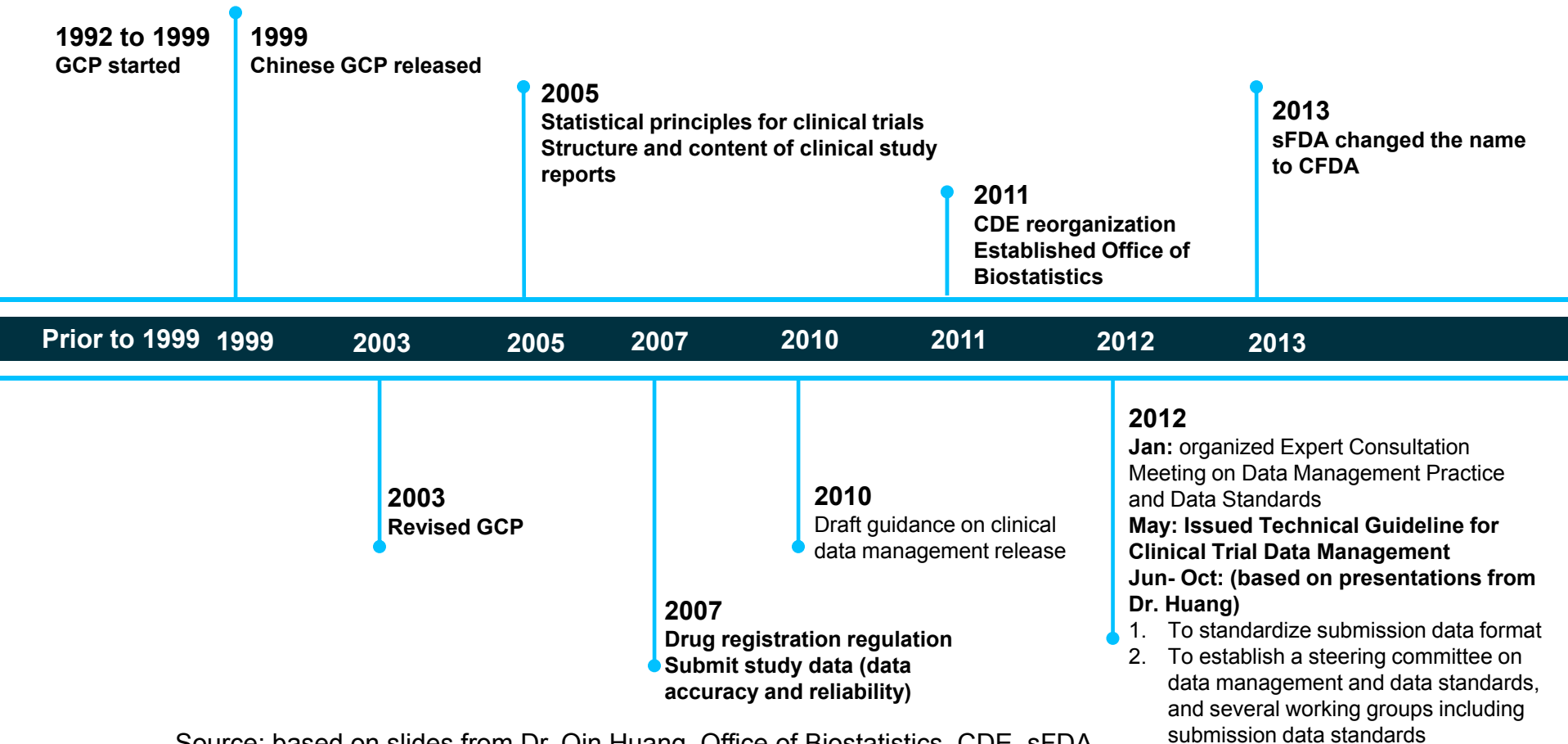
A decorative graphic element consisting of several overlapping wavy lines in shades of blue and green, extending horizontally across the lower portion of the slide.

Strength *through Collaboration*

Outline

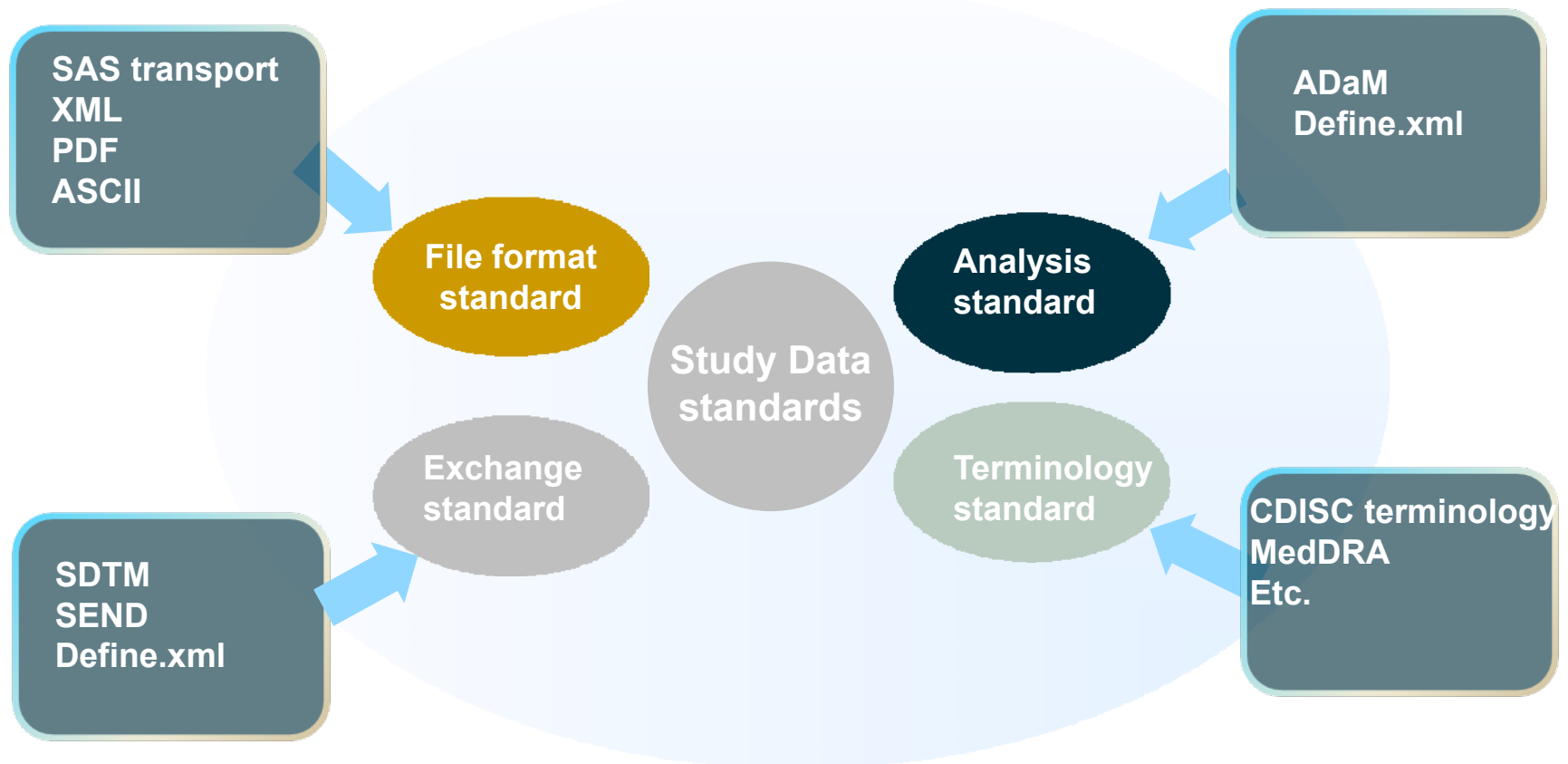
- Regulatory history of study data in China
- Study data standards for FDA
- CDISC application and history in China
- China CDISC coordinating committee (C3C)
- Future working plan of C3C

Regulatory History of Study Data in China



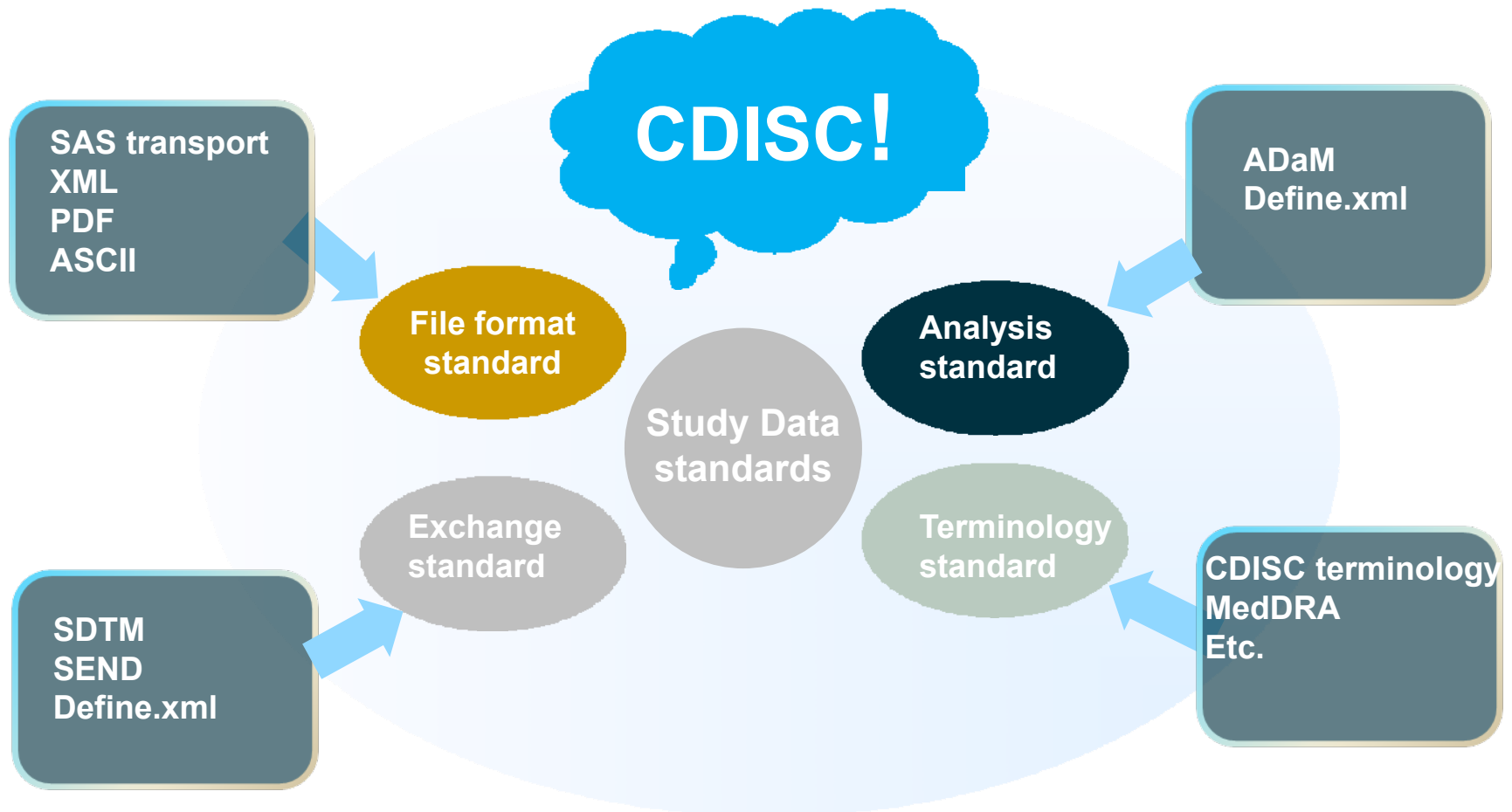
Source: based on slides from Dr. Qin Huang, Office of Biostatistics, CDE, sFDA

Standards for Study Data Submissions to FDA in Current Use



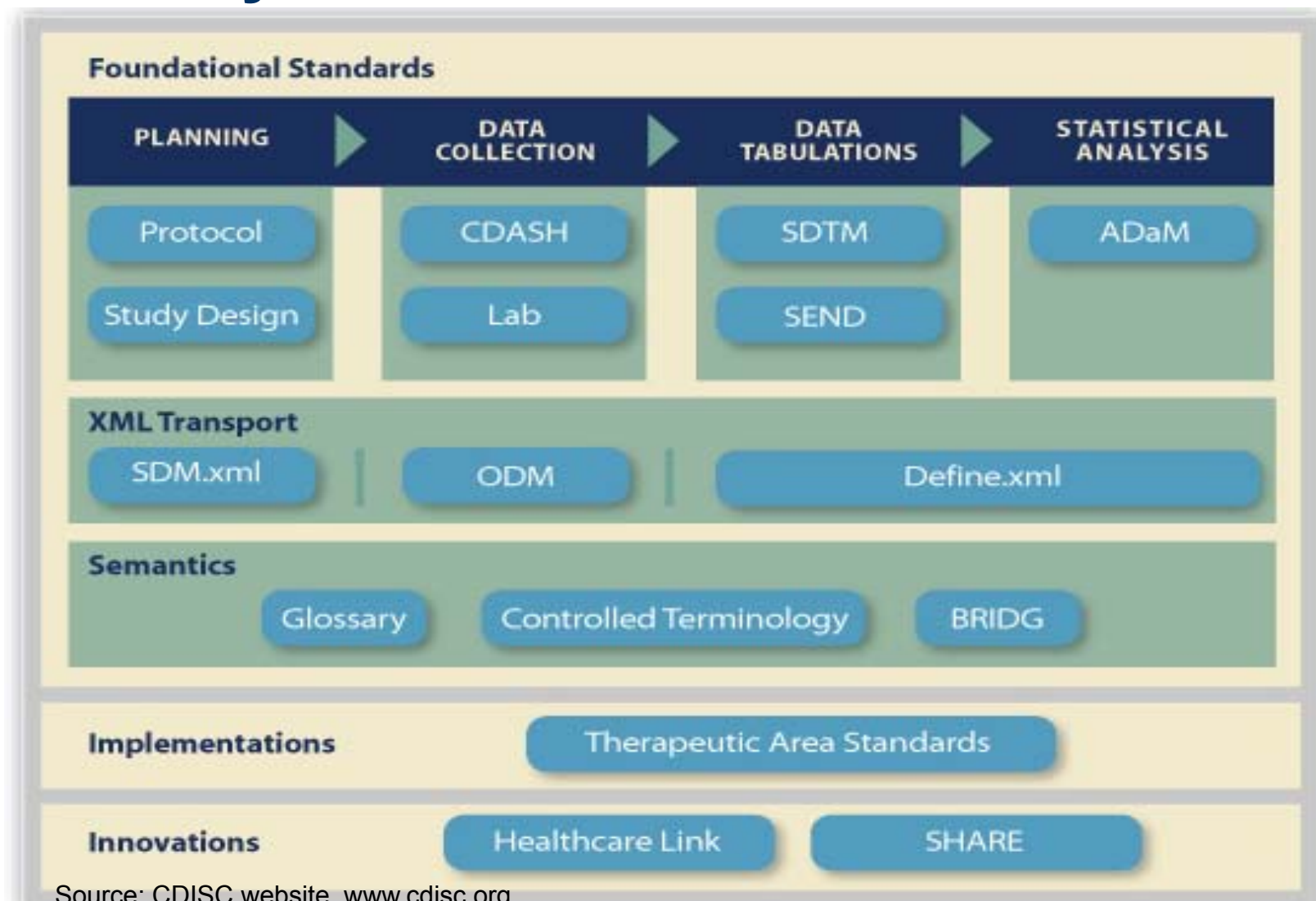
Source: FDA resources for data standards, <http://www.fda.gov/ForIndustry/DataStandards/default.htm>

Standards for Study Data Submissions to FDA in Current Use



Source: FDA resources for data standards, <http://www.fda.gov/ForIndustry/DataStandards/default.htm>

Why CDISC Standards?



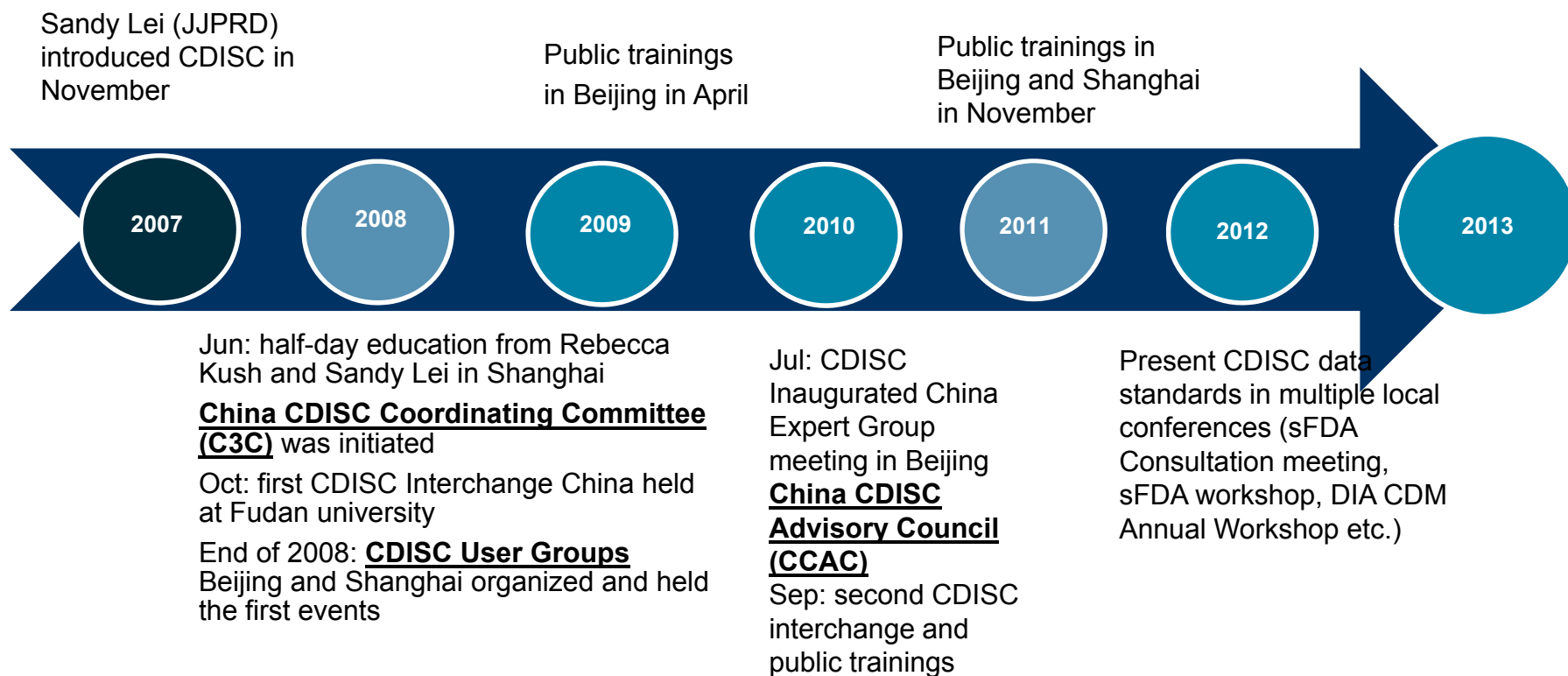
Source: CDISC website, www.cdisc.org.

CDISC Application in China

- A pilot survey conducted in this May with all participants from global CROs and pharmaceutical companies
- 100% companies currently adopt CDISC standards including CDASH, SDTM and AdaM
- The result cannot reflect the true application status of China industry but indicates the globalization and standardization of the companies
- The reasons for CDISC adoption are mainly for FDA submission, operational efficiency improvement and data share/exchange
- The survey shows the talent pool of CDISC standards is bigger and bigger

Source: based on the pilot survey conducted in May 2013

CDISC History in China



Certified Training Courses in China

	Intro to CDISC	PR	CDASH	SDTM	ADaM	Implementation Workshop
2009	✓			✓	✓	✓
2010	✓	✓	✓	✓	✓	✓
2011			✓	✓	✓	

Organizations in China

- **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 among users

- **CDISC China Advisory Council (CCAC)**

中国专家组/**CDISC**中国咨询委员会

Promote and advocate the use of CDISC to the regulators and investigators

CDISC China User Groups

- Beijing User Group: Chaired by Victor Wu
- Shanghai User Group: Chaired by Pamela Chen
- Guangzhou User Group: Was established in 2013



Beijing

Shanghai

Guangzhou

China CDISC Coordinating Committee (C3C)

- 3C is a group of volunteers, who support CDISC global for regional activities
- The current C3C members include
 - Zibao Zhang (PPD) – Chair
 - Victor Wu (Covance) – Vice Chair
 - John Wang (Johnson & Johnson)
 - Linda Wang (Novartis)
 - Michele Zhang (Wuxi AppTec)
 - Pamela Chen (MacroStat)
 - Simon Wang (Roche)
 - Stanley Wei (Novartis)
 - Wei Zhang (Otsuka)
 - Yazhong Deng (Covance)
- Call for nomination for new members!

CDISC Vision and Mission

CDISC

C3C

Vision

Informing patient care and safety through higher quality medical research.

Promote CDISC standards to enhance the development of medical research in China

Mission

Develop and support global, platform-independent data standards that enable information system interoperability to improve medical research and related areas of healthcare

- Support and facilitate CDISC implementation in China
- Contribute to the development of CDISC standards

Source: based on slides from Rebecca Kush, CDISC President and CEO

CDISC Strategic Goals

CDISC

- Increase adoption of existing standards
- Develop new therapeutic-area or specialty standards
- Enable interoperability between clinical care and clinical research
- Develop a global, accessible electronic library for CDISC content/semantics
- Leverage CDISC status and brand to provide value to stakeholders

C3C

- Increase CDISC awareness in China
 - Introduce standards to China
 - Facilitate CDISC standards into practices
 - Convince regulatory agency for adoption
-
- Training
 - Promotion
 - Knowledge Sharing
 - Translation
 - Communication with RA



Goals



Strategies

Source: based on slides from Rebecca Kush, CDISC President and CEO

C3C Plan for 2013

- **C-STAR project** and working groups to support **data submission standards** initiative for **cFDA**
- Development of **Traditional Chinese Medicine (TCM)** data standards
- **CDISC China Certified Trainer program**
- **CDISC China Users network**
- **Connection and collaborations** with other organizations to promote data standards
- **Operation excellence** and **communication** with CDISC global operation and other 3C organizations

CDISC Standards Translation And Review (C-STAR) Initiative

- Goal: Promote and develop CDISC standards in China
 - Take the lead in CDISC translation
 - Build C3C working groups
- C-STAR Project
 - Lead: Zibao Zhang
 - Co-Leaders: Stanley Wei, Victor Wu etc. (2-4 leads for each standard)
 - ~ 50 volunteers from > 20 organizations involved
- Well-defined process for the CDISC standards translation
 - The original translations by **Absolute Systems Clinical Data Co., Ltd.**
 - The editing, proofreading, review and then cross review by C-STAR members
- Current Updates:
 - CDASH, ADaM, ADaM IG, SDTM IG and SDTM are completed
 - Are released for 2-month public review till July 16th of 2013
<http://www.cdisc.org/may-2013-newsletter#foundational>

CDISC Interchange China 2008



CDISC Interchange China 2010



CDISC Interchange AP 2013 in Singapore





Thanks for your attentions!

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