A collaborative event to share progress, implementation experiences, and strategic ideas on worldwide data interchange standards for medical research.

**PROGRAMME**

**CHINA INTERCHANGE**

13th - 14th September 2010

13th - 14th, Pre-Conference Training

15th, Conference

16th - 17th, Post-Conference Training

The Mingdao Building

Fenglin Campus, Fudan University

Shanghai
Within the current economic situation, there is more reason than ever to understand what CDISC can bring to your organization. If you are working in the field of clinical research or healthcare and if you are working for an academic institution, a biopharmaceutical company, a technology provider, a clinical research organization (CRO), a hospital, an Ethics Committee, you should be interested in streamlining clinical research processes and how these link to healthcare. Standards for data interchange are key to the information flow that we all need in this century to make the best use of the research information and how it can improve healthcare.

CDISC has established global data interchange standards to facilitate information exchange from research protocol through analysis and reporting. CDISC has also jointly developed integration profiles to use electronic health records for clinical research. Implementing CDISC standards can reduce costs of clinical studies by 60% of the non-value added time overall. Attend the CDISC Interchange in Shanghai China on 17 September to learn how you and your organization can benefit from the products of CDISC. (www.cdisc.org)

CDISC is an open, multi-disciplinary standards developing organization (SDO) that has established worldwide standards for clinical research. The mission of CDISC is to develop and support global, platform-independent data standards that enable information system interoperability to improve medical research and related areas of healthcare.

This conference is for:
- Investigative Site Personnel,
- Clinical Project Managers (CPM),
- CRAs/Monitors,
- CRO Personnel and Contractors,
- CDM/Data Managers,
- Statisticians
Dear friends and colleagues,

On behalf of CDISC operations and China CDISC Coordinating Committee (C3C), I would like to invite you to attend the CDISC Interchange China 2010, which will be held on Wednesday, September 15th, 2010, at Fudan University in Fenglin Campus (Mingdao Building).

The aim of this meeting is to provide a discussion forum where the CDISC leaders and experts from countries around the world can share their experience on the CDISC development up-to-date and the practical applications in the process of drug development. Our exhibitors will also demonstrate you how CDISC standards can be adopted in your daily work during the conference in the exhibition area.

To better facilitate the understanding of CDISC standards, six public training courses will be provided by CDISC experts before and after the CDISC Interchange China, on September 13th – 14th and 16th – 17th, including Introduction to CDISC, Protocol Presentation, CDASH Implementation, SDTM Implementation, ADaM Implementation, and Practical Implementation Workshop.

We sincerely wish to thank many volunteers in the C3C for their hard working to make this conference an informative and exciting venue for all the participants. We also wish to thank those who contributed to the program which allows us to present a well-rounded and truly relevant event.

We look forward to seeing you in Shanghai for the CDISC China Interchange 2010.

With kind regards

Simon Wang, MBA, MS
Chairman of the China CDISC Coordinating Committee
CDISC CHINA INTERCHANGE 2010

PROGRAMS-AT-A-GLANCE

MONDAY, SEPTEMBER 13th
09:00 - 12:30  Introduction to CDISC - 1/2 Day Course
13:30 - 17:00  Introduction to Protocol - 1/2 Day Course

TUESDAY, SEPTEMBER 14th
09:00 - 17:00  CDASH Implementation - 1 Day Course

WEDNESDAY, SEPTEMBER 15th
09:00 - 18:00  CDISC China Interchange Conference - 1 Day Conference
Session 1, Welcome, CDISC Overview, J3C, K3C and C3C Updates
Session 2, CDISC/Industry Initiatives Updates
Session 3, CDISC End to End
Session 4, Vendor Application & Tools

THURSDAY, SEPTEMBER 16th
Track 1:
09:00 - 17:00  SDTM Theory & Application - 2 Day Course (Day 1)

Track 2:
09:00 - 17:00  ADaM Implementation - 1 Day Course

FRIDAY, SEPTEMBER 17th
Track 1:
09:00 - 17:00  SDTM Theory & Application - 2 Day Course (Day 2)

Track 2:
09:00 - 17:00  Workshop Practical Implementation Experiences - 1 Day Course
CDISC CHINA INTERCHANGE SESSION DETAILS

WEDNESDAY, SEPTEMBER 15th

08:00 - 10:00  Registration
09:00 - 16:00  Exhibit Booths

09:00 - 10:30  Session 1  Welcome, CDISC Overview, x3C Update
Chair: Simon Wang (C3C)
Speaker(s):
1. CDISC Worldwide – Highlights 2010 (including Healthcare Link, JIC, BRIDG)
   Frank Newby and Rebecca Kush (CDISC)

2. HL7-CDISC Relationship
   Charles Jaffe (CEO, HL7)

3. J3C Updates
   Yoshio Tsukada (J3C, GSK Japan)

4. K3C Updates
   Sukil Kim (K3C, Catholic University of Korea)

5. C3C Updates
   Simon Wang (C3C, Parexel China)

10:30 - 11:00  Coffee Break

11:00 - 12:30  Session 2  CDISC/Industry Initiatives Updates
Chair: Pamela Chen (C3C)
Speaker(s):
1. CDISC Standards for Study Start-up (Business Case, Protocol and Trial Registration, CDASH Standards for CRFs, eSource Data Interchange)
   Frank Newby and Rebecca Kush (CDISC)

2. The Future of Clinical Data: The Evolving Impact of CDISC and HL7 Standards on Data Management, Submission, and Pharmacovigilance
   Wayne R. Kubick (Phase Forward Lincoln Safety Group)
CDISC CHINA INTERCHANGE SESSION DETAILS

**WEDNESDAY, SEPTEMBER 15th**

08:00 - 10:00  
Registration

09:00 - 16:00  
Exhibit Booths

11:00 - 12:30  
**Session 2**  
CDISC/Industry Initiatives Updates  
Chair: Pamela Chen (C3C)  
Speaker(s): 3. CDISC/fDA Pilot for Integrated Safety Data (Pediatrics Studies)  
Yuguang Zhao (Eisai Global Clinical Development)

12:30 - 13:30  
Lunch

13:30 - 15:00  
**Session 3**  
CDISC End to End  
Chair: John Wang (C3C)  
Speaker(s): 1. Building an eCRF CDASH Library – A Case Study  
Paula Silva (Phase Forward Services)  
2. CAMD ADAS-cog Questionnaire SDTM and ADaM Implementation  
Sandy Lei (J&J)  
3. Update on Terminology and SHARE Project  
Chris Tolk (teach the SDTM course and she can also give a presentation)

15:00 - 15:30  
Coffee Break

15:30 - 17:00  
**Session 4**  
Vendor Application & Tools  
Chair: Stanley Wei (C3C)  
Speaker(s): 1. Integration of Electronic Data Capture (EDC) and Interactive Voice Response (IVR) randomization systems using ODM, vendor extensions and web services  
Andrew Newbigging (Medidata Solutions Worldwide)  
2. Achieve the Secondary Use of Healthcare Data by Creating a Standard-based Clinical Research Database  
Der-Ming Liou (Institute of Biomedical informatics, National Yang-Ming University, Taiwan)
CDISC CHINA INTERCHANGE SESSION DETAILS

WEDNESDAY, SEPTEMBER 15th

08:00 - 10:00  Registration
09:00 - 16:00  Exhibit Booths
15:30 - 17:00  Session 4  Vendor Application & Tools  
               Chair: Stanley Wei (C3C)  
               Speaker(s): John (Jiangtang) Hu and Na Ye  
                            (Sanofi Pasteur Biostatistics China)
17:15 - 18:00  Panel Discussion  
               Chair: Simon Wang (C3C)  
               Panelist invited
18:00 - 20:00  Dinner (Invited Only)  
               Organizer: C3C & CDISC