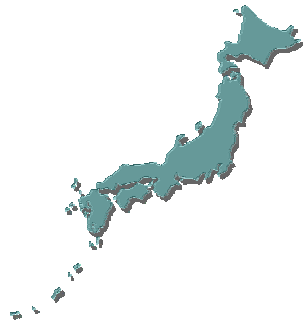
Setting the
Global Standard
for Clinical Data

CLINICAL DATA INTERCHANGE STANDARDS CONSORTIUM

CDISC global activities

Global CDISC Activities



- **2002 Japan CDISC Coordinating Committee (J3C)**
  - **Various meetings and conferences**
- **2003 India CDISC Coordinating Committee (I3C)**
  - Initiated mid-2003 with I3C meeting
  - December 2003 presentations for academic conference
    - International Symposium on CLINICAL DATA MANAGEMENT
    - Institute of Bioinformatics & Biotechnology, University of Pune, Pune, India
- **2002 Europe CDISC Coordinating Committee (E3C)**

CDISC European activities

European CDISC Teams

- Training / Education /“evangelizing“
- Case Studies / Implementation
- PR/ Communications
- Networking
- Logistics & Operations

e3C Steering Committee

- steering committee will provide guidance and direction for the sub-teams, set goals and monitor progress.

The team comprise:

- Pierre-Yves Lastic (Sanofi-Aventis),Dave Iberson-Hurst (Assero), Herbert Noack (Covidence), Barry Burnstead (Phaseforward); Udo Siegmann (Parexel)

Activities in 2005

- Conferences
  - Lisboa, Annual DIA meeting
  - Budapest, World Trade Association
  - Prague, CDM: workshop
  - Presentation at German society for medical documenters (DVMD) (= Clin. Data Manager)
  - PhUSE
  - TMF workshop
  - Workshop at VfA (German Society of Pharma)

Activities in 2005

- Alliances
  - DMB, ACDM, Nordic DMG, ICDMA
  - HL7 German User Group
- Training & Education
  - Copenhagen (NNIT) SDTM
  - Paris: SDTM/ ODM / Lab
  - 2 Company internal trainings

CDISC Interchange

- 2003 Dublin
- 2004 Brussels
- 2005 Paris
  - Incl. HL7 –CDISC day
- 24-27 April 2006 Berlin - Mariott
  - Watch for call for papers
  - Planned program incl.
    - Connectathon = CDISC proof of concept between systems / vendors
    - HL7 meeting (RCRIM)

Networks

- ECRIN = Europ. Clin Res. Integr. Network
  - Ca. 100 research institutes (DK, F, D, NL, B, Es, It, CND, UK)
  - No common processes, SOPs, systems, technologies
  - Goal: harmonization
  - CDISC = > database structures, data exchange etc (ODM, e-protocol)

Networks

- TMF = Telematik Forschungsnetze
  - German government sponsored
  - Evaluation, recommendation, implementation of systems, tools and technology for ca. 20 academic research centers (KKS)
  - CDISC compatibility project
    - 6 EDC application
    - ODM import / export functionality
  - New project started: ODM/SDTM conversion

Trial Registry

- Current status:
  - Various different trial registries / tracking ClinicalTrials.gov, Cochrane library, EudraCT, PDQ, WHO
- **World Health Organization (WHO)**
  - International Clinical Trials Registry Platform (ICTRP)
  - Goal: To set international norms and standards for trial registration and reporting
  - Within which trial registers and databases worldwide can operate in a coordinated fashion, while upholding scientific and ethical principles
  - Problems to solve are access / privacy during clinical development
  - CDISC => e-protocol, results (SDDM), Metadata (ODM)

EMEA

- EMEA – interested in harmonization of EudraCT requirements with Protocol Representation/Trial Tracking (and now WHO requirements)

Welcome New European Sponsors 2004/5

- ORION
- Novo Nordisk
- Assero
- ClinSource
- Accovion
- Bioskin
- Imform
- Schwarz
- Icon
- LAB Klin Forschung
- CliniTrac
- CRO24
- Dr. Koehler
- Oestreich & Partner
- Entimo
- TMF

Contact:

udo.siegmann@parexel.com
Fon: +49-171 55 35 921

WWW.CDISC.ORG