



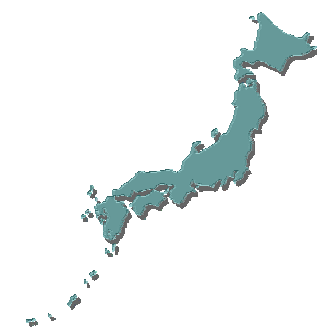
Setting the  
Global Standard  
for Clinical Data

**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 Ibersen-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 - Marriott
  - 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](mailto:udo.siegmann@parexel.com)

Fon: +49-171 55 35 921

[WWW.CDISC.ORG](http://WWW.CDISC.ORG)