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

  - 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
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- CliniTrac
- CRO24
- Dr. Koehler
- Oestreich & Partner
- Entimo
- TMF
Contact:
udo.siegmann@parexel.com
Fon: +49-171 55 35 921

WWW.CDISC.ORG