



2008 CDISC European Interchange conference programme

Opening Session

Length: 1 hour 1 minute

Chair: Tim M. Jaeger, Chairman of the European CDISC Coordinating Committee.

- Welcome to Copenhagen and the World of CDISC - Tim M. Jaeger, Chairman of the European CDISC Coordinating Committee and Ed Helton, Chair of CDISC Board of Directors.
- CDISC Worldwide - Rebecca Kush, CDISC President.
- CDISC Technical Update - Dave Ibersen-Hurst, CDISC VP Technical Strategy.

Key Note Presentation

Sir John Bell, University of Oxford and Office for Strategic Coordination of Health Research

Length: 33 minutes

- Introduction - Tim M. Jaeger, Chairman of the European CDISC Coordinating Committee.
- The Resurgence of Clinical Research in Public Health: Clinical Data Management and the Future of Health Care - Sir John Bell, University of Oxford and Office for Strategic Coordination of Health Research.

Session 2: Track 1: Scope of Implementation - Today and Tomorrow

Length: 1 hour 27 minutes

Chair: Dave Ibersen-Hurst, CDISC VP Technical Strategy

- Data-Elements, Analysis Model and Metadata Registry - Mark Regennass, Wega.
- Metadata Repository Use in an End to End, CDISC Standards - Based Clinical Data Lifecycle - Barry Cohen, Octagon Research.
- Pharmacogenomics Data: Transmission and Submission - Joyce Hernandez, Merck and Phil Pochon, Covance.

Session 2: Track 2: CDISC Scope Extended

Length: 1 hour 34 minutes

Chair: Ann-Sofie Bergstrom, European CDISC Coordinating Committee.

- CDISC/SEND Renewed Efforts in 2007: Updates on Standards for Exchange of Nonclinical Datasets for FDA Submissions with Emphasis on Operational Uses - Gitte Frausing, Novo Nordisk.
- NonLinear Mixed Effects Consortium: The Role of CDISC Standards in the Future of Clinical Modelling and Simulation - Steen Hvass Ingwersen, Novo Nordisk.
- Monitoring Risks in Clinical Trials for Medical Devices: The Point of View of National Competent Authorities - Daniela Luzi, National Research Council, Italy.

Session 3: Track 1: CDISC It! From Protocol to CRF

Length: 1 hour 33 minutes

Chair: Graham Bunn, European CDISC Coordinating Committee.

- Introduction to the CDASH Initiative - Ronda Facile, Project Director CDISC, Dorothy Dorotheo, Intermune Inc.
- Protocol Model v1.0 - Project Update - Lisa Chatterjee, CDISC Protocol Team Leader, Digital Infuzion.
- '2h protocol' - Trial Planning and Protocol Generator System for Explanatory Development - Ivan Miluska, Novartis.

Session 3: Track 2: Tools, Tools, Tools!

Length: 1 hour 27 minutes

Chair: Barry Burnstead, European CDISC Coordinating Committee.

- Challenges of Modelling Interdependent Study Schedule Instructions - Ed Seguire, Medidata.
- ODM can Foster EDC -Xavier Gobert, Flexcipio.
- Enabling the End to End eClinical Process Using ODM-Based Tools - Andrew Newbigging, Medidata.
- Bridging the Gap Between ODM and SDTM: Tools for Creating SDTM Datasets from ODM Data - Jozef Aerts, XML4Pharma.
- Technology Suppliers Perspective: The Journey to CDISC ODM Certification - Simon Hawken, eRT.
- Integrated Clinical Architecture - David Smith, SAS Institute.

Session 4: CDISC at the FDA: SDTM and Adam Pilot

Length: 1 hour 41 minutes

Chair: Herbert Noack, European CDISC Coordinating Committee.

- The CDISC SDTM/ADaM Pilot Project: Results and Learnings - Cathy Barrows, GlaxoSmithKline.
- Re-Modelling the CDISC SDTM/ADaM Pilot Analysis Datasets in the New ADaM Style - Susan Kenny, Inspire.
- Loading CDISC Data into the JANUS Data Warehouse: An Experience Report from a Recent Submission - Carol Vaughn and Pierre-Yves Lastic, Sanofi-Aventis.
- Question and Answer Session.



Session 5: Track 1: CDISC It! Legacy Conversion and SDTM and ADaM Implementation

Length: 1 hour 25 minutes

Chair: Niels Both, European CDISC Coordinating Committee.

- Case Study: Analysis and Metrics of End-to-End Legacy Data Conversion into SDTM, ADaM, and Define.XML - Robert Stemplinger, ICON.
- Implementing SDTM in a Small Sponsor Environment - Alex Helman, Sepracor.
- Clinical Trial Data Conversion into CDISC SDTM and ADaM Standards: First Experience from a FDA Submission Project - Berthold Traub, Nycomed.

Session 5: Track 2: eHealth and Clinical Research and Safety Monitoring

Length: 1 hour 33 minutes

Chair: Pierre-Yves Lastic, European CDISC Coordinating Committee.

- Experiences from the Trenches of eClinical to Healthcare Integration - Landen Bain, CDISC Liaison to Healthcare.
- Electronic Healthcare Record Systems and Clinical Research at G. Pompidou Hospital - Chistel Daniel, INSERM
- Secondary Use of Electronic Health Record Systems in the Area of Clinical Research - Miguel Valenzuela, Roche.

Session 6: Track 1: CDISC It! SDTM, ADaM, and Define.XML Implementation for Reporting and Submission

Length: 1 hour 29 minutes

Chair: Herbert Noack, European CDISC Coordinating Committee.

- Creation of CDISC Compliant Regulatory Submissions - Spencer Groves, Ipsen.
- Systematic Approach to Develop SDTM and ADaM Company Standards - Elke Sennewald, Kendle.
- Use of ADaM Specifications in the Submission of Analysis Datasets to the FDA - Zoe Williams, LEO Pharma.

Session 6: Track 2: Tools, Tools, Tools!

Length: 1 hour 18 minutes

Chair: Udo Siegmann, European CDISC Coordinating Committee.

- CDISC-Gateway Panacea for CDISC Standards - Sunil Agarwal, Cognizant.
- Data Migration/Submission Utility Tools - Ivan Li, Ipsen
- Signal Detection Throughout the Product Lifecycle - Robert Weber, Lincoln Technologies.
- Applied Benefits of Implementing CDISC Standards with SAS - David Smith, SAS Institute.
- Using ODM to Optimise Study Set Up and EDC System Build within a Multi-Vendor Environment - Mark Wheeldon, Formedix.
- SAP to Submission Output Using CDISC Metadata - Joel Hoffman, Waban Software.

Session 7: Track 1: CDISC It! SDTM, ADaM, and Define.XML Implementation for Reporting and Submission

Length: 1 hour 8 minutes

Chair: Barry Burnstead, European CDISC Coordinating Committee.

- Adoption of the SDTM from Data Capture to Statistical Analysis: A Case Study in Cardiology - Rolf Meinert, Datamap.
- Using CDISC Data Models to Generate Standard Safety Analysis and Reporting - David Handelsman, SAS Institute.
- Define.XML: Implementation Experiences and User Expectations - Monika Kawohl, Accovion.

Session 7: Track 2: CDISC It! From Protocol to CRF

Length: 1 hour 30 minutes

Chair: Wolfgang Summa, European CDISC Coordinating Committee.

- ePRO Integration and CDISC Certification of an ePRO Technology Provider - Valdo Arnera.
- A Plug-in for an Outlining Editor to CRF Planning in ODM - Johannes Huesing, KKS University Heidelberg.
- Experience with SDTM Value Level Metadata and Steps Towards CDASH in an Investigator-Oriented EDC Environment - Philippe Verplancke, XClinical.

Session 8: Closing Session

Length: 48 minutes

Chair: Tim M. Jaeger, Chairman of the European CDISC Coordinating Committee.

- European CDISC User Networks - Ann-Sofie Bergstrom, European CDISC Coordinating Committee.
- EU/EMA Collaboration with CDISC - Pierre-Yves Lastic, European CDISC Coordinating Committee.
- Closing Address - Tim M. Jaeger, Chairman of the European CDISC Coordinating Committee.