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

PROGRAMME INTERCHANGE EUROPE

11th - 15th April 2011

Crowne Plaza - Le Palace

Brussels

Belgium
Dear friends and colleagues,

I have the great pleasure to welcome you to the CDISC Interchange Europe 2011, with our main conference being held on April 13 - 14 in Brussels, Belgium.

After one year as the Chair of the European CDISC Coordinating (E3C), I’ll have the honour to celebrate the 10th anniversary of the launch of the European CDISC Organisation in the European Capital, close to the European Parliament and the Commission.

The growing success of the European CDISC Interchange is a clear sign of the increasing use of CDISC standards in Europe. And there is not only a growing number of participants, but also more and more participants from new health care stakeholders.

This year we will have the pleasure to welcome Ilias Iakovidis, from the European Commission, as our keynote speaker, who will give us insight into the European framework for Information and Telecommunication in Healthcare, an area in which CDISC plays an important role.

From Rebecca Kush, CDISC President and CEO, you’ll hear what is going on in the CDISC world and you’ll have opportunities to learn about CDISC’s growing activities throughout the world from the many other distinguished speakers from Europe, Asia and America.

This year again our programme will give you access to state-of-the-art presentations about the different CDISC standards and discussions on strategies for standards adoption or real-life CDISC case studies. As usual, we offer you a range of pre & post – Conference training sessions and opportunities to follow-up discussions with individual providers at the industry exhibition.

We also want to give you opportunities to give CDISC feedback about your needs and expectations and so we’ll offer you interactive round table discussions on various topics. The results will be used to make CDISC offerings better. Of course, the full minutes of these round table discussions will be available to the participants and the CDISC members on the CDISC website.

As the conference is being held in the heart of the European Capital, you will have plenty of opportunities to enjoy the beautiful monuments of Brussels’ city centre and taste Belgian cuisine in its many restaurants. And because Brussels is also the centre of what people call “the 8th Art”, we’ll offer you a very special social event at the Brussels Comic Strip Center.

Thank you to all of you that have devoted time and energy to ensuring that we have another fantastic conference and welcome to Brussels.

With kind regards

Pierre-Yves Lastic, PhD
Chairman of the European CDISC Coordinating Committee
MONDAY 11th APRIL
08:30 - 16:30 Training: ODM: An Implementation Course
08:30 - 16:30 Training: SDTM V3.1.2: An Implementation Course

TUESDAY 12th APRIL
08:30 - 16:30 Training: SDTM V3.1.2 (Cont): An Implementation Course
08:30 - 12:00 Training: **New** CDISC: A Global Approach to Accelerating Medical Research Course
08:30 - 12:00 Training: An Introduction to BRIDG
13:00 - 16:30 Training: **New** Controlled Terminology: An Implementation Course
13:00 - 16:30 Training: **New** An Introduction to Protocol Representation
17:00 - 19:00 European User Network Meetings
19:00 - 20:00 User Network Reception

WEDNESDAY 13th APRIL
08:00 - 16:00 Registration
09:00 - 10:30 Session 1: Welcome & Keynote
10:30 - 11:00 Coffee
11:00 - 12:30 Session 2: The Pharma Perspective
Break-out Session A: SDTM Discussion Group
12:30 - 14:00 Poster Session & Exhibits
12:30 - 14:00 Lunch
14:00 - 15:30 Session 3, Track 1: SDTM Compliance
Session 3, Track 2: ODM Innovations
Break-out Session B: Terminology Discussion Group
15:30 - 16:00 Coffee
16:00 - 17:30 Session 4, Track 1: Practical FDA Submission Experience
Session 4, Track 2: eHRs and the World Beyond
Break-out Session C: CDASH and ADaM Discussion Groups
19:00 - 22:30 CDISC Reception and Social Event

THURSDAY 14th APRIL
09:00 - 10:30 Session 5, Track 1: The ADaM Family
Session 5, Track 2: CDISC SHARE and Managed Metadata Repositories
Break-out Session D: SDTM Discussion Group
10:30 - 11:00 Coffee
11:00 - 12:30 Session 6, Track 1: The CRO Perspective
Session 6, Track 2: Emerging Devices Standards
Break-out Session E: ODM & ADaM Discussion Groups
12:30 - 14:00 Poster Session & Exhibits
12:30 - 14:00 Lunch
14:00 - 15:30 Session 7: Standards Enhancing Public Health
15:30 - 16:00 Coffee
16:00 - 17:30 Session 8: Closing Plenary

FRIDAY 15th APRIL
08:30 - 12:00 Workshop: Legacy Data Conversion
08:30 - 16:30 Training: ADaM: An Implementation Course
08:30 - 16:30 Training: CDASH: An Implementation Course
CDISC EUROPEAN INTERCHANGE SESSION DETAILS

MONDAY 11th APRIL 2011

07:30 - 16:00  Registration

08:30 - 16:30  Training: ODM: An Implementation Course
   Instructor: Phillippe Verplancke, XClinical

The ODM (Operational Data Model) is a vendor independent format used to store, interchange between data management systems or archive study data, study metadata or administrative data associated with clinical trials. The ODM has been presented to FDA as the standard for data archiving. This class consists of the technical framework for ODM, an in-depth understanding of the model structure, an overview of XSL and other tools for working with XML, strategies for implementing ODM within your organization.

08:30 - 16:30  Training: SDTM V3.1.2 Training: An Implementation Course
   Instructor: Shannon Labout, CDISC Director Education & Peter Van Reusel, Business & Decision Life Sciences

The SDTM (Study Data Tabulation Model) is a specification in the FDA eCTD Guidance as the model for submitting clinical and preclinical data to the FDA in support of marketing applications.
This class consists of:
- A detailed review of SDTM concepts, SDTM domain models, and relationship tables
- A discussion of common implementation issues, and exercises including CRF-annotations
- Creation of SDTM datasets that reinforce attendees’ understanding of the SDTM and the SDTM Implementation Guide.

12:00 - 13:00  Lunch

TUESDAY 12th APRIL 2011

07:30 - 16:30  Registration

08:30 - 16:30  Training (Continued): SDTM Application & Theory

08:30 - 12:30  Training: **New** CDISC: A Global Approach to Accelerating Medical Research
   Instructor: Rebecca Kush, CDISC President & CEO & Frank Newby, CDISC COO

Are you involved with medical research? Are you frustrated by a lack integrated solutions that will improve your processes? Does the thought of promoting change within your organization fill you with dread? Are you having issues around data quality? Then CDISC could provide your answers.

The existing typical process for biomedical research is antiquated and crying out for real technological transformation. Glaring inefficiencies remain to which solutions will require the adoption and implementation of key enablers; these enablers include workflow integration, eSource and efficient exchange of information from site to study sponsor to reviewer (whether this be a regulatory authority, an IRB or DSMB, an academic institution, a clinician investigator or scientist, or another reviewer of research information). In addition, addressing unnecessary data quality issues hinders workflow speed.
and uses excessive and expensive resources.

The Clinical Data Interchange Standards Consortium (CDISC) has collaborated with numerous other organizations on a global basis to analyze research regulations and processes; through these collaborations and the work of thousands of volunteers worldwide over the past 14 years, a set of enablers that can recognizably accelerate the medical research process, from protocol through analysis and reporting has emerged.

This course outlines these enablers so that you can understand their benefits, can demonstrate how you can improve your data quality and can streamline workflow at investigative research sites and sponsoring organizations. This course also delivers relevant business information that demonstrates the real world value of CDISC. Anyone who is involved in medical research in any capacity, at any level, should take this course.

08:30 - 12:00
Training: An Introduction to BRIDG
Instructor: Julie Evans, CDISC Senior Director Technical Services

The BRIDG Model is a Domain Analysis Model (DAM) that is being developed through a collaborative effort of stakeholders from the Clinical Data Interchange Standards Consortium (CDISC), the HL7 Regulated Clinical Research Information Management Technical Committee (RCRIM TC), the National Cancer Institute (NCI), and the US Food and Drug Administration (FDA). This session will cover a brief history of BRIDG, a quick look at basic UML modelling and an introductory look at the BRIDG model.

12:00 - 13:00
Lunch

13:00 - 16:30
Training: **New** Controlled Terminology: An Implementation Course
Instructor: Chris Tolk, CDISC Director Terminology

The CDISC Terminology Course will cover a brief history of how terminology started, primary objectives, guiding principles and working relationship with NCI EVS. The next section will cover how terminology is developed with the role and make-up of the teams. There will be a section on the Implementation Guide, how codelists are maintained for SDTM, CDASH, ADaM, SEND and oncology. There will be information on codelist extensibility, lab terms and how the TSPARM codelist links to other codelists. The next section will cover how to access controlled terminology, review of the spreadsheet and how to use the New Term Request Page.

13:00 - 16:30
Training: **New** An Introduction to Protocol Representation
Instructors: David Gemzik, Medidata & Rebecca Kush, CDISC President & CEO

Re-use of protocol sections to streamline clinical research processes is not inherent in the current typical paper-based or Word document format. However, a new protocol representation model now provides the potential to facilitate a number of key research processes, such as:

a) population of clinicaltrials.gov or EudraCT or other clinical trial registries;

b) identification of potential study subjects in a database;

c) automation of CRF development, visit scheduling and other innovative steps in the research process.

This half-day course describes the rationale and genesis for the Protocol Representation Model V 1.0, which is a core part of the
collaborative Biomedical Research Model (BRIDG) for protocol-driven research, defined in the broadest sense. Anyone who develops or uses research protocols should take this course.

17:00 - 19:00  European CDISC User Network Meetings
19:00 - 20:00  User Network Reception
17:00 - 21:00  Exhibit Booth Set-Up

**WEDNESDAY 13th APRIL 2011**

06:30 - 08:00  Exhibit Booth Set-Up
08:00 - 16:00  Registration
08:00 - 17:30  Exhibition Open

Coffee Available Throughout the Day

09:00 - 10:30  **Session 1: Welcome & Keynote**
Chair: Pierre-Yves Lastic, Chairman of the European CDISC Coordinating Committee

- **10 Years of CDISC in Europe**
  Pierre-Yves Lastic, Chairman of the European CDISC Coordinating Committee
- **Keynote Speech**
  Ilias Iakovidis, European Commission
  Ilias Iakovidis PhD is currently leading the “ICT for inclusion” unit responsible for the inclusion and ICT for Ageing research, policy and support to implementation. He is also part of team preparing the European Innovation Partnership on Active and Healthy Ageing. At the same time he continues as deputy Head of the “ICT for Health” Unit at DG INFSO, responsible for planning and implementation of the Research programme as well as the coordination of the international cooperation with non EU countries, in particular with US. He worked on policy and support to large scale deployment of eHealth in EU as described in the eHealth Action Plan (COM 2004 356), of which he was the main co-author, EC Recommendation on cross border Interoperability (C(2008)3282 - 2008/594/CE) and Communication on telemedicine (COM(2008)689 final). In 2001, Ilias Iakovidis has been elected fellow of American College of Medical Informatics for his contribution to the field.
- **State of the CDISC Union**
  Rebecca Kush, CDISC President & CEO
- **Technical Summary and Road Map**
  Frank Newby, CDISC, COO
- **Round Table Themes**
  Niels Both, European CDISC Coordinating Committee

10:30 - 11:00  Coffee

11:00 - 12:30  **Session 2: The Pharma Perspective**
Chair: Barry Burnstead, European CDISC Coordinating Committee

- **Integration of Clinical Trial Data Standards at Roche.**
  Part I – Process and Content
  Jonathan Chainey, Roche
- **Integration of Clinical Trial Data Standards at Roche.**
Part II – Models and Applications
Frederik Malfait, IMOS Consulting

• The Implementation of Standards Focusing on Bayer
  Susanne Pangritz, Bayer

• From ACE to ZINC - Examples of the Use of SDTM Controlled Terminology for Lab Tests
  Paul Vervuren, MSD

11:00 - 12:30 Session 2: Break-out session A: SDTM Discussion Group

12:30 - 14:00 Poster Session & Exhibits
12:30 - 14:00 Lunch

14:00 - 15:30 Session 3, Track 1: SDTM Compliance
Chair: Peter Van Reusel, European CDISC Coordinating Committee

• CDISC Advisory Board: Status Update on the CAB SDTM Validation Project
  Trisha Simpson, UCB Biosciences

• Validating Controlled Terminology in SDTM Domains
  John Gerlach, Independent Consultant

• Checking for SDTM Compliance: The Need for Human Involvement
  Fred Wood, Octagon Research Solutions

14:00 - 15:30 Session 3, Track 2: ODM Innovations
Chair: Wolfgang Summa, European CDISC Coordinating Committee

• Define.XML: Good Practices and Stylesheets
  Jozef Aerts, XML4Pharma

• The Re-use of define.XML as Metadata for CRF Design
  Philippe Verplancke, Xclinical

• How to Make a Standard Robust? What Can We Learn from the Music Industry and it’s MIDI Standard to Make ODM a Little Bit Better – Now and in the Future?
  Joerg Dillert, Oracle

14:00 - 15:30 Session 3: Break-out session B: Terminology Discussion Group

15:30 - 16:00 Coffee

16:00 - 17:30 Session 4, Track 1: Practical FDA Submission Experience
Chair: Herbert Noack, European CDISC Coordinating Committee

• Using CDISC Standards in FDA Submissions Today
  Monika Kawohl, Accovion

• Experiences with SDTM Submissions to FDA/CBER
  Christina Kramarsch, Baxter

• NDA Submissions: Reflections and Lessons Learned from a Recent and Successful Electronic NDA Submission and Approval Involving the CDISC SDTM Conversion of 42 Individual Legacy Clinical Studies
  Mark Williams, Applied Clinical Intelligence & Sam Tomioka, Sunovion Pharma

16:00 - 17:30 Session 4, Track 2: eHRs and the World Beyond
Chair: Philippe Verplancke, European CDISC Coordinating Committee

• The Research Protocol as an Executable Process in an Electronic Health Record
  Landen Bain, CDISC Liaison to Healthcare

• Japanese Sentinel Project
  Michio Kimura, Hamamatsu University School of Medicine & Kiyoteru Takenouchi, CMIC
• The EHR2 Roche Project: Investigating an Accessible Electronic Health Records Ecosystem
  Andrew Smith, Medidata Solutions
• Linked Data, an Opportunity to Improve the Research Utility of Clinical Datasets
  Kerstin Forsberg, AstraZeneca

16:00 - 17:30  Session 4: Break-out session C: CDASH and ADaM Discussion Groups
19:00 - 22:30 CDISC networking and social event

An Evening with TinTin at the Brussels Comic Strip Center!

evening begins with a short walk from the hotel to the Comic Strip Center. Here you will be greeted with a light aperitif and escorted by your guide on a tour of the exhibits (you will recognise many of the characters!). You will then be invited to partake of drinks and antipasti before enjoying a buffet dinner. Finally your meal is completed with freshly cooked waffles and pancakes! Throughout the evening you are free to explore this fascinating museum.
A wonderful experience!

THURSDAY 14th APRIL 2011
08:00 - 16:15  Exhibition Open
  Coffee Available Throughout the Day
09:00 - 10:30  Session 5: Track 1: The ADaM Family
  Chair: Ann-Sofie Bergström, European CDISC Coordinating Committee
• Application of a Standardized BDS Architecture to Manage and Deliver Analysis Ready ADaM Data Sets for Patient Reported Outcome Instruments (PRO)
  Jim Johnson, UCB Biosciences
• “Compliance” for Analysis Data
  Chris Decker, d-Wise
• ADaM 2.1 Implementation: A Challenging Next Step in the Process
  Tineke Callant, SGS Life Science Services

Session 5: Track 2: CDISC SHARE and Managed Metadata Repositories
  Chair: Dave Iberson-Hurst, European CDISC Coordinating Committee
• CDISC SHARE
  Dave Iberson-Hurst, Assero, Rhonda Facile, NCI-EVS
• Metadata Implementation at GSK
  Simon Bishop, GSK
• Beyond SHAREing: Research Project on Metadata Extraction, Exploration and Pooling
  Dimitri Kutsenko, Entimo

09:30 - 10:30

Session 5: Break-out session D: SDTM Discussion Group

10:30 - 11:00

Coffee

11:00 - 12:30

Session 6: Track 1: The CRO Perspective
Chair: Niels Both, European CDISC Coordinating Committee

• Getting the most out of CDASH and SDTM: automating the specification and validation process
  Peter van Reusel, Business & Decision Life Sciences

• Standards and Deliver! Optimising Trial Delivery with Standards
  Geoff Low, Parexel

• Leveraging CDISC Models to Drive Process Efficiency and Increase Product Quality
  Elke Sennewald, Kendle

11:00 - 12:30

Session 6: Track 2: Emerging Device Standards
Chair: Jörg Dillert, European CDISC Coordinating Committee

• CDISC Device Project - Towards an Initial Device Standard
  Rhonda Facile, NCI-EVS & Fred Wood, Octagon Research Solutions

• Three Case Studies of Converting to CDISC (CDASH and SDTM) Standards
  Jennifer Price, Bioclinica

• Serious Adverse Event Reporting in a National Registry of Clinical Investigation on Medical Devices
  Daniela Luzi & Fabrizio Pecoraro, National Research Council – Institute of Research on Population and Social Studies, Italy

11:00 - 12:30

Break-out session E: ODM & ADaM Discussion Groups

12:30 - 14:00

Poster Session & Exhibits

12:30 - 14:00

Lunch

14:00 - 15:30

Session 7: Standards Enhancing Public Health
Chair: Isabelle de Zegher, European CDISC Coordinating Committee

• CDISC Therapeutic Area Data Standards and Underlying Semantics
  Bron Kisler, CDISC VP Strategic Initiatives & Erin Muhlbradt, NCI-EVS

• Integrating Data Standards into the U.S. National Children’s Study
  Stephen Hirschfeld, US National Children’s Hospital

• Taking WHODRUG Into the 21st Century with CDISC Standards
  Ola Strandberg, Uppsala Monitoring Centre

• The Need for Standards in EHR-EDC Integration: The Case of EHR4CR
  Christel Daniel, Assistance Publique des Hôpitaux de Paris

15:30 - 16:00

Coffee

16:00 - 17:30

Session 8: Closing Plenary
Chair: Pierre-Yves Lastic, European CDISC Coordinating Committee

• The Role of Standards in Knowledge Management
  Ann Martin, Innovative Medicines Initiative
• Report from the CDASH Team - achievements in 2010  
  Shannon Laabout, CDISC & Rhonda Facile, NCI-EVS
• Report from the Round Table Discussion Groups  
  Wolfgang Summa, European CDISC Coordinating Committee
• CDISC in Asia  
  Yoshio Tsukada, GSK
• Closing  
  Pierre-Yves Lastic, Chairman of European CDISC Coordinating Committee

16:15 - 20:00  
Exhibit Booth Breakdown

FRIDAY 15th APRIL 2011

08:00 - 12:00  
Registration

08:30 - 12:00  
Workshop 1: Legacy Data Conversion  
  Peter Van Reusel, Business & Decision Life Sciences, Fred Wood, Octagon Research & Andrea Rauch, Boehringer Ingelheim

This workshop on Legacy Data Conversion will provide information, experiences and a demonstration on the following topics:
  • Skill positions and resources you need including the roles of data managers, programmers, and statisticians and the items and processes you have to organize “before” you convert your legacy data to SDTM
  • The effective use of off-the-shelf tools, with several examples lessons learned, and the respective roles of an automated map spec authoring tool, data integration technology, and an automated SDTM validation tool
  • Demonstration of how metadata can be leveraged to facilitate a metadata driven conversion methodology

08:30 - 16:30  
Training: ADaM: An Implementation Course  
  Instructor: Florence Somers, Business & Decision Life Sciences

The Analysis Dataset Model (ADaM) builds on the SDTM metadata model, adding attributes and examples specific to statistical analysis. This one-day course discusses the purpose of analysis datasets, the basic principles of the ADaM data standard, how ADaM fits in the CDISC framework, and the relationship between ADaM and SDTM. Attendees will learn the specifics about the subject-level analysis data model and how to start to apply the ADaM standards right now.

08:30 - 16:30  
Training: CDASH: An Implementation Course  
  Instructor: Lauren Shinnaberry, PRA International

This half-day course will provide attendees with an overview of the CDASH project including an overview of the important data collection fields/terminology in all domains. This course will provide attendees with basic information needed to access and use the CDASH standard for data collection. In addition the course will cover:
  • Relationship of CDASH to other CDISC standards
  • Normalized vs. De-normalized data structures
  • Implementation exercises
  • Best Practice recommendations
Prerequisite: A basic understanding of the clinical data collection process is helpful but not required

12:00 - 13:00  
Lunch
SAVE THE DATE!
CDISC INTERCHANGES 2011

Japan
Tokyo
12 - 15 July 2011

North America
Baltimore, Maryland, USA
9 - 15 October 2011

For full details and registration:
www.cdisc.org/interchange