



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

**PRELIMINARY
PROGRAMME
INTERCHANGE
EUROPE**
Subject to Change

26th - 30th April 2010

The Lancaster London Hotel

London

United Kingdom

CDISC INTERCHANGE, EUROPE 2010

CONFERENCE-AT-A-GLANCE

MONDAY 26th APRIL

- 09:00 - 17:00 ODM Training: An Implementation Course
09:00 - 17:00 *New* SDTM V3.1.2 Training: An Implementation Course
12:30 - 13:30 Lunch

TUESDAY 27th APRIL

- 09:00 - 17:00 *New* SDTM V3.1.2 Training (Cont): An Implementation Course
09:00 - 17:00 LAB Training: An Implementation Course
09:00 - 12:00 BRIDG Training: An Introduction
09:00 - 12:00 Introduction to CDISC Training
12:00 - 13:30 Lunch
13:30 - 17:00 CDASH & Terminology Training: An Introduction
13:30 - 17:00 Protocol Representation Training: An Introduction
(Attendees must have taken the BRIDG Training to take this course)

WEDNESDAY 28th APRIL

- 08:00 - 17:00 Registration
09:00 - 10:30 Session 1: Welcome & Keynote
10:30 - 11:00 Coffee
11:00 - 12:30 Session 2: CDASH - Right from the Beginning
Break-out Session A: Integration, PRG and ODM
12:30 - 13:30 Lunch
13:30 - 15:00 Session 3: Terminology - Transatlantic Perspectives
Break-out Session B: SDTM and ADaM
15:00 - 15:30 Coffee
15:30 - 17:00 Session 4: FDA Submission - Practical Experiences
Break-out Session C: CDASH and Terminology
18:00 - 22:30 CDISC Reception and Social Event

THURSDAY 29th APRIL

- 09:00 - 10:30 Session 5, Track 1: ODM - More Than Meets the Eye
Session 5, Track 2: Diverse Data Types - Contrasting Challenges
10:30 - 11:00 Coffee
11:00 - 12:30 Session 6, Track 1: eProtocol - "Yes we can do it!"
Session 6, Track 2: SDTM Mapping - Reporting on the Reality
12:30 - 13:30 Lunch
13:30 - 14:15 Poster Presentations
Break-out Session D: Popular Topics Revisited
14:15 - 15:45 Session 7, Track 1: eHR - The Holy Grail
Session 7, Track 2: SHARE - Managed Metadata Repositories
15:45 - 16:15 Coffee
16:15 - 17:15 Session 8: Closing Plenary Session

FRIDAY 30th APRIL

- 09:00 - 12:00 Workshop 1: Legacy Data Conversion
08:30 - 16:30 ADaM Training: An Implementation Course
13:00 - 16:00 Workshop 2: CDISC/HL7
09:00 - 15:00 Healthcare Link Training: How to use an EHR for Clinical Data Capture
12:00 - 13:00 Lunch

CDISC EUROPEAN INTERCHANGE SESSION DETAILS

MONDAY 26th APRIL 2010

08:00 - 17:00 **Registration**

09:00 - 17:00 **Training: ODM: An Implementation Course**

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 organisation.

09:00 - 17:00 **Training: *New* SDTM V3.1.2 Training: An Implementation Course**

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.

12:30 - 13:30 **Lunch**

TUESDAY 27th APRIL 2010

08:00 - 17:00 **Registration**

09:00 - 17:00 **Training (Continued): SDTM Application & Theory**

09:00 - 17:00 **Training: LAB: An Implementation Course**

The LAB Data Model is a vendor independent format used to store, interchange lab data between clinical lab vendors and sponsor companies. The LAB model is an approved HL7 model. This class consists of the technical framework for LAB, an in-depth understanding of the model structure, an overview of the implementation modes, and strategies for implementing LAB within your organisation.

09:00 - 12:00

Training: An Introduction to BRIDG

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.

09:00 - 12:00

Training: Introduction to CDISC

This workshop will give attendees the opportunity to learn about the history, organisation and philosophy of CDISC, the CDISC approach for standards development, the data modelling process as well as the benefits of CDISC standards. There will be a brief introduction to each of the currently published CDISC data standards/models and a discussion of future opportunities. The workshop is aimed at all those who have little or no experience of CDISC and want an introduction to CDISC operations, data standards/models and objectives.

12:00 - 13:30

Lunch

13:30 - 17:00

Training: CDASH & Terminology: An Introduction

This half-day course will provide attendees with an overview of the CDASH and Terminology projects as well as covering history, organisation, and philosophy. This course will provide attendees with the information needed to facilitate access, implementation and use of these important standards. Additionally the course will cover:

- The development approach
- Key collaborations
- The interrelationship of these projects
- The relationship to the Study Data Tabulation Model (SDTM)
- How to implement these standards
- Future plans and direction

13:30 - 17:00

Training: An Introduction to Protocol Representation

The objective of the Protocol Representation Group is publication of a standard, machine-readable model for protocol representation that will enable interchange of this data among systems and stakeholders. This course will describe the first release of the Protocol Representation Standard, which includes Clinical Trial Registry, Trial Design, and Eligibility Criteria.

NB: Attendees must have taken the BRIDG course to take this training.

17:00 - 19:30

CDISC User Network Meetings and Reception

17:00 - 23:00

Exhibit Booth Setup

WEDNESDAY 22nd APRIL 2009

08:00 - 17:00

Registration

08:00 - 17:00

Exhibition Open

08:00 - 09:00

Coffee

09:00 - 10:30

Session 1:

Welcome & Keynote

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

- **Welcome to London and the World of CDISC**
Tim M. Jaeger, Chairman of the European CDISC Coordinating Committee
- **State of the Union Address**
Rebecca Kush, CDISC President
- **CDISC Technical Activities - What's New and Why**
Dave Ibersen-Hurst, CDISC VP Technical Strategy
- **Keynote Speech**
The Importance of Communicating the Imperative and Principles of Data Standards to Mere Mortals
Frank Rockhold, GlaxoSmithKline Pharmaceuticals, CDISC Board of Directors
- **Keynote Speech**
European Medicines Agency - Strategy and Implementation of Data Standards
Speaker Invited

10:30 - 11:00

Coffee

11:00 - 12:30

Session 2:

CDASH - Right from the Beginning

Chair: Niels Both, European CDISC Coordinating Committee

- **Getting the Most out of CDASH, Metadata and Terminology**
Joris De Bondt, SGS Life Science Services
- **Building an eCRF CDASH Library – A Case Study**
Alison Sanders, Phase Forward
- **CDASH: Practical Use and Benefits**
Helene Devroye, Business & Decision

11:00 - 12:30

Session 2:

Break-out session A: Integration, PRG and ODM

12:30 - 13:30

Lunch

13:30 - 15:00

Session 3:

Terminology - Transatlantic Perspectives

Chair: Pierre-Yves Lastic, European CDISC Coordinating Committee

- **US National Cancer Institute's Enterprise Vocabulary Services and CDISC Terminology Collaboration: Building on the Foundation**
Muhlbradt, Quinn & Roth, NCI-EVS
- **Controlled Terminology: Let's Speak the Same Language**
Chris Tolk, CDISC
- **Leveraging CDISC Standards to Improve Business Practices**
Jason Housley, Shire & Lauren Shinaberry, PRA International

13:30 - 15:00

Session 3:
Break-out session B: SDTM and ADaM

15:00 - 15:30

Coffee

15:30 - 17:00

Session 4:
FDA Submission: Practical Experiences
Chair: Herbert Noack, European CDISC Coordinating Committee

- **Integrations via Connections between individual CDISC standards from CDASH to Define XML at Kendle**
Elke Sennewald, Kendle
- **The CDISC/FDA Integrated Data Pilot: A Final Summary of the Findings, Reviewer Feedback, and Recommendations Implementing CDISC Standards Within and Across Studies**
Chris Decker, d-Wise Technologies
- **FDA Submissions: SDTM Standard versus its implementation tools**
Sergio Sinchenko, Parexel

15:30 - 17:00

Session 4
Break-out session C: CDASH and Terminology

18:00 - 22:30

CDISC networking and social event



Madame Tussauds Spectacular! ***Tour, Dinner & Drinks***

If you have never experienced the amazing celebrity world of Madame Tussauds or if you have joined the tourists and been hustled through, then you should take advantage of the wonderful evening that has been arranged for you by the E3C.



Our evening begins with a short coach journey from the hotel to Madame Tussauds on Baker Street, where we have exclusive access to the venue. You will then be whisked away on a tour in a 'black cab' before arriving for dinner, where you will be treated in true celebrity fashion by the paparazzi snapping photographs. You can then enjoy dinner and drinks followed by a journey through the 'Chamber of Horrors' before you return to the hotel!

*This is an evening not to be missed! And there are only **200 places available!** Make sure you sign up when you register.*

THURSDAY 29th APRIL 2010

08:00 - 17:00 **Exhibition Open**

08:00 - 09:00 Coffee

09:00 - 10:30

Session 5: Track 1

ODM - More Than Meets the Eye

Chair: Wolfgang Summa, European CDISC Coordinating Committee

- **ODM Certification: Lessons Learned from those Implementing**
Dave Ibersen-Hurst, CDISC
- **Using Incremental ODM Transactions in Systems Integration**
Andrew Smith, Medidata
- **Production use of transactional ODM for data, metadata and audit trail archiving**
Claus Lindenau, XClinical

Session 5: Track 2

Diverse Data Types - Contrasting Challenges

Chair: Ann-Sofie Bergström, European CDISC Coordinating Committee

- **Defining a Process for Standardisation of Lab Data to Create SDTM Compliant LB Domains**
Karen Steenhoudt, Octagon Research
- **Advancing Child Health Research Through Harmonized Pediatric Terminology**
Steven Hirschfeld, NCI
- **How can CDISC SDTM Standards be Applied for Pharmacoepidemiological Studies?**
Doris Kolb, PRA International
- **Implementing SDTM in a Semi-Virtual Oncology-Focused Biotechnology Company**
Albert Chau, Antisoma Research Ltd

10:30 - 11:00 Coffee

11:00 - 12:30

Session 6: Track 1

eProtocol - "Yes We Can Do It"

Chair: Phillipe Verplancke, European CDISC Coordinating Committee

- **Towards a Fully Machine-Readable Protocol: The New ODM-Extension for Trial Design / Protocol**
Jozef Aerts, XML4Pharma
- **Automated Trial Design and the Standards Metadata Repository**
Barry Cohen, Octagon Research
- **It Can Be Done! – Creating an Implementation Model Based on the Protocol Representation Model in BRIDG 3.0**
Lisa Chatterjee, Digital Infusion

Session 6: Track 2

SDTM Mapping - Reporting on the Reality

Chair: Jason Housley, European CDISC Coordinating Committee

- **How SDTM Can Help to Identify Data Issues**
Carla Santillán, Astellas

- **Traceability between SDTM and ADaM converted analysis datasets**
Florence Somers, Business & Decision
- **Worldwide Distribution of the Workload Generated by the SDTM Mapping Process.**
Alois Reimer, Parexel

12:30 - 13:30

Lunch

13:30 - 14:15

Poster Presentations

Chair: Barry Burnstead, European CDISC Coordinating Committee

13:30 - 14:15

Break-out session D: Popular Topics Revisited

14:15 - 15:45

Session 7: Track 1

eHR - The Holy Grail?

Chair: Björn-Erik Erlandsson, European CDISC Coordinating Committee

- **Achieve the Secondary Use of Healthcare Data by Creating a Standard-based Clinical Research Database**
Hsing-Tzu Wu, Inst. Biomedical Informatics, National Yang-Ming University
- **Protecting Personally Identifiable Information in a Healthcare/Clinical Data Interchange/Sharing Environment**
Speaker Invited
- **EDC-EHR Integration**
Wolfgang Summa, Omnicom

Session 7: Track 2

SHARE - Managed Metadata Repositories

Chair: Isabelle De Zegher, Parexel

- **CDISC SHARE: What and Why**
Dave Ibersen-Hurst, CDISC
- **GSK's version of CDISC SHARE – A Summary of GSK's Approach and Experience**
Simon Bishop, GSK
- **Speaker Invited**
Speaker Invited

15:45 - 16:15

Coffee

16:15 - 17:15

Session 8:

Closing Session

Chair: Pierre-Yves Lastic, European CDISC Coordinating Committee

- **Reports from the European User Groups**
Ann-Sofie Bergström, European CDISC Coordinating Committee
- **What has been Achieved**
Tim M. Jaeger, European CDISC Coordinating Committee
- **The Future of Clinical Data: The Evolving Impact of CDISC and HL7 Standards on Data Management, Submission, and Pharmacovigilance**
Wayne Kubick, Phase Forward
- **Review of the Conference and Outlook for CDISC in Europe**
Pierre-Yves Lastic, Chairman of European CDISC Coordinating Committee

16:15 - 20:00

Exhibit Booth Breakdown

FRIDAY 30th APRIL 2010

08:00 - 12:00 **Registration**

09:00 - 12:00 **Workshop 1: Legacy Data Conversion**
Various Trainers

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**

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.

13:00 - 16:00 **Workshop 2: CDISC/HL7**

Harmonizing Standards Initiatives: An Overview of Collaborative Standards Initiatives for Clinical Research and Healthcare

Topics for discussion:

Data Standards: The foundation of interoperability in information interchange

The Biomedical Research Integrated Domain Group (BRIDG)

Model: A domain analysis model for Biomedical Research

CDISC and HL7 Collaborations

09:00 - 15:00 **Training: Healthcare Link Training: How to use an EHR for Clinical Data Capture**

CDISC's Healthcare Link project is now mainstream with the original RFD now incorporated in a HITSP interoperability specification, augmented by additional integration profiles and hooked into HL7's successful strategy of standardized clinical documents called template CDAs.

This course will focus on the following:

- CDISC interactions with health informatics standards organizations such as HL7 and IHE
- The electronic Source Document Initiative (eSDI)
- Scenarios for the use of electronic health records for clinical research
- The RFD (Retrieve Form for Data Capture), an IHE (Integrating the Healthcare Enterprise) integration profile in use now to support various EHR-research related use cases

12:00 - 13:00 **Lunch**

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