

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



PROGRAMME INTERCHANGE EUROPE

26th - 30th April 2010

The Lancaster London Hotel

London

United Kingdom

Spring 2010

Dear friends and colleagues,

It is with great pleasure that we welcome you to the CDISC Interchange Europe 2010, with our conference being held on the 28 - 29 in London, United Kingdom.

After 4 years service as the Chair of the European CDISC Coordinating (E3C), I will be handing over the reins to Pierre-Yves Lastic. As my tenure comes to an end, I have had time to reflect on the changing landscape of CDISC in Europe. I have been pleased to be associated with some great Interchanges that have delivered vibrant and interesting programmes, excellent training and increasing attendance. We have been to some truly spectacular locations, Montreux, Copenhagen, Budapest and this year, London. I would like to acknowledge the hard work of my colleagues on the E3C. With their support and enthusiasm, we have seen the development of the CDISC User Groups in Europe and the new format of this year's programme with the User Discussion Sessions. The E3C is a dynamic group and I look forward to seeing their future innovations and successes.

The CDISC European Interchange has enjoyed popularity among industry experts from pharmaceuticals and diagnostics, academia, regulators, solution providers and other key stakeholders. Since its inception six years ago the CDISC European Interchange has clearly established itself as the premier event in Europe to cover the advancement of medical research data standards.

Our delegates value not only the scientific program with state-of-the-art presentations about the different CDISC standards, the discussion of strategies for standards adoption or real-life CDISC case studies, they also enjoy the great networking opportunities provided by the conference. Furthermore, we offer a range of pre & post - Conference training sessions and opportunities to follow-up discussions with individual providers at the industry exhibition.

The many practical experiences with CDISC standards are again at the core of the conference and they clearly demonstrate the growing adoption of CDISC in Europe and across the world. We are very pleased to welcome Tim Buxton (European Medicines Agency) and Frank Rockhold (GlaxoSmithKline & CDISC Board of Directors) as our keynote speakers. They bring the voice of the European regulators to our conference and that of one of the largest global pharmaceutical companies; we are delighted that they could give up their valuable time to be part of our programme.

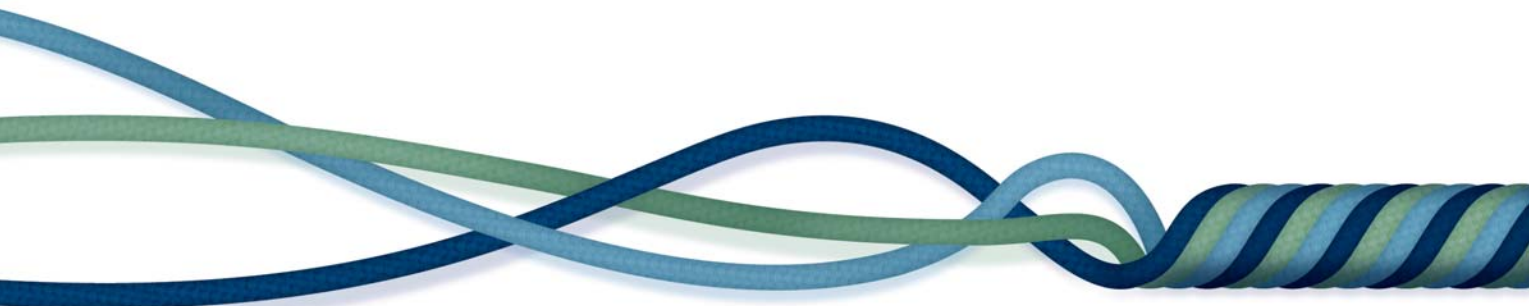
The conference is being held at the stylish Lancaster London Hotel which is located in the heart of London, opposite Hyde Park. We have an amazing social event at Madame Tussauds, one of the city's premier attractions.

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

With kind regards



Tim M. Jaeger, MD PhD MBA
Chairman of the European CDISC Coordinating Committee



Strength *through collaboration.*

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 - 12:30 BRIDG Training: An Introduction
09:00 - 12:30 Introduction to CDISC Training
12:30 - 13:30 Lunch
13:30 - 17:00 CDASH 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: SDTM & ADaM Discussion Group
12:30 - 13:30 Lunch
13:30 - 15:00 Session 3: Terminology - Transatlantic Perspectives
Break-out Session B: Integration, PRG and ODM Discussion Group
15:00 - 15:30 Coffee
15:30 - 17:00 Session 4: FDA Submission - Practical Experiences
Break-out Session C: CDASH and Terminology Discussion Group
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 Implementation - Reporting on the Reality
12:30 - 13:30 Lunch
13:30 - 14:15 Poster Presentations
Break-out Session D: Popular Topics Revisited Discussion Group
14:15 - 15:45 Session 7, Track 1: eHR - The Holy Grail
Session 7, Track 2: CDISC SHARE - Managed Metadata Repositories
15:45 - 16:15 Coffee
16:15 - 17:30 Session 8: Closing Plenary Session

FRIDAY 30th APRIL

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

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 - 12:30

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.

12:30 - 13:30

Lunch

13:30 - 17:00

Training: CDASH : An Introduction

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

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.

17:30 - 20:00

CDISC User Network Meetings and Reception

WEDNESDAY 28th APRIL 2010

06:30 - 08:00

Exhibit Booth Set-Up

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 CDISC Union**
Rebecca Kush, CDISC President
- **CDISC Technical Activities - What's New and Why**
Dave Ibersen-Hurst, CDISC Technical Architect
- **Keynote Speech**
European Medicines Agency - Strategy and Implementation of Data Standards
Tim Buxton, European Medicines Agency
- **Keynote Speech**
Data Stewardship and the Art and Science of Explaining Standards So That Everyone Gets It
Frank Rockhold, GlaxoSmithKline Pharmaceuticals, CDISC Board of Directors
- **Interchange Innovations: Discussion Sessions & Posters**
Jason Housley & Niels Both, European CDISC Coordinating Committee

10:30 - 11:00

Coffee

11:00 - 12:30

Session 2:

CDASH - Right from the Beginning

Chair: Niels Both, European CDISC Coordinating Committee

- **CDASH: Practical Use and Benefits**
Helene Devroye, Business & Decision Life Sciences
- **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

11:00 - 12:30

Session 2:

Break-out session A: SDTM & ADaM Discussion Group

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**
Erin Muhlbradt, Theresa Quinn & Laura 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: Integration, PRG and ODM Discussion Group

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 Discussion



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!

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 Implementation - 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 Life Sciences
- **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 & Der-Ming Liou, Inst. Biomedical Informatics, National Yang-Ming University
- **Protecting Personally Identifiable Information in a Healthcare/ Clinical Data Interchange/Sharing Environment**
Wai L. Tsang, Tecsec
- **EDC-EHR Integration**
Wolfgang Summa, Omnicom

Session 7: Track 2

CDISC 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
- **How Lilly's Adoption of ODM Aligns with CDISC SHARE**
Bruce Basson, Eli Lilly
- **Building the Foundation for the CDISC SHARE Library**
Erin Muhlbradt, NCI- EVS & Rhonda Facile, CDISC

15:45 - 16:15

Coffee

16:15 - 17:30

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
- **How HL7 CDA Helps Linking the Healthcare World with the CDISC Clinical Research World**
Charles Jaffe, Chairman of HL7 International
- **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**

08:30 - 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 (CDISC and HL7: 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

08:30 - 15:00 **Training: Healthcare Link Training: How to use an EHR for Clinical Data Capture**

CDISC's Healthcare Link initiative is now mainstream with the original Retrieve Form for Data Capture (RFD) Integration Profile now incorporated into a Health Information Technology (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 Data Interchange Initiative (eSDI)
- Scenarios for the use of electronic health records for clinical research - FDA collaboration and referenced by EMA in documentation for auditors
- 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**

SAVE THE DATE!

CDISC INTERCHANGES 2010

**Japan
Tokyo
20 - 23 July 2010**



**North America
Baltimore, Maryland, USA
1 - 5 November 2010**



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

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