



**A collaborative event**

**to share progress,**

**implementation experiences**

**and strategic ideas on**

**worldwide data interchange**

**standards for clinical trials.**

## **PROGRAMME**

**4th European Interchange**

**23rd—27th April 2007**

**Grand Hotel Suisse Majestic**

**Montreux, Switzerland**



Dear friends and colleagues,

It is with great pleasure that we invite you to attend the 4<sup>th</sup> CDISC European Interchange, the main conference being held April 25-26 in Montreux, Switzerland.

With over 21 billion Euros invested annually across the member states, Europe presents the second largest pharmaceutical research and development market in the world. This market faces unique challenges and opportunities due to its heterogeneous structure and geographic complexity. Such an environment underlines the ever growing need to provide all stakeholders and constituencies with a pervasive standard when collecting, processing and submitting clinical data.

Consequently, the CDISC European Interchange has enjoyed increasing popularity among industry experts, academia, regulators and other key stakeholders. Since its inception merely three years ago the CDISC European Interchange has quickly established itself as the premier event in Europe to cover the advancement of data standards in clinical trials.

Our participants value not only the state-of-the-art presentations about the different CDISC standards, the discussion of strategies for standards in clinical trials and healthcare or real-life CDISC case studies, they also enjoy the great networking opportunities provided by the conference. Furthermore, we have organized a range of pre-conference training sessions and an "End-to-end" demonstration event, which will show connectivity and data exchange across a number of systems and platforms. To follow-up discussions with individual providers we have once again organized an industry exhibition.

The focus of this year's conference clearly is on practical experiences implementing the CDISC standards. This will provide the user with valuable insights and lessons-learned from those who have not only established CDISC standards in their organizations but also submitted data to the regulators. We also have for the first time established a session specifically for industry decision makers and executives where we discuss the value proposition of standards in clinical trials.

The conference is being held at the beautiful Grand Hôtel Suisse Majestic which is located in the heart of Montreux and enjoys spectacular views over Lake Geneva and the Alps. We have prepared a truly spectacular social event where we will enjoy a private train tour to a typical Swiss mountain top restaurant.

We sincerely wish to thank the many volunteers in the European CDISC Coordinating Committee and the CDISC operations team for working hard to make this conference an informative and exciting venue for all the participants. We also wish to thank those who contributed to the programme which allows us to present once again a well-rounded and truly relevant event.

We look forward to seeing you in Montreux for the 4<sup>th</sup> CDISC European Interchange.

With kind regards

A handwritten signature in blue ink, appearing to read "Tim M. Jaeger".

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

A handwritten signature in blue ink, appearing to read "Rebecca Kush".

Rebecca Kush  
CDISC President and CEO

# CDISC EUROPEAN INTERCHANGE 2007

## CONFERENCE - AT - A - GLANCE

### MONDAY 23rd APRIL

09:00 - 12:30	Workshop 1: Introduction to CDISC
12:30 - 13:30	Lunch
13:00 - 17:30	SDTM Training: Application & Theory
13:30 - 17:00	Workshop 2: CDISC End to End

### TUESDAY 24th APRIL

09:00 - 16:00	SDTM Training (Continued): Application & Theory
09:00 - 16:00	Workshop 2 (Continued): CDISC End to End
16:00 - 17:30	CDISC User Group Meeting

### WEDNESDAY 25th APRIL

08:00 - 17:00	Registration
09:00 - 10:30	Session 1: Welcome
10:30 - 11:00	Coffee
11:00 - 12:30	Session 2: What's New? CDISC Model Highlights
12:30 - 13:30	Lunch
13:30 - 15:00	Session 3: CDISC Implementation Studies
15:00 - 15:30	Coffee
15:30 - 17:00	Session 4: European Research and Standards: Statements and Roundtable
17:30 - 22:45	CDISC Reception and Social Event <i>Dinner: Courtesy of Roche Diagnostics</i>

### THURSDAY 26th APRIL

09:00 - 10:30	Session 5: Parallel Streams Business Stream Technology Stream
10:30 - 11:00	Coffee
11:00 - 12:30	Session 6: Practical Experience Using SDTM/ADaM
12:30 - 13:30	Lunch
13:30 - 15:00	Session 7: Integrate As Much As Possible
15:00 - 15:30	Coffee
15:30 - 16:30	Session 8: The Way Forward
16:30 - 17:00	Closing Address

### FRIDAY 27th APRIL

09:00 - 12:30	Workshop 3: Legacy Conversion Workshop
09:00 - 16:00	Cross - Team Meeting

# CDISC EUROPEAN INTERCHANGE SESSION DETAILS

## MONDAY 23rd APRIL 2007

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

**09:00 - 12:30 *Workshop 1: Introduction to CDISC***

*Frank Newby - CDISC*

This workshop will give attendees the opportunity to learn about the history, organization 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 want an introduction to CDISC operations, data standards/models and objectives.

**13:00 - 17:30 *Training: SDTM Theory & Application***

*Mary Lenzen - Octagon Research*

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 workshop consists of:

- 1) a detailed review of SDTM concepts, SDTM domain models, and relationship tables,
- 2) a discussion of common implementation issues and
- 3) a workshop with CRF annotation exercises that reinforce attendees' understanding of the SDTM and the SDTM Implementation Guide.

**13:30 - 17:00 *Workshop 2: CDISC End to End***

*Dave Iberson-Hurst - CDISC/Assero Ltd*

This workshop will provide an understanding of how the main components of the CDISC standard - The Operational Data Model (ODM), The Study Data Tabulation Model (SDTM), The Analysis Data Model (ADaM), The Laboratory Model (LAB) and The Protocol Model - can work together to move data from the point of trial design through capture, submission and subsequent long-term archive. The workshop will use a combination of theory and practical demonstrations to provide attendees with a comprehensive overview of how the eClinical trial can be implemented today.

## **TUESDAY 24th APRIL 2007**

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

**09:00 - 16:00 *Training (Continued): SDTM Theory & Application***

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 workshop consists of:

- 1) a detailed review of SDTM concepts, SDTM domain models, and relationship tables,
- 2) a discussion of common implementation issues and
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**09:00 - 16:00 *Workshop 2 (Continued): CDISC End to End***

This workshop will provide an understanding of how the main components of the CDISC standard - The Operational Data Model (ODM), The Study Data Tabulation Model (SDTM), The Analysis Data Model (ADaM), The Laboratory Model (LAB) and The Protocol Model - can work together to move data from the point of trial design through capture, submission and subsequent long-term archive. The workshop will use a combination of theory and practical demonstrations to provide attendees with a comprehensive overview of how the eClinical trial can be implemented today.

**16:00 - 17:30 CDISC User Group Meeting**

Welcome: Tim M. Jaeger (Chairman, European CDISC Coordinating Committee)

Co-Chairs: Ann-Sofie Bergström (European CDISC Coordinating Committee) & Simon Bishop (GlaxoSmithKline, UK)

**17:30 - 23:00 Exhibit Booth Setup**

## WEDNESDAY 25th APRIL 2007

08:00 - 17:00      **Registration**

08:00 - 17:00      **Exhibit Booths**

08:00 - 09:00      **Morning Coffee**

09:00 - 10:30      **Session 1:  
Welcome**

- **Welcome Address**

*Tim M. Jaeger - Chairman, European CDISC Coordinating Committee*

- **Key Note Presentation**

*Tikki Pang - World Health Organization, Switzerland*

- **Presidential Address: CDISC - The Global Strategy**

*Rebecca Kush - CDISC President and CEO*

- **The Hot Topic: Two Worlds Collide - CDISC and Electronic Health Records**

*Landen Bain - CDISC Liaison to Healthcare*

10:30 - 11:00      **Coffee Break**

11:00 - 12:30      **Session 2:  
What's New? CDISC Model Highlights**

*Chair: Graham Bunn, European CDISC Coordinating Committee*

- **The CDISC Roadmap**

*Julie Evans - CDISC Director Technical Services*

- **CDASH - Purpose, Planning, Proof-of-Concept**

*Gary Walker - Quintiles Transitional, USA*

- **Update on ADaM**

*Joel Hoffman - Insightful, Switzerland*

- **Standard Controlled Terminology: A Shared Vision Between CDISC and NCI EVS**

*Margaret Haber - National Cancer Institute, USA*

12:30 - 13:30      **Lunch**

13:30 - 15:00

**Session 3:  
CDISC Implementation Studies**

*Chair: Ann-Sofie Bergström, European CDISC Coordinating Committee*

- **An Implementation of SDTM 3.1.1 within Eli Lilly and Company**  
*Jason Housley - Eli Lilly, UK*
- **Implementation of CDISC Standards within Lundbeck**  
*Niels Both - Lundbeck, Denmark*
- **Astellas going CDISC**  
*Robert Snijder – Astellas, The Netherlands*

15:00 - 15:30

**Coffee Break**

15:30 - 17:00

**Session 4:  
European Research and Standards: Statements & Roundtable**

*Moderator: David Hardison, Chairman of the Board, CDISC*

- **Charles Jaffe**  
*CEO HL7, Senior Global Strategist, Digital Health Group, Intel, USA.  
Member CDISC Board of Directors*
- **Davina Ghersi**  
*Coordinator/Team Leader, International Clinical Trials Registry Platform, Department of Research Policy and Cooperation, World Health Organisation, Switzerland*
- **Karima Boubekeur**  
*Innovative Medicines Initiative; Head of External R&D Policy, Roche Pharmaceuticals, Switzerland*
- **Otto Rienhoff**  
*Vice-chairman Board of Directors, Telematics Platform for Medical Research Networks, Germany*
- **Gerd Schmitz**  
*Head of The Institute for Clinical Chemistry and Laboratory Medicine, University Hospital Regensburg, Germany*

17:30 - 22:45

**CDISC Reception on board the scenic rack railway followed by dinner at the Panorama “Plein Roc” Restaurant**

*Dinner: Courtesy of Roche Diagnostics*

## THURSDAY 26th APRIL 2007

08:00 - 15:30 Exhibit Booths

08:00 - 09:00 Morning Coffee

09:00 - 10:30 **Session 5: (Parallel Streams)**

### Business Stream

*Chair: Wolfgang Summa, European CDISC Coordinating Committee*

- **CDISC - The Corporate Perspective**  
*Simon Bishop - GlaxoSmithKline, UK*
- **Implementation of Data Standards in a Pharma Company with Complete Outsourcing Strategy**  
*Annamaria Muraro - Helsinn Healthcare, Switzerland*
- **The CDISC Business Case**  
*Rebecca Kush - CDISC President and CEO*

**Session 5: (Parallel Streams)**

### Technology Stream

*Chair: Dave Iberson-Hurst, European CDISC Coordinating Committee*

- **Automated Mapping to Simplify Conversion of Clinical Data from ODM to SDTM**  
*Johannes Hüsing - Universitätsklinikum Heidelberg, Germany*
- **A Presentation on the Integration of the Drug Safety E2B Model with the CDISC Standard Models**  
*Jörg Dillert - Phase Forward, Germany*
- **eDiary and EDC System Integration: The Importance of Using CDISC ODM Standards**  
*Andrew Newbigging - Medidata Solutions, UK*

10:30 - 11:00 Coffee Break

11:00 - 12:30

**Session 6:  
Practical Experience Using SDTM/ADaM**

*Chair: Herbert Noack, European CDISC Coordinating Committee*

- **Evaluation and Implementation of Different Strategies to Create ADaM Datasets**  
*Elke Sennewald - Kendle, Germany*
- **A Harmonized, Report-friendly SDTM and ADaM Data Flow**  
*Aileen Yam - Sanofi-Aventis, USA*
- **The FDA-CDISC Pilot**  
*Ed Helton - SAS, USA, Member CDISC Board of Directors*

12:30 - 13:30

Lunch

13:30 - 15:00

**Session 7:  
Integrate As Much As Possible**

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

- **Practical Experience of Using an Integrated Electronic Trial Platform**  
*Ulrike Schwarz-Boeger - Frauenklinik, University Munich, Germany*
- **Aligning HL7 CDA Templates and CDISC ODM - An Experiment in Cardiovascular Radiology**  
*Christel Daniel-Le Bozec - University of René Descartes, France*
- **Development of Disease Specific Data Standards: A Global Project and Case Study in Tuberculosis**  
*Richard O'Brien - FIND Diagnostics, Switzerland*

15:00 - 15:30

Coffee Break

15:30 - 16:30

**Session 8:  
The Way Forward**

*Chair: Udo Siegmann, European CDISC Coordinating Committee*

- **The Changing Trial Landscape in Europe**  
*Pierre-Yves Lastic - European CDISC Coordinating Committee*
- **CDISC Activities for 2007**  
*Rebecca Kush - CDISC President and CEO*
- **E3C Activities for 2007**  
*Dave Ibersen-Hurst - Vice Chairman, European CDISC Coordinating Committee*

16:30 - 17:00

**Closing Address:**

*Tim M. Jaeger*

*Chairman, European CDISC Coordinating Committee*

15:30 - 23:00

**Exhibit Booths Break-down**

**FRIDAY 27th APRIL 2007**

09:00 - 12:30

***Workshop 3: Legacy Conversion Workshop***

*Presenters Invited*

This workshop will focus on process, methods and tools used to convert legacy data to the CDISC STDM standard. There will be 3-4 case studies presented with discussion and demonstration of examples included.

09:00 - 16:00

**Cross - Team Meeting**

# CDISC EUROPEAN INTERCHANGE 2007

## *Reception, Mountain Train Tour and Dinner*



Join your fellow attendees in the bar after a busy first day at the Interchange for drinks and then make your way to the station for this wonderful evening dining at the summit of the magnificent Swiss Alps.

In one hour, you climb by rack railway train from the palm trees on the lake shore to the alpine garden flowering above. The railway meanders between lake, forests and high mountain pastures taking less than an hour to reach the summit of more than 2,000 m. This beautiful location, the Rochers-de-Naye ("Naye Rocks"), overlooks the town of Montreux and provides the most spectacular view of Lake Geneva and the surrounding Alps. Whilst on board you can enjoy refreshments courtesy of CDISC.

With breathtaking views from the mountain, you will then enjoy a typical Swiss dinner in the "Plein Roc" Restaurant, where you can relax and enjoy a truly unique experience.

*Limited places available (maximum 120 people). Ensure you book early!*



**17:30 - 18:40** CDISC Reception on board the scenic rack railway

**19:00 - 21:30** Dinner in the Panorama "Plein Roc" Restaurant

**21:40 - 22:45** Return to the Suisse Majestic

*Dinner courtesy of Roche Diagnostics*

## MEDIA PARTNERS



## EVENT SPONSORS

