



2018  
EUROPE  
INTERCHANGE  
BERLIN  
23-27 APRIL



2018  
EUROPE INTERCHANGE



Very warm welcome in Berlin!  
Again!



# 2018 EUROPE INTERCHANGE

## Annual Meetings

### Workshops

- Frankfurt 2002
- Dublin 2003

### Interchanges

- Brussels 2004
- Paris 2005
- Berlin 2006
- Montreux 2007
- Copenhagen 2008
- Budapest 2009
- London 2010
- Brussels 2011
- Stockholm 2012
- Frankfurt 2013
- Paris 2014
- Basel 2015
- Vienna 2016
- London 2017
- **Berlin 2018**

# 15<sup>th</sup>



2018  
EUROPE INTERCHANGE



Berlin? Berlin!















October 29-31, 2001

Palais des Congrès, Paris, France

### Workshop Objectives

Data Management lies at the heart of clinical research and clinical data are our industry's single most valuable asset. Without data, products do not get approved and successfully marketed. Thus data managers find themselves providing the link between the gatherers of the data (patients, investigators) and the interpreters of the information (statisticians, clinical researchers, regulators). The pressure to get drugs on to the market results in a need to access the information more rapidly and data managers find themselves confronted with new and ever-evolving technology to capture and process data. The challenge is to manage data in a highly regulated environment.

### Key Topics

- CDM job roles and responsibilities
- The place of e-learning in clinical research
- New technology vendors and their solutions (which is the chick of the month)
- Regulatory Inspection and Audit
- Managing Serious Adverse Events
- Acquiring data directly from patients
- Data Standards - the future
- Internet/Intranet technologies

### Programme Co-Chairpersons

Pierre-Yves Lastic  
Sanofi-Synthelabo, France  
Alex Paton  
Quintiles, France

### Programme Committee

Barry Burnstead  
Clinsoft, UK  
Caroline Fenning  
Kendle International, UK  
Adrienne Motion  
Pfizer, UK  
Udo Siegmann  
Parexel, Germany



13:30

### Parallel Session 5B

#### CDISC WORKSHOP

Session Chairperson:

**Udo Siegmann, Parexel GmbH, Germany**

Judith Sromovsky, Merck & Co. Inc., USA

- An Industry Perspective
- General CDISC Progress Update

Wayne Kubick, Lincoln Technologies, USA

- Overview of the CDISC ODM Model and Labs Model
- Overview of the CDISC Submissions Data Model

#### Panel Discussion

Making CDISC more relevant in Europe and the rest of the World



17  
years  
ago!



# 2018 EUROPE INTERCHANGE

## 17 years E3C

October 29-31, 2001  
Palais des Congrès, Paris, France

### Workshop Objectives

Data Management lies at the heart of clinical research and clinical data are our industry's single most valuable asset. Without data, products do not get approved and successfully marketed. Thus data managers find themselves providing the link between the gatherers of the data (patients, investigators) and the interpreters of the information (statisticians, clinical researchers, regulators). The pressure to get drugs on to the market results in a need to access the information more rapidly and data managers find themselves confronted with new and ever-changing technology to capture and process data. The challenge in a highly regulated environment is to ensure that the data is accurate and reliable.

### Key Topics

- CDM job roles and responsibilities
- The place of e-learnings in CDMS
- New technology vendors (which is the chicken and which is the egg?)

### Programme Co-Chairpersons

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Sanofi-Synthelabo, France  
Alex Paton  
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Udo Siegmann  
Parexel, Germany



13:30 Parallel Session 5B

### CDISC WORKSHOP

Session Chairperson:

**Udo Siegmann, Parexel GmbH, Germany**

...sky, Merck & Co. Inc., USA  
... Perspective  
... SC Progress Update

Lincoln Technologies, USA  
... the CDISC ODM Model and Labs Model  
... the CDISC Submissions Data Model

... ion  
... more relevant in Europe and the rest of the World



# 2018 EUROPE INTERCHANGE

## *E3C Current Members*



- **Andrea Rauch, Boehringer-Ingelheim, Germany**
- **Angelo Tinazzi, Cytel, Switzerland**
- **Jozef Aerts, Joanneum University, Austria**
- **Stephane Auger, Danone, France**
- **Stijn Rogiers , SAS, Belgium**
- **Eanna Kiely, Syneos Health, Germany**
- **Silvia Faini, CROS NT, Italy**
- **Simon Lundberg, Astra Zeneca, Sweden**
- **Sujit Khune, Novo Nordisk, Denmark**
- **Xavier Gobert Mydata Trust, France**
- **Jörg Dillert, Oracle, Germany (Chair)**

### **CDISC E3C Liaison**

- **Peter van Reusel, Innovion, Belgium**

### **CDISC funded Support**

- **Andrea Vadakin, CDISC,**
  - **European Interchange Program support**
- **Dominik Ruisinger**
  - **European Interchange Logistics**



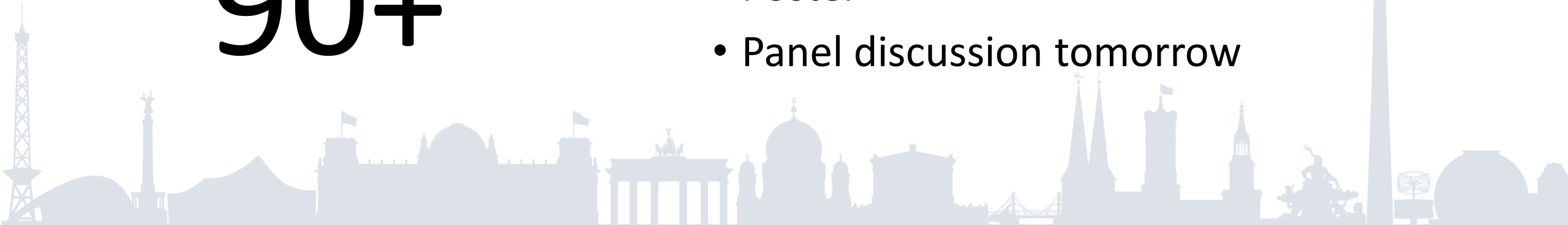
# World cloud from the abstracts



# Conference key topics

- Regulatory updates
- new / updated CDISC standards
- Global submission experiences
- Academia and Newbies
- Technology „is back“
- Poster
- Panel discussion tomorrow

90+



Enjoy the conference!

Learn & network!

Have fun!

