



WORKSHOP INVITATION

We cordially invite you to attend our workshop to be held on
May 6th, 2010 in Munich, Germany.

End-To-End CDM efficiency
from eCRF set-up to submission and archival

Thursday, May 6th, 2010
Begin: 09:45 - End: 16:00

Venue:	Mercure Hotel Munich City Center, Senefelderstraße 9, 80336 Munich
Organizer:	<i>XClinical GmbH</i>
Registration:	Participation is <u>free of charge</u> . If you are interested, please register via Fax (registration form attached) until April 30 th . After registration you will get a confirmation email including more detailed information.

We would be happy to see you on May 6th, 2010 in Munich!

WORKSHOP AGENDA

End-To-End CDM efficiency - from eCRF set-up to submission and archival

May 6th, 2010

Mercure Hotel City Center, Senefelderstraße 9, Munich, Germany

- 09:45 Breakfast and Welcome
- 10:00 Keynote: eCRF - The underestimated heart of a clinical trial
Speaker: Industry Keynote Speaker invited
Commonly eCRF Systems are seen solely as electronic input screens for clinical data. The overall potential of integrating or connecting these isolated systems with Sponsor processes and subsystems are by now unused opportunities to streamline the conduct of clinical trials.
- 10:20 Data Management implications and benefits of CDISC Data Standards
Speaker: Dr. Philippe Verplancke, XClinical GmbH, Germany
- 11:00 Coffee Break
- 11:15 Introduction to an efficient EDC workflow
Speaker: Dr. Claus Lindenau, XClinical GmbH, Germany
- 12:00 Lunch
- 13:00 Accelerating study set-up
Speaker: Dr. Philippe Verplancke, XClinical GmbH, Germany
Using library-based point-and-click tools instead of MS Word and MS Excel to set up the eCRF design and the data validation plan and to automatically generate annotated CRFs, blank CRFs, the visit matrix, the database specification, CDISC metadata, etc.
- 13:40 Combining data entry with different external data sources
Speaker: Kurt Hellstern, Hands-on GmbH, Switzerland
Modern ways of loading lab data, images, measurement device data, patient reported outcome data, etc. into an EDC/CDM system.
- 14:15 Coffee Break
- 14:30 From DB lock to data analyses, submission and archival
Speaker: Joachim Klinger, Harrison Clinical Research, Germany
SAS and/or XML-based tools can speed up the process of validation, analyses and preparation of submission-ready datasets. Study archiving can be easily done by using standardized transformations into archival PDFs based on CDISC ODM data
- 15:10 Introduction to the XClinical Data Management Partner Program
Speaker: Dr. Philippe Verplancke, XClinical GmbH, Germany



WORKSHOP REGISTRATION

Personal information

Title _____
Surname _____
Forename _____
Company _____
Position _____
Phone No. _____
Email address _____

Company information

Street _____
Postal code _____
City _____
Country _____

I would like to register for the following workshop:

“End-To-End CDM efficiency”
May 6th, 2010, Munich

Date _____ Signature _____

Please send the completed registration form via Fax to:

+49 (0)89 4522775900

Registration deadline is April 30th, 2010!

Until final confirmation of course registration XClinical cannot be held liable for any travel or accommodation expenses!