DIA Training Course on

Pre-Marketing Clinical Safety

Course #13526
18-19 April 2013
The Imperial Riding School, Renaissance Hotel, Vienna, Austria

Faculty

Dr. Jan Petracek
CEO, Consultant, PharmInvent, Czech Republic

Dr. Jan-Willem van der Velden
Director, Mesama Consulting, Switzerland

Overview

DIA is presenting an intensive course for professionals involved in management of safety information of clinical trials in the EU. Participants will be guided through all the regulations and guidelines pertinent to pre-marketing safety in the EU. The course offers an overview of all the current major methodological approaches and hands-on solutions for day-today challenges. Attendees will learn how to produce Development Safety Update Reports (DSURs), and how to bridge a Development Risk Management Plan, EU-Risk Management Plan (EU-RMP) and Risk Evaluation and Mitigation Strategies (REMS) to be ready for a marketing authorisation application.

Key Topics

- Management of adverse events
- Unblinding strategies
- SUSARs reporting
- How to inform of ethics committees
- Development safety update reports
- EudraVigilance CT module
- Risk assessment in clinical trials
- Safety risk management

Who Will Attend

- Drug safety managers, specialists and directors involved in clinical trials
- Clinical trial monitors and managers wishing to acquire deeper knowledge of drug safety
- science and regulations
- Pharmacovigilance professionals involved in pre-marketing safety

Objectives

At the conclusion of this course, participants should be able to:

- Understand key concepts of drug safety and pharmacovigilance and their application to clinical development
- Know how to comply with European regulations for clinical safety, including production,
- management and submission of an Adverse Event (AE), Serious Adverse Event (SAE), and
- Suspected Unexpected Serious Adverse Reactions (SUSARs)
- Be able to prepare DSURs
- Understand regulatory reporting requirements for products already marketed while their
- development continues
- Understand risk assessment methodology and its use in the development risk management
- plans, forming basis for EU-RMP and REMS

Continuing Education

DIA meetings and training courses are generally approved by the Commission for Professional Development (CPD) of the Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society of Pharmaceutical Medicine (SGPM) and will be honoured with credits for pharmaceutical medicine. All participants are eligible for these credits.

This course has limited capacity. Register early.

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THURSDAY | 18 APRIL 2013

08:30 REGISTRATION

08:45 INTRODUCTION AND WELCOME

9:00 Session 1

FUNDAMENTALS
- The Concepts, Principles and Terminology
- CIOMS, ICH, ISO, Investigators Brochure, Informed Consent
- European Clinical Trial Directive
- European Guidelines (Volume 10 and 9A)
- Examples of National Implementation

10:00 Session 2

PLAYERS
- Sponsor & Investigator Responsibilities
- Ethics Committees
- The National Authorities
- EMA, EU Commission, Expert working groups, GCP inspections

10:30 COFFEE BREAK

11:00 Session 3

MANAGEMENT OF ADVERSE EVENTS
- Case Capture, CRFs vs. EDC
- Organisation of a PV Unit Case Flow & EDC systems
- Assessing and coding AEs
- Good PV Practices
- Good Documentation Practices, Medical Records & Archiving
- Drug Interactions & Polypharmacy

13:00 LUNCH

14:00 Session 4

EXPEDITED REPORTING
- Expedited Reporting Rules
- EudraVigilance CT module
- Causality assessment
- SAE and SUSARs, unbliding rules

15:30 COFFEE BREAK

16:00 Session 5

AGGREGATE REPORTING
- Development Safety Update Report (ICH E2F)
- Regional - EU Annual Safety Report and US IND Annual Report
- Clinical Study Reports, ICH E3 & Lab Data

17:30 DRINKS RECEPTION

18:30 END OF DAY ONE

Unless otherwise disclosed, DIA Europe acknowledges that the statements made by speakers are their own opinion and not necessarily that of the organisation they represent, or that of the DIA Europe.

Speakers and agenda are subject to change without notice. Recording of any DIA Europe tutorial/workshop information in any type of media, is prohibited without prior written consent from DIA Europe.

FRIDAY | 19 APRIL 2013

08:30 Session 6

ORGANISATION AND OVERSIGHT
- CROs & Drug Safety
- Contractual Agreements
- Data Safety Monitoring Boards
- Quality & Key Performance Indicators
- Training
- Data Privacy
- Audits & Inspections
- Insurance
- Ethics & Conflicts of Interest

10:00 COFFEE BREAK

10:30 Session 7

MATHEMATICS OF DRUG SAFETY AND SAFETY RISK MANAGEMENT
- Mathematics of Drug Safety
- Risk Assessment in Clinical Trial
- Development Risk Management Plan
- Links to EU-RMP, REMS, DSUR and PSUR

12:00 LUNCH

13:00 Session 8

EXAMPLES AND PRACTICAL EXERCISES
- ICSR causality assessment
- SUSAR reporting
- DSUR preparation for a global trial involving EU, US and India.

14:50 WRAP-UP, END OF THE TRAINING

HOTEL INFORMATION

DIA has blocked a limited number of rooms at the following hotel:

The Imperial Riding School, Renaissance Hotel
Ungargasse 60 Vienna, 1030 Austria
Tel.: (43)151518 52 Fax: (43) 1 515188720
Email: imperial.group.reservations@renaissancehotels.com
www.imperialrenaissance.at

at a special rate of:
EUR 140.00 per room per night.
The rates are including American Buffet Breakfast and excluding service charge and VAT.

METHOD OF RESERVATIONS
To guarantee the above noted guest room rates and availability. Reservations are to be made directly with Marriott by using the link available on DIA website.

IMPORTANT
To be assured of accommodation at the hotel, registrants are recommended to complete their reservation by 20 February 2013 the latest. Reservations received after this date will be subject to availability and room rate may vary.

REGISTRATION FORM

Training Course on Pre-Marketing Clinical Safety

18-19 April 2013 I The Imperial Riding School, Renaissance Hotel, Vienna, Austria

DIA www.diahome.org

ID #13526

FEES

	Member*	Non-Member*
Industry	€ 1'365.00 ❑	€ 1'480.00 ❑
Academia/Charitable/Government/Non-profit (Full-Time)	€ 683.00 ❑	€ 798.00 ❑
Join DIA now to qualify for the member rate	€ 115.00 ❑	

*All fees will be subject to the Austrian VAT at 20%

Group discount/SME rates available. Special rates for students and patient representatives on offer, subject to avaibility – please contact DIA Europe for more information.

If DIA cannot verify your membership upon receipt of registration form, you will be charged the non-member fee.

Registration fee includes: refreshments, lunches and training course material

TOTAL AMOUNT DUE: _____

Payment is due 30 days after registration and must be paid in full by commencement of the event.

ATTENDEE DETAILS

PLEASE COMPLETE IN BLOCK CAPITAL LETTERS OR ATTACH THE ATTENDEE'S BUSINESS CARD HERE

❑ Prof ❑ Dr ❑ Ms ❑ Mr

Last Name

First Name

Company

Job Title

Address

Postal Code City

Country

Telephone

Fax

Email*

*(Required for confirmation)

DIA reserves the right to include your name and affiliation on the attendee list.

PAYMENT METHODS

Credit cards: Payments by VISA, Mastercard or AMEX can be made by completing the details below. Please note that other types of credit card cannot be accepted.

❑ **Please charge my** ❑ VISA ❑ MC ❑ AMEX

Card N°

Exp. Date /

Cardholder's Name

❑ **Bank transfers:** When DIA completes your registration, an email will be sent to the address on the registration form with instructions on how to complete the bank transfer. Payments in EURO should be addressed to "Account Holder: DIA." Please include your name, company, Event ID #13526 as well as the invoice number to ensure correct allocation of your payment.

Payments must be net of all charges and bank charges must be borne by the payer. **If you have not received your confirmation within five working days, please contact DIA Europe.**

If you require a hardcopy of our terms and conditions, please contact our Customer Service Team.

By signing below, I confirm that I agree with DIA Europe's Terms and Conditions of booking.

Date	Signature

Cancellation Policy

All cancellations must be made in writing and be received at the DIA Europe office five working days prior to the event start date. Cancellations are subject to an administrative fee:

- Full Meeting Cancellation: Industry (Member/Non-member) = € 200.00.
- Academia/Charitable/Government /Non-profit (Full-Time) (Member/Non-member) = € 100.00.
- Tutorial cancellation: € 50.00.

If you do not cancel five working days prior to the event start date and do not attend, you will be responsible for the full registration fee. DIA Europe reserves the right to alter the venue and dates if necessary. If an event is cancelled DIA Europe is not responsible for airfare, hotel or other costs incurred by registered attendees. Registered attendees are responsible for cancelling their own hotel and travel reservations.

Transfer Policy

You may transfer your registration to a colleague prior to the start of the event but membership is not transferable. Substitute attendees will be responsible for the non-member fee, if applicable. Please notify the DIA Europe office of any such substitutions as soon as possible.

Photography Policy

By attending the event, you give permission for images of you, captured during the conference through video, photo, and/or digital camera, to be used by DIA Europe in promotional materials, publications, and website and waive any and all rights including but not limited to compensation or ownership.

The DIA Europe Customer Services Team will be pleased to assist you with your registration from Monday to Friday between 08:00 and 17:00 CET.

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