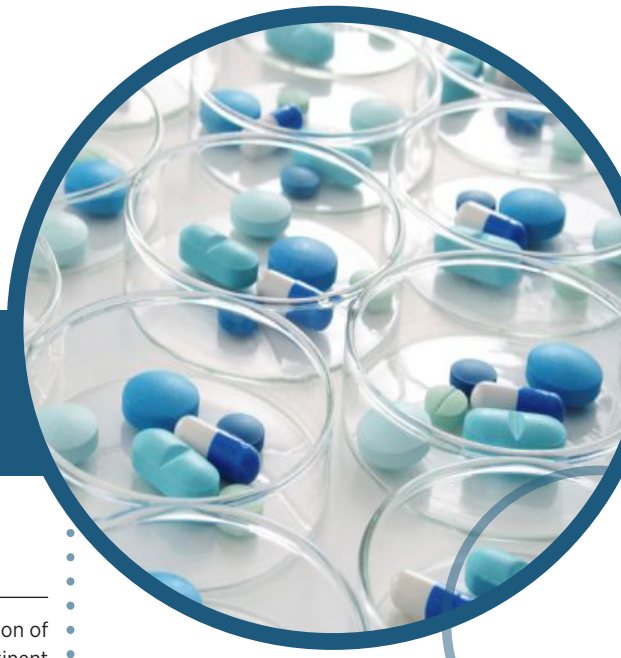
DIA Training Course on

Pre-Marketing Clinical Safety



Course #16539
26-27 January 2016
Holiday Inn – Kensington Forum, London, UK

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-to-day 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.

LEARNING OBJECTIVES

At the conclusion of this training course participants will m 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)
- 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

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

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

FACULTY

Jan Petracek
CEO, European PharmInvent, Czech Republic
Former Head of Risk Management, European Medicines Agency, EU

Michael Forstner
Managing Partner. Head of Risk Management & Business Process Management PracticeMesama Consulting International, Switzerland

CONTINUING EDUCATION

DIA meetings and training courses are generally approved by the Commission for Professional Development (ZCPD) 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.

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PharmaTrain MASTERING MEDICINES DEVELOPMENT

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DIA volunteers, members and staff provide a comprehensive catalogue of conferences, workshops, training courses, scientific publications and educational materials, throughout the year, all around the world.

DIAglobal.org

DAY 1

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**

DAY 2

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 — **COURSE ASSESSMENT**

15:20 — **END OF TRAINING COURSE**

COURSE VENUE

Holiday Inn London Kensington Forum

97 Cromwell Road

London, SW7 4DN

Tel: +44 871 942 9094

http://www.hikensingtonforumhotel.co.uk

DIA has blocked a limited number of hotel rooms for the course participants from 17 to 20 May 2015 at the rate of GBP 168.00 per single room per night including Full English Breakfast, taxes and service fee. In order to book a hotel room, please call the hotel directly and quote the booking reference "VGO".

The room rate is available until **5 April 2015** or until the room block is sold-out, whichever comes first. Cancellations received after 5 April 2015 will be subject to cancellation fee of 100% of the booking value.

REGISTRATION FORM

Pre-Marketing Clinical Safety # 16539
26-27 January 2016 | Holiday Inn London Kensington Forum | London, UK

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REGISTRATION FEES

Registration fee includes refreshment breaks and lunches and electronic access to training course material. Please check:

FEES	MEMBER	NON-MEMBER
INDUSTRY	€ 1'450.00 ❑	€ 1'605.00 ❑
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	€ 725.00 ❑	€ 880.00 ❑

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

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

DIA MEMBERSHIP

All non-members fees include a one year membership option. If you registered at one of the non-member rates noted above, you will automatically become a DIA member. Join DIA now to qualify to save on future events and to receive all the benefits of membership. Visit www.diaglobal.org and click on Membership for more details.

If you do not want a membership, please indicate your preference below:

❑ I do not want complimentary membership

The DIA Europe, Middle East & Africa Contact Centre Team will be pleased to assist you with your registration from Monday to Friday between 08:00 and 17:00 CET. Tel. :+41 61 225 51 51 Fax: +41 61 225 51 52

Email: EMEA@DIAglobal.org Mail: DIA Europe, Middle East & Africa, Küchengasse 16, 4051 Basel, Switzerland
Web: www.DIAglobal.org

Cancellation Policy

All cancellations must be made in writing and be received at the DIA Europe, Middle East and Africa office four weeks prior to the event start date. Cancellations are subject to an administrative fee:

- Industry (Member/Non-member) € 200.00
- Academia/Charitable/Government/Non-profit (Full-time) (Member/Non-member) € 100.00

If you do not cancel four weeks prior to the event start date and do not attend, you will be responsible for the full registration fee.
DIA reserves the right to alter the venue and dates if necessary. If an event is cancelled or postponed, DIA 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 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 in promotional materials, publications, and website and waive any and all rights including but not limited to compensation or ownership.

ATTENDEE DETAILS

Please complete in block capital letters or attach the attendee's business card here.

❑ Prof ❑ Dr ❑ Ms ❑ Mr

Last Name

First Name

Job Title

Company

Address

Postal Code

City

Country

Telephone Number Fax Number

email (Required for confirmation) Attendee email (Required for course material access)

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, Course ID # 16539 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, Middle East and Africa.**

By signing below, I confirm that I agree with DIA's Terms and Conditions of booking. These are available from the office or on http://www.diaglobal.org/EUTerms

Date	Signature