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 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

Participants will complete a knowledge check at the end of the course and will be provided with feedback to ensure learning objectives are attained.

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 Services, Czech Republic
Former Head of Risk Management, European Medicines Agency, EU

Michael Forstner
Managing Partner, Head of Risk Management & Business Process Management Practice
Mesama 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.

DIA is an authorised training organisation accredited under the number 11 99 53383 75 to the Préfet of Ile-de-France.
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

12:00 LUNCH

13:00 SESSION 4
EXPEDITED REPORTING
• Expedited Reporting Rules
• EudraVigilance CT module
• Causality assessment
• SAE and SUSARs, unblinding rules

15:00 END OF TRAINING COURSE

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.

15:00 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 25 to 27 January 2016 at the rate of GBP 178.00 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 “VCX”.

The room rate is available until 21 December 2016 or until the room block is sold-out, whichever comes first.

Cancellations received after 21 December 2015 will be subject to cancellation fee of 100% of the booking.

Unless otherwise disclosed, DIA 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. Speakers and agenda are subject to change without notice. Recording during DIA sessions is strictly prohibited without prior written consent from DIA.
**REGISTRATION FORM**

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

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

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<th>NON-MEMBER</th>
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<td>ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)</td>
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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

**ATTENDEE DETAILS**
Please complete in block capital letters or attach the attendee’s business card here.

☑ Prof ☐ Dr ☐ Ms ☐ Mr

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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

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☑ 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 ____________________________

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