OVERVIEW

The 22nd edition of this annual training course, considered by many experts as one of the pillars of medical training in pharmacovigilance, focuses on how to use medical knowledge in the diagnosis and management of selected Adverse Drug Reactions (ADRs). ADRs of the main systems / organs will be presented and explained by experts in their medical domain in order to provide practical clues to understand and manage the serious reactions in clinical trials as well as in post authorisation.

A medical approach is needed for the identification, labelling and understanding of ADR mechanisms. It can also help assess the probability that a medicinal product may have played a role in the occurrence of an adverse event. This is particularly useful for the first 2 or 3 cases of serious reactions occurring during clinical trials when important decisions must be taken regarding a new drug under development.

The medical approach presented in this training course will take into consideration the conclusions of international or national consensus meetings on adverse drug reactions.

This training course is designed to be followed as a stand-alone course for those who want to increase their knowledge on ADRs or as an advised complement to the course titled Diagnosis and Management of Drug-Induced Liver Injury (DILI), which is taking place in the same venue directly after the ADR Training Course.

LEARNING OBJECTIVES

At the conclusion of this training course participants will be able to:

• Classify and define drug-induced affective symptoms, skin reactions, QT interval prolongation, blood disorders and acute renal failure
• Describe their clinical patterns and appropriate investigations
• Discuss the main non drug causes of the described disorders

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

WHO WILL ATTEND

All healthcare professionals involved in the monitoring and assessment of adverse drug reactions occurred in drug development or after marketing; EU-GPPV, staff in charge of pharmacovigilance and/or drug safety investigators, staff in charge of clinical trials and safety studies, clinical research associates and monitors.

FACULTY

Gaby Danan (course director)
Hepatologist, Pharmacovigilance Expert
France

Philippe Nuss
Psychiatrist, Hopital Saint-Antoine, Service de Psychiatrie, France

Sarah Walsh
Consultant Dermatologist, King’s College Hospital NHS Foundation Trust, United Kingdom

CONTINUING EDUCATION

The Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the United Kingdom has accredited this training course with 8 CPD credits.

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited this training course with 8 credits.

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

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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

08:00  REGISTRATION

08:30  INTRODUCTION
MEDICAL APPROACH IN CLINICAL SAFETY AND PHARMACOVIGILANCE
Gaby Danan
The four pillars of the medical evaluation

09:15  SESSION 1
DRUGS-ASSOCIATED AFFECTIVE SYMPTOMS
Philippe Nuss
Clinical aspects, diagnosis, causality assessment and main principles of risk management

10:30  COFFEE BREAK

11:00  SESSION 2
DRUG-INDUCED SERIOUS SKIN REACTIONS
Sarah Walsh

12:30  LUNCH

13:30  SESSION 3
DRUG-INDUCED QT PROLONGATION
Gaby Danan
• Definitions of QT interval prolongation
• Risks associated with QT prolongation
• Physiology of QT interval
• How to evaluate drug-induced QT variations

14:45  COFFEE BREAK

15:15  SESSION 4
DRUG-INDUCED BLOOD DISORDERS
Gaby Danan
• Definition, mechanism, laboratory tests
• Causality assessment criteria

16:30  DRINKS RECEPTION

17:30  END OF DAY ONE

DAY 2

09:00  SESSION 5
DRUG-INDUCED ACUTE RENAL FAILURE
Gaby Danan
• Clinical aspects and diagnosis
• Case histories and discussion

10:30  COFFEE BREAK

11:00  SESSION 6
IATROGENIC AND DRUG-INDUCED RESPIRATORY REACTIONS
Gaby Danan

12:00  END OF TRAINING COURSE

Training Course Venue
The training course will take place at:

Holiday Inn London Kensington Forum
97 Cromwell Road
London, SW7 4DN
Tel: +44 871 942 9100
http://www.hikensingtonforumhotel.co.uk

DIA has blocked a limited number of hotel rooms for the course participants from 12 to 15 June 2016 at the rate of GBP 160.00 per standard double room for single use per night including full English breakfast, taxes and service fee.

In order to book a hotel room, please contact the hotel directly and quote the booking reference “VBX”.

The room rate is available until 9 May 2016 or until the room block is sold-out, whichever comes first.

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
Medical Approach in Diagnosis and Management of ADRs # 16540
13-14 June 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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<tr>
<th>FEES</th>
<th>MEMBER</th>
<th>NON-MEMBER</th>
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<tr>
<td>INDUSTRY</td>
<td>€ 1'240.00</td>
<td>€ 1'395.00</td>
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<tr>
<td>ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)</td>
<td>€ 620.00</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.

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 # 16540 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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