

# DIA Training Course on Medical Approach in Diagnosis and Management of ADRs

13-14 June 2016

Holiday Inn London Kensington Forum, London, United Kingdom

## 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

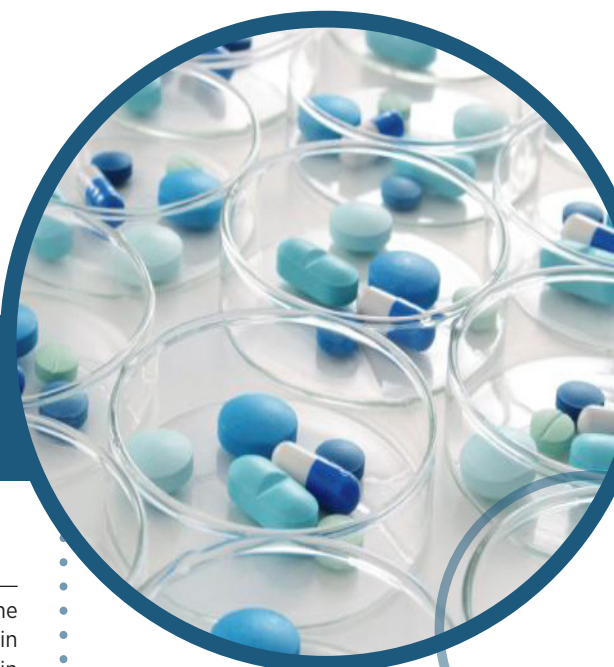
At the conclusion of this training course participants will be able to:

- 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-QPPV, 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, Hôpital 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.

## DEVELOP. INNOVATE. ADVANCE.

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MASTERING MEDICINES DEVELOPMENT

**DAY 1****08:00 REGISTRATION****08:30 INTRODUCTION****MEDICAL APPROACH IN CLINICAL SAFETY AND PHARMACO-VIGILANCE***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.



# 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:

FEES	MEMBER	NON-MEMBER
INDUSTRY	€ 1'240.00 <input type="checkbox"/>	€ 1'395.00 <input type="checkbox"/>
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	€ 620.00 <input type="checkbox"/>	€ 775.00 <input type="checkbox"/>

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](http://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](mailto:EMEA@DIAglobal.org) Mail: DIA Europe, Middle East & Africa, K uchengasse 16, 4051 Basel, Switzerland  
Web: [www.DIAglobal.org](http://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 # 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