

# Medical Approach in Diagnosis and Management of ADRs

28-29 November 2017

Mercure Paris La Défense Grande Arche, Paris, France



## OVERVIEW

The 24th edition of this 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 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.

## LEARNING OBJECTIVES

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

- Classify and define drug-induced affective symptoms, skin reactions, QT interval prolongation, blood disorders, drug-induced liver injury (DILI), and acute renal failure
- Describe their clinical patterns and appropriate investigations
- Discuss the main non drug causes of the described disorders
- Understand how to approach causality assessment in DILI

Participants will complete online knowledge check after the course and will be provided with feedback to ensure learning objectives are attained.

*Participants are kindly requested to take necessary steps in order to attend the course until the end.*

## WHO WILL ATTEND

This training course is designed for those who want to increase their knowledge on medical aspects of ADRs, especially 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

Hopital Saint-Antoine, Service de Psychiatrie, France

### **Laurence Valeyrie-Allanore**

Dermatologist, Saint Mande, France

## DAY 1

08:00 REGISTRATION

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08:30 INTRODUCTION

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### MEDICAL APPROACH IN CLINICAL SAFETY AND PHARMACOVIGILANCE

*Gaby Danan*

The four pillars of the medical evaluation

09:00 SESSION 1

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### 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

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### DRUG-INDUCED SERIOUS SKIN REACTIONS

*Laurence Valerie-Allanore*

12:30 LUNCH

13:30 SESSION 3

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### DRUG-INDUCED QT PROLONGATION

*Gaby Danan*

- Definition of QT interval prolongation
- Risks associated with QT prolongation
- How to evaluate drug-induced QT variations

14:45 COFFEE BREAK

15:15 SESSION 4

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### DRUG-INDUCED BLOOD DISORDERS

*Gaby Danan*

- Definition, mechanisms, laboratory tests
- Causality assessment criteria

16:45 NETWORKING RECEPTION

17:45 END OF DAY ONE

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## DAY 2

08:30 SESSION 5

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### DRUG-INDUCED ACUTE RENAL FAILURE

*Gaby Danan*

- Clinical aspects and diagnosis

10:00 COFFEE BREAK

10:30 SESSION 6

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### DRUG-INDUCED RESPIRATORY REACTIONS

*Gaby Danan*

11:30 SESSION 7A

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### DRUG-INDUCED LIVER INJURY (DILI)

*Gaby Danan*

- Definitions of liver injuries

12:00 LUNCH

13:00 SESSION 7A AND 7B

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### DRUG-INDUCED LIVER INJURY (DILI)

*Gaby Danan*

- Mechanisms of DILI
- Diagnosis of DILI

14:00 COFFEE BREAK

14:30 SESSION 7B AND 7C

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### DRUG-INDUCED LIVER INJURY (DILI)

*Gaby Danan*

- Causality assessment criteria
- RUCAM: description and exercises

16:00 END OF TRAINING COURSE

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### Plan Your Team's Professional Development

Why not take advantage and train your whole department (or even across different departments!) and benefit from increased:

- Focus
- Flexibility
- Convenience
- Cost Effectiveness

For more information please contact [EMEA@DIAglobal.org](mailto:EMEA@DIAglobal.org)

## Training Course Venue

### PARIS LA DÉFENSE GRANDE ARCHE

17/20 Esplanade Ch. de Gaulle - Rue des Trois Fontanot  
92000 Nanterre/Paris, France

Tel: +33 8 2580 5959

Fax: +33 1 4725 4624

Email: [H1982@accor.com](mailto:H1982@accor.com)

[www.mercure.com/gb/hotel-1982-mercure-paris-la-defense-grande-arche-hotel/index](http://www.mercure.com/gb/hotel-1982-mercure-paris-la-defense-grande-arche-hotel/index)

DIA has blocked a limited number of hotel rooms at the rate of EUR 180.00 per standard room per night including breakfast and VAT, excl. City-Tax. If you would like to make a booking, please fill in the booking form available on [www.DIAGlobal.org/ADR](http://www.DIAGlobal.org/ADR) and send it per email to [H1982@accor.com](mailto:H1982@accor.com) with a reference "DIA". Note: The hotel is located right above the train station, and it is a bit noisy.

The room rate is available until 27 October 2017 or until the room block is sold-out, whichever comes first.

### HOW TO GET THERE

From Charles de Gaulle airport take the Blue train line B towards city centre and get off at Chatelet.

Change there to Red train line A towards Cergy/Poissy/St. Germain en-Laye and get off at Nanterre Prefect.

The hotel is located right next to the train station.

[Paris train/metro map](#)



## About DIA

DIA is the global connector in the life sciences product development process. Our association of more than 18,000 members builds productive relationships by bringing together regulators, innovators, and influencers to exchange knowledge and collaborate in an impartial setting. DIA's network creates unparalleled opportunities for exchange of knowledge and has the inter-disciplinary experience to prepare for future developments.

The dedicated efforts of DIA staff, members and speakers enable DIA to provide a comprehensive catalogue of conferences, workshops, training courses, scientific publications and educational materials. DIA is a global community representing thousands of stakeholders working together to bring safe and effective products to patients.

DIA is an independent, non-profit organisation has its Global Center in Washington, DC, USA with the European office in Basel, Switzerland, and additional regional offices in Horsham, Pennsylvania, USA; Tokyo, Japan; Mumbai, India; and Beijing, China

## Continuing Education

The Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the United Kingdom has accredited this training course with 11.75 CPD credits.

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited this training course with 11.75 credits.



## Group Discounts

Register 3 individuals from the same company and receive a 50% discount for a 4th! All 4 individuals must register and prepay at the same time without exception. DIA will apply the value of the lowest applicable fee to this discounted registration; it does NOT include fees for optional events or DIA membership. You may substitute group participants of the same membership status at any time; however, administrative fees may be incurred.

Group registration is not available online and only available for the industry rate.

To take advantage of this offer, please print the registration form for each of the four registrants from your company. Include the names of all four group registrants on each of the forms and return them together to DIA.

For groups of 5 or more individuals, please contact [EMEA@DIAGlobal.org](mailto:EMEA@DIAGlobal.org) for a custom group rate.

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# REGISTRATION FORM

Medical Approach in Diagnosis and Management of ADRs # 17539  
28-29 November 2017 | Mercure Paris La Défense Grande Arche | Paris, France



## REGISTRATION FEES

Registration fee includes refreshment breaks, lunches and electronic access to training course material. Please note that the full amount must be received by DIA by commencement of the course to get the electronic access to the material. Please check:

FEES	MEMBER	NON-MEMBER
INDUSTRY	€ 1'450.00 <input type="checkbox"/>	€ 1'605.00 <input type="checkbox"/>
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	€ 725.00 <input type="checkbox"/>	€ 880.00 <input type="checkbox"/>

### All registration fees are subject to applicable French VAT

Please enter your company's French VAT number: \_\_\_\_\_

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, Kuchengasse 16, 4051 Basel, Switzerland

**Web:** [www.DIAglobal.org](http://www.DIAglobal.org)

## TERMS AND CONDITIONS

### 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 AND VIDEO 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

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 #17539 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