DIA Learning

Medical Approach in Diagnosis and Management of ADRs

11-12 December 2018
Mercure Paris La Défense Grande Arche Hotel, Nanterre/Paris, France

OVERVIEW

The 26th 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 a 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

PharmaTrain
MASTERING MEDICINES DEVELOPMENT

DAY 1

08:00 REGISTRATION

08:30 INTRODUCTION

MEDICAL APPROACH IN CLINICAL SAFETY AND PHARMACOVIGILANCE

Gaby Danan

The four pillars of the medical evaluation

09:30 SESSION 1

DRUG-INDUCED RESPIRATORY REACTIONS

Gaby Danan

10:30 COFFEE BREAK

11:00 SESSION 2

DRUG-INDUCED SERIOUS SKIN REACTIONS

Laurence Valeyrie-Allanore

12:30 LUNCH

13:30 SESSION 3

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

DRUG-INDUCED BLOOD DISORDERS

Gaby Danan

- Definition, mechanisms, laboratory tests
- Causality assessment criteria

16:45 NETWORKING RECEPTION

17:45 END OF DAY ONE

DAY 2

08:30 SESSION 5

DRUG-INDUCED LIVER INJURY (DILI)

Gaby Danan

- Definitions of liver injuries
- Mechanisms of DILI
- Diagnosis of DILI

10:00 COFFEE BREAK

10:30 SESSION 5 CONTINUED

DRUG-INDUCED LIVER INJURY (DILI)

Gaby Danan

- Causality assessment criteria
- RUCAM: description and exercises

12:00 LUNCH

13:00 SESSION 6

DRUG-INDUCED ACUTE RENAL FAILURE

Gaby Danan

- Clinical aspects and diagnosis

14:30 COFFEE BREAK

15:00 SESSION 7

DRUGS-ASSOCIATED AFFECTIVE SYMPTOMS

Philippe Nuss

Clinical aspects, diagnosis, causality assessment and main principles of risk management

16:00 END OF TRAINING COURSE

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 Basel@diaglobal.org

Training Course Venue

PARIS LA DÉFENSE GRANDE ARCHE

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

Tel: +33 8 2580 5959
Fax: +33 1 4725 4624
Email: H1982@accor.com

DIA has blocked a limited number of hotel rooms at the rate of EUR 155.00 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 and send it per email to aziza.elkharraze@accor.com with a reference "DIA". The room rate is available until 10 November 2018 or until the room block is sold-out, whichever comes first.
Note: The hotel is located right above the train station, and it is a bit noisy.

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 (the Nanterre Prefect station/hotel is located just outside this map, left from the square A2)

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

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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.

SwAPP Swiss Association of Pharmaceutical Professionals

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 Basel@diaglobal.org for a custom group rate.

REGISTRATION FORM

Medical Approach in Diagnosis and Management of ADRs # 18539
11-12 December 2018 | Mercure Paris La Défense Grande Arche Hotel | Paris, France

DIA Learning

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

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.

A special discount for SMEs on the standard fee is available for a limited number of places. To proof your status as an SME, a confirmation of the European Medicines Agency is necessary. Please contact DIA for more information.

DIA MEMBERSHIP

All non-member fees include a one year membership option. If you registered at one of the non-member rates, you have the opportunity to **become a DIA member** at no additional cost.

To explore membership benefits, please click www.DIAglobal.org/Membership. If you want a membership, please indicate your preference below.

❑ **I would like to receive a one year complimentary DIA membership at no additional cost**

The DIA 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: Basel@diaglobal.org **Mail:** DIA, Küchengasse 16, 4051 Basel, Switzerland
Web: www.DIAglobal.org

TERMS AND CONDITIONS

Cancellation Policy

All cancellations must be made in writing and be received at the DIA 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.

Event Stream and recording

If you attend a DIA event, we make video and audio recordings of events (both face-to-face and online) that may include your participation in the event, including your image, questions and comments. To view our full photography and video recording policy, click www.DIAglobal.org/Photography-Policy.

Privacy Policy

DIA respects the privacy of all of its members and customers. To view our privacy policy, click www.DIAglobal.org/Privacy. You agree that your personal data will be transferred to DIA in the US.

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 #18539 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.**

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