Medical Approach in Diagnosis and Management of ADRs

Course# 12565
15-16 October 2012
Mercure Paris Montmartre Sacre Coeur, Paris, France

Programme Chairperson

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Faculty

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Dr Philippe Nuss
Hôpital Saint-Antoine, Paris, France

This training course has been awarded with 12 CPD credits from the Faculty of Pharmaceutical Medicine (FPM) of the Royal College of Physicians (RCP) of the United Kingdom. Medical practitioners who are eligible for credits can click on http://www.fpm.org.uk/revalidationcpd/CPD/cpd for more information. If you are already a CPD member, please go directly to http://cpd.fpm.org.uk to claim your credits.

Course Overview

The 19th 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).

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 during this training course is mainly based on the conclusions of international or national consensus meetings on adverse drug reactions.

Learning Objectives

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

- Classify and define drug induced disorders for each system organ.
- Describe their clinical patterns and different etiological investigations.
- Discuss specifically drug-induced liver injury during clinical trials and in post-marketing.

Who Will Attend

All healthcare professionals involved in the monitoring and assessment of adverse drug reactions occurring in development or after marketing; EU–QPPV, people in charge of pharmacovigilance, investigators, clinical research associates and monitors.

Continuing Education

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited the training course on 'Medical Approach in Diagnosis and Management of ADRs' with 13 credits.

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MONDAY | 15 OCTOBER 2012

Chairperson:
Gaby Danan

07:30 **REGISTRATION**

08:30 **Introduction**

MEDICAL APPROACH IN CLINICAL SAFETY AND PHARMACOVIGILANCE

Gaby Danan, MD, PhD

The four pillars of the medical evaluation

09:15 **Session 1**

DRUGS-ASSOCIATED AFFECTIVE SYMPTOMS

Dr 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

Dr Laurence Allanore

12:30 **LUNCH**

14:00 **Session 3**

DRUG-INDUCED QT PROLONGATION

- Drug-induced QT interval prolongation: why concern?
- Physiology of QT interval: multiple sources of variability
- How to evaluate drug-induced QT variations

15:15 **COFFEE BREAK**

15:45 **Session 4**

DRUG-INDUCED BLOOD DISORDERS

- Definition, mechanism, laboratory tests
- Causality assessment criteria
- Drug-induced myelodysplasia
- Role of pharmacogenetics

17:00 **RECEPTION**

18:00 **END OF DAY 1**

TUESDAY | 16 OCTOBER 2012

Chairperson:
Gaby Danan

08:30 **Session 5**

DRUG-INDUCED ACUTE RENAL FAILURE

- Clinical aspects and diagnosis
- Case histories and discussion

10:00 **COFFEE BREAK**

10:30 **Session 6**

IATROGENIC AND DRUG-INDUCED RESPIRATORY REACTIONS

Prof. Philippe Camus

11:30 **Session 7**

DRUG-INDUCED LIVER INJURY

Prof. Dominique Larrey

Clinical Aspects and Diagnosis of Drug-Induced Liver Injury

13:00 **LUNCH**

14:00 **Session 7 continued**

RESULTS OF THE INTERNATIONAL CONSENSUS MEETING ON LIVER INJURIES AND SIGNAL DETECTION

Gaby Danan, MD, PhD

- Definitions of terms used to designate liver injuries
- Causality assessment criteria

15:30 **COFFEE BREAK**

15:50 **Session 7 continued**

DRUG-INDUCED LIVER INJURY: CAUSALITY ASSESSMENT AND CASE STUDIES

Gaby Danan, MD, PhD

- Scoring causality of case safety reports involving liver injury

17:00 **END OF THE TRAINING COURSE**

HOTEL INFORMATION

DIA has blocked a limited number of rooms at the following hotel:

Mercure Paris Montmartre Sacre Coeur
3 rue Caulaincourt
75018 - PARIS
France

Email: H0373@accor.com
Tel: 0033 8 258 0 7979
Fax: 0033 1 446 97071
Website: http://www.mercure.com/gb/hotel-0373-mercure-paris-montmartre-sacre-coeur/index.shtml

at the special rate of:
EUR 173.00 per standard room, single occupancy inclusive of breakfast buffet and VAT

To make your reservation please contact the hotel directly.

Important:
Please complete your reservation by 14 September 2012. Reservations received after this date will be subject to hotel availability and room rate may vary.

Cancellation:
Cancellations of reservations are possible until 73 hours prior to arrival. Any cancellation made less than 72 hours prior to arrival will be charged for the

DIA Upcoming Training Courses in Safety and Pharmacovigilance

■ **Benefit/Risk Management**
24-25 May 2012 | Munich, Germany | ID 12561

■ **EMA Excellence in Pharmacovigilance: Clinical trials and post-marketing**
13-17 February 2012 | London, United Kingdom | ID 12551
1-5 October 2012 | Prague, Czech Republic | ID 12566

■ **EudraVigilance Information Day at the European Medicines Agency**
27 April 2012 | London, United Kingdom | ID 12533
21 September 2012 | London, United Kingdom | ID 12534

■ **How to Prepare for Pharmacovigilance Audits and Inspections**
8-9 May 2012 | Berlin, Germany | ID 12556
November 2012 | Location to be confirmed | ID 12575

■ **IDMP Information Day at the European Medicines Agency**
8 May 2012 | London, United Kingdom | ID 12537
4 December 2012 | London, United Kingdom | ID 12536

■ **Information Day on the Implementation of Electronic Submission of Medicinal Product Information in the EU at the European Medicines Agency**
21 February 2012 | London, United Kingdom | ID 12581

■ **ICSR Information Day at the European Medicines Agency**
4 May 2012 | London, United Kingdom | ID 12535

■ **Introduction to Pharmacovigilance and Electronic Transmission of Individual Case Safety Reports (ICSR) for the Use of Eudravigilance at the European Medicines Agency**
17 April 2012 | London, United Kingdom | ID 12538
16 October 2012 | London, United Kingdom | ID 12539
20 November 2012 | London, United Kingdom | ID 12540

■ **Introduction to Signal Detection and Data Mining in Pharmacovigilance**
7-8 May 2012 | Berlin, Germany | ID 12555
November 2012 | Location to be confirmed | ID 12574

■ **Medical Approach in Diagnosis and Management of ADRs**
15–16 October 2012 | Paris, France | ID 12565

■ **Practical Guide for Pharmacovigilance: Clinical trials and post-marketing**
21-23 May 2012 | Berlin, Germany | ID 12562

■ **Pre-Marketing Clinical Safety**
26-27 April 2012 | Prague, Czech Republic | ID 12558

■ **EudraVigilance (EV) and Extended EudraVigilance Medicinal Product Dictionary (XEVMPD)**
Courses throughout the year | European Medicines Agency, London, United Kingdom and selected European cities.
For course details on EV, please visit www.diahome.org > Training > EudraVigilance > Click on > Related Courses

REGISTRATION FORM

Medical Approach in Diagnosis and Management of ADRs
15-16 October 2012 | Mercure Paris Montmartre Sacre Coeur, Paris, France

ID # 12565

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If DIA cannot verify your membership upon receipt of registration form, you will be charged the non-member fee. Registration fee includes course material. The fee is inclusive of lunch and coffee breaks of EUR 125.00 per day. * All fees are subject to local French VAT of 19.6%

CATEGORY	Member Fee*		Non-Member Fee*
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__ Professional Education & Training
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__ IT/Validation

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Payments must be net of all charges and bank charges must be borne by the payer.

CANCELLATION POLICY

Cancellations must be made in writing and be received at the DIA Europe office five working days prior to the course start date

Cancellations are subject to an administrative fee:
Full Meeting Cancellation: Industry (Member/Non-member) = € 200.00 - Government/Academia/Non-profit (Member/Non-member) = € 100.00
If you do not cancel five working days prior to the course start date and do not attend, you will be responsible for the full registration fee. DIA Europe reserves the right to alter the venue and dates if necessary. If an event is cancelled DIA Europe 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 Europe office of any such substitutions as soon as possible.

IMPORTANT: **Hotel and travel reservations should be made ONLY after receipt of written registration confirmation from DIA Europe. If you have not received your confirmation within five working days, please contact DIA Europe.**

HOW TO REGISTER

The DIA Europe Customer Services Team will be pleased to assist you with your registration. Please call us on +41 61 225 51 51 from Monday to Friday between 08:00 and 17:00 CET.

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