DIA Training Course on

Diagnosis and Management of Drug-Induced Liver Injury (DILI)

Course #14544 23-24 September 2014 Hotel Novotel Paris Charenton, France



Faculty

Gaby Danan, MD, PhD (Course Director) Hepatologist, Pharmacovigilance Expert, France

Prof. Dominique Larrey
Professor of Hepatology, Head of Liver and
Transplantation Unit,
Hôpital Saint-Eloi, France

Special Combo Discount

Register for both the *Diagnosis and Management* of *Drug-Induced Liver Injury (DILI)* and *Medical Approach in Diagnosis and Management of ADRs* training courses and save! See registration form on the back.

Continuing Education

DIA meetings and trainings are generally approved by the Commission for Professional Development (CPD) of the Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society of Pharmaceutical Medicine (SGPM) and will be honoured with credits for pharmaceutical medicine. All participants are eligible for these credits and certificates are available

This course has limited capacity. Register early.

Overview

This new DIA training course is entirely dedicated to Drug-Induced Liver Injury (DILI). It is led by a Hepatologist with extensive experience in clinical assessment of DILI and who published 'RUCAM' the widely used causality assessment method of DILI. The course will cover the progress that has been made in the clinical detection and prevention of DILI in clinical trials and in post marketing phase. Regulatory guidelines need to be understood for an optimal assessment of DILI cases. Better use of typical tools will be emphasised in order to improve patient safety and drug monitoring in new drug development, especially in large populations. This course will provide tools, explanations, examples and several exercises for a better understanding of DILI and how best to apply that knowledge in day to day work.

This training course is designed to be followed as a stand-alone course for those who want to increase their knowledge on DILI or as an advised complement to the course titled *Medical approach in diagnosis* and management of ADRs, which is taking place in the same venue directly before the DILI Training Course

Who Will Attend

All healthcare professionals involved in the monitoring and assessment of DILI occurring in development or after marketing:

- EU Qualified Persons for Pharmacovigilance
- People in charge of pharmacovigilance in regulatory authorities and in companies
- · Safety assessors in clinical trials and postmarketing
- Investigators
- Clinical Research Associates

Learning Objectives

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

- Define and classify Drug-Induced Liver Injuries
- Describe DILI clinical patterns and aetiological investigations
- Discuss specifically DILI during clinical trials and in post-marketing
- · Assess causality of DILI

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 headquartered 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.

For more information, visit www.diahome.org $\,$ or call DIA Europe +41 61 225 51 51.

PharmaTrain recognised





DAY 1

13:00 REGISTRATION OPENS

14:00 Session 1

THE LIVER: FUNCTIONAL ANATOMY AND PHYSIOLOGY CONCEPTS

Fundamentals of liver functional anatomy and physiology needed to understand mechanisms for DILI

15:30 COFFEE BREAK

16:00 Session 2

EPIDEMIOLOGY, DEFINITIONS AND CLASSIFICATION OF DILI

- Current biomarkers of DILI: Description and limitations
- · DILI Risk factors

17:30 Course Assessment

17:40 DRINKS RECEPTION

18:15 END OF DAY ONE

DAY 2

09:00 Session 3

CLINICAL ASPECTS OF DILI AND "HY'S LAW"

- Description
- Limitations
- Pitfalls
- · Case studies

10:30 COFFEE BREAK

11:00 Session 4

CAUSALITY ASSESSMENT OF DILI

- Causality assessment criteria
- Methods, with focus on RUCAM
- Exercises

12:30 LUNCH BREAK

13:30 Session 5

DILI: INDIVIDUAL AND AGGREGATED DATA

- · Data elements to collect
- Data analysis principles

15:00 COFFEE BREAK

15:30 Session 6

HOW TO MONITOR AND PREVENT DILI IN POST AUTHORISATION PHASE

- Principles
- Examples

16:30 QUESTIONS AND ANSWERS

ASSESSMENT: Multiple choice questions

16:30 Questions and answers

17:20 Course Assessment

17:30 END OF TRAINING COURSE

Unless otherwise disclosed, DIA Europe 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 Europe. Speakers and agenda are subject to change without notice. Recording during DIA Europe sessions is strictly prohibited without prior written consent from DIA Europe.

HOTEL INFORMATION

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

Hotel Novotel Paris Charenton

3-5 place des Marseillais 94227 CHARENTON LE PONT FRANCE

Tel (+33)1/46766060 Fax (+33)1/49776800 E-mail H1549@accor.com

Wehsite

http://www.novotel.com/gb/hotel-1549-novotel-paris-charenton/index.shtml

at the rates of EUR 150.00 per room inclusive of breakfast and VAT.

at the rates of EUR 150.00 per room inclusive of breakfast and exclusive of VAT. To make your reservation please use the hotel booking form available on the DIA website.

Important: The room rate is available until 11 August 2014 or until the group block is sold-out, whichever comes first.

In case of cancellation:

The room can be cancelled 43 hours prior arrival, after that the credit card will be charged for the 1st night.

The Hotel Novotel Paris Charenton is located 10 minutes from Gare de Lyon train station, the vibrant Bastille district & Bercy. The liberté metro station (line 8) opposite the hotel gives direct access to Paris's main attractions like Place de la Concorde, Eiffel Tower, Opéra, etc.

Safety and Pharmacovigilance

■ Signal Management in Pharmacovigilance

21-22 May 2014 | Prague, Czech Republic | ID 14534 November 2014 | Paris, France I ID 14549

■ Pre-Marketing Clinical Safety

16-17 June 2014 | Amsterdam, The Netherlands | ID 14539

■ Post-Authorisation Safety Studies (PASS) NEW OFFERING!

18-19 June 2014 | Amsterdam. The Netherlands | ID 14535

 Medical Approach in Diagnosis and Management of ADRs 22-23 September 2014 | Paris, France LID 14540

Diagnosis and Management of Drug-Induced Liver Injury (DILI) 23-24 September 2014 | Paris, France | |D 14544

■ ICH Endorsed Pharmacovigilance

21 October 2014 | Dakar, Senegal I ID 14559 November 2014 | Algiers, Algeria I ID 14560

■ How to Prepare for Pharmacovigilance Audits and Inspections
November 2014 | Paris, France | ID 14550

European Medicines Agency Information Days and Courses

■ PSUR Information Day

29 April 2014 | London, United Kingdom I ID 14504

■ ICSR Information Day

13 May 2014 | London, United Kingdom | ID 14502

- Excellence in Pharmacovigilance: Clinical trials and post-marketing 13-17 October 2014 | London, United Kingdom I ID 14548
- MedDRA Information Day

November 2014 | London, United Kingdom

■ EnCePP Information Day

Autumn 2014 | London, United Kingdom | ID 14503

REGISTRATION FORM

DIA Training Course on Diagnosis and Management of Drug-Induced Liver Injury (DILI) 23-24 September 2014 | Hotel Novotel Paris Charenton, France



FEES		Member*	Non-Member*
I would like to register for the course (only): Diagnosis and Management of Drug-Induced Liver Injur	y (DILI)		
Industry State Communication of the Communication o		€ 1′220.00 □	€ 1′350.00 □
Academia/Charitable/Government/Non-profit (Full-time)	0 10010 144 / 14 1 / 10	€ 610.00 □	€ 740.00 □
I would like register for the <i>Diagnosis and Management of Drug-Induced Liver Injury (DILI)</i> (23-24 Sept. 2014) and <i>Medical Aproach in Diagnosis and Management of ADRs</i> (22-23 Sept. 2014) courses to benefit from a combo discount:			
Industry		€ 1'950.00 □	€ 2'080.00 □
Join DIA now to qualify for the member rate € 130.00 □			
*All fees are subject to French VAT at 20 %. Please advise your French VAT number:			
If DIA cannot verify your membership upon receipt of registration form, you will be charged the non-member fee.			
Group discount/SME rates available. Special rates for students and patient representatives on offer, subject to availability – please contact DIA Europe for more information. Registration fee includes: refreshments, lunches and training course material. Payment is due 30 days after registration and must be paid in full by commencement of the course.			
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ATTENDED DETAILS			
Please complete in block capital letters or attach the attendee's business card here.		A, Mastercard or AMEX can be ma other types of credit card cannot be	, ,
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	have not received your confirmation within five working days, please contact DIA Europe.		
Fax			
	By signing below, I confirm that I agree with DIA Europe's Terms and Conditions of booking.		
Email*		ice or on http://www.diahome.org/	
*(Required for confirmation)	Date	Signature	
DIA reserves the right to include your name and affiliation on the attendee list.			

Cancellation Policy

All cancellations must be made in writing and be received at the DIA Europe office five working days prior to the event start date. Cancellations are subject to an administrative fee:

- Industry (Member/Non-member) € 200.00
- $\bullet \ \ \text{Academia/Charitable/Government/Non-profit (Full-time) (Member/Non-member)} \in 100.00$
- Tutorial cancellation € 50.00

If you do not cancel five working days prior to the event 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 or postponed, 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.

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 Europe in promotional materials, publications, and website and waive any and all rights including but not limited to compensation or ownership.