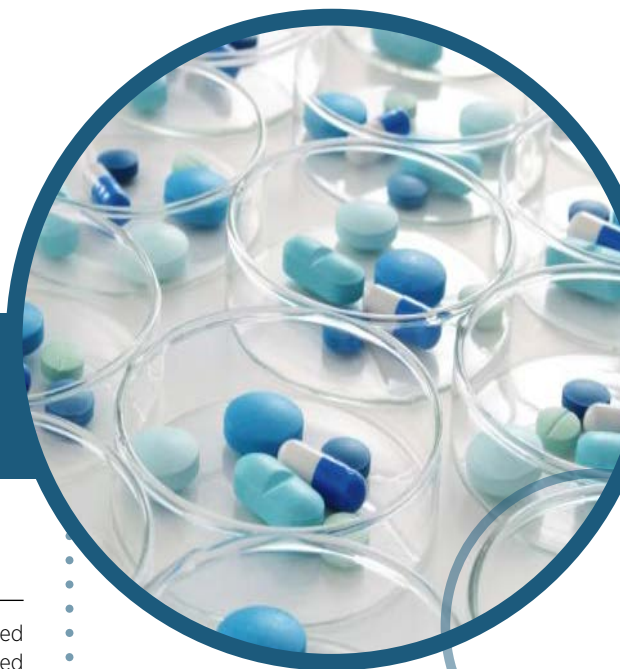


## DIA Training Course on

# Diagnosis and Management of Drug-Induced Liver Injury (DILI): Clinical Trials and Post-Marketing

14-15 June 2016

Holiday Inn London Kensington Forum, London, United Kingdom



## 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 would like 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 immediately before the DILI Training Course.*

## LEARNING OBJECTIVES

At the conclusion of this training course participants will 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

*Participants will complete a knowledge check at the end of the course and will be provided with feedback to ensure learning objectives are attained.*

## TARGET AUDIENCE

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 post-marketing
- Investigators
- Clinical Research Associates

## INSTRUCTOR

**Gaby Danan**

Hepatologist, Pharmacovigilance Expert  
France

## CONTINUING EDUCATION

The Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the United Kingdom has accredited this training course with 8.5 CPD credits.

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited this training course with 8.5 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.

DIA volunteers, members and staff provide a comprehensive catalogue of conferences, workshops, training courses, scientific publications and educational materials, throughout the year, all around the world.

**DIAglobal.org**

**DIA** DEVELOP  
INNOVATE  
ADVANCE

**PharmaTrain**  
MASTERING MEDICINES DEVELOPMENT

## DAY 1

### 12:30 REGISTRATION

### 13:00 SESSION 1

#### THE LIVER: FUNCTIONAL ANATOMY AND PHYSIOLOGY CONCEPTS

*Gaby Danan*

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

### 14:30 COFFEE BREAK

### 15:00 SESSION 2

#### EPIDEMIOLOGY, DEFINITIONS AND CLASSIFICATION OF DILI

*Gaby Danan*

- Current biomarkers of DILI: Description and limitations
- DILI risk factors
- Case studies

### 16:30 DRINKS RECEPTION

### 17:30 END OF DAY ONE

## DAY 2

### 08:30 SESSION 3

#### CLINICAL ASPECTS OF DILI

*Gaby Danan*

- Description
- Limitations
- Pitfalls
- Case studies

### 09:30 COFFEE BREAK

### 10:00 SESSION 4

#### CAUSALITY ASSESSMENT OF DILI

*Gaby Danan*

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

### 12:00 LUNCH BREAK

### 13:00 SESSION 5

#### INDIVIDUAL DATA, HY'S LAW AND AGGREGATED DATA

*Gaby Danan*

- Data elements to collect
- HY'S Law: Definition and conditions for use
- Case Studies
- Data analysis principles

### 14:30 COFFEE BREAK

### 15:00 SESSION 6

#### HOW TO MONITOR AND PREVENT DILI IN POST AUTHORIZATION PHASE

*Gaby Danan*

- Principles
- Examples

### 16:00 QUESTIONS AND ANSWERS

### 16:30 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

Diagnosis and Management of Drug-Induced Liver Injury (DILI) # 16544  
14-15 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, Kùchengasse 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 # 16544 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