

# Definitions and Methods in Pharmacovigilance

15 October 2018

De Vere Canary Wharf, London, United Kingdom



## COURSE DIRECTORS

**Gaby Danan**

Pharmacovigilance Expert, France

**Phil Tregunno**

Interim Group Manager, Vigilance, Intelligence and Research Group  
Medicines & Healthcare products Regulatory Agency (MHRA), United Kingdom

## OVERVIEW

This Module is part of the [MHRA/DIA Excellence in Pharmacovigilance training course](#)

Module 1 will provide a concise overview of the objectives and the scope of Pharmacovigilance. The development of key definitions based on Community legislation and consensus, such as the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) and the CIOMS Working Groups will be summarised. Practical examples and exercises will be used to illustrate the basic key definitions in Pharmacovigilance and the methods used in Pharmacovigilance.

Level: Beginner

## MODULE 1 - DEFINITIONS AND METHODS IN PHARMACOVIGILANCE

**08:00** REGISTRATION

**08:30** INTRODUCTION

Gaby Danan, Pharmacovigilance Expert  
Phil Tregunno, Signal Management Unit Manager, MHRA

**08:45** KEYNOTE PRESENTATION

Mick Foy, Head of Pharmacovigilance Strategy, Vigilance Intelligence and Research Group, MHRA

**09:15**

### DEFINITIONS AND METHODS IN PHARMACOVIGILANCE

**09:15** **Basic Definitions and Tools in Pharmacovigilance**

Gaby Danan, Pharmacovigilance Expert

**10:30** COFFEE BREAK

**11:00** **Basic Definitions and Tools in Pharmacovigilance continued**

Gaby Danan, Pharmacovigilance Expert

**13:00** LUNCH

**14:00** **Classical Methods in Pharmacovigilance**

Gaby Danan, Pharmacovigilance Expert

**15:30** COFFEE BREAK

**16:00** **Epidemiological Methods and Pharmacovigilance**

Katherine Donegan, Pharmacoepidemiology, Research & Intelligence Unit Manager, MHRA

**18:00** NETWORKING RECEPTION

**19:00** **END OF DAY 1 / MODULE 1**

# REGISTRATION FORM



Definitions and Methods in Pharmacovigilance # 18155

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## REGISTRATION FEES

Registration fee includes refreshment breaks, lunch 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	LENGTH	INDUSTRY		GOV/ACA/CHAR	
		MEMBER	NON-MEMBER	MEMBER	NON-MEMBER
MODULE 1: DEFINITIONS AND METHODS IN PHARMACOVIGILANCE	1 day	€ 800.00 <input type="checkbox"/>	€ 955.00 <input type="checkbox"/>	€ 400.00 <input type="checkbox"/>	€ 555.00 <input type="checkbox"/>
MODULE 2: REGULATORY ASPECTS IN PHARMACOVIGILANCE AND PRACTICAL EXAMPLES	2 days	€ 1'450.00 <input type="checkbox"/>	€ 1'605.00 <input type="checkbox"/>	€ 725.00 <input type="checkbox"/>	€ 880.00 <input type="checkbox"/>
MODULE 3: SIGNAL DETECTION AND SIGNAL MANAGEMENT	1 day	€ 800.00 <input type="checkbox"/>	€ 955.00 <input type="checkbox"/>	€ 400.00 <input type="checkbox"/>	€ 555.00 <input type="checkbox"/>
MODULE 4: RISK MANAGEMENT	1 day	€ 800.00 <input type="checkbox"/>	€ 955.00 <input type="checkbox"/>	€ 400.00 <input type="checkbox"/>	€ 555.00 <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-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 [here](#). 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](mailto:Basel@diaglobal.org)

Mail: DIA, K uchengasse 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 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 [here](#).

### Privacy Policy

DIA respects the privacy of all of its members and customers. To view our privacy policy, click [here](#). 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 #18155 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