# **Definitions and Methods in Pharmacovigilance**

5 February 2018 Holiday Inn London - Regent's Park, London, United Kingdom



**Gaby Danan** 

Pharmacovigilance Expert, France

### **Phil Tregunno**

Signal Management Unit Manager Medicines & Healthcare products Regulatory Agency (MHRA), UK

## **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	13:00	LUNCH
Gaby Danan, Pl	narmacovigilance Expert Signal Management Unit Manager, MHRA	14:00	Classical Methods in Pharmacovig Gaby Danan, Pharmacovigilance E
08:45	KEYNOTE PRESENTATION		
Mick Foy. Group	Manager, Vigilance Intelligence and Research	15:30	COFFEE BREAK
Group, MHRA		16:00	Epidemiological Methods and Ph

09:15

## **DEFINITIONS AND METHODS IN PHARMACOVIGILANCE**

**Basic Definitions and Tools in Pharmacovigilance** 

Gaby Danan, Pharmacovigilance Expert

10.70	COFFEE BREAK	
10.50	COFFEE BREAK	

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

continued

Gaby Danan, Pharmacovigilance Expert

igilance

Expert

emiological 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 # 18151
5 February 2018 | Holiday Inn London - Regent's Park | London, United Kingdom

#### **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:

	LENGTH	INDUSTRY		GOV/ACA/CHAR	
FEES		MEMBER	NON- MEMBER	MEMBER	NON- MEMBER
MODULE 1: DEFINITIONS AND METHODS IN PHARMACOVIGILANCE	1 day	€ 800.00 □	€ 955.00 🗆	€ 400.00 □	€ 555.00 🗖
MODULE 2: REGULATORY ASPECTS IN PHARMACOVIGILANCE AND PRACTICAL EXAMPLES	2 days	€ 1'450.00 □	€ 1′605.00 □	€ 725.00 🗖	€ 880.00 🗖
MODULE 3: SIGNAL DETECTION AND SIGNAL MANAGEMENT	1 day	€ 800.00 □	€ 955.00 🗖	€ 400.00 □	€ 555.00 🗖
MODULE 4: RISK MANAGEMENT	1 day	€ 800.00 □	€ 955.00 🗖	€ 400.00 □	€ 555.00 🗖

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 <a href="https://www.diaglobal.org">www.diaglobal.org</a> and click on Membership for more details.

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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 nonmember fee, if applicable. Please notify the DIA office of any such substitutions as soon as possible.

#### Photography and Video 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	PAYMENT METHODS				
Please complete in block capital letters or attach the attendee's business card here.	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.				
□ Prof □ Dr □ Ms □ Mr	□ Please charge my □ VISA □ MC □ AMEX  Card N°				
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First Name	Cardholder's Name				
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Address	"Account Holder: DIA." Please include your name, company, Course ID #18151 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,				
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