# **Definitions and Methods in Pharmacovigilance**

2 October 2017 The Crystal, London, United Kingdom

# **COURSE DIRECTORS**

**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 key definitions in Pharmacovigilance and the methods used in Pharmacovigilance.

MODULE	1 - DEFINITIONS AND METH	ODS IN PHARI	MACOVIGILANCE
08:00	REGISTRATION	13:00	LUNCH
08:30	INTRODUCTION	14:00	Classical Methods in Pha
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08:45 **KEYNOTE PRESENTATION** 

Phil Tregunno, Signal Management Unit Manager, MHRA

Mick Foy, Group Manager, 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

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Gaby Danan, Pharmacovigilance Expert

15:30 **COFFEE BREAK** 

16:00 **Epidemiological Methods and Pharmacovigilance** 

> Suzie Seabroke, Senior Pharmacoepidemiologist, Vigilance and Risk Management Division, MHRA

**NETWORKING RECEPTION** 18:00

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





# REGISTRATION FORM



Definitions and Methods in Pharmacovigilance # 17151 2 October 2017 | The Crystal | London, United Kingdom

# **REGISTRATION FEES**

Registration fee includes refreshment breaks and lunches and electronic access to training course 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.

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### **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.

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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.			
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