Signal Detection and Management

5 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

New safety signals may emerge at any time following product launch and must be evaluated for relative risk, medical importance, and likelihood of occurrence. This module will provide approaches to signal detection using quantitative methods illustrated in a workshop with examples as well as general considerations on signal management in the EEA.

08:00 **REGISTRATION**

08:30

DIAGNOSIS OF ADVERSE DRUG REACTIONS

Pharmacovigilance is first based on the medical assessment of the adverse events passively or actively collected in organised schemes. It is then essential to be able to identify consistently the nature of events and their seriousness as well as to assess causality with the suspect drug(s). This session will provide basic elements of the medical evaluation of ADRs.

08:30 **Medical Evaluation of Adverse Drug Reactions**
Gaby Danan, Pharmacovigilance Expert

09:30

SIGNAL DETECTION AND SIGNAL MANAGEMENT

09:30 **Introduction to Signal Detection**
Phil Tregunno, Signal Management Unit Manager, MHRA

10:30 **Mobile Technologies and Social Media in Signal Management**
Phil Tregunno, Signal Management Unit Manager, MHRA

11:00 COFFEE BREAK

11:30 **Signal Management in the European Union: Industry Perspective**
Jan Petracek, CEO, PharmInvent

13:00 LUNCH

14:30 **Signal Management – Workshop**
Phil Tregunno, Signal Management Unit Manager, MHRA
Jan Petracek, CEO, PharmInvent

16:00 **END OF MODULE**

DIA

MHRA
Regulating Medicines and Medical Devices

REGISTRATION FORM

Signal Detection and Management # 17153
5 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:

FEES	LENGTH	INDUSTRY		GOV/ACA/CHAR	
		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 www.diaglobal.org and click on Membership for more details.

If you do not want a membership, please indicate your preference below:

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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
Mail: DIA Europe, Middle East & Africa, Küchengasse 16, 4051 Basel, Switzerland
Web: 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

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 # 17153 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