

Signal Management



COURSE DIRECTOR

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FACULTY

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OVERVIEW

This Module is part of the [MEB/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

09:30

SIGNAL MANAGEMENT

09:30 Introduction to Signal Detection

Bianca Mulder, MEB

10:30 COFFEE BREAK

10:45 Signal Management in the European Union: Regulators Perspective

Bianca Mulder, MEB

12:15 LUNCH

13:15 Signal Management in the European Union: Industry Perspective

Jan Petracek

14:00 COFFEE BREAK

14:15 Signal Management – Workshop

Bianca Mulder, MEB

Jan Petracek

15:45 END OF MODULE

REGISTRATION FORM

Signal Detection and Management # 19153
16 May 2019 | Amsterdam, The Netherlands

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"/>
A special discount for SMEs on the standard fee is available for a limited number of places. To prove your status as an SME, a confirmation of the European Medicines Agency is necessary. Please contact DIA for more information					

***All fees are subject to the applicable Dutch VAT.**

Please enter your Company's European VAT number: _____

If DIA cannot verify your membership upon receipt of your registration form, you will be charged the non-member fee. **Please note that the full amount must be received by DIA by commencement of the course to get the electronic access to the material.**

DIA MEMBERSHIP

All nonmember fees include a one year DIA membership, at no additional cost. Explore membership benefits at DIAglobal.org/Membership.

DIA membership will renew automatically at the end of the complimentary membership term, at the then current membership rates. You may cancel automatic membership renewal at any time by accessing your account online at DIAglobal.org. If you would like to decline complimentary membership, please indicate your preference below.

☐ I would like to decline a one year complimentary DIA membership.

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 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

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

/

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☐ **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 #19153 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