

# Signal Management in Pharmacovigilance Virtual Live Training Course

9-12 October 2023 09:00-13:00 CEST

## OVERVIEW

This virtual live training course covers essential concepts of signal detection and signal management and provides guidance on how to apply these concepts at participants' function and their organisation, including the data mining techniques for large volume ADR data analysis.

The entire course is in line with the latest guidelines on EU Good Pharmacovigilance Practices (GVP): Module IX – Signal management (rev. 1), Commission Implementing Regulation (EU) No. 520/2012, CIOMS VIII and relevant EMA guidelines.

This training is primarily developed based on EU legislation, but it also covers regulatory expectations for signal management in the US, Switzerland, Canada, Australia, and few other countries.

Participants benefit from the hands-on experience of trainers who have worked for many years in signalling activities and are ready to not only explain the legislation, but also provide personal experience and most commonly followed practices that are often considered as industry standards.

## LEARNING OBJECTIVES

After the completion of this virtual live training course, participants will be able to:

- Apply the essential concepts and principles of signal management in PV and implement or improve this process in their own organisation
- Compare different approaches to signal management that are followed by various organisations
- Operate and implement EVDAS into signal management process
- Follow the regulatory expectations at different geographic regions

## KEY TOPICS

- Signal Detection – Theory, methods (frequentist (PRR, ROR) and Bayesian (MGPS, BCPNN)), data mining
  - Practical exercise on signal detection – analyse and discuss an article
  - Practical exercise on data mining methods – calculate RRR, ROR, PRR
- Signal Management – Detection, validation, confirmation, analysis and prioritisation, assessment, and recommendation for action
  - Signaling exercise in PSUR review - data visualisation and analysis
- Regulatory expectations in the EU, US, Switzerland, Canada, Australia
  - Exercise on signal management – manage information from PRAC
- EVDAS introduction and implementation in signal management
- Strategy for implementation of signal management process in your own organisation (covering both small and large companies)
  - Exercise on signal management processes – propose and discuss the most appropriate signal management procedure for various types of organisations

## WHO WILL ATTEND

This virtual live training course is designed for professionals working in:

- Pharmacovigilance (including EU QPPVs)
- Drug Safety and Risk Management
- Signal Management and Safety Science
- Pharmacoepidemiology
- Information Technology
- Pharmacovigilance Consultancies and Service Providers
- Quality and Compliance

Course level: Intermediate, for professionals with 2-3 years (or more) of experience in Pharmacovigilance, or related functions who are working in PV around signal management.

## FACULTY

### Jose Ortiz

QPPV  
PVpharm  
Spain

### Jan Kolouch

CEO, Strategic PV Advisor  
NextPV Services  
Czech Republic

### Margarida Guimaraes

European Medicines Agency  
Netherlands

## DAY 1

### 09:00 WELCOME AND INTRODUCTION

#### 09:30 SESSION 1

##### SIGNAL DETECTION – THEORY, METHODS, DATA MINING

- Terminology
- Sources of signals:
  - Traditional
  - Not (yet) traditional
  - Databases
- Group exercise on signal detection

#### 11:00 BREAK

#### 11:30 SESSION 1 (CONTINUED)

##### SIGNAL DETECTION – THEORY, METHODS, DATA MINING

- Data mining techniques:
  - Proportional Reporting Ratio
  - Reporting Odds Ratio
  - Multi-item Gamma Poisson Shrinker (MGPS)
  - Bayesian Confidence Propagation Neural Network (BCPNN)
- Principles of data mining in spontaneous reporting system (SRS)
- Group exercise on data mining methods
- Recent developments in data mining

#### 13:00 END OF DAY 1

## DAY 2

### 09:00 SESSION 2

##### SIGNAL MANAGEMENT – DETECTION, TRIAGE, EVALUATION, FURTHER ACTION

- PV system overview
- Signal management process:
  - CIOMS
  - GVP Module IX
- Identification of sources and signal detection
- Group exercise on Periodic Safety Update Report (PSUR) data visualisation

#### 11:00 BREAK

#### 11:30 SESSION 2 (CONTINUED)

##### SIGNAL MANAGEMENT – DETECTION, TRIAGE, EVALUATION, FURTHER ACTION

- Signal validation/prioritisation
- Signal assessment/evaluation
- Action plan/communication

#### 13:00 END OF DAY 2

## DAY 3

### 09:00 SESSION 3

##### SIGNAL MANAGEMENT – REGULATORY EXPECTATIONS

- Review of worldwide regulatory guidance
  - USA, Switzerland, Canada, Australia, Taiwan, Saudi Arabia
- Legal basis in the EU
  - GVP Module IX
  - Signal management process at EMA
  - Signal cycle at PRAC
  - Scientific guidance on signal detection
  - MAH role and responsibilities
  - EV access
- Link with other EU processes
  - PSUR/PBRER per E2C (R2)
  - Risk Management Plan (EU-RMP)
  - Company Core Data Sheet (CCDS/CCSI)

#### 11:00 BREAK

#### 11:30 SESSION 3 (CONTINUED)

##### SIGNAL MANAGEMENT – REGULATORY EXPECTATIONS

- How to handle signals coming from authorities
  - FDA Adverse Event Reporting System (FAERS)
  - PRAC
- Incoming signals – do's and don'ts
- Group exercise on signal management

#### 13:00 END OF DAY 3

## DAY 4

### 09:00 SESSION 4

##### SIGNAL MANAGEMENT PROCESS – STRATEGY FOR IMPLEMENTATION

- Overview of signal management process issues
  - Reporting, archiving, labelling changes, tools etc.
- Implications of EVDAS access
  - Principles of MAH access to EVDAS
  - electronic Reaction Monitoring Report (eRMR) and Reference periods
  - Line listing
  - Individual Case Safety Report (ICSR) form, L2B access

#### 11:00 BREAK

#### 11:30 SESSION 4 (CONTINUED)

##### SIGNAL MANAGEMENT PROCESS – STRATEGY FOR IMPLEMENTATION

- Approaches for small and large companies
  - Company differences
- Example of a signal management process
- Group exercise on signal management processes

#### 13:00 END OF THE TRAINING COURSE

Unless otherwise disclosed, DIA acknowledges that the statements made by speakers are their own opinion and not necessarily that of the organisation they represent, or that of the DIA. Speakers and agenda are subject to change without notice. Recording during DIA sessions is strictly prohibited without prior written consent from DIA.

## | About DIA

DIA is the global connector in the life sciences product development process. Our association of more than 18,000 members builds productive relationships by bringing together regulators, innovators, and influencers to exchange knowledge and collaborate in an impartial setting. DIA's network creates unparalleled opportunities for exchange of knowledge and has the inter-disciplinary experience to prepare for future developments.

The dedicated efforts of DIA staff, members and speakers enable DIA to provide a comprehensive catalogue of conferences, workshops, training courses, scientific publications and educational materials. DIA is a global community representing thousands of stakeholders working together to bring safe and effective products to patients.

DIA is an independent, non-profit organisation has its Global Center in Washington, DC, USA with the European office in Basel, Switzerland, and additional regional offices in Horsham, Pennsylvania, USA; Tokyo, Japan; Mumbai, India; and Beijing, China

## | Continuing Education

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited this training course with 13.5 credits.



## | Technical Requirements

To test your system compatibility, please click on the link:

<https://diaglobal.zoom.us/test>

For further information on system requirements, please visit the website:

<https://www.diaglobal.org/General/System-Requirements>

## | Group Discounts

**Register 3 individuals from the same company for the same course and receive complimentary registration for a 4th!**

- All 4 individuals must register and prepay at the same time – no exceptions
- DIA will apply the value of the lowest applicable fee to this complimentary registration; it does NOT include fees for optional events or DIA membership
- You may substitute group participants of the same membership status at any time; however, administrative fees may be incurred.

Group registration is not available online and does not apply to the already discounted fees for industry (early-bird), government or charitable nonprofit/academia.

To take advantage of this offer, please print the registration form for EACH of the four registrants from your company. Include the names of all four group registrants on each of the forms and return them together via email to [basel@diaglobal.org](mailto:basel@diaglobal.org).

## | Plan Your Team's Professional Development

Get a customized training for your department (or even across different departments!) and benefit from increased:

- Knowledge of a topic of your choice
- Flexibility & Convenience
- Cost Effectiveness

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For more information please contact [tereza.krucka@diaglobal.org](mailto:tereza.krucka@diaglobal.org)

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# REGISTRATION FORM

Signal Management in Pharmacovigilance Virtual Live Training Course # 23550  
9-12 October 2023 09:00-13:00 CEST



## REGISTRATION FEES

Registration fee includes full admission to virtual course, electronic access to training course materials.  
**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	MEMBER EARLY-BIRD valid until 14 Aug 2023	MEMBER valid from 15 Aug 2023	NON- MEMBER
INDUSTRY/ REPRESENTATIVE	€ 1'305.00 <input type="checkbox"/>	€ 1'450.00 <input type="checkbox"/>	€ 1'685.00 <input type="checkbox"/>
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	NA	€ 725.00 <input type="checkbox"/>	€ 960.00 <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 registration fees are subject to VAT if applicable.

Please enter your company's VAT number: \_\_\_\_\_

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 nonmember fees include a one year DIA membership, at no additional cost. Explore membership benefits at [DIAglobal.org/Membership](https://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](https://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 09:00 and 17:00 CE(S)T. **Tel.** :+41 61 225 51 51

**Email:** [Basel@DIAglobal.org](mailto:Basel@DIAglobal.org) **Mail:** DIA, Küchengasse 16, 4051 Basel, Switzerland

**Web:** [www.DIAglobal.org](https://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 <https://www.diaglobal.org/general/photography-policy>.

### Privacy Policy

DIA respects the privacy of all of its members and customers. To view our privacy policy, click <https://www.diaglobal.org/about-us/privacy-policy>.

## 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  /

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 #23550 as well as the invoice number to ensure correct allocation of your payment.

Please note: if you register 7 days or less before the start of the course, it is not possible to settle the registration fee by bank transfer, but only by credit card. Thank you for your understanding and cooperation.

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
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