DIA Learning

Signal Management in Pharmacovigilance
Virtual Live Training Course

18-21 November 2024 13:00-17:00 CET

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 current guidelines on EU 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, data mining, new trends
  - Practical exercise on signal detection – analyse and discuss an article
  - Practical exercise on data mining methods – calculate RRR, ROR, PRR
  - Proactive and predictive signal detection
  - Use of automation and AI
- 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

Calin Lungu
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Jose Ortiz
CEO
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Spain

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Scientific Administrator
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The Netherlands

PharmaTrain
MASTERING MEDICINES DEVELOPMENT
CENTRE RECOGNITION

DAY 1

13:00 WELCOME AND INTRODUCTION

13:30 SESSION 1

SIGNAL DETECTION – THEORY, METHODS, DATA MINING, NEW TRENDS

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

15:00 BREAK

15:30 SESSION 1 (CONTINUED)

SIGNAL DETECTION – THEORY, METHODS, DATA MINING, NEW TRENDS

- 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
- Proactive and predictive signal detection
- Use of automation and AI

17:00 END OF DAY 1

DAY 2

13:00 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

15:00 BREAK

15:30 SESSION 2 (CONTINUED)

SIGNAL MANAGEMENT – DETECTION, TRIAGE, EVALUATION, FURTHER ACTION

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

17:00 END OF DAY 2

DAY 3

13:00 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)

15:00 BREAK

15:30 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

17:00 END OF DAY 3

DAY 4

13:00 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

15:00 BREAK

15:30 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

17:00 END OF THE TRAINING COURSE

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

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.

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

Or explore eLearning to allow self-paced learning.

For more information please contact tereza.krucka@diaglobal.org

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.

SwAPP Swiss Association of Pharmaceutical Professionals

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

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REGISTRATION FORM

Signal Management in Pharmacovigilance Virtual Live Training Course # 24549
18-21 November 2024 13:00-17:00 CET

DIA Learning

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 23 Sep 2024	MEMBER valid from 24 Sep 2024	NON-MEMBER
INDUSTRY/ REPRESENTATIVE	€ 1'420.00 ❑	€ 1'580.00 ❑	€ 1'840.00 ❑
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	NA	€ 790.00 ❑	€ 1'050.00 ❑
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.

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 09:00 and 17:00 CE(S)T. **Tel.** :+41 61 225 51 51

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 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 METHOD

DIA accepts only Credit Card as a payment method.

Payments by VISA, Mastercard or AMEX are accepted. Other types of credit card are not accepted.

You will receive a payment link in the coming days to complete the payment.

Please complete payment within 7 days of receipt of the payment link.

Payments will be net of all charges and bank charges will be borne by the payer.

If you have not received your confirmation within five working days, please contact basel@diaglobal.org.

By signing below, I confirm that I read and agree with DIA's Terms and Conditions of booking.

These are available from the office or online by clicking:

http://www.diaglobal.org/EUterms

Date	Signature