DIA Learning

Signal Management in Pharmacovigilance

16-17 November 2017
Mercure Paris La Défense Grande Arche, Paris, France

OVERVIEW

This course will teach basic concepts of signal detection and signal management and how to apply them within the participants' functions, including the data mining techniques for large volume ADR data analysis, relevant EMA guidelines as well as a future outlook.

The entire course is updated in line with the latest guidelines on EU Good Pharmacovigilance Practices (GVP): Module IX – Signal management, Commission Implementing Regulation (EU) No. 520/2012, and CIOMS VIII. Time has been set aside for exercises, questions and discussions.

Participants will be provided with preparatory material in order to better participate in the group exercises.

LEARNING OBJECTIVES

At the conclusion of this training course participants wil be able to:

- Apply the basic concepts and principles of signal detection in pharmacovigilance, from simple visualisation and tabulation methods to sophisticated data mining techniques
- Design the signal management process for institutions and companies of various sizes, portfolios and geographical presence, based on the possibilities and limitations of their data and resources
- Understand key messages from the current European and US regulations on signal management, to best manage implications of signals for the future of pharmaceutical companies and products

Participants will complete a knowledge check at the end of the course and will be provided with feedback to ensure learning objectives are attained.

KEY TOPICS

- Signal detection – Theory, methods, data mining
- Signal management – Detection, triage, evaluation, further action
- Signal management – Regulatory expectations
- Signal management process: Strategy for implementation

WHO WILL ATTEND

This course is aimed at professionals who work in:

- Pharmacovigilance (including QPPVs)
- Drug safety and patient safety risk management
- Pharmacoepidemiology
- Information Technology
- Regulatory Affairs
- Pharmacovigilance consultancies
- Quality and Compliance
- Legal

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

PharmaTrain
MASTERING MEDICINES DEVELOPMENT

INSTRUCTOR

Jose Alberto Ayala Ortiz
Pharmacovigilance consultant
PVpharm, Spain

José is an expert in the field of Pharmacovigilance and Drug Safety. He has experience both from the Regulatory (Danish Medicines Agency), and from the Pharmaceutical Industry, where he has been responsible for Pharmacovigilance IT systems, databases and electronic transmissions. He has been training EVWeb and XEVMPD training courses since 2003, and collaborates in the development of these training courses. He provides also EU QPPV services and local QPPV services in Spain for Pharmaceutical Companies.

DAY 1

12:30 REGISTRATION

13:00 WELCOME AND INTRODUCTION

13:30 SESSION 1

SIGNAL DETECTION - THEORY, METHODS, DATA MINING (1)

Signal Detection is a key component of pharmacovigilance science – discovering new effects of medicines in their post-authorisation use. We will present concepts, definitions, data sources, traditional methods of detection, data mining and newest techniques. Participants will exercise the application of best practices in small teams.

15:00 COFFEE BREAK

15:30 SESSION 1 (continued)

SIGNAL DETECTION - THEORY, METHODS, DATA MINING (2)

16:30 SESSION 2

SIGNAL MANAGEMENT – DETECTION, TRIAGE, EVALUATION, FURTHER ACTION (1)

Signal Management is one of the key pharmacovigilance processes; in this session we will review its position relative to other key processes. The different steps and quality requirements in the process will be explained, with the goal of clarifying the need for IT tools and resources for implementation in various contexts. Participants will work on real life examples in small groups.

17:30 NETWORKING RECEPTION

18:30 END OF DAY ONE

DAY 2

08:30 SESSION 2 (continued)

SIGNAL MANAGEMENT – DETECTION, TRIAGE, EVALUATION, FURTHER ACTION (2)

10:30 COFFEE BREAK

11:00 SESSION 3

SIGNAL MANAGEMENT – REGULATORY EXPECTATIONS (1)

We will review the latest regulatory requirements on implementing and maintaining a signal management process. Again, practical exercises will allow participants to understand how they can develop a policy in signal management, and cope with any inspection on this topic.

12:30 LUNCH

13:30 SESSION 3 (continued)

SIGNAL MANAGEMENT – REGULATORY EXPECTATIONS (2)

14:00 SESSION 4

SIGNAL MANAGEMENT PROCESS: STRATEGY FOR IMPLEMENTATION (1)

This session reviews how regulators, big companies and small companies should design their signal management process, the expected timelines, resources and outcomes from this process, and how the communication of signals should be performed. We will discuss all of these critical issues during this final session, and look at the typical scenarios the industry and regulators face today.

15:00 COFFEE BREAK

15:30 SESSION 4 (continued)

SIGNAL MANAGEMENT PROCESS: STRATEGY FOR IMPLEMENTATION (2)

16:30 END OF TRAINING COURSE

Continuing Education

The Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the United Kingdom has accredited this training course with 9.5 CPD credits.

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited this training course with 9.5 credits.

SwAPP | Swiss Association of Pharmaceutical Professionals

Training Course Venue

Paris La Défense Grande Arche
17/20 Esplanade Ch. de Gaulle - Rue des Trois Fontanot
92000 Nanterre/Paris, France

Tel: +33 8 2580 5959
Fax: +33 1 4725 4624
Email: H1982@accor.com

DIA has blocked a limited number of hotel rooms at the rate of EUR 180.00 per standard room per night including breakfast and VAT, excl. City-Tax.
If you would like to make a booking, please fill in the booking form available on the DIA website and send it per email to H1982@accor.com with a reference "DIA".
The room rate is available until 01 November 2017 or until the room block is sold-out, whichever comes first.

REGISTRATION FORM

Signal Management in Pharmacovigilance # 17543
16-17 November 2017 | Mercure Paris La Défense Grande Arche | Paris, France

DIA Learning

REGISTRATION FEES

Registration fee includes refreshment breaks, lunch on the 2nd day of the course 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.

FEES	MEMBER	NON-MEMBER
INDUSTRY	€ 1'240.00 ❑	€ 1'395.00 ❑
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	€ 620.00 ❑	€ 775.00 ❑

All registration fees are subject to applicable French VAT

Please enter your company's French 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 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:

❑ I do not want complimentary 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: EMEA@DIAglobal.org **Mail**: DIA, Küchengasse 16, 4051 Basel, Switzerland **Web:** www.DIAglobal.org

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.

PHOTOGRAPHY AND VIDEO 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 #17543 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