Signal Management in Pharmacovigilance
Virtual Live Training Course

7-10 September 2020 09:00-12:00 CEST

OVERVIEW

This virtual live training 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 virtual course, participants will 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 also from a global perspective of signals for the future of pharmaceutical companies and products.

Participants will complete a knowledge check at the end of the course to ensure learning objectives are attained.

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 in Pharmacovigilance around signal management.

FACULTY

Jose Alberto Ayala Ortiz
QPPV, PVpharm, Spain

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

DAY 1

09:00 WELCOME AND INTRODUCTION

09:15 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, and traditional methods of detection, data mining and newest techniques.

Participants will exercise the application of best practices in small teams.

10:15 BREAK

10:30 SESSION 1 (CONTINUED)

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

11:45 QUESTIONS AND ANSWERS

12:00 END OF DAY 1

DAY 2

09:00 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.

10:30 BREAK

10:45 SESSION 2 (CONTINUED)

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

11:45 QUESTIONS AND ANSWERS

12:00 END OF DAY 2

DAY 3

09:00 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

Participants will work on real life examples in small groups.

10:30 BREAK

10:45 SESSION 3 (CONTINUED)

SIGNAL MANAGEMENT – REGULATORY EXPECTATIONS (2)

11:45 QUESTIONS AND ANSWERS

12:00 END OF DAY 3

DAY 4

09:00 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.

Participants will work on real life examples in small groups.

10:30 BREAK

10:45 SESSION 4 (CONTINUED)

SIGNAL MANAGEMENT PROCESS: STRATEGY FOR IMPLEMENTATION (2)

11:45 QUESTIONS AND ANSWERS

12:00 END OF DAY 4

Plan Your Team's Professional Development

Why not take advantage and train your whole department (or even across different departments!) and benefit from increased:

- Focus
- Flexibility
- Convenience
- Cost Effectiveness

For more information please contact Basel@DIAglobal.org

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

Follow @**DrugInfoAssn**

Continuing Education

The Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the United Kingdom has accredited this training course with 10 CPD credits.

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited this training course with 10 credits.

Technical Requirements

To test your system compatibility, please click on the link: https://diaglobal.zoom.us/test

Operating Systems

- Windows: XP 32-bit (SP3), 2003, Vista 32-bit/64-bit, Windows 7 32-bit/64-bit
- Mac OS X: 10.5, 10.6, 10.7
- Linux: 32-bit Ubuntu 10.x,11.x 32-bit Fedora 15/16, 32-bit Red Hat 5/6, 32-bit OpenSuSE 11.4

Minimum System Requirements

- Windows: Processor – Requires Sun Java 5 or higher, Recommend ActiveX be enabled for Internet Explorer, Recommend ActiveX be enabled for Internet Explorer
- Mac OS X: Processor – JavaScript and cookies enabled, Requires Apple Java 5 or higher, No support for Remote Access
- Linux: Processor – JavaScript and cookies enabled, Requires Apple Java 5 or higher, No support for Remote Access

Browsers

- Windows: Internet Explorer 6, 7, 8, 9, (Win7 Only), Firefox latest (32-bit), Chrome latest
- Mac OS X: Safari 4-Mar; Firefox 2/3/3.5
- Linux: Mozilla 1.7, Firefox 2/3/3.5

Internet Connection Speed

- Windows: Intel or AMD processor (1GHz or faster), At least 512 MB RAM (at least 2 GB RAM for Vista)
- Mac OS X: Intel processor, At least 512 MB RAM
- Linux: At least 512 MB RAM

Display

800x600 pixel resolution or greater (1024x768 pixels recommended).

REGISTRATION FORM

Signal Management in Pharmacovigilance Virtual Live Training Course # 20549

7-10 September 2020 09:00-12:00 CEST

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	NON-MEMBER
INDUSTRY/ REPRESENTATIVE	€ 1'450.00 ❑	€ 1'605.00 ❑
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	€ 725.00 ❑	€ 880.00 ❑
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 CET. **Tel.** :+41 61 225 51 51

Email: Basel@DIAglobal.org Mail: DIA, Küchengasse 16, 4051 Basel, Switzerland
Web: www.DIAglobal.org

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 #20549 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

© DIA 2020