DIA Learning

Signal Management in Pharmacovigilance

23-24 February 2017
Novotel Bucharest City Centre, Bucharest, Romania

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 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 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

FACULTY

Calin Lungu
CEO
Drug Development Consulting Services S.A. (DDCS)
Luxembourg
Dr. Lungu has worked for 15 years in drug development, clinical research, pharmacovigilance and quality assurance. Since 2004 he is a EudraVigilance trainer and trained more than 250 Eudravigilance and XEVMPD courses at the EMA, selected European cities and also in the US. He has also trained from 2008 to 2012 the EudraVigilance Data Analysis System course at the EMA and including participants from the EMA and the National Competent Authorities.

DAY 1

08:00 REGISTRATION

08:30 WELCOME AND INTRODUCTION

09:00 SESSION 1

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

Calin Lungu

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.

10:30 COFFEE BREAK

11:00 SESSION 1 (CONTINUED)

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

12:00 LUNCH

13:00 SESSION 2

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

Calin Lungu

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.

14:30 COFFEE BREAK

15:00 SESSION 2 (CONTINUED)

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

16:30 SESSION 3

SIGNAL MANAGEMENT – REGULATORY EXPECTATIONS (1)

Calin Lungu

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.

18:00 END OF DAY ONE

DAY 2

08:00 SESSION 3 (CONTINUED)

SIGNAL MANAGEMENT – REGULATORY EXPECTATIONS (2)

09:30 SESSION 4

SIGNAL MANAGEMENT PROCESS: STRATEGY FOR IMPLEMENTATION (1)

Calin Lungu

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.

10:00 COFFEE BREAK

10:30 SESSION 4 (CONTINUED)

SIGNAL MANAGEMENT PROCESS: STRATEGY FOR IMPLEMENTATION (2)

12:00 END OF TRAINING COURSE

REGISTRATION FORM

Signal Management in Pharmacovigilance
23-24 February 2017, Novotel Bucharest City Centre, Romania

FAX OR EMAIL YOUR COMPLETED REGISTRATION FORM TO Business Travel Turism S.R.L.
Fax : +4 021 2315622, Email: madalina.nedelciu@businesstravel.ro

REGISTRATION FEES

Registration fee includes refreshment breaks, lunch on the 1st day and training course material in electronic format.

FEES	
STANDARD	€ 1'000.00 ❑

*Fees are subject to Romanian VAT at 9% and 19%.

Payment of registration fees must be received before commencement of the course.

Cancellation Policy

All cancellations must be made in writing and be received at the DIA Europe, Middle East and Africa 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 - for the same course - to a colleague of the same organisation. Please notify the DIA office of such a substitution as soon as possible.

Photography 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

Participant Email (Required for confirmation)

PAYMENT METHODS

After reception of your payment, Business Travel will send you a confirmation/ invoice.

❑ **Bank transfers:**

Participants from Romania will be charged in RON.

S.C. BUSINESS TRAVEL TURISM S.R.L.
Aleea Alexandru nr. 9A, 1st Distict,
011821 Bucharest
Romania
Tel. +4 021 2315619
Fax. +4 021 2315622
Mob.+4 0729 835 337

Bank address: UNICREDIT TIRIAC BANK SA,
Bd. Expozitiei Nr.1F, Sect 1, Bucharest, Cod Postal 012101, Romania
Swift code: BACXROBU
IBAN: RO84 BACX 0000 0010 6285 7002

Payment should include your name, company and the remark „Signal" to ensure correct allocation of your payment. Payments must be net of all charges and bank charges must be borne by the payer.

❑ **Credit Card**
If you wish to pay by credit card, please contact Business Travel.

Date	Signature