DIA LEARNING

EudraVigilance Data Analysis System (EVDAS): Practical Approach on Use for Signal Management in the EU

18-20 February 2025 | 13:00-17:00 CET

Overview

This virtual live training course will teach concepts, access policy, and use of the EudraVigilance Data Analysis System (EVDAS) for signal detection. Experienced trainers using EVDAS on a regular basis will share practical advice on how to download and interpret the data and use it for signal detection.

The EVDAS supports EU pharmacovigilance safety monitoring activities with the focus on signal detection and evaluation of Individual Case Safety Reports (ICSRs). Marketing authorisation holders (MAH) with active substances included in the list published by the European Medicines Agency (EMA) have to monitor and inform authorities of validated signals with their medicines. EU Good Pharmacovigilance Practices (GVP) Module VII "Periodic Safety Update Reports (PSUR)" states that also for other active substances, MAHs are expected to include data from EudraVigilance (EV) whenever there are signal evaluations in the PSUR triggered by other sources of information.

The course is based on the current guidelines on GVP Module IX – Signal management, Commission Implementing Regulation (EU) No. 520/2012. Time has been set aside for practical exercises, questions, and discussions.

Learning Objectives

At the conclusion of this virtual live training course, participants will be able to:

- Identify regulatory requirements for Signal Management in Europe (GVP IX and Addendum I)
- Describe principles of screening EV for adverse reactions and the EV data access policy
- Identify levels and methods of access to ICSRs data and understand the terminology of EVDAS
- Discuss the use of active substance grouping reports, and electronic reaction monitoring reports (eRMRs)
- Analyse eRMRs with various reference periods and line listings and document your assessments
- Identify potential signals and know how to escalate them to the National Competent Authorities (NCAs) and the EMA

Who Will Attend

This virtual live training course is aimed at professionals who work in:

- Pharmacovigilance (including QPPVs)
- Drug Safety and Patient Safety Risk Management
- Information Technology
- Pharmacovigilance Data Management
- Pharmacovigilance Consultancies
- Quality and Compliance

Course level: Intermediate, for professionals with 2-3 years of experience in Pharmacovigilance who work in the area of signal management but have no or limited experience on how to use EVDAS for signal detection.

Faculty

Calin Lungu
CEO
Drug Development Consulting Services
Luxemburg

Vojtech Kvita
Executive Director
NextPV Services
Czech Republic

Rodrigo Postigo
Scientific Administrator
EMA
Netherlands

Key Topics

- GVP IX and Addendum I
- Screening for adverse reactions in EV
- Principles of access in EV
- Practical use of EVDAS and exercises
- eRMR analysis and documentation
- Line listing analysis
- CMDh list of safety concerns
- Referrals page on the EMA website
- List of signals discussed by the PRAC since 2012
- How to escalate signals, e.g. stand-alone notification, ESI

PharmaTrain
MASTERING MEDICINES DEVELOPMENT
CENTRE OF EXCELLENCE

DAY 1

13:00 WELCOME AND INTRODUCTION

13:30 SESSION 1

GVP IX

Calin Lungu and Vojtech Kvita

- GVP Module Changes
- Signal Management Terminology
- Signal Notification Process

14:30 SESSION 2

ADDENDUM I TO GVP IX AND SCREENING FOR ADVERSE REACTIONS IN EUDRAVIGILANCE

Calin Lungu and Vojtech Kvita

- Disproportionate Reporting
- Signal Detection Methods
- Introduction to EVDAS

15:30 BREAK

15:45 SESSION 3

PRINCIPLES OF ACCESS IN EUDRAVIGILANCE

Calin Lungu and Vojtech Kvita

- EudraVigilance Stakeholders
- EV Access Levels
- MLM Reports

17:00 END OF DAY 1

DAY 2

13:00 SESSION 4

EVDAS PILOT

Calin Lungu and Vojtech Kvita

- Transitional Arrangements
- EVDAS Pilot Experience

13:30 SESSION 5

EVDAS AND PRACTICAL EXERCISES

Calin Lungu and Vojtech Kvita

- eRMR analysis and documentation
- Line listing analysis
- Communication of potential duplicates to the EMA
- Other sources of information
  - CMDh list of safety concerns
  - Referrals page on the EMA website
  - List of signals discussed by the PRAC since 2012
  - Literature search including non-clinical safety findings
- How to escalate signals, e.g. stand-alone notification, ESI

17:00 END OF DAY 2

*There will be a 15 min break around 15:00.

DAY 3

13:00 SESSION 5 CONTINUED

EVDAS AND PRACTICAL EXERCISES

Calin Lungu and Vojtech Kvita

16:00 QUESTIONS AND ANSWERS

USE OF THE MAHS EVDAS DASHBOARD

Calin Lungu, Vojtech Kvita and Rodrigo Postigo

17:00 END OF THE VIRTUAL LIVE TRAINING COURSE

*There will be a 15 min break around 15:00.

Group Discounts

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

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.

**Terms and Conditions apply. Please contact DIA EMEA office for more information.*

Customized Professional Development for Your Team

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 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

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

Continuing Education

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited this training course with 9.50 credits.

REGISTRATION FORM

EVDAS Virtual Live Training Course # 25539
18-20 February 2025 | 13:00-17:00 CET

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 24 Dec 2024	MEMBER valid from 25 Dec 2024	NON-MEMBER
INDUSTRY/ REPRESENTATIVE	€ 1'215.00 ❑	€ 1'350.00 ❑	€ 1'610.00 ❑
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	NA	€ 675.00 ❑	€ 935.00 ❑
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