DIA Learning

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

## Virtual Live Training Course

**19-21 January 2022 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 course is based on the latest guidelines on EU Good Pharmacovigilance Practices (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

After the completion of this virtual live training course, participants will be able to:

- Understand regulatory requirements for Signal management in Europe (GVP IX and Addendum I)
- Describe principles of screening EudraVigilance for adverse reactions and the EudraVigilance data access policy
- Identify levels and methods of access to Individual Case Safety Reports (ICSRs) data and understand the terminology of EVDAS
- Learn to use active substance grouping reports, 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 European Medicines Agency (EMA)

## KEY TOPICS

- GVP IX
- Principles of access in EudraVigilance
- EVDAS
- eRMR analysis and documentation
- Line listing analysis
- Literature search including non-clinical safety findings
- How to escalate signals, e.g. stand-alone notification, ESI

## 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
Luxembourg

**Rodrigo Postigo**
Scientific Administrator
European Medicines Agency
Netherlands

**Vojtech Kvita**
Executive Director
NextPV Services
Czech Republic

PharmaTrain
MASTERING MEDICINES DEVELOPMENT
CENTRE RECOGNITION

## 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**

## 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, 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.



## 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.

## 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

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## Continuing Education

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

EVDAS Virtual Live Training Course # 22559
19-21 January 2022 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 24 Nov 2021 | MEMBER valid from 25 Nov 2021 | NON-MEMBER |
|---|---|---|---|
| INDUSTRY/ REPRESENTATIVE | € 1'115.00 ❑ | € 1'240.00 ❑ | € 1'425.00 ❑ |
| ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME) | NA | € 620.00 ❑ | € 805.00 ❑ |
| 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**

## 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 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 #22559 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 |
|---|---|
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