

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

## Virtual Live Training Course

4-6 October 2023 13:00-17:00 CEST



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

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:

- Identify 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)

### 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

#### Isabella Palagiano

- Deputy QPPV/LCPPV, PVCS Line Manager
- PVpharm
- Spain

#### Rodrigo Postigo

- Scientific Administrator
- European Medicines Agency
- The Netherlands

### KEY TOPICS

- GVP IX, Addendum I, screening for adverse reactions in EudraVigilance: principles, methodology and best practice
- Principles of access in EudraVigilance
- EVDAS: practical use and exercises
- eRMR analysis and documentation
- Line listing analysis
- Literature search including non-clinical safety findings
- How to escalate signals, e.g. stand-alone notification, ESI

## DAY 1

13:00 WELCOME AND INTRODUCTION

13:30 SESSION 1

### GVP IX

#### *Calin Lungu and Isabella Palagiano*

- 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 Isabella Palagiano*

- Disproportionate Reporting
- Signal Detection Methods
- Introduction to EVDAS

15:30 BREAK

15:45 SESSION 3

### PRINCIPLES OF ACCESS IN EUDRAVIGILANCE

#### *Calin Lungu and Isabella Palagiano*

- EudraVigilance Stakeholders
- EV Access Levels
- MLM Reports

17:00 END OF DAY 1

## DAY 2

13:00 SESSION 4

### EVDAS PILOT

#### *Calin Lungu and Isabella Palagiano*

- Transitional Arrangements
- EVDAS Pilot Experience

13:30 SESSION 5

### EVDAS AND PRACTICAL EXERCISES

#### *Calin Lungu and Isabella Palagiano*

- 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 Isabella Palagiano*

16:00 QUESTIONS AND ANSWERS

### USE OF THE MAHs EVDAS DASHBOARD

#### *Calin Lungu, Isabella Palagiano 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!**

- 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 (early-bird), 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](mailto:basel@diaglobal.org).

## | 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
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For more information please contact [tereza.krucka@diaglobal.org](mailto:tereza.krucka@diaglobal.org)

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## | 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

## | 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>

For further information on system requirements, please visit the website:

<https://www.diaglobal.org/General/System-Requirements>

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# REGISTRATION FORM

EVDAS Virtual Live Training Course # 23539  
4-6 October 2023 13:00-17:00 CEST



## 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 9 Aug 2023	MEMBER valid from 10 Aug 2023	NON- MEMBER
INDUSTRY/ REPRESENTATIVE	€ 1'115.00 <input type="checkbox"/>	€ 1'240.00 <input type="checkbox"/>	€ 1'475.00 <input type="checkbox"/>
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	NA	€ 620.00 <input type="checkbox"/>	€ 855.00 <input type="checkbox"/>

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](https://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](https://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](mailto:Basel@DIAglobal.org) **Mail:** DIA, KÜchengasse 16, 4051 Basel, Switzerland

**Web:** [www.DIAglobal.org](http://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 #23539 as well as the invoice number to ensure correct allocation of your payment.

Please note: if you register 7 days or less before the start of the course, it is not possible to settle the registration fee by bank transfer, but only by credit card. Thank you for your understanding and cooperation.

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