

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

16-18 June 2026 | 09:00-13:00 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 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.

Faculty

Calin Lungu

CEO

Drug Development Consulting Services
Luxemburg

Vojtech Kvita

Executive Director
NextPV Services
Czech Republic

Rodrigo Postigo

Scientific Administrator
EMA
Netherlands

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.

Schedule-At-A-Glance

DAY 1

09:00 WELCOME AND INTRODUCTION

09:30 SESSION 1

GVP IX

Calin Lungu and Vojtech Kvita

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

10:30 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

11:30 BREAK

11:45 SESSION 3

PRINCIPLES OF ACCESS IN EUDRAVIGILANCE

Calin Lungu and Vojtech Kvita

- EudraVigilance Stakeholders
- EV Access Levels
- MLM Reports

13:00 END OF DAY 1

DAY 2

09:00 SESSION 4

EVDAS PILOT

Calin Lungu and Vojtech Kvita

- Transitional Arrangements
- EVDAS Pilot Experience

09:30 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. ESI

13:00 END OF DAY 2

*There will be a 15 min break around 11:00.

DAY 3

09:00 SESSION 5 CONTINUED

EVDAS AND PRACTICAL EXERCISES

Calin Lungu and Vojtech Kvita

12:00 QUESTIONS AND ANSWERS

USE OF THE MAHS EVDAS DASHBOARD

Calin Lungu, Vojtech Kvita and Rodrigo Postigo

13:00 END OF THE VIRTUAL LIVE TRAINING COURSE

*There will be a 15 min break around 11:00.

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REGISTRATION FORM

EVDAS Virtual Live Training Course # 26536

16-18 June 2026 | 09:00-13:00 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 19 May 2026	MEMBER valid from 20 May 2026	NON- MEMBER
INDUSTRY/ REPRESENTATIVE	€ 1'215.00 <input type="checkbox"/>	€ 1'350.00 <input type="checkbox"/>	€ 1'610.00 <input type="checkbox"/>
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	NA	€ 675.00 <input type="checkbox"/>	€ 935.00 <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.

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Please enter your company's VAT number: _____

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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

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

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