DIA LEARNING

Workshop on Automation and AI in Signal Management

12-13 November 2025 | 13:30-17:30 CET

Overview

This interactive workshop explores the evolving role of automation and artificial intelligence (AI) in signal management.

Participants will gain a foundational understanding of signal detection principles and how emerging technologies from machine learning to large language models (LLMs) are reshaping traditional workflows.

The workshop combines theoretical insights with practical exercises, regulatory considerations, and real-world use cases across industry and regulatory settings.

Attendees will leave with a clearer view of where automation and AI can add value, what risks to manage, and how to begin implementing AI-enabled solutions in signal management.

Learning Objectives

By the end of this workshop, participants will be able to:

- Define key pharmacovigilance concepts related to signal detection, including qualitative and quantitative methods.
- Explain the fundamental principles behind automation and AI, including how LLMs work.
- Identify potential risks and limitations of AI systems, such as bias, hallucinations, and regulatory challenges.
- Interpret emerging AI guidance from EU, FDA, and CIOMS in the context of signal management.
- Evaluate AI use cases in pharmacovigilance from different organizational perspectives (small, medium, large pharmaceutical companies, regulators).
- Develop initial implementation strategies for AI/automation solutions, including validation and oversight requirements.
- Apply learning through group-based case scenarios using practical tools and platforms.

Who Will Attend

This workshop is designed for pharmacovigilance professionals seeking to understand and apply automation and AI in signal management. It is especially relevant for:

- Drug safety specialists and signal management teams looking to future-proof their practices
- Pharmacovigilance managers and QPPVs evaluating AI-based solutions
- Data scientists, PV analysts and IT professionals collaborating with PV teams on AI system implementation
- Quality assurance and compliance officers involved in system validation and oversight

Working knowledge of LLMs is recommended but not essential. Participants with prior exposure to PV signal detection will gain the most from the training, but those new to the topic will also benefit from the foundational content provided.

The course focuses on the use of automation and AI in signal management, a continuous activity throughout the product lifecycle, including clinical trials. While the topic will be addressed broadly, the primary emphasis will be on the post-marketing setting, where organizations can leverage larger data volumes and apply automation and AI more effectively.

Faculty

Jan Kolouch
CEO, Strategic PV Advisor
NextPV Services, Czech Republic

Luis Pinheiro
Senior Epidemiology Expert, RWE, Data Analytics and Methods Taskforce
European Medicines Agency, Netherlands

Julia Appelskog
Head of QPPV Office and PV Intelligence
CSL, Sweden

Philip Jones
Disease Area Cluster Lead in Safety Surveillance and Risk Management
Pfizer, UK

Mina Ebeid
Genmab, US

Nicole Schmid Davis
Associate Director, GDS&PV Signal Detection & Risk Management Scientist
Genmab, US

Michael Alexander Harborg
student worker in clinical trial analytics and visualization, Genmab, United States

Key Topics

- Fundamentals of signal detection: definitions, detection methods, and PV context
- Introduction to AI and automation: terminology, models, and practical relevance
- Principles of LLMs and generative AI in PV
- Oversight of AI: quality control, hallucination risks, bias mitigation
- Regulatory landscape: EU AI Act, FDA AI guidance, CIOMS WG outputs
- Intellectual property, confidentiality, and ethical considerations
- Strategic planning for AI implementation in PV processes
- Practical exercise and demonstration

PharmaTrain
MASTERING MEDICINES DEVELOPMENT
CENTRE OF EXCELLENCE

DAY 1

13:30 WELCOME AND INTRODUCTION

14:00 SESSION 1

INTRODUCTION TO SIGNAL MANAGEMENT

Jan Kolouch

- What is a signal
- How are signals detected
- Qualitative and quantitative methods

14:30 SESSION 2

INTRODUCTION TO AI

Philip Jones

- What is automation and AI
- How does AI work, principles of LLMs
- Quality control and oversight of AI, biases, hallucinations

15:30 BREAK

15:45 SESSION 3

AI GUIDANCE

Julia Appelskog

- Copyright, intellectual property, confidentiality
- AI guidance – EU AI act, FDA guideline, CIOMS XVI AI working group draft guidance

16:45 SESSION 4

GROUP WORK WITH PRACTICAL EXERCISES

Jan Kolouch

- Practical work with LLMs

17:30 END OF DAY 1

DAY 2

13:30 SESSION 5

IMPLEMENTATION STRATEGY (E.G., PROOF OF CONCEPTS, VALIDATION, APPROACHES TO FOLLOW)

Mina Ebeid, Nicole Schmid Davis, Michael Harborg, Jan Kolouch and Julia Appelskog

- Use case scenario – small/medium organisation
- Use case scenario – implementation of automation for medium sized organization
- PoCs, validation, and approaches to follow

15:30 BREAK

15:45 SESSION 6

GROUP WORK WITH PRACTICAL EXERCISES

Philip Jones, Julia Appelskog, Jan Kolouch, Mina Ebeid, Nicole Schmid Davis and Michael Alexander Harborg

- Practical work with LLMs and test data

17:00 Q&A WITH FACULTY & LUIS PINHEIRO, EMA

17:30 END OF THE WORKSHOP

AS A PRE-REQUISITE FOR THIS VIRTUAL LIVE TRAINING COURSE, PLEASE CREATE A FREE CHATGPT AND CLAUDE ACCOUNTS.

- Please feel free to use your company's or Pro accounts if you have these set up already.
- In case these platforms are blocked by your employer, please use your private laptop to participate at this virtual live training course.

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 6,5 credits.

REGISTRATION FORM

Automation and AI in Signal Management Virtual Live Training Course # 25558
12-13 November 2025 | 13:30-17:30 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 17 Sep 2025	MEMBER valid from 18 Sep 2025	NON-MEMBER
INDUSTRY/ REPRESENTATIVE	€ 900.00 ❑	€ 1'000.00 ❑	€ 1'260.00 ❑
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	NA	€ 500.00 ❑	€ 760.00 ❑
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