DA LEARNING

Artificial Intelligence in Pharmacovigilance

Virtual Live Training Course

24-26 February 2026 | 13:00-17:30 CET



Overview

This course provides a practical orientation for senior pharmacovigilance (PV) and IT professionals on the next level of technology transformation in PV. The rapid advancements in artificial intelligence (AI) over recent years have significantly impacted the way pharmacovigilance operates or may operate. With technologies such as machine learning and large language models being integrated into daily workflows, a new skillset is urgently needed.

This live virtual training is designed to equip experienced PV professionals with the knowledge and confidence to make informed decisions about AI adoption. Participants will learn how to apply AI tools in a smart, compliant, and impactful way.

The program is led by pharmacovigilance and IT veterans with hands-on experience in deploying AI technologies across PV systems. A regulatory viewpoint will be featured in dedicated panel discussions, including representation from the UK's MHRA, ensuring participants gain insight into evolving expectations and frameworks.

Learning Objectives

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

- Understand the fundamentals of key Al methodologies, including machine learning, natural language processing, classifications, large language models (LLMs), and other ML variants.
- Explain the benefits and limitations of leading AI tools already in use in PV, such as OpenAl ChatGPT, Google Gemini, Anthropic Claude, Microsoft Copilot, and
- Recognize and manage risks related to data privacy, data security, bias, and ethical concerns in AI applications.
- Discuss the organizational implications of AI, including governance, audit readiness, workforce enablement, and change management.
- Evaluate the AI capabilities of current PV IT platforms (e.g., Oracle Argus, IQVIA IVP, RxLogix, ArisGlobal LifeSphere).
- Envision the ideal intelligent PV IT system of the future and contribute ideas toward its development.
- Build a roadmap for successful AI implementation tailored to their organizational
- Learn how to integrate digital workforce technologies in pharmacovigilance operations.

Who Will Attend

This course is ideal for pharmacovigilance and IT professionals with at least 2 years of PV experience who seek a comprehensive and practical overview of the AI technologies transforming the pharmacovigilance industry. It is especially relevant for:

- PV team leaders and managers
- Quality and compliance professionals
- Business process owners
- Digital transformation and IT specialists
- Regulatory affairs professionals involved in PV oversight

Faculty

Jan Petracek

Director Institute of Pharmacovigilance EU

Andrew Mitchell

CFO and Founder YEZA.ai **United States**

Phil Tregunno

Deputy Director - Patient Safety Monitoring **MHRA** United Kingdom



DAY 1

13:00 WELCOME AND INTRODUCTION

13:30 SESSION 1

PV JOURNEY FROM MANUAL THROUGH ROBOTIC PROCESS **AUTOMATION (RPA) TO AI**

Jan Petracek

- Business experience from 10-year-long journey of implementation of intelligent automation in pharmacovigilance
- · Areas of immediate and near future impact of AI technologies, ethical and legal considerations
- What is changing in pharmacovigilance and why, the main trends and competencies needed for the near future
- · Al initiatives from major regulatory authorities and CIOMS

15:00 BREAK

15:30 SESSION 2

AI FUNDAMENTALS FOR PV

Andrew Mitchell

- Background and Introduction
- Adoption of AI in Pharmacovigilance
- · Use Cases & Classifications
- · Critical AI Techniques, including
 - Supervised vs Unsupervised vs Transfer Learning
 - Prompt Engineering
 - RAG Architectures
 - Small Language Models

17:00 DISCUSSION AND Q&A

17:30 END OF DAY 1

DAY 2

13:00 SESSION 3

COMPLIANCE AND MANAGEMENT PERSPECTIVE ON IMPLEMENTING INTELLIGENT AUTOMATION

Jan Petracek

- · Business case and management views how senior management and CEOs view investments in innovative technology
- Prepare your departments, teams, hire the right talent, and create your roadmaps
- What are some of the myths on either side management and business and how might we bridge them
- · Exercise a clever approach to validation and quality management requirements to stay compliant while using the most modern technology
- Defense of more intelligent data management practices in front of auditors and inspectors

BREAK 14:30

15:00 SESSION 4

TODAY'S PV INTERFACES AND SYSTEMS

Andrew Mitchell

- PV Systems: Vendor Landscape, Observations and Predictions
- Al in PV Use Cases
- Deploying AI for Pharmacovigilance
- · How Are Regulators Responding to AI in PV?
- Human-in/on-the-Loop (HITL/HOTL)
- · Key Principles to Adoption
- · Validation Categories for GxP AI Systems
- · Community Resources

16:30 DISCUSSION AND Q&A

17:30 END OF DAY 2

DAY 3

13:00 SESSION 5

NEAR FUTURE PV IT DEVELOPMENTS

Andrew Mitchell

- Rapid Shift from ML/NLP to GenAl
- · Transforming PV for Agentic AI
 - Organization Change
 - Infrastructure
 - Data
 - Business Transformation
- · Learning from a Risk-Based Approach

14:30 **BREAK**

15:00 SESSION 6

DEVELOPING REGULATORY ENVIRONMENT FOR AI IN PV

Jan Petracek, Andrew Mitchell and Phil Tregunno

- · Case studies
- · View of leading regulators
- · Discussion and Q&A

16:00 SESSION 7

STEP BY STEP AI IMPLEMENTATION

Jan Petracek

- Overview of all steps in pharmacovigilance and how to boost productivity and quality in each of them using various AI tools
- · Case studies demonstrating strengths and weaknesses
- Developing roadmap of AI implementation for your PV department
- Q&A

17:30 END OF THE VIRTUAL LIVE TRAINING COURSE

Unless otherwise disclosed, DIA acknowledges that the statements made by speakers are their own opinion and not necessarily that of the organisation they represent, or that of the DIA. Speakers and agenda are subject to change without notice. Recording during DIA sessions is strictly prohibited without prior written consent from DIA.



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Register 3 individuals from the same company for the same course and receive complimentary registration

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.



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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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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 10 credits.



REGISTRATION FORM

Al in PV | Virtual Live Training Course | # 26537 24-26 February 2026 | 13:00-17:30 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:

| EARLY-BIRD valid until 28 Jan 2026 | valid from 29 Jan 2026 | NON- MEMBER |
|--|-----------------------------|--|
| € 1′530.00 🗖 | € 1′700.00 □ | € 1′960.00 🗖 |
| NA | € 850.00 □ | € 1′110.00 🗖 |
| | 28 Jan 2026 € 1'530.00 □ | Valid until 28 Jan 2026 29 Jan 2026 € 1'530.00 □ € 1'700.00 □ |

A special discount is available for organisations which are listed in the <u>EMA SME register</u>. Number of discounted seats is limited.

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 DIAqlobal.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@DlAglobal.org Mail: DIA, Küchengasse 16, 4051 Basel, Switzerland Web: www.DlAglobal.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.

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