DIA LEARNING

Artificial Intelligence in Pharmacovigilance

Virtual Live Training Course

7-9 September 2027 | 13:00-17:30 CEST

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 AI 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 OpenAI ChatGPT, Google Gemini, Anthropic Claude, Microsoft Copilot, and others.
- 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 needs.
- 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
CEO and Founder
YEZA.ai
United States

Phil Tregunno
Deputy Director - Patient Safety Monitoring
MHRA
United Kingdom

PharmaTrain
MASTERING MEDICINES DEVELOPMENT
CENTRE OF EXCELLENCE

DAY 1

15:00 WELCOME AND INTRODUCTION

15:30 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
- AI initiatives from major regulatory authorities and CIOMS

17:00 BREAK

17:30 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

19:00 DISCUSSION AND Q&A

19:30 END OF DAY 1

DAY 2

15:00 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

16:30 BREAK

17:00 SESSION 4

TODAY'S PV INTERFACES AND SYSTEMS

Andrew Mitchell

- PV Systems: Vendor Landscape, Observations and Predictions
- AI 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

18:30 DISCUSSION AND Q&A

19:30 END OF DAY 2

DAY 3

15:00 SESSION 5

NEAR FUTURE PV IT DEVELOPMENTS

Andrew Mitchell

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

16:30 BREAK

17:00 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

18:00 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

19:30 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.

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.*

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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

Technical Requirements

As a pre-requisite for this virtual live training course, please create a free ChatGPT, Google Gemini, Claude accounts.

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

All DIA training courses have been awarded a PharmaTrain Centre Recognition.

PharmaTrain Federation is a not for profit organisation that started its activities as an IMI (Innovative Medicines Initiative) European Project. Its mission is to drive implementation of globally recognized high-level standards for postgraduate education and training in Medicines Development. To that aim, the Federation is assessing Continuous Professional Development (CPD) Courses and Course Providers around the world that deserve recognition.

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CENTRE RECOGNITION

REGISTRATION FORM

AI in PV | Virtual Live Training Course | # 27559
7-9 September 2027 | 15:00-19:30 CEST

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 10 Aug 2027	MEMBER valid from 11 Aug 2027	NON-MEMBER
INDUSTRY/ REPRESENTATIVE	€ 1'530.00 ❑	€ 1'700.00 ❑	€ 1'960.00 ❑
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	NA	€ 850.00 ❑	€ 1'110.00 ❑
A special discount is available for organisations which are listed in the EMA SME register. 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.

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.

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:

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Date	Signature

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