DIA LEARNING

Artificial Intelligence in Pharmacovigilance

Virtual Live Training Course

4-6 February 2025 | 13:00-17:30 CET

Overview

A practical orientation course for the next level of pharmacovigilance technology as it is being implemented across the industry. Over the last 7 years, major advances in artificial intelligence (AI) technology have reached the pharmacovigilance (PV) industry and are changing how we operate with ever-increasing speed. A new skillset for pharmacovigilance professionals is required.

The course is designed to give all senior pharmacovigilance professionals sufficient orientation to make an informed decision and use the new technology in a smart and compliant way.

The course is given by pharmacovigilance and IT veterans who are fearless in enabling sustainable innovation and have hands-on experience with AI tools in pharmacovigilance. A regulatory point of view is represented in panel discussions.

Learning Objectives

At the conclusion of this virtual live training course, participants will be able to:

- Understand how main AI methodologies work - machine learning, natural language processing, classifications, large language models, other ML
- Clearly explain pros and cons of AI models that are already being used in PV, including OpenAI ChatGPT (3.5 and 4.0), Google Gemini, Anthropic Claude 2, MS Copilot etc.
- Identify and manage risks to your data security, data privacy, bias and ethical concerns
- Discuss the management perspective and challenges - people, skills, governance, audits, and compliance
- Review what today's PV IT platforms deliver in terms of implementations, AI, and automation, including major systems such as Oracle Argus, IQVIA IVP, RxLogix, LifeSphere by ArisGlobal etc.
- Brainstorm what would be the perfect PV IT intelligent system of the future
- Roadmap for successful AI implementation in your PV system

Key Topics

- PV journey from manual through RPA to AI
- AI and NLP in PV
- Compliance and management perspective on implementing intelligent automation
- Today's PV interfaces and systems
- Near future PV IT developments
- Developing regulatory environment for AI in PV

Who Will Attend

Pharmacovigilance and IT professionals with 2+ years of PV experience who wish to gain a practical overview of all AI technologies coming to the pharmacovigilance industry.

Faculty

Jan Petracek
Director
Institute of Pharmacovigilance
EU

Robert Scheiner
Independent Consultant;
Experienced Technology Leader and Staff+ Engineer;
Expert in Advanced Generative AI Implementations within Pharmacovigilance, Regulatory & GxP Compliance
Czech Republic

Phil Tregunno
Deputy Director - Patient Safety Monitoring
MHRA
United Kingdom

PharmaTrain
MASTERING MEDICINES DEVELOPMENT
CENTRE OF EXCELLENCE

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 7-year-long development and implementation of intelligent automation in pharmacovigilance
- 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

15:00 BREAK

15:30 SESSION 2

AI AND NATURAL LANGUAGE LEARNING (NLP) IN PV

Robert Scheiner

- Main principles of AI technology, especially in the PV context
- Main use cases where AI is used within PV, where it augments human workflows and vice versa - where humans may complement what AI is primarily (or will be soon) doing

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
- Defence of more intelligent data management practices in front of auditors and inspectors

14:30 BREAK

15:00 SESSION 4

TODAY'S PV INTERFACES AND SYSTEMS

Robert Scheiner

- Current PV IT platforms and patterns
- What to expect from FDA, EMA, and MHRA in terms of intelligent automation
- Ongoing Prove of Concepts (PoCs) and development AI labs at major and smaller pharma, regulators, and service organisations

16:30 DISCUSSION AND Q&A

17:30 END OF DAY 2

DAY 3

13:00 SESSION 5

NEAR FUTURE PV IT DEVELOPMENTS

Robert Scheiner

- Future of PV IT platforms
- Technology architectural patterns supporting high scalability, throughput, and flexibility
- Wise and informed decisions about the future use of technology like NLP, RPA, and advanced ChatGPT-like technologies in their daily work
- Distinguish buzz from reality when assessing options
- How to go from labs to future production and build a real ML Ops
- How to build in explainability from early on and avoid compliance issues later

14:30 BREAK

15:00 SESSION 6

DEVELOPING REGULATORY ENVIRONMENT FOR AI IN PV

Jan Petracek, Robert Scheiner and Phil Tregunno

- Case studies
- View of leading regulators
- 2023 as a breakthrough year and what will happen in 2024+
- Discussion and Q&A

17:30 END OF THE 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 tereza.krucka@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

Please note: Most EU countries accept direct submission, by the participant, of training courses, conferences and other educational opportunities with the aim of obtaining CPD (Continuous Professional Development) points. Please do not hesitate to contact DIA directly if you need any further documentation to conclude your submission.

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

AI in PV | Virtual Live Training Course | # 25537
4-6 February 2025 | 13:00-17:30 CET

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 Dec 2024	MEMBER valid from 11 Dec 2024	NON-MEMBER
INDUSTRY/ REPRESENTATIVE	€ 1'420.00 ❑	€ 1'580.00 ❑	€ 1'840.00 ❑
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	NA	€ 790.00 ❑	€ 1'050.00 ❑
A special discount is available for organisations which are listed in the EMA SME register. Number of discounted seats are 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 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