

SEMINAR OF PANHELLENIC ASSOCIATION OF PHARMACISTS (PEF)

PHARMACOVIGILANCE: A SCIENCE CLOSELY CONNECTED TO AI AND A GROWTH LEVER OF ONE'S COUNTRY

12 MAY 2023

15.00-18.00 pm through WEBEX



Program

15.00-15.05 **Official hailing**

15.10-16.25 **Session 1.
Pharmacovigilance and AI**

Coordinator: **Sophia Trantz**, Pharmacist, MSc, MSc PV, President of PEF

15.10-15.40 **Pharmacovigilance and drug safety in clinical trials: Technological solutions and methods for data integrity and safety data analysis**

Speaker: **Gregory Farmakis**, CEO / Agilis SA

15.40-16.10 **Information Visualization Platform (InfoViP), an Artificial Intelligence-based Human-in-the-Loop Decision Support Tool for Pharmacovigilance**

Speaker: **Oanh Dang**,
Regulatory Science and Applied Research Lead for
Pharmacovigilance, FDA

16.10-16.25 **Discussion with the speakers**

16.25-16.30 **Break**

16.30-17.45 **Session 2:
Pharmacovigilance as a growth lever of one's country**

Coordinator: **Charalampos Nakos**, EU-QPPV at Drug Safety Solutions

16.30-17.00 **Pfizer's Safety Risk Leads in Thessaloniki**

Speaker: **Giovanni Furlan**,
PharmD, FISop, Worldwide Safety Site Lead, Pfizer, Safety Risk
Lead, Director

17.00-17.30 **Collaborative approaches to establishing and implementing pharmacovigilance systems - pharmacovigilance can be a driving force and a growth lever of one's country**

Speaker: **Dr Brian Edwards**,
Managing Director Husoteria Ltd and Vice-President
International Society of Pharmacovigilance

17.30-17.45 **Discussion with the speakers**

17.45-18.00 **Closing of the seminar**

CVs of presenters and coordinators

Coordinators

Charalampos Nakos

Pharmacovigilance professional of pharmacy background with more than 10 years of experience supporting all stages of a product lifecycle, from Phase I clinical trials through to post-marketing activities. Collaborated with a plethora of colleagues and clients across multiple regions and leading a team of more than 20 pharmacovigilance professionals, involved in various therapeutic areas (e.g., oncology, immunology, ophthalmology) and products (biologicals). Passionate Health Economist with an immense desire to provide realistic proposals, aiming to attract a higher number of clinical trials' investments in Greece.

Sophia Trantza

Sophia Trantza is a pharmacist, specialized in Pharmaceutical Technology and Pharmacovigilance and is certified in the field of Medical Affairs. She is currently a student in the CAS Advanced Studies degree for Radiopharmacy in the University of ETH, Zurich, Switzerland. She has over 7 years' experience as Qualified Person for Pharmacovigilance in the Pharmaceutical Industry and in parallel was ISO responsible and certified in ISO 9001: 2008, 2015 and ISO 13485. She has entered the National Organization for Medicines in 2016, serving as an employee in the Adverse Reactions' department and as PRAC alternate member for Greece. She currently holds the position of PRAC member, representing Greece at the European Medicines Agency (EMA), she is Assessor in the Evaluation's Department for medicinal products for human use and the responsible pharmacist in the Cosmetics' department and in the European Committee for Cosmetics and the relevant working groups.

Presenters

Gregory Farmakis

Gregory Farmakis is a founder and CEO of Agilis SA, a technology, clinical data management, and biostatistics service provider for clinical trials. As an information engineer by formation, he is personally involved in the architecture and design of Agilis' clinical data management cloud solution as well as the company's strategy for development of innovative technological solutions for clinical trials.

Oanh Dang

Oanh Dang is a pharmacist and the Regulatory Science and Applied Research Lead for Pharmacovigilance at the Food and Drug Administration's (FDA) Office of Surveillance and Epidemiology in the Center for Drug Evaluation and Research. She leads multiple Research and Development projects and serves as a pharmacovigilance subject matter expert on several artificial intelligence (AI) research initiatives that focus on the application of AI to enhance the efficiency and effectiveness of adverse event signal detection and evaluation. She has also co-authored a number of peer reviewed publications in this area.

Giovanni Furlan

More than 20 years' experience in the drug safety arena and a degree in Chemistry and Pharmaceutical Technology, as a qualified pharmacist. Has set up, developed and managed drug safety units, integrated the safety operations of pharmacovigilance departments. Qualified Person Responsible for Pharmacovigilance (EU QPPV) and Local Responsible Person for Pharmacovigilance. Worked at local, European, and global level in medium and big pharma and in a CRO. Joined Pfizer in 2018 as Safety Risk Lead Director, in 2022 has been given the responsibility to set up a pharmacovigilance department in Thessaloniki.

Dr Brian Edwards

Dr Edwards trained at Guy's Hospital, London and spent 14 years in hospital medicine and clinical research before joining the UK regulatory agency which used to be called the Medicines Control Agency. After 5 years there, he joined a global CRO, Parexel, for six years followed by 18 months at Johnson & Johnson as a deputy qualified person for pharmacovigilance.

For the last 13 years up until 2021, he was Principal Consultant in Pharmacovigilance at NDA Regulatory Science based in the UK.

In addition, he co-chairs the ISOP Medication Error Special Interest Group) and Chair of the UK Pharmaceutical Human Factors group.

Previously, he chaired the panel overseeing the 'Drug Safety Surveillance' module as part of Higher Medical Training for pharmaceutical medicine in the UK between January 2006 and 2012. He has been awarded a Fellowship with the International Society of Pharmacovigilance.

Currently he is Managing Director of his own consultancy Husoteria Ltd and has been co-leader of the DIA/ASA Benefit Risk Assessment Planning working group since 2020. More recently, he was elected back to the Executive Committee of ISOP and is Vice-President of ISOP and Director of ISOP Secretariat Ltd

Cost of attendance

Non-members of PEF:	€ 100 (including VAT)
Members of PEF:	€ 70 (including VAT)
Students / unemployed:	€ 25 (including VAT) - with demonstration of student pass / unemployment card

Note: All members of PEF should have completed their annual subscription even for 2023.

For companies or organizations registering more than 2 participants, please contact the PEF secretariat to ask for a discount.

To register, fill in the Online participation form **HERE**.

Payment can only be made by bank transfer to the following account:

Piraeus Bank

Account number: **6435-010070-731**

IBAN: **GR 9101714350006435010070731**

Beneficiary: PANHELLENIC ASSOCIATION OF PHARMACISTS (PEF)

Note in the reason for filing:

- Company name, if it is a corporate participation
- Name, if it is an individual participation

Caution:

- Bank charges should be borne entirely by the depositor.
- Avoid individual deposits if you are going to pay for more than 1 entry.
- Your participation is considered valid after its confirmation by the secretariat of PEF by relevant email.

Participants will be given a certificate of attendance.

The link to the seminar will be provided upon completion of your registration.

For any clarification or other additional information contact the secretariat of the Panhellenic Association of Pharmacists (PEF) at: info@pepharm.gr