EUROPEAN PHARMACO VIGILANCE CONGRESS 2025

19-20 November | Virtual
28 November | Milan

In collaboration with

INSTITUTE OF PHARMACOVIGILANCE

International Scientific Conference

PEC PHARMA EDUCATION CENTER

The **European Pharmacovigilance Congress**, organized by **Pharma Education Center**, is recognized as one of the most important and appreciated global pharmacovigilance conferences for the very high scientific content.
As in previous editions, the EUPV congress 2025 is asssured by the esteemed Scientific Advisory Group: a team of internationally renown key opinion leaders in charge of defining the congress content and identifying the most knowledgeable, prestigious and eloquent speakers. This year the scientific value of the congress will further increase thanks to the collaboration of the **Institute of Pharmacovigilance.**
The EUPV congress gathers PV professionals at all career levels, including key decision makers (e.g. VPs, Executives and Directors) interested in the always evolving pharmacovigilance world and its new trends, since they are always looking for new ideas to implement more efficient and effective strategies and tools for their departments.
EUPV Congress is the forum where all PV stakeholders from all over the world meet and exchange ideas.

CONGRESS DATES AND FORMAT

- 19-20 November | Virtual 9 am - 6 pm
- 27 November | Workshop + Evening Cocktail
  NH Milano Congress Centre 5 - 9 pm
- 28 November | Face to face,
  NH Milano Congress Centre 9 am - 6 pm

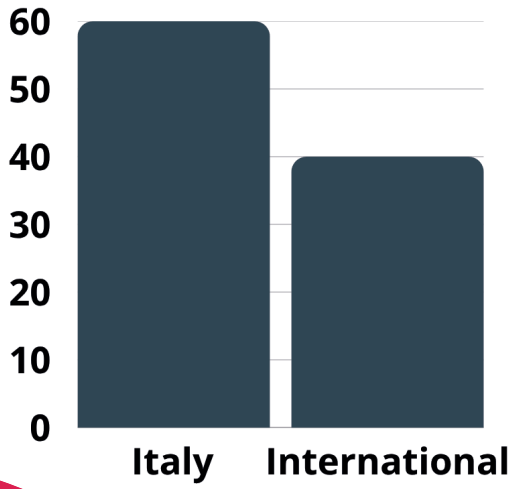
EVENING COCKTAIL
November 27 from 5 to 9 pm
Welcome evening cocktail and workshop
sponsored by iVigee
Reserve your place to meet and network with your colleagues and experts!

This year the congress will includes:
- 22 Topics
- 20 interactives round tables
- 6 virtual parallel sessions
- 2 face to face parallel workshops
- 2 LECTIO Magistralis

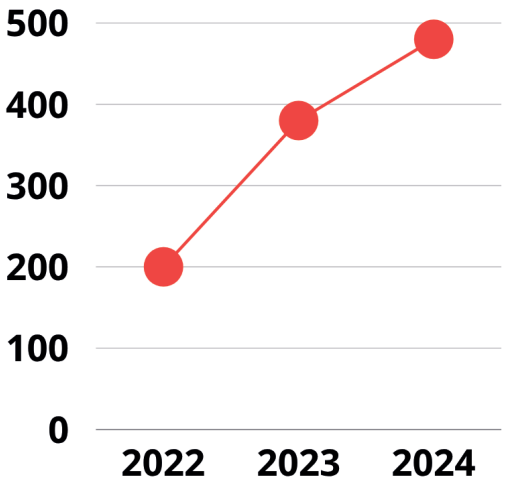
Our speakers are from: regulatory agencies, international pharmacovigilance organizations, patients' organizations, industry, academia.
The intense scientific interaction between speakers and delegates is a further invaluable plus of the event.

EUPV 2024 IN NUMBERS

ATTENDEES NATIONALITY



ATTENDEES TREND

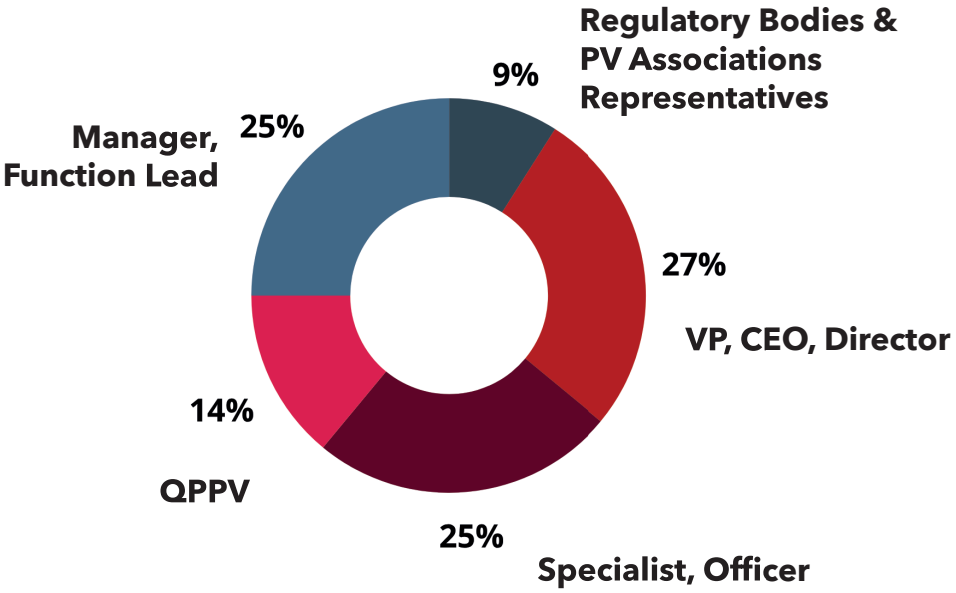


480 ATTENDEES representing

175 COMPANIES

5 CONTINENTS

50 COUNTRIES



Institute of Pharmacovigilance (IPV)

INSTITUTE OF PHARMACOVIGILANCE

Founded in 2015, the Institute of Pharmacovigilance (IPV) is a not-for-profit, non-governmental global organization with a clear goal – to elevate the pharmacovigilance industry by competency and seniority certification.

In 2020, IPV partnered with the International Society of Pharmacovigilance (ISoP) to develop the Global Pharmacovigilance Professional Certification (GPPC), creating a globally recognized standard for PV professionals. The certification works with competency standards including knowledge, skills and attitudes suitable for every role in pharmacovigilance.

Committed to continuous innovation, IPV regularly updates its programs to reflect the latest advancements, ensuring certified professionals have practical knowledge and skills they can immediately apply in their jobs immediately.

SCIENTIFIC ADVISORY GROUP

Felix Arellano
Senior Vice President and the Global Head of Safety & Risk Management | Roche

Andrew Bate
VP Safety Innovation & Analytics | GSK

Glyn Belcher
Honorary Member Scientific Advisory Group EUPV congress

Mattia Calissano
VP, Medical | SSI Strategy

Gian Nicola Castiglione
Pharmacovigilance Senior Consultant, Member and Secretary of SIMeF, ETS Board, Master of Labor. Head of Pharmacovigilance and QPPV

Mircea Ciuca
Global Therapeutic Area Head in Global Clinical Safety and Pharmacovigilance

Giovanni Furlan
Head Medical Safety Operations | Sandoz Germany

Calin A. Lungu
CEO | DDCS S.A.

Hrvoje Maček
VP, Medical & Scientific Affairs, EU QPPV | PrimeVigilance

Valentina Mancini
Senior Director Pharmacovigilance QPPV | Shionogi Europe

Jan Petracek
CEO | iVigee, Director Institute of Pharmacovigilance

Marco Sardella
Chief Pharmacovigilance Officer & EU-UK QPPV | ADIENNE Pharma & Biotech

CONFIRMED SPEAKERS

Marko Korenjak
President of the European Liver Patients' Association, former PRAC member, Slovenia

Petar Mas
PRAC member, HALMED, Croatia

Sophia Trantza
Senior Pharmacovigilance Expert former PRAC Member Greece

Cristina Arizmendi Vélez
Chief of Cosmetovigilance and Safety of Cosmetic Products | AEMPS, Spain

Pilar Rayón
PRAC member AEMPS, Spain

Lina Seibokiene
Senior expert at the Pharmacovigilance and Poison Information Unit, SMCA / PRAC alternate member, Lithuania

Ana Maria Velasco Calle
GCP/GVP Inspector from the Spanish Agency of Medicines and Medical Devices.

Elena Prokofyeva
Coordinator of Drug Safety Unit, DG Post, FAMHP, Belgium

Ana Sofia Martins
PRAC Member | INFARMED, I.P. – Portugal

João A. Pedras-Vasconcelos
Senior Pharmaceutical Scientist (Product Quality and Immunogenicity) CDER Integrative Immunogenicity Working Group Co-chair – FDA (tbc)

Antonella Caselli
Senior Clinical & Safety Assessor – Italian Medicines Agency (AIFA), Italy (tbc)

Lembit Rägo
Secretary-General | Council for International Organizations of Medical Sciences (CIOMS), Switzerlan

Phil Tregunno
Deputy Director, Patient Safety Monitoring, Safety and Surveillance | MHRA, UK (Tbc)

Elena Giovani
Head of the GVP Inspection Office | AIFA (Tbc)

Dirk Mentzer
Head of Pharmacovigilance | Paul-Ehrlich-Institut (PEI), Germany

Fazil Afzal
Senior Medical Assessor at Medicines and Healthcare products Regulatory Agency (MHRA), UK (tbc)

CONFIRMED SPEAKERS

Anita Blackburn
Labeling Lead | Fortrea, UK

Giuseppe Curigliano
Professor of Medical Oncology | University of Milano and European Institute of Oncology, IRCCS

Barbara De Bernardi
EU & UK Pharmacovigilance Qualified Person, VP, Head of Global QPPV Office Worldwide Medical & Safety | Pfizer, Italy

Margherita D'Antuono
EU-UK QPPV | Piramal Critical Care, Italy

Tina Amini
Director TA MedTech & Combination Products Consulting Ltd, UK

François Haguinet
Associate Director for Safety and Quantitative Innovation | GSK – Belgium

Ayman Ayoub
Labelling Lead, Research & Development | Pfizer – UK

Taxiarchis Botsis
Associate Professor | Johns Hopkins University School of Medicine – USA

Vjera Bilusic Vundac
Senior Director, Medical Writing | Primevigilance Ltd.-Croatia

Ahmed Diaa Eldin
CEO | Baupharma, Czech Republic

Arduino Mangoni
Strategic Professor in Clinical Pharmacology | Flinders University, Senior Consultant in Clinical Pharmacology and General Medicine, Australia

Panos Tsintis
Medical Director | PLM Med Ltd – UK

Hanae Bourji Chergui
Regulatory Affairs Senior Specialist | Becton and Dickinson, France

Marie-Laure Kurzinger
Associate VP, Head of Pharmacoepidemiology – General Medicines, Pharmacovigilance and Patient Safety | Sanofi, France

CONFIRMED SPEAKERS

Rory Littlebury
Head of PV System Oversight and QPPV Office | GSK – UK

Valeria Di Clemente
Director Pharmacovigilance EU Cluster and LATAM | Baxter, Italy

Antoine Pariente
Professor of Clinical Pharmacology and Pharmacoepidemiology, Head of the Public Health Research Dept. | Univ. Bordeaux, France

Adrian Roth
Principal Scientific Director Precision Safety, Pharma Development | Roche – Switzerland

Ilaria Grisoni
Exec. Dir., Head of International QPPV Office, EEA QPPV | Jazz Pharmaceuticals

Lisa Stagi
Patient Safety Country Cluster Lead | Roche, Italy

Michael Von Forstner
Managing Director | Mesa Laubela Consulting, Switzerland

Rajat Mohindra
Principal Medical Director, Precision Safety, Product Development Safety | F. Hoffmann-La Roche Ltd – Switzerland

Natasa Mihajlovic
Managing Director | Nostra Pharma, UK

Hadir Rostom
President of ISoP Egypt Chapter

Michael Glaser
Safety Innovation Technology Director | GSK – USA

Mariangela Amoroso
Country Medical Lead | Sanofi Italy

Nancy Dreyer
Chief Scientific Officer retired IQVIA and Professor | Univ of North Carolina, Chapel Hill - USA

Fabio De Gregorio
Vice President, Head of Safety | Shionogi Europe – UK

CONFIRMED SPEAKERS

Klaudija Marijanovic Barac
Sr. Director, Head of Teva Periodic reports and risk management Centre | Teva, Croatia

Antonella Fretta
Senior Director | Pfizer, Italy

David Chonzi
Medical Director | PV Safety Solutions

Dimitrios Zampatis
Director Product Patient Safety (DPPS) | Sandoz

Maddalena Lino
Safety risk Lead Director | Pfizer

Igor Copot
Executive Director of Safety Systems | Primevigilance

Alberto Gramaccioli
Director of Quality Management and Inspection | Pfizer, Italy

Marco Greco
Lawyer and EPF President, Italy (Tbc)

Paola Kruger
Expert Patient | EUPATI (European Patient's Academy for Therapeutic Innovation)

Catherine Tchinou
Head Medical Safety Biopharma | Sandoz

Linda Scarazzini
Former Senior Vice President Pharmacovigilance and Patient Safety, Epidemiology and R&D Quality Assurance Chief Safety Officer at AbbVie

Gabrièle Piaton-Breda
Research & Innovation Director | PLG

AGENDA 19 NOVEMBER

all times are UTC +1 **Virtual**

09.00 **Welcome by the Chairperson of the congress**
Marco Sardella, Chief Pharmacovigilance Officer & EU QPPV | ADIENNE Pharma & Biotech

09.10 **A word from the Editor-in-Chief of Therapeutic Advances in Drug Safety - EUPV Congress Media Partner**
Arduino Mangoni, Strategic Professor in Clinical Pharmacology | Flinders University, Senior Consultant in Clinical Pharmacology and General Medicine, Australia

09.15 **A word from the President of Institute of Pharmacovigilance**
Jan Petracek, Director | Institute of Pharmacovigilance

SESSION 1 - ADVANCING SIGNAL DETECTION IN PHARMACOVIGILANCE: MODERN METHODOLOGIES AND BEST PRACTICES

09.20 **Introduction by the Chairperson**
Andrew Bate, VP Safety Innovation & Analytics | GSK

09.25 **A new approach to quantitative signal detection using Bayesian Borrowing**
Francois Haguinet, Associate Director for Safety and Quantitative Innovation | GSK

09.45 **AI-based decision-support approaches in aspects of Signal Detection and Management**
Taxiarchis Botsis, Associate Professor, Johns Hopkins University School of Medicine | USA

10.05 **Enhancing signal detection: the challenge of data improvement**
Antoine Pariente, Professor of Clinical Pharmacology and Pharmacoepidemiology Head of the Public Health Research Department, Univ Bordeaux

10.25 **Round table**
A. Bate, T. Botsis, F. Haguinet, A. Pariente

11.00 **Coffee Break**

SESSION 2 - RISK MANAGEMENT

11.20 **Introduction by the Chairperson**
Mircea Ciuca, Global Therapeutic Area Head in Global Clinical Safety and Pharmacovigilance

11.25 **Patient centric additional risk minimization measures**
Klaudija Marijanovic Barac, Sr. Director, Head of Teva Periodic reports and risk management Centre | Teva

AGENDA 19 NOVEMBER

all times are UTC +1 **Virtual**

11.45 **Tbd**

12.05 **Round table**
M. Ciuca, K.M. Barac, Tbd

SESSION 3 - (PARALLEL) SAFETY OF COMBINATION PRODUCTS

11.20 **Introduction by the Chairperson**
Valeria Di Clemente, Director Pharmacovigilance EU Cluster and LATAM | Baxter, Italy

11.25 **EU Device regulatory submission content and consideration**
Tina Amini, Director TA MedTech & Combination Products Consulting Ltd

11.45 **Post-Market Surveillance for combination products**
Margherita D'Antuono, EU-UK QPPV | Piramal Critical Care

12.05 **Panel discussion and Q&A Time**
V. Di Clemente, M. D'Antuono, T. Amini

12.40 **LUNCH & NETWORKING**

SESSION 4 - IMPORTANCE OF REAL-WORLD DATA SOURCES AND EVIDENCE BEYOND SPONTANEOUS REPORTING

1.45 **Introduction by the Chairperson**
Lembit Rago, Secretary-General | Council for International Organizations of Medical Sciences (CIOMS)

1.50 **Tbd**
Dirk Mentzer, Head of Pharmacovigilance from Paul-Ehrlich-Institut (PEI)

2.10 **Use of artificial intelligence to leverage RWD in pharmacovigilance for patient safety**
Marie-Laure-Kürzinger, Associate VP, Head of Pharmacoepidemiology - General Medicines, Pharmacovigilance and Patient Safety, Sanofi

2.30 **The importance of Real Word Data (RWD) and Real World Evidence (RWE), beyond spontaneous reporting**
Nancy Dreyer, Chief Scientific Officer retired IQVIA and Professor | Univ of North Carolina, Chapel Hill - USA

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2.50 **Round table**
L. Rago, N. Dreyer, M.L. Kürzinger, D. Mentzer

SESSION 5 - (PARALLEL) COSMETOVIGILANCE

1.45 **Introduction by the Chairperson**
Sophia Trantza, Senior Cosmetic Assessor

1.55 **Pharmacovigilance vs Cosmetovigilance: Similarities and differences**
Sophia Trantza, Senior Cosmetic Assessor

2.15 **Spanish Cosmetovigilance System**
Cristina Arizmendi Vélez, Chief of Cosmetovigilance and Safety of Cosmetic Products, Spanish Agency of Medicines and Medical Devices (AEMPS)

2.35 **Panel discussion and Q&A Time**
S. Trantza, C. Arizmendi Vélez

3.20 **COFFEE BREAK**

SESSION 6 - PATIENTS' REPRESENTATIVES CONTRIBUTION TO PV

3.40 **Introduction by the Chairperson**
Gian Nicola Castiglione, Pharmacovigilance Senior Consultant, Member and Secretary of SIMeF, ETS Board, Master of Labor. Head of Pharmacovigilance and QPPV

3.45 Ilaria Grisoni, Exec. Dir., Head of International QPPV Office, EEA QPPV | Jazz Pharmaceuticals

4.05 Marco Greco, Lawyer and EPF President (tbc)

4.25 **Round Table**
G.N. Castiglione, M. Amoroso | Sanofi, M. Greco (tbc), I. Grisoni, M. Korenjak | ELPA, P. Kruger | EUPATI

SESSION 7 (PARALLEL) NON EU PV REQUIREMENTS

3.40 **Introduction by the Chairperson**
Margherita D'Antuono, EU-UK QPPV | Piramal Critical Care

3.45 **Saudi Arabia PV requirements and inspection**
Ahmed Diaa El Din, CEO | Baupharma

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4.10 **UK pharmacovigilance requirements - A regulator's perspective**
Fazil Afzal, Senior Medical Assessor at Medicines and Healthcare products Regulatory Agency (MHRA) (Tbc)

4.30 **Round Table**
M. D'Antuono, F. Afzal, A. Diaa El Din

SESSION 8 - LECTIO MAGISTRALIS

5.00 **The slings and arrows of outrageous product quality (mis)fortune - the impact of product quality factors on immunogenicity**
João A. Pedras-Vasconcelos, Senior Pharmaceutical Scientist (Product Quality and Immunogenicity) CDER Integrative Immunogenicity Working Group Co-chair – FDA (tbc)

5.25 **Closure of day**

AGENDA 20 NOVEMBER

all times are UTC +1 **Virtual**

09.00 **Welcome by the Chairperson of the congress**
Marco Sardella, Chief Pharmacovigilance Officer & EU QPPV | ADIENNE Pharma & Biotech

SESSION 9 - AUTHORITIES REVIEW OF PV DATA FROM CLINICAL DEVELOPMENT TO WHEN THINGS GO WRONG

09.10 **Introduction by the Chairperson**
Giovanni Furlan, Head Medical Safety Operations | Sandoz, Germany

09.15 **Safety oversight in clinical trials: the role of the competent authority in EU**
Antonella Caselli, Senior Clinical & Safety Assessor | AIFA, Italy (Tbc)

9.35 **From Signal to Action: How Authorities Respond to Safety Issues in Clinical Trials**
Elena Prokofyeva, Coordinator of Drug Safety Unit, DG Post, FAMHP

9.55 **Tbd**

10.15 **Round Table**
G. Furlan, A. Caselli, E. Prokofyeva, tbd

10.45 **Coffee Break**

SESSION 10 - BENEFIT/RISK EVALUATION OF MEDICINAL PRODUCTS

11.05 **Introduction by the Chairperson**
Maddalena Lino**,** Safety risk Lead Director at Pfizer | Pfizer

11.10 **Benefit-risk balance for medicinal products: CIOMS XII**
Panos Tsintis, Medical Director | PLM Med Ltd

11.30 **Making use of recent EMA, FDA and CIOMS guidance on lifecycle benefit-risk management?**
Michael Von Forstner, Managing Director | Mesa Laubela Consulting, Switzerland

11.50 **Tbd**
Catherine Tchinou, Head Medical Safety Biopharma | Sandoz

12.10 **Round Table**
M. Lino, P. Tsintis, C. Tchinou, M.Von Forstner

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SESSION 11 - (PARALLEL) LABELLING: A FUNDAMENTAL RISK COMMUNICATION AND MINIMIZATION TOOL

11.05 **Introduction by the Chairperson**
Fabio De Gregorio, Vice President, Head of Safety | Shionogi Europe

11.10 **Personalized labels and risk minimization: are we there yet?**
Ayman Ayoub, Labelling Lead, Pfizer Research & Development | Pfizer - UK

11.30 **PRAC recommendation and labelling risk management plan**
Hanae Bourji Chergui, Regulatory Affairs Senior Specialist | Beckton Dickinson

11.50 **Class Labelling as a risk management tool and communication to the patient**
Anita Blackburn, labeling Lead | Fortrea

12.10 **Round table**
F. De Gregorio, A. Ayoub, H. Bourji Chergui, A. Blackburn

12.40 **LUNCH**

SESSION 12 - REGULATORY ASPECTS FOR IMPLEMENTING ARTIFICIAL INTELLIGENCE IN PV

1.45 **Introduction by the Chairperson**
Jan Petracek, CEO | Ivigee, Director | Institute of Pharmacovigilance

1.50 **CIOMS WG XIV on artificial intelligence in PV: an update**
Lembit Rago, Secretary-General |Council for International Organizations of Medical Sciences (CIOMS)

2.15 **Governance of artificial intelligence and machine learning in pharmacovigilance: what works today and what more is needed?** *(Award - EUPV congress 2025)*
Rory Littlebury, Safety Governance Director | GSK
Michael Glaser, Safety Innovation Technology Director | GSK

2.45 **Round table**
J. Petracek, M. Glaser, R. Littlebury, L. Rago

AGENDA 20 NOVEMBER

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SESSION 13 - (PARALLEL) AGGREGATE REPORTS AROUND THE WORLD

1.45 **Introduction by the Chairperson**
Hrvoje Maček, VP, Medical & Scientific Affairs, EU QPPV | PrimeVigilance

1.50 **Optimizing DSUR: Pragmatic strategies for efficient safety updates**
Elena Prokofyeva, Coordinator of Drug Safety Unit, DG Post, FAMHP

2.10 **Japanese Development Safety Update Report (J-DSUR) and Japanese Periodic Benefit-Risk Evaluation Report (J-PBRER); specific requirements for aggregate reports in Japan**
Vjera Bilusic Vundac, Senior Director, Medical Writing | Primevigilance Ltd.-Croatia

2.30 **Challenges and possible solutions in meeting local regulatory requirements for safety aggregate reports**
Antonella Fretta, Senior Director Aggregate reporting Team Lead | Pfizer

2.50 **Round table**
H. Maček, V. Bilusic Vundac, A. Fretta, E. Prokofyeva

3.20 **COFFEE BREAK**

SESSION 14 - IMMUNOLOGICALLY DRIVEN ADVERSE REACTIONS

3.40 **Introduction by the Chairperson**
Mattia Calissano, VP, Medical | SSI Strategy

3.45 **Immunological reactions**
David Chonzi**,** Medical Director| PV Safety Solutions

4.05 **Signal management and immune related reactions in oncology studies**
Dimitrios Zampatis**,** Director Product Patient Safety (DPPS) | Sandoz

4.25 **TBD**
Maddalena Lino, Safety risk Lead Director | Pfizer

4.45 **Round Table**
M. Calissano, D. Chonzi, D. Zampatis, M. Lino

AGENDA 20 NOVEMBER

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SESSION 15 - (PARALLEL) PRACTICAL EXAMPLES OF AI IMPLEMENTATION IN PV PROCESSES

3.40 **Introduction by the Chairperson**
L. Scarazzini, Former Senior Vice President Pharmacovigilance and Patient Safety, Epidemiology and R&D Quality Assurance Chief Safety Officer | AbbVie

3.45 **AI-driven automation for non-indexed local literature screening**
Fabio de Gregorio, Vice President, Head of Safety | Shionogi Europe

4.05 **TBD**
Igor Copot, Executive Director of Safety Systems|Primevigilance

4.25 **Implementation and validation of an AI model in pharmacovigilance**
Giovanni Furlan, Head Medical Safety Operations | Sandoz, Germany

4.45 **Round table**
L. Scarazzini, I. Copot, F. De Gregorio, G. Furlan

SESSION 16 - LECTIO MAGISTRALIS

5.20 **Game theory: what impact could it have on pharmacovigilance?**
tbd

5.50 **Closure of Day 2**

AGENDA 28 NOVEMBER

all times are UTC +1 **Milan**

8.30 **Registration of Attendees & Welcome Coffee**

9.15 **Welcome by PEC & Chairperson of the Congress**
Lucia Costanzo, Senior Conference Manager | PEC
Marco Sardella, Chief Pharmacovigilance Officer & EU QPPV | ADIENNE Pharma & Biotech

9.25 **A word from the Editor-in-Chief of Therapeutic Advances in Drug Safety - Eu PV Congress Media Partner**
Arduino Mangoni, Strategic Professor in Clinical Pharmacology | Flinders University, Senior Consultant in Clinical Pharmacology and General Medicine, Australia

9.30 **A word from the president of Institute of Pharmacovigilance**
Jan Petracek, Director | Institute of Pharmacovigilance

SESSION 17 - OVERCOMING CHALLENGES AND PRIORITIZING VALUE IN THE EVOLVING PV LANDSACAPE

9.35 **Introduction by the Chairperson**
Jan Petracek, Director | Institute of Pharmacovigilance

9.40 **Does it make sense? High versus low value work in PV**
Andrew Bate, VP Safety Innovation & Analytics | GSK

9.50 **TBD**
Phil Tregunno, Patient Safety Monitoring, Safety and Surveillance, MHRA (tbc)

10.00 **Challenges and innovations in pharmacovigilance and signal management: from the COVID-19 pandemic experience to the future**
Barbara De Bernardi, EU & UK Pharmacovigilance Qualified Person, VP, Head of Global QPPV Office Worldwide Medical & Safety | Pfizer

10.10 **Round Table**
J. Petracek, F. Arellano| Roche, A. Bate, B. De Bernardi, Valeria Di Clemente | Baxter, E. Prokofyeva | FAMHP, L. Stagi | Roche, P. Tregunno, L. Scarazzini

11.00 **Coffee break & Networking**

AGENDA 28 NOVEMBER

all times are UTC +1 **Milan**

SESSION 18 - PERSONALIZED PV

11.30 **Introduction by the Chairperson**
Felix Arellano, Senior Vice President and the Global Head of Safety & Risk Management | Roche

11.35 **Precision oncology in the era of molecular tumor board**
Giuseppe Curigliano, Professor of Medical Oncology | University of Milano and European Institute of Oncology, IRCCS

11.50 **Applying advanced analytics and multiomic biomarker approaches in Precision Safety**
Rajat Mohindra, Principal Scientific Director Precision Safety, Pharma Development | Roche

12.05 **Novel human cell models to characterize toxicity**
Adrian Roth, Principal Scientific Director Precision Safety | Roche

12.20 **Round Table**
F. Arellano, G. Curigliano, R. Mohindra, A Roth

SESSION 19 F2F WORKSHOP (11.30 am - 12.40 pm) PARALLEL held by PRIMEVIGILANCE

12.45 **Aword Ceremony**

1.00 **Lunch & Networking**

SESSION 20 - PRAC AND OTHER EUROPEAN AUTHORITY PROCESSES FOR MONITORING THE BENEFIT RISK OF DRUGS

2.15 **Introduction by the Chairperson**
Sophia Trantza, Senior Pharmacovigilance expert, former PRAC member Greece

2.25 **Round Table**
S. Trantza, Petar Mas, PRAC member HALMED – Croatia; Pilar Rayon, PRAC Member AEMPS, Spain; Ana Sofia Martins, PRAC Member | INFARMED, I.P. – Portugal; Lina Seibokiene, PRAC alternate member, Lithuania; Marko Korenjak, President at European Liver Patients' Association, former PRAC member

AGENDA 28 NOVEMBER

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SESSION 21 - (PARALLEL) NEW SKILLS NEEDED IN PV

2.15 **Introduction by the Chairperson**
Gian Nicola Castiglione, Pharmacovigilance Senior Consultant, Member and Secretary of SIMeF, ETS Board, Master of Labor. Head of Pharmacovigilance and QPPV

2.20 **Skillset of Pharmacovigilance AI Supervisors**
Jan Petracek, Director Institute of Pharmacovigilance

2.40 **Tbd**
Gabrièle Piaton - Breda, Research & Innovation Director| PLG

3.00 **Panel discussion:** G.N Castiglione, G. Furlan | Sandoz, J. Petracek, G. Piaton - Breda, L. Scarazzini

3.20 **Coffee Break & Networking**

SESSION 22 - PRE & POST MARKETING AUDITS & INSPECTIONS

3.45 **Introduction by the Chairperson**
Valentina Mancini, Senior Director Pharmacovigilance QPPV | Shionogi Europe

3.50 **PV Inspections: trends and updates**
Elena Giovani, Head of the GVP Inspection Office | AIFA (Tbc)

4.10 **Tbd**
Ana Maria Velasco Calle, GCP/GVP Inspector from the Spanish Agency of Medicines and Medical Devices.

4.30 **PV Auditing on the brink: missed beats, blurred lines, and the AI wave ahead**
Natasa Mihajlovic, Managing Director | Nostra Pharma

4.50 **Audit of vendors and service providers**
Calin Lungu, CEO | DDCS S.A.

5.10 **Round Table**
V. Mancini, E. Giovani, N. Mihajlovic, C. Lungu, Alberto Gramaccioli | Pfizer, A. M. Velasco Calle

5.40 **CLOSURE OF THE CONGRESS**

CONFIRMED SPONSORS

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VENUE

NH MILANO CONGRESS CENTRE

- 5 minutes walking distance from Assago Forum Metro Stop
- Close to the highway exit
- 30 minutes by car from Linate airport, Duomo Cathedral and Milan Central Station

Plenary Room: up to 400 attendees
Parallel Room: up to 100 attendees

MEDIA PARTNER

Published by SAGE, Therapeutic Advances in Drug Safety (Impact Factor: 3,4) is an international peer-reviewed Open Access journal, delivering the highest quality original research articles, reviews, and scholarly comment on pioneering efforts and innovative studies pertaining to the safe use of drugs in patients. The journal has a strong clinical and pharmacological focus and is aimed at an international audience of clinicians and researchers in drug safety, providing an online forum for rapid dissemination of recent research and perspectives in this area.
As the official Media Partner of the 2025 edition of the European Pharmacovigilance Congress, Therapeutic Advances in Drug Safety will be publishing an online abstract supplement which will be free to access online.

For more info:
Website: https://journals.sagepub.com/home/taw
E-mail: shasha.sharief@sagepub.co.uk
Twitter: @TADrugSafety

EUPV CONGRESS SAGE AWARD

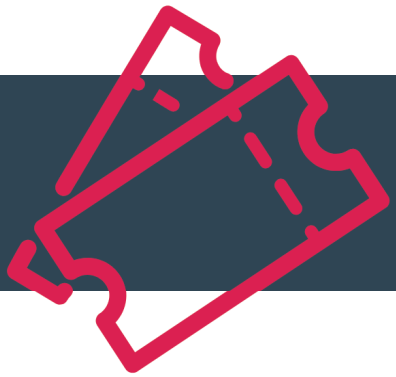
The intense, scientific interaction between speakers and delegates is a further invaluable plus of the event.

EUPV 2025 - AWARD
On November 28, in Milan,
The ***EUPV award*** will be presented to the author/s of the article published in 2024 in the SAGE Journal "Therapeutic Advances in Drug Safety" (Impact Factor: 3,4) that has been judged as being most noteworthy to be presented at a pharmacovigilance congress. The article will be selected by the ***Scientific Advisory Group*** and SAGE among those that have been downloaded more times.

EUPV Annual Booklet

All abstracts of the congress presentations will be published under an Open Access license. Therefore, they can be read online and downloaded at no cost.


The 7th European Pharmacovigilance Congress: speaker abstracts



ENTRY FEES

	Face to Face November 28	Virtual November 19-20	Virtual + Face to Face November 19-20 November 28	
Early bird	400 €	600 €	750 €	Deadline October 16
Full price	500 €	650 €	950 €	

VAT not included

Hospitals, universities and freelance professionals get a 40 % discount to be applied to published prices

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