INSTITUTE
OF PHARMACOVIGILANCE

UNIVERSITÀ DEGLI STUDI
DI MILANO
DIPARTIMENTO DI
SCIENZE FARMACOLOGICHE
E BIOMOLECOLARI

EUROPEAN PHARMACOVIGILANCE CONGRESS 2026

ANNIVERSARY
EUPV 10
INTERNATIONAL CONFERENCE

PEC PHARMA EDUCATION CENTER

18-19 November | Virtual
3-4 December | Milan

INFO@PHARMAEDUCATIONCENTER.IT WWW.PHARMAEDUCATIONCENTER.IT

The **European Pharmacovigilance Congress**, organized by **Pharma Education Center**, is recognized as one of the most important and appreciated global pharmacovigilance conferences thanks to its **top-tier scientific content.**
The high value of this year`s program is assured by the contribution of the key opinion leaders, experts and scientists included in the **Scientific Advisory Group** (SAG).
In addition, we are delighted to announce the new scientific partnership with the renowned **Department of Pharmacological and Biomolecular Sciences of the Milan University (Universita` degli Studi di Milano) and the confirmation of collaboration with the Institute of Pharmacovigilance.**
The EUPV Scientific Advisory Group has very clear that pharmacovigilance main pillars are: **Safety Science - Regulatory compliance - Operational excellence - Implementation of new technologies - Effective communication.**
All these aspects are reflected in the agenda of this year's congress.
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 FORMAT

VIRTUAL	MILAN	
● NOVEMBER 18 9.00-5.30 pm ● NOVEMBER 19 9.00-6.00 pm	● DECEMBER 3 3.00 - 7.00 pm 7.00-9.00 pm Networking Aperitivo	● DECEMBER 4 9.15 - 5.30 pm

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.

- **27 Topics**
- **24 round tables**
- **7 virtual parallel sessions**
- **1 LECTIO Magistralis**
- **3 F2F workshops**

EUPV 2025 IN NUMBERS

Delegates' feedbacks 2025 edition

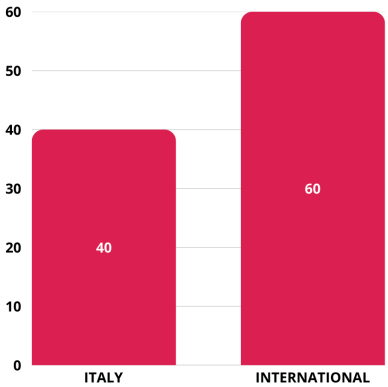
645 ATTENDEES representing

143 COMPANIES

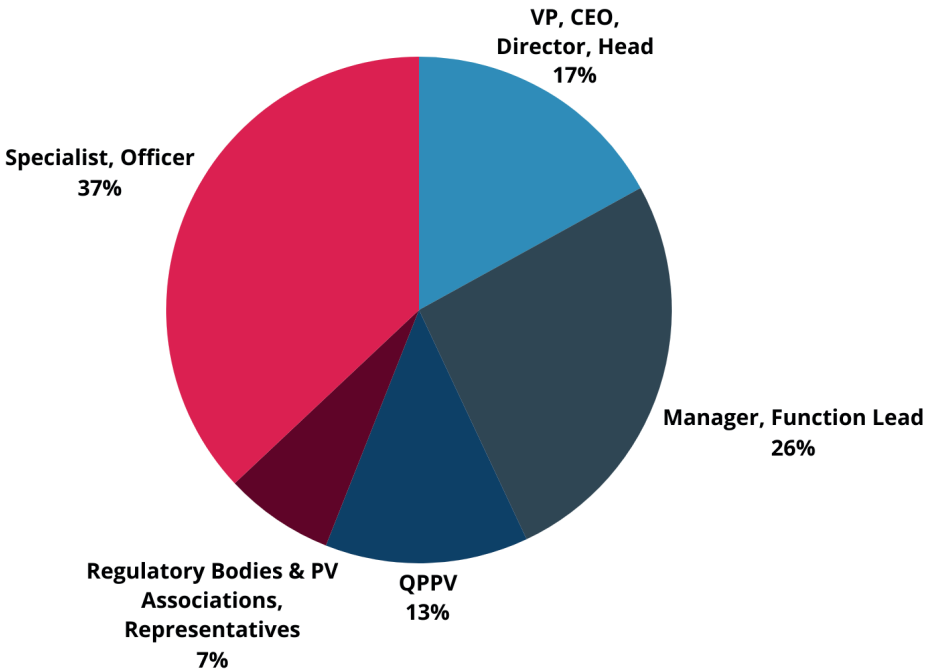
5 CONTINENTS

50 COUNTRIES

ATTENDEES NATIONALITY



EUPV 2025 - audience



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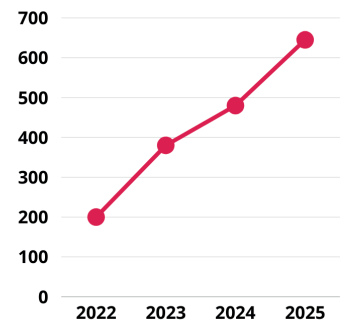

FEATURED TOPICS

- DEVELOPMENTAL SAFETY FROM FIRST IN HUMAN TO MARKETING AUTHORIZATION APPLICATION
- PREDICT, PREVENT, PROTECT: TRANSLATIONAL SAFETY AS THE CATALYST FOR SMARTER RISK STRATEGIES
- SAFETY OF GENE THERAPIES AND RARE DISEASES
- SYNTHETIC DATA IN PHARMACOVIGILANCE: OPPORTUNITIES, RISKS AND REGULATORY REALITY
- NON-EU PV REQUIREMENTS (Africa, Asia, Americas, UK)
- DECISIONS THAT MATTER: REAL LIFE IMPACT OF DRUG SAFETY WORK
- SAFETY OF MEDICINES IN EARLY ACCESS PROGRAM
- SAFETY OF DRUGS USED IN HEPATIC RARE DISEASES
- SAFETY ASPECTS OF NEW PRODUCTS USED FOR THE TREATMENT OF INFLAMMATORY DISORDERS
- IMPACT OF NEW REGULATIONS AND GUIDELINES ON PV OPERATIONS
- REGULATORY REQUIREMENTS AND PRACTICAL EXEMPLES FOR IMPLEMENTING AI IN PV
- MEDICAL DEVICES & COMBINATION PRODUCTS SAFETY
- SAFETY INFORMATION FROM PATIENTS´PERSPECTIVE
- COSMETOVIGILANCE AND SAFETY OF NUTRACEUTICALS PRODUCTS
- EMA COMPUTERIZED SYSTEMS UPDATES
- ECOPHARMACOVIGILANCE
- PHARMACOEPIDEMIOLOGY AND REAL-WORLD EVIDENCE IN PHARMACOVIGILANCE: FROM SIGNAL TO DECISION
- RISK MANAGEMENT SYSTEMS
- WHAT IS AI AND ITS IMPLEMENTATION IN CASE PROCESSING
- HUMAN MACHINE INTERFACE IN PV
- SIGNAL DETECTION AND MANAGEMENT: THE USE OF RWD/RWE, THE USE OF AI AND POSSIBLE LIMITATIONS
- EFFICIENCY AND EFFECTIVENESS IN A RAPIDLY CHANGING PV LANDSCAPE
- MASTERING SAUDI/GCC PHARMACOVIGILANCE 2026
- PV AUDIT & INSPECTION

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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.

EUPV CONGRESS SAGE AWARD

EUPV 2026 - AWARD
On December 4 , in Milan,
the Third **EUPV award** will be

presented to the author/s of the article
published in 2025 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

SCIENTIFIC ADVISORY GROUP

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

Ayman Ayoub
Vice President Safety Evaluation and Risk Management | GSK

Mattia Calissano
VP, Medical | SSI Strategy

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

Gian Nicola Castiglione
Pharmacovigilance Consultant, SIMeF ETS Board member, Past Head of Global Pharmacovigilance and EU-UK QPPV, Pharmacovigilance trainer

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

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Jan Petracek
CEO iVigee, Director | Institute of Pharmacovigilance

Marco Sardella
Chief Pharmacovigilance Officer & EU-UK QPPV | ADIENNE Pharma & Biotech, Chairperson of the Congress

Manuela Casula
Associate Professor at Department of Pharmacological and Biomolecular Sciences | University of Milan

Sophia Trantza
Senior Pharmacovigilance Expert, former PRAC Member Greece

CONFIRMED SPEAKERS

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

Amelia Cupelli
Pharmacologist, Italian Medicines Agency (AIFA), EMA PRAC Member, Italy (tbc)

Aurora María Rojo Sanchís
Head of GCP &GVP Inspectorate | Spanish Agency of Medicines and Medical Devices (AEMPS)

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

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

Oanh Dang
Regulatory Science and Applied Research Lead | Food and Drug Administration (FDA) – USA

Maia Uusküla
Head of the Department of Post-Authorisation Safety, State Agency of Medicines, Estonia

Jonathan Sutch
Principal Technical Specialist & Scheme Manager | BSI Group, Uk

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

Pilar Rayón
PRAC member AEMPS, Spain

David Sullivan
MHRA

Ursula Kirchmayer
Lazio Regional Health Service, President of the International Society for Pharmacoepidemiology - ISPE, Italy

Michelle English
GCP/PV Inspector HPRA, Ireland

Marko Korenjak
President of the European Liver Patients (ELPA), member of HMA management board of EMA - Slovenia

Zane Neikena
EMA PRAC Member from Latvia, Pharmacovigilance expert

Axelle Mutezinkwano
Pharmacovigilance Analyst Team Lead/ Rwanda Food and Drugs Authority

CONFIRMED SPEAKERS

Jens Ulrich Stegmann
Senior Vice President, Head Clinical Safety and Pharmacovigilance and EU QPPV | Gsk, Belgium

Annalisa Capuano
Full Professor of Pharmacology - Department of Experimental Medicine University of Campania "L. Vanvitelli"

Kaori Nomura
Associate Professor | Fukushima Medical University, Japan

Andrew Bate
VP, Head of Safety Innovation & Analytics | Gsk – Uk

Salvo Leone
General Director | Patient's Association AMICI, Italy

Emanuele Lettieri
Full Professor | Politecnico of Milan, Italy

Margherita D'Antuono
Deputy Chief Manager - QPPV| Piramal Critical Care

Vicky Edwards
Vice President, Cross Therapeutic Area Safety Science, Global

Anna Lombardo
Researcher | Istituto di Ricerche Farmacologiche Mario Negri

Giovanna Paolone
Associate Professor of Pharmacology – Department of diagnostics and public health | University of Verona – Italy

Emanuela Corsini
Professor of Toxicology at Department of Pharmacological and Biomolecular Sciences 'Rodolfo Paoletti' | University of Milan

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

Helaine Capucho
Access Director | Interfarma – Brazil

Ahmed Diaa Eldin
CEO | Baupharma, Czech Republic

Rajat Mohindra
Principal Medical Director Personalized Healthcare Safety | F.Hoffmann – La Roche, Switzerland

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

CONFIRMED SPEAKERS

Adrian Roth
Principal Scientific Director Precision Safety | Roche, Switzerland

Michael Von Forstner
Managing Director | Mesa Laubela Consulting, Switzerland

Klaudija Marijanovic Barac
Associate VP, EU QPPV Deputy | Eli Lilly Hrvatska d.o.o. , Croatia

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

Maddalena Lino
Senior Safety risk Lead Director | Pfizer Italy

Bogdana Ioana Balas
Group Medical Director | F. Hoffmann - La Roche Ltd, Switzerland

Alexandru Mihai Bica
Head of Early Development Safety | CSL Behring, Germany

Marie-Pierre Caby-Tosi
Executive Director, EEA/UK QPPV, Head of EMEA PV Clinical Safety & Pharmacovigilance | Moderna, France

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

Yiannoula Koulla
Patient Expert, Member of the EMA PRAC - Cipro

Daniela Gramaglia
Associate Director Medical Device Safety | Bayer

Maria Beatrice Panico
Chief Medical Officer | Scendea, UK

Daniela Marcozzi
Head of Corporate Clinical Safety, Pharmacovigilance and R&D Compliance – Company Representative for Competent Health Authorities | Fidia Farmaceutici – Italy

Lucia Biagiotti
Safety & Vigilance - BU Director | PL Italia

Mehmet Burcu
Senior Director, Epidemiology | Merck USA

Katerina Georgousaki
Regulatory Affairs Manager | ELAIS - Unilever Hellas S.A. , Greece

CONFIRMED SPEAKERS

Ramona Grigorescu
Senior Medical Monitor | Danone, Holland

Sadia Halim
SERM Medical Director | Gsk, Uk

Daniel Hyde
Associate Director, Pharmacovigilance Operations | Clinigen, Uk

Wojciech Masełbas
SERM Medical Director | Gsk, Poland

James Milligan
Vice President | SSI, UK

Darmendra Ramcharran
Sr Director, Safety & Quantitative Innovation | Gsk, USA

Hendrik Šuvalov
PhD Student in Health Informatics | University of Tartu, Estonia

Alina Tudor
Senior Director, Pharmacovigilance | Kyowa Kirin International plc. , Uk

Hans-Joerg Roemming
Executive Director, Head of RQS Information, Systems & Insights | Merck Healthcare KGaA

José Alberto Ayala Ortiz
CEO, QPPV, Pharmacovigilance consultant | PVpharm

Alexandra Lovett
Safety of Antisense Oligonucletides

AGENDA - November 18 | VIRTUAL

09.00 **Welcome by the Chairperson of the congress**
Marco Sardella, Chief Pharmacovigilance Officer & EU-UK 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

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

09.20 **A word from the Department of Pharmacological and Biomolecular Sciences | University of Milan**
Manuela Casula, Associate Professor at Department of Pharmacological and Biomolecular Sciences | University of Milan

SESSION 1 - DEVELOPMENTAL SAFETY FROM FIRST IN HUMAN TO MARKETING AUTHORIZATION APPLICATION

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

09.30 **CIOMS Working Group XVI on Development Safety Update Report**
Maria Beatrice Panico, Chief Medical Officer | Scendea

09.50 **Clinical Trial Safety Monitoring: Common Pitfalls and Regulatory Expectations**
Elena Prokofyeva, Head of Clinical Trial Safety Unit, Department of Pharmacovigilance, DG POST, FAMHP

10.10 **UK - Clinical trials regulations reform**
Fazil Afzal, Senior Medical Assessor | Medicines and Healthcare products Regulatory Agency (MHRA)

10.30 **Round table**
Moderator: M. Calissano, MB Panico, E. Prokofyeva, F. Afzal

11.00 **Coffee Break**

SESSION 2 - PREDICT, PREVENT, PROTECT: TRANSLATIONAL SAFETY AS THE CATALYST FOR SMARTER RISK STRATEGIES

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

AGENDA - November 18 | VIRTUAL

11.25 **Designing Predictive Safety: Translational Safety Intelligence as the Foundation for Risk Strategy**
Alexandru Mihai Bica, Head of Early Development Safety, CSL Behring

11.45 **Leveraging Real-World Evidence and AI for Safety Prediction Modelling**
Marie-Laure Kürzinger, Associate VP, Head of Pharmacoepidemiology - General Medicines, Pharmacovigilance and Patient Safety, Sanofi

12.05 **From vitro insight to human safety: NAMs as the foundation of predictive risk assessment**
Manuela Corsini, Professor of Toxicology, Department of Pharmacological and Biomolecular Sciences "Rodolfo Paoletti" | University of Milan

12.25 **Round table**
M. Ciuca, AM Bica, M.L. Kürzinger, M. Corsini

SESSION 3 (PARALLEL) - SAFETY OF GENE THERAPIES AND RARE DISEASES

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

11.25 **Panel of discussion: Safety of Gene therapies and rare diseases**
Alina Tudor, Senior Director, Pharmacovigilance |Kyowa Kirin International plc.

11.45 **Predicting Liver Injury for ATMPs**
James Milligan, Vice President SSI

12.05 Alexandra Lovett, Senior Director, Drug Safety and Pharmacovigilance | Dyne Therapeutics

12.25 **Round table**
M. Calissano, A. Lovett, J. Milligan, A. Tudor

12.50 **LUNCH & NETWORKING**

SESSION 4 - NON-EU PV REQUIREMENTS (ASIA – AFRICA)

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

AGENDA - November 18 | VIRTUAL

1.50 **Adverse Event Reporting in Rwanda: Regulatory Perspectives on ICSR and Aggregate Safety Reporting**
Axelle Mutezinkwano, Pharmacovigilance Analyst Team Lead/ Rwanda Food and Drugs Authority

2.10 **From Strategy to Practice: Risk Minimization Challenges in Egypt**
Ahmed Diaa Eldin, CEO | Baupharma

2.30 **Pharmacovigilance in Japan: Harmonised Standards and Distinct Regulatory Implementation**
Kaori Nomura, Associate Professor | Fukushima Medical University

2.50 **Round Table**
V. Mancini, A. Mutezinkwano, A.Diaa Eldin, K. Nomura

SESSION 5 (PARALLEL) - SYNTHETIC DATA IN PHARMACOVIGILANCE: OPPORTUNITIES, RISKS AND REGULATORY REALITY

1.45 **Introduction by the Chairperson**
Manuela Casula, Associate Professor at Department of Pharmacological and Biomolecular Sciences | University of Milan

1.50 **Crossing borders securely: synthetic data, challenges and opportunities**
Mehmet Burcu, Sr. Director, Epidemiology | Merck & Co., Inc., Rahway, NJ, USA

2.10 **From theory to practice: synthetic data in pharmacovigilance**
Darmendra Ramcharran, Sr Director: Safety & Quantitative Innovation | GSK

2.30 **tbd**

2.50 **Round table**
M. Casula, M. Burcu, D. Ramcharran, tbd

3.20 **COFFEE BREAK**

SESSION 6 – SAFETY ASPECTS OF NEW PRODUCTS USED FOR THE TREATMENT OF INFLAMMATORY DISORDERS

3.40 **Introduction by the Chairperson**
Ayman Ayoub, Vice President Safety Evaluation & Risk Management | GSK

AGENDA - November 18 | VIRTUAL

3.45 **Safety of Ultra-Long-Acting Drugs – focus on development**
Wojciech Masełbas, SERM Medical Director | GSK

4.05 **Assessing Hepatic Events in the Treatment of Inflammatory Disorders: Challenges, Methods, and Differentiation**
Sadia Halim, SERM Medical Director | GSK

4.25 **Round Table**
Ayoub, S. Halim, W. Maselbas

SESSION 7 (PARALLEL) - SAFETY OF MEDICINES IN EARLY ACCESS PROGRAM

3.40 **Introduction by the Chairperson**
Hrvoje Maček, VP Pharmacovigilance Services | Clinigen

3.45 **Managing Risk in Early Access and Compassionate Use**
Daniel Hyde, Associate Director, Pharmacovigilance Operations | Clinigen

4.05 **Challenges and Benefits of an Early Access Program: Safety and Compliance Perspective**
Maddalena Lino, Senior Safety risk Lead Director | Pfizer

4.25 **Round Table**
H. Macek, D. Hyde, M. Lino

SESSION 8 - COLLABORATIVE HORIZONS: STRENGTHENING THE LINK BETWEEN PHARMACOVIGILANCE, REGULATORY AFFAIRS, AND HEALTH TECHNOLOGY ASSESSMENT

5.00 **Introduction by the Chairperson**
Sophia Trantza, Senior Pharmacovigilance Expert former PRAC Member Greece

5.05 Vicki Edwards, Vice President, Cross Therapeutic Area Safety Science, Global Patient Safety | Abbvie

5.25 **TBD**

5.45 **Session Q&A**

LECTIO MAGISTRALIS

6.00 **SAFETY OF DRUGS USED IN HEPATIC RARE DISEASES (A DISCUSSION AT THE EUROPEAN PARLIAMENT)**
Sophia Trantza, Senior Pharmacovigilance Expert former PRAC Member Greece

6.20 **Closure of day 1**

AGENDA - November 19 | VIRTUAL

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

SESSION 9 - IMPACT OF NEW REGULATIONS AND GUIDELINES ON PV OPERATIONS

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

9.15 **What is new in PV in CIOMS**
Lembit Rago

9.35 **New era for management of long term safety issues and CIOMS Working Group XVII**
Marie-Pierre Caby-Tosi, Executive Director, EEA/UK QPPV, Head of EMEA PV Clinical Safety & Pharmacovigilance |Moderna

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

10.15 **Changes to the GVP module on ARRMs - opportunity to improve patient safety**
Maia Uusküla, Head of the Department of Post-Authorisation Safety, State Agency of Medicines, Estonia

10.35 **Round Table**
L. Rago, B. De Bernardi, M.P. Caby-Tosi, M. Uusküla

11.00 **Coffee Break**

SESSION 10 - REGULATORY REQUIREMENTS FOR IMPLEMENTING AI IN PV

11.20 **Introduction by the Chairperson**
Jan Petracek, CEO, iVigee, Director, Institute of Pharmacovigilance

11.25 **FDA/CDER Emerging Drug Safety Technology Meetings**
Oanh Dang, Regulatory Science and Applied Research Lead | Food and Drug Administration (FDA)

AGENDA - November 19 | VIRTUAL

11.45 **Use of AI in pharmacovigilance processes**
Aurora María Rojo Sanchís, Head of GCP & GVP Inspectorate | Spanish Agency of Medicines and Medical Devices (AEMPS)

12.05 David Sullivan, MHRA

12.25 **Round Table**
J. Petracek, O. Dang, A.M. Rocho Sanchís, D. Sullivan

SESSION 11 (PARALLEL) - MEDICAL DEVICES & COMBINATION PRODUCTS SAFETY

11.20 **Introduction by the Chairperson**
Ivana Šutalo, Innovative Products, Business Unit Lead / EU QPPV / LCPPV Croatia | PrimeVigilance

11.25 **The Role of the Notified Body and Device Suppliers in Combination Products Safety**
Jonathan Sutch, Principal Technical Specialist & Scheme Manager | BSI

11.45 **Effective communication between quality and safety teams in combination products**
Daniela Gramaglia, Associate Director Medical Device Safety | Bayer

12.05 **One Product, Two Vigilance Systems: Integrated Safety Oversight for Combination Products**
Daniela Marcozzi, Head of Corporate Clinical Safety, Pharmacovigilance and R&D Compliance - Company Representative for Competent Health Authorities | Fidia Farmaceutici

12.25 **Round table**
I. Šutalo, J. Sutch, D. Gramaglia, D. Marcozzi

12.50 **LUNCH**

SESSION 12 - PRACTICAL EXAMPLES OF APPLYING AI TO PV

1.45 **Introduction by the Chairperson**
Andrew Bate, VP, Head of Safety Innovation & Analytics | GSK

1.50 **Multimodal PV- unique contributions of AI**
Andrew Bate

2.10 **A framework for using AI in interoperable PV processes**
Giovanni Furlan, Head Medical Safety Operations | Sandoz

2.30 **Comparison of 3 AI Agents for Case Intake in production**
Jan Petracek, CEO iVigee, Director | Institute of Pharmacovigilance

2.50 **Round table**
A. Bate, G.Furlan, J. Petracek

SESSION 13 (PARALLEL) - SAFETY INFORMATION FROM PATIENTS´PERSPECTIVE

1.45 **Introduction by the chairperson**
Gian Nicola Castiglione, Pharmacovigilance Consultant, SIMeF ETS Board member, Past Head of Global Pharmacovigilance and EU-UK QPPV, Pharmacovigilance trainer

1.50 Emanuele Lettieri, Full Professor | Politecnico of Milan

2.10 Salvo Leone, General Director | Patient's Association AMICI

2.30 Yiannoula Koulla, Patient Expert | Member of the EMA PRAC

2.50 **Round table**
G.N. Castiglione, Marko Korenjak, President of the European Liver Patients (ELPA), member of HMA management board of EMA, E . Lettieri, S. Leone, Y. Koulla

3.20 **COFFEE BREAK**

SESSION 14 - NON-EU PV REQUIREMENTS: UK & Americas

3.20 **Introduction by the Chairperson**

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

3.45 **The Brazilian PV requirements** *(preliminary title)*
Helaine Capucho, Access Director | Interfarma

4.05 **LATAM latest Drug surveillance news and their implementation in a global PV system**
Margherita D'Antuono, Deputy Chief Manager - QPPV | Piramal Critical Care

4.25 **Round table**
H. Capucho, M. D'Antuono, F. Afzal

AGENDA - November 19 | VIRTUAL

SESSION 15 (PARALLEL) - COSMETOVIGILANCE AND SAFETY OF NUTRACEUTICALS PRODUCTS

3.40 **Introduction by the Chairperson**
Sophia Trantza, Senior Pharmacovigilance Expert former PRAC Member Greece

3.45 **Cosmetovigilance in the EU: Ensuring Consumer Safety and Regulatory Compliance**
Katerina Georgousaki, Regulatory Affairs Manager | ELAIS-Unilever Hellas S.A.

4.05 **Food, Drug... or Something in Between? Safety Monitoring in Nutrition Research**
Ramona Grigorescu, Senior Medical Monitor | Danone

4.25 **Round table**
S. Trantza, R. Grigorescu, K. Georgousaki

SESSION 16 - EMA COMPUTERIZED SYSTEMS UPDATES

5.00 **Introduction by the Chairperson**
Marco Sardella, Chief Pharmacovigilance Officer & EU QPPV | ADIENNE Pharma & Biotech

5.05 Calin A. Lungu, CEO | DDCS S.A

5.45 **Q&A Time**

SESSION 17 (PARALLEL) – ECOPHARMACOVIGILANCE

5.00 **Introduction by the chairperson**
Gian Nicola Castiglione, Pharmacovigilance Consultant, SIMeF ETS Board member, Past Head of Global Pharmacovigilance and EU-UK QPPV, Pharmacovigilance trainer

5.05 **Pharmaceuticals in the environment: The software system from the IMI PREMIER project.**
Anna Lombardo, Researcher | Istituto di Ricerche Farmacologiche Mario Negri IRCCS

5.25 **Ecopharmacovigilance: the effects of environmental relevant concentrations of selected pharmaceuticals in a zebrafish model**
Giovanna Paolone, Associate Professor of Pharmacology | University of Verona

5.45 **Q&A Time**

6.00 **Closure of Day 2**

AGENDA - December 3 | MILAN

3.00 pm **Registration of Attendees**

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

SESSION 18 - RISK MANAGEMENT SYSTEMS

3.30 **Introduction by the Chairperson**
Hrvoje Maček, VP Pharmacovigilance Services | Clinigen

3.35 **From one time treatment to long term monitoring: Risk management for ATMPs**
Klaudija Marijanovic Barac, Associate VP, EU QPPV Deputy | Eli Lilly Hrvatska d.o.o.

3.50 **Putting Systems into Risk Management**
Michael Von Forstner, Managing Director | Mesa Laubela Consulting

4.05 **Q&A session** – H. Maček, K. Marijanovic Barac, M. Von Forstner

SESSION 19 - PHARMACOEPIDEMIOLOGY AND REAL-WORLD EVIDENCE IN PHARMACOVIGILANCE: FROM SIGNAL TO DECISION

4.30 **Introduction by the Chairperson**
Manuela Casula, Associate Professor at Department of Pharmacological and Bio molecular Sciences | University of Milan

4.35 **Pharmacoepidemiology and Real-World Evidence for Public Health Decision-Making**
Ursula Kirchmayer, Lazio Regional Health Service, President of the International Society for Pharmacoepidemiology-ISPE

4.50 **From Pharmacoepidemiologic Evidence to Regulatory Safety Decisions**
Annalisa Capuano, Full Professor of Pharmacology - Department of Experimental Medicine | University of Campania "L. Vanvitelli"

5.05 **Q&A session:** M. Casula, A. Capuano, U. Kirchmayer

SESSION 20 – WHAT IS AI AND ITS IMPLEMENTATION IN CASE PROCESSING

5.30 **Chairperson of the session**
Giovanni Furlan, Head Medical Safety Operations | Sandoz

AGENDA - December 3 | MILAN

5.35 **Intro to AI tools applied in PV**
Hans-Joerg Roemming, Executive Director, Head of RQS Information, Systems & Insights | Merck Healthcare KGaA

5.50 **How LLMs can advance safety case intake–points to consider and insights from a proof of concept** *(article winner of award EUPV 2026)*
Hans-Joerg Roemming, Executive Director, Head of RQS Information, Systems & Insights | Merck Healthcare KGaA

6.05 **Q&A**

SESSION 21 – WORKSHOP BY IVIGEE
HUMAN MACHINE INTERFACE IN PV

6.20 **Start of workshop**

7.20 **Networking Aperitivo**

AGENDA - December 4 | 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

9.35 **A word from the Department of Pharmacological and Biomolecular Sciences | University of Milan**
Manuela Casula, Associate Professor at Department of Pharmacological and Biomolecular Sciences | University of Milan

SESSION 22 - EFFICIENCY AND EFFECTIVENESS IN A RAPIDLY CHANGING PV LANDSCAPE

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

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

10.00 Jens Ulrich Stegmann, Senior Vice President, Head Clinical Safety and Pharmacovigilance and EU QPPV | GSK

10.15 Serban Ghiorghiu | Vice President, Clinical Development, Late Development Oncology R&D | AstraZeneca

10.30 **Round Table -** G. Furlan, F. Arellano, J.U. Stegmann, S. Ghiorghiu

11.00 **CEREMONY AWARD**

11.10 **COFFEE BREAK & NETWORKING**

AGENDA - December 4 | MILAN

SESSION 23 - DECISIONS THAT MATTER: REAL LIFE IMPACT OF DRUG SAFETY WORK

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

11.45 **Analyzing novel biomarkers to enable Precision Safety approaches**
Rajat Mohindra, Principal Medical Director Personalized Healthcare Safety | F.Hoffmann - La Roche

11.55 **Novel experimental approaches to improve patient safety and de-risk clinical development**
Adrian Roth, Principal Scientific Director Precision Safety | Roche

12.05 **Patient-centric approach to mitigating Inavolisib-associated adverse events: Integrating mechanistic understanding and management strategies**
Bogdana Ioana Balas, Group Medical Director | F. Hoffmann-La Roche

12.15 **Round table**
F. Arellano, R. Mohindra, A. Roth, B. Balas

SESSION 24 (PARALLEL) – WORKSHOP by BAUPHARMA MASTERING SAUDI/GCC PHARMACOVIGILANCE 2026

11.40 **Start of workshop**

12.45 **LUNCH & NETWORKING**

SESSION 25 - SIGNAL DETECTION AND MANAGEMENT: THE USE OF RWD/RWE, THE USE OF AI AND POSSIBLE LIMITATIONS

2.15 **Introduction by the Chairperson**
Sophia Trantza, Senior Pharmacovigilance Expert former PRAC Member Greece

2.20 **Panel Discussion**
Sophia Trantza, Senior Pharmacovigilance Expert former PRAC Member Greece
Amelia Cupelli, Pharmacologist, Italian Medicines Agency (AIFA), EMA PRAC Member
Ana Sofia Martins, PRAC Member for Portugal
Zane Neikena, PRAC member Latvia
Maria del Pilar Rayon, PRAC member for Spain

AGENDA - December 4 | MILAN

Marko Korenjak, ELPA President, member of HMA management board of EMA
Hendrik Šuvalovc, PhD Student in Health Informatics | Univeristy of Tartu

SESSION 26 (PARALLEL) - WORKSHOP by PRIMEVIGILANCE

One year after Commission Implementing Regulation (EU) 2025/1466: lessons learned and emerging opportunities in pharmacovigilance operations

2.15 **Start of workshop**

3.10 **COFFEE BREAK & NETWORKING**

SESSION 27 - PV AUDIT & INSPECTIONS

3.40 **Introduction by the Chairperson**
Calin A. Lungu, CEO | DDCS S.A

3.45 **AIFA GVP Inspection report**
Elena Giovani, Head of the GVP Inspection Office | AIFA (Tbc)

4.00 Michelle English, GCP/PV Inspector HPRA

4.15 **Audits to service Providers: A Lever to Support MAH Compliance**
Lucia Biagiotti, Safety & Vigilance - BU Director | PL Italia

4.30 **A 5-Step Guide to Inspection-Ready PV Subcontracting**
José Alberto Ayala Ortiz, CEO, QPPV, Pharmacovigilance consultant | PVpharm

4.45 **Round Table**
Panelists: C. Lungu, E.Giovani (tbc), I. Grisoni | Jazz Pharmaceutical, M. English, A. Gramaccioli | Pfizer, V. Mancini | Shionogi Europe, D. Marcozzi | Fidia Farmaceutici, J.A. Ayala Ortiz | PVpharm

5.30 **Closure of the congress**

VENUE

NH MILANO CONGRESS CENTRE

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Parallel Room: up to 100 attendees

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