PEC PHARMA EDUCATION CENTER

18-19 November | Virtual
22 November | Milan

International Scientific Conference

EUROPEAN PHARMACOVIGILANCE CONGRESS 2024

The **European Pharmacovigilance Congress**, organized by **Pharma Education Center**, is recognized as one of the most important and appreciated **global pharmacovigilance conferences.**

EUPV congress is proud to have **high quality scientific content** as its main characteristic which has attracted growing interest from speakers, sponsors and **participants from all over the world.**

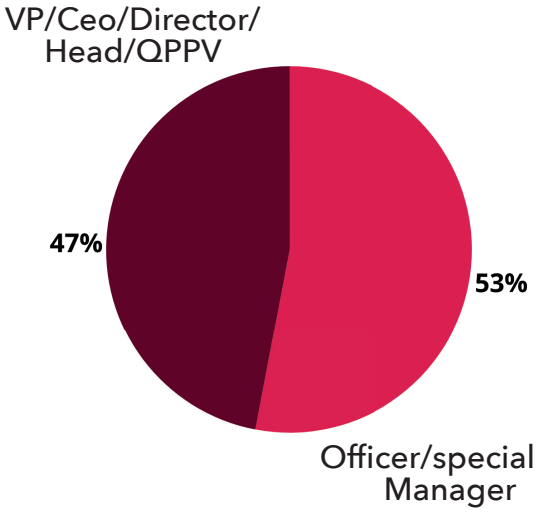
The EUPV congress gathers **PV professionals** at all career levels, including **key decision makers** (e.g. VPs, Executives and Directors,) interested in the always evolving pharmacovigilance world and its new trends, since they are always looking for new ideas to implement more efficient and effective strategies and tools for their departments.

To further improve the value of the congress and continuously make it more and more interesting by bringing new ideas and scientific contents, this year the **Scientific Advisory Group** has been further widened with the addition of new PV key opinion leaders who need no introduction since their knowledge and skills are world class.

EUPV congress is the forum where all **PV stakeholders from all over the world** meet and exchange ideas.

EUPV Congress 2023 IN NUMBERS

EUPV 2023 - AUDIENCE



380 ATTENDEES representing

120 COMPANIES

5 CONTINENTS

50 COUNTRIES

Delegates' feedback 2023 edition

- Extremely knowledgeable speakers and good variety of "topics".
- Very well-organized event. Excellent speakers and vast knowledge sharing forum.
- I loved the panel discussions following presentations, many relevant issues were addressed. One of the best conferences I attended!
- It was superb. Thank you for everything.

CONFERENCE FORMAT

- 18-19 November | Virtual 9 am - 6 pm
- 21 November | APERITIF TIME, NH Milano Congress Centre 6-9 pm
- 22 November | Face to face, NH Milano Congress Centre 9.30 am - 5 pm

APERITIF TIME - November 21 from 6 to 9 pm
NH Milano Congress Centre
Reserve your place to meet and network with experts and opinion leaders

Sponsored by ivigee

Are you interested in sponsoring the evening aperitif?
Contact us now!

This year the congress will include:
- ***25 Topics***
- **11** *Virtual & face to face* ***parallel sessions***
- ***25*** *Interactives round tables*
- ***2*** *Face to face workshops*
- ***2*** *LECTIO Magistralis*

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

SCIENTIFIC ADVISORY GROUP

Andrew Bate
Vp Safety Innovation & Analytics | GSK

Glyn Belcher
CEO of PV Consultancy Ltd

Mattia Calissano
Head of Pharmacovigilance | Orchard Therapeutics

Gian Nicola Castiglione
Pharmacovigilance Senior Consultant, Member and Secretary of SIMeF, ETS Board, Master of Labor. Past Head of Global Pharmacovigilance and EU-UK QPPV at Chiesi Farmaceutici S.p.A

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

Giovanni Furlan
Worldwide Safety Site Lead - Thessaloniki (Greece), Safety Risk Lead, Director | Pfizer S.r.l.

Calin A. Lungu
DDCS S.A., CEO

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

PEC PHARMA EDUCATION CENTER

CONFIRMED SPEAKERS

John - Joseph Borg
Director Post-Licensing | Malta Medicines Authority

Fazil Afzal
Medical Assessor | Medicines and Healthcare products Regulatory Agency (MHRA)

Phil Tregunno
Deputy Director, Patient Safety Monitoring, Safety and Surveillance | MHRA

Andrew Bate
Vp Safety Innovation & Analytics | GSK

Glyn Belcher
Senior Scientific Advisor - EU PV

Sofia Trantza
Senior pharmacovigilance expert, PRAC member Greece

Terenzio Ignoni
SVP Quality and CMC at Gain Therapeutics

Roxana Dondera
Head of Pharmacovigilance and Risk Management Unit | National Agency for Medicine and Medical Devices of Romania

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

Scott Proestel,
Senior Medical Officer | FDA (invited, tbc)

Lembit Rago
Secretary-General | Council for International Organizations of Medical Sciences (CIOMS)

Calin A. Lungu
DDCS S.A., CEO

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

Gabriel Westman
Head of Artificial Intelligence | Swedish Medical Products Agency

CONFIRMED SPEAKERS

Anne De Groot
CEO/CSO and Director | EpiVax

Nicholas Moore
Emeritus Professor of clinical pharmacology | University of Bordeaux

Georgios Papazisis
Professor of Clinical Pharmacology; Medical Director, Clinical Research Unit, School of Medicine, Aristotle University of Thessaloniki

Mayssa AbouGhannam
Country Safety Team Lead, Saudi Arabia, Gulf, Pakistan, Afghanistan | Johnson&Johnson

Maria Beatrice Panico
Principal Consultant | Scendea

Amy Rosemberg
Senior Director and Consultant, Immunology | EpiVax, Inc

Geeta Shanbhag
VP Pharmacovigilance and Medico - Regulatory Affairs |Ipca laboratories Ltd

Robert Massouh
Head of (PV) Risk Management and Benefit Risk Evaluation | Gsk

Chia Yu Chu
Prof. Department of Dermatology | National Taiwan University

Marcin Kruk
Drug Safety Regional Head Europe , Africa, Middle East, Worlwide Medical & Safety |Pfizer Inc.

Amanda Alexe
PV Policy and Liaison Lead, QPPV Office | Novartis

Maurizio Sessa
Associate Professor of Pharmacoepidemiology | University of Copenhagen

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

CONFIRMED SPEAKERS

Alqenae Fatema
Pharmacist | Kuwait - Winner EUPV 2023 Award

Dina B. Tresnan
Disease Area Cluster Lead - Immunolo-Oncology; Safety Surveillance and Risk Management, Worldwide Safety | Pfizer

Ilaria Grisoni
Exec. Dir., Head of EU/International PV & Office of QPPV, EEA QPPV | Jazz Pharmaceuticals

Vibha Jawa
Executive Director | Bristol Myers Squibb

Klaudija Marijanovic Barac
Sr. Director, EU&UK QPPV deputy, Head Periodic Reports and Risk Management Centre | TEVA

Zeljana Margan Koletic
Senior Manager, Risk Management Plans (RMP) Team Leader | Teva

Iva Novak
Head of European Pharmacovigilance and EU QPPV | Teva

Marcela Fialova
Chief Operating Officer | iVigee

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

Mônica da Luz Carvalho
Health Regulatory Expert, Pharmacovigilance Adviser | Brazilian Health Surveillance Agency (Anvisa)

AGENDA 18 NOVEMBER

all times are UTC +1 **Virtual**

SESSION 1 - BIOLOGICAL BASIS OF ADVERSE REACTIONS (WITH FOCUS ON SCARs)

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

Chia-Yu Chu, Prof. Department of Dermatology |National Taiwan University

Georgios Papazisis, Professor of Clinical Pharmacology; Medical Director, Clinical Research Unit, School of Medicine | Aristotle University of Thessaloniki, Greece

SESSION 2 - IMMUNOLOGICAL ADVERSE REACTIONS

Mattia Calissano, Head of Pharmacovigilance | Orchard Therapeutics

Anne de Groot, CEO/CSO and Director | EpiVax

Amy Rosenberg, Senior Director and Consultant, Immunology | EpiVax, Inc

SESSION 3 - PARALLEL - COMUNICATING SAFETY INFORMATION IN THE DIGITAL ERA *(in progress)*

Amanda Alexe, PV Policy and Liaison Lead, QPPV Office | Novartis

SESSION 4 - SIGNAL DETECTION

Natsiavas Pantelis, Researcher (Grade C) | Institute of Applied Biosciences of Centre for Research and Technology Hellas (INAB|CERTH), Thessaloniki, Greece

Gianluca Trifirò, Full Professor of Pharmacology - Department of diagnostics and public health | University of Verona

Vibha Jawa, Executive Director for Biotherapeutics Bioanalysis in clinical Pharmacology, Pharmacometrics and Bioanalysis (NDB) organization | Bristol Myers Squibb

SESSION 5 - PARALLEL - TBD

SESSION 6 - RISK MANAGEMENT

Robert Massouh, Head of (PV) Risk Management and Benefit Risk Evaluation | Gsk

Klaudija Marijanovic Barac, Sr. Director, EU&UK QPPV deputy, Head Periodic Reports and Risk Management Unit | TEVA

Giovanna Paolone, Associate Professor of Pharmacology - Department of diagnostics and public health | University of Verona

SESSION 7- PARALLEL - DRUG SAFETY IN MARKETING AUTHORIZATION APPLICATIONS *(in progress)*

Maria Beatrice Panico, Principal Consultant | Scendea

SESSION 8 - LECTIO MAGISTRALIS

Nicholas Moore, Emeritus Professor of clinical pharmacology | University of Bordeaux

AGENDA 19 NOVEMBER

all times are UTC +1 **Virtual**

SESSION 9 - AUTHORITIES' ASSESSMENT OF PV REPORTS

John Joseph Borg, Director Post-Licensing | Malta Medicines Authority

Roxana Dondera, Head of Pharmacovigilance and Risk Management Unit | National Agency for Medicine and Medical Devices of Romania

Sophia Trantza, Senior pharmacovigilance expert , PRAC member Greece

SESSION 10 - REAL WORD DATA & REAL WORD EVIDENCE

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

Željana Margan Koletić, Senior Manager, Risk Management Plans (RMP) Team Leader | Teva

Fatema Alqenae, Pharmacist |University of Manchester - Winner EUPV 2023 Award

SESSION 11- PARALLEL - EVOLVING LANDSCAPE OF ELECTRONIC SAFETY DATA IN PV *(in progress)*

Calin Lungu, DDCS S.A., CEO

SESSION 12 - MANUFACTURING & PV INTERFACES

AIFA Representative (tbc)

Terenzio Ignoni, SVP Quality and CMC | Gain Therapeutics

Dina B. Tresnan, Disease Area Cluster Lead - Immuno-lo-Oncology; Safety Surveillance and Risk Management, Worldwide Safety | Pfizer

Valentina Mancini, Senior Director Pharmacovigilance QPPV |Shionogi Europe

SESSION 13 - PARALLEL - SAFETY IN CLINICAL TRIALS *(in progress)*

SESSION 14 - MedDRA *(in progress)*

Scott Proestel, Senior Medical Officer | FDA (invited, tbc)

SESSION 15 - PARALLEL - NON EU PV REQUIREMENTS

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

Mayssa AbouGhannam, Country Safety Team Lead, Saudi Arabia, Gulf, Pakistan, Afghanistan |Jansenn

Robert Massouh, Head of (PV) Risk Management and Benefit Risk Evaluation | Gsk

Geeta Shanbhag, VP Pharmacovigilance and Medico-Regulatory Affairs | Ipca laboratories Ltd

SESSION 16 - LECTIO MAGISTRALIS

Glyn Belcher, Senior Scientific Advisor - EU PV Congress

AGENDA 22 NOVEMBER

all times are UTC +1 **Milan**

SESSION 17 - EVOLVING PHARMACOVIGILANCE STRATEGIES

Giovanni Furlan, Worldwide Safety Site Lead - Thessaloniki (Greece), Safety Risk Lead, Director | Pfizer S.r.l.

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

Andrew Bate, VP Safety Innovation & Analytics | GSK

Marcin Kruk, Drug Safety Regional Head Europe, Africa, Middle East, Worlwide Medical & Safety | Pfizer Inc.

Sophia Trantza, Senior pharmacovigilance expert , PRAC member Greece

SESSION 18 - MAIN GLOBAL AND LOCAL PV UPDATES

Calin Lungu, DDCS S.A., CEO

Ilaria Grisoni, Exec. Dir., Head of EU/International PV & Office of QPPV, EEA QPPV | Jazz Pharmaceuticals

Marcela Fialova, Chief Operating Officer | iVigee

SESSION 19 - PRACTICAL EXPERIENCE OF APPLYING ARTIFICIAL INTELLIGENCE IN PV

Andrew Bate, VP Safety Innovation & Analytics|GSK

Phil Tregunno, Deputy Director, Patient Safety Monitoring, Safety and Surveillance | MHRA

Gabriel Westman, Head of Artificial Intelligence | Swedish Medical Products Agency

Maurizio Sessa, Associate Professor of Pharmacoepidemiology | University of Copenhagen

SESSION 20 - AUDIT & INSPECTIONS

AIFA Representative (tbc)

Gian Nicola Castiglione, Pharmacovigilance Senior Consultant, Member and Secretary of SIMeF, ETS Board, Master of Labor. Past Head of Global Pharmacovigilance and EU-UK QPPV at Chiesi Farmaceutici S.p.A.

Mônica da Luz Carvalho, Health Regulatory Expert, Pharmacovigilance Adviser | Brazilian Health Surveillance Agency (Anvisa)

Iva Novak, Head of European Pharmacovigilance and EU QPPV | Teva

PARALLEL SESSIONS
21-22-23-24 *(In progress)*

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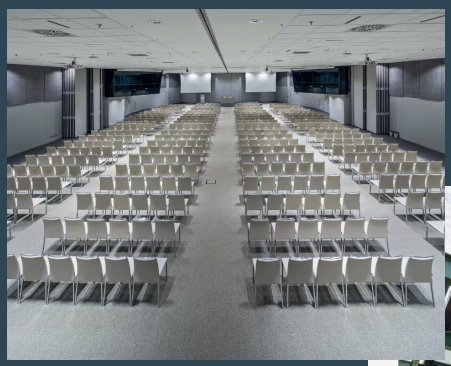
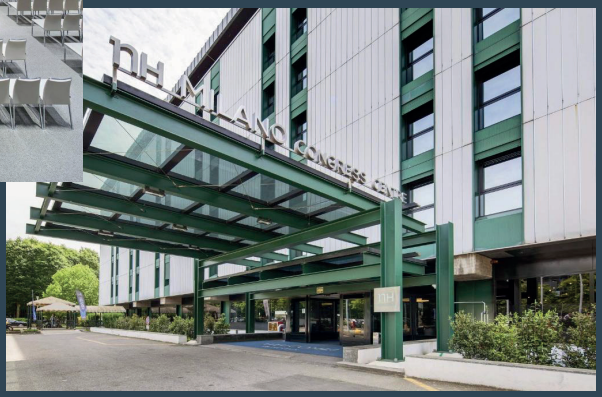
NEW VENUE!
NH MILANO CONGRESS CENTRE



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



- 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

EUPV CONGRESS SAGE AWARD

On November 22, in Milan, the EUPV CONGRESS SAGE AWARD 2024 will be presented to the author/s of the article published in 2024 in the SAGE Journal "Therapeutic Advances in Drug Safety" (Impact Factor: 4,4) that has been judged as being most noteworthy to be presented at a pharmacovigilance congress.

The article will be selected by the Scientific Board and SAGE among those that have been downloaded more times.

The 6th European Pharmacovigilance Congress: speaker abstracts

EUPV 2024 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.

MEDIA PARTNERS

Published by SAGE, Therapeutic Advances in Drug Safety (Impact Factor: 4,4) 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 6th 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: jonathan.collin@sagepub.co.uk
Twitter: @TADrugSafety

Sage

ENTRY FEES

	Face to Face November 22	Virtual November 18-19	Virtual + Face to Face November 18-19 November 22	
Early bird	400 €	600 €	750 €	Deadline October 18
Full price	500 €	650 €	950 €	

VAT not included

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

Discounts are not cumulative

For multiple registrations contact:
info@pharmaeducationcenter.it

TEL (+39) 055 7224179
(+39) 055 7224076
FAX (+39) 055 7227014

REGISTER HERE

For further information and/or further assistance please contact (+39) 055 7224179 or email: amministrazione@pharmaeducationcenter.it

EVENT CANCELLATION

If the minimum number of participants is not reached, Pharma Education Center reserves the right to cancel or schedule the event for another date. Formal communication will be given within 5 days before the event date. In this case Pharma Education Center will refund the registration fee in full and without additional charges. Alternatively, the participant can request a spendable coupon for participating in another PEC event scheduled in the current year.

CANCELLATION TERMS

In order to cancel enrolment to a event, please email info@pharmaeducationcenter.it within 2 weeks before the starting date of the event. Once this term will be expired, the entire fee will be charged.

ATTENDEE REPLACEMENT

It is possible to replace a participant with another without additional costs, simply by contacting info@pharmaeducationcenter.it. It is asked to notify the participant replacement request within 5 days before the starting date of the event, specifying the full name and surname of the enrolled participant as well as the full name and surname of the substitute.

PEC PHARMA EDUCATION CENTER

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