

18-19 November | Virtual 22 November | Milan

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EUROPEAN PHARMACOVIGILANCE CONGRESS 2024

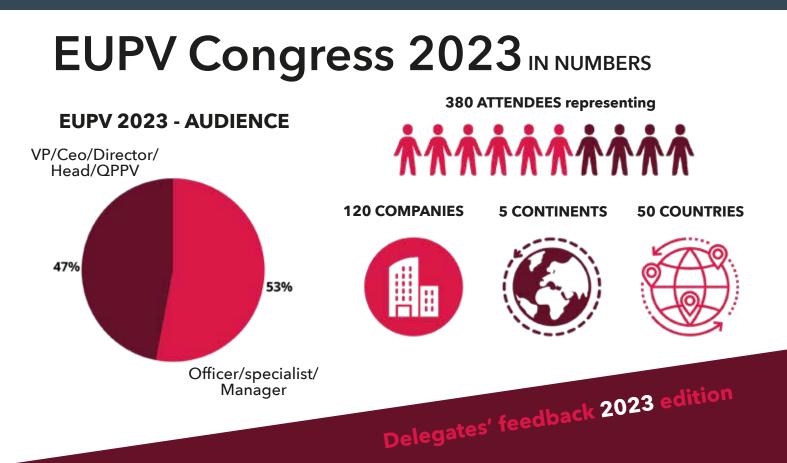
The European Pharmacovigilance Congress, organized by Pharma Education Center, is recognized as one of the most important and appreciated global pharmacovigilance conferences.

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.



- 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

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 pharmacovigilance 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



Giovanni Furlan

Worldwide Safety Site Lead - Thessa-Ioniki (Greece), Safety Risk Lead, Director | Pfizer S.r.l.



Glyn Belcher CEO of PV Consultancy Ltd



Calin A. Lungu DDCS S.A., CEO



Mattia Calissano Head of Pharmacovigilance | Orchard Therapeutics



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



Valentina Mancini Senior Director Pharmacovigilance QPPV | Shionogi Europe



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



Jan Petracek CEO, iVigee, Director, Institute of Pharmacovigilance



Marco Sardella

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





CONFIRMED SPEAKERS

Roxana Dondera

Romania

Ilaria Grisoni

Jazz Pharmaceuticals

Calin A. Lungu

DDCS S.A., CEO

Adelaide, Australia



John - JosephBorg Director Post-Licensing | Malta Medicines Authority



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



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



Terenzio Ignoni SVP Quality and CMC at Gain Therapeutics

Head of Pharmacovigilance and Risk

Management Unit | National Agency for Medicine and Medical Devices of

Exec. Dir., Head of EU/International

PV & Office of QPPV, EEA QPPV |



Andrew Bate Vp Safety Innovation & Analytics | GSK



Vibha Jawa Executive Director | Bristol Myers Squibb



<mark>Glyn Belcher</mark> Senior Scientific Advisor - EU PV



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



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



Arduino Mangoni Strategic Professor in Clinical Pharmacology | Flinders University, Senior Consultant in Clinical Phar-

macology and General Medicine,



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



<mark>Anne De Groot</mark> CEO/CSO and Director | EpiVax



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



CONFIRMED SPEAKERS



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



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.



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

University of Thessaloniki



<mark>Sofia Trantza</mark> Senior pharmacovigilance expert, PRAC member Greece



<mark>Maria Beatrice Panico</mark> Principal Consultant | Scendea



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



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



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



Iva Novak

Head of European Pharmacovigilance and EU QPPV | Teva



Phil Tregunno

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



Maurizio Sessa

Associate Professor of Pharmacoepidemiology | University of Copenhagen



Gabriel Westman Head of Artificial Intelligence |Swedish Medical Products Agency



Giovanna Paolone

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



Dina B. Tresnan

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



Marcela Fialova Chief Operating Officer | iVigee

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 - SIGNAL DETECTION

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

Gianluca Trifiro', 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 4 - 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 5 - LECTIO MAGISTRALIS

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

AGENDA 19 NOVEMBER

all times are UTC +1 Virtual

SESSION 6 - 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 7 -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 Algenae, Pharmacist |University of Manchester - Winner EUPV 2023 Award

SESSION 8 - MANUFACTURING & PV INTERFACES

AIFA Representative (tbc)

Terenzio Ignoni, SVP Quality and CMC | Gain Therapeutics

Dina B. Tresnan, Disease Area Cluster Lead - Immunolo-Oncology; Safety Surveillance and Risk Management, Worldwide Safety | Pfizer Valentina Mancini, Senior Director Pharmacovigilance QPPV |Shionogi Europe

SESSION 9 - DRUG SAFETY IN MARKETING AUTHORIZATION APPLICATIONS

Maria Beatrice Panico, Principal Consultant | Scendea

SESSION 10- LECTIO MAGISTRALIS

Glyn Belcher, Senior Scientific Advisor - EU PV Congress

AGENDA 22 NOVEMBER

all times are UTC +1

Milan

SESSION 11 - EVOLVING PHARMACOVIGILANCE STRATEGIES

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

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 12 - 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 13 - 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 14 - 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.

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

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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 CON-GRESS 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.

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| The 6th European Pharmacovigilance | | |
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| Introduction The sinks edition of the European Planma- certification Compress, separated by the Planma Education Comins, was a minut sevent breach control solitor on T and 8 November 2022, and | Me alory." The maniter insteam in utility report- ing second by the pandemic has fastlese controlstate to the background noise, thus mak- ing weaker associations even more difficult in detext (e.g. in Europe there has been a 937), improve of individual cases study research (2020). | |
| cution online on 7 and 8 Noromber 2022, and insporton in 3Man on 13 Noromber 2022. The rongene was remarkably susceredul, with speak- ers and delegates from fire suminana, from reg- ulatory againster, organization, | in EndocVighnor compared with the previous year as a consequence of the pandemit/* h is therefore of unsent importance to adopt new insingles that importe the affinizency and effec- | |
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| (DoP) and the Uppula Monitoring Conirv (UMC). | The European Pharmacerighnus Congress 2022 included 12 different sessions. Key topics were as follows: | |
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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



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 | | | | | | |
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| Discounts are not cumulative | | | | | | |
| For multiple registrations contact: info@pharmaeducationcenter.it | | | 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.



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