European Pharmacovigilance Congress

November 7 - 8, 2022
Virtual
November 10, 2022
Face to Face in Milan

PEC PHARMA EDUCATION CENTER

The European Pharmacovigilance Congress organized by **Pharma Education Center** has become one of the most appreciated international PV meetings.
Last year, the virtual edition of the congress enjoyed a great success with an exceptional participation of PV delegates from all over the world. International top speakers from marketing authorization holders, competent authorities, international pharmacovigilance organizations, European expert patient organizations and independent consultants animated the three days of conference with fruitful discussions, interactive sessions, Q&A, and focused round tables. The congress, now at its sixth edition, is a unique opportunity to get in touch with different international stakeholders, to learn more about the new requirements, the new emerging challenges in pharmacovigilance and to discuss the possible strategies and solutions to address them.

This year we have retained the traditional European focus but we have significantly expanded our footprint. We will have speakers from five continents from regulatory agencies, international organisations, pharma companies, service providers, patient organizations, academia.

The European Pharmacovigilance Congress...
Is more than a traditional conference, it is a great opportunity to learn, to develop your professional skills, to get in touch with international renowned experts and colleagues. Discuss and share the strategies and the main trends in the international pharmacovigilance scenario: be part of the community!

This year the European Pharmacovigilance Congress will be a **mixed event!** The first two days, November **7th and 8th**, will be **virtual** and will see the participation of worldwide experts and key opinion leaders. The third day, **November 10th**, will be a **face to face meeting in Milan**, where you will have the chance to meet colleagues and the speakers of the congress: a great opportunity for the PV community to get together!

EUPV 2022
FEATURED TOPICS

SESSION 1. BENEFIT - RISK & SIGNAL DETECTION

SESSION 2. SERIOUS CUTANEUS ADVERSE REACTIONS (SCARS)

SESSION 3. ARTIFICIAL INTELLIGENCE IN PV: OPPORTUNITIES AND CHALLENGES

SESSION 4. SAFETY OF GENE THERAPIES

SESSION 5. UPDATES ON EU AND EXTRA EU PV REGULATORY REQUIREMENTS

SESSION 6. PHARMACOVIGILANCE DATABASES & PHARMACOEPIDEMIOLOGY

SESSION 7. SAFETY OF COVID-19: PREVENTION AND THERAPEUTIC OPTIONS

SESSION 8. PATIENT CENTRICITY

SESSION 9. PV INSPECTIONS & AUDITS

SESSION 10. QUALITY IN GLOBAL PV SYSTEMS

SESSION 11. INTERFACE BETWEEN PV AND GMP/GDP

SESSION 12. EUDRAVIGILANCE AND CTIS

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VENUE

MELIÁ *****

Milan

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Published by SAGE, Therapeutic Advances in Drug Safety (Impact Factor: 3.842) 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.

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Pharma Tech Outlook is a monthly publication that has been a pioneer in bringing forth real-world solutions, news, product trends, solutions, and many more to subscribers. The unique learn-from-peers approach is creating a difference since the decision-makers are constantly sharing their experience, wisdom and thought leadership with each other. Pharma Tech Outlook has contributors from the most established organizations and institutions who have been presenting their viewpoints using this unique print platform. The magazine has been incorporated by some seasoned industry experts and has been at the forefront of presenting a comprehensive and detailed view of the technology arena. Pharma Tech Outlook aims at contributing to the transformation of innovations into services as well as creating a healthy and productive ecosystem.

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INTERNATIONAL SPEAKERS

Andrew Bate
Vp Safety Innovation & Analytics | GSK

Laura Boga
Head of Global Pharmacovigilance, EU&UK, QP for Pharmacovigilance | Dompé Pharmaceuticals

Glyn Belcher
CEO of PV Consultancy Ltd

Azira Čajić
Head of Division for PV and Materiovigilance | Agency for Medicinal Products and Medical Devices Bosnia & Herzegovina

Mattia Calissano
Head of Drug Safety and Italy and UK LPPV | Orchard Therapeutics

Helaine Carneiro Capucho
Professor | University of Brasilia and Pharmacovigilance Manager/ Brazilian Health Regulatory Agency (Anvisa)

Gian Nicola Castiglione
Director Global Pharmacovigilance | Chiesi Farmaceutici

David Chonzi
Global Head of PVE | Instil Bio

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

Mircea Ciuca
Global Therapeutic Area Head in Global Clinical Safety and Pharmacovigilance | CSL Behring

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

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

Domenico Di Giorgio
Head of Inspection & Certification Dept and of the Pharmaceutical Crime Counteracting Office at the Italian Medicines Agency (AIFA).

Irene Fermont
Chairperson | ERANIM, the Israeli Society for Medication and Vaccine Safety

Marcela Fialova
Chief Operating Officer | iVigee

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

Alberto Gramaccioli
Director, Quality Management and Inspections, World Wide Safety | Pfizer inc.

Dominique Hamerlijnck
EUPATI fellow, Patient Expert

Manfred Hauben
Senior Director | Pfizer Inc., Clinical Assistant Professor, Department of Medicine, NYU Grossman, School of Medicine

Shaun Hopgood
Chief Information Officer | ERGOMED/PrimeVigilance

Noelle Humphrey
Head of Quality | PrimeVigilance

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

Vojtech Kvita
CVO | NextPV Services s.r.o.

Hervé Le Louët
Head of PV policy intelligence strategy| Takeda, President of CIOMS, Past CEO of the UMC, Past President of ISOP

Maddalena Lino
Neurologist, Safety Risk Lead Director | Pfizer

Marianne Lorenzen
Senior Director Disease Area Cluster Lead | Pfizer

Pinelopi Lundquist
WHO Collaborating Centre Director | Uppsala Monitoring Centre

Calin A. Lungu
DDCS S.A., CEO

Valentina Mancini
Senior Director Pharmacovigilance QPPV | Shionogi Europe

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

Susan Mather
Senior Director | Pfizer

Helen Byomire Ndagije
Product Safety Director | the National Drug Authority in Uganda, President of the ISoP Africa chapter

Pier Paolo Olimpieri
Data analysis coordinator, Monitoring Registries - AIFA

Jan Petracek
CEO | iVigee, Director of Institute of Pharmacovigilance, ISoP Advisory Board

Paolo Porcelli
GVP Senior Inspector | AIFA (Italian Medicines Agency)

Elena Prokofyeva
Head of the Drug Safety Team, R&D Department, DG PRE | FAMHP

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

Hadir Rostom
Lecturer | MSA university & President of ISoP Egypt Chapter

Eva Josephine Runggaldier
Country Head of Trial Monitoring | Novartis

Mulugeta Russom
Head | Eritrean Pharmacovigilance Centre

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

Grazia Sirizzotti
Sr. Drug Safety Manager | Biogen Italia

Lisa Stagi
Drug Safety and Quality Lead | Roche Italia

Panos Tsintis
CIOMS Senior Advisor

Lothar Tremmel
Vice President, QCSR (Quantitative Clinical Sciences and Reporting) | CSL Behring

Marco Tuccori
Unit of Adverse Drug Reactions Monitoring | University Hospital of Pisa

Dennis Vargo
Vice President, Head of Drug Safety and Pharmacovigilance | Akebia Therapeutics

Isabella Ventura
Quality Management Operations Speacialist, Quality and Management | Pfizer Italy

Michael Von Forstner
Global Head of Clinical Safety and Pharmacovigilance | Biogen

Qun-Ying Yue
Senior Pharmacovigilance Expert | Uppsala Monitoring Centre

all times are UTC +1 **Virtual**

AGENDA November 7th

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 - Eu PV Congress Media Partner**
Arduino Mangoni, Strategic Professor in Clinical Pharmacology | Flinders University, Senior Consultant in Clinical Pharmacology and General Medicine, Adelaide, Australia

SESSION 1
BENEFIT - RISK & SIGNAL DETECTION

9.15 **Introduction by the Chairperson of the Session**
Mircea Ciuca, Global Therapeutic Area Head in Global Clinical Safety and Pharmacovigilance | CSL Behring

9.20 **Methodologies for evaluating benefit-risk balance as per current guidelines**
Giovanni Furlan, Worldwide Safety Site Lead - Thessaloniki (Greece), Safety Risk Lead, Director | Pfizer S.r.l.

9.40 **Benefit-risk in PBRER**
Jan Petracek, CEO | iVigee

10.00 **CIOMS Working Group on Benefit-Risk of Medicines**
Panos Tsintis, Senior Advisor | CIOMS

10.20 **Validation and use of a new probabilistic tool for assessing causality in signal detection**
Fabio De Gregorio, Vice President, Head of Drug Safety Europe | Shionogi Europe

10.40 **Round Table & Q&A Time**
Moderator: M. Ciuca
Panelists: F. De Gregorio
G. Furlan
J. Petracek
P. Tsintis
Michael Von Forstner | Biogen

11.10 **Coffee Break & Networking**

SESSION 2
SERIOUS CUTANEUS ADVERSE REACTIONS (SCARS)

11.30 **Introduction by the Chairperson of the Session**
Hervé Le Louët, Head of PV policy intelligence strategy | Takeda, President of CIOMS, Past CEO of the UMC, Past President of ISOP

11.35 **What are severe cutaneous adverse reactions (SCARs)? A dermatologic perspective**
Chia-Yu Chu, Professor, Department of Dermatology | National Taiwan University Hospital

11.55 **Skin eruptions and causality assessments; examples from pharmacovigilance practice**
Glyn Belcher, CEO | PV Consultancy Ltd

12.15 **Proceedings of CIOMS working group on SCARS**
Hervé Le Louët, Head of PV policy intelligence strategy | Takeda, President of CIOMS, Past CEO of the UMC, Past President of ISOP

12.35 **Round Table & Q&A Time**
Moderator: H. Le Louët
Panelists: G. Belcher
C.Y. Chu
Qun Ying Yue | UMC

1.0 pm **Lunch & Networking**

SESSION 3
ARTIFICIAL INTELLIGENCE IN PV: OPPORTUNITIES AND CHALLENGES

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

1.55 **The Digital Dilemma - the challenges of aligning pharmacovigilance process, regulatory compliance and technology capabilities**
Shaun Hopgood, Chief Information Officer | ERGOMED/PrimeVigilance

2.15 **Is Artificial Intelligence in Pharmacovigilance on a Hype Cycle?**
Manfred Hauben, Senior Director | Pfizer Inc., Clinical Assistant Professor | Department of Medicine, NYU Grossman, School of Medicine

2.35 **AI in Pharmacovigilance**
Andrew Bate, VP, Head of Safety Innovation & Analytics | GSK

2.55 **Round Table & Q&A Time**
Moderator: M. D'Antuono
Panelists: A. Bate
S. Hopgood
M. Hauben

3.25 **Coffee Break & Networking**

SESSION 4
SAFETY OF GENE THERAPIES

3.45 **Introduction by the Chairperson of the Session**
Giovanni Furlan, Worldwide Safety Site Lead - Thessaloniki (Greece), Safety Risk Lead, Director | Pfizer S.r.l.

3.50 **An overview of the history, evolution and characterization of gene therapies' safety profile**
Dennis Vargo, Vice President, Head of Drug Safety and Pharmacovigilance | Akebia Therapeutics

4.10 **Gene Therapy Safety in Clinical Development: ATMPs and auxiliary medicines**
Mattia Calissano, Head of Drug Safety and Italy and UK LPPV | Orchard Therapeutics

4.30 **Long term safety associated with Genetic therapies**
David Chonzi, Global Head of PVE | Instil Bio

4.50 **Round Table & Q&A Time**
Moderator: G. Furlan
Panelists: G. Belcher | PV Consultancy Ltd
M. Calissano
D. Chonzi
A. Mangoni
D. Vargo

5.10 **Closing Remarks by the Chairperson of the congress and introduction of Lectio Magistralis**
Marco Sardella, Chief Pharmacovigilance Officer & EU QPPV | ADIENNE Pharma & Biotech

5.15 **LECTIO MAGISTRALIS**
Pre-Marketing Safety Surveillance: Statistical Considerations
Lothar Tremmel, Vice President Quantitative Clinical Sciences & Reporting | CSL Behring

6.0 **Q&A Time**

6.15 **Closure of Day 1**

all times are UTC +1 **Virtual**

AGENDA November 8th

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 - Eu PV Congress Media Partner**
Arduino Mangoni, Strategic Professor in Clinical Pharmacology | Flinders University, Senior Consultant in Clinical Pharmacology and General Medicine, Adelaide, Australia

SESSION 5
UPDATES ON EU AND EXTRA EU PV REGULATORY REQUIREMENTS

9.15 **Introduction by the Chairperson of the Session**
Fabio de Gregorio, Vice President, Head of Drug Safety Europe | Shionogi Europe

9.20 **EU and exEU legislative requirements**
Margherita D'Antuono,
EU-UK QPPV | Piramal Critical Care

9.40 **CTR 536/2014: challenges and opportunities**
Eva J. Runggaldier, Country Head of Trial Monitoring | Novartis

10.00 **Efficient Road to Reliable Pharmacovigilance Regulatory Intelligence**
Marcela Fialova, Chief Operating Officer | iVigee

10.20 **Round Table & Q&A Time**
Moderator: F. De Gregorio
Panelists: M. D'Antuono
M. Fialova
Helen Ndagije | ISoP Africa Chapter
E. Prokofyeva | DG PRE, FAMHP
Hadir Rostom | ISoP Egypt Chapter
E.J. Runggaldier

10.50 **Coffee Break & Networking**

SESSION 6
PHARMACOVIGILANCE DATABASES & PHARMACOEPIDEMIOLOGY

11.10 **Introduction by the Chairperson of the Session**
Arduino Mangoni, Strategic Professor in Clinical Pharmacology | Flinders University, Senior Consultant in Clinical Pharmacology and General Medicine, Adelaide, Australia

11.15 **AIFA monitoring registries: Post marketing data collection and evidence evaluation**
Pierpaolo Olimpieri, AIFA's Monitoring Registers

11.35 **Uppsala Monitoring Centre and WHO Programme for International Drug Monitoring**
Pinelopi Lundquist, WHO Collaborating Centre Director | Uppsala Monitoring Centre

11.55 **Real-World Data and Evidence in Pharmacovigilance throughout the Product Lifecycle**
Michael Von Forstner, Global Head of Clinical Safety and Pharmacovigilance | Biogen

12.15 **Round Table & Q&A Time**
Moderator: **A. Mangoni**
Panelists: **G. Belcher**
P. Lundquist
P. Olimpieri
Mulugeta Russom
M. Von Forstner

12.40 **Lunch & Networking**

SESSION 7
SAFETY OF COVID - 19: PREVENTION AND THERAPEUTIC OPTIONS

1.40 **Introduction by the Chairperson of the Session**
Maddalena Lino, Safety Risk Lead Director | Pfizer

1.45 **Safety profile of Paxlovid (nirmatrelvir/ritonavir)**
Marianne Lorenzen, Senior Director Disease Area Cluster Lead | Pfizer

2.05 **Safety monitoring of COVID - 19 therapy and vaccines**
Qun Ying Yue, Senior Pharmacovigilance Expert | UMC

2.25 **Safety of Covid - 19 booster dose**
Maddalena Lino, Safety Risk Lead Director | Pfizer

2.45 **Round Table & Q&A Time**
Moderator: **M. Lino**
Panelists: **Irene Fermont** | ERANIM
M. Lorenzen
Susan Mather | Pfizer
Marco Tuccori | University Hospital of Pisa
Q.Y. Yue

3.15 **Coffee Break & Networking**

SESSION 8
PATIENT CENTRICITY

3.35 **Introduction to Patient Centricity**
Paola Kruger, Expert Patient | EUPATI (European Patient's Academy for Therapeutic Innovation)

3.45 **New CIOMS Report on Patient Involvement in the Development, Regulation and Safe Use of Medicines**
Lembit Rägo, Secretary-General | Council for International Organizations of Medical Sciences (CIOMS)

4.05 **Patient engagement is a requirement not a choice**
Dominique Hamerlijnck | EUPATI fellow, Patient Expert

4.25 **Round Table & Q&A Time**
Moderator: **P. Kruger**
Panelists: **L. Rägo**
Valentina Mancini | Shionogi Europe
D. Hamerlijnck
Lisa Stagi | Roche Italy

4.55 **Closing Remarks by the Chairperson of the congress**
Marco Sardella, Chief Pharmacovigilance Officer & EU QPPV /ADIENNE Pharma & Biotech

5.00 **Closure of Day 2**

In presence in Milan

AGENDA November 10th

08.30 **Registration of attendees**

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

09.20 **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, Adelaide, Australia

09.25 Hervé Le Louët, Head of PV policy intelligence strategy | Takeda, President of CIOMS, Past CEO of the UMC, Past President of ISOP

SESSION 9
PV INSPECTIONS & AUDITS

09.45 **Introduction by the Chairperson of the Session**
Gian Nicola Castiglione, Director Global Pharmacovigilance | Chiesi Farmaceutici

09.50 **PV National inspections: state of the Art & Trends**
Paolo Porcelli, GVP Senior Inspector | AIFA (Italian Medicines Agency)

10.10 **PV inspection in non-EU Countries / PV inspection of National competent authority**
Azira Cajic, Head of Division for Pharmacovigilance and Materiovigilance | ALMBIH (Agency for Medicinal Products and Medical Devices Bosnia & Herzegovina)

10.30 **PSMF extra EU requirements to consider for successful inspections**
Alberto Gramaccioli, Director, Quality Management and Inspections, World Wide Safety | Pfizer inc.
Isabella Ventura, Quality Management Operations Speacialist, Quality and Management | Pfizer Italy

10.50 **Coffee Break & Networking**

11.20 **Round Table & Q&A Time**
Moderator: Gian Nicola Castiglione
Panelists: A. Cajic
A. Gramaccioli
P. Porcelli
I. Ventura

SESSION 10
QUALITY IN GLOBAL PV SYSTEMS

11.45 **Introduction by the Chairperson of the Session**
Tools to create a customized PVA (TransCelerate)
Valentina Mancini, Senior Director Pharmacovigilance QPPV | Shionogi Europe

12.05 **Ensuring Successful Audits – The Challenges and Opportunities**
Noelle Humphrey, Head of Quality | PrimeVigilance

12.25 **ANVISA - PV Management Quality System Expectations**
Helaine Carneiro Capucho, Professor | University of Brasilia and Pharmacovigilance Manager | Brazilian Health Regulatory Agency (Anvisa)

12.45 **Round Table & Q&A Time**

Moderator: **V. Mancini**
Panelists: **H.Carneiro Capucho**
M. D'Antuono | Piramal Critical Care
N. Humphrey
Grazia Sirizzotti | Biogen Italia

1.10 **Lunch & Networking**

SESSION 11
INTERFACE BETWEEN PV AND GMP/GDP

2.10 **Introduction by the Chairperson of the Session**
Glyn Belcher, PV Consultancy Ltd

2.15 **Detection of counterfeit drugs that have potential impact on safety and efficacy of medicines. Some experiences from ANVISA**
Helaine Carneiro Capucho,
Professor | University of Brasilia and Pharmacovigilance Manager | Brazilian Health Regulatory Agency (Anvisa)

2.35 **Falsified medicines at the time of the Covid-19 Pandemic. Some experiences from the Italian Medicine Agency -AIFA**
Domenico Di Giorgio, Head of Inspection & Certification Dept and of the Pharmaceutical Crime Counteracting Office at the Italian Medicines Agency (AIFA)

2.55 **Round Table & Q&A Time**
Moderator: **G. Belcher** | PV Consultancy Ltd
Panelists: **H.Carneiro Capucho**
G.N. Castiglione | Chiesi
Mircea Ciuca
D. Di Giorgio

3.25 **Coffee & Networking**

SESSION 12
EUDRAVIGILANCE AND CTIS

4.00 **Introduction by the Chairperson of the Session**
Calin Lungu, DDCS S.A., CEO

4.05 **Update on EudraVigilance and on MHRA ICSR submission portal**
Vojtech Kvita, CVO | NextPV Services s.r.o.

4.25 **CTIS and interactions with other EMA systems**
Calin Lungu, DDCS S.A., CEO

4.50 **Round Table & Q&A Time**
Moderator: **Calin Lungu**
Panelists: **Laura Boga** | Dompè Pharmaceuticals
M. D'Antuono
V. Kvita
Elena Prokofyeva | DG PRE, FAMHP

5.10 **Chairperson Congress Closing Remarks and end of congress**
Marco Sardella, Chief Pharmacovigilance Officer & EU QPPV/ADIENNE Pharma & Biotech

5.15 **End of Congress**

ENTRY FEES

	Face to Face November, 10	Virtual November, 7 - 8	Virtual + Face to Face November, 7 - 8 - 10	
Early bird	600 €	675 €	950 €	Dead Line October, 7
Full Price	650 €	750 €	1150 €	

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