



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 CUTANEOUS 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 & PHARMACOEPIDEMOLOGY

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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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.

For more info:

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For more info: <http://www.pharmatechoutlook.com>

INTERNATIONAL SPEAKERS



Andrew Bate

Vp Safety Innovation & Analytics | GSK



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

Corporate PV Director, EU/UK QPPV | Italfarmaco



Fabio De Gregorio

Vice President, Head of Drug Safety Europe | Shionogi Europe



Irene Fermont

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



Marcela Fialova

Chief Operating Officer | iVigee



Giovanni Furlan

Safety Risk Lead, Director | Pfizer Inc.



Alberto Gramaccioli

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



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



Terenzio Ignoni

SVP Quality and CMC | Gain Therapeutics



Paola Kruger

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



Vojtech Kvita

CVO | NextPV Services s.r.o.



Hervé Le Louët

President of CIOMS, Past CEO of the UMC, Past President of ISOP



Lembit Rago

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



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

Director PV, EU QPPV | Shionogi Europe



Arduino Mangoni

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



Helen Byomire Ndagije

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



Jan Petracek

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



Elena Prokofyeva

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



Patrizia Rotunno

Pharmacovigilance Consultant, Drug Safety Manager | Pharma D&S



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



Doris Irene Stenver

Independent pharmacovigilance adviser, founder of Unique Advice



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



Bert Van Leeuwen

Deputy Qualified Person for Pharmacovigilance (QPPV) | Astellas Pharma Europe



Dennis Vargo

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



Isabella Ventura

Quality Management Operations Specialist, 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



Laura Boga

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

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, Safety Risk Lead,
Director | Pfizer Inc.

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

Doris Irene Stenver | Unique Advice

P. Tsintis

Michael Von Forstner | Biogen

11.10 **Coffee Break & Networking**

SESSION 2 SERIOUS CUTANEOUS ADVERSE REACTIONS (SCARS)

11.30 **Introduction by the Chairperson of the
Session**

Hervé Le Louët, 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, 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, Corporate PV Director, EU/UK QPPV | Italfarmaco
- 1.55 **The Digital Dilemma - the challenges of aligning pharmacovigilance process, regulatory compliance and technology capabilities**
Shawn Hopgood, Chief Information Officer | ERGOMED/PrimeVigilance
- 2.15 **Is Artificial Intelligence in Pharmacovigilance on a Hype Cycle?**
Manfred Huben, 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. Huben
- 3.25 **Coffee Break & Networking**

SESSION 4
SAFETY OF GENE THERAPIES

- 3.45 **Introduction by the Chairperson of the Session**

- Giovanni Furlan**, Safety Risk Lead, Director | Pfizer Inc.
- 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**
D. 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**

AGENDA November 8th

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

Helen Ndajie | ISoP Africa Chapter
E. Prokofyeva | DG PRE, FAMHP
Hadir Rostom | ISoP Egypt Chapter
E.J. Runggaldier
Mulugeta Russom | Eritrean Pharmacovigilance Centre

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

10.50 **Coffee Break & Networking**

SESSION 5 UPDATES ON EU AND EXTRA EU PV REGULATORY REQUIREMENTS

SESSION 6 PHARMAVOIGILANCE DATABASES & PHARMACOEPIDEMIOLOGY

9.15 **Introduction by the Chairperson of the Session**

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

11.10 **Introduction by the Chairperson of the Session**

Doris Irene Stenver, Independent pharmacovigilance adviser, founder | Unique Advice

9.20 **EU and exEU legislative requirements**
Bert Van Leeuwen, deputy Qualified Person for Pharmacovigilance (QPPV) | Astellas Pharma Europe

11.15 **AIFA monitoring registries: Post marketing data collection and evidence evaluation**

Pierluigi Russo, Head of AIFA's Monitoring Registers (tbc)
Pierpaolo Olimpieri, AIFA's Monitoring Registers (tbc)

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

11.35 **Uppsala Monitoring Centre and WHO Programme for International Drug Monitoring**

Pinelopi Lundquist, WHO Collaborating Centre Director | Uppsala Monitoring Centre

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

11.55 **Real-World Data and Evidence in Pharmacovigilance throughout the Product Lifecycle**

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

10.20 **Round Table & Q&A Time**
Moderator: **F. De Gregorio**
Panelists: **M. Fialova**
B.V. Leeuwen

12.15 **Round Table & Q&A Time**

Moderator: **D.I. Stenver**

Panelists: **G. Belcher**

P. Lundquist

A. Mangoni

P. Russo

Mulugeta Russom

M. Von Forstner

Mulugeta Russom

MarcoTuccori | University Hospital of Pisa

Q.Y. Yue

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

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)

3.50 **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)

4.10 **Patient engagement is a requirement not a choice**

Dominique Hamerlijnck | EUPATI fellow, Patient Expert

4.30 **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**

AGENDA November 10th

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

Safety | Pfizer inc.
Isabella Ventura, Quality Management Operations Specialist, Quality and Management | Pfizer Italy

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

10.50 **Coffee Break & Networking**

11.20 **Round Table & Q&A Time**
Moderator: **Gian Nicola Castiglione**
Panelists: **A. Cajic**
Senior GVP Inspector (TBC)
I. Ventura

09.25 **TBD**
Hervé Le Louët, 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**
 Senior GVP Inspector | AIFA (tbc)

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

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, Director PV, EU QPPV | Shionogi Europe

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

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

12.40 **Round Table & Q&A Time**
Moderator: **V. Mancini**
Panelists: **H. Carneiro Capucho**
M. D'Antuono | Italfarmaco
N. Humphrey
Grazia Sirizzotti | Biogen Italia

1.05 **Lunch & Networking**

SESSION 11 INTERFACE BETWEEN PV AND GMP/GDP

2.10 **Introduction by the Chairperson of the Session**

Terenzio Ignoni, SVP Quality and CMC | Gain Therapeutics

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 **TBD**
AIFA representative (TBC)

2.55 **TBD**
Christoph Hoeck, Global Manufacturing Site
Pharmacovigilance Representative | CLS
Behring

3.15 **Round Table & Q&A Time**
Moderator: **T. Ignoni**
Panelists: **Glyn Belcher** | PV Consultancy Ltd,
G.N. Castiglione | Chiesi
H. Carneiro Capucho
Mircea Ciuca
C. Hoeck
Representative AIFA (TBC)

3.40 **Coffee & Networking**

SESSION 12 EUDRAVIGILANCE AND CTIS

4.10 **Introduction by the Chairperson of the Session**

Calin Lungu, DDCS S.A., CEO

4.15 **Update on EudraVigilance and on MHRA ICSR submission portal**

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

4.35 **CTIS and interactions with other EMA systems**

Calin Lungu, DDCS S.A., CEO

5.00 **Round Table & Q&A Time**

Moderator: **Calin Lungu**

Panelists: **Laura Boga** | Dompè Pharmaceuticals

M. D'Antuono

V. Kvita

Elena Prokofyeva | DG PRE, FAMHP

5.20 **Chairperson Congress Closing Remarks and end of congress**

Marco Sardella, Chief Pharmacovigilance
Officer & EU QPPV/ADIENNE Pharma & Biotech

5.30 **End of Congress**

ENTRY FEES

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

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