EUROPEAN
PHARMACO
VIGILANCE
CONGRESS

www.eupharmacovigilance.com

#EUPV2020

ONLINE

November 26 - 27

European Pharmacovigilance Congress 2020

PEC PHARMA EDUCATION CENTER

ABOUT

The European Pharmacovigilance Congress organized by Pharma Education Center is the international meeting venue of experts from marketing authorization holders, competent authorities, international pharmacovigilance organizations and European expert patient organizations. The Congress, now at its 4th edition, is a unique opportunity to get insight from different PV stakeholders, to learn more about new requirements, new emerging challanges in Pharmacovigilance and to discuss possible strategies and solutions to address them.

WHY ATTEND?

- Learn about the latest PV trends and updates
- Share experiences and solutions at a leading european event
- Forge new collaborations with key decision makers
- Networking through the virtual platform with Pharma Companies delegates and Speakers

WHO SHOULD ATTEND?

Pharma, Biotech and Medical Devices Industries
Pharmacovigilance Associations
Regulatory Bodies
CROs and CMOs
Clinical Research Sites
Data Management Companies
Software Development Companies
University Faculties
PV Consultant Societies

FOCUS

What can you expect at the EUPV2020?

- Oral talks & keynote presentations
- Round Tables involving speakers and participants
- Poster session in the exhibition area. Selected posters abstract will be published by Sage.
- Exhibition area for Emerging Technologies and PV solutions
- Publication by Sage of the congress abstracts

EUPV CONGRESS is more than a traditional conference, it is a great opportunity to develop your professional skills and get in touch with renowned experts

FEATURED TOPICS

UPDATES FROM INTERNATIONAL PHARMACOVIGILANCE ORGANIZATIONS

SIGNAL DETECTION & EVALUATION

DIGITAL & TECHNOLOGY INNOVATION IN PV: OPPORTUNITIES FOR PATIENTS

DRUG INDUCED LIVER INJURY (DILI)

CLINICAL TRIALS REGULATION

COMUNICATION IN DRUG SAFETY

PHARMACOEPIDEMIOLOGY & RISK MANAGEMENT

EUDRAVIGILANCE/EVDAS UPDATES

PV QUALITY SYSTEM

LOCAL VS GLOBAL PV REGULATIONS

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AGENDA 26th

09:00 **Welcome and Opening remarks by the Chairperson of the European Pharmacovigilance Congress**
Marco Sardella - Chairperson of the EUPV congress
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
Professor and Head, Dep. of Clinical Pharmacology, School of Medicine, Flinders University, Australia

1.UPDATES FROM INTERNATIONAL PHARMACOVIGILANCE ORGANIZATIONS

Chairperson: **Marco Sardella** *- Chairperson of the EUPV congress*

09:15 **Updates from the CIOMS**
Hervé Le Louët
CEO of the WHO collaborative center for International Drug Monitoring (UMC), President of CIOMS, Past President of ISOP,Past Member of PRAC

09:35 **Updates from ISoP**
Jan Petracek
ISoP Advisory Board at International Society of Pharmacovigilance

09:55 **Updates from the Uppsala Monitoring Centre**
Daniele Sartori
Pharmacovigilance Scientist- Uppsala Monitoring Centre
DPhil student in Evidence-Based Medicine, University of Oxford

10:15 **Updates from PIPA**
Sarah Hall
HonFPIPA, Managing Director MIPSOL

10:35 **Q&A**
10:45 **Coffee Break e networking**

2. SIGNAL DETECTION & EVALUATION

Chairperson: **Fabio De Gregorio** *- V.P., Head of Drug Safety Europe, at Shionogi Europe*

11:10 **Signal detection and dissemination to members of the WHO Programme for International Drug Monitoring**
Daniele Sartori
Pharmacovigilance Scientist- Uppsala Monitoring Centre
DPhil student in Evidence-Based Medicine, University of Oxford

11:30 **Translating Pre- Marketing Adverse Drug Reactions and Signal Evaluation To The Routine Management of The Older Patient: Challenges and Opportunities**
Arduino Mangoni
Professor and Head, Dep. Of Clinical Pharmacology, School of Medicine, Flinders University, Australia

11:50 **Post marketing Signal detection – case studies**
Glyn Belcher
CEO of PV Consultancy Ltd

12:10 **Round table & Q&A Time**
Moderator: **F. De Gregorio**, *Shionogi Europe*
Participants: **G. Belcher,** *PV Consultancy Ltd*
M. Ciuca, *Area Head - Global Clinical Safety and Pharmacovigilance at CSL Behring*
A. Mangoni, *Flinders University, Australia*
D. Sartori, *Uppsala Monitoring Centre*
D. Stenver, *Indep. PV Adviser Founder of Unique Advice*

12:45 **Lunch & Networking**

3. DIGITAL & TECHNOLOGY INNOVATION IN PV: OPPORTUNITIES FOR PATIENTS

Chairperson: **Valentina Mancini,** *Director PV, EU QPPV - Shionogi Europe*

13:40 **Intelligent automation in Pharmacovigilance**
Juergen Schmider
President Drug and Device Vigilance Consulting LLC - Arisglobal

14:00 **Round table & Q&A Time**
Real World Evidence in PV, with digital tools for self-reporting by patients
Moderator: **V. Mancini**, *Shionogi Europe*
Participants: **S. Cazzaniga,** *Medical Affaire Excellence Head Janssen-Cilag Italy*
S. Hall, *HonFPIPA, Managing Director MIPSOL*
P. Kruger, *Expert patient Eupati*
J.Schmider, *Arisglobal*

14:30 **Networking Break**

4. DRUG INDUCED LIVER INJURY (DILI)

Chairperson: **Hervé Le Louët**, *CEO of the UMC, President of CIOMS*

14:50 **Drug Induced liver injury: from pre-clinical to post-marketing studies**
Marco Tuccori
Unit of Adverse Drug Reactions Monitoring, University Hospital of Pisa

15:10 **Pick a DILI – class effects**
Glyn Belcher
CEO of PV Consultancy Ltd

15:30 **Nimesulide Case Study: an example of Benefit-Risk Assessment and EU Referral Procedures**
Mario Bertazzoli
Director, Group Head of Drug Safety and Reference Physician to EU QPPV at Helsinn Healthcare SA

15:50 **Round table & Q&A Time**
Moderator: **H. Le Louët, CEO of the UMC,** *President of CIOMS*
Participants: **M. Bertazzoli**, *Helsinn Healthcare SA*
H. Le Louët, *CIOMS*
M. Tuccori, *University Hospital of Pisa*
Glyn Belcher, *CEO of PV Consultancy Ltd*

16:10 **Coffee break & networking**

5. CLINICAL TRIALS REGULATION

Chairperson: **Mircea Ciuca,** *Global Therapeutic Area Head - Global Clinical Safety and Pharmacovigilance at CSL Behring*

16:30 **CTFG Q&A RSI and CTR Q&A documents: what will change in terms of safety in clinical trials when CTR is in place?**
Elena Prokofyeva
Head of drug safety Unit, DG PRE Autorization/Division R&D (Humain)
Federal agency for medicines and health products - Bruxelles

16:50 **Round table & Q&A Time**
Moderator: **M. Ciuca,** *CSL Behring*
Participants: **E. Di Martino,** *Scientific Director PHARMA D&S*
M. Von Forstner, *Senior Director, Pharmacovigilance & Patient Safety - PRA Health Science*
E. Prokofyeva, *Head of drug safety Unit - AFMPS*
A. Traversa, *PV Net consulting*

17:20 **Marco Sardella - Chairperson's closing remarks**
Chairperson of the EUPV congress

AGENDA 27th

09:00 **Welcome and Opening remarks by the Chairperson of the European Pharmacovigilance Congress**
Marco Sardella - Chairperson of the EUPV congress
Chief Pharmacovigilance Officer & EU QPPV ADIENNE Pharma & Biotech

09:10 **A word from the Editor-in-Chief of Therapeutic Advances in Drug Safety**
Arduino Mangoni
Professor and Head, Dep. of Clinical Pharmacology, School of Medicine, Flinders University, Australia

6. COMMUNICATION IN DRUG SAFETY

Chairperson: **Michael Von Forstner,** *Senior Director, Pharmacovigilance & Patient Safety - PRA Health Science*

09:15 **Labelling**
Barbara De Bernardi
Vice President, EU QPPV - Pfizer

09:35 **Paradoxic effects of communicating information on adverse drug reactions**
Giovanni Furlan,
Safety Risk Lead Director - Pfizer

09:55 **Q&A**
10:05 **Coffee Break & networking**

7. PHARMACOEPIDEMIOLOGY & RISK MANAGEMENT

Chairperson: **Doris Stenver,** *Indep. PV Adviser, Founder of Unique Advice*

10:30 **RMP weaknesses and their evolution – Effectiveness of Risk minimization actions**
Jan Petracek
ISoP Advisory Board at International Society of Pharmacovigilance

10:50 **Systematic Lifecycle Benefit-Risk Management and Decision Making**
Michael Von Forstner
Senior Director, Pharmacovigilance & Patient Safety - PRA Health Science

11:10 **Round table & Q&A Time**
Moderator: **D. Stenver,** *Unique Advice*
Participants: **G. Belcher,** *PV Consultancy Ltd*
F. De Gregorio, *V.P. Head of Drug Safety Europe, UK QPPV - Shionogi Europe*
M. Von Forstner, *Senior Director, PV & Patient Safety PRA Health Science*
J. Petracek, *Board Member ISoP*
P. Rotunno, *Pharmacovigilance Consultant*

11:40 **Networking Break**

8. EUDRAVIGILANCE/EVDAS UPDATES

Chairperson: **Francoise Sillan,** *VP Head of Therapeutic area oncology – endocrinology Global patient safety, Ipsen*

12:00 **EVDAS-ISO IDMP- E2B R3**
Calin Lungu
MD, MRQA, BCPM, Eudravigilance and XEVMPD Trainer - EMA, CEO – DDCS

12:30 **Round table & Q&A Time**
Moderator: **F Sillan,** *Ipsen*
Participants: **L. Boga,** *QPPV - Dompé Pharmaceutical*
M. D'Antuono, *Corporate PV Director, EU QPPV- Italfarmaco*
C. Lungu, *CEO DDCS*
J.A. Ayala Ortiz, *PVpharm CEO*

13:00 **Lunch & networking**

9. PV QUALITY SYSTEM

Chairperson: **Fernanda Ferrazin,** *Independent Pharmaceutical Consultant, EuPV congress Scientific Board - PEC*

14:00 **PV System Inspection Readiness**
Raj Bhogal
Sr. Director, R&D Audits & Inspections - Jazz Pharmaceuticals

14:20 **Round table & Q&A Time**
Moderator: **Fernanda Ferrazin,** *Scientific Board - PEC*
Participants: **R. Bhogal, Sr. Director,** *R&D Audits & Inspections Jazz Pharmaceuticals*
I. Grisoni, *Sr. Director, EEA QPPV - Jazz Pharmaceuticals*
D. Marcozzi, *Head of R&D QA - Fidia Farmaceutici*

14:50 **Networking Break**

10. LOCAL VS GLOBAL PV REGULATIONS

Chairperson: **Valentina Mancini,** *Director PV, EU QPPV - Shionogi Europe*

15:10 **Getting the most from Patient Support Programmes–from a Safety Perspective**
Phillip Eichorn
Senior director, Pfizer Pharmaceuticals

15:30 **Management of global PSMF: compliance with local requirements**
Margherita D'Antuono
Corporate PV Director, EU QPPV - Italfarmaco

15:50 **Round table & Q&A Time**
Moderator: **V. Mancini,** *Shionogi Europe*
Participants: **J.A. Ayala Ortiz,** *PVpharm CEO*
M. D'Antuono, *Italfarmaco*
P. Eichorn, *Pfizer Pharmaceuticals*
I. Grisoni, *Sr. Director, EEA QPPV - Jazz Pharmaceuticals*
S. Hall, *HonFPIPA, Managing Director MIPSOL*

16:20 **End Closure Remarks**
Marco Sardella
Chairperson of the EUPV congress

16:30 **End of Congress**

SPEAKERS

José Alberto Ayala Ortiz
PVpharm CEO, EU QPPV, PV Consultant, LCPPV Services, Spain

Glyn Belcher
CEO of PV Consultancy Ltd

Mario Bertazzoli
M.D., Director, Group Head of Drug Safety and Reference Physician to EU QPPV at Helsinn Healthcare SA

Raj Bhogal
Sr. Director, R&D Audits & Inspections – Jazz Pharmaceuticals

Laura Boga
QPPV – Dompé Pharmaceutical Spa

Sara Cazzaniga
Medical Affaire Excellence Head at Janssen-Cilag Italy

Mircea Ciuca
Global Therapeutic Area Head in Global Clinical Safety and PV at CSL Behring - Scientific Board EUPV congress

Margherita D'Antuono
PharmD, PhD, Corporate PV Director, EU QPPV, Italfarmaco

Barbara De Bernardi
Vice President, EU QPPV Deputy, Pfizer

Fabio De Gregorio
M.D., Vice President, Head of Drug Safety Europe, Shionogi Europe

Elisabetta Di Martino
Scientific Director PHARMA D&S

Philip Eichorn
M.D., Senior Director Worldwide Safety & Regulatory – Pfizer Pharmaceuticals

Fernanda Ferrazin
Former Head of Pharmacovigilance Dept. – Italian Medicines Agency – Scientific Board PEC (Pharma Education Center)

Michael Von Forstner
PhD, Senior Director, Pharmacovigilance & Patient Safety – PRA Health Science

Giovanni Furlan
Pharm.D., Safety Risk Lead, Director, Pfizer -Scientific Board EUPV congress

Sarah Hall
PhD, HonFPIPA,Managing Director MIPSOL

Ilaria Grisoni
Sr. Director, EEA QPPV, Jazz Pharmaceutical

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

Hervé Le Louët
CEO of the UMC, President of CIOMS, Past President of ISOP, Past Member of PRAC

Calin A. Lungu
MD, MRQA, BCPM, Eudravigilance and XEVMPD Trainer - EMA, CEO – DDCS

Valentina Mancini
Director PV, EU QPPV, Shionogi Europe - Scientific Board EUPV congress

Arduino Mangoni
MBBS, MD (Hons), PhD, Professor and Head, Department of Clinical Pharmacology, School of Medicine, Flinders University, Australia

Daniela Marcozzi
Head of R&D QA Company Representative for Competent Health Authorities – Fidia Farmaceutici S.p.A.

Jan Petracek
MD. PhD, ISoP Advisory Board at International Society of Pharmacovigilance

Elena Prokofyeva
MD, MPH, PhD, Head of Drug Safety Unit – AFMPS

Patrizia Rotunno
PV Consultant, Scientific Board EUPV congress

Marco Sardella
Chief Pharmacovigilance Officer , EU QPPV ADIENNE Pharma & Biotech, Chairperson for EU PV Congress

Daniele Sartori
MSc Pharm, Pharmacovigilance Scientist- Uppsala Monitoring Centre

Schmider Juergen Schmider
M.D., Ph. D., President Drug and Device Vigilance Consulting LLC - Arisglobal

Francoise Dumas Sillan
M.D., VP Head of Therapeutic area oncology – endocrinology Global patient safety, Ipsen

Doris Irene Stenver
D.M., MPA, Indep. PV Adviser Founder of Unique Advice, former Chief Medical Officer Danish Medicines Agency and former member of PRAC

Alessandra Traversa
PV Net consulting

Marco Tuccori
Drug Safety Manager at University Hospital of Pisa

CONGRESS MEDIA PARTNER

Published by SAGE, Therapeutic Advances in Drug Safety (Impact Factor: 3.463) 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 4th 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 information:
Website: https://journals.sagepub.com/home/taw
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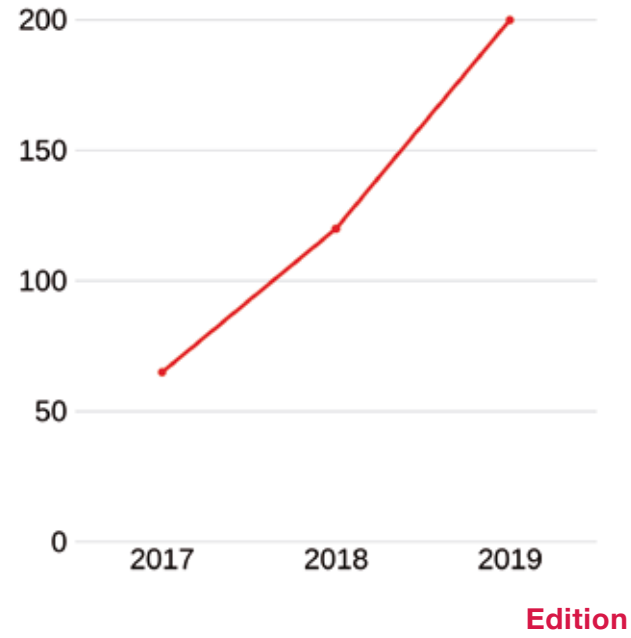
Gold Sponsor

The European Pharmacovigilance Congress 2020 provides an excellent opportunity to get in touch with PV professionals and decision makers through a powerful virtual exhibition area.
To sponsor the event, contact us at: **info@pharmaeducationcenter.it**

ATTENDANCE

Number of participants



Last edition

200 Participants

78 Pharma companies

34 Speakers

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HOW TO REGISTER

ENTRY FEE
650 € early bird before September 30, 2020
750 € early bird before October 31, 2020
950 € full price
VAT not included

BOOK NOW

TERMS OF PAYMENT
Advance payment is required with respect to the event date by bank transfer to BANCO BPM Spa – Florence (Italy),
IBAN: IT90U0503402815000000001400,
Bic/SWIFT: BAPPIT21G74 made payable to Pharma Education Center S.r.l., Via dei Pratoni 16, 50018 Scandicci (FI), VAT number 02173670486, specifying event title along with name and surname of the participant enrolling.
Attendance to the event will be allowed upon payment received.
Invoice of payment will be issued after the second half of the month after the course.

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

COURSE/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 refound 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 5 days before the starting date of the event. Once this term will be expired, the entire fee will be charged.

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

HOW TO REGISTER
Please, fill the form on the web site
https://www.eupharmacovigilance.com/

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