ONLINE
November 26 - 27

European Pharmacovigilance Congress 2020

#EUPV2020
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 challenges 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
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

#EUPV2020
09:10 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

09:20 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

09:30 Updates from the CIOMS
Hervé Le Louët - (tbc)
President of CIOMS, member of PRAC

09:50 Updates from ISoP
Jan Petracek
ISoP Advisory Board at International Society of Pharmacovigilance

10:10 Updates from the Uppsala Monitoring Centre
Daniele Sartori
Pharmacovigilance Scientist- Uppsala Monitoring Centre
DPhil student in Evidence-Based Medicine, University of Oxford

10:30 Updates from PIPA
Sarah Hall
HonFPIPA, Managing Director MIPSOL

10:50 Q&A
11:00 Coffee Break e networking

2. SIGNAL DETECTION & EVALUATION
Chairperson: Fabio De Gregorio - V.P., Head of Drug Safety Europe, UK QPPV at Shionogi Europe
11:20 **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

11:40 **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

12:00 **Post marketing Signal detection - case studies**
*Glyn Belcher*
CEO of PV Consultancy Ltd

12:20 **Round table & Q&A Time**
Moderator: *F. De Gregorio*, Shionogi Europe
Participants: *G. Belcher*, PV Consultancy Ltd
*M. Ciucca*, 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

12:50 **Lunch & Networking**

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### 3. DIGITAL & TECHNOLOGY INNOVATION IN PV: OPPORTUNITIES FOR PATIENTS
*Chairperson: Valentina Mancini*, Director PV, EU QPPV - Shionogi Europe

13:50 **Intelligent automation in Pharmacovigilance**
*Juergen Schmider*
President Drug and Device Vigilance Consulting LLC - Arisglobal

14:10 **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
*B. Van Leeuwen*, Deputy-QPPV - Astellas Pharma Europe
## 4. Drug Induced Liver Injury (DILI)

**Chairperson:** Furlan Giovanni, Safety Risk Lead, Director - Pfizer

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<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Speaker/Role</th>
<th>Institution/Company</th>
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<tr>
<td>14:40</td>
<td>Drug Induced liver injury: from pre-clinical to post-marketing studies</td>
<td>Marco Tuccori</td>
<td>Unit of Adverse Drug Reactions Monitoring, University Hospital of Pisa</td>
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<td>15:00</td>
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<td>Hervé Le Louët - (tbc)</td>
<td>President of CIOMS, member of PRAC</td>
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<td>15:20</td>
<td>Nimesulide Case Study: an example of Benefit-Risk Assessment and EU Referral Procedures</td>
<td>Mario Bertazzoli</td>
<td>Director, Group Head of Drug Safety and Reference Physician to EU QPPV at Helsinn Healthcare SA</td>
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<tr>
<td>15:40</td>
<td>Round table &amp; Q&amp;A Time</td>
<td>G. Furlan</td>
<td>Pfizer</td>
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<td>M. Bertazzoli, Helsinn Healthcare SA</td>
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<td>H. Le Louët, CIOMS</td>
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<td>M. Tuccori, University Hospital of Pisa</td>
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<td>16:00</td>
<td>Coffee break &amp; networking</td>
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## 5. Clinical Trials Regulation

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

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<tr>
<td>16:20</td>
<td>CTFG Q&amp;A RSI and CTR Q&amp;A documents: what will change in terms of safety in clinical trials when CTR is in place?</td>
<td>Elena Prokofyeva</td>
<td>Head of drug safety Unit, DG PRE Autorization/Division R&amp;D (Humain) Federal agency for medicines and health products - Bruxelles</td>
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<td>17:10</td>
<td>Marco Sardella - Chairperson’s closing remarks</td>
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<td>Chairperson of the EUPV congress</td>
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**6. COMMUNICATION IN DRUG SAFETY**

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

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<tr>
<td>09:20</td>
<td>Labelling</td>
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<td><strong>Barbara De Bernardi</strong></td>
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<td>Vice President, EU QPPV - Pfizer</td>
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<td>09:40</td>
<td>Paradoxic effects of communicating information on adverse drug reactions</td>
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<td><strong>Giovanni Furlan</strong></td>
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<td>Safety Risk Lead Director - Pfizer</td>
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<td>10:00</td>
<td>Q&amp;A</td>
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**7. PHARMACOEPIDEMIOLOGY & RISK MANAGEMENT**

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

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<tr>
<td>10:10</td>
<td>RMP weaknesses and their evolution - Effectiveness of Risk minimization actions</td>
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<td><strong>Jan Petracek</strong></td>
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<td>ISoP Advisory Board at International Society of Pharmacovigilance</td>
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10:30  Systematic Lifecycle Benefit-Risk Management and Decision Making  
**Michael Forstner**  
Senior Director, Pharmacovigilance & Patient Safety - PRA Health Science

10:50  Coffee Break e networking

11:15  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. Forstner**, Senior Director, PV & Patient Safety  
PRA Health Science  
**J. Petracek**, Board Member ISoP  
**P. Rotunno**, Pharmacovigilance Consultant

8. EUDRAVIGILANCE/EVDAS UPDATES

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

11:45  EVDAS-ISO IDMP- E2B R3  
**Calin Lungu**  
MDMRQA, BCPM, Eudravigilance and XEVMPD - EMA, CEO - DDCS

12:15  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

12:45  Lunch & networking

9. PV QUALITY SYSTEM

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

13:50  PV System Inspection Readiness  
**Raj Bhogal**  
Sr. Director, R&D Audits & Inspections - Jazz Pharmaceuticals
14:10  Round table & Q&A Time  
Moderator: Fernanda Ferrazin, Scientific Board - PEC  
Participants: R. Bhogal, Sr. Director, R&D Audits & Inspections Jazz Pharmaceuticals  
GN. Castiglione, EU QPPV & Director Global Pharmacovigilance - Chiesi  
I. Grisoni, Sr. Director, EEA QPPV - Jazz Pharmaceuticals  
D. Marcozzi, Head of R&D QA - Fidia Farmaceutici

10. LOCAL VS GLOBAL PV REGULATIONS
Chairperson: Valentina Mancini, Director PV, EU QPPV - Shionogi Europe

14:40  Is the limelight of PV regulation moving back to national?  
How to maintain global PV compliance with different/conflicting national regulations?  
Bert. Van Leeuwen  
Deputy-QPPV - Astellas Pharma Europe

15:00  Getting the most from Patient Support Programmes—from a Safety Perspective  
Phillip Eichorn  
Senior director, Pfizer Pharmaceuticals

15:20  Management of global PSMF: compliance with local requirements  
Margherita D’Antuono  
Corporate PV Director, EU QPPV - Italfarmaco

15:40  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  
B. Van Leewen, Deputy QPPV - Astellas Pharma Europe

16:10  End Closure Remarks  
Marco Sardella  
Chairperson of the EUPV congress

16:20  End of Congress
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

Gian Nicola Castiglione, M.D.  
M.D., EU QPPV & Director Global PV – Chiesi Farmaceutici

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  
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
SPONSORSHIP OPPORTUNITIES

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

Last edition

- 200 Participants
- 78 Pharma companies
- 34 Speakers

Number of participants

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

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 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.

CANCELATION 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/