

# EUROPEAN PHARMACOVIGILANCE CONGRESS 2023



27 - 28 November | Virtual  
1 December | Milan

**The European Pharmacovigilance Congress** is recognized as one of the most important and appreciated global conference on Pharmacovigilance.

Last year, delegates from more than 50 countries worldwide have joined the **two days of virtual event** followed by **the day in presence in Milan**.

The European Pharmacovigilance Congress gathers professionals at all career levels, including **key decision makers** (e.g. Directors, VPs and Executives) interested in the always evolving pharmacovigilance world and its new trends, and willing to implement more efficient and effective strategies and tools for their departments.

To further improve the value of the congress, the Scientific Board has been widened with the addition of new prestigious, renowned **international PV key opinion leaders**. Their deep knowledge and experience, as well as the involvement of excellent speakers on each topic, will ensure the highest scientific level of the program.

The conference will cover topics of global relevance offering in each session dedicated time for discussion with the involvement of delegates.

### PARALLEL SESSIONS

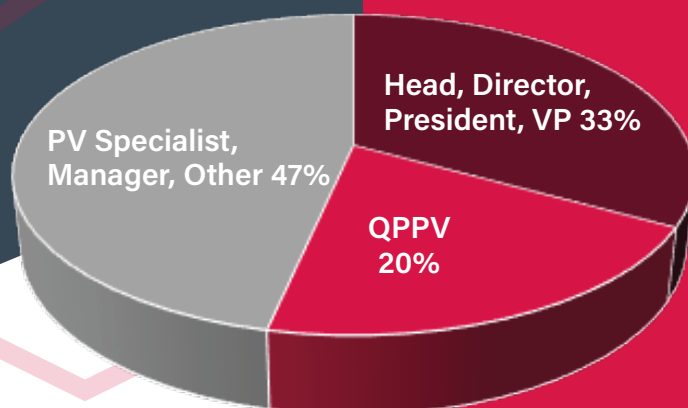
More practical aspects of specific topics will be addressed during the parallel sessions with the involvement of delegates.

### New!

The European Pharmacovigilance Congress 2023, in collaboration with the Media Partner SAGE, Therapeutic Advances in Drug Safety (Impact Factor: 4,4), an international peer-reviewed Open Access journal, will select the best scientific article published by the journal in 2022.

The authors will present their work in the event agenda.

### Audience composition



## FEATURED TOPICS

- ◀ EVOLVING PHARMACOVIGILANCE STRATEGIES
- ◀ PHARMACOVIGILANCE IN DRUG DEVELOPMENT
- ◀ PHARMACOVIGILANCE IN ATMP
- ◀ REGULATIONS IMPACTING ON THE GLOBAL PV SYSTEM
- ◀ EXTRA-EU PHARMACOVIGILANCE REGULATORY REQUIREMENTS
- ◀ SIGNAL DETECTION & RISK MINIMIZATION
- ◀ REAL WORLD EVIDENCE IN PHARMACOVIGILANCE
- ◀ RISK COMMUNICATION
- ◀ APPLYING ARTIFICIAL INTELLIGENCE TO PHARMACOVIGILANCE
- ◀ EUDRAVIGILANCE & CTIS UPDATES
- ◀ PHARMACOVIGILANCE QUALITY SYSTEM - INSPECTIONS & AUDITS
- ◀ PHARMACOEPIDEMOLOGY

**Delegates' feedbacks**

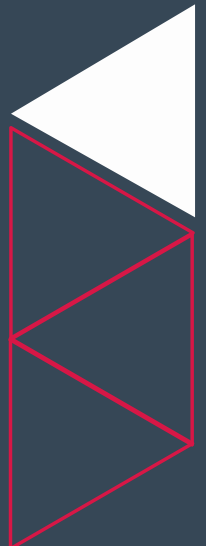
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***"Excellent congress!"***

***"It was well done with high level presentation"***

***"Excellent event, high quality content, very well organized, clear communication! I plan to attend every year. Thank you!!"***

***"Really interesting topics! Thank you!"***



# SCIENTIFIC BOARD



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**Marco Sardella**

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

# SPEAKERS



**Fazil Afzal**

Medical Assessor at Medicines and Healthcare products Regulatory Agency



**Ayman Ayoub**

Vice President, Business Unit Area Head, Safety Surveillance and Risk Management | Pfizer



**Amalia Alexe**

Policy and Liaison Lead, QPPV PRRC Office | Novartis



**Tea Babić**

Director, Head of global PV audits and inspections | Teva Pharmaceuticals



**Lana Arafat**

Associate Director, Pharmacovigilance at Hikma Pharmaceutical



**Klaudija Marijanovic Barac**

Sr. Director, EU&UK QPPV deputy, Head Periodic Reports and Risk Management Unit | TEVA



**Andrew Bate**

Vp Safety Innovation & Analytics | GSK



**Anita Blackburn**

Global Labeling Lead | Labcorp



**Laura Boga**

Head of Global Pharmacovigilance, EU&UK, QP for Pharmacovigilance



**Raj Bhogal**

Senior Director, R&D Business Strategy & Operations | Jazz Pharmaceuticals



**Frederic Emmanuel Boudier**

Professor in Risk Management | University of Stavanger, Norway



**Azira Čajić**

Head of Division for Pharmacovigilance and Materiovigilance | Agency for Medicinal Products and Medical Devices Bosnia & Herzegovina-ALMBIH



**Gian Nicola Castiglione**

Director Global Pharmacovigilance | Chiesi Farmaceutici



**David Chonzi**

Global Head of PVE | Instil Bio



**Margherita D'Antuono**

EU-UK QPPV | Piramal Critical Care



**Fabio De Gregorio**

Vice President, Head of Drug Safety Europe | Shionogi Europe



**Anne De Groot**

CEO/CSO and Director | | Epivax



**Thomas Debray**

Founder, Smart Data Analysis and Statistics B.V.



**Marcela Fialova**

Chief Operating Officer | iVigee



**Alberto Gramaccioli**

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



**Ilaria Grisoni**

Exec. Dir., Head of EU/International PV & Office of QPPV, EEA QPPV | Jazz Pharmaceuticals



**Sarah Hall**

Managing Director | Mipsol Limited



**Thierry Hamard**

Director, Safety Observer



**Kendal Harrison**

Head of Vigilance Development at Medicines and Healthcare products Regulatory Agency (MHRA)



**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



**Calin A. Lungu**  
DDCS S.A., CEO



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



**Zeljana Margan Koletic**  
Croatian PRAC Alternate Member, Head of Department for Pharmacovigilance and Rational Pharmacotherapy | HALMED



**Niteeka Maroo**  
Head Pharmacovigilance | Piramal Group-India



**Larissa Mege**  
Global Safety Officer, Sanofi Rare Diseases, Specialty Care Business Unit



**Nicholas Moore**  
Emeritus Professor, specialist in Cardiology and Pharmacology | University of Bordeaux



**Charalampos Nakos**  
EU-QPPV | Drug Safety Solutions



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



**Eriko Ogura**  
Global Head of Drug Safety | Shionogi & Co., Ltd.



**Nuccia Oneto**  
Patient Oriented Programs Governance Lead/Novartis Farma S.p.A.



**Maria Beatrice Panico**  
Principal Consultant | Scendea



**Susana Perez-Gutthann**  
VP, Global Head Epidemiology | RTI Health Solutions



**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



**Annette Rudolph**  
Pharmacovigilance scientist | Uppsala Monitoring Centre



**Jennifer Stevenson**

Consultant Pharmacist for Older People, Guy's and St Thomas' NHS Foundation Trust



**Monica Da Luz Carvalho Soares**

Health Regulatory Expert, Pharmacovigilance Adviser|Brazilian Health Surveillance Agency (Anvisa)



**Sofia Trantza**

MSc, MSc PV, Senior pharmacovigilance expert



**Michael Von Forstner**

Global Head of Clinical Safety and Pharmacovigilance | Biogen



**Anna Van Troostenburg De Bruyn**

EU QPPV and VP Pharmacovigilance & Epidemiology at Gilead Sciences



**Qun-Ying Yue**

Associate Professor Senior Pharmacovigilance Expert | Uppsala Monitoring Centre



**Gloria Bustos**

Senior Director, Head of Pharmacovigilance EMEA and APAC | Baxter



**Dominique Hamerlijnck**

EUPATI fellow, Patient Expert



**Romina Fernanda Heredia**

PV Intelligence Coordinator, Head of Project Managers and Business Development | PhV Latam



**Gianluca Trifirò**

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



**Lucia Biagiotti,**

EU & UK QPPV | Quality Assurance | Pharmacovigilance system assessment | Pharma D&S



**Andrea Pieri**

Business Development Director | Pharma D&S



**Sara Lazzarin**

Global Head of Pharmacovigilance Unit | OPIS s.r.l.



**Piero Francesco Franco**

Director, Information Management | Pfizer

# AGENDA 27 NOVEMBER

all times are UTC +1 Virtual

## 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. MAIN GLOBAL PV UPDATES

## 09.15 Introduction by the Chairperson of the Session

**Gian Nicola Castiglione**, Director Global Pharmacovigilance, EU QPPV | Chiesi

## 09.20 New regulations and guidelines in PV

**Thierry Hamard**, Pharmacovigilance & Regulatory Intelligence | Safety Observer

## 09.40 How to keep oversight over the pharmacovigilance regulatory intelligence landscape globally

**Marcela Fialova**, COO and Co-founder | iVigee

## 10.00 Global PV regulatory requirements - current challenges in handling Local PV requirements in a global setting

**Ilaria Grisoni**, Exec. Dir., Head of EU/International PV & Office of QPPV, EEA QPPV | Jazz Pharmaceuticals

## 10.20 Round Table & Q&A Time

Moderator: **GN. Castiglione**

Panelists: **M. Fialova**

**I. Grisoni**

**S. Hall** | Mipsol Limited

**T. Hamard**

## 10.50 Coffee Break & Networking

### SESSION 2. SIGNAL DETECTION & RISK MINIMIZATION

## 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 Risk minimization measures types and tools

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

## 11.35 Detection of high impact signals

**Qun-Ying Yue**, Associate Professor, Senior Pharmacovigilance Expert | Uppsala Monitoring Centre

## 11.55 Effectiveness of risk minimisation measures

**Zeljana Margan Koletic**, Croatian PRAC Alternate Member, Head of Department for Pharmacovigilance and Rational Pharmacotherapy | HALMED

## 12.15 Global safety monitoring of COVID-19 vaccines: how pharmacovigilance rose to the challenge

**Annette Rudolph**, Pharmacovigilance scientist | Uppsala Monitoring Centre



## 12.35 Round Table & Q&A Time

*Moderator:* **A. Mangoni**

*Panelists:* **K. M. Barac**,  
**F. De Gregorio** | Shionogi Europe,  
**Z.M. Koletic**  
**A. Rudolph**,  
**M. Von Forstner** |  
Biogen International  
**Q.Y. Yue**

## 1.05 Lunch & Networking

### SESSION 3. REAL WORLD EVIDENCE IN PHARMACOVIGILANCE

#### 2.00 p.m. Introduction by the Chairperson of the Session

**Michael Von Forstner**, Global Head, Patient Safety and Pharmacovigilance Biosimilars | Biogen International

#### 2.05 The European Health Data & Evidence Network (EHDEN) in pharmacovigilance

**Thomas Debray**, Founder, Smart Data Analysis and Statistics B.V.

#### 2.25 The role of real-world data and methods in evaluating the safety of medical interventions

**Susana Perez-Gutthann**, Vice President, Global Head Epidemiology | RTI International

#### 2.45 Interplay of spontaneous reporting system and longitudinal healthcare databases for signal management

**Gianluca Trifirò**, Full Professor of Pharmacology – Department of diagnostics and public health | University of Verona

#### 3.05 Round Table & Q&A Time

*Moderator:* **M. Von Forstner**

*Panelists:* **T. Debray**  
**S. Perez-Gutthann**  
**G. Trifirò**

## 3.30 Coffee Break & Networking

### SESSION 4. APPLYING ARTIFICIAL INTELLIGENCE TO PV

#### 3.50 Introduction by the Chairperson of the Session

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

#### 3.55 AI models in use/development at the MHRA

**Kendal Harrison**, Head of Vigilance Development | MHRA

#### 4.15 AI tools in pharmacovigilance

**Maria Beatrice Panico**, Principal consultant | Scendea

#### 4.35 Conscious use of AI in Pharmacovigilance

**Piero Francesco Franco**, Director, Information Management | Pfizer

#### 4.55 Round Table & Q&A Time

*Moderator:* **J. Petracek**

*Panelists:* **P.F. Franco**  
**M.B. Panico**  
**K. Harrison**

#### 5.20 Closing Remarks by the Chairperson of the congress and introduction of Lectio Magistralis

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

### SESSION 5. SIGNAL DETECTION & CAUSALITY ASSESSMENT (parallel session)

#### 3.50 Introduction by the Chairperson of the Session

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

3.55 **Signal detection in clinical trial settings - challenges in global environment**

**Ivona Bahník Bisevac**, Director Benefit-Risk Management | PrimeVigilance

4.20 **Causality assessment**

**Maddalena Lino**, Safety risk Lead Director | Pfizer

4.50 **Q&A Time with Experts:**

**I.B. Bisevac, G. Furlan, M. Lino**

5.15 **Closure of parallel session**

**SESSION 6. LECTIO MAGISTRALIS**

5.20 **Pharmacopidemiology is an important pharmacovigilance tool, but pay attention to biases and confounding factors**

**Nicholas Moore**, Emeritus professor of clinical pharmacology | University of Bordeaux

6.15 **Q&A Time**

6.30 **Closure of day 1**

# AGENDA 28 NOVEMBER

*all times are UTC +1* **Virtual**

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 7. EXTRA-EU PHARMACOVIGILANCE REGULATORY REQUIREMENTS (UK-Japan-India)**

09.15 **Introduction by the Chairperson of the Session**

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

09.20 **UK Pharmacovigilance Requirements - A Regulator's Perspective**

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

09.40 **A new emergency approval system and post-marketing PV activities in Japan**

**Eriko Ogura**, Global Head of Drug Safety | Shionogi & Co., Ltd

10.00 **Global Pharmacovigilance regulations**

**Niteeka Maroo**, Head Pharmacovigilance | Piramal Group-India

## 10.20 Round Table & Q&A Time

Moderator: **M. D'Antuono**

Panelists: **F. Afzal**

**S. Hall** | MIPSOL Limited

**N. Maroo**

**E. Ogura**

## 10.50 Coffee Break & Networking

### SESSION 8. RISK COMMUNICATION

#### 11.10 Introduction by the Chairperson of the Session

**Hervé Le Louët**, Head of PV policy intelligence strategy | Takeda, CIOMS President

#### 11.15 Evidence-based benefit-risk communication - what is next in the field of pharma?

**Frederic Boudier**, Professor in Risk Management | University of Stavanger, Norway

#### 11.35 Safety Information in the product and patient information

**Anita Blackburn**, Global Labeling Lead | Fortrea

#### 11.55 Pharmacogenomic information in the label

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

#### 12.15 Patients support programs: examples to communicate with patients, improve adherence and lower risks.

**Nuccia Oneto**, Patient Oriented Programmes Governance Lead | Novartis Italy

## 12.35 Round Table & Q&A Time

Moderator: **H. Le Louët**

Panelists: **A. Blackburn**

**F. Boudier**

**G. Furlan**

**P. Kruger** | EUPATI

**N. Oneto**

## 1.05 Lunch & Networking

### SESSION 9. EUDRAVIGILANCE: UPDATES (parallel session)

#### 12.05 Introduction by the Chairperson of the Session

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

#### 12.10 Eudravigilance updates

**Calin Lungu**, CEO | DDCS S.A.

#### 12.45 Q&A Time

#### 01.00 Closure of Parallel session

## 01.05 Lunch & Networking

### SESSION 10. PV IN ATMP

#### 02.00 Introduction by the Chairperson of the Session

**David Chonzi**, Global Head of PVE | Instil Bio

#### 02.05 The risk management of ATMP 's: practice and regulation

**Jan Petracek**, CEO | iVigee

#### 02.25 Safety aspects of Adeno-Associated Virus (AAV)-mediated Gene Therapy (GT)

**Larissa Mege**, Global Safety Officer, Sanofi Rare Diseases, Specialty Care Business Unit

#### 02.45 Application of Immunogenicity and Tolerance Principles to Immunogenicity Risk Assessment Advanced Therapy Medicinal Products (ATMPs)

**Anne De Groot**, CEO/CSO and Director | EpiVax

### 3.05 Round Table & Q&A Time

Moderator: **D. Chonzi**

Panelists: **A. De Groot**

**L. Mege**

**J Petracek**

## SESSION 11. CTIS: UPDATES (parallel session)

### 3.30 Introduction by the Chairperson of the Session

**Mircea Ciuca**, Global Therapeutic Area Head in Global Clinical Safety and Pharmacovigilance

### 3.35 Pharmacovigilance in Clinical Trial: highlights from the inside

**Sara Lazzarin**, Global Head of Pharmacovigilance Unit | OPIS s.r.l.

### 3.55 CTIS updates

**Vojtech Kvita**, CVO, Co-Founder | NextPV Services

### 4.15 Q&A Time

### 4.40 Closure of Parallel session

## SESSION 12. PV IN SPECIAL POPULATIONS

### 3.30 Introduction by the Chairperson of the Session

**Glyn Belcher**, CEO | PV Consultancy Ltd

### 3.35 Optimising data collection & risk management in pregnant and breastfeeding women

**Amalia Alexe**, Policy & Liaison Lead, QPPV PRRC Office | Novartis

### 3.55 Drug safety in older adults

**Jennifer Stevenson**, Consultant Pharmacist for Older People, Guy's and St Thomas' NHS Foundation Trust

### 4.15 Round Table & Q&A Time

Moderator: **G. Belcher**

Panelists: **A. Alexe**

**D. Hamerlijnck** | EUPATI

**J. Stevenson**

**Q.Y. Yue** | UMC

## SESSION 13. EXTRA-EU-PHARMACOVIGILANCE REGULATORY REQUIREMENTS (MENA-LATAM- CHINA)

### 4.40 Introduction by the Chairperson of the Session

**Valentina Mancini**, Senior Director Pharmacovigilance QPPV | Shionogi Europe

### 4.45 LATAM PV Regulatory requirements

**Romina Fernanda Heredia**, PV Intelligence Coordinator, Head of Project Managers and Business Development | PhV Latam

### 5.05 Middle East PV Regulatory requirements

**Lana Arafat**, Associate Director, Pharmacovigilance | Hikma Pharmaceuticals

### 5.25 PV regulatory requirements in China

**Gloria Bustos**, Senior Director, Head of Pharmacovigilance EMEA and APAC | Baxter

### 5.45 Round Table & Q&A Time

Moderator: **V. Mancini**

Panelists: **L. Arafat**

**G. Bustos**

**R. Heredia**

**H.B. Ndagije** | National Drug Authority in Uganda

**Hadir Rostom** | ISoP Egypt Chapter

### 6.10 Closing Remarks by the Chairperson of the congress

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



# AGENDA 1 DECEMBER

all times are UTC +1 Milan

08.45 **Registration of attendees**

09.20 **Welcome by the Chairperson of the congress**

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

09.30 **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 14. EVOLVING PHARMACOVIGILANCE STRATEGIES

09.35 **Introduction of the Round Table**

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

09.50 **Presentation & Panel Discussion**

**Eriko Ogura**, Global Head of Drug Safety- Shionogi

**Ayman Ayoub**, VP Business Unit Area Head Safety Surveillance & Risk Management | Pfizer

**Andrew Bate**, VP Safety Innovation & Analytics | GSK

**Sophia Trantz**, Senior pharmacovigilance expert

**Anna Ruth van Troostenburg De Bruyn**, Senior VP Pharmacovigilance & Epidemiology | Gilead Sciences

10.50 **Coffee Break & Networking**

## SESSION 15. PHARMACOVIGILANCE IN DRUG DEVELOPMENT

11.20 **Introduction by the Chairperson of the Session**

**Mircea Ciuca**, Global Therapeutic Area Head in Global Clinical Safety and Pharmacovigilance

11.25 **Aggregate data in clinical trials: a fresh perspective**

**Maria Beatrice Panico**, Principal consultant | Scendea

11.45 **TBD**

**Anne Ruth van Troostenburg De Bruyn**, EU QPPV and VP Pharmacovigilance & Epidemiology | Gilead Sciences

12.05 **Pharmacovigilance in clinical trials under CTR: an update, bridging from safety in clinical trials to postmarketing.**

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

12.35 **Round Table & Q&A Time**

*Moderator:* **M. Ciuca**

*Panelists:* **M.B. Panico**

**E. Prokofyeva**

**A.R. Van Troostenburg De Bruyn**

1.00 **Lunch & Networking**

## SESSION 16. PV QUALITY SYSTEM - INSPECTION & AUDIT

- 01.50 **Introduction by the Chairperson of the Session**  
**Calin Lungu**, DDCS S.A., CEO
- 01.55 **Inspection trends**  
**AIFA representative** (invited)
- 02.15 **Pharmacovigilance Inspections in Brazil**  
**Monica Da Luz Carvalho Soares**, Health Regulatory Expert, Pharmacovigilance Adviser | Brazilian Health Surveillance Agency (Anvisa)
- 02.35 **From present to future: behind the curtains of pharmacovigilance audits and inspections**  
**Tea Babić, Director**, Head of global PV audits and inspections | Teva Pharmaceuticals
- 2.55 **Round Table & Q&A Time**  
*Moderator:* **C. Lungu**  
*Panelists:* **T. Babic**,  
**Raj Bhogal**, Jazz Pharmaceuticals  
**M. Da Luz Carvalho Soares**  
**A. Gramaccioli** | Pfizer  
**C. Nakos** | Drug Safety Solutions
- 3.45 **Coffee Break & Networking**

## SESSION 17. IMPLEMENTING EFFICIENCY IN PHARMACOVIGILANCE OPERATIONS

- 4.15 **Introduction by the Chairperson of the Session**  
**Hrvoje Maček**, VP Medical & Scientific Affairs, EUQPPV | PrimeVigilance
- 4.20 **PV system efficiency, from theory to practice**  
**Laura Boga**, Head of Global Pharmacovigilance, EU&UK, QP for Pharmacovigilance | Dompé farmaceutici S.p.A.
- 4.35 **Opportunities coming from the partnership with PV providers**  
**Lucia Biagiotti**, EU & UK QPPV | Quality Assurance | Pharmacovigilance system assessment | Pharma D&S  
**Andrea Pieri**, Business Development Director | Pharma D&S
- 5.00 **Round Table & Q&A Time**  
*Moderator:* **H. Macek**  
*Panelists:* **L. Biagiotti**  
**L. Boga**  
**A. Pieri**
- 5.30 **Chairperson Congress Closing Remarks and end of congress**  
**Marco Sardella**, Chief Pharmacovigilance Officer & EU QPPV / ADIENNE Pharma & Biotech

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## VENUE December 1

Hilton Garden Inn Milan North



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	Face to Face December 1	Virtual November 27 - 28	Virtual + Face to Face November 27 - 28 December 1	
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In order to cancel enrolment to a event, please email [info@pharmaeducationcenter.it](mailto: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.

## PARTICIPANT REPLACEMENT

It is possible to replace a participant with another without additional costs, simply by contacting [info@pharmaeducationcenter.it](mailto: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.

