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LIFE SCIENCE ACADEMY

PHVday INTERNATIONAL 2019

International Pharmacovigilance Day

12th June 2019
from 13:15 to 17:50

13th June 2019
from 09:00 to 17:00

PHARMACOVIGILANCE WITHIN AND WITHOUT BORDERS

Barcelona, Spain

H10 Marina Barcelona

Avinguda del Bogatell, 64-68 - Barcelona, Spain

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A portion of the proceeds from this event are donated to the ***"Vase of Flowers" project.***

ABOUT

Official language: English

PHARMACOVIGILANCE
WITHIN AND WITHOUT BORDERS

Yesterday, today and in the future: "Safety first"!

Are you ready to enter the transformed landscape in Pharmacovigilance?

Pharmacovigilance is at the center of the health ecosystem, made up of alliances, partnerships and business cross-contaminations. Therefore, our focus during this conference will be on the importance of collaboration and communication at local, regional and international levels, to ensure pharmacovigilance delivers its full benefits.

The world of medicines and device safety is rapidly changing. The role of patients is more important than ever but how do we bring patient insight into drug safety? How can we make safety information more accessible? How will the device regulation be implemented in the face of recent crises? How digital tools will change the face of PV? What new skills are needed to grow and become the Pharmacovigilance professionals of the future? Also, new global PV legislation is being issued at a fast rate from emerging markets, bringing new harmonization challenges and more regulatory authority inspections from brand new inspectorates. Is industry prepared?

The International Pharmacovigilance Day conference brings together senior leaders and technical experts to discuss the hot topics of today and tomorrow, share learnings and explore solutions. It promises to be a lively exchange of ideas, learning and concepts during a one day and a half, where the topics to be treated, among many others, include:

- How can Patient Support Programs and Risk Management become more patient centered?
- What could be Risk minimization measures and how to be compliant with the quality requirements?
- What opportunities and challenges does the EU Electronic health record bring to PV?
- Preparing for regulatory inspections with new global inspectorates and in post-Brexit?
- Digital Pharmacovigilance: What is hype and what is hot?
- EudraVigilance - new approaches and new challenges
- How are companies expected to fulfil their requirements towards new regulations?
- How the future will look like, and what could be new skills for a new PV future?
- These are some of the questions that will make the future of PV, but how to be ready to embrace it?

We warmly welcome you to join us for this event of the future.

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ABOUT

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Scientific Board

Jabeen Ahmad
Regional Pharmacovigilance Director, Eastern Europe, Middle East & Africa (EEMEA)
at AbbVie

Marco Anelli
Head of "Data, Information, Knowledge & Intelligence" Platform
– PLG (Product Life Group)

Raffaele Di Marzo
EU QPPV
at Kedrion

Dr. Leonardo Ebeling
Managing Director
at Dr. Ebeling & Assoc. GmbH

Martin Holm-Petersen
CEO
at Insife

Betina Østergaard Eriksen
Vice President, Safety Surveillance
at Novo Nordisk

Dr Solange Corriol-Rohou
Sr. Director Regulatory Affairs & Policy, Europe
at AstraZeneca

Who should attend?

This conference is designed to benefit functional/technical professionals working in the pharmaceutical and health care area dealing with the Pharmacovigilance system, such as:

- Safety and Pharmacovigilance dept.
- Clinical operation dept.
- Statistic dept.
- Medical Affairs dept.
- Medical Information dept.
- Regulatory Affairs dept.
- Quality & Compliance dept.
- Legal dept.
- Software Developing dept.
- Medical Devices Manifacuring Companies
- University Faculties scientists who are related to clinical and medical research (Senior, Associate and Assistant Professors, Research Scholars, Phd students).

  Also, Directors/Seniors Directors/Executive Directors and Vice Presidents /Senior Vice Presidents/Executive Vice Presidents and Heads/Leaders/Partners of: CROs and CMOs, Clinical Research Sites, Pharma, Biotech and Medical Devices Industries.

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Day 1

Official Language: English

13:15 - 13:45 **Registration and Welcome coffee**

13:45 - 14:00 **Setting the scene with the new Regulations: CT Regulation**

Dr Solange Corriol-Rohou - *Sr. Director Regulatory Affairs & Policy, Europe* at AstraZeneca

14:00 - 14:40 **The New MDR: Safety By Design And By Vigilance**

Jan Bart Hak - *Head Medical Device Team* at ProPharma Group

14:40 - 15:20 **Structured Signal Management process as a tool to ensure patients' safety in clinical trials**

Mircea Ciuca - *Global Head Medical & Clinical Drug Safety* at Vifor Pharma

15:20 - 15:50 **Coffee break**

Signal Management using EVDAS

15:50 - 16:10 **The EViSiMa® Project**

Claudia Nowak - *Pharmacovigilance Advisor* at Dr. Ebeling & Assoc. GmbH

16:10 - 16:30 **A company's experience**

Cathrine Lange - *Safety Surveillance Principal Specialist* at Novo Nordisk A/S

16:30 - 17:10 **Safety in clinical trials and postmarketing in Europe: Major challenges**

Elena Prokofyeva - *Head of Drug Safety Unit, Department of Research & Development, DG PRE* at Federal Agency for Medicines and Health Products (FAMHP), Belgium

17:10 - 17:45 **Panel Discussion | Case processing in EU: special topics for EV cases availability**

CHAIR: Dr. Leonardo Ebeling - Managing Director at Dr. Ebeling & Assoc. GmbH

17:45 - 17:50 **Concluding remarks Day One**

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Day 2
Official Language: English

09:00 - 09:10 **Start Day Two**

Global Pharmacovigilance Session

CHAIR: Jabeen Ahmad - Regional Pharmacovigilance Director, Eastern Europe, Middle East & Africa (EEMEA) at AbbVie

09:10 - 09:30 **Pharmacovigilance in Pakistan, Challenges and Opportunities**
Farrukh Malik - *Drug Safety & Regulatory Consultant* at SYNTOF, France

09:30 - 09:50 **Chinese FDA: Implementation of the ICSR guidelines and local language issue**
Jabeen Ahmad - *Regional Pharmacovigilance Director, Eastern Europe, Middle East & Africa (EEMEA)* at AbbVie

09:50 - 10:10 **Pharmacovigilance in India – A Success Story**
Dr J Vijay Venkatraman - *Managing Director & CEO* at Oviya MedSafe Pvt Ltd

10:10 - 10:30 **Pharmacovigilance in Latin America: challenges and synergistic partnerships between regulators, industry associations and marketing authorization holders towards a harmonized and robust PV system in the region**
Renata Yoshida Shihomatsu - *Head of International Pharmacovigilance for Latin America* at Roche (Hoffman-La Roche

10:30 - 10:50 **Q&A session**

10:50 - 11:20 **Coffee break**

11:20 - 12:00 **Pharmacovigilance Inspections what's new?**
Dr Ernesto Vera-Sanchez - *Head of GCP and PHV Inspectorate* at AEMPS - Spanish Medicines and Medical Devices Agency

12:00 - 12:40 **Risk Minimisation Measures (RMM): How do we ensure that these measures are effective? Can real-world data help?**
Paola Nasuti - *Associate Principal* at IQVIA

12:40 - 13:40 **Networking lunch**

13:40 - 14:20 **AI and Machine Learning literature monitoring: improve quality and save time!**
Mark Drinkwater - *Co-founder of Pi2 Solutions* at ProQuest

14:20 - 15:00 **Electronic Product Information: How to change our communication with the patients?**
Dr Rüdiger Faust - *Regulatory Strategy & Intelligence Lead, Innovation Unit Devices & Technologies* at Grünenthal GmbH

15:00 - 15:30 **Coffee break**

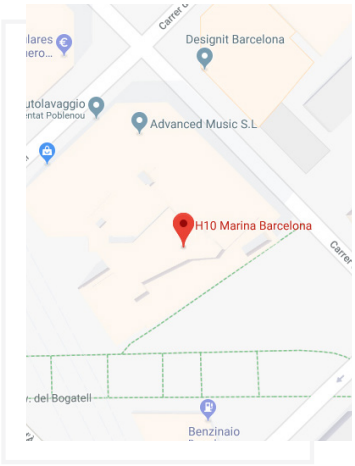
15:30 - 16:10 **WEB-RADR: App and Patient Support Programs experience**
Jabeen Ahmad - *Regional Pharmacovigilance Director, Eastern Europe, Middle East & Africa (EEMEA)* at AbbVie
Phil Tregunno - *Vigilance, Intelligence and Research Group Manager* at MHRA

16:10 - 16:40 **AI in PV: lesson learned in case studies**
Phil Tregunno - *Vigilance, Intelligence and Research Group Manager* at MHRA

16:40 - 17:00 **Digital Media: A Pharmacovigilance Challenge**
Sonia López - *Qualified Person Responsible for Pharmacovigilance* at Asphalion
Nuria Cabello - *Senior Drug Safety Officer* at Asphalion

17:00 **Concluding remarks**

HOW TO REACH THE CONFERENCE VENUE



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Avinguda del Bogatell, 64-68 - Barcelona, Spain

By taxi

A taxi from the airport should take about 25 minutes.

By train

The RENFE train leaves the airport every half an hour and will take you to Passeig de Gràcia station, in about 25 minutes. Then you have to change at Passeig de Gràcia for the Yellow Metro for Bogatell and your hotel is 3 minute walk from the metro stop.

By bus

The Aerobus will also take you from the Airport to Catalunya station. The journey time is around 30 minutes. From Catalunya you need to change for the Green line Metro to Passeig de Gràcia; at Passeig de Gràcia you need to change again for the for the Yellow Metro for Bogatell and your hotel is 3 minute walk from the metro stop.

By tube

The closer metro station is Bogatell.

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Download the **Events Summary** 2019

For further information

Please visit the conference website or contact the organisational offices:

Ilaria Butta Phone: +39 (0)35.4123594 | ilaria.butta@lsacademy.com

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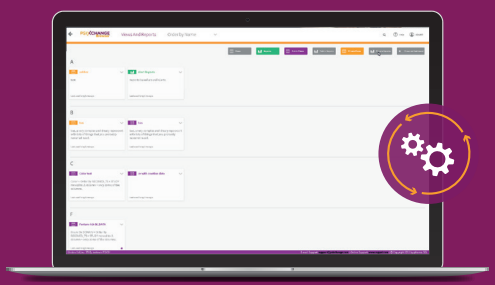

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Two ways to register

- **Online**

  please register here

  https://internationalpharmacovigilanceday2019.lsacademyevents.it/orders/new

  In this case, you can choose to pay **by credit card or by bank transfer**

- By **email o fax**

  please fill the registration form below for each attendee and send it by **email : ilaria.butta@lsacademy.com** or by **fax : +39(0)35.4501262**

  In this case, you can pay by bank transfer.

☐ **€ 1090,00 Early Bird fee extended until May 31st, 2019**

☐ **€ 1250,00** Ordinary fee (after May 31st, 2019)

☐ **€ 890,00*** Patronage members fee (Association _____)

☐ **€ 630,00*** Academy, Public Administration, Freelance

☐ **€ 300,00*** Asphalion reserved fee

The fee includes: seat at the conference, copy of presentations of Speakers who allow the distribution, informative literature for the day, welcome coffee, networking lunch, coffee break, organisational office assistance, certificate of attendance. ***For Italian companies: + 22% VAT**

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The full amount must be paid on registration to **EasyB S.r.l** by bank transfer. If you pay by bank transfer, please attach proof of payment to the registration form.

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For any additional information, please contact:

Ilaria Butta | Ilaria.butta@LSacademy.com **Phone:** +39 (0)35.4123594

Surname _____ Name _____

Company _____ Job title _____

Address _____

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Special Dietary Requests _____

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Cancellation Please note that refunds (70% refund of the registration fee) will only be given if cancellation is received at least one week before the event date. Cancellations will only be valid if made in writing. Transfer of registrations (or name changes) are allowed and should be made in writing within 7 days prior to the event. EasyB reserves the right to postpone or cancel an event, to change the location of an event or to alter the advertised speakers for an event. EasyB is not responsible for any loss or damage as a result of substitution, alteration, postponement or cancellation of an event due to causes beyond its control including without limitation, acts of God, natural disasters, sabotage, accident, trade of industrial disputes, terrorism, or hostilities.

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Date _____ Signature _____

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