PHVdays INTERNATIONAL 2021

LIFE SCIENCE ACADEMY

International Pharmacovigilance Days

Evolvement of Pharmacovigilance Today and in the Near Future

Date
14 - 18 June 2021

Language
English

Location
Online
Virtual Conference

MEDIA PARTNERS

PharmaVOICE

CREATIONKnowledge
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ABOUT

Evolvement of Pharmacovigilance Today and in the Near Future

Pharmacovigilance is ‘hotter’ than ever. A simple search on Social Media can give a good idea of the impact of pandemic on Pharmacovigilance. How the perceptions of clinical research, drug approval and adverse events among the public have evolved; adaptations to the regulatory framework to address challenges arising from the current situation; and the change to the way that ‘PV people’ work.

At the same time, Brexit and implementation of the new regulatory base of pharmacovigilance in the UK, as well as in the Eurasian Economic Union (EAEU) countries, have transformed Pharmacovigilance to a key element brought to the attention of all pharmaceutical industry players. For years, a globally harmonized approach to Pharmacovigilance has been discussed as a concept for integrated regulations. Considering the recent developments, are we Getting Closer or Further Away from Harmonized systems?

The third edition of the **International Pharmacovigilance Days,** organized by LS Academy, will focus on all these topics, among others:

- What are the points to be considered when a PV system is set up outside the EU?
- What are the inspection and quality aspects challenges under the new Legislation Era?
- Is a transition from an EU-QPPV Office to International QPPV Office required?
- How has the COVID-19 affected the digital transformation of PV? Is this ‘new way we work’ here to stay?
- PV Technologies reality check – where do we stand? Are the promises of technology coming true?
- Are new PV business models required to meet current and future needs? Pharmacovigilance outsourcing and vendor oversight – what are the trends and best practices?
- Current discussions for accelerated drug approval and safety monitoring: Will they have a further impact on patients’ involvement on drug development?

Register to attend this 5-day event that will be held online from June 14th to June 18th 2021.

Scientific Coordinator
Biomapas’ Pharmacovigilance Team

Who should attend?
The event is designed for professionals in the field of Pharmacovigilance from Pharmaceutical Industry, CROs, Patient Associations and Healthcare Organizations, Regulatory Authorities.

For any further information, and sponsorship opportunities contact us info@lsacademy.com

PROGRAMME

The conference will be divided in 5 virtual appointments from 14th to 18th June (afternoon CEST).

The Agenda will cover 3 main macro-areas:

- **Globalization of Pharmacovigilance: Getting Closer or Further Away from Harmonized Systems?**
- **Pharmacovigilance System: Best Practices and Case Studies**
- **Covid-19 and Patient Safety**

Please find below the complete programme

All the below mentioned times are CEST

14 June 2021	
2.30 pm **2.45 pm**	**Welcome Day 1**
2.45 pm **3.20 pm**	**Transition from EU-QPPV office to International QPPV Office** **Nina Sagbana** International Deputy QPPV at Vifor Pharma
3.20 pm **3.55 pm**	**From EU to International PSMF** **Willemijn van der Spuij** Executive Director Europe, Patient Safety at Bristol Myers Squibb
3.55 pm **4.10 pm**	**Coffee Break**
4.10 pm **4.45 pm**	**Inspection and Quality Aspects' Challenges under the new Legislation Era** **Ranjana Khanna** Head of Pharmacovigilance Quality Assurance at Vifor Pharma
4.45 pm **5.00 pm**	**Conclusion Day 1**
15 June 2021	
2.00 pm **2.15 pm**	**Welcome Day 2**

2.15 pm **3.15 pm**	**Roundtable | GVP-like legislation outside the EU: overlap and differences** **Lidia Maksyutkina** Regional Pharmacovigilance Manager, Russia and CIS at Biomapas **Mina George Awad** Pharmacovigilance Manager and QPPV, Middle East at Kyowa Kirin International **J Vijay Venkatraman** Managing Director & CEO at Oviya MedSafe **John Barber** Managing Director and Lead Consultant at Plain Pharma Consulting
3.15 pm **3.30 pm**	**Roundtable Q&A and Discussion**
3.30 pm **3.45 pm**	**Coffee Break**
3.45 pm **4.20 pm**	**Establish PV systems in USA: Points to consider** **Kristina Keeler** Senior Director of Global Safety Operations at Drug Safety Navigator (DSN)
4.20 pm **4.30 pm**	**Conclusion Day 2**
16 June 2021	
2.00 pm **2.15 pm**	**Welcome Day 3**
2.15 pm **2.50 pm**	**Distributed database network for post-marketing surveillance of drugs: the Italian experience** **Gianluca Trifirò** Full Professor of Pharmacology at University of Verona
2.50 pm **3.25 pm**	**Oversight of PV System: Quality Parameters and KPIs** **Marie-Charbel El Chalouhi** International Pharmacovigilance Operational Excellence Lead & EEMEA Pharmacovigilance Point of Contact at Abbvie Inc
3.25 pm **3.40 pm**	**Coffee Break**
3.40 pm **4.15 pm**	**Pharmacovigilance outsourcing and oversight** **Andras Berta** CEO and Principal Consultant at StratoServ Sciences AG

4.15 pm **4.30 pm**	**Conclusion Day 3**
17 June 2021	
2.00 pm **2.15 pm**	**Welcome Day 4**
2.15 pm **2.50 pm**	**Black spots in an end to end digital platform project: the non-technical considerations** **Claudia Lehmann** Vice President of Global Patient Safety & Pharmacovigilance Operations & Systems at Boehringer Ingelheim
2.50 pm **3.25 pm**	**Artificial Intelligence for conversation automation** **Laimonas Sutkus** Chief Technology Officer at Biomapas
3.25 pm **3.40 pm**	**Coffee Break**
3.40 pm **4.15 pm**	**Effect of Covid-19 situation on digital transformation** **Richard Wolf** Executive Director, Pv Operations Head in the Global Clinical Safety and Pharmacovigilance group at CSL Behring
4.15 pm **4.30 pm**	**Conclusion Day 4**
18 June 2021	
2.00 pm **2.15 pm**	**Welcome Day 5**
2.15 pm **2.50 pm**	**Safety aspects of Covid-19 vaccines** **Alex Bica** Director, Clinical Safety Physician, Department Global Clinical Safety and Pharmacovigilance at CSL Behring
2.50 pm **3.25 pm**	**The impact of COVID-19 on cancer patients in Europe** **Antonella Cardone** Director of European Cancer Patient Coalition (ECPC)
3.25 pm **3.50 pm**	**Patient Organisations role in Pharmacovigilance** **François Houÿez** Treatment Information and Access Director, Health Policy Advisor at European Organisation for Rare Diseases (Eurordis)
3.50 pm **4.00 pm**	**Coffee Break**

4.00 pm **4.35 pm**	**PV – did you know? – interactive close-out** **Olga Asimaki** International QPPV at Biomapas **Martijn van de Leur** Head of Global Pharmacovigilance at Biomapas
4.35 pm **4.45 pm**	**Conclusion Day 5**

SPEAKERS

Scientific Board
Olga Asimaki
International QPPV at Biomapas

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Martijn van de Leur
Head of Global Pharmacovigilance at Biomapas

Speaker
Mina George Awad
Pharmacovigilance Manager and QPPV, Middle East at Kyowa Kirin International

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John Barber
Managing Director and Lead Consultant at Plain Pharma Consulting

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REGISTRATION FEE

Full attendance | 5 appointments

€ 480,00* Super Early Bird fee until April 17th, 2021
€ 560,00* Early Bird fee until June 4th, 2021
€ 650,00* Ordinary fee
€ 320,00* Freelance, Academy, Public Administration

* *for Italian companies: +22% VAT*

Fee includes: access to the virtual conference, organizational support, certificate of attendance, slide presentations in pdf format provided post-event.

SEDE DELLA CONFERENZA

Virtual conference on Zoom platform.
LS Academy will provide the link to join the conference some days before.