PHVday PharmacoVigilance 2020

LIFE SCIENCE ACADEMY

Nordic Pharmacovigilance Day

New perspectives and future needs of Pharmacovigilance in the Nordic Countries: embracing the opportunities ahead

Data
28 October 2020

Lingua
Inglese

Location
Online
Conferenza Virtuale

Warning: Invalid argument supplied for foreach() in /var/www/clients/client0/web114/web/wp-content/uploads/cache/f9c8c433c661667d37c850adf5033710dd45f025.php on line 104

INTRODUZIONE

In Pharmacovigilance, we are entering extraordinary times. Evolutions in technology, regulations, and processes bring along unprecedented challenges as well as new opportunities for all involved parties including patients and their caregiver, the investigators, the health care professionals, the regulators, the sponsors, the vendors and CROs.

While the shorter-term benefits of digitalization are gradually becoming tangible, there are also longer-term aspirations to transform the entire operating model in the field of pharmacovigilance.

For the 7th Nordic Pharmacovigilance Day conference 2020 we are posed with the following questions:

- What are the challenges for our QPPVs – locally and globally?

- What is the impact of the new EU-medical device regulation on pharmacovigilance of devices and combination products?
- What are the Risk Minimization Measures outcomes and how to measure the effectiveness?
- RWE and Big Data - Signal management, how to manage in the best way?
- Inspection Readiness – What are the emerging trends in the field of pharmacovigilance and how to prepare your organization?
- New PV tools, machine learning and AI (data protection and Signal detection – requirements, challenges and compliance). Are we ready to monitor the patient safety in the new digital era?
- Outsourcing in PV, how to ensure oversight and how to be compliant?

The future is here, and we need to shape it to provide enhanced solutions for a better health and quality of life for patients. This meeting is a key opportunity to network and learn from knowledgeable speakers and experts in this area.

Scientific Board

Wasim Anwar - *Director, Safety Surveillance - Biopharm, Diabetes Insulin & Devices at Novo Nordisk A/S*
Caroline Susanne Sandström - *Senior Specialist GCP/GLP/GVP Compliance Global QA R&D at Ferring Pharmaceuticals A/S*
Doris Stenver - *Independent Pharmacovigilance Adviser, Founder of Unique Advice*

Who should attend?

This conference is designed to benefit functional/technical professionals working in the pharmaceutical and healthcare 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 Manufacturing Companies, University Faculties scientists who are related to clinical and medical research (Senior, Associate and Assistant Professors, Research Scholars, PhD students).

PROGRAMMA

All times indicated are Central Europe Summer Time

10:00 **10:20**	**Welcome**
10:20 **10:45**	**Ensuring Compliance in a Changing World - Inspection Perspectives** **Line Michan** Medicines Inspector at Danish Medicines Agency

10:45 **11:10**	**Outcome of Risk Minimization Measures** **Inge Zomerdijk** Senior Pharmacovigilance Assessor at Medicines Evaluation Board (MEB)
11:10 **11:30**	**Break**
11:30 **11:55**	**Outsourcing in Pharmacovigilance - Should Anyone Dare?** **Liliana Hansen** Senior Director, Head of Pharmacovigilance at Zealand Pharma
11:55 **12:20**	**New Medical Device Regulation in Europe – Are you Ready?** **Linda Matti** Senior Device Vigilance & Process Manager, Global Pharmacovigilance, PV Surveillance at Ferring
12:20 **13:20**	**Lunch break**
13:20 **14:05**	**INTERACTIVE SESSION | Patient Safety during Pandemic Situation - Sharing Lessons Learned** **Betina Østergaard Eriksen** Vice President, Safety Surveillance at Novo Nordisk
14:05 **14:30**	**Using Danish Registries as Sources of Real-World Data for Signal Detection, Validation and Assessments: Examples from the Danish Medicines Agency (DKMA)** **Kåre Kemp** Head of EU Pharmacovigilance at Danish Medicines Agency
14:30 **14:50**	**Break**
14:50 **15:15**	**Can Artificial Intelligence change our Fundamental Approach to Safety Signal Detection and How far is it Today?** **Martin Holm-Petersen** CEO at Insife
15:15 **15:40**	**ccAI – an Example of Using AI/ML (Artificial Intelligence & Machine Learning) in Case Intake** **Alex Aarsø** Sr. Project Manager at Novo Nordisk A/S
15:40 **15:45**	**Conclusion**

SPEAKERS

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QUOTE ISCRIZIONE

€ 560,00* Early Bird fee until October 5th, 2020
€ 680,00* Ordinary fee
€ 390,00* 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 DEL CORSO

Virtual conference with presentations, slots for Q&A and discussion among delegates.
LS Academy will provide the link to join the conference some days before.