Print Agenda

Day 1 Oct 11, 2022

12:00 PM — 5:30 PM

Pre-conference Workshop: Improving / Digitalizing Risk Minimisation - How to get the message across?

Day 2 Oct 12, 2022

8:00 AM — 8:45 AM Sunset Bar

Registration And Welcome Coffee

8:45 AM — 9:00 AM The Vista Suite

Welcome And Introduction To The Workshop

9:00 AM — 10:30 AM

The Vista Suite

Session 1: Pharmacovigilance Update – Introduction, Overview and Deep-dive – What You Always Wanted To Know But Were Afraid To Ask

In this opening session we will get to know each other, and find out who we are, what we know of PV and which topics are especially important to you. Pharmacovigilance is always changing, and to set the stage and get everyone up to speed, a quick overview of important changes to PV guidance and regulations will be provided. Supported by expert speakers we will then take a deep-dive into two of the more impactful recent changes: the Clinical Trial Regulation (EU CTR) and the post-Brexit guidance in the UK. The session will be interactive with plenty of possibilities to ask questions, challenge the panel or each other and to share experiences.

Session Chair(s)

Maarten Lagendijk, MSc

Deputy EU QPPV
MSD, Netherlands

Maarten Lagendijk is currently Deputy EU QPPV at MSD. Previously he has held different positions in pharmacovigilance at the Medicines Evaluation Board (MEB), the Dutch Regulatory Authority, with increasing responsibilities. With over 15 years of experience in pharmacovigilance, Maarten has a good understanding of all different aspects of safety and risk evaluation of medicines in a broad range of therapeutic areas, most notably in oncology and hematology, as well as in immunology and pulmonology. Through the years he has also focused on developments around risk communication and additional risk minimisation, as well as the evolution of risk management and efforts to streamline and harmonise risk management plans.

Wendy Huisman, PharmD

Director
Vigifit, Netherlands

Over the past 23 years Wendy has been dedicated to pharmacovigilance. She has broad experience as EU QPPV for generic and innovative products in complex companies. She also has wealth of experience in lobbying and networking in trade associations/working groups. In her current role, Wendy provides pharmacovigilance support to Pharmaceutical Industry and SMEs (startups). She enjoys setting up the PV system and supports in the development of the PSMF with associated documents. Since 2020 Wendy is a trained professional in Transactional Analysis (TA). TA is a theory of human personality and social behavior. TA gives a wealth of options to work with challenges and changes in organisational and personal development.

Speaker(s)

Deep Dive into Clinical Trial Regulation: Post-Implementation Experiences

Speaker Invited

Switzerland

Deep Dive – PV Guidance Post Brexit

Stephanie A Millican, PhD, MSc

Unit Manager
MHRA, United Kingdom

10:30 AM — 11:00 AM Sunset Bar

Coffee Break

11:00 AM — 12:30 PM The Vista Suite

Session 2: Globalisation Of PSMF : Practical Implementation

This session focusses on the PSMF requirements from a global perspective. With the expansion of PSMF, or similar, requirements, better understanding the landscape in which we operate will be beneficial to participants. Through the lens of various experts we will be looking at how varying global requirements impact the concept of the PV system and its description, its development and maintenance. The session will cover a deep dive into some of the PSMF requirements outside the EEA. We will explore the learnings to be taken from audit findings by looking at what trends have been observed and can be used as part of the global consideration and improvements. And the session will include a regulators view, what are the requirements and expectations specific to the UK for the PSMF. Why are these requirements so important.

The Q&A as part of this session will allow the participants to interact with the experts and discuss considerations for pragmatic ways of working for the PSMF in the global environment.

Session Chair(s)

Francoise Sillan, MD

VP GPS TA ENDO-ONCO & EU QPPV
Ipsen, France

Françoise is a medical doctor as background, working in Pharmacovigilance for more than 30 years in big Pharmaceutical companies with different managerial roles, interactions with Health Authorities, and coordination of international networks of Pharmacovigilance. She has spent 15 Years on Vaccine Pharmacovigilance where she contributed to the development of standards definitions and methods through CIOMS WHO working groups on vaccine safety. Within the EFPIA Pharmacovigilance expert group, she analysed the influence of EU pharmacovigilance regulations outside Europe and of non EU regulations on the EUQPPV role.

Willemijn van der Spuij, MSc

Executive Director, WorldWide Patient Safety International, Europe
Bristol-Myers Squibb, Switzerland

Responsible for Pharmacovigilance activities in the EU and Balkans, as well as PV Intelligence and Operational activities within the International PV organization. As part of the Operational activities she holds responsibility for the PSMF. She previously served as Intelligence and Training expert in PV as part of the Quality Standards and Training Group in Bristol Myers Squibb and managed PV projects. Willemijn is a member of the EFPIA Pharmacovigilance Expert Working Group and the International Pharmacovigilance Group where she chairs the CIS and Balkan sub-teams. She started her career in Quintiles, followed by Aventis where she was involved in GCP activities.

Speaker(s)

Global Perspective on The Implementation of the PSMF

Sean Burke, MS

Regional Director, Pharmacovigilance
MSD, United Kingdom

Audit Perspective on the PSMF

Melanie Weber, MSc

Pharmacovigilance Expert
Pietrek Associates Gmbh, Germany

Over 10 years of experience in the CRO industry, expert in drug safety processes and regulatory requirements. Special interests include process analysis and enhancement, pharmacovigilance system audits and mock inspections as well as in-depth knowledge of international PV regulations and guidelines.

MHRA Perspective

Speaker Invited

Switzerland

12:30 PM — 2:00 PM Skyline Restaurant

Lunch

2:00 PM — 3:30 PM The Vista Suite

Session 3: Lessons Learnt From The Regulator and Industry Experience With COVID-19 Vaccines

The COVID pandemic has made way for innovative options to be considered to allow proactive safety surveillance on a grand scale to ensure issues were identified and assessed in a timely manner. Furthermore, it brought to the front the importance of accurate, clear and concise communications tailored for healthcare professionals, patients and the public. All of this could only be achieved by effective risk management planning for COVID-19 vaccines.

This session aims to provoke thinking and provide participants with the tools and strategies to develop and conduct proactive safety surveillance utilising appropriate innovative tools such as artificial intelligence to identify, prioritise and assess safety signals in a timely manner. An insight will be given into achieving effective risk management and risk communication taking into account the sensitivities around COVID-19 vaccines. The interactive panel discussion will provide an invaluable opportunity to participants to actively discuss these topics in detail.

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Ipsen, France

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Shahin Kauser

Leading Senior Scientific Assessor
MHRA, United Kingdom

Shahin Kauser also has a Certificate in Pharmacoepidemiology & Pharmacovigilance from the London School of Hygiene and Tropical Medicine. Shahin is a Leading Senior Scientific Assessor and joined the MHRA Agency (former MCA) in 2001. She has extensive experience of the 'life-cycle' of pharmacovigilance both nationally and in Europe. Her current portfolio includes monitoring the post-marketing safety of medicines in various therapeutic areas including blood disorders, multiple myeloma and malignant melanoma. Shahin has expertise in assessing benefit/risk, PSURs, safety Variations and risk management plans, additional risk minimisation measures and assessing their effectiveness.

Speaker(s)

Proactive surveillance of COVID-19 vaccines

Lilly Wells

Associate signal assessor
MHRA, United Kingdom

Risk management including risk communication

Emil Andrei Cochino, MD, MHS

Scientific Officer, Risk Management Specialist, Office of vaccines and therapies
European Medicines Agency, Netherlands

Dr Emil Andrei Cochino is a Specialist in Public Health and Health Services Management. He has been a scientific officer at EMA from 2009, and is working in the Human Medicines Department as a Scientific Senior Specialist (Risk Management), where he is responsible for peer-reviewing risk management plans for centrally authorised products (ATMPs and vaccines) and improving the access of ATMPs to the market by supporting the collaboration with the HTA and payers organisations. Furthermore, he has overseen the revision 2 update of GVP Module V – Risk Management Systems and coreRMP19 guidance.

Risk management including risk communication

Catherine Tregunno

Head of Vaccines, Infectious Disease and Diagnostics
MHRA, United Kingdom

Industry Perspective

Robert Massouh, MPharm, RPh

Risk Management Product Lead
Pfizer Ltd, United Kingdom

Robert is a Risk Management Product Lead at Pfizer, supporting the development and execution of Risk Management strategies for Pfizer products. He was previously at the MHRA working as a Scientific Assessor within the Benefit Risk Management Group. Robert is a registered Pharmacist and received his MPharm at the University of Manchester.

3:30 PM — 4:00 PM Sunset Bar

Coffee Break

4:00 PM — 6:00 PM The Vista Suite

Session 4: Hackaton: Future Changes And Challenges In PV

Session Chair(s)

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Executive Director, WorldWide Patient Safety International, Europe
Bristol-Myers Squibb, Switzerland

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James Whitehead, MSc

Patient Safety Medical Device Lead
Astrazeneca, United Kingdom

James Whitehead is the Patient Safety Medical Device Lead at AstraZeneca working within Patient Safety Center of Excellence, having started his career with AZ as a Pharmacovigilance Scientist in Oncology and then Principal Process Owner. Since graduating with a BSc in Psychology from the University of Leicester, James has held positions at CROs, Pharmaceutical Companies and Consulting Practises with a focus on Signal and Risk Management. That passion for Signal and Risk Management culminated in a MSc in Pharmacovigilance from the University of Hertfordshire, James is now a Visiting Lecturer on the course.

Day 3 Oct 13, 2022

9:00 AM — 10:30 AM

The Vista Suite

Session 5: Data Science And Standards: Impact on Pharmacovigilance

Every day, massive amounts of data are generated from myriad sources that could potentially be harnessed to support the regulation and oversight of medicines. As a result, “big data” analysis is becoming more and more relevant every day, especially during the COVID pandemic. This session will give an insight into innovative regulatory and industry initiatives on big data and various data solutions

Session Chair(s)

Bianca Mulder, PharmD, MPharm, MSc

Pharmacovigilance Assessor
Medicines Evaluation Board, Netherlands

Bianca Mulder is a pharmacist with a PhD in pharmacoepidemiology. Her research focused on the use of medication during pregnancy and the development of atopic diseases in children. She worked briefly in a pharmacovigilance position at a pharmaceutical company before she started working as a pharmacovigilance assessor at the Dutch national agency (MEB) in 2016.

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Speaker(s)

Challenges of Signal Management for Vaccine and the Various Data Solutions

Isobel Anderson

Astrazeneca, United Kingdom

10:30 AM — 11:00 AM Sunset Bar

Coffee Break

11:00 AM — 12:30 PM The Vista Suite

Session 6: Public and Patient Involvement in Pharmacovigilance

Patient involvement is increasing in more areas of pharmacovigilance. What influence can patient representatives have on decision making? What is the influence of the public by for example social and regular media? How did public involvement influence the communication on the Covid vaccines. Can we ethically “use” influencers/social media as pharmaceutical industry?

Session Chair(s)

Wendy Huisman, PharmD

Director
Vigifit, Netherlands

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Speaker(s)

Patient Perspective

Virginie Hivert, PharmD, PhD

Therapeutic Development Director
Eurordis-Rare Disease Europe, France

Virginie Hivert joined EURORDIS in 2014 as Therapeutic Development Director.Virginie is responsible for following the development of orphan drugs as an observer on the Committee for Orphan Medicinal Products at the European Medicines Agency.She coordinates the group of high-level EURORDIS representatives/volunteers who sit on the various scientific committees/working parties at the EMA, known as the Therapeutic Action Group (TAG).

12:30 PM — 2:00 PM Skyline Restaurant

Lunch

2:00 PM — 3:30 PM The Vista Suite

Session 7: Medical Devices, Wearables, Combination Products

The digitalisation of the care pathway is accelerating and the past 24 months has only increased the pace of the digital health and medical devices revolution. We are seeing the influence of devices & digital on how patients are diagnosed, monitored and have their medicine administered. Everyone involved in patient care, from MAH's and Regulators to Hospitals and Pharmacies, is challenged to keep up. This session will look at how digital health tools and medical devices are being used in clinical trials, how they could be utilised in the post-marketing space and how regulators have to work across boundaries—all of this with the goal of enhancing patient safety.

Session Chair(s)

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Deputy EU QPPV
MSD, Netherlands

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Speaker(s)

Use of Wearables to Monitor Patients – Case Studies

Emma Woods

Astrazeneca, United Kingdom

3:30 PM — 4:00 PM Sunset Bar

Coffee Break

4:00 PM — 4:30 PM The Vista Suite

Conclusions and Wrap-Up of the Workshop and Closing Words