DIA

Pharmacovigilance Strategies Workshop

Navigating the changing PV landscape in your daily work

2-4 November 2020 | Virtual conference

A unique opportunity to engage in the sharing of good practices between industry representatives and seek the advice you need from regulators.

PROGRAMME COMMITTEE

Françoise Dumas-Sillan
Vice President Therapeutic Area Leader, Endocrinology/Oncology, Global Patient Safety, Ipsen, France

Wendy Huisman
Director, Vigifit, The Netherlands

Shahin Kauser
Leading Senior Scientific Assessor, MHRA, UK

Maarten Lagendijk
Director, Deputy EU QPPV, MSD, The Netherlands

Bianca Mulder
Pharmacovigilance Assessor, Medicines Evaluation Board (MEB), The Netherlands

Mette Stockner
Senior Pharmacovigilance Director, Savara ApS, Denmark

Willemijn Van Der Spuij
Regional Director, PV Intelligence & International Operations, Bristol-Myers Squibb, Switzerland

Elena Popa
Scientific Programmes Manager, Drug Information Association (DIA), Switzerland

Key Topics

- EMA GVPs Updates
- Medical Device Regulation: Impact on Pharmacovigilance
- Implementation of EU Clinical Trial Regulation
- Inspections and Audits
- Signalling Management
- Additional Pharmacovigilance Activities
- Risk Minimisation Measures and Risk Communication
- Future of Pharmacovigilance

Overview

DIA has a long history of working closely with Industry and Regulators to bring topics and speakers together with broad audiences in order to create stimulating and relevant discussion.

Join the DIA Pharmacovigilance Conference to discuss the current landscape and join intense and well-lead discussion that may help you to progress your knowledge and practices.

The conference format is designed to **stimulate dialogue** and **generate solutions** through a series of **interactive sessions and workshops** conducted in an informal setting allowing for in-depth discussion in smaller groups.

Objectives

- Seek direct answers to the business challenges you are facing every day
- Understand how other organisations are managing through the shift of sharing all information to sharing relevant information
- Understand the regulators expectations for signal assessment, risk management planning, and risk communication
- Ensure that your pharmacovigilance work matches up with inspector expectations and delivers the efficient outcomes for patients.

Target Audience

Established professionals who are seeking to increase their network of like-minded colleagues; share their thoughts and practices with others; learn the most current regulatory views and gain practical knowledge in key areas in pharmacovigilance, including:

- Signal management
- Data Privacy
- Risk Management Planning
- PSMF maintenance
- Clinical Trials

Professionals involved in:

- Drug Safety/Pharmacovigilance
- Risk Management, including Risk Evaluation and Mitigation Strategies (REMS)
- Benefit-risk assessment and communication
- Medical Product Safety Assessment
- Regulatory Affairs
- Clinical Trials
- Pharmaceuticals, biologics, combination products, devices
- Clinical Research and Clinical Research Organizations
- Health Outcomes
- Academic Research Centers
- Regulatory Agencies

PRE-CONFERENCE TUTORIAL | THURSDAY, 29 OCTOBER

THE PSMF IN 2020 - GENERAL DEVELOPMENTS IN - AND OUTSIDE EUROPE: WHERE ARE WE HEADING?

29 OCTOBER | 14:00-18:00

Limited Places Available.

The purpose of this tutorial is to share knowledge and come up with some best practices between participants so that delegates leave the session better equipped and with an informal network of colleagues to tap into for working on the PSMF outside the EU.

Workshop Chairs:

Clare Lavery, Pharmacovigilance Excellence Principal, AstraZeneca, UK
Dionne Usher, Associate Director, Office of the EU QPPV, MSD, UK
Willemijn Van Der Spuij, Regional Director, PV Intelligence & International Operations, Bristol-Myers Squibb, Switzerland

Separate Registration Required

Learning Objectives:

- Exploring the current PSMF landscape.
- Sharing of experiences and challenges across the world and discuss practical solutions to simplify work.
- Discuss and understand feedback received on existing PSMFs, sharing of strategies and processes.
- Encourage participants to work towards an approach that ensures compliance, good quality, simplification to deliver what is needed whilst eliminating duplication wherever possible.

Audience:

Pharmacovigilance/Industry experts involved in PSMF coordination and/or maintenance.

Level:

Pharmacovigilance audience; beginners and advanced, trying to better understand the PSMF landscape and requirements around the globe.

WORKSHOP AGENDA

14:00	**LOG IN AND CONNECT**
14:15	**INTRODUCTION AND WELCOME**
14:25	**THE CURRENT PSMF LANDSCAPE (LEGISLATIVE UPDATES AND RECENT LEARNINGS)**
15:15	**WORKSHOP I: AUDIT AND INSPECTIONS. FEEDBACK ON PSMFS AND LESSONS LEARNED**
16:00	**WORKSHOP II: BUILDING YOUR PSMF TO ALLOW GLOBAL USE (GLOBAL, EU AND REST OF WORLD)**
	- Listing pros and cons of each approach with example of specific areas where there are questions (eg do you list vendor SOPs and contents of non-EU PSMFs)
17:00	**WORKSHOP III: PSMF PROCESS AND OVERSIGHT FOR QPPVS**
17:45	**WORKSHOP FEEDBACK**
18:00	**END OF WORKSHOP**

About DIA

DIA is the global connector in the life sciences product development process. Our association of thousands of members builds productive relationships by bringing together regulators, innovators, and influencers to exchange knowledge and collaborate in an impartial setting. DIA's network creates unparalleled opportunities for exchange of knowledge and has the inter-disciplinary experience to prepare for future developments.

The dedicated efforts of DIA staff, members and speakers enable DIA to provide a comprehensive catalogue of conferences, workshops, training courses, scientific publications and educational materials. DIA is a global community representing thousands of stakeholders working together to bring safe and effective products to patients.

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DAY ONE | MONDAY, 2 NOVEMBER 2020

13:00 LOG-IN AND CONNECT

13:10 WELCOME AND INTRODUCTION TO THE WORKSHOP

Elena Popa, Scientific Programmes Manager, Drug Information Association, Switzerland

13:30 SESSION 1

RECENT AND FUTURE DEVELOPMENT ON PHARMACOVIGILANCE PRACTICES

Session Chair:

Françoise Dumas-Sillan, Vice President Therapeutic Area Leader, Endocrinology/Oncology, Global Patient Safety, Ipsen, France

This session will be dedicated to future trends of regulations and guidelines within and outside Europe. Following Brexit, the move of EMA from London to Amsterdam and the recent COVID 19 pandemic this activity has been deprioritized since end 2018. This session will present the challenges on pregnancy and lactation safety monitoring from EMA, MHRA and IMI perspectives. There will be an update on the future developments of post approval safety data management with the revision of ICHE2D guideline by Expert Working Group which will include the revision of the management of reports from patient support programmes and market research programmes.

E2D: update of Post Approval Safety Data Management - Definition and Standards for Expedited Reporting
Johan Hellmer, Senior Director PV at Takeda Pharmaceuticals, Sweden

EMA Pregnancy Guidelines
Corinne de Vries, Head of Science and Innovation Support, European Medicines Agency (EMA), EU

IMI Conception Project
David Lewis, EU QPPV Head QPPV Office, Novartis Pharma AG, Switzerland

Panel discussion with Q&A, with additional participation of:
Belen Granell Villen, Quality and Safety Policy Executive, The Association of the British Pharmaceutical Industry (ABPI), UK

15:00 BREAK

15:15 SESSION 2

IMPACT OF THE CLINICAL TRIAL REGULATION ON PHARMACOVIGILANCE

Session Chair:

Willemijn Van Der Spuij, Regional Director, PV Intelligence & International Operations, Bristol-Myers Squibb, Switzerland

This session will explore the current understanding of the impact of the Clinical Trial Regulation on safety activities in clinical trials.
Various aspects of the new Regulation will be explored and differences between the present and new requirements for managing clinical trials in the face of forthcoming changes will be looked at. This includes topics such as the CTA Portal and potential safety information (Serious Breach, Non-Clinical SUSARs and/or increase in non-serious AR), understanding the impact of the transition period on safety, the DSUR Portal, RSI and low risk trials.

Safety in Clinical Trials under the Clinical Trial Regulation: Major Challenges
Elena Prokofyeva, Head of Drug Safety Unit, Federal Agency for Medicines, Belgium
Barbara Reinhardt, Associate Director, Global Patient Safety Innovation, Merck Healthcare, Germany

Clinical Trial Portal Implementation: Implications for DSURs
Elke Stahl, CTFG Co-Chair; Clinical Trial Unit, Federal Institute For Drugs and Medical Devices (BfArM), Germany

Panel discussion with Q&A

16:45 BREAK

17:00 SESSION 3

THE FUTURE OF PHARMACOVIGILANCE

Session Chair:

Wendy Huisman, Director, Vigifit, The Netherlands

In this session we will focus on the nest steps in Pharmacovigilance. What will the future brings us? Where do we need new standards and where do we want to remove strict guidance. What is there to keep and what will be gone in 10 years? How far are we with automation and AI?

Are New Standards Needed? A Regulator's Perspective
Sabine Straus, PRAC Chair, Staff Member, Medicines Evaluation Board (MEB), The Netherlands

Evolving Safety: Value Provider, or Pure Necessity?
Sergio Ley-Acosta, Global Head Portfolio Clinical Safety, Genentech, USA

A.I. in Pharmacovigilance: Where Are We?
Patrick Caubel, Chief Safety Officer, Pfizer, USA

Visionary Approach to PV - Industry Perspective
Wendy Huisman, Director, Vigifit, The Netherlands

Panel discussion with Q&A

18:30 NETWORKING

19:10 END OF DAY 1

DAY TWO | TUESDAY, 3 NOVEMBER 2020

13:00 LOG-IN AND CONNECT

13:10 SESSION 4

WHAT THE MEDICAL DEVICE REGULATION MEANS FOR PHARMACOVIGILANCE

Session Chair:
James Whitehead, Patient Safety Centre of Excellance, CMO Office, AstraZeneca, UK

This session will be dedicated to reviewing and reflecting on the impact of the EU Medical Device Regulation which becomes effective on 26th May 2020. The session will explore the Person Responsible for Regulatory Compliance (Article 15), the impact on device constituents (Article 17) and how various stakeholders are implementing the regulation.

EU PRRC Role
James Whitehead, Patient Safety Centre of Excellance, CMO Office, AstraZeneca, UK

Notified Body's Role in Medicinal Products which Utilise a Medical Device (Combination Product)
Julia Frese, Department Manager Centre of Combination Products, TUV-SUD Germany

Combination Products: Definition and Differences Between US and EU
Khaudeja Bano, Sr. Medical Director, Abbott Diagnostics Division, Abbott Laboratories, USA

Panel discussion with Q&A, with the additional participation of:
Syed Muntasir, Medical Health Services Executive, TUV SUD, UK

14:40 BREAK

14:55 SESSION 5

PHARMACOVIGILANCE INSPECTIONS AND AUDITS

Session Chair:
Mette Stockner, Senior Pharmacovigilance Director, Savara ApS, Denmark

Audits and Inspections play an important role for the Pharmacovigilance System. In this session you will hear about the current trends in audit and inspection findings, some reflections on the challenges of organizational complexity, small/large, with outsourcing or in house operation, and the important interfaces between Pharmacovigilance and other functions in the companies. We will discuss some tips and tricks for remote audits and inspections and get the latest information from the MHRA Guidance on pharmacovigilance procedures. An interactive dialogue will allow participants to engage with the speakers and industry experts.

Trends in audit findings
Louise Mawer, Director, Mirabilitas Ltd, UK

Inspection Findings: Recommendations from an Inspector
Rory Littlebury, Pharmacovigilance Inspector, Medicines and Healthcare products Regulatory Agency (MHRA), UK

Panel discussion with Q&A

16:25 BREAK

16:40 SESSION 6

SIGNAL MANAGEMENT: 2 YEARS INTO EUDRAVIGILANCE

Session Chair:
Anja Van Haren, EudraVigilance Coordinator, Medicines Evaluation Board (MEB), The Netherlands

This session will explore the latest developments in signal detection activities in the EU and how the tools provided by the EMA and other data sources are used to support drug safety monitoring. This session will provide an opportunity to review experience with EudraVigilance from several perspectives more than two years since the launch of the pilot and will discuss the next steps to be taken. Additionally, this session will provide guidance on signal and causality assessment to improve the preparation of cumulative reviews within signal procedures. The Panel Discussion will allow participants to directly interact with individuals working on current issues and future development.

Cumulative Reviews in Signal Assessment
Natalie Bandoo, Scientific Assessor, MHRA, UK

Managing eRMR Assessment for Generics: Expert Recommendations
Andreas Iwanowitsch, Head Global Pharmacovigilance Unit, EU QPPV Backup, STADA Arzneimittel AG, Germany

Signaling Challenges for Innovators: Portal Access and Reporting
Catrinel Popescu, Head, Safety Surveillance and Aggregate Reports, Biogen, UK

Panel discussion with Q&A

18:10 NETWORKING

18:40 END OF DAY 2

Disclosure Policy

Unless otherwise disclosed, DIA acknowledges that the statements made by speakers are their own opinion and not necessarily that of the organisation they represent, or that of the DIA. Speakers and agenda are subject to change without notice. Recording during DIA sessions is strictly prohibited without prior written consent from DIA.

DAY THREE | WEDNESDAY, 4 NOVEMBER 2020

13:00 LOG-IN AND CONNECT

13:10 SESSION 7

POST-AUTHORISATION SAFETY STUDIES AND REGISTRIES

Session Chair:
Bianca Mulder, Pharmacovigilance Assessor, Medicines Evaluation Board (MEB), The Netherlands

Post authorisation safety studies and registries can provide valuable information on the safety of a medicinal product. The information from these studies and registries is used to evaluate the safety and benefit-risk profile of a medicine and support regulatory decision-making. This session will be dedicated to current developments and challenges with regard to these studies and registries. There will be perspectives from Industry, the EMA and the NL regulatory agency.

Post authorisation studies and implementation of results
Bianca Mulder, Pharmacovigilance Assessor, Medicines Evaluation Board (MEB), The Netherlands

The Impact of Non-European PAS on PV systems in Europe and Globally
Ulka Campbell, Senior Director, Epidemiology, Pfizer, USA

The Potential of Patient Disease Registries
Valerie Strassmann, Scientific Administrator, Data Analytics and Methods Task Force, European Medicines Agency (EMA), EU

Panel discussion with Q&A

14:40 BREAK

14:55 SESSION 8

RISK MINIMISATION MEASURES AND SAFETY COMMUNICATION

Session Chairs:
Shahin Kauser, Leading Senior Scientific Assessor, MHRA, UK
Maarten Lagendijk, Director, Deputy EU QPPV, MSD, The Netherlands

Revision 2, of GVP Module XVI, provide guidance use of additional risk minimisation measures including the selection tools and their evaluation of their effectiveness. Additional risk minimisation measures include educational materials, controlled access programmes and controlled distribution systems. This session will explore some examples of such measures and the measurement of effectiveness to help stimulate discussion. There will be perspectives from Industry and the UK regulatory agency.
In addition to hearing from the speakers, attendees will be encouraged to share their experience as part of the Panel Discussion.

Additional Risk Minimisation Measures (aRMM): Why do they matter?
Maarten Lagendijk, Director, Deputy EU QPPV, MSD, The Netherlands

Running Risk Minimisation Programs – Lessons Learned
Jan Petracek, EU QPPV, Czech Republic

Controlled Access Programmes
Shahin Kauser, Leading Senior Scientific Assessor, MHRA, UK

Measuring the Effectiveness of aRMM
Inge Zomerdijk, Pharmacovigilance Assessor, Medicines Evaluation Board (MEB), The Netherlands

Panel discussion with Q&A

16:25 END OF THE WORKSHOP WITH CLOSING WORDS

Maarten Lagendijk, Director, Deputy EU QPPV, MSD, The Netherlands
Elena Popa, Scientific Programmes Manager, Drug Information Association, Switzerland

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