DIA

Pharmacovigilance Strategies Workshop

Navigating the changing PV landscape in your daily work

5-6 June 2019 | DoubleTree by Hilton – Westminster London, UK
4 June: Pre-Conference Tutorials

PROGRAMME COMMITTEE

Gaby Danan
Pharmacovigilance Expert, France

Maria Wishart
Deputy EU Qualified Person for Pharmacovigilance, AstraZeneca, United Kingdom

Willemijn Van Der Spuij
EU Reg. Dir., PV Intelligence & Int. Operations, Bristol-Myers Squibb, Switzerland

Key Topics

- GDPR in Pharmacovigilance: Impact and Management of Data
- Signalling and emerging safety issues
- Inspections – Hot Topics
- Safety Agreements
- EV Requirements: Where are we now?
- Implementation of EU Clinical Trial Regulation
- Risk Management Plan

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

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 in the following areas:

1. **Data Privacy in Pharmacovigilance**
2. **Signaling and access policy to the EV database**
3. **Safety reporting** – concerns with use of new RSI guidance and issues that remain outstanding
4. **EU Clinical Trial Regulation:** Implementation and Readiness
5. **Risk-Management Plan**

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
- Ensure that your pharmacovigilance work matches up with inspector expectations, and delivers the efficient outcomes for patients.

Who Will Attend

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
- Pharmacoepidemiology
- Risk Management Planning
- PSMF maintenance

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 WORKSHOPS | TUESDAY, 4 JUNE 2019

WORKSHOP 2: THE PSMF IN 2019 - GENERAL DEVELOPMENTS IN - AND OUTSIDE EUROPE: WHERE ARE WE HEADING?

4 JUNE | 08:00-12:30

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, Senior Specialist, EU QPPV Office, MSD, UK
Willemijn Van Der Spuij, EU Reg. Dir., PV Intelligence & Int. Operations, Bristol-Myers Squibb, Switzerland

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: PV/Industry experts involved in PSMF coordination and/or maintenance.

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

Separate Registration Required

WORKSHOP AGENDA

Potentially some pre-meeting research by delegates (if they are not directly involved in the PSMF)

08:30 REGISTRATION

08:30 INTRODUCTION AND WELCOME

08:40 THE CURRENT PSMF LANDSCAPE (LEGISLATIVE UPDATES AND RECENT LEARNINGS)

09:30 WORKSHOP I

AUDIT AND INSPECTIONS. FEEDBACK ON PSMFS

10:15 COFFEE BREAK

10:30 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)

11:15 WORKSHOP III

PSMF PROCESS AND OVERSIGHT FOR QPPVS

12:00 WORKSHOP FEEDBACK

12:30 CLOSE OUT

WORKSHOP 1: INTRODUCTION TO THE ROLE OF QPPVS

4 JUNE | 12:00-17:30

Limited Places Available.

This small group session will provide an overview of the QPPV role, and also discuss legal considerations for QPPVs and some practical day to day issues for QPPVs in different company sizes and types. It will be of interest to those who need to understand more about the role, those who support the QPPV and those who may be thinking of taking on a QPPV role. It may also be of interest to any new or existing QPPVs who wish to refresh their knowledge.

Workshop Chairs:
Elspeth McIntosh, Director, Castle Pharmacovigilance Limited, UK
Maria Wishart, Deputy EU Qualified Person for Pharmacovigilance, AstraZeneca, UK

Separate Registration Required

WORKSHOP AGENDA

12:00 REGISTRATION

13:00 THE QPPV ROLE: REGULATORY AND LEGAL OVERVIEW

Elspeth McIntosh, Director, Castle Pharmacovigilance Limited, UK

14:00 PREPARATION FOR THE QPPV ROLE

Elspeth McIntosh, Director, Castle Pharmacovigilance Limited, United Kingdom
Maria Wishart, Deputy EU Qualified Person for Pharmacovigilance, AstraZeneca, UK

14:30 COFFEE BREAK

15:00 QPPVS IN PRACTICE: DAY TO DAY QPPV ACTIVITIES IN LARGE COMPANIES

Maria Wishart, Deputy EU Qualified Person for Pharmacovigilance, AstraZeneca, UK

15:30 DAY TO DAY QPPV ACTIVITIES IN SMALL COMPANIES/FOR A CONTRACT QPPV

Elspeth McIntosh, Director, Castle Pharmacovigilance Limited, United Kingdom

16:00 PRACTICAL ISSUE FOR QPPVS

Elspeth McIntosh, Director, Castle Pharmacovigilance Limited, UK
Maria Wishart, Deputy EU Qualified Person for Pharmacovigilance, AstraZeneca, UK

A number of short presentations to highlight the QPPV role in:
- Inspection
- Quality oversight and processes
- Business partner/PV Agreement management
- Outsourcing
- PSMF

Elspeth McIntosh, Director, Castle Pharmacovigilance Limited, UK
Maria Wishart, Deputy EU Qualified Person for Pharmacovigilance, AstraZeneca, UK

17:00 QUESTIONS AND DISCUSSION

DAY ONE | WEDNESDAY, 5 JUNE 2019

08:00 REGISTRATION AND WELCOME COFFEE

09:00 SESSION 1

DATA PRIVACY – GDPR IN PHARMACOVIGILANCE: IMPACT AND MANAGEMENT OF DATA

Session Chair:
Gaby Danan, Pharmacovigilance Expert, France

The aim of this session is to cover the key questions, examples on how has/is GDPR affecting pharmacovigilance. Incorporating different perspectives from industry and authorities, the 1st session of this interactive workshop will present what are the challenges and advantages when it comes to GDPR application in PV and what are the Non-EEA countries requirements vs. EAA harmonization.

Case Studies on how GDPR has/is Affecting Pharmacovigilance
Jean Kilgour-Christie, Deputy EU QPPV, Novartis Pharma AG, Germany

GDPR Application in PV
Naveen Yelkur, International Operations - PV Intelligence, Bristol-Myers Squibb, UK

Non-EEA Countries Requirements vs. EAA Harmonisation
Doris Stenver, Independent Pharmacovigilance Adviser, Unique Advice, Denmark

Panel discussion with Q&A

10:30 COFFEE BREAK

11:00 SESSION 2

IMPLEMENTATION OF EU CLINICAL TRIAL REGULATION

Session Chair:
Mette Stockner, Deputy QPPV and Head of Compliance, Novo Nordisk AS, Denmark

The Clinical Trial Regulation EU 536/2014 is set out to optimise the clinical trial processes running across Europe. This will have a major impact on Member States, Ethics Committees and companies/MAHs when it comes to safety reporting.
Are you ready for the implementation of the EU-CTR? Have you reviewed your current processes, systems and organisation for the clinical trial applications and safety reporting?

This session will provide a status of the implementation on the regulatory side and give some insights from the company/MAH perspective on the practicalities with the implementation and what the changes means for the organisation.

Challenges and Practical Issue: Implementing CTFG RSI Requirements
Britt Jørgensen, Safety Surveillance Specialist, Novo Nordisk, Denmark

Safety in Clinical Trials Under the Clinical Trial Regulation: Major Challenges
Elena Prokofyeva, Head of Drug Safety Unit, Federal Agency for Medicines, Belgium

Challenges and Practical Issues with the CTR Implementation from a Company point of view
Barbara Reinhardt, Associate Director, Global Patient Safety Innovation, Merck

Clinical Trial Safety Reporting in the new Regulation 536/2014
Massimiliano Sarra, CTFG Secretary, Italian Medicine Agency (AIFA), Italy

Panel discussion with Q&A

12:30 LUNCH

14:00 SESSION 3

INSPECTIONS – HOT TOPICS

Session Chair:
Maria Wishart, Deputy EU Qualified Person for Pharmacovigilance, AstraZeneca, United Kingdom

Achieving a successful outcome in an audit or inspection is, for many PV leaders, a formal objective. But what does 'success' look like? And how realistic are the goals we set ourselves, as we struggle to find ways to comply with dynamic and non-harmonised global regulations, to understand the nuances of newly established inspectorates and to agree amongst ourselves as industry professionals pragmatic, efficient and useful inter-company processes to assess compliance of our partners. We will focus on some particular areas of concern in this session and bring some thought-provoking ideas to the table for discussion.

Reference Safety Information - Findings
Elsa Ferrao, Inspector, INFARMED, Portugal

License Partner Audits
Carrie Scott, Director, Safety Compliance, Pharmacovigilance and Patient Safety, AbbVie, UK

Saudi Inspections
Dana Isleem, Pharmacovigilance Manager-Middle East & Africa at Bristol-Myers Squibb, Saudi Arabia

Panel discussion with Q&A

15:30 COFFEE BREAK

16:00 SESSION 4

PV BUSINESS RELATIONSHIPS – HOW TO SUCCESSFULLY COLLABORATE AND MEET REGULATORY REQUIREMENTS?

Session Chair:
Monika M. Pietrek, Managing Director and Senior Consultant, Pietrek Associates GmbH, Germany

The MAH PV system performance increasingly depends on the close collaboration with multiple licensing / development partners and PV relevant service providers. The session will discuss key aspects and innovative approaches in the life-cycle management of a contractual relationship.

Monika M Pietrek, Managing Director and Senior Consultant, Pietrek Associates GmbH, Germany
Sandra Verboven, Global Head, PV Licensing, PDS Basel Site Head, F. Hoffmann- La Roche Ltd., Switzerland
Kiernan Trevett, Senior Pharmacovigilance Inspector, Enforcement and Standards, Medicines and Healthcare products Regulatory Agency (MHRA), UK

Panel discussion with Q&A
Willemijn Van Der Spuij, EU Reg. Dir., PV Intelligence & Int. Operations, Bristol-Myers Squibb, Switzerland

17:30 END OF DAY ONE

Conference Venue

DoubleTree by Hilton London Westminster
30 John Islip Street
London, SW1P 4DD
United Kingdom

View Directional Map

Continuing Education

DIA meetings and training courses are generally approved by the Commission for Professional Development (CPD) of the Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society of Pharmaceutical Medicine (SGPM) and will be honoured with credits for pharmaceutical medicine. All participants are eligible for 12.00 credits.

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.

DIA is an independent, non-profit organisation has its Global Center in Washington, DC, USA with the European office in Basel, Switzerland, and additional regional offices in Horsham, Pennsylvania, USA; Tokyo, Japan; Mumbai, India; and Beijing, China. For more information, visit www.DIAglobal.org or call DIA: +41 61 225 51 51.

EVALUATION

We value your feedback on the content and organisation of this conference. The electronic survey will be sent to you after the conference.

ACCESS PRESENTATIONS

As a benefit of your registration, presentations are made available on the DIA website.

To access presentations, go to www.diaglobal.org and click on Sign in at the very top. Once you have successfully logged in, click on Welcome on the top, then My Account and on the left, go to My Events - Review Presentations.

No paper copies of the presentations will be provided.

NOTE: If a presentation is not available, the speaker either did not agree to publish it or did not provide us with the presentation. Updated versions of the slides will be made available shortly after the conference.

CERTIFICATE OF ATTENDANCE

A Certificate of Attendance will be sent to all attendees electronically after the conference. Please note certification requires full attendance. For more information please liaise with our DIA Contact Centre on Basel@DIAglobal.org or call +41 61 225 51 51.

DAY TWO | THURSDAY, 6 JUNE 2019

09:00 SESSION 5

EV REQUIREMENTS: WHERE ARE WE NOW?

Session Chair:
Willemijn Van Der Spuij, EU Reg. Dir., PV Intelligence & Int. Operations, Bristol-Myers Squibb, Switzerland

This session will provide an opportunity to review experience with EudraVigilance from several perspectives more than one year since launch. The speakers will also explore some of the more pressing practical challenges encountered to-date, including causes and possible mitigation towards preventing duplicate reporting

EV Requirements: Inspection Findings (Signalling, Download, Tracking)
Kiernan Trevett, Senior Pharmacovigilance Inspector, Enforcement and Standards, Medicines and Healthcare products Regulatory Agency (MHRA), UK

The new EV system – how are we doing
Maarten A.C. Lagendijk, Director, Deputy EU QPPV, MSD, The Netherlands

Challenges and Approaches to Handling High Volume Downloads
Balwant Heer, Global Head Product Safety & Risk Management, EEA QPPV, Mylan, UK

Panel discussion with Q&A

10:30 COFFEE BREAK

11:00 SESSION 6

SIGNALLING

Session Chair:
Menno Van Der Elst, PRAC member for The Netherlands, 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. The focus will be on the emergent safety issues (content, threshold, procedure), the latest development/outcome of the pilot by the participants from big or generic companies and the national competent authority point of view on these questions.

Emerging Safety Issues – Feedback from the Authorities (PRAC/NCA Perspective)
Menno Van Der Elst, PRAC member for The Netherlands, Medicines Evaluation Board (MEB), The Netherlands

Outcomes of the Current Pilot – Big Pharma Perspective
David Jones, Pharmacovigilance Process Analyst, Pfizer LTD, UK

Panel discussion with Q&A

12:30 LUNCH

14:00 SESSION 7

RISK MANAGEMENT WORKSHOP

Session Chair:
Françoise Dumas-Sillan, EU QPPV, Pfizer Italia SRL, Italy

The GVP Module V has been updated 2 years ago following fruitful interactions between MAHs and EMA. This session will present the expectations from medical assessment of RMP submitted in Europe and will further explore the lessons learned and pending questions on this update. The specific challenges for generic products will be discussed as well as ongoing initiatives to promote harmonization.

Risk Management Plans – An assessor's expectations
Shahin Kauser, Leading Senior Scientific Assessor, MHRA, UK

HaRP – CMDh Project to Harmonise RMPs for Products with the same Active Substance
Kora Doorduyn-van der Stoep, Vice-Chairperson CMDh (NL) and CMDh Member/Senior Policy Adviser, Medicines Evaluation Board (MEB), The Netherlands

Panel discussion with Q&A

15:30 END OF CONFERENCE

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.