Pharmacovigilance Conference

5-6 June 2018
(4 June: pre-conference workshop)
Crowne Plaza London The City, London, United Kingdom

PROGRAMME COMMITTEE

Gaby Danan
Pharmacovigilance Expert, France

Reena Harjai
Director, Clinical Safety & Pharmacovigilance Operations, APCER Life Sciences, United States of America

Joanna Harper
Expert Inspector, GPvP, Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom

Margaret Walters
Deputy EU Qualified Person for Pharmacovigilance, MSD, United Kingdom

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

Key Topics

- GVP Module II – pain points and experiences with PSMF beyond the EU
- EudraVigilance change
- Pharmacovigilance agreements – managing oversight
- Signalling and emerging safety issues
- Real world data: measures and implications and impact on decision making
- Experiences with the GVP Module V implementation

Overview

We are in the midst of a breathtaking series of changes in the world of pharmacovigilance, both within Europe and beyond and this has prompted new challenges for all stakeholders. The implementation of the new EudraVigilance system; reexamination of the way we assess and present safety concerns for authorized products; the intensification of evolving PV requirements in non-EU markets and the increasing complexity of business models leading to challenges in communication and oversight are just some of the things that this conference will address.

Pharmacovigilance is uniquely placed to nurture sharing of good practice between industry representatives and seeking advice from regulators and inspectors as we all strive to improve the way we manage patient safety and comply with legislation.

DIA have 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. **Pharmacovigilance System Master File** – keep up with evolving legislation
2. **EudraVigilance (EV)** system: practices and challenges
3. **Brexit consequences** for pharmacovigilance procedures
4. **Signaling** and access policy to the EV database
5. **Real World Data**: a challenge for industry and pricing assessment.
6. Experiences with **GVP Module V implementation**

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

Find out more at
DIAglobal.org/PV

HALF DAY PRE-CONFERENCE WORKSHOP | 4 JUNE 2018

INTRODUCTION TO THE ROLE OF QPPVS | Bridewell 1 Suite

Starting with Lunch at 12:00 | Foyer

4 June 13:00 - 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 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, United Kingdom

Magnus Ysander, EU QPPV and Head Risk Management & Pharmacovigilance Excellence, AstraZeneca, Sweden

Separate Registration Required

12:00	REGISTRATION
13:00	THE QPPV ROLE
13:00	REGULATORY AND LEGAL OVERVIEW
	Elspeth McIntosh
14:00	PREPARATION FOR THE QPPV ROLE
	Elspeth McIntosh and Magnus Ysander
14:30	COFFEE BREAK
15:00	QPPVS IN PRACTICE:
15:00	DAY TO DAY QPPV ACTIVITIES IN LARGE COMPANIES
	Magnus Ysander
15:30	DAY TO DAY QPPV ACTIVITIES IN SMALL COMPANIES/FOR A CONTRACT QPPV
	Elspeth McIntosh
16:00	PRACTICAL ISSUE FOR QPPVS
	Magnus Ysander/ Elspeth McIntosh

A number of short presentations to highlight the QPPV role in:

- Inspection
- Quality oversight and processes
- Business partner/PV Agreement management
- Outsourcing
- PSMF

17:00 QUESTIONS AND DISCUSSION

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 these credits.

SwAPP Swiss Association of Pharmaceutical Professionals

Hotel Information

Crowne Plaza London The City
19 New Bridge Street,
London, EC4V 6DB
United Kingdom
www.cplondoncityhotel.co.uk

You may either book:
1. On-line at www.cplondoncityhotel.co.uk
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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.

PHARMACOVIGILANCE CONFERENCE | TUESDAY, 5 JUNE

08:00 REGISTRATION AND WELCOME COFFEE

08:30 KEYNOTE

Peter Arlett, Head of Pharmacovigilance and Epidemiology Department European Medicines Agency, European Union

09:00 SESSION 1

THE EVOLUTION OF THE PSMF

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

The EU PSMF is widely considered by Industry as being a comprehensive and useful tool for PV oversight. This has come about following a period of 'embedding' during which the scope and interpretation of the legislation by companies and EU regulators has undergone much discussion and resolution. With the global awakening of pharmacovigilance regulations and the increasing global adoption of GVP-based legislation, it is a sincere wish from industry that the procedures already set up to fulfil the EU requirements for a PSMF can be easily adapted to suit global requirements. If non-EU regulators are willing and able to embrace the learnings gained since the 2012 release of the EU GVP and adopt a pragmatic approach to their local or regional PSMF requirements this will allow precious resource to be focussed on value-adding activities.

A small group of industry PSMF experts conducted a survey of non-EU PSMF experience last year and an update on the survey results will be presented along with a lively discussion of the known 'pain points' in PSMF preparation. A speaker from a non-EU region will also provide a candid and detailed account of managing the PSMF and regulatory interactions in their region. Delegates are encouraged to come with thoughts on what areas of GVP II may be more suitably adapted to create a global PSMF concept as opposed to a purely EU concept.

The PSMF: Perspective from an Inspector
Rory Littlebury, Pharmacovigilance Inspector, Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom

International/Non-EU PSMF / Harmonization
Olga Ermishina, Pharmacovigilance Country Head, Qualified Person for Pharmacovigilance in EAEU, Bayer, Russia

PSMF Globalisation
- **Update on the 2017 non-EU PSMF Industry Survey results**
- **Ad hoc PSMF Industry working group**

Dionne Usher, Senior Specialist, EU QPPV Office, MSD, UK

Q&A with the audience

10:30 COFFEE BREAK

11:00 SESSION 2

THE NEW EUDRAVIGILANCE (EV) SYSTEM – WHERE WE ARE NOW?

Session Chair:
Margaret Walters, Deputy EU Qualified Person for Pharmacovigilance, MSD, UK

Major system changes, of which EV is a prime example, inevitably have a settling period during which both technical and procedural issues not seen in testing are likely to arise. The EMA are already aware of many concerns and challenges raised by industry and are addressing them on an urgent basis, plus some more specific challenges can be related to how an MAH has understood and implemented the requirements in their company. This session will review the current situation with respect to ICSR download and (very early) signalling experience, sharing knowledge gained and taking into account perspectives from across Industry (large, small, generics etc.) and Regulators. Additionally, the Panel Discussion will allow participants to directly interact with individuals working on both current issues and future development.

New ICSR Processes – the SME Perspective
Elspeth McIntosh, Director, Castle Pharmacovigilance Limited, United Kingdom

Resolving, Ongoing and New Challenges – an ICSR Focus
Sabine Brosch, Principal Scientific Administrator, Surveillance and Epidemiology, European Medicines Agency, European Union

Initial Experience with the E/V Signal Pilot: Practicalities and Possibilities
Magnus Ysander, EU QPPV and Head Risk Management & Pharmacovigilance Excellence, AstraZeneca, Sweden

Panel discussion with Q&A

12:30 LUNCH

14:00 SESSION 3

PHARMACOVIGILANCE AGREEMENTS

Session Chair:
Reena Harjai, Director, Clinical Safety & Pharmacovigilance Operations, APCER Life Sciences, US

Companies that hold a marketing authorization in various territories must have a well-planned, structured document in place to define the responsibilities of each party. Ensuring the inclusion of key terms, responsibilities, and monitoring compliance can be challenging, but is essential to be compliant with the regulatory requirements to be more compliant.

QPPV Oversight and Compliance : Big Pharma Perspective
Michael Richardson, VP International and QPPV EU GV&E at Bristol-Myers Squibb, United Kingdom

QPPV Oversight and Compliance: Small Pharma Perspective
Vineet Kacker, Managing Director & QPPV, APCER Life Sciences Limited, US

Regulator Perspective
Anna Adams, GPvP Inspector, Inspection, Enforcement & Standards, Medicines and Healthcare Products Regulatory Agency (MHRA), United Kingdom

Panel discussion with Q&A

15:30 COFFEE BREAK

16:00 SESSION 4

BREXIT AND THE CONSEQUENCES ON PHARMACOVIGILANCE PROCEDURES IN THE EU

Session Chair:

Joanna Harper, Expert Inspector, GPvP, Medicines and Healthcare products Regulatory Agency (MHRA), UK

This session will review the current thinking and preparedness for the UK's exit from the EU. Companies and Regulators have been working to understand and manage the operational implications of Brexit, but what do we know and what is the current thinking on how it will affect pharmacovigilance?

In addition to hearing from the speakers, attendees will be encouraged to share their experience.

EMA: Timelines Worked Towards 2018 to have Everything Implemented in 2019

Anabela Marcal, Head of Committees and Inspections Department, European Medicines Agency (EMA), European Union

EFPIA Perspective

Vicki Edwards, Vice President, Pharmacovigilance Excellence and QPPV, AbbVie, United Kingdom

MHRA Perspective

Mick Foy, Head of Pharmacovigilance Strategy, Vigilance Intelligence and Research Group, Medicines and Healthcare products Regulatory Agency (MHRA)

Panel discussion with Q&A

17:30 NETWORKING RECEPTION

18:30 END OF DAY ONE

WEDNESDAY, 6 JUNE 2018

09:00 SESSION 5

SIGNALLING

Session Chair:

Mick Foy, Head of Pharmacovigilance Strategy, Vigilance Intelligence and Research Group, Medicines and Healthcare products Regulatory Agency (MHRA)

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. There will be perspectives from PRAC, industry and the UK regulatory agency.

Use of other Data Sources

Charlotte Goldsmith, Signal Management Coordinator, Vigilance Intelligence and Research Group, Medicines and Healthcare products Regulatory Agency (MHRA), UK
Industry Representatives Invited

Signal Management Metrics & Use of EVDAS by MAHs

David Lewis, Global Head of Pharmacovigilance, Novartis Pharma AG, Switzerland

Emerging safety issues

Sabine Straus, Head of Pharmacovigilance, Medicines Evaluation Board (MEB), The Netherlands

Panel discussion with Q&A

10:30 COFFEE BREAK

11:00 SESSION 6:

REAL WORLD DATA, MEASURES, IMPLICATIONS AND IMPACT ON DECISION MAKING

Session Chair

Katherine Donegan, Pharmacoepidemiology, Research & Intelligence Unit Manager, Medicines and Healthcare Products Regulatory Agency (MHRA), UK

Randomised controlled trials have long been considered the gold standard for generating robust evidence but data coming from a real-world perspective have a clear complementary role to play in ensuring the delivery of safe and effective medicines to patients. There is an increasing abundance of real world data generated across healthcare settings, but how do we continue to integrate it into the evidence base and move towards a strengthened system in which the timely evaluation of the safety and effectiveness of medicines is supported by robust real-world evidence? This session will consider some of the challenges presented to us by the complexities of such data and consider how these can be tackled while ensuring we maintain the high evidentiary standards that are vital for ensuring confidence in the decisions that we make. Examples from areas in which randomised controlled trials are particularly challenging, such as polypharmacy and pregnancy, where real-world data can provide valuable insights, and for issues where seemingly contradictory data have arisen from different sources, will be used to help stimulate discussion.

Speakers:

James Milligan, Vice President Patient Safety, AstraZeneca, 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

This session will provide an overview on Risk Management Plan preparation one year after of the implementation of the updated version of module V and the new template. The impact of the key changes will be analysed based on practical experiences from both the industry and EMA perspectives. The challenges and scientific questions raised during the preparation and the review of risk Management Plan will be discussed.

Experiences with the GVP Module V Implementation

Núria Semis Costa, Risk Management Specialist, Scientific and Regulatory Department, European Medicines Agency (EMA), European Union
Marin Banovac, European Medicines Agency (EMA), European Union
Sabine Straus, Head of Pharmacovigilance, Medicines Evaluation Board (MEB), The Netherlands

Panel discussion with Q&A

15:30 END OF 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 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 their 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 to the conference. For more information please liaise with our DIA Contact Centre on basel@diaglobal.org or call +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 and can also be accessed through the following link: https://bit.ly/2rLGCLa

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REGISTRATION FORM | ID# 18108

Pharmacovigilance Conference
5-6 June 2018 | London, UK

Early-bird discount

To qualify for the discount, registration form and accompanying payment must be received by the dates below. Early-bird applies to industry representatives with active DIA membership only.

Early bird discount: register by 25 April 2018 **€ 1'230.00** ❑

CATEGORY	Member *	Non-Member*
Industry	€ 1'430.00 ❑	€ 1'585.00 ❑
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Optional Pre-Conference Workshop | 4 June 2018 | Half day		
I wish to attend the Pre-Conference Workshop	€ 400.00 ❑	

If DIA cannot verify your membership upon receipt of registration form, you will be charged the non-member fee . Group discount/SME rates available. Special rates for students and patient representatives on offer, subject to avaibility. Please contact DIA in Basel for more information.
Registration fee includes: refreshments and lunches.

*All fees are subject to the applicable VAT. Payment due 30 days after registration and must be paid in full by commencement of the event.

TOTAL AMOUNT DUE: € _____

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TERMS AND CONDITIONS

Cancellations

All cancellations must be made in writing and be received at the DIA office in Basel four weeks prior to the event start date. Cancellations are subject to an administrative fee:

- Industry (Member/Non-member) € 200.00
- Academia/Charitable/Government/Non-profit (Full-time) (Member/Non-member) € 100.00
- Tutorial cancellation: € 50.00

For cancellations after this date, or if the delegate fails to attend the meeting, no refund of fees will be given and be responsible for the full registration fee. DIA reserves the right to alter the venue and dates if necessary. If an event is cancelled, DIA is not responsible for airfare, hotel or other costs incurred by registered attendees. Registered attendees are responsible for cancelling their own hotel and travel reservations.

Transfer Policy

You may transfer your registration to a colleague prior to the start of the event but membership is not transferable. Substitute attendees will be responsible for the non-member fee, if applicable. Please notify the DIA office in Basel of any such substitutions as soon as possible.

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By attending the event, you give permission for images of you, captured during the conference through video, photo, and/or digital camera, to be used by DIA in promotional materials, publications, and website and waive any and all rights including but not limited to compensation or ownership.

The DIA will be pleased to assist you with your registration from Monday to Friday between 08:30 and 17:00 CET.

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