acorn REGULATORY

Expertise You Can Trust

# Report on the Global DIA Forum for Qualified Persons for PV November 2023


## Background

We were delighted to attend the DIA Global Forum for Qualified Persons for Pharmacovigilance (QPPV) in Amsterdam this month. We joined likeminded professionals for an action packed two days discussing and sharing opinions on the vital role of the QPPV and the most pressing issues facing the industry today. Topics included the global QPPV challenges, trends requiring QPPV awareness and the impact of modern technology on PV. Here are some of our key take-aways and learnings from the two days.

## Key note address

In the keynote address from Sabine Straus, the Chair of EMA's Pharmacovigilance Risk Assessment Committee (PRAC) we learnt of the key role of patient involvement in decision-making, and how real-world evidence (RWE) has become increasingly relevant in regulatory decision making, including the importance of registry data in risk management of new therapies. Regulators predict that smarter collection and reporting of ICSRs, of measurement of on-market performance of medicines, and of improved engagement of patients and healthcare professionals will be the most significant changes in pharmacovigilance by 2030. We heard a moving testimony, a patient & parent story and their real life experiences, reminding us who we work for everyday.

## Role of AI in Pharmacovigilance

AI and Digitalization is a hot topic across all industries. There are many exciting opportunities and possibilities for AI in PV, however there are also risks and challenges involved and we learnt how the QPPV can be impacted. QPPVs need to be aware of and have a role in collaborating with AI experts, ensuring data quality and integrity with continuous monitoring, addressing the ethical and legal questions and ensuring all standards are adhered to and ensure the responsible use of AI in PV. AI will enhance the end to end PV Auditing Process using data analytics and reporting tools and generative AI (like ChatGPT).

# MHRA experience of AI

Sarah Vaughan, Head of Vigilance Operations at the MHRA gave us an update on the MHRA experience of implementation of AI and digitalization for Covid-19 data and their learnings such as (i) know your data set, (ii) test real scenarios, (iii) apply rules, (iv) engage staff, (v) monitor changes in reporting and (vi) measure impact. React to results, continue to train the model, and train your team. Sarah also updated us on the Regulatory Guidance for AI which needs collaboration between Regulators, Industry, IT Suppliers and Academics, and how the MHRA are working with the Council for International Organizations of Medical Sciences (CIOMS).
AI is a fast-moving space so the time to start having these conversations is now, although we did agree the QPPV remains human for now!!

MHRA
Regulating Medicines and Medical Devices

# Other topics discussed:

- We explored **MAH/QPPV Oversight** and how it needs to be tailored to specific scenarios, how oversight evolves over time and the level of oversight should be proportional to the **level of risk.** Relationships with business partners and suppliers are often unique and complex and require robust **Agreements, good governance** and **escalation pathways** which should be clearly documented and defined. **Audits** are irreplaceable to assess a partners capability to comply with PV obligations under EU GVP.

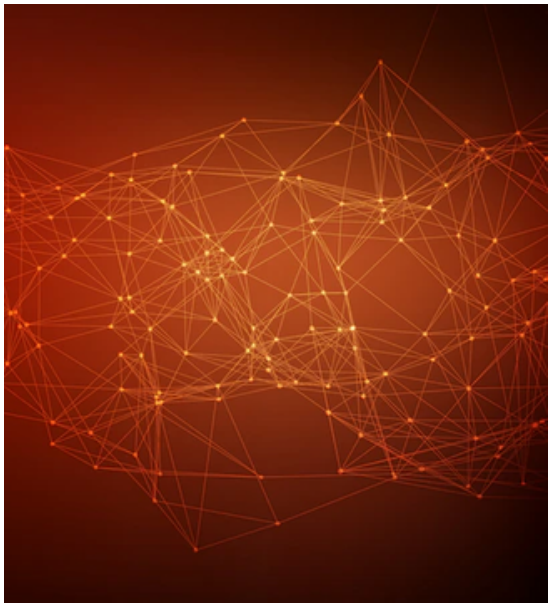
- An inspiring presentation on **"Deep Dive in Africa: Harmonization of Legislation"** was an insight into the work that is happening in Africa 55 towards the implementation and harmonisation of PV standards and processes and the creation of an **African Medicines Agency (AMA)**. Ultimately, leading to improved medicines and vaccine safety for patients in Africa. The development of **PV in China** was also presented including the role of the Responsible Person for Pharmacovigilance (RPPV), who is appointed by the Legal Representative in China and must be a member of the Senior Management Team and registered in the Chinese National ADR monitoring system.

- The **MHRA** provided an overview of their **PV Inspection programme** and PV inspection metrics for 2021/2022. There were 32 inspections of 30 MAHs; 18 planned, 9 as a result of intelligence received, and 5 due to previous critical findings. There were 6 critical findings (5 related to risk management, 1 related to on-going safety evaluation) and 72 major and 91 minor findings (largest proportion related to risk management and QMS, followed by management of ADRs). The four inspection arms within the MHRA GPvP inspection programme are: 1. Routine PV activities; 2. Routine Risk management and Safety Communication; 3. Additional Risk Minimisation Efforts (aRMMs); 4. Non-interventional post-authorisation safety studies (NI-PASS). With the introduction of the **revised GPvP inspection model** in 2021/2022 there is a **primary focus on risk management** hence the significance of findings in this area. It highlights the importance of managing risk to patients at all points of the product lifecycle and across critical PV processes.

- The benefits of an **effective PV QMS and Deviation Management** were explored in detail. Inspectors understand that non-compliances can happen. Inspectors are looking to see you have an effective QMS which can identify and act on non-compliances. Deviations help companies comply with regulatory requirements, reduce inspection findings, **enhance and improve processes, prevent issues from recurrence**, switch to **proactive management** of issues, and directly impact our common mission to ensure the safety of patients.

- **The Windsor Framework** was published in Feb 2023 with new arrangements effective for medicines from 01 Jan 2025. Under the new framework it will be the MHRA to approve all medicines for the whole UK market, NI will be reintegrated back into a UK only regulatory environment, with the EMA removed from having any role. As a result of the Windsor Framework there is much to be discussed and agreed from a PV perspective and the MHRA are working on plans but do not have answers today. And there are many questions we need answers to.... Will MHRA go back to the original plan of a UK QPPV residing and operating in the UK for all UK MAs? Will UK licences no longer be required to be entered into xEVMPD? Will there no longer be a requirement to report non-serious NI cases to EV? Can we still have a joint UK/EU PSMF? What will happen to the Northern Ireland country code (XI)? Will there be a transition period for any new requirement?

- There are some exciting developments in **Electronic Product Information** (ePI) that will create value for Patients, Industry, Health Authorities, HCPs and the Environment. Proposed legislative changes acknowledge the importance of ePI and makes the future transition from paper PI to ePI in a **phased approach** possible. However, **operational challenges** driven by Member State readiness are anticiapated. ePI can provide **immediate access** to the latest most current approved PI, supporting interoperability and advance features. ePI must be created within the regulatory dossier and based on **automated data filling** from systems such as **SPOR** for **structured data**. We will be keeping a regualtory watch on these very important legislative changes.



- We received an update on the proposed changes to **ICH E2D Post-approval Safety Data Management**. Patient Support Programs (PSPs) and Marketing Research Programs (MRPs) are to be defined and described in E2D with proposals for management of safety information from these programs. **Social media** and other types of digital data are to be defined and guidance on how to manage safety information from sources within and outside MAH control. The updated guidance will include **improved guidance** around Day O, MAH ownership of products, and translation and reporting of cases from literature. The draft guidance is nearing completion and set to be finalized in Jan 2024, and post public consultation and further reviews we can expect adoption by May 2025!

acorn REGULATORY | *Expertise You Can Trust*

- The importance of an effective **Regulatory PV Intelligence** system for monitoring **International Pharmacovigilance** and ensuring correct interpretation of local PV guidances was presented. It highlighted the importance of local experts, networking and support from industry groups and associations (e.g. EFPIA) and use of standard checklists when entering **new PV territories**.

- The importance of Compliance to Data Privacy laws and **GDPR** was discussed in the context of EMA letters received by QPPVs in Dec 2022 and April 2023 re: processing of data downloaded from Eudravigilance. EMA reiterated and reminded QPPVs about the core principles of accessing and processing data downloaded from EV. There were no technical changes required but companies are reminded to be vigilant on the relevance of data privacy in company procedures.

- Experienced QPPVs shared their real-life challenges in the **QPPV Talks** sessions covering a range of themes including **Harmonised Evaluation of PRAC PSUR ARs** to support QPPV oversight and feed continuous improvement, the role of the QPPV in a referral procedure, and assessing **PV competency** to support QPPV oversight.

**Your paragraph text**

It was a really enjoyable and informative two days in Amsterdam, lovely to meet PV colleagues old and new, and so nice to be back at face to face conferences again. We are already looking forward to the 2024 Forum

Acorn Regulatory team is staffed by experts with considerable expertise across all pharmaceutical services, assisting companies across the world with regulatory challenges.

**We would be delighted to support you in your regulatory jouney.**

**Please e-mail**
**enquiries@acornregulatory.com**