Turning Pharmacovigilance into a Strategic Advantage

Safety science complexity is on the rise as the volume of safety data explodes (case volumes are growing at a pace of 15 to 20% per year),[1] regulatory scrutiny continues to increase, and consumer demands grow. The pandemic and national health emergencies like Monkey Pox have put safety and public health benefit-risk discussions in the spotlight, and stricter regulations have emerged from local regulators as a result.

COVID-19 and growing health concerns have made it critical for marketing authorisation holders (MAH) to be able to act quickly on patient safety issues since it only takes hours to days for a local problem to impact patients globally. The demand for greater transparency and comparative benefit-risk analysis throughout the product lifecycle has shifted questions of ownership and accountability beyond the qualified person for pharmacovigilance (QPPV) and head of safety to the C-level.

Chief medical officers and safety leaders are becoming critical for end-to-end safety processes to drive timely and transparent communications. This means clear and transparent data sharing on drug benefits versus risks to patients, healthcare providers, and stakeholders. As regulations continue to evolve, more companies are leveraging technology to enable real-time information exchange, coordinated inspections, and seamless collaboration with regulatory agencies worldwide. Here are some of the regulatory changes brought on by the globalisation of pharmacovigilance and examples of how technology can help drive innovation for greater patient safety.

Upcoming Regulatory Changes Elevating Safety Beyond the PV Team

Emerging rules are shifting ownership of health information in accordance with federated governance models, which will result in more product benefit-risk and safety data not being managed by pharmacovigilance alone.[2] Simultaneously, outside statistics that are just being introduced to drug safety teams, such as data collected from social media and sales, will become an increasingly vital component of pharmacovigilance.

Several efforts in Europe will have considerable repercussions for the data surrounding the safety of drugs, and more generally, for healthcare data. These include:

- The European Union (EU) Health Data Space would facilitate the safe sharing of data such as electronic health records, genomics, and disease registries while maintaining patients' right to confidentiality.[3]
- The EU Data Governance Act establishes guidelines for the reuse and sharing of data among data intermediaries that serve as service providers.[4] Companies are embracing data altruism and the availability of data by making use of a standard framework.
- The European Medicines Agency's (EMA) strategy for the EU's telematics network sets the path for regulatory master data, governance, interactiveness, digitalisation, and regulatory innovation in the EU, which will boost quality, speed, and collaborative integration.[5]
- The EUDAMED database, founded on the EudraVigilance paradigm, offers data openness, patient participation, and real-time communications regarding the performance of medical devices already available on the market.
- The EUs Electronic Product Information (ePI) initiative to improve drug risk and benefit communication by creating more efficient labels and product information sheets that are directed toward end users via digital channels. This will allow the initiative to better integrate data accessibility and governance efforts.[6]

This points to patients and healthcare providers taking a more active role in decision-making as new models for information management emerge. Strategic transformation intends to affect each facet of healthcare, from improved patient access to questions regarding therapeutic interventions, safety, and open public communication.[7,8] As such, data related to one's health is a valuable commodity that will be used to generate innovative solutions to problems relating to safety and public health, as well as preventative measures.

With distributed data ownership, there is less of an opportunity to mine insights from safety data and conduct a cumulative benefit-risk analysis of the product during its entire existence. Medical safety teams may play a significant part in reducing or managing risks and improving patient outcomes when they have access to real-time data, analytics, and insights. With the right technology, safety teams can benefit from agile and flexible ways of using data to take action on patient insights.

Advancing Predictive PV and Data Visibility

In lieu of retrospective audits and corrective action and preventive action (CAPA) plans, an increasing number of businesses are employing artificial intelligence (AI), data analytics, and predictive models.[9] Long-established processes, such as the standard practice to collect and report key pharmacovigilance risk indicators to enterprise risk committees remain key. It is also becoming increasingly important to identify the leading indicators earlier in the research and development stage to protect patient safety. The use of innovative technologies allows for the rapid analysis of massive data sets by safety teams, and the discovery and dissemination of insights that may decrease risk.

With an advanced cloud-based safety system, companies can find answers to important pharmacovigilance questions, such as:

- How can we manage new risks when using AI and predictive algorithms across the research and development, commercialization, and post-market surveillance stages of the product lifecycle?
- What effects would the combination of federated data governance and an increasing amount of benefit-risk data that is stored outside the organization have?
- How can we develop an integrated pharmacovigilance system capable of monitoring performance and contributing to early interventions?

Under the present market conditions, it is even more important for pharmacovigilance teams to maintain the integrity of data. Using a safety system on a single cloud platform integrates content and information across the end-to-end value chain, from patients to product development, delivering transparency into actionable data. This enables safety leaders and C-level executives with a more holistic perspective of pharmacovigilance and in the end, can help improve information exchange, aggregation, and insights across healthcare.

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Sharmila Sabaratnam

Sharmila Sabaratnam is responsible for Veeva Vault Safety Strategy in Europe, helping customers transform their business through a unified safety solution. She is a physiologist by training with research experience in oncology and arthritis. Sharmila has over 10 years of experience in safety, previously leading safety and regulatory advisory services for Top-25 and Top-100 companies at Ernst & Young and Navitas. Her experience includes operating model design and safety strategy, PV automation, benefit-risk management, and performance benchmarking.