Commentary: Ravi Patel and Anna Melin

Pharmacovigilance is at a crossroads

The boundaries of medicine are rapidly changing. From gene editing to xenotransplantation, innovation is rapidly changing patient care as well as the requirements for drug safety, known as pharmacovigilance.

Traditionally, pharmacovigilance has been directed towards the surveillance of drugs after they have been licensed for use. Going forward these rules will have to change.

Competitive life sciences companies are increasingly embedding pharmacovigilance considerations into the earliest stages of product development to respond to evolving scientific, technological and economic pressures. These procedures must transcend their traditional roles and evolve into a strategic framework that ensures patient and product safety is integral to innovation from inception to end of life.

The emergence of novel therapies and artificial intelligence which are embedded in the new technologies demand a fundamental transformation of how pharmacovigilance is envisioned, executed and valued. Within the industry several key objectives are emerging:

- Minimising patient risk and enhancing outcomes: Life sciences companies are shifting from reactive to anticipatory safety measures, strategically embedding pharmacovigilance at the earliest stages of therapeutic development as an enabler of innovation. This is particularly true in the advanced therapy medicinal products (ATMP) and personalised medicine space. For example, companies developing targeted gene therapies, organ regeneration programmes and artificial organ development platforms are taking centre stage, making real time monitoring essential to preempt complications, and minimising patient impact as well as enhancing survival. Such foresight reflects the shift from reactive to anticipatory safety measures, cementing pharmacovigilance as an enabler of innovation rather than a checkpoint.
- Harnessing advanced technologies: Life sciences companies are making use of automated signal detection, predictive analytics, and real-time monitoring to ensure continuous surveillance and insight generation with use of AI. Digital health tools such as wearables, mobile apps and implantable sensors, are revolutionising pharmacovigilance in that respect, offering unprecedented opportunities to collect and analyse dynamic safety data, and detect and enable risk mitigation with precision and in real time. These advancements are transforming vigilance from a static process to a dynamic ecosystem of continuous surveillance and insight generation.
- Social media and real-world data (RWD): The rise of diverse data sources, including social media, offer new opportunities to identify and address safety signals. Life sciences companies and regulators are increasingly utilising these channels to deepen their understanding of adverse effects. Integrating electronic health records and unstructured data streams presents both rich opportunities and new challenges for data integrity, regulatory compliance, and actionable outcomes.
- Innovative clinical trial designs: Adaptive trial designs – such as basket, platform/decentralised, and phase-less trials – allow for the evaluation of multiple treatments or patient groups within a single trial structure and enable real-time adjustments based on emerging data. This flexibility and efficiency demands advanced, agile, and precise vigilance strategies. Responding rigorously to emerging safety signals often requires real-time, close and instantaneous collaboration with patients and care teams to ensure patient safety.

Good vigilance practices must evolve in response to these advancements, ensuring that patient safety remains at the forefront. As the landscape shifts, the priorities of the pharmacovigilance community will move beyond traditional compliance, embracing a patient-centred approach that actively enables and supports innovation. Key priorities will need to include:

- Designing user-friendly adverse event reporting systems: Developing intuitive and accessible tools for patients and healthcare teams to share safety concerns ensures transparency and reporting with ease and will be a first step in real-time monitoring.
- Direct patient engagement: Emphasising direct patient engagement with life sciences companies, and patient-centred vigilance, will foster a more nuanced understanding of therapeutic and clinical impacts, empowering patients as partners in safety. This can be achieved, *inter alia*, through patient-reported outcomes and by incorporating global learnings to enhance real-time safety insights.
- Embracing data science and AI: Advanced analytics and AI-enabled technology-supported algorithms/programmes ensures transparency, data quality and regulatory compliance, enabling vigilance teams to predict and mitigate safety risks with unprecedented accuracy.
- Elevating safety leadership: Safety considerations should have a voice and pathway to be raised to the highest levels of the biotech and pharmaceutical executive hierarchy. This is crucial for embedding patient protection into the corporate ethos, strategic priorities and aligning it with business success.

In summary, the rapid evolution of medicine and technology is transforming pharmacovigilance into a dynamic, strategic discipline that underpins both patient safety and business success. Organisations that approach these challenges with strategic foresight and multidisciplinary expertise will be best equipped to protect patients, foster innovation, and thrive in the new era of medicine.

This article was written by Ravi Patel, Senior Vice President, Global Patient Safety at United Therapeutics Corp and Anna Melin of Sidley Austin LLP.