Back to Basics:
What Will Drug Safety Look Like in 5–10 Years?

It's understandable that regulators' extensive demands and internal budget pressures have rendered pharmacovigilance primarily a compliance and risk management activity. But strategies now need to be revised - so that the drive to better serve patients is reinstated as the primary mission, says Lucinda Smith, Chief Safety Product Officer at ArisGlobal.

Between 2020 and 2022, as the COVID-19 pandemic peaked, the role of drug safety attracted unprecedented mainstream attention. As new vaccines entered the market and a range of treatments were applied, entire generations gained new appreciation of side-effects at scale, and of the fundamental assumption that the products they take are "safe".

The ability to quickly and efficiently capture accurate data, spot trends, draw robust conclusions about emerging safety issues, and act on them promptly was tangible and expected by the public. Yet the pharma industry largely missed this opportunity to more permanently reframe pharmacovigilance (PV) and its place in the drug development cycle.

From Caution to Controlled Extension of Opportunity

That the core remit of drug safety is to ensure optimal outcomes for patients has been overshadowed by the rising expectations of regulators over the last couple of decades. This has contributed to the function assuming "cost centre" status, and therefore a target for significant streamlining – the goal being to enable the absorption of increasing workloads (most notably around adverse event-AE-case processing) without adding costs.

To adjacent functions, meanwhile, Safety has been seen predominantly as a "naysayer"; an inhibitor to new drug delivery – a function that is always seeking additional assurances; always conservative.

In the process, something important has been lost. That is the extended value represented by Safety, by virtue of its insights, and through its expertise.

As products and therapies become more targeted and personalised, and expensive to develop, one of the challenges is to ensure that they are made available to as many applicable patients as possible. Early involvement from Safety enables prompter identification and management of safety issues. It can also help 'kill' products sooner. All of this reduces the risk to patients and to the company and maximises the reach and beneficial outcomes of the approved product.

What's Changed?

As long as the time and skills of Safety teams are caught up with the day-to-day burden of manually processing AEs, authoring aggregate reports and analysing false signals, their scope for more strategic deployment remains limited. The demands of regulators are so much more complex, and so divergent now, that there is rarely any capacity left after routine activities. It is why processes must be modernised, harnessing the available technology.

Artificial intelligence (AI), in particular Generative AI (GenAI) technology, can now readily streamline activities such as capturing AE information straight into a database. That's as long as teams trust the output sufficiently; if human experts are required to check everything, any productivity and cost-efficiency gains will be undermined. In more technologically advanced regulated industries like the financial services sector, advanced automation has been confidently applied to repeatable processes. This is largely thanks to appropriate governance and oversight, and adapted quality assurance measures, to verify any AI-supported output. The opportunity now is for pharma PV teams to adapt their own governance and quality processes, maximising the resource liberation that AI technology offers them.

At the same time, Safety teams are understanding afresh the need to assert their voice. This is as a supporter not only of patient outcomes, but also of the business's strategic interests including a drug's market success. The more that they can convey this potential, so that other internal groups see Safety as an ally (the way to get their products to market), the more influence they stand to gain. Where AEs can be anticipated in advance, there is greater scope for the company to manage risk effectively. This could result in more products succeeding, or conversely less financial exposure through waste (if a product can be "killed" earlier).

A national study in Italy published late last year, into the need for PV's reinvention, highlighted the need for greater strategic alignment between the Safety function with business objectives and stakeholder focus – including those around patient centricity and biotech innovation . The optimal transition is likely to be two-way: whereby Safety teams embrace opportunities to better manage their time and use their voice in more influential ways; while adjacent internal functions become more open and receptive

to the rounder value that Safety could bring to product advancement.

Closing The Loop: How to Move Forwards

With intensifying pressure to shorten drug development cycles, it is imperative that companies place new emphasis on managing the Safety data that is collected at each stage. This is not about capturing more of it for its own sake but rather appreciating and seeking the optimal combination of data to support appropriate analysis – and to enable a rounded understanding of the safety profile.

Arriving at this point requires earlier collaboration, and a development of trust between the groups, so that everyone is pulling in the same direction. And, given that products are often going to market with far less clinical data now than in the past – especially in areas of unmet medical need – careful planning and close collaboration with local markets is essential. This is to ensure that on-market data is collected and assessed quickly and effectively.

A further driver of positive change could arise from pharma companies' expansion into medical device development, presenting the opportunity for a greenfield Safety/PV scenario. Where established processes and ways of working in PV have become complex over time, the design of new approaches for medical devices can be built from the ground up in a more connected, streamlined, and digital-first way. Any emerging learnings and best practices could then set the tone for the changes in current PV practices.

Whatever the current state of play, Safety leaders should be looking to make some changes now, even if these are small iterative improvements to processes – for example applying GenAI to enable automatic AE data extraction in Individual Case Safety Report (ICSR) work.

Demonstrating incremental improvements in productivity, efficiency, and quality, and learning from them, will start to drive progress, even if this is modest initially. The more that advanced technologies can take on the heavy lifting, the easier it will be for the Safety function to take up a more proactive role. Ideally this will be both as a voice for patients, and as a strategic enabler of biopharma innovation.

REFERENCES

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Lucinda Smith

Lucinda Smith is ArisGlobal's new Chief Safety Product Officer, after more than two decades working in frontline scientific and strategic Pharmacovigilance and Drug Safety roles at a major pharma brand.

Web: www.arisglobal.com
Linkedin: lucinda-smith-68ab8b38/