A Five-year Roadmap for Technology-led PV Innovation

Technology is transforming pharmacovigilance (PV). The promise of artificial intelligence is of course one of the first things that springs to mind, and it is increasingly providing value. More mature technology solutions provide scalable, structured digital platforms to capture adverse event data at source, in multiple languages, across multiple use cases. It is also enabling direct reporting from healthcare professionals and patients with smarter digital ways for people to access, and contribute to, safety data.

The PV Problems of Today and Tomorrow

PV consumes around 10–15% of the total allocation of research and development investments in the pharmaceutical industry. COVID-19 raised awareness of the importance of PV but to ensure its continued evolution, and investment, we need to make sure it is fit-for-purpose, not just now but in the future.

In the past we have talked about a direct case-investment metric. More cases that have historically come in – and more complexity – mean we need more funds for PV. However, adverse event reports are no longer slated to increase with a CAGR of approx. 13% as we have been used to, in fact the FDA is reporting a decline from a peak of 2.3 million in 2022 to just over 2 million in 2024.[1] This has implications for how we focus our investment and innovations. Instead of planning to deal with increased volumes, we need to focus on improving quality and efficiency and ideally provide savings for the organisation. As an example, we are increasingly capturing adverse event data directly from source, while legacy systems capture this in unstructured formats like emails which make it harder to process and do not ensure quality. We need structured digital platforms which can capture data at source and flow it directly to clients.

Another challenge is the different approaches taken by organisations of different sizes. Big pharma companies have been building complex IT architecture diagrams to try to cater for all their needs. Small companies have been trying to deal with the complexity with a cornucopia of spreadsheets. About 90% of companies that operate with safety data and really should have a safety database to be compliant, do not have one because of the prohibitive cost. Here, it is somewhat problematic to observe that technology vendors are all trying to invent in the same space – the mid to large pharma segment – and right now this is very much for artificial intelligence (AI) investments. This works if you are a large company with a complex IT infrastructure and want to invest in simplification, but not if you are a spreadsheet company.

Why Don't We Simplify the Picture by Using AI for Prediction?

Can we simplify the systems architecture? Can we remove some of the legacy support like paper-based and scans? Can we remove parts of the PV ecosystem or the way we operate? Can we get simpler regulatory requirements to operate by? The answer, for the most part, is, no, not easily. We live in a complex reality and innovating in that space is complex.

All the components which make this complex landscape were the solution 20 years ago. Now they are the problem, and we need to apply new technology in smart ways to innovate.

Top Considerations for PV Innovation Over the Next 5 Years

It is important to remember first and foremost that our systems need to deliver compliance but that does not dictate the design. This is a legacy issue where everybody is thinking of the safety database in a specific way. Of course, compliance needs to be there, but we need to break up a bit of that mindset.

Secondly, if you look at the outside world, all of our users and colleagues are used to a completely different world now. They are used to user-friendly IT systems, and are used to using AI in their everyday lives. We are way behind in the PV area. We need to think about how we can generate a better use case for our users. Predicting data points is one thing, but it is not the only thing we need to do. We need to make sure our systems are more applicable and user-friendly and follow suit with what we are seeing elsewhere.

It is also important to remember that we are all connected in the value chain of PV across the industry. This means that we win or lose together. A larger pharma company has maybe 200 or 300 different partners. They all need to work together and there has not been a lot of investment in trying to solve that piece of the puzzle. Much of the complexity is driven by different partners failing to gel efficiently. We are also connected to the regulators, and they want to see cohesion and effective collaborative working.

Finally, the insights coming from data are key. The results we achieve will derive from the quality of the data.

Strategic Priorities for PV Innovation

There are three strategic priorities for PV from now until 2030 – lowering the cost to operate and standardise, utilising technology enhancements and easing cross-platform data integration.

We need to increase the availability of standardised technology for organisations of all sizes and share best practice processes to ensure all partners can work with efficient, high-quality data. By, for example, making AI and other scraping tools available to all, we can upgrade our quality across the span.

We need to improve user experience and access to information using generative AI (GenAI) and increase automation scope and quality. The focus of this work should be on confidence rather than just accuracy. If you are less confident about a data point you can create a human system to look at those data points which will allow you to utilise this concept.

Getting data to flow, more naturally integrated, is going to be part of the innovation roadmap for the next five years. There are a lot of things happening already in the space that are really interesting to see with more data sources becoming available. However, we also need to focus on quality to ensure there is high quality data for training purposes.

The Most Important Question to Ask

The key question to ask ourselves as we embark on this roadmap is: What questions do I want to ask my PV system? GenAI and chat-based technology is an area that can be used pervasively, for human interaction and supervision. The supervision will remain key. For example, if you are using natural language processing (NLP) for predictions and other technologies for automating, then you will need humans to oversee the control system. Humans must work efficiently with the PV system.

For example, you could ask the system to check for quality issues in the ICSR and emphasise medically important items. If we map out the questions we want to ask, we can have GenAI check its own work and have checks in some of the other models. This is going to be a much more efficient way to work. GenAI is perfectly capable of summarising confidence scores in literature, but it is not necessarily great at data predictions. Instead of focusing on predictions, we should be using GenAI to interact with data and make the voyage to understanding more pleasant.

You could also ask the system to produce a PBRER on Superdrug as an example, for a set period using standard template. GenAI is perfectly capable of pulling data points together and writing nice narratives. What is needed is structured content authoring in the back. You need some absolute truths that humans have created and then you use AI to pull all that data together.

Another example is asking the system to provide an overview of pending submissions and highlight negative acks. We are focusing too much on using AI to predict things and if we could ask these questions, it would be great because then we can use the data we have already generated, put it into our safety systems and surface them.

The final question is asking the system to schedule a daily overview of reports to a mailbox, sorted by incident seriousness. We can use GenAI to tap into the existing functionalities we have in our safety systems and make them work more efficiently for us.

Conclusion

There are some key steps we need to take on our roadmap to technology-led PV innovation. We need to make sure we expand our PV ecosystem to capture more high-quality data from all partners globally. We need to use the right models, feed them the right data and ask the right questions. We need to use technology not only to make predictions but to help us do our work more efficiently and ensure that the patient voice is heard.

People expect to be able to contribute towards, and access, safety data in smarter, digital ways. Setting out a clear roadmap for technology-led innovation will help to ensure PV remains a cross-industry priority and adapts to meet the demands of a patient-centric clinical trial landscape.

REFERENCES

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