The Lasting Impact Of The Pandemic On Pharmacovigilance

Despite the critical importance of pharmacovigilance (PV) activities, two years ago it was a concept with which most people outside the life sciences space were largely unfamiliar. Since the onset of the COVID-19 pandemic, however, this has changed immensely. Drug safety has become a topic frequently featured in mainstream media coverage, increasing public awareness substantially.

Along with bringing pharmacovigilance to the front of public consciousness, COVID-19 has had a significant impact on the way these activities are conducted. Annette Williams, vice president and global head of lifecycle safety at IQVIA, witnessed this first-hand. "There was complete disruption to the drug development ecosystem in the early stages of the pandemic. As in-person activities were no longer possible, the industry witnessed clinical trials being halted and delayed, and similar difficulties arose in pharmacovigilance."

Despite the challenge of having to adapt rapidly, there have been positive consequences for pharmacovigilance, in the form of automation initiatives, adoption and streamlined processes that can be carried forward well beyond the pandemic for adverse event (AE) reporting.

A New Era Of Adverse Event Reporting

The task of inoculating the global population, along with the speed at which manufacturers were able to mass-produce vaccines, meant that the potential scale of data resulting from AE reporting was well beyond anything the pharmacovigilance sector had previously experienced. "We very quickly realized that historical vaccine AE rate models simply did not apply to the COVID-19 situation. Working collaboratively with our vaccine manufacturer partners, IQVIA conducted significant analysis in the early days of the vaccination rollouts to build forecasts and refine AE modelling as vaccination data became available in real time," Williams states.

These predictions have materialized in 2021, Williams continues, "We have looked at the number of AEs being reported to the European Medicines Agency (EMA) in totality and expect a 50% increase in their total annual volume by the end of the year. While adverse events associated with the COVID vaccines is relatively small, one has to consider the actual total size of the universe of patients inoculated this year, which has led to this large increase in total number of cases processed in 2021. Even though it's a very small subset of patients that might experience an AE, it's a large amount of information to process and analyze."

Traditionally, most AE reports are reported by patients and health care professionals to the manufacturers initially, who would then relay this information to regulators. Regulators anticipated that there would be a need to change the way they received AE information for the COVID vaccines, so they could assess the emerging safety data in near real-time, and ultimately enable them to take quick action should that have been necessary. For example, the UK Medicines and Healthcare products Regulatory Agency (MHRA) invested in artificial intelligence (AI) to update their Yellow Card scheme: the UK's system for collecting and monitoring safety concerns through voluntary reporting, including possible side effects or AEs. This use of technology made it easier for patients and health care professionals to provide such information associated with vaccine administration directly to the UK agency.

In the US, the Centers for Disease Control and Prevention (CDC) implemented the v-safe tool. This allowed patients to opt in for personalized follow-ups following their COVID-19 vaccination, along with giving them the ability to report side effects should they have been experienced. While the extent to which the public adopts these programs long-term remains to be seen, now that the technology is in place, it offers the potential for wider application to medication reporting not related to the pandemic.

The outcome of this reporting paradigm shift for companies, like IQVIA, resulted in a data flow flip (now from regulators to industry), and companies had to be prepared to accept large volumes of information almost immediately. This required effective, connected systems and processes capable of managing significant amounts of information within the necessary timeframes. All of this was critical to reassure the public of the efficacy and safety of the vaccines.

As the acceptance by the public to proactively report adverse events grows, there is also a desire to simplify the process for reporting as much as possible. Williams predicts that "there is potential for further consolidation of how people report AEs versus the myriad of ways that currently exist." Doing so lowers barriers to patients' involvement in the reporting cycle, ultimately providing manufacturers and regulators with increased drug safety data.

Digital Disruption Here To Stay

While there were, of course, challenges in processing AE data, those working in PV stepped up to maintain safety standards. COVID-19 has been a catalyst for implementing exciting innovation that has been in the cards for many years but had yet to be fully realized.

IQVIA seized this opportunity, implementing technology such as AI to support automated AE report intake and retrieval, and robotic process automation (RPA) bots to support automated case processing. Auto-translation tools have also been indispensable for the management of non-English AE cases which need to be handled with as much speed as those coming from other regions.

The implementation of AI bodes extremely well for the future, as its benefits transcend the reporting of COVID-19 vaccine-related AEs. "We've additionally employed AI-enabled virtual agents to support medical information queries, which has helped enormously when we were experiencing very high call volumes," Williams notes. "In the longer term, this is allowing us to enhance the customer experience, by having improved out of hours coverage, but we also found that 15–25% of live calls that humans used to answer can be fielded by these virtual agents. Removing this workload allows human experts to focus on more complex queries."

As confidence in AI grows and it is applied to more PV tasks, staff can turn increased attention to oversight and management of the safety data generated.

AI and automation have created significant strategic opportunities for IQVIA and their clients. Williams says, "For one client alone, we developed and implemented more than a dozen different instances of automation to streamline their end-to-end case handling process. By looking at how this innovation can apply across the wider safety landscape, we are future-proofing our organization."

The Evolving Role Of Humans In Pharmacovigilance

As AI utilization grows, so does the need for skilled staffing. "In less than six months, we doubled the number of staff in our organization. While it was immediately clear that AI and automation were going to feature prominently in our COVID plan, we still needed to ramp up our team numbers because the amount of work was enormous and could not be completed by technology alone," says Williams. Remote working capabilities meant that the pool of candidates for these roles was expanded, as companies like IQVIA could focus on hiring wherever the talent was, without being limited to those within a certain proximity to offices.

Nonetheless, it was and still is pivotal to meet the urgent need for human resources without compromising on the quality of onboarding. While training was accelerated for those joining IQVIA, an onboarding compliance database was built to proactively monitor the progress of new hires and intervene early if they seemed to be struggling. Moreover, Williams notes, "Because we're talking about patient safety, it is key that we can monitor and measure their knowledge uptake to ensure that patients continue to have confidence in our industry and the safety of medications."

Improving Patient Prospects Beyond COVID-19

COVID-19 has disrupted pharmacovigilance like nothing before it, fundamentally changing the role of people, processes, and technology. However, despite the great challenges the industry has had to contend with, Williams is proud to say that everyone came together to ensure safety standards were maintained. "First and foremost, patient safety was never sacrificed. There was no relaxation of standards by regulatory agencies, and our reporting clocks for AEs did not change. We remained laser-focused on quality and compliance because we needed to maintain the confidence of the public."

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>
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Instead, the industry's rapid implementation of new frameworks and technologies is what allowed compliance and safety to be upheld. Williams notes that COVID-19 forced many industries to bring forward their planned tech investments for 2025 into 2020 and 2021, leading to pharmacovigilance processes and infrastructure that is robust and is future proof.

Finally, the industry will be forever changed by the new surge in public interest in drug safety. While there are still challenges surrounding misinformation spreading via word of mouth and on social media platforms, overall patients have a deeper understanding of the importance of providing feedback when taking medication or receiving vaccines. When combined with more accessible reporting systems, quicker AI-enabled processes, and more staff to deal with complex queries, there is great potential to further engage patients in the pharmacovigilance process well beyond COVID.