INSIGHT BRIEF

IQVIA TECHNOLOGIES

The Evolving Safety Technology Landscape

The pandemic has revealed emerging sources of safety information.

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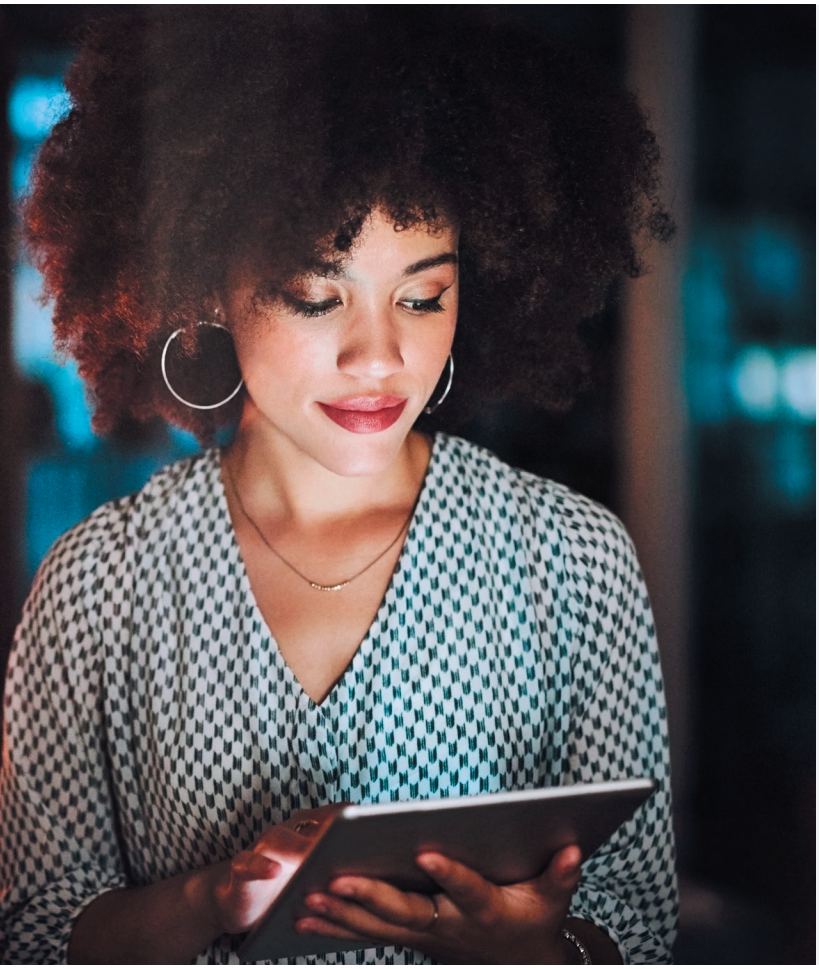
Introduction

The global pandemic has brought the reporting of adverse events by someone other than a healthcare professional to the forefront of drug safety. COVID-19 vaccine distribution has raised society's awareness of drug safety significantly. The word "pharmacovigilance" has entered the public domain for perhaps the first time. The public's reporting of side effects associated with the vaccines is encouraged and accessible.

When viewing reported adverse events associated with the COVID-19 vaccine in the EudraVigilance (European database of suspected adverse drug reactions reports), we see "non-healthcare professionals" account for the majority of COVID-19 vaccine individual case reports (64%[1]), a consistent observation across all approved COVID-19 vaccines.

Before the COVID-19 pandemic, healthcare professionals would have been the majority reporters, showing a potentially permanent shift in reporter dynamics. Social media has also become a growing source of safety information. Although organizations are still evaluating the value of this information's impact, there is no denying the rise in this medium and the potential for harnessing it for commercial and clinical insights.

All organizations need to understand the potential long-term benefit of new methods of patient safety reporting.



The global pandemic has brought to the forefront of drug safety, the reporting of adverse events by someone other than a healthcare professional.

Regulators' influence on safety technology

These emerging sources of reporting and safety bring about a new challenge, the sheer volume of data and, more specifically, how to harness it. In November 2019, just weeks before the pandemic, EMA published an article titled "Pharmacovigilance in 2030"[2] predicting "that improved engagement of patients and healthcare professionals would deliver the vision for the transformation of healthcare in the digitally networked era. Most significantly, regulators will need to engage patients and healthcare professionals more extensively to maximize the positive impact of pharmacovigilance on the safe and effective use of medicine."

hese predictions are taking form today, accelerated and underpinned by the pandemic. We need to look no further than the UK and US regulator and governmental investment in AI, e.g., the Yellow Card System and V-Safe launch, and smartphone-based tools to enable direct patient-to-regulator safety communication.

Additionally, the ICMRA (International Coalition of Medicines Regulatory Authorities) published a report issuing recommendations to help regulators address the challenges that the use of artificial intelligence poses for global medicines regulation[3]*. The report documented Swissmedic's digital initiative using NLP for literature review. It concluded: "Machine learning techniques are very likely appropriate in terms of time-saving and reliability to detect safety signals in investigational medicinal products."

Regulators have not only championed the use of safety technology but are openly recognizing the importance of the role technology will play in the future of drug safety.

What's next?

The new direction of data flow, formats, and sources demands the safety industry re-prioritize and change course on its trajectory.

There is no doubt that we are in an era of rapid digitization. The pandemic has accelerated what was already in progress. It has fast-tracked innovation evidenced by recent press releases and investments by Amazon, Apple, and Microsoft to revolutionize EHRs (electronic health records). We are seeing a convergence of the industry and its regulators reshaping the landscape, specifically the direction of data flow and format. For example, patients reporting directly to regulators require less focus from the industry on getting the events to the regulators within timeframes and more focus on digitizing the data capture upfront.

However, established technology solutions are already available to efficiently manage and de-risk this end-to-end process. IQVIA's Vigilance Collect empowers adverse event reporters, such as patient support programs, vendors, medical representatives, patients, and HCPs, to engage directly with safety teams. And IQVIA's Vigilance Detect uses AI and NLP to identify potential safety events across large and diverse data sets originating from social media, patient support programs, CRM systems, and advanced virtual agents (to name but a few).

Staying ahead

Over the past ten years, IQVIA's Vigilance Detect (formerly AETracker) has amassed more than 500,000 safety-specific keywords and patterns (ontologies) that power the Detect engine and the rapid and reliable identification of safety risk.

The new direction of data flow, formats and sources demands the safety industry re-prioritize and change course on its trajectory.

This unique feature, paired with a confidence-scoring mechanism, quickly and confidently routes safety risks forward in the workflow, eliminating the noise and reducing the need for human review. This end-to-end detection solution dramatically reduces the burden on our partners and the need for people in otherwise complex safety and medical information processes.

This technology enables the industry to stay ahead of emerging safety sources and evolving trends shaping the future of safety. Another example is the standardization of safety reporting "direct to the regulator," representing a seismic shift towards patient-HCP engagement. In addition, and perhaps most revolutionary, is the ability to identify adverse events directly from audio sources. With Gartner naming AVAs (advanced virtual assistants) as a top strategic trend for 2022[4]*, the rise of audio as a source of safety information is unquestionable.

IQVIA's Vigilance Detect proactively addresses this demand with its latest offering, "Detect Voice ." Working together with the leaders in the pharmaceutical industry, IQVIA has productized a unique solution for this rising data source. Detect Voice finds potential adverse events (AEs), PQCs (product quality complaints), and other safety risks within audio files by auto transcribing audio to text and applying AI and NLP to rapidly identify and rank safety risk and eliminate files that contain no safety risk from the workflow. It leverages bulk processing features and an optimized workflow and precisely pinpoints any human review required. This Voice technology is in production and has successfully processed 1.5M audio files with zero inspection findings. Its applications include support of commercial and medical call centers, medical information and safety teams, live and AI agents, and urgent remediation requirements.

Conclusion

Collectively, this safety technology allows the redirection of safety expertise to analyze large sets of data quickly and brings intelligent insights to the forefront.

COVID-19 has highlighted a problem we all knew - life sciences will evolve in unpredictable ways. Leveraging technology and AI to create flexibility for people and processes is one way to remain ahead of an unpredictable future.

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About the authors

MARIE FLANAGAN, MSC
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As Director, Offering Management, of IQVIA's Vigilance Detect (powered by AETracker®), Marie's focus is on developing the Detect portfolio and ensuring the offerings meet client and regulatory needs.

Marie joined Quintiles Drug Safety over 16 years ago. In her tenure, Marie has successfully held many leadership positions in operations and project management and leveraged learned skills and competencies across a broad spectrum of pharmacovigilance (PV) services. In 2017, as the Global Head of PV Services Integration, Marie led a team of PV Product Specialists that focused on the strategic expansion efforts of IQVIA's PV department, conducting PV landscape assessments and analyzing emerging trends. Throughout the years, she has supported Global Business Operations, Strategic Pricing, Business Development, PV Operational Management and the integration of Safety Technology and Services.

Marie graduated from University College Cork, Ireland, with an Honors degree in Microbiology and an MSc in Medical Microbiology. In 2021, she joined the Vigilance Detect team, leveraging her 15+ years of safety experience.

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