Insight Brief

The Future of Pharmacovigilance

How COVID-19 has inspired innovation

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Introduction

As with many areas of the pharmaceutical industry, COVID-19 created significant disruption for pharmacovigilance (PV) activities, including post-marketing surveillance.

Prior to the pandemic, the quantity and diversity of data that had to be processed and reviewed as part of routine pharmacovigilance activities had already been growing. The pandemic accelerated that trend, causing a surge in inquiries related to COVID-19 vaccines and an unprecedented increase in reporting of adverse reactions overall.

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Reimagine key PV strategies

Annually, IQVIA's Lifecycle Safety (LCS) team processes approximately one million individual case safety reports. In the first quarter of 2021, the LCS team processed more than 400,000 individual case safety reports (ICSRs) and handled more than 300,000 calls related to all aspects of COVID treatments and vaccines alone. These figures are in addition to the normal run rate of data processed each year.

This rapidly growing volume of data along with shifting regulatory and consumer trends due to the pandemic, forced IQVIA's PV leaders to rethink their typical safety data management processes and PV technology, in order to bring unprecedented levels of scalability, reliability and agility to their workflow.

IQVIA's Lifecycle Safety and Pharmacovigilance team has been on the front line of this pandemic from the start, providing support to several customers conducting research into COVID medicines and vaccines, as well as providing global PV and medical information support for vaccines approved for emergency use. Through this experience, IQVIA has witnessed firsthand the challenges to maintaining PV standards during this crisis. The disruption also presented opportunities to reimagine our pharmacovigilance strategies and accelerate the implementation of automation and process changes that the industry has been theorizing for years.

CONSISTENT COMMUNICATION VIA DATA DASHBOARDS

One of the biggest obstacles during this time was that the disruption wasn't a single event, as typically experienced under normal business continuity conditions. Rather it quickly became the norm. As regulations changed, and treatments and vaccines became available, the demand for pharmcovigilance and medical information expertise in vaccines increased quickly.

The disruption also presented opportunities to reimagine our pharmacovigilance strategies and accelerate the implementation of automation and process changes.

The heightened demand for pharmacovigilance services prompted IQVIA's leadership team to assess new technologies, adopt new tools, strategies and evolve day-to-day practices to consistently meet the safety and reporting needs of regulators, clients and consumers, while keeping all key stakeholders abreast of the latest trends. These included AI-enabled chatbots, robotic process automation (RPA), automated regulatory rules, supports for employees working from home and much more.

In the early stages of the pandemic, when information was evolving and changing daily, IQVIA established a portal that acted as a single source of the truth about everything related to COVID-19 and our response to the pandemic. We used the portal to keep employees informed about how we were handling global challenges related to COVID for the organization and for our customers; how we were customizing our response in different countries based on regulations, risks and absenteeism related to the virus; and how we continue to mobilize resources in response to changing needs. This portal also helped provide our employees with the latest clinical information on COVID-19 and emerging treatments as well as evolving travel restrictions and how employees could optimize their working-from-home connectivity and environment. This approach laid a solid foundation for IQVIA to deliver a response to customers' needs for PV expertise to address the pandemic.

Hired 4,000+

new employees globally in

<6 months

(doubling the total team)

with initial go-live of US EUA program

3 months

from notification

Early in the pandemic, it became clear that our existing PV team would not be sufficient to accommodate the sharp increase in expected adverse event (AE) volume and medical information (MI) calls. So we accelerated our global recruiting engine and were able to hire more than 4,000 employees globally in less than 6 months (in effect doubling our overall team footprint) with initial go-live in under 3 months.

The mass hiring and shifting of resources had the potential to introduce risk into the workflow. To manage that risk, we developed the Onboarding and Compliance Tracker (OCT) to monitor detailed metrics around global hiring (staffing mix, timing, etc.) and training and staff utilization. Our executives met weekly to review, providing oversight to ensure that all clients in every region had the support necessary to accommodate their emerging PV needs at global and local levels.

Managers also used the OCT tracker for monitoring staff training compliance and to ensure all training records remained audit- and inspection-ready.

AUTOMATED TECHNOLOGY ACCELERATES RESULTS

The most innovative changes made were in the areas of technology and the use of artificial intelligence (AI) and automation to streamline the MI and PV workflows. This speed would be critical for staying on top of vaccine- and treatment-related trends and potential side effects as the vaccines were introduced in various regions.

Throughout the past 15 months, IQVIA has adapted and expanded its use of AI and automation tools to reduce the time to complete repetitive tasks and free staffers to focus on more complex activities. This included expanding our use of auto-narratives for all adverse event case types, using robotic process automation for manual data management tasks, using machine learning algorithms to read databases and scan the internet for safety information and adverse event reports, and leveraging automated chatbots to handle basic inquiries, which account for up to 20% of all queries.

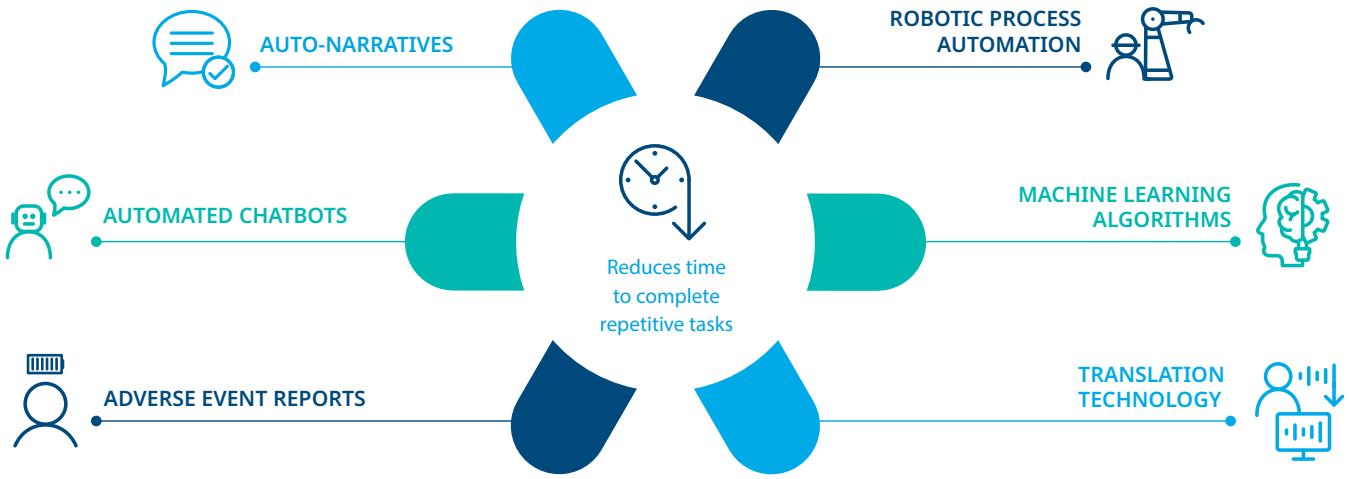
Additional digital interoperability and automation enable faster case processing while minimizing human touch to meet regulatory demands.

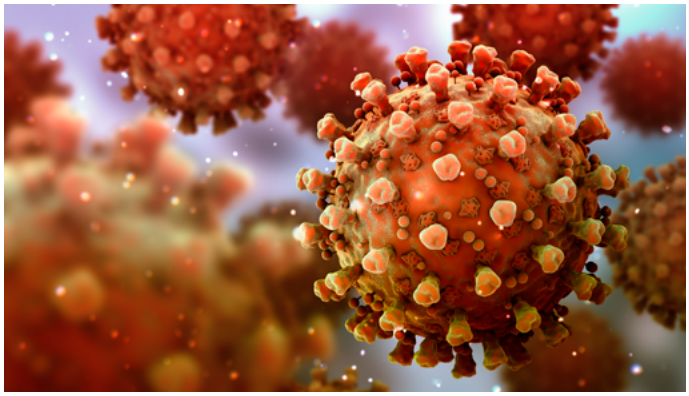
We also made greater use of translation technology, which not only lowered total time spent on language translation tasks but also maintained quality, resulting in much greater flexibility in terms of resourcing staff.

Typically, PV teams must translate data from multiple languages before they can be reviewed or submitted to regulators and partners. This means that team members must be multi-lingual along with having PV expertise, which makes recruiting more challenging and time-consuming. Translation technology assists with these tasks, reducing the time to deliver a fully translated document, thereby increasing the time available to complete the safety assessment and expanding the potential talent pool.

IQVIA's expanded use of AI and automation tools

Reduce time to complete repetitive tasks





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BETTER SIGNAL DETECTION WITH DATA ANALYTICS

Along with managing the increase in data volume, we had to adapt our use of data analytics to support new signal detection strategies tailored specifically for COVID-19 vaccines.

During the pandemic we saw a 60-100% week-on-week increase in the volume of data coming from authorities, direct to license holders putting a strain on IT and PV resources. Any constraints on IT or HR presented as a risk to deliver thorough signal reviews in near real time.

Additionally, we found that our routine analytics and signal detection methods weren't sufficient to keep up with demand. For example disproportionality analysis was not appropriate due to the high volume of data and low number of vaccine products compared to other products.

To adapt, IQVIA created a custom dashboard to provide enhanced analytics with signal detection. That allowed for better collaboration with health authorities and enabled timely intervention on safety issues that emerged in relation to COVID-19 vaccines and treatments.

AGILE METHODS AND THE NEED FOR SPEED

Prior to 2020 there were only 17 studies being conducted around COVID. But by March, 2020, the EU alone had almost 400 studies registered.

IQVIA's Lifecycle Safety Services team was able to set up safety databases 80% faster than in a typical trial, by adapting processes, eliminating downtime, and streamlining approvals.

Since then we've seen approval of 11 vaccines globally, with 93 in human trials, and 184 more in the lab as of May 20, 2021.

Because these trials were moving so fast, sponsors needed rapid strategies for setting up safety databases and monitoring results. Many of them partnered with IQVIA's Lifecycle Safety Services team, which was able to set up safety databases 80% faster than in a typical trial, by adapting processes, eliminating downtime, and streamlining approvals. This allowed the combined teams to move potential COVID medicines and vaccines quickly from early phase trials through to comprehensive post-market PV activities.

Through these collaborative partnerships, we worked together to streamline processes and introduce efficiencies that have been yielding measurable time savings.

REGULATORS LED THE WAY

Early in the pandemic, regulators made significant changes to PV reporting requirements focused on prioritizing products to treat COVID-19 and introducing concepts such as monthly periodic reports to balance the expedited approval of vaccines.

US and UK regulators also embraced new technology capabilities. For example, UK's Medicines and Healthcare Products Regulatory Agency (MHRA) overhauled its yellow card system for reporting suspected side effects and adverse events for COVID-related medicines, vaccines, medical devices, and diagnostics to ensure safe

and effective use. It also adopted artificial intelligence tools to rapidly ingest incoming reports and automate follow-up activities.

Similarly, the US Food and Drug Administration rolled out the V-safe program allowing patients to opt in for targeted follow-up after their first vaccination and to receive reminders to get their second dose.

Additionally, there is increased collaboration among regulators, with the International Coalition of Medicines Regulatory Authorities meeting every two weeks to discuss innovative ways to regulate vaccines and treatments, and to share knowledge and expertise.

Internally, we updated the IQVIA regulatory information database to include the latest emerging COVID-19 regulations, and provided daily information on global regulatory strategies and their impact on research. We shared that information with our customers and provided updated reports on requirements for every country prior to launching new trials or programs.

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Conclusion: The future

IQVIA prides itself on its ability to adapt to the changing needs of clients and regulators, and our willingness to innovate on their behalf. The pandemic gave our teams a chance to demonstrate that agility, and commitment to doing what needs to be done which helps to better ensure patient safety while meeting the needs of clients and regulators across the globe.

To learn how to meet your safety compliance objectives in a world of constant change and financial challenges, visit iqvia.com/lifecycle-safety.

About the authors

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Annette Williams, R.Ph, is Vice President of Lifecycle Safety at IQVIA, leading comprehensive global safety operations and project management, while serving as a member of the company's Lifecycle Safety Governance Committee. Williams is also leading the exploration and adoption of innovative technologies designed to streamline how Lifecycle Safety manages safety information on behalf of its customers. Prior to joining IQVIA, she held leadership positions with Drug Safety Alliance, Inc., Team Pharmaceuticals, and GlaxoSmithKline. Williams holds a Bachelor's degree in Pharmacy from the University of Rhode Island and a Master's of Business Administration from the University of Southern New Hampshire. She is also a Registered Pharmacist in the State of New Hampshire.

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As Senior Director and Head of IQVIA Pharmacovigilance Oversight and Analytics, Barry Mulchrone leads the department responsible for periodic safety reports, risk management solutions, signal management, pharmacovigilance agreements and Qualified Persons for Pharmacovigilance (QPPV). He also provides strategic leadership and oversight for major accounts within IQVIA Lifecycle Safety. Barry has over 18 years of experience in pharmacovigilance and risk management and has operated as an EU Qualified Person for Pharmacovigilance. He has participated in EMA and MHRA stakeholder meetings on new legislation and is a regular presenter at industry conferences and training courses.

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