Article

Sanofi Revolutionizes Pharmacovigilance with Project ARTEMIS

As seen in Informa Connect

Sanofi's pharmacovigilance journey to fully automate and streamline its case management processes — Project ARTEMIS — represents a significant leap forward in the company's approach to drug safety monitoring and adverse event reporting.

Sanofi records over 700,000 adverse event versions annually and case volume is growing up to 20% each year. Handling these cases manually resulted in inconsistent quality, inefficiencies, and rising costs. Julie Girod, associate vice president, global head of case management and medical evaluation at Sanofi, explained: "Case management is the foundation of pharmacovigilance. It consists of collecting adverse reaction phone calls, letters, emails, posts on the internet — anything. Once we know there is an adverse event, we need to enter a lot of information into a database. All of that was extremely manual."

The need for change became apparent as the volume and complexity of data continued to grow. Girod said: "Fifteen years ago, the Sanofi case management team was about 100 people, and it was Sanofi only. Fifteen years later, 99% of what is being done is outsourced and we have a service provider who is responsible for all the data entry and medical evaluation."

However, this outsourcing model, still relied heavily on manual processes. No matter who was doing it, the manual data entry was no longer sustainable. Sanofi wanted to adapt new technologies that changed and adapted with the changing nature of it's product portfolio. "Today we have innovative medicines which are requiring very specific knowledge, which means that our team really needs to keep up with all of the advancements," Girod noted.

Project ARTEMIS began to take shape in 2019 when Sanofi started its automation journey. The initial focus was on automating data entry, extracting information from source documents and populating their systems automatically. But it wasn't until the summer of 2023 that Sanofi decided to take a more comprehensive approach, leading to a partnership with IQVIA.

That partnership is to implement the latter's IQVIA Vigilance Platform, a comprehensive suite of tools designed to transform and scale Sanofi's pharmacovigilance operations.

Girod explains the decision:

"We decided to move forward with IQVIA for three main reasons. First, the tool as it was presented to us, as well as the roadmap for the future, were really aligned with our vision. Second, we have a long-term relationship with IQVIA. And third, we were really acknowledging the deep expertise and experience that the team has."

The IQVIA Vigilance Platform (IVP) encompasses a suite of Pharmacovigilance tools including Collect, Intake, Case, Periodics, Analytics and Signal. The first phase of implementation, completed in August 2024, focused on Collect, Intake, and Analytics, as well as the integration with their current safety system, maintaining the emphasis on automating data entry. However, Sanofi's vision extends far beyond this initial step.

"Our long-term vision is to replace our entire PV system," Girod reveals. "By the end of this year, we will have only one system, and that's going to be the IVP system from beginning to end. At that time, Sanofi is going to be one of the few pharma companies using a full system leveraging automation."

What sets Project ARTEMIS apart is its ambition to apply automation and AI not just to data entry, but to more complex medical evaluations as well. This approach is pioneering in the industry, as Girod points out: "Most companies are focusing on the intake component, not so much on trying to find where you can bring automation in activities which are more medical. We found a way and have been working with IQVIA to see how we can still benefit from new technology for that."

Daunielle Chipman, senior director at IQVIA, emphasized the collaborative nature of the project: "It's been a real true partnership. There's a lot of collaboration between Sanofi and IQVIA on expanding the functionality of the system, enhancing it to not only meet what Sanofi needs from a day-to-day business perspective but also how our tools can support others in the industry."

Chipman explained that Sanofi's work with IQVIA forms a continuous improvement feedback loop to bring enhancements to the tool, and to integrate best practices from the findings. "There is definitely a feedback loop withing IQVIA from project to project to enhance the platform based on real-world use and evolving needs, and the feedback we have received from Sanofi has only continues to improve the IVP functionality," said Chipman.

Savings but so much more

The impact of this automation is already evident. Girod reports, "We have seen that before the implementation of automation and in comparison to today, we saved an average of 15%. We are paying 15% less than what we used to pay in the past." Even more so, Girod believes they will be able to save 50% by 2027. Girod states. "We are really ambitious, but that's the objective, and I believe we can get there."

Outside of the cost savings and efficiencies, Project ARTEMIS represents a fundamental shift in how pharmacovigilance is conducted. Girod said, "We really want to strengthen our medical team which will lead to an improvement in the medical evaluation and medical content of our cases."

This shift aligns with broader industry trends, as Chipman notes: “The industry as a whole is definitely moving in that direction because companies are receiving more and more safety data. We have so many ways of getting information about adverse events and products that the volume has increased exponentially and the time spent on doing non-value added activies such as data entry and quality control is overshadowing the ability to do that analysis.”

Girod said, “The medical evaluation will establish if the patient’s experience is related to taking the product or if there could be any causing factors. The shift will bring more medical people into the team as we will decrease the time needed to oversee data entry as well as the other activities handled by the service providers. And we have to leverage AI and automation to achieve that.”

Girod believes that AI and automation will allow the teams to focus their energies where it can make a difference. “A few years ago, people were saying a case is a case, meaning that anyone can perform any type of entry or case assessment,” she explained. “I so much disagree with that concept because a post on a website [with little comprehensive information] does not require as much attention as clinical trial case with a drug that is not yet marketed. If we were not leveraging automation, we would not be able to focus on the cases of interest.”

Girod said that training the AI and bringing automation will put the resources where they need to be. “So a case is no longer a case. I think we need to change that,” she remarked.

About the authors

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Julie is an Associate VP in Sanofi’s Global Patient Safety organization with over 20 years of experience in pharmacovigilance and patient safety.

Julie is recognized as an industry thought leader in innovation through her leadership of multiple initiatives to transform patient safety. Her expertise and experience includes global business process optimization and harmonization, vendor outsourcing strategies, patient safety organizational design, and the first in industry implementation of global cognitive case processing automation.

In addition to her innovation stewardship, she leads an inhouse and vendor global patient safety team of over 600 people responsible for all aspects of case processing, reporting, vendor oversight and regulatory compliance.

Julie holds a PharmD from Paris-Sud University and is bilingual in French and English.

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Daunielle Chipman is a Senior Director with over 24 years of industry experience in PV operations, business process consulting, solution analysis, and safety system implementation.

As a leading industry Subject Matter Expert, she has successfully led global business process redesign initiatives, focusing on process optimization, increased efficiency, quality, and compliance improvements for top pharmaceutical and biotech organizations. Daunielle ensures continuous improvement by defining and implementing appropriate technology requirements.

Daunielle’s consultative approach swiftly identifies business problems, crafts tailored solutions, and leverages change management to ensure successful implementation and adoption.

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