Cognitive Pharmacovigilance: Business Perspective

Among the major functions of a life science company's pharmacovigilance (PV) department, case management is one of the most resource-intensive processes, involving considerable manual activities. The 'digital revolution' that has already transformed other industries has not yet been truly implemented in the world of pharmacovigilance. Changes in regulations focused on streamlining and simplifying the reporting of adverse reactions, introduction of new products into the market, and year-on-year increases in the number of individual case safety reports (ICSRs), is putting a lot of strain on pharmacovigilance departments within pharmaceutical organisations, requiring significantly higher budgets and resource allocation. These challenges can be effectively tackled by optimizing the pharmacovigilance processes using recent technological advances in the field of robotic process automation (RPA) and cognitive computing (artificial intelligence (AI), machine learning (ML), etc.).

When seen from the business perspective, automation of manual case-processing activities such as case intake, prioritisation, assignment, coding, workflow management, narrative generation, follow-up/query management, quality check and more will lead to extensive, yet welcome changes to resource-intensive PV processes. Automation technology is now seen as a business imperative that will lead to process efficiencies, quality improvement, cost savings and better health authority compliance.

A growing number of technology service providers are looking to offer varied levels of automation capabilities to the life sciences industry. A "buyer beware" approach is needed as the degree to which automation is achieved varies widely, due to how the cognitive technology has been designed and is being leveraged. For example, some of these organisations are offering solutions where robotic process automation (RPA) is applied only to limited steps within the case processing workflow. This short-sighted approach will not be beneficial in the long run and may even lead to technical challenges in the way it is integrated with or is 'talking to' the safety database.

Selecting the right product, suited to the current business requirements, is a critical and extremely important decision for a pharmaceutical organisation. A right decision can deliver considerable benefits while a wrong one can immediately impact thebusiness processes and health authority compliance.

Evaluating Automation Solutions:
Three Considerations from the Business Perspective

So how can a life sciences company know what to look for in evaluating an automation solution? These three key considerations from the business perspective will help a life science organisation understand its potential benefits and ask intelligent questions in determining what is best needed to meet its automation needs.

1. Question the life sciences background and capability of the vendor organisation in offering PV solutions, particularly the safety system.

This is one of the key parameters since ICSR processing is a highly regulated and compliance-driven process. A company in the business of designing and facilitating the safety system is in a better position to understand and appreciate each of the varied nuances of the process.

A true automation solution must be implemented within the safety database (native application), rather than through a 'third-party' tool/application; for sustainable, comprehensive and measurable efficiency gains.

To better understand true automation and AI capabilities of the proposed solution, here are a few key ways that will help during the assessment process:

Does the proposed automation solution provide only RPA-based automation or is it truly cognitive?

Robotic process-based automation limited to automating a few 'manual clicks' that are in today's world handled by a pharmacovigilance associate is neither going to significantly change the process, nor bring considerable 'time and effort' savings. In contrast, true cognitive automation requires a smart 'AIengine' based on intelligent algorithms, which are built within the safety database and leads to an 'evaluative process that learns as it goes'.

Pharmaceutical companies conduct various pre-marketing, post-marketing, observational and epidemiological studies and accrue a large database relevant to the drugs manufactured and marketed by their company. The cognitive computing algorithms enabled within the safety database can utilise this vast database for training themselves and use them in performing various pharmacovigilance tasks.

- **Is it truly native or simply a plug-in?**
  An important consideration during the selection process is – how does the proposed automation solution 'talk to' the safety database? This will determine how effective the solution is and how comprehensive the automation benefits are.

- **Is the vendor's automation solution "production ready" or is it just a nicely packaged vision?**
  What part of the automation suite is generally available (GA) now and ready to be implemented in the foreseeable future? If it isn't GA, how long will you have to wait before the vendor will deliver in order to reap the true benefits of automation?

The fact is that within the PV industry more and more 'pilots' with the third-party solutions fail to deliver promised results.

- **How significantly will the 'as-is' process change? And has the vendor mapped out the process changes? To what extent will your subject matter experts have to be involved in identifying the required changes to the process as a result of automation?**

This is an extremely critical component of the evaluation process. An organisation that has a track-record in providing safety databases globally will have established processes and know-how to determine the automation-driven process change.

2. Identify the business-critical problems that the proposed solution can potentially address
A nicely packaged software product, with flashy graphics and marketing collaterals are of no use if the automation functionalities offered fail to address pain points from the business perspective. Even conceptualisation of automated PV processes requires thorough PV knowledge, operational experience and PV-IT domain expertise.

During the evaluation process, it is important to find out how the proposed automation solution is going to change the way adverse reactions are currently reported: Is it going to automate case prioritisation and case assignment, and provide workflow management functionalities with intelligent data analytics for efficient case management? Will it provide a comprehensive in-built solution for compliance monitoring? How will it address the triage and duplicate check-related challenges? Will it simplify the way cases flow through the database? Will it provide a solution to manage follow-up queries in a more efficient manner? How will the drug and event coding become more efficient?

For the vendors you evaluate, ask whether their automation capabilities can help the safety system intelligently build a chronological narrative, which makes clinical or medical sense. For example, when writing a narrative within the safety system today, users have to make changes to the templates used, ensuring that it is in the right order and is sequential. Often, this leads to inconsistencies between the narrative and information captured within the safety database fields. Well-thought-out integration of different artificial intelligence technologies can not only construct a chronological narrative clearly detailing the clinical course of the patient, but can also enable users to intelligently plug in additional components within the narrative.

These constitute a fraction of pain points from a business perspective and, if the proposed automation solution isn't capable of handling the majority of these challenges in a manner that manual activities are considerably reduced leading to process optimisation, then the proposed automation solution may not be truly beneficial.

3. Establish a baseline to measure process optimisation:
Prior to testing any automation solution, it is essential to establish a baseline of various processes in the current state, be it the case intake, data entry, quality check or any other workflow step or an activity within that process. This must be done in collaboration between PV subject matter experts (SMEs), your business excellence team and PV IT SMEs.

At the core of this assessment is the fact that an understanding of the PV domain is essential in order to deliver the next-generation, automation-enabled platform. There is no 'shortcut' approach in pharmacovigilance, and anyone offering such an approach, or a half-baked solution, must be carefully evaluated. There is no doubt that various steps within PV processes can be automated; however, this must be done in a systematic manner, involving those who understand the domain from the PV as well as IT perspective.

Conclusion
Cognitive computing has the potential to transform the practice of pharmacovigilance, from a tedious, resource-intensive process to a dynamic and efficient practice. Instead of focusing on the manual and repetitive tasks of collecting and processing adverse event cases, pharmacovigilance departments can then focus on the truly scientific and endpoint oriented tasks such as benefit-risk assessment and risk management.

ArisGlobal is building the next-generation, automation-enabled platform that will revolutionise the way ICSR case processing is done today. Our approach to automation is focused on solving business/operational challenges faced by the industry. We have deployed a highly skilled team comprising domain experts in PV, IT and artificial intelligence, having significant years of experience in their respective domains. This team is backed up by our cognitive computing experts who have built and delivered a safety system to global pharmaceutical organisations for over 25 years.

More information about the role automation plays in pharmacovigilance can be found by viewing the ArisGlobal on-demand webcast "Productivity, Compliance and Quality: The Holy Grail in Pharmacovigilance."

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Until recently, he was responsible for Global Pharmacovigilance at Bioclinica, managing all components of pharmacovigilance, such as end-to-end case processing, aggregate reporting and signal management for global pharmaceutical organizations. Under his leadership, the safety business grew substantially with the acquisition of many large pharmaceutical accounts.

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