

Selecting a Strategic Artificial Intelligence and Pharmacovigilance Focused Technology Partner

Alejandra Guerchicoff, Ph.D.

Industry Leader, TCS ADD Safety Life Sciences Platform

Over the past decade, Life Science Industry has witnessed and been at the forefront of an unprecedented technological revolution in Pharmacovigilance (PV). With a spurt in innovations, advanced scientific discoveries, personalized medicines, and global portfolios, the Life Sciences industry relied on digital technologies that were able to handle the innate complexities. Technology organizations responded by conceptualizing and developing disruptive Artificial Intelligence (AI) and Machine Learning (ML) platforms and bring them into the market that have gradually replaced the traditional point automation PV tools.

Strategic early adopters and visionary industry leaders in the Life Sciences space have already realized the benefit of leveraging digital and advanced technological approach including AI& ML to solve complex challenges and introduce intelligent systems into the PV process. However, merely recognizing this aspect is half the battle won, it is essential to build applications partnering with the right cognitive automation provider. Collaborating early on offers multiple benefits including risk mitigation, innovative strategies, and a faster speed-to-market.

Secondly, it is imperative for Life Science Industries that wish to be successful in embracing the PV digital transformation to have alignment from key stakeholders within their organization on the following elements:

- Key business use cases for an automated platform
- Practical and achievable implementation timelines
- Effort estimation from Industry teams to implement new digital tools
- A robust rollout plan and effective change-management process
- Accurate support and feedback from the technology partner to build and understand the gaps, challenges, and risk they would need to overcome from its traditional PV model to the new digital automated system
- Ability to implement digital and flexible solutions to adapt and evolve to the evolving technology landscape

Only post alignment of key decision makers on all the above elements can any conversation on next-gen technology be pursued. Next up, selecting an experienced AI-ML technology provider can directly impact the outcome of the entire PV system, reporting, and risk management. Life Sciences industries need to evaluate the following considerations when selecting a digital technology provider that excels in the area of PV:

Technology Experience: Provide robust, reliable, and an impeccable track record of successful implementations in an integrated area of services and technology, specializing in Pharmacovigilance operational and scientific excellence and coupled with deep digital and cognitive automation development experience.

Product Implementation Experience: Demonstrate evidence of its AI Platform in production as well as offer Proof of Concept projects and be able to show metrics and experienced results. The provider should be able to guide the organization toward full adoption of cognitive automation-based PV model, function by function, beginning with a pilot project.

Value-based Roadmap: Provide an industry roadmap reflecting the technology providers understanding of where the Next Gen PV is evolving, illustrate the value driven developments, and define the key capabilities planned to be provided by technology is planned for addressing current and future PV challenges and needs.

Safety Case Processing Coverage: Enable safety case processing automation spanning the entire spectrum of activities from Case Intake, Triage, Data Entry, Processing, Medical Coding, Causality Assessment, Analysis, Narrative Writing and Reporting. Powered by niche technologies such as AI, ML and Natural Language Processing, the technology provider should be able to handle high safety case volume with quality, accuracy and consistency.

Scalable: Provide scalable cloud hosted platforms enabling quick handling of large safety case volumes & spikes, unpredicted safety situations (such as Covid-19 safety related issues), product launches, product acquisitions, and/or changes in regulatory requirements.

Minimal Disruption to Existing Process: The PV technology should be implemented with minimal or no Impact on the existing business process as well as with limited dependency on customer's resources.

Explainable Technology: Explanatory decision trees and audit logs for 'anytime inspection readiness' is an essential pre-requisite in pharmacovigilance. The technology provider should empower users with access to complete Audit Trail including full traceability of actions and decisions taken by the AI system in a human readable log.

Learning Management: The PV system should have the ability to learn and apply the new learning with every case processed and the repository of learnings should continue to grow with variety and volume of cases processed. The technology should also enable human governance on machines & human identified learnings through defined change management thereby facilitating machines to learn from its own and reviewer's action, draw inferences and solicit approval from human to inculcate the learnings gained.

Tangible Efficiencies: Implementation of an innovative automated PV model should augment efficiencies in PV delivery in view of current and future changes and challenges.

Every organization is different with varying business processes, organizational structures, and technical requirements. However, there are some common objectives where all of them converge: the need to implement PV automation with open platforms being one among them. There are different ways to implement a cognitive automation-based PV platform: build your own platform, assemble, and integrate disparate tools from other solutions, or deploy a ready to use AI solution. Depending on an organization's business goals and technology capabilities, any one of the above options works better than the rest. This article aims to provide a guiding philosophy for such organizations that are about to embark their next generation technology roadmap in pharmacovigilance with a best-fit Technology Partner.