A Beginners Guide to AI driven Pharmacovigilance Platform

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Introduction

The time for innovation is now. Innovation has always been at the heart of Life Sciences (LS) Industry to provide the ability for managing the ever-changing regulatory landscape. Within the next 5 years, new technologies like Artificial Intelligence (AI) and Machine Learning (ML) will have the potential to shape and revolutionize every step of the Pharmacovigilance (PV) process. It is with this vision that encourages LS organizations today to identify and look for adoption of an AI-based approach to intake and process safety cases in PV. Innovation also acted as a motivation for us to write this paper and share our experiences and recommendations in implementation process to other LS organizations that are exploring this area.

Traditionally, LS organizations haven't been a pioneer in adopting digital technologies. While few of them have seen significant benefits by being early adopters of AI-based technologies, widespread implementation of modern technologies has been extremely slow. However, with more organizations embracing AI automation-based technology adoption and benefiting from it, this will greatly influence others to follow. Thus, industry leaders are continuously looking for adoption tools and innovative practices to implement newer technologies and remain competitive.

Let's get back for a moment to our first line: ***The time for innovation is now, but why is it now****?*
We are living in the era of data and innovation, that is constantly changing our work landscape. In 2010 the Worldwide IP traffic exceeded 20 billion gigabytes per month[1]. In 2014, Global System for Mobile Communications Association (GSMA) reported the number of mobile devices at around 7.22 billion, while the US Census Bureau reported the number of people globally at around 7.20 billion[2]. And finally, a 2017 HBR report stated that the global electronic devices users generated 2.5 quintillion bytes of data per day[3.] Suffice to say, we are living in an era of data. At the same time, while handling this amount of data represents one of the biggest challenges for the industry, it is also the key foundation input for a validated AI system, to allow proper management and adoption[4].

The LS Industry is looking to transform legacy business practices & technology using digital PV services automation and AI[5]. Early adoption of AI provides an advantage to compete and build stronger global pipelines, enhanced efficiencies supporting faster turn-around-times, and support safer and more effective products through improved quality of data and regulatory compliance. Safety case processing is a high-value, high-data volume, transactional processing activity.

New-age AI technologies and cognitive automation solutions can make PV process faster, agile, consistent, accurate, compliant, and more efficient. Even though there is no viable "one-size-fits-all" approach to adopting an AI-based PV solution, there is a consensus that technology is an imperative for transforming LS Industry PV model. We believe the information gathered from our experience clearly presents benefits of AI on operational safety case processing and transformative impact on PV.

Core visions

- Leverage an AI-driven platform to increase productivity, improve product safety analysis, drive business growth, support in budgetary responsibility, and bring innovation
- Realize a digital organization with performance excellence capabilities through enterprise agility and digital AI case processing

Our objective

Sharing our experience on AI-driven technology adoption in PV

From adoption to value

There are 3 phases to the AI-PV based transformation process:

1. Cognitive automation Aware
2. Cognitive automation Ready
3. Cognitive automation Capable

Clearly understanding future capability requires proper forecasting in addition to investing in training high-caliber employees during the early stages to enable faster scale-up and improve success of the project. From a technology vendor perspective, a well-designed implementation model should include domain competency brought by the right team. To assist in accomplishing this, a seed team of domain PV Subject Matter Experts (SMEs) would kick start the project, establish the system training phases, set-up delivery support processes, Standard Operated Procedures (SOPs), and all measures of quality control as required.

The solution would be created/implemented by a team of technology and PV experts together to ensure that the project runs seamlessly. Proper planning from beginning to post completion through hyper care is required to ensure its success. The implementation process should be governed centrally by a Delivery Team and all milestones must be jointly owned and monitored closely to ensure effective quality control. The transformation journey enablement should use an agile methodology based on 5D approach (Define, Design, Develop, Demonstrate & Deliver. See Fig.1) to enable AI features aligned with maturity assessment and governance plans. When organizations undertake the agile approach, they can implement safety case processing automation quickly and receive significant value even if end-to-end safety case processing is not fully automated.

Figure 1: 5D transformation methodology

To succeed, organizations need to invest efforts and resources to the AI-PV initiative by creating a Business Process Mapping identifying business rules and scaling strategies for the selected approach. As stated earlier, each company will be different in their approach based on size, technology capabilities, and case

volumes/types to consider to be utilized for automation. The Business Process Mapping is a joint effort from the PV team in LS organization and technology provider with the aim to enhance adoption efficiencies while being able to anticipate and mitigate possible program risks, built off from a business case. The entire process should follow standardized protocols and procedures for scaling up to build, deliver, deploy, and adopt an integrated, coordinated, comprehensive, and functional AI-PV Platform. Equally important is to create an adoption consensus (strong Change Management) and a cross functional buy-in agreement across the organization along with 3rd party vendors, generating strong, symbiotic interactions amongst business, IT, PV and technology provider functions.

The Implementation Steps

An AI-PV driven Platform adoption follows the following 7 enablers (See Fig.2)

Figure 2: Adoption technology enablers - From cognitive automation aware to capable

1. PROGRAM STRATEGY

Development of a long-term strategy around an AI program is required for overall success. With newer innovations, companies must be nimble enough to adapt and modify their positioning on future goals and how they will achieve them. A road-map strategy will ensure proper planning and adoption for different stages along the program development.

Adoption of an AI-PV platform is not a proof-of-concept use case experience, or simply an exploratory experiment. To be successful, it is necessary to obtain executive management sponsorship and buy-in by demonstrating the overall benefits and Return on Investment (RoI). Changes from a traditional pharma process to an operating AI-based organization invites disruption and requires top-down leadership to understand the business value. Before implementing an AI-PV platform in any organization, its leadership team needs to set clear goals, define robust business cases for investment and financial commitment, as well as adopt an agile approach to design and scale up pilots. To succeed, it is essential to commit to the vision and the decision to make long-term strategic investments as well as be agile to adapt to those plans within evolving technology landscape.

A well-designed Program Strategy should consider the following:

a. Understand if AI for PV is a viable solution for the organization depending on maturity of PV along with defining success metrics
b. Prototype a business case that can be tested and piloted
c. Identify Key Performance Indicators (KPIs) that would be the driving factor in determining if the program would move forward. This will also assist with measuring the levels of success based on different implementations

d. Define implementation strategy built off from a business case to decide on different phased approach versus big bang launch. Speed of implementation might as well be a determining factor
e. Determine whether in-house, add-on or integrated solution from database is provided
f. Define budget required for build out
g. Determine Change Management activities early on in project to ensure acceptance of change and support aspects of project, including KPIs

2. PRE-REQUISITES FOR DIGITAL AUTOMATION

For a successful implementation following are the bare minimum pre-requisites

a. **Foundational technical capabilities:** A successful implementation requires establishing a data-integration connectivity layer to access historical and relevant data sources, including safety databases and other repository systems. At the same time, data-governance policies are required to ensure that existing and new data is immediately ready for machine training consumption and use. The data science team must develop algorithms and the required level of transparency of model outputs based on existing safety cases and the type of data available. The AI-PV Platform provider must also design technical foundational capabilities to scale from the start and create integrated, comprehensive protocols to build and deliver AI solutions that adopt learning loops and avoid increased technical complexity caused by incremental, uncoordinated technology choices. The platform's user interface is also created at this stage.
b. **Business processes architecture:** The PV department represents a technology paradigm for AI adoption. PV data usually resides in different databases, sometimes even in different siloed systems, in different languages, and mostly disconnected. In some cases, source documents and product labels are not digitized. The first step in adopting an AI-PV Platform is teaching the machine to think, make determinations and predictions as the PV team does. The machine training begins with existing data in digital format and enough volume of clean, target attribute, and labeled data available for consumption. This digital data "training sets" will act as a base model for each algorithm that shall be used by system when in production. Lack of digital data sets and poor quality and quantity of data will affect the possibility to achieve accurate output. Implementation is a long and intense phase, but once the models are created, they are very efficient in providing accurate results. Hence, before starting the program it is imperative to examine this challenge and solve this business process architecture step.

3. CHANGE MANAGEMENT

Successful transformation for any implementation should focus on Change Management aspects which begins with a centralized organization for support, such as a Center of Excellence (CoE). The CoE, focuses on initiatives driving innovation within an organization to ensure successful adaptation and acceptance of large-scale changes. As an optimal option, the CoE is responsible for defining the scope and impact of the project, operating model, standards and to build a transformation led thinking inside the organization as well as sponsor engagement/support. Digital transformation in PV requires essential mindset changes for not just staff within PV, but also cross functional teams who support the end-to-end processes. These changes result in major implications for the organization and for individuals, which should be managed through proper Change Management. There are several Change Management models to consider for an implementation, however consideration of certain factors is imperative to the overall success of the project

a. Define and communicate Change Management methodology
b. Create workstreams to support project and staff in Change Management for overall project
c. Key aspects for Change Management model include:

i. Stakeholder assessment
ii. Voice of customer feedback
iii. Monitoring of acceptance and risks
iv. Training support and models
v. Process and policy impacts
vi. Defined ambassadors to support change
vii. Messaging – forms and types of communications
viii. KPI measurements for success

A solid Change Management program will lead to acceptance and sustained results of the changes implemented, in addition to the optimal performance of people, processes, and technology.

4. IMPACT DRIVEN STRATEGIC ROADMAP

Most large-scale automation projects are implemented through a multi-phase approach and as such, possessing an accurate roadmap detailing out the path to final vision is critical to the success of the initiative. In-line with the modern agile-based project execution, it is a common practice to follow a Minimum Viable Product (MVP) based approach when designing the roadmap with the idea that initial phase of the roadmap will deploy a limited scope implementation for a quick validation. However, for automation-based initiatives where the drivers are to achieve effort efficiencies and/or increased process quality, the MVP based approach does not lend itself well. This is because, the effect of automation may not be significant or very visible until enough process components are automated.

The key pre-requisites for designing roadmap for automation-based initiatives is to perform an end-to-end baseline of the current process detailing out process steps at the lowest level possible and identifying opportunities for automation along with impact of automation towards the desired goal. The guiding philosophy when designing a roadmap to achieve end-to-end process automation should be to pursue automation in all approaches from the basic rule-based automation to integration based, robotic process automation and AI-based approach with a goal to maximize the process steps being automated. With the organizational interest in process automation being high during the initial phases of the program, designing a highly impactful roadmap with achievable tangible targets throughout is crucial for continued investments in automation technologies.

Since the PV process is being stratified across various sources, process steps, and product lines from where information comes in, it provides a natural way for designing impact-driven roadmaps. One example is where the entire road map was designed along the following source types (See Fig.3). Each phase is designed with an identified impact to the business KPIs to be achieved with the introduction of automation.

Figure 3: Road map-based model on source types

Another example of road map would be to design the phases by the process steps (See Fig.4).

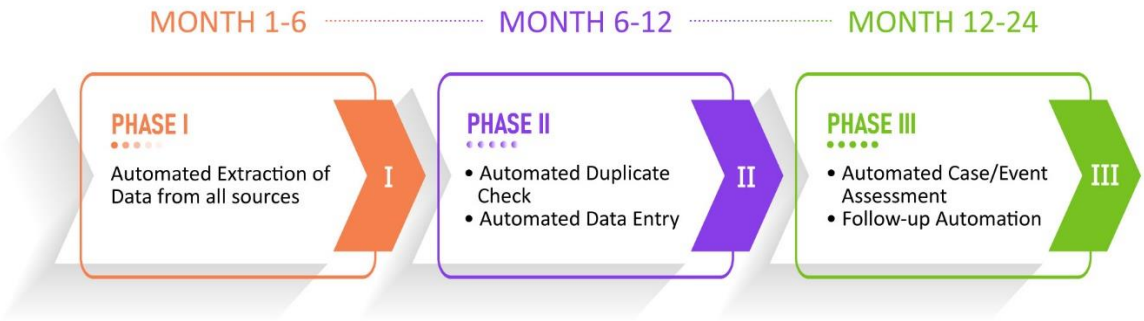

Figure 4: Road map-based model on process steps

5. A FOCUSED GOVERNANCE PLAN

A poorly designed implementation plan can cost more and take longer than a properly planned, governed, and executed one. To avoid this, it is necessary to create a focused governance and operational plan and team with the key objective to scale up, monitor project evolution and accelerate platform implementation. The governance model will ensure coordinated project management across functional, technical, and business areas and efficiently deploy the AI-PV Platform.

The governance plan should include the following 8 components:

Governance plans should comprise of efforts invested and personnel involved during end-to-end implementation. The governance and operation plan should ensure adherence to timelines and quality of the delivery protocol.

6. BUSINESS-DOMAIN ADOPTION MODEL

The move to an agile AI-PV platform adoption will more likely succeed if interest begins at the top with early engagements of the PV front-line team. PV leaders and company executives should be the first to support the implementation project, drive the mindset change, and follow the project through to results. Developing a business-domain data adoption strategy will separate a company from getting caught in an eternal Proof of Concept (PoC) to the one that is able to drive and implement a real digital transformation. The new AI-PV structure requires extensive re-organization of the existing structure and workforce, and this is only achievable if there is unified business, domain, and technical vision.

Final Remarks

Innovation has always been at the heart of the LS industry. However, only few organizations have experienced significant benefits from technology-based AI-PV Platforms. This may be due to the significant upfront investments required, and the fact that some organizations are not large enough to justify such investments. In other cases, the absence of quick wins, immediate performance benefits and investments required to build adequately sized AI-PV Platform and automation business cases, do not meet expectations for creating business value.

The urgency for new, safer, and more efficient drugs is greater than ever. Implemented timely and properly, AI-PV Platform will provide tangible business outcomes to an organization. AI-based platform enables agile, forward-thinking LS Industries to find new opportunities with a proactive PV approach; manage data volume, evolving regulatory requirements, product safety & quality signals, and deliver enhanced innovative products to market faster.

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