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Digital Advangage for Life Sciences

Building on belief

Next-gen pharmacovigilance- five key digital transformation drivers

Abstract

Digital technologies are being increasingly leveraged in the processing and handling of safety cases due to the advancement of novel, intelligent and automated pharmacovigilance (PV) platforms. Rapid development of these platforms has enabled the processing of safety report volumes in an extremely short period with reduced efforts, leading to improved safety analysis and regulatory compliance.

However, the adoption and shift from traditional pharmacovigilance model of mostly manual interventions to a next-generation automated and intelligent model represents technical challenges and organizational changes for the industry. The agile and decentralized nature of the next-generation pharmacovigilance approach brings in quality, efficiency, and more importantly, organizational adaptation that helps the industry to not only withstand but prosper amidst ever-evolving business and responsibility paradigms.

Introduction

The life sciences industry is at an inflection point with charting out its future journey and envisioning a new approach to pharmacovigilance. While the industry continues to innovate and remain one of the most advanced and cost-effective breeding grounds for new products and drugs, there is a pressing need for enabling and accelerating digital transformation of the safety surveillance process to facilitate next-generation pharmacovigilance.

Multiple factors have played their part in accelerating the introduction of intelligent automation in pharmacovigilance. With the ever-increasing volumes of safety reports from new and numerous structured and unstructured sources, there has been an exponential increase in workload and operational overheads for pharmacovigilance professionals. Coupled with the steadily increasing discovery, development, and marketing costs, the life sciences industry faces many challenges in bringing products to the market while meeting safety and compliance standards.

The PV paradigm is evolving, and traditional systems and processes are proving to be unsustainable to handle the data deluge in the near future. The industry needs to invest in novel and advanced PV platforms that enable the processing and analysis of data in real-time to bring safe products to patients in need, and on time. In this paper, we look at the five key digital transformation levers that have the potential to be gamechangers in conceptualizing an all-encompassing next-gen pharmacovigilance model.

1. End-to-end safety case processing using AI/ML

Product safety surveillance remains a top public health concern. The volume of safety reports continues to increase steadily with cases aggregating from a growing number of data sources (structured and unstructured). Regulatory agencies too have increased their safety surveillance requirements and practices to enhance transparency, data collection, processing, and safety signal detection procedures. A changing and evolving regulatory landscape requires technology adaptation, as its impact on existing operational model, processes, and procedures makes compliance costly and more difficult to achieve.

To manage this ever-increasing safety case volume in a continually evolving regulatory environment, organizations need to embrace disruptive technologies and automated, innovative, and intelligent solutions to handle safety cases in an efficient, cost-effective, and timely manner with improved accuracy and quality.

Companies in the life sciences industry need to carefully evaluate the choice of new technologies that provide the ability to derive safety information from human-readable text obtained through a variety of sources, including medical literature publications, information from legal cases, social media, etc. Industry leaders are looking at new digital technologies, such as artificial intelligence and machine learning, as a solution to improve compliance by remapping PV resources from repetitive administrative roles to value-driven medical and scientific tasks. The next-gen PV ecosystem provides a tectonic shift from point automation solutions with special-purpose tools to a broader reuse of machine learning capabilities across the PV lifecycle, and based on commonality across the use cases.

2. Proactive pharmacovigilance

In today's data-driven world, the life sciences industry faces multiple challenges to collect and analyze high data volumes in real-time. Traditional models offer mostly a reactive view in the form of past aggregate reports to understand and evaluate the product benefit-risk profile. This implies that decision-making is largely dependent on the past data.

The next-gen PV model leverages advanced and predictive analytics, global real-time information, and intelligent signal detection and management to assist human decision-making, improve safety, maintain the benefit profile, and minimize risks during the entire product life cycle. The futuristic model, unlike the traditional one, would be able to efficiently predict and manage workloads (for example, product launches, strategic merges, etc.) as well as manage unexpected spikes without affecting budgets.

Automated, integrated, intelligent and cognitive solutions reduce process times and provide cost efficiency, actionable insights, and evidence-based decisions, thereby transforming PV from being reactive into a proactive, sustainable, and agile model across portfolios worldwide.

3. Unified analytics data environment

The next-gen PV not only provides increased efficiency and quality of safety case processing but also creates an ecosystem wherein discovery, scientific and omics, R&D, clinical, safety, and real-world information is integrated and consolidated to improve human health.

The new approach can succeed only if it can support the development of personalized medicines and health products from the initial stages of scientific data to market use. As artificial intelligence and machine learning are the foundational technologies here to integrate data, thereby providing a synergistic benefit on the early identification and management of risks as new data is available, and the possibility to make more timely and strategic decisions.

Today's challenges for life sciences lie with siloed and disparate data not meeting the standards in addition to the intense manual effort required for processing datasets and extracting meaningful information. A unified analytical data environment is a key enabler to advance into strategies that rapidly bring medical innovations to the market.

4. Technology transformation

The entire pharmacovigilance process is undergoing a fundamental shift due to the introduction of disruptive technologies. The agile and decentralized nature of new technologies bring in quality, efficiency, and more importantly, organizational adaptation. The industry must adapt itself if it intends to stay afloat with evolving business and responsibility paradigms.

Traditional PV models and infrastructure are fast becoming obsolete. A cloud-first strategy will soon become a business imperative to enable cross-leverage of learnings across organizations with the ability to scale and amplify the pace of adapting to the fast-changing regulatory environment.

The next-gen PV model is business-driven and mapped to operational efficiencies. It is attuned to support variations in demand, such as product launches, mergers & acquisitions, different phases of the product development lifecycle, regulatory requirement changes, or any unexpected safety emergencies (for example, during COVID-19-related pandemics).

5. Integrated communication

Existing PV systems provide limited communication to stakeholders resulting in inefficiencies[1]. For any innovation in the industry and the evolution of the PV process, the industry needs to enhance communication of safety information among PV team members, across other functional areas, and externally with regulatory authorities, third-party organizations, physicians, and patients.

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[1] NCBI, Pharmacovigilance: A Worldwide Master Key for Drug Safety Monitoring (Jul-Sep 2010) *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2964775/, Accessed on Jun 02, 2021*

The next-gen pharmacovigilance changes the traditional PV paradigm. For an enterprise, it is a complete and comprehensive transformation that creates value for the industry and involves systems, technologies, processes, and people around the globe. Strategic and visionary industry leadership emphasizes the adoption of new and advanced digital technologies as a means to help people succeed in their roles, and to retain and upskill team members by transforming administrative and manual tasks into high value jobs.

Conclusion

Now more than ever, the life sciences industry is facing a new era of transformation and must look into reimagine existing PV processes to reduce cycle time, and bring in greater transparency, quality, efficiency, and agility to the organization.

This shift requires strategic and visionary leadership coupled with organizational change to drive the PV transformation. The implementation of a new, proactive, digitized, and innovative PV system based on collaborative partnership with a trusted technology innovator will allow the life sciences industry to operate efficiently with assuredness and success.

About the author

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Dr. Alejandra Guerchicoff is a Ph.D. in molecular genetics with a postdoctoral training in molecular cardiology. She is working as an Industry Advisor for TCS ADD platform with the Life Sciences unit at Tata Consultancy Services (TCS). Dr. Guerchicoff possesses a rich experience of more than 20 years in the domain of clinical research and post-marketing pharmacovigilance for medical devices, drugs, combination products, gene and cell therapy, and software as medical device products. She has authored many prestigious journal publications and books on diverse subjects and different therapeutic areas. In her current role, Dr. Guerchicoff is working for the development of innovative technology solutions with the use of artificial intelligence and other modern technologies across various life sciences operations.

About TCS ADD Platform

TCS ADD is a modern and open drug development platform for life sciences that enables digital ecosystems, simplifies data complexity and provides faster access to new and effective drugs for patients in need. The platform is powered by our proprietary cognitive intelligence engine data driven smart analytics and Internet of Things (IoT) that makes clinical trials more agile and safe. TCS ADD leverages the best of cloud architecture and personalized user experience design in compliance with quality guidelines and privacy regulations.

To know more

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