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Biopharma needs to smarten up:

The Role of Intelligent Automation in Pharmacovigilance

PVAutomate

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Summary

Drug safety professionals have long endured the monotony of entering clinical and demographic data. And their employers have incurred both the high cost of those salaries as well as the indirect cost of lost opportunity resulting from the burden of executing low-value tasks. Digital transformation has opened a watershed of new possibilities for pharmacovigilance (PV) professionals, and life sciences organizations alike. Intelligent automation (IA) in particular, with its inherent capabilities of delivering data-informed and expert rules-based activities, now enables biopharma organizations as a whole to benefit from improved safety, greater precision, higher accuracy, reduced costs, and deeper patient engagement. In this whitepaper, we review the challenges of the PV field, discuss opportunities for improvement, and showcase how IA can have a positive impact on both patient safety and an organization's operational efficiency.

Introduction

As defined by the World Health Organization (WHO), pharmacovigilance (PV) is known as "the science and activities relating to the detection, assessment, understanding, and prevention of adverse events or any other drug-related problem." Achieving the desired outcomes of a medical treatment (new or established); decreasing morbidity, mortality, and the cost of treating diseases; along with improving patient quality of life are some of the outcomes of effective PV. There's little question about the value and criticality of PV in healthcare or about the importance of a digital transformation strategy in biopharma. Without the latter, collaboration, data collection, and reporting are all compromised. However, the role of artificial intelligence and the benefits of intelligent automation (particularly within the content of biopharma research, development, and commercialization) are not well understood.

Intelligent automation is the informed application of higher technology. In simple terms, it is the intersection of robotic process automation (RPA), analytics, optional and/or intelligent character recognition, plus artificial intelligence (AI). Despite the business imperative of intelligent automation, the biopharma industry has yet to fully embrace it.

"Slow adoption rates" is not how the industry's behavior is typically described. That said, the industry appears to be playing catch-up and may even be lagging behind where it should be. Developing countries are increasingly becoming targets for expansion as emerging markets, particularly in Africa, Asia, and Latin America which is fueling rapid growth and the need for efficiency plus optimization of operational processes. And, as the Boomer cohort advances simultaneously down the paths of aging and expecting more healthcare treatment options with greater efficacy and a higher level of personalization, the global market cap is quickly accelerating towards $1.5 Trillion [1]. This figure was suggested by the International Federation of Pharmaceutical Manufacturers and Associations (IPFMA).

Global competition, patient-centricity, a growing demand for transparency, and enhanced regulatory pressures are collectively underscoring the need for biopharma—and the life sciences industry in general—to adopt more agile and efficient operational practices. In short, the need for intelligent automation is clear. COVID both catalyzed this need and demonstrated its value at the same time. Biopharma researchers around the world united, set aside the bureaucratic burdens around intellectual property ownership, and rallied together in a global battle against public enemy #1: Coronavirus. Although it's premature to declare victory in the pandemic, enabling communication and the rapid exchange of critical information in the spirit of collaboration via a digital, cloud-based research environment spurred a result that nobody previously thought possible. Both Pfizer and Moderna developed novel vaccines (mRNA) in about six to eight months whereas 10-15 years has been the observed standard [2].

Technologies like Next Generation Sequencing (NGS), rapid whole genome sequencing (rWGS), rapid polymerase chain reaction (PCR), and rapid prototyping all played a critical role in the timely identification of key genetic factors [3]. Specifically in reference to the pandemic, rWGS enabled researchers around the globe to quickly identify gene mutations, to track virulence, and to jointly analyze clinical outcomes of the world's largest clinical trials and population trials in the history of mankind [4]. In the absence of a cloud-based digital strategy, augmented by intelligent automation, it is highly unlikely that more than 9 billion COVID vaccine doses would have been administered worldwide in less than two years after the novel Coronavirus announced its arrival on Planet Earth: to date, 57.4% of the total global population has received at least one dose [5]. The heightened pressure on biopharma to develop a COVID treatment—and a cure—spurred accelerated adoption of digital transformation, the inclusion of AI, machine learning (ML), and natural language processing (NLP) technologies and set the stage for intelligent automation to emerge from a proof-of-concept phase to a proof-of-value stage.

Overview of Challenges

PV as a field has numerous challenges at the global level [6]. Some of these challenges are coupled with intellectual property rights issues and the fear of litigation for an adverse event. As a result, deliberate under-detection, under-reporting, and even parallel reporting by different providers creates anomalies in the data.

It all begins with case processing. Adverse event reporting enables the detection of early safety signals which can be analyzed for benefit-risk and inform next steps with the given therapy. Not surprisingly, the quality of the safety data collected, including its precision, are both critical at the foundational level to enable proper analysis. With accurate information, corrective actions can be made in a timely manner as well as safeguard the patients who are receiving the treatment.

COVID-19 treatments introduced a massive perturbation into the field of PV. As a result, adverse event (AE) reporting has increased exponentially which has further exacerbated the challenges of case processing [7]. Innovation is the mother of the necessity and the flurry of AE data required solutions that enabled automated intake, triage, and preliminary interpretation by intelligent software to streamline and optimize the efforts of the PV experts. Robotic Process Automation (RPA) is a tool that has been heavily leveraged; especially since the onslaught of the pandemic began. Back in 2018, a study revealed that only 62% of drug safety experts surveyed approved of using artificial intelligence in AE processing [8] but, by 2021, given the volumes, there really was no other traditional option to consider. One of first applications of AI in case processing is the translation of data into English—an absolute essential for the English—speaking PV experts who were amassing COVID-19 data collected from around the globe.

Case processing amasses vast quantities of safety data shared by and amongst numerous stakeholders. These include patients, caregivers, healthcare professionals, and authorities. Numerous steps including receiving the case report, registration, validation, triage, duplication checking, data entry, quality control, medical assessment, reporting, closure, and archiving the case. That's a lot of steps—and a lot of data passing to/from disparate sources and destinations. Given the number of steps and data transfers involved, case processing errors are commonplace.

During case processing quality audits, PV personnel frequently see errors.

Incomplete reports, including medical reports that are missing key details or the absence of accompanying medical data, are the error cited most often. Discordant data, such as a gender selection in the patient demographics followed by a note in the same report that references a different gender, is also common. Coding errors categorizing or mis-categorizing the treatment received routinely surface in case processing. Finally, general narrative errors like spelling mistakes, typos, unchecked boxes, and so on are encountered frequently.

A best practice is to ensure that whoever does the data entry is a different person than the one who performs the quality control review of the data entered. Randomized spot-check audits can go a long way in ensuring consistent quality in case processing. When an error is detected, analysis to understand the source of the error and how it can be prevented in the future via the Corrective & Preventive Action (CAPA) protocols is imperative to avoid repeats.

Opportunities for Improvement

Over the last decade or so, PV has evolved from low-level and basic regulatory compliance to a proactive, predictive field enabling risk profiling and modeling. This expanded remit and increased sophistication was partly spurred by 2012 EU legislation which included risk management plus minimization, as well as the introduction of national and regional reporting systems [9]. Increased regional (and even global) coordination of AE reporting has enabled swift recourse and corrective action at increasingly early stages of safety signaling.

Gene therapies are personalized treatments administered to one or only a handful of patients at a time. Small cohorts of patients that are typically immune-compromised, exhibiting multiple co-morbidities, and ingesting multiple pharmaceuticals, coupled with the complexity of biological medicines deliver a 1-2 knockout punch when it comes to accurately interpreting safety data. PV experts need tools to help them filter out the effects of the new therapy from the effects of the other therapy or the combination of other therapies. That's no small task. Here, intelligent automation offers great promise across the full value chain and biopharmaceutical research to commercialization life cycle.

Success of IA depends on three critical factors. Any organization implementing an IA strategy should consider the following:

1. Governance: Build trustworthiness into the automation ecosystem by tracking all processes including bot activity. Designed properly, it can help meet SLAs for superior process efficiency, refine human and bot deployment plus interaction, and guarantees compliance to standards.
2. Process Discovery: Data-driven process discovery tools can be coded to watch over complex pharma processes. They can be designed to identify bottlenecks as well as reduce their incidence via automation, resulting in increased operational efficiency.
3. Scalability: Ineffective human-bot governance, poor exception handling, incompatibility with disparate bot vendors and other technologies can prevent automation implementations from scaling. Organizations interested in operating at a scale beyond a few bots should consider enterprise-wide deployments of IA so that performance and efficiency are optimized at every point of data transfer.

The Application of Intelligent Automation

Replacing perfunctory tasks like upload, copy, paste, and save is an obvious application of intelligent automation (IA) and a simple augmentation of RPA functionality. IA offers a key to unlocking the success of digital transformation. Less obvious, and more impactful, are IA-enhanced workflows and other rulesbased solutions. Advanced capabilities including ML algorithms and sophisticated modeling have been demonstrated to have the ability of performing pre-emptive tasks and even predicting the next (and best) course of action [10]. Outcome-based ML, cognitive document processing (ML-enhanced optical character recognition), conversation agents (chatbots) and AI for business-centric solutions further enrich the quality of the operation across the entire organization.

The benefits of IA in life sciences are significant and will help organizations to scale organizational capabilities by automating processes and integrating systems—from operations to drug discovery—for flexible capacity on demand. Companies can improve quality and accuracy to reduce risk and costs with error-free complaint handling, PV, and AE reporting. Utilizing IA, real-time analysis and decision-making can both be leveraged to yield high quality care even in emerging situations with high data volumes. Faster regulatory documentation and reporting to fast-track clinical trials, the provision of timely regulatory updates, and reporting by automating data collection, collation, and audit via IA frees up high-value resources by minimizing or eliminating time wasted on manual or low-level and repetitive tasks.

Related peripheral benefits include shaping agile supply chains for business continuity by shielding volume surges to ensure an uninterrupted supply of drugs and medical supplies. One of the most significant ways IA can aid life sciences companies is through market access; automated product pricing and reimbursement is better for patients, providers, and payors.

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Nearly every department within the biopharmaceutical or life sciences company can be positively and directly impacted by IA and realize its benefits.

Medical Affairs

- Medical information service
- Adverse event reporting

R&D

- Hypothesis generation
- Drug discovery
- Data modeling & analytics

Clinical Trials

- Patient search
- Patient support
- Patient clinical trial enrollment

Supply Chain Management

- Invoice Process Automation
- Manufacturing
- Order Shipment

Marketing and Sales

- Sales Automation
- Outreach research
- CRM

Medical affairs: Streamlining the complex and highly regulated processes for pharmaceutical and medical device companies to report and process all product issues, adverse events, and complaints. For example, a typical global pharmaceutical company processes 100,000 adverse events worldwide. Automating this process can save millions of dollars and reducing cycle time by 40%.

R&D: Reducing time and delays in submitting new drug applications (NDA) and completing extensive regulatory documentation (FDA) to secure approval to bring new medicines to market can save lives. IA can help reduce submission process time by four months and reduce time by 33% for quality checking in regulatory documentation.

Clinical Trials: Applying AI-powered automation in clinical trials and research can accelerate participant recruiting and patient monitoring by integrating data. Additionally, IA can automate manual processes and extract document information.

Supply Chain Management: A common activity for life sciences companies is enterprise document management (EDM) which requires a lot of manual data entry, particularly in manufacturing. The EDM process can be automated through ML-assisted document classification with intelligent word recognition and extraction which can then be parsed (or translated) into key-value pairs to create a capability called "cognitive document processing." When linked with the use of RPA, significant cost savings and just-in-time updates can be automated, overriding the need for manual intervention.

Marketing and Sales: IA enables faster and error free customer-specific data, ensuring that patients get all and only the information pertinent to them or their caregivers. In essence, it enables personalized marketing. The outcome is an improved patient experience that can foster engagement as well as loyalty.

Conclusion

Internal optimization and efficiency which result in fewer missed drug safety signals and reduced operational costs are the end-game of most life sciences organizations implementing IA. However, beyond the key outcome of patient safety, an important benefit not to be overlooked is patient engagement and satisfaction. With increased access to medical information via the internet and a plethora of government-approved and accredited sources on the web, patients (and their families) demand a higher level of transparency and engagement from their providers.

IA-enabled bots can handle many of the patients' routine questions which frees up the human agents to address the more complicated patient queries. Conversely, patients need an accessible forum to report how they are feeling so that those data can be readily collated and analyzed as part of the company's safety signaling efforts. Such forums can be highly beneficial to capture and halt the use of unapproved and potentially dangerous "home remedies" that lack clinical evidence of efficacy. For developing countries where such remedies are routinely practiced are already compromised by poor or under-reporting; an IA solution can augment the vigilance for drug safety practitioners and strengthen reporting, documentation, and communication practices to minimize the potential harm of such remedies [11].

Digital transformation, with purpose-built automated solutions have already proven to be critical for improving and expediting treatment as evidenced by COVID-19 and the multiple vaccines and pills already in use. Safety and efficacy monitoring of new and novel treatments is essential to combatting the relentless scourge of the ongoing Coronavirus pandemic—and may perhaps become a panacea in the prevention of future outbreaks. The industry's collective ability to innovate, via data-informed discovery, is dependent on digital transformation. With intelligent automation applied to rote procedures and processes, high-caliber PV talent can be better leveraged to investigate and interpret subtle safety signals that have the potential to save lives. Being bogged down in data transfer bottlenecks and routine data handling tasks is no longer part of the job description of a drug safety professional. Today, organizations can unlock the benefits of a sophisticated PV solution enriched by IA and RPA and realize those benefits across the entire value chain from research to post-market monitoring.

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