



Optimizing Pharmacovigilance with Automation, and Beyond

**WHITEPAPER**

Safety teams are under enormous pressure to do more with less. As the volume of safety cases continues to rise at an exponential rate and the amount of data that must be processed grows, life sciences organizations are challenged to re-think pharmacovigilance.

Automation, artificial intelligence, and other innovative new technologies are presenting compelling alternatives to traditional processes and workflow.

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Introduction

Dr. Sameer Thapar holds a doctorate of pharmacy (PharmD) and is the Director of Pharmacovigilance Consulting at Oracle Health Sciences. Dr. Thapar has deep subject matter expertise in pharmacovigilance operations and compliance, and also teaches drug safety and pharmacovigilance at a major US University School of Pharmacy.

Dr. Thapar has extensive experience working with pharmaceutical, biotech, and Contract Research Organizations (CROs), leading cross-functional efforts across medical affairs, clinical operations, and quality assurance. He has built global departments and defended in successful FDA, MHRA, and EMA health authority inspections. Dr. Thapar is an active advisor in US-based life science industry conferences and participates as an invited speaker and panelist in global industry conferences.

Dr. Thapar has conducted numerous safety and pharmacovigilance department workshops in business process optimization and analysis of inspection readiness to help customers gain demonstrable efficiencies while yielding better resource utilization.

Understanding Automation

Automation is a buzzword, but the components that make up automated processes are not well understood. Automation is simply applying rule-based algorithms to tasks, so they can happen without manual effort. If a task is repetitive and non-changing, then it is a good candidate for automation. Automation is sometimes used interchangeably with Artificial Intelligence (AI), but this is not accurate. As mentioned, automation is rule-based whereas artificial intelligence blends automation with machine learning.

Automation is an excellent modality for data mining activities. The process of mining data has become increasingly difficult and time-consuming, as the volume of data has increased exponentially over the past decade. In order to harness “Big Data,” automation must be introduced.

Nearly every process in safety and pharmacovigilance can be automated. For example, automated algorithms can be applied to support processes such as data entry, triage, case processing, quality review, medical review, and report submission. For instance, technology exists that can scan incoming structured source data via optical rendering or E2B parsing to deposit data elements onto the data entry tab, which can add significant efficiency to the data entry process. Likewise, unstructured data can be converted into structured elements and then put through this routine to develop the first aspects of data entry.

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Workflow Process Automation

Regarding triage of incoming cases, just as safety and pharmacovigilance professionals apply a core set of parameters to distinguish between what constitutes an adverse event, medical information, or product complaint; likewise, an algorithm can be designed using the core parameters in use and deployed to initiate a through triage process. Apply such automation to processes like data entry and triage, common bottlenecks in safety and pharmacovigilance can be eliminated.

Another area ripe for automation is case processing. By applying automation to the process, the event narrative can approximate, via intelligent architecture, the cadence and syntax of how a member of the safety and pharmacovigilance team would write up the case narrative. In addition, with the application of automation, the process is standardized and consistent, two elements of case processing that routinely come under scrutiny in health authority audits. Finally, another benefit of applying this automation to data entry and triage is that metrics and reports can be created faster with less strain on team resources.

Quality is another area where automation can have a significant and positive impact to workflow. Quality review has been automated in other domains such as clinical affairs for nearly a decade, but given the regulatory burdens of a post-market case management, adoption in safety and pharmacovigilance has been slow. Automation can be applied to both soft and user guided validations in conjunction with the pre-coded hard validations to establish an in-line quality review that can provide a dynamic audit report of errors. This enables high-quality cases to be passed through to the next processing step without delay.



However, if quality review is straightforward, medical review is not. Medical review has historically been a largely subjective endeavor. It also comes with an inherent bias that precludes it from being standardized and consistently replicated. For these reasons, whenever the subject of automating medical review process is discussed, many shy away from the topic, fearing that the process will be error-prone or create redundant work, since the reviewer has to oversee the validity of the automated elements. However, automating medical review need not be wholly consuming. It should be treated as an adjunct process, meant to alleviate the medical reviewer's workload and prioritize review. The industry has already agreed that non-serious cases involving mature products where the adverse event profile has been unchanged for many years and the burst of a new serious adverse event is rare, should not be high priority.

As such, there is widespread support for automating medical review for non-serious/mature products, as the regulatory risk is very low or negligible. Implementing this automation frees up the medical reviewer to concentrate on the serious/launch products that constitute the higher risk to the company, which is a more strategic use of his or her time, and better for overall safety management. Automation of medical review has the potential to offer back up to 10% in efficiency gains to the department. Additionally, given that non-serious to serious cases make up 60% to 40% of incoming case volumes, it is more likely that a non-serious case will be chosen in an audit, so automation of medical review of these types of cases will reveal a standardized and consistent approach in interpretation, due to the algorithm that makes up the underlying automation.

Finally, at report submission, numerous business and regional reporting rules are running to determine where the final case report needs to be submitted and with which cover letter and/or questionnaire. Again, this is a perfect workflow for automation to assist. Automating the choosing of the correct letter, attaching the case report, and submitting these via the prescribed pathways reduces errors and speeds the process. All facets of report submission workflow can be automated to provide a quick and efficient transmission of data from the safety database to external sources.



Benefits of Automation

One of the greatest benefits of automation is time savings. By using automation throughout the case management process and workflow, safety and pharmacovigilance departments reap the benefits of 24/7/365 case processing and eliminate known bottlenecks. Safety and pharmacovigilance departments that have implemented automation to their workflow and processes have enjoyed efficiency gains of up to 51%.

Automation also allows for better use of resources by eliminating manual tasks and focusing teams on high-value work. This provides resource savings and ensures valuable human capital is optimized.

Finally, automation allows safety and pharmacovigilance teams to improve quality through standardization and consistency. By standardizing safety case processing, errors go down, and key performance metrics improve.

Automation for safety case processing is available today out-of-the-box, so pharmaceutical companies, biotechs, and CROs can start enjoying the benefits immediately and see a rapid return on investment.

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Beyond Automation

Automation is the first step in optimizing safety case processing and workflow, but the innovation will not stop there. Artificial intelligence (AI) holds great promise for safety and pharmacovigilance, and is already being proven in the industry. In order for AI to operate well, it needs to mine data at an exponential rate. Large data sets in the trillions of bytes have to pass through the AI machine for it to grasp and formulate its rules and algorithms. The need for real-time data mining is crucial. Gaining actionable insight from AI requires access to, and use of, real-time data. This has been a challenge in the life sciences and healthcare industries due to technology and labor requirements; however, the FDA is focused on addressing this challenge. The FDA currently receives approximately two million adverse event, use error, and product complaint reports each year from consumers, health care professionals, manufacturers, and others, so they are motivated to solve this problem.

The FDA established the Data Mining Council (DMC) in 2007 to serve as a forum for FDA scientists to share their experiences and challenges in analyzing data contained in the vast databases the FDA maintains, as well as to discuss new methods for such analyses with experts from other federal agencies, industry, and academia.

The FDA DMC is focused on the following, as it relates to automating data mining:

1. Process standardization

- automated analysis results removes manual analysis, which statistically improves the output of the data mining

2. Simultaneous analysis

- automation allows for analysis across an entire database at once

3. Efficiency

- automation in minutes instead of days or weeks

4. Signal investigation

- automation improves transparency with audit trails, drill-down capability, observation of signals over time, and study of a product in populations



In addition to the efforts of the FDA DMC, several pharmaceutical companies are now experimenting with the tools of automation and artificial intelligence, such as chatbots, which are outside the purview of current regulations. Chatbots, or “bots” as they are simply known, are assisting with routine tasks such as getting weather updates, flight messages, booking hotels, and now, answering simple health inquiries from physicians. Some key factors like the increase of media availability, mobile devices penetration and the decrease of time available, are resulting in a reduction of time spent navigating and searching on the web, and increased demand for bot technology.

Bots are the first layer of accessible and deployable AI that encompasses natural language processing (NLP) on the general lexicon. Anyone can deploy a bot via online free tools and building kits. As of now, bots are for the outreach activities and do not decipher well the complicated medical lexicons. Currently, the bot, no matter how strong the AI or NLP element, could not replace the human interaction for in-depth conversations on health, disease diagnosis, or exploratory conversations with the health professional. Its aim is different, and that is to relieve the health professional from answering the routine questions. Bots are best when utilized for social media outreach activities and fare extremely well in instances requiring a customer service orientation.

Yet, technology is advancing and these tools will as well. New processing power in chip technology, coupled with advances in algorithmic analysis, will yield better tools for the healthcare and life sciences industries. AI, NLP, bots, automation, machine learning, and data mining are not new. They have been used in other industries such as manufacturing, customer service, and finance for years. Now progress in these other industries and the elimination of the requirement for extensive resources has paved the way for life sciences organizations to explore these innovations. As new adopters of these technological advances share their experiences, the entire life sciences industry will benefit, having access to a new set of tools to transform itself for the future of drug development and to better serve patients around the world.

About Oracle Health Sciences

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CONTACT

+1 800 633 0643

healthsciences_ww_grp@oracle.com

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