# The Next Domino:

Automation, AI, and touchless safety case processing

eBook

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Managing drug and device safety effectively and efficiently has become more and more challenging, as companies face an enormous increase in the number of incoming cases. This has created the need for companies to streamline elements of the pharmacovigilance/multivigilance process with automation.

There are three main categories of automation available to safety professionals, each of which can be applied to different components of case management and signal management. Two of them, rules-based automation and robotic processes, can be applied to repetitive and static tasks that otherwise consume valuable staff time. The third, artificial intelligence (AI), is a powerful tool that enables companies to process larger volumes of data, identify signals and cases, and significantly improve the entire safety process.

Understanding the role played by each type of automation can help in the planning of their implementation for specific needs and growth rates, including a transition to safety case processing that is increasingly touchless. This transition is best implemented in a phased approach in order to achieve tangible results, especially when adding AI abilities to augment human-based systems. Thus, the conversion of many components of case processing to touchless operation can begin, allowing humans to focus their efforts on the areas that require the most detailed attention.

Executive summary

## Introduction

A robust drug and device safety case management process is necessary for identifying and evaluating adverse events (AE) and reporting them properly to regulators. In most organizations, safety management is a cost center that is contending with two competing forces: an ever-expanding set of data sources to process, and budgets under pressure. At the same time that caseloads are increasing by 30-50% a year[1], companies find that older models of offshoring and outsourcing case processing are colliding with the limited number of people who have the required skills.

A better way to raise the standards of efficiency in safety case management is to deploy solutions that can automate time-consuming parts of the process, or those parts where intervention by human experts is not necessary. A well-designed system using the right technology can eliminate tedious and repetitive tasks, reduce data entry errors, and even enable "predictive" signal detection.

Nearly every process in safety and pharmacovigilance can be automated. The key to success is understanding how the various types of automation function and where they fit into the overall process.

[1]Caseloads are increasing by
# 30–50%
a year

SOURCE:
IDC MARKETSCAPE: WORLDWIDE LIFE
SCIENCE DRUG SAFETY SERVICES
2019–2020 VENDOR ASSESSMENT —
BUILDING FOR INNOVATION

## Automation methods

There are a number of automation methods available to safety teams to overcome the increasing demands that they face on resources and budgets in the management of case processing activities. They fall into three main categories:

### Rule-based automation

### Robotic process automation

### Artificial intelligence

The first two categories are best applied to repetitive tasks that undergo little or no change, and so can be managed with fairly simple algorithms. They are intended to relieve safety staff from mundane or tedious tasks that don't require a high degree of human expertise. Ernst & Young estimates that large pharma companies handle an average of 700,000 AE cases annually, and that automating manual steps could save those companies 45% of their pharmacovigilance costs.[2]

The third category, artificial intelligence (AI), offers a much more sophisticated way to use computer technology that can be used to augment the human expertise of safety staff. AI allows companies to process the enormous amount of incoming safety data, in a wide range of structured and unstructured formats, so that the human experts are able to use their time more effectively, focusing on high-value cases. As AI continues to advance, it will enable even greater levels of automation that, combined with human expertise, can result in a highly efficient and highly accurate process.

# Rule-based automation

Rule-based automation (RBA) is just what it says: applying rule-based algorithms to tasks so that computers can perform the known, repetitive steps instead of humans. For example, rules-based systems can effectively automate case prioritization, field validations, letters, action items, coding, listedness, narrative, case lock, submission, and archiving.

Rules-based systems are already widely used by many companies for such repetitive static tasks. Companies may find that RBA is already available to them if it is built into the features of the application that they are automating, as they are in solutions like Oracle Argus.

While these basic algorithms offer advantages over purely manual methods, the technology can't be applied effectively beyond tasks that employ a fixed rule set for data that fits the expected structures.

[2] Large pharma companies handle an average of 700,000 AE cases annually

SOURCE:
ERNST & YOUNG: HOW ROBOTICS IS
RESHAPING THE BIOPHARMA VALUE CHAIN

# Robotic process automation

Robotic process automation (RPA), while similar to RBA, typically involves implementing a third-party tool, a software robot ("bot") that acts as if it were a human user of the case management system. There are a number of vendors who supply these bots, which are generic in nature. To be applied to the pharmacovigilance process, they must first be programmed to carry out safety-specific tasks.

So, in addition to licensing requirements, bots, once programmed, will need validation above and beyond the case management system. For those reasons, RPA is usually more expensive than RBA. If the case management system doesn't include built-in RBA or AI features, then RPA may be the only option. If the case management system does include built-in RBA or AI features, then RPA may not be a cost-effective or necessary effort.

Intended to relieve safety staff from mundane or tedious tasks that don't require a high degree of human expertise

# Artificial intelligence

AI is rapidly becoming a game-changer for safety. It is providing a crucial component for complying with changing global regulatory frameworks, lowering costs, and shifting human interaction into higher-value tasks — ultimately improving patient safety.

Because AI is such a frequently discussed term, it may be useful to examine what we mean by AI and some related concepts:

**Artificial intelligence (AI)** is the science of making intelligent computer systems that mimic cognitive human functions, such as learning and problem solving, using techniques such as statistical analysis of data, expert systems that rely on if-then statements, and machine learning

**Natural language processing (NLP)** is a subfield of AI concerned with the processing and analysis of human language data, typically in the form of unstructured free-text

**Natural language generation (NLG)** is a subfield of AI concerned with the production of human language, typically in the form of unstructured free-text

**Image processing** is a subfield of AI concerned with the processing and analysis of digital images, such as optical character recognition (OCR)

**Machine learning (ML)** is an AI technique used to train software algorithms to learn from data without using explicit instructions, relying on patterns and inference instead

**Deep learning** is the most advanced ML method, using artificial neural networks with multiple layers to progressively extract higher-level features from the raw input

**Neural networks** are computer systems composed of artificial neurons which are connected and organized into multiple layers, inspired by the human brain

## Artificial intelligence *continued*

Many aspects of AI, such as natural language processing (NLP) and deep learning, have been available for some time. Yet, it is only very recently that companies have had access to cloud platforms with the high-capacity computing resources, including graphics processing units (GPUs), that are needed to crunch the data swiftly enough to have a practical AI solution for a real-world problem like adverse event processing.

Using these aspects of AI, nearly every process in safety and pharmacovigilance can be automated. For example, each facet of a typical case management process — intake, triage, data entry, quality review, medical review, and report submission — can lessen the resource strain on the department and enable the automated features to take over.

AI is rapidly becoming a game-changer for safety

## Automating a manual workflow

At case intake, current AI technology like Oracle Safety One Intake is robust enough to extract unstructured data from incoming safety source documents ("paper reports") and convert them into structured E2B files for automatic ingestion into the case management system, effectively making the later data entry step much simpler and saving an enormous amount of time.

During triage, the next step after intake, basic case parameters such as "seriousness" are identified so that the case can be sent to the correct workflow. Rule-based algorithms can support this triage process in order to reduce the current manual workload. So, already, with intake and triage, areas of potential bottlenecks that every safety and pharmacovigilance organization faces are eliminated.

Data entry is the next step to be undertaken. With each paper source document converted into an E2B file during intake, most of the fields in the database are populated automatically and the traditional manual entry of data is almost entirely avoided. In case MedDRA and WHO Drug codes were not included in the incoming E2B report, coding will be the next step in the process. Synonym lists can be used to help auto-code verbatim terms and reduce manual efforts.

Today, an automatically generated narrative can approximate, via intelligent architecture, the cadence and syntax of a manually written one. However, the automated approach is standardized and consistent, which are two characteristics that routinely come under scrutiny in health authority inspections. Plus, the most obvious benefit is that this automation, coupled with the previous steps, is speeding up case processing significantly with less strain on team resources.

[2] Automating manual steps could save companies 45% of their pharmacovigilance costs

SOURCE:
ERNST & YOUNG:
HOW ROBOTICS IS RESHAPING
THE BIOPHARMA VALUE CHAIN

## Automating a manual workflow *continued*

The AI technology of natural language generation (NLG) has the potential to further improve the automated creation of narratives.

Quality review has been automated in other domains such as clinical development for nearly a decade, but given the regulatory burdens of safety case management, not all have adopted the automated approach in pharmacovigilance. It is beneficial to enable soft and user-guided validations in conjunction with preconfigured hard validations to establish an in-line quality review automation. This seamlessly provides a dynamic audit report of errors and enables high-quality cases to be passed through to the next processing step without holding up the workflow.

There also is consensus within the industry that medical review of non-serious cases, involving mature products where the AE profile has been unchanged for many years, should not be treated as high priority. That would indicate the appropriate use of medical review automation for products where the regulatory risk is very low or negligible. Taking this approach frees up the medical reviewers to concentrate on products treating serious conditions or that are new to the market, presenting a higher risk to patients and the company.

At report submission, numerous business and regional reporting rules are running to determine where the final case report needs to be submitted. Automation can be applied to this step as well. Choosing the correct cover letter, attaching the case report, and submitting these documents via the prescribed pathways no longer has to be an error-prone endeavor. All facets of report submission can be automated to provide a quick and accurate transmission of data from the safety case management solution to external sources.

## Safety case management workflow

- Case intake
- Triage
- Data entry
- Quality review
- Medical review
- Report submission
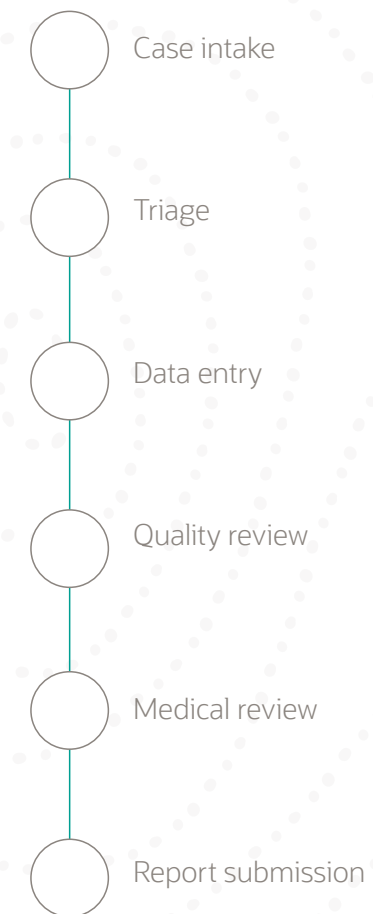
## Touchless case processing

Today, AI is best seen as a technology for augmenting human work. It may not replace humans at all points in the process, but might work with and support humans so they can focus on important higher-value work.  In safety case management, this application of AI allows safety staff to focus on high-value cases that affect the safety profile, while letting machines focus on the bulk of cases that have to be processed.

"For certain types of cases, like well-established products or non-serious cases, or in extracting information from literature, the potential exists in the next couple of years for them to be fully automated," says Bruce Palsulich, Vice President Safety Product Strategy, Oracle Life Sciences.

For more complex or serious cases, the combination of people plus AI can be powerful. A 2016 White House report on AI[3] studied this augmented approach for the examination of radiological images, and concluded that the machine had an error rate of 7.5% while humans alone had a 3.5% error rate. Combined, the error rate dropped to 0.5%.

The question then arises: when can we move to completely touchless case processing without any human involvement? Currently there is a lack of industry experience, not enough input from health authorities, and no clear regulations yet to give confidence in an all-touchless system. While the risk is too high now, touchless case processing is certainly a goal worth pursuing.

"For certain types of cases, like well-established products or non-serious cases, or in extracting information from literature, the potential exists in the next couple of years for them to be fully automated."

**BRUCE PALSULICH**
VICE PRESIDENT
SAFETY PRODUCT STRATEGY
ORACLE LIFE SCIENCES

[3] SOURCE:
PREPARING FOR THE FUTURE OF ARTIFICIAL INTELLIGENCE, EXECUTIVE OFFICE OF THE PRESIDENT OF THE UNITED STATES, OCTOBER 2016

## Touchless case processing *continued*

"You can't change case processing to be [entirely touchless] until you get something that actually works," says Mirza Rahman, MD, MPH, Senior Vice President & Global Head Of Pharmacovigilance, Otsuka Pharmaceutical Development & Commercialization, Inc. "There's hyperbole now where some people have said 'we have touchless case processing' and that is not true."

As capabilities improve over time, a phased approach of introducing automation and AI into the pharmacovigilance process can pay significant dividends. As companies and safety teams become more comfortable with automation and adjust workflows accordingly, they will gain the knowledge and confidence to move to increasing levels of automation.

Companies can prepare now for this shift toward more end-to-end use of AI, by having the right technology in place, and teams trained and ready. While there are issues ahead, including how to align with regulatory agencies, companies that start now will benefit from AI sooner and improve their safety management in a highly competitive market.

"It's important to focus on small steps, small wins, and not say we need to jump all the way to touchless processing and if we're not there, it's not successful," Palsulich says. "The adoption here should be a stepwise approach to get comfortable with the technology. Small steps here are going to pave the way for, ultimately, huge gains."

"You can't change case processing to be [entirely touchless] until you get something that actually works."

**MIRZA RAHMAN, MD, MPH**
SENIOR VICE PRESIDENT & GLOBAL HEAD OF PHARMACOVIGILANCE
OTSUKA PHARMACEUTICAL DEVELOPMENT & COMMERCIALIZATION, INC.

Rahman says the key for companies as well as regulators will be learning to use AI and, over time, learning to trust it. As the technology improves and the trust factor increases, the potential benefits of AI in pharmacovigilance to decrease costs, enhance compliance, and improve outcomes will be realized.
"The value that is going to be provided will allow us to overcome" the various obstacles to adoption as AI gets better, he says. "What we're really looking at is how we can allow human resources to be better applied."

## Conclusion

Using automation methods such as AI and RBA throughout the safety case workflow allows pharmacovigilance teams to reap the benefits of 24/7/365 case processing and avoid known bottlenecks. Real-world industry proofs of concept have demonstrated that the efficiency gains of such an automated approach approximate 50%. That is significant in times of high-volume influxes, backlog crises, and flat department budgets. At the same time, the deliberate addition of AI today to augment human safety resources lays the foundation for a future transition to touchless case processing, greatly increasing the efficiency of safety.

The efficiency gains of such an automated approach approximate

## 50%

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