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Intelligently Automating Safety And Regulatory Processes

How Artificial Intelligence is streamlining pharmacovigilance and regulatory workflows

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Pharmacovigilance (PV) and Regulatory leaders may have different goals, but they face many common obstacles. One of the biggest is the enormous number of manual steps involved in their workflows. More than half of the activities completed by both departments involves the manual collection and extraction of data from one format and/or database into another.

In addition, almost half of the source information received – by PV for example – requires translation to English before it can be submitted to regulators and partners; many submitted documents will require additional translations from English back to another language to complete the process.

The results of these manual efforts are frustratingly inconsistent. Data shows that on average, PV and regulatory teams spend 40 percent of their time on data entry and another five percent in training and retraining[1] because data extraction rules are constantly changing. Despite the time and training:

- 80 percent of PV source documents are found to be extracted incorrectly even after manual quality control.
- 50 percent of cases have significant data consistency errors between extracted fields, i.e. the same data entered differently in the same case.[2]

The lack of automation of these steps and the high rate of error, means a vast amount of time is spent on tasks that don't help meet core objectives – bringing products to market quickly and maintaining them in market. Instead, highly skilled PV and regulatory professionals are spending their days doing manual data entry tasks that fail to leverage their skills, training and expertise.

And the work is piling up. According to statistics compiled by Dell EMC, health data grew by 878 percent between 2016 and 2019. In safety/PV, the number of adverse events (AEs) alone is growing by about 20 percent per year. With this increasing volume, manual models of data creation, translation and management are no longer sustainable. To adapt, PV and regulatory professionals need to embark on a digital transformation process to streamline these steps and make better use of their resources and expertise.

Recent advances in artificial intelligence technologies are making that transformation possible.

AI TO THE RESCUE

A new range of AI solutions is bringing smart automation to many of these activities, making it possible to complete even complex evaluation, translation, and extraction steps with minimal to no human intervention. The evolution of these tools will change how safety and regulatory teams work, cutting costs and shrinking processing time, while delivering higher data quality.

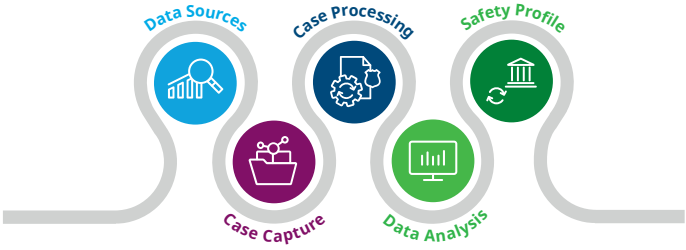
It may sound like an exaggerated value proposition. However, comparison data proves that using AI-driven automation tools for regulatory and PV consistently delivers higher quality results with fewer errors in less time than it takes humans to complete these tasks.

THE JOURNEY IS COMPLEX

Even when they have the time and resources to complete the work, the rate of human error is higher than that seen with AI tools. But these obstacles can be overcome.

By combining translation management and natural language processing (NLP) technology, new solutions can automate multi-sourced data extraction, translate documents, normalize formatting, and port data into relevant databases for further processing. These NLP solutions are specifically built for regulatory and PV workflows by life sciences industry experts who understand the complex and evolving nature of the regulatory environment. By working with industry experts, developers bring context to the technology design and algorithm training, ensuring consistent relevant interpretation for every local regulatory environment.

These technologies can extract the most common attributes relevant to PV and regulatory tasks, including as-reported events, event dates, patient details, reporter details and product/therapy



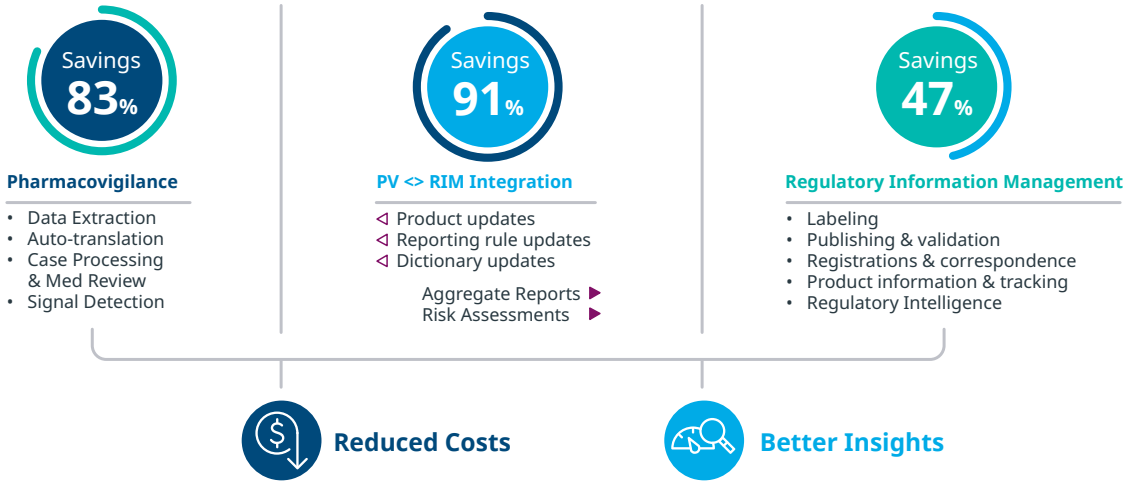
details. And the impact is significant.

Our data shows automation of PV and regulatory steps using AI-driven technology yields cost savings of up to 91 percent for case processing and system management; 83 percent for case intake steps; and roughly 50 percent on aggregate reporting, data analytics, signal detection and risk management.

HOW IT WORKS

In a typical PV workflow, data comes from a variety of sources in structured and unstructured formats. These range from case reports and clinical data to social media posts, academic literature, webinars and patient calls. PV professionals could dedicate hundreds of hours a month reviewing this information to identify potential adverse events, monitor data integrity, translate documents, and put them into the necessary formats – and still not cover it all. That can cause life sciences companies to miss critical regulatory deadlines, and delay identification of safety events.

BENEFITS ACROSS PV AND REGULATORY



AUTOMATED LANGUAGE TRANSLATION BENEFITS

The benefits include the ability to analyze and translate documents into multiple languages, which is key to the successful automation of regulatory and PV tasks.

When done manually, language translation steps can take days to complete. And because they require professionals with PV and regulatory expertise as well as full fluency in the languages being translated, the costs are significant.

Life sciences companies can spend up to 50 percent[3] of their PV and regulatory budgets on translation steps, and most of these documents still require substantial revisions due to translation errors. Some companies have tried to use commercial translation tools like Google Translate to mitigate the burden, but these tools aren't designed to handle complex regulatory language and can only deliver rough translations.

However, translation tools that are built specifically for the life sciences industry can handle even the most sophisticated translations. IQVIA's Linguamatics NLP system features Google's neural machine translation (NMT), which uses artificial neural networks to predict how sequences of words should be translated.

The technology can learn in-country speech patterns, along with rules, acronyms and abbreviations for any language and regulatory body, including Japanese Med-device entities, Chinese Pre-Ordering Rules, Korean Pharma Tokenizer, and Spanish Localization rules. The translations are supported by human review to ensure every translation aligns with the latest regulatory language.

In 2019, IQVIA's solution translated 45 million words, and it can now handle translations in 25+ languages across multiple file formats. The innovation achieved with this technology means regulatory and PV teams have almost instant access to translated

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documents that average a BLEU score of over 85.[4] In contrast, when life sciences companies rely on outsourced vendors to translate documents manually, the same quantity of work requires days to complete and best case delivers a BLEU score of 80. The cost of automated translation is also lower and more predictable because rates are based on number of documents translated, rather than time and complexity of the work.

50 YEARS OF DOCUMENTS

Using this technology, clients can translate hundreds of pages in minutes, while maintaining formatting in the same rendering as the original file. The impact is significant.

For example, IQVIA recently worked with a global pharmaceutical company that wanted to automate extraction of adverse event submissions from source documents to meet EU EudraVigilance mandates.

The company deployed IQVIA's Translation and NLP solutions, developing queries around specific business rules for English, French and German, and incorporating relevant specialist vocabularies, (including MedDRA, EDQM Standard Terms database). As a result, the company was able to index data for various uses in risk assessment which would have been impossible manually.

In another example, a tier 1 pharma company partnered with IQVIA to address a legacy data analysis issue related to a regulated medicinal product. The company had 1300 relevant documents in five languages (English, French, Spanish, German, Italian) spanning 50 years. To meet ISO Identification of Medicinal Products (IDMP) standards, they had to extract key data attributes from 30 different fields, and map them to internal schema.

Using a combination of IQVIA's Translation and NLP solutions, IQVIA's team was able to build and run automated queries in all five languages to extract data elements that were then mapped to the client's exact output schema.

The result showed that 94 percent[5] of the fields in the samples assessed corresponded to accurate extraction, enabling the client to reduce manual review time to a few days per expert.

AUTOMATION AND LABELING

AI-driven innovations are also benefitting labeling tasks, which are essential for maintaining products in the marketplace.

Labeling processes must comply with continually evolving rules for 150 regulatory bodies. Product labels can undergo frequent changes due to factors ranging from safety and efficacy concerns to graphics changes, and must be adapted to the unique requirements of every market.

Keeping track of these changes requires constant monitoring and creates many opportunities for human error that negatively impact or delay labeling approvals. Noncompliance could lead to lost market authorization and potentially jeopardize patient safety.

The use of AI in these tasks can drive down costs, freeing time and resources that can be invested in activities that drive strategic value.

As with translation steps, AI-driven automation brings speed and precision to the labeling process, reducing time and risk in the workflow. Current iterations of automation technology can process massive amounts of information, expediting regulatory processes, while freeing regulatory professionals to spend more time on activities that drive market advantage.

In the future, more advanced intelligence will make this speed even greater while adding a higher degree of accuracy. Labelers will be able to compare any number of countries' labels simultaneously, react to global regulatory insights proactively, and make adjustments before noncompliance becomes a possibility. This, in turn, will ensure resilience against the unpredictability of the regulatory compliance landscape.

Intelligence in labeling may also bring added safeguards for patients. These tools can process information in almost real-time, which means pharmaceutical companies may soon be able to relay label updates directly to patients taking those drugs. It will help them address potential adverse events more rapidly, and create greater transparency between developers, physicians and patients.

CONCLUSION

The benefits of AI for regulatory and PV tasks are clear. These tools reduce manual labor, while bringing unprecedented speed and accuracy to complex regulatory tasks. The tools have been trained using millions of regulatory documents, and have been proven repeatedly to deliver higher quality results in a fraction of the time. By adding AI and ML to these workflows, pharma companies can optimize their signal surveillance process in a simplified manner to monitor risks across multiple data sources.

The transition to automated systems will require time, planning, and partnerships with industry experts, but the sooner companies begin this transformation, the sooner they will slash time and risk from these tasks, and create a safer environment for all of the patients they serve.

Boost safety, regulatory speed and accuracy while lowering cost and complexity. Visit **iqvia.com/globalcompliance** to learn more.

REFERENCES
References 1-5, Internal IQVIA data 2019-2020