Insight Brief

Super-charging Your Drug Safety Process

Using NLP to find adverse events and create cases

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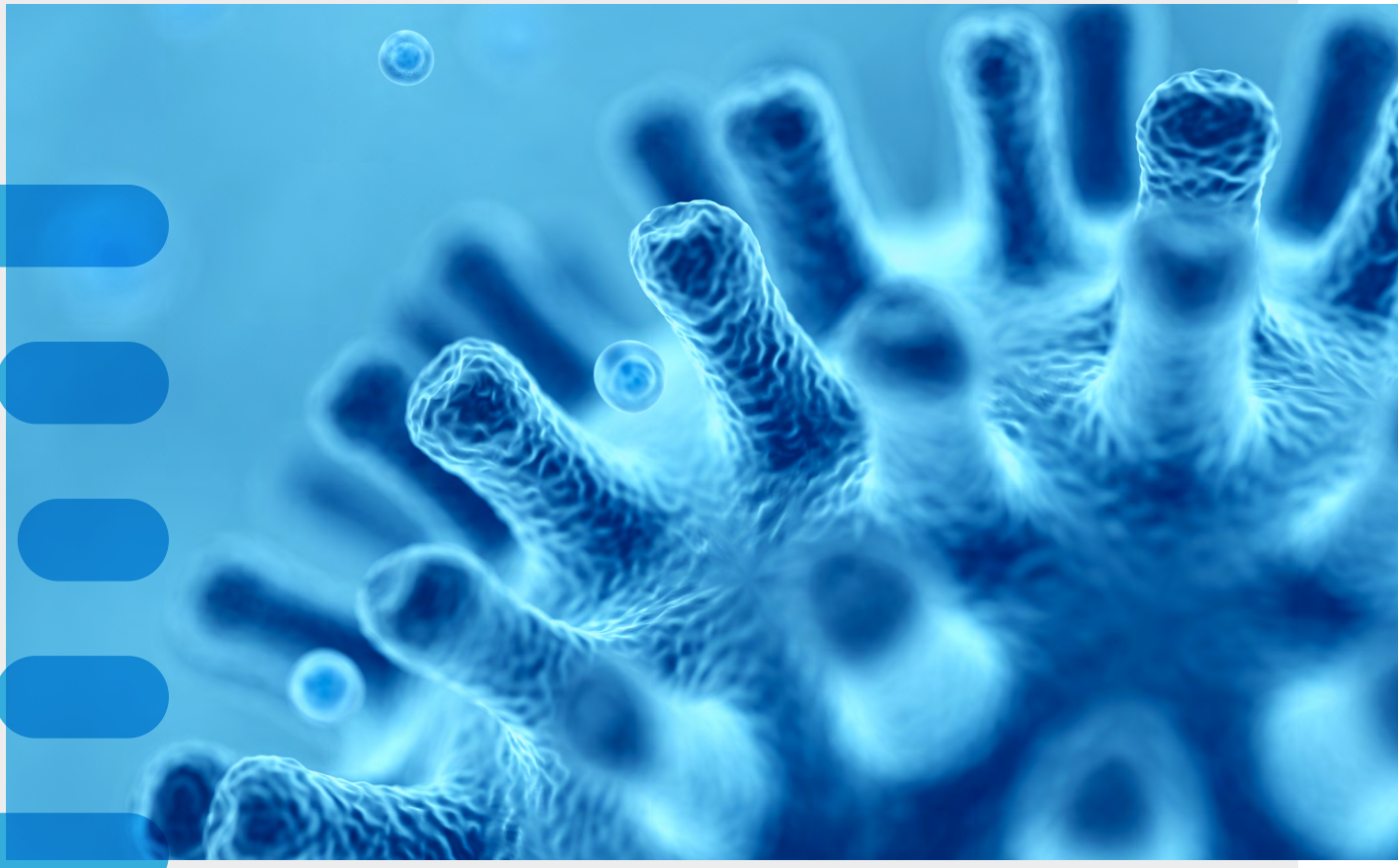

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Introduction

As the pharmaceutical industry grapples with increasing volumes of diverse data, more products, and growing regulatory and reporting requirements, pharmacovigilance (PV) teams see automation as a “must have” for compliance.

To understand context and the intricacies of natural language in massive data sets, many are turning to natural language processing (NLP) technology. NLP can automatically detect, extract, and intake structured and unstructured data from internal and external sources. Solutions like IQVIA Vigilance Platform Detect/Intake (Vigilance Detect/Intake) enables PV teams to standardize and automate processes like adverse event detection and case creation. The result is improved patient safety, speed, scalability and reduced costs.

Context

Updesh Dosanjh and Alison Sloane discussed how NLP can automate pharmacovigilance processes. They focused on upstream detection of potential adverse events and conversion to cases as necessary.

Key takeaways

AS DATA VOLUMES AND REGULATORY DEMANDS GROW, INTEREST IN NATURAL LANGUAGE PROCESSING IS INCREASING.

The pharmaceutical sector is dealing with growing volumes of data and the complexity of this data is on the rise. Identifying adverse events (AEs) is a major concern. Companies must ensure that AEs aren’t overlooked in data, whether the sources are incoming or have already been captured.

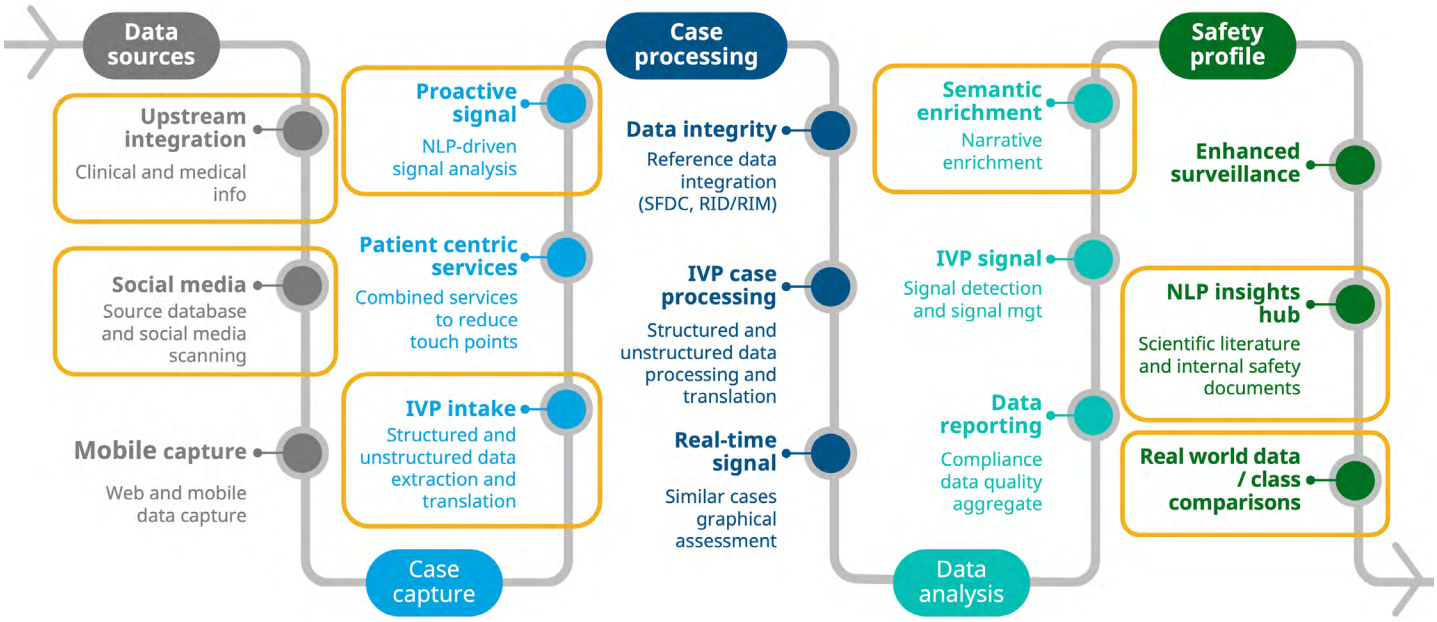
To identify potential reports of suspected AEs, Sponsors and MAH’s must continually screen voicemail messages, the internet, and digital media under their management. Much of this work is manual, which is expensive and error prone. With case volumes also growing 20% per year, there is a burning need to automate data extraction. Natural language processing can help to significantly reduce the burden associated with case processing.

TEXT EXTRACTION AND ANALYSIS ARE NEEDED AT MULTIPLE POINTS IN THE PHARMACOVIGILANCE PROCESS.

IQVIA is actively using NLP in areas like upstream integration, social media, proactive signal detection, intake, semantic search and enrichment, and more. NLP offers new ways of interpreting data. Rather than only analyzing data in structured fields and databases, teams can use NLP to read cases and develop a semantic understanding of the data.

With proactive signal detection, NLP identifies at-risk patients during clinical trials. Semantic enrichment takes signal detection one step further, the signal detection process finds cases and then semantic enrichment uses NLP to analyze the raw data in the cases. This analysis helps target the information that makes the cases particularly interesting.

Figure 1: Areas where text extraction & analysis are needed in the pharmacovigilance process



NLP SOLUTIONS MUST BE INDUSTRY SPECIFIC AND REGULARLY UPDATED.

IQVIA has been using NLP in various ways for over a decade. Based on this experience, IQVIA has identified two important lessons:

1. NLP must be built and trained for the language it is trying to understand. NLP solutions developed for the banking industry, for example, can't be applied to pharmacovigilance. Over time, IQVIA has created a large volume of ontologies specific to the pharmaceutical sector. No other solution has that range of built-in knowledge.
2. NLP systems must be updated quickly as new taxonomies emerge. NLP systems must understand non-text-based forms of language and emotion, as well as the evolution of language. When IQVIA's tech team started to look at Korean cases, for instance, it found that people included emojis. In addition

to the emergence of non-text-based forms of communication, the youngergeneration is also using less structured language. The meaning of words changes rapidly over time. Changes that used to take decades now happen within months.

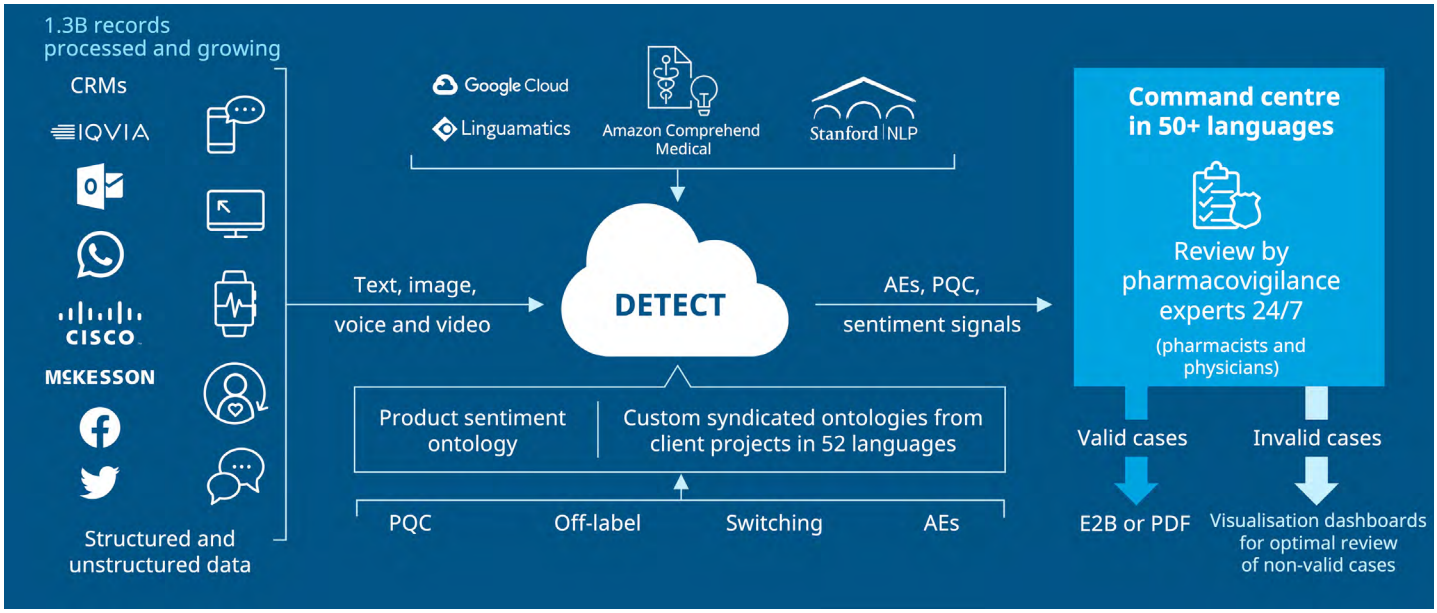
VIGILANCE DETECT IS A TECHNOLOGY-DRIVEN COMPLIANCE SOLUTION THAT AUTOMATICALLY FINDS AEs IN ANY DATA SOURCE.

IQVIA Vigilance Platform is composed of seven modules that address the entire PV process. The Vigilance Detect module impacts two points in the initial PV workflow where text extraction and analysis are required:
1) upstream integration of clinical, commercial and medical information sources which may contain adverse events or potential risks; and 2) scanning of sponsored social media sites for potential suspected adverse reactions.

Vigilance Detect offers several benefits to PV teams:

- **It automatically detects AEs and other potential risks in structured and unstructured data.** Vigilance Detect supports 52 languages and can process data sets like social media, mobile apps, online reviews, CRM information, call center data, emails, patient support programs, market research, vendor-supplied files, and more. The only type of data not automatically supported by Vigilance Detect is handwritten notes, such as handwritten hospital records, where human review is required as part of the process.
- **It is a technology-driven compliance solution adopted by Top 10 pharma companies.** Vigilance Detect currently supports over 1,000 patient support programs and 2.6 million social media posts annually. A team of PV domain experts monitor the output and verify whether events are valid or invalid for downstream Pharmacovigilance case processing and reporting. This group processes more than 3.2 million records a year across various sources. This has enabled IQVIA to build 500,000+ PV terms and patterns, custom and syndicated ontologies that power Vigilance Detect.
- **It delivers proven cost savings.** Vigilance Detect's Technology and Services solution provides 100% reduction in client's manual monitoring across all sources and all languages and removes 100% of records with no potential adverse events from the PV workflow.

Figure 2: AE detection with Vigilance Detect



Vigilance Detect case studies

CASE STUDY #1

A Tier 1 client is using Vigilance Detect to monitor 300 global channels for potential AEs. In 3 years, Vigilance Detect reviewed over 2.6 million records, an average of 72,000 records per month. These records included data in over 91 languages. Approximately 1.4 million records were identified as containing potential AEs

CASE STUDY #2

A Tier 1 client used Vigilance Detect to analyze over 290,000 chats that were received over 2 years. The system identified potential risks within approximately 62,000 conversations

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averaging **72,000** records per month.

which included data in over **91** languages

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VIGILANCE INTAKE LEVERAGES NLP TO STREAMLINE CASE CREATION.

Vigilance Intake uses NLP, artificial intelligence, and machine learning to automatically intake AEs from external and internal sources. It relies on structured and unstructured data extraction and translation.

> ***"Technology Solutions are available now for Safety Event Identification, that cater to all Pharmacovigilance and Commercial needs - any ecosystem, any source, any volume, any timescale."***
>
> *— Alison Sloane, IQVIA*

Vigilance Intake applies NLP in several ways to support automated case creation:

- Redaction and annotation. NLP identifies PII information that should be protected with ad hoc and automated redaction.
- Forms extraction. Vigilance Intake extracts information using OCR on configured forms and leverages NLP for unstructured sections.
- AI text mining. NLP identifies and extracts critical safety data from unstructured text.
- Machine translation. NLP streamlines Vigilance Intake's multi-channel inbox for incoming information.
- Dictionary coding. NLP supports automated coding of MedDRA, WhoDrug, company product and study dictionaries, and browsers.
- Case creation. NLP enables comprehensive case entry for drug, device, and vaccine cases, including country-specific localizations.

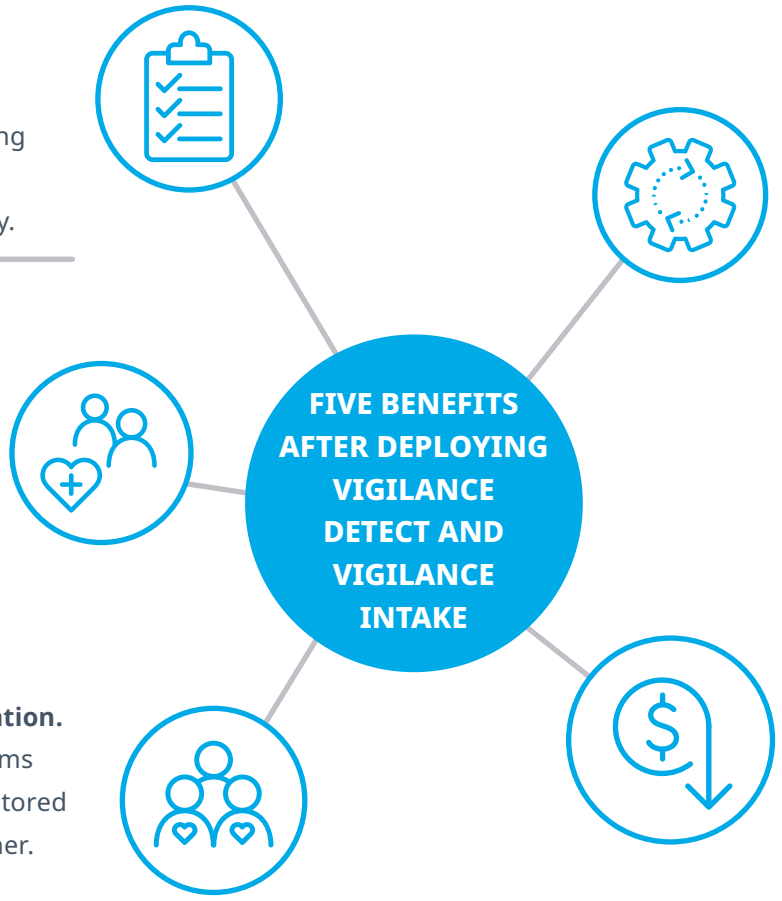
Integrating NLP into pharmacovigilance processes improves compliance, standardization, and patient engagement, while reducing costs.

Companies have reported five benefits after deploying Vigilance Detect and Vigilance Intake:

1. **Increased reporting compliance.** Consistent AE search capabilities result in higher levels of reporting compliance and increased patient safety.

2. **Greater patient engagement.** Organizations see greater digital patient engagement and increasedpatient centricity.

3. **Improved standardization.** Patient support programs worldwide can be monitored in a standardized manner. This facilitates rapid remediation, if issues arise.



4. **Reduced manual effort.** Automation enables drug safety teams to focus on higher-value work, like the science of safety, rather than manual reviews.

5. **Lower costs.** NLP eliminates costly manual review of large bodies of data.

> *"It's important to understand that NLP isn't something you buy off the shelf, throw at your data, and hope that it finds what you need."*
>
> *— Updesh Dosanjh, IQVIA*

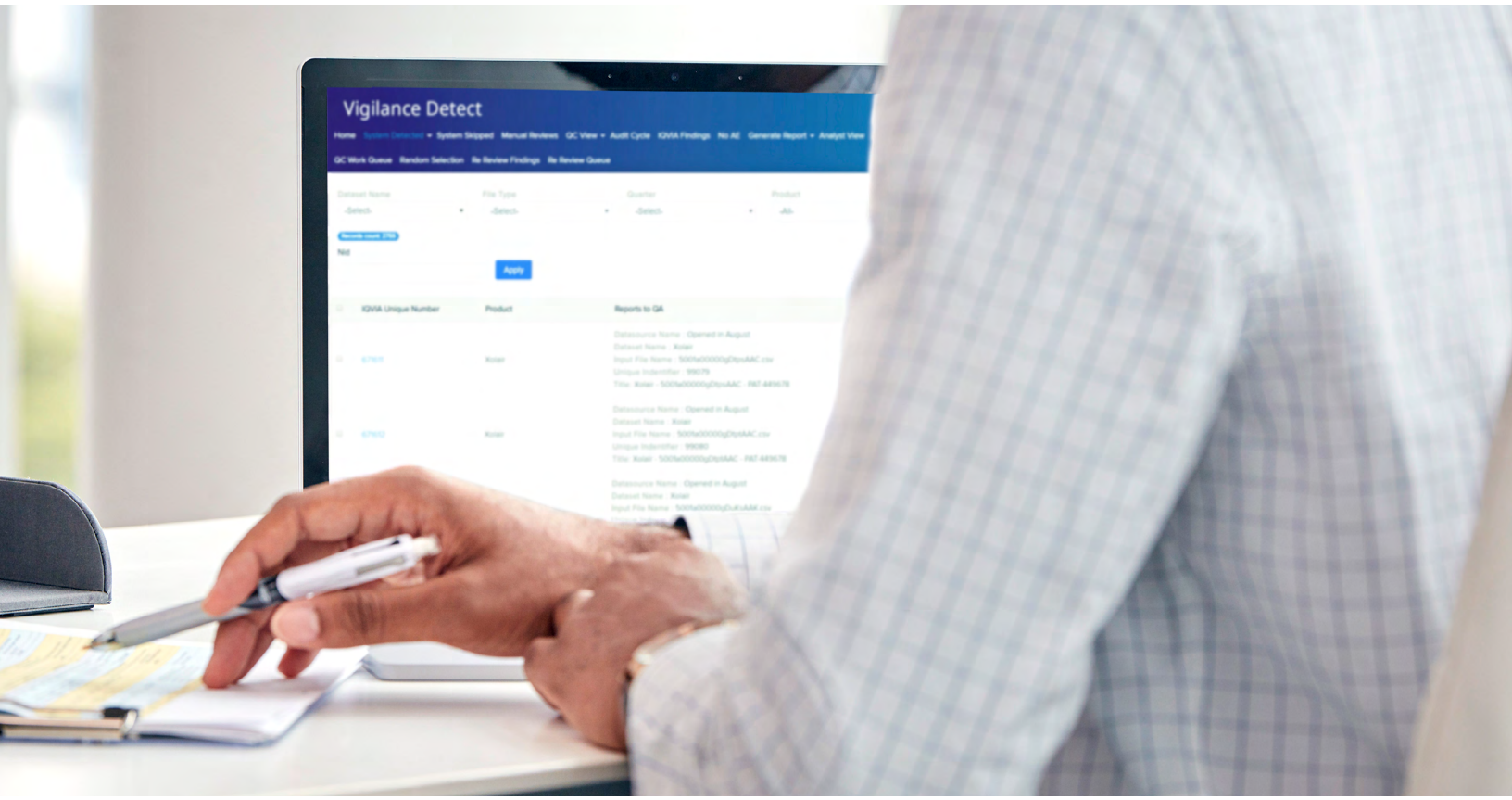
Conclusion

As data volumes and regulatory demands grow, interest in natural language processing is increasing.

- Text extraction and analysis are needed at multiple points in the pharmacovigilance process.
- NLP solutions must be industry specific and regularly updated.
- Vigilance Detect is a technology-driven compliance solution that automatically finds AEs in any data source.
- Vigilance Intake leverages NLP to streamline case creation.
- Integrating NLP into pharmacovigilance processes improves compliance, standardization, and patient engagement, while reducing costs.

"NLP can very reliably find adverse events in any source. More importantly, it provides you with the assurance that no adverse event is missed. When NLP is trained and deployed properly, you will create cases with much less effort than you do now."

— Updesh Dosanjh, IQVIA



About the authors

UPDESH DOSANJH
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As Practice Leader for the Technology Solutions business unit of IQVIA, Updesh Dosanjh is responsible developing the overarching strategy regarding Artificial Intelligence and Machine Learning as it relates to safety and pharmacovigilance. He is focused on the adoption of these innovative technologies and processes that will help optimize pharmacovigilance activities for better, faster results. Dosanjh has more than 25 years of knowledge and experience in the management, development, implementation, and operation of processes and systems within the life sciences and other industries. Most recently, Dosanjh was with Foresight and joined IQVIA as a result of an acquisition.

Over the course of his career, Dosanjh also worked with WCI, Logistics Consulting Partners, Amersys Systems Limited, and FJ Systems. Dosanjh holds a Bachelor's degree in Materials Science from Manchester University and a Master's degree in Advanced Manufacturing Systems and Technology from Liverpool University.

ALISON SLOANE, MSC, DIP STAT.
Senior Director and General Manager, Technology Solutions, IQVIA

As General Manager of Detect (powered by AETracker®), Alison's focus is on driving the vision to provide customers with a tech-enabled optimized approach to adverse event and risk detection in structured and unstructured data. Alison has more than 20 years of experience in Pharmacovigilance, with roles including leadership of the European Pharmacovigilance function, Clinical Endpoint Validation and Adjudication (CEVA) function and global leadership of the Regulatory Reporting function, and responsibilities including growing the teams, building out processes, and directing the operational, contractual, financial, and customer facing aspects of the organization.

Alison's most recent roles have been focused on PV automation and innovation, leveraging her 20+ years of safety experience. Alison graduated from Trinity College, Dublin, Ireland, with an Honors degree in Natural Science and an MSc and a Diploma in Statistics.

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