White Paper

Redefining Post-Market Surveillance: How AI Transforms Quality, Safety, and Global Compliance

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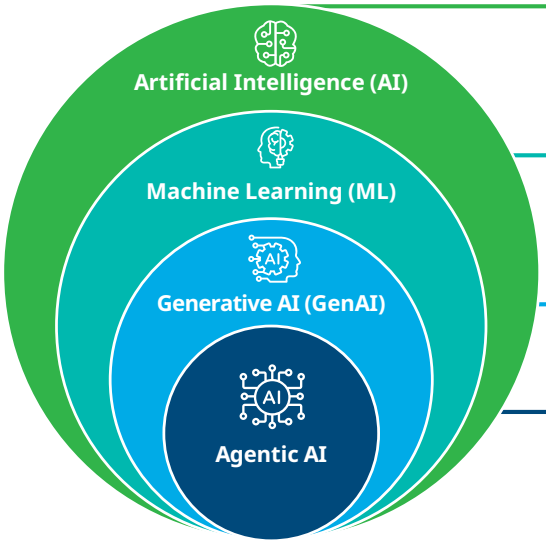
Introduction

Post-Market Surveillance (PMS) has become one of the fastest-evolving areas within the medical technology and pharmaceutical industries. Global regulatory authorities expect timely visibility into emerging risks, clearer evidence linking real-world data to a product's clinical performance and risk profile, and stronger connectivity from PMS activities back into mandatory quality and safety activities. At the same time, companies face unprecedented volumes of structured and unstructured data from sources that include customer call-center recordings, social media insights, an expanding scientific literature base, technical service records, and more. Gathering the right data at the right time, and then moving from data capture to actionable insight, is at the heart of successful PMS.

AI can be a significant enabler for quality, regulatory, and safety professionals working in PMS, helping teams transform data into information and action. A range of AI solutions deployed to support activities mandated by global regulation can amplify the human-in-the-loop professional, enabling teams to keep pace with complexity, identify signals earlier, and operate with greater consistency and compliance across global markets. When integrated into PMS processes, AI supports complaint handling, enhances Adverse Event Reporting (AER), expands organizations' ability to ingest data across formats, uncovers new failure modes and human-factor insights, and drives overall process optimization. Ultimately, these improvements help companies better understand product quality and the impact of these products on patient populations globally.

Artificial Intelligence (AI) is a broad set of complementary methods



Artificial Intelligence (AI) is the theory and development of computer systems able to perform characteristics of **human intelligence**, such as computer vision, speech recognition, machine learning and more. *John McCarthy, 1956.*

Machine Learning (ML) is the branch of AI concerned with the development and study of statistical algorithms that can learn from data, and generalize well to make **predictions** on unseen data without explicit instructions.

Generative AI is a sub-set of ML/deep-learning models that can **generate** high-quality text, images, and answers based on data they were trained on.

Agentic AI refers to **autonomous** AI agents able to understand, build, and perform complex workflows and business processes with limited direct human supervision. Agents don't replace point solutions; agents can orchestrate and operate point solutions in place of human capital.

Strengthening complaint handling: Volume, quality, and timeliness

Complaint handling remains central to PMS, but the volume and variability of incoming information can overwhelm even well-structured, experienced teams. AI can directly increase complaint-handling capacity of global teams by automating repetitive tasks and improving the quality and consistency of procedural outputs.

Automated intake and normalization

AI tools can parse free text narratives from call-center interactions, emails, social media, and technical service reports and automatically map them to standardized complaint categories specific to the range of products marketed by a given company. This improves the quality and timeliness of initial case data and reduces downstream investigation rework.

Language translation capabilities

When organizations use language-translation capabilities, cases can be captured in a local language while allowing an investigator to review the information in another language, while retaining the integrity of the original record. By enabling intake in a native language, both the quality and timeliness of case information can improve.

Case triage and clustering

Machine-learning techniques can identify similar cases, group related events, and prioritize those likely to have the greatest safety relevance. This allows teams to focus on the most critical issues, including potential adverse events, earlier in the lifecycle of a complaint.

Generative AI for investigation summaries

Generative AI can accelerate investigations by drafting concise summaries that integrate historical information, relevant precedents, and service or usage details. These drafts can populate company-specific templates that vary by organization, division, and product type. Human oversight remains essential, but the time required for initial drafting decreases substantially, increasing throughput while supporting data quality and compliance.

Improving Adverse Event Reporting (AER): Consistency and report quality

Adverse event reporting demands consistency, clarity, and timeliness in submissions to global authorities. Variability in narrative text and coded fields across similar complaints can extend dialogues with regulators and undermine confidence in the robustness of an organization's PMS operations.

Consistent coding

AI can recommend appropriate problem codes and patient-impact descriptors based on historical patterns. Reviewers retain full decision authority, while automated recommendations help reduce variability across reviewers and sites.

Enhanced drafting with GenAI

GenAI can prepopulate key sections of AER reports using approved templates and established precedents. This improves consistency, reduces administrative burden, and helps global teams maintain alignment in structure and language when reporting to regulatory authorities. GenAI-driven first drafts also allow human-in-the-loop experts to spend more time assessing clinical context and focusing on higher-value professional judgment.

Timely completion

By automating checks for completeness and coherence, AI reduces the risk of missing data elements and shortens report preparation time. This supports compliance with regulatory timelines and increases capacity for the quality, regulatory, and safety professionals who create, review, and approve AER content.

Expanding data gathering: Structured and unstructured sources

Traditional PMS processes rely heavily on structured data from complaint systems and vigilance databases. However, many early signals originate from unstructured content: technician notes, customer calls, service histories, medical literature, social posts, or training feedback. AI broadens the datasets organizations can meaningfully analyze.

Structured data optimization

NLP AI can support normalization, deduplication, and trend identification across structured datasets, including complaint logs, NC and CAPA records, technical service data, and others. Standardization enables clearer cross-regional insight, stronger data quality and integrity, and more reliable trending.

Unstructured data unlocking

NLP-driven AI enables organizations to analyze a broader range of sources essential to a holistic understanding of product quality and safety. These include call-center audio and transcripts, PDF field reports and service notes, published literature, conference abstracts, customer feedback and surveys, and social media content. By converting these inputs into searchable, analyzable data elements, AI helps surface signals and trends that might otherwise remain hidden.

Always on surveillance

AI enables continuous, real-time monitoring of sources rather than periodic manual reviews. Anomalies or unusual patterns can be flagged promptly, giving quality, regulatory, and safety leaders earlier visibility into potential issues and more time to investigate and mitigate patient impact where reasonably possible.

There are a wide range of data sources for AI/NLP solutions

Identifying the most suitable ‘proactive’ data sources is a key success criterion

Understanding new failure modes and human factor insights

Major product issues often emerge first as weak signals: a few unusual service notes, recurring user steps identified in call-center interactions, or an early report of an issue not yet known to be systematic. AI can help uncover these insights earlier and at greater scale by augmenting the human-in-the-loop professional with a “digital eye” that flags potential issues for expert review in the appropriate clinical context.

Literature and scientific mining

AI can continuously scan scientific publications and clinical reports for early indicators of new complications, off-label use concerns, or unexpected performance challenges. Patterns related to user errors, misinterpretation of instructions, and training gaps can provide valuable insights into where an organization should strengthen quality, regulatory, safety, and commercial activities. These insights can inform usability studies, labeling updates, risk mitigations, and targeted training initiatives, and may also drive updates to risk-management documentation and clinical/performance evaluation reports.

Cross source signal correlation

Connecting trends across multiple sources, including literature, service logs, complaints, and customer feedback, supports early hypothesis generation for deeper investigation and prioritization by quality, regulatory, and safety teams.

Pragmatic AI — MedTech examples

Patient safety, product quality, market access

Data search & extraction
- Product design and development
- Global regulatory requirements

Content review
- Literature publications
- Electronic health records

Market Insights
- Social media channels
- Internal and external records

Process optimization: Efficiency, consistency, and compliance

Beyond supporting individual tasks, AI contributes to end-to-end PMS process optimization, improving efficiency and strengthening compliance across Quality Management System (QMS), Regulatory Information Management (RIM), and safety activities.

Improved operating consistency

AI supports the use of common vocabularies, harmonized templates, and uniform coding practices. This consistency improves data capture, trending accuracy, and global execution of company activities in a way that is operationally consistent.

Better timeliness

Automated triage, drafting, data cleaning, and literature scanning reduce delays of data capture throughout PMS activities. Faster detection, analysis, and reporting support better decision-making and integration into company QMS solutions drives more timely Risk Management activities, NC, CAPA, and field actions as well as identifying the need to update Clinical Evaluation Reports (CERs) and Performance Evaluation Reports (PERs).

Resource utilization

By automating administrative and repetitive tasks, organizations can redeploy expert professionals to higher-value activities such as contextualizing investigations, conducting focused risk assessments, and supporting cross-functional safety governance.

Enhanced audit readiness

AI systems can support traceability through metadata, decision logs, and clear lineage for information sources. This strengthens inspection readiness for global authorities and helps ensure teams can explain how data were processed and how decisions were made.

The IQVIA SmartSolve® difference

As products, regulations, and data sources grow more complex, PMS effectiveness increasingly depends on integration within a company's QMS ecosystem. A single, digitized QMS creates a unified data platform that links PMS, complaint handling, CAPA, change control, labeling, training, and risk activities into one cohesive solution.

By consolidating QMS and RIM modules, organizations reduce the risk of human error associated with manual processes and disconnected systems. This enables quality, regulatory, and safety professionals to focus on improving product quality, enhancing patient safety, and supporting commercial performance.

In addition, an AI-enabled, unified QMS/RIM platform with advanced analytics helps organizations shift from reactive compliance, addressing issues after they emerge, to proactive, data-driven quality and safety management.

Conclusion

AI empowers PMS professionals by expanding analytical reach, improving process efficiency, and enabling earlier detection of emerging risks. When applied pragmatically and governed responsibly, AI strengthens the entire post-market ecosystem, from complaint intake and adverse event reporting to risk management, field actions, product improvements, and global submissions.

Organizations that combine AI-enabled insights with professional judgment, strong data governance, and modern digital eQMS solutions are best positioned to protect patient safety, meet global compliance requirements, and deliver consistently high product quality. Ultimately, this approach enables teams at every level to uphold trust in the organization's reputation and the integrity of its clinical solutions.

About SmartSolve®: SmartSolve is an AI-enabled, Microsoft Azure-based platform that helps Life Sciences organizations streamline and automate global quality management and regulatory compliance. SmartSolve® eQMS centralizes enterprise-wide quality processes, from design and manufacturing to post-market surveillance, while SmartSolve® RIM manages regulatory submissions, product registrations and health authority interactions. Built on industry best practices, SmartSolve connects teams, data, and workflows in a single platform to drive an optimized focus on patient safety, product quality and commercial performance.

About the author

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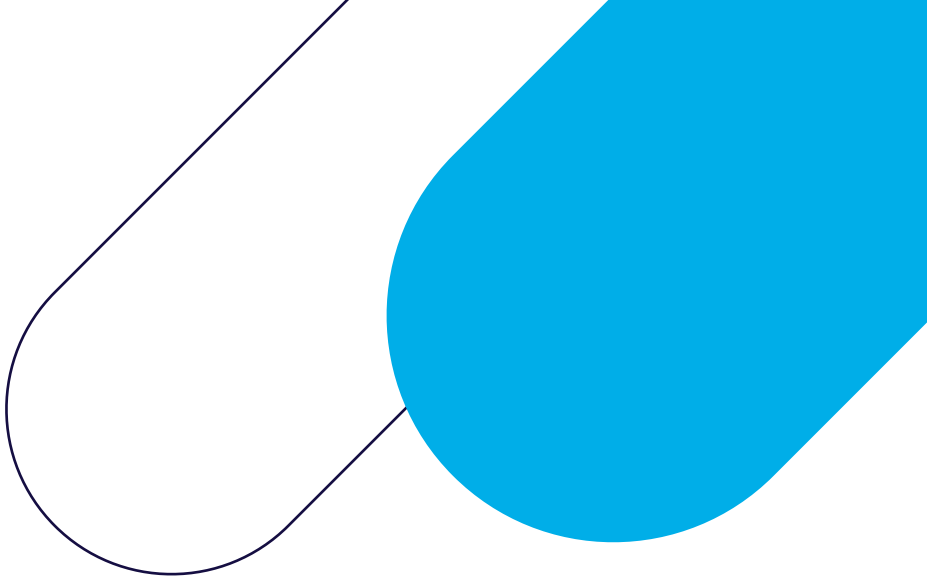
Mike King is the Senior Director of Product and Strategy at IQVIA, where he leads global teams across quality assurance and regulatory affairs. With over 20 years of experience in life sciences and enterprise software, Mike drives innovation for IQVIA's SmartSolve® solution including SmartSolve® eQMS, SmartSolve® RIM, and SmartSolve® Fundamentals, helping organizations streamline compliance and accelerate digital transformation. A recognized expert in AI for regulatory and quality functions, he is passionate about improving patient outcomes and empowering professionals to enhance safety and performance across healthcare systems.



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