

White Paper

The Future of Post-Market Surveillance: Digital, Integrated, and Patient-Focused

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Introduction: Why Post-Market Surveillance must be proactive

Post-Market Surveillance (PMS) is the continuous, proactive, and systematic collection and analysis of real-world data on device quality, performance, and safety throughout the product lifecycle. Under the EU Medical Device Regulation (MDR) and the In Vitro Diagnostic Regulation (IVDR), Post-Market Surveillance (PMS) is not a standalone process. It is an integral component of the manufacturer's Quality Management System (QMS), with explicit obligations to plan, execute, analyze, and act on field data.¹ In practice, this means manufacturers must maintain a documented PMS system and PMS plan, define data sources (e.g., complaints, trend reports, literature, registries), align methods and thresholds, and then feed conclusions into design control, clinical evaluation/performance evaluation, risk management, and, where necessary, create CAPAs and launch field actions.²

Heightened PMS expectations emerged from several high-profile safety issues, including Metal-on-Metal (MoM) hip implants and PIP breast implants, which exposed the shortcomings of complaint-driven vigilance.

Regulators concluded that broader, earlier, and more systematic evidence is required to detect underlying signals of poor product performance. In the case of MoM hip systems, risk understanding evolved over time, ultimately shifting the devices into the PMA pathway and necessitating mandated post-market studies. Similarly, UK authorities emphasized structured follow-up and imaging for early detection of soft-tissue reactions.^{3,4} For PIP breast implants, reviews integrated toxicology, rupture, and clinical evidence to guide patient management and underline the need for surveillance beyond traditional complaint handling.⁵

Global regulators echo this trend. In the U.S., Post-Market Surveillance orders under Section 522 require scientifically valid plans capable of generating useful data that identify unforeseen adverse events and inform public health decisions.^{6,7} Collectively, these frameworks reinforce a modern expectation: PMS must be proactive, multi-source, and fully closed-loop to ensure timely action and improved patient safety.

High public awareness of product quality issues

A dual focus on patient safety and commercial performance is universally beneficial

PIP breast implants

Impact

- **Patient** — 300,000 women affected in a 10-year period to 2020 with implants up to 6 times more likely to rupture
- **Company** — Shut down in March 2010, founder jailed, French court awarded damages
- **Brand** — Discontinued

Conclusions

- "...**adverse incident reporting** is an inherently **imperfect** way of collecting data..."
- "...obtain evidence from a **wider and more detailed set of sources**, including robust outcomes data from clinicians..."

Metal-on-Metal hips

Impact

- **Patient** — 1.5 million implants worldwide, revision surgery for those with an abnormal reaction to metal ions
- **Company** — One company settled for around \$1 Bn USD, others concluded settlements for several million dollars
- **Brand** — Rarely used since 2012, U.S. FDA changed to PMA

Conclusions

- "... reports in orthopaedic literature, data from international orthopaedic **implant registries** and **presentations** from **professional/scientific meetings** that have increasingly noted complications and potential problems of early failure of MoM hip systems, often requiring revision surgery..."

The interplay: PMS insights fuel clinical evaluation, risk management, and market actions

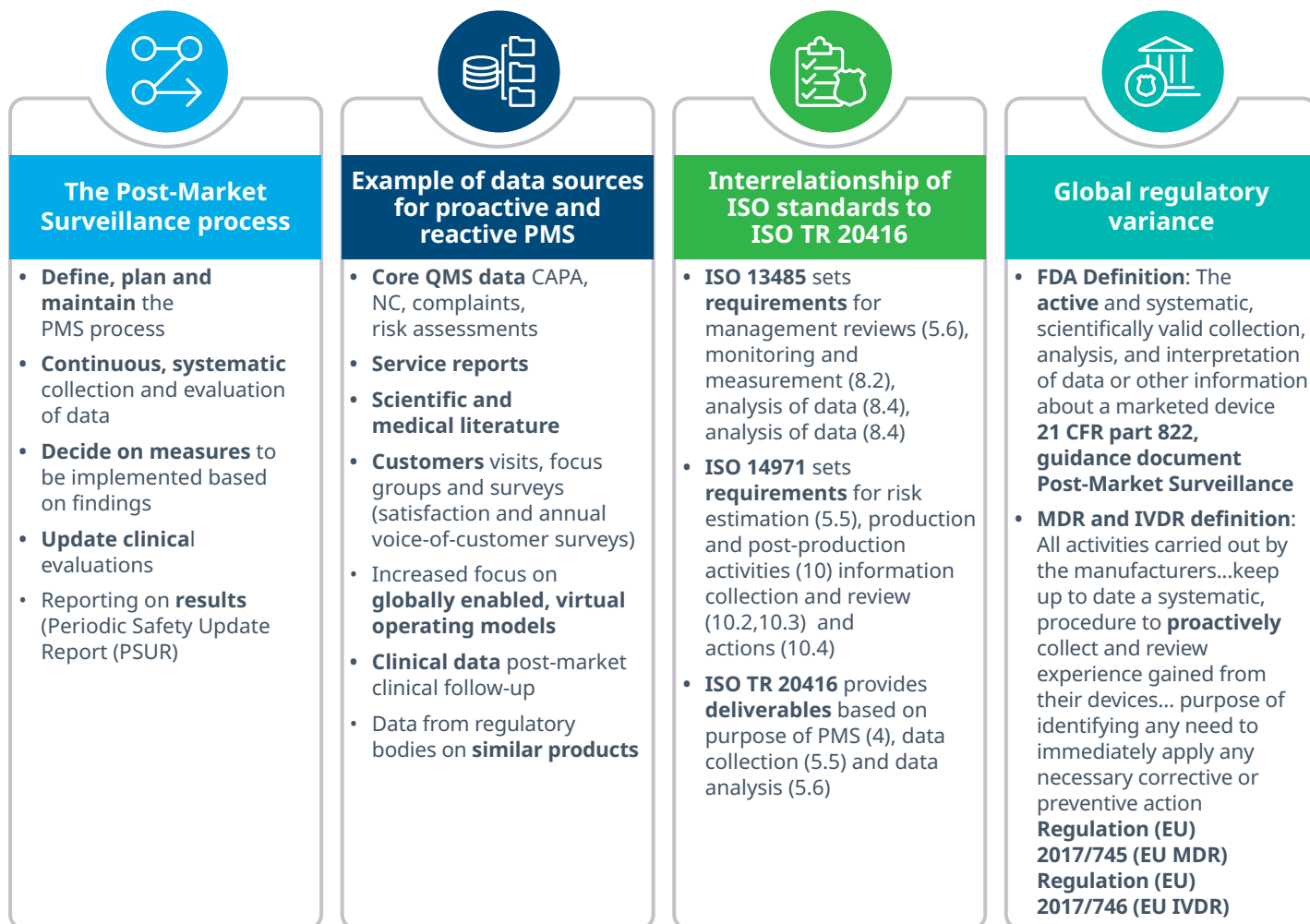
EU MDR and IVDR require PMS outputs to update benefit-risk determinations, risk management files, clinical evaluation/performance evaluation, labeling/IFU, and the summary of safety and clinical performance, informing trend reporting and any necessary corrective or preventive actions, including field actions.⁸

MDR Articles 85 and 86 formalize the PMS Report (PMSR) and Periodic Safety Update Report (PSUR), pushing manufacturers to synthesize findings at defined intervals and demonstrate that PMS is a living system, not a paper exercise.⁹ The IVDR mirrors this structure with PMSR for lower risk IVDs and PSUR for higher-risk classes; Post-Market Performance Follow-up (PMPF) provides the vehicle to maintain performance evidence in the field.¹⁰

These PMS feedback loops have direct clinical relevance. For example, **UK MHRA guidance on Metal-on-Metal (MoM) hip replacements** prioritizes MARS MRI or ultrasound over isolated metal ion levels for early detection of soft tissue reactions, demonstrating how PMS evidence reshapes clinical follow-up and improves patient outcomes.¹¹ Similarly, analyses of **PIP breast implants** integrated toxicology, rupture, and clinical data to guide patient communication and risk management — showing how the breadth and quality of PMS inputs strengthen clinical decision-making.¹²

ISO/TR 20416:2020 codifies this in a manufacturer-friendly process model: Plan PMS, collect from appropriate sources proactively, analyze with defined methods, and route outputs to design, risk, production, clinical/performance evaluation, and improvement. This is the practical blueprint for the MDR/IVDR requirement that company PMS activities are an integral part of their QMS.^{13,14}

PMS encompasses a broad range of activities and data



From reactive to proactive: Multi-source data, trending, and signal management

A proactive PMS program incorporates both reactive data (e.g., complaints, vigilance/adverse events) and proactive sources (e.g. scientific and medical literature, registries, technical service data, user surveys, social channels, supply chain audits, and product sampling). Methodologically, proactive PMS entails:

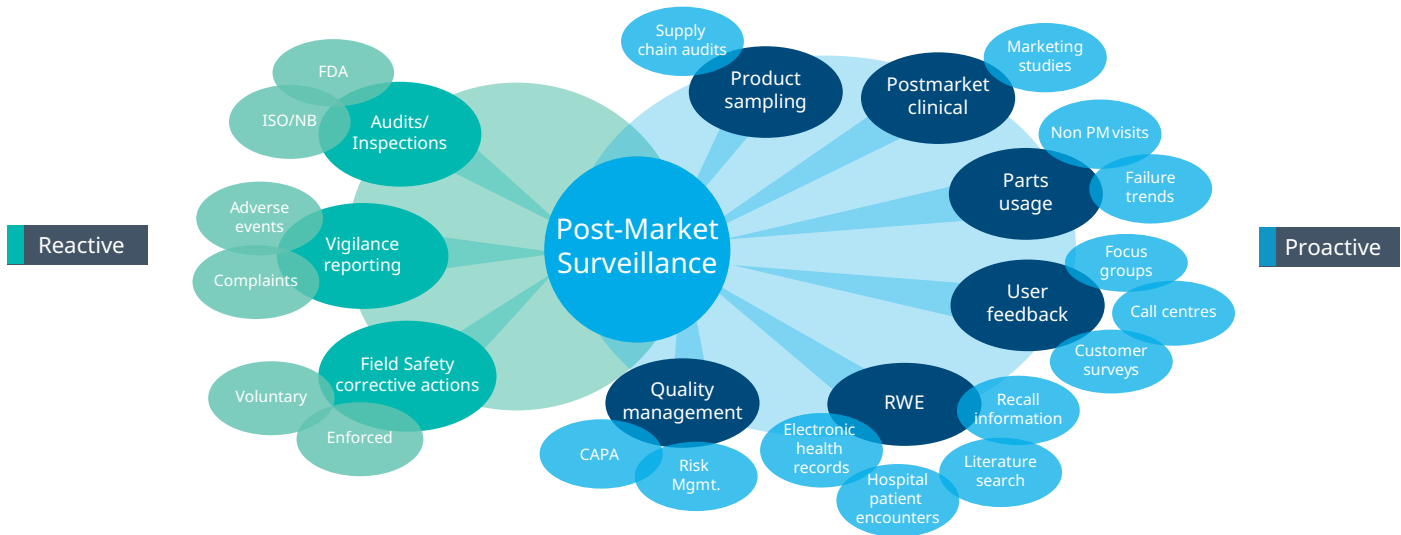
- Defined thresholds and indicators for trends and signals (e.g., statistically significant increases in frequency or severity under MDR Article 88)
- Data quality controls, including source reliability checks, deduplication, and harmonized data mapping

- Triaging and escalation rules aligned with risk management and CAPA processes
- Full traceability so each signal can be tracked through assessment, decision, and action^{15,16}

The business case is equally compelling. McKinsey's *The Business Case for Medical Device Quality* documents the rising cost and visibility of quality events and estimates sizable economic upside from modern, end-to-end quality practices. This translates to fewer recalls, faster investigations, and better margins when product issues are found early.^{17,18} Proactive PMS decreases the likelihood and severity of in-field product failures by enabling early detection and timely remediation through advanced analytics and structured escalation.

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

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



Digitizing the PMS core: Connecting plans, risks, NC/CAPA, complaints, recalls, and document management

Fragmented, manual processes hinder timely and effective post-market surveillance. EU MDR and IVDR require cross-functional integration across the PMS lifecycle, including alignment from PMS Plans to PMCF and PMPF activities, from trend detection to risk file updates, and from CAPA to labeling and document management. Annex III further requires PMS Plans to define methods for complaint investigation, trend management, stakeholder communication, and traceability. These capabilities are extremely difficult to execute consistently using siloed systems and spreadsheets.¹⁹

A modern, digital eQMS provides:

1. A single source of truth for PMS activities, including plans, signals, analyses, and PSURs, and their direct relationships to risk files, design history, and clinical or performance evaluation.
2. Integrated quality workflows for NC, CAPA, complaint handling, and recall or FSCA processes, supported by shared metadata, audit trails, and Part 11 controls to ensure defensible decisions and inspection readiness.
3. Advanced analytics and dashboards for trend detection and signal management, including real-time heatmaps by product, region, failure mode, and harm severity.
4. Change control orchestration that enables field signals to trigger design changes and aligned registration impact assessments, closing the loop to regulatory submissions and market certificates. These are the feedback loops that ISO/TR 20416 expects manufacturers to operationalize.²⁰



In the era of AI, significant pragmatic value can be added by using the right type of AI to enhance a specific activity within the framework of a regulated QMS activity:

- **Data acquisition and normalization:** Automated extraction and structuring of complaints, service records, MAUDE narratives, literature, and callcenter transcripts
- **NLP-assisted triage:** Similarity matching, code suggestions, and summarization to accelerate and standardize investigations
- **Drafting assistance:** Auto-generated PMS Plan sections and PSUR summaries for human review, improving cycle times
- **Live analytics:** Anomaly detection for early signal identification, enabling proactive rather than reactive action

These uses align with regulators' emphasis on scientifically valid, useful data and do not alter the fundamental requirement for human oversight and professional, contextual judgment in quality and regulatory decisions.^{21,22}

Pragmatic AI — MedTech examples

Patient safety, product quality, market access



Data search and extraction

- Product design and development
- Global regulatory requirements



Content review

- Literature publications
- Electronic health records



Market insights

- Social media channels
- Internal and external records

The SmartSolve® difference: A single, AI-enabled platform that unifies QMS and RIM

IQVIA SmartSolve is a cloud-based, AI-enabled eQMS that unifies core quality processes, including Change Management, Document Management, Training, Quality Events (NC/CAPA/Deviations), Inspections, and Complaint Management, forming the foundation of enterprise-wide post-market surveillance. Built on enterprise-grade technology, SmartSolve enables global scalability, validation, and inspection readiness through configurable workflows tailored to specific products, regions, and organizational roles.^{23,24}

When PMS insights drive design enhancements or technical documentation updates, SmartSolve's QMS modules integrate directly with IQVIA SmartSolve® RIM, enabling organizations to manage the full change lifecycle from impact assessment through global submissions and re-registration. This connected ecosystem enhances patient safety while strengthening commercial agility by equipping regulatory and quality teams with real-time, actionable intelligence.



Conclusion

Global regulators have set a clear mandate: Post-market surveillance must be proactive, systematic, and tightly integrated with design control, risk management, and clinical/performance evaluation. High-profile cases such as metal-on-metal hip implants and PIP breast implants underscore the critical need for multi-source evidence and disciplined, structured follow-up to identify risks early and safeguard patient safety.

Digitizing PMS within a unified QMS and RIM environment mitigates the inherent risks of fragmented, manual processes and enables faster insight generation, stronger data integrity, and more timely, coordinated decision-making. A connected digital platform reinforces both patient safety and commercial performance by sustaining a closed-loop feedback mechanism into design and clinical evaluation, while delivering real-time visibility into in-market product performance.

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.



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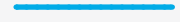
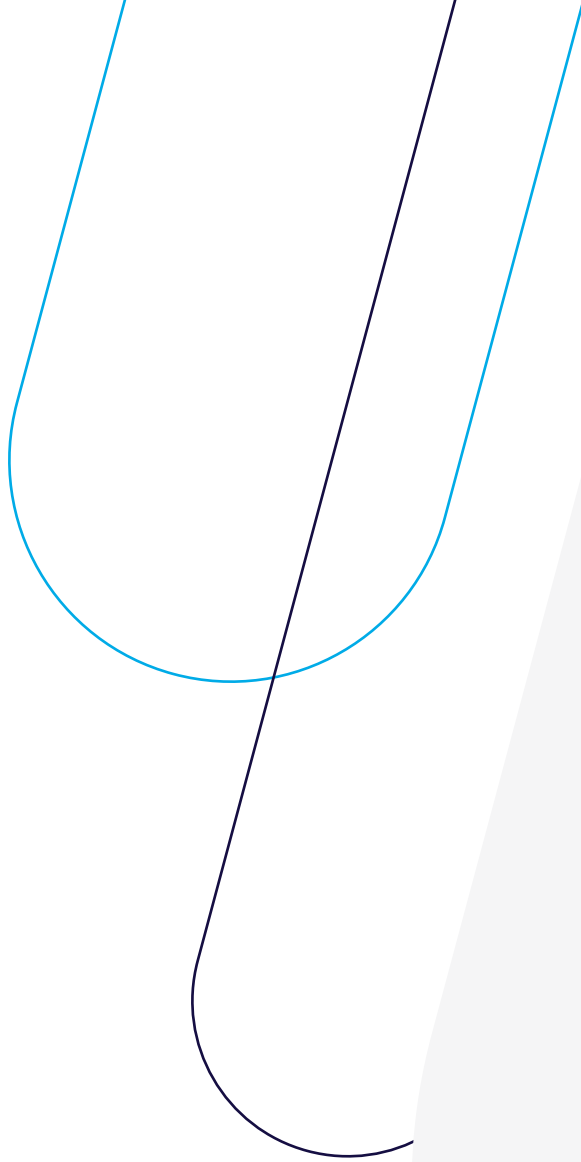
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Mike King is the Senior Director of Product and Strategy at IQVIA, where he leads global teams across quality assurance and regulatory affairs. With over 20 years of experience in life sciences and enterprise software, Mike drives innovation for IQVIA's 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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