Fact Sheet

SmartSolve® Postmarket Surveillance

Enhancing oversight of real world product performance. Empowering Patient Safety

Postmarket Surveillance (PMS) ensures products perform as intended, improve health outcomes, and minimize recalls. With stricter regulations like EU MDR and EU IVDR, proactive PMS is essential for maintaining safe, high-quality products. An effective PMS system unifies data from multiple sources, enables timely execution of surveillance activities, and integrates with Quality Management System (QMS) for clear oversight and rapid response in real-world settings.

Situation

Organizations in regulated industries must demonstrate robust postmarket surveillance controls for globally marketed products. Quality and Regulatory teams face complex regulatory expectations and diverse data sources. Efficiently collecting and analyzing real-world data, maintaining documentation, and responding quickly to safety signals and trends is essential for maintaining global compliance, high product quality and patient safety. Without an integrated PMS approach, companies risk delayed issue response, increased scrutiny, and potential impacts on market reputation and trust with customers, patients and regulators alike.

Our solution

SmartSolve Postmarket Surveillance empowers customers by providing a centralized, automated platform to track, execute, and record company-defined activities necessary under postmarket surveillance plans. By integrating seamlessly with other quality processes, SmartSolve helps organizations maintain high standards, improve patient outcomes, and build trust with regulators and end users — all while saving time and resources.

Key capabilities

Postmarket Surveillance workflow

- Define, plan, manage, and track the execution of a range of PMS activities necessary under a company's postmarket surveillance plans in one central solution
- Upload and record objective evidence and records, including PSURs, to demonstrate compliance with the latest regulations
- SmartSolve's dashboard provides visibility into surveillance tasks, evidence, and reports, supporting cross-departmental collaboration

Integrated quality processes

- Seamlessly connect the postmarket surveillance module with complaint management to support a holistic view of reactive and proactive postmarket activities
- Integration with CAPA, Risk Management, and Document Management modules ensures closed-loop traceability and compliance with ISO/TR 20416:2020
- Optimize automation of quality processes and business activities through the delivery of a range of connected SmartSolve QMS modules in a single platform

End-to-end complaint handling

- Take advantage of a range of AI enabled complaint management activities that support increased quality, volume, and timeliness of case intake information, which gives a direct pull-through to improved case investigations and improved adverse event reports

- AI-driven workflows support regulatory coding, translation, and investigation summaries, freeing professionals for critical thinking and customer-centric activities
- Utilize reporting, trend analysis, and Pareto charts to identify risks and drive product improvement and understanding of safety profiles. Quality Intelligence powered by Microsoft Power BI delivers actionable insights

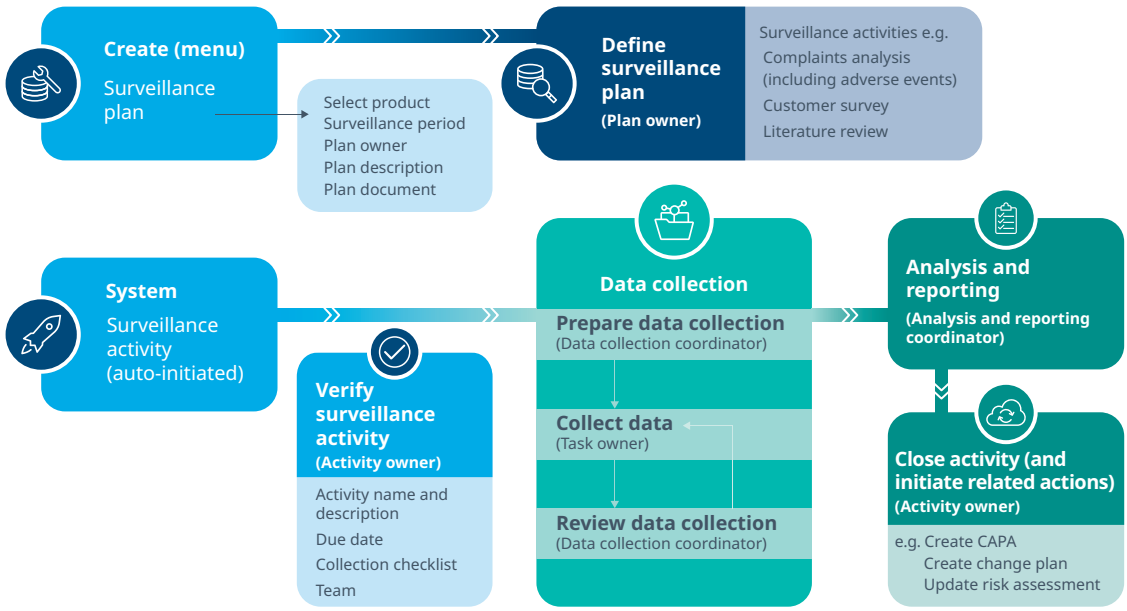
Advanced analytics and AI

- Quality Intelligence powered by Microsoft Power BI delivers actionable insights in real-time dashboards, KPIs, and custom reports within SmartSolve
- IQVIA AI solutions can support pattern detection to analyze historical records (e.g., FDA MAUDE data) to identify clusters, outliers, and recall trends

Data security and compliance

- Role-based security, audit trails, and electronic signatures support regulatory requirements
- SmartSolve is ISO 27001 and ISO 9001 certified

SmartSlove Postmarket Surveillance workflow



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.

IQVIA TECHNOLOGIES

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