FACT SHEET

IQVIA Postmarket Surveillance: A true postmarket surveillance solution

Manage, track and document all your PMS activities from planning through reporting with SmartSolve®

Postmarket Surveillance (PMS) means better performing products, improved outcomes for patients, and fewer recalls. And, with regulators tightening their PMS requirements (the new EU device Regulations include very specific provisions for PMS) good, pro-active PMS is crucial for ensuring that safe and performing products remain on the market and for reducing penalties.

An effective, robust PMS system requires the bringing together of different data-collection processes from different groups to assess how a given medical device is performing in the real world.

SmartSolve Postmarket Surveillance, the dedicated solution for MedTech, provides your organization with a workflow for managing, tracking and documenting across the entire PMS journey, from planning to data collection right through to analysis and reporting.

THE RISKS OF POOR PRODUCT PERFORMANCE ARE SUBSTANTIAL

- Patient health and safety
- Recalls
- License/registration withdrawals
- Financial penalties
- Legal ramifications

Effective PMS helps not only mitigate these risks, but also aligns with broader business imperatives that MedTech companies must deliver against to be successful.

THE GOALS OF PMS PROGRAMS

Making safer products: Realizing products' benefits while minimizing their risk profile.

Improving product performance

Engaging stakeholders: Working with practitioners and patients to ensure any risks that manifest over time are minimized or eliminated.

Improving reputation and compliance: Operating within legal frameworks to maintain and build trust.

Reducing cost: Proactive PMS saves companies from dealing with costs associated with downstream corrective actions and their effect on customer satisfaction.

THE BENEFITS OF A ROBUST POSTMARKET SURVEILLANCE PROGRAM

Effective PMS processes provide your company with a competitive edge.

BENEFITS OF A ROBUST POSTMARKET SURVEILLANCE PROGRAM

THE CHALLENGES FOR POSTMARKET SURVEILLANCE

Businesses seeking to make the most of their postmarket surveillance face several key challenges:

- With a complex and varied safety landscape, business face no shortage of new requirements, all needing their own processes and procedures.
- To build successful PMS processes, businesses need a foundation of effective quality management processes alongside proper monitoring and improvement metrics.
- Where departments aren't proactive in gathering data, analysis can become grueling. Siloed systems can make data sources feel hidden or leave information unnecessarily complicated to collect and use.
- Businesses without a solid integrated risk process aligned to ISO 14971:2019 can find that critical post-production monitoring is missed.

THE SOLUTION TO POSTMARKET SURVEILLANCE CHALLENGES

IQVIA's SmartSolve Postmarket Surveillance provides best-practice processes for centrally managing all your PMS activities.

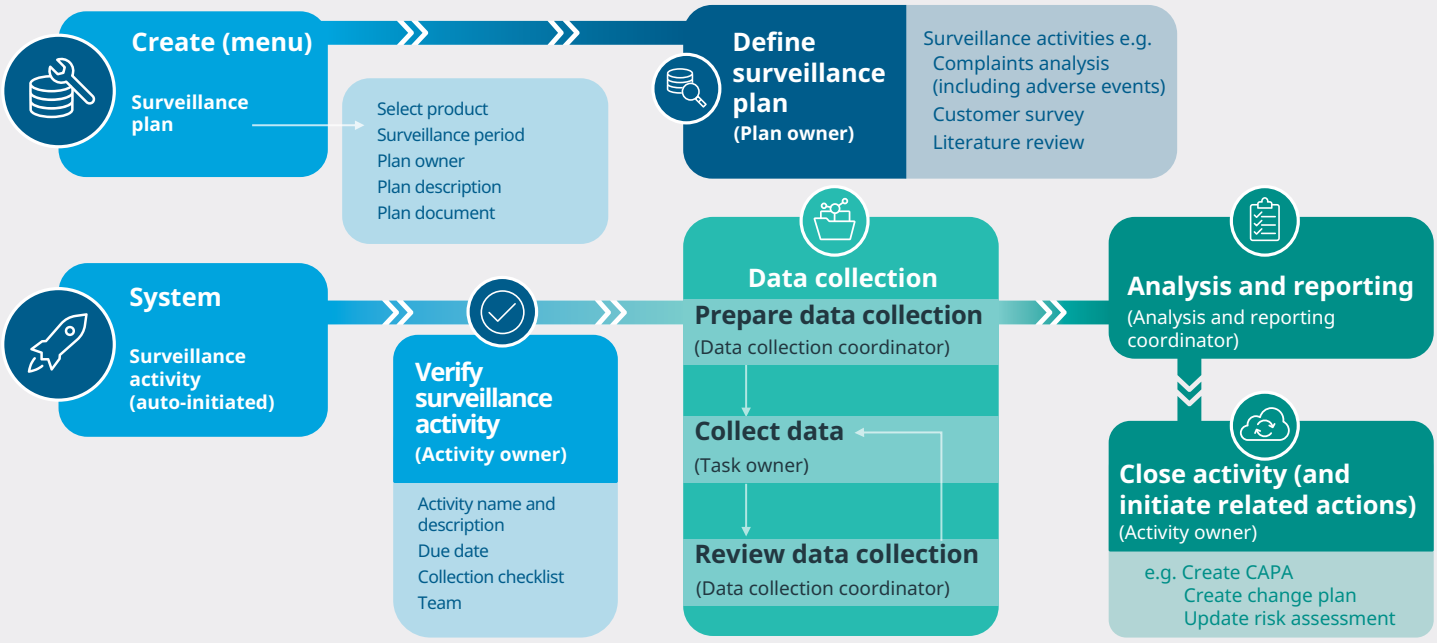
- The SmartSolve Dashboard organizes surveillance activities by task and task owner, facilitating and improving tracking and cross-department communication. The dashboard provides team members with clear visibility into the PMS process, helping to streamline activities.
- Real-time status of tasks, and access to all surveillance evidence and reports, ensures team members are always accessing the most up-to-date and accurate information.
- Module administration allows easy setup and maintenance of surveillance plans and activity details, to provide a consistent and complete record of the surveillance process and results.
- Each surveillance activity and its associated tasks are tracked from data collection through to analysis and reporting, delivering an end-to-end view of your PMS program.
- SmartSolve PMS module is written to take account of the international ISO/TR 20416:2020 Medical devices — postmarket surveillance for manufacturers.

SmartSolve Postmarket Surveillance's integration with other SmartSolve modules provides an end-to-end view of all your quality process activities.

- SmartSolve Postmarket Surveillance integrates with other key quality processes, including CAPA Management, Risk Management, and Change Management, to offer closed-loop traceability across the quality process journey.
- Integration with SmartSolve Document Management allows users to easily create PSURs and other postmarket surveillance reports from custom templates, and collaborate and review content with other team members.

As the complete solution for the PMS process, SmartSolve Postmarket Surveillance facilitates regulatory compliance while still delivering cost reductions and contributing to improved product safety and performance.

SMARTSOLVE POSTMARKET SURVEILLANCE WORKFLOW



REDUCE COSTS AND DEMANDS ON RESOURCES

A robust and effective postmarket surveillance (PMS) system can reduce both costs and demands on resources, while increasing product safety and performance.

The SmartSolve Postmarket Surveillance module for MedTech will provide your organization with a workflow to manage, track and document all the steps from PMS planning through data collection, analysis and reporting.

SMARTSOLVE POSTMARKET SURVEILLANCE SOLUTION OVERVIEW

Solution Overview

SmartSolve Postmarket Surveillance

Managed surveillance process

- Centrally-managed activities increase visibility and communication
- Real-time status and access to surveillance evidence and reports

Setup flexibility

- Customized surveillance activities and tasks
- Leverage own document/report templates including PSUR template

Integrated with other QMS

- Create Change Plan
- Initiate CAPA
- Perform Risk Assessment / Update Product Risk File

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