White Paper

Maximizing post-market surveillance with real world data

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Introduction

EU Medical Devices Regulation and In Vitro Diagnostics Regulation are bringing increased post-market surveillance (PMS) requirements for all MedTech firms. Multiple factors, including the rapid growth in device interoperability, the rise in Software as a Medical Device (SaMD), and increasingly frequent cybersecurity breaches, have been responsible, in part, for the continued rise in recalls, particularly software-related recalls.

Both the Medical Device (MD) and In Vitro Diagnostics (IVD) Regulations require a PMS plan, which should include a post-market clinical follow-up plan or justification for why the latter is not required. For higher-risk devices and IVDs, a periodic safety update report (PSUR) is required, and for lower-class devices, a post-market surveillance report (PMSR) is required.

In this environment, it's critical for device companies to maximize their post-market surveillance by using real world data to detect signals of defective devices in the field before a recall becomes necessary.

CHALLENGES WITH POST-MARKET SURVEILLANCE

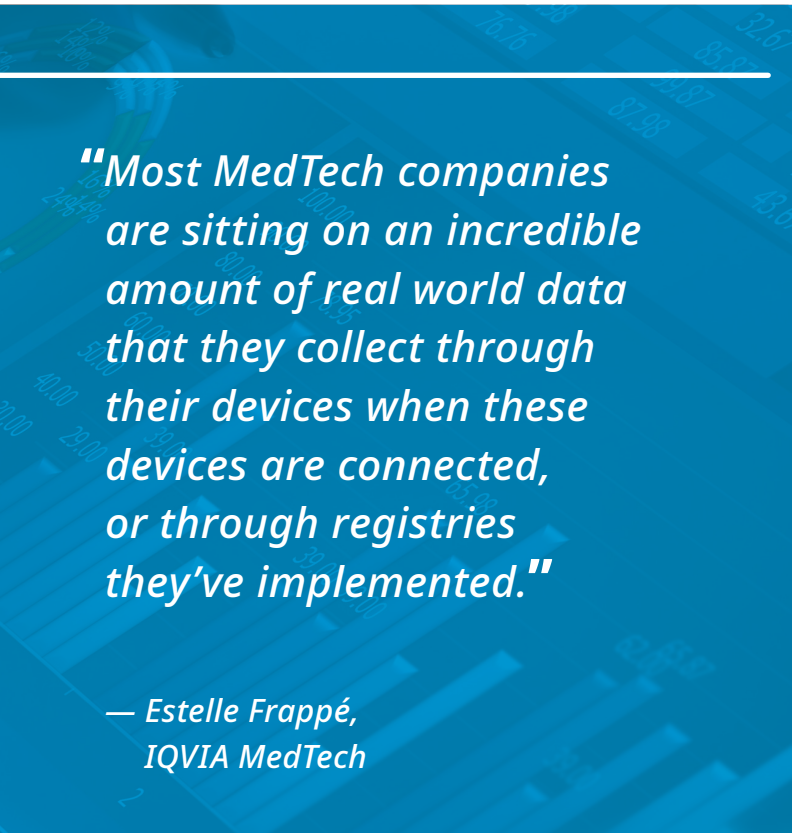
Manufacturers face several challenges in maximizing their PMS efforts, including:

- Identifying the data that can inform these efforts
- Generating new data to support PMS
- Dedicating time and resources to preparing PMS documentation

These challenges will be exacerbated by the new vigilance reporting timelines under the MDR and IVDR that require manufacturers to report incidents within 15 days, rather than 30 days. Also, it's important to be aware that under the transition arrangements, these new timelines will apply to all devices from the date of application, regardless of the route to CE Marking, including the Medical Device Directive and In Vitro Diagnostic Directive.

Manufacturers that want to improve their PMS efforts will need to proactively look for information to feed into their PMS systems, advised Caroline Freeman of IQVIA Quality Compliance Solutions in a recent webinar.

The first step for manufacturers setting up a robust PMS system is to scrutinize all types of activity carried out around the organization to identify the types of data gathered from those activities and assess the value of that data in terms of PMS. The second step is to investigate and analyze the data to decide on necessary actions.



UNDERSTANDING REAL WORLD EVIDENCE

MedTech firms' Post-Market Surveillance data sources should include real world evidence, which assesses the use, risks, and safety of a device in real life. It should also include real world data, meaning all data coming from different data sources related to a patient's health or device use. This data falls into four different families: electronic medical records (EMR), longitudinal prescription database data (information recorded in pharmacy software), hospital data, and claims data from payers.

"Most MedTech companies are sitting on an incredible amount of real world data that they collect through their devices when these devices are connected, or through registries they've implemented," notes Estelle Frappe of IQVIA MedTech.

This data could be easily linked to other sources of data like public registries to address a variety of regulatory requirements, such as:

- Post-market clinical follow-up
- Post-market performance follow-up
- Post-approval commitments/active surveillance
- Post-market continuous evaluation
- Safety and surveillance
- Outcomes research, retrospective database studies

An ideal PMS system would take in information from all of these sources and evaluate all of the available data as one set. Reactive data from vigilance reports, audits, complaints, out-of-specification reports, and recalls should be combined with proactive data from service reports, literature, social media, real world evidence, and customer surveys. Companies then need a set of processes, such as prioritization algorithms, to handle the incoming data and events in a timely and efficient way.

THE FUTURE POST-MARKET SURVEILLANCE SAFETY LANDSCAPE

In addition to pulling from new data sources, MedTech firms may find that a more centralized PMS/safety structure is needed to maximize effectiveness, Freeman said.

"Within MedTech companies, we often see siloed departments managing product safety and patient vigilance data, including Quality Assurance or Regulatory Affairs, and in such a scenario, PMS is decentralized. Yet some really valuable and useful information for PMS sits in departments that are outside the QA/RA Systems," she said, noting that information from user meetings, brand surveys, and social media often is not adequately captured, assessed, and trended.

> *"With the increased focus on PMS in the MDR and IVDR, centralized systems can be the way forward."*
>
> *— Caroline Freeman, IQVIA Quality Compliance Solutions*

Phil Johnson, IQVIA Quality & Regulatory Compliance, notes the ideal organization has a centralized group for Safety Surveillance and Medical Affairs to ensure proactive management of safety data. This central group provides medical services to all functional departments and provides medical input into Quality Management System elements including risk management, PMS, corrective and preventive actions, vigilance reporting, and field actions.

Already, IQVIA is starting to see MedTech firms implement a more centralized approach for PMS, with complaint-handling units covering both complaint investigation and regulatory reporting. For wider PMS needs, MedTech firms need to coordinate a number of different activities – periodic safety update reports (PSUR), post-market surveillance plans, post-market surveillance reports (PMSR), post-market clinical follow-up (PMCF), clinical evaluation reports (CER), increased vigilance reporting needs, and recall management. There is a lot of overlap among these needs and functions, so having one centralized group to manage them can be more effective.

The end result is a centralized approach with a master data set for reporting and signal detection, benefiting from processes and technology that mine the data for signals.

"This is an ideal future system that can provide earlier identification of issues, potentially reducing the number of recalls and allowing quick decisions before 'defective' devices are inadvertently placed on the market," Johnson said. The new technology available to support PMS systems, combined with a more centralized group within MedTech firms, provides an efficient and compliant solution for PMS.

Setting up a better Post-Market Surveillance approach

Some MedTech manufacturers are optimizing their PMS approach by creating their own evidence platforms, while some are still working out the details of where to start. No matter where they are in the process, a third party such as IQVIA MedTech can provide technical, regulatory, and scientific support to ensure that the PMS data collected will be useful for PMS analyses, and that the PMS system as a whole is compliant with all regulatory requirements.

With a centralized system that pulls PMS data from all available sources, MedTech firms can stay ahead of safety trends and signals, ensuring their devices in the field are high-quality and safe for their customers. This type of approach requires less work on the part of MedTech companies, while providing more and better insights to guide R&D and help bring and maintain the best and most effective products to market.

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