## Post-Market Surveillance: A Guide for Startups

*Understand your obligations. Avoid costly delays. Build a scalable PMS strategy that works.*

For startups in MedTech, it's easy to treat regulatory approval as the final hurdle. But under evolving frameworks like the EU MDR, your responsibilities don't end at market entry - they begin to multiply.

Post-Market Surveillance (PMS) is not just a checkbox exercise. It's a continuous, structured obligation to monitor the safety, quality, and clinical performance of your device once it's in use. Failing to plan for PMS early can lead to renewal delays, unexpected audits, or loss of CE marking , all of which can severely impact commercial strategy and investor confidence.

The good news? With a smart, scalable approach, PMS doesn't have to overburden your team. Whether you're preparing your first submission or retrofitting compliance for a legacy product, this guide breaks down the core components of PMS and shows how early planning can reduce risk, protect timelines, and strengthen your evidence base over time.

### What Is PMS?

PMS refers to a **systematic process for gathering and evaluating data** on your medical device after it's been placed on the market. It's how regulators and manufacturers ensure a device continues to perform as expected in real-world use.

PMS includes ongoing collection and evaluation of data such as:

- **Clinical data** (from real-world use, patient registries, post-market studies)
- **Complaints and adverse event reports**
- **Literature reviews** (including the subject device, comparable devices, and alternative therapies)
- **Feedback from users** (e.g., surveys, interviews, or field reports)

Under the EU Medical Device Regulation (MDR), manufacturers are required to proactively collect and evaluate this data, not just react to complaints. The goal is to confirm that the device continues to meet its safety, performance, and benefit-risk profile over time.

### Why It Matters

Unlike the legacy Medical Device Directive (MDD), the MDR demands a proactive and ongoing PMS strategy. This shift has caught many startups off guard.

We often see early-stage teams underestimate the role of PMS, until a Notified Body requests a Post-Market Clinical Follow-up (PMCF) Plan or an updated Clinical Evaluation Report (CER) during a

surveillance audit or renewal. At that point, it's far harder (and more expensive) to backfill missing data or explain gaps in oversight.

That's why embedding PMS early, even in lean or resource-constrained environments, pays off. It reduces risk, improves submission readiness, and builds trust with both regulators and commercial partners.

Proactive PMS = Lower regulatory risk + smoother renewals + stronger market confidence.

### Core Components of a PMS System

A well-designed PMS system is essential for meeting regulatory requirements and ensuring ongoing device safety and performance. Let's break it down into 5 key elements you'll need to address:

#### 1. PMS Plan

This is your roadmap for how you'll collect, analyze, and act on post-market data. Your plan should be tailored to the specific device and clearly define data sources, analysis frequency, and team responsibilities.

***Pro Tip:*** *Keep it proportionate to your device class and risk profile. A Class I wound dressing doesn't need the same plan as a Class III implantable.*

#### 2. PMS Report / Periodic Safety Update Report (PSUR)

For Class I devices, a summary of PMS activities is maintained internally and updated as needed. For higher-risk devices (Class II and above), a formal PSUR must be compiled regularly and submitted to your Notified Body or regulatory authority, detailing safety data and any emerging concerns.

#### 3. PMCF Plan and Evaluation Report

Many devices require an ongoing clinical evaluation through PMCF activities. This involves collecting real-world clinical data, either through targeted studies or continuous monitoring, to confirm ongoing safety and effectiveness.

#### 4. Literature Review & Vigilance Monitoring

Active surveillance of medical literature and adverse event databases (e.g., FDA MAUDE, Eudamed) is critical to identify any potential safety signals or performance issues. This is where tools like ***ECNE SafeSearch Pro*** can help automate and structure this monitoring, reducing manual workload and increasing accuracy.

#### 5. Corrective Actions & Risk Updates

Insights from your PMS activities should directly inform your Risk Management File. If a safety signal or risk threshold is identified, it may require updates to your Instructions for Use (IFU), labeling, Clinical Evaluation Report (CER), or other key documents. Ensure you have clear procedures for evaluating signals and triggering corrective actions promptly.

### Case Snapshot: Scaling PMS for a Startup

An early-stage medical device startup was pursuing CE marking and their Notified Body requested more detailed information about their PMCF plan. Their initial submission included general statements, but lacked a structured timeline, defined tools, and a proactive literature review plan.

Our ECNE team partnered with them to:

- Develop a tailored, device-specific PMS and PMCF Plan aligned with regulatory expectations
- Establish a simple yet effective reporting cadence and standardized templates for PSURs and PMCF evaluation reports
- Implement our ***SafeSearch Pro*** service to provide automated quarterly literature reviews with minimal internal effort
- Ensure insights from PSURs were fully integrated into their clinical evaluation and risk documentation

**Outcome:** The startup avoided rework, passed the notified body review without additional queries, and now have a scalable PMS model that will grow with them.

### PMS Self-Assessment Questions

Not sure where to start? Use these questions to assess your current Post-Market Surveillance system and identify areas for improvement:

1. Do you have a documented PMS Plan tailored specifically to your device?
2. Have you identified and rationalized the post-market data sources you plan to use?
3. Are you regularly conducting literature and vigilance monitoring?
4. Do you know whether PMCF applies to your device, and have you defined the data you need to collect?
5. Have you scheduled regular PMS reporting cycles, including PSUR submissions?
6. Is your PMS system fully integrated with your clinical evaluation and risk files?

### Final Thoughts

For lean teams with limited bandwidth, PMS can often seem like a secondary priority, until it becomes a regulatory bottleneck. The key to success is to start small, start early, and build a PMS system that is proportionate, compliant, and scalable.

At ECNE, we partner with MedTech startups daily to design right-sized PMS strategies that align seamlessly with clinical workflows and grow alongside your business. Whether you need assistance drafting your first PMCF plan or want a streamlined approach to literature monitoring, we're here to help.

Need a second set of eyes on your PMS plan?
Reach out to schedule a review or learn more about how ***SafeSearch Pro*** can support your team's ongoing compliance.

Contact us: https://ecneresearch.com/contact-us