What Are the Post-Market Surveillance Requirements for AI Devices?

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Abstract

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Introduction

The integration of artificial intelligence (AI) and machine learning (ML) into medical devices has ushered in a new era of healthcare, offering unprecedented capabilities in diagnostics, monitoring, and treatment. However, the dynamic and adaptive nature of these technologies presents unique challenges for regulatory oversight. Unlike traditional medical devices with fixed functionalities, AI-enabled medical devices (AIaMDs) can evolve, learn, and potentially change their performance over time. This necessitates a robust framework for post-market surveillance (PMS) to ensure their continued safety and effectiveness after they have been deployed in real-world clinical settings. For health professionals on the front lines, understanding these PMS requirements is not just a matter of compliance but a crucial component of patient safety and professional responsibility.

The Core Principles of Post-Market Surveillance for AI Devices

Post-market surveillance is a mandatory and systematic process that manufacturers must undertake to proactively collect and analyze data about a device's performance once it is on the market. For AIaMDs, this process is even more critical due to factors like data drift, where the real-world data a model encounters differs from the data it was trained on, potentially leading to performance degradation. The primary goal of PMS is to create a continuous feedback loop that informs the entire product lifecycle.

The regulatory landscape, particularly in regions like the European Union, is shaped by a combination of the Medical Device Regulation (MDR) and the new AI Act. Together, these regulations establish that PMS is not a one-time evaluation but a longitudinal assessment of a device's safety and performance [1]. Key activities under this framework include:

Proactive Data Collection: *Manufacturers must actively gather information on the device's quality, performance, and safety throughout its lifecycle.* **Trend Analysis:** Identifying patterns in performance, including non-serious incidents, to detect emerging risks or systematic issues. ***Lifecycle Updates:*** *The findings from PMS are used to continuously update the device's risk management documentation, clinical evaluation, and labeling.* **Corrective and Preventive Actions (CAPA):** Initiating necessary actions to address any identified safety or performance concerns.

Shared Responsibility: The Role of Providers and Health Professionals

While the formal legal responsibility for conducting PMS lies with the device manufacturer or provider, the regulatory framework acknowledges a system of shared responsibility. Health professionals and the institutions they work for, referred to as 'deployers' in the EU AI Act, are indispensable partners in this ecosystem. Their real-world experience and clinical feedback are vital for identifying latent risks, usability challenges, or underperformance in specific patient subgroups that may not have been apparent during pre-market testing [1].

Deployers are expected to monitor the AI system's outputs for unexpected behavior and report any serious incidents to the manufacturer and relevant authorities. This collaborative approach is essential for creating a comprehensive picture of the device's real-world performance and ensuring that it remains safe and effective for its intended use.

Post-Market Clinical Follow-up (PMCF)

A specific and critical component of PMS is the Post-Market Clinical Follow-up (PMCF). As detailed in the EU's MDR, PMCF is a continuous process of proactively collecting and evaluating clinical data from the use of a device to confirm its safety and performance under actual clinical conditions [1]. For AIaMDs, PMCF studies are crucial for:

Confirming Clinical Performance: *Verifying that the device's diagnostic accuracy and clinical utility hold true across diverse patient populations and clinical settings.* **Identifying Unknown Risks:** Detecting previously unknown side effects, complications, or long-term risks associated with the device. ***Updating the Benefit-Risk Analysis:*** *Continuously re-evaluating the device's benefit-risk profile based on emerging real-world evidence.*

The U.S. Perspective: The FDA and Real-World Performance

In the United States, the Food and Drug Administration (FDA) also emphasizes a "total product lifecycle" approach to regulating AI/ML-based

medical devices. The FDA's framework is designed to allow for the iterative nature of AI/ML software while ensuring patient safety. A key component of this is the Manufacturer and User Facility Device Experience (MAUDE) database, which serves as a central tool for tracking adverse events associated with marketed devices [2].

However, studies have suggested that traditional adverse event reporting systems like MAUDE may be insufficient for capturing the unique failure modes of AI/ML devices [2]. In response, the FDA is actively developing new methods and tools for monitoring real-world performance. This includes exploring predetermined change control plans (PCCPs), which would allow manufacturers to pre-specify planned modifications to their AI/ML models and the methods for validating those changes without requiring a new regulatory submission for each update. This approach aims to balance regulatory oversight with the need for agile, continuous improvement of AI algorithms.

Conclusion

Post-market surveillance for AI-enabled medical devices is a dynamic and evolving field. It moves beyond the traditional, static view of device regulation to a continuous, lifecycle-based approach. For health professionals, the key takeaway is that their role does not end with the adoption of a new AI tool. Active participation in monitoring, providing feedback, and reporting adverse events are essential contributions to the shared responsibility of ensuring patient safety. As AI becomes more deeply integrated into clinical practice, a thorough understanding of and engagement with PMS requirements will be fundamental to harnessing the full potential of these transformative technologies while safeguarding patient welfare.

References

[1] Cuocolo, R., Bernardini, D., Pinto dos Santos, D., Klontzas, M. E., Akinci D'Antonoli, T., Curvo Semedo, L., ... & Williams, M. C. (2025). AI medical device post-market surveillance regulations: consensus recommendations by the European Society of Radiology. Insights into Imaging, 16*(1), 1-1.*

[2] Babic, B., Cohen, I. G., Stern, A. D., Li, Y., & Ouellet, M. (2025). A general framework for governing marketed AI/ML medical devices. npj Digital Medicine, 8*(1), 1-8.