# Regulatory Oversight of Patient Safety in Medical Devices

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Background: The growing dependency on medical devices and in vitro diagnostic technologies is providing significant benefits in healthcare, but also necessitating market regulation to safeguard patient safety.

Purpose: The aims were to identify gaps in medical device patient-centred regulatory sciences, and to develop a post-market surveillance framework to ensure patient safety.

Method: The methodology design consisted of three phases. Phase I focused on identifying global procedures for the oversight of post-market surveillance and vigilance. A data collection tool was validated and disseminated to European regulatory experts. Evaluated observations from Phase I guided development of a regulatory framework in Phase II. Phase III consists of pilot testing the framework on a sample of incident reports from the Malta Medicines Authority database. Insights into opportunities, weaknesses, and risks will guide further framework refinement.

Results: Phase I identified 5 key areas where patient-centric regulatory gaps exist, forming the 5 domains of the data collection tool: (a) regulatory resources, (b) incident reporting, (c) legal requirements on legacy and custom-made devices, (d) recall process, and (e) artificial intelligence integration in surveillance and vigilance regulation.

The framework developed in Phase II maps the processes that ensure safety and performance of devices across risk classes, and outlines responsibilities of stakeholders involved in post-market surveillance and vigilance. Risk mitigation measures, including field safety corrective actions and recalls, are defined.

Discussion: The developed framework is intended to serve as a resource for regulatory authorities to overcome challenges encountered in the oversight of patient safety in medical device regulatory sciences.