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Engineering the extraordinary

Post-Market Surveillance
Experiences, Challenges and Evolving Regulations

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Focus on Quality and Safety

Focus on safety and quality

Tenet 3 of the Medtronic Mission emphasizes how patient safety, product quality and reliability are extremely important to Medtronic.

Tenet 3

"To strive without reserve for the greatest possible reliability and quality in our products; to be the unsurpassed standard of comparison and to be recognized as a company of dedication, honesty, integrity, and service."

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Post Market Surveillance Scope

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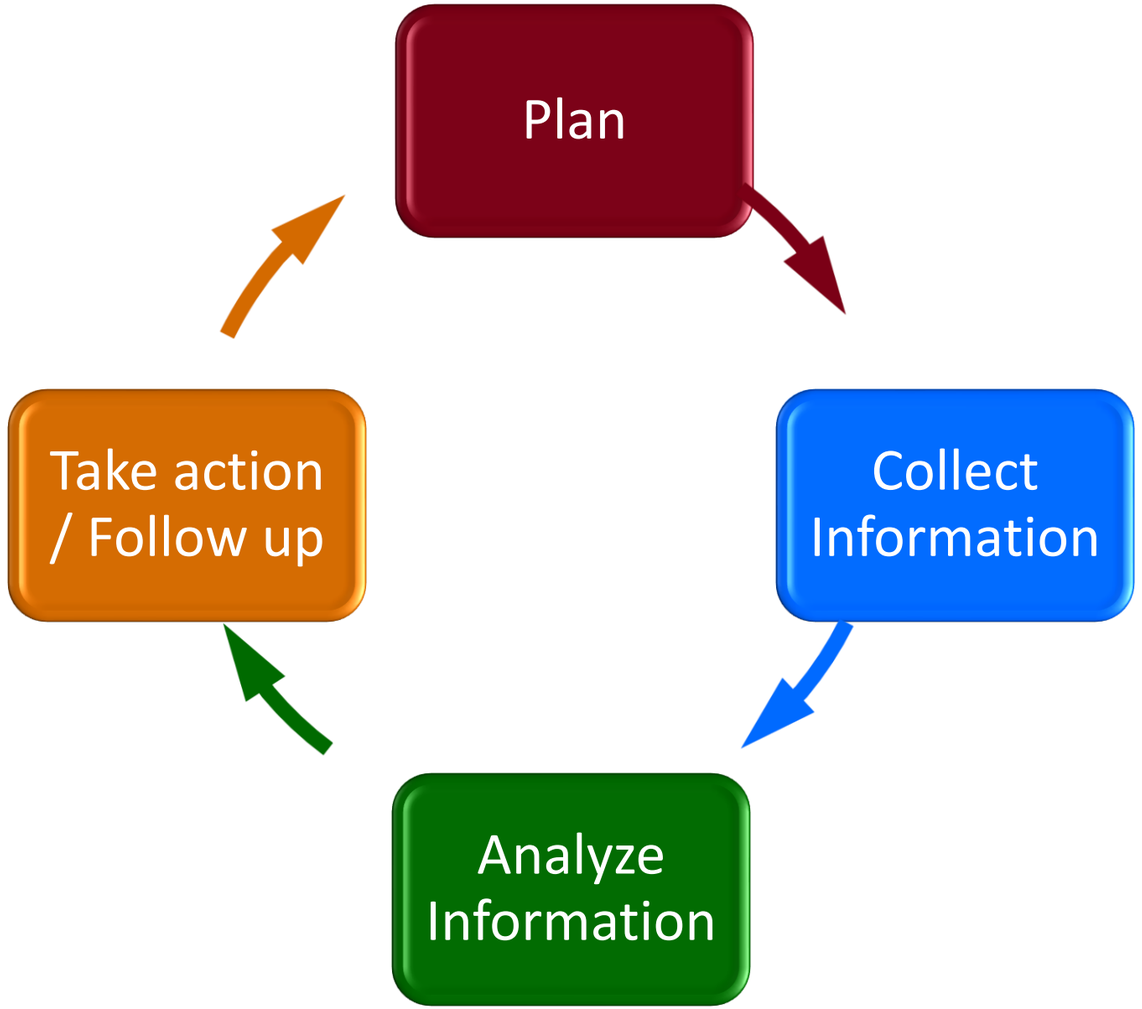
Post Market Surveillance - Framework

Intention: To actively and systematically collect, document and analyze data on the quality, performance, and safety of a device, and drive appropriate action to be taken



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Post Market Surveillance - Purpose

- **Ensure Patient Safety:** Prevent harm to patients/users from marketed products
- **Maintain Regulatory Compliance:** Fulfill legal obligations set by regulatory agencies such as notifying authorities of serious incidents
- **Risk Management:** Continuously assess and evaluate for new or emerging risks
- **Continuous Improvement:** Improve existing/future/related products

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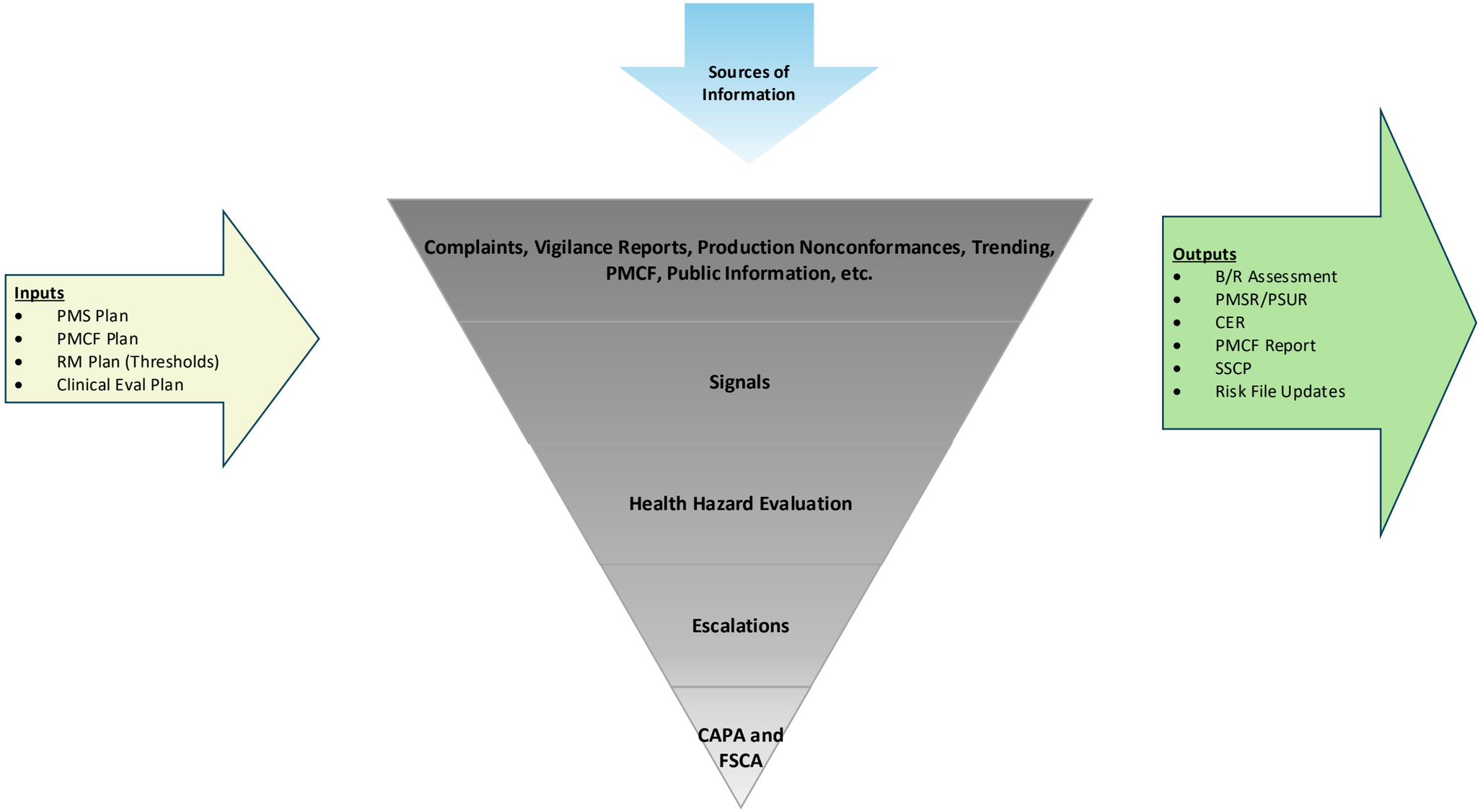
Post Market Surveillance System



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Post Market Surveillance Best Practices / Challenges

Best Practices

Complaints and Vigilance Reporting:

- Timely assessment to meet regulatory requirements
- Robust complaint handling system and process
- Robust input systems to the complaint handling process
- Utilize technology and other efficiencies when feasible to directly interface to regulatory databases

PSUR/PMSR

- Timeline management to align with CER/Literature/PMCF
- Utilization of IMDRF coding instead of any Medtronic specific/unique codes for PSUR/PMSR to align with MIR

FSCA

- Unified global process with well-defined and coordinated roles across global, regional and local teams

Challenges

- Inconsistent reporting timelines and templates across regions
- Constant churn of regulation
- Different jurisdictions are requiring a similar/copies of the EU PSUR plus a region-specific appendix resulting in significant resource burden to manage
- Separate vigilance and clinical SAE reporting requirements lead to unavoidable double reporting
- Uncertainty with the implementation of EUDAMED causing challenges in operationalizing

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EU Commission’s Proposed MDR Revision - 16 Dec 2025- PMS-Relevant Changes

PSUR Frequency Revisions	• Report every two years based on device risk • Exempt well-established and custom-made devices • Merge PSUR reviews with annual surveillance
Incident Reporting Timeline Adjustments	• Extend reporting from 15 to 30 days for incidents with no serious public health risk
CAPA Reporting to CA and NB	• No routine CA/NB notification for PMS-identified CAPAs • CAs may request details for safety or performance risks
NB Related Changes	• NBs review PSURs during surveillance only • NBs review vigilance data only on CA request, focusing on serious incidents/FSCAs • Oversight focuses on signals and impacts on certificate validity
Trend Reporting	• Focus on statistically significant increases in frequency or severity of non-serious incidents or expected undesirable side-effects that affect the benefit–risk profile
Cybersecurity	• Actively exploited vulnerabilities and severe cybersecurity incidents to be reported through EUDAMED within 30 days • Information goes to national CSIRTs and ENISA to enable EU-wide cybersecurity response

Current MDCG Guidance (Dec 2025) on PMS

MDCG 2025-10 (Dec 2025) provided guidance on implementing existing MDR PMS requirements (Articles 83–84) and supplements MDCG 2022-21
The guidance highlights:

- PMS as a continuous, proactive, risk-proportionate process embedded in the QMS
- Clear expectations for PMS plans and PMS system obligations throughout the device lifecycle
- Strong alignment with trend reporting, risk management and clinical evaluation

This guidance remains the practical baseline while the legislative revision is underway and sets out the expectations needed to uphold PMS quality.

ISO/TC 210/WG 6 - Application of post market surveillance systems to medical devices

ISO/TC 210/WG 6 - ISO working group responsible for the application of post-market surveillance (PMS) systems to medical devices.

Purpose: To develop international PMS standards and guidance that help manufacturers implement proactive, systematic PMS processes. This includes creating documents such as ISO/TR 20416, which provides guidance on PMS for manufacturers aligned with ISO 13485 and ISO 14971

ISO/ TR 20416 – Post market surveillance for manufacturers – Ongoing revision

- Provides guidance on the post-market surveillance process and is intended for use by medical device manufacturers
- Describes a proactive and systematic process that manufacturers can use to collect and analyze appropriate data, to provide information for the feedback processes and use this to meet applicable regulatory requirements to gain experience from the post-production activities.

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The Future of PMS

Forward-looking Summary

- More predictable and less repetitive PMS system, proactive and well-integrated into the QMS
- PMS becoming increasingly digital and data-driven
- Growing use of real-world evidence
- Shift toward risk-based surveillance
- Greater alignment expected between regulations, guidance and ISO standards, IMDRF / Global harmonization
- Cross-sector collaboration for sustainable PMS
- PMS evolving into a proactive safety-intelligence function, integrating diverse data sources to anticipate issues

Questions?

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