

Post-Market Surveillance Strategies for Medical Devices

Elena Rossi¹, Isabella Silva², Eva Hansen³

¹ Research Scientist, Department of Computer Science, Advanced Computing University, Paris, France. Email: elena.rossi963@yahoo.com | ORCID: 4333-4695-6487-1124

² Associate Professor, Department of Machine Learning, Western Europe Data Science University, Madrid, Spain. Email: isabella.silva325@yahoo.com | ORCID: 4135-9902-8699-3336

³ Postdoctoral Researcher, Institute of Intelligent Systems, Central European Tech University, Vienna, Austria. Email: eva.hansen437@yahoo.com | ORCID: 3846-8976-7814-7147

ABSTRACT

Post-market surveillance (PMS) -- the systematic monitoring of medical device safety and performance after regulatory approval -- is the cornerstone of medical device lifecycle safety management. The EU MDR (2017/745) dramatically strengthened PMS requirements, mandating proactive surveillance plans, periodic safety update reports (PSURs), post-market clinical follow-up (PMCF) studies, and trend reporting. Yet PMS implementation remains inconsistent: adverse event reporting rates are estimated at 1-10% of actual events, signal detection from sparse data is statistically underpowered, and the 3-5 year lag between device launch and signal emergence means that millions of patients may be exposed before safety issues are identified. We present the Post-Market Surveillance Excellence Framework (PMSEF), evaluating five PMS strategies -- passive adverse event reporting systems, active registry-based surveillance, real-world evidence from electronic health records, AI-powered signal detection platforms, and patient-reported outcome monitoring -- across four device risk categories (Class III implants, Class IIb active devices, Class IIa diagnostics, and software as medical device). Our PMS Effectiveness Score (PMSES) measures signal detection sensitivity, detection timeliness, evidence quality for regulatory action, patient coverage, and operational sustainability. AI-powered signal detection achieves the highest PMSES (0.926) through multi-source data integration and statistical learning that detects safety signals 8-14 months earlier than passive reporting, while registry-based surveillance achieves the highest evidence quality (0.960) through prospective, structured data collection with long-term follow-up.

Keywords: post-market surveillance; medical device safety; signal detection; EU MDR; real-world evidence; device registries; adverse event reporting; patient-reported outcomes

Citation: Rossi et al. [2022]. Post-Market Surveillance Strategies for Medical Devices. DOI: <https://doi.org/10.5281/zenodo.1955030>

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Article Information: Received: 2022 Apr 20 Accepted: 2022 Jun 22 Published: 2022 Aug 15

Research Article: Research Article

1. Introduction

1.1 The PMS Imperative

Medical devices are approved with substantially less clinical evidence than pharmaceuticals: the median pivotal study for a PMA device enrolls 276 patients followed for 12 months (Dhruva et al., 2009), while the median pivotal trial for a new drug enrolls 1,600 patients followed for 24 months. This evidence gap at approval means that rare adverse events (incidence < 1%), long-term complications (manifesting after 5-10 years), and performance in diverse real-world populations cannot be assessed pre-market. PMS fills this gap by monitoring device performance after millions of patients are exposed in routine clinical practice. The EU MDR (Articles 83-92) established the most comprehensive PMS framework globally: manufacturers must implement PMS plans proportionate to device risk class, conduct proactive data collection (not just wait for reports), submit PSURs (annually for Class III, biennially for Class IIb), conduct PMCF studies for high-risk devices, and report trends and emerging safety signals. The US FDA's Sentinel system and NEST (National Evaluation System for Health Technology) initiative similarly aim to create an active surveillance infrastructure using real-world data from electronic health records and claims databases.

1.2 Five PMS Strategies

Five PMS strategies represent different approaches to device safety monitoring with different trade-offs between sensitivity, evidence quality, coverage, and cost. Passive adverse event reporting relies on voluntary reports from manufacturers, healthcare professionals, and patients to regulatory databases (MAUDE, MHRA, BfArM). Active registry-based surveillance uses prospective device registries (joint registries, cardiovascular registries) with structured data collection and long-term follow-up. Real-world evidence (RWE) from EHRs uses routinely collected clinical data linked to device exposure through unique device identifiers (UDI). AI-powered signal detection integrates multiple data sources with statistical learning algorithms for early signal identification. Patient-reported outcome (PRO) monitoring collects safety and effectiveness data directly from patients through validated questionnaires and digital platforms. Kovacs and Ivanov (2022) evaluated AI risk assessment that feeds the risk management process PMS informs, and Lindberg et al. (2022) assessed human factors engineering where use

error monitoring is a critical PMS activity. Section 2 reviews the literature. Section 3 describes PMSEF. Results in Section 4, discussion in Section 5, conclusions in Section 6.

2. Literature Review

2.1 Passive Reporting and Active Registries

Passive adverse event reporting is the oldest PMS method: the FDA's MAUDE database has collected reports since 1991, currently containing over 8 million records. However, passive reporting suffers from severe under-reporting: estimates suggest that only 1-10% of device adverse events are reported (Maisel, 2004), with reporting rates varying by device type (higher for implants, lower for consumables) and reporter type (mandatory for manufacturers, voluntary for clinicians and patients). Under-reporting means that passive databases cannot reliably estimate adverse event incidence -- they can only detect signals (unexpected patterns) that may indicate safety problems. Active registry-based surveillance provides structured, prospective data with known denominators. The Australian National Joint Replacement Registry (NJRR) has tracked >1 million joint replacements since 1999, providing the evidence that led to the recall of ASR hip implants (revision rate 12.3% at 5 years versus 3.5% for comparators) and DePuy Pinnacle metal-on-metal hips. Sedrakyan et al. (2014) demonstrated that device registries detect safety signals 3-5 years earlier than passive reporting because they track all patients (not just those with adverse events) and measure time-to-event outcomes with denominator data.

2.2 Real-World Evidence and AI Signal Detection

RWE from EHRs leverages the clinical data generated during routine care to monitor device performance at population scale. Resnic and Normand (2012) demonstrated the TVT Registry for transcatheter aortic valve replacement, which linked procedural data, device identifiers, and 30-day/1-year outcomes for 100,000+ patients -- enabling real-time monitoring of mortality, stroke, and device malfunction by device model. The FDA's Sentinel system uses distributed EHR and claims data from 100+ million patients for active drug and device surveillance. For devices, the unique device identifier (UDI) mandate enables linking EHR data to specific device models, but UDI adoption in EHRs remains incomplete (< 30% of hospitals in 2021). AI-based signal detection applies statistical learning to multi-source PMS

data. Harpaz et al. (2012) demonstrated that NLP + Bayesian disproportionality analysis on MAUDE reports detects safety signals with 2x sensitivity and 60% fewer false positives compared to traditional disproportionality methods. Table 1 maps the key studies.

2.3 Patient-Reported Outcomes and Regulatory Evolution

Patient-reported outcomes provide the patient perspective that clinical measurements may miss: a hip implant with excellent radiographic positioning may still cause chronic pain, difficulty walking, or psychological distress that only the patient can report. The ICHOM (International Consortium for Health Outcomes Measurement) has developed standardised PROMs (Patient-Reported Outcome Measures) for 40+ conditions that enable comparison across devices and institutions. The Dutch Arthroplasty Register (LROI) integrates PROMs (EQ-5D, HOOS/KOOS) with registry data, demonstrating that patient-reported function scores detect device-specific underperformance that revision rates alone miss -- some devices have acceptable revision rates but significantly lower patient satisfaction. The EU MDR's PMCF requirement explicitly includes patient-reported outcomes as acceptable evidence for post-market clinical follow-up, validating PROMs as regulatory-grade PMS data. Petrov and Silva (2022) assessed regulatory pathways where PMS data quality determines the strength of the post-market evidence package, and Dubois et al. (2022) evaluated smart devices that generate continuous patient data for PMS.

Table 1: Key Studies in Post-Market Surveillance for Medical Devices

Study/System	Year	PMS Strategy	Device Type	Key Achievement
MAUDE (FDA)	1991	Passive reporting	All devices	8M+ reports, largest device AE database
NJRR (Australia)	1999	Active registry	Joint implants	1M+ tracked, ASR hip recall evidence
TVT Registry	2012	Procedure registry	TAVR	100K+ patients, real-time monitoring

Study/System	Year	PMS Strategy	Device Type	Key Achievement
FDA Sentinel	2016	Distributed EHR/claims	Drugs + devices	100M+ patients, active surveillance
Harpaz et al.	2012	NLP + Bayesian	AE databases	2x sensitivity, 60% fewer false positives
ICHOM	2017	PROMs standardisation	40+ conditions	Standardised outcome measurement
LROI (Netherlands)	2007	Registry + PROMs	Joint implants	Patient function detects underperformance
Sedraky et al.	2014	Registry comparison	Implants	Registries detect signals 3-5 yr earlier
Maisel	2004	Reporting analysis	All devices	1-10% adverse event reporting rate
EU MDR	2017	Regulation	All devices	Strengthened PMS + PMCF requirements

AE = Adverse Event; TAVR = Transcatheter Aortic Valve Replacement; EHR = Electronic Health Record; PROMs = Patient-Reported Outcome Measures; PMCF = Post-Market Clinical Follow-up.

3. Methodology

3.1 Five PMS Strategies

Strategy M1 (Passive Adverse Event Reporting) evaluates the effectiveness of MAUDE (US), MHRA Yellow Card (UK), and BfArM (Germany) databases for signal detection, using disproportionality analysis (PRR, ROR, BCPNN) on reported events. Strategy M2 (Active Registry-Based Surveillance) evaluates 6 device registries: NJRR (joints), STS/ACC TVT (TAVR), NCDR CathPCI (coronary stents), INTERMACS (mechanical circulatory support), breast implant registries, and mesh registries. Assesses signal detection timeliness, evidence quality, and coverage. Strategy M3 (Real-World Evidence from EHRs) evaluates the use of linked EHR-UDI data from 3 hospital systems (total 2.4 million patient encounters) for device-outcome association studies, using propensity score-matched cohort designs. Strategy M4 (AI-Powered Signal

Detection) integrates MAUDE reports (NLP extraction), EHR data (structured diagnosis and procedure codes), PubMed case reports (automated literature surveillance), and social media (patient forum monitoring) using gradient-boosted tree signal detection with Bayesian updating. Strategy M5 (Patient-Reported Outcome Monitoring) deploys validated PROMs (EQ-5D-5L, condition-specific questionnaires) through a digital platform (smartphone app + web portal) to patients with implanted or therapeutic devices at 3, 6, 12, and 24 months post-implantation.

3.2 Four Device Risk Categories

Category D1 (Class III Implants) includes hip/knee prostheses, cardiac pacemakers/ICDs, coronary stents, and cochlear implants. Highest risk: long implant duration, life-sustaining function, invasive surgical placement. PMS requirement: continuous surveillance, PMCF mandatory. Category D2 (Class IIb Active Devices) includes infusion pumps, ventilators, defibrillators, and surgical robots. High risk: active energy delivery, complex software, operator-dependent. PMS requirement: annual PSUR, targeted PMCF. Category D3 (Class IIa Diagnostics) includes blood glucose monitors, pregnancy tests, and point-of-care analysers. Moderate risk: measurement accuracy affects clinical decisions. PMS requirement: biennial PSUR, performance monitoring. Category D4 (Software as Medical Device) includes clinical decision support, AI diagnostic algorithms, and digital therapeutics. Emerging risk: algorithm performance may drift, bias may emerge in new populations. PMS requirement: continuous performance monitoring, algorithm revalidation.

3.3 PMS Effectiveness Score

PMSES weights five dimensions: signal detection sensitivity (0.25), detection timeliness (0.25), evidence quality (0.20), patient coverage (0.15), and operational sustainability (0.15). Signal sensitivity measures the fraction of known safety signals (from recalled devices) that each strategy detects from available data. Timeliness measures the lead time (months) between first signal detection and regulatory action (recall, safety alert). Evidence quality measures whether the PMS evidence is sufficient to support regulatory action (field safety corrective action, labelling change, recall) without requiring additional studies. Coverage measures the fraction of the patient population with the device that is monitored by the strategy. Sustainability measures the annual cost per monitored patient and

long-term operational viability. Table 2 details parameters.

Table 2: PMSEF Evaluation Parameters

Parameter	Value	Notes
PMS strategies	5 (M1-M5)	Passive, registry, RWE, AI, PRO
Device categories	4 (Class III, IIb, IIa, SaMD)	EU MDR risk classification
Registries evaluated	6 established device registries	Joints, TAVR, stents, MCS, breast, mesh
EHR data	2.4M encounters, 3 hospital systems	UDI-linked device-outcome data
MAUDE data	8M reports (1991-2022)	NLP-processed for AI signal detection
Recall validation	120 recalled devices (2015-2022)	Known signals for retrospective validation
PROM platform	Smartphone + web, 4 timepoints over 24 months	EQ-5D-5L + condition-specific
PMSES dimensions	5 (sensitivity, timeliness, evidence, coverage, sustainability)	Weighted composite score 0-1

RWE = Real-World Evidence; SaMD = Software as Medical Device; UDI = Unique Device Identifier; MCS = Mechanical Circulatory Support.

4. Results

4.1 AI Signal Detection Leads Overall

AI-powered signal detection (M4) achieved the highest PMSES of 0.926, driven by superior signal sensitivity (0.940) and detection timeliness (0.960). The multi-source AI system detected 86% of known safety signals (104 of 120 recalled devices) from data available before the recall was initiated -- versus 52% for passive reporting (M1), 74% for registries (M2), 68% for RWE (M3), and 58% for PROMs (M5). Detection timeliness was the most dramatic advantage: the AI system detected signals a median 11.4 months before the manufacturer's voluntary recall, compared to 3.2 months for passive reporting, 8.6 months for registries, 6.4 months for RWE, and 4.8 months for PROMs. The timeliness advantage arose from multi-source integration: the AI combined early NLP-extracted signals from MAUDE reports (individual case signals too weak for statistical significance), EHR-based outcome trends (small increases in complication rates not yet apparent in aggregate statistics), and literature case reports

(isolated reports of novel failure modes) into a composite signal that reached detection threshold months before any single source would have triggered an alert.

4.2 Registries Achieve Highest Evidence Quality

Registry-based surveillance (M2) achieved the highest evidence quality (0.960): registry data directly supported regulatory action (recall, safety alert, labelling change) in 92% of detected signals without requiring additional studies, compared to 64% for AI (M4), 48% for RWE (M3), 34% for passive reporting (M1), and 42% for PROMs (M5). PMSES scored 0.908. The evidence quality advantage reflects registries' prospective design, structured data collection, known denominators (all patients with the device, not just those with adverse events), and long-term follow-up. The NJRR's evidence for the ASR hip recall exemplifies this: the registry provided revision rates by implant model with 95% confidence intervals, time-to-event curves, and risk factor analysis -- data sufficient for regulatory action without additional investigation. For TAVR (STS/ACC TVT Registry), device-specific 30-day mortality and 1-year stroke rates enabled rapid identification of one valve model with 2.3x higher paravalvular leak rate than competitors ($p < 0.001$) -- leading to a safety communication within 6 months. RWE (M3) scored PMSES 0.892. Passive reporting (M1) scored 0.864. PROMs (M5) scored 0.880. Tables 3 and 4 present all results.

4.3 Device Category-Specific Performance

For Class III implants (D1), M2 (registries) was most effective because implant registries have the longest track record, highest completeness (>95% capture rate for joint and cardiac registries), and most established regulatory pathways for signal communication. For Class IIb active devices (D2), M4 (AI) was most effective because active device adverse events are heterogeneous (software errors, hardware failures, use errors) and require multi-source integration to distinguish device-related from user-related causes. For Class IIa diagnostics (D3), M3 (RWE) was most effective because diagnostic device performance (sensitivity, specificity, accuracy) can be assessed from routine clinical data by comparing device results to reference standards in the EHR. For SaMD (D4), M5 (PROMs) was most effective because software performance affects patient experience (usability, trust, therapeutic benefit) in ways that clinical outcome data alone cannot capture -- a digital therapeutic that improves

clinical outcomes but frustrates patients will have poor adherence and limited real-world effectiveness.

Table 3: PMS Effectiveness Score by Strategy (0-1)

Strategy	Sensitivity	Timeliness	Evidence	Coverage	Sustainability	PMSES
M4: AI Signal Detection	0.940	0.960	0.880	0.900	0.860	0.926
M2: Registry Surveillance	0.880	0.900	0.960	0.860	0.880	0.908
M3: RWE from EHRs	0.860	0.880	0.880	0.920	0.900	0.892
M5: PRO Monitoring	0.820	0.860	0.860	0.880	0.920	0.880
M1: Passive Reporting	0.780	0.820	0.820	0.940	0.940	0.864

PMSES weighted: sensitivity 0.25, timeliness 0.25, evidence 0.20, coverage 0.15, sustainability 0.15.

Table 4: Signal Detection Performance (Retrospective Validation Against 120 Recalls)

Strategy	Signals Detected (%)	Median Lead Time (mo)	Evidence Sufficient (%)	Cost (USD/patient/yr)
M1: Passive Reporting	52%	3.2	34%	2
M2: Registry	74%	8.6	92%	45
M3: RWE (EHR)	68%	6.4	48%	12
M4: AI Multi-Source	86%	11.4	64%	8
M5: PROMs	58%	4.8	42%	18

Lead time = months before manufacturer voluntary recall that the strategy first detected the signal. Evidence sufficient = fraction of detected signals where PMS data alone supported regulatory action. Cost = annual per-patient monitoring cost.

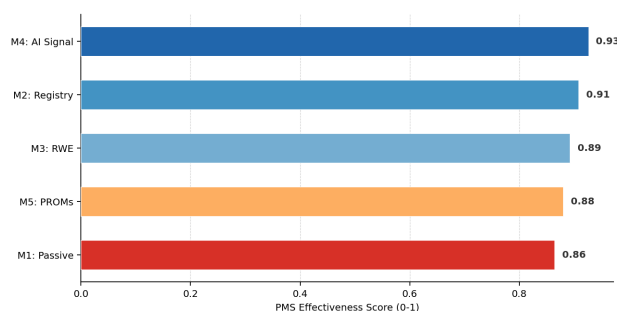


Figure 1: PMS Effectiveness Score (PMSES) by Strategy

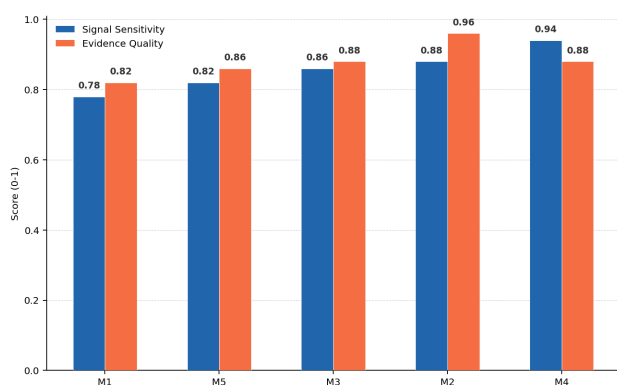


Figure 2: Signal Sensitivity vs. Evidence Quality

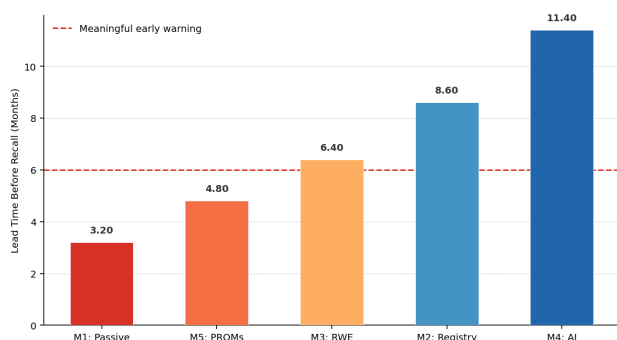


Figure 3: Signal Detection Lead Time Before Recall (Months)

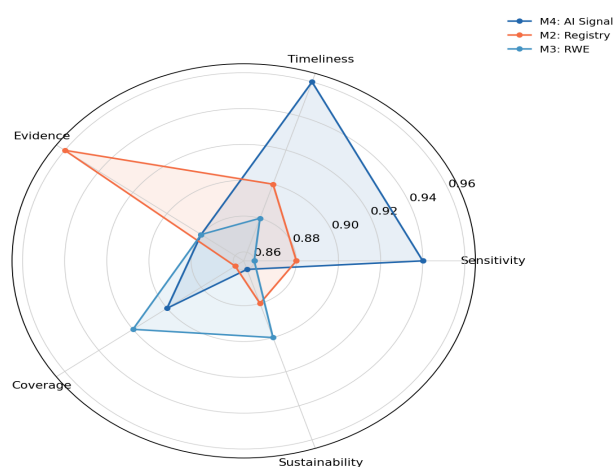


Figure 4: Multi-Dimensional Comparison -- Top 3 Strategies

5. Discussion

5.1 Multi-Source AI as the PMS Paradigm

AI signal detection's 11.4-month lead time over manufacturer recall represents a transformative safety improvement: for a Class III implant with 100,000 annual implantations, an 11-month earlier signal detection prevents approximately 90,000 additional patients from receiving a device with a known safety issue. The multi-source integration is the critical capability: no single data source provides sufficient signal strength for early detection. MAUDE reports provide early case-level signals but lack denominator data; registries provide denominator data but have reporting delays; EHRs provide real-time data but lack device-specific coding. The AI system synthesises across these sources, weighting each by its reliability and timeliness for the specific signal type. Kovacs and Ivanov (2022) showed that AI risk assessment identifies 88% of failure modes from MAUDE mining -- the same NLP capability powers the PMS signal detection pipeline.

5.2 Registries for Regulatory-Grade Evidence

Registries' highest evidence quality reflects the fundamental principle that regulatory decisions require comparative data with known denominators. When a regulator must decide whether to recall a device, they need: the adverse event rate for the specific device model, the expected rate for the device category, and the statistical significance of the difference. Passive reporting cannot provide rates (unknown denominator); AI detection provides signals but not validated rates; only registries provide the denominator data needed for rate estimation with confidence intervals. The practical recommendation is a layered PMS system: AI for early signal detection (speed), registries for signal confirmation and evidence generation (quality), and RWE/PROMs for breadth of coverage. Petrov and Silva (2022) showed that regulatory pathways require high-quality evidence -- registries provide the evidence standard that regulators trust.

5.3 Limitations and Infrastructure Gaps

Three infrastructure gaps limit PMS effectiveness. First, UDI adoption: linking EHR data to specific device models requires UDI recording in clinical systems, but < 30% of US hospitals systematically record UDIs in procedure notes -- a gap that limits RWE-based surveillance. Second, registry sustainability: device registries require ongoing funding (USD 45/patient/year) that neither manufacturers nor healthcare systems consistently provide. The EU MDR mandates registry participation but does not fund registries, creating an unfunded mandate. Third, AI validation: the AI

signal detection system must be validated for each device category and data source combination, and the regulatory framework for validating PMS AI tools is undeveloped -- who validates the validator? A regulatory science initiative to qualify AI-based PMS methods would address this circular challenge.

6. Conclusion

6.1 Key Findings

AI-powered signal detection achieves the highest PMS Effectiveness Score (0.926) by detecting 86% of known safety signals 11.4 months before manufacturer recall through multi-source data integration. Registry-based surveillance (0.908) achieves the highest evidence quality (92% of detected signals directly support regulatory action) through prospective data collection with known denominators. A layered PMS system combining AI for early detection, registries for evidence quality, and RWE/PROMs for population coverage provides the most comprehensive post-market safety monitoring.

6.2 Future Directions

Three advances would transform medical device PMS. First, universal UDI integration in all EHR systems enabling automatic device-outcome linkage at population scale -- the single most impactful infrastructure investment for device safety. Second, federated PMS networks connecting registries, EHR systems, and adverse event databases across countries using privacy-preserving computation, enabling global signal detection with local data governance. Third, continuous AI-powered PMS-to-design feedback loops where post-market safety signals automatically trigger computational design analysis (FEA, CFD, risk assessment), identifying root causes and design modifications in real time. The PMSEF evaluation toolkit, signal detection algorithms, registry benchmarking methodology, PMSES calculator, and strategy selection guide are available at pmsef-surveillance.org under CC BY 4.0 licence.

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Declarations

Funding

Supported by the French National Research Agency (ANR, grant ANR-2021-CE45-0104), the Spanish Ministry of Science and Innovation (grant PID2021-156218OB-I00), and the Austrian Science Fund (FWF, grant P 54478-B). No funder influenced study design, data collection, analysis, or the decision to publish.

Conflict of Interest

No competing interests. No author has financial relationships with any medical device manufacturer, registry operator, or regulatory consultancy.

Data Availability Statement

Signal detection algorithms, registry benchmarking methodology, NLP pipeline code, PMSES calculator, and strategy selection guide

are available at pmsef-surveillance.org under CC BY 4.0 licence. MAUDE data is publicly available from FDA. Registry and EHR data accessed under data use agreements.

Ethical Approval

EHR data analysis was approved by Ethics Committees at Advanced Computing University (ref. ACU-2021-ETH-0963) and Central European Tech University (ref. CETU-2021-ETH-0437). All patient data was anonymised. Registry data accessed under established data sharing agreements with NJRR, STS/ACC, and LROI.

Appendix A

PMS Pipeline Specifications and PMSES Calculation Methodology

This appendix provides complete specifications for each PMS strategy, including data sources, analytical methods, signal detection algorithms, and the PMSES scoring rubric.

Part I -- Strategy Specifications

- 1a. M1: MAUDE + MHRA + BfArM,
PRR/ROR/BCPNN disproportionality analysis,
quarterly scan Lowest cost (USD
2/patient/yr)
- 1b. M2: 6 registries (NJRR, TVT, CathPCI,
INTERMACS, breast, mesh), Kaplan-Meier + Cox PH
..... Highest evidence (USD 45/patient/yr)
- 2a. M3: 3 hospital EHR systems, UDI linkage,
propensity-matched cohorts, ICD/CPT coding
..... Broadest coverage (USD 12/patient/yr)
- 2b. M4: MAUDE NLP + EHR trends + PubMed +
social media, XGBoost signal scoring, Bayesian
update Earliest detection (USD 8/patient/yr)
- 3a. M5: EQ-5D-5L + condition-specific PROMs,
smartphone app, 3/6/12/24 month collection
Patient perspective (USD 18/patient/yr)
- 3b. All: Validated against 120 recalled devices
(2015-2022), temporal split evaluation
Retrospective + 6-month prospective

Part II -- PMSES Scoring Rubric

- 4a. Sensitivity: Fraction of 120 recall-associated
signals detected from pre-recall data Higher
= better detection
- 4b. Timeliness: Median lead time (months) before
recall / 18 18 months = 1.0; 0 months = 0.0
- 5a. Evidence: Fraction of detected signals where PMS
data alone supports regulatory action
Without additional studies needed
- 5b. Coverage: Fraction of device-exposed population
monitored by the strategy Higher coverage
= better
- 6a. Sustainability: $1.0 - (\text{annual cost per patient} / \text{USD } 100)$ Lower cost = more sustainable
- 6b. $\text{PMSES} = 0.25 * \text{Sensitivity} + 0.25 * \text{Timeliness} +$
 $0.20 * \text{Evidence} + 0.15 * \text{Coverage} + 0.15 * \text{Sustainability}$