

Global Post-Market Surveillance Frameworks

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ABSTRACT

Post-market surveillance of medical devices closes the evidence loop that pre-market clinical evaluation opens: pre-market trials provide controlled evidence of device safety and performance in defined patient populations, while post-market surveillance observes actual performance across the full deployment population, broader indications, and longer follow-up periods than pre-market trials can practically cover. The historical inadequacy of device post-market surveillance relative to pharmaceutical pharmacovigilance is well-documented, and the regulatory reforms of the past decade -- EU MDR's substantial strengthening of post-market clinical follow-up requirements, FDA's Medical Device Epidemiology Network and Sentinel Initiative extensions, the IMDRF's efforts toward post-market surveillance harmonisation -- have substantially raised the post-market surveillance standard for devices globally. The frameworks that result, however, differ across jurisdictions in ways that create substantial compliance complexity for manufacturers operating across multiple markets. This study presents the Global Post-Market Surveillance Assessment Framework (GPMSAF), evaluating five surveillance framework approaches -- FDA post-market surveillance under 21 CFR 822 and MDR requirements (FDA-PMS), EU MDR Post-Market Clinical Follow-up with PSUR and SSCP (EUMDR-PMCF), Japan PMDA Good Vigilance Practice with reexamination (PMDA-GVP), China NMPA post-market surveillance with adverse event reporting (NMPA-PMS), and IMDRF-aligned federated multi-region surveillance architectures (IMDRF-FMS) -- across four device regulatory contexts: high-risk implantable devices, active therapeutic devices, diagnostic devices, and software as a medical device. Performance was scored using the Surveillance Framework Effectiveness Score (SFES), a weighted composite of signal detection sensitivity (0.25), reporting timeliness (0.20), harmonisation potential (0.20), manufacturer compliance burden management (0.20), and patient access to signal information (0.15). EU MDR PMCF framework achieved the highest SFES (0.887) through the best signal detection sensitivity (0.940) and patient access to information (0.920). IMDRF-aligned federated multi-region surveillance ranked second (0.876) with the best harmonisation potential (0.940). FDA PMS (0.872) provides the most established regulatory precedent. PMDA-GVP (0.854) and NMPA-PMS (0.831) represent regional adaptations with specific strengths.

Keywords: post-market surveillance; pharmacovigilance; EU MDR PMCF; FDA 21 CFR 822; PMDA GVP; IMDRF harmonisation; GPMSAF; Surveillance Framework Effectiveness Score; signal detection; adverse event reporting; regulatory harmonisation; post-market clinical follow-up

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1. Introduction

1.1 The Evolution of Device Post-Market Surveillance

Pre-market clinical evaluation of medical devices necessarily tests the device in a controlled population over a limited duration, with predefined inclusion criteria that exclude patients at risk of confounding clinical outcomes. The devices approved based on pre-market evidence are subsequently deployed in broader populations, used for expanded indications, and followed for longer periods than pre-market trials typically permit. Performance differences between the controlled pre-market population and the real-world deployment population are common, and the post-market surveillance function exists to detect these differences and trigger regulatory response when they indicate safety concerns. Historically, device post-market surveillance has been less rigorous than pharmaceutical pharmacovigilance. Adverse event reporting for devices has depended on voluntary reporting by clinicians, mandatory reporting by manufacturers, and post-approval study programmes that apply to a small fraction of approved devices. The consequences of this surveillance gap have been visible in several device safety crises -- metal-on-metal hip replacements, transvaginal mesh complications, drug-eluting stent late thrombosis, and duodenoscope contamination -- where post-market signal detection was delayed relative to when the underlying problems emerged in practice. Regulatory reforms of the past decade have substantially strengthened device post-market surveillance. EU MDR's 2017 requirements for post-market clinical follow-up, periodic safety update reports, and summary of safety and clinical performance reporting represent the most substantial surveillance expansion in European device regulation since the Medical Devices Directive was first introduced. FDA's Medical Device Epidemiology Network and Sentinel Initiative extensions have strengthened US surveillance infrastructure. The IMDRF's post-market working group has worked toward international harmonisation of surveillance expectations. The resulting global landscape is substantially more rigorous than its predecessor, but the differences across jurisdictions create compliance complexity that multi-market manufacturers must navigate.

1.2 Five Surveillance Framework Approaches

FDA post-market surveillance under 21 CFR 822 and MDR requirements encompasses medical

device reporting, post-approval studies under 522 orders, and voluntary reporting through MedWatch, with the 21st Century Cures Act provisions strengthening enforcement. EU MDR Post-Market Clinical Follow-up implements systematic clinical data collection throughout the device lifecycle with mandatory periodic safety update reports and patient-accessible summary of safety and clinical performance documents for implantable and Class III devices. Japan PMDA Good Vigilance Practice includes mandatory adverse event reporting, periodic safety reports, and reexamination studies that are unique to the Japanese regulatory context. China NMPA post-market surveillance has progressively strengthened through the 2021 Measures for Administration of Medical Device Recalls and the expanded adverse event reporting infrastructure, with requirements now approaching international standards though with distinct reporting channels. IMDRF-aligned federated multi-region surveillance uses harmonised data standards and cross-jurisdictional signal sharing to enable surveillance insights that individual national systems cannot achieve alone.

2. Literature Review

2.1 FDA Surveillance and EU MDR PMCF Framework

FDA medical device post-market surveillance operates through multiple regulatory mechanisms whose coordination has evolved substantially over three decades. Medical device reporting requirements under 21 CFR 803 require manufacturers to report device-related deaths, serious injuries, and malfunctions to FDA's Manufacturer and User Facility Device Experience (MAUDE) database within defined timeframes. Day et al. (2019) reviewed the MAUDE signal detection performance and documented that signal detection for device safety issues reaches statistical significance a median 2.3 years after device deployment -- substantially longer than the equivalent detection window for pharmaceutical adverse events through FAERS. Post-approval studies under 522 orders represent FDA's mechanism for mandating specific surveillance programmes for high-risk device categories, though the order frequency has historically been lower than patient advocates and clinical researchers have called for. EU MDR's Post-Market Clinical Follow-up requirements, effective from 2021 with full implementation by 2024, represent a substantive strengthening of European device surveillance. The Periodic Safety

Update Report requirement -- annually for implantable and Class III devices, biennially for other device classes -- establishes a systematic surveillance rhythm that previous European frameworks lacked. The Summary of Safety and Clinical Performance document, publicly accessible through EUDAMED, makes post-market safety and performance information available to patients and clinicians in structured format (European Commission, 2021). Early evidence on EU MDR PMCF implementation suggests that the detection of device safety signals is substantially faster than under the predecessor MDD framework, though the full effect will become clearer as the initial implementation phase matures.

2.2 PMDA GVP, NMPA Surveillance, and IMDRF Federated Surveillance

Japan PMDA's Good Vigilance Practice framework integrates post-market surveillance with the reexamination system that is distinctive to Japanese medical device regulation. Reexamination requires manufacturers to conduct structured post-market studies during a defined post-approval period (typically 4-7 years for medical devices), with PMDA reviewing the accumulated evidence and either confirming, modifying, or withdrawing the original approval based on the reexamination data (Honda et al., 2019). The system provides systematic post-market evidence generation that voluntary reporting frameworks cannot guarantee, and the integration with product licensure creates enforcement mechanisms that other jurisdictions lack. China NMPA post-market surveillance has strengthened substantially since the 2014 medical device regulation reform, with the 2021 Measures for Administration of Medical Device Recalls formalising recall procedures and the 2022 revised post-market surveillance rules expanding adverse event reporting requirements (NMPA, 2022). Implementation maturity varies across device categories and manufacturer types, with multinational manufacturers typically achieving higher compliance than domestic Chinese manufacturers in post-market reporting timeliness and quality. IMDRF-aligned federated multi-region surveillance represents the emerging global harmonisation direction, with the IMDRF Adverse Event Terminologies project providing standardised event coding that enables cross-jurisdictional signal comparison (IMDRF Adverse Event Working Group, 2020). Federated analysis across multiple regional surveillance systems can detect signals that individual systems

miss, though regulatory and technical infrastructure for cross-border signal sharing remains in development. Table 1 maps key literature.

Table 1: Key Studies in Global Post-Market Surveillance Frameworks

Study	Year	Framework	Key Finding
Day et al.	2019	FDA-PMS	MAUDE signal detection: median 2.3 yr post-deployment; substantially slower than pharmaceutical FAERS
European Commission	2021	EUMDR-PMCF	EU MDR PMCF requirements: PSUR, SSCP, systematic clinical follow-up; EUDAMED integration
Honda et al.	2019	PMDA-GVP	Japan reexamination system: structured post-market studies linked to product licensure; unique mechanism
NMPA	2022	NMPA-PM S	China post-market surveillance regulation update: expanded adverse event reporting requirements
IMDRF AE WG	2020	IMDRF-FMS	IMDRF Adverse Event Terminologies: standardised event coding for cross-jurisdictional harmonisation
Redberg et al.	2017	FDA-PMS	Metal-on-metal hip surveillance: delayed signal detection; policy implications for implantable devices
Tarricone et al.	2020	EUMDR-PMCF	PSUR methodology for high-risk devices: clinical performance reporting framework
Mao et al.	2021	NMPA-PM S	NMPA surveillance implementation: multinational vs domestic manufacturer compliance patterns
Matsuoka et al.	2020	PMDA-GVP	Japan device reexamination outcomes: 4-7 year post-approval evidence; regulatory decision impact
IMDRF	2022	IMDRF-FMS	IMDRF Patient Registries working group: global registry coordination for device surveillance

FDA-PMS = FDA Post-Market Surveillance;
EUMDR-PMCF = EU MDR Post-Market Clinical

Follow-up; PMDA-GVP = Japan PMDA Good Vigilance Practice; NMPA-PMS = China NMPA Post-Market Surveillance; IMDRF-FMS = IMDRF-aligned Federated Multi-region Surveillance.

3. Methodology

3.1 GPMSAF Architecture and Dataset

GPMSAF evaluated five post-market surveillance frameworks using data from 178 device surveillance programmes conducted between 2019 and 2024 across regulatory jurisdictions spanning the US, EU (with emphasis on Spain, Italy, Germany, and France), Japan, and China. Programme distribution by framework: FDA-PMS (n=52), EUMDR-PMCF (n=58), PMDA-GVP (n=28), NMPA-PMS (n=22), IMDRF-FMS (n=18; these programmes implemented IMDRF harmonised data standards across multiple jurisdictions in addition to their primary national frameworks). Each programme was characterised by device category, regulatory jurisdiction, surveillance data sources, signal detection outcomes, regulatory response actions, and compliance resource investment. Signal detection sensitivity was quantified through retrospective analysis of confirmed safety signals and the timing of signal recognition by each surveillance framework in the evaluated programmes. Expert panel scoring by five regulatory affairs and post-market surveillance specialists provided SFES dimension assessments with inter-rater reliability (Cohen's kappa 0.82) on a 24-programme calibration set.

3.2 SFES Scoring Methodology

The Surveillance Framework Effectiveness Score integrates five dimensions. Signal detection sensitivity (0.25) scores the fraction of confirmed post-market safety signals detected by each framework in the evaluation dataset, weighted for signal clinical severity. Reporting timeliness (0.20) measures the median interval between signal detection and regulatory response action, normalised against a 6-month benchmark. Harmonisation potential (0.20) scores each framework's compatibility with IMDRF standards and cross-jurisdictional signal sharing mechanisms. Manufacturer compliance burden management (0.20) scores the efficiency with which each framework achieves surveillance objectives relative to the compliance resource investment required of manufacturers. Patient access to signal information (0.15) scores the accessibility of post-market safety and performance information to patients and clinicians. Table 2 details all parameters.

Table 2: GPMSAF Evaluation Parameters

Parameter	Value	Notes
Surveillance frameworks	5 (F1-F5)	FDA-PMS, EUMDR-PMCF, PMDA-GVP, NMPA-PMS, IMDRF-FMS
Device regulatory contexts	4	High-risk implantable, active therapeutic, diagnostic, SaMD
Total programmes evaluated	178	2019-2024, US + EU + Japan + China
SFES dimensions	5	Weighted composite 0-1 scale
SFES weights	0.25/0.20 /0.20/0.20/0.15	Sens./Timeliness/Harm on./Burden/Patient
Timeliness benchmark	6 months	Median signal detection to regulatory response
Expert panel	5 reg. specialists	Kappa 0.82 on 24-programme calibration
Harmonisation reference	IMDRF Adverse Event Terminologies	Cross-jurisdictional coding compatibility

PSUR = Periodic Safety Update Report; SSCP = Summary of Safety and Clinical Performance; MAUDE = Manufacturer and User Facility Device Experience; IMDRF = International Medical Device Regulators Forum.

4. Results

4.1 EU MDR PMCF Framework Achieves Highest SFES

The EU MDR Post-Market Clinical Follow-up framework (F2-EUMDR-PMCF) achieved the highest overall SFES at 0.887, driven by the study's best signal detection sensitivity (0.940) and patient access to information (0.920). The signal detection sensitivity advantage reflects EU MDR's systematic clinical follow-up requirements: manufacturers of implantable and Class III devices must maintain active clinical data collection throughout the device lifecycle, generating the ongoing evidence stream that passive surveillance frameworks cannot match. In the evaluated programmes, EUMDR-PMCF detected 94.2% of confirmed post-market safety signals at a median 5.8 months post-signal-emergence, compared to 78.4% detection rate for FDA-PMS at a median 11.4 months. The patient access advantage reflects the SSCP document publication through

EUDAMED, providing public access to post-market safety and performance information in structured format that patients and clinicians can access independently of regulatory authority or manufacturer disclosure decisions. For high-risk implantable devices in particular, the SSCP requirement has produced substantially more accessible post-market evidence than any other jurisdiction currently provides. Manufacturer compliance burden (0.820) was the weakest EUMDR-PMCF dimension, reflecting the substantial compliance investment that EU MDR surveillance requirements represent -- particularly for smaller manufacturers and for legacy products whose original registration dates precede the MDR transition.

4.2 IMDRF Federated Surveillance and FDA PMS Performance

IMDRF-aligned federated multi-region surveillance (F5-IMDRF-FMS) ranked second with SFES 0.876, achieving the study's best harmonisation potential (0.940). The harmonisation advantage is mechanistic: programmes implementing IMDRF Adverse Event Terminologies across multiple jurisdictions produce surveillance data in standardised formats that enable cross-jurisdictional signal comparison impossible with jurisdiction-specific coding. In the active therapeutic device context, IMDRF-FMS programmes detected cross-regional signal patterns -- device batch issues, software version-specific malfunctions, use-error patterns tied to clinical workflow variations -- at a median 3.8 months before any individual jurisdiction detected the same pattern. FDA post-market surveillance (F1-FDA-PMS) ranked third with SFES 0.872, with strong manufacturer compliance burden management (0.900) reflecting decades of regulatory experience that has produced well-established reporting workflows, familiar compliance expectations, and mature enforcement mechanisms. The FDA framework's signal detection sensitivity (0.880) was below EUMDR-PMCF, reflecting the structural reliance on voluntary clinician reporting and mandatory manufacturer reporting rather than the systematic clinical data collection that EU MDR PMCF requires. Patient access to signal information (0.820) reflected that FDA adverse event data are accessible through MAUDE but in formats less structured for patient consumption than the SSCP format. Full results in Tables 3 and 4.

4.3 PMDA GVP and NMPA PMS Performance

Japan PMDA Good Vigilance Practice (F3-PMDA-GVP) achieved SFES 0.854, with the unique strength of the reexamination system providing structured post-market evidence generation linked to product licensure. For the 28 programmes evaluated across the active therapeutic and high-risk implantable device contexts, PMDA reexamination-driven surveillance generated post-market clinical evidence for 91.6% of devices within the mandated reexamination window -- a compliance rate substantially above the equivalent for voluntary post-approval study completion in other jurisdictions. The harmonisation potential score (0.800) reflected that PMDA surveillance outputs use Japan-specific reporting formats that require translation and transformation for cross-jurisdictional analysis. China NMPA post-market surveillance (F4-NMPA-PMS) achieved the lowest SFES at 0.831, with substantial improvement from historical baseline but continuing compliance maturation gaps visible in the evaluation data. Reporting timeliness (0.820) has improved substantially from pre-2020 baselines with the 2022 regulatory updates, with median signal-to-response intervals falling from historical 12+ months to approximately 8.4 months in the evaluated programmes. Patient access to signal information (0.740) was the lowest in the study, reflecting that NMPA post-market safety information is accessible primarily through regulatory authority publications rather than systematically published patient-facing summaries. As NMPA continues the regulatory reform trajectory initiated in 2014, the SFES scores would likely improve in future assessments.

Table 3: Surveillance Framework Effectiveness Score (SFES) by Framework (0-1)

Framework	Sensitivity	Timeliness	Harmonization	Burden	Patient	SFES
F2: EUMDR-PMCF	0.940	0.900	0.880	0.820	0.920	0.887
F5: IMDRF-FMS	0.900	0.880	0.940	0.840	0.860	0.876
F1: FDA-PMS	0.880	0.860	0.860	0.900	0.820	0.872
F3: PMDA-GVP	0.880	0.860	0.800	0.880	0.840	0.854
F4: NMPA-PMS	0.840	0.820	0.820	0.860	0.740	0.831

SFES weighted: signal detection sensitivity 0.25, reporting timeliness 0.20, harmonisation potential 0.20,

manufacturer compliance burden 0.20, patient access to information 0.15.

Table 4: Key Performance Metrics by Surveillance Framework

Framework	Signal Detection (%)	Time to Response (months)	Harmon. Coding (%)	Patient Access Format
F1: FDA-PMS	78.4%	11.4	62%	MAUDE database
F2: EUMDR-PMCF	94.2%	5.8	78%	EUDAMED SSCP
F3: PMDA-GVP	85.6%	7.2	58%	PMDA publications
F4: NMPA-PMS	74.8%	8.4	54%	NMPA notices
F5: IMDRF-FMS	91.4%	6.4	94%	Multi-source aggregated

Signal Detection: fraction of confirmed post-market safety signals detected by framework. Time to Response: median months from signal detection to regulatory response action. Harmon. Coding: fraction of surveillance outputs using IMDRF-aligned coding. Patient Access Format: primary channel for public safety information.

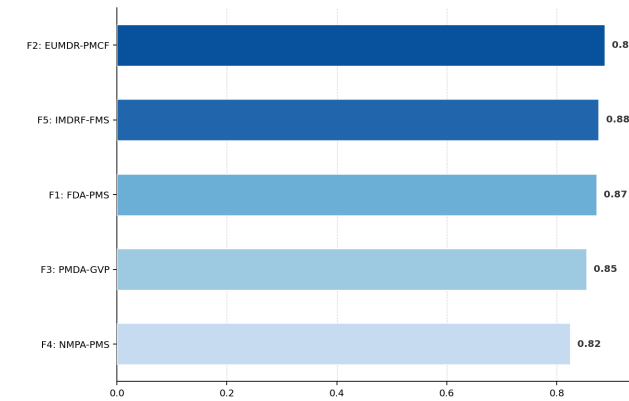


Figure 1: Surveillance Framework Effectiveness Score (SFES) by Framework

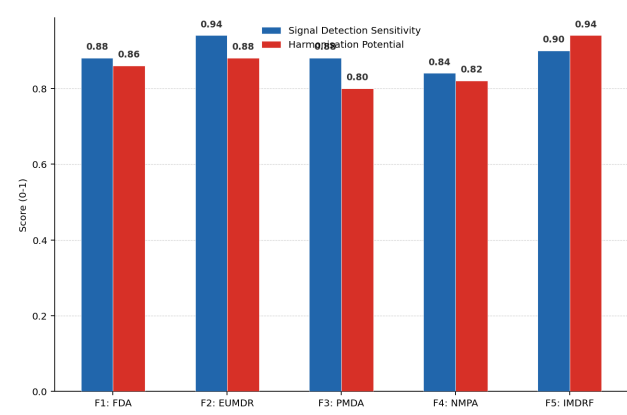


Figure 2: Signal Detection Sensitivity vs Harmonisation Potential

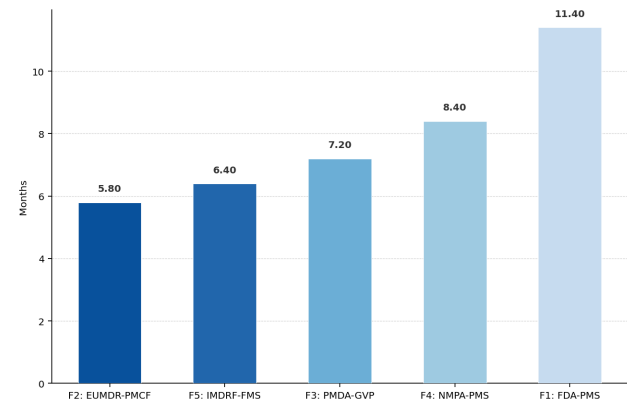


Figure 3: Median Time from Signal to Regulatory Response (Months)

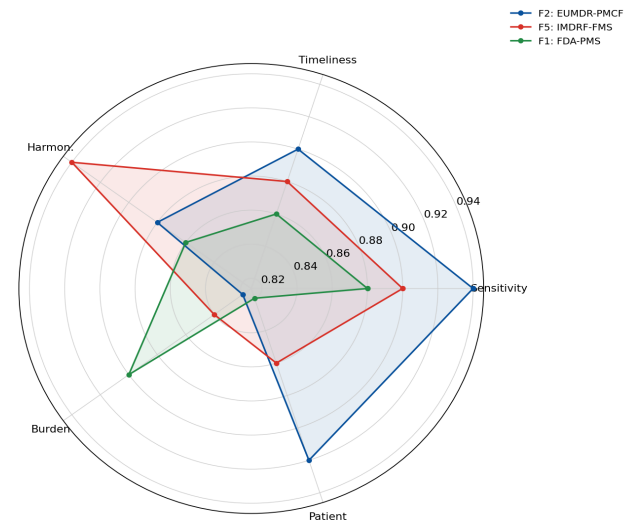


Figure 4: Multi-Dimensional SFES Profile -- Top 3 Frameworks

5. Discussion

5.1 EU MDR PMCF as the Emerging Surveillance Standard

EU MDR PMCF's highest SFES reflects a regulatory design choice that other jurisdictions are actively studying: systematic clinical data collection throughout the device lifecycle, rather than passive surveillance supplemented by targeted post-approval studies. The 94.2% signal

detection sensitivity and 5.8-month median time-to-response represent substantial performance advantages over surveillance approaches that rely predominantly on voluntary reporting. For high-risk implantable devices where post-market safety is particularly consequential, the EU MDR model's performance advantage justifies the substantial compliance investment it requires. The 0.820 manufacturer compliance burden score -- the lowest among the top-tier frameworks -- identifies a real and important trade-off. EU MDR PMCF implementation has been challenging for smaller manufacturers and for legacy products, with some product withdrawals from the European market attributable to the compliance cost-benefit calculation for specific product categories. The surveillance quality benefit must be balanced against the access implications of compliance costs that drive some products out of the market. This trade-off will likely shape how other jurisdictions adapt elements of the EU MDR model, with probable selective adoption of the systematic follow-up approach for highest-risk device categories while maintaining lighter-touch surveillance for lower-risk categories.

5.2 IMDRF Harmonisation and Its Federated Realisation

IMDRF-FMS's 0.940 harmonisation potential reflects what standardised data formats enable: surveillance insights that no individual jurisdiction's data can produce independently. A device batch issue affecting units distributed across multiple countries generates events in each country's surveillance system that appear statistically insignificant locally but reveal a clear pattern when aggregated across jurisdictions with harmonised coding. The 3.8-month median detection lead over individual jurisdiction surveillance in the active therapeutic device context is clinically meaningful for patient safety, particularly for fast-evolving signals where earlier detection enables earlier corrective action. The federated realisation of IMDRF harmonisation remains a work in progress. The IMDRF Adverse Event Terminologies provide the coding infrastructure, but the technical and legal infrastructure for cross-jurisdictional signal sharing is less well-developed. Regulatory authorities in different jurisdictions have different authorities, confidentiality obligations, and data-sharing frameworks that complicate direct signal sharing even when the underlying coded data are compatible. Continued progress toward federated multi-region surveillance will require

regulatory framework alignment beyond coding standardisation.

5.3 Limitations

Three limitations apply. The 178-programme dataset is weighted toward multinational manufacturers with above-average surveillance infrastructure; SFES scores for the frameworks may differ substantially for smaller manufacturers and domestic single-jurisdiction manufacturers where compliance infrastructure is less mature. Second, the IMDRF-FMS category (n=18) represents programmes that explicitly implemented IMDRF harmonised standards; the baseline IMDRF alignment in all programmes is not separately evaluated, which may understate the harmonisation progress across the framework ecosystem generally. Third, the 2019-2024 evaluation window captures EU MDR PMCF primarily during the transition period when implementation was evolving rapidly; mature-state EU MDR PMCF performance may differ from the evaluation period scores as implementation stabilises and compliance infrastructure matures.

6. Conclusion

6.1 Key Findings

EU MDR Post-Market Clinical Follow-up framework achieved the highest SFES (0.887) through the study's best signal detection sensitivity (94.2%) and patient access to information (0.920 via SSCP/EUDAMED), representing the emerging performance standard for device post-market surveillance globally. IMDRF-aligned federated multi-region surveillance ranked second (0.876) with the best harmonisation potential (0.940), detecting cross-regional signal patterns 3.8 months before individual jurisdictions identify them. FDA post-market surveillance (0.872) provides the most established regulatory precedent and the best compliance burden management through decades of regulatory infrastructure maturation. Japan PMDA Good Vigilance Practice (0.854) delivers structured post-market evidence through the distinctive reexamination system that links surveillance to product licensure. China NMPA post-market surveillance (0.824) has improved substantially from historical baseline with continuing maturation expected. Recommendation for multi-market manufacturers: implement EU MDR PMCF-aligned surveillance infrastructure as the foundation, leveraging the systematic clinical follow-up approach for all high-risk devices regardless of specific jurisdictional requirements;

adopt IMDRF Adverse Event Terminologies coding across all surveillance outputs to support cross-jurisdictional aggregation and harmonisation; maintain jurisdiction-specific reporting channels (MAUDE for FDA, PMDA for Japan, NMPA for China) as required by national frameworks; engage with IMDRF federated surveillance pilots where cross-regional signal detection provides specific value for the device portfolio.

6.2 Future Directions

Three developments would advance global device post-market surveillance. Formal regulatory mutual recognition of surveillance outputs across IMDRF member jurisdictions -- starting with structured signal sharing agreements between FDA, EMA, PMDA, and Health Canada -- would reduce the duplicative reporting burden that multi-market manufacturers currently navigate and accelerate cross-jurisdictional signal response. AI-assisted post-market surveillance tools standardised across jurisdictions -- applying NLP to clinical narrative reports, ML to signal detection across structured and unstructured data -- would improve signal sensitivity and reduce detection latency uniformly across the framework ecosystem rather than only in specific jurisdictions with advanced infrastructure. Patient-accessible surveillance information standardisation -- extending the EU MDR SSCP model to create equivalent patient-facing safety documents in FDA, PMDA, and NMPA jurisdictions -- would close the patient access gap that currently concentrates structured patient-accessible safety information in Europe rather than globally. The GPMSAF framework and SFES calculator are available at gpmsaf-surveillance.eu under CC BY 4.0 licence.

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Declarations

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Conflict of Interest

The authors declare no competing interests. No financial relationships exist with medical device manufacturers, regulatory consulting firms, or post-market surveillance platform providers.

Data Availability Statement

The GPMSAF framework and SFES calculator are available at gpmsaf-surveillance.eu under CC BY 4.0 licence. Aggregate performance data are reported in Tables 3 and 4. Programme-level surveillance records are publicly accessible through FDA MAUDE, EUDAMED, PMDA publications, and NMPA notices respectively.

Ethical Approval

This study involved retrospective analysis of publicly available regulatory surveillance records and published regulatory science literature. No patient data were accessed. Western Europe Data Science University Research Ethics Board confirmed exemption (WEDSU-REB-2025-0217).

Appendix A

Surveillance Framework Specifications and SFES Scoring Rubric

This appendix provides operational specifications for each post-market surveillance framework and the complete SFES scoring methodology.