Post-Market Surveillance (PMS)

> Regulatory & Compliance Trends
> Digital Transformation & Automation
> RWD & PM Evidence Generation
> Surveillance Beyond Compliance

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Regulatory & Compliance Trends

MDR & IVDR Challenges

- **Increased Documentation Burden**:
  Expanded Clinical Evidence & PMS Requirements
- **Notified Body (NB) Bottlenecks**:
  Long approval times, limited NB availability
- **Cost & Resource Strain:**
  Compliance costs doubled for many companies
- **Reclassification Issues**:
  Some devices need new clinical trials
- **Slow IVDR Transition**:
  Many IVDs at risk of being pulled from the market

Lessons Learned

- ✓ **Early Preparation is Key**
  Companies that engaged early faced fewer disruptions
- ✓ **Regulatory Strategy Must Be Proactive**
  Late movers struggled with NB capacity
- ✓ **PMS & PMCF Need Digital Integration**
  Manual processes slow down compliance

How Companies Are Adapting (or Not)

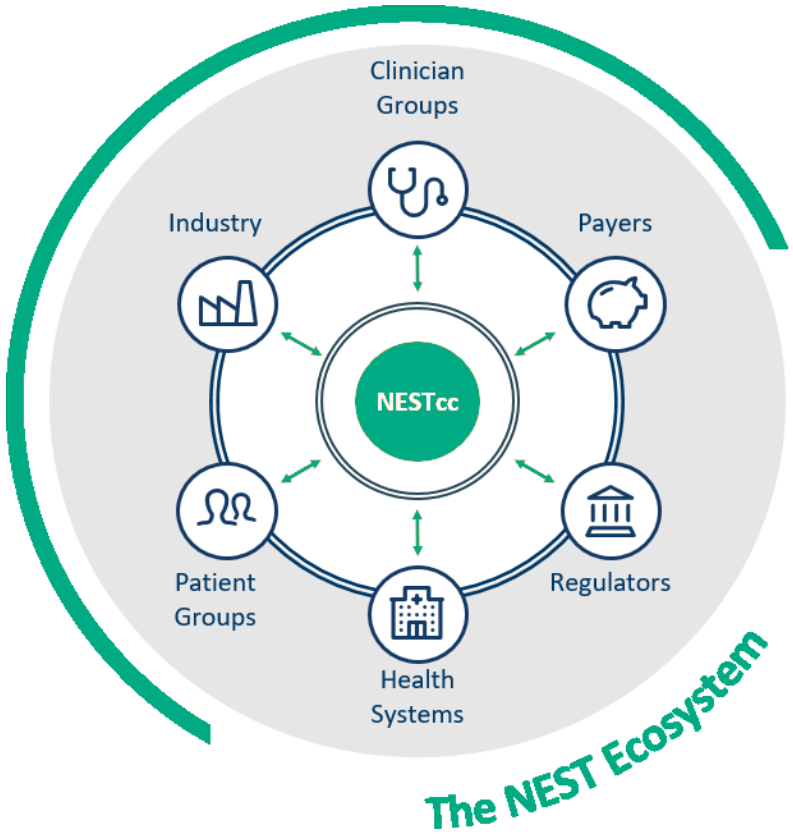
STRUGGLING OR FAILING

- High compliance costs > product withdrawal
- Lack of resources > delayed IVDR transition
- Late application > Notified Body rejection

ADAPTING SUCCESSFULLY

- Investing in Regulatory Intelligence Teams
- Automating PMS
- Engaging with Notified Bodies Early

National Evaluation System for Health Technology (NEST) Coordinating Center



NEST will:

- **Leverage real-world evidence and apply advanced analytics** to data tailored to the unique data needs and innovation cycles of medical devices.
- **Link and synthesize data** from different sources including clinical registries, electronic health records and medical billing claims.
- **Help improve the quality of real-world evidence** for better informed treatment decisions and balance between safety, innovation and patient access.

Taken from: https://nestcc.org/

Global Harmonization of PMS Systems

Why Harmonization Matters?

- Reduces regulatory burden and risk on non-compliance
- Enhances patient safety through consistent PMS practices
- Facilitates global market access

EXTERNAL

- ➢ **International Medical Device Regulators Forum (IMDRF)**
- ➢ **Medical Device Single Audit Program (MDSAP)**
- ➢ **EU-US Mutual Recognition Agreement (MRA) for Inspections**

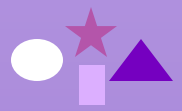
INTERNAL

- ✓ **Global Regulatory Intelligence Teams**
- ✓ **Centralized PMS Data Systems** with AI-driven platforms
- ✓ **Proactive Risk Management & Digital Transformation**
  - Trend reporting automation
  - Cloud-based PMS systems
- ✓ **Strategic Regulatory Partnerships** to shape future harmonization efforts

Digital Transformation & Automation

Connected PMS Ecosystem

DATA SOURCES



Unstructured Data

Structured Data

PROCESS ENGINES

- NLP Engine
- AI/ML Modules
- RPA & Automation Layer

OUTPUTS

- Internal dashboards
- Automated risk-based case triage
- Automated regulatory reports
- Competitive intelligence reports

Digital Transformation in PMS

AI & Machine Learning in PMS

- Early Detection of Adverse Events
- Predictive Trend Analysis

Automating Complaint Handling & Signal Detection

- RPA handles intake, triage, and routing of complaints, reducing manual burden.
- Signal detection accuracy by 30%.

Automated Reporting

- Near real-time generation and delivery of AE reports by integration with e-submission tools.
- Increased quality and reduced noncompliance risk by timely, standardized, and traceable submissions.

NLP – Natural Language Processing; AI – Artificial Intelligence; ML – Machine Learning; RPA – Robotic Process Automation; PMS – Post-Market Surveillance; AE – Adverse Events

Unstructured Data, Structured Insights

Leveraging NLP to Extract Insights

- Using clinical notes, customer feedback, social media posts, and MAUDE to detect previously underreported symptoms.
- AI systems monitor and analyze public databases, literature, and media mentions of competitor devices.
- Competitor safety reports for faster decision-making and preemptive risk strategies.

Impact on PMS

- ✓ Enhanced signal granularity and traceability and reduced time-to-insight for safety evaluations.
- ✓ Strengthened compliance with regulatory timelines.
- ✓ Shifting focus from reporting to strategic oversight.

Benefits Realized from Digital Transformation

Area	Traditional PMS	Digital PMS	Benefit
Adverse Event Detection	Weeks–Months	Hours–Days	+90% faster signal detection
Complaint Processing Time	3–5 Days	Same Day	–70% turnaround time
Report Accuracy	Human error-prone	Standardized	Fewer compliance issues
Competitive Monitoring	Manual	Automated	Continuous market awareness

Key Considerations for Implementation

Data Quality: Ensure clean, accessible, and diverse PMS data for ML training.

Change Management: Cross-functional alignment (Regulatory, Quality, IT, Legal) is critical.

Technology Stack: Evaluate NLP and automation platforms for PMS-specific capabilities.

Validation & Regulatory Readiness: AI/automation tools must be validated under applicable regulatory frameworks