Post-Market Surveillance (PMS)

Post-market surveillance is a system that **continuously monitors safety and performance** in **real-world environments**

📊 Performance Monitoring

Track accuracy, sensitivity, and specificity in real-world environments

🚨 Safety Surveillance

Report and analyze adverse events, malfunctions, and user errors

PMS Activities

- **Active Surveillance:** Regular performance data collection and analysis
- **Passive Surveillance:** Receive reports from users and patients
- **Complaint Management:** Investigate complaints and implement corrective actions
- **Field Safety Corrective Action (FSCA):** Recall or update when necessary

Periodic Reporting

- **PSUR (Periodic Safety Update Report):** EU MDR requirement
- **MDR (Medical Device Report):** FDA adverse event reporting
- **PMCF (Post-Market Clinical Follow-up):** Ongoing clinical data collection

📋 Data Collection

Usage patterns, performance metrics

📈 Trend Analysis

Performance changes over time

⚠️ Early Warning

Early detection of problem indicators

💡 **Key Point:** Since AI systems are sensitive to deployment environments and data distribution changes, proactive and continuous PMS is particularly important