PRIMEVIGILANCE

EU Implementing Regulation (EU) 2025/1466

What's Changed — What MAHs Should Do Now?

The adoption of Commission Implementing Regulation (EU) 2025/1466 marks a significant evolution of the EU pharmacovigilance framework. Amending Implementing Regulation (EU) No 520/2012, the update reflects today's digital, data-driven PV environment and introduces clearer expectations around oversight, transparency, and risk-based governance.

WHAT'S CHANGED

QPPV Oversight & Governance

- Stronger regulatory focus on continuous QPPV oversight
- Clearer expectations for organizational transparency and system control
- PSMF documentation streamlined to major and critical deviations only

Signal Management

- Mandatory routine monitoring of EudraVigilance from August 2025
- Standalone EMA signal notifications removed
- Signal evaluation embedded within PRAC-led processes

PSUR Requirements

- PSURs must now document implementation of risk-minimization measures
- Effectiveness alone is no longer sufficient

PASS Transparency

- Mandatory registration of non-interventional PASS in EMA register
- Protocol submission before data collection
- Final report abstracts required within one month of completion

ICSR Standards

- Harmonized minimum reporting criteria
- Enhanced requirements for literature cases (Vancouver style, DOI, English summary)
- Improved traceability and consistency

Third-Party & Vendor Oversight

- MAHs retain full accountability for outsourced PV activities
- Stronger controls over subcontracting and audit rights

Risk-Based Audits

- EU authorities and MAHs required to adopt risk-based audit approaches
- Increased focus on critical PV activities and vendors

WHAT MAHs SHOULD DO NOW

Strengthen QPPV Governance

- Reassess QPPV oversight model and delegation structures
- Ensure clear visibility of where and how key PV activities are performed

Update Signal Management Processes

- Integrate EudraVigilance monitoring into routine signal detection workflows
- Align internal procedures with PRAC-led signal assessments

Review and Update Core Documentation

- Update PSMF to reflect revised deviation requirements
- Revise PSUR templates to include implementation of risk-minimization measures

Prepare for PASS & RWE Transparency

- Align PASS governance with new EMA registration and submission timelines
- Ensure inspection-ready documentation throughout study lifecycle

Reassess Vendor Oversight

- Review SDEAs and PV agreements for audit, inspection, and subcontracting controls
- Apply risk-based oversight to all third-party PV activities

Plan Risk-Based Audits for 2026

- Update audit strategies in line with the new regulation
- Ensure independence and coverage of critical outsourced activities

Train Teams Early

- Educate PV, regulatory, and clinical teams on regulatory changes
- Monitor upcoming GVP Module updates expected in 2026

How PrimeVigilance Supports You

PrimeVigilance helps MAHs operationalize Regulation (EU) 2025/1466 through QPPV services, signal management, PV audits, PSUR and PASS support, and vendor oversight frameworks—ensuring inspection readiness, regulatory confidence, and patient protection across the product lifecycle.

PRIMEVIGILANCE

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Contact us.

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