

MASTER POST-MARKET DATA. STRENGTHEN ONGOING COMPLIANCE.

End-to-end PMS procedures, statistical trend analysis, and audit-proof PSUR authoring.

Turn post-market data into meaningful safety insights, robust regulatory evidence and sustained lifecycle compliance.

YOUR CHALLENGES

-  **PMS DOCUMENTATION COMPLEXITY** How to establish proportionate post-market surveillance (PMS) plans, reports and PSURs that meet EU MDR/IVDR requirements?
-  **TREND & SIGNAL INTERPRETATION** How to detect and justify significant incident trends without specialized in-house data science teams?
-  **EVOLVING POST-MARKET EVIDENCE** How to keep PMS conclusions, risk management and clinical/performance evidence aligned as new data emerge?

OUR APPROACH

01 ASSESS

- Audit of PMS data, procedures and outputs
- Alignment with EU MDR 2017/745 & IVDR 2017/746 PMS requirements
- Identify gaps across PMS, risk and clinical/performance evidence



02 IMPLEMENT

- Creation and integration of tailored PMS plans, procedures, and report templates
- Advanced statistical trend analysis and data validation methods
- End-to-end authoring of class-specific PMS Reports, PSURs, and trend reports
- Targeted review of PMS conclusions and supporting evidence for consistency



03 ASSURE

- Alignment of outputs with risk management and clinical/performance documentation
- On-demand technical expert hotline for post-market and vigilance queries
- Direct support for Notified Body audit defense and inspection readiness

YOUR BENEFITS



ROBUST PMS DOCUMENTATION

Clear, proportionate PMS plans, reports and PSURs supported by defensible evidence.



DEFENSIBLE TREND & SIGNAL ANALYSIS

Statistically sound methods that support reliable interpretation of trends and emerging safety signals



CONNECTED LIFECYCLE EVIDENCE

PMS insights consistently reflected across risk management, clinical/performance evaluation and technical documentation.

**READY TO MASTER YOUR
POST-MARKET DATA?**

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