AB CUBE MEDICAL DEVICE
SAFETY DATABASE

Key features

- Vigilance across all 3 classes of Medical Devices
- Integration of IMDRF & FDA MDR AE Codes within single coder
- Generation of MedWatch PDF or eMDR (XML HL7) for US cases
- Generation of MIR PDF or XML for post-market cases in EU
- Generation of MDCG 2020-10/2 for EU Clinical Investigation cases
- FDA Combination products

Your medical device vigilance partner

AB Cube is the trusted partner for pharmaceutical laboratories, CROs, pharmaceutical solution organizations and health authorities worldwide. Our solution SafetyEasy® Suite is the industry's best-in-class multivigilance safety database, delivering – in one unified platform – effortless pharmacovigilance, medical device vigilance, cosmetovigilance and nutrivigilance.

As a pioneer of SaaS vigilance applications, AB Cube provides an intuitive, agile and compliant solution adapted to your organizational needs. Thanks to our dedicated in-house team, AB Cube offers responsive, personalized support and training to optimize your vigilance strategy and day-to-day operations.

EU Regulatory Landscape

In Europe, the EU 2017/745 MDR introduced the following specific requirements for MedDev vigilance:

- New harmonized format for submission of cases: MIR, printable in PDF and XML
- Mandatory use of a common dictionary (IMDRF) to harmonize coding (comprising annexes), with correspondence to existing MedDRA dictionary
- New obligation to submit Periodic Safety Reports (PSUR MD, whose format is defined by guideline published by MDCG)

The vigilance module of the European Database on Medical Devices (EUDAMED) should be in mandatory use from July 2026. Expectations are that this module will enable centralized submissions to Europe (replacing current local submissions) plus e-submissions.

AB CUBE: YOUR MEDICAL DEVICE VIGILANCE PARTNER

US Regulatory Landscape

In the US, e-submissions can already be made using the eMDR (XML HL7) format, while paper submissions remain possible through MedWatch. The FDA has adopted the IMDRF dictionary but still accepts the respective FDA MDR AE codes in the eMDR or MedWatch.

In 2021, the FDA introduced guidelines on Combination Products to enable a single submission of cases involving products combining two or more vigilances (Pharmacovigilance, Biovigilance and Medical Devices Vigilance). This new regulation had an impact on the XML E2B (R2) submission file formats. The new E2B(R3) format for FDA Combination products will be implemented in SafetyEasy® Suite in 2025, ahead of estimated mandatory application in March 2026.

SAFETYEASY® SUITE: MEDICAL DEVICE VIGILANCE

Seamless evolution & upgrades
Constant evolution and seamless adaptation to latest regulations, eliminating the need for clients to go through long, extensive and resource-intensive upgrade projects.

Fully compliant solution
Fully compliant solution for vigilance management across the 3 recognised classes of Medical Devices – anticipating or following closely each regulatory change in the Europe or US.

Integrated reporting functionality
Medical device safety reporting made easier thanks to pre-integrated reporting functionalities including:

- MedWatch PDF or eMDR (XML HL7) for submission in the US
- MIR PDF or XML for post-market cases in the EU
- MDCG 2020-10/2 for Clinical Investigation cases in the EU

IMDRF & FDA MDR AE codes
Free IMDRF and FDA MDR AE codes integrated within a single coder, with full FDA combination products compliance ensured. SafetyEasy is natively multivigilance-oriented through an option added to the XML E2B (R2) file format.

Trusted by industry leaders

PLG ProductLifeGroup · VCLS · aixial GROUP · septodont · PSI

Ready to explore more?

Book a demo today

www.ab-cube.com/medical-device-vigilance

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