Medical Device Vigilance Training

Presented by Imen Ben Slama

Regulatory Affairs and Quality Assurance expert

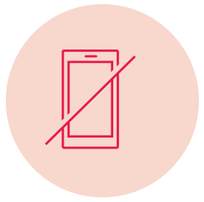
Imen Ben Slama

contact@quaraconseil.com

House-keeping

FEEL FREE TO ASK QUESTIONS

TAKE ADDITIONAL NOTES



PLEASE KEEP PHONES ON SILENT MODE

FOR ANY FOLLOW-UP QUESTIONS AFTER TODAY'S SESSION,

PLEASE CONTACT:

Imen Ben Slama

Contact@quaraconseil.com

Meet the instructor

Imen Ben Slama, PharmD
Quality & Regulatory Affairs Expert – MDR & IVDR
Founder & CEO of **QuaRa Conseil** | GMED-certified trainer
Pharmacist with hands-on expertise in **Vigilance, PMS, PSUR, PMCF**
Supporting manufacturers on **MDR/IVDR compliance**, NC/CAPA, audits & technical file remediation (Class II/III & IVDs)

Webinar Agenda

Regulatory Framework

Overview of MDR and IVDR vigilance requirements

MIR Requirements

Manufacturer Incident Report obligations and coding

Roles and Responsibilities

Serious Incident & Non-serious incident

Understanding reporting triggers and timelines

Trend Reporting

Statistical monitoring and signal detection

Key Takeaways

Introduction to Medical Device Vigilance

Key Vigilance Definitions

Vigilance is the regulatory system for the detection, assessment, reporting, and prevention of incidents and safety issues related to medical devices (MDR) and in vitro diagnostic medical devices (IVDR) once they are placed on the market or put into service.

Its primary objective is to protect patients, users, and third parties by ensuring that serious risks are identified early, reported without delay, and corrective actions are implemented to prevent recurrence.

Incident

Any malfunction, deterioration, or inadequacy in device characteristics or performance, including use-error due to ergonomic features

Serious Incident

Any incident that directly or indirectly led, might have led, or might lead to death or serious deterioration of health

Serious Public Health Threat

An incident likely to result in serious public health risk requiring rapid coordinated action

FSCA / FSN

Field Safety Corrective Action and Field Safety Notice – manufacturer actions to reduce risk or remedy non-compliance

Corrective Action

Action taken to eliminate the cause of a detected non-conformity or other undesirable situation

Recall / Withdrawal

Return of device from end user to manufacturer, or from market respectively

Periodic Summary Report: Consolidated report of vigilance data submitted at defined intervals, providing trend analysis and safety overview for device categories.

Regulatory Requirements - MDR /IVDR Chapter VII (MDR/IVDR)

Art. 87/82
Notification of serious incidents and safety corrective actions

Art. 92/87
Electronic system for vigilance and post-market surveillance

Art. 91/86
Implementing acts

Art. 88/83
Trend reporting

Art. 89/84
Analysis of serious incidents and safety corrective actions

Art. 90/85
Analysis of vigilance data

Actors involved in Vigilance activity

Vigilance involves numerous stakeholders who must coordinate and communicate effectively:

Economic Operators

- Manufacturer
- Distributor
- Importer

Medical Device Users

Healthcare professionls
Patients and caregivers

Surveillance Authorities

Competent authorities
Notified bodies

These three actor groups each play a key role. Let's focus now on the **responsibilities of Economic Operators!**

Economic operators' responsibilities

MANUFACTURER

Article
10, 87, 88 ad 89

DISTRIBUTEUR

Article
14(2), 14(4), 14(5)

IMPORTER

Article
13 (2), 13(6), 137)

Regulatory Obligations by Economic Operator

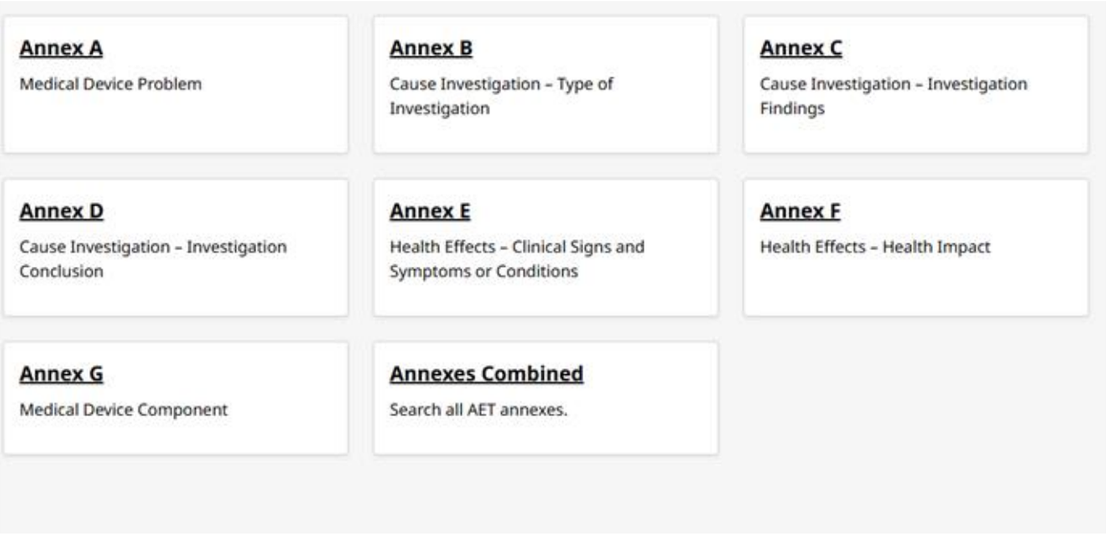
Obligations	Manufacturer	Distributor	Importer
Collect and record vigilance cases/non-conformities	Yes	Yes	Yes
Analyze cases	Yes	Yes	Yes
Notify approved vigilance cases to competent authorities	Yes	No	No
Define and implement corrective measures	Yes	No	No
Notify corrective measures to CA/NB	Yes	Yes	Yes
Apply corrective security measures and verify effectiveness	Yes	Yes	Yes

IMDRF Notification

The International Medical Device Regulators Forum (IMDRF) promotes standardized terminology and coding systems for adverse events across global markets.

This harmonization enhances signal detection through adverse event management systems and enables faster response to emerging safety issues.

The IMDRF guidance includes 7 annexes (A-J) that provide comprehensive standards for adverse event reporting and management.



IMDRF link: IMDRF Adverse Event Terminology Web Browser | International Medical Device Regulators Forum
Terminologies for Categorized Adverse Event Reporting (AER): terms, terminology and codes | International Medical Device Regulators Forum

Non-Serious Incidents

Any malfunction or deterioration in the characteristics or performance of a device made available on the market, including use errors due to ergonomic features, as well as any inadequacy in the information provided by the manufacturer and any undesirable side effect.

Example: Non-Serious Incident

Case Description

A single-use intravascular catheter shows minor surface discoloration on the shaft during preparation for use. The catheter maintains its mechanical integrity and intended performance within specifications, and the observation does not affect clinical performance or patient safety. No injury or deterioration in health has occurred.

Key Considerations

- Performance deviation is present
- No impact on patient safety
- No serious deterioration in health
- Must be recorded and monitored for trends

Serious Incidents

Definition

Any incident that led, might have led, or might lead to:

- The death of a patient, user, or other person
- A serious deterioration, temporary or permanent, in a person's health
- A serious public health threat

Reporting Requirement

The notification timeline depends on the severity of the incident:

- Serious public health threat: ≤ 2 days
- Death or unexpected serious deterioration: ≤ 10 days
- Other serious incidents: ≤ 15 days

Notification Timelines for Serious Incidents

Serious Public Health Threat

Events that could result in imminent risk of death,
serious deterioration in health, or serious illness requiring prompt remedial action

Death or Unexpected Serious Deterioration

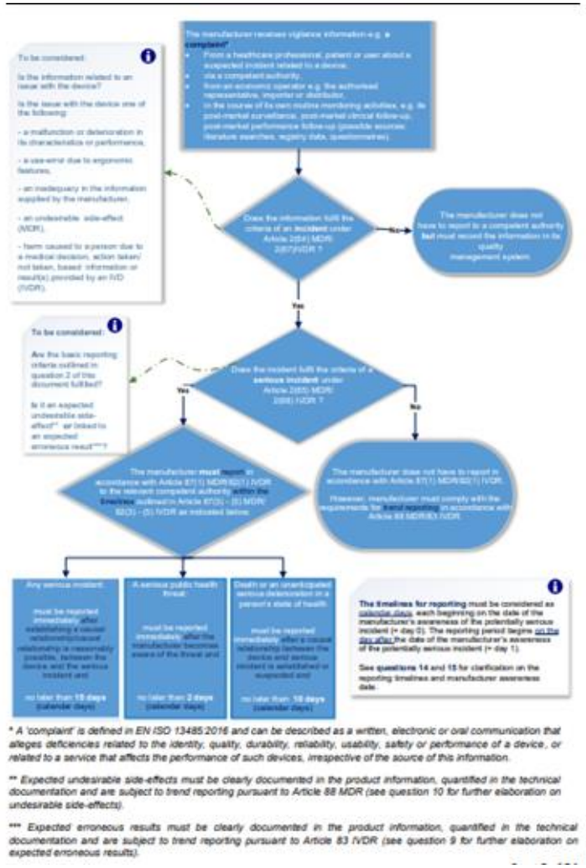
Incidents resulting in death or unanticipated serious deterioration in state of health

Other Serious Incidents

All other incidents meeting the definition of a serious incident

Field Safety Corrective Action (FSCA): To be notified *without undue delay* and *prior to implementation*.

Decision Tree: Should I Submit an Incident Report?

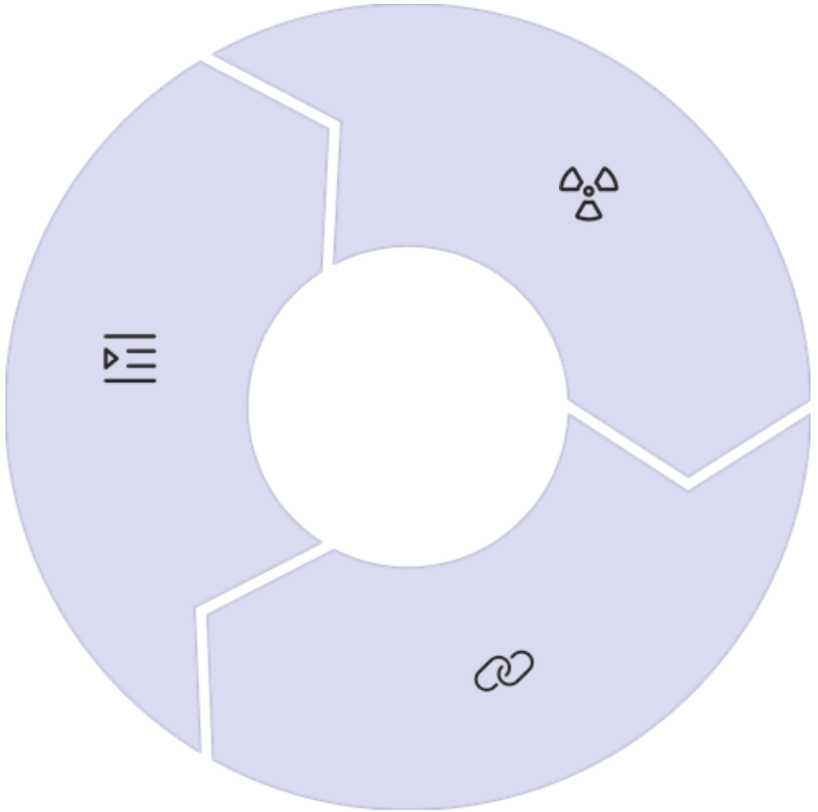


Source: MDCG 2023-3 rev.2 - Q&A on vigilance terms and concepts as outlined in the Regulation (EU) 2017/745 and Regulation (EU) 2017/746

MIR Submission Criteria

Incident Occurred

Any malfunction, deterioration, use error, or inadequate information affecting the device



Serious Outcome

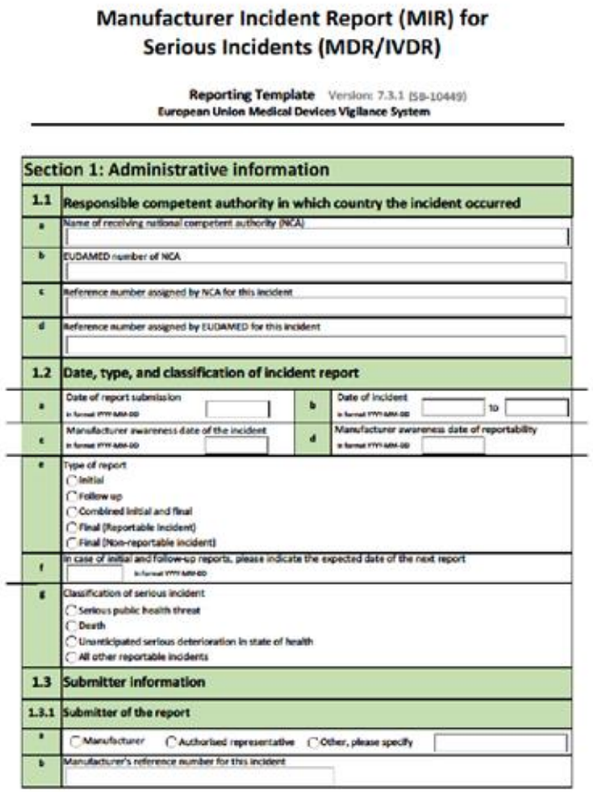
Led, might have led, or could lead to death, serious deterioration, or public health threat

Causal Relationship

Reasonable possibility of connection between device and event (confirmed, suspected, or cannot be excluded)

A Manufacturer Incident Report (MIR) must be submitted to the Competent Authority when all three of these criteria are met.

Manufacturer Incident Report (MIR)



Manufacturer Incident Report (MIR) for Serious Incidents (MDR/IVDR)

Reporting Template Version: 7.3.1 (SB-10449)
European Union Medical Devices Vigilance System

Section 1: Administrative information			
1.1	**Responsible competent authority in which country the incident occurred**		
a	Name of receiving national competent authority (NCA)		
b	EUDAMED number of NCA		
c	Reference number assigned by NCA for this incident		
d	Reference number assigned by EUDAMED for this incident		
1.2	**Date, type, and classification of incident report**		
a	Date of report submission in format YYYY-MM-DD	b	Date of incident in format YYYY-MM-DD to
c	Manufacturer awareness date of the incident in format YYYY-MM-DD	d	Manufacturer awareness date of reportability in format YYYY-MM-DD
e	Type of report ○ Initial ○ Follow up ○ Combined initial and final ○ Final (Reportable incident) ○ Final (Non-reportable incident)		
f	In case of initial and follow-up reports, please indicate the expected date of the next report in format YYYY-MM-DD		
g	Classification of serious incident ○ Serious public health threat ○ Death ○ Unanticipated serious deterioration in state of health ○ All other reportable incidents		
1.3	**Submitter information**		
1.3.1	**Submitter of the report**		
a	○ Manufacturer ○ Authorised representative ○ Other, please specify		
b	Manufacturer's reference number for this incident		

PMSV reporting forms - European Commission

Manufacturer Incident Report (MIR)

Key Components

- Administrative information (manufacturer, authorized representative)
- Device identification details (UDI, model, batch/lot)
- Incident description and chronology
- Patient information (anonymized)
- Preliminary investigation findings
- Risk assessment
- Corrective actions implemented or planned

MIR Workflow

1. Initial MIR submission within required timeline
2. Follow-up MIR reports as investigation progresses
3. Final MIR with complete investigation results
4. Coordination with competent authority as needed
5. Implementation of corrective actions
6. Verification of effectiveness

Non-Serious Incidents and Trend Reports

According to **MDR Article 88, IVDR article 83**, manufacturers must report any statistically significant increase in the frequency or severity of:

Non-Serious Incidents

Issues that do not meet serious incident criteria but still represent device problems

Expected Side Effects

Known effects that are documented in product information but occur at higher rates

Trend Reporting Requirements

- A trend report must be prepared when there is a **statistically significant increase** in non-serious incidents or expected side effects that could impact the benefit-risk ratio or pose risks to health and safety.
- Manufacturers must detail the **management measures** taken for these incidents.
- Define **thresholds and alerts** in the PMS plan.
- Describe the **methodology** used to assess statistical significance.
- Specify the **observation period** considered in the PMS plan.
- Until EUDAMED is fully functional, use the current reporting template per *MDCG 2021-1*.

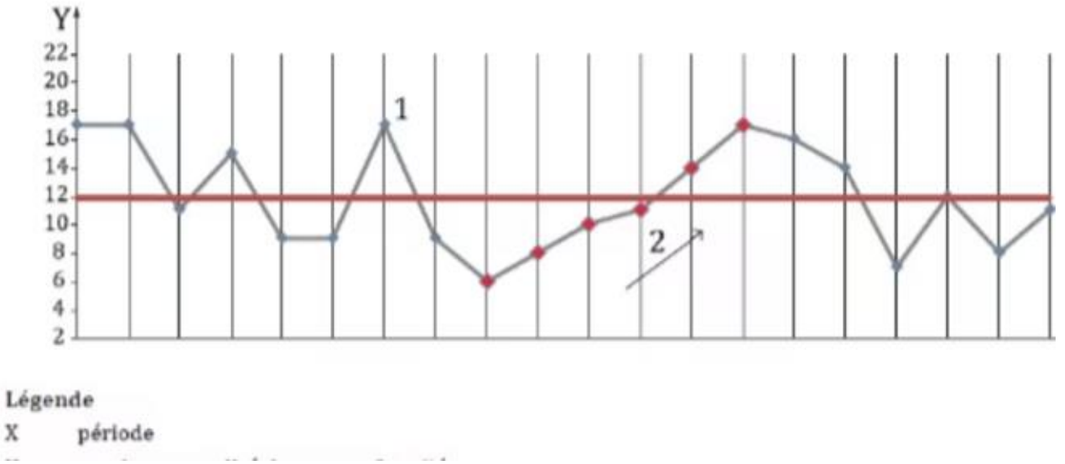
Statistical Trend Analysis Methods

Three Sigma Limits (U-chart)

A widely used statistical quality control method that:

- Observes variation in complaint-to-sales ratio
- Identifies points that fall outside ±3 standard deviations (σ) from the mean
- Provides standardized thresholds for detecting abnormal patterns

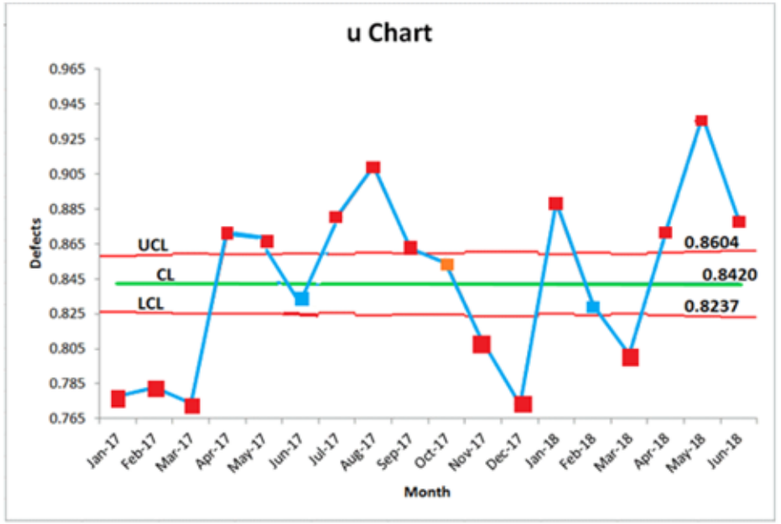
Other statistical methods include CUSUM charts, moving average control charts, and regression analysis.



Source: ISO 20416:2020

Statistical Trend Analysis Methods (Example)

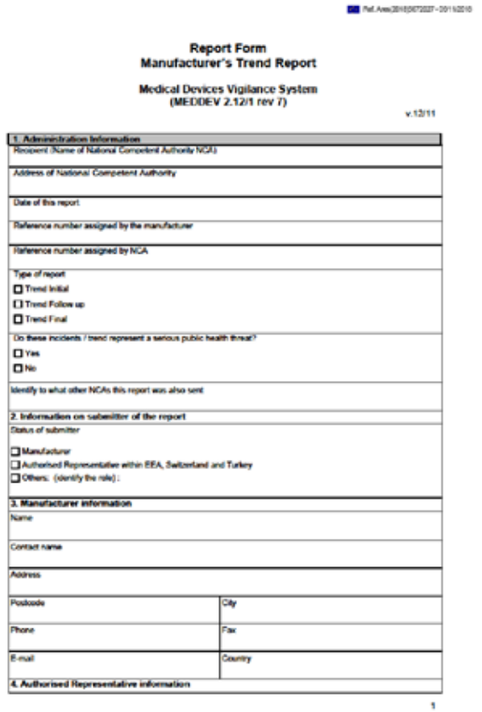
Complaint-to-Sales Ratio: Includes all product-related complaints divided by the volume of units sold (or installed units, if applicable).
Non-Serious Incident*: Any complaint related to a usage issue or identified problem that did not result in a report being submitted to the competent authorities.
U-Chart: A graphical representation used in statistical analysis to track the variation of a specific metric within predetermined control limits. In our case, it typically illustrates the evolution of the complaint-to-sales ratio within ±3σ from the mean.



Trend Report Documentation

Trend reports should include:

1. Description of the observed trend with supporting data
2. Statistical analysis demonstrating significance
3. Comparison to historical baseline
4. Assessment of potential impact on benefit-risk profile
5. Root cause analysis findings
6. Corrective and preventive actions implemented
7. Monitoring plan for effectiveness verification



Report Form
Manufacturer's Trend Report

Medical Devices Vigilance System
(MEDDEV 2.12/1 rev 7)

v.12/11

1. Administration Information
Recipient (Name of National Competent Authority NCA)
Address of National Competent Authority
Date of this report
Reference number assigned by the manufacturer
Reference number assigned by NCA
Type of report ☐ Trend Initial ☐ Trend Follow up ☐ Trend Final
Do these incidents / trend represent a serious public health threat? ☐ Yes ☐ No
Identify to what other NCAs this report was also sent
2. Information on submitter of the report
Status of submitter ☐ Manufacturer ☐ Authorised Representative within EEA, Switzerland and Turkey ☐ Others: (identify the role) :
3. Manufacturer information
Name
Contact name
Address
Postcode / City
Phone / Fax
E-mail / Country
4. Authorised Representative information

1

The format and content requirements are outlined in MDCG 2021-1 until the full implementation of EUDAMED.

Field Safety Corrective Action (FSCA) Case Study

Issue Identification

Many complaints received indicating persistent moderate swelling (>7 days), localized nodules and tissue hardening at injection sites, with one case escalating to require surgical intervention.

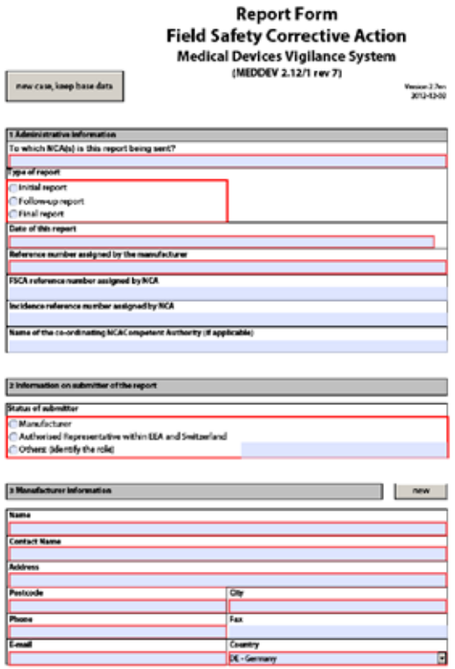
Investigation

Root cause analysis identified batch-specific instability of the excipient (Lot B235-LATAM) linked to storage deviation during shipment under extreme temperature.

FSCA Implementation

Field Safety Corrective Action initiated in June 2025, including withdrawal of impacted batches, FSN issuance, updated storage instructions, and real-time temperature monitoring implementation.

FSCA Report Form Overview



Report Form
Field Safety Corrective Action
Medical Devices Vigilance System
(MEDDEV 2.12/1 rev 7)

new case, keep base data

Version 2.7en
2012-12-10

1 Administrative information

To which NCA(s) is this report being sent?

Type of report
- ☐ Initial report
- ☐ Follow-up report
- ☐ Final report

Date of this report

Reference number assigned by the manufacturer

FSCA reference number assigned by NCA

Incidence reference number assigned by NCA

Name of the co-ordinating NCA/Competent Authority (if applicable)

2 Information on submitter of the report

Status of submitter
- ☐ Manufacturer
- ☐ Authorised Representative within EEA and Switzerland
- ☐ Others: (identify the role)

3 Manufacturer information | new

Name

Contact Name

Address

Postcode | City

Phone | Fax

E-mail | Country

DE - Germany

Field Safety Notice (FSN) Documentation

FSN report template: DocsRoom - European Commission

FSN Customer reply: DocsRoom - European Commission

FSN Distributor/impoter reply: DocsRoom - European Commission

Vigilance Reports Overview

Source: eudamed-vigilance-general

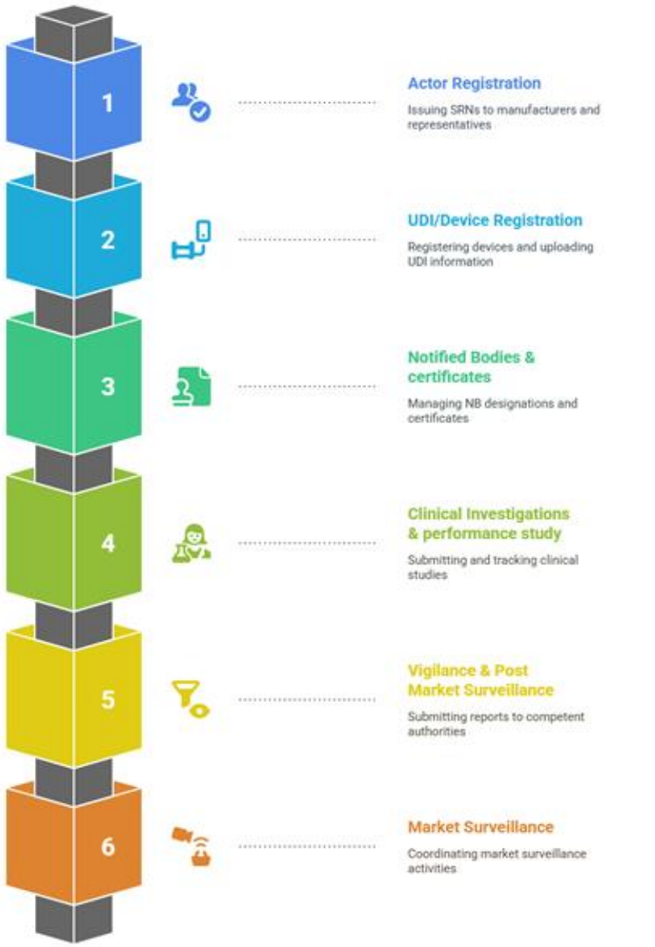
EUDAMED

EUDAMED Overview

EUDAMED = *European Database on Medical Devices*

NB: Use of modules becomes **mandatory six months after** a module is declared functional and published in the Official Journal per Regulation (EU) 2024/1860
EUDAMED Vigilance (VGL) module aligns with MDR Art. **92** / IVDR Art. **87**

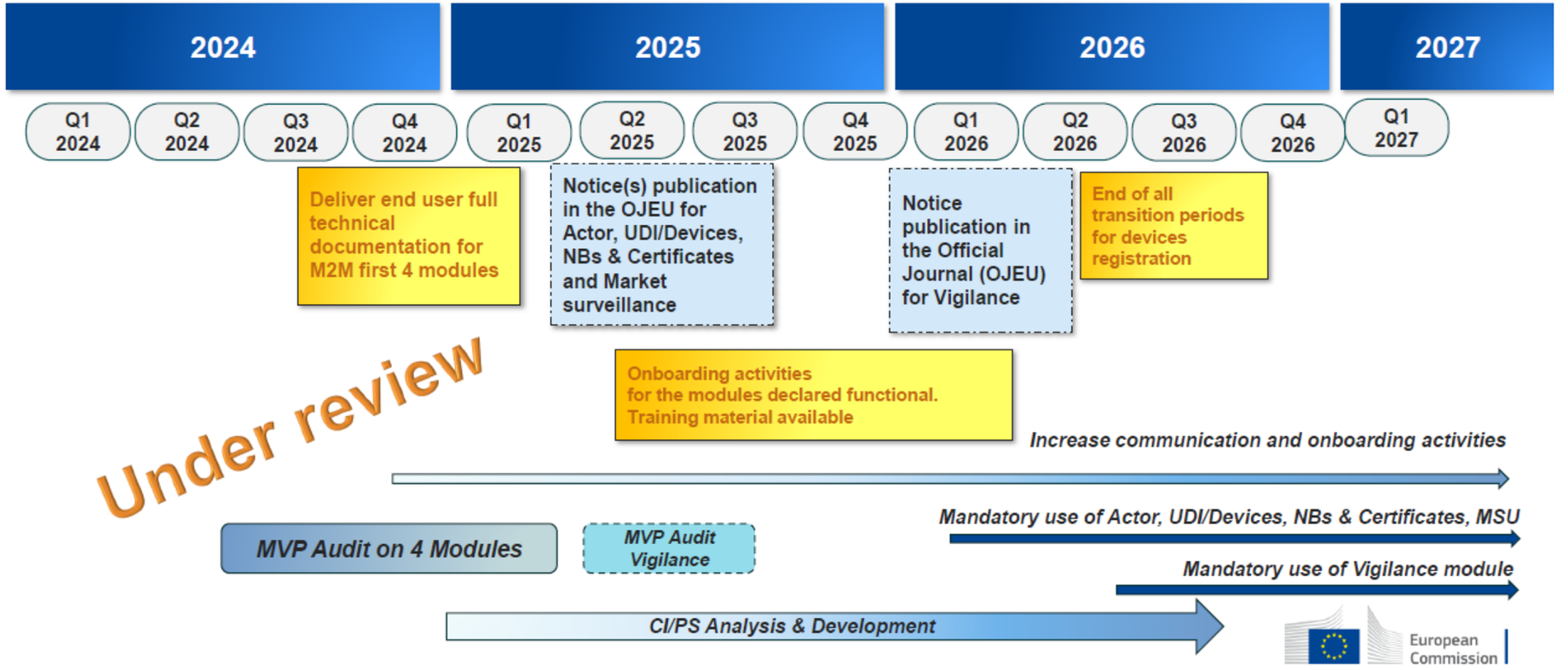
The Six Interlinked EUDAMED Modules



Source: MDCG 2021-1 REV.1
MDCG 2023-3 Rev.2 – Vigilance definitions and obligations

EUDAMED gradual roll out planning – July 2025

In view of the ongoing consultation process with the MDCG
and latest policy developments the timeline will be updated



Transition Measures Until EUDAMED is Fully Functional

Module	Status today	Mandatory use
Economic Operators (Actors)	Available since **Dec 2020** (voluntary)	**28 May 2026**
Notified Bodies & Certificates	Available since **2022** (voluntary)	**28 May 2026**
Devices, Systems & UDI	Available since **2022** (voluntary)	**28 May 2026**
Market Surveillance	Functional	**28 May 2026**
Vigilance	❌ Not yet fully functional	**TBD** (only after official notice)
Clinical Investigations / Performance Studies	❌ Not yet fully functional	**TBD** (only after official notice)

Until all modules are operational:

The manufacturer must follow **legacy methods**:

Vigilance reports (MIR, FSCA, etc.) → National competent authorities

Notified bodies are to be informed per **Annex VII §4.3 MDR**

EUDAMED Database (Vigilance and PMS Module)

Electronic System for Vigilance and Post-Market Surveillance

- Vigilance reports, including **MIR**, **PSR**, **TR**, and **FSCA** — are automatically transmitted to:
  - The **Competent Authority**
  - The **Notified Body** that issued the certificate for the device in question

Regulatory Reference: MDR / IVDR – **Annex VII §4.3**

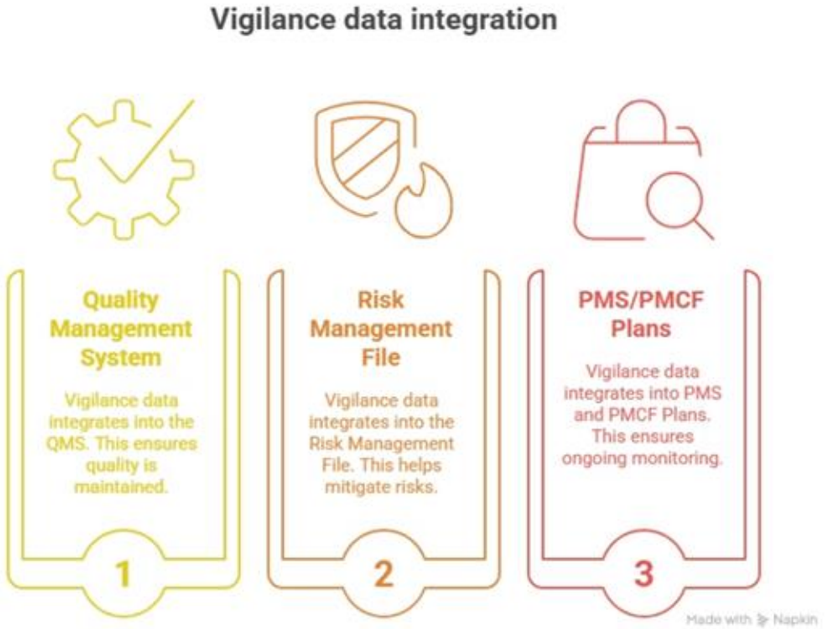
The contract must include specific terms and obligations enabling the notified body to fulfill its role under the Regulation **including the obligation for the manufacturer to inform the notified body of vigilance reports**.

Audit Feed-Back: Vigilance Integration

Key Audit Focus

Notified Bodies verify that vigilance data is actively integrated into key quality system elements:

- Risk Management File
- Clinical Evaluation Report
- Post-Market Surveillance Plan
- PSUR/PMS Reports
- Design inputs for new products



Manufacturers must provide **evidence of updates** following incidents, FSCAs, or trend detection

Practical Implementation

Vigilance SOPs must be complied with applicable regulations and standards

Auditors look beyond documented procedures to verify that vigilance processes are:

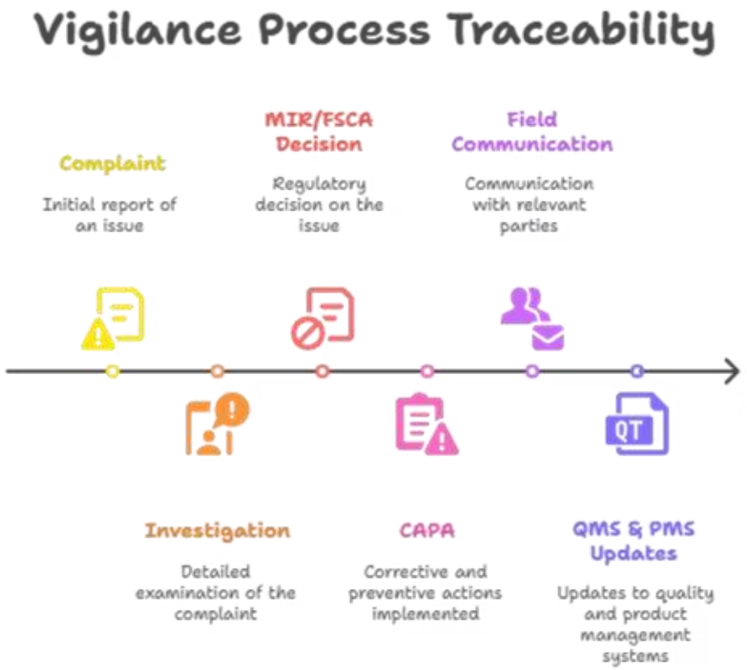
- Actually, implemented as described
- Known and understood by relevant personnel
- Supported by appropriate resources
- Regularly reviewed for effectiveness
- Followed consistently across the organization

Traceability is Key

Documentation Requirements

Auditors expect complete traceability throughout the vigilance process:

- Initial complaint receipt and assessment
- Decision-making rationale for classification
- Investigation activities and findings
- Regulatory reporting submissions and correspondence
- Corrective actions implementation and verification



Timeliness Monitoring

Compliance with Deadlines

Auditors closely scrutinize adherence to regulatory timelines:

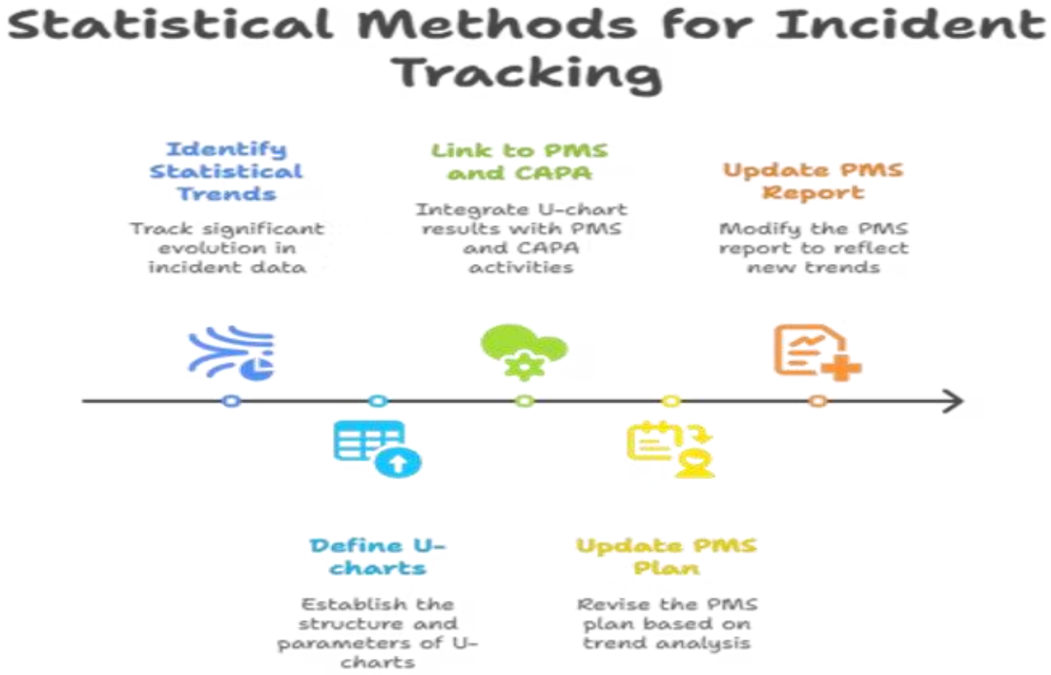
- Initial assessment of complaints
- Reporting of serious incidents (2/10/15 days)
- FSCA notifications
- Follow-up reporting
- Closure of investigations

Trend Analysis

Statistical Methodology

Auditors expect to see:

- Documented statistical methods for trend detection
- Clear thresholds for significant increases
- Regular analysis of complaint data
- Evidence-based decisions on trend reporting
- Integration with PMS activities

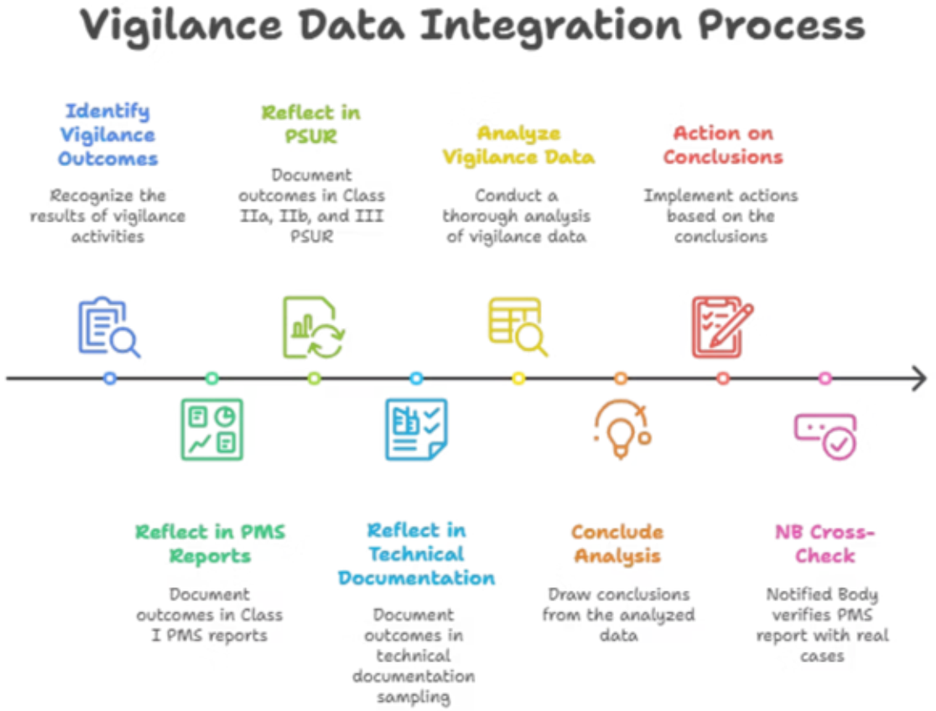


Vigilance Data Integration

Continuous Improvement Cycle

Auditors verify that vigilance data feeds into:

- Product risk assessment updates
- Design changes and improvements
- Clinical evaluation reports
- User training and instructions
- Manufacturing process controls
- Recertification documentation



How different is vigilance around the world?

Q&A

Thank you!

for attending the training