EFORT Implant & Patient Safety Initiative

Inauguration Workshop

SURVEILLANCE AND VIGILANCE
WHAT CAN MANUFACTURERS CONTRIBUTE?

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Brussels, January 21, 2020

PATIENT SAFETY, QUALITY AND INTEGRITY

Commit to the highest standards of patient safety, quality and integrity.

We commit to the highest standards of patient safety and quality in our products and services and to world-class integrity and ethical business practices.

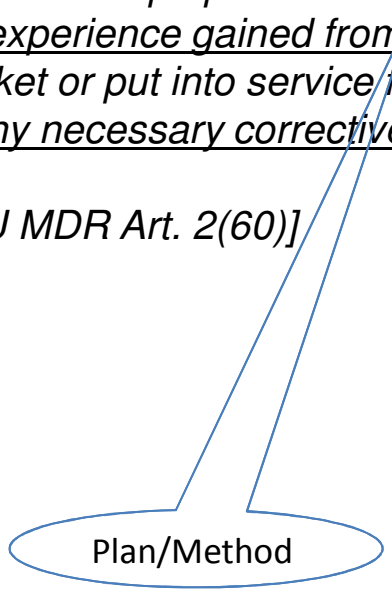
SURVEILLANCE AND VIGILANCE
WHAT CAN MANUFACTURERS CONTRIBUTE?

POST-MARKET SURVEILLANCE - DEFINITION

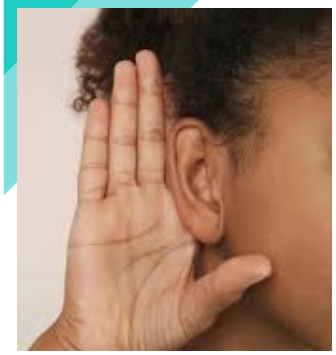
❑ What is Post-market Surveillance?

Post-market Surveillance means all activities carried out by manufacturers to institute and keep up to date a systematic procedure to proactively collect and review experience gained from devices they place on the market, make available on the market or put into service for the purpose of identifying any need to immediately apply any necessary corrective or preventive actions.

[Ref: EU MDR Art. 2(60)]



PMS PLAN ELEMENTS



"Re-active" –
Listen to Market
Investigate
& Report

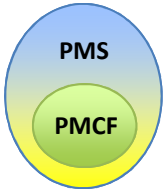
- ❑ Categorization and Trending of Complaints vs. Sales Data
- ❑ Comparison of Complaints to Risk Analysis
- ❑ CAPA, Recalls, FSCA, etc. (as applicable)
- ❑ Publicly available information about similar devices

Pro-active
Generate data,
Analyze
& Report

PMCF Plan

- ❑ PMCF (General methods)
  - Users' feedback (surveys)
  - Scientific literature
- ❑ PMCF (Specific Methods)
  - Analysis of data from suitable device registries
  - Analysis of data from PMCF studies
    - Manufacturer-managed
    - investigator-initiated

MDR PMCF – WHAT'S REQUIRED?

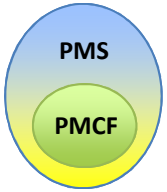


Data confirming:

1. **Safety:** less complications/AEs and revisions
2. **Performance:** according to manufacturer's claims
3. **Clinical benefits:** *positive impact of a device on the health of an individual, expressed in terms of a meaningful, measurable, patient-relevant clinical outcome, PROMs*

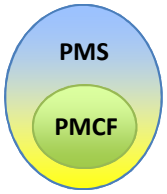
- In some circumstances PROMs can substantiate both performance and clinical benefits

MDR PMS WHAT'S REQUIRED?



	Class III (hip stem)	Class IIb (trauma plate)	Class IIa (robot)	Class I (rasp)
PMS Plan	Yes	Yes	Yes	Yes
PMS Report	-	-	-	Yes
Periodic Safety Update Report (PSUR)	Yes • Annually • EUDAMED	Yes • Annually • EUDAMED	Yes at least every 2 years	-

A TYPICAL ORTHOPEDICS PMS



PMS Plan

Vigilance

PMCF study

PMCF Study(ies)

3m, 6m, 1 yr | 2nd yr | 5th yr | 7th yr | 10th yr

PMCF report

Registries / RWE

Vigilance & other PMCF activities

1st yr | 2nd yr | 3rd yr | 4th yr | 5th yr | 6th yr | 7th yr | 8th yr | 9th yr | 10th yr | ....

PSUR

Risk-Benefit assessment

RISK-BASED APPROACH TO MDR COMPLIANCE
PMS ACTIVITIES

	Legacy Devices	New Devices with Equivalence	New Novel Devices
Pre-Market		Clinical Evaluation	Clinical Investigation* (short-term)
			Clinical Evaluation
CE-mark			
Post-Market		PMCF study (mid-term)	PMCF study* (mid-term)
	Vigilance	Vigilance	Vigilance
	Registries & Sys. Literature	Registries & Sys. Literature	Registries & Sys. Literature

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THANK YOU!