EU Regulation Vigilance and Other National Incident Reporting Requirements

RAPS Regulatory CONVERGENCE

1–4 October 2018
Vancouver, BC

Your Regulatory Meeting Place

RAPS REGULATORY AFFAIRS PROFESSIONALS SOCIETY
Driving Regulatory Excellence™

Agenda
Thursday 04 October – 16:00-17:00

- "What to Report"
- "When to Report"
- "Where to Report"
- Medical Device Single Audit Program (MDSAP) participating countries (Australia, Brazil, Canada, Japan, and the USA)
- European Union (EU)

bsi.

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Learning Objectives

- Discuss the vigilance reporting requirements as described in the EU MDR including how to report, where to report and reporting timelines.
- Compare and contrast the EU MDR requirements vigilance/adverse advent reporting requirement to those of the Medical Device Single Audit Program (MDSAP) participating countries.
- Assist other regulatory affairs and quality personnel in the development and maintenance of complaint handling and vigilance reporting procedures.

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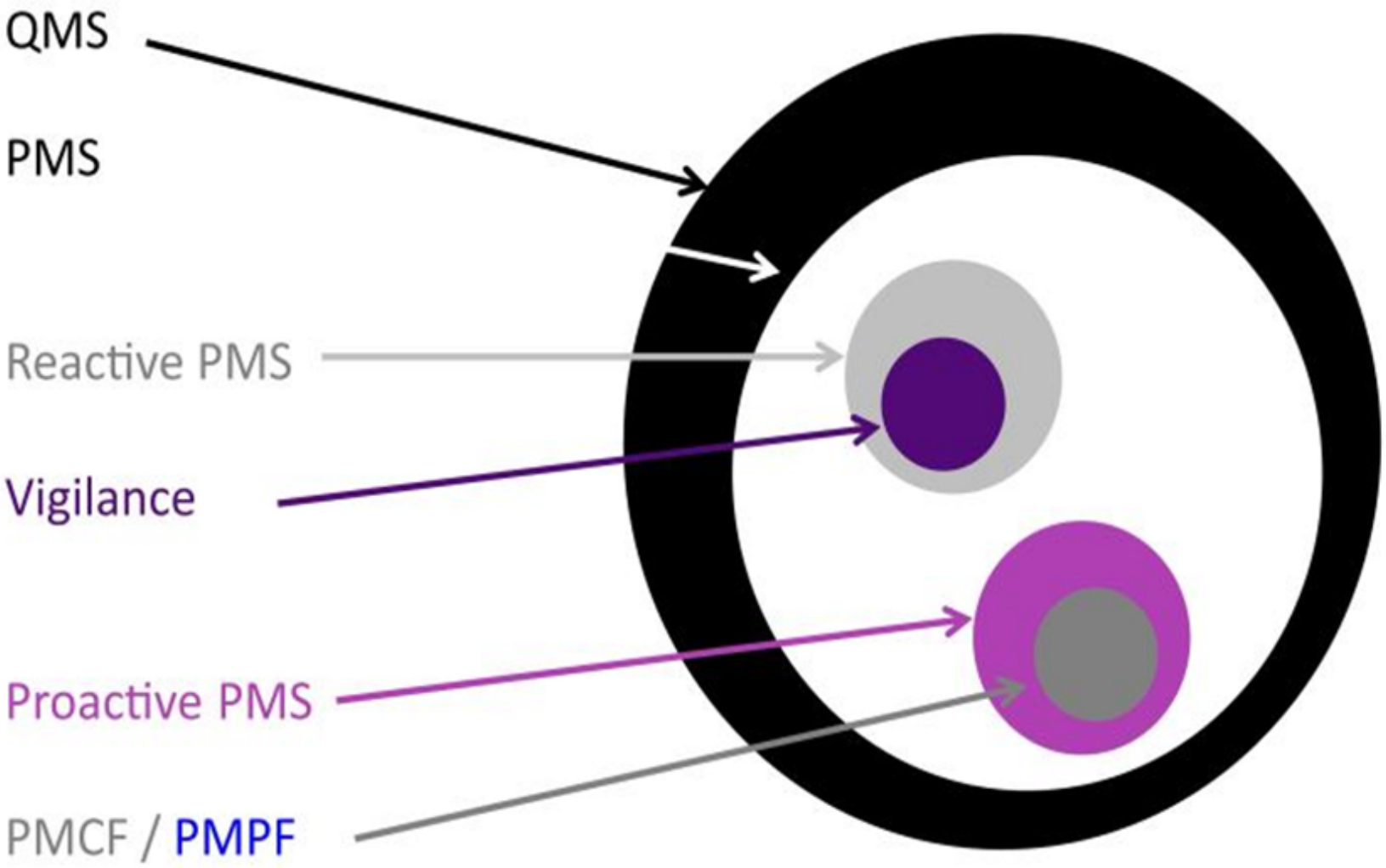
Measurement, Analysis & Improvement



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ISO 13485:2016 / TR 17223:2018

8.2 Monitoring and measurement

8.2.1 Feedback

- As one of the measurements of the effectiveness of the quality management system, the organization shall gather and monitor information relating to whether the organization has met customer requirements. The methods for obtaining and using this information shall be documented.
- The organization shall document procedures for the feedback process. This feedback process shall include provisions to gather data from production as well as post-production activities.
- The information gathered in the feedback process shall serve as potential input into risk management for monitoring and maintaining the product requirements as well as the product realization or improvement processes.
- If applicable regulatory requirements require the organization to gain specific experience from post-production activities, the review of this experience shall form part of the feedback process.

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ISO 13485:2016 / TR 17223:2018

8.2.2 Complaint handling

- The organization shall document procedures for timely complaint handling in accordance with applicable regulatory requirements.
- These procedures shall include at a minimum requirements and responsibilities for:

a) receiving and recording information;

b) evaluating information to determine if the feedback constitutes a complaint;

c) investigating complaints;

d) determining the need to report the information to the appropriate regulatory authorities;

e) handling of complaint-related product;

f) determining the need to initiate corrections or corrective actions.

- **If any complaint is not investigated, justification shall be documented.**
- **Any correction or corrective action resulting from the complaint handling process shall be documented.**
- If an investigation determines activities outside the organization contributed to the complaint, relevant information shall be exchanged between the organization and the external party involved.
- Complaint handling records shall be maintained.

"When to Report"

"What to Report"

"Where to Report"

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ISO 13485:2016 / TR 17223:2018

- **8.2.3 Reporting to regulatory authorities**
- If applicable regulatory requirements require notification of complaints that meet specified reporting criteria of adverse events or issuance of advisory notices, the organization shall document procedures for providing notification to the appropriate regulatory authorities.
- Records of reporting to regulatory authorities shall be maintained.

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Health Canada
Santé Canada
FDA
Agência Nacional de Vigilância Sanitária
TGA Health Safety Regulation
厚生労働省

Australia

	Who reports	What to report	When to report (calendar/working days)	Why (reference)	How (particular forms / websites)
	Manufacturer and the Australian Sponsor Events must be reported by the manufacturer to the TGA, or to the Sponsor	An adverse event is an event that led to: • Death • A serious injury or serious deterioration to a patient, user or other person, including a life-threatening illness or injury, permanent impairment of a body function, permanent damage to a body structure, a condition necessitating medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure A 'near adverse event' is an event that might have led to a death or serious injury.	Serious threat to public health – **2 days** An event that led to the death or serious deterioration in the state of health of a patient, a user, or other person – **10 days** An event that the recurrence of which might lead to the death or serious deterioration in the state of health of a patient, a user, or other person – **30 days**	Therapeutic Goods (Medical Devices) Regulations 2002 Schedule 3 Part 1 Clause 1.4(3)(c)(i)	IRIS (incident reporting and investigation scheme) – Drugs and Devices MDIR (Medical Device Incident Reporting) http://www.tga.gov.au/safety/problem.htm

Brazil

	Who reports	What to report	When to report (calendar/ working days)	Why (reference)	How (particular forms / websites)
	Manufacturer and the Brazilian Registration Holder	The following events related to health products and involving patients, users or other persons I - a serious threat to public health; II - death; III - serious adverse event that has not evolved to death; IV - technical complaint with the potential to cause death or serious adverse event; V - no severe adverse event; VI - technical complaint with the potential to cause no severe adverse event, and VII – fake (counterfeit device)	No later than **72 hours** after first knowledge of; a) death; b) serious threat to public health c) Forgery (counterfeit) No later than **10 calendar days** after knowledge of; a) serious adverse event, with no associated deaths; b) no severe adverse event, the recurrence has the potential to cause serious adverse event in Patient, User or other person. No later than **30 calendar days** after knowledge which can lead to adverse event in a patient, user or other person, provided that at least one of the following conditions be verified: a) the possibility of recurrence of the complaint is not remote; b) an occurrence of the same type has caused or contributed to death or serious damage to health in last two years; c) the holder of record of the product needs or need to take action to prevent imminent danger health; d) there is possibility of error induced by use of design, labelling or instructions. Not later than **10 calendar days** after knowledge, of the following observed in other countries and associated with a product registered in Brazil: a) death; b) serious threat to public health; c) Forgery (counterfeit)	RDC ANVISA 67/2009 – Article 6, 7 and 8	Tecnovigilância - National System of Sanitary Surveillance (SNVS) constituted by the Ministry of Health, National Health Surveillance Agency (ANVISA) http://portal.anvisa.gov.br/vigilancia-sanitaria-no-brasil *Not published in English

Canada

	Who reports	What to report	When to report (calendar/ working days)	Why (reference)	How (particular forms / websites)
	Manufacturer and the Canadian Importer	Death or serious deterioration in the state of health of a patient, user, or other person	An event that led to the death or serious deterioration in the state of health of a patient, a user, or other person – **10 days** An event that the recurrence of which might lead to the death or serious deterioration in the state of health of a patient, a user, or other person – **30 days**	Medical Device Regulations SOR/98-282, Section 59-61	On line .pdf form: www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/md-mm_form-eng.php Completed forms should be emailed to: hc.mdpr-dimm.sc@canada.ca or faxed to: 613-954-0941 or mailed to: Canada Vigilance - Medical Device Problem Reporting Marketed Health Products Directorate Health Canada Address Locator 1908C 200 Tunney's Pasture Driveway Ottawa Ontario K1A 0K9

Japan

	Who reports	What to report	When to report (calendar/ working days)	Why (reference)	How (particular forms/websites)
	Market Authorisation Holder	① Death ② Impediment ③ Case which has possibility of death or impediment ④ Hospital admission for curing or the case to extend admission period ⑤ Similar to ①-④serious cases ⑥ Congenital diseases in the later generation	**Within 15 calendar days:** ①-⑥ **Within 30 calendar days:** ①-⑥ cases that could attribute to the effect of the malfunction of the medical devices Other cases and infection diseases that could be attributed to the malfunction of the medical devices, or in addition, the user could not predict the cases from the IFU and precautions described in the container or the package	Ministerial Ordinance No. 135 Article 228 -20.2 *Not published in English	No details in English

USA

	Who reports	What to report	When to report (calendar/ working days)	Why (reference)	How (particular forms / websites)
	Manufacturer and Importer	Death, or Serious injury, which means an injury or illness that: • Is life threatening • Results in permanent damage to a body structure • Results in permanent impairment of a body function Device malfunction (or failure to meet performance specifications or otherwise perform as intended) such that the device or a similar device would be likely to cause a death or serious injury if the malfunction were to recur. Performance specifications include all claims made in the labelling for the device. A malfunction is considered likely to cause or contribute to a death or serious injury if: • the chance of it causing such an event is not remote or minute • it affects the device in a manner that may lead to a death or serious injury • the manufacturer would be required to take action to prevent a hazard as a result • a malfunction of the same type has actually contributed in the past two years	Manufacturer – Death, serious injury, reportable malfunctions: to FDA within **30 calendar days** User facility – Death: to FDA and manufacturer within **10 working days.** Serious injury: to manufacturer within **10 working days**. (reports to FDA if device manufacturer is not known) Distributor – Death, serious injury, and malfunctions: to manufacturer within **10 working days.** Death, serious injury to FDA within **10 working days** Manufacturer **5-Day Report**: the time runs (in working days) from the manufacturer became aware that a reportable MDR event necessitated remedial action to prevent an unreasonable risk of substantial harm to the public health to the date of the report; or becoming aware of a reportable event for which FDA has made a written request for the submission of a 5-day report. A 5-day report includes all subsequent events of the same nature that involve substantially similar devices for the time period specified in the written request.	Submit reports of MDR reportable events involving their medical devices [21 CFR 803.10(c) and 803.50]; Develop, maintain, and implement written procedures for identification and evaluation of all adverse medical device events to determine whether the event is an MDR [21 CFR 803.17] Establish and maintain complete files for complaints concerning adverse medical device events [21 CFR 803.18]	Mandatory adverse event report (MedWatch Form 3500A) for manufacturers, user facilities and importers http://www.fda.gov/ForIndustry/FDAeSubmitter/default.htm

Incidents, MDR, Mandatory Problem Reporting, Adverse Events, Serious Incidents

	Who reports	What to report	When to report	Database
	Manufacturer & Sponsor	*Incidents / corrective action in other countries *Definition of medical device – e.g. human tissue *Incidents on combination products	2-10-30	Database of Adverse Event Notification (DAEN)
	Manufacturer & Authorisation Holder		3-10-30	**Only in Portuguese**
	Manufacturer & Importer		10-30	MedEffect Database
	**Market Authorisation Holder**		15-30	**Only in Japanese**
	Manufacturer, User Facility & Importer – *forms stops duplication		5-10-30	Manufacturer and User Facility Device Experience (MAUDE)


Health Canada
Santé Canada
FDA
Agência Nacional
de Vigilância Sanitária
TGA
厚生労働省

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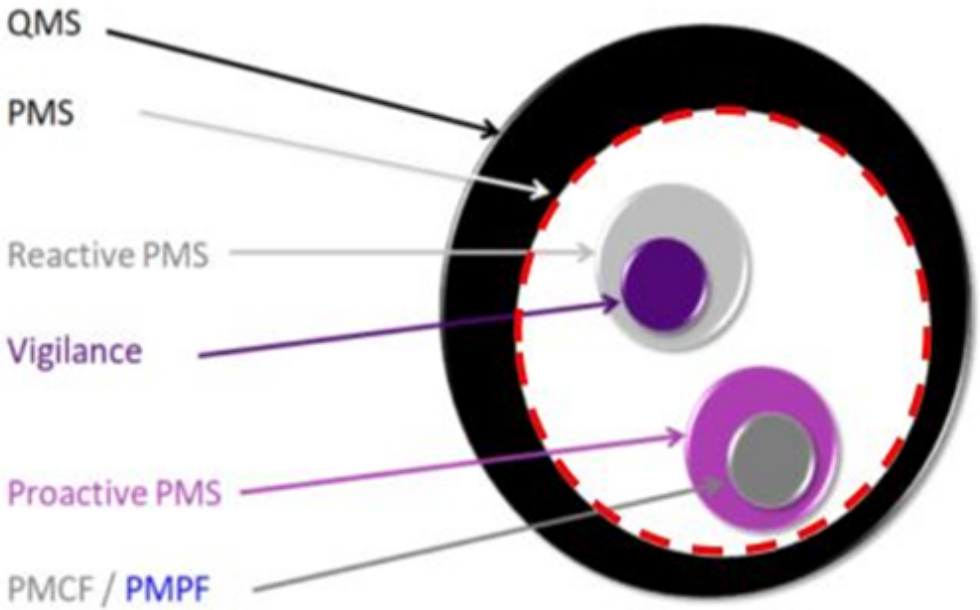
Article 2 Definitions – 'post market surveillance'

- all activities carried out by the manufacturers in cooperation with other economic operators 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;



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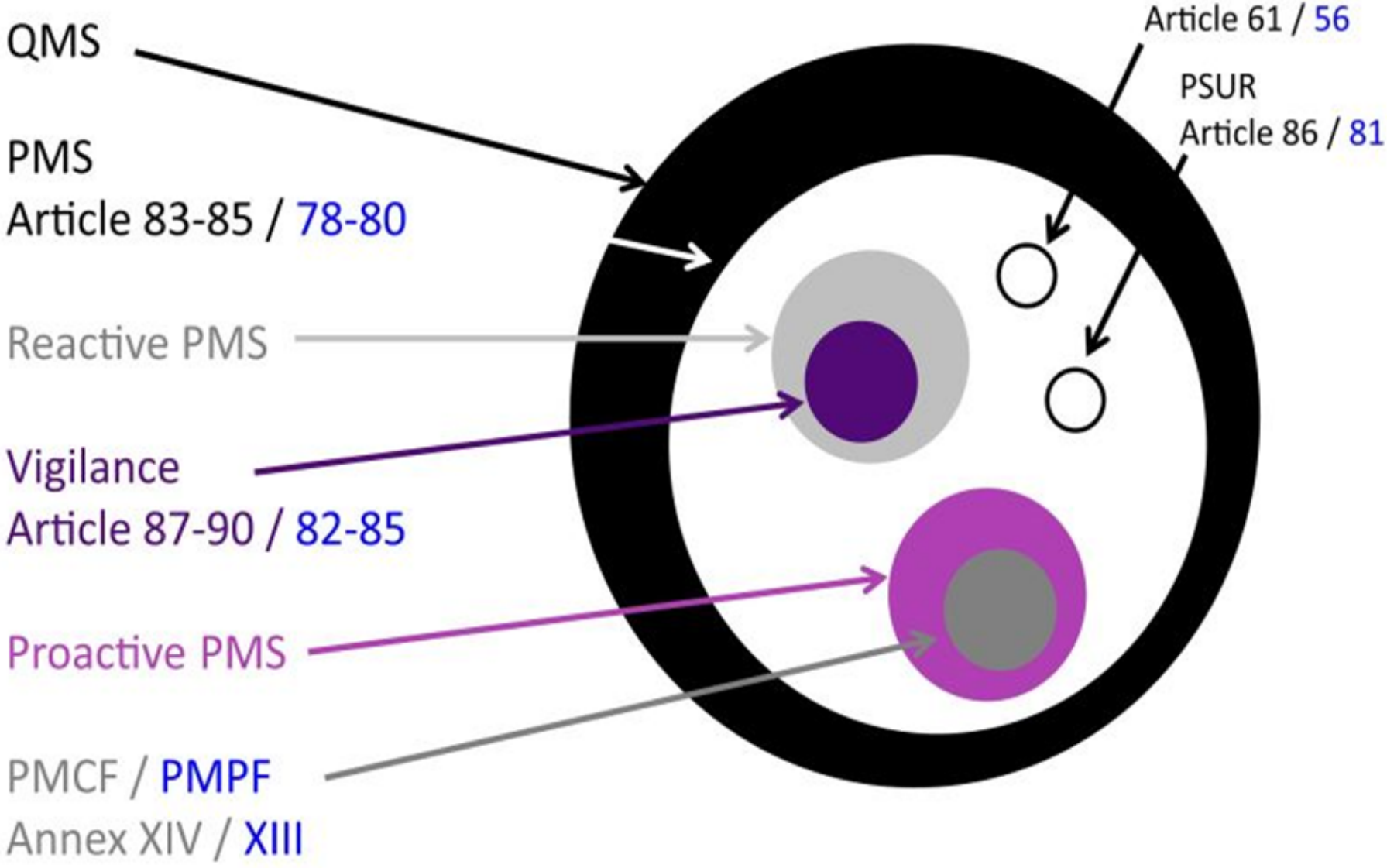
Post Market Surveillance

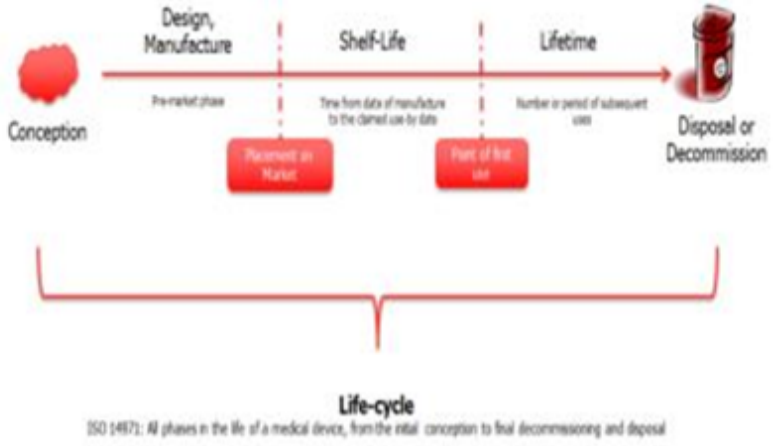


Chapter VII – Post-market surveillance, vigilance and market surveillance

SECTION 1 – POST-MARKET SURVEILLANCE

Article 83 – Post-market surveillance system of the manufacturer

1. For each device, manufacturers shall plan, establish, document, implement, maintain and update a post-market surveillance system in a manner that is proportionate to the risk class and appropriate for the type of device.
   - That system shall be an integral part of the manufacturer's quality management system referred to in Article 10(9).



Life-cycle

ISO 14971: All phases in the life of a medical device, from the initial conception to final decommissioning and disposal

2. The post-market surveillance system shall be suited to actively and systematically gathering, recording and analysing relevant data on the quality, performance and safety of a device throughout its entire lifetime, and to drawing the necessary conclusions and to determining, implementing and monitoring any preventive and corrective actions.

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Post Market Surveillance – Article 83

3. Data gathered by the manufacturer's post-market surveillance system shall in particular be used:

a) to update the benefit-risk determination and to improve the risk management as referred to in Chapter I of Annex I;

b) to update design and manufacturing information, the instructions for use and the labelling;

c) to update the clinical evaluation;

d) to update the summary of safety and clinical performance referred to in Article 32;

e) for the identification of needs for preventive, corrective or field safety corrective action ;

f) for the identification of options to improve the usability, performance and safety of the device;

g) when relevant, to contribute to the post-market surveillance of other devices;

h) to detect and report trends in accordance with Article 88.

- The technical documentation shall be updated accordingly.

... see next slide

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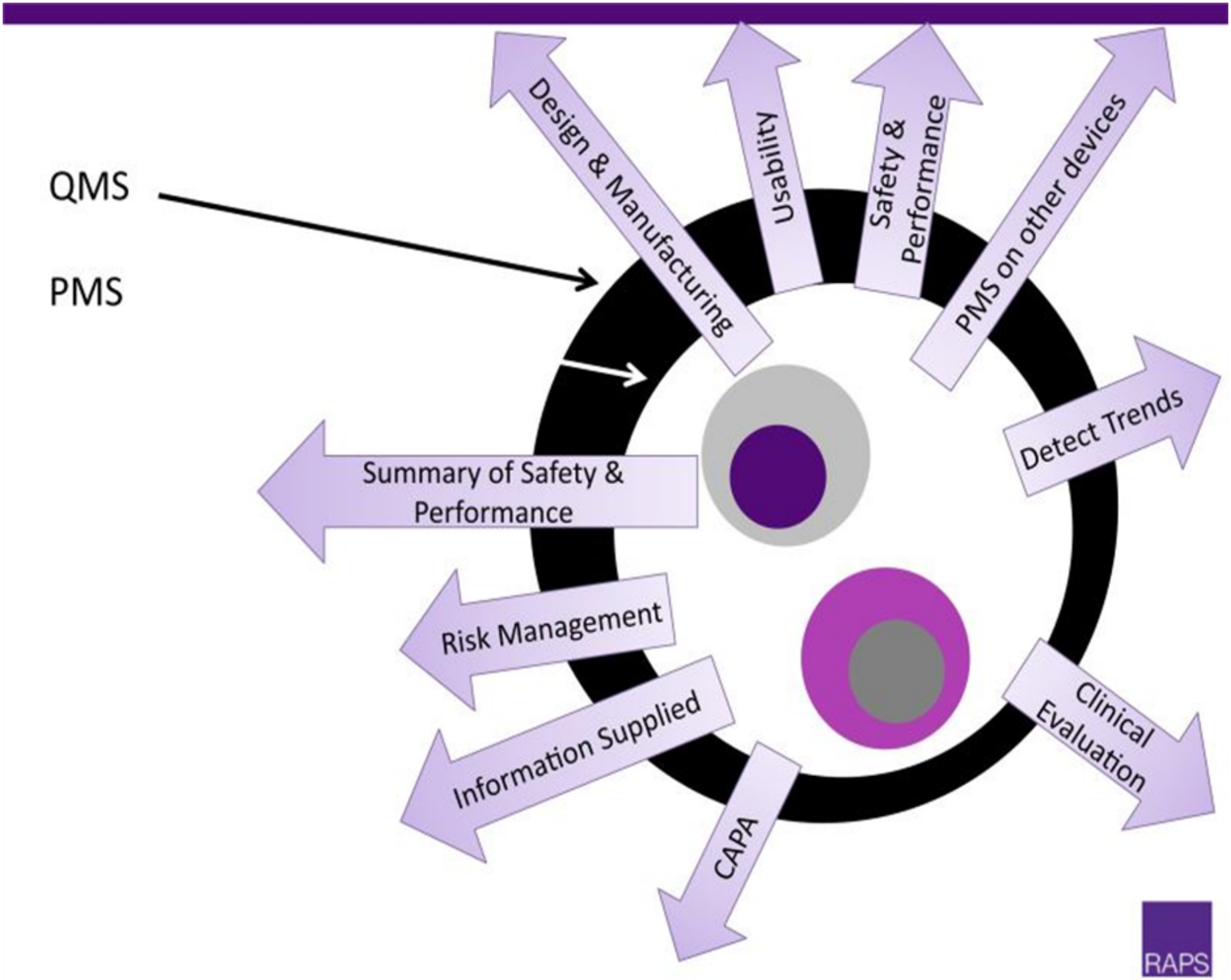
QMS
PMS
Design & Manufacturing
Usability
Safety & Performance
PMS on other devices
Detect Trends
Clinical Evaluation
CAPA
Information Supplied
Risk Management
Summary of Safety & Performance
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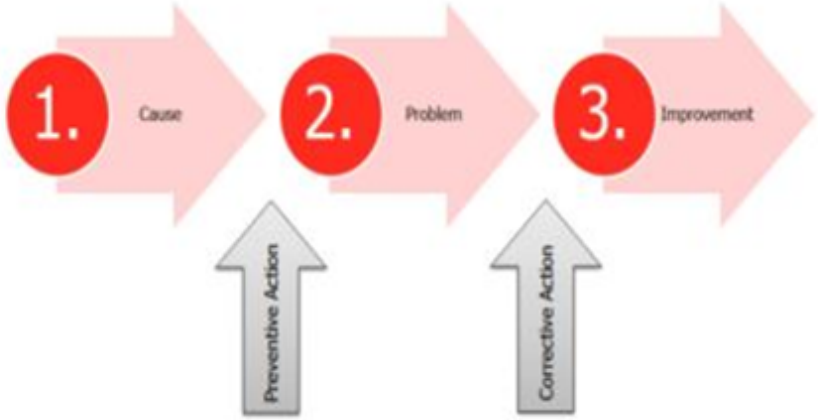
Post Market Surveillance – Article 83

4. If, in the course of the post-market surveillance, a need for preventive or corrective action or both is identified, the manufacturer shall implement the appropriate measures and inform the competent authorities concerned and, where applicable, the notified body.



'serious incident' means any incident that directly or indirectly led, might have led or might lead to any of the following:

a) the death of a patient, user or other person,
b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health,
c) a serious public health threat;

'field safety corrective action' means corrective action taken by a manufacturer for technical or medical reasons to prevent or reduce the risk of a serious incident in relation to a device made available on the market;

- Where a serious incident is identified or a field safety corrective action is implemented, it shall be reported in accordance with Article 87.

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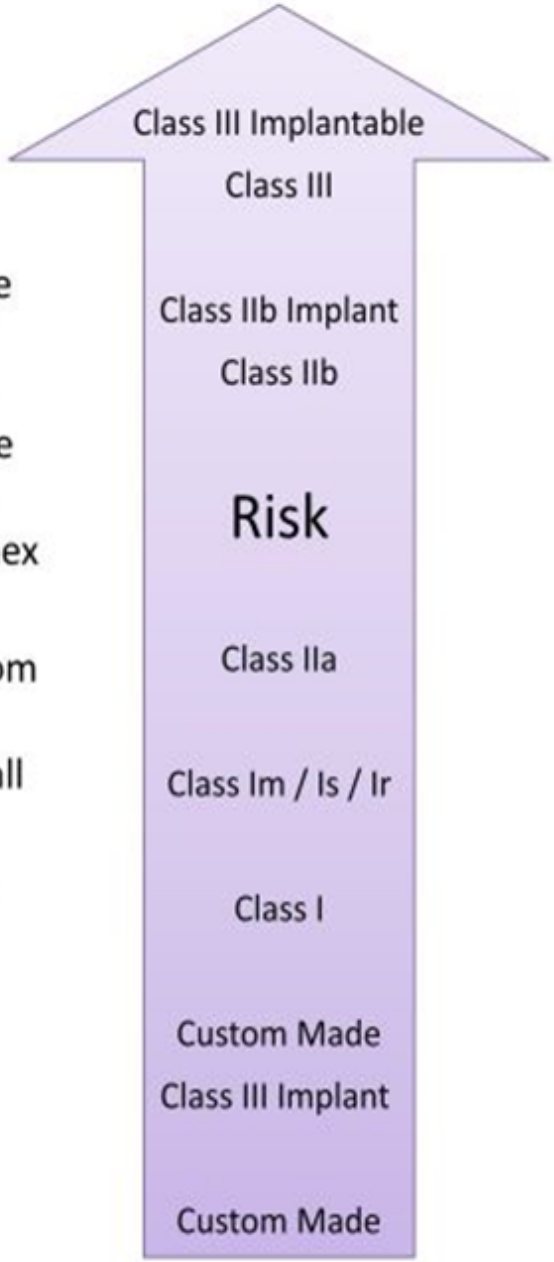
PMS – Article 84 & Article 85

Article 84 – PMS plan

- The post-market surveillance system referred to in Article 83 shall be based on a post-market surveillance plan, the requirements for which are set out in Section 1.1 of Annex III.
- For devices other than custom -made devices, the post-market surveillance plan shall be part of the technical documentation specified in Annex II.



Article 85 – PMS report

- Manufacturers of class I devices shall prepare a post-market surveillance report summarising the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan referred to in Article 84 together with a rationale and description of any preventive and corrective actions taken. The report shall be updated when necessary and made available to the competent authority upon request.

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Periodic Safety Update Report – Article 86

1. Manufacturers of class IIa, class IIb and class III devices shall prepare a PSUR for each device and where relevant for each category or group of devices summarising the results and conclusions of the analyses of the PMS data gathered as a result of the PMS plan referred to in Article 84 together with a rationale and description of any preventive and corrective actions taken.

- Throughout the lifetime of the device concerned that PSUR shall set out:

- **Article 86 – PSUR:**
  - Conclusions of the benefit risk determination
  - Main findings of PMCF
  - Volume of Sales
  - Estimate evaluation of the size and other characteristics of the population that use the device
  - Where practicable usage frequency of the device

- Manufacturers of class IIb and III devices shall update the PSUR at least annually.
- Manufacturers of class IIa devices shall update the PSUR at least every two years.
- For custom-made devices the PSUR shall be part of the documentation referred to in Section 2 of Annex XIII.

2. Manufacturers of devices in class III **or** implantable devices shall submit PSURs by means of the electronic system to the notified body.
- The notified body shall review the report and add its evaluation to that electronic system with details of any action taken. Such PSURs and the notified body evaluation shall be made available to competent authorities through that electronic system.

3. For devices other than class III or implantable, manufacturers shall make PSURs available to the notified body involved in the conformity assessment and, upon request, to competent authorities.

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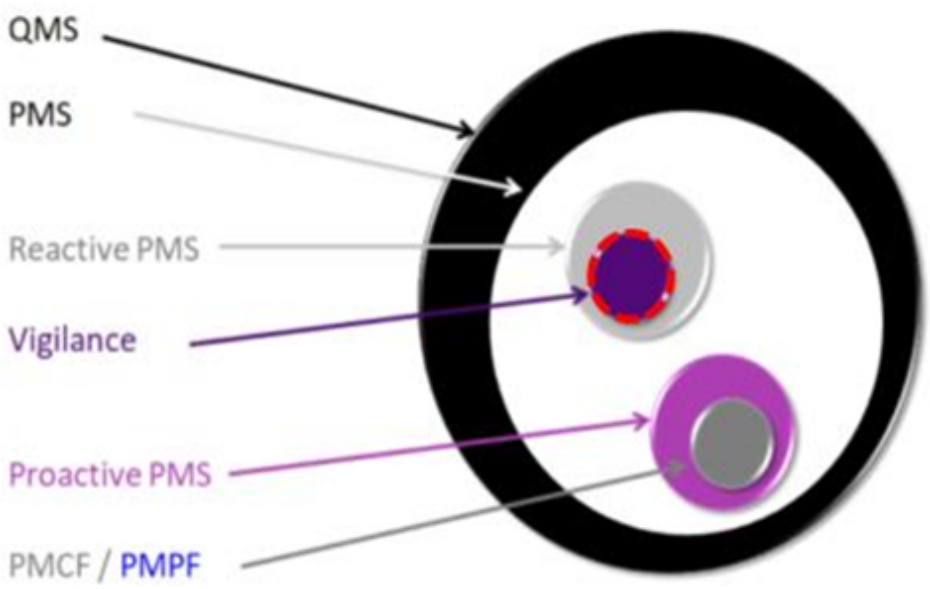
Chapter VII – Post-market surveillance, vigilance and market surveillance
SECTION 2 – VIGILANCE

Article 87 – Reporting of serious incidents and FSCA

- Manufacturers of devices made available on the Union market, other than investigational devices, shall report, to the relevant competent authorities, in accordance with Articles 92(5) and (7), the following:

a) any serious incident involving devices made available on the Union market, except expected side-effects which are clearly documented in the product information and quantified in the technical documentation and are subject to trend reporting pursuant to Article 88;

b) any field safety corrective action in respect of devices made available on the Union market, including any FSCA undertaken in a third country in relation to a device which is also legally made available on the Union market, if the reason for the FSCA is not limited to the device made available in the third country.



The reports referred to in the first subparagraph shall be submitted through the electronic system (Article 92)

Vigilance – Article 87 / Article 82

Question	Answer
Who reports	Manufacturers of devices, other than investigational / performance study devices. *EU AR – Article 11, Importers – Article 13, Distributors – Article 14
What to report	(a) any serious incident involving devices made available on the Union market, except expected side-effects / erroneous results which are clearly documented in the product information and quantified in the technical documentation and are subject to trend reporting pursuant to Article 88 / 83; (b) any field safety corrective action in respect of devices made available on the Union market, including any field safety corrective action undertaken in a third country in relation to a device which is also legally made available on the Union market, if the reason for the field safety corrective action is not limited to the device made available in the third country.

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Vigilance, Periodic Summary Reports & Trend Reporting

Question	Answer
What to report Article 87 / 82	For similar serious incidents that occur with the same device or device type and for which the root cause has been identified or a FSCA has been implemented or where the incidents are common and well documented, the manufacturer may provide periodic summary reports instead of individual serious incident reports, on condition that the coordinating competent authority has agreed with the manufacturer on the format, content and frequency of the periodic summary reporting.
	Where the manufacturer of the device concerned considers that the incident is not a serious incident or is an expected undesirable side effect, which will be covered by trend reporting in accordance with Article 88 / 83, it shall provide an explanatory statement. If the competent authority does not agree with the conclusion of the explanatory statement, it may require the manufacturer to provide a report in accordance with paragraphs 1 to 5 of Article 87 / 82 and require it to ensure that appropriate follow-up action is taken in accordance with Article 89 / 84.

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Vigilance, Periodic Summary Reports & Trend Reporting

Question	Answer
What to report Article 88 / 83	Manufacturers shall report, by means of the electronic system referred to in Article 92 / 87, any statistically significant increase in the frequency or severity of incidents that are not serious incidents or that are expected undesirable side- effects that could have a significant impact on the benefit-risk analysis referred to in Sections 1 and 5 of Annex I and which have led or may lead to risks to the health or safety of patients, users or other persons that are unacceptable when weighed against the intended benefits. The significant increase shall be established in comparison to the foreseeable frequency or severity of such incidents in respect of the device, or category or group of devices, in question during a specific period as specified in the technical documentation and product information. The manufacturer shall specify how to manage the incidents referred to in the first subparagraph and the methodology used for determining any statistically significant increase in the frequency or severity of such incidents, as well as the observation period, in the post-market surveillance plan referred to in Article 84 / 79.

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Vigilance – Article 87 / Article 82

Question	Answer
When to report	As a general rule, the period for reporting shall take account of the severity of the serious incident.
Serious Incident	• immediately after the manufacturer has established the causal relationship with their device or that such causal relationship is reasonably possible, and not later than 15 days after they have become aware of the incident.
Death or unanticipated serious deterioration in state of health	• immediately after the manufacturer established or suspected a causal relationship between the device and the event but not later than 10 days following the date of awareness of the serious incident.
Serious Public Health Threat	• immediately, and not later than 2 days after awareness by the manufacturer of that threat.

Vigilance – Article 87 / Article 82

Question	Answer
When to report	Where necessary to ensure timely reporting, the manufacturer may submit an initial report that is incomplete followed up by a complete report.
	If, after becoming aware of a potentially reportable incident, the manufacturer is uncertain about whether the incident is reportable, it shall nevertheless submit a report within the timeframe required in accordance with paragraphs 2 to 5.
	Except in cases of urgency in which the manufacturer needs to undertake field safety corrective action immediately, the manufacturer shall, without undue delay, report the field safety corrective action referred to in point (b) of paragraph 1 in advance of the field safety corrective action being undertaken.

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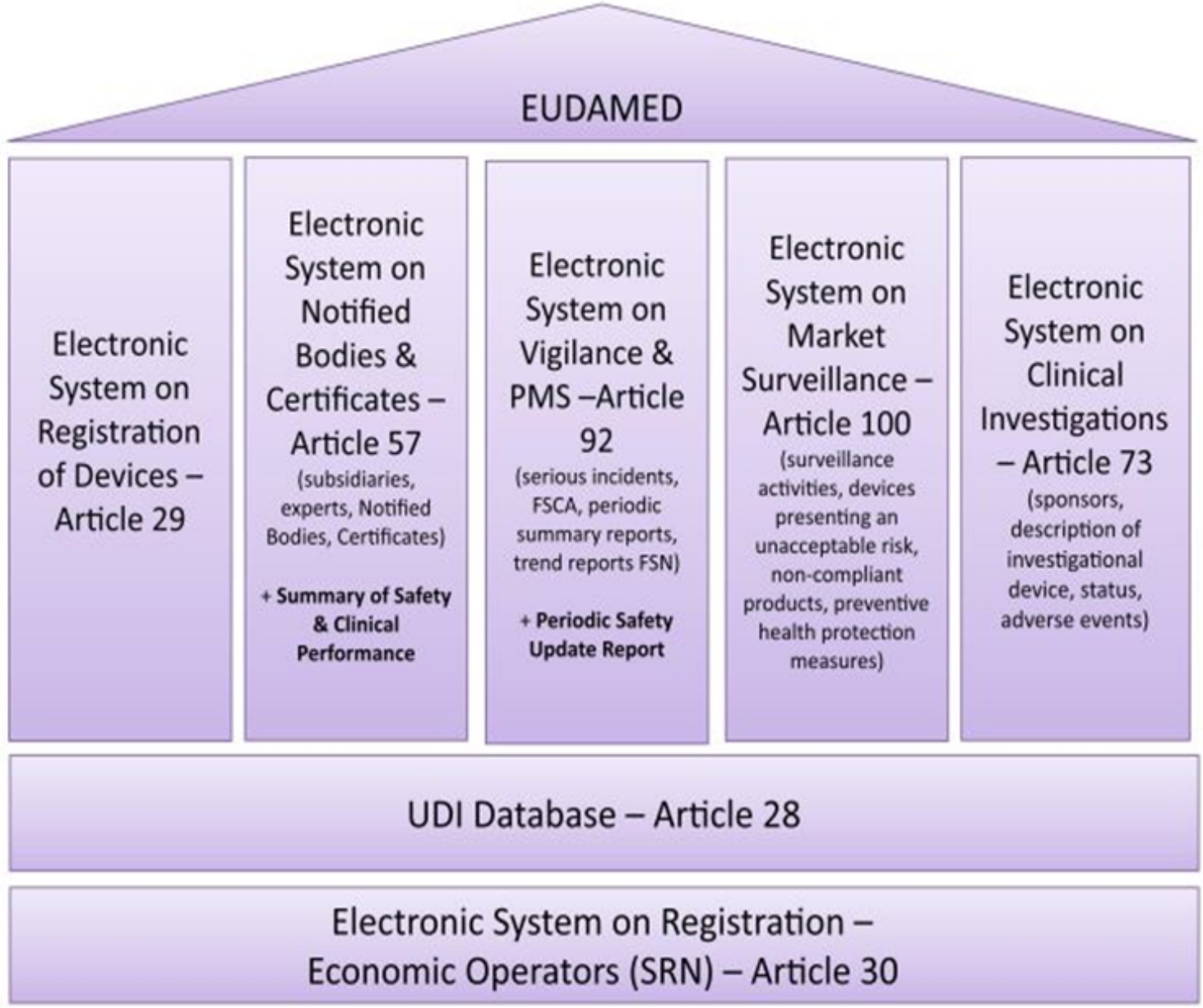
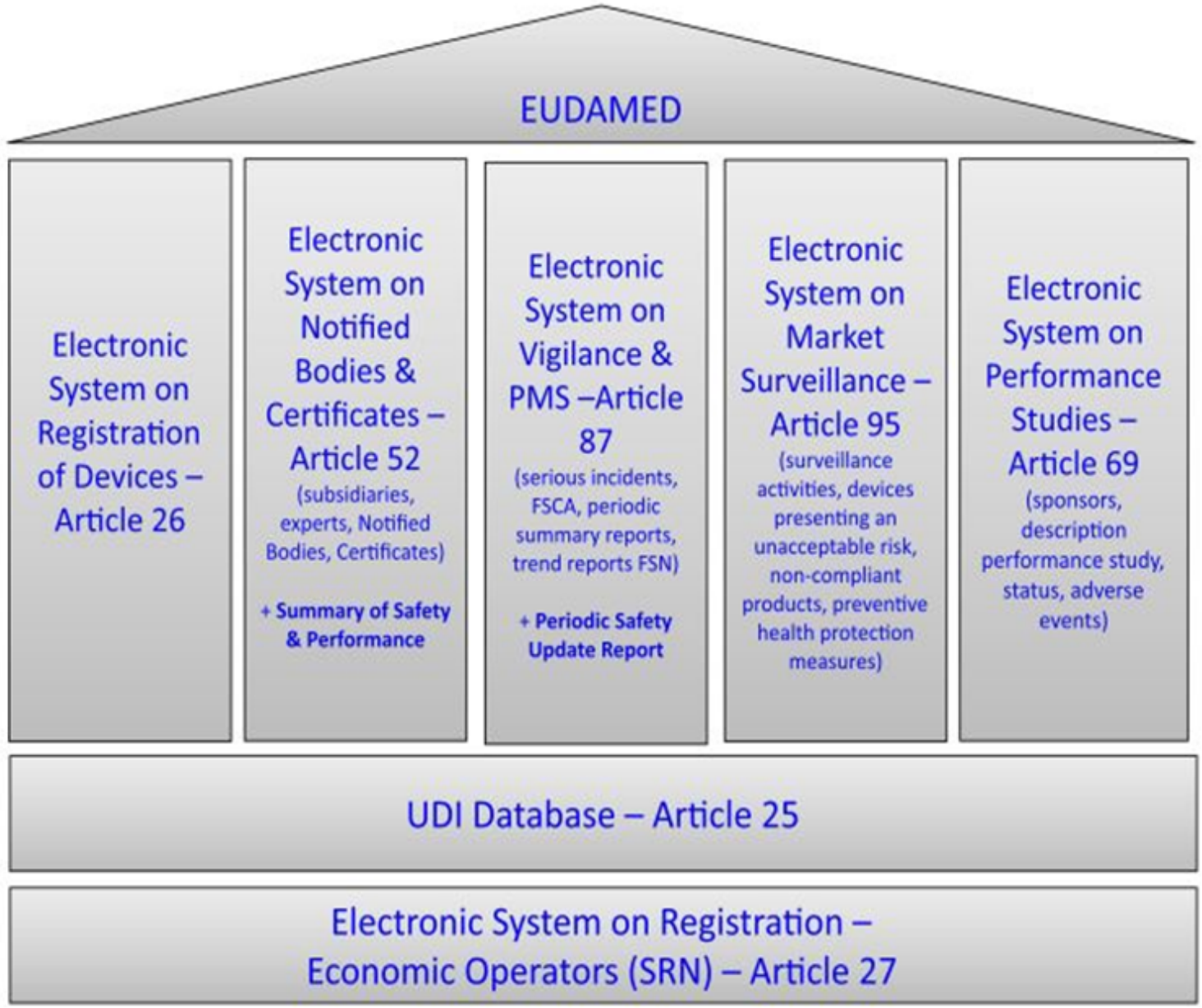
Vigilance – Article 87 / Article 82

Question	Answer
Where to report	Electronic system on vigilance and on post-market surveillance – Article 92 / 87 http://ec.europa.eu/growth/sectors/medical-devices/contacts/index_en.htm#vcp
How Implementing Act in the future	Article 92 / 87 – Electronic system on vigilance and on post-market surveillance a) reports by manufacturers on serious incidents and field safety corrective actions referred to in Article 87 / 82 and Article 89 / 84; b) periodic summary reports by manufacturers referred to in Article 87 / 82; c) reports by manufacturers on trends referred to in Article 88 / 83; d) periodic safety update reports referred to in Article 86 / 81; e) field safety notices by manufacturers referred to in Article 89 / 84; f) information to be exchanged between the competent authorities of the Member States and between them and the Commission in Article 89 / 84. **... see next slide**

MDR – European Database – Article 33



IVDR – European Database – Article 30

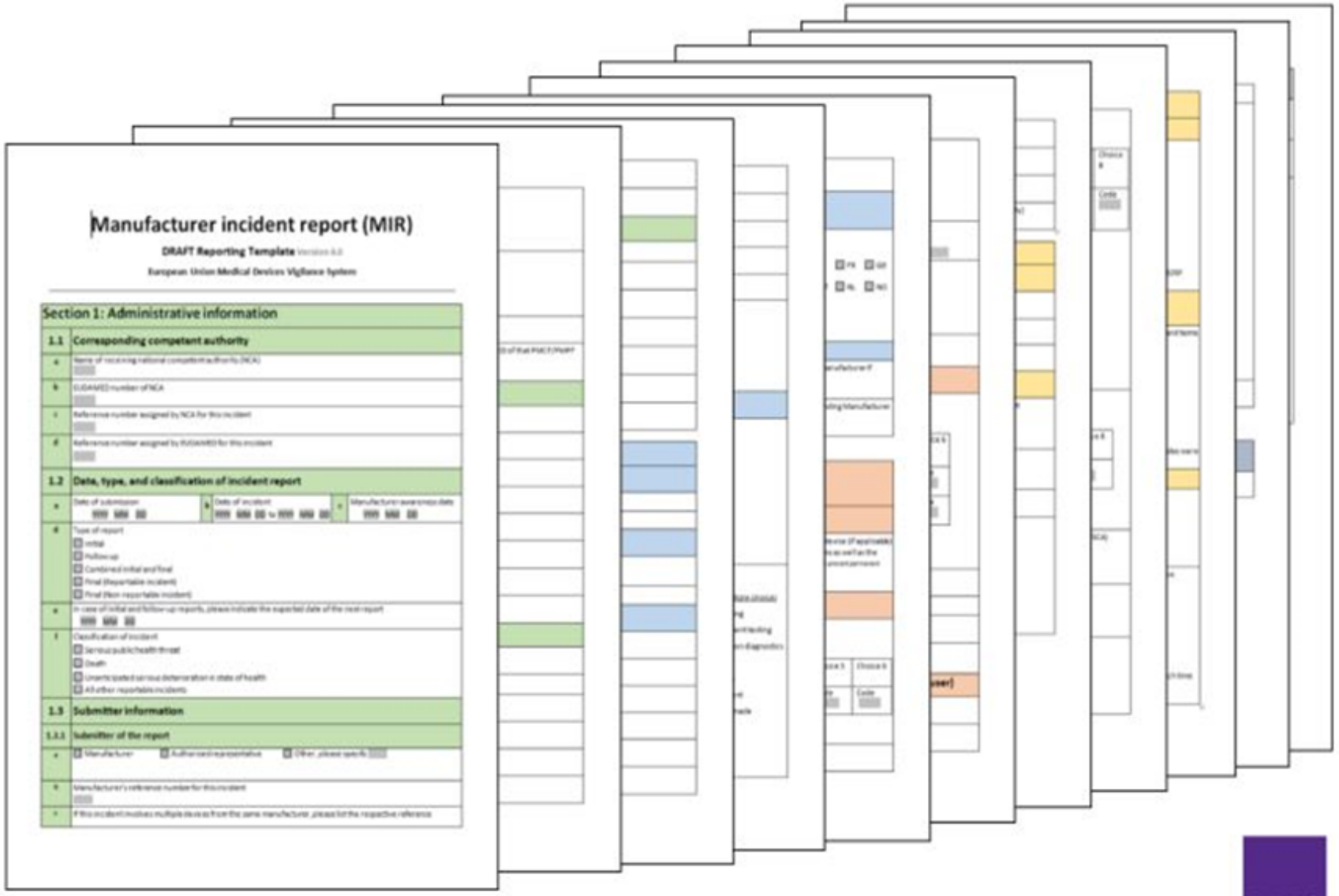


Incidents, MDR, Mandatory Problem Reporting, Adverse Events, Serious Incidents

	Who reports	What to report	When to report	Database
	Manufacturer &		2-10-30	Database of
	User Facility & Importer – *forms stops duplication	*Incid *Defini		and User Facility Device Experience (MAUDE)

	Who reports	What to report	When to report	Database
	Manufacturer EU AR Importer Distributor	1. Serious Incidents … see next slide 2. FSCA 3. Periodic Summary Reports 4. Trend Reports 5. Field Safety Notices 6. PSUR	2-10-**15**	European Database on Medical Devices (EUDAMED)

MedDev 2.12-1 DRAFT Rev 9 (?)



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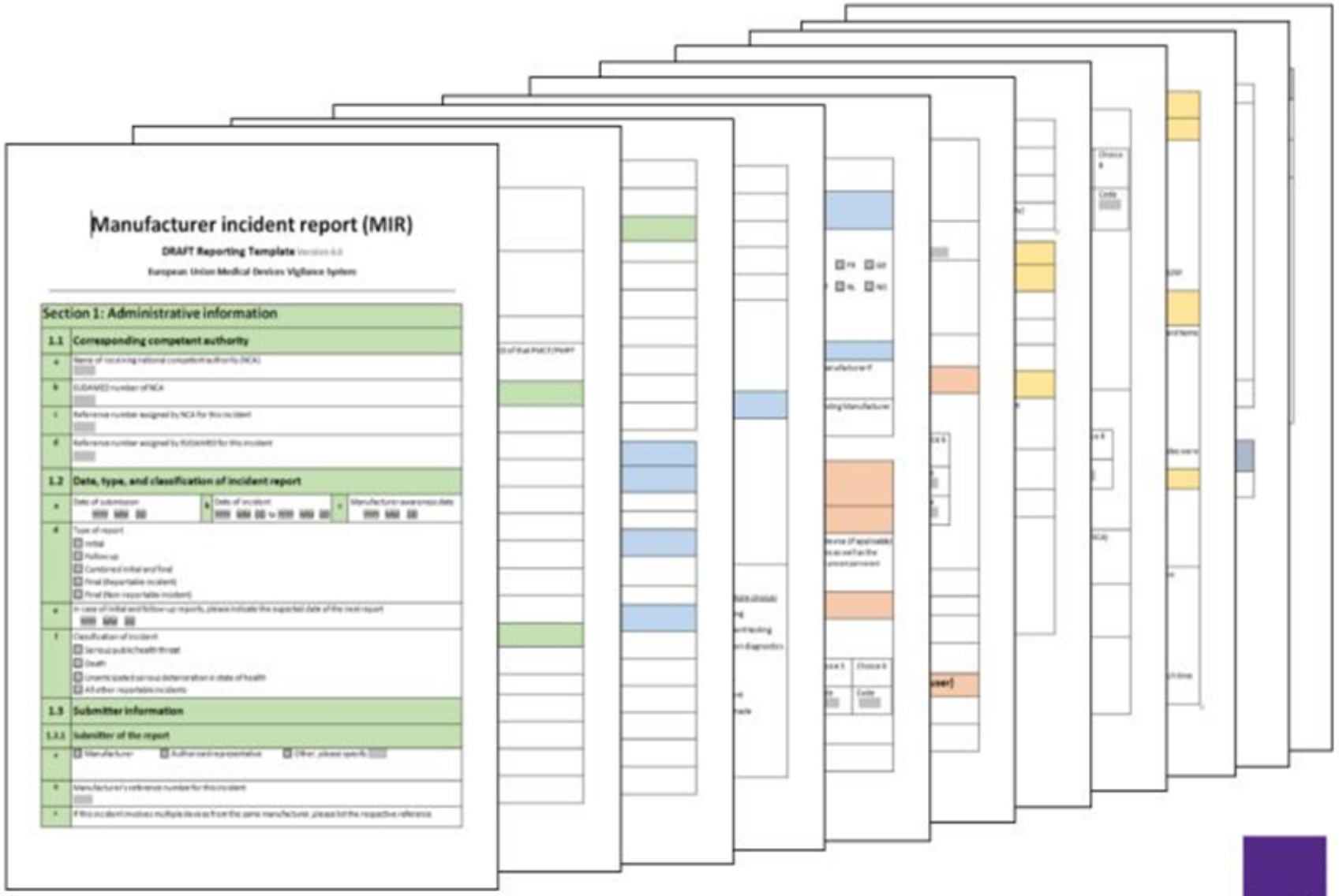
MedDev 2.12-1 DRAFT Rev 9 (?)



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MedDev 2.12-1 DRAFT Rev 9 (?)

Section 2: Medical device information			
2.1	Unique Device Identification (UDI)		
a	UDI-DI	b	UDI-PI
c	Basic UDI-DI	d	Unit of use UDI-DI
2.2	Categorisation of device		
a	Medical device terminology ☐ GMDN ☐ UMDNS(ECRI) ☐ GIVD/EDMS ☐ Other		
b	Medical device nomenclature code		

UDI

Nomenclature

N=372 Problem Codes

Section 3: Incident information derived from healthcare professional and/or lay user							
3.1	Nature of incident						
a	Provide a comprehensive description of the incident, including (1) what went wrong with the device (if applicable) and (2) a description of the health effects (if applicable), i.e. clinical signs, symptoms, conditions as well as the overall health impact (i.e. Death; life-threatening; hospitalization – initial or prolonged; required intervention to prevent permanent damage; disability or permanent damage; congenital anomaly/ Birth defects; indirect harm; no serious outcome)						
3.2	Medical device problem information						
a	IMDRF Medical device problem codes (Annex A) Coding with IMDRF terms is a mandatory requirement.						
		Choice 1 (most relevant)	Choice 2	Choice 3	Choice 4	Choice 5	Choice 6
	IMDRF 'Medical device problem codes'	Code	Code	Code	Code	Code	Code
	If you think the incident is unique and a suitable IMDRF term is missing, briefly explain:						

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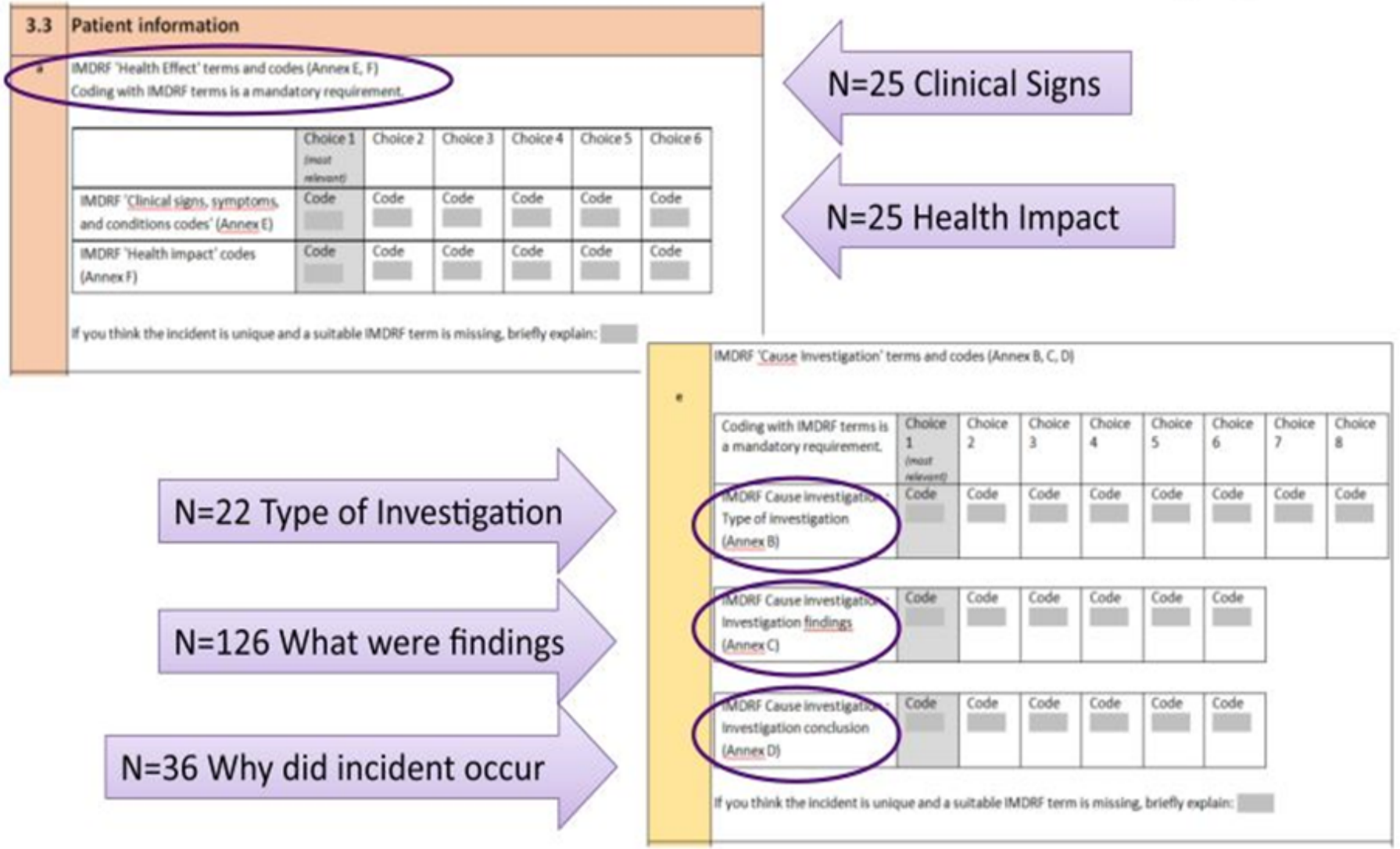
MedDev 2.12-1 DRAFT Rev 9 (?)



3.3 Patient information

IMDRF 'Health Effect' terms and codes (Annex E, F)
Coding with IMDRF terms is a mandatory requirement.

	Choice 1 (most relevant)	Choice 2	Choice 3	Choice 4	Choice 5	Choice 6
IMDRF 'Clinical signs, symptoms, and conditions codes' (Annex E)	Code	Code	Code	Code	Code	Code
IMDRF 'Health impact' codes (Annex F)	Code	Code	Code	Code	Code	Code

If you think the incident is unique and a suitable IMDRF term is missing, briefly explain:

N=25 Clinical Signs

N=25 Health Impact

IMDRF 'Cause Investigation' terms and codes (Annex B, C, D)

Coding with IMDRF terms is a mandatory requirement.	Choice 1 (most relevant)	Choice 2	Choice 3	Choice 4	Choice 5	Choice 6	Choice 7	Choice 8
IMDRF Cause investigation: Type of investigation (Annex B)	Code	Code	Code	Code	Code	Code	Code	Code
IMDRF Cause investigation: Investigation findings (Annex C)	Code	Code	Code	Code	Code	Code		
IMDRF Cause investigation: Investigation conclusion (Annex D)	Code	Code	Code	Code	Code	Code		

If you think the incident is unique and a suitable IMDRF term is missing, briefly explain:

N=22 Type of Investigation

N=126 What were findings

N=36 Why did incident occur

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IMDRF Component codes (Annex G)
Coding with IMDRF terms is a mandatory requirement

	Choice 1 (most relevant)	Choice 2	Choice 3	Choice 4	Choice 5	Choice 6
IMDRF 'Component' codes (Annex G)	Code	Code	Code	Code	Code	Code

If you think the incident is unique and a suitable IMDRF term is missing, briefly explain:

Annex G to be developed after Annex E & F

Incidents – Country, EEA + CH + TR, Global

c

Enter the number of similar incidents and devices on the market for the indicated time periods
You must use yearly time periods unless:
A: a different time period has been specified by the European vigilance Working Group
B: the device has not been on the European market for more than three years

	Time period (N) Year to date = incident year		Time period (N-1) calendar year one year before incident		Time period (N-2) calendar year two years before incident		Time period (N-3) calendar year three years before incident	
Start date								
End date								
	Number of similar incidents	Number of devices on market	Number of similar incidents	Number of devices on market	Number of similar incidents	Number of devices on market	Number of similar incidents	Number of devices on market
Country of incident								
EEA + CH + TR								
World								

RAPS

Questions & Answers

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