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How to get to the market and stay there!

Post Market Surveillance

February 22nd, 2017

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BSI, a Royal Charter Company

Agenda

1. Proposed Regulations
2. Post Market Surveillance
   - Vigilance
     - Periodic Safety Update Report
   - Post Market Clinical Follow Up
     - Summary of Safety and Clinical Performance

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Proposed Regulation

Draft November 2016

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MDR

- New Draft MDR
  - 101 Whereas
- 123 Articles in X Chapters
  - I. Scope and Definitions
  - II. Making available on the market and putting into service, obligations of economic operators, reprocessing, CE marking, free movement
  - III. Identification and traceability of devices, registration of devices and of economic operators, summary of safety and clinical performance, European database on medical devices
  - IV. Notified Bodies
  - V. Classification and conformity assessment
  - VI. Clinical evaluation and clinical investigations
  - **VII. Post-market surveillance, vigilance and market surveillance**
  - VIII. Cooperation between Member states, Medical Device Coordination Group, expert laboratories, expert panels and device registers
  - IX. Confidentiality, data protection, funding and penalties
  - X. Final Provisions

XVII Annexes

- I. General Safety and Performance Requirements
- II. Technical Documentation
- **III. Technical Documentation on Post-Market Surveillance**
- IV. EU Declaration of Conformity
- V. CE Marking of Conformity
- VI. Information to be submitted with registration of devices and economic operators and core data elements to be provided to the UDI data-base
- VII. Requirements to be met by Notified Bodies
- VIII. Classification Rules
- IX. Conformity Assessment – QMS & Technical Documentation
- X. Conformity Assessment – Type Examination
- XI. Conformity Assessment – Product Conformity Verification
- XII. Certificates issued by a Notified Body
- XIII. Procedure for Custom-made Devices
- **XIV. Clinical Evaluation and Post-market clinical follow-up**
- XV. Clinical Investigations
- XVI. List of groups of products without an intended medical purpose
- XVII. Correlation Table

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IVDR

- New Draft IVDR
  - 101 Whereas
- 113 Articles in X Chapters
  - I. Introductory provisions, Scope and Definitions, Regulatory status of products and counselling
  - II. Making available on the market and putting into service, obligations of economic operators, reprocessing, CE marking, free movement
  - III. Identification and traceability of devices, registration of devices and of economic operators, summary of safety and clinical performance, European database on medical devices
  - IV. Notified Bodies
  - V. Classification and conformity assessment
  - VI. Clinical evidence, performance evaluation and performance studies
  - **VII. Post-market surveillance, vigilance and market surveillance**
  - VIII. Cooperation between Member states, Medical Device Coordination Group, expert laboratories, expert panels and device registers
  - IX. Confidentiality, data protection, funding and penalties
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- X. Conformity Assessment – Type Examination
- XI. Conformity Assessment – Production Quality Assurance
- XII. Certificates issued by a Notified Body
- **XIII. Performance Evaluation and Post-market follow-up**
- XIV. Interventional Clinical Performance Studies and other performance studies involving risks for subjects of the studies
- XV. Correlation Table

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Post Market Surveillance

Articles

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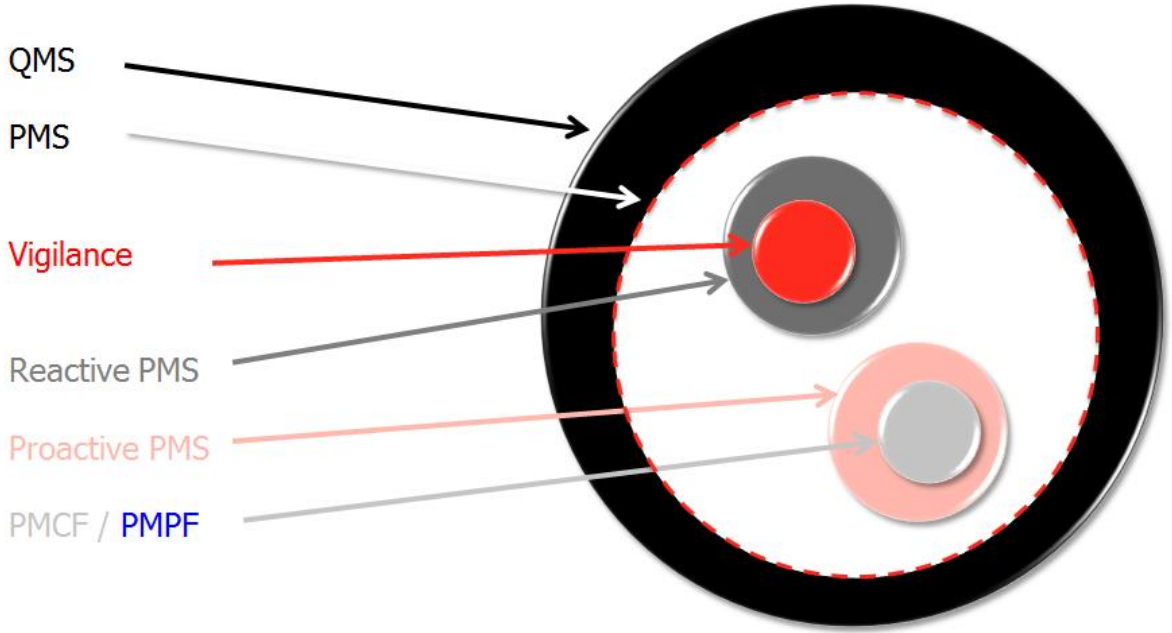
Article 2 Definitions – 'post market surveillance'

- 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 their devices placed on the market, made 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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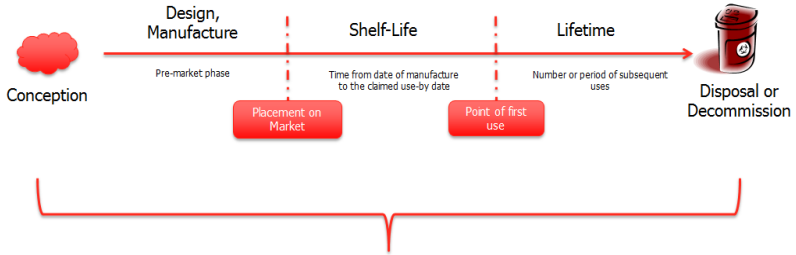
Chapter VII – Post-market surveillance, vigilance and market surveillance
SECTION 1 – POST-MARKET SURVEILLANCE

Article 83 – Post-market surveillance system of the manufacturer

- 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 plan 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

- 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 / Article 78

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

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

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

c) to update the clinical / performance evaluation;

d) to update the summary of safety and clinical performance referred to in Article 32 / Article 29;

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

f) for the identification of possibilities 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 / Article 83.

- The technical documentation shall be updated accordingly.

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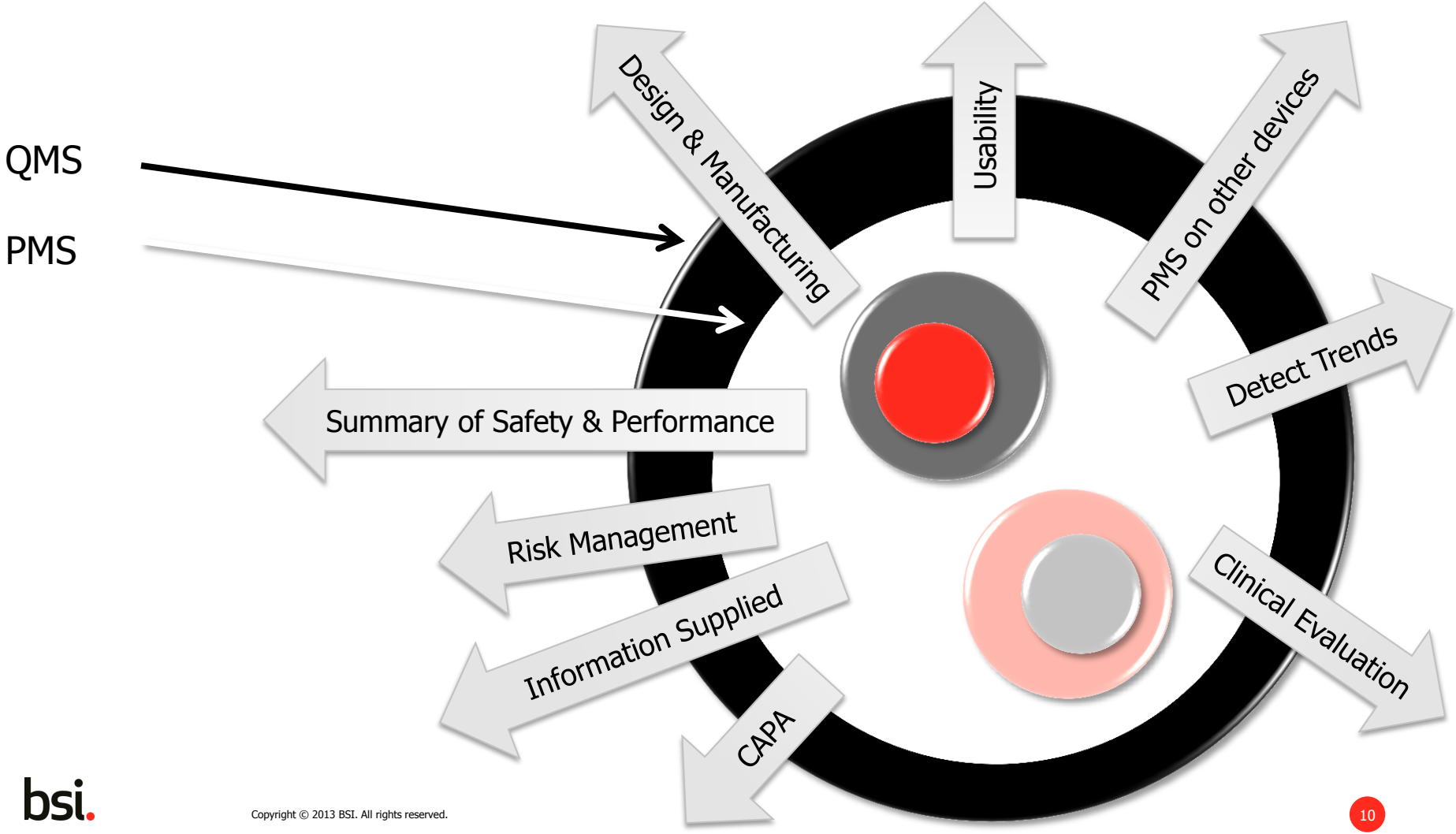

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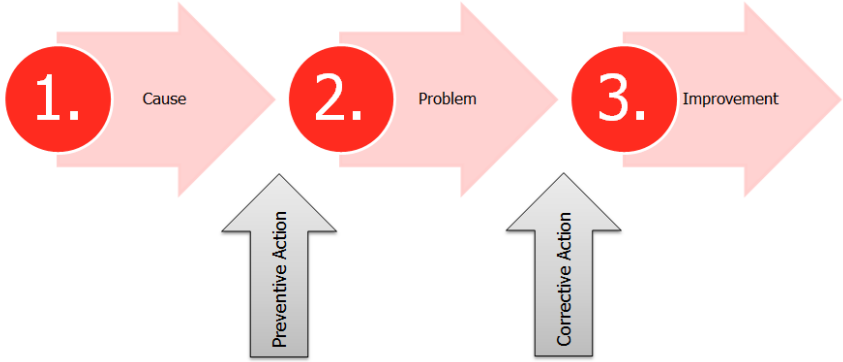
Post Market Surveillance – Article 83 / Article 78

- 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 impairment of the patient's, user's or other person's state of health,
c) a serious public health threat;

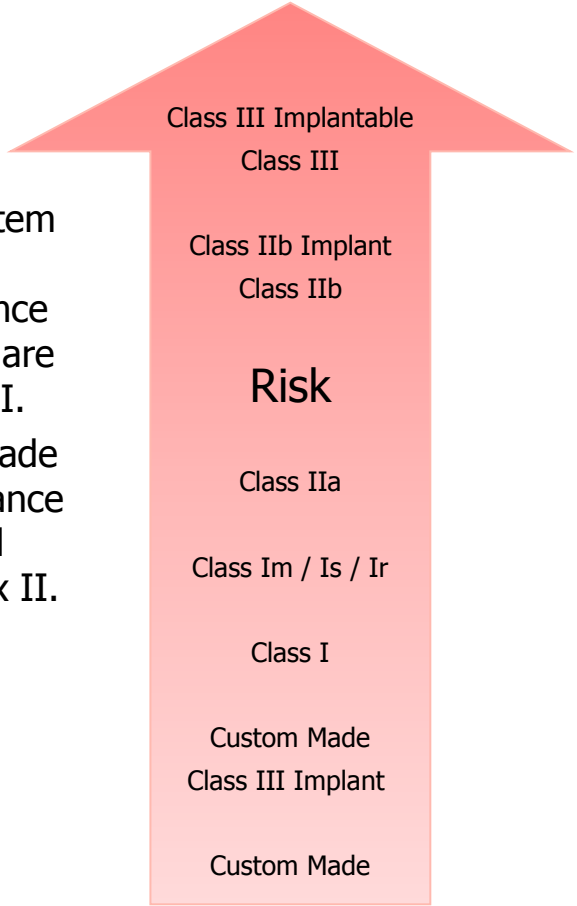
'field safety corrective action' means corrective action taken by a manufacturer for technical or medical reasons to prevent or reduce the risk of a serious incident in relation to a device made available on the market;

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

Post Market Surveillance – 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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Article 86 – Periodic safety update report

- 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 ...
- 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 of the Population that use the device
  - Where practicable usage frequency of the device

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

- Manufacturers of devices in class III **or** implantable devices shall submit reports by means of the electronic system to the notified body.
- The notified body shall review 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.

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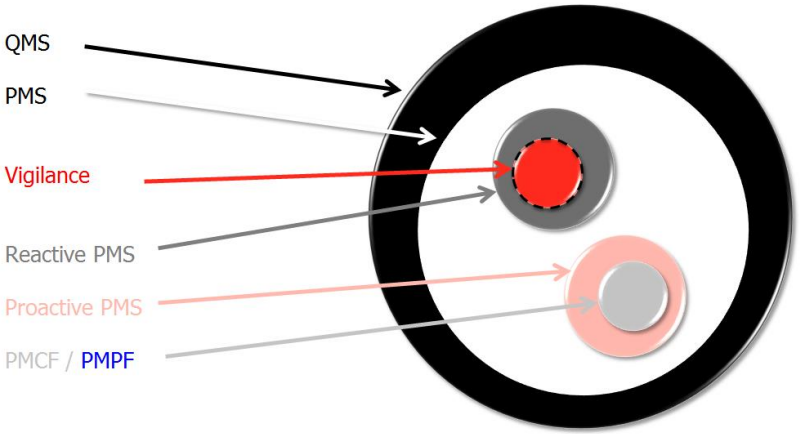
Chapter VII – Post-market surveillance, vigilance and market surveillance
SECTION 2 – VIGILANCE

Article 87 – Reporting of serious incidents and FSCA

- Manufacturers of devices made available on the Union market, other than investigational devices, shall report, through the electronic system, the following:

a) serious incident

b) field safety corrective action



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Vigilance – Article 87 / Article 82

Question	Answer
Who reports	Manufacturers of devices, other than investigational / performance study devices.
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	For similar serious incidents occurring 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 format, content and frequency of the periodic summary reporting is agreed with the Competent Authority.
	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, 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 Article 87 and require it to ensure that appropriate follow-up action is taken in accordance with Article 89.
Article 88	Manufacturers shall report 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 risk-benefit analysis referred to in Sections 1 and 5 of Annex I and which have led or may lead to unacceptable risks to the health or safety of patients, users or other persons 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 time period as specified in the technical documentation and product information. The manufacturer shall specify how to manage the incidents 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.

Vigilance – Article 87 / Article 82

Question	Answer
When to report	As a general rule, the time 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 incident.
Serious Public Health Threat	• immediately, and not later than 2 days after awareness by the manufacturer of that threat.

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Vigilance – Article 87 / Article 82

Question	Answer
When to report	Where necessary to ensure timely reporting, the manufacturer may submit an initial incomplete report followed up by a complete report.
	If after becoming aware of a potentially reportable incident there is still uncertainty about whether the event is reportable, the manufacturer shall submit a report within the timeframe required for that type of incident.
	Except in cases of urgency in which a manufacturer needs to undertake FSCA immediately, the manufacturer shall, without undue delay, report the field safety corrective action 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.

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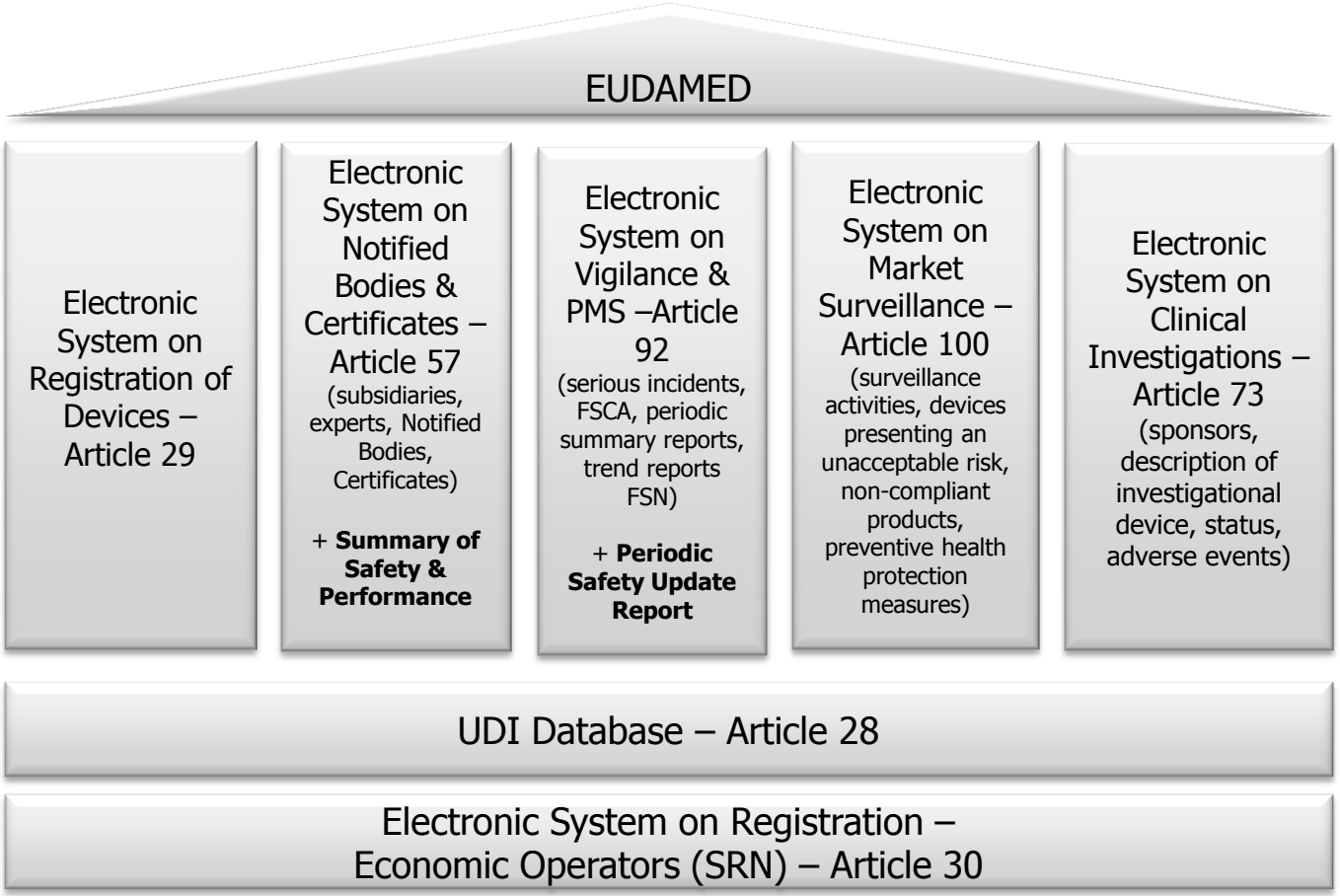
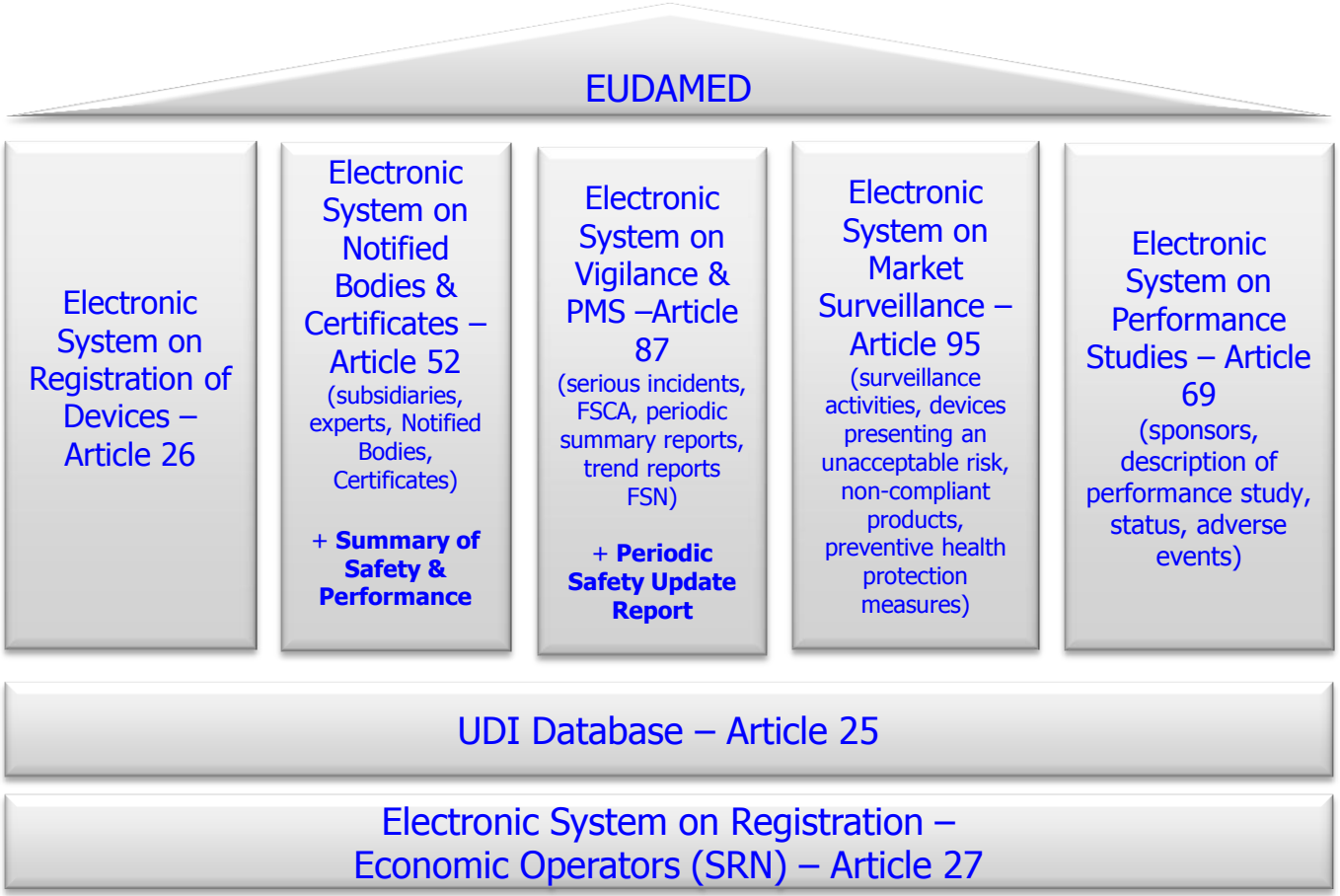
MDR – European Database on Medical Devices – Article 33



IVDR – European Database on Medical Devices – Article 30



Post Market Surveillance

Annexes

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ANNEX III – TECHNICAL DOCUMENTATION ON POST-MARKET SURVEILLANCE

1. The technical documentation on post-market surveillance to be drawn up by the manufacturer in accordance with Articles 83 to 86 shall be presented in a clear, organised, readily searchable and unambiguous manner and shall include in particular the elements described in this Annex.

a) The post-market surveillance plan shall address the collection and utilization of available information, in particular:

information concerning serious incidents, including information from PSURs, and field safety corrective actions

records referring to non-serious incidents and data on any undesirable side effects

information from trend reporting

relevant specialist or technical literature, databases and/or registers

information, including feedbacks and complaints, provided by users, distributors and importers

publicly available information about similar medical devices

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ANNEX III – TECHNICAL DOCUMENTATION ON POST-MARKET SURVEILLANCE

b) The post-market surveillance plan shall cover at least:

a proactive and systematic process to collect any information referred to (a), correctly characterise the performance of the devices and allow comparisons to be made to similar products available on the market;

effective and appropriate methods and processes to assess the collected data;

suitable indicators and threshold values that shall be used in the continuous reassessment of the risk-benefit analysis and of the risk management (Annex I);

effective and appropriate methods and tools to investigate complaints and analyse market-related experience collected in the field;

methods and protocols to manage the events subject to the trend report, including the establishment of any statistically significant increase in the frequency or severity of incidents as well as the observation period;

ANNEX III – TECHNICAL DOCUMENTATION ON POST-MARKET SURVEILLANCE

methods and protocols to communicate effectively with competent authorities, notified bodies, economic operators and users;

reference to procedures to fulfil the manufacturers obligations laid down in Articles 83, 84 and 86;

systematic procedures to identify and initiate appropriate measures including corrective actions;

effective tools to trace and identify devices for which corrective actions might be necessary;

a PMCF plan as referred to in Part B of Annex XIV, or a justification as to why a PMCF is not applicable

2. The PSUR referred to in Article 86 and the post-market surveillance report referred to in Article 85.

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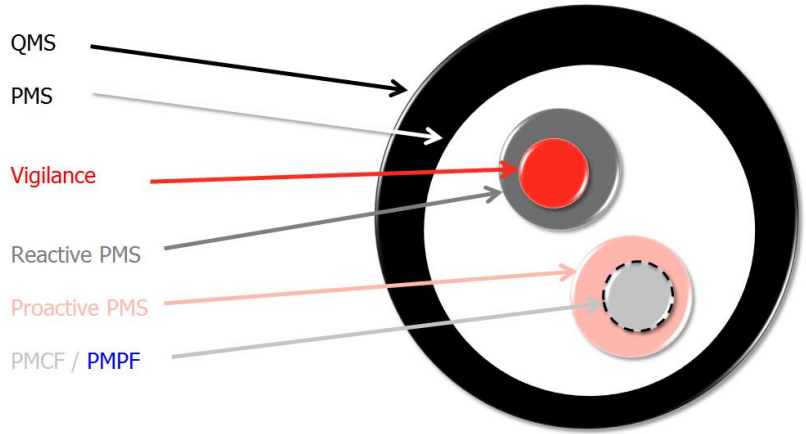
ANNEX XIV – CLINICAL EVALUATION AND POST-MARKET CLINICAL FOLLOW-UP
PART B: POST-MARKET CLINICAL FOLLOW-UP

5. PMCF shall be understood to be a continuous process that updates the clinical evaluation referred to in Article 61 and Part A of this Annex and shall be addressed in the manufacturer's post-market surveillance plan.

- When conducting PMCF, the manufacturer shall proactively collect and evaluate clinical data from the use in or on humans of a device, with the aim of confirming the safety and performance throughout the expected lifetime of the device, of ensuring the continued acceptability of identified risks and of detecting emerging risks on the basis of factual evidence.

6. PMCF shall be performed pursuant to a documented method laid down in a PMCF plan.



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ANNEX XIV – CLINICAL EVALUATION AND POST-MARKET CLINICAL FOLLOW-UP
PART B: POST-MARKET CLINICAL FOLLOW-UP

- The PMCF plan shall specify the methods and procedures for proactively collecting and evaluating clinical data with the aim of:

confirming the safety and performance of the device throughout its expected lifetime

identifying previously unknown side-effects and monitoring the identified side-effects and contraindications

identifying and analysing emergent risks on the basis of factual evidence

ensuring the continued acceptability of the risk-benefit ratio (Annex I)

identifying possible systematic misuse or off-label use of the device, with a view to verifying that the intended purpose is correct

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ANNEX XIV – CLINICAL EVALUATION AND POST-MARKET CLINICAL FOLLOW-UP
PART B: POST-MARKET CLINICAL FOLLOW-UP

b) The PMCF plan shall cover at least:

the general methods and procedures of the PMCF to be applied, such as gathering of clinical experience gained, feedback from users, screening of scientific literature and of other sources of clinical data;

the specific methods and procedures of PMCF to be applied, such as evaluation of suitable registers or PMCF studies;

a rationale for the appropriateness of the methods and procedures above;

a reference to the relevant parts of the clinical evaluation report and to the risk management (Annex I);

the specific objectives to be addressed by the PMCF;

ANNEX XIV – CLINICAL EVALUATION AND POST-MARKET CLINICAL FOLLOW-UP
PART B: POST-MARKET CLINICAL FOLLOW-UP

an evaluation of the clinical data related to equivalent or similar devices;

reference to any relevant CS, harmonised standards when used by the manufacturer, and relevant guidance on PMCF; and

a detailed and adequately justified time schedule for PMCF activities

7. The manufacturer shall analyse the findings of the PMCF and document the results in a PMCF evaluation report that shall be part of the clinical evaluation report and the technical documentation.
8. The conclusions of the PMCF evaluation report shall be taken into account for the clinical evaluation (Article 61 & Part A Annex XIV) and in the risk management (Annex I). If, through the PMCF, the need for preventive and/or corrective measures has been identified, the manufacturer shall implement them.

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MDR – Article 32 – Summary of Safety and Clinical Performance

- **Article 32 – SSCP:**
  - Manufacturer + SRN
  - Device + UDI
  - Intended Purpose, Indications, Contra-indications
  - Description, previous variant(s), differences, accessories, other products intended to be used in combination
  - Possible diagnostic or therapeutic alternatives
  - Harmonised Standards / Common Specifications
  - Summary of the Clinical Evaluation (Annex XIV) + PMCF
  - Suggested profile and training for users
  - Information on residual risks, undesirable effects, warnings & precautions

- For implantable devices and for class III devices, other than custom-made devices, the manufacturer shall draw up a summary of safety and clinical performance.

Article 61 – Clinical Evaluation

For devices classified as class III **and** implantable devices, the PMCF evaluation report and, if indicated, the summary of safety and clinical performance shall be updated at least annually with such data.

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Post Market Surveillance

QMS

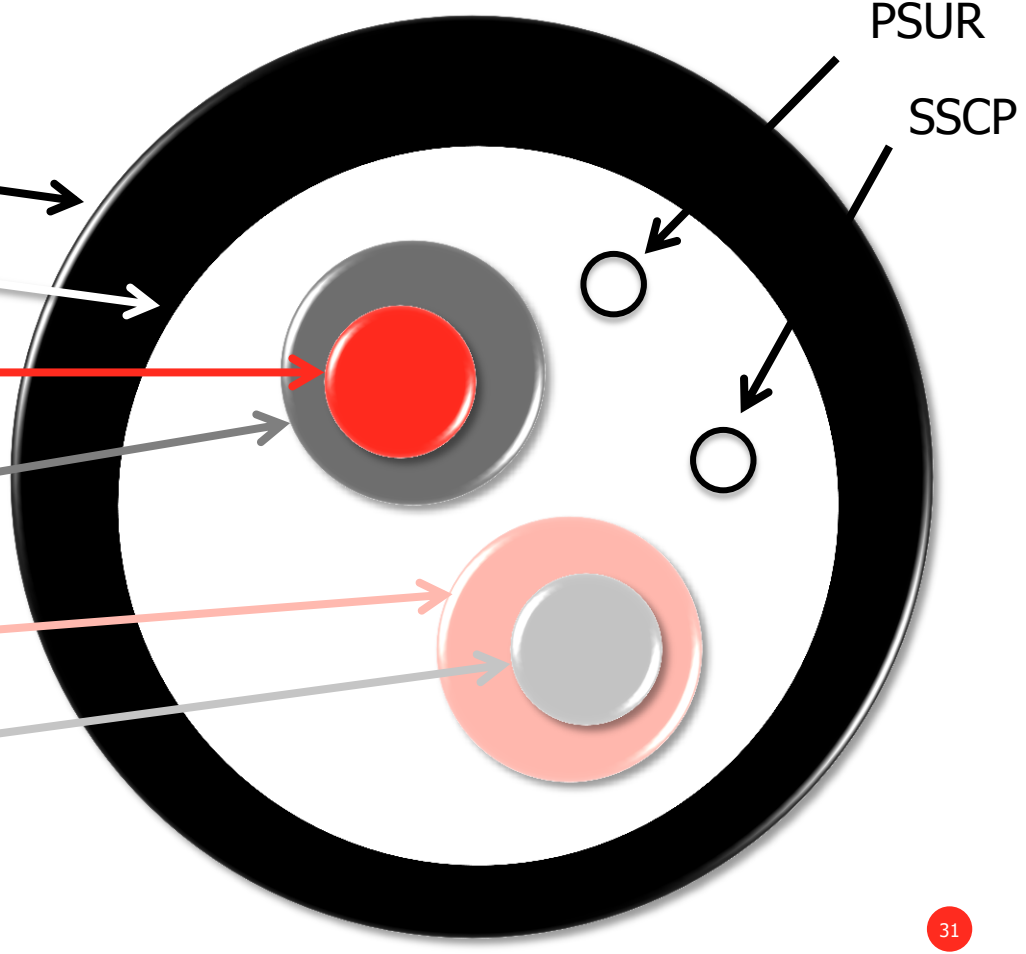
PMS
Article 83 / 78

Vigilance
Article 87-90 / 82-85

Reactive PMS

Proactive PMS

PMCF / PMPF
Annex XV / XIII



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Questions & Answers

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