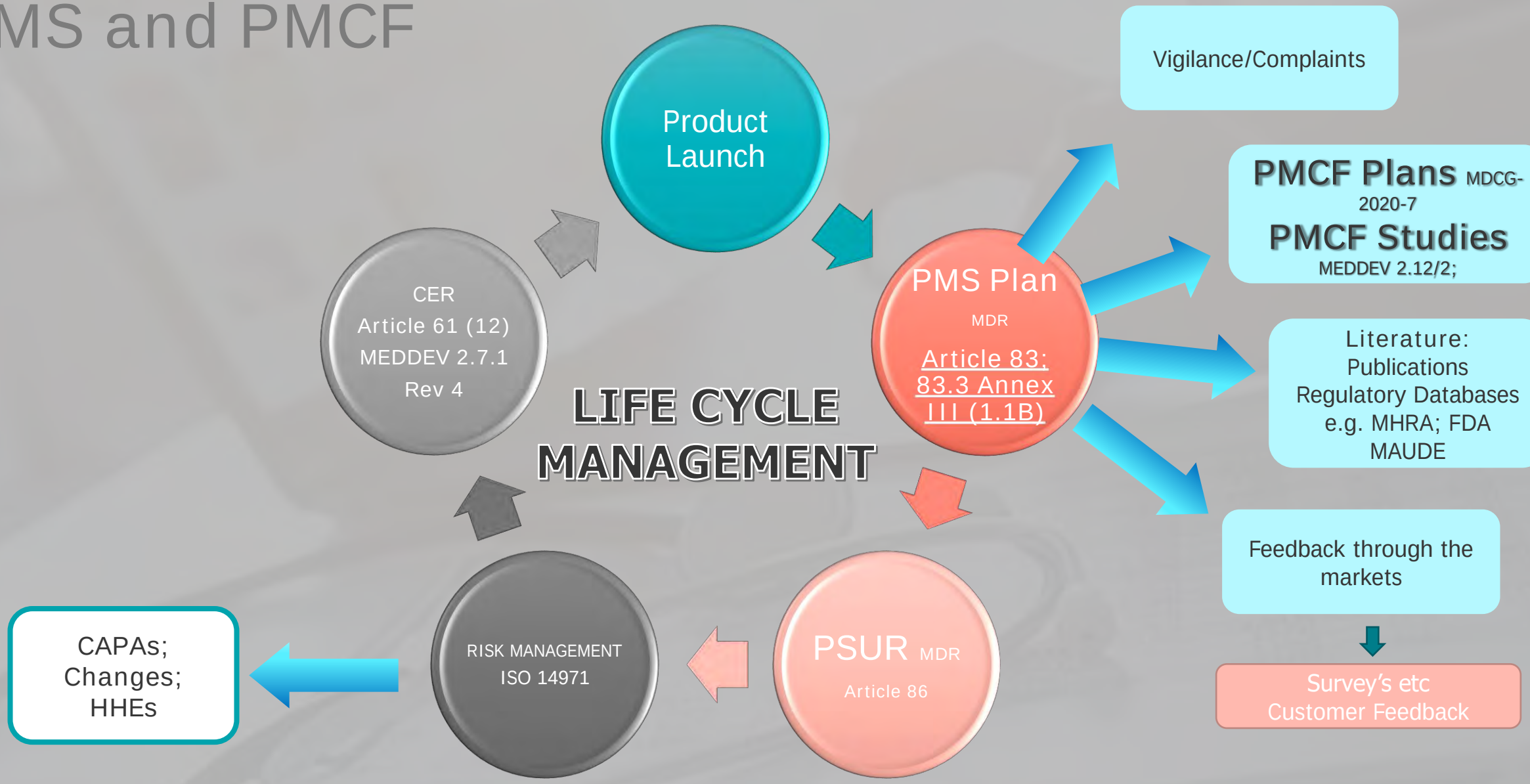
Understanding the requirements of PMCF

- Considerations for Manufacturers

Topics Covered in this presentation;

- MDR Requirements
- MDCG Guidance
- PMCF Plans
- Types of PMCF
- PMCF Reports
- Other Considerations
- Questions

PMS and PMCF


Product Launch
PMS Plan
MDR
Article 83; 83.3 Annex III (1.1B)
PSUR MDR
Article 86
RISK MANAGEMENT
ISO 14971
CER
Article 61 (12)
MEDDEV 2.7.1
Rev 4
LIFE CYCLE MANAGEMENT
Vigilance/Complaints
PMCF Plans MDCG-2020-7
PMCF Studies
MEDDEV 2.12/2;
Literature:
Publications
Regulatory Databases
e.g. MHRA; FDA MAUDE
Feedback through the markets
Survey's etc
Customer Feedback
CAPAs;
Changes;
HHEs

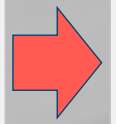
PMS and PMCF requirements: where are they defined?

Medical Devices Regulation

- Chapter II: Making Available On The Market And Putting Into Service Of Devices, Obligations Of Economic Operators, Reprocessing, Ce Marking, Free Movement
- Chapter VI: Clinical Evaluation And Clinical Investigations
- Chapter VII: Post-Market Surveillance, Vigilance and Market Surveillance
- Annex III: Technical Documentation on Post-Market Surveillance
- Annex XIV (Part B): Post Market Clinical Follow Up
- Annex XV (Article 74)
- Annex XIII [5]: Custom made devices
- ANNEX IX: Conformity Assessment Based On A Quality Management System And On Assessment Of Technical Documentation

Guidance documents

- MedDev 2.12/2 (rev 2) – Post Market Clinical Follow Up Studies: A Guide for Manufacturers and Notified Bodies
- MEDDEV 2.7.1/4 Clinical Evaluation: A Guide for Manufacturers and Notified Bodies



- MDCG 2020-7: PMCF Plan template. A guide for manufacturers and notified bodies
- MDCG 2020-8: PMCF Evaluation Report. A guide for manufacturers and notified bodies
- MDCG 2021-6 – Q&A on Clinical Investigations

https://ec.europa.eu/health/md_sector/new_regulations/guidance_en

MDR Definition: Article 2(48)

Clinical data: Information concerning safety or performance that is generated from the use of a device and is sourced from:

- Clinical investigation of devices concerned
- Clinical investigations or other studies reported in scientific literature of a device for which equivalence to the device in question is demonstrated
- Reports published in peer reviewed scientific literature on other clinical experience of either the device in question or a device for which equivalence is claimed and demonstrated
- Clinically relevant information coming from the post market surveillance, in particular post market clinical follow up

Does PMCF under the MDR mean the same as PMCF under the Directives?

MDD

Clinical evaluation: methodological, ongoing procedure to collect, appraise, analyse clinical data to evaluate whether there is sufficient clinical evidence to confirm compliance with relevant essential requirements for safety and performance when using the device according to the manufacturer's Instructions for Use.

MDR

Clinical evaluation: a systematic and planned process to continuously generate, collect, analyse and assess the clinical data pertaining to a device in order to verify the safety and performance, including clinical benefits, of the device when used as intended by the manufacturer (Article 2 (44)

Annex X and Annex 7 requirements:

- "The clinical evaluation and its documentation must be actively updated with data obtained from the post-market surveillance. Where post-market clinical follow-up as part of the post-market surveillance plan for the device is not deemed necessary, this must be duly justified and documented."

MDR Chapter VII requirements:

"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."

Annex III 1.1b says PMS should include: **"a PMCF plan"** as referred to in Part B of Annex XIV, or a justification as to why a PMCF is not applicable."

PMCF Plans

Medical Device

Medical Device Coordination Group Document MDCG 2020-7

MDCG 2020-7

Post-market clinical follow-up (PMCF) Plan Template

A guide for manufacturers and notified bodies

April 2020

PMCF Plan

• MEDDEV 2.12/2

Documented, proactive, organised methods and procedures set up by the manufacturer to collect clinical data based on the use of a CE-marked device

The objective is to confirm clinical performance and safety throughout the expected lifetime of the medical device, the acceptability of identified risks and to detect emerging risks on the basis of factual evidence.

MDCG – 2020 -7

Specify the methods and procedures set up by the manufacturer to proactively collect and evaluate clinical data from the use in or on humans of a CE marked medical device. The plan should describe if a general or specific procedure / method of obtaining data is adopted and state why PMCF is required.

The aim of the PMCF plan* is:

- confirming the safety and performance, clinical benefit if applicable, of the device throughout its expected lifetime;
- identifying previously unknown side-effects and monitor the identified side-effects and contraindications;
- identifying and analysing emergent risks on the basis of factual evidence;
- ensuring the continued acceptability of the benefit-risk ratio,
- identifying possible systematic misuse or off-label use of the device, with a view to verifying that the intended purpose is correct

*Ref: MDR Annex XIV Part B

MDR: Annex XIV PART B

The PMCF plan shall include at least:

(a) 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;

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

(c) a rationale for the *appropriateness of the methods* and *procedures* referred to in points (a) and (b);

(d) a reference to the relevant parts of the clinical evaluation report and to the risk management documentation

(e) the *specific objectives* to be addressed by the PMCF;

(f) an evaluation of the *clinical data relating to equivalent or similar devices*;

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

(h) a detailed and adequately *justified time schedule* for PMCF activities (e.g. analysis of PMCF data and reporting) to be undertaken by the manufacturer

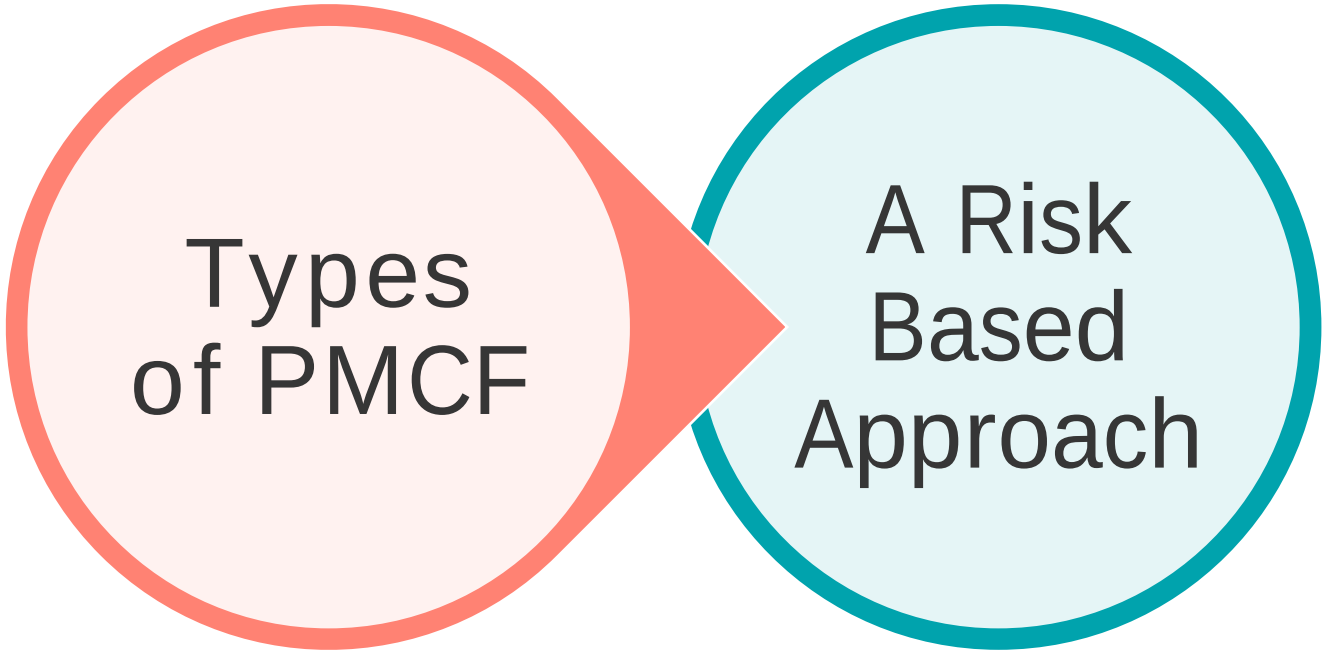
PMCF Plan

Key Message

- PMCF Plan can be part of the PMS Plan

"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".

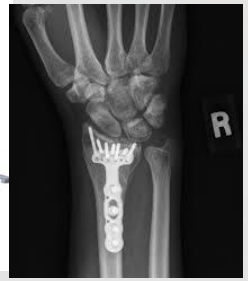
Ref: MDR Annex XIV PART B

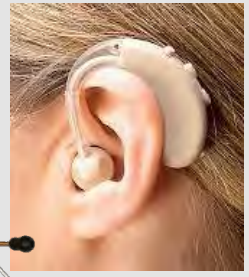

Types
of PMCF
A Risk
Based
Approach

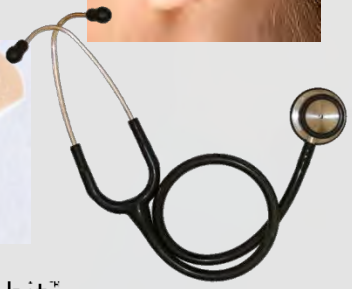
PMCF Studies & Risk

Selected methods should be justified, surveys for example may only be appropriate for lower risk devices , or established technologies



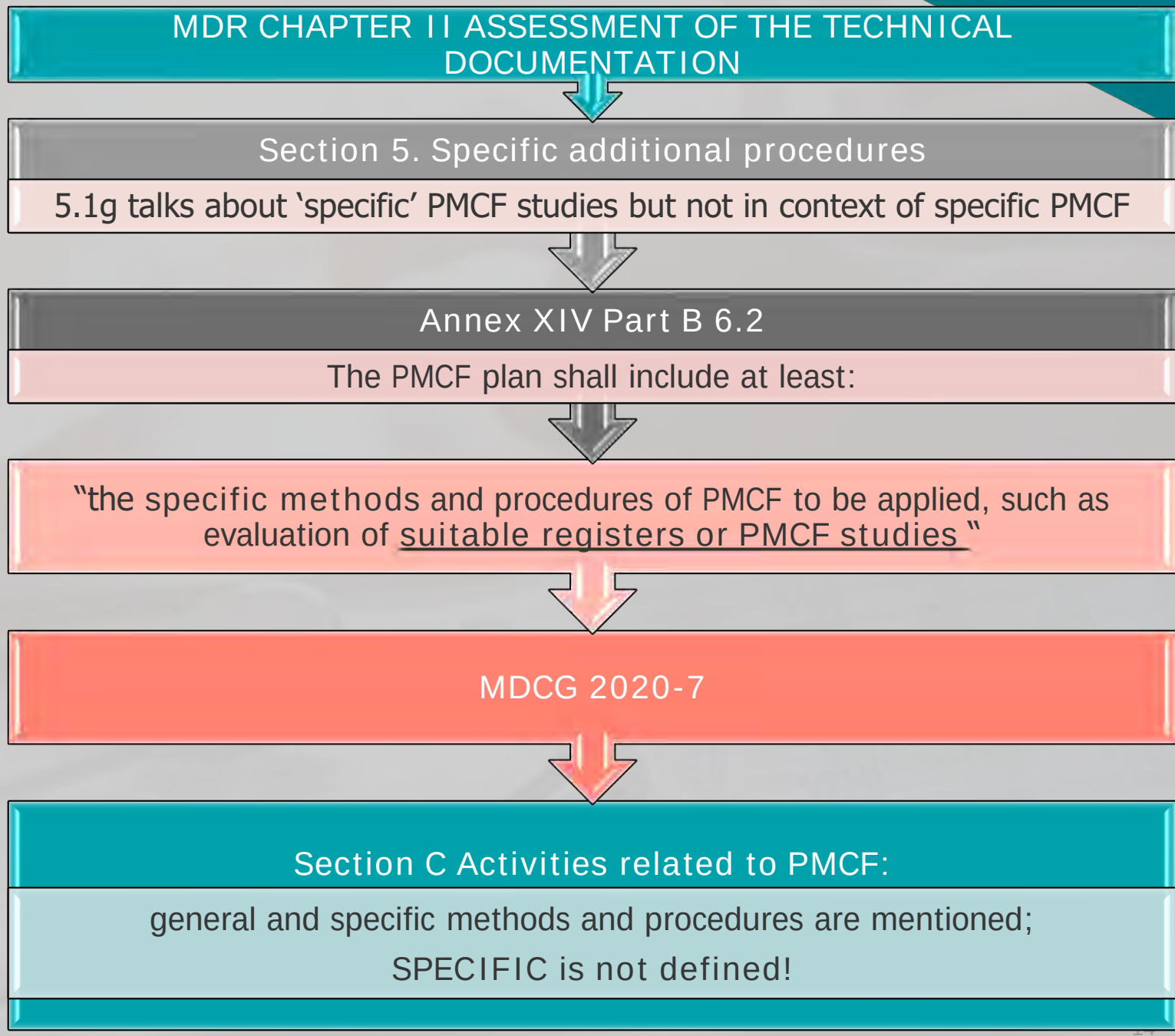




RISK, DURATION, INVASIVENESS or UNKNOWNS POST MARKET CLINICAL FOLLOW UP

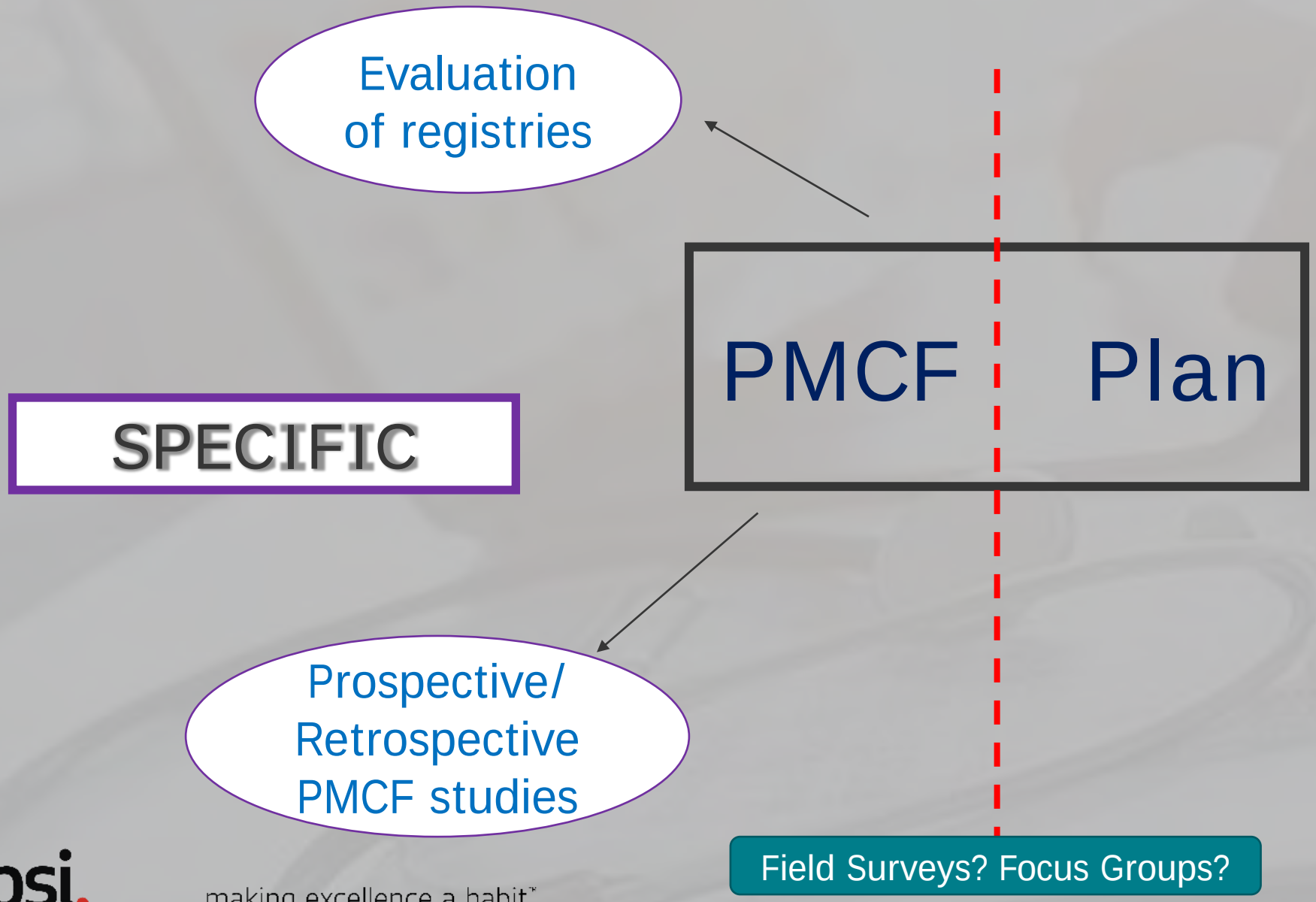
SPECIFIC	GENERAL
• Prospective trials (e.g. Expansion of pre-market study, New prospective clinical trial) • Device registries • Retrospective studies	• Patient / surgeon questionnaires? • Field surveys? • Feedback from users • Literature Review • Complaints/vigilance

What is Specific PMCF?



Specific Methods of PMCF

GENERAL



What is General PMCF?

MDR CHAPTER II
ASSESSMENT OF THE TECHNICAL DOCUMENTATION

Annex XIV Part B 6.2b

- The PMCF plan shall include at least:

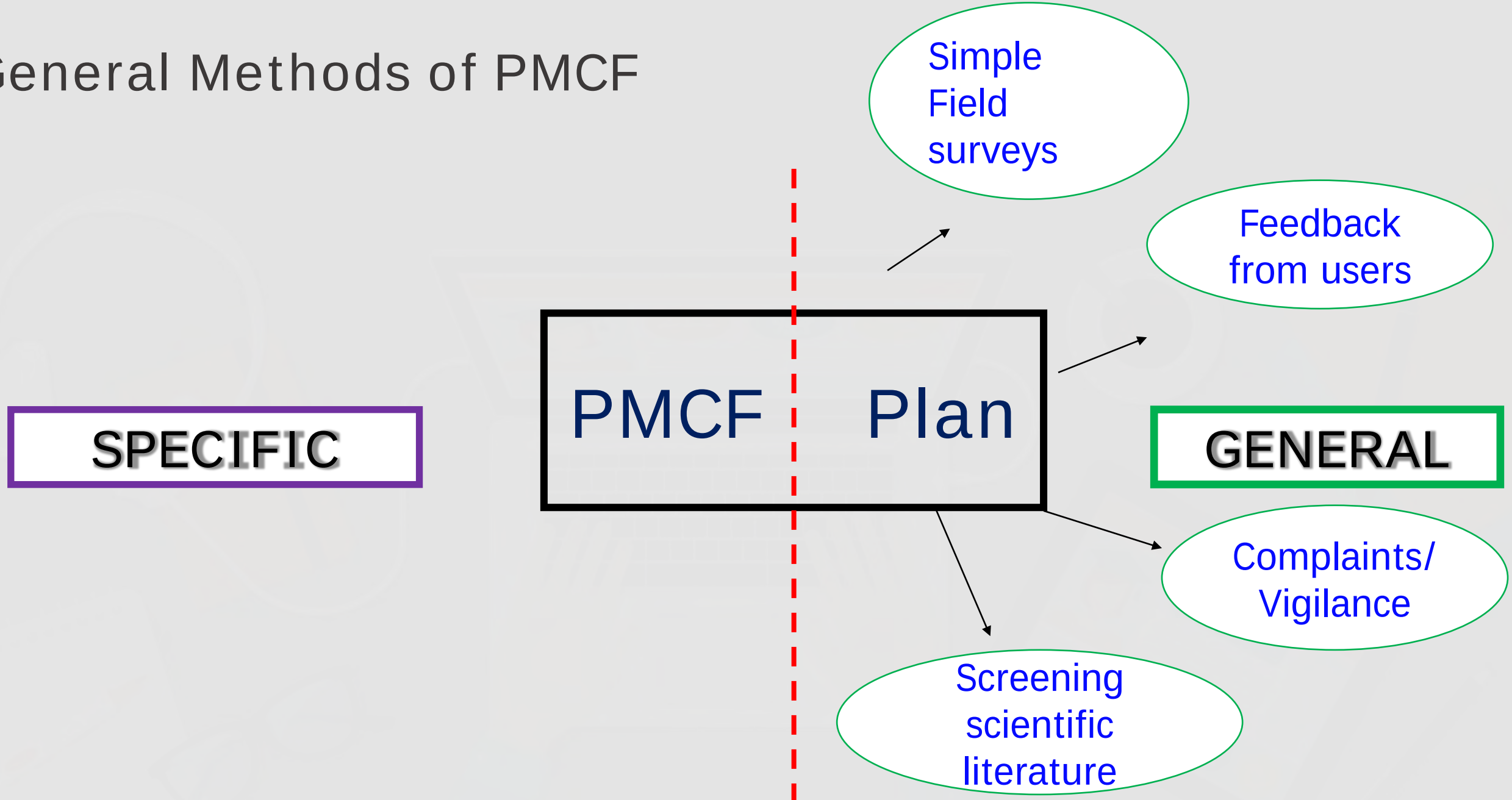
"the general methods and procedures of the PMCF to be applied, such as gathering of clinical experience gained, feedback from users, screening of scientific literature and of other sources of clinical data; "

MDCG 2020-7

Section C Activities related to PMCF: general and specific methods and procedures are mentioned;

GENERAL is not defined!

General Methods of PMCF



What is Proactive PMS? What is the difference with PMCF?

(60) 'post-market surveillance' means all activities carried out by 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;

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

— a proactive and systematic process to collect any information referred to in point (a). The process shall allow a correct characterisation of the performance of the devices and shall also allow a comparison to be made between the device and similar products available on the market;

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

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 which bears the CE marking and is placed on the market or put into service within its intended purpose as referred to in the relevant conformity assessment procedure, 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.

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

The term proactive is used in the MDR for both in the context of PMS and PMCF

Annex III

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

— a proactive and systematic process to collect any information referred to in point (a). The process shall allow a correct characterisation of the performance of the devices and shall also allow a comparison to be made between the device and similar products available on the market;

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

1.1. The post-market surveillance plan drawn up in accordance with Article 84.

The manufacturer shall prove in a post-market surveillance plan that it complies with the obligation referred to in Article 83.

(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; and

— publicly available information about similar medical devices.

We see Annex III Point B referring to the list in Annex A – But are all these proactive activities?

General vs Specific / Reactive Vs Proactive

General Methods

Complaints Vigilance

Screening of Literature
Passive feedback

Trend reporting

?Surveys
?User Feedback
? Information on other devices

Specific Methods

Registries

PMCF Studies

Considered Proactive PMS – but could be specific PMCF pending on the type and output of data. E.g. High quality survey

6.2. The PMCF plan shall include at least:

(a) 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;

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

Annex XIV Part B Section 6.2

When is a **PMCF Study** required?

PMCF Study is mandatory

When is PMCF Study required?

MEDDEV 2.12/2

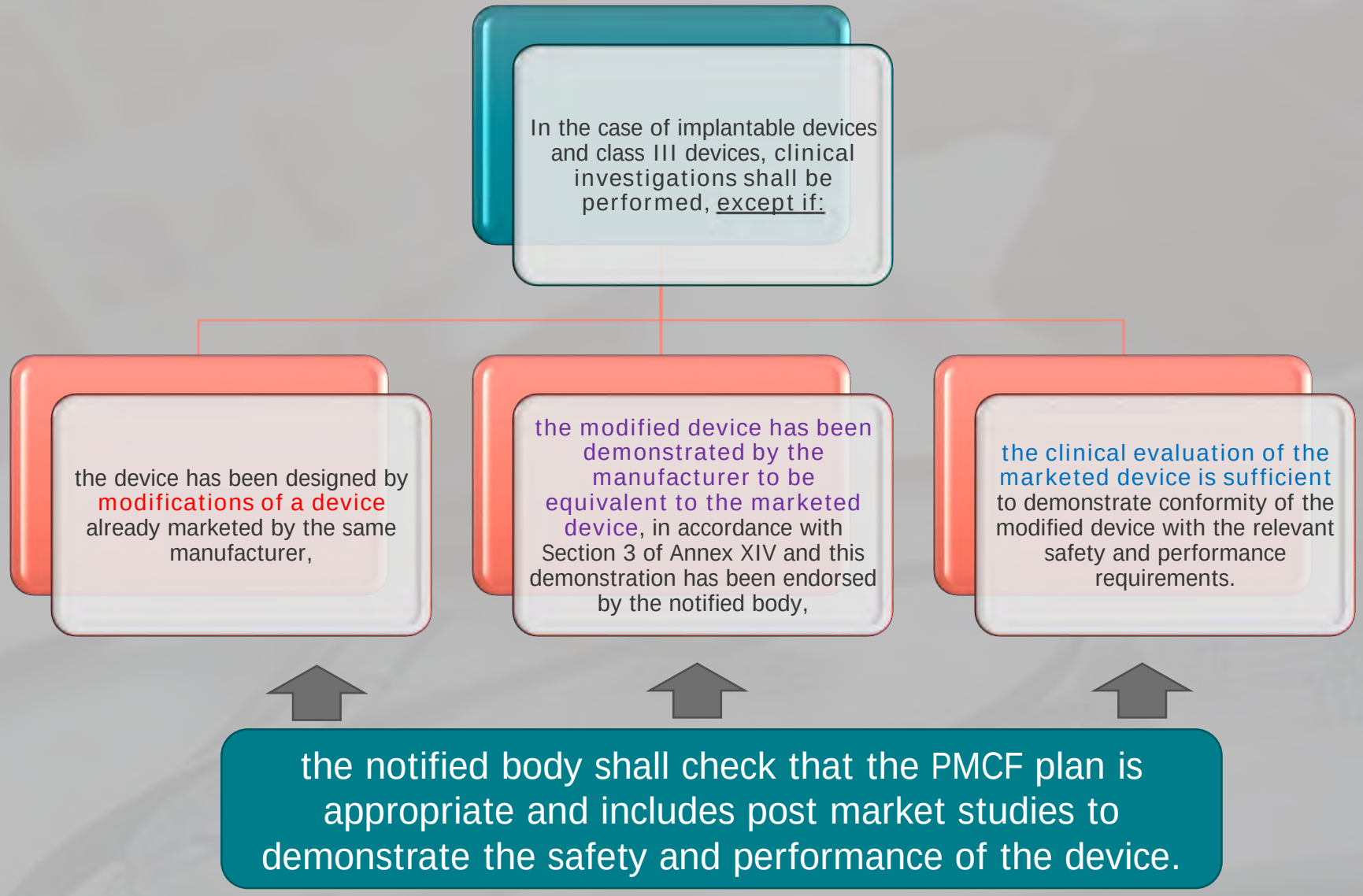
- CE mark based on equivalence
- Novel technology
- Long term safety or performance unknown
- High risk population
  e.g. patients with an implantable device (active or non-active
- Risks identified from other data sources
- To assess performance and/or safety of the device in a more representative population of users and patients.
- Occurrence of clinical events (e.g. delayed hypersensitivity reactions, thrombosis

Following a proper premarket clinical evaluation, the decision to conduct PMCF studies must be based on the identification of possible residual risks and/or unclarity on long term clinical performance that may impact the benefit/risk ratio.

MEDDEV 2.12/2

- **innovation**, e.g., where the design of the device, the materials, substances, the principles of operation, the technology or the medical indications are **Novel**
- **significant changes** to the device or to its intended use leading to pre market clinical evaluation and re-certification;
- high **product related risk** e.g. based on design, materials, components, invasiveness, clinical procedures;
- high risk **anatomical locations**;
- **high risk target populations** e.g. paediatrics, elderly; severity of disease/treatment challenges;
- questions of ability to generalise clinical investigation results;
- unanswered questions of long-term safety and performance;
- results from any previous clinical investigation, including **adverse events or from post-market surveillance activities**;
- identification of previously **unstudied subpopulations** which may show different benefit/risk-ratio
- continued validation in cases of discrepancy between reasonable premarket follow-up time scales and the expected life of the product;
- risks identified from the **literature** or **other data sources** for **similar marketed devices**;
- **interaction** with other medical products or treatments;
- verification of safety and performance of device when exposed to a larger and more varied population of clinical users;
- **new information** on safety or performance;
- **where CE marking was based on equivalence**.

MDR Article 61 [4]: High Risk Devices



When thinking about types of PMCF – all of these should be considered in this scenario and all would have a role in answering questions around ongoing safety and performance.

- What PMCF activities would be relevant to an implantable artificial cervical disc intended to be implanted for the lifetime of the patient?

A. Survey from the surgeons who implanted the device

B. PMCF clinical investigation

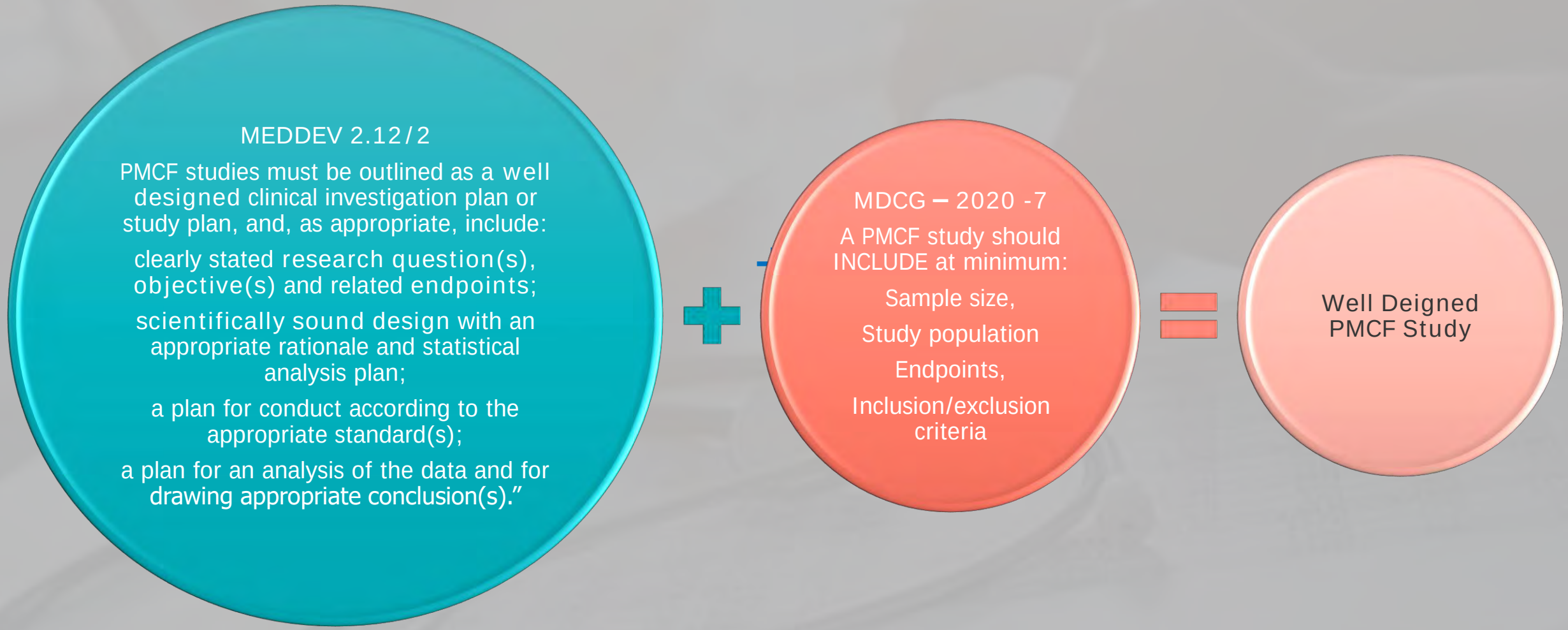
C. State of the art Literature search

D. Complaints and feedback from patients who were treated with the device

Specific PMCF

PMCF Studies

PMCF Study Requirements



Potential Study Types

RCT

- Large Sample
- Within Intended Purpose
- Defined **Study Objective**
- **Statistically Calculated** Sample Size
- Data on **safety & performance**
- Likely to be conducted to ISO 14155:2020

- Slow
- Costly
- May not reflect real world use
- Select Investigators
- Select patients

Prospective Controlled Study/Expansion of pre-market study

- Defined **study objectives**
- Sample size calculation: may be based on feasibility should be **statistically defined** with a **statistical analysis plan**
- Data on **safety & performance**
- Likely to be conducted to ISO 14155:2020

- Slow
- Potential for bias
- Costly
- May not reflect real world use
- Select Investigators
- Select patients

Retrospective Controlled Study

- Defined **study objectives;**
- **Sample size and statistical analysis plan**
- Multiple exposures
- Generalizable
- May be conducted in accordance with **ISO 14155:2020**

- Missing Data
- Illegible data
- May not answer all questions posed
- Misuse
- Variability in practice
- May not reliably report safety

Potential Study Types

Observational

Large Sample

Within Intended Purpose

Defined **Study Objective**

Statistically Calculated Sample Size

Data on **safety & performance**

Real World Use

Could to be conducted to ISO 14155:2020

User Error's

Registry Study

Defined **study objectives**

Sample size calculation: may be based on feasibility should be **statistically defined** with a **statistical analysis plan**

Data on **safety & performance**

Slow

Costly

Systematic review with Meta Analysis

Large Sample

Within Intended Purpose

Defined **Study Objective**

Statistically Calculated Sample Size

Data on **safety & performance**

Registry Studies

Registry Studies (ISO 14155:2020)

A REGISTRY is an organised system that uses observational study methods to collect defined clinical data under normal conditions of use relating to one or more devices to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure and that serves predetermined scientific, clinical or policy purpose(s)

Guidance:

IMDRF/REGISTRY WG/N33 FINAL. 2016 'Patient registry; Essential Principles' registry system', available at: http://www.imdrf.org/docs/imdrf/final/consultations/imdrf-cons-essential-principles-151124.pdf

IMDRF/Registry WG/N42FINAL: 2017 'Methodological Principles in the Use of International Medical Device Registry Data' (covering multiple applicable registries), available at: http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-170316-methodological-principles.pdf

When are Registries Applicable?

Long term implants

Limited follow up in Pre CE mark study

Side by side analysis of similar devices

Examples of registries:

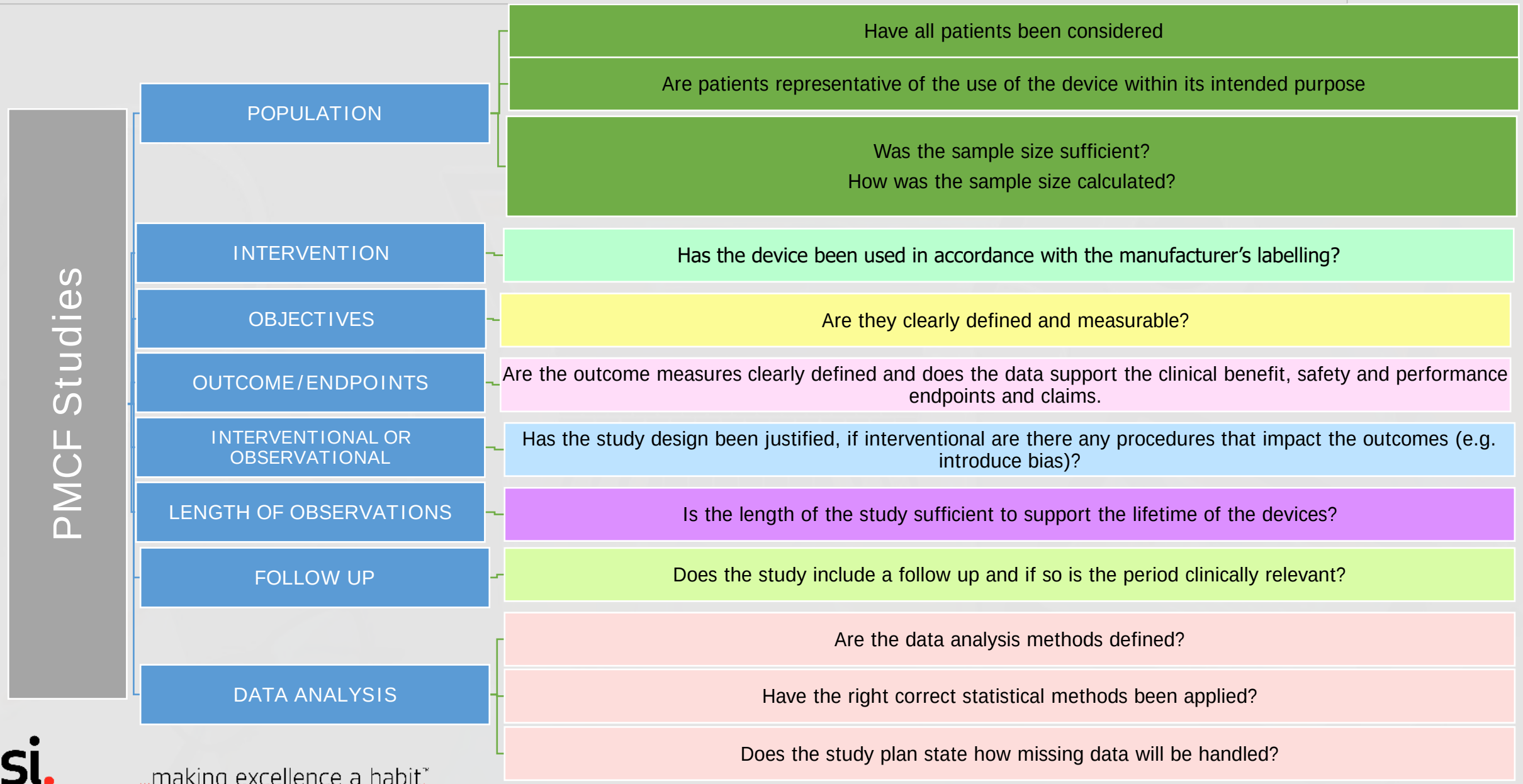
The National Joint Registry (NJR) of England, Wales and Northern Ireland

UK vascular registry e.g.

https://www.hqip.org.uk/a-z-of-nca/national-vascular-registry/#.YVGkZLhKg2w

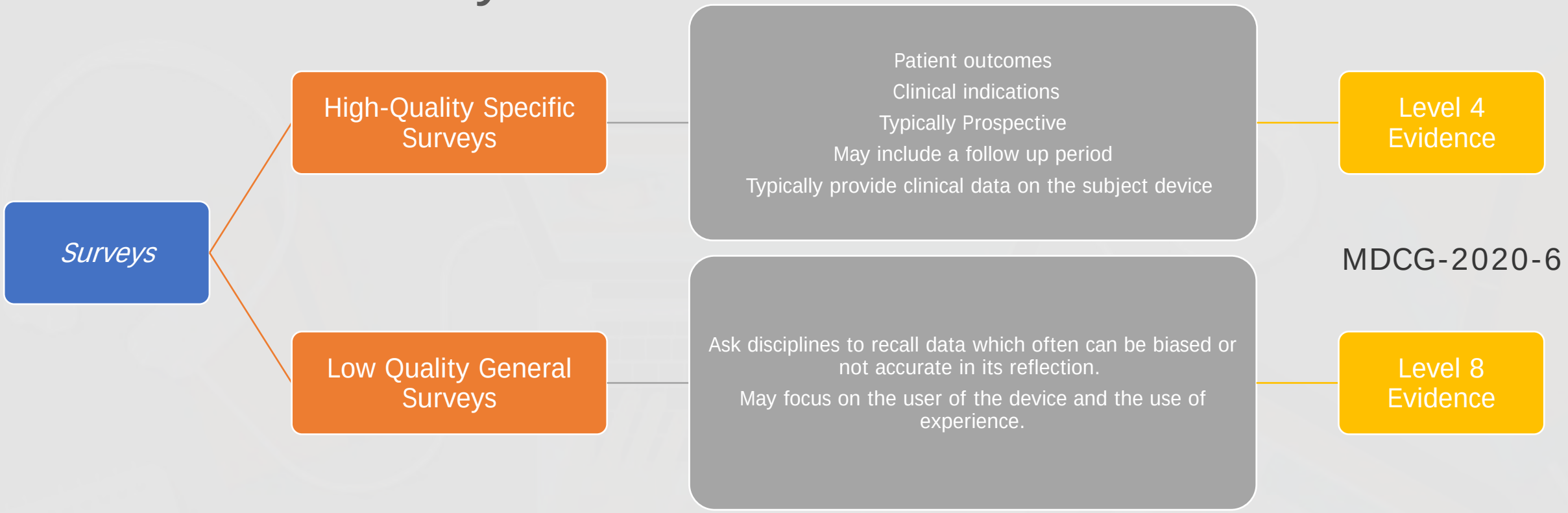
https://digital.nhs.uk/data-and-information/clinical-audits-and-registries/breast-and-cosmetic-implant-registry

PMCF Studies



Specific PMCF Surveys

What is a High-Quality Survey Versus a General Survey?



Surveys/User Evaluations

V Valid

a Applicable

l Labelling

i Indications

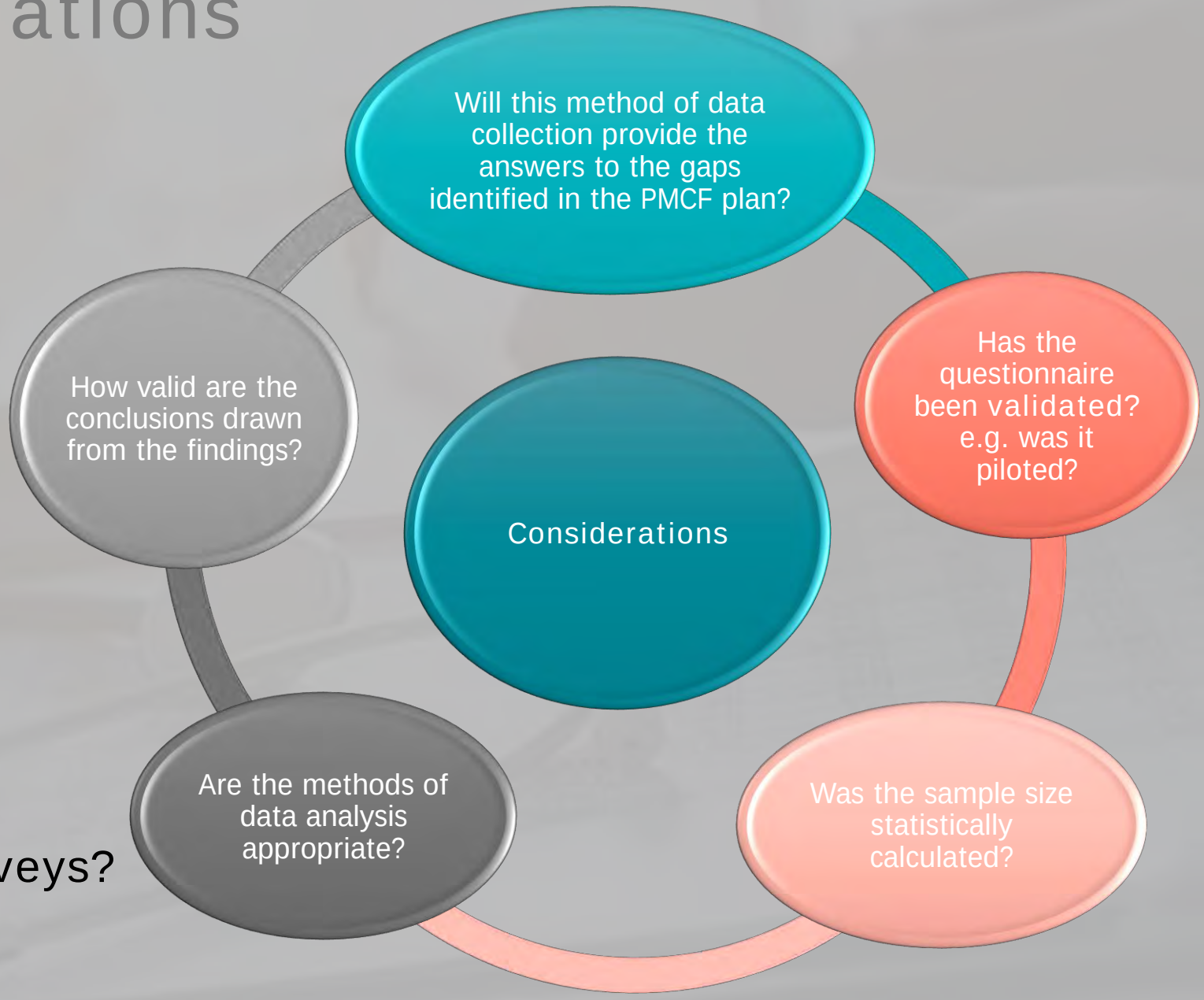
d Data

i Intended Use/Users

t Targeted

e Endpoints

? Is it possible to validate surveys?



General PMCF

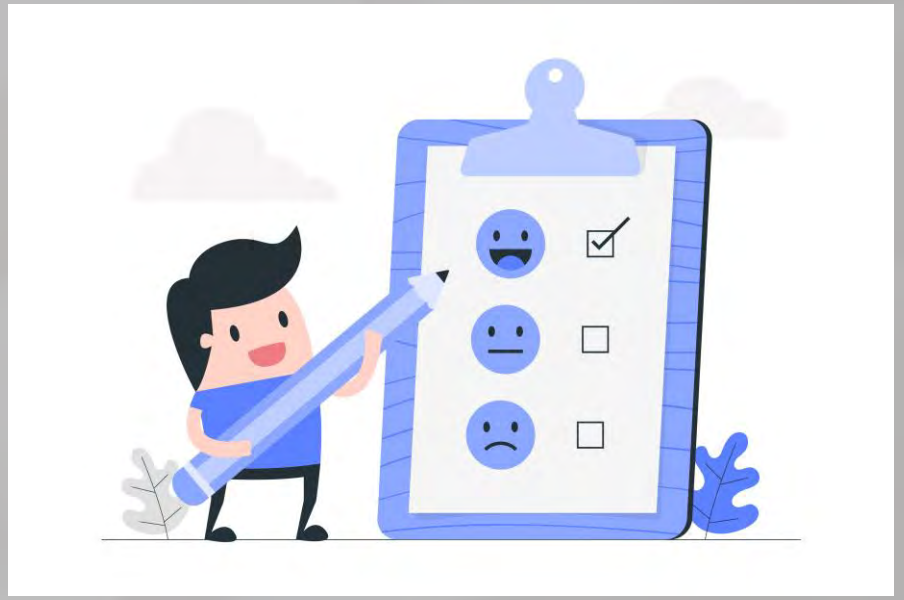
Types of General PMCF

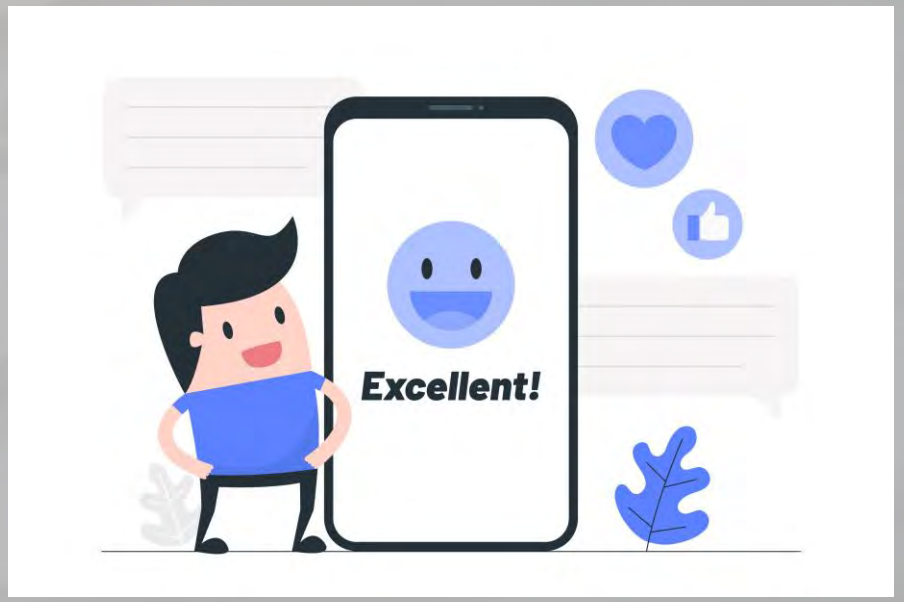
General PMCF

- Surveys
- Feedback from users
- Literature reviews
- Complaints/Incident reports/Trends

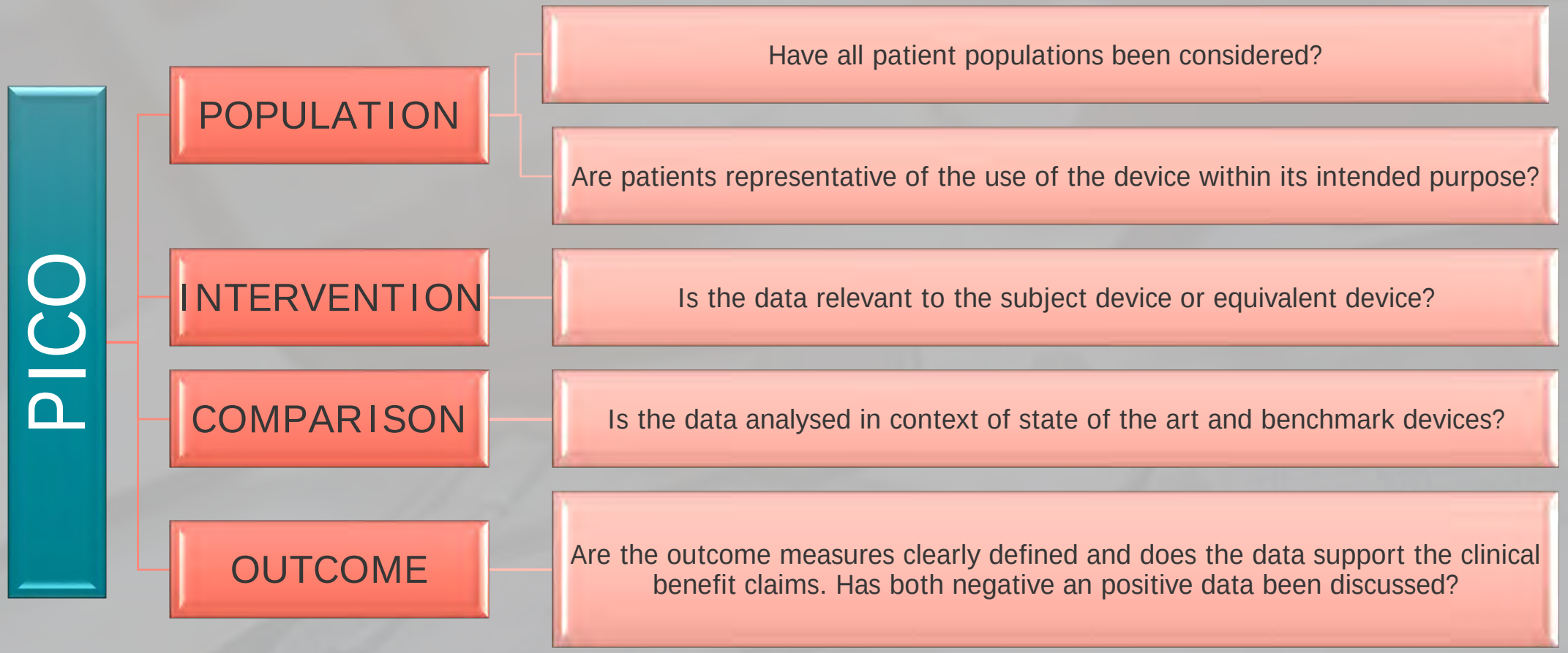
Surveys/User Evaluations

- Can be online or paper based
- Within the intended purpose
- Method must be justified
- Relevant to lower risk devices, established technologies and devices with an acceptable risk/benefit ratio





Literature Reviews



Complaints: Qualitative & Quantitative Analysis

Catalog Number	Product Description	Total Sales
3333-5678	Variant A	336,739
3333-5679	Variant B	585,507
Total		922,246

Complaint /Sale Ratio (132°) = 298/336,739 < 0.001
Complaint /Sale Ratio (127°) = 511/585,507< 0.001

Country	Hazard	Harm	Variant A	Variant B
Finland	Foreign object (unintended)	None	0	1
Germany	Excessive stress in bone	Periprosthetic fracture	1	0
	Foreign object (unintended)	None	1	1
	Packaging too difficult to open	Complications associated with extended surgery	0	1
Netherlands	Excessive stress in bone	Periprosthetic fracture	0	1
Poland	Foreign object (unintended)	None	1	0

Have GLOBAL COMPLAINTS been considered?

Are there any trends?

Have complaints been assessed in context of sales

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PMCF Report

MDCG Guidance MDCG-2020-8

MDR Annex XIV Part B

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PMCF Evaluation Report

- Should be written as per template in MDCG 2020-8
- Updated annually for Class III and implantable devices
- Will feed into the PSUR, SSCP & CER
- Used to update the IFU & risk management file
- Forms part of the technical documentation
- Follows the PMCF plan

MDR & PMCF

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 referred to in Article 61 and Part A of this Annex and in the risk management referred to in Section 3 of Annex I. If, through the PMCF, the need for preventive and/or corrective measures has been identified, the manufacturer shall implement them.

Article XIV Part B (7,8)

Impact on labelling:
Indications?
Intended Use?
Contraindications?
Warnings?
Precautions?

Impact on

Design?
Manufacturing Controls?

PMCF and Harmonized Standards

ISO 14155:2020 Clinical Investigations in Medical Devices: Good Clinical Practice

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MDR + Standards + Guidelines: The Link

Clinical Investigations
EN ISO 14155:2020 Clinical investigation of Medical Devices for human subjects Good clinical practice; Third Edition
PMCF
MDR: Article 8 Use of harmonised standards The first subparagraph shall also apply to system or process requirements ……..including those relating to quality management systems, risk management, post-market surveillance systems, clinical investigations, clinical evaluation or post-market clinical follow-up ('PMCF').

Study Phases: PMCF Studies

Regulatory status	Pre-market			Post-market
Clinical development stage	Pilot stage (I.3.2)	Pivotal stage (I.3.3)	Post-market stage (I.3.4)	
Type of design	Exploratory or confirmatory (I.4.2)	Confirmatory (I.4.3)		Observational (I.4.4)
Descriptors of clinical investigations	First in human clinical investigation (I.5.2) Early feasibility clinical investigation (I.5.3) Traditional feasibility clinical investigation (I.5.4)	Pivotal clinical investigation (I.5.5)	Post-market clinical investigation (I.2.3)	Registry[a] (I.5.6) Post-market clinical investigation[a] (I.2.3)
Burden to subject	Interventional (I.6.2)			Non-interventional (I.6.3)

[a] Registry data may be used for pre-market regulatory purposes (see I.5.6), this can also apply to the post-market clinical investigation data.

When Will The NB Assess PMCF?

- Initial conformity assessment
- Recertification review
- Significant change review (if applicable)
- During review of your PMS plan
- On demand by the NB e.g. During review of your SSCP, PSUR (as per MDCG 2019-9, MDCG 2020-6)
- Routine review cycle - Class dependent: E.g. Class IIb (Implantable) & Class III – Annually (via EUDAMED)- MDR, Article 61(11)
- Decide milestones for review of Clinical evaluation and incorporation of PMCF annex IX chapter II 4.7

Is PMCF always mandatory under the MDR?

MEDDEV 2.12/2

- **innovation**, e.g., where the design of the device, the materials, substances, the principles of operation, the te
  indications are **Novel**
- **significant changes** to the device or to its intended use leading to pre market clinical evaluation and
- high **product related risk** e.g. based on design, materials, components, invasiveness, clinical procedu
- high risk **anatomical locations**;
- **high risk target populations** e.g. paediatrics, elderly; severity of disease/treatment challenges;
- questions of ability to generalise clinical investigation results;
- unanswered questions of long-term safety and performance;
- results from any previous clinical investigation, including **adverse events or from post-market surveillance activities**;
- identification of previously **unstudied subpopulations** which may show different benefit/risk-ratio
- continued validation in cases of discrepancy between reasonable premarket follow-up time scales and the expected life of the product;
- risks identified from the **literature** or **other data sources** for **similar marketed devices**;
- **interaction** with other medical products or treatments;
- verification of safety and performance of device when exposed to a larger and more varied population of clinical users;
- **new information** on safety or performance;
- **where CE marking was based on equivalence**.

Are any of these points left open, unanswered, not addressed?

When Specific PMCF is not required

- Long term safety and performance is known
- CE marked under the directive for years with no trends identified and the manufacturer has demonstrated they have sufficient clinical data to support claims
- Acceptable risk benefit ratio

Article 61 (10) Devices

We know the article 61 (10) devices do not require clinical data as a route to conformity, this may be an example of types of devices where perhaps a PMCF justification could be considered acceptable.

Typically these devices will rely on:

- bench testing data
- animal study data
- common specifications.

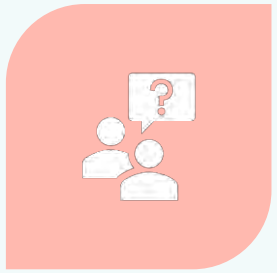
The manufacturer may choose to do some post-market clinical follow-up activity to further strengthen the evidence they hold on their device or may use PMCF to address any small gaps or confirm data that may have been identified from the pre-clinical data.

Key Points

REMEMBER
The PMCF plan is usually a part of the PMS Plan

Typically manufacturers should conduct some form of PMCF and these should be presented in a PMCF plan that mirrors MDCG 2020-7

If a manufacturer chooses not to conduct a PMCF study we should <u>always</u> expect a justification. <u>This justification should be in the PMCF plan.</u>



This justification should be clear and highlight that other PMCF activities are sufficient.

It may be acceptable for article 61 (10) and some class I devices not to conduct any PMCF.

Typical PMCF Study Challenges

Common PMCF Study Failings

- Poor study design; too many variables; no control; sample size to small
- Undefined or wrong research questions; objectives; study endpoints
- Wrong study population: indications, location
- Inadequate statistical justification for sample size
- Poorly defined or no statistical analysis plan
- Poorly executed PMCF Evaluation report
- Device not used according to CIP

PMCF: Key Points

Where clinical evaluation in initial conformity assessment under the MDD was based exclusively from clinical data of equivalent devices (MDCG 2020-6, section 5, page 8) the certifying notified body shall verify that PMCF studies have been conducted PRIOR TO MDR CERTIFICATION

MDR Article 74 [1]

This article is specific to PMCF studies or investigations conducted

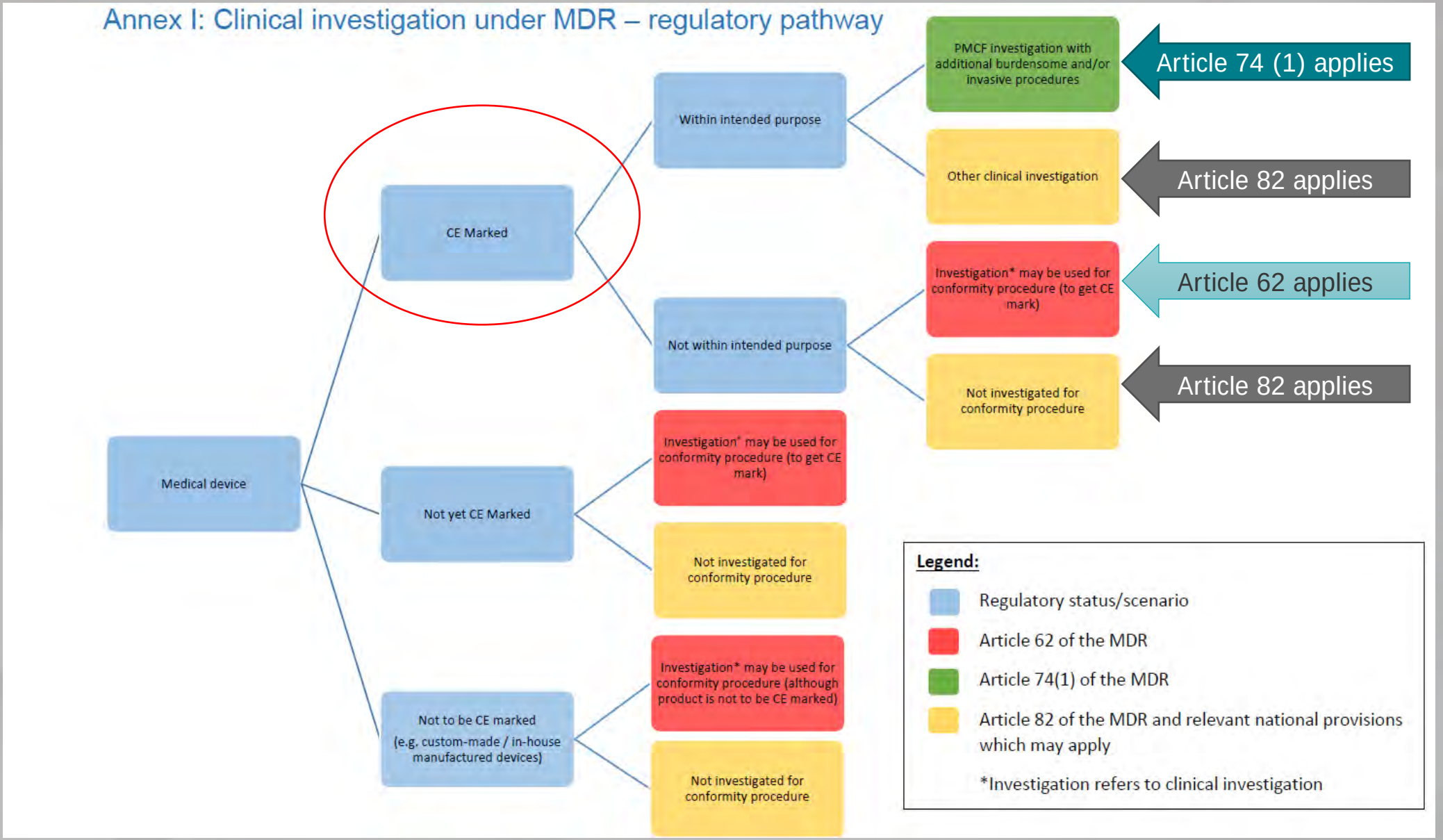
a. to further assess an already CE marked device within the scope of its intended purpose

a. Points (b) to (k) and (m) of Article 62(4), Article 75, Article 76, Article 77, Article 80(5) and the relevant provisions of Annex XV shall apply to PMCF investigations. and where the investigation would involve submitting subjects to procedures additional to those performed under the normal conditions of use of the device and those additional procedures are invasive or burdensome, the sponsor shall notify the Member States concerned at least 30 days prior to its commencement by means of the electronic

PMCF study would be treated in the same way as a pre market clinical investigation requiring review by the competent authority

Note competent authority timeline is reduced from 60 days to 30 days for devices bearing CE mark

MDCG 2021-6


Annex I: Clinical investigation under MDR – regulatory pathway
Medical device
CE Marked
Not yet CE Marked
Not to be CE marked
(e.g. custom-made / in-house manufactured devices)
Within intended purpose
Not within intended purpose
Investigation* may be used for conformity procedure (to get CE mark)
Not investigated for conformity procedure
Investigation* may be used for conformity procedure (although product is not to be CE marked)
Not investigated for conformity procedure
PMCF investigation with additional burdensome and/or invasive procedures
Other clinical investigation
Investigation* may be used for conformity procedure (to get CE mark)
Not investigated for conformity procedure
Article 74 (1) applies
Article 82 applies
Article 62 applies
Article 82 applies
Legend:
Regulatory status/scenario
Article 62 of the MDR
Article 74(1) of the MDR
Article 82 of the MDR and relevant national provisions which may apply
*Investigation refers to clinical investigation

What is considered burdensome or invasive? - MDCG 2021-6

Where the investigation would involve submitting subjects to procedures additional to those performed under the normal conditions of use of the device and those additional procedures are invasive or burdensome, the sponsor shall notify the Member States concerned at least 30 days prior to its commencement, in accordance with Article 74(1) of the MDR.

Additional procedures which are burdensome can include a wide variety of different interventions, such as:

- Pain
- Discomfort
- Fear
- Potential risks or complications/side-effects,
- Disturbances of lives and personal activities, or otherwise unpleasant experiences.

It is mostly determined from the perspective of the person bearing the burden.

Additional procedures which are invasive include (but are not limited to):

- Penetration inside the body through the surface of the body, including through mucous membranes of body orifices
- Penetration of a body cavity via a body orifice.

MDR: Annex XVI Devices

Clinical evaluation of these products shall be based on relevant data concerning safety including data from post market surveillance, PMCF and where applicable clinical investigations

Devices without an intended medical purpose

Devices without Medical Purpose

BSI Medical Devices – Use Our Resources

https://www.bsigroup.com/en-GB/medical-devices/resources

Brochures, Guides and Documents

MDR guidance

MDD Best Practice Guidelines >
MDR Best Practice Guidelines >
MDR Mapping Guide >
MedDev 2.7.1 Rev 4 changes >
MDR Conformity Routes >
MDR Readiness Review >

Webinars

MDR Conformity Assessment Routes webinar

MDR - What we know

Download the presentation >

White Papers and Articles

Person responsible for regulatory compliance (PRRC) - MDR/IVDR Article 15

With the MDR and IVDR, European regulators aim to ensure companies have a regulatory expert – a Person Responsible for Regulatory Compliance (PRRC) – at their disposal, to ensure that the company is meeting certain specific EU requirements.

Software as a medical device - A comparison of the EU's approach with the US's approach

The International Medical Device Regulators Forum (IMDRF) aims to accelerate international medical device regulatory convergence. Through the IMDRF, regulators reached consensus on what software is considered a medical device. Regulators call it 'software as a medical device (SaMD). This paper provides a comparison of how SaMD is regulated in the US and in the EU.

Machine learning AI in medical devices

How is AI different from traditional medical devices and medical software and what are the implications of those differences? What controls are necessary to ensure AI in healthcare is safe and effective?

Medical device clinical investigations – What's new under the MDR?

The conduct of a clinical investigation is one of the most time consuming and resource intensive activities that a medical device manufacturer can face. This paper discusses important new requirements for pre-market and post-market clinical investigations under the European MDR.

Training Resources

Medical devices regulation (MDR)	
Transition from MDD to MDR	1 day
Technical Documentation for CE - Marking	1 day
Requirements of MDR for CE - Marking	1 day
Implementing of MDR for CE- Marking	3 days
Further courses for medical devices manifacturers	
Medical Device Single Audit Program (MDSAP)	2 days
ISO 14971 Risk Management	1 day
Creating and Maintaining Technical Files	1 day
Post-market Surveillance and Vigilance	1 day
Clinical Evaluation for Medical Devices	1 day
Process Validation for the Medical Device Industry	1 day
Introduction to Medical Device Software	1 day

LinkedIn

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Share your knowledge, challenges and news with others on LinkedIn.

This was the last in our Clinical Masterclass Series of webinars.

To view all the on demand webinars in this series to date, please use the link below:

https://www.bsigroup.com/en-GB/medical-devices/resources/webinars/2022/mdr/clinical-masterclass/

All registrants will be sent a link to the recorded webinar and presentation slides after the event.
Look out for the Clinical toolkit with lots of useful information, whitepapers and resources, which will be sent to you automatically by the end of March.

Questions