

POST-MARKET SURVEILLANCE FROM A NOTIFIED BODY PERSPECTIVE

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01

MDR
Requirements

02

Experience,
common
challenges

03

Interacting with
the NB

01 MDR REQUIREMENTS



PMS IN THE REGULATIONS



Article 83: Post market surveillance system – **ALL DEVICES**

No device is exempt from PMS

Article 84: Post market surveillance plan – **ALL DEVICES**

PMCF may not be required in all cases

Article 85: Post market surveillance Report – **CLASS I devices only**

Article 86: Periodic Safety Update Report – **CLASS IIa, IIb and III devices**

No device is exempt from PMCF consideration

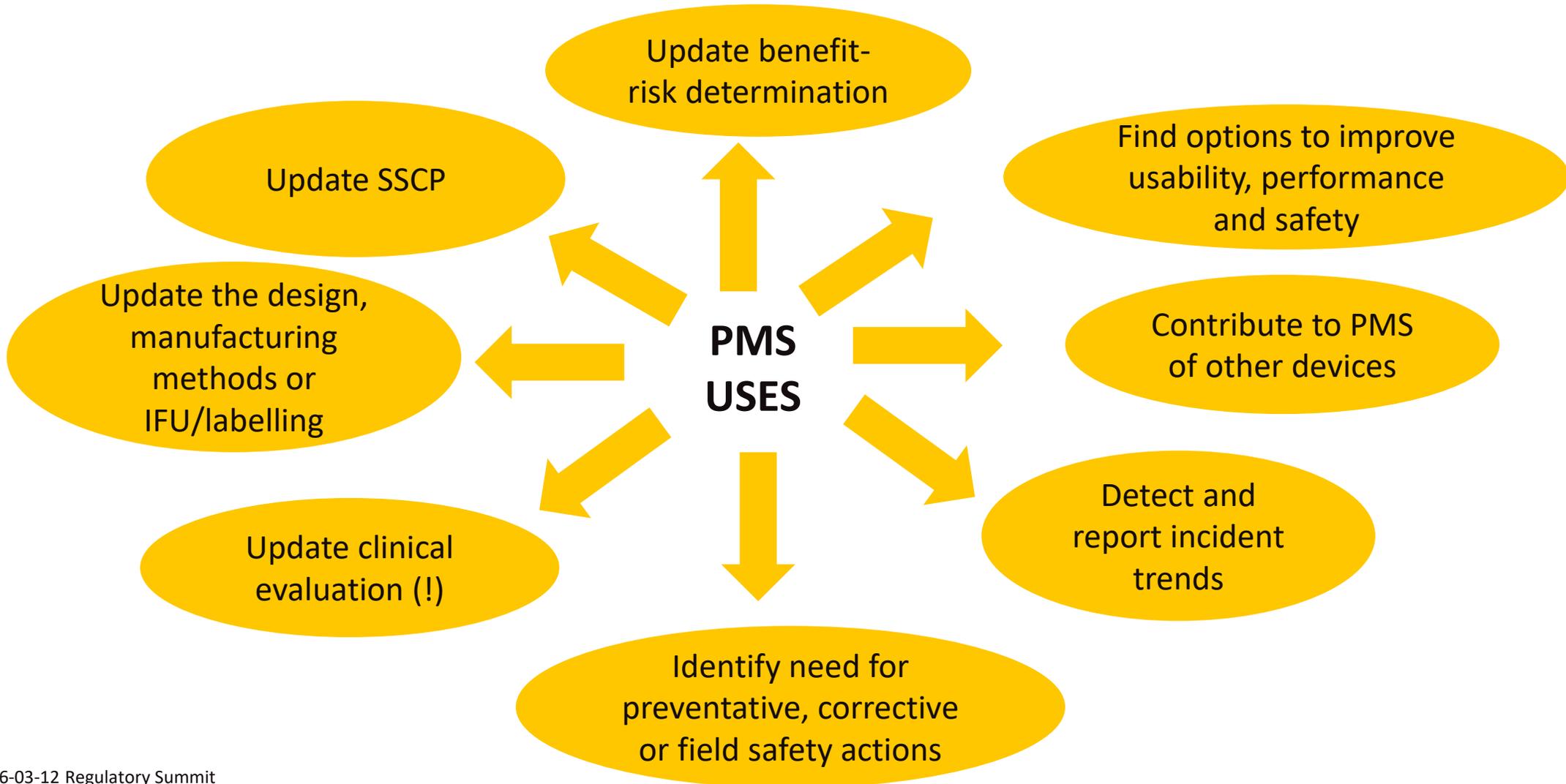
Annex III: Technical Documentation on post-market surveillance – **ALL DEVICES**

Annex XIV Part B: Post Market Clinical Follow up

ARTICLE 83: POST MARKET SURVEILLANCE SYSTEM



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



ANNEX III: TECHNICAL DOCUMENTATION ON POST MARKET SURVEILLANCE



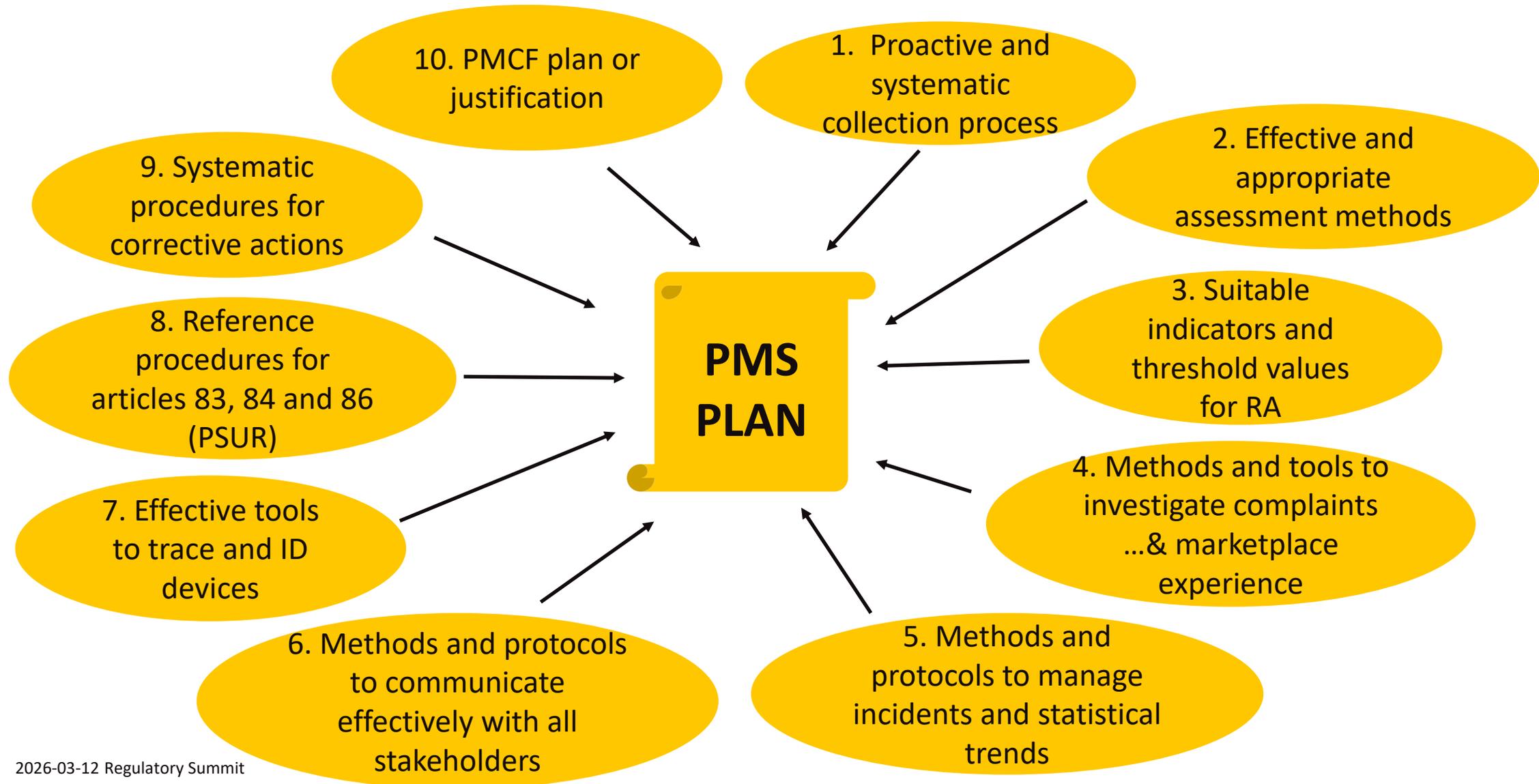
“1A Data to be collected and utilized includes but is not limited to:”



ANNEX III: TECHNICAL DOCUMENTATION ON POST MARKET SURVEILLANCE



“1B The post market surveillance plan shall cover at least:



THE PMS REPORT – CLASS I



Per Article 85, this should contain:

- Demonstration of how the PMS Plan has been met, identification of all actions initiated during the data collection period
- Report summarising the results and conclusions of the analyses of the post-market surveillance data
- Rationale and description of any preventive and corrective actions taken
- Updated when necessary and made available to the competent authority upon request

THE PSUR – PERIODIC SAFETY UPDATE REPORT



Use MDCG
2022-21
Guidance on
PSUR, annexes

This should contain:

- Demonstration of how the PMS Plan has been met, identification of all actions initiated during the data collection period
- Outline of any new or emerging risks identified or when common occurrences of poor performance or claimed benefits have not been achieved within the current reporting period.
- When there are new or emerging risks, consider any specific patient groups, device models, accessories used, geographical regions impacted, duration of risk etc. => *Specific information should be provided on the seriousness and the full potential clinical impact of these risks.*
- Description of any new benefits that have been identified from the reporting period
- Evidence-based conclusions to determine whether the benefit-risk profile of the device has changed. Positively or adversely
- Description of any specific actions that have been taken to address any newly identified or emerging risks and occurrences of poor performance.



KEY DECISIONS FROM PMS

Do the clinical benefits to patient **continue** to outweigh the risks to patient when compared to alternative treatments and devices (SOTA)...?

Are any preventative and corrective actions required to ensure an appropriate benefit vs risk ratio is achieved.

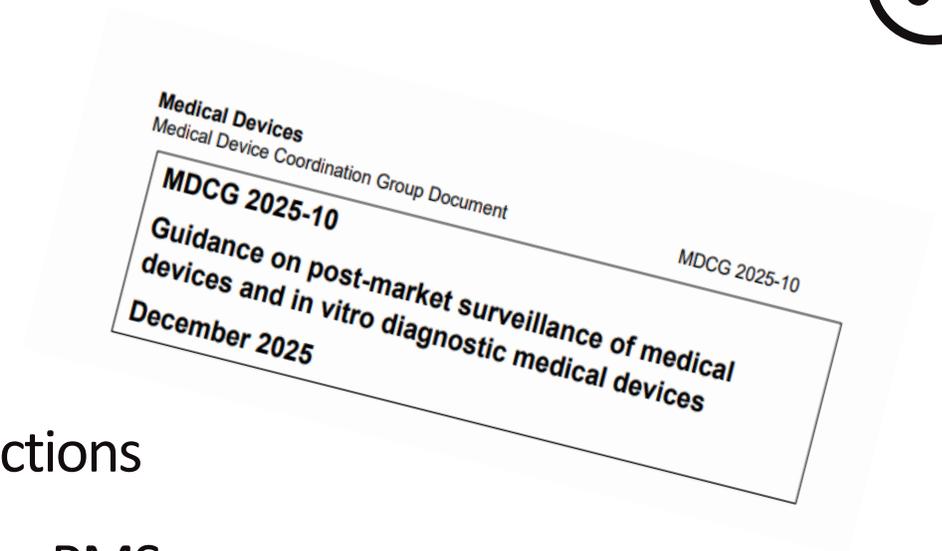
Device in conformity and remains on market

Action needed

Device may be taken off the market



MDCG 2025-10 GUIDANCE ON PMS



- ✓ Clearly presents the general requirements and interactions
- ✓ References ISO/TR 20416:2020 and WHO guidance on PMS
- ✓ Annex 1 provides an overview of PMS obligations in MDR & IVDR
- ✓ Annex 2 contains sample flowcharts to show how to use PMS data to update other processes

02 NB EXPERIENCES



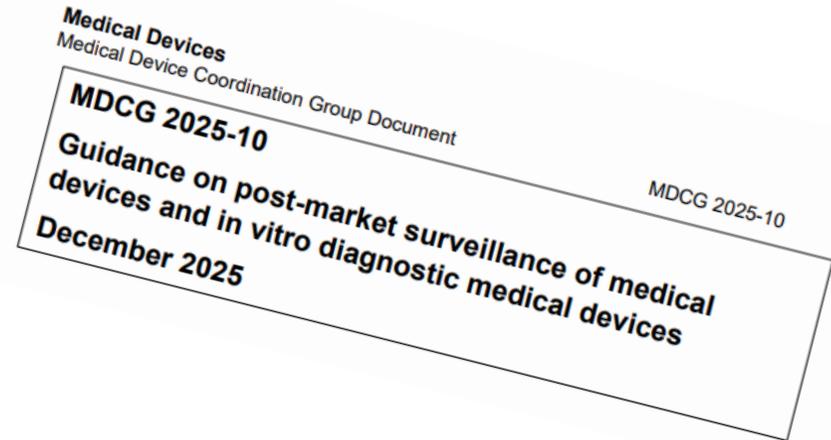


THE PMS PLAN

COMMON ISSUES

1. The PMS plan is not specific to a particular type of medical device

- Cannot be a procedure describing what you could do – must be a plan identifying what you will do
- Can cover a category or group of devices (e.g. associated with one Basic UDI-DI or devices used together as a system), with appropriate justification
- Refer to MDCG 2025-10 Guidance on post-market surveillance and ISO/TR 20416:2020 for additional guidance on scoping the PMS plan!



THE PMS PLAN

COMMON ISSUES



2. The level of information provided in the PMS plan lacks detail and is incomplete

Data Collection:

- What data sources are you planning to use and why are these data sources suitable for the device?
- How will you collect the data and who is responsible?
- When will the data be collected and how much do you need (e.g. sample size)?
- Adverse event databases do not cover expected market of sales

Data Analysis:

- How will you analyse the collected data (Qualitative or quantitative analysis..? Statistical methods..? Etc)
- What type of data analysis is required to allow comparison to similar products on the market?
- Who is responsible for analysing the collected data and when will this analysis occur?
- What methods and tools will be used to investigate complaints and analyse market-related experiences?
- How will you differentiate between serious and non-serious incidents? What will you do if a serious incident is identified?
- How will you determine if there is a trend ('statistically significant increase in the frequency or severity of non-serious incidents or expected undesirable side effects') (*i.e MDR Article 88*)?

THE PMS PLAN

COMMON ISSUES



3. The level of information provided in the PMS plan lacks detail and is incomplete (continued)

Acceptance Criteria:

- What indicators/thresholds and associated acceptance criteria will be used to identify the need to trigger an action, including reassessment of benefit-risk ratio?
- Are these indicators/thresholds appropriate to the device covered by the PMS plan considering the SOTA?

Link to other QMS processes:

- If a corrective action or field safety corrective action is needed, how will this be triggered and managed?

- How will you ensure that you can identify and trace any devices that require corrective actions?
- Method for communicating with: competent authorities, notified bodies, economic operators and users, as required?
- What processes/procedures/methods are in place to ensure that relevant data and information is fed back into the relevant QMS processes (such as design and development, risk management and clinical evaluation)?

Reporting:

- What procedures/methods are in place to ensure that results of the analysed data and conclusion are available to generate the PMSR or PSUR per the defined schedule ?

THE PMS PLAN

COMMON ISSUES



4. The PMS plan does not provide an adequate justification as to why PMCF is not applicable

- General PMCF methods are expected for all devices
- If the clinical evaluation concludes that there are no unknowns or gaps in the clinical evidence, a justification for not performing specific PMCF methods should be provided in the PMS plan



THE PSUR

COMMON ISSUES

5. Data not specific enough

- Data not specific enough to variants
- insufficient complaint and CAPA breakdown to understand the issues
- Lack of comparison to thresholds, insufficient analysis to verify benefit-risk data,
- Lack of information on an estimate evaluation of the size and other characteristics of the population using the device and, where practicable, the usage frequency of the device

MDCG 2022-21 -GUIDANCE ON PERIODIC SAFETY UPDATE REPORT (PSUR)



THE PMCF REPORTS

COMMON ISSUES

6. Plans not followed

- Time frames delayed and not reported to the NB (impact on certification conditions)
- Deviations not justified
- Data not fed into risk analysis and clinical evaluation

MDCG 2020-7 POST-MARKET CLINICAL FOLLOW-UP (PMCF) PLAN TEMPLATE A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES

MDCG 2020-8 POST-MARKET CLINICAL FOLLOW-UP (PMCF) EVALUATION REPORT TEMPLATE A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES

MDCG 2025-10 GUIDANCE ON POST-MARKET SURVEILLANCE



03 INTERACTING WITH THE NB





STRUCTURED DIALOGUE

CLARIFICATION OF REQUESTS FOR ADDITIONAL INFORMATION AND NON-CONFORMITIES



Prepare for the meeting



Do not go through each request or non-conformity



Focus on the requests or non-conformities that require clarification

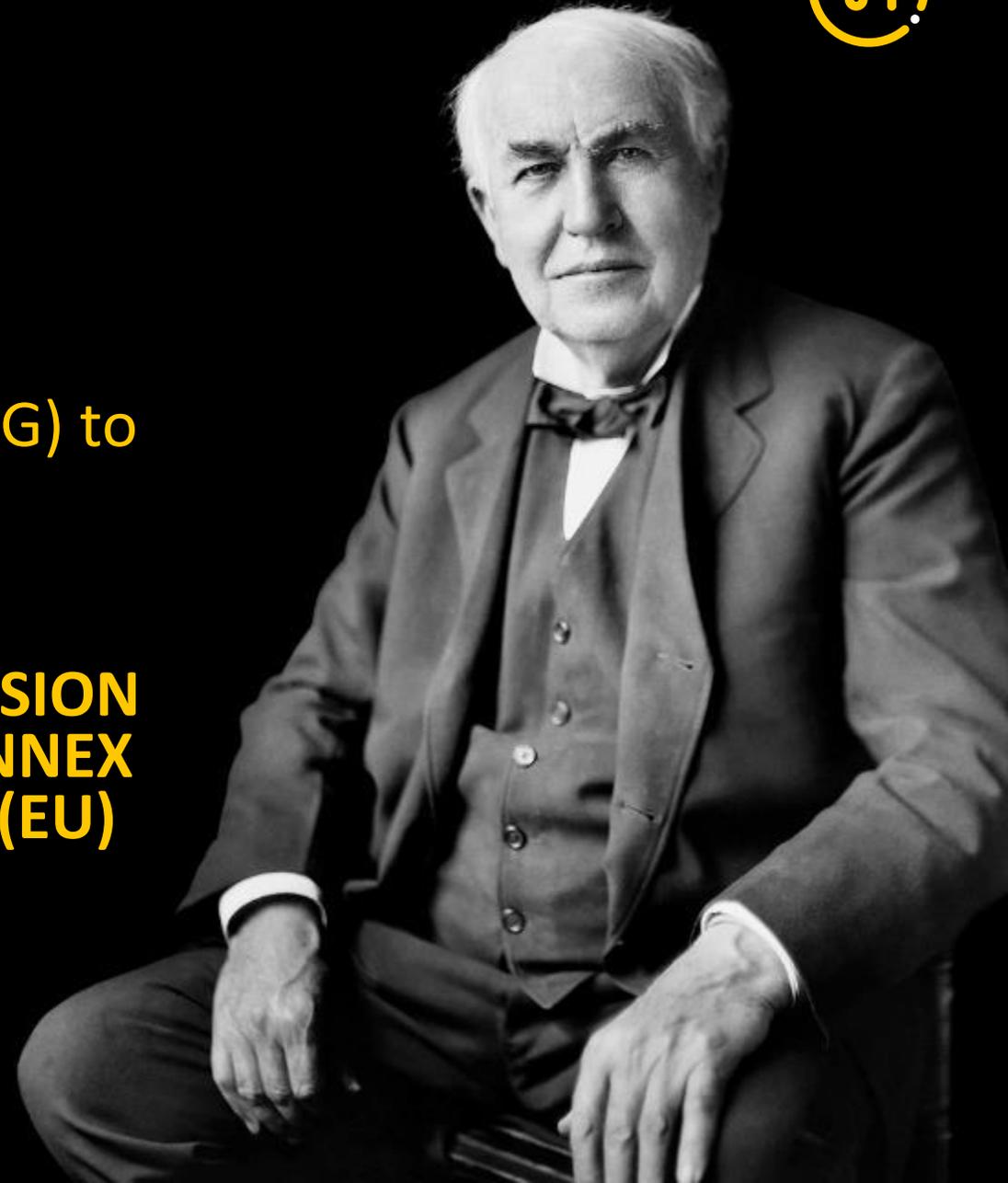
INCOMPLETE SUBMISSION TECHNICAL DOCUMENTATION



“There’s a way to do it better – find it”
- Thomas Edison

Refer to Team-NB Best Practice Guidance (BPG) to ensure your submission is complete

**BEST PRACTICE GUIDANCE FOR THE SUBMISSION
OF TECHNICAL DOCUMENTATION UNDER ANNEX
II AND III OF MEDICAL DEVICE REGULATION (EU)
2017/745**



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1. **Behöver PMS-planen specifikt täcka alla varianter på produkten, finns det något tips på hur man gör vid begränsad kliniska data till exempel?**

Svar: Ja. PMS-planen behöver samla in information om alla varianter. Om vissa storlekar till exempel har mycket låg försäljningsvolym och begränsat kliniskt data från början kan tillverkaren behöva överväga att specifikt samla proaktiv PMS från kirurger/kliniker som använder dessa ovanliga storlekar, för att säkerställa att viss PMS-data samlas in (om detta inte redan täcks av PMCF).

2. I din presentation nämnde du att ett vanligt problem är otillräcklig eller saknad motivering av “adequacy of methods and thresholds implemented” – hur kan tillverkare hantera det problemet?

Svar: Utgå från riskbedömning. Den ska innehålla acceptabla gränser för olika risker och motiveringar till varför de anses acceptabla. Läs även sektion 4 i MDCG 2025-10 (särskilt Tabell 1) om “methods and thresholds”.

Det är också viktigt att koppla detta till State of the Art (SOTA), eftersom PMS-planen syftar till att visa hur risknivån för produkten förhåller sig till liknande produkter och till alternativa behandlingsmetoder.

Det finns också viss vägledning och exempel i ISO/TR 20416 “Medical devices — Post-market surveillance for manufacturers”.

3. Om man har en produkt med låg risk som har funnits länge på marknaden, hur sätter man då rätt mål för PMS-planen?

Svar: Det kontinuerliga riskanalysarbete bör visa vilka risker som är under kontroll och där omfattande data redan visar på kontroll, baserat både på er egen produkt och på data från liknande produkter.

I planen, fokusera på PMS-aktiviteter som:

Verifierar att de mest framträdande kända riskerna (om sådana finns) fortsatt ligger inom det förväntade intervallet. Samla in data för att upptäcka nya eller tidigare okända risker.

Källor och metoder kan definieras genom att ställa några frågor, till exempel:

Har det skett några trender eller förändringar i hur produkten används? Detta kan göras genom att följa upp förändringar i användning (klinisk praxis/användarbeteende).

Har några förändringar gjorts i produktens design eller i tillverkningsprocessen som kräver specifika PMS-aktiviteter för att verifiera att riskerna inte påverkas?

Har det skett förändringar i omvärlden, till exempel nya och säkrare behandlingsalternativ, eller har större nytta vilket påverkar risk-nytta balansen (den totala rest-risken eller nytta-risk-balansen för er produkt inte längre är acceptabel eftersom bättre alternativ finns tillgängliga?)

Disclaimer

This material provides an overview of the Post Market Surveillance requirements under the MDR as applicable and in force on the date of publication of the material. Please note that this material is not an exhaustive list and that legal and regulatory requirements may be subject to changes.

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