Live Q&A on PMCF Surveys

Broadcast starts at 15.00 CEST on June 11th 2020

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Today’s Hosts

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Live Q&A on PMCF Surveys – June 11th 2020
What is PMCF and PMCF plan?

- Post-Market Clinical Follow-Up is a part of the Post-Market Surveillance
- Continuous and proactive process to update the Clinical Evaluation
- PMCF plan specifies *how* you will collect and evaluate clinical data
What’s a PMCF Survey?

- MDR does not have a preference on PMCF activities
- PMCF survey is one way of collecting data for PMCF evaluation report and possibly PSUR
- Simple way to get started with collecting data
“Is PMCF required for all device classes?”
QUESTION #1

"Is PMCF required for all device classes?"

In short, yes – see Article 10 p. 3 in the MDR

Article 10

General obligations of manufacturers

1. When placing their devices on the market or putting them into service, manufacturers shall ensure that they have been designed and manufactured in accordance with the requirements of this Regulation.

2. Manufacturers shall establish, document, implement and maintain a system for risk management as described in Section 3 of Annex I.

3. Manufacturers shall conduct a clinical evaluation in accordance with the requirements set out in Article 61 and Annex XIV, including a PMCF.
“Proper justification of not needing a PMCF (study) - is the MEDDEV 2.12/2 rev2, Revision January 2012. Can this be used as a reference for Post Market Clinical Follow-up Studies under the MDR?”
QUESTION #2

PMCF does not equal a PMCF study

Follow MDCG guidance, not MEDDEV guidelines

Notified Bodies can request access to clinical data

“Proper justification of not needing a PMCF (study) - is the MEDDEV 2.12/2 rev2, Revision January 2012. Can this be used as a reference for Post Market Clinical Follow-up Studies under the MDR?”

 Guidance

The European Commission provides a range of guidance documents to assist stakeholders in implementing the medical devices regulations.

Legally non-binding guidance documents, adopted by the medical device coordination group (MDCG) in accordance with Article 105 of Regulation 745/2017, pursue the objective of ensuring uniform application of the relevant provisions of the regulations within the EU.

**MDCG endorsed documents**

MDCG WORK IN PROGRESS

Ongoing guidance documents
"What are the minimum and the maximum periodicity of the interim report?"
**QUESTION #3**

“What are the minimum and the maximum periodicity of the interim report?”

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(Detail: Update Annually)

(Only for Implantable)

(Update at least every two years)
“Do I need informed consent when I process pseudonymized data? But what if they are anonymised?”
“Do I need informed consent when I process pseudonymized data? But what if they are anonymised?”

Be mindful of the different regulations at play (GDPR, CTD, MDR, Local legislation...)

Informed Consent and Data Processing Consent are not the same
“[Do] I have to strictly follow ISO 14155 when doing PMCF observational study using surveys/questionnaires? Surveys aren't really a part of ISO, so how would this work?”
QUESTION #5

ISO14155:2020 will cover PMCF and observational studies

Not all chapters are applicable

“[Do] I have to strictly follow ISO 14155 when doing PMCF observational study using surveys/questionnaires? Surveys aren't really a part of ISO, so how would this work?”

From an ISO14155:2020 draft:

Annex I.7 Applicability of the standard’s principles

Depending on the clinical development stage and the type of the clinical investigation design, the principles of this standard can be applied in full or in part. Significant exceptions from the requirements of this standard should be duly justified and noted in the CIP or other sponsor regulatory files."

The term “non-interventional” is synonymous with “observational”.
“Do survey questions need to be validated? If electronic data collections methods are used, do they need to be validated?”
QUESTION #6

“How do survey questions need to be validated? If electronic data collection methods are used, do they need to be validated?”

✔ Using validated scales can be beneficial if they fit your claims

✔ Only use validated software tools to collect data
“Is there a minimum content [requirement] for a PMCF survey?”
“Is there a minimum content [requirement] for a PMCF survey?”

No – focus on the evidence (data) you need to convey

Use gap analysis to identify evidence claims that lack data to support it
“What is the appropriate Sample size for a Survey - especially if it covers "lifetime" of the device?”
QUESTION #8

“What is the appropriate Sample size for a Survey - especially if it covers "lifetime" of the device?”

Sample size is calculated for a given project, not the total “lifetime”

Sample size is calculated by looking at what you are going to survey/test
“…what if response rates are even lower than previously expected, how can we justify that the survey results are still relevant?”
**QUESTION #9**

“...what if response rates are even lower than previously expected, how can we justify that the survey results are still relevant?”

1. Small sample size means lower evidence precision

2. Use statistical and clinical methods to justify why it’s still relevant
“Must Usability data collection be a separate survey from safety and performance clinical data collection?”
 QUESTION #10

“Must Usability data collection be a separate survey from safety and performance clinical data collection?”

- It can be combined in a single survey

- But only if the audience is representative for all areas
“How do we analyse a survey? Statistics, descriptive, or theme-picking?”
QUESTION #11  “How do we analyse a survey? Statistics, descriptive, or theme-picking?”

☑️ Think of it like a clinical study

☑️ Specify how you will analyse the data before you start
“What is the perceived value of a survey? In your view, what’s the difference between a survey addressing patients and a clinical investigation?”
QUESTION #12

“What is the perceived value of a survey? What is, in your view, the difference between a survey addressing patients and a clinical investigation?”

- Surveys are a cheaper alternative, but only if the data supports it

- Surveys “observe”, clinical investigations “interact and measure”
“Is there any standard on surveys?”
QUESTION #13

“Is there any standard on surveys?”

- New ISO14155 does apply within certain areas
- Follow “best practices” and guidelines from research associations and publications
“How would you link an anonymous survey to the PMS system?”
QUESTION #14  “How would you link an anonymous survey to the PMS system?”

Avoid to use purely anonymized data for PMS

If you do, be sure that you can document the source of origin and its validity
“Do the PMCF surveys have to be approved by the ethics committee?”
“Do the PMCF surveys have to be approved by the ethics committee?”

EC’s have different rules in different countries - no “one” answer

Sometimes you must notify or get approvals, other times you don’t
“If the medical device is a patient-specific device class III (TMJ replacement) used for treatment not very frequent how can I justify that I could get only 4 surveys a year?”
QUESTION #16

“If the medical device is a patient-specific device class III (TMJ replacement) used for treatment not very frequent how can I justify that I could get only 4 surveys a year?”

- Use risk-based statistical and clinical justifications to reason response rates

- Do “as well as you can” within a reasonable limit and justify/document the effort
"Can we approach patients few years after implantation, or should we have an informed consent signed on the day of implantation?"
QUESTION #17

“Can we approach patients few years after implantation, or should we have an informed consent signed on the day of implantation?”

- In short, yes, but it will probably require ethics approval/application
- Consents for participating in retrospective studies/surveys can be signed later
Live Answers

Questions from you
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