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Post-market Clinical Follow-up (PMCF) GAP Analysis for Legacy Devices Class III between the Medical Device Directive (MDD 93/42/EEC) and the Medical Device Regulation (MDR 2017/745)

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Abstract: The passage from the MDD 93/42/CEE to the MDR 2017/745 remains a big challenge for the manufactures. The interpretation of the regulatory requirements stays unclear and can differ from one source to another, especially when it comes to the clinical evaluation. Will the data collected under the MDD 93/42/CEE be sufficient to prove the safety and security of the device? Under the directive each country was establishing its own requirements for the conduct of the studies. The MDR has standardized these rules, so that all the clinical data collections follow the same pathway. We will examine the PMCF of the class III devices already CE marked under the directive (legacy devices) to find out if the new requirements will be asked to be in compliance with the MDR. A Gap analysis between the MDD and MDR will help us in our research. A matrix in the form of a questionnaire will be established to help us verify compliance of the PMCF under the MDR.

SCIENCE AND TECHNOLOGY PUBLICATIONS

1 INTRODUCTION

The Medical Devices Regulation 2017/745 (MDR) came in force on the 26th of May 2021 bringing significant regulatory changes.

The new MDR requirements reinforced clinical data, technical documentation, and labelling. However, the most significant change concerned the clinical part, as the manufacturers have to obtain a bigger clinical data to prove safety and performance of their products.

As the representative of the medium size company, manufacturing implantable medical devices class III we are at the heart of regulatory constraints, which are becoming more and more imposing. Our products already have a long marketing history; therefore, they enter in the category of legacy device.

"Legacy devices are all devices previously CE marked under the European Medical Devices Directive 93/42/EEC" (MDCG 2020-6).

We will analyse the requirements for the PMCF report under MDR 2017/745 to build the gap analysis between MDD and MDR, paying special attention to the interpretation of the meaning « sufficient clinical data », since this essential requirement of the MDR is not clearly explained.

We will rely our researches on the MDR, Medical Device Coordination Group (MDCG) and MEDDEV guidelines. A literature review will be done using scientific publications, notify body and consultancy agencies articles.

We will apply our research on the example of a Biotechni S.A.S., a family-owned company created in 1984 in Marseille and currently employing 48 members. Biotechni designs, producers and commercialises a range of implants for hip, shoulder and spine (classes I, IIa, IIb and III). All the products produced by Biotechni are marketed since at list 10 years and are covered by a valid certificate issued in accordance with Directive 93/42/EEC, valid until May 2024.

To illustrate our gap analysis, we will use an example of a femoral stem, used in association with a femoral head and acetabular cup for a hip joint replacement.

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Below is the brief description of the device in question.

Table 1: Filler-3ND femoral stem brief description.

MANUFACTURER	BIOTECHNI S.A.S
PRODUCT RANGE	FILLER-3ND® 135° Titanium cementless femoral hip stems (11 sizes)
PICTURE	
CLASS	III
INTENDED PURPOSE	For use in total and partial hip arthroplasty
Date of 1st CE marking	25/03/2004
TOTAL SALES	18 000

2 CLINICAL REQUIREMENTS FOR LEGACY DEVICE

"Past performance is no guarantee of future results. Study Proves Past Results Doesn't Predict Future Results…"

The founding fathers of the new MDR were obviously very inspired by those quotes while building the new regulations.

Therefore, even if the device has been marketed for decades with no significant change in design, it doesn't exempt the manufacturer from the complimentary clinical studies.

2.1 Exemptions from the Clinical Requirements for Legacy Device

According to MDR Article 61(4 and 6) clinical investigations shall be performed for Class III and implantable devices, except if they have been previously marketed under Directive and their clinical evaluation is based on sufficient clinical data. Another exemption from clinical investigations is given in MDR Annex XIV, Part A (3), where it is stipulated, that a clinical evaluation may be based on clinical data relating to a device for which equivalence to the device in question can be demonstrated by technical, biological and clinical characteristics with the authorisation of the full access to the technical documentation.

2.2 Sufficient Clinical Data

Different sources are attempting to explain the meaning of the word « sufficient ».

The Article 61(1) of the MDR states that: "The level of clinical evidence shall be appropriate in view of the characteristics of the device and its intended purpose."

Section 4 of MDCG 2020-6 guidance states: "Both the Directives and the MDR require the quantity and quality of clinical data to be sufficient to demonstrate safety, performance and the acceptability of the benefit-risk ratio…and require clinical evidence to be sound and the conclusions derived from this evidence to be scientifically valid."

Section 5 of the guidance tries to explain what does the word sufficient means by saying: "sufficient clinical evidence is understood as the present result of the qualified assessment which has reached the conclusion that the device is safe and achieves the intended benefits."

Does it really help to understand what does "sufficient" mean? We are not so sure…

The manufacturer should conduct an analysis to determine if additional data or change in PMCF design to support the clinical evidence are required to meet additional MDR requirements. This could be achieved through a gap analysis with respect to new MDR requirements.

The gap analysis is the difference between what we have with MDD and what we should have to comply with MDR.

To prepare the GAP analysis of the PMCF report in the most exhaustive way we decided to separate our researches in 3 main pillars:

1. Acceptable quantity of clinical data
2. Acceptable quality of clinical data
3. Additional sources of clinical and not clinical data

The acceptable quantity of clinical data is the quantity of information we need to make the study results reliable and representing of a real life.

The acceptable quality of clinical data will be appraised by its methodological quality and its relevance.

The additional sources of clinical and not clinical data will be considered to implement the PMCF results.

The goal is to establish a generic matrix that could be used for each legacy medical device.

2.3 Acceptable Quantity of Clinical Data

2.3.1 Sample Size

The choice of the sample size is one of the primary endpoints the sponsor has to determine for the clinical study.

As we can't include all the population of interest, we should determine what is the minimum number of patients that would reflect as much as possible the total population of interest, and therefore make study results statistically significant.

The MDR requires to document the choice of sample size, and to provide a rationale explication of the procedures and the methods used.

The sponsor should define what endpoints would be statistically measured through the clinical study to demonstrate the device general safety and performance conformity assessment. To assess quality and performance of an implantable medical device the survival rate is usually measured.

2.3.2 Duration of Clinical Study

The duration of a clinical investigation is also crucial and must be considered while planning the PMCF.

"The follow-up period during the clinical investigation shall permit the demonstration of clinical performance, effectiveness or safety over a period of time sufficient to represent a realistic test of the investigational device and allow any risks associated with adverse device effects to be identified and assessed" (ISO 14155 : 2020).

"Although there is not enough information yet available to calculate exactly how long a hip replacement will last, using available arthroplasty registry data, we estimate that about three-quarters of hip replacements last 15–20 years and just over half of hip replacements last 25 years in patients with osteoarthritis" (How long does a hip replacement last? A systematic review and meta-analysis of case series and national registry reports with more than 15 years of follow-up - Jonathan T Evans, Jonathan P Evans, Robert W Walker, Ashley W Blom, Michael R Whitehouse*, Adrian Sayers* - 2019).

Taking into consideration the average duration of the hip joint life cycle and the common practice in designing the hip replacement PMCF studies, we estimated the minimum duration of the study at 10 years.

2.4 Acceptable Quality of Clinical Data

"Clinical investigation that are currently being conducted with respect to Directive 93/42/EC and Directive 90/385/EC by the date of application of the MDR, can continue to be conducted" (MDCG 2021-6).

Therefore, the Clinical investigation protocols that have been approved under Directive 90/385/EC can be keep going, as long as the quantity and quality of the data are sufficient. But what constitutes the quality of the data?

The quality appraisal of the clinical data is uncertain, as it has to take into consideration several aspects.

MEDDEV 2.7/1 rev. 4. point 9. suggests to evaluate two main sources: the methodological quality of the data, and the relevance of the data.

2.4.1 Methodological Quality

Different methods are available to conduct a clinical study.

In case of legacy device observational prospective or retrospective studies are most commonly used.

We are encouraged to conduct the methodology evaluation to assess whether there are any points that can be improved.

We have grouped the information from Appendix A6 General principles of clinical evaluation of MEDDEV 2.7/1 rev. 4. to constitute the checklist of the desired parameters for a high-level scientific validity study to demonstrate adequate clinical performance and clinical safety.

Below are the points that should be taken into consideration while assessing the methodological quality of the study:

- Sufficient information on elementary aspects
- Proper statistical methods
- Adequate controls
- Proper collection of mortality and serious adverse events data
- Legal activities
- Schedule for PMCF activities

Let's see in details those points.

- Sufficient Information on Elementary Aspects

The clinical data should necessarily contain the following elementary aspects:

a) Methods used
b) Products used
c) Number of patients
d) Clinical outcomes
e) Undesirable side-effects
f) Confidence intervals/ calculation of statistical significance
g) Reference to the harmonised standards or guidances.

- Adequate Controls

  a) Objective control parameters
  b) Assessed endpoints are not subject to natural fluctuations
  c) No other treatments, that can influence the clinical outcome are taken
  d) Any other influencing factors

- Proper Collection of Mortality and Serious Adverse Events Data

The lost to follow-up should be avoided as much as possible. Therefore, the Investigator should have a contact person that will be contacted if a patient is lost to follow-up. The emergency contact should be provided while recruitment. It could be mentioned in the PMCF protocol.

The Sponsor should be immediately informed about all adverse events or any sort of failures.

- Legal Activities

MDR clinical investigation requirements are based on existing ethical and legal regulations. "Clinical investigations should be in line with well-established international guidance in this field, such as the international standard ISO 14155:2011" (Point 64 of the preamble to MDR).

Article 74 precises that rules provided in points (b) to (k) and (m) of article 62(4), article 75, article 76, article 77, article 80(5) and (6) and the relevant provisions of Annex XV shall apply to all PMCF investigations. This must be understood, that both PMCF investigations with invasive or burdensome procedures as well as the investigations free of such additional measures should comply with the same requirements.

Within MDR it must be understood that in-label, observational, non-interventional studies will however stay in a general category of clinical investigation. That means that all the requirements and obligations set up for the PMCF investigation within the framework of the MDR must be observed.

The fact that the studies stay in the scope of intended purpose and without bringing any additional risk to patients does not exempt them from general obligations.

Below is the list of the essential requirements to the clinical investigation according to the ISO14155: 2020, and the analysis of this new requirements applied to the Filler-3ND observational retro-prospective study, started under MDD.

As we can see the design study started under MDD can be improved and adjusted to comply as much as possible with the new requirements.

Table 2: List of essential requirements ISO14155:2020 applied to Filler-3ND PMCF report.

List of requirements ISO14155-2020	Filler-3ND PMCF report	Comments
Investigation brochure	No	Can be added
Clinical Investigation Plan	Yes (PMCF protocol)	
Principle Investigators CV	No	Can be added
List of investigation sites	No	Can be added
Ethics committee approval	For certain countries	Ask for a EC approval if a new country included
Regulatory authorities' approval	Yes	
Signed agreement between investigator and sponsor	Yes	
Financial agreement between investigator and sponsor - Yes	Yes	
Insurance	No	As the study started under MDD no need to include it a posteriori
Investigation site selection report	No	Can be added

- Schedule for PMCF Activities

Annex XIV, part B, point 6.2 (h) recommends "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 report should indicate the targeted study duration for subjects already enrolled or/and to be enrolled to achieve target sample size.

- Conclusion About Study Design

We analysed point by point all the aspects, that constitute the methodological quality of a study.

But as mentioned earlier, the quality of the study is based on 2 pillars: the methodology and the relevance of the data. In the next chapter we will analyse the second pillar of the quality assessment, what constitutes the data relevance of the study.

2.4.2 Relevance of the Data

Article 61 of the MDR specifies the general requirements regarding clinical investigations to demonstrate conformity of devices.
According to article 62 of the MDR the clinical study should demonstrate, that the following points have been achieved:

1. Device achieves the performance intended as specified by its manufacturer
2. Establish and verify the clinical benefits of a device as specified by its manufacturer
3. Establish and verify clinical safety, detect any undesirable side effects
4. Evaluate the benefit / risk ratio

All that information claimed by the manufacturer should be confirmed by clinical data.

- Conformity with the IFU Allegations

Annex I, CHAPTER III points 23.4 of the MDR precises the information that the manufacturer should supply in the instructions for use.
The assessor will examine whether there is sufficient clinical evidence to demonstrate that the device performs as intended in the IFU.

- Benefits Claimed in Marketing Material

The information given about a medical device in the marketing material must be consistent with the manufacturer's intended purpose and the scope of use of the medical device. Moreover, the allegations claimed by the manufacturer in the advertising information must be supported by clinical evidence.

- Target Groups

The target population should be identified in the PMCF through the inclusion and exclusion criteria. The inclusion/exclusion criteria must be strictly respected as it can compromise the clinical results.
Generally, the population included in the study should be homogenous which benefits from the same level of infrastructures. Investigation site selection report can be helpful to involve the centers of the same level. The investigators should have the same knowledge as well. Training records, providing evidence, that the investigators have been trained are very helpful.

3 ADDITIONAL SOURCES OF CLINICAL AND NON CLINICAL DATA

Annex XIV, part B, point 6.2 (a) of MDR precises what are the available sources of the PMCF data collection: “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”.

Therefore, feedback from users and screening of scientific literature can be put in place to implement the PMCF.

In fact, user surveys are listed in the MDR as a valid method of post-market clinical data collection.

3.1 Market Experience Feedback

PMCF surveys should not be ignored, as they represent many advantages.

With the PMCF surveys the clinical data can be significantly implemented.

The PMCF survey should have a clear objective and not have conflicting purposes that could confuse the PMCF results. PMCF surveys should be in line with the PMCF clinical data collection and reply to the same objectives, as precised in the Annex XIV, part B, point 6.1.

The regular collection of the feedback from users may help to identify any unknown side-effects, emergent risks, misuse or off-label use of the device.

3.2 Alternate Therapies/State of the Art/Current Knowledge

A critical review of the literature while assessing the state of the art, alternative examination and treatment methods should be considered when implementing the PMCF.

The literature search should demonstrate if the device in question is a well-established practice with numerous articles validating both design, longevity and security.

If the device is identified as belonging to the group of « well-established technologies » a lower level of clinical evidence may be justified to be sufficient for the confirmation of conformity with relevant GSPRs.

3.3 Benefit-Risk Analysis

The aim of the PMCF plan is ensuring the continued acceptability of the benefit-risk ratio, referred to in Section 1 and 9 of Annex I in the MDR.

The benefit-risk analysis should be documented in the clinical evaluation report using all the available sources of clinical and non-clinical data, obtained through the PMCF activities.

Aspects that influence the acceptability of benefits and risks can be found in Appendix A7.2 and in Appendix A7.4 of MEDDEV 2.7/1 rev. 4.

The information gathered through the PMCF activities should be sufficient to confirm the acceptable benefit-risk ratio.

3.4 Gap Analysis Matrix

The main goal of this thesis was to establish a check list, that will help to conduct a gap analysis of a PMCF report. We grouped all the collected information in a table-matrix.

We have illustrated this matrix with the example of the Filler-3ND PMCF report.

Table 3: GAP analysis Matrix.

Product Name			
Product Class			
Q.N°	Question	Response	Gaps, if any/recom-mendation
	Sample size		
Q1	What is the target size of the sample?		
Q2	Has the sample size calculation been justified?		
Q3	Has the sample size justification been approved by the Notify Body?		
Q4	Has the target sample size been reached?		
	Duration of the study		
Q5	Is the duration of the study enough to demonstrate its safety and performance?		
	Methodology		
	Elementary aspects		
Q6	Does the PMCF disclose the methods used?		
Q7	Does the PMCF disclose the products used?		
Q8	Does the PMCF disclose the number of patients included?		
Q9	Does the PMCF disclose all the clinical outcomes?		
Q10	Does the PMCF disclose data from others activities? (device registry, PMCF studies, real world evidence, surveys about the use of device, etc…)		
Q11	Have the undesirable side-effects been observed?		
Q12	Have confidence intervals/ calculation of statistical significance been used?		
Q13	Does the study PMCF reference to any harmonised standards, relevant guidance on PMCF		
	Adequate controls		
Q14	Are the endpoints assessment objective? (ex., pain is subjective)		
Q15	Are the endpoints or symptoms assessed are subject to natural fluctuations? (ex. when the natural evolution of the pathology is not clearly predictable)?		
Q16	Are any other treatments, that can influence the clinical outcome taken?		
Q17	May clinical outcomes can be affected by variability of the patient population, of the disease, of user skills, of infrastructure…?		
	Collection of mortality and serious adverse events data		
Q18	Has the consent of the subjects for contacting reference persons been obtained?		
Q19	Is any failure or adverse event immediately reported?		
	Legal activities		
Q20	Does the study have Investigation brochure?		
Q21	Does the study have Clinical Investigation Plan?		
Q22	Does the study have Principle Investigators CV?		
Q23	Does the study have List of investigation sites?		
Q24	Does the study have Ethics Committee approval?		
Q25	Does the study have Regulatory Authority approval?		
Q26	Does the study have signed agreement between investigator and sponsor?		
Q27	Does the study have financial agreement between investigator and sponsor?		
Q28	Does the study have insurance?		
Q29	Does the study have Investigation site selection report (verifies that the qualification of investigation site members has been approved)?		
Q30	Does the study have CRF?		
Q31	Does the study have Adverse events form?		
Q32	Does the study have Device deficiency form?		
Q33	Does the study have Training records (evidence, that the investigators have been trained)?		

Table 3: GAP analysis Matrix (cont.).

Product Name			
Product Class			
Q.N°	Question	Response	Gaps, if any/recom-mendation
	PMCF Schedule		
Q34	Is there a PMCF Follow-Up schedule for on-going subjects?		
Q35	Is there a PMCF Follow-Up schedule for additional planned subjects?		
	Relevance of the data		
	Indication/intended use/intended purpose in IFU		
Q36	Is the exact indication/intended use/intended purpose as described in the device's IFU captured? List down the indications/intended use/intended purpose in the below rows as per the IFU.		
Q37	Indication # 1		
Q38	Indication # 2		
	Benefits claimed in marketing material		
Q39	Are the claims as described in the marketing material captured? List down the claims in the below rows as per marketing material.		
Q40	Claim # 1		
Q41	Claim # 2		
	Contraindications/ Warnings & Cautions / Risks in IFU		
Q42	Are the exact contraindications as described in the device's IFU captured?		
Q43	Are the exact Warnings & Cautions as described in the device's IFU captured?		
Q44	Are the exact Risks as described in the device's IFU captured?		
Q45	Are previously unknown side-effects identified?		
Q46	Are emergent risks identified and analysed?		
Q47	Do the clinical results meet the expected benefits?		
Q48	Is the benefit-risk ratio continuously acceptable?		
Q49	Is the performance characteristics of the device demonstrated?		
	Target group(s)		
Q50	Has the inclusion/ exclusion criteria been respected by the target population?		
Q51	Are the infrastructures of the sample homogeneous?		
Q52	Is the social and economic level of the sample homogeneous?		
Q53	Is the morphology of the sample homogeneous?		
	Additional sources of clinical and not clinical data		
	Market Experience feedback		
Q54	Has market experience data been collected (complaints, medical device reports, customer surveys, etc)? List down the data, that has been collected from the market.		
Q55	Market experience data # 1		
Q56	Market experience data # 2		
Q57	Are possible systematic misuse or off-label use of the device identified?		
Q58	Are the usability forms filled in regularly?		
	Critical analysis of the literature		
Q59	Is a thorough literature search performed to identify state of the art therapy/management/diagnostic options available?		
Q60	Is a description of all the available therapeutic/management/diagnostic options, historical context and developments included?		
Q61	Is a thorough literature search performed to identify state of the art therapy/management/diagnostic options available?		
	Benefit-risk Analysis		
Q62	Are all the risks identified from different sources?		
Q63	Are the risks acceptable according to current knowledge/ the state of the art in the medical fields concerned and according to available medical alternatives?		
Q64	Is justification available for acceptability of risk(s)?		
Q65	Are there any new risk(s) identified?		
Q66	If new risks are identified, is the available clinical data sufficient to verify that the device is in conformity with all the essential requirements pertaining to clinical performance and clinical safety?		
Q67	Does the risk/benefit analysis summarized, considering the current knowledge/the state of the art?		
Q68	Does the report explain why the benefit/risk profile and the undesirable side-effects are acceptable in relation to current knowledge/the state of the art?		

Table 4: Non-compliances of the Filler-3ND PMCF report, detected by GAP analysis Matrix.

GAP Endpoint	Level of importance	Correction action
Collection of mortality and serious adverse events data	Medium	Include reference persons to contact in case of lost to follow-up during the recruitment
Legal activities	Minor	To add Investigation brochure
	Minor	To add Principle Investigators CV
	Minor	Ask for a EC approval if a new country included
Insurance	Minor	Not possible to add
	Medium	To add Investigation site selection report
	Medium	To add training records (evidence, that the investigators have been trained)
Indication/intended use in IFU	Medium	Precise « total or partial replacement » in the CRF
Target groups	Medium	Include training records, providing evidence, that the investigators have been trained
Market Experience feedback	Medium	Market feedback should be collected at list once a year

4 CONCLUSION/DISCUSSIONS

MDD to MDR transition is a very challenging step, and the key of success is the organization. The establishment of the regulatory roadmap with deadlines and budgeting is absolutely necessary.
GAP analysis for all the important endpoints could be very helpful. In our thesis we assessed PMCF report, but other topics could be reviewed:

- CE Marking Technical File or Design Dossier
- Current device class and product families
- Risk management file review
- Clinical Evaluation Report(s)…

Below is the table that resume all the identified non-compliances, detected by the GAP Analysis of the Filler-3ND femoral stem. We estimated the level of each non-compliance and suggested possible correction action.

We can see that the PMCF Gap Analysis results are good and some non-compliances can easily be corrected, except one, but it is a minor non-compliance.

We are convinced that the sufficient clinical data is the most important point of the new MDR. It is necessary to collect the data systemically in the most exhaustive way.

The key success in this process is the investigators implication. Therefore, our goal is to instill in investigators the importance of clinical follow-ups, by bringing arguments and following them in each step of data collection.

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