healthy data

KEEP YOUR MEDICAL DEVICE CE-MARKED!

IBA – POST MARKET STUDY, TECHNICAL FILE

iba Institute of Biostatistics and Analyses

Post-Market Study / MDR / IBA

Your device already has CE approval and you need a Post-Market Study?

The Regulation (MDR) requirements should be implemented and **applied on 26th May 2020**. At this time manufacturers of medical devices should have implemented Post-Market Clinical Follow-up (PMCF) procedures, that **should be the part of post-marketing surveillance and MD technical file**.

MDR

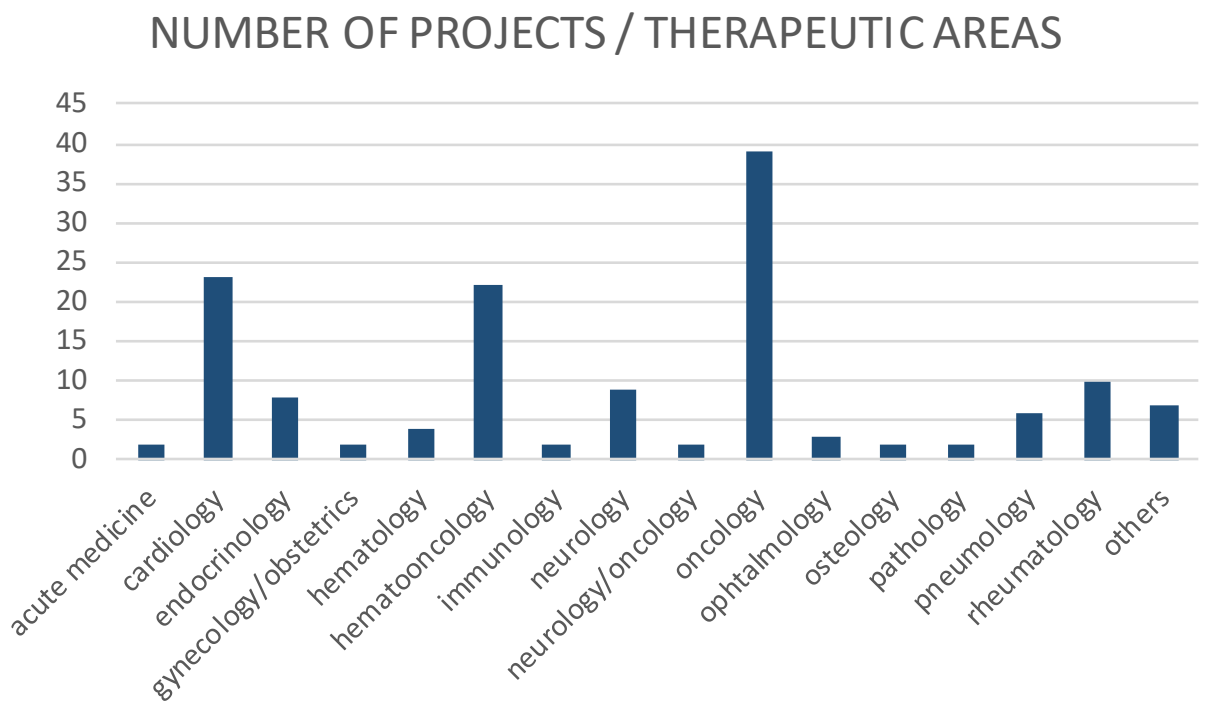
Regulations (EU) 2017/745 of European parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No. 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

New EU Legislative requirements = New Medical devices manufacturers obligations

IBA – Institute of Biostatistics and Analyses can help you.

IBA is spin-off organization of Masaryk University, based in the Czech Republic, EU.

IBA has got many years of experience in pharmaceutical and biotechnological industry, especially with the complete organization of post-marketing clinical studies and clinical registries from its design to final analytical processing and result interpretation.



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About MDR

Important facts about MDR

A PMCF study can determine whether the safety and performance of a medical device are still valid, even years after market launch. Through PMCF, potential changes in device usage and faults and weak traits of a device can be detected earlier and modified, leading to better, lower-risk products.

PMCF studies have been defined by MEDDEV years ago, but MEDDEV is not legally binding. MEDDEV 2.12/2 defines PMCF studies as an essential part of Post-Market Surveillance (PMS). Now, **with new MDR, PMCF investigation is not only recommended, but obligatory for each medical device manufacturer.**

The dramatical difference between PMCF according to MDD (Directive 93/42/EEC) and newly valid MDR (2017/745/EU) is the procedure for demonstration of clinical compliance. **Demonstration of clinical compliance** must be related to the device or a narrowly defined equivalent device, and **it must be based on methodologically sound data with medical scientific relevance (real-world evidence data).**

PMCF relates to proper clinical data of medical device already CE marked! Claims must be supported by data related to the actual device (or narrowly defined equivalent device) and **the data quality must be specified in detail!**

About PMCF

What is needed to know about PMCF?

- PMCF must be initiated by the manufacturer
- PMCF is mandatory regulatory requirement
- PMCF confirms the safety and clinical performance of the device throughout its lifetime (devices that have been on the market for a long time are especially vulnerable)
- PMCF can identify previously unknown side-effects and monitor the identified side-effects and contraindications (especially at new medical devices)
- PMCF studies are mandatory if the clinical evaluation for the initial conformity assessment of the medical device is based on equivalent devices
- Can bridge the gap in clinical data needed to comply with MDD and newly MDR (all patient data must be compliant with the Helsinki Declaration)
- PMCF is required for innovative products and for high risk devices
- PMCF is required if safety and efficacy of the medical device have so far only been shown for a selected patient population
- PMCF studies must be carried according to documented, pro-active and well-organized methods and procedure determined by a PMCF plan

PMCF studies may include:

- Continued follow-up of patients from clinical investigations before market approval
- New clinical investigations
- Analysis of data from prospective observational studies (non-interventional studies)
- Analysis of relevant retrospective data of treated patients (retrospective data collection)

It is high time to start gathering clinical data and generate clinical evidence for MD certified or re-certified in 2020.

Recommendation how to comply or maintain compliance under new MDR:

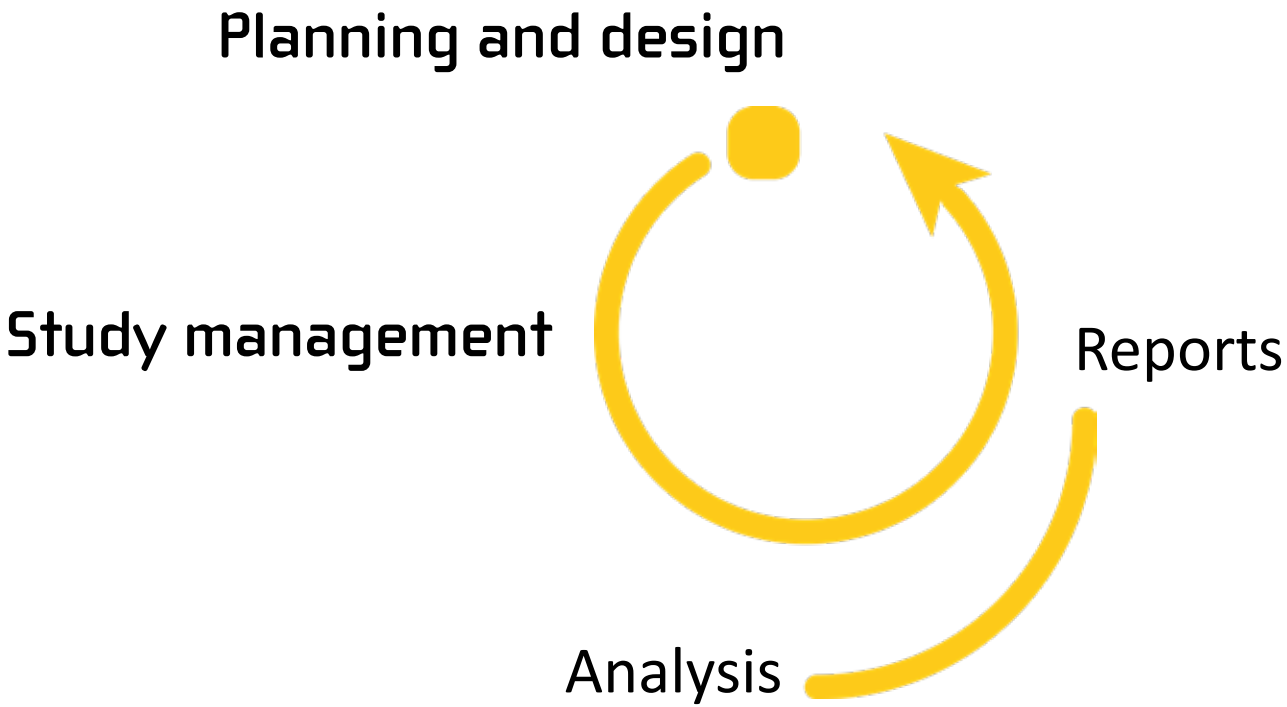
- Start PMCF investigation now, with medical device still CE-marked under current MDD to prepare certification under the new MDR
- Perform a clinical data gap analysis to see what clinical data you need to gather
- Design investigations complying with the new MDR requirements to obtain clinical data for certification under the MDR
- Verify the updated Clinical Master Plan with your Notified Body to ensure future acceptance of the results

IBA can help you

IBA can help you to meet the MDR requirements!

IBA can help you plan and conduct Post-Market Studies for medical devices!

Based on our extensive knowledge and profound experience of clinical data collection and post-marketing non-interventional studies (prospective or retrospective), we can take over either single tasks or the whole package of PMCF for you:



1. **Planning and design**
   a. Composition of study-hypotheses, aims and endpoints
   b. Sample size evaluation
   c. Specification of appropriate statistical tools, statistical reporting and analyses
   d. Developing study protocol and cooperation with preparation of clinical investigation plan (CIP)
2. **Study management**
   a. Selection of study centers and clinical investigators, contracting
   b. Preparation of documentation and case report forms (CRF, eCRF)
   c. Data collection and data management (quality, integrity and validity of data) complying with ISO/IEC 27001 requirements
   d. Communication with ethics committees and authorities (Notify Body)
3. **Analysis**
   a. Preparation of the data
   b. Descriptive and explorative data analysis
   c. Interpretation of the results
   d. Evaluation with regard to performance and effectiveness
4. **Reports**
   a. Monitoring reports
   b. Interim reports
   c. Final reports

We can manage your PMCF study and help you with planning and design. We offer consultation for eligibility and submission procedures. We can select your study sites, monitor your study, analyze the clinical data, and write the study reports. Thus, we can run your whole study or provide just the help you need to succeed.

Benefits for you:

- The results of managed studies and investigations by us, **can be used to evaluate cost-benefit ratio** for marketing and reimbursement purposes.
- Data of your own medical device will **support the re-certification of medical device without any problems.**
- You will collect long-term real-world data **to get experience on real world patients.**
- We can also help you with **Technical Files for all Classes of Medical Devices!**