Medical Devices

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Spotlight on similar devices under the Medical Device Regulation

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Abstract

This article evaluates the potential of similar devices in clinical documentations, such as clinical evaluation plans (CEPs), clinical evaluation reports (CERs), and post-market clinical follow-up evaluation (PMCF) documents, based on the Regulation (EU) 2017/745 (referred to as the medical device regulation [MDR] in this article) and relevant Medical Device Coordination Group (MDCG) documents. Beginning with the concept of similar devices, the article presents how to identify similar devices, use similar device data, and apply this knowledge to clinical documentations. A stepwise approach provided at the end of the article aims to assist manufacturers and medical writers in this process.

Understanding similar devices

According to the MDR,[1] similar devices belong to the same generic device group, which is defined as "a set of devices having the same or similar intended purposes or a commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics". In simpler words, any device can serve as a similar device if it has a similar or the same intended purpose OR is based on a common technology without exhaustive demonstration of technical, biological, and clinical characteristics, which are obligatory to claim equivalence. Another key difference between a similar and an equivalent device is that manufacturers are not required to have "sufficient levels of access to the data relating to devices…" for similar devices. As a result, claiming similarity will be more straightforward than claiming equivalence.

To give an example of an Ilizarov lower extremity ring external fixator, which is used to stabilise broken bones using rigid rods, pins, and connectors inserted through the skin into the bone, the abovementioned definition can be translated as:

- "same or similar intended purpose": various medical devices used for the fixation of a broken upper or lower leg

OR

- "commonality of technology": any external fixator.

An important detail to mention is the use of OR (not AND) between the two elements of the MDR definition, making them theoretically mutually exclusive. How this will be used in practice, both during preparation of clinical documentations and their review, remains to be seen.

Using similar device data

Similar device data for legacy devices based on well-established technologies (WETs)

According to MDCG 2020-6,[2] "It is important to identify all available sources of clinical data from both the pre-market and post-market phases. This will include all of the clinical data which is generated and held by the manufacturer as well as clinical data for equivalent or similar devices."

Similar devices can provide "soft" data, which rank roughly similar in level of evidence to the clinical evidence provided by the state of the art (SOTA) but lower to the clinical data coming from own and/or equivalent devices (see MDCG 2020-6 Appendix III). Nevertheless, manufacturers can use similar device data for setting benchmark values for evaluating clinical performance and safety of own devices. A CEP or PMCF plan would be great documents for this purpose. (See the September 2020 issue of *Medical Writing* for the article on new documents required by the medical device regulation, p. 24). According to MDCG 2020-6:

- "Data from similar devices may be used, for example, to demonstrate ubiquity of design, lack of novelty, known safety and performance profile of a generic group of devices, etc."
- For well-established technologies the clinical evaluation can be based on data coming from similar devices, under the conditions detailed in paragraph 6.5 (e).
- Data from similar devices may be also important to establish whether the device under evaluation and similar devices belong to the group of devices considered as "well established technologies (WET)."

Another key difference between a similar and an equivalent device is that manufacturers are not required to have "sufficient levels of access to the data relating to devices..." for similar devices.

Similar device data for clinical evaluations not based on equivalence

When clinical evaluations cannot be based on equivalence, manufacturers can make use of similar device data in several ways. According to MDCG 2020-5,[3] similar devices may be useful for the following:

1. "Ensuring that the risk management system is comprehensive by identifying relevant hazards and clinical risks.
2. Understanding the state of the art, the natural course of disease and alternative available treatment options.
3. Helping to define the scope of the clinical evaluation, by identifying any design features in similar devices that pose special performance or safety concerns.
4. Provide input for clinical investigation design or post market clinical follow-up design, and the post-market surveillance system.
5. Identification of relevant and specified clinical

outcome parameters for the intended clinical benefits, based on the published clinical data pertaining to the similar device(s).

6. To define minimum requirements for a quantified clinical benefit that is considered clinically relevant, and/or to identify acceptable occurrence rates of risks and adverse events."

In summary, similar device data can be beneficial for all types of clinical evaluations including those based on own, equivalent, or no clinical data. Additionally, similar device data can be used in both pre- and post-market stages of a clinical evaluation. Finally, similar device data could further support legacy devices based on WET.

In summary, similar device data can be beneficial for all types of clinical evaluations including those based on own, equivalent, or no clinical data.

Presenting similar device data in clinical documentations

According to MDR Annex II 1.2(b), technical documentation shall include "an overview of identified similar devices available on the Union or international markets, where such devices exist". Similarly, the template provided in MDC 2020-13 (Clinical evaluation assessment report template, section J)[4] insists that notified bodies check for similar device data. Therefore, manufacturers are expected to search for similar devices as well as identify and include them in their technical documentation where such devices exist. Where no such devices exist (in exceptional cases such as unique intended purpose and technology), manufacturers can state this clearly in the CER to manage reviewer expectations upfront.

Where similar devices exist, the following stepwise approach may be useful to identify and assess these devices and present them in clinical documentations. This follows the MEDDEV 2.7/1 revision 4 structure for CERs. Please note that this is not an exhaustive list; there are several approaches that can be used and are beyond the scope of this article.

1. Similar device identification and selection (stage 0, scoping)

a. **Identify:** As a manufacturer, the first step is to identify similar devices. It must be stressed that identifying similar devices can easily be the most challenging step of this process. Manufacturers will have to show that their selection is based on scientifically sound rationales such as market share of the devices, quality and quantity of the available data, known safety and performance profiles of the devices, etc.

b. **Justify:** Once similar devices are selected, manufacturers will have to justify their choice and address the question of why five and not 20 devices are selected. This would include showing strict compliance to the MDR definition i.e., same or similar intended purpose or commonality of technology as well as the criteria mentioned in MDCG 2020-7 section E (product name, intended purpose, intended users, intended patient population, medical condition, and indication). This must be done at the level of the PMCF plan and should ideally be done at the level of the CEP or CER as well.

2. Similar device data identification (stage 1, identification of pertinent data)

Once similar devices are selected, all data available on these devices and / or known to the manufacturer must be searched for and discussed in clinical documentations.

Similar device data sources may include:

a. Scientific literature including peer-reviewed scientific articles, Cochrane systematic reviews, etc.
b. Post-market clinical follow-up studies
c. Post-market surveillance data
d. Registries and other real-world evidence

3. Similar device data appraisal (stage 2, appraisal of pertinent data)

This could be optional. As for the clinical data, similar device data can also be appraised for suitability and contribution criteria.

4. Similar device data analysis (stage 3, analysis of clinical data)

a. Similar device data must be analysed at the level of the PMCF evaluation report (PMCFER) and ideally also in the CER. Within the PMCFER, manufacturers are encouraged to follow MDCG 2020-8 section D.[5] Within the CER, similar device data could be discussed separate from the SOTA or as part of the SOTA. Alternatively, similar device data can be discussed in an independent set of documentations with appropriate interfaces to the clinical documentations.

b. The conclusions drawn from similar device data shall be used to update risk management and post-market surveillance activities including PMCF.

All this for what?

At a first glance, all this may seem a lot of work. And undoubtedly, it is. But I am sure the industry will agree this is for the betterment. Imagine how identifying the so called "class effect" earlier could have saved several thousands of patients from the complications of metal-on-metal hips? If similar device data would have been analysed, these patients would have had a far better and much safer experience. The goal of all this effort is clear: patient safety first!

Conclusion

As per the MDR, manufacturers are expected to identify similar devices and discuss similar device data in their clinical documentations, especially CERs and PMCFERs. The process of identifying and selecting similar devices, however, is not well defined and therefore gives manufacturers several possibilities of how it could be approached. Similar device data are expected to be used to provide threshold / benchmark values that can be used for evaluating clinical safety and performance profiles of devices under evaluation. These data will not only strengthen clinical conclusions but also allow manufacturers to make important decisions in both pre- and post-market phases of their clinical evaluations. Additionally, all types of clinical evaluations (based on own, equivalent, or no clinical data) can benefit from similar devices. As with the whole clinical evaluation process, similar device data shall also be continuously and systematically updated.

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Disclosures and conflicts of interest

The author declares no conflicts of interest.

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