Clinical evaluation without clinical data

April 2024

Article 61(10) of the MDR regulates the possibility of conducting a clinical evaluation without clinical data. The cases in which this is possible and the conditions under which this article can be applied are explained below.

According to Article 61(10) of the Medical Device Regulation (MDR), a clinical evaluation can be performed without clinical data in certain cases. It is important to note that a clinical evaluation is still required when applying this article.

When is the application of Article 61(10) possible?

In the application of Article 61(10), the use of clinical data to demonstrate conformity with the general safety and performance requirements may be waived if this does not appear appropriate. In such cases, the manufacturer shall provide adequate justification based on:

- the results of risk management and
- the specific interactions between the product and the human body,
- the intended clinical performance and
- the manufacturer's specifications.

However, it should be noted that Article 61(10) cannot be applied to Class III devices or implantable devices. This restriction is expressed in the MDR by the half-sentence „Without prejudice to paragraph 4" and is also clearly stated in MDCG document 2020-6.

For all other device classes, i.e. Class I to IIb (excluding implants), Article 61(10) can be applied. However, this should be an exception.

The decision to apply Article 61(10) must be adequately justified by the manufacturer in the clinical evaluation. This justification should be based on an assessment of the available evidence in accordance with the requirements of the MDR.

It is important to note that the application of Article 61(10) should be carefully considered. The notified body does this as well: In accordance with MDCG document 2020-13 (Clinical Evaluation Assessment Report), notified bodies check whether

- there is sufficient justification,
- the available evidence, e.g. in the form of performance evaluations, bench tests and preclinical studies, is sufficient,
- clinical literature data on the product or an equivalent product was searched for,
- the results of risk management support the application of Art. 61(10),
- there is sufficient information on the interaction between the product and the human body,

Dr. rer. nat. Marion Fehlker
Director of Operations,
authorized representative
novineon CRO GmbH
marion.fehlker@novineon.com
+49 7071 / 98979 - 124

Friedrich-Miescher-Straße 9
72076 Tuebingen
www.novineon.com

novineon cro

- whether the intended performance of the product allows its demonstration to be based on non-clinical data,
- whether there are marketing claims that need to be supported by clinical data.

Examples of medical devices for which the application of Article 61(10) could be justified are

- mouth spatula
- dental treatment units
- patient positioning systems
- operating lights
- stand-alone software
- blood glucose meters
- wheelchairs
- walking aids

What these products have in common is that their use is associated with only minimal risks, which are often related to their usability. Contact with the human body, if any, is not critical. The clinical benefit is often indirect, e.g. by supporting a diagnosis or treatment.

Accordingly, the parameters for determining the safety and performance of the products are more of a technical nature. Parameters such as reproducibility of measurement or dimensional stability (for many aids) are easier to test in the laboratory than in clinical application.

Article 61(10) is by no means applicable to all „simpler" medical devices. As soon as there is a direct clinical benefit, the performance must generally be demonstrated on the basis of clinical data - for example, in the case of UV lamps for the treatment of skin diseases or compression stockings to improve blood circulation.

Despite the application of Article 61(10), clinical evaluation remains essential!

How can safety and performance be demonstrated?

If Article 61(10) of the MDR is applicable, appropriate data for demonstrating safety and performance can be obtained, for example, in the following ways:

- technical tests
- preclinical tests
- usability tests
- simulations

What does this mean for clinical evaluation?

Even when applying Article 61(10) of the MDR, the clinical evaluation remains indispensable. Clinical evaluation is an important part of the conformity assessment procedure according to the MDR. It includes the assessment of the safety and performance of a medical device when used for its intended purpose. If no clinical benefit is claimed for the device, which must be demonstrated based on clinical data, the clinical evaluation can also be based primarily on preclinical data.

It is important that an appropriate assessment of the benefit-risk ratio of the product is possible on the basis of the available data.

Conclusion

According to Article 61(10) of the MDR, a clinical evaluation may be performed without clinical data if the manufacturer provides an adequate justification based on the results of the risk management, the specific interactions between the medical device and the human body, the intended clinical performance and the information provided by the manufacturer. It should be noted, however, that despite the application of Article 61(10), clinical evaluation remains essential. Safety and performance must be demonstrated by other appropriate means, for example by technical tests.