Developers guidance

Demonstrating clinical performance of medical devices with a Clinical Evaluation Report (CER)

This is required guidance

It is legally required and it is an essential activity.

From:

- Medicines and Healthcare products Regulatory Agency (MHRA)

This Guide covers:

- Great Britain (England, Scotland, Wales)

To get a UKCA mark for medical devices, you need to include a Clinical Evaluation Report (CER) in your application documentation.

Clinical performance and why it's important

To meet the essential requirements of the Medical Devices Regulations (UK MDR 2002), you need to prove that your medical device is safe and effective. This will relate to the intended use of your medical device.

Demonstrating clinical performance will help you gain a UKCA mark. It will also provide the foundation for marketing materials and support discussions with potential customers.

If you do not show adequate clinical performance, you will not get a UKCA mark.

Medical devices: how you demonstrate clinical performance

You need to produce a Clinical Evaluation Report (CER) to demonstrate clinical performance.

The CER is a living document that you'll need to keep up to date throughout the lifecycle of your medical device. It includes the evidence used to prove that the benefits of medical devices outweigh the risks of using them.

The CER is produced and maintained by following the structured process of 'clinical evaluation'. During clinical evaluation, you need to demonstrate scientific, analytical and clinical validation.

Meeting these requirements is achieved through a variety of means including (but not limited to):

- defining the 'state of the art' through a literature review
- in-house testing
- prospective premarket trials
- post-market clinical follow-up studies

The complexity of creating the CER is related to the medical device, and it's intended use. So, an intended use statement will help you to clearly identify the evidence requirements you need to meet the regulations. Remember, you can only get a UKCA mark by showing adequate clinical performance.

The CER must be reviewed periodically and updated to represent changes in the state of the art and evidence relating to the device.

You can use the following guidance to support you in doing a clinical evaluation:

- International Medical Device Regulators Forum – Software as a Medical Device (SaMD): Clinical Evaluation
- MEDDEV 2.7/1 rev4 Clinical Evaluation: Guide for manufacturers and notified bodies
- Guidance MEDDEVs

This information is not intended to replace formal statutory guidance regarding legal requirements. For an authoritative view of what regulations require beyond this digest, please see the relevant gov.uk web pages pertaining to the MHRA.

