Developers guidance

Writing an intended purpose statement for software medical devices

This is required guidance

It is legally required and it is an essential activity.

This Guide covers:

- Great Britain (England, Scotland, Wales)

From:

- Medicines and Healthcare products Regulatory Agency (MHRA)

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To place your medical device on the health and social care market, you should have an intended purpose statement. You need to assess this regularly to make sure it remains fit for purpose. Changes to the intended purpose of a medical device will require regulatory reassessment.

Understanding an intended purpose statement

Software and apps that meet the definition of a medical device must comply with the UK Medical Device Regulations 2002 (UK MDR 2002). The intended use is legally determined by "data supplied on the labelling, the instructions for use and/or the promotional materials". Creating a master intended purpose statement ensures that regulatory requirements are more easily and consistently identified and met.

Think about your medical device's intended purpose early in its lifecycle. Creating a statement will help you plan the technology lifecycle more efficiently. It will also help you follow the appropriate regulatory requirements. This should stop you wasting resources on inappropriate evidence generation.

An intended purpose statement defines who will use your medical device, how it works and who it is for.

The intended purpose statement also helps determine:

- where the medical device fits within specific care pathways
- whether it meets the definition of a medical device
- its medical device risk class, and
- the evidence that needs to be generated

If your digital technology is not a medical device, you do not need to produce an intended purpose statement. But your technology may become a medical device if you change it to meet customer needs. So, consider creating an intended purpose statement for your digital technology early in its lifecycle. This may also help when generating your value proposition.

Creating an intended purpose statement

Use clear language and clinically-focused terminology.

Include these 4 key elements:

- structure and function of the device
- intended population
- intended user
- intended use environment

It is your responsibility as the developer to determine what level of detail is required for each of the elements. It is important to note that the MHRA interprets the elements of an intended purpose as broadly as possible and from the stance of an objective observer.

Think about whether you will be able to generate clinical evidence to demonstrate your device meets the specifics of the intended purpose. If not, then your intended purpose is likely to be unsuitable.

For more information, see crafting an intended purpose in the context of Software as a Medical Device from the Medicines and Healthcare products Regulatory Agency.

After you have written your intended purpose statement

The intended purpose statement forms part of your medical device's technical documentation.

Depending on the device's risk classification and your chosen route to market, you may need to make a submission to an approved body. If so, you will include the intended purpose statement in the submission documents for review alongside the provided clinical evidence to ensure adequate alignment.

The MHRA encourages you to make your intended purpose statement publicly available. This transparency will help you when engaging with regulators, adopters and the wider health and social care system.

What happens if the intended purpose changes?

There may be changes in the clinical pathway, the requirements of end users and patients, or the functionality of your medical device. These may affect the intended purpose.

If so, you will have to update the intended purpose statement and supporting evidence.

Changes to your medical device's intended purpose statement will need a review by your approved body, where applicable. This may require reassessment of the documentation if the change is significant enough to alter the original risk-to-benefit assessment.

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.

