Developers guidance

Aligning the intended purpose and value proposition of your digital technology in health and social

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This is best practice guidance

Although not legally required, it's an essential activity.

This Guide covers:

- Great Britain (England, Scotland, Wales)

From:

- Medicines and Healthcare products Regulatory Agency (MHRA)
- National Institute for Health and Care Excellence (NICE)

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Aligning the intended purpose and value proposition of your digital technology is vital to placing your technology on the health and social care market.

Risks of not aligning the intended purpose and value proposition of your digital technology

To place your digital technology on the health and social care market, you need to:

- define and document the intended purpose of your technology
- outline and document its value proposition and
- make sure the 2 align

Aligning your intended purpose and value proposition helps make sure you collect appropriate evidence and comply with the appropriate regulatory checks.

Not aligning the intended purpose and value proposition might:

- suggest to regulators, health technology assessment bodies or adopters that you have not understood your technology's regulations or have not complied with them
- raise doubts about the safety and effectiveness of your technology, because it suggests you have not done the regulatory checks appropriate to its intended purpose. This means the technology could have safety issues
- risk wasting resources on inappropriate evidence generation. You could be required to retrospectively generate further evidence, which would delay placing your product on the market

Align the intended purpose and value proposition at an early stage, ideally during technology conceptualisation. This will make sure you follow the correct regulations. Regularly review both documents throughout the lifecycle of your digital technology, especially if your technology changes. This will help you place your technology on the health and social care market.

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.

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