Adopters guidance

Understanding post-market surveillance of medical devices

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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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Post-market surveillance of medical devices is the legal responsibility of the developer. But it is important for adopters to understand and support post-market surveillance of medical devices.

Adopters' role in supporting post-market surveillance of medical devices

As an adopter, you play a role in making sure a medical device is safe to use. This includes understanding how the developer does post-market surveillance for the device, so you can support it.

When developers place medical devices on the UK market, they have a legal requirement to:

- collect and analyse data on the performance and safety of the device
- have a system in place to do this
- report safety issues to the MHRA and investigate the root cause

This 'post-market surveillance' makes sure an adopted device is acceptably safe to use for as long as it is in use. You play an essential role in supporting this (for example, helping the developer understand how the device is performing). You should also report safety concerns about medical devices directly to the MHRA using the Yellow Card reporting site.

How adopters support post-market surveillance

You and the developer should agree a plan for ongoing data collection about the performance and safety of the device. You will consider together what data the developer needs and how this should be collected and distributed. You should also discuss and agree on how quickly these activities can occur; developers will be required to meet timelines set by regulations. For example, does the developer need actual clinical outcomes to assess the clinical performance of the device? If so, you will need to consider data regulations for digital technologies and allocate staff time.

Your organisation should have a clearly identified person responsible for collecting and providing the required data to the developer.

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For more information about ongoing data collection, see NICE's Evidence Standards Framework. The Evidence Standards Framework is designed to support local or regional evaluations of a digital technology.

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