Developers guidance

Post-market surveillance of 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)

Last reviewed: 14 July 2023

Last updated: 14 July 2023

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After your medical device is placed on the UK market, you should monitor the device and report any safety incidents to the MHRA. This is known as post-market surveillance.

Why you should do post-market surveillance

Post-market surveillance makes sure your device is acceptably safe to use for as long as it is in use. If you do not follow the requirements the MHRA may prosecute you. This could result in 6 months in prison or an unlimited fine.

How to do post-market surveillance

Make sure your quality management system is set up appropriately

You should collect and analyse data on the performance and safety of your medical device in a systematic manner. You will use your quality management system to help you do this. Having this system in place is a core part of medical device safety. So, it's important to make sure the system is set up appropriately.

Your quality management system will likely need:

- processes for collecting information (for example, feedback or complaints from users and audit findings)
- analytical methods to assess collected data and identify reportable incidents
- procedures and systems for investigating the cause of safety concerns and implementing corrective actions
- tools to trace and identify the device in case corrective actions are needed (for example, traceability of a potentially defective device so it can be recalled)

See our guidance on planning your quality management system and the relevant standards you should follow to create it.

Identifying an adverse incident

A safety concern is deemed to be a reportable adverse incident when it meets these 3 criteria:

- an event has occurred

- the device is suspected to be a contributory cause of the event
- the event resulted in, or may have resulted in, death or a serious deterioration in the state of health of a patient or person

Note that an ‘event’ is not limited to use of the device by or for a patient. An ‘event’ includes device testing, examination of supplied information or wider scientific information that could lead or has led to an event.

Not all reportable events result in direct harm from the situation or an intervention. An event is still reportable if no injury was sustained but could occur if the event is repeated.

Reporting an adverse incident to the MHRA

You should notify the MHRA as soon as you become aware that your device may have caused or contributed to a reportable incident. Report individual incidents on the MORE portal.

Each individual report must lead to a final vigilance report, unless you combine the initial and final report into one report. The final report should include your root cause analysis and details of any similar incidents that have occurred, along with the corrective or preventative measures that you took.

You can find guidance on how to analyse the root cause in ISO 14971.

Some adverse incidents can be submitted as part of periodic summary reporting. You would have to arrange details of the timing and content of periodic summary reports on an individual basis with the MHRA.

For more information on the vigilance system and what constitutes a reportable incident, see the MHRA’s guidance on vigilance.

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If your technology is Software as a Medical Device (SaMD), indirect harm is the most probable outcome of an adverse incident. It is important you understand types of indirect harm and how it is caused, so you can identify adverse incidents.

Identifying adverse incidents

Indirect harm from using SaMD may be a consequence of:

- the medical decision
- action taken or not taken by healthcare professionals based on information provided by the SaMD
- action taken or not taken by patients or the public based on information provided by the SaMD

Below are some types of adverse incidents from using SaMD, with examples.

Performance issues: a technology remotely monitoring vital signs in a care home fails to correctly detect the assigned parameters (pulse rate, respiratory rate and oxygen saturation). This leads to a delay in diagnosis or treatment

Diagnostic accuracy issue: a dermatology app used for detecting melanoma gives an inaccurate result. As a consequence, the user decides not to seek an expert clinical opinion

Decision support software resulting in harm: a clinical calculator produces an incorrect calculation. A patient is prescribed the wrong amount of medication as a result

Issues with connected hardware or software: antivirus software installed on a device is non-compatible with the SaMD and causes it to malfunction (that is, the device that runs the software causes harm)

User error resulting in harm: a user enters the wrong value into a contraception app. The user relies on an incorrect output and unintentionally becomes pregnant

Inadequate labelling and instructions for use: a tablet-based SaMD is not labelled with the correct cleaning instructions, which leads to cross contamination between patients

Computer system security problem: a SaMD is the target of a cyber attack, causing corruption of patient data stored on the device. This leads to an incorrect or delayed diagnosis

Read the MHRA's guidance on reporting adverse incidents for Software as a Medical Device for more information, including examples of indirect harm and its causes.

You should notify the MHRA as soon as you become aware that your SaMD may have caused or contributed to a reportable incident. Report individual incidents on the MORE portal.

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