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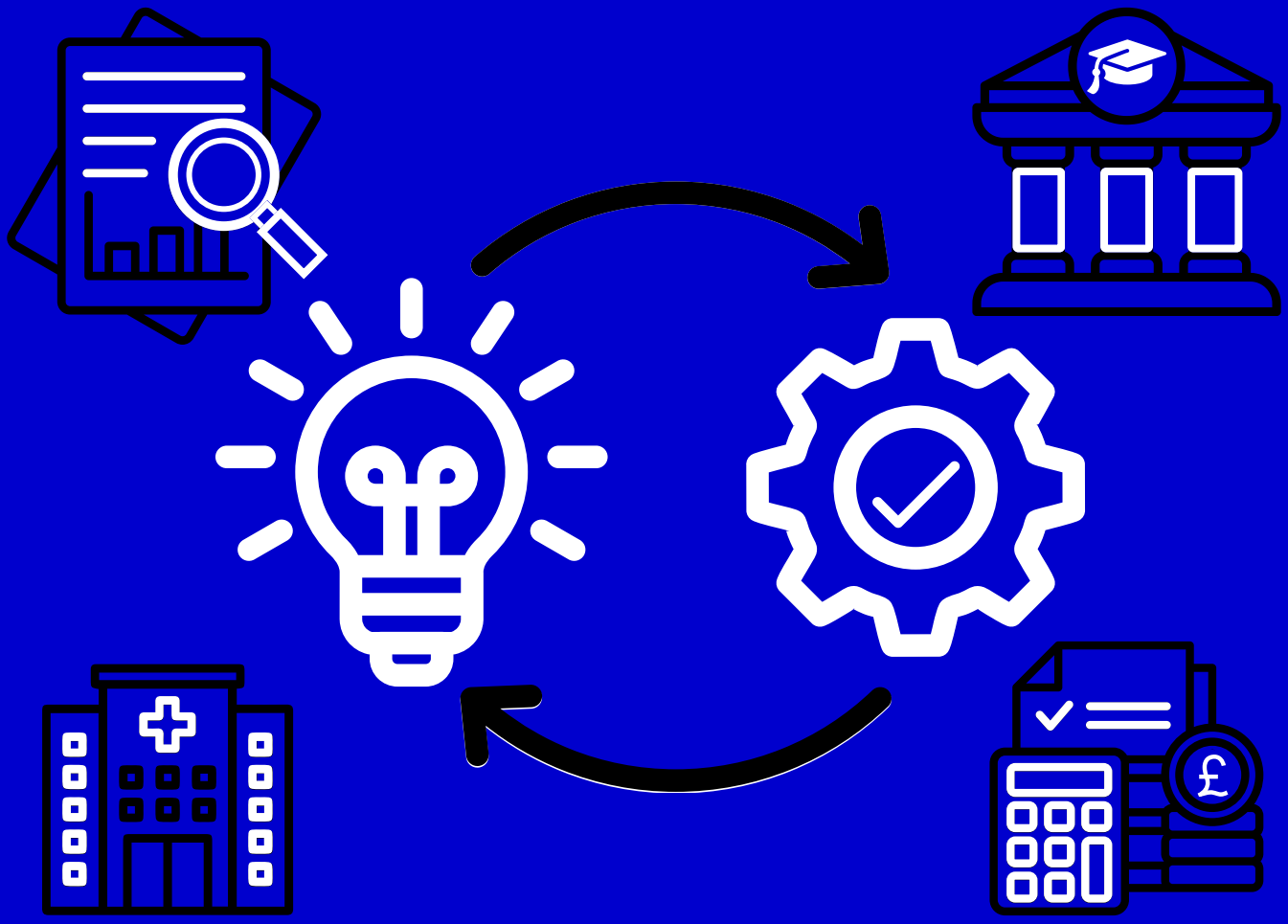
MedTechONE

FROM IDEA TO ADOPTION

PART 9



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FROM IDEA TO ADOPTION

The path to commercialisation is long and complex. From the synthesis of an innovative idea, through testing and iterations, through clinical trials, and through regulatory and commercialisation processes, this set of resources aims to de-mystify some of the key concepts you should be aware of.

As it was too bulky to have all of the information in a single resource, we recommend you read this document alongside the other parts of this piece on the MedTechONE Collaborative webpage.

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POST-MARKET SURVEILLANCE

POST-MARKET SURVEILLANCE

"... the practice of monitoring the safety of a pharmaceutical drug or medical device after it has been released on the market and is an important part of the science of pharmacovigilance."

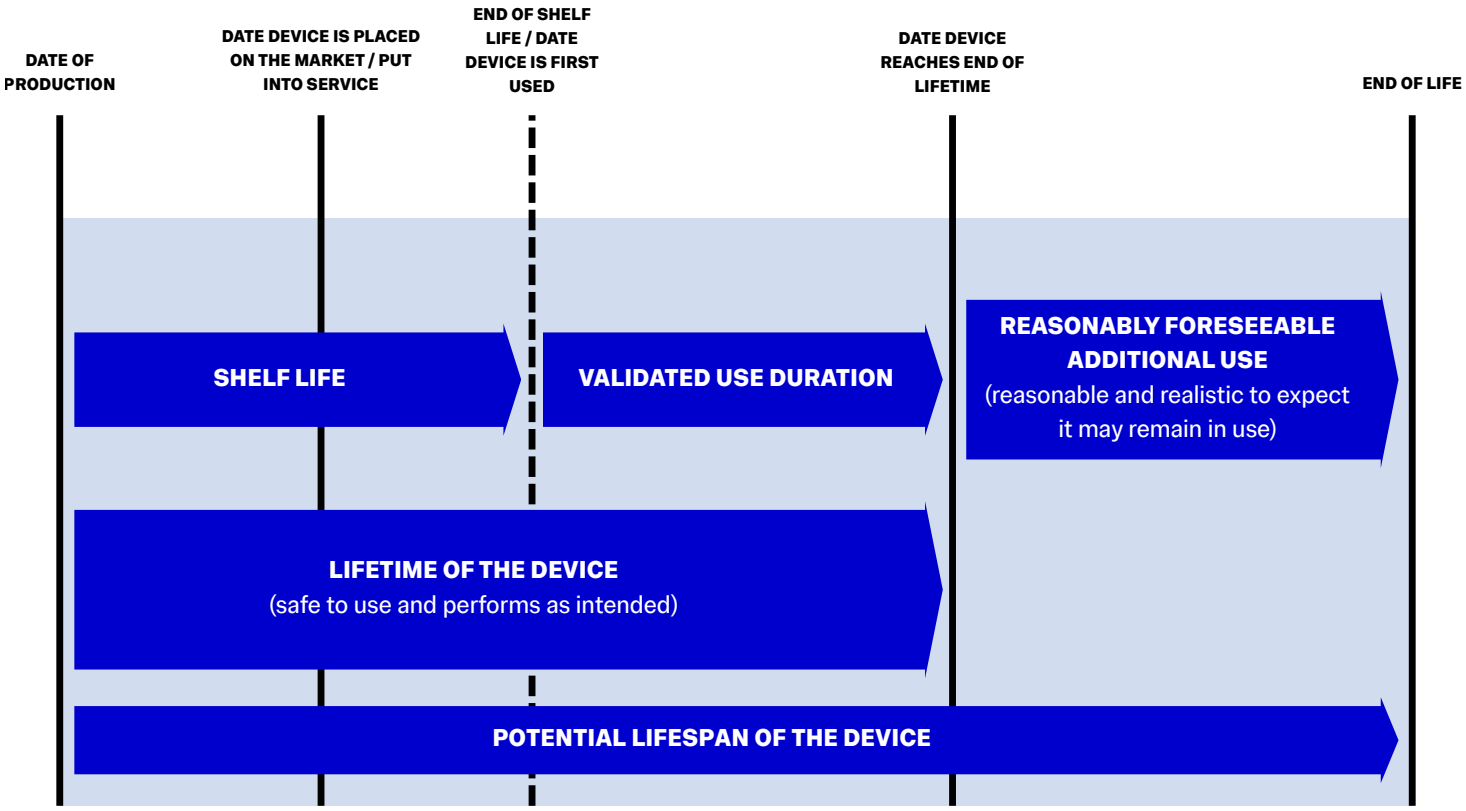
The Medical Devices (Post-market Surveillance Requirements) (Amendment)(Great Britain) Regulations 2024 amends the UK Medical Devices Regulations 2002 (MDR 2002) by adding a new Part 4A on this topic.

Devices to which the PMS Regulations do not apply:

- Devices subject to clinical investigation or performance study. This includes where the device already has a UKCA/CE mark but is being used outside of the exact conditions of that approval for the purposes of a clinical investigation. You will still need to adhere to Serious Adverse Event Reporting as per the guidance on Clinical Investigations for Medical Devices.
- Devices that have a valid Exceptional Use Authorisation in Great Britain.
- Where the device placed on the market has an authorisation issued by the Secretary of State under regulation 12(5), 26(3), or 39(2). However, you will still be required to monitor the safety and performance of the device..
- Discontinued devices, if the manufacturer no longer places any new devices of a model on the market. Different requirements apply for discontinued devices on the EU and NI markets, under "legacy devices".
- Devices manufactured in house, only for devices manufactured in house by a healthcare establishment, including custom made items, where there is no intention to place the device on the market.

LIFETIME OF A DEVICE

Defined as **"... the time of manufacture / production date to the end of the period the manufacturer has validated the device will perform as intended, sometimes referred to as the expected service life."** Which includes the device shelf life, where applicable.



POST-MARKET SURVEILLANCE

POST-MARKET SURVEILLANCE PERIOD

Defined as **"... beginning with the day on which the first device of a device model is put into service by the manufacturer or placed on the market, whichever is sooner, and ending with the end of the lifetime of the last device of that device model that is put into service by the manufacturer or placed on the market, whichever is later."**

PMS data refers to data from users and customers about a device's functioning, efficacy, any errors or malfunctions, and any other information of note.

As it is common for devices to be used beyond their lifetime, **manufacturers are encouraged to continue collecting PMS data both throughout the lifespan and after.** This can be a holistic process, and manufacturers can use their experience to decide on the natural lifespan of a device, as a starting point. Naturally this will change over time as the result of the collection of PMS data.

SERIOUS INCIDENTS & PUBLIC HEALTH THREATS

All serious incidents involving a medical device must be reported to the MHRA as part of the GB Vigilance System.

An "incident" is where any one or more of the following has occurred:

- The **device has malfunctioned or deteriorated** in performance when used as intended;
- A diagnostic device where **the device produces incorrect or inaccurate results** that inform clinical decisions;

POST-MARKET SURVEILLANCE

SERIOUS INCIDENTS & PUBLIC HEALTH THREATS

- **Users identify shortcomings in the device design or report difficulties using the device safely** (which can increase instances of user error), including deficiencies in provided instructions and information;
  - An inadequacy in the design of the device causing an inability on the part of the user to use the device safely and as intended by the manufacturer, including design failures in ergonomic components;
  - An inadequacy in the information supplied with the device by the manufacturer;

- The **device causes side effects** that negatively impact user/patient health, their care, or wide public health. Known possible side effects must be documented in the device's technical information but must be reported if they meet the "serious" threshold.

"Serious" incidents include those that directly, indirectly, or under different circumstances could have led to:

- Death, or;

- Serious deterioration in state of health;
  - Life-threatening illness or injury
  - Permanent impairment of a body structure or body function
  - Hospitalisation or prolongation of hospitalisation
  - Medical treatment required to prevent life-threatening illness, injury, or permanent impairment, including self-administered treatments.
  - Chronic disease
  - Foetal distress, foetal death, or congenital physical or mental impairment or other birth defect.

- A serious public health threat
  - Where the risk of death, serious illness, or serious deterioration could affect a significant population and needs urgent action to remedy.

POST-MARKET SURVEILLANCE

Other incidents may not need to be reported to the MHRA but will need to be reported in the manufacturer's post-market surveillance data, which is reported to the MHRA in accordance with the TREND Reporting Requirements.

In addition to the above definition of a "serious incident", there are three criteria that will be met when an incident needs to be reported:

1. **An incident has occurred, or an issue has been identified, including during performance testing completed by the manufacturer.** This also includes reviews of the information supplied with the device, and the event of any scientific evidence or information indicating a factor that could cause an incident.

2. **The device is suspected to be a contributor to, or the cause of, the incident,** including in incidents relating to side effects.

3. **The incident directly, or indirectly, caused, or may have caused, a death or a serious deterioration in the health of a patient**, user or other person.

The event officially becomes an incident when the second criteria applies, and becomes serious (and therefore reportable) when the third criteria applies.

VIGILANCE REPORTING REQUIREMENTS (REG 44CZ)

Who must report to the MHRA – The manufacturer, UK Responsible Person, or Authorised Representative must notify the MHRA about any incident or Field Safety Corrective Action (FSCA) that meets reporting criteria, including any periodic safety or trend reports that meet the criteria. Where the incident relates to the simultaneous or combined usage of two or more separate devices, then all related manufacturers must make the report on behalf of their involved device.

What must be reported – All serious incidents (as defined above), Field Safety Corrective Actions, and adverse trends. This is regardless of how the manufacturer became aware of the incident, and includes incidents reported to manufacturers via the MHRA as industry notifications of a public report (INPRs).

Reporting timescales – The manufacturer must notify the MHRA immediately upon being made aware of an incident. The maximum permitted timeframes are:

- **Serious Public Health threat** – No later than 2 calendar days after the manufacturer is made aware.
- **Death or unanticipated serious deterioration** – No later than 10 calendar days after the manufacturer is made aware.
- **All other serious incidents** – No later than 15 calendar days after the manufacturer is made aware.

If it is unclear whether an event is serious, or needs to be reported, the manufacturer must still make the report within the above timelines. **You must not delay reporting due to incomplete information** – You can make follow up reports with additional information later in the process.

VIGILANCE REPORTING REQUIREMENTS (REG 44CZ)

How to report to the MHRA – Reports should be submitted via the MORE Portal. The MHRA does not accept reports received through other channels.

What to include in the initial report:

- **Details of the initial reporter:**
  - **Healthcare professional** – Name, profession, contact details including email and phone number.
  - **Member of the public** – The manufacturer must verify with the person that they agree to their details being shared with the MHRA.
  - **Journal article, registry, social media etc.** – Provide details, cite sources, and provide copies of articles where possible, including any unique DOI numbers. When citing social media, ensure you adhere to data protection regulations when submitting the report.
- **Unique Device Identifier (UDI) information** – The manufacturer should be using a UDI system derived from a standardised issuing authority where possible e.g. GS1, HIBCC. This number can identify a specific device, even if other information is missing.
- **Information on other incidents related to the same device model or a variant** – "Same model" includes available devices even in different sizes, colours, naming variants, or manufacturer sites.

VIGILANCE REPORTING REQUIREMENTS (REG 44CZ)

Periodic Summary Reports – Manufacturers can submit a request to make a report via a "periodic summary report" to report multiple similar incidents with the same device / device type in a consolidated manner. This will require an overview analysis of the incident data.

Trend Reports – Part of the standard system of data recording and reporting for device manufacturers, these reports will detect when there is an increase in frequency or severity of incidents.

Vigilance Reporting must be baked into your Post-Market Surveillance procedures from the very beginning.

OVERALL TIMELINE

OVERALL TIMELINE

The natural, but rather unhelpful, answer to the question of an overall, innovation to commercialisation, timeline is: **It depends.**

As these resources show, there are many factors in bringing a medical technology to market. **Clinical research essential to the evidence base can take multiple years to complete** and may not necessarily always provide the desired results. Furthermore, **regulatory pathways can also take years to navigate**, though institutions in the UK such as NICE and the NHS are piloting programmes to improve these timelines. All of this is also dependent on achieving financial support. Then there are **the challenges of scale up** to work through, from staffing to manufacturing, all the way through to market access.

No two technologies are the same, but **studies from the UK government indicate that it takes an average of 3-7 years to get an innovation from concept to market** (on the UK market).

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CONTACTS

https://www.imperial.ac.uk/medtechone/

mt1-info@imperial.ac.uk

LinkedIn@MedTechONE