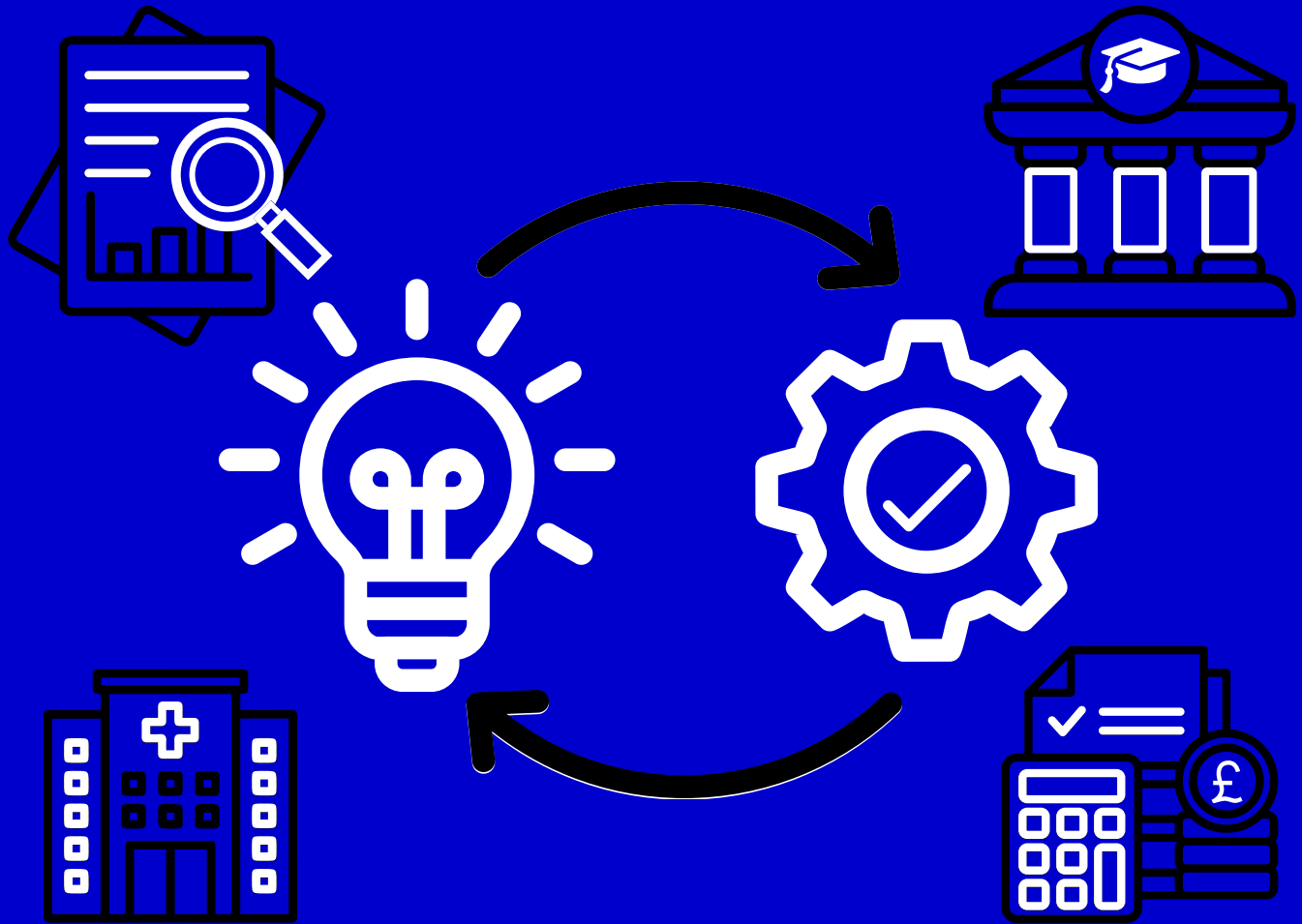


**FROM IDEA
TO
ADOPTION**

PART 1



**MT1
COLLABORATIVE**





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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CLINICAL RESEARCH VS MARKET RELEASE

The choice between pursuing a clinical research project vs market release depends on multiple factors:

WHAT EVIDENCE DO YOU NEED TO GO TO MARKET?

What is required by regulatory standards?

If aiming for the NHS, what evidence is required?

What Risk Classification does your product come under? Higher risk devices will require more evidence.

Reimbursement needs - You need to be able to demonstrate cost effectiveness

What is the target market? Adoption of more novel, non-standard technologies is reliant on a solid evidence base and scientific proof of efficacy.

REGULATORY PATHWAY

Have you achieved CE / UKCA marking?

Do you need FDA approval?

Do you need MHRA approval?



CLINICAL RESEARCH VS MARKET RELEASE

READINESS LEVELS: WHERE DOES YOUR INNOVATION SIT ON THE:

Technology Readiness Level

Business Readiness Level

Commercial Readiness Level

PRODUCT MATURITY

What evidence of efficacy and / or value do you have?

Is the product ready for market or still in development?

Have you planned manufacturing?

Have you completed economic assessments to price out scale up into a company, and also studies on how to price the end product?

Ultimately you should choose clinical research first if:

- The technology is entirely novel, and there is no existing evidence base for safety and efficacy.
- The technology is high risk e.g. implantables, life-sustaining technologies etc.
- Costs – The device is expensive.
- Support is needed from Key Opinion Leaders



CLINICAL RESEARCH VS MARKET RELEASE

Alternatively, you could go straight to market release if:

- The technology is an incremental innovation, builds on existing work and evidence, and is based on well-understood existing scientific evidence.
- The technology is low risk, requires minimal intervention, and has a low invasiveness e.g. mobility aids, eyeglasses, reusable surgical instruments.
- You can demonstrate there is a very real need for real world data that cannot be measure through scientific study.

Overall, this is not a decision that would be made by a single person, and it is recommended to consult financial, legal and other experts within the field to ensure you are compliant with regulatory and safety standards across the course of your innovations journey, and to give your technology the best chance of success.



REGULATORY LEGISLATION



REGULATORY LEGISLATION

CE MARKING & OTHER REGULATIONS

CE MARKING FOR THE UK AND EU MARKET

The EU no longer recognises UK Notified Bodies, and UK Notified Bodies are no longer able to issue CE Certifications. These Bodies have become UK Approved Bodies. Refer to the IES CE Marking & UKCA Marking Guide for detailed information.

REGULATING MEDICAL DEVICES IN THE UK

The Medicines and Healthcare Products Regulatory Agency (MHRA) is responsible for the regulation of medical devices made available on the market in Great Britain. As part of this, **all medical devices must be registered with the MHRA before being placed on the market** – This includes in vitro diagnostic tools, implantable devices, and any custom-made devices, systems, or procedure packs, as well as more classical definitions for “medical devices”.

The MHRA is responsible for:

- Performing market surveillance in the UK and making decisions about the marketing and supply of medical devices in the UK.
- The designation and monitoring of UK conformity assessment bodies.
- Enforcement of legislation on medical devices in the UK.

The MHRA will only accept registrations for devices manufactured in the UK.

For devices being manufactured outside of the UK, but being placed on the UK market, you must appoint an appropriately qualified Responsible Person to carry out all necessary tasks, including MHRA registration (the full responsibilities of the Responsible Person are laid out in the UK MDR 2002).



REGULATORY LEGISLATION

REGULATING MEDICAL DEVICES IN THE UK

All device manufacturers must comply with relevant product marking and conformity assessment requirements for medical devices.

Below is a short summary of the general responsibilities of the Responsible Person;

They must:

- Ensure that the declaration of conformity and technical documentation have been written, and that, where applicable, an assessment of conformity has been conducted by the manufacturer.
- Keep available a copy of the:
 - Technical documentation
 - Declaration of Conformity
 - Certificates

This includes any amendments and supplements and must be available on any request from the MHRA.

- When requested by the MHRA, provide any and all documentation required to prove the conformity of the device.

- When requested by the MHRA, and where the Responsible Person has access to the following, provide the MHRA with samples or access to the device.
- Where the Responsible Person does not have samples or access to the device, communicate any request from the MHRA to the manufacturer, and communicate to the MHRA the manufacturer's ability or willingness to provide samples or device access.
- Fully co-operate with the MHRA to eliminate and/or mitigate any risks associated with the device.
- Immediately inform the manufacturer of any complaints or incidents reported by users, clinicians, healthcare professionals or patients relating to the device.
- Where the manufacturer acts contrary to its regulated obligations under this legislation, the Responsible Person must:
 - Terminate the legal relationship with the manufacturer; and
 - Inform the MHRA, and any other relevant Approved Body, of the termination.



REGULATORY LEGISLATION

REGULATING MEDICAL DEVICES IN THE UK

N.B. Failure to register your device with the MHRA via an appropriate channel means you will not be able to lawfully place your device on the market.

Due to the UK leaving the EU, **there are some upcoming changes about the requirements for CE marks** on medical devices.

CE marked devices may be placed on the Great British / UK market to the following timelines:

- General medical devices compliant with the EU Medical Devices Directive (EU MDD) or EU Active Implantable Medical Devices Directive (AIMDD) with a valid declaration and CE marking can be placed on the market in Great Britain until the certification expiry, or 30th June 2028, whichever date is closest.

- In vitro Diagnostic Medical Devices (IVDs) compliant with the EU In Vitro Diagnostic Medical Devices Directive (EU IVDD) can be placed on the market in Great Britain until the certification expiry, or 30th June 2030, whichever date is closest.
- General medical devices including custom-made devices, compliant with the EU Medical Devices Regulation (EU MDR) and IVDs compliant with the EU In Vitro Diagnostic Medical Devices Regulation (EU IVDR) can be placed on the market in Great Britain until 30th June 2030.

It is a legal obligation to register your device with the MHRA, via an appropriate channel.



REGULATORY LEGISLATION

REGULATING MEDICAL DEVICES IN THE UK

Below is a short summary of the legislation that currently applies in Great Britain, note **that the route to market in Great Britain is informed by the below EU Directives, and may change at the end of the transition period:**

- Devices in Great Britain are regulated under the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002). This overarching legislation gave effect in UK law to the following:
 - **Directive 90/385/EEC** – Active implantable medical devices
 - **Directive 93/42/EEC** – Medical Devices
 - **Directive 98/79/EC** – In vitro diagnostic medical devices

You should consider obtaining professional expert advice and may need to check with a solicitor who specialises in this area to check which legislative framework applies to your device.



REGULATORY LEGISLATION

MHRA CLINICAL INVESTIGATIONS

CLINICAL INVESTIGATIONS UNDER THE MHRA - FOR THE APPROVAL OF NOVEL MEDICAL DEVICES

You may need to conduct a clinical assessment as part of the UKCA / CE Marking process, or equivalent. **You must inform the MHRA of the planned investigation at least 60 days prior to commencement.**

N.B. A notification is not required where the device under investigation is already approved/marked for the purpose under investigation.

The process for Clinical Investigations is as follows:

- MHRA applications are submitted automatically via IRAS.



- **Coordinated Assessment Pathway**
 - MHRA collaborates with the HRA to share information when assessing medical device clinical investigations. The MHRA application should be submitted first, and then the REC application submitted as soon as the MHRA approval is received.
 - When the MHRA receives the documentation, they will contact the Lead Investigator within 5 days to confirm the 60-day assessment period has commenced.
 - The assessment will involve experts assessing the medical device, and the design and safety of the planned project.
 - If you require a clarification, or if you object to any decisions, you must immediately contact the MHRA to arrange a teleconference to discuss a resolution.
 - A letter will be sent by the 60th day of the timeframe to confirm the decision as either “No Objection”, or “Objection” to the commencement of the proposed project.



REGULATORY LEGISLATION

MHRA CLINICAL INVESTIGATIONS

You will be required to pay a fee to conduct a Clinical Investigation. **N.B.** A final decision will not be received until payment has been received by the MHRA.

- For specific enquiries, email info@mhra.gov.uk
- If you require a Regulatory Advice meeting, contact the Head of Clinical Investigations at mark.grumbridge@mhra.gov.uk

Over the course of a Clinical Investigation, **you must comply with any instructions from the MHRA**, including the submission of Quarterly Summary Reports, and End of Study Reports (EoS Reports should be emailed to CI-applications@mhra.gov.uk).

AMENDMENTS

Once a Letter of No Objection is received, you must subsequently immediately notify the MHRA of any amendments or changes to the project, including:

- The device under investigation.

- Study documentation, including the clinical investigation plan.
- Investigators or investigating institutions.
- Changes requested by an ethics committee.

N.B. If you do not notify the MHRA of amendments, you may be subject to prosecution.

Amendments should be completed in IRAS.

Additionally, the MHRA requires receipt of:

- A cover letter with the MHRA Registration ID, Company/Organisation name and address, contact name and email address of the person responsible for paying the fee, and, if applicable, a PO number or equivalent.
- A table with each proposed change and the justification for each item.
- Track changes and clean copies of all amended study documents.
- Proof of payment – The website includes instructions for making payments.



REGULATORY LEGISLATION

SPECIAL CIRCUMSTANCES

SPECIAL CIRCUMSTANCES FOR HEALTHCARE INSTITUTIONS

You do not need to notify the MHRA of a clinical investigation if:

- You have manufactured the medical device in-house, for your own patients only, with no intention to place the device on the market.

You may need to notify the MHRA if:

- You want to provide a medical device to another organisation, that up until now has been manufactured in-house for your patients only, including sharing the device with another organisation as part of data gathering and research exercises to support the safety and performance of a commercial product.



REGULATORY LEGISLATION

REGULATING IVDs IN GREAT BRITAIN

GUIDANCE ON THE REGULATION OF IN VITRO DIAGNOSTIC MEDICAL DEVICES IN GREAT BRITAIN

Of note, devices that are manufactured within a healthcare institution for sole use on/by their patients (in-house manufacture) are exempt from the UK MDR 2002.

Documentation: You must retain, and make fully available for inspection, the Declaration of Conformity, and any technical documentation, formal decisions, reports, and certificates from UK Approved Bodies (or equivalent), for 5 years after the manufacture of the last device.

CE Marking: CE marked medical devices will continue to be accepted on the GB market until June 2030.

UKCA Marking: Manufacturers may voluntarily use UKCA marking until June 2030. The manufacturer must not apply UKCA marking unless they have fulfilled the applicable UK MDR 2002 requirements.

Health Institutions: A body whose primary purpose is the care and/or promotion of public health (free standing labs, including those for diagnostics, do not qualify) (clinics established for purely diagnostic purposes also do not qualify) (establishments with the primary goal of “healthy lifestyles”, such as gyms or spas, do not qualify).

The MHRA broadly considers a healthcare institution as a single legal entity (e.g. an NHS Trust rather than a single hospital), though there may be exceptions where two legal entities may be treated as a single healthcare institution; this is dependent on precise circumstances, including:

- Close association and common identity.
- Shared premises and facilities.

The exemption will apply when:

- A device is manufactured and used within the same health institution, on the premises of manufacture; or
- A device is manufactured and used within the same health institution, on premises in the immediate vicinity (provided the device has not been transferred to another legal entity).



REGULATORY LEGISLATION

REGULATING IVDs IN GREAT BRITAIN

The full guidance contains a comprehensive list of scenarios and when the exemption from UK MDR 2002 requirements applies.

The UK MDR 2002 may apply for joint ventures between multiple establishments, even if the device will be placed on the market by a third party.

If uncertain of whether the exemption applies, check the above guidance, or submit an application via IRAS (which will be sent to the MHRA automatically).

Check the “Further Reading & Resources” section of this document for a link to the full regulatory guidance.



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