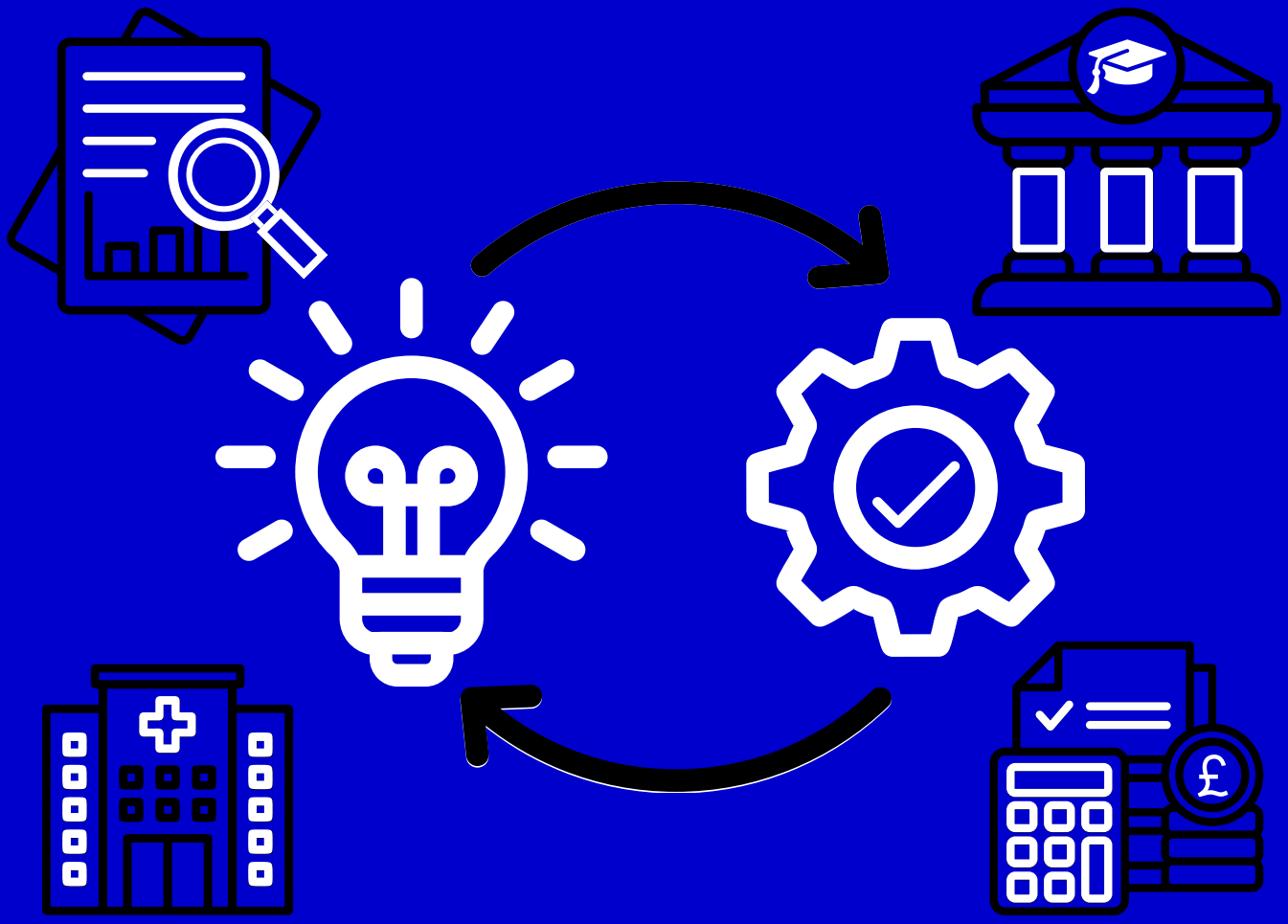
IMPERIAL

MedTechONE

FROM IDEA TO ADOPTION

PART 7



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COLLABORATIVE

www.imperial.ac.uk/medtechone/

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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MARKET ACCESS

KEY REQUIREMENTS SUMMARY

- **All medical devices must be MHRA registered.** This includes:
  - In vitro diagnostic devices (IVDs)
  - Custom-made devices
  - Systems or procedure packs
  - Any other, more standardly categorised medical device

- If your manufacturer is based outside of the UK, you must appoint a single UK responsible person for all of your devices who will act on your behalf to carry out specified tasks such as MHRA registration.

- **CE marked devices can be placed on the GB market up to the following dates:**
  - General medical devices compliant with EU Medical Devices Directive, or EU Active Implantable Medical Devices can be placed on the GB market up to 30th June 2028, or prior to the certificate expiry, whichever is soonest.
  - IVDs compliant with the EU IVD Medical Devices Directive can be placed on the GB market up to 30th June 2030, or prior to the certificate expiry, whichever is soonest.

- In addition to a valid CE / UKCA marking, **you may need to make the number of the approved / notified body available on the label.** Alternatively, where applicable, the name and address of the UK Responsible Person must be available on either the product label, packaging, and/or within accompanying information.

- **You must adhere to Post-Market Surveillance requirements**, including submission of vigilance reports.

MARKET ACCESS

NICE FOR MARKET ACCESS TO THE NHS

NICE can support the adoption of a pharmaceutical or technology into the NHS through their rigorous assessment and evaluation programmes.

Identifying routes into the NHS

NICE provides training and insight on how to get your innovation into the NHS, including:

- **NICE Surgery –** A 1 hour meeting with a NICE expert plus an optional written summary of the points discussed. You can access this at any point in the market access process.

- **Therapeutic Landscape Review –** An in-depth review of past NICE appraisals, trends and developments in care standards. NICE provides a virtual / in-person session with experts who can discuss the review findings, facilitate discussion, and answer questions. Designed for companies at early product development stages.

- **System Engagement Meeting –** A 2-3 hour engagement meeting facilitated and hosted by NICE. Involves relevant experts, key opinion leaders, and wider health system stakeholders and is designed to address the most pressing market access issues for your innovation. Designed for companies finishing stage 3 clinical trials, up to the start of a NICE appraisal, and is of most benefit to companies who have generated at least some clinical evidence.

- **Evidence Gap Analysis –** Supports medtech companies in refining their product's value proposition, and in identifying gaps in both planned and existing evidence. Includes a meeting with a NICE expert and a report highlighting gaps and recommended actions. You can access this at any point in the market access process.

MARKET ACCESS

NICE FOR MARKET ACCESS TO THE NHS

- **Health Economic Model Assessment –** For developers of pharmaceuticals and certain medtech innovations, this assessment is an independent, critical review and quality assessment of your existing economic model. NICE will provide a technical report that includes model optimisation and recommendations. Designed to be accessed prior to a formal NICE appraisal. You need to have completed the majority of your evidence generation and should have at least started your economic model.

The first step for any innovation is to register the product with NICE, which can be completed at one of the links available here https://www.nice.org.uk/what-nice-does/life-sciences-how-to-get-your-product-to-market - You can choose between registering a pharmaceutical or a non-pharmaceutical product.

For next steps and further advice on how to progress through the NICE infrastructure, you should consult the NICE Advice Service: https://www.nice.org.uk/what-nice-does/life-sciences-how-to-get-your-product-to-market/nice-advice-service

NICE can work with you to find the right pathway for your innovation

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