Strands of Medical Device Activity

Research & Development (R&D)

The R&D lifecycle of a medical device involves the work directed towards the development of an innovation, and/or the improvement of products and processes that are undertaken by researchers (e.g. at an academic/clinical institution or within industry R&D teams).

R&D1. Basic/generic research

R&D2. Requirements and prior knowledge

R&D3. Concept development and refinement leading to prototype

R&D4. Human factors

R&D5. Responsible innovation

R&D6. Technical feasibility (pilot demonstration, materials biocompatibility/formulation)

R&D7. Adapting/extending to achieve health and care feasibility and efficacy

R&D8. Adapting/extending to achieve health and care effectiveness

R&D9. Freeze design

Health Economics & Service Transformation (HEST)

The translation of a health technology innovation to a medical device used in clinical practice requires an understanding of the costs and benefits of the device as well as of how the device will be embedded in the clinical service.

HEST1. Healthcare context (e.g. problem addressed, scale, current QALY/£ cost)

HEST2. Current clinical care pathway (guidelines)

HEST3. Real-world evaluation of clinical care pathway (delivery)

HEST4. Service transformation model (change in clinical care pathway)

HEST5. Value proposition (e.g. expected benefit, cost savings, improving efficiency, improving patient satisfaction) / Target Product Profile

HEST6. Health economic analysis to address the value proposition claims (cost-benefit analysis)

HEST7. End-user business model / Procurement case

HEST8. NICE Health Technology Evaluation

Regulation (R)

The development, manufacturing, marketing, distribution and use of a medical device are governed by a set of laws, standards and guidelines. These regulations are put in place to ensure the safety and effectiveness of the medical device.

R1. Research governance / Ethics

R2. Intended use and device categorisation

R3. Quality management system (ISO 13485 certification)

R4. Clinical investigation approval

R5. CE / UKCA marking

R6. Post-market surveillance (PMS) and post-market clinical follow up (PMCF)

Productisation & Distribution (P&D)

The innovative technology needs to be manufactured into a regulated medical device product for it to be delivered to the end user (e.g. healthcare provider, patient). This process includes activities around quality control, packaging/labelling as well as distribution and sales.

P&D1. Manufacturing/software-engineering
- Requirements analysis
- Design
- Development
- Test
- Implementation

P&D2. Testing protocols

P&D3. Safety, compliance, interoperability and usability

P&D4. Quality control

P&D5. Scale-up

P&D6. Production and distribution

Business Model (BM)

A business model is required to understand the commercial opportunities for the innovation and to plan the sustainable delivery of value. The business model for a medical device addresses how value is created and delivered to patients and healthcare providers. This applies to both for-profit and non-profit endeavours.

BM1. Intellectual property and branding

BM2. Market size (UK, Worldwide)

BM3. Market share (realistic assumptions)

BM4. Product vs service

BM5. Spinout vs licence

BM6. Business plan / canvas

BM7. Investment required and Return on Investment (RoI)

BM8. Marketing and promotion

Health and Care Evaluation (HCE)

Health and care evaluation of a health technology innovation involves assessing its safety, efficacy and effectiveness. This assessment is necessary for regulatory approval of the innovation as medical device before it enters the market. It also includes ongoing monitoring of the device once it is being used in clinical practice.

HCE1. Critical evaluation of concept

HCE2. Health and care feasibility

HCE3. Health and care evaluation of safety and efficacy

HCE4. Health and care validation of safety and efficacy, effectiveness

HCE5. Real world evidence post-launch