# Commercializing medical device innovation

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Medical technology in action Credit: Institute for Manufacturing

(Medical Xpress) -- New medical devices take a long time to reach the market – and many never make it. Jon Johnson, a researcher at Cambridge's Institute for Manufacturing, is looking at ways of making the process of commercialisation more efficient.

Biotechnology and healthcare developments require huge financial and resource investment, in-depth research and clinical trials. Consequently, these developments involve a complex multidisciplinary structure, which is inherently full of risks and uncertainty. Jon Johnson, a researcher in the Institute for Manufacturing, is looking at the process by which medical devices are taken from early concept through to commercialization, including technology confidence, early testing, investment implications, and regulatory compliance.

The feasibility stage of medical device design is critical, and there is

currently little guidance for practitioners to navigate this inherently complex set of activities. In a similar fashion to high-tech industries, the medical sector has huge incentives to increase development efficiency, reduce time to market and increase profits. The medical industry has unique requirements, including extensive science and technology management, considerable testing, clinical trials and regulatory control. When addressing scientific and technical innovation within this industry, it is critical to have a clear understanding of the clinical need, market potential and technical risks.

A major challenge lies in the process of determining technical feasibility without demonstrating preliminary function and early test data. These requirements mean that the development of medical devices is often extremely expensive, with project schedules taking between four and ten years. There is genuine pressure on industry to reduce these costs and improve time to market by reducing the inherent risks at the feasibility stage of development. Therefore it is necessary to gain confidence within the technology as soon as possible and preferably before investing excessively.

Johnson is particularly interested in the early stages of medical device development – the early feasibility studies which determine whether a technology is viable years down the line – and how designers, engineers and scientists work closely with medical practitioners, healthcare providers and patients. He believes that this stage offers the biggest potential to test concept viability, establish whether the technology will function sufficiently, meet critical user needs, identify genuine health benefits and determine regulatory viability.

“According to the FDA (Food and Drug Administration), a vast majority of investigational products never make it through clinical approval and market adoption.  This failure represents a huge loss of time and investment,” said Johnson.

What is needed is better evaluation at the early stages of development. In order to understand how a product makes the journey from first concept to commercial adoption, Johnson has been working with eight leading medical organisations to track this complex process. The output from this study includes an original approach by which companies can better analyse, manage and measure the success of early technology innovation within the healthcare sector. Such studies would also improve regulatory viability, provide significant cost savings and maximise benefits to the healthcare industry.

Jon Johnson is a PhD candidate in the Institute for Manufacturing, Department of Engineering at the University of Cambridge. He is supervised by Dr James Moultrie.

Provided by University of Cambridge