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Product Development Fact Sheet

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This is part of a series of fact sheets designed for innovators by the Eastern AHSN Innovation and Industry team.

1. Intellectual Property
2. Product Development
3. Market Assessment
4. Commercialisation Models
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Download a digital edition from the Innovation Pathway hub on the Eastern AHSN's website:

www.eahsn.org/our-work/innovation-and-industry/the-innovation-pathway

Each fact sheet forms a comprehensive but not exhaustive source of information outlining the intricacies of the Innovation Pathway and are designed to help you navigate your way to a successful outcome. At the end of each fact sheet you will find the hyperlinks to referenced organisations.

You can also access Funding Resources directory at www.eahsn.org/our-work/innovation-and-industry/funding-resources

Overview

This fact sheet focuses on the product development pathway from idea to market ready product and highlights the diverse range of skills required to complete the process.

Having an appreciation of the steps in the product development pathway is critical to the success of commercialising an idea.

The product development pathway presents many commercial and technical risks, along with many common pitfalls and this guide aims to provide insights and advice to assist in navigating the pathway.

The product development mantra is the same for any technology: design, prototype, test, and repeat.

Stage 1: Idea Creation

By this stage an innovator will have identified the unmet need for which he or she has a created a solution, carried out an assessment of the market and intellectual property (IP) landscape to identify competitors and developed a business case for the development of a new technology or service.

This will provide the innovator with the evidence base to decide as to whether to move an innovation forward from an idea into development.

At this stage it is recommended to write a draft proposal or specification capturing the idea along with any designs/features of the technology conceived to date.

This document will help understand and communicate the support necessary for prototype development.

The Eastern AHSN Intellectual Property fact sheet can help. For further information refer to www.eahsn.org/our-work/innovation-and-industry/the-innovation-pathway/.

Stage 2: Prototyping

Prototyping is the process of creating early, experimental versions of a product and is at a crucial early stage. The prototyping process is often iterative, with rapid prototyping methods providing a useful approach to quickly and inexpensively evaluate a range of potential designs against key criteria before deciding on a final concept.

As the prototyping process progresses, the technical specification, designs and models, become more advanced. Eventually well-developed prototypes can be used to test and refine product features and functionality through a combination of laboratory and user testing.

The goal is to prove that the components making up the final product will work together as expected. Consideration of the human factors and use of case scenarios is vital at this early stage. This process is central in mitigating risk to ensure that the final product is fit for its intended use.

An innovator will need to evidence each of the steps he or she takes for any regulatory and clinical environment.

Further information on the regulatory requirements can be found at: www.eahsn.org/our-work/innovation-and-industry/nhs-clinical-trials-webkit/

Concept development and design

Before embarking on prototyping, it is important to determine the objective of creating a prototype. Is it better to get it created purely as a visual aid to use to persuade investors? Does it require working functionality to enable laboratory demonstration? Is it intended for use in a clinic on a patient?

Suffice to say, prototypes come in many forms, often progressing through the stages outlined below:

i. Virtual Prototype – A computer-aided design (CAD) to enable the concept to be considered from different angles, iterations to be quickly made and validated ahead of committing to a physical prototype.

ii. 3D Model Prototype or a "Looks-like model" – A physical model of the product in terms of shape, colour and size, normally lacking functionality. These are cheap to produce and are excellent communication tools for stakeholders (including users and investors). For software applications, mocked up screenshots can be used to gather feedback about the user interface and design.

iii. Proof of Concept Prototype or "Works-like model" – Such prototypes are used to prove an idea will work and demonstrate technical feasibility. Typically, prototypes are built from cheap, readily available materials to reflect the iterative modifications required achieve the required functionality at this critical stage.

iv. Clinical Prototype or "Is-like model" – These prototypes must possess the required functionality and work as intended, however, it is not essential for this type to resemble the final product form. For a medical device, this could mean using materials that are biocompatible and/or sterilisable. For software solutions, this could be a functional alpha or beta version of a software solution that is still undergoing testing.

v. Pre-production product or "Looks-like, is-like model" – a prototype that has both the functionality and form of the final product. In this instance, the design and materials are moving towards a product designed with full production manufacture in mind and ready for the market. Consideration of costs associated with manufacturing techniques and materials is of particular importance.

Development of a specific prototype can be carried out in-house or outsourced depending on the prototyping stage and the resources available. The early prototypes can be mocked up easily and cheaply to achieve a 'rough and ready' model for proof of concept to ensure the idea works ahead of more significant investment. It may be possible to build initial prototypes for non-clinical testing in house drawing upon readily available materials and/or technical capability. As prototyping progresses, it is advisable to use specialist skills to ensure the necessary expertise and technical capability is acquired for the project.

There are many external design and development organisations offering such services. Before engaging with an external company, a non-disclosure agreement should be put in place ahead of sharing the idea and specification. It is wise to obtain written quotes or proposals from several external service providers and consider more than just the costs and objectives. Understanding if a potential provider meets the required timelines and possesses the right technical capabilities and resources is also important.

Development agreements should be scrutinised to ensure to IP ownership is retained, this is especially important as the development process will typically yield further IP.

As prototyping is iterative, it can often be difficult to determine a definitive timeline to reach a final product design. However, an experienced development house will provide a time estimate based on previous project experience and the activities to be conducted. Establishing clear objectives and milestones will assist in managing these outsourced stages of the project.

Methods used in prototyping

Prototyping uses a variety of different techniques or methods. Some of these methods are briefly described below:

i. Virtual Methods – computer modelling systems are an extremely powerful tool in product design. Examples include Computer Aided Design (CAD), Computational Fluid Dynamics (CFD) and Finite Element Analysis (FEA).

ii. Rapid Prototyping – this is a popular and relatively cheap method to produce a model of a device. This type will not produce a functional prototype for testing but can be useful in demonstrating the concept. Examples include stereo lithography, laser sintering and 3D printing. 3D printing has become hugely popular in the last decade and can produce virtually unlimited geometries which are useful for rapid iteration of complex designs.

iii. Fabrication – for one-off prototypes, conventional fabrications techniques, such as Computer Numerical Control (CNC) machining, is suitable for prototyping with end-use production of medical device parts. Compared to rapid prototyping, there is a greater choice of materials and they are typically more robust. However, this type of prototyping requires attention to the machinability of the design, therefore the techniques involved are often more time-intensive.

iv. Semi-production methods – Such techniques are used to generate higher volumes of product for laboratory or clinical testing. Methods include casting, injection moulding, extrusion, laser sintering and vacuum forming. The set-up costs for some of these methods can be expensive due to the requirement to invest in tooling.

Testing and validating your prototype

The key aim of the various stages of prototyping is to provide product examples for testing. Testing is conducted throughout the development process.

Indeed iterative testing is essential to ensure the final design is fit for purpose. Testing may be either pre-clinical (user, bench, simulated use, tissue testing) or at a later stage in development clinical (live situation testing, cadaver testing and human testing).

The aim of testing is to collect information to feed into the user and technical specifications of the product.

User-led testing will be important to the success of a product/service. It is important to think who the end user will be and seek to secure input from this group at the earliest stage.

Once a final design is ready, an innovator is required to gain regulatory approval to validate the design based on a feasibility or pilot clinical study to carry out a test.

These proof-of-concept studies are generally small, for example, between 20 and 60 patients, and measure training effectiveness and ease-of-use (human factors and ergonomic testing) to highlight device issues before enrolling further subjects to define acute safety and effectiveness.

Favourable outcomes can provide the clinical evidence for regulatory approval. These studies will need to meet clinical standards and expectations to validate a product in a healthcare environment.

Stage 3: Full Production and Market Launch

Bear in mind that the design agency and/or product development company involved, might not have the resource or capabilities for scale up and may require a high-volume product manufacturer to be sought.

Modifications to the prototype may be required to transition from small to large scale, where different methods are used depending on the volumes required for manufacturing.

When operating in the medical technology space, the product requires regulatory approval before entering the market.

Once available on the market, the post-market activities are vital to the success of the product and future product variants. At this stage, feedback gathered from the first-generation product users provides valuable information, often leading desirable tweaks, next generation product ideas or even a new unmet need.

Take home messages

- Involve end-users at the earliest opportunity in the product development process to gain feedback and continue to do so throughout the process.
- Don't be afraid to learn from others, even from competitors. Understand how their solutions work to provide guidance for your own product development.
- A new medical technology must prove to be safe and functional. Whilst safety and function is essential, the product must also be cost-effective to ensure market adoption. This should be kept in mind during the development process.
- Consider IP at each stage of the product development pathway to ensure the necessary protection is in place. IP can protect both the product and the manufacturing process of a technology. In addition, once set on a final product design, it is also important to protect your product's brand identity (copyright, trademark and design rights).
- Consider the regulatory requirements from idea creation. Product development partners should have quality management systems (such as ISO9001 or ISO13485 accreditation) in place to ensure robust processes are followed and the correct documentation generated during the development process. This will ensure the regulatory bodies can be provided with the necessary evidence required to support regulatory approval.

Summary

Medical product development is a long road requiring a wide range of disciplines and skills. However, stakeholders should be at the heart of the process to ensure the final product concept is useful and relevant.

Throughout the product development process it is important to retain focus - clearly define what the product is intended to do, the benefits, claims it will offer and for whom.

As communication and transparency is often crucial for success, careful consideration must be given before collaborating with a development partner(s) to ensure the right commercial terms and development path flexibility are attained.

Useful links

Biodesign Book

https://books.google.co.uk/books?id=5gREBgAAQBAJ&printsec=frontcover&dq=biodesign&hl=en&sa=X&ved=0ahUKEwixmcLI8aDSAhXIC8AKHcuPCLAQ6AEIHDAA#v=onepage&q=biodesign&f=false

NESTA prototyping guidance

www.nesta.org.uk/sites/default/files/prototyping_framework.pdf

NHS National Innovation Centre Guide to Working with New Product Design and Development companies

http://knowledge.nic.nhs.uk/documentDetails.aspx?docId=20

This fact sheet is for your guidance only. It is not exhaustive nor is it meant to replace any official NHS policies or guidelines.