Innovating in Ophthalmology

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Healthcare innovation is the creation of a novel idea, product, service or care pathway that improves patient care. Successful implementation and adoption require the innovation not only to be centered on the patient's needs, but also to meet the needs of other stakeholders such as healthcare staff, organisations and regulatory and professional bodies.

Historically the NHS and its academic partners have led the world in inventing and testing innovations however, all too often, these ideas have been realised in other countries which have benefitted from their subsequent commercial success. Ophthalmology has the highest out-patient workload and most common operative procedures; the ability to deliver the service in the face of increasing workforce and capacity restraints makes innovation in our specialty a necessity.

First, the bad news: over 90% of health start-up businesses fail, the Valley of Death (Figure 1) describes the phase of development between research and product development where most meet their end. The few that succeed can take a decade for the innovation to be implemented. The better news is that, as clinicians and academics immersed in delivering patient care within a pressured healthcare environment, we are in an ideal position to be successful in identifying solutions to meet clinical need which are affordable or cost-effective for the NHS to adopt.

In business parlance, we have an innate understanding of the market relevance, economic environment, human factors and usability. This paper describes some of the steps involved in healthcare innovation and how to access advice from the programmes and innovation bodies which have recently been developed to promote and support clinician-led innovation within the NHS.

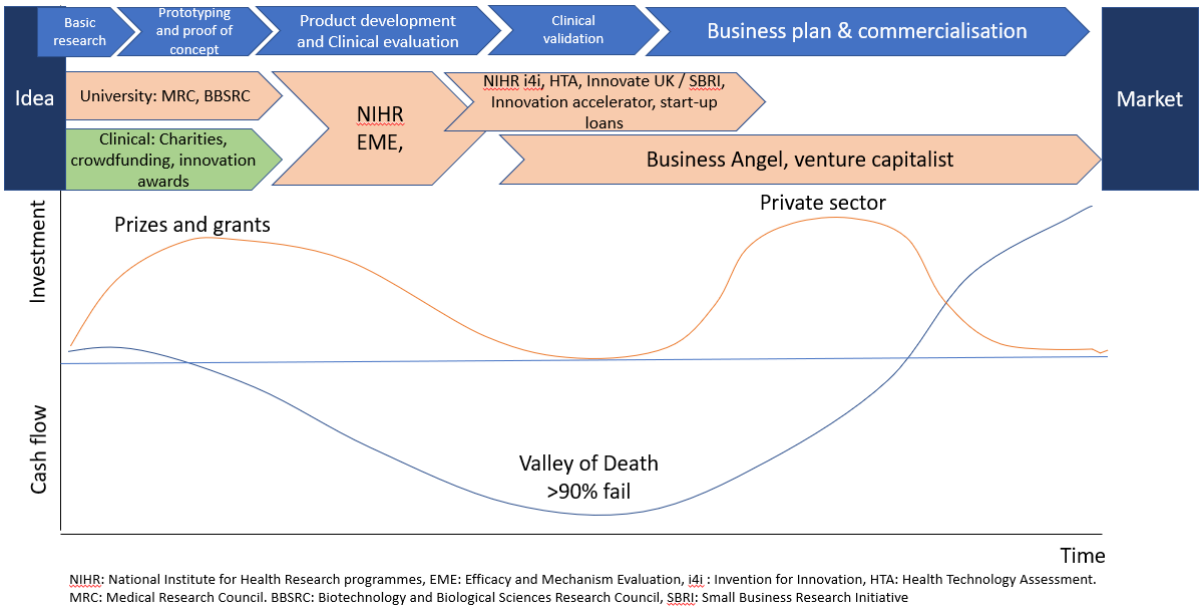

Figure 1: Funding streams and the Valley of Death, where most innovations fail due to inability to attract further investment

So, you have an idea?

Is your idea novel and protectable? Figure 2 shows the typical stages through which an innovation has to travel to be adopted in the NHS. Intellectual Property (IP) is the tangible output of any intellectual or creative activity including inventions, processes, software, data, designs and images. IP is a commodity that can be exploited by licensing or selling the right to use it. IP rights protect the holder against “copycats” and are especially important in the biotechnology and pharmaceutical industries. If you think that your idea might be patentable, you can check for “prior art” (a previous description of the invention) on websites such as Google patents. You should also check that you have “freedom to operate” (i.e. you are not infringing somebody else’s patent).

It is important that you do not disclose a potentially patentable idea in a public arena such as a conference or publication since this will undermine a future patent application. Patent application, and its subsequent prosecution and maintenance, requires an IP lawyer and is extremely expensive. When considering whether to submit a patent application, it is critical to assess how easily the patent could be bypassed by a small modification in the design of the product. If this is foreseeable, then the costs associated with the patent application may be better spent elsewhere in the product development pathway. However, without a patent the attractiveness of the innovation to external investment will be reduced. Even if you innovation is not patentable, you will have other forms of IP, including “know-how”, copyright (particularly in respect to software code), trademarks and designs.

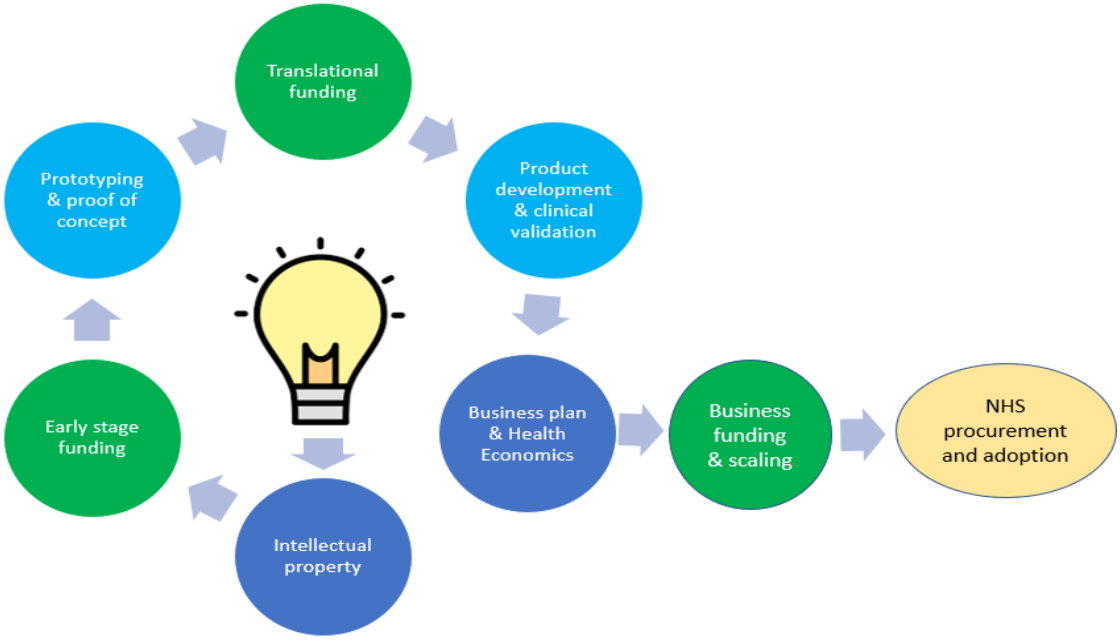

Figure 2: The typical innovation cycle from idea to NHS adoption

Intellectual property rights and contracts

All NHS trusts and Universities have an IP policy and you should ensure that you have read and understood your institution's contracts. Under UK law, any IP generated in the course of employment belongs to the employer, although you can be credited as being the inventor. If the innovation was developed outside your job role, or in partnership with someone outside the organisation and this argument is accepted by your employer, it may be possible for you to own the IP. Unfortunately, IP battles about who owns what can result in great ideas being stifled, with the result that their potential is never realised.

If your trust or University own the IP, they have the right to sell or license the IP to business for revenue, a proportion of which will be passed on to you, as the inventor, and your department. Where potential revenue is high, for example pharmaceuticals, the University's commercialisation arm will support these next steps. For more niche clinical or technological innovation with lower potential revenue or non-protectable IP, Universities and NHS trusts are unlikely to invest time in supporting commercialisation. Instead, the onus to achieve success will remain with the innovator to push through the steps of gaining funding, proving the concept and clinically validating the innovation. This requires hard graft, with many unremunerated years of dogged determination and entrepreneurial skills quite unlike those we have acquired during medical training. Juggling this with the clinical day job is difficult and recognition of this has led to the development of the Clinical Entrepreneur training programme www.england.nhs.uk/aac/what-we-do/how-can-the-aac-help-me/clinical-entrepreneur-training-programme/. This programme is available at any career stage and offers mentoring, networking and advice to support clinicians in the process of innovation development and commercialisation whilst enabling them to maintain their clinical practice.

Early-Stage Funding

Prototype development requires early-stage funding. If you are a clinician, innovation grants and prizes are often available from trust charitable funds or regional innovation hub competition. If you have a link with a University, National Institute for Health Research (NIHR) and UK Research and Innovation (UKRI) / Medical Research Council (MRC) grants may be available for prototype development. All these grants and prizes will come with a contract giving ownership of IP developed with the funds to the funding body. Ensure that you do not sign away the IP rights to your future innovative ideas as well as those which are subject of the application. Other sources of early-stage funding might be from friends and family or crowdfunding, which may not have the same IP obligations.

Prototyping and proof-of concept

Developing a prototype can be expensive and it is easy to waste money. When beginning the process of prototype development one of the most important tasks is to select an appropriate company to partner with to develop your software /manufacture your prototype and subsequent product. When approaching possible partners, ensure a non-disclosure agreement (NDA) is signed prior to disclosing any specific details about your innovation. Often these companies will have their own NDA template, which makes things simpler and avoids legal fees.

During the initial discussions with your chosen partner company/manufacturer, it is important to have a clear idea of what your product specifications are and communicate these clearly. Making multiple changes to the design/function of your product during the development process is best avoided as each modification will be associated with costs.

If your innovation is a medical device, you will need to determine what Medicines and Healthcare products Regulatory Agency (MHRA) class your medical device will eventually be, this can be found at www.gov.uk/guidance/medical-devices-how-to-comply-with-the-legal-requirements. Ensure that you use a manufacturer with Quality Management System (QMS) and manufacturing compliance. Such companies will have certification for International Organization for Standardization (ISO) 13485 for medical devices and ISO 62304 for medical device software. This will ensure compliance with MHRA medical device certification and the 2018 the General Data Protection Regulation. Be aware that different countries classify medical devices differently, especially after Brexit, therefore think about which countries you would like to eventually market your device in and manufacture according to the strictest regulations. Likewise, avoid commissioning the production of tools/moulds for your device until you are completely happy with the design of the prototype. It is far easier and cheaper to make changes at the 3D printed stage than when moulds have been developed.

If you plan to develop the proof-of-concept for your innovation in your trust, your initial prototype will not require regulatory approval. Studies may take the form of a small clinical trial or pilot with a prototype which has been safety assessed by the trust's clinical engineering department. In this respect, clinical and academic innovators have a great advantage of over businesses because of our access to the patient population for early-stage evaluation.

The design of the proof-of-concept study is important since this will provide the evidence you need to get further investment. If you are not an academic and not used to study design or the Integrated Research Application System, your Research & Development department may be able to help or you may wish to seek advice from the relevant Clinical Study Group (CSG) for the sub-specialty www.nihr.ac.uk/explore-nihr/specialties/ophthalmology.htm . Each of the five CSGs have academic consultant ophthalmologist and lay representation. The CSG offer peer-review support for new study ideas, support to develop studies in set-up and investigator-led studies to attract external funding. The UK-wide Ophthalmology Clinical Research Strategy is being developed by the NIHR to explore areas of unmet need in the population and to develop a 'research pipeline' of therapies and technologies.

Product development and translational funding

Good guides to funding streams, healthcare product regulations and information governance are available as toolkits from the Academic Health Science Network https://www.ahsnnetwork.com/supporting-innovators . There is an AHSN in every region and their purpose is to support NHS adoption of innovative ideas which will benefit the NHS and our patients.

Once you have demonstrated proof of concept, there is a choice of applying for a product development grant from the NIHR or MRC (eg EME, i4i), seeking funds from a regional medtech acclerator, seed funding or investment from a business angel or venture capitalist. With this funding you can develop your product to make it commercially viable. If planning a larger trial to clinically validate the product prior to potential commercialisation, the MHRA will require manufacturer's proof that your product confirms to its regulations for the investigation.

Start-ups and spin-out commercialisation

We have arrived at the Valley of Death (Figure 1). The next step is to write a business case or plan. An excellent downloadable business case toolkit is available from the AHSN https://www.easternahsn.org/resources/business-case-toolkit/ . Your business case should evaluate the benefit, cost, risk of different strategic options and a rationale for the proposed solution. It will contain information such as a market analysis, health economics, expected benefits to both patients and the health service, competitors in the field and expected return on investment. A strong business case is required to attract further investment for scaling up and delivering your innovation to the marketplace.

A start-up is a small business which is in the process of developing or refining its product or service, it is owned by its founder(s) and taking its first steps to recruiting staff and renting premises. If you are developing your product outside a University, this is likely to be your vehicle for commercialisation. A spin-out is at a similar stage but in addition to its founder(s) the University is a minority shareholder. In this model the University moves some of its assets (often the IP and employees) into the spin-out company to commercialise the product. Business angels

and venture capitalists (rather like the Dragon's Den angels) demand equity in the company for their investment but may bring in valuable knowledge, skills and contacts to ensure successful and widespread adoption.

Having formed a microbusiness (no salaried employees) or a small or medium sized enterprise (SME, fewer than 250 employees), there are different funding streams to access, such as United Kingdom Research and Innovation (UKRI) Innovate UK grants, the Small Business Research Initiative (SBRI), product development grants such as the NIHR i4i or medtech accelerators. Ensure you trademark the name of your business/product and secure the website address early to avoid disappointment. Likewise ensure your chosen name is not used elsewhere or inadvertently means something else in another language.

Adoption in the NHS and other healthcare settings

The AHSN can be a helpful in finding test beds in which to pilot your innovation and give support for start-ups and SMEs to develop a good health economic and business case to take to procurement departments within Clinical Commissioning Groups and NHS Trusts. Finding clinical champions who believe in your innovation and who will support the clinical and business case to enable procurement in NHS organisations is important. Adoption in the NHS often requires promotion through National Institute for Health and Care Excellence (NICE) programmes such as the Medical Technologies Evaluation programme or ORCHA , the health app evaluation service for NHS Digital.

Clinicians with an innovative product ready for market can apply to the NHS Innovation Accelerator Fellowship to support its successful implementation and adoption in the NHS. www.england.nhs.uk/aac/what-we-do/how-can-the-aac-help-me/nhs-innovation-accelerator/

Depending on your innovation, you may seek procurement through individual Trusts and Clinical Commissioning Groups. This will require a business case and a Budget Impact Analysis – a health economic evaluation to demonstrate that the innovation is cost saving. More expensive products may have to be procured through through the NHS Supply Chain (NHS SC) Framework. To become an approved supplier to the NHS SC, the manufacturing process of your device must meet minimum ethical requirements and labour standards. Suppliers must provide NHS SC with proof of audit compliance against Labour Standards Assurance System (LSAS) requirements. These audits are conducted by external partners, and the costs of these audits, which are not insignificant, fall on the supplier of the device.

Summary

It is a long uphill struggle from idea to NHS adoption, with many great ideas falling by the wayside in the process. However, the importance of innovation within the NHS is well recognised and increasingly supported by new funding streams and organisations. Understanding the hurdles and expectations of the innovation journey will enable clinicians to focus their time and energy on their inventions and seeing them used in the NHS, rather than re-inventing the wheels needed to carry them there.