Health Innovation Hub Ireland

BUILDING A CASE FOR COMMERCIALISATION SUPPORT

Overview

Many solutions to unmet needs (problems) in healthcare require additional funding and supports to bring them to reality. This may include technical development or another expensive process.

As the cost and time to develop a new solution in healthcare is great, a common route is to raise funding and support to develop the solution as a commercial product.

This fact-sheet is a non-exhaustive guide on how to build a case for commercialisation support.

Building a case

Three key elements of bringing a solution to market is to ensure there is an unmet clinical need, a robust solution or solution direction, and a strong market. The first step before applying for support is to define and validate the unmet need you intend to address.

What is the unmet need?

To determine the unmet clinical need, speak to the end users or those with the greatest understanding of the problem. What are their problems? How could you make their day easier? End users will include:

– Clinical key opinion leaders (KOLs)
  – Local
  – National
  – International
– Patients

When speaking to potential users or opinion leaders it is advised to have an open conversation using a strategy such as that in "**The Mom Test**". Do not use leading questions. Allow the conversation to flow by asking questions about what their main problems/challenges are. If what you have identified as the unmet need/problem is mentioned you should explore this further. HIHI can facilitate introductions to clinical personnel and KOLs. Contact us via **info@hih.ie**

What are the current solutions?

What is being used locally, nationally, and internationally?

This should include all common methods (direct/indirect) currently in use to solve the unmet need/problem. For example, there may be many different ways to treat a condition including medication, physiotherapy, medical device, digital interventions, etc.

Why are the current solutions not good enough?

This is an opportunity to showcase the disadvantages of the current solutions identified in the previous point based on tangible criteria such as cost, usability, efficacy, safety, skill required to use it, time of intervention (e.g., before, during, after surgery), etc. A comparison table can be used as a graphical overview (see Table 1 below). Your solution can also be compared in the table.

What are the current companies on the market?

What companies are operating in the space? This can be found out using google to search for the global market in (insert disease) e.g., diabetes (**link**). Once you know what you are looking for you can request a market report from **Enterprise Ireland's Market Research Centre** (**link**). Ensure the report you want is from a company/provider on the list (**link**). In addition, you can see what products are being used in the local hospital or healthcare provider if you have access to the same or through HIHI.

What new technologies are in development?

Academic landscape – what research is being conducted in universities and institutes of technology (ITs)? Search google scholar to get the titles and authors of the most up to date research publications (**link**).

Who is leading in this research – you may know if the local academic intuitions are working in this area. Certain academic institutions specialise in particular areas of industry focused research – see **SFI research centres**, **EI technology gateways**, **Institutes of Technology** (IT), and **universities**. See the lists of people working there and their areas of expertise.

Table 1: Example of a competitor analysis table comparing solutions based on critical factors

Competitor	Critical Success Factor					
	Cost Effective	Usability	Efficiency	Efficacy	Sustainable	Scalable
Your Solution	€	+++	++	+++	+++	++
Competitor 1	€	+	++	++	++	+++
Competitor 2	€€	+	+	+++	+	+++
Competitor 3	€€	++	+++	+	+++	+
Competitor 4	€€€	+++	++	+++	++	+++
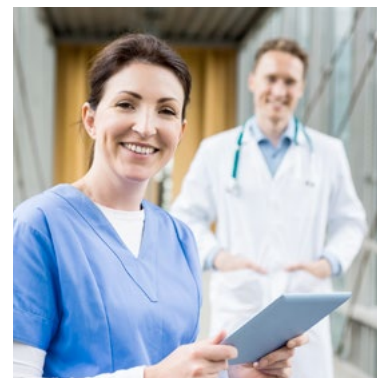
Current investments – follow investors and news feeds to see what is moving in this space e.g., **Fierce**, **Financial Times**, **MedTech Strategist**, **Medgadget**, **Fountain Healthcare**, **Silicon Republic**, etc. List of investors (**link**).

Trade journals – see above

Conferences – attend some conferences to see key note speakers and to understand the direction of the industry. Contact HIHI for support, advice, and connections in these areas.

Regulatory

HIHI provide an overview on the regulatory or medical device classification (**here**).

All medical devices or therapeutics are regulated products. The most widely known regulatory body is the US FDA. The majority of countries will have a regulatory authority such as the Health Product Regulatory Authority of Ireland or the HPRA (**link**). There is a lot of information on their site to help navigate the regulatory space. Class 1 medical devices are "safer" than Class 2, and Class 2 medical devices are "safer" than Class 3. The higher the class the more work (time, money, proof) required to show it is safe for use. Software can be a medical device and is subject to regulatory authorisation.

Reimbursement

HIHI provide an overview on reimbursement and on reimbursement in the US and EU (**link**).

Reimbursement is the payment by a public or private insurer or "Payer" to a healthcare provider for using a device or in preforming a procedure. Is the procedure or device you intend to replace already covered by reimbursement (is it currently being paid for), does it have a code, what is the payment rate (how much is being paid), and in what setting does it apply to?

Route-to-market

• One product vs Platform technology
• License opportunity vs Spin out company/new company

The route-to-market is a strategy that determines how a product/service should enter the marketplace or reach customers. At this point it requires a high level knowledge of how competitor products reach the market i.e., distribution channels. What would be the right channels to reach the right customers for the right reasons? A successful route-to-market strategy must have a sound business model (see more below on Business Model). It can be innovative and different to the standard approaches. Consider utilising channels and approaches differently than those that are currently available on the basis that today's unique route-to-market channel, is tomorrow's standard offering.

Team

• Technical
• Clinical
• Commercial lead

The team is a critical component of any project. In the case of developing a product/service for healthcare, it is important to recognise the strengths and gaps in the current project team. The minimum requirement for a technical solution to a significant healthcare need with market potential requires clinical, technical and commercial input. Enterprise Ireland and HIHI may be able to introduce you to people with the relevant expertise. The team should understand and participate in the planning of the projects to ensure their role and responsibilities, even at an early stage, are within their bandwidth.

Network/Advisory boards

• Clinical
• Medtech industry

Networking and making contacts in the relevant industry is important. Connect with people on Linked In, engage with people at conferences and trade events, and grow your professional network. Get peoples' opinions on the problem you are trying address. Identify people who you may be willing to work with in the future. Some people may join an advisory board to provide advice on your project as it develops. Advisory board positions at the early stage may be unpaid or good will positions, which can develop into more established roles if the project succeeds or gains investment.

Business plan beyond initial commercialisation funding

• Value proposition
• Business model

The value proposition canvas is a useful tool to articulate and identify the stakeholders and the value proposition of your solution. Further information on the value proposition canvas is available **here**. The value proposition canvas informs the business model.

The business model canvas is a tool used to interrogate and develop a business model based on nine different areas of a business. This 2 minute **video** is a good example of how the business model canvas can work. There is a lot of literature available on the business model canvas **online**.

It is important to consider what your business model could/should look like early on in the development of a product/service. It will help you understand what your product is and what it means to your customer, who your customer is, how it will get to them, how the relationship will be maintained, and how you will generate income/revenue. In addition, it covers the back end of the business such as what you need to do, what resources you have or need, who you can partner with, what it will cost to implement. Contact HIHI for addition support in this area.