**HEALTH TECH INNOVATION STRUCTURE**

**Step 1**

In the first **step**, an innovative solution is proposed to address an unmet clinical need. From a demand perspective, innovation is a way to meet specific unmet that firms or research have not yet addressed. Regulation Commissioning & Adoption Best Practice and Tips**.** From a supply driven perspective, innovation in medical technologies has been described as the result of progress along three different pathways: advances in scientific understanding, improvement in the ability to develop new tools and learning in practice.

There are different ways innovators identify unmet needs. i.e.

* Clinical research & academic papers
* Clinical experience or opinion
* NHS Long Term Plan
* Local needs assessment

After the unmet clinical need has been identified, solution is proposed. The proposed solution may come from,

* Advances in scientific understanding
* Exploitation of new opportunities
* Existing Technology solution

**Step2**

**Value Proposition and Care Pathway Analysis**

A value proposition is a positioning statement that explains what benefits you are providing for a healthcare organisation and your capacity and capability to deliver those benefits well. The Value Proposition will evolve as you develop your product. Innovators and companies increasingly must articulate a broader value proposition to an increasingly diverse set of stakeholders, which is often required to access funding and support. A market requirement document could also be produced. It is also best practice to conduct a care pathway analysis to consider the impact on patient pathways, which can be used to support the value proposition.

The value of value proposition includes:

* **Market-**This refers to specific patients or clinicians you are targeting
* **Value experience-** Benefits minus cost, as perceived by customers
* **Offering-** The product/service mix you are selling
* **Alternatives and differentiation-** How you are different from and better than alternatives
* **Vision proof-** Credibility and believability of your offering
* **Benefits-** How your offering delivers clear value
* **System benefits-** This may include Optimal treatment reduced

Hospitalisation, speed up Recovery, Different staff grade and Reduced Process Time Required

* **Patient benefits-** • This involves: Improved outcomes, Enhanced dignity, enable self-care, Reduce unnecessary interventions.

After the above have been adhered to, this results to clear value preposition.

**Step 3**

**Device classification strategy**

The clinical data required by the regulators to demonstrate that a MedTech product performs as intended and is safe to use is dependent on the class of technology, with higher risk MedTech products requiring more extensive clinical evaluation and evidence standards before they can be launched onto the market. Innovators should be aware of the class of device during the creation stage to inform planning in later stages.

When you have established your product is a general medical device, you need to decide which class your device falls under. The categories are:

* Class I - generally regarded as low risk
* Class IIa -generally regarded as medium risk
* Class IIb -generally regarded as medium risk
* Class III - generally regarded as high risk

**Step 4**

**Intellectual Property Strategy**

Intellectual property (IP) is a legal framework that protects ideas, concepts and the products of creative and mental effort. Regulation. IP rights promote innovation by rewarding the owner of the IP with a monopoly right over the idea, preventing others from exploiting it without their consent. Innovators need to secure the appropriate IP to ensure their business remains viable, and to attract investors. Innovators should ensure the IP for their idea does not already exist, understand who else might have a claim on the IP (e.g. employers, collaborators and / or funders), and where appropriate apply for the right IP protection.

As an innovator make sure the following is adhered to:

• Identify the right IP protection required for your Health Technology Innovation

• Identify your IP Goals

• Ensure your technology does not infringe any existing patents

• If other parties have contributed to your IP, ensure you are clear on what contractual obligations you may have Commissioning & Adoption Best Practice and Tips General Information about Intellectual Property

• Information on Basic IP Guidance and Licensing intellectual property can be found on the government website.

• The IP Health Check is a free tool that can be used to identify your IP assets.

• Use the IP Equip service to find out which type of intellectual property you have

• Clear understanding of IP Protection required for your Health Technology Innovation

• Evidence that your health technology does not already exist

• If your innovation relies on the use of IP from third parties, ensure that you have secured the relevant rights

• Keep detailed and up to date records of your Intellectual Property, and take steps to ensure the information remains confidential

• If applicable, engage the services of a patent lawyer

• If relevant, prepare detailed documents which describe your invention and file these documents with the Intellectual Property Office (IPO)

**Step 5**

**Financial Support –Securing Seed Funding**

Innovators in the early stages of a start-ups face high-cost and low-revenue, which leads them to seek outside investors for capital, which is usually needed to demonstrate proof of the concept and develop a prototype. Pre-seed is a colloquial term for the earliest stage of the fundraising process.

Pre-seed options tend to be friends and family, Public/Third Sector, or Private Investment or Self-Funded.

**Step 6**

**Prototyping and Pre-Clinical Testing**

The development of product prototypes is an iterative process with multiple versions often tested and refined until a final product is developed to progress to the market.

This stage typically might involve small scale user testing or evaluation, depending on the technology.