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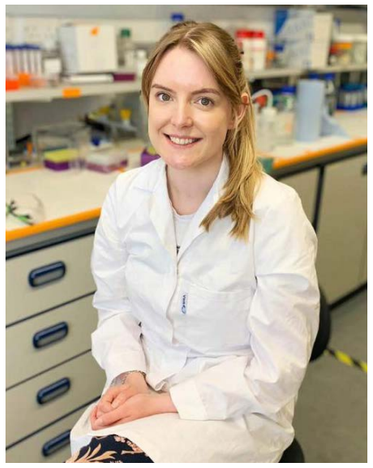
MEDICAL INNOVATION

An introductory guide to advancing your healthcare technology

Dr Sarah Madeline Fothergill

For academics, enterprises, healthcare workers and all innovators.

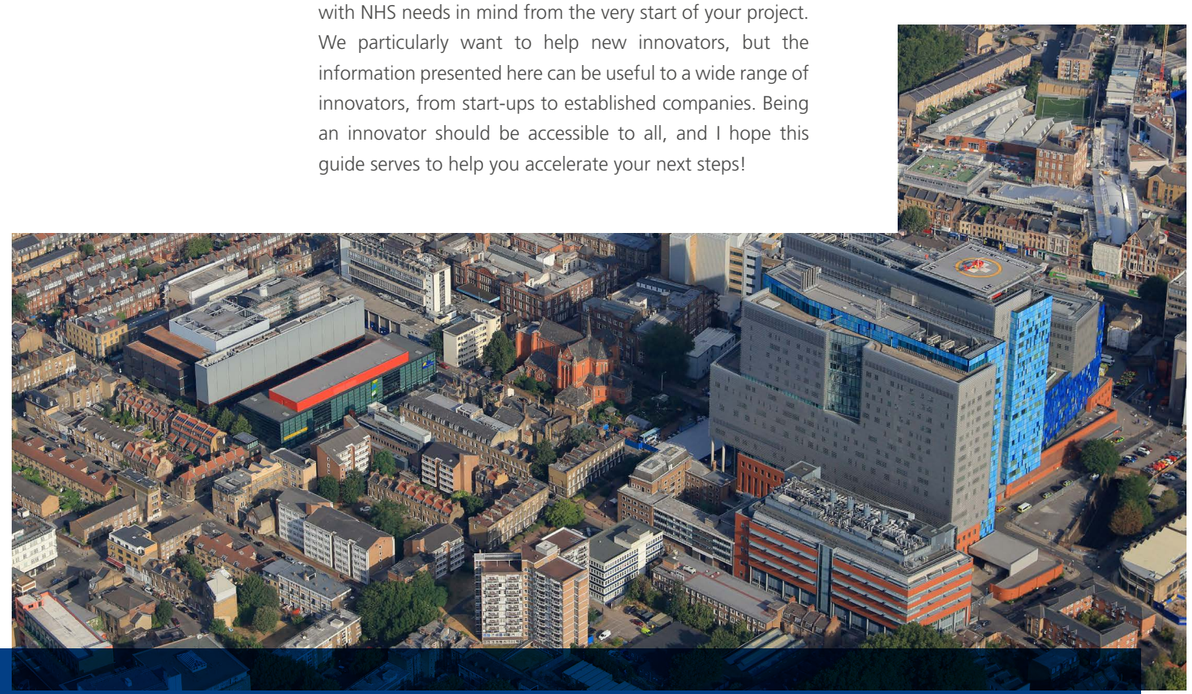
USING THIS GUIDE



Dr Sarah Madeline Fothergill, Barts Life Sciences

Foreword: The UK undoubtedly has some of the most impressive healthcare research in the world, but many researchers and innovators are unsure how to progress their idea. It is difficult to understand the next steps, not only in commercialising, but also with partnering with the NHS. How do you take that idea out of the lab? How does this idea move away from just a concept? Is it even feasible? And how do I gain the interest of the NHS? What is regulation and intellectual property? And where do I find funding? Where do I even start? There are so many questions that new innovators face, and it can be overwhelming.

We want to make it easy for everyone to transition their healthcare innovation from an idea to a product, that could have real world impact and benefit patients and communities. This guide is intended to act as a basic introduction into the world of medical technology commercialisation. We want to not only make you aware of the 'next steps' but also educate you, so that your innovations can be developed with NHS needs in mind from the very start of your project. We particularly want to help new innovators, but the information presented here can be useful to a wide range of innovators, from start-ups to established companies. Being an innovator should be accessible to all, and I hope this guide serves to help you accelerate your next steps!



1 Introduction to the NHS
An overview of the structure of the NHS and its levels of care. Understanding the NHS will help you identify who your key end users are.

2 Starting your journey
You have an idea for an innovative healthcare technology. How do you identify your end users, your main assumptions and if this has clinical need? The first step is to test your idea!

3 Developing your idea
Is your idea a feasible business (start-up)? How can you add value with your idea or technology and ensure you have a sustainable product / s?

4 Health economics
For any product to attract the attention of the NHS, it needs to be cost effective and benefit patients. This section introduces some simple ways to determine this for your innovation.

5 Intellectual property
Is your idea novel? Learn more about intellectual property and what is needed to protect your idea.

6 Funding
Here we explore the possible funding routes for your innovation, and how to secure different types of funding.

7 Regulation
Exploring the key regulatory frameworks that apply to the NHS, as well as data protection and data governance.

8 Partnering with the NHS
Here we provide some key advice for partnering with the NHS and the evidence that you will need to be able to demonstrate.

9 Developing your idea with Barts Life Sciences
Barts Life Sciences are able to help a wide range of innovators looking to partner with the NHS. Here we explore how we can help, and provide our key insights.

BARTS LIFE SCIENCES

At the heart of innovation

Barts Health NHS Trust and Queen Mary University of London, supported by Barts Charity, have come together to help accelerate the latest healthcare innovations from bench to bedside in a powerful partnership that we call **Barts Life Sciences**.

For centuries, our two organisations have discovered and delivered cutting-edge and transformative health solutions for people around the world. Now, as Barts Life Sciences we have a once in a lifetime opportunity to revolutionise healthcare and deliver better outcomes for everyone.

The need for pioneering, effective and affordable innovations in healthcare has never been greater. People in the UK, and the world, are living longer but not necessarily healthier lives. We exist to shape the future of healthcare for the benefit of people in London, the wider UK and the world.

Pioneers, visionaries and disruptors wanted

We aim to help all innovators, in all areas of healthcare. We work closely with small to medium enterprises, clinicians, academics, industry and many more to accelerate the adoption of new technologies. Ask us about the space available at our Whitechapel home to build and grow your vision, taking advantage of the access to our world-renowned clinicians and academics, rich diversity and data, as well as our excellent connectivity. Contact us about research and collaboration opportunities available with us.

Regardless of who you are, talk to us if you have an innovation that could transform healthcare.

www.bartslifesciences.org

Our vision is made possible through transformative partnerships. We will:

Accelerate, with confidence and safety, research and development through the innovation chain from the bench to the patient.

Reduce health inequalities and transform patient care in East London and the wider UK.

Create a sustainable NHS which will be recognised as world-leading in prevention, prediction and precision healthcare.

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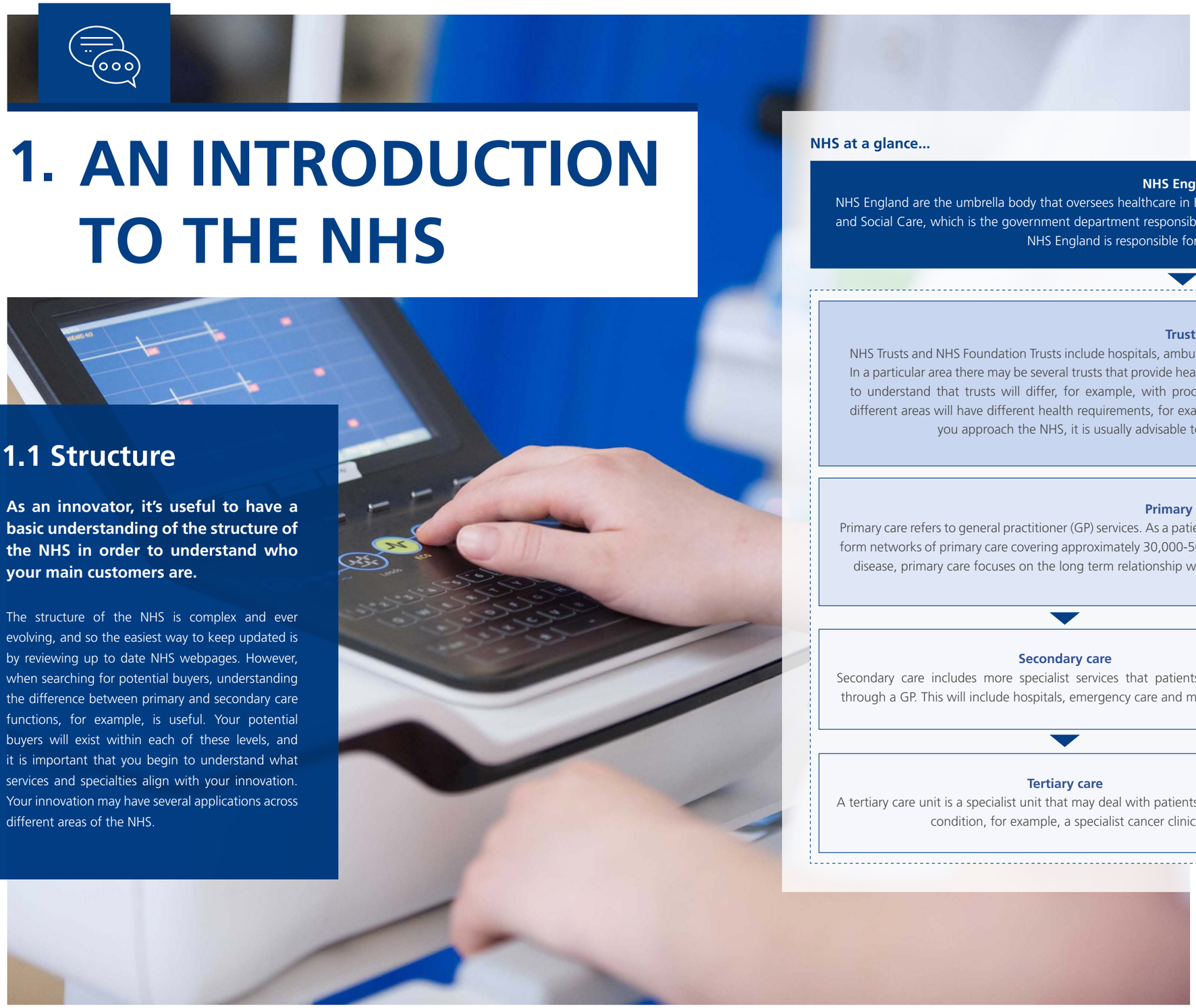
1. AN INTRODUCTION TO THE NHS



1.1 Structure

As an innovator, it's useful to have a basic understanding of the structure of the NHS in order to understand who your main customers are.

The structure of the NHS is complex and ever evolving, and so the easiest way to keep updated is by reviewing up to date NHS webpages. However, when searching for potential buyers, understanding the difference between primary and secondary care functions, for example, is useful. Your potential buyers will exist within each of these levels, and it is important that you begin to understand what services and specialties align with your innovation. Your innovation may have several applications across different areas of the NHS.

NHS at a glance...

NHS England

NHS England are the umbrella body that oversees healthcare in England. They are accountable to the Department of Health and Social Care, which is the government department responsible for health care policy and funding in England and Wales. NHS England is responsible for an effective care system.

Trusts

NHS Trusts and NHS Foundation Trusts include hospitals, ambulance, mental health, social care and primary care services. In a particular area there may be several trusts that provide healthcare to local population. As an innovator, it is important to understand that trusts will differ, for example, with procurement and commercial processes. In addition to this, different areas will have different health requirements, for example they may focus more on different specialties. When you approach the NHS, it is usually advisable to approach different trusts independently.

Primary care

Primary care refers to general practitioner (GP) services. As a patient, this is often your first contact with the NHS. GP practices form networks of primary care covering approximately 30,000-50,000 people. Rather than providing treatment for a specific disease, primary care focuses on the long term relationship with patients for a wide variety of condition management.

Secondary care

Secondary care includes more specialist services that patients are referred to through a GP. This will include hospitals, emergency care and maternity services.

Tertiary care

A tertiary care unit is a specialist unit that may deal with patients with a particular condition, for example, a specialist cancer clinic.

Community care

Community care includes at home and remote services such as district nurses and care homes. This will also include mental health services.

1.2 Academic Health Science Networks (AHSN's)

Identify and engage with your local AHSN

If you don't already know who your AHSN is, you should identify this via www.ahsnnetwork.com. This is one of the strongest pieces of advice we can give. Your AHSN will have a standard engagement process to connect with their teams and have a conversation to understand what stage you are at and what might help you in this moment, as well as resources available to help you. You will find that some run events and workshops that are specifically aimed at new innovators, guiding you on how to access the NHS. The AHSNs can provide access and signpost to a range of expert support and services across health and social care.

We strongly recommend you identify and connect with your academic health science network.

What are Academic Health Science Networks?

Academic Health Science Networks (AHSNs) work in partnership with universities, industry, and the NHS to support with improving standards of clinical care, health outcomes, and cost efficiencies through research, innovation and education. Working with the NHS, they develop, test and implement solutions for the benefit of patients, public and staff.

There are 15 regional AHSNs. Barts Life Sciences' AHSN is UCLPartners. Each AHSN is associated with universities, as well as a range of primary, secondary and tertiary care (community through to specialist hospitals) in a geographical area. AHSNs can offer advice and guidance on whether there is an identified need within the NHS for your innovation, assess commercial viability and support you to explore evidence generation to evaluate the impact that your innovation could have on the health and social care system.

AHSNs can support a broad spectrum of innovations, from MedTech devices to digital solutions, and at different stages of maturity. They have the unique role of bridging the gap between the NHS and the industry sector, and can provide high potential innovators with access to clinical expertise, commercialisation support and signposting to innovation programmes and funding.

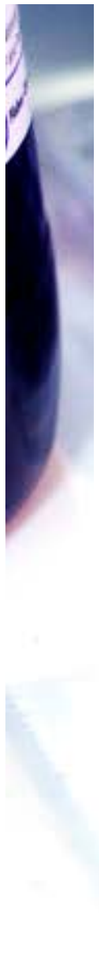
2. STARTING YOUR INNOVATION JOURNEY

We strongly suggest that you work through the following steps methodically from day 1 of idea development

Testing your assumptions

Customer discovery

Developing business experiments



So you have an idea for an innovation? Great!

Before you rush off to develop your idea, gain funding and tell the world, you need to take a pause to ask yourself some ***very fundamental questions***. All new innovators are passionate about their innovation, and it can be common to see this through 'rose tinted glasses' and believe that your new innovation is going to be hugely impactful. When considering partnering with the NHS, or applying for any funding, **evidence is crucial**. And this is not just evidence that the innovation works, but also that it is feasible or required.

When developing your innovation, it is normal to have a set of assumptions (such as 'this technology is needed by patients' or 'this can easily be integrated into the care system' amongst many). But until you really go out and test these assumptions, that is all they are, assumptions!

By addressing some of these key assumptions at an early stage, ideally before you embark on a project, this will put you in a stronger position when developing your innovation. Not only will you be able to demonstrate on funding applications that you have done your research, but you will be able to design your innovation with the real clinical need, and the NHS in mind.

2.1 Testing assumptions

When first embarking on an innovative journey, there are many unknowns and there are a lot of assumptions that are made. The easiest way to test if your assumptions are valid is through an idea canvas. There are lots of models of idea canvasses online, but essentially without research you are jotting down what you already know and assume.

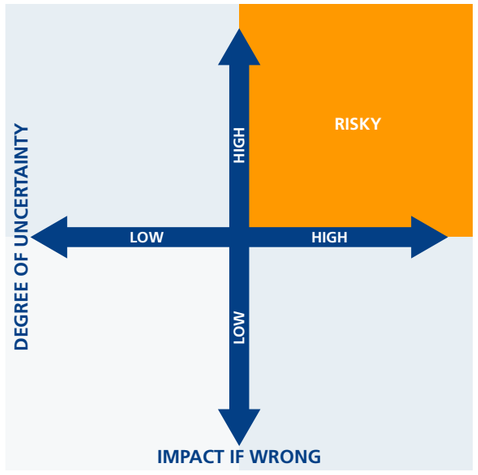
STEP 1: IDENTIFY YOUR ASSUMPTIONS

Ask yourself these four questions, and then jot down assumptions that you are making in answering them. An assumption can be any answer you haven't yet gathered hard evidence for.

1. What are the problems you are trying to solve? How big is the potential market?
2. What is the solution you are offering? Are there any existing alternatives?
3. Who would be your first user(s)? How will you reach them?
4. What will be your revenue? What will you charge?
5. How will you keep your innovation sustainable, i.e. financially and relevant to market?

STEP 2: PLOT YOUR RISK

Now you have your assumptions listed, you need to decide which you need to test. The easiest way is to plot a matrix of risk as shown on the right. Place all of your assumptions somewhere within this matrix which maps uncertainty and impact. The assumptions that fall into the top right are your riskiest assumptions, and you should address these first. These are the assumptions that are the most uncertain and should they be disproven will impact your innovation the most. Examples could be 'this is actually a problem' or 'customers would be willing to pay X amount' or 'this could be reused'.



STEP 3: TEST YOUR ASSUMPTIONS

You need to now think of a way you are going to either prove or disprove these risky assumptions. Treat this like a scientific method, with a hypothesis, test, measurement and conclusion.

1. **Your hypothesis:** This is what you are assuming based on your risky assumptions, and need evidence for or against, e.g. your hypothesis could be 'customers would be willing to pay X'.
2. **Your test:** How are you going to test this assumption? Interviews, research online, talking to your AHSN? E.g., to verify this we will interview X amount of individuals during customer discovery (next page!)
3. **To measure this:** You need to quantify the data that you will gather from this research. For example 'we will plot the responses, or rate the responses 1-5 from agree to disagree'.
4. **The conclusion:** You need to set a limit above or below which you can prove or disprove your assumption, for example 'we will set our limit as being 70% positive responses', above this we can say with some certainty that our assumption is valid.

After planning how you will test your assumptions, you need to begin talking to those who can provide you answers surrounding them. The following section will address how to talk to end users (your key stakeholders), to prove or disprove these risky assumptions. (see section 2.2).

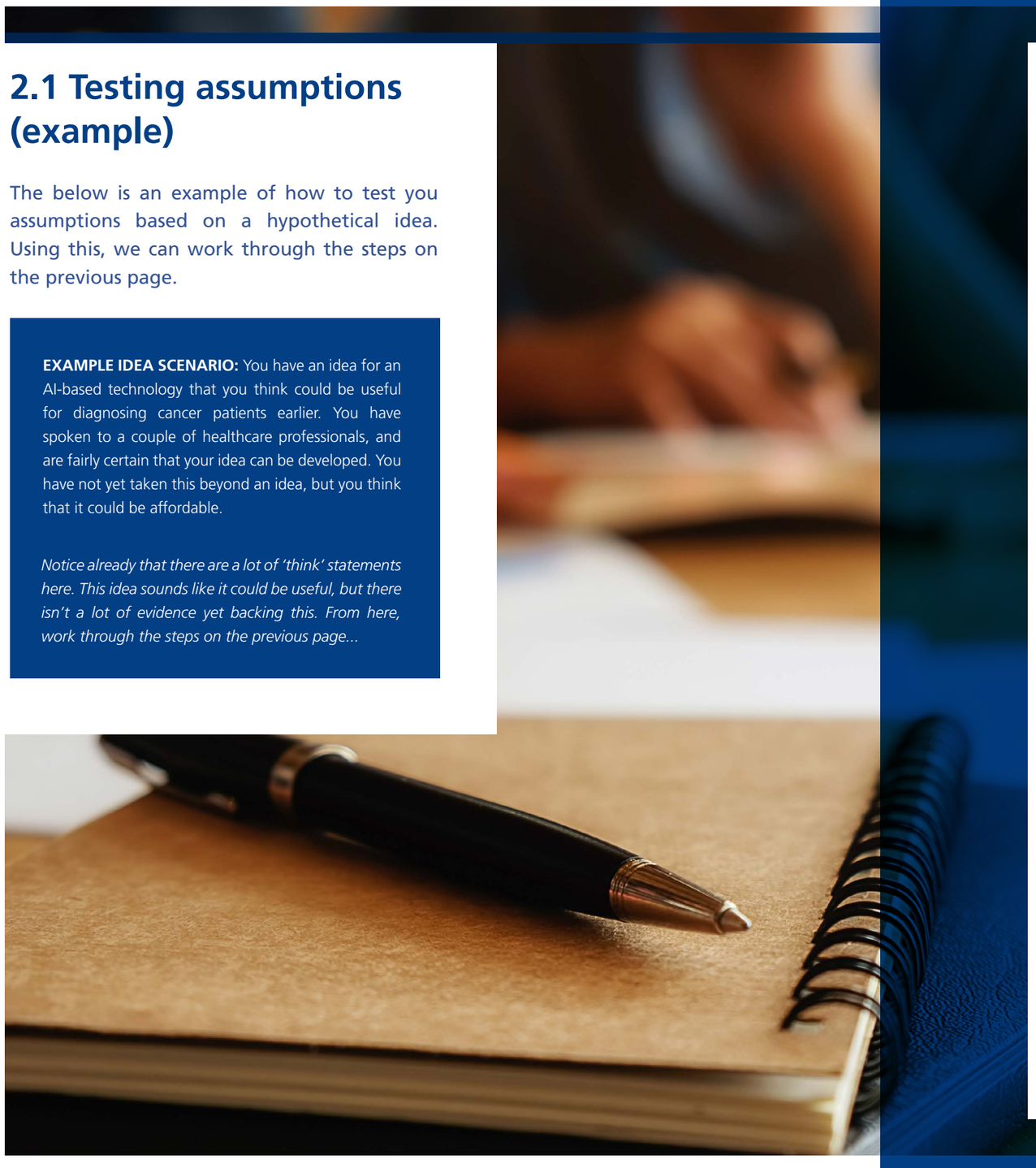
Be aware that any funder may potentially want to see the evidence of all of this research!

2.1 Testing assumptions (example)

The below is an example of how to test you assumptions based on a hypothetical idea. Using this, we can work through the steps on the previous page.

EXAMPLE IDEA SCENARIO: You have an idea for an AI-based technology that you think could be useful for diagnosing cancer patients earlier. You have spoken to a couple of healthcare professionals, and are fairly certain that your idea can be developed. You have not yet taken this beyond an idea, but you think that it could be affordable.

Notice already that there are a lot of 'think' statements here. This idea sounds like it could be useful, but there isn't a lot of evidence yet backing this. From here, work through the steps on the previous page...



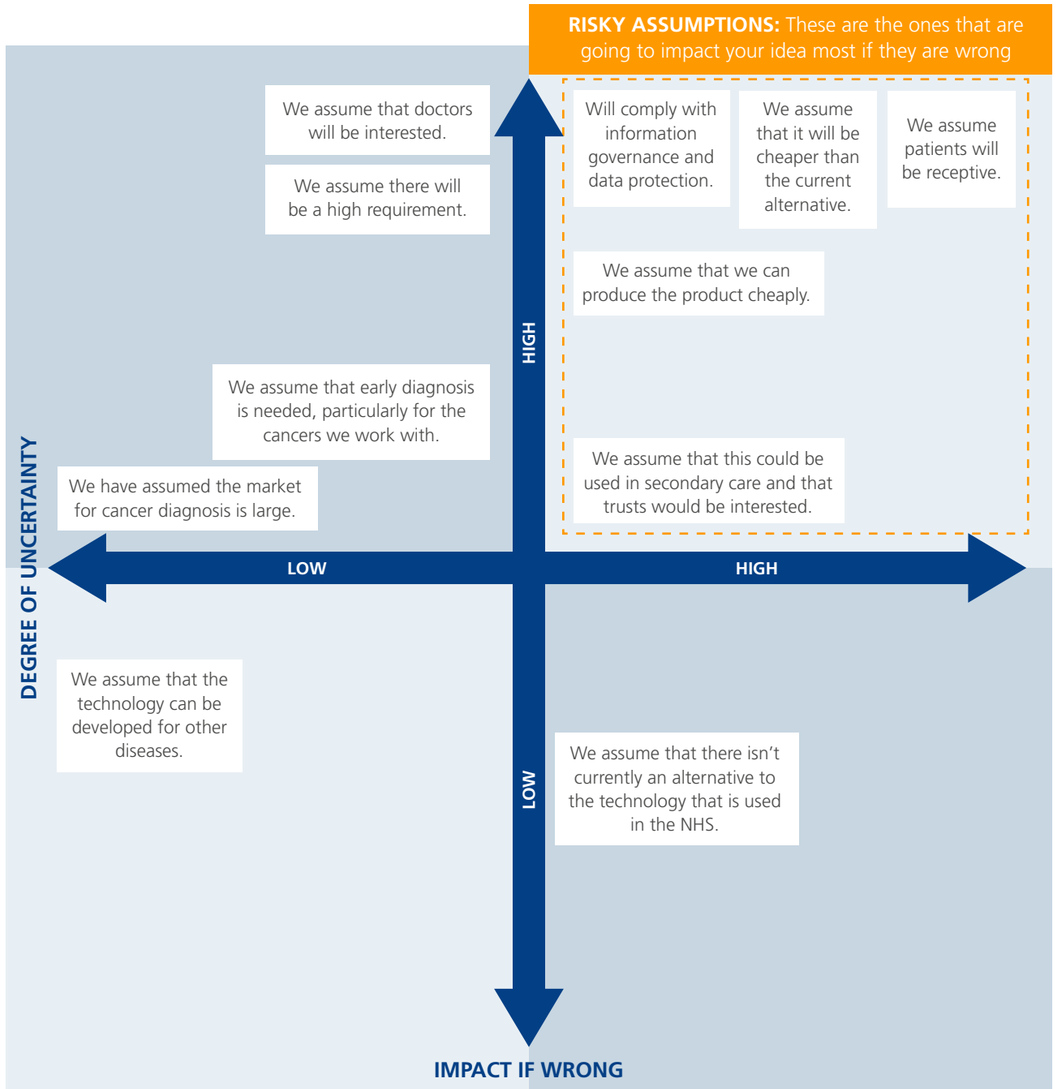
STEP 1: ASK YOURSELF THE FOLLOWING TO IDENTIFY ASSUMPTIONS

Answer the following, then add 3-5 assumptions.
(We've shown a couple of assumptions here but add as many as you can!)

Question to ask	Your answer	You assumptions
What are the problems you are trying to solve? How big is the potential market?	We want to diagnose cancer patients sooner. The market is pretty big – there are a lot of patients.	• We have assumed the market for cancer diagnosis is large. • We assume that early diagnosis is needed.
What is the solution you are offering? Are there any existing alternatives?	We have an AI technology that diagnose cancers early. We don't know what the competitor technologies, we don't think there are any that fit into this niche.	• We assume that there isn't currently an alternative to our technology that is used in the NHS.
Who would be your first user(s)? How will you reach them?	We think that the first users could be in secondary care.	• We assume that this could be used in secondary care and that trusts would be interested. • We assume that this will comply with data protection and information governance (IG). • We assume that doctors will be interested. • We assume patients will be receptive.
What will be your revenue? What will you charge?	We will sell the technology per one patient, and there will be a lot of patients.	• We assume that it will be cheaper than the current alternative. • We assume that we can produce the product cheaply. • We assume there will be a high requirement.
How will you keep your innovation sustainable, i.e. financially, and relevant to market?	We will adapt the technology for other diseases in the future.	• We assume that the technology can be developed for other diseases.

STEP 2: PLOT YOUR RISK.

The assumptions that fall into the top right quadrant are the risky assumptions. These are the ones you need to address first.



So your risky assumptions are the following:

- We assume that it will be cheaper than the current alternative.
- We assume that we can produce the product cheaply.
- We assume that this could be used in secondary care and that trusts would be interested.
- We assume patients will be receptive.
- Will comply with information governance and data protection.

STEP 3: TEST YOUR ASSUMPTIONS.

Using the assumptions gathered for the example scenario (AI-based technology for early cancer diagnosis) on the previous pages, you can begin to map out how you are going to test each of these assumptions. The table below gives an example of how you could test, measure, and conclude each hypothesis. It will be helpful to read the next section on talking to users, which will aid you in the design of any interviews or focus groups that you may need to conduct.

Hypothesis	Test	Measure	Conclusion
We assume that it will be cheaper than the current alternative.	We need to identify the cost of production. Market research and health economics needed.	Identify the total cost. Compare to the current alternative.	Only can be proven true if the alternative is more expensive than our method.
We assume that we can produce the product cheaply.	This is similar to above, so could be combined into the same test.	How can the manufacturing cost be kept low?	Only can be proven if a an affordable sustainable manufacturing process can be developed.
We assume that this could be used in secondary care and that trusts would be interested.	You need to talk to healthcare workers, as well as a wide variety of trust representatives.	Talk to 10-20 healthcare workers. Talk to trust representatives. Identify if trusts have their own way of managing the problem.	If 70% of healthcare workers have identified a similar problem to you then proven true. If trusts do not already have a pathway for managing the problem, then proven true.
We assume patients will be receptive.	Patient and Public Involvement and Engagement is needed (PPIE). See section 2.4.	Patients understand the problem presented and feel the technology could benefit them. Patients are comfortable with the change in patient pathway (the steps of care they receive) and experience that this technology would present.	Set a limit, for example 60%, of patients feel that this could benefit their care, then proven true. If patients understand and accept the changes that this technology would make to their care, then proven true.
Will comply with Information Governance and Data Protection.	Advice is needed on regulation, data protection and IG, see section 7.	Speak to experts on regulation including a relevant regulatory body. Identify if the regulations that you need are feasible with your technology.	If you are able to adapt your technology so that it fits into current NHS regulatory pathways, then proven true.

REMEMBER– ANY FUNDER MAY WANT TO SEE THIS EVIDENCE.

You may be asked to present evidence for statements that you make, particularly if you are trying to attract funding. Remember to keep note of where you have gathered the data from, as you could be asked for this.

2.2 Customer discovery

Customer (user) discovery is important on so many levels when developing an innovation. By talking to your end users, you are able to gather information on what needs they have, what the market competition is and ultimately develop your product with them in mind. You can also test any assumptions you may have about your innovation – for example, 'is this needed?', 'does this fit into the clinical pathway?' (see section 2.1). It's ***really important*** at the early stages of product development to remember **that you are not trying to sell any product to your end user** – you simply need to gather information. For example, when working with the NHS, your end user may be a variety of healthcare professionals, procurement, laboratory staff, etc. You must talk to these people to discover their experiences.

1. ASSESS YOUR END USERS

The first thing to do is to segment who you consider your customers and users to be. This is often known as *customer segments*, i.e. clusters of users who share the same needs and characteristics. For example, are they clinicians, software companies, the pharmaceutical industry? Each one of these groups will have their own requirements and set of questions about your technology. Begin by jotting down who you think will need your innovation the most. Once you have identified this group *think broader*, who could use your technology perhaps in the future, and are there any far reaching users you could think of? It is important to identify even wide reaching customers. This is not only to keep your business sustainable, as you may find that your key users are not who you initially thought! *We strongly advise that for each of these user segments, you talk to as many customers as possible* (at least 20!). Reach out to any relevant NHS specialities relating to your innovation, as well any industries or existing companies you could partner with.

2. FIND YOUR CUSTOMERS

In healthcare, your customer base could be huge. Start by reaching out to those in your network for chats. Go to networking events, search LinkedIn and attend any available meet-ups or talks. Connect with us at Barts Life Sciences, or other MedTech organisations in your area. There are so many ways you can reach out to end users. Ask for referrals, and try to avoid cold emails. If you do have to send cold emails, try to offer something in return, for example talking about your work, or offering to be first on a mailing list. If you're uncertain, talk to us at Barts Life Sciences, your enterprise division (if based at a university) or your local AHSN, and they may be able to advise.

3. LISTEN TO EXPERIENCES

Remember, you are not trying to sell! But you do need to do some research. For example, when gathering information on a healthcare need you may need to determine the following:

1. Does the problem that we are trying to solve actually exist?

2. If so, how much of an impact is this problem?

3. How is the problem currently dealt with?

4. Are there set budgets for this problem?

4. WHAT YOU SAY MATTERS

When talking to any new end user during this stage it is important to gather *unbiased information* (Google 'mom test'!) and ask open ended information. **Do not enter the conversation trying to 'sell' your product**. This isn't helpful. For example if you asked a clinician – 'I have a software that does X, is this useful?', they may likely just say 'yes' but in doing so, you have gathered no real information on what their actual problems are, how much this impacts them and what they are doing to solve the issue. Instead, ask open ended questions to gather as much information as possible:

E.g. 'Tell me about X, when did this last happen?'; 'What are the implications of X for your patients?'; 'What solutions do you have in your speciality (etc.) to overcome problem X?'; 'Who else should I talk to?'; ' Do you have a budget allocated to X problem?'; 'What else have you tried?'; 'Is there anything else that you struggle with?'.

You can have this whole conversation, without even telling the end user what you are developing. For example 'I want to talk about how you deal with X problem', rather than 'I have a technology that solves X problem'.

5. MAKE SENSE OF OUTCOMES

Go back to your original assumptions (section 2.1). How do your responses compare to your assumptions now that you have the end user data? Look for patterns in the data – for example – did multiple clinicians express the same problem? Did they have the same solutions? Was there any suggestion that was given multiple times?

Be aware of your own bias – you may think your innovation is amazing, but try not to fit the data to prove your own assumptions, be realistic! If your idea is not needed, your idea is not needed, and its better to know this now rather than later. **Some ideas just do not work, it's not a failure, it's ok!**

2.3 Assessing your Technology Readiness Level

The Technology Readiness Level (TRL) scale is a useful way to express the current stage of development that your innovation is at. This is a useful way of talking to potential funders and helps you understand what actions may need to be taken for it to develop further.

STAGES 1-3: This represents the beginning of the development of the idea that leads to proof of concept. For this level, it is advisable to target research council grants and the NIHR (National Institute for Health and Care Research).

STAGES 3-6: This is when your technology begins to be taken out of the traditional lab or research setting and validated through the relevant environment (for example, modelled on a clinical setting). For this level, target NIHR and Innovate UK.

STAGES 6-9: This is when the product is tested in its final destination. The innovation at this stage should be attracting private funding.

Stage	Activity	Description
1	Discovery	Basic principles observed
2	Research	Technology concept formulated
3	Innovation	Experimental proof of concept
4	Innovation	Technology validated in lab
5	Innovation	Technology validated in relevant environment (e.g., end testing destination)
6	Innovation	Technology demonstrated in relevant environment (industrially relevant environment)
7	Innovation	System prototype demonstration in operational environment
8	Commercialisation	System complete and qualified
9	Commercialisation	Actual system proven in operational environment

It's useful at all stages of development to be thinking about commercialisation. Thinking about this early on will avoid the development of a product that has no commercial potential and clinical need.

2.4 The importance of Patient and Public Involvement

What is Patient and Public Involvement and Engagement?

Patient and Public Involvement and Engagement (PPIE), is any research that is carried out with or by members of the public.

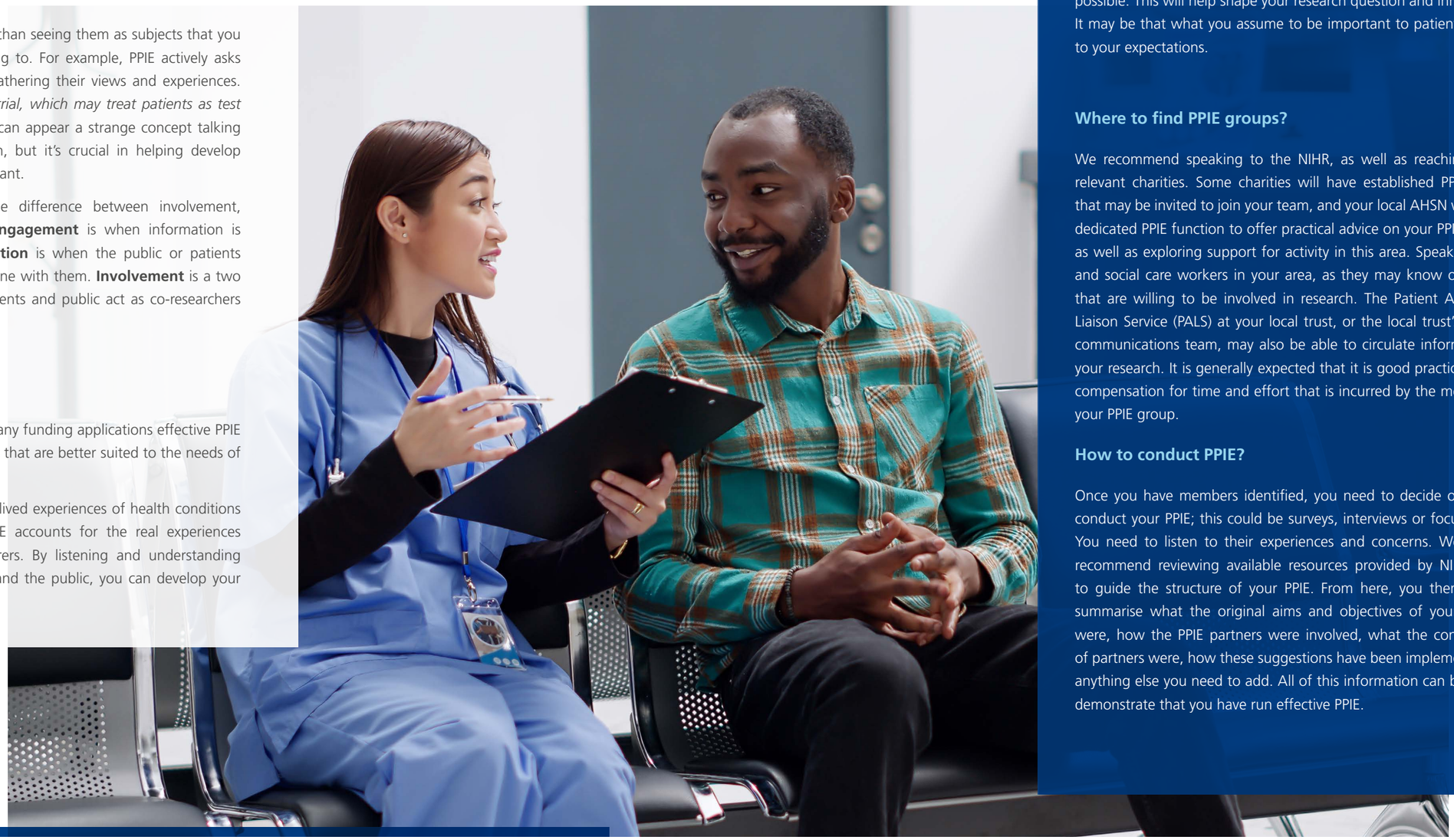
It actively involves patients, rather than seeing them as subjects that you are developing for or administering to. For example, PPIE actively asks patients about your innovation, gathering their views and experiences. *This is not the same as a clinical trial, which may treat patients as test subjects.* If you're new to PPIE, it can appear a strange concept talking to patients about your innovation, but it's crucial in helping develop technology that patients actually want.

It's good to be clear about the difference between involvement, engagement and participation. **Engagement** is when information is shared with the public. **Participation** is when the public or patients are subjects and the research is done with them. **Involvement** is a two way process. In this case, the patients and public act as co-researchers alongside you.

Why Is PPIE Important?

Beyond being a requirement for many funding applications effective PPIE will develop healthcare innovations that are better suited to the needs of the patients and public.

As researchers, you may not have lived experiences of health conditions that you are researching for. PPIE accounts for the real experiences and opinions of patients and carers. By listening and understanding the requirements of the patients and the public, you can develop your innovation with them in mind.



When should you be conducting PPIE?

PPIE can occur at any stage of your innovation process, from early idea development to disseminating results. The earlier the better! Before you have secured any funding, start talking to patient groups where possible. This will help shape your research question and innovation. It may be that what you assume to be important to patients differs to your expectations.

Where to find PPIE groups?

We recommend speaking to the NIHR, as well as reaching out to relevant charities. Some charities will have established PPIE groups that may be invited to join your team, and your local AHSN will have a dedicated PPIE function to offer practical advice on your PPIE strategy as well as exploring support for activity in this area. Speak to health and social care workers in your area, as they may know of patients that are willing to be involved in research. The Patient Advice and Liaison Service (PALS) at your local trust, or the local trust's research communications team, may also be able to circulate information on your research. It is generally expected that it is good practice to offer compensation for time and effort that is incurred by the members of your PPIE group.

How to conduct PPIE?

Once you have members identified, you need to decide on how to conduct your PPIE; this could be surveys, interviews or focus groups. You need to listen to their experiences and concerns. We strongly recommend reviewing available resources provided by NIHR online to guide the structure of your PPIE. From here, you then need to summarise what the original aims and objectives of your meeting were, how the PPIE partners were involved, what the contributions of partners were, how these suggestions have been implemented and anything else you need to add. All of this information can be used to demonstrate that you have run effective PPIE.

3. DEVELOPING YOUR IDEA

3.1. Value propositions

When developing your innovation, any potential funder may ask you about your value proposition and potential business model. We aren't going to look into these too deeply in this section, but it's worth understanding what these mean in practicality, and what the NHS may expect to develop a partnership.

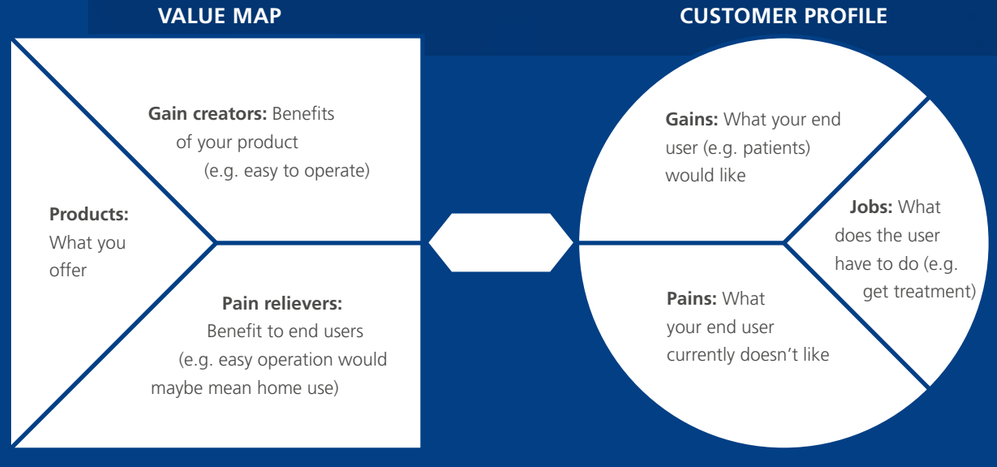
Your NHS value proposition

A value proposition is a simple statement that summarises why a customer would choose your product or service.

You can represent this visually on a *value proposition canvas*. This is composed of two parts, the customer profile and the value map. With the customer profile, you describe the jobs that your customer is trying to get done, their pains (things that annoy them, not just physical pain!), and outline the customer gains (which measure how well an outcome is achieved). As you speak to customers, patients, healthcare professionals and your other customer groups, you can begin to map out what you are learning about your customers.

The second part of the canvas is a value map. Here you list the products and services that are on offer through your innovation, what pain relievers (how they reduce issues that customers care about), and outline your gain creators (how they produce, increase or maximise benefits).

Having visualised both of these, you can compare and fit both parts of the value proposition to match up what end users expect compared to what your product offers.



For your NHS value proposition you will need to be able to define:

- What is the innovation?
- Where will it be used?
- Who is it relevant to?
- What is the pathway your innovation supports or replaces?
- What is the consequence of the problem you are solving for patients or staff?
- How does this work? Can you explain this simply?
- How are you going to deliver this?
- What organisational changes will need to be made?
- What outcomes do the patients report? Quality of life? Satisfaction, etc.?

Be prepared to be able to describe your innovation simply to anyone

When people ask you what your innovation is, remember they are **not experts**, and may not want to hear the technicalities of how it works. But they will be interested in *what it offers them*. Don't assume that clinicians, or even other researchers in your field know (or want to know) the technicalities. *Keep language simple* so everyone can understand what your innovation offers.

A good skill is to be able to describe your innovation in one sentence...

For example rather than diving into complex technicalities about how your product works, *convey what it offers*.

Keep it concise. Say this: We have developed [product name / service], which helps [insert customer segment], by [what you offer].

For example: We have developed a diagnostic device, that helps clinicians and patients by diagnosing this disease earlier.

In the above example, you can easily state what your innovation offers without delving into the complexities of how it works. It's likely that the NHS and funders will be far more interested in what you offer, than how it works. Keep the heavy science to a minimum!

3.2. Business models

If you are thinking of forming a start-up with your innovation, it's good to have an awareness of your business model. This is best displayed through a business model canvas.

There are plenty of resources online that can help you understand how to develop your business model. For each customer segment, you will have a specific value proposition.

A Business model canvas consists of 9 key segments:

1. **You customer segments** (Who are the end users?)
2. **Your value proposition** (What can you offer the customers? [see section 2.2])
3. **Your channels** (How you will reach your end users?)
4. **Customer relationships** (you establish)
5. **Your revenue streams** (How your potential start-up will create financial value)
6. **Key activities and key resources** (Required to create value)
8. **Your key partnerships** (Who are your key partners that you require to make the model work?)
9. **The cost structure of the business model** (How will you make the finance of your business viable and sustainable?)

KEY PARTNERS

- Who are your key partners / suppliers?
- Which key resources are being acquired from partners?
- Which key activities do partners perform?

KEY ACTIVITIES

- What key activities does your value proposition require?
- What activities are the most important for your distribution channels, customer relationships, revenue streams, etc.?
- What key activities do you need to deliver your customer experience?

KEY RESOURCES

- What key resources does your value proposition require?
- What key resources do you need for distribution?
- What key resources do you need for customer relationship management?

VALUE PROPOSITION

- What core values do you deliver to your audience?
- What bundles of product / services are you offering to each customer segment?
- What jobs are your customers trying to complete?
- What pains do they experience when trying to achieve their goals?
- How does your product / service help them achieve their goals / relief pains?

CUSTOMER RELATIONSHIP

- What relationship does the target audience expect you to establish and maintain with them?
- Which ones have you established?
- How costly are they?
- How are they integrated with the rest of your business model?

CHANNELS

- Through which channel does your audience want to be reached?
- How are you reaching them now?
- How are the channels integrated?
- Which ones work best?
- Which ones are the most cost efficient?
- How are you integrating them with customer routines?

CUSTOMER SEGMENTS

- Which groups of customers are you creating value for?
- Who are your most important customers? Why?
- What differentiates your customer segments?
- What opportunities are there to reach new customer segments?

COST STRUCTURE

- What are the most important costs?
- Which key resources are the most expensive?
- What can be changed from a fixed cost to a variable cost?

REVENUE STREAM(S)

- For what value are customers really willing to pay?
- For what do they currently pay?
- How are they currently paying?
- How much does each revenue stream contribute to the overall revenues?

3.3 Designing business cases

What is a business case?

A business case provides justification for undertaking a project, programme or portfolio.

Why do you need a business case?

For innovators coming from outside the NHS, introducing a new procedure or product may require a business case to be developed to make the case for change and justify costs that incur. It is useful to know what a business case could look like. This could also apply to those within the NHS wanting to implement an innovation with a company that they may want to work with. It is useful for SMEs (small and medium enterprises) to be aware of this, so they understand what the NHS must do in order to get their product or service implemented and approved. This may also help SMEs understand what information they will need to be able to provide to the NHS for a case to be written.

Not all investments need detailed business cases. Projects with one-off costs less than £50,000, or annual costs less than £10,000 will need a shorter paper to demonstrate that the new product will save money and improve quality. However, even in these cases, the justification will need to be supported by good evidence on quality, safety, value for money, and deliverability

The five case model

The five case model is the approach used for developing business cases. By having an agreed standardised way in which a decision is made, then there is less likelihood that decisions are made on perception. Using the five case model, there is structure in how you arrive at the best possible decision. The model can address, and can address specific questions to provide evidence to.

The case	The question	What the business case must demonstrate	
Strategic case	Is the proposal needed?	Will it further the aims and objectives?	Is there a clear case for change?
Economic case	Is it value for money?	Has a range of options been considered?	Is it the best balance of costs, benefits and risk?
Commercial case	Is it viable?	Is there a supplier who can meet our needs?	Can we secure a value for money deal?
Financial case	Is it affordable?	Are the costs realistic and affordable?	Is the required funding available and supported?
Management case	Is it achievable	Are we capable of delivering the project?	Do we have robust systems and processes in place?

Levels of business case

There are different levels of business case that have varying levels of detail. Each level is a separate document that requires separate approval and support before moving onto the next stage in the overall project life cycle. At each of the three stages, the business case needs to consider each of the five cases.

SOC — **The Strategic Outline Case**
The concept stage – ascertains 'strategic fit', makes the case for change, determines short list of potential affordable options, conveys management capacity and capability to deliver

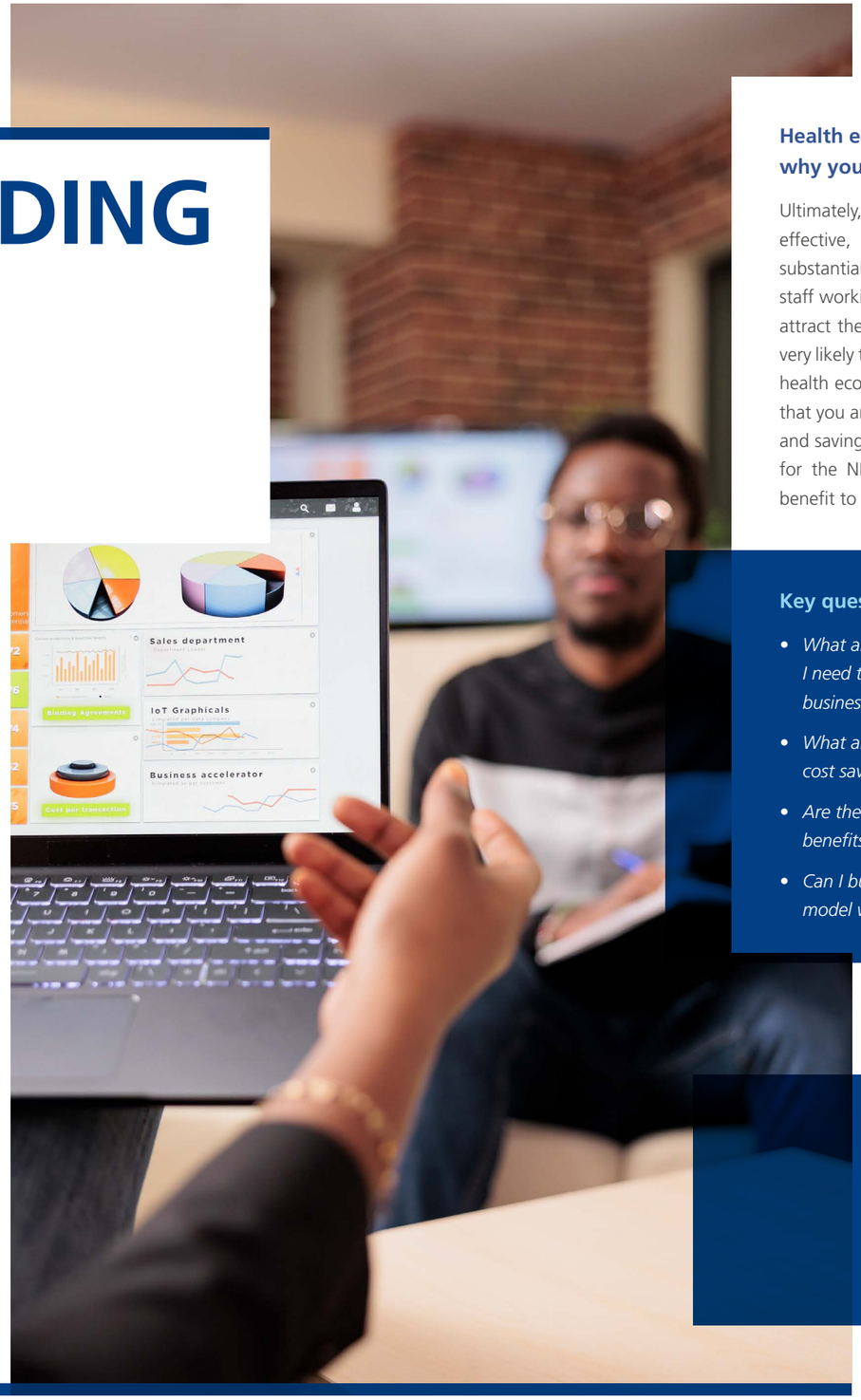
OBC — **The Outline Business Case**
The detailed appraisal of options – determines the best value for money solution, prepares for procurement, confirms funding and affordability and the detailed management plan for delivery

FBC — **The Full Business Case**
A final, technical document – the outcome of the procurement process, final check on affordability and value for money, the contract details, comprehensive delivery plan and benefits realisation

4. UNDERSTANDING HEALTH ECONOMICS

4.1 What is health economics?

According to the National Institute for Health Care and Excellence (NICE) 'Health economics is about using resources efficiently to improve the population's health'. Health economic analysis and evaluation forms an integral part of the public health guidance development process. This is an evaluation that compares different courses of action in terms of their costs (financial) and their consequences (e.g. benefit to patients). It's important that there is a maximum health gain versus cost for any healthcare innovation as there are a finite amount of resources allocated to the NHS. It is also useful, as we want to allow for the general population to obtain these health benefits, while not spending too much. This can be a complex balance.



Health economics for innovators – why you should you care?

Ultimately, if your innovation is not cost effective, or if it cannot demonstrate a substantial improvement to patient care or staff working, then it is unlikely that it will attract the attention of the NHS. You are very likely to be asked if you have done any health economics studies so it's important that you are able to demonstrate the costs and savings that your innovation will have for the NHS, and balance this with the benefit to patients.

Key questions to consider:

- *What are the core functions that I need to offer to be an attractive business to a healthcare buyer?*
- *What are my barriers to the cost savings?*
- *Are there any non-financial benefits that are offered?*
- *Can I build a sustainable business model with the expected revenue?*

When to consider health economics?

You should be considering very basic health economics from the start of your innovation journey.

What are the uses of a health economic model?

Useful for when discussing your innovation with clinicians / NHS

- A good model will help when applying for grant funding
- It will improve marketing materials
- It will strengthen the pricing position in negotiations
- Useful if applying for NICE technology appraisal or a Heath Technology Assessment

Note: you can get help with your health economics assessment from an evidence-based medicine consultancy. Speak to your AHSN for further advice.

4.2 Health economic assessments

There are two analyses that need to run in parallel here, how much you innovation will cost (or save) and the overall benefit to patients. When thinking of partnering with the NHS, you need to understand the impact your innovation on both of these.

Financial cost

How much does your innovation cost or save the NHS? Although seemingly obvious, this doesn't just include purchase price, but also any additional costs that may be incurred due to the modification of the pathway compared to the current route. For example, training, maintenance, additional resource or consumables. Are there financial costs incurred due to the change in patient pathway?

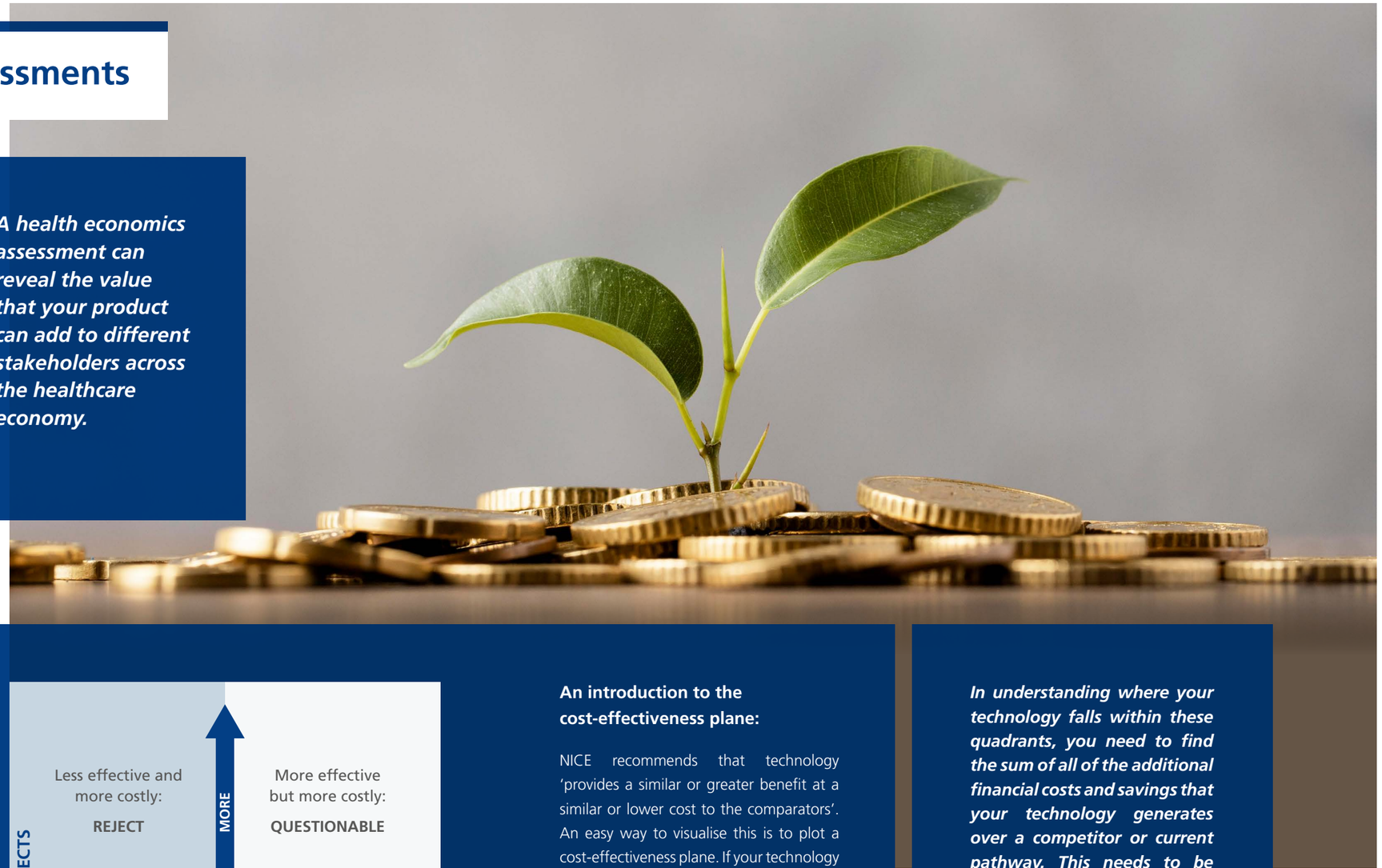
Measurement on health effects

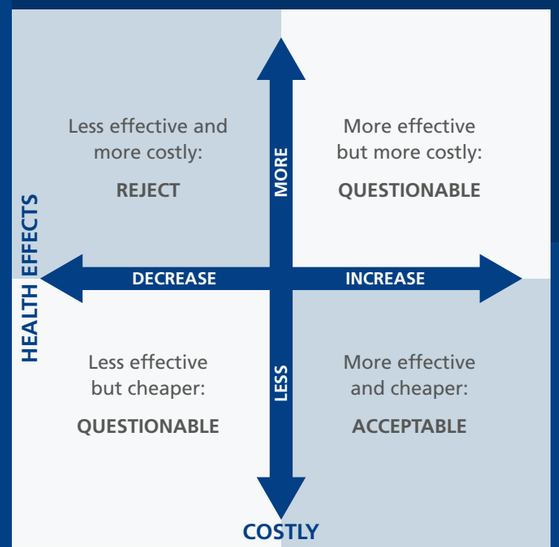
The health effects are typically measured in QALYs (Quality of Life Adjusted Year) and QoL (Quality of Life). They can be helpful terms to express what benefit your innovation will bring to patients.

QALYs: This is a measure of the state of health of a person, where one QALY is equal to one year of perfect health. They are calculated by estimating the years of life remaining (before or after treatment) and weighting each year with a quality of life score (0 to 1).

QoL: Quality of Life. This is often measured in terms of the person's ability to carry out their activities in daily life, as well as freedom from pain and mental disturbance.

A health economics assessment can reveal the value that your product can add to different stakeholders across the healthcare economy.





An introduction to the cost-effectiveness plane:

NICE recommends that technology 'provides a similar or greater benefit at a similar or lower cost to the comparators'. An easy way to visualise this is to plot a cost-effectiveness plane. If your technology falls into the top right quadrant, then QoL and QALYs can be used to justify the expenditure. However, most medical devices to qualify for consideration the NHS will need to reside in the bottom two quadrants, i.e. it generally is required to be cheaper to alternatives.

In understanding where your technology falls within these quadrants, you need to find the sum of all of the additional financial costs and savings that your technology generates over a competitor or current pathway. This needs to be analysed from procurement to decommissioning. You need to look at every step that the product will go through, including staffing, training, care, related consumables etc,.

4.3 Step-by-step guide to health economic assessments

If this is your first time doing a health economics assessment on your innovation, you need to start simple and cover the basics. It's important at the early stages just to get a 'feel' for the costs and savings per year that your technology can have for the NHS. For example, does your product cost £100 or £10,000? And does it save £100,000 or does it save nothing? You don't need exact figures at this stage, but as you gather more data (e.g. through trials), then you can adjust your health economics model.

STEP 1: UNDERSTANDING YOUR INNOVATION'S JOURNEY

Firstly, you need to map out what the journey of your product would be, from procurement to decommissioning. This needs to be compared to the current competitor journey, i.e. what would be the current pathway if your technology is not used. *For example this could be procurement, installation, staff training, process changes, repair, replacement or decommissioning.* Try to think of as many steps as you possibly can here. This is not the same as a patient journey. Once you have a rough idea of what the steps would be – draw two flow charts, one detailing your technology, and one detailing the competitors and what the pathway of costs would be if your technology didn't exist.

Need help with this? Look at journals, similar technology, NHS statistics, NHS tariffs, NHS reference cost, NICE guidance and NICE assessments. Your model doesn't need to be perfect at this stage but keep a record of where you gather this information from.

Some considerations on cost could be, does your innovation…

- *Reduce the number of outpatient appointments?*
- *Reduce the time patients spend in hospital?*
- *Reduce or negate the need for expensive treatment (e.g. surgery / drugs / etc?)*
- *Does it require more or less staff?*
- *Does it have any ongoing maintenance costs?*

STEP 2: BEGIN ADDING ROUGH DATA

Identify in your flow chart what you think may be the challenges for a smooth flow of this product journey. For example, add rough numbers, statistics and rates to as many chunks of the pathway that you can. Try to think about volumes of patients that may be involved, or clinicians who may be interested. Don't worry if you can't put down exact figures, this is normal, but make a note of the sources of your data for each steps. You may also find conflicting data, make a note of any of this too, and go with either a mean or justify which you feel is the most credible source of data. Your sources of data can be wide, and can include talking to clinicians, charities, the NHS directly or your AHSN. Remember to always compare this to the competitor (the current standard used!).

STEP 3: WIDEN YOUR SCOPE

It's likely up until this point that you have only included one set flow chart, with a set of data as above. You need to widen your scope here, and begin to have multiple flow charts for different health events or different alternative pathways for your technology. Using the information in section 2.2, you have likely already identified your key users. Map the flow chat in step 1-2 for these users too.

STEP 4: BUILD YOUR MODEL

Once you have your flow chart, with some rough numbers, it's time to start adding these to a spreadsheet. Start by adding up the current pathway for one year, then do the same for your technology in a different column. At the end of both columns, total up the cost or savings. Do this for five years, and total up the rough cost or savings for this time. Remember to keep a note of where all of the data has come from. Try to demonstrate within here, the number of patients that would use your technology.

Below is a very basic demonstration of what you are trying to show. Your final model will be a lot more complex than this, and include many sources of data and possible pathways for your product.

Year 1 steps	Current model	Your model	Alternative model (Map a few options for pathways relating to your technology based on users)	Notes	References
Cost of installation	£XXX	£XXX	£XXX	E.g. how many patients, how many beds?	Data source
Cost of running	£XXX	£XXX	£XXX	List any assumptions	Data source
Cost of training	£XXX	£XXX	£XXX	Do you need to pay for additional training?	Data source
Staff	£XXX	£XXX	£XXX	Do you require more staff costs?	Data source
Energy cost	£XXX	£XXX	£XXX	Does this require more energy to power?	Data source
Cost to NHS	E.g. total is £XXX currently	E.g. our tech would be £XXX	E.g. our tech would be £XXX	Here, it is worth thinking about time involving NHS staff in set up. I.e. ICT / IG approvals, interoperability with systems already in use procurement, any board approvals as well as staff cost.	Data source
Cost / Saving to NHS			= £XXX year 1		Data source

STEP 5: LIST YOUR UNCERTAINTY

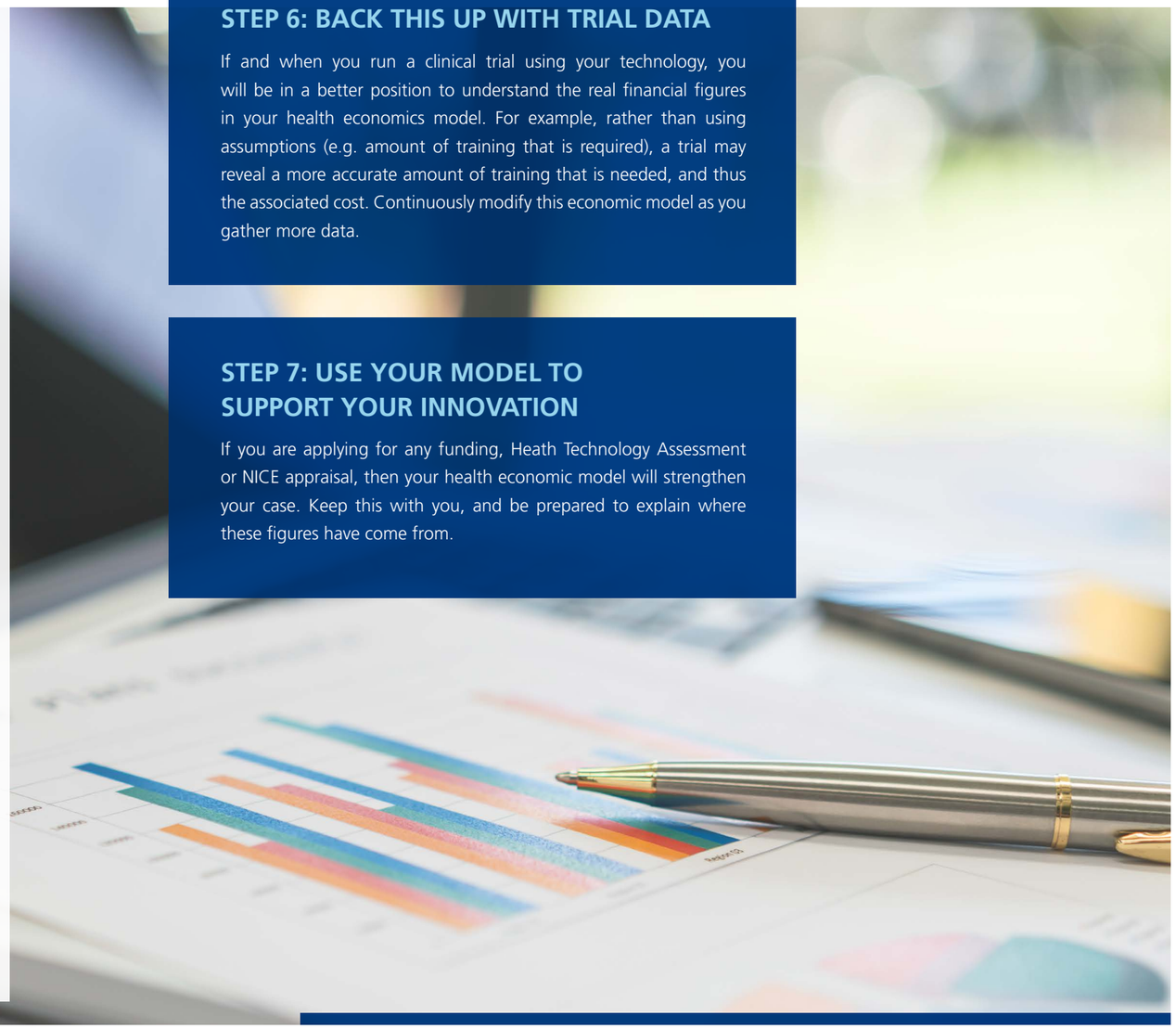
Each number, value or statistic that you have entered into this rough calculation will have a level of uncertainty. Identify what these are. For example, are you unsure what the staff or training costs would be? Whatever value you are uncertain of, make note of this.

STEP 6: BACK THIS UP WITH TRIAL DATA

If and when you run a clinical trial using your technology, you will be in a better position to understand the real financial figures in your health economics model. For example, rather than using assumptions (e.g. amount of training that is required), a trial may reveal a more accurate amount of training that is needed, and thus the associated cost. Continuously modify this economic model as you gather more data.

STEP 7: USE YOUR MODEL TO SUPPORT YOUR INNOVATION

If you are applying for any funding, Heath Technology Assessment or NICE appraisal, then your health economic model will strengthen your case. Keep this with you, and be prepared to explain where these figures have come from.



5. INTELLECTUAL PROPERTY

5.1. An introduction to intellectual property

'Intellectual property' (IP) is a description used for a set of intangible assets owned and legally protected by a company or individual for use or implementation without consent.

It can be confusing to understand if you've never encountered it before, but it's good to have a basic understanding of it, even if you don't yet have an innovation developed. It broadly consists of many types of assets including trademarks, patents, and copyrights. This all depends on what you are trying to protect.

Patents: For inventions

Copyright: Can include software code

Database rights: Protects collections of data

Trademarks: Protects brands

Typically most medical innovations created in the lab will be patents, which will be the main focus of this guide.

What do you need to protect your innovation?

To be protected by IP, your idea must be novel. This is really important. Your idea *cannot exist anywhere in the public domain*. And by anywhere this means websites, presented to the public at conferences, and even in publications. It must have a non-obvious step and it cannot be a small iteration from what already exists. For example, you can't just modify what exists in a research paper. To be deemed non-obvious this is something that isn't already apparent, particularly to a 'skilled person in your field'.

For medical researchers this can get complex and it's best to talk to a patent office or patent lawyer. But broadly speaking, there needs to be evidence that this is *a novel idea, it is your idea and it isn't obvious*.

PRIOR ART: Any previously available information that is similar to your invention (for example has this already been published?)

NON-OBVIOUS STEP: Something that is not already apparent to a skilled person working in your field. Patents have a non-obvious step.

For innovators, understanding IP is vital

IP can help determine who owns the idea / invention. Is this idea already owned by someone else who has already protected it? And if you own this IP, how are you going to exploit it? Are you going to licence it? When (if at all) can you publish your results?

If you don't protect your idea, you may find that others are able to use your innovation, sometimes commercially, and you do not have the legal right to stop them.

IP Licence: Allows individuals or business to use another's IP rights in exchange for a fee.

Royalties: Intellectual property (IP) royalties are payments that are made by a licensee to a licensor in exchange for the use of the licensor's intellectual property.

Inventor: Named on the IP as the inventors. They may get a share of royalties, but they don't necessarily own the IP. For example, a university may own the IP and be responsible for licence agreements, but name researchers as inventors.

A WORD ON PATENTS: If you haven't seen a patent document before, it's worth looking at one and understanding how to read one; there are plenty of examples online. They typically consist of **claims** (we are protecting these features) and **applications** and are supported by **preliminary data** and **figures**. Legal wording can be confusing, but it is very precise.

Speaking to a legal expert will help. Unlike research papers, they can be broad applications. For example, 'I have invented X device, but we think that X device could be used for applications A, B, C, D…'.

5.2. Intellectual property: Example flow chart

Intellectual property is complex, and there many be multiple steps involved. It's easiest to understand using a case study. Below is an example of the basic steps that you will need to go through when protecting your intellectual property.

START: YOU HAVE AN AN IDEA

For example, you invent something in the lab. You're certain that you haven't seen anything like this before, and you think this could be exploited commercially (e.g. to help patients). **Here are some key next steps to take...**

STEP 1: Identify if you have potential IP. For example, do you have any potential patents, new designs, copyright, databases or branding that is novel? Has this been done before?

The quickest way to assess if you think this is patentable, is to do a patent search (for example, look on Google Patents). *Does any IP out there look similar to yours? Are there publications revealing something similar? Or do you see products available in the market that overlap? (Any prior art?)*

I found prior art?

Invention may not be patentable, but talk to a lawyer

STEP 2: Don't talk, publish or disclose your invention to **anyone anywhere, apart from those involved in the IP process**. This is **really important**. For academics, this can mean with holding publications until **after any IP is filed**. If you do disclose any information, this may affect the IP

STEP 3: If you do need to talk about your invention, ensure you have appropriate non-disclosure agreements (NDAs) in place. This is a contract where parties agree not to disclose confidential information.

STEP 4: Speak to your relevant IP office. If you're at a university, this may include working with their IP teams and filling in an invention disclosure. They will work with you to identify the key features of your IP. If you are employed, this may be at your workplace.

STEP 5: It's a good idea at this stage to check **who owns the IP?** For example, if you work at a university (or company) your university may own any IP you generate. Your workplace or university should have their own IP policy in place; don't be afraid to ask. If you are not employed, self-employed, a freelancer, student or volunteer, you generally can own your IP (meaning that you have control over this). But it's best to check.

STEP 6: Protect the IP, in particular in the main geographical markets of interest. A legal specialist will help you.

STEP 7: Consider what you would like to do with the IP. Filing IP is generally an expensive process and has ongoing costs, so it's good to have a plan in place.

STEP 8: If you wish to exploit your IP, there are two main routes to do so, through a **licence** or through a **start-up**.

For a licence, you may allow a company (or companies) to use your IP for a fee (royalties). Typically the inventors will also get royalties.

For a start-up, the owners or the company do not have to be inventors of the IP. The IP of the invention can be licenced to the company. But those who work at and own the company do not necessarily have to have been inventors. If the company succeeds (and makes substantial amounts of money for example) this will mean royalties are typically paid to the inventors named on the IP, but the inventors do not have to get a share of the company profits.

STEP 9: Be aware your IP can be challenged, so it is best early on to ensure that the IP is correctly protected.

If in doubt, always consult a legal specialist.

6. FUNDING

For any new product that is developed, funding is required to take an idea to market. However, there are different options available depending on the stage of development and the type of innovation that is being developed.

Key considerations: Regardless, applying for any funding for your idea or product, it's good to have in mind several key considerations. Considering each of these from an early stage will help you secure funding.

6.1 Funding considerations

1. HAVE A PLAN:

The key question that you should be asking yourself is *'what is it that I want to develop?'* Almost all funders will want to see a well researched plan, and require clarity right from the start. If you're developing a product for the NHS, *'does this product / service add value to the healthcare system?'*. It's also good to ask yourself *'what is this going to be – are you a start-up, an established company and / or is this a research project or clinical trial?'* If you're planning on working with the NHS it's good to have clinical partners and a strong team established with a clear clinical need and to enquire about strategic and operational priorities depending on the trust (s) you speak to.

2. CONSIDER TIME AND RESOURCE:

This depends on what you are aiming to achieve. It is important to consider how long it will take for not only product development, but also any regulatory approvals. Funding can vary from short term (e.g. 6 months, typically called 'seed funding') to longer term (e.g. 5 years). Often projects take longer than expected, so this should be accounted for. In a similar manner, resource is important, for example, who is going to be your core team and staff, how much time can each member commit and what are the resource requirements? *Do you need space? Consumables?*

3. CONSIDER YOUR TEAM:

This isn't just technical development staff, but this also includes any advisors or mentors that you wish to work with. You may have the expertise with developing the product, but you will need business skills, sales skills, advisc, executive level support / approval... Funders will look favourably on teams that are formed from collaborations with a diverse range of skillsets.

4. SCOPE OUT FUNDING STREAM REQUIREMENTS:

There is a lot of funding available, but funders will have a specific set of criteria that they want to see met in order for your product / service to be suitable.

6.2 Routes to Funding

We suggest both the research councils and the National Institute for Health Research (NIHR) as your starting point. It's important to consider your Technology Readiness Level which will help you determine which funding streams to target.

RESEARCH COUNCILS

The easiest place to start is UK Research and Innovation, UKRI: (www.ukri.org/opportunity). Here they list all available funding for projects and you can filter easily by research area.

We particularly recommend looking the following:

- Medical Research Council (www.mrc.ac.uk)
- Biotechnology and Biological Sciences Research Council (www.bbsrc.ac.uk)
- Engineering and Physical Research Council (www.epsrc.ac.uk)
- UKRI's Development Pathway Awards (DPA) and the Knowledge Transfer Partnerships (KTP's)
- If your host institution offers it, an Impact Accelerator Award is also a great way to have short term small scale funding to test your idea

NATIONAL INSTITUTE FOR HEALTH AND CARE RESEARCH (NIHR)

NIHR is a government organisation that is the British government's major funder of clinical, public health, social care and translational research. They aim to support and fund the translation of research into products, medicines, treatments and devices. If you are looking to transition a new product into the NHS, we highly recommend NIHR as a place to start.

We particularly recommend looking at the following:

- NIHR Invention for Innovation (i4i) Grants
- Healthcare Technology Assessments (HTA)
- Research for Patient Benefit Grants (RfPB)

Further information can be found on the NIHR website, and depends on the stage of development and partnerships.

One of the key advantages of these grants is that they are intended to be designed in partnership with the NHS. We particularly advocate the 'Product Development Awards' for new products at early stage development. These schemes can help with feasibility studies, product development, health economics, UKCA (UK Conformity Assessed) marking, adoption and training, and much more.

Be aware that any grant for NIHR will need to demonstrate a clear clinical need. We also recommend conducting PPIE before submission.

Charities

Alongside UKRI funding searches, it is worth doing a search of relevant charities. There are many charities out there, and many offer their own sources of funding for research and innovation. For example, if your technology relates to cancer, look at Cancer Research UK (CRUK), or if it relates to heart diseases, look at British Heart Foundation (BHF). It is likely that any clinically focused technology will have a charity associated with it. In addition to this, many larger teaching hospitals also have a charity associated with them, for example Barts Charity for Barts Health NHS Trust.

British Heart Foundation

CANCER RESEARCH UK

BARTS CHARITY

Innovate UK

Innovate UK is the UK's innovation agency, with a purpose to accelerate science innovations for the benefit of the UK economy.

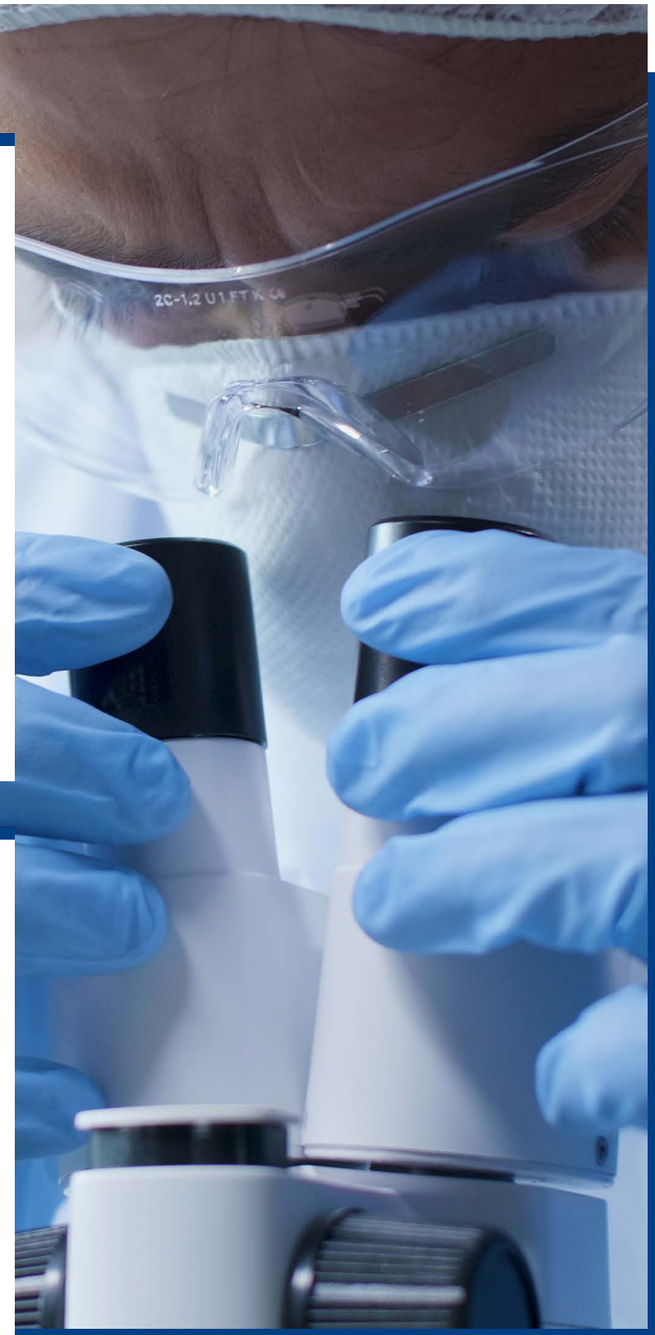
Innovate UK runs various support programs including the digital health catalyst and biomedical catalyst.

Innovate UK also joint fund the Small Business and Research Initiative (SBRI) with the NHS (www.sbrihealthcare.co.uk). In the UK, the NHS puts forward challenges through this programme, and businesses can apply for an opportunity for a contract to address these.

UKRI Innovate UK

Accelerator funding

It's worth noting that many biomedical accelerators offer small scale funding as either part of participating in the scheme or as a prize. If your idea is still in development, or you are beginning to look at commercialisation, an accelerator is a great way of expanding your knowledge while also potentially securing small scale funding.



Business angels

A business angel or 'Angel Investor' is the most significant source of private sector investment for start-ups. Put simply, this is a high net worth individual who invests in a company in return for a share of equity of the business (think Dragon's Den). The value invested can range dramatically from a few thousands up to millions. In return, some Business Angels may want to take a personal interest in the company, for example, through board membership.

There are many Business Angel Networks, we recommend looking at the 'London Business Angels' and 'Angels4lifesciences' or looking on www.ukbaa.org.uk.

Venture capital

Private equity provided by venture capitalists is a medium to long term finance option that is provided in return for an equity stake in a company. VCs typically raise money from institutional investors, for example pension funds, and VCs typically expect a return in under a decade.

The investment from VCs can be in the millions.

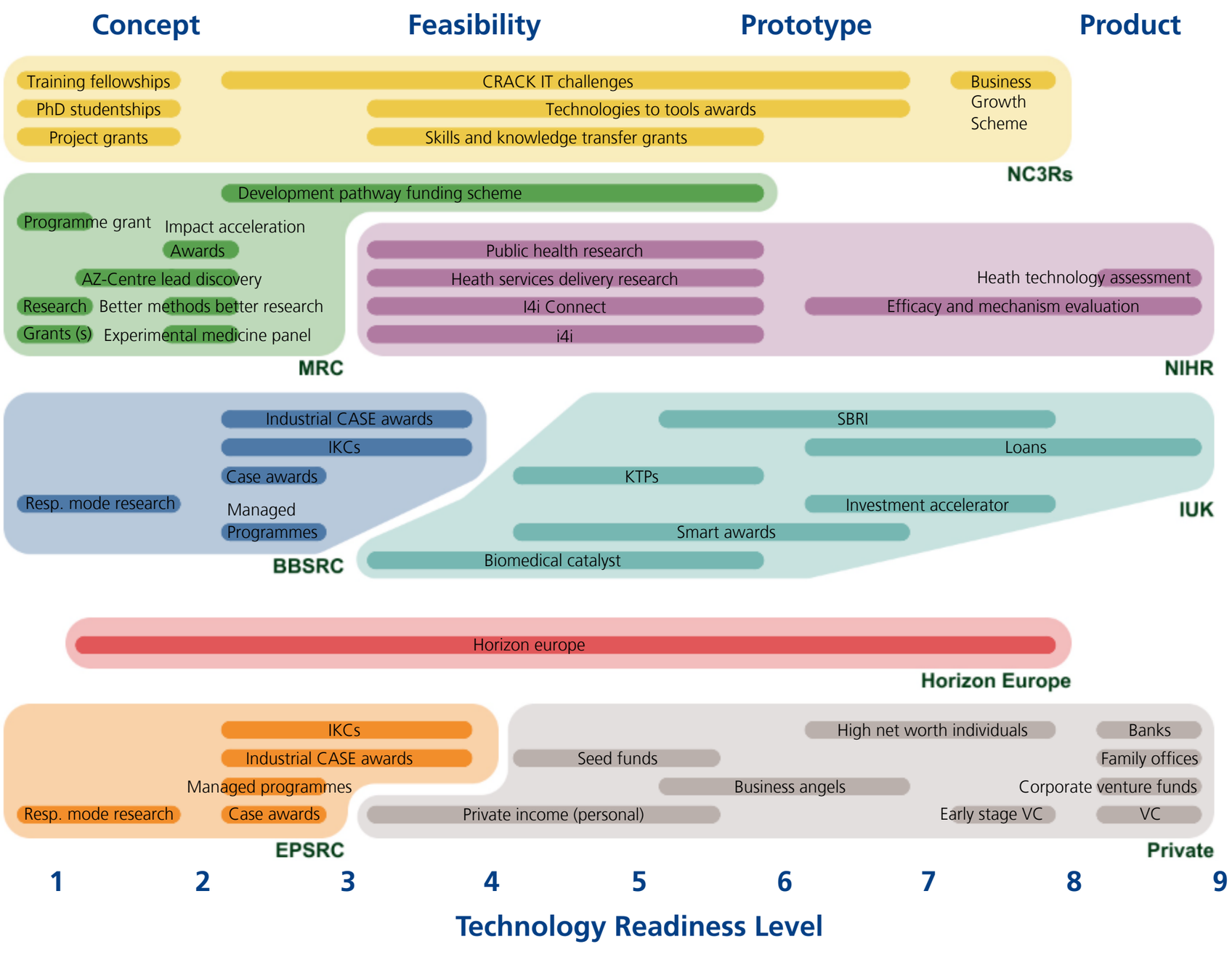
Before reaching this stage of investment, a large amount of evidence is required, as well as evidence of valuable product, and initial sales.

We recommend looking at www.bva.co.uk.

Private funding

We don't recommend using your own funding as a route to supporting your innovation. However, there are ways to obtain private funding. For example, crowdfunding has become a popular way to raise funds. There are different types of crowd funding available, varying from free donations, to donations that expect a return. There are many websites to raise crowd funds. The disadvantage is that your innovation (s) are not developed in partnership with the NHS, and many small investors can be hard to manage. We recommend looking at other routes of funding (e.g. NIHR) before this.

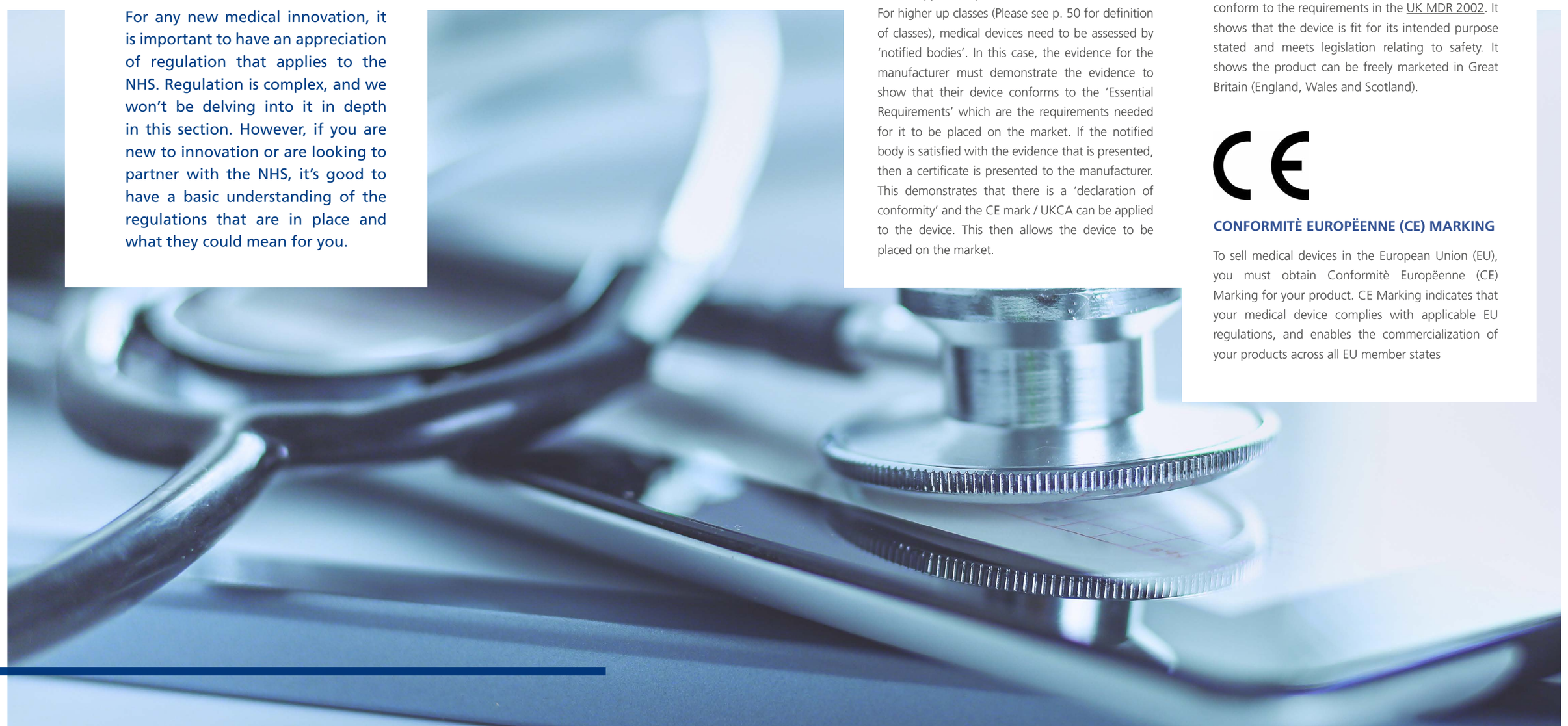
6.3 Funding with Technology Readiness Level Training



7. REGULATION

7.1. An introduction to regulation

For any new medical innovation, it is important to have an appreciation of regulation that applies to the NHS. Regulation is complex, and we won't be delving into it in depth in this section. However, if you are new to innovation or are looking to partner with the NHS, it's good to have a basic understanding of the regulations that are in place and what they could mean for you.



Medicine and Healthcare Products Regulatory Agency (MHRA)

The MHRA has a wide remit, and is responsible for the regulation of medicine, medical devices and blood components for transfusion. As well as assessing the safety, quality and efficacy of medicines, the MHRA are also responsible for the regulations governing medical devices, which likely includes your innovation. The amount of regulation that is applied depends on the risk of the device. For higher up classes (Please see p. 50 for definition of classes), medical devices need to be assessed by 'notified bodies'. In this case, the evidence for the manufacturer must demonstrate the evidence to show that their device conforms to the 'Essential Requirements' which are the requirements needed for it to be placed on the market. If the notified body is satisfied with the evidence that is presented, then a certificate is presented to the manufacturer. This demonstrates that there is a 'declaration of conformity' and the CE mark / UKCA can be applied to the device. This then allows the device to be placed on the market.

Conformity assessments

THE UK CONFORMITY ASSESSED MARKING (UKCA)

The UKCA mark is a product marking which can be used for medical devices placed in the Great Britain (England, Wales, Scotland) market. A UKCA mark is a logo that is placed on medical devices to show they conform to the requirements in the UK MDR 2002. It shows that the device is fit for its intended purpose stated and meets legislation relating to safety. It shows the product can be freely marketed in Great Britain (England, Wales and Scotland).

CONFORMITÈ EUROPËENNE (CE) MARKING

To sell medical devices in the European Union (EU), you must obtain Conformitè Europëenne (CE) Marking for your product. CE Marking indicates that your medical device complies with applicable EU regulations, and enables the commercialization of your products across all EU member states

7.2. Medical Device Classification

A medical device is classified into four risk classes which will ultimately depend on factors including time of use, invasive nature, active, purpose etc. For devices that are low risk, then the manufacturer can self-assess their device, but must register them with the MHRA. If you are developing a medical innovation, it is likely that it falls under a medical device classification. It's also worth noting that it could be an *'In vitro'* diagnostic medical device, one that does not directly interact with the body – for example a blood test is used outside the body, but is still a medical device. Be aware that even software applications (apps) can be considered medical devices!

		Medical Devices		*In Vitro* Diagnostic Medical Devices	
Notified Body approval required	HIGH RISK	Examples: Pacemakers, Heart valves, Implanted cerebral stimulators	Class III	Class D	Examples: Hepatitis B blood-donor screening, HIV blood diagnostic test, ABO blood grouping
	INCREASING RISK	Examples: Condoms, Lung ventilators, Bone fixation plate	Class IIb	Class C	Examples: Blood glucose self-testing, PSA screening, HLA typing
		Examples: Dental fillings, Surgical clamps, Tracheotomy tubes	Class IIa	Class B	Examples: Pregnancy self-testing, Urine test strips, Cholesterol self-testing
Self assessment	LOW RISK	Examples: Wheelchairs, Stethoscopes, Spectacles*	Class I	Class A	Examples: Clinical chemistry analysers, Specimen receptacles Prepared selective culture media

* Class I medical devices will require involvement of a Notified Body if they are sterile, have a measuring function or are re-usable surgical instruments

What is a medical device?

In short it is any device that is to be used relating to healthcare. But this is the full definition:

According to the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002), a medical device is described as any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnosis or therapeutic purposes or both and necessary for its proper application, which is intended by the manufacturer to be used for human beings for the purpose of:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap
- Investigation, replacement or modification of the anatomy or of a physiological process, or control of conception
- A medical device does not achieve its main intended action by pharmacological, immunological or metabolic means although it can be assisted by these.

A medical device includes devices intended to administer a medicinal product or which incorporates as an integral part, a substance which, if used separately, would be a medicinal product and which is liable to act upon the body with action ancillary to that of the device.

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE (NICE)

NICE is not strictly a regulatory body, but it does develop clinical guidelines on the treatment of specific diseases and conditions. NICE produces guidance and advice on the use of treatments, medicines, medical devices, techniques and procedures. This involves clinical and economic evidence focusing on both the efficacy of the product and value for money for the NHS. It is important to have an understanding of who NICE are. For example, if your product were to be taken to market, then NICE may be providing the clinical guidelines surrounding this.

NICE National Institute for Health and Care Excellence

HUMAN TISSUE AUTHORITY (HTA) and the HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY (HFEA)

The HTA is responsible for the regulation and licencing of human tissue and cells. It regulates the use of human tissues and cells for research, medical treatment, examination, training and display. The HFEA is similar but is responsible for the reproductive tissues and cells.

Human Fertilisation & Embryology Authority

HTA Human Tissue Authority

7.3 Flow chart medical device regulation

STEP 1

Get advice early on

Medical device regulation is complex, and our strongest piece of advice is to get advice early on from experts. If you are based at a research institute, university or hospital then you need to talk to your research management office (at Queen Mary University and Barts Health NHS Trust, this would be the Joint Research Management Office). And speak to your sponsor. Your sponsor is the organisation that takes responsibility and legality. We also strongly advise that you speak to the MHRA early on.

STEP 2

Identify the manufacturer and speak to the MHRA

It's really important that you document who the manufacturer is. Is this your start-up, or an agreement between a manufacturer? There are guidelines available for manufacturing types of medical devices, so speak to the MHRA at this point. They can offer consultations to provide advice on the type of medical device and what is needed. Document all the manufacturing processes and routes.

STEP 3

Conformity assessment and investigation

A clinical investigation is part of your conformity assessment. Your conformity assessment ensures that the manufacturers can demonstrate that the medical device meets the requirements stated for that device. Your clinical investigation may be a small scale proof of concept study, or research project that evaluates the efficacy of the product. Again, speak to your research management office, MHRA and sponsor for advice.

STEP 4

UCKA and CE marking

Once you have gathered and presented your evidence to the MHRA, they carry out third party activities including calibration, testing, certification and inspection. Manufacturers can then place a mark on the product to show that it has met the requirements for conformity assessment.

CE mark: required for products to be used in Northern Ireland, EU and EEA.

UKCA Marking: required for products to be used in Great Britain.

STEP 5

Trials and pilots

Once you have your CE / UKCA marking, you may need to run a trial or pilot with your product. You will need to speak to the Health Research Authority and the Research Ethics Committee. But again, speak to your Research Management Office and Sponsor. You are also welcome to speak to us at Barts Life Sciences.

An interventional study is any study that changes the care or treatment plan.

STEP 6

Keep updated with your CE / UKCA marking

If you want to modify or change the use of your product, you need to speak to the MHRA. If at any point you are uncertain, get expert advice.

STEP 7

Evidence through trials

Some trials are transferable from one trust to the next, but some are not. For example, you may need to run several trials or include multiple sites in your trial.

STEP 8

New equipment process / post-market surveillance

If you eventually reach the point where you no longer need trials, or the NHS deems that sufficient evidence is available, you may need to go through The New Equipment Process. You will have to speak to specific trusts about this, as this is not something we will go into in this guide. You will also need to conduct post market surveillance alongside the MHRA.

7.4. Information Governance and Data Protection

Universal search for Information governance and data protection are important, and you must comply with legal and regulatory requirements, and follow any customer specific protocols. As always, if in any doubt consult an expert – for example your research management office.

Information governance

Information governance is about how you collect, store, manage and share data appropriately. In the case of your innovation this could relate to any patient information and if and when you should share information with others.

The basic principles of patient information are as follows:

Any information should be:

- Used fairly, lawfully and transparently
- For specified purposes
- Used in a way that is necessary and only what is necessary
- Accurately kept and up to date
- Kept for no longer than necessary
- Handled in a way that ensures appropriate security

If you have any doubts regarding information governance it is important that you address these and discuss with an expert. It is good to have an IG strategy in place when handling any patient information.

Data protection

Personal data is any data that can identify an individual. The general data protection regulation (GDPR) brings about strict obligations and responsibilities for those who handle personal data. Healthcare data is a special category that has particular protection.

As an innovator, it is good to understand GDPR from the start of your project, particularly if you are working with patients. To use and share data you need a lawful basis to do so.

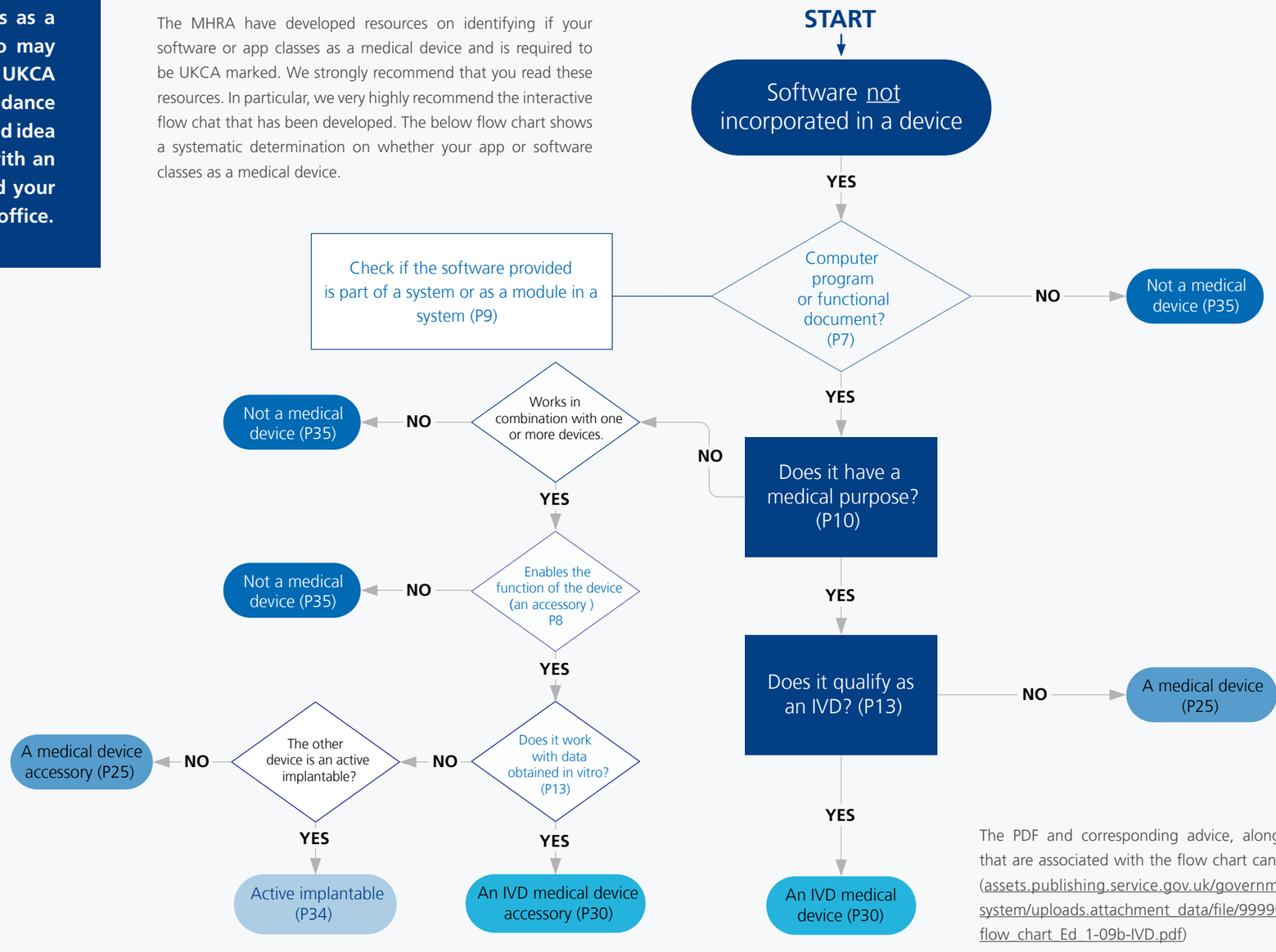
When developing your products or tools (particularly for big data projects) it is important for you to design in privacy from the offset, which is known as data protection by design. For example, can you minimise patient data, or anonymise this? Patients in particular should be fully aware of how their personal data is being used. This also applies if patients are involved in PPIE or trials.

Remember to make privacy notices transparent, and upload policies and cookie notices to any website you develop.

7.5. Software as a medical device

As healthcare evolves, there are an increasing number of apps and software that are being developed. Software and apps can still class as a medical device, and so may need to obtain CE or UKCA marking. As with all guidance in this section, it's a good idea to have a discussion with an expert from MHRA and your research management office.

The MHRA have developed resources on identifying if your software or app classes as a medical device and is required to be UKCA marked. We strongly recommend that you read these resources. In particular, we very highly recommend the interactive flow chat that has been developed. The below flow chart shows a systematic determination on whether your app or software classes as a medical device.



The PDF and corresponding advice, along with pages that are associated with the flow chart can be found at: (assets.publishing.service.gov.uk/government/uploads/system/uploads.attachment_data/file/999908/Software_flow_chart_Ed_1-09b-IVD.pdf)

Digital Technology Assessment Criteria (DTAC)

The digital technology assessment criteria are a set of criteria that organisations use when introducing new digital technology. Using it will give staff, patients and the public that the technology meets the minimum standards on clinical safety, data protection, technical security, interoperability, usability and accessibility. Using this assessing digital technologies will be simple, quick and consistent. DTAC assessments will be carried out by local health and social care organisations.

8. PARTNERING WITH THE NHS

8.1 The need for evidence

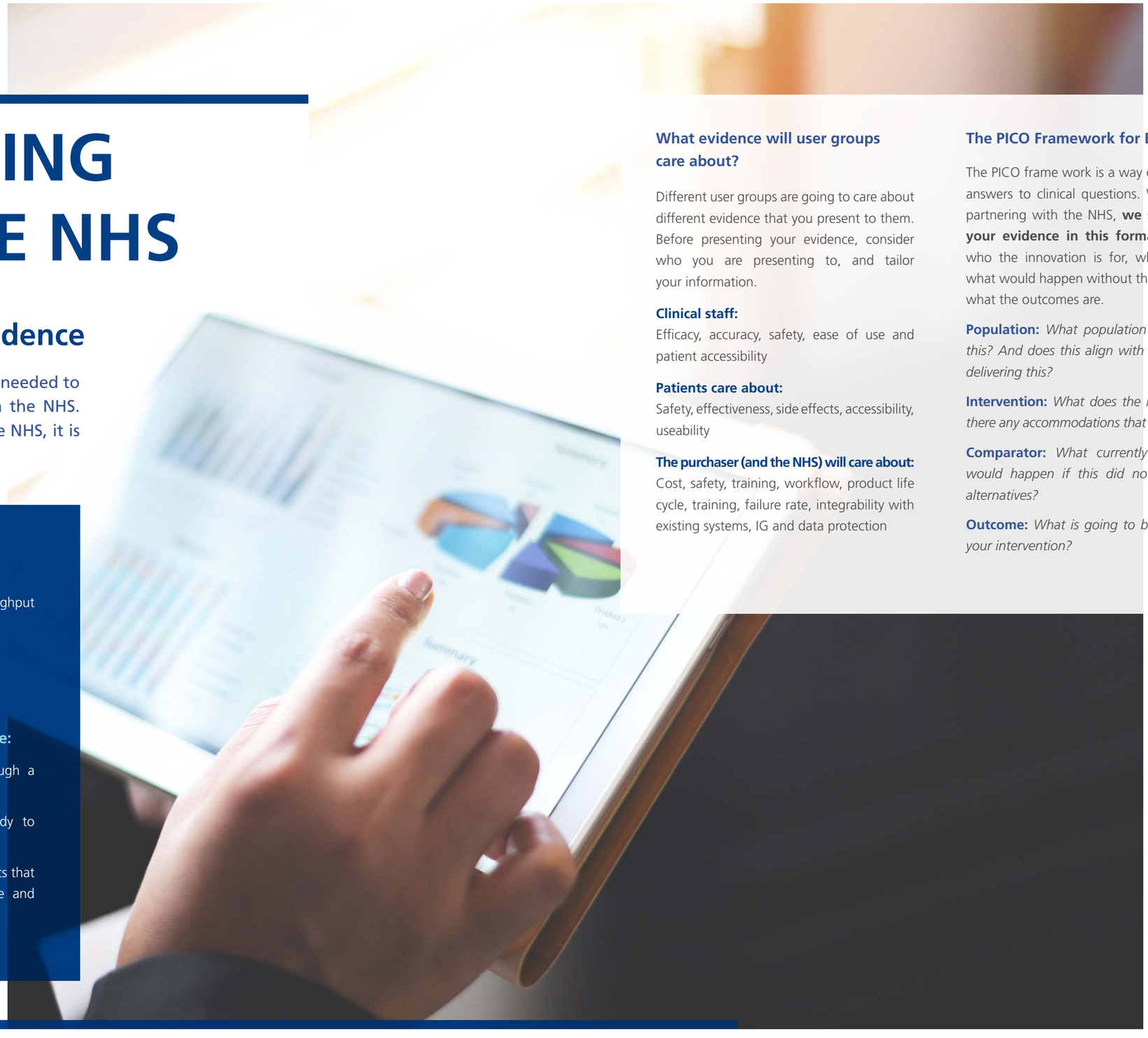
For any new innovation, evidence is needed to support the use of your product in the NHS. When beginning to partner with the NHS, it is good to have this evidence to hand.

Questions that you need to be able to answer:

- Does the product increase patient throughput without detriment to clinical outcome?
- Will this save the NHS money?
- What are the benefits in QALY?

Consider how you will answer these:

- Does this need to be answered through a clinical trial?
- Is there evidence you can use already to support answering these questions?
- Can you use data that relates to products that already exist in your innovation space and extract information from these?
- Can you use existing literature?



What evidence will user groups care about?

Different user groups are going to care about different evidence that you present to them. Before presenting your evidence, consider who you are presenting to, and tailor your information.

Clinical staff:
Efficacy, accuracy, safety, ease of use and patient accessibility

Patients care about:
Safety, effectiveness, side effects, accessibility, useability

The purchaser (and the NHS) will care about:
Cost, safety, training, workflow, product life cycle, training, failure rate, integrability with existing systems, IG and data protection

The PICO Framework for Evidence

The PICO frame work is a way of formulating the answers to clinical questions. When considering partnering with the NHS, **we suggest framing your evidence in this format**. This considers who the innovation is for, what is happening, what would happen without the intervention and what the outcomes are.

Population: *What population will benefit from this? And does this align with the service that is delivering this?*

Intervention: *What does the innovation do, are there any accommodations that need to be made?*

Comparator: *What currently happens? What would happen if this did not exist; are there alternatives?*

Outcome: *What is going to be the outcome of your intervention?*

8.2 Trials and pilots

Randomised control trials:

The best way to gather evidence for your innovation is through a randomised control trial (RCT). In its most basic form, this is segmenting users / patients into two groups, the *control and intervention*. The control group uses the current standard of care whereas the intervention group uses the innovation.

You can then measure the changes between both groups, in terms of clinical outcomes, experiences, side effects, quality of life, or any other metric that you may need to account for.

Clinical trials

Clinical trials are the most common type of randomised control trial. These consist of 4 phases.

Phase I: Test new treatments for the first time in humans. This uses a small group of people. Here you can evaluate dosage or intensity of the intervention and side effects / harms associated with its use.

Phase II: In phase 2, you test treatments which have been shown to be safe in a phase I trial. This uses a larger group of people and any adverse side effects are monitored.

Phase III: Phase 3 consists of a larger group of people from different regions or countries to demonstrate safety and effectiveness. In this phase dosage is confirmed, side effects are identified and benefits and risks of the treatment are measured. Where applicable, the new treatment is compared with existing treatments or the current standard of care.

Phase IV: Phase 4 is for approved and licensed treatments and monitors the safety and effectiveness of the innovation, as well as long term risks, benefits and rare side effects.

How long does a trial take?

This process can often be called 'from bench to bedside'. There is no typical length of time it takes for a new medical device to be approved. It may take a few months to a few years depending on the device. Clinical trials for new drugs can take 10-15 years!

What is a pilot study?

A pilot study is a small scale study that is conducted in preparation for a larger investigation. A pilot study explores the likelihood of a successful future randomised clinical trial by exploring the efficiency and validity of the proposed trial.

Pilot studies should test the logistics of the proposed study methods as well as recruitment, retention, intervention, data collection and adherence to the study.

Additional trial types:

Quantitative observational studies: Observation of people without full randomisation, for example before and after studies.

Qualitative studies: These gather information on perceptions, behaviours and experiences from example focus groups and interviews.

All studies of a medical device that are governed by the Medical Device Regulations require authorisation by the Medicines and Healthcare products Regulatory Agency

8.3. Advice for new innovators

1.

Gather your evidence beforehand:

There are different ways in which you can begin to partner with the NHS if you are a new innovator. Before you approach the NHS, we strongly suggest that you have read through the previous sections in this document first. The NHS will require evidence, and any potential partnership will require demonstrating that you have well researched the feasibility of your innovation. From here, there is no one set route to partnering with the NHS, however, we recommend strongly recommend the following for new products.

2.

Join an accelerator program or gain some formal entrepreneurial training:

Although we hope this guide has been useful, the more entrepreneurial training you can gain the better. You are going to face not just scientific problems, but also business problems. Accelerators are a great way to rapidly gain knowledge on how to progress your idea. There are many available depending on the innovation. We recommend checking with your local AHSN, your university (if affiliated) and relevant charities. There are many accelerators available nationally, and most don't expect payment. They're also a great way to begin connecting you with key stakeholders. If you are a clinician, the NHS runs a clinical entrepreneurial program that may be useful to you!

3.

Connect with your local Academic Health Science Network:

Your local academic health science network may have its own resources and advice, as well as run networking events and workshops. They may also be able to help you if you need specialist advice.

TheAHSNNetwork

4.

Find a funding route that preferably partners with the NHS:

We highly recommend looking at NIHR, as they have funding streams for innovations at different Technology Readiness Levels, and are a great way to access the NHS.

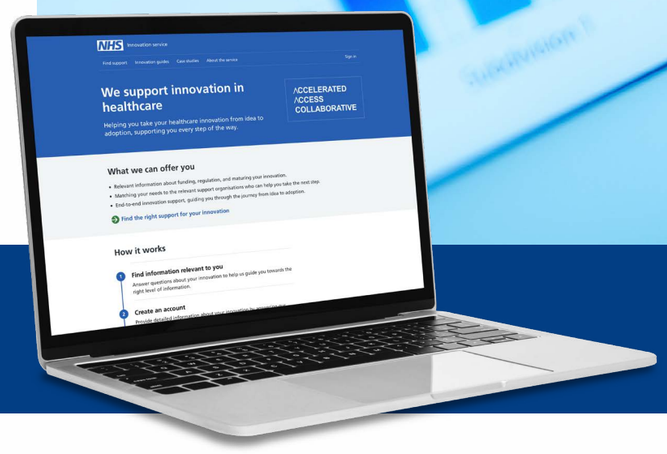
NIHR | National Institute for Health Research

5.

Look into the Accelerated Access Collaborative (AAC) and NHS Innovation

The AAC supports all types of innovations: medicines, diagnostics, devices, digital products, pathway changes and new workforce models. This is a partnership between patient groups, government bodies, industry and NHS that work together to streamline the adoption of new innovations in healthcare. It is also worth reviewing resources through NHS Innovation.

ACCELERATED ACCESS COLLABORATIVE



For more information on how the NHS support innovation in healthcare please visit innovation.nhs.uk

8.4. Advice for developed products / companies

1.

Connect with relevant Healthcare Technology Networks

There are many Healthcare Technology Networks nationally and internationally and they can be very useful to connect with. For example if you are based in London you could connect with MedCity, SEHTA and DigitalHealth.London to name a few.

2.

NHS innovation support

The NHS Innovation Service (innovation.nhs.uk) has resources for new and developed innovations. They are able to provide guidance and end-to-end support connecting you to the right network. The NHS Innovation Accelerator (National Innovation Accelerator) supports innovations that are in use in at least one site, NHS or elsewhere. You can also connect with the National Innovation Service.

TheAHSNNetwork NHS England
NHS Innovation Accelerator

3.

Speak to a wide range of trusts, specialities and services

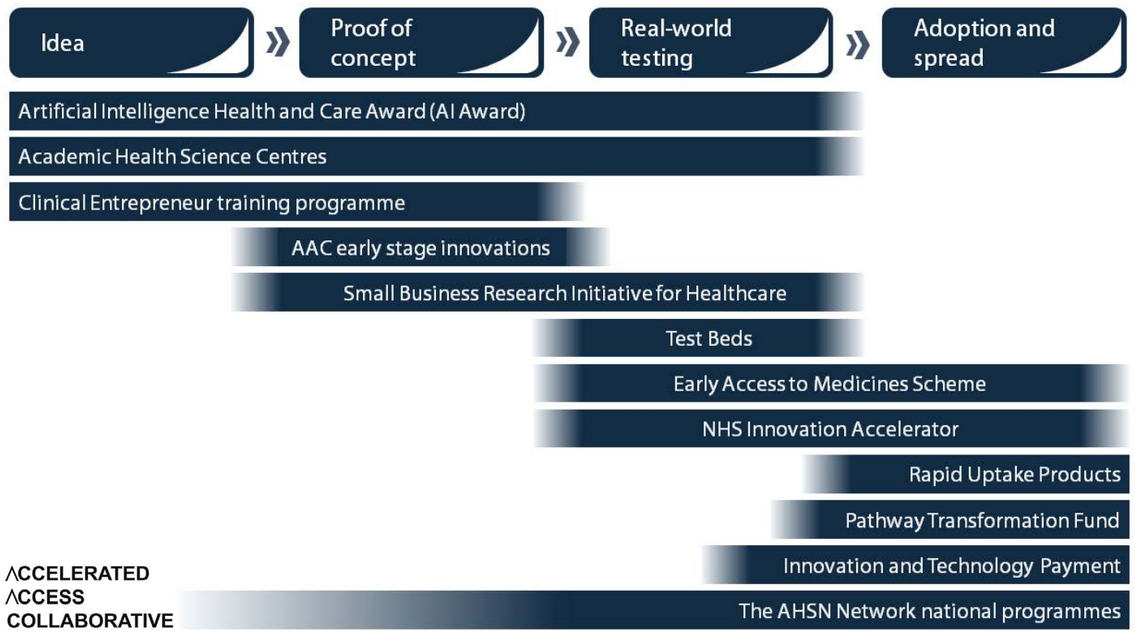
As you try to translate your new technology into the NHS, it's important that you talk to a wide range of trusts, specialities and services. Each trust will have their own method of managing new innovations, and different requirements based on their population and health needs. Reach out to you local AHSN, who may be able to connect you to trusts and hospitals that may be of interest to you.

4.

MedTech Funding Mandate (MTFM)

The MedTech Funding Mandate (MTFM) is an NHS Long Term Plan commitment to get selected NICE-approved cost-saving devices, diagnostics and digital products to NHS patients more quickly. To be considered for the MTFM, technologies need to effective, cost saving and affordable. The 15 regional Academic Health Science Networks (AHSNs) are the responsible for the delivery and implementation of these products.

Below are schemes that the Accelerate Access Collaborative run depending on your TRL.



8.5 Adoption by the NHS

Routes to market

There are six main routes to market for companies interested in supplying their MedTech product directly to the NHS:

- Selling direct to trusts or primary care organisations
- Selling through the NHS Supply Chain
- Selling through collaborative purchasing arrangements
- National framework collaborations and contracts
- Government tenders and contracts
- Selling to a company which then uses the product in the delivery of their service to an NHS provider

NICE, Health Technology Assessments

NICE Centre for Health Technology Evaluation undertakes Healthcare Technology Assessments, and produces guidance for NHS England on the use of new and existing technologies. A Health Technology Assessment includes the evaluation of the clinical, economic and other types of evidence about the use of the innovation or existing treatments. NICE produces guidance on the ways that different innovations are assessed. We recommend reviewing the advice that NICE publishes on the adoption of new technologies.

The MedTech Funding Mandate (MTFM):

The MTFM is part of the NHS Accelerated Access Collaborative and aims to direct healthcare providers and commissioners within the NHS organisations towards cost effective MedTech innovations that have been recommended by NICE diagnostic guidance or medical technologies.

9. DEVELOPING YOUR IDEA WITH BARTS LIFE SCIENCES

9.1 How we can help you

At Barts Life Sciences, we are able to support you at any stage of your entrepreneurial journey.

We are well connected to primary, secondary, speciality and community services across Barts Health NHS Trust, as well as external organisations. We will happily respond to enquiries, and will happily respond to enquiries from internal (Queen Mary or Barts Health NHS Trust) and external innovators and companies. We would like to hear from innovations at all Technology Readiness Levels. We want to make innovating and partnering with the NHS easier, and support those with innovations that could help patients and the wider community.

www.bartslifesciences.org

Below are some suggested organisations that we recommend you talk to if you are Queen Mary of Barts Health NHS Trust based. If you are external, then you will find that most university institutions have their own Innovation (IP) department or entrepreneurial training department.

For IP and commercialisation support: Queen Mary Innovation is responsible for Queen Mary's commercialisation and management of the universities IP and portfolio of spin-out companies. QMI protects and exploits Queen Mary's research-derived intellectual property. If you have IP queries then QMI can be consulted.

For work space and training: Queen Mary University Enterprise Zone is an innovation hub that offers workspace for start-ups with a focus on digital health, MedTech and AI. This space offers events and training.

For lab space: Queen Mary Bioenterprises (QMB) is the largest purpose-built innovation centre available for rent in London. The innovation centre is ideal for existing science and technology companies looking to expand, or start-up companies and later stage companies seeking an entrepreneurial base. They offer flexible leases, as well as laboratory and write-up spaces.

For translational support: UCLPartners is the local academic health science network for those working at Queen Mary University and Barts Health NHS Trust. UCLPartners works with universities across North and East London, as well as Mid and South Essex.

10. SUMMARY AND OVERVIEW

We hope that this guide has served as a basic introduction to the steps that you may need to consider as a new innovator wishing to partner with the NHS. The below flow chart is a summary of the key points throughout this guide. We advise reaching out to Barts Life Sciences if you have any further questions: info@bartslifesciences.org.

Best of luck!

1. Understand the NHS
- Identify trusts
- Identify care service
- Connect to your AHSN

2.Start your journey
- Identify your risky assumptions
- Customer discovery
- Speak to key users. Patients? Clinicians?
- Listen to experiences and compare user experiences to your assumptions

3. Develop your idea
- Fill out a value map and customer profile
- Develop your NHS value proposition
- Connect with relevant MedTech networks, and join a training programme/ accelerator if necessary

4. Health Economics
- Health economic assessment
- Back up with real / trial data
- Develop a cost-effectiveness plane

5. Understand Intellectual property
- Identify your IP type
- Consider NDA's
- Prior art search
- Speak to IP office
- File for IP if necessary

6. Funding
- What is your TRL?
- Identify sources of funding
- Research councils / NIHR
- Consider private funding

7. Understand Regulation
- Identify if your innovation is a medical device
- Register with the MHRA
- Understand IG, DP
- Understand UKCA/CE

8. Partner with the NHS
- Prepare all evidence with PICO evidence framework
- Connect with AAC / NHS Innovation
- Talk to Barts Life Sciences
- Talk to your AHSN
- Trials and pilots

11. FAQs

Below is a list of commonly asked questions, but if you have any additional questions, please contact us:

info@bartslifesciences.org

www.bartslifescience.org

I have an idea for a healthcare technology but I don't know the next steps, what do I do with this?

We suggest following the pathway outlined on page 2 of this document. We also suggest at this stage that you connect with any local networks that may be of use to you. This could be your local AHSN, your Research Management Office, or Barts Life Sciences.

I am a small to medium enterprise / start-up, how do I begin to partner with the NHS?

Before you do this, ensure that you have some evidence of what you can offer the NHS. If you are an established company, with IP and relevant regulations in place, then we suggest that you talk to us. We have a vast network within our Trust and beyond. We will be able to provide feedback or advice on your innovation, or point you in the right direction. If you have not already connected with your local academic health science network, we suggest doing so.

I am a PhD / early stage researcher, I want to learn how to commercialise my idea, where do I go?

Transitioning your innovation outside of the lab for the first time can be challenging. We suggest that you gain training either through your local university department, or by joining an accelerator. Before you dive straight into commercialising, it's good to have some foundation knowledge in place. There are plenty of MedTech accelerators in London and the UK that can provide step by step support when starting out on your innovation journey. Take advantage of workshops hosted by your academic health science network, university or beyond. Talk to us if you are based at Queen Mary or Barts Health NHS Trust, and we can offer advice.

I am a clinician / researcher and would like some entrepreneurial training and support, where do I go?

As above, we recommend your local enterprise department or accelerators. If you are a clinician based at Barts Health NHS Trust, then talk to us and we will be able to help you.

I want to meet clinical leads to discuss the feasibility of my idea, how do I do this?

At Barts Life Sciences, we have a vast network of healthcare teams and specialists. If you have a health innovation, we want to hear from you, regardless of your location. Although you can, we do not advise cold emailing clinicians. Try to utilise your network first, reach out to your AHSN or attend conferences where you can network.

Where can I find funding for my innovation?

This depends on the status and readiness of your innovation. We recommend reviewing the information in section 6 of this document. In particular we recommend looking at the funding routes provided by NIHR, and the research councils.

I'm thinking of starting a company with my idea, any advice?

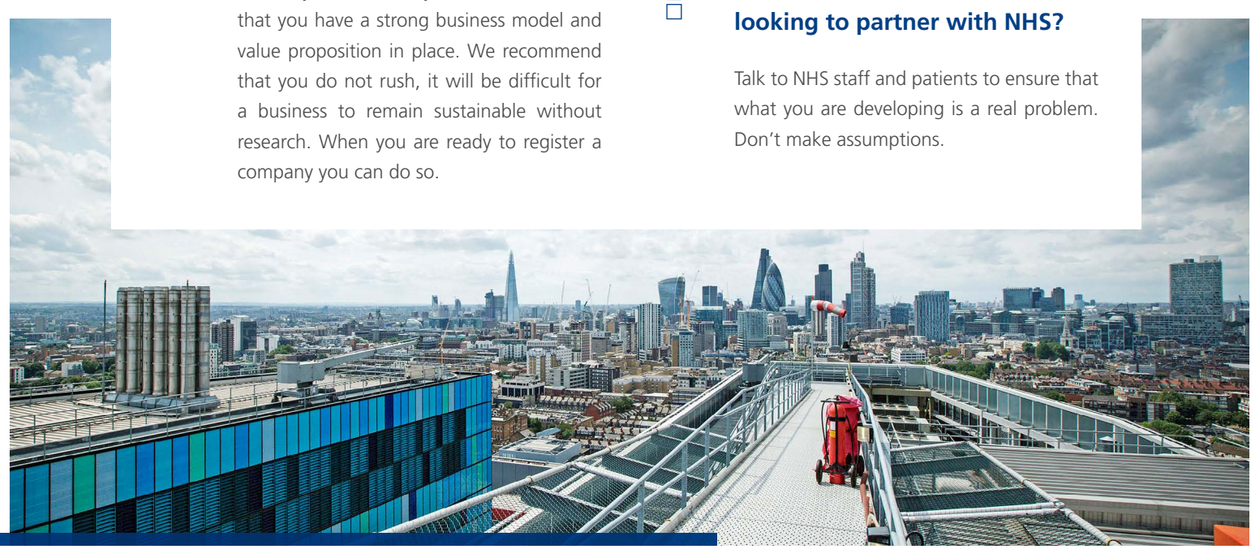
Before you do this, you need to ensure that you have a strong business model and value proposition in place. We recommend that you do not rush, it will be difficult for a business to remain sustainable without research. When you are ready to register a company you can do so.

What evidence does the NHS need to see for my innovation to be considered?

This very much depends on what the innovation is. Talk to your research management office, academic health science network or Barts Life Sciences. We suggest following the pathway outlined on page 2 of this document. You need to develop ways in which you can text your assumptions, identify who your key end users are, and if and how you will add value to the NHS. In broad terms, you need to be able to demonstrate that your innovation is beneficial both in terms of cost and patient / staff outcomes. This evidence can be gathered in a number of ways from clinical investigations, to trials and pilot studies. We suggest that you also align your innovation with the current needs of the NHS, so speak to those in your chosen area of health care to identify their problems. Assessing the NHS Long Term Plan will also help you identify what the current target issues are.

What is your main piece of advice for new innovators looking to partner with NHS?

Talk to NHS staff and patients to ensure that what you are developing is a real problem. Don't make assumptions.



12. GLOSSARY AND RESOURCES

Term	Definition
AAC	The Accelerated Access Collaborative (AAC), supports all types of innovations: medicines, diagnostics, devices, digital products, pathway changes and new workforce models.
Accelerator	An accelerator program aims to provide intense business training and support for cohorts of start-ups and start-ups. The term incubator may also be used.
AHSN	Academic Health Science Network. There are multiple across the country, aiming to spread innovation.
Barts Life Sciences	A research and innovation partnership between Queen Mary University and Barts Health NHS Trust. Support innovations at all levels of readiness.
Business angel	A high net worth individual who provides funding for a business / start-up in exchange usually for investment or ownership equity.
Business model	A business model is a plan for the successful operation of a business.
Conformity assessment	A conformity assessment ensures that you conform with the legal requirements for placing medical devices on the market. After the conformity assessment you may be granted UKCA or CE marking. You register for your conformity assessment with the MHRA.
Data protection	Data protection controls how personal information is used by organisations, businesses or the government.
DTAC	The Digital Technology Assessment Criteria for health and social care (DTAC) gives staff, patients and citizens confidence that the digital health tools they use meet our clinical safety, data protection, technical security, interoperability and usability and accessibility standards.
Health economics	Health economics is a branch of economics concerned with issues related to efficiency, effectiveness, value and behaviour in the production and consumption of health and healthcare.
HTA / HFEA	Human Tissue Authority (HTA) and the Human Fertilisation and Embryology Authority (HFEA), are regulators.
Information governance	Information governance allow us manage and share information or data appropriately.
Inventorship	Inventorship relates to those who create the IP (see below). They do not necessarily own the IP.
Investment	A person or organisation that puts money into financial schemes with the expectation of achieving profit.
Intellectual property	Intellectual property (IP) is a category of property that includes intangible creations of the human intellect (e.g. copyright, trade marks, patents, trade secrets) which protect your creation from unlawful use by others.
Licence	A licence is an official permission or permit to do, use or own something.
Medical device	A medical device can be any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination for a medical purpose.
MHRA	The Medicines and Healthcare products Regulatory Agency (MHRA) is an executive agency of the Department of Health and Social Care in the United Kingdom which is responsible for ensuring that medicines and medical devices work and are acceptably safe.
MTFM	The MedTech Funding Mandate (MTFM) is a NHS Long Term Plan commitment to get selected NICE-approved cost-saving devices, diagnostics and digital products to NHS patients more quickly.
NHS England	NHS England leads the National Health Service (NHS) in England
NICE	The National Institute for Health and Care Excellence (NICE) provides national guidance and advice to improve health and social care. NICE is an executive non-departmental public body, sponsored by the Department of Health and Social Care.
NIHR	The National Institute for Health and Care Research (NIHR) is a United Kingdom government agency which funds research into health and social care in England.
PICO framework	This stands for Population, Intervention, Comparator, Outcome. The PICO process (or framework) is a mnemonic used in evidence-based practice (and specifically evidence-based medicine) to frame and answer a clinical or healthcare related question. The PICO framework is also used to develop literature search strategies, for instance in systematic reviews.

Term	Definition
PPIE	Patient and Public Involvement and Engagement. Involving people in health and social care research, and is about giving the people who are meant to benefit from this research a say in shaping the research agenda.
Prior art	Any previously available information that is similar to your invention (for example that already been published).
QALY	Quality Adjusted Life Year. In the context of cost-benefit analysis – a unit used in the prediction of both quality and duration of life after medical or surgical treatment.
QoL	Quality of Life – the standard of health, comfort and happiness experienced by an individual or a group.
Royalties	Intellectual property royalties are payments that are made by a licensee to a licensor in exchange for the use of the licensor's intellectual property.
Start-up	A start-up is a company in the first stage of its operations, often being financed by its entrepreneurial founders during the initial starting period.
Technology Readiness Level	Technology Readiness Levels (TRLs) are a method for understanding the technical maturity of a technology during its acquisition phase.
Trusts	An NHS Trust is an organisational unit of the NHS that covers a geographical area. Trusts include hospitals, ambulance, mental health, social care and primary care services.
UKCA / CE	UK Conformity Assessed marking (UKCA) is a conformity mark that indicates conformity with the applicable requirements for products sold within Great Britain. On commercial products, the letters CE mean that the manufacturer or importer affirms the good's conformity with European health, safety, and environmental protection standards. It is not a quality indicator or a certification mark.
UKRI	UK Research and Innovation is a non-departmental public body of the Government of the United Kingdom that directs research and innovation funding, funded through the science budget of the Department for Business, Energy and Industrial Strategy.
Value proposition	A value proposition is a feature that is intended to make a company or product attractive to customers (what you offer).

USEFUL LINKS AND RESOURCES:

The following is a list of useful links and resources that will deepen your knowledge on the information presented within each of the sections of this guide.

Resources for intellectual property

The intellectual property Office: registers trademarks, patents, registered designs. Copyright, know-how and database rights do not require registration here (www.gov.uk/government/organisations/intellectual-property-office)

What is IP?: (www.gov.uk/intellectual-property-an-overview)

WIPO: check that you aren't using someone else's IP (patentscope.wipo.int/search/en/search.jsf)

Basic IP Guidance: from gov.uk (www.gov.uk/government/publications/ip-basics/ip-basics)

Applying for patents: Advice on applying for patents (www.gov.uk/patent-your-invention)

IP training tools: Intellectual property office (www.ipo.gov.uk/iphealthcheck)

Example Non-Disclosure Agreement (NDA): As supplied by gov.uk
www.gov.uk/government/publications/non-disclosure-agreements.
NDAs: To be signed by anyone outside of the company or legal entity where the invention arose, including patients.

For help gathering evidence

NICE scientific advice: Provides a fee-based service to help develop evidence that demonstrates clinical and cost effectiveness for all types of technology.
(www.nice.org.uk/about/what-we-do/life-sciences/scientific-advice/standard-scientific-advice-process)

NICE MedTech Early Technical Assessment (META) tool: is a fee based platform that helps developers understand what evidence is needed to convince healthcare commissioners about the value of their technology (meta.nice.org.uk)

NICE Guidance: (www.nice.org.uk/guidance)

NIHR research design service and clinical research networks: they provide free advice on study design, funding, PPI.
(www.nihr.ac.uk/explore-nihr/support/research-design-service.htm)

Information on the types of clinical trials available: Available through Cancer Research UK
(www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/what-clinical-trials-are/types-of-clinical-trials)

AHSN guide on PPI:
(www.ahsnnetwork.com/wp-content/uploads/2018/12/Patient-and-public-involvement-PPI-in-a-digital-world-May-2018.pdf)

Additional links: regulation

Software guidance for medical device registration: as provided by gov.uk (www.gov.uk/government/publications/medical-devices-software-applications-apps)

Understanding conformity assessment: (www.gov.uk/guidance/medical-devices-conformity-assessment-and-the-ukca-mark)

Data Protection Act: If your innovation uses personal data, then you must comply with the Data Protection Act (www.gov.uk/data-protection)

About UKCA marking: (www.gov.uk/guidance/using-the-ukca-marking)

Digital Technology Assessment Criteria: (transform.england.nhs.uk/key-tools-and-info/digital-technology-assessment-criteria-dtac/

Further guidance on medical devices

There are three main types of medical devices; general medical devices, active implantable devices and in vitro diagnostics (IVDs). Check if your innovation is a medical device and which of the three main types it is. You can find further guidance on each using the links below:

MHRA guidance: (assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/640404/MDR_guidance_Print_13.pdf)

General medical devices: (www.legislation.gov.uk/uksi/2002/618/part/II/made)

Active implantable medical devices: (www.legislation.gov.uk/uksi/2002/618/part/III/made)

IVDs: (www.legislation.gov.uk/uksi/2002/618/part/III/made)

Information for medical devices, stand-alone software including apps: (www.gov.uk/government/publications/borderlines-with-medical-devices)

Software as medical devices: (www.gov.uk/government/publications/medical-devices-software-applications-apps)

How to tell if your product is a medical device: (www.gov.uk/guidance/borderline-products-how-to-tell-if-your-product-is-a-medical-device)

In vitro diagnostic guidance: (www.gov.uk/government/publications/in-vitro-diagnostic-medical-devices-guidance-on-legislation)

Guidance on registering medical devices for the UK market: (www.gov.uk/guidance/register-medical-devices-to-place-on-the-market)

Adoption By the NHS

NHS Supply Chain: Browse available products that will help you research the existing market competition (my.supplychain.nhs.uk/Catalogue/browse/0/browsecatalogue)

NHS Innovation Service: A portal of resources provided by the NHS (https://innovation.nhs.uk)

NICE clinical evaluation: (www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-medical-technologies-evaluation-programme)

NICE advice on routes to NHS access: (www.nice.org.uk/about/what-we-do/life-sciences/office-for-market-access/identify-the-most-appropriate-routes-to-nhs-access)

NHS Long Term Plan: This provides a strong indicator for how the NHS will focus investments going forward

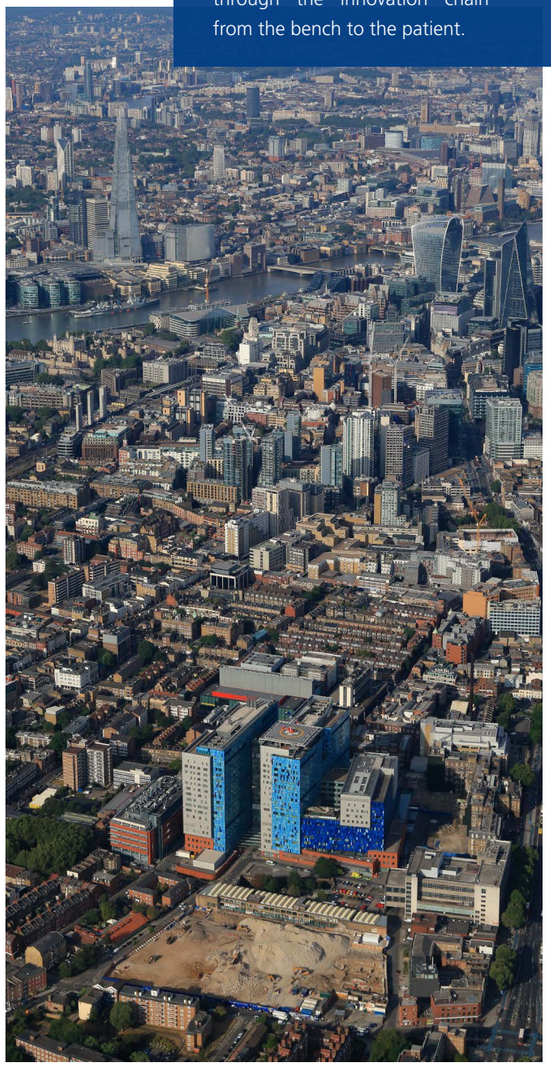
National Innovation Accelerator: nhsaccelerator.com

Our vision is made possible through transformative partnerships. We will:

Accelerate, with confidence and safety, research and development through the innovation chain from the bench to the patient.

Reduce health inequalities and transform patient care in East London and the wider UK.

Create a sustainable NHS which will be recognised as world-leading in prevention, prediction and precision healthcare.



About the author:

Sarah Madeline Fothergill: *"I work within innovation at Barts Life Sciences. I work closely with Barts Health NHS Trust and Queen Mary University. One of my key interests is connecting promising technologies to Barts Health Trust. I work with our local academic health science network UCLPartners, as well as MedTech networks nationally and internationally. I care about the acceleration of technologies that could ultimately have a benefit to the NHS and patients. Before working at Barts Life Sciences, I undertook both a PhD and a postdoctoral research position at Imperial College London, where by I was within the Faculty of Engineering developing biosensors. I have encountered first hand the struggle that new innovators face when trying to commercialise their work, and how difficult it can be to navigate the NHS. I would like to make it easier for new innovators to understand the requirements of the NHS and how to develop their technology with the NHS in mind."*

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Medical Innovation: An introductory guide to advancing your technology