

Your guide to innovation in the NHS **Development stage**

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Development

Once you have defined the fundamentals of your innovation, you can progress onto the development phase.

During this phase, you will prepare your innovation for regulatory submission and market launch.

Identify a need and market value

Before investing significant time and effort in developing an innovation for healthcare, you should first ask yourself the question:

Is my innovation really needed?

It is very important to do some research to understand the user need and market. By doing so, you will avoid wasting time and money on something that offers limited market value. You should be able to articulate:

- why your innovation is needed
- who will benefit from your innovation
- how those people will benefit

Do not skip this stage! It is important to understand that monetary value is tied to the benefits of an innovation, so you always identify market value. It is a harsh reality that companies often fail because there is little or no need for their product or service.

It is also important to identify the needs of the people your innovation will benefit, and that it meets those needs throughout development.



- Will my innovation be completely new to the market, or will it have a competitive advantage over similar existing products?
- Does my innovation address an unmet need for care providers, patients or the target population?
- Does my innovation align with the priorities of the NHS?

You should also consider how your innovation supports national priorities. The <u>10 Year</u> <u>Health Plan for England</u> sets out a long-term vision to improve care by making three key shifts: from hospital to community, from analogue to digital, and from sickness to prevention. These shifts aim to bring care closer to home, use technology to improve access and efficiency, and help people stay healthier for longer. The plan also outlines five areas of focus known as the five big bets which are integral to the new model of care: data, AI, genomics, wearables, and robotics. Explaining how your innovation is aligned with these priorities can improve its chances of adoption.

You can learn more about how the government aims to make the UK a global leader in health innovation, supporting faster development and adoption of new technologies in the <u>Life Sciences Sector Plan</u>.

<u>A Healthier Wales: our Plan for Health and Social Care</u> is the Welsh Government's long term plan for health and care.

Market research

You should do market research to determine the demand and need for your innovation. You should budget for this stage, as it is an integral part of your strategy to succeed.

Conducting rigorous, systematic market research can help to reduce risk and increase the chances of a successful product launch. However, with increasing market research regulations, and the often-high costs of talking with healthcare professionals, it is critical to ensure you are talking to the correct person and asking the right questions.

Early research with familiar professionals (friends, family, colleagues) is an excellent start and helps establish the questions to ask in wider research. Going on to speak in detail with a range of independent professionals who do not know the innovator and innovation are essential.

A genuine information or opinion-gathering approach should be used. Avoid using this time as a sales opportunity as much less will be learnt. If the individual is interested in following up, they will ask for this unprompted.

NICE's <u>Office for Market Access (OMA)</u> helps the life sciences industry engage with NICE, system partners and wider NHS stakeholders through fee-for-service engagement opportunities. NICE OMA also actively collaborates across the health landscape to direct enquiries to the most appropriate function. This service operates outside of NICE's guidance-producing programmes. It help innovators engage at any stage along the development-to-adoption pathway, while gaining valuable insight to help inform the development of their market access strategy. This includes:

- identifying the most appropriate routes into the NHS
- understanding the changing healthcare landscape
- exploring the value proposition

Some innovators spend a great deal of time, money and effort to register their products successfully, only to learn too late that there was no market opportunity for their product.

It is important that you define your product's unique selling point early on in your value proposition. For example, if it is a remote monitoring system, what is different from competitors? Is it integrated with electronic patient records (EPRs), additional kit that monitors vital signs, more portable for patients, easier for clinicians to monitor?

You can browse the NHS Supply Chain catalogue for existing products and suppliers as part of your research into the existing market and competition.

Market research methodologies

There are different market research methodologies available which you could combine:

- in-depth interviews
- focus groups
- telephone interviews
- patient record forms (PRFs)
- computer-assisted telephone interviews
- online surveys
- market research online communities
- observational studies

Research should be undertaken with:

- relevant healthcare professionals (not just doctors, but all professions involved in the service)
- service business managers (who will have a different perspective than clinicians)
- commissioners (where relevant)
- senior IT staff (for innovations with a digital component)
- patients or the public

Clinicians may be a good place to start for introductions to these groups. If you are going to engage with an external company to do your market research, the <u>Market</u> <u>Research Society (MRS)</u> is a good place to learn more about engaging a company. They are the UK professional body for research, insight and analytics. Read their <u>top ten tips</u> <u>on buying research</u>.

Many <u>Health Innovation Networks (HINs)</u> will support local qualitative market research with clinicians and NHS managers, and can support quantitative research with NHS databases they have access to.

Finding patients and users for testing and development

Patient and Public Involvement (PPI) is the process of involving patients and public to help inform the design and improvement of an innovation or service.

The word public can refer to patients, potential patients, carers and people who use health and social care services, people from organisations that represent people who use services, as well as general members of the public.

PPI is an important part of the innovation pathway. It ensures that innovations focus on what matters to those who will ultimately benefit from a new service or product, that will be both useful and usable. Failing to involve patients and public in the development of your innovation risks your innovation not meeting real world need or being optimised effectively.

Seek to understand the needs of all users of the device or service

When we think of users of a device or service, it is natural to immediately think of who is using it in closest contact with the patient. This is often a doctor or nurse. Whilst it is usually critical to understand how these professionals use the device and what their needs are, it is also extremely important to explore the needs of everyone who comes in contact with the device.

This could include maintenance technicians, clinical support staff, service managers, finance staff, domestic service staff, patients or carers. If the device or service does not incorporate the needs of every person that touches it, it ultimately will not be successful.

It is also important to think about diversity and cultural implications. What may be acceptable to some users is not always for others. <u>Health inequalities</u> are unfair and avoidable differences in health across the population, and between different groups within society. These include how long people are likely to live, the health conditions they may experience and the care that is available to them.

By only talking to current customers, you will miss key voices with unique needs who may give insight as to why someone is not purchasing your innovation today. Recruiting non-customers may be easier than you think. There are many high-quality research panels you can partner with that specialise in recruiting healthcare professionals of all specialties. This costs money, so you will need to set aside a budget if you use a specialist market research firm.

Keep in mind that different questions may be best suited for different audiences

When conducting health innovation market research, it is often assumed that you need to talk to professionals that will use what you are creating.

However, depending on your specific research questions, professionals may not be the right people to approach. For example, if you want to conduct pricing research to understand the purchase and decision-making process for a new medical device, you should not only talk to the clinician using the device.

Pricing feedback is best undertaken with business managers and procurement leads. Failing to gain pricing feedback is one of the first issues seen in this kind of research. Consider the types of questions you want to ask and who is be best placed to answer them beforehand, to gain more insightful conversations and data.

Consider alternative methods if you can not visit a hospital, health centre or GP practice

Often, the goal of health innovation market research is to get into a hospital to watch the device or competitive devices in use.

If this is not possible, consider conducting research at a central facility, or over a video call. Many healthcare experts may appreciate a focus group where they can share their feedback with their peers. Many nurses and nurse practitioners work off hours and are readily available to come to a central facility during the day.

If you need to get into a hospital or operating room, consider seeking approval via hospital administrators before reaching out to staff members. This will help to build trust with the right people.

Do not assume that health professionals know what you know

When you are doing research, do not expect healthcare professionals to know brands and available devices inside-out. If you are conducting a qualitative interview, you may find that healthcare professionals know the brand of the device but do not remember the model, or vice versa. To ensure you are speaking about the same device, use images or video of your innovation and relevant competitors.

Explore the patient journey

You could routinely interview, observe, and survey the clinicians that use your products, but do not overlook the patients who will ultimately benefit. Developing a patient journey or pathway map can help navigate product development and customer experience design.

A patient journey or pathway map describes the various stages of care. It begins with the onset of symptoms, through diagnosis and therapy, and ends with either complete recovery or adjustment to a new way of life. At each stage, it shows the tasks patients complete, some clinical and some personal, and their needs. These could be medical, emotional, financial, or relational. Mapping the patient journey can help to make functional innovations that work for both the clinicians using them and the patients needing care.

It is also possible to do this with non-patient journeys if your product or service is not clinical.

This will reveal:

- unnecessary steps, handovers and delays
- waste, such as duplication of effort
- things that do not add value in the patient journey
- bottlenecks and constraints
- unhelpful variation in clinical and non-clinical practice
- potential for creating safer care
- understanding of the patient experience
- where to undertake further analysis, such as understanding demand and capacity and the flow through parts of the journey

The potential approaches to exploring the patient journey include:

- conventional process mapping
- value stream mapping
- spaghetti diagram
- mapping the last 10 patients
- process templates
- tracer study

Further information on patient and public involvement NHS England

<u>Get involved</u> has training, guides and a wide selection of resources available, including how to use social media to develop working relationships with patient and public partners.

NHS Wales

<u>Get involved - Health in Wales</u> provide links to local Health Boards and the Board of Community Health Councils in Wales.

National Voices

<u>National Voices</u> is a coalition of more than 190 health and social care charities in England, both large and small. Most members are patient and service user charities that aim to understand and advocate for what matters to people, and work to drive change health and care services for good.

Health Innovation Networks (HIN)

HINs are the key innovation arm of the NHS. Their role is to spread innovation across the NHS in England. They have published <u>guidance on PPI in the digital age.</u>

You can get in touch with the AHSN Network through the Innovation Service.

The Association of the British Pharmaceutical Industry

The Association of the British Pharmaceutical Industry aims to make the UK the best place in the world to research, develop and use new medicines and vaccines. It

represents companies of all sizes who want to invest in discovering the medicines of the future.

They have produced <u>a sourcebook to support pharmaceutical companies in working</u> <u>successfully and collaboratively with patients</u> and patient organisations.

Budget impact model

From your market research you can create a budget impact model. This tells both buyers and sellers what finance or other resources will be needed to bridge the gap between current and future steady-state, and what the impact of using the innovation will be on the services and an organisation's budget.

You will need to think carefully about how you present your cost. If you have an expensive machine that lowers the cost of a common procedure, try to quote an estimated cost per patient, or per use. For example, saying that your machine, which costs £30,000, is less expensive than a £2 test could put off NHS buyers, as it looks like there are upfront capital costs.

Consider these points when developing your budget impact model:

- service costs, by department or area and by year separating pay and nonpay
- link current costs to future steady-state cost
- hidden cost such as ongoing training, licenses, maintenance needed to maintain future steady state
- transition costs to the service (the initial implementation may need to manage an existing higher or lower demand before achieving steady-state)
- the cost of driving the transition (the resources required to deliver the change, clinical leadership, training and education costs, data collection and analysis)
- releasable savings that will result from using the innovation taking into account current costs and the above expenditures (some apparent financial savings may not be releasable, such as savings made in a different organisation from the organisation buying and using the innovation)
- <u>NHS payment system</u> and <u>national tariff</u>
- <u>NHS pay scales</u>
- Pay and conditions circulars for medical and dental staff

Up-to-date research will be needed to understand the funding arrangements for current services.

Prototyping and product development

Developing an innovation requires going through a number of iterations. During this process you will create, test and refine multiple versions before arriving at a solution that is ready to progress to market.

During this step, it is critical to maintain the focus on the needs of all users to deliver a successful end product. This can include clinicians, carers and commissioners, as well as the 'end users'. To understand more on this and being user-centered in your design and development, <u>visit the Design Council.</u>

Collaborating with different users builds value into the product and ensures that it can be manufactured in a cost-effective manner. This provides evidence to support the product's value proposition.

The Innovate UK Knowledge Transfer Network is a network of innovators and has further detail on <u>navigating the design to manufacture journey</u>.

If you are based in Wales, you can optimise your plans and route to market with help from Health Technology Wales (HTW). You can access support from HTW through the NHS Innovation Service. The <u>Scientific Advice Service</u> is an expert consultancy that supports developers and innovators in Wales to generate evidence and demonstrate value that meets the needs of care commissioners, care providers, patients and service users. Companies based in Wales may also benefit from support in this area delivered by the <u>Accelerate Wales</u> programme.

Integrating with NHS digital services and APIs

There are many existing NHS digital services and APIs available that can be integrated into your innovation.

NHS England have produced a range of useful resources for those looking to connect with their APIs:

- read the guide on getting started with NHS England's APIs
- see what NHS digital services are available through the digital service catalogue
- see which NHS APIs are available through the API and integration catalogue
- read NHS England's API polices and best practice

If you need support with integrating with any of the APIs, you can search for answers or post questions on the <u>developer community</u>. You can also suggest, comment, or vote on upcoming features using the <u>interactive product backlog</u>.

To integrate NHS digital technologies into your innovation you will need to be an accredited supplier. Engage early so you can factor this approval into your development timelines.