

Your guide to innovation in the NHS

# Creation stage

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# Creation

In this section, we will outline the essential elements that you need to understand and address at the very start of your innovation journey.

As you begin creating your innovation, it is important to know which organisations to reach out to. The NHS Innovation Service can help you with this, connecting you to the relevant organisations at the right time.

In the early stage of your innovation journey you might be connected to the [Health Innovation Network \(HIN\)](#) in England, or [Life Sciences Hub Wales](#) in Wales. If you live in Scotland, you can get support from [InnoScot Health](#).

If you work in the NHS, you can apply to the [Clinical Entrepreneurs Programme](#) for support with your innovation. It offers expert mentoring, exclusive networking and bespoke training to develop innovative ideas into products and businesses to benefit NHS patients.

# Value proposition structure

First things first. What is your innovation? Can you describe it easily? Is it memorable?

You might feel that you can describe the benefit your innovation brings to the end user or patient, but what about the person who buys your innovation?

Launching into a slick elevator pitch may not be the best approach when it comes to speaking to the NHS about your innovation.

## 1) Scene-setting

This will really help your audience (including buyers and decision-makers) to understand the opportunity you are bringing to them.

You will need to cover:

- what the innovation is
- where you intend your innovation to be used within the health system
- who the innovation is relevant to
- what process or pathway your innovation supports or replaces

In this example we have used a hypothetical medical intervention for identifying patients at risk of a stroke, but you can apply this kind of structure to any innovation that you are developing.

### ► [For example](#)

Patients presenting at a GP practice suspected of atrial fibrillation will have a history taken, relevant notes reviewed and a finger pulse check (pulse is checked by the GP using a finger). When the pulse is believed to be varying, the patient will be referred to secondary care for a more detailed examination.

This medical intervention is a portable device intended to be used in primary care by GP practices, to identify patients at risk of a stroke arising from atrial fibrillation. The device is worn by patients over a 7-day period monitoring the heart rate continuously. This allows for a more accurate diagnosis of atrial fibrillation to be made in comparison to the current method used to measure a patients pulse in the GP surgery.

## 2) What is the problem or unmet need?

You will need to describe the problem or unmet need that the innovation addresses. What is the cause of the problem? What are the limitations, or inefficiencies of the current best practice, or existing pathway of treatment (assuming there is an existing approach to the problem your innovation is addressing)?

NHS Digital (now part of NHS England) manages healthcare data which can be used to improve our understanding of health problems, and supports research and innovation. Data can be made available to clinicians, researchers and commissioners to support the development of new treatments and services. Explore the [NHS Digital data dashboards](#) to find out more.

### ► [For example](#)

The current method to check a patient's pulse, and determine if there is atrial fibrillation, uses the finger and watch method. This can wrongly indicate that the condition is either present (false positive) or absent (false negative). This new method correctly identifies atrial fibrillation in approximately 75% of people with the condition. It is able to correctly rule out atrial fibrillation in 85% of people without the condition.

If you make a claim, you will need to provide the evidence that backs up this claim. It can be evidence from your own research or evidence from someone else. Multiple sources of evidence that back up these claims would strengthen the case.

## 3) What is the consequence of the problem?

Describe how this unresolved problem or unmet need affects patients and NHS services, even perhaps the whole population, including:

- patient and staff experience
- clinical outcomes
- resource utilisation and service organisation

Details given here should be specific to the context of what your innovation addresses. Avoid giving general details that may dilute the message about your innovation. The details should directly relate to the issue(s) you have identified.

► [For example](#)

Using the current method of checking a patient's pulse, approximately 25% of patients are not referred to secondary care who should be (false negative) and 15% of patients who are referred are referred unnecessarily (false positive). For those 25% of patients who are not picked up at this stage, their underlying disease is likely to progress before being correctly diagnosed.

Of the patients who are not referred to secondary care but should be, 5% of these patients (approximately 5,000 patients a year in the UK) will have a stroke within the next 5 years. Those patients who are referred to secondary care unnecessarily may experience anxiety over a false diagnosis, and will have unnecessary and costly hospital trips.

## 4) What is the intervention?

Describe your improvement. What will happen differently? How might that lead to a reduction in the consequences of the problem? Include a description (if appropriate) of:

- what the innovation is and how it works
- how the service will be delivered
- how patients will be identified
- how the organisational change and the process of implementation will occur. This includes any key enabling work, training and baseline measurements
- any clinical pathway changes to be made in order to implement the innovation

► [For example](#)

GPs will identify patients with suspected atrial fibrillation from their history and reported symptoms. This innovation is a portable device that patients wear over a 7-day period. The device will monitor the patient's heart rate continuously whilst they are wearing it.

GPs will need to be trained in using the device and interpreting the results, and GP practices will need to store the device and consumables.

Improving the diagnostic accuracy in identifying patients with atrial fibrillation will lead to patients being treated quicker, so that preventative measures are started, reducing the risk of a future stroke.

## 5) What is the impact, benefit or difference in outcome?

In this last section of building your value proposition, you will need to describe and quantify (meaning the proportion and scale of) the improvements in patient or user experience, patient outcomes or use of resources from this new way of working. Where possible and relevant, describe the impact on patients, staff, services, organisations and the wider health system. Examples of measures that you could use to demonstrate the effectiveness of your innovation include:

- clinical outcomes such as blood pressure, 1-year mortality, functional outcome, adverse events
- patient reported outcomes such as, quality of life, patient preferences, patient satisfaction
- service organisation such as length of stay in hospital, staff resource required, GP attendances, hospital admissions, readmissions

Provide a comparative measure so that the impact your innovation is clear. For example, provide figures for when the innovation is used, alongside figures for when the alternative intervention or pathway is used, or provide a percentage for the improvement.

Retain the original currency of the benefit and do not (at this stage) convert benefits into a cash equivalent or number of bed stays saved.

### ► [For example](#)

In a pilot study a medical intervention was used by GPs visiting care homes, there was a 20% reduction in emergency referrals from care homes to secondary care. For an Integrated Care System (ICS) covering a population of 250,000, this would equate to 150-200 referrals per year.

# Intellectual property

Through every stage of your innovation's development, you will need to consider protecting your idea with intellectual property (IP).

Intellectual property (IP) is a legal framework that protects ideas, concepts and the products of creative and mental effort. IP rights aim to promote innovation by rewarding the owner of the IP with a monopoly right over the idea, preventing others from exploiting it without their consent.

Should you need to discuss your idea or innovation with someone, you should have a non-disclosure agreement (NDA), also known as a confidentiality agreement (CDA), in place beforehand.

Intellectual property includes creations of the mind and non-physical assets, including:

- the names of your products or brands
- your inventions
- the design or look of your products
- things you write, make or produce

There are seven types of IP:

- copyright
- trademarks
- patents
- registered designs
- unregistered designs
- know-how
- database rights

These seven types of IP can be separated into two distinct groups:

1. IP rights requiring registration at the Intellectual Property Office including trademarks, patents, and registered designs.
2. IP rights that do not require registration at the Intellectual Property Office are copyright, unregistered designs, know-how, and database rights.

As well as protecting your own IP, it is worth checking to see if you are using anyone else's protected IP as part of your innovation.

## Copyright

Copyright is a form of IP protection that protects the expression of an idea rather than the idea itself. It protects software, original literary, dramatic, musical or artistic works (for example, written information including charts and drawings), and the arrangement of published editions (such as booklets, brochures and learning packages).

Copyright protection prevents anyone from copying the work, and issuing copies of the work to the public, without consent from the owner.

Copyright is achieved automatically when the work is created, and it does not normally require registration. However, it is advisable to include a statement to discourage infringement, such as the following:

© [Owner of the Copyright] [The Year of Creation] Not to be reproduced in whole or in part without the permission of the copyright owner.

## Trademarks

Trademarks can be used to protect words, logos, slogans, sounds, colours, shapes and smells, which are used as an indicator of origin.

The main function of a trademark is to demonstrate where goods and services labelled with the trademark originate from.

You have to apply for this type of IP and you should keep it secret until registered. This takes around 4 months.

Should you need to discuss the idea with someone, you should have a NDA in place beforehand. You can find out more about registering a trademark from the UK Intellectual Property Office. You can also check to see if a similar trademark already exists in the UK.

## Patents

A patent is a monopoly right that is used to protect the functionality of an invention. If the invention is a product, then third parties are prevented from making or selling the product, without the permission of the owner.

In order to be patentable, an invention must be completely new and inventive (that is, not obvious to a person skilled in the art), and capable of industrial application (it cannot be purely speculative). Exclusions from this include methods of treatment by surgery or therapy, or methods of diagnosis.

Patents protect inventions and products including machines, tools and medicines. You have to apply for this type of IP and you should keep it secret until registered, this takes around 5 years.

Should you need to discuss the idea with someone, you should have a NDA in place beforehand. Patents are costly and difficult to obtain. You can [find more about what you can patent and how to apply](#) from the UK Intellectual Property Office. Before you apply for IP, it is worth checking to see if there is already registered IP in place for an existing invention that is similar to your innovation. You can search for patents registered in the [UK](#) or [worldwide](#).

## Registered designs

A design registration protects the design of a product (how it looks aesthetically).

Protection is limited to designs that are new, have individual character, are not offensive, and do not relate to a functional aspect of a product, such as how it works.

You do not need to apply for this type of IP but you can [register your design with the UK Intellectual Property Office](#). Registered designs rights protect the products packaging, patterns, colours and decoration. You can check to see if your design is unique to those already registered in the [UK](#), [EU](#) or [worldwide](#).

## Unregistered designs

Designs can also acquire protection without being registered, using the unregistered design process.

## Know-how

Know-how is information which may be commercially or technically valuable and is regarded as secret. In all cases, the know-how will only retain its value if it is managed effectively.

Know-how includes technical information, procedures, processes, methodology, experimental techniques, chemical structures and source code. These should remain secret and undisclosed. You should protect your know-how with a NDA if you need to discuss the idea with someone.

## Database rights

Databases can be protected by a specific form of copyright, if substantial skill and judgement is involved in the compilation of the database. To be protected using database rights, the database must be compiled in a methodical way.

## Intellectual property guidance for the NHS in England

The Department of Health and Social Care and NHS England, with support from NIHR, have published [Intellectual Property Guidance for the NHS in England](#), which outlines practical steps and good practice principles that organisations providing or commissioning NHS services should follow in the management, ownership, development, and commercialisation of IP that arises within organisations and through collaborations. This guidance may be useful for innovators in understanding how to navigate IP when working with the NHS.

## Additional information

- [UK Intellectual Property Office](#)
- [IP health check](#)
- [licensing IP](#)
- [basic IP guidance](#)
- use the IP Equip service to find out which [type of intellectual property you have](#)
- speak to a professional, such as a [patent attorney](#) or [trademark attorney](#)

- go to a local [IP clinic](#) or the [British Library Business and IP Centre](#) in London
- if you are in Wales you can use [IP Wales](#)