NHS
Innovation Service

Your guide to innovation in the NHS

Contents

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.

IP rights requiring registration at the Intellectual Property Office including trademarks, patents, and registered designs.

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.

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

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.

Key questions to ask yourself

- 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?

The NHS Long Term Plan provides a strong indicator for where the NHS will focus their future investment.

A Healthier Wales: our Plan for Health and Social Care 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 Office for Market Access (OMA) 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 Market Research Society (MRS) is a good place to learn more about engaging a company. They are the UK professional body for research, insight and analytics. Read their top ten tips on buying research.

Many Health Innovation Networks (HINs) 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. Health inequalities 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

Get involved 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

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

National Voices

National Voices 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 guidance on PPI in the digital age.

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 a sourcebook to support pharmaceutical companies in working successfully and collaboratively with patients 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)
- NHS payment system and national tariff
- NHS pay scales
- 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, visit the Design Council.

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 navigating the design to manufacture journey.

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 Scientific Advice Service 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 Accelerate Wales 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 developer community. You can also suggest, comment, or vote on upcoming features using the interactive product backlog.

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.

Evidence

Generating high quality evidence to support your innovation is needed for regulatory approval and to demonstrate the value of your innovation to payers and commissioners. You will also need to generate evidence to demonstrate that your innovation can deliver benefits for the NHS.

Where applicable, you will need to provide evidence to demonstrate how your innovation improves existing NHS standards of care.

Outcome measures

You will need to make a case for your innovation. This includes showcasing the outcomes from a variety of perspectives, such as:

- the patients or target population
- the user of your innovation, for example a clinician
- the healthcare system as a whole

For example, if you are developing an innovation for patients, it is worthwhile understanding what the current care pathway. This means mapping out the entire patient journey, and work done with a patient at different stages in the healthcare system.

It is also important to understand existing routines for clinical and care professionals, administrators, and anyone else who will be affected by your innovation.

By researching and mapping these perspectives, you will better understand whether your innovation fits into the wider healthcare system.

Questions to consider

- Would the introduction of my innovation increase the likelihood of failure or big mistakes?
- Would my innovation work with clinicians' routines, and the legal responsibility they have for a patient's safety?
- How would my innovation fit in with existing governance?
- Who is my audience? Who makes the decisions to use my innovation and who will use this?

Another consideration is to build in the involvement of patient groups, public and other stakeholders. This will ensure that you include the patient voice in your design and implementation work.

Quantitative experimental studies

Randomised control trials (RCTs) are the most rigorous approach to generating evidence. RCTs are experiments which show an outcome has occurred as a result of the innovation that has been implemented. The simplest RCT would involve a group of people who are randomised into two separate groups. One of the groups is the ‘control’ group and the other are the ‘intervention’ group. The intervention group will use the innovation, but the control group will not or will use standard care.

Measuring outcomes, or changes, in both groups enables you to directly compare and determine if the innovation provides added benefits. As well as outcome measures related to the specific disease or clinical situation, you will need to measure whether there are any negative outcomes, side effects or harms.

Quality of life is also a useful outcome measure to include. This will help to establish how your innovation affects aspects of patients' daily living. You should involve patients or users of the intervention in the design of the research to ensure their views and preferences are taken into account. For example, they may suggest that certain outcome measures are particularly important to assess.

Designing the RCT and how it will be delivered requires a lot of planning. This will be key to the success of the experiment and the strength of the evidence that it generates.

Clinical trials are the most common type of RCT. If the RCT is being used to test new treatments such as medicines, procedures, devices or any other type of therapeutic intervention then it is a clinical trial. There are four phases of clinical trials:

Phase one

- test new treatments for the first time in humans
- small group of people
- evaluate dosage or intensity of the intervention and side effects or harms associated with its use

Phase two

- test treatments which have been shown to be safe in a phase one trial
- larger group of people
- monitor any adverse side effects

Phase three

- larger group of people from different regions or countries
- demonstrates safety and effectiveness
- confirm dosage or intensity
- identifies side effects
- measures the benefits and risks of the treatment
- where applicable, the new treatment is compared with existing treatments or the current standard of care

Phase four

- approved and licensed treatments
- monitoring the safety and effectiveness
- long-term risks and benefits
- identifying rare and long-term side effects

RCTs can take years to complete, but generating evidence through these studies is often an essential requirement for a therapeutic intervention to be adopted by the NHS. You can find out more on how to design, fund and deliver clinical trials from NIHR and NICE. It may be beneficial for you to seek advice from the outset around what the evidence requirements will be for your innovation. You can do that through registering with the NHS Innovation Service.

Other types of quantitative experimental studies include:

- non-randomised control trials
- before-and-after studies

Quantitative observational studies

There are instances where an experimental study design is inappropriate, so observational studies are used instead. Observational studies do not have an experimental intervention. They rely on the observation of people without full randomisation. These types of studies can inform cause and effect associations and can be applied to existing data sets. Types of observational studies include:

- before-and-after study
- case-control study
- cohort study
- correlation study
- cross-sectional study
- interrupted time series

Visit NICE's website for more information on scientific evidence.

Qualitative studies

These types of study do not collect numerical data. They gather information on participants experiences, perceptions and behaviours. Types of qualitative studies are:

- document analysis
- focus groups
- interview studies
- observation and participant observation

Visit the NICE website for more information on qualitative studies.

Economic studies

Health economic studies investigate the cost of care. Types of analysis include:

- cost-benefit
- cost-consequence
- cost-effectiveness
- cost-utility

Visit NICE's website for more information on scientific evidence.

Real world evidence

Real world data (RWD) is used to generate real world evidence (RWE). Clinical trials demonstrate how well a treatment or intervention works under specific controlled conditions, but these studies often do not take into account the variability of the real-world application, or capture the diverse demographics of the target patient population.

RWD is collected through real life situations and can be used to generate RWE to support the uptake of the innovation. RWD may include clinical, economic and patient reported outcomes. These types of outcomes data can be derived from several sources including retrospective studies, observational studies, patient registries and anonymised electronic health records. The RWE navigator decision support tool can help you understand if and how RWE can support your innovation.

Presenting evidence

When you are preparing to present your evidence, you will need to think about what is most important to each of your user groups.

Clinical staff will care about:

- efficacy (does it work)
- accuracy (how well does it work in terms of sensitivity and specificity)
- safety
- workflows
- ease of use
- patient acceptability
- duplication of effort (overlap with existing systems or processes)

Patients will care about:

- safety
- effectiveness
- side effects
- accessibility
- usability
- involvement of patients during evidence generation

A purchaser will care about:

- cost
- safety
- training and implementation
- productive workflows
- product lifecycle (how robust is it and how often does it need to be replaced)
- failure or downtime
- software interoperability with existing core systems
- information governance, including data and cyber security

Population, intervention, comparator and outcomes framework

The population, intervention, comparator and outcomes (PICO) framework helps the formulation and answering of clinical questions. It can also be used to help you structure and present your evidence.

Population

- Who will benefit from your innovation?
- Is the population of people who will benefit similar to the population of people that the service delivers healthcare to?

Intervention

- What is the innovation?
- What is the innovation doing?
- Are there any details about pathway changes needed to accommodate the intervention?

Comparator

- What currently happens?
- What would people use if your innovation did not exist?
- What is the main alternative to the innovation in current practice?

Outcomes

- What definitive, objective improvements or changes occurred as a result of the innovation?
- How did these impact on patient care, clinicians, services and organisations?

Support services

NHS Innovation Service

The NHS Innovation Service can put you in touch with organisations that can help you with your evidence generation such as NICE and NIHR. Find out more about the organisations involved and what sort of support they can provide.

NICE Scientific Advice Service

The NICE Scientific Advice Service provides a fee-based consultancy to help develop evidence that demonstrates the clinical and cost-effectiveness for all types of technology. They provide feedback on evidence generation plans, and help companies understand health technology assessment and the perspective of decision makers. They also provide a comprehensive peer review service for economic models that helps companies optimise the model's structure, computation, coding, usability and transparency.

NICE MedTech Early Technical Assessment tool

The NICE MedTech Early Technical Assessment tool is a fee-based platform to help product developers understand what evidence they need to generate to convince healthcare commissioners of the value their technology can bring to the NHS.

NIHR Research Support Service and Clinical Research Network

The NIHR Research Support Service (RSS) and Clinical Research Network (CRN) provide support for funding applications, study design and study delivery of clinical research in applied health and social care. The RSS is a national service delivered collaboratively through eight hubs across England, each a partnership of research groups and organisations. The service provides free and confidential advice to develop funding applications within the remit of the NIHR, including clinical, applied health and social care research, and post-award advice to award holders. Find out more about the services offered by the RSS.

The CRN is made up of fifteen local clinical research networks which coordinate and support the delivery of health and care research in England. The CRN study support service can help you plan, set up, deliver and performance monitor clinical research studies. Find out more about the CRN study support service eligibility criteria and how to apply.

NHS Digital (now part of NHS England)

NHS Digital (now part of NHS England) are the statutory custodian for health and care data for England. For a fee they offer access to certain data sets through their Data Access Request service (DARS). The data may be provided in the Secure Data Environment or as an extract. For clinical trials you may also want to use the DigiTrials Service which can also provide access to this data.

The Developer Hub can help innovators learn how to build healthcare software and integrate with NHS APIs. It has resources including a step-by-step introduction on what their APIs can do and how your team can get connected, and an API catalogue.

Regulation

There are regulatory requirements that must be met before an innovation can enter the UK market. The Medicines and Healthcare products Regulatory Agency (MHRA) is responsible for ensuring that medicines and medical devices are effective and safe. All medical devices, including software, must be registered with the MHRA before they can be sold in the UK.

Medical devices are assigned one of four different classes, ranging from low risk (Class I) to high risk (Class III). Depending on the classification of your innovation, there will be different levels of evaluation required for the necessary regulatory approval.

Examples of medical device classification:

Class I: Low risk (examination lights, bandages, syringes without needles).

Class IIa: Medium risk (standard hearing aids, suture needles and short-term corrective lenses). Includes software which provides information that may be used to make a diagnosis, clinical decision or for therapeutic purposes.

Class IIb: Medium risk (apnoea monitors, ventilators, surgical lasers). Software classification is similar to Class IIa, but includes software which informs clinical decisions that might result in serious harm or require a surgical intervention.

Class III: Higher risk (pacemakers, total hip joint replacement system, breast implants, contraceptive IUDs, devices containing medicinal substances). Includes software which informs clinical decisions that could lead to irreversible deterioration of a health condition or death.

Digital health tools that may be medical devices include:

- patient-facing apps that enable self-management or remote monitoring of medical conditions such as diabetes or depression
- symptom checkers that offer medical advice based on information entered by a patient
- online digital tools to assist in diagnosis, e.g. a cloud-based software programme that identifies melanomas from dermatoscope images
- an app that advises on insulin dose based on a diabetic patient's blood glucose level and dietary input
- medical calculators and algorithms

If you would like to understand what regulations apply to digital health technologies (DHTs), and how to meet them, visit the AI and Digital Regulations Service. You can learn more about what regulations to follow and how to evaluate effectiveness. The website is aimed at both developers of AI and digital technology, or adopters who will buy or use DHTs in health and social care.

You can access support from the AI and Digital Regulations Service through the NHS Innovation Service.

Medical devices

This guidance is specific to the provisions in Great Britain (England, Wales and Scotland). For information on how to comply with the legal requirements in Northern Ireland, please see the MHRA guidance for Northern Ireland.

Medical devices are products or equipment used for medical purposes but work differently to a medicine or drug.

The clinical data required by regulators to demonstrate that a medical technology product performs as intended and is safe to use is dependent on the class of technology. Higher risk products require more extensive clinical evaluation and evidence standards before they can be launched onto the market.

There are three main types of medical devices:

- general medical devices
- active implantable medical devices
- in vitro diagnostics (IVDs)

Technologies and products whose primary purpose is not medical may not be considered a medical device. For example, breast pumps, toothbrushes and insect repellents are not typically considered medical devices. However, a similar product may be considered a medical device if it is primarily intended for medical purposes. For example, a breast pump which is designed for the treatment of inverted nipples.

Check if your innovation is a medical device, and which of the three main types it is. Further guidance is available:

- medical device stand – alone software including apps
- borderline products – how to tell if your product is a medical device

General medical device and active implantable medical devices

If your product is a general medical device, or an active implantable device, you need to determine which class your device is in. Guidance is available from the MHRA.

Examples include:

Class I: Low risk (examination lights, bandages, syringes without needles).

Class IIa: Medium risk (standard hearing aids, suture needles and short-term corrective lenses). Includes software which provides information that may be used to make a diagnosis, clinical decision or for therapeutic purposes.

Class IIb: Medium risk (apnoea monitors, ventilators, surgical lasers). Software classification is similar to Class IIa, but includes software which informs clinical decisions that might result in serious harm or require a surgical intervention.

Class III: Higher risk (pacemakers, total hip joint replacement system, breast implants, contraceptive IUDs, devices containing medicinal substances). Includes software, which informs clinical decisions that could lead to irreversible deterioration of a health condition or death.

If your product is a general medical device or an active implantable device and it is in Class IIa, IIb, III, or is a Class I device that is sterile or has a measuring function, then you will need to contact a UK approved body or EU notified body. They can carry out the necessary assessments to ensure your device meets the regulatory requirements for its intended use.

UK approved bodies can certify devices for England, Wales and Scotland through UKCA mark certification. The UKCA mark is a UK product marking (introduced in January 2021) for goods placed on the market in Great Britain. The UKCA mark covers most goods which previously required the CE marking. The UKCA mark is not recognised by the EU market. To certify a device for both UK and EU markets you will need to use an EU notified body. Find out more about using the UKCA marking. CE marks for medical devices are currently valid in the UK until at least 2028, after which a UKCA mark will be required.

In Northern Ireland, medical devices must have either a UKNI mark or a CE mark.

UK approved bodies are designated by the MHRA to ensure that manufacturers comply with the regulations set out in UK MDR 2002. If the device meets the regulatory requirements, then the UK approved body has the authority to issue an UKCA certificate. The manufacturer should add the UKCA mark to their device when certification has been provided and register the device with the MHRA. The device can then be placed on the market in England, Wales and Scotland.

If you have a Class I general medical device that is not sterile and does not have a measuring function, you can self-certify your device for the UKCA as outlined below:

- confirm that your products are Class I medical devices as described in Part II of the UK MDR 2002, Annex IX (as modified by Part II of Schedule 2A to the UK MDR 2002)
- check that your products meet the relevant essential requirements of Part II of the UK MDR 2002, Annex I (as modified by Part II of Schedule 2A to the UK MDR 2002)
- carry out a clinical evaluation as described in Part II of the UK MDR 2002, Annex X (as modified by Part II of Schedule 2A to the UK MDR 2002)
- notify the MHRA of any proposals to carry out a clinical investigation to demonstrate safety and performance
- prepare technical documentation
- draw up the declaration of conformity
- put the UKCA mark on your device as described in Regulation 10 of the UK MDR 2002
- register the device with the MHRA
- implement and maintain corrective action and vigilance procedures including a systematic procedure to review experience gained in the post-production phase
- provide relevant documentation if requested by the MHRA

You will need strong quality management and risk management systems for successful certification of medical devices. The requirements for these systems in UKCA-marked medical devices are harmonised with international standards ISO 13485 and ISO 14971 respectively.

In vitro diagnostic medical devices

In vitro diagnostic (IVD) medical devices are usually a reagent, calibrator, apparatus, equipment or system used in vitro to examine specimens such as blood, tissue and urine for a clinical purpose. Examples include:

- pregnancy tests
- blood glucose monitors
- HIV test kits
- certain blood collection tubes
- immunoassays

IVDs include specimen receptacles, and products specifically designed for use in IVD examination, but not products which are for general laboratory use.

IVDs are regulated by Part IV of the UK MDR 2002 and all IVDs must be registered with the MHRA. There are four categories of IVDs, listed in order of perceived risk:

- general IVDs. This can include hormone tests and clinical chemistry tests
- IVDs for self-testing which are intended to be used by people in a home environment, excluding those that fall into the two categories below
- IVDs in the classifications stated in Part IV of the UK MDR 2002, Annex II List B (as modified by Part Ill of Schedule 2A to the UK MDR 2002). This includes reagents for measuring blood sugar and products for rubella, toxoplasmosis and phenylketonuria
- IVDs in the classifications stated in Part IV of the UK MDR 2002, Annex II List A (as modified by Part Ill of Schedule 2A to the UK MDR 2002). This includes reagents and products for HIV I and II, hepatitis B, C and D, and reagent products for determining ABO systems and anti-Kell, including those used to test donated blood, plus tests for screening

General IVDs can be self-certified, but all other IVDs need approval from a UK approved body or EU notified body before they can be registered with the MHRA and placed on the UK market. Find out more about the IVD directive and what regulatory approval your IVD needs to go through. CE mark certification for IVDs is valid until 2030, after which a UKCA mark will be required.

Further guidance is provided by the MHRA.

Registering your medical device with MHRA

Medical devices, including IVDs and custom-made devices, need to be registered with the MHRA after they have been certified by an UK approved body, an EU notified body, or where they have been self-certified, and prior to being put onto the UK market. The MHRA performs market surveillance of medical devices in the UK.

There is a fee of £240 for each registration application. You will need to provide detailed information about the manufacturer and device when registering.

Manufacturer details:

- legal entity name and address as it appears on the device labelling or packaging
- company type (for example, limited company or sole trader)
- administrative contact, you can have up to 15 people with access
- a letter of designation for a UK Responsible Person (where applicable)

The letter of designation must be a legal contract, stating that you are the exclusive UK Responsible Person acting for the manufacturer and the mandatory tasks you are contracted to undertake on behalf of the manufacturer. The mandatory tasks that must appear in the designation contract can be found in regulatory guidance for UK Responsible Persons.

Device details when registering a device with the MHRA:

- which regulations apply
- the class of device you are registering
- Global Medical Devices Nomenclature (GMDN) code and term to describe your device
- basic unique device identification- device identifier (UDI-DI) (if applicable)
- medical device name (brand, trade, or proprietary name)
- model or version detail
- catalogue or reference number
- UK approved body (or EU notified body) where applicable
- attributes (such as sterility, contains latex, MRI compatible)
- copies of any applicable conformity assessments

Find out more about how to register your device with the MHRA.

Medicinal product

Get in touch with the MHRA as soon as possible if your innovation is a medicinal product. You can access support from MHRA through the NHS Innovation Service. You should also register new medicines with UK Pharmascan. This supports the uptake of new medicines into the NHS. They will help you understand what is required from the marketing authorisation process and how to comply with the Human Medicines Regulations 2012.

Marketing authorisation is the process of reviewing and assessing the supporting evidence for a medicinal product in relation to its marketing. The process is finalised by the granting of a licence to be sold. The marketing authorisation process has a number of routes to follow and takes 6 to 12 months. The MHRA provides guidance on your application for a licence, which includes:

- MHRA fee and proof of payment
- Summary of Product Characteristics (SmPC) and label and leaflet
- Reference Medicinal Product
- Pharmacovigilance System Summary
- Risk Management Plan
- Active Substance Master File (ASMF)

If your application is for a new active substance, a pre-submission meeting with the MHRA 90 days before your intended submission is recommended. You can arrange this by emailing presubmission@mhra.gov.uk.

The Innovative Licensing and Access Pathway (ILAP) aims to accelerate the time to market, facilitating patient access to medicines. These medicines include new chemical entities, biological medicines, new indications and repurposed medicines. The ILAP works with UK-based and global developers of medicines (both commercial and non-commercial). The entry point into ILAP is the innovation passport application. This is open to medicines at the pre-clinical trial stage through to the mid-development programme point.

Surgical or invasive procedure

This applies to a new surgical technique or interventional procedure.

A new procedure must be a:

- surgical procedure (making a cut or a hole to gain access to the inside of a patient's body)
- procedure accessing the body cavity without cutting
- procedure using electromagnetic radiation, such as x-rays or lasers

It must also:

- be available within the NHS or independent sector, or be about to be used for the first time outside of formal research
- not yet be considered standard clinical practice

NICE publishes guidance on the use of interventional procedures in the UK. This guidance assesses the safety and efficacy of new techniques and procedures. Notify NICE about a new procedure or find out more about surgical innovations and advancing surgical care from the Royal College of Surgeons England.

Digital healthcare technologies

Digital healthcare technologies (DHTs) are apps, software, artificial intelligence (AI) and digital platforms or services used for health or social care. Some DHTs are considered to be medical devices.

Software is likely to be a medical device if:

- it results in a diagnosis or prognosis
- influences treatment and decision making, including calculating risk
- is linked to a medical device or medicine (potentially as an accessory)

Digital technology assessment criteria

The digital technology assessment criteria (DTAC) are the NHSE recommended criteria for NHS organisations to use when introducing new digital technologies. Companies demonstrating that they have met the requirements of DTAC are showing that they have met the minimum standards for:

- clinical safety
- data protection
- technical assurance
- interoperability
- usability and accessibility

Technical security requirements:

- cyber essentials certificate
- penetration testing
- custom code review
- multi-factor authentication
- logging and reporting

DTAC is available as a document which details the questions which developers must answer and guidance on how to do so. Further guidance on good practice in developing digital healthcare technologies is provided by the DHSC.

Artificial intelligence technology development standards

The international standard ISO/IEC 42001 was introduced as best practice for artificial intelligence management systems in December 2023 for organisations which are developing and using AI-based technologies, including in healthcare. ISO/IEC 42001 details the steps which companies should take as they establish, implement, maintain and improve these AI technologies, to provide confidence that their AI technologies are being developed in an open, ethical and transparent manner while managing any risks.

The key aims of ISO/IEC 42001 are:

- determination of organisational objectives, involvement of interested parties and organisational policy
- management of risks and opportunities
- ensuring suitable processes for the management of concerns related to the trustworthiness of AI systems, such as security, safety, fairness, transparency, data quality and quality of AI systems throughout their life cycle
- ensuring suitable processes for the management of suppliers, partners and third parties that provide or develop AI systems for the organisation

Adherence to ISO/IEC 42001 demonstrates to NHS organisations that your AI technology has been responsibly developed, implemented and maintained in compliance with legal and ethical regulatory standards, and that AI-specific risks are being managed effectively.

To understand what regulations apply to digital technologies and how to meet them, see the AI and Digital Regulations Service. This explains what regulations you need to follow, how to evaluate effectiveness, and how to generate evidence for the NHS organisations who will buy or use your technology.

If you are unsure about your innovation category

If you are unsure which category your innovation falls under, read the MHRA guidance on:

- how to tell if your product is a medicine
- how to tell if your product is a medical device

Commissioning and adoption

Throughout the development of your healthcare innovation, the ultimate aim is for it to be spread and adopted by NHS services.

The NHS Innovation Service can put you in touch with organisations that can support you along a pathway towards this goal.

This section outlines some of the frameworks within the NHS that might lead to successful commissioning and adoption.

Health technology evaluation

NICE Centre for Health Technology Evaluation (CHTE) undertakes health technology evaluations and produces guidance for NHS England on the use of new and existing treatments such as medicines, medical devices and surgical procedures. The process includes the evaluation of clinical, economic and other types of evidence about the use of the innovation or existing treatments.

There are different types of NICE guidance and advice, including:

- diagnostics guidance assesses innovative diagnostic technologies.
- highly specialised technologies guidance assesses technologies that are intended for people with very-rare conditions that are likely to be very expensive.
- interventional procedures guidance assesses whether new or significantly modified interventional procedures are effective and safe enough for use in the NHS.
- medical technologies guidance assesses innovative medical devices that are likely to be cost saving or cost neutral to the NHS.
- technology appraisal guidance assesses medicines and other innovations that cannot be assessed in the other types of NICE guidance.
- NICE guidelines sets out care and services for people with a specific condition or need, or in particular circumstances or settings.

Delivering a net zero health service

The NHS in England is aiming to become a net zero carbon national health service, in response to the profound and growing threat to health posed by climate change. To support this, the NHS has committed to

- reaching net zero by 2040 for the emissions the NHS controls directly
- reaching net zero by 2045 for the emissions the NHS influences, through the goods and services it buys from partners and suppliers

To achieve this goal, the support of all suppliers is required.

The NHS has set out the Net Zero Supplier Roadmap to help suppliers align to its net zero ambition between now and 2030. If you intended to supply your innovation to the NHS you will need to consider several of the milestones in the supplier roadmap. This includes the first milestone, implemented in April 2022, that added a minimum of 10% weighting for net zero and social value in all NHS procurements.

Since April 2023, for all new contracts above £5 million per annum, the NHS has also required suppliers to publish a carbon reduction plan (CRP) for their UK Scope 1 and 2 emissions, and a subset of scope 3 emissions as a minimum.

From April 2024, the CRP requirements have been proportionally extended to cover all new procurements. A CRP template has been published by the Cabinet Office.

Further guidance is available on these net zero requirements for NHS contexts. The NHS England Net Zero and Sustainable Procurement Team are also running a programme of webinars where you can access support.

Understanding the NHS

To understand more about the NHS and its ongoing development, read the NHS Long Term Plan. Find out more about how the NHS works from The Kings Fund charity which works to improve health and care in England.

To have your innovation adopted into the NHS you need to understand the complexity of the NHS and the related barriers this creates to procurement. Integrated care systems (ICSs) are partnerships that join up the care provided by local councils, the NHS and other partners. There are 42 regional ICSs covering England. They embed collaboration between care providers with a regional focus, to ensure that communities receive joined up support from local health and care providers.

ICSs comprise two components:

- Integrated care boards (ICBs) - statutory bodies that are responsible for planning and funding most NHS services in the area
- Integrated care partnerships (ICPs) - statutory committees that bring together a broad set of system partners (including local government, the voluntary, community and social enterprise sector (VCSE), NHS organisations and others) to develop a health and care strategy for the area.

Working through their ICB and ICP, ICSs have four key aims:

- improving outcomes in population health and health care
- tackling inequalities in outcomes, experience and access
- enhancing productivity and value for money
- helping the NHS to support broader social and economic development.

ICSs have a statutory duty to support innovation adoption and spread. The Accelerated Access Collaborative (AAC) has co-developed a series of case studies with AAC partners on the implementation approaches taken in local integrated care systems (ICS) to promote the adoption and spread of proven innovation.

Find out more about ICSs from The Kings Fund.

Commissioning in the NHS

The commissioning of services in the NHS changed with the introduction of ICS partnerships. NHS England retains some funding for the commissioning of specific services including primary care services and specialised services such as pioneering procedures and new treatments. The national tariff payment system is a set of pricing rules established to help commissioners and providers of NHS care to provide the best value to their patients.

Who is going to pay for your innovation? Who would be responsible for commissioning your innovation, ICSs or NHS England?

It is not enough to create a product that simply makes patients better. Your innovation will need to:

- be something that clinicians will be able to accommodate in their clinical practice
- work in the whole organisation
- be something that someone is willing to pay for

Often the person paying for the innovation is completely different to those who deliver care. The evidence needed to make a decision about the uptake of innovation into the NHS is different depending on the part of the NHS the person works in. Healthcare professionals will support the uptake of an innovation if they can see the benefits that it can bring to patients. Those commissioning the innovation also need to weigh this up against how cost effective it will be for the NHS. The Clinical Priorities Advisory Group (CPAG) make recommendations on what innovations NHS England should consider commissioning. Find out more about how CPAG advise NHS England.

Supporting the adoption of new innovations into the NHS

The Artificial Intelligence (AI) Award is an NHS AI Lab programme run by the Accelerated Access Collaborative (AAC) in partnership with the NIHR. It will accelerate the testing and evaluation of AI technologies. The awards support technologies at various stages of development, from initial feasibility to evaluation within the NHS.

The Early Access Medicines Scheme (EAMS) aims to give patients with life threatening or seriously debilitating conditions access to medicines that do not yet have a marketing authorisation.

The MedTech Funding Mandate from the AAC aims to direct healthcare providers and commissioners within NHS organisations towards cost-effective MedTech innovations that have been recommended by NICE diagnostics guidance, or medical technologies guidance.

NHS Supply Chain

NHS Supply Chains' role is to source, deliver and supply healthcare products, services and food for NHS trusts and healthcare organisations across England and Wales.

NHS Supply Chain have the expertise to ensure that goods are clinically safe and reflect the needs and preferences of the NHS.

You can access support from NHS Supply Chain through the NHS Innovation Service.

Find out more about NHS Supply Chain Innovation Services.

Procurement frameworks

Procurement frameworks are agreements that enable NHS organisations to buy services and goods from one or more supplier. New suppliers cannot be added to an agreed procurement framework. These agreements usually last a maximum of four years before a tender for a new framework is published. You can access the procurement and savings calendar for an overview of upcoming tender activities. This enables new or existing suppliers to forward plan for procurement frameworks which are coming up for tender.

There are other places you can go to search for upcoming tenders and opportunities:

- Find a Tender for high-value opportunities or awarded contracts across the whole of the UK
- Public Contracts Scotland
- Sell2Wales
- eSourcing NI and eTendersNI for Northern Ireland

The suppliers must pass rigorous selection criteria to become part of a procurement framework.

Procurement frameworks that are already implemented within the NHS

- Health Systems Support Framework. This enables NHS organisations to buy supportive services from innovative third-party suppliers including advanced analytics, population health management, digital and service transformations.
- G-Cloud Framework. This enables providers to sell cloud services including hosting, software and support to the public sector including the NHS.
- Dynamic Purchasing System. Unlike the other purchasing frameworks, suppliers can join this electronic system at any time. It is an 'open market' solution designed to give NHS organisations a pool of suppliers who they can buy works, services or goods from. This system is particularly beneficial for small to medium-sized enterprises (SMEs) who want to become NHS suppliers but have little or no experience in tendering for work with the public sector.

There are four NHS procurement hubs:

- London Procurement Partnership
- North of England Commercial Procurement Collaborative
- East of England Collaborative Procurement Hub
- NHS Commercial Solutions

Contact the relevant procurement hub to find out more about becoming a supplier of services or goods in the NHS.

We hope you have found this guide useful and we wish you well on your innovation journey.

NHS Innovation Service, brought to you by the Accelerated Access Collaborative.