The Innovation Canvas

A guide to how the NHS in Scotland considers innovation adoption in health and care

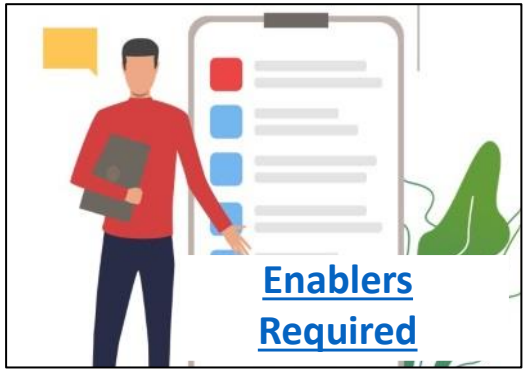
Critical Success Factors

Getting on the right track for your innovation

Creating the value proposition

Understanding the context for scaling

Enablers Required



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NHS National Services Scotland

This section covers the essential criteria for the NHS when adoption of an innovation at scale is being considered.

See also: our guide to checking the strength of your value proposition.

Cost Structure for Affordability at Scale

All of the costs of adopting an innovative approach, procedure or pathway and then maintaining it in a "business as usual" model need to be understood to assess the viability of the innovation within health and care, where finance is always under pressure.

Innovation partners in NHS Scotland will make detailed considerations set out in the Finance canvas.

Key questions include:

- ❑ How does the target cost per patient compare with current approaches?
- ❑ How will savings be realised by using the proposed innovation?
- ❑ When can savings be realised following transition to business as usual?
- ❑ How do costs change with volume or scale?

To develop a value case for adoption of the innovation, NHS will need:

- ❑ A Health Economic Assessment
- ❑ A short-medium-long term cost analysis
- ❑ Data from costs of implementation in trial sites or implementation in comparable sites in UK.

Realistic Change Requirements

Implementation projects for an innovative approach, procedure or pathway will involve a range of national partners and local NHS Boards, often in multi-year programmes. This is a significant investment.

Innovation partners in NHS Scotland will make detailed considerations set out in the Implementation canvas.

Key questions include:

- ❑ Which parts of the NHS system will be required to adjust or change?
- ❑ What is the appetite for change by NHS Boards, professional groups and patients?
- ❑ What pace and scale of change is acceptable by those who need to be involved?

To develop a value case for adoption of the innovation, NHS will need:

- ❑ A detailed plan of what change is required and a model for what is required nationally and locally to achieve the change.
- ❑ An understanding of how long it will take to embed the change and become business as usual.

Leadership and Governance to Embed

Consider who will make change happen:

NHS Boards, Chief Executives and Directors of Finance are consulted during the development of a value case.
Relevant professionals review innovations, in national specialty groups and clinician associations

Champions and local leaders will also be consulted:

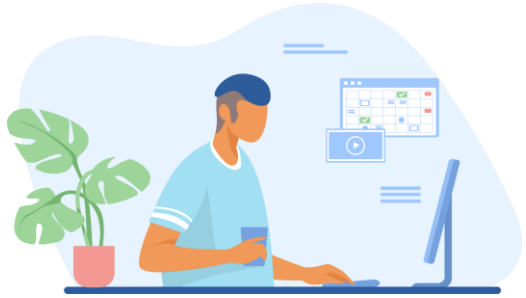
- RDI Leads
- E-Health Leads
- IG Leads
- Clinical Safety Officers and Clinical Governance Leads
- Operational and General Managers
- Allied Health Professionals
- Nursing and Care Staff

National innovation pathways co-ordinate engagement during assessment, development of value cases and during implementation projects. This takes time but pays off in successfully embedded innovation.

Getting on the right track for your innovation

This section is a guide to the options for support and opportunities for engagement, for innovations at different stages of their development.

Navigate to the right place in the canvas for your stage of development



A new tool or technology for health or care

Consider these canvas pages first:

Regulatory requirements

Technology and cyber security requirements

NHS priorities

A new product for health or care environments

Consider these canvas pages first:

Procurement requirements

Regulatory requirements

Cost structure

New approaches for effectiveness or efficiency

Consider these canvas pages first:

The pain points addressed

Connection with health and care systems

Opportunities for support and partnership for early innovations in health and care in Scotland

An early innovation is still at concept or in prototyping, or with limited clinical trials

- Civtech: challenges to create solutions to real world problems
- Scottish Health & Industry Partnership Group
- Scottish Enterprise
- South of Scotland Enterprise
- Highlands and Islands Enterprise
- Innovate UK

Further help and support:

- Heriot Watt Medical Device Manufacturing Centre
- University of Glasgow Living Lab and Innovation Hub and Clinical Innovation Zone
- University of Edinburgh Usher Institute
- Scottish Rural Health Partnership
- Precision Medicine Scotland
- Industrial Centre for Artificial Intelligence Research in Digital Diagnostics

Opportunities for support and partnership for proven innovations in health and care in Scotland

A proven innovation is ready for clinical trials, wider adoption or procurement by NHS and Health & Social Care Partnerships

- ANIA: Accelerated National Innovation Adoption
- Scotland Innovates
- West of Scotland Health Innovation Hub
- North of Scotland Health Innovation Hub
- Health Innovation South East Scotland

NHS Scotland Assure for innovation concerning the built environment in health and care

NSS RDI for innovation concerning logistics, Scottish National Blood Transfusion Service, Counter Fraud and other national services

Creating the value proposition

This section helps innovators identify the benefits of their innovation.

Innovation pathways are looking for a really strong rationale for supporting an innovation: resources are tight, services are under pressure, and the number of innovations is competitive.

Clear evidence of benefits helps reduce risk and increase the likelihood of success.

Use this guide to check the strength of your value proposition.

Addressing pain points

This aspect of considering an innovation is based on the understanding that change (even beneficial change) is difficult for busy people, so for an innovation to be rolled out successfully, it has to also promise to address common pain points.

The relevant pain points will be different for all innovations, but may include:

- ❑ Addressing poor patient/carer experience or frustrations.
- ❑ Resolving barriers to achieving targets / performance.
- ❑ Making a process or pathway easier, smoother, introducing more certainty or reducing uncertainty.
- ❑ Reducing stress hindrance in day to day working.

A **strong rationale** for supporting the innovation will show:

- ❑ A well mapped pathway for all participants (citizen, admin, practitioner) and an understanding of Time-Motion / workflow in the pathway
- ❑ Consideration of local/regional/national options for parts of the pathway (e.g. centralised lab or other services, Once for Scotland approach)
- ❑ Consideration of the different operational contexts for delivery (island, remote, rural and urban)

May **need more work** to strengthen the rationale for supporting an innovation:

- ❑ A single-setting map or pathway, which could be selectively replicated in other kinds of settings to test applicability and replicability of benefits
- ❑ A literature review or other indirect research on pain points in comparable settings

Not ready yet - innovations at this stage are still some way off adoption in a live healthcare setting:

- ❑ A set of well-argued assumptions that have not yet been robustly tested in practice in a health and care setting.

Keep in mind

- Staff time in all health and care services is precious - processes with multiple parts can be difficult for staff to comply with;
- Space in health and care services is at a premium, and hard to adapt - new equipment or activity will be difficult to roll out in some locations;
- There is a strong rationale for supporting innovations that take interventions closer to patients in communities or at home;
- There are workforce pressures throughout the system - interventions carried out by other practitioners to save clinician time, may outstrip capacity in other areas.

Clear evidence of need/demand

In addition to the evidence in other sections on this page, public bodies will want to know:

- ❑ There is evidence the target audience agrees the innovation is likely to be an acceptable or effective solution – that there will be sufficient uptake
- ❑ The likely uptake of the innovation leads to a scale of implementation and a positive balance of cost and effort of change vs benefits.

A **strong rationale** for supporting the innovation will show:

- ❑ Patient demand supports the case for adoption - patient/user representative bodies express support based on consultation or research
- ❑ Practitioner representative networks or national bodies support the case based on consultation or formal governance for review and support
- ❑ Research evidence of impact of patient or practitioner views

May **need more work** to strengthen the rationale for supporting an innovation:

- ❑ Demand data which does not include patients or practitioners' views or lived experience
- ❑ Limited endorsement from patients or practitioners (does not cover the whole pathway, or draws findings from an unrepresentative sample)

Not ready yet - innovations at this stage are still some way off adoption in a live healthcare setting:

- ❑ A set of well-argued assumptions that have not yet been robustly tested in practice in a health and care setting.

Keep in mind

•The evidence of demand relevant to the *likely uptake* of your innovation is different than defining the problem in terms of health outcomes – *likely uptake* relates to a number of factors:

- will patients find your innovation acceptable and preferable to the interventions they currently experience
- will practitioners believe the change is positive for their way of working and for their patients

•People's experience of existing solutions may influence their receptivity to new ideas: does your innovation address clear gaps in current solutions, or address any perverse impacts of other solutions?

•Scaling up or preparing for adoption does not need to be "big bang" implementation (unless this is appropriate); skilled design of adoption or implementation often identifies an approach which is more like a "movement" starting with a cohort of early adopters and using their experience to influence those planning to adopt later in the programme.

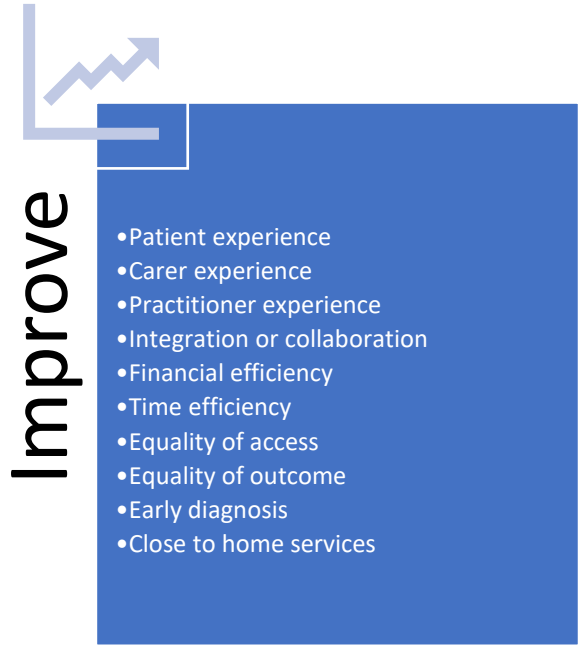
Describing the benefits of your innovation

Support for your innovation by public bodies is based on clear evidence of impact. You need to show:

- ❑ Clear "problem definition" - understanding of the current 'state of play', a baseline for what is happening now.
- ❑ The proposed change and improvement is specific and measurable

Initiatives well aligned with national priorities for health and care also attract support for innovation by public bodies, by realising benefits in one or more of their priorities.

Resources to help you describe your innovation simply and clearly:
Problem definition
Log Frames



Showing you understand the beneficiaries

Public bodies want to know who the innovation will help and to know you have connected with the intended beneficiaries. There should be evidence the target audience / focus of the innovation is thoroughly understood and agreement the innovation is likely to be an acceptable or effective solution for beneficiaries.

A list of tips on evidence of citizen engagement and professional engagement, is in the resources section.

A **strong rationale** for supporting the innovation will show:

- ❑ Information on how beneficiaries were engaged, and evidence gathered on their views
- ❑ Professionals providing services, or citizens, have been involved in either development or feedback
- ❑ Professional bodies or networks have expressed views
- ❑ An **Equalities Impact Assessment** shows the innovation ensures equality, or addresses inequality
- ❑ If relevant, a statement on ethics during the innovation's development / scale-up
- ❑ If relevant, a mapped process by which user feedback or complaints will continue to be gathered, recorded and addressed during implementation

May **need more work** to strengthen the rationale for supporting an innovation:

- ❑ A stakeholder mapping exercise that is relevant to wider adoption of the innovation, and consideration of how further engagement could be achieved - but not yet actioned

Not ready yet - innovations at this stage are still some way off adoption in a live healthcare setting:

- ❑ Customer engagement and supporting policies (e.g stakeholder mapping, ethics approval, equalities impact assessment), are underway but it is not yet available for review

Keep in mind

•Do patients, carers or professionals experience things differently in urban, rural, remote or island settings?
•Do patients or carers of different genders, ethnic groups or other characteristics share the same perspective or experience?
•Is the nature of this beneficiary engagement collaborative (co-production or significant engagement in ideas generation and testing) or is it more aligned to market research (asking beneficiaries if they are interested in an existing product)
•Has the innovation been designed with systems thinking? How will it impact other parts of the health or care system?

Clear outcomes

Successfully scaling up or enabling wide adoption of an innovation requires decision makers, nationally and locally, to **believe the innovation will deliver outcomes they want, at a cost they can accept, for a level of time and effort they can realistically commit.**

This is the innovation's promise to deliver. The outcome needs to convey the difference the innovation will make in ways that are meaningful in our complex health and care systems:

- **As a result of this innovation, what will be better?**
- **How will we know?**

In Scotland, public bodies want to support innovation that is clinically credible and evidence-based and connected to the 9 National Health and Wellbeing Outcomes.

A **strong rationale** for supporting the innovation will show:

- ❑ A well-evaluated trial or pilot in a comparable setting, that identifies evidence on
  - ❑ clinical safety and efficacy;
  - ❑ practitioner time and training requirements;
  - ❑ savings (cash and productivity) and
  - ❑ long-term liabilities (renewal periods/costs; waste management; ongoing training etc).
- ❑ A clear plan for the introduction of change (how long and what resources the innovation will take to implement and embed), before outcomes are achieved - so that performance targets and outcome measures can be applied in an appropriate time period, to fully illustrate cost vs benefits.

May **need more work** to strengthen the rationale for supporting an innovation:

- ❑ Proposed outcomes are generalised from evidence that is too short term, limited in scale or narrowly focused to substantiate them;
- ❑ Proposed outcomes are ambitious and attractive but not supported by a realistic plan of how to achieve them (see also the log frame or logic model approach)
- ❑ The assumptions used to inform the outcomes are not explicit

Not ready yet - innovations at this stage are still some way off adoption in a live healthcare setting:

- ❑ Outcomes are broad, with no quantitative or qualitative measures proposed that help decision makers answer the crucial question "how will we know its made a difference?"

Keep in mind

•Health services in Scotland face a critical challenge in knowing that investment in an innovation will quickly be able to achieve intended outcomes that benefit patients, practitioners and the wider healthcare system. Budget pressures mean that innovations must "pay off" quickly.

- **Scottish Health Technology Group** will advise innovators on designing ways of gathering appropriate evidence of outcomes. Health Improvement Scotland also has advice, guidance and intelligence, as well as a range of standards and indicators. Public Health Scotland also has an atlas of variation in health care and other intelligence.
- **Scotland's Innovation Hubs and test beds** will collaborate with innovators to trial innovations in order to measure the outcomes; however, they will require fair recompense for this.
- **Explore the COSMIN** guide to tools and resources for outcome measurement in health outcomes
- **Explore the COMET Initiative** for core outcome measures in relevant specialties
- Be familiar with the data Scotland collects and publishes nationally through Public Health Scotland's Open Data

Innovation Pathways in Scotland are driven by national policy and strategy.

This section will help innovators demonstrate how your innovation supports national priorities. Simple tools in the resources section can help you to communicate this to innovation assessors or adopters.

Policy Drivers

Scotland wants to achieve ambitious health and social care improvements. In the context of limited resources, public bodies will look to invest in innovation that helps to deliver on these commitments. The majority of innovations are likely to support the current policy framework for health and care generally, specific conditions or populations, or ways of working (such as early intervention).

Scotland's policy imperatives are similar to those in many UK and European health care systems. But priorities are not always the same. Health is a devolved matter and the culture, approach, systems and relationships are uniquely Scottish, with some UK-led legislation applying in Scotland (e.g. Medical Device Regulation, product standards and safety)

Keep abreast of issues impacting on the health of Scottish people through:

- Scottish Public Health Observatory;
- Public Health Scotland;
- Healthcare Improvement Scotland;
- Scottish Government.

Connection with the health and care ecosystem

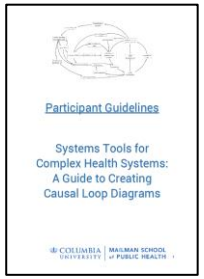
The different parts of our health and social care systems work together in one whole system: what happens in one part of the system may have a positive or perverse impact on another part.

Consider how your innovation creates a "ripple effect" or how its effective implementation may be impacted by something happening in another part of the system. Think about the connections between preventive health measures, community based social care, primary care, secondary care and emergency care. Think about the full life-cycle of products and assets, from production to storage and disposal, as well as workforce and patient education, use and support.

Systems Thinking Toolkits can help you to map out the health and care ecosystem around your innovation and its implementation within the NHS.

A Systems Approach to Healthcare: from thinking to practice makes the case for systems thinking with helpful illustrations of similarities with engineering.

Download this useful guide to creating causal loop diagrams.



Strategic Imperatives

A range of strategies guide health and care services in Scotland, led by Scottish Government and national NHS Boards:
NHS Recovery Plan 2021-2026
Health & Social Care National Workforce Strategy
Digital Health & Care Strategy
Mental Health Strategy 2017-2027
Scotland's Public Health Priorities

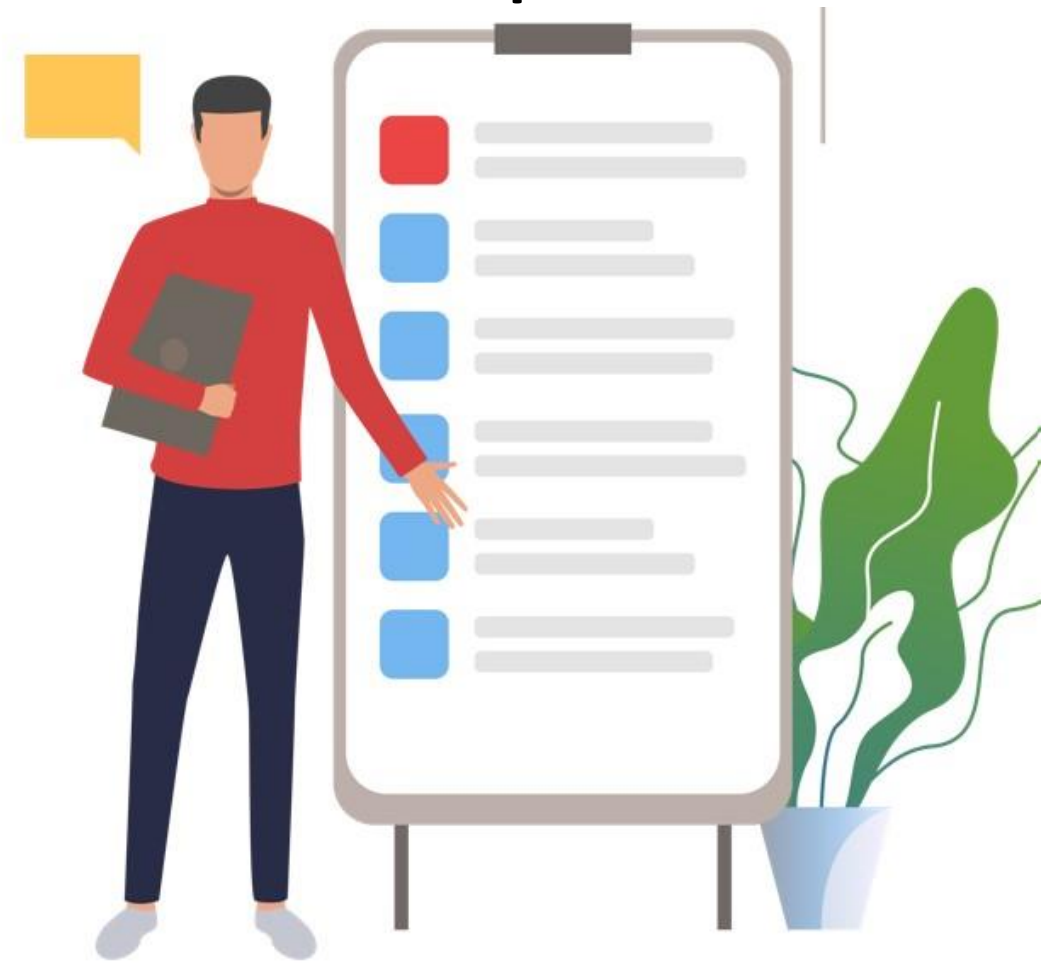
Scottish Government Healthcare Quality and Improvement Directorate oversees a range of Healthcare Standards for local NHS Board plans and delivery
NSS Strategy 2019-2024
A Strategy for Supporting Better Care in Scotland (HIS)
Public Health Scotland's Strategic Plan 2022-2025
A Skilled and Sustainable Workforce for a Healthier Scotland (NES)

The NHS is guided by the Scottish Capital Investment Manual when investing in assets.

Key strategic issues across all health and care in Scotland informing support for innovations:

- ❑ Financial pressures
- ❑ Workforce pressures
- ❑ Waiting times recovery following Covid 19
- ❑ Safe, caring and efficient discharge from hospital
- ❑ Managed and appropriate admissions to hospital

Enablers Required



This section explains the **essential requirements** for innovations in health and care in Scotland. Without assurance of safety and compliance, innovations cannot progress into adoption.

Regulatory Requirements

Health and care are highly regulated environments. It is **essential** that patient, practitioner and environmental safety come first when we consider adoption of an innovation. Innovations that do not meet regulatory requirements ***will not progress*** beyond trial into adoption in Scotland's health and care services. This applies to **products, devices and software**.

It can take significant time and commitment to take an innovation through all of the regulatory approvals required for a product to become widely used in health and care.

Early-stage innovators may find support and expertise to navigate regulatory requirements at Innoscot; Scottish Enterprise; Highlands & Islands Enterprise or South of Scotland Enterprise, or the Association of British HealthTech Industries.

- Is your innovation a medical device?
- A Quality Management System and Post Market Surveillance
- Medicines and Healthcare Products Regulatory Agency
- Conformity Markings

Safety Requirements

Safety in health and care is paramount, for all products, devices, software and novel approaches introduced into health and care settings.

Innovation pathways focus on **Safety by Design**. We don't wait for harm to happen and then

This requires engaging clinicians, practitioners and innovation adoption teams in mapping the pathway, considering the range of risks, and developing approaches that mitigate risks by incorporating features from the outset that increase safety and reduce risk.

NHS Boards clinical governance and Clinical Safety Officers should oversee the adoption of innovations in their own Boards and in compliance with their own systems. The approach of hazard mapping and the hazard log assists their full consideration.

Safety by Design means we don't wait for harm to happen and then respond.

5 stages of risk assessment

Tools and templates for Safety by Design

Reporting adverse events

Information Governance Requirements

Many innovations will rely on digital technologies which record, process, analyse or store patient data. In health and care "data protection by design and default" underpins innovation.
There are key areas of assessment for innovation adoption:

- The functions of information governance have been mapped out with clear roles and responsibilities
- The innovation is compliant with the legal framework for citizen rights and information governance
- A Data Protection Impact Assessment (DPIA) has identified and minimised the data protection risks linked to the innovation

National adoption of an innovation implies that each legally accountable body adopting the innovation (i.e. each Health Board, care provider etc) will be required to integrate the innovation into their own information governance approach and, even with a national model DPIA, will conduct their own impact assessment.

The Scottish Government's Scottish Information Sharing Toolkit

Guidance on developing a DPIA

Assessors of innovations for adoption will look for:

- Any Caldicott advice that has been obtained during development
- Any DPIA currently in place to support early development / piloting
- Details of any governing body, health board or other organisational approvals already obtained
- Public Benefit and Privacy Panel (PBPP) application or approval
- Community Health Index Advisory Group (CHIAG) application or approval

Technology Requirements and Cyber Security Considerations

Technology is commonly a key part of innovation in health and care, whether through apps for patients or practitioners, capturing or transferring data, or relatively sophisticated technology-driven innovation such as Artificial Intelligence.

There are key areas of assessment for innovation adoption:

- Medical Device Regulation
- Health and care cybersecurity standards
- The extent to which a digital product can interface with national platforms and diverse local platforms necessary for its use, in particular, with patient records.
- The IP/ownership of the product and how this will impact on sustainable development and public procurement legislation
- The capacity, nationally or locally, for ongoing support and development for upgrades etc.
- The view of the Scottish Health Technology Group which has been established to ensure technology used in Scottish health and care is effective, safe, patient-focused, best value and likely to comply with regulatory requirements as well as keep pace with the rapid development of technology over time.

Consultation with local and national bodies
Integration of new apps and systems with existing NHS platforms and infrastructure is essential. These parts of the NHS are under pressure. It is essential that E-Health leads across Scotland are consulted. **This should be led and co-ordinated by the innovation pathways**, to avoid further pressure.

More information on assessment and compliance

Intellectual property, ownership and rights

All innovation pathways in health and care wish to support innovators' intellectual property rights (including Trademarks, Copyright or Design Right) and comply with the law.

Many innovations, by their nature, will continue to develop iteratively as they are adopted into wider use, and as technology matures, creating a collaboration which may lead to new IP considerations.

Public bodies supporting innovation also seek to balance the need for innovators to recoup their investment and benefit from their work, whilst protecting the health and care sector from the risks of obsolescence, inability to flex and integrate with other new developments, or systems that do not develop in pace with changing needs.

Support to innovators on their IP Strategy is available from Innoscot; Scottish Enterprise; Highlands & Islands Enterprise and South of Scotland Enterprise.

Sharing IP with an NHS Board

Assessors of innovations for adoption will look for:

- Documentary evidence of intellectual property/ownership, or applications for this
- Contracts or SLAs between partners on shared rights / ownership (drafts may also be appropriate)
- Communication from legal or other experts advising on these areas

Innovation pathways will seek a fair deal for NHS Scotland and our patients when introducing licensing deals for use of an innovation. This is because there is often a huge cost of change when introducing an innovation into the NHS; or at times innovations have been trialled in Scotland with support from NHS or government partners.

Procurement, Supply Chain and Logistics

Procurement for the public sector in Scotland adheres to rigorous standards and regulations.

Health Innovation in Scotland may be supported by a "Once for Scotland" approach with a single national procurement on behalf of all Boards. In this case, national distribution services may be provided.

Diversity is critical to the design of our national health services and our adoption of innovation:

- Scotland has 3 island health boards, each providing services to groups of islands in their area.
- 5 mainland Boards serve remote and rural areas, including islands.
- 3 mainland Boards provide services to Boards serving island groups, remote and rural areas, with all Boards supporting flexibility.
- 1 national Board, the Golden Jubilee, provides services to patients directly from all over Scotland.
- 1 national Board, National Services Scotland, provides services to Boards (procurement, logistics, blood & tissue services).
- 1 national Board leads the Scottish Ambulance Service.
- There is 1 national Board providing high security psychiatric services.

More about Once for Scotland

Read this guide to the stages of innovation and the approach to procurement in the NHS.

Procurement colleagues supporting innovation pathways will seek this information.

Resources

NHS National Services Scotland

Health and Care Innovation Adoption Readiness Canvas – Finance

Affordable

Realistic

	Laying the Foundation	Cost of Change	Investment Required	Transition to BAU
Post-Triage	1. Capture all the costs of the pilot 2 2. Research comparative costs e.g. similar projects 3. Identify potential cost differences e.g. urban/rural	4. Map and monitor staff time and incidental costs (e.g. waste)	5. Learn from the evidence on implementation elsewhere	6. What will still be required nationally to make it work locally in BAU? 7. What will be required locally once implementation is complete?
Further strategic assessment	8. Explore both ends of the economies of scale dimension[1] 9. Conduct options appraisals for components of the innovation where there are choices for decision	10. Assess financial benefit from evidence supplied in the health economics case	11. Collaborate with procurement on market assessment 12. Collaborate with digital on cost of integration and interfacing	13. The full cost of the implementation project itself 14. The financial proposition for Boards (national investment + local contribution)
Value Case	15. Set out the framework for full cost recovery and in-kind contribution	16. Agree the basis of the model: • Number of Boards • Scale/scope of change • Timescale of implementation to BAU • What will be purchased, built • Risk and contingency	17. Create the full cost model	18. Outline governance for financial management during investment

[1]Least viable number of Boards /optimum number of Boards (or patients etc)

Health and Care Innovation Adoption Readiness Canvas – National Implementation Project Planning

Affordable

Realistic

	Laying the Foundation	Realistic objectives	Design recommendations	Implementation Plan
Post-Triage	1. Maintain pilot project documentation: • Action log • Risk register • Key decisions • Timelines and milestones	4. Share lessons learned.	5. Understand context-specific enablers and barriers	7. What will be required locally for final transition to BAU?
Further strategic assessment	9. What are the ideal "once for Scotland" components? 9. What are the critical factors for safety, inclusion, quality and positive patient outcomes	10. What is best led nationally, and what is best led locally?	12. What time, skills and resources are needed for national and local implementation teams?	13. What would be the best timing for this (system pressures) 14. How long will it really take to tee up implementation and take it to completion
Value Case	15. Agree the basis of the model: • Number of Boards, cohorting • Scale/scope of change • Timescale of implementation to BAU • What will be purchased, built • Risk and contingency	16. Map out the "order of business" – the dependencies and clear stages for preparation, engagement, recruitment of Boards and timescale for each cohort to complete	17. Plan the workstreams and RACI: • Digital / technical • Pathway guidance/SOPs • Assurance (safety, IG) • Stakeholder engagement • Workforce development • Procurement • Local project teams • Governance & reporting	18. Create a high-level schematic Create a realistic budget

Check the strength of your value proposition

Examples of a strong rationale for supporting an innovation

- ❑ The improvement is related specifically to the sector or discipline targeted by the innovation
- ❑ The evidence is from a comparable health or care system (i.e. Scotland, UK, European; or, if international, is evidence likely to be replicated in a UK context)
- ❑ A range of expert opinion supports the likelihood of benefit (e.g. health economists, research or other specialists in the target sector or discipline, based on detailed examination of the proposition)

May need more work to strengthen the rationale for supporting an innovation

- ❑ A small-scale pilot in a health or care setting has delivered promising results from a rigorous evaluation which appears likely to be replicable in comparable settings
- ❑ A mature application of the innovation in a non-health or care setting has delivered positive results which appears likely to be replicable in health and care settings

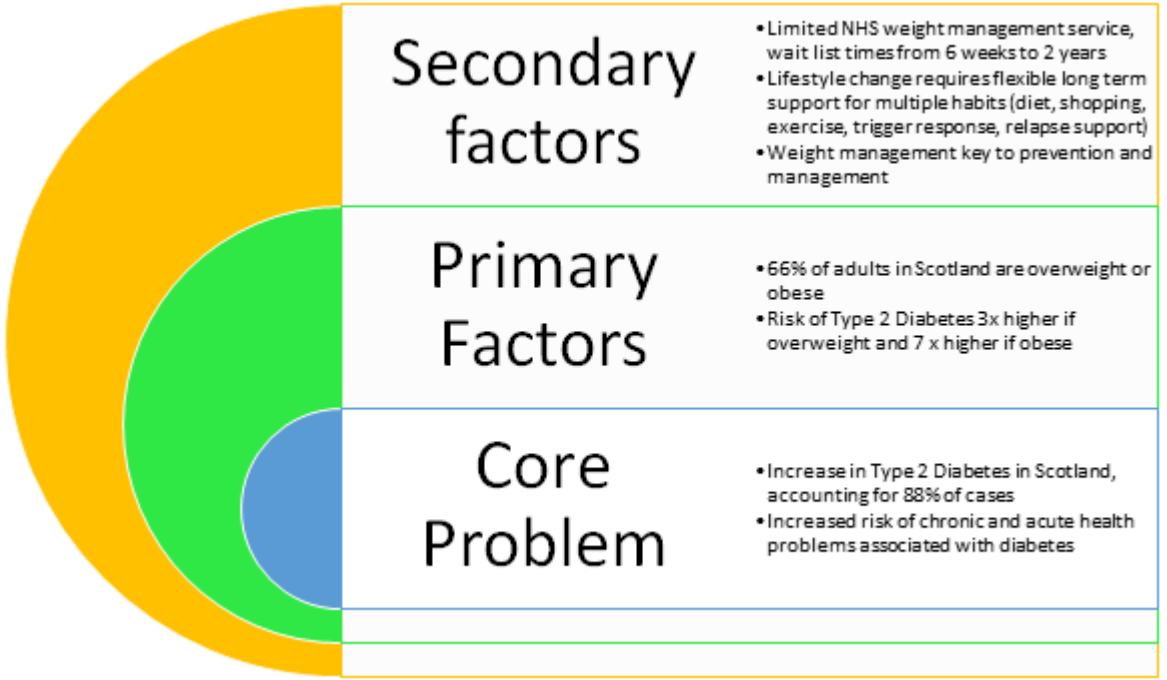
For further help to strengthen your case, consider:

- Scottish Health Technologies Group, for advice on evaluation for evidence
- Using a Small Business Research Initiative opportunity to develop and trial your ideas with an NHS partner
- Working with one of Scotland's Enterprise Agencies (SE, SOSE, HIE) to explore alternatives

Not ready yet - if you are at this stage, you are still some way off trial or adoption in a live health and care setting

- ❑ There is no formal evidence from research or evaluation but early results from using the innovation are promising
- ❑ There is academic research supporting the benefits of the innovation but as yet, no “real world” data
- ❑ Evidence gathering is underway but it is not yet available as conclusive evidence

Example of presenting your “problem definition” simply and clearly



Capture the data and connected factors clearly

Example of how to show specific goals and measures

Log Frames help to set out information in a concise, coherent and logical way

The Problem	**Core:** Oesophageal adenocarcinoma has increased 6 fold over the last 20 years. Scotland has one of the highest incidences in the world. **Often detected at late stage disease and therefore poor prognostic outcome. 5-year survival rates are <20%.** **Primary problem:** Backlogs in patient investigation post-pandemic is delaying investigations. **Secondary problem:** Endoscopy is a resource intensive, invasive procedure, which may be unnecessary if patients can receive a simpler procedure to identify risk and prioritise patients for investigation by endoscopy		
	Summary	Indicators	Assumptions (Risks)
Goal	Introduce a method of collecting oesophogeal cells which can be implemented by nurses and supports prioritisation of patients	• Reduced waiting times for endoscopy • Earlier investigation of high risk patients • Equitable access to Cytosponge for patients across all island and mainland Boards • Evidence of diagnostic accuracy	Nurse-led procedure can be carried out in community health and care settings, reducing attendance at GI outpatients (Minimal failure rate leading to device requiring Endoscopic removal)
Outcome	Earlier diagnosis of both pre-cancer (Barrett's oesophagus) and early oesophageal cancer		
Output	Nurse-led cytosponge procedures	• Number of procedures	Workforce capacity for training and new procedure
Activity	Nurse practitioner training	• Number of nurses trained • Nurse feedback	Accessible, online training and support
	Patient information	• Number of patients consenting to procedure • Patient feedback	Once for Scotland standardised information
	Laboratory sampling	• % viable samples received • Result turnaround times • % Results to patient record • Cost efficiency of managed service	Single national supplier contract
	Clinical safety & Information Governance	• % adverse events • % Data loss / error	Ongoing clinical governance group
	Evaluation of patient pathway	• Time taken from positive sample to further investigation • % failed procedures • Numbers of patients diverted from Endoscopy	Ongoing national service management function to collate and analyse data

Potential sources for evidence of impact for Citizens (patients, service users, carers, families)

- **Service user / patient research**

  This should connect citizen experience to the defined problem and illustrate how the innovation will change this experience.

  Assessors will consider the scale (sample size), quality and objectivity of the research.

- **Active participation and co-design with citizens**

  This is evidence from the involvement of citizens in developing how an innovation is established within their health or care journey

  Assessors will consider the replicability of evidence in different settings and with different patient groups.

- **Consideration of equalities and ethics**

  Equalities Impact Assessments are a standard requirement in health and care innovation adoption

Resources

- The Patient Experience Journal (PXJ) and the Beryl Institute
- Me First for engaging children and young people
- Patient involvement toolkit for researchers by the Cancer Research Institute
- Developing Patient Reported Outcome Measures (PROMS) Gov.UK guidance
- Quality, service improvement and redesign tools NHS England
- Equalities Impact Assessments (Health Improvement Scotland) and UKRI Guidance and template

Potential sources for evidence of impact for clinicians, health and care professionals

Practitioner involvement in design and development of an innovation and the pathway.
This should engage practitioners to be involved in the innovation's use at all levels, including care staff, allied health professionals, nursing teams, primary and secondary care clinicians, pharmacists, as well as leading experts in the relevant speciality.

Points to consider:

- adoption of an innovation requires the buy-in of leaders in a field, in every profession involved including administration and finance.
- health care is a system - change in one area impacts other parts of the system. When adopting an innovation, assessors consider:
- the training requirements for all practitioners involved to safely implement the innovation - the cost and sustainability locally (staff time, grade, capacity, maintenance) and nationally (centralised online training)
- the administrative requirements of delivering to patients effectively, from appointments and pre-procedure requirements to post-procedure requirements; patient information requirements; integration with existing data systems etc.

Involvement of leads in key areas of change management and governance
This should engage relevant local or national leads in:

- e-Health
- Information Governance
- Clinical Safety Officers or equivalent managers of risk and compliance

National leadership groups or representative bodies for professions or specialities
Endorsement by a national body may be a strong predictor of successful implementation locally.

Resources

- Managing digital change successfully in health and social care, Kings Fund
- Quality, service improvement and redesign tools NHS England
- Case studies on adoption and spread of innovation in the NHS, Kings Fund
- IDEO design methodology design kit and prototyping kit
- Information on national strategic, clinical, diagnostic and cancer networks in Scotland
- Specialty delivery groups and Once for Scotland pathways, Centre for Sustainable Delivery

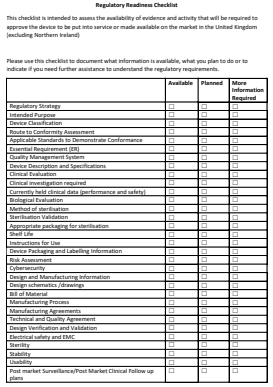
A quality management system (QMS)

A QMS is not in itself a regulatory requirement but many regulations see this as a requisite of approval.
ISO QMS systems are the most common accredited standard.
The British Standards Institution (BSI) is the accreditation body for a wide range of standards for the health care industry. Gaining accreditation can be a slow process and should be planned at the earliest possible stage of your innovation.

Post market surveillance is an important part of Quality Management and clinical safety.

Medicines and Healthcare products Regulatory Agency

This checklist compiled by Innoscot Health indicates the basic requirements for registration with MHRA.


Regulatory Readiness Checklist

This checklist is intended to assess the availability of evidence and activity that will be required to approve the device to be put into service or made available on the market in the United Kingdom (excluding Northern Ireland)

Please use this checklist to document what information is available, what you plan to do or to indicate if you need further assistance to understand the regulatory requirements.

	Available	Planned	More Information Required
Regulatory Strategy	☐	☐	☐
Intended Purpose	☐	☐	☐
Device Classification	☐	☐	☐
Route to Conformity Assessment	☐	☐	☐
Applicable Standards to Demonstrate Conformance	☐	☐	☐
Essential Requirement (ER)	☐	☐	☐
Quality Management System	☐	☐	☐
Device Description and Specifications	☐	☐	☐
Clinical Evaluation	☐	☐	☐
Clinical investigation required	☐	☐	☐
Currently held clinical data (performance and safety)	☐	☐	☐
Biological Evaluation	☐	☐	☐
Method of sterilisation	☐	☐	☐
Sterilisation Validation	☐	☐	☐
Appropriate packaging for sterilisation	☐	☐	☐
Shelf Life	☐	☐	☐
Instructions for Use	☐	☐	☐
Device Packaging and Labelling Information	☐	☐	☐
Risk Assessment	☐	☐	☐
Cybersecurity	☐	☐	☐
Design and Manufacturing Information	☐	☐	☐
Design schematics /drawings	☐	☐	☐
Bill of Material	☐	☐	☐
Manufacturing Process	☐	☐	☐
Manufacturing Agreements	☐	☐	☐
Technical and Quality Agreement	☐	☐	☐
Design Verification and Validation	☐	☐	☐
Electrical safety and EMC	☐	☐	☐
Sterility	☐	☐	☐
Stability	☐	☐	☐
Usability	☐	☐	☐
Post market Surveillance/Post Market Clinical Follow up plans	☐	☐	☐

Conformity Markings

All manufactured goods or components of your innovation should have evidence of conformity with health and safety regulations for the UK.
Until December 2024, CE Marking is a requirement.
UKCA marking is replacing CE Marking by December 2024, which covers items such as measuring equipment and Personal Protective Equipment (PPE).
However, there are specific regulations for Medical Devices and Hazardous Substances in Electrical and Electronic Equipment.

Is Your Innovation a Medical Device?

The regulation of Medical Devices is changing.

'Medical device' means any physical or digital tool that helps in diagnosis or in therapeutic purposes. Medical devices have different classifications from I (low risk) to class III (high risk). There is also a classification of "In-Vitro Diagnostic Medical Device," a device which is used to examine human body specimens such as blood or tissue etc. These have different classifications from A (low risk) to D (high risk).
This introductory guide helps to identify whether your innovation is a medical device.

Further advice and support is available to companies from:

- The Association of British HealthTech Industries (see ABHI resource Hub)
- Gov.uk guidance

The 5 Stages of Risk Assessment

Risk is an unavoidable aspect of innovation. Innovators can support considerations for scaled adoption by introducing risk assessment and risk management during trials - this allows for more effective risk scoring, using logged occurrences and mitigations during the trial period.

Assessing clinical and care risk when preparing for adoption of an innovation benefits from this trial data.

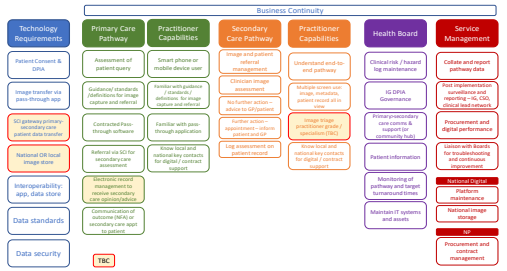
Generally, the 5 stages of risk assessment apply in health and care, and relate to the ***whole*** pathway, which encompasses:

- the innovative product or procedure
- the data flow and security associated with using it with patients
- the whole pathway (e.g. a test kit from use, to lab, to result returned to patient)
- the human knowledge/skills/behaviours required to make it work, by practitioners or patients
- any issues around storage, use-by or other criteria for a product
- how faults are identified, flagged and reported

1. Identify hazards
2. Assess the risks
3. Control the risks
4. Record your findings
5. Review the controls

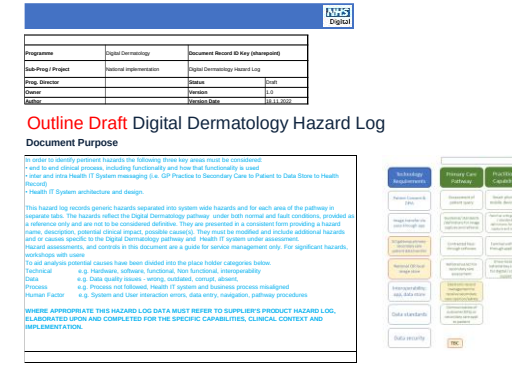
ANIA pathway

1. Develop a hazard map



Example from Digital Dermatology pathway

2-3. Involve practitioners and clinical safety officers in assessing risks



Example from Digital Dermatology pathway

4-5. Share information and experience during adoption and change management

Regulation | Safety#1 | Safety#2 | Safety#3 | Technology | Rights | Procurement#1 | Procurement#2

Tools and templates for Safety by Design

Safety by Design is the principle of proactive safety management by looking at the whole system around an innovation or service improvement – the parts (products or procedures) and the relationship between the parts and the system. This also creates better flow and reduces cost.

The Scottish Patient Safety Programme is a useful source of information on specific patient safety programmes in Scotland.
NHS75 England provides comprehensive frameworks for patient safety systems, including patient involvement in patient safety.

NHS75 Digital Clinical Safety Documentation tools for clinical risk management and clinical safety guidance assist innovation pathways in Scotland to ensure safety by design. Although these are not mandatory in Scotland, their alignment with MHRA requirements and other regulations strongly supports their use.

Innoscot Health

Innoscot Health supports innovators to develop the portfolio required to meet regulatory guidelines.

NSS Clinical Informatics Service

The NSS Clinical Informatics Team supports the development of Medical Device Regulation-compliant, safe and secure hardware and software solutions. Consultancy is available for all lifecycle stages from concept to design and for remediation solutions or retrospective planning. The team can be commissioned to conduct full Clinical Safety Assessments.

Further reading:

Safety by design, why wait for harm to happen?

Design for Patient Safety

Ensuring Clinical Safety by Design (podcast)

Principles of Safer Online Platform Design

Reporting adverse events

During trials and innovation adoption, health and care practitioners are obliged to report any adverse event or near miss within a health or social care procedure, service or setting.

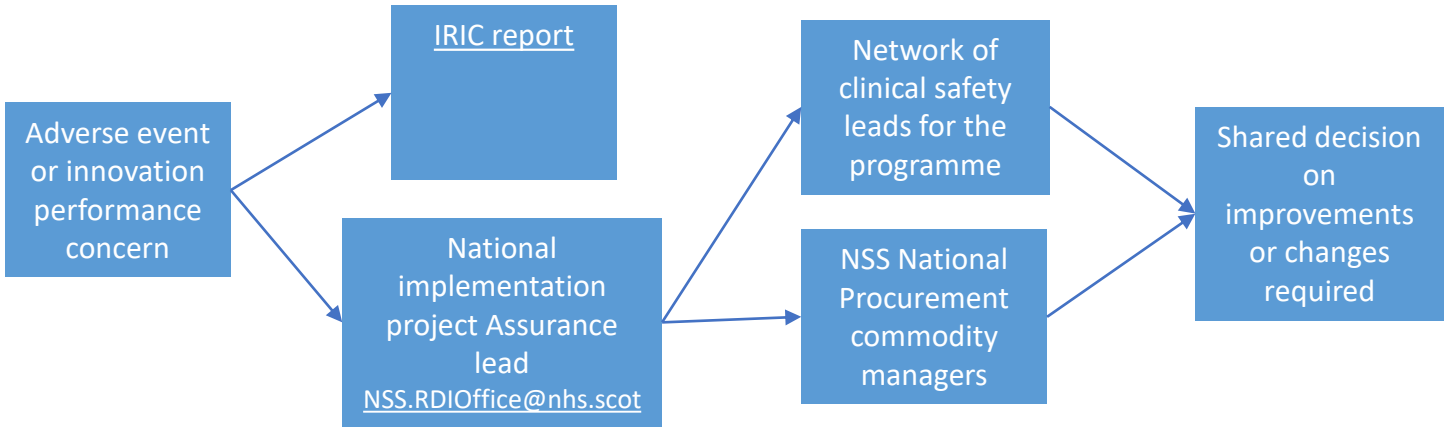
However, information sharing between practitioners, clinical safety leads and national implementation programme leads is critical to ensuring continuous improvement and rapid, effective response to concerns about safety or performance of products or purchased managed services.

National incident or near miss reporting form (IRIC)

Each local health board also has a reporting system - Datix

Post market surveillance is a requirement of MHRA and MDR registration referred to in Regulatory Requirements

ANIA pathway process



Assessors of technology innovations for adoption will look for:

- Secure Design Principles as outlined in the UK National Cyber Security Centre
- Evidence of a thorough assessment of data security and protection, and performance against standards, for example following the Data Security and Assessment Guides of NHS England.
- Details of any specifications, contracts or SLAs for any outsourced requirements or partnership-provided requirements
- Detailed controls and monitoring processes to ensure network integrity, security and confidentiality of data
- Architectural reports, technical roadmaps or other reports on recommendations regarding solutions
- Details of compliance with NHS technical and accessibility standards, Digital First Service standards, or other accredited standards
- Reports from user experience studies
- Models for integration or technology transition
- Minutes or responses from meetings with E-Health Leads of NHS Boards
- Project tools such as implementation plans/reviews, RAID logs
- Feedback from the Scottish Health Technology Group

Compliance with Scotland's Digital Health & Care Strategy

All innovations adopted by NHS Scotland Boards will be required to follow the Scottish Government standards of the Digital Health and Care Strategy

- Use the Scottish Approach to Service Design, engaging users in the definition, design and delivery.
- Develop using the Digital Scotland Service Standard, with 14 criteria, to make sure of continuous improvement and keep users in focus and build in security and privacy.
- Use internationally recognised open technical standards to improve interoperability and workflows between systems.
- Ensure clinical safety and security is embedded and is compliant with UK regulations.
- Based on ethical and impact assessments.

Sharing IP with an NHS Board

NHS Boards have policies on development of IP and exploitation of IP based on partnerships between external organisations and their own staff.

Example policies provide insight into Board expectations:

NHS Tayside Policy Ownership and Exploitation of Intellectual Property

NHS Lanarkshire Policy Management-and-Exploitation-of-Intellectual-Property-and-Inventions–IP

NHS Fife Procedure for the Management Of Intellectual Property

Further advice

Scottish Government guidance on Intellectual Property

The UK Intellectual Property Office

Essential requirements for Procurement

It is key that all goods and services purchased by NHSS must adhere to the principles of open, fair, and transparent commercial arrangements. To achieve this a commercial competition process must be part of any new product introduction.
This is the case even when an innovator has partnered with the NHS to develop an innovation.

The pull model of innovation - when the NHS or Scottish Government invites suppliers to help solve a problem

To enable the PULL model of innovation, public bodies must establish a fair, open, and transparent method to make innovators aware of the need, to receive potential solutions and to assess these against the requirement prior to deciding whether to progress further and enter a formal commercial process. This is called **Pre-Commercial Procurement (PCP).**

The PCP model
•A competitive process of research and development (R&D) that supports the design, development and testing of new products or services to meet the specific needs of public bodies.
•Advertised on the Public Contracts Scotland (PCS) portal and in some instances the Innovate UK portal.
•Market engagement events before and following the project going live on the PCS Portal.

Small Business Research Initiatives (SBRIs)
Generally completed over phases:
1. Feasibility Study
2. Product Development;
3. Operational Testing (only when the operating context has specific challenges)

At the conclusion of the PCP or SBRI, the development process STOPS and a new commercial tender process starts. A Public Procurement of Innovation (PPI) must be conducted under the relevant procurement regulations and this stop period must be factored into programme timescales.

The push model of innovation - when suppliers approach the NHS

Innovators approach the Scotland Innovates portal.
•NSS National Procurement Innovation Team reviews the submissions, checks for compliance, and shares innovations with clinical specialists, facilities managers or other leads for the relevant part of the NHS.
•For innovations looking for a trial site to evidence their innovation's benefits, the team alerts the NHS Innovation Hubs to find a test bed in the NHS, if the innovation fits current priorities.
•For innovations that are "market ready", the innovator is directed to current procurement opportunities - these are also advertised on Public Contracts Scotland.
Innovators are interested in applying for Challenges or Small Business Research Initiatives
•The Scottish Health Industry Partnership (SHIP) develops a Demand Signalling Plan.
•Challenges or SBRIs are open to competition. Successful selected innovators work with NHS Innovation Hubs to collaborate on designing a solution.
ANIA innovation pathway is open to submissions, but tends to prioritise innovations that have already been successfully trialled in an NHS setting.

Routes to commercial procurement

Procurement routes must adhere to the legal requirements set out in the Public Contracts (Scotland) Regulations 2015 and the Procurement Reform (Scotland) Act 2014. The route depends on whether the innovation is nor market ready (a concept, untested or unproven); or market ready.

Market Ready

A business case will be developed by the public body, and a regulated procurement procedure is undertaken:

Regulated Open Tender Procedure - Single stage procurement

- Fully defined specification
- "Off the shelf" solutions available.

Dynamic Purchasing System (DPS) call off or mini-competition

- Suppliers are invited to show they can meet requirements / qualification criteria for goods/services. They can join a DPS at any time.
- When a purchased wishes to enter a new contract or renew a contract, all suppliers on the DPS can tender.
- Call-off competitions in a DPS are generally shorter.

Framework – Direct call-off or conduct a mini-competition

- A framework involves pre-selected suppliers who meet criteria for a specified good or service.
- A Direct Call Off contracts a first-ranked supplier
- A Call-off is a mini-competition of suppliers on the framework.

Voluntary Ex Ante Transparency (VEAT)

Only used when a single named organisation is in a unique position to deliver a service to the requirement. A decision is made without competition.

Competitive Procedure with Negotiation (CPN)

Used when the requirement can't be met without adaptation or refinement of existing solutions, or where the specification cannot be fully developed due to complexity. Further design and development would likely be needed from the supplier.

Competitive Dialogue

Like CPN, competitive dialogue us used in highly complex and outcome-based contracts.

Not Market Ready

Innovation Partnership

This is a regulated process which is only undertaken when there is a high level of confidence that the resulting innovation will be purchased by the public sector.

It is only undertaken where no suitable solution exists on the market.

A procedural framework is developed by which an innovative solution is researched, developed, prototyped and rolled out within a single procurement process.

NSS National Procurement Innovation Team will advise NHS colleagues' Strategic Sourcing Plan