A guide to navigating the innovation pathway in England

May 2016

Please note that this is a beta version of the guide. If you would like to make comments for inclusion in the next version, please email acceleratedaccess@officeforlifesciences.gsi.gov.uk
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Purpose of this guide

This document provides guidance for navigating the innovation pathway in England* from idea generation, through development, regulation, reimbursement, endorsement, commissioning and adoption, for the following product types:

**Pharmaceuticals**
Pharmaceuticals include all drug-based products and vaccinations

**Medical devices and in vitro diagnostics**
Medical technology includes healthcare products used to diagnose, monitor or treat diseases or medical conditions

**Digital health**
Digital health considers medical products such as apps and data analytics which could be sold to the NHS

**What does this guide cover?**

The guide is designed for innovators, the life sciences and health tech industry and other health stakeholders seeking:

- An overview of the innovation pathway for products to be used by the NHS in England, including idea generation, development, regulation, reimbursement, endorsement (including health technology assessments), commissioning and adoption
- Key organisations and contacts at each stage of the pathway
- A check-list of key considerations at each stage of the pathway

Please note that every product will be different and the details of the innovation pathway will vary from one to the next. This guide is designed to provide a high-level overview, and does not include all pathway details; innovators are encouraged to reach out to recommended stakeholders or seek further guidance online.

**Who should read this guide?**

This guide does not cover processes specific to NHS Wales or Scotland or HSC Northern Ireland, and it does not provide guidance on selling health products to non-NHS bodies

**How was it compiled?**

This is a beta version, correct as of April 14th 2016. This publication compiles materials produced by Deloitte as well as data from external sources, public source materials and stakeholder views. Beyond basic consistency checks, the data received has not been externally validated.

**Comments?**

This guide will be regularly updated. If you would like to make comments for inclusion in the next version, please email acceleratedaccess@officeforlifesciences.gsi.gov.uk

*This guide does not cover processes specific to NHS Wales or Scotland or HSC Northern Ireland, and it does not provide guidance on selling health products to non-NHS bodies
Innovation pathway

To view the pathway and timelines for your product type, click the buttons below:

- Pharmaceutical
- Medical Device / Diagnostic
- Digital

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Information correct as of 14th April 2016
How to use this guide

Innovation pathway and key questions for innovators

A high-level, product agnostic summary shows the main stages required to get a product to market

Navigate by stage

You can view a high-level pathway that applies to all products, and link to relevant organisations and online guidance

Navigate by question

You can deep-dive on a specific question, view the answer and link to the relevant organisations and online guidance for your product type

Navigate by product

You can view a pathway for a specific product type and link to details for a specific step

All details supported by a directory of key contacts
Overall pathway by stage
Creation / idea generation

Description: At the idea generation stage, companies / innovators should identify key clinical areas or unmet needs and consider the type of solution that could be used to address this. This stage should also include testing the concept with patients, healthcare professionals and regulators before deciding to take an idea forward to development. Research should also be conducted around the current pathway and comparator treatments.

Key items to be completed at this stage:

- Confirm whether system needs align with your product and whether the NHS could pay for your product by speaking with key stakeholders e.g. NIHR Healthcare Technology Co-Operatives (work collaboratively with industry to develop concepts to improve patient treatment and quality of life); Clinical Commissioning Groups (NHS organisations responsible for planning, commissioning health care services for their local area); GP federations and AHSNs (Academic Health Science Networks)
- Understand outcomes important to patients and how your product will meet them by engaging with charities or directly with patients (more information available here)
- Develop an understanding of the evidence required by speaking with regulators and health assessors including conformity to existing EU data protection regulations (new regulation expected early 2016)

Key bodies by industry

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<th>Key bodies by industry</th>
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To view the pathway and timelines for your product type, click the below buttons:

- Pharmaceutical
- Medical Device / Diagnostic
- Digital

Next phase: Development
Development

Description: During this stage the product is developed and refined until it is ready to be submitted for regulatory and reimbursement/endorsement processes. Although the key actions at this stage will vary by product, they should generally include product development, evidence generation and business case development around clinical utility and effectiveness and economic effectiveness. Evidence should also support patient needs identified in the creation stage and may include patient reported outcomes.

**Key items to be completed at this stage:**
- Engage with researchers, patient groups, charities and the NIHR in the design of trials/evidence capture; bodies associated with the NIHR include NOCRI, BioMedical Research Units, Clinical Practice Research Datalink, Healthcare Technology Cooperatives, Diagnostic Evidence Cooperatives, Catapults, Collaboration for Leadership in Applied Heath Research and Care.
- Use early dialogue with health technology assessors and feed back into product development/testing.
- Consult regulatory websites and consider services such as Scientific Advice meetings (MHRA, EMA) and Protocol Assistance (EMA). Investigate whether orphan designation (EMA), paediatric investigation plans (EMA) and accelerated processes (EAMS for MHRA; PRIME for EMA) are relevant.
- Register relevant products on horizon scanning databases (UK PharmaScan or NIHR HSRIC).
- Develop the value proposition of a product as early as possible, considering pricing/market access.

**Key bodies by industry:**
- Pharmaceuticals: ABHI, ABPI, BIA, BIVDA, DHACA, EMIG, AHSNs
- Med device / diagnostics: Yes
- Digital: Yes
- NICE Office for Market Access: Yes
- NIHR Office for Clinical Research Infrastructure: Yes
- UK PharmaScan or NIHR HSRIC: Yes

To view the pathway and timelines for your product type, click the below buttons:
- Pharmaceutical
- Medical Device / Diagnostic
- Digital

Previous step: Creation / idea generation

Next step: Regulation

Information correct as of 14th April 2016
Description: Regulatory approval is required for most medical products to be marketed in the UK. The type of approval varies by product type, but approval processes consist of demonstrating through evidence that your product meets required quality, safety, and efficacy requirements of the UK (or EU if applying for European marketing authorisation). There are often opportunities to engage early with regulators in scientific advice. Non-medicine, non-medical device products such as digital health products may be subject to guidance but not regulatory control.

Key items to be completed at this stage:

- Ensure guidance and advice from any prior engagement with regulators is taken into account (e.g. endpoints, patient outcomes, comparators, patient sub-group analysis etc.)
- Respond to requests for additional data and clarifications in a timely manner
- Use early dialogue with HTAs (Health Technology Assessors) to support national reimbursement and commissioning applications

Key bodies by industry:

- **Pharmaceuticals**: British Standards Institute, EMA, MHRA, Notified Bodies
- **Med device / diagnostics**: British Standards Institute, EMA, MHRA, Notified Bodies
- **Digital**: British Standards Institute, EMA, MHRA, Notified Bodies

*For technologies involving a pharmaceutical only

To view the pathway and timelines for your product type, click the below buttons:

- Pharmaceutical
- Medical Device / Diagnostic
- Digital

Previous step: Development | Return to landing page | Next step: National Reimbursement

Information correct as of 14th April 2016
Endorsement / reimbursement

Description: Some products require national endorsement and assessment before they can be reimbursed, whilst for others the reimbursement decision making is local. During this stage, health technology assessors such as the National Institute for Health and Care Excellence (NICE) may assess the clinical and cost-effectiveness of the product compared to current clinical practice. Depending on the results, the assessor may recommend the product for routine use, selected patient groups or in research only. In the current pathway some recommendations result in a funding direction and formulary inclusion, meaning that Clinical Commissioning Groups (in charge of commissioning local services) must allow the use of these products, according to the NHS Constitution.

Key items to be completed at this stage:

- Ensure up-to-date product characteristics are viewable by Horizon Scanning bodies
- Ensure information from early dialogue with HTAs has been used to inform application
- Investigate which organisations are likely to assess or fund your product
- Engage with other key stakeholders before submission (e.g. Clinical Reference Groups)
- Ensure business case clearly demonstrates how the product meets unmet patient needs and the implications on the current pathway

Key bodies by industry:

- Commercial Medicines Unit
- NICE (HTA:STA/MTA, DAP, MTEP)
- NICE Office for Market Access
- NHS Supply Chain

Pharmaceuticals: ✔ ✔
Med device / diagnostics: ✔ ✔
Digital: ✔ ✔

To view the pathway and timelines for your product type, click the below buttons:

Pharmaceutical
Medical Device / Diagnostic
Digital

Previous step: Regulation
Return to landing page
Next step: Adoption

Information correct as of 14th April 2016
Commissioning and adoption

Description: Once a service has been commissioned and included in the formulary (if relevant to your product), it will be available to healthcare professionals, resulting in patient access. For products not included on a formulary, local decision-makers will assess your product and decide on usage in providers, including consideration of how the product fits into the local pathway. This is particularly important for devices, diagnostics and digital products.

Key items to be completed at this stage:

- Develop or refine a clear business case which can demonstrate to commissioners and / or providers the clinical and health economic benefits to their local health economy (e.g. disinvesting in alternatives)
- Engage with stakeholders from across multiple functions and consider engagement with patients (e.g. via advocacy groups) and healthcare professionals to disseminate information
- Identify and engage with relevant adoption support bodies (e.g. AHSNs)
- Consider strategies for mitigating common barriers to adoption (e.g. healthcare professional education)

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- Pharmaceutical
- Medical Device / Diagnostic
- Digital

Previous step: National Reimbursement

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Information correct as of 14th April 2016
Answers to innovator questions
FAQs: Creation / idea development

The National Health Service (NHS) is used to refer to the publicly funded healthcare systems in the UK. It generally refers to the collective of each of the four systems (English government, Scottish Government, Welsh Government and Irish Executive), however this guide will focus on the English NHS. More details about the structure of the English NHS can be seen below:

Public health has renewed priority through the creation of Public Health England.

Patient involvement throughout the NHS is increasing and HealthWatch strengthens the voice of the patient.

GPs are key providers of Primary Care. GP Federations are groups of GP practices which work together to improve care and achieve economies of scale through sharing functions such as back office services.

Clinical Commissioning Groups, led by healthcare professionals, are responsible for commissioning the majority of services.

NHS England oversees the planning, delivery and day-to-day operation of the NHS in England, including some commissioning responsibilities.

New from 2013
Previously existing

Return to landing page

Next question: How does the NHS work? (2/2)
How does the NHS work? (2/2)

The 2012 Health and Social Care Act led to fundamental change across the health system in England in 2013. Leadership responsibility for planning and commissioning care moved to healthcare professionals. Patient choice was embedded at the heart of the NHS by allowing healthcare market competition when it is in the best interests of the patient. The King’s Fund Video below provides a useful background on the new structure of the NHS:

**NHS England**

Public health researchers and think tanks e.g. The King’s Fund, Nuffield Trust, CASMI.

Key bodies by industry

- Pharmaceuticals
- Med device / diagnostics
- Digital

Next question: Why should I develop or launch my product in the UK?

Previous question: How does the NHS work? (1/2)
The UK is home to a dynamic healthcare and life science industry driven by a large National Health Service, supportive national policies and investment, and strong academic talent.

- The National Health Service deals with over 1 million patients every 36 hours, and the UK population is projected to increase to 67 million by 2020
  - The overall NHS expenditure on medicines in 2014-15 was £15.5 billion and £4.5 billion was spent on clinical supplies and services, including medical devices and consumables, in 2011/12
- The UK Life Science Strategy involved an investment of £310m to support the discovery, development and commercialisation of research
- The UK has a strong heritage in medical innovation: UK-led research reduced the time taken to sequence the human genome from 10 years to a single day
- The UK is renowned for health research and has the most integrated clinical research system in the world, the NIHR (National Institute for Health Research)
- According to the 2015 Ease of doing business index, the UK is the sixth highest-ranked country in the world
- The UK life sciences industry turns over c. £50bn annually

For more information, please visit the Office for Life Sciences website.
FAQs: Creation / idea development

There are many sources of finance available for businesses developing healthcare products in the UK. These include:

- University funding for those affiliated with a university: Visit your technology transfer office for more information
- Grants: Public, private and EU grants are available See InnovateUK for more information
- Crowdfunding
- Angel investors: Invest in companies at an early stage - see the Angel Investment Network
- Venture Capital: Invest in slightly more established companies - see the British Venture Capital and Private Equity Association

For a list of sources of funding and further explanation, please see the UK Life Sciences Portal. There is also guidance from MedCity (note that MedCity is focused on the South East)

Academic Health Science Networks (AHSNs) aim to improve the process of developing and adopting innovations in healthcare and can give advice on funding amongst many other things. AHSNs are found locally but can be accessed by any business in England so you should consider which is the most suitable one for your product and area of interest.

The NIHR (National Institute for Health Research) can also provide some guidance on funding for clinical testing.

Key bodies by industry

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Understanding system and patient needs is critical to the adoption and impact of your product. Whilst there is currently no centralised or comprehensive source to find all available information around system and patient needs, there are two strategies to finding this information:

1. Review publicly-available health strategies / reviews including (but not limited to):
   - The NHS Outcomes Framework gives a high-level view of key system needs
   - The NHS Five Year Forward View illustrates the future direction of the NHS
   - Individual plans and priorities for Clinical Commissioning Groups (CCGs), responsible for planning and commissioning health care services for their local area
   - Therapeutic area strategies such as the UK Strategy for Rare Diseases
   - Charitable research such as the Macmillan Cancer Patient Experience Survey and Bloodwise’s Patient Need report
   - James Lind Alliance’s Priority Setting Partnerships which bring patients, carers and healthcare professionals together to identify and prioritise topics for future research

2. Engage with key stakeholders: these may include NHS England, CCGs, healthcare professionals, patients (via patient advocacy groups) and Academic Health Science Networks (AHSNs)

### Key bodies by industry

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**Previous question:** What investment is available?

**Next question:** What are the outcomes that are important to patients?
What are the outcomes that are important to patients?

Understanding the outcomes desired by patients can guide the process of creating a medical innovation. As with system and patient needs (see previous page) there is not a single, comprehensive source of information for this but a number of organisations that can be engaged:

- **Clinical Commissioning Groups** (CCGs), responsible for planning and commissioning health care services for their local area
- Healthcare professionals (e.g. via GPs, Acute Trusts, Clinical Directors)
- Academic Health Science Networks (**AHSNs**), which connect the NHS, academia, private sector and others
- Patients via advocacy groups, support organisations and charities (a list of potential charities and advocacy groups can be found [here](#))
- For example, the [James Lind Alliance](#) brings patients, carers and healthcare professionals together in Priority Setting Partnerships to identify and prioritise topics for future research

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<th>Key bodies by industry</th>
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FAQs: Creation / idea development

Who are the organisations involved in the innovation pathway in England?

Click on the organisations below to link to our glossary for more information. Arrow lengths refer to suggested timings for contact; colours connect with the relevant main pathway stage:

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<td>Medicines and Healthcare products Regulatory Authority</td>
<td>European Medicines Agency</td>
<td>Academic Health Science Networks</td>
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<td>National Institute for Health and Care Excellence</td>
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<td>Trade bodies and support organisations e.g. ABHI, ABPI, BIA, BIVDA, DHACA, EMIG, Medilink</td>
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Previous: What are the outcomes that are important to patients?  
Return to landing page  
Next: How would my product impact the care pathway and resources required?

Information correct as of 14th April 2016
FAQs: Creation / idea development

A care pathway outlines the journey taken by a patient with a specific condition or set of symptoms as they progress through a clinical experience to positive outcomes, from diagnosis to post-treatment or long term care.

To understand how an existing pathway could be changed through use of your product, it is important to first understand current care pathways:

- Contact AHSNs who will have information on local healthcare services and may be able to put you in contact with healthcare professionals
- CCGs often have information on the care pathways in their locality on their websites, whilst Vanguards provide new care models
- Charities can be a useful source of information on care pathways - a list of potential charities and advocacy groups can be found here
- Health and Wellbeing Boards and NHS Improving Quality may also provide relevant materials for your product

It is also important to consider that technologies that change pathways need to take into account the training and education needs of frontline clinicians to support adoption.

Key bodies by industry

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How would my product impact the care pathway and resources required?

Previous: What are the organisations involved in the innovation pathway in England?

Next: What support and advice is available at each stage in this process? (1/2)
FAQs: Creation / idea development

You can find support and advice from many different organisations. Some are specific to the stage of the innovation pathway that the product is at (see below) whilst others can give more general advice. Academic Health Science Networks (AHSNs) aim to improve the process of developing and adopting innovations in healthcare and can give advice on all stages of the process including funding. You should find the most suitable one for your product and area of interest. Trade bodies, including ABHI, ABPI, BIA, BIVDA, DHACA, and EMIG, can also provide broader advice and support appropriate to your product. Other support bodies such as Medilink UK, Tech UK, Knowledge Transfer Network, Innovate UK, BHTA, GAMBICA may be helpful.

Creation / idea generation
Academic Health Science Networks (AHSNs) or Medilinks may be useful for early conversations. Patient advocacy groups and charities are a good source of information about patients and unmet patient needs. For example, the James Lind Alliance’s Priority Setting Partnerships bring patients, carers and healthcare professionals together to identify and prioritise topics for future research.

Development
The National Institute for Health Research (NIHR) organises health research in the NHS and can help with clinical testing. NOCRI can provide guidance on clinical trials through the National Institute for Health Research, the research arm of the NHS. You can receive advice on requirements from the Diagnostic Evidence Co-operatives, Efficacy and Mechanism Evaluation, Healthcare Technology Co-operatives and NIHR CLAHRC.

Regulation
The Medicines and Healthcare Products Regulatory Agency (MHRA) and European Medicines Agency (EMA) regulate medicines and medical devices in the UK, providing advice on required approvals and evidence needed for your product.
FAQs: Creation / idea development

What support is available at each stage of this process? (2/2)

Endorsement / Reimbursement

NICE Office for Market Access can give advice on NICE processes including the Early Access to Medicines Scheme (EAMS). They should be the first point of contact for talking to NICE about products in development. If you think that your product may be offered under Specialised Services, contact your relevant CRG (Clinical Reference Group) for information and advice. For digital health products, the National Innovation Board Workstream 1.2 is under development and will relate to endorsement.

Commissioning and adoption

AHSNs can support you at the adoption stage by providing useful contacts and local procurement information. NHS Supply Chain has category managers you can contact and the NHS Business Services Authority helps companies understand the contracting and procurement landscape. More information on European and UK procurement regulations can be found here.

Key bodies by industry

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Previous: What support and advice is available at each stage in this process? (1/2)
Evidence is required to support a product’s value proposition and business case, to obtain regulatory approval and achieve reimbursement. In order to obtain regulatory approval it is necessary to have the appropriate evidence demonstrating that your product is safe and performs as intended. The extent of the evidence needed and whether clinical investigation is required depends on the product and the regulatory process:

Pharmaceuticals: Extensive clinical investigation required

Medical devices and diagnostics: All devices are required to show that they work as intended and do not compromise the health or safety of the patient/user. The amount of clinical information / evidence required for CE marking generally increases with the class of the device. IVDs must comply with the essential requirements of Annex 1 of the IVD Directive 98/79/EC. The amount of clinical information / evidence required for CE marking is likely to increase for Annex II List A / B and for self-testing devices. If the product is a companion diagnostic, also consider the total evidence required for the combined diagnostic and treatment

All products require safety and cost effectiveness evidence for successful reimbursement. Refer to the regulatory or assessment body for your product for information on evidence requirements (MHRA, NICE Office for Market access), as well as the NHS Business Services Authority. The NIHR Office for Clinical Research Infrastructure (NOCRI) can give guidance on clinical trials in the NHS.

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Information correct as of 14th April 2016
**FAQs: Development**

Clinical research in the NHS is supported by the National Institute for Health Research (NIHR), which can help with design of clinical trials and related patient recruitment. Contact the NIHR Office for Clinical Research Infrastructure (NOCRi) to access advice and support across the NIHR.

Patient advocacy groups or charities can be a good way to access information on patient needs and may be able to facilitate access to key opinion leaders. A list of potential charities and advocacy groups can be found [here](#). AHSNs are a good source of local advice and may be able to put you in touch with the relevant group. For innovations involving the use of data, specific organisations may be of use, such as the Farr Institute or NorthWest Ehealth.

The Diagnostic Evidence Co-operatives, Healthcare Technology Co-operatives and NIHR CLAHRC may also play a role in helping you to test your product. There are also specific local

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If you think that your product may be offered under Specialised Services, contact your relevant CRG (Clinical Reference Group) for information and advice. These groups are made up of healthcare professionals, commissioners, public health experts, patients and carers.
Early dialogue with key stakeholders such as the MHRA, NICE, NOCRI and AHSNs will increase awareness of your product as well as helping you to prepare for regulatory and funding evaluation requirements.

Horizon scanning is a process carried out by national health bodies in order to gain advance information on new medicines for budget and service planning. UK PharmaScan is a centralised database for new pharmaceutical products, used by a number of national bodies for Horizon Scanning (NICE, NIHR, Scottish Medicines Consortium, All Wales Strategy Medicines Group, Northern Ireland Health and Social Care Board and NHS England)

- Companies provide information on medicines up to three years before UK launch or the start of phase III development
- Registering medicines on UK PharmaScan (and adding timely updates) has a number of benefits for companies, including visibility of new medicines to six bodies during development, potentially enhanced medicine uptake as the NHS receives consistent, timely and relevant information on new medicines and time savings as information is distributed to multiple organisations in the same format

A horizon scanning tool for medical devices and diagnostics is currently under development. Companies with medical technology before CE mark can also alert the NIHR Horizon Scanning Research and Intelligence Centre

Key bodies by industry

<table>
<thead>
<tr>
<th>MHRA Scientific Advice</th>
<th>NICE Office for Market access</th>
<th>NIHR HSRIC</th>
<th>UK PharmaScan</th>
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It is important to ensure that your product is compatible with the current systems and products in the NHS.

- NHS England has interoperability standards for digital communications to help ensure that information can be shared across organisations. These can be found here.
- Further information on NHS technology systems, particularly digital requirements can be found here.
- It may also be helpful to discuss the current systems and processes in use in the organisation of interest with the local AHSN.

### Key bodies by industry

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<th>AHSN</th>
<th>NHS Digital Technology</th>
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FAQs: Regulation

What regulatory approval do I need?

Regulatory approval is required for most medical products to be marketed in the UK; the type of approval varies greatly by product; guidance on product safety for manufacturers can be found [here](#).

Pharmaceutical products are regulated by the EMA (or in some circumstances, by the MHRA in the UK using national, Mutual Recognition or the Decentralised Procedures). Companies submit a regulatory dossier containing data on the quality, safety and efficacy properties of the proposed drug. If the EMA grants marketing authorisation, the drug can be used across the EU and EEA.

Medical devices, in vitro diagnostics and digital applications that meet the definition of a medical devices (e.g. apps that diagnose, prevent or treat diseases- for full definition see the Medical Devices Directive) must demonstrate that they conform to the requirements outlined within the appropriate European Directive before the product can be freely marketed in Europe. Devices are divided into four classes: Class I, Class IIa, Class IIb and Class III, further explained in [MHRA guidance](#). There is further MHRA guidance on in vitro diagnostic medical devices [here](#). Some Class I devices and low-risk in vitro diagnostics (General IVDs) can currently self-certify compliance. Other classes of device and higher risk IVDs (Annex II List A / B) must undergo a conformity assessment by a notified body. A CE mark is a declaration by the manufacturer/developer that that the device demonstrates compliance with these requirements.

Key bodies by industry

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<th>Key bodies by industry</th>
<th>EMA</th>
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*For medical devices only
The key factor in accelerating progress through the innovation pathway is having the appropriate evidence available at each stage of the process. Early engagement with key bodies such as MHRA, NICE and NIHR will help you achieve this.

For pharmaceutical products only, you could consider access to the Early Access to Medicines Scheme (EAMS). EAMS is a scheme to facilitate access to promising new medicines before they are licensed. It is worth considering application for EAMS if your medicine serves unmet need for life threatening / debilitating conditions; is likely to offer major advantage over current UK methods and potential adverse effects likely to be outweighed by benefits. Evaluation involves a two step process, the promising innovative medicine (PIM) designation and the early access to medicines scientific opinion. There are costs involved with the EAMS process which are listed on the MHRA website.

PRIME is a scheme launched by the European Medicines Agency (EMA) to enhance support for the development of medicines that target an unmet medical need. This voluntary scheme is based on enhanced interaction and early dialogue with developers of promising medicines, to optimise development plans and speed up evaluation so these medicines can reach patients earlier. The EMA is also accepting applications for a pilot project on an adaptive licensing approach, Adaptive Pathways, based on iterative development, use of real-life data to supplement clinical trial data and involvement of patients and HTAs in development. The pilot provides companies with a framework for informal dialogue in a safe-harbour environment with HTAs and patients.

---

**Is there a way to accelerate the regulatory process?**

**Previous: What regulatory approval do I need?**

**Return to landing page**

**Next: How do I get the NHS to buy my product (get reimbursement)?**

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**Key bodies by industry**

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*For technologies involving a pharmaceutical only
The NHS will consider the clinical and cost effectiveness of medicines, medical devices and diagnostics before they will be procured. A common way to demonstrate that the product is appropriate is through **NICE** evaluation. However, the method of endorsement or route to reimbursement may vary depending on the type of product and the addressable population of your product—please see the relevant pathway diagram for your product.

- For example, specialised medicines can be evaluated through **Specialised Commissioning**. To receive a favourable decision you will need to provide evidence on clinical and cost effectiveness to support your business case as well as explaining how the product meets patient needs.

There is currently no central route to national endorsement or reimbursement for digital products (although one is being developed as part of the Accelerated Access Review and NIB Workstream 1.2), so companies typically currently focus on gaining reimbursement locally with relevant local health economies.

**NICE’s Office for Market Access** or an **AHSN** with particular focus on your product type can offer you additional guidance. In addition, further information around the drug tariff can be found on the **NHS Business Services Authority** website.

Use the table below to find resources that are suitable for your product:

<table>
<thead>
<tr>
<th>Key bodies by industry</th>
<th>AHSNs</th>
<th>Cancer Drugs Fund</th>
<th>NHS BSA: Drug tariff</th>
<th>NICE Office for Market access</th>
<th>Specialised commissioning</th>
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**Previous: Is there a way to accelerate the regulatory process?**

**Next: What does my company need to demonstrate for NHS procurement?**
FAQs: Endorsement / reimbursement

The NHS Supply Chain, an agent of the NHS Business Services Authority, procures products in accordance with EU procurement regulations. Products must be procured through tenders and listed on a framework agreement. If you are a new supplier you would normally be required to wait until the relevant tender process commences. Forthcoming tender opportunities are listed in the NHS **procurement calendar** before being published on the **Tenders Electronic Daily website**. Evaluation of tenders is typically based on financial criteria, clinical acceptability and ease of use.

Additionally, a company must meet criteria to be able to sell to the NHS. These include:

- Abiding to the NHS Supply Chain **Code of Conduct**
- Providing management accounts for the relevant time period required

For more information, visit the **NHS Supply Chain** website, speak with an **AHSN**, or view the **public sector procurement process**

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<thead>
<tr>
<th>Key bodies by industry</th>
<th>Gov.uk procurement</th>
<th>NHS Supply Chain</th>
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FAQs: Endorsement / reimbursement

How does the NHS procure products?

Local providers are able to choose the products that they use to deliver services commissioned by the local CCG (or NHS England for Specialised Services), provided they comply with any guidance published. Commissioning policy around this guidance can be found here. Therefore in order for your product to be chosen, key stakeholders need to understand the clinical and cost-effectiveness benefits as well as how it meets patient needs.

Products may be bought through national, regional and local procurement routes, usually depending on the value, size and complexity of requirements:

- **NHS Supply Chain / National Framework Tenders** (national). Constitutes end to end supply chain services.
- Collaborative Procurement Hubs / Confederations (regional). Most NHS Trusts are now partners in these organisations.
- Individual Organisation Contracts (local)

The procurement team within the target provider will be able to provide guidance about which mechanism they would like to use to purchase the product. Guideline product prices are agreed nationally and can be found on the National Tariff. Branded pharmaceutical products sold to the NHS are covered by the **Pharmaceutical Price Regulation Scheme**, a voluntary agreement to control prices negotiated between the Department for Health and the branded pharmaceutical industry, represented by ABPI.
If local adoption is not occurring despite positive reimbursement decisions, it is important to ensure that your value proposition is relevant and consider strengthening your business case.

To avoid low uptake, it is important to consider the main barriers (for example, changes to care pathway, in-year budget considerations and lack of awareness) and plan ways to mitigate these, (e.g. using resources such as the NICE Resource Impact Assessments and support of the NICE Adoption team) and ideally at the earliest possible stage through early dialogue with funders.

There are a number of options to encourage product uptake, from engagement of healthcare professionals and patients to the use of policy drivers (e.g. NICE Clinical Guidelines, Prescribing Guidelines and the General Medical Services Contract). Additionally, there are tools available to strengthen compliance of the uptake of NICE Technology Appraisals (TAs):

- The Innovation Scorecard is a quarterly scorecard produced by HSCIC which enables benchmarking and increases transparency around uptake
- The Medicines Optimisation dashboard highlights variation in local practice
- The NICE Implementation Collaborative “harnesses organisations across the healthcare system to support faster and more consistent access to NICE-recommended medicines, treatments and technologies”
- NICE uptake data is also available online

### Key bodies by industry

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<th>Innovation Scorecard</th>
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FAQs: Commissioning and adoption

Ensure that your business case can answer these key questions:
1. Is the unmet need in the NHS clearly articulated?
2. Does the product meet the patient needs and required outcomes?
3. Is there adequate evidence that the product meets the described clinical needs?
4. Is there adequate evidence that the product is a cost effective option in a care pathway?
5. How might the current pathway need to change? If the product is a diagnostic, what is the cost of implementing this test including training, running in parallel with current options and decommissioning?
6. Does the product meet the standards required of medical products in the UK and has it received regulatory approval? If it has a digital element, does it meet data security requirements?
7. Does the product have clinical champions? Has feedback from clinical champions been included?

When the product has been adopted, the business case can be strengthened with evidence from use with patients through Case Studies and Real World Evidence.

Use the table below to find resources that are suitable for your product:

<table>
<thead>
<tr>
<th>Key bodies by industry</th>
<th>ABPI: Real World Data</th>
<th>AHSNs</th>
<th>James Lind Alliance</th>
<th>NICE Office for Market Access</th>
<th>The King’s Fund</th>
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Information correct as of 14th April 2016
Pharmaceutical pathway
**Pharmaceutical pathway**

**Creation / idea generation**
- Pre-clinical development

**Development**
- Phase I
- Phase II
- Phase III
- Phase IV
- Further evidence could be gathered to strengthen business case
- Should we apply for EAMS?
- Early Access to Medicines Scheme
- Marketing authorisation

**Regulation**
- Early Dialogue
- NICE Topic Selection
- Specialised commissioning
- NICE assessment
- Cancer Drugs Fund evaluation

**National Reimbursement**
- Horizon scanning input
- Vaccine reimbursement
- NICE assessment
- Cancer Drugs Fund evaluation

**Commissioning and Adoption**
- Primary care commissioning
- Secondary care commissioning
- Local adoption (point of market access)

**Timeline (average)**
- Pre-clinical research: 2 years
- Early clinical development: 2-3 years
- Advanced clinical development: 2-3 years
- National reimbursement and commissioning: 6 months - 2 years
- Local commissioning and adoption: 2+ years

Timings are estimates from the company’s perspective, and include e.g. time taken to prepare submissions.
Creation / idea generation
Pre-clinical development

- During the drug discovery process, scientists conduct basic research in order to discover new candidate medications
  - The aim of this stage is to demonstrate that there is a biological activity that has relevance for disease states and broadly test early safety
  - Interaction with external bodies is not required at this stage (unless filing a patent) but early conversations are possible around trial design for subsequent stages
- Patent application protects the intellectual property behind any findings found during this stage and can be done at any time

Checklist

- Check how system and patient needs align to the product mechanism of action before progressing to clinical development, consider how the product could fulfil them at the earliest design stage to ensure the product is relevant
  - NIHR has infrastructure and expertise that can provide input into idea generation and identifying needs
- Understand the outcomes important to patients through dialogue with patient advocacy groups, charities and other organisations. For example, the James Lind Alliance brings patients, carers and healthcare professionals together in Priority Setting Partnerships to identify and prioritise topics for future research
- Ensure Good Laboratory Practice is used (MHRA is the competent authority for further information)

Key organisations

- Intellectual Property Office
- MHRA
- World Intellectual Property Organisation

Process guidance (if available)

- Health Technologies Adoption Programme- Building a business case guidance
- Health Technologies Adoption Programme- Mapping care pathways guidance

Other resources

- ABPI medical development process
- ABPI guidelines
- Guidelines for Patent Applications
- Patent search
- Preclinical checklist

Next step: Phase I and II

Information correct as of 14th April 2016
Development
The aim of Phase I trials is for researchers to test a new drug or treatment in a small group of people to evaluate its safety, determine dosage ranges and identify side effects. Phase II trials further evaluate a drug’s safety with a wider group of people (can be up to 100). Whereas Phase I uses healthy volunteers, Phase II volunteers are usually receiving their first treatment; and pharmaceutical companies have the following aims:

- To test whether the new treatment works, and if it works well enough to continue to Phase III
- To deepen understanding of side effects and their management
- To understand dosing levels or test options around formulation and presentation

Apply to MHRA for clinical trials authorisation, HRA for ethics approval and NHS trusts for R&D approval.

Set up early interactions with regulators for scientific advice which can include approaches to product development, trial design.

Set up early interactions with health technology assessors for early dialogue on evidence and reimbursement requirements.

Work with NOCRI (NIHR Office for Clinical Research Infrastructure) to ensure required evidence for key patient outcomes and clinical endpoints are embedded within trial design.

Consider early commercial considerations of full clinical development including formulation and presentation, frequency and patient outcomes (including funding options and sources for Phase III).

Key organisations:
- HRA
- MHRA Scientific Advice / EMA
- NICE Office for Market Access
- NICE Scientific Advice
- NIHR- NOCRI

Process guidance (if available):

Other resources:
- ABPI medical development process
- ABPI guidelines
- Clinical trials toolkit

Previous step: Preclinical development

Next step: Phase III

Information correct as of 14th April 2016
Phase III

- Phase III trials are only for medicines that have passed Phases I and II
- Phase III trials involve giving a medicine to large groups of people (up to thousands) to collect information on its effectiveness, compare the drug to comparator treatments and monitor side-effects. They often last a year or more
- These trials may test new treatments, new dosage levels or new methods of action
- Once Phase III studies have been completed, all available evidence is compiled for the regulatory dossier
- Cost effectiveness analyses are often carried out alongside clinical trials with comparators that reflect current practice; the UK has a number of expert organisations that can support this process

### Checklist
- Ensure relevant clinical trials authorisation (MHRA), ethics approval (HRA) and R&D approval (NHS Trusts) are in place
- Continue to interact with regulators and HTAs for scientific and regulatory advice, especially in advance of preparing for regulatory submission
- Ensure data required for regulatory submission is in the correct format (e.g. using MHRA marketing authorisation pre-submission checklist or EMA equivalent)
- Consider contacting NIHR Clinical Research Network for free services and support tools to deliver high quality research
- Ensure proactive safety management is used

### Key organisations

- HRA
- MHRA Scientific Advice / EMA
- NICE Office for Market Access
- NICE Scientific Advice
- NIHR- NOCRI and CRN

### Process guidance (if available)

### Other resources

- ABPI medical development process
- ABPI guidelines
- MHRA Marketing authorisation pre-submission checklist
- NIHR INVOLVE
- Clinical trails toolkit

---

Information correct as of 14th April 2016
Phase IV

- Phase IV trials take place once new medicines have passed all previous stages and received marketing authorisation.
- They involve the safety surveillance and ongoing technical support of a drug after it receives marketing authorisation, designed to detect rare or long-term adverse effects over a larger patient population and time period (usually at least two years).
- Phase IV trials can include post-approval commitments, interventional and non-interventional actions; these feed into pharmacovigilance activities and broader safety management as well as supporting reimbursement decisions.
- Companies are required to submit a risk-management plan (RMP) to the European Medicines Agency (EMA) when applying for a marketing authorisation; this may relate to post-authorisation measures (PAM).

**Checklist**

- Consider national / international data and privacy regulations
- Consider likelihood of outcomes-based payments, implications for reimbursement rates based on Phase IV evidence
- Ensure correct capabilities are in place for the collection and analysis of Real World Evidence if required
- Consider contacting NIHR Clinical Research Network for free services and support tools to deliver high quality research

**Key organisations**

- NICE Office for Market Access
- NIHR CRN

**Process guidance (if available)**

- EMA Risk Management Plan guidance

**Other resources**

- ABPI Vision for Real World Data

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**Previous step:** Regulatory approval  
**Next step:** Reimbursement / commissioning / adoption

Information correct as of 14th April 2016
Regulation
• The Early Access to Medicines Scheme (EAMS) provides a framework in which patients can receive a promising new medicine prior to EMA approval on the basis of Phase III data (or in exceptional circumstances, during Phase II), significantly speeding access to medicines for certain products.

• It is worth considering application for EAMS if your medicine displays all of the following criteria:
  – Serves unmet need for life threatening / debilitating condition
  – Likely to offer major advantage over current UK methods
  – Potential adverse effects likely to be outweighed by benefits

**Key organisations**
- MHRA

**Process guidance (if available)**
- Guidance for applicants of EAMS (step I)
- Guidance for applicants of EAMS (step II)

**Other resources**
- ABPI and BIA guide to EAMS
- Apply for EAMS- overview and guidance
The Early Access to Medicines Scheme is a scheme to facilitate access to promising new medicines before they are licensed by the European Union. It is conducted in parallel with the development process. The first stage - receiving a Promising Innovative Medicine (PIM) designation - is an early indication that a product is a future candidate for EAMS following further development; PIM designation can support businesses’ ability to attract capital from investors during drug development.

The second stage, MHRA approval following a scientific review, assesses the benefits and risks of a medicine and supports healthcare professionals and patients to make a treatment decision on using the medicine before it has been approved by the EMA.

Medicines can apply to EAMS if they meet the following criteria:
- Serves unmet need for life-threatening / debilitating condition
- Likely to offer major advantage over current UK methods
- Potential adverse effects likely to be outweighed by benefits

**Key organisations**
- MHRA
- NHS England
- NHS Scotland
- NHS Wales
- NICE

**Process guidance (if available)**
- Guidance for applicants of EAMS (step I)
- Guidance for applicants of EAMS (step II)

**Other resources**
- ABPI and BIA guide to EAMS
- Apply for EAMS- overview and guidance
- MHRA Innovation Office

**Criteria for EAMS selection**:
1. Addresses life-threatening diseases with unmet needs
2. Likely to offer major benefits over current treatments
3. Provides a positive benefit/risk balance

**Next step:** Regulatory approval

Information correct as of 14th April 2016
Regulatory Approval

- Regulatory approval evaluates the quality, safety, and efficacy of a product in order to grant marketing authorisation, allowing a product to be placed on the market.
- The centralised procedure is carried out by the European Medicines Agency (EMA) for marketing authorisation to all EU / EEA countries.
- The centralised procedure is the primary route for marketing authorisation and can be used by small molecules, biologics, and vaccines:
  - The centralised procedure is mandatory for medicines for HIV/AIDS, cancer, diabetes, neurodegenerative diseases, immune dysfunctions, and viral diseases, and for ATMPs, ‘orphan medicines’, and medicines derived from biotechnology processes.
  - For some innovative products, it is possible to go via the national / decentralised / mutual recognition route but this is rare.
  - Note that there is an accelerated procedure available for vaccines which is approximately two months shorter.
  - A marketing authorisation under exceptional circumstances may be granted to medicines where the applicant is unable to provide comprehensive data on efficacy and safety under normal conditions of use.
  - An accelerated assessment procedure is available for medicines which are of major public health interest.
  - Conditional marketing authorisation may be granted on the basis of less complete data than normal for medicines for orphan designations, seriously debilitating or life-threatening diseases, and use in emergency situations.

Centralised procedure by Committee for Medicinal Products for Human Use (CHMP), EMA

- c. 6-9 months

Key:
- Red: Small molecules
- Blue: Biologics
- Green: Vaccines

Note: these timelines are estimates and there are significant variations depending on product type etc.

Note: European Commission decision takes places c. 60 days after CHMP opinion.
**Regulatory Approval**

- Select most appropriate procedure for your product’s marketing authorisation application (centralised procedure or not)
- Ensure regular engagement with regulators prior to submission e.g. MHRA Innovation Office / scientific advice
- Ensure appropriate data included in the submission (end points, comparators, patient sub-group analysis etc.)
- Ensure rapid response to requests for additional data and clarifications
- Begin national reimbursement process

### CHECKLIST

- **ADDITIONAL RESOURCES**
  - Key organisations
    - EMA
    - EMA Scientific Advice
    - MHRA
    - MHRA Scientific Advice
  - Process guidance *(if available)*
    - EMA Guide for small businesses
    - EMA submission guidance
    - How to license a medicine for sale in the UK and Europe
  - Other resources
    - Decentralised procedure (DCP) information and application
    - EMA: Electronic submission of data
    - EMA: Regulatory information

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*Previous step: Phase III*  
*Return to map*  
*Return to FAQs*  
*Next step: NICE Topic selection*  
*Information correct as of 14th April 2016*
Endorsement / reimbursement
Horizon scanning input (1/2)

- Horizon scanning is carried out by national health bodies in order to gain advance information on new medicines for budget and service planning
- Pharmaceutical company input into horizon scanning can begin as early as Phase I of the development process, and it is an important precursor to the reimbursement process as it allows endorsement bodies such as NICE to be aware of your product in advance
- UK PharmaScan is a secure horizon scanning database populated with information on new medicines in development from up to three years before their launch in the UK or start of phase III clinical development, whichever is the earlier.
- Registering medicines on UK PharmaScan (and adding timely updates) has a number of benefits for companies:
  - Visibility of new medicines to all the national horizon scanning organisations during development - NICE, NIHR HSRIC, UKMi, Scottish Medicines Consortium, All Wales Strategy Medicines Group, Northern Ireland Health and Social Care Board and NHS England Specialised Services
  - Potentially enhanced medicine uptake as the NHS receives consistent, timely and relevant information on new medicines. The earlier the product is on the NHS radar the more can be done to prepare. This is particularly important for breakthrough, high aggregate cost products
  - Time savings as information is distributed to multiple organisations in the same format
- Data required across the horizon scanning process include general information on the medicine and indication, clinical trial information, regulatory information and cost and budget impact information
  - Information should be updated at least every three months with the exception of specified regulatory information which should be updated immediately

Information correct as of 14th April 2016
### Checklist
- Register company on UK PharmaScan (if not already registered)
- Ensure relevant data is collected for the registered drug
- Add drug information and update in a timely manner

### Key organisations
- UK PharmaScan

### Process guidance (if available)
- UK PharmaScan: how to register

### Other resources
- ABPI: UK PharmaScan
The main benefits of early dialogue for companies is to boost their understanding around requirements for approval and relevant evidence for the payer, allowing a company to make strategic decisions around product development.

Feedback from stakeholders can be used to develop the best possible evidence for reimbursement and build the business case.

Engage with external stakeholders including NIHR, patient advocacy groups (e.g. charities) and providers.

In particular, early dialogue with HTAs (Health Technology Assessors) should be considered alongside scientific advice and online guidance from regulatory bodies such as the MHRA.

Engage with local AHSNs to determine the appropriate approach to CCGs and providers. They can also give advice on how to tailor the business case to best demonstrate that the product meets the local requirements.

Key organisations:
- EMA
- MHRA
- NICE Scientific Advice, NICE Office for Market Access
- NIHR Office for Clinical Research Infrastructure

Process guidance (if available):
- EMA/HTA best practice guidance

Other resources:

Previous step: Phase I and II

Return to map

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Next step: Phase III
Vaccine reimbursement

- Vaccinations have a separate reimbursement process to other pharmaceutical products, usually taking 1+ years between market approval and vaccine availability in the NHS.
- Following marketing approval, vaccines are reviewed by the Joint Committee on Vaccines and Reimbursement (JCVI), an independent expert advisory committee which provides a recommendation or advice around vaccine use.
  - Prior to this, the JCVI carries out horizon scanning to identify and prepare for vaccines likely to be licensed in the next 3-5 years.
- The JCVI bases its advice and recommendations around the clinical and cost-effectiveness of new vaccination or immunisation schedules, using the same methodology and criteria as NICE.
- If recommended, the vaccine manufacturer enters central procurement negotiations with the Commercial Medicines Unit.

Ensure vaccine is entered onto relevant horizon scanning databases
Hold early dialogue with both regulators and JCVI where possible to ensure vaccine development and evidence generation (including post-authorisation data) will meet approval requirements and support cost-effectiveness.

Key organisations
- Commercial Medicines Unit
- Department of Health
- Joint Committee on Vaccination and Immunisation
- Public Health England

Process guidance *(if available)*

Other resources
- Vaccine Update

Next step: Secondary care commissioning

Information correct as of 14th April 2016
The NICE Topic Selection process for Technology Appraisals (TA) and highly specialised technologies (HST) is a process for deciding which topics NICE will produce technology appraisal guidance on. Most topics are identified by the National Institute for Health Research (NIHR) horizon scanning activities; NIHR aims to notify NICE of new drugs in development 20 months before marketing authorisation and 15 months for new indications.

The Topic Selection process aims to achieve the following:
- Address topics of importance to patients, carers, healthcare professionals, commissioners and other key stakeholders
- Use a standardised, transparent and rapid process that makes the best use of NHS resources
- Topics are considered when all the following are true:
  - There is likely to be significant patient benefit in terms of efficacy, administration or improved side-effect profile
  - The new product is likely to be at a significantly different price to current standard treatment
  - There is appropriate evidence to support the appraisal
  - The relevant clinical questions can be addressed by applying the technology appraisal methodology
- Topics are given importance based on a prioritisation criteria, including population size, disease severity, resource impact and the incremental benefit of NICE carrying out a technology appraisal.

Key organisations:
- NICE Office for Market Access

Process guidance (if available):
- NICE Guide to the process of selection of technologies

Other resources:
- NICE Topic Selection

Next step: NICE Assessment or Specialised Commissioning

Previous step: Regulatory approval

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Information correct as of 14th April 2016
NICE Assessment

- The National Institute for Health and Care Excellence (NICE) conducts Health Technology Assessments (HTAs) on pharmaceutical products; if a drug is found to be both clinically and cost effective compared to a comparator, NICE will issue a positive recommendation.
- NICE HTAs are a common route to national endorsement for many products (some specialised products are evaluated by the Specialised Commissioning Evaluation).
- Positive recommendations indicate that the product should be reimbursed either by CCGs or NHS England (for Specialised or Highly Specialised products); medicines can also receive negative or “only in research” recommendations (for promising interventions not yet supported by sufficiently robust evidence).
- The HTA process varies depending on the medicine under evaluation, for example there are single technology appraisal processes for a single medicine with a single indication, multiple technology appraisal processes for multiple medicines with one or more indications and highly specialised technology evaluations for single medicines for a single, very rare, condition.
- Patient Access Schemes, ways to improve the cost-effectiveness of a medicine, are also considered at this stage.

**CHECKLIST**
- Engage with NICE in early dialogue / scientific advice as early as possible to discuss areas including comparators, populations, and clinical / economic effectiveness.
- Use early discussion with NICE Office for Market Access to confirm evidence requirements and templates.
- Ensure submission is concise.
- Ensure that patient needs form the basis of your case. Note that NICE involves patients across the technology appraisal process, from scoping to the committee stage to ensure that the most relevant outcomes are considered.

**ADDITIONAL RESOURCES**
- NICE Office for Market Access
- Patient Access Scheme Liaison Unit

**Process guidance (if available)**
- Guidance for Multiple technology appraisal
- Guidance for Single technology appraisal
- Guide to methods of technology appraisal

**Other resources**
- FAQs: Achieving and demonstrating compliance with NICE
- NICE technology appraisal home
- Online evidence search
- Specification of evidence submission

**Next step:** Primary or Secondary Care Commissioning

Information correct as of 14th April 2016
Specialised Commissioning (1/2)

- NHS England commissions Specialised Services at a national level
- Four factors determine whether NHS England classes a product under Specialised Commissioning:
  - The number of individuals who require the service (less than 500 nationally);
  - The cost of providing the service or facility;
  - The number of people able to provide the service or facility and;
  - The financial implications for Clinical Commissioning Groups (CCGs) if they were required to arrange for provision of the service or facility themselves
- Specialised Services Clinical Reference Groups (CRGs) decide which products to put forward for consideration by NHS England. In order for your product to be put forward for assessment, contact the relevant CRG:
  - CRGs exist for each type of service, such as ‘Radiotherapy’, ‘Chemotherapy’, and ‘Complex disability equipment’ amongst many others. Find the relevant CRG for your device [here](#).
  - CRGs will prioritise products based on unmet need and improvement in cost-effectiveness
- Propositions put forward by CRGs are evaluated for clinical effectiveness based on published evidence from peer reviewed journals as well as finance and activity impact assessments. All policy propositions are then tested with key stakeholders and the public through consultations. Note that NHS England will not consider evidence that is not yet published.
- After public consultation, a recommendation will be made by the Clinical Priorities Advisory Group (CPAG) for the treatment to be either routinely commissioned or not to be routinely commissioned. The final decision is made by NHS England.
- For products that are not recommended for routine use, Commissioning through Evaluation (launched in 2013) could be an alternative route to patient access- see the NHS England page [here](#).

NB. On 12th April NHSE launched a consultation on a new process for specialised commissioning.
Specialised Commissioning (2/2)

**CHECKLIST**

- Determine whether the product should be considered under Specialised Services for a target patient population
- Engage with the relevant Clinical Reference Group for advice and put the product forward for assessment
- Ensure you are aligned with the strategy for the relevant National Programme of Care
- Ensure appropriate information and data is published in peer-review journals in order for evidence to be considered
- Register as a Clinical Reference Group stakeholder
- Consider whether a parallel route to reimbursement is required for other target patient populations

**Key organisations**

- NHS England (Specialised Services)

**Other resources**

- ABPI guide to Clinical Reference Groups for Pharmaceutical companies
- Clinical Reference Groups
- Clinical Priorities Advisory Group

**Previous step:** NICE Topic Selection  
**Next step:** Local adoption

NB. On 12th April NHSE launched a consultation on a new process for specialised commissioning.
The Cancer Drugs fund is a managed access fund which provides funding for cancer drugs. All new licensed cancer drugs will first be referred to NICE for appraisal. NICE will then make one of three recommendations:

- That drug should be routinely commissioned – where there is clear evidence of the drugs clinical and cost effectiveness
- That the drug should not be routinely commissioned - where there is clear evidence that the drug is not clinically and cost effective
- That the drug should be considered for funding within the new CDF for a time limited period - where the clinical and cost effectiveness of the drug is uncertain

Engage early with NICE through the NICE Office of Market Access
Ensure timely submission of information to relevant bodies
Ensure a clear understanding of data requirements and that these can be met
Ensure early thinking about the commercial access deal and the value proposition
Consider engaging with NOCRI around trial design

Key organisations:
- National Programmes of Care and Clinical Reference Groups

Process guidance (if available)

Other resources:
- Cancer Drugs Fund
- CDF decision summaries

Next step: Primary or Secondary Care Commissioning
Information correct as of 14th April 2016
Local Commissioning and Adoption
Primary Care Commissioning

- Commissioning - the process of planning, agreeing and monitoring services - is conducted by over 200 Clinical Commissioning Group (CCG) and regional / area prescribing committees
- Primary care commissioning includes all drugs that are prescribed by GPs; this includes drugs approved by NICE with a CCG funding mandate and any drugs seeking local reimbursement
- Although a drug may have been approved in a reimbursement process, these commissioners also consider local factors such as demographics, healthcare priorities and in-year budgets and for this reason may impose further access restrictions in line with NICE guidance or delay formulary approval
- Engaging with local commissioners and other stakeholders can help boost understanding of a drug's benefits and improve uptake

- Identify and engage with bodies to support innovation such as AHSNs, Vanguards and Test Beds most relevant for your product
- Develop or refine a clear business case which can demonstrate to commissioners the clinical and health economic benefits to their local health economy (e.g. including Innovation Scorecard)
- Engage with stakeholders from across multiple functions within commissioning bodies:
  - Clinical stakeholders (e.g. Heads of Commissioning, Clinical Leads)
  - Financial stakeholders (e.g. Finance Directors)
- Consider engagement with patients (e.g. via advocacy groups) and healthcare professionals to disseminate information

Key organisations
- AHSNs
- CCGs / Regional/Area Prescribing Committee
- NHS Vanguard Sites and Test Beds
- NICE Adoption team

Process guidance (if available)
- National Tariff payment system (includes local tariff variations)

Other resources
- CCG Outcome Indicator Set 2014/15
- Commercial Medicines Unit
- Innovation Scorecard
- NHS Right Care
- NICE Resource Impact Assessments

Next Step: Local Adoption

Information correct as of 14th April 2016
Secondary Care Commissioning

- Commissioning - the process of planning, agreeing and monitoring services - is conducted by over 200 Clinical Commissioning Group (CCG) and trust prescribing committees
- Secondary care commissioning includes all drugs that are prescribed in a secondary care setting; this includes drugs approved by NICE, some Specialised Commissioning and drugs seeking local reimbursement
- Although a drug may have been approved in a reimbursement process, these commissioners also consider local factors such as demographics, healthcare priorities and in-year budgets and for this reason may impose further access restrictions in line with NICE guidance or delay formulary approval
- Engaging with local commissioners and other stakeholders can help boost understanding of a drug’s benefits and improve uptake

**Checklist**

- Identify and engage with bodies to support innovation such as AHSNs, Vanguards and Test Beds most relevant for your product
- Develop or refine a clear business case which can demonstrate to commissioners the clinical and health economic benefits to their local health economy (e.g. including Innovation Scorecard)
- Engage with stakeholders from across multiple functions within commissioning bodies:
  - Clinical stakeholders (e.g. Heads of Department, Chief Pharmacists)
  - Financial stakeholders (e.g. Finance Directors)
- Consider engagement with patients (e.g. via advocacy groups) and healthcare professionals to disseminate information

**Key organisations**

- AHSNs
- CCGs / Trust Prescribing Committees
- NHS Vanguards and Test Beds
- NICE Adoption team

**Process guidance (if available)**

**Other resources**

- CCG Outcome Indicator Set 2014/15
- Commercial Medicines Unit
- Innovation Scorecard
- NHS Right Care
- NICE Resource Impact Assessments

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Next Step: Local Adoption

Information correct as of 14th April 2016
Once a drug is commissioned by primary care, secondary care or national commissioners, local adoption occurs as clinicians prescribe treatments. If local adoption is slow, despite positive reimbursement decisions, companies can consider a number of options to encourage healthcare professionals:

- These include direct clinical or patient engagement and education to policy routes, using e.g. NICE Clinical Guidelines, Prescribing Guidelines and local Prescribing Protocols.

There are tools available to strengthen compliance of the uptake of NICE Technology Appraisals (TAs):

- The Innovation Scorecard is a quarterly scorecard produced by HSCIC which enables benchmarking of adoption of NICE TAs, increasing transparency around local uptake.
- The Medicines Optimisation dashboard highlights variation in local practice.
- The NICE Implementation Collaborative involves organisations across the healthcare system to support consistent local implementation of NICE guidance.

After adoption, there is an opportunity to monitor the impact of the change through audit or other service improvement methodologies; this can be used to further strengthen the business case.

- Develop or tailor education materials for healthcare professionals.
- Conduct local clinical engagement.
- Conduct patient awareness and education, perhaps through patient advocacy groups. Consider use of patient online platforms like HealthUnlocked.
- Optional: conduct patient awareness and education, perhaps through patient advocacy groups.
- Optional: use Real World Evidence to update and refine business case and education materials.

Key organisations:
- Commercial Medicines Unit
- HSCIC
- NHS Supply Chain
- NICE Adoption team

Process guidance (if available):
- NICE Implementation Collaborative

Other resources:
- General Medical Services Contract NHS Innovation Scorecard
- HealthUnlocked
- Medicines Optimisation Dashboard
- Pharmaceutical Price Regulation Scheme

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Information correct as of 14th April 2016
Medical devices and in vitro diagnostics (IVD) pathway
Further evidence could be gathered to strengthen business case

What is the route to reimbursement?

Regulation

Development

Idea generation and identification of needs

Product development

Non-clinical product testing

Clinical evidence development and testing

Further testing

Further testing

Registration with competent authority or involvement of Notified Body

What is your product?

Self-declaration or conformity assessment by a Notified Body

Early dialogue

Development

6 months-2 years

Regulation

1 month-1 year

National reimbursement

9 months-3 years

Commissioning and adoption

2 years +

Timings are estimates from the company’s perspective, and include e.g. time taken to prepare submissions

Note that there is no national reimbursement for IVDs
Creation / idea generation
Idea generation and identification of needs

At the earliest design stage it is important to consider whether the technology will address an unmet need in the NHS and with patients; this will form the basis of your business case and value proposition.

- Currently there is no single outline of requirements for devices within the NHS, however NHS-wide priorities (e.g. NHS England Five Year Forward View) and CCG plans should be considered.
- Patient views on unmet needs are likely to be incorporated into NHS system unmet needs, however, patient groups such as charities may be able to provide additional insight.

Additionally, consider whether the NHS is likely to be interested in purchasing the new technology based on the cost-effectiveness including both impact on the direct procedure/ activity and the complete patient care requirements compared to any existing competitor products.

- The NIHR has infrastructure and expertise that can provide input into idea generation and identifying needs.
- At this stage it is also crucial to look ahead to other requirements along the pathway, such as financial requirements of companies selling to the NHS (e.g. credit rating, published accounts).
- Patient involvement in research and development is increasingly a priority for regulators and other official bodies. Involving current patients in the specification stage will ensure relevance of the final product and will highlight any accessibility issues early, as well as strengthening the business case. Patient advocacy groups and charities are a good source of information about patients. For example, the James Lind Alliance’s Priority Setting Partnerships bring patients, carers and healthcare professionals together to identify and prioritise topics for future research.
- A good place to find out more information is Academic Health Science Networks (AHSNs). AHSNs aim to improve the process of developing and adopting innovations in healthcare and can help with many stages of the development pathway. AHSNs are found locally but can be accessed by any business in England; you should find the most suitable one for your product and area of interest.

- There are many sources of funding for life sciences businesses in England. These range from venture capital funds, grants from public and private sectors to crowdfunding—see this link for a comprehensive list. AHSNs can also give advice on funding.
## Idea generation and identification of needs (2/2)

### Checklist
- View NHS-wide and CCG priorities to see whether your device addresses an unmet need
- Identify potential end user and buyer (e.g. hospital, outsourced private laboratory etc.)
- Determine potential demand and identify competitive devices
- Consult healthcare practitioners to understand the current care pathway and how your device might impact this
- Identify patient needs through patient advocacy groups, charities and patient online platforms such as HealthUnlocked
- Consult AHSNs for funding information
- Consider national / international data and privacy regulations
- Identify what type of patent is required and which locations could be covered (e.g. UK or international)
- Start to identify possible future clinical champions to involve in development and uptake of your device
- Consider business requirements for companies selling to the NHS

### Key organisations
- AHSNs
- Intellectual Property Office
- Medilink
- MHRA (Medical devices)
- NHS England
- NIHR
- Public Health England
- Trade associations e.g. BIVDA
- World Intellectual Property Organisation

### Process guidance (if available)
- Health Technologies Adoption programme- Building a business case guidance
- Health Technologies Adoption programme- Mapping care pathways guidance
- The King’s Fund guide to the NHS

### Other resources
- Guidelines for Patent Applications
- HealthUnlocked
- MedCity: Grow your business
- Medilink
- NHS Supply Chain
- Patent search
- Public Access Database for Medical Device Registration

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Information correct as of 14th April 2016
Development
Product development and testing

- Product prototyping is an iterative process; prototypes may be tested and refined until a 'final' product is ready to be taken through to market
  - Developers should continue to refer back to the unmet needs of the NHS and patients. Involving end-users in the development stage is helpful (e.g. designing for usability)
- For medical devices, product testing requirements are dependent on the class of Medical Device, with higher risk devices requiring more extensive clinical testing (see 'What class is your product?' and 'Clinical evidence development' steps for more details)
  - Cost effectiveness evidence is required for all types of medical device and diagnostics to support your value proposition
  - Clinical evaluation is required to verify safety and performance, however, the level of testing varies by product class and could involve clinical testing, clinical experience review and/or literature review (where applicable)
- Before finalising the design of clinical and non-clinical testing, engage with regulators and research stakeholders to assess whether your trials will satisfy requirements and support the value proposition for your product

- Set up early interactions or seek online advice with MHRA and NICE Office for Market Access for advice on clinical and non-clinical testing design (usability testing, patient reported outcomes, cost effectiveness etc.)
- Engage with external stakeholders including NIHR, NICE, patient advocacy groups (e.g. charities) and providers
  - The NIHR Office for Clinical Research Infrastructure (NOCRI) can refer you to the relevant part of the NIHR
  - The Diagnostic Evidence Co-operatives are a good resource for in vitro diagnostics

Key organisations
- MHRA (Medical devices)
- NICE
- NIHR Clinical Research Network

Process guidance (if available)
- EU Medical device classifications

Other resources
- NIHR Biomedical Research Centres
- NIHR Clinical Research Network Centre
- NIHR Diagnostic Evidence Co-operatives
- NIHR Healthcare Technology Co-operatives

Previous step: Idea generation and identification of needs

Return to map
Return to FAQs
Next step: What class is your product?

Information correct as of 14th April 2016
What class is your product?

• Medical devices, including software are defined as those used to diagnose, prevent, monitor, treat or alleviate disease or injury; to diagnose, monitor, treat, alleviate or compensate an injury or handicap, to investigate, replace or modify the human body or a physiological process; or as a contraceptive. Medical devices may be classified as Class I, Class IIa, Class IIb or Class III according to their associated complexity and risk
  – Class I has the lowest risk and Class III the highest
  – For guidance about classifying your device please refer to the European Commission

• In vitro diagnostic medical devices are defined as: medical devices, such as reagents, calibrators, control material test tubes, to perform a diagnostic test, like checking blood for signs of infections or urine for the presence of glucose, using material from the human body. In vitro diagnostics are also categorised according to risk:
  – General (low risk), Self test, Annex II List B, Annex II List A (high risk)
  – For guidance about in vitro diagnostics please refer to online MHRA advice here
  – The active implantable medical devices directive can be found here

Key organisations
• MHRA (Medical devices)
• NICE
• NIHR Clinical Research Network, Biomedical Research Centres, Diagnostic Evidence Cooperatives and Healthcare Technology Cooperatives

Process guidance (if available)
• Guidance on the in vitro medical devices directive
• Guidance on the medical devices directive (includes EU Medical device classifications)

Other resources
• NIHR Clinical Research Network Centre
Clinical evidence development and testing

• In the EU, clinical evaluation (assessment of clinical data) is required to demonstrate that a medical device or diagnostic is safe and performs as intended
• The NIHR can help with clinical research in the UK. For in vitro diagnostic devices they have funded four Diagnostic Evidence Co-operatives (DECs) to help generate information on clinical and cost-effectiveness
• The clinical evaluation requirement depends on the device class and/or evidence available
  – Low-to-medium risk devices (Class I, Class IIa and IIb) a literature review and/or clinical evaluation can be sufficient
  – Whereas high risk devices (Class III) may require clinical investigation
• For support designing clinical testing, engage with external stakeholders such as the NIHR and NICE Office of Market Access early on in the process to ensure that the study design is appropriate for regulatory approval processes
• Further clinical and cost-effectiveness evidence may be gathered later in the development pathway to support the value proposition of the product

Consider whether testing design provides evidence for value proposition, including patient reported outcomes showing the product addresses any patient needs originally identified in the pathway
Add testing evidence into business case and value proposition for all stakeholders (clinical and non-clinical e.g. procurement)
Gather evidence on cost-effectiveness
Consider likelihood of outcomes-based payments or whether further testing might be required e.g. Real World Evidence (evaluation of clinical and cost effectiveness data gathered when the product has been adopted)
Consider alerting NIHR Horizon Scanning Research Intelligence Centre about your product’s development

Key organisations
- Health Research Authority (HRA)
- MHRA (Medical devices)
- NICE
- NIHR Clinical Research Network, Collaborations for Leadership in Applied Health and Care Research

Process guidance (if available)
- Guidance on the in vitro medical devices directive
- Guidance on the medical devices directive

Other resources
- Diagnostic Evidence Co-operatives
- NIHR
- NIHR Clinical Research Network Centre
- NIHR INVOLVE

Previous step: What class is your product?
Return to map
Return to FAQs
Next step: Conformation to EU standards
Information correct as of 14th April 2016
Regulation
In the EU, manufacturers / developers of medical and diagnostic devices must demonstrate that they conform to the requirements outlined in the relevant European Directive before the product can be freely marketed in Europe:

- **Medical Devices Directive**
- **In Vitro Diagnostic Medical Devices Directive**
- **Active Implantable Medical Devices**

The CE mark is a key indicator of a product's compliance with EU legislation.

The requirements and assessment process varies by class of device and diagnostic. For more information see guidance by the MHRA.

- **Medical devices**
  - Non sterile, non measuring Class I devices can self-certify by writing a statement to declare this and applying to a notified body to approve.
  - Other Class I and Class II-III devices must undergo a conformity assessment by a European notified body (you can choose to be assessed by a notified body in any European country); in the UK details can be found here.

- **IVD**
  - There are a number of ways you can demonstrate conformity with the IVD Directive, which involve a choice of testing and quality assurance modules; the choices depend on the classification of the device. For more information on this process, please see BSI guidance here.

- **International standards** that have been harmonised to the medical device directives can be used to comply with relevant parts of the directives. The use of these standards is not mandatory, however most manufacturers choose to use them.
  - The European Commission lists harmonised standards for medical devices, in vitro diagnostic medical devices, and active implantable medical devices.

- **Best practice** is to prepare a technical file / design dossier to record evidence of your conformity with EU requirements (for both self-assessment or to be used as part of an assessment by a Notified Body (see next stage).
Self-declaration or conformity assessment by a notified body (2/2)

- Confirm European Directive requirements for product
- Ensure sufficient clinical evidence has been collected
- Complete conformity assessment (e.g. MDD, AIDD, IVD Directive) if required for your product
- Ensure appropriate information and data is included in submissions
- Ensure rapid response to requests for additional data and clarifications

### Key organisations
- European Commission: Medical Devices
- MHRA (Medical devices)

### Process guidance (if available)
- BSI guide to the IVDD
- Guidance to implementing Medical Device Directives
- Medical devices: conformity assessment and the CE mark

### Other resources
- CE approval process for different classes
- Harmonised standards for medical devices

**Previous step:** Clinical evidence development and testing

**Next step:** Registration with competent authority

Information correct as of 14th April 2016
This stage involves engagement with either the competent authority or Notified Body, depending on the class of your device.

- Class I medical devices, where these have been self-assessed for conformation to EU standards, you, or your authorised representative, must register with the competent authority in the EU state where you have an office or place of business.
  - In the UK, the MHRA is the competent authority and will only register manufacturers or authorise representatives that have a place of business in the UK.
  - Manufacturers without a place of business in the EU need to appoint an authorised representative in the EU.

- For Class IIa and above, a notified body will assess your conformation with EU standards (no additional registration with a competent authority is required).

### Checklist
- Consider appropriate route to reimbursement and reimbursement assessment requirements.
- Finalise the price of the device for cost-effectiveness and pricing discussions, including what approach to pricing is most appropriate for the device (e.g. leasing, tendering, etc.).

### Key organisations
- European Commission: Medical Devices
- MHRA (Medical devices)

### Process guidance (if available)
- MHRA: Device Online Registration System

### Other resources
- CE approval process for different classes
- Harmonised standards for medical devices
National endorsement
The main benefits of early dialogue for companies is to boost their understanding around requirements for approval and relevant evidence for the payer, allowing a company to make strategic decisions around product development.

Feedback from stakeholders can be used to develop the best possible evidence for reimbursement and build the business case.

Engage with external stakeholders including NICE (if relevant), NIHR, patient advocacy groups (e.g. charities) and providers.

The NIHR Office for Clinical Research Infrastructure (NOCRI) can refer you to the relevant part of the NIHR; the Diagnostic Evidence Co-operatives are a good resource for in vitro diagnostics.

Engage with local AHSNs to determine the appropriate approach to CCGs and providers. They can also give advice on how to tailor the business case to best demonstrate that the product meets the local requirements.

- Set up early interactions for advice on clinical and non-clinical testing design
- Refer to MHRA website for regulatory information
- Have a plan for communicating feedback from early dialogue to internal stakeholders
- Use early dialogue to design a local study that addresses local data requirements
- Consider what UK clinical practice might look like at the time of a NICE appraisal, which can affect appropriate comparators

Key organisations:
- MHRA
- NICE Scientific Advice
- NOCRI

Process guidance (if available)

Other resources:
- Academic Health Science Networks
- NIHR Diagnostic Evidence Co-operatives
- Patient advocacy groups
What is the route to reimbursement?

• Once a device has received a CE mark, it is possible to sell, lease, lend or gift the product in Europe
• In the UK, the NHS will consider a device’s clinical and cost-effectiveness before it will be reimbursed (paid for by the NHS)
• This may be done at national, regional or organisational level depending on the product; it is important to note that there is no funding direction associated with a NICE evaluation
• Most medical devices and diagnostics do not require assessment at the national level before being considered by the local commissioner or provider, however it is possible to have a health technology assessment performed by NICE and guidance published to support uptake of your device or diagnostic
  – If you do choose to put your device forward for NICE assessment, the Medical Technology Advisory Committee will consider new and innovative medical devices and diagnostics taking into account the clinical and cost effectiveness evidence before routing the application to the relevant assessment programme. The programmes include:
    • MTP: Medical Technologies Programme. Considers a single medical device or diagnostic
    • IPP: Interventional Procedure Programme. Considers surgical/irradiative procedures
    • DAP: Diagnostics Assessment Programme. Considers innovative medical diagnostic technologies
    • TAP: Technology Appraisal Programme. Considers medicines, less commonly used for devices and diagnostics
• Some devices associated with specialised services are reimbursed by NHS England at a national level with a funding mandate for specialised commissioners. NHS England conducts an assessment process and publishes guidance for these products
  – Specialised services are those provided in relatively few hospitals, accessed by small numbers of patients but with catchment populations of more than one million. Click here for information on specialised services
• Please note: The reimbursement route for a device or diagnostic depends on who is the commissioner / provider of services for that target patient population. If there are multiple target populations (e.g. some specialised and others not) reimbursement decisions may be required from different bodies for each population

Key organisations
• MHRA
• MTAC
• MTEP
• NHS England (Specialised Services)
• NICE

Process guidance (if available)
• Medtech Innovation Briefing Processes and Methods statement
• MTEP process and methods guidance

Other resources
• DAP
• IPP
• MTP
• Online evidence search
• TAP

Information correct as of 14th April 2016
Specialised Commissioning (1/2)

- NHS England commissions Specialised Services at a national level
- Four factors determine whether NHS England classes a product under Specialised Commissioning:
  - The number of individuals who require the service (less than 500 nationally);
  - The cost of providing the service or facility;
  - The number of people able to provide the service or facility and;
  - The financial implications for Clinical Commissioning Groups (CCGs) if they were required to arrange for provision of the service or facility themselves
- Specialised Services Clinical Reference Groups (CRGs) decide which products to put forward for consideration by NHS England. In order for your product to be put forward for assessment, contact the relevant CRG:
  - CRGs exist for each type of service, such as ‘Radiotherapy’, ‘Chemotherapy’, and ‘Complex disability equipment’ amongst many others. Find the relevant CRG for your device here.
  - CRGs will prioritise products based on unmet need and improvement in cost-effectiveness
- Propositions put forward by CRGs are evaluated for clinical effectiveness based on published evidence from peer reviewed journals as well as finance and activity impact assessments. All policy propositions are then tested with key stakeholders and the public through consultations. Note that NHS England will not consider evidence that is not yet published.
- After public consultation, a recommendation will be made by the Clinical Priorities Advisory Group (CPAG) for the treatment to be either routinely commissioned or not to be routinely commissioned. The final decision is made by NHS England.
- For products that are not recommended for routine use, Commissioning through Evaluation (launched in 2013) could be an alternative route to patient access- see the NHS England page here
Specialised Commissioning (2/2)

- Determine whether the medical technology should be considered under Specialised Services for a target patient population
- Engage with the relevant Clinical Reference Group for advice and put forward the medical technology for assessment
- Ensure you are aligned with the strategy for the relevant National Programme of Care
- Ensure appropriate information and data is published in peer-review journals in order for evidence to be considered
- Register as a Clinical Reference Group stakeholder
- Consider whether a parallel route to reimbursement is required for other target patient populations

**Key organisations**
- NHS England (Specialised Services)

**Process guidance (if available)**

**Other resources**
- Clinical Priorities Advisory Group
- Clinical Reference Groups
- Clinical Reference Groups; a guide for stakeholders

Previous step: What is the route to reimbursement?

Return to map

Return to FAQs

Next step: Local adoption

Information correct as of 14th April 2016
NICE Evaluation (1/2)

• NICE conducts assessments and produces guidance on new medical technologies based on clinical and cost effectiveness evidence

• A NICE assessment is not mandatory, however, published guidance can support CCG decision-making and local adoption

• NICE Medical Technologies Evaluation Programme (MTEP) selects and evaluates new or innovative medical devices and diagnostics. Products are usually notified to the programme by clinicians, but anyone can complete the notification form. Technologies evaluated by the programme are those which offer substantial benefits to patients and are likely to be adopted more rapidly if NICE develops guidance on them. Scientific evidence supporting the advantages the product has over current practices increases the likelihood of the product being selected for assessment.

• Upon receipt of request for an assessment the NICE Medical Technologies Advisory Committee (MTAC) checks suitability of devices and diagnostics for assessment and routes them to the appropriate assessment programme (MTP, IPP, DAP or TAP)

• The approval process varies depending on the device under evaluation. For more information please use the links below:
  – **MTP**: Medical Technologies Programme: Considers a single medical device or diagnostic which provides equivalent or enhanced clinical outcomes for equivalent or reduced cost
  – **IPP**: Interventional Procedure Programme. For surgical procedures, where irradiative energy is used, and where body cavities are accessed
  – **DAP**: Diagnostics Assessment Programme. Considers innovative medical diagnostic technologies
  – **TAP**: Technology Appraisal Programme. Considers new and existing medicines and treatments through either the Single or Multiple Technology Appraisal Process. Less commonly used for devices and diagnostics

NICE Assessment: MTP, IPP, DAP, TAP
c. 9-15 months
*Note pathway and timing will vary between appraisals*

Scoping and evidence gathering → Assessment and consultation → Draft recommendations → Consultation → Final recommendations → Pre-publishing final checks → Guidance published

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Information correct as of 14th April 2016
NICE Evaluation (2/2)

CHECKLIST

- Engage with NICE as early as possible around key topics (e.g. clinical / economic effectiveness)
- Ensure the product meets eligibility criteria
- Notify device/diagnostic to MTEP
- Ensure existing clinical evidence meets requirements
- Ensure the correct templates are used
- Ensure submission is concise

ADDITIONAL RESOURCES

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<td>Programme eligibility criteria</td>
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<td>DAP</td>
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<tr>
<td>IPP</td>
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<tr>
<td>MTP</td>
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<tr>
<td>Online evidence search</td>
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<tr>
<td>TAP</td>
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</table>

Previous step: What is the route to reimbursement?

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Next step: Is this a new procedure, will it significantly change the patient pathway or does it require a large investment?
Commissioning and Adoption
Is this a new procedure, will it significantly change the patient pathway or does it require a large investment?

**DESCRIPTION**

- Not all medical technologies will need to be considered by the Clinical Commissioning Group (CCG - responsible for commissioning health products and services for their local economy) before local adoption can take place. The CCG only needs to consider the product where a change in commissioned services or tariff is required. This includes cases when:
  - The device or procedure is new or innovative
  - The medical technology will significantly change the current patient pathway requiring a new service design and/or amendments to either the locally determined prices or the National Tariff for health services
  - The device represents a large investment
- If the device provides an upgrade to a procedure already commissioned and no changes to tariff are required, then it may be possible to go directly to the end-user and start pricing negotiations
- If it is necessary to get CCG approval then a business case detailing the clinical and cost effective evidence supporting the device will be required
- Note that there is also an option for commissioners and providers to negotiate a local tariff, which can be done for a number of reasons including:
  - National tariff does not exist
  - National tariff does not reflect actual costs
  - Savings or costs are likely to fall to different organisations

**ADDITIONAL RESOURCES**

- Key organisations
  - AHSNs
  - CCGs
  - NHS England (commissioning)
- Process guidance *(if available)*
  - Becoming an NHS supplier
  - National Tariff payment system (includes local tariff variations)
- Other resources
  - Innovation Scorecard
  - National Tariff

**Next step: Primary and Secondary Care Commissioning**

Information correct as of 14th April 2016
Commissioning is the process of planning, agreeing and monitoring services, and is conducted by over 200 Clinical Commissioning Groups (CCGs) and regional / area prescribing committees.

- Each CCG is an independent decision-maker for services in that area, so you will need approval from each CCG and engagement processes may differ slightly.

- For an innovative device that significantly changes patient treatment to be adopted, the CCG must commission the new treatment.

- The CCG will consider the business case for commissioning the new medical device or diagnostic, including clinical and cost-effectiveness evidence.

- If approved for commissioning the CCG will update guidance for the area.

- Local variation in pricing may required to enable the new service or care pathway to occur.

- Negotiation with the commissioner may happen in parallel with negotiations with providers.

**Checklist**

- Identify and engage with the AHSN, Vanguards and Test Beds most relevant for your product.
- Share, develop or refine a clear business case which can demonstrate to commissioners the clinical and health economic benefits to their local health economy (e.g. including Innovation Scorecard).
- Engage with stakeholders from across multiple functions within commissioning bodies:
  - Clinical stakeholders (e.g. heads of department, Chief Pharmacists)
  - Financial stakeholders (e.g. Finance Directors)
- Consider engagement with patients and healthcare professionals via advocacy / medical groups to disseminate information.

**Key Organisations**

- AHSNs
- CCGs
- NHS Test Beds
- NHS Vanguard Sites
- Regional/Area Prescribing Committee

**Process Guidance (if available)**

- National Tariff
- National Tariff payment system (includes local tariff variations)

**Other Resources**

- CCG Outcome Indicator Set 2014/15
- Innovation Scorecard

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Previous step: Is this a new procedure, will it significantly change the patient pathway or does it require a large investment?

Next step: Local adoption

Information correct as of 14th April 2016
**Local Adoption (1/2)**

**Introduction**
- Medical devices and in vitro diagnostics are procured and used by various providers across the NHS including GP surgeries, NHS Trusts and diagnostic laboratories (in-hospital or outsourced private labs).
- Local providers are able to choose the products that they use to deliver services commissioned by the local CCG (or NHS England for Specialised Services), provided they comply with any guidance published. Therefore in order for a device or diagnostic to be used, key stakeholders need to understand the clinical and cost-effectiveness benefits (e.g. if a new diagnostic completes a test more efficiently to the same level of effectiveness, this could provide cost savings).
  - It is important to engage with both clinical and financial stakeholders with a value proposition that addresses both requirements.
  - AHSNs, Vanguards and clinical champions may be able to help companies identify and access key stakeholders and be influential in provider decision-making.

**Procurement**
- Medical devices and in vitro diagnostics may be bought through national, regional and local procurement routes, usually depending on the value, size and complexity of requirements.
  - NHS Supply Chain / National Framework Tenders (national). Constitutes end to end supply chain services.
  - Collaborative Procurement Hubs / Confederations (regional). Most NHS Trusts are now partners in these organisations.
  - Individual Organisation Contracts (local).
- The procurement team within the target provider will be able to provide guidance about which mechanism they would like to use to purchase the product.

**Encouraging use within providers**
- Finally, to encourage use of the product, companies can consider a number of options:
  - Promote any positive commissioning decisions, such as NHS England Specialised Services funding.
  - Use clinical champions and develop clinical education materials.
  - Engage patient advocacy groups (e.g. charities).
  - Clarify value proposition and ensure it applies to all current stakeholders.
  - The Innovation Scorecard can be used by those with a NICE HTA.
- After adoption, there is an opportunity to monitor the impact of the change through audit or other service improvement methodologies; this can be used to further strengthen the business case.
## Local Adoption (2/2)

### Checklist
- Engage end-user, buyer and other key decision-makers in providers to promote the value proposition of the device
- Understand procurement route (national, regional or local) and requirements (e.g. getting on the national framework)
- Develop or tailor education materials for healthcare professionals
- Explore whether additional testing would support change in guidelines and if so, revisit clinical evidence development
- Optional: explore amending NICE treatment guidance in order to ensure local adoption
- Optional: update and refine business case and education materials

### Key organisations
- AHSNs
- NHS Supply Chain
- NICE adoption team

### Process guidance (if available)

### Other resources
- Collaborative Procurement organisation
- National Framework tenders
- National Tariff
- Innovation Scorecard
Digital health pathway
What is the route to reimbursement?

What regulatory approval is required?

Further evidence could be gathered to strengthen business case

Further testing

Early dialogue

Endorsement / impact evaluation (under development)

Primary and secondary care commissioning

Other routes to funding

Local adoption

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Information correct as of 14th April 2016
Creation / idea generation
Idea generation and identification of needs (1/2)

- Idea generation is an iterative process of generating and testing ideas with key stakeholders (e.g. patients, healthcare professionals, commissioners and the NHS).
  - At the earliest design stage it is important to consider whether the technology will address an unmet need in the NHS and with patients; this will form the basis of your business case and value proposition.
    - Currently there is no single outline of requirements for devices within the NHS, however NHS-wide priorities (e.g. NHS England Five Year Forward View) and CCG plans should be considered.
    - Patient views on unmet needs are likely to be incorporated into NHS system unmet needs, however, patient groups such as charities may be able to provide additional insight.
    - Depending on your business model design (business-to-business, business-to-patient or business-to-business-to-patient) you may consider different routes to market.
- Even at this early stage, innovators should be thinking about their business case; a good business case should outline a value proposition to key stakeholders (e.g. healthcare professional, patients, national and local commissioners) including the following:
  - Articulation of unmet need: are there patients currently untreated in this therapeutic area / in particular geographies?
  - Whether a product will change the pathway to meet this unmet need, and what this might mean in terms of allocating resources (e.g. will the technology allow a patient to be cared for at home; or help with prevention and early triage of patients?)
  - Financial and clinical impact.
  - A number of organisations can provide input into this stage, including Digital Health London, Innovate UK, MedCity etc.
- At this stage it is also crucial to look ahead to other requirements along the pathway, such as financial requirements of companies selling to the NHS (e.g. credit rating, published accounts); again these are likely to vary depending on your business model and sales model – whether you plan to sell directly into the NHS, partner with a company on an existing framework etc.
  - The NIB Workstream 1.2 (a future evaluation option in development) includes an element of self-assessment against a set of questions around key quality dimensions, such as safety, privacy, data sharing, accessibility, usability, technical stability and interoperability- for more information, see the evaluation section.
- Patient involvement in research and development is increasingly a priority for regulators and other official bodies, especially for patient-facing apps. Involving current patients in the specification stage will ensure relevance of the final product and will highlight any accessibility issues early, as well as strengthening the business case.
  - Patient advocacy groups and charities are a good source of information about patients. For example, the James Lind Alliance’s Priority Setting Partnerships bring patients, carers and healthcare professionals together to identify and prioritise topics for future research.
  - The NIB Workstream 1.2 (a future evaluation option in development) will include an element of patient and healthcare provider research at the second stage, which involves community evaluation through an engaged group of professionals, commissioners or end-users, giving opinions of usability, functionality and any early stories around impact- see evaluation for more details.
A good place to find out more information is Academic Health Science Networks (AHSNs). AHSNs aim to improve the process of developing and adopting innovations in healthcare and can help with many stages of the development pathway. AHSNs are found locally but can be accessed by any business in England; you should find the most suitable one for your product and area of interest.

- There are many sources of funding for life sciences businesses in England. These range from venture capital funds, grants from public and private sectors to crowdfunding - see this link for a comprehensive list. AHSNs can also give advice on funding.
Development
Product development, testing and proof of concept

• Product prototyping is an iterative process, which can be supported by researching user and system requirements:
  – A user requirements specification can be created in collaboration with the end user, highlighting key user needs
  – A systems requirements specification identifies and plans for the organisational and user impact, for example data and device security, interoperability with existing systems and other safety requirements
• As well as basic usability and interoperability, most products should be tested for clinical and economic effectiveness and patient/end user outcomes
• It is helpful to gain early buy-in with key stakeholders around test design and how it proves the value proposition/desired patient outcomes; these stakeholders could also later become champions to support adoption later in the pathway
• If your product is low-risk and can be launched without regulatory/reimbursement approval (see 'What regulatory approval does my product need?' under FAQs), the data derived from testing the product or can be used as part of the iterative product development cycle
• The National Information Board Workstream 1.2 Roadmap shows a potential future pathway for apps, which includes community evaluation, an element of iterative product development and testing

Before beginning development, confirm user requirements and test value proposition/willingness to pay
Investigate whether the product will need to connect to personal health and care data held in external databases; if so seek guidance according to European Commission policies
Test product with any systems which it might need to interact with - consider product security, including protection of personal data
Involve key stakeholders (e.g. patients, hospitals, healthcare professionals), including gaining feedback on the type of evidence required to support your value proposition (e.g. patient outcomes, measurements)

Key organisations
- AHSNs/Vanguards
- Digital Health and Care Alliance
- MHRA
- National Information Board
- SEHTA/Digital Health London
- TSA

Process guidance (if available)
- Conformity assessments
- DHACA Medical Apps Process
- NHS Innovations South East: An NHS Guide for developing Mobile Healthcare Applications

Other resources
- An introduction to Patient Activation
- Information Governance Toolkit
- Interoperability Toolkit
- Medical devices: conformity assessments and CE marks
- Notified bodies for Medical Devices

It is best practice for digital health technologies to develop clinical evidence around their safety and efficacy; you may want to consider the type of evidence you are collecting based on whether the technology is for prevention or intervention, and whether it will be bought by clinicians or patients.

Furthermore, EU legislation requires all claims around health and wellbeing to be supported by evidence.

In addition to this, some digital health technologies may be classed as medical devices. For more information on whether your product would be classed as a medical device, and which class they would be, see the MHRA’s Medical Devices Directive.

The clinical evaluation requirement depends on the classification of the device / diagnostic, which can be found in MHRA guidance:

- All devices are required to show that they work as intended and do not compromise the health or safety of the patient / user.
- The amount of clinical information/evidence required (e.g. for CE marking or creating a business case) generally increases with the class of the device: most digital health apps are Class I.
- For support designing clinical testing you can engage with the NIHR.

Incorporate feedback from users, healthcare professionals, CCGs and other key stakeholders or partners around evidence required to support your value proposition, including patient reported outcomes addressing key patient needs.

Incorporate evidence gathered into business case and value proposition.

Consider whether further testing might be required e.g. Real World Evidence (data collected from patients or end-users using a product) to strengthen the business case or if an an outcomes-based payment model (payment dependent on achieving pre-agreed outcomes) may be used.

Consider alerting NIHR Horizon Scanning Research Intelligence Centre about your product’s development, if applicable.

**Key organisations**

- Digital Health and Care Alliance
- Health Research Authority (HRA)
- MHRA (Medical devices)
- NICE
- NIHR Clinical Research Network

**Process guidance (if available)**

- DHACA Process Guidance

**Other resources**

- Digital Health London
- NIHR Clinical Research Network Centre
- NIHR INVOLVE

Information correct as of 14th April 2016.
Regulation
If your product is classed as a medical device it will need to follow the appropriate medical device regulatory procedure: in the EU, manufacturers / developers of medical and diagnostic devices must demonstrate that they conform with the requirements outlined in the relevant European Directive before the product can be freely marketed in Europe; a CE mark is a key indicator (but not proof) of a product’s compliance with EU legislation

- Your product is likely to be classed as a medical device if it is an accessory to a medical device or meets the criteria specified in the European Commission Medical Device regulatory framework MEDDEV 2.1/6; the MHRA can also advise on this
- Class I medical devices must be registered with the competent authority (MHRA in the UK) before a CE mark can be granted
- The requirements and assessment process varies by class of device, but will involve approval by a European notified body; you can choose to be assessed by a notified body in any European country; in the UK details can be found here:
  - Non-sterile, non-measuring Class I devices can self-certify by writing a statement and applying to a notified body to approve
  - Other Class I and Class II-III devices (or those that measure) must undergo a conformity assessment by a notified body as well as complying with quality standards (e.g. ISO 13485, 14971, IEC 62304) and data protection regulation, including the upcoming General Data Protection Regulation; risk management standard relevant to medical devices is ISO:14971
- Accessories to medical devices must also complete the same requirements as medical devices themselves
- Going forward, some of these regulatory requirements may be flagged during Stage 1 of the NIB Workstream 1.2 assessment

Ensure your product addresses the Caldicott Principles
Ensure if your product is classified as a medical device or in vitro diagnostic using MHRA guidance
If your product is a medical device, use MHRA Directives to determine which class, demonstrate conformity to the European Directive and finally, register your device with the competent authority in order to get final CE mark approval
Ensure sufficient clinical evidence has been collected for regulatory requirements and respond promptly to requests for additional data and clarifications

Key organisations
- Digital Health and Care Alliance
- European Commission: Medical Devices
- MHRA (Medical devices)

Process guidance (if available)
- Conformity assessments
- DHACA Medical Apps interim process guidance
- MHRA: Device Online Registration System

Other resources
- CE approval process for different classes
- Harmonised standards for medical devices
- Notified bodies for Medical Devices

Previous step: Clinical evidence development
Next step: Endorsement / impact evaluation

Information correct as of 14th April 2016
National endorsement
Early Dialogue

- Early dialogue is most relevant for digital health products which are classed as a medical device; the main benefit is to boost their understanding around requirements for approval and relevant evidence for the payer, allowing a company to make strategic decisions around product development.
- Engage with external stakeholders including NICE Office for Market Access, NIHR, patient advocacy groups (e.g. charities) and providers. The NIHR Office for Clinical Research Infrastructure (NOCRI) can refer you to the relevant part of the NIHR.
- Engage with local AHSNs to determine the appropriate approach to CCGs and providers. They can also give advice on how to look at all aspects of the business, clinical and operating model to demonstrate local value.

Checklist:
- Set up early interactions for advice on clinical and non-clinical testing design
- Refer to MHRA website for regulatory information
- Have a plan for communicating feedback from early dialogue to internal stakeholders
- Use early dialogue to design a local study that addresses local data requirements

Key organisations:
- MHRA
- NICE Scientific Advice
- NOCRI

Process guidance (if available)

Other resources:
- Academic Health Science Networks
- Commissioning Support Units
- NHSE Patients and Information Doctorate
- Patient advocacy groups

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Clinical evidence development

Information correct as of 14th April 2016
Endorsement / impact evaluation

• Currently there is no formal national endorsement model and associated funding direction for digital health products
• The National Information Board (NIB) Workstream 1.2 Roadmap could partly address this for apps; it will help patients and carers to access an assessed set of NHS and social care apps. It aims to be open to new innovators, involve the health and care community, and deliver value to applicants
• The proposed NIB 1.2 assessment framework is split into the following stages, of which Stages 3 and 4 are relevant to this stage
  – **Stage 1**: Self-assessment against a set of questions around key quality dimensions, such as safety, privacy, data sharing, accessibility, usability, technical stability and interoperability
    - Some apps may be identified through the responses given as higher-risk apps (for example, classed as a medical device) and are required to follow external regulatory procedures (see previous page)
  – **Stage 2**: Community evaluation through an engaged group of professionals, commissioners or end-users, giving opinions of usability, functionality and any early stories around impact
  – **Stage 3**: Preparing a benefit case for a robust evaluation of evidence to support the app’s claims
  – **Stage 4**: Independent impact evaluation by an NHS body- apps passing this final stage may be formally recommended by the NHS and receive adoption support mechanisms which could include reimbursement, commissioning support and NHS branding
• Few apps are expected to complete all the stages, but successful evaluation at any stage will be a positive indicator for commissioners and this process will interact with both the regulation and commissioning and adoption stages when complete
• Other app endorsements are also being tested by a range of health organisations and networks

Consider entering the NIB Workstream 1.2 process (described above)
Ensure you have sufficient clinical and economic effectiveness data; a guide to evidence collection is coming soon from NICE
Consider how your product fits into the current system

Key organisations
• AHSNs / Vanguards
• National Information Board
• MHRA
• SEHTA / Digital Health London
• TSA

Process guidance *(if available)*
• National Information Board Workstream 1.2

Other resources
• DHACA Medical Apps interim process guidance
• NICE

Next step: Primary and Secondary care commissioning or other routes to funding

Information correct as of 14th April 2016
Commissioning and Adoption
Primary and Secondary Care Commissioning

**Description**

- Commissioning is the process of planning, procuring and monitoring services, conducted at a primary and secondary care level by over 200 Clinical Commissioning Groups (CCGs) as well as regional / area / hospital trust prescribing committees and NHS England
  - Each CCG is an independent decision-maker for services in that area, so you will need to engage with and sell to each CCG if they are the buyer for your technology
- Unlike pharmaceutical products which typically receive a funding direction from NICE or NHS England, many digital health products may reach local commissioning stage without national reimbursement or endorsement; as a result, it is crucial to communicate the value proposition, business case and supporting evidence to relevant stakeholders within local health economies, including healthcare professionals, commissioners
  - This will include clinical and economic evidence
- Many products will follow two key routes:
  - Competitive tendering: if you choose to undergo this route you must ensure your business meets tendering requirements (including financial accounts and evidence of where the product has been used elsewhere)
  - Framework contracts: these include the NHS G-Cloud

**Checklist**

- Identify and engage with relevant bodies to support innovation such as AHSNs and Vanguards
- Share, develop or refine a clear business case which can demonstrate to commissioners the clinical and health economic benefits to their local health economy (e.g. including Innovation Scorecard); this includes Clinical Support Units and Lead Providers
- Engage with stakeholders from across multiple functions within commissioning bodies:
  - Clinical stakeholders (e.g. Heads of Department, Chief Pharmacists)
  - Financial stakeholders (e.g. Finance Directors)

**Key organisations**

- CCGs
- NHS Supply Chain
- NHS Test Beds
- NHS Vanguard Sites
- Regional prescribing committees

**Process guidance (if available)**

- National Tariff payment system (if applicable, includes local tariff variations)

**Other resources**

- NHS Digital Marketplace
- NHS G-Cloud
- NICE Health Technologies Adoption Team

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Information correct as of 14th April 2016
Other routes to funding (e.g. self pay)

- As well as selling to the NHS, a number of health and wellness products could be sold to local authorities and directly to patients (e.g. via a subscription model, fee for service, pay per download)
- As with CCGs, local authorities should be individually engaged, with a full business case demonstrating clinical and economic value properly tracked
  - Hospitals and GP surgeries may also buy a product directly if it is under the OJEU threshold (this may be different for GP Federations considering risk-based contracts)
  - In general, providers entering into risk-based contracts may be more motivated to introduce solutions which can be tied to desired outcomes
- A direct to patient model is possible for digital health products since they can be made available directly to patients through app stores or online
  - This can also be an opportunity for developers to test / iterate their product and gain effectiveness evidence if properly tracked; however, gaining some form of endorsement can support access to patients (e.g. such as app store reviews, GPs who recommend your product, other AHSN-led endorsements or endorsement by NHS Choices)

Checklist:
- Decide the most appropriate funding model for your product; if seeking venture capital, recurring revenue streams may be important
- Ensure value proposition and target users are clearly defined
- Consider whether any data generated can be safely and securely be used meaningfully by patients or clinicians

Key organisations:
- Local authorities
- NHSE Patients and Information Doctorate

Process guidance (if available):

Other resources:
- NHS Choices
- NICE Implementation Collaborative
- General Medical Services Contract
- Personal Health Budgets

Previous step: Endorsement / impact evaluation
Next step: Local adoption
This stage focuses on encouraging product uptake following national and/or local reimbursement; the AHSN network can provide guidance and support around this. If local adoption is slow, despite positive commissioning decisions, companies can consider a number of options to encourage healthcare professionals to recommend your product:

- Direct engagement with healthcare professionals and patient advisory groups (e.g. around education and support)
- Influencing local clinical guidelines

Innovators may also have to invest in training staff and tailoring technology to remove barriers to adoption. After adoption, there is an opportunity to monitor the impact of the change through audit or other service improvement methodologies; this can be used to further strengthen the business case.

Contact relevant AHSNs to find out available support for developing and scaling local adoption.

Prepare engagement and marketing materials supporting the clinical benefits of your product.

Conduct clinical and patient engagement, using feedback from these sessions to continually refine and update business case.

Consider engagement with patient advocacy groups, charities and patient online platforms like HealthUnlocked.

Gather ongoing evidence from real world use of the product to update and refine business case and education materials, including but not limited to clinical evidence around patient outcomes, patient endorsement, usage/downloads.

**Key organisations**

- AHSNs
- HSCIC
- NICE adoption team

**Process guidance (if available)**

**Other resources**

- General Medical Services Contract
- Medicines Optimisation Dashboard
- NHS Innovation Scorecard
- NICE Implementation Collaborative
Appendix, Definitions and Key Contacts
# Directory: Public bodies and definitions

<table>
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<tr>
<th>Acronym</th>
<th>Name</th>
<th>Description</th>
<th>When to contact</th>
<th>Link</th>
</tr>
</thead>
<tbody>
<tr>
<td>AHSN</td>
<td>Academic Health Science Network</td>
<td>Set up to spread innovation, improve health and generate economic growth by connecting academics, the NHS, social care and industry. They create partnerships, enabling collaboration and response to the needs of patients and populations.</td>
<td>Across innovation pathway to test ideas and stimulate adoption</td>
<td><a href="https://www.england.nhs.uk/ourwork/part-rel/ahsn/">https://www.england.nhs.uk/ourwork/part-rel/ahsn/</a></td>
</tr>
<tr>
<td>AWSMG</td>
<td>All Wales Strategy Medicines Group</td>
<td>Provides advice on medicines management and prescribing to the Welsh Government’s Minister for Health and Social Services</td>
<td>-</td>
<td><a href="http://www.awmsg.org/">http://www.awmsg.org/</a></td>
</tr>
<tr>
<td>BRC</td>
<td>Biomedical Research Centre (NIHR)</td>
<td>Formed through partnerships between England’s leading NHS organisations and universities, 11 NIHR Biomedical Research Centres conduct translational research to transform scientific breakthroughs into life-saving treatments for patients.</td>
<td>At development / clinical testing stage</td>
<td><a href="http://www.nihr.ac.uk/about/biomedical-research-centres.htm">http://www.nihr.ac.uk/about/biomedical-research-centres.htm</a></td>
</tr>
<tr>
<td>BRU</td>
<td>Biomedical Research Units (NIHR)</td>
<td>Based within England’s leading NHS organisations and universities, 20 NIHR Biomedical Research Units undertake translational research in priority areas of high disease burden and clinical need.</td>
<td>At development / clinical testing stage</td>
<td><a href="http://www.nihr.ac.uk/about/biomedical-research-units.htm">http://www.nihr.ac.uk/about/biomedical-research-units.htm</a></td>
</tr>
<tr>
<td>CDF</td>
<td>Cancer Drugs Fund</td>
<td>A managed access fund which provides funding for cancer drugs</td>
<td>For pharma companies seeking clarity on CDF in the lead in to Technology Appraisal</td>
<td><a href="https://www.england.nhs.uk/ourwork/cancer/cdf/">https://www.england.nhs.uk/ourwork/cancer/cdf/</a></td>
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<tr>
<td>CCG</td>
<td>Clinical Commissioning Group</td>
<td>Responsible for planning and commissioning health care services for their local area</td>
<td>Across innovation pathway to test ideas and stimulate adoption</td>
<td><a href="http://www.nhscc.org/ccgs/">http://www.nhscc.org/ccgs/</a></td>
</tr>
<tr>
<td>CPAG</td>
<td>Clinical Priorities Advisory Group</td>
<td>Makes recommendations to NHS England’s Directly Commissioned Services Committee on the commissioning of services where there could be a substantial change in service provision.</td>
<td>At endorsement / reimbursement stage</td>
<td><a href="https://www.england.nhs.uk/commissioning/cpag/">https://www.england.nhs.uk/commissioning/cpag/</a></td>
</tr>
<tr>
<td>CRG</td>
<td>Clinical Reference Groups</td>
<td>CRGs bring together groups of clinicians, commissioners, public health experts, patients and carers. They use their specific knowledge and expertise to advise NHS England on the best ways that specialised services should be provided.</td>
<td>For companies with a product that may be commissioned by specialised services</td>
<td><a href="https://www.england.nhs.uk/commissioning/spec-servicesnpc.org/">https://www.england.nhs.uk/commissioning/spec-servicesnpc.org/</a></td>
</tr>
</tbody>
</table>

Please note that this list consists of examples only and is not exhaustive.
## Directory: Public bodies and definitions

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</tr>
</thead>
<tbody>
<tr>
<td>CRN</td>
<td>Clinical Research Network (NIHR)</td>
<td>NIHR network that helps set up clinical studies, supports the life-sciences industry, provides health professionals with research training; and works with patients to ensure their needs are at the centre of research activity</td>
<td>At development / clinical testing stage</td>
<td><a href="https://www.crn.nihr.ac.uk/">https://www.crn.nihr.ac.uk/</a></td>
</tr>
<tr>
<td>CLARHCs</td>
<td>Collaborations for Leadership in Applied Health Research and Care</td>
<td>CLAHRCs conduct applied health research across the NHS, and translate research findings into improved outcomes for patients.</td>
<td>At development / clinical testing stage</td>
<td><a href="http://www.nihr.ac.uk/about/collaborations-for-leadership-in-applied-health-research-and-care.htm">http://www.nihr.ac.uk/about/collaborations-for-leadership-in-applied-health-research-and-care.htm</a></td>
</tr>
<tr>
<td>CMU</td>
<td>Commercial Medicines Unit</td>
<td>The CMU is part of the Medicine, Pharmacy and Industry Group of the Department of Health which looks at supply and procurement in hospitals</td>
<td>For pharmaceutical companies following marketing authorisation</td>
<td><a href="https://www.gov.uk/government/collections/commercial-medicines-unit-cmu">https://www.gov.uk/government/collections/commercial-medicines-unit-cmu</a></td>
</tr>
<tr>
<td>CMA</td>
<td>Competition and Markets Authority</td>
<td>Work to promote competition for the benefit of consumers, both within and outside the UK. Aim is to make markets work well for consumers, businesses and the economy.</td>
<td>-</td>
<td><a href="https://www.gov.uk/government/organisations/competition-and-markets-authority">https://www.gov.uk/government/organisations/competition-and-markets-authority</a></td>
</tr>
<tr>
<td>CPRD</td>
<td>Clinical Practice Research Datalink</td>
<td>A not-for profit research service, jointly funded by the NHS National Institute for the NIHR and MHRA; providing anonymised primary care records for public health research since 1987</td>
<td>-</td>
<td><a href="https://www.cprd.com/intro.asp">https://www.cprd.com/intro.asp</a></td>
</tr>
<tr>
<td>DH</td>
<td>Department of Health</td>
<td>A ministerial department which leads, shapes and funds health and care in England</td>
<td>-</td>
<td><a href="https://www.gov.uk/government/organisations/department-of-health">https://www.gov.uk/government/organisations/department-of-health</a></td>
</tr>
<tr>
<td>DECs</td>
<td>Diagnostic Evidence Co-operatives (NIHR)</td>
<td>Funded by the NIHR, these research co-operatives aim to help generate information on the clinical and cost-effectiveness of in vitro diagnostic devices which are important in helping to improve the way diseases are diagnosed</td>
<td>At development / clinical testing stage</td>
<td><a href="http://www.nihr.ac.uk/about/diagnostic-evidence-co-operatives.htm">http://www.nihr.ac.uk/about/diagnostic-evidence-co-operatives.htm</a></td>
</tr>
<tr>
<td>EME</td>
<td>Efficiency and Mechanism Evaluation Programme</td>
<td>The EME Programme funds clinical efficacy studies. The studies supported usually test if an intervention works as expected in a well-defined population or group of patients.</td>
<td>At development / clinical testing stage</td>
<td><a href="http://www.nets.nihr.ac.uk/programmes/eme">http://www.nets.nihr.ac.uk/programmes/eme</a></td>
</tr>
<tr>
<td>EMA</td>
<td>European Medicines Agency</td>
<td>Responsible for the scientific evaluation, supervision and safety monitoring of medicines developed by pharmaceutical companies for use in the EU</td>
<td>For all companies seeking EU regulatory approval</td>
<td><a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000235.jsp&amp;mid=">http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000235.jsp&amp;mid=</a></td>
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</tr>
</thead>
<tbody>
<tr>
<td>HSCIC</td>
<td>Health and Social Care Information Centre</td>
<td>National provider of information, data and IT systems for commissioners, analysts and clinicians in health and social care</td>
<td>For all companies seeking advice around data and interoperability</td>
<td><a href="http://www.hscic.gov.uk/">http://www.hscic.gov.uk/</a></td>
</tr>
<tr>
<td>HRA</td>
<td>Health Research Authority</td>
<td>Protects and promotes the interests of patients and the public in health and social care research</td>
<td>For companies wishing to carry out clinical research</td>
<td><a href="http://www.hra.nhs.uk/">http://www.hra.nhs.uk/</a></td>
</tr>
<tr>
<td>HTC</td>
<td>Healthcare Technology Co-operatives (NIHR)</td>
<td>NIHR centres of expertise that work collaboratively with industry to develop concepts of new medical devices, healthcare technologies and technology-dependent interventions that improve treatment and quality of life for patients.</td>
<td>At development / testing stage for medical technology companies</td>
<td><a href="http://www.nihr.ac.uk/about/healthcare-technology-co-operatives.htm">http://www.nihr.ac.uk/about/healthcare-technology-co-operatives.htm</a></td>
</tr>
<tr>
<td>HFEA</td>
<td>Human Fertilisation and Embryology Authority</td>
<td>The HFEA licenses fertility clinics and centres carrying out in vitro fertilisation (IVF), other assisted conception procedures and human embryo research.</td>
<td>For companies wishing to use human embryos in research</td>
<td><a href="http://www.hfea.gov.uk/">http://www.hfea.gov.uk/</a></td>
</tr>
<tr>
<td>-</td>
<td>Innovation Scout Programmes / Schemes</td>
<td>A network of healthcare professionals across a region to encourage the development of innovation, stimulate the creation of ideas, and drive a culture of innovation within their respective organisations. See local AHSNs for details</td>
<td>At development stage for all companies</td>
<td>-</td>
</tr>
<tr>
<td>IPO</td>
<td>Intellectual Property Office</td>
<td>The official UK government body responsible for intellectual property (IP) rights including patents, designs, trade marks and copyright</td>
<td>For all companies seeking a UK patent during the idea generation or product development stage</td>
<td><a href="https://www.gov.uk/government/organisations/intellectual-property-office">https://www.gov.uk/government/organisations/intellectual-property-office</a></td>
</tr>
<tr>
<td>i4i</td>
<td>Invention for Innovation (NIHR)</td>
<td>An NIHR scheme that supports collaborative research and development projects that have a clear pathway towards adoption and commercialisation. The expected output is an advanced or clinically validated prototype medical device, technology or intervention.</td>
<td>After the development / testing stage</td>
<td><a href="http://www.nihr.ac.uk/funding/invention-for-innovation.htm">http://www.nihr.ac.uk/funding/invention-for-innovation.htm</a></td>
</tr>
<tr>
<td>JCVI</td>
<td>Joint Committee on Vaccination and Immunisation</td>
<td>Advises UK health departments on immunisation</td>
<td>For manufacturers of vaccines seeking reimbursement after regulatory approval</td>
<td><a href="https://www.gov.uk/government/groups/joint-committee-on-vaccination-and-immunisation">https://www.gov.uk/government/groups/joint-committee-on-vaccination-and-immunisation</a></td>
</tr>
<tr>
<td>MHRA</td>
<td>Medicines and healthcare products regulatory agency</td>
<td>Regulates medicines, medical devices and blood components for transfusion in the UK</td>
<td>For all companies seeking UK regulatory approval</td>
<td><a href="https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency">https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency</a></td>
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<tbody>
<tr>
<td>-</td>
<td>MHRA Innovation Office</td>
<td>The office has been set up to help companies, small and medium-sized enterprises (SMEs), academics and individuals who have developed a novel medicine or device, or a novel approach to the development or manufacture of a product, in their regulation</td>
<td>For SMEs seeking advice about regulation</td>
<td><a href="https://www.gov.uk/government/groups/mhra-innovation-office">https://www.gov.uk/government/groups/mhra-innovation-office</a></td>
</tr>
<tr>
<td>NIB</td>
<td>National Information Board</td>
<td>The role of the National Information Board is to put data and technology safely to work for patients, service users, citizens and the professionals who serve them</td>
<td>For companies with a digital element to their product</td>
<td><a href="https://www.gov.uk/government/organisations/national-information-board">https://www.gov.uk/government/organisations/national-information-board</a></td>
</tr>
<tr>
<td>NICE</td>
<td>National Institute for Health and Care Excellence</td>
<td>Provides national guidance and advice to improve health and social care</td>
<td>For all companies seeking advice on and taking part in health technology appraisals</td>
<td><a href="http://www.nice.org.uk/">http://www.nice.org.uk/</a></td>
</tr>
<tr>
<td>NIHR</td>
<td>National Institute for Health Research</td>
<td>Funded through the Department of Health to improve the health and wealth of the nation through research</td>
<td>For companies wishing to carry out clinical research</td>
<td><a href="http://www.nihr.ac.uk/">http://www.nihr.ac.uk/</a></td>
</tr>
<tr>
<td>NIHR HSRIC</td>
<td>National Institute for Health Research Horizon Scanning Research and Intelligence Centre</td>
<td>Aims to supply timely information to key policy- and decision-makers and research funders within the English National Health Service (NHS) about emerging health technologies that may have a significant impact on patients or the provision of health services in the near future</td>
<td></td>
<td><a href="http://www.hsric.nihr.ac.uk/">http://www.hsric.nihr.ac.uk/</a></td>
</tr>
<tr>
<td>BSA</td>
<td>NHS Business Services Authority</td>
<td>The NHS Business Services Authority is a Special Health Authority and an Arms Length Body of the Department of Health which provides a range of critical central services to NHS organisations, NHS contractors, patients and the public</td>
<td>For all companies at the adoption stage</td>
<td><a href="http://www.nhsbsa.nhs.uk/Index.aspx">http://www.nhsbsa.nhs.uk/Index.aspx</a></td>
</tr>
<tr>
<td>-</td>
<td>NHS Choices</td>
<td>Official NHS website providing information to patients</td>
<td>For all companies seeking information about the NHS and patient needs</td>
<td><a href="http://www.nhs.uk/pages/home.aspx">http://www.nhs.uk/pages/home.aspx</a></td>
</tr>
<tr>
<td>-</td>
<td>NHS England</td>
<td>Leads the National Health Service (NHS) in England. Sets the priorities and direction of the NHS and encourages and informs the national debate to improve health and care.</td>
<td></td>
<td><a href="https://www.england.nhs.uk/">https://www.england.nhs.uk/</a></td>
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<tr>
<td>NHS Right Care</td>
<td>Primary objective is to maximise value that the patient derives from their own care and treatment and the value the whole population derives from the investment in their healthcare</td>
<td>For companies seeking information about patient needs</td>
<td><a href="http://www.rightcare.nhs.uk/">http://www.rightcare.nhs.uk/</a></td>
<td></td>
</tr>
<tr>
<td>NHS Supply Chain</td>
<td>NHS Supply Chain provides patient-focused healthcare products and supply chain services to the UK’s National Health Service</td>
<td>For companies at the adoption stage in the pathway</td>
<td><a href="https://www.supplychain.nhs.uk/">https://www.supplychain.nhs.uk/</a></td>
<td></td>
</tr>
<tr>
<td>NIA</td>
<td>The aim of the NIA is to create the conditions and cultural change necessary for proven innovations to be adopted faster and more systematically through the NHS, and to deliver examples into practice for demonstrable patient and population benefit</td>
<td>If considering NIA Fellowship</td>
<td><a href="https://www.england.nhs.uk/ourwork/innovation/nia/">https://www.england.nhs.uk/ourwork/innovation/nia/</a></td>
<td></td>
</tr>
<tr>
<td>NICE</td>
<td>The National Institute for Health and Care Excellence</td>
<td>Provides national guidance and advice to improve health and social care</td>
<td>For companies seeking evaluation of their product</td>
<td><a href="http://www.nice.org.uk/">http://www.nice.org.uk/</a></td>
</tr>
<tr>
<td>NICE Office for Market Access</td>
<td>The first point of contact for talking to NICE about future products. Provide expert advice and direction to help engage with NICE technology evaluation.</td>
<td>For all companies seeking advice on and taking part in health technology appraisals</td>
<td><a href="https://www.nice.org.uk/about/what-we-do/office-for-market-access">https://www.nice.org.uk/about/what-we-do/office-for-market-access</a></td>
<td></td>
</tr>
<tr>
<td>NICE `</td>
<td>Consultancy service to medicines, devices and diagnostics around generating evidence to inform future NICE evaluations and enabling market access</td>
<td>For companies prior to NICE evaluation</td>
<td><a href="https://www.nice.org.uk/about/what-we-do/scientific-advice">https://www.nice.org.uk/about/what-we-do/scientific-advice</a></td>
<td></td>
</tr>
<tr>
<td>NOCRI</td>
<td>NIHR Office for Clinical Research Infrastructure</td>
<td>Includes expert individuals, research facilities and technology platforms that have been designed to support high quality clinical research across the innovation pathway</td>
<td>For companies wishing to carry out clinical research</td>
<td><a href="http://www.nocri.nihr.ac.uk/">http://www.nocri.nihr.ac.uk/</a></td>
</tr>
<tr>
<td>Northern Ireland Health and Social Care Board</td>
<td>Commissions health and social services, ensures health and social care trusts provide services that meet patient needs, and manages annual funding from the Northern Ireland Executive</td>
<td>-</td>
<td><a href="http://www.hscboard.hscni.net/">http://www.hscboard.hscni.net/</a></td>
<td></td>
</tr>
<tr>
<td>OLS</td>
<td>Office for Life Sciences</td>
<td>The Office for Life Sciences champions research, innovation and the use of technology to transform health and care service</td>
<td>For companies seeking context on the UK Life Science industry and for useful resources</td>
<td><a href="https://www.gov.uk/government/organisations/office-for-life-sciences/about">https://www.gov.uk/government/organisations/office-for-life-sciences/about</a></td>
</tr>
<tr>
<td>PASLU</td>
<td>Patient Access Scheme Liaison Unit</td>
<td>PASLU has been set up by NICE to work with manufacturers who are considering a patient access scheme for their drug or treatment to see if it is a scheme that would work in the NHS</td>
<td>For pharmaceutical companies considering a patient access scheme</td>
<td><a href="https://www.nice.org.uk/about/what-we-do/patient-access-schemes-liaison-unit">https://www.nice.org.uk/about/what-we-do/patient-access-schemes-liaison-unit</a></td>
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</thead>
<tbody>
<tr>
<td>RDAG</td>
<td>Rare Diseases Advisory Group</td>
<td>Makes recommendations to NHS England on developing and implementing the strategy for rare diseases and highly specialised services</td>
<td>At the idea generation / development stage if appropriate to product</td>
<td><a href="https://www.england.nhs.uk/commissioning/rdag/">https://www.england.nhs.uk/commissioning/rdag/</a></td>
</tr>
<tr>
<td>SMC</td>
<td>Scottish Medicines Consortium</td>
<td>Accepts newly licensed medicines that clearly represent good value for money to NHS Scotland. SMC analyses information supplied by the medicine manufacturer on the health benefits of the medicine and justification of its price</td>
<td>-</td>
<td><a href="https://www.scottishmedicines.org.uk/">https://www.scottishmedicines.org.uk/</a></td>
</tr>
<tr>
<td>UKMi</td>
<td>UK Medicines information</td>
<td>An NHS pharmacy based service. Its aim is to support the safe, effective and efficient use of medicines by the provision of evidence-based information and advice on their therapeutic use</td>
<td>For pharmaceutical companies</td>
<td><a href="http://www.ukmi.nhs.uk/">http://www.ukmi.nhs.uk/</a></td>
</tr>
</tbody>
</table>

Please note that this list consists of examples only and is not exhaustive.

Information correct as of 14th April 2016
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</thead>
<tbody>
<tr>
<td>ABHI</td>
<td>Association of British Healthcare Industries</td>
<td>The industry association for the medical technology sector in the UK. Their mission is to champion the benefits and use of safe and effective medical technologies to deliver high quality patient outcomes.</td>
<td>For medtech companies across all stages</td>
<td><a href="http://www.abhi.org.uk/">http://www.abhi.org.uk/</a></td>
</tr>
<tr>
<td></td>
<td>Bloodwise</td>
<td>UK’s biggest blood cancer charity</td>
<td>Across innovation pathway to test ideas (if appropriate product)</td>
<td><a href="https://bloodwise.org.uk/about-us">https://bloodwise.org.uk/about-us</a></td>
</tr>
<tr>
<td>CASMI</td>
<td>Centre for the Advancement of Sustainable Medical innovation</td>
<td>The centre aims to address the issues that have led to current failures in the translation of basic bioscience into affordable and widely adopted new treatments.</td>
<td>Across innovation pathway for information on adoption</td>
<td><a href="http://casmi.org.uk/">http://casmi.org.uk/</a></td>
</tr>
<tr>
<td>CPRD</td>
<td>Clinical Practise Research Datalink</td>
<td>Research service jointly funded by the NIHR and the MHRA, provides anonymised primary care records for public health research</td>
<td>For development / clinical testing stage</td>
<td><a href="https://www.cprd.com/intro.asp">https://www.cprd.com/intro.asp</a></td>
</tr>
<tr>
<td>DHACA</td>
<td>Digital health and care alliance</td>
<td>DHACA is a non-profit sector-led organisation that furthers the cause of digital health and care systems in the UK and Europe, championing scalability and interoperability</td>
<td>For companies with a digital element across all stages</td>
<td><a href="http://dhaca.org.uk/dhaca/">http://dhaca.org.uk/dhaca/</a></td>
</tr>
<tr>
<td>EMIG</td>
<td>Ethical Medicines Industry Group</td>
<td>The UK research-based trade association that represents the interests of small to medium-sized Pharmaceutical, Biotech and Medtech companies (SMEs)</td>
<td>For SMEs seeking information about clinical research and policy in the UK</td>
<td><a href="http://www.emig.org.uk/">http://www.emig.org.uk/</a></td>
</tr>
<tr>
<td></td>
<td>The Farr Institute of Health Informatics Research</td>
<td>The Farr Institute aims to deliver high-quality, cutting-edge research linking electronic health data with other forms of research and routinely collected data, as well as build capacity in health informatics research</td>
<td>For companies seeking health research data</td>
<td><a href="http://www.farrinstitute.org/">http://www.farrinstitute.org/</a></td>
</tr>
<tr>
<td>GMC</td>
<td>General Medical Council</td>
<td>Help to protect patients and improve medical education and practice in the UK by setting standards for students and doctors</td>
<td>For information on medical practice in the UK</td>
<td><a href="http://www.gmc-uk.org/">http://www.gmc-uk.org/</a></td>
</tr>
</tbody>
</table>

Please note that this list consists of examples only and is not exhaustive, there may be more appropriate trade bodies / patient advocacy groups / charities for your product.
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<tbody>
<tr>
<td>-</td>
<td>HealthUnlocked</td>
<td>HealthUnlocked is a social network for health</td>
<td>Across innovation pathway to test ideas</td>
<td><a href="https://healthunlocked.com/">https://healthunlocked.com/</a></td>
</tr>
<tr>
<td>-</td>
<td>Healthwatch</td>
<td>The national consumer champion in health and care with significant statutory powers to ensure the voice of the consumer is strengthened and heard by those who commission, deliver and regulate health and care services</td>
<td>Across innovation pathway to test ideas</td>
<td><a href="http://www.healthwatch.co.uk/">http://www.healthwatch.co.uk/</a></td>
</tr>
<tr>
<td>-</td>
<td>Innovate UK</td>
<td>Work with people, companies and partner organisations to find and drive the science and technology innovations that will grow the UK economy</td>
<td>Across innovation pathway for connecting with key partners / funding</td>
<td><a href="https://www.gov.uk/government/organisations/innovate-uk">https://www.gov.uk/government/organisations/innovate-uk</a></td>
</tr>
<tr>
<td>-</td>
<td>James Lind Alliance</td>
<td>A non-profit making initiative which brings patients, carers and clinicians together in Priority Setting Partnerships (PSPs) to identify and prioritise top uncertainties. The aim of this is to help ensure that those who fund health research are aware of what matters to both patients and clinicians</td>
<td>Prior to clinical research and testing</td>
<td><a href="http://www.jla.nihr.ac.uk/">http://www.jla.nihr.ac.uk/</a></td>
</tr>
<tr>
<td>-</td>
<td>King’s Fund</td>
<td>The King’s Fund is an independent charity working to improve health and care in England. We help to shape policy and practice through research and analysis; develop individuals, teams and organisations; promote understanding of the health and social care system; and bring people together to learn, share knowledge and debate</td>
<td>For up to date information on the</td>
<td><a href="http://www.kingsfund.org.uk/">http://www.kingsfund.org.uk/</a></td>
</tr>
<tr>
<td>-</td>
<td>MedCity</td>
<td>MedCity is a collaboration between the Mayor of London and the capital’s three Academic Health Science Centres - Imperial College Academic Health Science Centre, King’s Health Partners, and UCL Partners. It promotes life sciences in the South East region</td>
<td>Across innovation pathway to test ideas</td>
<td><a href="http://www.medcityhq.com/">http://www.medcityhq.com/</a></td>
</tr>
<tr>
<td></td>
<td>MRC</td>
<td>Medicines Research Council Fund research across the biomedical spectrum, from fundamental lab-based science to clinical trials, and in all major disease areas</td>
<td>For companies wishing to carry out clinical research</td>
<td><a href="http://www.mrc.ac.uk/?nav=main">http://www.mrc.ac.uk/?nav=main</a></td>
</tr>
<tr>
<td>-</td>
<td>Medilink</td>
<td>A national health technology business support organisation, which helps companies from concept through to commercialisation and nurtures collaborations between academics, clinicians and industry</td>
<td>For medtech and digital companies</td>
<td><a href="http://www.medilinkuk.com/">http://www.medilinkuk.com/</a></td>
</tr>
<tr>
<td>-</td>
<td>Myeloma UK</td>
<td>Myeloma UK aim to accelerate the discovery, development and access to new treatments for myeloma, while helping patients and their families cope with everything a diagnosis brings</td>
<td>For companies focused on Myeloma</td>
<td><a href="https://www.myeloma.org.uk/">https://www.myeloma.org.uk/</a></td>
</tr>
</tbody>
</table>

Please note that this list consists of examples only and is not exhaustive, there may be more appropriate trade bodies / patient advocacy groups / charities for your product.
## Directory: Other contacts

<table>
<thead>
<tr>
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<th>Name</th>
<th>Description</th>
<th>When to contact</th>
<th>Link</th>
</tr>
</thead>
<tbody>
<tr>
<td>-</td>
<td>NHS Confederation</td>
<td>Membership body that brings together, and speaks on behalf of, the whole health and care system</td>
<td>-</td>
<td><a href="http://www.nhsconfed.org/">http://www.nhsconfed.org/</a></td>
</tr>
<tr>
<td>NWEH</td>
<td>NorthWest EHealth</td>
<td>Develops innovative software that unlocks the value of health and care data for the benefit of patients.</td>
<td>-</td>
<td><a href="http://nweh.co.uk/">http://nweh.co.uk/</a></td>
</tr>
<tr>
<td>SBRI</td>
<td>Small Business Research Initiative for Healthcare</td>
<td>sets industry the challenge in a series of health related competitions which resulted in fully funded development contracts between the awarded company and the NHS</td>
<td>For SMEs seeking funding</td>
<td><a href="http://www.sbrihealthcare.co.uk/">http://www.sbrihealthcare.co.uk/</a></td>
</tr>
<tr>
<td>-</td>
<td>techUK</td>
<td>techUK represents the companies and technologies that are defining today the world that we will live in tomorrow</td>
<td>For digital companies across all stages</td>
<td><a href="https://www.techuk.org/about">https://www.techuk.org/about</a></td>
</tr>
<tr>
<td>ABPI</td>
<td>The Association of the British Pharmaceutical Industry</td>
<td>Recognised by government as the industry body negotiating on behalf of the branded pharmaceutical industry for statutory consultation requirements including the pricing scheme for medicines in the UK</td>
<td>For pharma companies across all stages</td>
<td><a href="http://www.abpi.org.uk/about-us/Pages/default.aspx">http://www.abpi.org.uk/about-us/Pages/default.aspx</a></td>
</tr>
<tr>
<td>BIVDA</td>
<td>The British In Vitro Diagnostics Association</td>
<td>The national industry association for companies with major involvement and interest in the in vitro diagnostics (IVD) industry. BIVDA represents both manufacturers and distributors who are active in the UK</td>
<td>For diagnostic companies across all stages</td>
<td><a href="http://www.bivda.co.uk/">http://www.bivda.co.uk/</a></td>
</tr>
<tr>
<td>BIA</td>
<td>UK Bioindustry Association</td>
<td>The BIA is at the forefront of UK bioscience, serving as its voice, connecting individuals and organisations, from SMEs to multinational companies</td>
<td>For all companies seeking advice on policy and regulation in the UK</td>
<td><a href="http://www.bioindustry.org/home/">http://www.bioindustry.org/home/</a></td>
</tr>
<tr>
<td>-</td>
<td>UK PharmaScan</td>
<td>Horizon scanning database populated with information on new medicines in development from up to three years before their launch in the UK</td>
<td>For pharma companies during Phases I - III</td>
<td><a href="https://www.ukpharmascan.org.uk/login">https://www.ukpharmascan.org.uk/login</a></td>
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## Glossary of key terms

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<tbody>
<tr>
<td>-</td>
<td>Acute Trusts</td>
<td>Hospitals in England are managed by acute trusts. Acute trusts ensure hospitals provide high-quality healthcare and check that they spend their money efficiently</td>
<td><a href="http://www.nhs.uk/NHSEngland/thenhs/about/Pages/authoritiesandtrusts.aspx">http://www.nhs.uk/NHSEngland/thenhs/about/Pages/authoritiesandtrusts.aspx</a></td>
</tr>
<tr>
<td>-</td>
<td>CE mark</td>
<td>Shows that the product meets EU safety, health or environmental requirements as well as compliance with EU legislation. It allows free movement of products in the EEA (European Economic Area)</td>
<td><a href="https://www.gov.uk/guidance/ce-marking">https://www.gov.uk/guidance/ce-marking</a></td>
</tr>
<tr>
<td>EAMS</td>
<td>Early Access to Medicines Scheme</td>
<td>Scheme to improve access to innovative medicines for patients with life threatening or seriously debilitating conditions without adequate treatment options</td>
<td><a href="https://www.gov.uk/guidance/apply-for-the-early-access-to-medicines-scheme-eams">https://www.gov.uk/guidance/apply-for-the-early-access-to-medicines-scheme-eams</a></td>
</tr>
<tr>
<td>GMS</td>
<td>General Medical Services Contract</td>
<td>The General Medical Services (GMS) contract is the contract between general practices and NHS England for delivering primary care services to local communities</td>
<td><a href="https://www.england.nhs.uk/commissioning/gp-contract/">https://www.england.nhs.uk/commissioning/gp-contract/</a></td>
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<tr>
<td>-</td>
<td>GP Federations</td>
<td>GP Federations are groups of GP practices which achieve economies of scale through sharing functions such as back office services. In general, Federations deal with products and services that doctors themselves dispense; CCGs are more likely to deal with the commissioning of services they may use, or those for secondary care</td>
<td>-</td>
</tr>
<tr>
<td>HTAP / HTAT</td>
<td>Health Technologies Adoption Team</td>
<td>The Adoption team (formerly known as the Health Technologies Adoption Programme HTAP) is responsible for identifying ways to overcome potential barriers to the implementation of NICE guidance.</td>
<td><a href="https://www.nice.org.uk/about/what-we-do/into-practice/health-technologies-adoption-team">https://www.nice.org.uk/about/what-we-do/into-practice/health-technologies-adoption-team</a></td>
</tr>
<tr>
<td>HTA</td>
<td>Health Technology Assessment / Health Technology Assessor / Health Technology Appraisal (NICE)</td>
<td>Technology appraisals are carried out by NICE and give recommendations on the use of new and existing medicines and treatments within the NHS</td>
<td><a href="https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance">https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance</a></td>
</tr>
<tr>
<td>HST</td>
<td>Highly Specialised Technology (NICE)</td>
<td>Highly specialised technology (HST) evaluations by NICE are recommendations on the use of new and existing highly specialised medicines and treatments within the NHS in England</td>
<td><a href="https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-highly-specialised-technologies-guidance">https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-highly-specialised-technologies-guidance</a></td>
</tr>
<tr>
<td>ICDF</td>
<td>Individual Cancer Drugs Fund Request</td>
<td>Application to the Cancer Drugs Fund for a single drug and indication</td>
<td><a href="https://www.england.nhs.uk/ourwork/cancer/cdf/">https://www.england.nhs.uk/ourwork/cancer/cdf/</a></td>
</tr>
<tr>
<td>-</td>
<td>Innovation Scorecard</td>
<td>For products with NICE Technology Appraisal to enable benchmarking and increase transparency to patients and the public. It is produced on a quarterly basis by the Health and Social Care Information Centre (HSCIC)</td>
<td><a href="https://www.england.nhs.uk/ourwork/innovation/innovation-scorecard/">https://www.england.nhs.uk/ourwork/innovation/innovation-scorecard/</a></td>
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<tr>
<td>IPP</td>
<td>Interventional Procedure Programme (NICE)</td>
<td>NICE approval programme. For surgical procedures, where irritative energy is used, and where body cavities are accessed</td>
<td><a href="https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-interventional-procedures-guidance">https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-interventional-procedures-guidance</a></td>
</tr>
<tr>
<td>MDD</td>
<td>Medical device directive</td>
<td>European Directive covering the requirements for Medical Devices in the European Economic Community</td>
<td><a href="http://ec.europa.eu/growth/sectors/medical-devices/index_en.htm">http://ec.europa.eu/growth/sectors/medical-devices/index_en.htm</a></td>
</tr>
<tr>
<td>MTAC</td>
<td>Medical Technologies Advisory Committee (NICE)</td>
<td>The committee which advises NICE on the suitability of devices and diagnostics for evaluation and routes them to the appropriate assessment programme (MTP, IPP, DAP or TAP)</td>
<td><a href="https://www.nice.org.uk/get-involved/meetings-in-public/medical-technologies-advisory-committee">https://www.nice.org.uk/get-involved/meetings-in-public/medical-technologies-advisory-committee</a></td>
</tr>
<tr>
<td>MTP</td>
<td>Medical Technologies Programme (NICE)</td>
<td>NICE approval programme. Considers a single medical device or diagnostic which provides equivalent or enhanced clinical outcomes for equivalent or reduced cost</td>
<td><a href="https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-medical-technologies-guidance">https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-medical-technologies-guidance</a></td>
</tr>
<tr>
<td></td>
<td>Medicines optimisation dashboard</td>
<td>Used by CCGs to understand how well their local populations are being supported, to optimise medicines use and inform local planning</td>
<td><a href="https://www.england.nhs.uk/ourwork/pe/mo-dash/">https://www.england.nhs.uk/ourwork/pe/mo-dash/</a></td>
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<tr>
<td></td>
<td>National Programmes of Care</td>
<td>Six National Programmes of Care (NPoC) group together the prescribed (nationally agreed range of) specialised services: Internal medicine, cancer, mental health, trauma, women and children, blood and infection</td>
<td><a href="https://www.england.nhs.uk/commissioning/spec-services/npc-crg/">https://www.england.nhs.uk/commissioning/spec-services/npc-crg/</a></td>
</tr>
<tr>
<td></td>
<td>National Tariff</td>
<td>A set of nationally agreed prices and rules which helps local Clinical Commissioning Groups work with Health Care providers, such as NHS Trusts and NHS Foundation Trusts to identify which services provide best value to their patients</td>
<td><a href="https://www.england.nhs.uk/resources/pay-syst/">https://www.england.nhs.uk/resources/pay-syst/</a></td>
</tr>
<tr>
<td></td>
<td>NHS Five Year Forward View</td>
<td>Published on 23 October 2014. Sets out a new shared vision for the future of the NHS based around the new models of care</td>
<td><a href="https://www.england.nhs.uk/ourwork/futurenhs/">https://www.england.nhs.uk/ourwork/futurenhs/</a></td>
</tr>
<tr>
<td></td>
<td>NHS Outcomes Framework</td>
<td>Provides a national overview of how well the NHS is performing and is an accountability mechanism which improves quality throughout the NHS by focusing on health outcomes not process</td>
<td><a href="https://www.england.nhs.uk/resources/resources-for-ccgs/out-frwrk/">https://www.england.nhs.uk/resources/resources-for-ccgs/out-frwrk/</a></td>
</tr>
<tr>
<td></td>
<td>Patient Advocacy groups</td>
<td>Groups and organisations which represent patients, usually with a particular disease or disability</td>
<td><a href="http://www.gmc-uk.org/information_for_you/organisations_working_for_patients.asp#2">http://www.gmc-uk.org/information_for_you/organisations_working_for_patients.asp#2</a></td>
</tr>
<tr>
<td>PPRS</td>
<td>Pharmaceutical Price Regulation Scheme</td>
<td>The PPRS is a voluntary agreement to control the prices of branded drugs sold to the NHS. It is negotiated between DH, acting on behalf of the UK government and Northern Ireland, and the branded pharmaceutical industry, represented by the ABPI</td>
<td><a href="https://www.gov.uk/government/publications/pharmaceutical-price-regulation-scheme-2014">https://www.gov.uk/government/publications/pharmaceutical-price-regulation-scheme-2014</a></td>
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<td>-</td>
<td>PRIME</td>
<td>A scheme in development by the EMA for priority medicines, to optimise the development and accelerated assessment of medicines of major public health interest</td>
<td><a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000660.jsp&amp;mid=WC0b01ac058096f643">http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000660.jsp&amp;mid=WC0b01ac058096f643</a></td>
</tr>
<tr>
<td>QOF</td>
<td>Quality and Outcomes Framework</td>
<td>The annual reward and incentive programme detailing GP practice achievement results. It rewards practices for the provision of quality care and helps standardise improvement in the delivery of primary medical services.</td>
<td><a href="http://www.hscic.gov.uk/qof">http://www.hscic.gov.uk/qof</a></td>
</tr>
<tr>
<td>-</td>
<td>Specialised Commissioning</td>
<td>Specialised services are those provided in relatively few hospitals, accessed by comparatively small numbers of patients but with catchment populations of usually more than one million. Commissioned nationally by NHS England</td>
<td><a href="https://www.england.nhs.uk/commissioning/spec-services/">https://www.england.nhs.uk/commissioning/spec-services/</a></td>
</tr>
<tr>
<td>TA</td>
<td>Technology Appraisal (NICE)</td>
<td>NICE technology appraisals are recommendations on the use of new and existing medicines and treatments within the NHS</td>
<td><a href="https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance">https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance</a></td>
</tr>
<tr>
<td>TAP</td>
<td>Technology Appraisal Programme (NICE)</td>
<td>NICE approval programme. Considers new and existing medicines and treatments through either the Single or Multiple Technology Appraisal Process. Less commonly used for devices and diagnostics</td>
<td><a href="https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance">https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance</a></td>
</tr>
<tr>
<td>-</td>
<td>Test Beds</td>
<td>These sites will evaluate the real world impact of new technologies offering both better care and better value for taxpayers, testing them together with innovations in how NHS services are delivered</td>
<td><a href="https://www.england.nhs.uk/ourwork/innovation/test-beds/">https://www.england.nhs.uk/ourwork/innovation/test-beds/</a></td>
</tr>
<tr>
<td>-</td>
<td>Vanguards</td>
<td>Individual organisations and partnerships chosen by NHS to take the lead on development of new care models which will act as the blueprints for the NHS moving forward</td>
<td><a href="https://www.england.nhs.uk/ourwork/futurenhs/new-care-models/">https://www.england.nhs.uk/ourwork/futurenhs/new-care-models/</a></td>
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