Monitor Deloitte.

Office for Life Sciences: a How To guide

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

Guide contents

Contents	Page
Purpose and how to use this guide	3
Overall pathway by stage	6
Answers to key questions for innovators	12
Pharmaceuticals pathway	34
Medical technologies pathway	60
Digital health pathway	85
Appendix, definitions and key contacts	101

Information correct as of 14th April 2016

Purpose of this guide

What does this guide cover?

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

Who should read this guide?

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.

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

Information correct as of 14th April 2016

Innovation pathway

How to use this guide

Navigate by stage

Innovation pathway

Key questions for innovators

Navigate by question

- How does the NHS work?
- What are the existing system and patient needs?
- How would my product impact the care pathway and resources required?
- Why should I develop or launch my product in the UK?
- What are the outcomes that are important to patients?
- What support and advice is available at each stage of this process?
- What investment is available?
- Who are the organisations involved in the innovation pathway in England?
- How do I let the system know my product is coming?
- What evidence do I need to collect?
- How can I test my product with patients, healthcare professionals and the NHS?
- How can I check my product links with existing systems?
- What regulatory approval do I need?
- Is there a way to accelerate the regulatory process?
- What does my company need to demonstrate for NHS procurement?
- How do I encourage a wider use of my product?
- How do I get the NHS to buy my product / get reimbursed?
- How does the NHS procure products?
- How do I strengthen my business case?

Navigate by product

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

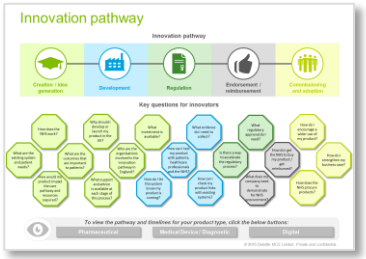
Pharmaceutical | **Medical Device / Diagnostic** | **Digital**

Information correct as of 14th April 2016

How to use this guide

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

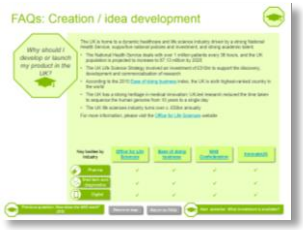
Innovation pathway and key questions for innovators



Navigate by stage

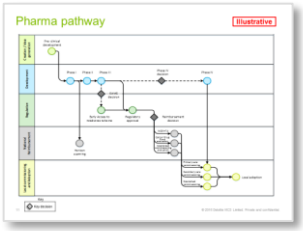
You can view a high-level pathway that applies to all products, and link to relevant organisations and online guidance

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

Information correct as of 14th April 2016

Overall pathway by stage

Creation / idea generation

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	AHSNs	Medilink	NIHR Healthcare Technology Cooperatives	Innovate UK
Pharmaceuticals	✓	✓	✓	✓
Med device / diagnostics	✓	✓	✓	✓
Digital	✓	✓	✓	✓

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

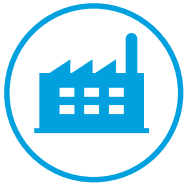
Pharmaceutical | Medical Device / Diagnostic | Digital

Return to landing page

Next phase: Development

Information correct as of 14th April 2016

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	ABHI, ABPI, BIA, BIVDA, DHACA, EMIG, AHSNs	NICE Office for Market Access	NIHR Office for Clinical Research Infrastructure	UK PharmaScan or NIHR HSRIC
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: Creation / idea generation | ***Return to landing page*** | ***Next step: Regulation***

Information correct as of 14th April 2016

Regulation

Regulation

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	British Standards Institute	EMA	MHRA	Notified Bodies
Pharmaceuticals	✓	✓	✓	✓
Med device / diagnostics	✓	✓*	✓	✓
Digital	✓		✓	✓

*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

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

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)

	AHSNs	Authorities/Trusts e.g. community / mental health	CCGs / NHS England	GP practices / Federations	Vanguards
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: National Reimbursement

Return to landing page

Information correct as of 14th April 2016

Answers to innovator questions

FAQs: Creation / idea development

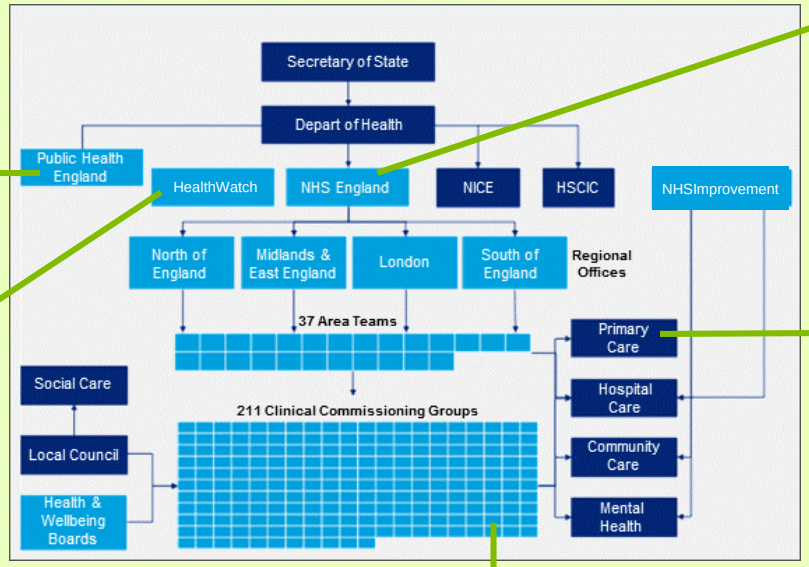
How does the NHS work? (1/2)

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:

English NHS structure

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



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

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

Return to landing page

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

Information correct as of 14th April 2016

FAQs: Creation / idea development

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:

Key bodies by industry	NHS England	Public health researchers and think tanks e.g. The King's Fund, Nuffield Trust, CASMI,
Pharmaceuticals	✓	✓
Med device / diagnostics	✓	✓
Digital	✓	✓

Previous question: How does the NHS work? (1/2)

Return to landing page

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

Information correct as of 14th April 2016

FAQs: Creation / idea development

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

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

Key bodies by industry	Ease of doing business	InnovateUK	NHS Confederation	Office for Life Sciences
Pharmaceuticals	✓	✓	✓	✓
Med device / diagnostics	✓	✓	✓	✓
Digital	✓	✓	✓	✓

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

Return to landing page

Next question: What investment is available?

Information correct as of 14th April 2016

FAQs: Creation / idea development

What investment is available?

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	AHSNs	InnovateUK	NIHR	Office for Life Sciences
Pharmaceuticals	✓	✓	✓	✓
Med device / diagnostics	✓	✓	✓	✓
Digital	✓	✓	✓	✓

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

Return to landing page

Next: What are the existing system and patient needs?

Information correct as of 14th April 2016

FAQs: Creation / idea development

What are the existing system and patient needs?

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	AHSNs	CCGs or NHS England	Trusts, e.g. mental health, acute, GPs
Pharmaceuticals	✓	✓	✓
Med device / diagnostics	✓	✓	✓
Digital	✓	✓	✓

Previous question: What investment is available?

Return to landing page

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

Information correct as of 14th April 2016

FAQs: Creation / idea development

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

Key bodies by industry	AHSNs	CCGs	GMC: Charities	James Lind Alliance
Pharmaceuticals	✓	✓	✓	✓
Med device / diagnostics	✓	✓	✓	✓
Digital	✓	✓	✓	✓

Previous question: What are the existing system and patient needs?

Return to landing page

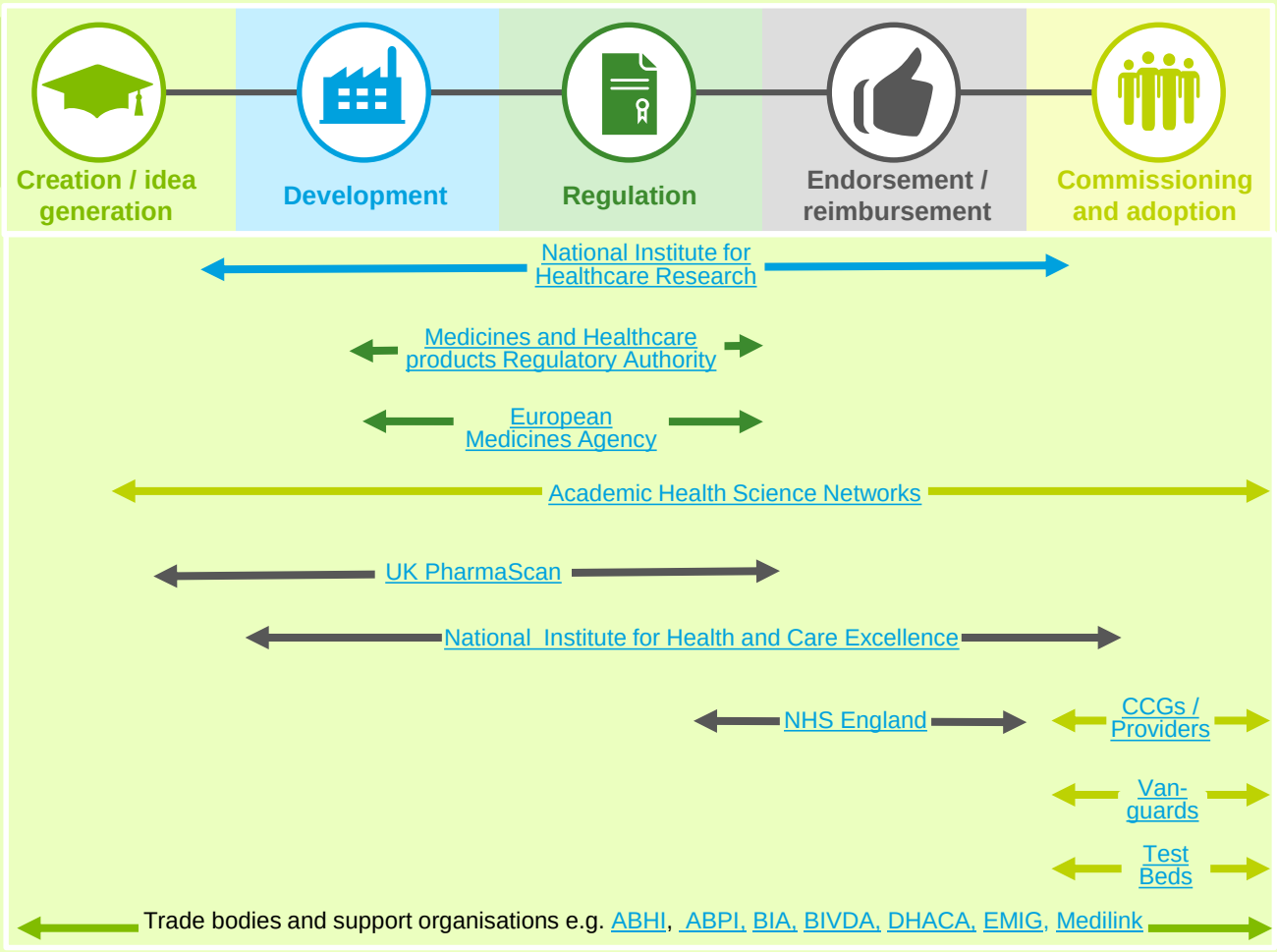
Next question: Who are the organisations involved in the innovation pathway in the UK?

Information correct as of 14th April 2016

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:



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

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

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	AHSNs	GMC: Charities	Vanguards
Pharmaceuticals	✓	✓	✓
Med device / diagnostics	✓	✓	✓
Digital	✓	✓	✓

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

Return to landing page

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

Information correct as of 14th April 2016

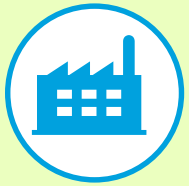
FAQs: Creation / idea development

What support and advice is available at each stage of this process? (1/2)

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

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

Return to landing page

Next: What support is available at each stage in this process? (2/2)

Information correct as of 14th April 2016

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	AHSNs	MHRA	NICE Office for Market access	NHS Supply Chain
Pharmaceuticals	✓	✓	✓	✓
Med device / diagnostics	✓	✓	✓	✓
Digital	✓	✓	✓	✓

Previous: What support and advice is available at each stage in this process? (1/2)

Return to landing page

Next: What evidence do I need to collect?

FAQs: Development

What evidence do I need to collect?

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.

Key bodies by industry	EMA, MHRA or Notified Bodies	NICE Office for Market access	NOCRI
Pharmaceuticals	✓	✓	✓
Med device / diagnostics	✓	✓	✓
Digital	✓	✓	✓

Previous: What support is available at each stage in this process? (2/2)

Return to landing page

Next: How can I test my product with patients, healthcare professionals and the NHS?

FAQs: Development

How can I test my product with patients, healthcare professionals and the NHS?

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

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.

Key bodies by industry	Clinical Reference Groups	GMC: Organisations working with patients	NOCRI
Pharmaceuticals	✓	✓	✓
Med device / diagnostics	✓	✓	✓
Digital	✓	✓	✓

Previous: What evidence do I need to collect?

Return to landing page

Next: How do I let the system know my product is coming?

Information correct as of 14th April 2016

FAQs: Development

How do I let the system know my product is coming?

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	MHRA Scientific Advice	NICE Office for Market access	NIHR HSRIC	UK PharmaScan
Pharmaceuticals	✓	✓	✓	✓
Med device / diagnostics	✓		✓	
Digital	✓		✓	

Previous: How can I test my product with patients, healthcare professionals and the NHS?

Return to landing page

Next: How can I check my product links with existing systems?

Information correct as of 14th April 2016

FAQs: Development

How can I check my product links with existing systems?

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	AHSN	NHS Digital Technology
Pharmaceuticals	✓	✓
Med device / diagnostics	✓	✓
Digital	✓	✓

Previous: How do I let the system know my product is coming?

Return to landing page

Next: what regulatory approval do I need?

Information correct as of 14th April 2016

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	EMA	MHRA
Pharmaceuticals	✓	✓
Med device / diagnostics	✓*	✓
Digital		✓

*For medical devices only

Previous: How can I check my product links with existing systems?

Return to landing page

Next: Is there a way to accelerate the regulatory process?

Information correct as of 14th April 2016

FAQs: Regulation

Is there a way to accelerate the regulatory process?

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.

Key bodies by industry	MHRA	EMA
Pharmaceuticals	✓	✓
Med device / diagnostics	✓	✓*
Digital	✓	

*For technologies involving a pharmaceutical only

Previous: What regulatory approval do I need?

Return to landing page

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

FAQs: Endorsement / reimbursement

How do I get the NHS to buy my product / get reimbursement?

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 heath 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:

Key bodies by industry	AHSNs	Cancer Drugs Fund	NHS BSA: Drug tariff	NICE Office for Market access	Specialised com-missioning
Pharmaceuticals	✓	✓	✓	✓	✓
Med device / diagnostics	✓	✓	✓	✓	✓
Digital	✓			✓	

Previous: Is there a way to accelerate the regulatory process?

Return to landing page

Next: What does my company need to demonstrate for NHS procurement?

FAQs: Endorsement / reimbursement

What does my company need to demonstrate for NHS procurement?

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

Key bodies by industry	Gov.uk procurement	NHS Supply Chain
Pharmaceuticals	✓	✓
Med device / diagnostics	✓	✓
Digital	✓	✓

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

Return to landing page

Next: How does the NHS procure products?

Information correct as of 14th April 2016

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

Key bodies by industry	AHSNs	Commercial Medicines Unit	National Framework tenders	NHS Supply Chain	NHS structure (The King's Fund)
Pharmaceuticals	✓	✓	✓	✓	✓
Med device / diagnostics	✓		✓	✓	✓
Digital	✓		✓	✓	✓

Previous: What does my company need to demonstrate for NHS procurement?

Return to landing page

Next: How do I encourage a wider use of my product?

Information correct as of 14th April 2016

FAQs: Commissioning and adoption

How do I encourage a wider use of my product?

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	Innovation Scorecard	Medicines Optimisation	NHS Supply Chain	NICE Implementation Collaborative
Pharmaceuticals	✓	✓	✓	✓
Med device / diagnostics	✓		✓	✓
Digital	✓		✓	✓

Previous: How does the NHS procure products?

Return to landing page

Next: How do I strengthen my business case?

Information correct as of 14th April 2016

FAQs: Commissioning and adoption

How do I strengthen my business case?

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 t**o 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:

Key bodies by industry	ABPI: Real World Data	AHSNs	James Lind Alliance	NICE Office for Market Access	The King's Fund
Pharmaceuticals	✓	✓	✓	✓	✓
Med device / diagnostics		✓	✓	✓	✓
Digital		✓	✓	✓	✓

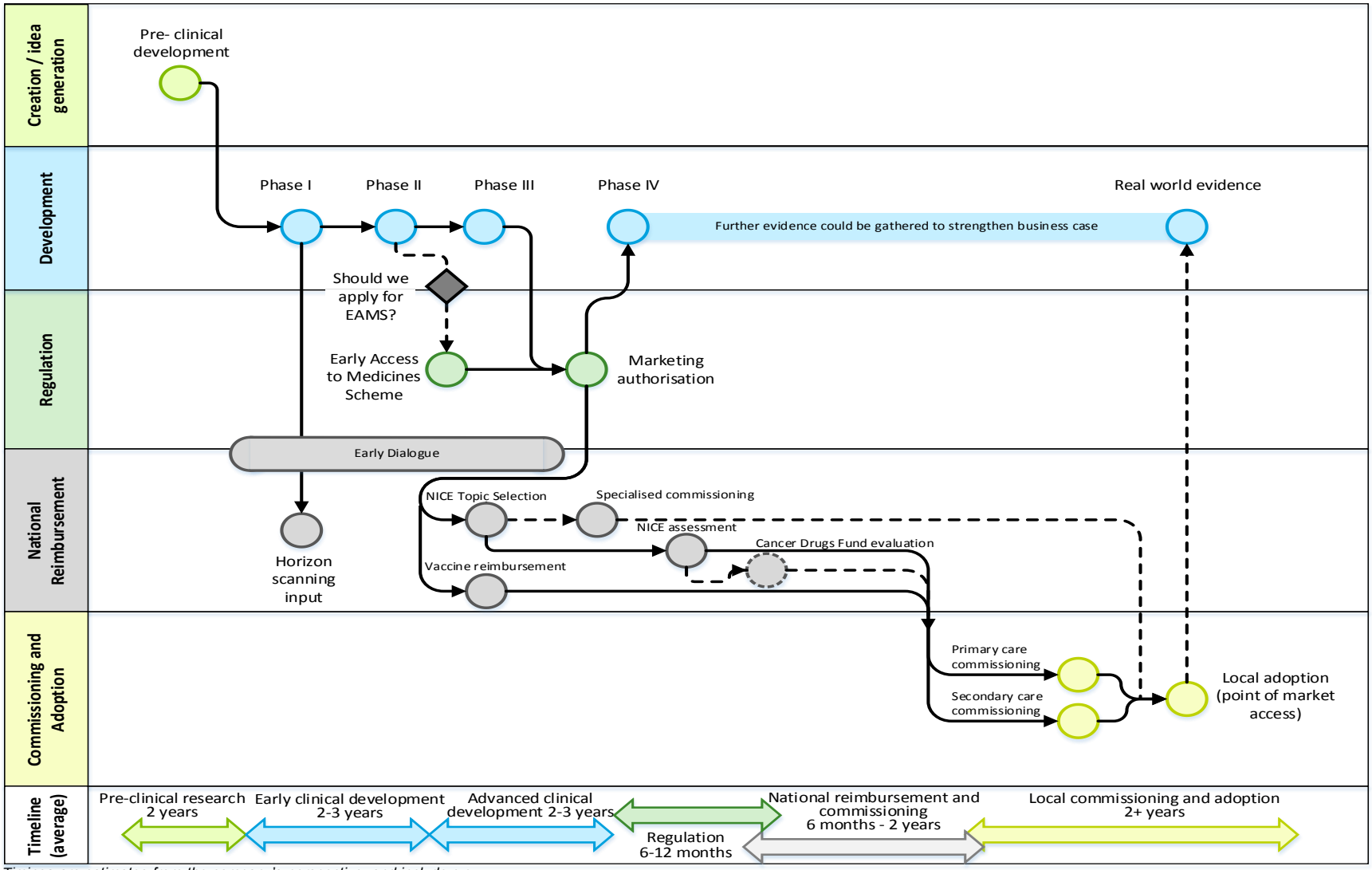
Previous: How do I encourage a wider use of my product?

Return to landing page

Information correct as of 14th April 2016

Pharmaceutical pathway

Pharmaceutical pathway



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

Return to landing page

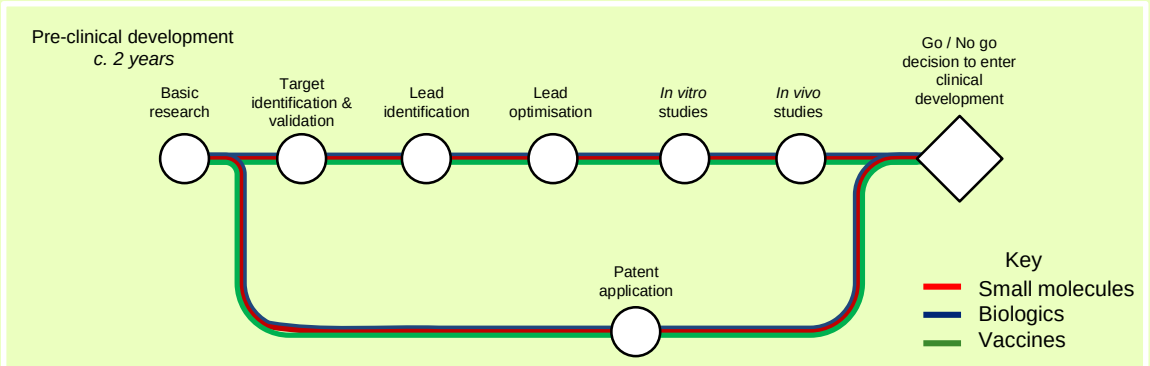
Information correct as of 14th April 2016

Creation / idea generation

Pre-clinical development

DESCRIPTION

- 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)

ADDITIONAL RESOURCES

Key organisations

- Intellectual Property Office
- MHRA
- World Intellectual Property Organisation

Process guidance *(if available)*

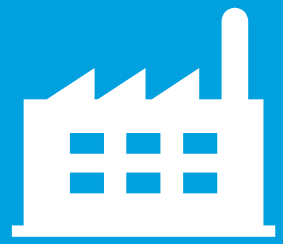
- Health Technologies Adoption Programme- Building a business case guidance
- Health Technologies Adoption Programme- Mapping care pathways guidance

Other resources

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

Return to map | Return to FAQs | Next step: Phase I and II

Information correct as of 14th April 2016

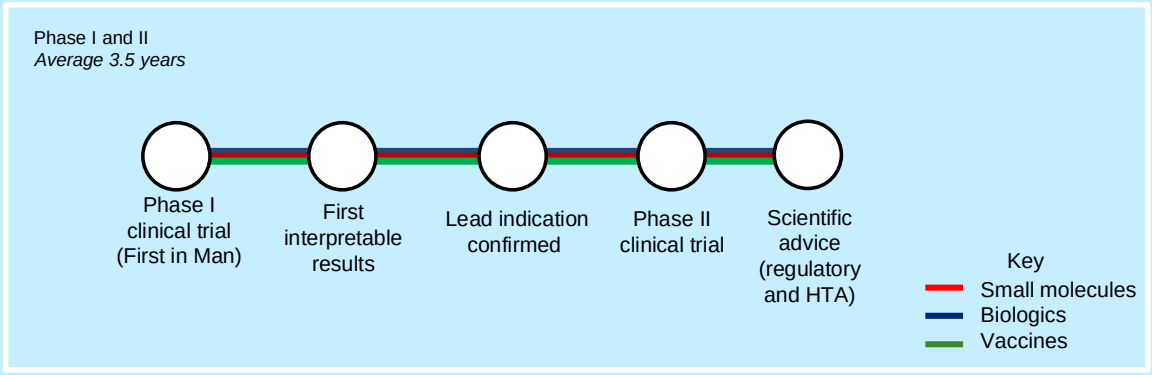


Development

Phase I and II

DESCRIPTION

- 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



CHECKLIST

- ❑ 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)

ADDITIONAL RESOURCES

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 trails toolkit

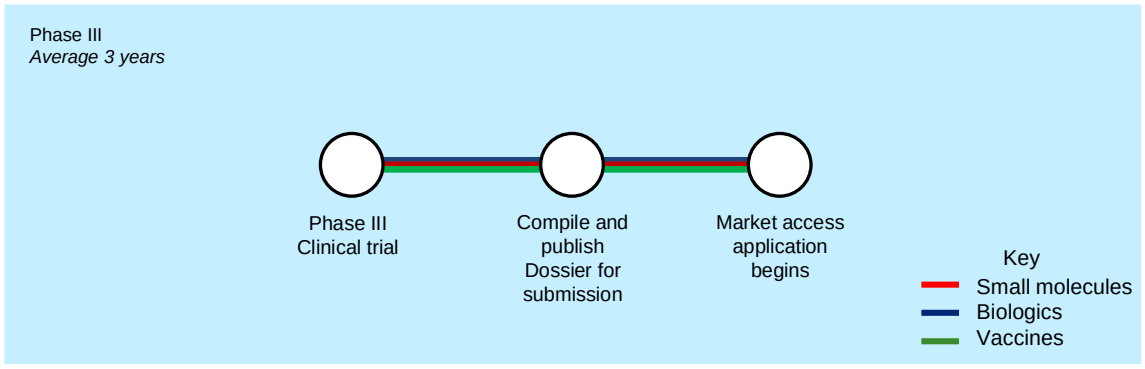
Previous step: Preclinical development | Return to map | Return to FAQs | Next step: Phase III

Information correct as of 14th April 2016

Phase III

DESCRIPTION

- 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 trails 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

ADDITIONAL RESOURCES

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

Previous step: Phase I and II

Return to map

Return to FAQs

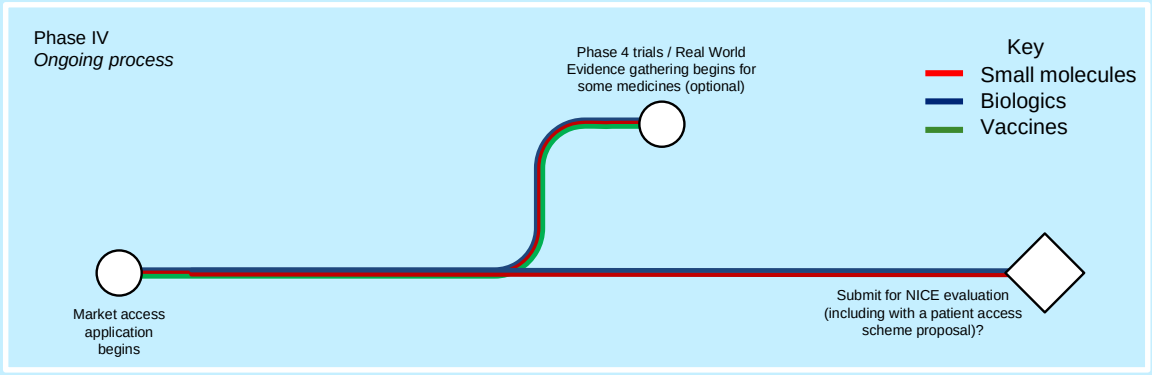
Next step: Regulatory approval

Information correct as of 14th April 2016

Phase IV

DESCRIPTION

- 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

ADDITIONAL RESOURCES

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

Previous step: Regulatory approval

Return to map

Return to FAQs

Next step: Reimbursement / commissioning / adoption

Information correct as of 14th April 2016

Regulation

Should we apply for EAMS?

DESCRIPTION

- 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

ADDITIONAL RESOURCES

Key organisations

- MHRA

Process guidance *(if available)*

- Guidance for applicants of EAMS (step I)
- Guidance for applicants of EAMS (step II)

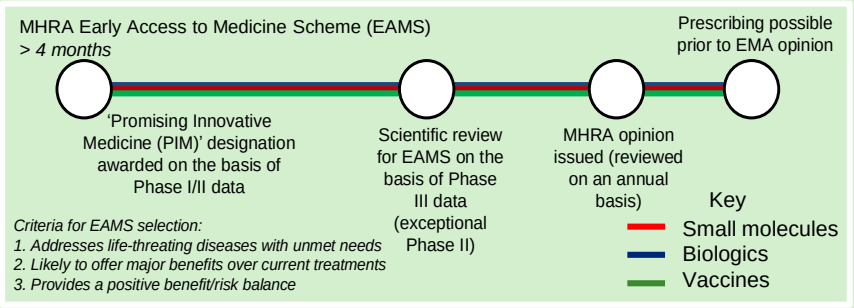
Other resources

- ABPI and BIA guide to EAMS
- Apply for EAMS- overview and guidance

Early Access to Medicines Scheme

DESCRIPTION

- 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

CHECKLIST

- ❑ Engage early with MHRA through scientific advice meetings / the Innovation Office
- ❑ Gather evidence to support PIMS criteria
- ❑ Gain a positive PIM designation before applying for MHRA scientific review
- ❑ Engage early with NICE, NHS England and devolved administrations as required

ADDITIONAL RESOURCES

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

Previous step: Should we apply for EAMS?

Return to map

Return to FAQs

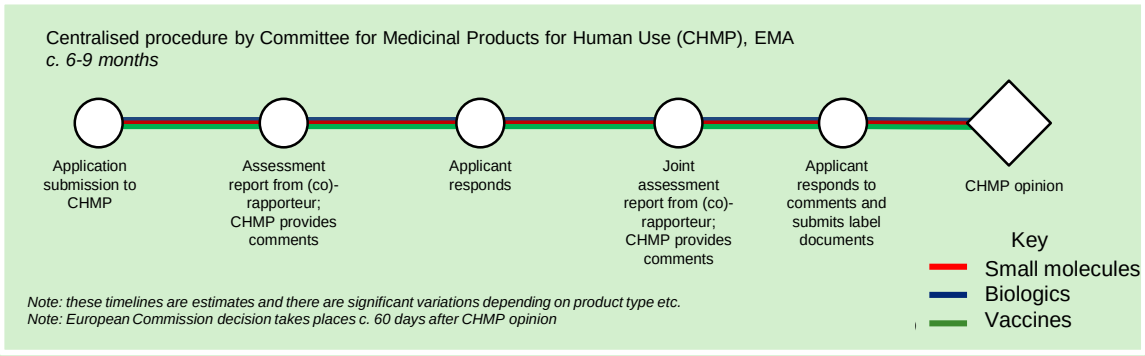
Next step: Regulatory approval

Information correct as of 14th April 2016

Regulatory Approval

DESCRIPTION

- 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

Previous step: Phase III

Return to map

Return to FAQs

Next step: NICE Topic selection

Information correct as of 14th April 2016

Regulatory Approval

CHECKLIST

- ❑ 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

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

Information correct as of 14th April 2016

Endorsement / reimbursement

Horizon scanning input (1/2)

DESCRIPTION

- 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

Horizon scanning input (2/2)

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

ADDITIONAL RESOURCES

Key organisations

- UK PharmaScan

Process guidance *(if available)*

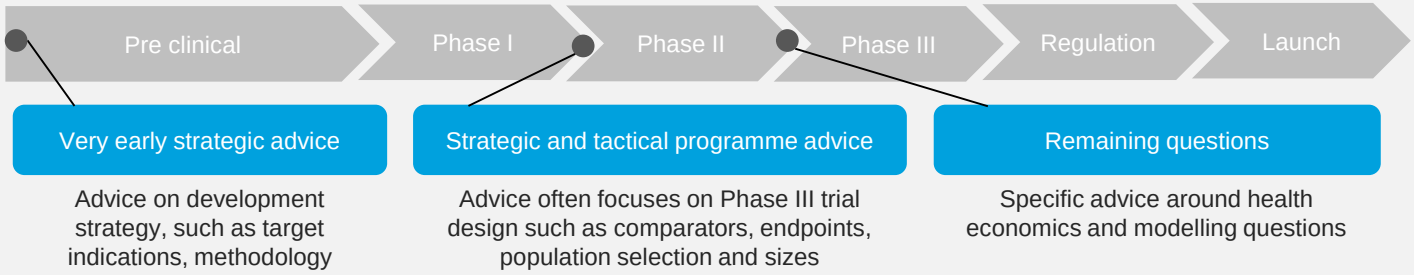
- UK PharmaScan: how to register

Other resources

- ABPI: UK PharmaScan

Early Dialogue

DESCRIPTION



- 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.

CHECKLIST

- ❑ Contact key organisations in advance of early dialogue to understand data and evidence requirements
- ❑ Have a plan for communicating feedback from early dialogue to internal stakeholders
- ❑ Use early dialogue outputs to design 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

ADDITIONAL RESOURCES

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

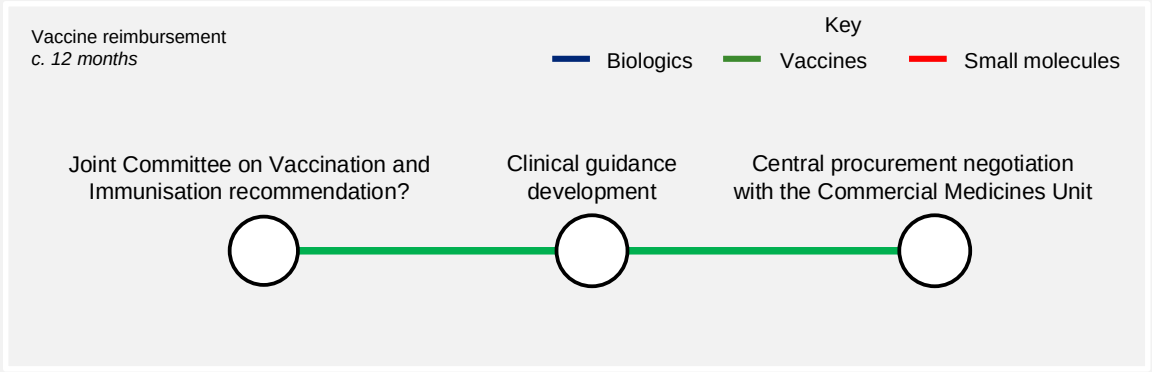
Previous step: Phase I and II | *Return to map* | *Return to FAQs* | *Next step: Phase III*

Information correct as of 14th April 2016

Vaccine reimbursement

DESCRIPTION

- 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



CHECKLIST

- ❑ 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

ADDITIONAL RESOURCES

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

Previous step: Regulatory approval

Return to map

Return to FAQs

Next step: Secondary care commissioning

Information correct as of 14th April 2016

NICE Topic Selection

DESCRIPTION

- 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

CHECKLIST

- ❑ Review prioritisation criteria as early as possible
- ❑ Ensure product is on UK PharmaScan
- ❑ Ensure evidence available is in line with NICE health technology assessments

ADDITIONAL RESOURCES

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

Previous step: Regulatory approval

Return to map

Return to FAQs

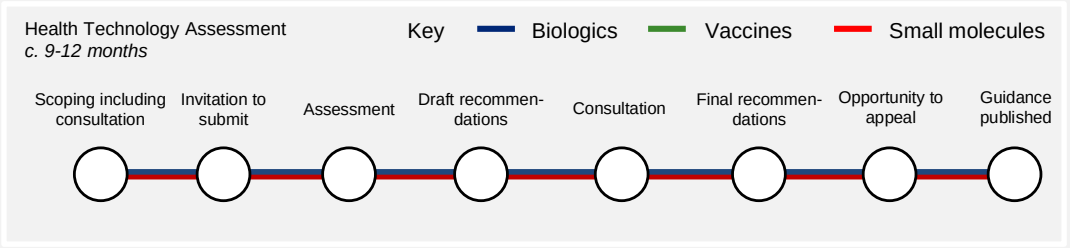
Next step: NICE Assessment or Specialised Commissioning

Information correct as of 14th April 2016

NICE Assessment

DESCRIPTION

- 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

Key organisations

- 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

Previous step: NICE Topic Selection

Return to map

Return to FAQs

Next step: Primary or Secondary Care Commissioning

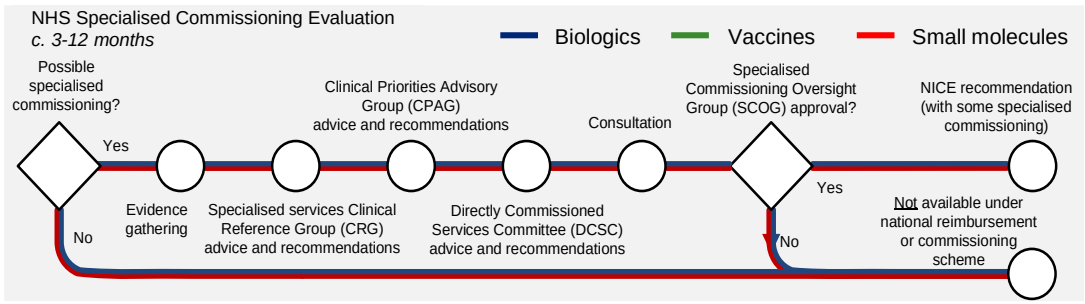
Information correct as of 14th April 2016

Specialised Commissioning (1/2)

NB. On 12th April NHSE launched a consultation on a new process for specialised commissioning.

DESCRIPTION

- 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)

NB. On 12th April NHSE launched a consultation on a new process for specialised commissioning.

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

ADDITIONAL RESOURCES

Key organisations

- NHS England (Specialised Services)

Process guidance *(if available)*

Other resources

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

Information correct as of 14th April 2016

Cancer Drugs Fund evaluation

ILLUSTRATIVE CONTENT BASED ON PUBLIC CONSULTATION, SUBJECT TO CHANGE

DESCRIPTION

- 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

CHECKLIST

- ❑ 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

ADDITIONAL RESOURCES

Key organisations

- National Programmes of Care and Clinical Reference Groups

Process guidance *(if available)*

Other resources

- Cancer Drugs Fund
- CDF decision summaries

Previous step: NICE Assessment

Return to map

Return to FAQs

Next step: Primary or Secondary Care Commissioning

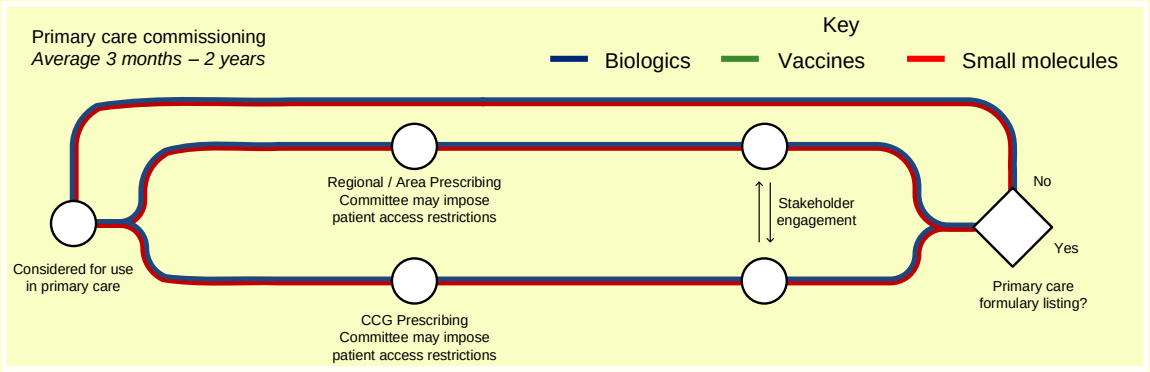
Information correct as of 14th April 2016

Local Commissioning and Adoption

Primary Care Commissioning

DESCRIPTION

- 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



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 Commissioning, Clinical Leads)
  - Financial stakeholders (e.g. Finance Directors)
- ❑ Consider engagement with patients (e.g. via advocacy groups) and healthcare professionals to disseminate information

ADDITIONAL RESOURCES

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

Previous step: NICE Assessment, CDF or Specialised Commissioning

Return to map

Return to FAQs

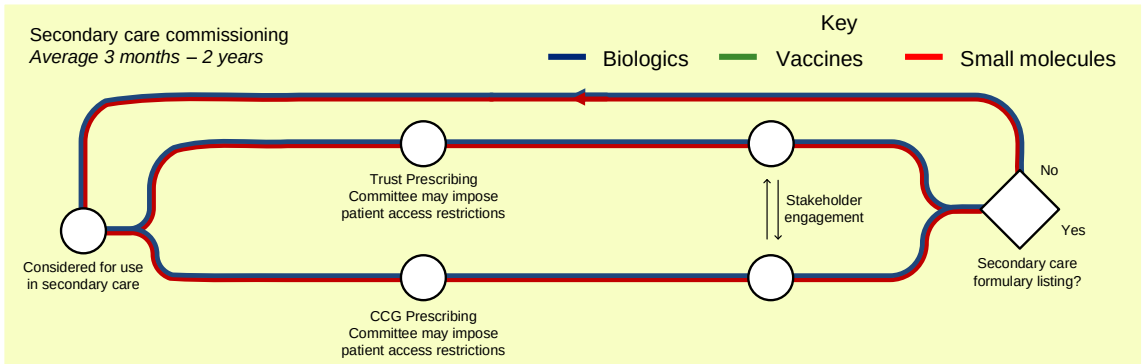
Next Step: Local Adoption

Information correct as of 14th April 2016

Secondary Care Commissioning

DESCRIPTION

- 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

ADDITIONAL RESOURCES

Key organisations

- AHSNs
- CCGs / Trust Prescribing Committees
- NHS Vanguard Sites 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

Previous step: NICE Assessment, CDF or Specialised Commissioning

Return to map

Return to FAQs

Next Step: Local Adoption

Information correct as of 14th April 2016

Local Adoption

DESCRIPTION

- 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

CHECKLIST

- ❑ 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

ADDITIONAL RESOURCES

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

Previous step: Primary, Secondary or Specialised Commissioning

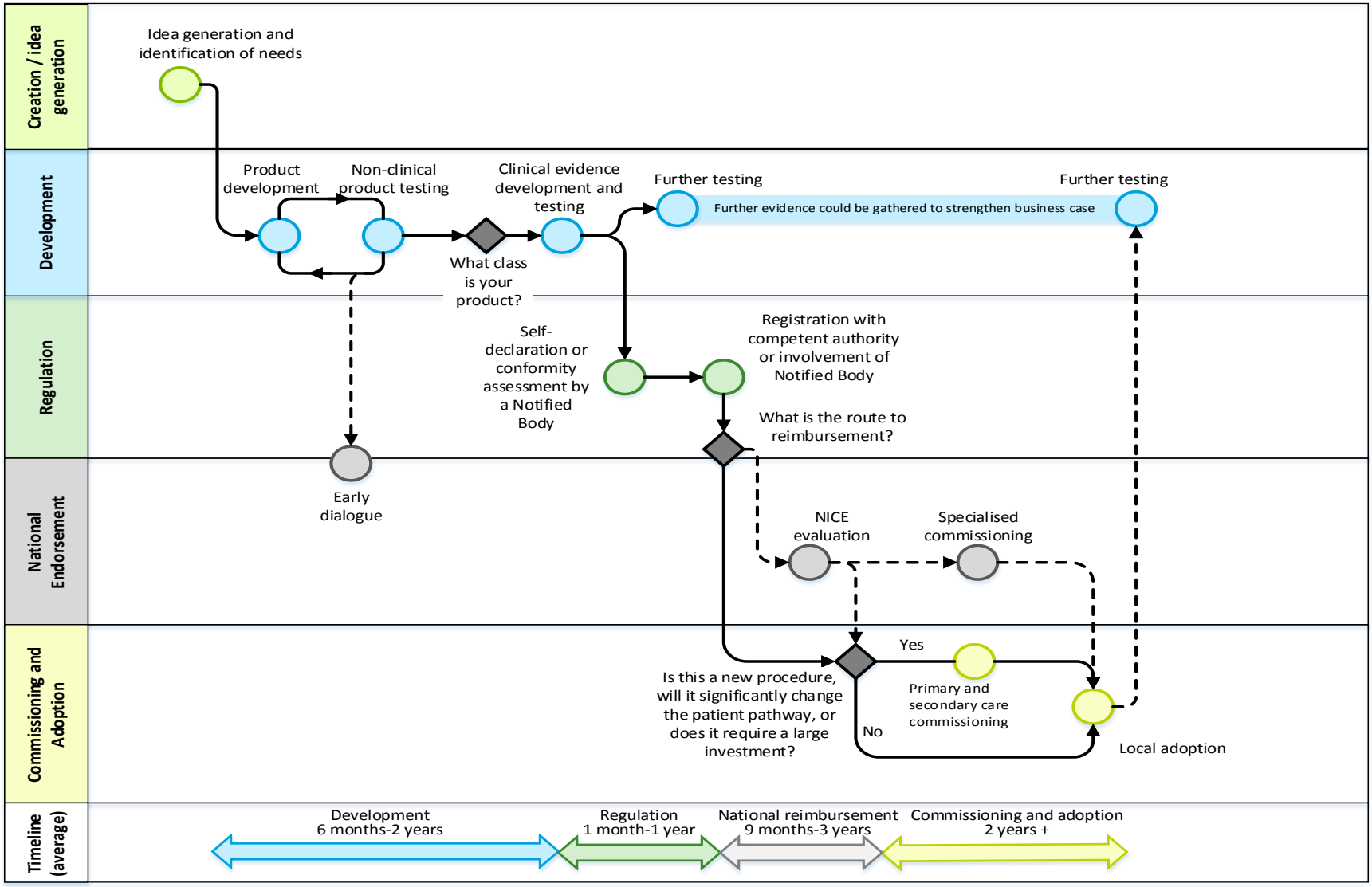
Return to map

Return to FAQs

Information correct as of 14th April 2016

Medical devices and in vitro diagnostics (IVD) pathway

Medical technology and IVD pathway



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

Return to landing page

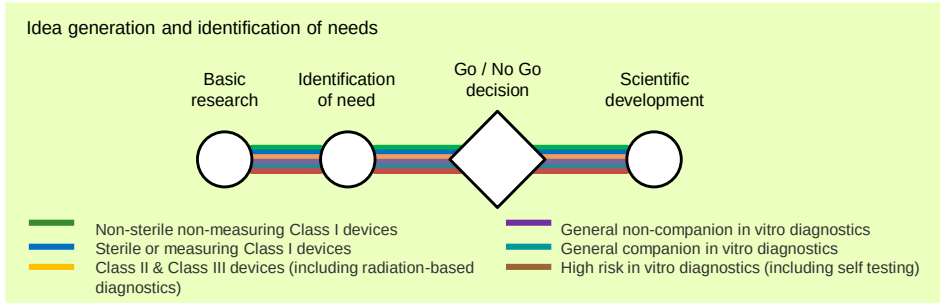
Information correct as of 14th April 2016

Creation / idea generation

Idea generation and identification of needs (1/2)

DESCRIPTION

- 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

Information correct as of 14th April 2016

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

ADDITIONAL RESOURCES

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)*

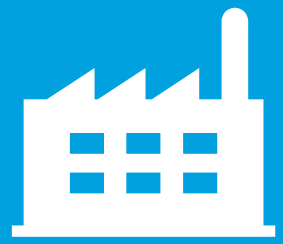
- Health Technologies Adoption programme- Building a business case guidance
- Health Technologies Adoption programme- Mapping care pathways guidance
- The King's Fund guide to the NHS

Other resources

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

Return to map *Return to FAQs* *Next step: Product development and testing*

Information correct as of 14th April 2016

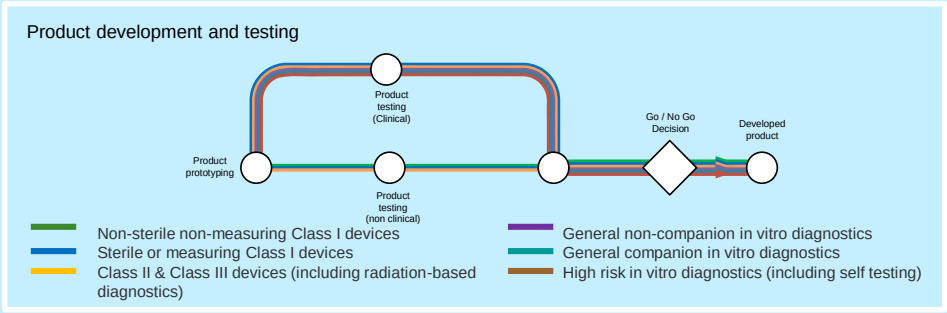


Development

Product development and testing

DESCRIPTION

- 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



CHECKLIST

- ❑ 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

ADDITIONAL RESOURCES

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?

DESCRIPTION

- 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

ADDITIONAL RESOURCES

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)

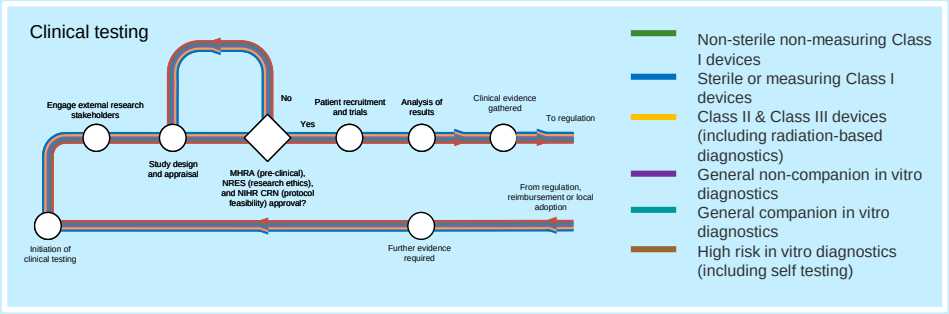
Other resources

- NIHR Clinical Research Network Centre

Clinical evidence development and testing

DESCRIPTION

- 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



CHECKLIST

- ❑ 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

ADDITIONAL RESOURCES

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

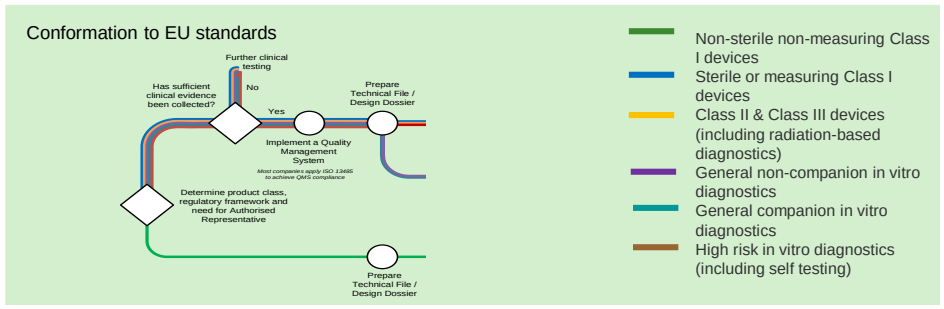
Next step: Conformation to EU standards

Regulation

Self-declaration or conformity assessment by a Notified Body (1/2)

DESCRIPTION

- 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)

CHECKLIST

- ❑ 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

ADDITIONAL RESOURCES

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

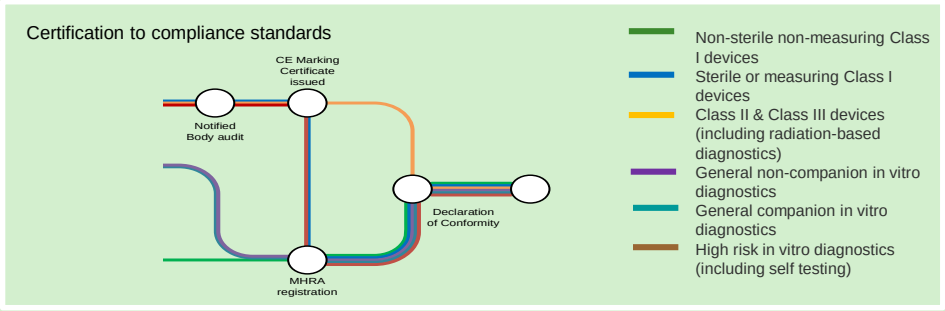
- CE approval process for different classes
- Harmonised standards for medical devices

Information correct as of 14th April 2016

Registration with competent authority or involvement of Notified Body

DESCRIPTION

- 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.)

ADDITIONAL RESOURCES

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

Previous step: Conformation to EU standards

Return to map

Return to FAQs

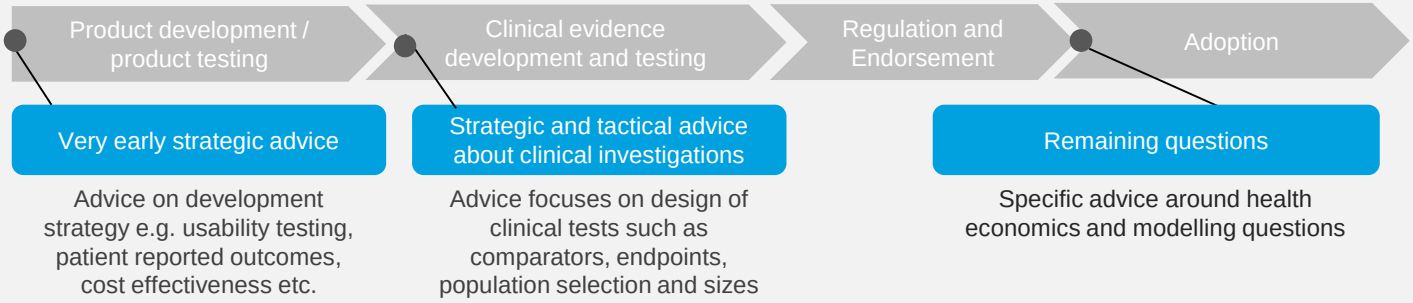
Next step: What is the route to reimbursement?

Information correct as of 14th April 2016

National endorsement

Early Dialogue

DESCRIPTION



- 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.

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
- ❑ Consider what UK clinical practice might look like at the time of a NICE appraisal, which can affect appropriate comparators

ADDITIONAL RESOURCES

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

Previous step: Product development and testing

Return to map

Return to FAQs

What class is your product?

Information correct as of 14th April 2016

What is the route to reimbursement?

DESCRIPTION

- 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

ADDITIONAL RESOURCES

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

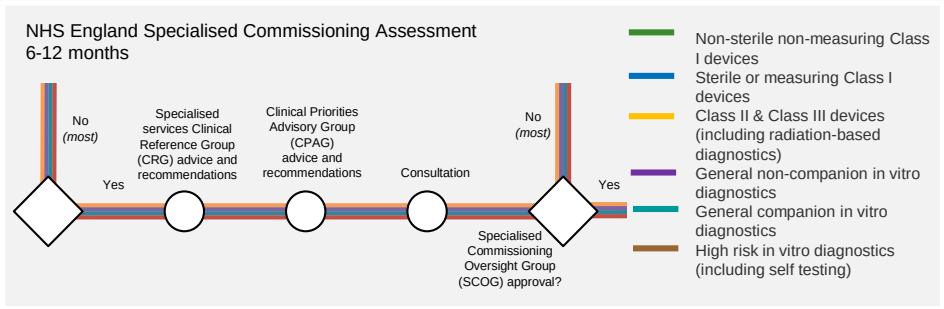
- DAP
- IPP
- MTP
- Online evidence search
- TAP

Information correct as of 14th April 2016

Specialised Commissioning (1/2)

DESCRIPTION

- 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

Return to map Return to FAQs

Information correct as of 14th April 2016

Specialised Commissioning (2/2)

CHECKLIST

- ❑ 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

ADDITIONAL RESOURCES

Key organisations

- NHS England (Specialised Services)

Process guidance *(if available)*

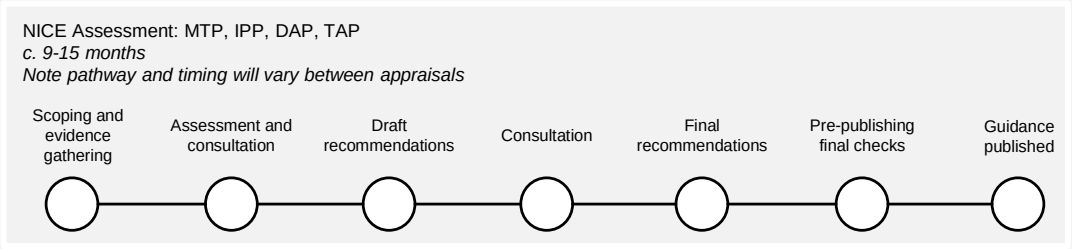
Other resources

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

NICE Evaluation (1/2)

DESCRIPTION

- 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

Return to map *Return to FAQs*

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

Key organisations

- MTAC
- MTEP
- NICE Office for Market Access

Process guidance *(if available)*

- MTEP process and methods guidance
- Programme eligibility criteria

Other resources

- DAP
- IPP
- MTP
- Online evidence search
- TAP

Previous step: What is the route to reimbursement?

Return to map

Return to FAQs

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

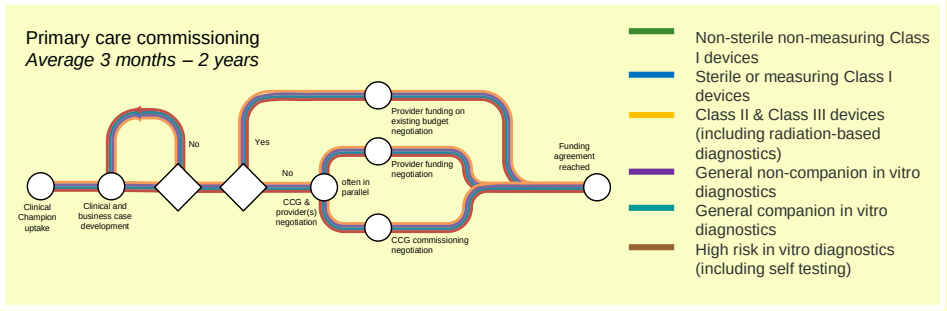
- Innovation Scorecard
- National Tariff

Information correct as of 14th April 2016

Primary and Secondary Care Commissioning

DESCRIPTION

- 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

ADDITIONAL RESOURCES

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

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

Return to map

Return to FAQs

Next step: Local adoption

Information correct as of 14th April 2016

Local Adoption (1/2)

DESCRIPTION

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

Information correct as of 14th April 2016

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

ADDITIONAL RESOURCES

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

Previous step: Primary and Secondary Care Commissioning

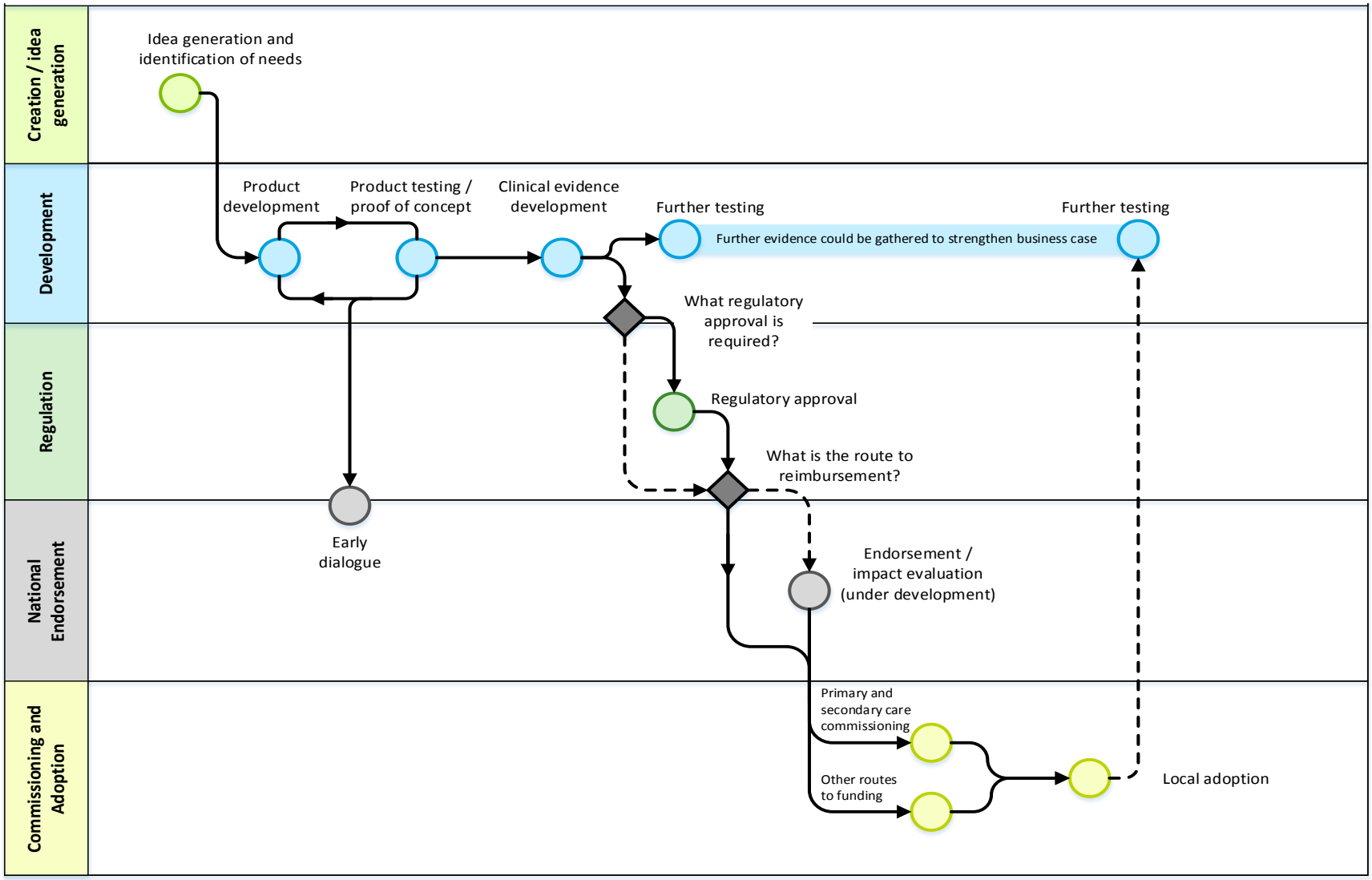
Return to map

Return to FAQs

Information correct as of 14th April 2016

Digital health pathway

Digital health pathway



Return to landing page

Information correct as of 14th April 2016

Creation / idea generation

Idea generation and identification of needs (1/2)

DESCRIPTION

- 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

Idea generation and identification of needs (2/2)

DESCRIPTION

- 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

CHECKLIST

- ❑ View CCG and NHS priorities (e.g. NHS England Five Year Forward View) to see whether your product (particularly relevant for B2B companies) addresses an unmet need
- ❑ Identify potential end user, buyer and other key stakeholders (e.g. hospital, system integrators, Lead Providers / Commissioning Support Units etc.)
- ❑ Determine potential demand and identify competitive technologies
- ❑ Consult healthcare practitioners to understand the current care pathway and how your technology might impact this
- ❑ Identify patient needs through patient advocacy groups, charities and patient online platforms such as HealthUnlocked
- ❑ Consider national / international data and privacy regulations
- ❑ Identify what type of IP protection is required and which locations could be covered (e.g. UK or international)
- ❑ Start to identify possible future clinical champions or partners to involve in development and uptake of your device
- ❑ Consider business requirements for companies selling to the NHS
- ❑ Identify any AHSNs which may have an interest in your product using the AHSN priorities matrix

ADDITIONAL RESOURCES

Key organisations

- Academic Health Science Networks
- CCGs
- Digital Health and Care Alliance
- techUK
- Innovate UK
- National Information Board

Process guidance *(if available)*

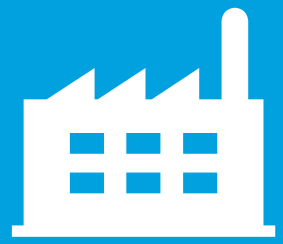
- Building a business case guidance
- DHACA Medical Apps Process
- Mapping care pathways guidance
- NHS Innovations South East: An NHS Guide for developing Mobile Healthcare Applications

Other resources

- Interoperability Toolkit
- Information Governance Toolkit
- Medilink
- NHS Choices Health Apps Library (currently being upgraded)
- NHS England Five Year Forward View
- Patient platforms e.g. HealthUnlocked
- SEHTA / Digital Health London

Return to map *Return to FAQs* *Next step: Product development, testing and proof of concept*

Information correct as of 14th April 2016



Development

Product development, testing and proof of concept

DESCRIPTION

- 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

CHECKLIST

- ❑ 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)

ADDITIONAL RESOURCES

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

Previous step: Idea generation and identification of needs

Return to map

Return to FAQs

Next step: Clinical evidence development

Information correct as of 14th April 2016

Clinical evidence development

DESCRIPTION

- 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 be 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

CHECKLIST

- ❑ 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

ADDITIONAL RESOURCES

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

Previous step: Product development, testing and proof of concept

Return to map

Return to FAQs

Next step: Regulatory approval

Information correct as of 14th April 2016

Regulation

Regulatory Approval

DESCRIPTION

- 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

CHECKLIST

- ❑ Ensure your product addresses the Caldicott Principles
- ❑ Understand 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

ADDITIONAL RESOURCES

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

Return to map

Return to FAQs

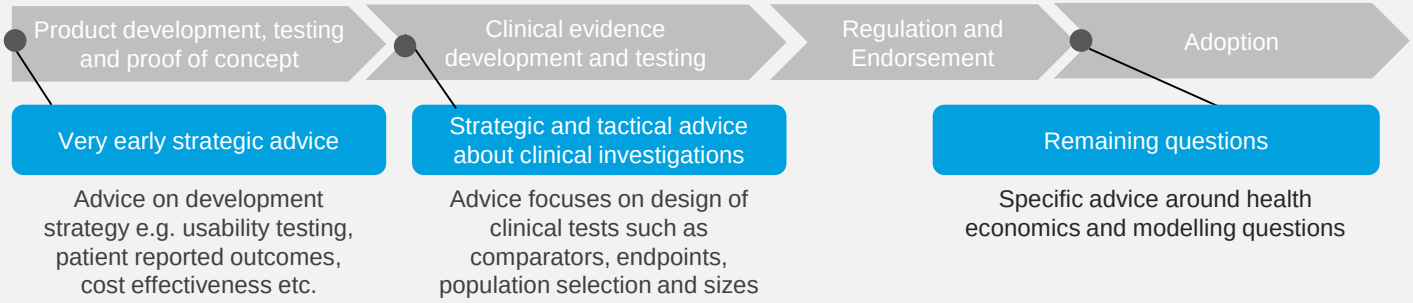
Next step: Endorsement / impact evaluation

Information correct as of 14th April 2016

National endorsement

Early Dialogue

DESCRIPTION



- 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

ADDITIONAL RESOURCES

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

Previous step: Product development, testing and proof of concept

Return to map

Return to FAQs

Clinical evidence development

Information correct as of 14th April 2016

Endorsement / impact evaluation

DESCRIPTION

- 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

CHECKLIST

- ❑ 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

ADDITIONAL RESOURCES

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

Previous step: Regulatory approval | ***Return to map*** | ***Return to FAQs*** | ***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)

ADDITIONAL RESOURCES

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

Previous step: Endorsement / impact evaluation

Return to map

Return to FAQs

Next step: Local adoption

Information correct as of 14th April 2016

Other routes to funding (e.g. self pay)

DESCRIPTION

- 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

ADDITIONAL RESOURCES

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

Return to map

Return to FAQs

Next step: Local adoption

Information correct as of 14th April 2016

Local Adoption

DESCRIPTION

- 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

CHECKLIST

- ❑ 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

ADDITIONAL RESOURCES

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

Previous step: Primary or Secondary care or other routes to funding

Return to map

Return to FAQs

Information correct as of 14th April 2016

Appendix, Definitions and Key Contacts

Return to landing page

Directory: Public bodies and definitions

Acronym	Name	Description	When to contact	Link
AHSN	Academic Health Science Network	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.	Across innovation pathway to test ideas and stimulate adoption	https://www.england.nhs.uk/ourwork/part-rel/ahsn/
AWSMG	All Wales Strategy Medicines Group	Provides advice on medicines management and prescribing to the Welsh Government's Minister for Health and Social Services	-	http://www.awmsg.org/
BRC	Biomedical Research Centre (NIHR)	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	At development / clinical testing stage	http://www.nihr.ac.uk/about/biomedical-research-centres.htm
BRU	Biomedical Research Units (NIHR)	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.	At development / clinical testing stage	http://www.nihr.ac.uk/about/biomedical-research-units.htm
CDF	Cancer Drugs Fund	A managed access fund which provides funding for cancer drugs	For pharma companies seeking clarity on CDF in the lead in to Technology Appraisal	https://www.england.nhs.uk/ourwork/cancer/cdf/
CCG	Clinical Commissioning Group	Responsible for planning and commissioning health care services for their local area	Across innovation pathway to test ideas and stimulate adoption	http://www.nhscc.org/ccgs/
CPAG	Clinical Priorities Advisory Group	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	At endorsement / reimbursement stage	https://www.england.nhs.uk/commissioning/cpag/
CRG	Clinical Reference Groups	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.	For companies with a product that may be commissioned by specialised services	https://www.england.nhs.uk/commissioning/spec-services/npc-crg/

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

Information correct as of 14th April 2016

Return to landing page

Directory: Public bodies and definitions

Acronym	Name	Description	When to contact	Link
CRN	Clinical Research Network (NIHR)	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	At development / clinical testing stage	https://www.crn.nihr.ac.uk/
CLARHCs	Collaborations for Leadership in Applied Health Research and Care	CLAHRCs conduct applied health research across the NHS, and translate research findings into improved outcomes for patients.	At development / clinical testing stage	http://www.nihr.ac.uk/about/collaborations-for-leadership-in-applied-health-research-and-care.htm
CMU	Commercial Medicines Unit	The CMU is part of the Medicine, Pharmacy and Industry Group of the Department of Health which looks at supply and procurement in hospitals	For pharmaceutical companies following marketing authorisation	https://www.gov.uk/government/collections/commercial-medicines-unit-cmu
CMA	Competition and Markets Authority	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.	-	https://www.gov.uk/government/organisations/competition-and-markets-authority
CPRD	Clinical Practice Research Datalink	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	-	https://www.cprd.com/intro.asp
DH	Department of Health	A ministerial department which leads, shapes and funds health and care in England	-	https://www.gov.uk/government/organisations/department-of-health
DECs	Diagnostic Evidence Co-operatives (NIHR)	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	At development / clinical testing stage	http://www.nihr.ac.uk/about/diagnostic-evidence-co-operatives.htm
EME	Efficiency and Mechanism Evaluation Programme	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.	At development / clinical testing stage	http://www.nets.nihr.ac.uk/programmes/eme
EMA	European Medicines Agency	Responsible for the scientific evaluation, supervision and safety monitoring of medicines developed by pharmaceutical companies for use in the EU	For all companies seeking EU regulatory approval	http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000235.jsp&mid=

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

Information correct as of 14th April 2016

Return to landing page

Directory: Public bodies and definitions

Acronym	Name	Description	When to contact	Link
HSCIC	Health and Social Care Information Centre	National provider of information, data and IT systems for commissioners, analysts and clinicians in health and social care	For all companies seeking advice around data and interoperability	http://www.hscic.gov.uk/
HRA	Health Research Authority	Protects and promotes the interests of patients and the public in health and social care research	For companies wishing to carry out clinical research	http://www.hra.nhs.uk/
HTC	Healthcare Technology Co-operatives (NIHR)	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.	At development / testing stage for medical technology companies	http://www.nihr.ac.uk/about/healthcare-technology-co-operatives.htm
HFEA	Human Fertilisation and Embryology Authority	The HFEA licenses fertility clinics and centres carrying out in vitro fertilisation (IVF), other assisted conception procedures and human embryo research.	For companies wishing to use human embryos in research	http://www.hfea.gov.uk/
-	Innovation Scout Programmes / Schemes	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	At development stage for all companies	-
IPO	Intellectual Property Office	The official UK government body responsible for intellectual property (IP) rights including patents, designs, trade marks and copyright	For all companies seeking a UK patent during the idea generation or product development stage	https://www.gov.uk/government/organisations/intellectual-property-office
i4i	Invention for Innovation (NIHR)	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.	After the development / testing stage	http://www.nihr.ac.uk/funding/invention-for-innovation.htm
JCVI	Joint Committee on Vaccination and Immunisation	Advises UK health departments on immunisation	For manufacturers of vaccines seeking reimbursement after regulatory approval	https://www.gov.uk/government/groups/joint-committee-on-vaccination-and-immunisation
MHRA	Medicines and healthcare products regulatory agency	Regulates medicines, medical devices and blood components for transfusion in the UK	For all companies seeking UK regulatory approval	https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency

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

Information correct as of 14th April 2016

Return to landing page

Directory: Public bodies and definitions

Acronym	Name	Description	When to contact	Link
-	MHRA Innovation Office	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	For SMEs seeking advice about regulation	https://www.gov.uk/government/groups/mhra-innovation-office
NIB	National Information Board	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	For companies with a digital element to their product	https://www.gov.uk/government/organisations/national-information-board
NICE	National Institute for Health and Care Excellence	Provides national guidance and advice to improve health and social care	For all companies seeking advice on and taking part in health technology appraisals	http://www.nice.org.uk/
NIHR	National Institute for Health Research	Funded through the Department of Health to improve the health and wealth of the nation through research	For companies wishing to carry out clinical research	http://www.nihr.ac.uk/
NIHR HSRIC	National Institute for Health Research Horizon Scanning Research and Intelligence Centre	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	-	http://www.hsric.nihr.ac.uk/
BSA	NHS Business Services Authority	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	For all companies at the adoption stage	http://www.nhsbsa.nhs.uk/Index.aspx
-	NHS Choices	Official NHS website providing information to patients	For all companies seeking information about the NHS and patient needs	http://www.nhs.uk/pages/home.aspx
-	NHS England	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.	-	https://www.england.nhs.uk/

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

Information correct as of 14th April 2016

Return to landing page

Directory: Public bodies and definitions

Acronym	Name	Description	When to contact	Link
	NHS Right Care	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	For companies seeking information about patient needs	http://www.rightcare.nhs.uk/
-	NHS Supply Chain	NHS Supply Chain provides patient-focussed healthcare products and supply chain services to the UK's National Health Service	For companies at the adoption stage in the pathway	https://www.supplychain.nhs.uk/
NIA	NHS Innovation Accelerator	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	If considering NIA Fellowship	https://www.england.nhs.uk/ourwork/innovation/nia/
NICE	The National Institute for Health and Care Excellence	Provides national guidance and advice to improve health and social care	For companies seeking evaluation of their product	http://www.nice.org.uk/
-	NICE Office for Market Access	The first point of contact for talking to NICE about future products. Provide expert advice and direction to help engage with NICE technology evaluation.	For all companies seeking advice on and taking part in health technology appraisals	https://www.nice.org.uk/about/what-we-do/office-for-market-access
-	NICE `	Consultancy service to medicines, devices and diagnostics around generating evidence to inform future NICE evaluations and enabling market access	For companies prior to NICE evaluation	https://www.nice.org.uk/about/what-we-do/scientific-advice
NOCRI	NIHR Office for Clinical Research Infrastructure	Includes expert individuals, research facilities and technology platforms that have been designed to support high quality clinical research across the innovation pathway	For companies wishing to carry out clinical research	http://www.nocri.nihr.ac.uk/
-	Northern Ireland Health and Social Care Board	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	-	http://www.hscboard.hscni.net/
OLS	Office for Life Sciences	The Office for Life Sciences champions research, innovation and the use of technology to transform health and care service	For companies seeking context on the UK Life Science industry and for useful resources	https://www.gov.uk/government/organisations/office-for-life-sciences/about
PASLU	Patient Access Scheme Liaison Unit	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	For pharmaceutical companies considering a patient access scheme	https://www.nice.org.uk/about/what-we-do/patient-access-schemes-liaison-unit

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

Information correct as of 14th April 2016

Return to landing page

Directory: Public bodies and definitions

Acronym	Name	Description	When to contact	Link
PHE	Public Health England	An executive agency, sponsored by the Department of Health. Aims to protect and improve the nation's health and wellbeing, and reduce health inequalities.	-	https://www.gov.uk/government/organisations/public-health-england
RDAG	Rare Diseases Advisory Group	Makes recommendations to NHS England on developing and implementing the strategy for rare diseases and highly specialised services	At the idea generation / development stage if appropriate to product	https://www.england.nhs.uk/commissioning/rdag/
SMC	Scottish Medicines Consortium	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	-	https://www.scottishmedicines.org.uk/
UKMi	UK Medicines information	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	For pharmaceutical companies	http://www.ukmi.nhs.uk/

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

Information correct as of 14th April 2016

Directory: Other contacts

Return to landing page

Acronym	Name	Description	When to contact	Link
ABHI	Association of British Healthcare Industries	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.	For medtech companies across all stages	http://www.abhi.org.uk/
-	Bloodwise	UK's biggest blood cancer charity	Across innovation pathway to test ideas (if appropriate product)	https://bloodwise.org.uk/about-us
CASMI	Centre for the Advancement of Sustainable Medical innovation	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.	Across innovation pathway for information on adoption	http://casmi.org.uk/
CPRD	Clinical Practise Research Datalink	Research service jointly funded by the NIHR and the MHRA, provides anonymised primary care records for public health research	For development / clinical testing stage	https://www.cprd.com/intro.asp
DHACA	Digital health and care alliance	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	For companies with a digital element across all stages	http://dhaca.org.uk/dhaca/
EMIG	Ethical Medicines Industry Group	The UK research-based trade association that represents the interests of small to medium-sized Pharmaceutical, Biotech and Medtech companies (SMEs)	For SMEs seeking information about clinical research and policy in the UK	http://www.emig.org.uk/
-	The Farr Institute of Health Informatics Research	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	For companies seeking health research data	http://www.farrinstitute.org/
GMC	General Medical Council	Help to protect patients and improve medical education and practice in the UK by setting standards for students and doctors	For information on medical practice in the UK	http://www.gmc-uk.org/

 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

Information correct as of 14th April 2016

Directory: Other contacts

Return to landing page

Acronym	Name	Description	When to contact	Link
-	HealthUnlocked	HealthUnlocked is a social network for health	Across innovation pathway to test ideas	https://healthunlocked.com/
-	Healthwatch	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	Across innovation pathway to test ideas	http://www.healthwatch.co.uk/
-	Innovate UK	Work with people, companies and partner organisations to find and drive the science and technology innovations that will grow the UK economy	Across innovation pathway for connecting with key partners / funding	https://www.gov.uk/government/organisations/innovate-uk
-	James Lind Alliance	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	Prior to clinical research and testing	http://www.jla.nihr.ac.uk/
-	King's Fund	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	For up to date information on the	http://www.kingsfund.org.uk/
-	MedCity	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	Across innovation pathway to test ideas	http://www.medcityhq.com/
MRC	Medicines Research Council	Fund research across the biomedical spectrum, from fundamental lab-based science to clinical trials, and in all major disease areas	For companies wishing to carry out clinical research	http://www.mrc.ac.uk/?nav=main
-	Medilink	A national health technology business support organisation, which helps companies from concept through to commercialisation and nurtures collaborations between academics, clinicians and industry	For medtech and digital companies	http://www.medilinkuk.com/
-	Myeloma UK	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	For companies focused on Myeloma	https://www.myeloma.org.uk/

 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

Information correct as of 14th April 2016

Directory: Other contacts

Return to landing page

Acronym	Name	Description	When to contact	Link
-	NHS Confederation	Membership body that brings together, and speaks on behalf of, the whole health and care system	-	http://www.nhsconfed.org/
NWEH	NorthWest EHealth	Develops innovative software that unlocks the value of health and care data for the benefit of patients.	-	http://nweh.co.uk/
SBRI	Small Business Research Initiative for Healthcare	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	For SMEs seeking funding	http://www.sbrihealthcare.co.uk/
-	techUK	techUK represents the companies and technologies that are defining today the world that we will live in tomorrow	For digital companies across all stages	https://www.techuk.org/about
ABPI	The Association of the British Pharmaceutical Industry	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	For pharma companies across all stages	http://www.abpi.org.uk/about-us/Pages/default.aspx
BIVDA	The British In Vitro Diagnostics Association	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	For diagnostic companies across all stages	http://www.bivda.co.uk/
BIA	UK Bioindustry Association	The BIA is at the forefront of UK bioscience, serving as its voice, connecting individuals and organisations, from SMEs to multi-national companies	For all companies seeking advice on policy and regulation in the UK	http://www.bioindustry.org/home/
-	UK PharmaScan	Horizon scanning database populated with information on new medicines in development from up to three years before their launch in the UK	For pharma companies during Phases I - III	https://www.ukpharmascan.org.uk/login

 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

Information correct as of 14th April 2016

Glossary of key terms

Return to landing page

Acronym	Name	Description	Link
AIMDD	Active Implantable Medical Device Directive	European Directive covering the requirements for Active Implantable Medical devices in the European Economic Community	http://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/implantable-medical-devices/index_en.htm
-	Acute Trusts	Hospitals in England are managed by acute trusts. Acute trusts ensure hospitals provide high-quality healthcare and check that they spend their money efficiently	http://www.nhs.uk/NHSEngland/thenhs/about/Pages/authoritiesandtrusts.aspx
-	CE mark	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)	https://www.gov.uk/guidance/ce-marking
DAP	Diagnostics Assessment Programme (NICE)	NICE approval programme. Considers innovative medical diagnostic technologies	https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-diagnostics-guidance
EAMS	Early Access to Medicines Scheme	Scheme to improve access to innovative medicines for patients with life threatening or seriously debilitating conditions without adequate treatment options	https://www.gov.uk/guidance/apply-for-the-early-access-to-medicines-scheme-eams
GMS	General Medical Services Contract	The General Medical Services (GMS) contract is the contract between general practices and NHS England for delivering primary care services to local communities	https://www.england.nhs.uk/commissioning/gp-contract/

Information correct as of 14th April 2016

Glossary of key terms

Return to landing page

Acronym	Name	Description	Link
-	GP Federations	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	-
HTAP / HTAT	Health Technologies Adoption Team	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.	https://www.nice.org.uk/about/what-we-do/into-practice/health-technologies-adoption-team
HTA	Health Technology Assessment / Health Technology Assessor / Health Technology Appraisal (NICE)	Technology appraisals are carried out by NICE and give recommendations on the use of new and existing medicines and treatments within the NHS	https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance
HST	Highly Specialised Technology (NICE)	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	https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-highly-specialised-technologies-guidance
IVDMDD	In Vitro Diagnostic Medical Device Directive	European Directive covering the requirements for In Vitro Diagnostic Medical Devices in the European Economic Community	http://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/iv-diagnostic-medical-devices/index_en.htm
ICDF	Individual Cancer Drugs Fund Request	Application to the Cancer Drugs Fund for a single drug and indication	https://www.england.nhs.uk/ourwork/cancer/cdf/
-	Innovation Scorecard	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)	https://www.england.nhs.uk/ourwork/innovation/innovation-scorecard/

Information correct as of 14th April 2016

Glossary of key terms

Return to landing page

Acronym	Name	Description	Link
IPP	Interventional Procedure Programme (NICE)	NICE approval programme. For surgical procedures, where irradiative energy is used, and where body cavities are accessed	https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-interventional-procedures-guidance
MDD	Medical device directive	European Directive covering the requirements for Medical Devices in the European Economic Community	http://ec.europa.eu/growth/sectors/medical-devices/index_en.htm
MTAC	Medical Technologies Advisory Committee (NICE)	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)	https://www.nice.org.uk/get-involved/meetings-in-public/medical-technologies-advisory-committee
MTEP	Medical Technologies Evaluation Programme (NICE)	The NICE medical technologies evaluation programme (MTEP) selects and evaluates new or innovative medical technologies (including devices and diagnostics).	https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-medical-technologies-evaluation-programme
MTP	Medical Technologies Programme (NICE)	NICE approval programme. Considers a single medical device or diagnostic which provides equivalent or enhanced clinical outcomes for equivalent or reduced cost	https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-medical-technologies-guidance
-	Medicines optimisation dashboard	Used by CCGs to understand how well their local populations are being supported, to optimise medicines use and inform local planning	https://www.england.nhs.uk/ourwork/pe/mo-dash/

Information correct as of 14th April 2016

Glossary of key terms

Return to landing page

Acronym	Name	Description	Link
NIB Workstream 1.2	National Information Board Workstream 1.2	A proposed assessment framework for Digital health applications	https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/442833/Work_Stream_1_2.pdf
-	National Programmes of Care	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	https://www.england.nhs.uk/commissioning/spec-services/npc-crg/
-	National Tariff	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	https://www.england.nhs.uk/resources/pay-syst/
-	NHS Five Year Forward View	Published on 23 October 2014. Sets out a new shared vision for the future of the NHS based around the new models of care	https://www.england.nhs.uk/ourwork/futurenhs/
-	NHS Outcomes Framework	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	https://www.england.nhs.uk/resources/resources-for-ccgs/out-frwrk/
-	Patient Advocacy groups	Groups and organisations which represent patients, usually with a particular disease or disability	http://www.gmc-uk.org/information_for_you/organisations_working_for_patients.asp#2
PPRS	Pharmaceutical Price Regulation Scheme	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	https://www.gov.uk/government/publications/pharmaceutical-price-regulation-scheme-2014

Information correct as of 14th April 2016

Glossary of key terms

Return to landing page

Acronym	Name	Description	Link
-	PRIME	A scheme in development by the EMA for priority medicines, to optimise the development and accelerated assessment of medicines of major public health interest	http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000660.jsp&mid=WC0b01ac058096f643
QOF	Quality and Outcomes Framework	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.	http://www.hscic.gov.uk/qof
-	Specialised Commissioning	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	https://www.england.nhs.uk/commissioning/spec-services/
TA	Technology Appraisal (NICE)	NICE technology appraisals are recommendations on the use of new and existing medicines and treatments within the NHS	https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance
TAP	Technology Appraisal Programme (NICE)	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	https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance
-	Test Beds	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	https://www.england.nhs.uk/ourwork/innovation/test-beds/
-	Vanguards	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	https://www.england.nhs.uk/ourwork/futurenhs/new-care-models/

Information correct as of 14th April 2016

Monitor
Deloitte.