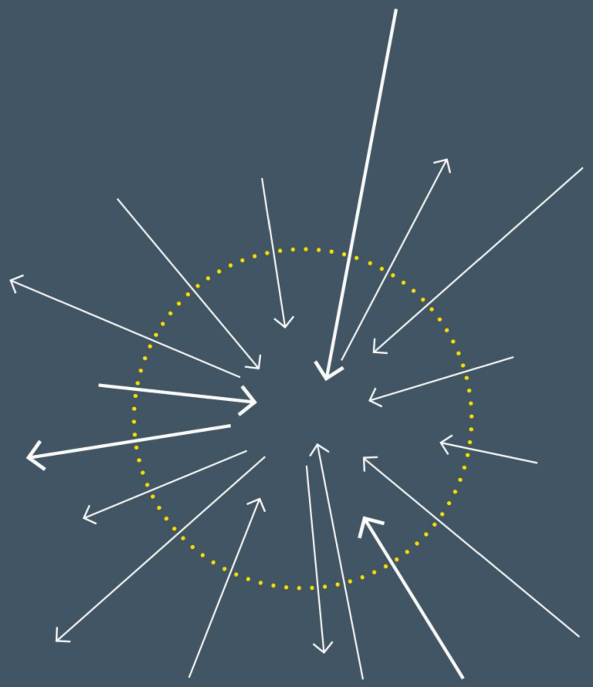
AAC005a Appendix 1

Health Technology Pathway: Navigation Tool for Innovators in England

Published March 2023



Accelerated Access Collaborative

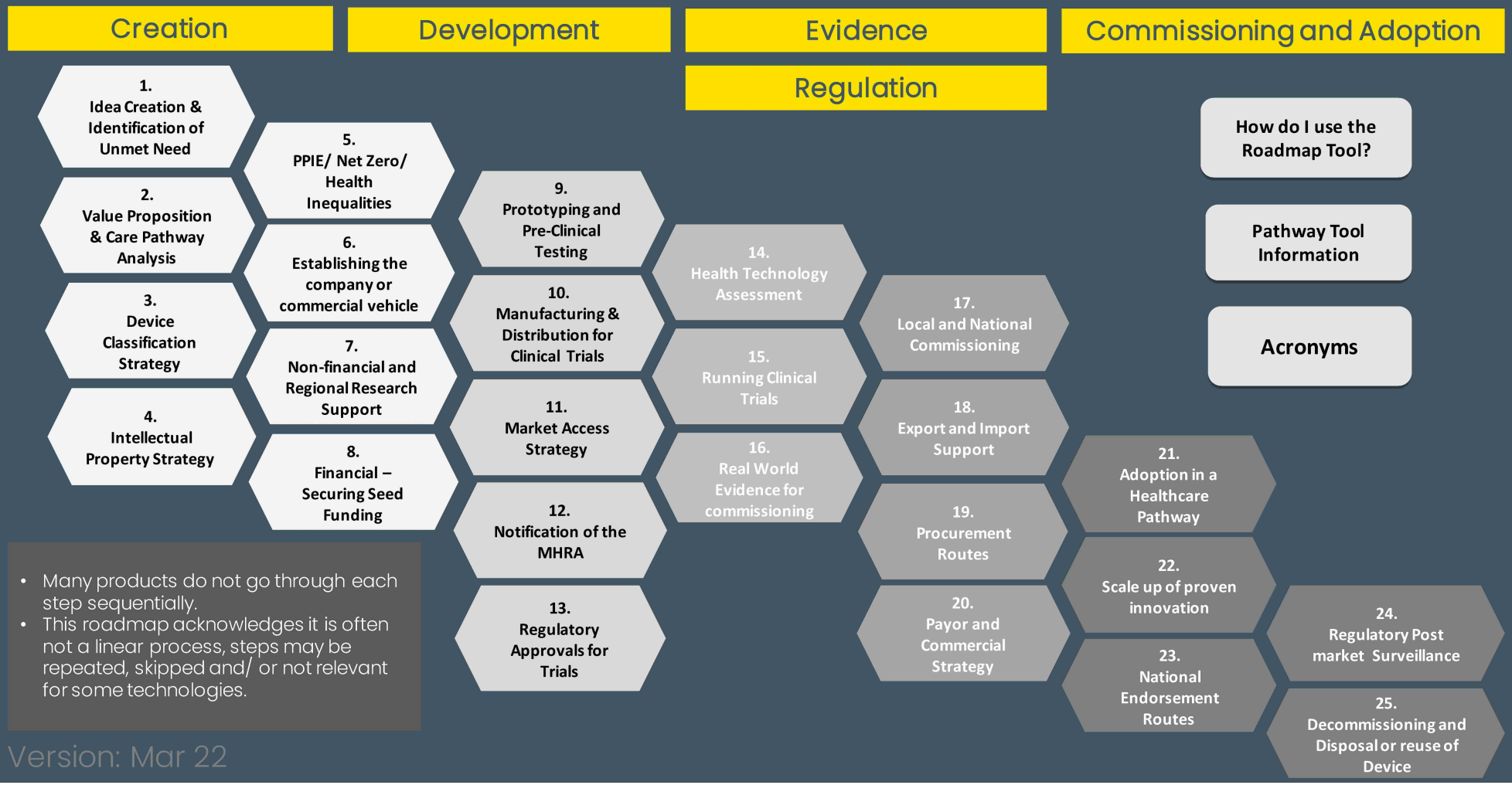
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Health Technology Pathway

This 25 Step Model sets out the key steps and activities in the end-to-end pathway for Health Technology in England from creation through to product commissioning & monitoring.



- Many products do not go through each step sequentially.
- This roadmap acknowledges it is often not a linear process, steps may be repeated, skipped and/ or not relevant for some technologies.

Version: Mar 22

Accelerated Access Collaborative

Health Technology Pathway

This work has been co-developed by AAC, a unique partnership between patient groups, government bodies, industry and NHS bodies

We work together to **streamline** the **adoption** of new innovations in healthcare:

PARTNER ORGANISATIONS

The AHSN Network

Academy of Medical Royal Colleges

ABHI HealthTech for Life

abpi Bringing medicines to life

amrc Association of Medical Research Charities

BIA UK BioIndustry Association

Medicines & Healthcare products Regulatory Agency

NICE National Institute for Health and Care Excellence

NIHR | National Institute for Health Research

National Voices

NHS Supply Chain

NHS Digital

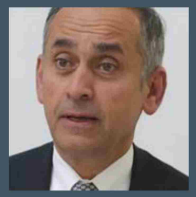
NHS

BIVDA

HM Government

UKRI UK Research and Innovation

BOARD*


Lord Darzi


Amanda Pritchard


Matt Whitty


Dr Sam Roberts


Prof. Lucy Chappell


Dr Gail Marzetti

Accelerated Access Collaborative

Our five priorities



Research

Increase the speed, scale and diversity of the research in the NHS.



Demand signalling and horizon scanning

Clearly identifying and articulating NHS needs and systematically searching for solutions.



Uptake of proven innovation

Supporting the uptake of medicines, medical devices, diagnostics and digital products.



Building innovation capacity

Supporting NHS organisations and workforce to develop, test and implement innovative solutions



Innovator support

Making it easier to navigate innovation ecosystem and delivering transformation al commercial deals at scale

Cross cutting themes - Health inequalities | Patient public participation | Life Sciences Vision | Net zero | NHS England Clinical Priorities

Accelerated Access Collaborative | Health Technology Pathway

Context

Vision and role of the AAC

- Our vision is to have a UK ecosystem in which all patients have timely access to transformative, innovative technologies that lead to improved outcomes and experience, more efficient NHS delivery of care, and benefits for the wider economy.

- The AAC has a responsibility to accelerate innovation through partnership working. We believe there are strategic benefits in working together with our partners to identify barriers and co-ordinate solutions across the entire pathway to help address the causes of issues, rather than having multiple programmes to address isolated symptoms.

- To support this vision, the AAC has comprehensively mapped out the key steps an innovator should go through, from concept development through to widespread implementation across the NHS, as well as the support already available at each stage in this journey.

Health Technology Pathway Mapping Work

- The mapping identifies 25 steps, themed around five key phases. It represents an innovator's stylised, illustrative journey through the product development process.

- This work is primarily aimed to inform and guide SMEs without a deep history of working in the NHS, but it will also be relevant to innovation partners already familiar with the NHS.

- Each step includes a schematic flowchart of milestones, key organisations, timelines, policies, guidelines, a 'to do' list, and other relevant issues innovators need to be aware of. These have been identified through a literature review and engagement with key partners and stakeholders.

- The flowchart has been developed using a medical devices and diagnostics lens, but it also has applicability for DHTs.

- Issues and policy levers have been identified through a literature review, industry analysis, government recommendations, and discussions with key stakeholders and partners. These continue to feed into the AAC's ongoing work.

Accelerated Access Collaborative | Health Technology Pathway

Health-Technology Pathway Information

What is the Health-Technology Pathway Tool?

This tool sets out the key steps and activities in the end-to-end pathway for Health Technology in England from research through to patient treatment.

England has a nationalised healthcare system with a single set of NHS payor organisations, a single regulator (MHRA), and a single Health Technology Assessment body (NICE), which makes market access reimbursement decisions for medicines and some health technologies. The National Screening Committee supports commissioning processes for tools deployed in national screening pathways.

Who should use the Health Technology Pathway Tool?

This tool has primarily been designed for innovators and developers, as well as other ecosystem partners and stakeholders, looking to navigate England's Med-Tech landscape and gain a deeper understanding of:

- Steps and activities that are mandatory (and optional) at each stage.
- When these steps and activities should be conducted.
- The external guidance available at each stage and where to find it.
- The stakeholders involved at each point through the pathway.
- Best practices/tips to help navigate the pathway.

What Best Practice Principles should users keep in mind?

There are some suggested best practice principles to keep in mind whilst bringing medical technology and diagnostics through the end-to-end pathway. These will help to bring innovations to NHS patients as efficiently as possible.

Engage early

Early engagement and collaboration between manufacturers and healthcare system stakeholders such as MHRA, NHSE and NICE during the product development and regulatory stages of the pathway can ensure alignment on future product-specific requirements. This helps to ensure system readiness.

Seek advice and support

Take advantage of the wide range of available guidance and support offered by the NHS and other ecosystem stakeholders throughout the pathway. This will help you gain an understanding of the UK landscape and how to meet the specific requirements of the regulators, commissioners and providers.

Minimise complexity

Medical Technology and Diagnostics can be very complex, but innovators should always seek to minimise additional complexity wherever possible and look to exploit standardisation opportunities. e.g., through service delivery requirements, as they'll help to speed up time to market and patient access.

Patient centricity

Keep the patient in mind throughout the end-to-end pathway and engage with patient groups to keep them at the heart of development, from identifying real world need, to user involvement in design, testing and adoptions resources. Ensure consideration of the diversity of patient populations.

Accelerated Access Collaborative | Health Technology Pathway

How to Use this Pathway Tool

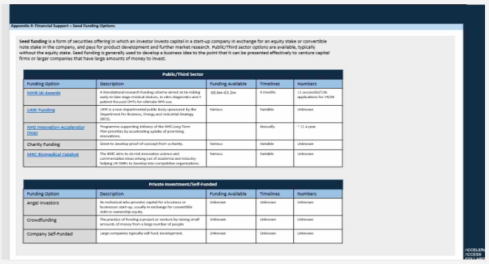
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Explore the Pathway overview to view all of the steps.

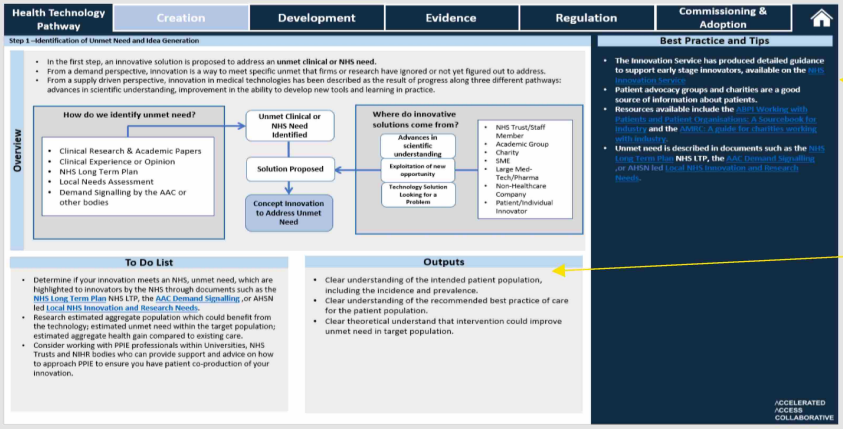
Click the section of the Pathway you would like to find out more about. *You will be taken to the first Topic deep-dive slide of that section.*

3



Appendixes can be found at the end of the Roadmap slide decks.

2



Navigate by Roadmap Section

The Overview section provides high level information on this step in the pathway.

The To Do List section reminds innovators the key activities required at this step in the pathway.

The home button returns to the main pathway diagram.

The Best Practice and Tip section provides links to external guidance and information.

The Outputs section highlights the key outputs that should be completed by this stage in the innovation development journey.

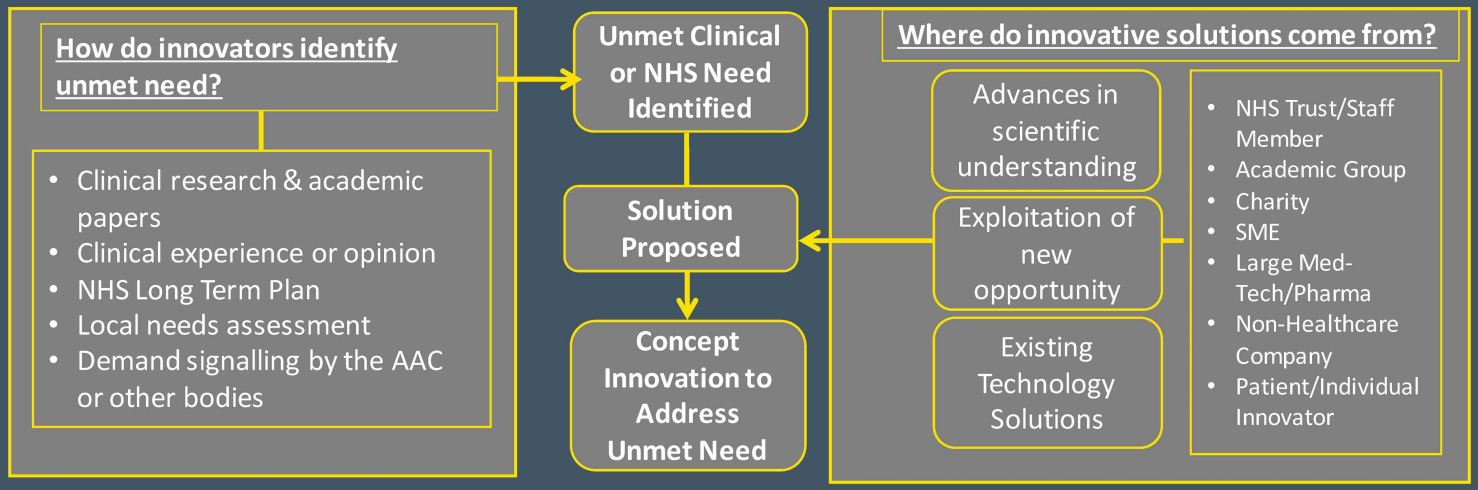
There may be links to more information in the appendixes.

Accelerated Access Collaborative | Health Technology Pathway

Creation | Development | Evidence | Regulation | Commissioning & Adoption

Step 1 – Idea creation and identification of unmet need

- In the first step, an innovative solution is proposed to address an **unmet clinical or NHS need.**
- From a demand perspective, innovation is a way to meet specific unmet that firms or research have not yet addressed.
- From a supply driven perspective, innovation in medical technologies has been described as the result of progress along three different pathways: advances in scientific understanding, improvement in the ability to develop new tools and learning in practice.



To do List

- Determine if your innovation meets an NHS, unmet need, which are highlighted to innovators by the NHS through documents such as the **NHS Long Term Plan** NHS LTP, the **AAC Demand Signalling** ,or AHSN led **Local NHS Innovation and Research Needs**.
- Research estimated aggregate population which could benefit from the technology; estimated unmet need within the target population; estimated aggregate health gain compared to existing care.
- Consider working with PPIE professionals within Universities, NHS Trusts and NIHR bodies who can provide support and advice on how to approach PPIE to ensure you have patient co-production of your innovation.

Outputs

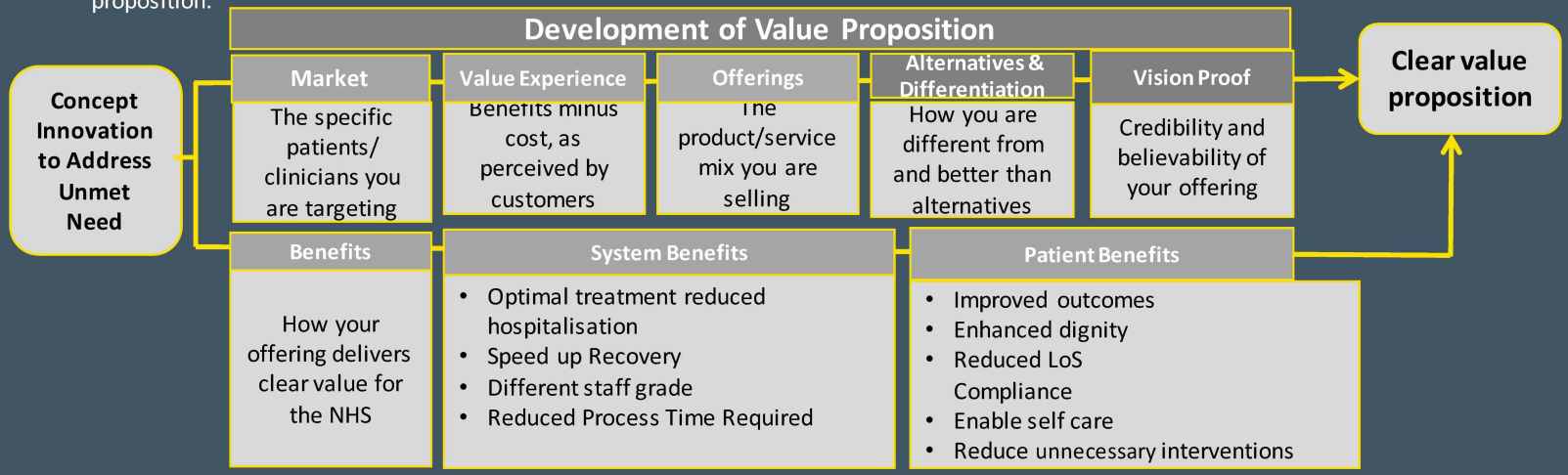
- Clear understanding of the intended patient population, including the incidence and prevalence.
- Clear understanding of the recommended best practice of care for the patient population.
- Clear theoretical understanding that the intervention could improve unmet need in target population.

Best Practice and Tips

- **The Innovation Service has produced detailed guidance to support early stage innovators, available on the NHS Innovation Service**
- **Patient advocacy groups and charities are a good source of information about patients.**
- **Resources available include the ABPI Working with Patients and Patient Organisations: A Sourcebook for Industry and the AMRC: A guide for charities working with industry.**
- **Unmet need is described in documents such as the NHS Long Term Plan NHS LTP, the AAC Demand Signalling ,or AHSN led Local NHS Innovation and Research Needs.**

Step 2 – Value Proposition and Care Pathway Analysis

- A value proposition is a positioning statement that explains what benefits you are providing for a healthcare organisation and your capacity and capability to deliver those benefits well. The Value Proposition will evolve as you develop your product.
- Innovators and companies increasingly must articulate a broader value proposition to an increasingly diverse set of stakeholders, which is often required to access funding and support. A market requirement document could also be produced.
- It is also best practice to conduct a care pathway analysis to consider the impact on patient pathways, which can be used to support the value proposition.



To do List

- Research and develop your value proposition, taking into account the likely range of stakeholders.
- Consider performing and care pathway analysis, either in house or outsourced.
- Consider developing a market requirement document.
- Test value proposition with clinical experts and patient groups.

Outputs

- Initial value proposition for use with stakeholders.
- If appropriate, a Care pathway analysis to understand how your intervention could be implemented. This may come later in the developmental period.
- Market requirement document *(if applicable)*.

Best Practice and Tips

- **NICE offers a service to explore your value proposition with them.**
- **Innovators can outsource care pathway analysis, for example the NIHR Newcastle In Vitro Diagnostics Co-Operative has expertise (methods in open access journal here)**
- **Check if your innovation provides value above direct patient benefits. This value includes:**
  1. **Solving the Covid-19 backlog**
  2. **Reducing health inequalities**
  3. **Supporting the NHS Net Zero Agenda.**
  4. **Improving the health and wellbeing of staff**

Step 3– Device Classification Strategy

- The clinical data required by the regulators to demonstrate that a MedTech product performs as intended and is safe to use is dependent on the class of technology, with higher risk MedTech products requiring more extensive clinical evaluation and evidence standards before they can be launched onto the market.
- Innovators should be aware of the class of device during the creation stage to inform planning in later stages.

Minimum Viable Product → **Classification of Device**

Medical Device

General medical devices and active implantable devices

When you have established your product is a general medical device, you need to decide which class your device falls under. The categories are:

- Class I - generally regarded as low risk
- Class IIa - generally regarded as medium risk
- Class IIb - generally regarded as medium risk
- Class III - generally regarded as high risk

Diagnostic

In vitro diagnostic medical devices (IVDs)

In vitro diagnostic medical devices are categorized differently into 4 main groups, which are devices:

- considered as general IVD medical devices
- within the classifications stated in Part IV of the UK MDR 2002, Annex II List A (as modified by Part III of Schedule 2A to the UK MDR 2002)
- within the classifications stated in Part IV of the UK MDR 2002, Annex II List B (as modified by Part III of Schedule 2A to the UK MDR 2002)
- for 'self-test' intended to be used by a person at home

To do List

- Read the appropriate guidance from MHRA and, if necessary, consult an expert.
- Determine your device classification.
- Start to implement the appropriate Quality Management System (QMS) appropriate for the device classification – the complexity of the QMS will depend on the device.

Outputs

- Clear device classification.
- Clear understanding of differences between device classification and understanding of what that means for regulatory strategy.
- Appropriate Quality Management System (QMS) in place.

Best Practice and Tips

MHRA Support and Guidance

- The MHRA has A Guide to What is a Medicinal Product
- The European Commission has produced a guidance document for the classification of Medical Devices
- There is further guidance produced by the Medical Device Coordination Group here.
- The MHRA has guidance on medical technology for the United Kingdom here.
- The MHRA has guidance for Borderline Products
- Guidance on the Regulation of In Vitro Diagnostic Medical Devices here.
- Guidance on Custom medical devices here.
- Guidance on In-House Manufacture of Medical Devices in great Britain here.
- NHS Digital Interoperability Toolkit (ITK) is a set of common specifications, frameworks and implementation guides.

NHS England

- **Digital Technology Assessment Criteria here.**

HRA Support and Guidance

- HRA Medical Devices elearning modules (Medical devices, Use of the HRA Schedule of Events, Research involving participants lacking mental capacity, Research involving exposure to ionising radiation, Research involving human tissue, HRA Approval: training for commercial and non-commercial studies, Reviewing the research design of clinical trials).
- The HRA Best Practice websites.
- Policies and standards for medical devices and software applications.
- HRA Guidance for using patient data.

Step 4– Intellectual Property Strategy

- Intellectual property (IP) is a legal framework that protects ideas, concepts and the products of creative and mental effort.
- IP rights promote innovation by rewarding the owner of the IP with a monopoly right over the idea, preventing others from exploiting it without their consent. The different types of IP are below.
- Innovators need to secure the appropriate IP to ensure their business remains viable, and to attract investors. Innovators should ensure the IP for their idea does not already exist, understand who else might have a claim on the IP (e.g. employers, collaborators and / or funders), and where appropriate apply for the right IP protection. A full description of the different types are found in appendix 2.

Not Requiring Registration at Intellectual Property Office

Copyright	Know How	Database
Automatic	n/a	n/a
Free	n/a	n/a

Requiring Registration at Intellectual Property Office

Trademarks	Patents	Registered Designs	Freedom to Operate
~4 mo.	4- 6 years	8 weeks	
Around £400-1000	~£4000 for the UK,	£60 for once design	~£5000 to £10000

To do List

- Identify the right IP protection required for your Health Technology Innovation
- Identify your IP Goals
- Ensure your technology does not infringe any existing patents
- If other parties have contributed to your IP, ensure you are clear on what contractual obligations you may have
- If your innovation relies on the use of IP from third parties, ensure that you have secured the relevant rights
- Keep detailed and up to date records of your Intellectual Property, and take steps to ensure the information remains confidential
- If applicable, engage the services of a patent lawyer
- If relevant, prepare detailed documents which describe your invention and file these documents with the Intellectual Property Office (IPO)

Outputs

- Clear understanding of IP Protection required for your Health Technology Innovation
- Evidence that your health technology does not already exist
- Application filed with the initial public offering (IPO)
- IP protection granted

More details on Intellectual Property Strategy can be found in Appendix 1

Best Practice and Tips

General Information about Intellectual Property

- The UK's Intellectual Property Office
- Information on Basic IP Guidance and licensing intellectual property can be found on the government website.
- The IP Health Check is a free tool that can be used to identify your IP assets.
- Use the IP Equip service to find out which type of intellectual property you have
- Speak to a professional, such as a patent attorney patent attorney or trademark attorney
- Go to a local IP clinic or the British Library Business and IP Centre in London
- If you're in Wales you can use IP Wales
- Government guidance on Intellectual Property Rights in the USA
- The UK Government Office of Tech Transfer can provide support for innovators in the public sector to identify, protect and exploit IP

Health Technology & Intellectual Property

- The government has produced guidance on examining patent applications for medical inventions
- A timeline of patent process is found on the IPO website.

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Creation | Development | Evidence | Regulation | Commissioning & Adoption

Step 5 – PPIE/ Net Zero/ Health Inequalities

Net Zero:

- Environmental impact and carbon emissions should be considered at the core of product and business development. Innovators need to build **their environmental impact / net zero strategy** early to align with the NHS commitment to reach net zero by 2045 and respond to the climate emergency and health threat.
- Products/services are required to demonstrate their carbon impact and therefore need to evaluate and quantify their carbon emissions (scope 1, 2 and 3). At an organisation level, **carbon reduction plans** will need to be published to demonstrate the organisation's commitment towards achieving net zero, a carbon reduction plan template can be found here.
- Innovators need to start considering the carbon impact of the solution(s) they are developing and how to minimise any emissions along the lifecycle of the innovation, including from their own suppliers all the way to the use and disposal of the product.

April 2022	April 2023	April 2024	April 2027	April 2028
All NHS procurements to include a minimum 10% net zero and social value weighting: (PPN 06/20)	For all contracts above £5 million/annum, suppliers need to publish a carbon reduction plan: (PPN 06/21)	Extension of the requirement for a carbon reduction plan to cover all procurements.	All suppliers required to publidy report targets, emissions and publish a carbon reduction plan for global emissions (scope 1,2 and 3)	Provision of carbon foot printing for individual products supplied to the NHS

PPIE:

- Patient and public involvement and engagement (PPIE) is important to the work of the Accelerated Access Collaborative (AAC) and the NHS.
- It is important to work with people and communities to ensure research priorities and innovations are developed in collaboration with people with lived experience of a particular service or health condition.
- It is useful to involve patients, people who access services, carers, charities, community groups and others to bring diverse perspectives into the development and adoption planning for new innovations.
- Failing to involve people with lived experience in the development of innovations, risks the innovation not meeting real word need or being optimally effective.
- We co-produce spread and adoption plans and patient information for MedTech products with patients, charities, Academic Health Science Networks, Clinicians and AAC stakeholders

Health Inequalities:

- Health inequalities are unfair and avoidable differences in health across the population, and between different groups within society.
- Within this wider context, healthcare inequalities are about the access people have to health services and their experience and outcomes.
- Equality and Health Inequalities Impact Assessments (EHIAs) are a tool to document service, programme and product impact on different populations including protected characteristics: age, disability, gender reassignment, marriage or civil partnership, pregnancy and maternity, race, religion or belief, sex and sexual orientation (Equality Act 2010) - example: 1901-Equality-and-Health-Inequalities-Impact-Assessment.pdf (england.nhs.uk)

To do List

- Develop a net zero strategy:
- Map out the environmental impact of the innovation on the chosen care pathway
- Consider how to assess and report carbon emissions at the organisation level (starting with UK scope 1 and 2 emissions)
- Adopted the Core20Plus5 framework
- Include PPIE across the five pathway phases, i.e. creation, development, evidence, regulation and commissioning/ adoption
- Adoption of EHIA approach across five pathway phases
- Baseline assessment of PPIE and HI knowledge with developers to inform training and PPIE needs

Outputs

- Net zero plans and strategy developed to meet the net zero NHS targets with a clear understanding of the requirements
- Evidence of PPIE co-production throughout process
- Completion of EHIA's including action plans on reducing health inequalities

Best Practice and Tips

Net zero tips

NHS England and the Greener NHS Programme

- The Greener NHS has published their supplier roadmap and invited suppliers to engage with the NHS through their Evergreen sustainable supplier assessment forum. The Evergreen sustainable supplier assessment will be a voluntary tool for suppliers to engage with the NHS on their sustainability journey Support organisations
- Guidance for applying net zero and social value in NHS procurements

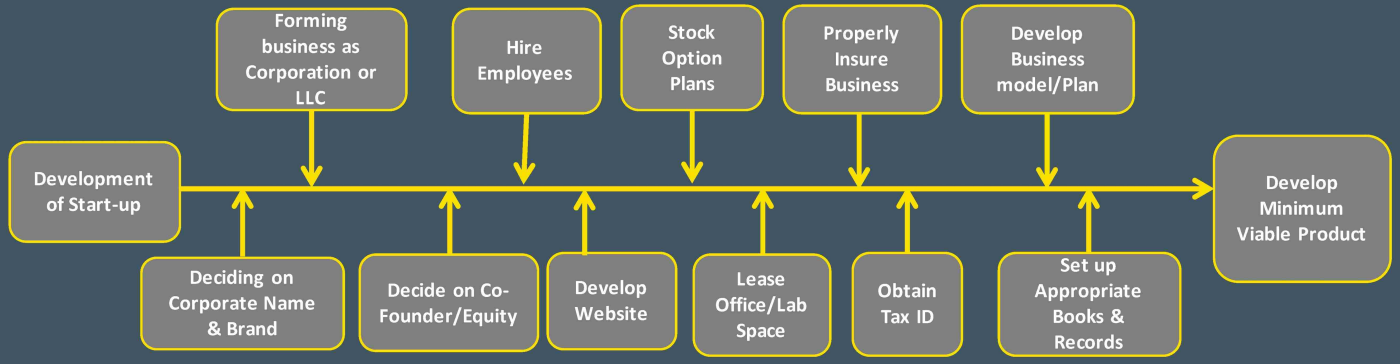
PPIE tips:

- Involve people early and throughout the process.
- Ensure that a diversity of views and perspectives are heard (including from patients, people with lived experience and carers).
- Involve patient advocate organisations, e.g. the charity, voluntary and community sector.
- Ensure that PPIE is appropriately resourced, including staff time, and that people who get involved are appropriately supported (access and training and support needs are met, and people are not financially out of pocket from their involvement).
- Extensive resources are available to support working with patients and the public, including guides outlining NHS statutory involvement duties, working with specific communities, accessible involvement, different involvement methodologies and ways of working with patients.
- NHS England » Bite size guides to participation
- PPI (Patient and Public Involvement) resources for applicants to NIHR research programmes | NIHR
- Patients must be at the heart of the NHS – and of innovation - Innovation Unit | creating impact - reducing inequalities - transforming systems
- NHS Accelerated Access Collaborative » Patient and public involvement (england.nhs.uk)
- Health Inequalities & CORE20PLUS5: NHS England » National Healthcare Inequalities Improvement Programme / NHS England » Case studies
- Reimbursement: NHS England » Working with our Patient and Public Voice Partners – Reimbursing expenses and paying involvement payments
- Usability testing: qualitative studies- GOV.UK (www.gov.uk)
- NHS England » Working in partnership with people and communities: statutory guidance

More details on PPIE/ NetZero/ Health Inequalities framework can be found in Appendix 2, 2a and 2b

Step 6 – Establishing the company/ commercial vehicle

- A new healthcare innovation requires the set-up of a registered business, and innovators need to consider staffing, overheads, office and lab space, and the business name. Innovations in large companies require many of the same considerations.
- A wealth of information is available on other sites, so this section has been kept deliberately short. Below are some of the key milestones in starting up a business.
- Registering Company takes 8-10 days.



Spin-out company:

- Spin-outs are strategically valuable because they provide a low-cost transfer of firm assets
- Spin-out have minority shareholders, often a university or other higher education institution (sometime know as 'the parent')

Pros and Cons of Spin-out company:

- Great potential for growth due to their smaller size and management motivation to achieve success
- The parent/ university will have in place an IP-sharing policy with spin-out/off through a share of royalties
- Downside includes spin-out share prices can be more volatile and can tend to underperform in weak markets or be outperformed in strong markets

To do List

- Decide on type of business structure
- Decide on business location
- Register your business with company's house
- Insure business
- Hire Employees
- Insure business
- Obtain Tax ID
- Develop business model
- Set up appropriate accounting processes

Outputs

- Company set-up

Best Practice and Tips

Guidance on supporting a business is available at:

- British Business Bank
- https://www.gov.uk/set-up-business
- gov.com A Guide to Starting and Developing a New Business
- Gov. database of business finance support options
- Nesta Resources for Start-ups
- Imperial College London: A Founder's Guide to Spinouts
- Independent small business advice platform https://startups.co.uk/

Patient Involvement

- Some companies set up Patient Advisory Board (PAB) Programmes to leverage insight and diversity.

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- Use of LEAN Start-up methodologies may decrease costs and timescales and increase the likelihood of survival.

Stats and Figures

- OLS estimate Core MedTech Sector is 2900 business employing 106,500 people (plus 1290 businesses employing 31,600 in Service & Supply Chain businesses).
- The combined turnover is £27.6bn, source.
- The Digital Health segment is included in the Core Med Tech sector, 670 businesses employing 14,400 employees

Setting up a company

- Register the company using the UK Government Companies House website

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Creation | Development | Evidence | Regulation | Commissioning & Adoption

Step 7– Non-Financial and Regional Research Support

Non-Financial Support and support for Market Research is available for manufacturers for idea creation and the development of value proposition which includes PPI, mentoring, networking and training. Listed below are some of the more common support organisations available to innovators.

NHS staff

- NHS staff can apply for the Clinical Entrepreneur Programme, which is a free annual competition available to NHS staff that has trained over 900 entrepreneurs to date. The Local Trust IP team can support commercialisation of in-house developments and testing in the NHS.

Data

Data - NHS Digital Can offer business support, funding and being connected to partners. Data Access Request Service (DARS) can help researchers develop new treatments and services. Costs listed here but between £1000 and £10000.

- NHS Digital Developer Hub provides information and tools to help developers create software for health and social care. Currently 89 API's in catalogue.
- NHSE's Data for R&D programme is investing £200m in Secure Data Environment and other capabilities to enable the NHS to make life-saving linked data more securely and quickly accessible to researchers, while offering the highest levels of privacy.

Advice and Guidance

- Trade Bodies (ABHI and BIVDA) can offer advice and support at this stage to companies
- NICE/MHRA Scientific Advice offer meetings with developers to discuss specific scientific issues about the development of a medicinal product.
- Charities and INVOLVE can help support PPI into development

Building Capacity for Real World Evidence Generation

- NIHR MICs aims to build expertise and capacity in the NHS to develop and evaluate new medical technologies and in vitro diagnostic tests. Each MIC has a different focus and is hosted by a different NHS trust.
- Innovate UK Edge offer growth and support for established innovative SMEs, including Scale Up Programme, Sourcing Funding, and Entering New Markets
- Biomedical Research Centres across England work together with NHS Trust to deliver impactful research with local, national and global patient benefit.
- Applied Research Collaborations undertake research on various themes that drive progress in national priority areas.

Step 7 – Extended Non-Financial Support and Local Innovation Infrastructure

There are various accelerator programs that can help innovators accelerate within Health Tech and Digital Health. Accelerator Program

A 12-month programme for digital health companies that have products or services with high potential to meet NHS and social care challenges. Organised via AHSNs. Digital Health London

The NHS Innovation Accelerator supports exceptional individuals to scale promising innovations across England's NHS for greater patient and staff benefit. NHS Innovation Accelerator

The Digital North accelerator programme is a collaborative enterprise established by the four northern AHSNs. It aims to support regional digital health technology firms in adopting and spreading proven innovations within the healthcare system. Digital North

The AHSN network have skills to help generate a rich pipeline of demonstrably useful, evidence-based innovations and support adoption and spread of proven evidence-based innovations across England. The AHSN can also support innovation that need to demonstrate their environmental impact and net zero commitment. Academic Health Science Network

The Catapult Network provide businesses with access to their expertise and facilities, enabling them to test, demonstrate and improve their ideas. This includes access to infrastructure, tailored SME support, collaboration and partnerships. NIHR CRN

The CRN is comprised of 15 Local Clinical Research Networks and 30 Specialties who coordinate and support the delivery of high-quality research both by geography and therapy area. NIHR Med Tech and IVD co-operatives

The NIHR Med-tech and In vitro diagnostics Co-operatives (MICs) can help you to develop new medical technologies and provide evidence on commercially-supplied in vitro diagnostic (IVD) tests. accelerators.

Best Practice and Tips

Academic Health Science Networks:

- *Imperial College Health Partners (Greater London)*
- Wessex AHSN (Hampshire, Dorset, Isle of Wight)
- South West AHSN (Cornwall, Devon, Somerset)
- Kent, Surrey and Sussex (East Sussex, Surrey, Kent)
- Health Innovation Network (Greater London)
- West England (Gloucestershire, Wiltshire)
- East Midlands (Leicestershire, Rutland, Warwickshire, Northamptonshire, Nottingham, Lincolnshire)
- UCL Partners (Hertfordshire, Bedfordshire, Essex)
- Oxford (Buckinghamshire, Oxfordshire, Berkshire)
- Eastern (Norfolk, Suffolk, Cambridgeshire)
- West Midlands (Herefordshire, West Midlands Worcestershire, Shropshire)
- Health Innovation Manchester (Greater Manchester)
- Yorkshire and Humber (North Yorkshire, East Riding of Yorkshire, West Yorkshire)
- North West Coast (Lancashire, Merseyside, Cheshire)
- North East and North Cumbria (Northumberland, Tyne and Wear, Durham, Cumbria)

More details on Non-Financial and Regional support Accelerators programmes can be found in Appendix 3

Accelerated Access Collaborative | Health Technology Pathway

Creation | Development | Evidence | Regulation | Commissioning & Adoption

Step 8 – Financial Support – Securing Seed Funding

- Innovators in the early stages of a start-ups face high-cost and low-revenue, which leads them to seek outside investors for capital, which is usually needed to demonstrate proof of the concept and develop a prototype. Pre-seed is a colloquial term for the earliest stage of the fundraising process.
- The pre-seed round is nuanced, and over time the lines have blurred on precisely what level of business is in this stage. Essentially it depends on the market, business model, and investor preferences. However, as the name implies, pre-seed signals an incubatory point in the start-up lifecycle. Typically, it is one where there is some exploration of a potential solution to a problem. At the pre-seed stage, the founders identified a market gap; however, the solution is still being formed and validated.
- Pre-seed options tends to be friends and family, Public/Third Sector, or Private Investment or Self-Funded.

Friends and Family
- Small business loans
- Friends and Family
- Angel Investors
- Crowdfunding
- Company Self Funded

Private Sector
For extensive list of Top 5 Health Care Start-up Investors in United Kingdom, use this link.

Public/Third Sector
- government Start-up Loan/British Business Bank
- SBRI Healthcare (Phase 1)
- Charitable Grants
- Q-Exchange – Health Foundation

Public/Third Sector
- NIHR
- UKRI Funding
- Knowledge Transfer Networks
- Local Enterprise Partnerships Growth Hub

- Seed funding is a form of securities offering in which an investor invests capital in a start-up company in exchange for an equity stake or convertible note stake in the company and pays for product development and further market research.
- Public/Third sector options are available, typically without the equity stake.
- Seed funding is generally used to develop a business idea to the point that it can be presented effectively to venture capital firms or larger companies that have large amounts of money to invest.

Venture Capitalist:

Many companies look to secure venture capitalist funding to expand research activities. In the UK:
- 60 different VC organisations have been identified that serve UK Life Sciences businesses
- More than one third of these (21) are entirely or predominantly focussed on supporting Life Science businesses and most organisations
- identified have Life Sciences as a considerable focus
- VC firms identified cover all stages of investment from pre-seed to post-IPO and provide support from £10k - £100m+

To do List

- Ensure your value proposition and business plan align with the funding mandate of your pre-seed funding source.
- Develop an initial and plausible revenue strategy
- Develop a Minimum Viable Product (MVP)
- Develop a pitch deck or a business proposal

Outputs

- Secure Pre-seed funding (Typically 50k to 250k)
- Secure funding across Series A; Series B, Series C and Series D

More details on Seed/Funding can be found in Appendix 4 and 4a

Best Practice and Tips

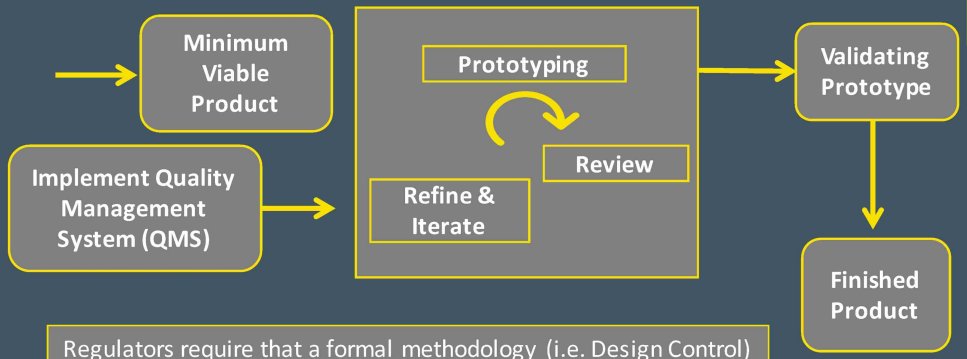
General Information
- **The seed funding stage requires the company to present the developed MVP, whereas the pre-seed funded firm seeks funds to complete the prototype of the product, build the team, and more.**
- **The typical amount varies, but typical pre-seeding amount is between 25k and 250k.**
- **The timeline target is 2-9 months.**

Funding opportunity news:
- Wessex AHSN
- Knowledge Transfer Network
- Innovate UK
- UK Research and Innovation

Links Venture Capital firms in the Life Sciences field:
- Top 50 Biotech VC funds
- Life Sciences VCs in UK

Step 9 – Prototyping and Pre-clinical Testing

The development of product prototypes is an iterative process with multiple versions often tested and refined until a final product is developed to progress to the market. This stage typically might involve small scale user testing or evaluation, depending on the technology. Products have to meet the standards seen below.



Products then need to be validated to ensure they are accurate against an external dataset and/or through pre-clinical validation using animal models or otherwise.

Research Considerations at this stage include:

- Ergonomics / ease of use
- Meeting all essential safety & performance requirements (Next Slide)
- 'In-house' versus contracted, external GLP-testing?
- Scalable processes/considerations for 'clinical' manufacture?
- 'De-bugging'; iterative user & operator enhancements?

Regulators require that a formal methodology (i.e. Design Control) be applied to the conduct of medical device design & development. EU and US processes are very much aligned (Section 7.3 of ISO 13485 2016; FDA 21 CFR 820.30)

To do List

- Check DTAC guidance
- Medical Technology and Diagnostic Standards and Technical Reports

Outputs

- Minimum Viable Product

Best Practice and Tips

Developers of products have to ensure the they meet the regulations.
The key standards are not mandatory, but if you follow the standards you can demonstrate you meet the regulations.

Medical Technology and Diagnostic Standards and Technical Reports

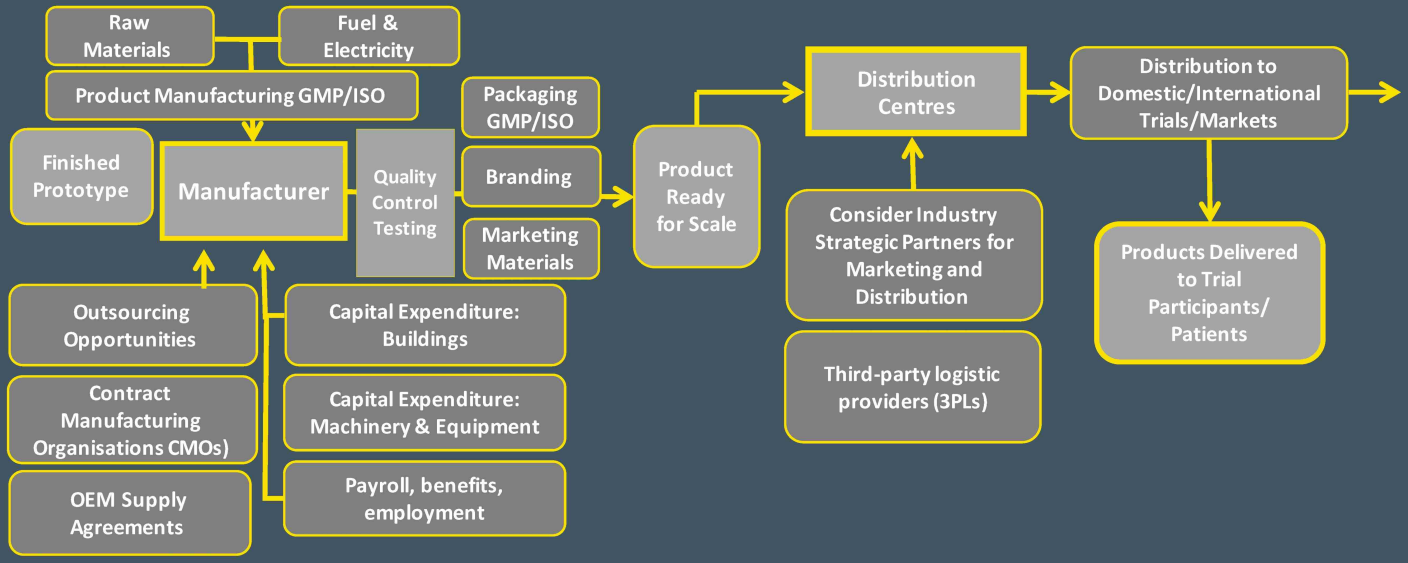
- The Regulation on Medical Devices 2017/745
- The Regulation on In Vitro Diagnostic Medical Devices 2017/746
- ISO 13485:2016: Medical devices — Quality management systems — Requirements for regulatory purposes
- ISO 14971:2019: Medical devices — Application of risk management to medical devices
- ISO 14155:2020: Clinical investigation of medical devices for human subjects — Good clinical practice
- ISO 10993-1:2018: Medical Devices – Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk Management Process
- ISO 15223-1:2021: Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements
- ISO 20417:2021: Medical devices — Information to be supplied by the manufacturer
- ISO/TR 20416:2020: Medical devices — Post-market surveillance for manufacturers (Technical Report)

Products with a Digital Component

- NHSE have published a Digital Technology Assessment Criteria (DTAC). For developers, it sets out what is expected for entry into the NHS and social care
- Compliance with the Data Protection Act
- NICE Evidence standards framework for digital health technologies
- The EU's General Data Protection Regulation

Step 10 – Manufacturing and Distribution

Manufacturing. The manufacture of a 'clinical prototype' for clinical trials and beyond needs to be considered and can be achieved in different ways. Usually, key aspects include agreeing which organisation shall be the legal 'Device Manufacturer' responsible for the design, manufacture, packaging and labelling of a product, manufacturing costs, and ensuring the provision of technical documentation to legal manufacturer or its appointed delegate. The reality is that the prototyping to production process is fluid and looks slightly different for everyone—there is no tried-and-true formula for getting your unique product through the production line.



To do List

Distribution Innovators also have to consider the methods by which manufactured medical devices or diagnostics are distributed to customer sites. Distribution will depend on the technology and its supply chain requirements, company, and stage in development. We are including this here as it is usually considered at the stage of manufacturer.

Carbon footprint – Innovators need to evaluate their own supply chain, manufacturing location, distribution channels and disposal options to ensure they reduce their organisation's carbon emissions.

Outputs

Key Considerations:

- The production quantity
- Product tolerances
- The ideal end timeline
- Your total manufacturing budget

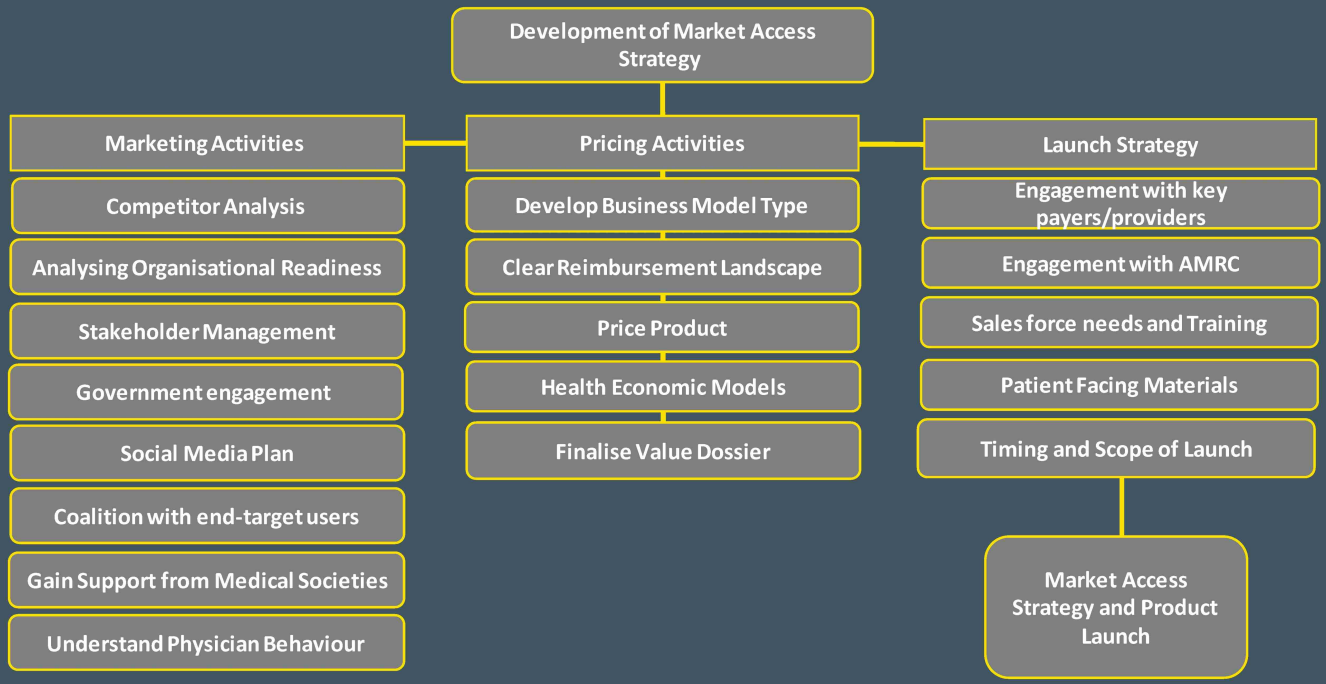
Best Practice and Tips

Key tips:

- Early Scientific advise on manufacturing and distribution process- the medical technology industry is dominated by large number of subject matter experts. Access to early scientific advice on both subject matter could support starts-up/innovators on adopting best practices of clinical trials for medical device manufacturers.
- Plan Manufacturing Early in the Design and Development Process- the medical device manufacturing method must be considered early on in the 'creation' phase of the MedTech Pathway. Early consideration of the basic product or digital solution requirements would be reduced on the iterative processes during the manufacturing and distribution of the medical device.
- Understand Cost Targets and Target Market- a poor understanding of product cost targets and price sensitivity within the target markets can be detrimental to the success of a medical device. Early market research is recommended to understand the landscape with competitor products/ solutions and to gauge competitive pricing.
- Select the Right Manufacturing Partner - when it comes to medical devices, a good manufacturing partner will offer more than just technical expertise. The right manufacturing partner should work within a quality management system, have established processes, and understand the critical requirements for manufacturing similar products with similar processes, both in small batches and full-scale production.

Step 11 – Market Access Strategy

Market Access is a broad term that is used to describe activities and processes that diagnostics and biotech companies undertake to secure a reimbursed price, which reflects the product's value for the broadest possible patient population within the shortest feasible time-frame. The below schematic outlines some of the key activities in developing a robust market access strategy, but this will vary depending on the product.



Best Practice and Tips

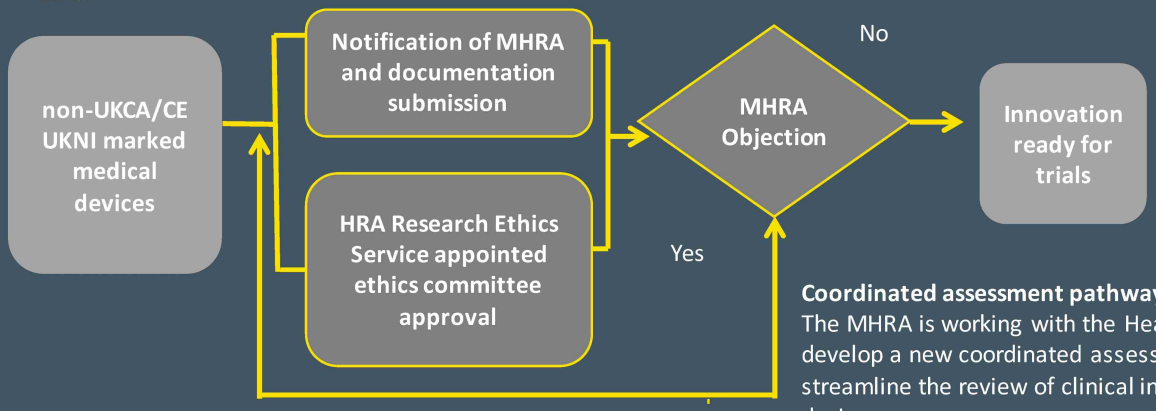
Organisations that can help develop health economic models

The AAC has worked with arrange of evaluation partners before who have supported many of its AI Awardees with developing evidence required by NICE for adoption and spread of medical devices into the NHS.

The group of experienced health technology evaluators include: KiTech; University of Leeds; iCAIRD; NENC AHSN; London South Bank University; The Strategy Unit; Unity Insights (spin-out of KSS AHSN) and University of Surrey; Swansea University; University of York; Cambridge Centre for Health Services Research; MedCity Diagnostics Growth Hub; UCL; Hardian Health; University of Edinburgh; University of Sheffield.

Step 12 – Notification of MHRA

Process for non-UKCA/CE UKNI marked medical devices. **Manufacturers must notify** the MHRA via the Integrated Research Application System (IRAS), and must Complete the Clinical Investigation Application form on IRAS and upload the relevant supporting documents onto IRAS.



Manufacturer may re-submit an application for a proposed clinical investigation, provided the reason(s) for refusal of the original submission are addressed.

Role of local Research Ethics Committee:
The role of a Research Ethics Committee (often referred to as REC) is to ensure that the dignity, rights, safety and well-being of research participants are preserved. Before a study can commence, ethical approval by an NHS-Trust and sometimes a Higher Education Institution (HEI) is required to confirm the Trust/ HEI can support the delivery of the study and that the research will be carried out safely, in line with appropriate policies and procedures.

If possible, please provide the MHRA with advanced notice of your intention to submit a clinical investigation by emailing devices.regulatory@mhra.gov.uk with some basic details about the investigational device, the intended population, the type of study, and estimated application date. Please provide as much notice as possible. An advanced notice is helpful to the MHRA, however is not a substitute for the formal clinical investigation notification.

Coordinated assessment pathway process
The MHRA is working with the Health Research Authority (HRA) to develop a new coordinated assessment pathway which will streamline the review of clinical investigations involving medical devices.
During this phase of testing the MHRA Medical Devices review, and the Research Ethics Committee (REC) review are being completed in parallel and information will be shared. If you would like more information on the pathway, please read the guidance.

Sponsorship:
The sponsor of a research study is the organisation responsible for the research. A sponsor can be an individual, organisation or group taking legal responsibility for the arrangements to initiate, manage, monitor and report on a study. An NHS Trust, HEI, a charity or a commercial organisation usually takes on the sponsor role.

Best Practice and Tips

MHRA guidance

- Follow the guidance on compiling a submission (PDF, 211 KB, 16 pages) and guidance for manufacturers when preparing your notification application.
- Applications are submitted electronically using the Integrated Research Application System (IRAS)
- See information for clinical investigators (PDF, 133 KB, 10 pages) for what is required by clinicians involved in the investigation.
- Check the information on the biological safety assessment (PDF, 144 KB, 7 pages) for the scientific data you must submit.
- Check statistical considerations (PDF, 163 KB, 14 pages) for presenting statistical information for your clinical investigation.
- Check guidance on applying human factors and usability engineering to medical devices including drug-device combination products.
- See the guidance on UKCA markings.

Step 13– Regulatory Approvals for Trials

UKCA Marking

- Manufacturers need to demonstrate that their MedTech meets the requirements in the MDR or IVDR by carrying out a conformity assessment.
- The conformity assessment route depends on the classification of the device. List of suitable NBs can be found on the EU Commission's 'Nando' website and is not held by the MHRA since we left the EU.
- The 'Declaration of Conformity' is a manufacturer responsibility and not issued by the MHRA. This chart can be found in more detail at MHRA Conformity Assessment Routes Chart . In high level terms, the process follows the below schematic.

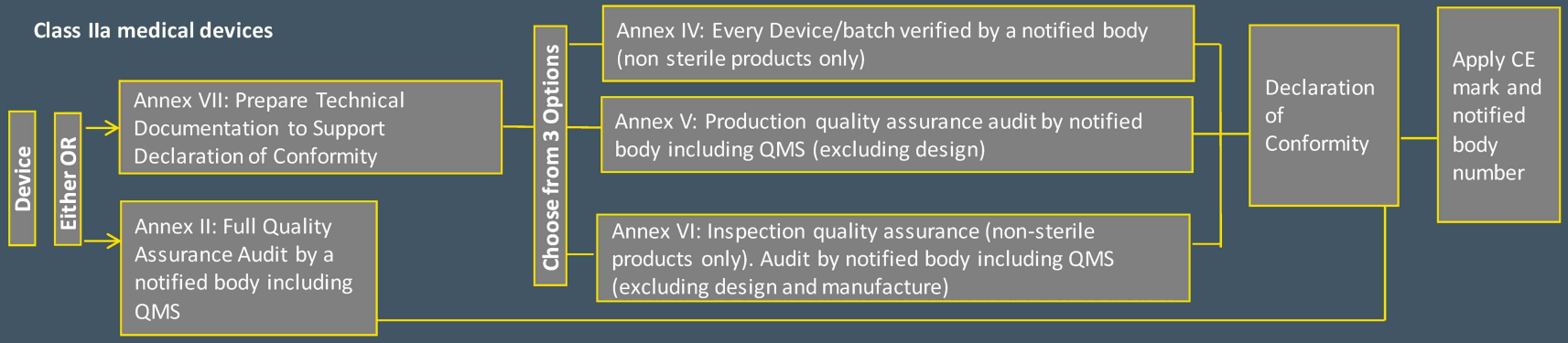


The diagram above describes the general process. There are different conformity assessments for manufacturers to confirm by; these include:

- General medical devices: Part II of the UK Medical Devices Regulations (MDR)
- Active implantable medical devices: Part III of the UK MDR 2022
- In vitro diagnostic medical devices (IVDs): Part IV of UK MDR 2002

Innovators need to demonstrate that their medical device meets the requirements of the UK MDR 2002 by carrying out a conformity assessment. The assessment routes are explained in depth in Appendix 4; shown below is a summary of the process for conformity assessment, for Class IIIa Medical Devices.

Class IIa medical devices



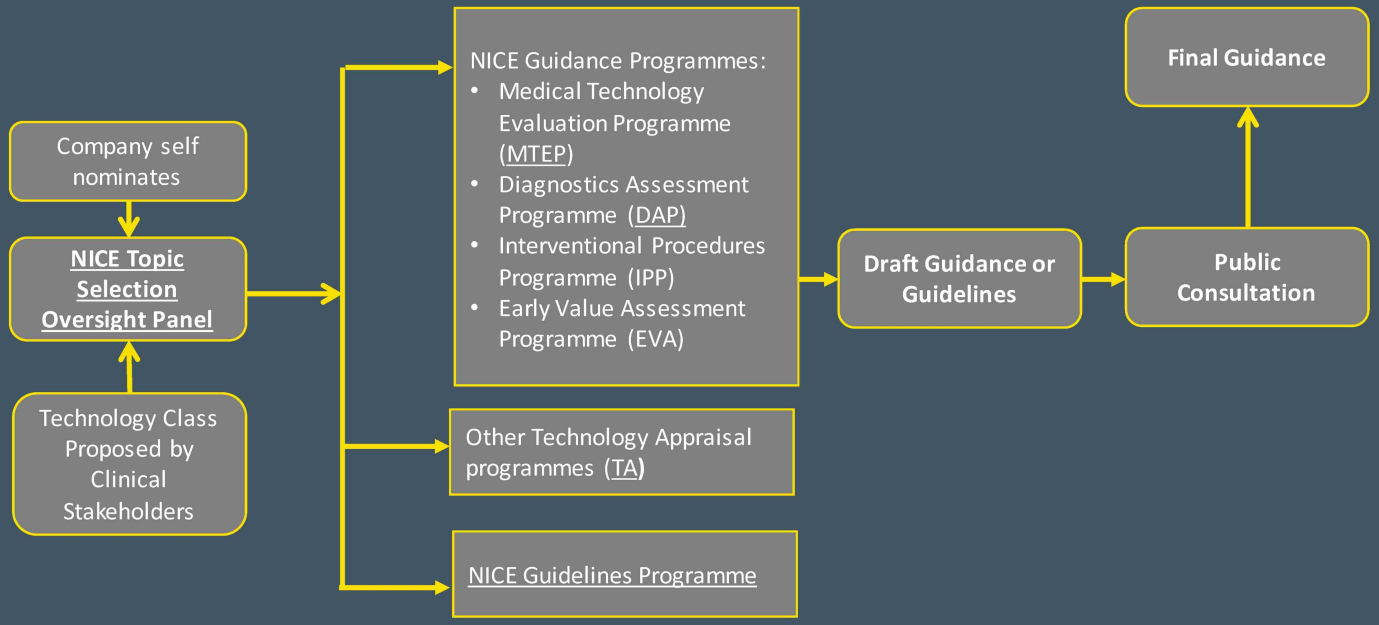
Best Practice and Tips

More details about medical devices can be found in Appendix 5

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Step 14– Health Technology Assessment



To do List

- Engage with NICE Office for Market Access to understand the most appropriate guidance route
- Engage with NICE Topic Intelligence team for advice on evidence support
- Prepare documentation necessary for your submission

Outputs

- Final guidance on your technology individually or as part of a Technology Class published on NICE website

Best Practice and Tips

NICE guidance (use link)

- MTFM assess Medical Technology Guidance (MTG) published from the MTEP and Diagnostic Guidance (DG) published from the DAP
- Technologies that meet the current criteria can be supported by the MTFM policy here
- Application for MTFM support is not required. Assessments are carried out as part of an ongoing collaboration between the AAC and NICE
- NICE assesses the majority of health technologies in the UK however, some technologies route via UK National Screening Programme or Genomics England
- Scottish Health Technologies Group and Health Technology Wales also do health technology assessments for Scotland and Wales respectively

For the Guidance programmes there are a range of recommendations:

- Recommended for Use
- Recommended for use in specific circumstances
- Recommendation for specific circumstances & further evidence
- Recommendation for use in a research context
- Recommendation case for adoption not supported

- 75% off for smaller companies NICE charging

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Step 15– Running Clinical Trials

Running pilot clinical trials:

- A pilot study is defined as "A small-scale test of the methods and procedures to be used on a larger scale". The purpose of a pilot study is to increase the likelihood of a successful future larger study randomised control trial (RCT) by exploring the efficiency, internal validity and fundamentally, the delivery of proposed trials.
- The goal of pilot work is not to test hypotheses about the effects of an intervention, but rather, to assess the feasibility of an approach to be used in a larger scale study. Thus, in a pilot study you are not answering the question "Does this intervention work?" Instead you are gathering information to help you answer "Can I do this?".
- In addition to providing important feasibility data as described above, pilot studies also provide an opportunity for study teams to develop good clinical practices to enhance the rigor and reproducibility of their research. This includes the development of documentation and informed consent procedures, data collection tools, regulatory reporting procedures, and monitoring procedures.

Manufacturers must conduct a specifically designed clinical investigation in order to data generate data that can be used to demonstrate compliance for the required regulations. Advice for Manufacturers is available from the MHRA.

Product Socialisation Innovators will often be working very closely with as many clinical leaders as possible to inform and promote their trials as a prelude to market launch.

Innovation ready for trials → Identification of Sponsor/ legal representative → Identification of Principle Investigator → Subject Recruitment → Randomisation → Data Controller and Collection → Data Analysis and Reporting → Trial Management and Data Management → Device Ready for Regulatory Submission → Clinically Tested Innovation

Support for clinical Trials:

Several organisations are available to help conduct clinical trials for medical devices and diagnostics.

Support/Services for Trial Design and Infrastructure	
NHS Digitrials	NHS DigiTrials offers data services to support clinical trials.
NIHR (NOCRI)	NIHR has the infrastructure and expertise to support early stage research and development, and to identify health and care provider and patient needs
Contract Research Organisations (CROs)	CRO Partnership) for the completion of the clinical testing of MedTech products will ensure that the process is completed to a standard sufficient to meet regulatory requirements
MedTech and in Vitro Diagnostics Co-operatives (MICs)	MICs act as a centre of expertise and can support the development and evaluation of MedTech products in a clinical setting

Advice for Trial Design and Infrastructure	
The Multi-agency Advice Service (MAAS)	A one stop shop for support, information and guidance on the regulation and evaluation of AI technologies (due Summer 2022)
NICE META Tool	The Medtech Early Technical Assessment (META) Tool supports and informs a face to face discussion to identify the gaps in your product's development and evidence generation plans.
NICE Scientific Advice	NICE offers a fee-based consultancy service to developers of MedTech, and can provide detailed feedback on clinical, economic development and evidence generation plans

Step 16 - Real World Evidence for commissioning

- Real-world data are the data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources.
- Real-world evidence is the clinical evidence regarding the usage and potential benefits or risks of a medical product derived from analysis of RWD. RWE can be generated by different study designs or analyses, including but not limited to, randomized trials, including large simple trials, pragmatic trials, and observational studies (prospective and/or retrospective).
- Real-world data (RWD) and real-world evidence (RWE) are playing an increasing role in health care decisions.

NICE Evidence Framework for Real-World-Evidence:
NICE have developed the real-world evidence framework to help deliver the organisation's ambition to:

- Identifying when real-world evidence framework can be used to reduce uncertainties and improve guidance
- Clearly describing best practices for planning, conducting and reporting real-world evidence studies to improve the quality and transparency of evidence.
- The framework aims to improve the quality of real-world evidence to inform NICE guidance. However, the framework does not set a minimum acceptable standards for the quality of evidence. Users should refer to the relevant NICE manuals for further information on recommendations (see NICE guidance).

To do List

- Identify and work with decision makers and users to understand what evidence you should generate. You may need to pay for their time and expertise.
- If needed, work with methodologists, trials specialists and/or statisticians to design your RWE. You may need to pay for these services.
- Ensure you have funding in place to generate your RWE – you may have this already, or may need to apply for funding
- Ensure you have all the approvals and permissions necessary to undertake your work before commencing
- After generating your RWE, share you outcomes with users, and thank them for their input where they have guided your work.

NICE Early Value Assessment Programme (EVA): assess those technologies that most reflect system need and demand. With guidance from NICE, and support from research funders and the NHS, technology developers can use real-world evidence generation to gather detailed evidence within a live environment. This enables rapid assessment of digital products, devices and diagnostics for clinical effectiveness and value for money.

Outputs

- Clear and methodologically sound evidence of the impact of intervention on all users and chosen clinical pathway.

Best Practice and Tips

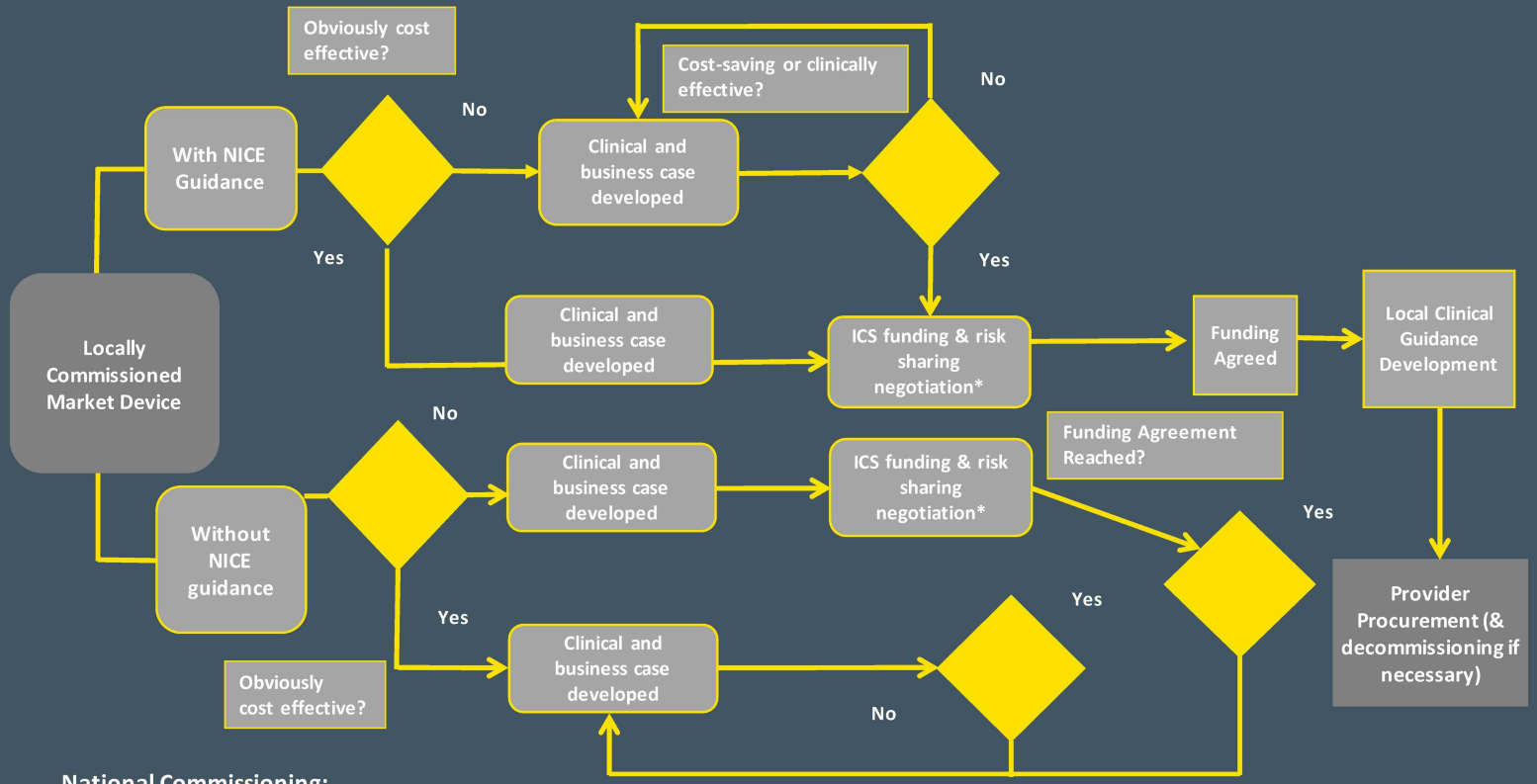
- Consider what evidence will be needed by the people who make decisions to use your technology and those who make purchasing decisions – these are not always the same people.
- Speak to the people who will potentially use your technology – patient or service user input is vital, and anyone else who may use or interact with your technology, including anyone who might be involved in integrating your technology with data systems. What is important to them? Make sure the evidence you generate captures your users needs and experiences, as this can help with how well users accept your product and can also help you improve your product.
- Where in a clinical pathway does your technology fit? Your RWE should explore the effects of your intervention both upstream and downstream of your technology.
- Evidence generation can take longer than you expect and can be costly: ensure you have enough time and resource to do it properly and find expert guidance to help you design your RWE.
- Make sure you capture qualitative as well as quantitative evidence during your RWE.

More details about medical devices can be found in Appendix 6

Step 17 – Local and National Commissioning

Local Commissioning:

The vast majority of medical devices and diagnostics are locally commissioned. The below schematic diagram shows an idealised pathway for local commissioning.



National Commissioning:

The reimbursement route for a device or diagnostic depends on who is the commissioner / provider of services for that target patient population. 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. Some devices associated with specialised services are reimbursed by NHS England at a national level with a funding mandate for specialised commissioners. This diagram outlines the pathway for national commissioning.

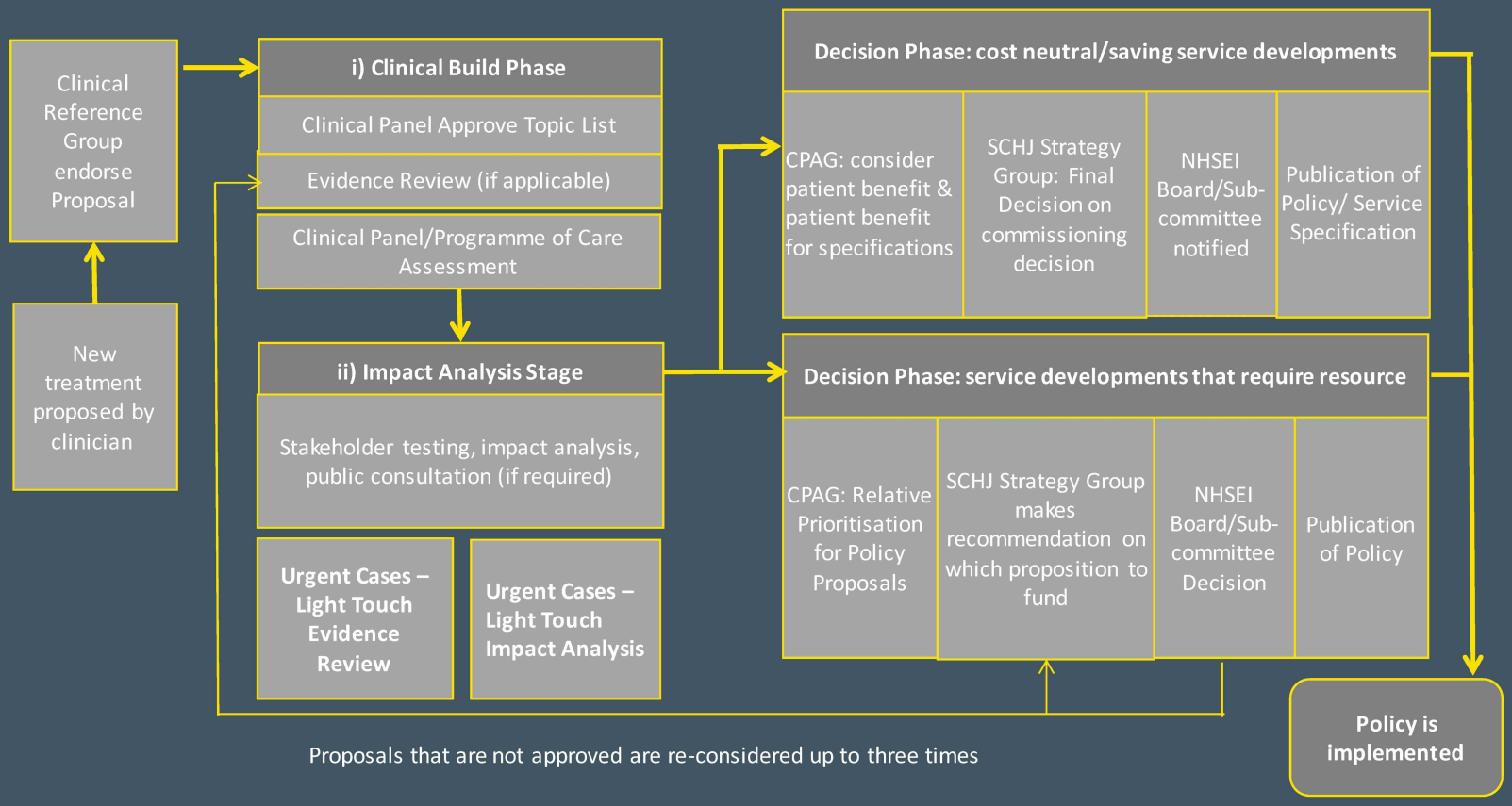
Best Practice and Tips

- **Refer to the NHS England website and follow the correct process for your device.**
- **Things you may want to consider when thinking about commissioning:**
- **Understanding what services their device is used in (cardiology physiology / primary care / diagnostic centres)**
- **How is that activity commissioned?**
- **How is that activity identified? (ICD10/OPCS/HRG coded in datasets?)**
- **What difference that technology makes to a patient's pathway – how is that measured?**

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Step 17 continued – Local and National Commissioning



Best Practice and Tips

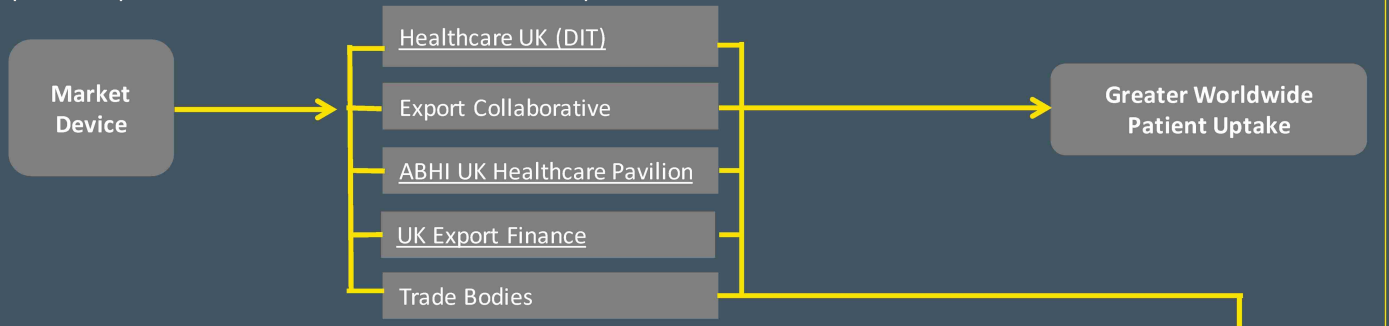
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- **What difference that technology makes to a patient's pathway – how is that measured?**

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Step 18– Export and Import Support

There is additional support for UK healthcare providers and companies to do more business overseas, and to help overseas companies do business in the UK. This can include promoting the UK healthcare sector to overseas markets and supporting healthcare partnerships between the UK and overseas healthcare providers.



Exporting to the EU – Updated Advice

The UKCA marking is not recognised on the EU market. To place a device on the EU market you must adhere to the relevant EU legislation and affix a CE mark to demonstrate compliance. If you use a UK-based Notified Body to conduct any mandatory third-party conformity assessment for your device, the following will apply:

- if your device was placed on the EU market before 1 January 2021, in accordance with the terms of the Withdrawal Agreement, it may remain on the EU market
- from 1 January 2021, you are not able to place a device on the EU market unless it has been assessed by an EU-recognised Notified Body
- Great Britain-based Authorised Representatives are no longer recognised in the EU. This means that they are not able to carry out tasks on the manufacturer's behalf for the purposes of placing devices on the EU market.
- If you are a manufacturer based in Great Britain or another country outside the EU, you must appoint an Authorised Representative based in the EU or Northern Ireland if you wish to supply devices to the EU market. You must ensure that your device meets EU labelling requirements in order to place it on the EU market. Both the CE marking and UKCA marking can be placed on a product so long as neither impedes the visibility of the other and both marking requirements are met. Devices placed on the Northern Ireland market must meet EU labelling requirements.

- Expansion of medical device/ digital technology in UK market/ or internationally
- International trade mission with Department of Trade/ BEIS to showcase medical/digital technology to overseas buyers

Best Practice and Tips

- **ABHI Guidance for Medical Device Advertising.**
- **ABHI US Accelerator**
- **Association of British HealthTech Industries (ABHI): enquiries@abhi.org.uk**
- **British In Vitro Diagnostics Association (BIVDA): enquiries@bivda.org.uk**
- **Proprietary Association of Great Britain (PAGB): regulatory@pagb.co.uk**
- **The British Healthcare Trades Association (BHTA): info@bhta.com**
- **UK Responsible Persons Association (UKRPA): enquiries@ukrp-association.org**
- **The Department of Trade: Build Back Better: Our Export Plan**
- **Government Export Support Team**

Example 1: ABHI US Accelerator

The ABHI US Accelerator is a platform for companies looking to upscale their US business.
Designed specifically to enable medical device, diagnostic and digital health companies flourish, the 12-month programme of support provides companies with the opportunity to define and strengthen their US strategy, de-risk market entry and grow their US business by utilising ABHI's advice, expertise and connections within the US.

Example 2: UK Export Finance

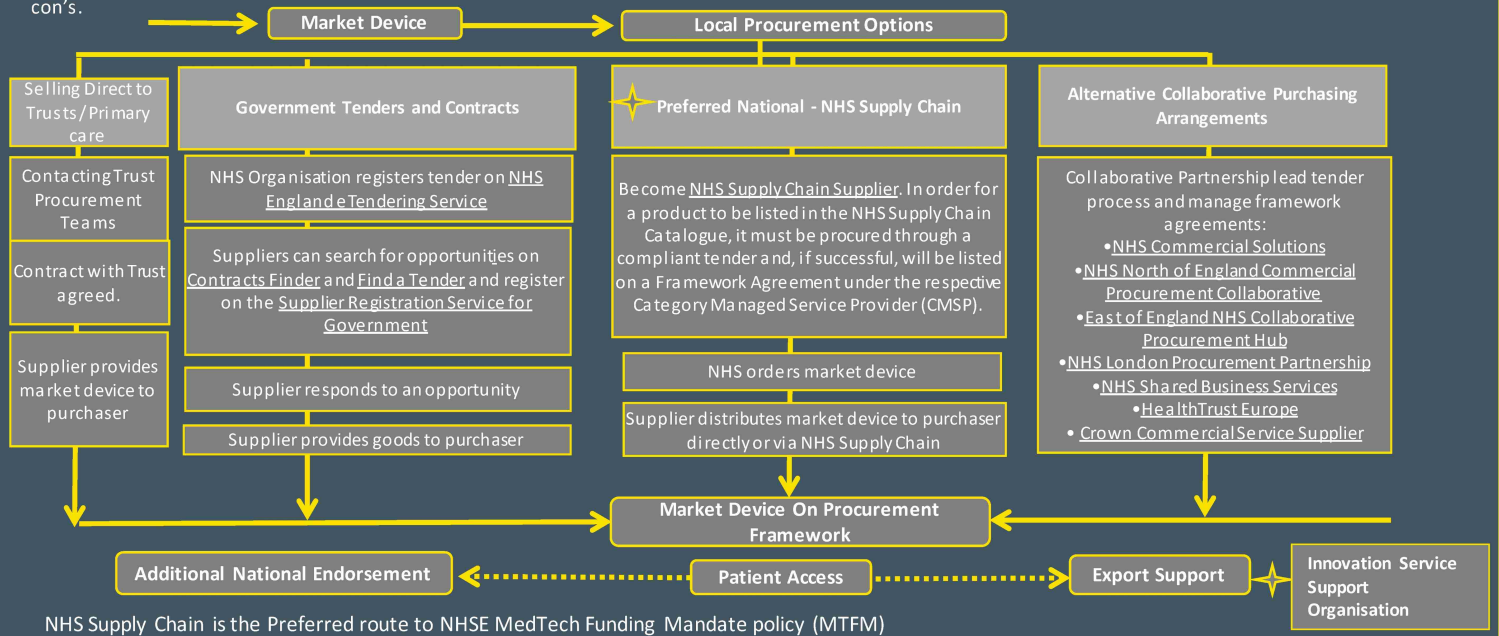
UK Export Finance's mission is to ensure no viable UK export fails for lack of finance or insurance from the private sector. They were was awarded the Healthcare Export Finance Deal of the Year: £130 million for six new hospitals in Côte D'Ivoire, reaching a combined catchment of more than 1 million people

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Step 19 – Procurement Routes

There are five main routes to market for companies interested in supplying their MedTech product directly to the NHS; this methods each have different pro's and con's.



NHS Supply Chain is the Preferred route to NHSE MedTech Funding Mandate policy (MTFM)
https://www.england.nhs.uk/aac/what-we-do/how-can-the-aac-help-me/the-medtech-funding-mandate/

NHS Supply Chain is the mandated route for the NHSE Specialised Services Device Program (SSDP) https://www.england.nhs.uk/commissioning/spec-services/key-docs/medical-devices/

To Do List

- Early engagement with NHS supply chain via Innovation service
- Keep record updated with regulatory process
- Register interest on Find a Tender
- Respond to PIN
- Undertake training videos in preparation for contract notice

Outputs

- Insight of procurement framework and route to market
- Understanding of specifics requirements within specifications
- Training and preparation
- Ongoing support and information via Category and SRM team

NHS Supply Chain covers the following elements as a Preferred route to market:

- Ward Based Consumables
- Sterile Intervention and Associated Consumables
- Infection Control and Woundcare
- Orthopaedics, Trauma and Spine, and Ophthalmology
- Rehabilitation, Disabled Services, Women's Health and Associated Consumables
- Cardio-vascular, Radiology, Endoscopy, Audiology and Pain Management
- Large Diagnostic Capital Equipment Including Mobile and Services
- Diagnostic, Pathology and Therapy Technologies and Services
- Office Solutions
- Food
- Hotel Services
- MedTech Funding Mandate
- Medical IT with the proprietary software to run in conjunction with Diagnostics equipment

- NHS Supply Chain Catalogue Find your log in links here - 'My Supply Chain' page - NHS Supply Chain
- Frameworks Contracts » NHS Supply Chain
- Procurement calendar Procurement and Savings Calendar » NHS Supply Chain

More details about Procurement Route via NHS Supply Chain can be found in Appendix 6

Step 20 – Payor and Commercial Strategy

The NHS payment system for secondary healthcare is called the National Tariff. The tariff is a set of rules, prices and guidance that governs the payments made by commissioners to secondary healthcare providers for the provision of NHS services.
While NHS medical services are free at the point of use for the patient, the system is taxpayer funded. The NHS payment system must support the delivery of more and better health care within the level of funding available.

NHS England is responsible for the direct commissioning of services outside the remit of clinical commissioning groups, namely primary care, public health, offender health, military and veteran health and specialised services. In addition, some integrated care boards (ICBs) have fully delegated responsibility for the commissioning and contract management of primary medical care. More information about NHSE's commissioning role can be found here.

Specialist Services are directly commissioned by NHSE. There are 149 specialist services currently with an annual spend of £23bn.

How services are commissioned in England is evolving with the creation of Integrated Care Board in Summer 2022. NHSE publishes regular policy updates.

To do List

- Understand who the payor for your solution is
- Understand what the source of funds is that your payor will use to commission your solution
- Understand any timing windows relating to your solution's commissioning
- Understand the NHS Planning Guidance which directs the NHS on its priorities

Outputs

- A route to market strategy that reflects customer and payor needs

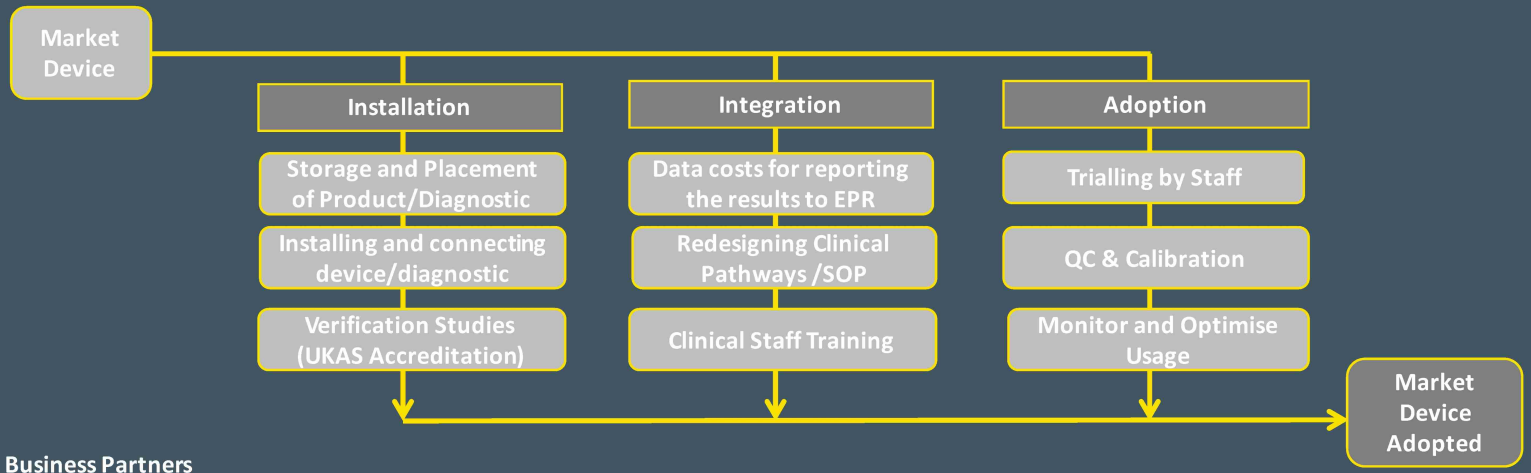
Best Practice and Tips

Build the case for change
To enter into a commissioning conversation commissioners will want to know why they should invest in your technology. By investing in your technology, it removes the opportunity to invest in something else. So a robust case for change is needed.

- **Keep abreast of any NHS Payment System changes – the consultation period includes webinars to help describe the direction of travel**
- **Read the NHS Planning Guidance which outlines the priorities for the forthcoming year, how does your technology help with the challenges?**
- **Which specialties e.g. urology, haematology would use your technology? Where are the capacity challenges in these services? Is the activity coded by Where can your technology bring the best benefit. Work with providers to understand the current activity in their services and how this will change by implementing your technology. Commissioners will be keen to understand how services How will the implementor measure performance to monitor the improvement?**
- **Understand any risk share options – would your technology be purchased by one sector but another sector benefit? Commissioners will need to ensure that the risk is mitigated.**
- **Consider producing a business case template with current adopters that can be shared to make the process simple.**
- **Are there any additional benefits to the technology? Tackling health inequalities or helping towards Net Zero challenge?**

Step 21– Adoption in a Healthcare Pathway

Innovators and NHS staff also have to be cognizant of the resources needed to physically (or virtually) adopt a new med-tech or diagnostic in an NHS setting, which includes the important step of staff acceptance.



Role of Innovation Business Partners

The role of an innovation business partner is to align the business objectives of a start-up/ technology company with the key health priorities of an NH-Trust. Several innovation business partners support start-up/ technology companies entering an NHS Trust; these include the Applied Digital Healthcare team at University Hospital Birmingham, the Clinical Scientific Computing team at Guy's and St Thomas Hospital, the Innovation team at Royal Free Hospital and Digital Health London.

Role of Academic Health Science Networks (AHSN)

AHSNs connect NHS and academic organisations, local authorities, charities and industry and provide practical support to facilitate change across health and social care economies, focusing on improving patient outcomes. AHSN is uniquely placed to identify and spread health innovation at pace and scale, driving the adoption and spread of innovative ideas and technologies across large populations. In addition to national adoption and spread programmes, AHNSs deliver local programmes that address specific local needs and challenges within their geographies.

To do List

- Engage with your local AHSN and business partners to enable alignment
- Develop your business case approach

Outputs

- A business case that supports NHS needs and highlights the benefits and costs of your technology

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Creation | Development | Evidence | Regulation | Commissioning & Adoption

Step 22– Scale-up of proven innovation

After successful adoption in a few sites, innovations should then spread across the NHS. Some innovations do spread, going from the marginal and cutting edge to everyday routine practice. However, many proven innovations and best practice tend to spread slowly and unevenly in the NHS, often leading to unacceptable variations in quality, cost and patient experience. Scaling and spreading innovation within the NHS, public health and social care is a well-recognised and long standing challenge. Too often promising innovations remain on the margins, benefiting the lucky few, but leaving the majority with poorer outcomes and experience.

Device adopted in one site → **Device adopted in several sites** → **Device adopted in many sites** → **Standard practice across the NHS**

More details for Integrated care systems can be found in Appendix 7

All parts of England are now covered by one of 42 Integrated care systems (ICSs). ICSs are partnerships that bring together providers and commissioners of NHS services across a geographical area with local authorities and other local partners to collectively plan care services to meet the needs of their population.

Local Adaptability ⟷ **Methods for spread and scale** ⟷ **Central standardisation**

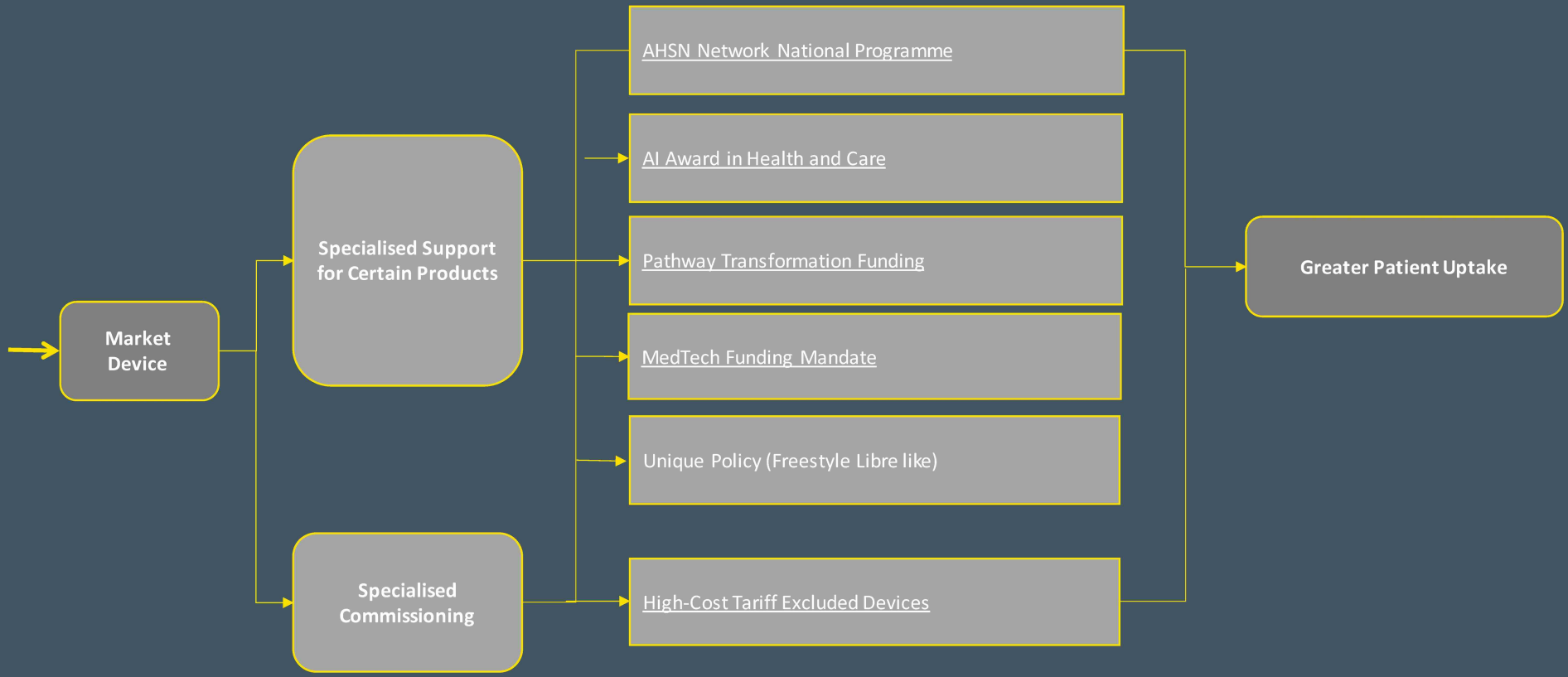
	Building capacity and capability	Networking, peer learning and collaboration	Piloting and Roll out	Coordinating engagement	Understanding and communicating priorities	Investing and incentivising	Governing and assuring
Methods or levers	• National development programme • Dedicated resource provision • Broad education • Intervention specific capacity building	• Networks • Co-production • Patient voice enablement • Leadership support • Community of practice • Collaboratives • Honest broker	• Demonstrator sites • Pilot and roll out / wave or phases	• Central coordination • Competition and crowdsourcing • Social franchising and licensing	• National signals/campaigns • Product signal • National mandates • Local needs identification • Horizon scanning • National clinical guidelines • Commissioning guidelines	• Performance related funding • Flexible commercial deals • Commercial agreement • Pricing incentives • Pathway funding	• Uptake tracking • Benchmarking • Standards • Regulation and inspection • Contractual oversight
Examples	NHS Innovation Accelerator, Quality Improvement fellowships	Cancer Improvement Collaboratives, Rapid Uptake Products, SBRI Healthcare	Improving access to general practice AF Demonstrator Site Programme	GIRFT, Solving Together, PINCER, AAC programmes	Early Cancer Diagnosis in Life Sciences Vision Missions, MedTech Funding Mandate	Innovation Technology Payment, Freestyle Libre, Inclisiran	CQC Inspection frameworks, Model Health System
Effectiveness	Sustainable approach Supports workforce development Can influence cultures Promotes system wide action Can support ideation *However:* Challenges releasing staff Impact may be crowded out by other priorities if implemented alone	Can be self-sustaining Supports local adaption Creates a 'pull' for the intervention *However:* Some areas may be lacking engagement Networks may not be enough alone for intractable challenges	Involves funding small number of NHS sites to provide understanding of implementation challenges to generate evidence for spread. *However:* Additional follow-on support may be required to fully achieve desired level of spread	Addresses complex, cross cutting barriers Can be tailored to meet local challenges Leverages diverse perspectives *However:* Other supporting levers may be required in addition	Large range of methods to reach different audiences May not require additional resources May influence system culture *However:* Must be targeted– to avoid getting lost in system 'noise' Clinical and professional consensus required	Substantial impact Can be implemented rapidly Can be cost-effective *However*: May not be sustainable May favour organisations which are already high-performing Resource implications can be significant	Clarity on requirements Encourages peer learning Provides local intelligence *However:* Unpopular Doesn't change culture Perverse incentives

Accelerated Access Collaborative | Health Technology Pathway

Creation | Development | Evidence | Regulation | Commissioning & Adoption

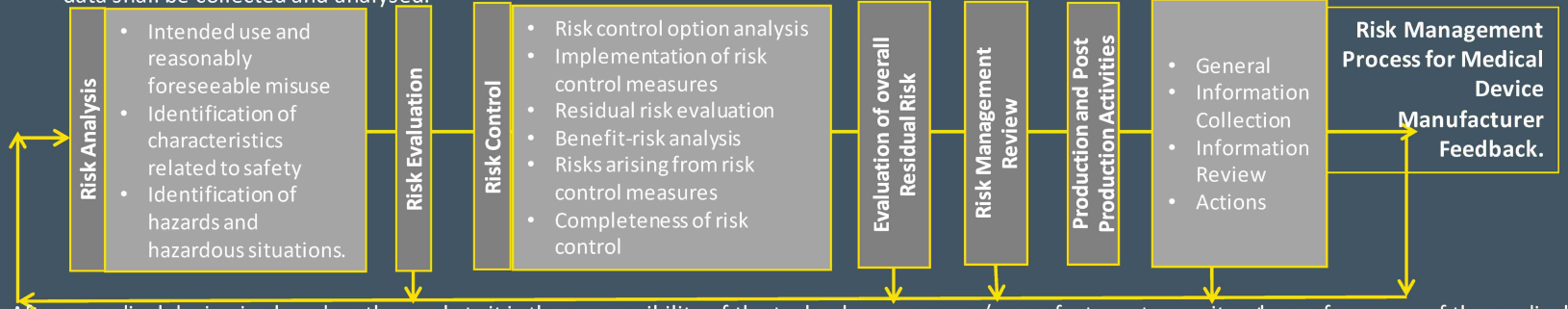
Step 23– National Endorsement Routes

There are several schemes that signify national endorsement of products, which some transformative, innovative products will be eligible for. This range from extensive support such as the RUPs project, from recommendations for local commissioners to fund certain products (MedTech Funding Mandate).



Step 24 – Regulatory Post-market Surveillance

Post-market surveillance is a set of activities conducted by manufacturers, to collect and evaluate experience gained from medical devices that have been placed on the market, and to identify the need to take any action. Post-market surveillance depends upon the information that can be/is to be collected. The manufacturer shall first establish the objectives of the post-market surveillance activities for each specific medical device or group of medical devices. Then, the manufacturer shall decide which sources are needed to fulfil these objectives. Based on this, the data shall be collected and analysed.



After a medical device is placed on the market, it is the responsibility of the technology company/ manufacturer to monitor the performance of the medical device continually.

To do List

The manufacturer (and their economic operators, as applicable) shall have a post-market surveillance plan in place, which, at minimum, includes the following steps (7):

1. **Scope** of the post-market surveillance plan: the manufacturer shall indicate for which specific medical device, medical device type or family the plan is applicable.
2. **Objective** of the post-market surveillance plan: the manufacturer shall indicate what is to be achieved by the post-market surveillance for that device.
3. **Responsibilities:** the manufacturer shall indicate responsibilities for all stages of the post-market surveillance process.
4. **Data collection**: the data collection method shall be described.
5. **Data analysis**: the method for data analysis shall be described.
6. **Using data analysis in risk management** and other processes: a system shall be in place to input the data obtained from post-market surveillance into other processes, such as risk management, improvement, clinical evaluation.
7. **Consider, decide upon and implement required actions:** based on the data analyses and further analysis in the appropriate processes.

Outputs

- Post-market surveillance plan in place.
- Ongoing patient data collection
- Adverse events reported to the MHRA
- Adverse events recorded as part of hospital processes within patient medical record

Best Practice and Tips

The MHRA operates the Yellow Card Scheme, which allows healthcare professionals and patients to report a side effect or adverse event from a medicine or medical device.

Guidance on adverse event monitoring can be found here

If applicable, report the advert event to the MHRA yellow card scheme here

Guidance on reporting to the yellow card scheme can be found here

In-hospital monitoring processes and procedures should be in line with Good Clinical Practice guidelines

Guidance for post-market surveillance and market surveillance of medical devices, including in vitro diagnostics. WHO

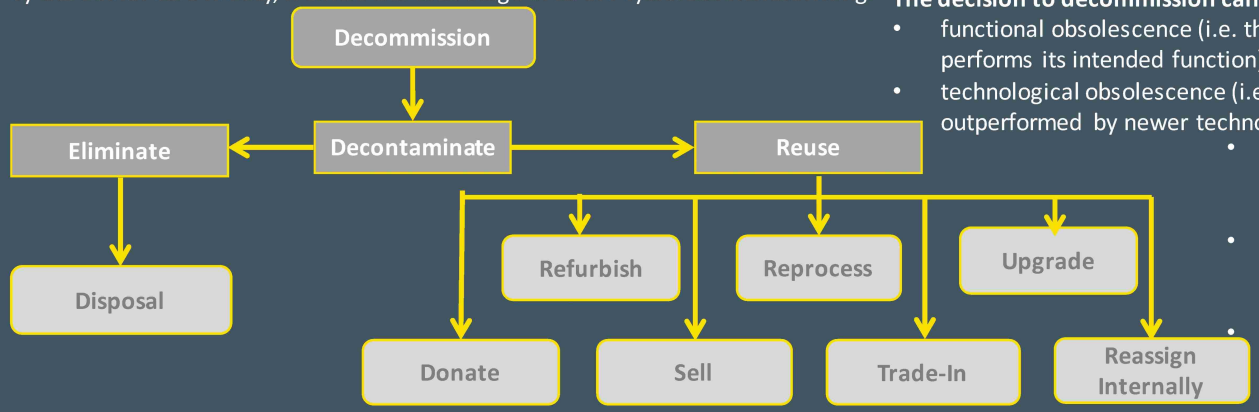
MHRA Managing Medical Devices

https://www.bsigroup.com/meddev/LocalFiles/en-US/Whitepapers/WP-Post-market-surveillance.pdf

Further information about reporting adverse incidents and corrective actions to the MHRA is available for manufacturers of medical devices.

Step 25 – Decommissioning and Disposal of Device

Decommissioning is the removal of medical devices from their originally intended use in a health care facility to an alternative use or disposal. After extended use, medical devices deteriorate and reach a state in which the cost–benefit ratio is negative, with declining performance, unreliability and regular failure. Their replacement should follow a clear policy, with evidence-based procedures, and the replacement plan should be based on the history of existing devices, including their safety, reliability and cost. When a medical device becomes obsolete or unusable or is no longer required by the health care facility, it enters the final stage of its life cycle: decommissioning.



The decision to decommission can be due to:

- functional obsolescence (i.e. the product no longer performs its intended function)
- technological obsolescence (i.e. the product is outperformed by newer technology)
- economic obsolescence (i.e. the product's use is no longer profitable)
- regulatory obsolescence (i.e. the product is no longer legal) or
- aesthetic obsolescence (i.e. the product is outmoded or its aesthetic appeal is damaged).

To do List

- **Perform Risk auditing and Cost assessment -** Consideration given to the health and safety of patients, the public, the environment and health care workers.
- **Develop Guidance for Personnel -** Guidance on decommissioning should be provided for different categories of personnel.
- **Consider Infrastructure** – Infrastructure may not have to be prepared for decommissioning smaller devices; however, it is essential when decommissioning large devices.
- **Plan for Decontamination -** Decontamination is required for decommissioning both single-use and reusable medical devices
- **Ensure Removal of Patient Data -** Patient data and information stored in medical devices should be erased or removed by the person responsible for the information before a medical device is decommissioned to protect sensitive information and patient confidentiality.
- **Consider the Waste management Approach for your Product** - Sound health care waste management ensures safety and minimal effects on health care workers, the population and the environment.
- **Inventory system and decommissioning report** - Decommissioning of medical devices should be documented and the listing of the device removed from the inventory database.

Best Practice and Tips

- **WHO Decommissioning Medical Devices - WHO Medical Device Technical Series**
- **MHRA Managing Medical Devices**
- **Health and Safety Executive - Waste Electrical and Electronic Equipment recycling (WEEE)**
- **Article: Towards design strategies for circular medical products**
- **Refurbishment of Promising KETs based Product - European Commission**

Special Cases of Medical Devices Decommissioning

- Some health technologies require special care in decommissioning. They include sharps, devices containing mercury or radioactive sources, IVDs and laboratory devices, chemicals, implants, assistive devices and computer hardware and software. Location of these devices is subject to safety and security as well as access for disposal by others.

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APPENDIX SECTION

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Appendix 1: Description of Different Types of Intellectual Property

Intellectual property (IP) is a legal framework that protects ideas, concepts and the products of creative and mental effort. The aim of IP rights is to promote innovation by rewarding the owner of the IP with a monopoly right over the idea, preventing others from exploiting it without their consent. Innovators need to secure the appropriate IP to ensure their business remains viable, and to attract investors.

	Type	Description	Timescales	Costs
Requiring Registration at Intellectual Property Office	Trademarks	Trademarks can be used to protect words, logos, slogans, sounds, colours, shapes and smells, which are used as an indicator of origin. You have to apply for this type of IP and you should keep it secret until registered. Should you need to discuss the idea with someone you should have a NDA in place beforehand. You can also check to see if a similar trademark already exists in the UK.	Around 4 months.	Around £400-1000
	Patents	Patents protect inventions and products including machines, tools and medicines. You have to apply for this type of IP and you should keep it secret until registered. Should you need to discuss the idea with someone you should have a NDA in place beforehand. Patents are costly and difficult to obtain, you can find more about what you can patent and how to apply from the UK Intellectual Property Office. Before you apply for IP its worth checking to see if there is already registered IP in place for an existing invention that is similar to your innovation. You can search for patents registered in the UK or Worldwide.	4- 6 years	~£4000 for the UK, more other countries.
	Registered Designs	A design registration protects the design of a product, that is, how it looks aesthetically, and does not link to a functional aspect of a product such as how it works. You don't need to apply for this type of IP but you can register your design with the Intellectual Property Office. Registered designs rights protect the products packaging, patterns, colours and decoration. You can check to see if your design is unique to those already registered in the UK , EU or Worldwide.	8 weeks	£60 for once design
Not Requiring Registration at Intellectual Property Office	Copyright	Copyright is a form of IP protection that protects the expression of an idea rather than the idea itself. It protects software, original literary, dramatic, musical or artistic works (for example written information including charts and drawings) and the arrangement of published editions (such as booklets, brochures and learning packages). Copyright is a form of IP protection that protects the expression of an idea rather than the idea itself. It protects software, original literary, dramatic, musical or artistic works (for example written information including charts and drawings) and the arrangement of published editions.	Automatic	Free
	Know How	Know-how is information which may be commercially or technically valuable and which is regarded as secret. In all cases, the know-how will only retain its value if it is managed effectively. Includes technical information, procedures, processes, methodology, experimental techniques, chemical structures and source code. These should be kept secret and not disclosed. You should protect your know-how with a NDA if you need to discuss the idea with someone.	n/a	n/a
	Database Rights	Databases can be protected by a specific form of copyright, if substantial skill and judgement is involved in the compilation of the database. To be protected using database rights, the database must be compiled in a methodical way.	n/a	n/a
	Freedom to Operate (FTO	Generally, the ability to use or commercialize a product or process without infringing another party's valid intellectual property (IP) rights. Freedom to Operate (FTO) is an analysis to determine whether a product, technology or invention may infringe on someone else's patent claims. The goal of an FTO is to give the client (inventor or company) a list of patents upon which their product or technology could be infringing. This analysis is recommended before submitting IP.		~£5000 to £10000

Appendix

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Appendix 2: Net zero NHS

Environmental impact should be considered as early as possible in the pathway to ensure each decision align with the NHS commitment to reach net zero by 2040 for the emissions we control directly and 2045 for the emissions we can influence. HealthTech developers and innovators should:

- Understand the requirements set by the NHS to reach net zero through the 'Delivering a net zero report' and the 'supplier roadmap'
- Identify relevant stakeholders that can provide advice and support such as the Greener NHS, the AHSNs, the trade associations, and third party organisations, including the charity sector, to access the support and expertise required on the journey towards net zero and carbon assessment and quantification.

Understanding the carbon impact of your innovation	Understand the scope 1, 2 and 3 associated with the innovation (information can be found on the delivering a net zero report) Realise and evaluate the environmental outcome(s) of the innovation on the services it impacts (clinical and service impact), in granularity, to map out the potential emissions associated with the implementation of the new product/service and its use.
Building your evidence	• Experts refer to the triple bottom line that include financial, as well as social and environmental impact, with each having specific indicators. The environmental impact is measured by the carbon footprint indicator. Consider: 1) The product & organisation's operations, including supply chain, manufacturing, distribution and use 2) The innovation's impact on the care pathway and potential changes or pathway redesign associated. • Build your carbon emissions evidence using appropriate tools and methodologies – You can set carbon reduction target across scope 1, 2 and 3, the most trusted and internationally recognised is the Science Based Targets Initiative (SBTi). • Assess your progress. You may want to work with a third-party consultancy to maintain accountability and measuring of your carbon footprint
Collaboration	Consultation and collaboration is key - On net zero specific topic, find experts, knowledge hubs and/or partners that will help you understand and measure the environmental impact of your innovation
Manufacturing, distribution and end of life	Consider the supply chain associated with the product/innovation and evaluate its footprint. Then consider the manufacturing processes involved, including scaling up operations. Links in Central Commercial Function (CCF) on remanufacturing: Medical Device Remanufacture How-to Guide - CCF Hub - FutureNHS Collaboration Platform Evaluate your distribution channels and, if applicable, the products' end of life and how you can reduce emissions throughout.
Resources	Developing a net zero strategy and quantifying an organisation and product/solution carbon emissions require resources (people/financial). Please plan and allocate resources considering the NHS net zero requirements .

Case studies – Drones & Apian Ltd

Drones are being used (initially in trials) to deliver life saving treatment, such as chemotherapy, to be picked up and dropped to patients directly on the same day. This mode of transport helps minimise wastage and treatment delays, while also saving staff time that can be used for direct patient care instead. Each drone delivery replaces at least two car journeys and one hovercraft or ferry journey per delivery – saving carbon emissions and contributing to improving air quality for patients and the community.

It will also help the NHS become the first health system in the world to become carbon neutral.

Other case studies: Case studies - Greener NHS Knowledge Hub - FutureNHS Collaboration Platform

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Appendix 2a: Public and Patient Involvement and Engagement with Patient Groups

Patient and public involvement should be included throughout the end-to-end health-technology pathway and should start as early as possible; engagement with patient groups will be key to product development. It is recommended that health technology developers research and understand who are the key active organisations in their field or disease area. Below is a summary of the touchpoints with patient groups detailed throughout the pathway

In vitro and *in vivo* studies	Developers are advised to consider how to involve patient groups in the development phase to ensure that the health technology targets and addresses the priorities of those it intends to treat.
Delivery Route Assessment	Developers are advised to consult patient groups and use patient and public involvement (PPI) organisations to help refine the patient journey and diagnostic pathways. Links to useful guidance from National Institute for Health Research (NIHR) can be found here.
Clinical trial Planning, Design and Protocol Development	Consultation with patient groups through PPI is becoming increasingly important and may be considered as a key element in every developer's clinical trial design. Developers should also consider when to alert disease specific non-profit organisations supporting patients to notify them of upcoming treatments.
Informed Consent Procedure Approval	When developing informed consent procedures, developers are advised to involve relevant patient groups for co-development. Documentation of this must be included in the dossier for ethics approval as part of the clinical trial application
Health Technology Assessment Technology Appraisal	Patient groups and PPI will form an essential part of the scope preparation stage during HTA and input from patients and the community will be important in the appraisal process.
Data Collection	It is recommended to engage with patient groups to understand the impact on patients of long-term data collection and follow-up obligations

See this call to action for why it is important to include patient groups.
Other useful resources for PPI include:

- Findacure
- HTAi SITE - Health Technology Assessment International (HTAi)
- Patient and public involvement in research (abpi.org.uk)
- PPI (Patient and Public Involvement) resources for applicants to NIHR research programmes | NIHR

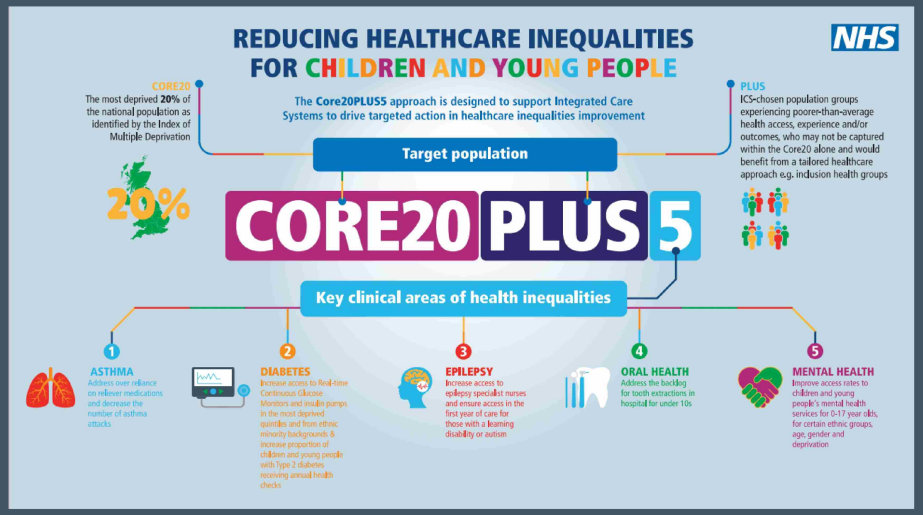
Note: whilst it is critical to engage with patient groups and patient organisations, developers should remain conscious that the vast majority are volunteer-led and operated and may have limited resources. Developers are therefore advised to ensure that when engaging with patient organisations that they are fully prepared.

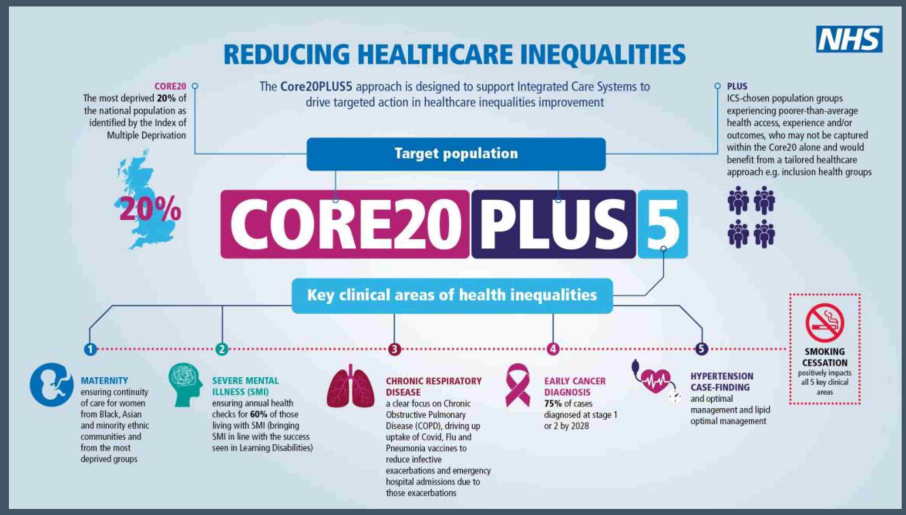
Appendix

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Appendix 2b: Health Inequalities and Core20PLUS5 framework and 2b: AAC Rapid Uptake Products

CORE20PLUS5 is a national NHS England approach to inform action to reduce healthcare inequalities at both national and system level. The approach defines a target population – the 'Core20PLUS' – and identifies '5' focus clinical areas requiring accelerated improvement – for adults these are Maternity, Severe Mental Illness, Chronic Respiratory Disease, Early Cancer Detection and Hypertension case-finding and optimal management and lipid optimal management. For Children and Young People the focus clinical areas are: Asthma, Diabetes, Epilepsy, Oral Health and Mental Health.





The AAC Rapdi Uptake Products programme was designed to support stronger adoption and spread of proven innovations. It identifies and supports products with NICE approval that support the NHS Long Term Plan's key clinical priorities, but have lower than expected uptake to date. Examples of resources co-produced with patients include:

Asthma Biologics are an innovative group of medicines used by specialists to treat people with severe asthma. AAC Patient and Public Voice Partners (PPVs) co-produced patient information leaflets with translations in Arabic, Bengali, Gujarati, Polish, Punjabi, Somali and Urdu. We collaborated with Oxford Academic Health Science Network to produce a toolkit including podcasts and clinical education resources.

FeNO testing is a method that assists with the diagnosis of asthma by measuring fractional exhaled nitric oxide (FeNO) in the breath of patients suspected of having asthma. AAC PPVs collaborated with Wessex Academic Health Science Network to produce resources including patient leaflets in seven languages ; clinician e-learning and partnered with Asthma and Lung UK on an explanatory video .

Appendix

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Appendix 3: List of Med-Tech Digital Health Accelerators

There are several MedTech/digital health accelerators which can support prototyping. Key ones are listed below that are NHS affiliated (left) and ones representing the wider landscape (right), but this is non-exhaustive. BEIS has more information on all incubators and accelerators.

6

DigitalHealth London	A 12-month programme for digital health companies that have products or services aimed at solving NHS and social care challenges (these are normally already been piloted in the NHS and are ready to scale).
AHSN Digital North Accelerator	A programme of support for digital health technology firms to support the adoption and spread of proven innovations within the healthcare system.
Wessex AHSN Health Innovation Programme	A multi-day training course to support early-stage concept development for innovations in the Healthcare industry. It is targeted at candidates in the West or South West of England.
Propel@YH	A six-month digital health accelerator programme targeted at SMEs with digital health innovations for the Yorkshire and Humber region.
MedTech Accelerator	A programme to support the early stage development of innovations in the broad area of medical technology (devices, diagnostics, software and eHealth) that meet unmet clinical needs within the NHS.

Health Social Innovators (HIS)	A 12-week accelerator that supports the growth of early-stage social entrepreneurs who are pioneering new ways to tackle health inequality in the UK.
AWS Healthcare Accelerator	A four-week technical, business, and mentorship accelerator opportunity, open to UK-based healthcare start-ups or international healthcare start-ups that have existing UK operations
Deep Science Ventures	An accelerator targeting deep tech companies in the life sciences, health, manufacturing, engineering, digital technology, energy and environmental industries.
Imagine IF!	An accelerator for companies starting and working in the fields of life science and health tech with start-ups based on a genuine, novel scientific and/or technological idea that has a significant impact on improving human or animal well-being
Edison™ Accelerator	A start-up and scale-up acceleration & healthcare provider collaboration programme aimed to accelerate innovative solutions.

The 15 ARCs are:

NIHR Applied Research Collaboration East of England
NIHR Applied Research Collaboration East Midlands
NIHR Applied Research Collaboration Greater Manchester
NIHR Applied Research Collaboration Kent, Surrey and Sussex
NIHR Applied Research Collaboration North East and North Cumbria
NIHR Applied Research Collaboration North Thames
NIHR Applied Research Collaboration Northwest London
NIHR Applied Research Collaboration North West Coast
NIHR Applied Research Collaboration Oxford and Thames Valley
NIHR Applied Research Collaboration South London
NIHR Applied Research Collaboration South West Peninsula
NIHR Applied Research Collaboration Wessex
NIHR Applied Research Collaboration West
NIHR Applied Research Collaboration West Midlands
NIHR Applied Research Collaboration Yorkshire and Humber

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Appendix

Appendix 4: Financial Support – Securing Pre-Seed Funding Options

Public/Third Sector				
Funding Option	Description	Funding Available	Timelines	Numbers
government Start-up Loan/British Business Bank	A government-backed Start-up Loan, with free support and guidance and up to 12 months of free mentoring.	£500 to £25,000	Unknown	Unknown
SBRI Healthcare (Phase 1)	Based on taking a two-phased development approach, projects start with initial feasibility and can then move on to more detailed product development	**Phase 1: £200,000** Phase 2: £1 million	2 calls per year	Ten companies per year
Charitable Grants	Grant to develop proof-of-concept from a charity.	Various	Variable	Unknown
Q-Exchange – Health Foundation	Aim to start-ups boost ideas that have the best potential to generate value for the health and care system.	800k Total, up to 40k per winner.	Annual	
UKRI Funding	Non-departmental public body sponsored by BEIS, providing funding from every stage of research.	~£150,000	Unknown	Unknown
Knowledge Transfer Networks	Can offer business support, funding and being connected to partners.	Up to £75,000	Between 12 and 36 months	Unknown
Local Enterprise Partnerships Growth Hubs	The network of 38 Growth Hubs are local public/private sector partnerships .They join up national and local business support so it is easy for businesses to find help.	**n/a**	n/a	N/a

Private Investment/Self-Funded				
Funding Option	Description	Funding Available	Timelines	Numbers
Small Business Loans	Small business loans are available from a variety of banks.	£1000 to £750,000	Unknown	Unknown
Friends and Family	Securing funding from friends and family is a common strategy.	~£15,000	Unknown	Unknown
Angel Investors	An individual who provides capital for a business or businesses start-up, usually in exchange for convertible debt or ownership equity.	Unknown	Unknown	Unknown
Crowdfunding	The practice of funding a project or venture by raising small amounts of money from a large number of people	Unknown	Unknown	Unknown
Company Self-Funded	Large companies typically self-fund development.	Unknown	Unknown	Unknown

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Appendix 4a: Financial Support – Securing Pre-Seed Funding Options

Seed funding is a form of securities offering in which an investor invests capital in a start-up company in exchange for an equity stake or convertible note stake in the company, and pays for product development and further market research. Public/Third sector options are available, typically without the equity stake. Seed funding is generally used to develop a business idea to the point that it can be presented effectively to venture capital firms or larger companies that have large amounts of money to invest.

Public/Third Sector				
Funding Option	Description	Funding Available	Timelines	Numbers
NIHR i4i Awards	A translational research funding scheme aimed at de-risking early-to-late stage medical devices, in vitro diagnostics and t patient-focused DHTs for ultimate NHS use.	£0.6m-£1.2m	4 months	11 successful/126 applications for 19/20
UKRI Funding	UKRI is a non-departmental public body sponsored by the Department for Business, Energy and Industrial Strategy (BEIS).	Various	Variable	Unknown
NHS Innovation Accelerator (NIA)	Programme supporting delivery of the *NHS Long Term Plan* priorities by accelerating uptake of promising innovations.		Annually	~ 11 a year.
Charity Funding	Grant to develop proof-of-concept from a charity.	Various	Variable	Unknown
MRC Biomedical Catalyst	The BMC aims to de-risk innovative science and commercialise ideas arising out of academia and industry helping UK SMEs to develop into competitive organisations.	Various	Variable	Unknown

Private Investment/Self-Funded				
Funding Option	Description	Funding Available	Timelines	Numbers
Angel Investors	An individual who provides capital for a business or businesses start-up, usually in exchange for convertible debt or ownership equity.	Unknown	Unknown	Unknown
Crowdfunding	The practice of funding a project or venture by raising small amounts of money from a large number of people	Unknown	Unknown	Unknown
Company Self-Funded	Large companies typically self-fund development.	Unknown	Unknown	Unknown

Back to the Financial Support – Securing Seed Funding Slide

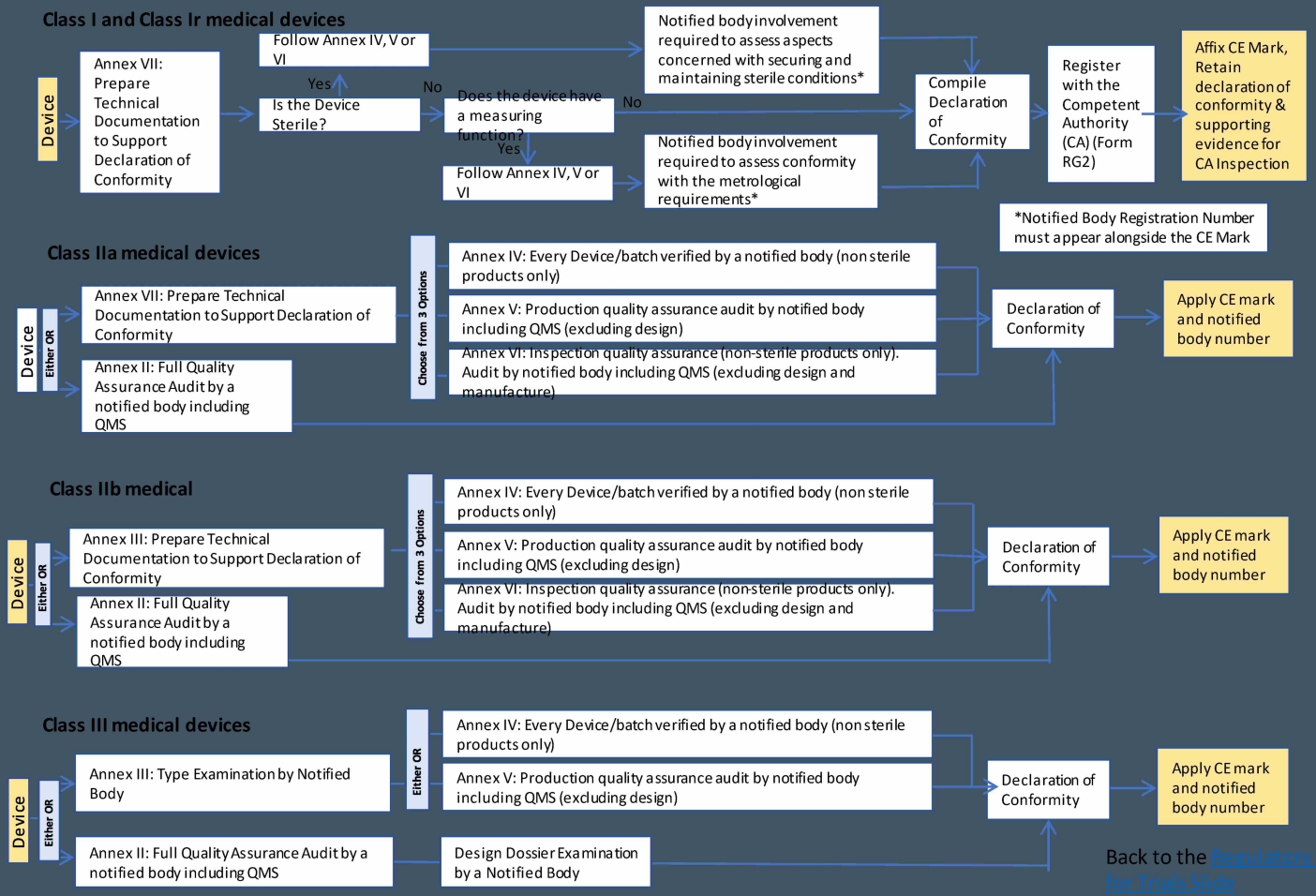
Appendix

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Appendix 5: Gaining UKCA Marking

Manufacturers need to demonstrate that their MedTech meets the requirements in the MDR or IVDR by carrying out a conformity assessment. The conformity assessment route depends on the classification of the device. List of suitable NBs can be found on the EU Commission's 'Nando' website and is not held by the MHRA since we left the EU. The 'Declaration of Conformity' is a manufacturer responsibility and not issued by the MHRA. This chart can be found in more detail at MHRA Conformity Assessment Routes Chart .

MHRA Conformity Assessment Routes Chart

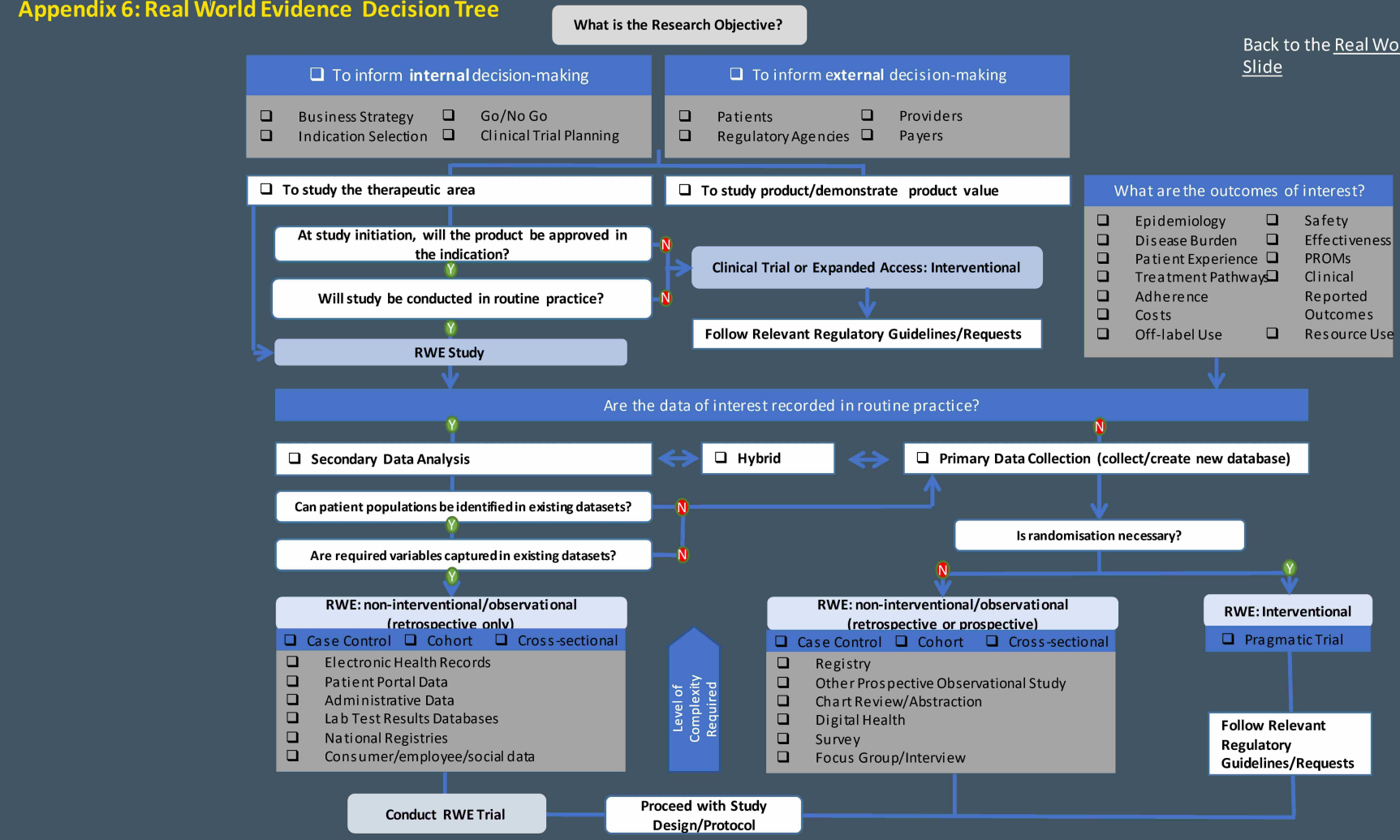


Appendix

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Appendix 6: Real World Evidence Decision Tree



Back to the Real World Evidence for commissioning Slide

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Health Technology Pathway

Appendix 6

Creation	Development	Evidence	Regulation	Commissioning & Adoption

Creation of Medical technology product

Submit technology via NHS innovation service Welcome | NHS Innovation Service

NHS Supply Chain

Early knowledge of Framework, approximately procurement dates, category, regulatory and technology requirements,

Development

Evidence and Regulation

NHS Supply Chain

Market knowledge, secondary review for framework and route to market

Commissioning and Adoption

Procurement Options

Government Tenders and Contracts

NHS Organisation registers tender on NHS England retendering Service

Suppliers can search for opportunitjes on Contracts Finder and Find a Tender and register on the Supplier Registration Service for Government

NHS Supply Chain

Supplier responds to an opportunity

Become NHS Supply Chain Supplier. In order for a product to be listed in the NHS Supply Chain Catalogue, it must be procured through a compliant tender and, if successful, will be listed on a Framework Agreement under the respective Category Tower Service Provider (CTSP).

NHS orders market device

Supplier distributes market device to purchaser directly or via NHS Supply Chain

Market Device

Market Device On Procurement Framework

Patient Access

Value based Pilot

Export Support

Additional National Endorsement

Innovation Service Support Organisation

- Early engagement with NHS supply chain via Innovation service
- Keep record updated with regulatory process
- Register interest on Find a Tender
- Respond to PIN
- Undertake training videos in preparation for contract notice.

- Insight of procurement framework and route to market
- Understanding of specifics requirements within specifications
- Training and preparation
- Ongoing support and information via Category and SRM team

- A procurement Framework is an agreement put in place with a provider or range of providers that **enables buyers to place orders for services without running lengthy full tendering exercises**.
- Frameworks are based on large volume buying. Aggregating different buyers' potential needs means individual buyers can source services at lower prices, or with special added benefits and/or more advantageous conditions.
- Frameworks are often divided into 'lots' by product or service type, and sometimes by region. This means that suppliers offering certain kinds of specialist goods or services, sometimes in a specific geographic location, can bid to join the lot that best suits their offer.
- Once awarded, frameworks run for a given timeframe, usually between 1 to 4 years, after which they are re-tendered, giving new suppliers the chance to bid to join them.
- Supplier eProcurement Portal is a digital transaction process that involves using the internet to buy and sell goods and services. This process employs a supplier's closed system, meaning that only their registered customers can use and gain benefits from it.
- The web-based system brings together a suite of collaborative tools that enable NHS Supply Chain and suppliers to conduct the strategic activities of the procurement lifecycle.
- NHS Supply chain Procurement portal https://nhs.supplychain.app.jaggaer.com/web/login.html

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Appendix 7 Integrated Care Systems

What are integrated care systems?

- Integrated care systems (ICSs) are partnerships that bring together NHS organisations, local authorities and others to take collective responsibility for planning services, improving health and reducing inequalities across geographical areas.
- ICSs were created in July 2022 and commissioned from nationally devolved budgets.
- There are 42 ICSs across England, covering populations of around 500,000 to 3 million people.

Why are ICSs needed?

- ICSs are critical in driving efforts to improve population health and tackle inequalities in local areas.

What do ICSs look like?

- Integrated care boards (ICBs)- responsible for allocating the NHS budget and commission services for the population, taking over the function previously held by clinical commissioning groups (CCGs) and some of the direct commissioning functions of NHS England.
- Integrated care partnerships (ICPs) – a joint statutory committee of ICBs and local authorities in the area. The ICP brings together a broad set of system partners to support partnership working and developing an integrated care strategy, a plan to address more comprehensive health care, public health and social care needs of the population.

What doe this mean for commissioning?

- ICBs have taken on commissioning responsibilities from NHS England, including commissioning primary care and some specialised services.

What does this mean for NHS providers?

- NHS providers are expected to work with ICS to plan and transform services and improve system performance.
- NHS providers are expected to participate in multiple collaborative forums, including membership to ICBs and forming collaboratives with other providers.

What does this mean for local government?

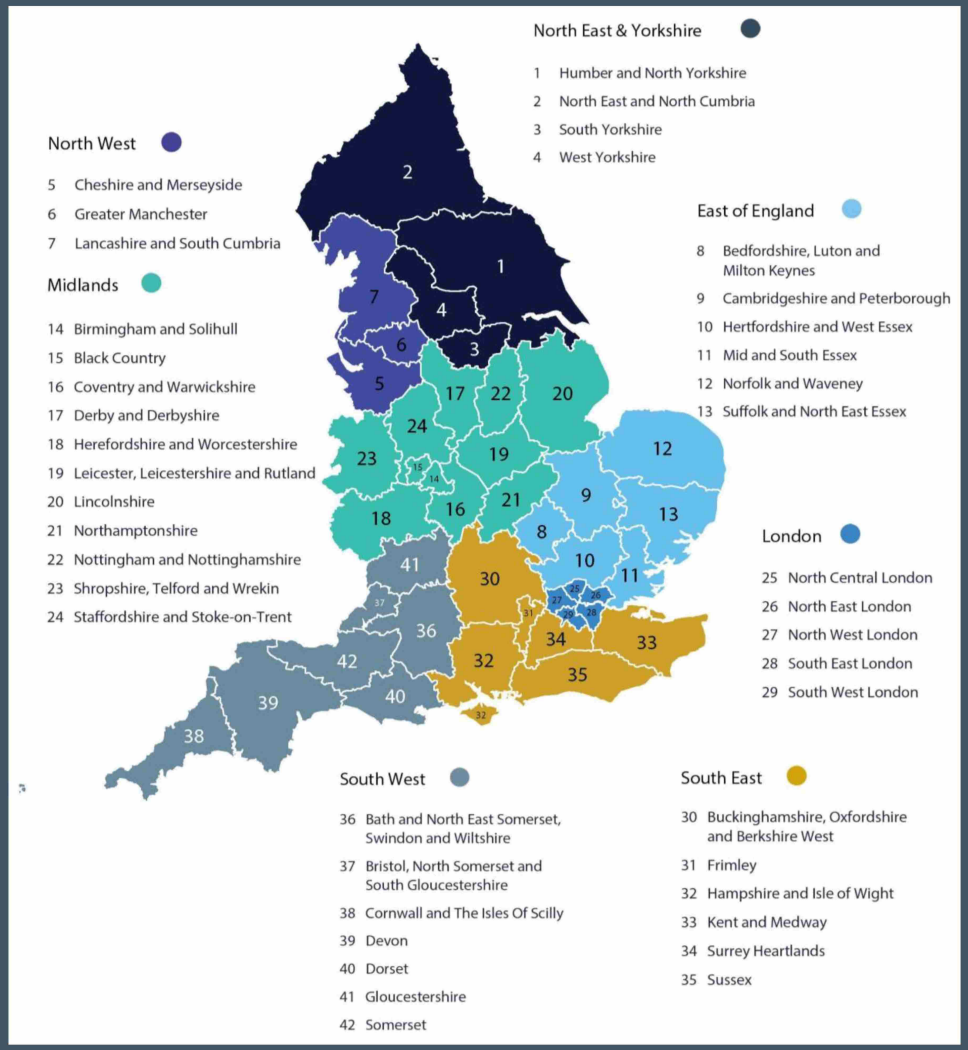
- Local authorities are expected to work with ICPs and ICBs to create systems ad partnerships to improve population health and wellbeing and tackle health inequalities.

What does this mean for VCSE organisations?

- VCSEs are important strategic partners for ICSs to deliver health and well-being improvements and reduce inequalities.
- VCSEs are expected to be involved within governance structures and deliver critical workstreams in ICSs through membership in ICPs.

What does this mean for oversight and regulation?

- A new integration index is under development to better capture the role of regulatory stakeholders in ICSs.



Appendix

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Health Technology Pathway

ACRONYM SECTION

Accelerated Access Collaborative

Health Technology Pathway

Acronyms

Acronym	Name
AAC	Accelerated Access Collaborative
ABHI	Association of the British Healthcare Industry
ATTC	Advanced Therapy Treatment Centre Network
AWTTC	All Wales Medicines Strategy Group
CAA	Commercial Access Agreement
CE	Conformité Européenne (European Conformity)
CRO	Contract Research Organisation
CTA	Clinical Trial Application
DHSC	Department of Health and Social Care
EAG	Expert Advisory Group
EMA	European Medicines Agency
FDA	Food and Drug Administration
FIH	First in Human

Acronym	Name
GCP	Good Clinical Practice
GLP	Good Laboratory Practices
GLPMA	Good Laboratory Practice Monitoring Authority
GMO	Genetically Modified Organism
GMP	Good Manufacturing Practices
GMS	Genomic Medicine Service
GPVP	Good Pharmacovigilance Practice
HRA	Health Research Authority
HSE	Health and Safety Executive
HTA	Human Tissue Authority
HTA	Health Technology Assessment
ICSR	Individual Case Safety Reports
IDAP	Innovative Devices Access Pathway
IMF	Innovative Medicines Fund

Accelerated Access Collaborative

Health Technology Pathway

Acronym	Name
GCP	Good Clinical Practice
GLP	Good Laboratory Practices
GLPMA	Good Laboratory Practice Monitoring Authority
GMO	Genetically Modified Organism
GMP	Good Manufacturing Practices
GMS	Genomic Medicine Service
GPVP	Good Pharmacovigilance Practice
HRA	Health Research Authority
HSE	Health and Safety Executive
HTA	Human Tissue Authority
HTA	Health Technology Assessment
ICSR	Individual Case Safety Reports
IDAP	Innovative Devices Access Pathway
IMF	Innovative Medicines Fund

Acronym	Name
IRAS	Integrated Research Application System
ISRCTN	International Standard Randomised Controlled Trial Number
MA	Marketing Authorisation
MAA	Managed Access Agreement
MHRA	Medicines and Healthcare products Regulatory Agency
NHSE	NHSE National Health Service England
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health Research
NOCRI	NIHR Office for Clinical Research Infrastructure
OMA	NICE Office for Market Access
PACE	Patient and Clinician Engagement
PIL	Patient Information Leaflet
PPI	Patient and Public Involvement

Acronym	Name
PREMs	Patient Reported Experience Measures
PROMs	Patient Reported Outcome Measures
QC	Quality Control
QMS	Quality Management System
REC	Research Ethics Committee
RMP	Risk Management Plans
SMC	Scottish Medicines Consortium
TA	Technology Appraisal
UKCA	United Kingdom Conformity Assessed

Acronyms