BIVDA

Medicines & Healthcare products Regulatory Agency

IVD Roadmap

Friday 10th February 2023 (10:00 – 16:00)

MHRA offices, 1st Floor Conference Suite, 10 South Colonnade, London, E14 5EA

Overview of OLS and our role in the IVD landscape

February 2023

[redacted]

Office for Life Sciences

The Office for Life Sciences – who we are

OLS is responsible for improving the health and wealth of the nation by leveraging the strengths of the UK Life Sciences sector.

The Life Sciences Vision is our 10 year strategy which sets out how Government, the sector and NHS will work together to make the UK a globally leading location for life science investment and innovation.

Life Sciences Vision

The Vision has three areas of policy focus – **1) Science and Research; 2) the NHS as an Innovation Partner; and 3) Business Environment** – which build on the themes of the 2017 Life Science Industrial Strategy, while recognising that the national and global landscape have changed significantly in recent years due to Brexit and COVID-19.

Science and Research

Build on the UK's **world class science and research capabilities** – making the UK the **best place in the world to trial and test products at scale**, underpinned by an ever improving genomic and health data infrastructure.

NHS as an Innovation Partner

Make the **NHS the country's most powerful driver of innovation** – through the development, testing and adoption of new technologies at a population-scale, **using new technology to get diagnosis and treatment right first time**, and building genuine trust between the NHS and the Sector.

Business Environment

Create an **outstanding business environment for Life Science companies** – underpinned by a **world class regulatory environment** and bringing to bear the **full financial firepower of the City of London** to support companies to grow.

What have we done, and what's next?

OLS delivered the Medicines and Diagnostics Transformation Fund. The £20m Fund Provided grants to support UK Life Science manufacturing.

Several OLS mission areas have a focus on diagnostics. Including Cancer, Ageing and Obesity.

Our aim is to work jointly with our partners across the system to create a best-in-class regulatory environment for both Devices and Diagnostics in the UK.

What's next?

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Department of Health & Social Care

DHSC MedTech Directorate

IVD Roadmap Workshop

[redacted]

10 February 2023

One mission

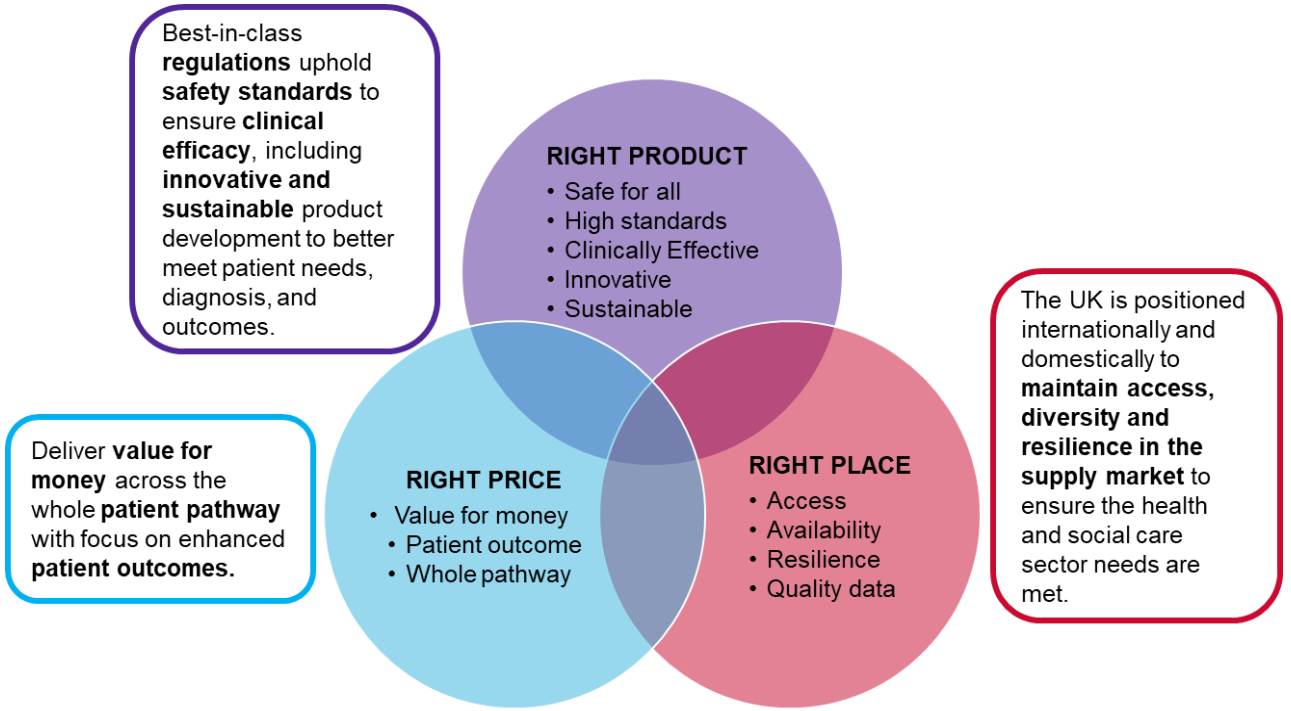
- We aim to ensure the health and social care system can reliably access safe, effective, innovative, and ground breaking medical technologies that support the continued delivery of high quality care and excellent patient outcomes in a way that makes best use of taxpayer money.

Two objectives

- Don't let the NHS run out of MedTech
- Drive best value from the £8-10 Billion annual spend on MedTech

Three priorities

- Right Product
- Right Place
- Right Price



Four teams

Medical Technology Director
David Lawson

- Diagnostics
- Digital Health

Key responsibilities by:
- Enduring responsibility
- Sub-sector responsibility
- Transformation project responsibility

Supply Resilience & Engagement DD [redacted]

- Industry expertise, Supplier & industry body engagement
- Clinical Engagement
- Resilience strategies
- Shortage response coordination
- Liaison with Other Government Departments, Arms Length Bodies, The Devolved Administrations and Crown Dependencies.
- Renal
- Enteral
- IV Therapies

- Reuse and remanufacture

Strategy, Policy & Regulation DD [redacted]

- Overall MedTech strategy
- Supporting Innovation
- Sustainability
- Regulatory improvements
- Correspondence / PQ / FOI / Ministerial handling

- Subsector landscape
- Social and Community
- Diabetes

- Regulatory reform
- Device Inequalities Review

Operations DD [redacted]

- National ICU Equipment & Consumables Reserves
- Oxygen resilience
- Reserve horizon scanning, volume control & allocation
- SCCL logistics and warehouse oversight
- Contract negotiation, management and monitoring

- Respiratory and Airway
- Medical Gasses

- Asset management
- Future resilience prep

Data & Analysis DD [redacted]

- Data strategy
- Data monitoring, improvement and transparency
- Analytical support (e.g. Supply & demand, spend tracking)

- Market segmentation data
- Sub sector analysis

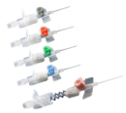
- Business Case support
- Benefit delivery tracking

• Supply Resilience and Engagement Team

Shortage Management:

2021 saw large increase in significant (non Covid) supply disruptions from 1 in 2020 to 8 in 2021

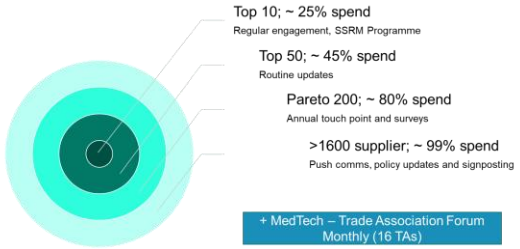
CPAP 

Cannula 

Blood Tubes 

Biopsy probes 

Supplier Engagement:



Stakeholder Engagement:

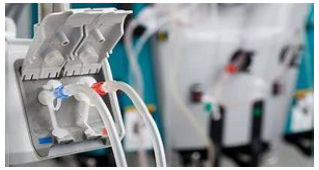
Facilitating coordination between NHS SC, NHSE&I and MHRA with the DACDOTs

Exploration of transformational technologies for reuse and remanufacture

Supply Resilience:

Supply resilience strategies to enhance resilience in the short, medium and long term, for Products of High Concern Contract management Renal and Enteral contingency

Renal Replacement Therapy



Enteral Feeding

IV Therapies

Strategy, Policy and Regulation

The **MedTech Strategy** builds on and supports the Life Sciences Vision to help secure the position of the UK as a global science superpower.

The strategic priority areas are:

- ensuring resilience and continuity of supply of medtech products
- supporting innovation and encouraging thriving, dynamic markets
- developing enabling infrastructure
- specific focuses on key issues and markets

1

Resilience / Continuity of Supply
- Strategic Reserve
- Standardisation and Interoperability
- Reuse / remanufacture
- UK Flexible manufacturing capability

2

Innovative and Dynamic Markets
- Demand Signalling
- Coherent evaluation including real world evidence
- Aligned clinical and commercial leadership to drive adoption of transformative innovations

3

Enabling Infrastructure
- Transparent, comparable data
- Progressive collaboration with industry
- Sub sector strategies

Future Medical Devices Regulation

Following our exit from the EU, we have a unique opportunity to improve how medical devices and IVDs are regulated in the UK.

The MHRA's purpose is clear: to protect patients and the public and facilitate access for UK patients to the latest advances the MedTech sector can offer. The new regulatory framework will serve as the cornerstone to realising these opportunities and will be built on five pillars:

• Strengthening MHRA power to act to keep patients safe

• Making the UK a focus for innovation

• Addressing health inequalities and mitigating biases throughout medical device product lifecycles

• Proportionate regulation which builds on synergies with both EU and wider global standards

• Setting world leading standards

In 2020, the **Independent Medicines and Medical Device Safety Review** published its report, "First do no harm".

The report included a recommendation that "there should be mandatory reporting for the pharmaceutical and medical device industries of payments made to teaching hospitals, research institutions and individual clinicians".

This recommendation was accepted in principle and work is ongoing to launch a public consultation on Government proposals in the first half of 2023.

- MedTech Operations

Oxygen Resilience

National Reserves

National ICU Equipment & Consumables Reserves

Equipment: 86,000 devices worth £312m in reserve, with 38,000 devices worth £172.8m allocated.

Consumables: 1 billion items worth £200m from 330 different product areas purchased from 276 Suppliers. Critical in UK response to 4 major national supply disruptions.

SCCL: Logistics including emergency 24-hour delivery timescales.

Successor to the DHSC – NHSE/I Covid O2VMD&CC Programme.

Data & Analysis

Routine responsibilities

- Data strategy
- Data monitoring, improvement and transparency
- Analytical support

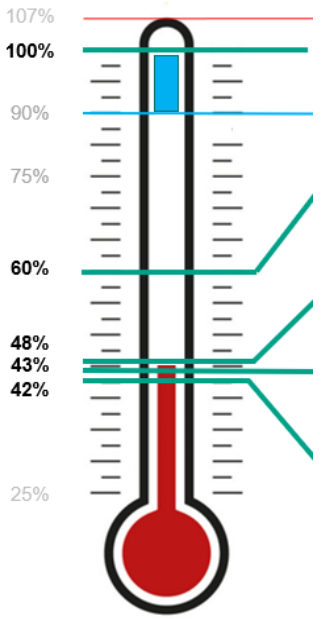
Sub-sector responsibilities

- Market segmentation data
- Sub sector analysis

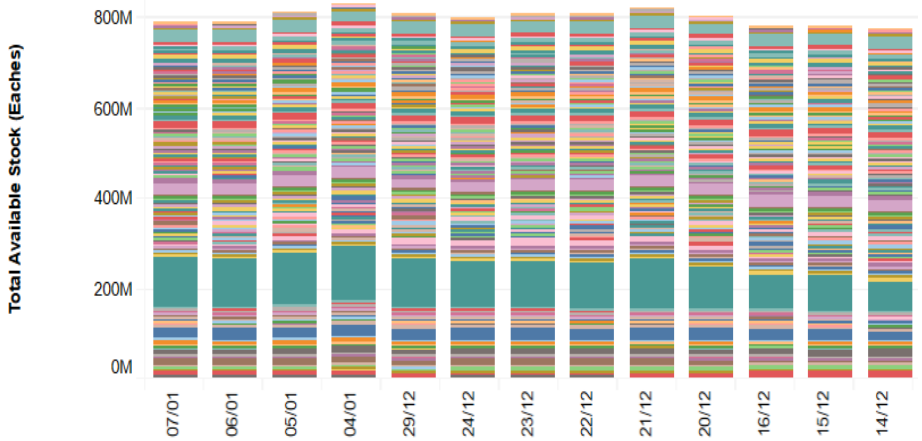
Transformation responsibilities

- Business Case support
- Benefit delivery tracking

UK Oxygen Utilisation



Granular daily consumable figures



• MedTech in a nutshell

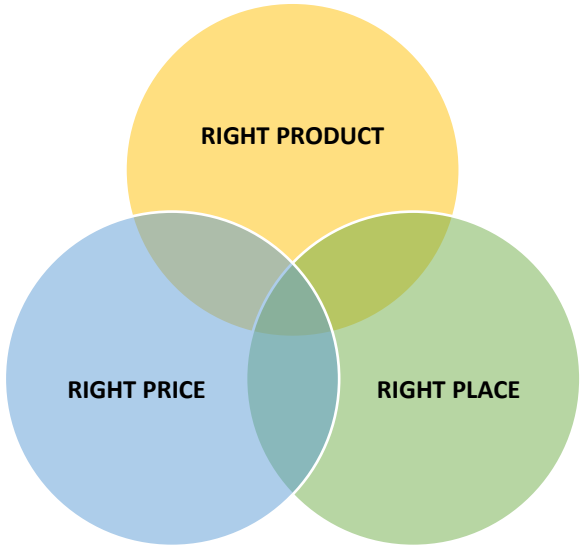
1
Mission

We aim to ensure the health and social care system can reliably access safe, effective, innovative, and ground breaking medical technologies that support the continued delivery of high quality care and excellent patient outcomes in a way that makes best use of taxpayer money.

2
Core objectives

- Don't let the NHS run out
- Drive best value from the £8-10 Billion annual spend on MedTech

3
Priorities



4
Teams

- Supply Resilience & Engagement DD [redacted]
- Operations DD [redacted]
- Strategy, Policy & Regulation DD [redacted]
- Data & Analysis DD [redacted]

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Innovate UK Products and Services for IVD

[redacted] - Innovation Lead Health Technologies

UKRI Innovate UK

Innovate UK

- We are the UK’s innovation agency
- We support business-led innovation in all sectors, technologies and UK regions
- A key delivery body of the Government’s Innovation Strategy

Our Mission

To help UK businesses grow through the development and commercialisation of new products, processes, and services, supported by an outstanding innovation ecosystem that is agile, inclusive, and easy to navigate.

Biomedical Catalyst

Overview

- Primary Innovate UK grant funding mechanism for supporting UK health & life sciences SMEs
- Running since 2012 & Innovate UK provided £320 million funding awards
- Technology agnostic and open to any human health and life science SME with an innovative idea

Aims of the programme

1. deliver growth to the UK health & life sciences sectors
2. deliver innovative life sciences products and services more quickly and more effectively into healthcare
3. provide support to commercially led R&D in a seamless, effective and efficient manner

Programme Structure:

Stream 1:	Collaborative R&D Grant Funding
Stream 2:	Accelerators and Feasibility Funding
Stream 3:	Investor Partnerships

The Health Technology Regulatory and Innovation Programme (HealthTRIP)

To provide a wide package of support to the UK HealthTech industry to help them in a changing regulatory environment

Regulatory Support

£7.3m funding competition, awarded to 317 SMEs up to £30,000 to fund regulatory consultancy advice and support

Training

Developed a webinar series about changing medical device regulations and the regulatory journey that was accessed more than 11,000 times

MedTech Challenges and Opportunities Report

Utilised all project inputs, surveys and interviews to identify the key challenges facing SMEs and developed actionable recommendations to address them

IVD Technology Roadmap

Developed a technology and capability roadmap for in vitro diagnostics to support future industry planning and government interventions

www.uk-cpi.com/HTRIP

www.uk-cpi.com/IVD-roadmap

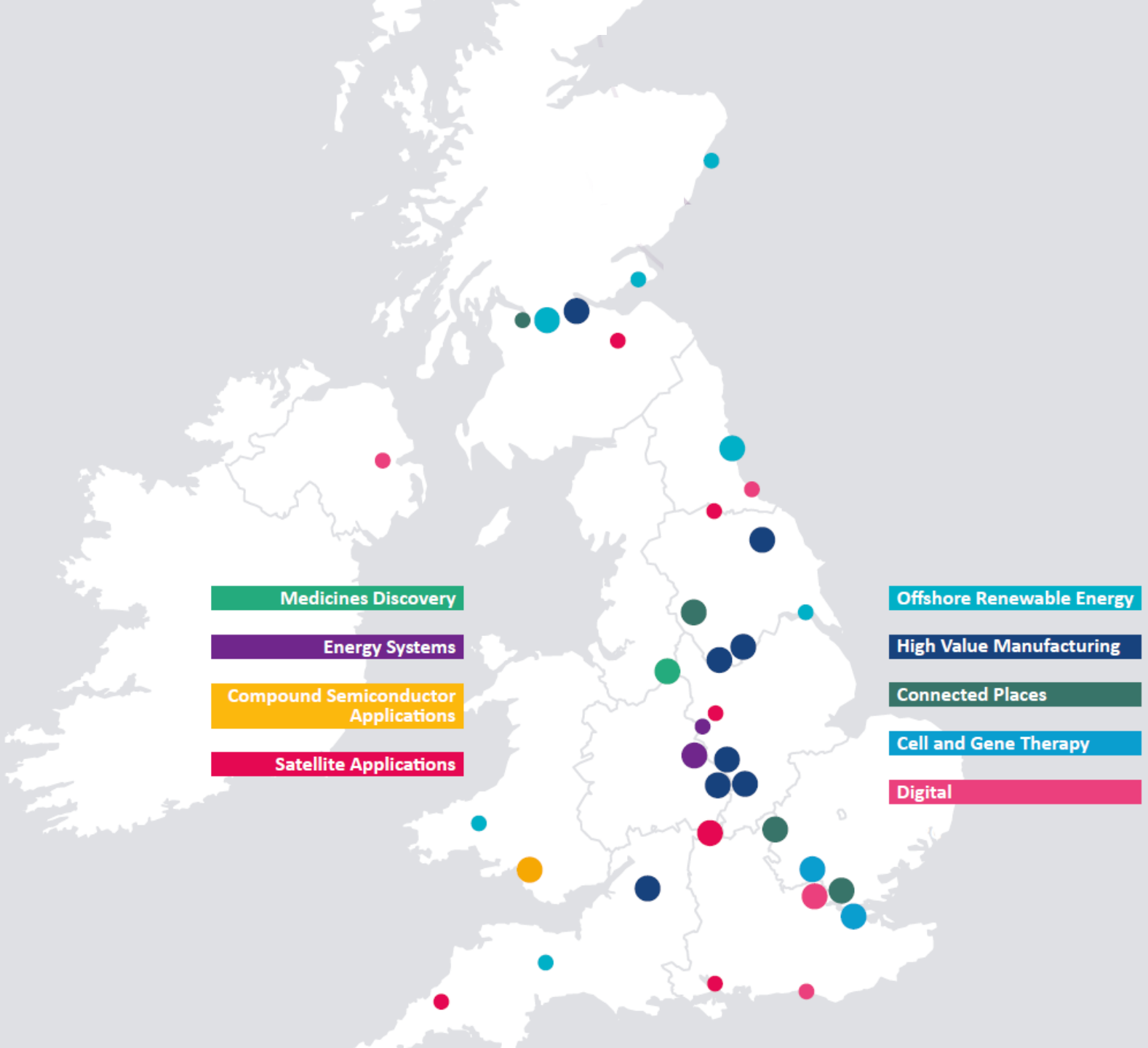
cpi

www.uk-cpi.com

Catapult Network

Fostering innovation to drive economic growth

- bridge the gap between businesses, academia, research and government
- transforming the UK's ability to create new products and services
- ensure global opportunities for the UK and sustained economic growth for the future



UKRI Innovate UK

Innovate UK KTN

Innovate UK KTN exists to connect innovators with new partners and new opportunities beyond their existing thinking – accelerating ambitious ideas into real-world solutions.

Net Zero | Diversity & Inclusion | Global Innovation | Innovation Adoption & Diffusion | Place

UKRI Innovate UK KTN

Innovate UK EDGE

Bespoke support that grows & scales innovative businesses

We enable innovation-driven businesses to grow at pace and deliver on their industry and society-transforming ambitions.

Our innovation and growth specialists provide invaluable advice and access to critical resources to help clients make step changes towards scale.

For intensive support with your growth strategy, including exploiting innovation, securing funding & finance and entering new markets, please get in touch.

innovateukedge.ukri.org

UKRI Innovate UK

Find out how Innovate UK EDGE helped
Photocentric double the size of their business year on year

Innovate UK

Thank You

Download the Plan for Action

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Accelerated Access Collaborative

NHS Innovation Service

- **Introducing the New NHS Innovation Service**

innovation.nhs.uk

Accelerated Access Collaborative

NHS Innovation Service

What is the NHS Innovation Service?

Information on how to develop an innovation for market

Coordinated support from support organisations

NICE National Institute for Health and Care Excellence

NIHR | National Institute for Health and Care Research

The AHSN Network

Department for International Trade

Healthcare Improvement Scotland | SHTG Advice on health technologies

Medicines & Healthcare products Regulatory Agency

Technoleg Iechyd Cymru Health Technology Wales

Hwb Gwyddorau Bywyd Cymru | Life Sciences Hub Wales

NHS Supply Chain

The NHS Innovation Service replaced HealthTech Connect.

Accelerated Access Collaborative

NHS Innovation Service

Who is the NHS Innovation Service for?

	Core target user group	The service will also be useful for	The service is not aimed at
Who	Innovators (industry, SMEs, clinicians, patients)	Academics (translational researchers)	
What	Medical devices, digital, AI, diagnostics, services, models of care	Pharmaceuticals	
When	Idea for innovation, development, scale	Basic research	Established products
Where	England, Wales, Scotland, Northern Ireland	International companies interested in UK	UK companies looking abroad only

Accelerated Access Collaborative

NHS Innovation Service

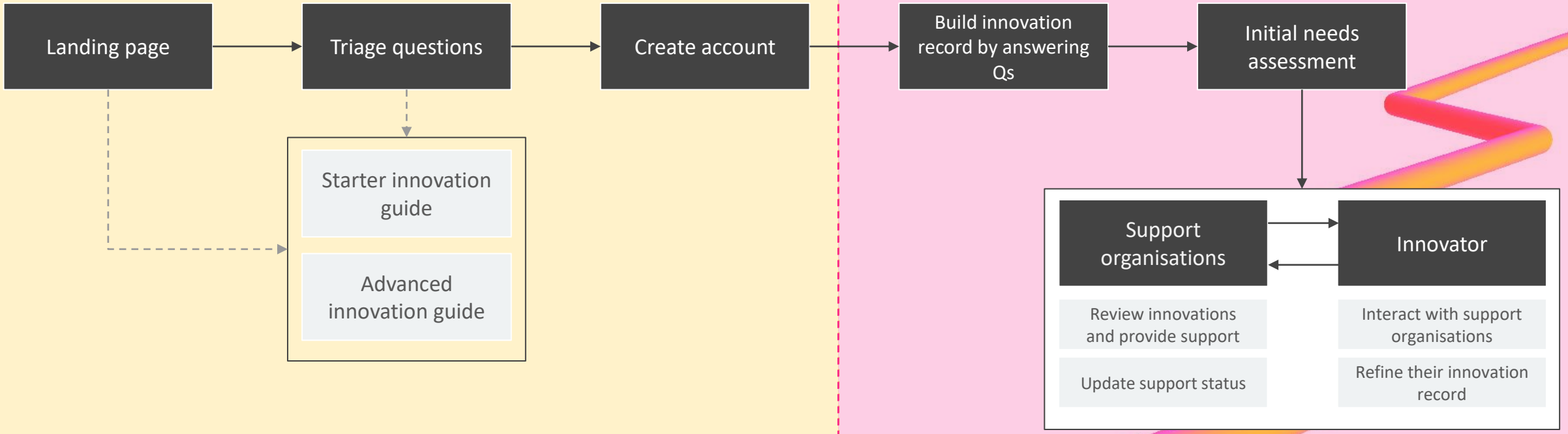
Innovator journey

INFORMATIONAL:

Open, readily available and educational information regarding the healthcare innovation system.

TRANSACTIONAL:

Upon successful registration, innovators can start receiving support from a wide range of government commissioned organisations in one centralised process



Accelerated Access Collaborative

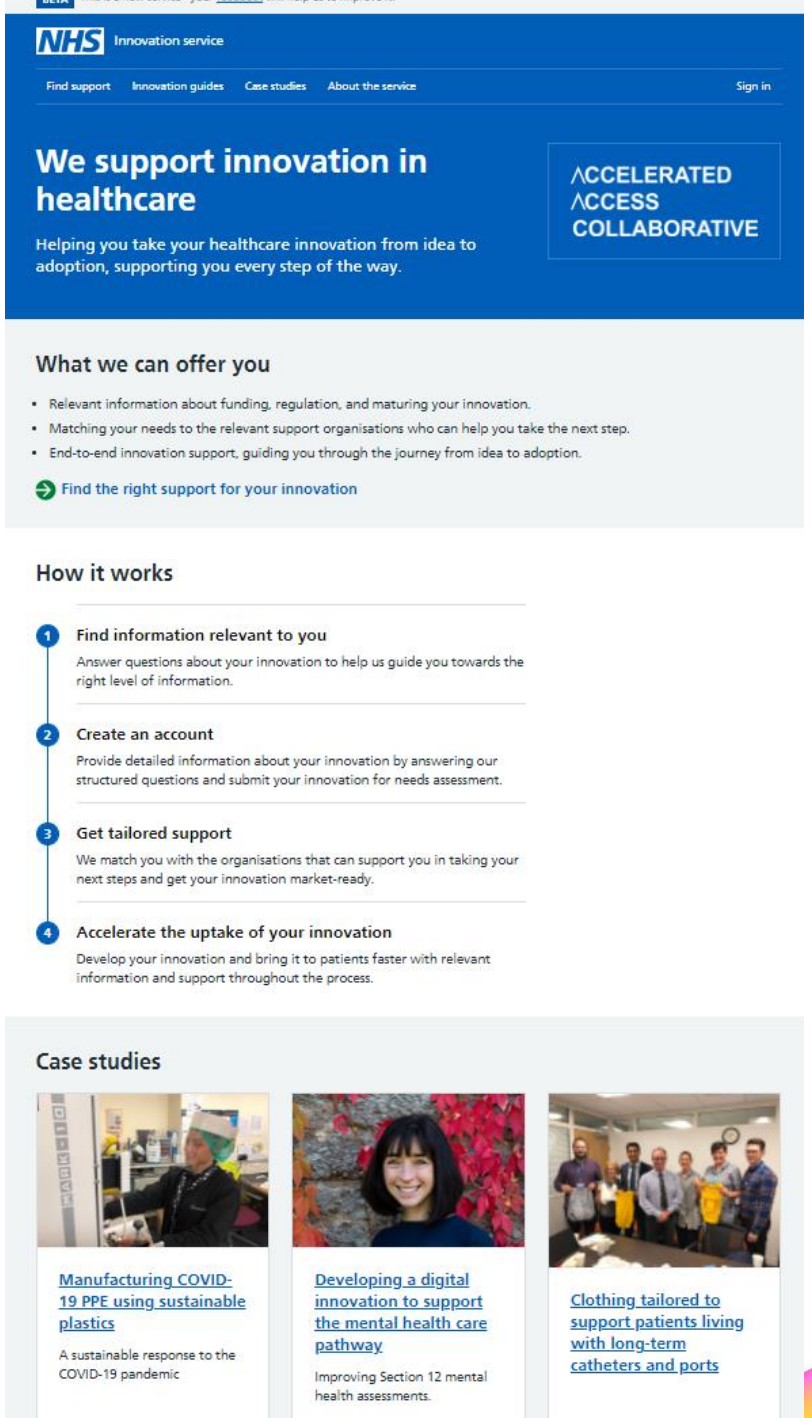
NHS Innovation Service

How does it work?

Access useful resources and information

‘Find support’ by completing a questionnaire and creating an account

Fill in the ‘innovation record’ and submit it for needs assessment, where you will be put in touch with the right organisation based on your requirements



Accelerated Access Collaborative

NHS Innovation Service

In the six months since launch…

- 500 accounts have been created
- 10 leading healthcare innovation organisations onboard and supporting innovators
- 100% of innovators contacted by Needs Assessment Team within two days of submitting innovation record
- 150 innovation records been through Needs Assessment Service and innovators are now receiving support
- Increasing demand – number of innovation records doubled in December compared to November

innovation.nhs.uk

Medtech Innovation Pathway Update

Sept 2022

Context

Vision and role of AAC

- Our vision is to have an UK ecosystem in which all patients have timely access to transformative, innovative technologies, leading 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, and we believe there are strategic benefits to identify barriers and co-ordinate solutions across the entire pathway which may address causes of issues, rather than having programme's set-up to operate in isolation to address symptoms.

- To support this vision, the AAC has set out to comprehensively map the key steps an innovator should go through from developing a concept to widespread use in the NHS and the support that is already available.

Medtech Pathway Mapping Work

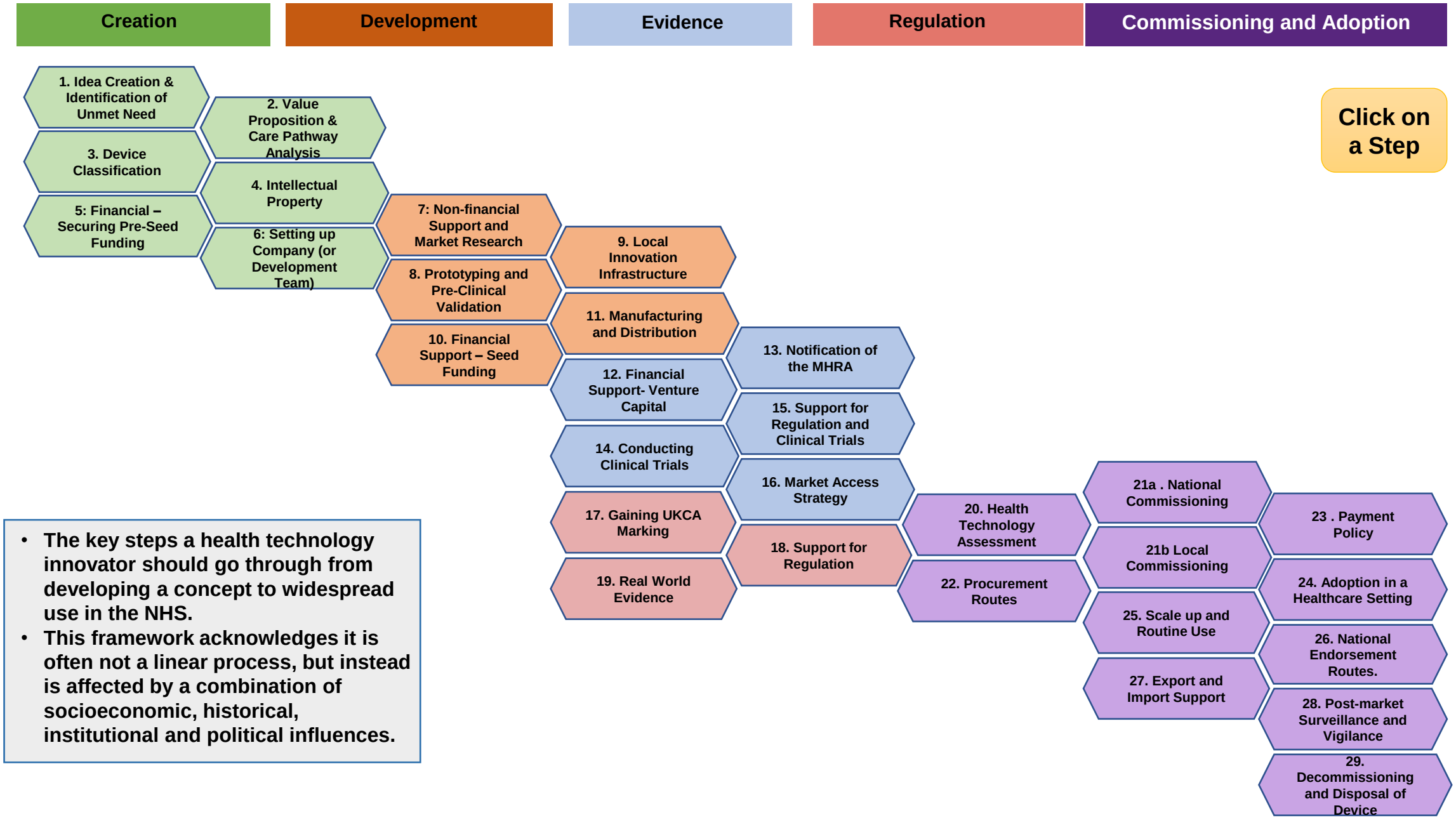
- The mapping identifies 30 steps, themed around five key phases (Creation, Prototype Development, Clinical Trials & Regulation, Evaluation and Commissioning, and Adoption and Spread). Many innovators will overlap steps and not go through each one sequentially.

- Each step displays a schematic flowchart of milestones and organisations, key information such as timelines and number of products, and contains a list of issues identified for the step from the literature or through engagement with key individuals from AAC partners.

- The flowchart has been developed primarily for medical technologies and diagnostics but hope that many sections will be applicable for DHTs.

- Issues and policy levers have been identified through a literature review, analysis of industry and government recommendations, and discussions with key organisations.

Vision: Overview of MedTech Pathway



- The key steps a health technology innovator should go through from developing a concept to widespread use in the NHS.
- This framework acknowledges it is often not a linear process, but instead is affected by a combination of socioeconomic, historical, institutional and political influences.

Thematic Barriers

	Thematic Barrier	Why this matters
1	NHS does not use **Demand Signalling** to systematically communicate the key problems we need innovators to solve	• Researchers, SME and corporate R&D departments to make sub-optimal R&D decisions, raising the aggregate costs and time of bringing key innovations to market • Failure to realise the 'AAC coordination benefits' through integrated support/ guidance through the pathway (e.g. successes during Covid)
2	The **regulatory landscape is evolving** with an ongoing consultation to UK MDR, with a view to making UK the best place to develop and introduce innovative medical devices	• Passing on legislation will create investment and regulatory strategy certainty for innovators reducing the costs of innovation in UK
3	Unlike medicines, the **market access pathway** for health technologies does not enable Medtech to demonstrate the incremental clinical and costs benefits that is afforded to medicines	• Uncertainty regarding optimal market access strategies, increasing the time and cost to bring innovations to market. • Encourages innovators to allocate resources away from building out their evidence bases in favour of marketing and lobbying
4	There is **uncertainty regarding the level of clinical and health economic evidence** required by commissioners, national evidence review bodies and key opinion leaders to make purchasing decisions. Further, there is a historical bias towards evidence development that necessitates high cost trial methods (e.g. multi-year RCTs).	• This raises the cost and the time required to generate the evidence commissioners require and creates unwarranted variation in levels of evidence accepted by economic buyers
5	Innovations with compelling evidence of system and patient benefit **fail to be sufficiently widely adopted** across NHS.	• This leads to unwarranted variation in clinical outcomes and the cost bases of delivery models. • Raises the effect cost of conducting R&D in UK by lengthening the commercial return period. • NHS is unable to use it buying power, scale and commercial insight to shape markets

Focus of this AAC Steering Group Review

3 Thematic Barrier: Market Access Pathway

Barrier	Solution Approach	AAC Owner
There is **no single front door** for health-tech innovation in NHS, with a consolidated description of the pathway steps and associated processes, governance, available support (eg PPIE) and timelines. Industry require greater transparency and more predictability on how to bring innovations to market, with an integrated approach across national approval bodies (e.g. proactive communications re new spec comm treatments).	Use the NHS Innovation service as the single gateway for health-tech innovators and publish a clear, interactive overview of the Medtech innovation pathway. This will be particularly important for technologies that do not route via NICE, where support from Innovation Service can help innovators reach commissioners at scale.	NHSE (IRLS)
The health technology **supplier landscape is highly fragmented** with a very large volume of suppliers as, unlike medicine, there is no market access need to prove cost effectiveness. This creates challenges for economic buyers in discerning the strongest value propositions in market.	AAC should reinforce the need for commissioning to be evidence-based. For mature products, we must maintain the expectation that NICE guidance is the key evidential review. For the most promising products, the use of NICE's Early Value Assessment (EVA) and associated NHSE support will act as a signal of value.	NICE, NHSE (EVA)
Unlike Medicines, **recommendation by NICE (Guidance or EVA), does not come with a funding stream**, inhibiting adoption. NHS England does, however, run multiple healthtech funding programmes but these are highly fragmented, leading to additional process complexity and sub-optimal of use of funds to spread the most high impact innovations.	Create a unified Medtech market access fund of £50-75m per year to fund NICE-recommended technologies. For EVA products this will support commissioning for evidence generation. For full guidance products, the fund will support MTFM products on a tapered subsidy basis, with clear exit strategies to avoid market distortion. NICE will support class-based assessments for mature technologies, based on clear thresholds for assessing cost effectiveness that reflect the policy priority that innovation-class supports (e.g. early cancer diagnostics with longer pay-back periods vs digital productivity tools with shorter pay-back periods). The timelines and processes for assessment will be clear and transparent. MTFM selection criteria will be suitably aligned to the class-based cost-effectiveness thresholds.	NHSE (multiple), with OLS support, NICE
There is currently **no centrally driven NHS commercial strategy** that leverages NHS collective buying power or provides a clear, consistent guideline on how to contract with the NHS. This has resulted in unwarranted variation in commercial arrangements with suppliers and missed opportunities to drive additional value and leverage scale.	Develop a Central Commercial Function (CCF) to unify the NHS commercial community to unlock opportunities for the NHS, deliver value for every pound spent and improve patient outcomes. This will be based on the 7 service offerings (inc Commercial Strategies) agreed by NHSE Board. Our commercial approach must reflect the fact that Medtech innovation is not subject to the same price protections as Medicines. It needs to balance delivering taxpayer value for money with strong commercial incentives to solve NHS priority problems.	NHSE Commercial

4 Thematic Barrier: Evidence Requirements

Barrier	Solution Approach	AAC Owner
Perceived restrictions on the evidence that can be submitted for NICE Technology Appraisal programmes, raise the cost and timescales involved in evidencing compliance with the relevant NICE ESF.	Ongoing engagement with industry regarding what real world data can be used following the Jun 22 launch of the NICE ESF for RWE generation. To include guidance on: 1) Building an evidence base beyond the traditional control trial approach, with a specific review of the use of data from post surveillance registries (e.g. NICOR registry being used by GIRFT). 2) How NICE committees will review RWE 3) How NHS commissioners should interpret RWE	NICE, ABHI, BIVDA, AHSNs
Uptake of existing, proven innovation into **additional healthcare settings** where there is a clear value proposition is too slow, driven by a evidence review approach that does not recognise the high probability of value transferring beyond the current setting.	Evidence requirements for technologies with proven value to the healthcare system in a given setting should follow a streamlined process to understand value in other settings	NICE
A **fragmented data environment relating to real-world outcomes** means we fail to realise the evidential value of clinical insights across linked datasets, inhibiting our ability to act as a learning healthy system.	Conduct scoping exercise to understand the tactical and longer-term opportunities for optimising the data environment to enable outcomes-based analysis that support NICE evidence submissions (e.g review clinical registry strategy)	NHSE, ABHI, BIVDA, NICE
Historical uncertainties about the **differing evidence requirements for data-driven vs non data-driven technologies**, including adaptive algorithms.	Ongoing engagement with industry regarding what real world data can be used following the Aug 22 update of the NICE ESF for DHTs	NICE
The evolution of evidence standard requirements for health tech have led to uncertainty amongst innovators of the **most cost and time effective lifecycle approach for generating the evidence required** for regulatory filing, NICE HTA, and NHS commissioning requirements. Whilst there is a clear role for advice, it is unclear whether national bodies (eg NHSE, NICE, MHRA) or third-parties (eg regulatory advisers) are best placed to support here.	Work with NIHR to learn the lessons from their programme to fund regulatory advice for innovators.	MHRA, NICE

5 Thematic Barrier: Insufficient Adoption of Proven Technologies

Barrier	Solution Approach	AAC Owner
The different routes for **how NHS commissions innovative health technology**, and when each should be used, are unclear to innovators. Further, **ICS healthtech investment mechanisms are nascent**, with implications for the funding of solutions whose costs and benefits are unevenly distributed across the system.	Design and publish guidance on 1) how Medtech innovators could approach and sell to ICSs. 2) Commercial models and strategic finance approaches ICSs may wish to consider to support partnership with innovators. For national procurement routes (bespoke deals, MTFM, funding post NICE guidance) agree the eligibility criteria and mechanisms for funding/ support.	NHSE (IRLS, Commercial)
Traditional approaches to health technology procurement have historically focused solely on price and cost containment. A shift from a purely price-focused approach to a **value-based commissioning (VBC) approach** has the potential to create long-term efficiencies and better health for patients, as well as identifying opportunities for innovation.	Build on existing DHSC policy, AHSN and Industry Association work in this area to feed into ongoing Commercial Strategy development work, including consideration of the commercial models that support a VBC approach. The approach should also reflect mechanisms for decommissioning of ineffective or non-evidence based tech. This would incentivise evidence generation and release resources to adopt proven tech.	AHSN, ABHI/BIVDA and NSHE (Commercial) DSHC
There are **no standardised NHS approaches to health technology business case development**, contracting, Information Governance and Intellectual Property treatment, leading to significant unwarranted variation in the commercial processes and requirements that act to slow the spread of innovation.	Reduce contracting costs by supporting NHS local commissioners and ICS to align around common commercial and set-up processes (e..g IG), building on the INSITES pilot, IP work and other in flight Commercial programmes.	NHSE (Commercial and IRLS) Digital Policy Unit
Change management for health tech tends to be under-resourced and involve significant pathway or ways of working changes. For digital technologies, accessing IT resources, IG experts at customer sites and dealing with 3rd party suppliers on interoperability issues (eg EPR, PACS) pose additional challenges.	Enable the development of local change management capability to support implementation via a tool-kit approach, drawing on best practice (eg Royal Free Innovation Team, Chelwest Navigators, HINM 'solutioning' approach)	AHSNs NICE (via adoption support team)

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NIHR | Community Healthcare MedTech and In Vitro Diagnostics Co-operative

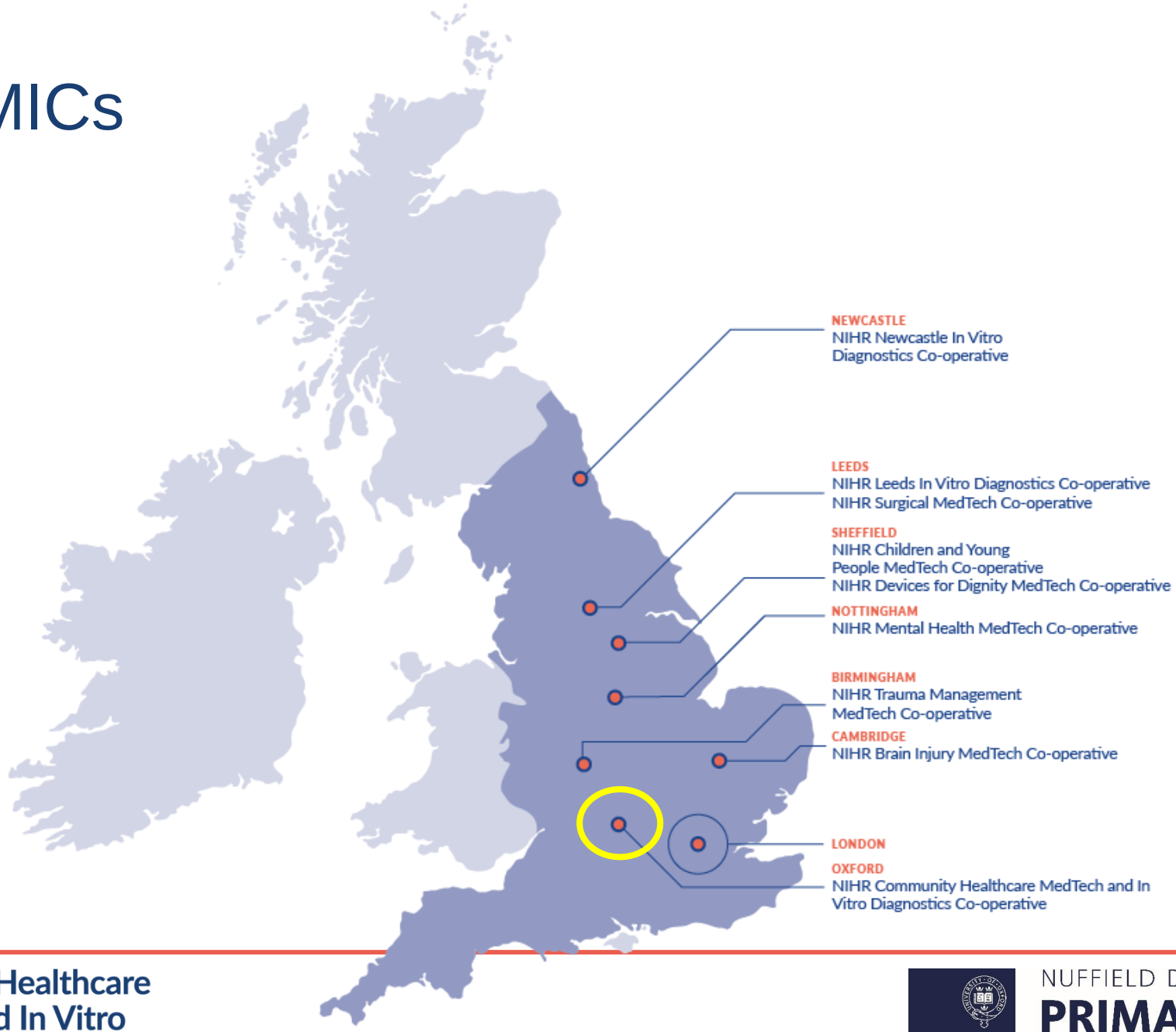
Evaluation and developmental support of diagnostic tests for the 90%

[redacted] Manager NIHR Community Healthcare MIC, Senior Researcher, Infections and Acute Care Research Group

Nuffield Department of Primary Care Health Sciences, University of Oxford

MHRA & BIVDA IVD-Roadmap,10th Feb 2023

The NIHR MICs



Diagnostics in Community Healthcare

- **90%** of healthcare contacts
- Multiple lab test requests common
- Ageing population
- Focus on NHS cost-containment
- Medico-legal risk
- Frontline of antibiotic stewardship

- **Little current use of diagnostic technology**

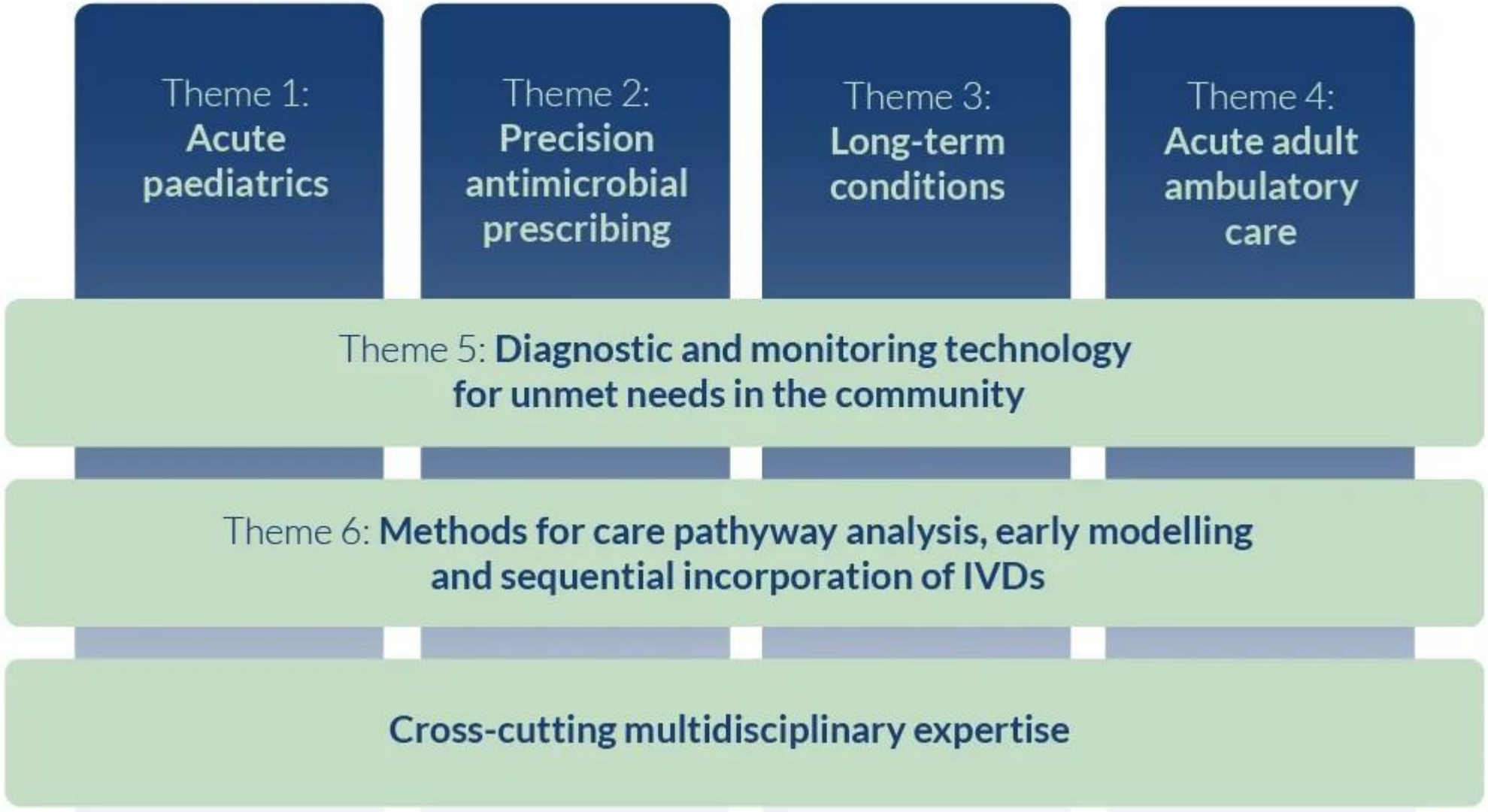
Key Aims of the NIHR Community Healthcare MIC

Operates under the leadership of Clinical Director,

Professor Gail Hayward

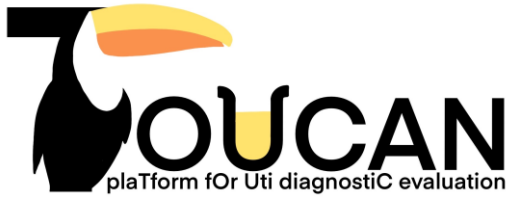
- Evidence generation for commercially available IVDs in community healthcare settings

- Development and evaluation of new diagnostic technology fit for purpose in community healthcare settings


Theme 1: Acute paediatrics
Theme 2: Precision antimicrobial prescribing
Theme 3: Long-term conditions
Theme 4: Acute adult ambulatory care
Theme 5: Diagnostic and monitoring technology for unmet needs in the community
Theme 6: Methods for care pathyway analysis, early modelling and sequential incorporation of IVDs
Cross-cutting multidisciplinary expertise

Collaboration: Support from concept through to evidence generation

- Advice on technology design and development based on NHS data sources, expert clinical opinion and access to patients
- New health economics and statistical approaches to efficiently demonstrate test performance and likely impact of new diagnostic pathways
- Lab based analytical performance
- Diagnostic accuracy studies and randomised trials to demonstrate clinical impact, including platform studies



NIHR | Community Healthcare MedTech and In Vitro Diagnostics Co-operative

Thank you

[redacted]@phc.ox.ac.uk

https://www.community.healthcare.mic.nihr.ac.uk/

@NIHR_CH_MIC
@GailHayward1
[redacted]

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AHSN Network and the IVD Landscape

[redacted]
Associate Director – Industry and Innovation

BIVDA and MHRA IVD Roadmap Workshop
Friday 10th February 2023

BIVDA

Medicines & Healthcare products Regulatory Agency

IVD Roadmap

Friday 10th February 2023 (10:00 – 16:00)

MHRA offices, 1st Floor Conference Suite, 10 South Colonnade, London, E14 5EA

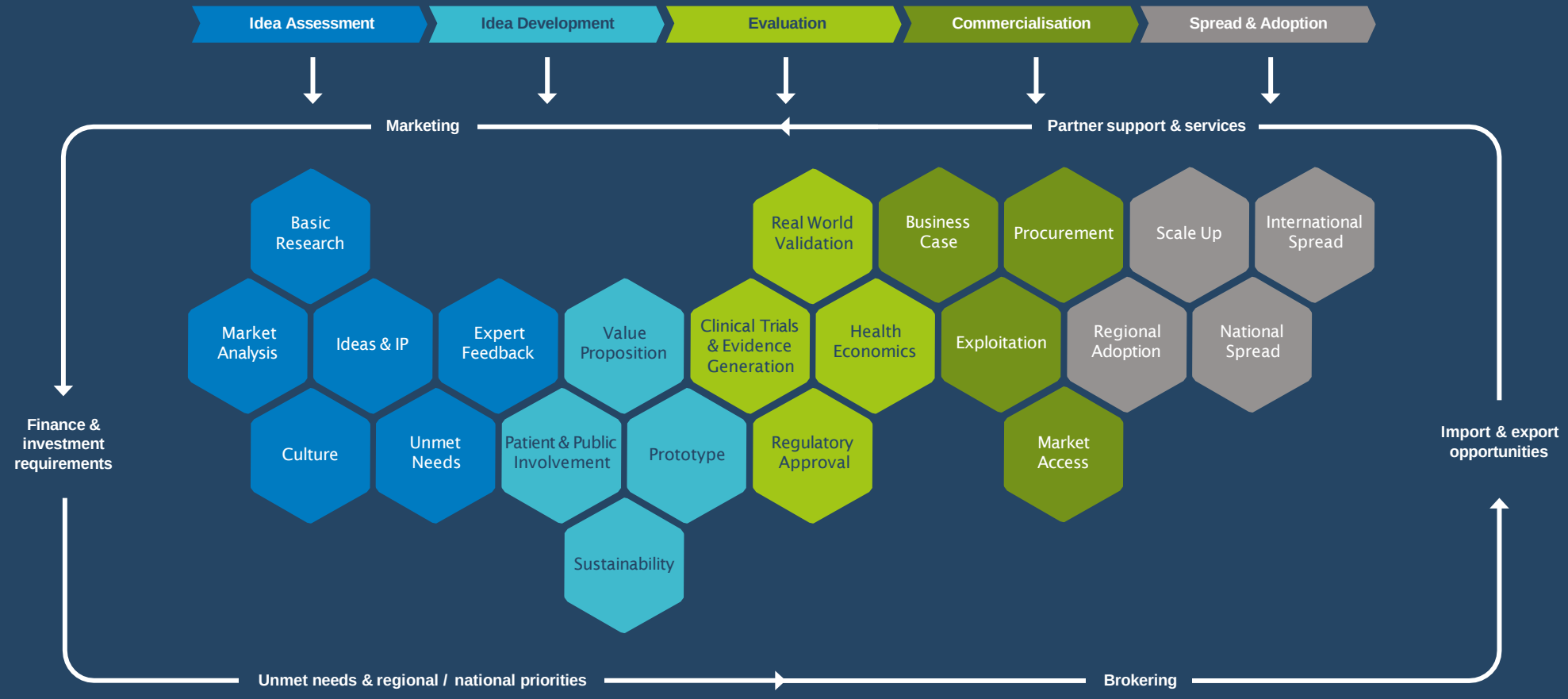
How AHSNs support innovation

Support and advice around:

- Navigating the NHS
- Market research
- Developing a value proposition
- Evaluating real-world impact
- Health economic reports, business cases
- Implementation
- Grant funding opportunities
- Product development & regulatory
- Signposting to resources

THE INNOVATION PATHWAY

DISCOVER
DEVELOP
DEPLOY.



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NHS AAC: MTFM and Rapid Uptake Products - IVDs

- Placental growth factor (PIGF) based testing for suspected preeclampsia
  - Two tests for early diagnosis of pre-eclampsia in pregnant women, which if unmonitored, can cause serious complications for mother and baby.
    - Elecsys immunoassay sFlt-1/PLGF ratio [Roche Diagnostics]
    - Triage PlGF test [Quidel Corporation]

- High sensitivity troponin tests for early rule out of myocardial infarction
  - Two diagnostic tests that detect whether or not a patient is at risk or previously had a heart attack.
    - Elecsys Troponin T high-sensitive [Roche Diagnostics]
    - ARCHITECT STAT High Sensitive Troponin-I [Abbott Diagnostics]

- Quantitative faecal immunochemical tests for colorectal cancer
  - Three diagnostic tests that reduce referrals for patients with suspected colorectal cancer.
    - OC Sensor [MAST Diagnostics]
    - HM-JACKarc [Alpha Laboratories]
    - FOB Gold [Sysmex]

ACCELERATED ACCESS COLLABORATIVE

NHS Innovation Service

What is the NHS Innovation Service?

Information on how to develop an innovation for market

Coordinated support from support organisations

NICE National Institute for Health and Care Excellence

NIHR | National Institute for Health and Care Research

The AHSN Network

Department for International Trade

Healthcare Improvement Scotland | SHTG Advice on health technologies

Medicines & Healthcare products Regulatory Agency

Technoleg Iechyd Cymru Health Technology Wales

Hwb Gwyddorau Bywyd Cymru | Life Sciences Hub Wales

NHS Supply Chain

The NHS Innovation Service replaces HealthTech Connect.

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Scientific advice

Early insight on clinical and economic development plans

to generate robust evidence and to demonstrate value

for use in NICE evaluations or in discussions with commissioners

META Tool for evidence generation

Standard or express advice

Preliminary Independent Model Advice (PRIMA)

Facilitate engagement with commissioners about market access

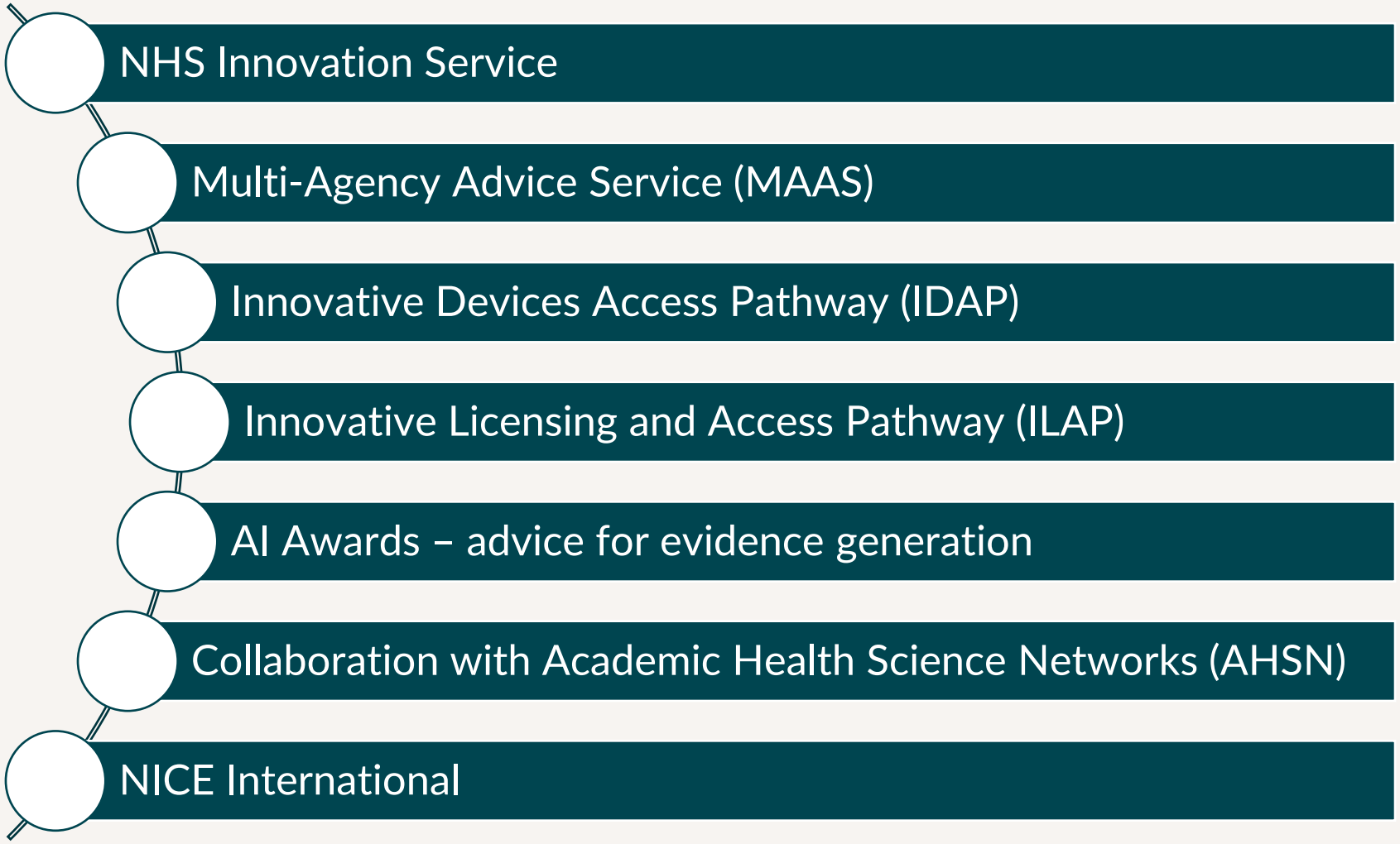
fee-based advice service

input from leading experts

confidential advice

NICE

Programmatic overview



NICE