Academic Health Science Network
North East and North Cumbria

FCDO/DIT Health Tech Event

Stephen Lynn
Associate Director, AHSN NENC

19 October 2021

Content

- The AHSN Network
- NHS Innovation Service
- Innovation Pathway
- Regulatory Changes for the UK
- Digital Technology Assessment Criteria (DTAC)
- NICE Evidence Standards Framework for DHTs

The AHSN Network

- **15** regional Academic Health Science Networks (AHSN), established by NHS England in **2013** to spread innovation at pace and scale
- Connecting – academia, NHS, innovators, local authorities, 3rd sector, policy, regulators, funders, investors, international partners
- 3 core objectives

1. Transform patient safety
2. Improve population health
3. Generate Economic growth

Academic Health Science Network
North East and North Cumbria

www.ahsn-nenc.org.uk
@AHSN_NENC

ACCELERATED ACCESS COLLABORATIVE

National Innovation Service

NHS England and NHS Improvement

Functionality

The **‘front end’** will focus on information provision, including:

- Helping innovators understand where they are on the **innovation pathway**
- Helping innovators **understand the NHS’s needs** (“demand signalling”)
- Encouraging innovators to feed into our pipelines (“**horizon scanning**”)
- Supporting innovators with relevant information **on regulatory requirements, and how they build up an evidence base**
- Helping signpost innovators to **relevant funding opportunities**
- Helping innovators understand **who’s who** (“landscape review”)
- Supporting innovators gain adoption and spread, by understanding **procurement, reimbursement and commercialisation**

The **‘marketplace’** will connect users with support structures:

- Helping innovators connect with **Support Organisations** for personalised support
- Absorbing Health Tech Connect to streamline support

‘Front-End’ Functionality

Category	Vision
Innovation Pathway & Support Triage	An interactive tool which sets out the innovation pathway, and helps innovators understand where they sit within it, the key activities they need to progress, and what tools/organisations/support services are relevant for them at their point in the journey
Demand Signalling	A page which provides national demand signalling, and sends clear signals to the market/innovators about what the NHS needs, the problems it is facing and would like the market to address. This page will also signpost to local external sites providing regional / local demand signalling.
Horizon Scanning	Signposts innovators to the appropriate horizon-scanning tools which can help the innovator highlight their product to the relevant organisation(s) at the right time, and provides rationale to innovators on the benefits of providing this information
Regulatory requirements	High level guidance for innovators looking to understand who the UK’s regulators are, and identify where to go / what to do to comply with relevant regulations. This page will not provide advice on compliance with regulations – it will focus on signposting to the relevant regulations
Evidence & Testing	Set out all support and guidance for innovators hoping to understand (i) evidence requirements for all types of products – post regulatory approval – and (ii) where to go / who to speak to / opportunities for support in order to generate this evidence.
Funding	A central catalogue of national funders and the types of schemes they offer.
Landscape	An interactive, searchable, detailed infographic laying out the organisations involved in innovation
Adoption & Spread	Information, tools and organisations to support innovators getting their products spread in the NHS (including procurement, and NHS commercial).

Customised for:

Digital | Medicines | Diagnostics | Med Tech | Hybrids

SMEs | Large firms | NHS Clinicians

Who is involved in the Marketplace

- AHSN Network
  - All 15 supporting Innovators
  - 3 AHSNs involved in the Needs Assessment Function
- NICE
- Department for International Trade
- MHRA
- NHS Supply Chain
- NHSE Specialised Commissioning
- NIHR Office for Clinical Research Infrastructure

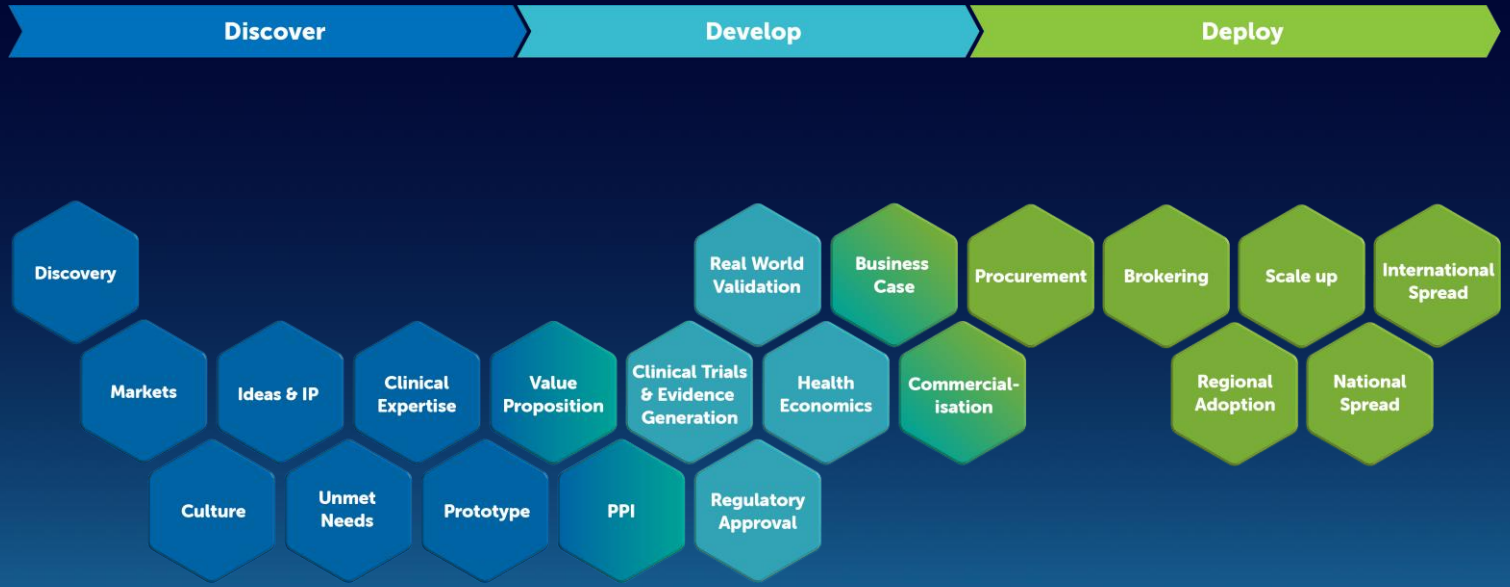
Devolved administrations

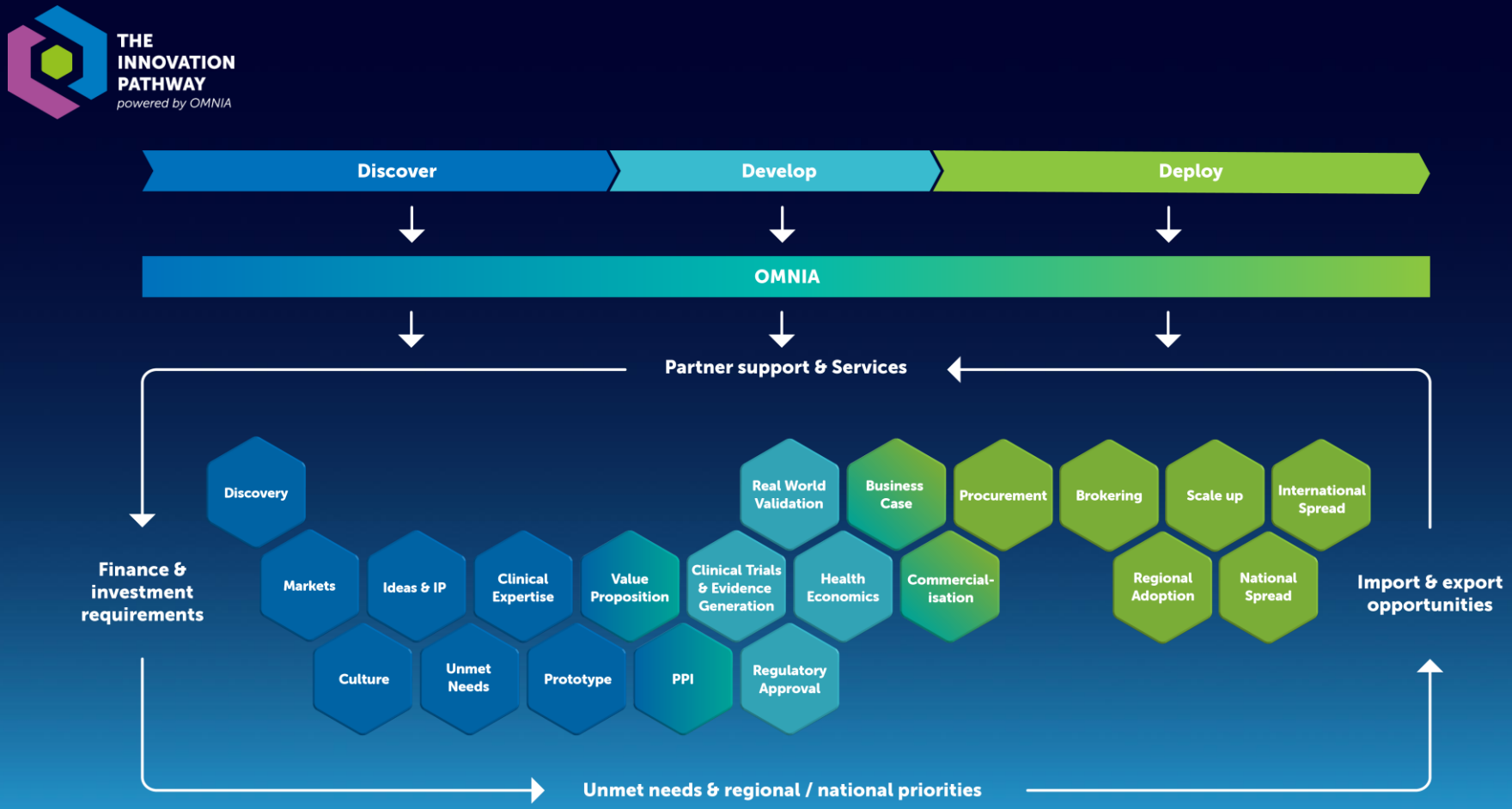
- Scottish Heath Technology Group
- Health Technology Wales
- Life Sciences Hub Wales
- Northern Ireland (NHSE to engage)

To engage

- NHSX
- Others such as NHS National Procurement Scotland - Health Innovation Assessment Portal (HIAP)

THE INNOVATION PATHWAY
powered by OMNIA




THE INNOVATION PATHWAY
powered by OMNIA
Discover
Develop
Deploy
OMNIA
Partner support & Services
Finance & investment requirements
Discovery
Markets
Ideas & IP
Clinical Expertise
Value Proposition
Culture
Unmet Needs
Prototype
PPI
Clinical Trials & Evidence Generation
Health Economics
Regulatory Approval
Real World Validation
Business Case
Commercial-isation
Procurement
Brokering
Regional Adoption
Scale up
National Spread
International Spread
Import & export opportunities
Unmet needs & regional / national priorities

AHSN Support for Innovators and the NHS

- Unmet Need Challenges
- Effective Signposting
- Real World Validation
- Articulating Value Proposition
- Supporting Adoption and Spread

Regulatory Overview: Post-Brexit

The Medicines and Healthcare products Regulatory Agency (MHRA) is responsible for regulating the UK medical devices market.

With the end of the transition period on 1st January 2021 the MHRA has published new guidance on how medical devices* are regulated (CE marking and the new UK Conformity Assessed mark (UKCA))

- This guidance now covers the different rules that apply to Great Britain, Northern Ireland and the EU

CE marked products will continue to be recognised in Great Britain until 30 June 2023

- Certificates issued by EU-recognised Notified Bodies will continue to be valid for the Great Britain market until 30 June 2023
- UK Notified Bodies are no longer recognized by the EU

The UKCA mark will be the new route to market and is now available for manufacturers wishing to place a device on the market in Great Britain

- UKCA is not recognised by the EU, EEA or Northern Ireland markets (a CE mark will be required for these markets)
- UKCA marks can be used voluntarily until 30 June 2023 – from 1 July 2023 a UKCA mark is required before placing on the market in Great Britain

MHRA will designate UK Approved Bodies (current UK Notified Bodies have been designated automatically)

- UK Approved Bodies are unable to perform conformity assessments for CE marking (except for CE UKNI marks)

*for purposes of clarity medical devices includes in vitro diagnostic medical devices and active implantable medical devices

Standalone software and apps that meet the definition of a medical device are still required to be UKCA marked in line with the Medical Device Regulations 2002 (as amended) (UK MDR 2002) in order to ensure they are regulated and acceptably safe to use and perform in the way the manufacturer/developer intends them to.

Product Registration with the MHRA

From 1 January 2021, all medical devices placed on the market in Great Britain need to be registered with the MHRA

Manufacturers of Class I devices must still register their devices with MHRA as they do now

Manufacturers outside the UK need to appoint a single UK Responsible Person if they are to place a device on the market in Great Britain

Once on the market manufacturers should implement post-market surveillance systems to monitor ongoing safety and efficacy of the product

MHRA Innovation Office

Single point of access for free and confidential regulatory information, advice and guidance

Digital Health Technologies (NHSX)

Digital Technology Assessment Criteria (DTAC)

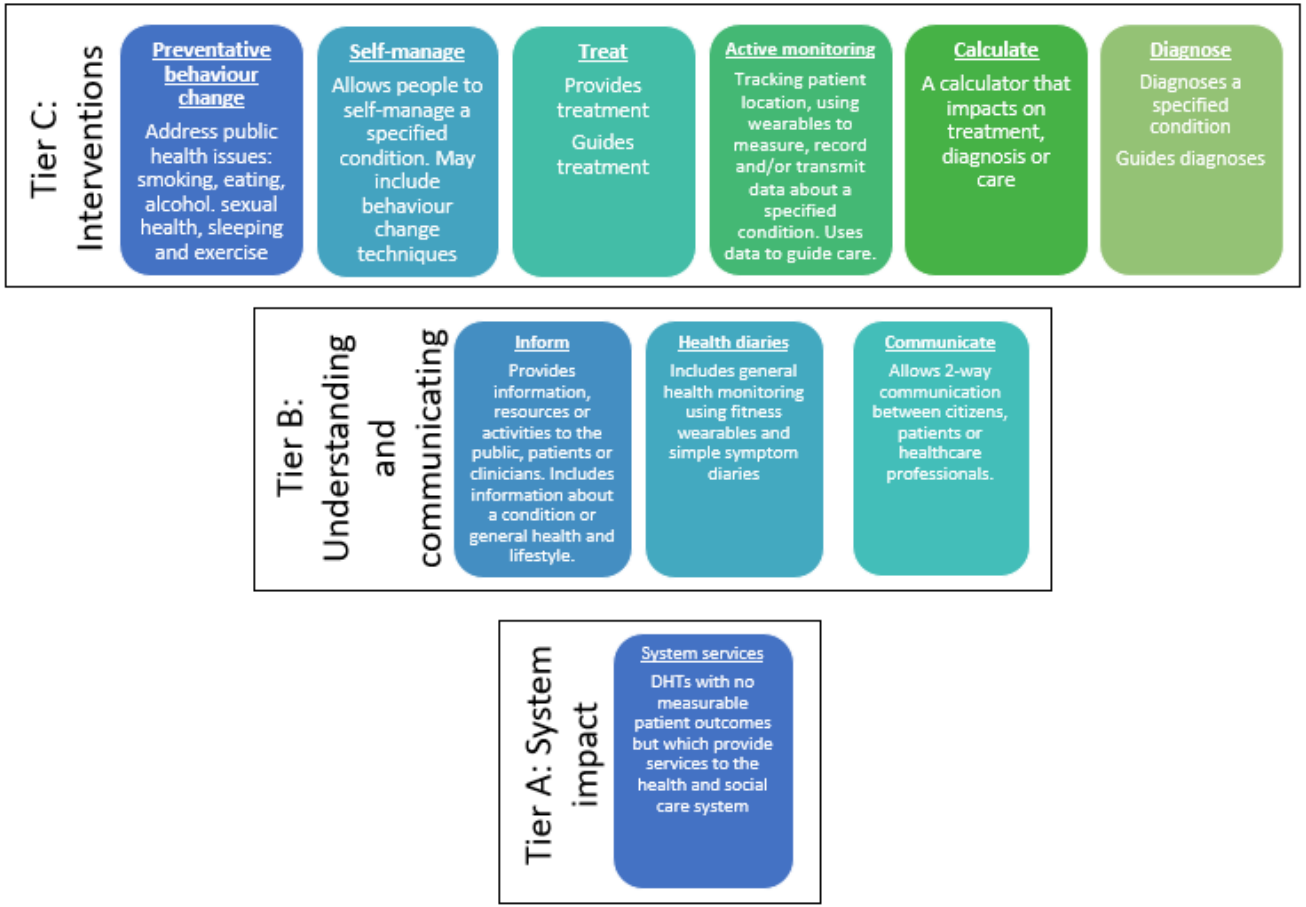
- New national baseline criteria for digital health technologies entering the NHS and social care
- DTAC will be used by healthcare providers to assess suppliers at the point of procurement or as part of the due diligence process to ensure new digital technologies meet the minimum baseline standards
- It outlines what is expected for entry into the NHS and social care

Digital Health Technologies (NICE)

Evidence Standards Framework for DHTs

- Standards to ensure new technologies are clinically effective and provide economic value
- Developed for innovators and commissioners to understand what good levels of evidence for digital health technologies look like
- DHTs are classified into one of three evidence tiers based on risk:
  - Tier A – system impact (no measurable patient outcomes, service support only)
  - Tier B – understanding and communication (information and monitoring)
  - Tier C – interventions (diagnosis, treatment and management)

DHTs classified by function and stratified into evidence tiers



Some Useful Contacts and Links

MHRA

info@mhra.gov.uk

devices.regulatory@mhra.gov.uk

https://www.gov.uk/guidance/medical-devices-how-to-comply-with-the-legal-requirements

https://www.gov.uk/uk-market-conformity-assessment-bodies

MHRA Innovation Office

https://www.gov.uk/government/groups/mhra-innovation-office

DTAC (NHSX)

https://www.nhsx.nhs.uk/key-tools-and-info/digital-technology-assessment-criteria-dtac/

NICE

https://www.nice.org.uk/about/what-we-do/our-programmes/evidence-standards-framework-for-digital-health-technologies

https://www.nice.org.uk/about/what-we-do/our-programmes

HRA/IRAS

https://www.myresearchproject.org.uk/

Further information

Contact

stephen.lynn@ahsn-nenc.org.uk

Website

http://www.ahsn-nenc.org.uk/

Academic Health Science Network
North East and North Cumbria

www.ahsn-nenc.org.uk
@AHSN_NENC