



Evidence Standards and AI

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We are creating a digital ecosystem that provides a consistent and trusted experience across digital tools and services to its users.

We now need to provide a place where commissioners can easily find the evidenced-based digital products that will meet the needs of their populations. **To do this we will further develop and scale the digital assurance process.**



Utilising digital tools is key to meeting user needs

Digital tools and services offer opportunities to drive positive outcomes for all users;

Improved patient outcomes

Tools on the apps library already help patients to achieve better outcomes

Evidence based care

Digital tools facilitate more efficient care and decision making for the workforce

Improved population health

Digital tools can collect data that enables localities to better understand and respond to population health needs

The Apps Library is a platform that brings together digital tools and services in a single market place. It's users include;



Commissioners



Developers



Patients



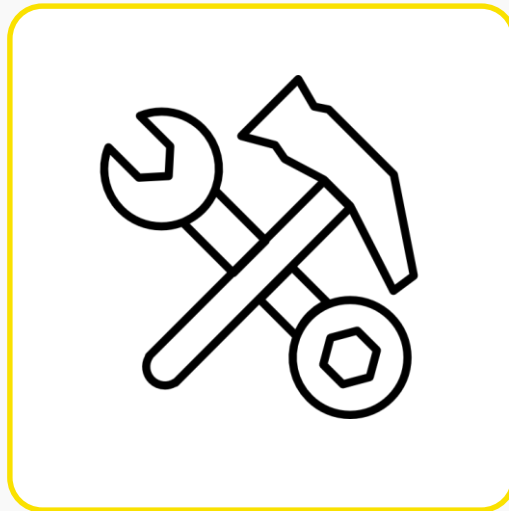
Health and care professionals

How do I know if its effective?

The key question for commissioners is being able to understand if the digital tools they are commissioning are effective. We can answer this by ensuring there is **evidence for effectiveness**.



Evidence Standards have been produced developed in conjunction with NICE



A discovery is underway at PHE to create a **toolkit** on how to develop digital tools with **evidence generation** in mind



Commissioners will be able to access **evidence submitted** as part of assurance

Evidence Standards Framework

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

Evidence standards framework for digital health technologies

As digital health technologies develop at an increasing pace, we've worked with partners to develop standards that ensure new technologies are clinically effective and offer economic value.

The aim of these standards is to make it easier for innovators and commissioners to understand what good levels of evidence for digital healthcare technologies look like, while meeting the needs of the health and care system, patients, and users.

We've created these standards as part of a working group led by NHS England. The group also includes:

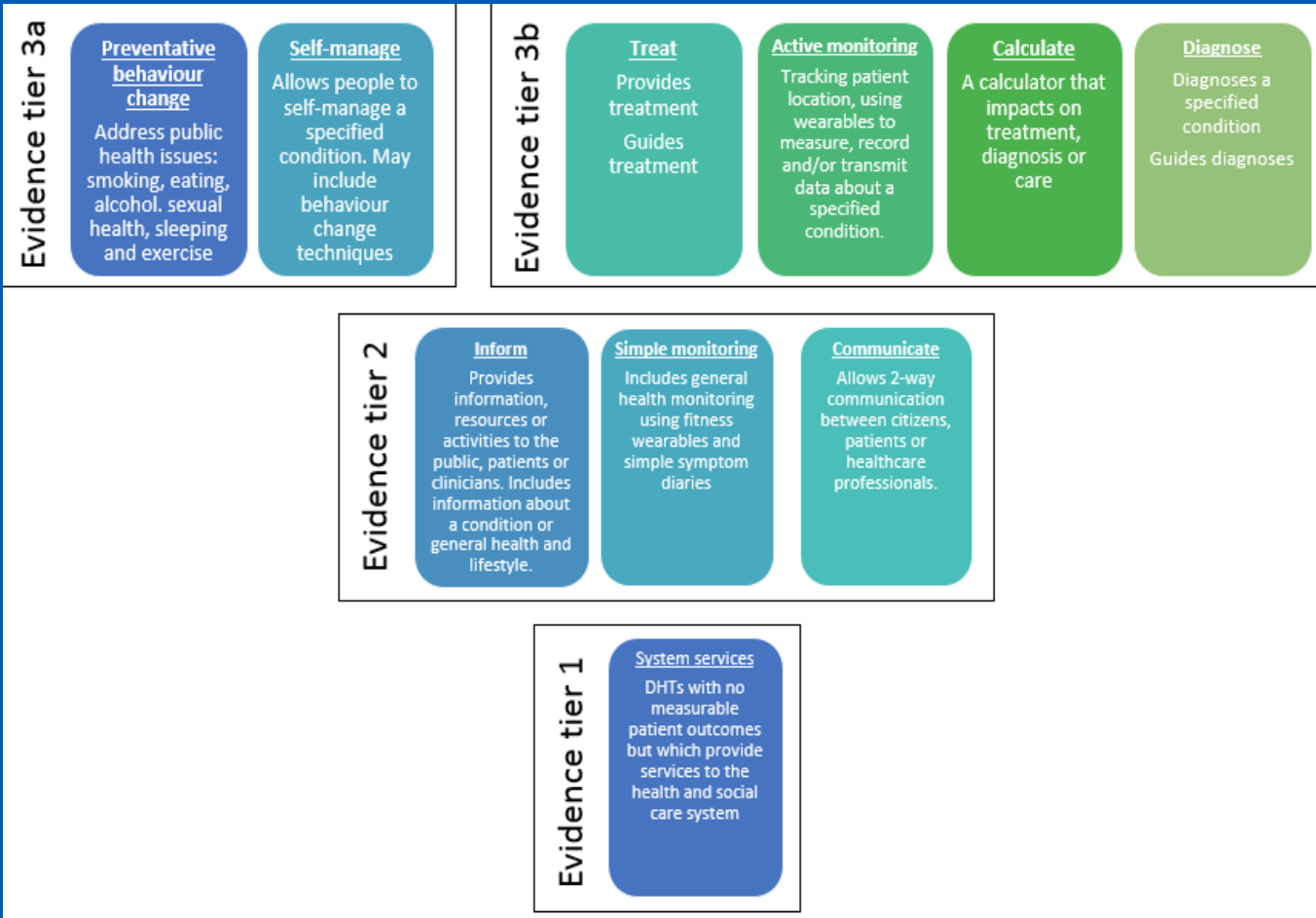
- Public Health England
- MedCity
- DigitalHealth.London.



NICE National Institute for Health and Care Excellence



Functional Classification



Example

Tier 2: Simple Monitoring:

Allows users to records a health parameter; information is hosted on device and not shared with others

e.g. health tracker – *active 10, chill panda*

Excludes: data sharing with a professional or products that provide treatment

Contextual questions

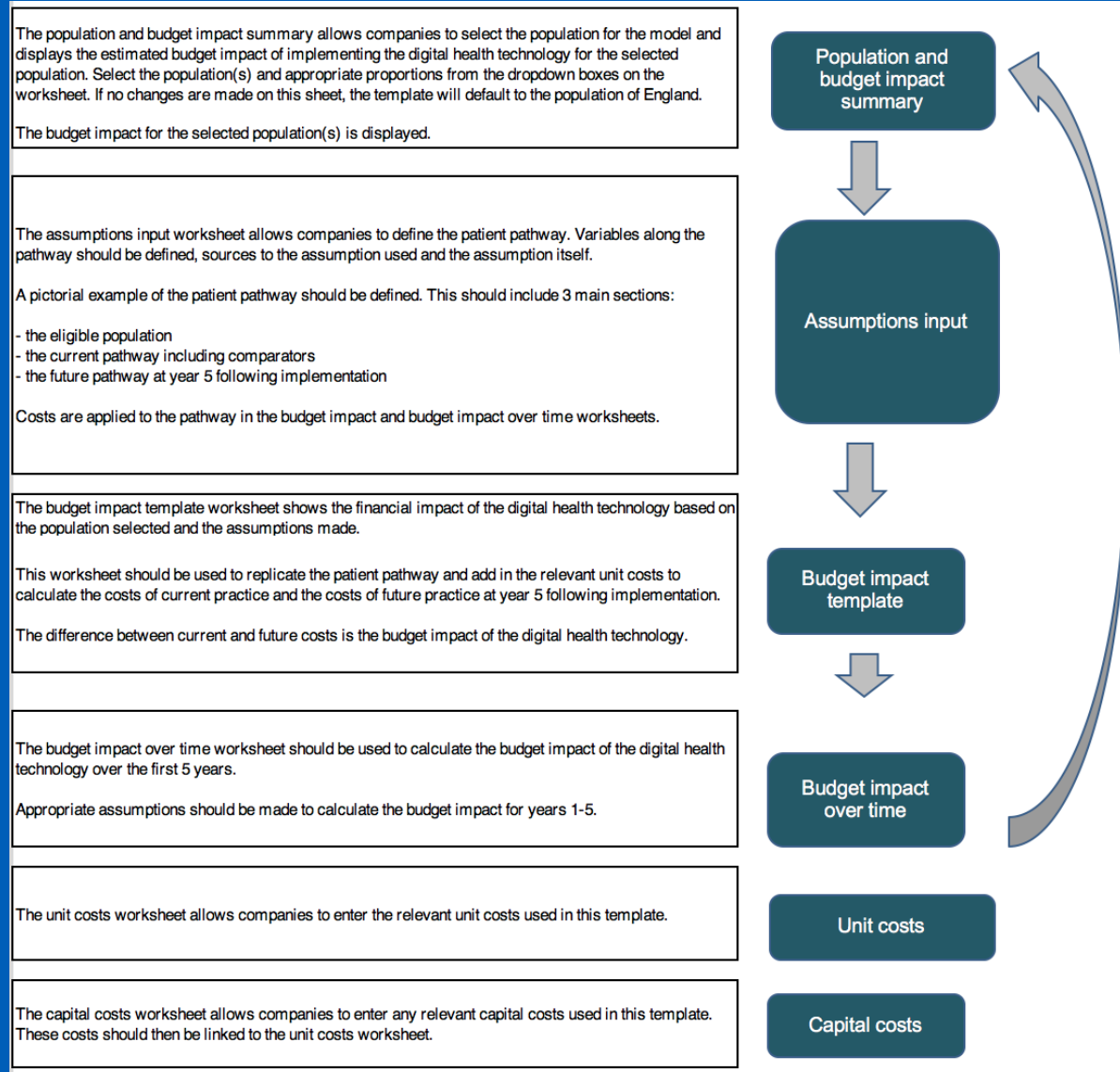
e.g. at risk adults/children as users

Evidence for Effectiveness of Intended Use

- Table of evidence category, minimum and best practice standard for each category

Evidence category	Minimum evidence standard	Best practice standard
Credibility with UK health and social care professionals.	A plausible mode of action that is viewed as useful and relevant by professional experts or expert groups in the relevant field. Either: <ul style="list-style-type: none">- show that relevant clinical or social care professionals working within the UK health and social care system have been involved in the design, development or testing of the DHT, or- show that relevant clinical or social care professionals working within the UK health and social care system have been involved in signing-off the DHT, indicating their informed approval of the DHT.	Published or publicly available evidence documenting the role of relevant UK health or social care experts in the design, development, testing or sign-off of the DHT.
Relevance to current care pathways in the UK health and social care system.	Evidence to show that the DHT has been successfully piloted in the UK health and social care system, showing that it is relevant to current care pathways and service provision in the UK. Also evidence that the DHT is able to perform its intended function to the scale needed (for example, having servers that can scale to manage the expected number of users).	Evidence to show successful implementation of the DHT in the UK health and social care system

Evidence for Economic Impact



We've developed a budget impact template to support digital health innovators in using the economic impact standards.

Chronic heart failure in adults given as an example

Bigger picture



Code of Conduct for data driven technologies

10 Principles

1. Understand the users, their needs, and the context
2. Define the outcome and how the technology will contribute to it
3. Use the data that is in line with appropriate guidelines for the purpose for which it is being used
4. Use data that is proportionate to the identified user need
5. Make use of open standards
6. Be transparent to the limitation of the data used and algorithms deployed
7. Show what type of algorithm is being deployed (data use, performance validation, system integration)
8. Generate evidence of effectiveness for the intended use and value for money
9. Make security integral to the design
10. Define the commercial strategy [contracts]

<https://www.gov.uk/government/publications/code-of-conduct-for-data-driven-health-and-care-technology/initial-code-of-conduct-for-data-driven-health-and-care-technology>

The rules

Principle	Regulation	Required Standards and Guidance	Resources and Support
1. Understand the users, their needs, and the context	UK Policy for Health and Social Care Research		Government Digital Service manual NHS Digital design service manual
2. Define the outcome and how the technology will contribute to it			
3. Use data that is in line with appropriate guidelines for the purpose for which it is being used	<ul style="list-style-type: none"> EU General Data Protection Regulation (GDPR) 2018 UK Data Protection Act 2018 	<ul style="list-style-type: none"> Information Governance Data Security and Protection (DSP Toolkit) 2018 National Data Guardian 10 data security standards DCMS Data Ethics Framework ICO Code of Practice Information Governance Alliance 	<p>ICO tools – data flow map, DPIA</p> <p>NHSE IG Group will dedicate staff to work with those 'signed up' to the CoC</p>
4. Use data that is proportionate to the identified user need	<ul style="list-style-type: none"> EU General Data Protection Regulation (GDPR) 2018 	<ul style="list-style-type: none"> DCMS Data Ethics Framework ICO Code of Practice 	As above
5. Make use of open standards		<p>NHS Digital standards:</p> <ul style="list-style-type: none"> Information standards Data collection Technology clinical safety Interoperability Toolkit <p>NHS England interoperability standards InterOpen current FHIR, Care Connect, HL7 and PRSB standards UK government open standards</p>	NHS Digital leading discovery work exploring an Open Framework for Health and Care / Open API Standards. Partnership with InterOpen.org.
6. Be transparent to the limitation of the data used and algorithms deployed		<p>Guidance on data quality from:</p> <ul style="list-style-type: none"> NHS England UK Statistics Authority National Institutes of Health 	Sources of health data
7. Show what type of algorithm is being deployed (data use, performance validation, system integration]	EU General Data Protection Regulation (GDPR) 2018		Academic discovery with Future Advocacy. NHS Digital/MHRA synthetic data 'sandbox'. Applied AI in healthcare reporting standards.
8. Generate evidence of effectiveness for the intended use and value for money		EFE Working Group Standards for evidence of effectiveness and economic impact <i>In development</i>	Work with MedCity, NICE Evidence Standards Framework for Digital Health Technologies
9. Make security integral to the design		NHS Digital Data and Security Toolkit OWASP Application Security Verification	
10. Define the commercial strategy [contracts]	Contract Law		

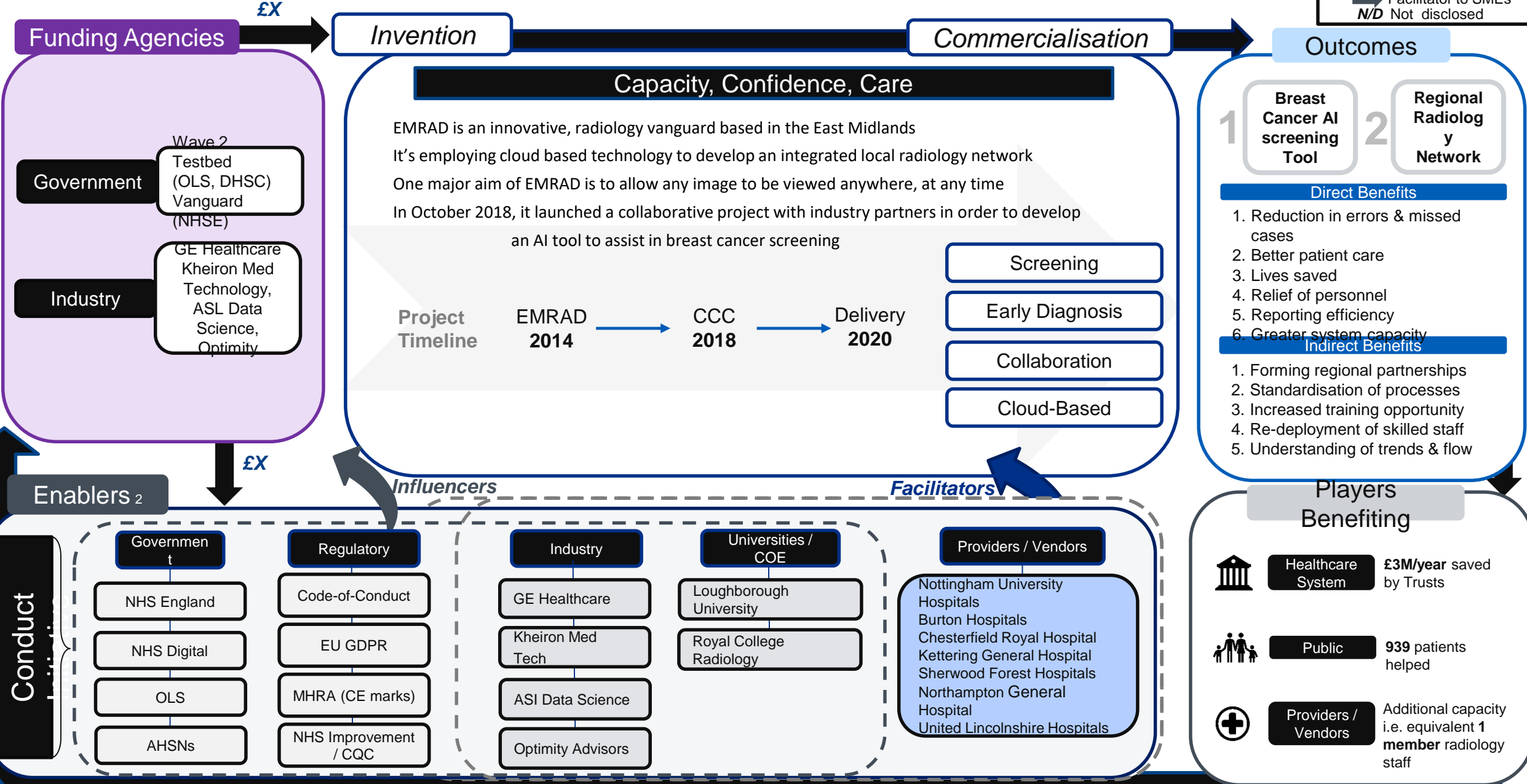
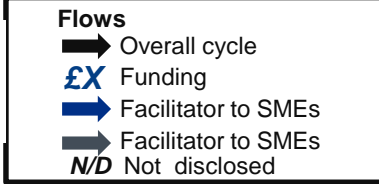
Implementable case studies



Case studies working through principles of CoC

- Patient groups: what does automated decision making mean; Uses of data; secondary uses of data
- Workforce: how do you implement; accountability; what do automated decisions affecting me mean; cost

EMRAD - Breast Cancer Screening

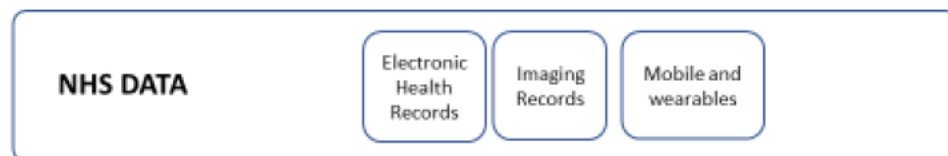


Data access and standards

Local Health Care Record Exemplars and Digital Innovation Hubs



Digital Innovation Hubs (to be established)

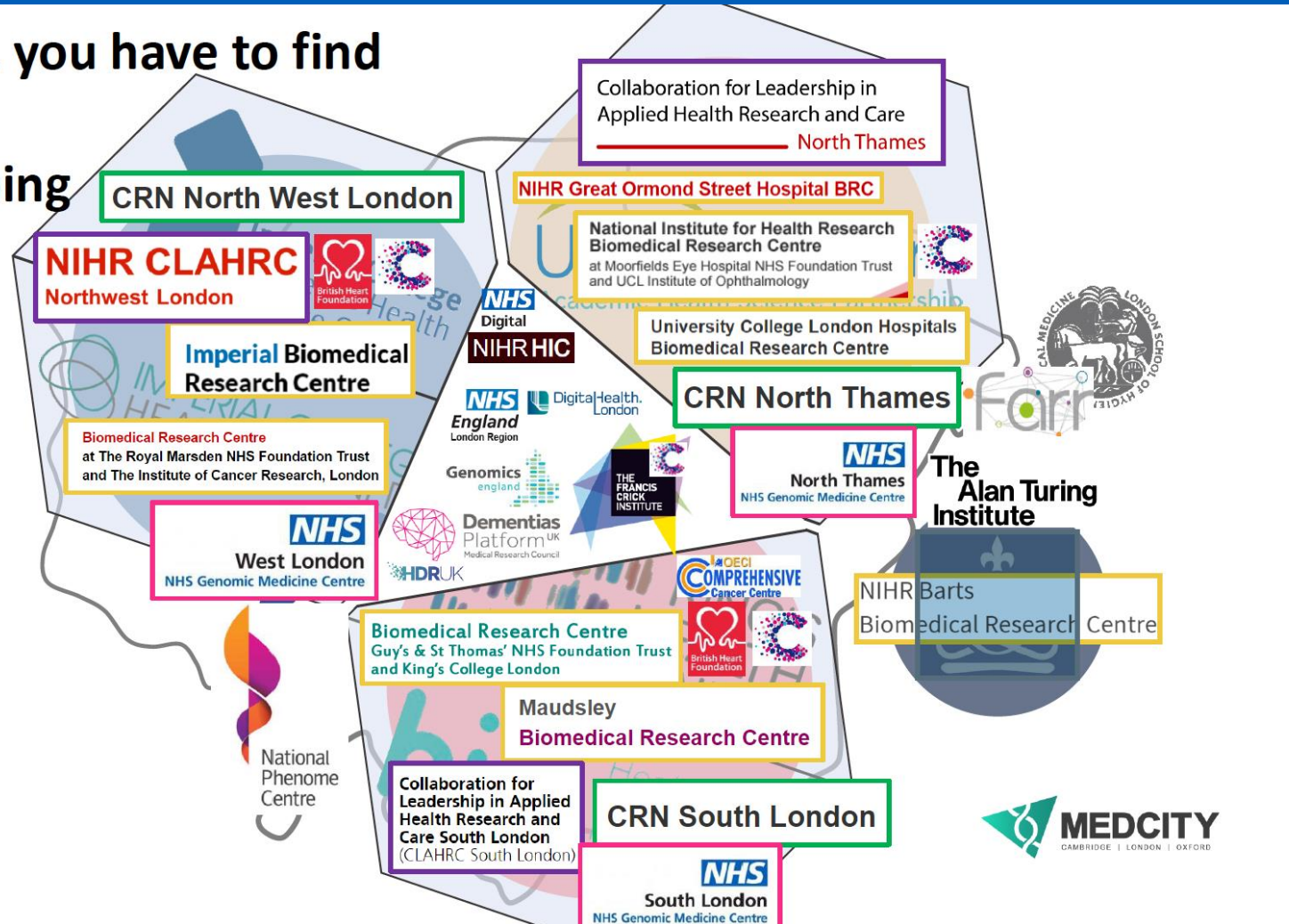


Local Health Care Record Exemplars

Primary and secondary care clinical data in Local safe havens

e.g.

DATA- first, you have to find it...
Data Mapping Project London



The Workforce



The Topol Review

Exploring how to prepare the healthcare workforce, through education and training, to deliver the digital future

The hard stuff

- What are the evidence standards of applied AI in healthcare?
 - Partnered with international collaborative research group led through IGHI
<http://www.imperial.ac.uk/global-health-innovation/our-research/artificial-intelligence/>
- Explore *principle 7*: Show what type of algorithm is being developed or deployed, the ethical examination of how the data is used, how its performance will be validated and how it will be integrated into health and care provision
 - What does this mean and how can we demonstrate?
 - International comparisons
- Regulatory changes
 - Sandbox - MHRA/NHSD
 - Model management VS live audit

