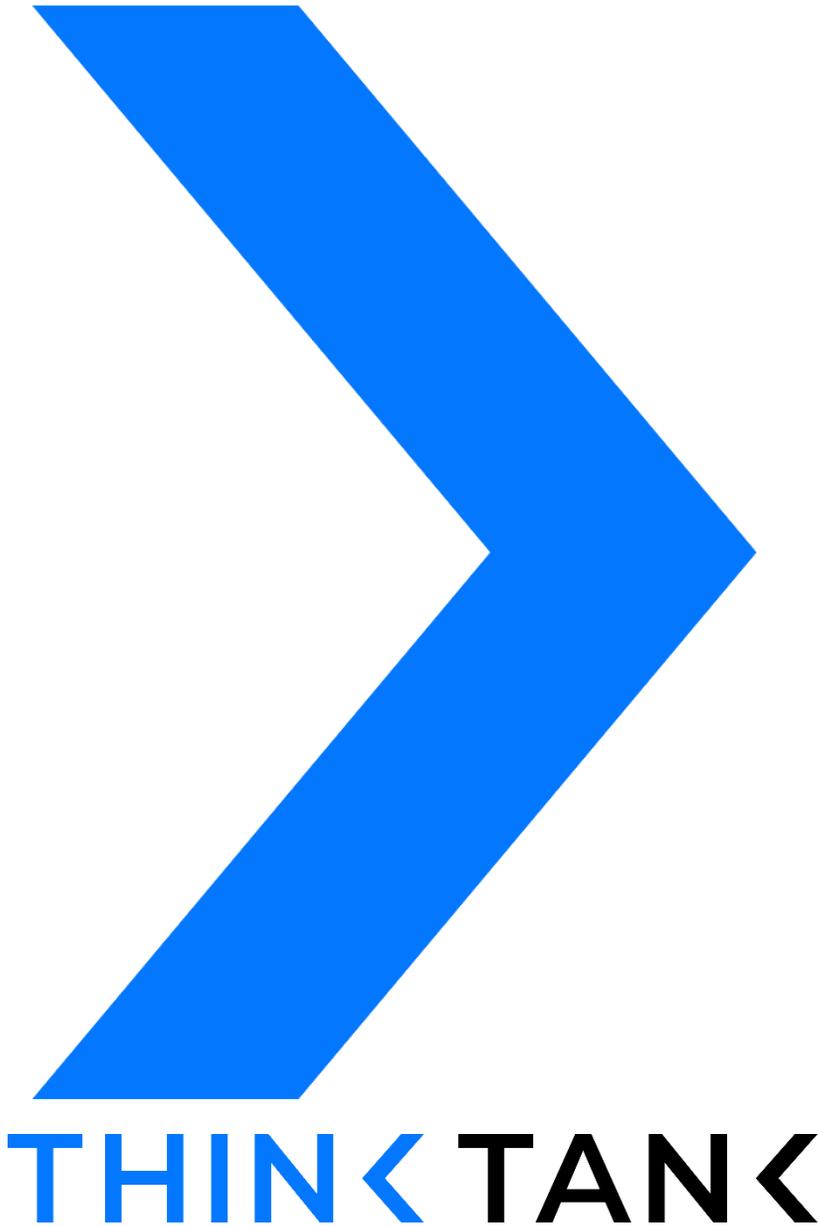# Optimising Innovation Pathways: Future Proofing for Success

EIT Health

Think Tank Round Table Meeting Proceedings

Worcester College, Oxford, United Kingdom
27.09.19

THINK TANK

Contents

Context for the selection of the 2019 Round Table Series Topic

In recent years there has been rapid growth in the field of medical and health technology products. Not only has the number of players in this sector increased over this time but the type of products has changed too, and this has implications for the overall fit and suitability of the steps that companies need to navigate to take an innovation from an idea to a marketable product, in a field which is highly regulated and complex.

This changing landscape poses new challenges in terms of development, testing, implementation, usability and adoption of new health technologies. As a result, innovators and other stakeholders can face hurdles, not only for regulatory approval but also to achieve sustainable adoption, with users who often require substantial evidence of impact and value before deciding to purchase.

In light of this ever-changing external environment in which innovative solutions aim to launch, the task of 'Optimising Innovation Pathways: Future Proofing for Success' was chosen as EIT Health's Think Tank's Round Table Series topic for 2019.

Through a series of National Round Table Meetings, such as the UK Round Table Meeting reported here, the aim is to identify barriers and opportunities that exist across the EU that either support or impede the widespread uptake of innovative solutions.

To better incorporate the innovator perspective in the National Round Table Meeting discussions, local companies that have developed innovation projects were interviewed prior to each Round Table Meeting about their pathway experiences. This information was used to help map the existing pathway process, steps, requirements and gatekeepers as well as gather insight on the practicalities of navigating the pathway in the real-world setting.

At the end of this 2019 Round Table Series, key actions and practically devised recommendations proposed during each meeting will be consolidated to provide a pan-EU perspective on optimising innovation pathways aimed to accelerate the sustainable adoption and diffusion of innovation in health technologies for the benefit of all citizens.

Objectives of the National Round Table Meetings

> To validate the current innovation pathways for a selected innovation type – Hardware Technologies, Digital Health or Healthcare Solutions in each region – and the key stages, gatekeepers and criteria that innovators must meet to move through the pathway with ease and timeliness, whilst also identifying similarities and differences that exist between them.

> To review insight gained from the real-life experiences based on case study interviews with selected innovators in each region (within the EIT Health Partner Network) currently navigating these existing pathways to identify barriers and opportunities.

> To highlight any barriers and best practices to this process and recommend practical solutions towards an ideal innovation pathway that would address the needs of both national/regional and pan-EU stage gatekeepers and of innovators and would help expedite the journey to adoption of innovative solutions in health.

Agenda and participants: UK Round Table

Hosted by EIT Health UK–Ireland and Oxford Academic Health Science Network (AHSN)

Facilitated by 2019 Round Table Series Chair: Professor Finn Boerlum Kristensen MD, PhD

Moderated by: Paul Wicks, PhD

Other participants: A full list of meeting participants can be found in Appendix 1.

Discussion topics

> **Session I:** The current state of the Digital Health Innovation Pathway in the UK

> **Session II:** Optimising the innovation pathway in the UK

> **Session III:** Proposals for actionable recommendations

Session I: The current Digital Health Innovation Pathway in the UK – summary of pre-meeting research and discussion

Focus of the UK Round Table

The innovation type selected for discussion at the UK Round Table was Digital Health. As a fast-developing field, the term 'Digital Health' covers many different definitions, which still lack consensus. For the scope of this Think Tank, Digital Health refers to:

> Software-based solutions that focus on healthcare interventions (related to patients or users' health). These solutions may be classified as:

> Medical Devices, regardless of the kind of technology, if they have a medical indication (diagnostic, prevention, therapeutic, etc.).

> Wellness Products if they do not have a medical indication.

In the EU, the new Medical Device Regulations (MDR) extend the definition of the scope of Medical Device software. With it, many Telemedicine solutions which represent Digital Health solutions (and therefore have a direct influence of the clinical aspects of healthcare) will be now considered as Medical Devices, when previously they were not. Given the need to determine if a Digital Health solution fits into the Medical Device classification, the pathway should always include this assessment step, regardless of its endpoint as a Medical Device or a wellness product. The main difference in the pathway is that a Wellness Digital Health solution will skip the regulatory process required for market authorisation of Medical Devices and can be sold without major limitations.

Overview of UK Digital Health Ecosystem

The findings of EIT Health's research into the UK's Digital Health ecosystem were circulated to participants in advance of the meeting. These were supported by insights from interviews undertaken with local companies that had developed Digital Health innovation projects. Key points from the research were:

> According to a Deloitte study on <u>Digital Health in the UK</u>, the UK Digital Health market was

worth £2.9 billion in 2018, growing from £2 billion in 2014, and driven mostly by mHealth apps.

> For this Think Tank, Digitised Health Systems and Health Analytics are classified under Healthcare Solutions and represent the largest market, both globally and in the UK (66% of sales). The TeleHealthcare and mHealth fields are covered under the broader concept of Digital Health, and represent the remainder of the market.

> The ongoing Brexit process may affect the market for medical devices, given the reliance of international trade on extensive standards and regulations. However, there are precedents in non-EU countries fully integrated into the EU framework, for example Norway or Australia, with recognition of a CE mark and governance with trade agreements and within international standards organisations.

> While the pharmaceutical industry has traditionally stood at the forefront of the healthcare industry, the recent shift towards digitalisation has meant that giants such as Google, Apple and Amazon have begun to diversify into the healthcare arena.

> Many investors are also keen to support start-ups and small-to-medium enterprises who apply artificial intelligence (AI) and technological approaches within a healthcare environment, with non-profit companies also keen to harness technology to solve problems and improve access to care.

> According to a recent EY report (NextWave Health Survey, 2019) on general digital health technologies, the main usages among the clinicians surveyed in England were: 61% for clinical decision support, 47% for messaging, and 44% for patients portals. For the consumers who were surveyed, the main adoption of digital technology for their health was as follows: 35% used technology to look for online information on possible diagnosis and treatments, 31% to make appointments online for healthcare services, and 20% use a personal activity tracker.

The Digital Health Innovation Pathway

The proposed innovation pathway in the UK was presented based on EIT Health's research into the existing literature on the topic. The current pathway (illustrated below) reflects the usual innovation development stages, but adapted for the specifics of new health technologies.

FIGURE 1

Although often considered as a linear path towards the ultimate objective of successful and sustainable adoption of the innovation, it is in fact a continuous and a cyclic pathway, whereby the growing obsolescence of a product supports further research and development, and the design and development of new innovations.

Digital Health clearly fits this overall pathway for health innovation. However, it faces specific challenges at different steps as the technology is still in its infancy, compared to MedTech, for example, and will therefore require adaptation by the various stakeholders along the pathway to reflect the new paradigm.

Discussion of Research Findings – the Overall Pathway

Participants discussed to what extent the overall pathway presented was executed in the UK as described and were asked to advise:

If the pathway, its stages and stage gates, reflected today's reality in the UK

> The pathway as presented is linear but that is not the reality of how it works – it is a modular pathway, more like a jigsaw.

> There is no single pathway that looks the same for all stakeholders.

> The pathway presented reflects an outdated regulatory system that is not appropriate for new technologies which need a more agile framework.

> The current pathway leans heavily on 'pharmaceutical' language. Use of the term 'clinical need' is outdated; it is derived from the drug development pathway and so should be revised to reflect the new environment and the focus not only on treatment but also on disease prevention and maintenance of wellbeing.

> The term 'unmet need' is redundant – very few needs are truly unmet – most problems do in fact have a solution; the innovation market is incremental and therefore the objective is to develop a more efficient solution that delivers improved value over the current option.

> If the pathway is optimised for innovators, this will in turn benefit patients and citizens, and they will have access to innovations in a timely manner.

> The NHS is a publicly-funded body and therefore requires demonstration of value from new innovations in order to pass through the process – the bar is set high.

> The complexities of the UK system mean that some SMEs go abroad to develop their products (often coming back to the UK later).

> Progressing through all stages of the pathway does not necessarily guarantee success – in parallel, the systems' readiness to receive the new innovation is an important factor.

What an ideal pathway, stages and stage gates would need to include and consider to be more suitable for the future reality

> The term 'clinical need' should be changed to 'system need' – the underlying need may often be the same, but the environment and context defining it are different.

> There should be a greater emphasis on 'problem identification' beyond just clinical or system need. This problem also needs to be validated from the perspective of the different stakeholders.

> 'Solutions-led' ideation – where there is no defined need at the start – could still have a value.

> The process for 'identification of needs' requires standardisation. It may be of value to have a step before this to 'observe users in their natural environment' to help identify problems.

> Continuous evidence generation and validation is needed to support the Adoption phase.

> Generation of evidence occurs too late in the pathway; it is needed throughout the process.

> Those commissioning services are interested in value, quality and outcomes; 'what is the best value for the resources I actually have'. This should be borne in mind when articulating the need.

Session II: Optimising the Digital Health Innovation Pathway in the UK: discussions and recommendations

Participants were asked to consider what changes to the pathway phases and stage gates would be necessary for an optimised or ideal pathway for the future. Each phase and stage of the pathway was considered in detail focusing on barriers and challenges, as well as identified best practices.

FIGURE 1

1. IDEATION

1. CLINICAL NEED
2. IDEA

Challenges and barriers: What is not working/what needs to change in the ideation phase of the current pathway to get closer to an optimised one?

Topic	Key discussion points
Co-creation	> Co-creation with end users is essential to successful innovation – co-creation should be developed from an art into a science.
Funding	> Clear information and decision-making are needed regarding NHS

	funding for innovations to address internal identified needs.
Market knowledge	> It is important to have a good knowledge of the existing solutions already on the market in order to identify appropriate new opportunities as well as having a comprehensive knowledge of the relevant marketplace. > It would be helpful to share market knowledge data.
Identification of needs	> The focus should be not only on clinical needs but also on 'system needs'. > A structured process should be established for the systematic identification of needs.
Support and resources	> There appears to be variability in the support (incubators, accelerators) and resources (funding) for innovations around the UK's countries and regions – this requires comprehensive mapping. > HTA bodies in Scotland are often used as test beds to enter the market as they are more agile than the English ones. > A clear national support system is needed that innovators can connect to, instead of fragmented support programmes. The AHSN network is well placed to assist here – see below example of AHSN Network Innovation Exchange. > Health Tech Connect is a secure single digital platform launched by NICE in May 2019 for identifying and supporting health technologies as they move from ideation to adoption in the UK health and care systems. It has a key role in bringing stakeholders together early on and for signposting innovators to supporting resources. > Need better awareness of who can provide support to innovators on the ecosystem – a 'one-stop shop'.

Disinvestment	> The NHS is slow to change so it is key at this stage to demonstrate to the relevant parts of the organisation (e.g. commissioners) the benefits of disinvestment and adoption of new ideas that bring better value.
Early evaluation and funnelling	> It is important to identify as early as possible what innovations have value and not put resources behind those which are unlikely to progress. > There is a lack of knowledge/awareness of tools for assessment that innovators can access to help funnel ideas early on in the process – a need for education.
Stakeholder views and input	> Need to become better at ensuring all stakeholder views are represented in this phase, particularly patients/end-users. > Effective co-creation requires independent feedback from different stakeholders. This is a key step in early collection of evidence and requires a systematic approach.
Key points	> **Clear information is needed on NHS funding of innovations.** > **Good market knowledge is critical to the success of a solution.** > **The process of needs identification should be standardised and allow for early assessment to determine which innovations should progress.** > **There is a need for a clear national support system that innovators can access for resources and advice.** > **Co-creation with all stakeholders, particularly patients and citizens is key from the earliest stage.**

What is working well/best practices identified in this phase

Positive experiences
Value Proposition Canvas (developed in the US) – a tool which helps ensure that a product or service is positioned around what the customer values and needs.

Best practice examples
AHSN Network Innovation Exchange: A new programme designed to help innovators understand what the NHS challenges are and connect them with the help they need.
Health Tech Connect: A new platform provided by The National Institute for Health and Care Excellence (NICE) to support the development and adoption of new health technologies.

FIGURE 1

2. DEVELOPMENT

3. PROOF OF CONCEPT

4. PROOF OF FEASIBILITY

5. PROOF OF VALUE

Challenges and barriers: What is not working/what needs to change in the development phase of the current pathway to get closer to an optimised one?

Topic	Key discussion points
The Development phase	> From the perspective of a start-up, this is not a distinct phase but will blend with the previous (Ideation) and subsequent (Market entry)

	phases.
	> Repurposing the biotechnology pathway is not helpful as the Digital Health pathway is very different. Digital Health is more aligned to a consumer-focused product pathway which constantly evolves in response to needs and will often not be 'perfect' when it reaches the market.
Valley of death concept	> The terminology 'valley of death' (a recognised concept in entrepreneurship describing checkpoints at which a new idea going through the pathway fails to progress) sounds negative but should be considered in a positive way – a 'recycling centre' that is evaluating, not stopping, innovations. > Investors are key gatekeepers so better engagement is needed with them in this phase in order to ensure good investment decisions. They need to be better educated about the requirements of the whole pathway to allow investments to better align with the resource requirements of each phase and stage.
Product–Market fit	> Innovators need to (a) understand their market and (b) know where their product fits within that market. > While some products are niche (relevant for a specific hospital or practice) others are more scalable.
Proof steps	> Evidence for proof of concept, feasibility and value should be generated as a continuum along the innovation pathway. The volume and intensity of these individual steps may vary along the way, but they should be integrated throughout the process. > What is the threshold for a minimum viable product? It is important to consider in this phase what will be required by the regulator in the

	subsequent Market Entry phase.
Early dialogue	> Early dialogue with regulators and other gatekeepers is key in this phase.
Accelerators	> There are a large number of accelerators in healthcare, but they lack good networks in order to share the learnings from product development.
	> Accelerators are too far upstream within the pathway; they should be blended into organisations and institutions in order to iterate in the 'real-world' setting where solutions will be deployed, rather than just facilitating product and business plan development.
	> NHS accelerators may be focused on certain stages of the innovation development process, for example market access, which may not be helpful for all innovations. As an example, the NHS Innovation Accelerator (NIA) programme focuses on scale-up of innovations rather than the early development stage.
	> With the range of different NHS innovation accelerators, it would be helpful for innovators to have a clear understanding of the journey through this phase, and what the requirements are for the next steps of the process.
Innovation failure	> It is important to capture why innovations fail at this stage and to share this knowledge in order that everyone can learn from these mistakes.
	> Accelerators should be encouraged to share information about both successes and failures.

Local versus national focus	> Local knowledge can be key to developing and innovation and having it adopted – decisions of Clinical Commissioning Groups around the UK reflect the population they serve.
	> Attempts to 'fit' an innovation to the local ecosystem need to be balanced against the opportunity of scaling up nationally or internationally – it is possible to 'overfit' a proposition for one market making it challenging to launch in other markets; also, some products only fit a very particular niche market, making them largely 'unscalable'.
Changes in NHS structures & processes	> NHSX is currently responsible for implementing the digital transformation of health and social care in the UK. It brings together teams from the Department of Health and Social Care, NHS England and NHS Improvement, and is continuing to progress the digital transformation of health and social care.
	> The structure of procurement process in the UK changed in October 2019 and will be more supportive of innovation and digital technology.
	> Approval/regulatory processes both locally and nationally are also likely to change in the near future – although this is not fully defined as yet – and will probably become less autonomous at a local level which will impact on the pathway progression of Digital Health innovations – innovators need to be aware of, and prepare for, this market change.
	> As the UK market changes, innovators need to be aware of the many different processes and systems across the NHS that they will need to take into account.
Innovation function within	> As organisations aggregate and become larger, distinct solutions (those that are not system-wide initiatives, such as Electronic Health

organisations	Records) become less visible to the decision makers, so it becomes more difficult for innovators to sell them – this highlights the need for an innovations function embedded within organisations. > A central point of contact within an organisation would could give advice about the market and procedures. This would enable a more systematic internal view and approach to innovation in this phase.
Intrapreneurship	> We need to find ways to support the sustainability of 'intrapreneurship' – innovations arising from within the NHS – including securing funding for their development and ongoing maintenance within the system. > Establishing intellectual property (IP) protection in the setting of NHS funded projects is important. > The time that clinicians can allocate to innovation development can be limited due to their work demands, so personal motivation is often the main driver to engage with innovators in this setting. Initiatives such as the Clinical Entrepreneur Programme (see below) are helpful here. > There appears to be a move towards establishing infrastructures and processes that allows innovation to take place within the NHS – there is a strong national policy direction for this that innovators can link their value proposition to.
The role of Universities	> The relationship between Universities and entrepreneurs needs to be improved to ensure better translation of research into ideas and valuable solutions.
Input from diverse	> 'Healthcare' is often siloed within institutions. Innovation development would benefit from input from a diverse range of

specialities	professional specialties and skill sets – clinicians, academics, business, humanities etc.
	> Digital agencies within the community can be of value in providing resources for developing products and undertaking proof of concepts for solutions.
Cost effectiveness and budget impact	> There is a lack of literacy about the difference between cost-effectiveness and budget impact.
	> Both aspects need to be considered from the beginning of the innovation pathway as most procurement processes will require information about this and will want to know the impact of implementing an innovation. For the system, knowing the budget impact is key information to enable adoption.
	> Methods to generate this information and experience in this setting can be expensive and difficult to access – there is a need to educate innovators.
	> The wider system benefits of an innovation need to be articulated to enhance its adoption – value-based healthcare.
	> The NHS needs to move away from the rigid 12-month budget cycle which can stifle innovation.
Key points	> **Establish product–market fit as early as possible in the development process and avoid 'overfitting' to a single, local market**
	> **Embrace failure of innovations and systematize learnings across the ecosystem**
	> **Improve accelerator networks and encourage their incorporation into 'real' world' settings**
	> **Facilitate early dialogue with regulators and other stakeholders to fully understand proof requirements**

	> The diversity across local ecosystems needs to be balanced against the ability to scale nationally and internationally on the innovation pathway
	> Innovators need to be aware of the forthcoming changes in the UK market and NHS processes
	> Innovation functions should be embedded in organisations as a central point of contact
	> Sustainability of 'intrapreneurship' within the NHS needs to be supported
	> The wider system benefits and value of innovations needs to be communicated to enhance their adoption

What is working well/best practices identified in this phase

Positive experiences
The Clinical Entrepreneur Programme within the NHS is designed to offer opportunities for clinical staff and other health professionals to develop their entrepreneurial aspirations during their clinical training period.
'Development procurement' is a new approach to help fund development at the early stage, and involves having stakeholders engaged from beginning, including Commissioners and Health Systems.
There is a developing trend for companies and systems to be less shy about communicating failure – language is important here: it is not about failing, but about everyone learning how to improve for the future.
Some Universities, for example Oxford, have established technology transfer organisations that have defined processes, good networks and access to funding to enable translation of research into solutions.

Best practice examples
European Network for Health Technology Assessment (EUnetHTA) has programmes to encourage early dialogue with manufacturers to understand evidence needs.

Ontario, Canada has the <u>MaRS EXCITE</u> programme to help navigate health system market access.
The <u>NHS Innovation Accelerator</u> (NIA) programme supports the uptake and spread of proven, impactful innovations across the NHS.
<u>NHSX</u> has a new <u>Artificial Intelligence (AI) Laboratory</u> which aims to use AI to help solve some of healthcare's toughest challenges, including earlier cancer detection, discovering new treatments and supporting the NHS workforce. NHSX has recently released their first foundation policy document about the initiative: '<u>Artificial Intelligence: How to get it right – Putting policy into practice for safe data-driven innovation in health and care</u>'.
'<u>The Hill</u>', a digital health innovation community based in Oxford brings together multiple stakeholders –patients, carers, nurses, doctors, healthcare professionals, designers, developers, researchers, business leaders and investors – to help solve healthcare challenges.

3. MARKET ENTRY

6. INITIAL CLINICAL TRIAL

7. VALIDATION OF SOLUTION

8. APPROVAL AND LAUNCH

Challenges and barriers: What is not working/what needs to change in the market entry phase of the current pathway to get closer to an optimised one?

Topic	Key discussion points
Impact of new EU Regulations for Medical Devices	> The regulators' capacity to assess innovations will be an issue for innovators. Currently, about only 300 products can be evaluated

(MDR)	per year; about 3,000 are expected to be impacted by the new MDR.
	> The new MDR may impact access to some current medical technologies within the healthcare system if the product is not compliant with the new regulations, meaning that it will need to come off the market.
	> It is understood that the Medicines & Healthcare products Regulatory Agency (MHRA) will fully embrace the new MDR. Evidence will need to be provided for the whole life-cycle of the product
	> New evidence requirements associated with the new MDR need to be considered early on the pathway to ensure the right the level of evidence is generated. There is still, however, much uncertainty about what this will mean for Digital Health products and software.
	> There is currently a lack of consensus on what constitutes a medical device as opposed to a wellness product – does it depend on the product or its application?
	> Strict regulations may push some innovators to seek ways to bypass the regulation as the requirements are currently unclear.
	> Conversely, regulations can be seen as positive – if a digital health product can gain a CE mark for example, this is likely to enhance adoption.
Clinical trials	> A clear definition and framework for the standards and requirements of clinical trials for Digital Health products is needed.
	> Innovators need a better understanding of the levels of evidence that they need to provide – what is good enough?
	> Guidelines and frameworks for clinical trials for medicines, devices and diagnostics are well defined, but those for digital products and AI applications are not.
	> The 'randomised clinical trial' model is not appropriate for digital

	technologies – regulators and technology assessors, who are used to the pharma model, need to be educated about new methodologies. > Real-world data and evidence are more appropriate in this setting and will enable digital solutions to better respond to user needs. > 'Risk-based' assessment should be considered. > Methodologies are needed that take into account the iterative development of digital products – will incremental changes require a new 'trial'? Process rather than product standards are needed. Rigorous evidence generation by way of adaptive piloting may be a better approach than the clinical trial paradigm. > The FDA have drafted specifications for how they intend to regulate AI and machine learning applications.
Data security	> New data security requirements and standards must be developed to meet the needs of the new digital solutions and the information they collect.
Applicability	> Digital Health products are often personalised in their application therefore the 'testing' data sets may not reflect the 'real-world' datasets in actual use – how do we define what is applicable?
Key points	> **Assessment of the impact of new MDR on the future access to health technologies, particularly digital technologies, is required** > **New evidence-generation methodologies, including the use of real-world data, are needed which take the healthcare systems environment into account – the standard 'clinical trial' model is not suitable for digital technologies**

	> **Risk-based approval requirements** should be considered, as not every Digital Health solution is associated with the same degree of efficacy and safety concerns > **'Process' standards** rather than 'product' standards are needed to account for the continuous innovation and incremental evidence generation of Digital Health products > **Develop product** endorsements beyond the CE mark to encourage adoption

What is working well/best practices identified in this phase

Best practice examples
Ontario, Canada has the <u>MaRS EXCITE</u> programme to help navigate health system market access.
The <u>NHS Innovation Accelerator</u> (NIA) programme supports the uptake and spread of proven, impactful innovations across the NHS.

FIGURE 1

4. ADOPTION

9. CLINICAL\COST ASSESSMENT

10. REIMBURSMENT

11. STANDARD OF CARE

12. OBSOLESCENCE

Challenges and barriers: What is not working/what needs to change in the adoption phase of the current pathway to get closer to an optimised one?

Topic	Key discussion points
Addressing needs	> Addressing a real need is key to successful adoption.
Change management	> Change management is key to the adoption of new innovations, particularly in the setting of 'service' rather than 'product' provision common to digital health solutions. > Change management needs to be addressed systematically within the system. This needs to include discussion of attrition – for example, staff may be concerned that their jobs are at risk if digital health products decrease their contact with patients. > Digital Health solutions, for example mobile apps, may be well accepted by some populations but not others.
Changing standards of care	> The standard of care has changed to a model that discourages bringing patients into the clinic, preferring remote monitoring and digital communication, but clinicians can be slow to change.
Incentives	> Incentives are a key driver for the adoption of new innovations. > One barrier to adoption is misaligned incentives whereby a new solution may be perceived as taking resources away from the current environment or replacing a pathway that generates revenue.

	> In the UK, new locally-agreed tariffs for outpatient care will help establish these incentives and support the paradigm of providing healthcare outside of the clinic where possible to alleviate stretched hospital resources. > New business models are needed to support adoption of these new innovations.
Implementation	> Few companies are able to deliver a fully integrated offer, including business development, sales and marketing, that can sustain the adoption effort. > These factors need to be considered as part of the Product–Market fit much earlier in the pathway. > There is a significant cost pressure related to implementing a new solution due to the need for transformation of the existing system and structures.
Cost and value	> In the payer environment there is often a major focus on the 'cost replacement' that a new innovation can provide rather than on the improvement in quality of care, outcomes and value. > Education around 'value' is important for payers and providers in order to manage their expectations – new innovations are not all about cost savings but also about their impact on other factors such as care quality, safety and patient adherence. > Value-based healthcare provides a new method for capturing the value generated by Digital Health innovations based on outcomes.
Product approval	> A survey of clinicians indicated that one thing that would give them confidence to prescribe an app or another digital product to

	patients was an NHS 'badge of approval'. > It is likely that such certifications or endorsements beyond the CE mark will become increasingly important in a product gaining adoption.
Key points	> **Systematic change management is required to support adoption of new innovations.** > **There is a need to provide incentives to implement internal change and adopt new innovations** > **There is a need to educate and manage the expectations of stakeholders, about the value of an innovation and the benefits it can provide to the system over and above cost savings** > **Procedures across national and international boundaries need to be coordinated focusing on quality improvement, outcomes and value, taking into account context and local ecosystems. EUnetHTA is an example of a longstanding process towards more International cooperation in HTA and alignment with regulatory requirements.**

What is working well/best practices identified in this phase

Best practice examples
EIT Health project: The Future Healthcare Manager in Europe. This includes training in Digital Health to better understand the holistic benefits of digital health technologies over and above costs.
The Cambridge Health Network promotes collaboration between the public, private and academic sectors.
The European Network for Health Technology Assessment (EUnetHTA) facilitates high-quality HTA collaboration across Europe.

Session III: Conclusions and recommendations for actionable outcomes

Drawing on the aforementioned discussions of barriers and opportunities in the current innovation pathway for Digital Health, in the final Session participants developed a list of recommendations for specific actions that , if implemented, could help optimise the pathway and make it more suited to the development and progress of Digital Health technologies. Where possible, they also identified potential target stakeholders who would need to be engaged with to realise these outcomes. It was recognised, however, that further discussions would need to take place with each key stakeholder identified in order to refine specific the actions required.

IDEATION	TARGET STAKEHOLDER(S)

ACTION
 	
> Develop a systematic process for needs identification and assessment to provide better guidance on the evaluation of solutions
 	
   > Create a centralised repository of granular needs (specific details rather than big picture); <u>Health Tech Connect</u> is an example already in place in the UK, which can be connected to rather than replicated. EIT Health can facilitate discussions between NICE (who provide the repository), and EIT Health partners to encourage further registrations to Health Tech Connect.
 	
   > Create systematic structures that allow access to needs observation inside the system, including methodologies for mapping those needs, the landscape of possible solutions, and current practices.
 	
   > AHSN to develop link with stakeholders to identify specific local needs and priorities within the network, beyond the bigger national priorities.
 	
> From the beginning of the pathway, educate innovators about
	
	EIT Health
	NICE
	AHSN Network

what is required to deliver value inside the healthcare system (namely increased efficiency and improved costs) to enable them to create a strong case for adoption > Promote early access to and dialogue with stakeholders (HTA bodies, commissioners, trust executive teams, etc.) to develop and sustain a strong value proposition. EIT Health can help facilitate. Early dialogue should include discussions about how innovators can access internal metrics and strategic plans, ensuring that the proposed solutions fit the stakeholders' plans. > Have clear expectations of the value and standards required to address a certain need > Linked with the above recommendation. > Develop a clear pathway of co-creation to ensure product reimbursement and sales at the later stage > Establish designated contact points for innovators within institutions who have a gatekeeper role (an 'innovation facilitator') to help progress (or weed out) innovations. EIT Health can facilitate events that would create this ecosystem > Develop appropriate structures and governance arrangements to embed trust between stakeholders and innovators.	**AHSN Network** **AHSN Network** **AHSN Network** **Regional and local ecosystems**

DEVELOPMENT
 	
ACTION
 	
> Ensure a good product–market fit early in the Development phase, over and above outcomes value
 	
    > Create incentives for institutions to undertake early testing and de-risking of innovations.
 	
> Ensure failure is embraced as part of the process – be prepared to 'fail fast' – and systematise learnings from these projects across the ecosystem
 	
    > Communicate the results and learning of EIT Health-funded projects that failed – develop a centralised internal resource to track these?
	TARGET STAKEHOLDER(S)
	
	AHSN Network
	
	EIT Health

> Facilitate early dialogue with regulators and other stakeholders (e.g. payers) to obtain advice on Development phase requirements and generating evidence of proof of value	
> Create regulatory sandbox environments for new technologies that enable collaborative conversation between innovators and regulators.	**NHSX**
> The NICE MedTech Early Technical Assessment (META) tool may be helpful in supporting discussions.	**MHRA**
> Increase the awareness of the availability of open-access databases from NHS Digital and other initiatives that can be used for testing.	
> Ensure the diversity across local ecosystems is balanced against the ability to scale nationally and internationally	

MARKET ENTRY

ACTION

> Assess the impact of the new MDR on the access to health technologies, particularly Digital Health

> ORCHA has developed a briefing on this for Digital Health Apps (circulated to participants post-meeting)

> Develop more risk-based approval requirements, as not every Digital Health solution is associated with the same degree of efficacy and safety concerns

  > Develop methodologies and requirements for a Digital Health pathway that facilitate assessment by regulators.

  > Expand the role of Public–Industry development research initiatives, such as IMI, to address topics related to Digital Health.

  > Define appropriate language and move away from pharma/biotech wording.

> Develop new evidence-generation methodologies that take the healthcare systems environment into account

> Set 'process standards' rather than 'product standards' to account for the continuous innovation and evidence-generation required for digital technologies

TARGET STAKEHOLDER(S)

ORCHA

NHS England
MHRA

AHSN Network
NICE

NICE

TBC

> Define the role of the different stakeholders in self-regulation of the ecosystem > Develop systems for product endorsements beyond the CE mark to encourage adoption of Digital Health products (the NHS is currently developing such a project)	**NHS England**

ADOPTION
 	
ACTION
 	
> Educate stakeholders, including investors, about the expected value of an innovation and the adoption process
 	
  > Advise innovators that they should consider their expansion roadmap from an early stage.
 	
  > Develop investor education programs on the Digital Health pathway.
 	
  > Encourage co-investment in innovations. E.g. EIT Health Venture Centre of Excellence
 	
> Coordinate procedures across national and international borders that take account of context and local ecosystems
 	
  > Support transnational coordination of HTA initiatives, based on a sustainable framework.
 	
  > Increase the sharing of knowledge and best practices in the pathway to adoption of Digital Health innovations across multiple healthcare systems beyond Europe, including the US, Canada, New Zealand.
 	
> Promote incentives to implement internal changes to the healthcare system that enable the capture of new kinds of values (e.g. sustainability goals).
 	
  > Learn from existing value-based payment and procurement systems to determine the best future NHS system
 	
> Develop a systematic change management process for innovation
 	
  > Facilitate access to key influential decision makers inside the system, including clinical leadership.
 	
  > Communicate the benefits of incorporation of innovation
	TARGET STAKEHOLDER(S)
	
	TBC
	
	TBC
	
	NHS England

| to Senior Management.

> Support the connection with the patients to allow co-creation of innovation. | |

Appendix 1: Round Table Meeting participants

EIT Health would like to thank the following participants for their input into the Round Table Meeting:

Name	Organisation
Advisers	
Finn Boerlum Kristensen	Think Tank Round Table Series Chair 2019 & Independent Consultant
Paul Wicks (Meeting Moderator)	Independent Consultant, Wicks Digital Health
Liz Ashall-Payne	Founding CEO, ORCHA Health Ltd
Tracey Davison	Director of Clinical Innovation Adoption, Oxford Academic Health Science Network
Nick De Pennington	Innovation and Population Health Lead, Oxford University Hospitals NHS Trust,
Lisa Hollins	Innovation Lead, NHSX
Graham Jackson	Chair, NHS Clinical Commissioners
Susan Myles	Director, Health Technology Wales
Sian Rees	Director of Patient & Public Involvement, Engagement & Experience, Oxford Academic Health Science Network
James Rose	Head of Innovation, Oxford Academic Health Science Network
Carmelo Veldardo	Senior Research Fellow, Sensyne Health PLC
Organisers and other attendees	
Mayra Marin	Think Tank Manager, EIT Health
Sameena Conning	Director of External Affairs, EIT Health
Leslie Harris	Managing Director, EIT Health UK-Ireland
Adam Mohamed	Communications Manager, EIT Health UK-Ireland

Erin Anderson	Communications Coordinator, EIT Health UK-Ireland
Kirstie Clegg	Innovation Manager, EIT Health UK-Ireland
Miguel Amador	Researcher
Karen Wolstencroft	Rapporteur