EIT Health is supported by the EIT, a body of the European Union

EIT Health Think Tank

Optimising Innovation Pathways:
Future Proofing for Success

UK Round Table Meeting

APRIL 2020

Executive summary

The healthcare industry is an ever-evolving space and there is a need to consistently reassess the pathways for innovation so as not to hinder new and exciting developments from reaching the market. For this reason, in 2019 EIT Health hosted a series of round tables across Europe , attended by key stakeholders, to examine the areas of the innovation pathway where improvements can be made.

The UK Round Table focused on the digital health market as the introduction and evolution of mHealth applications has seen this market grow rapidly over the past few years in the UK. According to a study from Deloitte, the UK market rose from £2bn to £2.9bn between 2014 and 2018.

This trend shows the long-established structure of the healthcare industry, where the pharmaceutical sector has traditionally stood at the forefront, is beginning to shift towards digitalisation – opening the path for new entrants, and for giants such as Google, Apple and Amazon, to diversify into the healthcare space. In fact, only 32% of mHealth developers come from traditional healthcare stakeholders such as hospitals, health insurers and Pharma companies (Liquid State, 2018).

Of course, it remains to be seen how markets such as digital health and medical devices in the UK may be affected by the Brexit process, given the reliance on international trade and extensive standards and regulations. However, there are precedents in non-EU countries fully integrated into the EU framework (e.g. Norway and Australia) with recognition of a CE mark and governance with trade agreements and within international standards organisations.

The UK Round Table identified a number of key stages within the innovation pathway where improvements could be made to aid and speed up the route to market for promising innovative solutions.

We face challenges in the regulatory pathway, with new regulations threatening serious backlogs to the approval of new and existing medical products, and we also have unique challenges in the UK. A fragmented landscape and a system with finite resources means that it is incredibly important that ideas are rigorously tested for need and market, but it's difficult for innovators to have a comprehensive understanding of what's available and what is really needed. Furthermore, fragmentation in the landscape and local commissioning means it's advantageous to tailor a new product for the local context, but over tailoring can limit the ability to scale.

We would like to give our sincere thanks to all of those who participated and special thanks to Oxford Academic Health Science Network (AHSN) who co-hosted the UK Round Table alongside EIT Health UK and Ireland.

Leslie Harris,
Managing Director, EIT Health UK and Ireland

Contents

Introduction

In recent years, there has been rapid growth in the field of medical and health technology.

Not only has the number of players in this sector increased, but the diversity of products and services has evolved exponentially. While there are clear benefits in this change in dynamic, we must consider the impact this has in terms of how adequately innovators (those developing products and services) are able to navigate the path to market in a field that is highly regulated and often complex and slow to evolve in line with new technologies. This is particularly relevant when we consider that we are seeing more and more solutions being developed by innovators who are not sector specific, and therefore may lack relevant experience and understanding of the specificities of the healthcare market.

The regulatory and reimbursement landscapes are also ever-changing, posing new challenges in terms of development, testing, implementation, usability and adoption of new healthcare solutions. As a result, innovators and other stakeholders can face further hurdles in simply keeping abreast of how to access the healthcare market. In light of this environment, the EIT Health Think Tank selected the topic 'Optimising Innovation Pathways: Future Proofing for Success' for consideration and debate in its 2019 Round Table Series.

The current situation:
a focus on today's innovation pathway

The innovation pathway, or route to market for new products and services, is comparable in the UK to the rest of Europe. Although presented in a linear format in figure 1 below, it is in fact a continuous and modular pathway whereby all parts are interconnected and reliant on each other.

Regulatory and reimbursement stages of the pathway were historically developed to support the introduction of more traditional treatments such as pharmaceutical medicines or medical devices. This has led to a pathway that favours more traditional innovation, and in need of reform in order to address emerging technologies such as digital health in all its many forms. This is particularly relevant when assessing the regulatory processes, which is struggling to keep pace with the rapid introduction of new technologies. In the current landscape, where new technological discoveries are constantly being made, there is increasing need for a more agile regulatory framework.

Such reform of the regulatory pathway in Europe, and consequently, the UK, has indeed been addressed recently as evidenced by the European Medicines Agency with the proposed introduction of new guidance for medical devices and in-vitro diagnostics which are planned to be introduced in 2021. These new guidelines have been developed in response to the increasing pace of innovation and evolution of the types of products and services requiring assessment. Regulatory capacity to assess innovations based on the introduction of these guidelines, however, is expected to be challenging. Currently, regulators have the capacity to evaluate approximately 500 products per year; whereas approximately 6,000 are expected to be impacted by the new MDR. This will create a backlog of solutions both new and already on the market that require review via the new guidance and may interrupt and slow access for patients and citizens.

Pathway optimisation is profoundly important for health innovation, as it will in turn ensure that patients and citizens benefit from access to promising solutions as quickly as possible.

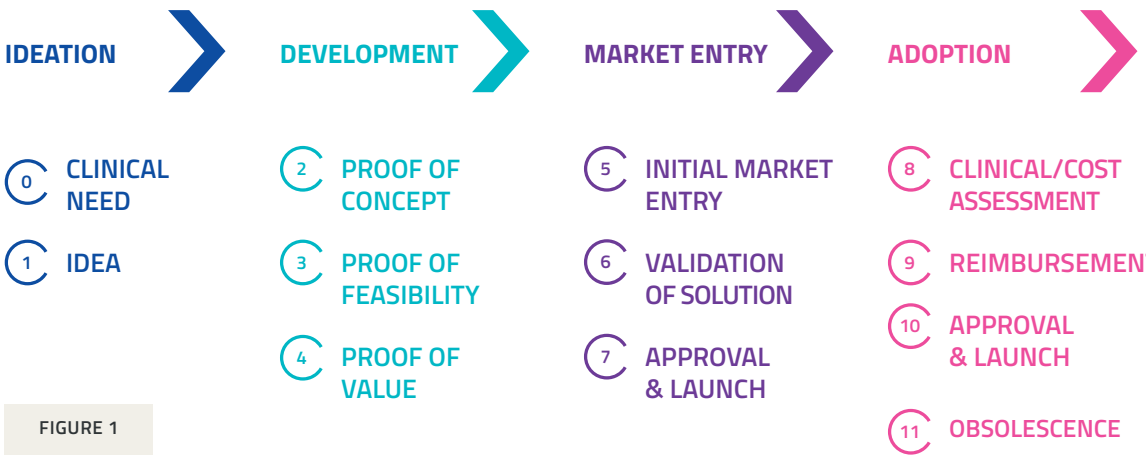


FIGURE 1

Ideation – grasping the 'unmet need'

The term 'unmet need' refers to the clinical shortfall of solutions for a disease, condition or patient experience in managing, maintaining or regaining their health.

While unmet clinical need is a crucial consideration in the ideation phase, there is also a need to modernise the understanding of such terminology. In today's landscape, there are few truly unmet needs due to the advent of effective solutions for the majority of health conditions we face. What today's innovators are frequently addressing is incremental innovation that provides a more effective or efficient solution versus the standard of care or current options. The focus here is on improved value to the patient and healthcare system, and less so about addressing an unmet need as such. The focus should not only be on clinical need, but likewise system need, as innovation is more likely to gain traction if it integrates into current systems and process. Currently, the process for innovators in identifying needs – both clinical and systematic – remains informal. As a result, it is often approached locally and lacks wider geographical context required for later scaling out solutions to other regions or countries. It would therefore be beneficial to develop a structured and established approach for the identification of needs during the ideation phase.

Additionally, co-creation with end users is essential for successful innovation and should be a key part of the 'value story'. As with needs identification, co-creation is currently approached informally and therefore structure and agreement on requirements is lacking. In order to assess whether new innovations truly offer value to patients, co-creation as a discipline should be transformed from an art form to a science.

The National Health Service is a publicly funded body and therefore requires significant demonstration of value from new innovations in order to pass through the process. As such, it is important for innovators to have good oversight of what already exists on the market, and what is coming soon in order to identify where their proposed solution may fit within the landscape. Within a value-driven landscape, it is important to acknowledge that resources are limited, and time and resources should be put towards transformative solutions as opposed to those unlikely to have real impact.

Supportive resources and funding for innovators in the ideation phase are variable across the UK's countries and regions. While incubators and accelerators are in existence, they are often embedded into the local innovation ecosystem leading to fragmentation and lack of widespread visibility. It would be beneficial to comprehensively map the health-related incubators and accelerators available across the UK to encourage more widespread engagement with such supports. Additionally, fragmentation could be overcome if a national support system were assigned to oversee the experience of innovators and ensure that they can adequately connect to available support. Existing platforms such as the Academic Health Science Networks, the National Institute of Health and Care Excellences' HealthTech Connect or the NHS Innovation Accelerator would be ideally placed to facilitate such a service and generate awareness and engagement amongst innovators.

The terminology 'valley of death' - a recognised concept in entrepreneurship describing checkpoints at which a new idea going through the pathway fails to progress -should also be considered as a positive and necessary step in the innovation process as opposed to viewed negatively. It is through failures that we learn what works and what does not, and every lesson enables innovators to avoid pitfalls in the future. There is a developing trend for companies and systems to be less concerned about communicating failure. It would be beneficial to consider a route for sharing and learning from failures amongst the health innovation community, as well as culturally readdressing the perception of failure.

Development and market entry

Developing a product or service for the UK market has many steps that are intrinsically linked to the market entry phase of the innovation pathway outlined in figure 1. Market entry must be at the forefront of innovators' minds throughout the development phase as comprehensive data are required to evidence the proof of concept, feasibility, efficacy, safety and value of a new solution.

There is currently insufficient definition of the standards and requirements for clinical trials of digital health products and services, which makes the generation of evidence a blurry area for innovators. In order to produce the required evidence, innovators need a better understanding of the level of evidence that is required for digital health products and services. Guidelines and frameworks are in existence for the medicines, devices and diagnostics, however certain solutions such as artificial intelligence are not adequately covered.

The 'randomised clinical trial' model associated with pharmaceuticals is often not appropriate for digital technologies, and real-world data are often more informative in supporting the value proposition of such solutions. Additionally, methodologies in this space must take into account the iterative development process for digital technologies. Unlike pharmaceuticals, incremental improvements are regularly implemented with digital health solutions and a new clinical trial for such updates would neither be feasible nor beneficial.

A clear definition and framework for the standards and requirements of clinical trials for digital health solutions specifically would be beneficial in clarifying the evidential requirements. In line with this, education for regulators and technology assessors would be required to aid the expansion of varying models and methodologies beyond traditional pharmaceuticals and medical devices. Rigorous evidence generation by way of adaptive piloting may be a better approach than the clinical trial paradigm. While changes in regulations and uncertainty surrounding how certain digital health solutions will be affected in the real-world, CE marking for health solutions remains a strong indicator for uptake and adoption and therefore early dialogue between regulators and innovators is key.

Adoption – gaining reimbursement and long-term use

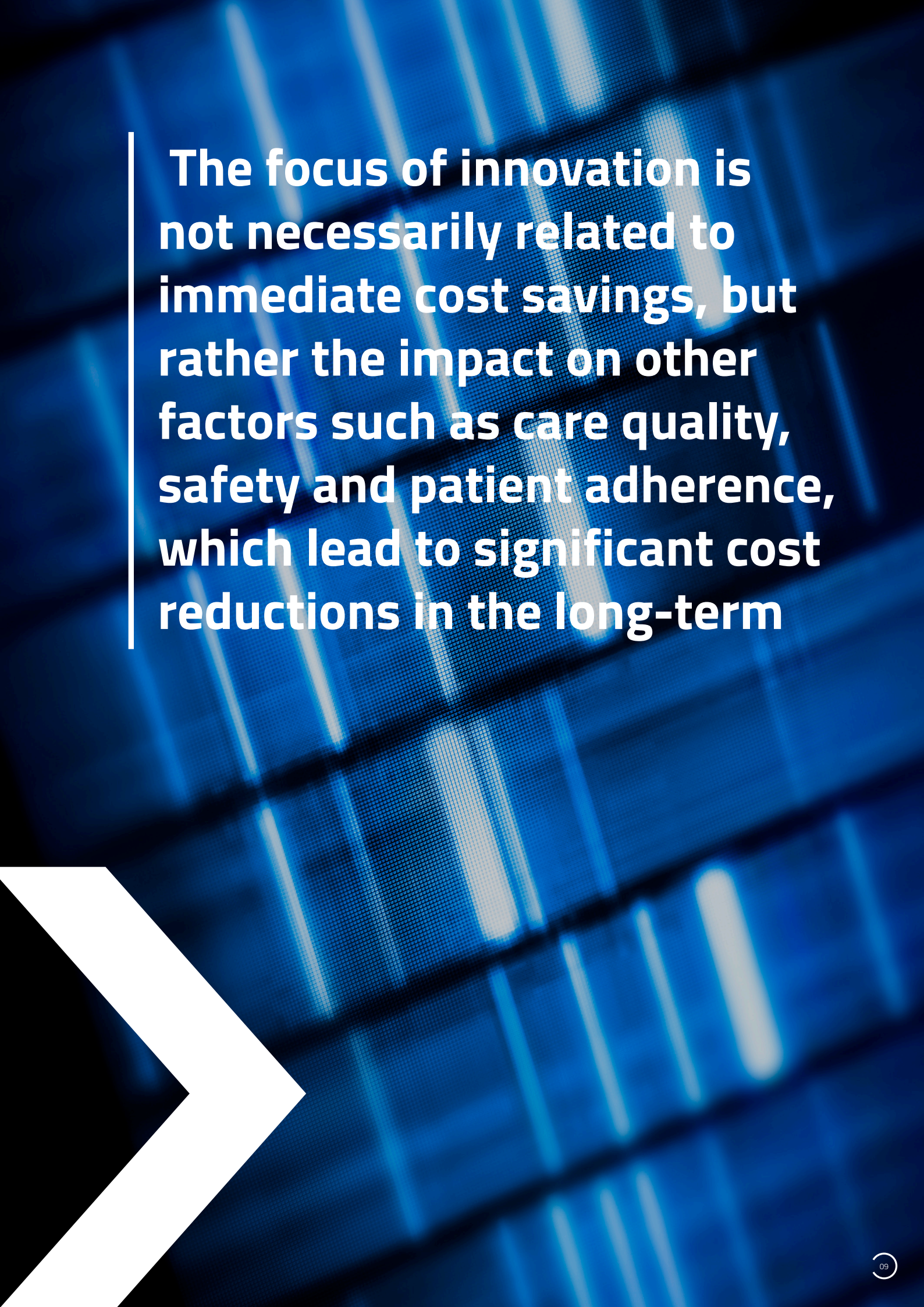
Regulatory approval, or CE marking, is confirmation that the solution meets European standards relating to safety and efficacy. This, however, is not a declaration of cost-effectiveness which brings us to adoption. Progressing through all stages of the pathway does not necessarily guarantee adoption.

As the NHS is publicly funded, the adoption stage represents true market entry for many solutions in the UK – since reimbursement bodies within the UK must assess cost-effectiveness and agree funding mechanisms to make the solution available to patients on the NHS.

In the payer environment there is often a focus on the 'cost replacement' that a new innovation can provide over an existing solution rather than on the improvement in quality of care, outcomes and value. The focus of innovation is not necessarily related to immediate cost savings, but rather the impact on other factors such as care quality, safety and patient adherence, which lead to significant cost reductions in the long-term. Value-based healthcare provides a new method for capturing the value generated by digital health solutions based on outcomes, and this movement is gathering speed and momentum.

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, via digital health solutions, to alleviate stretched hospital resources. Data, gathered by Orcha and published in The Lancet, demonstrates that UK clinicians feel a need for further confidence following positive reimbursement decisions to prescribe digital health solutions to patients, such as an NHS 'badge of approval' (The Lancet, 2019). It is likely that such certifications or endorsements beyond the CE mark and reimbursement will become increasingly important in a product gaining adoption.

In parallel, the systems' readiness to receive the new innovation is an important factor. Change management is key to the adoption of new innovations, particularly in the setting of 'service' rather than 'product' provision, which is common in the case of digital health solutions. Change management needs to address systematic reform and behavioural issues such as concern that jobs or quality may be at risk if digital health products decrease human tasks. Additionally, successful adoption requires business development, sales and marketing in order to generate high visibility and familiarity with a new solution, and many smaller companies do not hold the resources to do so.



The focus of innovation is not necessarily related to immediate cost savings, but rather the impact on other factors such as care quality, safety and patient adherence, which lead to significant cost reductions in the long-term

Conclusions and recommendations for optimising the path to market in the UK

The body of evidence collected during the Round Table Series, demonstrated that there are a number of key stages within the innovation pathway where improvements could be made to aid and speed up the route to market for promising innovative solutions. Participants of the UK Round Table Meeting were asked to agree on a set of recommendations that, if implemented, could help to optimise the pathway for digital health solutions. Where possible, they also identified potential stakeholders who would need to be engaged for further discussion.

Bolstering the ideation stage

Develop a systematic process for needs identification and assessment to provide better guidance on the evaluation of solutions

Digital health solution should consider both the 'clinical need' and the 'system need'. While the underlying need may be similar for the two, the environment and context can be vastly different. Therefore, innovators should be encouraged to place greater emphasis on the broader 'problem identification and mapping' and this process should be structured and standardised to offer clarity. HealthTech Connect, provided by NICE, offers a service that presents a centralised repository of granular needs, and EIT Health should consider consulting and promoting this service to ensure innovators are effectively engaging with this resource. Additionally, the needs of the end user (i.e. patient or citizen) should be fundamental to this process, and a co-creation strategy should be at the forefront throughout the innovation pathway.

Map incubators and accelerators available in the UK and promote engagement amongst innovators

Many impactful incubators and accelerators are in existence across the UK, however they are often accessed locally and awareness may be low amongst the wider context of the innovation community. EIT Health should consider conducting a mapping exercise of quality health incubators and accelerators in the countries and regions and promoting this as resource to the EIT Health network. Further discussions should also take place with Academic Health Science Networks, the National Institute of Health and Care Excellences' HealthTech Connect or the NHS innovation accelerator to capitalise on existing resources and add value where necessary.

Improving the development phase

- **Embrace failure as part of the innovation process – be prepared to 'fail fast' – and systematise learnings**
  There is great value in failing within the innovation process – failure allows us to learn and strengthen our ability to innovate. Failing fast also allows for time, cost and resource efficiency. However, culturally, we are still fearful of admitting failure which hampers our ability to learn. EIT Health can help in changing attitudes to failure and promoting positive sharing of learnings within health innovation. EIT Health should consider sharing results and learnings from funded innovation projects that have failed or not continued.

- **Clarify the evidence generation requirements for digital health solutions to demonstrate true value and facilitate conversation between innovators and regulatory and reimbursement bodies**
  The generation of evidence occurs too late in the pathway; it is needed throughout the process. There should also be clarity around the appropriate body of evidence required for regulatory and reimbursement bodies for digital health solutions as a distinct methodology in contrast to evidential requirements for medicines and medical devices. Innovators should be supported by early access to, and dialogue with, such stakeholders (HTA bodies, commissioners, trust executive teams, etc.) to develop and sustain a strong value proposition. There are a number of resources in existence in the UK which may help including the NICE MedTech Early Technical Assessment (META) tool. Additionally, open-access databases that can be used for testing, such as from NHS Digital. EIT Health can help to facilitate such a relationship, connecting innovators with decision making authorities to clarify data collection requirements, as well as signposting innovators within the network to existing resources in the UK.

Market entry – navigating the changing regulatory landscape

- **Assess the impact of the new medical device regulation on the access to digital health solutions**
  The introduction of the medical device regulation in 2020 is expected to slow access to digital health solutions due to changing guidance as well as regulatory capacity. While estimations have been calculated, it is not clear what the full impact will be on digital health solutions, and guidance is lacking for innovators in approaching the new regulation.

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

Adoption

- **Promote incentives and a value-based approach to the provision of new digital health technologies**
  The current reimbursement system is heavily focussed on cost, which presents a challenge for digital health solutions which aim to improve more long-term outcomes such as adherence or care quality. EIT Health should consider assessing the value-based healthcare procurement landscape for digital health solutions in Europe specifically, and discuss potential reform with policy makers and reimbursement bodies.

Appendices

Round Table Meeting agenda attendees

Host: EIT Health UK and Ireland and Oxford Academic Health Science Network

Facilitation: Professor Finn Boerlum Kristensen MD, PhD (EIT Health 2019 Think Tank Round Table Meeting Chair)

Moderator: Paul Wicks

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

Finn Boerlum Kristensen (Meeting Chair), Think Tank 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 & 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, EIT Health UK-Ireland

Miguel Amador, Researcher

Karen Wolstencroft, Rapporteur

EIT Health Think Tank

Optimising Innovation Pathways: Future Proofing for Success

UK Round Table Meeting

EIT Health is supported by the EIT, a body of the European Union