Optimising Innovation Pathways: Future Proofing for Success

Think Tank Round Table Meeting Proceedings

Glintt,
Beloura Office Park,
Sintra, Portugal
19.09.19

THINK TANK

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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 the Think Tank's Round Table Series topic for 2019.

Through a series of National Round Table Meetings, such as the Portuguese 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: Portuguese Round Table

Hosted by EIT Health Innostars and Glintt

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

Moderated by: David Magboule

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

Discussion topics

- **Session I:** The current state of the Telemedicine (Digital Health and Healthcare Solutions) Innovation Pathway in Portugal
- **Session II:** Optimising the innovation pathway in Portugal
- **Session III:** Proposals for actionable recommendations

Session I: The current Telemedicine Innovation Pathway in Portugal – summary of pre-meeting research and discussion

Focus of the Portuguese Round Table

The innovation type selected for discussion at the Portuguese Round Table was Telemedicine, which results from a mix of Digital Health and Healthcare Solutions.

For the scope of this Think Tank, Telemedicine refers to:

Solutions that aim to improve patient care at home or in more accessible locations with the use of technology to extend the reach or automate the work of healthcare services. 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, or just assist communication with patients.

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 the Portuguese Telemedicine Ecosystem

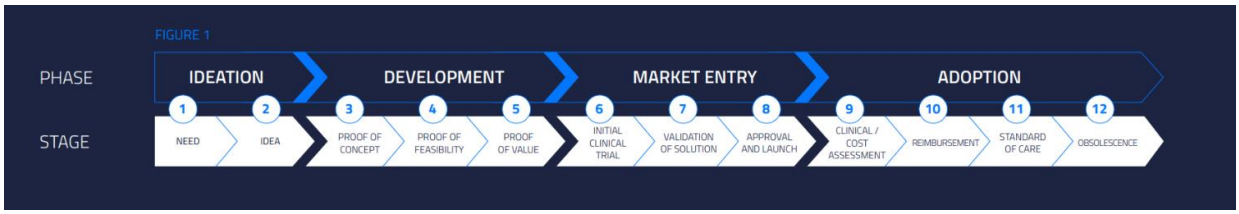
The findings of EIT Health's research into the Portuguese Telemedicine ecosystem were circulated to participants in advance of the meeting. These were supported by insights from interviews undertaken with local companies that had developed Telemedicine innovation projects. Key points from the research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

- Portugal has approximately 200 companies distributing medical products largely comprised of small or medium-sized companies employing on average 15 to 60 people.

- The field of telemedicine is quite active in the public sector, which now has 20 years of telemedicine experience. Since 2006, following the consolidation of this practice, telemedicine services have been used inside the National Healthcare System and are reimbursed similarly to in-person services.
- In 2013, the National Health Ministry defined specific goals for using IT to increase the reach to the national healthcare system. The Administração Central do Sistema de Saúde I.P. (ACSS), as the public payer main agent, developed procedures to promote telemedicine, focusing on the areas of: Telemonitoring, comprising monitoring and screening devices to be used at home which provide information that medical staff can act upon); Real-Time TeleConsultation which aims to provide access to normal consultations with medical doctors overcoming geographical limitations; and Deferred TeleConsultation, where the material collected is subsequently reviewed by medical staff for screening purposes, such in the case of TeleRadiology or TeleDermatology.
- In October 2016, the Portuguese Government created the Centro Nacional de TeleSaúde (CNTS) as an entity to further promote the adoption of telemedicine inside the healthcare system.
- Recent report by Associação Portuguesa de Administradores Hospitalares and Glintt, from 2019, state that 87% of public hospitals are now using telemedicine (with higher representation of primary care facilities), however a lack of proper IT infrastructure (61%), lack of knowledge in telemedicine (53%) and low motivation for adoption by healthcare professionals (44%) are the main barriers to telemedicine use in the institutions surveyed.

The Telemedicine Innovation Pathway

The proposed innovation pathway in Portugal 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.



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 obsolescence of the product supports further research and development, and the design and development of new innovations.

Telemedicine fits this overall pathway for health innovation. However, it faces specific challenges at different steps as the technology is still relatively immature in terms its widespread application 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 Portugal as described and were asked to advise:

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

- A robust definition of 'telemedicine' needs to be agreed as it covers a much broader scope than just 'remote consultation'.
- The pathway as presented is linear, but in reality, it is more flexible and circular. For example, the 'clinical need' aspect should be considered throughout all phases, as well as allowing steps to be repeated.
- The current pathway has been developed from the perspective of clinicians/hospital users and relates primarily to 'healthcare' products. 'Wellbeing' innovations are more consumer focused and may have different requirements; innovators need to assess the difference between both and therefore possibly requires a separate pathway.
- In the Ideation phase, the term 'clinical need' does not necessarily encompass the 'wellbeing' aspects addressed by some new innovations. More focus need to be put on systems' needs.
- The Market Entry phase differs depending on whether the product is a Medical Device (so more like the traditional healthcare innovation pathway) or a wellbeing intervention. The 'wellbeing' pathway at this phase is still poorly defined and unclear, especially since it often falls under the scope of the social care system, which works in parallel with the healthcare system.

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

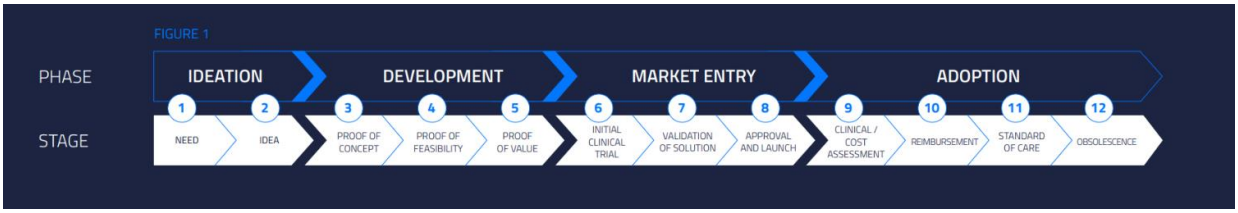
- The engagement of all stakeholders throughout each phase and stage of the pathway needs to be improved, ideally getting input from patients, clinicians, payers etc., right from the beginning.
- It is essential to engage public interest is supporting ideation in order to identify the gaps and unmet needs for innovative healthcare solutions, providing more clear systems' needs.
- There is recognition of the existence of a number of instruments within the EU framework that support innovators along all the entire pathway, however, these are often not explored effectively enough.
- Currently, funding and resources tend to be focused on a small part of the innovation pathway, with less support for the upstream phases, such as Ideation.
- The pathway needs to be more agile, in particular to allow faster testing of innovations. This is

a challenge due to the time required to gather robust evidence and validate the efficacy, safety and budget impact of an innovation.

- The Ideation phase needs to link the innovation to identified clinical and social needs; good ideas on their own are not enough.
- Knowledge transfer from research centres in Universities needs to be improved, particularly information arising from publicly-funded research.
- The rise of Digital Health, and the development of both Health and Wellbeing innovations, offers a good opportunity to better integrate health and social care.
- Portugal lacks access to large health datasets leaving the country at a disadvantage in terms of Big Data initiatives, algorithms and artificial intelligence (AI). This is also the case across many other European countries but requires rapid resolution in the face of the progress being made in this area by the USA and China. We also need standardised methodology to collect, store and share data.
- Governance models need to be developed to address the data privacy and ethical issues relating to non-medical devices.
- Innovators often rely on not following the normal pathway, creating and validating thus disruptive innovations, while then comply with the pathway once the final market outcome is less risky. There is the needed to allow for such freedom at the start to fuel innovation.

Session II: Optimising the Telemedicine Innovation Pathway in Portugal: 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.



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
User-driven innovation	> For citizens and patients, the 'need' is generally to solve problems in their daily lives and this is not specifically related to a disease – patients with different diseases may have the same problem that requires an innovative solution. Therefore, solutions should not be 'compartmentalised' by disease, but impact on people lives. > Successful innovations will generally arise from a strong need and provide and immediate solution to the problem.

	> It is essential to include the end-user in collaborative co-creation from the beginning – currently, most innovation does not do this. Discussion between innovators and end-users is important to develop an understanding of the real community needs – don't develop something without asking the end users. > Some education in digitalisation may be necessary for end-users (and other stakeholders) so they can better influence ideation.
Multiple stakeholder engagement	> In addition to end-users, it is valuable to engage other stakeholders at the Ideation phase, e.g. businesses, regulators, to determine if an idea is feasible. > It is necessary to have an implementation plan: engaging a multidisciplinary team at the earliest possible stage is important to understand, and prepare for, the requirements and challenges that will come along in later phases of the pathway – this is currently not happening. The concept of the multidisciplinary team doesn't exist in Portugal, for example they lack dedicated innovation teams within healthcare institutions.
Academia/Research	> Needs-driven innovation is the only approach that really works, however robust methodologies to integrate the end user into the process don't really exist. > Academia is research focused, generating knowledge – researchers generally do not have a commercial dimension, nor do they think about the 'practical' solutions to challenges. The ideation phase needs to also focus on the business/commercial aspects by engaging with the relevant stakeholders. > Often researchers do not think about the bigger picture and the how their idea would eventually be integrated into existing healthcare systems. > Need a method to enable us to 'pick the brains of researchers' to facilitate ideation so that start-up companies can develop value propositions and business models around this (example – Manchester University, UK).

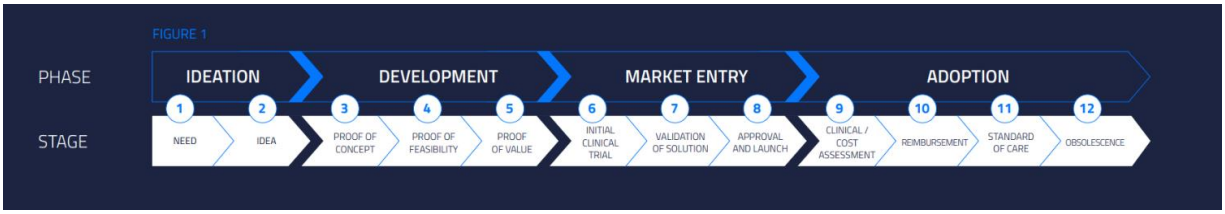
Knowledge transfer	> Knowledge transfer from Universities is important. In particular, if the research is publicly funded, the institution should be obligated to disseminate the resulting knowledge/data. > The granting of project funding should require a plan to be in place for stepwise knowledge transfer into innovation. > It also needs to be specified how this transfer should be undertaken –structures need to be put in place to do this as it falls outside of the researcher's role. It requires qualified people and adequate resources.
'Moon shot' goals	> The US Congress launched a 'moon shot' programme in the field of oncology which aimed to suggest innovative ideas for challenges that were so big they seemed impossible – in the health innovations setting, researchers and other stakeholders could have a role in suggesting ideas, and provide a focus of the stakeholders along the pathway around addressing concrete needs and problems. > The next Horizon Europe programme will incorporate several 'mission areas' (e.g. health, cancer) and take a 'moon shot' approach. > The Innovative Health Initiative will be the follow-up program to the Innovative Medicines Initiative.
Industry-driven innovation	> It should be recognised that there are other drivers of innovation beyond users, for example industry players. > The high cost of clinical trials is unsustainable so it will be important to develop new and cost-effective methods of data generation, for example wearable devices.
Pathway guidance	> There is a need for education/guidance on the innovation pathway that is accessible to all innovators (healthcare professionals, citizens, researchers) – a '101' guide. > Portugal lacks specific support programmes for health innovators to provide guidance along the pathway.

Non-medical devices	> It is much easier for non-medical devices to reach the market than for medical devices as the regulatory process is less complex.
Integrating health and social care	> Adoption of innovations into the 'home care' environment can be a challenge due to lack of interoperability and difficulties in integrating data collected in the social setting with current healthcare systems. > There needs to be an improved focus on providing integrated solutions, rather than stand-alone innovations – currently there is a lack of strategy to achieve this, despite the focus in Portugal on bringing 'hospital to home'.
The innovation 'funnel'	> Innovation is a funnel and requires investment at the beginning to evaluate products to see if they are suitable to be progressed. > There can often be a big gap between an innovative idea and what is actually useful to citizens - ideas that do not meet users' needs should not be progressed. > Companies can encounter a 'catch-22' in that they need to develop a prototype (which requires funding) before they are allowed to test it in a clinical setting.
Key points	> **Ensure co-creation with the end user to ensure that solutions meet their needs.** > **Get advice from a multidisciplinary team of stakeholders from the beginning.** > **Need better integration of health and social care and more focus on the development of integrated solutions.** > **Need better dissemination of research results in a systematic manner towards innovation and implementation.**

What is working well/best practices identified in this phase

Positive experiences
Examples of a user-driven innovations: > The combined skills of a carpenter in the USA and a surgeon in South Africa who met online enabled the development and 3D printing of artificial hands. > A patient who had an ileostomy bag developed a sensor to determine when it was full resulting in an alert sent to his mobile phone.

Best practice examples
Manchester University, UK (see above).
US Congress 'moon shot' programme in the field of oncology which aimed to suggest innovative ideas for challenges that were so big they seemed impossible to overcome (see above).



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
Failure in the development	> Failure is a natural, and often necessary, part of the development process – early and decisive termination of a

process	project or idea is often the best outcome – this should be recognised in the ecosystem as a positive step. > Most start-ups are likely to fail. Incubators should not try to keep non-viable projects or start-ups alive and make sure those that cannot demonstrate value and a potential for success 'fail fast'. > Maybe start-ups should be given a time limit in an incubator so that there are external pressures to avoid them continuously trying to progress an innovation which is not able to move further along the pathway.
Proof of concept	> There is a lack of available funding for the 'proof of concept' stage, after scientific research, and before more concrete development efforts.
Legal framework	> The legal framework within universities may limit the ability of researchers leave academia to test innovations that they perceive are still risky. > It is important at the early stages that companies set out a robust legal framework, company structure and IP strategy for collaborating with partners.
Change management	> In addition to the new technology, change management – how the innovation can be incorporated into the working practices of the institution – needs to be considered.
The Medical Device pathway	> For medicinal products, stakeholders generally have a clear understanding of the regulatory requirements however for Medical Devices the pathway is less well defined. It can be difficult for innovators to understand what is required. > Similarly, HTA bodies may find it difficult to determine how best to assess these new digital technologies.

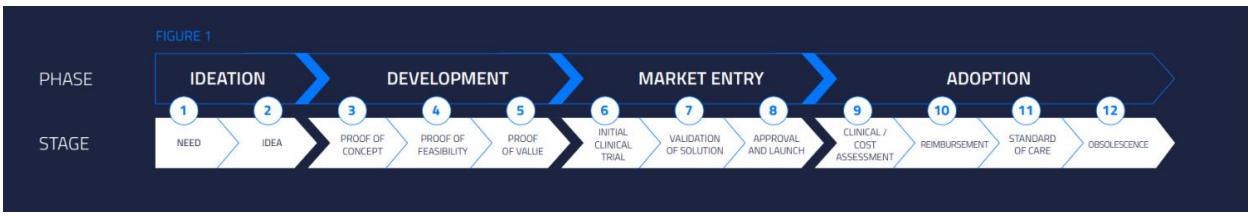
Data protection	> Good data protection and governance processes are needed. > Servicos Partilhados do Ministerio de Saude (SPMS; the Health Ministry's central purchasing and IT authority) does review and check health apps and inform about them to citizens on its website, but they do not cover all available health apps, and do not intend to.
Funding	> There is a need for new approaches to tendering for European funds: ideally one more agile for the early testing and ideation and another to support those innovations that have showed positive results. > This aligns with the new European focus on the 'pathfinder' and 'accelerator' stages.
Key stakeholders	> The Ministries for Science, Health, Finance, Social Affairs and Economy are key stakeholders who need to be aligned in the Development phase in order to facilitate the frameworks needed for innovations to reach the market. > In Portugal these stakeholders lack expertise in science and innovation and a structure to facilitate these initiatives between the different key stakeholders. > There is a network of informal advisors to these Ministries but maybe a more formal 'joint task force' is needed with a coordinated strategy to align these different pillars and educate them about digital health innovations.
Proof of value	> Beyond improved health outcomes, decreased costs, increased access, and improved quality are the three key aspects that innovations need to demonstrate in order to provide clear evidence of value. > However, the 'value of health' is not just measured in monetary terms: an innovation may not necessarily be cheaper, but it might improve a patient's quality of life. > There is a move to value-based healthcare focusing on outcomes. > Value for users and investors are measured using different Key

	Performance Indicators; for sustainable development, return on investment (ROI) is key.
Key points	> **Greater efforts are needed in the Development phase, particularly on access to resources and settings for proof of concept testing.** > **Better cross-sectorial structures need to be put in place for funding, to allow collaboration and co-creation between stakeholders in the Development phase, and to help progress innovations to market.** > **It is important to track success stories and as well as learning from those who failed to the benefit of the innovation ecosystem.**

What is working well/best practices identified in this phase

Positive experiences
Living laboratories that allow real world testing.
Nursing school links with nursing homes that allow innovation testing with users.

Best practice examples
YesDelft, the Incubator from TU Delft promotes lean design by ensuring developers include end-users in the validation of a product during development. This ensures input about product value and interest is received early on in the pathway.



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?

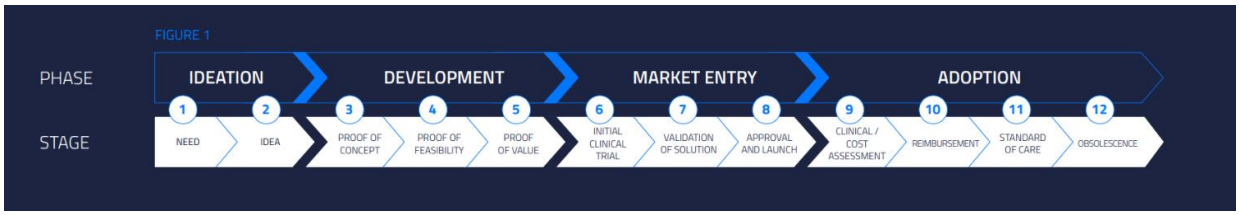
Topic	Key discussion points
Certification	> The rules and requirements of certification and reimbursement need to be clearly explained and understood at the earliest possible stage – it can be costly to go back if certain requirements have not been met.
Clinical research	> Clinical Research Organisations (CROs) can be key to facilitating the engagement of hospitals in clinical trials, however their primary focus in Portugal is pharmaceuticals and they may be less familiar with digital technologies. > While public hospitals may undertake clinical trials, research and innovation are not valued or seen as bringing benefit to the organisation. > Few hospitals have dedicated Clinical Trials Facilities, or an assigned Clinical Trials Manager role, meaning that starting a clinical trial and gaining approval is a slow process with lots of bureaucracy. > Dedicated Innovation Departments are also lacking in hospitals. > Need more funds for start-ups to undertake clinical research in Portuguese hospitals (see example below).
Hospitals	> Hospital administrators are an important stakeholder group for The Development phase > Hospitals lack the structure, culture or ability to seek competitive funding opportunities for clinical research.

The regulatory process	> Traditionally, and in contrast to the case for pharmaceutical products, regulators have not given advice or provided support for those navigating the regulatory process, they have only facilitated the process. > With the developing regulation of new digital technologies, such advice will be increasingly necessary, and this problem requires a rapid (EU-wide) solution. > 'Early scientific advice', including from HTAs, in terms of what data or trials are needed, is established for pharmaceutical products but far less common for Medical Devices. > Regulators need to allow companies in Europe to be competitive. Currently, there are strict regulations for certain technologies, and limited or no regulations at all for others, with a grey area in the middle – this needs to be clarified and more adapted to the spectrum of products risk. > It is important to strike a balance between being agile while still ensuring public health protection – although 'clinical trials' are specified in the regulations they may not be a suitable design for some digital technologies and there is a need to look for new approaches to generate clinical evidence.
Wellness products	> There is a need for clarity on the evaluation and regulatory requirements for digital wellness products – this needs a robust ethical framework and standards (linked with GDPR).
Key points	> **Increase the clinical research activity of hospitals so they are better able to support and drive clinical innovation.** > **Improve processes and methods for the evaluation of healthcare technologies, both for medical and wellbeing applications.** > **Increase the role of regulators in providing guidance and clarity for innovators in navigating the regulatory requirements.**

What is working well/best practices identified in this phase

Positive experiences
Porto is starting a culture of supporting clinical trials research within its hospitals. The income, which is normally provided by large companies, is important for the hospital. The downside is that there is less opportunity for smaller companies who do not have the same capital to invest, to engage with the hospitals.
Hospital de Braga is an example of public–private partnership which has the agility to focus on for-profit clinical research with larger companies. The funds generated are then used to provide grants for small start-ups and clinical researchers to perform their own clinical trials, and for engagement of clinical staff.

Best practice examples
The US Food and Drug Administration (FDA) works closely with innovation development teams and supports value creation by providing constructive comments about product development and requirements. A similar approach and function is necessary in country-specific regulatory agencies in the EU.



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
Needs-driven innovations	> Innovations driven by a clear patient need are more likely to reach the market successfully.
Digital literacy and education	> There is a need to address the digital literacy of citizens (including patients and caregivers) so they understand the value of new digital solutions and feel confident and motivated to use them. > The accessibility and usability of a technology is an important consideration and can often overcome the limitations of digital literacy of citizens and caregivers. > Need to include digital health as part of healthcare professional education curricula so they understand and embrace technology, particularly as they are key adopters – need to future proof professional education. As an example, in the US, medical students need to pass a digital health module before they can graduate. > Healthcare professionals need to see the benefits of an innovation in order to drive adoption – it should not be perceived as adding to their workload.
Clinical assessment	> For HTA assessment it is important that clinical trials (design and data collection) reflects clinical practice. > Currently, there is a lack of information about how clinical trials of digital technologies should be conducted.
Wellness products	> Even if a digital wellness product does not require evaluation for regulatory purposes, when reimbursement and procurement are considered it is likely that some kind of assessment will be necessary, so companies need to be prepared for this.
Reimbursement and	> Insurance companies are aware of and keen to use

budget considerations	technology (telemedicine and telemonitoring) for preventive care and to avoid emergency admissions – they may be a driver of adoption. > Healthcare budgets are driven by capacity and service, and not by the quality which reduces the incentive to innovate within healthcare systems. > Need to develop sustainable payment models that focus on outcomes rather than outputs.
Global considerations	> The lack of knowledge and support to innovators in Europe to navigate the regulatory and reimbursement system for new digital health technologies is creating a competitive disadvantage compared with countries such as the US and China who are progressing in this area.
Consumer products	> There is a need to address the competition between regulated products and consumer products that perform similar tasks but are not required to provide evidence of efficacy and safety.
Key points	> **Need to better predict and prepare new business models for innovations that are being developed.** > **Increase the digital health literacy of citizens, patients and caregivers.** > **Need for new outcome-based indicators and incentives for healthcare institutions to promote innovation.** > **Improve HTA guidance on evidence development requirements and develop scientific advice on study and data requirements.**

What is working well/best practices identified in this phase

Positive experiences
The government of California in the US has accepted telemedicine as a component of their healthcare system and actively supports it.

Session III: Conclusions and recommendations for actionable outcomes

IDEATION ACTION	TARGET STAKEHOLDER(S)
> Develop an integrated approach to citizen care by breaking down the barriers between health and social care > > Create ecosystems that merge these different areas, and the stakeholders involved, and which focus on creating sustainability for the future > Improve opportunities for co-creation in the Ideation and Development phases involving multiple stakeholders > > Include such requirements in any funding calls > > Create more opportunities for immersion in healthcare settings to facilitate needs discovery > Needs often require integrated solutions, however innovations commonly only address isolated aspects of this need > > Promote open, standardised health databases, with a structured management process > > Create 'needs repositories' and make them available to the different stakeholders > Improve the dissemination of research results in a systematic way that achieves impact > > Specify requirements for data sharing and dissemination in research funding applications > Define clear innovation goals that allow focusing of resources and efforts within the ecosystem on broader system's needs.	**Health services, governments**
DEVELOPMENT	TARGET

ACTION	STAKEHOLDER(S)
> Promote early identification of failure in the development ecosystem	
> > Create innovation ecosystems that promote small grant funding and the use of test beds, incorporating multiple different stakeholders	**National Funding Agencies and Regional Authorities**
> Develop a funding structure and ecosystem that accommodates smaller iterations to an innovation and testing	
> > Create access to small and staggered testing grants at a regional level	
> Increase the awareness of innovation pathway requirements from the early stages	
> > Develop training and education programmes for certification, HTA and evidence/safety requirements	**Regulators, Tech Transfer Offices and Incubators**
> Incorporate change management concerns from the start of the innovation development process	
> > Upper management should define best practices guided by internal innovation departments	**APAH**
> > Focus on value-based healthcare, which will drive change	
> Increase the political coordination for innovation in healthcare	
> > Set up an inter-ministerial taskforce focused on Healthcare Innovation	
MARKET ENTRY	**TARGET STAKEHOLDER(S)**
ACTION	
> Increase the clinical research activity and coordination within hospitals so that it is better able to support innovation	
> > Create of innovation and clinical trials departments inside health systems	**Ministry of Health and Ministry of Economy**
> > Create funding incentives to drive a change of culture towards involving caregivers in clinical research and data gathering	**Ministry of Health and Ministry of Economy**
> Improve the evaluation of healthcare technologies both	

for medical and wellbeing applications > Improve the registration of clinical trials and promote the publication of negative results > Increase the role of regulators in providing guidance for innovators to navigate the regulatory requirements > Push for alignment on certification and HTA requirements across Europe > Develop an awareness campaign on the new MDR and GDPR (data governance, data donation, data management) requirements and reference models for health industry and citizens > Create support offices that have an active advisory role to help companies navigate the regulatory requirements	**Local regulators (including CNPD)** **Local regulators (including CNPD)**
ADOPTION **ACTION** > Develop methods/tools to better predict and prepare new business models for innovations being developed > Promote the role of insurers in the testing of new business models > Increase awareness and clarity for adoption of new payment approaches in different healthcare systems > Increase the digital health literacy of citizens and caregivers > Include more digital health modules within university curricula and training of health professionals (focus on both future and current professionals) > Promote and extend patients' Digital Health literacy programmes > Develop new outcome-based indicators and incentives for healthcare institutions to promote innovation > Improve HTA guidance on evidence development requirements and develop scientific advice on study and data requirements > Promote harmonisation of HTA procedures and methodologies on medical devices across Europe > Promote continuous evidence-generation	**TARGET STAKEHOLDER(S)** **Universities, DGS and Professional Societies** **Ministry of Health** **Portuguese Government**

capabilities on health technology	

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
David Magboule (Meeting Moderator)	Founder, LabToMarket
Paulo Azambuja	Head of Business Development, Santa Casa da Mesiricordia do Porto
Joao Borga	Executive Director, Startup Portugal
Paulo Bota	Process Manager, Infarmed
Patricia Calado	National Innovation Agency (ANI), the National Contact Point and National Delegate for the areas of Health in Horizon 2020
Helena Canhao	Professor of Medicine, NOVA Medical School, Lisbon, and Patient Innovation Association – ONG
Elisio Costa	Professor, Faculty of Pharmacy, University of Porto
Antonio Cunha	Executive Director, Automatics Laboratory, Instituto Pedro Nunes, Coimbra
Carina Dantas	Innovation Department Director, Cáritas Diocesana de Coimbra
Filipa Fixe	Executive Board Member, Glintt
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Gloria Ribeiro	Technical Director Cuidados Domiciliários CUF (Home Care Cuf), Jose de Mello Saude
Tania Vinagre	Director of Scientific and Technological Platforms, Fundacao Champalimou
Organisers and other attendees	

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Karen Wolstencroft	Rapporteur