# Optimising Innovation Pathways: Future Proofing for Success

Think Tank Round Table Meeting Proceedings

**CaixaForum Madrid, Paseo del Prado, Madrid, Spain**
**10.09.19**

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 Spanish 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: Spanish Round Table

Hosted by EIT Health Spain and la Caixa Banking Foundation

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

Moderated by: Jaime del Barrio Seoane

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 Spain
- **Session II:** Optimising the innovation pathway in Spain
- **Session III:** Proposals for actionable recommendations

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

## Focus of the Spanish Round Table

The innovation type selected for discussion at the Spanish Round Table was Digital Health. As a new 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 scope of Medical Device software. With it, many Digital Health solutions will be now considered as Medical Devices, when previously they were not. 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 Spanish Digital Health Ecosystem

The findings of EIT Health's research into the Spanish 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:

- The '2018 Consumer Survey on Digital Health' survey undertaken by Accenture found that
  - 41% of the Spanish population uses a health application on their mobile phones or tablets
  - 40% use intelligent scales
  - 21% had had access to their electronic health record during the previous year.
- Only 6% has used some kind of artificial intelligence (AI) service but, 63% of participants were willing to use AI in the future
- The most popular digital services are home-based services like blood tests, digital

healthcare professionals, and digital nurses that monitor health status.

- In terms of Health Technology Assessment (HTA), currently there are seven HTA agencies within Spain: six regional agencies and one in the national Instituto Carlos III. These agencies combined comprise the 'Spanish Network of HTA Agencies' with the Presidency of the Network rotating each year to one of the Agencies.

## The Digital Health Innovation Pathway

The proposed innovation pathway in Spain 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 is 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.

Digital Health fits this overall pathway for health innovation. However, it faces specific challenges at different steps as the technology is still in its infancy 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 Spain as described and were asked to advise:

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

- It was agreed that the proposed pathway does in general reflect what is happening for innovations in Digital Health within Spain, however:
  - In practice, it is often navigated in a non-linear manner and is more interactive on an ongoing basis with multiple stakeholders. For some innovations, a sequential approach to the phases of the pathway work best, for others it may be better to navigate them in parallel or in a cyclic manner
  - Not all innovations will follow the same pathway; some will miss out certain steps

- The current pathway focuses mainly on individual products. Digital Health innovations are often provided as integrated services, not just standalone solutions. We are entering the 'post-digital era' and what is seen as the 'product' is now changing – namely, digital may no longer be the product itself but an underlying condition for the solution. The innovation pathway will need to transform to reflect this shift
- Some specific steps need to be added for Digital Health:
  - More rigorous evaluation of ideas and technologies in the early stages, particularly ensuring sustained engagement with the patient and citizen throughout the process
  - Cybersecurity and data privacy: these are an issue for both hardware and software; they need to be built into all phases of the pathway

- Regulation and Product Assessment are necessary and important and should be seen in a positive way, not solely as barriers. They exist to ensure products brought to market are safe, efficacious and cost-effective for citizens
- Although the information presented suggested that some stages had no specific requirements or gatekeepers, it was considered that every stage has some stakeholder who can help or hinder the process

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

- When navigating the pathway, early action and proactive planning are key in order to:
  - Define the expectations of the various stakeholders along the different phases of the pathway
  - Determine the resources required to successfully navigate the subsequent phases
  - Engage in scientific dialogue at the earliest timepoint to determine the evidence generation needed to demonstrate value
  - Engage with end users from the very start to elicit feedback
  - Identification of the relevant players from the get-go, which in turn will encourage a co-creative approach. This will enhance trust between multi-disciplinary groups , augmenting the collaboration process
- Optimising/minimising the duration of each phase of the pathway is critical, particularly in a competitive environment
  - Stages 2/3/4 could happen in parallel
- Throughout the innovation process, public institutions/administrators can be key players in identifying needs and requirements

- 'Clinical need' should encompass both patients' and clinicians' needs; the value proposition should be continually reviewed throughout the innovation pathway and adapted to ensure the product meets the needs of society as well as individual citizens
- To reach market successfully requires a solid and well considered business plan, and a thorough understanding of the commercial environment into which the product will be launched, combined with strong team (which may change over time); the pathway process needs to maximise return-on-investment and the value delivered to the healthcare system
- It will be valuable to capture both the positive and negative learnings from 'valley of death' experiences for a pathway that also focus on continuous accumulation of knowledge

# Session II: Optimising the Digital Health Innovation Pathway in Spain: 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 |
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| **Co-creation** | > The process of co-creation is more than just asking people what they want and generating innovative ideas – these innovations need to link to the reality of real-world use for hospitals, patients and citizens.<br>> There is a lack of trust between stakeholders to support and facilitate co-creation.<br>> Patient/end-user engagement in the co-creation process is key; they |

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| | can also help create political pressure to adopt innovations.<br>> There is a need to include contributions from other stakeholders in the co-creation process, for example professionals with a humanistic profile such as sociology or anthropology. This could help bridge the gap between technical expertise and university/clinical expertise and ensure ideas fit peoples' behaviours and needs to facilitate adoption. |
| **User-driven innovation** | > The idea should be driven by an identified clinical need – not just a business idea – and supported by user-driven innovation. |
| **Trust amongst stakeholders** | > There is a lack of knowledge amongst stakeholders in this phase regarding who has the power to make decisions.<br>> There is a lack of trust between stakeholders to support and facilitate co-creation. |
| **Behaviour analysis** | > There is a lack of research into behaviours and the involvement of behavioural scientists in this phase would be of value (mental mapping).<br>> It is important to determine not only who will gain value from an innovation, but also who will lose, so new business models are required. |
| **Clinical institutions** | > There is a high degree of fragmentation of stakeholders within clinical institutions which can hinder the progression of good innovative ideas further along the pathway. It is often difficult for innovators to determine the correct person or department to talk to.<br>> There is a conflict in that clinical institutions are asked to sustain the business model but also to provide and validate the need.<br>> The creation of Innovation Departments within hospitals is key to avoiding fragmentation of communication and to create trust among stakeholders.<br>> The creation of 'Innovation Teams' comprising stakeholders from hospitals and universities would facilitate the sharing of needs and ideas.<br>> There is room for improvement in innovation management – it needs a more strategic focus. |

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| **National strategy** | > An integrated national strategy of needs on Digital Health should be developed that can drive and guide innovation efforts and stakeholder engagement. A roadmap with clear objectives. This has already been done at a university level but not in hospitals. It should take into account the wider European ecosystem. |
| **Evaluation of ideas** | > There is a need to be more self-critical in the evaluation of ideas and technologies at an early stage, and to decide what deserves to be financed and what does not. Otherwise resources are deployed to develop innovations that do not have an effective team or a worthwhile product in place to succeed later on.<br>> An assessment and understanding of how a solution is to be paid for (through which procurement mechanism) as well as who will have responsibility for paying for it would be useful.<br>> It is important to create the mindset and structure that is able to de-risk projects and also to make the decision to stop projects that are likely to fail. |
| **Patients and citizens** | > It would be of value to engage with patient associations and they will have a clear idea of clinical needs and could contribute to the development of ideas (for example in rare diseases). |
| **Key points** | > **Develop an ecosystem of trust amongst stakeholders from the outset. The co-creation process should seek input from a multidisciplinary team, including innovators, businesses, patients, citizens, end-users, and patient associations to foster collaborative partnerships.**<br>> **Insight and advice should also be sought from other specialities from an early stage, for example behavioural scientists, sociologists and anthropologists who might provide valuable input regarding the real-world impact of an idea.**<br>> **Innovation management within clinical institutions needs to be improved to develop a more strategic focus and facilitate easy and effective communication and sharing of ideas with innovators and academic institutions.** |

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| | > Increased understanding of the commercially focused aspects is a critical success factor - effective business planning, creation of market need, as well as clinical/patient need is vital<br>> Identify 'where' this solution is needed? What specific patient cohort?<br>> Define the specific problem that is being addressed and ensure a new problem isn't being created in its place.<br>> Stakeholders should embrace a culture of de-risking and high standards of value for evaluation in the early stages of research<br>> An integrated national strategy of needs on Digital Health should be developed within Spain – similar to what has already been done at a University level - that can drive and guide innovation efforts and stakeholder engagement |

## What is working well/best practices identified in this phase

| Positive experiences |
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| Living laboratories that include patients in the innovation process |
| EIT Health facilitation and support for innovators to get access to clinical institutions |
| Involving all stakeholders – innovators, businesses, end-users etc –as a multidisciplinary team from the beginning to contribute ideas and create synergies |
| The design of the healthcare system in Spain, which covers primary to tertiary care and incorporates innovation as part of the system, makes some steps of the pathway easier (ideation and adoption) |
| Patients and citizens are more actively engaged and knowledgeable about healthcare today, and are key drivers of innovation |

| Best practice examples |
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| At the Centre for Innovative Medical Technology at Odense University Hospital and the University of Southern Denmark (https://cimt.dk/gb/) they have regular collaborative meetings with the University as a way to overcome fragmentation of communication between clinical practice and technology research. |
| 'Catalyst' is a program developed by the Massachusetts Institute of Technology (MIT) to facilitate collaboration across medicine, technology, and business which might be an example of best practice in the future. UH Madrid is part of this consortium. |
| Mobio/dHealth is a reference program for needs-driven innovation. |

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| EIT Health: Hospital Clinic is a reference on openness to develop and work with innovation. |
| EIT Health partner, Biocat, the organisation that promotes the health and life sciences sector in Catalonia and undertakes initiatives to encourage research, innovation and business growth. |
| 3D Traumatology, Seville: an example of successful private–public cooperation. They use 3D printing and aim to reduce complications in the operating theatre and have a portal to share knowledge. |


## 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 |
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| **Pathway process** | > The stages of the pathway in the development phase (proof of concept, proof of feasibility, proof of value) should not be undertaken in a linear manner, but in parallel for the greatest likelihood of success. All aspects need to be considered together.<br>> Stage 2 (concept) and 3 (feasibility) can be combined or condensed. |
| **Stakeholders** | > It is advisable to include input from a diverse range of stakeholders at all these stages.<br>> The innovation project team may need to change depending on the needs of the particular pathway step. |

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| | > A strong project team is critical (a good idea is not enough in itself) – they should ideally have previous experience of developing products in this sector. |
| **Advisers and partners** | > The development phase is critical to create value for an innovation.<br>> Institutions benefit from co-creation of innovation in partnership with players who will take the idea forward to commercialisation.<br>> An Advisory Panel of independent experts and other stakeholders (can also include patients) should form part of the leadership team. They can provide expertise to companies that other stakeholders may not have, for example from a finance/investment perspective, to suggest opportunities, and also to provide independent advice on viability and value of what is being development (which is often a limitation of internal teams) |
| **Investors** | > Overall, there is a lack of trust and cooperation with investors.<br>> There is a lack of suitable Business Angels who are familiar with the healthcare sector, in particular Digital Health, which limits opportunities to attract investment at early stages.<br>> The venture capital ecosystem is more mature but has a greater focus on biotechnology. The sector is mostly driven by finance specialists, but lacks people experienced in healthcare. |
| **Design** | > Aside from the technology of the innovation, it is important to have a scalable, safe and efficient design. |
| **Testing** | > Concept and feasibility testing in the real-world environment can be challenging if the innovation is a service rather than a product as there are many dimensions to consider; testing needs to reflect the real-world situation. This could be enhanced by incorporating information that is specifically provided by payors. |
| **Assessment** | > Regular assessment and 'funnelling' of innovations in this phase is critical to determine realistically what should be progressed and what |

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| | should be discontinued. |
| **Portfolio management** | > Regular assessment and 'funnelling' of innovations in this phase is critical to determine realistically what should be progressed and what should be discontinued<br>> Innovation portfolio management is key in the development phase but is a 'valley of death' in Spain. Needs to be improved and best practices developed. |
| **Key points** | > **The stages of the pathway in the development phase (proof of concept, proof of feasibility, proof of value) should be considered in parallel.**<br>> **An Advisory Panel of independent experts and other stakeholders should form part of the leadership team within an innovation company for independent review of value, and to overcome team knowledge limitations.**<br>> **Innovation portfolio management with regular scrutiny and 'funnelling' of innovations should be standard practice to ensure effective use of resources with only viable projects being progressed, but needs to be improved and best practices developed.**<br>> **Relationships with, and access to, suitable investors with experience in healthcare need to be improved; investors need to be provided with information and education about Digital Health.** |

## What is working well/best practices identified in this phase

| Positive experiences |
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| Taking a 'low cost' approach from the beginning (in terms of materials etc) means that cost efficiency at later stages will be higher. |

| Best practice examples |
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| In a collaborative artificial intelligence (AI) project with Fujitsu in hospitals, all steps of the development phase (proof of concept, proof of feasibility, proof of value) were undertaken in parallel. The Fujitsu team were present within the hospital which facilitated exchange of ideas and |

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| maintained accountability. This approach not only allows sharing of key learnings, but also means that the innovation will stay in the institution, plus it has financial benefits. |
| The Alpha Initiative uses a 'funnel' system whereby stakeholders meet together every few weeks to determine if development of an innovation should be (a) continued, (b) discontinued or (c) moved on to iteration. |
| Technology Transfer Group. This is not exclusive to health. Similar to 'Collider'. |


# 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 |
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| **Barriers** | > The different types of digital technology solutions – software, hardware, apps and services – all face different barriers to market entry.<br>> As a result of recent experiences with electronic health records (EHR) some clinical institutions may be concerned about getting 'locked in' to particular digital health solutions, which could be a barrier to market entry. |
| **Standard of care** | > For most innovations in Digital Health, there is no recognised 'standard of care' to compare with. |

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| **Clinical trials** | > There are currently no suitable methodologies to evaluate Digital Health technologies; undertaking classical randomised clinical trials is not straightforward with digital technologies and as a result, technologies are reaching the market without having undergone clinical trial evaluation.<br>> Since they are not suitable for these technologies, there is likely to be a move away from clinical trials and use of alternative validation of efficacy and safety tools such as gradual evaluation using assessment methodology and generation of real-world data. |
| **New Medical Device Regulations (MDR)** | > Implementation of the new MDR on 26th May 2020 will create a 'Wild West' in terms of new digital technologies.<br>> There is currently no consensus on how the efficacy and safety of these technologies should be properly evaluated and what methodology is suitable.<br>> There is an urgent need for solutions to ensure standardised assessment and validation.<br>> The new MDR will mean that technologies that don't have the necessary quality are removed from the market, which will increase the perceived value of those that remain.<br>> The new regulation will clear up some of the current ambiguity around classification and evidential requirements, but conversely, many apps. currently in use will not meet the requirements of the new evaluation process. |
| **Validation** | > Hospitals are likely to need support to validate new digital health concepts. |
| **Interoperability** | > Interoperability can be a major obstacle to market entry. Purchasers and administrators may want evidence of compatibility with other products and systems already in place. |

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| | > There are currently no standards to follow.<br>> Some innovations use third-party structures and frameworks which may not be compatible with hospital IT systems, for example. |
| **Accessibility/usability** | > Accessibility and usability of digital technologies can be a problem for some end-users, for example due to their age, intellectual ability, or a particular disability – innovators must take account of the capabilities of all potential end-users. |
| **Evidence generalisation** | > Clinical requirements should be defined in clinical network that support scalability after initial testing. These are stronger than local clinical trials, which does not consider other contexts. |
| **Stakeholder roles** | > Need to determine which stakeholders (internal and external) will undertake:<br>a. Evaluation?<br>b. Accreditation – standards/guidelines?<br>c. Standardisation? |
| **Key points** | > **Develop standards/guidelines for evaluation, accreditation and standardisation of digital health technologies.**<br>> **Create units that use recognised processes to test and assess new innovations, including their interoperability with other systems.**<br>> **Create validation units in hospitals to assess new digital health technologies; develop as business model. – EIT Health could facilitate** |

## What is working well/best practices identified in this phase

| Positive experiences |
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| Consortiums and close collaborative relationships between large and smaller companies. |
| Regulation is necessary and positive – 'money goes away from uncertainty'. |

| Best practice examples |
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| Software for cardiologists to determine whether patients need a defibrillator in addition to their pacemaker. |
| UK company – ORCHA – which assesses and rates digital health apps for use in public healthcare settings. |
| Station 4.0 concept in the Madrid Underground – to ensure interoperability of systems, all potential new products and services need to be approved for their compatibility before the company can bid. |

# 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 |
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| **Communication with citizens** | > 'Data' does not equal 'information'; currently, the amount of information that users receive about the benefits of Digital Health is very limited.<br>> Neutral and objective training on new innovations is needed for end-users so they can see the clear benefits of adoption.<br>> Patient Associations may play a key role in education and information about new products and services as well as directing patients and citizens to reliable resources.<br>> Need to understand behaviours patterns – why do citizens choose one technology over another? – as this will influence |

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| | adoption. |
| **Healthcare professionals/change management** | > One of the main barriers to adoption is gaining acceptance by healthcare professionals who may be resistant to change and feel that a new product or process may result in an increased workload.<br>> Human factors (trust and social capital) are the drivers of innovation adoption and acceptance of the changes that result from its introduction into existing healthcare systems and institutions.<br>> Clinicians will want to understand the clear advantage and immediate impact of a new innovation (and its required behaviour change) – decisions should be based not solely on budget but on clinical results.<br>> Communication and careful marketing, including social media, are key to produce the changes needed for adoption of an innovation. |
| **Procurement** | > European standards are reflecting the change of from 'product procurement', to 'service procurement' (management of a full process including provision of the product). |
| **Clinical/cost assessment** | > In general, the reproducibility of clinical trials is low (around 20% in the oncology sector), so these results may not be the main driver of adoption.<br>> Agreed 'units of evaluation' to show actual cost-savings and improved efficiencies must be identified - create more units to undertake evaluation/validation of technologies so that the value of a product and how much money its introduction will save the healthcare system can be justified.<br>> An assessment of costs should consider:<br>a. economic cost (how should this be measured and against what should it be compared?).<br>b. cost of transition (trust is important here).<br>c. cost of opportunity (what happens if I use Product A versus Product B). |

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| | d. purchasing of comprehensive/improved services versus a solution in isolation of other elements of the system.<br>> Empower patients – many tests could be done at home by patients themselves. |
| **Reimbursement** | > One of the main barriers to adoption is gaining reimbursement.<br>> We need to create new value-based payment/reimbursement schemes suitable for Digital Health innovations, instead of activity-based reimbursement. Payments schemes are key to drive adoption.<br>> Reimbursement Innovation Schemes in some regions of Spain provide a quick pathway for innovations (Catalonia 40M – 17 innovations). |
| **Funding** | > Access to scale-up funding for entry into new markets is difficult for small start-ups to obtain – a weak point for the Digital Health ecosystem.<br>> A product may have demonstrated its efficacy, but it may not be possible to finance it within the public health system – the market needs must be considered from the start. |
| **Scalability** | > The current adoption phase of the pathway does not facilitate the easy scale-up of businesses.<br>> Adoption needs to be considered in terms of its scalability, both across regions in Europe and globally. |
| **Key points** | > **Objective criteria and best practices should be developed for the adoption phase of Digital Health innovations; these should be applicable to all stakeholders – clinicians, hospitals, researchers, investors etc.**<br>> **Digital Health innovation strategy should be incorporated into the clinical service procurement framework.** |

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| | > New methods for the assessment of the clinical and economic impact of innovations should be developed.<br>> Information and education on adoption of new technologies should be communicated and targeted to stakeholders' needs.<br>> The positive, immediate benefit of an innovation (and the required behaviour change) should be promoted to all stakeholders.<br>> The scale-up of innovations should be supported, in particular to international markets. |

## What is working well/best practices identified in this phase

| Best practice examples |
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| HealthHub and Barcelona Tech City – helping start-ups. |
| Catalonia 40M – Reimbursement Innovation Schemes. |
| CIMIT - Acceleration of projects with final support in the end of the funnel. |
| Odense University Hospital in Denmark has assessed 150 digital health apps with another 180 in the pipeline. These are not implemented without a full assessment of the implications of their introduction. |

# Session III: Conclusions and recommendations for actionable outcomes

| IDEATION<br><br>ACTION | TARGET STAKEHOLDER(S) |
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| > Create trust amongst stakeholders.<br>> Create opportunities for public health decisions makers and innovators to connect face-to-face to help build trust, e.g. informal meetings and group activities.<br>> Seek input from a more diverse range of stakeholders (e.g. citizens, public administration, humanities experts, businesses, researchers, scientific societies, patient organisations, procurement, etc.).<br>> Develop a structure for systematic knowledge creation and management to advise and channel innovations.<br>> Promote education about innovation to the different stakeholders; it should be included as part of the University curriculum for clinicians and other healthcare professionals.<br>> Creation of a 'Network of Needs': define strategic clinical/patient needs and implement portfolio management.<br>> Promote these networked hubs to evaluate and prioritise stakeholders' needs in a network of centres at an international level.<br>> Create strategic objectives for the development of Digital Health innovations.<br>> De-fragment access to clinical settings.<br>> Create Innovation Departments within healthcare institutions or City Councils that act a single point of contact for innovators – a 'one-stop shop'. | |

| DEVELOPMENT | TARGET STAKEHOLDER(S) |
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| **ACTION**<br>> Develop structures for rigorous assessment and funnelling of innovations (innovation committees, internal governance) to determine what should be progressed.<br>> Support the recruitment of people who have previous experience of development in the sector.<br>> Consult independent experts and include them on Executive Boards, Advisory Boards, etc.<br>> Stimulate the creation of Innovation Committees that comprise multidisciplinary teams able to assess the overall development challenge.<br>> Better equip Angel Investors/Venture Capitalists (VC) to support Digital Health solutions.<br>> Promote education/information for investors to understand the business models and development pathway for Digital Health innovations.<br>> Ensure that professionals with experience in the healthcare sector become Angel Investors.<br>> Stimulate the allocation of VC funding to focus on Digital Health.<br>> Promote the availability of VC funds to start-ups in Spain.<br>> Ensure consistent integration of innovations into existing healthcare environments.<br>> Stimulate proof-of-concept testing that is more closely aligned to the real-world setting, and focused on the risker assumptions.<br>> Facilitate trials of innovations in clinical settings.<br>> Promote scalable, efficient, value-based, ethical and safe product design for all.<br>> Promote best practices and generate information for the development of products that follow European values and principles of healthcare.<br>> Publicly funded innovations should be able to demonstrate a return-on-investment, so impact | |

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| assessment and cost-benefit analyses should be undertaken in this phase. | |
| **MARKET ENTRY**<br><br>**ACTION**<br>> Develop standards/guidelines for evaluation, accreditation and standardisation (regulatory/HTA) in an integrated way.<br>> Ensure rigorous evaluation that certifies the efficacy and safety of innovations (CE Mark for Medical Devices).<br>> Consider adaptive evaluation of products, with gradual market entry and continuous evidence collection.<br>> Accelerate the use of real-world data by regulatory agencies for evaluation.<br>> Develop new methodologies that allow for continuous development and evaluation of digital technologies.<br>> Notified Bodies to contact other experts who know how to effectively assess similar innovation types (e.g. cross fertilisation with other players such as HTA actors in Europe).<br>> Develop requirements and evaluation guidelines that are more specific for the various different types of technologies.<br>> Create units that facilitate and guide on the process of securing regulatory evaluation and HTA assessment.<br>> Improve evaluation of usability, interoperability and cyber security. | **TARGET STAKEHOLDER(S)** |
| **ADOPTION**<br><br>**ACTION**<br>> Develop new methods for the assessment of the economic impact of innovations. | **TARGET STAKEHOLDER(S)** |

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| > Incorporate Digital Health innovation strategy into the new clinical service procurement framework (according to European law).<br>> Promote information and education for adoption of new technologies for all stakeholders.<br>> > Support education to facilitate the development of suitable solutions by innovators.<br>> > Provide information and education to the end-users of new technologies.<br>> > Introduce behaviour and change management in health institutions to facilitate adoption.<br>> Promote the perceived positive immediate benefit of an innovation as a key focus for all stakeholders.<br>> Stimulate the process of continuous evaluation, surveillance (similar to post-marketing pharmacovigilance) and if necessary, disinvestment of the technology if it becomes obsolete, in order to reassign resources for the identification of new needs and innovations.<br>> Support the scale-up to international markets.<br>> > Facilitate access to international experts and talent that can help companies expand into new markets.<br>> > Stimulate VC funding to support the scaling-up of start-ups. | |

# 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 |
| **Jaime del Barrio Seoane (Moderator)** | President, Digital Health Association |
| **Alberto Betella** | Chief Technology Officer, Telefonica Alpha Health |
| **Amparo De San José** | Director, IESE Business School, Barcelona |
| **Francisca García Lizana** | Integrated Care Coordinator, Castilla-La Mancha Region |
| **Francesc Iglesias** | Deputy Director, Institut Català de la Salut (ICS) |
| **Blanca Jordán Rodríguez** | Head of Healthcare Market, Atos Research and Innovation |
| **Esteban Manuel Keenoy** | Director, Kronikgune Institute for Health Services Research, Basque Country |
| **Julio Mayol** | Professor of Surgery, Universidad Complutense de Madrid; Chief Medical and Innovation Officer and Vice President of Hospital Clinico San Carlos Biomedical Research Foundation |
| **Javier Padillo** | Head Of Department Of Surgery, Coordinator of Innovation Strategy, University Hospital Virgen Del Rocio, Ministry Of Health of Andalucia |
| **Laura Sampietro Colom** | Deputy Director Innovation, Head Assessment of Innovation and New Technologies, Hospital Clinic Barcelona |
| **Jordi Serrano Pons** | Founder and Chief Executive Officer, UniversalDoctor |
| **Jose Terencio** | Vice President, Innovation and R&D Coordination, Giant |
| **César Velasco** | Director, Agency for Health Quality and Assessment of Catalonia (AQuAS) |

| Organisers and other attendees | |
|---|---|
| **Mayra Marin** | Think Tank Manager, EIT Health |
| **Sameena Conning** | Director of External Affairs, EIT Health |
| **Cristina Bescos** | Managing Director, EIT Health Spain |
| **Laia Cendrós** | Communications Lead, EIT Health Spain |
| **Miguel Amador** | Researcher |
| **Karen Wolstencroft** | Rapporteur |