

Optimising
Innovation
Pathways:
Future Proofing
for Success

Think Tank Round Table
Meeting Proceedings

Health House,
Leuven, Belgium
15.11.19

A large, stylized graphic element consisting of a blue 'X' shape on the left and a black 'X' shape on the right, both pointing towards the center. The blue 'X' is formed by two thick, parallel lines, and the black 'X' is also formed by two thick, parallel lines.

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Contents

Context for the selection of the 2019 Round Table Series Topic.....	3
Objectives of the National Round Table Meetings.....	4
Agenda and participants: Belgian Round Table.....	5
Session I: The current Digital Health Innovation Pathway in Belgium – summary of pre-meeting research and discussion	6
Focus of the Belgian Round Table.....	6
Overview of Belgian Digital Health Ecosystem	6
The Digital Health Innovation Pathway.....	7
Discussion of Research Findings – the Overall Pathway.....	8
Session II: Optimising the Digital Health Innovation Pathway in Belgium: discussions and recommendations	10
1. IDEATION.....	10
2. DEVELOPMENT	13
3. MARKET ENTRY	16
4. ADOPTION.....	18
Session III: Conclusions and recommendations for actionable outcomes	23
Appendix 1: Round Table Meeting participants.....	26

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 Belgian 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: Belgian Round Table

Hosted by EIT Health Belgium/Netherlands and Health House

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

Moderated by: Menno Kok, Managing Director, EIT Health Belgium/Netherlands

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

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

Focus of the Belgian Round Table

The innovation type selected for discussion at the Belgian 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 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 Belgian Digital Health Ecosystem

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

- > Data from the 2017 showed that Health Technology (a collective name for CareTech, RegMed and MedTech companies including Digital Health) developed by Sirris and Startup.be revealed that Health Technology remains the largest start-up sector in Belgium: 10.7% of the Belgian technology companies are working on health solutions.
- > The heart of the Health Technology scene is located in Brussels, Ghent, Leuven and Hasselt.
- > There are now more than 200 companies in this area – a growth from less than 50 in 2018 – and 18% are spin-offs and spin-outs from research organisations.
- > A quarter of the Belgian scale-ups have grown out of research institutions. Almost 25% of health scale-ups in Belgium have followed an accelerator program, a high number compared with other countries in the EU.
- > In Europe as a whole, 66% of Health Technology scale-ups are located in the business-to-business (B2B) sector, while in Belgium around 78% are oriented towards B2B.
- > It is often challenging for companies in this sector to integrate into the care process, develop a business model at an international level, and to source risk and growth capital.
 - > Source: Belgium Health Tech by Sirris and Startup.be, 2017

The Digital Health Innovation Pathway

The proposed innovation pathway in Belgium 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.

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

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

- > There is an increasing trend for patients and citizens to develop their own innovations in certain areas – they often become experts in the diseases and conditions that affect their lives and share ideas on social media. However, this can mean that some conditions and needs that have less of a voice get overlooked.
- > Patients and citizens can have a considerable influence on adoption as they are generally the ones who ultimately decide what products they will use.

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

- > The pathway should encourage input from all Digital Health consumers – both citizens and patients – at all stages, since the prevention of disease and maintenance of citizen's health is as important as treatment.
- > Financing should not only consider reimbursement, but also include other requirements for funding that are necessary to bring innovative solutions to market where they can deliver health benefits.
- > Payers (health insurance companies, for example) should be redefined as 'health funds' rather than 'sickness funds'; they can play a key role in articulating the patient viewpoint.
- > Collaboration between healthcare professionals (HCPs) and businesses in Belgium can be a challenge due to the commercial aspects of the interaction. In the past, HCPs routinely worked with companies but in recent years this has declined due to stricter rules about potential conflicts of interest. This represents a significant limitation to innovation progression in Belgium, limiting collaboration at the early stages, and greater transparency is needed.
 - > To overcome this limitation, larger companies often employ HCPs to give advice and allow early incorporation of feedback.
 - > The pharmaceutical industry has developed successful strategies for collaborating with healthcare professionals and patients – good examples that could be learnt from.

- > In Israel, HCPs are actively encouraged to collaborate with start-ups and small companies to share knowledge.
- > Ensuring citizen trust and transparency in the use of data is critical and needs to be considered as a priority for any innovation from the start of the pathway; a lack of trust could limit the use of a solution.
 - > Privacy of citizen data needs to be guaranteed.
 - > Transparency in the processes for sharing of information between companies, hospitals, payers etc. is needed to provide reassurance to patients and citizens.
 - > Objective information from the collected data needs to be fed back to consumers so that they can make informed choices is consultation with their healthcare team.
- > The Development and Market Entry phases should be merged. Proof of concept and testing stages should be undertaken quickly, so that necessary changes and adaptations to Digital Health solutions can be made rapidly. Fast and accurate validation is key.
 - > Many spin-offs relocate to the USA as it is easier to access population groups (who often have significant budgets) for testing. This allows rapid feedback and adjustment, and quick entry to the market while gathering further data for the next stage of FDA approval.
- > The reimbursement process in Belgium needs to be improved – it is very slow - in some cases to the degree that once the process has concluded, a product or service may be obsolete. Companies need to be able to launch with a temporary use permit while continuing to gather real-world evidence of use. Some frameworks have been developed for medicines (e.g. [Article 80 of Regulation \(EC\) No 726/2004](#) on procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (see also: https://www.ema.europa.eu/en/documents/other/european-medicines-agency-policy-publication-clinical-data-medicinal-products-human-use_en.pdf) and the [ADAPT-SMART IMI initiative](#)), but nothing so far for Digital Health.
- > The trend is for data-driven innovations, rather than devices, and these require access to considerable amounts of data for testing and validation – strategies and frameworks need to be developed for this that also ensure data privacy and transparent processes.
- > The current CE marking process is a barrier to progression of Digital Health innovations due to the lack of Notified Bodies and the cost of the process.
 - > Hospitals need to develop frameworks that give easy access to proof of concept testing in real-world patient populations.
 - > Something similar to the ‘compassionate use’ category of medicines is needed for Digital Health products so that relevant products can temporarily ‘circumvent’ the CE process.

Session II: Optimising the Digital Health Innovation Pathway in Belgium: 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
Understanding the ecosystem to develop a business model	<ul style="list-style-type: none"> > For new start-ups, it can be difficult to understand the ecosystem, in particular the likely future ecosystem (arising as a result of globalisation) – it is a challenge to develop a robust business model when working with many unknowns. > It is important to integrate the value of the innovation into the business model – this requires awareness of how value is

	<p>generated and captured within the current system and how this might change in the future.</p> <ul style="list-style-type: none"> > The business model should take potential international markets into account .
<p>Early collaboration and expertise</p>	<ul style="list-style-type: none"> > Most start-ups underestimate the complexity of the Digital Health ecosystem – it is therefore essential that they get early advice and input from appropriate experts to ensure they are aware of all the regulatory and economic aspects of the pathway process. > Greater opportunities for collaboration between multidisciplinary stakeholder groups is needed to share knowledge, ideas and best practices – improved structures and better organisation are needed for this. > Better education on Digital Health is needed at the University level, including for health professionals.
<p>Generation of needs-led ideas</p>	<ul style="list-style-type: none"> > The term ‘user need’ is more appropriate than ‘clinical need’ in the Ideation phase. > Some pharmaceutical companies are promoting open challenges on their websites to generate ideas for solutions that will meet healthcare needs. > Often, the most sustainable innovation ideas and start-up companies arise from users and organisations who are facing the need themselves, and then develop an idea for how to address it. > Posing broad challenges, such as ‘what will the nurse role look like 20 years from now?’ is a good way to generate ideas. > Posing societal level challenges can also be of value – allowing citizens to generate creative solutions to healthcare needs. > Any ideas generated (by entrepreneurs, by citizens) would benefit from early review by experts representative of the ecosystem (along the lines of a ‘pitching’ session) to get

	<p>feedback on feasibility, in a way that does not compromise intellectual property (IP).</p>
<p>Intellectual property (IP) in collaborations</p>	<ul style="list-style-type: none"> > There are often collaboration challenges within companies regarding IP, with lots of restrictions and regulations – more openness and transparency of the process is needed, along with pre-competitive assessment of ideas with others.
<p>Value-based healthcare driven innovation</p>	<ul style="list-style-type: none"> > Digital Health is a complex and changing ecosystem and solutions are increasingly evaluated on whether they are able to provide value-based health benefits. How this value concept might change in the future needs to be considered at the start of the process. > Innovators need a broad understanding of what ‘value’ looks like, how it is generated, and that it may differ depending on the stakeholder.
<p>Challenges in the EU</p>	<ul style="list-style-type: none"> > Many start-ups prefer to deal with large US organisations, rather than those in the EU, due to prohibitive regulations and costs in Europe to start a collaboration. > To encourage companies to stay in the EU, better collaboration is needed with public organisations to develop and fund innovations.
<p>Key points</p>	<ul style="list-style-type: none"> > Facilitate access to the right network and people from the start of the pathway to gain insight into the best business model, the value of the proposed solution, and the feasibility of its implementation > Leverage organisation, ecosystem and user-led challenges to generate ideas > Increase innovation that is led and financed by public

organisations within the EU



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
Incubators	<ul style="list-style-type: none"> > For start-ups, the incubation phase is often an important stage in transitioning from proof of concept to independence.
Best practices	<ul style="list-style-type: none"> > Similar to 'good clinical practice' guidelines for the testing of medicines, 'good development practice' guidelines should be developed for Digital Health products to set out quality and reproducibility standards.
Proof of feasibility and	<ul style="list-style-type: none"> > The 'Proof of feasibility' and 'Proof of value' stages should be combined.

<p>proof of value</p>	<ul style="list-style-type: none"> > 'Proof of value' is often perceived wrongly as 'proof of willingness to pay' – they are not the same thing. > It can be difficult to secure funding to generate health economic evidence to determine proof of value.
<p>Investors</p>	<ul style="list-style-type: none"> > Venture capital (VC) companies looking to provide funding to support clinical trials often demand the involvement of large US VC investors, which can present a challenge. > Investors need a clear understanding of the business model and why they should invest in an innovation, over and above the fact that it works – where does it fit into the ecosystem and how does it integrate with other systems (proof of integration)? > VC need to see more good examples of Digital Health companies scaling-up in Europe to help them to see the potential returns of investing in this sector.
<p>Public–private partnerships and funding</p>	<ul style="list-style-type: none"> > Greater collaboration is needed between private companies and public institutions to fund and support innovation. > The mentality of private companies regarding selling to public institutions needs to change. > Hospital budgets are often low, which can limit their ability to invest in innovation – they need to be incentivised to do so. > Public healthcare institutions and private statutory health insurance companies should invest a percentage of their spending in small innovation companies (below a set threshold) so that more funding is directed to innovation without the need to rely on subsidies and grants. > The Belgian Government has launched an implementation fund to support implementation of innovations in hospitals, which is returned if the solution works and provides value to the institution. However, there is the need for other sources of funding in this setting. <ul style="list-style-type: none"> > For such funding schemes to work there needs to be coordination between the triangle of industry–government–hospitals, however some stakeholders may be more risk

	<p>averse than others.</p>
<p>Challenges in the EU</p>	<ul style="list-style-type: none"> > Europe has a complex Digital Health innovation ecosystem, which often pushes companies to look to the US for feasible business models. <ul style="list-style-type: none"> > Moving to the US is generally not an issue for a company but it means the EU loses the valuable skills of its own innovators and their contribution to the ecosystem. > In the US the ecosystem allows for a quicker return of investment and the mentality is different to that in the EU – it is easier from both an investor and a customer perspective to get engagement and funding for projects. > To generate evidence, companies need to undertake studies. In the US there is substantial funding available for research and better collaboration between researchers and healthcare professionals than in Europe. > A change of mindset is needed in Europe – to embrace risk and also make quick decisions when innovations are not viable and should therefore not be progressed.
<p>Key points</p>	<ul style="list-style-type: none"> > Facilitate and incentivise the economic engagement of different types of payers (insurers, companies, local governments, institutions (hospitals) etc.) in early-stage innovations > Promote 'good clinical – and development – practices' among industry from the start of the innovation pathway > Encourage a change of mentality to embrace risk and recognise failures early on in the Development phase > Facilitate the validation and proof of integration and adoption in the early stages of an innovation's development

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
<p>New Medical Device Regulations (MDR)</p>	<ul style="list-style-type: none"> > The new MDR and the limited number of Notified Bodies (NBs) is an issues for small start-up companies. <ul style="list-style-type: none"> > Larger companies generally have a 'monopoly' in terms of access to NBs > The MDR process is extremely protracted and costly so many companies go to the US to get regulatory approval before coming back to Europe > Educational programmes in Medical Device/Digital Health regulation are needed across the EU to train people how the new MDR should be applied to Digital Health products and how they should be evaluated. > Best practice guidelines need to be developed for the evaluation of Digital Health technologies that can be reused and shared, and are recognised/approved by regulators. > Regulations are necessary to ensure only safe and effective products and services that deliver health benefits and value reach citizens. <ul style="list-style-type: none"> > Need strategies in place to tackle the 'black market' in unregulated products that may arise due to consumer demand. > There are possibilities for self-regulation and assessment of products by a body that is independent of the regulatory

	<p>authorities to provide information to citizens (e.g. mHealth Belgium).</p> <ul style="list-style-type: none"> > Endorsement/certification of products outside of CE marking are valuable for companies in terms of marketing their products.
<p>Initial clinical trial</p>	<ul style="list-style-type: none"> > New clinical research tools are needed for Digital Health technologies that reflect the fact that undertaking traditional randomised controlled trials for these products is difficult, if not impossible. > As a consequence, greater funding is needed for clinical research in Digital Health; this needs to be driven by hospitals and patient organisations. > It is important to determine at an early stage what the evidence requirements are and what should be evaluated (what evidence should be generated?). > Not all Digital Health technologies will need to undertake a Clinical Trial; a Pilot Study which focuses on real-world user assessment and experience may be more appropriate. > Better terms for this stage may be: 'clinical study' or 'market validation'.
<p>New funding models</p>	<ul style="list-style-type: none"> > New public–private partnership funding models are needed, driven by the public sector, that focus on what citizens are willing to pay for.
<p>Key points</p>	<ul style="list-style-type: none"> > Provide educational programmes to develop more experts and awareness in the field of Medical Device/Digital Health regulation > Create best practices and methodologies for product development, evidence generation and assessment of Digital Health technologies > Develop clear regulatory and economic assessment requirements

at the start of the development process

- > Increase funding for clinical research in Digital Health driven by hospitals and patient organisations

What is working well/best practices identified in this phase

Best practice examples

mHealth Belgium is an example of an initiative that works as an independent information resource for consumers, beyond the CE mark. It is the Belgian platform for mobile applications that are CE-marked as a medical device and offers information to patients, healthcare professionals and healthcare institutions regarding these applications. The information it provides includes CE-marking and General Data Protection Regulation information, compliance with security and authentication rules, and how the app is financed.



3. ADOPTION

9. CLINICAL \ COST ASSESSMENT

10. REIMBURSEMENT

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
Reimbursement	<ul style="list-style-type: none"> > As presented, the pathway suggests that reimbursement is essential – not all innovations will be reimbursed, and it is not the only way to finance innovative solutions. > The pay-per-service model and conventional financial schemes in Belgium are not focused on the outcomes, but on the services provided. <ul style="list-style-type: none"> > This system limits the possibility for reimbursement of innovations that are evaluated on value. > This represents a significant barrier in Belgium that needs to change, however there has been a lack of political support for this in recent years. > Payment needs to be focused on the <u>delivery of value</u>, rather than on paying for particular services.
Payers	<ul style="list-style-type: none"> > In Belgium, the government decides which products get reimbursement whereas in The Netherlands there is an open payment scheme and payers (e.g. insurance companies) can decide if they want to fund innovations themselves. > There is now a wide range of possible payers: insurance companies, local governments, employers on behalf of their employees etc., so it is important to define at an early stage who the payer may be for a given innovation. > Health insurance companies are looking at new ways of funding beyond reimbursement, for example investment in health innovation companies. > Procurement in hospitals is generally biased towards larger companies which are more established in the market, putting smaller companies at a disadvantage.
The cost of	<ul style="list-style-type: none"> > Funding is needed to support the cost of implementing an

implementation	<p>innovation – start-ups often lack the capacity to fund marketing efforts and to undertake lobbying and education of users.</p>
Drivers of adoption	<ul style="list-style-type: none"> > Positive HTA reports are key to supporting adoption and changing clinical practice. However, it takes time to generate such reports, and there is limited capacity to produce them. > There are challenges in coordinating and harmonising the various bodies undertaking HTA in Belgium. However, positive collaborations are ongoing between of the <u>Belgian Healthcare Knowledge Centre (KCE)</u> and The Netherlands authorities (and in <u>EUnetHTA</u>, the European network for HTA that is coordinated by the <u>Dutch Zorginstituut Nederlands (ZIN)</u>) to help streamline HTA assessment and avoid duplication of work across countries. Close collaboration like this is essential both nationally and across borders. > As seen from the pharmaceutical sector, the marketing campaigns of private companies are also important in driving adoption. > Public entities, such as the KCE, can also play a role in promoting implementation of innovative solutions and changes in clinical practice.
Extended clinical studies	<ul style="list-style-type: none"> > Although it can be a challenge, clinical studies should ideally be undertaken at an international, multicentre level to support wide adoption and meet different national requirements. > Greater collaboration is needed between industry and research centres to undertake clinical studies – an ecosystem is needed that helps promote strong partnerships based on trust so that innovative solutions are developed that better address the needs of the market.
Market access collaboration opportunities	<ul style="list-style-type: none"> > At the European level there are opportunities for international collaboration and partnerships to develop joint market access strategies – rather than several individual companies doing it in

	<p>isolation.</p> <ul style="list-style-type: none"> > These collaborations do take a lot of effort and focus, and all stakeholders need to be willing to participate and share ideas – building trust and good relationships is essential. > Collaborations between large and small companies can be difficult, given the difference in size, and the restrictions and rules that often exist within larger companies > Sometimes cross-industry collaborations can be successful, for example with insurance companies or health providers, and facilitate reaching common goals. > It may be possible to learn from examples in other industries, such as the media or the automotive industry, where resistance to change is less.
<p>New business models</p>	<ul style="list-style-type: none"> > New business models are needed to reflect the Digital Health ecosystem. > Platforms are needed so that companies producing innovations can engage with public domains – for example ‘matchmaking’ events in a pre-competitive space – EIT Health could facilitate. > Company mergers and acquisitions are well established in the pharmaceutical industry, but are new to Digital Health, and may require new kinds of business models.
<p>Key points</p>	<ul style="list-style-type: none"> > Greater support is needed for implementation funds for organisations > Increase multinational collaborations and clinical research within Europe > Promote new payment schemes beyond the insurance service and pay-per-service reimbursement models currently established in Belgium – develop value-based healthcare payment schemes > Increase the capacity of KCE in the production of HTA reports and support their implementation > Strengthen coordination and avoid duplication of work between

regulatory and HTA bodies at both a national and EU level

- > New business models are needed for collaborations, mergers and acquisitions among industry in Digital Health (both start-ups and large companies) in order to facilitate the implementation of innovations

What is working well/best practices identified in this phase

Best practice examples

MassChallenge is an example of an initiative that pairs larger companies with small companies to accelerate innovation.

Session III: Conclusions and recommendations for actionable outcomes

<p>IDEATION</p> <p>ACTION</p> <ul style="list-style-type: none"> > Facilitate access to the right network and expertise from the start of the Ideation phase to gain insight into the suitability of the business model, the solution’s value and the feasibility of its implementation <ul style="list-style-type: none"> > Create a checklist that defines the proper language/terminology surrounding digital innovation in the healthcare sector and the requirements of the Ideation phase > Link local, regional, and international strategies to determine best practices – EIT Health could facilitate > Promote peer-to-peer learning > Support organisations to navigate the ecosystem from the start of the Ideation phase > Develop proof of integration networks > Leverage organisation, ecosystem and end-user led challenges to generate ideas > Increase innovation-led and publicly financed organisations throughout EU based on user needs <ul style="list-style-type: none"> > Stimulate cross-functional interactions and collaborations; break down silos 	<p>TARGET STAKEHOLDER(S)</p> <p>Incubators/accelerators for Digital Health innovation</p> <p>Local organisations and networks</p> <p>Network of European Hospitals</p>
<p>DEVELOPMENT</p> <p>ACTION</p> <ul style="list-style-type: none"> > Facilitate and incentivise the economic engagement of the 	<p>TARGET STAKEHOLDER(S)</p>

<p>different types of Payer (insurers, companies, local governments, etc.) in early-stage innovations</p> <ul style="list-style-type: none"> > Promote 'good clinical - and development – practice' amongst industry from the start of the pathway <ul style="list-style-type: none"> > IMI-like consortium and grants for university research, with more public–private pre-competitive partnerships - EIT Health can facilitate > Support the development of strong product dossiers, with a good scientific foundation but also with robust market/business plans – this require better knowledge of the EU ecosystem and improved education about innovation from the research level > Change the local mentality to embrace risk, and recognise failures early on in the process > Facilitate the validation and proof of integration and adoption in the early stages of development <ul style="list-style-type: none"> > Address information flows, ownership, business models, and process management > Facilitate and incentivise collaborations between clinical research and start-up innovators 	
<p>MARKET ENTRY</p> <p>ACTION</p> <ul style="list-style-type: none"> > Educate and develop more experts in the field of Medical Device/Digital Health regulation > Document best practices and methodologies for development, evidence generation and assessment of Digital Health products and systems > Develop clear requirements for regulatory assessment and HTA from the start of innovation development > Increase funding for clinical research in Digital Health driven by hospitals and patients' organisations 	<p>TARGET STAKEHOLDER(S)</p>
<p>ADOPTION</p>	<p>TARGET</p>

ACTION	STAKEHOLDER(S)
<ul style="list-style-type: none"> > Develop new models for collaboration, mergers and acquisitions among industry in Digital Health (both start-ups and large companies) to facilitate the implementation of innovations > Create funding opportunities for organisations to support implementation > Increase multinational collaborations and clinical research within Europe <ul style="list-style-type: none"> > Develop a referral network for start-ups across Europe to identify the best markets for each innovation - EIT Health can facilitate > Share examples of navigating different ecosystems for easier development and deployment (Georgia, US, other EU countries, etc.) > Promote new payment schemes beyond the insurance service and pay-per-service reimbursement models currently established in Belgium – develop value-based healthcare payment schemes > Increase the role of KCE in the production of HTA reports and to support their implementation <ul style="list-style-type: none"> > Raise awareness of the challenges of navigating the HTA process, bringing stakeholders together to explore opportunities and best practices > Strengthen coordination and avoid duplication work between regulatory and HTA bodies at both a national and an EU level <ul style="list-style-type: none"> > Leverage existing networks 	

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
Menno Kok (Moderator)	Managing Director, EIT Health Belgium/Netherlands
Tim Buckinx	Chief Executive Officer, Epihunter
Peter Dedrij	Channel Manager Healthcare, Microsoft
Ludo Deferm	Executive Vice President, IMEC
Georges De Feu	CEO, LynxCare
Kathleen D'Hondt	Policy Analyst, Dept. Economy, Science and Innovation – Flemish Government
Bert Hartog	Senior Director Clinical Innovation, Janssen Pharmaceutica NV
Steven Hermans	Director of Business Development and Innovation, CM
Carlotte Kiekens	Physical and Rehabilitation Medicine University Hospitals Leuven; Cochrane Rehabilitation
Frank Luyten	Professor and Chairman of Division of Rheumatology, University Hospitals Leuven
Alain Thielemans	Adviser, Flanders Innovation & Entrepreneurship (VLAIO)
Pascal Verdonck	Professor of Medical Technology, Ghent University
Griet Verhenneman	DPO - Affiliated Researcher, University Hospitals Leuven CiTiP
Organisers and other attendees	

Mayra Marin	Think Tank Manager, EIT Health
Sameena Conning	Director of External Affairs, EIT Health
Sari Makkonen	Communications Officer, EIT Health BeNe
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