Optimising Innovation Pathways: Future Proofing for Success

Think Tank Round Table
Meeting Proceedings

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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 Swedish 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: Swedish Round Table

Hosted by EIT Health Scandinavia

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

Moderated by: Professor Jan-Olov Höög, PhD

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

Discussion topics

- **Session I:** The current state of the Digital Health Innovation Pathway in Sweden
- **Session II:** Optimising the innovation pathway in Sweden
- **Session III:** Proposals for actionable recommendations

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

Focus of the Swedish Round Table

The innovation type selected for discussion at the Swedish Round Table was Digital Health, with a focus on the potential for personalised medicine. 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 Sweden's Digital Health Ecosystem

The findings of EIT Health's research into Sweden'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:

- Sweden has close collaborative links within the Nordic region and there are some similarities between systems in the individual Nordic countries.
- Within Sweden, a total of 21 healthcare regions are responsible for providing and paying for

healthcare.

- Despite a national Health Information Exchange (HIE), interoperability challenges exist amongst the different healthcare regions
- 95% of all documentation in primary care is undertaken using Electronic Health Records (EHRs), while the corresponding figure for specialised hospital care is estimated at 69%.
- There is a wide range of Swedish national quality registries (Source: Swedish National Quality Registries http://www.kvalitetsregister.se/englishpages.2040.html)
- Sweden was one of the first countries, together with UK, to adopt value-based pricing.
- Swedish County Councils invest around SEK 8.5 billion (USD 1.2 billion) annually in healthcare IT, of which SEK 6 billion (USD 0.9 billion) is used for the purchase of equipment and supplies.
- In terms of Global rankings:
    - Sweden was in second place (behind Switzerland) in the Global Innovation Index 2017 (Source: Cornell University, INSEAD, and the World Intellectual Property Organization, 2017)
    - Sweden was in fourth place on the Global Entrepreneurship Index 2017 (Source: The Global Entrepreneurship and Development Institute (GEDI), 2017)
- There are around100 health tech companies identified in Sweden: 52 focus on sustainable hospitals, 27 focus on assisted living, 15 focus on smart digital solutions, and 6 focus on personalised care. (Source: Nordic Health Tech Ecosystem)

At the Swedish Round Table Meeting, Karina Tellinger McNeil from the Swedish Association of Local Authorities and Regions (SKL) gave an overview of a key ongoing national initiative: 'Organised introduction of digital services and products' for which she is Project Manager.

- The project was initiated in 2017 as a collaboration between the Swedish Association of Local Authorities and Regions (SKL), Stockholm Science City Foundation (SSCi), UppsalaBio and Region Norrbotten. The project will continue until 2019 and is co-financed with the Swedish Agency for Economic and Regional Growth.
- It aims to facilitate the smooth introduction of digital products and services for home monitoring and prescribed self-care into the Swedish healthcare system for the benefit of County Council and Regions, to contribute to increased growth of small and medium-sized companies, and to support the national initiative 'Vision e-health 2025'.
- In collaboration with a range of stakeholders, the project has identified needs, challenges and opportunities relating to this process and proposed a series of recommendations in order to clarify, and provide a structure for, the procedure of procuring and introducing digital services.
- The project's key conclusions so far are that Sweden is an immature market for digital products and services. This creates uncertainty both for buyers and for companies that

develop innovative digital services, but also reduces the interest of investors. The market could be improved by creating clearer overall rules of play and supporting coordination and skill-enhancing efforts for both County Councils/Regions and for companies. The following activities are recommended:

1. Develop and adopt a common framework.
2. Create coordination and synergies for medical technology and IT.
3. Adopt proposals for a national infrastructure that supports information handling for prescribed digital self-care services.
4. Create a 'requirement library' to clarify and coordinate requirements.
5. National coordination of priorities and recommendations for digital services.
6. Investigate mutual national purchasing.
7. Increase the capability for digital transformation.
8. Industry-developed product compilation.

The Digital Health Innovation Pathway

The proposed innovation pathway in Sweden 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 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 Sweden as described and were asked to advise:

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

- The pathway presented generally reflects the reality in Sweden.
- However, compared with the established process for pharmaceuticals which is relatively clear, the Digital Health pathway is much more complex and probably more similar to the IT pathway.
- The Digital Health market is Sweden is gradually maturing, both on the supplier side and the procurement side, regarding the requirements of the pathway.
- Although Sweden is a relatively small country, it is seen as a leader in innovation and a valuable source of data (e.g. health data registers and biobanks) for validation of potential solutions – this is something to capitalise on when optimising the Digital Health pathway.

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

- There needs to be greater clarity and integration of national versus regional requirements of the pathway in Sweden – strategic direction at a national level is required.
- Priorities must be set within the Swedish healthcare system regarding what specific needs should be targeted with new digital technologies so that the most appropriate products are progressed.
- Clearer working methods and agreements need to be in place for collaboration between companies and the healthcare sector.
- Procurement strategy needs to be considered right from the beginning of the pathway.
- Evidence also needs to be considered from the start of the process with companies and the healthcare sector working closely together to generate it.
- A 'checklist' of requirements would be of value – what to do, where information can be found, and who should be contacted. The details of the checklist may change on a case-by-case basis, but it is important to set expectations about the overall requirements.

- A clearer process is needed for the proof steps in the Development phase; pilots are important for testing on a small scale, but a strategy is needed from the beginning to allow scale-up.
- Ownership and return on investment issues need to be clarified when there is investment (funding and resources) from both the Region and a company, which then transitions to a vendor–purchaser relationship.
- Access to the healthcare sector is a prerequisite in order for companies to understand how it works, the requirements and challenges, but also how best to cooperate on innovations with stakeholders.
- A key challenge in the introduction of Digital Health technologies is not the technology itself but the requirement for change management and adaptation to reflect new processes and workflows. It is often difficult for Public Sector organisations to change at the pace required to introduce Digital Health.
- With Digital Health technologies there is a need to change how we estimate the value of healthcare, taking into account long-term benefits and the move to prevention not just treatment. In light of this, new finance models are needed, moving away from the current annual budget cycle.

Session II: Optimising the Digital Health Innovation Pathway in Sweden: 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
Stakeholder interaction	> There are limitations on the opportunities for industry to engage directly with the healthcare system, citizens and patients. > A structure is needed to allow meetings/interaction between stakeholders in the healthcare sector and companies/innovators, so they can pool experience and identify needs – 'innovation arenas'. > Patients, caregivers and social care providers should also be

	involved in these interactions. > Processes for ethical communication between these stakeholders need to be developed in order to create an ecosystem that supports co-creation and evidence generation – EIT Health can help facilitate. > There is a great need to reduce the 'fear' and lack of trust in these collaborations. > There is a need to build early awareness of the requirements of all phases and stages of the pathway process for all stakeholders. > Structures are needed to ensure valuable research is translated into useful solutions and does not just stay in the research setting.
Needs identification	> Increased stakeholder collaboration is needed in this phase to facilitate ideation however it is important the needs are prioritised to ensure resources are allocated where the needs are greatest.
Funding	> Funding should extend to the 'non-technical' developments that are required for the innovation's eventual implementation, e.g. changes in processes and workflows. > Innovation implementation costs need to be considered in calculations.
Access to data	> Structures and processes for access to data, e.g. health data registers and biobanks, are vital to supporting innovation. > It will also be important to prospectively collect data (similar to Phase IV studies), particularly in light of the increasingly ageing population.
Procurement	> Strategic procurement (i.e. 'innovation procurement') procedures need to be considered from the start of the process to define what is needed and provide a clear pathway moving forwards. > Cost-benefit and value need to be demonstrated and included in

	any checklist of requirements.
Scaling-up	> One barrier to scaling up is the variability in requirements between regions (e.g. data platforms, hardware systems). Since the regions make independent decisions, standardisation is not a viable path, but coordination is essential. In addition, SME's need to have a relationship with the major system providers for the healthcare. > Often SMEs do not scale-up within Sweden as it is perceived as too complex to break into the public healthcare sector. This means a risk that talent innovators are lost. > The process of scaling up should be approached in a systematic way and provide opportunities to do so (needs clarification) – but there also need to be coordination regarding what should be scaled up and what should not. For the healthcare providers umbrella organisation (SKL), scaling up is dependent on proof that a product/service is fulfilling a need and is working well. In Sweden, scaling up will have to be done equally over the country. > What can we learn from other sectors (e.g. banking, finance) that can be applied to healthcare?
Competitive marketplace	> Digitalisation will result in a more competitive marketplace and a decrease in monopolies. > Patient choice will become a key driver so it will become increasingly important that products and services are effective and show value in order to be competitive in this new environment.
Knowledge and experience sharing	> Interfaces at the national level for the sharing of experience and evidence-based knowledge are important. – EIT Health can help facilitate. > This should also extend internationally across borders to enable businesses to have global channels.

Key points	> Create opportunities for greater stakeholder collaboration. > Structures and methods are required to allow systematic needs assessment and prioritisation by stakeholders based on experience and evidence. > Increase the funding available for 'non-technical' developments that are a necessary part of the innovation process. > Consider implementation costs and workflow changes in overall project costs from the start. > Have a strategic procurement plan from the start that create a pathway for innovation to meet identified needs. > Address barriers (regional, national, international) to scaling-up and allow businesses to develop and have a global reach.

What is working well/best practices identified in this phase

Positive experiences
The Health Informatics Centre (HIC) at the Karolinska Institutet undertakes research in the areas of clinical decision making, integrated patient-centred information systems for collaborative care and patient e-services with special focus on usability.
Quality Registers Stockholm is a regional registry centre for National Quality Registries (NQR) and also forms a strategic cooperation between Karolinska Institutet and the Stockholm County Council.

Best practice examples
The banking sector works well, and is advanced in terms of digitalisation. Many small tech companies can sell their products/services to large banks because of common EU rules.

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
Access to funding	> Securing financing is key to the Development phase and supporting progress of an innovation. > Clear guidance and 'checklists' on the steps and requirements of this phase of the pathway for Digital Health innovations are essential in order to support evaluation within funding opportunities and by Venture Capital.
Partnerships and risk-sharing	> Developing partnerships is key to accessing the right kind of expertise to support development and provide clear evidence of value. > Industry needs to be more engaged and agile in its partnerships with other smaller companies and also with academia. Good example: AstraZeneca Bioventure Hub, in Mölndal, Sweden – see below. > Companies should look to develop open application programming interfaces (APIs) and standards – should not have to continually

	'reinvent the wheel' or be locked into one system. > Public–private partnerships need to be encouraged and facilitated in the Development phase. > National/regional coordination is required to develop new models that allow companies (and other stakeholders) to contribute to the healthcare sector, rather than being perceived as a barrier. > Shared risk as well as shared benefit models are needed so the public sector can benefit from commercialisation of an innovation it has supported the development of – procurement rules can be a barrier here. > Need to ensure that companies in EU countries can collaborate while also being competitive – similar to the non-competitive space in the pharmaceutical industry, e.g. the Innovative Medicines Initiative (IMI). This kind of structure needs to be facilitated for Digital Health. > In Sweden, the 21 different healthcare regions have different strategies for their data platform use. Therefore, there are several different platform providers, and in addition, some regions build their data platforms themselves. For an innovation SME, a relationship with the platform actor is therefore crucial.
Proof of value	> It is important to demonstrate value to all stakeholders, including the wider impact and benefits for society. > Good health economics input and experience is important when generating evidence of overall value, due to the complexities of different stakeholder budgets and economic workflows. > Calculations also need to consider the cost of NOT implementing a new initiative. > Benefits also need to be considered in terms of prevention, not just management, of ill health or disease.
Regulatory requirements	> Regulatory experience with Digital Health products is still limited. > Companies and researchers need to lead the way by engaging with, and advising, regulators of the best processes in this new environment. Based on this input, regulators can then define

	guidelines and best practice. > The regulations are defined at an EU level, so Swedish national regulatory agencies need to take an active role in engaging in dialogue with the network of Competent Authorities for Medical Devices and other relevant stakeholders – EIT Health can help facilitate.
Evidence generation	> Clinical studies and evidence generation should be undertaken in several markets from the start – this will save time when launching into markets outside of Sweden, as locally-derived evidence is usually required.
Financial models	> New financial models are needed for Digital Health innovations to enable companies to scale-up and be competitive in the marketplace. > Need to develop 'innovation partnerships' for procurement. > New models for financing are needed, e.g. health impact bonds.
Value of data	> Companies may use a range of different business models, often in a combination of (a) consumer pays, (b) public healthcare pays (c) the data collected are sold (for example, to the pharmaceutical industry) – this last option is a recent development but becoming more common and recognises the inherent 'value' of data that are generated by Digital Health products. > Clear guidance and ethical guidelines are needed around the ownership and use of data generated in this way. > National strategies covering data usage and how the patients can contribute are needed.
The patient voice	> As citizens are being encouraged to take greater responsibility for their own health, patients and patient groups can bring pressure to support the development of innovations.

Key points	
	> Create clear guidance on the Development phase requirements and steps. > Companies and researchers should engage with regulators to propose guidelines and best practice for the assessment of Digital Health products. > Develop new financial models for Digital Health innovations to enable companies to scale-up and be competitive. > Create risk-sharing and benefit-sharing structures for innovation development among industry partners and private-public partnerships. > Encourage sustainable business models and create ethical guidelines around ownership and use of data generated by Digital Health products and services. > Have clear models for the calculation of value that take into account both the long-term impacts of an innovation as well as the impact of not implementing it. > Explore new payment models that reflect the correlation between investment and health outcomes over the long term.

What is working well/best practices identified in this phase

Positive experiences
AstraZeneca Bioventure Hub, in Mölndal, Sweden allows academic groups and biotech companies access to their offices, laboratory space and facilities to help them gain competitive advantage by tapping into the company's resources and expertise.

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
Regulatory challenges	> The border between consumer and medical products is becoming increasingly blurred – often they access the same data and have broadly similar efficacy (e.g. FDA clearance of the EKG and irregular rhythm notification functions of the Apple watch in the category of a Class II Medical Device). > Obtaining a professional-level classification is more desirable for companies but requires greater regulatory hurdles and is complex to navigate. > The new medical Device Regulations (MDR) will be even more demanding and make it particularly difficult for SMEs to progress their ideas – a clear 'checklist' of requirements is essential, and training opportunities will be needed. > To soften the impact on smaller companies, one option is to provide additional funding to help sustain their development efforts while the new MDR come into force. > Regulations are necessary and should be seen in a positive light as they will filter out innovations that do not meet the required standards or provide value to citizens and patients. > A platform where companies can access an external multidisciplinary network to get advice on the best approach to the regulatory requirements and to exchange information, prior to approaching the regulators for validation, is needed. > Traditionally regulators have taken an independent and non-involvement stance and have been reluctant to give specific

	advice; a network collaboration is now needed to move forward with Digital Health products.
Clinical trials	> The healthcare sector is used to working with the traditional pharmaceutical approval based on randomised clinical trials – these are most often not suitable for assessment of Digital Health products, so there needs to be development and education around new assessment methodologies. Digital Health products and services generate data while being used, which allows for continuous assessment.
Key points	> **A standardised approach to the assessment of health technology is required, regardless of whether it is targeted to consumers or to professionals, and whether it is a wellness product or a medical device.** > **Funding mechanisms are needed to enable start-ups to survive the challenges associated with introduction of the new MDR and until there is a clear definition of the required regulations.** > **Structures are needed to allow collaboration with stakeholders who have experience in the field to help define regulatory guidelines and methods which can subsequently be shared with, and adopted by, regulators.** > **New clinical trial methodologies suitable for assessment of Digital Health products are required.**

FIGURE 1

4. ADOPTION

9. CLINICAL\COST ASSESSMENT

10. REIMBURSMENT

11. STANDARD OF CARE

12. OBSOLESCENCE

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

Topic	Key discussion points
Living Labs	> Living Labs are currently underused as test beds in Sweden – this is something that needs to change. The EIT Health Living Labs could be used more. > Ideally, they should be integrated into organisations. > Should be used for early assessment of value and impact of the implementation of innovations that are close to market.
Implementation strategies	> Best practices in implementation strategies and methods for Digital Health products should be shared nationally across regions, as is done within the aforementioned national project 'Organised introduction…', and also between countries which will reduce fragmentation and enable easier scale-up – EIT Health can help facilitate. > EIT Health may have a role in supporting pilots and tests across borders. As an example: Bridgehead – where you can get incubator support to test a product or service abroad. > Collaboration between public bodies are key to defining shared stakeholders needs. > This can then inform better engagement with innovators and drive implementation of initiatives that meet those identified needs. > Implementation is just as important as innovation – some

	innovations are never implemented and used.
Change management	> Systematic change management is important and will require the allocation of resources. Organisational capability to handle change is equally important to new technology. > Sometimes innovations may be adding to an existing process, rather than changing them.
Risk management	> Risk management is a major challenge in this phase. > To protect their brand, large companies may not be able to take the risks that small companies can take; smaller companies may also be more flexible and agile. > On the other hand, larger established companies may have better procurement partnerships, and can easier manage long procurement timelines. In addition, reimbursement models can disadvantage small companies.
Guidelines	> National guidelines for Digital Health products are key, and the RT participants therefore expressed their strong support for the ongoing 'Ordered introduction…' process. > EIT Health can contribute through dissemination of good examples and best practices.
Patient associations	> Patient associations need to remain market neutral so while they cannot advocate for specific products, they can push for greater choice, and for better conditions for enabling new solutions.
Evidence requirements	> The requirement for extensive clinical and cost evidence can be a challenge. However, evaluation and follow-up can also be simplified due to the data generated by the digital products and

	services. > Need to make better use of 'real world' follow-up data generated by digital products to assess outcomes, and also registries.
International markets	> Geographical boundaries are being challenged. Innovators in Sweden and elsewhere no longer see single countries as their market but think on an international scale.
Patient motivation	> With the move to self-treatment at home, one important point to consider is the continued motivation of patients to use these relatively expensive innovations for monitoring etc. on a long-term basis, otherwise value will not be generated. > Collection and feedback of outcomes data direct to patients may help encourage continued use.
Key points	> **Increase the impact of Living Labs as test sites for early assessment of the impact of implementing innovations within organisations.** > **Promote structured dissemination between regions and countries of best practice implementation strategies and methods for Digital Health innovations.** > **Coordinated efforts to develop guidelines for Digital Health are essential.** > **Implement initiatives that are driven by stakeholders' needs rather than innovators' proposals.** > **Encourage better dialogue and collaboration around risk management.** > **Systematic change management is required to support adoption of new innovations.**

Session III: Conclusions and recommendations for actionable outcomes

IDEATION	TARGET STAKEHOLDER(S)
ACTION	
> Continue to develop structures and methods to allow systematic needs assessment and prioritisation by stakeholders based on experience and evidence.	
> > Patient Organizations and Caregivers should have input into functional needs identification at a national level.	
> > Higher-tier organisations, such as Regions, should take on the role of facilitators and develop proper structures to allow the participation of multiple stakeholders.	**Regions**
> > Institutions (Authorities, Regions, Regulators) should understand the gaps in the ecosystem, and create an environment to address them that will attract innovation to those areas.	**Authorities, Regions, Regulators**
> Increase the funding available for 'non-technical' developments.	
> Consider implementation costs and workflow changes in the overall costs from the beginning of the project.	
> Strengthen strategic procurement processes, such as 'innovation procurements', that create a pathway for innovation based on strategic needs.	
> > Municipalities should define these innovation strategies based on needs assessment	
> > Broad dialogue is needed for understanding of all implications relating to Digital Health.	

> Ensure flexibility to take into account innovations outside of these strategic areas. > Collaborate across geographical barriers (regional, national, international) to scaling-up to allow businesses to develop and have a global reach.	
DEVELOPMENT **ACTION** > Guidance on the Development phase requirements and steps is essential. > Create a clear framework of responsibilities among stakeholders for Digital Health, which is discussed and agreed at the governmental level. > Ensure infrastructures and support for stakeholders to navigate the innovation pathway. > Anticipate the impact of new innovations within existing systems. > Improve preparedness for managing the uptake, budget allocations and implementation of effective change management for new innovations. > Identify and define the requirements for change within institutions and systems that will result from implementation of digital products and services. > Encourage sustainable business models and clarify ethical guidelines around ownership and use of data generated by Digital Health products, with citizens ownership as a key element. > Create risk-sharing and benefit-sharing structures for innovation development among industry partners and private-public partnerships. > Encourage agile business models for private-public development within healthcare institutions. > Create clear structures for co-creation of products with users and caregivers between healthcare organizations and industry. > Reduce the timeframe between pilot testing and	**TARGET STAKEHOLDER(S)**

procurement. > Have clear models for the estimation of value that take into account both the long-term impacts of an innovation as well as the impact of not implementing it.	
MARKET ENTRY **ACTION** > Ensure standardisation of approaches to the assessment of health technology, regardless of whether it is targeted to consumers or to professionals, and whether it is a wellness product or a medical device. > Promote interoperability guidelines and standards among manufacturers and health data platforms for data transfer – data platform companies are key players for defining this, but inter-regional collaborations is necessary to develop such a strategy. > Create funding mechanisms to enable start-ups to survive the challenges associated with introduction of the new MDR and develop a clear definition of the required regulations. > Ensure structures that allow collaboration of stakeholders who have experience in the field to help define regulatory guidelines and methods which can subsequently be adopted by regulators. > Ensure multidisciplinary networks of competence, outside of regulatory bodies, that can support innovators navigating the requirements. > Increase the awareness and role of healthcare providers' innovation departments and healthcare hubs as support systems for innovators. > Develop clear checklists that signpost support for innovators within the system to address any knowledge gaps; mentoring/support could be provided by research centres and healthcare institutions.	**TARGET STAKEHOLDER(S)** **Regions, SKL, platform providers** **Vinnova, SKL, EIT Health**
ADOPTION	**TARGET STAKEHOLDER(S)**

ACTION	
> Increase the impact of Living Labs as test sites for early assessment of the impact of implementing innovations > Assign resources to integrate test beds into healthcare institutions to sustain change management within organizations, based around sustainable business models. > The EIT Health Living Labs can be used more. > Ensure a coordinated approach to developing clinical guidelines for Digital Health assessment. > Establish validation mechanisms for innovations in Digital Health which support and promote implementation within the healthcare system. > Promote structured dissemination between national regions and countries of the best implementation strategies and methods. > Implement initiatives driven by stakeholders needs rather than innovators proposals. > Encourage better dialogue and collaboration around risk management for different areas and stakeholders.	**EIT Health, SKL**

Next steps in the process:

- Several participants asked if it was possible to convene more regularly. Jan-Philipp Beck confirmed that EIT Health would welcome the opportunity to play a part in future collaborations.
- It was considered important to identify areas that provide a competitive advantage for Sweden, for example as a place where you can validate products and services, such as the ongoing biobanks project which supports validation with the help of registers and biobank health data.

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
Jan-Olov Höög (Meeting Moderator)	Professor of Medical Chemistry and former Dean for Higher Education at Karolinska Institutet, Stockholm
Lena Alksten	Strategist, City of Stockholm, Elderly Care Department
Annette Boije	Operations Developer in Primary Care, Region Jamtland Harjedalen
Annette Brodin Rampe	Chief Executive Officer, LifeCareX
Marie Gårdmark	Chief Executive Officer, Regsmart Life Science AB
Mikael Gidhagen	Director of Executive Education, Uppsala University, Department of Business Studies
Per Hamid Ghatan	Senior Medical Manager, Akademiska Sjukhuset, Uppsala
Jakob Hellman	Acting Head of Health Division, Vinnova
Lise Lidbäck	Chair, Neuroförbundet
Cecilia Lindholm	Senior Lecturer, Uppsala University, Department of Business Studies
Lisa Lundgren	Development Strategist, Region Norrbotten
Per Matsson	Senior Scientific Adviser, Phadia Thermofisher
Sofia Medin	Head of Policy, Swedish Medtech
Karin Melén	Enhetschef, Tandvårds och läkemedelsförmånsverket (TLV)
Sofia Rydgren Stale	Andre Vice Ordförande, Sveriges Läkarförbund

Patrik Sundström	Programansvarig för Ehälsa, Swedish Association of Local Authorities and Regions (SKL)
Karina Tellinger McNeil	Samordnare, Swedish Association of Local Authorities and Regions (SKL)
Maria Winkvist	Marketing and Product Manager, Kontigo Care
Organisers and other attendees	
Mayra Marin	Think Tank Manager, EIT Health
Jan-Philipp Beck	Chief Executive Officer, EIT Health
Erik Forsberg	Managing Director, EIT Health Scandinavia
Marianne Ekdahl	Communications & Public Affairs Lead, , EIT Health Scandinavia
Christina Bergstrand	Community Communications Manager, EIT Health Scandinavia
Zara Pons Vila	Business Creation Project Coordinator, EIT Health Scandinavia
Miguel Amador	Researcher
Karen Wolstencroft	Rapporteur