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EIT Health Think Tank

Optimising Innovation Pathways:
Future Proofing for Success

Belgium-Netherlands
Round Table Meeting

APRIL 2020

Executive summary

Brussels, Ghent, Leuven and Hasselt are known as rapidly expanding hubs for the health technology sector. More than 200 companies are now based in these regions (a 300% annual increase from 2018). Based on our rapidly increasing abilities to gather, store, analyse and interpret data, the growth of the Digital Health sector in Belgium is impressive and its potential impact on our lives is even more astonishing. Yet, the sector faces a number of critical challenges, some of a local/national nature, others exemplary for any other country in Europe. The EIT Health Think Tank Round Table of November 15 in the Leuven Health House critically analysed a number of these challenges, concluding:

- Early user-participation in innovation processes, driven by actual needs, commitment and trust, is a critical success factor in health technology and it needs to go hand-in-hand with transparent and participative data management;
- Innovators and health care providers need to invest in reshaping their relationships, so as to model market pull into technology development processes;
- Regulatory issues may become a bottle neck to innovation in (digital-) health due to the new Medical Device Regulation; in Belgium the number of notified bodies will need to be increased soon;
- The approach to business models in digital health needs to be revisited; innovators, payers, users and governments need to pick up on this challenge together.

Interestingly the bigger picture that emerged from this Round Table is one of shared interests and shared responsibilities within the national context but most certainly also in the international one.

The Round Table has delivered its homework to the EIT Health network, and, in the true spirit of the meeting, its participants can't wait to hear about the next steps!

I would like to thank all the participants and organisers of this Round Table event and invite them to be part of the future of digital health. Special thanks go to Health House that provided a very inspiring environment for the Round Table meeting.

Menno Kok
Managing Director, EIT Health Belgium-Netherlands

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Introduction

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

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

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

The Round Table Series took place in various locations across Europe organised in conjunction with the EIT Health regional hubs. Leuven (Belgium) was selected as the location for the Belgium-Netherlands Round Table Meeting which took place on the 15th November 2019 and saw participation from key stakeholders involved in the innovation pathway in Belgium and more particularly in Flanders, including healthcare providers, innovators, key opinion leaders, funding agencies, regulatory and reimbursement bodies and local and national government. Rather than opting for input from all four member countries of the Regional Innovation Hub (Netherlands, Belgium, Luxembourg and Israel) this Round Table brought together some 20 experts from a single region, allowing them to address the key issues relevant in the local context from a single homogeneous socio-economic perspective thus avoiding discussions on the rather substantial country-to-country differences.

Each host regional hub selected to focus on a choice of innovation type relevant to the local context – Belgium-Netherlands selected digital health, which refers to software-based solutions.

In the EU, the new Medical Device Regulations (MDR) will extend the scope of medical device software. With it, many digital health solutions will soon be considered as medical devices.

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

The innovation pathway, or route to market for new products and services, is comparable in Belgium to the rest of Europe. Although presented in a linear format in figure 1 below, it is in fact a continuous and a cyclic pathway. The clinical and user needs, in particular, should be 'front of mind' throughout the pathway. Additionally, certain steps, such as proof of value, will be recurring considerations throughout the lifecycle of any product or service.

IDEATION

- 0 CLINICAL NEED
- 1 IDEA

DEVELOPMENT

- 2 PROOF OF CONCEPT
- 3 PROOF OF FEASIBILITY
- 4 PROOF OF VALUE

MARKET ENTRY

- 5 INITIAL MARKET ENTRY
- 6 VALIDATION OF SOLUTION
- 7 APPROVAL & LAUNCH

ADOPTION

- 8 CLINICAL/COST ASSESSMENT
- 9 REIMBURSEMENT
- 10 APPROVAL & LAUNCH
- 11 OBSOLESCENCE

FIGURE 1

Ideation – grasping the 'unmet need'

Defining the clinical need at ideation is crucial to the innovation pathway – any innovation must meet a clear unmet need or be a significant improvement on current methods. Additionally, innovation must fit seamlessly into the lives of patients, the practice of clinicians, and existing healthcare systems and therefore 'user need' is equally important.

Collaboration between healthcare professionals (HCPs) and companies in Belgium can be a challenge due to the commercial aspects of the interaction. In the past, HCPs routinely worked with companies, however in recent years this has declined due to stricter rules about potential conflicts of interest. This represents a significant barrier to innovation progression, limiting collaboration at the early stages. To overcome this limitation, larger companies often employ HCPs to provide advice and allow early incorporation of feedback.

For example, the pharmaceutical industry has developed successful strategies for collaborating with HCPs and patients. This, however, may not be easily replicated by small companies such as start-ups.

There is an increasing trend for patients and citizens to develop their own innovations – they often become experts in their disease or condition and are active and vocal contributors within the innovation pathway. Patients and citizens can also have considerable influence on the adoption phase of the pathway as they, in many cases, will be the direct recipient of the product or service. Innovators collaborate with patients and citizens on vastly differing levels, and the full potential of such collaborations are often not reached.

Accessing data

Data-driven innovations, rather than devices, are becoming more commonplace however such innovations require access to considerable amounts of data for testing and validation – strategies and frameworks are underdeveloped in this area,with privacy and transparency being key concerns.

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. Transparency in the processes for the sharing of information between companies, hospitals, payers etc. is needed to provide reassurance to patients and citizens.

Availability of funding and resources is also a concern at this stage in the pathway. This is, in large part, due to the lack of evidence supporting the product or solution at this early phase, and the risk aversity of investors in the healthcare sector. At the ideation stage, it will be many years before an innovation can demonstrate potential return on investment. 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 – innovators need to provide sufficient evidence of where their product or service fits within the ecosystem and how it will integrate with current systems and processes in order for them to predict the return on investment.

There are clear challenges faced by innovators at ideation stage within the current pathway, which has significant impact in terms of ability to attract investment and ultimately bring solutions to market. Access to stakeholders so that the clinical and user unmet need and design of co-creation strategies can be established are crucial to this stage in the pathway.

Development and market entry

The development stage of the innovation pathway begins the official route to market. At this stage of the pathway, innovators must be able to prove the feasibility of their solution as well as present clear technical and scientific validation to begin developing a regulatory submission so that a CE mark can be considered. A compelling value proposition is also a key part of the development stage to attract market interest and begin the necessary groundwork for later reimbursement.

The 'randomised clinical trial' model associated with pharmaceuticals is often not appropriate for digital technologies when gathering evidence for their submissions, and real-world data are often more informative in supporting the value proposition of such solutions. There is a gap for digital health innovators in terms of standard evidential requirements and testing guidance specifically for this type of innovation – for example to set out quality and reproducibility standards. A clear definition and framework for the standards and requirements of evidence requirements for digital health solutions specifically would be beneficial.

At the earliest phase, innovators should also consider their future launch strategy including whether this should include markets beyond their immediate geography. Clinical studies should ideally be undertaken at an international, multicentre level to support wide adoption and meet different national requirements.

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 and understood at the beginning of the pathway. Innovators need a broad understanding of what 'value' looks like, how it is generated, and that it may differ depending on the stakeholder.

Making the case for CE

This stage of the innovation pathway represents market entry, whereby innovators can legally sell and market their solution. If deemed a medical device, compliance with regulations must be adhered to throughout the life cycle of the solution.

Innovators must also select the right route for regulatory review of their innovation. The new Medical Device Regulation (MDR) will see digital health solutions classified as medical devices, which will come into existence in May 2021. There are currently some concerns amongst the innovation community with regards to the MDR, such as the limited number of notified bodies, which presents challenges for smaller companies such as start-ups.

The process is also expected to be lengthy and costly, which presents further challenge for smaller companies who have limited funding and resources. There is concern that larger companies will have a clear advantage and support for smaller companies, such as education, to help them compete would be beneficial.

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

Adoption – gaining reimbursement and long-term use

Getting an innovation to the stage of regulatory approval is often considered the most important, and innovators may consider that this 'seal of approval' means adoption will inevitably follow. This, however, is not the case and innovators need to have a clear reimbursement strategy.

Within this a compelling value proposition to payers must be presented, as well as a demonstration that the innovation fits easily and seamlessly into existing workflows and processes. An innovation that disrupts current practice, or requires new systems, for example, is likely to face a difficult journey. Failure to properly address this phase will have a significant impact as health system cost and time pressures continue to increase. While the regulation phase of the pathway is fairly standardised in Europe, reimbursement varies by country, and in some cases, even by region or hospital.

In Belgium, the government decides which products and services get reimbursement whereas in the Netherlands there is an open payment scheme and payers (i.e. insurance companies) can decide if they want to fund innovations themselves. There is now a wide range of possible payers: insurance companies, local governments etc., so it is important for innovators to define, at an early stage, who will be funding their product or service.

Hospital budgets are often limited, which can limit the ability to invest in innovation due to the focus on treatment rather than assistive or preventative solutions which digital health solutions often fall into. Incentivisation is needed to facilitate the ability of reimburses to evaluate solutions based on value outcomes rather than the existing 'pay-per-service' model. Incentivisation of reimbursement reform towards value-based healthcare is a challenge shared across Europe, and requires significant political support if it is to become the norm.

The reimbursement process in Belgium is considered slow and in need of reform by innovators in order to keep pace with the rapid developments of the digital health sector. Hospital frameworks that provide access opportunities to innovators for gathering evidence in real-world patient populations would be beneficial in providing access for patients prior to completion of reimbursement decisions. In medicine, this has been achieved with 'compassionate or expanded use' programmes.

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Conclusions and recommendations for optimising the path to market for innovators in Belgium

The body of evidence collected during the Round Table Series, demonstrated that there are a number of key stages of the innovation pathway where improvements could be made to aid and speed up the route to market for promising digital health solutions. Recommendations presented included:

Facilitation of collaboration and co-creation

- **Ensure equal focus on clinical and user needs throughout the innovation pathway, with particular emphasis on the development stage**

  Innovators should be educated and supported in the early and continuous process of identifying, understanding and translating both the clinical need and the user need that their product or solution will meet.

- **Facilitate collaboration between innovators and HCPs in a forum that allows for conflicts of interest to be managed without impacting on the potential to gain crucial insight**

  In order to adequately meet the clinical need with their products and services, innovators need access to relevant HCPs in order to gather insights and create solutions that will integrate into their current processes, systems and behavioural norms.

- **Connect innovators with patients and citizens for end-to-end co-creation of products and solutions**

  Patients and citizens have a vital role to play throughout the innovation pathway, yet engagement with these audience differs between innovators. Guidance should be available to innovators, particularly those approaching the pathway for the first time such as start-ups, to demonstrate what a good co-creation strategy looks like and help connect start-ups with opportunities to engage with patients and citizens. processes, systems and behavioural norms.

Support innovators in producing evidence based products and in navigating regulatory procedures

Support innovators with guidance on the evidential requirements for their digital health solutions

Similar to 'good clinical practice' guidelines for the testing of medicines, 'good development practice' guidelines should be developed for digital health products and services to set out quality and reproducibility standards.

Provide support for smaller companies, such as start-ups, in navigating the MDR

Education and guidance should be provided to small companies, including start-ups, on what the MDR will mean for their existing and / or future products and services. This should include how they can navigate the process as efficiently as possible, and what to expect in terms of requirements, timings and outcomes.

Facilitate access to high quality data

Provide access to data for innovators and promote good data practices so that public trust (including privacy and transparency) are respected and protected

Innovators should be supported in accessing relevant existing big data sources such as biobanks to speed up the process of innovation and drive down inefficiencies. Education and guidance should also be provided to innovators to ensure that they are well prepared to address privacy, transparency and other concerns when it comes to patient and citizen data.

Support innovators in developing a viable market approach

Support innovators with development of value-based proposition to support with reimbursement and adoption

Support should be made available to innovators to help them navigate the reimbursement process and build a value case for their product or service. This begins with evidential requirements, but also includes payer mapping, cost effectiveness and navigating the transition towards value-based healthcare. In parallel, further discussion should take place with payers and policy makers about how to drive speed in the adoption of new approaches for the procurement of innovation so that we can move away from a 'pay-by-service' towards a 'pay-by-results' by model.

Appendices

Round Table Meeting agenda attendees

Host: EIT Health Belgium-Netherlands and Health House, Leuven

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

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