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EIT Health Think Tank

Optimising Innovation Pathways:
Future Proofing for Success

France Round Table Meeting

APRIL 2020

Executive summary

On one hand, the Medical Device market in France is valued at €20 billion and comprises more than 1,000 medical device manufacturers, 94% of which are small-to-medium enterprises (SMEs). The Digital Health market is a dynamic sector representing 30,000 jobs and a €3 billion market. (Source: The French Healthcare Industries and Technologies Strategic Committee, 2018). These figures show how important the medtech and digital health sectors are. However, the very large number of small start-ups that make them up also shows how their structuring is still in its infancy, and therefore the importance of supporting its development.

On the other hand, 81% percent of French people think that connected healthcare offers opportunities for better quality treatment, while 77% of people and 84% of doctors in France believe that it can lead to better prevention. Some 80% of patients with chronic illnesses are already using consumer connected devices to manage their health, e.g. smartphones (Source: Odoxa, Connected Healthcare Survey, 2018).

Several recent reforms, new legislation, and policy measures adopted by the French government with a view to modernising health and social care delivery shows that the French authorities are gradually becoming aware of the key challenges to modernise our health systems, namely the empowerment of patients and better management of their health data.

- **'Rapport Gagneaux'** proposes initiatives to improve the coherence of **eHealth governance**.
- **'Hôpital, patients, santé et territories' is responsible for the creation of ASIP, the French eHealth competence centre.**
- **The Government published France's National eHealth strategy in October 2016** which included the introduction and sharing of Electronic Health Records (EHR).
- **The National Health Data System (SNDS) was launched in April 2017** and is recognised as one of the world's most important medico-administrative databases. It is an integrated health database merging together data from several health databases, including information on healthcare consumption from statutory health insurance or data from long term care institutions. As such, it is an important asset that could provide a significant boost to innovation.
- **The French Health law 'Ma santé 2022' was adopted by Parliament in July 2019** and aims to establish a better-organised regional healthcare system, in particular to introduce new local healthcare structures. It promotes the development of digital healthcare including:
  - **Creation of a 'Health Data Hub'** thereby increasing the opportunities to use health data.
  - **Creation of 'Espace Numérique de Santé' (ENS)**, a digital health space for each patient.

The health crisis caused by the Covid-19 that we are experiencing shows that this awareness has now turned into an emergency to transform our innovation potential into impactful solutions for our European health systems. In this report you will find the recommendations proposed by our partners and stakeholders

Our sincere thanks to them and especially to Robert Picard and Juan Fernando Ramirez who accepted to moderate the debates.

Jean-Marc Bourez
Managing Director,
EIT Health France

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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 exponentially. 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. Paris, France was selected as the location for the French Round Table Meeting which took place on the 18th October 2019 and saw participation from key stakeholders involved in the innovation pathway in France including healthcare providers, innovators, and regulatory and reimbursement bodies.

Each host regional hub selected to focus on a choice of innovation type relevant to the local context – France 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 France to the rest of Europe. Although presented in a linear format in figure 1 below, it is in fact a continuous and 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.

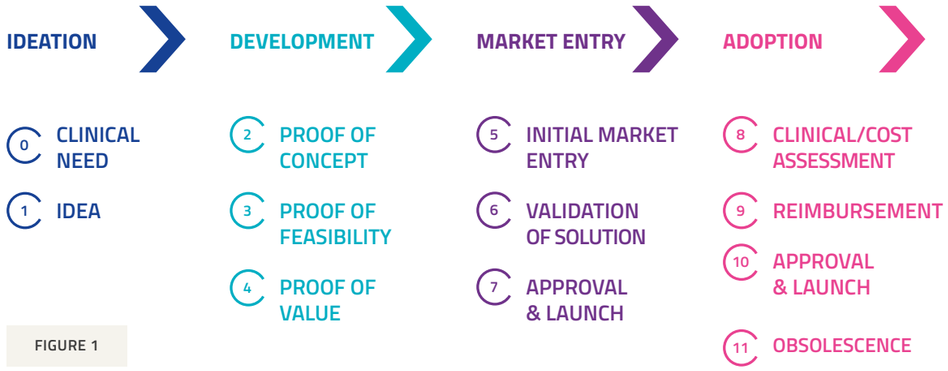

FIGURE 1

Ideation – grasping the ‘unmet need’

Defining the clinical need at the ideation stage 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.

Co-creation with multiple stakeholders (patients, citizens, healthcare providers) from the start of the process can help to ensure that the product or service fits the identified need and can be successfully deployed in its intended setting – this is likely to speed up adoption at a later stage. While these are crucial considerations, there are currently no standards for innovators to follow.

Additionally, support should be provided to enable researchers and academics in the ‘pre-innovation’ phase to connect with start-ups to help further develop their ideas. Industry involvement and investment in research is lacking, and there is need to develop ecosystems that allow risk sharing and knowledge sharing, with clarity regarding return on investment for all stakeholders. Economic and business models need to be considered and developed early, from the ideation phase.

We are experiencing a diversification of players now entering the healthcare space thanks to the boom in digital solutions. While historically, those developing healthcare solutions would be medical technology or pharmaceutical companies, we are increasingly seeing solutions developed by technology companies, who may not have the same knowledge and experience in healthcare. It is especially important for such innovators to gain extensive knowledge of those who will use or implement their product or service in order to create their value proposition, as well as determining how, where and when it will be used.

Regulatory requirements need to be considered even in the early ideation phase, otherwise barriers may arise further down the pathway. Innovators must anticipate and plan for eventual regulatory submission and it may require recruitment of team members with expertise in this area. There are a number of organisations in France already providing support to innovators in this space including the French Association of Medical Devices Companies (SNITEM) and the Tech4Health platform.

Any innovation must meet a clear unmet need or be a significant improvement on current methods.

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 and adoption.

The different types of digital health solutions – software, hardware, apps and services – all face different barriers to market entry. Traditional clinical trial methodologies may not be appropriate for some digital health solutions, and real-world data presents a key opportunity for constant monitoring of efficacy, safety and value. Methods for assessment of the 'value' of digital health solutions are the subject of considerable debate – further research and discussion is needed to determine how to capture the full value offered by digital health. New assessment methodologies are also needed for the evaluation of digital products and services that change or evolve over time. The use of modelling and in-silico testing, using virtual patients or healthcare settings should be considered to mitigate the lengthy timeframe for clinical trials and adoption testing. Test beds are also needed for the validation of digital tools, such as AI and algorithms, that will exist in complex systems. A good example that is in place in France is the HyAIAI Inria Project Lab, which has developed an artificial intelligence platform for the validation of algorithms for biomarker discovery.

Standardised protocols are needed for the management, sharing, access, and use of data derived from the wide range of digital devices, beyond what is required for regulatory assessment, and ownership rights need to be defined. A social model for data protection and privacy for citizens and patients should be incorporated as part of this in order to create an environment of trust alongside the General Data Protection Regulation (GDPR). Health data are now recognised as having an inherent value – regions outside of the EU are more advanced in their efforts to capitalise on this and set standards, so EU countries need to move quickly to define their own approach. The interoperability of data is also key in order for digital solutions to be successfully deployed in a wide range of healthcare settings, and therefore standards need to be developed.

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. This also includes the ecosystem in which the product or service will sit – a study may show feasibility within one setting, but this can change when scaled up to a larger system.

The new Medical Device Regulation (MDR) will see digital health solutions classified as medical devices, which will come into existence in May 2021. While there are currently some concerns amongst the innovation community, the MDR should be viewed as a positive opportunity for learning and education of stakeholders in all aspects of digital health (similar to the recent introduction of the GDPR), rather than just an obstacle. Clear guidelines about the new regulatory requirements are needed along with a central point of contact where innovators can go to get answers about what is needed.

The new regulations need to take into account assessment of integrated systems and services, not just individual products, and current guidance is not suitable or agile enough for the assessment of software-based solutions that evolve rapidly.

A more pragmatic approach is needed for the assessment of 'low-risk' digital health products and services, which could potentially reduce the timelines for assessment. This could, for example, apply to periodic software updates.

Once some of the initial concerns are resolved, such as the increased administrative burden for innovators, the new regulation is expected to clear up some of the current ambiguity around classification and evidential requirements which would have clear benefits. All stakeholders, including regulators, need to understand the concepts of digital health beyond regulation alone, and acquire new skills to deal with them. EIT Health could help facilitate such educational programmes.

Gaining investment to support the development stage of the pathway can present a challenge for innovators. Relationships with, and access to, suitable investors with experience in digital health should be improved, and crucial education about the stages, opportunities and benefits of investing in digital health solutions would be highly beneficial. EIT Health can help to facilitate access to finance for innovators for example via its investor network.

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 payors 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.

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. Consequently, innovators must have a clear understanding of how a solution is to be paid for (through which procurement mechanism) as well as who will have responsibility for paying for it.

In Europe, reimbursement processes can be considered as lengthy and represents a substantial risk to the company when compared with other markets such as the US. This is partly due to the fragmented payor authorities across Europe, which are often nationally and regionally focussed. Discussions should take place to determine how European countries could move towards agreed methods and standards that allow for products and services to approach adoption in an integrated way rather than being required to approach each national or regional payor individually. Sharing and exchange of information and evidence standards is needed amongst payers, administrators and healthcare managers internationally to ensure the adoption of innovations across borders

Training of patients, their care network and healthcare providers about any new digital health solution and its impact on them (e.g. quality of life, survival) and the healthcare system is vital to facilitating adoption. This can be important for patients and citizens who may be fearful of new technology and their capacity to use it.

Effective change management processes may also be needed within healthcare services to ensure providers understand the beneficial impact of innovations. They need to be aware of the workflow changes new solutions may bring and have economic incentives to use them, so there is less resistance to adoption.

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

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:

Facilitate collaboration between innovators and relevant stakeholders to support the development of needs-based innovation

Input from a diverse range of stakeholders is crucial to the development of new products and services in digital health, both in the early stages of ideation and throughout the whole pathway. A structure, process and adequate facilitation of co-creation is advised. For example, Living Labs – a network of Living Labs are already supported by EIT Health and is available via the Clinical Investigation Centre for Innovative Technology (CIC-IT) network.

Consider new ways of generating and presenting evidence to determine the full value of digital health solutions to facilitate the reimbursement and adoption phases of the pathway

Initiate discussions about how we can develop new methods for the assessment of the economic impact of innovations that acknowledges the preventative and assistive nature of digital health solutions and overcome the challenge that traditional measures of 'cost effectiveness' may not be fully appropriate. Promote information and education for the adoption of new technologies for all stakeholders, particularly end users. EIT Health can represent the health innovation community in discussions with policy makers by bringing opportunities, challenges and suggestions to the table for consideration.

Provide guidance and protocols for the management of health data generated by digital health solutions. Promote clear data standards within trust environments that support interoperability and accessibility, data sharing, and allow for real-time data collection and evidence generation

Initiate discussions about how we can develop new standardised protocols and guidance for innovators on the management, sharing, interoperability, ownership, access and use of data.

Support innovators in navigating the new Medical Device Regulations (MDR)

Provide guidance and training to innovators to enable them to navigate the changes that will be brought in as a result of the MDR in 2021. Initiate discussions with regulators on the appropriate approach for regulating iterative digital health solutions.

Link up innovators with appropriate investors in digital health

Facilitate access to, and relationship building, with investors open to digital health solutions.

Initiate discussions with payors and reimbursement bodies to overcome fragmentation across Europe

Reimbursement across Europe can be lengthy and difficult for innovators as procurement decisions are made on a national or regional level and therefore there is little chance that a product or service can easily gain reimbursement across Europe. Discussions should take place with payors to ascertain whether standards can be put in place to make it easier for innovators to access multiple markets.

Support and empower patients, their care network, and healthcare providers

Ensure they understand the impact of innovation, can contribute actively to innovation, and benefit from training.

Appendices

Round Table Meeting agenda attendees

Host: EIT Health France at Meridien Etoile, Paris

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

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