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EIT Health Think Tank

Optimising Innovation Pathways:
Future Proofing for Success

Spain Round Table Meeting

APRIL 2020

Executive summary

- The '2018 Consumer Survey on Digital Health' survey undertaken by Accenture found that 41% of the Spanish population uses a health application on their mobile phones or tablets. The most popular digital services are home-based services like blood tests, digital healthcare professionals, and digital nurses that monitor health status
- In terms of Health Technology Assessment (HTA), currently there are seven HTA agencies within Spain: six regional agencies and one in the national Instituto Carlos III. These agencies combined comprise the 'Spanish Network of HTA Agencies' with the Presidency of the Network rotating each year to one of the Agencies

Our sincere thanks to la Caixa Banking Foundation

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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. Madrid, Spain was selected as the location for the Spanish Round Table Meeting which took place on the 10th September 2019 and saw participation from key stakeholders involved in the innovation pathway in Spain 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 – Spain 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 Spain 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.

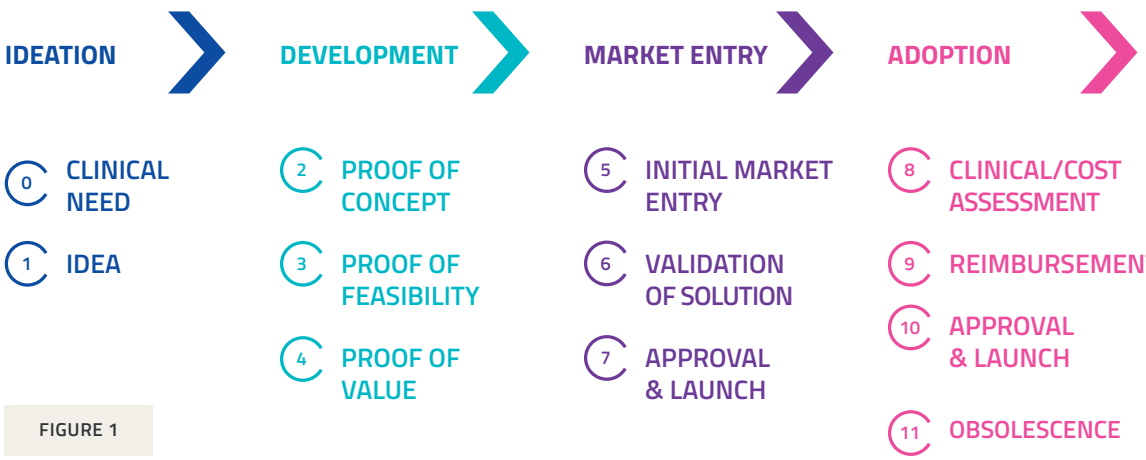

FIGURE 1

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. In order to denote feasibility, innovators must ensure that the full real-world impact of their solution has been fully considered – a solution that solves one problem, while creating others (such as interoperability issues) is unlikely to be adopted by healthcare providers. While these are crucial considerations, there are currently no standards to for innovators to follow.

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. Finally, the end beneficiary i.e. the patient or citizen who will ultimately benefit should be well understood.

Collaborating with the relevant stakeholders early, and throughout the innovation pathway will serve innovators well, and so mapping the key stakeholders at the very beginning is recommended. Creating a process to elicit feedback from such stakeholders will allow innovators to spend their time developing their solution and evidence based on invaluable insight. Co-creation is considered to be the 'gold standard' approach, and ensures that not only is feedback elicited sporadically, but that stakeholders are actively involved in the development of the product or service and are consulted at relevant milestones.

From the clinical perspective, strategic 'innovation teams' could form to represent stakeholders from hospitals and universities to facilitate the sharing of needs directly to innovators. This would enable a 'two-way street' to be facilitated whereby it is not only innovators engaging with clinical representatives to assess how their idea would work in practice, but also clinical representatives sharing their needs with innovators. A national strategy (taking into account the wider European ecosystem) that could provide guidance on where in the system innovation could help to address an existing or future challenge would be beneficial in concentrating the development of innovative solutions to be more in line with national priorities. Such strategies could be actively shared with innovators to drive the direction of the products or services they are developing. Validation units within hospitals that use recognised processes to test and assess new innovations, including their interoperability with other systems could also be considered within a national strategy. Such units could be used to assess new digital health technologies, as well as provide early access to patients within a controlled environment.

A further consideration in the co-creation or stakeholder engagement aspect of developing a new digital health product or service is the role of behavioural scientists. While there remains a lack of research around the value that is created by involving behavioural science in the development of innovative solutions, it is thought that such experts could provide valuable insight. As digital health solutions are often created to support those with long-term or chronic conditions, psychological and behavioural barriers are likely to exist which could impact the ability of the solution to achieve its optimal outcomes. As such, exploring such subjects as part of the co-creation strategy would be beneficial. Patient associations and groups could also play a vital role in identifying psychological or behavioural challenges patients are likely to experience.

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 technology solutions – software, hardware, apps and services – all face different barriers to market entry. The develop of guidelines outlining the evaluation, accreditation and standardisation of digital health technologies would be highly beneficial and an optimal environment for innovators would be created if such guidance were considered alongside evidential i.e. clinical trials requirements specifically for digital health solutions. 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.

Optimising and minimising the duration of each phase of the pathway is critical within the competitive environment. Various stages of the development stage of the pathway can and should be approached in parallel. Proof of concept, proof of feasibility and proof of value, for example, are interlinked. Aside from the technology of the innovation, it is important to have a scalable, safe and efficient design. 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.

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. Consensus is also lacking on how the efficacy and safety of digital health solutions should be appropriately evaluated and what methodology is suitable. Once resolved, the new regulation is expected to clear up some of the current ambiguity around classification and evidential requirements which would have clear benefits. However, conversely, many technologies that are currently in use will not meet the requirements of the new evaluation process.

Access to funding

Gaining investment to support the development stage of the pathway can present a challenge for innovators. There is a perception of a lack of trust and cooperation between healthcare innovators and investors.

It is also thought that there is a lack of business angels who are familiar with, and experienced, in the healthcare sector, in particular digital health, which limits opportunities to attract investment at early stages. The venture capital ecosystem is more mature but has a greater focus on biotechnology. Relationships with, and access to, suitable investors with experience in healthcare should be improved, and crucial education about the stages, opportunities and benefits of investing in digital health solutions would be highly beneficial.

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.

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. 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.

Existing reimbursement methodologies currently do not favour digital health solutions, which are often assistive or preventative in nature. While immediate cost efficacy calculation based on current methodologies may not be favourable, the longer-term impact of digital health solutions can be significant. We need to create new value-based reimbursement schemes suitable for digital health solutions to facilitate the ability to recognise and reward a wider view of cost efficacy. For example, if a digital health solution led to the prevention of a disease diagnosis altogether, how do we measure the cost savings of something that does not yet exist?

Neutral and objective training on new innovations is needed for end users so they can see the clear benefits of adoption and adherence. Patient Associations may play a key role in education and information about new products and services as well as directing patients and citizens to reliable resources. Healthcare professional must also be trained to assist in the use of new digital health products and services and concerns amongstthis group may exist around changing from current processes or perceived increased workload. Clinicians will want to understand the clear advantage and immediate impact of a new innovation.

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

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, and stakeholders will differ depending on the health condition or disease it is addressing. A structure and process for co-creation alongside such stakeholders should be developed so that a trusted, knowledge sharing environment can be created.

- **A strategic 'network of needs' should be established to allow for the evaluation and prioritisation of needs to be planned at national and international levels**

  A national network should be established of stakeholders such as clinicians, patient representatives, payers and policy makers to define the strategic needs of the nation and objectives when it comes to health innovation. This would facilitate a more directive involvement in the direction of travel for digital health solutions, which innovators could then respond to.

Better equip angel investors and venture capitalists to understand and invest in digital health solutions

Promote information and education for investors to understand the business models and development pathway for digital health innovations to ensure that it becomes an attractive prospect to investors who may have traditionally shied away from digital health.

Consider new ways of generating and presenting evidence of value for 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.

Provide clarity for innovators on the evidential requirements and regulatory pathway for digital health solutions, and advise regulators on new and appropriate approaches for digital health solutions

Initiate discussions with innovators and regulators on how regulatory requirements can be adapted to ensure smooth regulatory review of digital health products and services. New methodologies could be considered to enable continuous evidence collection and development afforded by the nature of digital health solutions, such as adaptive evaluation of product and services, with gradual market entry and continuous evidence collection and use of real-world data. Notified Bodies and other experts who have specific knowledge in the required area of digital health should also be considered.to help adequately assess the value of digital health solutions for healthcare systems.

Appendices

Round Table Meeting agenda attendees

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