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EIT Health Think Tank

Optimising Innovation Pathways: Future Proofing for Success

InnoStars Round Table Meeting

JANUARY 2020

Executive summary

- Portugal has approximately 200 companies distributing medical products largely comprised of small or medium-sized companies employing on average 15 to 60 people.
- The field of telemedicine is quite active in the public sector, which now has 20 years of telemedicine experience. Since 2006, following the consolidation of this practice, telemedicine services have been used inside the National Healthcare System and are reimbursed similarly to in-person services.
- In 2013, the National Health Ministry defined specific goals for using IT to increase the reach to the national healthcare system. The Administração Central do Sistema de Saúde I.P. (ACSS), as the public payer main agent, developed procedures to promote telemedicine, focusing on the areas of: Telemonitoring, comprising monitoring and screening devices to be used at home which provide information that medical staff can act upon); Real-Time TeleConsultation which aims to provide access to normal consultations with medical doctors overcoming geographical limitations; and Deferred TeleConsultation, where the material collected is subsequently reviewed by medical staff for screening purposes, such in the case of TeleRadiology or TeleDermatology.
- In October 2016, the Portuguese Government created the Centro Nacional de TeleSaúde (CNTS) as an entity to further promote the adoption of telemedicine inside the healthcare system.
- Recent report by Associação Portuguesa de Administradores Hospitalares and Glintt, from 2019, state that 87% of public hospitals are now using telemedicine (with higher representation of primary care facilities), however a lack of proper IT infrastructure (61%), lack of knowledge in telemedicine (53%) and low motivation for adoption by healthcare professionals (44%) are the main barriers to telemedicine use in the institutions surveyed.
- Our sincere thanks to Glintt to provide venue and logistical support for the event.

Balázs Fürjes, Managing Director, InnoStars

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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. Lisbon, Portugal was selected as the location for the InnoStars Round Table Meeting which took place on the 19th September 2019 and saw participation from key stakeholders involved in the innovation pathway in Portugal 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 – InnoStars selected telemedicine, which refers to digital solutions aimed at improving patient care remotely to extend the reach or automate the work of healthcare services.

In the EU, the new Medical Device Regulations (MDR) will extend the scope of Medical Device software. With it, many Telemedicine solutions which represent 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 Portugal 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 need, 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 produce or service.

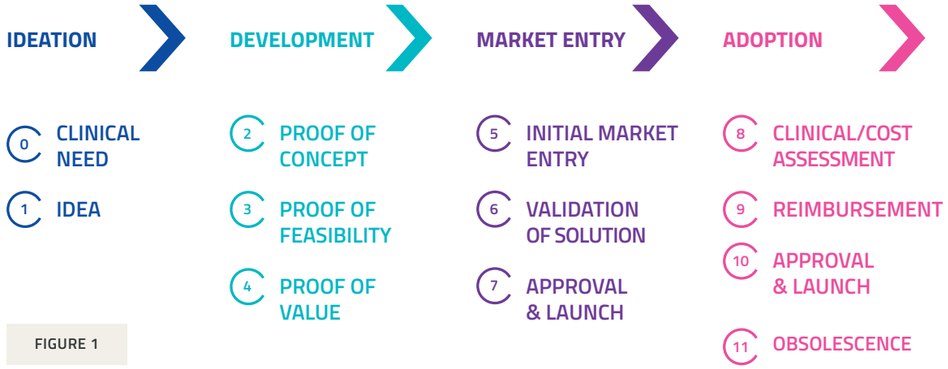

FIGURE 1

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. 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. Additionally, innovators in Portugal often struggle to connect with healthcare providers or clinicians to allow them to collaboratively define and test the clinical need. A firm understanding of all stakeholder needs including patients, clinicians and payers is equally important to the potential of the solution in achieving long-term success. Without this step, innovators will find the task of raising funds or investment to support their development particularly challenging as the market for their solution will remain unclear. 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.

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. Grants to support the development of the solution, and access to stakeholders so that the clinical unmet need, and design of co-creation development platform can be established are crucial to this stage in the pathway.

Development – gearing up for CE mark

At the early ideation phase, innovators should also consider their future launch strategy beyond their immediate geography. To launch in other European countries, further research will likely be required to determine clinical and stakeholder needs.

Portugal lacks access to large health datasets leaving the country at a disadvantage in terms of big data initiatives, algorithms and artificial intelligence. In addressing this, Portugal also needs to plan for the standardisation of methodologies to collect, store and share data, as well as defining governance models to address data privacy and ethical issues.

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 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. Innovators may lack access to experienced talent to support their regulatory strategy, particularly if they do not have heritage in the healthcare sector. Developing a regulatory submission, including the collection of evidence, is a substantial part of the process and one that cannot be spontaneously approached.

Approval and launch – making the case for CE

The market entry phase constitutes a key stage of the healthcare innovation pathway, given the regulatory oversight and evidence-driven industry. Innovators often need to satisfy a series of evidential requirements before market entry.

Innovators must also select the right route for regulatory review of their innovation, which can be a challenge, as definition of medical device is broad and still raises doubts when regarding digital tools.

Also relevant is the introduction of the new Medical Device Regulation (MDR), which would require for medical devices further requirements and clinical evidences, in particular to software-based ones.

This part of the pathway is heavily focussed on evidence collection, even if not required for market entry of a non-medical device innovation, and therefore significant financing is required to allow for robust clinical trials. A related challenge is considering the scalability of the evidence, as regulatory approval and reimbursement will be awarded based on the strength of the evidence.

In Portugal, planned clinical trials are submitted to Infarmed, I.P., as the National Competent Authority who should be notified, and to the National Ethics Committee for Clinical Research (CEIC), which grants the authorisation. In some cases, a designated CES - local ethics committee for health (based on the clinical centre) may be designated for the purpose. A favourable opinion is then required from the Competent Ethics Committee (CEC), which is usually issued within 30 working days. Without this, the trial cannot be conducted. In addition, high Class medical devices (Class III and implantable and long-term invasive devices falling within Class IIa or IIb), and additional authorisation from the Board of Infarmed is required within the same time frame. *(Reference: https://www.infarmed.pt/web/infarmed/entidades/dispositivos-medicos/investigacao-clinica-avaliacao-funcional/dm_meio_clinico_humano_adequado).*

Approval and launch

This stage represents market entry, whereby innovators can legally sell and market their solution.

If deemed a medical device, need to assure the continuous compliance with the appropriate regulations throughout the life cycle of the solution (namely ISO 13485 under CE Mark). If it is not deemed a medical device (for example wellness solutions addressing life style or outside clinical scope, such as health trackers, nutrition apps, communications tools, among other non-clinical related solutions…), innovators may already have started sales in previous steps of the pathway, however buyers often require substantial impact evidence. *(Reference: https://www.infarmed.pt/web/infarmed/entidades/dispositivos-medicos/registo-de-dm-e-div and https://www.infarmed.pt/web/infarmed/perguntas-frequentes-area-transversal/dm).*

Moreover, Portugal has specific body of norms and rules for the implementation of telemedicine services inside the Public Healthcare System, issued by the Minister of Health (i.e. Portaria n.º 567/2006, Portaria n.º 163/2013, Despacho n.º 3571/2013, Despacho n.º 8445/2014), Autoridade Central do Sistema de Saúde (ACSS) (i.e. as part of Termos de Referência para contratualização de cuidados de saúde no SNS para 2019), Ordem dos Médicos (reflected on their deontological code under CD-OM-2016) and by Direcção Geral de Saúde (i.e. Normas 005/2014, 004/2015, 005/2015 and 010/2015), which represent a framework focus on the develier inside the Public Healthcare system and subject to continuous update.

During this stage, particular attention must be given to the General Data Protection Regulation (GDPR), which sets out rules for the protection of individuals with respect the processing of personal data.

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 usage

Getting an innovation to be regulatory approved is often considered the most important stage, 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 go-to-market strategy, namely on distribution channels, pricing, procurements, and of course, in most of the cases reimbursement. 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.

Portuguese citizens are covered by the National Health Service (Sistema Nacional de Saúde – SNS). The SNS is managed by the government and the main stakeholder is Autoridade Central do Sistema de Saúde (ACSS), which manages the funding of the different health regions. However, the reimbursement process of products starts with the request to Infarmed and at this stage an effectiveness study, and a cost-effectiveness study against a relevant comparator will be required. However, today most Medical Devices are mostly delivered within the individual Hospital budgets and decision. SiNATS is the HTA national body, acting as part of Infarmed, which had its work include also Health Technologies comprising of Medical Devices since creation on 2015, supporting Hospital intake, and general reimbursement decision. The key challenge is to consider an effectiveness and cost assessment that becomes part of the technology life cycle, with reflects on its price and usage, in response to in real practice performance, no longer limited to market introductions, in line with a recent process that started in 2013, and led to the creation of SiNATS in 2015. *(Reference: https://www.infarmed.pt/web/infarmed/entidades/medicamentos-uso-humano/avaliacao-tecnologias-de-saude)*

Most Medical Devices products have a maximum price set by the Government agency, ACSS, based on a historical price comparison scheme, following the device coding defined by Infarmed for such technology, listing general product categories, where not always a Digital Health innovation may fit in (i.e. as defined on Health Minister Despacho n.º 1571-B/2016 and Circular Informativa Conjunta Nº 01/2016/ACSS/Infarmed/SPMS). A higher price can be considered alongside additional benefits presented as part of the effectiveness and cost-effectiveness study, namely on the introduction of first in the market products, under the scope of the previous mentioned mandated to Serviços Partilhados do Ministério da Saúde (SPMS). In many cases, hospitals have complete discretion about which technologies they choose to spend their budget on, regardless of a national reimbursement decision, which is the main driver for many service type solutions, which most Digital Health innovation offer. This means that in Telemecidine Hospital procurement is the main route for innovators to enter the market.

There is a clear need to support Portuguese innovators with this phase of the pathway, so that they can navigate complex and individualised processes, and ultimately scale their solution across hospitals, regions and countries. This is not only important for the return on investment for the innovator, but also for patient access equality across regions and countries. Linked to this is becoming standard of care once a solution has been successfully reimbursed. In order to change current practice and see the solution used with frequency and longevity, there must be continued evidence, education and support for reimbursement bodies, healthcare professionals and patients to determine the ongoing value of the technology based on real-world experience. Direcção Geral de Saúde (DGS) develops guidelines for clinical practice *(Reference: https://www.dgs.pt/normas-orientacoes-e-informacoes.aspx)*, which are regularly updated according to the latest scientific evidence. Medical Associations in Portugal also play an informal role in defining the best practices alongside the DGS and in clinical practice.

Conclusions and recommendations for optimising the path to market for Portuguese innovators

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 innovative solutions. Recommendations presented included:

Linking innovators with stakeholders for co-definition of need and co-creation

At the earlier stages of the pathway, barriers exist for innovators in accessing the clinical stakeholders and clinics required to test and define clinical need, which is a crucial first building block of a case for any health telemedicine solution.

Linked to this is also access to patients who may one day use the solution, so that patient need can be equally assessed, and depending upon the solution even co-created alongside the eventual users.

Developing big data access points for innovators

Further discussion should take place within the Portuguese health ecosystem to define and plan the development of health big data initiatives that can enable innovators to significantly strengthen the research base for their solution.

Investigate and highlight funding opportunities for innovators at the ideation phase of the pathway

Public funding is in large part the most likely route for innovators at this early stage in the pathway, yet the opportunities and processes can be considered confusing and convoluted. Innovators would benefit from a clear overview of the funding mechanisms available to them, and support in accessing such frameworks.

Additionally, introductions to private investors who are active in the investment of early stage health innovation would be highly beneficial.

Road-mapping regulatory and reimbursement routes and requirements

Providing clarity to innovators on regulatory and reimbursement routes to allow them to access the market would also be very beneficial, particularly in light of the changing regulatory environment.

This would drive much speed and efficiency amongst innovators allowing them to develop compelling evidence at the right time, and progress with appropriate routes to market for their solution.

Supporting Portuguese innovators to scale their solution

Helping innovators to focus on an international market access strategy from an early stage will have significant benefits for both the innovators and for the patients who may benefit. Training should be provided to promising innovators to support them in this area, as well as supporting them in making connections with clinics and key stakeholders outside of their national and regional environment.

Appendices

Round Table Meeting agenda attendees

Host: EIT Health Innostars and Glintt

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