Optimising Innovation Pathways: Future Proofing for Success

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EIT Health White Paper
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Think Tank Round Table series

THINK TANK

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Background

The European Institute of Innovation and Technology (EIT) is an independent body of the European Union set up in 2008, under Horizon 2020, to strengthen Europe's ability to innovate in a wide variety of disciplines. EIT Health, one of eight EIT Knowledge and Innovation Communities (KICs), brings together approximately 150 partners from leading organisations and institutions from academia, business, research and healthcare delivery to answer some of the biggest healthcare and ageing challenges facing our society today. EIT Health collaborates across disciplines, borders and sectors to accelerate and prepare the ground for the launch of transformative products and services, including bridging the gap between academia and enterprise to upskill professionals on new innovative techniques.

Each year, a topic that is high on the European health agenda is selected for deeper exploration in meetings that take place at Round Tables across the EIT Health regions, drawing on the experience, knowledge and skills of subject matter experts from EIT Health's broader community. The 2019 Think Thank Round Table Series focussed on *'Optimising Innovation Pathways: Future Proofing for Success'*. Through a dedicated programme of research, including a series of seven Round Tables in Member States (Belgium, France, Germany, Portugal, Spain, Sweden and the UK) and discussions with local innovators, it gathered on-the-ground insights into the practicalities of bringing a digital health solution from idea to market through the digital health innovation pathway in a real-world setting. The objective of the 2019 EIT Health Think Tank was to drive analysis and insight into the innovation pathways across multiple European regions and provide recommendations for removing barriers and speeding up the process of delivering innovations to patients and citizens.

Through the active engagement of relevant multidisciplinary experts, the 2019 Think Tank:

- Assessed the effectiveness of existing digital health innovation pathways in each relevant region, in order to understand the ability of innovators to move through the pathway, from idea generation to commercialisation.
- Identified key objectives that need to be met at each stage of the innovation pathway in order to expedite innovation and help improve the likelihood of a successful positive reimbursement decision leading to uptake and adoption of innovation.

- Agreed on a series of actions and recommendations to improve or streamline the innovation pathway where change could be feasible, applicable to a range of stakeholders across government, policy makers, regulators, payers, clinicians, patients etc.

  While the research programme was undertaken prior to the COVID-19 pandemic, the crisis underlined the urgent need for digital health innovation in Europe, and has brought to light some of the strengths and weaknesses of the current innovation pathway that the Think Tank identified. This White Paper synthesises some of the key recommendations suitable for action at EU level. It builds on the output of the Think Tank's research in order to address some of the main barriers that currently impede new innovations in making timely progress to market. In doing so, it suggests a number of actionable EU policy recommendations that could hasten and streamline the process of bringing digital health innovation to the European market.

Optimising Innovation Pathways

For some healthcare solutions, such as pharmaceutical products and traditional medical devices, the steps of the innovation pathway to bring a product from idea to market are relatively well defined. The regulation of the evolving field of digital health technology, which includes software-based solutions and emerging AI-driven devices, is however less well demarcated and is to some extent still in development. Furthermore, even when the regulatory and reimbursement processes have been navigated, innovators and other stakeholders developing digital health products can often face difficulties in achieving widespread adoption, due to local procurement barriers or other infrastructural challenges. Such barriers can delay impactful solutions from reaching patients and citizens at a time at when such innovation is sorely needed.

Focussing on these hurdles, the 2019 Think Tank identified five action areas where the European Union could work together, at Member State level and through EU level institutions, to ameliorate the innovation pathway to allow digital health products to come to market more quickly and with fewer challenges for innovators and the innovative organisations that wish to implement exciting new digital health solutions. They embrace the full innovation pathway, from fostering integration of new digital health solutions within healthcare organisations; developing new adaptive and continuous assessment models; reshaping incentives and business models; addressing certification challenges and making core changes in the organisation of European healthcare solutions markets to address market fragmentation.

1 Fostering integration

A digital health solution cannot be considered as a standalone product. Digital health solutions are mostly offered as a service, with technology embedded in an overall offer consisting of other products. It is impossible to consider, and especially to evaluate, a digital health technology without considering the different systems and users with which it interacts. This challenge is often labelled as one of interoperability, but it should be noted that this is not a matter of semantic and technical interoperability alone, but also of organisational and legal interoperability. The challenge is therefore to meet the full range of interoperability challenges set out in the refinement of the eHealth European Interoperability

Framework adopted by the European Commission's eHealth Network in 2015. [1] In doing so, action is needed on technical and semantic interoperability standards to ensure that data are accessible and useable across and between healthcare providers and systems; while on the organisational and legal level it is necessary to ensure compliance with legal requirements of privacy and security. These actions must be supported by targeted training to ensure that system procurers fully appreciate the interoperability needs and how they can be met.

Recommendations:

- **Drive semantic and technical interoperability** – the European Commission should work in close partnership with Member States to drive greater uptake of health data standards to ensure that data are FAIR – findable, accessible, interoperable and reusable. [2]
- **Drive operational and legal interoperability** – the European Commission should work in close partnership with the European Data Protection Board to reduce fragmentation on the interpretation of the GDPR across the EU, as identified in the Commission's recent GDPR review.
- **Education, training and support on data governance** – a key tool in making digital health tools FAIR and GDPR compliant could be EU level education, training and support to both end users and SME developers.
- **Interoperability requirements in public procurement** – insofar as the European Commission has the capacity to define core aspects of tender specifications, every effort should be made to use such normative capacity to require interoperability when public procurements for digital health solutions are undertaken.

2 Adapting and continuous assessment

Traditional health products, including pharmaceuticals, diagnostic devices or core digital tools such as Electronic Health Records, are 'finished' products when they are certified as fit for use. Many new digital health tools do not fit into this category, they are not 'final' when they enter into use, but are constantly updated and improved, often based on real-time user feedback. Software development allows for quick iteration of solutions, and what would be a timeframe of several months for traditional hardware devices, could represent a few days for newer digital health products. The existing innovation pathway is too slow to be useable

[1] eHealth European Interoperability Framework
[2] FAIR

for such product update cycles. This issue becomes all the more critical as AI tools that are self-learning are integrated into health and care solutions.

Reimbursement, procurement and adoption of innovation in the EU is increasingly supported by Health Technology Assessment (HTA) evaluations before reaching the market. However, the wider adoption of digital technologies is limited by a lack of evidence. Conversely, evidence generation is limited by a lack of wider adoption. Most existing evidence-generation methodologies, such as the gold-standard randomised clinical trials, are not fit for digital health technologies. Therefore, there is a need for a more adaptive and continuous assessment of such solutions, with a greater reliance on real-world evidence requiring earlier and staged access to the market and end users.

Digital health enables new ways of collecting and evaluating the evidence, as in most cases data are a key component of the solution. To enable a fundamental change in the innovation pathway to accommodate a more continuous and iterative development process suitable for digital health, there is the need to change to adaptive assessment frameworks, both at the regulatory and HTA level.

Recommendations:

- **Adapt HTA Regulation to the needs of digital solutions** – the European Commission should ensure that future EU level HTA legislative and other normative tools are fully adapted to the needs of digital health solutions, including self-learning solutions.
- **Develop harmonised evidence requirements** – in the context of HTA legislation development, the European Commission should support the development of shared and harmonised evidence requirements for digital health solution evaluation.
- **Support new models of risk sharing** – the European Commission should work closely with industry to support the development of new risk-sharing agreements, addressing long-term outcomes and economics.
- **Continuous evaluation** – the European Commission should work in close partnership with notified bodies to support continuous assessment systems for digital health solutions, similar to post-marketing pharmacovigilance, and where necessary, disinvestment of obsolete technology. This can help reassign valuable, and often scarce, resources to identify new needs and innovations.

3 Reshaping incentives to new business models

The nature of digital health technologies enables new practices of healthcare delivery which in turn demand new models of incentives and business models. Solutions in digital health are often built around real-time data collection and sharing, allowing for new business models based on the provision of healthcare anywhere, anytime. They also allow a focus on prevention and wellbeing, outcomes of which are hard to determine in the short-term. Digital health innovators are however often faced with hurdles when they develop solutions based on new business models, because stakeholders' systems have not yet been adapted to the business models proposed.

A particular stumbling block is the reliance of the reimbursement mechanisms of publicly governed healthcare systems on pay per-service or per-product models, rather than value-based or outcomes-based models. Although many systems are experimenting with such models now, the approach is still very cautious and is often useable only by large corporate players who can afford long lead times for return on investment in bringing new technologies to market.

Recommendations:

- **Investment in disease prevention and wellness innovation** – as the European Commission develops new funding streams such as EU4Health, Digital Europe and Horizon Europe, it should invest in supporting new models of care provision that favour disease prevention and wellbeing, as well as more traditional disease response-based models of healthcare.
- **Investment in development of risk sharing payment schemes** – as the European Commission develops new funding streams such as EU4Health, Digital Europe and Horizon Europe, it should support research into new models of risk sharing, including assessment of emerging good practices around Europe and wider afield.

4 Addressing certification issues

The new Medical Devices Regulation (MDR), due to enter into operation in 2021, requires software products to receive a certification by Notified Bodies, along with additional requirements with which products and companies need to comply. While much has been done in the past year to increase the capacity of Notified Bodies, concerns remain that time

to market will be slow as Notified Bodies struggle to meet the demands created by the new legislation.

While the expansion of the MDR to fully embrace software is seen as positive, it is also expected to create a delay in the rate at which new products and product versions will be able to enter the market. This demands new models for more streamlined certification, and also poses a particular challenge for start-ups and SMEs who may struggle to meet new evidential requirements following this reclassification. It is noted also that some grey areas of regulation still exist, notably for those digital technologies used in healthcare that do not have a clinical claim, and so may not fall under the new MDR.

Recommendations

- **Support MDR transition** – the European Commission should support Member States and notified bodies in the development of education and training materials to support a smooth transition into the application of the new Regulation, with particular attention to the specific issues and challenges faced by SMEs.
- **Update MDR guidelines** – new medical device guidelines should be developed to support clarification on classification of software medical devices
- **Adapt to integration with AI legislation** – as the European Commission moves to the adoption of legislation on the use of AI, special attention must be paid to the use of AI in healthcare solutions, including the potential of dedicated health sector specific AI legislation.

5 Addressing market fragmentation

Although stakeholders agree that there is an innovation pathway that follows similar stages, steps and principles in each country, the reality is that a significantly fragmented healthcare market persists for Digital Health. Innovators are faced with a vast set of different requirements and processes for reimbursement in order to achieve accessibility and sustainable adoption of solutions. There is lack of guidance and knowledge available regarding how best to navigate across the different regions, as most are still in the process of defining the rules and frameworks for the adoption of digital health technology. The result is that very few Digital Health innovations achieve significant market penetration beyond their home country, with many companies prioritising the larger and less complex US market, before expanding within the EU. Even within the same country, the specificity of digital health means that if the innovator does not consider several contexts during the development

phase, there is a risk of 'overfitting' of the solution to a particular context, meaning it may not work in another setting and ecosystem.

Recommendations:

- **Early stakeholder engagement** – the European Commission should explore the potential of developing new collaborative platforms that allow innovators more direct models for engagement with a wide range of stakeholders in early stages of product innovation.
- **Investment in procurement networks** – in order to help harmonise the EU market, the European Commission should continue to invest in pre-procurement initiatives to support EU-wide digital health solution development.

Conclusion

As the COVID-19 crisis has highlighted, Europe cannot afford to wait to adopt health innovation. The time to act is now; digital health is a key component of sustainable, accessible and equitable health and care in Europe. The regulatory frameworks to allow innovative products and services to come to market must be made more user-friendly for industry, addressing the full innovation cycle from initial development to implementation. Over the coming months, policymakers, regulators, healthcare systems and key stakeholders must work hand in hand with the innovation community to address some of the existing barriers and streamline the process of bringing digital health innovation to European citizens.