

2020



THINK<TANK<

Round Table Series: Recommendations

Future-proofing Europe's digital
health innovation pathway

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EUROPEAN
REPORT

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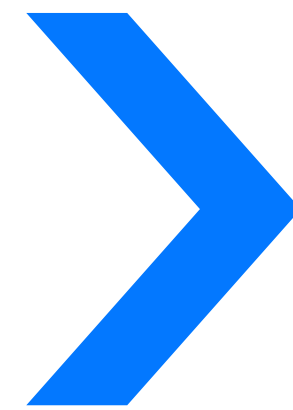
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THINK<TANK<



The purpose of the EIT Health Think Tank Round Table series



The EIT Health Think Tank is a forum of experts and thought leaders collaborating to shape the future of healthcare in Europe. This could ultimately ensure patients and citizens have access to healthcare innovations that could potentially transform outcomes.

Each year a topic high on the European health agenda is selected for deeper exploration in meetings, which take place at Round Tables across the EIT Health regions. These draw on the experience, knowledge and skills of experts from EIT Health's broader community.

These regional meetings focus on specific local needs, opportunities and barriers, while also identifying successful solutions and examples of best practice that could be replicated at a European level.

The Think Tank aims to ensure that expert recommendations are translated into realistic and meaningful outcomes, accelerating innovation in health for the benefit of all European citizens - so they are able to live longer, healthier lives.



Round Table series 2019 Overview



For the 2019 Think Tank Round Table Series, participants discussed the topic ‘Optimising Innovation Pathways: Future Proofing for Success’. The ‘innovation pathway’ describes the progress healthcare innovations make from a need and an idea to a product or service on the market that is adopted, or even becomes the standard of care.



For traditional medicinal products and devices, the steps of the innovation pathway in EU member states are relatively clear and well-defined. However, in recent years there has been rapid growth in a new sector: medical and health technology products, such as software or digital diagnostic tools.



The evolving landscape poses new challenges across the whole system. These include: product development, testing, generation of evidence, proof of value, implementation, usability and adoption of these novel medical and health technologies.



Innovators and other stakeholders developing these products can often face difficulties in achieving widespread adoption, due to local procurement barriers or other infrastructural challenges. Such barriers can delay potentially impactful solutions from reaching patients and citizens.



‘Optimising Innovation Pathways: Future Proofing for Success’ was chosen to address these challenges, as well as accelerate and streamline the sustainable adoption of innovations for the benefit of patients and citizens.





Round Table series process for 2019

Seven Round Tables were held across Europe in 2019 across Belgium, France, Germany, Portugal, Spain, Sweden and the UK.

Each meeting aimed to **identify, clear, actionable recommendations to improve the pathway process.**

Each EIT Health region was asked to select a specific innovation type as a focus for their Round Table based on the regional or national health innovation landscape – either hardware technologies, digital health or healthcare solutions. For the 2019 Round Table Series, all regions selected **digital health.**

For the purpose of the Round Tables, digital health was defined as **software-based solutions** that focus on healthcare interventions (related to patients' or users' health). These solutions are classified as:

- **Medical devices**, regardless of the kind of technology, if they have a medical indication (diagnostic, prevention, therapeutic, etc.).
- **Wellness products**, if they do not have a medical indication.

To provide additional context and background for the Round Table discussions in 2019, desk research was undertaken to examine the digital health ecosystem in each region, the current innovation pathway, key stages and gatekeepers, and the requirements that need to be met to move through the pathway.

To incorporate their perspective in the discussions, local innovators within the EIT Health Partner community, with experiences of navigating the pathway, were interviewed. This information was used to help map the existing pathway process, and provide insight into the practicalities of working through the pathway in the real-world setting.



To allow comparative analysis of the discussions and recommendations between regions, the Round Tables had a common agenda.

SESSION I

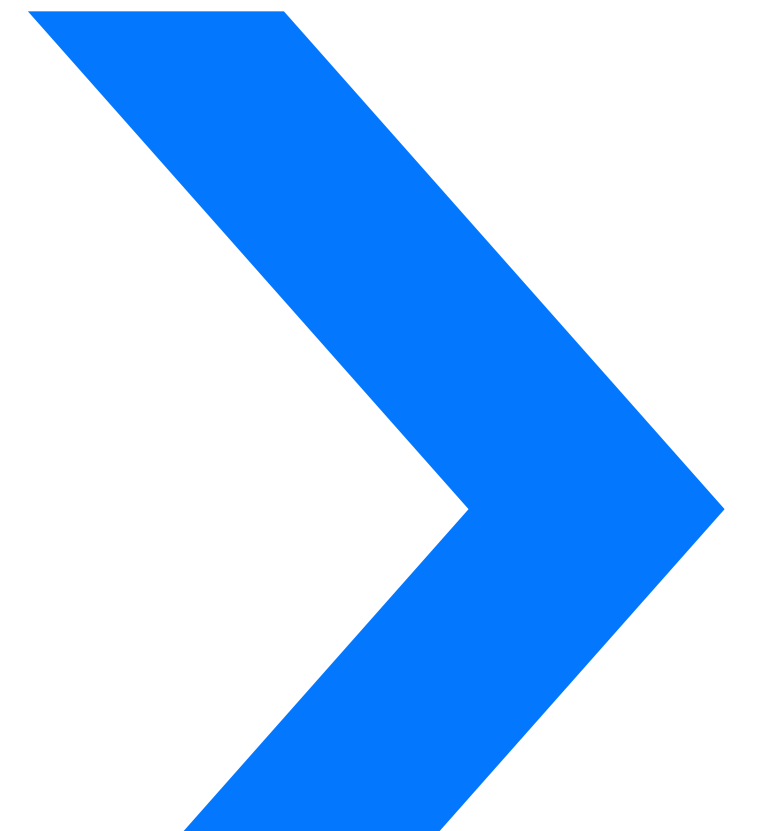
Based on EIT Health's research findings, the proposed description of the digital health innovation pathway in the region was reviewed and participants discussed whether it reflected today's reality.

SESSION II

The individual phases of the innovation pathway in the region were discussed and suggestions made for how these could be optimised; best practices in each phase were identified.

SESSION III

A list of proposals for actionable recommendations for each of the pathway phases was developed, identifying key stakeholders where possible.



Round Table meeting feedback

MAPPING THE CURRENT INNOVATION PATHWAY FOR DIGITAL HEALTH

1. Developing a proposed innovation pathway framework for digital health

In healthcare, the best-known pathway is for pharmaceuticals. This particular pathway is characterised by regulatory and cost-effectiveness assessment or reimbursement approval, along with several phases of development and clinical trials, before entry to market. Other health technologies, such as digital health technologies, share a comparable regulated environment. Pathways for these innovations are also assumed to follow similar milestones, progressing from an idea until a product or solution becomes widely adopted by the market.

Based on the desk research, a proposed innovation pathway for digital health was developed for discussion at the Round Tables. The pathway took into account where certain additional milestones are relevant, such as assessments of the impact on healthcare budgets or cost-effectiveness.

The resulting framework is a genericised pathway to develop innovations in the digital health field; starting with the clinical need and idea, progressing through development, market entry, and eventually adoption (Figure 1).

Although often considered a linear path towards successful and sustainable adoption of the innovation, it is in fact a continuous (often reiterative) and cyclical pathway, where certain steps can be revisited or repeated to support continuous research and development, and the design and development of new innovations.

FIGURE 1



FIGURE 1. (ON PREVIOUS PAGE)

The Innovation Pathway as presented at the Round Table Meetings

Although the development of innovation in healthcare faces the same challenges as other high-technology innovation areas, the complexity of the stakeholders involved, the regulatory barriers to market entry and the complex processes associated with market adoption create a shared pathway which innovators must navigate.



This often involves passing three ‘Valleys of Death’ or ‘Desert Crossings’ for innovations – points at which a new idea going through the pathway may fail to progress. These work as either gateways or major barriers:

INNOVATION VIABILITY

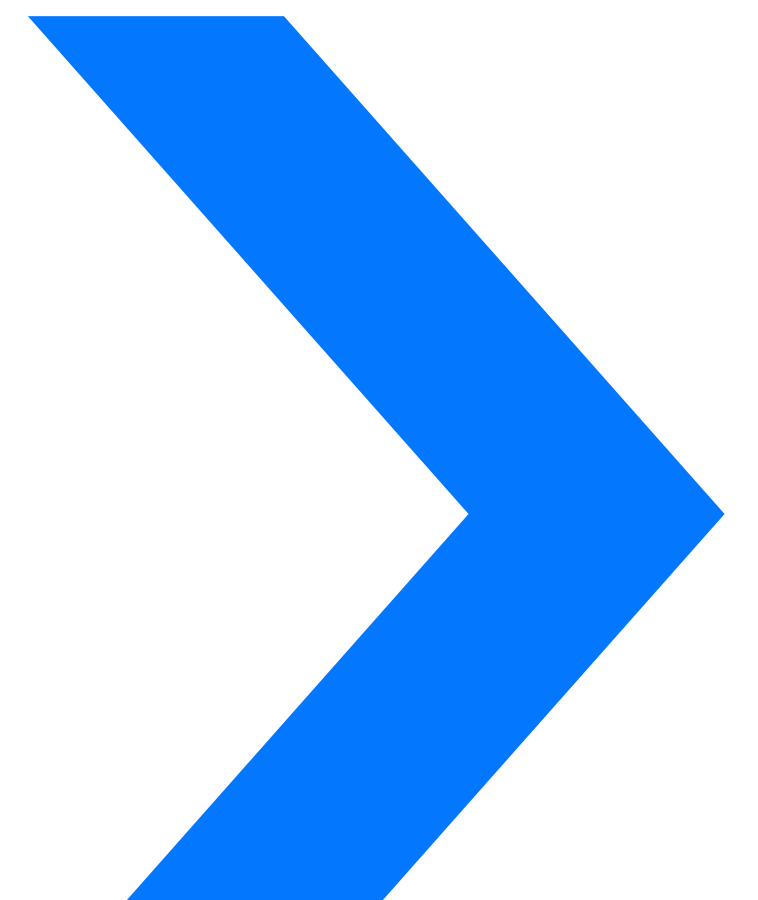
Do you have the required resources and can you make an assessment of whether it is both commercially viable and sustainable?

MARKET APPROVAL

Do you have the ability to scale-up the product and meet requirements from regulators?

MARKET ADOPTION

Will your product be used and adopted in the clinical setting? Will it be reimbursed/procured by those who purchase healthcare (ie ‘payors’)?

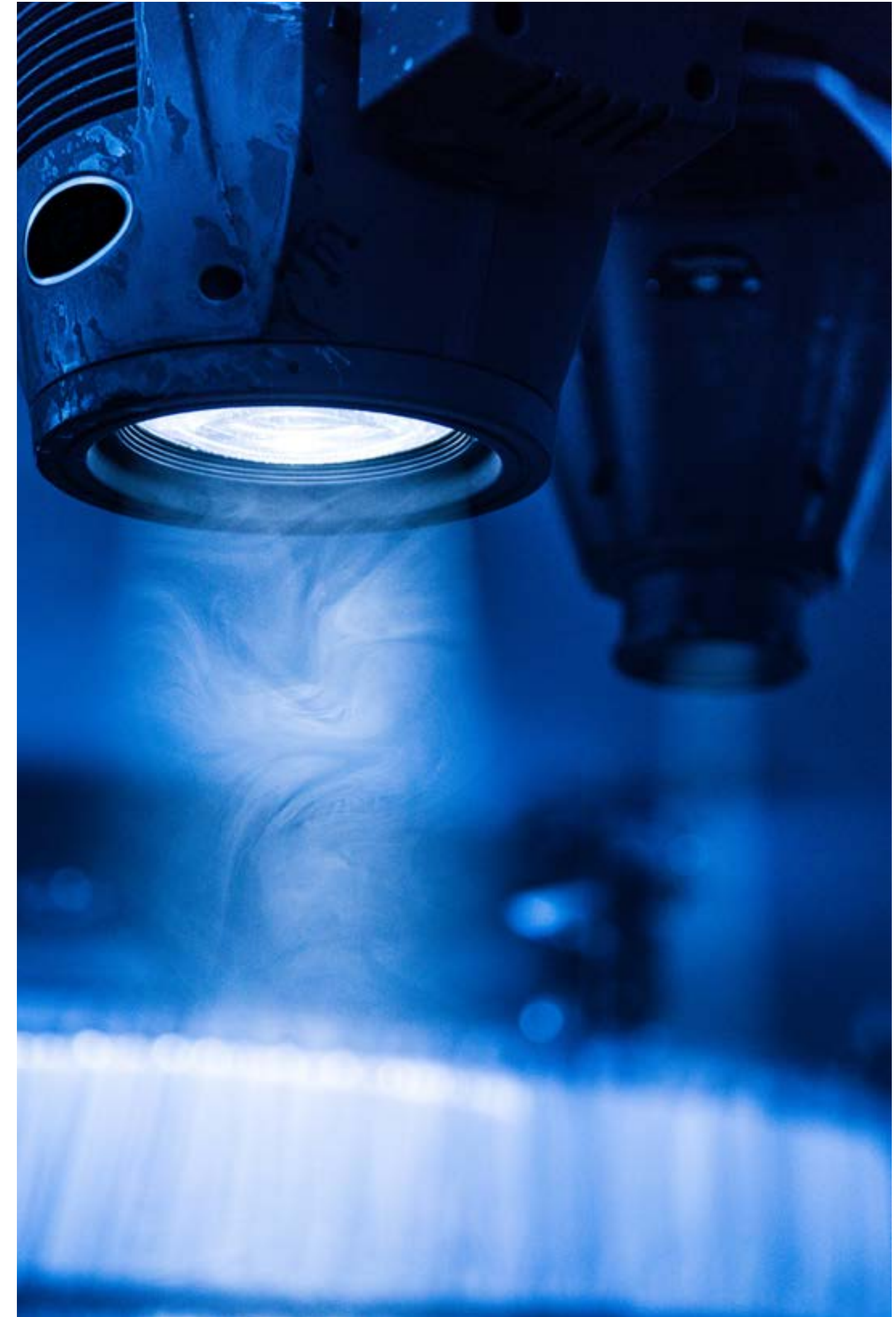


IDEATION – GRASPING THE UNMET NEED

The ideation phase relates to when the innovation is being created. At this time, innovators must be able to articulate a clear potential solution to an existing problem, which addresses current shortcomings (an unmet need or a limited existing solution). Innovators must also contribute to new approaches to healthcare.

The innovation should result from a specific identified or validated unmet need by healthcare professionals, patients or citizens. The key question innovators must answer in this phase is:

- › **Does my technology help solve an identified clinical need?**



DEVELOPMENT – DE-RISKING TOWARDS THE MARKET

The development phase is vital to take the idea, or initial prototype of the innovation, into a product that can be made available to users. This is the phase for thinking about what resources are needed to move it forward into the market.

The development phase is also the time to align with other relevant stakeholders, avoiding later failures which could have been dealt with earlier in the pathway (either by addressing them early on, or by pivoting to other ideas due to new insights or priorities).

This is a phase common to all innovators, regardless of their geographical location. The main differences between countries are the supporting resources available, and existing networks to reach out to all stakeholders. The critical question innovators must answer in this phase is:

> Do I believe the product can be taken into the market in a viable way?

MARKET ENTRY – VALIDATION OF GATEKEEPERS' REQUIREMENTS

The market entry phase is about being able to deliver the innovation in a scalable way, while maintaining quality, and generating and collecting supporting evidence for the market. This is a key stage of the pathway, given the oversight from regulatory bodies and the requirement of the right evidence that demonstrates the product works and is safe.

Wellness products do not need any additional approval to start selling, but medical devices require marketing authorisation before any commercial activity. Increasingly, even non-medical devices may now be required to collect impact evidence.

At this stage, innovators need to have the required regulatory pathway confirmed, as many innovations can fit into one or other category, depending on product claims and function. What evidence needs to be collected depends on how the digital health solution is categorised. This dictates whether healthcare systems will pay for it and make it available.

Given the increasing costs of compliant clinical trials, regulatory filings, or engaging with partners, the development phase is critical to avoid unnecessary changes and failures. The key question innovators must answer in this phase is:

- › **Can I scale delivery while assuring quality and safety? What evidence do I need to meet regulators' and the target stakeholders' requirements?**



ADOPTION – GAINING ACCESS, BUSINESS SUSTAINABILITY AND WIDER DISSEMINATION

Adoption has become one of the main challenges for innovators today. Meeting regulatory requirements, then reimbursement, followed by adoption is no longer a valid expectation. Demonstrating the product has value is now more complex, while reimbursement or procurement is pressured by budget constraints in healthcare systems, and there is an increasing need for evidence of economic and other impacts on healthcare beyond typical effectiveness and safety requirements.

While medical device regulation is uniform across Europe, adoption of innovation depends on regional ecosystems and frameworks, which create the need for innovators to address this region-by-region.

Moreover, innovators face different requirements, and often different stakeholder needs, which may limit diffusion and scale beyond initial markets. The critical question innovators must be able to answer when entering this phase is:

- > What evidence about innovation usage and impact do I need more of, so the product will be used in the clinical setting and I can be sure it will be paid for?**

2. Testing the reality of the proposed innovation pathway for digital health

Before discussing how best to optimise the innovation pathway for digital health technologies, the proposed pathway description was discussed within each Round Table Meeting, in order to review and validate how it reflects the current reality for digital health innovation in each participating country.



The general feedback resulting from this was:

- Innovation in digital health requires looking beyond the immediate clinical need as a starting point.
- Stakeholder diversity and new health approaches enable a wider focus on areas including wellbeing, prevention, home healthcare.
- These areas extend beyond the more traditional treatment-focused innovation and so require consideration of different user and system needs.
- During the ideation and development stages, issues such as usability, interoperability and integration become more relevant in digital health, which must embrace a wider spectrum of stakeholders' perspectives and involvement beyond the technical and clinical aspects of the technology.
- A wider co-creation process is needed with input and perspective from patients and citizens, as well as experts in humanistic sciences, such as anthropology, to get broader insights on other dimensions of human life.
- The addition of those with commercial or investment experiences at this earlier stage would also help strengthen the development of an appropriate business plan, enhancing prospective commercial success.
- A stepwise, linear representation of the pathway does not reflect the need to take all phases of the pathway into account from the start.
- Later phases, such as those impacting market entry and adoption, need to be considered from the beginning of the process.
- The 'Valleys of Death' were important parts of the pathway where innovations were informally or formally filtered to identify the most promising and viable.
- This is key to allow resources to be focused on innovation solutions with the greatest potential for impact. Innovators can learn from failure and take forward solutions that hold the greatest promise.

Due to the fact that digital health technologies are still in their infancy and evolving, the proposed innovation pathway faces specific challenges in different phases and will therefore require adaptation to reflect the new paradigm. As a result, many of the requirements and specific steps are still being defined among the various stakeholders – and there is clear need for improvement.

FIGURE 2

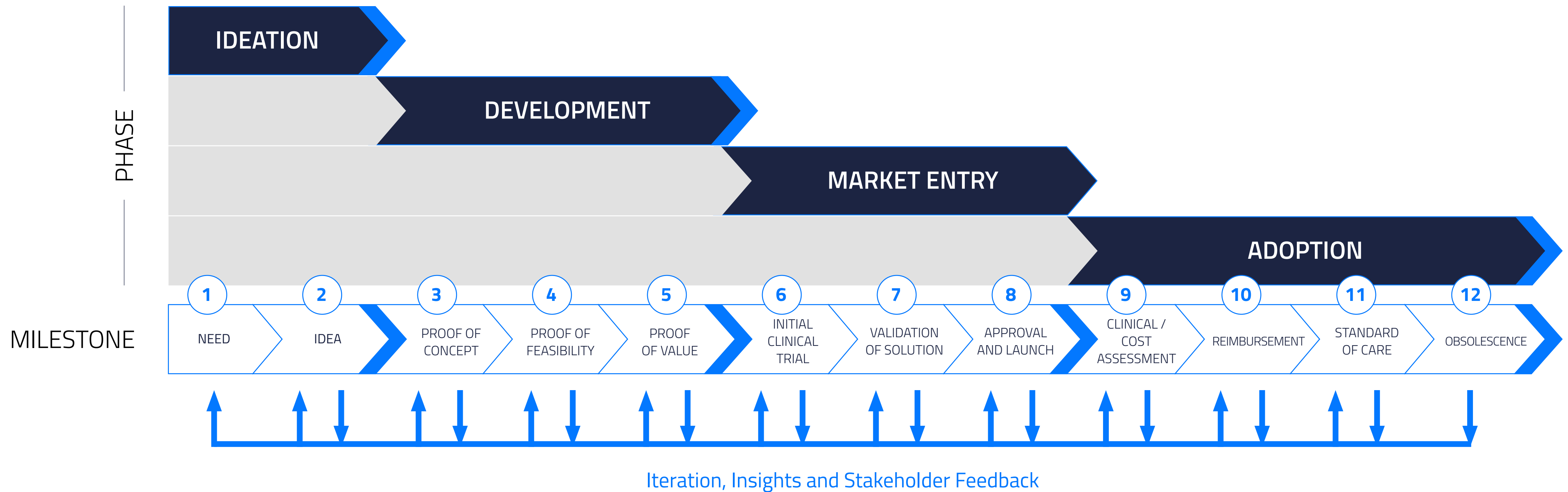




FIGURE 2. (ON PREVIOUS PAGE)

Proposed improvement – The current innovation pathway showing multiple points of stakeholder involvement along the pathway, with later milestones considered early, and a clear iterative process, both within and between phases, as innovations may need to be reviewed as they fail to pass later milestones.

Digital health innovation pathway challenges

Digital health technology represents a new subset of health technologies that are very different to the kinds of innovations in the medical device sector that stakeholders are used to working with. Differences in the development, business and deployment of solutions underline the need to look at the digital health innovation pathway within a much more integrated, agile and iterative framework.

Integrated services

It is impossible to consider, and especially to evaluate, a digital health technology without considering the different system and users it needs to interact with. Interoperability was cited as a major issue in the majority of the cases when developing digital health solutions, as it varies for each implementation context - for example, with different electronic health record vendors, different digital data interchange protocols, etc.

Also, a digital health solution can no longer be considered as a standalone product that can be simply distributed and used independently. Digital health solutions are mostly offered as a service, with technology embedded in an overall offer consisting of other products. The service often requires extensive support, and is heavily dependent on its usage (both by citizens and healthcare professionals). How impactful they are in terms of outcomes depend on the implementation context and usage in the real-world setting and the need for iteration, which often means going back to the development phase to start all over again. 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.

Shorter development cycles

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 in digital health. Software development in other sectors outside healthcare is itself moving to quicker iterations and continuous release of updates. This poses a challenge for development within the regulatory constraints of the healthcare technologies pathway.

Firstly, the existing pathway is considered too slow compared with the pace at which a product is updated. When a certain version manages to navigate the multiple evaluation steps and reaches the users, it is already outdated, as the process can take several months to several years, depending on the clinical evidence required and the expedition in the process.

Secondly, the existing pathway considers products as final versions that result from a development process. This doesn't take account of the dynamic and iterative scope of developing digital tools, requiring continuous testing and adjustments. Plus, real-world usage feedback is what drives the need for iteration, which often means going back to the development phase to start all over again. 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.

New business models

One of the main challenges is the assumption that digital innovations will fit into existing practices. The nature of digital health technologies enables and requires new practices in how healthcare is delivered and paid for.

Solutions in digital health are often built around real-time data collection and sharing, allowing for new business models around data and for 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 often faced with hurdles to introduce new business models, mainly because stakeholders rely on an incentives structure which needs to be updated to encompass digital technologies.

A key topic at this level is the need to move beyond a pay per-service model, which is still prevalent in many healthcare systems, to value-based healthcare, which requires new payments schemes.



The new EU Medical Device Regulation (MDR)

This is expected in 2020, or early 2021, reflecting a clear need for a strong and clear regulatory framework for digital health technologies. It is critical to guarantee that technologies reaching people are safe and deliver on the outcomes they intend to. Moreover, CE Mark certification is key to securing the necessary recognition by users and other stakeholders, leading to the successful uptake of the innovation.

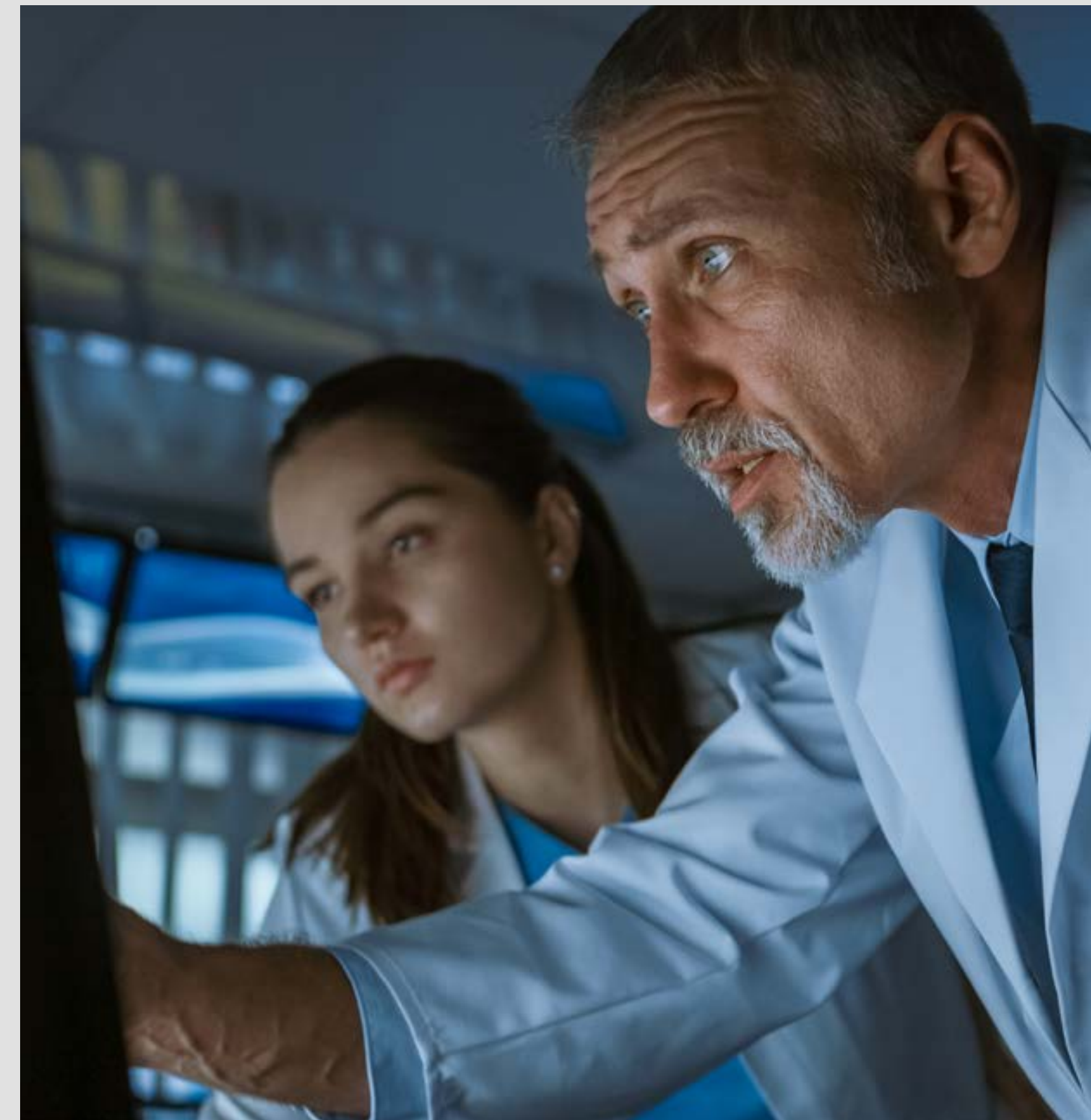
The MDR has introduced strict clinical evidence requirements for most products, and moved all software to at least Class II (medium/high risk devices), while previously several were classified as Class I (low to medium risk). Class II devices require certification by notified bodies (responsible for assessing medical devices) and additional requirements that products and companies need to comply with.

There are concerns whether notified bodies will be able to undertake all necessary evaluations for existing and new products. Lack of capacity is likely to have a significant impact on innovations developed by small and medium-sized companies, as they will find it more difficult to engage with the Notified Bodies. Another key factor is the level of preparedness and lack of clarity by the various national competent authorities to deal and support the MDR process and offer advice on the new MDR requirements.

There is concern that existing solutions on the market may need to be withdrawn, but much remains uncertain.

However, if digital technologies in health do not have a clinical claim, they may not fall under the new MDR. This information is often a 'grey area' in prevention or healthcare delivery as it can be difficult to make a distinction between different technologies. This could mean two quite similar digital solutions have completely different regulatory oversight and requirements.

As a result, the pathway for innovators is expected to become slower, and the additional requirements are likely to create a delay in the rate at which new versions will be able to enter the market.



Across the different geographies, the innovation pathway follows similar stages, steps and principles but the reality is that, for digital health, the EU is a significantly fragmented healthcare market.

Unified EU regulation (CE Mark)

Up to market entry, innovators face a quite similar pathway, as gatekeepers and most regulations are defined at the EU level.

Despite the intentions of the CE Mark to facilitate access for medical devices in all EU markets, adoption in healthcare is still dependent on local stakeholders. Most countries across the EU have a dominant public healthcare system (or statutory health insurance). This is key to the widespread uptake of an innovation, since it depends on securing reimbursement or on complex procurement processes. As a result, market access within the EU was highlighted as a major challenge, with few digital health innovations truly spreading beyond their home country. Many companies prioritised the larger and less complex US market, before expanding within the EU.

Localisation of products

Launching a digital health innovation in other markets beyond the country of origin may require significant changes to the product. These changes go beyond language translation, since national healthcare systems are often organised differently, and different users play an important role. Consequently, business models and go-to-market strategies often need to be adapted. Each market may require further evidence and revalidation. 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.



28+ Healthcare systems

The practice, rules and procedures surrounding healthcare vary significantly throughout the 28 EU member states, but also within national regions, and often among institutions. Innovators are faced with a vast set of different requirements and processes for reimbursement in order to achieve sustainable adoption. 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.

As innovations in digital health technology offer more complex and integrated services, their success is increasingly dependent on the engagement of stakeholders from the beginning of the process.

User needs-led innovation

Digital health innovation should address system needs (not just clinical needs) from the start.

Evidence generation to meet intended outcomes is key for adoption (reimbursement and recommendation) beyond that required for market entry, but it is a major challenge. Digital health enables new ways of collecting and evaluating the evidence, as in most cases, data is a key component of the solution.

Health Technology Assessment (HTA)

Reimbursement, procurement and adoption of innovation in the EU is increasingly supported by 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.

New real-world assessment methods

Most existing evidence-generation methodologies, such as the gold-standard randomised clinical trials, are not fit for digital health technologies. This is because users, for example, play such a significant role in the outcomes. Digital health products require new methods that also allow continuous assessment of effectiveness and cost implications in real-world settings - the primary source of relevant evidence.

Harmonised evidence requirements

There is a need to increase the predictability and clarity of requirements across countries or regions, while taking context specificities into account.

Digital health innovation needs to be accommodated within a working ecosystem that requires preparation and change management.

Reshaping incentives to new business models

The scope of the changes needed to accommodate these new paradigms implies that all relevant stakeholders, and not just the innovators themselves (who have limited resources), also need to create the necessary conditions for the successful uptake of solutions. Effective change management is a key aspect of the adoption process.

However, the support for change management inside institutions is lacking in most cases, as innovation adoption is not considered as part (or only a limited part) of the day-to-day activities of healthcare institutions in the countries surveyed.

Prevention and long-term healthcare

Another challenge is how digital health can enable new business models to support investment in prevention and long-term outcomes within healthcare systems. However, limited access restricts the generation of the evidence needed to sustain this fundamental change from disease management towards health management.

Dominant mainstream public pathway

Public reimbursement or procurement is the only sustainable way of entering the market for digital solutions. Wider adoption is often limited by the need to fit the reimbursement mechanisms of publicly-governed healthcare systems. Healthcare systems must proactively prepare for the necessary changes to deliver on its potential impact in healthcare.

How the innovation pathway for digital health varies between countries

In the following analysis it is important to bear in mind that if a topic was not highlighted during a particular Round Table, it does not necessarily mean that the country does not have relevant activities, frameworks, and stakeholders which mitigate, or would fit, the challenges and opportunities identified.



In 2019, specific positive initiatives have included new laws focussing on health innovation and the publication of important guidelines to drive digital health. The level of governmental strategy for digital health innovation in the surveyed countries can be categorised as follows:

- **Comprehensive innovation supporting frameworks for digital health**
Germany (new laws), France (new laws), Sweden (clear governmental strategy).
- **General innovation supporting frameworks for digital health**
UK (NHS and NICE with active roles in creating innovation frameworks for digital health), Belgium (implementation of some initiatives to foster digital health are ongoing, initiated by the previous Health Ministry).
- **No innovation supporting framework**
Portugal (strategy only within public innovation initiatives), Spain (policies mainly defined at the regional government level, but without coordinated or strategic efforts to drive Digital Health innovation).

The Round Table was also an opportunity to evaluate the scope and focus on different topics across the seven countries within the EU, to identify those that were similar across most, and those where relevant differences were found. The analysis that follows summarises this information, building on the pathway challenges discussed in the previous section, and aiming to identify opportunities for optimisation explored in the subsequent sections of this report. The discussion topics are grouped around each phase of the pathway, reflecting the order in which they were discussed at the Round Tables.

TOPICS	<input type="checkbox"/> Optimisation opportunity <input type="checkbox"/> Positive landscape	Spain	Portugal	UK	Sweden	Germany	France	Belgium
	Needs Assessment							
Systematic and strategic needs assessment within healthcare systems		∨	∨	∨	∨	∨	∨	∨
Integration of health and social care systems			∨					
Engagement of patient organisations on needs-driven innovation (helps shape the innovation priorities within their healthcare systems)							∨	∨
Co-creation								
Diversity of stakeholders and scientific disciplines in co-creation		∨	∨	∨			∨	
Trust in collaboration among stakeholders		∨			∨	∨	∨	∨
Access to end-users within clinical settings		∨	∨	∨			∨	∨
Reach to key stakeholders and decision makers		∨						
Innovation education for health professionals						∨		
Innovation Pathway Awareness								
Pathway education for innovators			∨	∨	∨	∨		
Clarity and transparency on value expectations and requirements along the pathway		∨		∨		∨		
Early dialogue and advice from gatekeepers				∨				
Regional barriers for innovators					∨			
International barriers for innovators					∨			
Innovation Incentives/Constraints								
Knowledge transfer from research			∨		∨			
Health insurers competing for innovation						∧		
Health funds/insurers as innovation investors						∧		∨
Legal and ethical frameworks for medical liability for automated devices						∨		
Relevant large health datasets to be used for innovation			∨		∧			

IDEATION



The topics raised about awareness of the innovation pathway found that the differences between each country are likely to result from the different experience and perceptions of the Round Table participants. For some, the impact of such knowledge is already key at the point of selecting ideas to address needs. For others, the impact of understanding the pathway that needs to be taken only comes later when the innovator is looking to bring it to the market; namely, the required steps and validation from development onwards.



At the ecosystem level, the specifics of the healthcare system in Germany were noted, where funding from private and competing insurers drives innovation. In contrast, most other countries have some form of single, public payor decision-maker (regardless of whether it is at the national or a regional level). Also, of note in Germany is the influence clinicians have in the decision to use an innovation or not, often driven by concerns about medical practice liability.



The Round Table discussions provided a better understanding of the role of health data as a fuel for innovation. Sweden seems to have a high capacity to explore its wealth of data banks, however Portugal currently appears to be lacking the capacity to use such data to drive innovators.

TOPICS	<input checked="" type="checkbox"/> Optimisation opportunity <input type="checkbox"/> Positive landscape	Spain	Portugal	UK	Sweden	Germany	France	Belgium
	Facilitation of Iterative Development and De-risking							
Proactive and independent testing, evaluation and failure culture inside and outside of innovation projects		∨	∨			∨	∨	∨
Sharing of learning about innovation testing and support				∨	∨			
Support for academics to leave academia to test innovation businesses			∨					
Accommodate smaller testing and iteration			∨	∨			∨	
Validation of Business Models and Innovation in Real-World Settings								
Testing in real-world settings		∨					∨	∨
Implementation and procurement/reimbursement entry and support channels for innovation in healthcare systems		∨	∨	∨	∨		∨	∨
Investment and Funding								
Familiarity of early-stage investors (i.e. business angels) with the specific requirements of digital health		∨		∨		∨		
Experience of investors as digital health entrepreneurs		∨						
Adequate and solid digital health business models for investors						∨		
Awareness of funding and supporting tools for innovation			∨					
Funding to support technical development			∨			∧		
Funding to support non-technical development and commercialisation		∨			∨	∨	∨	
Getting Ready to Enter the Market and Scale								
Good development and clinical practices for digital health		∨						∨
Awareness of stakeholders' value expectations and requirements			∨				∨	
Clarity on evaluation and assessment methods			∨	∨			∨	
Early dialogue and advice from gatekeepers				∨			∨	
Early procurement/reimbursement engagement					∨	∨		∨
Ensure innovation scalability nationally and internationally				∨				
Pathway guidance for innovators					∨		∨	
Change management considerations and preparation			∨		∨		∨	
Health Data								
Harmonisation and integration of health data platforms nationally					∨	∨	∨	
Health data governance and utilisation					∨	∨	∨	
Pre-competitive Collaboration								
Better assessment methods to determine digital health innovation impact					∨			
Agile collaboration between industry with other smaller companies and academia					∨			∨
Engagement and investment of industry at early stages							∨	
Risk-sharing of development by industry and healthcare institutions					∨		∨	

DEVELOPMENT

- In the development phase, most countries raised concerns about the lack of testing and willingness to embrace failure. In contrast, in the UK and Sweden it was noted that several university or clinical innovation organisations were willing to test innovations. However, these countries did also note the challenge of sharing knowledge among different organisation and regions. In Portugal, a specific concern was raised about the limitations on academics to temporarily fully transition into start-ups, due to the rigid nature of their academic careers.
- Spain, France and Belgium all cited access to real-world settings as a challenge. In general, countries raised concerns about the specific points of access to healthcare institutions. This was primarily due to the lack of dedicated innovation teams who not only support testing, but who can also open doors to other stakeholders critical to the purchase of solutions once they reach the market.
- In terms of funding, the picture was quite similar across the countries where this was discussed, notably a lack of investors with previous business experience in leading digital health ventures. However, Sweden showed a quite mature investment ecosystem, with several companies already on the stock market, and connected with the US. Portugal raised concerns about the financing of technical developments, compared with France, where levels of funding were considered adequate. Some countries stated that funding for non-technical developments was a challenge, which is important since adoption of digital health relies heavily on education, implementation and awareness to fulfil its impact.
- Differences over the level of market readiness and scaling-up, mostly related to varying levels of awareness and experience, show innovators tend to face similar challenges when expanding internationally, regardless of their country or origin.
- Discussions about health data revealed considerable differences between countries over integration and accessibility, highlighting the need for better standardisation of data regulation, governance and utilisation by industry across the EU.
- For pre-competitive collaboration, France, Belgium and Sweden raised the most concerns. This was possibly due to their greater experience with the local medical device industry, or reflecting the level of interest of their national healthcare institutions in commercial activities and embracing the risk of development.

TOPICS	<input checked="" type="checkbox"/> Optimisation opportunity <input checked="" type="checkbox"/> Positive landscape	Spain	Portugal	UK	Sweden	Germany	France	Belgium
	Regulatory Scope of Digital Health							
Importance of regulatory barriers as promoters of market value		^		^	^	^	^	
Expansion of standards and assessment to all digital health technologies beyond medical devices			v	v	v		v	v
Stakeholder roles regarding evaluation, accreditation and standardisation activities		v						
Ecosystem-led evaluation and endorsement of digital health		v		^		v		
Regulatory Pathways for Digital Health								
New adaptive regulatory pathways (risk-based staged approval, continuous evaluation, real-world evidence)		v		v	v	v	v	
Pre-evaluation advice from regulators		v	v		v		v	
Evaluation and Assessment Methods for Digital Health								
Specific evaluation standards and assessment methods for digital health		v		v	v	v	v	v
Standards and evaluation of usability, accessibility, privacy, cybersecurity and interoperability of digital health		v		v	v	v	v	
Build competencies and research in regulatory science and clinical research for digital health outside regulatory bodies			v		v	v	v	v
Clarity on HTA assessment methods and requirements for digital health			v					
Evaluation Capabilities								
Improve clinical research capabilities and procedures			v				^ ¹	v
Awareness and mitigation of MDR impact on digital health		v		v	v	v		

¹ Identified good infrastructures, but a timely approval process needed for clinical trials.

MARKET ENTRY



In the market entry phase, the regulatory process and its suitability for digital health technologies was considered a critical issue for most countries. A more gradual, staged process to evaluate potential risks was suggested, rather than two completely distinct tiers of requirements used currently, often for very similar types of solutions. Some countries also highlighted the need for local stakeholders and ecosystems to play an active role in the evaluation of digital health, beyond just formal regulators. The UK appears to be leading in this respect with several initiatives led by the NHS and by private organisations, while in Germany concerns were raised about their capability to evaluate digital health apps for their suitability to receive one-year reimbursement, as recently defined in a new law.



In general, most countries agreed there was a need for new methods to evaluate digital health technologies, with a greater focus on criteria that will lead to successful implementation and usage of the solution, which regulators often overlook today. This broader scope of evaluation is especially crucial as it was noted that HTA considerations need to be taken into account from the early development stage. This will lead to a blend of regulatory evaluation and HTA as the required evidence is collected. The lack of clarity regarding the classification of software medical devices was a significant issue in Germany, where the current classification of digital health solutions as either a 'product' or a 'method' results in separate regulatory and reimbursement requirements.



With the new MDR requiring a greater focus on clinical evidence, countries such as France have identified this as an opportunity to enhance their internal capacity for clinical research. On the other hand, countries such as Portugal and Belgium identified the need to improve their internal clinical research capabilities to meet this demand.

TOPICS	<input checked="" type="checkbox"/> Optimisation opportunity <input checked="" type="checkbox"/> Positive landscape	Spain	Portugal	UK	Sweden	Germany	France	Belgium
	Health Technology Assessment (HTA)							
New HTA methods for digital health		∨	∨				∨	
HTA scientific advice			∨					
Increase HTA capacity		∨						∨
International harmonisation and coordination of HTA initiatives towards long-term health management and prevention				∨		∨	∨	∨
Assessment of Digital Health Technologies								
Continuous evaluation and assessment of digital health technologies		∨	∨		∨			
Enable resources and methods for early real-world assessment of digital health technologies					∨	∨		
Change from assessment that focuses on 'cost replacement' of innovation to include improved quality of care, outcomes and value				∨				
Reimbursement/Procurement								
Enable resources and methods for early real-world assessment of digital health technologies						∨ ¹		
Integrate needs-led service procurement frameworks for digital health		∧		∧	∨			
Innovation pathways for reimbursement/procurement						∨	∨	
Awareness of payors and providers on the impact value of innovations				∨				
Rigid annual budget cycle for reimbursement of new products and small companies				∨	∨	∨		∨
Diversity and alternative financing path for innovative products within a network of payors						∧		
Financing of Digital Health Technologies								
Develop new business models able to accommodate digital health			∨					
Implement financing and incentives based on value-based healthcare		∨	∨	∨		∨		∨
Better risk-management and sharing among stakeholders					∨	∨		
Private insurance companies as drivers of early adoption		∧			∧	∧		
Change Management								
Increase literacy and education of end-users regarding digital health innovation		∨	∨	∨		∨	∨	∨
Empower citizens to implement at-home healthcare		∨		∨	∨			
Patient organisations as neutral drivers of adoption		∧			∧			
Enable resources and infrastructures to lead change management				∨	∨		∨	
Healthcare professional incentives to promote value and engage in innovation adoption efforts as part of routine practice			∨	∨				
Usage of living labs/test beds to guide adoption within organisations					∨		∨	
International and national sharing of best implementation practices				∨	∨			
Scaling and International Expansion								
Mature mergers and acquisitions digital health ecosystem								∨
Scalability of innovations within the healthcare system		∨			∨			
Guidance and networks to evaluate international market			∨				∨	∨
Access to funding to scale-up to new markets		∨						

¹ New digital health law allows reimbursement prior to positive HTA evaluation in order to collect real-world evidence.

ADOPTION

- While formal (or informal) HTA is key to drive adoption and, in many cases, reimbursement, the need for new assessment methods for digital health technologies was a common theme in the discussions. Alongside this was the need to further early HTA engagement in the innovation process, clarity of requirements, and harmonisation across countries. However, HTA is perceived as having different standards among EU countries, which is one barrier to harmonisation. Spain and Belgium raised concerns about the capacity of their HTA bodies to deal with the number of assessment that digital health requires and the prolonged timeframe to undertake this.
- Demonstrating an adaptive approach, the UK is the first to put forward a digital evidence standards framework (issued by NICE).
- The reimbursement pathway is generally perceived as being too strict and not innovation-friendly. The UK, Sweden, Germany and Belgium raised concerns about the impact that their traditional annual review cycle of reimbursement may have on innovation progression, as this process is generally too long for the usual shorter lifecycle of a digital health product.
- Notably, not all digital health products require reimbursement, and when considering procurement, Spain and UK highlighted that there have been advances in their countries regarding the ability to procure services, in a way that is much more suited to digital health. This follows the new EU directives on this topic. Germany, however, highlighted the advantage of the diversity of their payment system. While still part of a centralised reimbursement system, the nature of digital health fits well with the budget autonomy of many of its private insurance companies, allowing for alternative financing pathways for innovations. Portugal and Sweden highlighted the role of private insurers as early adopters of innovation in digital health.
- Almost all countries recommended developing new ways of financing healthcare that can accommodate digital health technologies, such as those focused on value. However, few have implemented such models yet. Sweden and Germany suggested that risk-sharing payment schemes are key to fostering innovation since they build the necessary evidence in real-world settings.
- A negative attitude to digital health was noted in Spain, due to their negative experience with the introduction of electronic health records, highlighting the need for better education of end-users and healthcare professionals about innovation and its positive impact. Even Sweden and France, who have positive examples of successful 'living labs', pointed out that they fall short in being able to drive adoption of innovation within organisations and with users.
- As companies look to scale-up for adoption, the challenge of scaling internationally, or accessing funding for these stages was noted, when profits are not yet realised. In Belgium, the lack of maturity of mergers and acquisitions in the digital health market was discussed and considered a barrier to businesses achieving the scale needed for broader reach and adoption.

Optimising the innovation pathway for digital health



SHAPING A NEW INNOVATION PATHWAY FOR DIGITAL HEALTH

Such a 'future proofed' pathway should represent the ideal situation, which aligns and clarifies the role and status of each stakeholder. It should provide guidance regarding necessary frameworks and resources that need to be coordinated and in place in order to support the path to successful uptake of a digital health innovation that has a beneficial impact on society.



Three main concepts stood out as important when considering an optimised innovation pathway for digital health:

MULTIPLE ACTORS

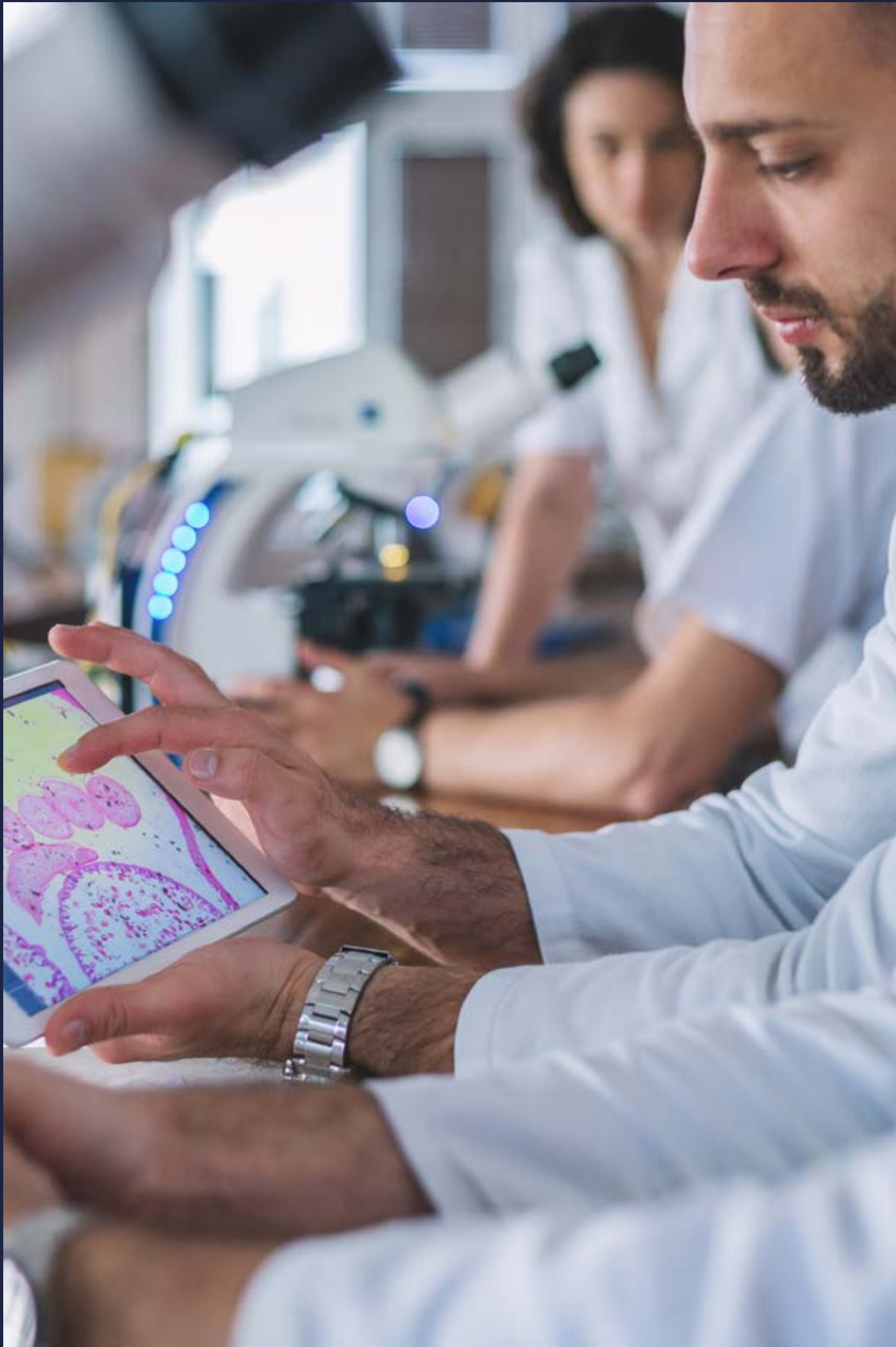
The innovation process comprises several stakeholder levels beyond the innovator alone in a co-creation process, and it supports change and implementation.

MULTIPLE PARALLEL PATHWAYS

Each stakeholder has a proactive role along the pathway, extending beyond the role of the innovator. They will need to integrate with other stakeholders at key points along the path from the beginning of the process but will also need to act proactively in parallel.

SYSTEM-DRIVEN

While the innovator is depicted as the one who identifies the problem and proposes a solution, innovation needs to be carried out at an ecosystem level. This is so stakeholders can be proactive, rather than reactive – key to supporting continuous learning and development of knowledge beyond technology, towards implementation, incentives, and new forms of healthcare.



On this basis, a four-layer pathway framework is proposed, led by different actors, which captures the specifics of digital health, and expands on the current innovator-focused pathway presented at the Round Table meetings:

- **LEARN AND DEFINE**
ECOSYSTEM-LED
- **PREPARE AND SUPPORT**
HEALTHCARE SYSTEM-LED
- **DEVELOP AND DELIVER**
INNOVATOR-LED
- **EVALUATE AND MONITOR**
GATEKEEPER-LED

Firstly, two layers are proposed covering aspects that are often overlooked when considering innovation- they are novel proposals and indicate proactive roles from all relevant stakeholders:

1. LEARN AND DEFINE

(led by the overall ecosystem)



1 . LEARN AND DEFINE – ECOSYSTEM-LED

- PHASE 1:
Needs Assessment
Systematic assessment of users' needs at a system level.
- PHASE 2:
Need Definition and Context
Systematic definition of the need by multi-stakeholder teams.
- PHASE 3:
Requirements Based on Need and Context (Outcomes, Interoperability, Integration, Usability, Security)
Clear definition of evaluation criteria for a potential solution.
- PHASE 4:
Solutions Mapping
Continuous monitoring of the proposed solution, and re-iteration of requirements and knowledge based on learnings.

2. PREPARE AND SUPPORT

(led by the target healthcare system)



2. PREPARE AND SUPPORT - HEALTHCARE SYSTEM-LED

- **PHASE 1:
Stakeholder Requirements**
Mapping of all stakeholder requirements in the context of the defined need to guide the innovator.
- **PHASE 2:
Innovation Testing**
Promotion of access to real-world settings in order to test and co-create solutions.
- **PHASE 3:
Screening for Solutions and Validation**
Continuous validation of potential solutions given defined requirements.
- **PHASE 4:
Financing and Reimbursement Framework**
Preparation and implementation of adequate frameworks to enable co-created finance plans.
- **PHASE 5:
Processes and Workflow Change Requirements**
Systematic evaluation of the changes required to enable an innovation.
- **PHASE 6:
Implementation Plan and Funding**
Preparation and allocation of resources to support the implementation of an innovation according to the necessary changes identified.

3. DEVELOP AND DELIVER

The next layer expands on previous frameworks, currently used by various organisations. This layer amalgamates the market entry phase into an iterative process of learn-development-validation-deploy-learn. The adoption process is continuous from ideation onwards.

Therefore, after an initial phase of first successful usage and implementation, innovators move on to address the challenge of scaling delivery and adoption to new contexts and markets.

Within this layer, the milestones should be seen as puzzle pieces which need to be completed at certain phases, but which are always considered from the start of the pathway. These milestones can be divided under broad and self-explanatory domains, Technology/Engineering, Compliance/Regulatory, Need/Usage, and Business/Market.

3. DEVELOP AND DELIVER - INNOVATOR-LED

Domains:

Technology/Engineering, Compliance/Regulatory, Need/Usage, Business/Market.

> PHASE 1:

Ideation and Requirements Definition

Need and requirements assessment with stakeholders, particularly regulators and HTAs towards possible innovation for target markets.

> PHASE 2:

Development and Validation

Continuous de-risking and validation against requirements and stakeholder feedback.

> PHASE 3:

Pilot Delivery

First certification and initial real-world deployment in target markets and iteration (learn-development-validation-deploy-learn).

> PHASE 4:

At-scale Deployment

Scale implementation beyond pilot in target markets and continue evidence collection and iteration of the solution.

4. EVALUATE AND MONITOR

Finally, layer four, led by gatekeepers, mostly focuses on the need to continuously develop new methodologies, prepare in advance for new technologies and emerging paradigms, and evaluate during the lifecycle of innovation, rather than relying on evaluation before it reaches the market.

Analysing the domains mentioned at this level, the following topics emerged: Health, Healthcare Impact, Usability and Accessibility, Cost of Adoption/Non-Adoption and Delivery, Business Sustainability, Technology, Data Security and Privacy. However, this is not a systematic collection of domains. It is also a layer where several gatekeeper institutions actively develop evaluation and assessment frameworks.

Ultimately it is important to note that while all stakeholders are involved at each level in parallel, their level of activity varies along the timeline of the innovation.

4. EVALUATE AND MONITOR - GATEKEEPER-LED

Domains:

Health problem and characteristics of the application (including impact, solution maturity); safety; clinical effectiveness; user perspectives (incl. usability, accessibility); economic aspects (including sustainability and cost of adoption/non-adoption and delivery); organisational aspects (including interoperability); socio-cultural, ethical and legal aspects (including data security and privacy)Business/Market.

➤ PHASE 1:

Assessment Methods Development

Technology vigilance and co-development of adequate assessment methods with stakeholders.

➤ PHASE 2:

Harmonised Guidelines and Requirements

Coordination with other gatekeepers to harmonise requirements and methods, and communication of clear guidelines to stakeholders.

➤ PHASE 3:

Initial Assessment and Validation

Validation of innovations based on requirements and guidelines.

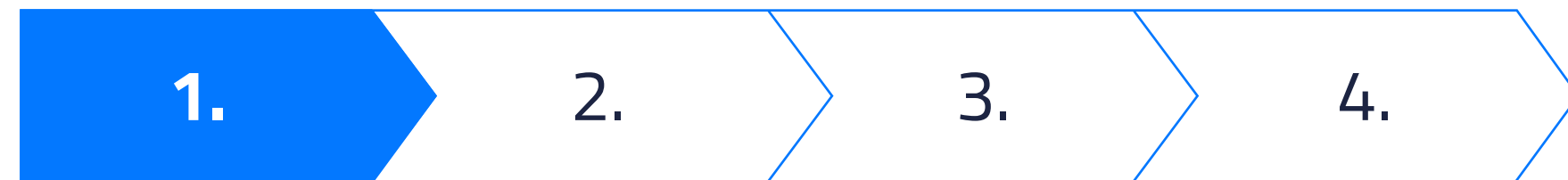
➤ PHASE 4:

Continuous Monitoring

Continuous re-validation of solution based on new evidence.

Moving towards an optimised innovation pathway for digital health

When considering an optimised innovation pathway for digital health, Round Table discussions identified specific areas where changes need to happen to achieve this. These changes are key to enabling the fundamental activities expected at each level.



1. LEARN AND DEFINE – ECOSYSTEM-LED



The ecosystem should promote innovation frameworks that evaluate user and system needs that then lead the innovation pathway. Needs should consider not only clinical needs, but the wider integrated care need – breaking down walls between ‘silos’ in healthcare, social care, wellbeing. This should have a structured approach which supports quick testing and co-creation, embracing risk and failure, alongside the capability to learn and share knowledge with the ecosystem.



The ecosystem should be proactive in mapping and defining of needs, taking into account the relevant scope of different systems. Alongside this, a set of requirements or standards should be proposed, and articulated among stakeholders, regarding interoperability, integration, usability and data security to guide innovators when developing their solutions.



The ecosystem should promote awareness of the innovation pathway process and milestones to all relevant stakeholders, and they can also guide the appropriate actions to enable innovation. Education and guidance should be given to all stakeholders, not only innovators, at early stages, so they are aware of their role and what they need to do to support innovation.

Moving towards an optimised innovation pathway for digital health



2. PREPARE AND SUPPORT – HEALTHCARE SYSTEM-LED



An innovation needs to be considered as a whole in a broad context.

The pathway should allow for proper innovation access pathways, while also defining and putting in place screening and validation frameworks or agents, allowing for an iterative development of the solution.

The pathway should provide the necessary frameworks for sustainable financing and reimbursement, and address required changes in processes and workflows, to fully address the potential of such solutions, and the changing paradigms. For this, not only is it essential to have the resources in place to develop the solution but also have an adequately resourced adoption and implementation plan.



There is a need to reshape healthcare system incentives, so they are more favourable to adopt innovations. For this purpose, clear change management approaches within the organisations must exist, which align with those incentives.

Innovation activities should be an integrated part of organisations, and incentives aligned to actions that promote innovation adoption in daily activities. This requires an overall shift towards value-based healthcare financing, where, for example, new risk-sharing agreement frameworks with innovators can drive testing and validation towards a sustainable adoption of innovation.



Health data has a significant value that can help foster innovation. There is the need for proper mechanisms for sharing and creating value from data amongst stakeholders. For this to happen, there is a need to define clear privacy, ownership, security and ethical frameworks.

Moving towards an optimised innovation pathway for digital health



3. DEVELOPMENT AND DELIVERY – INNOVATOR-LED



In order to enable a more agile development, innovators should follow good development and clinical practices for digital health. These should account for requirements of being scalable, efficient, value-based, ethical, and safe-by-design. At the digital health technologies level, these still need to be properly defined but are key to raising awareness and moving the focus from final product validation towards development process validation.

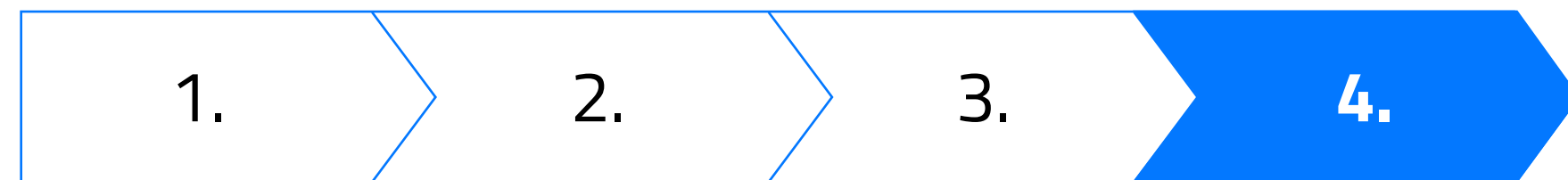


Innovators should be provided with clear requirements and guidelines on the assessment process, both at the regulatory and HTA levels. These should take into account the specific aspects and risks associated with digital health technologies. Moreover, there is a need to foster harmonisation within the EU on these requirements and guidelines, in order to provide a more transparent access for innovators to national healthcare markets, as well as to facilitate scalable development.



Clear guidance and a support network for scalability across EU market access should be promoted. Access to talent and education in the fields that support innovation adoption and development of digital health should be supported, taking into account its specificities (regulatory science, service design, evidence generation and assessment, health economics, etc).

Moving towards an optimised innovation pathway for digital health



4. EVALUATE AND MONITOR – GATEKEEPER-LED



Create collaborative multidisciplinary frameworks for stakeholders' participation and co-creation that promote mutual trust, allowing development, and testing in real-world settings from the early stages. This needs to be supported by: increased creation of trust among the stakeholders, incentives and support for health and clinical research, integration of social sciences as relevant stakeholders, proper finance and funding mechanisms to foster these collaborations, partnerships within collaborative and transparent frameworks, as well as sharing of results.



There is the need to improve regulatory and HTA science and methods. They should account for real-world evidence and consider assessment within integrated systems. To support this, there is a need for new methods, or new ways of applying existing methods, to evaluate digital health technologies, education at many levels, and an increase in regulatory and HTA capacity to apply, implement, and deliver these methods.



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. These levels need to be able to consider an integrated assessment and monitoring of digital health technologies and services, beyond a single innovation perspective, for lifecycle management. HTA needs to be able to inform risk-sharing agreements, address long-term outcomes and economics, and provide policy recommendations based on their assessments.



Conclusions

The Think Tank Round Table Series 2019 has gained valuable insight from seven EU countries on how the traditional healthcare innovation pathway must be adapted to meet the needs of new digital health technologies. The nature of these new types of products and services means that alternative approaches are urgently needed at all phases and stages of the pathway, from ideation through to product development, methods of testing, generation of evidence, proof of value, implementation, usability and adoption. It also requires engagement with a wider range of stakeholders and the development of new business and financing models.

Digital health innovations urgently need new approaches which take into account that they are often not discreet single products, but 'services' integrated within existing systems, and that they generally have a rapid, iterative development process.

Feedback from the Round Table discussions has identified several key aspects that need to be addressed to optimise the pathway for digital health technologies and deliver impactful health solution to citizens:

- Clear regulatory requirements for digital health technologies should be developed with appropriate stakeholder involvement.
- Evidence requirements for HTA of digital health technologies should be developed with appropriate stakeholder involvement.
- Regulatory and HTA processes and requirements for digital health technologies should be aligned with each other and communicated to all stakeholders.
- A Europe-wide approach to HTA of digital health technologies should be implemented with the proposed legislation for sustainable EU cooperation on HTA.
- 'Process standards' rather than 'product standards' are needed to account for the continuous innovation and evidence-generation required for digital health technologies.
- The ability to regulate and assess an integrated system and methods, not just individual products, is required.
- A process for continuous evaluation, surveillance (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.

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