Optimising Innovation Pathways: Future Proofing for Success

Think Tank Round Table Meeting Proceedings

Le Méridien Etoile Hotel, Paris, France

18.10.19

THINK TANK

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Contents

Context for the selection of the 2019 Round Table Series Topic

In recent years there has been rapid growth in the field of medical and health technology products. Not only has the number of players in this sector increased over this time but the type of products has changed too, and this has implications for the overall fit and suitability of the steps that companies need to navigate to take an innovation from an idea to a marketable product, in a field which is highly regulated and complex.

This changing landscape poses new challenges in terms of development, testing, implementation, usability and adoption of new health technologies. As a result, innovators and other stakeholders can face hurdles, not only for regulatory approval but also to achieve sustainable adoption, with users who often require substantial evidence of impact and value before deciding to purchase.

In light of this ever-changing external environment in which innovative solutions aim to launch, the task of 'Optimising Innovation Pathways: Future Proofing for Success' was chosen as the Think Tank's Round Table Series topic for 2019.

Through a series of National Round Table Meetings, such as the French Round Table Meeting reported here, the aim is to identify barriers and opportunities that exist across the EU that either support or impede the widespread uptake of innovative solutions.

To better incorporate the innovator perspective in the National Round Table Meeting discussions, local companies that have developed innovation projects were interviewed prior to each Round Table Meeting about their pathway experiences. This information was used to help map the existing pathway process, steps, requirements and gatekeepers as well as gather insight on the practicalities of navigating the pathway in the real-world setting.

At the end of this 2019 Round Table Series, key actions and practically devised recommendations proposed during each meeting will be consolidated to provide a pan-EU perspective on optimising innovation pathways aimed to accelerate the sustainable adoption and diffusion of innovation in health technologies for the benefit of all citizens.

Objectives of the National Round Table Meetings

- To validate the current innovation pathways for a selected innovation type – Hardware Technologies, Digital Health or Healthcare Solutions in each region – and the key stages, gatekeepers and criteria that innovators must meet to move through the pathway with ease and timeliness, whilst also identifying similarities and differences that exist between them.
- To review insight gained from the real-life experiences based on case study interviews with selected innovators in each region (within the EIT Health Partner Network) currently navigating these existing pathways to identify barriers and opportunities.
- To highlight any barriers and best practices to this process and recommend practical solutions towards an ideal innovation pathway that would address the needs of both national/regional and pan-EU stage gatekeepers and of innovators and would help expedite the journey to adoption of innovative solutions in health.

Agenda and participants: France Round Table

Hosted by EIT Health France

Facilitated by 2019 Round Table Series Chair: Professor Finn Boerlum Kristensen MD, PhD

Moderated by: Robert Picard, PhD, Health Referee at CGE, Ministry of Economy and Finance, and Juan Fernando Ramirez, MD, PhD, Vice President and Chief Medical Officer, Air Liquide; Vice President of the Board of EIT Health France

Other participants: A full list of meeting participants can be found in Appendix 1.

Discussion topics

- **Session I:** The current state of the Digital Health Innovation Pathway in France
- **Session II:** Optimising the innovation pathway in France
- **Session III:** Proposals for actionable recommendations

Session I: The current Digital Health Innovation Pathway in France – summary of pre-meeting research and discussion

Focus of the French Round Table

The innovation type selected for discussion at the French Round Table was Digital Health. As a new field, the term 'Digital Health' covers many different definitions, which still lack consensus. For the scope of this Think Tank, Digital Health refers to:

- Software-based solutions that focus on healthcare interventions (related to patients or users' health). These solutions may be 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.

In the EU, the new Medical Device Regulations (MDR) extend the definition of the scope of Medical Device software. With it, many Telemedicine solutions which represent Digital Health solutions (and therefore have a direct influence of the clinical aspects of healthcare) will be now considered as Medical Devices, when previously they were not. Given the need to determine if a Digital Health solution fits into the Medical Device classification, the pathway should always include this assessment step, regardless of its endpoint as a Medical Device or a wellness product. The main difference in the pathway is that a Wellness Digital Health solution will skip the regulatory process required for market authorisation of Medical Devices and can be sold without major limitations

Overview of French Digital Health Ecosystem

The findings of EIT Health's research into France's Digital Health ecosystem were circulated to participants in advance of the meeting. These were supported by insights from interviews undertaken with local companies that had developed Digital Health innovation projects. Key points from the research were:

- The Medical Device market in France is valued at €20 billion and comprises more than 1,000 medical device manufacturers, 94% of which are small-to-medium enterprises (SMEs). The Digital Health market is a dynamic sector representing 30,000 jobs and a €3 billion market. (Source: The French Healthcare Industries and Technologies Strategic Committee, 2018).

- Eighty-one percent of French people think that connected healthcare offers opportunities for better quality treatment, while 77% of people and 84% of doctors in France believe that it can lead to better prevention. Some 80% of patients with chronic illnesses are already using consumer connected devices to manage their health, e.g. smartphones (Source: Odoxa, Connected Healthcare Survey, 2018). For further information about digital applications in the health sector in France see: https://www.credoc.fr/publications/barometre-du-numerique-2018
- There are several innovation clusters throughout France focusing exclusively on the pharma/biotech and MedTech sector: Alsace Biovalley, Atlantic Biotherapies, Cancer Bio Santé, EuraSanté, Eurobiomed, Lyon Biopôle, Medicen, and Nutrition Santé Longévité. Some clusters are cross-sector but have a strategic domain of activities, for example Cap Digital addresses wellbeing and ageing as a result of digital transformation.
- France's research tax credit is considered as an incentive for companies who undertake a high volume of research activity and can be used against eligible R&D expenditure up to marketing approval for pharmaceutical products, and CE marking for medical devices.
- Established in 2015, the association France Digital Health now has around 190 members. It aims to foster eHealth initiatives by bringing together entrepreneurs and French digital health investors.
- French Tech Acceleration is a €200 million fund dedicated entirely to the fuelling the growth of the best start-up accelerators across the country.
- There have been several recent reforms, new legislation, and policy measures adopted by the French government with a view to modernising health and social care delivery.
    - 'Rapport Gagneaux' proposes initiatives to improve the coherence of eHealth governance.
    - 'Hôpital, patients, santé et territoires' is responsible for the creation of ASIP, the French eHealth competence centre.
    - The Government published France's National eHealth strategy in October 2016 which included the introduction and sharing of Electronic Health Records (EHR).
    - The National Health Data System (SNDS) was launched in April 2017 and is recognised as one of the world's most important medico-administrative databases. It is an integrated health database merging together data from several health databases, including information on healthcare consumption from statutory health insurance or data from long-term care institutions. As such, it is an important asset that could provide a significant boost to innovation.
    - The French Health law 'Ma santé 2022' was adopted by Parliament in July 2019 and aims to establish a better-organised regional healthcare system, in particular to introduce new local healthcare structures. It promotes the development of digital healthcare including:
        1. Creation of a 'Health Data Hub' thereby increasing the opportunities to use health data.
        2. Creation of 'Espace Numérique de Santé' (ENS), a digital health space for

each patient.

To add context to the discussions on the Digital Health ecosystem in France, Robert Picard gave an overview of the Ministry's proposed public policies for innovation pathways for Medical Devices, and plans for their deployment (see: https://www.economie.gouv.fr/files/files/directions_services/cge/Rapports/Rap2019/CGE_Rapport_Mission_DM.pdf).

- The innovation process for Medical Devices is particularly complex due to the wide variety of skills needed to take an innovation from idea to market, and the number of different actors and stakeholders involved.
- The Medical Device sector is strategically important for the French Ministry of Economy; however, it is recognised that the value chain is changing drastically, due to the increase in Digital Health products and the greater involvement of patients in their own health and care.
- The diversity of actors involved in supporting the innovation process has highlighted an urgent need for a common language.
- There is now a trend away from individual products and a move towards 'systems' – networks of connected medical devices and data sources. This will require a greater degree of collaboration and the need for integration.
- The Ministry has developed policy recommendations and associated actions that reflect the innovation pathway for these new types of products:
    - Concept maturity level (CML) – developed initially by NASA, CML describes a structured method of assessment to determine the maturity of a product or system and its readiness to move to the next stage – it is expressed as a numerical value from 1–9. When applied to Digital Health innovations, this will give greater clarity to the early phases and evolution of the innovation process, recognising that it is complex and non-linear and involves multidisciplinary tasks. Using this concept, the aim is that all actors, support structures, public and private funders will have a greater understanding of the requirements at each stage.
    - Collaborative platforms - establishment of a network of secure digital collaborative platforms for the dissemination and secure digitisation of best practices for Medical Device innovation.
    - Data services – collection, structuring, sharing and analysis of Medical Device data and more generally 'medical systems' data within the framework of the 'Health Data Hub'.
    - Market preparation – support for pre-market configuration/pre-industrialisation platforms for innovative Medical Devices and medical systems.
- Deployment of the CML platform is ongoing at four locations in France during 2019/2020 and should also be explored at the EU level.
- Field research has also been undertaken with selected companies to evaluate the innovation pathway in practice.

To add further context to the discussions on the Digital Health ecosystem in France and the new EU MD regulation which will enter into force in May 2020 , Jean-Marc Bourez, gave an overview of the National Research Agency initiative, backed by the French Higher Education Research and Innovation Ministry, which aims to set up a pan-European consortium to develop and promote methodological approaches, that will be accepted by sponsors and recognised by the evaluators, in order to enhance the evaluation of High-Risk Medical Devices (HRMD). The consortium is led by INSERM, a French EIT Health France member, and includes Tech4Health, ECRIN, EIT Health France and EIT Health Europe.

Rationale

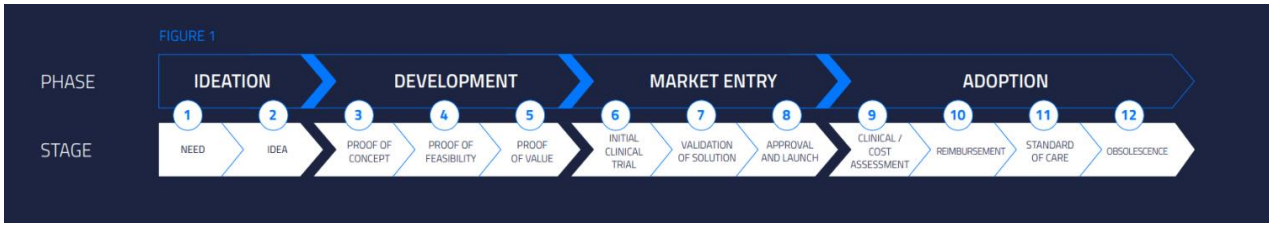
- Several recent major scandals have tarnished public confidence in the evaluation and monitoring system for HRMD. These situations and the 'implant files' investigation, which denounced the ease with which companies can obtain the right to market medical devices in Europe, highlighted the weaknesses and flaws in the health control system for placing a product on the market and monitoring it, particularly for HRMD.
- The new European regulations (EU MDR 2017/745) will come into effect in spring 2020. This new regulation sets out stricter rules for the generation of clinical evidence, in particular for HRMD (current class III and implantable devices) for which clinical investigation will be compulsory.
- This represents a big challenge for European Health SMEs (some 25,000 companies, representing 95% of the MedTech sector in Europe) to maintain their competitiveness and innovation capacity, with limited internal resources, especially in clinical trial skills. On the other hand, patients and physicians would like to ensure that the knowledge of the innovation allows for safe and efficient use of the new product.
- HRMD have specific features compared to drugs, such as the long-term use with unknown interactions with the human body, the means of explanting and replacing implantable devices, the user's skills, the human-machine interfaces, the management of generated data flows, etc. These specificities require specific evaluation methodologies to generate better clinical evidence.

Aim of the project

- The objective of the research program will be to develop and promote methodological approaches accepted by sponsors and recognised by the evaluators. These approaches include patient involvement, mixed hybrid methods, numerical modelling, AI and Big Data mining, and alternative statistical methodologies, adapted to the specificities of HRMD.
- The goal will be to propose a new HRMD evaluation and approval process based on robust methodological approaches to the clinical data needed for the different phases of the product's life, such as clinical proof of concept, usability, premarket approval compliance, high quality clinical evidence for reimbursement, and adequate post-marketing clinical follow-up.

The Digital Health Innovation Pathway

The proposed innovation pathway in France was presented based on EIT Health's research into the existing literature on the topic. The current pathway (illustrated below) reflects the usual innovation development stages, but adapted for the specifics of new health technologies.



Although often considered as a linear path towards the ultimate objective of successful and sustainable adoption of the innovation, it is in fact a continuous and a cyclic pathway, whereby the obsolescence of the product supports further research and development, and the design and development of new innovations.

Digital Health fits this overall pathway for health innovation. However, it faces specific challenges at different steps as the technology is still in its infancy and will therefore require adaptation by the various stakeholders along the pathway to reflect the new paradigm.

Discussion of Research Findings – the Overall Pathway

Participants discussed to what extent the overall pathway presented was executed in France as described and were asked to advise:

If the pathway, its stages and stage gates, reflected today's reality in France

- The pathway as presented is generally correct in terms of phases and steps but it is navigated in a more agile and non-linear manner.
- Currently, standards for the assessment of Digital Health products are lacking across EU countries, primarily due to the diversity of different healthcare systems and their legislative backgrounds, governance and management practices - standards need to be developed and shared at a European level.

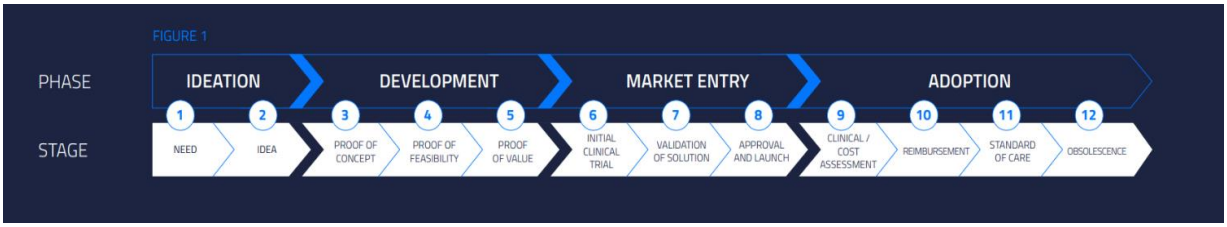
What an ideal pathway, stages and stage gates would need to include and consider to be more suitable for the future reality

- Clear distinction is needed between those Digital Health products that are classified as Medical Devices, and therefore subject to rigorous standards for assessment, and those that are categorised as 'Wellness Products' and are subject to much less stringent regulation.
- The cooperation between research and industry needs to be improved in order to progress innovations; we need to build an ecosystem of trust to allow this to happen, otherwise it will have a negative impact on the innovation pipeline.
- Increasingly, there is less money available to fund the upstream phases of the innovation pathway – new business models need to be developed that recognise the intellectual property (IP) generated by research to ensure there is return on investment.
- New financial models are needed that encourage, and create a market for, innovations.
    - These models need to reflect the value of new products to patients, healthcare systems and other stakeholders
    - Systematic tools are required to better assess economic value in the real world, particularly due to the long timespan of chronic diseases.
- Data quality, storage and sharing need to be considered in the process:
    - Data are necessary to develop reference standards for objective testing of the specificity of algorithms for artificial intelligence (AI) applications and other Medical Devices.
    - Need to develop strategies for how data are used, in particular for 'real world' testing and assessment.
- In order to achieve rapid product testing while maintaining ethical standards and minimising risk to patient safety, greater use should be made of in-silico testing, using
- virtual patients and healthcare settings.
- Digital Health requires a change of focus from regulation and assessment of individual products to evaluation of more complex integrated systems and services.
- Better integrated structures are needed to include patients in the creation, development and assessment of innovations – the role and place of patients in the innovation process needs to be better defined.
- There is the need to improve access to multidisciplinary experts in the innovation product area, who can provide advice during the pathway process.
- Change management is an important consideration in the introduction of Digital Health products as they may alter the workflow of health professionals and their interaction with patients.
- Lack of education about the benefits and use of Digital Health products can be a barrier to change – better education of multiple stakeholders (patients, healthcare professionals, etc.) is needed so they understand the value that these new innovations can bring.
- Accessibility and usability of Digital Health tools by patients/end-users needs to be considered during the development of innovations.

- Assessment of new innovations is complex and needs to take into account not only the direct clinical impact and value but also 'non-tangible' aspects resulting from adoption of an innovation that give context to its overall value. This is particularly true for solutions used by the citizen or the patient at home.

Session II: Optimising the Digital Health Innovation Pathway in France: discussions and recommendations

Participants were asked to consider what changes to the pathway phases and stage gates would be necessary for an optimised or ideal pathway for the future. Each phase and stage of the pathway was considered in detail focusing on barriers and challenges, as well as identified best practices.



1. IDEATION

1. CLINICAL NEED

2. IDEA

Challenges and barriers: What is not working/what needs to change in the ideation phase of the current pathway to get closer to an optimised one?

Topic	Key discussion points
Regulatory requirements	> Regulatory requirements need to be considered even in the early Ideation phase, otherwise they could be a barrier to adoption further down the pathway – innovators must anticipate and plan for this; it may require recruitment of team members with expertise in this area. > An objective of the French Association of Medical Devices Companies (SNITEM) is to support start-ups in this context. > The Tech4Health platform, part of the F-CRIN (France) an E-CRIN (Europe) networks, plays a key role here, specifically through the CIC-IT network (public CRO"s within CHU's, labelled by the Health

	Ministry).
Support for the early stages of innovation	> Ecosystems need to be developed to support researchers and academics in the 'pre-innovation' phase so they can connect with start-ups to further develop their ideas – this will require financial resources. > In the Ideation phase, the CML is low (1 to 3), so the expenses for a start-up company are minimal, although they will increase in subsequent stages. Reducing risk requires various skills, which generally not available at the start-up level. > Industry involvement and investment in research is lacking – need to develop ecosystems that allow risk sharing and knowledge sharing, with clarity regarding return on investment for all stakeholders.
Economic and business models and value assessment	> Economic and business models need to be considered and developed early, from the Ideation phase. > Business models are often considered too late and there is then a disconnect between the ideation/development teams and the business team in existing larger companies.
Key points	> **Create structures for developing innovations in a strategic manner with a clear pathway, economic/business models, and engagement of multiple stakeholders** > **Develop funding mechanisms for this early phase to enable risk-sharing within public-private partnerships.**

What is working well/best practices identified in this phase

Positive experiences
> Networking of the >35 Living Labs in the health sector (Forum LLSA) covering a broad spectrum of knowledge (human sciences, engineering, design, legal, medical) to be leveraged and combined in the concept formulation phase. Thanks to this network, Living Labs share their experiences within thematic working groups, allowing efficient

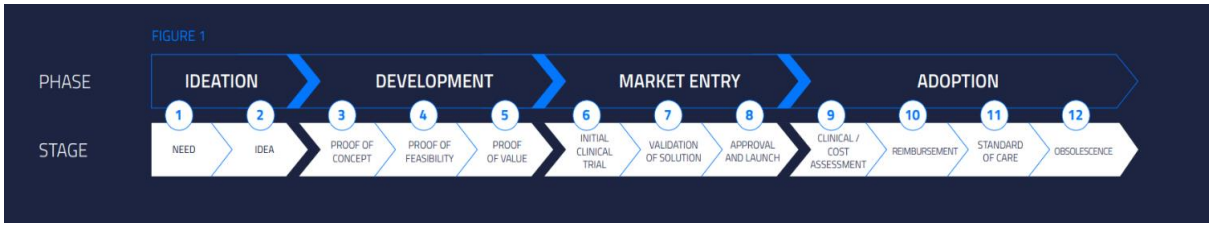
collaboration between them, and so providing opportunities for larger organisations to grasp external skills and develop open innovation as well as disruptive solutions.

> For instance, some Living Labs in this network are presently collaborating to provide joint offers to an insurance company supporting a user association, a big pharma company, and a consortium led by a local authority.

Best practice examples

> Following best practices of the space industry, the Forum LLSA network, with the help of scholars, developed a comprehensive framework of the innovation process in the health sector, named 'Concept Maturity Levels' (CMLs). It includes the continuous assessment of the concept maturity for an innovative solution. Particular attention has been given to the early concept formulation phases (the 'fuzzy front end'). (Note that the Defence Sector is transposing this framework in the Netherlands). CMLs include the description of tasks, tools and skills needed for the innovation process, and so can be used by any organisation to describe its own value proposition and associated tools and skills.

> A collaborative platform based on CMLs has been prototyped. It has been fuelled by the positive experiences reported above. The platform aims to accelerate and secure information exchanges as well collaborations between research labs, Living Labs, enterprises and users. Several partners of EIT Health France are involved in this work, namely: CEA, INSERM, ALTRAN, MADoPA - Forum LLSA being a Network Partner.



2. DEVELOPMENT

3. PROOF OF CONCEPT

4. PROOF OF FEASIBILITY

5. PROOF OF VALUE

Challenges and barriers: What is not working/what needs to change in the development phase of the current pathway to get closer to an optimised one?

Topic	Key discussion points
Impact of the new MDR	> Introduction of the new MDR in May 2020 will require collection of upstream data for proof of concept so this will need to be considered early in the pathway process.
Education of stakeholders	> The new MDR should be viewed as a positive opportunity for learning and education of stakeholders in all aspects of Digital Health (similar to the recent introduction of the General Data Protection Regulation [GDPR]), rather than just an obstacle. > Currently, only three Universities in France train future regulatory experts. > All stakeholders, including regulators, need to understand the concepts of Digital Health, AI, software etc., beyond regulation alone, and acquire new skills to deal with them. > They need to be aware of the changing job roles that will be required as a result of these products in the new environment, and the adjustments to workflow etc., that will result from adoption of these new innovations. > EIT Health could help facilitate such educational programmes on an EU-wide basis. > The Strategic Council for Healthcare Industries (CSIS) reports directly to the French Prime Minister and acts as a sharing platform between the Government and the healthcare industry. Its objectives are to address the strategic issues confronting France in relation to healthcare and industrial competitiveness, and to ensure France is as an international centre for health innovation and excellence. > CSIS has developed a long-term roadmap which recognises the need to develop a plan for capacity building and training in data science and the regulatory aspects of new innovations.
New evaluation methods	> New assessment methodologies are needed for the evaluation of digital products that change or evolve, and those that impact healthcare systems. > The use of Living Labs, introducing evaluation of use at an individual or collective level, can reduce the risk of non-acceptance

	by the targeted users. > The use of modelling and in-silico testing, using virtual patients or healthcare settings should be considered to mitigate the lengthy timeframe for clinical trials and adoption testing. > Test beds are needed for the validation of digital tools, such as AI and algorithms, in complex systems. > A platform already exists in France which could be expanded across the EU. For example, HyAIAI Inria Project Lab developed an artificial intelligence platform for the validation of algorithms for biomarker discovery; a DARPA-like process has been initiated (innovation councils) with two challenges: (1) health diagnosis and (2) biomarkers. > Test beds are needed not only for products at the research/development stage but also for products nearing market entry to test implementation.
Funding and economic models	> Funding models are needed to support upstream testing and validation. > However, funding is not just about supporting upstream activities or gaining reimbursement, but also about having a good business model that demonstrates sustainability and economic viability, thereby allowing access to private stakeholders who will share risk. > EIT Health can facilitate access to loans/grants/equity. > Business Angels can provide structures to manage risk, particularly for start-ups. > Structures should be put in place to allow real-time testing of innovations supported by real-time funding of innovators. > New funding models are needed to reflect the development, assessment and validation of Digital Health 'systems', not just single products. > The value of health data needs to be considered within the business model.
Early engagement with payers	> Although considered as part of the Adoption phase, early engagement with payers is important in progressing innovations in an agile way and mitigating risk both to patients and to investors. > As an example, gaining reimbursement for a limited

	population over a defined time period in order to gather real-time data on clinical and economic benefits by continuous monitoring (Diabeloop). > Protracted reimbursement processes represent a substantial risk to an innovation company – in the US, the process can take 3–6 months while in the EU it can be more than three years. > France has some good examples of upstream engagement with reimbursement authorities, e.g. Article 51 (Organisational Innovations for Health System Transformation). > Lessons should be drawn from existing risk-sharing schemes for innovations.
Key points	**> Promote education and research into all aspects of Digital Health products including regulatory requirements and HTA science** **> Promote the development of new evaluation tools for Digital Health products** **> Enable structures for real-time testing and funding of innovations** **> Consider new business models and frameworks for health data sharing that acknowledge the value of patient healthcare data beyond ownership**

What is working well/best practices identified in this phase

Best practice examples
The network of Living Labs supported by EIT Health that allow real-world testing of innovations.

3. MARKET ENTRY

6. INITIAL CLINICAL TRIAL

7. VALIDATION OF SOLUTION

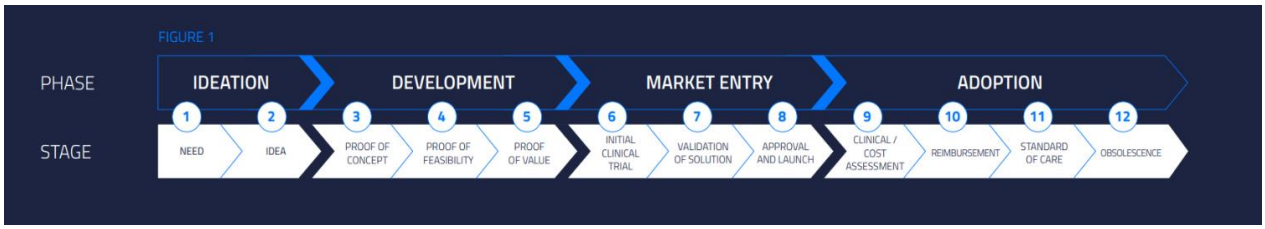
8. APPROVAL AND LAUNCH

Challenges and barriers: What is not working/what needs to change in the market entry phase of the current pathway to get closer to an optimised one?

Topic	Key discussion points
New MDR requirements	> While the new MDR will be applied at an EU level, they will be implemented nationally by Notified Bodies. Designation of these Notified Bodies is likely to be a challenge and may impact on the timelines for regulatory assessment. > Clear guidelines about the new regulatory requirements are needed along with a central point of contact where innovators can go to get answers about what is needed for their products. > The new regulations need to take into account assessment of integrated systems and services, not just individual products – they are currently not suitable or agile enough for the assessment of Digital Health products and AI systems that evolve rapidly. > A more pragmatic approach is needed for the assessment of 'low-risk' Digital Health products, which should in theory reduce the timelines for assessment. This applies for example, to periodic software updates. > The more stringent requirement for evidence generation will increase the administrative burden for innovation companies. > The regulatory risk for innovators is much more of a challenge in Europe, compared with the US – the process needs to be much more agile, not 'go' or 'no go'. > There are examples of fast-track, agile regulatory processes, particularly in the US; in France, products can be given 'temporary authorisation for usage' (ATU) while validation data for full authorisation and deployment are collected in parallel – 'lean' regulation. > If the regulatory process does not become more agile, there is a danger that the demand from patients and citizens will result in

	attempts to bypass the system or patients' own use of unregulated and possibly unethical products. Alternatively, there could be a legal challenge resulting in lawsuits against authorities if a patient does not have access to a digital solution in France that is available elsewhere. > An EU consortium is currently involved in developing new methodology for Evaluating and approving High-Risk Medical Devices (Eval-HRMD; European project CSA3): 'Developing methodological approaches for improved clinical investigation and evaluation of high-risk medical devices'. Collaborators include the French National Institute of Health and Medical Research (Inserm), EIT Health and CIC-IT.
Clinical trials	> The new MDR will harmonise the requirements for clinical trial authorisation and conduct across the EU, which, given the country conditions for this activity, may make France a more attractive place to undertake research. > However, the lengthy timelines for authorisation of clinical trials can be a hindrance to the progression of innovations and represent a business risk for companies. > Current clinical trial design and methodology is not suited to connected Digital Health products – research/academia should be proactive in developing and validating new methodologies to share with regulators, however there is currently a lack of funding to support this – EIT Health could facilitate.
Data standards	> Standardised protocols are needed for the management, sharing, access, and use of data derived from the wide range of digital devices, beyond what is required for regulatory assessment – these need to clearly define ownership rights. > A social model for data protection and privacy for citizens and patients should be incorporated as part of this – create an environment of trust alongside the GDPR. > Health data are now recognised as having an inherent value – regions outside of the EU are more advanced in their efforts to capitalise on this and set standards, so EU countries need to get organised and move quickly. > The interoperability of data is also key in order for digital solutions to be successfully deployed in a wide range of healthcare settings – standards need to be developed. > As part of France's digital roadmap, a digital health space has

	been created for each patient: 'Espace Numérique de Santé' (ENS)
Key points	> Enable more efficient and agile regulatory assessment process for innovation, focused on the speed of access for citizens and patients to safe and effective innovations > Ensure that low-risk Digital Health products have a more pragmatic regulatory evaluation to reduce assessment times > Develop specifications for key contacts and access to guidance on regulatory requirements > Reduce the timeline for clinical trial authorisation in France to reduce the risk to innovation companies > Promote data quality and sharing standards within trusted environments that enable accessibility and interoperability



4. ADOPTION

9. CLINICAL\COST ASSESSMENT

10. REIMBURSMENT

11. STANDARD OF CARE

12. OBSOLESCENCE

Challenges and barriers: What is not working/what needs to change in the adoption phase of the current pathway to get closer to an optimised one?

Topic	Key discussion points

Improving the chance of adoption	> A CE mark gives assurance of a product's safety, but does not guarantee that it will obtain reimbursement or adoption – innovators need to think ahead and develop good economic models, ensuring that their product meets the end users' needs. > Co-creation with multiple stakeholders (patients, citizens, healthcare providers) from the start of the process, as undertaken in Living Labs, will ensure that the product fits the identified need and can be successfully deployed in its intended setting – this is likely to speed up adoption. > Training of patients, their care network and healthcare providers about any new Digital Health solution and its impact on them (e.g. quality of life, survival) and the healthcare system is vital to facilitating adoption. > This can be important for patients and citizens who may be fearful of new technology and their capacity to use it. > The pathway to adoption may not always be the most straightforward one – innovators need to determine the critical path that will be most favourable for them to gain adoption.
Harmonisation of national standards	> Need to ensure that the standards that allow adoption of a product in one EU country, are also valid in others – develop processes to share and exchange information, standards, and assessment methods.
Assessment	> Methods for assessment of the 'value' of Digital health products are the subject of considerable debate – further research and method development is needed.
Sales and distribution	> These need to be considered as part of the overall business model – the distribution channel and the need for a sales force should be anticipated and planned for well in advance.
Scaling-up	> When scaling up it is important to consider carefully the

	ecosystem in which the product will sit – a pilot study may show that a product works well, but this can change when scaled up to a larger system.
Change management	> Effective change management processes are needed within organisations to ensure stakeholders understand the beneficial impact of innovations. > They need to be aware of the workflow changes new solutions may bring and have economic incentives to use them, so there is less resistance to adoption.
New communication channels	> New channels of communication, for example social media connections between patients, are becoming increasingly relevant and can influence the impact of innovations – smarter ways of communicating with patients are needed.
Key points	> **Co-creation of innovations with patients, caregivers and other stakeholders, as undertaken in Living Labs, will help ensure a product meets the end users' needs and improve its chance of adoption** > **Training and support for patients, healthcare providers and carers should be provided so they can understand new Digital Health innovations and their impact on the system** > **Sharing and exchange of information and evidence standards is needed amongst payers, administrators and healthcare managers internationally to ensure the adoption of innovations across borders** > **Change management within healthcare organisations needs to be improved in terms of understanding changes to workflow and incentives resulting from the adoption of new Digital Health innovations.**

Session III: Conclusions and recommendations for actionable outcomes

IDEATION	TARGET STAKEHOLDER(S)
ACTION > Create structures that enable innovations to be developed in a strategic manner with a clear pathway, economic/business models and ensuring engagement of multiple stakeholders > Living Labs – a network of Living Labs are already supported by EIT Health and is available via the Clinical Investigation Centre for Innovative Technology (CIC-IT) network > Engage with patient organisations (using the CML classification) > An EU consortium is currently involved in developing new methodology for Evaluating and approving High-Risk Medical Devices (Eval-HRMD; European project CSA3) – includes the French National Institute of Health and Medical Research (Inserm), EIT Health and CIC-IT. > Promote co-creation of innovations with patients, healthcare providers and other stakeholders > Develop training and education programmes on Digital Health and the requirements of the innovation pathway for all stakeholders	
DEVELOPMENT	**TARGET STAKEHOLDER(S)**
ACTION > Develop funding mechanisms for the validation process of innovations to enable risk-sharing with private entities > Enable structures for real-time testing and funding of innovations > CIC-IT is developing competence training and usage testing	

> Develop new business models and frameworks for health data access and sharing, that reflect the value of patient healthcare data, IP ownership, open source access, and provider-generated data > New data anonymisation methods are being developed > Create ecosystems for research and innovation that bring together all stakeholders in a real-market ecosystem, including the use of virtual ecosystems that act as test beds and allow risk sharing > EIT Health can act as a neutral facilitator by engaging and connecting their network of partners and Living Labs > EIT Health can provide training and guidance > Implement educational programmes for stakeholders about Digital Health concepts and changes to the role of patients and the workplace activities of healthcare professionals, that will result from new innovations > Improve the internal competence of companies to manage the wide scope of the pathway and the skills required to navigate it successfully (regulatory, sales, market access, etc.) > Promote the development of new evaluation tools for Digital Health products	
MARKET ENTRY **ACTION** > Reduce the bureaucracy and time taken to achieve authorisation to undertake clinical trials in France > Promote the development and acceptance of new assessment and validation tools for Digital Health, including in-silico simulation methods; assessment should include measures of patient adherence. > Engage and educate regulators on the current use of new assessment methods by industry and academia > Turn the new MDR evidence requirements into an opportunity	**TARGET STAKEHOLDER(S)**

> Promote education and research on regulatory and HTA science > Increase cross-disciplinary collaboration between industry, professionals and academia (including social and humanistic sciences), for assessment of the broad range of complex digital solutions > Develop new pathways and assessment methods for Digital Health products that enable a more efficient and agile regulatory process, focused on the speed of access for patients to safe and effective innovations > Ensure all stakeholders in France work in close collaboration with their European peers > Ensure low-risk medical devices have a more pragmatic regulatory evaluation > Provide clear contacts and guidance on regulatory requirements > Promote clear data standards within trust environments that support interoperability and accessibility, data sharing, and allow for real-time data collection and evidence generation > EIT Health help facilitate	
ADOPTION **ACTION** > Create standards and methods for comparative assessment of value across Europe, which also take into account the long-term nature of chronic diseases. > Promote sharing and exchange of information and evidence standards internationally, particularly at the administrative level, to ensure standardisation across Europe and the adoption of innovations across borders > Support and empower patients, their care network, and healthcare providers to ensure they understand the impact of innovation, can contribute actively to innovation, and benefit from training > Increase the sharing of patient empowerment initiatives across national boundaries > Improve change management within healthcare	**TARGET STAKEHOLDER(S)**

organisations so that changes to workflow and incentives resulting from the adoption of new Digital Health innovations are accepted positively > Develop new finance models that support early access to market	

Appendix 1: Round Table Meeting participants

EIT Health would like to thank the following participants for their input into the Round Table Meeting:

Name	Organisation
Advisers	
Finn Boerlum Kristensen	Think Tank Round Table Series Chair 2019 & Independent Consultant
Robert Picard (Moderator)	Health Referee at CGE, Ministry of Economy and Finance
Juan Fernando Ramirez (Moderator)	Vice President and Chief Medical Officer, Air Liquide; Vice President of the Board of EIT Health France
Patricia Alegre	Global Market Access Director, Air Liquide Healthcare
Anne-Françoise Berthon	Innovation Officer, Ministry of Health
Sylvie Bothorel	VP Healthcare Technology and Innovation, Air Liquide
Beatrice Falise Mirat	Scientific Director, Care Insight
Angela Martin	Strategist and eHealth Expert, Altran Frog
Patrick Olivier	General Manager, Ivbar France
Sylvia Pelayo	Professor and Associate Director, Lille Clinical Investigation Centre for Innovative Technologies
Pierre Yves Traynard	Coordinator, Pole de Ressources Ile de France for Patient Health Education
Cécile Vaugelade	SME Director, Snitem
Organisers and other attendees	
Mayra Marin	Think Tank Manager, EIT Health
Sameena Conning	Director of External Affairs, EIT Health
Jean-Marc Bourez	Managing Director, EIT Health France
Jérôme Fabiano	Communication and Public Affairs Officer, EIT Health France

Miguel Amador	Researcher
Karen Wolstencroft	Rapporteur