Optimising Innovation Pathways: Future Proofing for Success

Think Tank Round Table Meeting Proceedings

Baden-Württemberg State Representation, Berlin, Germany 11.10.19

THINK TANK

EIT Health is supported by the EIT, a body of the European Union

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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. Not only has the number of players in this sector increased over this time but the type of products and services has changed too. This has implications for the overall fit and suitability of the steps that companies need to navigate when taking 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, validation, implementation, usability and adoption of new health technologies. As a result, innovators can face hurdles, not only for regulatory approval but also to achieve sustainable adoption, with stakeholders 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 German 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 in healthcare.

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: Germany Round Table

Hosted by EIT Health Germany

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

Moderated by: Professor Alexander Ehlers MD, Dr. jur

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 Germany
- **Session II:** Optimising the innovation pathway in Germany
- **Session III:** Proposals for actionable recommendations

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

Focus of the German Round Table

The innovation type selected for discussion at the German 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 scope of Medical Device software. With it, many Digital Health solutions will be now considered as Medical Devices, when previously they were not. The main difference in the pathway is that a Wellness Digital Health solutions will skip the regulatory process required for market authorisation of Medical Devices and can be sold without major limitations. Alongside the rise in Digital Health products is a new spectrum of human, privacy, legal and ethical challenges arise, since it is an area that is heavily reliant on data and individual/social behaviours.

Overview of German Digital Health Ecosystem

The findings of EIT Health's research into Germany'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:

- Germany is Europe's largest healthcare market with more than €320 billion spent on health annually (not including expenditure for fitness and wellness), representing 11.2% of the country's total gross domestic product.
- Forecasts estimated that the German mobile health technology (mHealth) market was set to grow to around €3 billion in 2017. Hardware is the largest segment of this market, with hardware sales accounting for 59%, over €1.7 billion, of mHealth revenue.
- A key segment of mHealth market in Germany is health monitoring which was estimated to generate 72% of the total mHealth revenue in 2017, primarily as a result of the increased uptake of wearable devices (Source: PricewaterhouseCoopers and Germany Trade & Invest, 2018).
    - 31% of the German population uses fitness trackers to monitor their vital signs.
    - 30% of smartphone users install health apps.
    - Nutrition apps are the most popular medical apps, demonstrating that mHealth plays important role in the shift towards preventive healthcare.
    - Of the 325,000 global mHealth apps, around 100,000 focus on the German-speaking market (Source: research2guidance).
- Despite this opportunity to harness Digital Health in Germany, a survey has shown that compared with some other countries, Germany lags behind in terms of digitalising its healthcare sector (Source: #SmartHealthSystems). Of the 17 countries surveyed, Germany ranks 16th, with Estonia, Canada, Denmark, Israel and Spain at the top of the list.
    - It is estimated that up to €34.0 billion in potential value could have been realised in 2018 if the German healthcare system had been fully digitised. This is equivalent to around 12% of its actual total projected costs of around €290 billion in 2019 (Source: McKinsey).
- Relevant German laws relating to Digital Health include:
    - The E-Health Law which came into force in 2015 enabled the use of telemedicine, and paved the way for Electronic Health Records (HER) and IT interoperability standards for new Digital Health applications.
    - In July 2019, the Digitalisation and Innovation Act (Digital Supply Law) was drafted, which will make it possible for doctors to prescribe digital apps with health benefits, that could be reimbursed by the country's health insurance system. This law paves the way for the national regulation of medical apps, and for reimbursement coverage and meanwhile has passed the German Bundestag.

The Digital Health Innovation Pathway

The proposed innovation pathway in Germany 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 Germany as described and were asked to advise:

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

- The pathway as presented is generally correct however due to the speed of development of Digital Health products, they need to be assessed very differently to pharmaceutical products or traditional Medical Devices.
- The linear timeline and process do not reflect the realities of product development in this area. Rather than a linear series of steps, the pathway is often navigated in a more complex way.
- Although the McKinsey study suggested there would be considerable cost savings as a result of digitisation of the German healthcare system, its complexity makes it difficult to predict this accurately.

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

- Aspects such as regulatory approval and reimbursement need to be considered much earlier in the pathway as they are critical success factors – innovators need to be prepared for this well in advance, and be aware of the potential 'valley of death' stages.
- Innovators need to understand the complexities of both the regulatory environment (e.g., assessing an app for use in the home will need a differing strategy to one that is used in hospital) and the reimbursement environment from the outset, and this can differ depending on the context (for example, a selective agreement with a health insurance fund or collective agreements).
- Investors can often be too ambitious in terms of the business plan and not be aware of all the challenges that innovators face along the pathway – need to encourage greater dialogue in order to manage expectations in an industry that is still developing; also need to ensure investors are embedded in the strategic process from the start.
- There is no single Health Technology Assessment (HTA) body in Germany. There is a process that is defined by legislation (AMNOG). The independent Institute for Quality and Efficiency in Health Care (Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen; IQWiG; https://www.iqwig.de/en/home.2724.html) has an evidence-based approach and is responsible for assessing the benefits and harms of medical interventions for patients on the request of the Federal Joint Committee (G-BA). IQWiG offers a dialogue programme with representatives from science and industry for a scientific and technical discussion on various topics related to the work of the IQWiG. It is recognised that it is very difficult to generate prognostic evidence that IQWiG will accept and therefore they create a bottleneck.
- There is adequate funding and subsidies for research (in universities for example) into digital technologies and this has generated some interesting Digital Health product developments. However, often researchers have no understanding of the relevant processes; when they get to the stage of testing in a (real life) clinical setting, companies are often ask for a CE mark - they are therefore stuck in a 'Catch-22' situation of being unable to test a product at the research stage. In the clinical community there is a fear of negative consequences, (e.g. lawsuits) and using products 'off-label'.
- Transparency is needed regarding the framework conditions and environment for the pathway for Digital Health products and this will require greater dialogue between stakeholders – EIT Health could help facilitate this dialogue.
    - A clear definition is needed for medical health products and wellness products, and how they are differentiated.
    - Clarity is needed regarding the different risk categories for digital technologies, as is currently done only those that are medical products at the EU level.

- These categories may need to be expanded, for example for medical devices that include software (which also needs to be clearly defined) and artificial intelligence (AI)-empowered algorithms.
- New risk assessment tools need to be developed for these types of products.
- Test facilities and clinical contract research organisations (CROs) must expand their service portfolio while meeting all applicable (pivotal) clinical trial regulations
- Regulation of Digital Health Solutions is needed at the EU level, focused on high quality standards but also on interoperability.

- The current pathway process is defined for traditional technologies with a long life-cycle, and needs to be redefined to reflect digital innovations that have a very different, much shorter-term, life-cycle.
- Generation of evidence is critical for approval and adoption in order to demonstrate efficacy, safety and, in particular, value when reimbursed from social funds. However, the challenge is that meeting the hard criteria for 'evidence-based medicine' takes time, which is difficult to realise in the ecosystem of Digital health, which moves fast.

Session II: Optimising the Digital Health Innovation Pathway in Germany: 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
Needs assessment	> A structure for systematic needs assessment with input from all stakeholders is required at the earliest stage of the process – currently there is no firmly established framework for this.

	> The patient/end-users' journey and point of view is the most important and should be included from the start of the process to ensure acceptance and usability. > 'Clinical need' is too narrow a description and needs to be expanded – need to consider the needs of user subgroups such as patients, clinicians, health insurers, etc, as well as the system needs. > Research into the 'technology acceptance model' suggest that 'ease of use' and 'value for the physician' are key product attributes.
User research	> User research (with patients, physicians, nurses etc) can be challenging as they need to have a clear understanding of the benefits that using a potential new innovation can provide to them – this may require a certain amount of education before use. > Key areas for clinical research in any particular therapy area may differ between clinicians' and patients' viewpoints – there is a need for management of expectations and an alignment between the scientific community and the real world of the patient's experience.
Stakeholder requirements and roles	> Management of the 'customer interface' (in terms of which stakeholders provide which services and what the implications are for established workflows) is key. > A clear definition of requirements, roles and expectations of the different stakeholders is required from the start of the innovation pathway. > The continued collaboration with relevant German and European expert and umbrella organisations and their working groups dedicated to Digital Health is recommended.
Patients and patient organisations	> In the US, patients associations have significant funds and participate in the development of start-ups, however they have limited political influence. > In Germany, the culture is different: patient associations are more engaged in political discussions, however, there is a need to organise

	more direct engagement between patient organisations and innovators so that valuable needs-driven products can be developed. > (Cultural) barriers preventing an effective collaboration between patients and industry to be addressed in Germany.
Support for start-ups entering healthcare	> Start-ups entering the market need education in the complexities of the German healthcare system in which they are innovating. > Health Innovation Hubs can act as a valuable support system for start-ups, in particular matching with the right mentors and investors who have experience of the healthcare sector and therefore can advise on realistic business goals.
Health Insurance Companies	> The National Association of Statutory Health Insurance Funds (GKV-Spitzenverband; https://www.eu-patienten.de/en/glossar/gkv_spitzenverband.jsp) is a key stakeholder in Germany. They represent statutory healthcare and long-term care insurers at central level and define the framework conditions for quality and economic viability in healthcare and long-term care. > There is an increase in competition between health insurance companies aiming to position themselves as health care providers for contact with innovation start-ups. In this setting, the outcome for the start-up is primarily developing their knowledge of the system. > In the Ideation phase, investment is more difficult for statutory insurance companies than for private insurance companies. > There are three ways in which an individual insurance company can bring innovations into the healthcare system: > By selective agreement – generally late in the pathway for mature products. > An innovation fund – academic institutions will fund the innovation. > Under the Digital Supply Law – this is a new possibility that

	enable health insurance companies to invest their own capital into start-ups and becomes involved in co-creation. However, no insurance company is allowed to invest in 'risky' products.
Funding	> More support is needed for early-stage innovations, otherwise companies will look outside of Germany to realise the economic success of their ideas. > Although the Joint Federal Committee (G-BA) has implemented a financially well-positioned innovation fund for sponsoring healthcare research, this format does not support trials in the frameworks of drug and medical device efficiency evaluation, conformity assessment procedures, early benefit assessment according to the drug reorganization law (Arzneimittelneuordnungsgesetz), or research and development of new product innovations. Therefore, additional sources of finance are needed for other stages of product development.
Legal and ethical frameworks	> There may be a need to develop new legal and ethical frameworks relating to the liability of Digital Health products, particularly automated devices making therapy decisions, for example closed-loop metabolic control (artificial pancreas) systems for people with diabetes who require insulin. > While Germany has an existing legal framework for liability, in practical terms health technology innovations are still perceived as outside the usual clinical sector.
Education	> Education on the practical application of digital technology in healthcare and how it can become part of clinical workflows is important in order to motivate young scientists to become entrepreneurs.

	> It should be part of university curricula for healthcare professionals and should include: > Entrepreneurship > Regulatory framework and decision making > Stakeholder landscape > Product life-cycle
Developing trust	> There is a need for a cultural change towards greater trust in the collaboration between industry, research/academia, patient and expert associations, and health insurance companies, otherwise this will be a barrier to innovation. > A culture of well-justified confidence is also key when considering health data security and privacy.
Key points	> **A firm structural framework for a systematic needs assessment is required with the involvement of all relevant stakeholders** > **A clear definition of requirements and expectations of the different stakeholders, including the targeted user groups, is needed from the start of the innovation pathway** > **The alignment of patient organisations' needs with the research/innovation being undertaken needs to be improved** > **A continuous collaboration with relevant expert associations is needed to build trust and ensure good market acceptance.** > **More funding support is needed for early-stage innovations to encourage companies to do business within Germany** > **A culture of trust between all stakeholders in the innovation process needs to be established** > **Training and education on entrepreneurship and the practical integration of digital technology in healthcare provision as well as on the innovation pathway phases, stages and requirements is needed for all healthcare professionals and to motivate young innovators**

What is working well/best practices identified in this phase

Positive experiences
An application for children with eye disease. Previously, the children would be required to wear an eye patch; now they can download software and use a computer screen game which sends signals to the eye to improve the condition. This has been very successful and is reimbursed by certain health insurance companies.
Germany is a centre of scientific excellence and there is no shortage of innovation ideas in the pipeline, but better funding opportunities are needed.
The Innovation Fund can help evaluate the process of implementation and the finances necessary for this process (although it does not evaluate or finance the innovation itself).

Best practice examples
RAMP Medical
The CLOSE (automated glucose control at home for people with chronic disease) EIT Health innovation project is a good example of the advantage of being part of an innovation portfolio curated by a business-oriented public–private partnership (EIT Health). CLOSE took advantage of the input of entrepreneurially-oriented students and different stakeholders in a six-week CLOSE-CDTM (Centre for Digital Technology and Management) Trend Seminar on digital innovation in diabetes care (TU Munich) and the InnoDiaCare Summer School (MU Lodz). Although initially targeting the French market (due to optimum prerequisites in the French homecare service provision segment) the consortium welcomed the opportunity for an early dialogue with the European Network for Health Technology Assessment (EUnetHTA) when addressing opportunities in the German market.

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
Investors and finance	> The hesitancy of some investors to finance Digital Health innovations is partly due to the fact that innovation companies fail to present a good business model, and not to the investors' lack of knowledge of the digital healthcare sector – there are several experienced investors in this area. > Large investment companies will know the Digital Health market well but may not be so familiar with the specifics of the pathway processes. > There is currently no platform in Germany that allows companies, investors, payers and providers to meet and discuss these issues and share best practices in order to support start-ups in the Development phase. > Supporting start-ups grants are associated with significant administrative costs, so there needs to be a drive for greater efficiency in the process. > It could be argued that investors are faced with a monopoly market from the insurance companies, so they may restrain without more clarity on how they will engage with the innovation.
Trust and data security	> There are ongoing concerns from citizens and patients about digital technology and the use of artificial intelligence (AI) in healthcare, which need to be dealt with.

	> Despite a high degree of casual, routine personal data sharing through social media and in the context of everyday tasks, there is an overall lack of trust in sharing of healthcare data and in the motives of private companies having access to this. > It is difficult to develop a good business case in this distrustful environment, so it is important to find ways to improve the level of trust and create a societal ecosystem that supports digital innovation by valuing its impact on the well-being of individuals and societies. > In particular, there is a lack of transparency regarding the secondary and subsequent usage of data arising from Digital Health innovations.
Success factors	> The success of an innovation is not always about the technology involved, but about the team's network and connections. Such a support network is more than just a source of information but is key to progressing successfully through the pathway. > This is also compounded by the fact that start-ups often don't have the funding to bring the right level of expertise/professional mix into their own internal teams.
Key points	> **More calculability and transparency in key decision and reimbursement processes of payers is required for embedding them from the start of the Development process** > **A collaborative platform is needed to support start-ups in engaging with the different stakeholders (key decision makers and relevant networks)** > **Transparency and trust around the use of healthcare data by private institutions (innovators) should be promoted**

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
Market surveillance	> Market surveillance is an important requirement in the Market Entry phase however many start-ups lack the capacity and know-how to fulfil this commitment and ensure a good market fit for their product – EIT Health could help orchestrate support and share experiences.
Software	> It is important for companies to display greater transparency when developing software or AI-based applications. > While there is a good understanding of this form of technology, the regulatory path is not well-defined. > A checklist/catalogue is needed at a national/EU level for how software can be launched onto the market.

Impact of new MDR	> The new MDR pose a significant challenge both for young start-ups and for SMEs, and create a backlog of investment in innovation – this needs to be addressed urgently as it will increase the time to market. > In particular, the requirements for low-risk products are too high and therefore a considerable hurdle. > Low-risk and high-risk products need to be clearly defined and distinguished – otherwise it could have a significant impact on the economy. > The requirements for the assessment of software and its regular updates have been underestimated.
Real-world data	> Better use should be made of real-world data. The healthcare sector already uses this to analyse the outcomes of using Medical Devices, but it requires cooperation between stakeholders. > As an example, in the field of oncology, they are already looking at new concepts for evaluating medicinal products without jeopardising safety – if data are generated quickly, feedback is gained, and adjustments to the product can be made very rapidly.
Validation	> In the Digital Health market there are now complex products that need to be regulated and assessed as part of a system, and not as individual products. > The new MDR do not account for this and are still based around three classifications of individual products. > There is a need for an additional category for AI-based applications that adjust therapy (e.g. AI-powered closed-loop metabolic control systems by means of an artificial pancreas) – this will require a different methodology for testing. > Clinical CROs should provide test environments that offer the evaluation of AI-powered medical devices, along with a full array of integrated Data Sciences services, of a quality which is compliant with all applicable regulations. For AI-powered medical devices used for a real-world monitoring of health, the clinical trial (drug

	development) market could serve as a stepping-stone to the more complex chronic care markets –by providing a well-regulated commercial framework which holds opportunities for learning experiences, gathering evidence and disseminating early success. > It can be a challenge to determine if a digital health product is a 'product' or part of a 'method', each of which has different regulatory requirements – The Joint Federal Committee (G-BA) or The Federal Institute for Drugs and Medical Devices (BfArM). > The Federal Social Court recently expanded the concept of methods, such that whenever a doctor analyses data, then that is considered as a method and is subject to regulation. > However, G-BA can be a hurdle regarding the requirements for methods and how they are assessed. G-BA can start to assess the method without waiting for BfArM decision. > Assessment of AI applications requires a substantial amount of data – need to decide who pays for this and who owns the data that have been analysed.
Financing and reimbursement	> There is currently an overlap between a free-market economy and social security funding in the German healthcare ecosystem. > New business models are needed to reflect creation and assessment of innovations using public funds, and the sharing of knowledge and data that are subsequently generated.
Key points	> **The acquisition and (AI-powered) exploitation of real-world data in the framework of pivotal clinical trials should be enabled and encouraged to generate evidence supporting the validity of digital health innovations** > **Clear guidelines and instructions on the requirements for the different Digital Health product categories are needed** > **Processes for assessment of an overall system and methodology, not just individual products, needs to be developed** > **The way data are generated and shared by innovators for the**

	benefit of society as a whole needs to be improved > The backlog that MDR will create needs to be recognised and effectively managed > Assessment pathways and environments that are suited to the rapid development pathway of Digital Health products need to be developed > The clinical trial (drug development) market might be considered a stepping-stone towards the more complex chronic care markets > Clinical CROs should adapt their service portfolios by integrating the real-world acquisition and AI-powered exploitation of health data in (pivotal) clinical trials and expanding Data Management & Statistics towards a full array of Data Sciences services fully compliant with applicable law and regulations.

What is working well/best practices identified in this phase

Positive experiences
Good examples of successful Digital Health products in Germany can be seen in the area of prevention. They have shown excellent scaling-up and good collaboration with clinical centres and sports institutes. One example is the use of an AI tool to assist with the reading of mammograms in Baden-Württemberg.
Reimbursement of continuous glucose monitoring (CGM), flash glucose monitoring (Abbott) and a hybrid closed-loop metabolic control system (MiniMed670G, Medtronic) for defined subgroups of diabetes patients in Germany.

Best practice examples
DiaDigital quality seal. The German Diabetes Association (DDG) has implemented a Working Group on Diabetes and Technology (AGDT). Through the AGPD and in collaboration with diabetesDE, Deutsche Diabetes Hilfe Menschen mit Diabetes (DDH-M) and the Verband der Diabetes-Beratungs- und Schulungsberufe in Deutschland (VDBD) the DDG has established the DiaDigital quality seal. The DiaDigital initiative is the first to evaluate the quality of diabetes Apps and digital support tools in Germany. As part of the DiaDigital initiative, apps and digital support tools are evaluated by applying a set of dedicated criteria. App and device manufacturers can apply by providing a

structured self-declaration. The technological evaluation is offered in collaboration with the Centre for Telematics and Telemedicine (ZTG) in Bochum (Germany) which also creates the Test Report. Following successful evaluation, a seal is awarded, and the information collected during the process is made public on the website of the AGDT in order to ensure the necessary transparency and rapid implementation of the evaluation outcomes for further development of apps and digital devices.
TK (Technik Krankenkasse, the largest health insurance fund in Germany) has developed a portal where health start-ups can present their concepts.

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
Adoption strategy	> An Adoption strategy needs to be included as part of the project plan from the start.

	> A clear strategy of where in the market the final product will be placed is essential for successful adoption.
Assessment	> Consider the use of real-world data for assessment, as a form of 'rapid prototyping'.
Reimbursement	> A project is likely to fail if reimbursement is only considered at the end of the process. > The reimbursement system in Germany is very diverse – direct agreement, selective agreement, in-patient or outpatient product etc. – and the chosen pathway will depend on the type of product, therefore a clear direction is needed from the beginning. > There are many different reimbursement pathways in Germany, and they differ from those in other EU countries – ideally the systems should be standardised on an EU-wide basis. > For innovations and digital solutions, selective agreements with health insurance funds are the usual option, but the process can lengthy and complex. > A 'golden path' by way of application submission to G-BA is an alternative but less explored and riskier option – it is the pathway that should ideally be pursued for innovations. No small start-ups have successfully negotiated this path as the hurdles are significant and the risk of a negative assessment outcome from the G-BA will mean the product is excluded from the healthcare market completely. Taking advice from expert associations which have regular discussions with G-BA representatives is recommended. > In the case of digital solutions to operational healthcare management – the developers may be able to sell to private companies when other pathways have failed. These are generally not considered scalable and sustainable models.

	> These pathways require substantial effort, a network of resources as well as considerable investment funds that start-ups don't usually have. > It should be understood that in fact Germany is not a reimbursement market, but an 'agreement market', so the partners to the agreement negotiate and define not only the price but the scope of the product (type of patient, conditions etc.) – this is an aspect specific to the German market and reflects the fact that Germany consists of different and diverse federal states and shows a high diversity of statutory and private health insurance companies. > Depending on the need for an innovation and the drive from end-users, companies may seek reimbursement options outside of the usual structure (example: Abbott diabetes monitoring products). > It is important to distinguish between the many aspects to reimbursement, beyond just payment for services and products – insurance company budgets need to include costs for marketing, education etc., which is often paid out of the administration budget but is an important component that can have a significant impact on adoption.
Self-payer market	> Patients paying out of their own pocket is an increasing trend in Germany but is still at a low level as it is not really necessary with the system of social healthcare provision. > For service providers (e.g. hospitals) there is already an established self-payer market for products that improve in-patient processes, such as information systems.
Treatment versus prevention	> A clear distinction is needed between products that are developed for treatment/management of a disease and those that are intended for health protection and disease prevention. > In contrast to the situation in Germany, many countries in Europe disease management products are categorised under 'chronic' or 'non-chronic' diseases, and are regulated differently from those for prevention.

	> The prevention sector is a growing market and there have been several examples of companies in Germany successfully scaling up in this area. > With prevention-focused digital healthcare products there is an opportunity for reimbursement through health insurance funds. > Prevention is a persuasive tool but requires incentives to encourage users to continue to use the solutions in the longer term.
Employee health management	> There has been a huge increase in companies focusing on employee health management, including the use of digital technologies. > This is an opportunity for innovators to expand in this area and also to develop agreements with companies to test new products in this setting.
Value proposition	> In some cases, added value beyond reimbursement can be built into the value proposition, for example the means of dissemination (e.g. use of Abbott FreeStyle diabetes monitoring system used in schools).
Value-based healthcare	> Need to ensure at this stage that there is strong evidence of the economic benefit and value of an innovation to help facilitate its adoption. > Value-based healthcare offers the opportunity to accelerate the pathway by allowing implementation of temporary reimbursement arrangements while data are being generated and analysed in parallel – based on outcomes, a decision can then be made whether to provide further financing. > To undertake this would require an assessment of risk, however the current pathway that aims to reduce the risk close to zero is very cost intensive, meaning that smaller innovation companies

	are excluded from the market, resulting in a backlog of innovations. > Small companies may find it difficult to engage in shared-risk contract agreements. > This form of outcomes-based payment is also being discussed in the pharmaceutical sector. > A problem with performance- or outcomes-based agreements is that it can be very difficult to prove causality.
Legislation	> New legislation is on the way that may enable certain digital solutions to be reimbursed and therefore facilitate adoption – once approval is given by G-BA or BfArM, there will then be a free pricing reimbursement agreement for one year. > Statutory healthcare systems are not currently allowed to fund innovation or research but, under the new law they are will be allowed to spend up to 2% of their budget for implementing and fostering innovation.
EU harmonisation	> Harmonisation of HTA assessment across the EU, for example, by entering into early dialogue with the European Network for Health Technology Assessment (EUnetHTA, https://eunethta.eu/) is advised. > The argument against HTA transfer of results relates to the challenge of accepting 'low' standard thresholds that are said by the German IQWiG to be accepted by some other countries.
Key points	> **Use real world data to embrace risk and uncertainty while generating evidence** > **Consider the costs for marketing and dissemination of innovations as part of the overall reimbursement budget** > **Develop a reimbursement pathway that is more suited to the rapid development of Digital Health products**

	> Push for value-based healthcare, but consider the risk-sharing limitations of SMEs > Harmonise the assessment of product benefit across Europe and take advantage of early dialogue with EUnetHTA

What is working well/best practices identified in this phase

Positive experiences
Abbott FreeStyle glucose monitoring system for diabetes.

Session III: Conclusions and recommendations for actionable outcomes

IDEATION ACTION	TARGET STAKEHOLDER(S)
> Develop a firm framework and procedures for systematic needs assessment involving all stakeholders including the different user groups > Promote stakeholder meetings and networks to give advice relating to user needs - EIT Health can facilitate > Create a platform of key stakeholders where innovators from both start-ups and large companies can engage to gain feedback - EIT Health can facilitate > Provide a clear definition of the requirements and expectations of all the different stakeholders from the start of the innovation pathway > Increase alignment of patient organisation needs with the research/innovation being undertaken > Define clear healthcare needs and goals at a top level, which then guide the best science research – Health Innovation Hubs > Increase the trust in collaboration between all stakeholders throughout the innovation process > Promote a legal framework for research, allowing small and large companies to cooperate and share in a trusted environment.	

> Promote education about a new role for healthcare that will result from digital health innovations. > Further develop the EU guidelines on 'Trustworthy Artificial Intelligence' by making them more specific for the healthcare sector > Create an EIT Health Data Platform populated by data from EIT Health projects and other EU initiatives (such as IMI) that is open to research groups in the framework of peer-reviewed projects curated by EIT Health. > Promote education on entrepreneurship and the practical application of digital technology in healthcare and the innovation pathway phases, stages and requirements for all healthcare professionals and to motivate young innovators > Develop additional indicators to measure research output. > Include teaching about entrepreneurship and innovation from the early stages of healthcare professional education – create a new type of culture. > Provide individual coaching of innovators to navigate specific stages of the pathway.	**Universities**
DEVELOPMENT **ACTION** > The key decision and reimbursement process of payers should be transparent and predictable and confirmed from the beginning of the development > Monitor the criteria for eligibility for reimbursement across several areas (look into pilot programmes with several innovators, for example developing AI-powered solutions). > Engage payer experts to assess the real-world viability of innovations as early as possible. > Develop collaborative platforms to support the engagement of	**TARGET STAKEHOLDER(S)** **Health Insurance funds** **Health Insurance funds** **Key decision makers and relevant networks**

start-ups with the different stakeholders > Create structures for multiple stakeholder assessment at the early stages > Promote a culture of transparency and well-justified trust that values the societal benefit that the exploitation of data in healthcare by private institutions can generate > Adapt the EU guidelines for 'Trustworthy Artificial Intelligence' specifically to the healthcare sector and create solution-specific examples of their usability	**Innovators**
MARKET ENTRY **ACTION** > Enable and encourage the use of real-world data to generate evidence to support assessment of innovations > Develop clear guidelines and instructions on the requirements for the for the different Digital Health product categories > Develop new methodologies for evidence generation in digital health focused on the value endpoints for the healthcare system > Consider the clinical trial (drug development) market as a stepping-stone towards the much more complex chronic care markets > Provide a well-regulated commercial framework which generates opportunities for learning experiences, gathering evidence and disseminating early success. > Adapt the service portfolio of clinical CROs by integrating the real-world acquisition and AI-powered exploitation of health data in (pivotal) clinical trials > Establish secured validation environments for the clinical evaluation of AI-powered Digital Health solutions perceived as risky > Develop AI-powered methodologies for improving the external validity of clinical trials by narrowing the gap between the efficiency of drugs and devices in well-controlled clinical trials and their effectiveness in real-	**TARGET STAKEHOLDER(S)**

world healthcare provision > Expand Data Management & Statistics towards a full array of Data Sciences services compliant with applicable law and regulations > Improve the ability to regulate and assess an integrated system and methods, not just individual products > Improve the way data are created and shared by innovators for the benefit of society as a whole > Recognise and effectively manage the backlog that the new MDR will create > Collaborate with German and European medical associations to co-create assessment pathways that are better suited to the rapid development pathway of Digital Health products	
ADOPTION **ACTION** > Use real world data to embrace risk and uncertainty while generating evidence > Consider the costs for marketing and dissemination of innovations as part of the overall insurance company budgets > Define and clarify the brokers for digital health solutions (limiting direct contact between patients and manufacturers without consultation) > Adapt reimbursement pathways to make them more suitable for the rapid development of Digital Health products > Create early risk-potential assessment of innovations to enable accelerated pathways > Explore the diverse range of possible reimbursement paths > Push for value-based healthcare and risk-sharing, while being aware of the limited capabilities of SMEs as compared to the large corporations in healthcare. > Create a data space and scenarios that enable testing of innovations using real-world data and value-based healthcare principles - EIT Health could curate such a data space	**TARGET STAKEHOLDER(S)**

populated by data from EIT Heath projects and other EU initiatives, such as IMI > Support harmonised product benefit assessment across Europe and provide advice on using the early dialogue offer from the European Network for Health Technology Assessment (EUnetHTA).	

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
Alexander Ehlers (Meeting Moderator)	Ehlers, Ehlers & Partner Rechtsanwaltsgesellschaft MBB
Martin Danner	BAG Selbsthilfe
Manuel Mandler	Gothaer Krankenversicherung AG
Dirk Müller-Wieland	Universitätsklinikum Aachen
Holger Pfaff	GBA Innovationsauschuss - Institut für Medizinsoziologie, Versorgungsforschung, Medizinischen Fakultät der Universität zu Köln
Jared Sebhatu	Smart Helios GmbH
Freimut Schliess	Profil Institut für Stoffwechselforschung
Wilhelm Stork	Karlsruher Institut für Technology, FZI Forschungszentrum Informatik
Andreas Vogt	Techniker Krankenkasse, Landesvertretung Baden-Württemberg
Organisers and other attendees	
Mayra Marin	Think Tank Manager, EIT Health
Sameena Conning	Director of External Affairs, EIT Health
Katharina Ladewig	Managing Director, EIT Health Germany
Michael Luettgen	Key Account – Liason Manager, EIT Health Germany
Simin Werner	Events and Communications Coordinator, EIT Health Germany

Miguel Amador	Researcher
Karen Wolstencroft	Rapporteur