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

EIT Health Think Tank

Optimising Innovation Pathways:
Future Proofing for Success

German Round Table Meeting

APRIL 2020

Each host selected to focus on a choice of innovation type relevant to the local context – Germany selected digital health solutions which refers to software-based solutions that focus on healthcare interventions (related to patients or citizen health)

Contents

Executive summary 2

Introduction 4

The current situation: a focus on today's innovation pathway 5

Ideation – grasping the unmet need 6

Development and market entry 7

Overcoming data barriers 8

Adoption – gaining reimbursement and long-term use 8

Conclusions and recommendations for optimising the path to market in Germany 10

Appendices 12

Introduction

In recent years, there has been rapid growth in the field of medical and health technology.

Not only has the number of players in this sector increased 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 or service, 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 the EU, the new Medical Device Regulation (MDR) will 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.

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

The Round Table Series took place in various locations across Europe organised in conjunction with the EIT Health Regional Hubs. Berlin was selected as the location for the German Round Table Meeting which took place on the 11th October 2019 and saw participation from key stakeholders involved in the innovation pathway in Germany.

Each host selected to focus on a choice of innovation type relevant to the local context – Germany selected digital health solutions which refers to software-based solutions that focus on healthcare interventions (related to patients or citizen health).

The current situation:
a focus on today's innovation pathway

The innovation pathway, or route to market for new products and services, is comparable in Germany to the rest of Europe. Although presented in a linear format in figure 1 below, it is in fact a continuous and cyclic pathway whereby all parts are interconnected and reliant on each other.

IDEATION

0 CLINICAL NEED

1 IDEA

DEVELOPMENT

2 PROOF OF CONCEPT

3 PROOF OF FEASIBILITY

4 PROOF OF VALUE

MARKET ENTRY

5 INITIAL MARKET ENTRY

6 VALIDATION OF SOLUTION

7 APPROVAL & LAUNCH

ADOPTION

8 CLINICAL/COST ASSESSMENT

9 REIMBURSEMENT

10 APPROVAL & LAUNCH

11 OBSOLESCENCE

FIGURE 1

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.

Ideation – grasping the ‘unmet need’

The term ‘unmet need’ refers to the clinical shortfall of solutions for a disease, condition or patient experience in managing, maintaining or regaining their health.

While unmet clinical need is a crucial consideration in the ideation phase, there is also a need to focus on overall need, including patient needs, healthcare professional needs, and the needs of existing healthcare systems such as hospitals. A key challenge for digital health solutions is not the technology itself, but the requirement for change management and adaptation to reflect new processes and workflows. Therefore, it is more important than ever to assess the full context for any product or service through engagement with stakeholders at the earliest time point and throughout the pathway.

In Germany, cultural barriers exist preventing effective collaboration between innovators and patients (or the patient organisations representing them). Discussion about how direct involvement can be organised should be conducted so that valuable needs-driven products and services can be developed.

At the earliest stage, it is also important for the innovator to consider their business plan as this will become a barrier to the next steps in the pathway. The hesitancy of some investors to finance digital health solutions is partly due to issues with the business model presented, rather than the common perception that investors lack of knowledge of the digital healthcare sector. Large investment companies are familiar with the digital health market but may not be familiar with the specifics of the pathway and processes. Start-ups should be supported in preparing their business model and pitch to investors so that there can be common understanding between the two groups.

Development and market entry

The development stage of the innovation pathway begins the official route to market. At this stage of the pathway, innovators must be able to prove the feasibility of their solution as well as present clear technical and scientific validation to begin developing a regulatory submission so that a CE mark can be considered. A compelling value proposition is also a key part of the development stage to attract market interest and begin the necessary groundwork for later reimbursement and adoption.

The regulatory and reimbursement (market entry and adoption) stages of the pathway were historically developed to support the introduction of more traditional treatments such as pharmaceutical medicines or medical devices. Compared with well-established processes, the digital health pathway is somewhat less clear and more complex as a result. This is particularly relevant when assessing the regulatory processes, which is struggling to keep pace with the rapid introduction of new technologies. In the current landscape, where new technological discoveries are constantly being made, there is increasing need for a more agile regulatory framework.

Such reform of the regulatory pathway in Europe has indeed been addressed recently as evidenced by the European Medicines Agency with the proposed introduction of new Medical Devices and In Vitro Diagnostic Medical Devices Regulations (MDR) which are planned to be introduced in 2021. The new MDR poses significant challenges both for young start-ups and SMEs, with the new process expected to increase the time to market for many products and services.

As a result, smaller companies may struggle to respond within their available resources. An additional concern amongst health innovators is that the guidance does not distinguish between high and low risk products and services, and therefore the same rigorous process will need to be approached despite the possible impact on considerations such as patient safety. The requirements for the assessment of software and its iterative process, for example small updates, have also not been factored into the guidance.

In Germany specifically, it can be a challenge to determine if a digital health solution is a 'product' or part of a 'method', each of which has different regulatory requirements – The Federal Joint 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.

It is important for companies to display greater transparency when developing software or artificial intelligence (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 regulated and launched.

Overcoming data barriers

There are ongoing concerns from citizens and patients about digital technology and the use of AI in healthcare, which requires attention. Despite a high degree and familiarity with 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.

Better use should be made of real-world data with regards to digital health solutions where real-world data is being constantly generated – this introduces a vastly different and continuous evidence generation environment when compared to traditional pharmaceuticals. 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, new concepts for evaluating medicinal products without jeopardising safety are already being developed. If data are generated quickly, and feedback is gained, then adjustments to the product can be made very rapidly.

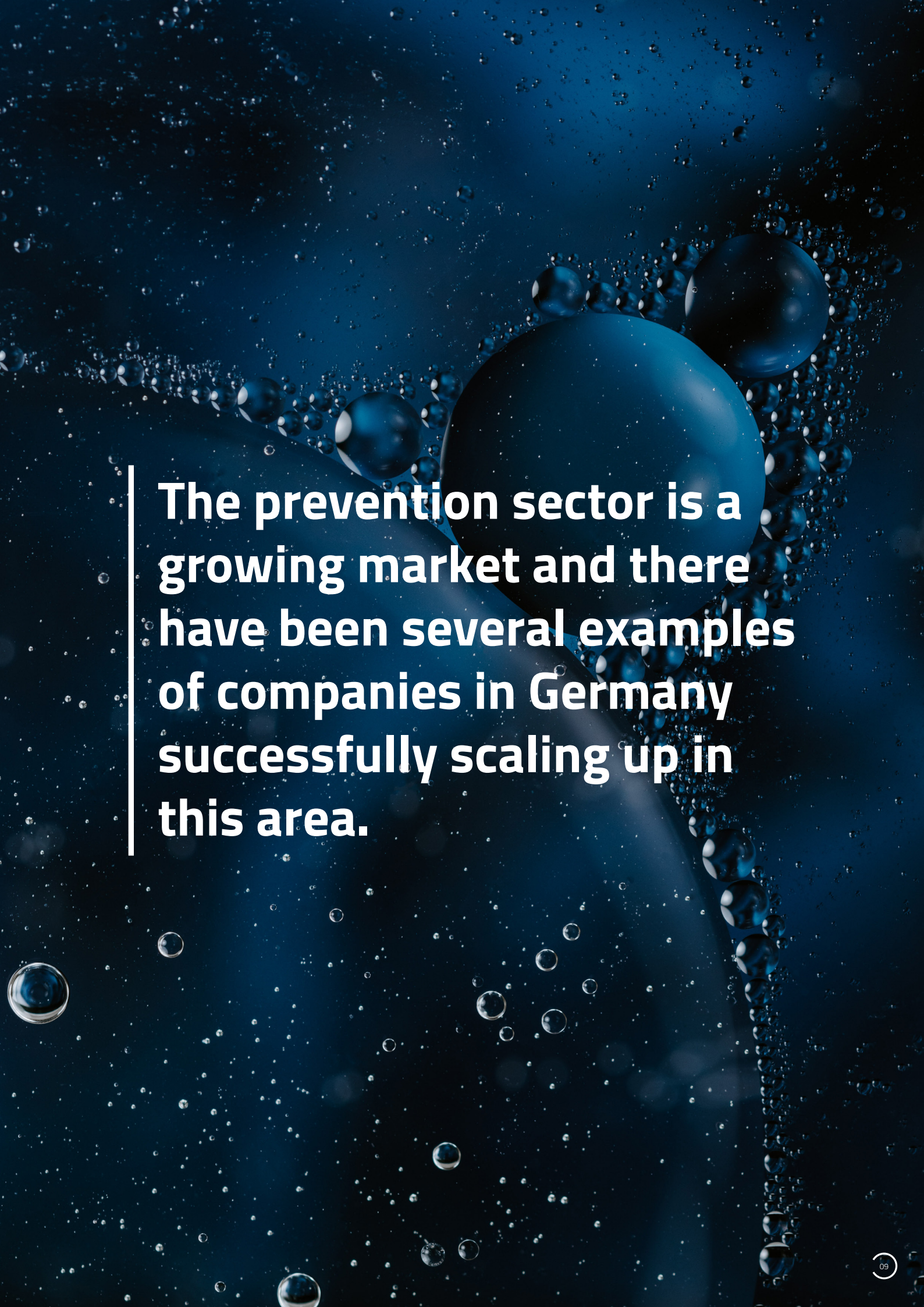
Adoption – gaining reimbursement and long-term use

Regulatory approval, or CE marking, is confirmation that the solution meets standards relating to safety and efficacy. This, however, is not a declaration of cost-effectiveness or value which brings us to adoption. Progressing through all stages of the pathway does not necessarily guarantee adoption. An adoption strategy needs to be rigorously planned from an early stage and this must include strong evidence of the economic benefit and value of an innovation to help facilitate its adoption. A clear strategy of where in the market the final product and service will be placed, who will pay for it, and who will use it is essential for successful adoption.

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 or service, 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. This presents a challenge for innovators as their reimbursement strategy must consider each country, and in some cases even regions, separately. There is then also the significant resources required to submit products and services for individual reimbursement. Harmonisation of health technology assessment (HTA) across the EU, for example, by entering into early dialogue with the European Network for Health Technology Assessment (EUnetHTA) is advised.

Further clarity needs to be provided on reimbursement of preventative products and services – while prevention is a persuasive tool, it requires incentives for reimbursement and adoption. 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 solutions there is an opportunity for reimbursement through health insurance funds.

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.



The prevention sector is a growing market and there have been several examples of companies in Germany successfully scaling up in this area.

Conclusions and recommendations for optimising the path to market in Germany

The body of evidence collected during the Round Table Series, demonstrated that there are a number of key stages within the innovation pathway where improvements could be made to aid and speed up the route to market for promising innovative solutions. Participants of the German Round Table meeting were asked to agree on a set of recommendations that, if implemented, could help to optimise the pathway for digital health solutions.

Develop methodologies for the appropriate frameworks of systematic needs assessment

Clarity and best practice should be provided to innovators to support them in the process of identifying stakeholder needs, for example clinical, systematic and patient, to facilitate the creation of a trusted and collaborative innovation process. Stakeholder meetings, networks and platforms would be beneficial to share relevant insights, and EIT Health could support in facilitating such methods.

Ensure representation of the health innovation community in discussions on the European Commission draft guidance on trustworthy AI

AI is a rapidly developing area of digital health, and it is important that regulation around AI considers impact on sectors with unique specificities such as healthcare, so that regulation is a positive step while not impeding Europe's ability to innovate. Data sharing, trust and transparency are key areas of concern for both health innovators and the general public and strategies should be explored to provide clarity. EIT Health can represent the health innovation community in discussions with policy makers by bringing opportunities, challenges and suggestions to the table for consideration.

Support innovators with approaching the changing regulatory environment surrounding digital health

Clear guidance and instructions on how innovators should navigate the MDR would be beneficial including training on the changes to be introduced for digital health products and services. Methodologies for the generation of evidence, such as use of real-world data, should also be discussed further with regulators to help adequately assess the value of digital health solutions for healthcare systems.

Address reimbursement challenges in relation to digital health with European and national reimbursement bodies and policy makers

Discussions should be initiated to input on how reimbursement pathways across Europe could be better aligned and streamlined to make them more suitable for the rapid uptake of digital health products and services. Additionally, advance discussions on how the adoption of value-based healthcare reimbursement decisions could become more commonplace to facilitate the ongoing economic value story offered by digital health solutions.

Appendices

Round Table Meeting agenda attendees

Host: EIT Health Germany

Facilitation: Professor Finn Boerlum Kristensen MD, PhD (EIT Health 2019 Think Tank Round Table Series Chair)

Moderator: Alexander Ehlers

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

Advisers

Finn Boerlum Kristensen, Think Tank Roundtable 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-Württember

Organisers & 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

EIT Health Think Tank

Optimising Innovation Pathways: Future Proofing for Success

German Round Table Meeting

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