MEDTECH AND DIGITAL HEALTH

A COMPREHENSIVE GUIDE TO MARKET ACCESS IN GERMANY

EIT Health

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CONTENTS

GLOSSARY

- **AOK** Allgemeine Ortskrankenkasse
- **BfArM:** Bundesoberbehörde, Federal Institute for Drugs and Medical Devices
- **BMG:** Federal Ministry of Health
- **CE Mark:** Conformité Européene, signifies that products sold in the EEA have been assessed to meet high safety, health, and environmental protection requirements.
- **Clinical investigations:** Are defined as systematic studies involving human subjects to assess a medical device's functionality, safety, and intended performance before or after it is placed on the market.
- **DiGA:** Digital Health Applications, Digitale Gesundheitsanwendungen
- **DRG:** Diagnosis-Related Group
- **EBM:** Einheitlicher Bewertungsmaßstab is the standardised reimbursement catalogue used primarily by Statutory Health Insurance (SHI) bodies to determine the fees physicians receive for outpatient services.
- **EU:** European Union
- **G-BA:** Federal Joint Committee
- **GDPR:** General Data Protection Regulation
- **GOÄ:** Gebührenordnung für Ärzte is the fee schedule used for services billed to patients with Private Health Insurance (PHI) or for services outside SHI coverage.
- **IKK:** Innungskrankenkasse
- **IVDR:** In Vitro Medical Device Regulation
- **KBV:** National Association of Statutory Health Insurance Physicians.
- **KKH:** Kaufmännische Krankenkasse
- **MDD:** Medical Device Directive
- **MDR:** Medical Device Regulations
- **OPS:** Operationen und Prozedurenschlüssel (The German Ürecedure ad Classification)
- **PHI:** Private Health Insurance
- **Severely disabled people:** People are classed as severely disabled if a pension office has determined a degree of disablement of 50 or more, and provided a valid disability pass.
- **SHI:** Statutory Health Insurance
- **TK:** Techniker Krankenkasse

INTRODUCTION

EIT Health has developed this report as an all-encompassing guide to assist healthcare start-ups throughout Europe in navigating the intricacies of the German healthcare system. As a prominent leader in accelerating and supporting innovative healthcare solutions across Europe, EIT Health is dedicated to enhancing the development, accessibility, and success of digital and MedTech health solutions. This report reflects our core mission to promote innovation and improve patient care in Europe by aiding start-ups in overcoming the unique regulatory and operational challenges of the German market .

Drawing from our vast experience of supporting over 1,500 start-ups through our programs and various opportunities, this report offers expert insights into Germany's healthcare structure, regulatory environment, and reimbursement pathways. It covers crucial reimbursement routes, such as the Digital Health Application (DIGA) and the widely recognized Medical Device Regulation (MDR), while also shining a light on lesser-known initiatives like health hubs. This report is essential reading, providing start-ups with the vital knowledge required to achieve market access in Germany.

Created in collaboration with leading experts in the German healthcare market, this report is designed to equip you with the strategic insights necessary to formulate a focused go-to-market strategy tailored to the German healthcare landscape.

EXECUTIVE SUMMARY

Germany stands out as Europe's largest healthcare market, offering unparalleled opportunities for healthcare start-ups to drive growth within the European landscape. With a population of over 84 million and healthcare expenditure exceeding €470 billion, the market holds great potential, particularly in the MedTech and Digital Health sectors. Renowned for its comprehensive healthcare system, Germany ensures most residents have access to a primary care physician within walking distance of their homes[1]. The country has also addressed long-term care needs through a compulsory long-term care insurance system funded by payroll taxes, providing a model for sustainable healthcare financing. However, for start-ups, navigating Germany's complex healthcare system can be challenging, with more than 100 sickness funds and diverse regulations and reimbursement routes to consider.

In this report we outline the key factors affecting market access that healthcare start-ups should consider, including reimbursement routes, regulatory frameworks and various diverse stakeholders they might need to engage with. It delves into the complexities of the German healthcare system, highlighting the differences between Statutory Health Insurance (SHI) and Private Health Insurance (PHI) coding systems, as well as providing guidance on how to navigate the reimbursement routes. Additionally, the report examines initiatives that can support healthcare start-ups to fast-track their market entry. We also take a deep dive into the CE marking process through compliance with the EU Medical Device Regulation (MDR), including conformity assessment and clinical studies. Furthermore, the report considers essential non-sector specific legal and regulatory requirements such as compliance with, and adherence to, cybersecurity standards, ensuring interoperability and fulfilling marketing rules and regulation that start-ups must observe.

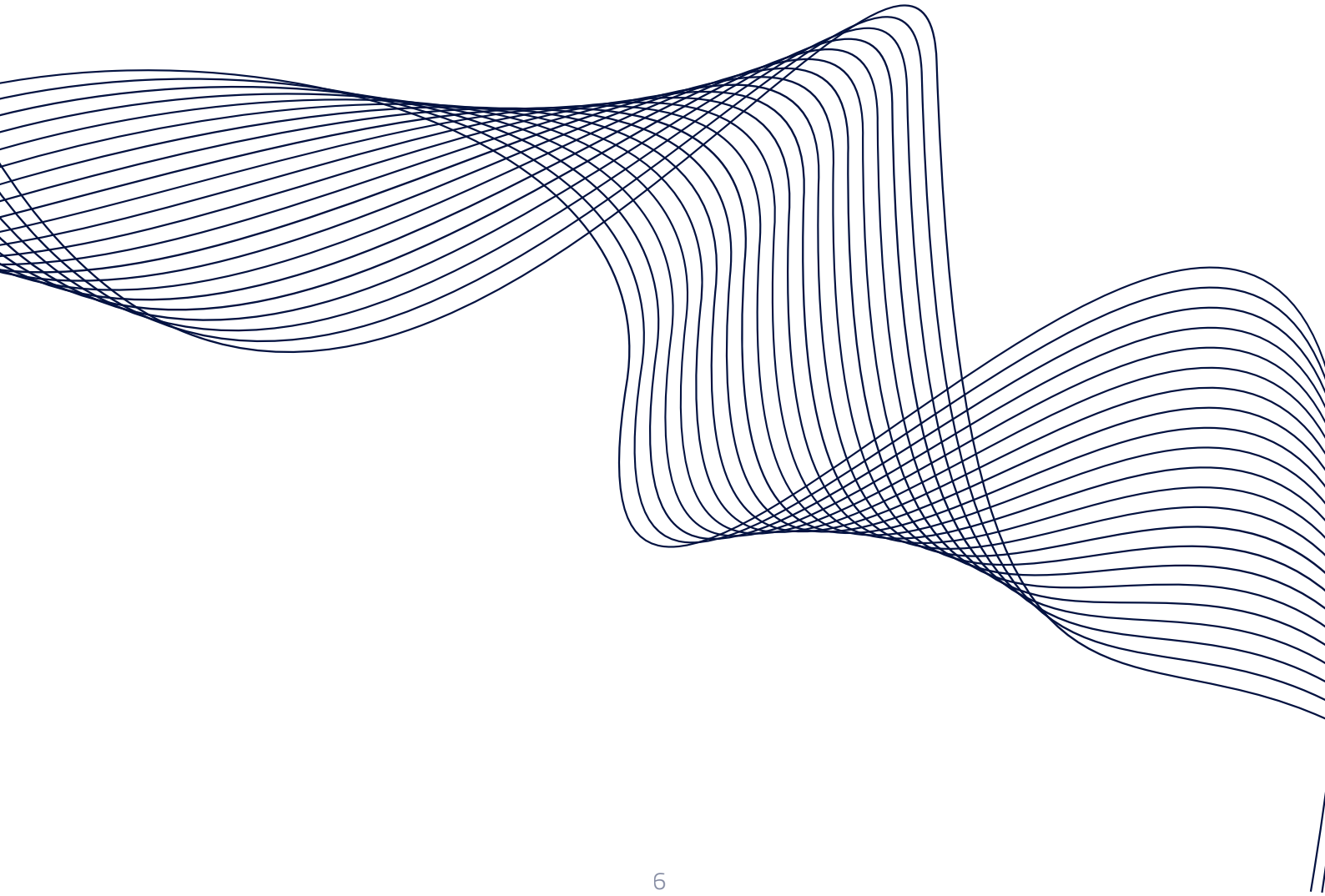
The report concludes by presenting key market access strategies that start-ups should consider to have their solution adopted or prescribed by healthcare providers and therefore, generate revenue.

Developed by EIT Health and rigorously reviewed by industry experts, this report serves as a must-read guide for healthcare start-ups across Europe aiming to access the German market. It features insights from leading professionals, including Jovan Stevovic, an expert in data protection regulatory requirements in healthcare; Robin Toorneman, a specialist in market access and reimbursement; Karina Candrian, Founder and CEO with expertise in MedTech and Healthtech innovation; Julia Enders, a regulatory expert, and finally Rolf Kaufmann, an authority on medical device software and AI. This report combines extensive industry knowledge with EIT Health's pan-European network to deliver an authoritative roadmap for navigating Germany's healthcare landscape.

[1] Emanuel, E.J. (2022) Which country has the world's Best Health Care? New York, NY: PublicAffairs.

DISCLAIMER

This report is intended for informational purposes only and is based on the best available sources at the time of publication. While every effort has been made to ensure accuracy using primary and secondary data and experts' involvement, the healthcare landscape especially in regard to regulatory and reimbursement frameworks is subject to change. The content herein does not constitute legal, regulatory, or medical advice, and should not be relied upon for specific business or legal decisions. Start-ups and businesses are strongly encouraged to seek professional legal and regulatory guidance tailored to their specific circumstances when navigating the German healthcare system.



GERMAN MARKET OVERVIEW

The German Market in Numbers:

Before beginning to navigate the complexities of the German healthcare system, let's start with something universally clear: numbers. Before entering any market, it's crucial to assess whether that market is attractive and capable of driving growth. There is no doubt the German market is one of the best for any start-up looking to access in the European Union (EU) and has consistently ranked as one of the most attractive investment directions[2]. So, let's break it down through key figures to better understand its potential.

Demographics

Germany's population is growing. At the end of 2023, it was approximately 84.7 million, continuing its status as the most populated country in the European Union, above France and Italy. This figure reflects a slight increase over previous years, primarily driven by immigration, as the natural birth-to-death ratio remains negative (more deaths than births annually).[3]

Looking ahead, Germany faces significant demographic changes, particularly as its population ages. This shift places a growing demand on long-term care services, with projections estimating a 37% increase in those needing long-term care by 2055, reaching about 6.8 million individuals. This trend underlines the importance of enhancing care infrastructure and services to accommodate the ageing demographic.[4]

Germany also has a substantial number of individuals with severe disabilities, accounting for 9.4% of the total population, approximately 7.8 million, in 2021. This figure highlights the demand for accessible healthcare solutions and ongoing support services to cater for diverse needs within the healthcare system.[5]

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Germany's demographic landscape, with its ageing and sizeable population, creates a unique healthcare market in the EU, posing both challenges and opportunities for healthcare innovations and services designed to support these population needs.

[2] 2024 Investment Climate Statements: Germany (2024) U.S. Department of State. Available at: https://www.state.gov/reports/2024-investment-climate-statements/germany/ (Accessed: 20 July 2024).
[3] Bevölkerungsstand (2024) Statistisches Bundesamt. Available at: https://www.destatis.de/DE/Themen/Gesellschaft-Umwelt/Bevoelkerung/Bevoelkerungsstand/_inhalt.html (Accessed: 20 November 2024).
[4] Bevölkerungsstand (2024a) Statistisches Bundesamt. Available at: https://www.destatis.de/DE/Themen/Gesellschaft-Umwelt/Bevoelkerung/Bevoelkerungsstand/_inhalt.html (Accessed: 20 November 2024).
[5] Disabled people (2019) Federal Statistical Office. Available at: https://www.destatis.de/EN/Themes/Society-Environment/Health/Disabled-People/_node.html#267100 (Accessed: 20 November 2024).

Healthcare

In 2022, Germany's healthcare expenditure was approximately €498.1 billion, accounting for 12.9% of the nation's gross domestic product (GDP), demonstrating its significant financial commitment to healthcare.[6]

On top of this large healthcare expenditure per capita, Germany also maintains one of the highest physician-to-patient and nurse-to-patient ratios within the European Union, with approximately 4.5 doctors and 12 nurses per 1,000 residents.[7] This strong healthcare workforce enables Germany to provide high-quality, accessible medical services – a cornerstone of its healthcare system.

The rehabilitation sector also receives particular attention in Germany, where 1,079 specialised facilities operate with a total of 161,430 beds. These facilities collectively handle around 1.89 million cases annually, with an average patient stay of 25.5 days and an occupancy rate of 81.5%.[8] It is worth noting that rehabilitation centres offer preventive care as well. These figures underscore Germany's role as one of the leaders in the healthcare sector within the EU.

> ***Prevention looks to me as an important segment that is more developed (or coded and reimbursed) in Germany than in other EU states, and there are many startups in the prevention that don't find opportunities elsewhere.***
>
> ***Robin Toorneman***

Sales

Germany's MedTech and Digital Health sectors are expected to show strong growth in the coming years. In the MedTech sector, Germany stands as one of the five largest markets in Europe and one of the most significant globally.[9] This market is forecast to reach approximately €32 billion by 2024, with a compound annual growth rate (CAGR) of 4.73% and could potentially expand to €45 billion by 2029.[10]

Similarly, Germany's Digital Health market is projected to generate around €4.5 billion in revenue by 2024, with an impressive CAGR of 8.09% from 2024 to 2029, potentially reaching approximately €6.7 billion. This growth is supported by Germany's increasing emphasis on digital health innovation and digital transformation.

[6] vdek - Verband der Ersatzkassen e. V. (2024a) Daten zum Gesundheitswesen: Versorgung. Available at: https://www.vdek.com/presse/daten/d_ausgaben.html (Accessed: 21 November 2024).
[7] Medical doctors per 1,000 people (2024) Our World in Data. Available at: https://ourworldindata.org/grapher/physicians-per-1000-people#all-charts (Accessed: 21 November 2024).
[8] Prevention and rehabilitation facilities, beds provided, movement of patient by länder (2024) Federal Statistical Office. Available at: https://www.destatis.de/EN/Themes/Society-Environment/Health/Prevention-Rehabilitation-Facilities/Tables/gd-reha-centers-laender.html (Accessed: 21 October 2024).
[9] The European Medical Technology Industry in figures (2023) MedTech Europe. Available at: www.medtecheurope.org/datahub (Accessed: 21 October 2024).
[10] Medical Technology: market data & analysis (2024) Statista. Available at: https://www.statista.com/outlook/hmo/medical-technology/germany (Accessed: 21 November 2024).

Emerging Trends

The numbers presented in the last section clearly highlight the current state of the German market and its forecasted growth in the next few years. However, let's take a closer look at some of the key emerging trends in the healthcare sector today. According to Pitchbook, there are 15 trends shaping the current healthcare industry. Since our focus is on the German market, we will concentrate on the trends relevant to this article.

- Digital Transformation: Germany's healthcare system is digitising rapidly. This ranges from infrastructure architecture, e.g., data exchange and electronic health records, to digitisation of care processes, e.g., digital therapeutics and telemonitoring.
- Assistive Technology: Germany is facing a big challenge to meet the demand for care against its ageing population. That's why the assistive technology market size in Germany, such as mobility aids, is projected to reach €4.7 billion by 2025.
- Mental Health Tech: 31% of the German population is diagnosed with at least one mental health issue, including depression and anxiety. With the increasing awareness of this issue, especially after the COVID-19 pandemic, the mental health tech market value is anticipated to reach €3 billion by 2026, focusing on apps and platforms for therapy and mental wellness.
- Gene Therapies: Germany is one of the main leaders in gene therapies. The market size is forecast to reach €2.5 billion by 2026. The main goal is to target genetic disorders with innovative treatments.
- Nanomedicine: The global nanomedicine market was valued at €200 billion in 2021 and Germany, with its strong research ecosystem, has a significant share. The main areas of focus for nanomedicine are diagnostics that empower early detection and targeted drug delivery systems that improve treatment efficacy.
- Medical Exoskeletons and Prosthetics: This market is growing rapidly mainly due to technology advancement, increased demand and government support. The global market is projected to reach €4.5 billion and Germany is one of the leading European countries in this space, primarily due to its healthcare structure and strong research sector.
- Medical Robotics: This specific space is focusing on enhancing surgical precision and saving costs for hospitals. The medical robotics market in Germany is projected to grow to €2 billion by 2026.

> ***It is true that there are many startups developing Exoskeletons. However, my experience is, that due to the lack/restricted reimbursement it is very difficult for them to achieve meaningful sales and/or struggle with securing funding.***
>
> ***Karina Candrian***

Summary

To provide a global perspective on the German healthcare market, the table below compares Germany with France and the United States across key metrics. Germany stands out as the largest MedTech and digital health market in Europe, significantly surpassing France in market size. However, the U.S., with a much larger population, outpaces both Germany and France, reflecting its substantial investment in MedTech and digital health. Germany also boasts a higher ratio of doctors and nurses per 1,000 residents compared to the U.S., with 4.5 doctors and 13.2 nurses per 1,000 people. This indicates the robustness of Germany's healthcare workforce, which plays a vital role in maintaining high standards of care. While the U.S. leads in overall market size, Germany's efficient healthcare delivery and significant investment in MedTech and digital health underscore its position as a key player in the global healthcare landscape.

	FRANCE	GERMANY	US
Population (2024)	68 million	83 million	335 million
Expenditure per Capita	€4,187 (2023)	€5,691 (2023)	€12,275 (2022)
Number of Doctors per 1000 People	3.4	4.5	2.9
Number of Nurses per 1000 People	11.1	13.2	11.7
The MedTech Market	€31 billion (2022)	€44 billion (2023)	€178 billion (2022)
The Digital Health Market	€4 billion (2023)	€7.8 billion (2023)	€64 billion (2023)

Recognising emerging trends is essential for start-ups aiming to drive growth by targeting expanding, high-potential markets. While several key trends offer substantial opportunities for exploration, there are still untapped areas with great potential for innovation and disruption. Staying up-to-date with these trends can provide a competitive advantage and help start-ups mitigate the risk of losing market share to competitors.

GERMANY HEALTHCARE STRUCTURE AND STAKEHOLDERS

Overview

The German healthcare system is quite complex, with many parties involved in the overall structure. As a start-up, it is important to know the overall structure and how the system works so you can plan accordingly.

Health insurance in Germany is provided by two completely different subsystems: Statutory Health Insurance (SHI), known as sickness funds and Private Health Insurance (PHI), with approximately 86% of the German population covered by Statutory Health Insurance. It is important to note that not all residents have freedom of choice to opt for Private Health Insurance; in 2025, you need to earn more than €74,000 annually.[11]

For Statutory Health Insurance, it is important to note that the government has virtually no role in the direct delivery of healthcare. Although it can provide overall supervision and some tax subsidies, the administrative process is handled by the Federal Joint Committee. This committee along with The Federal Association of Sickness Funds, work hand-in-hand to develop the ambulatory care fee schedule for sickness funds and the diagnosis-related group (DRG) catalogue. The 16 states, on the other hand, are responsible for managing hospital capacity and financing hospital investments.

Private Health Insurance is regulated by the Ministry of Health and the Federal Financial Supervisory Authority to ensure that patients covered by PHI do not face large premiums and are not burdened if their income decreases. **Private Health Insurance might have more flexibility in terms of operation for some solutions,** and it can also play a complementary and supplementary role for sickness funds (SHI) where it can cover some co-payments such as dental care and private hospital rooms.

> ***People with chronic illnesses or complex/multimorbid diseases often go to the public system because it's more equipped to handle costly disease. Private is better at less complex/elective procedures. Most startups I know that have entered the German market are focussed on SHIs.***
>
> ***Robin Toorneman***

[11] Versicherungspflichtgrenze 2025: Wechsel in die PKV wird Weiter Erschwert (2024) PKV. Available at: https://www.pkv.de/verband/presse/meldungen/versicherungspflichtgrenze-wechsel-in-die-pkv-wird-weiter-erschwert/#:~:text=Die%20Anhebung%20der%20Versicherungspflichtgrenze%20begrenzt,auf%2073.800%20Euro%20ab%202025. (Accessed: 20 November 2024).

Now let's dive one level down within the German healthcare structure and better define the outpatient and inpatient sectors and the hospital setting.

- **Outpatient sector:** Outpatient treatment is performed outside hospitals. In Germany, there are general practitioners and specialists who have an existing contract with the National Association of Statutory Health Insurance Physicians (KBV). Patients with SHI have free access to those general practitioners. Free access to hospitals is limited to emergency or privately insured people. Patients with SHI must consult a general practitioner before getting inpatient treatment. Patients with SHI are billed based on the EBM (Einheitlicher Bewertungsmaßstab) while patients with Private Health Insurance, are billed based on the GOÄ (Gebührenordnung für Ärzte).[12]
- **Inpatient sector:** Inpatient treatment takes place inside one of 1,903 hospitals in Germany. The hospitals operate using a dual financing system; the federal states are responsible for hospital investment, whilethe cost of care delivery is covered though health insurance funds in the form of a lump-sum reimbursement via the G-DRG system. Compared to other countries, in German hospitals there is a strong hierarchical structure especially in the surgical disciplines. The cooperative leadership model is very rare. The federal state is responsible for the federal state hospital plan and can determine what kind of services can be offered. A distinction must be made between public hospitals, run by municipalities, for example, non-profit hospitals, run by churches, and private hospitals, run by private groups. Each group has hospital associations or chains that aim to strengthen market power, but it is important to note that the funding of all hospitals is the same; essentially, there is no difference between private and other hospitals. The reimbursement within the hospital is made by the DRG system which is used by both SHI and PHI.

The PHI is not governed by the Federal Joint Committee and therefore has greater autonomy in setting premiums, determining covered services, and structuring plans.

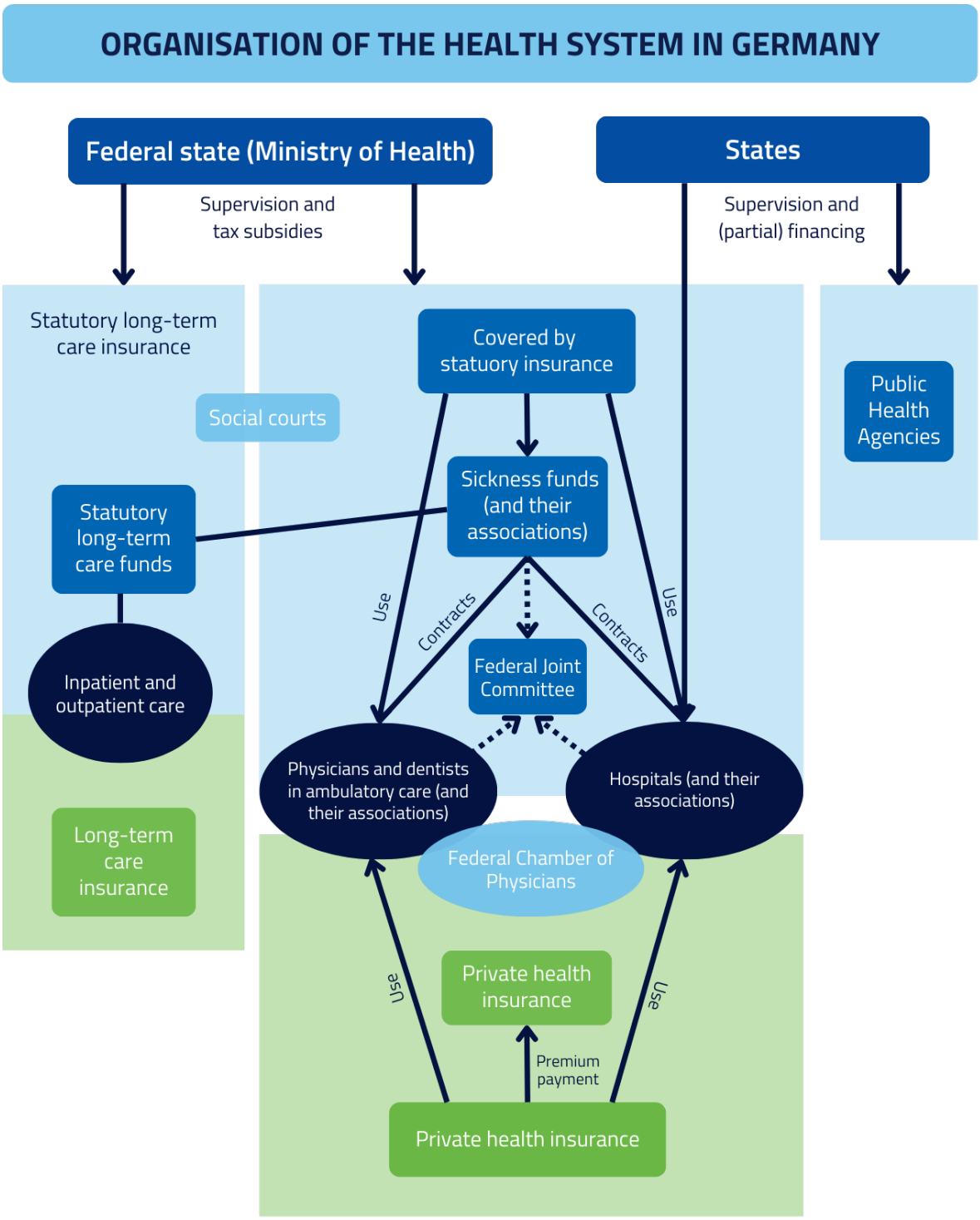
This can allow it to be more innovation-friendly and adapt its service offerings accordingly. This is particularly useful for start-ups that are seeking agile reimbursement routes since the PHI policies often support a wider range of treatments and, in some cases, allow faster access to specialty care compared to SHI.

It's essential to discuss long-term care insurance in Germany, which is a vital component of the social security system and mandatory for all citizens. With the ageing population, the demand for long-term care services is steadily increasing. In response, the German government is focused on enhancing the system by improving care quality and introducing innovative solutions aimed at alleviating the challenges faced by home caregivers. These efforts include promoting technological advancements and support services designed to streamline care processes and improve overall quality of life for both patients and their families.

[12] Market Access to the German healthcare system (2022) Healthcare Heads. Available at: https://www.healthcareheads.com/ (Accessed: 20 November 2024)

Organisation of the Health System

The figure below provides a general overview of the healthcare system in Germany and shows how different stakeholders interact.



Source: Adapted from R. Busse and M. Blümel, "Germany:Health System Review," Health Systems in Transition, vol. 16, no. 2, 2014, p. 20

What should I take from all this?

- While 86% of the German population is covered by SHI it might not always be the best starting point for some start-ups that want to access the German market. The PHI sector might be more attractive as it is more flexible, and if you successfully sign with a private insurance provider, it can provide real-world data that can support your negotiation with the SHI. It is always worth undertaking deep market research on different insurance sectors and target the one that would align with your vision and your product.

- The SHI still covers the majority of the German population and accessing it may eliminate the need to engage in a selective contract with PHI. Additionally, there are some highly innovative SHIs.

- A solid understanding of the G-DRG system, the EBM (Einheitlicher Bewertungsmaßstab), and the GOÄ (Gebührenordnung für Ärzte) catalogue is essential. While you don't need to master every category, it's important to have in-depth knowledge of those that align with your specific solution. This focused expertise will enable you to navigate the reimbursement landscape effectively and engage with stakeholders in the healthcare system more confidently.

- There are many sickness funds and Private Health Insurance schemes on the market. It is essential to select them carefully by developing a clear and well-defined market entry strategy and, on this basis, selecting the appropriate SHIs and PHIs. It is also worth noting that sickness funds often have a regional focus, allowing them to adjust their coverage based on regional healthcare needs, hospital availability and the cost of medical services in that area, which can vary across Germany's states.

- Stay updated on the Federal Joint Committee (G-BA) meetings, which are open to the public and accessible for review by anyone. These meetings usually occur monthly, and the key sessions related to the EBM and GOÄ updates are held once a year. It is recommended to regularly check their website for news or updates related to your solution: https://www.g-ba.de/.

- In previous years, the federal states have failed to meet their financing obligations to hospitals. As a result, hospitals were forced to generate profits from the G-DRG system, which was not established for this purpose, and allows only minimal increases in the number of cases. This creates an opportunity for start-ups to play a crucial role in helping hospitals indirectly improving their financial position, despite state funding shortages, through digital health innovations and efficiency-driven solutions.

- It is important to note that the billing system for the outpatient system is more complex and might require more time than the inpatient process. Additionally, the entire process often involves multiple stakeholders with different needs and goals, which can lead to conflicts of interest and can make the process less standardised and structured.

REGULATORY ENVIRONMENT

Key Stakeholders / Different Actors

Main Stakeholders

Notified Bodies

The most important stakeholders are notified bodies as they are involved in the conformity assessment of medical devices, the process which eventually allows manufacturers to affix CE marking to their devices and place them on the EU market. Notified bodies are private organisations that have been notified under the regulations (MDR, IVDR) to conduct conformity assessments of medical devices against the requirements of the regulations. Medical device manufacturers need to file an application for certification for their devices according to MDR or IVDR (as applicable) with a notified body. The notified body will then conduct a conformity assessment in collaboration with the manufacturer and, after the conformity assessment has been completed successfully, issue a certificate. The certificate is valid for a limited period of time. Recertification occurs periodically, in the context of continuous surveillance activities of the notified body (audits, technical documentation sampling, etc.).

You can search the NANDO website for notified bodies that have been designated under the regulations and are therefore authorised to conduct conformity assessments: https://webgate.ec.europa.eu/single-market-compliance-space/notified-bodies

It should be noted that notified bodies are designated for certain device categories, i.e., not all notified bodies are competent to conduct conformity assessments of all device categories. Device categories are identified by MDN/MDA (non-active and active medical devices) or IVR (*in vitro* diagnostic medical devices) codes in Commission Implementing Regulation (EU) 2017/2185. To find a notified body that can assess your device, you should first determine which code applies to your medical device. The notified body will confirm in the context of the initial feasibility check whether they are authorised to assess your device.

Regulatory Authorities

Regulatory authorities are either governmental or non-governmental, and are the main authorities that regulate the healthcare system in Germany; start-ups might need to interact with them directly or indirectly.

- BMG (Federal Ministry of Health): The BMG is the top-level governmental authority responsible for health policy. While they oversee all regulations and ensure its proper implementation, they do not have any operational power on healthcare delivery.
- BfArM (Federal Institute for Drugs and Medical Devices)): The BfArM is the main authority responsible for the approval of digital health

solutions, medical devices and pharmaceuticals. BfArM is not involved in the conformity assessment of medical devices but has responsibilities with regard to qualification and classification, market surveillance and vigilance, clinical investigations and performance studies, as well as various other topics.

- Federal State Authorities (Landesbehörden): These authorities have responsibilities in the following areas: placing on the market, qualification and classification, clinical investigations, market surveillance and vigilance (can conduct audits at manufacturers).
- The Federal Joint Committee (G-BA): The G-BA is the highest decision-making body in the German healthcare system. It operates independently of the BMG and consists of 13 voting members (five representatives from associations of sickness funds, five from associations of healthcare providers, and three unaffiliated members; there is also a patient representative who does not have voting rights). This authority is responsible for setting guidelines and defining which medical treatments and services are covered by health insurance (GKV). While start-ups might not interact with it directly it is worth staying updated on the committee's meetings and decisions.
- InEK (Institute for the Hospital Remuneration System): The InEK is responsible for developing and maintaining the German Diagnosis Related Groups (G-DRG) system.
- KV (Kassenärztliche Vereinigung): This is the National Association of Statutory Health Insurance Physicians and plays a key role in the German healthcare system by ensuring that outpatient care is provided to individuals covered by Statutory Health Insurance (Gesetzliche Krankenversicherung, GKV). There are **17 regional KVs** in Germany, one for each federal state or a combination of states, and one central KV for psychotherapists.

Health Insurance Companies:

Statutory Health Insurance (SHI) and Private Health Insurance (PHI) providers play a crucial role in funding healthcare services. For start-ups it is crucial to know which healthcare insurance to reach out to. The main players in the German market are the following:

- **SHI**[13]

[14]

[13] Largest health insurance funds in Germany (no date) insurance.de. Available at: https://www.health-insurance.de/statutory-health-insurance/comparison/largest/ (Accessed: 22 November 2024).

[14] The percentage refers to the percentage of the German population.

- **PHI**

Allianz	Allianz
Debeka	Debeka
AXA	AXA
HanseMerkur	HanseMerkur
Signal Iduna	SIGNAL IDUNA
Barmenia	Barmenia Versicherungen

Healthcare Providers

If your solution is aimed at the inpatient or outpatient setting, you will probably interact with:

- Hospitals and Clinics
- General Practitioners (GPs) and specialists
- Nursing Homes and Home Care Services: Particularly relevant for elderly care solutions.

We will give further insights on how to interact with these stakeholders in the coming sections.

Support Stakeholders

While engaging with the main stakeholders is necessary to access the German market, interacting with support stakeholders can also provide useful market insights. Although not mandatory, it is highly recommended to interact with them at an early stage. The key support stakeholders are:

Patients and Patient Advocacy Groups

- Stiftung Patientenrechte (German Patient Advocacy Foundation): focuses on promoting patient rights and ensuring quality care in the healthcare system.
- Patientenbeauftragte der Bundesregierung (Federal Government Commissioner for Patient Affairs): represents patient interests within the federal government and works on improving patient care and rights.
- BAG Selbsthilfe (BAG Self-Help): an umbrella organisation for various self-help groups in Germany, focusing on patient empowerment and community support.

There are other specific patient groups that focus on specific conditions such as diabetes, oncology, mental health, etc.

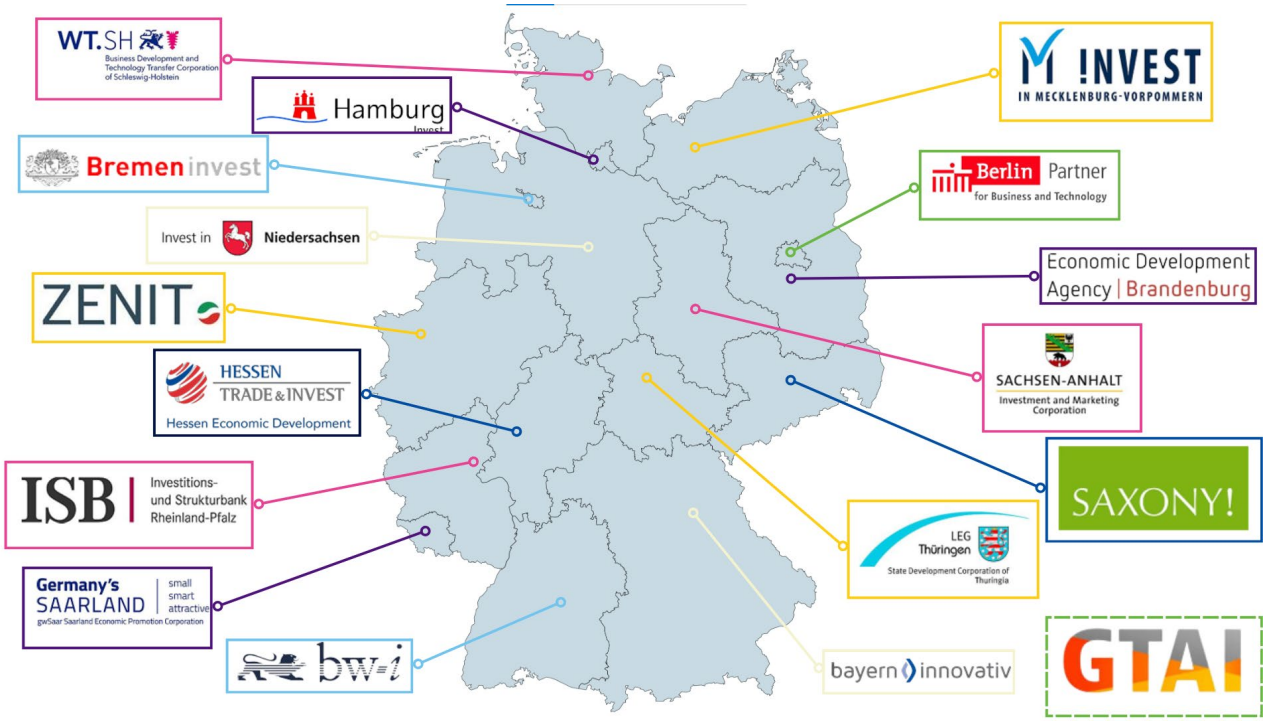
Local Development regions / Agencies

Germany has various local development agencies that support the healthcare sector. These agencies focus on fostering innovation, promoting research, and facilitating collaboration among stakeholders in the healthcare ecosystem. Key roles include funding research projects, supporting start-ups, and enhancing healthcare infrastructure. The agencies work closely with universities, businesses, and local governments to address regional healthcare challenges and improve services.[15]

You may find a list of German development agencies below:

> ***Over the years, I found them very, very helpful. Actually I would consider them as a starting point if I want to explore entering the German market. Berlin Partner for example also gave us subsidised exhibition space at their booths at DMEA or Medica, even though we were still in the process of establishing a German legal entity.***
>
> ***Jovan Stevovic***

[15] Regional Development Agencies in Germany. Available at: https://www.eurada.org/fileadmin/user_upload/docs/RDAs-from-Germany.pdf (Accessed: 22 November 2024).



Regulation

While there are many different regulations, not all of them might be applicable to your case. Regulatory requirements will be based on your business model, strategy for entering the market, and, more technically, on your solution and its risk class. Here is a breakdown of the most important regulations.

Regulation (EU) 2017/745 (MDR) / Regulation (EU) 2017/746 (IVDR)

A detailed explanation of the the Medical Device Regulation (MDR) and In Vitro Diagnostic (IVDR) Regulations may well require a separate report, however, we will provide a brief overview here.

The MDR has replaced the previous Medical Device Directive (MDD). It applies to all medical devices **except** *in vitro* diagnostic medical devices, note, that software in your phone can also be classified as a medical device, and it ensures a high standard of safety and performance while trying to harmonise regulatory requirements across the EU. *In vitro* diagnostic medical devices, which are a subcategory of medical devices, were formerly regulated under the In Vitro Diagnostic Medical Devices Directive (IVDD) and are now regulated under the IVDR.

Below are some of the main differences between the former directives and the new regulations:

- The Regulations are EU law and, as such, are directly legally binding, while the Directives needed to be translated into national law, e.g., the German Medizinproduktegesetz (Medical Devices Act), which was legally binding
- Changes to the classification rules and the risk classes

- Additional and more detailed requirements with regard to the safety and performance of products as well as product-related technical documentation
- Additional and more detailed requirements regarding post-market surveillance activities and their documentation
- Unique Device Identification (UDI) requirements implemented
- Increased transparency with an EU medical device database (EUDAMED).

In the following subsections, we outline the main steps to achieve conformity with the relevant regulations. Please note, however, there are additional requirements that need to be fulfilled to establish conformity with the relevant regulations.

Device Qualification

Before you do anything else, you should confirm that your product is indeed a medical device according to the definition of the regulations and falls into the scope of either the MDR or the IVDR, it cannot fall into the scope of both regulations. This process is called "device qualification". If your product does not meet the definition of a medical device according to Article 2(1) of the MDR or of an *in vitro* diagnostic medical device according to Article 2(2) of the IVDR, if it is not an accessory as defined in Article 2(2) of the MDR and Article 2(4) of the IVDR, and if it is not one of the products listed in Annex XVI of the MDR, then your product does not need to fulfil the requirements of the MDR or the IVDR. To perform a device qualification, you need to know the intended purpose of your device and understand how it achieves its principal intended action. Please note, that even a standalone medical device software can be an *in vitro* diagnostic medical device and thus fall into the scope of the IVDR.

Also, be aware that even if your product does not fall under the MDR or the IVDR, other national and European regulatory requirements are likely to be applicable depending on the purpose and characteristics of your product.

Risk Classification

If you determine your product does fall under the scope of the MDR or IVDR, you need to assess the risk class of the device. This is a crucial step because it has an influence on the conformity assessment procedure that needs to be conducted. Device classification is performed by applying the 22 or 7 classification rules as set out in the MDR or IVDR respectively.

As a result, your device will fall into one of the following risk classes:

Risk Class		Risk
MDR	IVDR	
I and class Is/m/r*	A and As	Low risk
IIa	B	Medium risk
IIb	C	Higher risk
III	D	High risk

**s = sterile; m = with a measuring function; r = reusable surgical instruments*

Scrutiny by regulatory authorities and notified bodies will increase with the risk class of your device.

Quality Management System:

Implementation of a Quality Management System (QMS) and developing your device within the framework of such a system is required both by the MDR and the IVDR. Article 10 of both regulations sets out the specific requirements for a QMS. Conformity with the requirements of the regulations can be demonstrated by applying the harmonised standard EN ISO 13485 and obtaining certification according to this standard. If a notified body is involved in the conformity assessment of your medical device, they will not only confirm conformity of your product with the regulatory requirements, but also the conformity of your QMS with the regulatory requirements.

Technical Documentation

Both the MDR and IVDR require that you compile technical documentation of your device. The requirements on content and structure are set out in Annex II and Annex III of the MDR and IVDR, respectively. Your QMS should also ensure relevant records that need to be included in the technical documentation are produced as part of your design and development process. In many conformity assessment procedures, the notified body will examine the technical documentation of your device.

Conformity Assessment

The purpose of the conformity assessment is to demonstrate that your system and your device meet all applicable requirements of the regulations. The assessment of your product will focus on confirming conformity with the applicable general safety and performance requirements as set out in Annex I of the MDR and IVDR. Conformity with the requirements can be achieved by applying standards. Of particular relevance in the EU, are harmonised standards. Application of these standards will lead to a so-called "presumption of conformity", i.e., by applying these standards, it is assumed that your product is in conformity with the relevant requirements (please note, the application of standards is voluntary)[16]. The evidence that demonstrates conformity with the requirements which you produce as part of the design and development process, will be filed in your technical documentation.

For class Is/m/r, IIa/b, III as well as As, B, C, D devices, a notified body needs to be involved in the conformity assessment of your device. Once it has been confirmed that all applicable requirements of the relevant regulation are fulfilled, the notified body issues a certificate and the manufacturer signs an EU Declaration of Conformity. With this declaration, the manufacturer declares under their sole responsibility

[16] Standards which are currently harmonised under the MDR and IVDR can be found here: https://single-market-economy.ec.europa.eu/single-market/european-standards/harmonised-standards_en (Please note that the EU is currently in the process of harmonising a large number of standards under the regulations and that the lists are updated from time to time).

that the device is in conformity with the applicable requirements of the regulation.

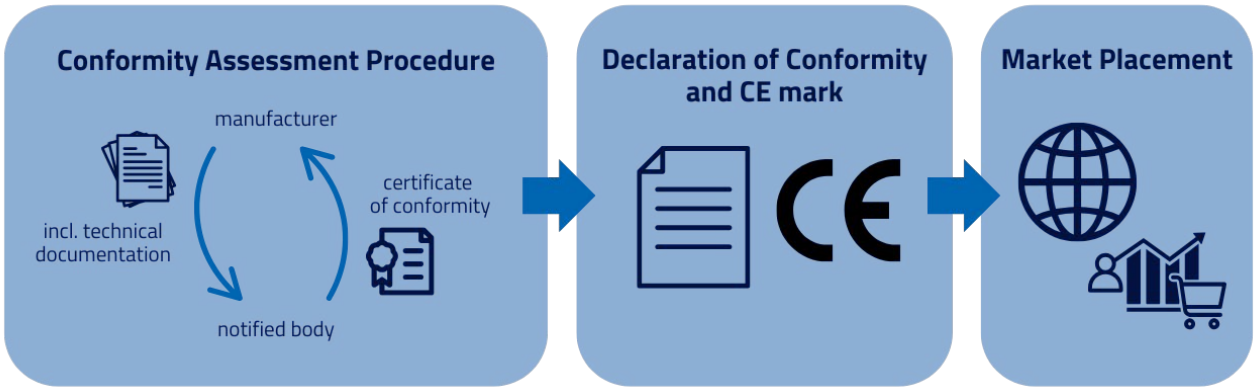
The conformity assessment of class Is/m/r as devices will also require involvement of a notified body. However, the notified body will only review those parts of the technical documentation that are related to the device's sterility, measurement function, or reuse. A certificate will also be issued for these devices.

For class I and A devices, the involvement of a notified body in the conformity assessment is not required. The manufacturer alone ensures that all applicable requirements are fulfilled and then issues the EU Declaration of Conformity. As no notified body is involved in the process, no certificate will be issued for these products. This conformity assessment is also referred to as "self-declaration".

It is worth mentioning that BfArM is not involved in the conformity assessment, but you can reach out to them with any questions regarding the requirements.

CE Marking

Once the conformity assessment of the device is complete and the EU Declaration of Conformity has been issued by the manufacturer, the manufacturer can affix CE marking to the device and its packaging. If you want to sell your product in the European market, you will need to affix CE marking to your product. While the new regulations have provided more safety and quality to the market, they have also introduced additional regulatory hurdles and increased the cost of time to market.



Post-Market Surveillance

Once CE marking has been affixed and you have placed your device on the market, you also need to monitor the use of the device in the market. This process is called post-market surveillance. Manufacturers of class IIa/b and III as well as class C and D devices must prepare a periodic safety update report (PSUR) for each device summarising the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan. Manufacturers of class IIa devices must update the PSUR when necessary, and at least every two years; manufacturers of implantable and class III devices as well as class C and D devices must update the PSUR at least once a year. The PSUR shall be part of the technical documentation.

Manufacturers of class I, A and B devices must prepare a post-market surveillance report summarising the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan. The report should be updated when necessary.

Data Protection, Cybersecurity and Certifications

Another relevant regulation is the General Data Protection Regulation (GDPR), which ensures compliance with data security and defines principles and best practices for data protection laws and the handling of personal data (data associated directly or indirectly to EU citizens). There are many misconceptions about this specific rule law, mainly because there is no certification yet. However, it is key for your business from the first day, since it will define your business module in terms of what you can and can't do with health data, or requirements for obtaining and processing personal data within your product, AI, or user interaction journey. If you offer a B2B solution, then your customers will perform a strict assessment of your GDPR posture (also known as Vendor Risk Assessment). They will check how you process data, obtain consent from end-users, ensure data security, and anonymise data for AI training. Implementing a sufficient level of GDPR compliance requires time, typically between 3 to 6 months, so make sure to start at an early stage to get it right!

In Germany, in addition to GDPR, you will need to consider state laws for secondary usage of data, for example using health data for research or AI development.

With regard to cybersecurity, the Bundesamt für Sicherheit in der Informationstechnik (BSI), (the Federal Office for Information Security), defines standards and certification schemes for the digital sector in Germany. Certain BSI standards, such as the BSI TR -03161, are defined for healthcare applications, and are adopted as a requirement in specific sub-markets, such as telemedicine providers or DiGA/DVG reimbursement pathways. Frequently, an external audit or a pen test is also required as part of your proof on cybersecurity, e.g., in DiGA/DVG.

One final point related to data protection and cybersecurity, as a start-up you need to keep an eye on related certifications such as ISO27001. Germany is renowned for its certification processes, and there is no exemption in the digital health and Medtech space.

It is worth noting that any communication with other devices or servers needs to fulfil cybersecurity requirements, as outlined in the standard IEC 81001-5-1 for example. Additionally, data protection must be guaranteed (GDPR), which can be supported by relying on the ISO/IEC 27001 standard. It is important that data is stored within the EU.

Finally, integrating GDPR within a QMS framework in your strategy can not only ensure regulatory compliance, but also enhance the overall quality, security, and transparency of your processes. This holistic approach can provide better management, reduce risks, and ensure both product and data quality.

Enterprises with more than 50 people and/or €10 million turnover need to follow the EU's NIS2 regulation for cybersecurity (DIRECTIVE (EU) 2022/2555). It has many aspects in common with the ISO 27001 standard, but there are still small differences. Therefore, even if you have an ISO 27001 certificate, you should still conduct a gap analysis with the NIS2 requirements.

Interoperability Standards

Interoperability is the ability of different health information systems to access, exchange, integrate, and cooperatively use data in a coordinated and compliant way. There are many aspects that you, as a start-up, need to be aware of since your solution may need to integrate with other systems in one way or another. The most basic way is to comply with the coding of the DRG and OPS to facilitate reimbursement by insurance providers. Aspects of the standard compliance can be summarised as follows:

- Ensure your digital health solution or health application is compliant with the internationally recognised health IT standards, e.g., HL7, FHIR
- Be compliant with Germany's Telematics Infrastructure, your platform might need to be certified by gematik (National Agency for Digital Medicine) in case your application interacts with electronic patient records ePA
- Ensure compliance with the KBV and their guidelines regarding interoperability.

Additionally, it is crucial to keep an eye on the EU-wide interoperability standards. If you are thinking of expanding to other EU countries, it is worth mentioning that Germany is part of the MyHealth@EU initiative, which facilitates cross-border exchange of health data.

Interoperability standards are not regulatory requirement, but they can help to market the device and for being reimbursed.

Rolf Kaufmann

Artificial Intelligence Act

The Artificial Intelligence (AI) Act came into force in August 2024, with provisions becoming mandatory during the transition period that lasts from 6 to 36 months, depending on the requirements. Any medical device utilising machine learning or AI needs to be in conformity with the requirements of this European law after a transition period, which depends on the risk category of the device. Depending on this risk category, a notified body may need to be involved in the conformity assessment procedure. Even though this can be impactful for medical device producers, there is a 36 month transition period to give notified bodies and consultants time to prepare necessary support and policies.

The German and European associations for notified bodies for medical devices have jointly developed a valuable questionnaire to help guide the early assessment of AI applicability in medical devices under MDR and IVDR regulations. This resource provides a structured approach for evaluating compliance requirements and can be accessed here.

Marketing and Promotion Regulations

Marketing and promotion of your solution must also adhere to applicable regulatory requirements. Here is a breakdown of what you should be aware of:

- Comply with Heilmittelwerbegesetz (HWG), the German Act on Advertising of Medicinal Products.
- Marketing should not be misleading or use aggressive sales tactics following the Unfair Competition Law (UWG)
- The Medical Device Regulations also govern how the device is marketed, refer to Article 7 on claims in both MDR and IVDR. It is important to note that any medical benefit claimed must be fully substantiated with clinical data.
- If you are marketing directly to healthcare professionals, there are some additional rules:
    - No financial incentives
    - Provide scientific evidence
- While the regulations in Germany are federal, some federal states have further rules, especially regarding hospital advertising. Start-ups might need to check the regional **Hospital-Specific Advertising Rules**.

Other Regulatory Framework

Please note, other European Directives and Regulations may be applicable to your medical device in addition to those mentioned above. It is the responsibility of the manufacturer to identify any applicable legal and/or regulatory requirements and ensure conformity of the products with these requirements. Below are some examples (list non-exhaustive):

- Machinery Directive: Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (recast) (Text with EEA relevance)
- REACH Regulation: Regulation (EC) No 1907/2006 Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
- RoHS Directive: Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment Text with EEA relevance

The regulatory requirements define what is needed for a product to be in conformity with the regulatory frameworks; the normative requirements define the technical and/or procedural specifications that can be used to establish conformity with the regulatory requirements, so standards describe the 'how'. As noted elsewhere in the text, the application of standards is voluntary. If the manufacturer can demonstrate that conformity with the regulatory requirements is established through other means than a relevant standard, then that is a valid approach as well.

Julia Enders

- eIFU Regulation: Commission Implementing Regulation (EU) 2021/2226 of 14 December 2021 laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards electronic instructions for use of medical devices
- WEEE Directive: Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment Text with EEA relevance.
- Packaging Directive: Council Directive 94/62/EC EUROPEAN PARLIAMENT AND COUNCIL DIRECTIVE 94/62/EC of 20 December 1994 on packaging and packaging waste.
- Radio Equipment Directive (RED): Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC (Text with EEA relevance).

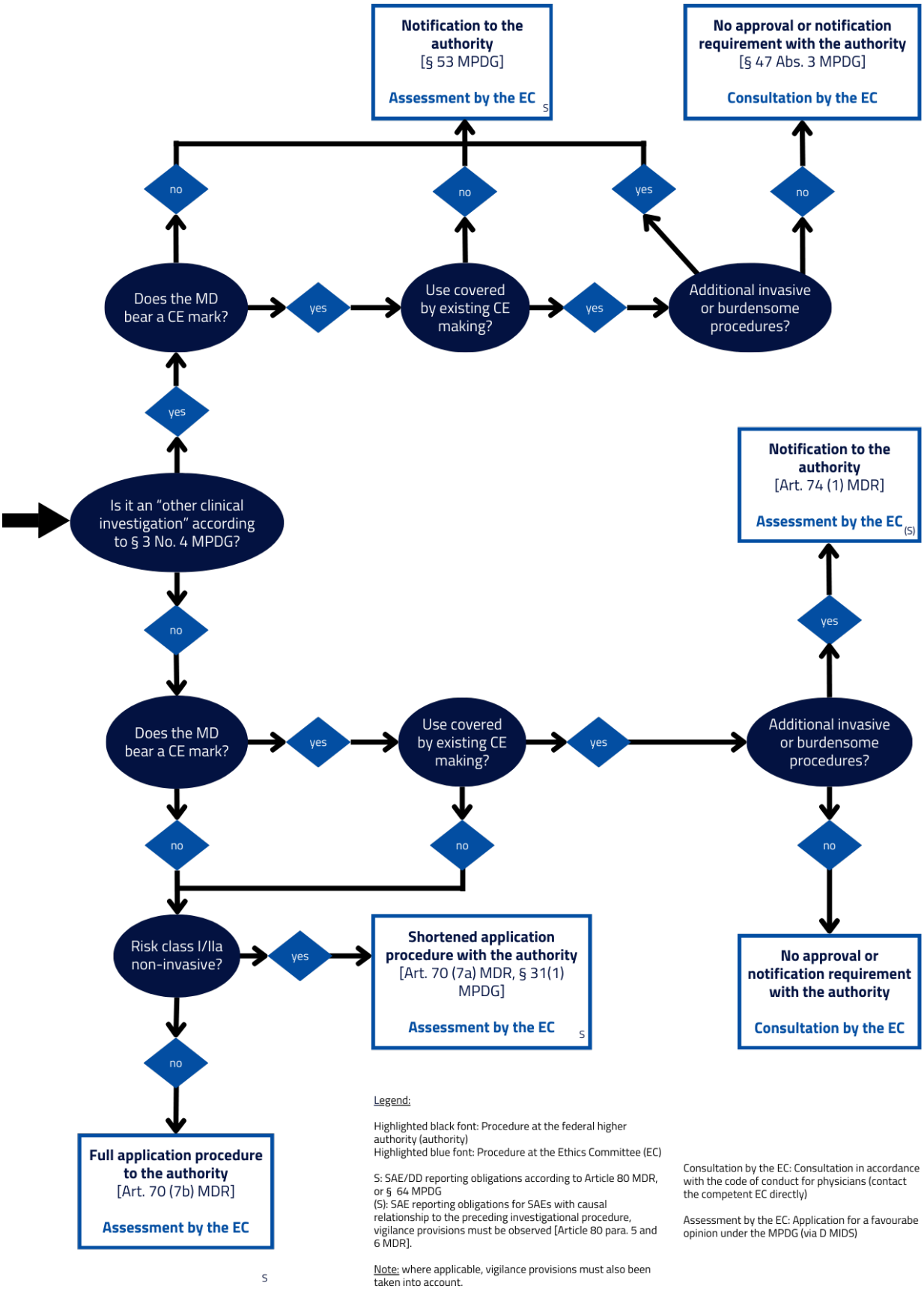
Clinical Investigation

It is important to provide clinical evidence demonstrating that your device is both safe and effective in achieving its intended clinical benefits. For this you need clinical and/or performance data; that means data generated from the use of a device and sourced from clinical investigations/ performance studies or other clinical experience, or scientific publications or other clinically relevant information on your device, or equivalent or comparative devices. The clinical evidence for your device is analysed in the context of the so-called clinical evaluation, or performance evaluation in the case of IVDs, a key part of technical documentation that needs to be prepared by all medical device manufacturers. If the initial analysis of available clinical and/or performance data reveals gaps about the available clinical evidence, it may be necessary to conduct a clinical investigation or performance study with your device to collect additional clinical data and address any open questions regarding the safety or performance of the device. This is a very simplified description of the requirement, and it is recommended to involve qualified professionals to assess the need and availability of clinical evidence with regard to your device.

Before conducting a clinical investigation/ performance study in Germany, you will need both a favourable opinion of the competent ethics committee as well as approval from the competent authority (BfArM or Paul-Ehrlich Institut [PEI]). The ethics committee is responsible for assessing the application from an ethical and legal point of view. It is important to note that even if approval from the competent authority has been obtained, a clinical investigation/performance study can only be initiated once a favourable opinion of the ethics committee is also available. Depending on the device and study and the suitable legal procedure, either an approval by the competent authority or only a notification to this institution is necessary. In the figure below taken from the BfArM website, you can check whether you need only a notification or an approval.

Ethical Committee

The sponsor must submit the respective applications online via the German Medical Devices Information and Database System (DMIDS).

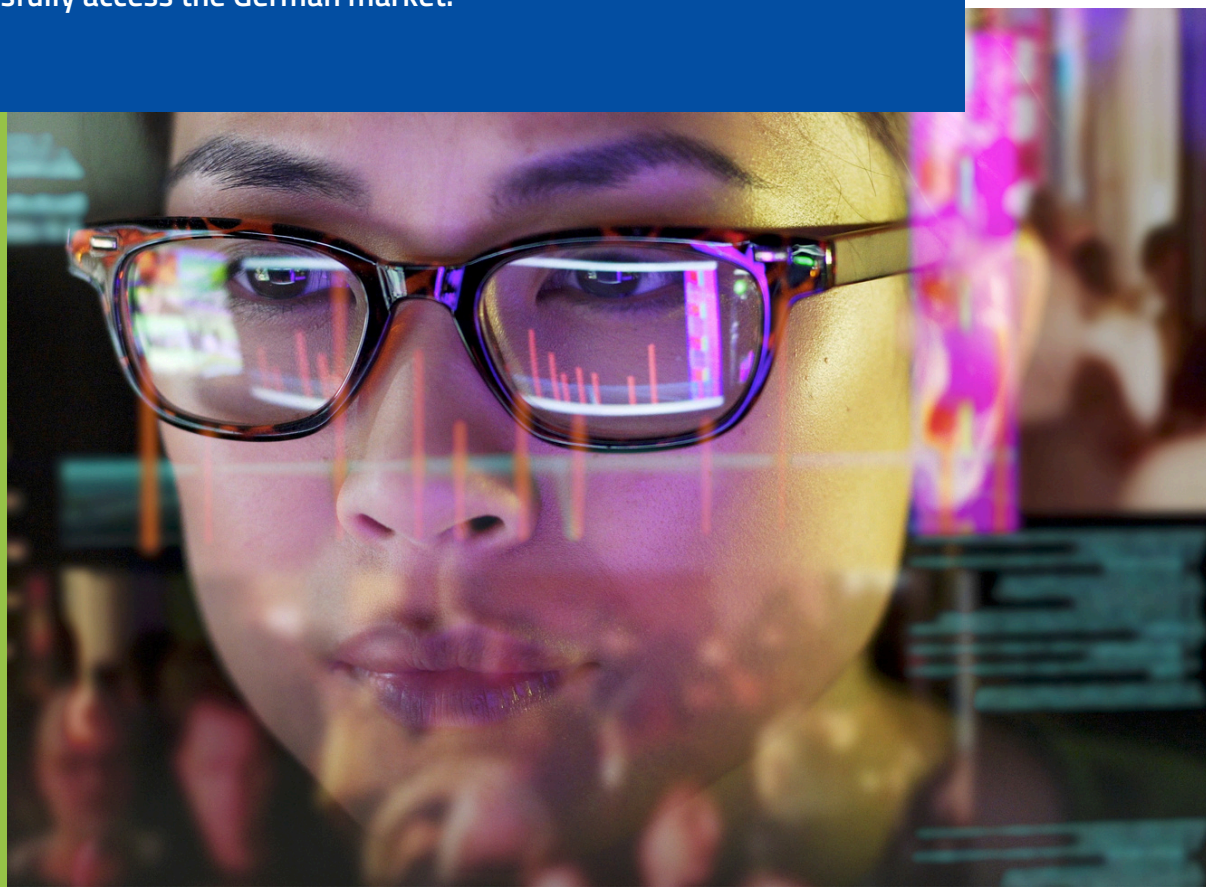


Source: Clinical investigations according to MDR / MPDG (no date) BfArM. Available at: https://www.bfarm.de/EN/Medical-devices/Tasks/Clinical-investigations-and-performance-studies/Clinical-investigations/_node.html (Accessed: 22 November 2024).

Summary

If your start-up plans to conduct clinical investigations or performance studies in Germany in collaboration with hospitals or clinics, it is important to understand all the necessary steps and ensure all required processes are in place, including ethics committee assessment and BfArM approval or notification. Usually, unless agreed otherwise in the contract, your start-up will be responsible for notifying the BfArM and obtaining the ethics committee approval with the support of the hospital or clinic.

If you have already conducted clinical investigations or performance studies outside Germany, and they comply with EU and BfArM requirements, they may be used to apply for the conformity assessment. Otherwise, a new clinical investigation or performance study must be performed in Germany, which is why the design of the clinical investigation or performance study is crucial to successfully access the German market.



REIMBURSEMENT ROUTES

Now that you've completed your clinical trial, obtained the CE mark, and navigated all the regulatory hurdles to bring your product to market, it's time to focus on the next crucial step: reimbursement. As mentioned, health insurance is mandatory in Germany, and most Germans are unlikely to opt for out-of-pocket payments. Therefore, your solution should mainly target the primary healthcare system. It's essential to explore the various reimbursement mechanisms in Germany to ensure that your product is covered by insurance and accessible to patients through the healthcare system.

> ***It is good to note that the clinical trial(s) needed for MDR are different to those needed for reimbursement. For instance, all products that are in the DiGa application process have a valid CE-mark, but they still need to complete a robust clinical trial to prove their relative effectiveness (RCT). Sometimes studies for MDR can be combined with studies for reimbursement, but very often this is not the case or not done in practice.***
>
> ***Robin Toorneman***

Care Provider Route

The care provider route is a central reimbursement mechanism within the German healthcare system. It outlines how healthcare providers, including hospitals, physicians, and clinics, are compensated for the medical services delivered to patients insured under either Statutory Health Insurance (SHI) or Private Health Insurance (PHI).

Inpatient Setting

While start-ups may not directly invoice under the Diagnosis-Related Groups (DRG) system, understanding its structure is essential for developing solutions that align with how hospitals are reimbursed for care. The DRG system and the OPS code are integral components of the German healthcare reimbursement system. Start-ups need to understand them and align their solution with these systems to ensure reimbursement through this route.

As a first step, it is crucial to identify and analyse the relevant DRGs for your specific solution. Familiarising yourself with these categories will help you understand how your product fits within the existing healthcare framework. Next, determine the appropriate OPS codes that correspond to the procedures impacted by your product.

Engaging in communication with the Institut für das Entgeltsystem im Krankenhaus (Institute for the Hospital Remuneration System (InEK)), as well as involving insurers, is essential for gaining insights into the market and understanding what is necessary for your solution to be adopted by hospitals.

Finally, it is important to regularly monitor updates to the DRG and OPS coding systems, as they can change annually. Adapt your strategy as needed to ensure continued alignment with these evolving standards.

Outpatient Setting

Outpatient care reimbursement routes differ for SHI and PHI patients. SHI reimbursement is primarily based on two key coding systems: EBM and GOÄ/UV-GOÄ for PHI.

Engaging with SHI

EBM (Einheitlicher Bewertungsmaßstab) is the Uniform Value Scale, used to reimburse physicians for outpatient services rendered to SHI patients. It is managed by the KV (Kassenärztliche Vereinigung), the National Association of Statutory Health Insurance Physicians.

The physician invoices their services according to the EBM catalogue, which assigns points to various treatments and procedures. These points translate into payments based on a negotiated conversion factor between healthcare providers and the SHI funds.

If the innovation is an outpatient service, it must be incorporated into the EBM code list to be reimbursed by SHI. This requires approval through the G-BA (Federal Joint Committee), which decides if new diagnostic or treatment methods are covered by SHI.

Engaging with PHI

GOÄ (Gebührenordnung für Ärzte) is the fee schedule for physicians used for PHI patients.

Private doctors invoice according to the GOÄ catalogue, which allows for greater flexibility in pricing compared to the SHI system.

For start-ups targeting the private insurance market, they need to ensure their services or products are part of the GOÄ catalogue. Unlike SHI, which has more stringent rules, the PHI market allows more flexible pricing and easier entry of innovative technologies or services.

DiGA / DiPA

DiGA is unique because it combines the route of regulatory approval by the German competent authority (BfArM) and reimbursement in one streamlined process. Please note however, that you need to complete the appropriate conformity assessment of your medical device and affix CE marking before submitting your DiGa application to BfArM. Once your digital health solution has gone through the regulatory hurdles, it can be listed in the DiGA directory and reimbursed by the SHI.

To qualify, the product must meet certain eligibility criteria. For instance, the application must be a class I or class IIa medical device under MDR, its main functionality must be based on digital technologies and the medical purpose must be primarily achieved through this digital functionality, it is not intended for primary prevention and is used by both the patient and the healthcare professional. Furthermore, the device must demonstrate positive healthcare effects, either as a medical benefit or a process improvement. Additionally, for data protection and cybersecurity you need to implement GDPR requirements, carry out a pen test, and have ISO27001 and BSI TR-03161 certification. Within the following period, GDPR certifications will also be introduced, so it is recommended to double check the requirements.

Applications are submitted to the BfArM, which evaluates the solution within a three-month review period, and consideris clinical evidence, data privacy, and security.

The fast-track process allows start-ups that show promising potential but lack comprehensive evidence to be provisionally listed for 12 months, during which they can collect additional clinical evidence to prove the benefits of their product. After this period, the BfArM reviews the new data to determine if the product should remain in the DiGA directory for long-term reimbursement.

It is worth noting that being listed in the DIGA directory does not guarantee coverage by the PHI. Start-ups need to negotiate with different private insurers for reimbursement, as PHI coverage is not provided under the DiGA scheme.

DiPA, quite similar to DiGA, is focused on digital solutions for long-term care. The key difference is that DiPA is integrated into the long-term care insurance system (Pflegeversicherung), which aims to support nursing care, particularly for elderly and disabled patients. The process enables a faster adoption of innovative solutions aimed at improving caregiving and supporting caregivers.

Medical Aids Directory

The Medical Aids Directory (Hilfsmittelverzeichnis) is a listing of medical devices and aids designed to help individuals with disabilities, chronic conditions or temporary limitations. They can cover a wide range of products, from wheelchairs to hearing aids. The directory is managed by the National Association of Statutory Health Insurance Funds (GKV-Spitzenverband), and once the solution is approved and listed, it can be reimbursed by the SHI. Unlike the DiGA, the solution is not always fully covered; it might only be partially covered depending on the terms of the SHI.

The process might take several months depending on the complexity of the solution since high-risk class solutions may require the involvement of the BfArM.

The assessment by GKV and BfArM is mainly based on the therapeutic benefit, cost-effectiveness, and necessity for patient care.

Before taking the first step in this reimbursement route, it is crucial to identify the class risk of your solution and if it qualifies as a medical aid, because sometimes the line can be blurred. If in doubt, it is recommended that you reach out to the authorities directly.

You can find the list of medical aids directory here: https://hilfsmittel.gkv-spitzenverband.de/home/verzeichnis/339cc855-29fa-4f9e-b822-e024ed90637b

Selective Contract

Selective contracts are another form of reimbursement that can give more flexibility to start-ups. These contracts allow patients to access other methods that are not in the G-DRG and EBM catalogues. Selective contracts are not a national level reimbursement route and therefore may require a lot of work. These contracts are mainly for solutions that are positioned between the hospital and outpatient care, or if the solution is completely new to outpatient care and cannot be categorised within the existing EBM and G-DRG catalogues.

While selective contracts are flexible, they are also quite complex in terms of negotiation between the insurers. Economic and medical advantages need to be clearly shown and explained for the negotiating partners. These contracts are governed by **Section 140a** of the German Social Code Book, but still give the insurers and service providers the freedom to negotiate terms, including pricing, performance metrics, regional scope, and patient populations.

One of the main positive aspects of selective contracts is the freedom for customisation to cover specific populations or geographical areas. This can offer start-ups a potential for pilot projects or limited-scope solutions that can support their case for further market access routes.

Even after identifying the insurers that align with your value proposition, sitting at the same table with them to negotiate selective contracts is not always easy. For that we recommend the following:

- While it is always very attractive to reach large SHI funds such as AOK, TK or Barmer, you could also consider smaller, regional SHIs, which may be more open to innovative partnerships.
- You can use innovation cluster networking opportunities such as Health Innovation Hub (HIH) and Zukunftsregion Digitale Gesundheit (ZDG).
- Attend industry conferences and workshops, e.g., Medica, DMEA, etc.
- Connect with regional development agencies; while their focus is not primarily healthcare, you may find some interesting opportunities.

Since selective contracts offer flexibility to insurers and service providers, there are many existing types:

- **Contract of Special Care:** These contracts aim to provide integrated, multidisciplinary care for complex or chronic conditions, often involving specialised care structures and better coordination across various healthcare settings.
- **Disease Management Programmes (DMP) Contracts:** These contracts are mandatory for insurers to offer and are regulated by the G-BA. They are structured care programmes developed for the long-term management of chronic diseases, such as diabetes, asthma, COPD, or coronary heart disease.
- **GP-centred Healthcare:** These contracts prioritise the general practitioner as the primary point of contact for patient care.

- **Model Project:** These allow for innovative healthcare concepts to be tested in a real-world setting under the German healthcare system. These projects are often temporary, with the goal of evaluating the effectiveness and efficiency of new treatment pathways, care models or technologies.

Others

NUB (Neue Untersuchungs- und Behandlungsmethoden):

The NUB process allows a temporary reimbursement of new medical technologies or procedures that are not included in the standard healthcare framework. This process is designed for innovative inpatient treatments and isn't generally applied for outpatient services. Applications are submitted by hospitals through the InEK (Institute for the Hospital Remuneration System). Usually, the application is on yearly basis and should be submitted by 31 October. The InEK releases the results in the following January, and once the NUB status is granted, hospitals can negotiate additional remuneration with SHIs.

It is important to note, the ultimate goal is to include the new technology or procedure in the G-DRG reimbursement system. The NUB status allows for temporary reimbursement and can be renewed annually. It can be fully integrated into the system once sufficient data and evidence on the method's efficacy and cost-effectiveness is collected.

For start-ups with a solution that falls under the NUB framework, it is crucial to partner with one or more hospitals that are willing to apply, since direct application by companies is not possible. It is worth noting that multiple hospitals can apply for the same new treatment or diagnostic tool. This strengthens your application and improves your chances of being successful.

Zusatzentgelt (ZE) – Add-on Reimbursement:

Zusatzentgelt (ZE) is an add-on reimbursement mechanism in Germany that covers the additional costs of expensive medical devices, procedures, or drugs not adequately funded by the standard DRG system. Hospitals can apply for ZE when standard DRG tariffs do not cover the full cost of a specific procedure or device. The following list outlines the key aspects and procedural considerations for securing ZE reimbursement in Germany, ensuring that hospitals and manufacturers understand the eligibility, application, and review processes:

- Eligibility: Typically applies to high-cost medical technologies or treatments that introduce new innovations, such as advanced implants or complex surgical techniques.
- National or Local Application: Some ZEs have nationally fixed tariffs, while others require individual negotiations between hospitals and health insurers. The decision depends on whether a national tariff has been established for the particular device or procedure.
- Annual Review: The list of eligible ZEs and associated tariffs is updated annually, meaning that hospitals and manufacturers must regularly apply or renegotiate to ensure continued coverage.

Co-funded Studies (§137e SGB V):

The §137e SGB V framework provides funding for co-sponsored studies of medical methods and technologies that show promise but lack sufficient clinical evidence for full integration into the Statutory Health Insurance benefits package.

Purpose: This mechanism supports the collection of necessary clinical evidence for methods or technologies that have potential but are not yet fully proven. It allows manufacturers and hospitals to work with the German healthcare system to generate data on safety, efficacy, and cost-effectiveness.

Process:

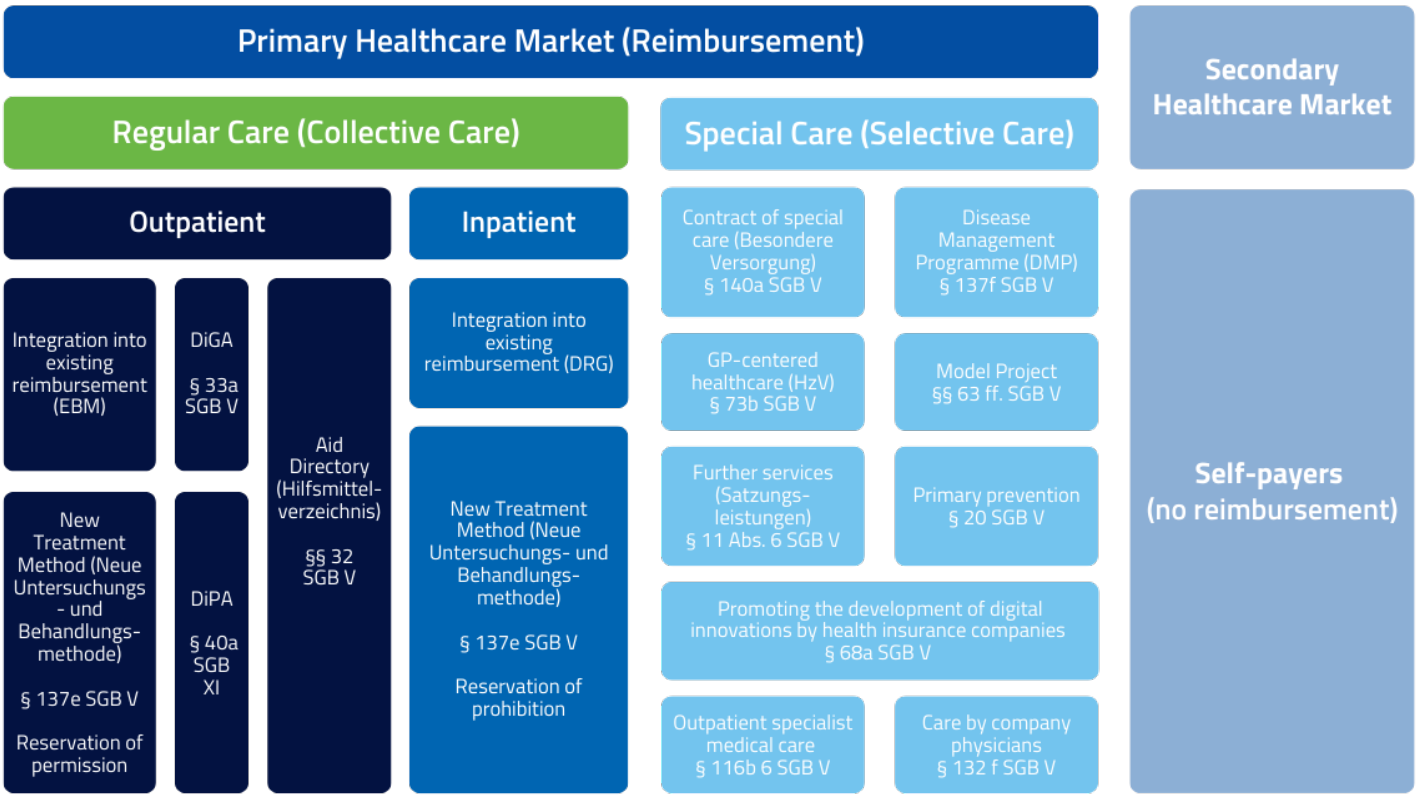
- Manufacturers or hospitals apply to the Federal Joint Committee (G-BA) for a study.
- If approved, the G-BA provides funding for the study, co-financed by the Statutory Health Insurance system, and the results help inform the inclusion of the technology in the healthcare system.
- Studies are typically conducted in hospitals, with the findings determining whether the technology should be reimbursed under Statutory Health Insurance.

Healthy Hub

Healthy Hub is a joint initiative by several SHIs such as BARMER, KKH and Siemens-Betriebskrankenkasse (SBK). It aims to support early-stage start-ups by providing them with an opportunity to collaborate with these insurers. The goal is to introduce digital health solutions that can be integrated into the SHI ecosystem. While this initiative is very interesting and can support fast-track integration into the German healthcare system, it does not directly provide a formal reimbursement route; rather it facilitates pilot projects and selective contracts.

For more information you can visit: https://www.healthy-hub.de/home.html#start

Summary


Primary Healthcare Market (Reimbursement)
Secondary Healthcare Market
Regular Care (Collective Care)
Special Care (Selective Care)
Outpatient
Inpatient
Integration into existing reimbursement (EBM)
DiGA
§ 33a SGB V
Aid Directory (Hilfsmittel-verzeichnis)
§§ 32 SGB V
Integration into existing reimbursement (DRG)
New Treatment Method (Neue Untersuchungs- und Behandlungs-methode)
§ 137e SGB V
Reservation of permission
DiPA
§ 40a SGB XI
New Treatment Method (Neue Untersuchungs- und Behandlungs-methode)
§ 137e SGB V
Reservation of prohibition
Contract of special care (Besondere Versorgung)
§ 140a SGB V
Disease Management Programme (DMP)
§ 137f SGB V
GP-centered healthcare (HzV)
§ 73b SGB V
Model Project
§§ 63 ff. SGB V
Further services (Satzungs-leistungen)
§ 11 Abs. 6 SGB V
Primary prevention
§ 20 SGB V
Promoting the development of digital innovations by health insurance companies
§ 68a SGB V
Outpatient specialist medical care
§ 116b 6 SGB V
Care by company physicians
§ 132 f SGB V
Self-payers (no reimbursement)

MARKET ACCESS STRATEGIES

Distribution and Sales Channel:

Selling to Hospitals

In Germany, there are three types of hospitals: public hospitals, non-profit hospitals, and private hospitals. While they are different in terms of governing bodies, they have the same process in terms of funding. For start-ups to sell directly to hospitals, they need to gain approval through stringent procurement processes. Public hospitals typically require participation in competitive tenders, while private hospitals may have more flexibility in procurement.

Products must comply with the Medical Device Regulation (MDR) and might need evaluation by the Federal Joint Committee (G-BA).

Another option for start-ups is to connect with hospital groups and purchasing networks to negotiate better prices and serve as essential channels for distribution.

Hospital Groups

- **Fresenius Helios:** One of the largest private hospital operators in Germany, Fresenius Helios operates over 130 hospitals and offers a range of medical services.
- **Asklepios Kliniken:** This group manages around 160 hospitals and specialised clinics across Germany, focusing on various medical disciplines.
- **Rhoen-Klinikum AG:** Operates numerous hospitals in Germany, emphasising high-quality care and innovative treatment options.
- **Sana Kliniken:** With over 50 hospitals, Sana Kliniken is committed to providing comprehensive healthcare services throughout Germany.
- **Klinikum Stuttgart:** A major hospital group in the Stuttgart region, offering a wide array of medical specialties and advanced healthcare services.

Purchasing Groups

- **Health Alliance (Gesundheitsverbund):** A purchasing group that consolidates the purchasing power of member hospitals to negotiate better prices for medical supplies and equipment.
- **VSA (Verband der Krankenhausapotheker):** A network of hospital pharmacies that collaborates on purchasing agreements and shared resources.
- **KHB (Krankenhausgesellschaft Baden-Württemberg):** This association represents hospitals in Baden-Württemberg and also engages in collective purchasing for its members.
- **MEV (Medizintechnik Einkaufsverband):** A purchasing group focused on medical technology, helping its members negotiate favourable purchasing agreements.
- **Prospitalia GmbH:** A purchasing organisation that provides hospital operators with solutions for procurement and supply chain management, optimising costs and efficiency.

Regional Hospital Associations

- **Bavarian Hospital Association (Bayerische Krankenhausgesellschaft):** Represents hospitals in Bavaria, supporting collective purchasing and negotiating favourable terms with suppliers.
- **Landesverband der Krankenhausgesellschaft Nordrhein-Westfalen:** Represents hospitals in North Rhine-Westphalia, focusing on procurement strategies and collaborative purchasing.

Healthcare Networks

- **MEDI:** A network of healthcare providers that focuses on collaborative purchasing and resource sharing among member facilities.
- **Carenet:** A network that connects hospitals and healthcare providers, facilitating cooperation in purchasing and shared services.

Contacting and Negotiating with Insurers

Whether you are contacting insurance providers for selective contracts or to get reimbursement through the care provider route, preparation is always key. There are many factors that start-ups should consider in order to successfully connect with insurers:

- Is it at all possible to offer our product or service within the framework of a selective contract?
- What requirements and objectives must my product fulfil?
- Which health insurance company's product strategy fits our product in terms of supply, level of innovation, types of therapy and target group?
- How does the health insurance company improve its market position through our product? For example, can new target groups be won or savings achieved?
- What expectations do we have of the health insurance company in return?
- Which other partners, such as doctors, patient associations and management companies, are necessary for our success?

How to connect with practitioners?

If you have successfully negotiated with insurers to get your solution reimbursed, you still need a healthcare professional to be willing to provide your treatment or use your device/solution.

Physicians in Germany are well-regulated by regional physician associations. To reach healthcare professionals, companies need to establish relationships with hospitals, medical practices and university clinics. Direct marketing efforts may include:

- Partnering with Kassenärztliche Vereinigungen (KBV) (National Association of Statutory Health Insurance Physicians) to connect with practitioners.
- Medical conferences, continuing education programmes, and direct marketing are crucial for practitioner engagement.
- Digital channels like professional platforms are becoming more influential for connecting with medical professionals.

When should you have a distribution partner?

Having a distribution partner might become beneficial once you have the CE mark. Their support with relationships and existing networks is crucial, especially if your solution requires deep market penetration. For medical aids solutions, for instance, it's quite common to have a distribution partner due to the structure of the German market, with some special shops for medical aids or large medical aids distributors. Not having one will make market penetration more challenging, but not impossible. There is also the possibility for a medical aid solution to partner with Reha Kliniken and have them promote your product.

There are some potential disadvantages of entering into exclusive distributorships: if you are seeking an early exit/trade sale, the company acquiring the start-up most likely will already have their own distribution partners. Having to take over exclusive distribution agreements might make the deal less attractive.

Karina Candrian

Pricing Strategies and Pricing Index

In Germany, the pricing of healthcare products, especially medical devices and pharmaceuticals, is highly regulated and influenced by a variety of frameworks and market factors. As a start-up entering the German market, you should be aware of these elements to optimise your pricing strategy and align your business model based on these parameters.

The pricing of medical devices is more flexible than pharmaceuticals, but their inclusion in the reimbursement system requires negotiation with healthcare providers and insurers. For DiGAs, start-ups are free to set their own prices in the first year of provisional approval, but once the start-ups have provided the information for the post-approval year, a negotiation with the SHI is needed to establish the long-term pricing model.

Germany uses reference pricing systems and health technology assessment for certain product categories, meaning that reimbursement is set according to similar products already on the market. This can cap the prices start-ups are able to charge, which is especially relevant for pharmaceuticals and medical devices. That's why start-ups need to develop pricing strategies that will ensure both market penetration and profitability. Talking with an expert in pricing at an early stage can be very beneficial in the long run.

Marketing and Communications

The previous section outlines the main rules and regulations that healthcare start-ups need to align with regarding marketing and promotions. This is a crucial step in giving your solution visibility. One of the most important elements is creating a clear and unique value proposition and also convincing your final customers of the benefits of your solution. The use of social media is important and a clear strategy that aligns with your branding and communication is key. The choice of the right channels depends largely on the target audiences (clinicians, nurses, patients, etc.), the decision-makers for your product, and your business model (B2B or B2C).

Germans are used to receiving information in their mother tongue. The command of English in the healthcare sector is sometimes problematic. I would recommend start-ups looking to enter the German market to develop German materials and localise their information/marketing strategy.

Visibility and audience outreach efforts can focus on:

- Healthcare professionals and decision-makers (hospital administrators, insurance heads) via industry events, conferences and medical journals.
- Leveraging digital marketing channels for non-prescription healthcare products, focusing on social media, webinars, and online communities where medical professionals gather.
- Building a presence through thought-leadership, publishing in peer-reviewed medical journals, and participating in clinical trials.

- Engaging with patient advocacy groups and providing educational content through health apps or telemedicine platforms.

If you lack expertise in drafting marketing campaigns, it might be beneficial to work with a mentor or a consultant to guide and support you in this aspect since unique messaging and branding are crucial to leverage your solution in a very competitive market.

Cultural Considerations

- Compared to other countries, the German communication style tends to be more formal, especially in professional settings. You should ensure that the tone of all marketing materials and outreach reflects this formality.
- While many healthcare professionals speak English, presenting materials in German will significantly enhance engagement. Consider investing in professional translations to ensure the message is both clear and culturally resonant. If the German language is not used correctly and in the right context and tone, brand trust might be lost.
- Highlight the importance of building brand trust in the German market. Endorsements from respected healthcare professionals, partnerships with local institutions, or data from clinical trials conducted in Germany would significantly boost credibility.
- Integrate an omnichannel strategy into your existing plan. Integrating offline (such as conferences, medical expos) and online (social media, webinars) channels can ensure a unified brand presence.

Summary

DO

- Connect with hospital groups and purchasing networks to negotiate better prices.
- Ensure that you conduct thorough market research on insurance providers to identify those that align with your objectives and audience.
- Develop German materials and to localise your information/marketing strategy.

DON'T

- Do not have the same strategy or communication plan if you are talking to different stakeholders.
- Avoid contacting distribution partners with a tightly constrained schedule (couple of months for instance)
- Avoid setting your product's price solely based on your own assessment.

CASE STUDIES

Cue2Walk (Medical Aid Directory)

To better understand the Medical Aid Directory process we have conducted an interview with Floor Waardenburg, CEO and Managing Director at Cue2Walk. For their solution, they have applied to the Medical Aid Directory route, and are currently in an ongoing process with the National Association of SHI funds.

Cue2Walk is a wearable product designed for people with Parkinson's disease that detects a freeze and automatically provides cues to help minimise the drawbacks of the freeze. This is called 'smart cueing'. Parkinson's patients encounter freezes during daily life. A freeze is a sudden error in the brain, which results in motion of the lower limbs. This can occur during walking, turning, etc. During walking especially, it can be very obtrusive for the patient and can lead to accidents. This smart cueing helps the patient prevent or minimise freezes during daily life in an unobtrusive way, leading to an improved quality of life.

How did you initially navigate the market access process in Germany?

Although the startup began developing the Cue2walk solution eight years ago, it only acquired the CE mark in April 2022. The MDR regulation and the assessment to get the CE mark took around two months to finalise the technical documentation and requirements needed.

While developing the product over many years, the startup was always aware of the regulatory requirements, as even a simple addition to your product could change its classification risk, potentially needing a notified body to obtain the CE mark. Once a notified body is needed, the process is lengthier and requires much more effort and resources.

One of the initial steps to accessing the German market is participating in the Patient Complex Therapy ecosystem within hospitals. In this setting, patients typically stay in the hospital for three to four weeks, providing start-ups with an excellent opportunity to pilot their solutions. This allows them to test and refine their innovations in a real-world clinical environment. To take advantage of this opportunity and connect with hospitals and clinics, start-ups must ensure their solution has a CE mark, as this certification is required to join the programme.

Can you explain the challenges you've faced while applying to the Medical Aid Directory?

The approval process for the Medical Aid Directory is still ongoing, as the start-up has not yet received the final authorisation. This process is particularly challenging, requiring careful submission of the right documentation and identifying the appropriate contacts. To navigate these complexities, the start-up is working with a consultant who extensive knowledge of the German market. Having a consultant is crucial, as establishing connections and finding the right people can be difficult without a presence in the market. The Medical Aid Directory process is also time-consuming, with approval taking a significant amount of time to complete.

How did you plan your marketing efforts?

The focus for Cue2Walk is primarily general practitioners, specifically neurologists, and key opinion leaders (KOLs) in the field. Although they don't currently have a dedicated sales representative, their approach centres on direct networking and building strong connections with these healthcare professionals. Additionally, Cue2Walk is actively engaging with patient groups to enhance patient adoption of their solution. By working closely with these groups, they aim to improve awareness and adaptation among patients, ensuring their solution meets the needs of those who benefit most.

Are you planning to negotiate with Private Health Insurance providers?

Currently, Cue2Walk has not made significant efforts to negotiate with Private Health Insurance providers, although this is part of their long-term business strategy. Currently, their primary focus is on securing reimbursement through the Medical Aid Directory and establishing a strong market presence by expanding their network and connections.

Additionally, the start-up is developing a pricing strategy to ensure their solution is affordable for patients, as they have observed a clear willingness to pay during direct engagement. While reimbursement is critical, Cue2Walk is also focusing on direct sales to customers as part of their approach.

From your own perspective how important are partnerships, and did you find any support in the German health institutions?

Partnerships and networking are crucial when entering any market, not just the German one, and this becomes even more important when you lack a local presence or 'boots on the ground'. Engaging the consultant has made a significant difference for Cue2Walk in accessing the market, as they bring the necessary network and expertise to navigate potential pitfalls and avoid costly mistakes. While hiring a consultant requires considerable financial resources, it has proven to be a worthwhile investment.

Cue2Walk has also engaged with patient groups to have direct conversations with end users to get their feedback and improve the adoption rate.

Any final advice that you want to share with start-ups?

Three main points of advice were shared by Floor that can be summarise as follow:

- **Start small and find the right network:** To fully access the German market, it's crucial to run pilot programmes. While this can sometimes be challenging, there are many opportunities in some areas where the need for innovative solutions is evident, and the willingness to engage with new technologies is high. As a result, it's not necessary to focus on large hospitals or clinics as the first step. Starting small and finding the right opinion leaders can provide valuable insights, build early credibility, and pave the way for broader market entry.
- **Connection with clinic and hospitals:** Building a strong network and connections is just as important as engaging directly with clinics and hospitals. These relationships can be tremendously beneficial, opening doors to pilot opportunities, providing valuable insights, and accelerating market entry.
- **Don't try on your own:** Finding a reliable partner with the knowledge and expertise to support you in the market access process is essential. They can help you avoid costly mistakes and guide you through the complexities of the market. They can also assist in building a strong and trustworthy network of connections, which is crucial for long-term success.

ProCarement (DiGA Directory)

For a more practical context regarding the DiGA process, we interviewed Sebastian Eckl, Founder of ProCarement, which recently went through the DiGA process. As of 15 May 2024, the solution ProHerz is provisionally listed in the DiGA directory. The purpose of the interview was to gather insights into the application challenges, timeline and some recommendation that you, as a start-up, may find useful for your own process.

ProHerz is a digital therapy companion designed for patients with heart failure, aimed at enhancing self-management and serving as an early warning system for recognising changes in the condition. The app facilitates daily monitoring of vital signs, such as blood pressure, oxygen saturation, pulse, temperature, and weight, which patients record on mobile devices like smartphones or tablets. This data is then automatically analysed to track the patient's health status. The app also provides personalised health coaching and other risk prevention tools based on the user's health and therapy profile. By using ProHerz regularly, patients can improve their ability to manage heart failure independently, follow guideline-based therapies and identify warning signs early, helping to prevent emergencies. Ultimately, ProHerz offers continuous therapeutic support across the patient's care journey.

How did you navigate the initial market entry process?

The ProHerz solution tackles chronic heart failure for elderly people (65 years and more), and the success, so far, has removed the prejudice that older people are less willing to adopt digital health applications. In fact, many older people are open to using digital solutions, especially when these tools help them improve and maintain their health.

The solution is currently classified as a Class I Medical Device under the Medical Device Directive (MDD), with an ongoing process to achieve MDR classification for Class IIa. The low-risk nature of the product has made the assessment process relatively straightforward and manageable. ProHerz obtained its CE mark in 2021, completing the certification in approximately three months at a reasonable cost of around €20,000.

Can you provide an overview of the DiGA process?

The DiGA process can be one of the most challenging pathways for start-ups seeking reimbursement, as it involves navigating numerous layers of regulations and aligning with various stakeholders. ProHerz submitted its first application to DiGA shortly after obtaining its CE mark in 2022. However, this initial application was rejected, primarily because the assessors at BfArM required a randomised controlled trial (RCT) for the solution, which had not been conducted and was not deemed necessary based on the start-up's initial assessment.

After addressing the feedback, ProHerz resubmitted the application with the same concept one year later, investing an additional €1.5 million in the process. The solution is now provisionally approved and listed in the DiGA directory.

During the first year, ProHerz is required to provide evidence of health economic benefits, specifically focusing on reducing hospital visits, which must be submitted before March 2024. Additionally, the start-up has the flexibility to set its own price during this initial year, benchmarking against similar solutions in the market.

Final negotiations with Statutory Health Insurance will occur at the end of the year, once the solution is permanently listed. These negotiations take place in a closed setting at an undisclosed location, with five representatives from each side coming together to discuss and agree on the reimbursement pricing for the solution.

Are there any plans to start negotiating with Private Health Insurance?

At this stage there are no plans to start negotiating the selective contracts with Private Health Insurances. The focus now is to get a permanent listing in the DiGA, and from the start-up's perspective, this route is enough for a successful and stable company.

How was the process with BfArM and how would you define their requirements?

You are typically assigned one assessor from BfArM for your solution review. The assessors change quite often. You do not have a direct connection with your assessor, any decision related to the product might need the BfArM assessors' approval, and you must go through the process of submitting an application and waiting for their reply. As an example, a request to translate the app from German to Italian to conduct a pilot study with some Italian partners took 6 months.

The process and communication with BfArM are neither the best and nor straightforward. There are always new requirements that your solution needs to adhere to, and you need to deal with different regulations every time. The solution might need to be adjusted to align with this requirement and regulation. To put some numbers into how much effort goes into dealing with BfArM requirements, the start-up dedicated five developers solely to meeting BfArM's requirements, incurring a cost of €500,000 for ISO and BSI certifications.

This heavy administrative burden can be overwhelming for startups, potentially hindering their ability to focus on business growth and scaling. But with all the challenges mentioned, it is still worth being reimbursed by DiGA as the market access that this route provides can be enough to have a successful company.

From your own perspective, how important are partnerships, and did you find any support in the German health institutions?

Partnerships are absolutely essential for successful market entry. It gives you a bypass and a chance to compete at a higher level. The strong connections we have accumulated through the year have supported us in the DiGA process and we were able to get more valuable connections during the process.

There are some useful networks that can support you in getting access to different stakeholders. The Medical Valley Network that the start-up was part of has helped in getting access to different hospitals, the fundraising process, and talking with investors.

Would being reimbursed by DiGA make it easier to access other markets?

No, because there is no harmonisation between different reimbursement routes in Europe. Getting reimbursed through DiGA definitely gives you a big market to access, however, the process is quite different in other countries.

How did you manage the marketing efforts once the solution was listed in the DiGA?

In the outpatient setting, the DiGA process requires a strong, on-the-ground presence, making direct sales efforts vital for success.

The start-up has focused towards building its own sales force. By specifically targeting the heart disease sector, they aimed to connect directly with rehabilitation facilities, a key area for their product's adoption. To support this strategy, the company employed five dedicated sales representatives who are responsible for establishing these connections, introducing the product, and driving its adoption within the facilities. To access the market faster, having a sales partner would also make sense.

Any final advice you would give for other start-ups?

While the DiGA process is demanding and requires significant human and financial investment, it can still be a worthwhile route. Successfully navigating the process, grants access to a substantial market, which can be pivotal in establishing a stable and successful company.

Additionally, focusing on the patient experience is crucial. Understanding and addressing patient needs can, not only, enhance the solution's appeal but also ensure its long-term success in the market.

RECOMMENDATIONS

Wrap up

Navigating Germany's healthcare system requires compliance with multiple regulations, including MDR (Medical Device Regulation), IVDR (In Vitro Diagnostic Regulation), and DiGA-specific requirements for digital health applications. Start-ups should align their solutions with these frameworks, leveraging the DiGA process for outpatient reimbursement or the Medical Aid Directory for medical aids. Regulatory hurdles are significant, requiring extensive resources for approval, but the market access provided is substantial.

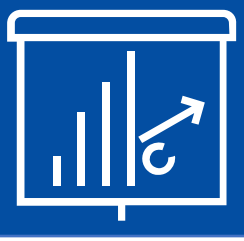
Germany's healthcare system, comprising SHI (Statutory Health Insurance) and PHI (Private Health Insurance), covers nearly all residents. SHI is more rigid but offers expansive reach (over 73 million insured), while PHI provides more flexibility and could serve as an easier initial target for start-ups. Partnerships with insurers via selective contracts, e.g., Disease Management Programmes or GP-centred care, provide another reimbursement pathway, though negotiation demands careful preparation.

Hospitals and care providers are reimbursed primarily through the DRG system for inpatient care, while outpatient care relies on systems like EBM (Uniform Value Scale). Start-ups can create a compelling case by demonstrating economic benefits, such as reducing operational costs or enhancing care efficiency, addressing gaps left by underfunded hospital budgets.

Distribution or sales partners can accelerate market penetration but require strategic alignment on timelines and goals. Start-ups should ensure proper validation of their solutions to minimise potential collaboration issues. Hospitals and clinics are increasingly open to digital and innovative solutions that address staffing shortages or improve care without raising operational costs.

The approval process, especially under the DiGA framework, is resource-intensive, involving detailed patient benefit documentation and iterative alignment with changing requirements. Costs can reach hundreds of thousands of euros. Start-ups must allocate resources, e.g., dedicated developers, to meet these demands, but they benefit from the significant market access DiGA offers upon approval.

Trends such as mental health tech, nanomedicine, and medical exoskeletons present growth opportunities. Startups can leverage these trends to address unmet needs while tackling critical healthcare challenges like regional disparities in care or operational inefficiencies. Emphasising interoperability and data security (GDPR compliance) is critical for market trust and scalability.



What should you keep in mind? Experts' View

As an entrepreneur, I found the German market very approachable via events and F2F opportunities. Sectorial fairs like DMEA or Medica, conferences like health.tech by Bits and Pretzels or Xpomet, or local events organised by small groups are very affordable and will provide you with a great opportunity to meet competitors, healthcare stakeholders, and potential investors or advisors.

To get a foot into the German market, I found that local development agencies, like Berlin Partner in Berlin, are always eager to help, connect and share knowledge.

Finally, you shouldn't copy, but learn from other's journeys. By working with 100+ start-ups over the last 10 years, I've never seen a roadmap and strategy that was identical to someone else's. Every entrepreneur had different ideas, strategies in mind, key people, connections, and supporters. This has also the case in the last 3-4 years with DiGAs, who all target the same goal of being listed in the category, but vary heavily in their strategy for marketing, sales, clinical validation and overall product development roadmap.

Jovan Stevovic

From a regulatory point of view, the most important steps in the beginning are the correct qualification and classification of a medical device according to the relevant regulation because these determine the conformity assessment procedure that needs to be applied to obtain CE marking for the product. However, in order to qualify and classify a device, the intended purpose must be defined, and a detailed description of the product, including its principal mode of action, must be available. The conformity assessment procedure has a significant impact on time to market and the costs associated with obtaining CE marking.

Karina Candrian

When entering a new market, be aware that European healthcare systems differ significantly. What holds true in your home market may not apply in Germany. Keep an open mind and do your research thoroughly. Understanding the intricate dynamics of a new healthcare system is essential. Consider hiring a consultant, engaging an intern, or seeking support from a local development agency to build this knowledge base.

In shaping your market entry strategy, remember that Germany is a vast territory. Starting in one or two states, rather than targeting all 16 at once, can be a strategic approach, leaving room for healthy opportunism. Additionally, while many Germans have a good command of English, they generally prefer receiving informational materials in German. When it's time to make serious inroads, be prepared to invest in translation and localisation. Finally, make sure you navigate the German bureaucracy to your advantage, while there are defined reimbursement pathways, success depends on thorough preparation and persistence.

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