



DiGA-Fast-Track

Getting Your Digital Health App Ready For Reimbursement in Germany



New opportunities for healthcare innovators: Germany sets framework for the prescription and reimbursement of digital health apps

With the “Digital Healthcare Act” (DVG), “apps on prescription” (DiGA) have been introduced into the German statutory healthcare system, creating new and exciting market access and compensation opportunities for digital health companies. But to navigate safely from product idea through assessment procedures to market entry, companies need to be aware of numerous regulatory requirements.

Healthcare systems are facing major challenges: demographic change, skyrocketing healthcare costs, and a shortage of skilled workers. In this context, the need for efficient healthcare delivery has provoked a renewed push towards digitalization.

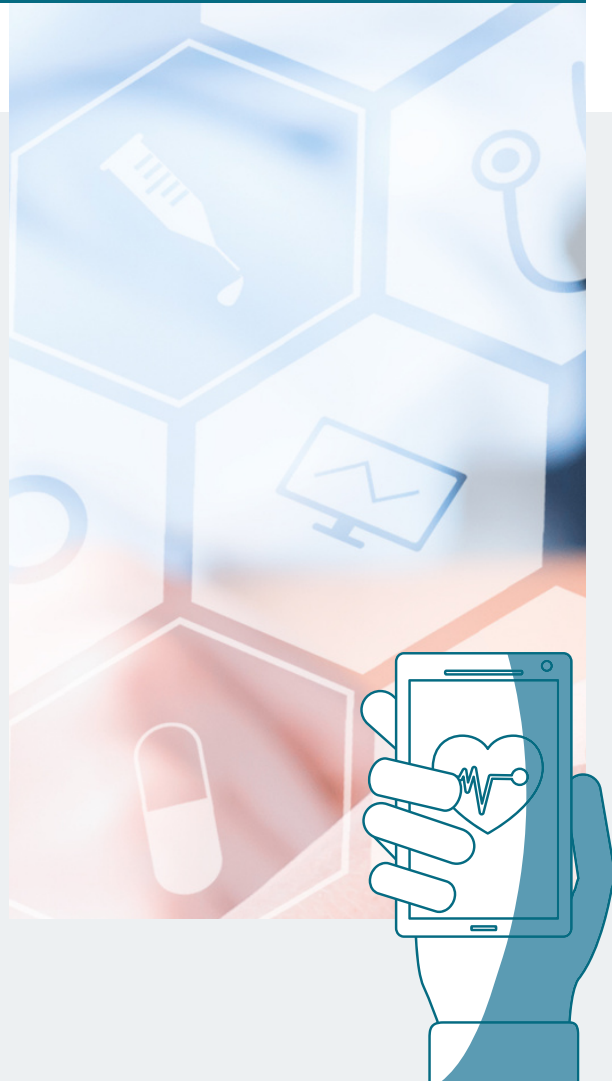
But digital health also responds to the desire of patients to take ownership of their health journey, promoting a connected and patient-centered healthcare system.

Germany is one of the first countries to recognize digital health apps as full-fledged treatment options.

The “Digital Healthcare Act” (DVG, 2019) and “Digital Health Applications Ordinance” (DiGAV, 2020) provide a comprehensive legal framework for the prescription and reimbursement of digital health applications (DiGA) in the German statutory healthcare system.

For digital health companies, this opens up a new market of 73 million users.

Of course, to enter a new market, companies may need to revisit their product and business model. But in the context of statutory health insurance, they also need to identify suitable modes of reimbursement, negotiate appropriate pricing, and demonstrate their product’s medical efficacy.



Finally, legal requirements regarding medical device law, data privacy, information security, and technical interoperability need to be taken into account.

For speedy, efficient access to the German healthcare reimbursement market, all relevant requirements are best identified and attended to from the early stages of product development on.

We can help you get there.

Don't miss your chance: Fast-track your digital health application (DiGA)!

We support digital health companies and start-ups in choosing the perfect route to success as we guide you through new approval processes and established reimbursement systems alike.

You know you stay on track on your way to market access while you focus on your mission: Developing innovative healthcare solutions for patients!



We can help you on your way to reimbursement

■ **Digital health applications can speed up their market entry by following a fast-track** to approval and market access. But with user-centered and agile companies / start-ups on the one hand and a highly regulated healthcare system on the other hand, two ways of thinking tend to collide. If regulatory hurdles on the fast track are not jumped at the right moment or in the right order, there is a high risk for digital health companies to run an extra lap.

We know the ins and outs of DiGA regulation. We have accompanied the German Federal Ministry of Health (BMG) throughout the digital health legislative process. And we have acted as a sparring partner for the Federal Institute for Drugs and Medical Devices (BfArM) regarding the application submission portal.

We also know how to navigate the process in practice, supporting and consulting digital health companies throughout the application procedure and until their products are listed in the directory of reimbursable digital health apps. Thereby, we know the success factors and can anticipate the hurdles and pitfalls to make sure your journey is both safe and successful.

We can help you to

- Make sure that typically quick software release cycles are compatible with regulatory frameworks
- Determine how you can meet the basic regulatory / reimbursement criteria and assess all other applicable requirements (e.g., interoperability, data privacy, information security)
- Develop an efficient strategy to demonstrate positive care effects for both benefit assessment (BfArM) and price negotiations (statutory health insurance)
- Prepare for consultations with the Federal Institute for Drugs and Medical Devices (BfArM) and price negotiations with payers
- Coordinate all your fast-track-related steps for maximum speed

Not sure if you are a DiGA? There is more than one route to success!

Not all digital health apps meet the DiGA criteria. Perhaps, you have developed an incredible blended care solution. Or your idea revolutionizes inpatient care. What then?



Custom-tailored support for your digital health app

In the German healthcare system, "apps on prescription" are not the only reimbursement option for digital health apps. But alternative compensation models, such as "Selektivvertrag" or "Besondere Versorgungsformen", follow different processes and requirements.

Thus, knowing the regulatory conditions and the national market environment surrounding digital health is key to successfully gain access to the reimbursement market and to effectively position your product.

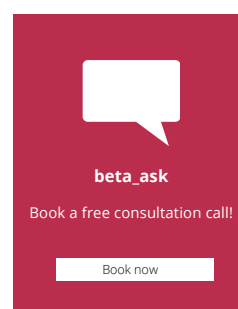
We can help you find out which compensation model best fits your idea, determine the corresponding regulatory requirements, and pave your way through to market entry.

With our modular digital health portfolio, we offer custom-tailored support in all aspects pertaining to reimbursable digital health apps – not only DiGAs.

You can find more information about our modular consulting services on our website:
<https://fbeta.de/leistungen/digital-health/>



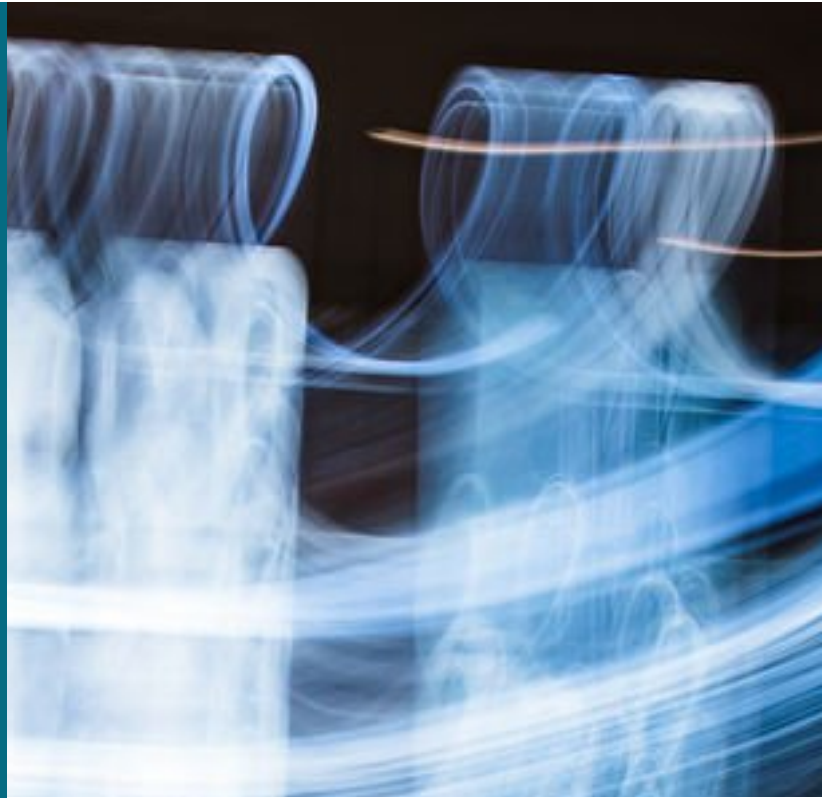
You have a specific question?
You want to find out how we can help you?
Be sure to book a free consultation call!



_fbeta has a proven track record in

Healthcare. Digitalization. Transformation.

Our offering ranges from specialized consulting to full-service support.



The Digital Health Team

Healthcare needs innovative ideas. And we want your idea to reach its full potential. That's why we assembled an interdisciplinary group of experts: The Digital Health Team.

The team has:

- The knowledge of over 100 digital health projects
- More than 20 years of practical experience in healthcare management, in designing product-specific payer compensation models, and in managing digital transformation projects
- Thorough expertise in data privacy and technical interoperability
- And exclusive first-hand knowledge of Germany's digital health regulation

_fbeta

_fbeta stands for healthcare, digitalization, and transformation. We specialize in the areas of digital health, healthcare research and market access, health information exchange, technology and architecture, as well as digital transformation. We offer our clients reliable support and specialized consulting from a single source.

We combine professional expertise in healthcare, technical expertise in digitalization, and experience in the management of healthcare transformation processes. We blend consulting with science and management. The result is an agile, state-of-the-art approach to healthcare and IT innovation.

We join our clients in the desire to shape top-grade, yet affordable, healthcare solutions. Together, we can change healthcare for the better.

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