Association for Information Systems

AIS Electronic Library (AISeL)

CONF-IRM 2022 Proceedings

International Conference on Information Resources Management (CONF-IRM)

10-2022

A Viable Business Model for Innovations with Digital Healthcare Applications in Germany

Paul Alpar

Andreas Rösch

David Schmoldt

Luisa De Witte

Follow this and additional works at: https://aisel.aisnet.org/confirm2022

This material is brought to you by the International Conference on Information Resources Management (CONF-IRM) at AIS Electronic Library (AISeL). It has been accepted for inclusion in CONF-IRM 2022 Proceedings by an authorized administrator of AIS Electronic Library (AISeL). For more information, please contact elibrary@aisnet.org.

3. A Viable Business Model for Innovations with Digital Healthcare Applications in Germany

Abstract

Germany established laws to quickly introduce digital innovations in healthcare by forcing statutory insurances to reimburse companies producing digital applications. This could enhance the well-being of patients. For example, an application in psychotherapy can cut the waiting time for a psychotherapist in Germany. However, such enhancements will reach the patients only if companies offering digital applications have a viable business model to survive. Our analysis of the business model of a company offering a recognized digital application shows that such business models are not easy to develop. The analysis is transferrable to other countries, if they establish similar laws.

First, we describe the legal framework for digital healthcare applications set up in Germany. We also describe the conditions that must be met for such an application to be recognized by the relevant body so that statutory insurances must pay for it. This is followed by a discussion of the reimbursement amount. Then, we develop the business model of a producer of a specific digital healthcare application. Although the possibility of reimbursement for accepted applications constitutes a competitive advantage, underestimating costs from the approval process and marketing may be dangerous. The same is true for relying on revenues from reimbursement.

Keywords: Healthcare digitalization, digital healthcare application, medical app, mobile application.

1. Introduction

We concentrate on digital healthcare applications on the web or mobile devices that must be reimbursed by statutory health insurances in Germany. Only 33 digital healthcare applications (as of August 2022) achieved such a status granted by the Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, abbreviated BfArM), which is an independent part of the German Ministry of Health. Such an app is called a DiGA, an abbreviation for "Digitale Gesundheitsanwendung" (digital healthcare application). A report of the association of statutory insurances for the time frame from Sept. 1, 2020 to Sept. 30, 2021 stated that DiGAs were reimbursed about 40,000 times (GKV 2022). However, by September 2021, companies submitted 89 applications to become a recognized DiGA, but four of them were declined acceptance while 42 applications were withdrawn (Vetters and Schaffelhofer 2021). More than 318,000 apps for healthcare and wellness existed all over the world already in 2017 (Aitken et al. 2017), but Germany is a pioneer in reimbursing healthcare applications. While Germany is often considered a laggard in digitalization among developed countries (see Thiel et al. 2018 for digitalization with a focus on the healthcare area), it will be followed in this case by other countries in the European Union (EU). The French President Macron stated not only that France will pass laws allowing DiGAs, but that France will simply replicate the German model (Lovel 2021). Experts suggest that the EU should pass appropriate laws for all of its members (EIT Health 2021), but it is more likely that individual countries will do it by themselves. Thus, although our analysis must be specific to Germany where appropriate laws already exist, it is applicable to countries with a similar legal environment.

The acceptance by BfArM means that statutory healthcare insurances must reimburse DiGAs (i. e., pay for them to producers) which makes them different from other such applications. Consequently, the business model of firms producing DiGAs needs to account for this special status and the fact that DiGAs are considered medical products. On one hand, the reimbursement obligation is an advantage. On the other hand, the status is difficult to achieve and may include costs (e. g., to prove the beneficial effects of a DiGA on patients) which other digital applications do not carry. For example, some digital

health applications follow the advertising-based business model while other digital health applications just support the medication made by the same producer.

In the following, we will first describe how to become a DiGA. Then we will discuss the reimbursement fees. On this basis, we will sketch the business model for an exemplary DiGA and then discuss its strengths and weaknesses. If the company producing the DiGA does not survive then patients will not be able to benefit from the DiGA (unless someone else buys and offers it in the future).

2. A reimbursable health application

There are three levels of law which establish DiGAs. First, the German parliament laid the foundation with a law called the "Digital Healthcare Act," in original "Digitales Versorgungsgesetz (DVG)," effective since Dec. 19, 2019. The DiGA model has borrowed from another law (abbreviated AMNOG) which was passed in 2011 to regulate the introduction of innovative drugs. In the same time, DiGAs are only one aspect of digitalization of healthcare in Germany. Electronic patient records or electronic recipes are other examples in this area where Germany is definitely not a pioneer. The German Ministry of Health issued on the basis of DVG the "Digital Health Applications Ordinance (DiGAV)," a regulation on how to implement the law. This regulation has been recently updated so we also refer to planned changes below. Finally, BfArM published an administrative regulation that describes the so called fast-track procedure to become a DiGA. The accepted DiGAs are listed on the website of BfArM at https://diga.bfarm.de. The legal fundament of DiGAs is also shown in Fig. 1.

According to laws and regulations, following four conditions must be met by a digital health application to be recognized and listed by BfArM:

1. the fulfillment of requirements related to general security, functionality, and quality of the application,
2. an electronic application to BfArM,
3. proof of fulfillment of requirements related to data protection and data security, and
4. a proof of medical benefits for patients or patient-relevant structural and procedural improvements.

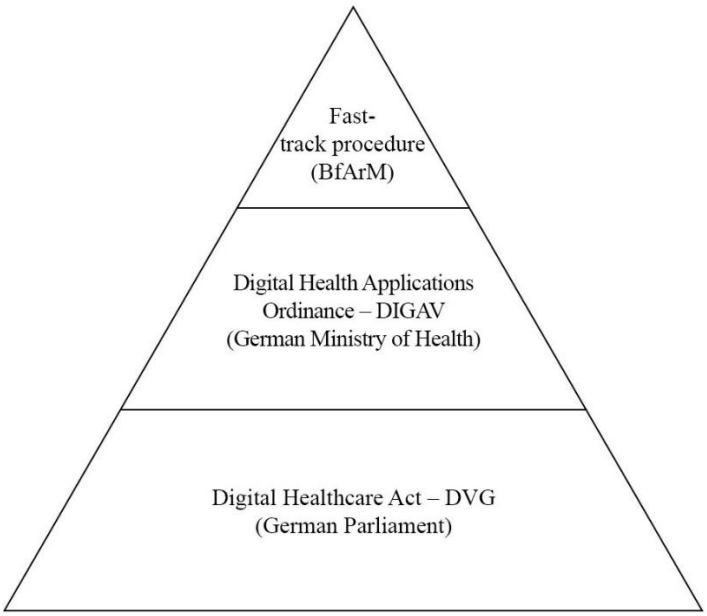

Fig. 1: Legal basis for digital health applications in Germany

The first condition is fulfilled if the health application receives the CE mark (which in French stands for "conformité européenne"). This means that the manufacturer or importer of a good affirms the good's conformity with European health, safety, and environmental protection standards. In this case, a body in the EU needs to be notified of the conformity and will check it according to the Medical Devices Regulation (MDR) from 2017 which must be applied since May 2021. The Medical Devices Directive (MDD) was in place before MDR. There are four risk-based classes of medical devices in the EU. It is only possible to become a DiGA with low-risk applications, i.e., class I or IIa. According to MDD, a device of a risk class IIa (or IIb or III) had to be checked by a notified body. The notified bodies also need to be accredited to be allowed to issue certificates according to MDR. There are only 27 bodies that received such certification from the EU as of Feb. 2022 (European Commission 2022). A recertification of devices (hardware or software) certified according to MDD will be needed by Mai 2024, so the certification of medical devices has become a serious bottleneck. If a medical device was of risk class I, only a self-declaration of conformity was needed according to MDD. Then, the producer of the application could put a CE on the device without having a number from a notified body.

So far, most of the DiGAs have been certified through a self-declaration as class I devices according to MDD. Only a few DiGAs have been certified according to MDR, all in class I. However, most class I medical devices must now be classified in the higher class IIa due to the new MDR, so self-declaration does not seem to be enough anymore. The MDR did not directly eliminate class I software. However, Rule 11 in Annex VIII MDR raises the question among all stakeholders as to what software still falls within class I at all. Many experts see an ambiguous wording in the text of the law, which leaves room for self-interpretation. After receiving the CE mark, the application can be submitted to BfArM.

The third condition "only" needs to be fulfilled by a statement of the producer and is not further checked by BfArM. Obviously, breaches against data protection can be costly in the EU so that producers should not state the fulfillment of this condition without proper proof. Benevolent hackers have shown recently that two of the DiGAs had serious "holes" which have been closed quickly (Larraondo 2022) but we do not really know whether other hackers discovered these problems, too. However, from April 1, 2022 all DiGA suppliers, even the producers of already listed DiGAs, must prove that they have an information security management in place according to ISO 27001. From January 1, 2023 the producers must have

a certificate relating to data security from BSI (the Federal Office for Security in Information Technology in Germany).

Medical benefits (abbreviated mN in the documents) or improvements in patient-relevant structure and procedures (abbreviated pSVV in the documents), fourth condition, must be shown for all or only certain patients (BfArM 2020). The patients need to be exactly named (e.g., women above 40 years of age) for who positive effects are expected or the indications need to be stated according to ICD-10 (ICD-10 is the International Statistical Classification of Diseases and Related Health Problems). Such claims are usually proven through appropriate studies. At this point, it should be mentioned that manufacturers must specify the request for provisional or final inclusion in the directory. When applying for provisional inclusion, only study designs and explanatory information on how a medical benefit and/or pSVV will be demonstrated must be submitted, but the evidence itself can be provided within 12 months. The majority of DiGAs has only the status of provisional inclusion as of August 2022. BfArM even states in its guideline brochure which studies are acceptable (e.g., randomized control studies) and which not (e.g., descriptive studies are usually not enough). Several DiGAs that were developed before the relevant legislation was in place have been tested via randomized control studies (e. g., Berger et al. 2017).

Although DiGAs are also popularly called "app per prescription," a patient can also request some DiGAs directly from his health insurance company without a prescription of a physician (about 11% of cases according to (GKV 2022)). In this case, the patient must prove a need for the application which he can do with a treatment or diagnosis of the relating illness made by a physician. The prescription can also be made through a telemedicine service provider. In any case, the patient sends the request or the prescription to his insurance which, then, sends an activation code to unlock the DiGA. The patient downloads the DiGA from an app store or uses it on the web.

The above conditions are required but they are not sufficient. A DiGA must also fulfill the needs of its stakeholders to be successful (Urbanek 2021). If physicians do not prescribe a DiGA because they do not know about it, they cannot test it themselves, they think that they are not appropriately reimbursed for its use, or they do not believe that it is beneficial to their patients, the DiGA will even not reach the patients.

In contrast to prescription drugs, medical devices such as DiGAs of classes I or IIa may be advertised not only to physicians, but also to medical laypersons, i. e., also to patients. However, advertising a DiGA must comply with the requirements of the German Drug Advertising Act (HWG) – it must not be misleading or deceptive. According to Section 12 HWG, a general ban on advertising also applies to mobile health products in connection with addictive diseases (with the exception of nicotine addiction), pathological complications of pregnancy, childbirth and the postpartum period, and in connection with notifiable diseases under the Infection Protection Act.

3. Reimbursement amount

A producer of a DiGA can, in principle, ask any amount to be reimbursed in the first year that the DiGA has been listed unless a specific agreement is made with insurances. However, the calculation must be explained to the insurances. There is also a revenue ceiling of 750,000€ (incl. value added tax) above which the price for a DiGA must be agreed upon. Otherwise, after a year, the price is determined by an agreement between The National Association of Statutory Health Insurance Funds (representing about 90% of the German population or about 73 million people) and various associations of producers of DiGAs. This agreement was reached through an intermediation between these two parties in two phases, with the last agreement version published on December 16, 2021. The agreement determines the highest

price the producers of DiGAs can ask for. It is based on formulas which also depend on the number of DiGAs for the same use. Thus, the current competitive situation also plays a role in price determination. The current average reimbursement amount is about 444€ and it ranges from about 119€ to 743€ per quarter of a year. The price limit is not valid for applications addressing a disease with an "orphan status."

In the time frame of the mentioned report, the most prescribed DiGA was the app against tinnitus, Kalmeda, which has been reimbursed 8,600 times (GKV 2022). This app can be reimbursed up to four times, so we do not know how many unique patients got a prescription for it. The physician who is the "spiritual father" of the app and the founder of the firm that produces it, estimates the development costs to be almost 1,000,000€ and the development time to be about six years (Mitternacht 2021).

Physicians also get reimbursed for writing a recipe for a DiGA, although this is not a big amount (2€ flat), on one hand. On the other hand, there may be other efforts (e. g., for the control of a DiGA therapy) that they can charge for. The regulation regarding additional charges for related services is often still missing so this can be a reason for physicians' hesitance to prescribe DiGAs. In the case of the DiGA somnio (see below), prescribers can charge 7,12€ for follow-up controls. The prescription of a DiGA or follow-ups can also be conducted via video (telemedicine). In any case, prescriptions of a DiGA and follow-ups do not burden the physician's or psychotherapist's budget, which is usually capped for drugs or remedies.

4. Business model

In this section, we will draw a possible business model for a specific DiGA in the form and structure of a lean business model canvas (Maurya 2012). There is a criticism of the lean startup approach in general (Felin et al. 2020) but we apply the lean version since it is more suitable to the needs of an independent startup (Maurya 2012) which all DiGA producers are, so far. It also explicitly names the model's competitive advantage (under "unfair advantage"), which we consider important for a business model to be defensible. Finally, the good performance of lean startups has been proven (Harms and Schwery 2020). We use the DiGA somnio (somnio 2022 and BfArM 2022) as an example in this section because different DiGAs may use different business models which may depend of who is financing their development and other criteria. We choose somnio because it is permanently listed in the DiGA directory of BfArM, meaning that the proof of medical benefit has already been provided. Also, it has been graded well by end-users in GooglePlay (4.2 stars out of 5 at 332 evaluations) and in the AppleStore (4.4 stars out of 5 at 370 evaluations). The developed canvas relates actually to the producer of somnio (mementor DE GmbH) but we use the name of the product because the company has only this product, at the moment, on the list of accepted DiGAs. The product name, somnio, is also much better known than the company behind it.

4.1 Problem

somnio is a medical app for the treatment of problems falling asleep and staying asleep, so-called non-organic insomnia. (IDC-10 code: F51.0). Primary insomnia has a prevalence of about 3% in the general German population (Wikipedia 2021). If non-organic sleep disorders with or without daytime sleepiness are considered independently of the criteria, the prevalence is up to one third of the total population. The general therapy suggestions for non-organic insomnia include psychotherapy and, if necessary, support with medication. Psychotherapy includes elements such as keeping a sleep diary, improving sleep hygiene, behavioral control measures, and also cognitive techniques. The number of specialists and psychotherapists, on the other hand, is far from enough to provide all patients willing to receive therapy with sufficient intensity and in a timely manner.

4.2 Solution

With the help of the app somnio, a cognitive behavioral therapy is implemented as a treatment method, according to the recommendations of the German Society for Sleep Research and Sleep Medicine (DGSM). In the center of the somnio app are functions for keeping a digital sleep diary, document sleep times and analyze progress. The goal is to understand and correctly classify sleep problems, deal with circling thoughts and musings, and learn relaxation techniques to fall asleep faster. Ultimately, sleep times should be optimized and the ability to perform and concentrate during the day should be increased.

4.3 Key Metrics

The most important key metric is the number of activation codes transmitted by health insurers that were ultimately used by patients to activate the somnio app, as only these can be billed. Self-payers are excluded, as these patients pay in advance, i.e. before activation. In addition, the number of prescriptions from physicians and psychotherapists billed to the health insurer (billing code 01470), the number of follow-up visits billed to the health insurer (billing code 01471) and the number of prescriptions from telemedicine providers are important metrics.

In addition, a metric of interest is the data shared by patients with medical staff via a patient-created access code. Patients can create an access code that is valid for 30 minutes. This code allows the physician to view the data documented in the somnio app in a web portal. This metric can be used to infer the level of interaction between patient and physician or psychotherapist and answer the question of whether patients are more likely to use the app on their own or with consultation with their physician or psychotherapist.

Note that all these metrics can differ because patients may get an activation code directly from their insurance, i. e., without a prescription. When they get the code, patients still may not use it and register in the DiGA (Urbanek 2021). Finally, even when they register within the DiGA they may not use it or not as often as they should.

4.4 Value Proposition

Patients who want to be seen by a specialist in sleep disorders and especially a psychotherapist must wait on average over 20 weeks in Germany (Onmeda 2022). They do not have a short-term access to an adequate therapy. somnio offers a complementary treatment option that helps to avoid bottlenecks in specialist care by allowing a larger number of patients to be treated. With the alternative of an app, patients can be cared for promptly with a therapy in line with current guidelines. It can also be a low-entry into a type of psychological treatment which may be postponed otherwise.

4.5 Unfair advantage

Recognition of BfArM and the consequent listing of a DiGA as reimbursable constitute an advantage. The effort is considerable both monetarily and in terms of time. In order to meet all the requirements for compliance with the MDR and to be listed permanently by BfArM require a proof of benefit through a randomized controlled trial, extensive know-how, investment capital, and time. It is also possible for companies to make direct reimbursement contracts with health insurances (Stüber 2020), but then a one-to-one contract needs to be made with each of the many insurances. If the health insurances are not covered by DiGA-laws (e.g., for privately insured patients or insurances outside of Germany), then the individual contracts lead both to a competitive advantage and additional revenues.

However, the advantage of a listed DiGA or individual contracts is not as strong as a patent for a drug because competitors can develop alternative products, bring them to approval, and establish them on the DiGA market. Analogies can be drawn with the market for generic drugs.

4.6 Channels

The most important sales channel for the app are undoubtedly physicians and psychotherapists who are familiar with somnio. Alternative prescription options are offered by telemedicine service providers. However, this form of prescription is still little used in Germany. Further support for distribution is achieved through the website of the manufacturer of somnio, the DiGA directory at BfArM, and recommendations from health insurance companies.

4.7 Customer Segments

somnio is suitable for patients 18 years of age and older who suffer from symptoms of insomnia with no underlying organic cause. The app can be prescribed by physicians and psychotherapists who treat patients with insomnia.

Privately insured patients should contact their health insurance company directly for cost coverage with a confirmation of the indication from a physician, psychotherapist or telemedicine service provider. After confirmation of cost coverage by the health insurance company, the activation code is obtained directly from somnio.

Patients who want to use the app but have no insurance (or whose insurance does not want to cover the costs) can pay by themselves. These patients also get the activation code directly from somnio.

4.8 Cost Structure

There are now suppliers of services for each step of DiGA development, certification, and registration with BfArM. The exact cost will depend, among others, on the service done in-house or bought. A physician with an idea but without programming skills (or without willingness to make such people part of his team) can hire another firm to develop the app. Usually, this firm will already be certified according to relevant standards (i.e. IEC 62304, ISO 13485) in order to prove the compliance requirements within the process of CE acquisition. If the app should (also) run on mobile phones, it should be programmed for iPhones and Android-devices.

Once the app works, there will be operation costs for the server on which the web version runs but also for the functioning of apps on mobile phones. Even if there is no web version, it makes sense to have a website devoted to the app. Maintenance cost will accrue when bugs need to be corrected or new versions of the digital application will be released.

New apps need a certification following MDR (while apps certified following MDD will need to be recertified according to MDR). A working app also needs to show improvements in the medical care as described above which is shown through appropriate studies (before or latest within 12 months after it has been accepted by BfArM).

Stakeholders (e.g., patients and physicians) should know about the app and how to use it so marketing costs will also accrue. Advertising in outlets for patients (e.g., widespread journals that are given for free in pharmacies) may be needed. Advertising in outlets geared towards physicians is also meaningful and there will be costs to explain the working of the app (through trials by physicians, demonstrations by sales representatives, or explanations of the app by other company employees).

All these steps create internal or external costs.

4.9 Revenue Streams

Publicly insured patients receive an activation code from their insurance based on a prescription from a physician, a psychotherapist, or a telemedicine service, or because the insurance allows the use of the

app (see above). As long as the activation code is not used, no payment is made by the insurance company to the manufacturer of somnio.

For privately insured patients or self-pay patients, the activation code is purchased before use and billed immediately to the patient, regardless of whether the activation code is ever used.

Finally, somnio also generates revenues from patients who are insured by companies with which they have a special contract (be the insurances covered by DiGA-laws or not).

Since revenues of manufacturers are in the same time costs of insurances, insurances will try to lower their cost for DiGAs through negotiations and the process mentioned in section 3. This will lower the revenue per activation code in the business model. In the case of somnio, the listed price for the app went down from about 400€ (Stüber 2020) to 224,99€! Revenues from insurances with which individual contracts exist, may be good, but they require negotiation skills which may not be available in the startup team yet. The value of a "blanket" regulation like DiGA-laws is diminished if suppliers need many individual contracts to gain an acceptable level of revenues. Fig. 2 summarizes our view of the business model of somnio in a canvas.

5. Prescribed Digital Therapeutics in the U.S.A.

The U.S.A. healthcare market is not only the largest singular healthcare market in the world, but also a major leader in digital healthcare due to the broad base of high-tech companies, as well as the very high level of healthcare expertise and quality available. In the U.S.A. the Food and Drug Administration (FDA) is responsible for approving mobile medical applications (MMAs). Similar to the German DiGAs, there are so-called Prescription Digital Therapeutics (PDTx). PDTx are software-based therapeutic interventions prescribed by a healthcare provider. They are evidence-based therapies with proven clinical effectiveness that are approved by regulatory agencies (FDA) for the treatment of specific conditions. Already back in September 2017, Pear Therapeutic's mobile application "reSET®" became the first PDTx to be approved by the FDA for use in patients with substance abuse disorder. Today, the number of approved PDTx stands at around 40.

FDA approval contains many parallels to the approval process in Germany. Likewise, PDTx undergo rigorous evaluation for safety and effectiveness in clinical trials with clinically-meaningful results published in peer-reviewed journals before approval is granted by FDA. The differences between a DiGA and a PDTx with regulatory approval lie in many details that can only be touched upon in this paper due to the abundance and complexity. One major difference, however, is the reimbursement by insurance companies. While in Germany after BfArM approval the health insurance provider (payer) are obliged to make the agreed payments to the DiGA manufacturers and healthcare providers, the reimbursement of PDTx depends on the respective payer. A prior authorization/claim has to be raised with the health insurance provider prior to prescription and needs to be approved by the payer before reimbursement is granted (Virtusa n.y.). For example, Aetna Inc. (Aetna n.y.), a health insurance owned by CVS Health Corporation, states that PDTs are experimental and investigational because in their opinion there is insufficient evidence in the published peer-reviewed literature to support their effectiveness. Aetna currently reimburses only 13 PDTs.

The success of PDTx depends on how well it is accepted by healthcare providers, which in turn depends on the willingness of payers to adequately reimburse for digital therapies. A survey conducted jointly by Pear Therapeutics and Avalere (Avalere 2021) found that only 40% of payers will cover PDTx in 2021, while 50% plan to do so in the next 18 months.

6. Implications

The average cost per app will go down for producers when an app is billed more often. This is especially true if other EU countries adopt the German model, thus creating a bigger market for producers. In economic terms, the producers will enjoy economies of scale. However, this will be also associated with new costs of translating the apps and perhaps adapting them to the local market. For example, only four out of currently listed 33 DiGAs have a French version (with somnio being one of them).

If a company has several products (e.g., as GET.ON GmbH or GAIA AG do), then they also enjoy economies of scope because they know the approval process and, if apps are in the same specialization, their representative can discuss more than one product with a physician or psychotherapist who are supposed to prescribe the DiGA.

Unfortunately, it is not enough to develop a good DiGA (and have it listed by BfArM). Physicians also need to prescribe it. Physicians will not prescribe a DiGA if they do not know about it. If they know about it, they should be able to investigate it without asking for activation codes (Mittermeier 2022). If they cannot examine it by themselves or they do not have the time for it, they must believe that it is beneficial based on the studies done with it. If a DiGA is listed by BfArM temporarily but no studies have been executed yet, the physicians probably will not prescribe it. Finally, physicians will recommend an application to their patients if this is also beneficial to them in some way (Alpar and Driebe 2021). It is helpful in this context that prescribing a DiGA is budget-neutral for physicians who otherwise receive a fixed budget from statutory insurances for prescribing medication.

Alternatively, patients can demand the activation code for a DiGA from their insurances based on previously diagnosed problems. If patients do not get a cue from their physician, they will ask their insurance for the code only if they perceive the application to be beneficial. This is especially true, if the application can or should be used more than one quarter.

Another threat to the above business model comes from the financing of the firm. If big pharmaceutical or other big companies “discover” the market (see, for example, the takeover of MySugr by Roche (Schade and Scherkamp 2017)), they may participate with stronger financial support and business models that support other activities where revenues from DiGAs are less important. The regulations on the reimbursement of DiGAs explicitly advocate establishing alternative apps in each indication group and thereby advocate price competition among companies. If a DiGA supports the use of a drug with high revenues, for example, then the revenues from the DiGA itself are not important. If a buy-out by a big company takes place, this may make the founders of an app wealthy (and/or the early investors), but the above business model will not work. Many DiGAs, like somnio, are currently financed by relatively small venture funds and (local) business angels (Stüber 2020) who may not have or do not want to spend enough capital to finance the growth of DiGA producers.

To summarize our analysis, the business model of a DiGA can be quite vulnerable on the cost dimension (the approval process and marketing) and the revenues dimension (strong insurances may wish to lower their costs). This may drive some startups out of the business, lower the competition in the healthcare market, and slow down the desired process of innovation with digital applications.

Problem	Solution	Unique Value Proposition	Unfair Advantage	Customer Segments
▪ disorders of falling asleep and sleeping through the night (insomnia)	▪ understand and correctly classify sleep problems ▪ deal with circling thoughts and ruminations ▪ learn relaxation techniques to fall asleep faster ▪ optimize sleep times ▪ increase the ability to perform and concentrate during the day ▪ use a digital sleep diary to document sleep times and analyze their progress	▪ quick access to therapy following professional guidelines	▪ certification following MDR ▪ listing by BfArM ▪ contracts with insurances	▪ patients 18 years of age and older who are experiencing symptoms of insomnia
Key Metrics		**Channels**		
▪ # activation codes ▪ # app used ▪ # prescriptions ▪ # prescriptions via telemedicine ▪ data shared with medical staff		▪ physicians and psychotherapists ▪ telemedicine providers ▪ DiGA directory website of company ▪ health insurances		
Cost Structure		**Revenue Structure**		
▪ sortware development ▪ certification following MDR ▪ registration with BfArM ▪ evidence studies ▪ operations cost ▪ maintenance cost ▪ marketing cost		▪ reimbursement after subscription and activation of DiGA ▪ billed use (privately insured and self-pay patients) ▪ revenues from contracts with insurances		

Fig. 2: Lean business canvas of somnio

References

Aitken, M, Clancy, B., and Nass, D., The Growing Value of Digital Health, IQVIA Institute, 2017.

Alpar, P., Driebe, T., Motivation of Physicians to Use and Recommend Apps for the Treatment of Haemophilia, INQUIRY: The Journal of Health Care Organization, Provision, and Financing (2021).

Aetna, https://www.aetna.com/cpb/medical/data/900_999/0999.html, (n.y.).

Avalere, Survey Shows Potential, Challenges, and Solutions for Broad PDT Access (2021)

Berger, T. et al., Effects of a Transdiagnostic Unguided Internet Intervention ('velibra') for Anxiety Disorders in Primary Care: Results of a Randomized Controlled Trial, Psychological Medicine 47 (1), 67-80 (2017).

BfArM, https://www.bfarm.de/SharedDocs/Downloads/DE/Medizinprodukte/diga_leitfaden.html?nn=597198 (2020).

BfArM, https://diga.bfarm.de/de/verzeichnis/508 (2022)

EIT Health, DiGAs – A Model for Europe? A round-table discussion on Sep 21, 2021.

European Commission, https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=34 (2022).

FDA, https://www.fda.gov/medical-devices/digital-health-center-excellence/device-software-functions-including-mobile-medical-applications, (n.y.).

Felin, F., Gambardella, A., Stern, S., Zenger, T., Lean startup and the business model: Experimentation revisited, Long Range Planning 53 (4) (2020).

GKV – Bericht des GKV-Spitzenverbandes (2022).

Harms, R., Schwery, M., Lean Startup: Operationalizing Lean Startup Capability and testing its performance implications, Journal of Small Business Management, 58 (1), 200-223 (2020).

Larraondo, J., Computerexperten entdecken Datenlücken bei Gesundheits-Apps, aerzteblatt.de (2022).

Lorenz, N., Heim, E., Roetger, A., Birrer, E., Maercker, A., Randomized Controlled Trial to Test the Efficacy of an Unguided Online Intervention with Automated Feedback for the Treatment of Insomnia, Behavioural and Cognitive Psychotherapy 47 (3), 287–302 (2019).

Lovel, T., France to enable rapid market access for digital therapeutics, https://www.healthcareitnews.com/news/emea/france-enable-rapid-market-access-digital-therapeutics (2021).

Maruya, A.: Running Lean: Iterate from Plan A to a Plan That Works (Lean Series), O'Rilley, 2012

Mittermaier, M. et al., Praktische Anwendung digitaler Gesundheitsanwendungen (DiGA) in der Inneren Medizin, Der Internist, 1-8, Jan. (2022).

Mitternacht, K., Wenn's im Ohr klingelt: HNO-Arzt klärt auf vielen Kanälen über Tinnitus auf, https://www.aerztezeitung.de/ (2021).

Onmeda, https://www.onmeda.de/therapie/wartezeit-psychotherapie-id202639 (2022).

Schade, A-K. and Scherkamp, H. Pharma-Riese Roche kauft Diabetes-Startup MySugr, https://www.businessinsider.de/gruenderszene/allgemein/roche-kauft-diabetes-startup-mysugr/ (2017).

somnio, https://somn.io/ (2022).

Stüber, J., https://www.businessinsider.de/gruenderszene/health/somnio-mementor-app-auf-rezept/ (2020).

Thiel, R. et al., #SmartHealthSystems - Digitalisierungsstrategien im internationalen Vergleich, Empirica and Bertelsmann Stiftung (2018).

Urbanek, M., https://www.aerztezeitung.de/Wirtschaft/DiGA-Erfolg-steht-und-faellt-mit-den-Aerzten-423470.html (2021).

Vetter, R. and Schaffelhoffer, F., https://www.ey.com/de_de/consulting/wie-sich-der-markt-fuer-apps-auf-rezept-weiterentwickelt (2021).

Virtusa, https://www.virtusa.com/perspectives/article/prescription-digital-therapeutics (n.y.)

Wikipedia, https://de.wikipedia.org/wiki/Prim%C3%A4re_Insomnie (2021).