Digital Health Applications: DiGAs—Pathway to Reimbursement

Stefan Walzer and Jan-Marc Hodek

Looking at the concept of digitalisation in healthcare, it can be said that digital healthcare encompasses various areas. On the one hand, it creates new diagnostic and treatment options, such as personalised medicine, and on the other hand, it enables easier communication between the individual actors in the healthcare system. In addition, the individual patient can control his or her health better, for example through apps. Digitisation in the healthcare sector creates the opportunity to counteract the shortage of skilled workers and to relieve doctors and nurses, for example in administrative activities and documentation, diagnostics and everyday practical activities (Cf. PricewaterhouseCoopers GmbH n.d.).

When it comes to digitalisation in the health sector, Germany lags far behind. In the Bertelsmann Foundation's international comparative study, Germany ranked 16th out of 17 countries (Cf. Bertelsmann Stiftung 2018, p. 1). While video consultations and electronic patient records are standard in other European countries, many possibilities and the associated opportunities of digital innovations in the healthcare system are hardly used in Germany. Although there are some innovative ideas and approaches, these have often not been part of the standard service of statutory health insurance before the introduction of the DiGA pathway. This is also shown by the DIGITAL economic index of the Federal Ministry for Economic Affairs and Energy (BMWi), which measures sector-specific progress in digital

S. Walzer (✉)
MArS Market Access & Pricing Strategy GmbH, Weil am Rhein, Germany

State University Baden-Wuerttemberg, Lörrach, Germany

RWU – Ravensburg-Weingarten University of Applied Sciences, Weingarten, Germany
e-mail: Stefan.walzer@marketaccess-pricingstrategy.de

J.-M. Hodek
RWU – Ravensburg-Weingarten University of Applied Sciences, Weingarten, Germany
e-mail: hodek@rwu.de

S. Walzer (ed.), *Digital Healthcare in Germany*, Contributions to Economics,
https://doi.org/10.1007/978-3-030-94025-6_4

transformation. Here, the healthcare sector scored comparatively poorly in 2018 with 37 out of 100 points (Cf. Pfannstiel et al. 2020, p. 254).

To ensure that the development of digitalisation in the health sector in Germany progresses more quickly, the Federal Ministry has adopted some legal measures. These include, for example, the Digital Health Care Act (DVG) which includes reimbursement of costs for health apps, promotion of telemedical services and expansion of the telematics infrastructure.

1 What Is the DiGA System and How Does It Work?

With the entry into force of the Digital Healthcare Act on 19 December 2019, the "app on prescription" for patients was introduced into healthcare, thus laying an important foundation for advancing digital health care in Germany. According to § 33a SGB V, a DiGA is a class I or IIa medical device according to MDR or MDD. These are products with CE-marking and with a low risk of potential harm caused by a defect or functional failure of the medical device; for example as a web-application for the treatment of phobias (Velibra) or an app for the treatment of sleep disorders (Somnio). A DiGA must have the following characteristics:

- The main function relies mainly on digital technologies;
- The medical purpose is essentially achieved through the main digital function;
- The DiGA supports the detection, monitoring, treatment or mitigation of disease or disability;
- The DiGA is used by the patient or by the healthcare provider and the patient together (Cf. BfArM 2021).

A patient-relevant procedural and structural improvement is said to exist if the patient is able to cope better in everyday life with the help of the digital health application, for example. This is because it reminds him or her to take medication, supports family caregivers in providing care, or improves the exchange between doctors, caregiver and patients (Bundesinstitut für Arzneimittel und Medizinprodukte 2021).

For this purpose, the German Federal Institute for Drugs and Medical Devices (BfArM) provides a register that lists those digital applications that have successfully passed the assessment for reimbursable DiGA (Bundesinstitut für Arzneimittel und Medizinprodukte 2021). Only those DiGA that have been classified for the official list by the BfArM are then included in the reimbursement system of statutory health insurance. The digital health applications must have successfully passed a procedure at the BfArM and be listed in a newly created directory of reimbursable digital health applications, named "DiGA-Verzeichnis".[1] The application procedure is designed as a fast-track and takes a maximum of 3 months after receipt of the complete application. After that, the manufacturer can enter price negotiations with the Head Association of Health Insurance Funds (GKV-SV). Important for a successful

[1] The current list is available at: https://diga.bfarm.de/de

assessment by the BfArM is proof of a positive healthcare effect, but also product characteristics such as data protection and user-friendliness (Cf. BMG 2020).

According to the definition in the Digital Healthcare Act, positive health care effects (benefits) are either a medical benefit or patient-relevant structural and procedural process improvements in healthcare. To prove the benefit, a manufacturer must submit the results of clinical studies in the form of the final clinical study report, which must be drawn up according to recognised scientific standards. In the comparative study it must be shown that using the DiGA is better than not using it (Cf. BfArM 2021, S. 82 ff). Medical benefit means that the digital healthcare application has a positive influence on patient-relevant outcomes such as morbidity, mortality or health-related quality of life. For example, the use of a DiGA can extend a patient's life or shorten the course of the disease. Health applications with positive outcomes in the area of patient-relevant structural and procedural improvements strengthen the role of patients in their own course of therapy by improving the coordination of treatment between care providers and patients, which makes the patient's own situation more understandable, and increases the patient's participation. Health-related outcomes must be provided by means of a study conducted in Germany, which demonstrates that application has more advantages than non-application would have (Bundesinstitut für Arzneimittel und Medizinprodukte 2021).

In order to be included in the DiGA register of the BfArM, the digital health application must meet the aforementioned requirements. For this purpose, the manufacturer submits proof to the BfArM that the DiGA fulfils all requirements under medical device law. To guarantee the manufacturer's commitment to data protection laws and handling of patient information, evidence and declarations must be submitted (Bundesinstitut für Arzneimittel und Medizinprodukte 2021). General requirements also include interoperability of the technical requirements, robustness against disruptions, user-friendliness for people of all ages, quality of the medical content while maintaining the professional standards from medical guidelines, and patient safety (Bundesinstitut für Arzneimittel und Medizinprodukte 2021).

Depending on whether or not a comparative study and corresponding evidence of a positive outcome is already available for the DiGA, the manufacturer decides whether to apply for provisional or final inclusion in the BfArM listing. Without a suitable study, there can only be an application for provisional inclusion. In this case, proof of positive outcomes must be submitted subsequently at the end of the trial period. Only then does the final assessment by the BfArM begin. However, if the manufacturer immediately submits an application for final inclusion, there is no trial period and review of the submitted documents begins (Bundesinstitut für Arzneimittel und Medizinprodukte 2021).

The entire process from application to inclusion in the DiGA register and thus reimbursement by the statutory health insurance is called 'fast-track procedure'. The evaluation time by the BfArM is only 3 months. Once the application documents are fully submitted, a 3-month processing period begins. The BfArM's task is to review the manufacturer's information regarding the requirements for the DiGA and to assess the submitted proof of positive health outcomes (Bundesinstitut für Arzneimittel und Medizinprodukte 2021). The following figures illustrates the fast-track process (Figs. 1 and 2).

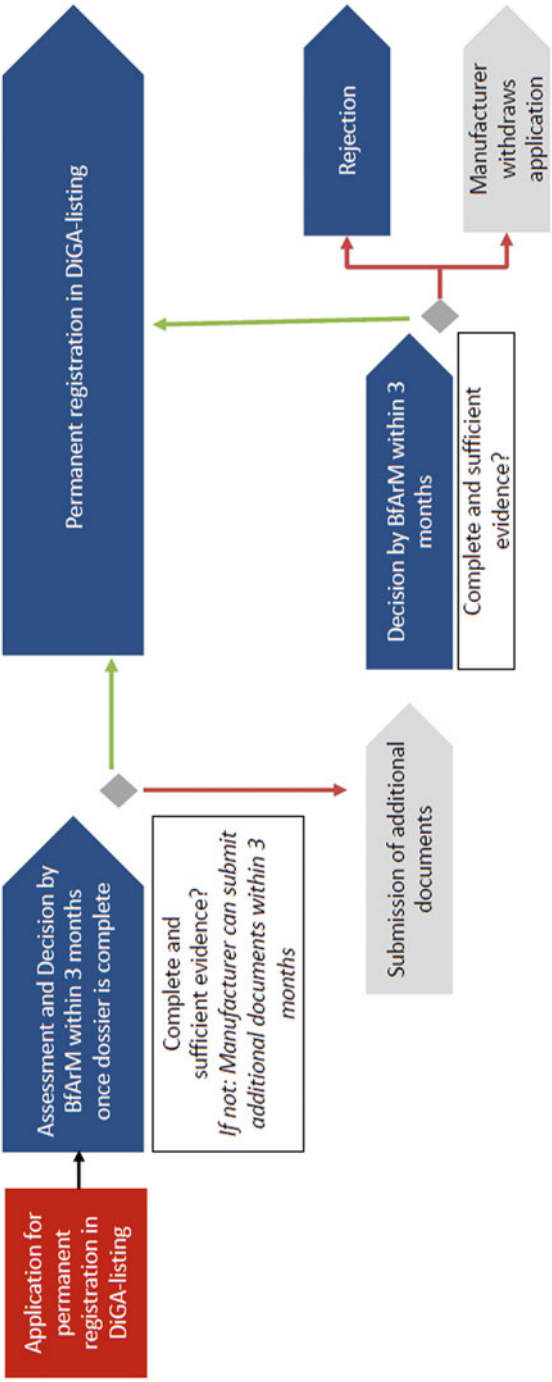

Fig. 1 Process of permanent registration in DiGA-listing

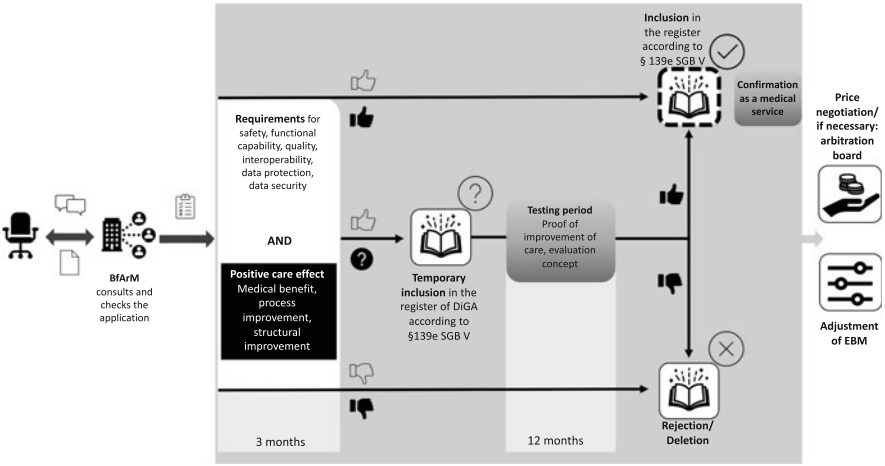

Fig. 2 Process of preliminary registration in DiGA-listing

The number of digital health applications that can be prescribed is growing rapidly. The applications officially listed by the BfArM and, therefore, eligible for prescription currently focus primarily on the indications migraine, multiple sclerosis, panic and anxiety disorders/phobias, tinnitus, depression, insomnia, obesity and coxarthrosis.

Three DiGAs have already proven the benefit by means of studies and are permanently registered in the DiGA registry:

- Elevida (multiple sclerosis)
- Somnio (non-organic insomnia)
- Velibra (phobias).

Elevida is a digital health app for people with multiple sclerosis who also have fatigue and are at least 18 years old. Elevida aims to reduce fatigue. The programme is to be used in addition to an otherwise usual treatment (for example by a GP or specialist). Elevida is based on established psychotherapeutic approaches and procedures, especially cognitive behavioural therapy (CBT). Elevida is intended for self-administration by the patient for 180 days. First registration in the DiGA list was on 15 December 2020. Elevida costs 743.75 Euros per licence for 90 days (Cf. BfArM n.d.-a). The main outcome of the elevida RCT revealed that the combination of elevida and usual medical treatment led to a significantly greater reduction in fatigue than the usual medical treatment alone by patients with multiple sclerosis who also suffered from fatigue. Furthermore, the combination led to a significant reduction in anxiety symptoms and a significant improvement in certain aspects of disease-related quality of life: fatigue, thinking ability, and leg mobility. Furthermore, the combination treatment led to significantly improved management of activities of daily living (Cf. BfArM n.d.-a).

Somnio is a digital application for the treatment of sleep disorders (insomnia). The application teaches evidence-based and guideline-compliant content from the field of cognitive behavioural therapy for insomnia (CBT-I). Users learn, for example, to optimise their sleep times, to follow an individually coordinated sleep-wake rhythm, to deal with thoughts or to use relaxation techniques. Somnio is available as a web application directly from the browser and as an app for smartphones. First registration in the DiGA list was on 22 October 2020. Somnio costs 464.00 Euros per licence for 90 days (Cf. BfArM n.d.-b). Somnio also proved a large treatment effect in a RCT: 56% of the participants in the treatment group achieved remission, compared to 11% in the control group. Furthermore, depression symptoms, sleep-related cognitions, safety behaviours and somatisation decreased significantly in the treatment group compared to the control group (Cf. BfArM n.d.-b).

Velibra is a web-based programme for patients with generalised anxiety disorder, panic disorder with or without agoraphobia or social anxiety disorder. Velibra teaches established cognitive behavioural therapy methods and exercises. The programme is intended as a supplement to a usual treatment for patients aged at least 18 years old. The prescription period for velibra is 90 days. To stabilise the effects, use for 180 days is recommended. First registration in the DiGA list was on 01.10.2020. Velibra costs 476.00 Euros per licence for 90 days (Cf. BfArM n.d.-c). The RCT of Velibra showed that the combination of Velibra and standard GP care led to significantly lower anxiety and depressive symptoms in patients with generalised anxiety disorder, panic disorder with or without agoraphobia or social anxiety disorder than usual GP care alone. The effects were detectable for up to 6 months (Cf. BfArM n.d.-c).

If the manufacturer cannot provide sufficient evidence of the positive supply effects of the DiGA, but still fulfils all other requirements, the manufacturer is allowed to submit an application for preliminary inclusion in the registry. The necessary comparative study, that demonstrates the positive effect can then be conducted within a period of up to 1 year. Exceptions allow a 2-year period. Furthermore, the manufacturer must set the price for the DiGA during the trial period. There are seven applications in the preliminary DiGA list at the beginning of 2021: Invirto, Kalmeda, M-sense, Rehappy, Selfapy, Vivira and Zanadio.

Invirto enables people with agoraphobia, panic disorder or social phobia to treat their anxiety disorder from home. Patients learn from therapists or doctors accompanied by an app and virtual reality glasses to understand their anxiety better, to cope with high levels of tension, to manage anxious thoughts and to revisit anxious situations. The accompaniment of psychotherapists or doctors ensures high-quality care and supports the users. Invirto makes it possible to reduce the symptoms of the anxiety disorder, to reduce avoidance behaviour and to regain more freedom of movement in everyday life. Invirto is based on cognitive behavioural therapy. First registration in the DiGA list was on 3 December 2020. Invirto costs 428.40 Euros (with hardware) (Cf. BfArM n.d.-d).

Kalmeda offers patients (over the age of 18) with chronic tinnitus a guideline-based, behavioural therapy. The structured programme is supplemented by relaxation instructions, soothing nature and background sounds as well as a knowledge

section. The behavioural therapy programme, which lasts several months, consists of five levels with nine stages each and shows patients step by step the way to a self-determined handling of the tinnitus and to a reduction of the tinnitus burden. First registration in the DiGA list was on 25 September 2020. Kalmeda costs 116.97 Euros per licence for 90 days (Cf. BfArM n.d.-e).

M-sense offers a comprehensive digital treatment programme for migraine patients. The application includes a digital headache diary and guideline-compliant procedures for migraine prophylaxis and acute treatment of attacks. Migraine patients can access customised knowledge transfer, animated physiotherapeutic exercises, instructions for endurance sports as well as audio files for relaxation and imagination exercises. The documentation of lifestyle factors in the diary enables individual trigger management. First registration in the DiGA list was on 16 December 2020. M-sense costs 219.99 Euros per licence for 90 days (Cf. BfArM n.d.-f).

The digital health application **Rehappy** supports the follow-up care of stroke patients. Support takes the form of an individually compiled supply of motivation and knowledge with a mobile app, an activity tracker and a web portal. Patients are activated, informed and accompanied to be able to tackle their path to recovery in a sustained, self-determined, competent and confident manner. Support is based on educational information and positive reinforcement for the perception of personal responsibility and an increase in therapy adherence as well as intrinsic motivation. The prescription period for Rehappy is 90 days. With the first prescription, the activity tracker belonging to the digital health application is sent to the patient. No co-payment is required. In order to sustain the effects, it is recommended to use Rehappy for longer than the minimum prescription period. First registration in the DiGA list was on 29 December 2020. Rehappy costs 449.00 Euros per licence for the first 90 days (with hardware) and 299.00 Euros for the next 90 days (Cf. BfArM n.d.-g).

Selfapy offers depression sufferers an individual online course based on evidence-based theories and cognitive behavioural therapy techniques. Patients can follow the therapeutic content on the internet-based course on their own. The course is divided into individual lessons. Each lesson deals with one topic, such as dealing with negative thoughts, sleep problems, which creates a positive daily structure, relaxation techniques and prevention strategies. Content is taught with the help of audio and video clips, texts and exercises. Contents are individually adapted to the person's personal situation. To ensure patient safety, the patient is monitored by a personal psychologist. In case of acute need, the psychologist is available via a message function to answer questions about the application. Preliminary results from 401 participants in a study with the Charité Berlin show a significant reduction in depressive symptoms after completion of the 12-week course. First registration in the DiGA list was on 16 December 2020. Selfapy costs 540.00 Euros per licence for 90 days and access to the content for a total of 12 months (Cf. BfArM n.d.-h).

Vivira is a digital health app for the treatment of back, knee and hip pain, non-specific low back pain, osteochondrosis, osteoarthritis of the knee and hip. The Vivira movement therapy app offers four daily exercises that continuously

adjust their intensity and complexity based on feedback from the patient. Daily exercises are supported by weekly health questionnaires, progress monitoring, monthly exercise tests and educational content. The effectiveness of Vivira has already been investigated in a retrospective controlled study. Patients who used Vivira showed a significant intra-individual reduction in pain. The study will be completed with a prospective randomised controlled trial and another retrospective study in 2021. First registration in the DiGA list was on 22 October 2020. Vivira costs 239.97 Euros per licence for 90 days (Cf. BfArM n.d.-i).

Zanadio is an application that helps users to reduce their weight in the long term by changing their habits in terms of exercise, nutrition and other behaviours. The DiGA is based on the scientific concept of multimodal, conservative obesity therapy, which focuses on the various relevant areas and thereby brings permanent weight reduction in the long-term. First registration in the DiGA list was on 22 October 2020. Zanadio costs 499.80 Euros per licence for 90 days (Cf. BfArM n.d.-j).

The costs of an approved digital health application will be reimbursed by the statutory health insurance if a doctor's prescription is available (or if there is a direct application to the health insurer and this insurer agrees). If the application is approved, the health insurer sends an activation code and further instructions on how to obtain the DiGA directly to the insured person. The activation marks the start of the usage period and the manufacturer settles the costs directly with the health insurance (Fig. 3).

According to current status, health insurers must reimburse the price set by the manufacturer for all approved DiGA for the first year. During this first year (after inclusion of the DiGA in the register), the price set by the manufacturer is not questioned. From the 13th month onwards, the reimbursement amount negotiated between health insurers and the manufacturer then applies. If no agreement can be reached, an arbitration board must determine the reimbursement payment. It is

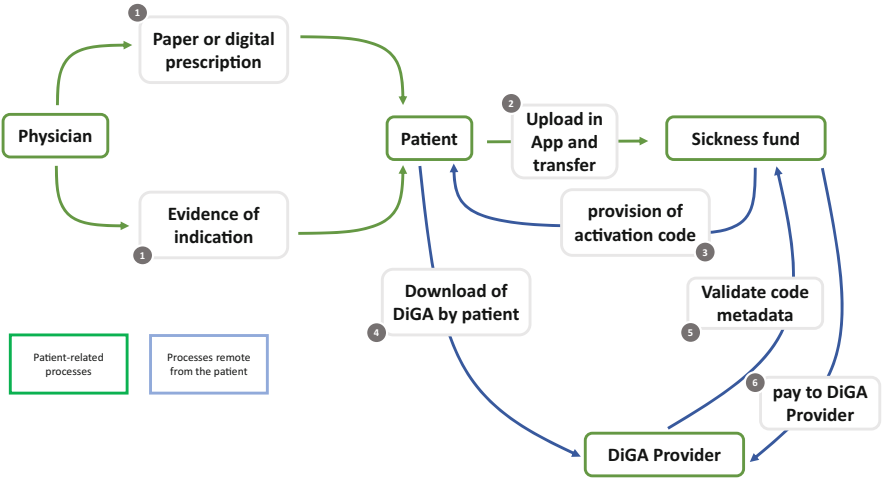

Fig. 3 Prescription process

stipulated by law that medical services associated with use of the DiGA are also reimbursed by health insurers.

What is the appropriate price? The same evidence requirements must also apply to DiGA as to other services paid by the health insurance. Currently, the requirements for proof of benefits of a DiGA are comparatively low. In future, it would be conceivable that—similar to the German reference price system for pharmaceuticals—maximum amounts for groups of comparable applications could also be set for DiGAs.

2 How Do Private Health Insurances (PKV) Manage DiGAs?

First of all a DiGA must be prescribed also for a privately insured patient. The privately insured person is well advised to ask their private health insurance (PKV) whether the costs of the DiGA will be reimbursed before making any advance payments. Obviously, DiGAs cannot be explicitly covered by the insurance contracts of the existing insured, simply because DiGAs have only been around for a short time. In principle, a private health insurance company cannot intervene in the contracts of the existing insured. So "pacta sunt servanda" applies. For reasons of antitrust law, the PKV association cannot bring about a generally applicable regulation. The same applies to the so-called "Beihilfe". The "Beihilfe" subsumes DiGAs to the aids § 25 Bundesbeihilfeverordnung (BBhV). The respective relevant annex is Annex 11 which however does not yet include any DiGAs. However, in the context of the "Beihilfe" it has been decided that digital health applications may be reimbursed in individual cases for up to 12 months. The prerequisites for recognition are the prescription of a doctor or psychotherapist and the approval of the digital health application by the BfArM in the DiGA registry. Once the insured's PKV has agreed to reimburse the costs, the insured person pays themselves and submits the bill for reimbursement to their PKV.

References

Bertelsmann Stiftung (Hrsg.). Thiel R, Deimel L, Schmidtmann D, Piesche K, Hüsing T, Rennoch J, Stroetmann V, Stroetmann K, Kostera T. (2018): #SmartHealthSystems - Digitalisierungsstrategien im internationalen Vergleich. https://www.bertelsmann-stiftung.de/de/publikationen/publikation/did/smarthealthsystems (last accessed February 23 2022)
BfArM. (n.d.-a): https://diga.bfarm.de/de/verzeichnis/419 (last accessed February 23 2022)
BfArM. (n.d.-b): https://diga.bfarm.de/de/verzeichnis/508 (last accessed February 23 2022)
BfArM. (n.d.-c): https://diga.bfarm.de/de/verzeichnis/316 (last accessed February 23 2022)
BfArM. (n.d.-d): https://diga.bfarm.de/de/verzeichnis/300 (last accessed February 23 2022)
BfArM. (n.d.-e): https://diga.bfarm.de/de/verzeichnis/350 (last accessed February 23 2022)
BfArM. (n.d.-f): https://diga.bfarm.de/de/verzeichnis/315 (last accessed February 23 2022)

BfArM. (n.d.-g): https://diga.bfarm.de/de/verzeichnis/691 (last accessed February 23 2022)
BfArM. (n.d.-h): https://diga.bfarm.de/de/verzeichnis/876 (last accessed February 23 2022)
BfArM. (n.d.-i): https://diga.bfarm.de/de/verzeichnis/387 (last accessed February 23 2022)
BfArM. (n.d.-j): https://diga.bfarm.de/de/verzeichnis/294 (last accessed February 23 2022)
Bundesministerium für Gesundheit. (2020): Verordnung über das Verfahren und die Anforderungen zur Prüfung der Erstattungsfähigkeit digitaler Gesundheitsanwendungen in der gesetzlichen Krankenversicherung (Digitale Gesundheitsanwendungen- Verordnung – DiGAV. https://www.gesetze-im-internet.de/digav/DiGAV.pdf (last accesses February 23 2022)
Bundesinstitut für Arzneimittel und Medizinprodukte. (2021): Das Fast-Track-Verfahren für digitale Gesundheitsanwendungen (DiGA) nach § 139e SGB V Ein Leitfaden für Hersteller, Leistungserbringer und Anwender. https://www.bfarm.de/SharedDocs/Downloads/DE/Medizinprodukte/diga_leitfaden.html;jsessionid=6E16D8393937F616233F46B27FCAD657.internet561?nn=597198 (last accessed February 23 2022)
PricewaterhouseCoopers GmbH. (n.d.): Digitalisierung im Gesundheitswesen, URL: https://www.pwc.de/de/gesundheitswesen-undpharma/digitalisierung-im-gesundheitswesen.html, 30.08.2020.
Pfannstiel, M., Kassel, K., Rasche, C. (2020): Innovationen und Innovationsmanagement im Gesundheitswesen, Technologien, Produkte und Dienstleistungen voranbringen, Wiesbaden: Springer