eit Health Germany

ROUND-TABLE DISCUSSION

DiGAs – A MODEL FOR EUROPE?

Possible options for achieving a European system

Statements from the EIT Health Germany Round-table held as part of the 16th Kassengipfel (health-insurer summit) on
16 September 2021
in Berlin

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Contents

Context for ‘DiGAs – a model for Europe?’ as the choice of topic

Digital health applications (DiGAs) are key drivers of innovation in modern health, which is why funding digital health solutions has been one of our focus areas ever since EIT Health’s founding in 2015. It is therefore very pleasing to see the increasing emergence of such technologies in European society. The pandemic played a significant part in this, for digital health services saw a rapid rise in popularity among large sections of Europe. They demonstrated that they could be a worthwhile addition to the healthcare landscape.

With the passing of the Digital Healthcare Act (Digitales-Versorgungs-Gesetz, DVG) in 2019 and the resulting legal option of obtaining ‘apps on prescription’ from Q3 2020, Germany became a pioneer in billing digital health applications, as, to date, no other European country has implemented stringent structures enabling health funds to cover the costs of health apps.

The system established in Germany allows manufacturers of digital health applications (DiGAs) to request for their app to be included in the DiGA directory, and then gives them 12 months to prove the app has improved patients’ health. In order to be listed, DiGA manufacturers must adequately prove the quality, security and effectiveness of these apps, as well as fulfil extensive interoperability and privacy criteria. This system has been met with great interest in Europe, for it enables patients to use new digital innovations faster and with less bureaucracy.

As a European institution, it is of particular importance to EIT Health to always view health solutions in a transnational context, and to find ways of benefiting all citizens. For this reason, EIT Health wishes to utilise its network to intensify reflection and discussion on the DiGA model at a European level. The title ‘DiGAs – a model for Europe?’ reflects this, while simultaneously referencing the Europe-wide interest in the DiGA model.
The format of an EIT Health round-table discussion provides excellent opportunities to bring stakeholders from all fields together to discuss what has been achieved to date, and to recommend potential optimisations worth bearing in mind when introducing the system in other EU member states.

This document summarises all the key points of the EIT Health Germany round-table discussion. It acts as important input for subsequent discussions in other European countries, which we are holding in co-operation with our colleagues from the regional innovation hubs (RIHs) in France, Spain, Luxembourg, Scandinavia and the Innostar countries (Poland, Portugal, Italy, Hungary). We would like to thank all players from the fields of science, industry and healthcare who shared their vision, expertise and experiences with us.

We hope you find the report a useful and interesting read, and look forward to your feedback.

Dr Katharina Ladewig
Managing Director of EIT Health Germany GmbH

Health round-table discussion – DiGA fast-track approval: a model for Europe?

Right across Germany and Europe, there are great expectations for digital health applications (DiGAs). The promise is that high-quality, clinically tested health apps could, in future, help fill healthcare gaps, improve or even replace existing therapies, and make health systems resilient and lastingly financially feasible. This particularly applies to common (chronic) illnesses such as obesity and diabetes, which – as incidence rates continue to increase – still have no therapies, despite a series of treatment options being available. As digital therapeutics, DiGAs could be extremely helpful operating alongside pharmaceuticals, medicines and aids as a fourth pillar and new, evidence-based solution in these areas.

DiGAs function as 'software as a service', an approach fundamentally different to medication-based therapies or analogue medical devices. Obtaining evidence through high-quality clinical studies is proving challenging. Experience in approval criteria for DiGAs and in the approval process is currently still extremely hard to come by. As such, the range of prescribable DiGAs does not yet adequately cover the spectrum of relevant chronic diseases. Health policymakers worldwide are thus being called on to establish appropriate framework conditions for swiftly launching safe and effective DiGAs on the market.

Germany has already begun developing and implementing such an approach. The Digital Healthcare Act (DVG) took effect there on 19 December 2019, providing a legal framework for accrediting and reimbursing the costs of 'apps on prescription' as part of routine patient care. Doctors and psychotherapists can order for patients to be treated with DiGAs listed in the DiGA directory run by the German Federal Institute for Drugs and Medical Devices (BfArM) at the expense of the statutory health funds. According to Section 33a of Vol. V of the German Social Code (SGB V), some 73 million parties insured under Germany's statutory health insurance scheme (GKV) are entitled to such treatment. These insured parties are also able to directly prove to their health fund that a DiGA is indicated for their treatment, and subsequently receive this over the counter.

The fact that Germany initiated this development and is currently acting as a pioneer in Europe when it comes to implementing digital therapies is something the participants of the round-table discussion have recognised as being particularly noteworthy and an important development. Given that comprehensively modernising the health sector, which goes hand in hand with 'digitalising' health apps, poses a challenging but essential task, all participants believe it should be further expedited. Work is underway with all stakeholders to intensively focus on transforming the German health system. DiGAs have now been used to turn an initially abstract discussion on digitalisation into concrete application examples that enable the prospectively changing roles of patients, health professions and health funds to already start being identified.

This context gives rise to the introduction of a fast-track process based on the DVG and the German Digital Health Applications Ordinance (DiGAV), which aims to rapidly enable DiGAs to be prescribed and applied in clinical settings. The fast-track process allows DiGAs to be prescribed even before a positive healthcare effect has been proven by a clinical study. Provisional listing in the BfArM's curated directory of prescribable DiGAs does, however,

require a systematic data analysis which must plausibly justify the fact that the DiGA admitted for trialling is helping improve healthcare.

The aims of the round-table discussion were:

- To highlight the current status of digital health applications at a national level. Strengths and weaknesses of the fast-track approval method must particularly be identified, based on the experiences gained in the first year of implementation
- To ascertain whether the experiences gained after a year of DiGA fast-track could also be incorporated at a macro-European level in order to boost momentum for a co-ordinated, harmonised approval process. These could lie in areas such as interoperability, data protection or cyber-security, as well as in harmonised proof of clinical benefit and potential advantages in terms of health economics.

The health authorities in seven European nations are currently discussing the experiences gained from the DiGA fast-track process. German health experts thus see it as a great opportunity to establish transnational synergies in this early phase of DiGA implementation, e.g. by harmonising the approval process for DiGAs in Europe.

Section 1: A year of DiGA fast-track processes in Germany

Status quo and reality check: have expectations been met?
Until 16 September 2021 inclusive, the BfArM handled 91 requests as part of the DiGA fast-track process. The number of requests exceeded some expectations. A high number of listings so soon after the fast-track process was introduced was particularly considered indicative of the fact that some market-ready digital health solutions already existed in Germany. But: Of 91 requests submitted, only 21 were approved.[1] As at 6 September 2021, four out of the five DiGAs to have been permanently included in the directory had been developed by a large provider already established in the sector. These are deprexis, elevida, velibra and vorvida, made by GAIA AG. 70 requests were rejected or withdrawn by the manufacturer. The fact that nearly half the requests were retracted initially seemed surprising.

The BfArM's strict requirements for approval requests, and the associated investments, were cited as the main reason for rejections and manufacturer retractions. The intention here is to assess safety, effectiveness and data-protection standards. The proof of effectiveness of the DiGAs provisionally or permanently approved to date is aimed at confirming a positive healthcare impact, which can be reflected through additional medical benefit or improved processes and structures.

- The DiGA fast-track process did not result in the market being flooded. At present, 25% of the DiGAs have been definitively, and 75% provisionally, approved for trialling. But there are still no prescribable DiGAs for a number of chronic diseases.

[1] https://diga.bfarm.de/de/verzeichnis (page visited on 12 October 2021)

- Earlier assessments by observers who had predicted that most DiGAs approved would have low quality standards is yet to be confirmed. While no conclusive statement can be made about the actual quality in terms of healthcare benefit, the approval process does require uniform quality standards.

An inadequate clinical evaluation concept is grounds for elimination
According to information from the BfArM, it is assumed that the overwhelming majority of DiGAs were rejected due to insufficient evidence/inadequate study design. 'This shows how rigorously the BfArM is checking the quality of the solutions; some people had expected a very different approach', said one participant.

- Inadequate quality in terms of study design and the underlying scientific evaluation concept is by far the most common reason for rejected approval requests/manufacturer retractions in the fast-track process.

Approval criteria need to be clearly documented –
Requirements for the BfArM: Greater transparency, more dialogue
One of the main difficulties reported was the fact that some DiGA manufacturers struggled considerably to define positive healthcare impacts in the scientific evaluation concept and suitably prove these in the approval request. Information was also lacking in the systematic analysis of the approval data. The BfArM was found to conduct very thorough checks, particularly of the statistical plan for proof of evidence. As neither the approval-request form nor the BfArM guidelines provide a detailed description of the criteria for checking proof of benefit, many requests seemingly had to be revised, in some cases at short notice. These time-critical supplementary requirements within a set three-month period especially posed a challenge for businesses, and crucial deadlines could not always be met in these cases.

As one participant reported from their advisory work, the requirement for manufacturers to demonstrate proof of benefit involved the most intensive advisory work. The need to formulate these DiGA-acceptance criteria clearly and in detail has been identified here. 'What we would have liked from the advisors' end were, for example, uniform assessment criteria, and to be given more than just the meagre guidelines on what the BfArM envisages the process for proving healthcare impacts to be.'

- An annual BfArM analysis of the number of retracted requests, and the reasons for this, was considered insightful.
- Similar to pharmaceutical approvals, a half-yearly discussion among the scientific community ('BfArM in dialogue'), e.g. on methodological issues, could make criteria and obstacles transparent and help manufacturers better plan market launches overall.

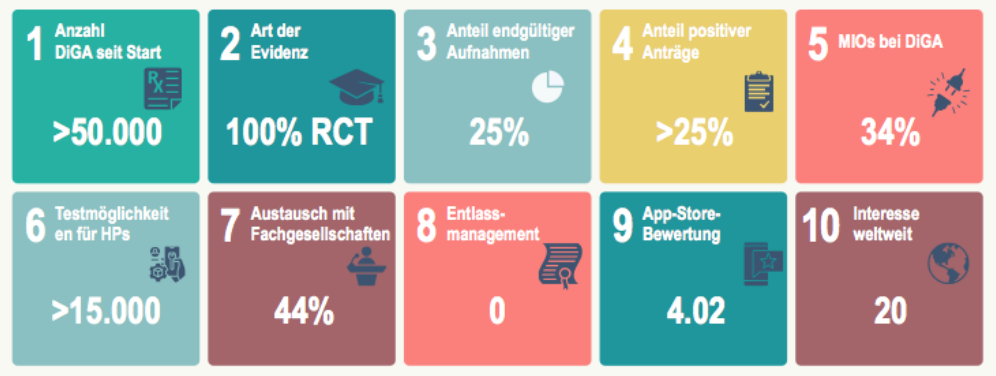
Approval requirements: A challenge for many businesses
Based on the views of some participants, the switch from the Medical Device Directive (MDD, 93/42/EEC) to the Medical Device Regulation (MDR, EU 2017/745) has had a significant effect. As one participant stated, the switch to the MDR has once again massively restricted professional (advisory) capacities. Contacts familiar with this area are hard to come by on the market. 'Because these resources are lacking, the transformation process cannot proceed as

intended; we would definitely like more support for manufacturers', they said. As such, the fast-track process has resulted in reports according to which companies were still basing the approval of their DiGA on the MDD where possible, i.e. wanted to obtain DiGA approval as a Class I medical device.

- The requirements for approving DiGAs are strict, and are challenging overall for what are generally medium-sized manufacturers or start-ups. Many DiGA manufacturers significantly underestimated the effort and expense involved with the approval process.
- One major learning from the conversations with manufacturers was that successful approval of DiGAs requires applicants to simultaneously plan and expedite the necessary streams – incl. app development and evidence-based proof of benefit – right from the start. One participant reported that the manufacturers who initially only concentrated on technological development and practical implementation often had to retract their requests.

Organisations such as the Bundesverband Internetmedizin called for the need to exercise sound judgement in terms of the effort and expense associated with RCTs. It finds it problematic that the high expenses are reflected in sales prices above the generally expected level for the currently listed DiGAs. This means that, at present, the only DiGAs making it to market are those that successfully address medical successes in diseases that are expensive to treat, not products that facilitate small progress for chronic illnesses. RCTs conducted only a short time prior to market launch are ultimately rarely able to prove any benefit. Coupled with the fact that, due to the availability of generic therapy alternatives, providers of such solutions cannot expect to be remunerated appropriately.

Fig.: DiGA KPIs 12 months after the start of the fast-track process (Source: healthinnovation hub, hih, version: 4 November 2021)



1. Number of DiGAs since start >50,000 - 2. Type of evidence 100% RCT - 3. Proportion of final acceptances 25%/ - 4. Proportion of positive requests >25% - 5. MIOs for DiGAs 34% - 6. Testing options for HPs >15,000 - 7. Discussion with professional associations 44% - 8. Discharge management 0 - 9. App Store rating 4.02 - 10. Interest worldwide 20.

Intensive communications required: Many doctors in Germany are still not aware of DiGAs

Around 50,000 DiGA prescriptions were registered in the first year of the fast-track process.[2] In addition to this are positive experiences gained by certain manufacturers, whose expectations were fulfilled or even exceeded after the slow prescription rollout. Some panel participants, meanwhile, found that things generally went according to their rather conservative expectations. One participant, for instance, believed that critical voices from associations of statutory health insurance physicians and some medical associations could have had a negative effect on DiGA prescriptions. What was found to be a given, however, was the fact that merely being included in the DiGA directory does not result in a business receiving prescriptions and therefore reimbursement of development costs. Smaller and medium-sized businesses in particular clearly noticed here that successful marketing requires that the tedious approval process be followed up with many other, often cost-intensive steps. Unlike major pharmaceutical business operators, most of these manufacturers do not have a sales structure capable of convincing doctors of a digital application's clinical benefit. As such, many businesses are currently finding it very difficult to make potential prescribers – doctors/psychotherapists – aware of their innovative DiGA solutions.
Test accounts that enable interested doctors to gain initial experience with DiGAs early on were not available at the start. Most DiGA manufacturers have now facilitated this and made over 10,000 such accounts available.[3]

Changing the German health system requires powers of persuasion
One participant considered it a positive sign that 90% of DiGAs are prescribed by participating physicians and psychotherapists. Only 10% are obtained by insured parties via direct approval from the health fund. 'We consider this to be a positive development, because a DiGA needs to fit into a holistic treatment concept', says the participant. But the issue of DiGA prescription is yet to take root Germany-wide. While prescriptions do not put any strain on participating physicians' budgets, they are noticeably reticent. There are concerns, for example, that additional work – such as in relation to explaining the DiGA and conducting individual data analyses – will need to be done with no guarantee of remuneration. The level of information available on DiGAs at present also appears to still be low. There have been reports, for instance, that, in many cases, the requirements for prescription are not known. Another aspect mentioned was the fact that other digital tools, such as electronic patient files and e-prescriptions, are currently given comparatively greater importance in everyday medical practice, taking attention away from the DiGAs. After all, patients would have to be informed of these new digital therapy offerings – but the question is, by whom?

In a bid to promote acceptance of their products, some providers are currently going through professional medical associations. Nearly half are engaged in professional dialogue, aimed at illustrating the relevance of DiGAs in everyday medical practice. This process is expected to still take some time. 'The health system in Germany is not known for rapidly and openly

[2] This figure was still 20,000 on the day of reporting. According to the latest figures, however, there were approx. 50,000 DiGA prescriptions by 4 November 2021 (written notice from healthinnovation hub, hih).
[3]This figure was accurate on the day of reporting. Approx. 15,000 test accounts had been made available by 4 November 2021 (written notice from healthinnovation hub, hih).

adopting and embracing innovations; it takes a lot of persuading over an extended period of time', said one participant. Another participant had a similar opinion: 'It hasn't even been 12 months since the first DiGA was prescribed; no one can expect a miracle in such a short space of time.'

From a practicalities perspective, it was considered important to improve the processes associated with prescribing a DiGA. One main point here is the call to replace the currently commonplace paper-based prescriptions with an electronic prescription option. The Spitzenverband Digitale Gesundheitsversorgung digital healthcare association is among those to have advocated strongly for this; the option of electronic prescriptions is set forth in the German Law on Digital Modernisation of Healthcare and Nursing (Digitales-Versorgungs-und-Pflege-Modernisierungs-Gesetz, DVPMG). One participant said this change would, above all, help patients. At present, patients need to submit their paper prescription to their health fund in order for it to then undergo a long-winded activation process. 'This is not the kind of process we want in terms of user-friendliness. The current process was only intended to facilitate a swift introduction of DiGA prescriptions, but it has also resulted in us losing a lot of patients.'

- Doctors in Germany are still sceptical about the clinical and other benefits of DiGAs for patients, and are thus hesitant to issue prescriptions.
- Proven evidence of DiGAs' clinical benefits, as well as the achievable added value for doctors and patients, must be communicated both in reviewed scientific publications and in layman's terms for patients.

What should DiGAs cost?

One aspect for which intensive discussions are expected revolves around the costs of DiGAs. In particular, there is the question of how much the – necessarily – strict requirements for evidence, privacy, data security and robustness should be reflected in the price. 'If we set the same evidence standards for DiGAs here as we do for, say, pharmaceuticals, that should be remunerated in a comparable manner', said one participant.

The process generally stipulates that manufacturers set their own DiGA prices during the first year of approval. According to the Verband der Ersatzkassen, the prices from selective contracts and the self-payer market should ideally serve as reference values during this initial phase. This expectation was not met overall. Instead, it seems that, in some cases, the fears about DiGA manufacturers' price policies have been confirmed. An association representative advised beforehand that, during the first year, free pricing had, as expected, led to excessive reimbursement prices that were disproportionate to 'analogue' treatment methods. '500 euros per 90 days of activation is beyond anything that could be considered profitable,' the representative said in the lead-up to the discussions, adding that, in the price negotiations currently underway, there would be a push for a price level that takes into account the statutory health insurance providers' 'generally difficult' financial situation. Long-term treatment outcomes achieved by DiGAs are of course not currently available for a comprehensive health-economics evaluation. Only once they are could an assessment of therapy costs (conventional versus treatment using DiGAs) possibly justify what are presently still high DiGA activation costs.

On the other hand, one participant said that opinions on pricing rules, some of which have been discussed publicly, are too complex to be reflected in a simplified manner. The necessary proof of positive healthcare impact alone involves various levels of detail (incl. on the comparison group and healthcare context) that cannot be covered by sweeping statements. At an overarching level, DiGAs only make up a small fraction of the total costs in the statutory health insurance system.

As one participant mentioned, some insurers are aspiring to achieve solutions facilitating the most flexible possible combination of DiGAs and selective contracts in order to systematically integrate digital therapies into holistic/'hybrid' healthcare concepts. In some specific cases, DiGA approval had significantly changed existing cost models from selective contracts, which can be seen as an indication of price models that do not cover costs. According to one individual opinion, the current costs are also comparatively high because proof of benefit is still lacking, and it was assumed providers would adopt a strategic approach. 'I can understand this, as the AMNOG (German Pharmaceutical Market Restructuring Act) has shown us how hard a negotiator the leading association for statutory health insurance funds is. There will be considerable markdowns', said one person. Another participant provided a subjective impression of the general sentiment at present. 'There is a tremendous amount of untapped potential for dialogue between manufacturers and health funds, if not a wall of silence.'

- Many health funds fear the introduction of DiGAs will cause a massive rise in costs. And they don't always see them bringing potential added value either. Informative long-term studies are needed.
- In view of this, it would appear important to use high-quality clinical studies to prove the positive healthcare impacts of DiGAs and, in particular, relevant potential for positive effects on health economics.
- The extent to which the development of DiGAs is profitable for providers in the current framework conditions will become apparent in the framework agreement and in ongoing individual price negotiations.
- Also worth factoring in here is the notion that apps constantly need to be further developed, because, among other things, technical framework conditions are constantly changing.

DiGA: A possible tool in clinical research?

One area of application that should be examined independently from a DiGA's medical benefit as a therapy relates to the potentially supportive use of DiGAs in clinical research. As part of a legally compliant clinical study, the participants consent to precisely defined application of a subsequent analysis of the data obtained from the DiGA beforehand. Professional clinical studies also meet the legal data-protection and data-security requirements. In clinical studies, digital health applications provide another way of generating real-world evidence, so as to potentially help with the evaluation of medications and other devices and, for example, to facilitate the implementation of remote decentralised clinical trials (RDCTs). Equipped with the functions of a study app, DiGAs could also help when it comes to fulfilling legal requirements (such as in relation to recruiting participants), facilitate the process of obtaining informed consent, or be used to randomise study participants. In combination with medically

qualified sensor systems, there are also better prospects for recording study checkpoints or patient-reported outcomes under real-world conditions. Such patient-oriented concepts of clinical research are conducive to research aimed at closing the current gaps between outcomes in well controlled clinical studies conducted with scientific accuracy and the results achieved in real healthcare settings. The expectation here is to implement clinical development programmes more effectively, i.e. ultimately with much lower failure rates, by improving the external validity of clinical studies.

- DiGAs could help democratise access to clinical studies and, by generating real-world evidence, enrich the availability of healthcare data.
- DiGAs and medically qualified sensor systems could be used to increasingly record real-world study checkpoints or patient-reported outcomes (PROMs) and more intensively gear clinical development around these value-based healthcare models.

Section 2: DiGA fast-track processes – a model for Europe?

The second section of the round-table discussion focused on the question of the extent to which the German DiGA model could serve as inspiration and a guide for other European countries. As the requirements established in the DiGa fast-track process build on from MDR-compliant medical-device certification, it would appear that the model could be adopted in other European countries. After all, these are medical devices already approved within the EU, which simply have to prove they have an additional positive impact on healthcare and fulfil certain data-protection requirements.

The European Medical Device Regulation, which has been in effect since May 2021, provides a general framework of performance and safety requirements for official approval of medical devices. The EU member states can, for example, control DiGA access to the market and healthcare by implementing country-specific procedures in order to, among other things, comply with national health-economic requirements. Parameters geared around this can be established, defining, for example, whether or the extent to which DiGA costs are reimbursed.

Two general options for a possible Europe-wide DiGA approval process were discussed. The first option, which is currently also set out in the BfArM process, requires manufacturers to prove that a study and its results can be applied to a healthcare context in a different country. A decision regarding DiGA approval would then be made at the respective national level based on set criteria. Alternatively, the question was raised as to whether a single, Europe-wide randomised clinical study could be conducted in relation to making DiGAs eligible for reimbursement in all EU countries. The aim here would be to do away with individual tests in the respective national health systems. This would involve setting up a testing authority capable of appropriately assessing applications – e.g. modelled on the European Medicines Agency (EMA). ‘What I would like to see is us setting up an EMA-like European authority that performs the general DiGA registration tasks, leaving only small adjustments to be made in the individual countries,’ said one participant.

Europe-wide generation of evidence appears possible

In order for such a joint European approval process to exist, the participating countries would have to agree on parameters for generating evidence in relation to DiGAs. There would have to be discussion on aspects such as evidence basis, i.e. study-design standards, and end-point categories (e.g. quality of life, morbidity, compliance etc.). 'If a consensus is reached on these points, Europe-wide generation of evidence could be feasible', said one participant. It still remains to be seen how studies could be made comparable in the different healthcare contexts. Additional rules regarding the applicability of certain elements or results to these contexts or the individual health systems may be needed. The respective economic assessment certainly could not be replicated between countries, i.e. factors such as structures and reimbursement options of the respective health systems would also need to be taken into account. A health-technology assessment process (HTA) could be one initial way of establishing benefit and thus the general ability to make a product eligible for reimbursement as a first step. Such overarching European assessments are already being conducted in existing networks, including the European Network for Health Technology Assessment (EUnetHTA). The respective DiGA reimbursement conditions would then need to be specified in the countries.

One participant did not believe this sort of centrally structured process would bring any advantages. They believe this approach would only shift the issue of comparability between the various health systems onto the study-design aspect, i.e. various questions regarding methodological details would have to be answered, in some cases in a very time-consuming manner, at a national level. They believe it would be particularly necessary to assess the extent to which this sort of three-stage process – comprising MDR approval, lodgement of requests to the European authority, and country-specific regulations for market access – is improving the current situation.

One possible proposed approach was to generally tie DiGA cost reimbursement in with documented proof of performance (value-based healthcare models). Thereafter, products could be introduced as part of an adaptive approval process once they have been confirmed safe for users. It would then be possible to scientifically supervise whether the promised value is fulfilled or not – and the cost reimbursement/approval adjusted on this basis. As such evaluations are conducted based on patient-reported outcome measures, the relevant data-protection regulations must be followed in routine care settings.

It may be more difficult to apply DiGAs to other systems in relation to patient-related structural and procedural improvements compared to for medical benefit. An approval process setting less strict requirements for providing proof of evidence may be chosen accordingly for DiGAs solely addressing structural and procedural improvements, and which belong to risk class I. This could help keep approaches outside the highly priced markets with a sufficiently high degree of medical benefit.

- The participants hoped the processes for approving DiGAs in European countries could be harmonised in the near future.
- The findings obtained in Germany are also considered to be helpful, even though the model developed here is still in the trial phase.

- Not all participants expect a potential European concept to fully comply with the process currently being implemented in Germany.
- Adaptive reimbursement mechanisms that control cost reimbursement based on evidence of possible additional benefit in the specific system could be introduced in the respective health systems.

In a bid to find a European solution, there needs to be work done on transnational technological and data-protection standards, in addition to agreeing on valid proof processes. In terms of the necessary interoperability, FHIR[4], as a standard recognised Europe-wide/internationally, could be an option for an initial approach.

Some participants of the round-table discussion saw highly attractive potential in being able to use DiGA-based data for medical research. But the legal requirements for using health data in research vary significantly. While the DVG strictly prohibits data from generally being shared with third parties, Finland, for example, has adopted the approach of making all health data available for research. The participants believe this approach places efforts to achieve a possibly improved medical care system above certain privacy concerns.

DiGA-based data collection would enable insight into the everyday healthcare of potentially millions of people. As a result of this broader access, it would no longer just be data on specific appointments at a hospital or doctor's surgery that would be collected. Instead, real-world data sets, i.e. data generated outside of studies, and which therefore provides a higher degree of healthcare-related insights, would be available.

In view of this, one participant advocated a systematic, AI-based (Europe-wide) analysis of structured, standardised datasets generated by the relevant DiGAs. As such, documented movement and metabolic patterns or specific sets of symptoms could be used to draw conclusions that enable much more precise, evidence-based treatments of individual patients, while simultaneously making it easier to set up robust and sustainably financeable health systems.

One ambitious goal would be to develop a European DiGA ecosystem in which all DiGA-produced data is incorporated into a structure database, which would then also facilitate well curated, quality-assured research projects. Despite a strong ethical momentum, there is currently no possibility of implementing such approaches in Europe – and, according to the subjective expectations of some participants, this is not expected in the foreseeable future either.

- Developing evaluation components that can be applied across-the-board in approval processes is an attractive prospect. Not every DiGA manufacturer needs to find their own solutions; existing elements could also be used, e.g. in terms of tried-and-tested study designs, common data-protection agreements, secure data storage and data interoperability.

[4]FHIR (Fast Healthcare Interoperable Resources) is a technical standard for data exchange between software systems in the health industry.

Summary

Europe is facing the challenge of developing a regulatory and implementation framework for introducing onto the market electronic applications (apps) with digital health solutions. This is a completely new field in which experience in, among other things, the approval criteria and approval process for the digital health applications (DiGAs) is so far largely lacking. Germany is acting as a pioneer here, as, based on the Digital Healthcare Act (DVG) and Digital Health Applications Ordinance (DiGAV), it has introduced an approval process (fast-track process) that could see DiGAs rapidly prescribed and used in clinical settings.

After one year of the fast-track process, 70 of 91 requests were rejected or retracted by the manufacturer, with inadequate clinical evidence in the study design being by far the most common reason for this. There is particular room for improvement in relation to detailed publication of requirement and assessment criteria. At the same time, the change in approval regulations brought further uncertainty to an already difficult market. A lot more competent dialogue partners will be needed in order to switch from the Medical Device Directive (MDD, 93/42/EEC) to the Medical Device Regulation (MDR, EU 2017/745).

Some doctors in Germany are still sceptical about the clinical or other benefit of DiGAs for patients, and are thus still holding off with prescriptions. Even in future, it will be necessary for them to communicate the added value achievable. A lack of sales/distribution structures means the predominantly small and medium-sized developers of DiGAs face challenges in terms of promoting their innovative solutions to the prescribing doctors.

Many health funds fear the introduction of DiGAs will cause a massive rise in costs. And they don't always see them bringing potential added value either, even in terms of the cost level that exists in some settings already. Clinical studies will have to convincingly demonstrate the DiGAs' positive impacts on healthcare and, in particular, relevant potential for positive effects on health economics.

The findings obtained in Germany are considered helpful in relation to a European approval model for DiGAs. It remains to be seen whether and how a potential European concept will differ from the process currently in place in Germany today.

The participants were convinced that the enabling of the prescription of digital health applications could make Germany a pioneer in Europe. Given the growing importance of digital healthcare, this role is very timely and, in view of the potential for patients, health systems and healthcare research, also appears necessary at an ethical level. Generating real-world evidence and enabling patient participation could allow data collected longitudinally via DiGAs to answer important research questions. This approach would not only generate evidence for more accurate treatment of individual patients, but also enable robust, sustainably financeable health systems to be established in Europe based on fact.

Source: Round-table discussion during the KassenGipfel *(health-insurer summit) in Berlin on 16 September 2021.*

The EIT Health Germany Round-table was held as a satellite event during the German health-insurer summit on 16 September 2021 from 2 p.m. – 5 p.m. live, with streaming, from the Steigenberger Hotel Berlin.

Appendix 1: Round-table participants

EIT Health would like to thank the following participants for their expert contribution to the round-table discussion:

Name	Organisation
Moderator	
Dr Anke Diehl	Universitätsmedizin Essen, Digital Change Manager
Participants	
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Pia Maier	Executive, Bundesverband Internetmedizin
Dr Henrik Matthies	Managing Director, Health Innovation Hub
Nora Müller	Head of Health Insurance, Flying Health
Matthias Zurth	Business Development Manager, LOB Health,adesso SE
Michael Rosenstock	Head of Sana Digital, Sana Kliniken AG
Prof Freimut Schliess	Director Science & Innovation, Profil Institut für Stoffwechselforschung GmbH
Christian Weigand	Head of Mobile Health Lab, Fraunhofer IIS CTO, Digital Health Application Center (dmac) GmbH
Daniel Neubacher	Medical journalist
EIT Health staff	
Dr Katharina Ladewig	Managing Director, EIT Health Germany
Dr Michael Lüttgen	Liaison Manager, EIT Health Germany
Carolin Schanz	Strategic Project Manager, EIT Health Germany
Lena Weller	Communications and Events Lead, EIT Health Germany

'One of EIT Health's core tasks is to identify regionally outstanding innovations in health and to provide fertile ground for these as part of our Europe-wide network with partners from research, education and industry. This enables the resulting products and services to start benefiting citizens across Germany as swiftly as possible.'

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