Spitzenverband
Digitale
Gesundheitsversorgung

Key Points for a Practical Implementation of Accompanying Success Measurement (AbEM)

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Executive Summary

Following the „Act to Accelerate the Digitalization of Healthcare“ (Digital-Gesetz - DigiG), manufacturers of digital health applications (DiGA) will conduct an accompanying success measurement (AbEM) starting January 1, 2026.

The German Digital Healthcare Association (SVDGV) welcomes the plan to develop implementation details in a broad discussion process. To this end, SVDGV has developed this paper outlining five key points that should be considered in the further design of AbEM:

1. **AbEM must not compromise therapeutic efficacy.**
2. **AbEM must consider scientific and context-specific aspects.**
3. **AbEM is a complementary component of comprehensive quality assurance, not a replacement.**
4. **Preventive measures are needed to avoid misleading conclusions from the presentation of AbEM results.**
5. **AbEM should be designed to minimize bureaucracy.**

SVDGV is convinced that AbEM for DiGA, with a patient-friendly and scientifically sound design, can take a leading role on the path to value-based healthcare. This could potentially benefit all stakeholders, especially the patients.

Background

On March 26, 2024, the „Act to Accelerate the Digitalization of Healthcare“ (Digital-Gesetz - DigiG) came into force. It includes many important improvements for digital healthcare for patients in Germany. For example, legally insured individuals will also have access to higher-risk class digital health applications (DiGA) and DiGA that include complementary telemonitoring services. DiGA will also be used to support during pregnancy and will be more integrated into disease management programs. Additionally, starting January 1, 2026, DiGA manufacturers will conduct an accompanying success measurement (AbEM), the results of which will be regularly published in the DiGA directory of the Federal Institute for Drugs and Medical Devices (BfArM).

Key metrics of AbEM include:

- Duration and frequency of use of DiGA
- Patient satisfaction regarding the quality of DiGA
- Patient-reported health status during the use of DiGA

Detailed provisions on data submission deadlines, methods, processes, and content of the success measurement, as well as on publication in the DiGA directory, are to be regulated in an upcoming amendment to the DiGA Ordinance (DiGAV).

The German Digital Healthcare Association (SVDGV) appreciates that the development of these provisions will take place in a broad discussion process. If the new requirements are designed to be patient-friendly and scientifically robust, AbEM for DiGA can make a significant contribution to value-based healthcare. When setting the implementation details, DiGA manufacturers should be extensively involved to ensure a practical and optimal implementation.

This paper is intended as a basis for further discussion and defines five key points that SVDGV believes should be considered in the further design of AbEM.

1. Accompanying success measurement (AbEM) must not compromise therapeutic efficacy

The surveys conducted within the framework of AbEM must not hinder the actual use of DiGA, as the users of DiGA are patients with important medical needs, not consumers. Many DiGA are based on behavioral therapy and educational principles that must facilitate habit formation or competence gain in patients to achieve a positive healthcare effect. Conversely, the effectiveness of a DiGA can be impaired if complex AbEM surveys disrupt these principles. Thus, for optimal effectiveness of DiGA, the principle of unhindered usage is absolutely essential. Therefore, two premises of the AbEM surveys are indispensable:

- **AbEM surveys must be voluntary and must not disrupt the interaction design of the DiGA**. Any collection of AbEM-relevant parameters by the patients must be able to be carried out without disrupting the use of DiGA or can be declined. Possible disruptions include, for example, blocking further use of DiGA for non-participation or recurring reminder messages. Additionally, it must also be permissible for DiGA manufacturers to implement AbEM outside of the DiGA (for example, via email surveys).

- **AbEM must be proportionate to the purpose of the application**. AbEM surveys must not disrupt nor replace the capture of inputs that are necessary for the indication-specific and DiGA-specific active principles. It would be disruptive, for example, if an AbEM survey were to immediately follow a DiGA-specific survey for feedback-based adjustment of the therapeutic stimulus.

These principles are also desirable for reasons of user-friendliness. Patients always compare the convenience of their interaction with the prescribed DiGA with the comfort of their non-therapeutic apps they use in everyday life. Therefore, the interaction with DiGA should be made as familiar as possible to facilitate the best possible use of a DiGA for patients. At the same time, both unusual disruptions of use and the incentivization of rigid usage patterns should be avoided. A DiGA is not entertainment software. Commercial performance metrics (for example, number of log-ins, time spent in the app, number of units completed per time unit) are not indicative of the therapeutic success of the application. Rather, DiGA are CE-certified medical products with an indication-specific, digitally mediated mechanism of action and proven efficacy.

2. Accompanying Success Measurement (AbEM) Must Consider Scientific and Context-Specific Aspects

In principle, the selection of AbEM measurement tools should align with scientific standards. Nevertheless, the accompanying character of the assessment, which is not comparable to data collection in a randomized controlled trial (RCT), must be significantly considered. Here are some examples:

- In the context of an accompanying assessment, it cannot be guaranteed that all patients will complete it at the same measurement point (e.g., ten weeks after starting the application).
- The response rate of an accompanying assessment cannot be directly compared to that of an RCT since the AbEM assessment should be optional for patients (see point 1).

These and similar aspects are typical for an accompanying assessment and do not contradict scientific standards. Therefore, meeting scientific standards within AbEM should pragmatically focus on criteria that are not equivalent to those of RCTs. It may be sensible to adapt the choice of measurement instruments to the requirements of an accompanying assessment: A shorter procedure (e.g., a 1-item instrument) could be used instead of a longer established instrument to minimize the assessment effort for the patients.

Given the diversity of DiGA applications and the complex requirements of AbEM, the individual choice of measurement instruments must lie with the DiGA manufacturers.
This selection process also prevents any false impression of comparability among the different DiGA applications.

In this context, the following cross-application requirements arise for the three aforementioned key metrics of AbEM (usage, patient satisfaction, patient-reported health status):

2.1 Requirements for Measuring the Duration and Frequency of DiGA Usage

Data on the duration and frequency of use of an application can provide added value for assessing a DiGA. However, the ideal usage frequency and duration can vary significantly between different DiGA, and the significance of these metrics for therapeutic success varies depending on the application and diagnosis. Thus, measurement results regarding usage duration and frequency may have apparent validity within the context of AbEM, without providing insights into clinically significant interactions with the application. Therefore, first, the choice of reported metrics regarding the duration and frequency of DiGA usage should lie with the manufacturer, and second, it should be considered that a cross-application comparison of even similar metrics is not appropriate.

2.2 Requirements for Assessing Patient Satisfaction Regarding the Quality of DiGA

Patient satisfaction is a multidimensional construct, the measurement of which involves challenges for several reasons:

- Initially, a clear definition of patient satisfaction is required within an application before it can be reliably measured. The variety of techniques and modalities used within a DiGA results in numerous definitions of patient satisfaction, and consequently, numerous possibilities for choosing a suitable measurement instrument.
- Satisfaction with the application is often closely linked to the improved health status due to the DiGA regarding the covered diagnosis. Therefore, diagnosis-dependent differences in satisfaction, considering healing opportunities or the potential for symptom improvement and the associated expectations, must be considered (see info box).

Why Apples Should Not Be Compared to Pears
Even if the measurement instruments used meet standards of reliability and validity, it does not mean that the resulting statements are comparable across different diagnoses or DiGA (digital health applications.

1. Example: Duration and frequency do not correlate proportionally with the success of the application
For instance, the number of log-ins to an application does not indicate whether the contents of the DiGA were understood or implemented. Conversely, the knowledge imparted within the DiGA can have its effect on an analog level, even if the application is not opened several times a week.

2. Example: Patient satisfaction also depends on the medical condition
The personal satisfaction experience with the outcome of a DiGA-supported therapy can vary significantly—for example, between patients using a DiGA for a chronic disease with no medical prospects of cure, and patients for whom the use of DiGA can support symptom relief. The context-free satisfaction values may seem comparable at first glance but overlook the different starting situations of the patients.

2.3 Requirements for Collecting Patient-Reported Health Status During DiGA Usage

Assessing the patient-reported health status during the use of DiGA requires a nuanced approach for several reasons, including:

- Immediate improvement in health status cannot be expected. Typically, positive effects, such as an increase in quality of life, often develop weeks after the start of DiGA usage, once patients have had sufficient time to integrate what they have learned into their daily lives.
- Each disease has its own challenges and impacts on health status, which are not uniformly comparable and can affect individuals differently. Therefore, it is important to avoid comparing measurement results across different DiGA.

3. Accompanying Success Measurement (AbEM) is a Supplemental Part of Comprehensive Quality Assurance, Not a Replacement

The proof of medical benefit or a patient-relevant improvement in structure and procedures is established at the latest with the permanent inclusion in the DiGA directory. To this end, DiGA are examined in high-quality studies—predominantly through randomized controlled trials (RCTs). Against this backdrop, AbEM can be considered an additional component of comprehensive quality assurance. However, the uncontrolled accompanying data collections cannot be compared with the results obtained under defined conditions from pivotal studies. The respective datasets differ in various aspects, including measurement points, response rates, potential biases, and populations, thereby differing in their interpretation and use.

In presenting the AbEM results, it is therefore crucial to explicitly inform about the already proven positive healthcare effects of the DiGA (for instance, by providing supplementary notes for context. In this context, it would be desirable for the Federal Institute for Drugs and Medical Devices (BfArM) to report more actively on the high standards required for demonstrating a positive healthcare effect.

4. Preventive Measures Are Needed to Avoid Misleading Conclusions from the Presentation of AbEM Results

For the successful implementation of AbEM, it is important to consider the challenges of presenting results to a diverse audience with different expectations. **Properly implemented**, the insights from AbEM help all involved:

- Patients and healthcare providers can benefit from the additional information from AbEM when selecting a suitable DiGA for themselves or their patients.
- DiGA manufacturers can more easily identify opportunities for improvement through AbEM. Additionally, they gain further insights through a presentation of the timeline of implemented improvements. Thanks to the focus on empirical data, DiGA manufacturers also benefit from a reputation gain, as they are in a particularly advantageous position to provide scientifically substantiated proof of success efficiently and promptly.

DiGA could thus take a leading role in value-based healthcare. However, careless presentation of the data can lead to unfavorable or even abusive conclusions. Therefore, it must not be a goal of transparent presentation to make cross-indication comparisons or interpretations. Even comparisons between DiGA within the same indication are generally excluded, as there are significant differences in the respective therapeutic approaches. Therefore, in presenting and publishing the AbEM results, not only indication-specific differences but also DiGA-specific particularities must be identified.

Regardless of the methodology and scope of data collection, it is imperative to clarify how and in what form aggregated data will be made available to the public. From our perspective, it is crucial to avoid thoughtless and unfiltered representations to prevent exaggerated, unrealistic, or even false conclusions that could harm all stakeholders, particularly the patients.

In the interest of a presentation of AbEM results that benefits all parties, the implementation of guidance for categorization and usage is absolutely necessary.

In developing a solution, it should be urgently considered that publication in the DiGA directory could create the impression of pseudo-comparability, which is not actually present. The basis of consideration should continue to be the clinical evidence that each manufacturer must demonstrate upon inclusion, which is also found in the DiGA directory. Otherwise, there is a risk that healthcare providers, patients, or laypersons might interpret the presented data from the accompanying data collection as the sole status quo and fail to recognize the objective clinical value of the application. As a result, affected individuals might be denied access to a DiGA, although it could actually help them.

Therefore, it is desirable to coordinate the presentation of results further as soon as the nature and extent of the data collection are specified.

5. Accompanying Success Measurement (AbEM) Must Be Designed with Minimal Bureaucracy

The introduction of AbEM represents additional bureaucratic effort for all involved parties:

- Patients, after consenting to voluntary participation in AbEM, repeatedly answer additional questions.
- DiGA manufacturers must additionally collect, aggregate, and report these data to the Federal Institute for Drugs and Medical Devices (BfArM).
- The BfArM must provide additional resources for the collection, processing, and publication of these data.

To ensure that AbEM is practical, it must be designed to minimize bureaucracy. An excessively high burden on patients, DiGA manufacturers, and the BfArM must be avoided.

This is especially important given the existing resource shortages at the BfArM. The collection process must be feasible for DiGA manufacturers without additional costs for translations and licenses for measurement instruments. Also, updating the measurement values published in the DiGA directory should be possible for DiGA manufacturers in the short term, straightforwardly, and without additional fees.

Moreover, we greatly welcome the decision to exclude the medical profession from participating in data collection, to avoid additional administrative burden given their limited time and personnel resources.

About the German Digital Healthcare Association (SVDGV):

The German Digital Healthcare Association (SVDGV) is the largest industry representative of digital health application manufacturers and is part of the circle of leading industry organizations representing the economic interests of digital health application manufacturers at the national level. The SVDGV sees its role as being the central „voice“ of its members towards politicians, authorities, and other stakeholders in the healthcare sector. Currently, 100% of the listed DiGA manufacturers are also members of the SVDGV.

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