# TRENDS IN CLINICAL EVIDENCE FOR DIGITAL HEALTH APPLICATIONS (DIGA) REIMBURSED IN THE GERMAN DIGA DIRECTORY

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## BACKGROUND

- Germany's Digital Healthcare Act (Digitale–Versorgung–Gesetz or DVG), passed in November 2019, introduced a reimbursement pathway for certain digital health apps ("Digitale Gesundheitsanwendungen", known as "DiGA).[1]
  - The DiGA Fast Track process aims to allow rapid approval, testing, and reimbursement of digital health apps classified as class I and IIa (low to medium risk) medical devices.[1]
  - DiGAs are for the use of the patient only, or patient and healthcare provider.[1] They can be mobile or web applications and are typically apps on a patient's smartphone.
- Digital health apps can be prescribed by healthcare providers ("apps on prescription") and reimbursed by the statutory health insurance if they are listed in the listed in the Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM) DiGA directory.[1]
- A dedicated HTA process carried out by BfArM sets assessment criteria for digital health applications and provides two listing options: permanent, or provisional listing for a 12-24 month trial period while further evidence is collected to prove positive effects on care.[1,2]
  - DiGA must demonstrate positive effects on care as either medical benefits and/or patient related structural or procedural improvements.[2]
  - Permanent (final) listing requires evidence from a quantitative comparative study conducted in Germany, demonstrating that use of DiGA is superior to SoC without the DiGA. Based on this evidence, the BfArM decides if the DiGA will be permanently reimbursed.[2]
- Twelve months after the BfArM decision on provisional or final listing in the DiGA directory, the remuneration (price) must be negotiated with the National Association of Statutory Health Insurance Funds (GKV-SV), replacing the manufacturer price.[2]

## OBJECTIVE

- This research aimed to understand the types of digital apps listed in the DiGA directory and the types of clinical evidence submitted and/or intended for the trial period for DiGAs with permanent and provisional listing.

## METHODS

- Records for DiGAs listed on the directory website on 08/06/2022 (diga.bfarm.de/de) were reviewed.
- For each DiGA, details of the DiGA listing, indication, clinical evidence, and price were recorded in a data extraction table.

## RESULTS

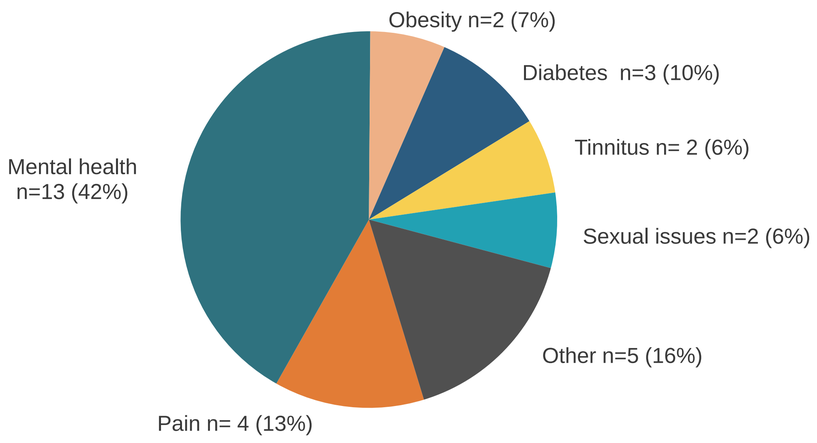
### Permanent vs temporary listings

Of the 31 DiGAs in the directory, 39% (n=12) were permanently listed, while 61% (n=19) were provisionally listed.

### DiGA indications

- The majority (39%, n=12) of DiGAs in the directory are indicated for mental health conditions, including depression, anxiety, and addiction (**Figure 1**).
- The next most frequent indications were pain (13%, n=4) and diabetes (10%, n=3).
- Other indications included obesity, tinnitus, sexual issues (2 of each), as well as multiple sclerosis, aphasia, irritable bowel syndrome, and breast cancer.

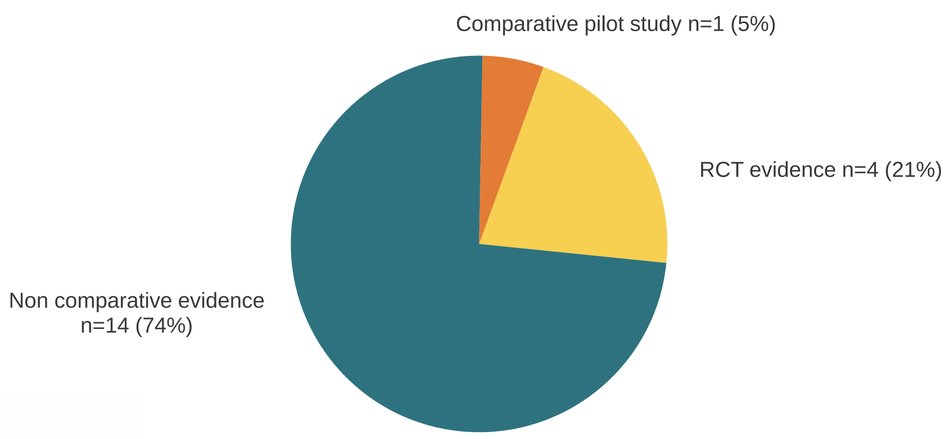
**Figure 1. Listed DiGAs by indication**




### Study designs

- For DiGAs with permanent listing, randomised controlled trial (RCT) evidence was provided for all DiGAs.
- For the provisionally listed DiGAs, 73% (n=14) provided evidence from non-comparative studies, 21% (n=4) provided evidence from RCTs, and 5% (n=1) provided evidence from a comparative pilot study (**Figure 2**).

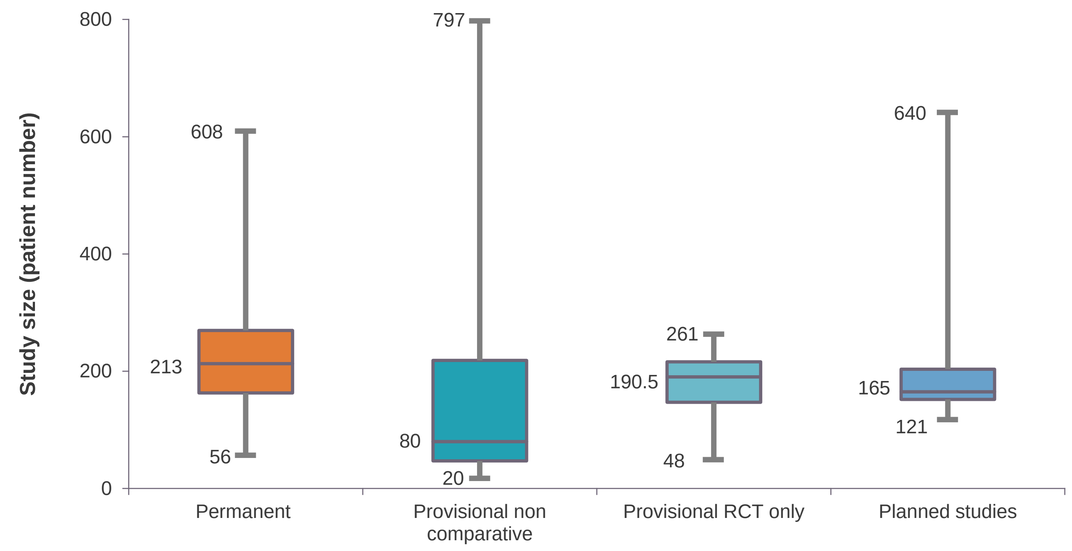
**Figure 2. Design of studies used to provide evidence for DiGAs with provisional listing**




### Study size

- For permanently listed DiGAs, RCTs included 56–608 patients (mean 244) (**Figure 3**).
- For provisionally listed DiGAs:
  - RCTs included 48–261 patients (mean 241)
  - Non-comparative studies included 20–797 patients (mean 186).
  - Studies planned for the trial period included 121–640 patients (mean 212).

**Figure 3. Size of studies/planned studies providing evidence for listing in the DiGA directory**

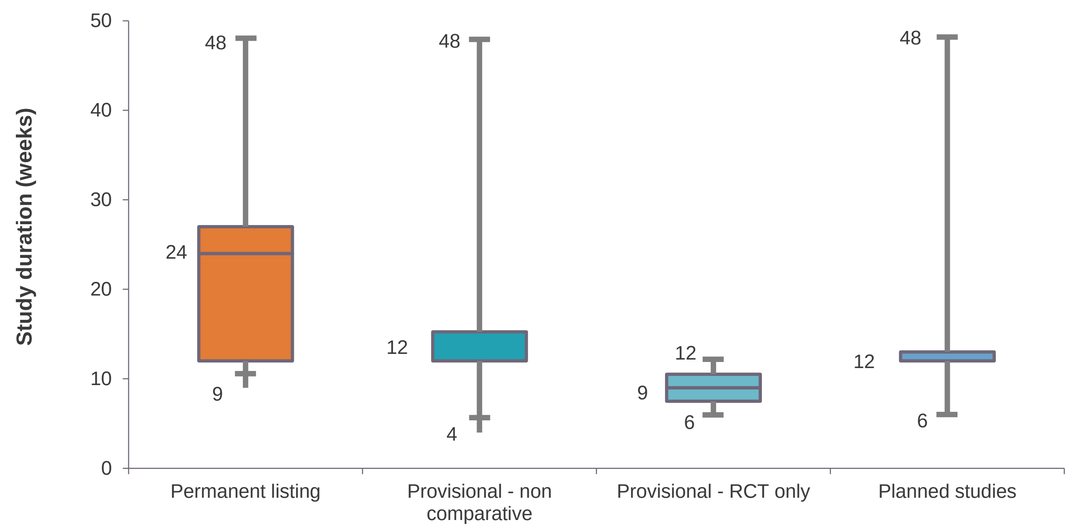



Whiskers show the minimum and maximum range, centre line displays the median value

### Study duration

- For permanently listed DiGAs, RCT duration was 9–48 weeks (mean 24) (**Figure 4**).
- For provisionally listed DiGAs:
  - RCT duration was 6–12 weeks (mean 9)
  - Non-RCT study duration was 4–48 weeks (mean 17).
  - Studies planned for the trial period were 6–48 weeks long (mean 16).

**Figure 4. Duration of studies/planned studies providing evidence for listing in the DiGA directory**




Whiskers show the minimum and maximum range, centre line displays the median value

### Pricing

- Of the 31 listed DiGAs, prices reported on the DiGA directory (standardized for 90 days of use) ranged from €119 to €718 (mean €440). However, for permanently listed DiGAs, it is unclear if reported prices reflect the price negotiated after 12 months of listing.

## CONCLUSIONS

- The use of digital health technologies has increased in recent years and has been shown to improve health and well-being, as well as supporting the drive towards personalised medicine.
- Although digital health technology development has increased rapidly, few have robust clinical evidence to demonstrate a positive healthcare effect.
- This research demonstrates the range of different study designs, sizes and durations that have been provided as evidence to achieve listing in the DiGA directory, with DiGAs achieving provisional listing based on lower-quality evidence (non-comparative, smaller patient numbers and/or shorter duration) compared to permanently listed DiGAs.
  - Median study size for RCT: n=213, vs non comparative study: n=80.
    Median study length for RCT = 24 weeks, vs non comparative study = 12 weeks.
- Dedicated reimbursement processes such as the German DiGA Fast Track that enable early access prior to full comparative trial results being available help speed up availability of these innovative applications while high-quality evidence is collected.

## REFERENCES

1. BfArM. Digital Health Applications (DiGA). 2021 [cited 2021 Aug 9]. Available from: https://www.bfarm.de/EN/Medical-devices/Tasks/Digital-Health-Applications/_node.html
2. Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM). The Fast-Track Process for Digital Health Applications (DiGA) according to Section 139e SGB V. 2020.

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