How Have Manufacturers Maximised Their Digital Health Technologies' Chances of Successful Reimbursement in Germany?

Patel M[1], Desai A[2], Ng E[1]
[1]Red Nucleus, London, UK, [2]Red Nucleus, San Francisco, CA, USA

BACKGROUND & OBJECTIVES

Digital health technologies (DHTs) allow patients to monitor, report and improve their own health and wellbeing through the use of mobile technology. Germany lead the way in the EU thanks to the introduction of a relatively new act to help accelerate the growth and uptake of DHTs within Germany. Under the Digital Healthcare Act, Germany introduced the Digital Health Applications (DiGA) Fast Track Process, a rapid approval, testing, and reimbursement process for digital health apps. The BfArM (Federal Institute for Drugs and Medical Devices) requires 4 main components for a DHT to be listed on the DiGA Directory: safety and suitability for use; data protection and information security; quality, particularly interoperability; and proof of a positive care effect as demonstrated in a clinical trial / phase IV study. DiGAs can be listed as final or provisional. DiGAs listed as final have proven positive care effect within the time specified in 'trial', usually between 6-12 months, and are reimbursed by insurers. Provisional listings have the length of their respective 'trial' period (lasting up to 12 months), where the DHT can be used in real-world settings in Germany, to prove positive care effect, otherwise will be removed from the directory and thus not reimbursed. This research explores how the evidence for proving positive care effect for a DHT impacts reimbursement and pricing outcomes in Germany.

METHODS

This study assesses the framework for the DiGA approval process in parallel to DHT applications that have failed or succeeded in gaining reimbursement. Evidence generated during studies, study design, and app design for each DHT are analysed and compared versus DiGA criteria for reimbursement, and GKV-SV (National Association of Statutory Health Insurance Funds) requirements for pricing. The correlation between the evidence package vs. reimbursement and pricing outcomes identifies the critical success factors in an optimised DHT pricing and reimbursement application.

RESULTS

The DiGA Fast Track Process sets out stringent criteria that must be adhered to in order for DHTs to be eligible for reimbursement. Obviously, technologies must demonstrate medical benefit, but showing long-term cost savings strengthens the pricing argument. Manufacturers who invest in appropriately designed intervention studies, with systematic data evaluation, prior to submission have been most successful in achieving reimbursement. The majority of technologies which failed to achieve reimbursement do so due to inappropriate study design or insufficient data evaluation.

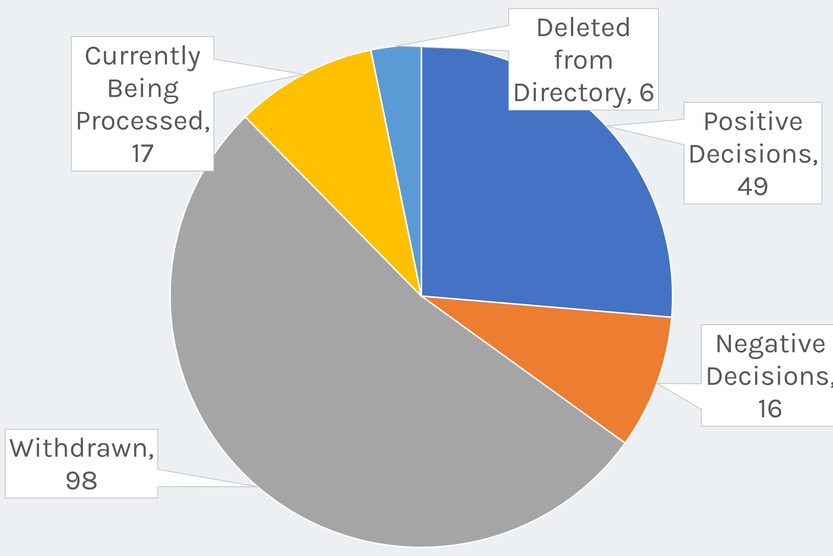

Figure 1. Current Results of BfArM Assessments (updated on 04/10/23)

Of the 186 DiGA assessments to date, 6 have been deleted from the directory. One was due to inability to complete planned trials, three were from lack of positive care effect, and two were following manufacturer request. The 3 DiGAs unable to prove positive care effects were for a breast cancer app, a stroke recovery app and a panic disorder app. Given the diverse nature of these applications, it is clear that provisional listing into the DiGA directory does not correlate to final listing, and manufacturers must prove the positive care effect upon provisional listing onto the DiGA directory.

Further analysis of DiGAs that are listed as final in the directory reveals that all 26 are produced by German companies, solidifying German placement within the DiGA landscape, as well as establishing growth of the DiGA space within Germany. Out of 26 final listed DiGAs, 13 are apps, 12 are web applications, and 1 is a combination of both, showing a lack of preference towards a particular platform for DHTs.

The largest proportion of DiGAs are available for mental health disorders, such as depression, anxiety and stress; almost 50% of final listed DiGAs fall under this category. It is also seen that final listed DiGA trials are exclusively RCTs (Randomised Controlled Trials), in which there will be a group using the DHT, and a group treated with standard of care. Depending on the category of the DHT, the standard of care may mean some patients do not receive any treatment, whilst others (particularly in the depression category) may continue an antidepressant regimen. All trials were conducted in Germany as stipulated in the DiGA approval process document. Germany requiring trials to be conducted in the country helps strengthen DHT use in Germany, as prescribers know that data collected by DHTs are relevant to their patient population. Whilst studies must be conducted in Germany, manufacturers can publish their data with a non-German public study registry helping manufacturers gain recognition internationally, if desired.

DiGA assessment accepts universally approved criteria to demonstrate positive care effect. Examples include PHQ-9 for depression, VAS for pain reduction studies. By using established and indication-specific scales, treatment effect may be more robustly demonstrated, and in a way that is patient-relevant, increasing payer acceptance of effect.

Whilst the majority of final listed DHTs are priced in the €200- €300 range per course, some exceptions exist, namely in the mental health and muscle/bone/joint (MBJ) groups. The average cost for each subgroup is €302 and €382 respectively. Both make up over 70% of final listed DHTs, showing that manufacturers and the German health system see great value in DHTs in these therapy areas. There are 5 final listed DHTs in the directory with an initial course of therapy price above €500; three are for mental health indications, and two for MBJ. For these DHTs, we see a minimum of 4 total primary and secondary endpoints measured, depicting the high burden of proof to justify higher pricing within the directory.

It is important to know the difference in price between provisionally listed prices and final listed ones. Looking at the 23 provisionally listed DHT prices, we see that the lowest price is set at €290, and the highest is at over €2,000. As was with the AMNOG procedure, manufacturers are allowed to price freely for the first year of being published, and in the 13th month, they must negotiate a price with GKV-SV. Evidence suggests that manufacturers must be prepared to accept a significant price reduction upon final approval, which is determined by proving the a DHTs positive care effect. Adding further endpoints aside from a sole primary goal has been proven to warrant higher starter prices, as shown by the higher-cost, final listed DHTs.

These treatments' typical initial course timeline ranges between 12 weeks and 3 months, which is much shorter than many of the clinical trials cited by current DHTs. It is clear that the GKV-SV is not prepared to allow for elongated usage in case a positive effect is not seen quickly, showing need for near-instant results through DHT use.

CONCLUSIONS

Digital applications must be evidence-based and guideline-compliant. In addition to showing an overall positive healthcare effect to optimise P&R negotiations, DHTs must ensure regulatory, privacy, and user-friendliness requirements are aptly met.

Germany introduced its DiGA program to help stimulate the creation of new DHTs and help improve access to resources for patients. The program has not only improved access to new technologies but has also caused an influx of new manufacturers rising within the space, further promising that DiGA will continue to be a success for years to come. Manufacturers can be assured that Germany will continue to support DHT service providers, and with the consistent growth of the DiGA program, Germany is primed to continue its position as a leader in the digital health technology age.

REFERENCES/ETC

1. Germany Government Website. https://diga.bfarm.de/de/verzeichnis (last accessed October 2023)
2. Germany Government Website. https://www.bfarm.de/SharedDocs/Downloads/EN/MedicalDevices/DiGA_Guide.pdf?__blob=publicationFile (last accessed October 2023)

Author contact details: **Mitun Patel** - Director, Market Access & Commercialisation Services - mpatel@rednucleus.com