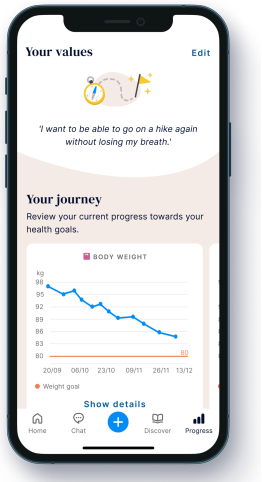
Case study

Oviva: Leveraged UK data in Germany

About Oviva

Oviva combines personalized dietary guidance with a digital app to support patients with weight-related diseases adopting healthy behaviors.

Relevant product: Oviva Direkt for Obesity is a scientifically validated, app-based therapy for individuals with obesity (BMI between 30-40). In October 2021, it was successfully included in the Digital Health Application (DiGA) directory of the Federal Institute for Drugs and Medical Devices (BfArM).



Background

Although nearly 25% of German adults are affected by obesity, DiGA provides the only patient treatment option that is reimbursable.

Strategy & approach

- After a pre-submission consultation with BfArM, Oviva successfully leveraged data from the United Kingdom (UK) for a preliminary DiGA listing of Oviva Direkt for Obesity in 2021.
- To achieve permanent listing in 2023, product effectiveness was validated through a German randomized controlled trial (RCT) by the Technical University of Munich.

National engagement

- Despite 55 products listed in the DiGA directory (as of October 2024), Ovivia represents the only case where preliminary data from another country was accepted by BfArM.
- Since then, Oviva has proposed using similar types of evidence generated outside of Germany in formal BfArM advice meetings regarding other indications, but this approach has not been accepted again.

Key takeaways

- ✔ Even if core national regulations do not change, agency requirements and practices can evolve.
- ✔ Developers need to rely on formal agency advice meetings to develop trial methodology.
- ✔ Conclusions from experiences with other products in different indications should be drawn with caution.

> "Given the evolving requirements, it is crucial to seek case-by-case guidance from the relevant authorities."
>
> **— Lucy Jones**
> *Chief Clinical Officer, Oviva*