Case study

WELT: Navigating clinical trial comparators

About WELT

WELT leverages data and insights collected via its digital biomarkers platform to develop digital therapeutics that deliver personalized, guideline-recommended therapies to manage, treat, and prevent various diseases and disorders.

Relevant product: SleepQ leverages digital biomarkers and cognitive behavioral therapy for insomnia (CBT-i). It received regulatory approval in April 2023 and is commercially available in South Korea, with plans for expansion into the German market.

Background

- In South Korea and Germany, clinical trial comparator requirements differ across agencies.
- Regulatory bodies typically expect a randomized, sham-controlled trial to demonstrate safety and efficacy.
- Whereas, Health Technology Assessment (HTA) agencies typically expect the comparator to be the national standard of care.

Strategy & approach

- Without clearly published comparator expectations, WELT is engaging directly with the government in South Korea and with consultants in Germany to better understand expectations.
- They aim to identify study components that can be translated across both countries or conduct a smaller-scale trial in one country if a full trial is successfully completed and recognized in the other.

National engagement

- WELT hopes for further harmonization in how “standard of care” is defined within and across jurisdictions, particularly for the indications they focus on.
- This task is complicated by differences in what is considered standard treatment, as well as variations between clinical practice guidelines and typical care delivery practices.

Key takeaways

- ✔ Developers benefit from discussions with government agencies to identify and finalize trial designs.
- ✔ Well-defined and broadly accepted measures are key to enabling greater applicability of comparators.
- ✔ Differences in recommended clinical guidelines versus real-world practices can highlight unmet needs.

> “Variations in the definitions of ‘standard care’ and ‘treatment as usual’ present challenges when seeking to apply clinical evidence across countries.”
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> **— Yujin Lee, MD**
> *Chief Medical Officer, WELT*