Sleep architecture exhibits unique electroencephalogram (EEG) signatures that can aid diagnosis of narcolepsy type 1 (NT1).

In-lab polysomnography (PSG) remains the only accepted approach to determining sleep architecture; however, multiple nights of PSG are required to elucidate treatment effects.

The validation of a user-friendly device that can be used at home would reduce the burden and cost of obtaining PSGs in large-scale clinical studies.

We conducted a multi-center study to assess the agreement between an at-home EEG device and in-lab PSG to better measures sleep.

Our whole team used DiMe's V3 Framework to collaborate on this study, including the clinical team, the CRO, the device vendors, and the digital device SME.

We used the clinical validation framework as a guide for how to structure the study, what measurements to capture and how to compare the results from both devices.

Patients with NT1 underwent two nights of in-lab PSG while also wearing a wrist accelerometer, a high-resolution heart rate monitor, and making daily diary entries at home for 5 days to determine agreement between devices.

The V3 framework provided a justification for why the study should be conducted in the first place to validate the digital tool.

Validation of a novel device intended for remote clinical monitoring is essential to determine if the device is fit-for-purpose for the specific patient population.

— Ariel Dowling, Director of Digital Strategy, Takeda

Takeda is the largest pharmaceutical company in Asia and one of the top 20 largest pharmaceutical companies in the world.

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