

Sleep-wake disorders are a key disease area of focus for <u>Takeda Pharmaceuticals</u>, which aims to bring innovative and potentially disease-modifying medicines to individuals with these disorders.

Including napping in the core measures set is invaluable to those wishing to study sleep disorders outside typical lab conditions whether intentional or not, daytime napping is a key marker of excessive daytime sleepiness and a meaningful outcome for patients.

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The opportunity

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- Central disorders of hypersomnolence are characterized by excessive daytime sleepiness (EDS) and disrupted nighttime sleep (DNS).
- Takeda is conducting clinical trials to investigate EDS and DNS in these disorders and is committed to developing novel digital biomarkers to identify EDS and DNS symptoms.

The impact 📋

- Daytime nap detection from digital wearable devices may enable the objective quantification of EDS in patients with central disorders of hypersomnolence.
- Takeda is developing a novel nap detection algorithm using actigraphy data to quantify daytime napping events objectively. The algorithm draws on identifying total napping time as a core digital measure of sleep and daytime sleepiness as a key symptom.





- The <u>Core Digital Measures of Sleep</u> provide key support to developing novel digital biomarkers for sleep-wake disorders, including central disorders of hypersomnolence.
- Drawing on patient voices, the Conceptual Model identifies clinically relevant symptoms for measurement in clinical trials, including daytime sleepiness and unplanned daytime sleeping.
- The industry-leading ontology from the Core Digital Measures of Sleep provides an essential framework for developing new ways to measure clinically relevant symptoms.
- The formal definition of total napping time as a core measure reinforces the importance of developing novel digital tools for measuring EDS.

