

Bayer Pharmaceuticals' development portfolio often raises the question of sleep assessment as an important quality-of-life pillar of patients' health, which can be positively affected by the new therapies.

Sleep is being increasingly recognized as a critical aspect of health. Sleep disturbances are often seen as symptoms of underlying chronic conditions. We viewed the Core Measures of Sleep project as an opportunity to unite resources on a pre-competitive basis and present the case for the development of novel digital endpoints for assessing sleep function. A pharmaceutical trial endpoint is not just a measurement, it is a clinically validated development tool.

- Michael Kremliovsky

Sr. Director, Medical Devices & eHealth, Baver

The opportunity



- Bayer's partner companies, BlueRock and AskBio, are developing novel cell and gene therapies to treat Parkinson's disease (PD). The therapies, which are hoped to produce lasting effects, will significantly improve patients' lives.
- Many patients with PD experience changes in their sleep quality as the disease progresses. Quantifying the changes and showing positive long-term effects of the cure can be an important measure of therapeutic success.

The impact



- The Core Digital Measures of Sleep allow Bayer to draw on the knowledge of relevant aspects of patient health arising from the conceptual model of sleep disturbances.
- Cataloging sleep monitoring technologies within the Core Digital Measures of Sleep system gives Bayer a basis for measuring sleep in PD patients longitudinally in real-life settings, allowing the development of a relevant biomarker for the disease progression.

The resources



- The Core Digital Measures of Sleep project developed a conceptual model highlighting the meaningful aspects of health that are important to patients.
- Bayer chose the Core Digital Measures of Sleep based on clinical and patient relevance and technological maturity in collecting the necessary data.
- The sleep measurement system describes the underlying variables in the core measures and heavily focuses on sleep staging and the evidence needed to offer a transparent account of sleep measurements. As evidenced by ongoing clinical studies, the system also allows Bayer to select clinical measures outside the defined Core Digital Measures specific to their needs.



