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Assessing Sleep and Wakefulness in Health and Diseases

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The relationship between sleep quality and a person's cognitive function cannot be underestimated. Sleep is an important period for our brains to consolidate memories, process information, and have the capacity to focus and learn throughout the day, partly due to sleep allowing the repair of cellular damage. People who sleep well show better-sustained attention, faster reaction times, fewer fluctuations in their ability to focus, and better emotional regulation, leading to clearer decision-making. It is also true that good sleep hygiene can optimize our cognitive function during daily activities and reduce age-related cognitive decline and the risk of developing cognitive disorders.

Objective assessment of sleep or wakefulness is critical since these are disrupted in many psychiatric, neurological, and non-central nervous system diseases. Moreover, drugs developed to address sleep issues like insomnia may have an unwanted prolonged effect (i.e., a next-day residual effect) and, therefore, impact patient safety.

While many sleep-related patient-reported outcomes or observer-reported outcomes are generally used in clinical trials, these are subjective by nature and may not have the ability to detect small, clinically relevant effects. Objective measurements of a patient's wakefulness are therefore of importance and can be achieved by using performance-based outcomes that are sensitive to change.

The number of hours a person sleeps has an important relationship with the quality of their cognitive function. Lack of sleep impacts various cognitive domains[1] with attention and vigilance being the most affected measures, as reaction time slows down[3]. Given this, there is a valuable place for computerized cognitive assessment batteries being used in such studies, and more specifically attentional tasks, are suitable tools enabling objective assessment of sleep and wakefulness.

CDR System Case Study 1: Efficacy of Armodafinil

The CDR system has been extensively involved in the assessment of armodafinil during its clinical development. A first study in healthy volunteers submitted to a 24-hour sleep deprivation paradigm established that armodafinil alongside its racemate Provigil® prevented the sleep deprivation-induced decrease in Speed of Attention[3].

Following this successful trial, the efficacy of armodafinil was subsequently assessed using the CDR System in participants with narcolpesy[4], shift work disorder[5], and obstructive sleep apnea[6,7]. Since the attentional module of the CDR System has been and still is used in clinical trials specifically aiming at alleviating excessive daytime sleepiness symptoms observed in many diseases.

CDR System Case Study 2: Next-day residual effect of Gaboxadol

The proven high sensitivity of the CDR System allowed for the detection of subtle changes in wakefulness following drug treatments in many insomnia trials[8,9], and in particular, showed that the selective GABA A agonist Gaboxadol was deprived of residual effect the next morning after taking the medication[10]. The attentional module of the CDR System is a proven and fit-to-purpose tool to assess the residual effects of study drugs developed to improve sleep in patients with insomnia.

Summary

Objective measurement of sleep and wakefulness can be gathered by using brief computerized attentional tasks, offering a detailed understanding of the safety or efficacy of investigational drugs.

As drug developers strive to bring new therapies to market, the judicious use of these assessments early in the development process can provide critical information for decision-making, ultimately contributing to safer and more effective treatments for patients.

Selecting an effective computerized attentional processes test solution

Effective computerized Attentional processes assessment solutions should provide specific capabilities to fulfill their objectives. They should:

- Be brief and simple to administer, yet highly sensitive
- Allow for testing at multiple time points to establish relationships with other PK and PD measures without inducing practice/ learning effects
- Demonstrate good test-retest reliability, as well as bi-directional sensitivity
- Be available in multiple language versions
- Not be cost-prohibitive

Signant Health's CDR System® attentional tasks module: A computerized attentional processes assessment solution

The Signant SmartSignals® CDR System®, backed by 40 years of validation data, is a comprehensive and proven solution for cognitive assessment across all phases of clinical trials. Well-received by volunteers, patients, and clinicians, the CDR System can be seamlessly integrated into any phase of the drug development process without requiring additional volunteers, extending trial duration, or needing specialized units or staff.

Its 7-minute Attentional tasks module, widely used in clinical trials, takes just seven minutes and assesses information processing speed, attention and vigilance through three tasks: simple reaction time, digit vigilance, and choice reaction time. This provides sponsors with signals to guide either efficacy for drug aiming at improving wakefulness or safety for drug aiming at improving sleep.

EXPLORE SIGNANT SMARTSIGNALS® CDR SYSTEM®, BACKED BY 40 YEARS OF VALIDATION DATA.

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