



International Society for CNS Clinical Trials and Methodology

Sleep Methodology in CNS Trials Working Group

Friday 13 September 2024

Chairs: Margaret Moline & Georg Dorffner

Disclosures

Georg Dorffner: Shareholder and part-time employee of The Siesta Group Schlafanalyse GmbH

Margaret Moline: full-time employee of Eisai, Inc.

Original foci of the Working Group

- A critical assessment of various modalities for characterizing sleep, wakefulness and related states and for assessing the impact of clinical trial interventions for different sleep disorders.
 - This includes an analysis of alternative methods of measuring sleep and wakefulness and their potential applicability in CNS trials.
- Criteria for proper validation of such methods against the gold standard
- The relationship of objective methods of measurement with subjective assessments of sleep and wakefulness and the exploitation thereof
- Necessary activities to achieve acceptance for alternative instruments by regulatory bodies

Potential Deliverables

1. Systematic reviews on the evidence of the reliability and validity of different instruments for measuring sleep and wakefulness
2. A consensus paper on criteria and validation strategies for measurement modalities
3. Regulatory engagement with FDA
4. The initiation of a pre-competitive study with industry participation aimed at benchmarking certain instruments for their use in CNS trials

First step 2024:

Sleep biomarkers for CNS disorders

- What are the main sleep endpoints used in research on different CNS disorders (neurologic, psychiatric)(e.g. WASO, sleep efficiency, sleep latency, REM density, spindle distribution, etc.)
- Input gathered via online Excel Sheet

Agenda for today

- Review of entries collected
- What are we still missing?
- What necessary next steps would make impact?

Future step: validation of measurement devices