



International Society for CNS Clinical Trials and Methodology

Sleep Working Group

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Amsterdam

Chairs: Margaret Moline & Georg Dorffner

Major Contributor: David McLaughlin

Disclosures

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

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

David McLaughlin: Owner of Cerebral Innovations

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

Deliverables:

1. Review paper on the current evidence for objective sleep endpoints as biomarkers for neurological or psychiatric disorders in CNS trials
2. A consensus paper on criteria and validation strategies for measurement instruments, as compared to gold standard (PSG)

Agenda

- Review of contributions to Deliverable 1
 - Results of AI evaluation
 - Determination of gaps
- Agreement on next steps and timelines for Deliverable 1
- Discussion on Deliverable 2: Validation methods