

ISCTM Working Group “Sleep Methodology in Clinical Trials”

13 Sept 2024, San Diego, CA

Chairs: Margaret Moline, Georg Dorffner

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The original goals and potential deliverables of the working group were again introduced. Then, the results of the first exercise – filling in evidence for sleep-endpoints in different neurological and psychiatric disorders using an Excel sheet in the cloud – were reviewed and discussed. The following arguments were put forward:

- It needed to be clarified that the focus was on variables – hence the term “endpoints” – not phenotypes or other aspects of sleep
- The ultimate result of the ongoing exercise – a consensus for the proper validation of novel instruments for measuring the collected endpoints – are actually disorder-agnostic
- This led to the observation that a second paper – a review on sleep endpoints in different disorders – could be another deliverable of the WG
- Other aspects – such as nightmares in PTSD – were raised, but the consensus was that we focus on what today can be measured by PSG (as the gold standard method any instrument will have to be validated against).
- Similarly, the consensus was that for now we focus on objective measures, leaving out self-assessments or scales
- Additionally, the focus at first should be on assessment of nocturnal sleep. Daytime/napping sleep would be a topic for the future.

The next steps are therefore:

- A continuation of the exercise of filling the Excel sheet. Every participant of the WG is motivated to add new entries. Those who are new to the WG will be also granted access. Deadline: mid-November
- An online meeting will be held in early December
- After that, the second step – an Excel sheet collecting evidence for different validation methods – will be initiated.
- The results of the second step will be discussed in a (potentially hybrid) meeting in February in DC.