

ISCTM Working Group „Sleep Methodology in Clinical Trials“

Kickoff meeting, Feb 23, 2024, Washington, DC

Chairs: Margaret Moline, Georg Dorffner

Participants: Gary Zammit, Jacob Donoghue, Jontahon Parker, Adam Savitz, Martin Dunbar, Seth Hopkins, Alan Lipschitz, Remy Luthringer, Bronagh McCoy, Jean Daphney, Meagan Farrell, Peter Sorantin

The main ideas of the working group and its goals and deliverables aimed at were presented (see attachment).

A quite diverse discussion ensued including, among others, the following arguments:

- Perhaps the focus should be more on daytime functioning (as a result of good/bad sleep) than nocturnal sleep itself, or circadian rhythms
 - Need to determine which aspects of sleep architecture are associated with ratings of restorative sleep
 - Mapping cognitive measures to objective measures
- Sleep is a part of a set of exploration tools, and we need 24-hour portable tools for measuring it
- Devices should be applicable to pediatric sleep and daytime assessment
- We need to understand how sleep or sleep subtypes can predict aspects of disease
- We have no good sense of what is sleep quality
- We need more insights into real world data
- We need to measure in a patient's home environment but taking potential confounders into account, such as spouse, pets, television, etc
- The patient's view is also important
- Cost as a factor

Despite diverging opinions a first consensus was reached:

- We need an organizing principle and look at what needs to be measured (macrostructure, microstructure, etc.) for investigating certain disorders. This could be the focus of paper 1.
 - For example, for some disorders, WASO could be sufficient, but for others, sleep architecture may be important
 - Is the treatment for which the method would be used disease modifying or symptomatic?
- Then we should look at which technology can be used to measure what is important and focus on how this needs to be validated. This could be the focus of paper 2.

Next meetings:

- Mid to end April, Online
- At Sleep 2024, Houston (June 1-5), in person