

White Paper

# Measuring Real-World Sleep with Actigraphy: Three Clinical Trial Use Cases



# Measuring Real-World Sleep with Actigraphy: Three ActiGraph Use Cases

Disturbed or impaired sleep has been the subject of increased research attention in recent years, as both a primary disorder and in cases where disturbed sleep is a symptom of another disease. Disturbed sleep is common in people with arthritis, atopic dermatitis, Alzheimer's Disease, Parkinson's Disease, and many other conditions. Research is focused on measuring and diagnosing these sleep disorders, as well as the development of new treatments to improve sleep across a broad range of indications. Wearable devices provide a low-burden and remote approach to objectively quantify people's sleep in their real life, often revealing meaningful insights that might not be available with polysomnography or selfreport data. While sleep architecture and sleep staging are difficult to estimate with accelerometry alone, actigraphy is sensitive to treatment effects in previous studies of sleep disorders.<sup>1</sup>



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# Use Case 1: Measuring Sleep in Rheumatoid Arthritis

More than 80% of people with rheumatoid arthritis (RA) report fatigue as part of their symptoms.<sup>2</sup> While most interventions are focused on reduction in pain, impaired sleep is an important indicator of disease severity and treatment effect. In studies with primary pain endpoints, actigraphy-derived sleep endpoints can help more fully characterize the participant's experience. With continuous day and night wear periods, additional daily measures of physical activity can also be measured.

- In previous studies of rheumatoid arthritis, ActiGraph devices have shown high sensitivity and specificity for classification of sedentary time, light intensity, and moderate intensity physical activity.<sup>3</sup>
- In a current Phase 2 global RA trial, an ActiGraph CentrePoint Insight Watch is being used to measure total sleep time (TST), wake after sleep onset (WASO), and daily step counts as exploratory measures.



# Use Case 2: Detecting Impaired Sleep in Patients with Neurodegenerative Diseases

Cognitive and functional decline are typical endpoints in neurodegenerative disorders. Sleep disturbances are the second most frequent nonmotor complaints among people with Parkinson's disease.<sup>4</sup> Those with Alzheimer's Disease have a higher prevalence of sleep disorders and behavioral disturbances than healthy elderly adults.<sup>5</sup> Actigraphy has been shown to be an appropriate method to examine sleep disorders in dementia patients.<sup>6</sup> Past studies have shown correlation between actigraphy measures can be valid predictors of tau pathology with potential clinical use.<sup>7</sup>



- Actigraphy-derived sleep measures detected significant treatment responses to a novel brain stimulation therapy in a recent PhI/II RCT study, corroborating improvements in Activity of Daily Living.<sup>8</sup>
- Walking speed and stride length have both been shown to be impacted in patients with dementia.<sup>9</sup> With continuous day and night wear periods, additional measures of gait and walking speed can also be collected.
- In a recent Phase 2 global study of patients with dementia, researchers used an ActiGraph GT9X to track movement counts during sleep.

# Use Case 3: Assess Treatment Efficacy in Chronic Insomnia

One of the most common sleep disorders is insomnia, characterized by the recurring difficulty to fall or remain asleep despite motivation and means to do so. Most adults experience insomnia at some point of their lives, but when people exhibit symptoms at least three times per week for at least three months, insomnia is considered a chronic condition and clinical interventions might be necessary.

• The ActiGraph GT9X was used in a recent Phase 2 study to assess the efficacy of medicinal cannabis on treating chronic insomnia.<sup>10</sup> Actigraphy measures of total sleep time and sleep efficiency detected significant and substantial improvements associated with the treatment, corroborating self-reported sleep diary. On the other hand, polysomnography did not detect treatment effects, potentially due to the infrequency and laboratory setup of the assessments.



# Compliance

Past studies have reported good compliance when using ActiGraph devices for collecting sleep measures in clinical trials. Participant compliance as high as 95% has been shown with wrist-worn device data collection wear periods.<sup>11</sup> ActiGraph devices are easy to use, and every site and participant is trained on how to operate the device during a trial. CentrePoint, ActiGraph's software ecosystem, allows for near real-time monitoring of compliance and wear periods.



#### Actigraphy-Derived Sleep Measures

Commonly used sleep measures	Additional measures
Sleep latency (SL)	Awakenings: length, number
Total sleep time (TST)	Fragmentation
Wake after sleep onset (WASO)	Disruptive sleep identification*
Sleep efficiency (SE; SE = TST/time in bed)	Nocturnal scratch*
Circadian rhythms: sleep onset/offset	Daytime sleep*

\* Work in Progress



### End-to-End Data Transparency

ActiGraph's fully transparent system relies on proven, open-source algorithms developed by the scientific community to generate meaningful, reliable measures. Full access to **"future-proof"** raw sensor data means that new and more sophisticated sleep algorithms and analysis techniques can be applied to collected data as they emerge. Trial sponsors are able maintain data comparability across phases and studies and derive the highest quality outcomes, now and in the future.

## Experience

The ActiGraph platform has been used to measure sleep in dozens of indications across a broad range of therapeutic areas. ActiGraph devices have been used to measure sleep endpoints in more than 50 Phase 2 and Phase 3 industry-sponsored clinical trials since 2015.

#### **Therapeutic Areas**

Neurology • Oncology • Psychiatry • Respiratory • Rheumatology & Immunology

#### Indications

Anemia • Angelman Syndrome • Arthritis • Asthma • Celiac Disease Chronic Obstructive Pulmonary Disease (COPD) • Cystic Fibrosis Duchenne Muscular Dystrophy • Endometriosis • Narcolepsy • Lung Cancer Lupus Erythematosus • Painful Diabetic Neuropathy • Sickle Cell Disease Sleep Apnea • Systemic Sjogren's Syndrome

Are you interested in learning more about how actigraphy-derived sleep measures can enhance your clinical development program? Contact us to speak with a member of our team.



### References

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### ActiGraph.

ActiGraph is pioneering the digital transformation of clinical research. We provide end-to-end digital health technology (DHT) solutions by integrating and operationalizing the best hardware, software, and algorithms to generate reliable evidence and get the right treatments to the right patients, faster. ActiGraph's medical-grade wearable technology platform has been used to capture real-world, continuous digital measures of activity, sleep, and mobility for nearly 250 industry-sponsored clinical trials and thousands of academic research studies. Appearing in over 22,000 published scientific papers to date, ActiGraph is the most experienced and trusted wearable technology partner in the industry.