Clinical Trial

Sample Use Cases

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ActiGraph activity monitoring hardware and software products have been used in numerous global clinical drug trials and observational academic research studies. These sample use cases demonstrate how ActiGraph solutions have been deployed to deliver objective activity and sleep endpoints in trials of varying phases, sizes, and patient populations.

1

Use Case

ActiGraph's activity monitoring system was selected for a Phase II trial studying the efficacy and safety of an investigational therapy for a chronic, inherited neuromuscular disease in male and female subjects aged 12-45 years. Subjects were monitored for a period of 7 consecutive days at screening, baseline, dosing, and follow up. The ActiGraph system provided secondary endpoints of daily bouts of activity, steps taken, and energy expenditure. Investigators analyzed the percent change in these endpoints from baseline to follow up.

2

Use Case

ActiGraph's activity monitoring system was used in a Phase IIa trial studying the efficacy of an experimental treatment against a placebo in COPD patients. The trial was conducted at 56 sites in 5 countries with over 200 participants. Subjects were asked to wear ActiGraph activity monitors 24 hours a day during four 2-week periods at baseline, treatment, and follow up. Investigators examined changes in physical activity and sleep behavior throughout the course of the trial.

3

Use Case

ActiGraph's activity monitoring system was used during a Phase I trial examining the effects of an experimental treatment on 90 otherwise healthy adults with a muscle wasting disease. The aim of the trial was to determine whether the drug was responsible for any increase in muscle mass or decrease in muscle wasting. The ActiGraph system was used to verify that subjects met the inclusion/exclusion criteria by remaining sedentary throughout the study, thus meaning that any muscle increase was a direct reflection of the drug and not an increase in physical activity.

For this trial, ActiGraph retained a world-renowned subject matter expert to develop and validate a set of activity threshold cutpoints specifically for this population and provide consultation and data interpretation support throughout the project.

4

Use Case

ActiGraph's activity monitoring system is being used in a Phase II study on 1500 subjects with late stage lung cancer. Over 350 participants in a specific study arm wore ActiGraph devices for 24 hours/day for 7 consecutive days at baseline, at dosing, and at follow up. ActiGraph data is being used to quantify increases in physical activity and sleep efficiency after each dosing period. These data are then compared to a group receiving standard therapy (chemotherapy), with the aim of supporting the hypothesis that this experimental drug allows for a faster recovery time after dosing.

5

Use Case

ActiGraph's activity monitoring system was used in a Phase II trial on 270 Osteoarthritis patients across 90 clinical sites. During this 12-month study, subjects wore activity monitors during 5 2-week periods through screening, baseline, dosing and follow-up. Investigators looked for increases in daily physical activity from baseline in subjects receiving the experimental treatment as compared to those receiving the standard therapy for pain.

6

Use Case

ActiGraph's activity monitoring system was selected for use in an observational study to collect baseline and longitudinal physical activity data in approximately 25 pediatric patients with Duchenne Muscular Dystrophy (DMD). During this 12-month study, subjects wear the activity monitor during daytime hours for 7 consecutive days every month. After each wear period, the patient's caregiver or guardian uploads the data remotely via mobile device and/or home computer. The study team reviews this data at regular intervals to verify wear compliance and assess subject activity levels.