

Summary of Statistical Review Findings

The sponsor presents data from 4 clinical studies. One was a pilot study utilizing 10 unimpaired, non-wheelchair users and 4 expert manual wheelchair users with spinal cord injury, to gain experience with the IBOT at home and in the community. The second was another pilot study of 4 impaired veterans who used the IBOT in the work environment. Third was a 98 subject study of the IBOT in a controlled environment. The fourth, and only study which utilized the current version of the device in a real-world setting, and trained the participants in the manner they will be trained when the device is marketed, is considered the Pivotal Trial. It consisted of 20 subjects: 2 pilot cases, 6 skilled manual wheelchair users, 6 slow manual wheelchair users, and 6 power wheelchair users. Each Pilot Trial subject spent one week in their own device, and one week in the investigational device. Each Real World Trial subject spent two weeks in their own device and two weeks in the investigational device. At the end of the trial the subjects were given the Community Driving Test, consisting of 15 tasks one would encounter in everyday life, scored on a 7-point scale. This was the primary efficacy endpoint. Adverse events, device failures/replacements, accessibility problems, and mechanical/operational problems were all recorded.

Comments:

The sponsor used appropriate statistical techniques for each patient serving as his/her own control. In spite of the small sample size, the Wilcoxon Signed Rank Test (the non-parametric version of the paired-t test) showed a statistically significant difference in favor of the IBOT for 12 of the 15 tasks. The 3 where there was no difference were tasks which could easily be handled by a manual wheelchair (e.g., cross street with curb cut).

The Community Driving Test was always administered first using the subject's own device, and then the IBOT. Thus, there is a degree of familiarity with the course when the IBOT is used, which may or may not contribute to the perception of ease or higher scores. Given the dramatic results, however, I don't think this bias is significant.

The sponsor chose the participants very carefully, as the protocol called for the replacement of those participants who were not able to perform in all of the modes. The resultant group was destined to be "successes". Normally, this kind of "pick the winner" mentality is not allowed in clinical trials. However, it appears the sponsor selected the participants in the same way as would be done post-market. As long as the labeling reflects this, it should be okay.

Seven of the 20 subjects had 1 or more protocol deviations during the trial. Most of these had to do with not returning in the allotted time frame for DAY 2 training, having the device more than the 2 weeks before returning for testing, or not being contacted for the daily activity logs. In the broad scope of things, I would consider these deviations minor and inflict little bias on the primary efficacy endpoint.

The safety profile seemed acceptable, but should be evaluated from a clinical/engineering perspective. There cannot be any statistical analysis of safety issues with this device because there were so few. Some mishaps (e.g., falls) that happened were due to operator error and the sponsor will address it in the labeling. I assume these risky behaviors will be pointed out in the training program.

In summary, the sponsor has shown a highly statistically significant preference for the IBOT as compared to the subject's own device irrespective of whether the subject was a skilled or slow manual wheelchair user or a power user. The only negative comments were that the device may be less maneuverable in the confines of the home because of its size and seat height, and that it was more difficult to load in a van. However, it would seem to me that the benefits out in the real world would outweigh those inconveniences, especially since the user can always use a manual wheelchair while they are at home and switch to the IBOT when going out. Because efficacy is so "observable", I believe that evaluation of this device should focus on the engineering and human factors issues.