

# AN ENHANCED COMPREHENSIVE TRAINING PROGRAM FOR THE SEVERE IMPAIRMENT BATTERY (SIB)

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## ABSTRACT

The Severe Impairment Battery (SIB; Saxton et al., 1990) is the most widely used psychometrically validated instrument for assessing cognitive and behavioral changes in clinical trial subjects with moderate to severe and severe Alzheimer’s disease (AD) (Mecocci et al., 2009; Suh & Kang, 2006; Wild & Kaye, 1998). However, there is a critical scarcity of site raters with experience administering this scale as compared to other AD scales used in the more common mild to moderate trials. A survey conducted by the authors of this poster revealed that 47% of experienced AD raters had no experience administering this scale. This finding becomes understandable given that between 2003 and 2015, per a review of clinicaltrials.gov studies by this poster’s authors, only 10 moderate to severe and severe AD trials were found using the SIB as an outcome measure versus over 130 mild to moderate AD trials which did not use the SIB. These results indicate that

research studies using the SIB as their primary efficacy variable may be ill equipped to detect changes, especially considering that the SIB is a complex scale with intricate administration requirements. Since scale experience and training are essential in accurately administering scales (Kobak et al., 2004), a comprehensive training program which provides raters with enhanced SIB administration experience is required similar to other trials in which complex neuropsychological assessments are mandated. The current poster describes a rater training program implemented in an industry sponsored interventional clinical trial using the SIB as the primary outcome measure. The training was provided to over 70 SIB study raters and involved didactics on SIB administration and scoring conventions, preparatory pre-Investigators’ Meeting training, multiple optional practice sessions, video illustrations of standard administrations, and applied skills evaluations to

assess the efficacy of the training. This poster details how the combination of these training methodologies provides a unique, enriched process to ensure SIB conventions are followed. Of the 70 SIB study raters trained using this comprehensive training program, only two (2) SIB raters (3%) required remediation following their Applied Skills Evaluation. In addition, of the 86 total SIB scale source reviews completed to date, zero (0) raters have required re-training/remediation on the SIB administration and scoring conventions. It is clearly demonstrated, based on this data, that a comprehensive training program like the one detailed below significantly reduces the number of raters requiring additional follow-up and/or remediation.

## THE SIB ENRICHED TRAINING PROGRAM WAS COMPREHENSIVE AND CONSISTED OF THE FOLLOWING STEPS:

APPROVED  
RATERS

### DIDACTIC SLIDES

- PowerPoint presentation on the SIB administration and scoring conventions.
- The purpose was to enhance raters’ knowledge and ability to administer and score the SIB by providing SIB-related Protocol guidelines and administration and scoring conventions.

### ADMINISTRATION VIDEO REVIEW

- Raters were asked to follow along and score the 2 videos using SIB materials.
- The purpose was to enhance raters’ knowledge and ability to administer and score the SIB by observing it administered by a trained clinician to a mock patient.

### “GOLD STANDARD” SCORE REVIEW

- Correct/gold standard scoring for the 2 videos mentioned at left.
- Raters were asked to review the gold standard scores and compare to their individual scores. The gold standard scores were derived from expert clinicians’ scores.

### OPTIONAL SIBPRACTICE SESSION

- Available to the SIB raters in attendance at the IM.
- Raters were split into small groups and took turns administering the SIB scale on mock patients and received immediate feedback from trained clinicians.

### SUGGESTED ON- SITE PRACTICE

- The raters were encouraged to practice as much as they needed (with a colleague) in order to feel comfortable administering the SIB scale.

### APPLIED SKILLS ASSESSMENT (ASA)

- All SIB raters were required to complete an ASA with a mock patient.
- Immediate feedback was provided to the rater by the trained clinician via email. A pass/fail status was also provided to the rater. If a rater failed the initial ASA, he/she was able to provide a second submission.

CERTIFIED  
RATERS