An Enhanced Comprehensive Training Program for the Severe Impairment Battery (SIB)

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NOTE: The below abstract does not employ the ISCTM abstract sections because the proposed poster is not based on empirical data. However, the authors believe the poster topic is crucial for this conference given that the Severe Impairment Battery, the most commonly used primary measure to assess moderate to severe Alzheimer's disease in clinical trials, has historically been administered by site raters with minimal to no experience conducting this intricate scale - the current poster provides a comprehensive training program recommendation implemented in an industry sponsored interventional clinical trial.

The Methodological Question Being Addressed: how can site raters with minimal to no experience administering the Severe Impairment Battery receive comprehensive, efficient, evaluative, and sponsor-approved training on this complex scale?

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) (Mecoccil et al., 2009). However, there is a critical scarcity of research 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 raters whom AD sites recommended to administer the SIB 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. The poster will detail how the combination of these training methodologies illustrates a unique, enriched process to ensure SIB conventions are followed. The poster will also explain how these training procedures can be implemented across cost-conscious programs and extrapolated to studies when training on other scales.
**Keywords:** rater; training

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