ISCTM Poster Abstract – Intend to Attend (ITA) scale

Title: Addressing the Problems of Data Missingness: Building on the legacy of Andy Leon

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Methodological Question Being Addressed: To evaluate the performance of a revised version of the *Intend to Attend* (ITA) scale to predict dropout in clinical trials.

Introduction: In neuroscience clinical trials attrition rates range between 20% to over 50%. Attrition can decrease the statistical power, precision, and generalizability of study results. The National Research Council guidance on *The Prevention and Treatment of Missing Data in Clinical Trials* encourages the development of mechanisms to predict, prevent and adjust for patient dropout. Leon and colleagues (2007) developed the *Intend to Attend* (ITA) scale for that purpose. The ITA is a 2-item instrument designed to assess patients' self-rated risk of study dropout at baseline and subsequent visits. The ITA has both logistical and statistical value. It can improve patient retention and can be used to clarify the types of missing data (i.e., missing at random vs missing not at random). If the dropout risk is imminent, follow-up questions can be asked to help identify reason for dropout or hurdles to study completion. The ITA has been incorporated in the statistical models of a number of clinical trials, such as schizophrenia, bipolar disorders, and depression. However, the performance of the ITA scale has not been evaluated and a standardized approach to collecting information on dropout reasons is needed.

Objectives: A revised version of Leon's original ITA that modifies the question; provides structured responses and gives input on how the rater is to respond to the patient's responses (ITA-Plus) is being developed. These modifications were reviewed using Survey Monkey to get input from clinical trial experts identified by ICSTM. Based on the received input, the ITA-Plus was further modified. The resulting scale will be presented.

Methods: The survey of the ITA-Plus included 9 questions regarding the value of and possible improvements to the ITA-Plus scale. This questionnaire was sent electronically to members and former attendees of ISCTM meetings. Potential respondents were given two weeks to reply. Responses were structured for both Likert scale and free text responses.

Results: Of the 2091 invitations sent, 696 were opened and 63 responses were received; 54% self-identified as clinical leaders and 21% as statisticians. Of these, 65% regarded data missingness as important or very important and 69% regard the ITA-Plus as easy or very easy to understand. Many valuable comments were provided on how to improve the scale, how to use it in special populations and potential limitations. Respondents indicated that data missingness is an important issue since it can strongly influence the interpretation of clinical trial results. It may also introduce bias and reduce statistical power. The ITA-Plus scale was reported to have the potential to anticipate and prevent future missing data and can facilitate the discussion of potential hurdle for trial completion.

Conclusion: Data missingness represents an important problem for the work for many members of ISCTM. Based on the valuable input from ISCTM's broad membership the ITA-Plus has been further modified. Inclusion of the revised ITA-Plus scale in clinical trials should provide methodological, logistical, and statistical advantages for their conduct.