

Satellite symposium

C.14 The failure of multi-national placebo-controlled studies

Abstract: C.14.01

Citation: European Neuropsychopharmacology
The Journal of the European College of Neuropsychopharmacology
Volume 19, Supplement 3, Page S717

Ensuring data quality in multi-national clinical trials

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Data quality is a critical issue for Central Nervous System (CNS) clinical trials which frequently rely on subjective outcome measures. Data must be collected appropriately, understood and analyzed in a way to show appropriate results. Good clinical judgment and adequate experience with the indicated population must be combined with adherence to administrative guidelines and scoring conventions to obtain accurate data sets and minimize placebo responses [1,2]. Globalization of clinical trials further jeopardizes data quality due to cultural, ethnic and educational inter-country differences [3]. These differences may be responsible for failed international trials, and could also affect placebo response. The role of the clinical rater in reducing placebo response and improving signal detection in CNS trials is paramount to improving success rates. Addressing the inherent variability across sites in global studies is a required step to improving the quality of clinical ratings in global trials. A comprehensive rater training program to address cultural differences in rating patterns as well as differences in global practices will be discussed. Through rater training programs, a standard approach to rating scales can be developed and enhance efficacy of the scale. In the session, the speaker will present data supporting the effectiveness of rater training, certification and rater monitoring as proven methodologies to ensure data quality in multi-national CNS clinical trials. These approaches have been used successfully in many multi-national CNS clinical trials to enhance efficacy.

Reference:

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