

P-640 - THE POWER OF EXPECTATION BIAS

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Introduction: Expectation bias (EB) occurs when an individual's expectations about an outcome influence perceptions of one's own or others' behavior. In clinical trials, both raters and subjects may enter trials with expectations. Rater EB occurs when raters expect that subjects will improve over the course of the trial. Subject EB occurs when subjects themselves expect to get better. Rater and subject expectations can interact to create a therapeutic alliance.

Objectives: To examine the impact of EB on placebo response and drug-placebo separation.

Aims: To identify methods for avoiding expectation bias in CNS clinical trials.

Methods: We review eight studies that illustrate the problem of rater and subject EB across therapeutic areas.

Results: Studies examining rater EB suggest it can affect diagnosis and decrease IRR when subjects do not behave according to expectations. Studies of subject EB suggest subject expectations can increase placebo response and affect study outcome. Studies of the interaction of rater and subject expectations find placebo response increases with number of follow-up visits, and having a different rater for baseline, endpoint, and sequential visits may decrease placebo response.

Conclusions: Patient expectations, rater expectations, and rater-patient relationships can increase placebo response and decrease signal detection. Blinding raters to protocol details, including entry criteria and visit number, reduces expectations of improvement. Using different raters at baseline, endpoint and consecutive visits reduces the possibility that relationship bias could influence ratings. Utilizing remote, independent raters is one means to adequately blind and vary raters.