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ARE DIFFERENT METHODS TO REDUCE PLACEBO RESPONSE IN CNS TRIALS MUTUALLY EXCLUSIVE OR HAVE ADDITIVE EFFECTS?

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Over the past two decades, numerous methodologies have been developed with the specific goal of reducing the placebo effect in CNS trials. This presentation will discuss how three of these strategies, Central Ratings, use of the SAFER interview, and use of Sequential Parallel Comparison Design (SPCD), in combination, may offer a 'triple safety' net that ensures maximum reduction of the risk of a failed trial. Central Ratings have been shown to reduce variability in ratings by limiting the pool of raters for a given trial, ensuring consistent high reliability and calibration of raters, and reduction of expectation bias due to blinding and independence from the site. Novel study designs such as SPCD have been shown to significantly reduce the overall placebo response rate of the trial by pooling data from both phases of the trial, given the marked reduction in placebo response in the placebo non-responders of phase 2 of these trials. Finally, the use of highly experienced, independent remote interviewers to administer diagnostic and treatment history checks such as the SAFER interview and to perform unbiased assessment of baseline symptom severity improves the quality of subject selection, preventing the randomization of subjects with inadequate severity of illness or without the appropriate diagnosis or treatment history. This presentation will review the evidence in support of the utility of combining these three common methodological approaches to reduce the placebo response in CNS trials, providing a 'triple safety' net for CNS trials and the opportunity to enhance signal detection.

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