

Case Study

Addressing Placebo Response

November 22, 2017

Area of concern

Major Depressive Disorder

Location

International

Size

150 Sites, 550 Raters

Services Provided

Full suite of services (scale management, rater training, in-study quality assurance), with special emphasis on applied training in interview technique.

Challenge

High placebo response in affective disorders

Although there is placebo response in almost all disease areas in CNS, it is particularly high in affective disorders. There has been limited research to show which methodological approaches reduce placebo response or enhance signal detection.

Solution

Applied training in interview technique

One of very few variables that have been empirically associated with improved signal detection and better separation from placebo is the quality of the clinical interview through which outcome data is collected. We designed an individual applied training program that would specifically address interview technique and used a variety of other data points to target this approach to a subset of investigators.

Result

High-impact low-burden intervention

With minimal intrusion into research site activities and with no impact on overall project timelines, we were able to deploy individualized applied training for a global cohort of investigators and improve the validity of the data they collected. This experience with placebo response has compelled us to further research the reason for unreliability in clinical trials.

