

# PLACEBO RESPONSE MITIGATION



High rates of placebo response are recognized as a major cause of clinical trial failure. Study results are simple mathematical comparisons between response to investigational product and response to placebo. Investigator meetings, however, tend to focus almost exclusively on the investigational product and count on randomization along with blinding to cancel out placebo effects. Research demonstrating this so-called efficacy paradox supports a sophisticated approach to placebo response mitigation and identifies multiple opportunities to prevent and/or minimize the impact of excessive placebo response.



**Improve  
Interview  
Skills**



**Encourage  
Neutral  
Interactions**



**Modulate  
Participant  
Expectations**

#### **DID YOU KNOW?**

Placebo response reflects actual activity triggered by mind-body processes related to receiving an intervention, rather than the direct physiological activity of the investigational product.

## **Why Choose Signant's Placebo Response Mitigation Training Program?**

- 1** Multi-tiered, evidence-based approach to placebo response mitigation
- 2** 20 years of experience delivering successful training
- 3** Reusable training modules, including custom videos, that can be used across sites and programs

## Our Multi-Tiered Placebo Response Mitigation Strategy

Signant Health begins by defining placebo response as two discrete components: true placebo response and pseudoplacebo response.

Mitigation strategies for **true placebo response** are based on data showing placebo treatment is an active intervention, which largely arises when expectation triggers true improvement. Strategies to mitigate true placebo response emphasize communication style and teach interview skills:

- ① Improve awareness of how behaviors augment placebo response
- ② Prepare study teams for consistent verbal and nonverbal communication
- ③ Empower site staff to train their coworkers
- ④ Engage with clinical trial participants using scripted responses

**Pseudo-placebo response**, on the other hand, is the component of improvement that may be due to inclusion of inappropriate participants, measurement error, operational problems, and/or intentional misreporting of symptoms. Strategies to mitigate pseudo-placebo response include rigorous rater training, in-study monitoring, and blinded data analytics:

- ① Target accurate measurement
- ② Ensure the right participants are enrolled, and select sites with lower placebo response
- ③ Detect intentional mischievous by the participant or rater
- ④ Proactively monitor study data for inconsistencies and anomalies

## Comprehensive Solutions For Placebo Response Mitigation

### Prevention

Signant's placebo response mitigation training for investigators, site personnel, and participants employs methods such as didactic training, video materials, and tip sheets.

You can integrate these trainings with Signant's Rater Training curriculum, which covers standardized administration and scoring techniques for clinical assessments as well as interview skills to help studies maintain intra- and interrater reliability. Our enhanced program even includes a self-scripting workshop that will share verbal and non-verbal communication tips to help your raters aim for modest rapport during interviews to keep participants' expectations neutral.

Our in-house eLearning team can also create custom training videos that you can choose to own or license which can be applied to a single study or across a program.

### Remediation

Signant's PureSignal Analytics solution will proactively monitor study data as they flow in to detect data quality concerns such as inconsistent ratings, outliers, or anomalies before they propagate throughout the study.

Then, leverage our Advisory services to receive expert guidance on corrective actions or how to implement preventative measures for future risks.

Contact our clinical science and medicine experts to discuss a plan for minimizing the impact of placebo response in your programs

Connect with us

### WHO IS SIGNANT HEALTH?

Signant Health is the evidence generation company. We are focused on leveraging software, deep therapeutic and scientific knowledge, and operational expertise to consistently capture, aggregate, and reveal quality evidence for clinical studies across traditional, virtual, and hybrid trial models. For more than 25 years, over 600 sponsors and CROs of all sizes – including all Top 20 pharma – have trusted Signant solutions for remote and site-based eCOA, EDC, eConsent, RTSM, supply chain management, and data quality analytics. Learn more at [www.signanthealth.com](http://www.signanthealth.com).