# How a Top 25 Pharma Company Reduced the Placebo Response for their Phase II Study

## THE CHALLENGE

A Top 25 Pharma Sponsor was concerned that high placebo responses would impede the results of their upcoming Phase II clinical trial for Lumbosacral Radiculopathy (LSR).

Large improvements in the placebo arm (i.e. a high placebo response) is a common reason clinical trials fail to separate drug from placebo.

More than this, high placebo responses are even more common in trials with patient-reported outcome measures, an instrument Sponsor X had selected to define their primary endpoint for this study.

# THE SOLUTION

One effective way to reduce the placebo response is by neutralizing patients' expectations and increasing patients' ability to report their symptoms more accurately[1,2].

WCG's Accurate Symptom Reporting and Placebo Response Reduction trainings are two evidence-based intervention programs that train patients and study staff accordingly.

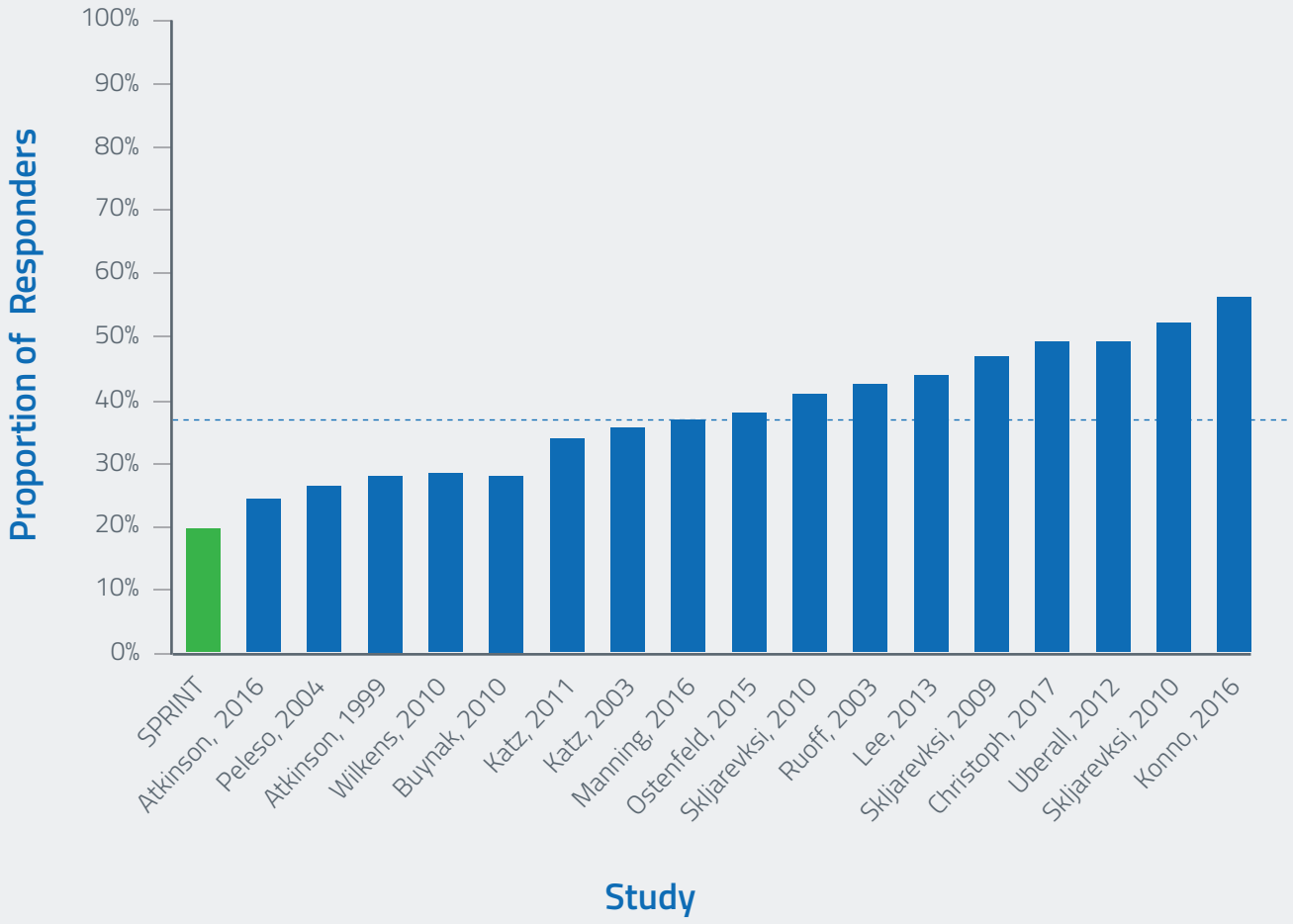
## Results

- By implementing WCG's Accurate Symptom Reporting and Placebo Response Reduction training interventions, Sponsor X's Phase II clinical trial[3] resulted in a much lower than average placebo response (compared to other similarly designed clinical trials for LSR and Chronic Lower-Back Pain or CLBP).
- By employing these interventions, Sponsor X increased the reliability of their clinical trial's results—and decreased the risk of trial failure.

# Scientific Highlights

- Sponsor X's Phase II trial had a much lower placebo response rate of 19.1% than the average placebo response rate of 36.6% for comparable studies.
- The proportion of placebo responders in the Phase II trial (patients in the placebo arm with ≥30% reduction in pain intensity) was compared to the proportion of placebo responders in similar studies found through a systematic literature review of parallel, placebo-controlled, double-blind clinical trials on the treatment for LSR or CLBP.

## Proportion of Placebo Responders by Study




Placebo responders are defined as patients with ≥30% reduction in pain intensity in the placebo arm. Blue dotted line denotes the mean value of proportion of placebo responders across comparator studies Articles referenced[3-20]

# Abbreviated References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