

## Fibromyalgia: Gaining Knowledge of a Little-Understood Disease

Joining in the elusive pursuit of fibromyalgia pain relief, a small pharmaceutical company engaged Premier Research for a Phase III trial following our completion of the product's Phase II research. The compound under study: a muscle relaxer on the market for decades, repurposed for the possible treatment of fibromyalgia.

The sponsor chose Premier Research largely based on our experience – in analgesia, where we lead the industry with more than 870 trials, and specifically in fibromyalgia, where 15 studies over the past decade put us ahead of all other contract researchers. While experience always counts, the drug company sought our expertise because of the very specific nature of this poorly understood indication.

After getting a lot of attention about a decade ago, fibromyalgia kind of fell off the pharmaceutical map. What's more, despite an American College of Rheumatology defining criteria issued in 1990, some physicians didn't recognize it as a real medical condition even five years ago. The three currently approved fibromyalgia drugs have been

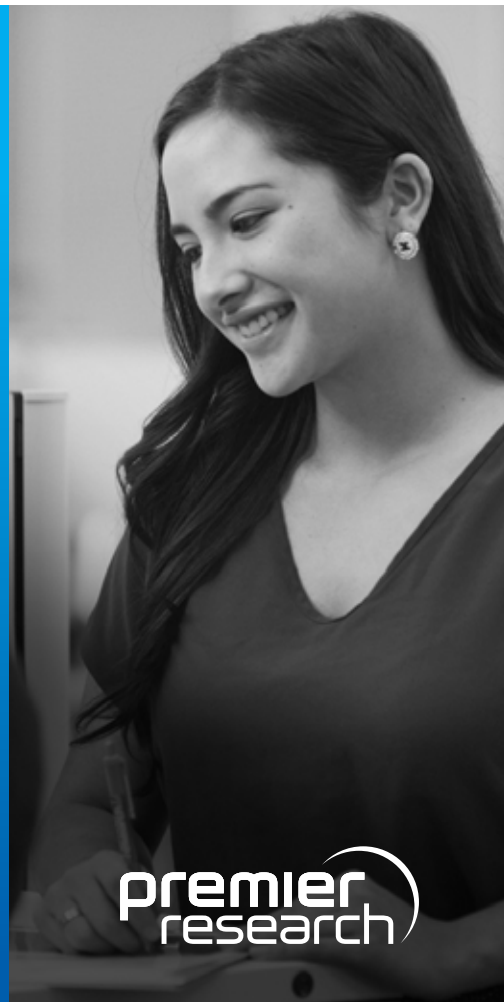
around for years, and having run programs for two of them, we knew the indication, the sites, and the researchers – and how to find the right patients.

Indeed, we started work on the first of these drugs in 2001, and in the past 15 years have worked on 11 single- and multi-trial programs.

### **A lot at stake**

That experience paid off in recruitment, enabling us to enroll 500 randomized patients (of 800 screened) across 35 U.S. sites in just 12 months – three months ahead of schedule. We combined site-level advertising with a central outreach effort and maintained constant contact with the sponsor, recognizing that the company had a lot at stake. The trial ran smoothly, with enrollment ending three months early, and Premier Research delivered topline results just one week after database lock. Based on these early results, the sponsor made development decisions for the remainder of the Phase III program.

# ANALGESIA



# In This Pain Trial, There Was Just No Substitute for Experience

## Study Description:

Phase III study of an established muscle relaxant repurposed for treatment of fibromyalgia pain

## Therapeutic Area:

Analgesia

## Geographic Scope:

35 sites in the United States

## Patient Population:

800 screened, 500 randomized

## Length of Enrollment Period:

12 months

## Outcome:

Trial completed on schedule, but product did not meet its primary efficacy endpoint



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