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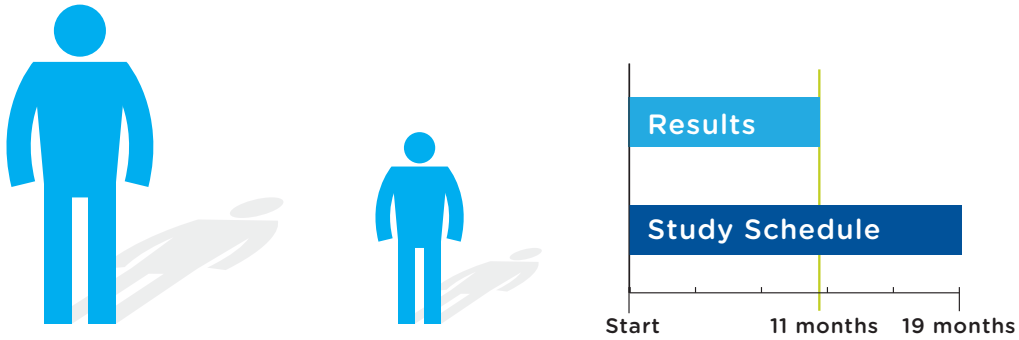
Conclusive & Positive Results Delivered Ahead of Time – By Eight Months

Background

Patients rushed to enroll almost as soon as word of the study got out. We were dealing with a significant unmet need: Most patients with Binge Eating Disorder (BED) seek help from psychiatrists, nutritionists, or obesity specialists. But there was no approved, effective pharmacologic treatment. And patients desperately wanted one.

Objective

With unanticipated interest in these pivotal Phase 3 studies, Premier Research needed to line up and train the right resources while collaborating effectively with the central laboratory, data manager, and other participants.



720 subjects screened

356 subjects randomized

Results delivered **8 months** in advance

NEUROSCIENCE

Everyone contributed and supported good ideas. It was collaboration all the way.

Dealing with the unexpected: Surprisingly fast enrollment

Our Strategy

We quickly saw what was happening and geared up to deal with it. With enrollment moving so fast in the U.S., we immediately downsized the European arm of the study. That was the easy part. We had to line up and train the right resources, well beyond our original staffing plan.

We doubled the number of CRAs to 45. We assigned 10 clinical managers. We arranged for strong team members at all levels, so we could divide the tasks and confidently delegate responsibilities.

Equally important, the team collaborated effectively with the central laboratory, data manager, and other participants the sponsor had assigned to the project. Everyone contributed and supported good ideas. It was collaboration all the way.

Together, we delivered conclusive, positive results eight months ahead of time, in a study that was originally scheduled to last 19 months.

Takeaway

The results were proof that a CRO of our size – if it's the right one – can deliver the resources to support even large, parallel global studies like these. In fact, our size likely contributed to our flexibility to keep pace with the unexpected.

Study Description
Two identical, pivotal Phase 3 studies evaluating the efficacy and safety of a compound to treat adult Binge Eating Disorder

Therapeutic Area
Central Nervous System

Indication
Binge Eating Disorder

Geographic Scope
U.S. and Europe

Patient Population
356 randomized subjects; 178 per treatment group

Duration
The studies consisted of a minimum two-week screening period, a 12-week treatment phase, and a follow-up one week after the last treatment. Subjects visited the site up to 11 times over a 15-week period.

Outcome
Conclusive and positive results delivered ahead of schedule – by eight months

premier research

North America: **+1 919 627 9069** | Europe: **+44 118 936 4000** | info@premier-research.com **premier-research.com**