

# Case Study: Supporting the FDA Approvals of Two Novel Agents for the Acute Treatment of Migraine

## BACKGROUND



A clinical-stage biopharmaceutical company engaged Cognitive Research Corporation to help design, implement, and conduct a series of studies to investigate two innovative therapies for the acute treatment of migraine over the course of two years.

## CRC SOLUTIONS

\*Normal Healthy Volunteer (NHV) studies included pharmacokinetics, bioavailability, drug-drug interaction, and food effect for both programs.

### PROGRAM A

Provided monitoring / management for **16 NHV\* Phase I Studies.**

Conducted a pivotal Phase III trial with a novel agent, across **69 sites, randomizing over 1,400 subjects within 6 months.**

### PROGRAM B

Provided monitoring / management for **9 NHV\* Phase I Studies.**

Conducted a pivotal Phase II/III trial with a unique route of delivery, across **82 sites, randomizing over 1,600 subjects in 6 months.**

### CHALLENGE

Ensuring Primary Endpoint Diary Data were Captured for all Subjects at Critical Timepoints

### CRC SOLUTIONS

- Daily Examination of Data
- Dedicated Personnel
- Real-Time Electronic Diary Review
- Identify Non-Compliance with Documentation of Endpoints
- Collaboration with Sites to Reduce Diary Non-Compliance
- Site Connects with Patients to Remedy

### IMPACT

This Level of Data Review and Proactive Measures Helped Ensure the Success of Both Programs

## KEYS TO SUCCESS



Ensuring Data Integrity Before Continuing Site Enrollment



Real-Time Discussion & Resolution of Study Issues

## OUTCOME

The partnership between CRC and the sponsor from Phase I through Phase III led to two successful NDA applications and two FDA approvals.

Looking for a Better CRO Experience?

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