



CASE STUDY: 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 Time Points

SOLUTION

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 and outcome

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.

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