CLINiLABS
THE CRO FOR CNS

CASE STUDY

Clinilabs Drug Development Corporation Achieves CNS Trial Start-Up in 1/3 the Time of Industry Standard

CHALLENGE

Execute a rapid start-up for a Phase 3, 100-site CNS trial that requires the approval, execution, and filing of thousands of clinical, legal, and regulatory documents prior to enrolling patients.

SOLUTION

Clinilabs implemented a best-in-class, all digital cloud-based solution that streamlined document management, leading to a fast, efficient, and relatively inexpensive pathway to clinical trial success for our customers.

RESULT

The site start-up duration for this 100-site study was **3.2 months**, beating the industry standard of **9.6 months** for CNS trials.

OVERVIEW

Clinilabs Drug Development Corporation, the only global, full-service contract research organization (CRO) focused exclusively on central nervous system (CNS) drug development, was engaged by a large, clinical-stage biopharmaceutical company to manage a randomized, double-blind, placebo-controlled study of a therapy for patients with acute migraine headache. The pivotal trial, involving 100 sites, various demographics, and a diverse geographic disbursement, called for an approximate six-month start-up period, which began at contract execution and ended once all site initiation visits (SIVs) were completed.

Challenges to the start-up of this trial were the volume of documents involved, the variety of document formats, the number of signatures required to execute documents, and document filing requirements. Start-up document tasks to be completed included the execution of more than 200 Confidential Disclosure Agreements; the distribution, site completion, and return of site qualification questionnaires; 100 site essential document packages; and the submission of all 100 sites' Institutional review board applications. These documents include, but are not limited to, confidential disclosure agreements, clinical trial agreements, budgets, protocol signature pages, financial disclosure forms, investigator CVs, licenses, and site documents.

Committed to rapid study start-up and high-quality execution for our customers, Clinilabs turned to the SureClinical platform of validated, life science cloud applications to help our clinical team streamline the processes and accelerate study start-up. Among the

> **"Clinilabs' brand has become synonymous with high-quality and cost-efficient CNS trials that speed new drugs to market. Its success in 19 new drug applications is made possible through the use of innovative technology that meets each customer's specific clinical development needs. In this case, SureClinical provided the optimal solution for the company's start-up challenges."**
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> – Jeanine Estrada, Vice President, Marketing and Communications

MIGRAINE FACTS

1B
people globally suffer from migraine

2ND
leading cause of disability worldwide in terms of years lost to disability

243M
lost workdays annually in the U.S. and Europe

$47B
annually in estimated healthcare and lost productivity costs in the U.S. and Europe

$8.7B
expected growth in migraine treatments sales globally by 2026

$1B
plus annual peak sales of a leading migraine treatment

applications deployed were SurePortal, a time-saving, automated document handling platform, and SureEsign™, an electronic signature utility to support eSignature workflows.

As a result, every key milestone in the start-up process was achieved well ahead of schedule and far in advance of the industry standard for CNS indication trials, including the duration from site selection to regulatory package distribution; regulatory package receipt by site to submission; and regulatory package approval to site initiation. In the end, the site start-up duration was 3.2 months, more than 6 months faster than the industry norm for large CNS trials, which currently is 9.6 months.

“When you’re initiating a huge, complex clinical trial for an important new therapy, you want to start out on the right foot,” said Eileen McAuley, Clinilabs’ Chief Operating Officer. “Clinilabs uses validated, innovative technology systems to meet all of our customers’ objectives in a high-quality, timely and cost-efficient manner, and in this case, the SureClinical platform and applications provided the optimal solution for the company’s start-up challenges.”

Ultimately, by achieving rapid study start-up and meeting project milestones early, Clinilabs is speeding up the development of new, effective therapies for the billions of people worldwide who suffer from migraine.