

# Rare Solutions

Sophisticated clinical trials for challenging therapeutic areas

## Visual Snapshot

### Clinical Trial

Phase III trial in the treatment of super-refractory status epilepticus (SRSE)

### Condition

Super-refractory status epilepticus (SRSE)

### Purpose

Evaluate the efficacy and safety of intravenous agent in patients with SRSE

### Patient-Type

Older than 2 years of age, suffering from SRSE, located in the U.S., Canada, or Europe

## Ergomed's solutions to the challenges of clinical trials

At a time when clinical trials are becoming more and more complex – due in no small part to increased regulatory requirements – phase III trials are especially complicated, with few drugs (approximately one-third) proceeding from phase II. In such an environment, an organization seeking to conduct a trial for a rare and complicated disease state, such as life-altering central nervous system (CNS) disorders, already faces an inordinate challenge.

### The Challenge

#### A complicated condition with limited understanding or standardized care

Ergomed was selected by a clinical-stage biopharmaceutical company to create a project plan and execute all aspects of phase II and phase III clinical trials SRSE. This life-threatening, devastating neurological condition is considered exceptionally rare, resulting in large variances in how doctors around the globe treat each patient.

### The Strategy

#### Securing the subjects

Ergomed was successful in securing the participation of close to 300 subjects. This was accomplished through the efficient process established by Ergomed to ensure that no patient who presented and fit the study requirements would be missed.

#### Collecting and presenting the data

Ergomed worked closely with all sites to ensure the drug was administered and data was collected.

#### Employing flexible and focused solutions to deliver high-quality data

A flexible approach was implemented to ensure high-quality data was being collected, even considering the multiple and complex additional assessments that were undertaken and the varied patient histories.

### The Outcome

Ergomed utilized an expert team to overcome the many notable challenges a complex trial such as this brings. This included a rare patient group spread across continents with multiple and varied medical histories and medication plans; operating in an urgent ICU setting; and the critical need for around-the-clock support and communication with each site's hospital staff, sponsors, and clinical partners. Reaching a clear conclusion to this particular trial, despite the statistical outcome, established a strong foundation to aid in the development of future treatments for SRSE patients and increased understanding of this rare but serious condition, its cause, and the efficacy of treatments being employed today.

