ERGOMED

Case Study

# Idea to Market

## Delivering clinical trial success in record time

### Visual Snapshot

**Clinical Trial**

Two separate phase III trials in the treatment of moderate and severe postpartum depression (PPD)

**Condition**

Moderate and severe PPD

**Purpose**

Evaluate the efficacy and safety of intravenous agent in patients with PPD and deliver improvements on the Hamilton Rating Scale for Depression

**Patient-Type**

Mothers (18 - 45, US) who had given birth within 6 months of the trial, showing symptoms of moderate or severe PPD that began no earlier than the 3rd trimester and no later than the first 4 weeks following delivery

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

With both time and money at stake, organizations need a clinical research organization (CRO) partner that has a proven record of successfully operating under significant time constraints, while still delivering a high-quality and successful clinical trial, moving an agent from proof of concept (POC) through to New Drug Application (NDA) status quickly and efficiently.

### The Challenge

**POC to registration in three years**
Ergomed was selected by a clinical-stage biopharmaceutical company to deliver a small POC study that included only six subjects. The study was fast-tracked by the FDA, and Ergomed was tasked with executing two phase III trials of an intravenous neurosteroid in the treatment of moderate and severe postpartum depression (PPD).

### The Strategy

**Awareness campaign to secure trial subjects**
To combat the stigma attached to PPD, an awareness campaign was deployed.

**Resourcing the trial quickly and effectively**
Given Ergomed's previous experience with the neurosteroid from a different trial, the team was already familiar with the agent, necessitating less time to get up to speed.

**Managing the trial sites**
Ergomed worked with the sites to ensure that all of this information was properly communicated to the patients.

**Regular data reviews**
The client required regular data pulls after every 20 subjects to be analyzed.

### The Outcome

Ergomed was successful in securing more than 220 patients and delivering a quality clinical trial with positive results in less than three years, adapting to the changing environment throughout this time that included the fast-tracking process from the FDA. The success of this trial can be attributed in part to Ergomed's ability to anticipate what the client wanted or might need, before being asked, something only a true partner can do. The team's dedication and availability at all hours of the trial – both to the site staff as well as to the client – ensured quick responses, which resulted in not only securing enough subjects, but also delivering the regular datasets needed to make decisions about the trial's progress.