

# Ensuring true results through accurate assessments, WCG helped a client bring a post-partum depression therapy to market

By providing training, expertise, and a new assessment tool, WCG ensured the success of a pivotal trial in post-partum depression, leading to approval of an important new treatment.

## THE OVERVIEW

A leading CNS-focused pharmaceutical company was conducting a series of double-blind, placebo-controlled late phase studies (including a pivotal clinical trial) in adult and adolescent patients with post-partum depression (PPD) at psychiatry and non-psychiatry trial sites in the United States.



## THE RESULTS

The sponsor had a successful pivotal trial and produced results that supported regulatory approval, giving clinicians and patients an important new treatment for post-partum depression

## THE CHALLENGE

The client encountered several challenges in obtaining true outcomes:



The primary study endpoint – the Hamilton Depression Rating Scale (HAM-D) score – was not developed for use in PPD. It had to be adapted to capture both rapid change and presentation of mood disorder.



The study included adolescents, so the sponsor needed a better way to evaluate the pediatric presentation in an efficient, cost effective manner.



The non-psychiatry sites were using less-experienced raters—a great concern to the sponsor

## OUR SOLUTION

WCG SERVICES FOR CNS:

- 01 Developed training, manualization of measures, and quality assurance methodologies for the primary endpoint.
- 02 Adapted the interview guide, which helped raters efficiently capture all the information required for both adult and adolescent assessments.
- 03 Introduced the ComPADRE assessment – created by WCG – to capture the experience of the adolescent trial participants. WCG's training maximized signal detection by increasing ComPADRE's reliability and decreasing noise, allowing them to hear the true effect of their drug.
- 04 Conducted tailored training sessions – including mock interviews – to ensure that raters were prepared, reliable, and confident in their ability to perform these assessments.
- 05 Developed methods to verify the ability of raters to conduct sensitive, valid evaluations in this heterogeneous population.