CASE STUDY

See How WCG Helped Sponsor Effectively Demonstrate that their CNS-active Drug had Low Potential for Abuse

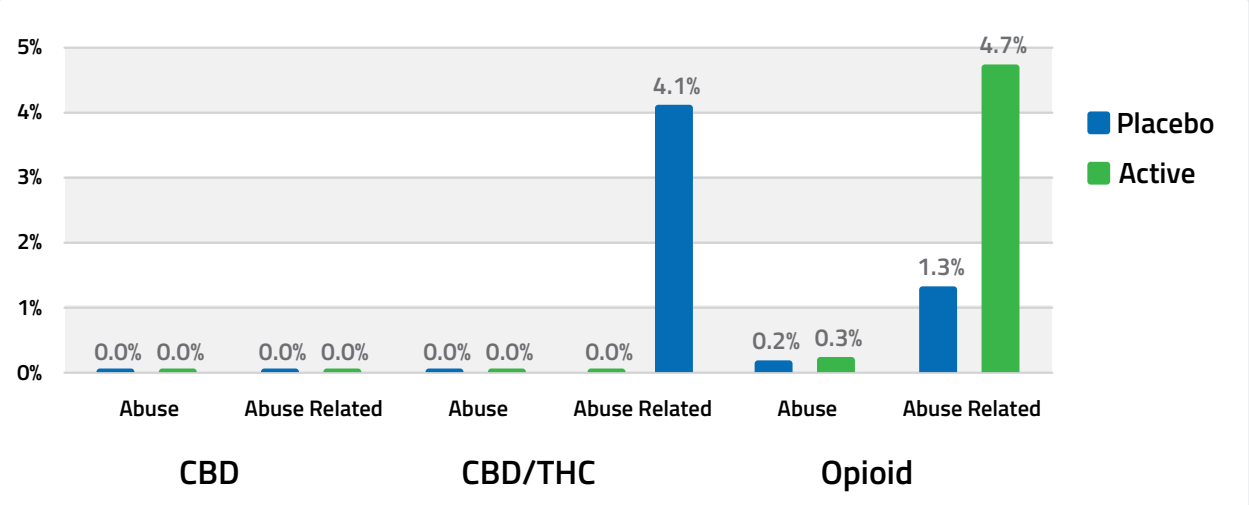
WCG's Abuse-Potential Solution, also known as MADDERS® (Misuse, Abuse, and Diversion Drug Event Reporting System), is the only system to comprehensively capture data on abuse-related events in clinical trials per FDA guidance.

VALIDATION OF MADDERS®

A meta-analysis of studies using MADDERS® demonstrates that as the abuse liability of the drug class increases, MADDERS® detects more abuse-related events.

Abuse and Abuse-related Events:

Percentage of Patients with Abuse-Potential Event Classification



CHALLENGE

In the wake of the opioid epidemic, it has become imperative to reliably and comprehensively assess all abuse-related events in the development of central nervous system (CNS) therapies.

To that end, a prominent pharma company had concerns about the submission of their safety data to the regulatory authorities for their Phase III studies related to:

1. The unique chemical properties of the Sponsor's investigational new drug (IND)
2. The safety profile of the product
3. Subsequent scheduling
4. Fulfilling FDA requirements on the "Assessment of Abuse Potential of Drugs" (2017)

SOLUTION

Sponsor X selected MADDERS® to effectively define and assess abuse-related events for their Phase III trials.

In four critical steps, Sponsor X was able to:

1. Identify prospective, potentially abuse-related events by trained investigators and site staff
2. Collect all relevant information in real time using standardized forms
3. Formally adjudicate events by substance-abuse experts
4. Tabulate and report events

RESULTS

By implementing MADDERS®, Sponsor X was able to submit evidence to the regulatory authorities demonstrating that there were no instances of abuse or misuse for their CNS-active drug.

Sponsor X's data on abuse potential supported a rescheduling from Class I to Class V when the treatment was approved.