Abuse-Potential Solution

WCG's Abuse-Potential Solution, also known as MADDERS® (Misuse, Abuse, and Diversion Drug Event Reporting System), is the first standardized system to systematically assess potentially abuse-related events in Phase II-III clinical trials.

ASSESSING ABUSE POTENTIAL

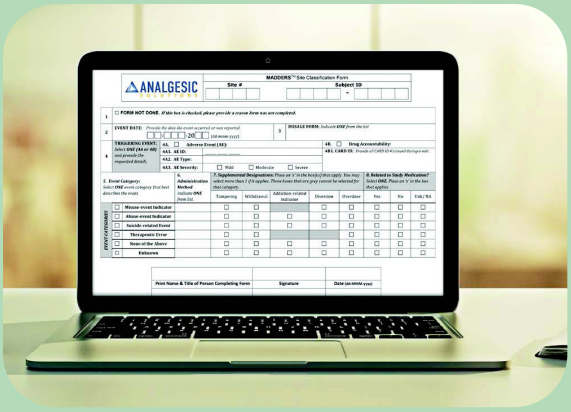
In 2017, the FDA issued guidance on the Assessment of Abuse Potential of Drug. The guidance recommends and expects all drugs with central nervous system (CNS) activity to systematically capture abuse liability/ potential. Traditional methods can be flawed and lead to misclassification of events, affecting the approval, labeling and scheduling of any CNS-acting drug.

MADDERS was developed in collaboration with the FDA-ACTTION initiative and designed to obtain more thorough information on intent, behavior, and other contextual factors associated with potentially abuse-related events by training the investigators to:

1. Play an active role in identifying trigger events
2. Obtain additional information from study subjects as soon as possible, after the event occurs

The Final MADDERS report assists in the generation of evidence to support approval, labeling, and scheduling decisions.

MADDERS®



The MADDERS approach allows for more comprehensive information to be gathered which can lead to greater accuracy in the classification

1

IDENTIFY TRIGGERING EVENTS

Trained staff identifies a triggering event, either an Adverse Event (AE) of Drug Accountability Discrepancy (DA).

2

INTERVIEW STUDY SUBJECT

Suplemental AE or DA Form is completed by the staff through a guided interview with the subject.

3

MEDICATION USE SURVEY

All Study Subject complete the Medication Use Survey upon completion of the study to ensure all events are captured.

4

CLASSIFY EACH EVENT

MADDERS Forms are used by the investigators and the MADDERS Adjudication Committee to independently classify each event.

5

INDEPENDENT REVIEW

Adjudicators independently review all relevant patient and event-related information to come to a consensus classification and an Adjudicator Final Classification for is completed.

MADDERS ADJUDICATION COMMITTEE

The MADDERS Adjudication Committee is a key component to the success of MADDERS in clinical trials. The MADDERS Adjudication Committee is tailor-made for each trial to ensure the appropriate subject matter experts are on the committee.

Each MADDERS Adjudication Committee consists of subject matter experts in:

- Addiction Psychiatry
- Substance Abuse
- Specification Indication or Drug Class

MADDERS IN CLINICAL TRIALS

MADDERS is appropriate for any Phase II or Phase III clinical trial of a drug with central nervous system activity. Sponsors developing drugs with known or suspected abuse potential particularly benefit from clean data from a validated system on abuse-related events in their studies. To date, MADDERS has been successfully implemented in over 22 clinical trials and has shown to be a useful and reliable tool for prospectively assessing abuse potential of drugs in late-phase trials.

MADDERS is applicable to:

- Anti-Depressants
- Analgesics
- Anxiolytics
- Anti-Epileptics
- Sedatives
- Stimulants
- Any medication with suspected CNS activity