MADDERS®

Misuse, Abuse, and Diversion Drug Event Reporting System

double-marketing

Client: Analgesic Solutions Date: 5/22/18 Job #: ANA-18144

Project: MADDERS one-sheet Vers: 5 FIN
Size: 8.5" x 11" Production: 4C, float

Are You Meeting Your Regulatory Needs for Assessing Abuse-Potential?

The Misuse, Abuse, and Diversion Drug Event Reporting System (MADDERS®) is the *only* standardized system which systematically assesses abuse-related events in clinical trials.[1]

Assessing Abuse Potential: Regulatory Requirements

As of 2017, all investigational drug products with possible Central Nervous System (CNS) activity are required by the FDA to be comprehensively assessed for abuse liability.[2] MADDERS provides a robust assessment of your medication's abuse liability to support appropriate approval, labeling, and scheduling decisions.

MADDERS, developed in collaboration with the FDA-ACTTION initiative, is applicable to all CNS-acting drugs including such indications as pain, depression, anxiety, ADHD and epilepsy.

MADDERS utilizes trained investigators and an Adjudication Committee to:

- Actively identify potentially-abuse related events
- Complete event-related questionnaires
- Classify events according to consensus terminology

MADDERS 5-Step Process

Evidence Supporting MADDERS

The development and validation of MADDERS was presented in a recent paper published by the *The American Journal of Addiction.*[3] MADDERS has been successfully implemented in over 14 clinical trials in various indications, including chronic pain and epilepsy.

"*We are aware of no assessment other than MADDERS that gathers as much information about inappropriate medication use events in an attempt to discern the putative intent underlying the event. In fact, the value of the system lies in its focus on sufficiently documenting triggering events that occur in trials, rather than characteristics of the individuals in the trial.*"
— ALERTT Working Group of ACTTION.

1. Smith SM, Jones JK, Katz NP, Roland CL, Setnik B et al. Measures that identify prescription medication misuse, abuse, and related events in clinical trials: ACTTION critique and recommended considerations J Pain, 2017;18(11)1287-94.

2. Food and Drug Administration Center for Drug Evaluation and Research (2017). Guidance for Industry: Assessment of Abuse Potential of Drugs (FDA Maryland).

3. Treister R, Trudeau JJ, Van Inwegen R, Jones JK, Katz NP. Development and feasibility of the misuse, abuse, and diversion drug event reporting system (MADDERS®). Am J Addict. 2016;25(8):641-651.

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