



Cognitive Research Corporation

The exclusive provider of the state-of-the-art
PC-based driving simulator, the CRCDS

Fully validated for multicenter clinical trials, the CRCDS is used to evaluate the effects of a wide variety of drugs on the driving performance of healthy and patient populations. The driving scenarios developed for the CRCDS were designed to assess a range of psychomotor, divided attention, and cognitive tasks involved in driving.

FDA GUIDANCE

In 2017 the FDA published [Evaluating Drug Effects on the Ability to Operate a Motor Vehicle Guidance for Industry](#). This guidance states that a dedicated driving study is required (pre-approval) under conditions where evidence indicates a potential for driving impairment. The CRCDS has been used in more than 20 clinical trials for the pharmaceutical industry and regulatory agencies.

What drugs need to be evaluated?

- Drugs intended for chronic (or chronic-intermittent) outpatient use by adults who drive
- Drugs that may increase risk-taking

Driving studies may also be needed if a drug approved for a particular use is proposed for:

- a different indication
- a different dose or dosing schedule
- a new patient population

APPLICATIONS REQUIRING A DEDICATED DRIVING STUDY

- Antidepressants
- Antiepileptics
- Antihistamines
- Anxiolytics
- Cannabinoids
- Dosing changes/reformulation
- Hypnotics
- Sedatives
- Stimulants

Check out a recent [Journal of Clinical Pharmacy and Therapeutics](#) publication demonstrating the CRCDS-MiniSim driving simulator

LEADERSHIP



Thomas Hochadel, Pharm.D.
Chief Executive Officer



Gary G. Kay, Ph.D.
President, Chief Scientific Officer

CONTACT:

Bobbie Theodore, M.S.

clinicaltrials@alliancesites.com

(916) 803-7149

www.cogres.com

www.alliancesites.com