



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.

What drugs need to be evaluated?

- Drugs intended for chronic (including 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 DRIVING STUDY

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

The CRCDS has been used in more than 25 clinical trials for the pharmaceutical industry and regulatory agencies.

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

LEADERSHIP



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Apex's sites, CNS Research and Hassman Research Institute, have CRCDS driving simulators and experience conducting driving studies with Cognitive Research Corporation.

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