

# Clinical Trial Centers Alliance<sup>SM</sup>

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## COGNITIVE RESEARCH CORPORATION DRIVING SIMULATOR “CRCDS”

[Cognitive Research Corporation](http://www.cognitive-research.com) (“CRC”) is the exclusive provider of the state-of-the-art PC-based driving simulator, the CRCDS MiniSim. Fully validated for use in clinical trials, the CRCDS is used to evaluate the effects of age, trauma, neurologic disease, alcohol, fatigue, and a wide variety of drugs on driving performance in both normal and patient populations.

CRC has a fleet of identical driving simulators capable of conducting single or multi-site trials in the U.S., Canada, and Europe.

### TECHNOLOGY

The CRCDS utilizes the University of Iowa’s National Advanced Driving Simulator (NADS) PC-based simulator technology known as the MiniSim™, and optimizes it for pharmaceutical research.

The CRCDS has undergone extensive system and performance validation. The documentation of these validation efforts sets it apart from other systems in terms of its readiness to meet the regulatory requirements of pharmaceutical research.

### The CRCDS consists of:

- Driving cockpit with:
  - full-size steering wheel
  - realistic pedals
  - actual automotive seat
- Single high-end PC
- Three front channel displays
- Instrument panel display
- 2.1 audio system
- Tactile transducer (generates steering wheel vibration)
- Separate display for Operator/Instructor.



### FDA GUIDANCE

The latest [FDA Guidance](#) released in November 2017 indicates that a dedicated driving study using either a driving simulator or on-the-road testing is required pre-approval under certain conditions when evidence indicate a potential for driving impairment. The guidance applies to drugs intended for chronic (or chronic-intermittent) outpatient use by adults, and previously approved drugs with a different indication, different dose, or dosing schedule, or when developed for a new patient population where there is insufficient information about how the drug may impair driving.

### APPLICATIONS FOR DRIVING SIMULATION STUDIES

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

### CRC’S LEADERSHIP



**Gary G. Kay, PhD**  
President



**Thomas Hochadel, PharmD**  
Chief Operating Officer

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