

# Pharmaceutical Outsourcing™

The Journal of Pharmaceutical & Biopharmaceutical Contract Services

## For Sleep Drugs, MiniSim Driving Simulator Offers Faster, Cost-Effective Solution To Obtaining Required Data on Drug-Impaired Driving

Wednesday, July 03, 2013

*MiniSim To Be On Display at DIA Show In Boston June 24-26*

Print



**St. Petersburg, FL, June 24, 2013**, – In a year when the Food and Drug Administration (FDA) has made highly publicized moves to emphasize driving data in sleep dosage recommendations and labeling issues, Cognitive Research Corporation (CRC, [www.cogres.com](http://www.cogres.com)) offers pharmaceutical companies the methodology to conduct studies of drug-impaired driving utilizing a state-of-the-art MiniSim driving simulator. The MiniSim provides a faster, safer, and more flexible in-depth data-gathering approach, and at markedly reduced costs compared to current on-road testing methods.

On January 10, 2013 the FDA announced that due in part to driving simulator studies, the agency was requiring manufacturers to change the label for zolpidem (e.g., Ambien®) cutting in half the recommended dosing for women.

Dr. Gary Kay, president of CRC stated, “The FDA’s action shows that next day driving will be a focus for the agency for both marketed sleep drugs and sleep drugs that are in development.” He also pointed out that the FDA’s May 2013 review of the Suvorexant, a sleep drug under development by Merck, focused on next day driving concerns, particularly at higher doses, in their review of the drug application.

Dr. Kay, who was commissioned in 2011 by the U.S. Department of Transportation’s National Highway Traffic Safety Administration (NHTSA) to co-author a report on a protocol for evaluating the effect of drugs on driving performance, says pharmaceutical companies are faced with the challenge of assessing their existing and future sleep products for

driving impairment. “The drugs with the lowest next day residual effects on performance will show a clear prescribing and marketing advantage. “

### **About CRC**

Founded in 2006, Cognitive Research Corporation (CRC) is a full-service CRO based in Saint Petersburg, Florida specializing in CNS product development for pharmaceutical, nutraceutical, food/beverage, and biotechnology companies. CRC is recognized as one the world’s leading cognitive and central nervous system full-service contract research organizations. In the past five years CRC has conducted more than 75 studies and clinic trials, and its clients include the majority of the Top Ten pharmaceutical companies as well as the world’s largest food and beverage companies. In addition to our CRO services, CRC offers state-of-the-art computerized driving simulation and cognitive testing (i.e., the CogScreen computerized test battery). CRC has partnered with the National Advanced Driving Simulator at the University of Iowa to offer validated driving simulator methodology for assessing the therapeutic effectiveness or side effects of drugs, medicinal foods, and food/beverage products on driving performance.

Contact:

Greg Jones for Cognitive Research

908-310-3508

[rgjones@mccpr.com](mailto:rgjones@mccpr.com)

•

**[Contract Research Organizations / Contract Research Services \(CRO Services\) »](#)**