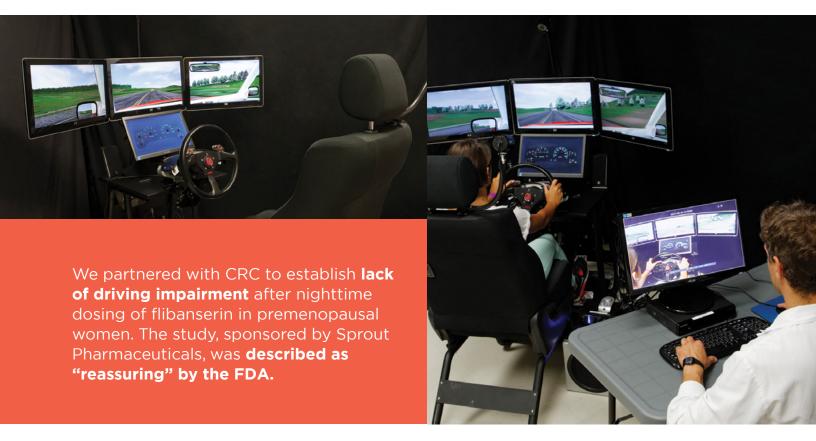


## DRIVING SIMULATION STUDIES

- Suite of 10 STATE-0F-THE-ART driving simulators on-site at our clinic, with space to house more than 20
- Driving studies designed and conducted to meet regulatory requirements, i.e. FDA guidance dated 2017
- Rapid participant recruitment and study startup
- Participant database of 350,000, additional access to patients and special populations via collaborative relationships with hospitals and clinics
- Professional oversight by fully-certified, in-house driving simulation study specialists
- In partnership with Cognitive Research Corporation (CRC)

Over 3,000 drives at our clinical







## Accurate driving performance data

comparable in sensitivity to over-the-road testing, with:

- Faster study startup
- Lower cost
- No risk of property damage
- No risk of injuries

The CRC driving simulator has **proven** sensitivity to the effects of

- Age
- Trauma
- Neurological disease
- Drowsiness
- CNS depressants
- CNS stimulants

## **Key Features**

- Proven to be highly sensitive to both therapeutic and adverse drug effects
- Advanced 3D graphics generate realistic representations of driving environment, including and interacting traffic
- of vehicle speed
- Auditory feedback is provided for engine speed, acceleration limits, and for indication of excessive cornering speed or excessive deceleration when braking
- functioning, divided attention, situational awareness, and other cognitive behaviors



CRC has developed equivalent versions of various driving simulation tasks (scenarios) that allow for re-testing while minimizing practice effects.

The FDA has defined a path forward for all new drugs. It is clear that all new drugs should be evaluated for adverse effects on the central nervous system during first-inhuman studies. If any adverse effects are observed, such as somnolence, additional clinical trials should be conducted to understand the impact on patients.

The ability of Altasciences to design and conduct these specialized tests, combined with the highly-recognized battery of psychomotor and neurocognitive tests offered by CRC, allow us to seamlessly incorporate these elements into our trials.



