ALTASCIENCES
CLINICAL SERVICES

Driving Simulation Studies

- Suite of **10 STATE-OF-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 345,000,** 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 10,000 drives at our clinical facilities to date

We partnered with CRC to establish **lack of driving impairment** after nighttime dosing of flibanserin in premenopausal women. The study, sponsored by Sprout Pharmaceuticals, was **described as "reassuring" by the FDA.**

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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 the vehicle dashboard, roadway, horizon, secondary task displays, intersections, traffic control devices, and interacting traffic
- Steering sensitivity is adjusted as a function of vehicle speed
- Auditory feedback is provided for engine speed, acceleration limits, and for indication of excessive cornering speed or excessive deceleration when braking
- Automated measurement of psychomotor 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-in-human 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.

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