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*Early Stage studies now produce enough critical data to drive decision making and help predict the technical and commercial success of drug candidates. At Kendle, we can help you find the winners earlier.*

*Edward Sellers, MD, PhD  
Vice President, Early Stage, Kendle*

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## Preview Kendle's global full-service capabilities

- Neurocognitive effects assessment
- Abuse liability assessment
- Controlled-release products
- Alcohol-interaction and drug-drug interaction studies
- Proof-of-concept studies
- Positron Emission Tomography (PET)
- Sleep Electroencephalography (EEG)
- Experience with all classes (traditional and novel) of CNS compounds (anxiolytics, antidepressants, analgesics, stimulants and cognitive enhancers)
- Regulatory meeting preparation and participation
- Use of validated, computerized Scheduled Measurement System (SMS) for all pharmacodynamic assessments

## Investing in Central Nervous System research

Disorders of the Central Nervous System (CNS) represent the second largest therapeutic area in terms of research and development (R&D) spending by biopharmaceutical and biotechnology companies, and account for more than 15 percent of the global cost of disease treatment.<sup>1,2</sup> With such a large proportion of R&D resources dedicated to CNS disorders, companies developing in this field need to choose a research partner with leading CNS expertise to maximize the impact of their investment.

### The Kendle difference

At Kendle, we offer extensive expertise in the clinical development of psychotropic compounds. We are world leaders in designing and conducting critical abuse liability studies and in evaluating the neurocognitive and behavioral effects of CNS drugs. Our scientific team includes internationally recognized opinion leaders with a diverse base of preclinical and clinical knowledge.

More than 75 percent of Phase I clinical studies performed at our research facility in Toronto, Canada, during the last five years have involved new drug candidates for the treatment of CNS diseases and disorders, including depression, anxiety, schizophrenia, Attention Deficit Hyperactivity Disorder (ADHD), insomnia, pain, Alzheimer's and Parkinson's disease.



### Specialty population recruitment

Kendle's Early Stage team has a full-time recruitment department with database access to specialty populations, including drug use disorders and dementia. We also can customize campaigns to draw on our local network of referring physicians and have referral arrangements in place with the Universities of Toronto and Utrecht.

### Neurocognitive assessment

We have a dedicated team to meet the increasing demands for characterizing the cognitive and behavioral effects of new and emerging compounds, critical to determining the safety and efficacy of many CNS drugs.

Our team includes clinical neuropsychologists, neuroscientists, a psychiatrist, nurses, trained research associates and software validation experts. In addition, we have consulting arrangements with neurologists and geriatric specialists. Collectively, this team has extensive experience in the study design, administration and interpretation of neurocognitive assessments for clinical trials.

Kendle's state-of-the-art in-patient unit is ideally suited for Early Stage neurocognitive studies, offering flexible study room configurations, private examination rooms and private bedrooms for subjects and caregivers.

In contrast to traditional pencil and paper research methods, which are often criticized for confounding the range of cognitive functions and for their inability to distinguish between speed and accuracy measurements, Kendle offers highly effective, computerized and validated cognitive assessment techniques. Through the use of individual computer workstations, our clinical staff are able to measure multiple cognitive domain functions efficiently and repeatedly within a short period of time, as required in Phase I and IIa studies.

### Scheduled Measurement System

At the heart of our neurocognitive assessment service is our SMS, a proprietary validated computerized system through which various neurocognitive performance tests, behavioral measures and questionnaires are available. Cognitive functions, such as simple and choice reaction times, visual-manual coordination, attention, working memory, verbal and non-verbal learning and memory, as well as executive functions, can be assessed through the SMS. In addition, we can incorporate other specific tests into the system if required.



#### References

1. *Epicom. New Drug Futures: Central Nervous System. May 2006 Report.*
2. *Business Insights. The CNS Market Outlook to 2011.*

### For more information

about Kendle's capabilities in CNS disorders, please contact us at [info@kendle.com](mailto:info@kendle.com) or one of the telephone numbers listed below:

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