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*As a provider for our early phase MTD and abuse liability trials, Kendle served a critical role in the development of one of the highest priority programs in our organization.*

*Senior Manager, Clinical Operations – CNS  
Eisai Medical Research Inc.*

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## Preview Kendle's global full-service capabilities

- Early assessment of abuse liability potential for optimal clinical development
- Preparation of pre-clinical, human experimental abuse liability and clinical trial data for New Drug Applications (NDA)
- Proprietary Scheduled Measurement System (SMS) software for efficient and optimal capture of pharmacodynamic endpoints
- Recruitment through largest database of experienced drug users for rapid patient enrollment
- Facilitation of efficient ethics approval and study completion
- Full data management and biostatistical support
- Preparation of required eight-factor New Drug Application submission section
- Development of post-marketing surveillance and data analysis strategies
- Expertise recognized by global regulatory authorities

## World leaders in abuse liability assessment

The abuse of prescription drugs has become a serious health concern for healthcare providers, drug manufacturers and governmental regulators. According to the National Institute on Drug Abuse, an estimated 48 million people in the United States have used prescription drugs for non-medical reasons.<sup>1</sup>

Abuse liability assessments, which evaluate the likelihood that a licensed drug may be abused or cause dependency, are a regulatory requirement for all central nervous system (CNS) drugs with sedation, stimulant or hallucinogenic properties. Coupled with pre-clinical and other clinical data, these assessments provide regulatory agencies with a scientific basis on which to schedule drugs.

### The Kendle difference

Kendle has more experience and has conducted more abuse liability assessments than any other CRO in the world.

Our facility in Toronto, Canada, is recognized internationally by global regulatory authorities and we have the world's largest database of recreational drug users, ensuring that subjects are enrolled rapidly and efficiently.

In addition, the approval period for Clinical Trial Applications (CTAs) for healthy volunteers in Canada is just seven days.



## Abuse liability assessment

Our abuse liability team is headed by an internationally recognized scientist with more than 500 published articles, chapters and monographs, who is assisted by a highly regarded recipient of numerous academic awards and author of more than 30 research and review articles, book chapters and scientific presentations.<sup>2</sup>

Our Toronto-based team routinely advises and assists on matters related to drug abuse, frequently attends U.S. Food and Drug Administration (FDA) meetings with customers and sits on advisory boards.

Through our computerized, validated SMS, we can measure a wide range of pharmacodynamic endpoints critical to abuse liability assessments. This proprietary software allows us to schedule tests in advance so that we can match the flow and timing of study events and dosing, and collect and present pharmacodynamic data in real time.

Our work in abuse liability assessment is supported by an enviable expertise in the CNS therapeutic area. Our scientific team, consisting of MD- and PhD-qualified research scientists, includes internationally recognized opinion leaders with a diverse base of clinical experience and CNS therapeutic expertise. More than 75 percent of the studies performed by Kendle in Toronto over the past five years have been in the CNS therapeutic area.

Kendle's Early Stage experts have the knowledge and experience to assist in risk management planning from pre-clinical studies to submission. We also are involved in the development of risk minimization action plans and post-marketing surveillance studies.

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*On top of their excellence in execution of the studies, I also can say that dealing with Kendle has been transparent and straightforward. At all levels of interaction, whether consultancy services, business development or project management, I have been impressed. I would have no hesitation in recommending them for Phase I work, including thorough QTc studies and abuse liability studies.*

Stephen Wright, MA, MD, FRCP (Ed), FFPM  
Research & Development Director  
GW Pharmaceuticals

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#### References:

1. National Institute on Drug Abuse Research Report Series, August 2005.
2. Schoedel KA and Sellers EM. Clin Pharmacol Ther 2008;83(4):622-626. doi:10.1038/sj.clpt.6100492.

### For more information

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

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