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*We have carried out two challenging studies in partnership with Kendle. On both occasions they have risen to the challenge and made both studies a success, where each could have failed. They deserve great credit and kudos for managing our studies so effectively.*

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

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## Preview Kendle's global full-service capabilities

- Expertise to conduct studies measuring the effects of alcohol or other drugs on investigational medications
- Clinical pharmacologists and in-house medical staff to provide expert input into practical study design
- Titrated ethanol concentrations and individualized doses
- Acute and chronic dosing of test agent
- Inpatient confinement in our state-of-the-art clinical facility
- Use of validated Scheduled Measurement System (SMS) for all pharmacodynamic measures

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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.*

*R & D Director  
UK-based pharmaceutical company*

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## Alcohol interactions

Given the widespread consumption of alcohol worldwide, there is a strong probability of it being consumed with prescribed drugs, including pain medications and anxiolytic, antidepressant or other psychotropic drugs. It is important, therefore, to determine the effect of concomitant alcohol use on the pharmacokinetics of the prescribed drug, as well as alterations to its safety profile and the combined effects on cognitive functioning such as alertness, attention and memory and on motor functioning. Such information is requested by regulatory authorities when filing for a New Drug Application (NDA) and the U.S. Food and Drug Administration (FDA) has outlined the type of data that is necessary for submission.

Additionally, if you have a delayed-release compound, there is often a need to establish that there is no alcohol-induced “dose dumping” of the drug. This typically requires measuring both pharmacokinetic and pharmacodynamic endpoints to establish clinical relevance. As well as designing and conducting studies, our scientists have extensive experience in recommending *in vitro* studies, regulatory strategies and achievable labeling for “tamper-resistant” products.



## Alcohol interaction studies

### The Kendle difference

Our Early Stage team is expert in the conduct of studies to measure the effects of the interaction of alcohol or other drugs on investigational medications.

Our in-house medical staff works with our Clinical Pharmacology Consulting team, a group of MD- and PhD-qualified research scientists including internationally established clinical pharmacologists, to provide expert input into practical study design. This team has extensive experience in designing and interpreting alcohol and drug interaction studies that are customized to the investigational product and tailored to meet the study objectives. Our study methodology includes the use of titrated ethanol concentrations and individualized study doses.

Pivotal to our success in the conduct of alcohol interaction studies is our SMS, a proprietary validated computerized system that allows the measurement of a wide range of pharmacodynamic endpoints critical to early stage studies. The SMS can incorporate a variety of cognitive, subjective, behavioral and physiological assessments that measure psychomotor speed, balance, visual and manual coordination, reaction times, memory and attention, among others. These assessments can be customized for a specific investigational drug to optimize outcome data. With skillful interpretation of these pharmacodynamic data, we are able to deliver a study report that enables you to determine labeling and other regulatory information on a scientific basis.



### For more information

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

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