



Human Abuse Liability Testing

About Human Abuse Liability

Under the current draft guidance issued by the United States Food and Drug Administration (FDA), sponsors must submit, in their New Drug Applications (NDAs), an assessment of studies and other information related to the potential abuse of a drug if the drug affects the central nervous system (CNS), is chemically or pharmacologically similar to other drugs with known abuse potential, or produces psychoactive effects such as sedation, euphoria, or mood changes. One of the most effective strategies to assess drug abuse liability in humans is to compare the dose- and time-response profiles of subjective and pharmacologic effects of an investigational drug against placebo and a comparator(s). Such trials typically are randomized, double-blind, crossover studies conducted in recreational drug users with no history of prior treatment for drug abuse. The nature of these studies requires that they be managed by a seasoned Phase I team with experience in the assessment of abuse-related parameters and wide access to this specialty subject population.

Abuse Potential Studies at Clinilabs' Phase I Units

Our phase 1 units in New York and New Jersey offer 100 beds to support human abuse liability (HAL) studies, providing two of the most advanced facilities of their kind. Our team of specialists includes investigators with significant experience in HAL and abuse deterrent studies, as well as in the treatment of opioid dependence. Each investigator is complemented by a Phase I staff that includes project managers, clinical research coordinators, nursing staff, psychometrists, and medical technologists who ensure that studies are executed with attention to detail. We have conducted over 300 clinical trials, and have experience working with classes of drugs that commonly are abused, including sedatives, hypnotics, stimulants, opioids, ketamine and ketamine-like drugs, and gamma hydroxybutyrate.

Computerized Cognitive Assessment

Our cognitive testing laboratory is staffed by two psychometrists, and is supervised by a licensed clinical neuropsychologist. This team utilizes the latest commercially-available computerized systems to provide screen-based assessment and electronic data capture.

Large Database of Specialty Subjects

Clinilabs maintains one of the largest subject databases in the industry, with over 80,000 study candidates available for study participation. Our database includes normal healthy volunteers, patient populations, and specialty populations (e.g., Asian, recreational drug abusers). Nearly one million New Yorkers report using illicit drugs in the past year (16%). The national rate is 14%. We authenticate our subjects and confirm they are not screening or enrolled in competing trials, or locked out due to prior trial participation.

Abuse Liability Studies

- Abuse potential studies
- Studies of abuse deterrent formulations

Specialty Assessments

- Visual Analogue Scales (VAS) for
 - Drug liking (primary endpoint)
 - Drug effects
 - Overall drug liking
 - Take drug again
 - Drug similarity
- Price value assessment questionnaire
- Addiction Research Centre Inventory (ARCI)