ALTASCIENCES

HUMAN ABUSE POTENTIAL (HAP) STUDIES

With **decades of experience in conducting HAP,** also referred to as human abuse liability (HAL) studies, Altasciences is a trusted partner for sponsors needing rigorous abuse potential evaluations and clear regulatory pathways.

WHAT ARE HAP STUDIES?

HAP studies assess a drug's likelihood of recreational abuse by comparing subjective and pharmacologic effects to placebo and active controls. These findings inform:

- FDA drug scheduling and labeling
- Approval and development strategy
- Risk-management planning

100+

HAP, substance-abuse, and abuse-deterrent formulation (ADF) studies

WHY CHOOSE ALTASCIENCES FOR HAP STUDIES?

- Experience that matters, and experience you can trust
- Decades of CNS and abuse-liability expertise
- Thorough understanding of FDA expectations and key endpoints
- Experience with FDA- and NIH-funded research
- Data packages aligned with 8-Factor Analyses and scheduling requirements

RAPID, RELIABLE RECRUITMENT

Our robust database of recreational and dependent drug users provides access to a diverse, well-characterized participant pool, enabling rapid recruitment and rigorous assessment of abuse liability and pharmacodynamic outcomes across multiple drug classes, including:

Opioids	Stimulants
Sedative-Hypnotics	Cannabinoids
Psychedelics	Dissociatives

contact@altasciences.com
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RAPID STUDY START-UP

HAP trials can be initiated in as little as four weeks, supported by:

- A dual project-management structure that aligns sponsor and internal timelines
- Streamlined contracts and regulatory document preparation
- Efficient recruitment, even for specialized populations

Our integrated model includes **three clinical pharmacology units and co-located bioanalytical labs in the U.S. and Canada**, providing multiple regulatory pathways for speed and flexibility.

Study start-up in as little as
4 weeks

DELIVERING FULLY INTEGRATED SOLUTIONS FOR YOUR HAP TRIALS

We deliver fully integrated, industry-leading services to streamline every step of your HAP studies, including clinical pharmacology, bioanalysis, PK/PD, statistics, and regulatory strategy:

- **Expert CNS Team**
  Internationally recognized scientists with 25+ years in abuse-potential research, including a seasoned PI/psychiatrist, CSO specializing in CNS trials, and a clinical neuropsychologist experienced in PD assessments.

- **Specialized Clinical and Pharmacy Capabilities**
  Highly-trained CNS clinic staff, a DEA-licensed on-site pharmacy (Schedule I–V), and strict protocol fidelity ensure safe, compliant, and efficient study execution.

- **Regulatory-Aligned Protocol and Scientific Support**
  Experts develop and refine protocols, provide 8-Factor Analyses, FDA-recommended hypothesis testing, and deliver rigorous scientific and regulatory guidance.

- **Integrated PK/PD, Bioanalysis, and Data Management**
  Co-located bioanalytical labs, robust PK/PD expertise, and validated EDC/data platforms ensure timely, precise, audit-ready results.

- **Flexible Designs and End-to-End Support**
  Experience in crossover, randomized, and placebo-controlled designs, with support for regulatory submissions and peer-reviewed publications.

Partner with us and place your abuse-potential studies in expert hands—from protocol development through final reporting.

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