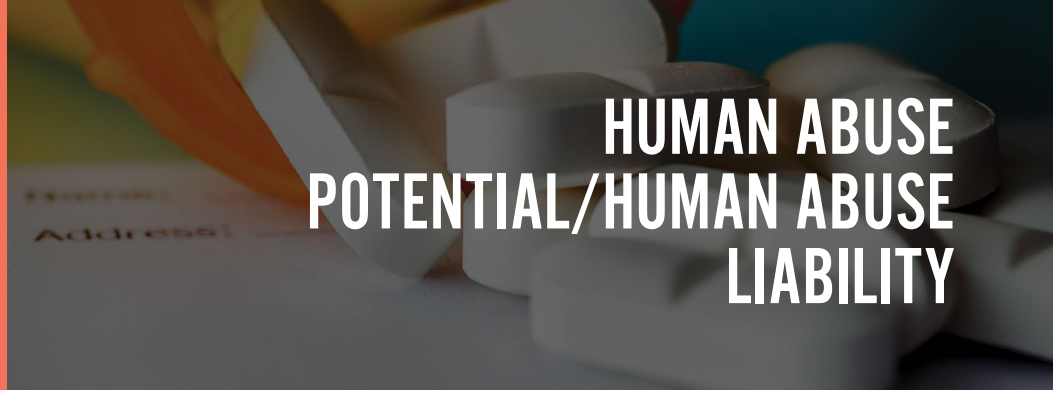
ALTASCIENCES
CLINICAL SERVICES



HUMAN ABUSE POTENTIAL/HUMAN ABUSE LIABILITY

Human Abuse Potential (HAP) Clinical Studies

HAP clinical studies, also known as human abuse liability (HAL) studies, may be required by the FDA as part of the safety evaluation for New Chemical Entities (NCEs) that are CNS-active, chemically or pharmacologically similar to other drugs with known abuse potential, or produce psychoactive effects such as sedation or euphoria.

In other instances, sponsors may be required to evaluate the effectiveness of an Abuse-Deterrent Formulation (ADF). For ADF trials, the objective is to assess the ability of the new formulation to be tampered with and abused in comparison to similar products that do not have abuse-deterrent features, or in comparison to other approved ADFs. ADF trials are often pursuant to a 505(b)(2) strategy. The complicated regulatory pathway for HAP and ADF protocol designs (selection of comparator, recruiting, etc.) requires individualized consulting for each type of study.

HAP Experience

Our Principal Investigators have over 40 years combined substance abuse clinical experience.

- Industry leader in the conduct of substance abuse clinical trials
- Conducted 60+ HAP and substance abuse studies
- Experienced with a diverse range of HAP studies, including stimulants, opioids and sedative hypnotics
- Access to a large database of recreational drug users for rapid study enrollment
- Full-time clinical research pharmacists
- USP 797-certified clean room with a Class II Biological Safety Cabinet
- Negative Pressure, HEPA-filtered extemporaneous compounding room equipped with a PowderSafe™ Ductless Balance enclosure
- Extemporaneous and intravenous preparation, for both large and small molecules
- DEA Schedule I licenses to conduct research with Tetrahydrocannabinol (THC) and Cannabidiol

Our physicians work with both recreational drug users and substance-dependent participants, and have significant expertise in the identification of appropriate subjects for substance abuse studies.

We were twice awarded a 5-year, $10-million contract with the National Institute on Drug Abuse (NIDA) to conduct clinical pharmacology studies to support the development of new medications for the treatment of substance abuse disorders.

Furthermore, we were granted a contract with the FDA Office of Generic Drugs (OGD) to conduct a clinical study to assess the bioavailability of milled opioid drug products following nasal snorting.

We also recently completed an inpatient study assessing the psychological effects of Cannabidiol (CBD) which was fully funded by NIDA. The study findings will be used to add to the body of scientific evidence related to the abuse potential effects of CBD in humans and to inform scheduling decisions under the Controlled Substances Act.

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Pharmacy Expertise

Our pharmacists have extensive knowledge and experience in preparing and dosing HAP and substance abuse studies via several routes, including oral, sublingual, intranasal, and parenteral.

Additionally, our pharmacy capabilities include over-encapsulation, manipulation and usability processing of abuse-deterrent oral dosage forms, and the blinding of referenced and comparator products. Our specialized pharmacy services include a multitude of formulation preparations and administration routes.

Our clinical research pharmacists have been trained at the Professional Compounding Centers of America and have specialized abuse-deterrent preparation and manipulation training.

Bioanalytical assays developed include:

- Amphetamine Mixed Salts
- Buprenorphine/ Norbuprenorphine
- Cocaine
- Codeine (and metabolites)
- Hydrocodone
- Hydromorphone
- Lorazepam
- M6G
- Methylphenidate (chiral method also available)
- Morphine Noroxycodone
- Oxycodone/Noroxycodone/ Oxymorphone
- Zolpidem

Additional assays can be developed and tailored to your program upon request.

COMPREHENSIVE RESEARCH SUPPORT

Program Management

- Dedicated program manager to oversee all aspects of program conduct and deliverables
- Close collaboration with key internal and external stakeholders to ensure seamless and timely communication for successful program completion

Project Management

- Project management team to coordinate all aspects of each study
- Expertise in a wide range of study types and therapeutic areas

Protocol Development and Medical Writing

- Clinical trial protocol development, review, and evaluation
- Integrated ICH E3-compliant clinical study report (CSR)

Scientific Publication Writing

- Strategic guidance and quality writing for manuscripts, posters, and abstracts
- Expert review and editing of your publication drafts

Regulatory Support

- Extensive experience in preparing study design to meet regulatory requirements
- Preparation and submission of regulatory documents
  - IND/CTA
  - NDA
  - IRB
- Post-submission regulatory deficiency remediation

PK/PD Data Analysis and Interpretation

- Rapid turnaround for interim PK evaluation between dose escalation cohorts
- Stand-alone report and/or CSR integration

Data Management

- CDISC standards fully integrated in workflow
- Database lock available typically within 2 to 4 weeks of last subject's final visit

Clinical Monitoring

- Highly experienced, well-trained CRAs to oversee all relevant aspects of clinical trial conduct
- Ensures data integrity, patient safety, and compliance with your protocol and GCP

Biostatistics

- All programming done using SAS®
- Statistical analysis plan, including mock TFLs
- Statistical results and appendices (TFLs) for CSR
- Creation of CDISC-compliant, FDA submission-ready package

Support Services for Nonclinical Studies

- Analytical chemistry
- Analytical biology
- Immunohistochemistry
- Specialized necropsies
- Anatomic pathology and clinical pathology
- Toxicokinetics
- SEND – Standard for Exchange of Nonclinical Data
- Archiving
- Histology

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