ALTASCIENCES
CLINICAL SERVICES

GENERIC OPIOID
ABUSE-DETERRENT FORMULATIONS

Clinical Studies for Generic Abuse-Deterrent Formulations

The FDA's final guidance on the regulatory pathway for generic versions of opioid abuse-deterrent formulations clears up the uncertainty around these programs and demonstrates that there are similarities and differences in the development of a novel abuse-deterrent formulation.

As with any generic formulation, sponsors are required to demonstrate that their test product is bioequivalent to the reference product, under fasted and potentially fed conditions. At Altasciences, we have run over 100 generic bioequivalence studies on opioid products that have included both clinical and bioanalytical components. In fact, we have experience with 15 opioids and 22 related bioanalytical methods.

Additionally, the guidance indicates that it is important to examine the abuse-deterrent properties under each potential route of abuse, using the same tiered approach as with new formulations. In many cases, Category 2 studies (pharmacokinetic comparisons after chewing or insufflation) are required. Depending on the method of abuse-deterrence, such as with aversive agents like nasal irritants, Category 3 studies (human abuse potential studies) may be required. Altasciences is a leader in performing both Category 2 and 3 studies, with a robust database of recreational users of opioids across our Kansas and Montreal clinical sites.

Clinical Expertise

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

- Industry leader in the conduct of opioid clinical trials, ranging from bioequivalence to human abuse potential (HAP) studies
- Conducted over 100 opioid bioequivalence studies
- Conducted 35+ HAP and substance abuse studies in the last 5 years
- Study designs, including sample size justification for over 1,000 bioequivalence studies involving opioids
- Study designs for Category 2 studies for all approved abuse-deterrent formulations
- Access to a large database of recreational opioid users for oral and insufflation studies leading to rapid study enrollment
- Five 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
- Controlled substance licenses across all three clinical sites
- Programs can be conducted across the three clinics to speed up development

Leader for over 25 years in generic drug development from study design, to clinical conduct, to bioanalysis, to reporting.

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.

contact@altasciences.com
altasciences.com

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.

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

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:

- Buprenorphine/Norbuprenorphine
- Hydrocodone
- Hydromorphone
- Methadone
- Morphine/Morphine-6-Glucoronide
- Naloxone/Naloxone-3-Glucuronide
- Naltrexone
- Oxycodone/Noroxycodone/Oxymorphone

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

Support Services

Bioanalysis

- Bioanalytical capabilities are supported by over 100 highly-trained specialists, working with the latest equipment in state-of-the-art, purpose-built laboratories
- High throughput bioassays for drug quantitation (operating 24/7), capacity of 60,000 samples per month
- Method feasibility, transfer, development and validations in multiple matrices
- LC-MS/MS and ligand binding assay capabilities

Toxicokinetics and Pharmacokinetic Analysis

- Comprehensive preclinical TK and clinical PK and PD data analysis and interpretation
- Robust non-compartmental analysis using WinNonlin® v8 (Phoenix)
- Rapid turnaround for interim PK evaluation between dose escalation cohorts
- Stand-alone report and/or CSR integration

Medical Writing

- Team with over 20 years of experience
- Study design in line with current regulations
- Clinical trial protocol development, review and evaluation
- Integrated ICH E3-compliant clinical study report (CSR)

Data Management

- Team with over 20 years of experience
- Electronic Data Capture
- CDISC standards fully integrated in workflow
- Medical coding using latest versions of medical dictionaries (MedDRA, WHO-DDE)
- Database lock available typically within 2 to 4 weeks of last subject's final visit

Project Management

- Project Manager (Project Leader) oversees the complete program conduct and deliverables
- Extensive expertise in managing single or multiple site clinical trials, across a wide range of therapeutic areas
- Close collaboration with key internal and external stakeholders ensures seamless and timely communication for successful project completion

Biostatistics

- All Programming done using SAS®
- Randomization list
- Statistical Analysis Plan, including mock TFLs
- Statistical results and appendices (TFLs) for CSR
- Reconciliation of external data e.g. safety lab
- Creation of CDISC-compliant FDA submission-ready package

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