ALTASCIENCES
CLINICAL SERVICES

Cannabis Clinical Trials

EXPERIENCE

- Over **10 years**
- More than **40 total** studies:
  - 15 pharmacokinetic (PK)
  - 1 human abuse potential (CBD to THC)
  - 6 first-in-human (safety and tolerability)

PRODUCT EVALUATIONS

- Assessments using hedonic scale to evaluate:
  - Device ease of use
  - Product taste

CLINICAL OPERATIONS

- Trials can be **conducted in Canada or the U.S.A.**
- **Database of over 15,000** cannabis users for rapid recruitment
- **Fully licensed** for clinical and bioanalytical research in Canada
  - Research license
  - Cannabis drug license
- Regulatory licenses obtained per trial as required in the U.S.A.
- **Purpose-built inhalation rooms** replace smoke-filled air with fresh air and prevent cross-contamination between active and placebo participants
- Experience with **all forms of administration** – edible, oil, inhaled, capsule, spray, etc.
- **Cognitive** and **psychometric** testing
- **Early cardiac safety** assessment
- **Abuse Potential** of cannabis products
  - Smoked, vaped, edible, etc.
  - Medicinal, pharmaceutical, recreational, etc.
- **Experts in safety**
  - Biomarkers of exposure
  - Biomarkers of potential harm

BIOANALYTICAL CAPABILITIES

- Over **16,000 study samples** analyzed
- **Validated methods to measure**
  - Tetrahydrocannabinol
  - 11-Hydroxy-Δ9-THC
  - 11-Nor-9-Carboxy-Δ9-THC
  - Cannabidiol
  - Cannabidiolic Acid
  - Cannabinol
  - Trans-Δ9-THC-Acid
- **Validated methods** for all forms of administration
- **Multiple ranges** — from pg to ng LLOQ
- Preclinical capabilities in development

COMPREHENSIVE RESEARCH SERVICES

DATA MANAGEMENT

- Team with over 20 years of experience
- eClinical EDC
- CDISC standards fully integrated in workflow
- Medical coding using latest versions of medical dictionaries (MedDRA, WHO-DDE)

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)

PROJECT MANAGEMENT

- Project Manager (Project Leader) oversees the complete program conduct and deliverables
- Extensive expertise in managing single or multiple site clinical trials
- 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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