

# **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-∆9-THC
- Cannabinol
- 11-Nor-9-Carboxy-Δ9-THC Trans-Δ9-THC-Acid
- Cannabidiol

- Validated methods for all forms of administration
- Cannabidiolic Acid Multiple ranges from pg to ng LLOQ
  - Preclinical capabilities in development

# **COMPREHENSIVE RESEARCH SERVICES**

#### DATA MANAGEMENT

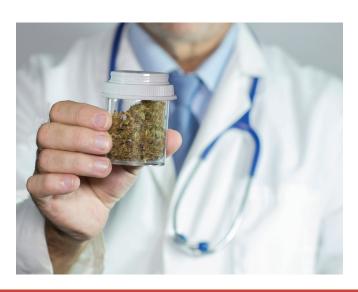
- Team with over 20 years of experience
- eClinical EDC
- CDISC standards fully integrated in workflow
- Medical coding using latest versions of medical dictionaries (MedDRA, WHO-DDE)

### 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

### **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)





### **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