Early development

Austin Clinic – ADME study capabilities

Absorption, distribution, metabolism and excretion (ADME) studies are critical in understanding how a drug is processed by the human body to assess safety and toxicity. Our Austin clinical research unit (CRU) holds a radioactive research license for the State of Texas and has supported over 30 early development clinical trials with 200+ subjects involving C-14 labeled compounds. The Austin CRU provides onsite scintillation counting and has the capability to measure decays per minute (DPM) in different types of biological samples.

Austin CRU Highlights

Pharmacy Services

- USP 795/797/800 regulations compliant
- Full time registered pharmacists (On call 24/7)
- Full time certified technicians
- Aseptic [c14] RL/parenteral compounding room
- Early client engagement to meet any pharmacy needs
- On-site controlled access BA/BE drug retention room
- Extensive experience with complex nonsterile, sterile, radiolabeled and high-risk compounding (HRC)
- QC procedures for subject specific label and dose preparation
- Controlled investigational drug storage
- Rees® environmental monitoring system

Laboratory Services

- Wide clinical menu of tests / 7-day operations
- Bar coded samples
- Same day reporting
- Electronic data transfer
- Results posted to our data portal for sponsor viewing
- Onsite Liquid scintillation counting (total radioactivity measured)
- PK/PD processing lab (Plasma, Urine and Feces)
- Flow cytometry
- Extensive library and custom assay development
- Assays run locally or processed and shipped to PPD™ Laboratory services Bioanalytical lab

Aseptic [c14] RL/parenteral compounding room

Onsite liquid scintillation counting

Extensive experience with complex nonsterile, sterile, radiolabeled and high-risk compounding (HRC)

ThermoFisher SCIENTIFIC

Case Study: Mass Balance

Background

- Study conducted at the Austin Texas CRU
- Study drug class: opioid receptor antagonist
- Key inclusion/exclusion criteria:
  - Males up to 55 years of age
  - BMI up to 32 allowed
  - Can't have participated in another radiolabeled study in the last year
  - Can't have any problems affecting venous access or bowel/bladder function
  - No medical history with any issues affecting absorption or metabolism
  - Any problems affecting venous access or bowel/bladder function

Strategy

- The study called for 10 subjects to be enrolled into a 3 period study with 2 of the periods requiring C14 radiolabelled doses
- The screening and enrollment plan called for a single cohort with subject domiciled from Day 1 to Day 21
- Contingency planning accounted for the possibility of subjects needing to stay past Day 21 until less than 1% of the C14 dose is recovered per day for 2 consecutive days
- Special menu prepared by our dietician to restrict poorly digestible foods and to increase fiber intake

Results

- 32 subjects screened
- 10 + 4 backups checked in and 10 subjects enrolled per protocol
- Blood, urine and fecal samples processed per protocol with emesis captured up to 4 hours postdose for C14 analysis
- 4 subjects exited on Day 21 as planned, 1 subject exited on Day 22, 4 exited on 25 and 1 exited on Day 28

Learn more at **thermofisher.com/ppd**

ppd