



## Capabilities: PK/TK & Non-GLP Toxicity

### Rodent PK/TK

#### Species:

Mice (CD-1, C57BL/6, etc.), rats (Sprague Dawley, Wistar, Wistar-Han, etc.), Hamsters, Guinea pigs

#### Administration Route:

Oral (PO), intravenous (IV bolus, infusion), intraarterial (IA), intramuscular (IM), intraperitoneal (IP), intratracheal (IT), subcutaneous (SC), transdermal (TD)

#### Surgical rats:

Bile-duct cannulation (BDC), jugular cannulation (JVC), portal vein cannulation (PVC), carotid artery cannulation (CAC), JVC/CAC, JVC/PVC

#### Biological Matrices:

Blood/plasma/serum, bile/urine/feces, cerebrospinal fluid (CSF), bone marrow, tissues (liver, brain, kidney, etc.) or tumor specimens

- Mouse PK: Serial bleeding
- Cassette-dosing
- Excretion pathways

### Dog & Monkey PK/TK

#### Dog PK:

- In-house dog colony: 48 Beagle dogs
- Admin. Route: PO and IV (bolus, infusion), SC.
- Crossover or non-crossover; fast/fed (food effect); PK/PD evaluation

#### Monkey PK :

- Off-site NHP colony: 32 male Cynomolgus monkeys
- Partner: Dosing and Sampling
- BioDuro: Formulation prep., monitoring for dosing and sampling, bioanalytical method development and sample analysis, and report writing
- Excretion pathways

### Exploratory Toxicity (MTD, DRF) in Rodents, & in Dogs/Monkeys with Partners

- Maximum toleration dose
- Dose ranging finding/toxicokinetics (7,14 & 28 days)
  - Clinical observation
  - Clinical pathology (serum chemistry, hematology & coagulation)
  - Histopathology (samples analyzed by the partners)
- Turnaround Time: 10 working days for TK, clinical pathology; 5-6 weeks for histopathology report after in-life