



# In Vivo Pharmacokinetic and Metabolism Services

## Pharmacokinetic Studies

These studies establish pharmacokinetic parameters such as half-life, exposure ( $C_{max}$  and AUC), bioavailability, clearance, and volume of distribution. Unlabeled drug is administered both intravenously and by the intended clinical route to allow comparison of circulating drug levels. Parent drug levels and metabolites can be determined and modeled in the species intended for preclinical development.

- Pharmacokinetic modeling, all standard species
- Bioavailability in Rats
- Bioavailability in Dogs and Monkeys

## ADME Studies

These studies assess the distribution of radiolabeled drug in tissues over time and determine the routes and rates of excretion. Selected excreta, plasma, and tissue samples are used to produce metabolite profiles for the toxicology species and these profiles may be compared to those obtained in humans. Typically,  $^{14}C$  labeled drug is used for these studies, but other isotopes ( $^3H$ ,  $^{35}S$ ) can be used.

- Excretion Balance in Rats
- Tissue Distribution in Rats
- Excretion Balance in Dogs and Monkeys

## Additional Studies:

- Biliary elimination and enterohepatic recirculation
- Metabolite identification and profiling
- LC-MS/MS pharmacokinetic comparison for parent drug and metabolites
- Repeat-dose pharmacokinetic and distribution studies
- ADME in other species
- Metabolite profiling from human metabolism studies
- Radiochemistry synthesis support