



Measuring the drug and its metabolites to understand the interaction of the drug with the body

HEALTHY VOLUNTEER SAFETY STUDIES

- + Administer treatment under investigation
- + Draw samples at pre-determined time intervals

PATIENT EFFICACY STUDIES

- + Multiple visits per trial protocol
- + Samples collected and analyzed to correlate drug levels with patient response
- + Data are not returned to the investigator for patient management

PRECLINICAL SUBJECTS



HEALTHY VOLUNTEERS



PATIENT



Administer treatment



INVESTIGATOR SITE OR PHASE I CLINIC

Specimens sent to lab

BIOANALYTICAL LAB



Data file to project team

CLIENT



- + Testing to establish and validate drug safety via carcinogenicity, toxicity, mutagenicity and/or teratogenicity studies



BIOANALYTICAL LAB SERVICES

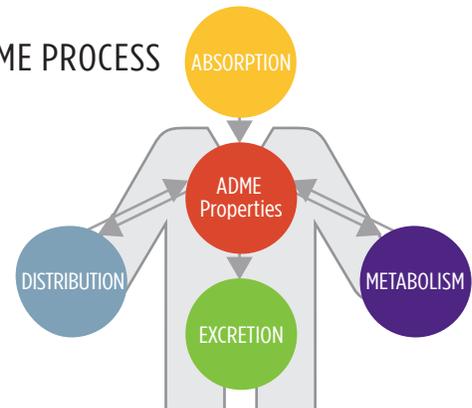
Drug Testing

- + Understand the pharmacokinetics and pharmacodynamics (PK/PD) of the drug
- + Measure the *In vivo* absorption, distribution, metabolism and excretion (ADME) of the parent drug and its metabolites
- + Monitor for adverse drug reaction
- + *In vivo* ADME testing of the parent drug and its metabolites
- + Proof of concept (POC)
- + Dose escalation and ranging studies
- + Pharmacokinetics and pharmacodynamics (PK/PD) studies
- + Population PK
- + Post-approval marketing trials
- + Investigator-initiated trials

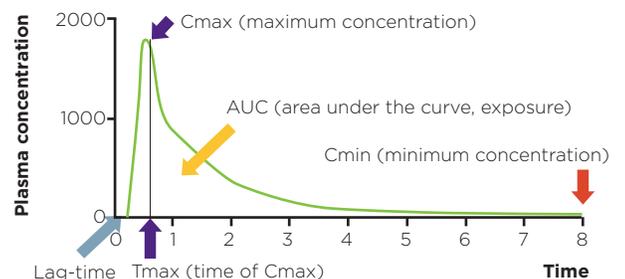
Immunogenicity Testing for Large Molecules

- + Antibodies and antibody-drug conjugates
- + Determine immune response
- + Understand potential for neutralization of antibody
- + Proof of concept (POC)

ADME PROCESS



PHARMACOKINETIC CURVE



HALLMARKS OF PPD LABORATORIES

- + Extensive experience with BOTH small molecules and biologics
- + The bioanalytical lab excels at creating custom solutions for clients' most challenging problems
- + Development and validation of robust custom assays
- + Top-quality biologics services
- + Deep expertise in antibody-drug conjugate (ADC) testing
- + Strong reputation for being technology leaders
- + Extensive LC/MS experience