



Preclinical Technologies

FACTSHEET



Preclinical and Clinical Pharmacokinetics

Our Pharmacokinetics Group provide comprehensive pharmacokinetic (PK) support for a wide range of preclinical studies (toxicology, pharmacology, ADME, etc.) and also provide PK, pharmacodynamic (PD) and statistical support for First-Time-In-Human through to proof of concept clinical trials. We can help you with the following:

PK Analyses

Assess the rate and extent of systemic exposure to your test compound (eg. C_{max} , t_{max} , AUC, $t_{1/2}$, etc.) using non-compartmental and compartmental modelling techniques.

Fast PK Turnaround

Help guide dose escalation decisions, and enable optimal assessment of the maximum tolerated dose.

Statistical Analyses

Includes assessment of bioequivalence, bioavailability, food effect, drug-drug interactions, dose proportionality and special populations.

PD Analyses

Understand the effects of your test compound on various PD variables using graphical and statistical approaches.

PK/PD Modelling

Use non-linear and non-linear mixed modelling techniques to understand the PK/PD relationship, which is an essential component of proof of concept studies.

Simulation

Help predict systemic exposure and PD effects for alternative dose regimens.

Study Design

Use our considerable background to ensure study objectives are met by estimating sample size, optimizing PK sampling and simulating data.

Reporting

Concise and comprehensive PKPD reports where quality is everything. Report tables, listings and figures can be produced using WinNonlin Pro or SAS, as required.

Regulatory Compliance

Studies are analyzed and reported in accordance with GLP and GCP regulations (as appropriate), and relevant ICH, EMEA and FDA guidelines.

Software

SAS and WinNonlin Pro (validated to meet regulatory requirements).

Additional Aptuit Capabilities

Aptuit offers a comprehensive suite of drug development services that range from candidate selection through to market, including consultancy services, API development and manufacture, preclinical and clinical technologies, pharmaceutical services, large and small scale manufacturing, IVRS, and clinical packaging and logistics, across a wide range of compounds, dosage forms and delivery systems.

For information about Aptuit's services, please call or email:

+1 816 767 3900 North America

+44 131 451 2451 Europe

email: info@aptuit.com

or visit our website: www.aptuit.com

Engineering a better drug development process through scientific excellence.