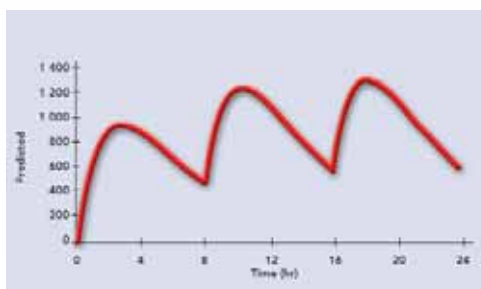




Pharmacokinetic Services

PAREXEL Clinical Pharmacology is able to offer clients the benefit of extensive experience in pharmacokinetic evaluation of drug and metabolite concentration data collected from a number of Phase I-III study designs. In addition to this, PAREXEL Clinical Pharmacology can provide clients with PK consultancy services to aid the drug development planning process.



Pharmacokinetic Consultancy

The Pharmacokinetic consultancy services available include:

- Development of pharmacokinetic strategies for incorporation within the drug development plan
- Designing studies to meet specific pharmacokinetic objectives
- Review of pre-clinical and clinical PK data and reports

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Pharmacokinetic Analysis

PAREXEL Clinical Pharmacology is highly experienced in providing pharmacokinetic analysis using the software WinNonlin Version 5.x, SAS Version 9.x.

A site specific validation plan and reports are readily available for inspection.

The source data could be Bioanalytical data generated by client, by the PAREXEL Bioanalytical laboratory based in Bloemfontein, South Africa or could also be Bioanalytical data from our preferred provider laboratories based in Poitiers, France and South Africa

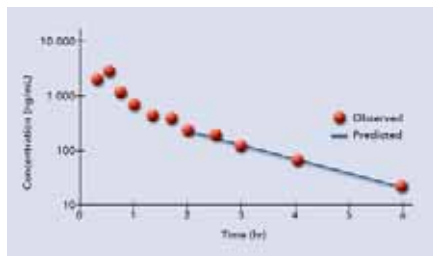
Analytes:

- Drug
- Metabolites
- Biomarkers

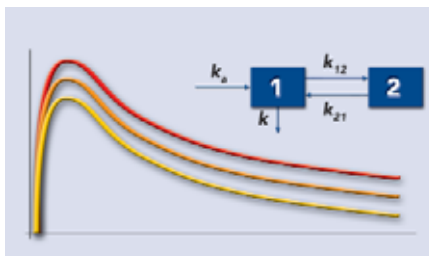
PAREXEL Clinical Pharmacology can provide pharmacokinetic analysis on a number of study types such as:

- ADME mass balance
- Bioavailability (BA)/Bioequivalence (BE)
- Single ascending dose
- Multiple ascending dose
- Drug-drug interaction
- Food interaction
- Special populations
- Hepatic/renal impairment
- Gender effect
- Age effect

Non-compartmental Analysis



Compartmental Analysis



PK/PD Modeling and Simulation includes:

- Emax
- Sigmoid Emax
- Inhibitory models
- Effect-link

Statistical Evaluation Services

Services available from PAREXEL Clinical Pharmacology include:

- Dose proportionality
- Bioequivalence assessment
- Regression/correlation analyses
- Summary statistics, tabulation and graphical display of study data

Medical Writing Services

The service offerings include:

- Preparation of pre-clinical and clinical pharmacokinetic reports
- Preparation of pharmacokinetic sections of protocols and integrated reports

PAREXEL Clinical Pharmacology

Strategic Locations

North America

PAREXEL International CPRU,
Baltimore. USA.
Tel: +1 410 350 7979
Fax: +1 410 3544281
E-mail: clinpharmbaltimore@parexel.com

California Clinical Trials - A division of
PAREXEL International.
Los Angeles and San Diego. USA.
Tel: +1 818 254 1602
Fax: +1 818 545 8048
E-mail: cct@parexel.com

Europe

PAREXEL International CPRU,
Berlin. Germany.
Tel: +49 303 068 5111
Fax: +49 303 068 5299
E-Mail: clinpharmerlin@parexel.com

PAREXEL International CPRU, London. UK.
Tel: +44 189 561 4659
Fax: +44 208 422 6070
E-mail: clinpharmlondon@parexel.com

South Africa

PAREXEL International CPRU,
Bloemfontein. South Africa.
Tel: +27 51 410 3111
Fax: +27 51 444 5969
E-mail: clinpharmsouthafrica@parexel.com

PAREXEL International CPRU,
George. South Africa.
Tel: +27 44 884 1560
Fax: +27 44 884 1566
E-mail: clinpharmsouthafrica@parexel.com

PAREXEL International CPRU,
Port Elizabeth. South Africa.
Tel: +27 41 505 8237
Fax: +27 41 505 8238
E-mail: clinpharmsouthafrica@parexel.com

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