DRUG DEVELOPMENT SOLUTIONS
Part of Alliance Pharma, Inc.

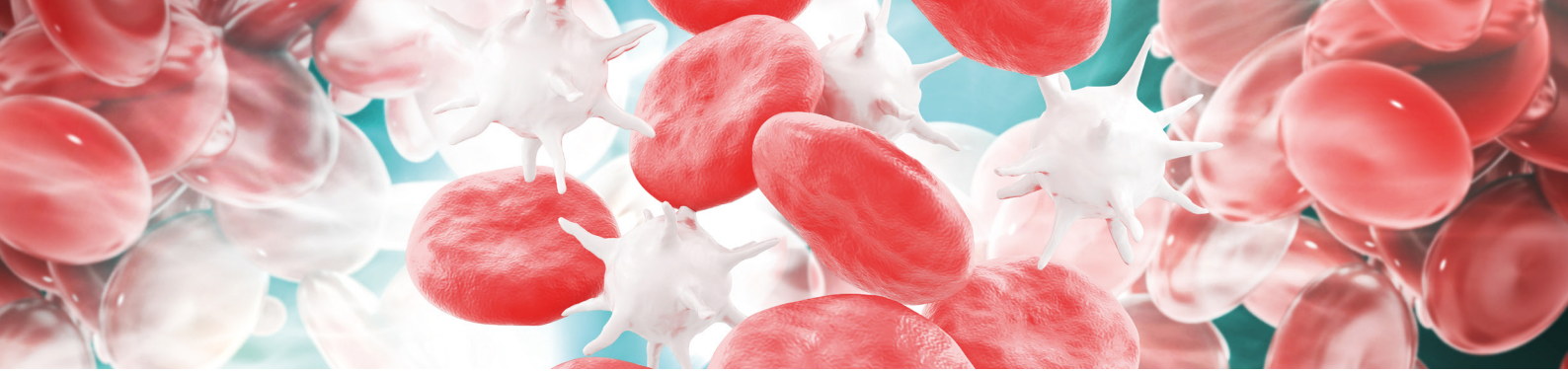
Pharmacokinectics

Drug Development Solutions has experience carrying out pharmacokinetic (PK), pharmacodynamic (PD) and toxicokinetic (TK) studies for all stages of drug development, providing expertise and quality to clients.

We use industry standard Phoenix WinNonlin® for non-compartmental data analysis (NCA), giving you access to a complete bioanalytical PK and TK service to support your pre-clinical and clinical studies:

- High quality report tables and figures suitable for IND and NDA submissions
- Data transfers generated to SDTM/SEND standards
- Comprehensive standard operating procedures (SOPs and validated software systems in conjunction with full QA facilities ensure regulatory compliance
- Customisable client specific templates
- Data presented in clear tabular and graphic reports combined with expert advice and interpretation
- Advice on study design.

Drug Development Solutions provides analysis of bioanalytical data and preparation of the TK appendix to toxicology study reports. We also offer drug discovery support – providing rapid data to select candidates with the required PK properties.



Clinical studies

We carry out PK support for clinical studies from Phase I to Phase IV across a broad range of therapeutic applications. Our pharmacokineticists provide analyses for:

» SAD/MAD studies
» Bioavailability studies
» Food effect studies
» Renal studies
» Gender/age comparison.

Biologicals

Along with standard small molecule PK reporting we also support analysis of protein and peptide drugs.

Standalone services

A range of standalone services are also available:

» Full PK/TK data analysis and reporting on data generated outside of Drug Development Solutions
» Project management within the PK team as a discrete study phase or project
» Advice on preclinical and clinical study designs
» Reporting in client specific format.

Parameters

Standard parameters are reported, which are fully customisable to client requirements:

» Maximum plasma concentration (Cmax)
» Time to the maximum concentration (Tmax)
» Area under the plasma concentration vs time curve, AUC(0-t)
» Area under the plasma concentration vs time curve, with extrapolation to infinity (AUC(0-∞))
» Apparent terminal half-life (t1/2)
» Mean residence time (MRT)
» Clearance (Cl)
» Volume of distribution (Vd)
» Amount of drug excreted in urine (Ae)
» Renal clearance (Clr).

We also offer a number of additional parameters and ratios to aid in PK/TK interpretation such as assessment of the accumulation index, dose proportionality and bioavailability.

Let's discuss your project:
drugdevelopmentsolutions.com
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