



## Clinical Design



### Early Phase Drug Development

We are able to integrate your pre-clinical PK/PD and toxicokinetic data to design and maximise the value of your first in human (FIH) studies (Phase I).

For example:

- Advice on the choice of starting dose in FIH studies
- Interim PK analysis, chiefly during single and multiple ascending dose studies, to aid Study Safety Review Committees make decisions around further dose escalation
- Interpretation of emerging data, for example non-linear PK, in early phase studies (Phase I-II eg ascending dose studies) will help you make critical business decisions around the viability of your compounds
- Evaluation of drug drug interaction data to aid concomitant medicine use in patient studies

### Clinical Pharmacology Strategy

By close collaboration with you we can deliver pragmatic, scientifically robust advice to help make your clinical development programme efficient and successful.

This includes:

- Novel clinical study design
- Assessing the impact of clinical trial results on the further development of the compound
- Scientific reviews of the literature
- Due diligence for licensing opportunities
- Advice on the drug interaction potential of your compound; from clinical trial design to the collation of a co-medication policy in early patient studies
- Evaluation of novel formulations through the design, analysis and interpretation of bioavailability and bioequivalence studies

### Key Input for Regulatory Submissions

We are able to provide you with expert pharmacokinetic and clinical pharmacology input to help you achieve global regulatory success with:

- Clinical Trial Applications (particularly FIH studies)
- Investigational New Drugs submissions and updates
- European marketing authorisation applications
- Investigator Brochures
- Responses to Questions from regulatory authorities
- Regulatory advisory meetings such as pre-IND
- PK interpretation for abridged licensing applications