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Pharmacokinetic / Toxicokinetic / Pharmacodynamic Services

Inotiv's PK services provide a broad range of expertise and unparalleled turn-around time for all stages of R&D, from lead optimization in Discovery to IND and NDA. We offer a collaborative and investigative approach towards understanding your compounds Pharmacokinetic properties. Our team of industry-trained scientists have a track record of providing leading pharma and biotech companies with attentive and decisive consulting and laboratory services.

PK/PD/TK Analysis

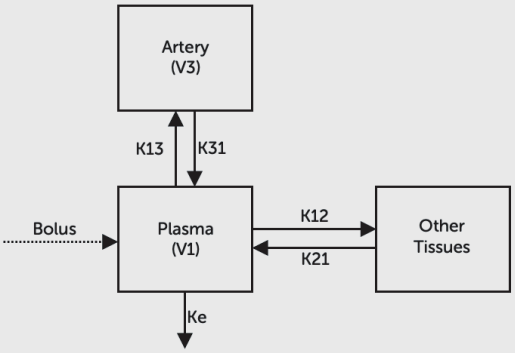
- GXP Compliant - using validated, industry-standard Phoenix WinNonlin® software
- Non-compartmental and compartmental approaches
- Bioequivalence/Bioavailability assessments
- Determination of effects of dose, formulation, dosing regimen, drug interactions, genotype, gender, and other factors on PK
- Leverage preclinical data for clinical PK projections (e.g., allometry and clinical dose projections)
- Clinical PK Analysis and third party support, interim data available for dose escalation analysis and review

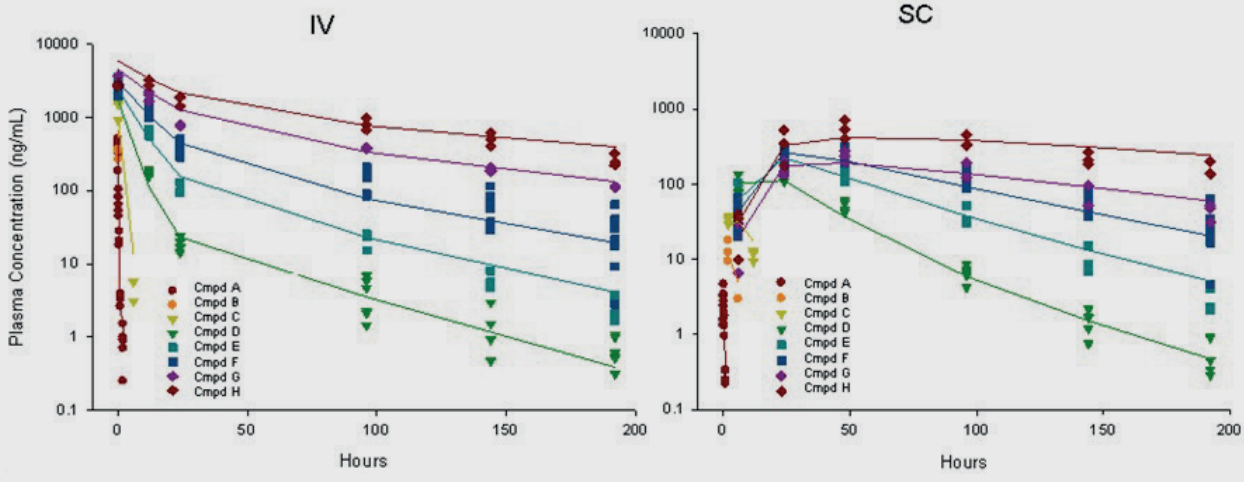
Advanced Modeling & Simulation

- Multiple software platforms (e.g., Phoenix WinNonlin®, NONMEM, etc.)
- Empirical or mechanistic modeling, Mixed effects modeling (e.g., Population PK/PD modeling)
- Optimization of population PK/PD sampling
- Clinical trial simulation
- Meta analysis to leverage previous and published data

Protocol and Report Generation

- Protocol writing support
- Provide Abbreviated or full study reports
- Stand-alone immunogencity reports
- Support technical and regulatory reports
- Publications, abstracts, and posters
- Use of client preferred formats





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General Information / Support for PK/PD/TK Services

Quality

- Dedicated Scientific Writers and QC/QA staff
- Industry standard Phoenix WinNonlin®, fully validated and GXP compliant
- Culture of getting it right the first time
- Our pharmacokineticists have expertise in discovery, preclinical, and clinical stages with core pharmacometric modeling and simulation skills.

On-time Delivery

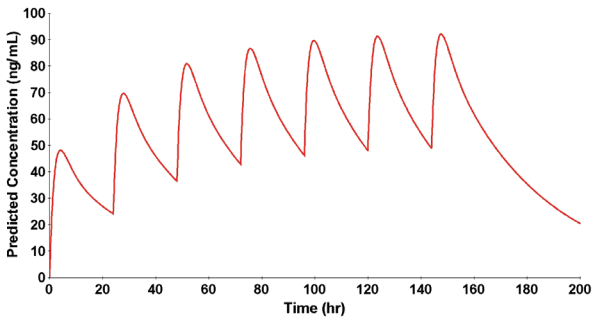
- Turn-around times for non-GLP data analysis are frequently less than 1 week. Depending on the scope, non-GLP data analysis can often be completed within 48 hours of receipt of data.
- Turn-around times for GLP data analysis and audited TK contributor report is 3 weeks from receipt of audited BA data (and pertinent deviations/amendments).
- Turn-around times for GCP clinical data analysis and audited PK/PD contributor reports are case-by-case depending on the size of the study. Frequently, these are still in the 3 week turn-around timeframe.

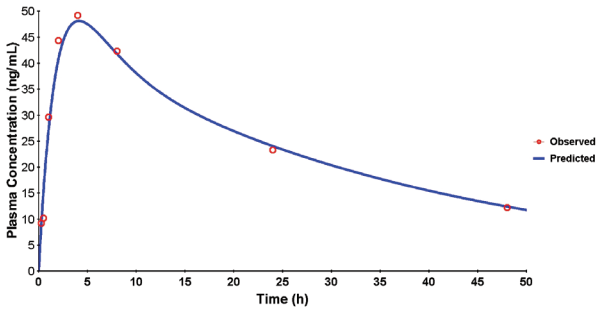
Value Proposition

- Inotiv's PK/PD/TK Services are priced competitively with unparalleled speed and quality
- Typical pricing for non-GLP, GLP, and Clinical PK/PD analysis and reporting is case-by-case depending on the study and scope of analysis and reporting requirements.

Consulting

- We offer a breadth of consulting services related to ADME (bioanalysis, *in vitro* ADME, *in vivo* ADME, regulatory considerations for both preclinical and clinical support) of both small organics and biologics.
- Our team provides third party PK services supporting overflow preclinical and clinical work of other CROs. We have also performed technical and quality systems audits for a number of CRO laboratories.





Contact us at inotivco.com/contact to discuss how our models and services can support your research.