



Pharmacokinetic/Toxicokinetic Services

GLP-compliant Pre-clinical PK/TK NCA Analysis and Reporting

The ever-increasing complexity and demands in bringing novel drugs to market are challenges that can impact productivity and escalate drug development costs. Solutions to validate drug candidate safety and efficacy faster and earlier, or help achieve regulatory compliance, can result in significant time and cost savings.

Introducing Certara Pre-clinical PK/TK Services

At Certara we are focused and committed to developing modeling and simulation technologies and solutions that will streamline and accelerate your R&D productivity to achieve your goals faster.

As your partner for drug development and regulatory strategy we have expanded our services to offer GLP-compliant pre-clinical PK/TK NCA analysis and reporting.

Navigating pre-clinical regulatory safety assessments for drug candidate selection is a crucial step in the drug discovery and development process. Certara's comprehensive PK/TK services offering integrates proven and extensive pre-clinical expertise with advanced modeling and simulation approaches using Phoenix WinNonlin®, the trusted industry standard for PK/PD modeling and simulation.

Pre-clinical PK/TK NCA Analysis and Reporting Services

Certara PK/TK services and expertise are used by pharmaceutical companies, CRO's and toxicology consultants to expedite candidate selection for IND submissions, outsource PK/TK workload, and support sponsor programs.

- + Small and large molecules
- + Modeling and dose-response prediction
- + Serum, plasma, urine, tissue, CSF
- + CDISC SEND packages for PC and PP domains
- + PK/PD for biomarker evaluation
- + GLP compliant/on-site QA auditing
- + ADA Effect

Certara PK/TK Services deliver operational excellence and regulatory compliance:

- High quality personalized services
- GLP-compliant
- Integrated QA capabilities
- IND-ready reports
- Fast turnaround times
- Predictable scheduling and competitive pricing

Certara offers a full range of drug development services, including clinical pharmacology and regulatory strategy, first-in-man dosing, modeling and simulation, Simcyp PBPK, PopPK, QSP, and Synchrogenix regulatory solutions.

Routes of Administration





About Certara

Certara is a leading provider of decision support technology and consulting services for optimizing drug development and improving health outcomes. Certara's solutions, which span the drug development and patient care lifecycle, help increase the probability of regulatory and commercial success by using the most scientifically advanced modeling and simulation technologies and regulatory strategies. Its clients include hundreds of global biopharmaceutical companies, leading academic institutions and key regulatory agencies.

For more information visit www.certara.com or email sales@certara.com.