FRONTAGE

EUROPE

Pharmacokinetics

At Frontage Europe, our scientific team leverages cutting-edge technologies and industry-leading methodologies to deliver high-quality data supporting key milestones and informed decision-making throughout drug discovery and development.

Timely results depend not only on high-throughput analysis but also on effective pharmacokinetic (PK) evaluation, which guides study design, endpoint selection, and regulatory documentation.

Expert support to reduce clinical-phase risks
The team provides high-quality services to enable confident decisions and minimize drug attrition.

PK and TK services under EMA/FDA compliance, including:

- Pharmacokinetics and toxicokinetics aligned with EMA/FDA guidelines
- Non-compartmental and compartmental analysis, dose proportionality, food effect, bioequivalence/bioavailability, inter-species scaling
- Statistical analysis and reporting for Safety Pharmacology
- Support of pharmacodynamic and efficacy study design

PK in early clinical development under GCP and regulatory standards, including:

- Prediction of human PK parameters from animal data
- PK data transfer agreements
- Fast turnaround interim analyses and presentation to Sponsor/Investigators
- High quality PK reports are prepared using Phoenix WinNonlin® and SAS®.

Extended support for regulatory documentation

The team provides scientific advice for preparing **IND applications** and assists with summarizing data for the **Investigator Brochure (IB)**.

You can rely on our expertise even beyond the end of the study when it is time to prepare key regulatory documents. As added value, our team provides scientific advice for the preparation of the Investigational New Drug (IND) application and supports you with the comprehensive summary of relevant data for the Investigator Brochure (IB).