SocraTec R&D
Concepts in Drug Research and Development

Pharmacokinetics

PK evaluations – implemented for drug approval

SocraTec R&D performs classical non-compartmental (NCA) pharmacokinetic (PK) analyses for pilot studies and pivotal trials used for approval in the EU and worldwide including the FDA and ANVISA. From first-in-man to bioequivalence trials – our experience covers all relevant settings over decades of practical experience:

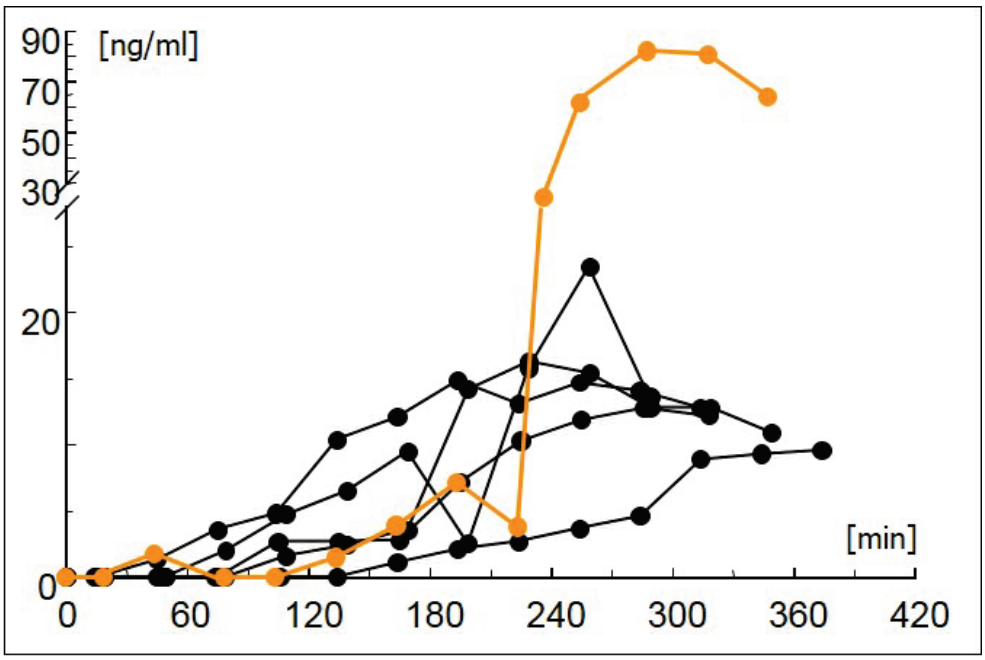
- Design development and sample size estimations
- Trial protocol writing
- Logistical support for multicentre PK studies in patients
- Study performance in phase-I settings as well as later phases
- Statistical Analysis Plan development
- Evaluation and interpretation of study results

Evaluations are run by a team of experienced PK analysts, all of them with a university background. All evaluation steps are SOP-based and embedded in a comprehensive quality assurance system with internal quality control procedures for all potentially vulnerable steps, based on a systematic risk analysis. Scientifically critical steps affected by subjective components, e.g., the selection of data points for determining the terminal elimination rate are always done under the Scientific Director's supervision.

Technical details

Our NCA evaluation is based on Phoenix WinNonlin and established in a validated IT environment. Statistical analyses of PK parameters are either done in WinNonlin or SAS depending on the sponsor's requirements.

The principles of US-FDA CFR 21 part 11 are applied for FDA approvals.



Wedemeyer R (2007). "Anwendungen der magnetischen Markierung hydroxypropymethyl-cellulosebasierender Retardtabletten zur Aufklärung ihres Verhaltens in vivo". Ph.D. Thesis. University of Greifswald: Germany

SocraTec R&D
Concepts in Drug Research and Development

BA/BE – decades of experience that matter

BA/BE – practical experience that helps

SocraTec R&D represents decades of experience in bioavailability (BA) and bioequivalence (BE) studies. This means that we have experience in all aspects of relevance for a successful BA/BE trial:

- "Probability of success" estimation based on in-vitro investigations
- Authorities' approval requirements worldwide
- Optimised standardisation of administration conditions
- A huge diversity of administration routes and dosage forms
- Highly variable drugs
- Clinical conduct in healthy subjects and patients – both mono- and multi-centric
- Adequate sequential designs and pilot studies
- Measures to improve inspection safety in all steps of the trial

BA/BE – expert evaluation

We have a lot of experience with expert evaluation of BA/BE studies in dossiers of products intended to be in-licensed. Our highly experienced scientists contribute all their experience to identify potential pitfalls as well as promising candidates.

Address

SocraTec R&D GmbH
Im Setzling 35
61440 Oberursel

Telefon +49 (0)6171 58571-0
Fax +49 (0)6171 5857-25

info@socratec-pharma.de
www.socratec-pharma.de

Managing Directors

Dr. Barbara Schug
André Warnke

Commercial Register

Bad Homburg v. d. Höhe
HRB 6590

VAT ID DE197498889