One partner, all the brains you need

Clinical Development

Increasing your chances of success

Over the past decade, early phase clinical development has evolved towards an intensive, knowledge-driven process, stimulated by the need to reduce attrition rates and to increase the chance of success in the expensive late stage of development. For many years, Kinesis Pharma has been a recognized leader for the provision of clinical pharmacology and translational expertise, as a partner for (innovative) pharmaceutical companies. With the involvement of well trained, very experienced experts, a large number of innovative early phase clinical development plans, protocols and reports have been delivered, and subsequently approved by regulatory authorities or acknowledged in due diligence processes.

Kinesis
Consultants in drug development

What Kinesis offers

- **Clinical consultancy**

Kinesis' consultants offer state-of-the-art expertise in measurement, quantification and evaluation of a drug's biological activity in humans. This extensive personal expertise will help sponsors to design the optimal early phase development program and clinical trials. To achieve that goal, up-to-date knowledge of biomarkers, measurement techniques and indications is required. Therefore Kinesis' (senior) consultants continuously update their knowledge, especially in those areas requiring their regular involvement. A close collaboration with an academic network of specialized clinics ensures utilization of best practices and the latest knowledge and techniques. Kinesis' consultants can help sponsors with various activities in clinical development, ranging from designing a (synopsis for a) single clinical trial, or providing input to dose escalation steps during a trial, to providing full clinical development programs, pediatric investigation plans and participation as clinical representatives in project teams.

- **Medical writing**

Kinesis' medical writers are experts in preparing clinical trial documentation. This highly experienced team is dedicated to writing Clinical Trial Protocols, Subject Information Sheets, Investigator's Brochures, and Clinical Trial Reports. Kinesis has its own templates for all medical writing documents, but sponsor templates can be used, if preferred.

- **Clinical trial operations**

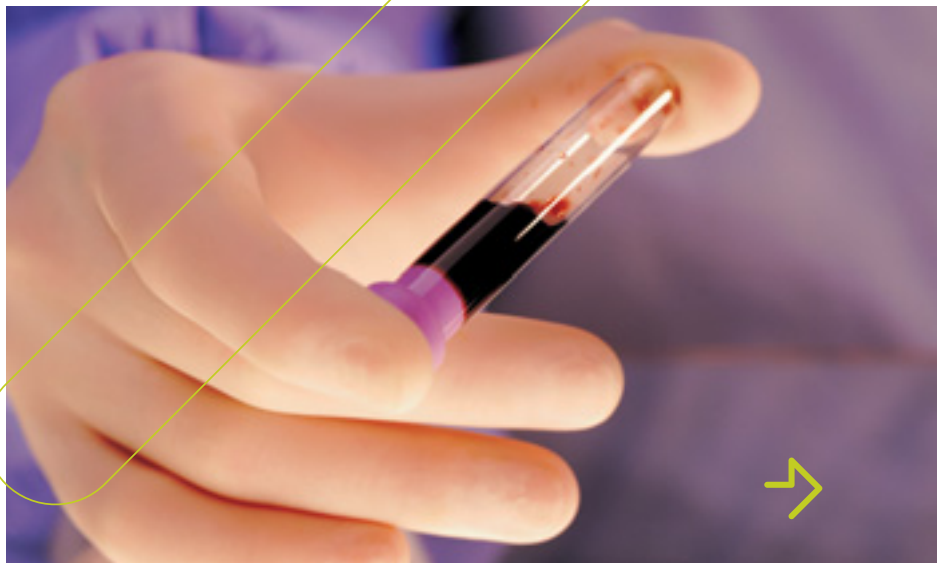
Kinesis' clinical trial operations group has the expertise to set-up, organize, outsource, submit, coordinate and deliver clinical trials. Timely delivery of high quality clinical trial results is the primary objective.

Main services include

- Create/coordinate the production of necessary trial documentation
- Identify and select the best clinics or Contract Research Organizations (CROs) for the needs of the protocol, clear of any selection bias
- Coordinate the clinical execution and data management, ICH-GCP monitoring, analysis and reporting

- **Classical pharmacokinetics**

Kinesis has a long history of performing non-compartmental pharmacokinetic (PK) analysis based on drug concentration versus time data that are derived from clinical trials, according to high quality standards, within agreed timeframes. These include first-in-man studies, interaction studies, bioequivalence studies (including statistics), special populations



and phase II/III studies. Kinesis' team of experienced data analysts is committed to delivering optimal quality on time for each (interim) analysis.

- **PK/PD Modeling & Simulation**

Kinesis' Pharmacometricians offer population pharmacokinetic (PK), pharmacodynamic (PD) and PK/PD analyses of clinical trials. To facilitate decision making within the sponsor's drug development program, Kinesis can perform exploratory analysis and interim evaluations with short turn-around times. Please find more details in the PK/PD Modeling & Simulation flyer.

- **Statistics & database programming**

Kinesis has specialists in SAS programming and data management, and dedicated statisticians to fulfill the needs for efficacy and biomarker analysis (especially in phase II, proof of concept type of studies), and safety and demographic analysis. Complete data management of clinical trials can be offered in collaboration with third parties.

Kinesis' specialists are familiar with more advanced statistical methods, including Bayesian evaluation, utilized for exploratory efficacy, biomarker and safety evaluations. Intelligent and adaptive trial designs are common practice for Kinesis' experts.

- **Pharmacovigilance**

Pharmacovigilance has recently been added to Kinesis' service offerings, recognizing the fact that many start-up companies appreciate help in organizing the mandatory pharmacovigilance arrangements before starting clinical activities. In collaboration with a Qualified Person for Pharmacovigilance, Kinesis has developed a complete pharmacovigilance system including 24/7 availability and the mandatory electronic (expedited) reporting of Suspected Unexpected Serious Adverse Reactions (SUSARs) and Serious Adverse Reactions (SARs) to authorities (including Eudravigilance), and (expedited) reporting to ethical committees and investigators.

Key achievements

- Clinical responsibility of the drug development program delegated to Kinesis
- Contribution to timely delivery of data, interim evaluations, reports and required documentation for an Investigational New Drug Application (IND) submission
- Timely delivery of clinical development plans (early phase), including expert validation and decision analysis for various indications
- Preferred provider for pharmacokinetic analysis for over 100 clients, including 3 of the top 10 big pharma companies

Why Kinesis Pharma?

- Experienced team of clinical (senior) consultants
- Surrounded by an in-house multi-disciplinary team
- Extensive clinical expert network
- Broad experience in clinical non-compartmental Pharmacometrics evaluations
- Broad experience in exploratory clinical evaluations
- Dedicated Pharmacometrics experts
- Extensive regulatory experience
- Committed to sponsor's projects and timelines
- Flexible approach
- Independent of outsourcing activities to third parties

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'Early phase clinical development is an intensive knowledge-driven process'

About Kinesis Pharma

Kinesis Pharma is an independent drug development organization with headquarters in Breda, the Netherlands. Kinesis Pharma aims to facilitate an efficient and high quality development and registration process for medicinal products and nutraceuticals through consultancy and contract research services. Kinesis Pharma's service offering includes CMC, non-clinical, clinical, regulatory, quality and project management activities for pharmaceutical, nutraceutical and biotech companies.

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