Clinical Development

Clinical Trial Operations & Pharmacovigilance

Timely delivery of high quality clinical trial results is the primary objective of our team of well trained, very experienced trial managers, monitors and pharmacovigilance experts. We have delivered a large number of innovative early phase clinical development plans, protocols, clinical trials and reports which were subsequently approved by regulatory authorities or acknowledged in due diligence processes.

The Clinical Trial Operations team partners with you to consult about study- and project design, regulatory decision criteria and selection of sites and vendors. We combine high level consultancy with fluent trial execution.

Kinesis
Consultants in drug development

What Kinesis offers

- **End-to-End support**

Kinesis' clinical trial operations group has the expertise to set-up, coordinate and deliver clinical trials. We have experience with new chemical entities, vaccines, biologicals and generic compounds.

- **Scientific and independent approach**

The clinical trial operations and pharmacovigilance (CTO-PV) group is surrounded by (senior) pharmacological, pharmacokinetic and regulatory consultants. Kinesis is an independent organization and has no clinical site. This will enable us to independently select the clinical site that has the best experience to execute your study. We do not design a study for a site but we select the best site to investigate the objectives of your protocol.

- **Pharmacovigilance support**

Many start-up companies appreciate help in organizing the mandatory pharmacovigilance arrangements when starting clinical activities. Kinesis can offer these pharmacovigilance services with a well-trained pharmacovigilance staff including a Qualified Person for Pharmacovigilance (QP-PV) and a validated and ICH-E2B compliant safety database for expedited reporting.

- **Flexibility**

Kinesis' CTO-PV group can support your projects from end-to-end, but you can also decide to use only some aspects of our services in tailor-made modules. Kinesis' trial managers work according to GCP compliant standard operating procedures but of course sponsor SOPs can be used as well.

Kinesis special expertise

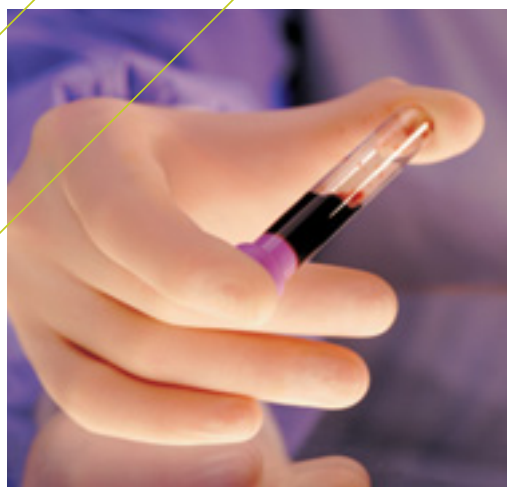
Kinesis' staff members have developed special expertise in the following areas in clinical development:

- **Early development**

We are aware of the special position of early development studies in the pharmaceutical development process. Kinesis has developed a key expertise in phase I and IIA studies. These include first-in-man studies, interaction studies, bioequivalence studies (including statistics) and special populations. Timelines in early phase studies are short, and go no-go decisions have to be taken quickly. Kinesis will commit to your timelines and will make sure your early development process will be completed in the most efficient way.

- **Pediatric studies**

Pediatric studies require additional attention to the safety of the subjects. Kinesis has in-house expertise on the special regulations, design issues and execution of pediatric studies. Kinesis has an extensive pediatric network capable of providing expert opinions in any indication area.



One partner, all the brains you need

Summary of services

Clinical Trial Operations

- Preparation of all necessary trial documents
- Management of all aspects of study medication (importation, labeling, blinding)
- Identification and selection of the most suited clinical sites
- Management of all regulatory aspects of the study including complete submissions
- Management of bioanalysis and Pharmacometrics analysis
- Coordination of CRF design and data management
- (Coordination of) ICH-GCP monitoring
- Statistics, analysis and clinical study reporting (ICH-E3)
- Legal representation for sponsors outside the EU

Pharmacovigilance

- 24/7 medical and safety coverage
- Pharmacovigilance training to study personnel
- Complete AE/SAE management including expedited reporting
- Registration of sponsors with Eudravigilance
- Literature search
- Periodic reporting (DSURs, PSURs)
- Qualified Person for Pharmacovigilance

Key achievements

- Successful completion including reporting of a package of early phase studies of a combination compound up to phase III
- Site selection, trial optimization and trial management of a FIM study with a vaccine with special objectives and biomarkers
- Arrangement of pharmacovigilance obligations for start-up companies including Legal Representation, Qualified Person for Pharmacovigilance and Eudravigilance registration

Why Kinesis Pharma?

- The clinical trial operations and pharmacoviglance team is surrounded by pharmacological, pharmacokinetic and regulatory consultants
- Extensive clinical expert network, including pediatrics
- Broad experience in exploratory clinical evaluations
- Committed to sponsor's projects and timelines
- Flexible approach
- Independent of outsourcing activities to third parties

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'We combine high level consultancy with fluent trial execution.'

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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