Non-Clinical Development

A fast way to assurance of safety

Non-clinical testing is conducted throughout all phases of drug development in order to assess the safety profile and pharmacokinetic/toxicokinetic (PK/TK) characteristics of candidate medicinal products. If performed well, it can maximize the chances of success in the clinical development phases. Strategies for the non-clinical development of products follow general regulatory guidelines, but are designed on a case-by-case basis according to the specifics of the drug. It is essential to design an optimal non-clinical development program that allows the medicinal product to be taken forward to the next step in clinical development, or to product registration. Kinesis Pharma has a team of non-clinical experts with broad experience who can guide sponsors through all the phases of non-clinical development.

Kinesis
Consultants in drug development

What Kinesis offers

- **Non-clinical consultancy**

The Kinesis consultancy services range from designing the non-clinical development plan - aiming at facilitation of fast and efficient development - to overall non-clinical consultancy, including, e.g., due diligence activities, GAP analysis of non-clinical programs and dedicated advice in case toxicology issues arise. In addition, the Kinesis non-clinical experts can also participate in the sponsor's multi-disciplinary development team(s).

- **Pharmacokinetic and toxicokinetic evaluation**

Kinesis has a long history of performing non-clinical PK and TK evaluations, in accordance with Good Laboratory Practice (GLP) procedures. Kinesis participates in the GLP compliance program of the Dutch monitoring authorities, and is accredited to claim GLP for non-clinical PK and TK evaluations. The Kinesis data analysts routinely participate as Principal Investigator in multi-site (GLP) studies and make use of validated software. See the back of this leaflet for further information.

- **Designing and monitoring non-clinical studies**

Kinesis has broad experience in designing and monitoring non-clinical studies in all disciplines of toxicology (e.g., genotoxicity, safety pharmacology, general toxicology and reproductive toxicology), as well as in PK/TK and metabolism studies (ADME). The professional management of a non-clinical project or program ensures that scientific and regulatory milestones are achieved, timelines are met and budgets are respected. Kinesis can take responsibility for execution of the non-clinical development program, by selecting the most suitable Contract Research Organization (CRO), discussing study designs, authorizing protocols and reviewing draft study reports, all on behalf of the sponsor.
Our non-clinical representative will be the first point of contact for the study director at the CRO and will coordinate in-life parts of the studies and the reporting of all study phases. Furthermore, the non-clinical study monitor will be the intermediate between CRO and sponsor.

- **Preparation of regulatory documentation and non-clinical reports**

Kinesis can take care of the preparation of all non-clinical documents for regulatory submissions for various types of applications, like non-clinical reports, non-clinical overviews, summaries and tables (INDs), contributions to IBs and IMPDs, and Kinesis can prepare manuscripts for scientific journals (ghostwriting).

One partner, all the brains you need

Assured quality within non-clinical PK/TK studies

One of the services offered by the non-clinical development department of Kinesis Pharma is the PK/TK evaluation of bioanalytical data obtained from non-clinical studies. The majority of these studies is performed under GLP.
In this respect, Kinesis has already been inspected several times by the Dutch GLP Inspectorate (Voedsel- en Waren Autoriteit) and, in June 2009, the endorsement of GLP compliance was obtained for the third consecutive time. This strongly motivates the non-clinical department to continuously monitor and optimize the Kinesis quality system in close collaboration with the quality assurance (QA) department.

The involvement of the Kinesis QA department in studies is significant. For non-clinical GLP studies all critical phases such as the study plan, study procedures, raw data and the final report are audited.

Even for non-GLP studies, which are also performed frequently, the Kinesis Pharma QA department is involved in checking the final reports. Furthermore, all studies are performed by competent and qualified staff, according to standard operating procedures using validated software. Additionally, all data and calculations are checked by an independent reviewer, before the final report is peer reviewed internally and subsequently checked by QA.

The non-clinical department has gained extensive experience and expertise over many years in working according to the OECD GLP guidelines, particularly those concerning multi-site studies, in collaboration with various test facilities and test sites from all over the world. The combination of specific scientific (non-clinical) knowledge and the constant pursuit of quality excellence make Kinesis Pharma a good choice for the outsourcing of non-clinical PK/TK studies, in addition to a reliable source for non-clinical development consultancy.

Track record PK/TK evaluations

- GLP accreditation since November 2003
- Number of GLP studies involved in since November 2003: > 90
- Number of non-GLP studies involved in: > 100
- Performed ghostwriting of PK/TK and metabolism reports for > 35 studies

Why Kinesis Pharma?

- Experienced team of non-clinical (senior) consultants
- Surrounded by an in-house multi-disciplinary team
- Broad experience in non-clinical (non)-GLP PK/TK evaluations
- Broad scientific and CRO network
- Committed to sponsor's projects and timelines
- Flexible approach
- Independent of outsourcing activities to third parties

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'In non-clinical development you must always expect the unexpected!'

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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