Venn Life Sciences

part of hVIVO

Non-Clinical Development

Optimising Drug Safety Evaluation For Rapid Decision Making

Non-clinical testing is conducted throughout all phases of drug development to assess the safety profile and pharmacokinetic/toxicokinetic (PK/TK) characteristics of drug candidates. If performed well, it can identify key 'knock-out' criteria early, maximizing the chances of success in subsequent clinical development.

Strategies for the non-clinical development of candidate drugs follow general regulatory guidelines but are developed 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 enables the medicinal product to be taken forward to the next phase in clinical development, or to product registration.

Venn has a team of non-clinical experts with broad experience who can guide you through all aspects of non-clinical development from lead candidate selection to market.

Drug Safety Evaluation Strategy

Venn's non-clinical consultancy services range from drug development planning to project outsourcing, monitoring and execution, reporting, writing expert summaries and reviews, collation of regulatory documentation and submissions.

Venn's non-clinical experts can seamlessly integrate with your in-house experts and participate in multi-disciplinary development team(s) to facilitate accelerated drug development.

Non-Clinical studies and related activities

Venn has broad experience in designing and monitoring non-clinical studies in all disciplines of 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.

Venn can take responsibility for execution of your non-clinical development program, by selecting the most suitable Contract Research Organization (CRO), discussing study designs, reviewing draft protocols, authorising final protocols as study monitor and reviewing draft study reports on your behalf.

Our non-clinical expert will be the first point of contact with the study director at the CRO, enabling you to focus on other aspects of drug development.

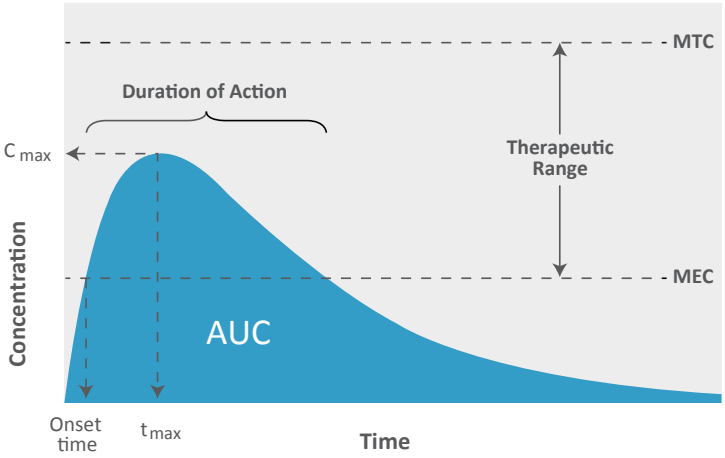
Venn Non-Clinical Services

Strategic	Studies	Study Related	Regulatory Documents
Non-Clinical Program Design & Management	Full range of Toxicity Studies (non GLP / GLP)	Study Design & Initiation	Investigator's Brochure (IB)
Risk Analysis / Risk Mitigation	ADME & PK / TK studies	CRO Selection & Management	Investigational New Drug (IND)
Consultancy, Advice, Support	Coordination & Monitoring of BA (Bioanalytical) studies	Execution & Coordination (onsite (insourcing) / off-site)	Clinical Trial Applications (CTA)
TPPs / DDPs Due diligence & GAP Analysis	PK / TK Evaluations (GLP)	Analysis / Review & Reporting PK / TK Evaluations (GLP) of Study Results	Expert Reports

Non-Clinical Development

Non-Clinical PK/TK Evaluations

Venn performs Pharmacokinetic and Toxicokinetic (PK/TK) evaluations of bioanalytical data obtained from all types of non-clinical studies. The non-clinical department of Venn is accredited to perform these evaluations in accordance with the OECD principles of **Good Laboratory Practice** (GLP).



The non-clinical department has broad experience in participating in multi-site studies, in collaboration with test facilities and test sites from all over the world. At request, SEND files can be created.

Experience Of Venn's Non-Clinical Development Team
Multidisciplinary - and Non-Clinical Projects (last 5 years): 35 Regulatory Documents (last 5 years): 15 PK/TK studies (last 5 years): 35
Broad Scientific Expertise & CRO Network
Small Molecules chemically synthesized products, syntheticoligonucleotides, synthetic oligopeptides, radiopharmaceuticals
Large Molecules Biological/biotechnological proteins and polypeptides, monoclonal antibodies, vaccines
Generics, Orphans Drugs, ADC's & Biosimilars

Regulatory Documents

Venn can prepare all non-clinical documents for regulatory submissions for a variety of applications, such as non-clinical reports, non-clinical overviews, summaries and tables (INDs/CTAs), contributions to IBs and IMPDs. We can support you in discussions with the regulatory authorities by preparing briefing notes and Venn experts can accompany you to discuss non clinical aspects of drug development with regulators.

Why Venn's Non-Clinical Team

The combination of specific scientific (non-clinical) knowledge, commitment to your projects and the constant pursuit of quality excellence make Venn a reliable source for **Non-Clinical Consultancy Services** and for **Preparation of Regulatory Documentation** to support submission and a good choice for the outsourcing of **PK/TK Evaluation** according to GLP regulations, including writing of PK/TK study reports.

Case study

Non-clinical: consultancy

A project for a small-size pharmaceutical company that already performed proof-of-concept studies started with the question 'how to bring my product into the clinic as soon as possible'. For this client, our Venn Life Science non-clinical team first compiled a drug development plan with an overview of non-clinical studies that had to be performed before starting phase I studies including an estimation of the costs and timelines. Subsequently, CRO's were selected based on timelines for performing the studies and costs, in accordance with the wishes of the client. The study designs for the relevant studies were discussed with the CRO and the resulting protocols were reviewed. During the performance of the studies, the Venn consultant was the main contact person for the study directors at the CRO's and was in close contact with the client's contact person. During and after the performance of the study we discussed the study results with the client and reviewed the study reports. As the final step in the process, we compiled all non-clinical information and drafted the Investigators Brochure and the non-clinical modules of the IND.

Case study

Case study PK/TK

A small biotech company approached us for performing the noncompartmental pharmacokinetic analysis for one of their animal studies and correlating exposure and other PK parameters with results of performed immunogenicity assays in the animals. The PK analysis was performed as a GLP study as phase in a multisite study performed at a European CRO. Pharmacokinetic parameters were calculated using the validated program Phoenix® WinNonlin ®. The data of animals with and without an immunogenic reaction were compared and the client was advised on the PK-consequences of developed immunogenicity in the animals.

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