Venn Life Sciences

part of hVIVO

CLINICAL TRIAL MANAGEMENT

Team experience

» Small dedicated team of experienced (senior) clinical project managers, clinical trial assistant, and a group leader with total team experience in clinical trials of more than 60 years. In addition, Venn has resources to provide flexible trial management support, if needed

General experience/expertise

» First-in-Human (FiH) clinical trials, clinical pharmacology trials e.g., single ascending dose, multiple ascending dose, drug-drug interaction, bioequivalence, food effect, mass balance healthy volunteer trials

» More than 15 early phase clinical trials in total, of which 5 FiH trials

Therapeutic area's

» Infectious diseases including vaccines

» Immunology

» CNS

» Osteoporosis

» Haematology / coagulation

» Dermatology

CLINICAL TRIAL MANAGEMENT

Added value for working with Venn Clinical Trial Management group

- **End-to-end support:** The Venn clinical trial management group has the expertise to set-up, coordinate and deliver clinical trials including vendor selection, investigational product logistics, data management, safety analyses, reporting, and clinical monitoring. We have experience with chemical entities, vaccines, and generic compounds.
- **Scientific and independent approach:** The Venn clinical trial management group is surrounded by pharmacological, pharmacokinetic and regulatory consultants. Venn combines high level consultancy with fluent clinical trial execution. Venn is an independent organization and has no clinical site or labs. This enables us to independently select the clinical site and labs that have the best experience to execute your clinical trial. We select the best site to investigate the objectives of your protocol.
- **Flexibility:** The Venn clinical trial management 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. Venn clinical project managers work according to GCP-compliant standard operating procedures, but sponsor SOPs can be used as well.
- **Commitment:** The Venn clinical trial management group is committed to sponsor's projects and timelines. We work with a range of clients from big pharma companies to small biotech companies.

Key achievements

- Successful completion including reporting of a package of early phase clinical trials of a combination product up to phase III
- Site and vendor selection, trial optimization, and trial management of a FiH clinical trial with an intranasal vaccine with special objectives and mucosal biomarkers
- Site and vendor selection, trial optimization, and trial management of a FiH clinical trial with a chemical compound with special biomarker assessments on fresh blood requiring proximity of the biomarker lab and the clinical unit.

Case study

Venn Life Sciences was responsible for the management of a FiH clinical trial investigating the safety, pharmacokinetics, pharmacodynamics and Holter monitoring of the sponsor's lead compound in a healthy volunteer trial. For this trial, multiple escalating doses were explored in healthy subjects. Venn's clinical project manager performed the trial management tasks on behalf of the sponsor and managed the Venn internal activities (CMC, medical writing, clinical monitoring, data management, biostatistics, pharmacokinetic and pharmacodynamic analyses, clinical consultancy) and external partners (sponsor, clinical site, bioanalytical labs, Holter monitoring vendor). Efficient trial management resulted in timely dose escalations, trial completion and reporting to meet timelines for IND opening of the phase 1b trial in the US.

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Netherlands Office
Lage Mosten 29, 4822 NK Breda,
The Netherlands.

www.vennlifesciences.com