Venn Life Sciences

part of hVIVO

MEDICAL WRITING

Team experience

» Small dedicated team of experienced senior medical writers and a group leader with total team experience in clinical and regulatory writing of more than 75 years

» In addition, Venn has resources to provide flexible medical writing support, if needed

General experience/expertise

» First-in-Human clinical trials

» Early phase clinical trials (e.g., single ascending dose, multiple ascending dose, drug-drug interaction, renal impaired, bioequvalence, food effect, thorough QT, mass balance)

» Human viral challenge studies

» Clinical trial protocols with adaptive trial design

» 10-15 clinical trial protocols/year

» 3-5 clinical trial reports per year

» Regulatory documents (clinical pharmacology-related)

Document level

» Clinical
- Clinical trial outlines and clinical trial protocols
- Protocol amendments
- Investigator's Brochures
- Lab manuals, other supportive trial documents
- Clinical trial reports, pharmacokinetic reports
- Narratives
- Scientific writing (papers)
- Development safety update reports

» Regulatory
- Briefing books & briefing packages
- Clinical modules of the CTD (clinical overview, clinical summaries)
- Clinical expert reports for (generic) compounds (study reports and/or literature)

» Support on editing and formatting of documents

Therapeutic area's

» Infectious diseases including
- vaccines
- challenge studies (flu, RSV, malaria, COVID-19)

» Immunology

» CNS

» Chagas disease

» Sanfilippo type B syndrome

» Osteoporosis

» Haematology / coagulation

» Pulmonary arterial hypertension

» Multiple sclerosis

MEDICAL WRITING

Added value for working with Venn Medical Writing group

- **Scientific approach:** The Venn medical writing group is highly qualified and surrounded by pharmacological, pharmacokinetic, and regulatory consultants. Venn combines state-of-the-art knowledge with efficient medical writing support.
- **Flexibility:** The Venn medical writing group can support your projects from end-to-end, but you can also use our writing services for parts of the project. Venn medical writers work according to GCP-compliant standard operating procedures, but are also used to working with sponsor SOPs or templates.
- **Commitment:** The Venn medical writing group is a dynamic team committed to sponsor's projects and timelines. On request of the sponsor, the team can also deliver under expedited timelines. We work with a range of clients from big pharma companies to small biotech companies.

Key achievements

- Written more than 200 early phase clinical trial protocols in total
- Experience in protocol writing for First-in-Human (FiH) clinical trials (more than 15 protocols)
- Supported on regulatory writing for multiple INDs, NDAs, MAAs

Case study

Venn Life Sciences was responsible for the reporting of a FiH clinical trial while preparing a number of documents in parallel necessary for the opening of an IND for the Phase 1b trial. These documents included the Investigator's Brochure and the clinical modules of the CTD. In doing so, Venn's medical writer had to assure consistency and alignment across these documents. This required close collaboration with contributing authors and strict planning, as some documents could only be written once others were completed. Venn's medical writer had to assure correct messaging and alignment over the clinical trial report, the IB and the clinical modules of the IND. All documents were delivered in accordance with the requested timelines and the IND was submitted as planned.

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