Venn Life Sciences

part of Open Orphan plc

MEDICAL WRITING

Team experience

- Small dedicated team of Senior Medical Writers and Clinical Trial Assistant with total team experience in clinical and regulatory writing of more than 75 years
- In addition, Venn is working with a flexible shell to increase Medical Writing resources if needed
- Group Leader Clinical Trial Management & Medical Writing, PhD Immunology - More than 25 years of experience
- Senior Medical Writer, PhD Biomedical Science - 13 years of experience
- Senior Medical Writer, MSc Chemistry - 20 years of experience
- Senior Medical Writer, MSc Food Science and Technology - 17 years of experience

Flexible shell

- Senior Project Manager with medical writing experience, MSc Biomedical Science - More than 20 years of experience
- Senior Medical Writer, PhD Pharmacology & Toxicology - 9 years of experience (freelancer)

General experience/expertise

- First-in-Human clinical trials
- Early phase clinical trials (SAD, MAD, DDI, hepatic impaired, renal impaired, BE, FE, thorough QT, mass balance)
- 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)
  - DSURs
- Regulatory
  - Briefing books & briefing packages
  - Modules of the CTD (Clinical overview, Clinical summaries, 2.7.1, 2.7.2, 2.7.4)
  - Clinical expert reports for (generic) compounds (CTRs 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 medical writing group is surrounded by pharmacological, pharmacokinetic and regulatory consultants. Venn combines state-of-art knowledge with efficient medical writing support.
- **Flexibility:** 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 work with sponsor SOPs or templates.
- **Commitment:** Venn medical writing group is a dynamic team committed to sponsor's projects and timelines and is also used to 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 a FiH clinical trial in parallel to the preparation of the submission documents including the Investigator's Brochure for the IND submission of the phase 1b trial. 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 IND was submitted as planned.

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