Medical Writing Services
From Protocol Development to Publication

Transforming Complex Clinical Programs into Success Stories

With decades of experience in clinical research documentation, we offer comprehensive medical writing services that go beyond traditional documentation support. Our team of experts combine deep scientific and industry knowledge with regulatory insight to deliver reliable results across all phases of clinical development. Our medical writers produce timely, cost-effective clinical and regulatory documents, transforming complex data into an accurate, evidence-based account of your drug's clinical profile.

Pharmnet actively participates in initial discussions on overall clinical program setup, with statisticians involved from the earliest consultancy phase. Our goal is to maximize the scientific information gathered about your compound or device throughout the entire trial process, while ensuring efficient use of every unit of your investment. Understanding common challenges, such as providing timely results to investors and managing funding constraints, we offer strategic consultancy on endpoint modifications and their impact on sample size through initial power analysis. This helps determine the necessary budget for project execution.

Through an adaptive design approach and various study design options, such as incorporation of safety cohorts, open-label cohorts, or additional safety data groups into your trial, we provide flexibility in trial planning. This approach allows clients to gain early insights into product efficacy and safety, well before project completion. By incorporating multiple decision-making timepoints into the project roadmap, clients can begin or continue to the next development step sooner while significantly reducing risk. Our medical writing team provides comprehensive support throughout your development program, from protocol development through final study reporting.

Strategic Consultancy | Regulatory Expertise | Project Management | Multi-Country Compliance | KOL Collaboration

- ✓ **Protocol Development &Amendments** - efficient protocol adaptations supported by strong scientific accuracy
- ✓ **Informed Consent Forms** – country-specific expertise, proven track record of regulatory approval with minimal or zero comments
- ✓ **Investigator's Brochures** - reviewing and updating throughout product development, IMPD review
- ✓ **Regulatory Documentation** - knowledge across multiple jurisdictions, experience with complex projects with specialized requirements such as ATMP clinical trials, controlled substances, or pediatric studies
- ✓ **Case Report Forms (CRFs)** – paper or electronic, integration of statistical considerations from design through analysis
- ✓ **Patient related documents** – covering all types of documents tailor-made for your project
- ✓ **SmPC Preparation** - assistance during preparation in collaboration with subject matter experts
- ✓ **Clinical Study Reports** - professional presentation of study results with track record of publications in prestigious journals, including The Lancet, Vaccine or Clinical Endoscopy

Statistical Integration | Scientific Accuracy | Quality Assurance | Data Management | End-to-End Support

Protocol Development Excellence

Our protocol writing services are differentiated via a strategic, consultative approach.

- ➢ We partner with sponsors from the earliest stages, helping shape study design and select optimal indications (experience in phases I, II and III including first-in-human, medical devices or Advanced Therapy Medicinal Products (ATMP) studies).
- ➢ Our team collaborates with Key Opinion Leaders (KOLs) to ensure protocols reflect the latest scientific insights and local standards of care making the protocol execution faster and more efficient.
- ➢ Pharmnet also assures consultation with experienced statistician when setting goals, endpoints and calculating sample size for a CT/medical device trial.
- ➢ We excel at adapting study designs to meet varying regulatory requirements across different countries.
- ➢ Our innovative solutions help overcome regulatory challenges while maintaining study integrity and receiving minimum comments from authorities during the review process.

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Case study 1: Accelerating Clinical Development

Our strategic approach to clinical development is exemplified by a recent collaboration with a biotech company seeking to advance their development program. Initially limited by data from PK studies in healthy volunteers from India, the company faced recruitment challenges in their Phase I trial conducted by another CRO. Pharmnet's innovative solution involved parallel preparation of Phase II and Phase IIb/III documentation, securing approvals across four EU countries. To address the immediate need for patient data, we implemented a strategic protocol amendment incorporating a targeted open-label cohort of 12 subjects.

Through our extensive site network, we achieved complete recruitment of the open-label cohort within two months, delivering preliminary safety and efficacy insights within seven days of the last patient visit. The favorable risk-benefit profile enabled us to seek and gain approval of an extension study in time for subject transition. In this way, long-term use data was also collected, further strengthening the safety profile of the compound under development. Our flexible contracting approach, anchored by a Master Service Agreement, allowed the client to proceed with confidence while maintaining financial flexibility.

Case study 2: Innovative Protocol Design in Ophthalmology

When a regulatory agency rejected a planned placebo-controlled design for a neovascular AMD study, our team developed an alternative approach using an active comparator that satisfied both scientific and regulatory requirements. We also crafted country-specific solutions to address varying regulatory demands, demonstrating our ability to navigate complex regulatory landscapes while maintaining study feasibility. With frequent patient visits required by RAs to ensure that this rapidly deteriorating pathology is under nearly continuous control, Pharmnet provided a solution to maintain an acceptable visit frequency for patients and addressed the RAs' concerns through slight modification of the endpoints and combining use of a mobile app that alerted investigators when self-control assessment of visual acuity declined. A site visit for the patient was scheduled. This approach was fully accepted by the RAs, and the visits were limited to once every two weeks.

To ensure the safety of trial subjects, the Czech RA requested that the upper age limit was reduced to 75 years. Pharmnet suggested implementing this change in the form of a "Dear Investigator" letter valid only for the Czech Republic to avoid negatively impacting the pool of suitable subjects in other participating countries. Furthermore, to remove this recruitment limitation, Pharmnet negotiated with the RA the possibility of submitting an interim safety report after 10 completed subjects. This case study demonstrates Pharmnet's capability to implement regulatory agency requirements while maintaining study integrity across different countries, finding creative solutions that address safety concerns without compromising the overall study population or data quality.

Real Results, Real Impact

Our impact is demonstrated through publications in prestigious medical journals, including The Lancet (Phase I/Ib study of innovative solid metastatic tumor treatment), Vaccine (Phase III study of pneumococcal vaccine booster dose in children), and Clinical Endoscopy (first in human novel upper gastrointestinal bleeding sensor capsule trial). Through successful regulatory negotiations, efficient protocol adaptations, and streamlined documentation processes, we accelerate your path to approval while maintaining study integrity.

Transform your clinical development program with our expert medical writing services.
Contact us today to discuss how we can support your success.

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