Syner·G

Case Study

Establishment of a Long-Term Medical Writing Partnership

Quality is the most important factor in producing any document. At Syner-G, our highly experienced team of medical writers is committed to providing our clients with clear and concise documents that are sound from both a scientific and regulatory perspective. In this case study, we look at how our relationship with a mid-size global pharmaceutical company grew from a single project into a long-term partnership.

The Project

The medical writing professionals at Syner-G were contracted by this client to prepare two Phase 3 clinical study reports (CSRs) for a biologic agent for the treatment of Crohn's disease. Following the successful completion of these two CSRs and the establishment of a highly positive collaborative relationship with the client, Syner-G was subsequently contracted over the next two years to prepare nine additional CSRs, as well as a clinical study protocol and sections of a Pediatric Investigational Plan.

The Project

Given the highly successful working relationship that evolved over time, the client established a Strategic Alliance Partnership with us. The ongoing work consists of the preparation of approximately twenty-five to thirty CSRs per year across numerous development programs.

As a result of this partnership, Syner-G medical writers are considered an integral part of the client's team, and our role encompasses all of the roles traditionally held by the client's internal medical writers. Therefore, in addition to authoring the CSRs and managing the review and quality control (QC) process, our authors serve as the primary medical writing contact for the client's project team, managing document timelines and scheduling roundtables or other team meetings.

Syner-G also manages the compilation of CSR appendices and performs electronic publishing of the CSR and appendices to ensure all documents are submission-ready.

Outcome

To date, our collaboration has encompassed a portfolio of four established products and eight new chemical entities. Therapeutic areas targeted by these products range from rheumatology to central nervous system disorders. Our team members have also prepared a number of New Drug Application (NDA)/Biologics License Application (BLA) components during our partnership with the client, including several Summaries of Clinical Efficacy and Safety (Modules 2.7.3 and 2.7.4, respectively) and 120-day Safety Updates.

Throughout our years of working closely with this client, we have continued to gain their trust, and our relationship has expanded to allow us to gain broader responsibilities beyond simply providing medical writing and QC services. Members of our staff have become a valued extension of the client's internal teams, and we have succeeded in making this integration seamless. As a result, a productive, long-term collaborative relationship has been forged.

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The Client's Perspective

"When it was time for our company to enter into a large, full scale strategic partnership I found it difficult to trust a large CRO with our submission-relevant CSRs. Based on previous experiences with Syner-G, I knew our CSRs would be in excellent hands and therefore we entered into a partnership that was specific for our medical writing deliverables. The writers at Syner-G are scientifically-oriented but are also operationally strong, which is a unique combination that perfectly matches our internal medical writers. They have become a true extension of our internal team and feedback from our project teams has been absolutely glowing! I cannot thank them enough for the contributions they have provided over the last several years. Our partnership is and will continue to be a real success story!"

Client's Head of Global Medical Writing

About Us

Syner-G provides in-depth expertise across the three key elements of Chemistry, Manufacturing, and Controls (CMC): Regulatory Services, Technical Development, and Quality/IT. We call this CMC 360™. We also provide medical writing services, with expertise in authoring a variety of regulatory documents across a wide range of therapeutic areas and in all phases of development. Our regulatory affairs services include the development and implementation of global regulatory strategic plans, regulatory agency meeting support, and electronic submissions to regulatory authorities around the world.

We have the skill set and experience to guide your prime asset through any development challenges and along the ever-changing maze of regulatory filing pathways, to a position of full compliance, and high quality. Our expertise spans small molecules, peptides, oligonucleotides, biologics, monoclonal antibodies, antibody-drug conjugates, and cell and gene therapy products.

Ready to learn more about how Syner-G can support your organization?