Case Study:
The Journey Leading to an Approved NDA

INTRODUCTION:

Following a referral from another company, IMPACT (now part of Syner-G BioPharma Group) was contacted by a mid-size biopharmaceutical company to assist them with an upcoming NDA for a new chemical entity in the treatment of an orphan condition.

THE PROJECT

Over the next year, IMPACT authored the following documents for the client:

- Pre-NDA meeting package
- 5 clinical study reports
- All clinical components of the NDA, including the Integrated Summaries of Efficacy and Safety (ISE and ISS), the Summaries of Clinical Efficacy and Safety (Modules 2.7.3 and 2.7.4), and the Clinical Overview (Module 2.5)

IMPACT was also responsible for managing the NDA, which entailed the following:

- Coordinating all medical writing and quality control activities
- Collaborating with the client's third party biostatistics vendor during the production of statistical analysis plans and the generation of final tables, listings, and figures
- Working with the company's electronic publishing vendor to ensure that fully-compiled, submission-ready documents were produced

In addition, the IMPACT team worked very closely with the client in developing the key message points that needed to be addressed across all of the submission documents in support of the proposed label, and the IMPACT Project Manager provided input on ways to address a number of challenging clinical and regulatory issues within the application.

Subsequent to the on-time submission of the NDA, IMPACT was asked to author the client's FDA Advisory Committee Briefing Document. Although the Advisory Committee recommended approval of the client's drug, the Agency ultimately did not approve the NDA and requested that a second pivotal trial be conducted.

Following completion of the second trial, IMPACT was again asked to provide medical writing services for the client. IMPACT authored the CSR for the newly-conducted trial as well as the updated ISS, and provided critical reviews of the updated ISE and Clinical Overview.

After the submission of the amended application, IMPACT wrote the client's Briefing Document for their second meeting with the FDA Advisory Committee. Following an overwhelmingly positive vote at the second meeting, the FDA approved the client's product for the treatment of a debilitating orphan condition for which, prior to this approval, there existed a significant unmet medical need.

Over the life of this project, the relationship that evolved between this particular client and IMPACT is something we strive for with all of our clients. The IMPACT team became emotionally invested in this project because of our belief in and dedication to the client, as well as our desire to help them address a significant unmet medical need. The client did not view us simply as "contractors" but, instead, we became trusted members of their overall project team. And together, despite a number of roadblocks that needed to be circumvented along the way, we helped to get a drug to market that may drastically improve patients' overall quality of life.

THE CLIENT'S PERSPECTIVE

"Hiring the team at IMPACT was one of the best moves my company made in getting our drug approved. The team at IMPACT was not only critical to our success, they de facto became an extension of our company! Nobody knew the issues, the data, and the strategy behind our project more than the team at IMPACT. They took a complicated and challenging project and turned it into a total success, despite the odds against us. I heartily recommend IMPACT for anyone dealing with FDA or requiring other regulatory and medical writing work – they are a class act through and through."

– Client's Chief Medical Officer

ABOUT US

Syner-G BioPharma Group 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?

Contact Frank Sorce, Senior Director, Business Development
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Syner-G's Mission: Enable our clients to achieve success and enhance human health through the efficient development of new therapeutic agents while inspiring our team members to excel.