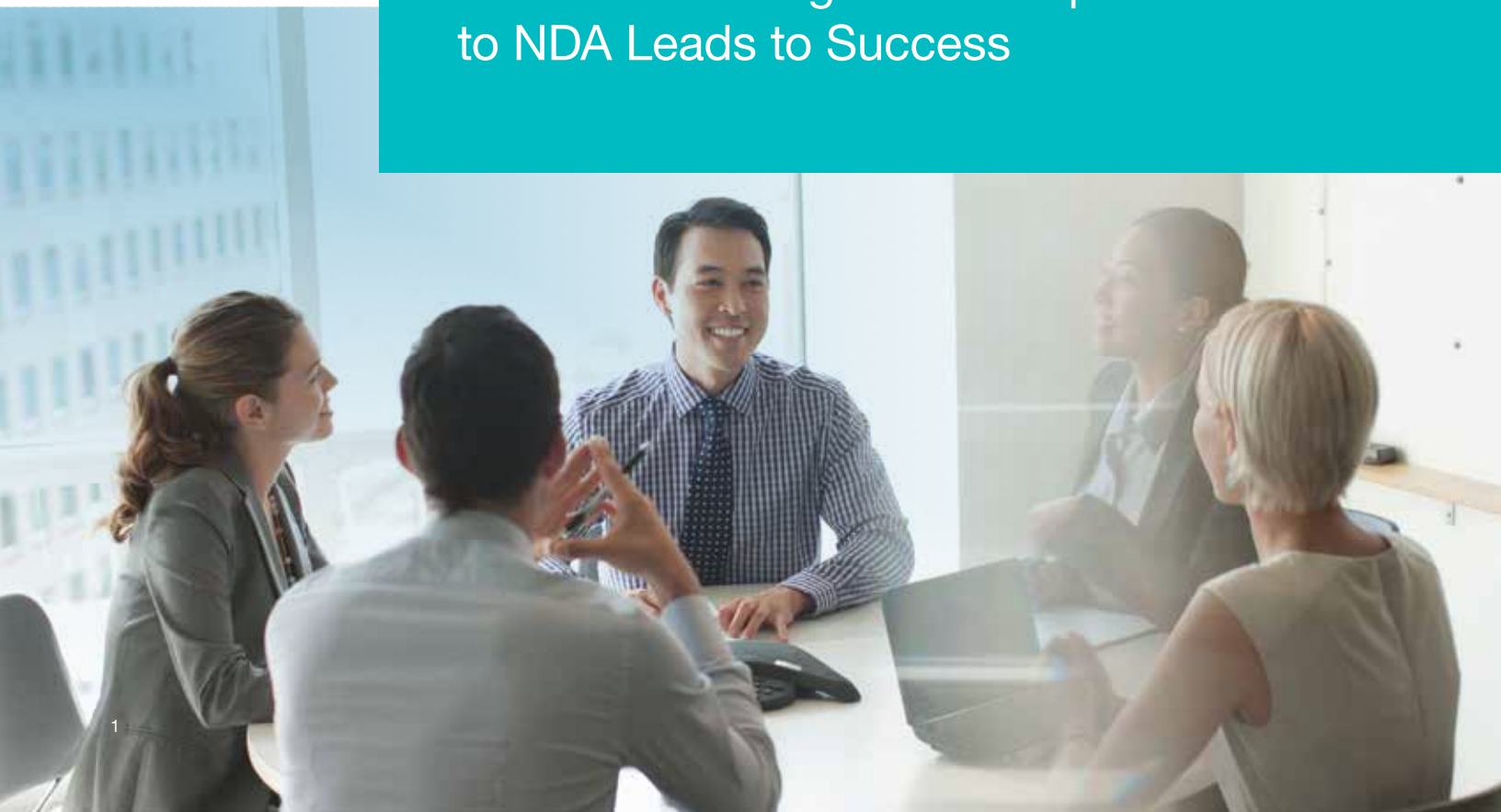
› CASE STUDY

VERISTAT

Advancing a Therapy for Rare Cancers to Regulatory Submission

A Medical Writing Partnership from IND to NDA Leads to Success



Background

When the Chief Medical Officer at a biopharmaceutical company specializing in cancers and rare diseases contacted Veristat to help prepare a briefing book, he learned that he'd found a medical writing team with the expertise needed to create a clear, concise document completed on time. After the document was finished, the simple briefing book request evolved into a multi-year medical writing partnership that remains ongoing.

Throughout the course of this relationship, the Veristat medical writing team has provided medical writing support for four drug therapy programs – which has included three Investigational New Drug Applications (INDs), protocol amendments and Investigational Brochure (IB) updates, and the preparation of two New Drug Applications (NDAs) for this company.

Program Demographics

Medical writing oversight and support for a rare cancer program from IND to NDA for a product now approved by FDA

SOLUTIONS

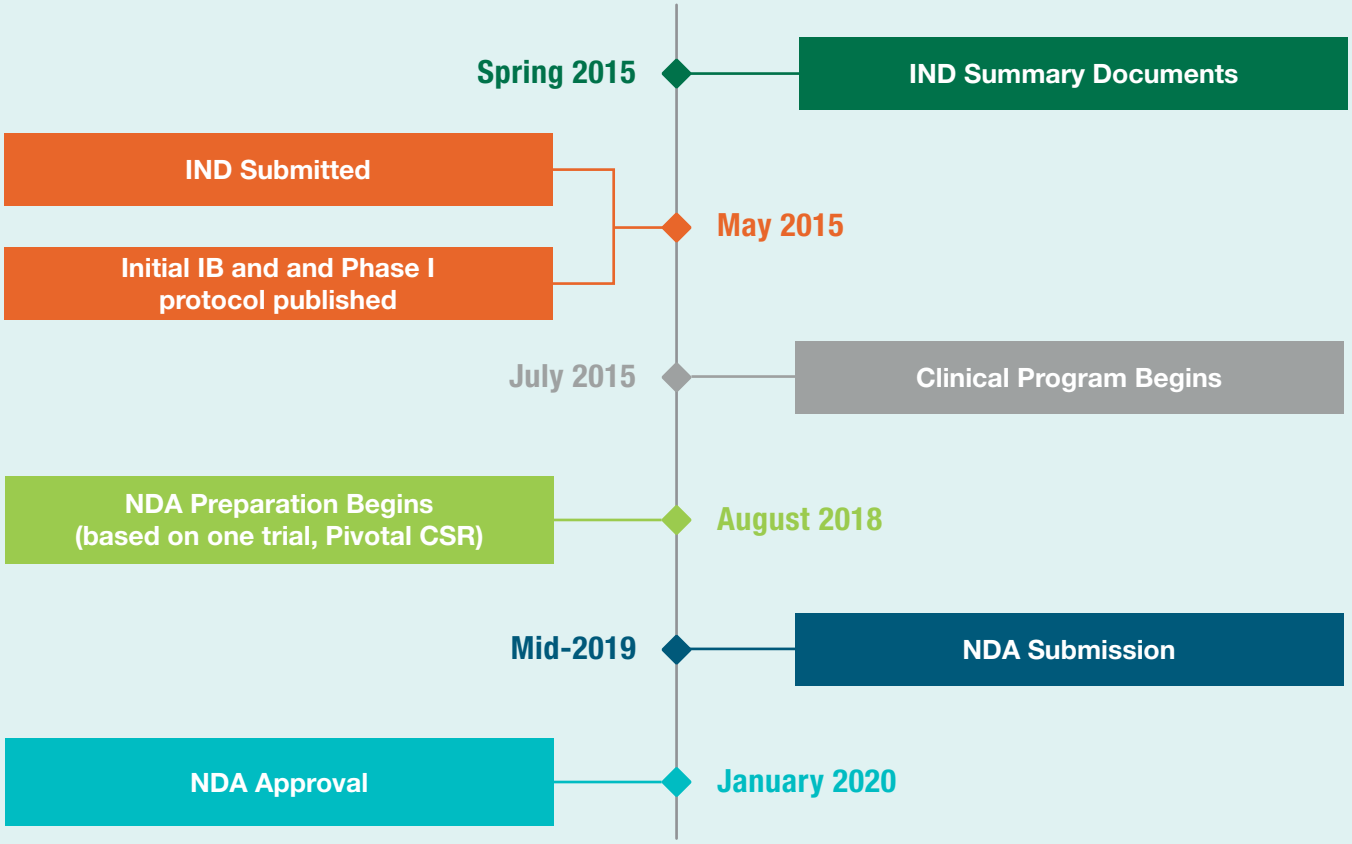
Starting with the IND

From the beginning of this partnership, we have acted as the client's medical writing team. Most of the medical writers in our group worked on writing and editing the protocols, IBs, and written and tabular summaries for the three IND submissions we were asked to support. In addition, we reviewed the non-clinical reports and chemistry, manufacturing, and control (CMC) modules for formatting, grammar, and consistency and prepublished them in PDF format. Together, our team collaborated with the client to review, write, format, and prepublish documents for Module 1, Module 2, Module 3, and Module 5.

Continuing During the Clinical Program

Within the client's ongoing clinical program, our medical writers continue to be a critical part of the client's project team by writing and editing the client's IB updates and protocol amendments. We have monthly calls with the client to understand their need for future medical writing support. This communication strategy enables us to provide swift service and respond to our client's ever-advancing needs. Our medical writers collaborate with the client to create the timelines, draft and revise documents, and ensure that all medical writing projects handed off to us are completed on time.

Timeline



Preparing the NDA

When the time came for the client to prepare two NDAs, the Veristat medical writing team was called upon again. We wrote the Pivotal Clinical Study Report (CSR), which included over 150 narratives, and we wrote the Summaries of Clinical Efficacy and Safety, which included nearly 200 narratives. Based on the scope of the project, the narratives were written using programmed narrative headers, which meant our writers collaborated with our client and the Veristat SAS programmers to develop a narrative format that was suitable for programmed for data to be automatically input using SAS programming processes.

Veristat medical writers are uniquely adept at working with programmers to create programmed narrative headers, thereby shortening timelines for writing the narratives.

Critical Success Factors

- **Collaboration & Desire to Be an Integrated Team**

  Both Veristat and the sponsor were committed to collaborating. The Veristat medical writers work with our client's subject matter experts (SMEs) to create high-quality documents as quickly as possible.

- **Continual Communications**

  Regular meetings are ongoing with supplemental ad-hoc communications in between that have included phone calls and text messages.

- **Flexibility & Dedication**

  Rapid response times to client needs by the Veristat medical writing team

***30%** of the Veristat medical writers who worked on the IND also worked on the NDA*

IMPACT

Our medical writing team has supported this sponsor from IND to NDA and beyond. Thirty percent of the original writers who worked on the IND remained engaged in the program and continued writing the NDA. It's been a tremendously exciting program to be a part of over the last four years. **We helped our client prepare its first NDA, which was accepted by the FDA, granted Priority Review, and has now received FDA approval. Our team is currently supporting a second NDA for the same product to treat an additional indication.**

Contact Veristat Today

Learn more about Veristat and how we can assist you with your clinical trial development, execution, and regulatory submission preparation.

www.veristat.com