GLOBAL CASE STUDY

Partnering for Efficient Medical Writing Solutions

Therapeutic Area: Oncology

Product Type: Small Molecule

Documents: IB, Clinical Overview, SCS, Protocol Amendment, and DSUR

GLOBAL'S MEDICAL WRITING CAPABILITIES

- Experienced writers with regulatory and therapeutic knowledge
- Flexible project management approach with customized solutions
- High-quality deliverables with consistent client satisfaction and repeat business
- Focus on efficient practices and streamlined workflows
- Integrative partnership versus provider-client relationship

ABOUT THE CLIENT

A small biotech company described accurately as "two people and a molecule" was introduced to the GLOBAL Medical Writing Team. This Sponsor had an ongoing oncology study in Europe and was looking to add clinical sites to their study in the US. They needed several documents updated and/or developed to support an IND to enable the addition of US sites to their ongoing EU study.

ABOUT THE PROJECT

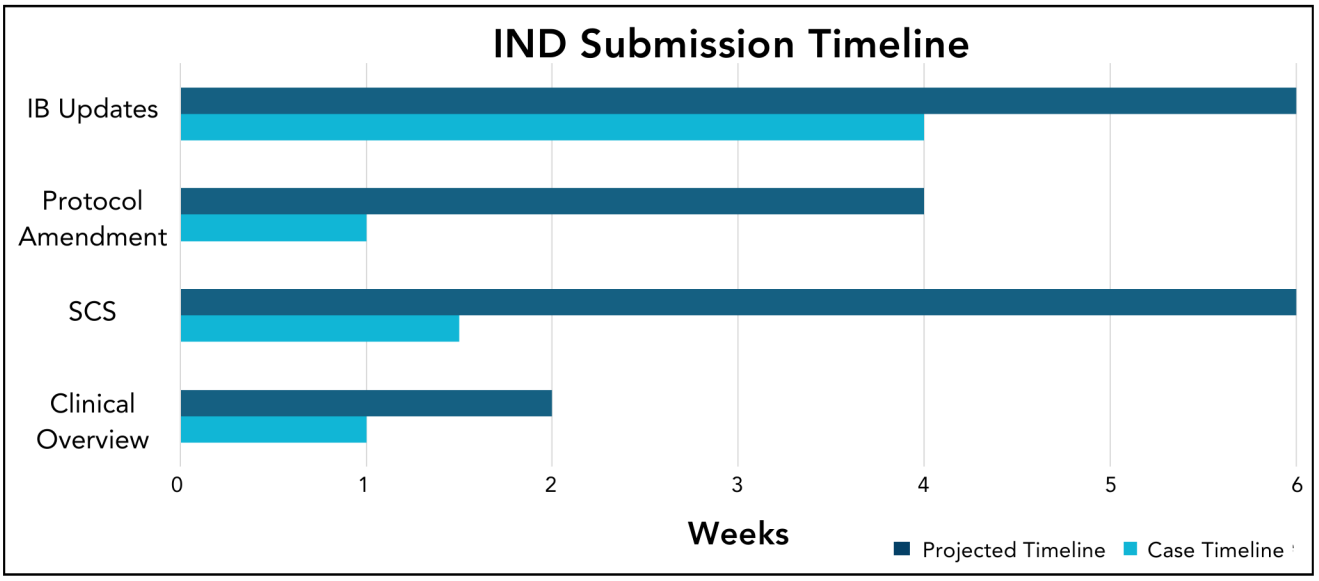
1. Program had not been in the US at all previously
2. GLOBAL had not been engaged during early FDA interactions (Type B Meeting)
3. Corporate goal was to submit the IND within 4 months of initial introduction to GLOBAL, requiring the following:
    - Update of the Investigator's Brochure (adding the first clinical data cut from the ongoing EU study)
    - Development of the Summary of Safety
    - Development of the Clinical Overview
    - Support Protocol Amendment
4. Establish a communication plan to ensure frequent check-ins throughout document development until all projects are final and ready for submission

GLOBAL SOLUTIONS

1. Get intro meeting scheduled to understand the players (Sponsor team members), scope of work, and timing of needs
2. Determine extent of effort needed across all required activities (5 documents)
3. Create a project plan that leans on appropriate resources as needed to ensure efficient document development
4. Develop realistic timelines that strategically align documents to enable content leverage from one document to another as much as possible
5. Establish a communication plan to ensure frequent check-ins throughout document development until all projects are final and ready for submission

OUTCOME

Content was strategically completed to ensure that the content in each document could be leveraged for other documents to expedite authoring time. The IND was submitted on time and was cleared by the FDA. The DSUR was submitted on time.



CONCLUSIONS

This was a successful project! Read our client's testimonial below.

"Our GLOBAL writer was efficient, communicative, and delivered high-quality documents on time and with a focus on our submission timing goal.

We look forward to continuing our relationship with GLOBAL for future medical writing needs.

I would strongly recommend GLOBAL to others who are in need of high-quality writing support."