GLOBAL
REGULATORY WRITING & CONSULTING

# CASE STUDY

## Partnering for Efficient Medical Writing Solutions – IND

**Therapeutic Area:** Oncology

**Product Type:** Small Molecule

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

We support Medtech and Biopharma innovators with strong, collaborative partnerships, tailored regulatory consulting and writing services, and deep strategic expertise.

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## 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
- Focus on efficient practices and streamlined workflows
- Integrative partnership versus provider-client relationship

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## ABOUT THE CLIENT

The client was a small biotech company conducting an early phase oncology study in the EU and planning to add sites in the US on an aggressive timeline.

They needed several clinical documents updated and/or developed in order to file an IND and expand the study footprint into the US.

## ABOUT THE PROJECT

The client's goal was to submit the IND within 4 months of initial engagement, with GLOBAL responsible for the following deliverables:

- Update the Investigator's Brochure to add the first data cut from the ongoing EU study
- Develop the Summary of Safety and Clinical Overview
- Author the Protocol Amendment
- Author the Development Safety Update Report (DSUR)

GLOBAL developed a project plan to ensure that all documents would be final and submission-ready on time.

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## GLOBAL SOLUTIONS

- Create a project plan with appropriate timelines and resources
- Develop an authoring strategy to leverage content across documents for efficient document development
- Establish a communication plan with frequent check-ins with the client throughout the process

## OUTCOME

All documents were completed, the IND was submitted on time, and the study was cleared to proceed by the FDA. The DSUR was also submitted on time shortly thereafter.

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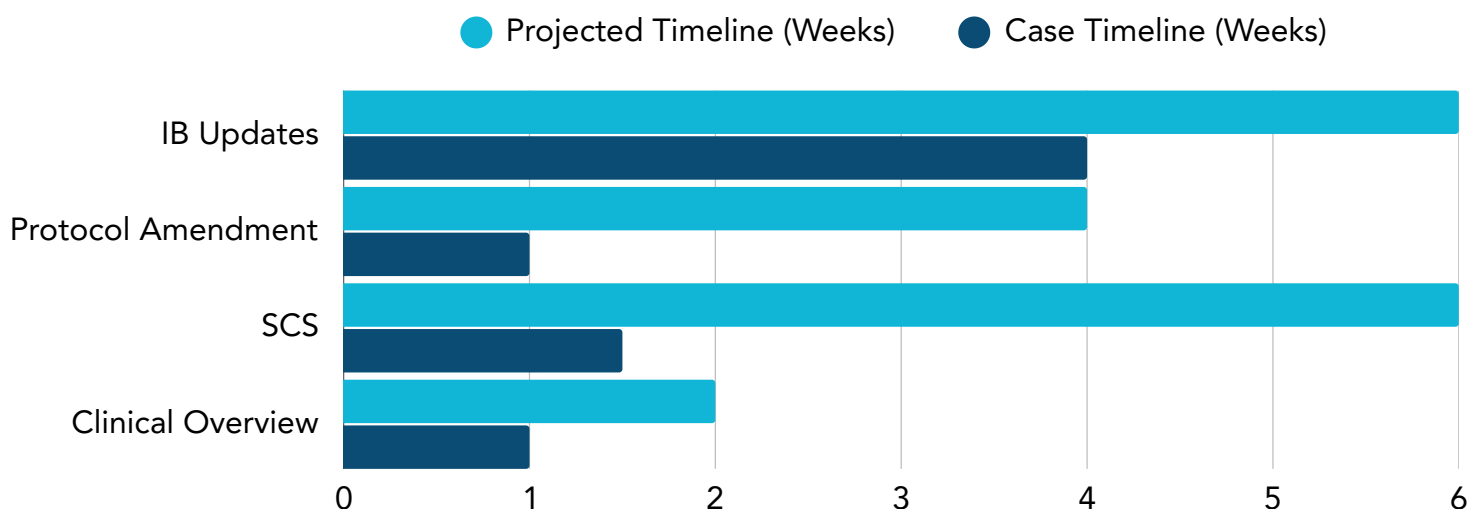


## CONCLUSIONS

Our client shared the below testimonial:

"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."

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