

CASE STUDY

Developing a Leaner, More Readable Investigator's Brochure

Our regulatory writing expert helped a client refine and improve the usability of an Investigator's Brochure.

Challenges

A global biopharmaceutical client needed expert regulatory writing assistance with an Investigator's Brochure (IB) that had grown to an unmanageable length through annual updates.

Solution

Our writer worked with each of the stakeholders who had contributed to the IB to reduce extraneous material without deleting critical information.

Impact

The revised IB was significantly more accessible to investigators and clinical staff. The concise format helped improve site engagement, reduced the burden of information overload, and supported regulatory readiness for the upcoming clinical studies.

Background

Client: Global biopharmaceutical client needed help making their Investigator's Brochure (IB) easier to navigate.

For one global biopharmaceutical company, the IB for their mid-stage drug candidate had grown to over 200 pages due to annual updates paired with minimal editing of the existing content. The team had captured the entire development history of their product in the IB, without considering the actual function of the document: providing investigators and clinical site staff with the information they need to make an unbiased risk-benefit assessment of the investigational product. The sheer length of the IB made it both inefficient and ineffective.

With new clinical trials set to start in the coming year, the team recognized the need to revise the IB into a more concise, reader-friendly document.

Challenge

The client set a challenging goal for their next annual update: reduce the IB to a more manageable length of less than 120 pages. However, each section of the IB was managed by a different functional group, each of which brought its own presentation style, preferred level of detail, and perspective on what constituted "essential" content. There was no clear consensus on what could be condensed, summarized, or removed altogether. The client needed a regulatory writing partner who could engage collaboratively with functional stakeholders and lead the effort to streamline the content.

Solution

Our experienced regulatory writer began with a comprehensive analysis of the existing 200-page IB, identifying sections that were redundant, overly detailed, or outdated. For each major section (and each functional area), our writer proposed specific page reduction targets based on the existing data and its relevance to the IB's intended audience. She then facilitated collaborative discussions with representatives from each functional area to evaluate the content in context. Our writer asked the right questions: Is this level of detail necessary for investigators? Can these data be summarized without losing key messages? Is this content relevant with the addition of more recent data?

Our regulatory writer worked closely with each functional area to rewrite and restructure their sections, focusing on clarity, consistency, and alignment with ICH E6(R2) guidelines. Data tables were removed or reformatted to be more concise, text blocks were rewritten to eliminate repetition, and detailed information was summarized to prioritize the most current and relevant findings. Throughout the process, we ensured that the scientific integrity of the IB remained intact, with clear justification for any content that was summarized or removed.

At 118 pages, the final revised IB was within the target range. The new document was easier to navigate and significantly more accessible to investigators and clinical staff.

Business Impact

The concise format helped improve site engagement, reduced the burden of information overload, and supported regulatory readiness for the upcoming clinical studies. The client was impressed with both the process and the outcome, noting that the approach we used has since been adopted as a template for future IB updates across their development programs. This project demonstrated how expert regulatory writers can bring structure, clarity, and strategic insight to even the most complex documents, delivering high-impact results with real-world operational benefits.

- **Our writer helped cut more than 80 pages from the IB with no loss of necessary information.**
- **The client has adopted our approach as a template for future IB updates across their development programs.**