APCER LIFE SCIENCES
Together for better health

CASE STUDY

Updating a complex Investigator Brochure (IB) for an oncology product within demanding timelines

Therapeutic area: Oncology

Product type: Drugs

Geography: US

Product life cycle stage: Clinical trial phases 2 and 3

About the Client

The client is a global bio-pharmaceutical company committed to discovering, developing, and delivering innovative medicines to patients with serious ailments. The company has a diversified portfolio across a wide range of therapeutic areas that includes oncology.

Business Challenge

For updating the investigator brochure of an oncology product, the source documents received from the client were TLFs (Tables, listings, and figures) for three clinical studies and an integrated analysis of the safety data of approximately 350 subjects.

While APCER was almost halfway through in updating the IB with the relevant information from the existing source data, the health authorities (HAs) informed about the requirement of including additional data on neurologic and hepatic events in the IB. This information had to be incorporated and the updated IB had to be submitted to the regulators within a strict timeline of 60 days of the datalock time.

Overview - Investigator's Brochure

The Investigator's Brochure (IB) is a comprehensive compilation of clinical and nonclinical data on the investigational product (drug, supplement, device or other product) maintained by the innovator that contains the information related to the chemical composition, dose, safety monitoring procedures, pharmacological, toxicological, and clinical information on the investigational product(s) obtained during its development phase. It is critical to maintain the information throughout the drug development process and is updated with new information as and when it becomes available from the trials. The IB needs to be revised annually by the sponsor with the most updated information and this should be effectively communicated to the investigators, health authority regulators, ethics committee, and the review board. This "Summary of Data and Guidance for the Investigator" section, provides the investigator with a clear understanding of the possible risks and adverse reactions, contraindications and observations required in the clinical trial.

A sponsor may outsource investigator brochure preparation and update activities to leverage the expertise of service providers in producing high-quality content with quick turnaround time as a cost-effective solution.

Solution

APCER's experienced Medical Writing (MW) team collated data from the available sources like clinical study reports, briefing documents, integrated summary of safety and effectiveness, development update safety reports, and periodic safety update reports. During the first review of the updated IB containing relevant data, the Client informed APCER about the need to include additional data on neurologic and hepatic events in the IB by the health authorities (HAs). The MW team at APCER quickly identified that the information in the TLFs shared with them for updating the IB did not have adequate data to address the requirements of HAs.

- APCER flagged this concern in a timely manner to the Client.
- APCER also further proactively guided the Client's statisticians to generate new tables by providing necessary inputs.
- Though this additional data was made available to APCER during later stage of the project, APCER was able to complete and deliver the updated IB to the client within 2 working days.

The factors enabling APCER for this rapid turnaround of the document to meet these extremely challenging timelines are as follows:

- Expertise of APCER's medical writers.
- Quick but thorough review by the reviewer.
- Efficient query resolution for document finalization.
- Tight supervision of the timelines by the project manager.

Outcome

The project helped the client achieve:

- Timely delivery of high-quality submission-ready Investigator Brochure.
- Satisfactory response to the queries raised by the health authority.
- Readiness of the in-house statistical team in preparing format of tables required for the next annual IB update.

Our Medical Writing Capabilities

A team with 30+ members having rich experience across therapeutic areas and expertise in preparing regulatory documents and scientific communications.

Robust two-step review process to ensure 100% quality control.

High-quality deliverables consistently exceeding expectations.

Customized solutions fully compliant to the ever-changing regulatory landscape.

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Part of APC Group

APCER Life Sciences is committed to improving health in partnership with its clients. We bring together safety, medical, regulatory and technology resources to ensure that patients receive the safest, most effective therapies possible.

We are an ISO 9001:2015, ISO 27001:2022, and ISO 27701:2019 certified company

Learn more at www.apcerls.com or contact us at one of our global offices: Americas: (+1) 609 455 1600 • Europe: (+49) 2409 725 6120 • UK: (+44) 208 326 3220 • Asia: (91) 79 6677 8600

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