APCER LIFE SCIENCES
Together for better health

CASE STUDY

Navigating FDA Type B Meetings: Harnessing Collaboration for Success

Therapeutic area: Oncology

Product type: Drugs

Geography: Unites States

Product life cycle stage: Investigational new drug (IND)

About the Client

The client is a United States (US)-based biopharmaceutical company having diversified portfolios across a wide range of therapeutic areas including oncology.

Business Challenge

A pharmaceutical company (the Sponsor) needed support for a **Type B meeting request** with the US Food and Drug Administration (FDA) to discuss their investigational new drug (IND) for oncology. Their specific challenges included:

- **Seeking guidance** on Phase 1 strategy and chemistry, manufacturing, and controls (CMC) development.
- **Summarizing extensive data** from over 40 non-clinical studies for the briefing document.
- **Drafting questions** on complex clinical and CMC topics related to Phase 1 study design, preclinical data adequacy, and non-clinical data requirements for a future combination study.
- **Publishing the meeting package** according to the eCTD (Electronic Common Technical Document) guidelines.

Overview – Briefing Documents

Briefing documents are comprehensive reports submitted by sponsors or applicants to provide detailed information about their products to the Agency in preparation for advisory committee meetings or other regulatory interactions. Writing effective briefing documents for the Agency requires a combination of scientific expertise, regulatory knowledge, and excellent communication skills. Briefing documents are also termed as briefing book, briefing package, or meeting request document.

A **Type B meeting** is a pre-scheduled discussion with the FDA on specific topics related to drug development, ranging from pre-IND to post-marketing considerations. The US FDA has revised the draft guidance, announced in the Federal Register on 21 September 2023, adds two new types of meetings, a Type D meeting for topics of narrow interest and meetings through the INitial Targeted Engagement for Regulatory Advice on CBER ProducTs (INTERACT) pathway for new and innovative technologies.

- *FDA guidance is available **here.***
- *European Medical Agency (EMA) guidance for sponsors seeking scientific advice and protocol assistance is available **here.***

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

Solution

APCER, a provider of integrated **Medical Writing** (MW) and **Regulatory Affairs** (RA) services, offered a collaborative solution to fulfill the Sponsor's request for the FDA meeting.

Jointly addressing critical needs:

To prepare for the meeting, the MW and RA Teams worked together on several key areas:

- **Data compilation and briefing document:** The MW Team extracted key insights by compiling and summarizing data from over 40 non-clinical studies. This information was used to create a concise and informative briefing document for the Sponsor and the FDA reviewers.
- **Question development and regulatory guidance:** Through collaborative discussions with the Sponsor, the MW and RA Teams co-developed well-defined questions on crucial topics such as,
  - **Dose selection and toxicokinetics for the Phase 1 study.**
  - **Preclinical data adequacy for the planned combination study.**
  - **Preclinical-to-clinical transition and Phase 1a/b study design.**

  Additionally, the RA Team provided guidance on relevant CMC regulations concerning starting materials and controls.
- **eCTD compliance and timely submission:** To ensure a smooth and compliant submission process, the RA Team prepared and formatted the meeting package according to the eCTD guidelines. They also facilitated a timely and error-free submission of the package to the FDA, meeting the Sponsor's critical deadline.

Outcome

APCER's integrated MW and RA services enabled the Sponsor in achieving the following outcomes:

- **Successful meeting request and briefing document:** APCER's collaborative approach facilitated the creation of a well-structured package, leading to the acceptance of the meeting request by the FDA.
- **Valuable agency insights:** The Type B meeting yielded crucial information on Phase 1 dose calculation, combination therapy feasibility, CMC development, and IND application clarity.
- **Enhanced confidence and direction:** The Sponsor gained valuable insights to guide their clinical development program with greater confidence.

APCER's Integrated Regulatory Affairs and Medical Writing Services

APCER comprises a team of highly qualified healthcare professionals having extensive experience in regulatory writing including both **CMC and MW**, providing end-to-end support to clients throughout the product life cycle.

High-quality deliverables consistently exceed client expectations and comply with regulatory authorities' requirements.

Publication and submission of electronic dossiers in different countries such as the US, the European Union, the United Kingdom, and Canada.

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

From meticulously crafted documents to navigating regulatory hurdles, APCER's interwoven MW and RA Teams become an extension to the client's team. This powerhouse synergy dismantles the complexities of drug development, empowering sponsors to bring life-saving treatments to patients faster.

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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.

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