APCER LIFE SCIENCES
Together for better health

CASE STUDY

Significance of Medical Monitoring for smooth progression of clinical trials

Therapeutic area: Oncology

Product type: Drugs

Geography: US, Australia and New Zealand

Product life cycle stage: Clinical trial phases 1 and 2

About the Client

The client is an innovative biopharmaceutical company committed to the discovery and development of combination therapies to achieve meaningful responses and to enhance patient outcomes in the complex area of oncology.

Business Challenge

- The pharma company was facing challenges in early clinical development. The site investigators had identified inconsistencies in reporting safety data of the cohorts for a dose determination study. There were challenges in assessing the safety data, especially the DLTs, to form the basis of the decision regarding the advancement of the program.
- This led to an assumption that the study drug was unduly toxic, which placed undue risk on the progression of drug development for this molecule. Because there was a series of findings by the Safety Review Committee (SRC), the sponsor was concerned about the consequences of a delay in trial advancement from the dose derivation to the disease expansion phase.

Overview - Medical Monitoring

Medical monitoring is an essential component of the clinical research process. Medical monitors provide medical expertise and oversight for the entire clinical trial, from initial study design through final study closeout. They must assure that reported trial data are accurate, complete and verifiable from the source documents, such as eCRF and medical records. If not done per the requirement, there exists a possibility of incurring huge fines and legal penalties from the regulators.

Typically, in oncology trials, the pre-specified dose limiting toxicities (DLTs) criteria may not properly reflect the clinician's practical experience with some adverse events (AEs), while others may actually be related more to the disease status than to the investigational drug and could be misclassified.

Therefore, it is important to verify the AEs more thoroughly, as they might interfere with interpretation of the clinical data.

Solution

APCER Life Sciences was selected as the service delivery partner due to our experience in oncology as well as our cost and ability to scale with their growth projections. The trial data were assessed and monitored by APCER physicians, and a medical monitoring plan was formulated in collaboration with the sponsor. Our medical monitoring team, consisting of experienced physicians, provided complete support to the sponsor in the following tasks:

- In-depth review of the complete safety data (AEs, laboratory data, screening values and medical history).
- Identification of and reporting inconsistencies in safety data and subsequent rectification.
- Providing medical evidence-based rationale for the AEs, which were incorrectly marked as DLTs. The investigators were trained to capture the appropriate AE terms and diagnosis.
- Presentation of safety data in a scientifically appropriate way to the SRC, which was well received and accepted by all SRC members.

Outcome

- APCER demonstrated its experience and expertise in early clinical development stages overseeing all clinical data related to safety from beginning to end.
- Proactive collaboration with sites/investigators and monitors helped review, trend, query, and clean data on an ongoing basis.
- Establishment of robust processes and standard operating procedures (SOPs) helped to deliver realtime feedback for entry and monitoring.
- Data were reviewed and leveraged with actionable insights.
- Presentation of safety data was accepted by all SRC members.
- The trial moved to the next dosing cohort without delay and the clinical development program moved forward.

Our Pharmacovigilance Capabilities - Clinical Trials

- Expertise in **safety services** for global, multi-center clinical trials.
- Expertise in **early-phase dose derivation studies.**
- A dedicated global team of **qualified and experienced medical monitors** mainly physicians.
- Rich experience in **SRC and DSMB meetings** and governance.
- Expertise in **end-to-end medical data review** from eCRFs.

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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 27001:2013, and ISO 27701:2019 certified company.

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