ERGOMED Clinical Research

Case Study

Planning and Executing an Early Phase Oncology Study to Expedite Development

Visual Snapshot

Customer

Small biotech with innovative cancer therapy.

Challenges

- Need to streamline the development process to facilitate decision making as quickly as possible.
- Innovative therapy requiring additional site support.

Outcome

Ergomed worked with the sponsor on the development of an adaptive design protocol and executed a strategic operational delivery plan to achieve the needs of the sponsor.

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"Improving Access to Cancer Immunotherapy"

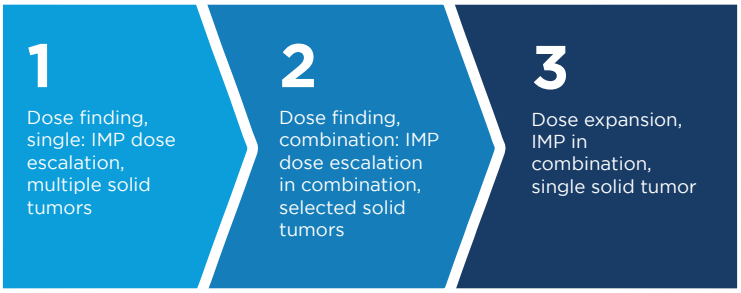
Ergomed Strategy

Study Design & Protocol Development

Working together with their counterparts, Ergomed Team supported development of the final study design and writing of the protocol ensuring clear definition of objectives, as well as planned adaptations; definition of the criteria for subject allocation to each of the cohorts, and contribution of each of the planned parts/cohorts to the main objectives.

A single protocol was developed to gather information to support multiple decisions:

- Recommended dose both as single agent and in combination
- Identifying early activity signals and defining potential patient population(s) for further investigation



Strategic Delivery Plan

Selection of the IT systems to ensure ability to appropriately manage opening and closure of the cohorts, triggering appropriate IMP management, as well as entry and registration of subjects. This included a patient profile data system to streamline relevant signals.

Utilization of Ergomed's site management team throughout the clinical trial to ensure appropriate site training, availability of all required lab kits and IP, and providing logistical support for specialized assays including next gen sequencing and immune biomarkers.

Going beyond the traditional approach to medical monitoring, and supporting investigator engagement by Ergomed Study Physicians to work locally and specifically with the investigators at sites to review subjects, and address and queries or concerns of the sites.

Individualized site plans to allow monitors to focus on timely data entry by sites and data cleaning to support decision making related to safety review.

Successful Outcome

Ergomed's involvement from the study design stage, enabled additional input and review of the objectives towards a final concept and design of the trial that should allow for a faster data availability for assessment of the main primary objectives and in the final target population that should benefit the most of the IMP and the combination being introduced.

Working jointly with the Client from the initial concept and involving all functions, allowed for identification of an optimal way to organize the expected high-volume inflow of complex data. Timepoints for data review and analyses were planned to maximize the information available at any time. This approach allowed for efficient alerts for any additional signals and possible adaptations needed for a highest possible chance of success.

While most clinical research organizations (CROs) focus exclusively on executing clinical trials, smaller, start-up biotechnology companies need more strategic guidance from the outset. They need an expert CRO that can understand the unique challenges faced in the drug development process and customize the work with them to develop a creative, strategic, and data-driven clinical development plan (CDP).

To learn more about Ergomed's expertise in early phase Oncology studies, contact us at:

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About ERGOMED

Founded in 1997, ERGOMED is a global provider of high-quality services to the biopharmaceutical industry, spanning all phases of clinical trials, post-approval pharmacovigilance, and medical information. ERGOMED Clinical Research is acomplete, global Phase I-IV clinical development and trial management service with a strong heritage in the development of drugs in rare diseases and oncology.

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