HiRO
Harvest Integrated Research Organization

Boutique Global CRO

CASE STUDY

Successful Rescue and Transition of Phase I Oncology Study for a US Biotech Company

Overview

A US biotech company's Phase I oncology study had stalled under the management of a US/EU oncology-focused CRO. During the initial patient enrollment phase, the sponsor was experiencing a lack of progress, expertise, and communication, and they decided to transition to HiRO as their new CRO partner.

Challenges

The transition presented significant operational complexities. At the time of transfer, 12 US and 3 EU sites were either already enrolling patients or very close to being activated. Patients were continuing to be enrolled into one of 7 different cohorts, creating a 2-month overlap of transition activities with accelerating patient enrollment.

The sponsor did not have a safety database, and the outgoing CRO was 80 cases behind in processing of periodic SAEs. Additionally, the existing clinical database was not adequate to support the additional patient cohorts planned for the study.

Solutions

We transferred and mapped all regulatory documents into our TMF within 1 month and completed all transition activities within 6.5 weeks. Our pharmacovigilance team implemented an ARGUS safety database and entered and processed all previously reported SAEs, clearing the backlog left by the previous CRO.

We worked with the sponsor to migrate data to a new clinical database while continuing to enroll patients. Throughout the transition, we set up regular communications and site visits with all sites to establish close relationships and demonstrate short response times, providing answers quickly to keep sponsors and PIs/sites motivated to enroll more patients.

Outcome

Enrollment rates increased post-transition, and sites were added in the US and EU to support an additional study 'basket' in a specific tumor indication. Protocol amendment implementation to support the additional study part went smoothly without any enrollment gaps between the study parts.

We built new clinical and pharmacovigilance databases and migrated data while continuing enrollment, implementing a Phase II protocol amendment and initiating new sites.

The study completed enrollment of 278 patients just 12 months after CRO transition, including the additional Phase II cohort, and the project resulted in 5 additional study awards from the sponsor.