HiRO
Harvest Integrated Research Organization

Boutique Global CRO

CASE STUDY

Rescuing a Rare Disease Trial: Accelerating MRCT RA Submissions for a Taiwan Biotech Company

This case study highlights HiRO's effective intervention in accelerating the regulatory submission process for a clinical trial focused on a rare disease. Through rapid and strategic action, HiRO successfully navigated complex regulatory landscapes, facilitating timely approvals across multiple regions.

Background

A biotech company based in Taipei engaged HiRO to rescue a Phase II/III clinical trial for a rare disease across multiple regions, including the US, UK, European countries, and Asia-Pacific nations. The project initially faced several challenges:

- The trial experienced major timeline delays, making no significant progress over the past six months while working with another global CRO.
- Existing vendors were unresponsive, hindering overall advancement.
- CMC issues including changes in the DS supplier, the necessity of DMF filings, issues with an unqualified CMC testing study vendor, and difficulties selecting a CDMO.

These hurdles required immediate attention and strategic intervention to ensure the successful execution of the clinical trial.

HiRO's Proactive Solutions and Strategic Planning

Upon taking over the project from the former CRO, HiRO quickly implemented a range of solutions to address the existing challenges. By prioritizing the resolution of CMC issues, our team achieved several critical tasks ahead of schedule, resulting in a significant improvement in overall project timelines. Key actions taken include:

- Supplier Transition and CMC Preparation: Our team managed the transition to a new DS supplier and conducted a comprehensive gap analysis for CMC submission materials, authoring the necessary IMPD and M3 documents for US submission.

- Engagement of New QP Vendor: After the original QP vendor remained inactive despite multiple communications, our team swiftly sourced a new vendor, ensuring a smooth transition and securing five QP declarations within five months, along with support for on-site audits and CAPA management.
- IMP Management Support: We assisted the sponsor in planning and managing IMP production, as well as label design, relabeling arrangements, and depot management.
- Strategic Submission Planning: Simultaneously with the resolution of the above CMC problems, we implemented a strategic submission plan and established a timeline outlining the readiness of the final documents, ensuring prompt submission as soon as all materials were complete.

To streamline the submission process, HiRO developed a strategic submission plan per region that optimized document preparation and ensured timely submissions, with the application of different expedited review pathways, significantly enhancing project efficiency.

The Result

Throughout the multi-region submission phase, HiRO's swift response, adherence to global standards, and adaptability resulted in remarkable achievements:

- Timely Regulatory Submissions and Achievements: Successfully completed the first regulatory and IRB submission within 1.5 months of the kick-off meeting, securing RA approval in Taiwan within 2 weeks and in the Philippines and South Korea within 2 months—significantly faster than the industry average of 3 months. In the UK, approval was also achieved in just 2 months.
- Expanded Global Reach: Continuously integrated new countries and sites into the study to meet patient enrollment objectives, expanding to 18 countries and regions with a proactive submission strategy and timeline for each.
- Efficient Submission Processes and Effective Planning: Maintained a quick turnaround for submission preparation, consistently addressing RFIs ahead of deadlines. Developed and executed an extrapolation plan in advance, enhancing overall study efficiency.

By prioritizing efficient multi-regional regulatory submissions, HiRO effectively rescued this critical study, ensuring it remained on track to meet essential timelines and fulfill recruitment objectives.