HiRO
Harvest Integrated Research Organization

Boutique Global CRO

CASE STUDY

Rapid Study Start-up for Phase 1 Dermatology Study in Australia for a UK Biotech Company

Overview

HiRO was contracted by a small UK-based biotech company to conduct a Phase 1 dermatology clinical trial in Australia. The sponsor was looking to get the study started within a short period of time to achieve the 'first patient in' milestone for their investors.

Australia has some of the fastest and most streamlined ethics and regulatory frameworks, enabling the first patient to be enrolled faster than anywhere else in the world. Due to this, the sponsor selected Australia as the destination of their clinical trial.

Choosing a CRO who knows and understands the nuances of the region in which the trial is being conducted is highly beneficial. Despite Australia's relatively straightforward regulatory processes, there are unique regional and cultural requirements that play vital roles in the application process.

HiRO's ANZ team was considered a good fit for the small biotech as a knowledgeable and well-connected CRO in Australia – with strong, longstanding relationships with ethics and regulatory body representatives and established relationships with trial sites and local experts. This can have a significant impact on the success of a clinical trial.

The sponsor also recognized the importance of HiRO's specialized regional expertise in navigating the complex ethics and regulatory environments, as well as its reputation as a CRO that delivers efficient and flexible solutions within tight timeframes and limited budgets.

Our Key Strategies to Achieve a 3-month Start-up

HiRO employed a proactive approach to achieve rapid start-up, focusing on swift ethics and regulatory approvals and concurrent site activation. HiRO ANZ has a dedicated rapid start-up team consisting of regulatory and clinical professionals with more than 20 years of experience in the ANZ clinical trial industry.

Our team understands country-specific and regional regulations, enabling us to implement proactive solutions to potential challenges and accelerate the timelines from trial site selection to first patient in.

We were able to achieve the start-up for this Phase 1 dermatology study in a rapid 3-month window.

The full regulatory approval was achieved merely 40 days from the final protocol receipt. The team worked tirelessly to ensure the first SIV was achieved only 4 days after the full regulatory and ethics approvals were granted. The first patient was screened only 3 days after site activation.

Our team implemented four key strategies:

- Streamlined communication: Ensuring immediate internal kickoff post-final protocol receipt to align all stakeholders.
- Efficient submission process: Preparing the pre-ethics submission and submited key documents just 10 days after receiving the final protocol to meet the prescribed ethics meeting dates by the committee.
- Rapid response to challenges: Addressing the requirement for an ethics re-submission with additional information promptly to mitigate potential delays.

Successful Outcomes and Study Continuation

At HiRO, our Start-Up team strategically leverages our position in Australia. Our proven track record underscores the effectiveness of our approach, emphasising that clinical trials can be swift, efficient, and cost-effective whilst maintaining the highest standards of excellence.

Our team delivered a well-coordinated, collaborative and customised approach to support this small biotech achieve their rapid start-up timeline of just 3 months.

Our comprehensive service allowed us to guide our overseas client team effectively. We provided crucial regional support, flexibility, and tailored solutions to ensure that all regulatory and safety/quality aspects were considered and study milestones were achieved. Our strong partnership with the client assured rapid attention and proactive solutions to any potential issues.

As the study progresses, continuous monitoring and adaptive management strategies will be essential to maintain momentum and promptly address any challenges.