HiRO
Harvest Integrated Research Organization

Boutique Global CRO

CASE STUDY

Exceeding Recruitment Targets for Phase II Obesity Clinical Trial for a US Biotech Company

Overview

HiRO was contracted by a small US-based biotech company to conduct a Phase II obesity clinical trial. The study required the recruitment of 325 eligible participants across 16 sites in Australia and New Zealand.

New Zealand has the unfortunate statistic of having the third-highest adult obesity rate in the OECD. Therefore, this, combined with HiRO's ANZ team's over 20 years of experience across Australia and New Zealand, led to their selection as the CRO for the region.

We were chosen for our bespoke size and our strong regional connections as a CRO. This can significantly impact the success of a clinical trial and the sponsor recognized our reputation as a CRO that delivers efficient and flexible solutions within tight timelines and limited budgets.

Overachieving Recruitment Targets

Through the selection of quality, high-performing sites with strong recruitment track records, and meticulous planning and collaboration, we supported the first-participant, first-visit (FPFV) milestone, achieved on the same day as site activation.

The ANZ region delivered a strong recruitment performance, and after initial global targets were reviewed, the ANZ region recruitment targets were increased to 325 participants, and 327 participants were successfully recruited, all within the study's recruitment timelines.

Innovative Strategies for Participant Retention

Obesity trials are recognized as high-risk for high participant dropout rates. Dropouts occur due to various reasons, such as excess weight loss, lack of

motivation, stalled weight loss, loss of muscle, and general study/time commitments.

Understanding these challenges, HiRO's ANZ team, in partnership with the sponsor and sites, implemented creative participant-centric strategies to retain participants and minimize dropouts. These included developing participant support materials, such as an ethics-approved BMI scale for participants to monitor their weight loss, participant reimbursement for phone call visits and DXA visits, and dietitian support throughout the study.

To implement these retention strategies, we needed to manage resubmissions to ethics committees across Australia and New Zealand to get these participant reimbursement strategies approved. Our dedicated study start-up team supported these resubmissions, quickly getting these approvals to support participant retention.

Successful Outcomes and Strategic Impact

We were able to support this small biotech company in running an efficient and effective clinical trial. Our deep and comprehensive service allowed us to guide our client and provide crucial regional support, flexibility, and tailored solutions to ensure that all regulatory and safety/quality aspects were considered and that study milestones were achieved. Our strong partnership with the client assured rapid attention and proactive solutions to any potential issues.

With all studies, recruitment is a vital component for the overall success of a clinical trial. By delivering an increased participant targets and ensuring high-quality data outcomes, our ANZ team played a crucial role.

The efficient execution of this Phase II clinical trial in the ANZ region reflected our strong capability in managing large-scale, multi-site studies while delivering exceptional results. Our expertise in project management, site selection, participant recruitment, study start-up and regulatory compliance all contributed to the study's success.