CASE STUDY: ADVANCING OBESITY AND TYPE 2 DIABETES TREATMENT

TRIAL OVERVIEW

The successful execution of two sequential obesity and type 2 diabetes mellitus (T2DM) clinical trials showcases our expertise in managing complex clinical studies. By proactively addressing study challenges and optimizing trial design, we delivered participant safety, high-quality data, and the sponsor's continued trust.

TRIAL #1: 28 DAY MULTIPLE DOSE PATIENT STUDY

QPS conducted a 28 day inpatient study that evaluated the safety, tolerability, pharmacokinetics, and pharmacodynamics of an investigational product in overweight/obese patients with T2DM on stable metformin monotherapy.

Study Design and Execution

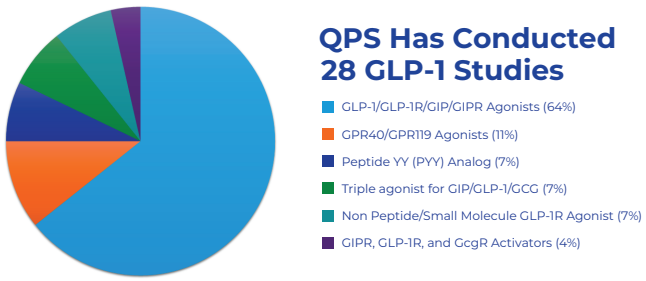
- 24 overweight/obese individuals with T2DM were enrolled. Two panels of 12 participants. All participants completed the full 28 day inpatient stay.
- Baseline caloric needs were calculated using the Harris-Benedict equation. Weight and food intake were tracked daily.
- Real-time data revealed the need to optimize dose escalation design and further characterize the weight loss pattern.
- High incidence of GI-related adverse events (AEs) on initial dosing led to modifications to the titration design. The dose was adjusted based on tolerability and safety. Through close monitoring and proactive management of AEs, the initially planned dose was safely achieved.
- Unexpected weight loss observed in placebo subjects prompted the introduction of ad libitum snacking to better simulate a real-world environment.

TRIAL #2: 42 DAY MULTIPLE DOSE PATIENT STUDY

QPS conducted a 42 day follow-up trial seeking to optimize the dosing regimen and improve tolerability while maintaining robust metabolic assessments.

Study Design and Execution

- 32 overweight/obese individuals with T2DM. Three groups enrolled sequentially; no overlap with Trial #1 participants. 98% of participants completed the trial.
- Calorie-specific meals and the addition to ad libitum snacks reduced placebo-related variability in weight loss data.
- GI AEs were significantly reduced not only through optimization of the titration design, but also through diligent and proactive clinical management to ensure subjects safety and retention in the next trial.



Results

Rapid full enrollment of both trials, adaptive trial design leveraging real time data, an on-staff dietician developing calorie-specific meal plans, and high touch clinical care to overcome initial tolerability challenges led to an ongoing relationship and additional awards.

Discover how QPS can accelerate your obesity research.

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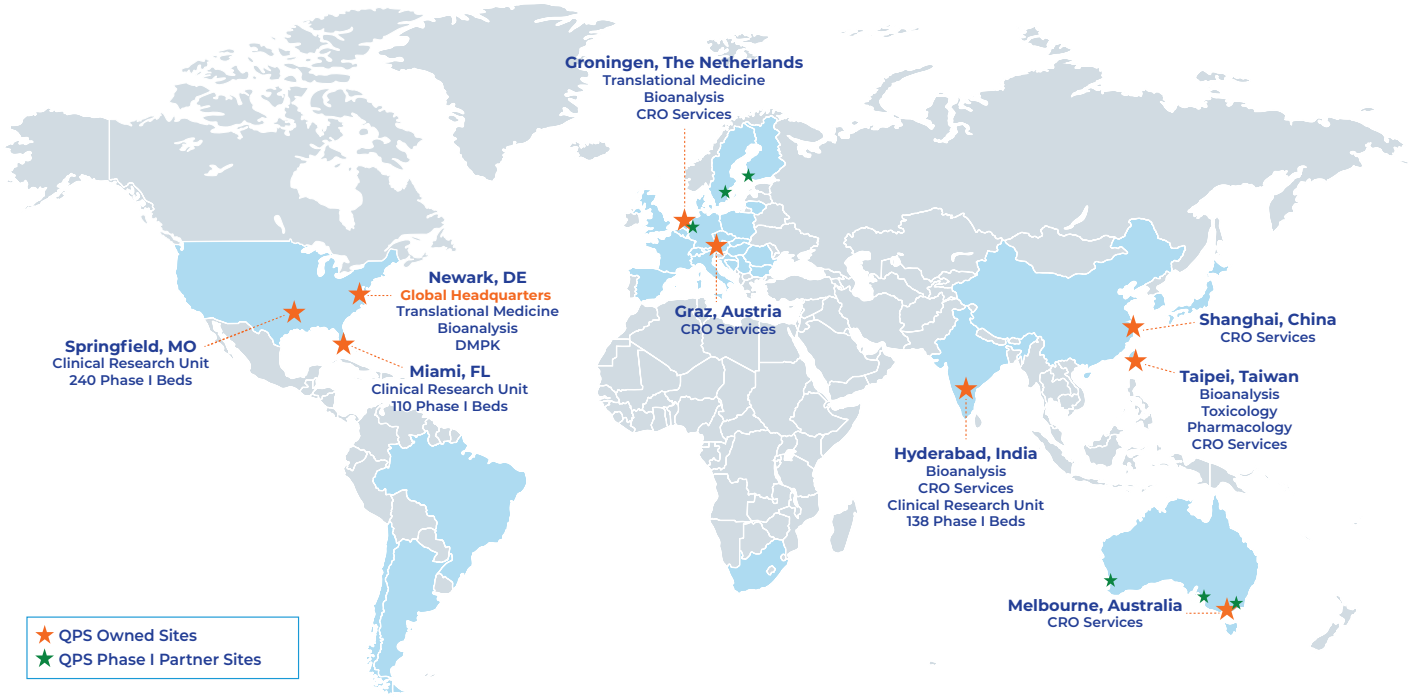

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