QPS PATIENT STUDY EXPERIENCE **OBESITY**

QPS is a leading full-service global CRO with extensive experience conducting obesity studies, offering comprehensive services to ensure successful clinical trials. Our experienced and dedicated global team provides unmatched support for obesity research, from preclinical studies to bioanalysis and all phases of clinical trials.

WHY CHOOSE QPS FOR OBESITY STUDIES?

1. Expert Clinical Team

- **Specialized Expertise:** Our team includes board-certified obesity medicine physicians, experienced clinical research coordinators, project managers, and skilled data analysts specializing in obesity.
- **Patient-Centric Approach:** We prioritize patient comfort and compliance, ensuring high retention rates and reliable data collection.

2. Phase I State-of-the-Art Facilities

- **Over 500 Phase I beds:** Multiple clinics across 3 countries accommodate short- and long-stay trials.
- **On-Site Pharmacy:** Facilitates seamless medication management and ensures adherence to study protocols.
- **Site Services:** Central and safety labs, clinical trial kit production, cell therapy products, and a negative pressure room.

3. Comprehensive Services

- **Advanced Research Centers:** Equipped with cutting-edge technology for precise diagnostics and monitoring.
- **End-to-End Support:** From protocol development to regulatory submissions, QPS handles every aspect of your obesity study.
- **Customized Solutions:** Tailored study designs to meet the specific needs of obesity research, including biomarker analysis and nutritionists on staff.

4. Proven Track Record

- **Successful Trials:** Over 13 successful obesity trials since 2015, including multiple GLP-1, GIP, and GIP/GLP-1 studies.
- **Global Reach:** Access to a diverse patient population through our extensive network of clinical sites.

KEY BENEFITS:

Patient Recruitment: Robust strategies to identify and enroll qualified patients quickly.

Data Quality: Rigorous quality control measures ensure high-quality, reliable data.

Regulatory Compliance: Adherence to global regulatory standards and best practices.

Since 1995, QPS has provided discovery, preclinical, and clinical drug development services. An award winning leader focused on bioanalytics and clinical trials, QPS is known for proven quality standards, technical expertise, a flexible approach to research, client satisfaction and turnkey laboratories and facilities. For more information on QPS, visit www.qps.com, or email infobd@qps.com.

CASE STUDIES

Study #1

In 2022, QPS participated in a 28 day multiple dose study to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of a drug in overweight/obese patients with Type 2 Diabetes Mellitus. The outcome of the study demonstrated that the drug tested was generally safe and well-tolerated by patients. The pharmacokinetic and pharmacodynamic profiles showed promising results, indicating that both compounds effectively stimulated the secretion of the targeted satiety hormones. QPS was able to overcome challenges, including managing potential side effects and ensuring patient adherence to the medication regimen.

Study #2

QPS conducted a randomized, double-blind, placebo-controlled, parallel-group study designed to assess the effect of a drug on body weight in overweight and obese subjects, including those with Type 2 Diabetes. The study demonstrated that the drug effectively contributed to weight loss by enhancing the feeling of fullness, leading to reduced food intake. The placebo-controlled design ensured that the observed effects were directly attributable to the drug. Challenges included maintaining the double-blind condition due to the unique nature of the gel particles, and ensuring consistent hydration levels in participants.

TRIAL COMPLEXITIES

Both clinical trials faced significant challenges related to maintaining trial integrity and ensuring treatment effectiveness. These challenges were overcome through careful trial design, rigorous monitoring, and patient education. By addressing these complexities, researchers were able to maintain patient safety, uphold the integrity of the trials, and gather reliable data that supported the effectiveness of the treatments.

QPS EXPERIENCE ACHIEVING RESULTS

Our experience in these trials has paved the way for successfully managing Phase I programs and transitioning to patient cohorts.

1. Phase I Expertise: Our clinics are highly experienced in complex FIH SAD/MAD trials, supported by a large healthy volunteer database. Studies are conducted seamlessly, using alternates to ensure timelines are met. Our staff, including investigators, coordinators, nurses, and paramedics, are seasoned in Phase I studies. Principal investigators are full-time employees, accessible to both patients and sponsors for questions and concerns, with a very hands on approach.

2. Subject Matter Experts: QPS's full-time staff includes physicians with both early and late phase clinical trial experience. They provide support before the trial starts with protocol eligibility questions and during the trial to resolve adverse events and patient complexities. Additionally, QPS has clinical pharmacology experts to support proper design and to answer pharmacokinetic (PK) questions.

3. Proper Site Selection: Selecting the right number of sites for obesity trials from the start ensures timely enrollment and study cohort success. Based on your experience, rapid enrollment of obesity trials can often be done at one site. QPS has experience rapidly enrolling large numbers of study subjects for obesity trials in just one clinical trial site.

4. Pre-identification of Obesity Subjects: Successful cohorts rely on more than databases alone. Social media (Instagram and Facebook), radio, well-targeted advertisements, and recruitment at local events can all help identify new subjects. Ideally, subject identification for the patient cohort should begin while completing the healthy volunteer portion of the trial, ensuring patients are available once the patient portion starts.

5. Full Service Global Clinical Research Services: QPS can manage your Phase I - IV clinical trials from start to finish. With regulatory and medical affairs support, sample analysis, clinical trial kit production, data management, project management, site selection and monitoring, QPS can ensure your trial is completed successfully.

CONTACT US

Discover how QPS can accelerate your obesity research.

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- **Website:** www.qps.com

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QPS
CUSTOM-BUILT RESEARCH™

A GLOBAL FULL SERVICE CRO ACROSS **USA**, **EUROPE** AND **ASIA**

QPS is a global CRO providing preclinical services, bioanalysis, clinical trials, and clinical research services. We accelerate treatment breakthroughs by delivering custom-built research services, specializing in cell & gene therapy and obesity.

Drug Development Services:

- Pharmacology
- Toxicology
- DMPK
- Bioanalysis
- Translational Medicine
- Clinical Trial Conduct
- Clinical Trial Kits
- Cell Therapy and PBMCs
- Leukopaks
- Clinical Research Services

Clinical Research Services

- Project Management
- Clinical Program Management
- Clinical & Medical Monitoring
- Site Selection & Monitoring
- Data Management & Biostatistics
- Medical Affairs
- Medical Writing
- Regulatory Affairs
- Quality Assurance
- Safety & Pharmacovigilance

PHARMACOLOGY

TOXICOLOGY

DMPK

BIOANALYSIS

TRANSLATIONAL MEDICINE

CLINICAL DEVELOPMENT

REGULATORY AND MEDICAL

CELL THERAPY & LEUKOPAK

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