QPS CLINICAL TRIALS SITE EXPERIENCE **VACCINE STUDIES**

QPS is a leading full-service global CRO with extensive experience conducting vaccine studies, offering comprehensive services to ensure successful clinical trials. Our experienced and dedicated global team provides unmatched support for vaccine research, from preclinical studies to bioanalysis and all phases of clinical trials. Our clinical trial sites in Miami, Florida and Springfield, Missouri have unmatched experience in multiple populations across a myriad of disease states.

WHY CHOOSE QPS FOR VACCINE STUDIES?

1. Expert Clinical Team

- **Specialized Expertise:** Our site-specific teams include board-certified physicians, experienced clinical research coordinators, project managers, and skilled data analysts specializing in vaccine studies.
- **Patient-Centric Approach:** We prioritize study subject comfort and compliance, ensuring high retention rates and reliable data collection.

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

- **Advanced Research Centers:** Equipped with cutting-edge technology for precise diagnostics and monitoring.
- **On-Site PBMC Labs:** Both sites have fully equipped PBMC labs with trained personnel and cryopreservation capabilities.
- **Additional Site Services:** On-site pharmacies, central and safety labs, clinical trial kit productions, leukopaks, and a negative pressure room.

3. Comprehensive Services

- **End-to-End Support:** From preclinical and bioanalytical services, to protocol development, clinical trial management, and regulatory submissions, QPS handles every aspect of your vaccine study.
- **Customized Solutions:** Tailored study designs to meet the specific needs of vaccine research, including biomarker analysis and imaging services.

4. Proven Track Record

- **Successful Trials:** QPS has completed almost 100 vaccine studies with high enrollment rates and timely data delivery. Of these trials, approximately 20% were gene-based, including 14 mRNA, five DNA, and four viral vector vaccines.
- **Therapy Areas:** RSV, Influenza, Pneumonia, Menningitis, Rabies, E.Coli, Norovirus, c-diff, SARS-CoV-2, Dengue, Herpes, HPV, HIV, CMV, DTP, Typhoid, Ebola and Zika.
- **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: Success Amidst a Global Pandemic

In 2021, as the world grappled with the COVID-19 pandemic, our team embarked on a critical Phase 1 multi-site study. Evaluate the safety and immunogenicity of a replication-competent chimeric virus vaccine platform developed to protect against SARS-CoV-2.

Leading a collaborative effort to complete PBMC sampling across multiple visits and multiple sites was a complex task. Our team not only met the enrollment expectations but also extended support to the other sites by running PBMC samples on their behalf.

Study #2 Rapid Execution (Influenza Vaccine)

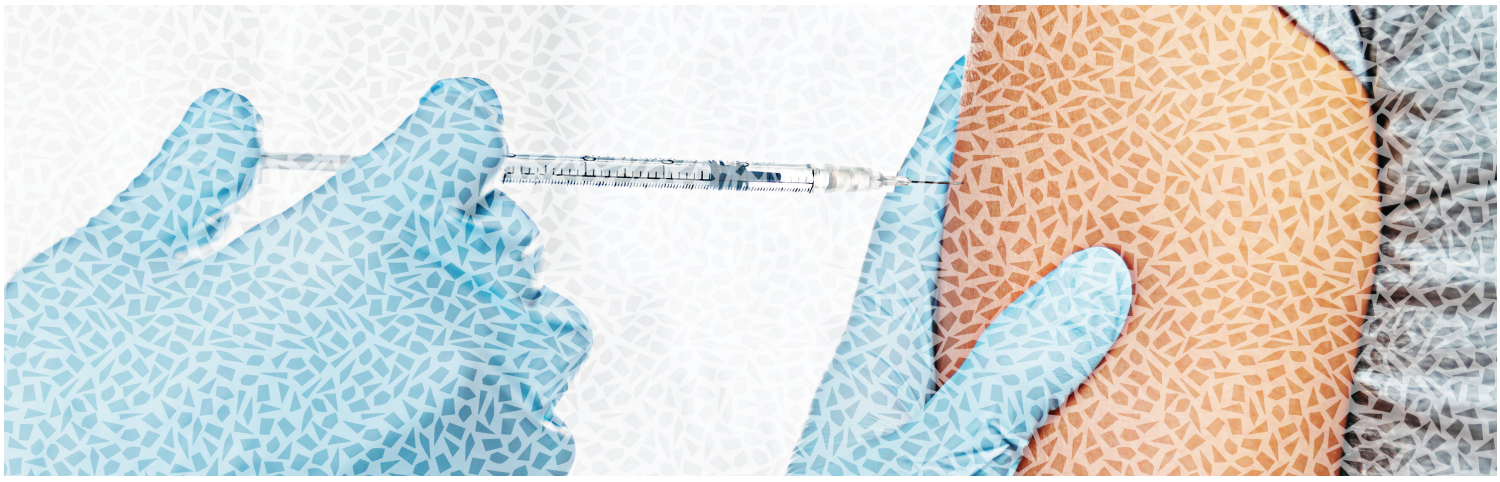
QPS received a large Influenza vaccine trial awarded under very strict, short timelines. The target was 100 healthy volunteers.

Leveraging our robust volunteer database, the QPS team swiftly identified and contacted potential participants and recruited 120 in less than a week. In addition, the team screened 107 subjects and dosed 105 subjects in just one day.

Our dedicated team performed thorough quality control (QC) on all participant charts on the same day of dosing. This proactive approach ensured that the information was clean and ready for immediate EDC entry, facilitating seamless data management and analysis.

TRIAL COMPLEXITIES

Navigating the complexities of conducting a clinical trial during a pandemic, recruiting, screening and dosing large numbers of study subjects quickly, and collaborating with other local sites to run their PBMC samples concurrently are great examples of our ability to execute complex studies under tight timelines with remarkable efficiency and precision.



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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 board certified 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 vaccine trials from the start ensures timely enrollment and study cohort success. Based on our experience, rapid enrollment of vaccine trials can often be done at one site. QPS has experience rapidly enrolling large numbers of study subjects for vaccine trials in just one clinical trial site.

4. Pre-identification of 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.

CONTACT US

Discover how QPS can accelerate your vaccine research.

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