QPS PATIENT STUDY EXPERIENCE
RHEUMATOID ARTHRITIS

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

WHY CHOOSE QPS FOR RA STUDIES?

1. Expert Clinical Team

- **Specialized Expertise:** Our team includes board-certified rheumatologists, experienced clinical research coordinators, project managers, and skilled data analysts specializing in RA.
- **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

- **Advanced Research Centers:** Equipped with cutting-edge technology for precise diagnostics and monitoring.
- **On-Site Pharmacy:** Facilitates seamless medication management and ensures adherence to study protocols.

3. Comprehensive Services

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

4. Proven Track Record

- **Successful Trials:** Numerous RA studies completed with high enrollment rates and timely data delivery.
- **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 was awarded a three-part First-in-Human (FIH) study to evaluate the safety and tolerability of an investigational monoclonal antibody intended for use in Rheumatoid Arthritis (RA). Part one consisted of five cohorts with an eight-subject Single Ascending Dose (SAD) design in healthy volunteers. Part two involved a single dose in eight RA patients on stable Methotrexate (MTX). Part three included two multiple dosing cohorts of eight healthy subjects each. This trial was completed in 2024.

Study #2

QPS recently participated in a four-part study for a first-in-class humanized monoclonal antibody to be administered both intravenously (IV) and subcutaneously (SC). Part A involved single ascending IV doses in healthy volunteers. Part B evaluated the safety and tolerability of a single IV dose in healthy volunteers challenged with Lipopolysaccharides (LPS). Part C assessed the safety and tolerability of single subcutaneous doses. Part D examined the safety of two subcutaneous doses in both RA patients and healthy volunteers, requiring a total of 11 RA subjects on stable disease modifying antirheumatic drugs (DMARDs). This study is nearing completion.

TRIAL COMPLEXITIES

Both trials were FIH studies requiring sentinel dosing with Safety Review Committee meetings between cohorts for safety assessments. Expertise was essential in managing IV and SC dosing and potential adverse events associated with biologic medications. Additionally, identification of RA subjects on stable MTX for the patient arms has been challenging at times, but achievable. Notably, retention was excellent with no dropouts.

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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 rheumatologists 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 pharmacokinetic (PK) questions.

3. Proper Site Selection: Selecting the right number of sites for RA trials from the start ensures timely enrollment and patient cohort success. Based on our experience, rapid enrollment of 15 RA subjects typically requires two to three sites. Relying on a single site risks patient depletion and delayed timelines.

4. Pre-identification of RA Subjects: Successful RA cohorts rely on more than databases alone, as background medications and medical status can change over time. Referrals from rheumatology practices often yield mixed results since Phase I trials offer little clinical benefit to patients and provide doctors with minimal incentive to refer their stable subjects. Social media (Instagram and Facebook) and well-targeted advertisements can help identify new subjects. Ideally, subject pre-identification for the patient cohort should begin while completing the healthy volunteer portion of the trial, ensuring RA patients are available once the patient portion starts.

CONTACT US

Discover how QPS can accelerate your Rheumatoid Arthritis research.

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