How do I achieve rapid study startup and fast participant recruitment?

Clinical Pharmacology at Quotient Is Your Answer

When you need a Phase I clinical pharmacology study, you can expect rapid study startup and recruitment through our locations in Jacksonville and Miami in Florida and Nottingham, U.K.

Our full-service science and medical teams will work with you to design a tailored program to meet the rigorous requirements of major regulatory agencies. Your clinical pharmacology program will include details of drug metabolism pathways, drug-drug interactions and an assessment of cardiac safety. This program will be delivered under the leadership of a single project manager to ensure that you reach your targets as efficiently as possible.

- Purpose-built Phase I units in U.S. and U.K.
- More than 400 beds globally
- 15 physicians and 10 principal investigators
- Database of > 25,000 healthy volunteers
- > 1,200 Phase I studies completed
- MHRA- and FDA-approved facilities
- Industry-leading U.S. IRB and U.K. CTA approval timelines

We are dedicated to your study with:

- **Clinical pharmacology expertise** including first-in-human (SAD/MAD), DDI, food effect and ADME experience
- **Experienced project managers** who guide your study to successful delivery on time and on budget
- **On-site pharmacy** and ISO Class 7 clean room and Class 5 laminar flow for aseptic preparation
- **Integrated, real-time adaptive GMP manufacturing**
- **Capabilities for all dosage forms** including oral solutions and suspensions, capsules and tablets, sterile preparations (IV and SC), inhaled and oral dosage forms, topical creams and gels
- **Rapid subject recruitment** based on a database of a broad population and more than 25,000 healthy volunteers
- **Full-service data management and medical writing** to support protocol development, data analysis and reporting
- **Regulatory support** to ensure a seamless FDA or MHRA submission and approval process for clinical trial applications

What can Quotient's clinical pharmacology do for me?

- Conduct complex study protocols in state-of-the-art facilities
- Leverage the expertise of our Phase I specialists with more than 1,200 studies completed
- Deliver clinical data and insights quickly to move you to the next milestone
- Ensure rapid, high-quality regulatory submissions

Quotient Sciences
Assess. Adapt. Accelerate.

Edinburgh | Jacksonville | Miami | Nottingham | Philadelphia
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Experience and study types

- First-in-human (SAD/MAD)
- Drug-drug interaction (DDI)
- Food effect
- Thorough QT (TQT)/cardiac safety
- Bioavailability, dose proportionality and absolute bioavailability
- Bioequivalence
- Biosimilars
- ^{14}C ADME/mass balance
- Proof-of-concept
- Pharmacodynamics/biomarkers
- Japanese bridging

Special populations

- Healthy participants
- Ages 65 and older
- Post-menopausal
- Male and female infertility
- Hypertensive
- Type II diabetics
- Asthma and allergic rhinitis
- Obesity
- Healthy smokers
- Gastrointestinal diseases
- Japanese

Bioanalytical services

- Method development, validation and sample analysis support across a myriad of prevalidated assays and new chemical entities
- Seasoned scientists committed to providing rapid turnaround on bioanalytical data for SAD/MAD and all other clinical studies
- Strong GLP compliance record in support of FDA, ANVISA, OECD and MHLW regulations

Facilities

We operate from three purpose-built Phase I units with more than 400 beds. At all facilities, we provide clinical excellence, volunteer safety and data integrity to enhance both protocol conduct and participant comfort.

Miami and Jacksonville, Florida, U.S.

- Physicians with specialties including critical care medicine, infectious disease, family medicine and internal medicine
- Ten experienced physician assistants or registered nurses with ACLS training
- Over 650 Phase I and early Phase II clinical studies completed
- 320-bed capacity across two clinical pharmacology units
- 20,000 active participants in our database across a broad demographic

Nottingham, U.K.

- Medical director with PI experience on over 200 clinical studies
- 45 Phase I CTA submissions annually (more than any other U.K. unit)
- 85-bed, purpose-built clinical unit
- 7,500 active healthy volunteers in our database
- 70 CDISC-compliant datasets issued in the past two years
- Draft CSRs delivered within eight weeks of LSLD

Data sciences and biometrics

Our data scientists staff provides expert services for early phase clinical studies for both healthy volunteers and patients studies. Access rapid data delivery for crucial dosing decisions during your study.

Standardizing study data with CDISC

When you need compliant datasets, enlist experts who understand CDISC's impact on early phase studies and its importance to your future regulatory submission.

Statistics, pharmacokinetics and scintigraphy

Our statistical, pharmacokinetic and scintigraphic experts understand clinical pharmacology studies and their specialized challenges. Optimize your study objectives, design and subject numbers, and maximize your use of study data.