How do I find an integrated solution for first-in-human and clinical pharmacology programs?

Clinical Pharmacology at Quotient Is Your Answer

When you are looking for a partner who is dedicated to Phase I trials and early development, rely on Quotient Sciences. We accelerate your molecule from first-in-human to proof-of-concept, helping you make critical decisions earlier. Whatever clinical pharmacology study you require, you can expect a fully integrated program from study design to data reporting.

We are dedicated to your Phase I study with our:

- Proven track record of more than 30 years
- >1,300 Phase I studies completed
- Experts in first-in-human (FIH) and drug-drug interaction (DDI) studies
- Industry-leading Phase I medical directors
- Ability to recruit large cohorts of volunteers
- Fully integrated programs led by experienced project managers

Clinical Pharmacology Expertise

Our experience spans more than 30 years and 1,300 Phase I studies, including FIH (SAD/MAD), DDI, bioavailability, food effect and ^{14}C ADME studies. Our industry-leading medical directors and principal investigators will deliver your study while ensuring compliance and the highest level of volunteer safety.

Input to Study Design

To maximize your clinical data output, we design flexible study protocols. And, because we conduct 70 to 80 studies per year, we continuously deepen our understanding of trial design and regulatory guidance to improve the robustness of your program. Partner with scientists who understand your molecule, and leverage our expertise for your clinical program design.

- **First-in-Human**
  Quotient will guide you through the FIH trial process and outline approaches to single and multiple ascending dose trials. Our experience includes multi-part adaptive protocols to maximize value from your study and obtain knowledge of your compound much earlier in development, including initial assessments of cardiac safety, metabolism and exploratory pharmacodynamics or biomarkers.

- **Drug-Drug Interaction**
  Access the expertise Quotient has gained from more than 200 DDI studies. Our experience includes exploratory investigations and registration studies, enzyme induction and inhibition, oral contraceptives, interactions with specific concomitant medicines and probe cocktail studies. We will also genotype volunteers and access our large database of poor and extensive metabolizers.

What can Quotient's clinical pharmacology do for me?

- Conduct study protocols to the highest quality in state-of-the-art facilities
- Leverage the expertise of Phase I specialists
- Rapidly deliver clinical data and insights to move you to the next milestone

Quotient Sciences
Assess. Adapt. Accelerate.

Edinburgh | Miami | Nottingham | Philadelphia | Reading
UK: +44 (0)115 974 9000 | US: +1 800 769 3518 | info@quotientsciences.com | quotientsciences.com

Experienced Project Managers

Your dedicated early phase project manager will provide you with customized service. We deliver full-service programs on time, within budget and to the highest quality to meet your rigorous requirements and those of the regulatory agencies.

Rapid Recruitment and Study Startup

Accelerate your study startup at Quotient's clinical units in Miami (U.S.) and Nottingham (U.K.) with industry-leading IRB and CTA approval timelines. In addition, 99 percent of our studies start on time, 98 percent enroll with full cohorts and 99 percent of our subjects are retained throughout. If you need to access a challenging healthy volunteer population for your study, we rapidly recruit large cohorts of volunteers.

On-site Pharmacy and Manufacturing

Whether you need on-site pharmacy compounding or real-time adaptive GMP manufacturing of clinical trial materials, gain flexible solutions from formulation development through manufacturing with our integrated capabilities.

Formulation Development

Save time with our strategic approach. Our drug product teams help formulate your compound and develop scalable drug products to transition you from Phase I into Phase II patient trials and beyond. Leverage our experience in all dosage forms, including oral solutions and suspensions, capsules and tablets, sterile preparations, inhaled and nasal devices, topical creams and gels.

Early Phase Data Sciences

Enlist full-service data management, statistics and medical writing services to support your protocol development, data analysis and reporting. With a data sciences team that is dedicated to early phase research, get your data faster — as quickly as 40 days from completion of the clinical phase to the issue of the draft clinical study report.

Facilities

Serving a global client base, we operate two purpose-built Phase I units with a total of 245 beds. At both facilities, we provide clinical excellence, volunteer safety and data integrity to enhance both protocol conduct and participant comfort.

Miami (U.S.)

- Over 650 Phase I clinical studies completed
- 160-bed clinical unit with dedicated FIH wards
- On-site pharmacy, with clean rooms for aseptic products
- 18,000 active healthy volunteers in our database
- Recruitment for special subject populations

Nottingham (U.K.)

- Over 650 Phase I studies completed
- 85-bed clinical unit with a dedicated ^{14}C ADME ward
- On-site pharmaceutical laboratories and GMP manufacturing
- 7,500 active healthy volunteers in our database
- 45 Phase I CTA submissions annually (more than any other U.K. unit)

Experience and Study Types

- FIH (SAD/MAD)
- 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
- Obese
- Healthy smokers
- Japanese
- Asthma and allergic rhinitis
- Gastrointestinal diseases

Ready to accelerate your molecule from FIH to proof-of-concept? Quotient is your answer. Partner with us to develop your integrated early drug development program.

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