



Clinical Pharmacology

(Complete Early Phase Solution)

The clinical pharmacology team at ICON has extensive experience in the design, study conduct and interpretation of clinical pharmacology studies with a strong reputation in high science approaches, including a full suite of pharmacodynamic markers. Across all elements of your program from study synopsis to CSR, we apply integrated medical, scientific and operational excellence that's dedicated to early phase development essential to reaching decision milestones on-time and with the highest quality insights.

Design

ICON's consultancy services offer advice on clinical pharmacology study design based on preclinical data including potential use of surrogate markers and pharmacodynamic models, validation of those markers and models, clear objective setting, and flexible protocol design. We offer outcome-oriented thinking to help make critical development decisions early in the process. The extensive experience of our scientists and medical staff will ensure that the most appropriate and cost-effective program is designed for your compound development.

Delivery

With a clinical operations team experienced in the unique needs of Phase I-IIa studies, ICON is well positioned to fully implement early phase clinical development programmes involving healthy volunteers, patients and special populations. We provide the full suite of clinical pharmacology studies including all elements of a regulatory package programme, as well as translational early efficacy indication solutions with proven experience in:

- First-In-Human
- Single and Multiple Dose Escalation Studies
- Drug Interaction Studies
- Bioavailability, Bioequivalence

- Pharmacodynamic Studies
- Biomarkers, Imaging
- Thorough QTC Studies
- Phase I-IIa Patient Studies
- Special Population Studies

Interpretation

With bioanalytical, immunoassay and clinical pathology laboratories, ICON is able to provide rapid analysis of samples for quick decision-making about your molecule. With data management, biostatistics, pharmacokinetics and clinical pharmacology staff in the US and in Europe, we are able to provide expert, regulatory-ready analysis and reports.

Scientific Services Dedicated to Early Phase

- Strategic & Operational Medical/Scientific Support from Pre-clinical Through Phase IIa
- Data Management & Programming
 - PK & Biostatistics
 - Medical Writing & Publishing
 - Project Management
 - Clinical Monitoring

Clinical Research Unit

Our state-of-the-art facility in San Antonio, TX features:

- 180 beds capacity separated into 2 floors, including a 10 Bed ICU
- 48-channel continuous 12 lead Mortara Telemetry system, core ECG Data Storage — ideal for tQTC studies
- In-house CLIA/COLA certified, clinical laboratory providing hematology, coagulation, platelet aggregation, chemistry, drug testing, urinalysis
- Pulmonary function and exercise stress testing
- Large screening to accommodate outpatient visits
- On-site GMP accredited pharmacy with Bio hood Central IRB
- Generator Emergency Systems Backup for disaster preparedness
- Security Controlled, 24 hour monitoring for subject safety
- Controlled document storage rooms with water and fire protection, and limited access
- Centralised nursing stations for added supervision
- Dedicated PK laboratory with multiple refrigerated centrifuges
- Synchronised atomic time system
- Crash carts & ACLS certified staff

Special Clinical Capabilities

Techniques

ICON offers a wide array of special clinical techniques from Imaging to ophthalmologic evaluations in the areas of Cardiovascular, Respiratory, Pain, Metabolic and Central Nervous System. This includes clinical pharmacodynamics models for a broad range of clinical conditions including:

- Diabetes
- Pain (Acute and Chronic)
- Anxiety

Excellence In Recruitment

We have robust volunteer databases of both healthy volunteers and special populations – and we regularly access other select patient populations through our relationships with local physicians. Recognising that the foundation for a successful study begins with successful recruitment, all our units have a dedicated team whose sole focus is recruiting and screening, regularly employing ongoing and study-specific media campaigns to enhance our ever-growing network of volunteers.



Clinical Research Unit, San Antonio, Texas