ICON
A Symbol of Excellence

Excellence in Early Phase Development

(Phase I-IIa/ Proof-of-Concept)

We offer extensive experience in the design, conduct and interpretation of Phase I-IIa/Proof-of-Concept studies. Across all elements of your program - from study synopsis to CSR, we apply integrated medical, scientific and operational excellence with a dedicated early phase development team. We have a proven track record of reaching decision milestones on-time/within budget with the highest quality.

Design

ICON offers full study design (Phase I-IIa/Proof-of-Concept) including potential use and validation of surrogate markers, pharmacodynamic models, and flexible/combination designs, to optimize the information needed for early stage asset development. Our highly innovative approach facilitates earlier critical decisions in the development process enhancing speed to patients and subjects as well as cost effective approaches.

Delivery

ICON's expertise in healthy volunteers, patients and special populations, combined with our dedicated Early Phase Project Management and medical oversight to the entire process (from protocol synopsis to final clinical study report) is industry leading. We leverage our in-house Early Phase Clinical Research Unit and our established partner network of third party clinical sites around the globe (including special populations) to successfully operationalize your studies.

We provide the full suite of clinical pharmacology studies, all elements of a regulatory package program, and translational early efficacy indication solutions in:

- First-In-Human
- Single/Multiple Dose Escalation/Proof-of-Concept
- Drug Interaction Studies
- Bioavailability, Bioequivalence, Biosimilar PK similarity and Bridging Studies
- Pharmacokinetic/Pharmacodynamic (PK/PD) Studies
- Biomarkers, Imaging
- Thorough QTc Studies
- Phase IIa (PoC) Patient Studies
- Special Population Studies (Renal/Hepatic impairment, ethnic bridging and elderly subjects)
- Diabetic Clamp Studies

Data Interpretation & Pharmacokinetic/ Pharmacodynamic Modelling & Simulation

With bioanalytical, immunoassay and clinical pathology laboratories, ICON provides real-time analysis for quicker decision-making about your compound. We leverage our industry leading Automated Data Visualization technologies to quickly (and earlier) identify safety signals, reduce data errors resulting in improved quality, and reduced timelines for the final clinical study report. NONMEM : ICON is the exclusive developer and licensor with globally trained team of experts. NONMEM is industry gold standard in Population PK and PK/PD analyses.

Scientific Services Dedicated to Early Phase

- Strategic & Operational Medical/Scientific Support from Pre-clinical Through Phase IIa(PoC)
- Data Management & SAS Programming
- Pharmacokinetics/Pharmacodynamics Modeling and Simulation
- Biostatistics
- Medical Writing & Publishing
- Project Management
- Clinical Monitoring
- Dedicated Early Phase Medical Monitors

ICON's state-of-the-art facility features:

- 180 beds capacity separated into 2 floors, (including a 10 Bed ICU) and a 6 bed clamping ward
- 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, chemistry, drug testing, urinalysis, and a host of other tests
- Pulmonary function and exercise stress testing
- Large screening to accommodate outpatient visits
- On-site pharmacy with Bio hood
- Central IRB
- Generator Emergency Systems Backup for disaster preparedness
- Controlled document storage rooms with water and fire protection, and limited access
- Centralized nursing stations for added supervision
- Dedicated PK laboratory with multiple refrigerated centrifuges
- Synchronized atomic time system
- Crash carts & A(C)LS certified staff
- Radiation
- Radioactive Pharmacy
- Add Rapid review timeframe content
- Access to clean rooms

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.

Pharmacodynamic Models

ICON has a dedicated Clinical Pharmacodynamics group with over 15 years' experience developing and validating PD Models for a broad range of clinical conditions including:

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 local relationships. Recognizing that the foundation for a successful study begins with successful recruitment, we have a dedicated team whose sole focus is recruiting and screening, regularly managing ongoing and study-specific media campaigns to enhance our ever-growing network of volunteers.

Glucose Clamping

- Dedicated Clamping Ward
- Clamp Protocol, Design, and Consulting
- Clamping Data analysis
- Manual and Computer Algorithm Controlled Clamping
  - ICON's "in-house" algorithm uniquely allows ICON to take into account the difference from target concentration of the most recent blood glucose measurement and the behavior of the glucose over the last few samples i.e. any overlying increasing / decreasing trends.
- Clamps offered:
  - Euglycemic Clamp,
  - Hyperinsulinemic Euglycemic Clamp,
  - Hyperglycemic Clamp,
  - Hypoglycemic Clamp

For more information, please contact:

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