Early Phase Services

Overview

The Worldwide Clinical Trials' Early Phase Services modern clinical research and development site in San Antonio, Texas, houses a total of 300 beds and is GCP/ICH compliant. These facilities offer the essentials for storing and dispensing study drugs, along with maintaining regulatory documents and study data. Specimens are seamlessly transferred to our Bioanalytical Sciences division, or lab of your choice, for sample analysis.

Facility Capabilities

- Centralized atomic clock system
- Class 10,000 clean room
- Federal and State Schedule II-V Drug Licensure
- Fully equipped sample processing laboratory
- Full service clinical laboratory
- Limited access Phase I unit
- Serial and continuous CSF equipment
- Security alarmed -70°C and -20°C freezers
- Spacious procedure areas
- Telemetry equipment

Phase I-IIa

Our Early Phase Services' staff has enrolled thousands of participants for both inpatient and outpatient trials. Our staff works closely with you to customize data entry and other processes to meet your specific needs. Our 85,000-square-foot center in San Antonio, Texas, contains extensive security measures to ensure that study drug supplies, patient information, study samples and associated documentation remain confidential and secure.

Our ability to accommodate large, or even multiple, cohort trials, combined with our dedicated, experienced staff enables effective integrated planning and implementation for Phase I-IIa clinical trials.

Bioequivalence Studies

Early Phase Services' comprehensive services for bioequivalence studies include protocol design and development, clinical conduct, bioanalysis and statistical analysis. Our final study reports for FDA submission are produced using Liquent InSight Publisher™, which automatically compiles source documents with varying file formats into one seamless publication. This technology also supports reporting from Thermo Electron Watson™ LIMS and other software programs.

THERAPEUTIC EXPERIENCE

- Allergies
- Alzheimer's disease
- Anxiety disorders
- Bipolar disorder
- Cardiovascular disease
- Depression
- Diabetes
- Hypertension
- Mild cognitive impairment
- Ophthalmology
- Pain models and management
- Parkinson's disease
- Women's health studies

PHASE I-IIa STUDY CAPABILITIES

- Pharmacokinetics/pharmacodynamics
- First-in-man
- Bioavailability
- Bioequivalence
- Dose ranging
- Multiple dose tolerance
- Drug-drug interactions
- ADME studies

WORLDWIDE CLINICAL TRIALS
SCIENTIFICALLY MINDED · MEDICALLY DRIVEN

Pharmacokinetic and Statistical Services

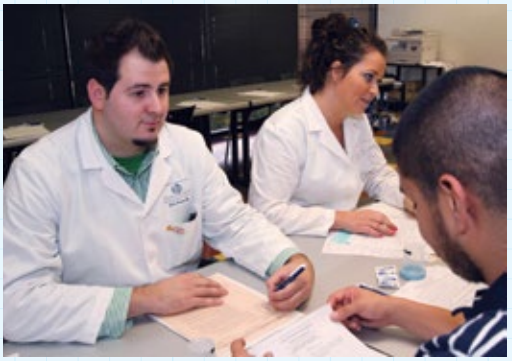
- Pharmacokinetic and pharmacokinetic/pharmacodynamic modeling
- Noncompartmental analysis
- Bioequivalence and bioavailability testing
- Preclinical (toxicokinetics) and clinical pharmacokinetics
- Determining the effects of dosing regimen, patient demographics, etc. on pharmacokinetics
- Interim safety and pharmacokinetic analysis for early phase/ *first-in-man* studies
- Experience in ADME studies, plasma and urine pharmacokinetics, dose escalation (SAD), multiple dose (MAD), toxicokinetic (preclinical), *first-in-man*, bioavailability and bioequivalence

Biostatistical Services

- Design and implementation of randomization scheme
- Development of Statistical Analysis Plan (SAP)
- Sample size rationale and statistical power
- Methodology for summary and analysis of demographic, baseline, efficacy and safety data
- Description of statistical methodology
- SAS programming for tables, listings and figures
- Production of tables, listings and graphs in compliance with ICH guidelines
- Performance and validation of statistical analysis
- Interim analysis
- Bioequivalence
- Linear and non-linear modeling
- Parametric and non-parametric analysis of clinical and PK endpoints
- Production of statistical report/assistance with clinical report
- Statistical management throughout the project

Early Phase Services

Experienced physicians on staff



Participants learning about the study

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