veeda clinical research®

Quality driven clinical development solutions for your next Phase I Trial

We are now supporting you through all the stages in a drug development continuum

The objective of Phase I trials is to establish the safety and dosage of a new drug in humans. Phase I trials generally involve 20 to 100 healthy volunteers or patients. Clinical Pharmacology Information derived from Phase I trials help in designing Phase II and Phase III trials.

Types of Studies in Phase I trials

Clinical Pharmacology Studies

- Single Ascending Dose & Multiple Ascending Dose PK studies
- Healthy vs Patient population
- ADME (Mass Balance)
- Studies in Specific Population
  - Renal Impairment
  - Hepatic Impairment
  - Age, Gender
  - Pediatrics
- Drug Interactions
- Population PK
- Biomarkers
- Pharmacogenomics
- Special Safety

Exposure-response (PK/PD)

- Dose selection and optimization
- Efficacy vs. Safety
- Quantitative approaches
  - Clinical Trial Simulation
  - Disease models

Biopharmaceutics

- Bioavailability/Bioequivalence (BA/BE)
- Food Effect

In Vitro Studies

- Protein Binding
- Blood to Plasma Partitioning
- Invitro drug metabolism, transport, and drug interactions

Expediting Phase I Trials with Experience, Robust Infrastructure, and Streamlined Operation

veeda clinical research

Study Design and Execution

- SAD & MAD PK Studies
- ADME Studies
- Phase I BA/BE Studies
- Food Effect Studies
- Formulation Change Studies to determine PK and Safety
- Glucose Clamp Studies
- Special Safety Studies (QT/QTc trials)
- Drug Interaction Studies
- Special Population Studies

Project Management

Medical Affairs

Volunteer Recruitment

Bioanalytical Services

Conducting Feasibility & Site Set up Activity

Data management & Biostatistics

Site Monitoring and Safety Monitoring

Regulatory Guidance

Our Experience in Phase I Trial encompasses studies involving healthy volunteers & patients

Total Phase I Studies, 23

Type of Studies	No. of Studies
First-in-Human (FIH)	3
SAD Study	1
MAD Studies	5
Phase I Vaccine Study	1
Drug Interaction Studies	2
Glucose Clamp Study	1
Food Effect Studies	3
Proof-of-Concept Study	1

Completed: 17

Ongoing: 1

Planned: 5

Veeda's Experience in First-In-Human Studies

Synopsis	Therapeutic Area
FIH study to Evaluate Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics in Healthy, Adult Volunteers and Adult **Type II Diabetic** Volunteers	Endocrinology
FIH study to Evaluate the Safety, Tolerability, Food effect & Pharmacokinetics in Healthy Male Subjects and Efficacy & Safety in Patients with **Acute Dental Pain.**	Inflammation and Pain
FIH study to Determine **Pharmacokinetics and Tolerability** in Healthy Male Subjects.	Cardiology
Safety and immunogenicity study of Polio Vaccine in healthy adult human male subjects.	Polio Vaccine

Drug-Drug Interaction Study

A Study to Assess the Effects of Multiple Oral Doses of calcium-channel blockers drug, a Moderate CYP3A4 Inhibitor, on the Single-Dose Pharmacokinetics of XYZ drug in Healthy Volunteers.

A Study to Evaluate the Effect of Multiple Oral Doses of calcium-channel blockers drug on Single-Dose Pharmacokinetics of ABC drug in Healthy Volunteers.

Food Effect Studies Experience

Studies to evaluate food effect of pharmacokinetics of test formulations as three-way crossover design under different conditions as follow:

- **High-fat, high-calorie breakfast**
- **Sprinkled on one tablespoon of applesauce**
- **Under fasting state with 240 mL of water**

Two-way crossover – oral bioavailability (pharmacokinetic comparison) studies under fasting and fed state of test formulations.

Two-Treatment, Three-Period, Six-Sequence, Crossover, Bioequivalence studies under fasting and fed conditions to assess the effect of food:

- **Test formulation under fasting and fed states**
- **Reference formulation under fed condition**

Experience in handling 505(b)(2) studies

505(b)(2)	Design
Salt change	Single dose BE
Change in formulation & dosage form	Comparative BA
Change in formulation & strength	Comparative BA
Change in formulation	Single dose BE
Fixed Dose Combination (FDC)	Single dose BE
Change in formulation	Single dose BE
Change in formulation	Comparative PK Study
Strength change	Multiple doses BE

Team Experience Across Various Therapeutic Areas and Indications

veeda clinical research

Therapeutic Area	Indication	Regulatory Submission
Psychiatry	Major Depressive Disorder, Schizophrenia, Bipolar disorder, Bipolar I depression	USFDA, EMA and DCGI
Medical Devices	CAD, Arrhythmia, Heart failure, Uncontrolled hypertensions	USFDA & DCGI
Cardiology	Hypertension, Ischemic cardiomyopathy, CVD, ACS	USFDA, EMA and DCGI
Endocrinology	DM-I, DM-II, Diabetic nephropathy	USFDA, EMA and DCGI
Oncology	Advanced Ovarian Cancer, Metastatic breast cancer, Renal Cell Carcinoma, Multiple Myeloma, Colorectal Cancer, Solid Tumors / Lymphoma, NSCLC, Cervix Cancer	USFDA, EMA, ENVISA and DCGI
Respiratory	Asthma, COPD	USFDA & DCGI
Dermatology	Atopic dermatitis, Oral lichen planus, Dermatomycoses	DCGI
Nephrology	CKD, Urinary tract infection and pyelonephritis	USFDA & DCGI
Gastroenterology	Arsenic Poisoning, GERD, Constipation, Ulcerative Colitis	USFDA & DCGI
Infectious Diseases	Bacterial Infection, Skin Infection, Hepatitis B Infection	USFDA & DCGI
Ophthalmology	Chronic Open Angle Glaucoma, Ocular Hypertension	USFDA & DCGI
Neurology	Epilepsy, Seizures	DCGI
Vaccines	Rabies, Leishmaniasis & serious fungal infections	DCGI
Orthopedic	Psoriasis and Rheumatoid Arthritis & Osteoporosis	USFDA & DCGI

Patient Based PK End Point Studies Experience

Therapeutic Areas and Indications	No. of Studies	No. of Patients	Type of Study
Antiviral			
HIV	1	48	PK Endpoint Study
Oncology (22 studies)			
Chronic Myeloid Leukemia (CML)	6	160	PK Endpoint Study
CML & Gastrointestinal stromal tumor (GIST)	1	40	PK Endpoint Study
Metastatic Breast Cancer (MBC)	3	203	PK Endpoint Study
Metastatic Breast Cancer (MBC) and Colorectal Cancer (CRC)	2	99	PK Endpoint Study
Multiple Myeloma (MM)	1	54	PK Endpoint Study
Orthopedic Cancer	1	58	PK Endpoint Study
Ovarian Cancer	2	120	PK Endpoint Study
Ovarian and MBC	3	202	PK Endpoint Study
Renal Cell Carcinoma (RCC)	3	86	PK Endpoint Study
Psychiatry			
Schizophrenia	7	463	PK Endpoint Study
Rheumatology			
Rheumatoid Arthritis (RA) and Psoriasis	1	42	PK Endpoint Study

Clinical End Point Studies Experience

Therapeutic Area	Completed Studies	Study Phase
Oncology	6	Phase I, Phase II
Orthopedic	3	Phase III
Ophthalmology	1	Bioequivalence Clinical Endpoint

Our Ongoing Patient Trials

Study Type	Therapeutic Area	Indication
Phase I/II	Thrombolytic	Acute ST segment Elevation Myocardial Infarction
Phase I	Oncology	Solid Tumor

Specialized Study Expertise for the following indications

- Myocardial Infarction
- Breast Cancer
- Advance Prostatic Cancer
- Ovarian Cancer
- Open-Angle Glaucoma or Ocular Hypertension
- Solid Tumor
- Iron Deficiency Anemia
- SARS-CoV-2 Infection in healthy subject
- Mild symptomatic patients with COVID-19

30 bedded Phase-I capacity, spread across two units

Strong Bioanalytical Capabilities to keep your study on track

- Method development and validation for a wide range of drug substances
- Chiral Molecule Analysis
- Hormones and vitamin analysis
- Optimized acceptable methodology for endogenous moieties, unstable drug & metabolite(s) and chiral separation
- Trained Bio analysts to handle complex sample processing
- State of the art Bio analytical Lab equipped with high-end sensitive equipments to achieve the required LLOQ
- 100% data review by Bio-analytical Quality Monitors
- Capability to develop methods with the lowest quantification level- up to 0.1 pg
- Average processing capacity of 1,00,000 samples per month
- More than 1066 available Bioanalytical Methods for NCEs, Generics, Complex Generics, Large Molecule Assays, & Pharmacodynamics/Immunogenicity

Supporting Early Phase development of Biosimilars

Our JV Partner Somru BioScience has developed a portfolio of reagents, tools, solutions, and a knowledge database that will enable companies to capitalize on biosimilar opportunities. The product categories include Antibodies, Protein, Immunogenicity, and Pharmacokinetic

Veeda Group's Biosimilar services include:

- Biosimilar Characterization
- Biomarker Testing Solutions
- PK and Immunogenicity analysis
- BioNMR Services
- Providing Regulatory Guidance

Our Completed Projects

- Comparative PK and PD study on GCSF, Erythropoietin, Streptokinase.
- Glucose Clamp studies on Insulin Aspart and Insulin Glargine
- Pharmacodynamics and Immunogenicity analysis for Enoxaparin

Our Ongoing Project - Biosimilars

- Omalizumab
- Pegfilgrastim
- Filgrastim
- Recombinant Follicle Stimulating Hormone

Accelerate Your Research with our experience of Handling New Chemical Entities

Bioanalysis proficiency in handling new chemical entities (NCEs) is backed by:

- Team of bioscientists having over 10 years of experience in handling NCE molecules involving different phases of clinical trials to support:
  a) Dose escalation – safety, PK & route
  b) Multiple-dose studies to identify dose regime - frequency/route
  c) Formulation for effective bioavailability
  d) Populations based studies
- Sensitive equipment's to support subpicogram level quantitation for the micro-dosing studies to assess minimum effective dose
- 69 validated NCE methods for different sponsors involving different biological matrices like human blood, serum, plasma, tissues, and urine
- Validated methods that have a dynamic range of over 2000 times linearity to support SAD and MAD studies sample analysis

What makes Veeda Clinical Research a perfect choice for your next Phase I Trial?

veeda clinical research

- Extensive Scientific Competence to service a Diverse client base
- High Customer Centricity and Satisfaction
- Skilled personnel with focus on Continuous Professional Development
- Robust Quality & Regulatory Compliance
- State of the Art Infrastructure for handling complex studies
- Experience of handling studies for different dosage forms (solid, semisolid, suspension, injectables, inhalation, topical drugs etc.)
- Providing full service as well as functional services in all the stages of drug discovery and development to support critical drug development programs of global (Bio) Pharmaceutical companies

To know more about
our expertise in Phase I Studies, mail us at
info@veedacr.com

Partners in creating a healthier tomorrow

+91 79 6777 3000

www.veedacr.com