veeda clinical research®

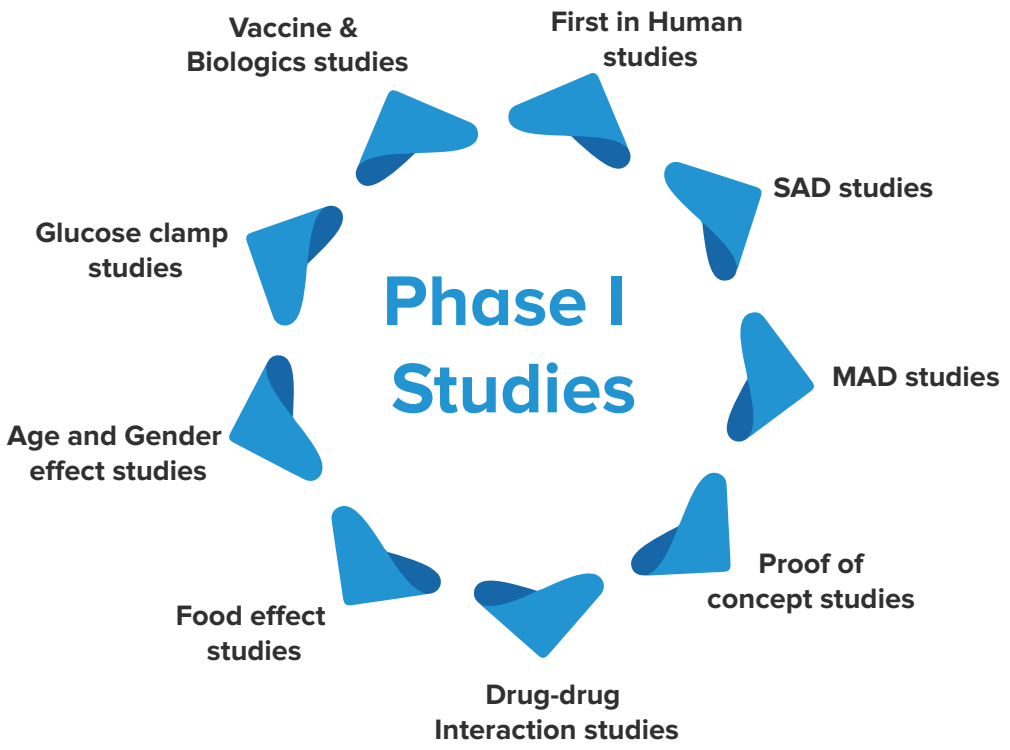
# Simplified & Dedicated Approach:

## Phase I Solutions for Novel Drug-development Program

# Overview

Veeda is an India-based independent CRO aimed at assisting large, small, and emerging pharmaceutical and biopharmaceutical companies accelerate the delivery of much-needed therapies to market. With our Phase I services, we strive to expedite clinical programs and build the foundation for the continued development of the product. With our broad range of clinical development services, we can tailor our offerings to your company's specific needs.

We have a vast experience in various study designs in all major therapeutic areas, along with a wide range of dosage forms to facilitate protocol development and study conduction for efficient regulatory submissions.




# Our Clinical Infrastructure

**19 Unique Sponsors** associated for **Phase I** studies across the globe

**>1000 Volunteers enrolled** for Phase I Studies in last 2 years

Well-developed **30** Bedded Phase I units spread across sites to support Phase I studies

Team of scientists having **in-depth knowledge and experience** of handling Phase I studies

**Modern, Purpose Designed facilities** with rigorous monitoring of medication to ensure subject safety

# Veeda's Phase I Experience

## Types of Studies

| |
|---|
| Single Ascending Dose Studies |
| Multiple Ascending Dose Studies |
| Safety and Immunogenicity Studies |
| Drug-Drug Interaction Studies |
| Glucose Clamp Studies |
| Food Effect Studies |
| Safety and Tolerability Study |
| Relative Bioavailability |

## Phase Study in Patients / Hospital Sites

| Type of Study | Therapeutic Area | Indication | Submission | Sample Size |
|---|---|---|---|---|
| Phase I | Infectious Disease | Covid-19 Vaccine | DCGI | 100 |
| Phase II | Oncology | Relapsed Advanced Tumors & classical Hodgkin Lymphoma (cHL) | USFDA | 130 |
| | Infectious Disease | SARS-CoV-2 Infection | DCGI | 60 |
| | Infectious Disease | COVID-19 | USFDA | 112 |
| | Anti-retroviral | HIV Positive Patients | DCGI | 30 |
| | Infectious Disease | Covid-19 Vaccine | DCGI | 1500 |
| | Respiratory | Asthma / COPD | USFDA | 25+30 |
| | Infectious Disease | HIV Positive Patients | DCGI | 18 |

# We provide support to our sponsors during the application & regulatory review stages for Phase I studies in India

Initial application submission

Initial review by the regulatory agency within 1-1.5 months, if any query is found, it needs to be raised in the online portal

SEC body discussion and approval, if any query is raised, then a response /clarification has to be sumitted

Meeting & discussion with the SEC body to present the proposal (Once in a month for each therapy/ indication)

Once the SEC body approves the protocol, final approval is received within 10-15 days. The overall approval timeline takes around 3-3.5 months

# Volunteer Recruitment & Safety

With our extensive volunteer database of >**77,000,** we have access to a wide pool of possible participants, including a variety of healthy volunteers, special populations, and patients. We are associated with more than **900** investigators across various therapeutic areas and have strategic partnerships with local hospitals. We customize recruitment strategies to suit the patient population and the therapeutic area.

- Qualified and ACLS / BLS trained personnel
- Appropriately designed Phase I facilities
- Well equipped & maintained Special Care area
- Stretcher lifts with Emergency Power back up System
- Emergency Management with near by tertiary care hospital
- In-house 24x7 Ambulance
- Fire & Chemical Hazard Management systems

## To know more about

our expertise in Phase I Trials, mail us at

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**Partners in creating a healthier tomorrow**

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