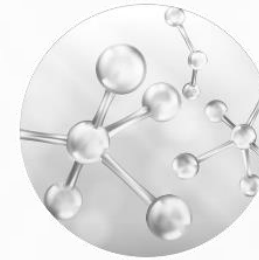




Partners in creating a healthier tomorrow

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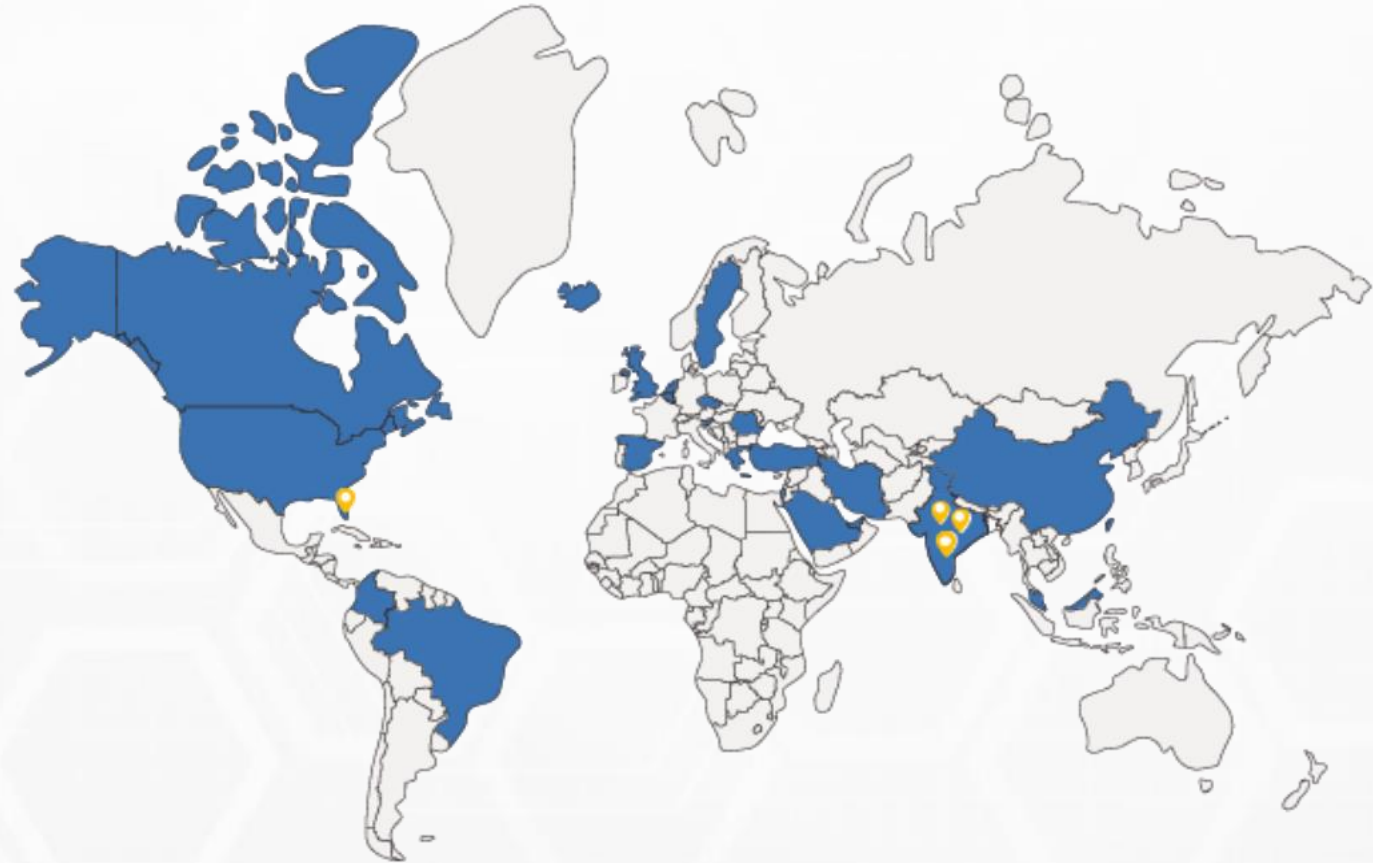
Corporate Overview




Veeda Group

- Veeda Clinical Research Limited (“Veeda”) together with its subsidiary, Bionees India Private Limited (“Bionees”), (together referred to as the “Veeda Group”) offers a comprehensive portfolio of clinical, preclinical and bio/analytical services to support innovator, biosimilar and generic drug development programs of our global clientele
- We are an independent, institutional investors owned, Board governed and professionally managed contract research group offering scientific leadership, global quality management systems and long term operational and financial stability through a continuing investment in our people, processes, systems, infrastructure and technology and a deep commitment to quality
- Together, we serve clients globally in the following industries:
 - Pharmaceutical and Biopharmaceutical
 - Agrochemical and Industrial Chemicals
 - Herbal/ Nutraceuticals
 - Medical Devices

Our Global Foot Print



 Serving clients across these geographies

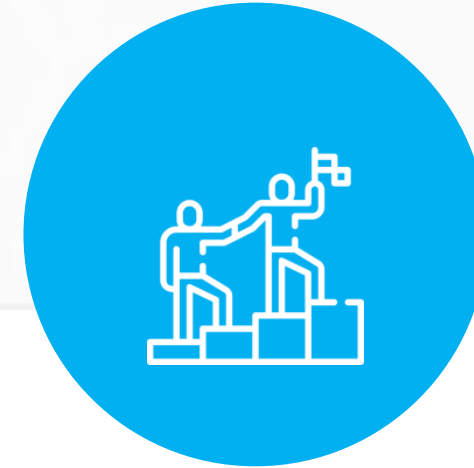
 Veeda's Team Presence

Corporate Philosophy



Vision

In an industry where innovation is increasingly multifaceted and collaborative, we aspire to be the research partner of choice for innovative (bio)pharmaceutical companies worldwide for their critical product development programs



Mission

To be the pre eminent independent Indian contract research Organization, with global execution capabilities, distinguished by the breadth of our services and by excellence in the quality of our Scientific and regulatory knowledge Research design, execution and insights and Client centricity

Our Values

Humility

Innovation

Accountability



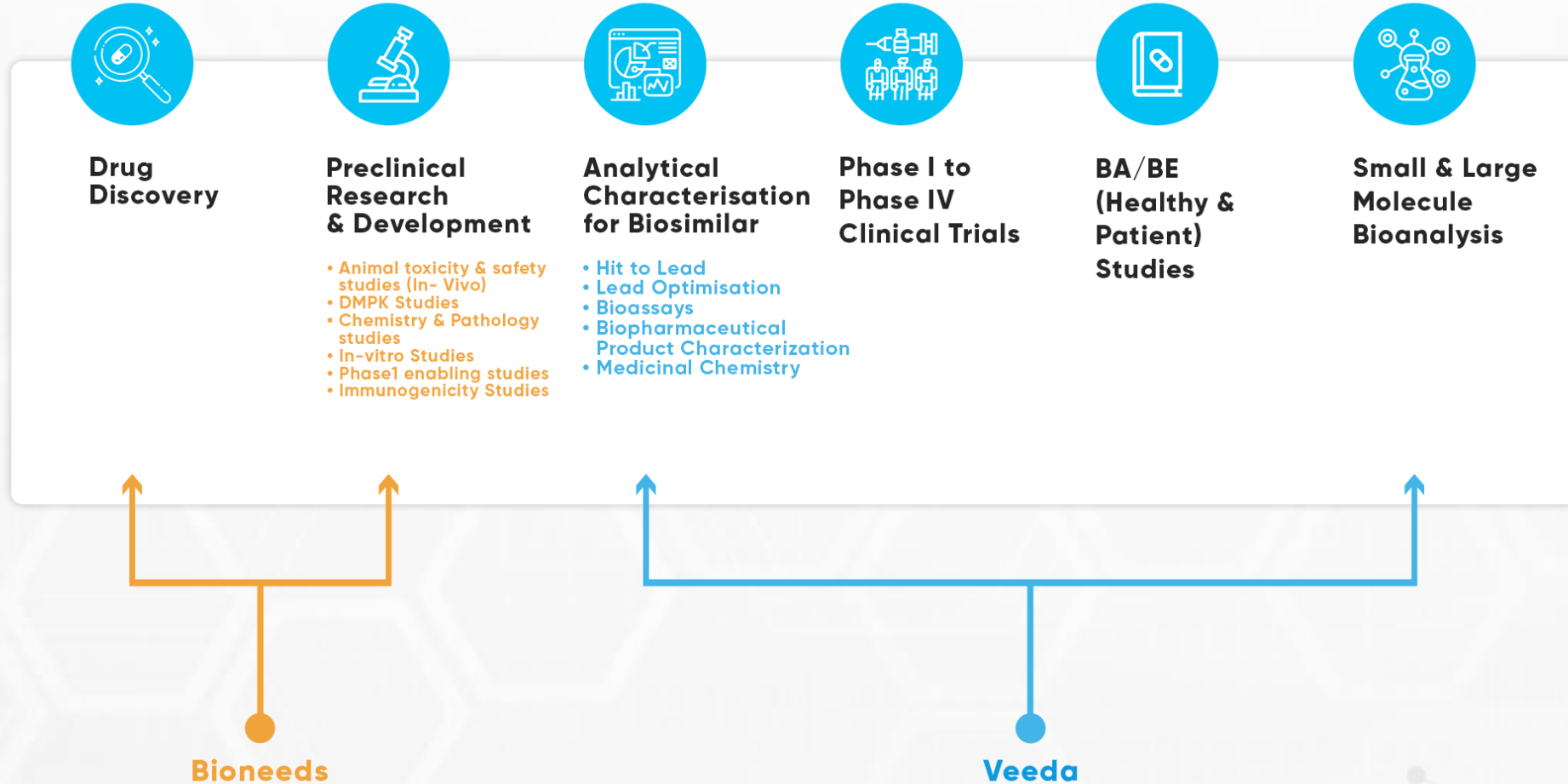
Integrity

Excellence

Collaboration

Nurturing
Individual Growth

Your Drug Development Journey



Executive Leadership

Dr. Kiran Marthak. M.D. F.C.C.P. T.D.D.

Director – Medical Affairs and Regulatory Affairs



Current Responsibility:

Director: Medical Affairs, Phase –I and Regulatory Affairs

Safety of the subjects, protocol designing, Business Development of NCEs and the Clinical Trials with NCEs

Liaison with Regulatory authorities

Profile Overview (Career and Education)

- Post graduate in Internal Medicine
- Fellow of Faculty of Pharmacology University of London, U.K.
- Fellow of American College of Clinical Pharmacology. Chairman of ISBEC- Ethics Committee
- Senior management positions in Novartis, Pfizer, GSK, Ranbaxy and Member of Board of Director in Lambda Therapeutic Research Ltd.
- Faculty in Academic Institutions, invited speakers in International and National conferences

Experience :

- Total Industrial experience of more than 40 years

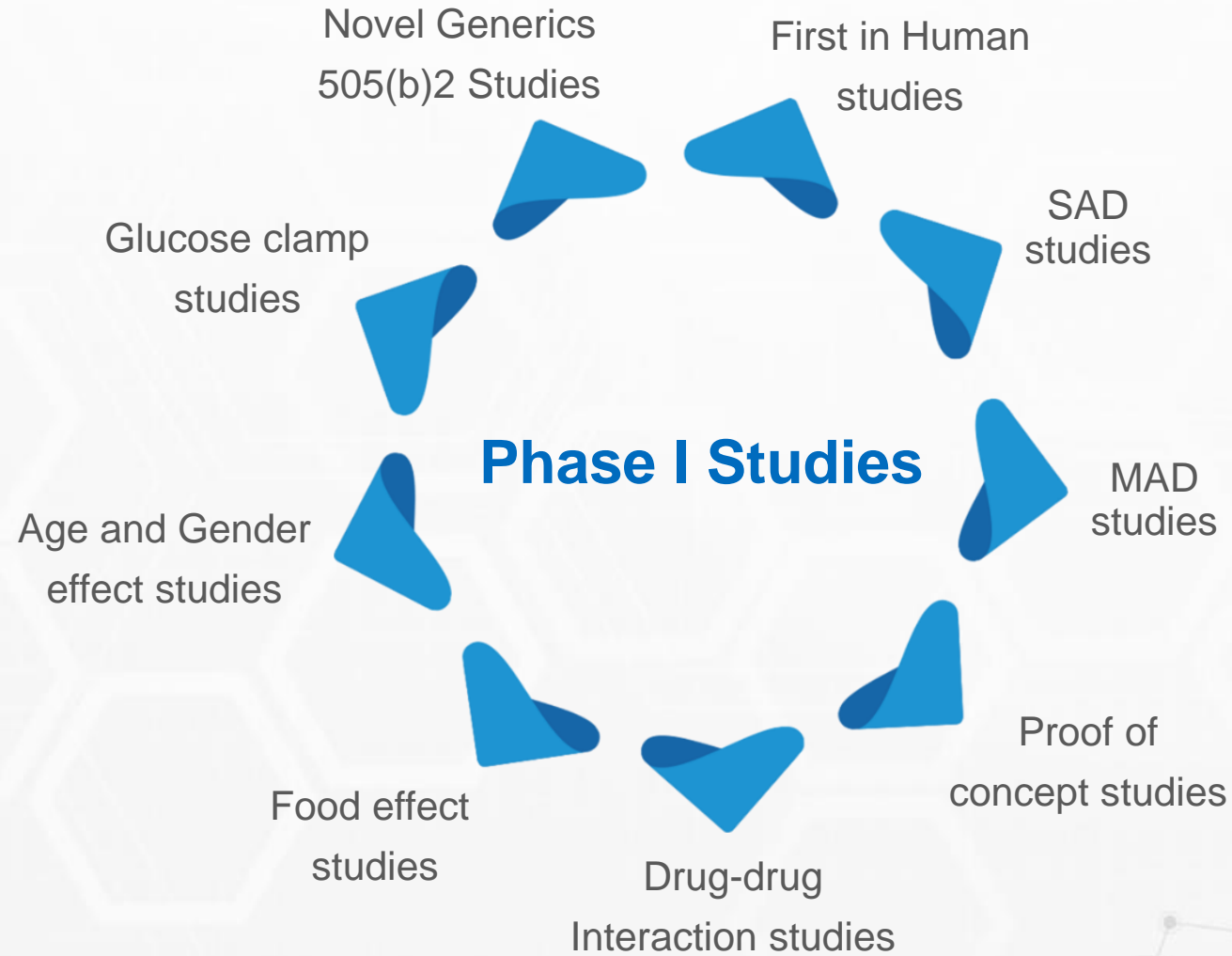
Special Areas of Expertise:

- Managed more than 25 Phase-1 studies, Expertise in dealing with Drug Discovery and Development, expertise in International Regulatory affairs mainly related to Drug Discovery programs.

Introduction

- A Phase 1 study is defined as a non-therapeutic, exploratory trial in human subjects who may be healthy or have a specific disease. In contrast to later phase studies, subjects can usually expect no therapeutic benefit from a Phase 1 trial.
- The primary parameters tested in Phase 1 studies (which can involve single or multiple doses of the IMP) are:
 - Safety and tolerability
 - Pharmacokinetics
 - Pharmacodynamics
 - Early measurement of drug activity

Phase I: Experience



Phase I: Experience

Type of Studies	No. of Studies
NAV	7
NAV+Patient	1
SAD Studies	6
MAD Studies	3
Safety and Immunogenicity study with Multiple-dose regime (with only one dose)	1
Drug Interaction Studies	3
Glucose Clamp Studies	1
Food Effect Studies	2
MD+Safety+Tolrability+PK+PD+Patients	1
Relative BA	1

Our Ongoing Patient Trials

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

Experience in First In Man Studies

Project No	Drug synopsis	No. of subjects	No. of Cohorts	Therapeutic Indication
09-VIN-199 (GKM-001)	ADV-1002401 oral solution-A First in Human, Placebo-Controlled, Randomized, Double Blind, Rising Single Dose Study of ADV 1002401 to Evaluate Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics in Healthy, Adult Volunteers and Adult Type II Diabetic Volunteers.	30	5	
10-VIN-232 (P3914/48/10)	P3914 Tablets, SAD study, Randomized, Double-blind, Placebo-controlled Phase I-Ib Study of P3914 to Evaluate the Safety, Tolerability, Food effect & Pharmacokinetics in Healthy Male Subject sand Efficacy & Safety of P3914 in Patients With Acute Dental Pain.	30	5	
CSSK-SMRX11 (12-VIN-073)	SMRX 11 Injection, SAD FIM -Open Label, Placebo- Controlled, Single Ascending Dose, Phase I Safety Study of SMRX 11 (Clot Specific Streptokinase) to Determine Pharmacokinetics and Tolerability in Healthy Male Subjects.	20	5	

Experience in Other Phase I Studies

Types of Phase I Studies	Primary Objective	Secondary Objective	Number of subjects	Therapeutic Indication
Glucose Clamp study: 1 study	PD/PK	Safety	12 (4 subjects/cohort)	
MAD (Multiple Ascending Dose): 4 studies: Type 2 Diabetes Mellitus 1 study: Hypertension	Safety and Tolerability	PK	T2DM: 88 subjects Hypertension: 14 subjects	
SAD (Single Ascending Dose): 1 study	Safety and Tolerability	PK	16 subjects	
Drug-drug Interaction: 2 studies	PK	Safety	12 subjects 12 subjects	
Food Effect studies on NCE molecule 2 studies: Type 2 Diabetes Mellitus 1 study: Hypertension	PK	Safety	T2DM: 72 subjects Hypertension: 15 subjects	
Proof of concept study	Efficacy/PK	Safety	16 (8 subjects/group)	
Administration of Vaccine	Safety	Immunogenicity, PK	24 subjects (3 cohorts)	

Ongoing and Forthcoming/Planned studies

- A Phase 1, double-blind, randomized, placebo-controlled, Parallel study to assess the safety, tolerability, and pharmacokinetics of single and multiple doses of MKP 10241 Suspension administered orally in healthy adult subjects. **(Antidiabetic drug)**
- A Randomized, Controlled, Phase-I Study to Evaluate Safety and Cumulative Skin Irritation Potential of Gel Under Occlusive Patch Conditions in Healthy Subjects **(xxxxxx drug)**
- A Phase 1, Open-label, Multiple-dose, Two-treatment, Three-period, Non-randomized Single Sequence, Steady State, Two-way Interaction Study Under Fasting Conditions to Evaluate the Pharmacokinetic Interactions Between HRF-10071 and Tenofovir alafenamide/Lamivudine. **(Antiretroviral drug)**
- A Phase 1, Open-label, Multiple-dose, Two-treatment, Three-period, Non-randomized Single Sequence, Steady State, Two-way Interaction Study Under Fasting Conditions to Evaluate the Pharmacokinetic Interactions Between HRF-10071 and Tenofovir alafenamide/ Emtricitabine. **(Antiretroviral drug)**
- A Phase 1, Open-label, Multiple-dose, Two-treatment, Three-period, Non-randomized Single Sequence, Steady State, Two-way Interaction Study Under Fasting Conditions to Evaluate the Pharmacokinetic Interactions Between HRF-10071 and Tenofovir alafenamide. **(Antiretroviral drug)**
- Open-label, non-randomized, no control, prospective clinical trial to assess Safety and Tolerability of DUVAC Cellular Vaccination Therapy in Advanced Pancreatic Cancer **(Oncology drug)**

Diverse Therapeutic Areas Of Expertise



Cardiology



Rheumatology



Dermatology



Ophthalmology



Gynecology



Gastroenterology



ENT



Oncology



Psychiatry



Respiratory



Endocrinology

Infrastructure

Clinical Infrastructure

- **VEDANT**

Clinical,
Bio-analytical facility

- **SATYAMEV CORPORATE PARK**

Corporate Office

- **SHIVALIK**

Dedicated Clinical facility

- **MEHSANA**

Clinical and
Screening facility

- **SKYLAR**

Common screening
facility for both Shivalik
and Vedant

- **INSIGNIA**

Dedicated
Bio-analytical facility

- **ARCHIVES**

Internal archival area in each facility.
Separate long term archival facility at
Changodar and Unjha

Spread across **16** clinics

Shivalik

170 Beds +

7 Special care beds +

12 Intensively monitored
beds to conduct Phase I
study

Vedant

226 Beds +

8 Special care beds +
18 Intensively monitored
beds to conduct Phase I
study



Mehsana

162 Beds +

7 Special care beds

Phase 1 - Infrastructure

- Total 30 bedded Phase-I capacity, spread across two units.
- Well developed **12 bedded Phase 1 unit** to support Phase 1 studies.
- Additional **18 bedded Phase 1 unit**; operational since February 2021.
- Team of scientists having **in-depth knowledge and experience** of handling Phase 1 studies.



Phase I Unit Infrastructure - Shivalik



PHASE I UNIT



PHASE I UNIT

Phase I Unit Infrastructure - Vedant



Phase 1 – Infrastructure (Equipment's)



MAC 2000 ECG Machine
ECG Recording



Infusion Pump
For continuous drug infusion



DASH® 4000 Monitor
For continuous cardiac monitoring (Vitals, ECG, O2 saturation etc.)



Heated Hand Boxes : Provides a realistic alternative which minimizes the difficulties inherent in venous sampling.

Healthy volunteer data base who have previously participated in studies; Healthy (more than 53,000), elderly (more than 3000), postmenopausal (more than 2000)

Phase 1 – Infrastructure (Equipment's)



YSI 2300 Glucose Analyser
Blood glucose measurement



Central Monitor
To observe centrally all DASH monitors



Syringe Driver
Use to gradually administer small amount of fluids (with or without medication) to a patient



**Oxygen Cylinder
Suction Machine
Crash Cart Trolley
Defibrillator**

Phase 1 - Infrastructure

Sample Processing

- Two Refrigerated Centrifuge
- Two -78° C Deep freezers (range -70° C to -86° C)
- Two -25° C Deep freezers (range -15° C to -30° C)
- One Pharmaceutical Refrigerator (range 20° C to 80° C)
- Weighing Balance
- Four Micropipettes & Two Multipipette
- Vortex Shaker
- Eurotherm temperature monitoring system

Pathology Services

- **Primary** : Supratech Micropath pathology laboratory.
- **Back up Lab**: I-genetics pathology laboratory NABL accredited.
 - CAP accredited
 - Barcode generation
 - Software –Audit trail
 - Monthly back up to Veeda

Pharmacy Area, IP Storage

- Pharmacy (Local FDA approved)
- 2 humidity chamber
- 2 walk in stability chamber
- 3 Pharmaceutical refrigerator
- 1 Air paLaminar
- 1 Analytical balance

IRB –Sangini Hospital EC (SHEC)

- Constituted since 05 years (in 2012)
- Registered at DCG(I)
- Registered at DHHS (Department of Health and Human Services) and OHRP (Office for Human Research Protections)
- Highly qualified and experienced members

Phase 1 - Subject Safety

In case of shifting the volunteers to the higher centre, an ambulance with basic emergency medicine and equipment's is readily available.

Facility has all-in-one resuscitation establishment such as Resuscitation Trolley, having all necessary medicines and equipment which can be moved at any area of the clinic to handle medical emergency.

Well equipped and maintained special care area

In-house ambulance

Stature lift

Special set up

Fire and chemical hazard systems

To handle medical emergency there is provisions of cardiac monitor, defibrillator, ECG machine, suction machine, oxygen cylinder and handy kits like Cardiac Arrest Kit and Anaphylaxis Kit.

To rapidly shift volunteer to the ambulance, proper stature lift with generator back up is available.

Facility has proper equipment's and SOP to overcome any fire or chemical hazards as it can indirectly affect volunteer safety.

Safety Team and Safety aspects

- Qualified, educated and trained study staff
- ACLS, BLS trained Investigators, Clinical Research physician and Nursing staff
- Ambulance and driver 24 hr. available
- Stature lift and Special set up
- Designated Resuscitation officer
- More than 150 + active sites currently for late phase studies
- BLS trained Phlebotomist, Clinical custodian, security and Clinical Quality Monitor team
- Well equipped Special Care to handle the emergency
- Regular mock-drill
- Tertiary care contract with sterling hospital

Volunteer Database

- **Complex studies:**
 - Cotinine free studies
 - High number of ambulatory samples
 - Long Washout periods
- **FTF studies**
- **Intensive Safety Monitoring**

Volunteer Database (More than 81,881)

Male Volunteers	>60,677
Female Volunteers	>5,388
Elderly Males	>12,363
Post - Menopausal Females	>3,453

Routes of administration

20 different dosage forms

- Inhalation
- Transdermal Patches
- Rectal/Vaginal suppositories
- Orals
- Glucose clamps
- LAIs

Experience

Capabilities

Total available Bioanalytical methods are more than 1185

975 + 20

Generics +
Pharmacodynamics/
Immunogenicity

103

Complex
Generics

87

NCEs

Salient Features

- Average processing capacity of 1,00,000 samples per month
- Central Bioanalytical Laboratory for global Phase II/ Phase III trials

Types of Methods

- Capability to develop methods with lowest quantification level- up to 0.1 pg
- Methods developed for:
 - Endogenous molecules
 - Amino Acids (Multiple analysis in single injection)
 - Hormones
 - Steroids
 - Inhalation formulation
 - Elemental Bioanalysis (Other matrix- Urine)
 - Immunogenicity
 - Large molecules/ECLIA/ELISA
 - Chiral and Liposomal
- Tissue distribution studies.

Veeda's Vaccine Study Experience

Vaccine Study (Covid)

- A randomized, double-blinded, placebo-controlled, parallel-group, multi-centre, adaptive, seamless bridging study followed by a phase II/III study to assess the safety and immunogenicity of Anti-COVID-19 AKS-452 vaccine for SARS-Cov-2 infection in Indian healthy subjects.
- Phase: Bridging phase II/III study
- No of Subject: 100 (Bridging) 1500 (Phase II/III study)
- Sites: 12 centres

Vaccine Study (Polio)

- Open Label Phase 1 Clinical Study for Evaluation of Safety and Immunogenicity of Sabin based Inactivated Polio Vaccine in Healthy Adult Human Male Subjects
- No. of subjects- 3

Complex Methods Experience

- **Iron Sucrose:** For Transferrin bound iron the serum samples are filtered through SPE cartridges to remove free and formulation bound iron while the filtrate contains TBI which is further analyzed by ICP OES.
- **Peptides (small molecules) by LCMSMS:** sensitivity and extraction issues
 - Desmopressin
 - Leuprolide
 - Octreotide
- **Biomarker analysis - α 1 Acid Glycoprotein – AAG:** Method HPLC-UV, large molecule (biomarker) validated method for clinical support.

Recognitions



Recognitions

Celebrating
19 YEARS
of excellence in Clinical Research

Organization	Award Category
	Best Clinical Research Organization - India
	Clinical Trial Company of the Year
	Bharat Udhog Ratan Award in Clinical Research

Organization	Award Category
	Top CLRO Company
	Best Quality Clinical Research Services in India



Organization	Award Category
	National Excellence Award
	Best Pharmaceutical CRO
Health & Safety Awards	Best Clinical Research- India
	Best Clinical Research- India
	Mark of Excellence
	Indian Clinical Research company of the year

Organization	Award Category
	Best Quality Clinical Research Organization in India
	Best Quality Clinical Research Organization in India
	Indian Clinical Research company of the year

Organization	Award Category
 Excellence in Science & BRINGING TECHNOLOGY. ENABLING SCIENCE.	MS Excellence in BABE Services, Largest Indian CRO

Veeda Group Advantage

Extensive Scientific
Competence to service a
Diverse client base

One of the largest
Independent Full
Service CROs in India

High Customer
Centricity and
Satisfaction

Robust Quality &
Regulatory
Compliance

Skilled personnel with
focus on Continuous
Professional
Development

One stop solution
for complex studies

Partners in creating a healthier tomorrow

Thank You

Partners in creating
a healthier tomorrow

Visit us at www.veedacr.com

