Partners in creating a healthier tomorrow

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Corporate Overview

Veeda Group

- Veeda Clinical Research Limited (“Veeda”) together with its subsidiary, Bioneeds India Private Limited (“Bioneeds”), and its joint venture, Ingenuity Biosciences Private Limited (“Ingenuity”), (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

Current Geographical Presence

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

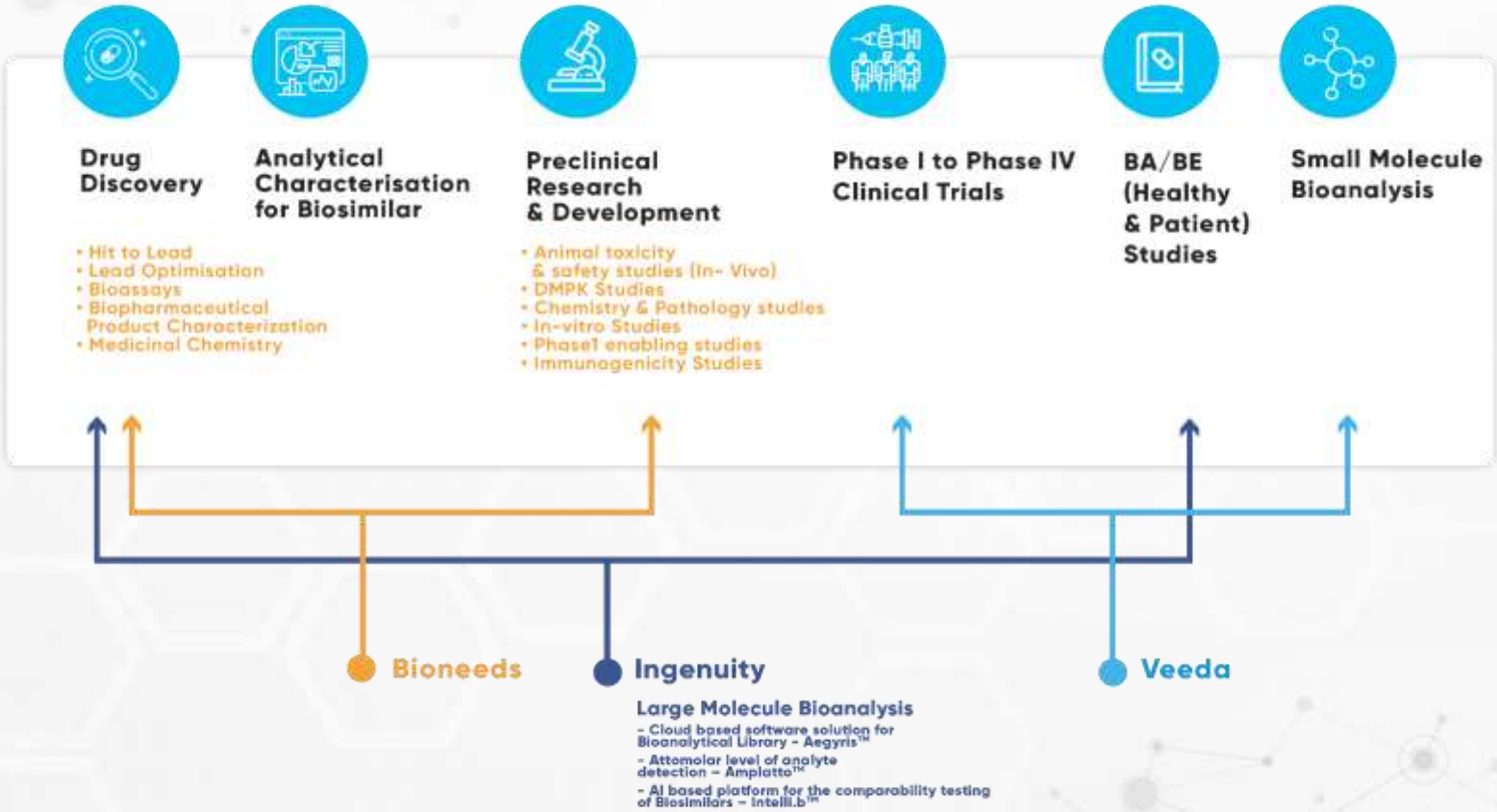
Integrity

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.

Mr. Manoj Shukla,

Head of Bioavailability & Bioequivalence

Current Responsibility

- Head of Bioavailability & Bioequivalence Department
- He is responsible for the overall operations of our BA/BE clinical research facilities, project management, and regulatory functions.

Profile Overview (Career and Education)

- Manoj Shukla has completed a Master in science, Master in Instrumentation and chemical analysis (MICA) from Jiwaji University – Gwalior.
- Before Veeda he has been part of Panexcell as Vice president of operation where he devised, deployed, and monitored processes to boost long-term business success. Before that, he was Head of bioanalytical in Lambda Therapeutic Research Ahmedabad India and Toronto, Canada.

Special Areas of Expertise:

- Excellent reputation for resolving problems, improving customer satisfaction, and driving overall operational improvements.Manoj Shukla has a unique set of knowledge and skills which includes an in-depth understanding of business processes and operational management at the floor and strategic level.
- He is Biopharmaceutical & bioanalytical & Clinical research management expert. He has successfully, led many regulatory inspections: USFDA, WHO, EMEA ANVISA, NPRA, MHRA, DCGI, CAP, NABL, GLP (Thailand), GLP (OECD) & Clients (300+).
- He has numerous international publications and presented scientific posters at global conferences.

Experience:

- Manoj Shukla has over 20 years of experience in Clinical research in CRO and Pharmaceutical.

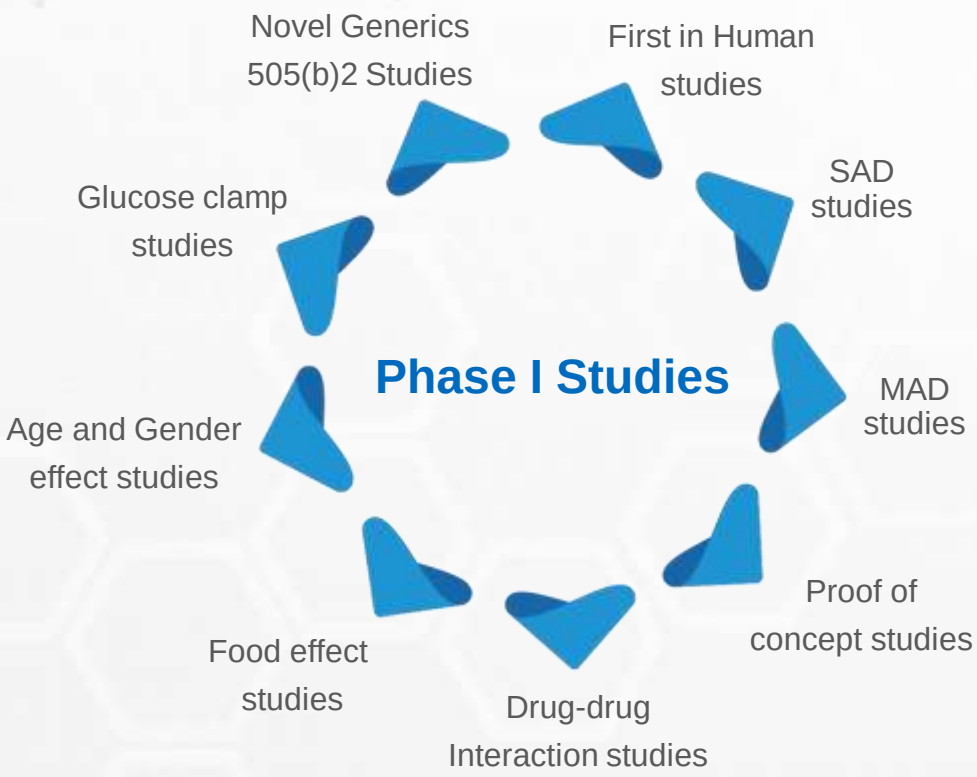
Introduction

- 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



Studies Summary

No. of studies conducted	17
No. of studies ongoing	01
No. of studies planned	05

Phase I: Experience

Type of Studies	No. of Studies
First-in-Human (FIH)	3
SAD Studies	1
MAD Studies	5
Phase 1 Vaccine Study	1
Drug Interaction Studies	2
Glucose Clamp Studies	1
Food Effect Studies	3
Proof-of-Concept Study	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
- **MAGNET CORPORATE PARK**
  Administrative 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 14 clinics

Shivalik

170 Beds +
7 Special care beds +
12 Intensively monitored beds to conduct Phase I study

Vedant

226 Beds +
6 Special care beds +
18 Intensively monitored beds to conduct Phase I study

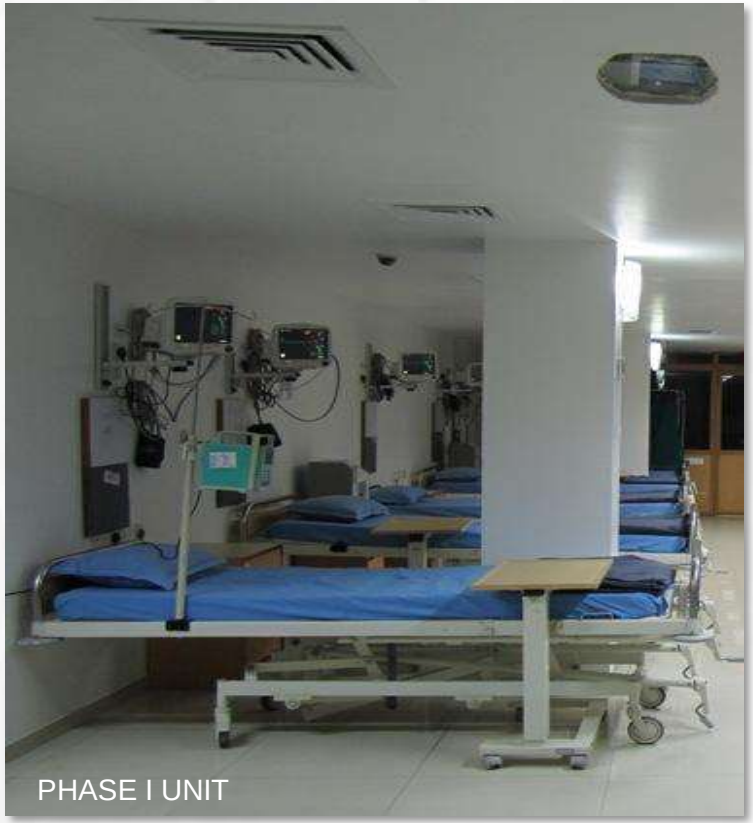
Mehsana

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 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 -78º C Deep freezers (range -70º C to -86º C)
- Two -25º C Deep freezers (range -15º C to -30º C)
- One Pharmaceutical Refrigerator (range 20º C to 80º 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 pacLaminar
- 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

Well equipped and maintained special care area

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.

In-house ambulance

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

Stature lift

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

Special set up

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.

Fire and chemical hazard systems

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

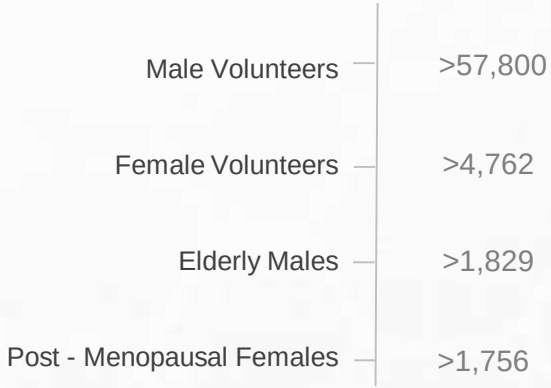
Safety Team and Safety aspects

- 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 66,147)



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 1040

875 + 20	Generics + Pharmacodynamics/ Immunogenicity
85	Complex Generics
69	NCEs
7	Large Molecule Assays

Salient Features

- 46 LC-MS/MS machines
- Average processing capacity of 1,00,000 samples per month
- Central Bioanalytical Laboratory for global Phase II/ Phase III trials
- 45 Deep freezers with capacity to store 11,25,000 samples at -80 ℃

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 centers

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 - α1 Acid Glycoprotein – AAG:** Method HPLC-UV, large molecule (biomarker) validated method for clinical support.

Recognitions

Celebrating
17 YEARS
of excellence in
Clinical Research

2004

2017

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

2018

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

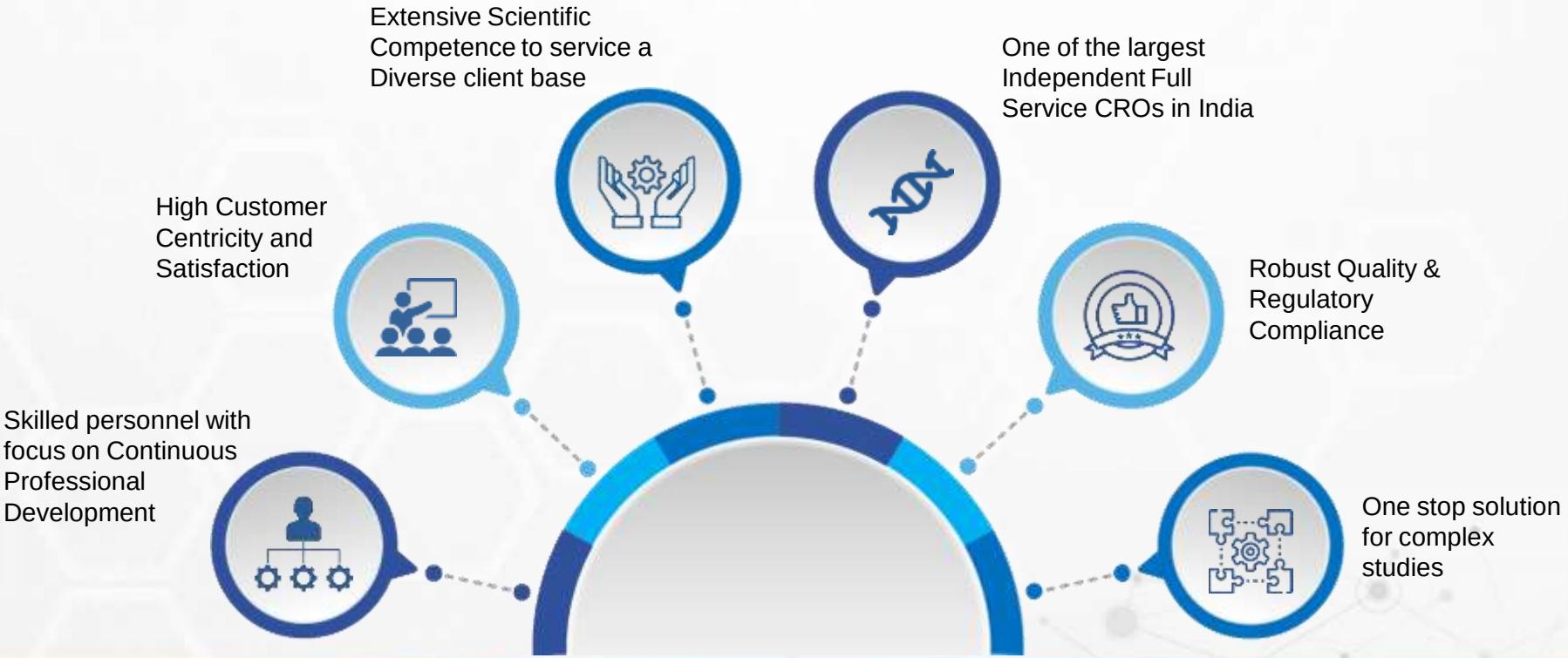
2019

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

2020

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

Veeda Group Advantage



THANK YOU

For any further assistance kindly write to us at **info@veedacr.com**
Visit us at **www.veedacr.com**

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