BIONEEDS

Table Of Contents

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

Veeda's Current Geographical Presence

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

Drug Development Services Overview

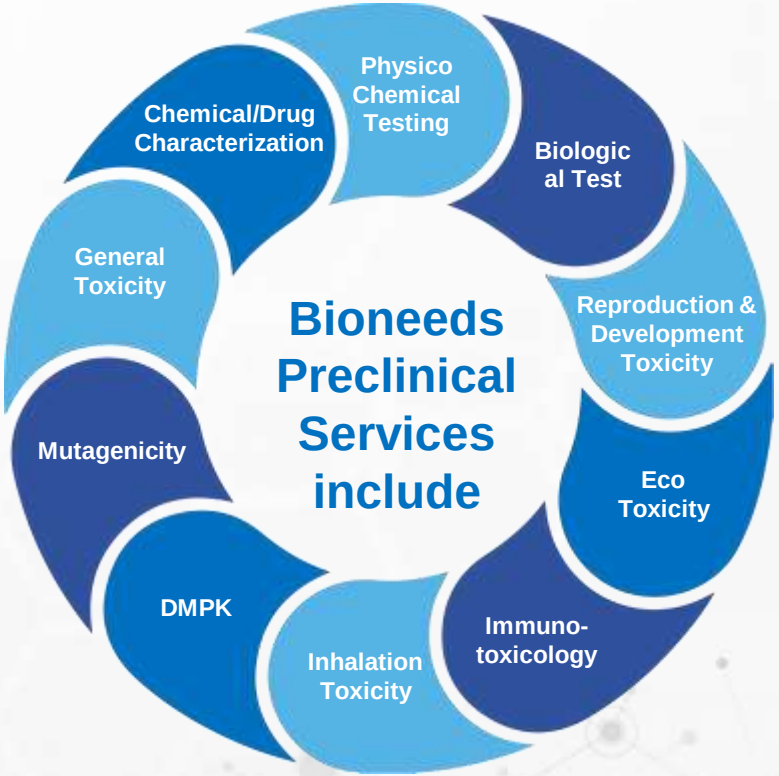
Your Drug Development Journey

Preclinical Research & Development

Bioneeds

A Bangalore based Preclinical Contract Research Organization providing Integrated Discovery, Development and Regulatory Services for more than 12 years

- A trusted Preclinical CRO providing comprehensive services for Pharma, Biopharma, Medical devices & Agrochemicals
- Bioneeds has successfully delivered 300+ impurity qualification package studies & has experience in 8000+ GLP Studies
- Team of 300; 80% M.Sc; M.Pharm; M.VSc; 13% PhD, 2 DABT, 3 Veterinary pathologists(board certified); 50 + experienced study directors
- Global client base of 410+ spanning from big pharma, small biotech's to research / academic institutions



Accreditations & Certifications:

- GLP certified test facility and Accredited by the AAALAC International
- ISO 17025 accredited by the NABL (National Accreditation Board for testing and calibration laboratories)
- Research and Development (R&D) unit recognized by Department of Scientific and Industrial Research (DSIR)
- CPCSEA Registered - Committee for the purpose of control, and supervision of experiments on animals (CPCSEA), ministry of environment, forests, and climate change, GOI

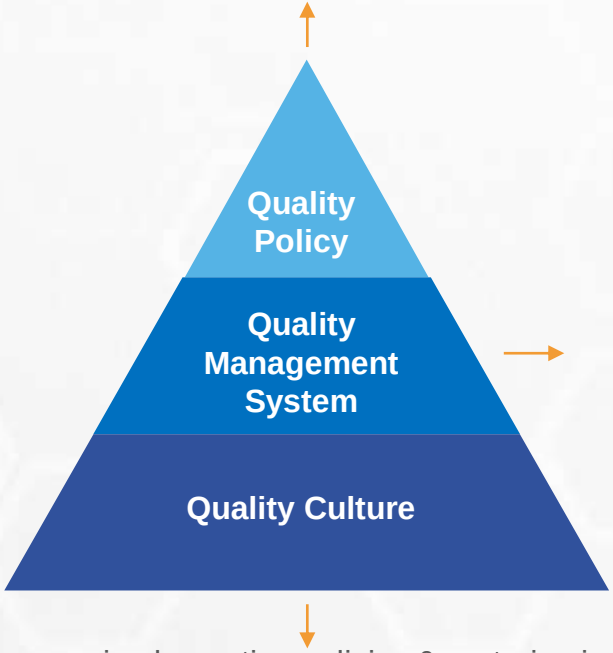
Infrastructure

Vivarium with 85 exclusive animal rooms built as per international standards Cutting edge drug and development labs to support biology, in vivo pharmacology, pharmacokinetics, toxicology, medicinal chemistry, custom synthesis, process R&D, cGMP manufacturing, formulation and analytical development support services.

Best-in-class infrastructure in a 2,00,000 Sq. ft. built-up area equipped with state-of-the-art facilities	Well-equipped In vitro cell culture and microbiology laboratory
Also, synthetic chemistry and BioPharma laboratories are housed in our Peenya facility spanning about 50,000 Sq. ft area.	World class Inhalation units to support toxicology studies

Quality Framework

"Our management is committed to continuous improvement in the effectiveness of our Quality culture, to providing quality research solutions that meet sponsor and regulatory requirements and to protecting the rights, safety and well being of the study volunteers"



- Comprehensive system with more than 350 SOPs
- QC & QA monitoring
- Monthly Quality Review Meetings
- CAPA Management

Focus on implementing policies & nurturing individual behavior to sustain our culture of quality

Balanced Score Cards (BSC) for augmenting corporate strategy

Quantifiable Performance Metrics for all departments

Individual KPI's & KRA's linked to BSC

Continuous process improvement

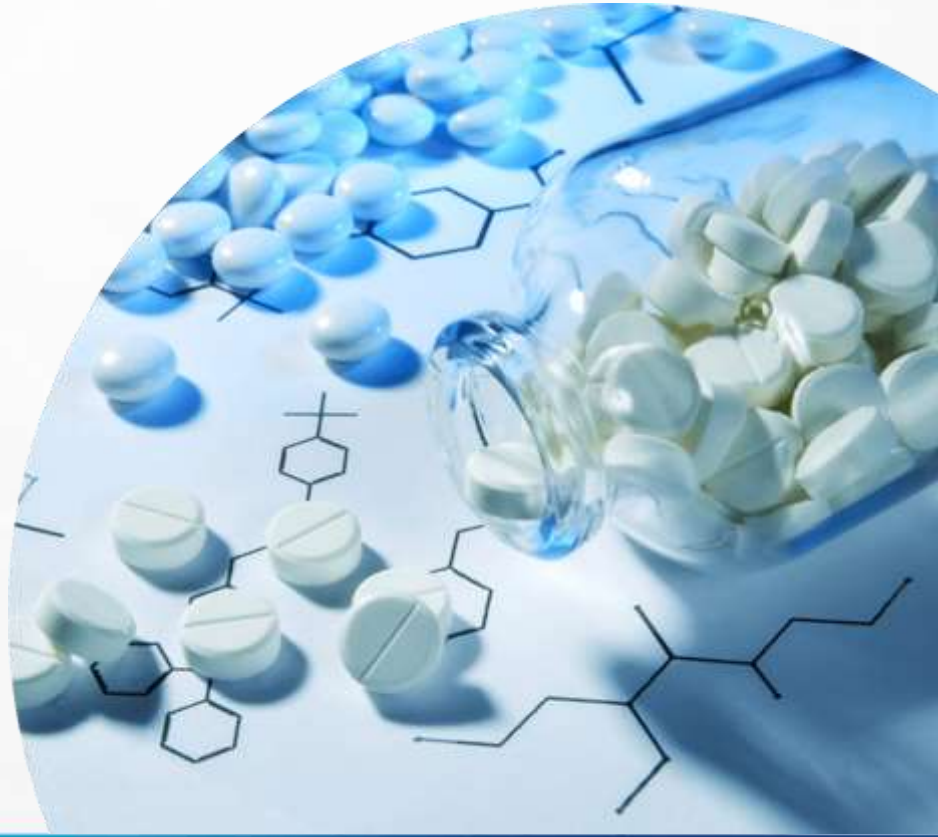
Regulatory Credentials

- 79 successful regulatory audits till date
- 09 successful regulatory audits in last 24 months

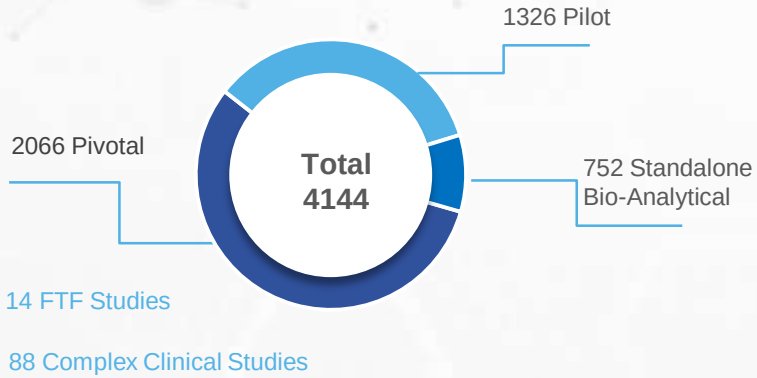
US FDA	→	37*	ANSM	→	1
MHRA	→	3	AGES	→	1
ANVISA	→	08	MCC	→	1
WHO	→	5	DCGI	→	18
NPRA Malaysia	→	5			

**FDA : 17 AUDITS FOR PATIENT BASED STUDIES*
20 AUDITS FOR HEALTHY SUBJECTS STUDIES

Bioavailability &
Bioequivalence Studies



Experience



57 Special Studies

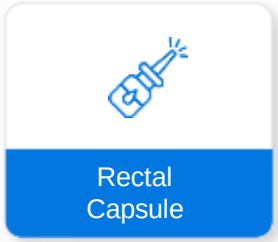
*Both Pilot and Pivotal BA/BE

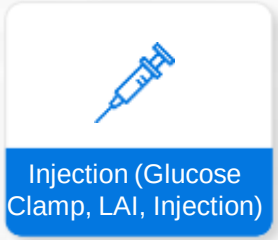
- 13 Glucose Clamps studies (810 clamps)
- 28 Inhalation Studies
- 6 Suppositories
- 10 Patches Studies
- 26 Phase – I Studies
  1 Phase – II Study

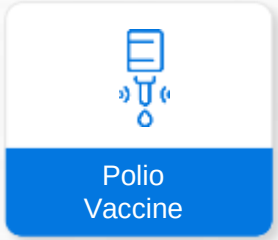
Volunteer Database (More than 72,123)

Male Volunteers	–	> 54,751
Female Volunteers	–	> 4,246
Elderly Males	–	> 10,066
Post - Menopausal Females	–	> 3,060

Routes of Administration







Different Formulations

- Tablets
- Capsule
- Oral Suspension
- Oro-Dispersible Tablet (ODT)
- Powder for oral suspension / Solution
- Oral Granules
- Orally Disintegrating strip (OD Strip)
- Oral Sachet
- Oral Solution
- Oral Powder
- Topical Product
- Syrup

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

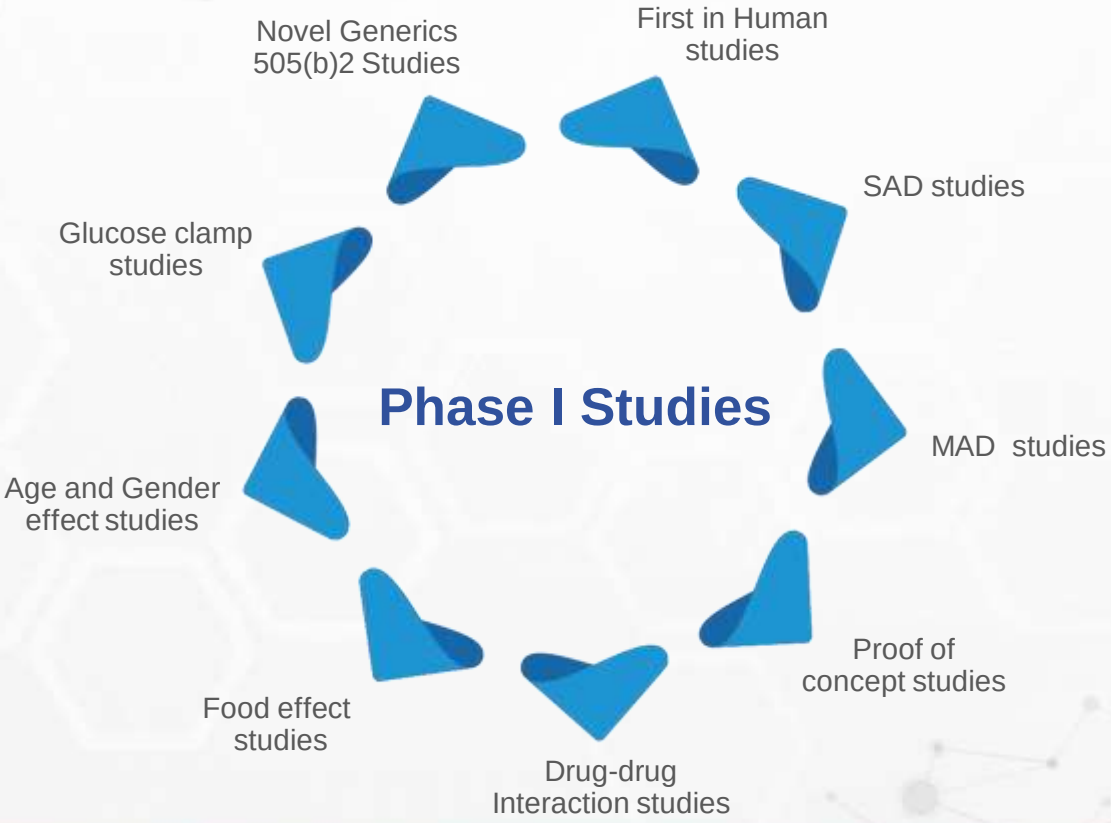
Mehsana

162 Beds +
7 Special care beds

Early to Late Phase Clinical Trials

Partners in creating a healthier tomorrow

Phase I Trial Experience



Therapeutic Areas Of Expertise

- Cardiology
- Rheumatology
- Dermatology
- Ophthalmology
- Gynecology
- Gastroenterology
- ENT
- Oncology
- Psychiatry
- Respiratory
- Endocrinology

Clinical Trial Services

Veeda Clinical Trial Experience

Veeda's Clinical End Point Studies Experience			
Therapeutic area	**Completed Studies**	**Ongoing Studies**	**Study Phase**
Oncology	6	1	Phase 1, Phase2
Orthopaedic	3		Phase 3
Ophthalmology	1	1	Bioequivalence Clinical End Point

Veeda's PK End Point Studies Experience		
Therapeutic area	**Completed Studies**	**Ongoing Studies**
Antiviral	1	
Covid		1
Haematology		1
Oncology	19	5
Psychiatry	9	1
Rheumatology	2	

Vaccine Study (Covid)

- Phase 1 ongoing
- Followed by Phase II/Phase III

Covid mild to moderate patient anti-viral drug study

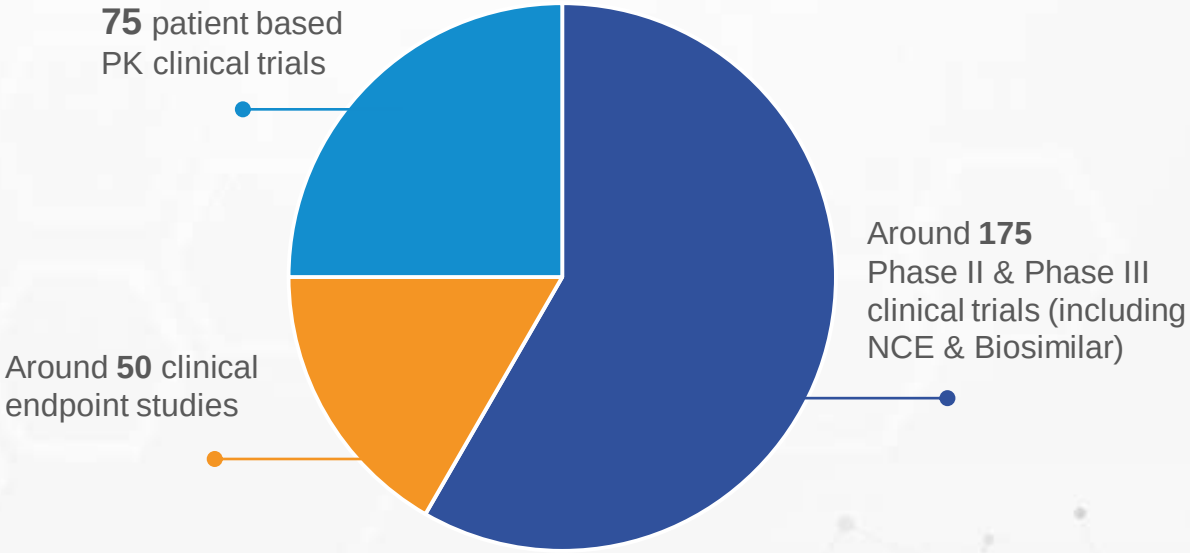
- Phase 2 trial
- SEC Meeting Completed, waiting for DCGI Approval

Veeda's Investigator & Sites Database

Therapeutic Area	Investigators Database	No. of sites associated with Veeda
Oncology	150 Oncologists	90 sites
Psychiatry	90 Psychiatrists	35 sites
Orthopedics and Rhuematology	72 Orthopedics and Rheumatologists	25 sites
Infectious Disease	79 MD Physicians	25 sites
Dermatology	87 Dermatologists	40 sites
Cardiology	20 Cardiologists	35 sites
Opthalmology	90 Ophthalmologists	40 sites
Urologist	27 Urologists	12 sites
Nephrology	66 Nephrologists	15 sites
Pulmonology	80 Pulmonologists	40 sites
Gastroenterology	45 Gastroenterologists	10 sites
Endocrinology	38 Endocrinologists	20 sites
Hematology	16 Hematologists	15 sites
ENT	35 ENT Specialists	10 sites
Gynaecology-Obs	70 Gynecologists	20 sites

Combined Team Experience in Clinical Trials

More than **300** clinical trials that includes



Bioanalytical Research

Infrastructure

Scale and Range

- **49 LC-MS/MS** machines
  - Insignia (33) and Vedant (16)
  - API 6500/5500/4000/3200/3000/2000
  - Shimadzu 8060/8050/8040
  - Quattro Premier
- **2 ICP-OES**
- **Watson LIMS**
- **BSL-2 Laboratory**

Storage Capacity

Plasma Sample:

- 40 Deep freezers of -80˚C (1 M samples capacity) and 11 Deep freezers of -20˚C (0.15 M samples capacity)
- 01 Cold Room -20C (0.3 M samples capacity)

IP Storage:

- 3 Walking type stability chambers with overall capacity to store 34000 Ltr for retention at room temperature
- 4 Humidity chambers with overall capacity of 3200 Ltr
- 4 Pharmaceutical refrigerators having storage capacity of 3550 Ltr at 2-8 ℃

Experience

Capabilities

Total available Bioanalytical methods are more than 1096

923 + 20	Generics + Pharmacodynamics/ Immunogenicity	95	Complex Generics
76	NCEs	6	Large Molecule Assays

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.

Central Bioanalytical Lab Services

Dedicated team for Central Lab Services

- Project Manager
- Sample management team (BRD custodians)
- Kits & Logistics coordinator
- Analytical Team (PK analysis – based on projects)
- Watson Team

Central Bioanalytical Lab Experience

1. Multicenter study (which involved more than 35 sites (150 subjects, 10 Analytes)

- Required screening sample analysis within 10 days from sample collection
- Estimated 10 analytes for this study- Total 4 bio-analytical methods
- Provided sample collection kits to all sites- within stipulated time

2. Sponsor- Global Pharmaceutical company

- Type of studies : NCE (Multisite)
- Total studies : More than 40 studies ongoing (from Multisites globally, 20000 samples per year)
- Services provided: Sample management, method development, method validation and analysis of NCEs
- Sample receipt to analysis within 5 days
- Sponsor specific reports with e-CTD
- More than 64 methods developed and validated for NCEs
- Exploratory studies, e.g. skin tissues , plasma protein binding experiment, chiral impurity estimation in the sample

Large Molecules Bioanalysis

Ingenuity Biosciences

- Joint venture between Veeda Clinical Research and Somru BioScience, Canada offering niche services
  - Pharmacokinetics
  - Immunogenicity
  - Biosimilar Characterization
  - Biomarkers
  - Neutralizing Antibodies
  - BioNMR

- Ingenuity's capabilities include state-of-the-art technology platforms needed for performing advanced analytical assays for various Biosimilar products

  - Multimode plate reader (UV, Fluroscence and Luminiscence), plate washer, LC-MS/MS
  - Access to advanced Biological NMR capabilities
  - Proprietary Aegyris™: A software suite that is highly specialized and advanced to perform method validation and statistical analysis
  - Intelli.b™ (AI based) : A platform for Next Gen Biosimilar "Fingerprinting" service, utilizing proprietary curated database of over 2000 antibodies
  - Amplatto™ immunoassay platform offers: Attomolar detection, Low background & improved precision and Improved quantitative accuracy

Vaccine Studies Experience

Our ongoing vaccine studies

IgG Titer Studies-

- IgG Titre Clinical studies involve the measurement of human anti-SP/RBD IgG titers in human serum samples
- RBD Specific target
- Method optimization and Validation, followed by clinical studies

ELISPOT Studies-

- The enzyme-linked immunospot [ELISPOT] assay is a highly sensitive immunoassay that measures the frequency of cytokine-secreting cells at the single-cell
- Expertise in PBMC isolation and culturing
- State-of-the-art infrastructure for ELISPOT assays

PRNT Studies [Outsourced lab]-

- Measures the levels of Neutralizing antibodies in an individual against SARS-CoV-2
- BSL3- Facility and scientific liaison between the client and the lab performing PRNT assay

Large Molecules Bioanalytical Experience

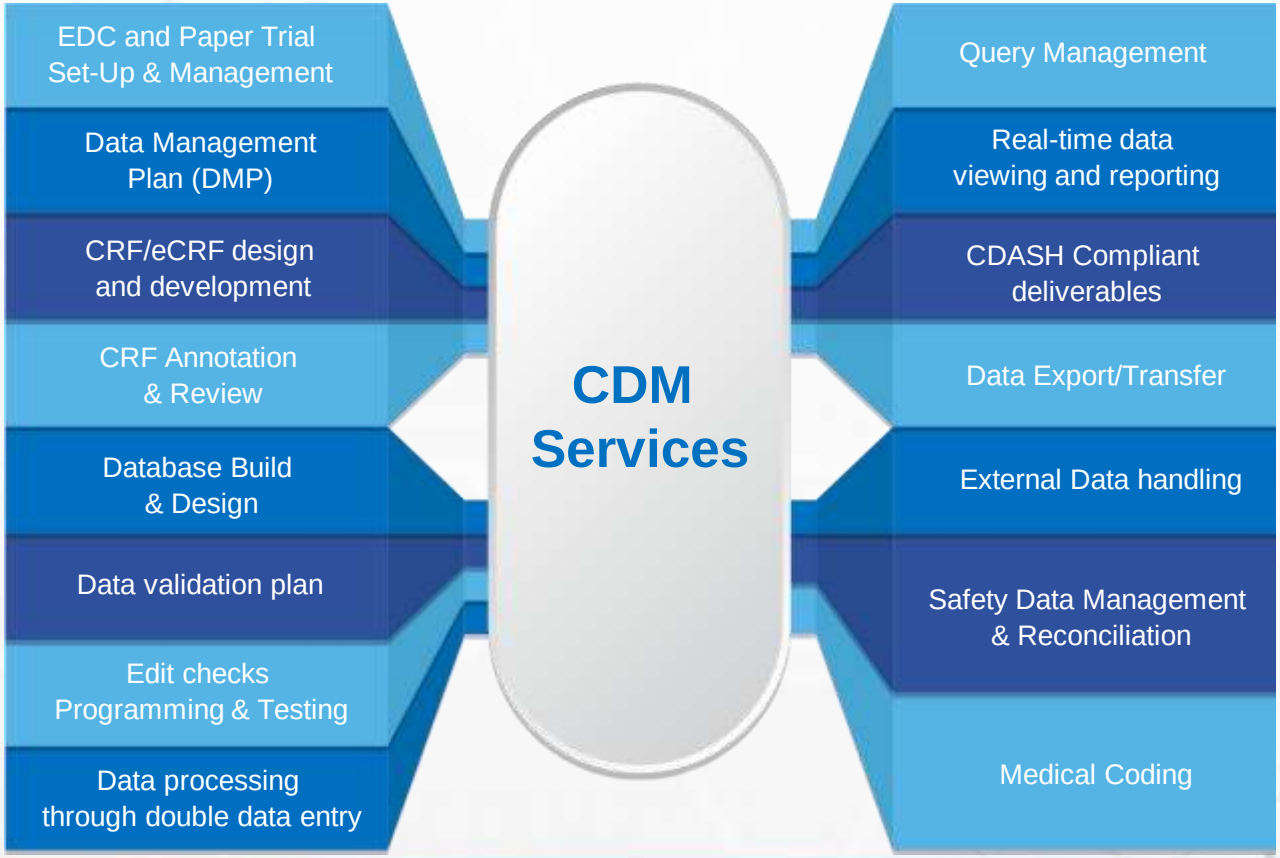
- Recently developed and validated below large molecules as per current EMEA guidance using commercially available kits by ELISA technique
    - Insulin Aspart and C peptide
    - Filgrastim
    - PTH (Teriparatide)
    - Denosumab
    - Romiplostim

- Enoxaparin: PD endpoint and Immunogenicity for FDA, EU and ANVISA submission
- Pipeline Project: Cetuximab

Sr. No.	Analyte	No. of samples analyzed	No. of samples analyzed for ISR	% of ISR samples within acceptance
1	G-CSF	2142	158	98.70%
2	Insulin Aspart	2139	158	94.90%
3	C- Peptide	2400	176	98.20%
4	PTH	340	34	88.33%

Biopharmaceutics & Data Science

Clinical Data Management Services



Biostatistics Capabilities

Key Strengths

Quick setup

Reconciliation and oversight

Timely Database lock

Periodic tracking

- Our team has experience in various statistical evaluations for
  - Design of experiment (DoE)
  - In-vitro population bioequivalence (PBE)
  - In-vitro equilibrium binding
  - Kinetic binding studies
  - Dose proportionality studies
  - Pharmacodynamics end point studies

- Our team also has expertise in the prediction and simulation analysis

Recognitions

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

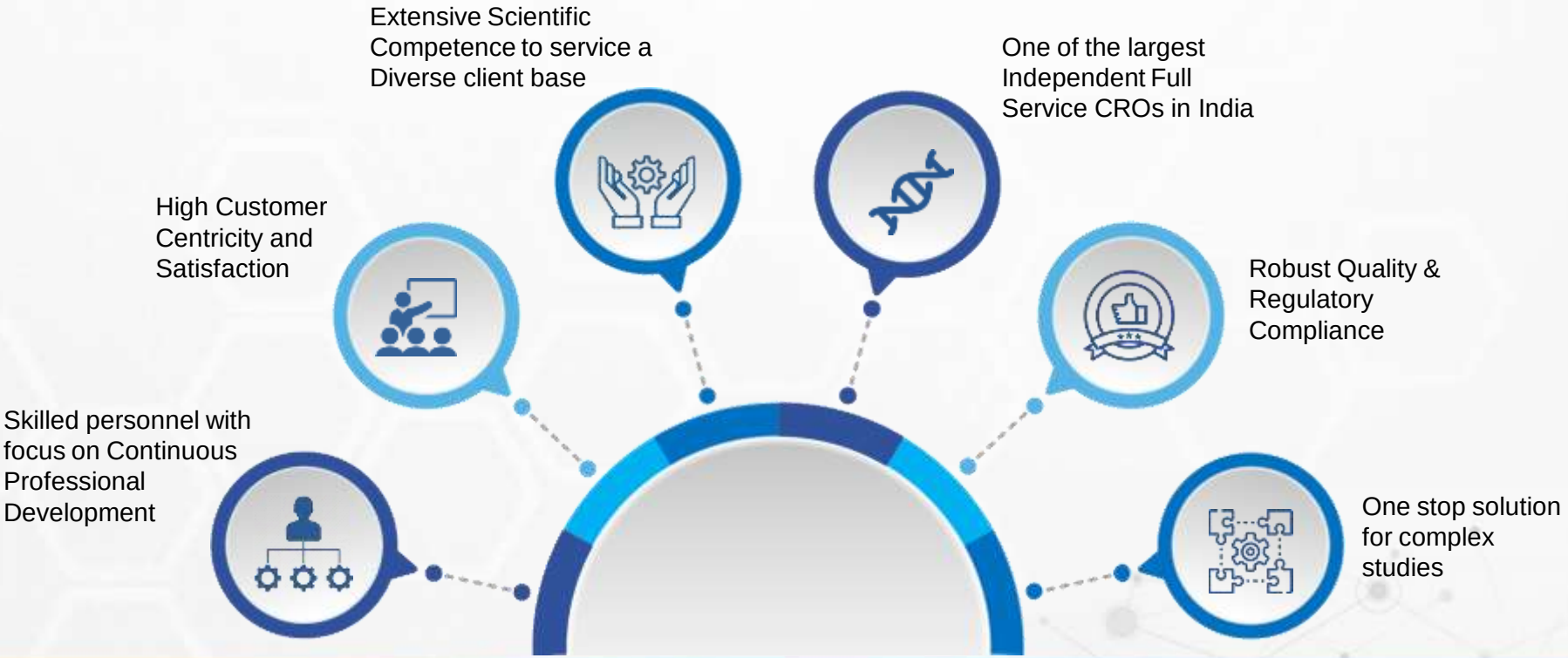
2019

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**

Partners in creating
a healthier tomorrow