BIONEEDS

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Corporate Overview

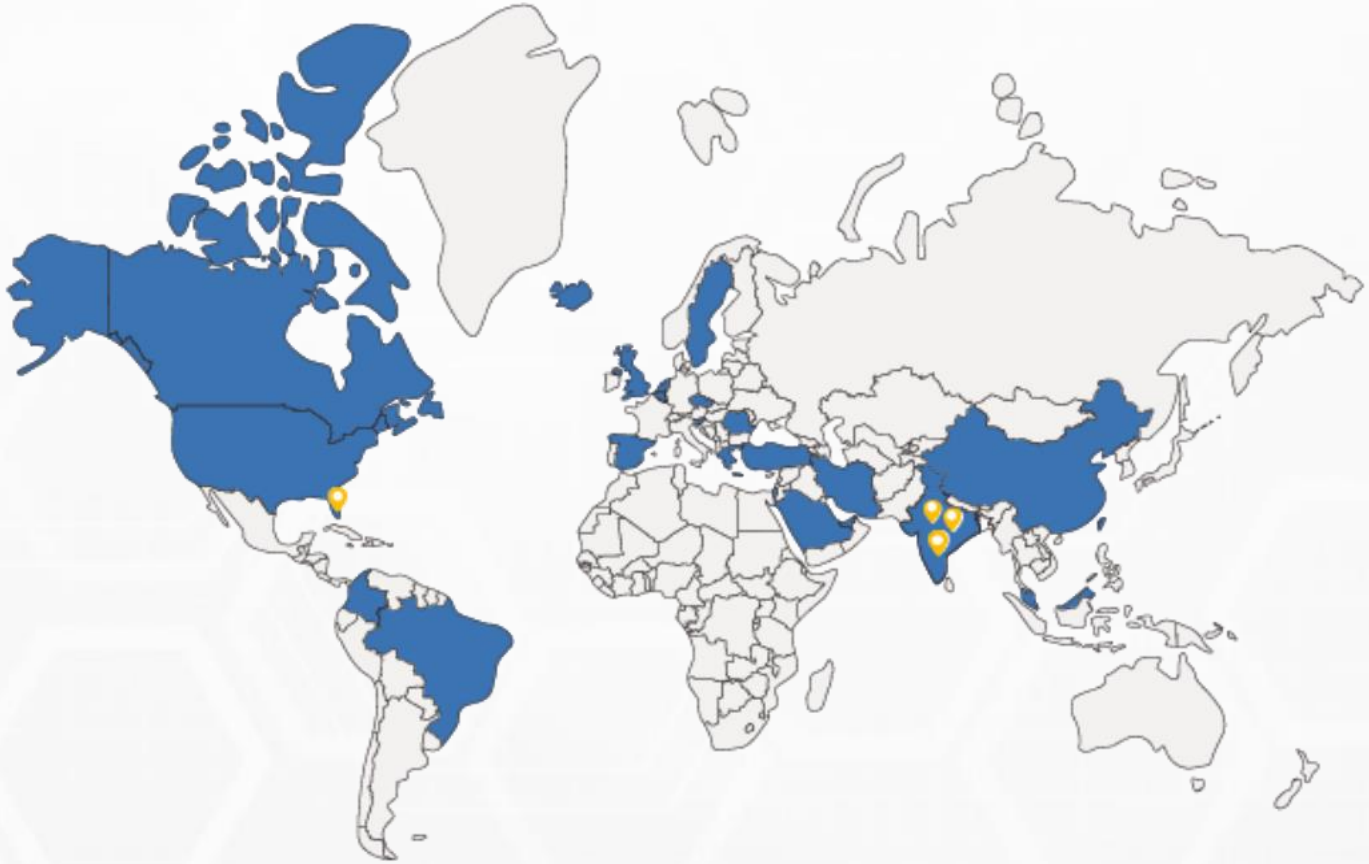
Veeda Group

- Veeda Clinical Research Limited (“Veeda”) together with its subsidiary, Bioneeds India Private Limited (“Bioneeds”), (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

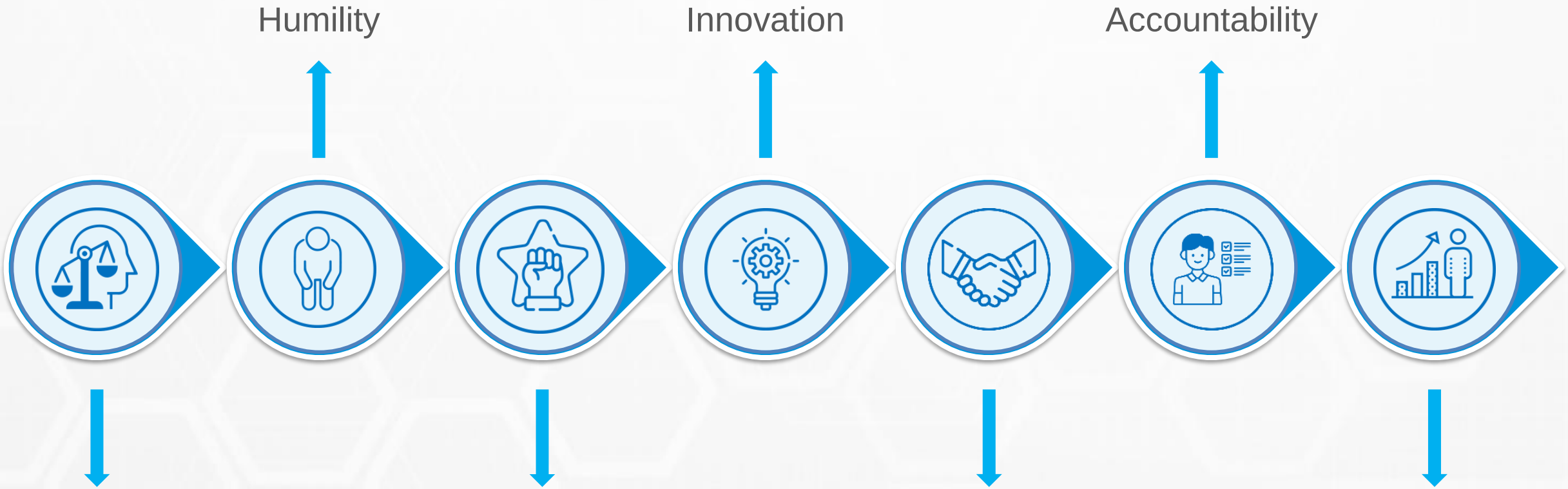
Vision

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

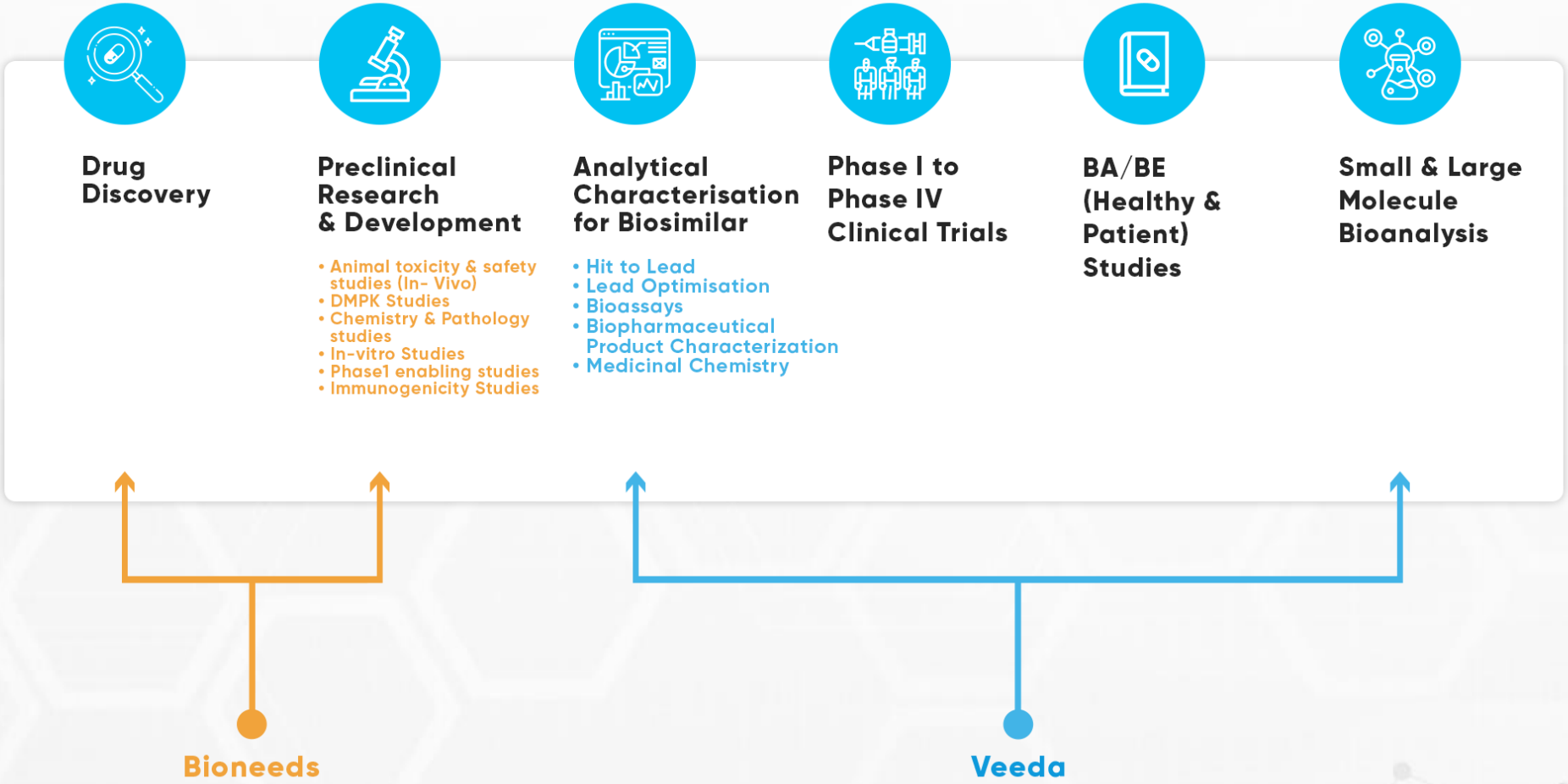
To be the pre eminent independent Indian contract research Organization, with global execution capabilities, distinguished by the breadth of our services and by excellence in the quality of our Scientific and regulatory knowledge Research design, execution and insights and Client centricity

Our Values


Humility
Innovation
Accountability
Integrity
Excellence
Collaboration
Nurturing
Individual Growth

Drug Development Services Overview

Drug Development Journey

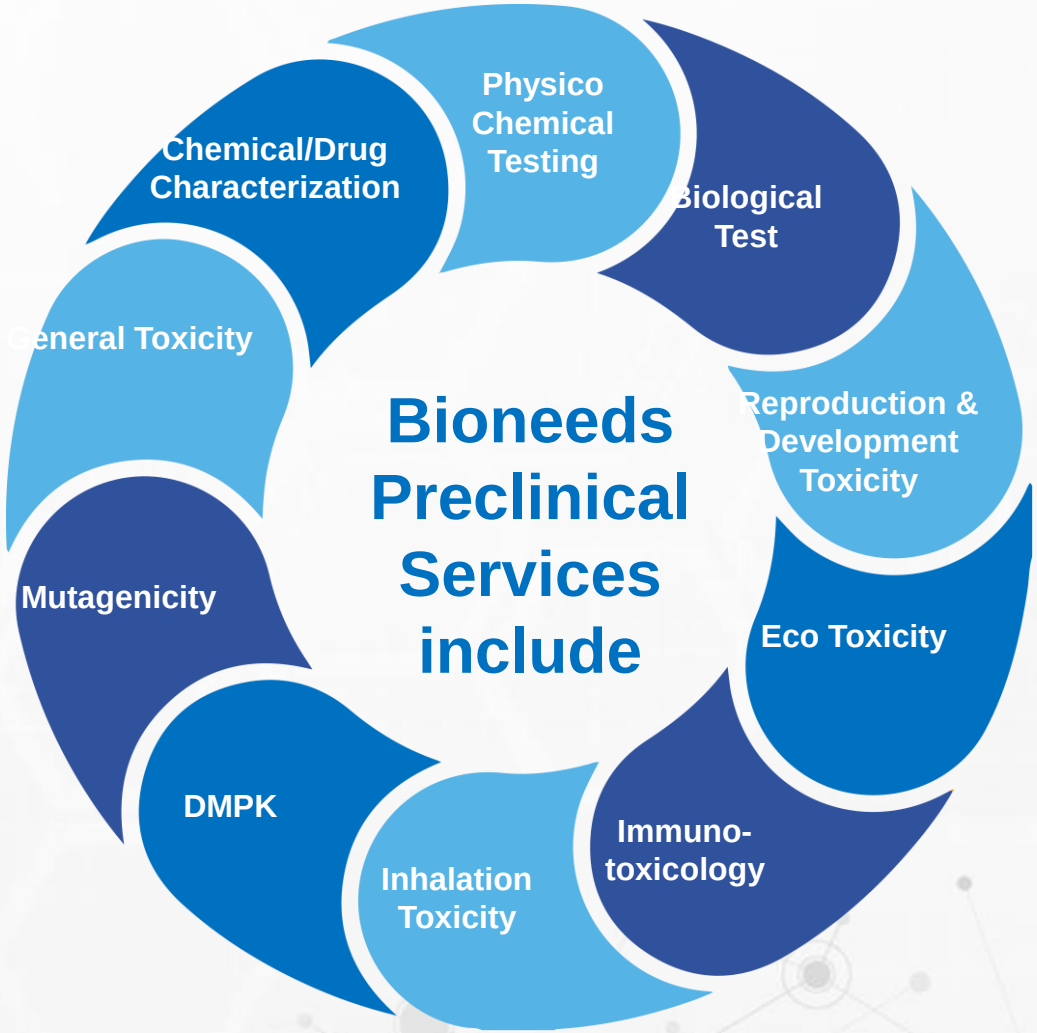


Preclinical Research & Development

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

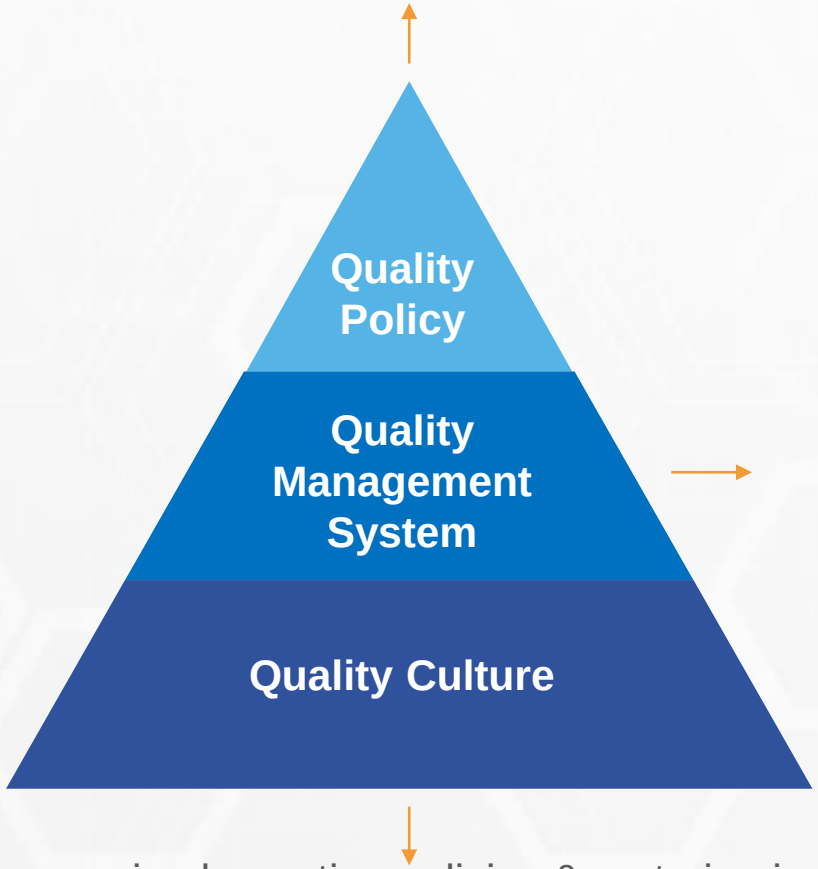
Infrastructure

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

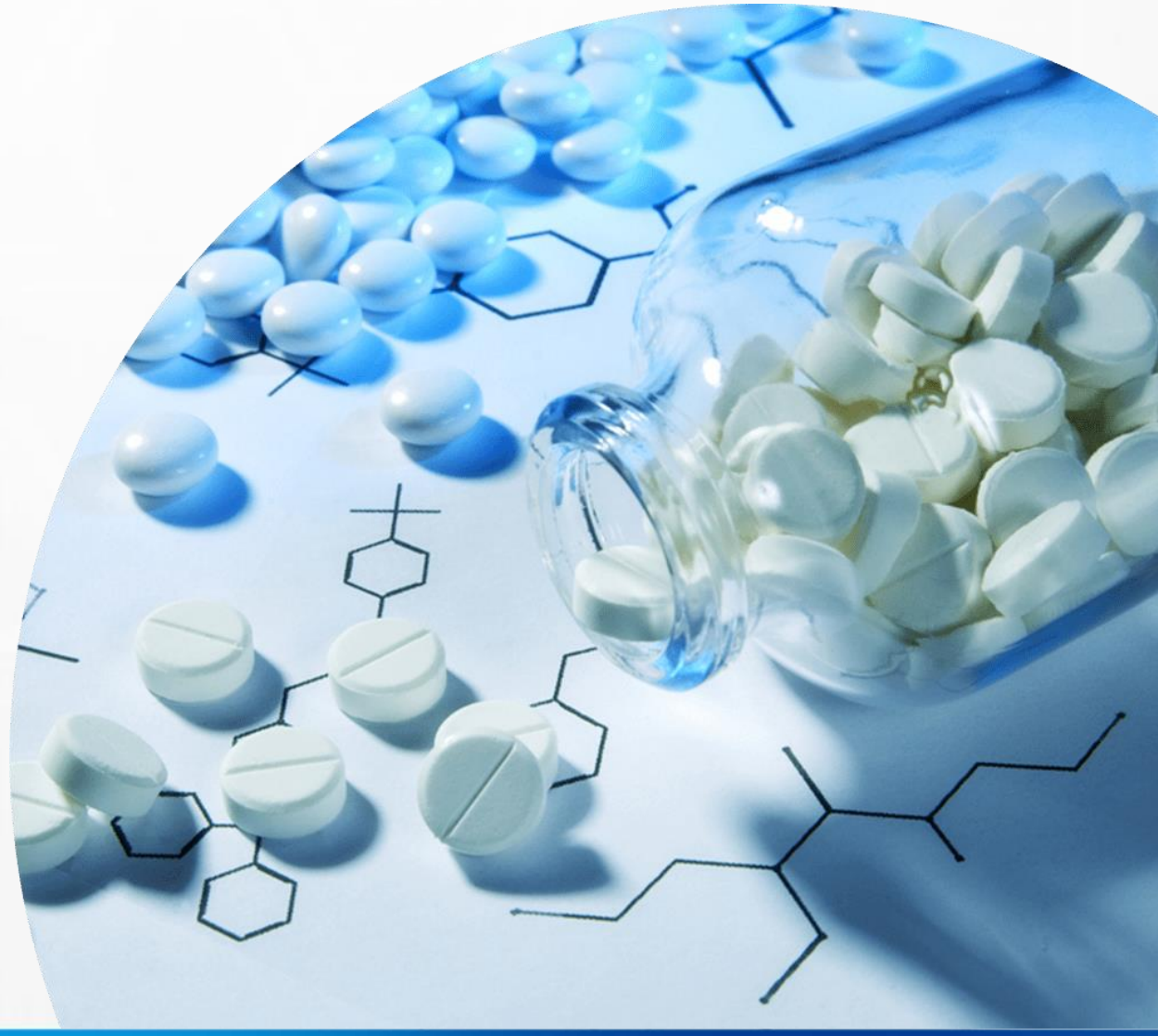
- 93 successful regulatory audits till date
- 12 successful regulatory audits in the last year.

US FDA	→	45*	ANSM	→	1
MHRA	→	4	AGES	→	5*
ANVISA	→	8	MCC	→	1
WHO	→	6	DCGI	→	19
NPRA Malaysia	→	5			

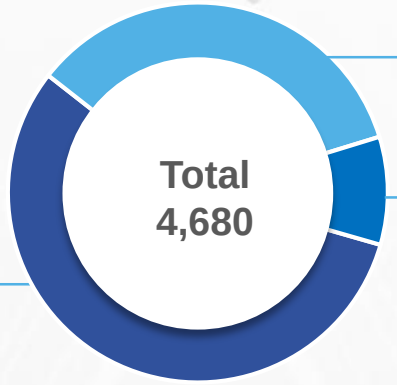
*FDA : 23 AUDITS FOR PATIENT BASED STUDIES
22 AUDITS FOR HEALTHY SUBJECTS STUDIES

AGES : 2 AUDIT FOR PATIENT BASED STUDIES
3 AUDITS FOR HEALTHY SUBJECTS STUDIES

Bioavailability & Bioequivalence Studies



Experience



1464 Pilot

2350 Pivotal

866 Standalone
Bio-Analytical

14 FTF Studies

88 Complex Clinical Studies

75 Special
Studies

*Both Pilot and
Pivotal BA/BE

16 Glucose Clamps studies
(810 clamps)

36 Inhalation Studies

8 Suppositories

15 Patches Studies

27 Phase – I Studies
1 Phase – II Study

Volunteer Database (More than 82,948)

Male Volunteers	–	> 61,254
Female Volunteers	–	> 5,489
Elderly Males	–	> 12,649
Post - Menopausal Females	–	> 3,556

Routes of Administration

Transdermal System/Patches

Inhalation Powder

Inhalation Solution

Nasal Spray

Rectal Capsule

Rectal/Vaginal Suppository / Foam

Injectable Emulsion

Injection (Glucose Clamp, LAI, Injection)

Injectable Vaccine

Polio Vaccine

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

- **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 +

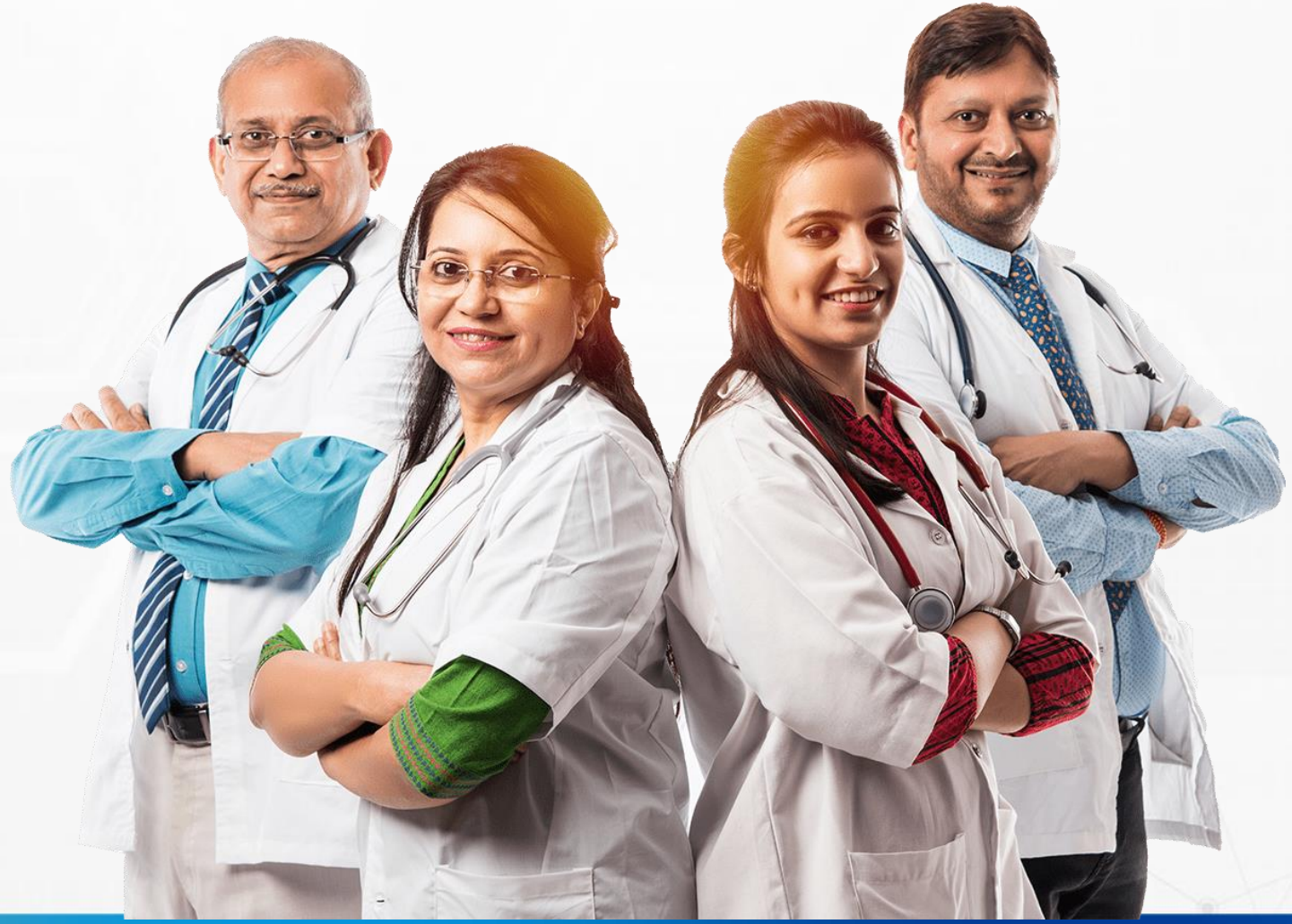
18 Intensively monitored beds to conduct Phase I study

Mehsana

162 Beds +

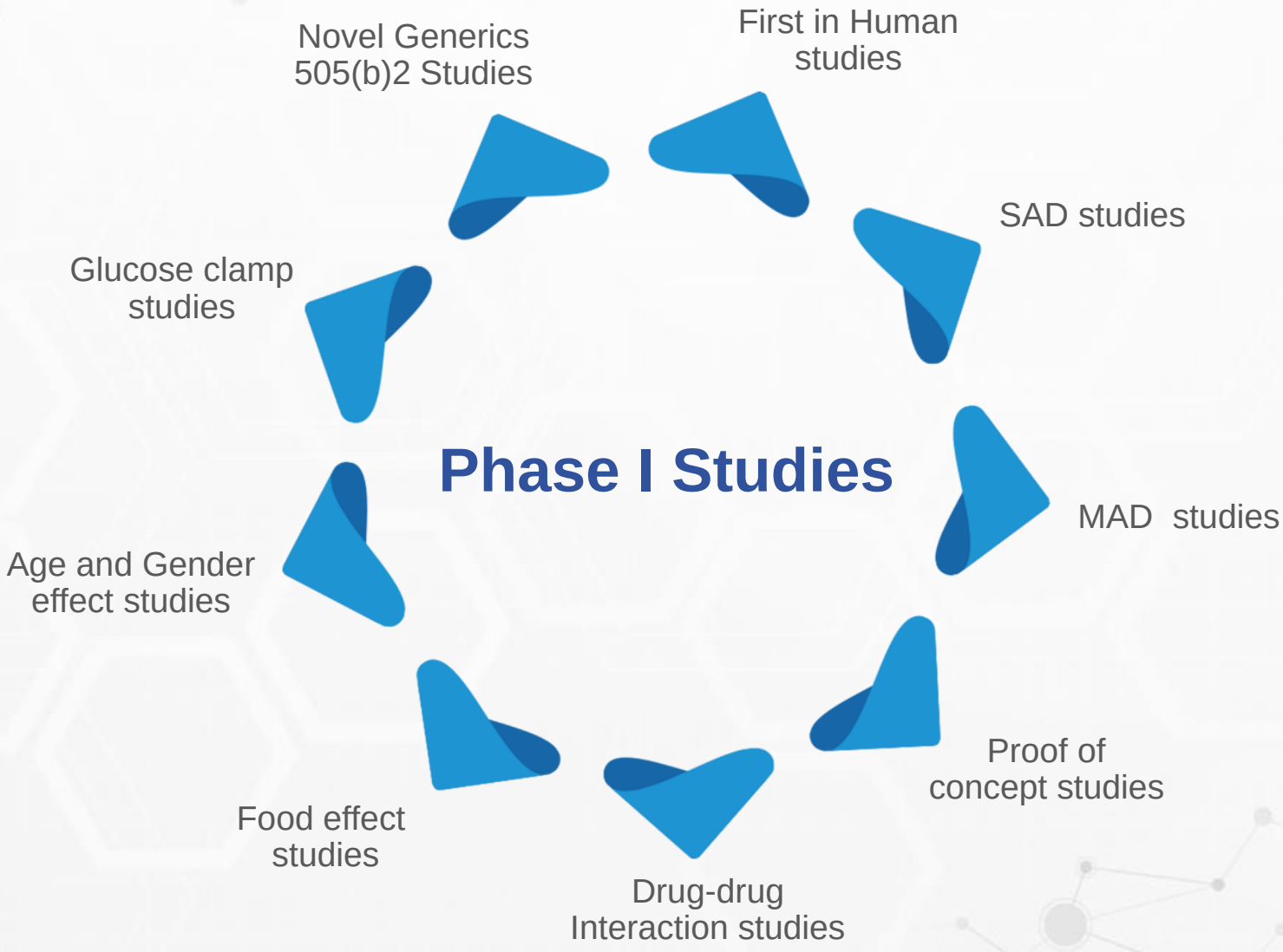
7 Special care beds

Early to Late Phase Clinical Trials



Partners in creating a healthier tomorrow

Phase I Trial Experience



Therapeutic Areas Of Expertise

veeda clinical research

BIONEEDS

Cardiology

Rheumatology

Dermatology

Ophthalmology

Gynecology

Gastroenterology

ENT

Oncology

Psychiatry

Respiratory

Endocrinology

Clinical Trial Services

Our Patient Trials Capabilities

Our in-depth of experience, capabilities and experienced project team enables us to deliver high-quality and timely outcomes for your clinical studies.

THERAPEUTIC EXPERTISE

- **Oncology**
- **Psychiatry**
- **Infectious disease**
- **Ophthalmology**
- **Rheumatology**

40+ Patient bioequivalence studies

4,000+ Patients

300+ Sites

10 Phase Trials

900+ Investigator Database

16+ Ongoing Studies

- 3 Phase I/II/IIa studies
- 9 Patient PK studies
- 3 Clinical end point studies

Anti-COVID-19 vaccine SARS-Cov-2 infection in Healthy subjects– 1600 subjects

Successfully completed 23 USFDA inspections across sites without 483 observations.

Successfully Completed EMA inspections across 02 sites.

Phase Study Experience

Type of Study	Therapeutic Area	Indication	Submission	Number of subjects
Phase I	Oncology	Colon or pancreatic cancer	DCGI	45
Phase II	Oncology	Relapsed Advanced Tumors and classical Hodgkin Lymphoma (cHL)	USFDA	130
	Infectious disease	SARS- CoV-2 Infection	DCGI	60
	Infectious disease	COVID-19	USFDA	112
	Antiretro viral	HIV positive patients	DCGI	30
	Infectious disease	Covid -19 Vaccine	DCGI	1600
	Respiratory	Asthma /COPD	USFDA	25+ 30
	Infectious disease	HIV positive patients	DCGI	18
	Autoimmune skin diseases	Atopic dermatitis, Psoriasis (Ongoing)	POC for USFDA	Up to 30 patients in each indication

Team Experience in Clinical Trials

Sr. No.	Area	Indication	Regulatory Submissions
1	Psychiatry	Major Depressive Disorder, Schizophrenia, Bipolar disorder, Bipolar I depression	USFDA, EMA and DCGI
2	Medical Devices	CAD, Arrhythmia, Heart failure, Uncontrolled hypertensions,	USFDA & DCGI
3	Cardiology	Hypertension, Ischemic cardiomyopathy, CVD, ACS	USFDA, EMA and DCGI
4	Endocrinology	DM-I, DM-II, Diabetic nephropathy	USFDA, EMA and DCGI
5	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
6	Respiratory	Asthma, COPD	USFDA & DCGI
7	Dermatology	Atopic dermatisis, Oral lichen planus, Dermatomycoses	DCGI
8	Nephrology	CKD, Urinary tract infection and pyelonephritis	USFDA & DCGI
9	Gastroenterology	Arsenic Poisoning, GERD, Constipation, Ulcerative Colitis	USFDA & DCGI
10	Infectious diseases	Bacterial Infection, Skin Infection, Hepatitis B Infection	USFDA & DCGI
11	Ophthalmology	Chronic Open Angle Glaucoma, Ocular Hypertension	USFDA & DCGI
12	Neurology	Epilepsy, Seizures	DCGI
13	Vaccine	Rabies, Leishmaniasis & serious fungal infections	DCGI
14	Orthopaedic	Psoriasis and Rheumatoid Arthritis& Osteoporosis	USFDA & DCGI

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
Orthopaedics and Rheumatology	72 Orthopaedics 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 Gynaecologists	20 sites

Bioanalytical Research

Infrastructure

Scale and Range

- **54 LC-MS/MS** machines
  - Insignia (31), Vedant (16) and Satyamev(07)
  - API 6500/5500/4000/4500/3200/3000/2000
  - Shimadzu 8060/8050/8040
  - Quattro Premier
- **2 ICP-OES**
- **Watson LIMS**
- **BSL-2 Laboratory**

Storage Capacity

Plasma Sample:

- 41 Deep freezers of -80˚C (1 M samples capacity) and 12 Deep freezers of -20˚C (0.15 M samples capacity)
- 01 Cold Room -20C (0.3 M samples capacity)

IP Storage:

- 6 Walking type stability chambers with overall capacity to store 74,000 Ltr for retention at room temperature
- 5 Humidity chambers with overall capacity of 4,200 Ltr
- 4 Pharmaceutical refrigerators having storage capacity of 11,350 Ltr at 2-8 ℃

Experience

Capabilities

Total available Bioanalytical methods are more than 1205

986 + 20 Generics + Pharmacodynamics/ Immunogenicity

104 Complex Generics

95 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.

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

Large Molecule Experience

Biosimilars

- Denusomab
- Pertuzumab
- Prembrolizumab
- Abatacept
- Adalimumab
- Etanacerpt
- Infliximab

Vaccines

- PCV
- HPV
- Hepatitis A
- COVID Vaccine
- Typhoid
- Pentavalent
- Hexavalent
- MMR

Therapeutic Proteins

- Filgrastim (I/III)
- Pegfilgrastim (I)
- Romiplostim (I)
- r-FSH (I/IV)
- Teriparatide (I)
- Erythropoetin (II/III)
- Darbepoetin

Large Molecule Studies Experience

- Insulin Aspart and C peptide
- Filgrastim
- PTH (Teriparatide)
- Denosumab
- Romiplostim
- r-FSH
- COVID Vaccine (Anti SARS CO2 Igg Titer)

- Enoxaparin: PD endpoint and Immunogenicity
- Ongoing Project - Ustekinumab

- The average ISR value for the study which we have conducted is 94%

Vaccine Studies Experience

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

In Pipeline: HI Assay (Influenza Vaccine)

Instrumentation and associated software

Globally recommended assay platforms and validated software used for harmonization of data

Technology	Platform	Software
LCMS	• Sciex Tandem Quad (1 nos)	• Analyst/Sciex OS
ELISA	• Molecular Devices (1 nos) • Biotek Microplate (4 nos)	• SoftMax Pro v 5.4.1 • Gen5 Secure v 3.03
ECL	• MSD Quickplex SQ 120 (1 nos)	• Discovery Workbench v 4.0.12
SPR	• Biacore 1S + (1 nos)	• Biacore Insight Software • Biacore Intelligent Analysis Software
Automated affinity purification and immunodepletion	• KingFisher Flex (1 nos)	• BINDIT software v 3.3.1
Alphalisa	• BMG Pherastar	• MARS Data Analysis Software
Cell based	• Cell culture laboratory	• PLA v 3.0
Automation (for bulk STDs and QCs)	• Integra Assist Plus (1 nos)	• VIALAB Pipetting Automation Software
Data and sample movement	• WATSON LIMS	• Version 7.7.1 SP1
ELISPOT	• AID VSPOT Spectrum	
Flow Cytometer	• BD FACSLyric	• BD FAC Suite Clinical Software

Pharmacometrics Capabilities

Pharmacometrics Capabilities for Early Phase Trials

- **Biostatistics Team**

- The Head of biostat and a total of 5 trained biostatisticians, 10 SAS/statistical programmers and a dedicated CDISC team
- All with background in M.S. (statistics) and/or Ph.D and average 9 years of experience into statistical data analysis of early as well as late phase trials
- Bootstrapping/simulations, dose-response curve (Emax), PK-PD correlations, compartmental modelling
- A robust library of SAS programs for most types of studies, double-programing provision
- Publication experience into reputed journals
- Software/tools: SAS 9.4, Pinnacle 4.0.1, R and PASS (for sample size), latest validation suites

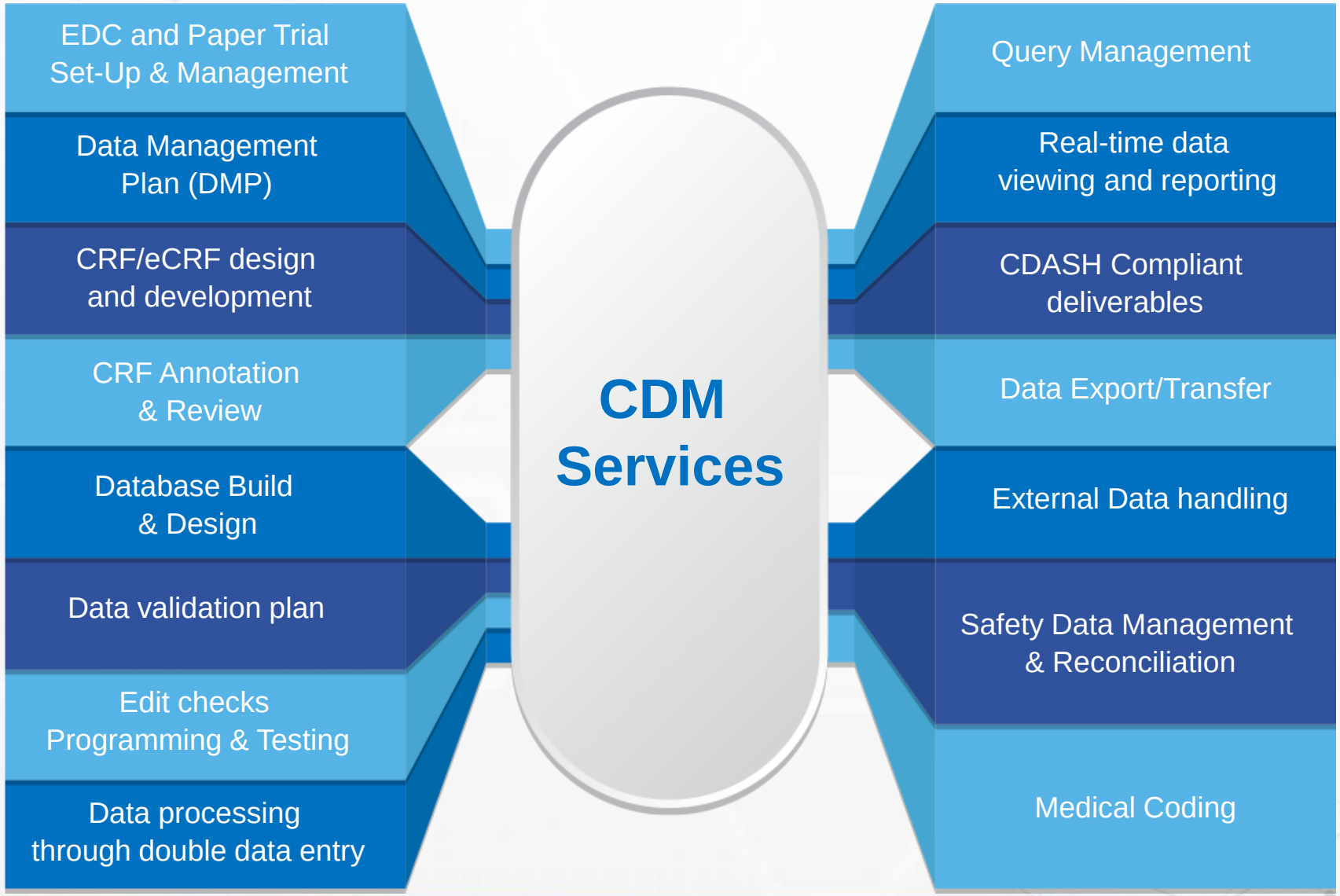
Pharmacometrics Capabilities for Early Phase Trials

- **Pharmacokinetics Team**

- The Head of PK and a total of 5 Certara (Phoenix WinNonlin) trained PK/PD scientists and pharmacokineticist
- All with background in M.S. in pharmacology/pharmaceutical sciences) and/or Ph.D and average 7 years of experience into PK/PD data analysis
- Experienced in data analysis of early phase trials (phase 1, food-effect, through QT, DDI, reanl/hepatic impair studies, PK/PD correlation)
- Quick turn around for interim analysis for SAD/MAD studies (2 days), blinded/unblinded analysis
- A strong publication record into PK/PD data analysis (a total of 18) by different team members
- Software/tools: Phoenix WNL version 8.3, R software, test license of NLME (for mixed effect)

Biopharmaceutics & Data Science

Clinical Data Management Services



Biostatistics Capabilities

Quick setup

Reconciliation and oversight

Key Strengths

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
19 YEARS
of excellence in Clinical Research

Organization	Award Category
ASSOCHAM INDIA	Best Clinical Research Organization - India
Health & Wellness	Clinical Trial Company of the Year
ECONOMIC GROWTH FOUNDATION	Bharat Udhyog Ratan Award in Clinical Research

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

2004 → **2017** → **2018** → **2019** → **2020** → **2022**

Organization	Award Category
Praxis Media	National Excellence Award
AI Global	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

Organization	Award Category
WORLD QUALITY CONGRESS & AWARDS	Best Quality Clinical Research Organization in India
INDIAN PHARMA EXPO	Best Quality Clinical Research Organization in India
	Indian Clinical Research company of the year

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

Veeda Group Advantage

Extensive Scientific Competence to service a Diverse client base

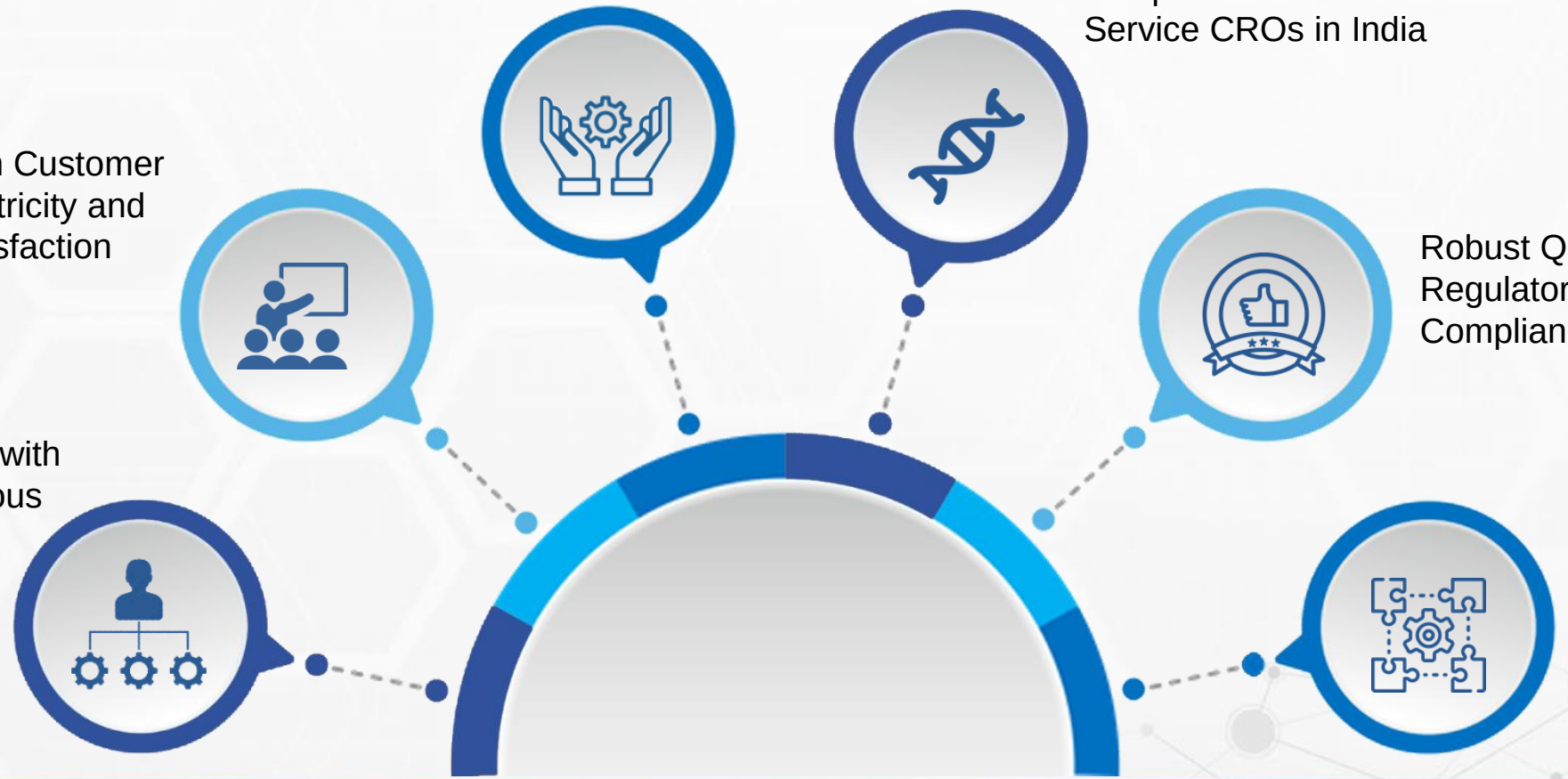
One of the largest Independent Full Service CROs in India

High Customer Centricity and Satisfaction

Robust Quality & Regulatory Compliance

Skilled personnel with focus on Continuous Professional Development

One stop solution for complex studies



Thank You

Partners in creating

a healthier tomorrow

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