



Partners in creating a healthier tomorrow

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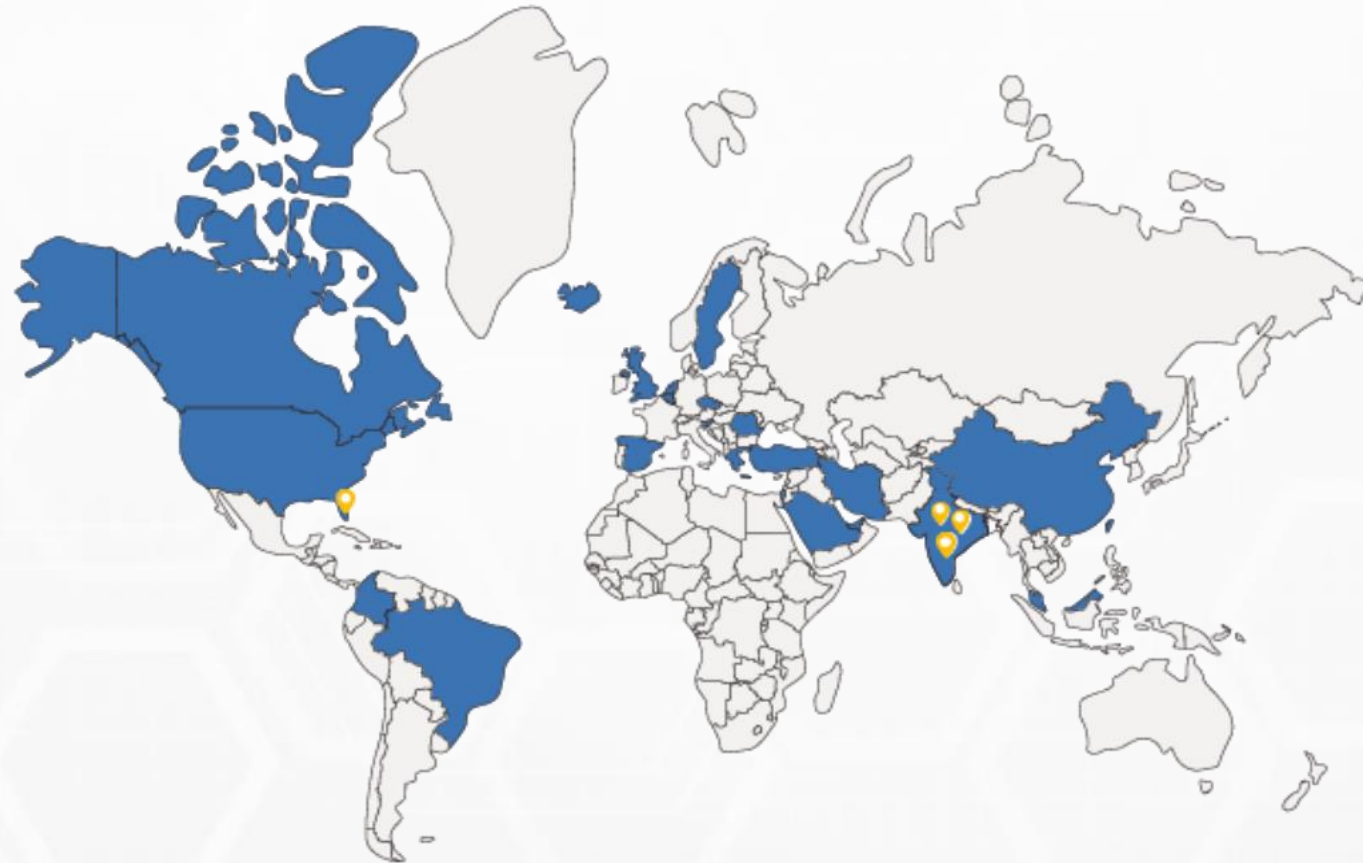



# Corporate Overview



- 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

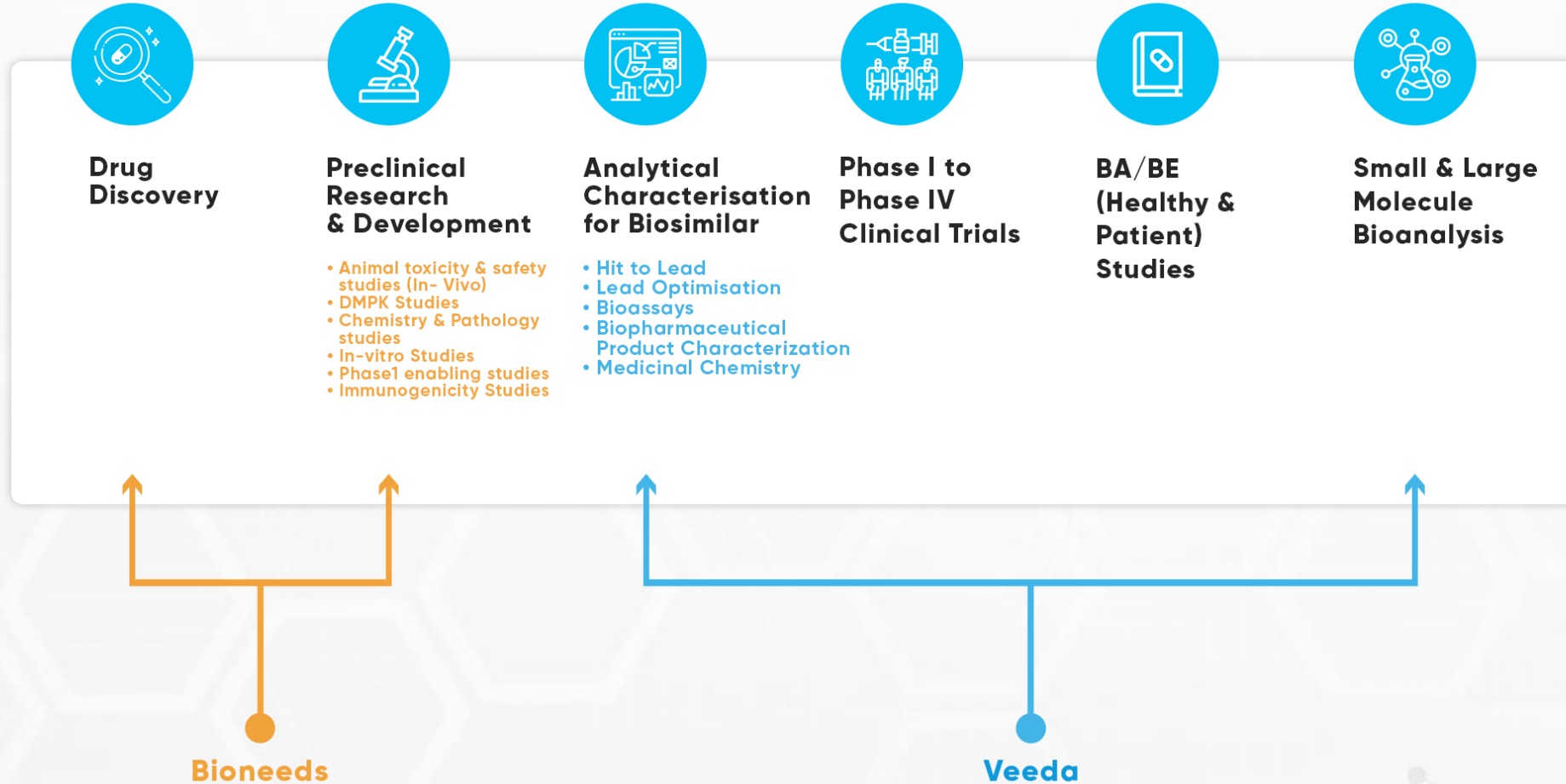
Nurturing  
Individual Growth

# Drug Development Services Overview





# Drug Development Journey

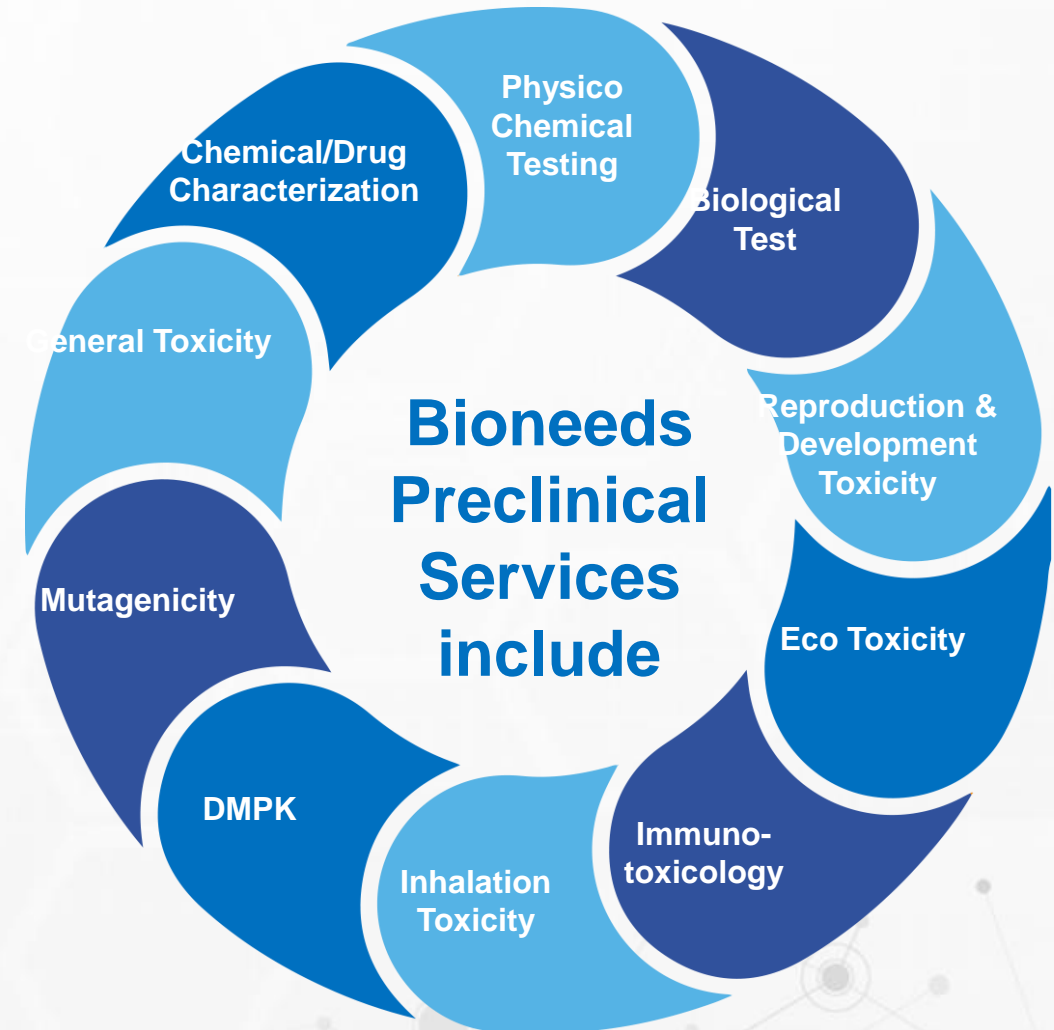


# Preclinical Research & Development



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
- Bionees 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

- 98 successful regulatory audits till date
- 15 successful regulatory audits in the last year.

US FDA → 49<sup>\*</sup>

MHRA → 4

ANVISA → 8

WHO → 6

NPRA  
Malaysia → 5

ANSM → 1

AGES → 5<sup>\*</sup>

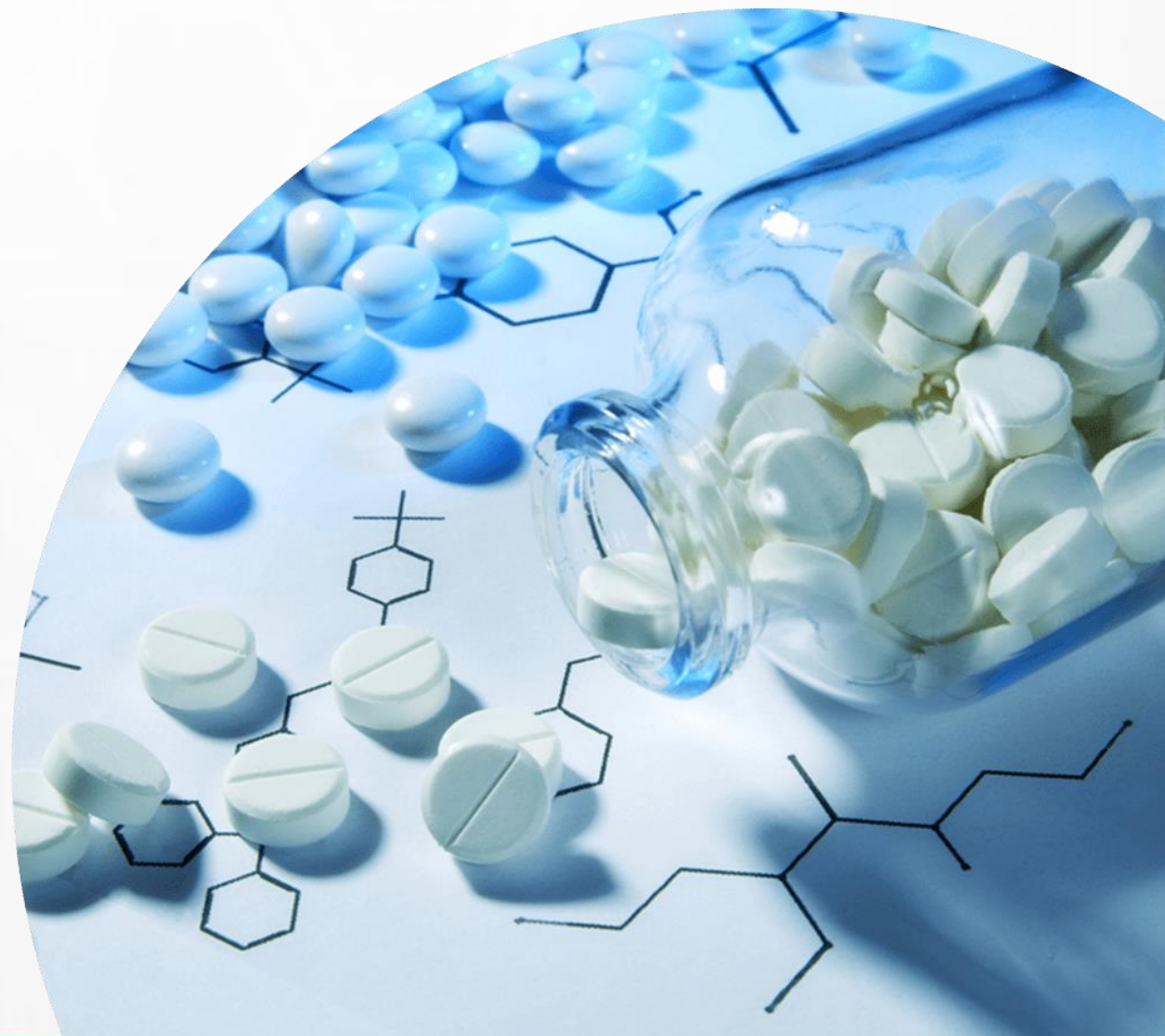
MCC → 1

DCGI → 19

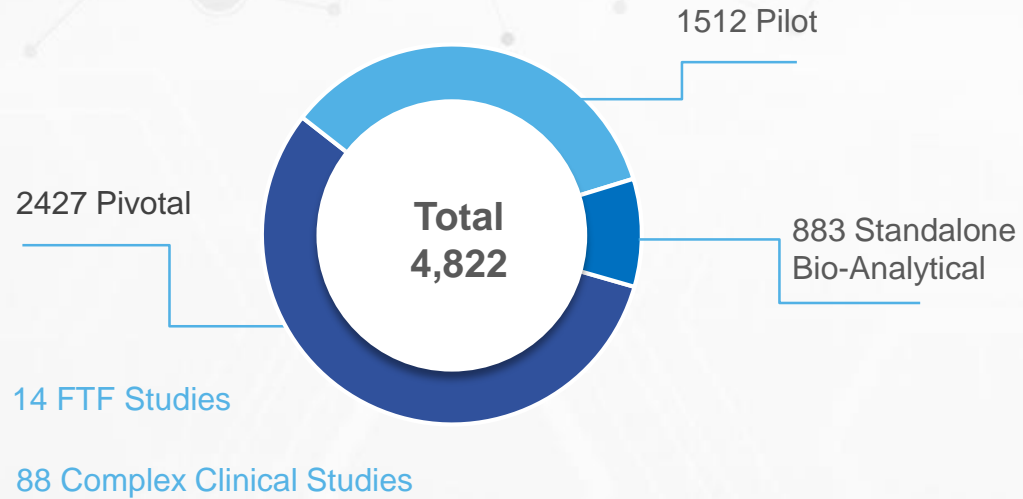
*\*FDA : 25 AUDITS FOR PATIENT BASED STUDIES  
24 AUDITS FOR HEALTHY SUBJECTS STUDIES*

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

# Bioavailability & Bioequivalence Studies



# Experience



75 Special Studies

\*Both Pilot and Pivotal BA/BE

16 Glucose Clamps studies  
(1322 clamps)

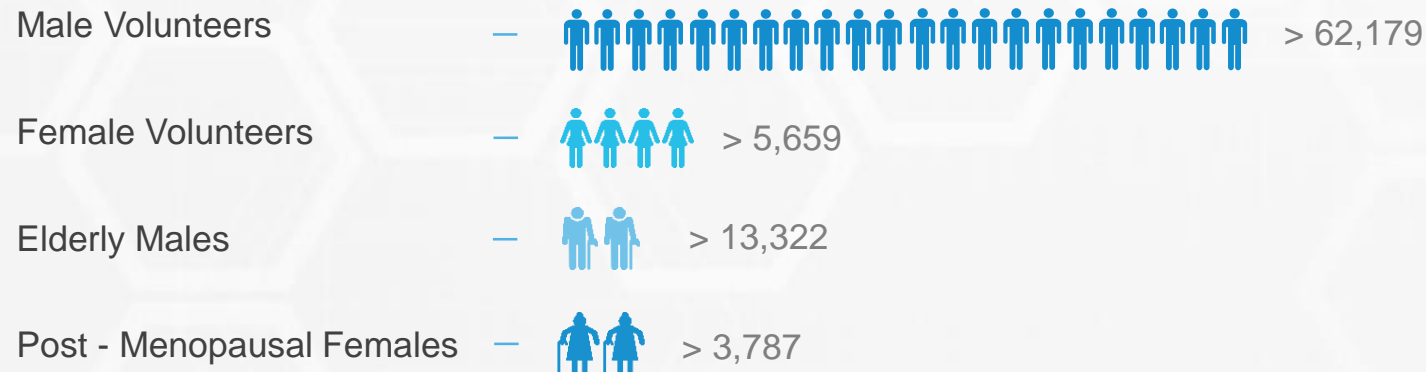
36 Inhalation Studies

8 Suppositories

15 Patches Studies

27 Phase – I Studies  
1 Phase – II Study

## Volunteer Database (More than 84,947)



# 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  
Bio-analytical facility

- **SHIVALIK**

Dedicated Clinical facility

- **MEHSANA**

Clinical and  
Screening facility

- **SKYLAR**

Common screening  
facility for both Shivalik  
and Vedant

- **INSIGNIA**

Dedicated  
Bio-analytical facility

- **ARCHIVES**

Archival area in each facility.  
Separate archival facility at Changodar

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



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# Phase I Trial Experience



# Therapeutic Areas Of Expertise



**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

**50+**

Patient  
bioequivalence  
studies

**4,400+**

Patients

**500+**

Sites

**10**

Phase  
Trials

**900+**

Investigator  
Database

**16+**

Ongoing Studies
 

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

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

***Successfully completed 25 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
	Infectious disease	HIV positive patients	DCGI	18
	Respiratory/Dermatology	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 dermatitis, 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
Ophthalmology	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



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# 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 °C

# Experience

## Capabilities

Total available Bioanalytical methods are more than 1234

1003 + 20

Generics +  
Pharmacodynamics/  
Immunogenicity

110

Complex  
Generics

101

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
- Pembrolizumab
- Abatacept
- Adalimumab
- Etanercept
- 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)
- Erythropoietin (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	<ul style="list-style-type: none"><li>Sciex Tandem Quad (1 nos)</li></ul>	<ul style="list-style-type: none"><li>Analyst/Sciex OS</li></ul>
ELISA	<ul style="list-style-type: none"><li>Molecular Devices ( 1 nos)</li><li>Biotek Microplate ( 4 nos)</li></ul>	<ul style="list-style-type: none"><li>SoftMax Pro v 5.4.1</li><li>Gen5 Secure v 3.03</li></ul>
ECL	<ul style="list-style-type: none"><li>MSD Quickplex SQ 120 (1 nos)</li></ul>	<ul style="list-style-type: none"><li>Discovery Workbench v 4.0.12</li></ul>
SPR	<ul style="list-style-type: none"><li>Biacore 1S + (1 nos)</li></ul>	<ul style="list-style-type: none"><li>Biacore Insight Software</li><li>Biacore Intelligent Analysis Software</li></ul>
Automated affinity purification and immunodepletion	<ul style="list-style-type: none"><li>KingFisher Flex (1 nos)</li></ul>	<ul style="list-style-type: none"><li>BINDIT software v 3.3.1</li></ul>
Alphalisa	<ul style="list-style-type: none"><li>BMG Pherastar</li></ul>	<ul style="list-style-type: none"><li>MARS Data Analysis Software</li></ul>
Cell based	<ul style="list-style-type: none"><li>Cell culture laboratory</li></ul>	<ul style="list-style-type: none"><li>PLA v 3.0</li></ul>
Automation (for bulk STDs and QCs)	<ul style="list-style-type: none"><li>Integra Assist Plus (1 nos)</li></ul>	<ul style="list-style-type: none"><li>VIALAB Pipetting Automation Software</li></ul>
Data and sample movement	<ul style="list-style-type: none"><li>WATSON LIMS</li></ul>	<ul style="list-style-type: none"><li>Version 7.7.1 SP1</li></ul>
ELISPOT	<ul style="list-style-type: none"><li>AID VSPOT Spectrum</li></ul>	
Flow Cytometer	<ul style="list-style-type: none"><li>BD FACSLytic</li></ul>	<ul style="list-style-type: none"><li>BD FAC Suite Clinical Software</li></ul>

# 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**

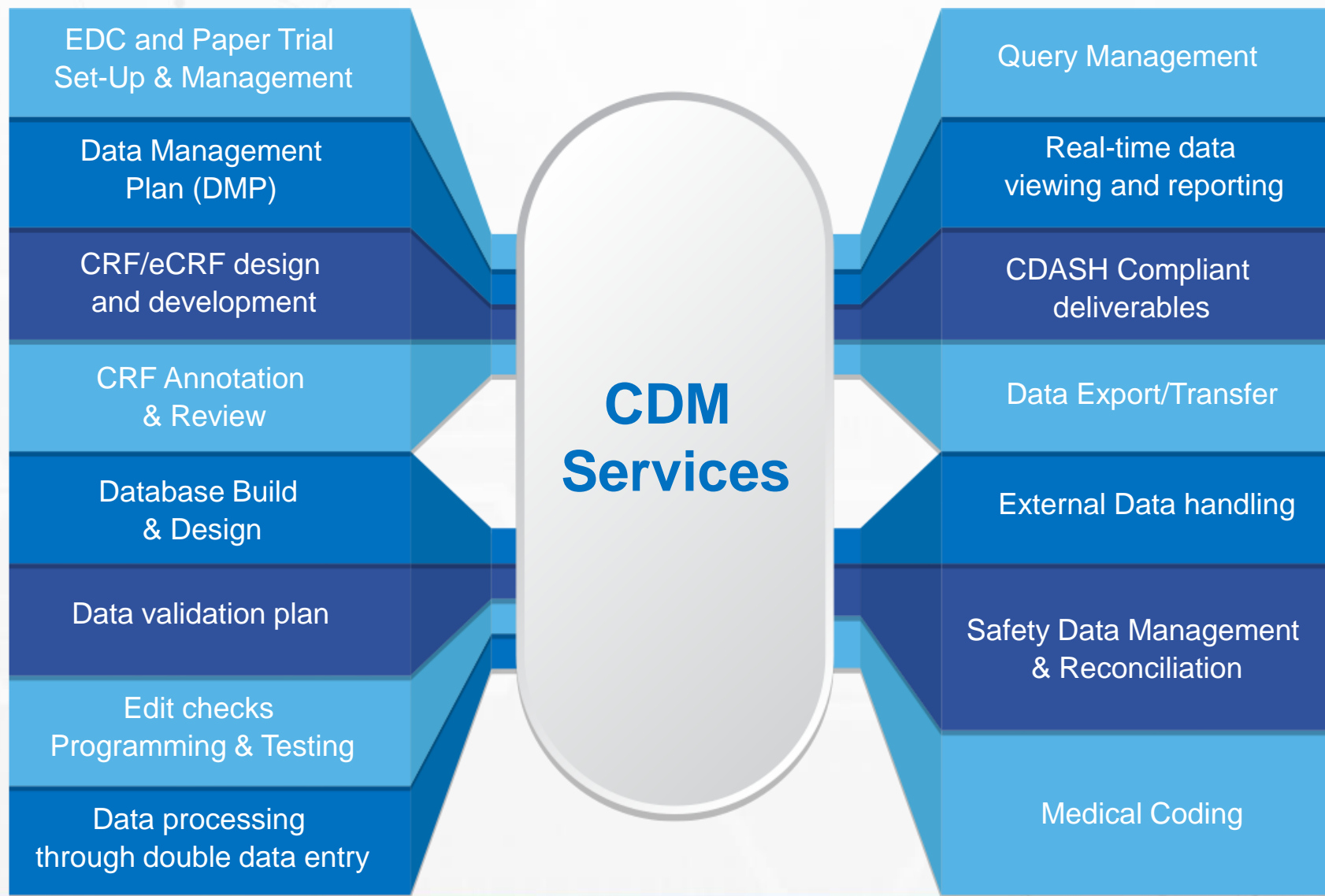
- The Head of PK and a total of 5 Certara (Phoenix WinNonlin) trained PK/PD scientists and pharmacokineticist
- All with background in M.S. in pharmacology/pharmaceutical sciences) and/or Ph.D and average 7 years of experience into PK/PD data analysis
- Experienced in data analysis of early phase trials (phase 1, food-effect, through QT, DDI, renal/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)



# Biopharmaceuticals & 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
	Best Clinical Research Organization - India
	Clinical Trial Company of the Year
	Bharat Udyog 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

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**a healthier tomorrow**

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