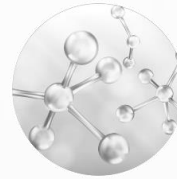




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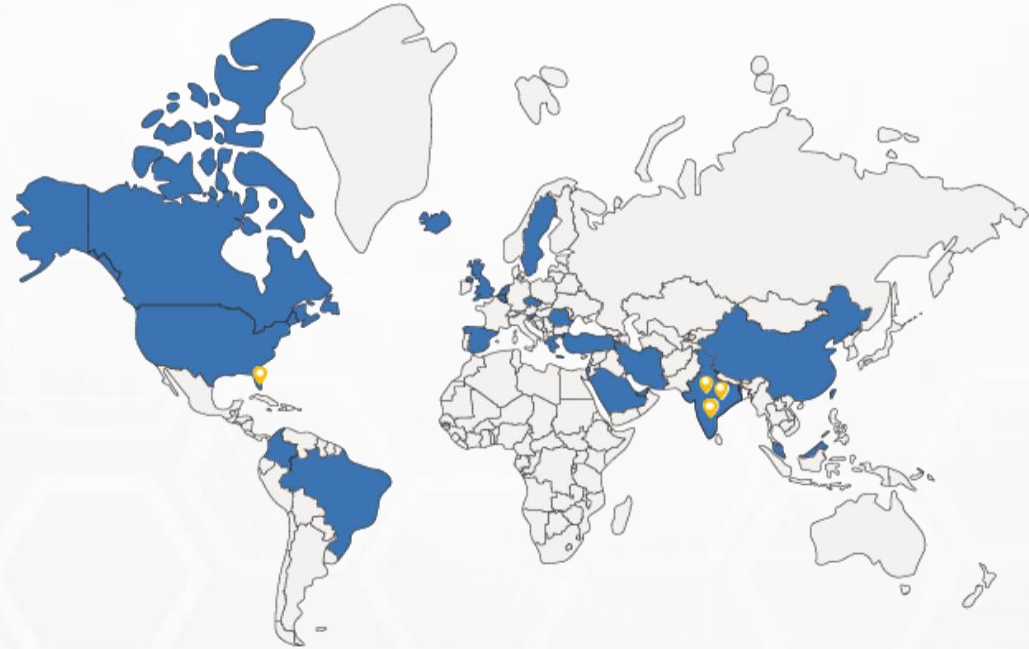


Corporate Overview



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



 Serving clients across these geographies

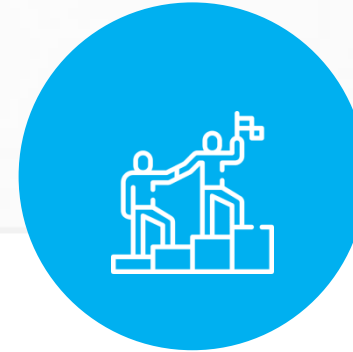
 Veeda's Team Presence

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



Your Drug Development Journey



Drug Discovery

- Hit to Lead
- Lead Optimisation
- Bioassays
- Biopharmaceutical Product Characterization
- Medicinal Chemistry



Analytical Characterisation for Biosimilar



Preclinical Research & Development

- Animal toxicity & safety studies (In- Vivo)
- DMPK Studies
- Chemistry & Pathology studies
- In-vitro Studies
- Phase1 enabling studies
- Immunogenicity Studies



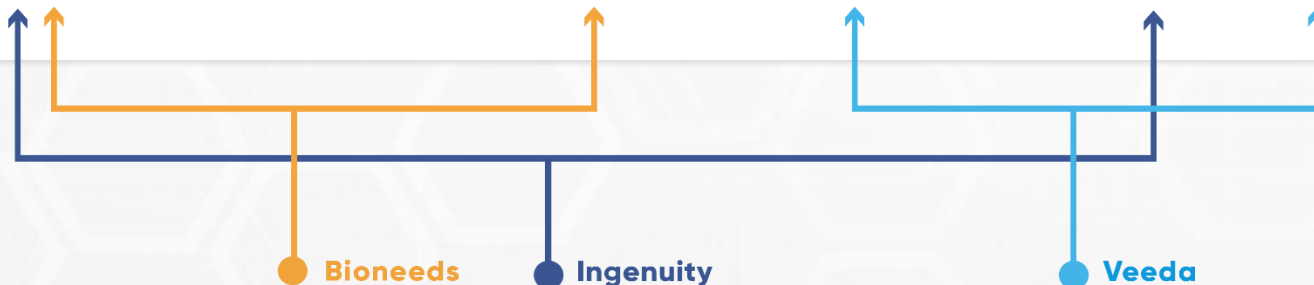
Phase I to Phase IV Clinical Trials



BA/BE (Healthy & Patient) Studies



Small Molecule Bioanalysis



Bionees

Ingenuity

Veeda

Large Molecule Bioanalysis

- Cloud based software solution for Bioanalytical Library - Aegyris™
- Attomolar level of analyte detection - Amplatto™
- AI based platform for the comparability testing of Biosimilars - Intelli.b™

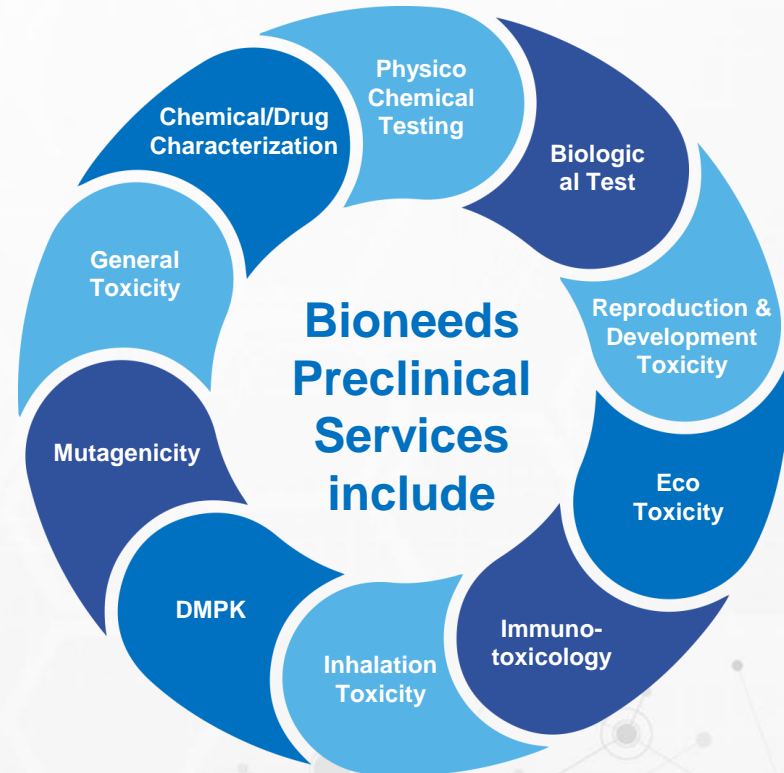


Preclinical Research & Development



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
- Bioneesds 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

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

US FDA → 37*

MHRA → 4

ANVISA → 8

WHO → 5

NPRA
Malaysia → 5

ANSM → 1

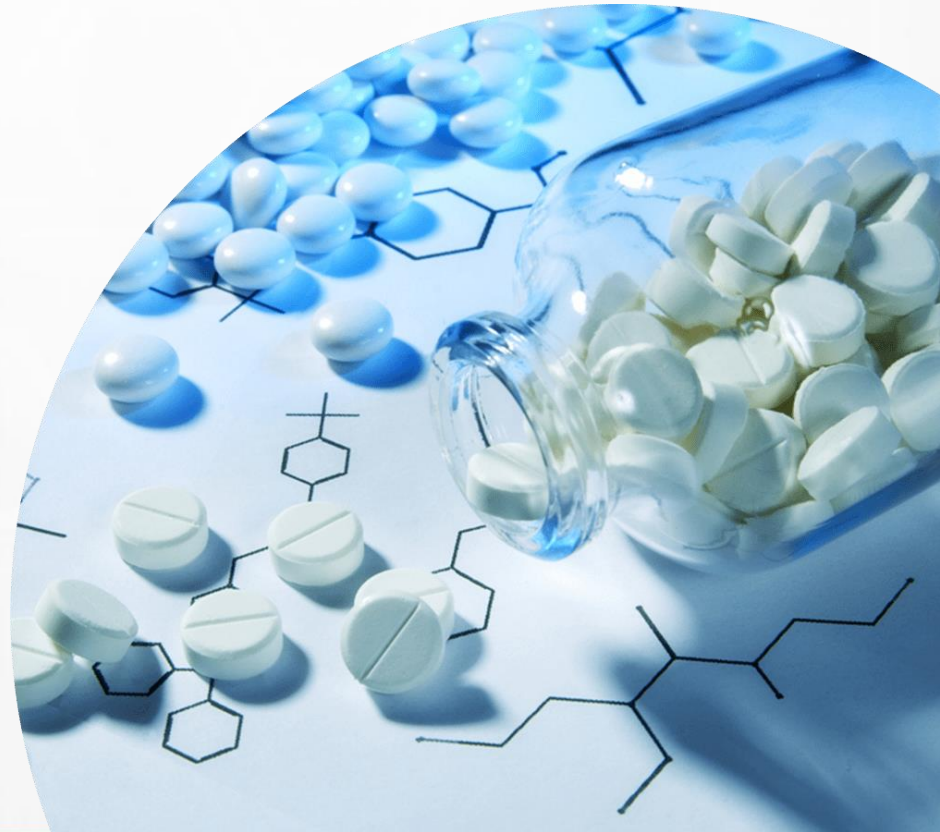
AGES → 1

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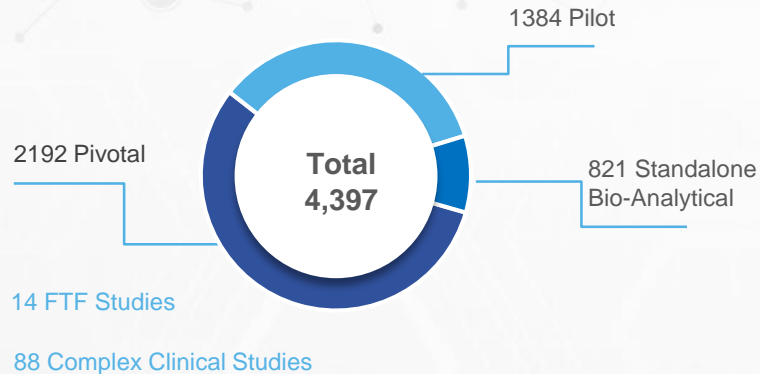
DCGI → 18

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

Bioavailability & Bioequivalence Studies



Experience



69 Special Studies

*Both Pilot and Pivotal BA/BE

16 Glucose Clamps studies (810 clamps)

33 Inhalation Studies

6 Suppositories


14 Patches Studies


27 Phase – I Studies
1 Phase – II Study

Volunteer Database (More than 77,670)

Male Volunteers —  > 58,363

Female Volunteers —  > 4,768

Elderly Males —  > 11,299

Post - Menopausal Females —  > 3,240

Routes of Administration



Transdermal
System/Patches



Inhalation
Solution



Rectal
Capsule



Inhalation
Powder



Nasal
Spray



Rectal/Vaginal
Suppository / Foam



Injection (Glucose
Clamp, LAI, Injection)



Polio
Vaccine



Injectable
Emulsion



Injectable
Vaccine

Different Formulations



Tablets



Capsule



Oral Suspension



Oro-Dispersible
Tablet (ODT)



Powder for oral
suspension / Solution



Oral
Granules



Orally Disintegrating
strip (OD Strip)



Oral
Solution



Topical
Product



Oral
Sachet



Oral
Powder



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 **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



Phase I Trial Experience



Therapeutic Areas Of Expertise



Cardiology



Rheumatology



Dermatology



Ophthalmology



Gynecology



Gastroenterology



ENT



Oncology



Psychiatry



Respiratory



Endocrinology

Clinical Trial Services



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	2	Bioequivalence Clinical End Point

Veeda's PK End Point Studies Experience

Therapeutic area	Completed Studies	Ongoing Studies
Antiviral	1	1
Covid		1
Haematology		1
Oncology	22	2
Psychiatry	9	1
Rheumatology	2	1

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

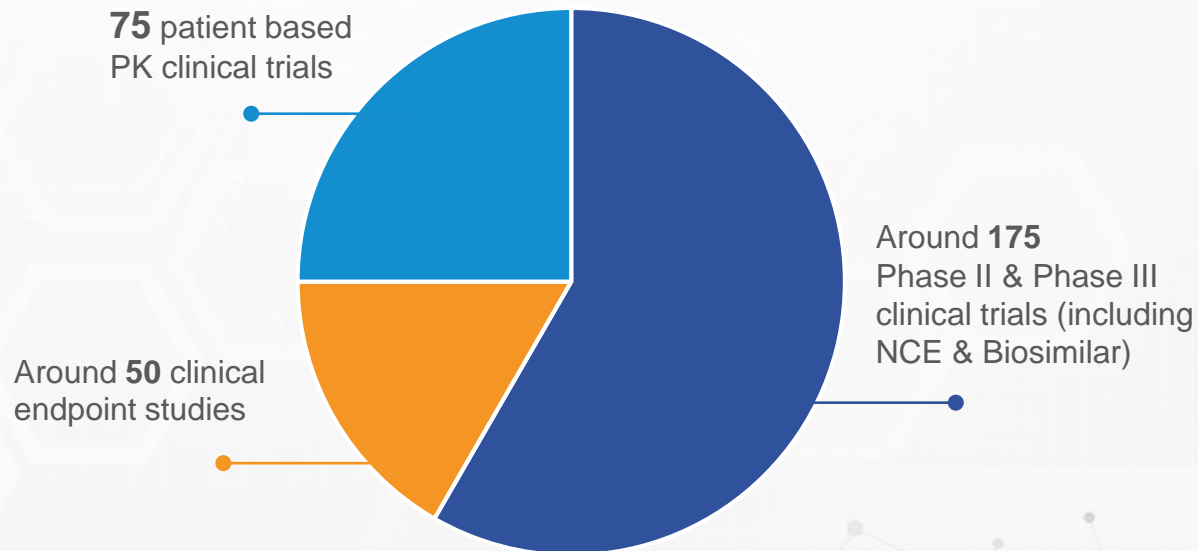


Therapeutic Area	Investigators Database	No. of sites associated with Veeda
Oncology	150 Oncologists	90 sites
Psychiatry	90 Psychiatrists	35 sites
Orthopedics and Rheumatology	72 Orthopedics and Rheumatologists	25 sites
Infectious Disease	79 MD Physicians	25 sites
Dermatology	87 Dermatologists	40 sites
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 Gynecologists	20 sites

Combined Team Experience in Clinical Trials



More than **300** clinical trials that includes



Bioanalytical Research



Scale and Range

- **49 LC-MS/MS machines**
 - Insignia (33) and Vedant (16)
 - 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:

- 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:

- 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 1147

948 + 20

Generics +
Pharmacodynamics/
Immunogenicity

96

Complex
Generics

83

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



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, Fluorescence and Luminescence), 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



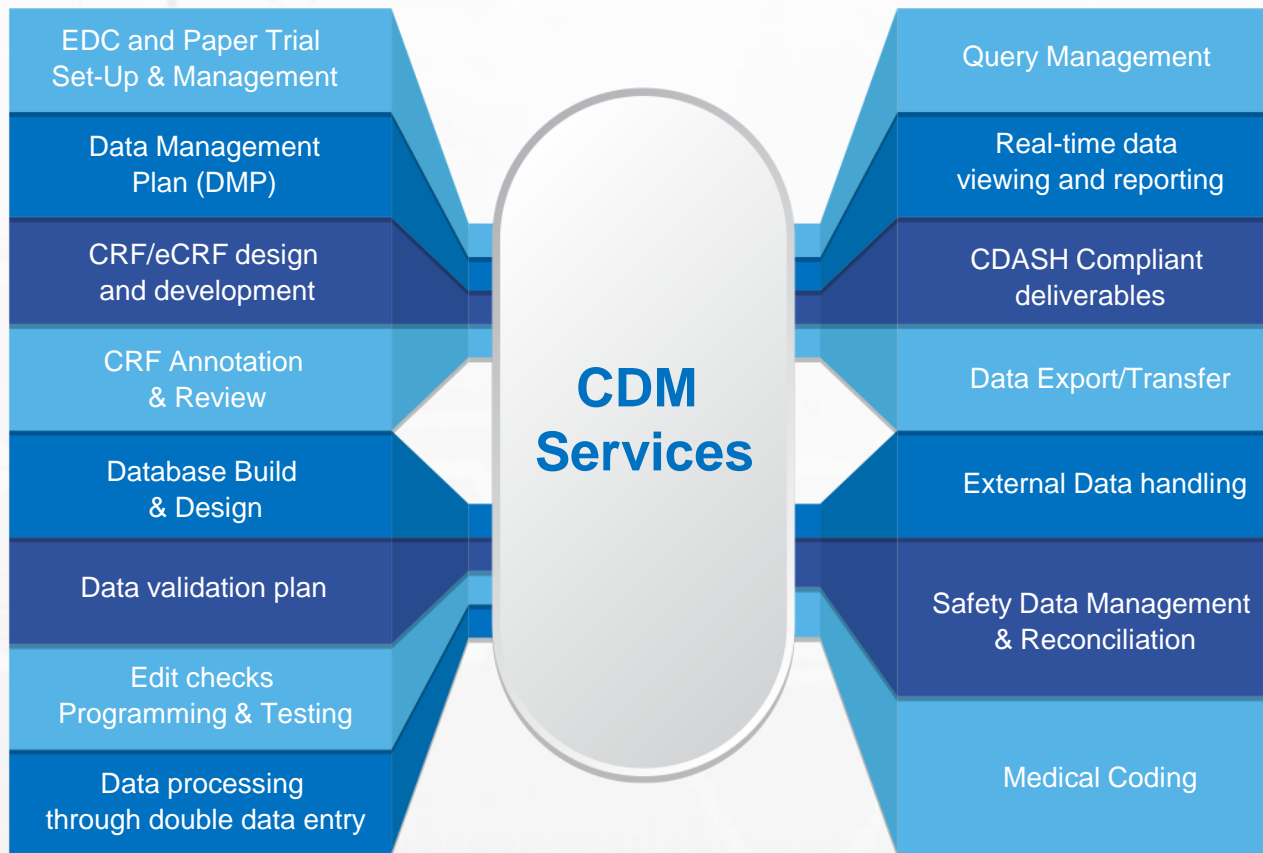
- Recently developed and validated below large molecules as per current EMEA guidance using commercially available kits by ELISA technique
 - Insulin Aspart and C peptide
 - Filgrastim
 - PTH (Teriparatide)
 - Denosumab
 - Romiplostim
- Enoxaparin: PD endpoint and Immunogenicity for FDA, EU and ANVISA 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%

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
17 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

2004

2017

2018

2019

2020

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

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

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

Partners in creating
a healthier tomorrow

