BIONEEDS

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

Veeda's Current Geographical Presence

Veeda's Team Presence

Corporate Philosophy

Vision

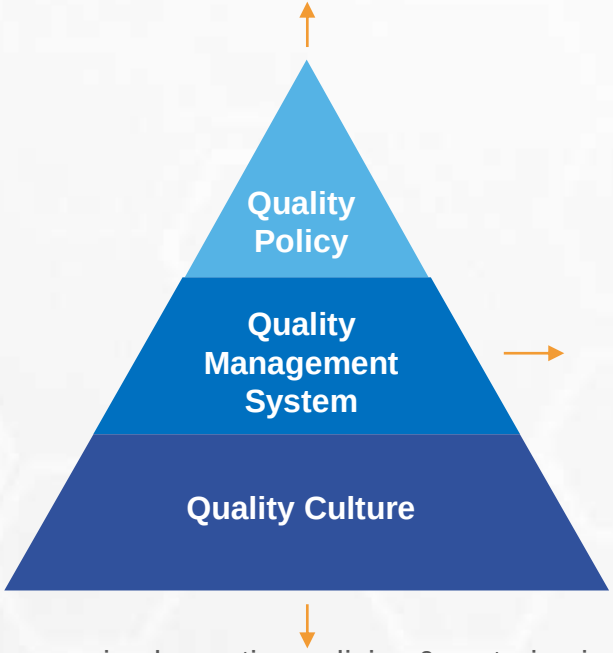
In an industry where innovation is increasingly multifaceted and collaborative, we aspire to be the research partner of choice for innovative (bio)pharmaceutical companies worldwide for their critical product development programs

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

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

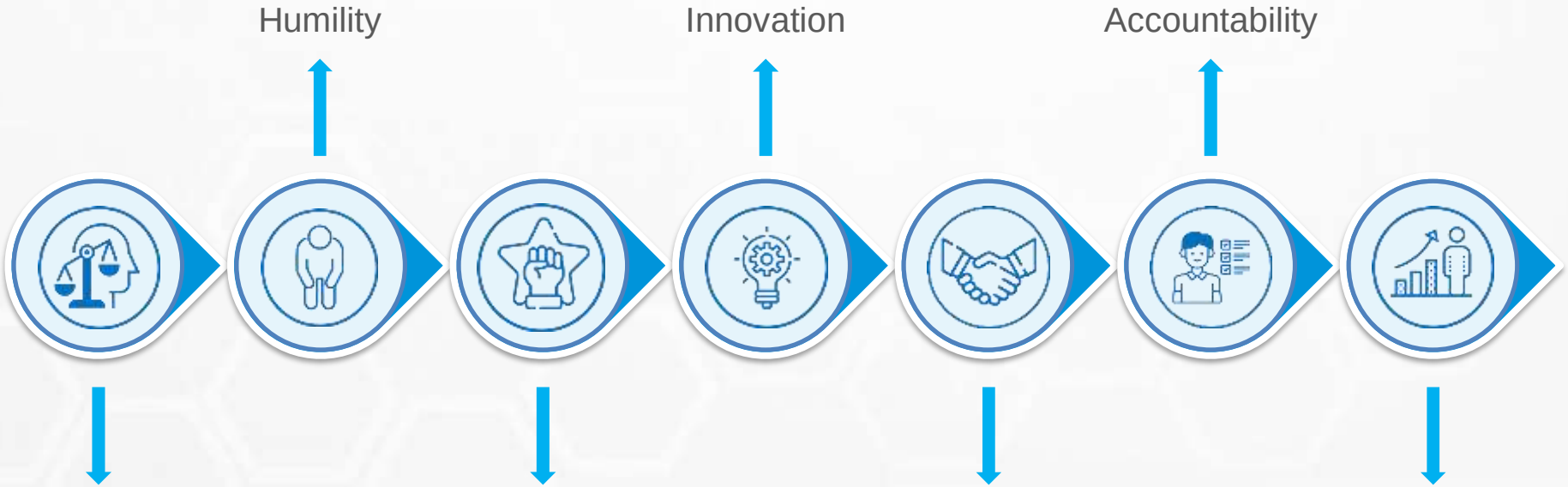
Regulatory Credentials

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

US FDA	→	34*	ANSM	→	1
MHRA	→	3	AGES	→	1
ANVISA	→	14	MCC	→	1
WHO	→	5	DCGI	→	18
NPRA Malaysia	→	5			

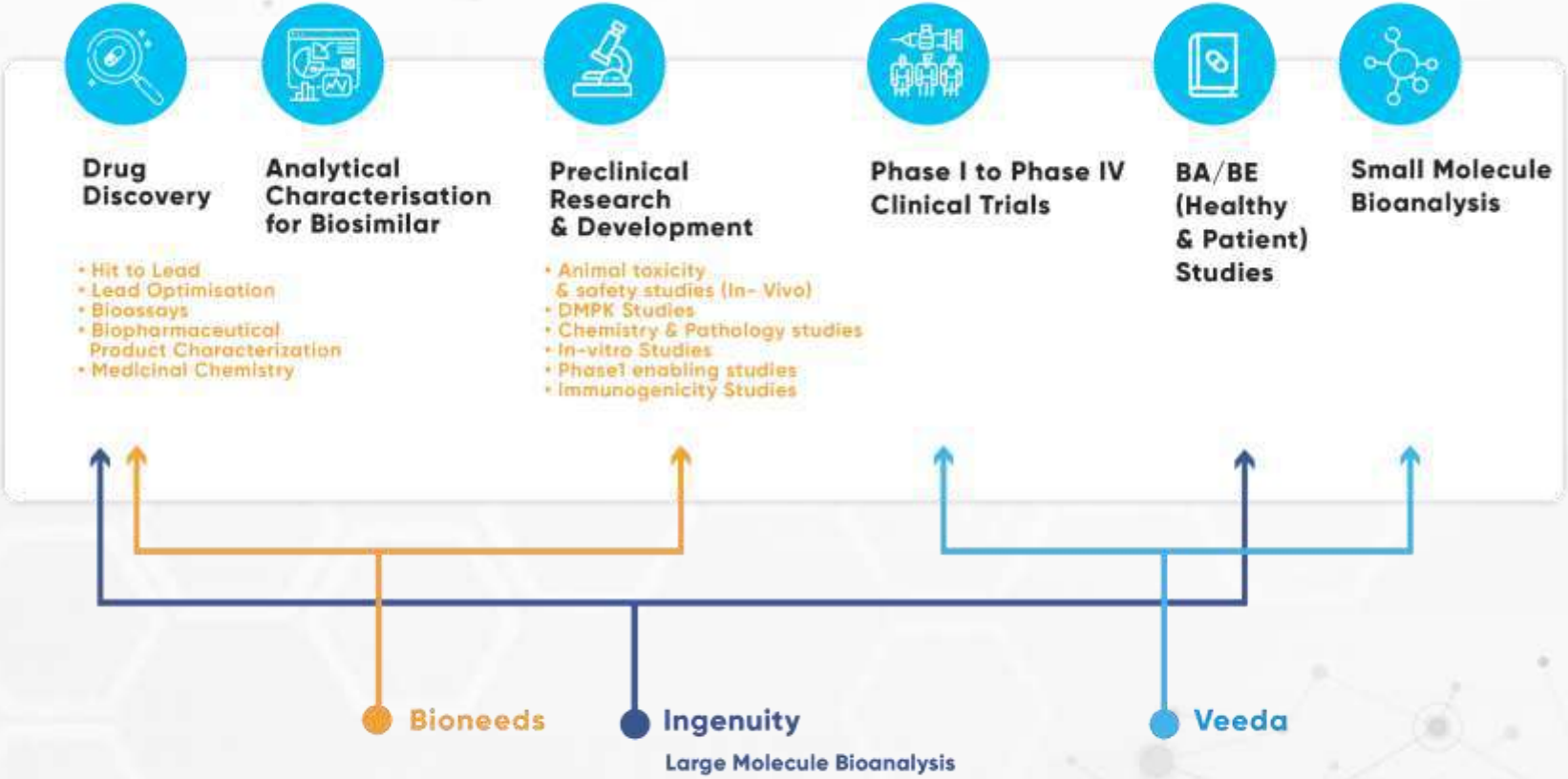
**FDA : 17 AUDITS FOR PATIENT BASED STUDIES*
17 AUDITS FOR HEALTHY SUBJECTS STUDIES

Our Values


Humility
Innovation
Accountability
Integrity
Excellence
Collaboration
Nurturing Individual Growth

Drug Development Services Overview

Your Drug Development Journey



Drug Development Service

Discovery and Development

Assay development

- Pharmacodynamics
- Pharmacokinetics
- Immunogenicity
- Biomarker Assessment

Immunogenicity Testing

- Screening ELISA
- Confirmatory ELISA
- NAb Assay
- In vitro Immunogenicity

Characterization

- Intact mass , Reduced Mass
- Subunit analysis
- Peptide mapping
- Disulfide bond locations
- Glycan analysis

Other Services

- Critical reagent preparation
- HCP and HCD
- Polyclonal and Monoclonal antibody production
- Cascade Immunization

Early to Late Phase Clinical Trials

Partners in creating a healthier tomorrow

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 +

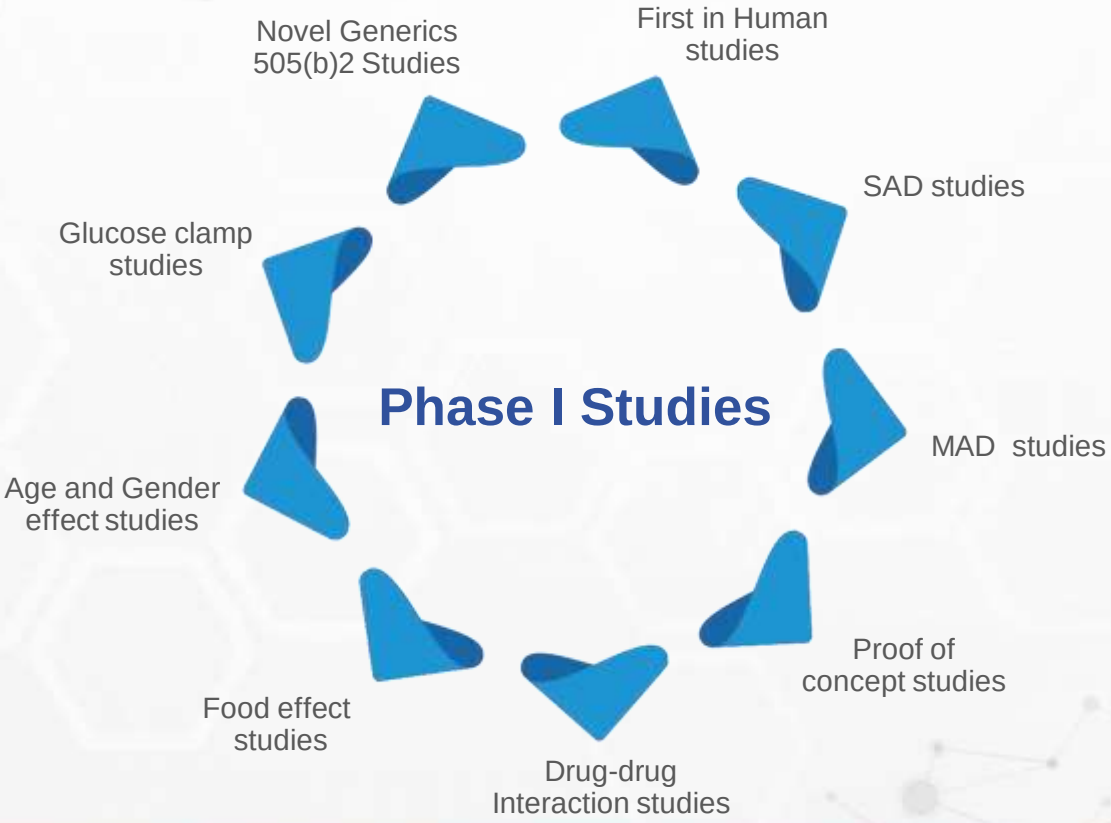
18 Intensively monitored beds to conduct Phase I study

Mehsana

162 Beds +

7 Special care beds

Phase I Trial Experience



Clinical Trial Services

Patient based PK end point studies experience

Therapeutic Areas and Indications	No. of Studies	No. of Patients	Type of Study
Antiviral			
HIV	1	48	PK Endpoint Study
Oncology			
Chronic Myeloid Leukemia (CML)	6	160	PK Endpoint Study
CML & Gastrointestinal stomal tumor (GIST)	1	40	PK Endpoint Study
Metastatic Breast Cancer (MBC)	3	203	PK Endpoint Study
Metastatic Breast Cancer (MBC) and Colo Rectal Cancer (CRC)	2	99	PK Endpoint Study
Multiple Myeloma (MM)	1	54	PK Endpoint Study
Orthopaedic Cancer	1	58	PK Endpoint Study
Ovarian Cancer	2	120	PK Endpoint Study
Ovarian and MBC	3	202	PK Endpoint Study
Renal Cell Carcinoma (RCC)	3	86	PK Endpoint Study
Psychiatry			
Schizophrenia	7	463	PK Endpoint Study
Rheumatology			
Rheumatoid Arthritis (RA) and Psoriasis	1	42	PK Endpoint Study

Clinical End Point Studies Experience

Therapeutic Area	Completed Studies	Study Phase
Oncology	6	Phase 1, Phase2
Orthopaedic	3	Phase 3
Ophthalmology	1	Bioequivalence Clinical Endpoint

Our Ongoing Patient Trials for Diverse Therapy Area

Study Type	Therapeutic Area	Indication
Phase I/II	Thrombolytic	Acute ST segment Elevation Myocardial Infarction
Pk end point	Oncology	Breast Cancer
Pk end point	Oncology	Advance prostatic cancer
Phase II	COVID-19	mildly symptomatic patients with SARS-CoV-2 Infection (Covid-19)
Pk End Point	Oncology	Ovarian Cancer
Clinical End Point	Ophthalmic	open-angle glaucoma or ocular hypertension
Phase I	Oncology	Solid Tumor
Pk End Point	Hematology	Iron Deficiency Anemia
Pk End Point	Oncology	Breast Cancer
Phase II/III	COVID-19	SARS-CoV-2 Infection in healthy subject

Veeda's Vaccine Study Experience

Vaccine Study (Covid)

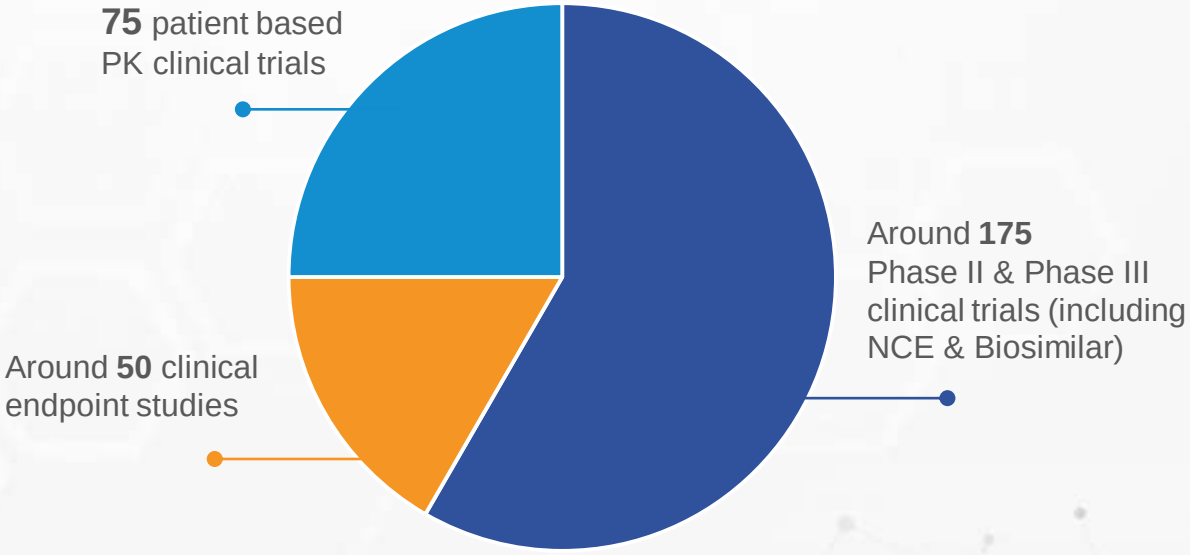
- A randomized, double-blinded, placebo-controlled, parallel-group, multi-centre, adaptive, seamless bridging study followed by a phase II/III study to assess the safety and immunogenicity of Anti-COVID-19 AKS-452 vaccine for SARS-Cov-2 infection in Indian healthy subjects.
- Phase: Bridging phase II/III 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

Combined Team Experience in Clinical Trials

More than **300** clinical trials that includes



Integrated Service Model
Drug Development

- Centre for Biosimilar Excellence Laboratory: Synergy between Somru and Veeda
- Somru BioScience brings in scientific and regulatory expertise in the area of bioanalysis, which includes
- Custom reagent development and qualification,
- Method development and validation
- Pre-clinical/clinical sample analysis
- Technology transfer from Somru [ADA, PK, Nab validated assays]
- Somru supplies all Critical Reagents
- Ingenuity team performs Method Validation and Sample Analysis in consultation with Somru team

Biosimilar Solutions

- **Biocomparability Testing Solutions** — Wide range of Biocomparability testing solutions so that you can test your biosimilar early in the development process and minimize the risk of failure during late phases of the drug development.
- **Bioassay Solutions** — Evaluate functionality of your biosimilar using cell-based assay based on the drug's mechanism of actions such as cell proliferation, cell viability, cell signaling, receptor activation, and ligand binding assays to measure various downstream proteins.
- **Antibody Functionality Testing** — Evaluate antibody function utilizing following assays: ADCC assays, CDC assays, Fc Receptor binding assays (i.e, FcγRI(CD64), FcγRII(CD32a), FcγRIII(CD16a), and FcRn etc.) and C1q binding assays.

Somru Expertise — Breadth and Depth

Innovative Technologies:

- ***mAbY™*** - Recombinant antibody platform
- ***Aegyris™*** - Laboratory Informatics Solutions
- ***Intelli.b™*** - Biosimilar Characterization Solutions

In-depth Experience: approximately 122 validated methods supporting 70 biosimilar/biobetter molecules

Regulatory experience: Global regulatory - US FDA, EMA and Strategy meetings

PK Assay Summary: Biosimilars

Product Name	Cetuximab	Rituximab	Bevacizumab	Trastuzumab	Denosumab	Adalimumab	Ranibizumab
Detection Method	Colorimetric	Colorimetric	Colorimetric	Colorimetric	Colorimetric	Colorimetric	Colorimetric
Precision (%CV)	Intra assay: 4% to 9%	Intra assay: 2% to 6%	Intra assay: 2% to 6%	Intra assay: 8% to 11%	Intra assay: ≤ 10%	Intra assay: 5% to 10%	Intra assay: ≤ 10%
	Inter assay: ≤ 10%	Inter assay: ≤ 5%	Inter assay: ≤ 5%	Inter assay: ≤ 9%	Inter assay: ≤ 15%	Inter assay: ≤ 11%	Inter assay: ≤ 15%
Accuracy (%RE)	less than 7%	less than 6%	less than 4%	less than 7%	less than 15%	less than 8%	less than 15%
Sensitivity	156 ng/mL	55 ng/mL	40 ng/mL	63 ng/mL	25 ng/mL	156 ng/mL	250 pg/mL
Dilutional Linearity	up to 40 fold	up to 1000 fold	up to 40 fold	up to 1000 fold	Data not available	up to 40 fold	Data not available
Hook effect	No (up to 400 µg/mL)	No (up to 500 µg/mL)	No (up to 200 µg/mL)	No (up to 300 µg/mL)	Data not available	No (up to 500 µg/mL)	Data not available

PK/ADA Validated Methods List

Molecule	Validated Method		Reference Product
	PK	ADA	
Adalimumab	✓	✓	Humira
Trastuzumab	✓	✓	Herceptin
Bevacizumab	✓	✓	Avastin
Ranibizumab	✓	✓	Lucentis
Pegfilgrastim	✓	✓	Neulasta
Infliximab	✓	✓	Remicade
Rituxumab	✓	✓	Rituxan
Insulin Glargine	✓	✓	Lantus
Insulin Aspart	✓	✓	Novolog
Aflibercept	✓	✓	Eylea
Etanercept	✓	✓	Enbrel
Erythropoietin	✓	✓	Epogen
Pembrolizumab	✓	✓	Keytruda
Nivolumab	✓	✓	Opdivo
Omalizumab	✓	✓	Xolair
Denosumab	✓	✓	Prolia

Veeda's Biosimilar Experience

Ongoing Studies	Therapy Area	No. Of Patients
Omalizumab		
Filgrastim & Pefilgrastin		
Recombinant FSH		

Our Team's Cumulative Large Molecule Experience

Molecule Name	
Filgrastim	Filgrastim
Erythropoetin	Pegfilgrastim
Denosumab	Tocilizumab
FSH	Teriparatide
Romiplostim	H1N1 Vaccine
Ranibizumab	Covid Vaccine

Veeda's Biosimilar Experience- Ongoing Studies

Omalizumab

A randomized, double blind, two-arm, parallel group, single dose comparative pk, pd and immunogenicity study comparing adl-018 lyophilized powder with us-licensed xolair lyophilized powder administered through subcutaneous route in healthy adult subjects

- 120 subjects (60 in each treatment arm) (+ stand by subjects)

A randomized, double blind, three-arm, parallel group, single dose comparative pk, pd, safety and immunogenicity study comparing adl-018 with us-licensed xolair and eu-approved xolair administered through subcutaneous route in healthy adult subjects

- 306 subjects (102 in each treatment arm) (+ stand by subjects)

Pegfilgrastim

A Two-Part, Randomized, Double-Blind, Single-Dose, Three-Period, Crossover Study Evaluating the Pharmacokinetics (PK), Pharmacodynamics (PD), Safety, and Immunogenicity between BSC-0826 and US-licensed Neulasta and EU-approved Neulasta Part 1, and Randomized, Double-Blind, Two-Dose, Parallel Arm Study Evaluating the Safety and Immunogenicity in Part 2 of BSC-0826 to EU-Neulasta following Subcutaneous Administration to Healthy Subjects

- **Part 1:** A total of one hundred and eighty-six (186) healthy adult male and female subjects will be enrolled. Study will be conducted in multiple groups.
- **Part 2:** Two hundred and forty (240) healthy, adult male and female subjects will be enrolled (120 subjects per treatment arm).

Veeda's Biosimilar Experience- Ongoing Studies

Filgrastim

A Two-Part, Randomized, Open-Label, Single-Dose, Multiple-Dose, Parallel Arm Study Evaluating the Pharmacokinetics, Pharmacodynamics, Safety and Immunogenicity of Biosimilar Sciences Filgrastim (BSC-1020) to Neupogen Following Subcutaneous Administration to Healthy Subjects

- **Part 1:** A total of two hundred and one (201) healthy adult male and female subjects will be enrolled. Subjects will be randomized to 1 of 3 treatment groups (67 subjects per treatment).
- **Part 2:** A total of one hundred thirty four (134) healthy adult male and female subjects will be enrolled. Subjects will continue the study from Part 1 to Part 2 for Treatments A and B (67 subjects per treatment).

Recombinant Follicle Stimulating Hormone

A Randomized, Open Label, Balanced, Two-Treatment, Two-Period, Two-Sequence, Single Dose, Crossover, Bioequivalence Study of Foligraf 900 IU (66.0 µg) / 1.5mL Solution for Injection in Prefilled Pen [Follicle Stimulating Hormone (Human Recombinant)] of Bharat Serums and Vaccines Limited, India and GONAL-f 900 IU (66.0 µg) / 1.5 mL solution for injection in pre-filled pen of Merck Serono at a dose of 300 IU in Healthy, Adult, Female, Human Subjects.

- In regards to ensure 36 completer subjects for the study, up to 72 healthy, adult, female, human subjects will be enrolled in the study.

Vaccine 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

Overview of Biosimilar Lab - Infrastructure

- Ingenuity Biosciences has state-of-the-art Biosimilar laboratory Bioequivalence study center co-located with Insignia site of Veeda clinical research

Equipment & Software	No.
Microplate Reader	1
Microplate Washer	2
BOD Incubator	1
Deep Freezer (-20°C ± 5°C)	1
Refrigerator	1
Aegyris Software	1

Biosimilar Lab Infrastructure

Microplate Reader

Synergy™ H1 is a flexible monochromator-based multi-mode microplate reader that can be turned into a high-performance hybrid system with the addition of a filter-based optical module. The monochromator optics use a third generation quadruple grating design that works at any excitation or emission wavelength with a 1 nm step.

Microplate Washer

The 50™ TS Washer offers functionality that is unsurpassed in its class. The color touchscreen provides a visual interface that makes creating protocols fast and intuitive. Its performance for conventional plate washing is excellent, and it is also ideal for cell-based assay washing and for processing biomagnetic or polystyrene bead and vacuum filtration protocols.

BOD incubator

BOD Incubator (Bio-Oxygen Demand) are used to maintain temperature for test tissue culture growth, storage of bacterial cultures and incubation where high degree of constant temperature accuracy is required. Thermolab BOD Incubators provide with accurate conditions and uniformity throughout the chamber.

Critical Instruments and Monitoring

- BD FACSLyric Flow cytometer
- Shimadzu Nexera UHPLC and HPLC
- Q Exactive Orbitrap Mass Spectrometer -LC-MS/MS
- ICP-MS
- 2D Electrophoresis- BioRad
- Plate Readers Softmax Pro and Biotek
- Real time PCR- Thermo Fisher
- Bioreactors (5 lts)
- Ekta Purification system
- Gas Chromatography
- Stability Chambers

Qualified instruments, Software validated and 21 CFR Part 11 compliance

LC MS Capabilities

Q Exactive Orbitrap Mass Spectrometer

Make : Thermo Fisher Scientific Inc

Model : Q Exactive Basic

UHPLC – Front End

Make : Shimadzu Corporation

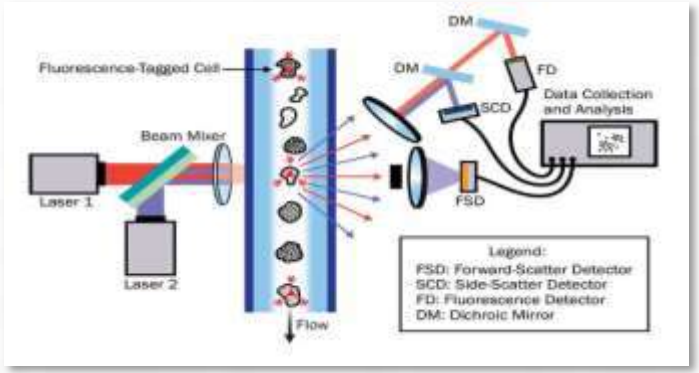
Model: Shimadzu Nexera

Software components

Xcalibur 4.0.27.19 (Thermo Fisher Scientific Inc.)

Biopharma Finder 2.0 Data Analysis Software

Flow Cytometry



- Flow cytometry is a technique that can provide quantitative and qualitative information about biological cells and micro particles.
- The information is in the light that interacts with the cells as they pass one after another and one at a time through a narrow region illuminated by one or more lasers.
- Its design consists of fluidics, illumination optics, photo detection, data analysis, and, in some models cell sorting.

BD FACSLyric™ Flow Cytometry System

Specifications of the system:

- 3 lasers - Blue, Red and Violet
- 12 fluorescence channels and 14 parameters.
- Acquisition rate: 35,000 events per second maximum
- Loading options: plates or tubes: Automated loader can accommodate 30 tubes and 96-well plate
- 21 CFR Part 11 compliant BD FACSuite™ data management software (BD FACSuite-Version No.: 1.4)

Applications

- Study specific cell populations and sub-populations analysis
- Cell proliferations, Cell death and intracellular proteins analysis
- Cell surfaces markers Analysis (Example: CD54, CD86, CD3, CD4, CD8, CD14, CD 43, CD 34, CD19, CD20, CD56 etc.)
- Analysis of certain functional immune characteristics, biological effects associated with particular immune defects
- Bead-Based Multiplexed Assay for Simultaneous Quantification of intra cellular cytokines and secreted cytokines using specific fluorescence-labeled antibodies.

Bioanalytical Research

LCMS Capabilities

Particulars of Capability	Drug Product
Intact/Subunit mass / reduced Mass	Proteins, Protein Conjugates, Peptides
Modifications at intact mass level	Monoclonal Antibodies , Proteins
Peptide Mapping and sequence coverage	Monoclonal Antibodies , Proteins
N Terminal and C Terminal sequence analysis	Monoclonal Antibodies , Proteins
Disulfide bonding analysis	Monoclonal Antibodies , Proteins
Glycan profiling of mAbs	Monoclonal Antibodies

Infrastructure

Scale and Range

- **46 LC-MS/MS** machines
  - Insignia (33) and Vedant (13)
  - API 5500/4000/3200/3000/2000
  - Shimadzu 8060/8050/8040
  - Quattro Premier
- **2 ICP-OES**
- **Watson LIMS**

Storage Capacity

Plasma Sample:

45 Deep freezers with capacity to store 11,25,000 samples at -80 ℃

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 ℃

Large Molecules Bioanalysis

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%

Central Bioanalytical Lab Experience

Handling Complex study - 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

Our Broad Experience for NCE molecules with Global Pharmaceutical company

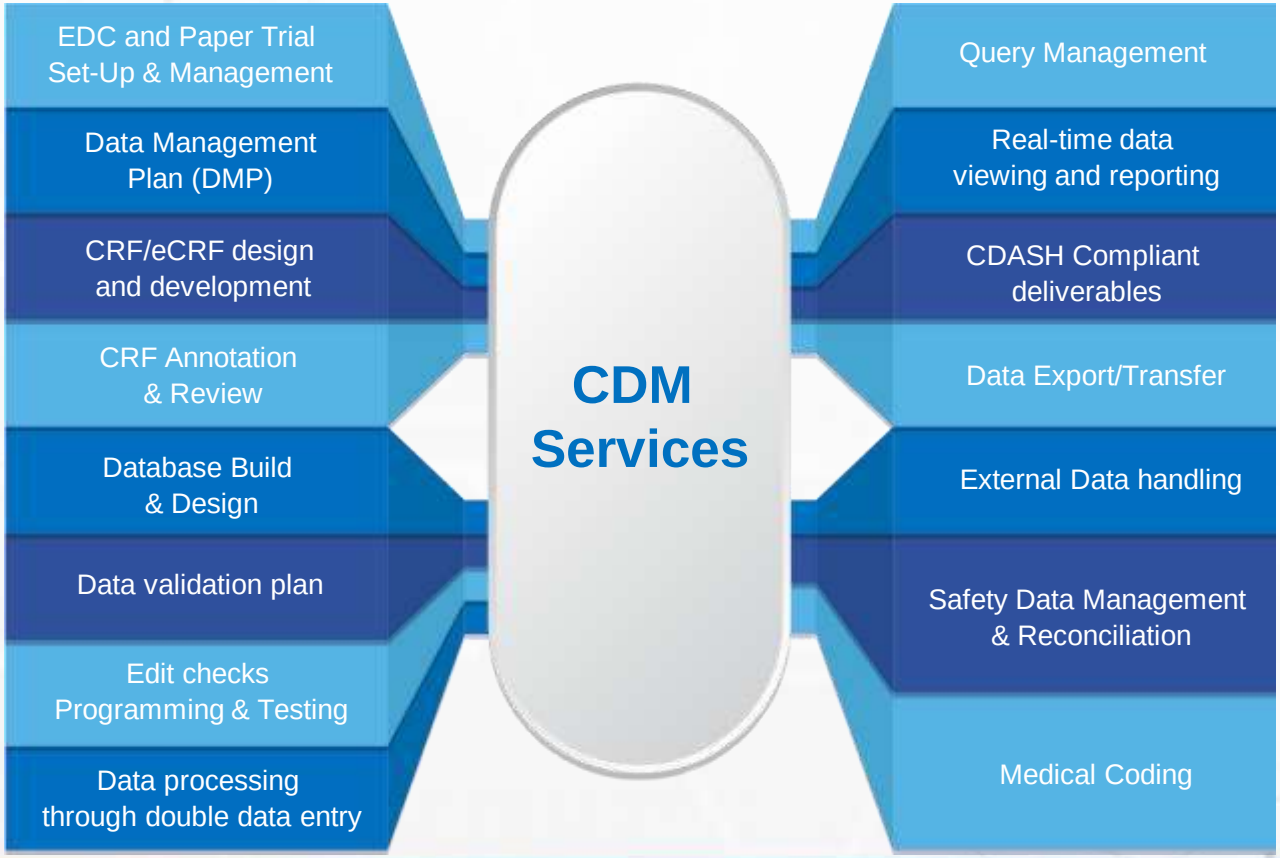
- Total studies : More than 40 studies ongoing (from Multisites globally, 20000 samples per year)
- Services provided: Sample management, method development, method validation and analysis of NCEs
- Sample receipt to analysis within 5 days
- Sponsor specific reports with e-CTD
- More than 64 methods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

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.

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

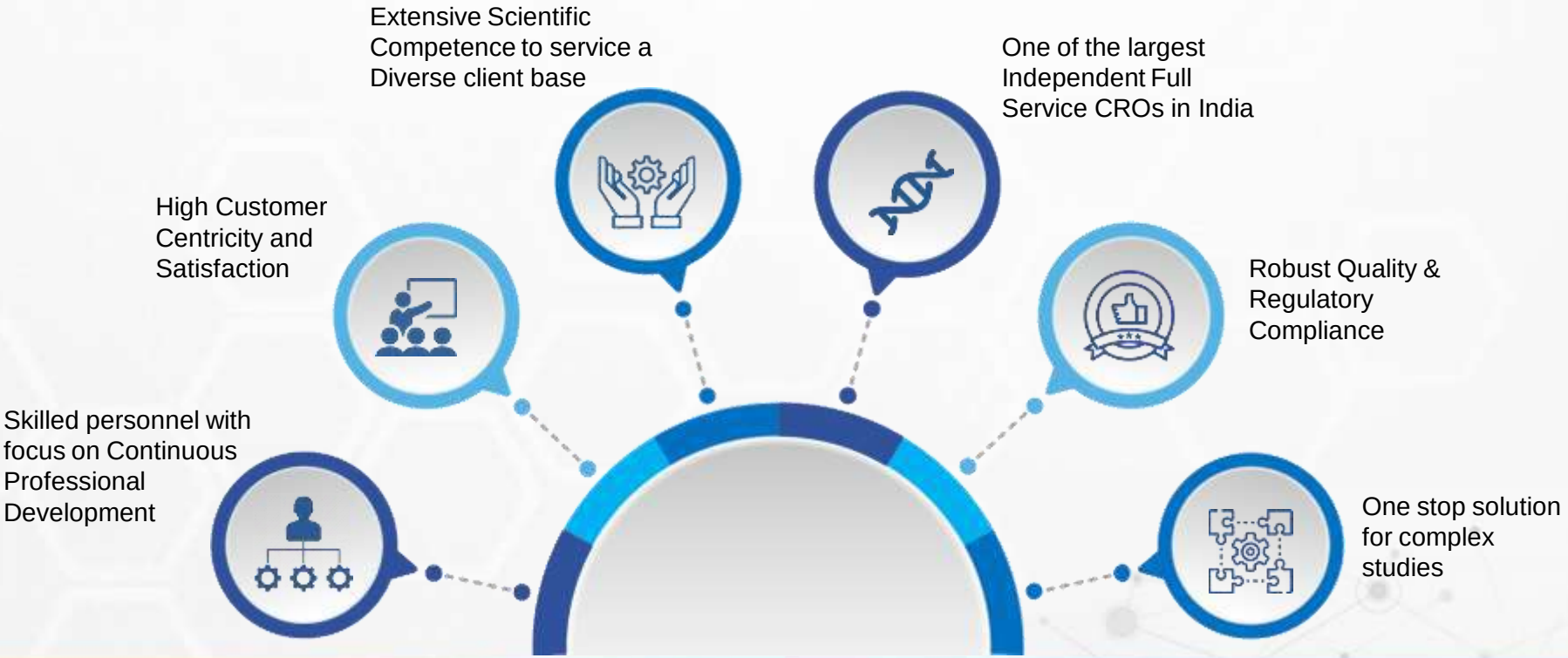
2019

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