



Table Of Contents

- Corporate Overview
- Bioanalytical Research
- Central Lab
- Complex Method
- Why Veeda Group



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



Current Geographical Presence



Team Presence

Corporate Philosophy



Vision

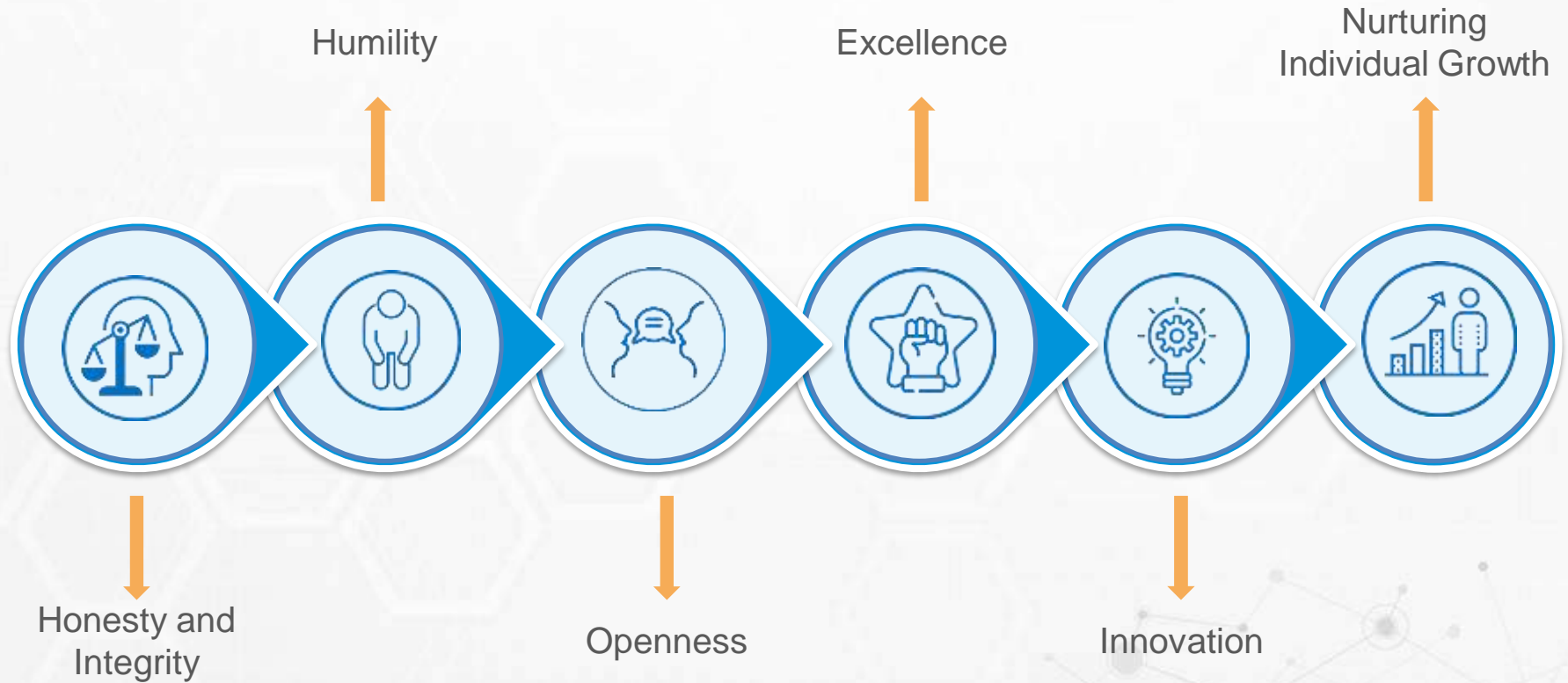
In an industry where innovation is increasingly multifaceted and collaborative, we aspire to be the research partner of choice for innovative (bio)pharmaceutical companies worldwide for their critical product development programs



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



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



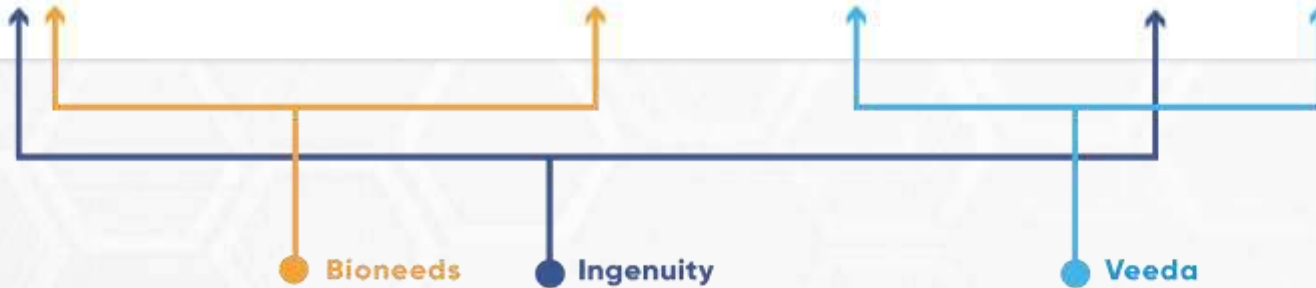
Phase I to Phase IV Clinical Trials



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™

Bioanalytical Research - Veeda

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 °C



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 °C

Team



Function

15
Senior Scientists



210
Operation

23
QC

15
Report and LIMS

Education

219
Post Graduate



6
Ph. D.

36
Graduate

Experience

Capabilities

Total available Bioanalytical methods are more than 1040

876 + 20

Generics +
Pharmacodynamics/
Immunogenicity

77

Complex
Generics

68

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 Lab



Central Bioanalytical Lab Services



- **Central Lab Services**

- Project Management (COD)
- Analyte Testing
- Kit preparation and supply
- Sample Storage & Management
- Linking between clinical site and diagnostic laboratories (COD)
- Data management (PK data – Analyte)
- Training - Investigator sites and study teams (Lab Manual-- PK sample collection and Shipment)

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 Services



How we can benefit our clients?

- We can offer all services including protocol preparation, project management, data management, lab manual preparation, analysis to report preparation for multi site studies (BA-BE studies).
- Optimize sample collections (blood volume) for protocol.
- Resolution of queries (sponsor and regulatory).
- PK sample reconciliation.
- Protocol and Analysis with respect to current regulatory requirements.
- Support for PK samples collection with specialized requirement e.g. buffer addition, temperature controlled sample handling.
- Lab manual Preparation- Preparation of lab manual which includes sample collection procedure and sample handling and distribution to all sites.

Central Bioanalytical Lab Experience



BIONEEDS



- **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

Complex Methods Experience

1. Methods for Endogenous Compounds:

- Levothyroxine
- Hydrocortisone
- Isotretinoin
- Estrone (total)
- Estrone (Unconjugated) +Estradiol (Unconjugated)
- Trans and Cis –Phytonadione (Geometric isomers)
- Free Thiamine

2. Methods for Enantiomers (Chiral Methods):

- R & S Ibuprofen
- R-SSS & S-RRR Nebivolol
- R-trans & S-trans Tranylcyproamine
- R & S Ketoprofen
- R & S Lercanidipine
- R & S Warfarin
- R & S Praziquantel
- R & S-Metoprolol

3. Methods for Elemental Analysis (By ICP-OES):

- Potassium (from Potassium Chloride)
- Lithium (from Lithium Carbonate)
- Total iron and Transferrin Bound Iron (from Iron Sucrose)
- Magnesium (from Magnesium glycerophosphate)
- Zinc (from Zinc Acetate)

Complex Methods Experience



- **Liposomal Doxorubicin and Amphotericin :** Challenging method in terms of preventing leaching of doxorubicin from liposome while storage and analysis. Analytes to be measured are free and liposomal.
- **Amino Acids Analysis:** Separation of 20 amino acids and their quantification
- **Paclitaxel:** Estimation of protein free (unbound) paclitaxel by filtration through ultrafiltration device.

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 - α 1 Acid Glycoprotein – AAG:** Method HPLC-UV, large molecule (biomarker) validated method for clinical support.

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

2018

2020

2017

2019

| 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

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

