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 Values

Humility

Innovation

Accountability

Integrity

Excellence

Collaboration

Nurturing Individual Growth

Regulatory Credentials

- 92 successful regulatory audits till date
- 09 successful regulatory audits in last five months

US FDA	→	45*	ANSM	→	1
MHRA	→	4	AGES	→	4*
ANVISA	→	8	MCC	→	1
WHO	→	6	DCGI	→	18
NPRA Malaysia	→	5			

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

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

veeda clinical research

BIONEEDS

veeda clinical research

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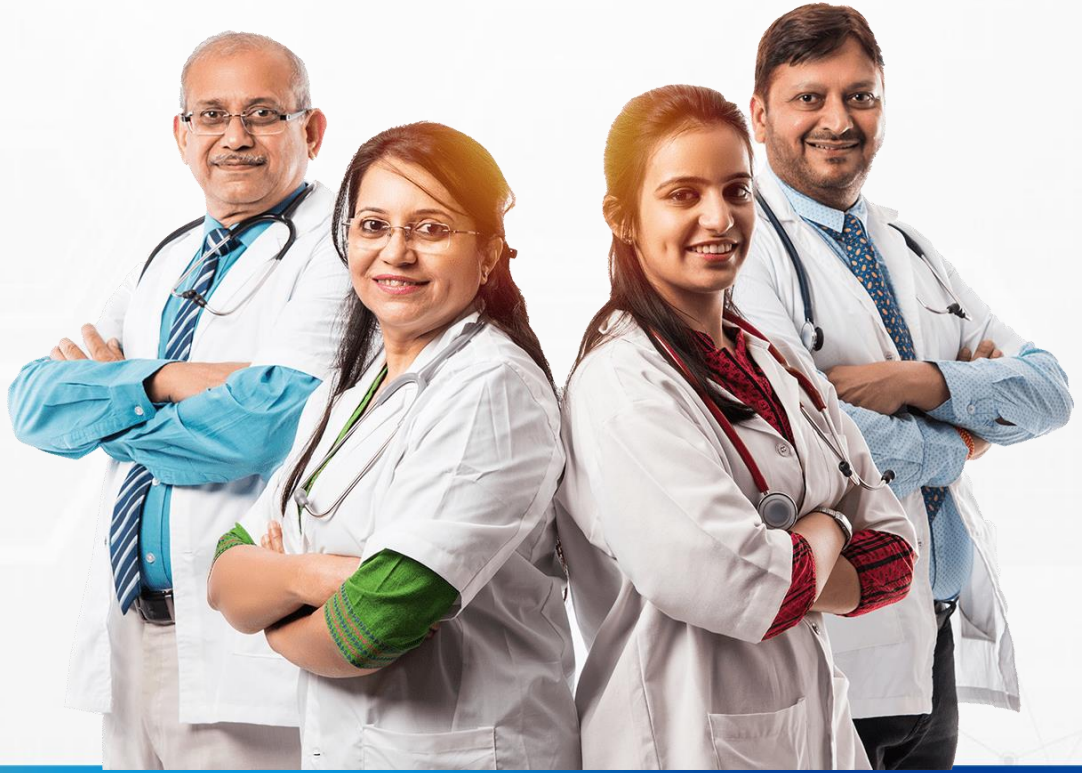
Early to Late Phase Clinical Trials



Partners in creating a healthier tomorrow

Infrastructure

- **VEDANT**

  Clinical,
  Bio-analytical facility

- **STAYAMEV**

  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 +

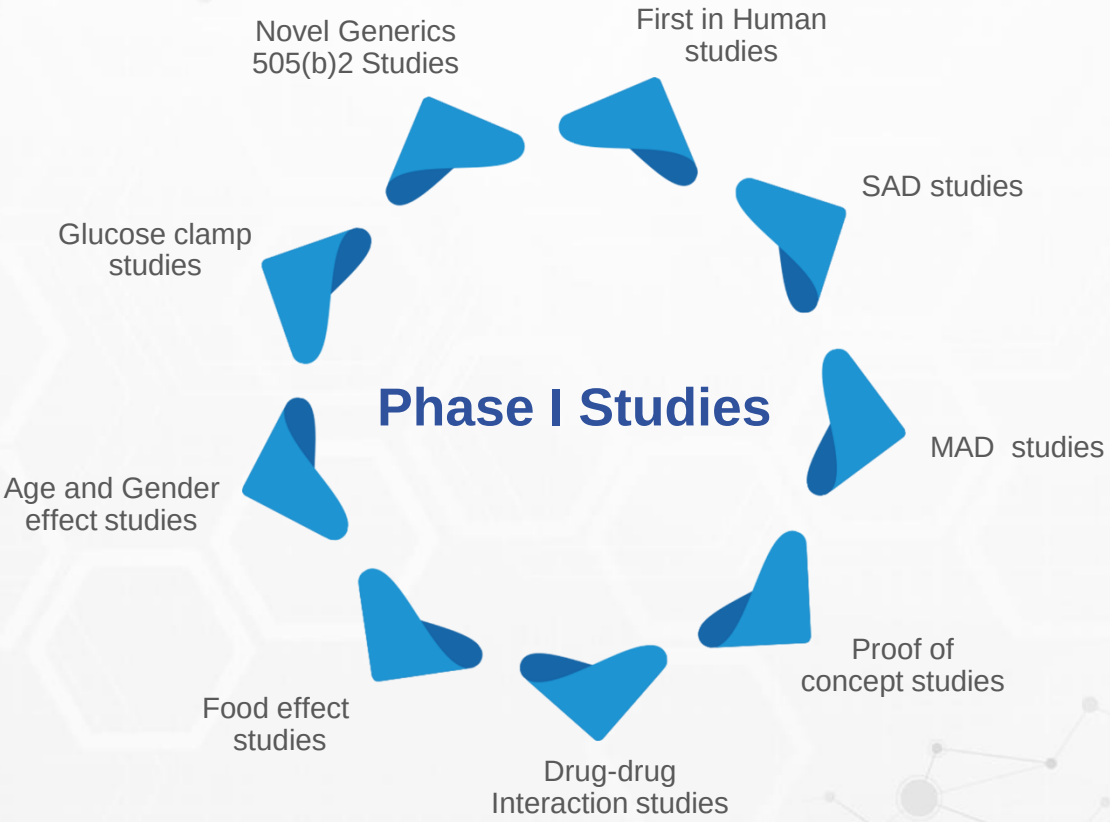
18 Intensively monitored beds to conduct Phase I study

Mehsana

162 Beds +

7 Special care beds

Phase I Trial Experience



Patient based PK end point studies experience

Antiviral
(HIV)

1 No. of Studies

48 No. of Patients

Oncology
(CML,GIST,MBC, MM,RCC)

22 No. of Studies

1022 No. of Patients

Psychiatry
(Schizophrenia)

9 No. of Studies

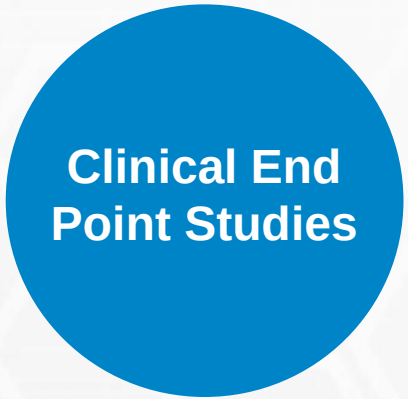
463 No. of Patients

Rheumatology
(RA and Psoriasis)

2 No. of Studies

42 No. of Patients

Clinical End Point Studies Experience



Oncology

- 6 – Completed Studies
- Phase I, Phase II

Orthopaedic

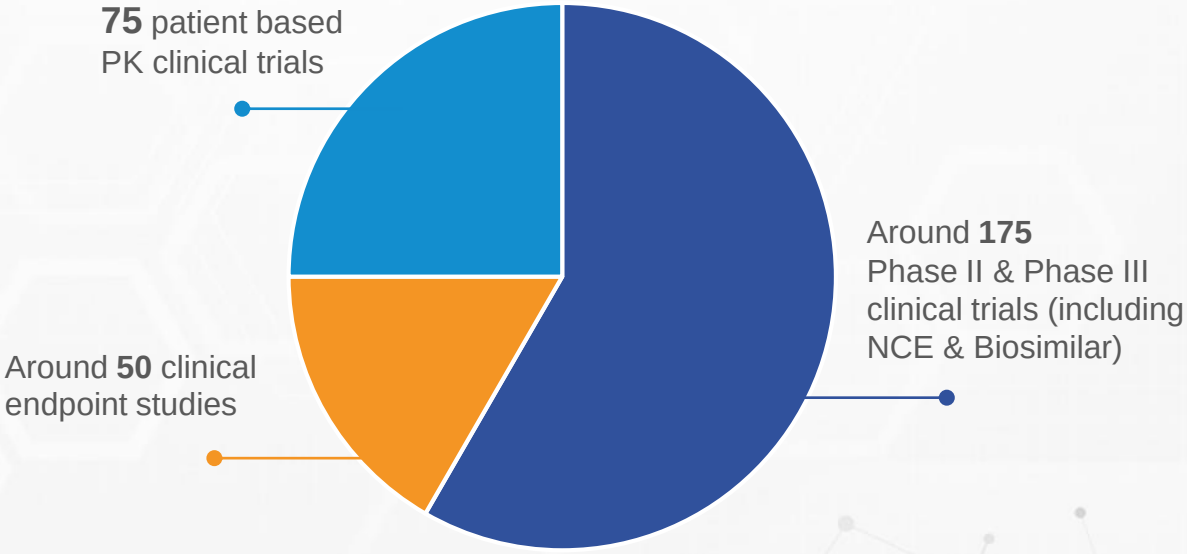
- 3 – Completed Studies
- Phase III

Ophthalmology

- 1 – Completed Studies
- Bioequivalence Clinical Endpoint

Combined Team Experience in Clinical Trials

More than **300** clinical trials that includes



Veeda's Clinical Team Large Molecule Experience

Biosimilars

- Omalizumab (I)
- Denusomab (III/IV)
- Tocilizumab (I)
- Ranibizumab (III/IV)
- Vedolizumab (I)

Therapeutic Protein

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

Veeda's Clinical Team Vaccine Experience

- **112** No. of sites in database
- **28** No. of sites in active touch base
- **7** No. of sites presently working

Vaccine Name	Type	Phase
COVID Vaccine	Healthy	II/III
Pneumococcal Vaccine	Healthy	III
Rotavirus	Healthy	III

Pipeline		
Vaccine Name	**Type**	**Phase**
Covid Vaccine	Healthy	I/II

Biosmilar Studies Conducted in Veeda

Molecule	Study Title	Market Submission	Phase	Type	No. of Subjects
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	USFDA	I	Healthy	204 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	USFDA	I	Healthy	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).

Biosmilar Study Conducted in Veeda

Molecule	Study Title	Market Submission	Phase	Type	No. of Subjects
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	USFDA	I	Healthy	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)] with 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.	EU	I	Healthy	In regards to ensure 36 completer subjects for the study, up to 72 healthy, adult, female, human subjects will be enrolled in the study.

Biosmilar Study Conducted in Veeda

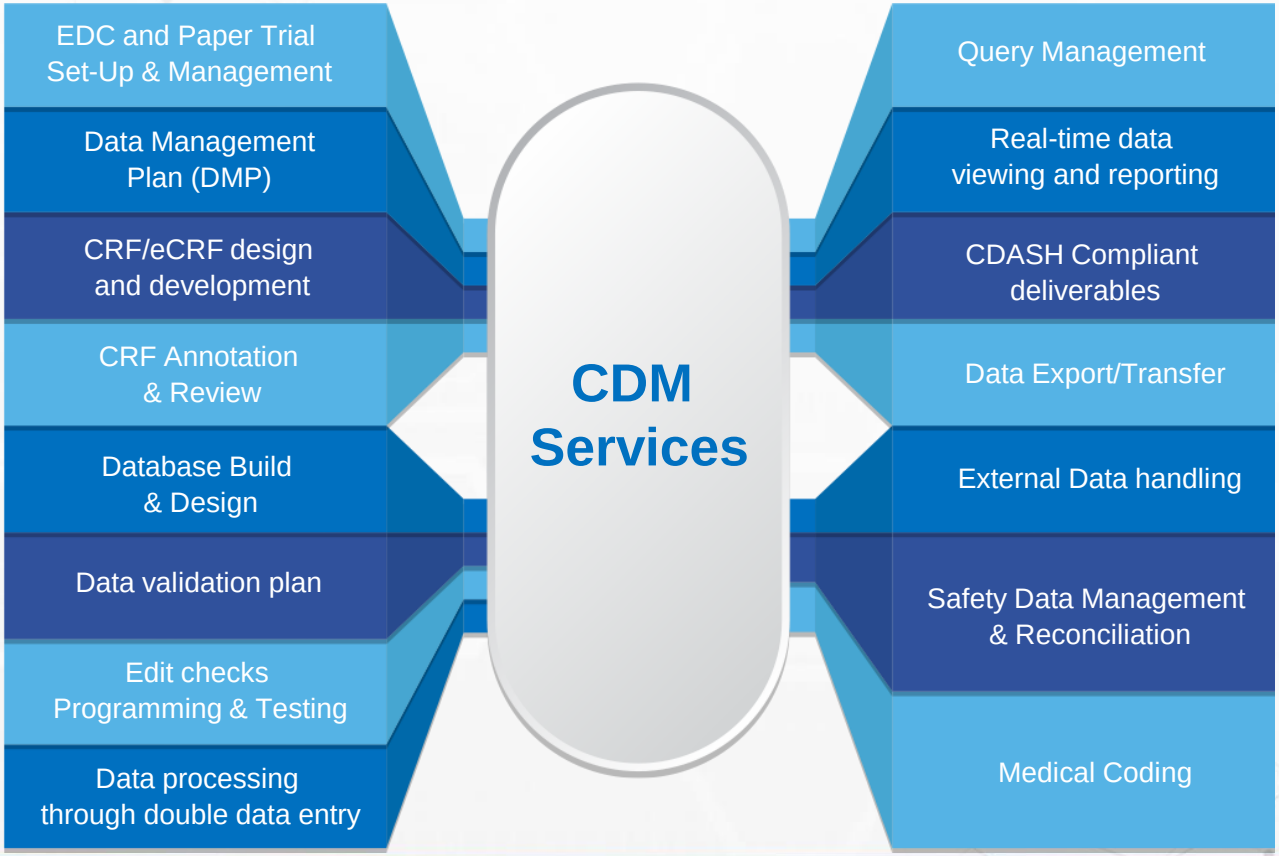
Molecule	Study Title	Market Submission	Phase	Type	No. of Subjects
Vedolizumab	A Single Dose, Double-Blind, Parallel Arm, Comparative Pharmacokinetic Study of Test VZ with US approved Reference Vedolizumab (Entyvio®) and EU approved Reference Vedolizumab (Entyvio®), Administered by the Intravenous Route to Normal Healthy Male Volunteers	USFDA/EU	I	Healthy	132 subjects
Darbepoetin	A Single Dose, Double-Blind, Two-Period, Crossover, Balanced Sequences, Comparative Pharmacokinetic Study with Separate Comparisons of Three Pairs of Products of Test Darbepoetin), US licensed Reference Product (Aranesp®), and EU approved Reference Medicinal Product (Aranesp®), Administered by the Subcutaneous Route to Male Healthy Volunteers.	USFDA/EU	I	Healthy	194 subjects

Vaccine Study Conducted in Veeda

Molecule	Study Title	Phase	Type	No. of Subjects	Sites
Covid Vaccine	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	Bridging phase II/III study	Healthy	100 (Bridging) 1500 (Phase II/III study)	12

Pipeline		
Vaccine Name	**Type**	**Phase**
Covid Vaccine	Healthy	I/II

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

Bioanalytical Capabilities

Introduction to Bioanalytical Solution

A Global CRO

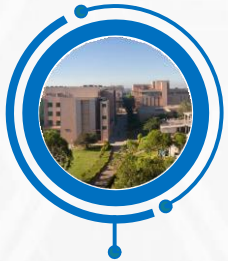
- Integrated Early and Late Stage Drug Development and R&D Scale Manufacturing solution provider
- Large Molecules: Novel Biologics, Biosimilars (mAbs), Peptides, Vaccines, ADCs, Therapeutics Proteins

IP Position

- IP assigned to clients
- Strong track record of Data Integrity and Security

Quality Focus

- Quality driven organization
- Excellent track record of compliance with global regulators



Scientific Ecosystem

- State of art facility with 50000 Sq.ft campus
- 45+ strong scientific team
- Experienced in global Pharma and Biotech companies

Clientele

- Partnering with large / mid-size / emerging BioPharma (EBP) and other industries
- Clients concentrated in US, Europe, APAC

Integrated and/or standalone Drug Development Solutions

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Biopharma Unit

Clinical Trial Samples

Clinical Bioanalytical

- **Vaccines**
  - Bacterial, Viral/ VLP vaccines
    - Primary end-point analysis, Neutralizing antibodies, Serum Bactericidal Assay,
- **Biologics**
  - NBE/Peptides
    - Clinical Biomarkers, In-vitro PD, etc.
  - Biosimilar/Bio-better
    - PK, ADA, PD, Cytokine response, Nab, etc.

Non- Clinical Characterization

- **Upstream/ Downstream**
  - Lab-scale manufacturing and purification, Cell-line characterization and qualification
- **Structural Characterization**
  - Primary Structure, Higher Order Structure, Glycosylation, Product/ Process-related variants, Impurities
- **Functional Characterization**
  - Cell-free analysis, Cell-based MoA, Label free Binding Kinetics, Flow cytometry/ Luminex based analysis
- **DMPK/ADME**

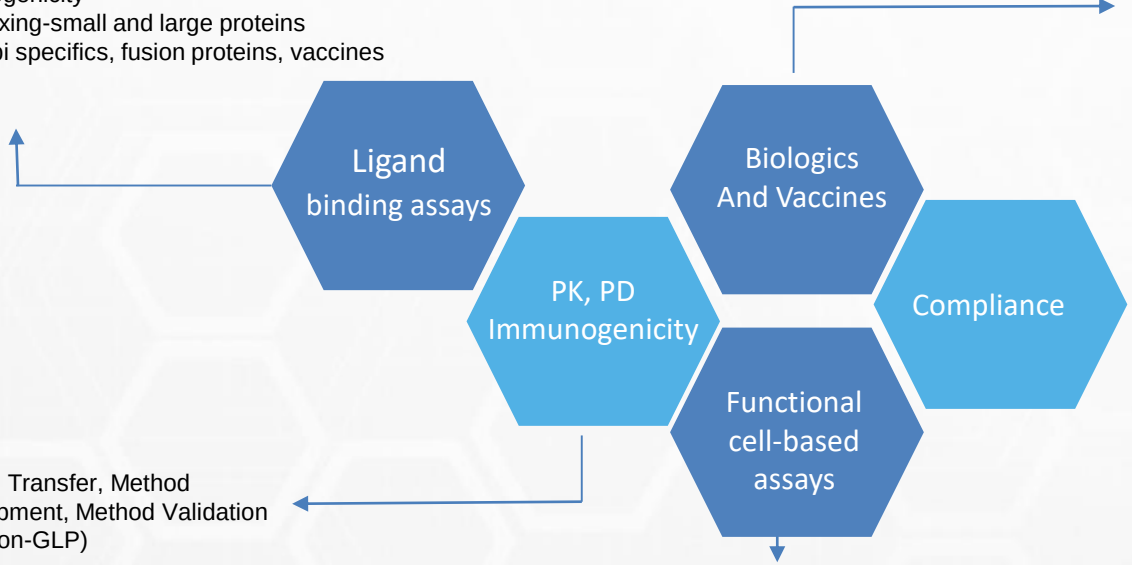
Associated Support Functions:

1. **Central Lab / Sample Accession**
2. **QAU**
3. **Quality Control**
4. **Archives**

Large molecule bioanalytical – OECD GLP Compliant laboratory

Immunoassays for PK, PD, Immunogenicity and Biomarkers

- Ligand binding assays for PK, PD and
- Immunogenicity
- Multiplexing-small and large proteins
- MAbs, bi specifics, fusion proteins, vaccines etc.



- Develop matrix specific methods
- ELISA, MSD, SPR, Cell based
- Validate for intended use
- Setup analysis for animal and human studies
- Immunogenicity and seroconversion

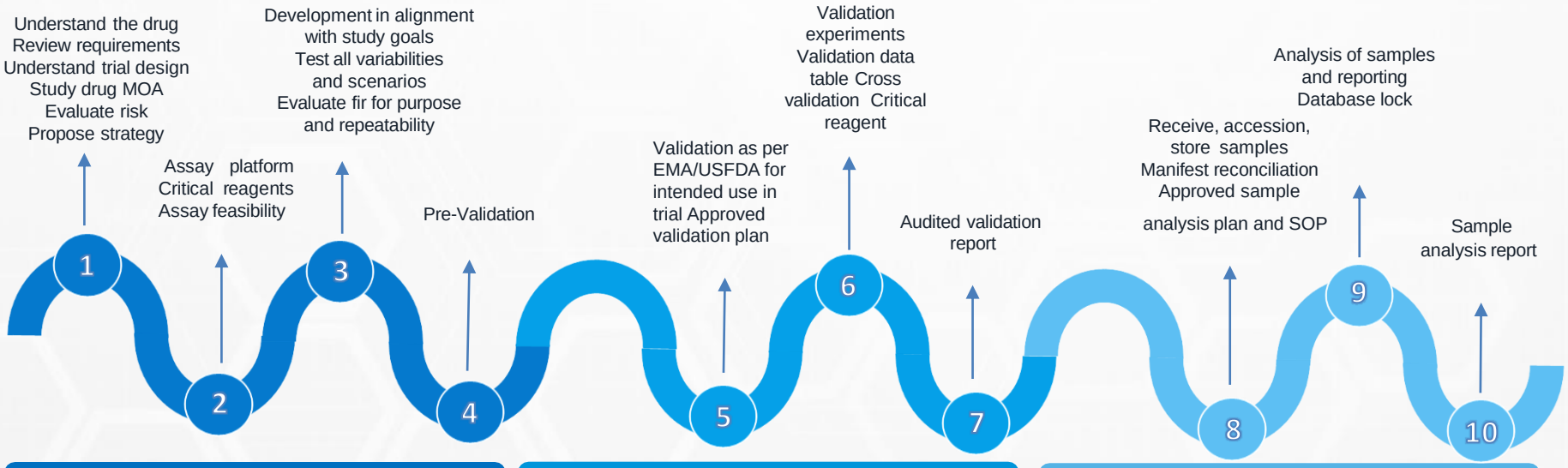
- GLP, EMA and USFDA guidance
- adherence in assay
- development/validation
- Inspected by FDA
- scientific teams

- Method Transfer, Method
- Development, Method Validation
- (GLP/non-GLP)

- Invitro Functional neutralizing antibody assays
- Potency assays for biological activity,
- characterization and comparability

Regulated Assay Transfer/Development/Validation

The journey of an assay from concept to data is well planned & monitored throughout the assay lifecycle



*4 weeks

*4 weeks

*QC data in 10 days from shipment receipt

GLP SOPs, SD allocation, Analyst training, QC, QA, WATSON LIMS, Project management

** Estimated timelines for non cell based methods*

Veeda Team 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 Conducted in Veeda

- 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 Study Conducted in Veeda

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

Recognitions

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Celebrating
19 YEARS
of excellence in Clinical Research

2004

2017

Organization	Award Category
Praxis Media	National Excellence Award
AI Global	Best Pharmaceutical CRO
Health & Safety Awards	Best Clinical Research- India
[illegible]	Best Clinical Research- India
[illegible]	Mark of Excellence
FROST & SULLIVAN	Indian Clinical Research company of the year

2018

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

2019

Organization	Award Category
[illegible]	Best Quality Clinical Research Organization in India
[illegible]	Best Quality Clinical Research Organization in India
[illegible]	Indian Clinical Research company of the year

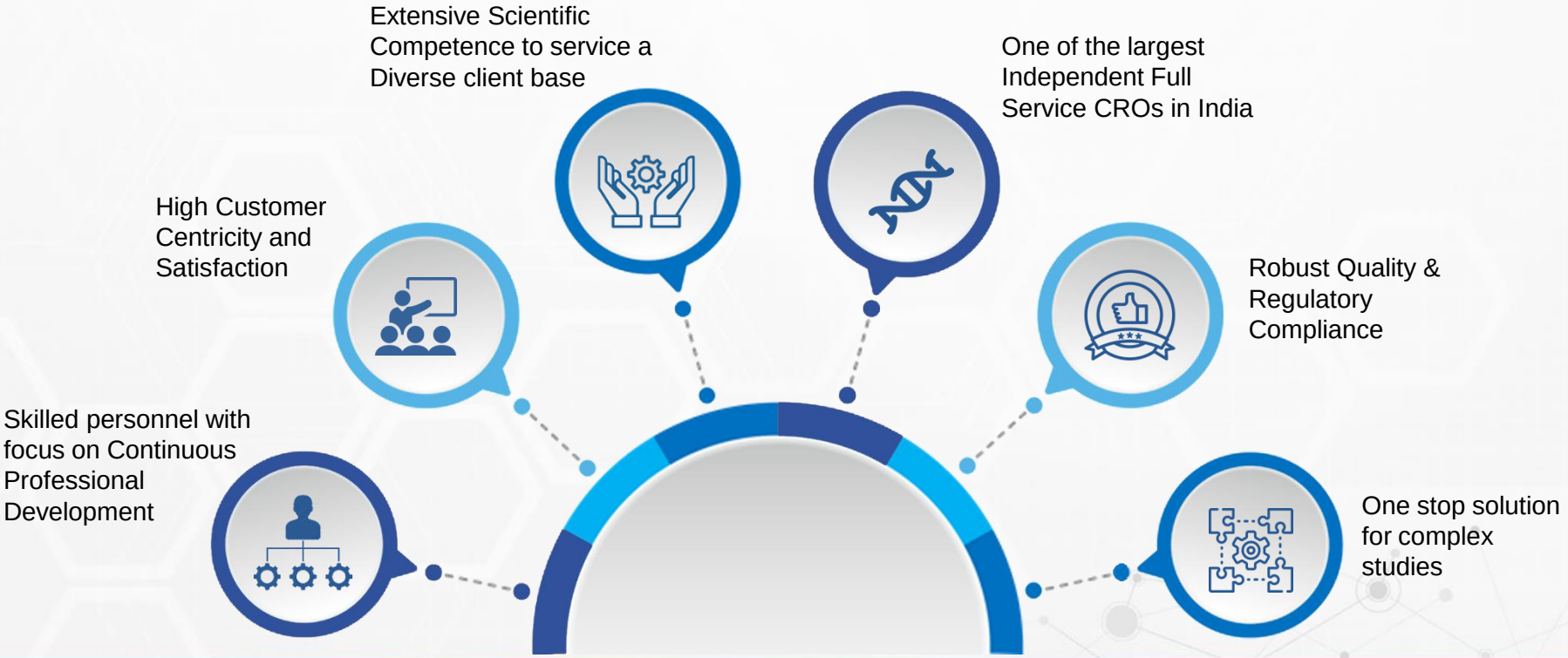
2020

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

2022

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

Veeda Group Advantage



THANK YOU

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

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a healthier tomorrow