veeda clinical research®

BIONEEDS

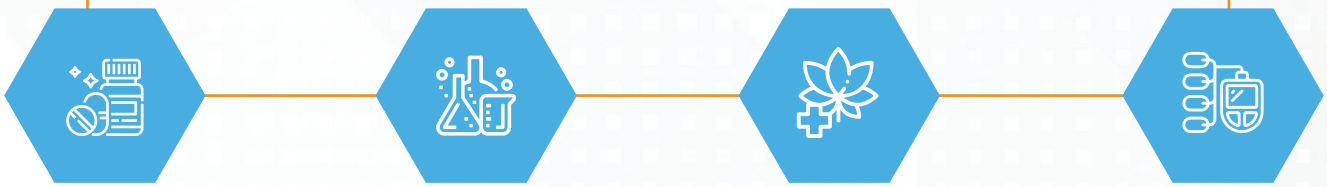
Ingenuity BioSciences

A Capable, Knowledgeable and Reliable partner for your drug development journey

Veeda Group Overview

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 Bio-pharmaceutical**
- **Agrochemical and Industrial Chemicals**
- **Herbal/ Nutraceuticals**
- **Medical Devices**

The group entities offers distinct services, both as independent modules as well as integrated services

Assisting you the right way in your end-to-end Drug Development Journey

Drug Discovery

Analytical Characterisation for Biosimilar

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

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

Regulatory Services

Bioneeds

Ingenuity
Large Molecule Bioanalysis

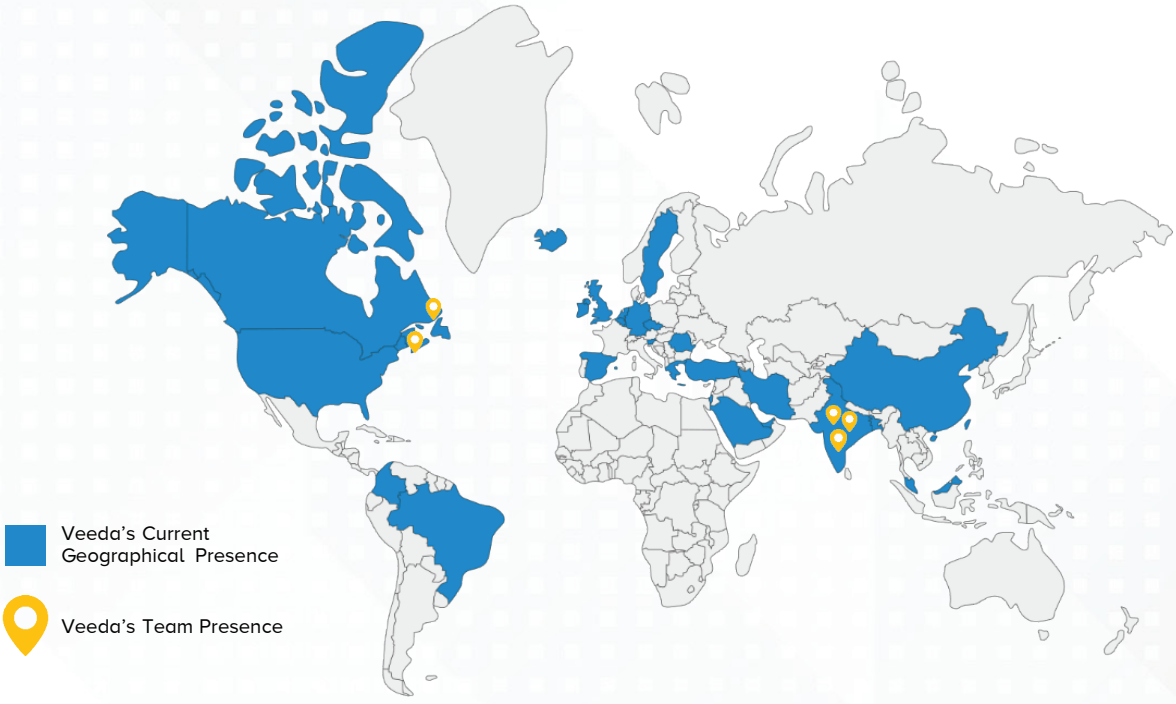
Veeda

Veeda Clinical Research

One of the leading independent Clinical Research Organizations in India

Veeda has state-of-the-art clinical research facilities, resources and scientific expertise for investigator led and commercially sponsored large scale healthy volunteer & patient based trials that offer faster turnaround time with end-to-end clinical research support.

Global Footprint



We provide access to Expertise & Knowledge that enables global (Bio)pharmaceutical companies to develop their new products

Our end to end services complement the research and development and marketing functions of global (Bio)pharmaceutical companies. Outsourcing these services to us enables our clients to move their molecules from preclinical development to clinical, and eventual commercialization in a timely and efficient manner

Infrastructure Capabilities

- **VEDANT**
  Clinical,
  Bio-analytical facility
- **MAGNET CORPORATE PARK**
  Administrative office
- **SKYLAR**
  Common screening facility for both Shivalik and Vedant
- **INSIGNIA**
  Dedicated Bio-analyticalfacility
- **SHIVALIK**
  Dedicated Clinical facility
- **MEHSANA**
  Clinical and Screening 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

Our Solutions Include

- Study Design & Study Conduction
- Project Management
- Medical Affairs
- Bio Analytical Services
- Data management & Biostatistics
- Regulatory Guidance

Veeda Edge: Our Expertise & Capabilities in handling BA/BE (Bioavailability & Bioequivalence) Studies

Generic Drugs Capabilities

End-to-End BA/BE study development and execution (pilot and pivotal) towards ANDA submission for different regulatory authorities like USFDA, EMA, ANVISA, Health Canada, WHO, MHRAUK, CDSCO and many more

Toxicity testing for special products, Impurity synthesis & LCMS characterization, Invitro microbial kill rate study, generic drug stability testing

505(b)(2) method development and submission for branded generics, orphan drugs, prodrugs, and Drug Efficacy Study Implementation (DESI) drugs

Our experience in Healthy Volunteer (BA/BE) Studies

- **2046 Pivotal**
  14 FTF Studies
  88 Complex Clinical Studies
- **1318 Pilot**
- **752 Standalone Bio-Analytical**

57 Special Studies both Pilot and Pivotal BA/BE

- 13 Glucose Clamp studies (810 Clamp)
- 28 Inhalation Studies
- 6 Suppositories Studies
- 10 Patches Studies
- 26 Phase I Studies
- 1 Phase II Studies

Strong Bioanalytical Capabilities to keep your study on track

- Method development and validation for a wide range of drug substances
- Chiral Molecule Analysis
- Hormones and vitamin analysis
- Optimized acceptable methodology for endogenous moieties, unstable drug & metabolite(s) and chiral separation
- Trained Bio analysts to handle complex sample processing
- State of the art Bio analytical Lab equipped with high-end sensitive equipments to achieve the required LLOQ
- 100% data review by Bio-analytical Quality Monitors
- Capability to develop methods with the lowest quantification level- up to 0.1 pg
- Average processing capacity of 1,00,000 samples per month
- More than 1100 available Bioanalytical Methods for NCEs, Generics, Complex Generics, Large Molecule Assays, & Pharmacodynamics/Immunogenicity

Total available Bioanalytical methods are more than 1100

910 + 20
Generics + Pharmacodynamics/ Immunogenicity

93
Complex Generics

73
NCEs

6
Large Molecule Assays

Covering broad range of differentiated dosage forms

- Transdermal System/Patches
- Inhalation Powder
- Inhalation Solution
- Nasal Spray
- Rectal Capsule
- Rectal/Vaginal Suppository/Foam
- Injectable Emulsion
- Long Acting Injectables
- Polio Vaccine
- Tablets
- Orally Disintegrating Strip
- Oral Suspension
- Oral Solution
- Powder for Oral Suspension/ Solution
- Topical Product

Simplifying your Road to Complex Generics Development

Experience with LAI antipsychotic drugs

- Aripiprazole depot injection
- Olanzapine modified release injection
- Paliperidone palmitate modified release injection
- Risperidone modified release injection
- Leuprolide acetate injection

Experience with Glucose Clamp Studies

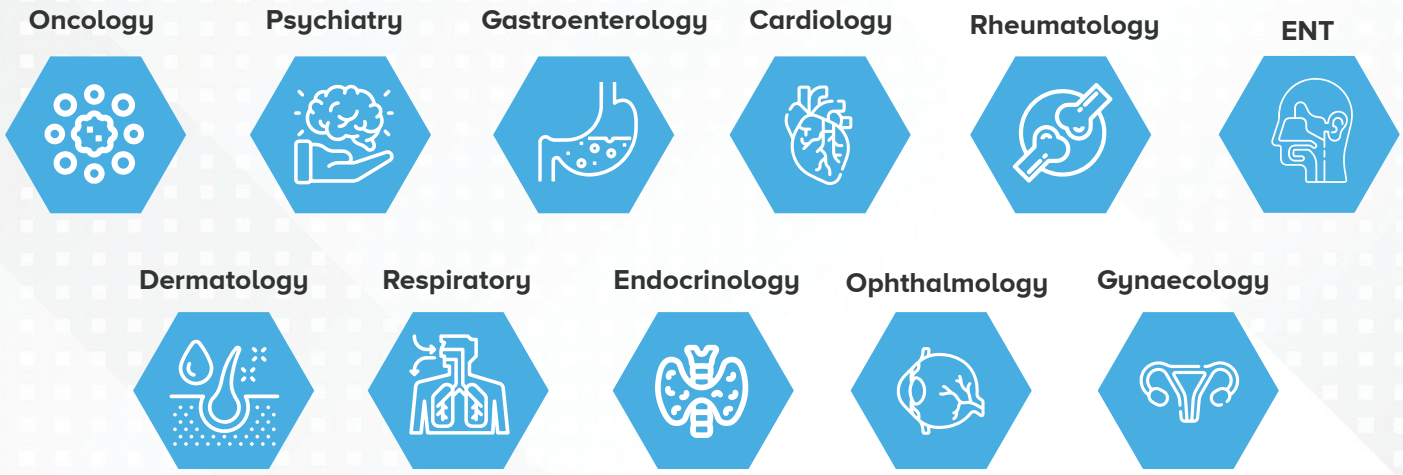
- Extensive experience and professional expertise in conducting complex Glucose Clamp Studies
- Till date we have used 810 Glucose Clamps in 13 different studies
- We have an experience of clamp ranging from 8 hours to 36 hours duration

Maximizing the 505(b)(2) Approval Prospects for your Complex Generics

Veeda provides best-in-class services with a combination of expertise and experience to conduct patient-based bioequivalence studies for various 505 B2 and complex generic products. Veeda CR has been a partner in supporting 505(b) (2) applications with ~45 studies experience with various clients.

Charting the course for Early to Late Phase Clinical Development

We cater to key therapeutic areas including:

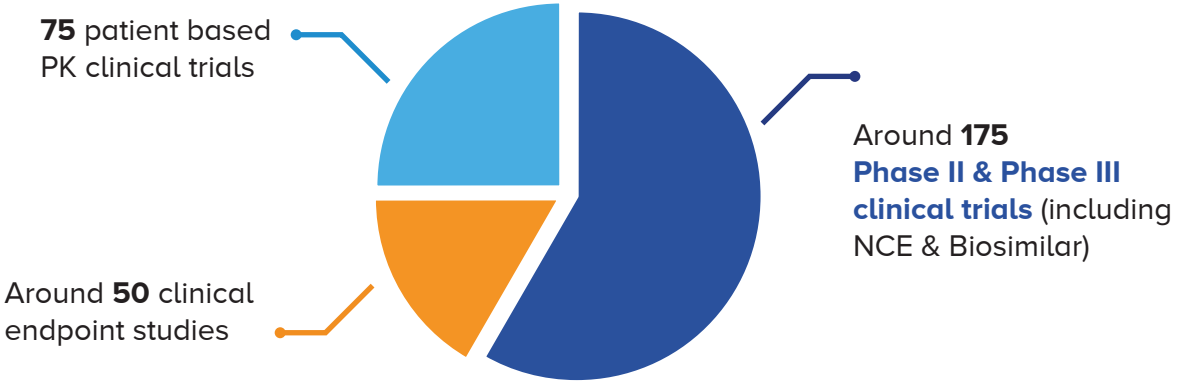


Quality Driven Clinical Development Solutions for your next Phase I Trial

Our Late Phase Clinical Trial Services Include

Combined Team Experience in Clinical Trials

More than **300** clinical trials that includes



Team Experience Across various Therapeutic Areas and Indications

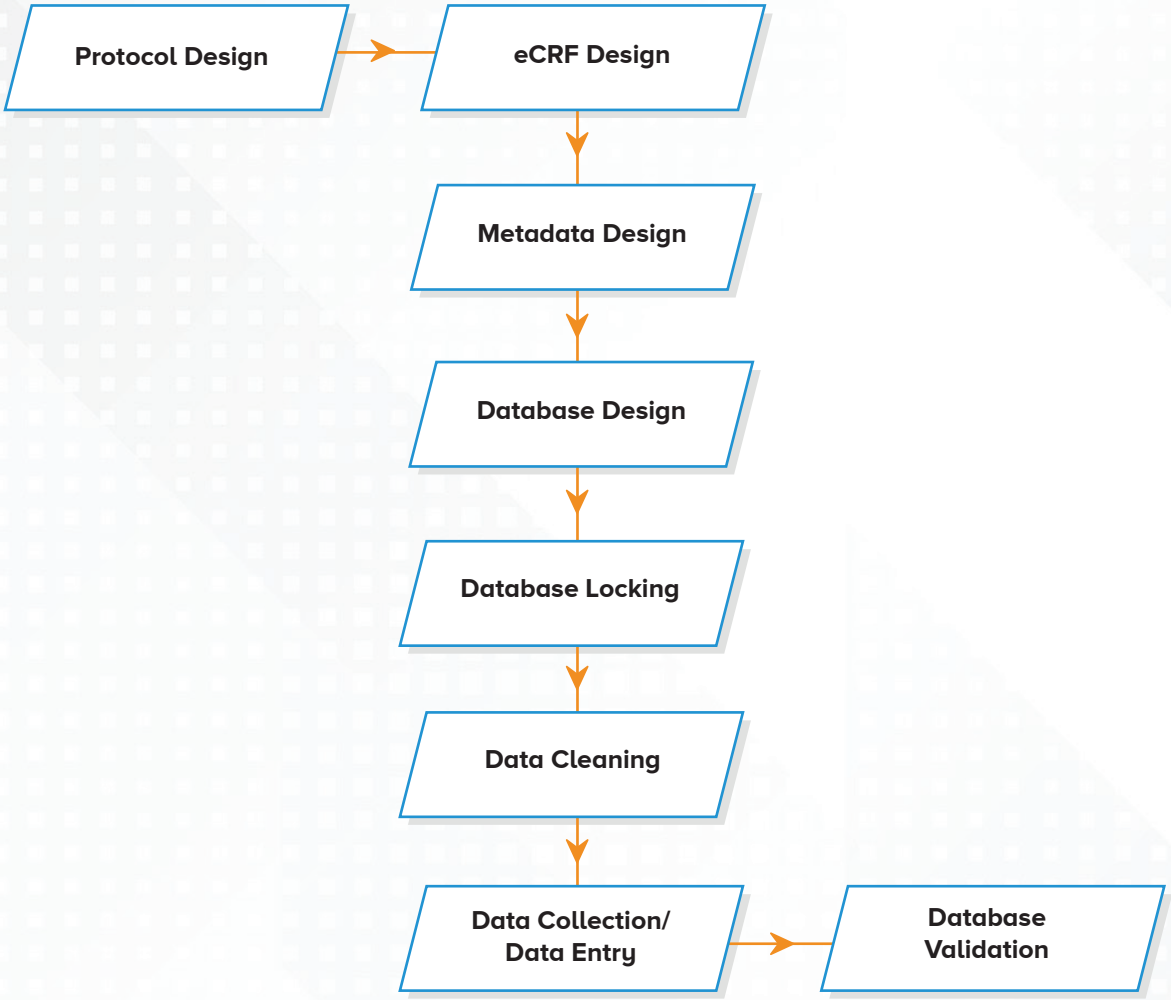
Area	Indication	Regulatory Submissions
Psychiatry	Major Depressive Disorder, Schizophrenia, Bipolar disorder, Bipolar I depression	USFDA, EMA & DCGI
Medical Devices	Coronary artery disease, Arrhythmia, Heart failure, Uncontrolled hypertensions,	USFDA & DCGI
Cardiology	Hypertension, Ischemic cardiomyopathy, Cardiovascular disease, Acute coronary syndrome	USFDA, EMA & DCGI
Endocrinology	DM-I, DM-II, Diabetic nephropathy	USFDA, EMA & DCGI
Oncology	Advanced Ovarian Cancer, Metastatic breast cancer, Renal Cell Carcinoma, Multiple Myeloma, Colorectal Cancer, Solid Tumors / Lymphoma, NSCLC, Cervix Cancer,	USFDA, EMA, ANVISA & DCGI
Respiratory	Non-small cell lung cancer, Asthma, Chronic obstructive pulmonary disease	USFDA & DCGI
Dermatology	Atopic dermatisis, Oral lichen planus, Dermatomycoses	DCGI
Nephrology	Chronic kidney disease, Urinary tract infection and pyelonephritis	USFDA & DCGI
Gastroenterology	Arsenic Poisoning, Gastroesophageal reflux disease, Constipation, Ulcerative Colitis	USFDA & DCGI
Infectious diseases	Bacterial Infection, Skin Infection, Hepatitis B Infection	USFDA & DCGI
Ophthalmology	Chronic Open Angle Glaucoma, Ocular Hypertension	USFDA & DCGI
Neurology	Epilepsy, Seizures	DCGI
Vaccine	Rabies, Leishmaniasis & serious fungal infections	DCGI
Orthopaedic	Psoriasis, Rheumatoid Arthritis & Osteoporosis	USFDA & DCGI

Strong Relationships with Investigators and Sites Drive Our Clinical Trial Continuity

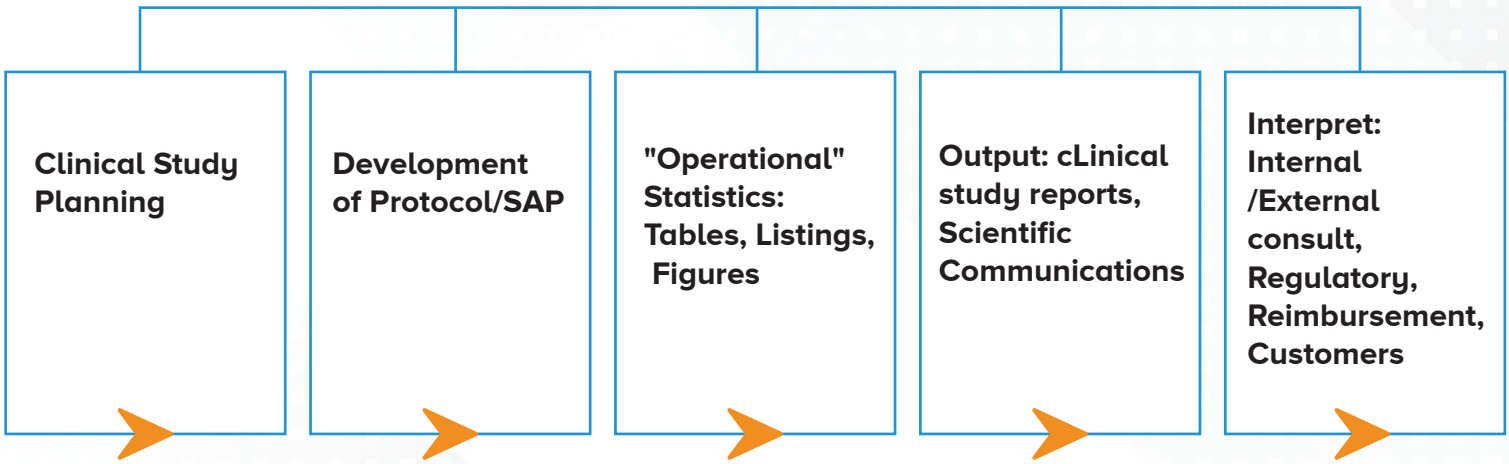
Therapeutic Area	Investigators Database	No. of sites Veeda worked with
Oncology	150 Oncologists	90 sites
Psychiatry	90 Psychiatrists	35 sites
Orthopedics and Rhuematology	72 Orthopedics and Rheumatologists	25 sites
Infectious Disease	79 MD Physicians	25 sites
Dermatology	87 Dermatologists	40 sites
Cardiology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

As a full service CRO, with extensive experience in clinical operations and drug development processes, Veeda integrates its clinical expertise and knowledge into its data management and biostatistical capabilities.

Clinical Data Management



Biostatistics



Bioneeds

Globally Acclaimed Preclinical Contract Research Organization

With over 12 years of experience, Bioneeds is a leading Preclinical Contract Research Organization (CRO) providing Integrated Discovery, Development & Regulatory Services to Pharmaceutical, Biopharmaceutical, Agrochemical, Industrial Chemical, Herbal, Nutraceutical & Medical Device companies. Bioneeds has a state of the art facility with 200,000 sq ft built-up area in 5 acre campus in the outskirts of Bangalore.

Preclinical Services include

- General Toxicity
- Mutagenicity
- Drug metabolism and pharmacokinetics (DMPK)
- Immunotoxicology
- Inhalation Toxicity
- Eco Toxicity
- Reproduction & Development Toxicity
- Biological Tests
- Physico Chemical Testing, Chemical/Drug Characterization

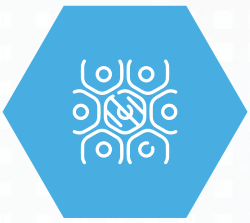
Discovery and Development

Assay development

- Study Design & Study Conduction
- Project Management
- Medical Affairs

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
- Hereditary coproporphyria (HCP) and Hernia, Congenital Diaphragmatic (HCD)
- Polyclonal and Monoclonal antibody production
- Cascade Immunization

Ingenuity BioSciences

Accelerating your Biosimilar Development

Centre for Biosimilar Excellence Laboratory: Synergy between Somru and Veeda

Ingenuity BioSciences is built on the complementary strengths to deliver Integrated Service Model for Drug Development, also bringing a strong synergy in offering a comprehensive bioanalytical solution to therapeutic and biosimilar development.

Biosimilar Services Include

- Pharmacokinetics
- Immunogenicity
- Biosimilar Characterization
- Biomarkers
- Neutralizing Antibodies
- BioNMR

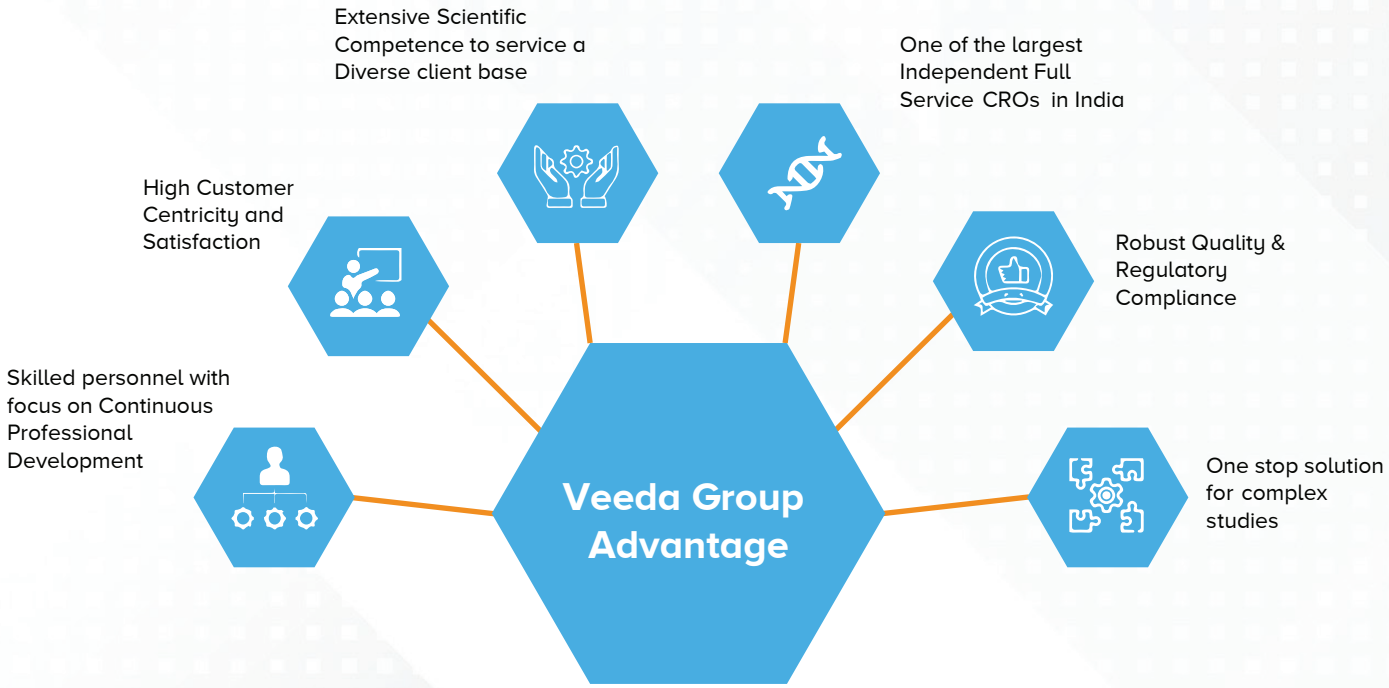
Our Regulatory Credentials

79 successful regulatory audits till date
09 successful regulatory audits in last 24 months

US FDA	37*	ANSM	1
MHRA	3	AGES	1
ANVISA	08	MCC	1
WHO	5	DCGI	18
NPRA Malaysia	5		

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

What makes Veeda Group a perfect choice for your next Drug Development Program?



Veeda's 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.

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info@veedacr.com
www.veedacr.com
+91 7967773000

BIONEEDS

bioneeds@bioneeds.in
www.bioneeds.in
+91 8162214400

Ingenuity BioSciences

info@ingenuitybiosciences.com
www.ingenuitybiosciences.com
+91 9712919739

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