Partners in creating a healthier tomorrow

Corporate Overview

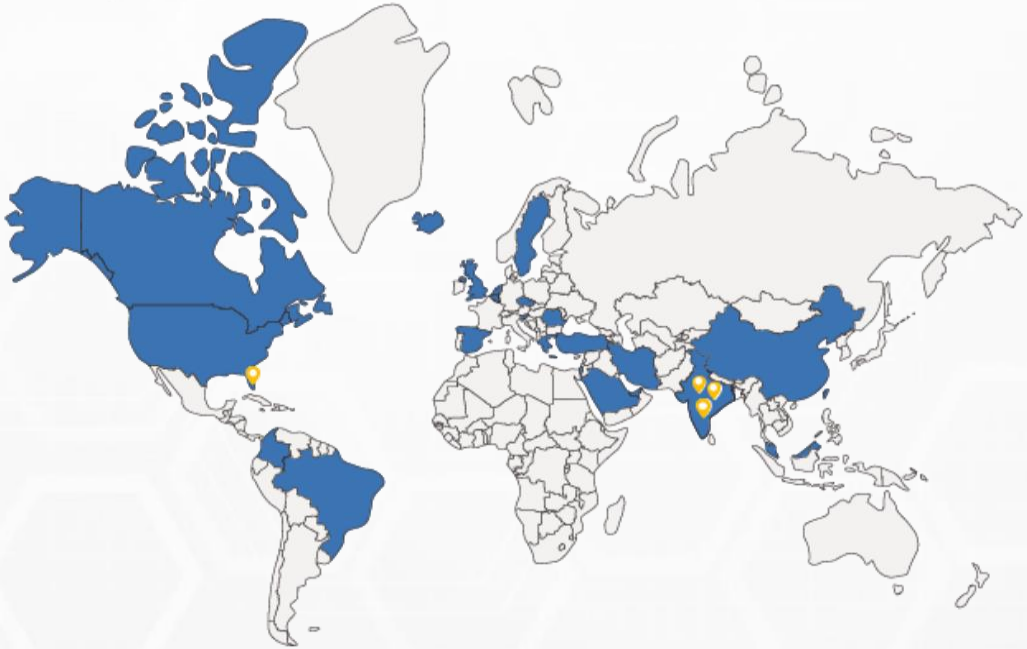
Veeda Group

- 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



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

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

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

US FDA	→	40*	ANSM	→	1
MHRA	→	4	AGES	→	1
ANVISA	→	8	MCC	→	1
WHO	→	5	DCGI	→	18
NPRA Malaysia	→	5			

*FDA : 19 AUDITS FOR PATIENT BASED STUDIES
20 AUDITS FOR HEALTHY SUBJECTS STUDIES

Our Values


Humility
Innovation
Accountability
Integrity
Excellence
Collaboration
Nurturing
Individual Growth

Drug Development Services Overview

Your Drug Development Journey

veeda clinical research | BIONEEDS | Ingenuity BioSciences

Drug Discovery

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

Analytical Characterisation for Biosimilar

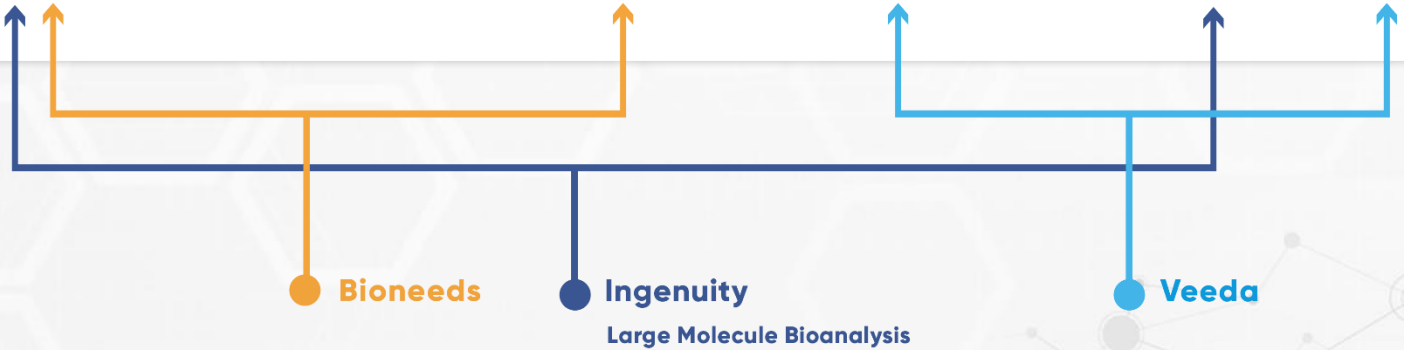
Preclinical Research & Development

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

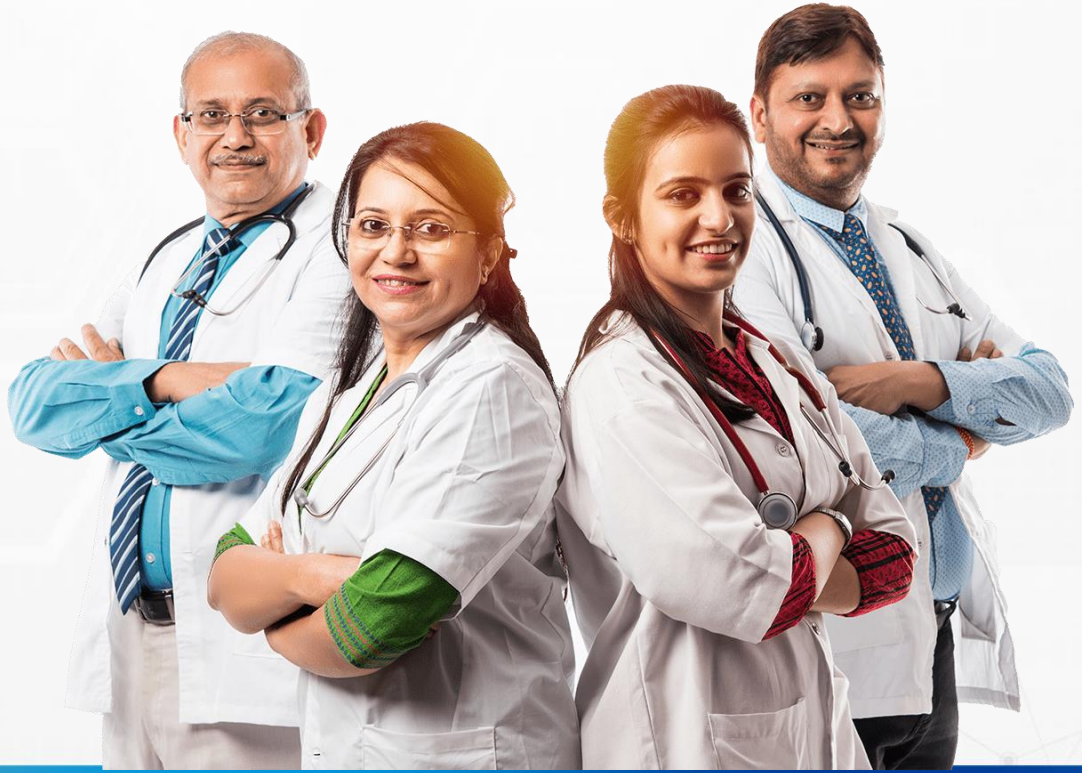
Phase I to Phase IV Clinical Trials

BA/BE (Healthy & Patient) Studies

Small Molecule Bioanalysis



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 **16** 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

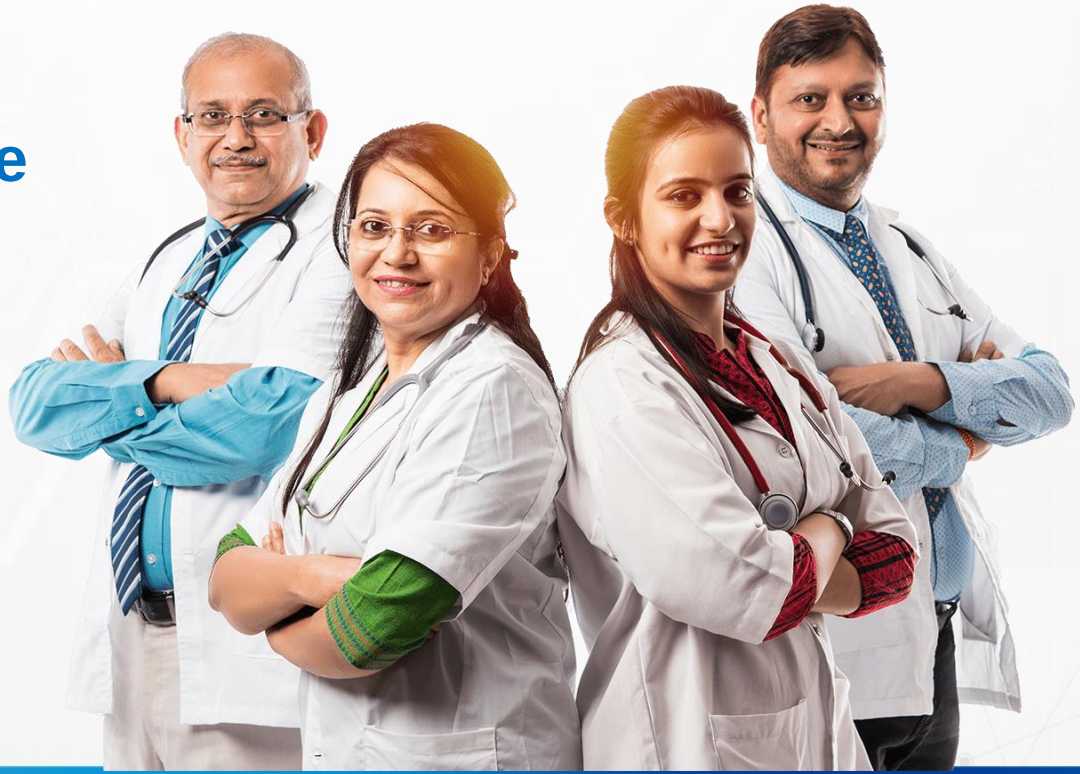
162 Beds +

7 Special care beds

Clinical Trials Overview

Clinical Trial Services

Clinical Trials Experience And Capabilities



Diverse Therapeutic Areas Of Expertise

- Cardiology
- Rheumatology
- Dermatology
- Ophthalmology
- Gynecology
- Gastroenterology
- ENT
- Oncology
- Psychiatry
- Respiratory
- Endocrinology

Our Patient Trials Capabilities

Our in-depth of experience, capabilities and experienced project team enables us to deliver high-quality and timely outcomes for your clinical studies.

30+
Patient bioequivalence studies

2,400+
Patients

250+
Sites

10
Phase Trials

900+
Investigator Database

16+
Ongoing Studies
- 3 Phase I/II/IIa studies
- 9 Patient PK studies
- 3 Clinical end point studies

THERAPEUTIC EXPERTISE
- Oncology
- Psychiatry
- Infectious disease
- Ophthalmology
- Rheumatology

Anti-COVID-19 vaccine SARS-Cov-2 infection in Healthy subjects– 1600 subjects

Successfully completed 19 USFDA inspections across sites without 483 observations.

Deep expertise across multiple therapeutic areas

Therapeutic Area and Indication	No. of Studies	No. of Sites	No. of Sample Size
Infectious disease	2	12	1660
Covid -19 Vaccine	1	6	1600
SARS- CoV-2 Infection	1	6	60
Oncology	24	255	1026
Advanced prostatic cancer	1	10	32
Advanced renal cell carcinoma	2	30	25
Chonical myeloid Leukemia/ Gastrointestinal Stromal Tumor	6	34	143
Ovarian Cancer	3	52	220
Patient with solid tumors	1	5	46
Relapsed Advanced Tumors and classical Hodgkin Lymphoma	1	17	130
Metastatic Breast Cancer (MBC)	3	48	188
Small cell lung cancers	1		
Breast cancer and Colorectal cancer	3	6	39
Multiple Myeloma	1	19	44
Advanced Ovarian cancer and Metastatic breast cancer	2	34	159
Orthopaedic	1		30
Postmenopausal Osteoporosis	1		30
Psychiatric	7	30	355
Schizophrenia	7	30	355
Rheumatology	1		
Rheumatoid Arthritis	1		
Ophthalmology	2	26	400
Open angle glaucoma or ocular hypertension	2	26	400
Haematology	4	22	184
Iron deficiency anaemia	1	10	120
Sickle cell anaemia	1	4	36
Anti-HIV	2	48	34
HIV	2	48	34

Ongoing Studies

Therapeutic Area and Indication	No. of Studies	No. of Sites	No. of Sample Size
Dermatology	2	13	47
Atopic dermatitis	1	5	25
Human head lice infestation	1	8	22
Gastroenterology	1	15	450
Chronic idiopathic constipation	1	15	450
Haematology	2	15	128
Iron deficiency anaemia	2	15	128
Infectious disease	1		18
HIV	1		18
Oncology	5	62	246
Advanced prostatic cancer	1	10	32
Colon or pancreatic cancer	1	1	45
Metastatic Breast Cancer (MBC)	2	32	99
Ovarian cancer and Metastatic breast cancer	1	19	70
Ophthalmology	1		204
Open angle glaucoma or ocular hypertension	1		204
Psychiatric	1	14	284
Schizophrenia	1	14	284
Respiratory	2	10	135
Asthma	1	5	110
COPD	1	5	25
Rheumatology	1	3	48
Rheumatoid Arthritis	1	3	48

Team Experience in Clinical Trials

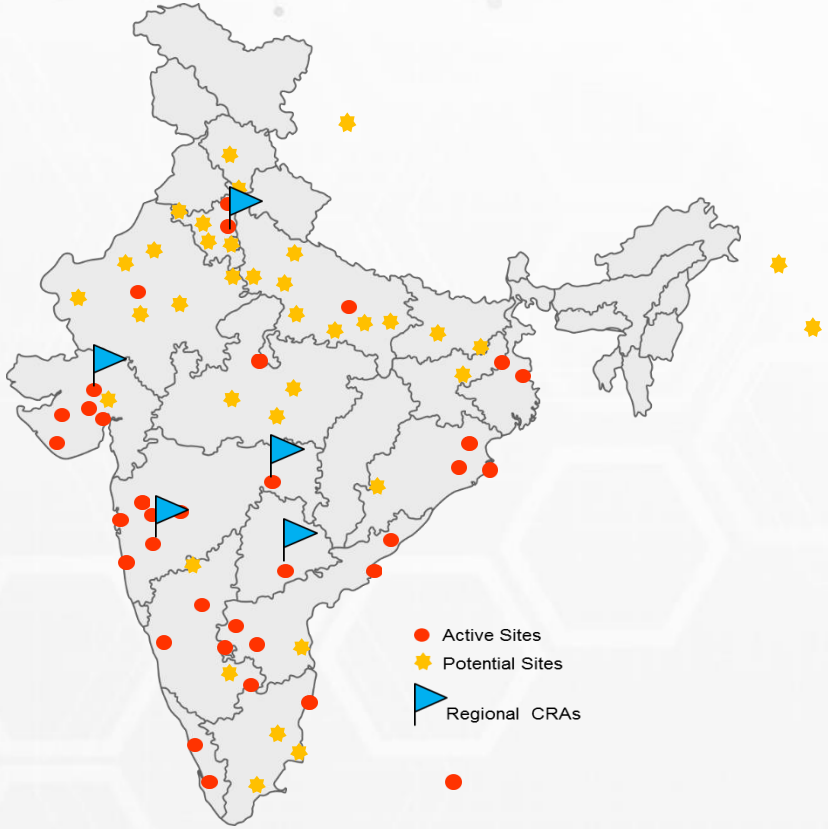
Sr. No.	Area	Indication	Regulatory Submissions
1	Psychiatry	Major Depressive Disorder, Schizophrenia, Bipolar disorder, Bipolar I depression	USFDA, EMA and DCGI
2	Medical Devices	CAD, Arrhythmia, Heart failure, Uncontrolled hypertensions,	USFDA & DCGI
3	Cardiology	Hypertension, Ischemic cardiomyopathy, CVD, ACS	USFDA, EMA and DCGI
4	Endocrinology	DM-I, DM-II, Diabetic nephropathy	USFDA, EMA and DCGI
5	Oncology	Advanced Ovarian Cancer, Metastatic breast cancer, Renal Cell Carcinoma, Multiple Myeloma, Colorectal Cancer, Solid Tumors / Lymphoma, NSCLC, Cervix Cancer,	USFDA, EMA, ENVISA and DCGI
6	Respiratory	Asthma, COPD	USFDA & DCGI
7	Dermatology	Atopic dermatisis, Oral lichen planus, Dermatomycoses	DCGI
8	Nephrology	CKD, Urinary tract infection and pyelonephritis	USFDA & DCGI
9	Gastroenterology	Arsenic Poisoning, GERD, Constipation, Ulcerative Colitis	USFDA & DCGI
10	Infectious diseases	Bacterial Infection, Skin Infection, Hepatitis B Infection	USFDA & DCGI
11	Ophthalmology	Chronic Open Angle Glaucoma, Ocular Hypertension	USFDA & DCGI
12	Neurology	Epilepsy, Seizures	DCGI
13	Vaccine	Rabies, Leishmaniasis & serious fungal infections	DCGI
14	Orthopaedic	Psoriasis and Rheumatoid Arthritis& Osteoporosis	USFDA & DCGI

Veeda's Investigator & Site Database

Therapeutic Area	Investigators Database	No. of sites Veeda worked with
Oncology	352 Oncologist	120 sites
Psychiatry	40 Psychiatrists	40 sites
Orthopedics and Rhuematology	69 Rheumatologists	4 sites
Infectious Disease	56 MD Physicians	54 sites
Dermatology	67 Dermatologist	40 sites
Cardiology	50 Cardiologist	6 sites
Opthalmology	108 Ophthalmologists	107 sites
Urologist	115 Urologist	48 sites
Physician	81 MD Physician	50sites
Neurologist	40 Neurologist	13 Sites
Surgeons	19 MS Surgeons	20 sites
Pulmonology	42 Pulmonologists	32 sites
Gastroenterology	57 Gastroenterologists	47 sites
Endocrinology	100 Endocrinologist	9 sites
Hematology	68 Hematologists	68 sites
ENT	89 ENT	5 sites
Gynaecology-Obs	28 Gynaecologist	6 sites

Database of more than 1300+ Investigators, Veeda team has worked with more than 600+ Clinical Research Investigators.

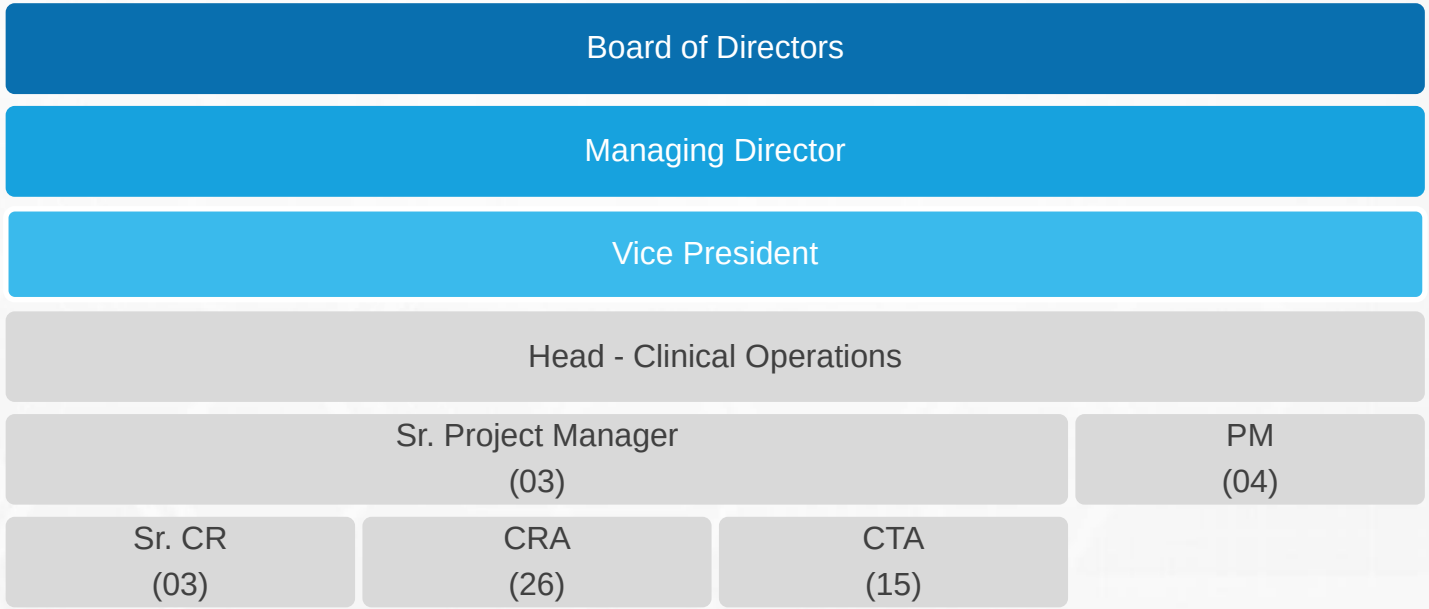
Services offered – Site Network



- Sites across all major cities
- More than 150 active sites currently
- CRAs based in > 6 cities.
- 17 sites audited by regulatory agencies

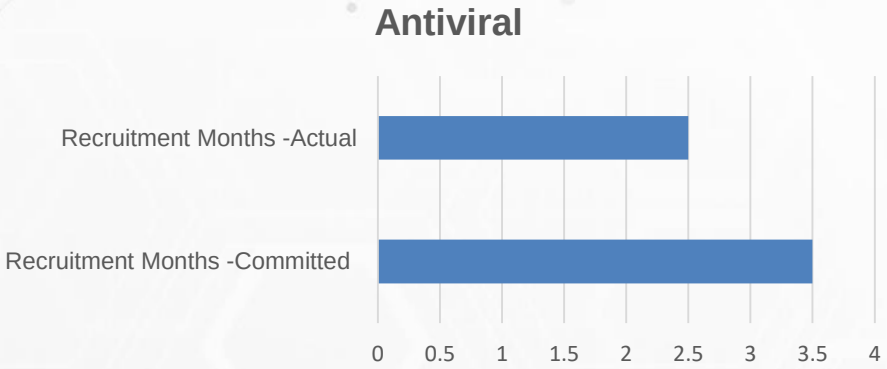
Clinical Project team Experience

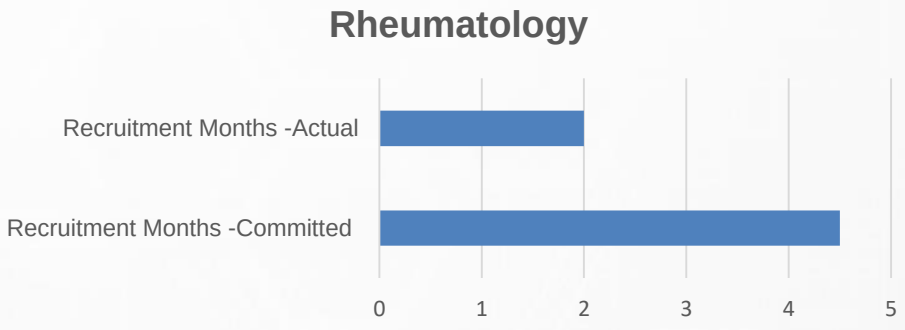
11+ Years of Average Experience in multiple therapeutic areas such as Oncology, Ophthalmology, Dermatology, Infectious Diseases and many more.

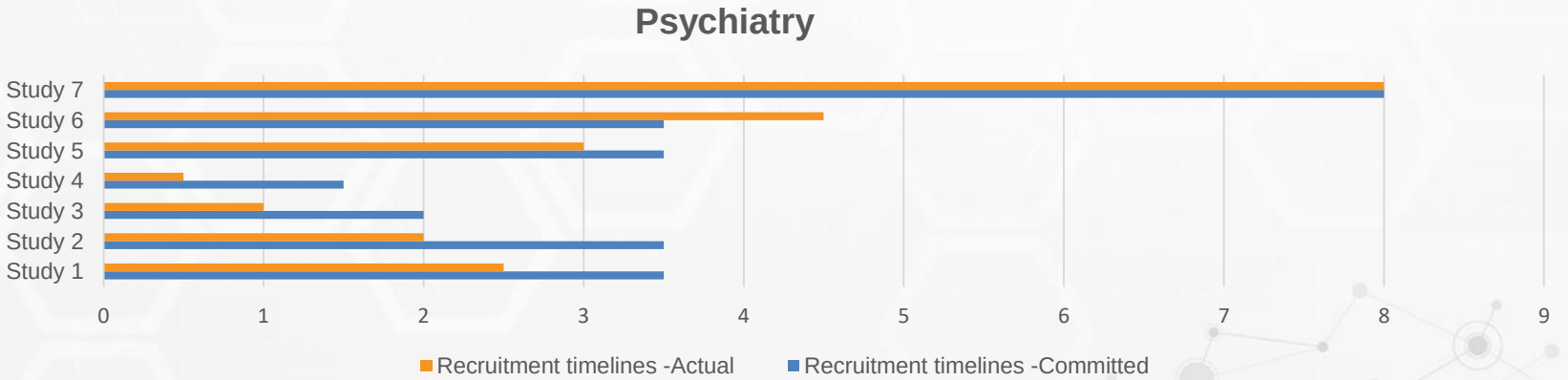


Team Training

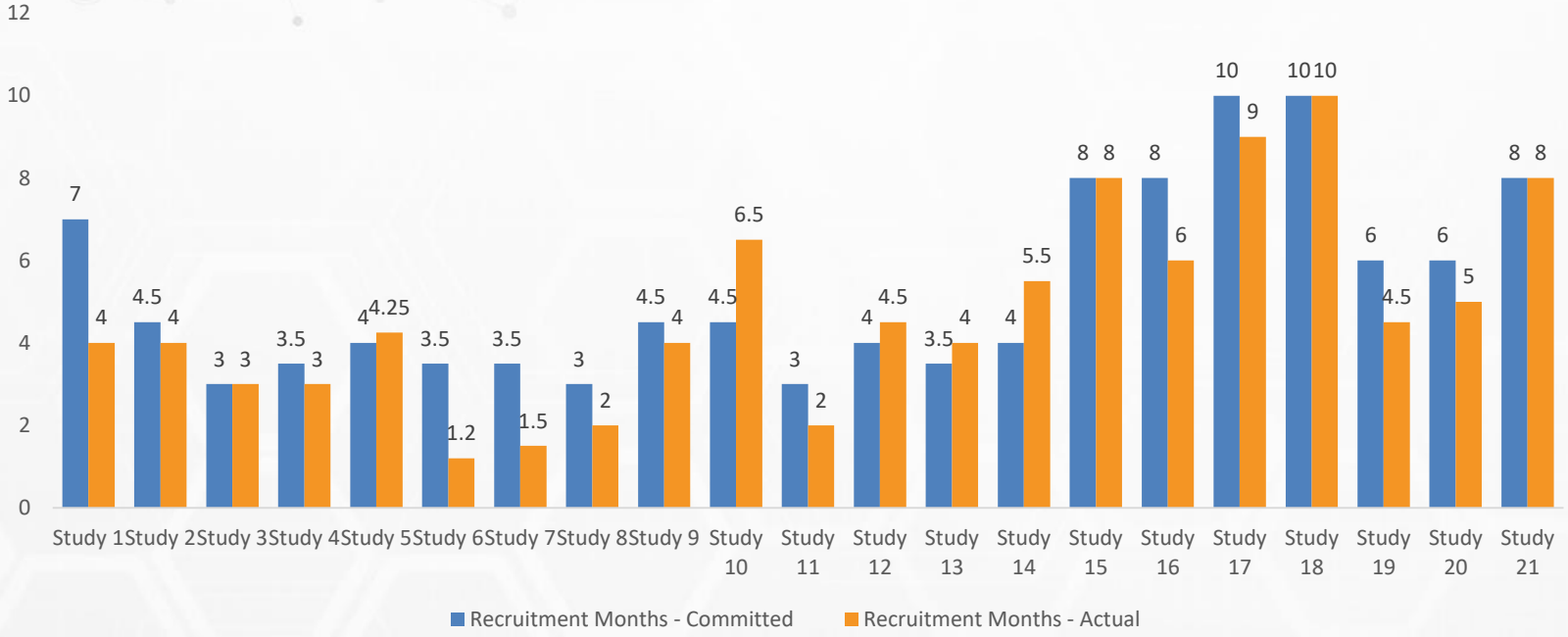
Meeting Recruitment Timelines





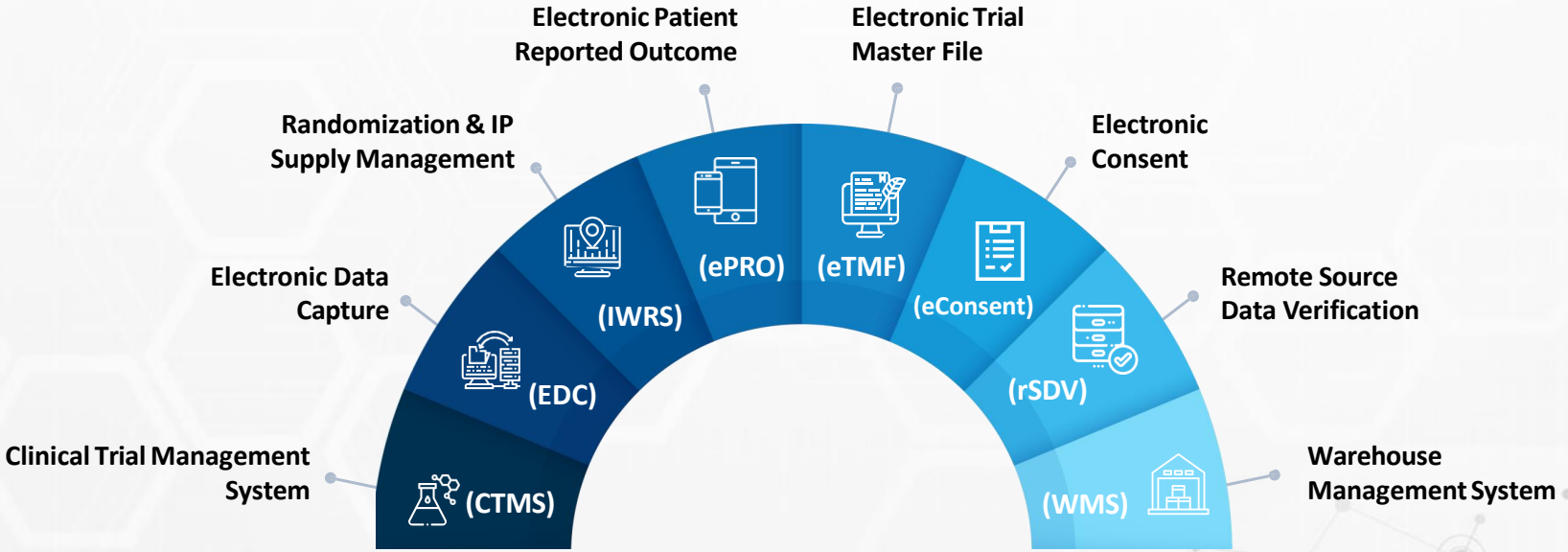


Meeting Recruitment Timelines



Average drop out rate of 7% across all completed Clinical Endpoint, Patient PK, Interventional and Phase II studies.

Access to eClinical Platforms



CTMS

Centralized Database:

- One consolidated, centralized database for your trial data
- Facilitates collaboration and favors proactive management
- Make time-critical decisions and resolve issues promptly

Site and Subject Management:

- Track study progress from start-up through enrollment
- Integrated calendar helps track subject visits and milestones
- Standardize CRA Trip Reports
- Track Open Issues, Protocol Deviations, and site communication

Finance Management

- Define, manage and track Trial Budget
- Define and manage CTAs with Sites
- Automate Investigator payment based on pre-agreed milestones
- Integrate required workflow in invoice generation and payment

Project Reporting

- Project Status & Progress Reports
- GANTT Chart
- Create and Customize Reports with filters on Projects, Tasks, Priorities, Status and Users

eTMF & Doc. Management

- DIA Reference Model Compliant
- Standardized eTMF TOC and Site ISF
- Store and organize Project Documents
- Version Control
- Manage Complete Life Cycle of Documents

Comprehensive Solution

- Integrated IMP Tracking module
- Integrated eTMF and Doc. Mgt Module
- Integrated Safety Management Module
- Enable integration with EDC/IWRS

CTMS –Value adds

Performance Improvement Levers	Realized Value
Faster Clinical Trials	Gain up to 25% resource efficiency in Trial Planning and execution resulting in: • Manage **end-to-end trial process** from one centralized database • Quickly identify and **replace low-recruiting sites** • Gain **Real-time insight** in bottlenecks encountered and remediate • **Process Automation** and **Workflow enabled** processes increases collaboration and productivity
Improved Finance Management	Save up to 20% cost in conducting a clinical trial: • Gain **Site Monitoring efficiencies** with reduced efforts in writing trip reports • Save on **CRA Travel costs, IMP Shipping Costs, IMP Wastage, and Printing Cost** • **Automated PI payment** process ensures site is paid based on their performance • Define Study Budget; **Track Actuals** against Budget
Site Monitoring Efficiencies	• Monitor **Subject enrollment** against goals. • Complete **targeted Subject enrollment** at a faster rate. • **Workflow enabled** Site Monitoring Reports. • **Automated Investigator Payment** reconciliation • **Automated IMP Reconciliation** • Investigator/**Site Issue Management**
Audit Ready	• **Real-time tracking** of Trial Master File • Shortened Clinical Trial Time • Better **GCP Compliance**

Electronic Data Capture

Capture, manage and report clinical trial data securely:

- Web-based and mobile-enabled
- Capture data faster and more accurately
- Online validation at the point of data entry
- Streamline monitoring visits
- Integrated Query Management
- Integrate medical dictionary (MedDRA, WHO..)
- Automated alerts/ notifications
- 21 CFR Part 11 compliant, maintains complete audit trail

Clinical Data Management

Study Setup

- Data Management Plan
- Database Design
- Data Management Guidelines
- CDISC Compliance

Data Review

- CRF Data Review
- DCF
- Lab Data Review
- Medical Coding

Data Processing

- Data Management Plan
- Database Design
- Data Management Guidelines
- CDISC Compliance

Electronic File Management

- Data Transfer to Sponsor
- Study Document Management

Remote Source - Data Verification (rSDV)

Connects Sponsors / CROs to Sites for:

- Remote Access
- Remote Monitoring
- Source Data Review/Verification

Purpose-built system includes capabilities:

- View documents
- Share comments
- Assign tasks and review response

Compliant with Regulatory requirements:

- 21 CFR Part 11
- HIPAA

Cloud Based

- High Security
- Scalable
- Role-based access to data

rSDV - Key Features

Deploy as a standalone portal or integrated with Octalsoft eClinical Platform

FLEXIBLE DEPLOYMENT OPTIONS

Upload scanned and redacted documents. Site Administrator retains control of their documents

UPLOAD DOCUMENTS SECURELY

Configurable document review workflow along with integrated collaborate feedback mechanism

DOCUMENT REVIEW WORKFLOW

STANDARDIZE DOCUMENT FOLDERS

Standardize Document Folder structure across sites enabling easy access and review of source documents

CONTROLLED DOCUMENT ACCESS

Permission based controls to limit document visibility and functional capabilities

REPORTS AND DASHBOARDS

Management reports and dashboards provide insight into real-time progress at site

Quality Compliance

Study specific Quality Management Plan

PM review issue escalations

Ongoing Protocol Deviation Analysis

Proactive Quality and Compliance Control

- ✓ **Sponsor** and CRO Processes, aligned
- ✓ Detailed ***Quality Management Plan***

CRA Resource:

- ✓ GCP Trained CRAs
- ✓ Study specific training for CRAs
- ✓ Mandatory **protocol training** with knowledge assessment
- ✓ **Accompanied site visit** by PM, as needed
- ✓ TMF review

Site Education:

- ✓ **GCP** training
- ✓ **Protocol** training during IM, SIV
- ✓ Ongoing training at IMVs
- ✓ Tools, aids provided

Executive Profiles

Dr. Kiran Marthak, M.D. F.C.C.P. T.D.D. Director- Medical and Regulatory Affairs

Current Responsibility

- Safety of the subjects, protocol designing,
- Business Development of NCEs and the Clinical Trials with NCEs
- Liaison with Regulatory authorities

Profile Overview (Career and Education)

- Post graduate in Internal Medicine
- Fellow of Faculty of Pharmacology University of London, U.K.
- Fellow of American College of Clinical Pharmacology. Chairman of ISBEC- Ethics Committee
- Senior management positions in Novartis, Pfizer, GSK, Ranbaxy and Member of Board of Director in Lambda Therapeutic Research Ltd.
- Faculty in Academic Institutions, invited speakers in International and National conferences

Experience :

- Total Industrial experience of more than 40 years

Special Areas of Expertise:

- Managed more than 25 Phase-1 studies, Expertise in dealing with Drug Discovery and Development, expertise in International Regulatory affairs mainly related to Drug Discovery programs.

Mr. Sivakumar Vaidyanathan, Head – Clinical Trials

Current Responsibility

- Clinical Operations
- Medical Affairs
- Pharmacovigilance

Profile Overview

- Mr. Sivakumar has professional experience of more than 20 years in clinical research with significant exposure of working closely with CROs and Pharmaceutical Industry.

Experience

- He was associated with Biocon Biologics India Limited, Glenmark Pharmaceuticals, Novartis, Jubilant Clinsys, and Torrent Pharmaceuticals Limited. His overall work experience also includes his association with academic institutes wherein he taught pharmacology and physiology to college and university students.

Special Areas of Expertise

- During his tenures, He has played a crucial role in various clinical research studies which include studies related to Biosimilars, novel biologics, small molecules and generics in various therapeutic areas.

Dr. Rakesh Patel, MBBS, MD. Associate Vice President, Project management, Clinical Operations

Current Responsibility

- Project Management, Clinical Operations (Late phase trials)

Profile Overview

- Rakesh Patel is a physician with specialization in Clinical Pharmacology (MBBS, MD-Pharmacology) with over 18 + years of experience in the field of Clinical Operations of early and late phase clinical trials. He is currently assigned the responsibility of managing the teams in Project management, Clinical Operations department.

Experience

- His experience includes working in both Pharmaceutical companies and Contract Research Organizations like Zydus lifesciences Ltd, Wockhardt Ltd, Eris lifesciences Ltd, Jubilant Clinsys Ltd and Lambda Therapeutic Research before joining Veeda Clinical Research Ltd.

Special Areas of Expertise

- During his tenures, he has developed and led teams involved in clinical operations (involved in execution of Phase I-IV clinical studies).
- He has been a key stake holder and head of dept. for setting up the new clinical research centre for conducting glucose clamp studies for testing of Insulin formulations.
- He has been instrumental in preparation and hosting many regulatory inspections e.g. USFDA, EMA, ANVISA, Turkey, DCGI etc.

Dr. Ashutosh Jani, Ph.D. (Pharmacology), Head- Clinical Operations

Current Responsibility

- To Provide Strategic and Managerial Oversight for all Clinical Operations functions.
- Organize and Implement Operational Strategies for Clinical Operations.
- Ensure effective stake holder management.

Profile Overview

- Pharmacy Professional with Doctorate in Pharmacology and over 17 years of experience in the field of Clinical Research

Experience

- Ashutosh has experience working in Academia, Pharmaceutical companies and Contract Research Organizations like Claris, Acutest Research, Lambda Therapeutic Research before joining Veeda Clinical Research. During his tenures, he has managed teams involved in Clinical operations & BD and is having good rich experience in Clinical Development , Project management, contract negotiations, Implementation of programs in Therapeutic Areas like Oncology, Psychiatry, Endocrinology and Inflammatory disease including multiple rare and complex indications.

Special Areas of Expertise

- Patient based Pharmacokinetic studies for Precision Medicine, 505/b2, NCE, biologics & complex generics in Oncology and Psychiatry.

Dr. Ravi Alamchandani, M.D., GM- Medical Affairs & PV

Current Responsibility

- To Provide Strategic and Managerial Oversight for all Medical Monitoring & Medical Writing activities
- To Support Safety Reporting and Pharmacovigilance Activities

Profile Overview

- Dr Ravi Alamchandani is MD Pharmacology (Gold Medalist) with over 6 years of experience in the field of Medical Affairs and Safety Reporting.

Experience

- His experience includes working in Hospital, Pharmaceutical companies and Contract Research Organizations like DDMM Heart Institute, Torrent Pharmaceuticals ltd., Lambda Therapeutic Research Ltd., before joining Veeda Clinical Research. He is currently associated with Veeda Clinical Research as DGM – MPD and is leading Medical Monitoring, Medical Writing and Pharmacovigilance team.

Special Areas of Expertise

- Dr. Ravi has been involved in and managed teams involved in medical monitoring, medical writing and safety reporting activities of Phase I-IV clinical studies (Efficacy studies, Patient PK studies including SAD & MAD studies and BE with Clinical endpoint studies) involving NCE, Biologics and Generics. He has also been involved in organizing DSMB meets for NCEs wherein he has acted as local medical monitor. He has been a Medical Advisor for new product development and involved in developing medical rationales for new formulations.

Recognitions

Recognitions

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
	Best Clinical Research- India
	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

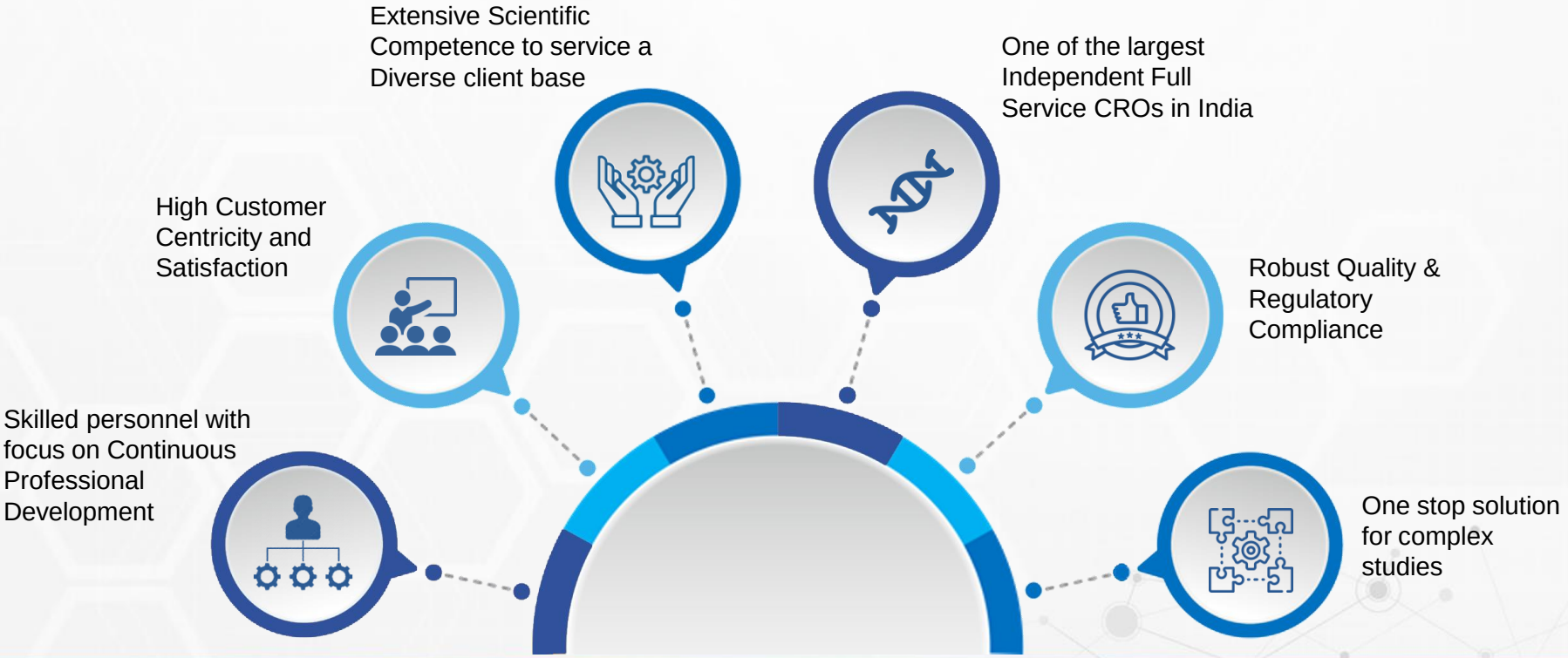
2019

Organization	Award Category
WORLD QUALITY CONGRESS & AWARDS	Best Quality Clinical Research Organization in India
INDIAN PHARMA EXPO & BUSINESS EXCELLENCE AWARDS	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