BIONEEDS

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

Veeda's Current Geographical Presence

Veeda's Team Presence

Corporate Philosophy

Vision

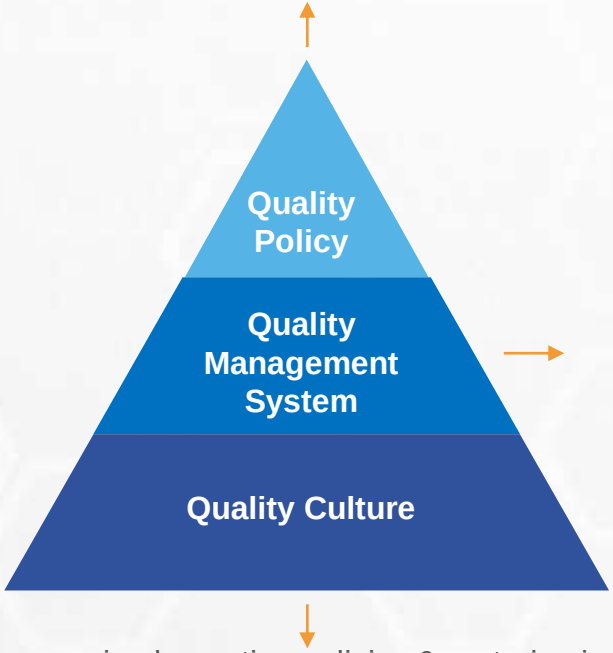
In an industry where innovation is increasingly multifaceted and collaborative, we aspire to be the research partner of choice for innovative (bio)pharmaceutical companies worldwide for their critical product development programs

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

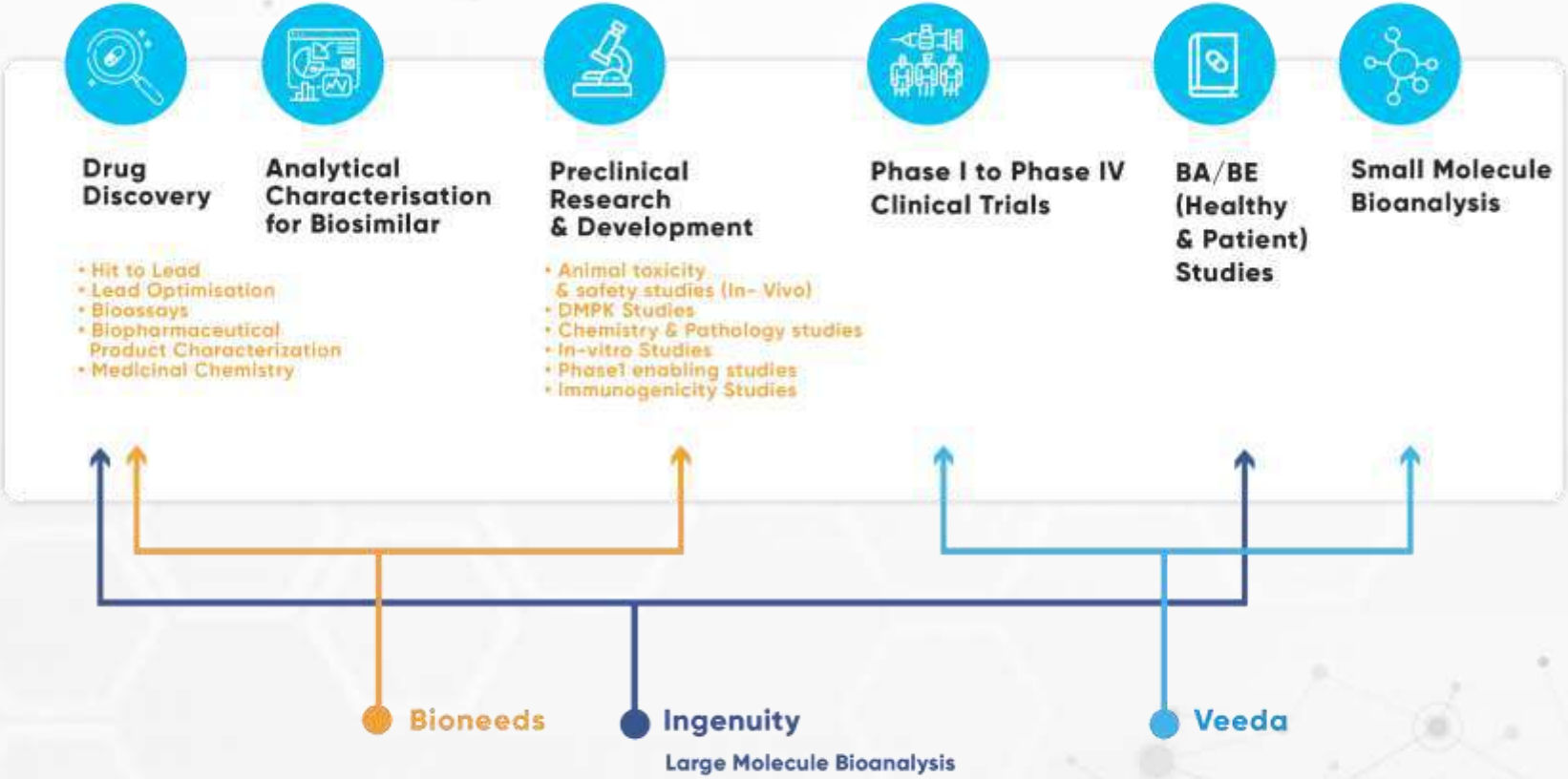
Excellence

Collaboration

Nurturing
Individual Growth

Drug Development Services Overview

Your Drug Development Journey



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

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

Deep expertise for Patient PK end point studies

Therapeutic Areas and Indications	No. of Studies	No. of Patients	Type of Study
Antiviral			
HIV	1	48	PK Endpoint Study
Oncology (22 studies)			
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

Ongoing Patient Trial Studies

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

Completed Projects

Study detail	Submission	Recruitment timelines		Comments
		Committed	Actual	
Etoposide 50 mg capsule – SCLC	US FDA	7 months	4 months	Sample size-24 No of sites-8
Imatinib 400 mg tablet – CML	US FDA	4.5 months	4 months	Sample size-32 No of sites-4
Capcitabine 500mg Cap in MBC and CRC	EU	3.0 months	3.0 Months	Sample size – 54 No. sites – 8
Methotrexate 2.5 mg Tab in RA & Psoariasis	US FDA	4.5 months	2.0 Months	Sample size – 42 No. sites – 10
Everolimus 10 mg tab – RCC	US FDA	3.5 months	3 months	Sample size- 58 No. of sites -25
Doxorubicin Hcl (Pegylated liposomal) Ovarian & Breast Ca.	EU	3 months	14 patients in one month	Sample size- 58 No. of Sites - 12 The study was discontinued by the sponsor
Doxorubicin Hcl (Pegylated liposomal) Ovarian & Breast Ca.	EU	4 months	4.25 months	Sample size-65 No of sites-14 The second study was repeat study of above discontinued study

Completed Projects

Study detail	Submission	Recruitment timelines		Comments
		Committed	Actual	
Imatinib 400 mg tab CML	US FDA	3.5 months	1.2 months	Sample size-32 No of sites-4
Imatinib 400 mg tab CML	US FDA	3.5 months	1.5 months	Sample size-34 No of sites-4
Imatinib 400 mg tab CML	US FDA	3.0 months	2.0 months	Sample size-30 No of sites-4
Quetiapine 400 mg ER tab in Schizophrenia	EU	3.5 months	2.5 months	Sample size – 64 No. sites – 4
Imatinib 400 mg tab CML	US FDA	4.5 months	4 months	Sample size-32 No of sites-4
Imatinib 400 mg tab CML	EU	4.5 months	6.5 months	Sample size 32. 1.Planned with 2 indications. GIST and CML. Just prior to recruitment it was decided to recruit only CML patients. 1.Planned in 8 sites but 4 sites did not recruit at all.

Completed Projects

Study detail	Submission	Recruitment timelines		Comments
		Committed	Actual	
Nevirapine Tab 400 mg HIV-1	EU	3.5 months	2.5 months	Sample size – 48 No. of Sites 4
Paliperidone PR 9 mg tab, Schizophrenia	EU	3.5 months	2 months	Sample size – 75 No. of Sites 5
Clozapine Tab 100 mg, Schizophrenia	USFDA	2 months	1 month	Sample size – 28 No. of Sites 2
Clozapine Tab 25 mg, Schizophrenia	CFDA	1.5 months	0.5 month	Sample size – 14 No. of Sites 1
Imatinib 400 mg tab – CML & GIST	US FDA	3 months	2 months	Sample size-40 No of sites-4
Paclitaxel 100 mg/vial MBC	US FDA	4 months	4.5 months	Sample size- 76 No of sites-15
Everolimus 10 mg tab – RCC	US FDA	3.5 months	4 months	Sample size- 30 No. of sites -15
Quetiapine 600 mg PR tab in Schizophrenia	EU	3.5 months	3.0 months	Sample size – 52 No. sites – 3

Completed Projects

Study detail	Submission	Recruitment timelines		Comments
		Committed	Actual	
Risperidone LA Injection 25 mg in Schizophrenia	EU	3.5 months (100 randomized)	4.5 months (108 randomized)	Sample size – 108 (randomize) No. sites – 7 Note: Due to Investigator's decision to withdraw from the trial due to administrative issues at the site, patients were withdrawn at that site and additional patients were randomized from other sites.
Capecitabine Tablets 500 mg in MBC and CRC	US FDA	4 months	5.5 months	Sample size: 45 No. of sites: 6
Liposomal doxorubicin Injectable IV infusion in ovarian cancer	US FDA	8 months	8 months	Sample Size – 66 No. of site – 14
Liposomal doxorubicin Injectable IV infusion in **ovarian cancer and MBC**	EU	8 months	6 months	Sample Size – 79 No. of site – 15

Completed Projects

Study detail	Submission	Recruitment timelines		Comments
		Committed	Actual	
Liposomal doxorubicin Injectable IV infusion in **ovarian cancer**	USFDA	10 months	9 months	Sample Size – 54 No. of site – 15
Bortezomib in **Multiple Myloma**	USFDA	10 months	10 months	Sample Size – 54 No. of site – 15
Leuprolide in Patients with **RCC**	Pilot Study	06 months	4.5 months	Sample Size – 32 No. of site – 10
Risperidone 25 mg Inj Patient with schizophrenia	EU	08 Months	08 Months	Sample Size – 122 No. of site – 10
Capecitabine 500 mg tablets in Patient with MBC	USFDA	06 Months	05 Months	Sample Size – 51 No. of site – 9
Paclitaxel 500 mg tablets in Patient with MBC	USFDA	08 Months	08 Months	Sample Size – 76 No. of site – 9

Completed Phase II & III Projects

Sr. No.	Therapeutic Indication	Therapeutic Areas	Subjects randomized
1	A Phase II Study in Non-Small Cell Lung Cancer-	Oncology	53
2	A Phase I Followed by a Randomized, Phase II Study in Small Cell Lung Cancer (SCLC)	Oncology	5
3	Phase II clinical study in non-small cell lung cancer and colorectal cancer	Oncology	40
4	Phase 2b Study in Advanced Non-Small Cell Lung Cancer	Oncology	26
5	Phase III Study in Subjects with Articular	Orthopedic	14
6	Bioequivalence with Clinical End Point	Ophthalmology	200

Completed Phase II & III Projects

Sr. No.	Therapeutic Indication	Therapeutic Area	Subjects randomized
7	Phase II study of Inhibitor of PD-L1, PD-L2, and VISTA pathways in Different tumor types (5 cohorts)	Oncology	130
8	CA-170	Oncology	62
9	Cartilage Defects of the Articulating Joint(s)	Orthopedic	14
10	Phase III Study in Subjects with Avascular Necrosis (AVN)	Orthopedic	14
11	Bioequivalence with Clinical End Point	Ophthalmology	200

Current Projects Patient Based PK Studies

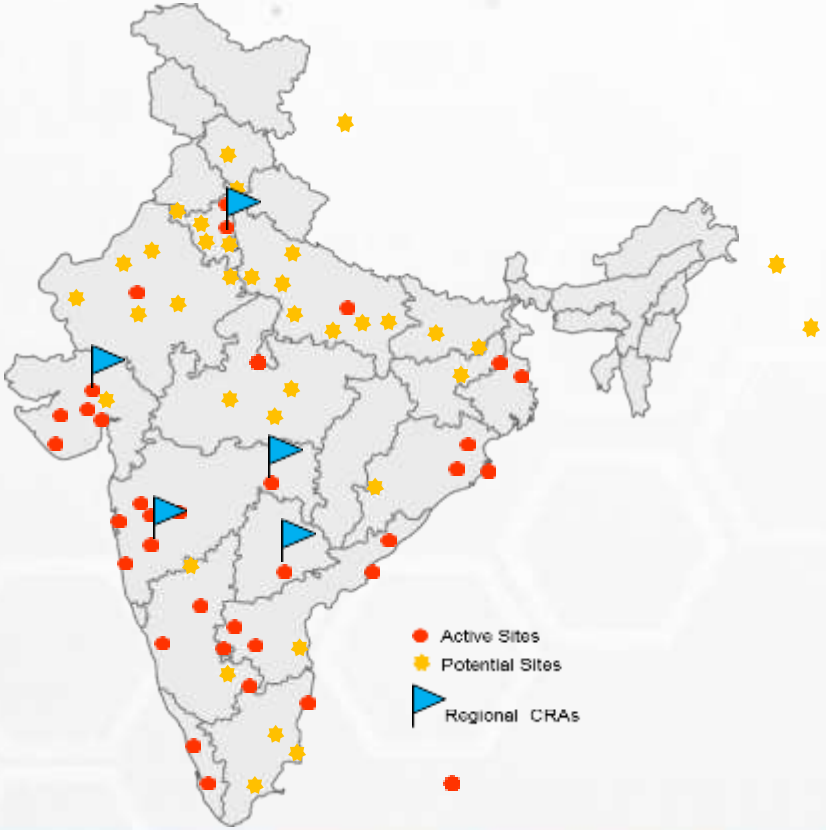
Drug	Submission	Sites/Sample size (Randomized)	Indication	Number of studies
Liposomal doxorubicin Injectable IV infusion	USFDA	Sites-18*/15, N-103*/51 *Recruitment completed	Ovarian Cancer	2
Bortezomib s.c. 3.5 mg/vial	USFDA	15 sites; Subjects – 40 (evaluable)	Multiple myeloma	1
Paclitaxel Protein Bound Particles for injectable suspension	US FDA	15 sites; Subjects – 32	CRC	1
Clozapine 100mg tablet	US FDA	2 sites; Subjects – 12(evaluable)	Schizophrenia	1
Leuprolide acetate lyophilisate powder for injectable suspension 3.75 mg	ANVISA	15 Sites; Subjects – 200 (evaluable)	Endometriosis	1
Amphotericin B 50mg/vial	USFDA	5 Sites; Subjects – 140 (evaluable)	Infectious disease	1
Paliperidone palmitate 156 mg injectable suspension (LAI)	EU	Sites- 10, Subjects – 130 (evaluable)	Schizophrenia	1

Veeda's Investigator & Site Database

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

Database of more than 900 Investigators, Veeda team has worked with more than 300+ 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

Project team

Board of Directors

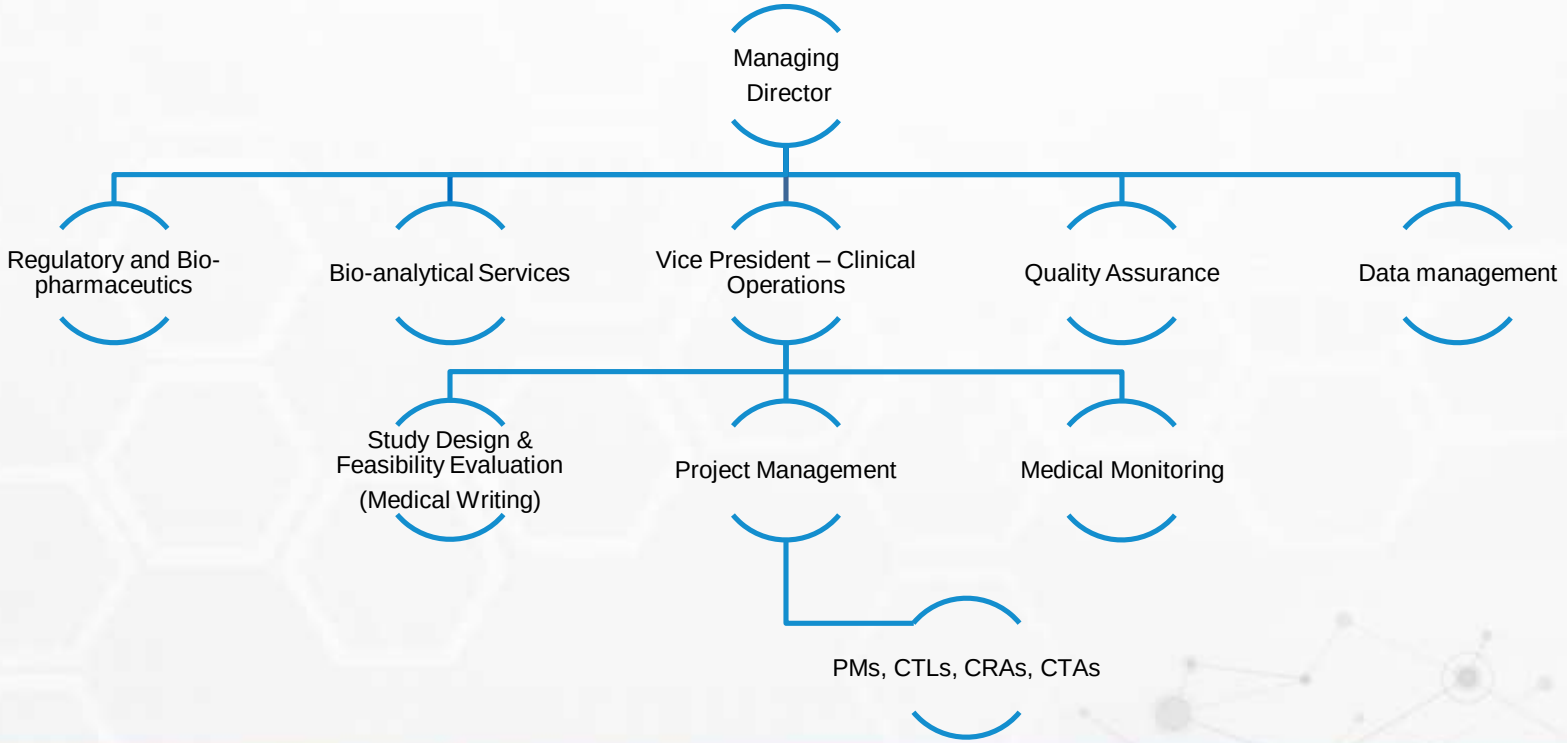
Managing Director

Vice President

Head - Clinical Operations

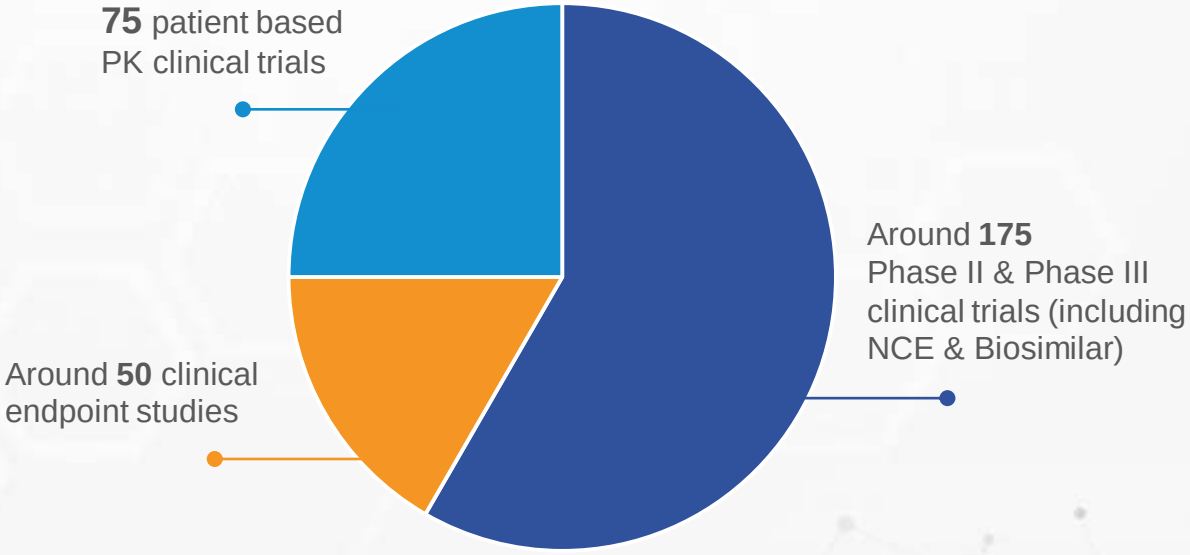
Sr. Project Manager (03)			PM (04)
Sr. CR (03)	CRA (26)	CTA (15)	

Team Overview - Clinical Operations - Organogram



Combined Team Experience in Clinical Trials

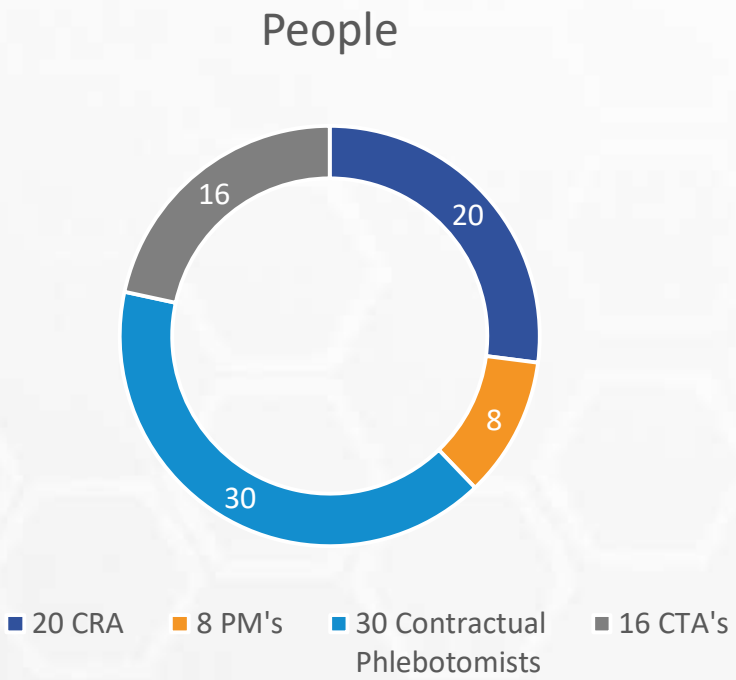
More than **300** clinical trials that includes



Team Experience Across various Therapeutic Areas and Indications

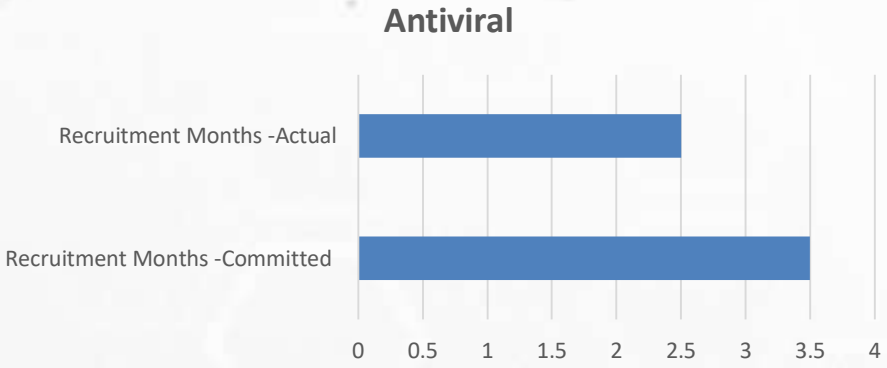
Sr. No.	Area	Indication	Regulatory Submissions
1	Psychiatry	Major Depressive Disorder, Schizophrenia, Bipolar disorder, Bipolar I depression	USFDA, EMA and DCGI
2	Medical Devices	CAD, Arrhythmia, Heart failure, Uncontrolled hypertensions,	USFDA & DCGI
3	Cardiology	Hypertension, Ischemic cardiomyopathy, 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

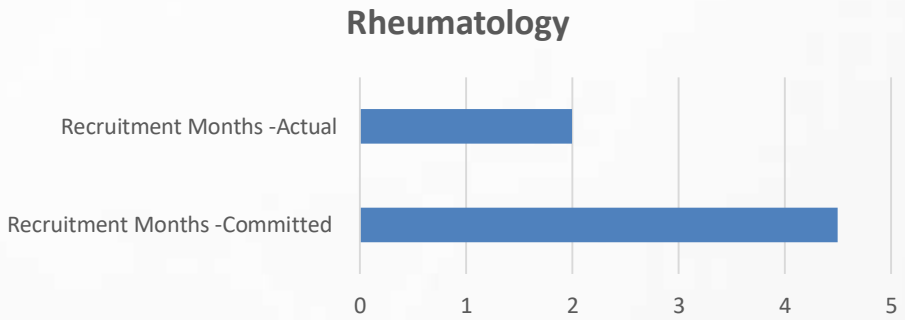
Training & Development

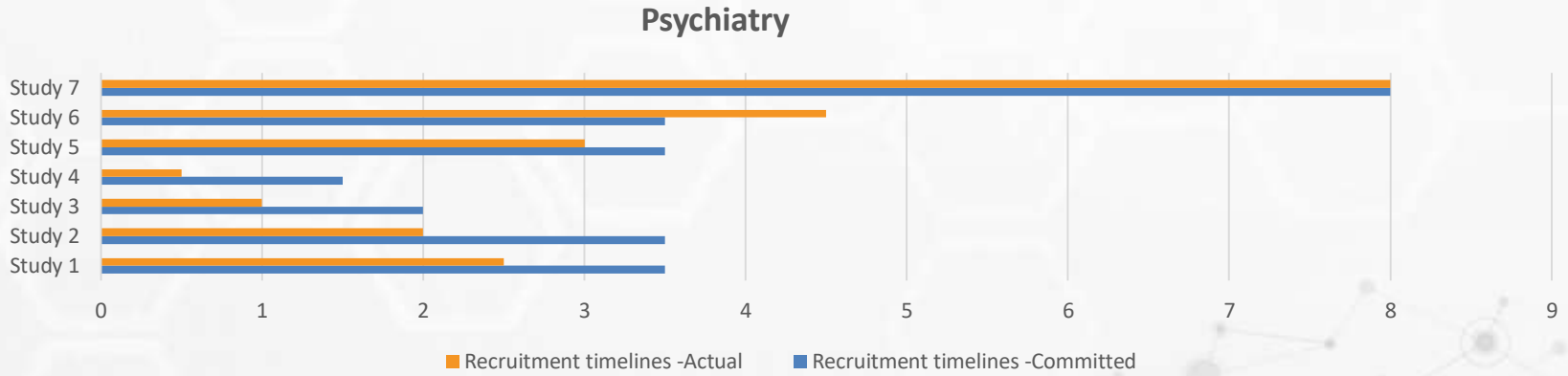


- 12 Continuous Professional Development (CPD) program topics/year/department
- Dedicated Training Team and Learning Management System
- Refresher training conducted every year
- eModules Training done through iPads
- GCP/GLP training conducted externally once every year SOP training conducted on an ongoing basis

Meeting Recruitment Timelines







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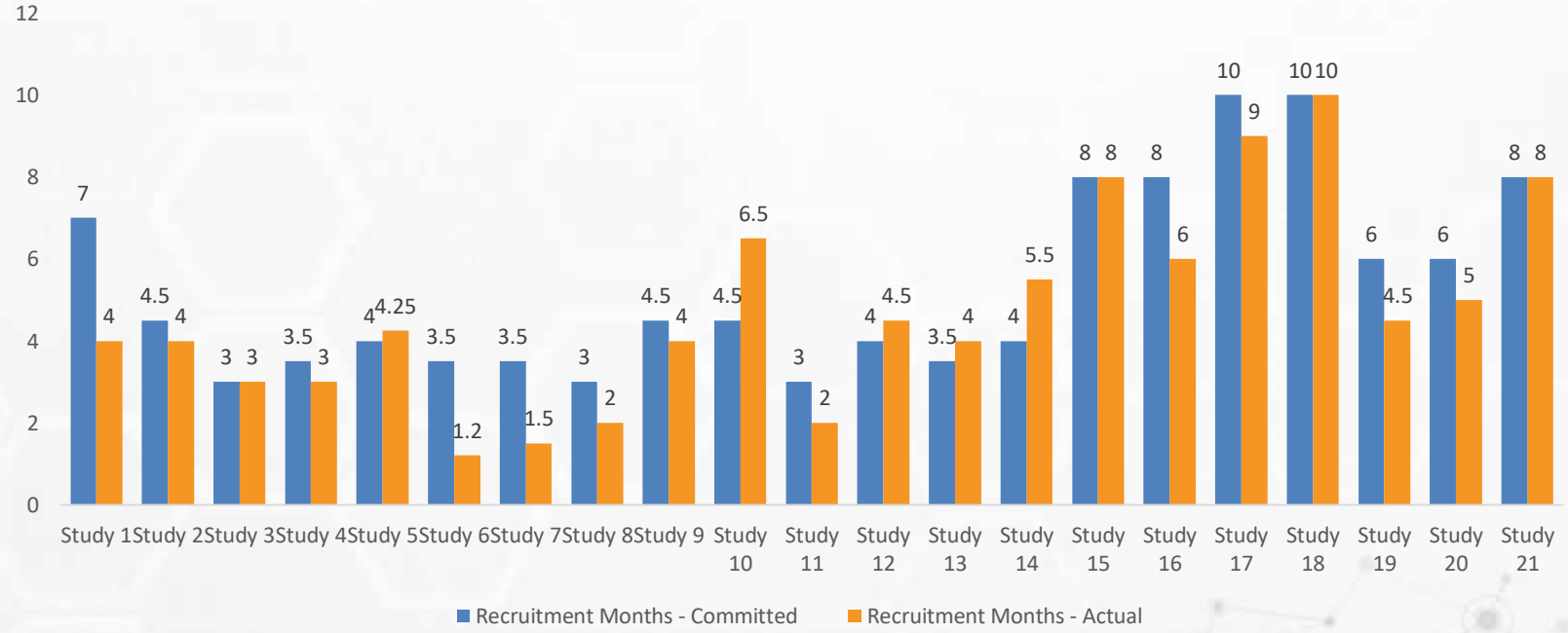


Pre-study activies- Project Plans

Project Management Plan	**Communication Plan**	**Risk Management Plan (Identified Risk & Mitigation)**	**Bio Analysis Plan**	**PK sample handling Plan**
Data Management Plan & Data Validation Plan (Data entry and system Validation) • Edit check Plan (Checking Edits in CRFs)	**Lab Data Transfer Plan**	**Investigational Product Plan & IMP Manual**	**Medical Monitoring Plan – MMP**	**Safety Management Plan**
	Site Monitoring Plan	**Quality Plan**	**Working Instructions and Site Operations Manual for sites**	

- Our project team ensures development of comprehensive project plans to successfully manage triple constraints of projects – cost, time and resources.

Our Monitoring Approach

Monitoring Assumptions

Monitoring Frequency
- During Recruitment & Treatment – 1 /month
- Multiple CRAs visits
- In house support to CRAs
- 100% SDV
- Sponsor reviewed report
- QC oversight

In process Monitoring
- 8 hr on site during 1st dosing
- Key parameters to be focused

Remote Monitoring
- During Lockdown or Curfew
- rSDV platform
- Key parameters to be focused

Clinical Monitoring Objectives

- ICF review
- Eligibility verifications
- Source data file review
- Laboratory data review
- Safety review
- Site staff training
- Communication with site staff
- Site file review
- Study Product management
- Non-compliance management (if any)

Our Approach Handling Patient PK studies

Experienced and Well trained Phlebotomist team:

- Network of contractual phlebotomist. Having average experience of 05 -06 years.
- Trained on GCP, GDP, Study protocol and PK sample handling manual.
- Phlebotomist represent part of site team and are delegated in the log.
- They are contractual and are responsible for sample collection and processing.

Ensure sites have adequate infrastructure and well trained

- SIV Kits to sites.
- Site Training.

Timely Shipment

- Regular follow up with sites for tracking patient visit and to track PK sample storage conditions.
- Established vendor support to arrange the shipment of IMP to sites and to arrange the PK sample shipment from sites to Veeda Facility.

CTMS


One centralized database for all study data
Track study budget & passthrough budget
Automate investigator payments
Gain complete control over your clinical trial operations:
Real-time visibility into study milestones & metrics
Streamline monitoring visits
Integrated IP Inventory tracking
Maintain electronic Trial Master File (eTMF)
Automated email alerts/notifications

CTMS – Key Features

Monitor Site Recruitment:
Real-time metrics and visibility to site recruitment performance enables earlier corrective action, if needed

Site Monitoring:
Plan site visits, track action items and open issues, and submit monitoring report (workflow enabled)

Automated Alerts:
Configurable automated alerts enable proactive monitoring and follow up

CRA Visit Calendar:
Allows CRAs and Project Managers to plan their site visits effectively.

Robust reporting capability:
Interactive reporting feature allows users to report on trial data promptly and stakeholders can take effective decisions to ensure timely completion of study

Study Contacts Database:
Centralized repository of study contacts

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

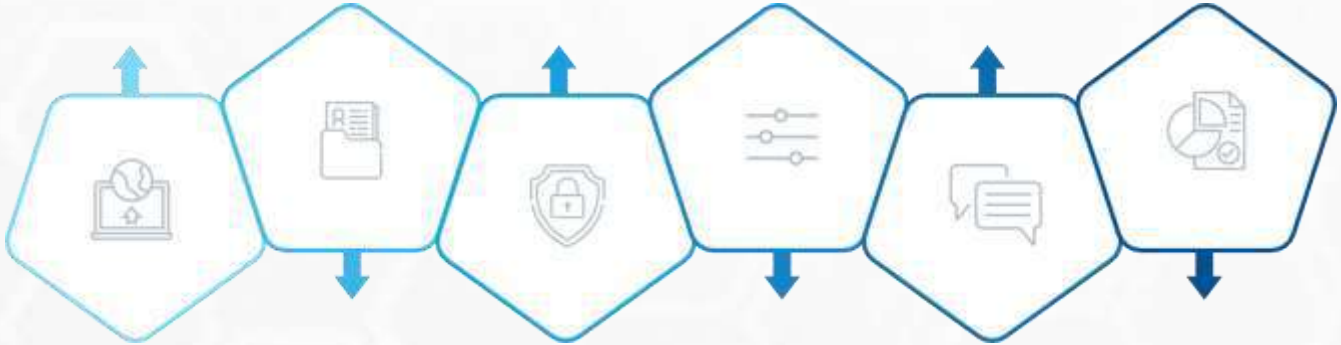
FLEXIBLE DEPLOYMENT OPTIONS

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

rSDV - Process Flow

STEP 01
Site User Collects Source Documents

STEP 02
Site User scans & redacts source documents

STEP 03
Site User uploads redacted documents on rSDV Portal

STEP 04
Site Monitor reviews source documents

STEP 05
Site User addresses Site Monitor's comments, if any

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

Quality Assurance

Site Audits

- Conduction of site audit as per audit plan
- Complacence of QA audit
- QA audit of 100% site data (Including source data, CRF and Site files)
- Main objective of audit will be to ensure Protocol adherence, meeting SOPs and regulatory requirements and to ensure traceability of study conduct.

Focus during QA audits

- Safety of subjects (Have all the adverse events been promptly documented)
- Reporting of AE/SAEs to IRB, Regulatory and sponsor
- Regulatory aspects of the trial such as regulatory and IRB/IEC approval
- Protocol Compliance (including inclusion and exclusion criteria check)
- Availability of current version of all essential documents (such as Protocol, ICD, e-CRF completion guidelines etc.)
- Review of study team training and experience.
- Overall GCP and applicable Regulatory Requirements Compliance

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.

Dr. Sumit Arora, M.D., Vice President - Clinical Operations and MPD

Current Responsibility

- Clinical Operations
- Medical Affairs
- Pharmacovigilance

Profile Overview

- Sumit Arora is a physician with specialization in Clinical Pharmacology with over 18 years of experience in the field of Medical Affairs and Clinical Research. He is currently assigned the responsibility of managing the teams in Clinical Operations, Medical Affairs and Pharmacovigilance departments.

Experience

- His experience includes working in both Pharmaceutical companies and Contract Research Organizations like Dabur, Ranbaxy, PAREXEL, Lotus Labs (subsidiary of Allergan, US; Actavis, now Teva) and Lambda Therapeutic Research before joining Veeda Clinical Research.

Special Areas of Expertise

- During his tenures, he has developed and led teams involved in clinical operations (project management, onsite and remote monitoring teams involved in Phase II-IV clinical studies involving NCE, patient PK and clinical endpoint studies) , medical affairs, medical monitoring, central/remote monitoring, pharmacovigilance. He has been a Medical Advisor for new product development, medical rationales for new formulations and has formulated strategies for launches and promotion of new and existing brands

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.

Our Key Site Oncologists

Gopi Chand

Gopi Chand is an Independent Hospital & Health Care Professional at City Care Center. He has completed his M.S., D.N.B., M.Ch., Surgical Oncology from Kidwai Memorial Institute of Oncology

Dr Chirag Desai

Dr. Chirag Desai is one of the most dynamic oncologists in India. He completed MD (Medicine) in 1991 and DM (Oncology) in 1993. He graduated in the first batch of DM (Oncology) from Gujarat Cancer and Research Institute (GCRI), Ahmedabad. He started his oncology practice in 1999 and laid the foundation of the group oncology practice that has flourished today as HOC Vedanta with 11 colleagues and 3 branches in Ahmedabad

Dr Minish Jain

Dr Minish Jain is a Medical Oncologist at Grant Medical Foundation, Ruby Hall Clinic. He has completed his fellowship in Oncology from P D Hinduja Hospital and Research Center and pursed his research fellowhip from Massachusetts General Hospital from Boston.

Chandan Das

Chadan Das is a Medical Oncologist and Associate Professor at PGIMER. He has completed his post graduate in Medical Oncology from Institute of Medical Sciences.

Recognitions

Recognitions

Celebrating
16 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

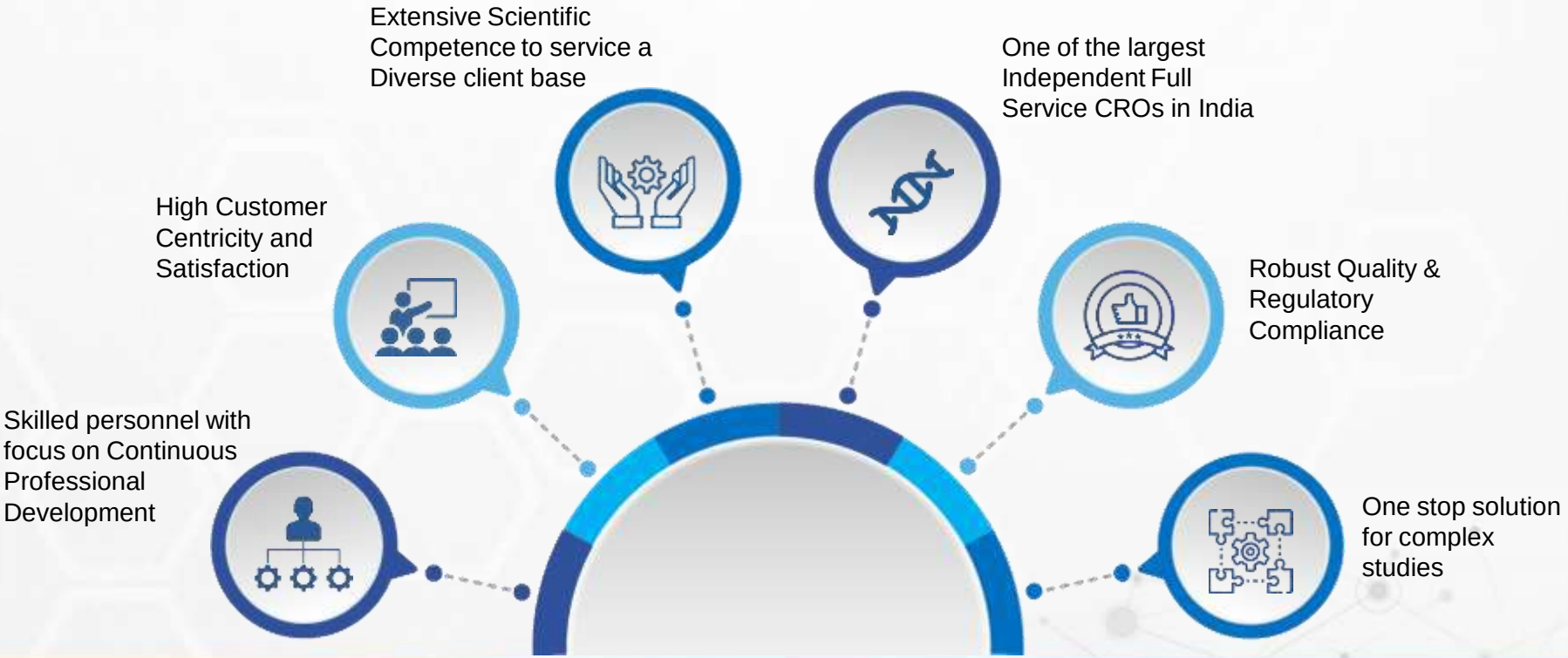
2019

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