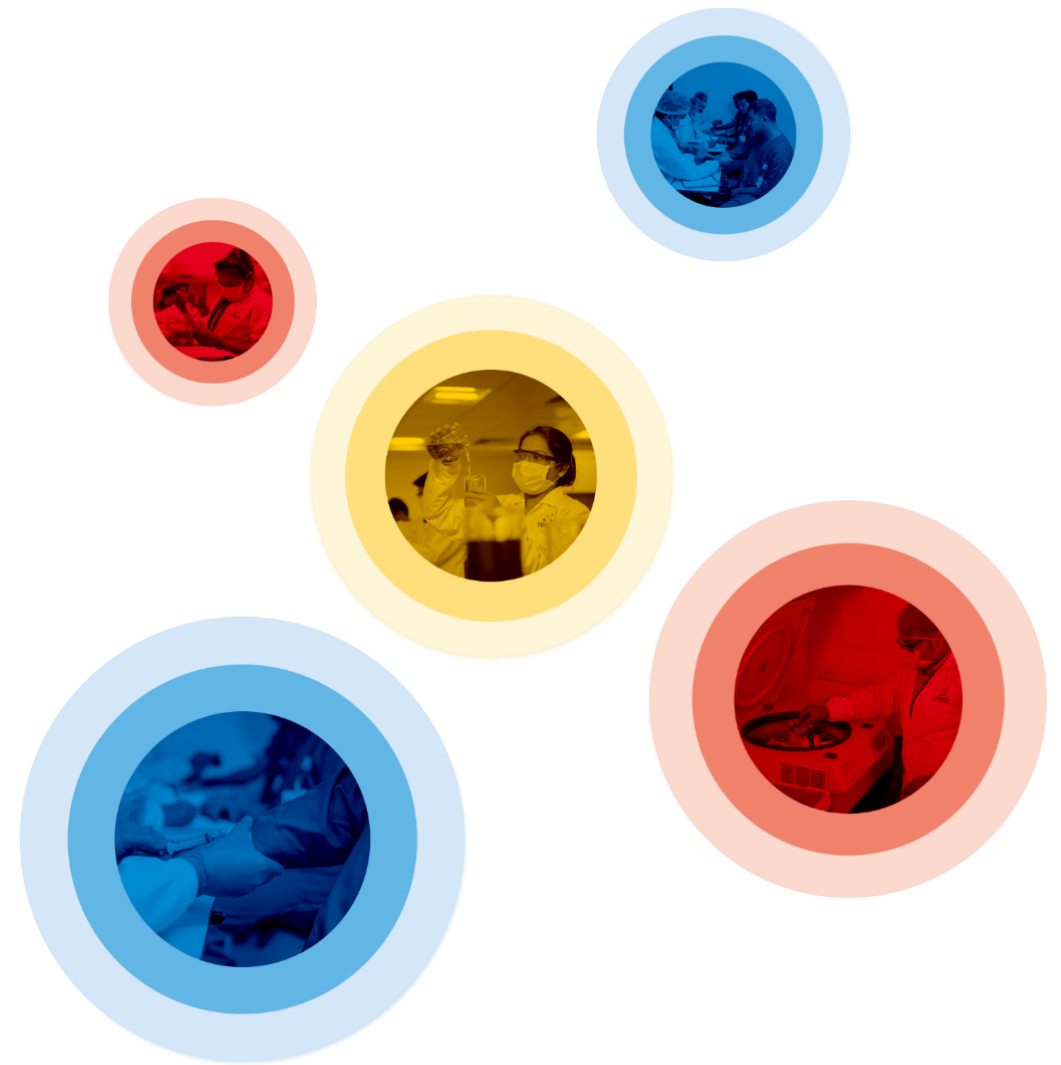




Global Clinical Development Partner



Providing Quality Clinical Research Solutions



veeda clinical research®

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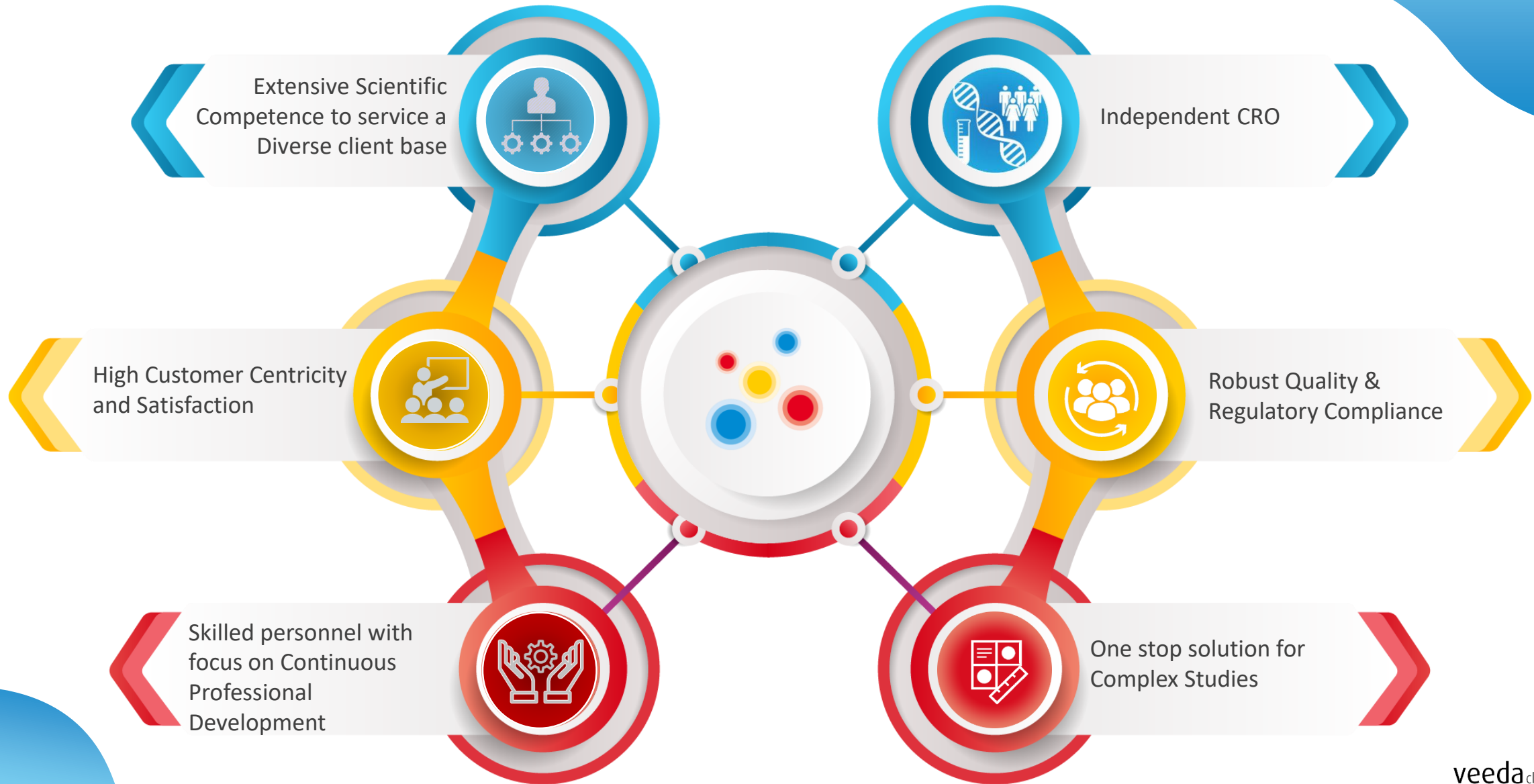
 Investigator Database and Feasibility Information

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# The Veeda Advantage





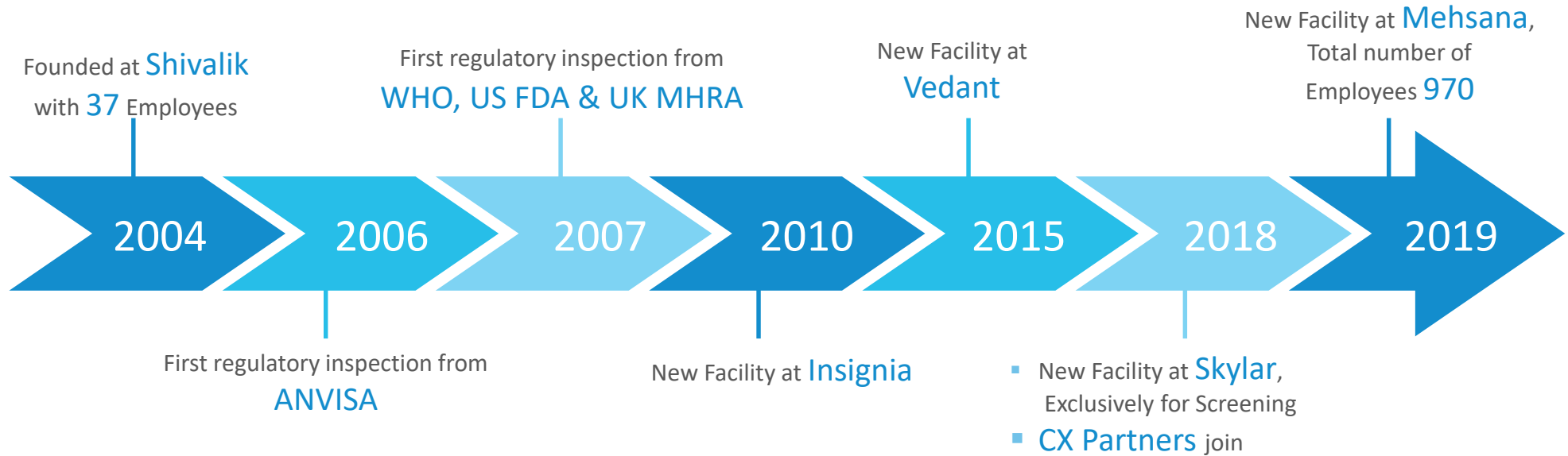
# CORPORATE OVERVIEW

# Evolution

Privately owned,  
board managed  
company



Ahmedabad



## Corporate Outlook



Focus on Organic and Inorganic growth strategies to enhance service capabilities



Financial Stability based on prudent management & Private Equity sponsorship



Operational Stability based on experienced professional management and strong quality culture



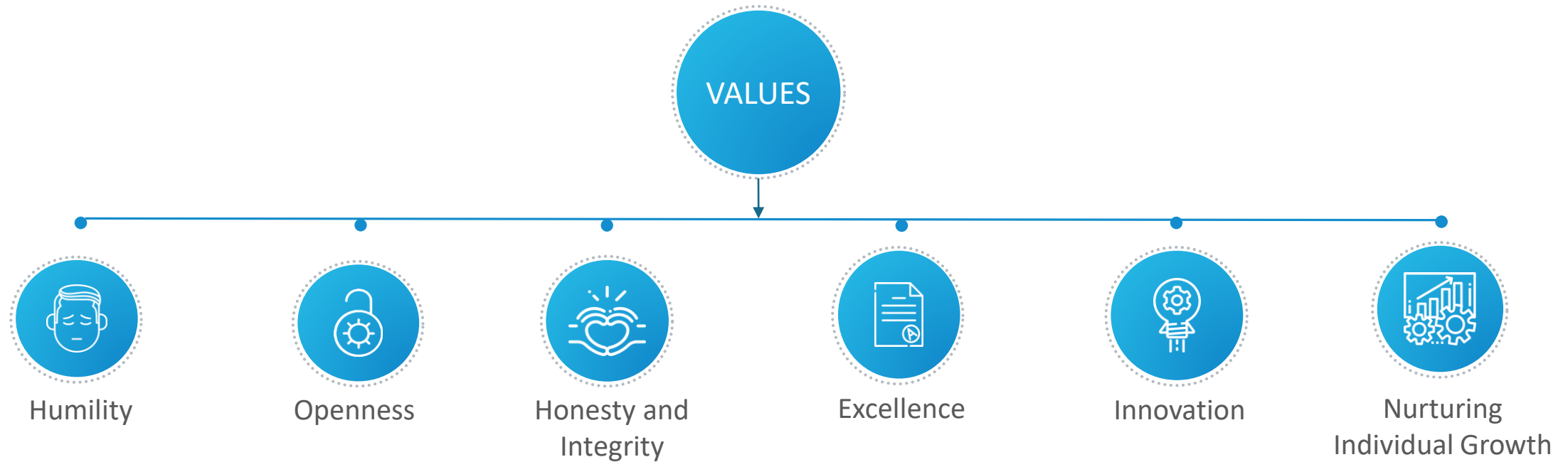
Ongoing investments in technology to enhance operating efficiencies and compliance management





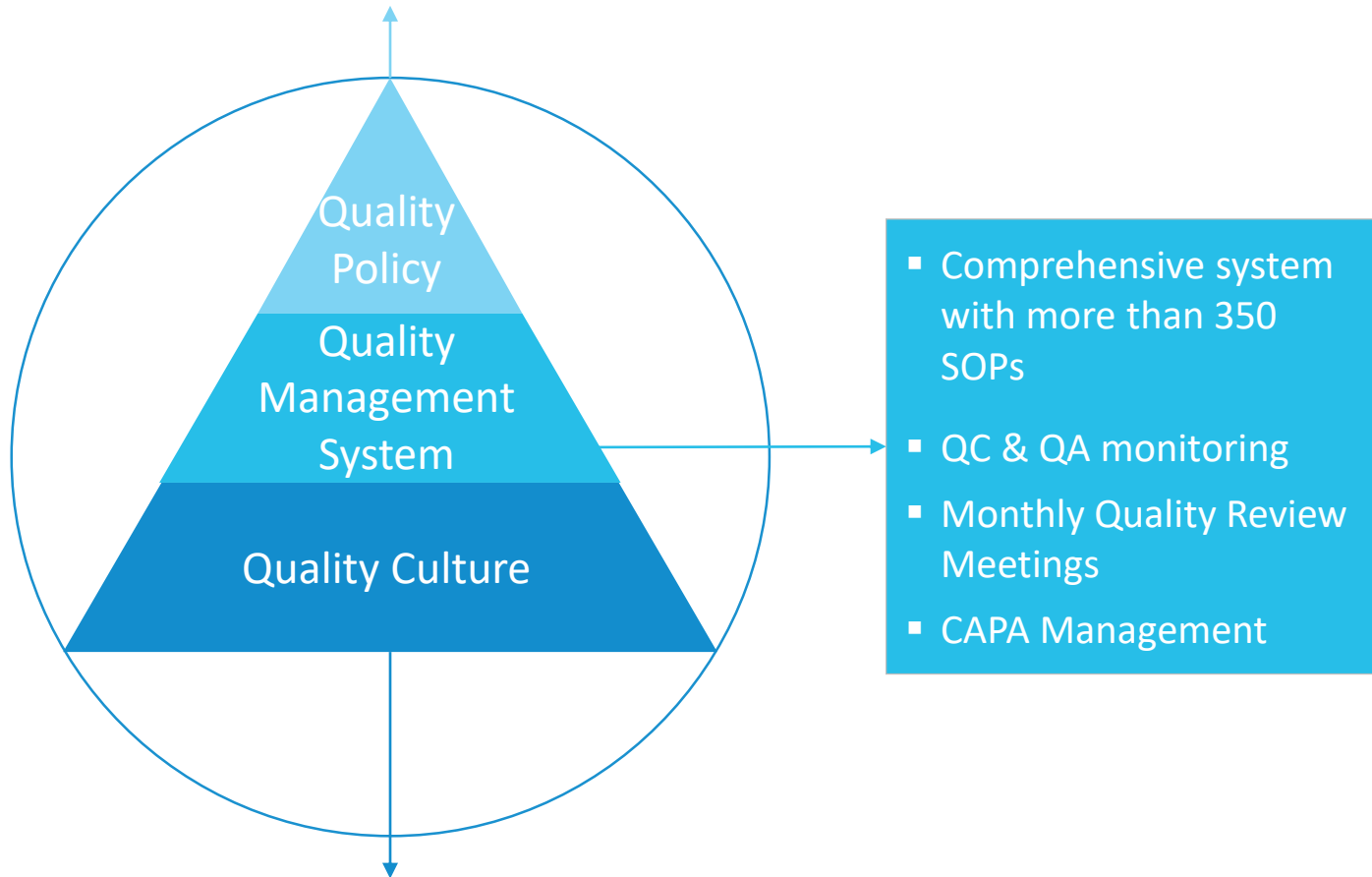
## MISSION & VISION

To strive for Excellence in Quality and Endeavour to become the Partner of choice for our Sponsors and our Stakeholders



# Quality Structure

“Veeda’s 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”



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



\*FDA : 17 AUDITS FOR PATIENT BASED STUDIES  
16 AUDITS FOR HEALTHY SUBJECTS STUDIES





# INFRASTRUCTURE

# Clinical Infrastructure

## VEDANT

Clinical, Bioanalytical with administrative offices

## SHIVALIK

Dedicated Clinical facility

## MEHSANA

Clinical and Screening facility

## INSIGNIA

Dedicated Bioanalytical facility

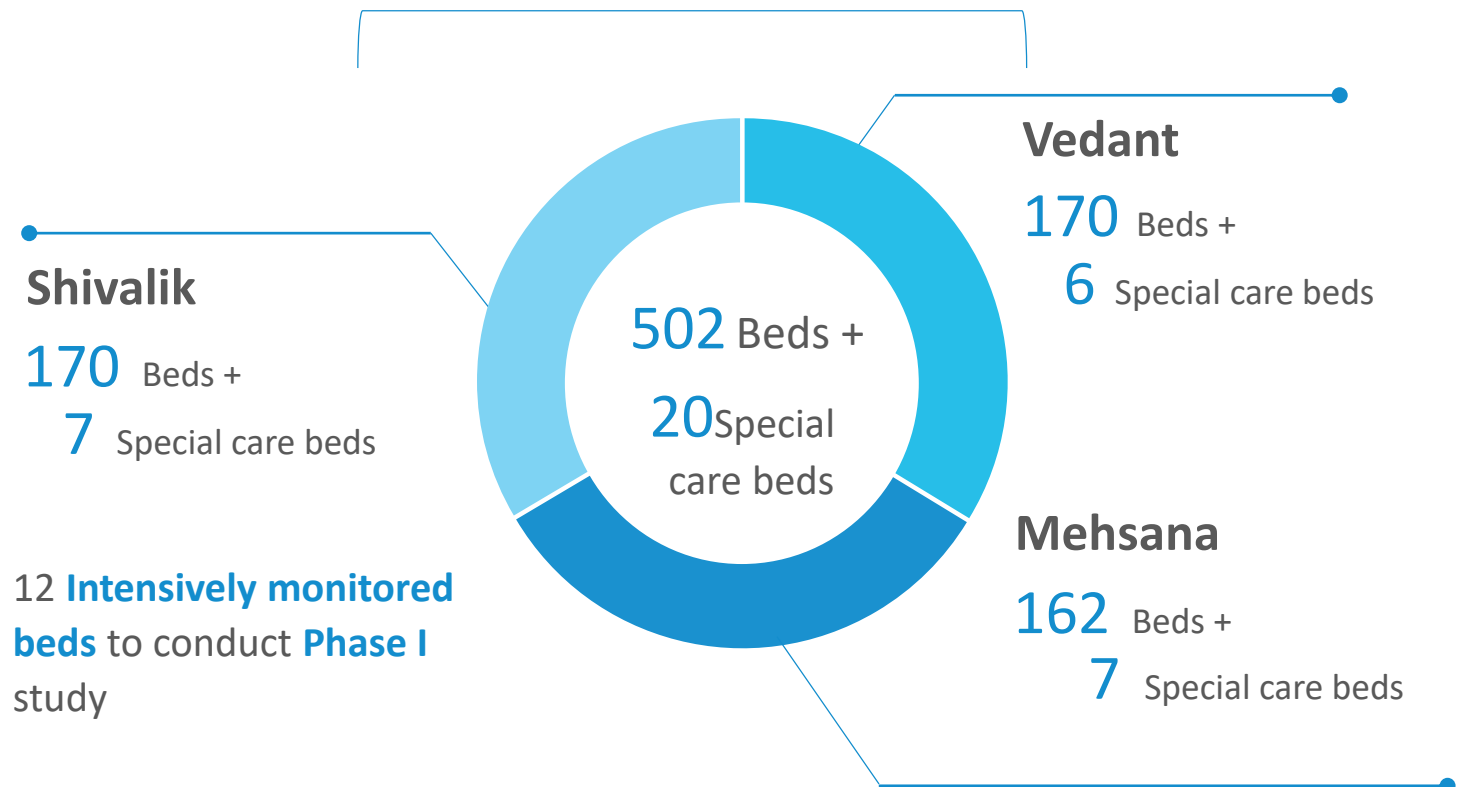
## SKYLAR

Common screening facility for both Shivalik and Vedant

## ARCHIVES

Internal archival area in each facility. Separate long term archival facility at Mehsana and Unjha

Spread across 17 clinics



## Storage Capacity

- 46 LC-MS/MS machines
  - Insignia - 33
  - Vedant - 13
  - API 5500/4000/3200/3000/2000
  - Shimadzu 8060/8050/8040
  - Quattro Premier
- 2 ICP-OES
- Watson LIMS



### Plasma Sample:

45 Deep freezers with capacity to store 11,25,000 samples at -80 C°



### IP Storage:

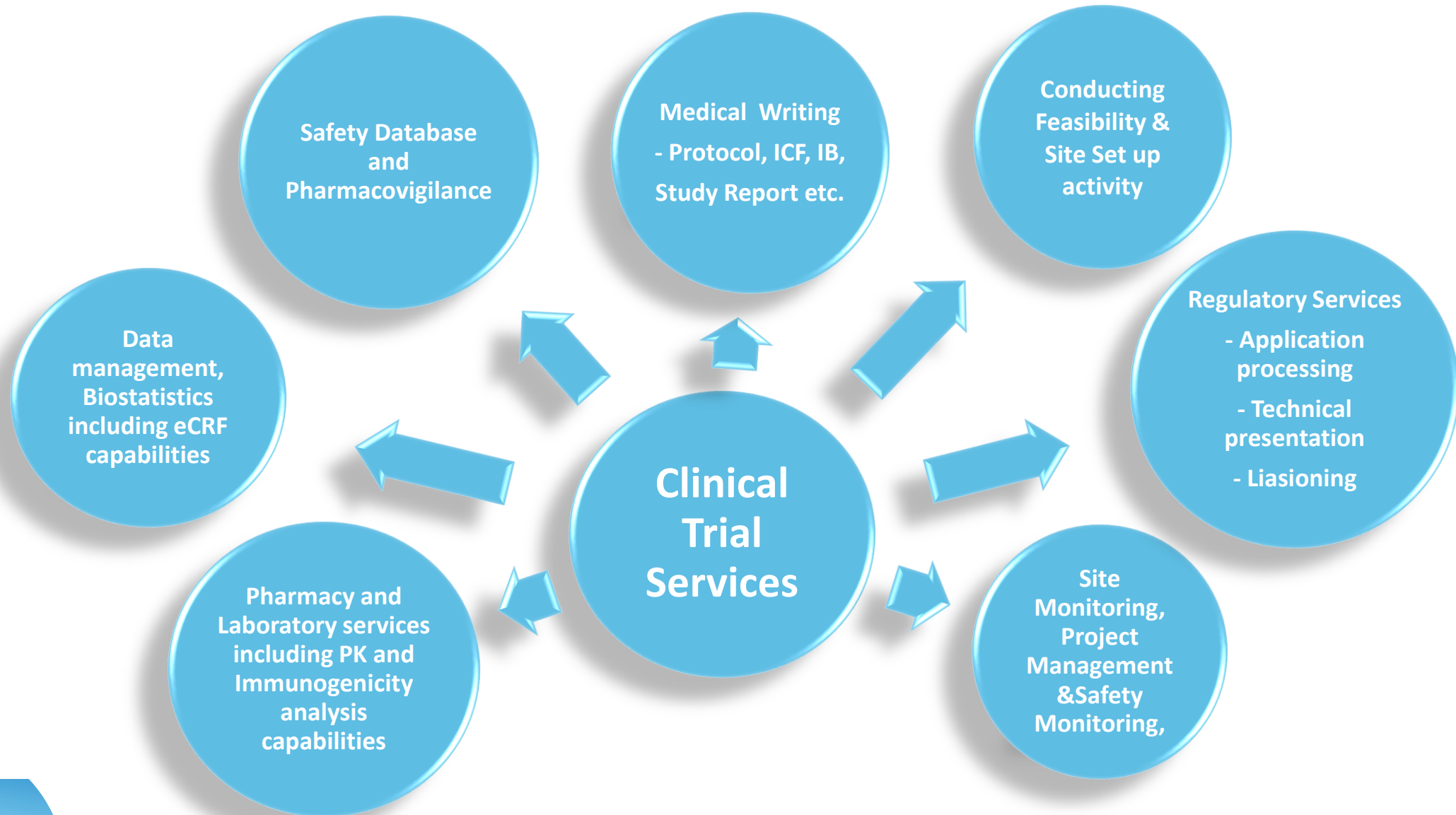
- 3 Walking type stability chambers with overall capacity to store 34000 Ltr for retention at room temperature
- 4 Humidity chambers with overall capacity of 3200 Ltr
- 4 Pharmaceutical refrigerators having storage capacity of 3550 Ltr at 2-8 C°



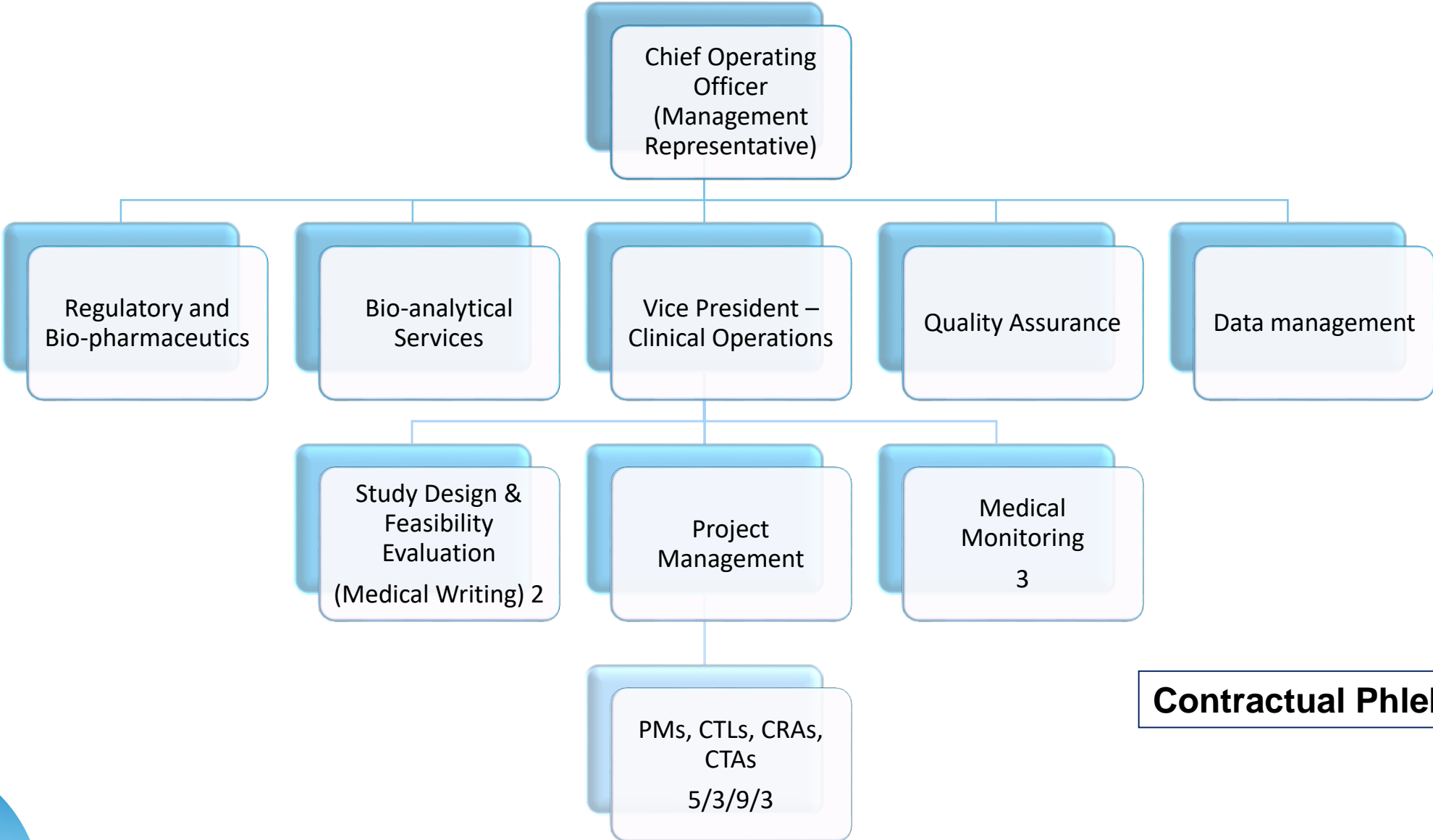
**Archival:** Capacity to archive approximately 51000 files

✓ Privately owned CRO with no conflict of Interest
✓ 15 yrs history and 8 yrs of patient based Clinical trial experience
✓ Experienced team to handle the criticalities and challenges of the studies
✓ Scalable team
✓ Proven track record of timely recruitment even for rare indications like RCC and SCLC
✓ Data base of prescreened experienced, GCP compliant Investigators with good tested recruiting potential
✓ Dependable and consistent regulatory audit compliance track record.
✓ Worked with more than 125 Investigators' sites in different TAs
✓ Excellent regulatory liaison for obtaining DCGI approval/BE- NOC

# Our Clinical Trial Services



# Team Overview - Clinical Operations - Organogram



**Total - 24**

**Contractual Phlebotomist - 35**

# Team Overview

Functional Role	Vice President – Clinical Operations	Senior Manager-Clinical Operations	Senior Manager-Clinical Operations
Qualification	M. D. (Pharmacology)	B. A. M. S.	M. Sc., D. Pharm.
Total exp.		~15	> 13 years
Expertise		<ul style="list-style-type: none"> <li>•Has been involved in more than 40 multicentric trials in below therapeutic areas.</li> <li>•Cardiology</li> <li>•Ophthalmology</li> <li>•Psychiatry</li> <li>•Oncology</li> <li>•Rheumatology</li> <li>•Gynecology</li> <li>•Endocrinology</li> <li>•URTI</li> </ul>	<ul style="list-style-type: none"> <li>•Has been involved in studies like First in Man, SAD, MAD, dose proportionality studies, glucose clamps, biosimilars.</li> <li>•Lead the team of project managers, report-writing, and project co-ordination.</li> </ul>

# Team Overview

Qualification	M. Pham	M. Pham.	B. A. M. S.
Total exp.	> 8 Years	> 8 Years	> 11 Years
Therapeutic Area exp.	<ul style="list-style-type: none"> <li>• Oncology</li> <li>• Psychiatry</li> <li>• Nephrology</li> <li>• Rheumatology</li> <li>• Infectious disease</li> <li>• Immunology</li> </ul>	<ul style="list-style-type: none"> <li>• Oncology</li> <li>• Psychiatry</li> <li>• Ophthalmology</li> <li>• Rheumatology</li> <li>• Infectious Disease</li> </ul>	<ul style="list-style-type: none"> <li>• Cardiology</li> <li>• Ophthalmology</li> <li>• Psychiatry</li> <li>• Oncology</li> <li>• Dermatology</li> <li>• Rheumatology</li> <li>• Endocrinology</li> <li>• Respiratory</li> <li>• Infectious diseases</li> </ul>
No. of trials handled	➤ 20	> 20	>25
Exposed to	EDC, CTMS, IWRS, IVRS	EDC, IWRS, CTMS	EDC, CTMS, IWRS, IVRS

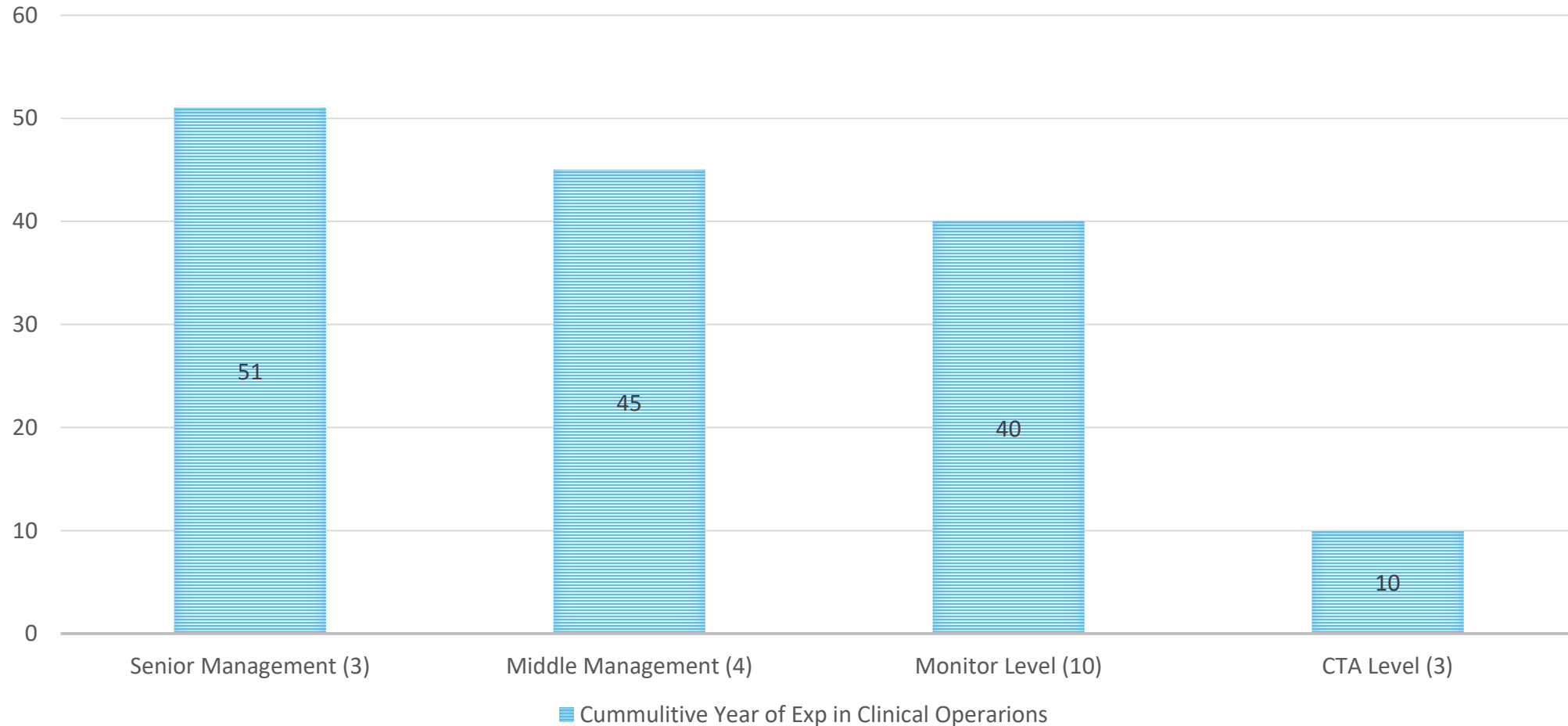
Other team members	No.	Average exp.
CTL	3	6-7 years
Medical Monitors	3	4-10 years

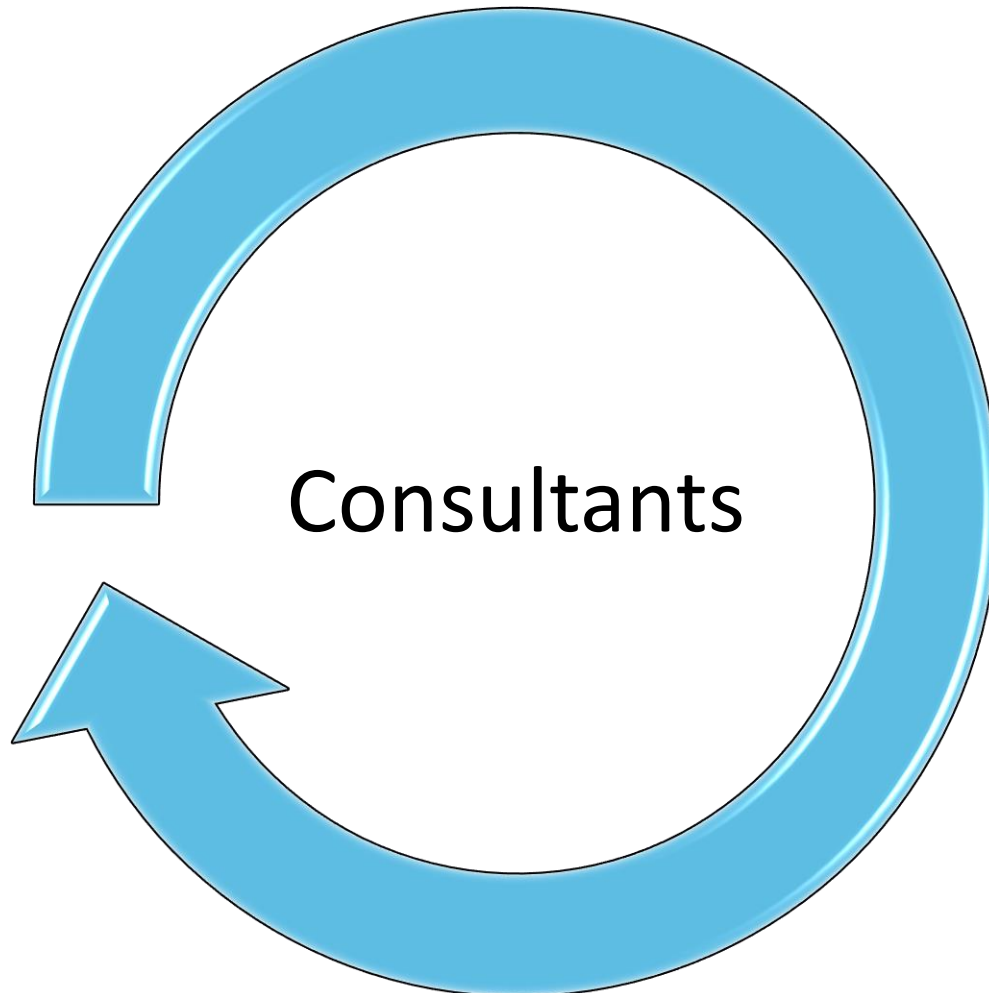
Other team members	No.	Average exp.
CRAs	9	2-3 years
CTAs	3	2-3 years



# Team Experience

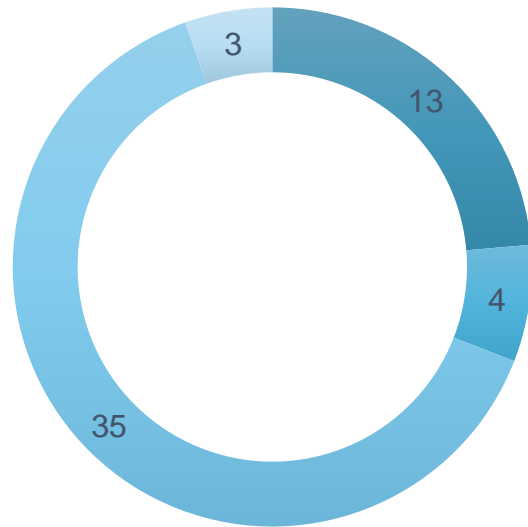
## CUMULATIVE YEAR OF EXPERIENCE IN CLINICAL OPERATIONS





- Statistician
- Oncologist
- Ophthalmologist
- Psychiatrist
- Cardiologist
- Endocrinologist
- Physician

## People



■ 13 CRA   ■ 4 PM's   ■ 35 Contractual Phlebotomists   ■ 3 CTA's

- ❖ 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

# Study execution – Processes

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- 01 Site selection
- 02 Training and Infrastructure Support to the sites
- 03 Assistance to site in Screening Patients
- 04 Site Monitoring
- 05 Shipment of IMPs and biological samples
- 06 Phlebotomy Services
- 07 Quality Assurance

## Organization experience

### ❖ Competed Projects

- 4 global multi-centric phase II clinical trials in Oncology
- 2 phase III studies of injectable implants
- 24 patient based PK clinical trials
- 4 Stand-alone Medical Writing BE-PK studies

### ❖ Ongoing Projects

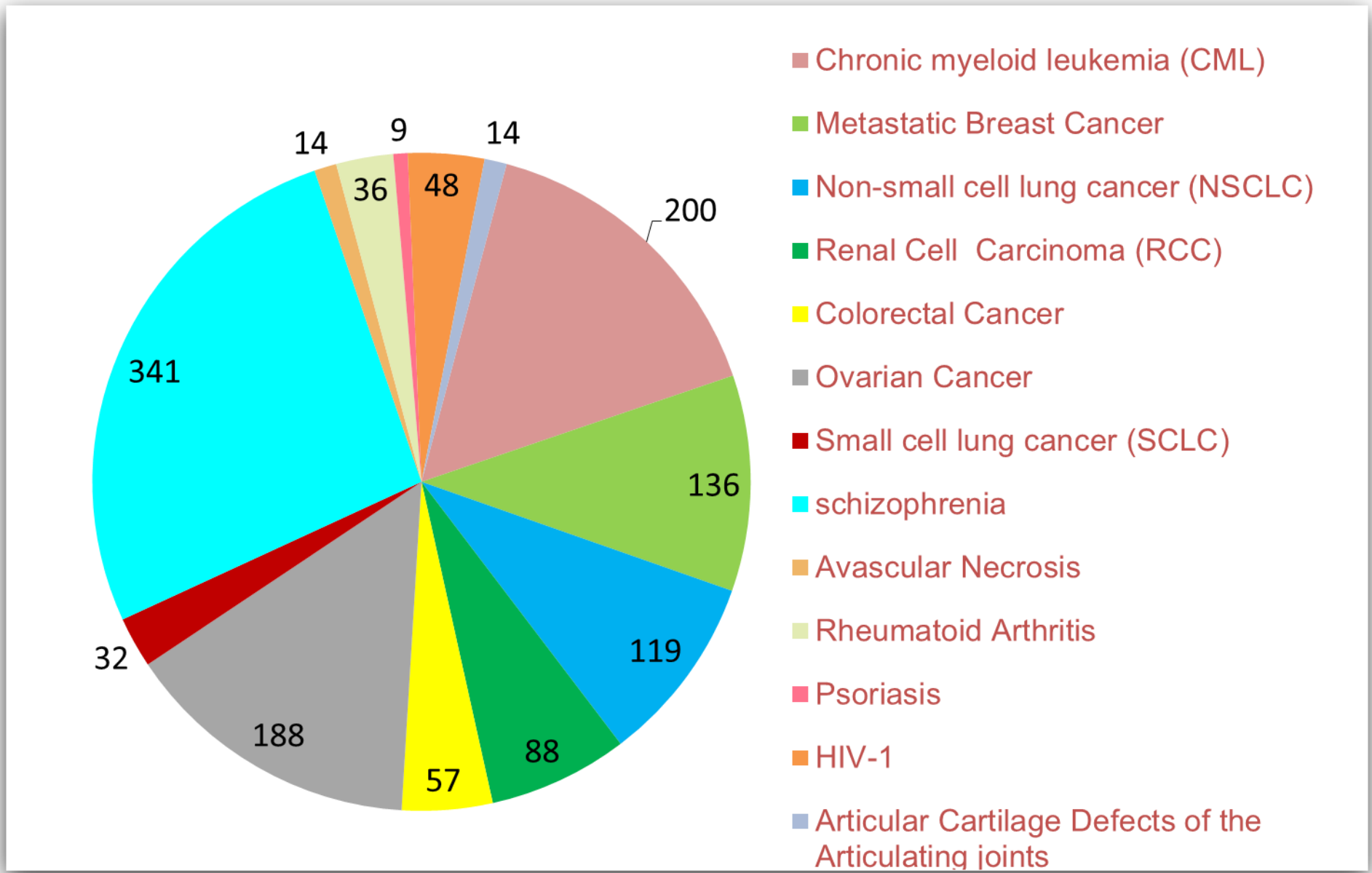
- 9 Ongoing PK studies in different stages of execution
- 2 Ongoing phase II study

## Team Experience (Previous Organization)

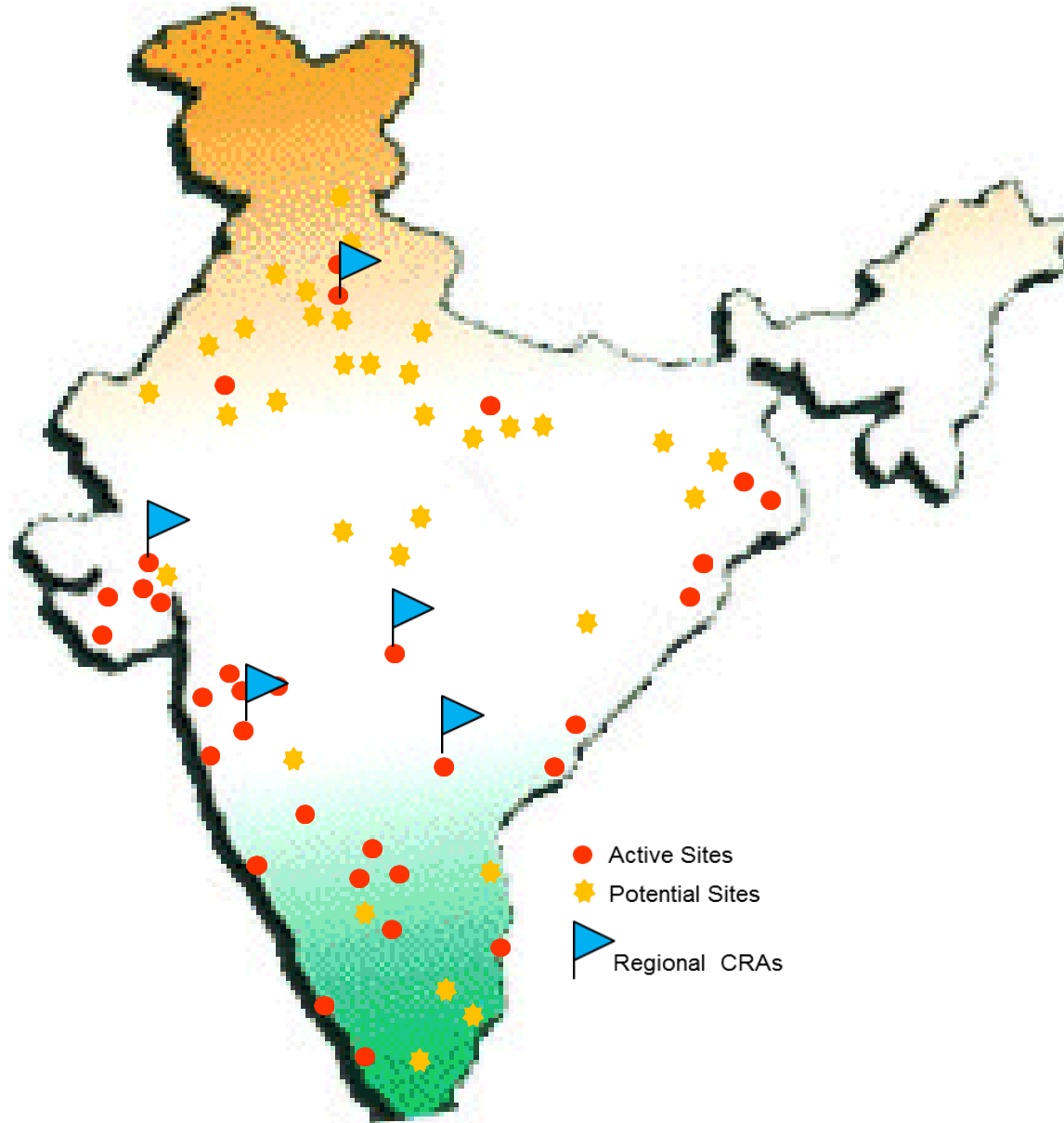
### ❖ Combined Team Experience in Clinical Trials. More than 130 clinical trials that includes.

- Around 25 global clinical trials
- Around 30 clinical endpoint studies
- 75 patient based PK clinical trials

# Veeda Experience in Clinical Trials



# Network Footprints



- Sites across all major cities
- More than 100 active sites currently
- CRAs based in 5 cities

# Completed Projects

Study detail	Submission	Recruitment timelines		Comments
		Committed	Actual	
Etoposide 50 mg capsule – <b>SCLC</b>	US FDA	7 months	4 months	Sample size-24 No of sites-8
Imatinib 400 mg tablet – <b>CML</b>	US FDA	4.5 months	4 months	Sample size-32 No of sites-4
Capcitabine 500mg Cap in <b>MBC and CRC</b>	EU	3.0 months	3.0 Months	Sample size – 54 No. sites – 8
Methotrexate 2.5 mg Tab in <b>RA &amp; Psoriasis</b>	US FDA	4.5 months	2.0 Months	Sample size – 42 No. sites – 10
Everolimus 10 mg tab – <b>RCC</b>	US FDA	3.5 months	3 months	Sample size- 58 No. of sites -25
Doxorubicin Hcl (Pegylated liposomal) <b>Ovarian &amp; Breast Ca.</b>	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) <b>Ovarian &amp; Breast Ca.</b>	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 <b>CML</b>	US FDA	3.5 months	1.2 months	Sample size-32 No of sites-4
Imatinib 400 mg tab <b>CML</b>	US FDA	3.5 months	1.5 months	Sample size-34 No of sites-4
Imatinib 400 mg tab <b>CML</b>	US FDA	3.0 months	2.0 months	Sample size-30 No of sites-4
Quetiapine 400 mg ER tab in <b>Schizophrenia</b>	EU	3.5 months	2.5 months	Sample size – 64 No. sites – 4
Imatinib 400 mg tab <b>CML</b>	US FDA	4.5 months	4 months	Sample size-32 No of sites-4
Imatinib 400 mg tab <b>CML</b>	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 <b>HIV-1</b>	EU	3.5 months	2.5 months	Sample size – 48 No. of Sites 4
Paliperidone PR 9 mg tab, <b>Schizophrenia</b>	EU	3.5 months	2 months	Sample size – 75 No. of Sites 5
Clozapine Tab 100 mg, <b>Schizophrenia</b>	USFDA	2 months	1 month	Sample size – 28 No. of Sites 2
Clozapine Tab 25 mg, <b>Schizophrenia</b>	CFDA	1.5 months	0.5 month	Sample size – 14 No. of Sites 1
Imatinib 400 mg tab – <b>CML &amp; GIST</b>	US FDA	3 months	2 months	Sample size-40 No of sites-4
Paclitaxel 100 mg/vial <b>MBC</b>	US FDA	4 months	4.5 months	Sample size- 76 No of sites-15
Everolimus 10 mg tab – <b>RCC</b>	US FDA	3.5 months	4 months	Sample size- 30 No. of sites -15
Quetiapine 600 mg PR tab in <b>Schizophrenia</b>	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 <b>Schizophrenia</b>	EU	3.5 months (100 randomized)	4.5 months (108 randomized)	<p>Sample size – 108 (randomize) No. sites – 7</p> <p>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.</p>
Capecitabine Tablets 500 mg in <b>MBC and CRC</b>	US FDA	4 months	5.5 months	<p>Sample size: 45 No. of sites: 6</p>
Liposomal doxorubicin Injectable IV infusion in <b>ovarian cancer</b>	US FDA	8 months	8 months	<p>Sample Size – 66 No. of site – 14</p>

# Completed Phase II & III Projects

Sr. No.	Therapeutic Indication	Subjects randomized
1	A Phase II Study in Non-Small Cell Lung Cancer-	53
2	A Phase I Followed by a Randomized, Phase II Study in Small Cell Lung Cancer (SCLC)	5
3	Phase II clinical study in non-small cell lung cancer and colorectal cancer	40
4	Phase 2b Study in Advanced Non-Small Cell Lung Cancer	26
5	Phase III Study in Subjects with Articular Cartilage Defects of the Articulating Joint(s)	14
6	Phase III Study in Subjects with Avascular Necrosis (AVN)	14

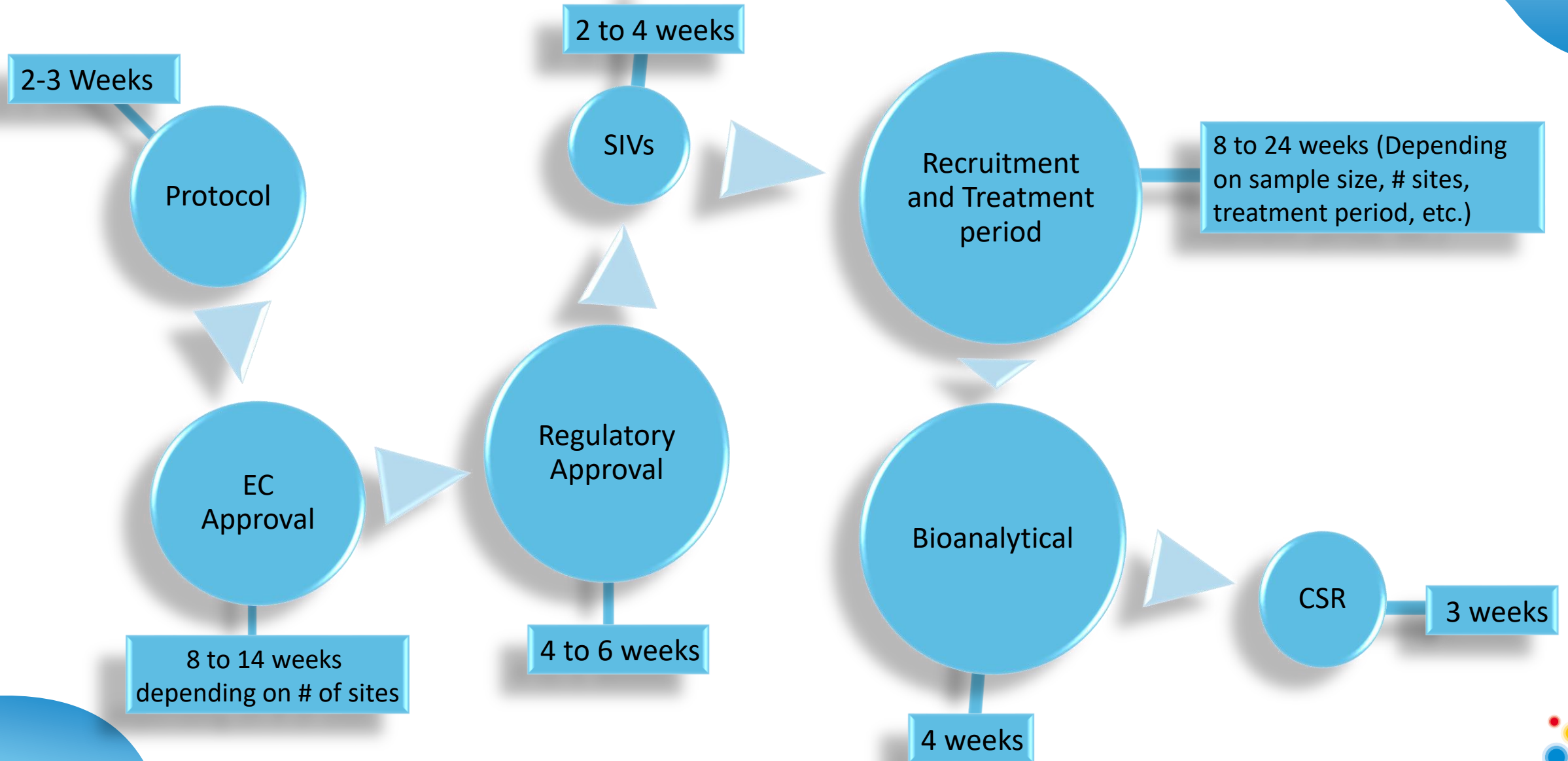
# Current projects Patients based PK studies

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
Liposomal doxorubicin Injectable IV infusion	EU	Sites-15, N-54(evaluable) Recruitment completed	Ovarian Cancer & Breast Cancer	1
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

# Current projects - Phase II studies

Drug/Class	Phase	Sites/Sample size	Indication
Inhibitor of PD-L1, PD-L2, and VISTA pathways	II	Sites-11, Subject 130	Different tumor types (5 cohorts)
Novel Thrombolytic Agent	II	Sites-6, Subjects 70	Acute ST-segment Elevation Myocardial Infarction

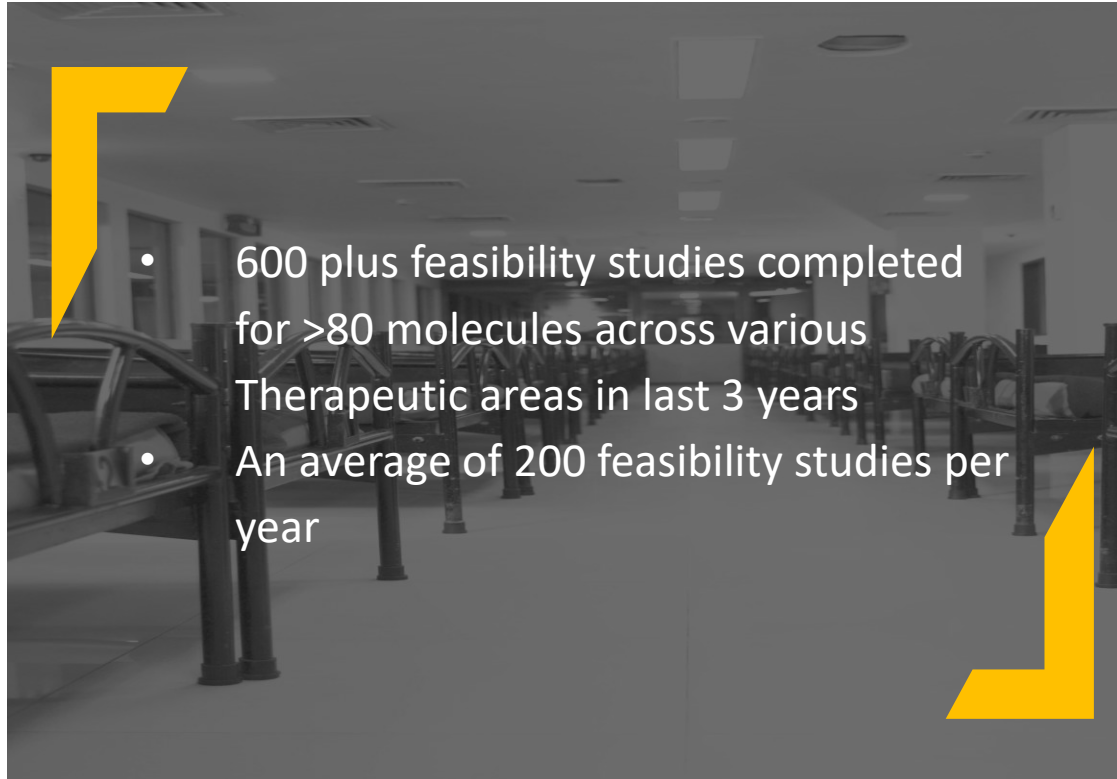
# General Project Timelines for Patient Based Studies



# Database of Investigators

Therapeutic Area	Investigators Database	No. sites Veeda worked with
Oncology	135 Oncologists	75 sites
Psychiatry	90 Psychiatrists	16 sites
Orthopedics and Rheumatology	72 Orthopedics and Rheumatologists	21 sites
MD Physicians	79 MD Physicians	10 sites
Dermatology	87 Dermatologists	4 sites
Cardiology	20 Cardiologists	05 sites
Ophthalmology	80 Ophthalmologists	NA
Urologist	27 Urologists	12 sites
Nephrology	66 Nephrologists	NA
Pulmonology	80 Pulmonologists	NA
Gastroenterology	45 Gastroenterologists	NA
Endocrinology	38 Endocrinologists	NA
Hematology	16 Hematologists	NA
ENT	35 ENT Specialists	NA
Gynaecology-Obs	70 Gynecologists	NA
Paediatrics	70 Pediatricians	NA





Therapeutic Area	# Molecules
Oncology	28
Psychiatry	14
Dermatology	17
Respiratory	08
Biosimilars	06
Endocrinology	04
Gastro	06
Rheumatology	05
Ophthalmology	04
Obs/Gyne	04
Others	05

# TESTIMONIALS

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“ In a highly regulated environment, such as the pharmaceutical industry, where quality is critical and time is precious, having a trustworthy partner is one of the key elements of success. Working with Veeda provides a peace of mind, with respect to consistently and timely delivering quality work. I've worked with Veeda on several projects and plan to continue doing so for the foreseeable future. ”

- Our Esteemed Client from Europe



“ When it comes to choosing your partner for a clinical program, Veeda is the first CRO you can think of. All these years of partnership with Veeda we came across with high qualified personnel, fully-dedicated to our challenging demands. ”

- Our Esteemed Client from Europe



“ It has been a pleasure having Veeda CR as a contract research organization for the conduct of our bio equivalence studies. Being an independent CRO, it is good to see Veeda have a wide range of analytical methods and good clinical experience. Their quality practices, open communication and timely delivery has been a highlight of their work system which enables us stay on top of our project. Looking forward to see the good work continue in the coming years. ”

- Our Esteemed Client from India



# TESTIMONIALS

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“As a Sponsor in different time zone (USA), I have found Veeda Team to be very responsive in providing timely operational updates to enable our team to make quick decisions”.

- Our Esteemed Client from USA



“ The excellent project management and support and openness from a experienced, well trained and scientifically oriented team along with quality of the deliverables are some of the reasons that kept us close partners for more than 12 years. Congratulations and keep up with good work Veeda team! ”.

- Our Esteemed Client from Europe



“ Our organization has worked with Veeda for a number of years, and we are continually impressed with the team’s speed of responsiveness to their customers. The Veeda team is available, knowledgeable and always willing to work through any queries we might have. We greatly value Veeda’s customer service, expertise and seamless project management. Congratulations on 15 years of Clinical Excellence! ”

- Our Esteemed Client from USA



# ACHIEVEMENTS



2004 — 2017

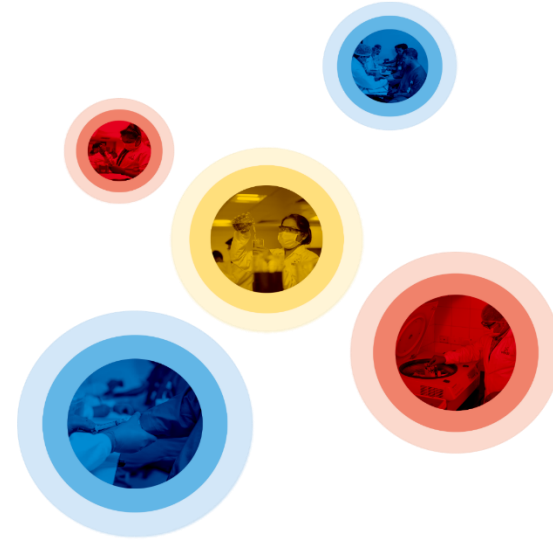
Organization	Award Category
	National Excellence Award
	Best Pharmaceutical CRO
Health & Safety Awards	Best Clinical Research- India
	Best Clinical Research- India
	Mark of Excellence
	Indian Clinical Research company of the year

Organization	Award Category
	Best Clinical Research Organization - India Organization - India
	Clinical Trial Company of the Year Year
	Bharat Udhog Ratan Award in Clinical Clinical Research

2018

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

2019



veeda clinical research<sup>®</sup>

Thank You

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