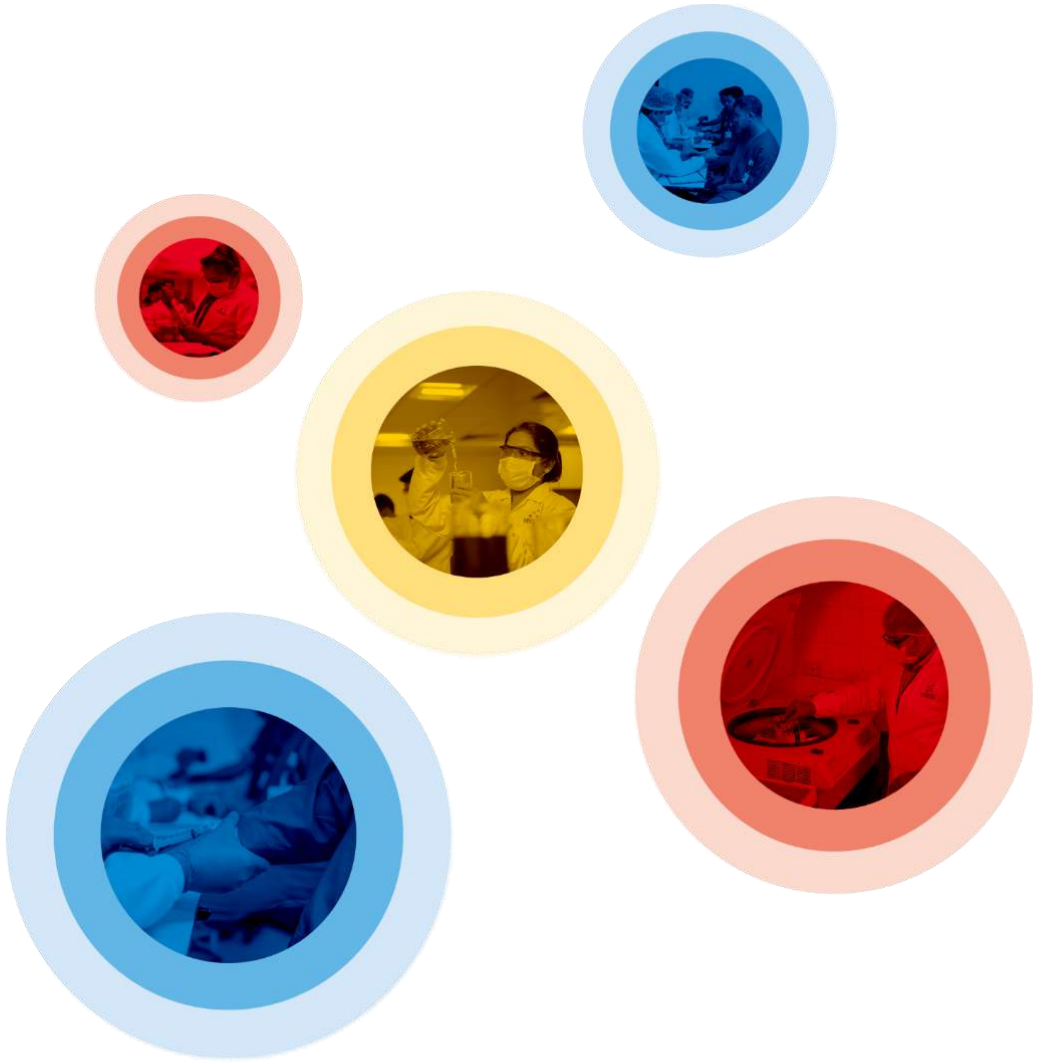
Global Clinical Development Partner

Providing Quality Clinical Research Solutions



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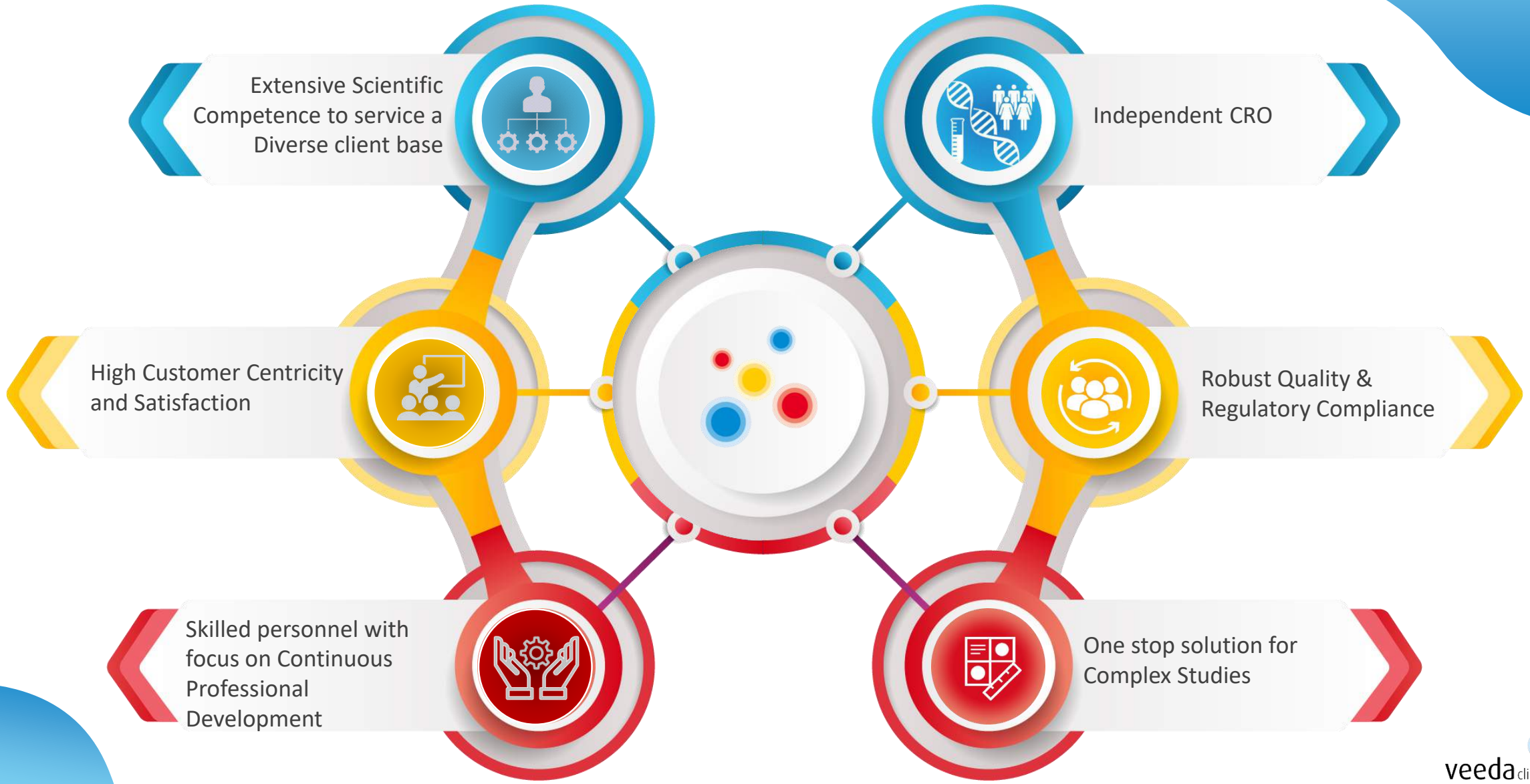
The Veeda Advantage



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Corporate Overview

Evolution

Privately owned, board managed company

2004 — Founded at Shivalik with 37 Employees

2006 — First regulatory inspection from ANVISA

2007 — First regulatory inspection from WHO, US FDA & UK MHRA

2010 — New Facility at Insignia

2015 — New Facility at Vedant

2018
- New Facility at Skylar, Exclusively for Screening
- CX Partners join

2019 — New Facility at Mehsana, Total number of Employees 970

2020 — Completed 100+ **Studies** Milestone in Mehsana Facility.

2021 — Biosimilar Lab **(Ingenuity Biosciences Pvt Ltd)** Veeda and Somru Biosciences Joint Venture

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

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 Organisation, 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.

Our Values

- Honesty and Integrity
- Humility
- Openness
- Excellence
- Innovation
- Nurturing Individual Growth

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"

- 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

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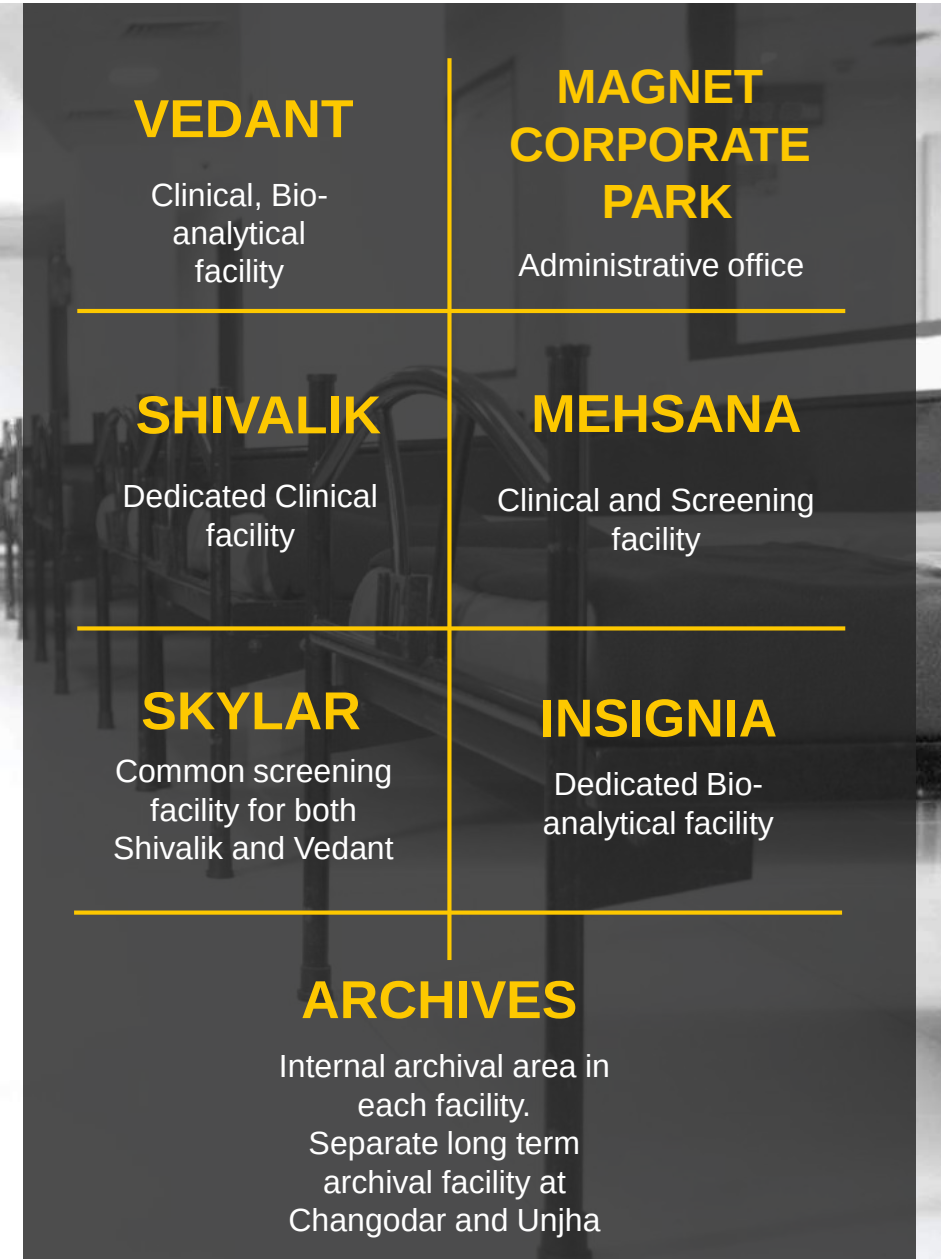
Regulatory Credentials

FDA	33*
ansm – Agence nationale de sécurité du médicament et des produits de santé	1
MHRA – Regulating Medicines and Medical Devices	3
AGES	1
ANVISA	14
mcc – Medicines Control Council	1
World Health Organization	5
DCGI	18
NPRA Malaysia	5

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

INFRASTRUCTURE

Clinical Infrastructure



VEDANT
Clinical, Bio-analytical facility

MAGNET CORPORATE PARK
Administrative office

SHIVALIK
Dedicated Clinical facility

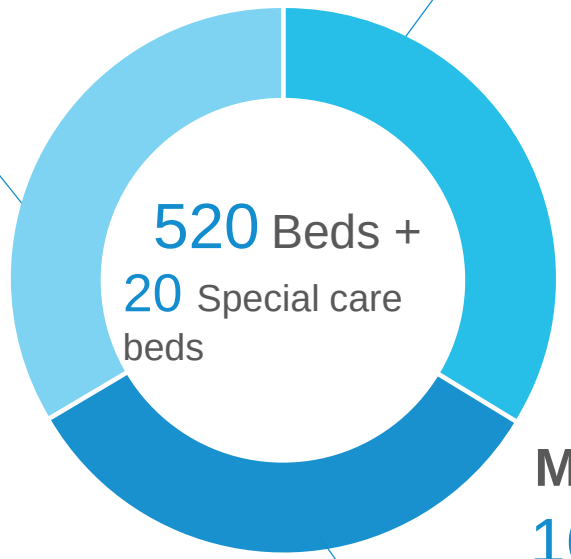
MEHSANA
Clinical and Screening facility

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
170 Beds +
6 Special care beds +
18 **Intensively monitored beds** to conduct **Phase I** study

Mehsana
162 Beds +
7 Special care beds

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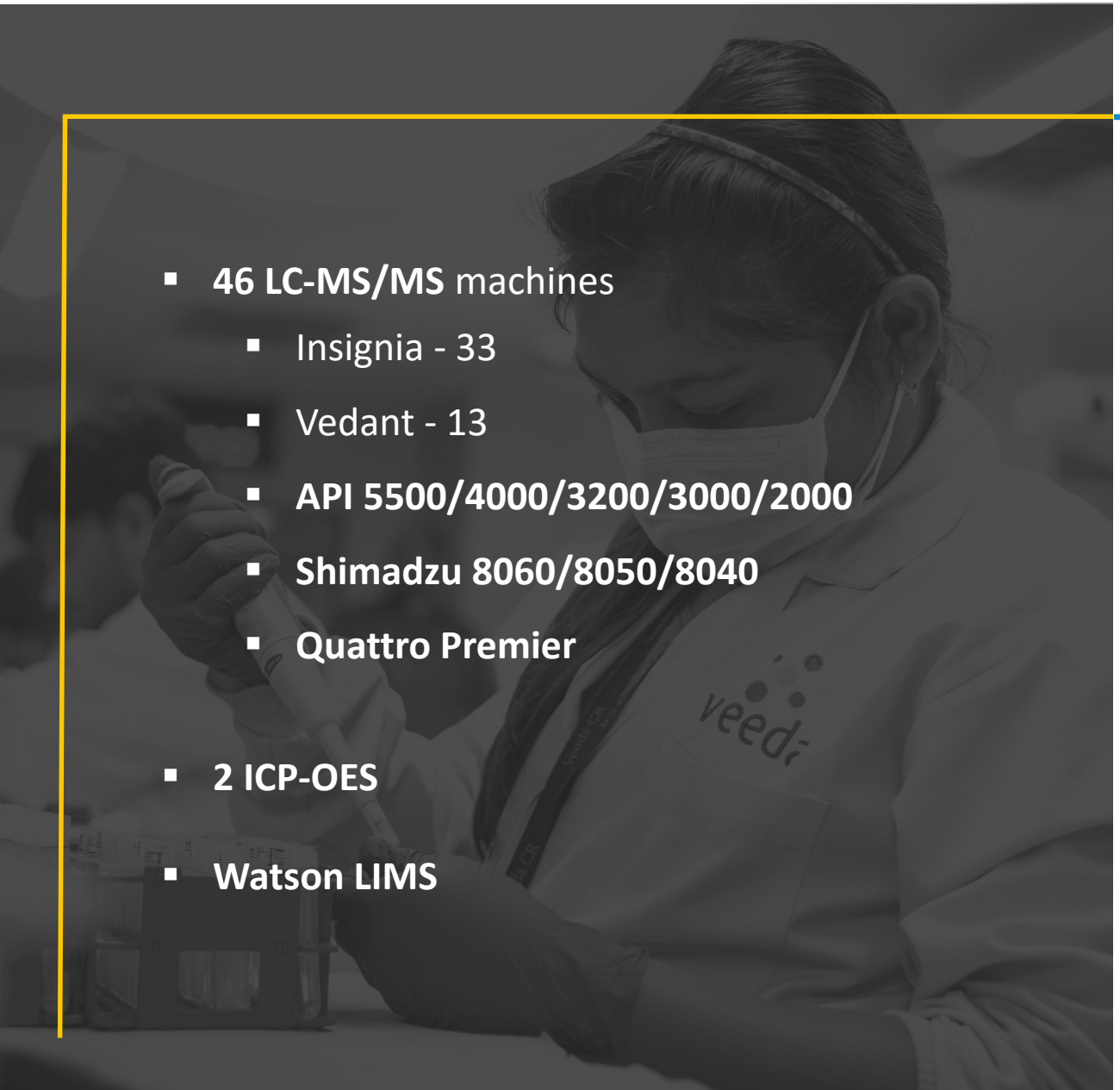
Bioanalytical Infrastructure



- **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**

Storage Capacity

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

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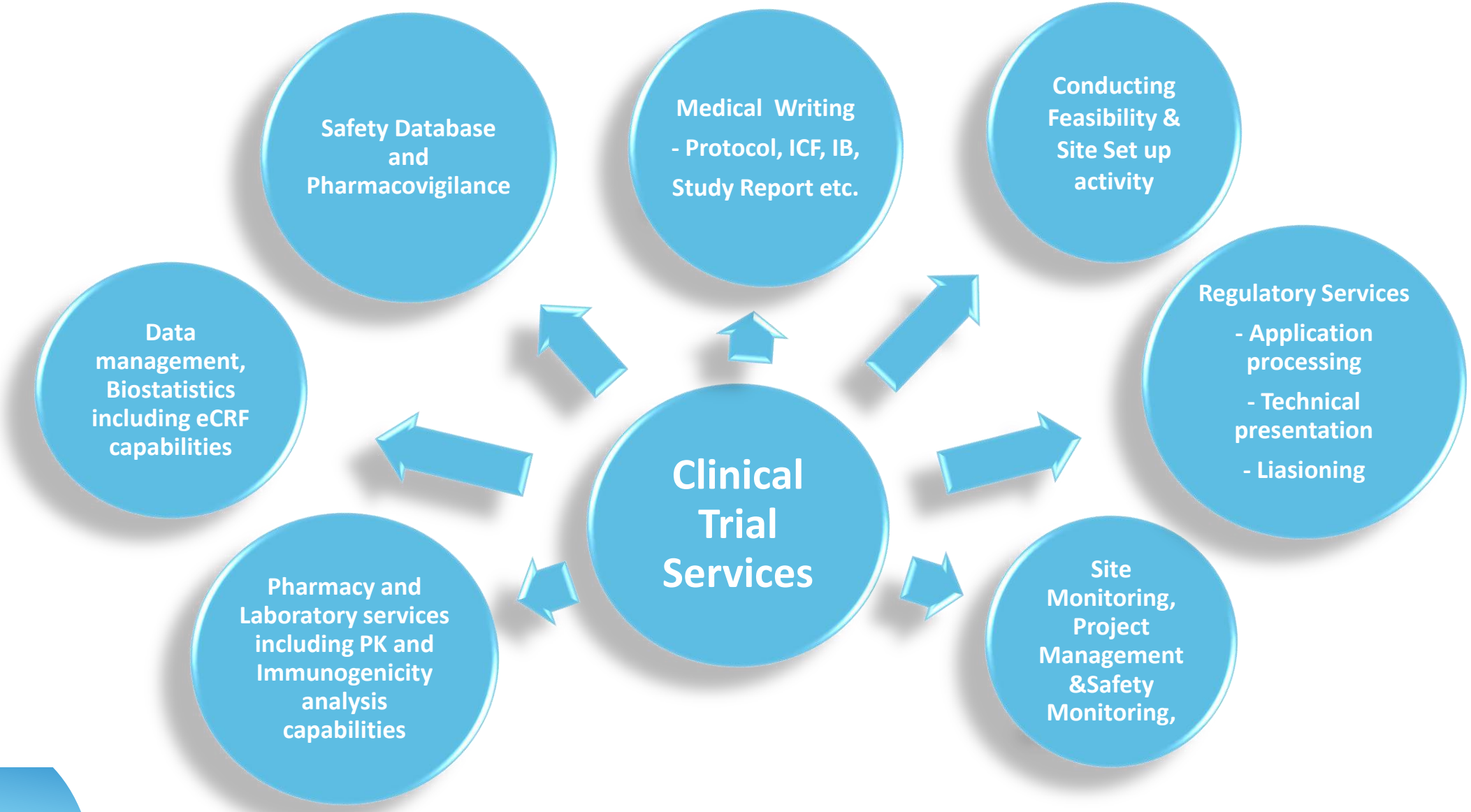
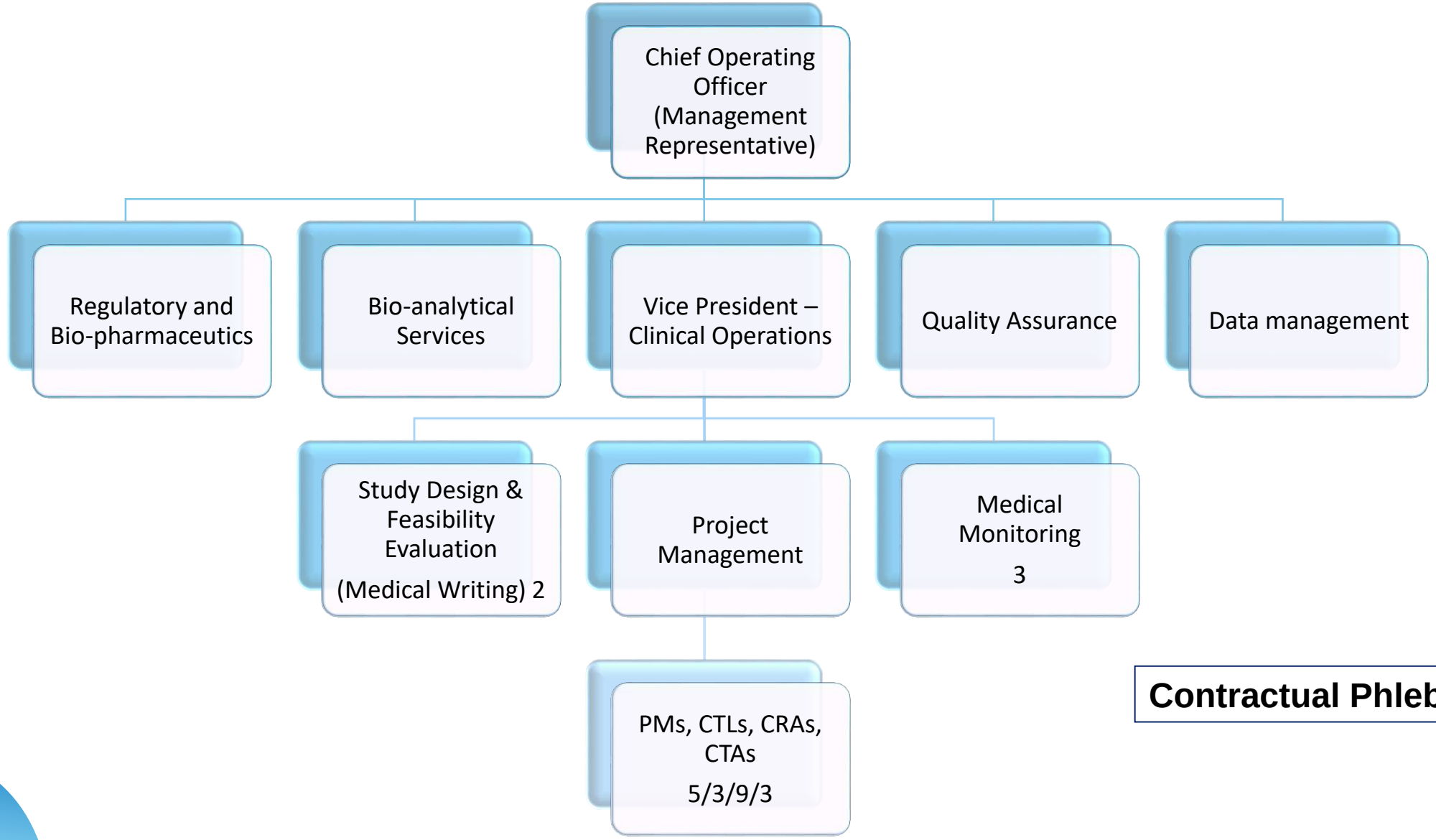
Veeda Edge

✓ 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

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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		•Has been involved in more than 40 multicentric trials in below therapeutic areas. •Cardiology •Ophthalmology •Psychiatry •Oncology •Rheumatology •Gynecology •Endocrinology •URTI	•Has been involved in studies like First in Man, SAD, MAD, dose proportionality studies, glucose clamps, biosimilars. •Lead the team of project managers, report-writing, and project co-ordination.

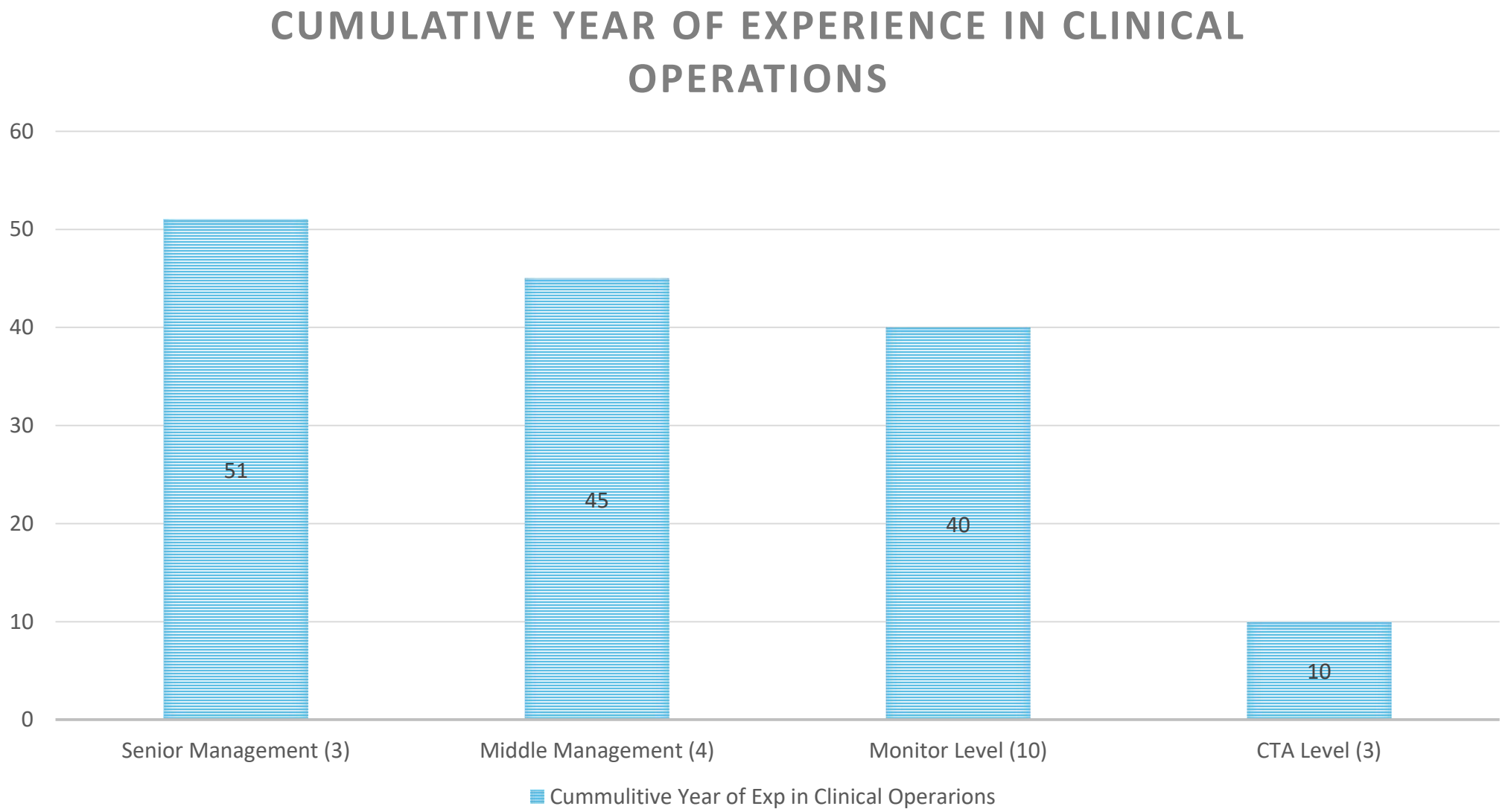
Team Overview

Qualification	M. Pham	M. Pham.	B. A. M. S.
Total exp.	> 8 Years	> 8 Years	> 11 Years
Therapeutic Area exp.	• Oncology • Psychiatry •Nephrology •Rheumatology •Infectious disease •Immunology	• Oncology •Psychiatry •Ophthalmology •Rheumatology •Infectious Disease	•Cardiology •Ophthalmology •Psychiatry •Oncology •Dermatology •Rheumatology •Endocrinology •Respiratory •Infectious diseases
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

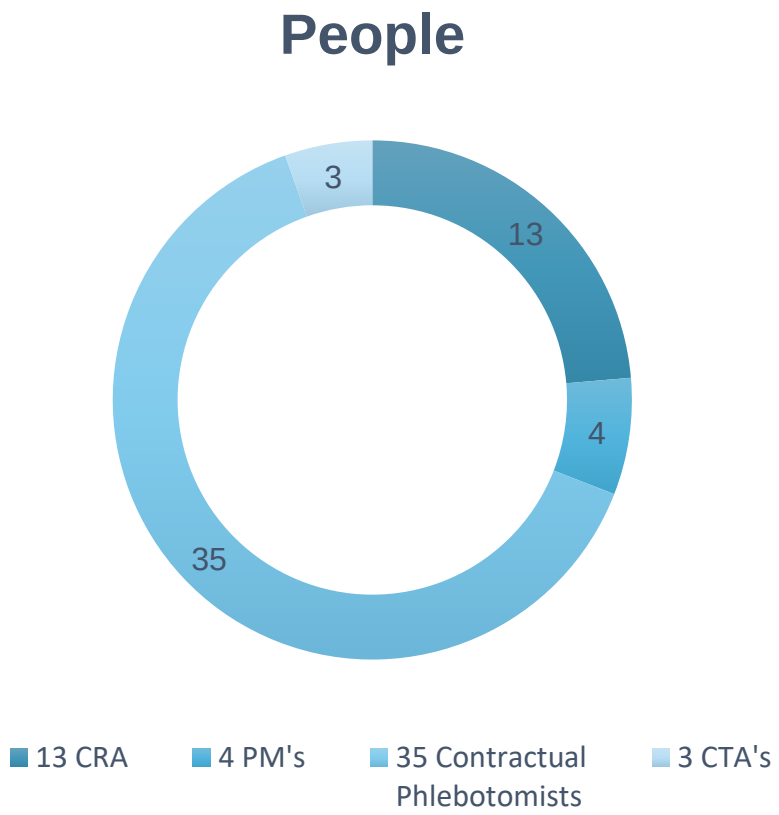
Team Experience



Extended Team

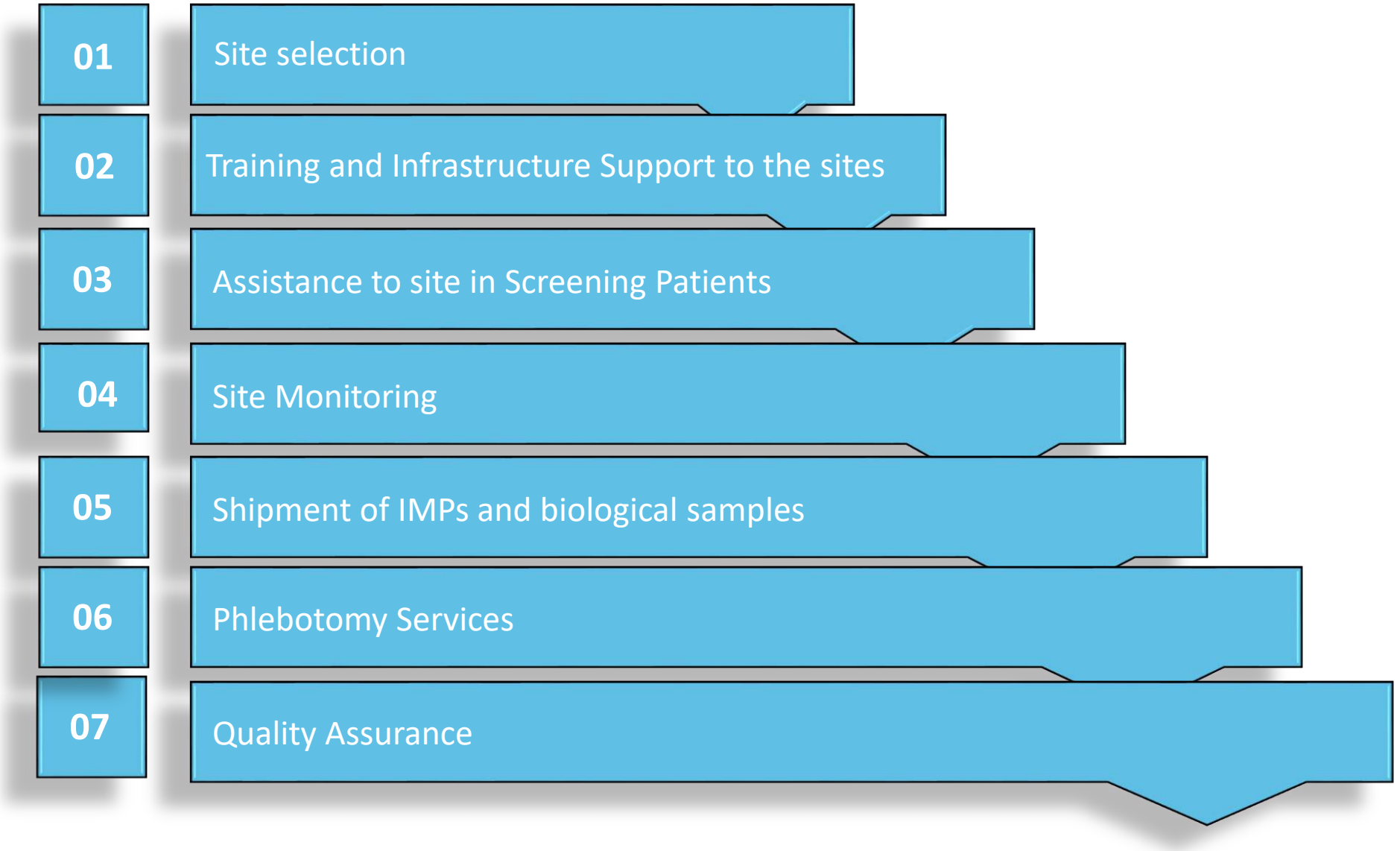
- Statistician
- Oncologist
- Ophthalmologist
- Psychiatrist
- Cardiologist
- Endocrinologist
- Physician

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

Study execution – Processes



Veeda Experience in Clinical Trials

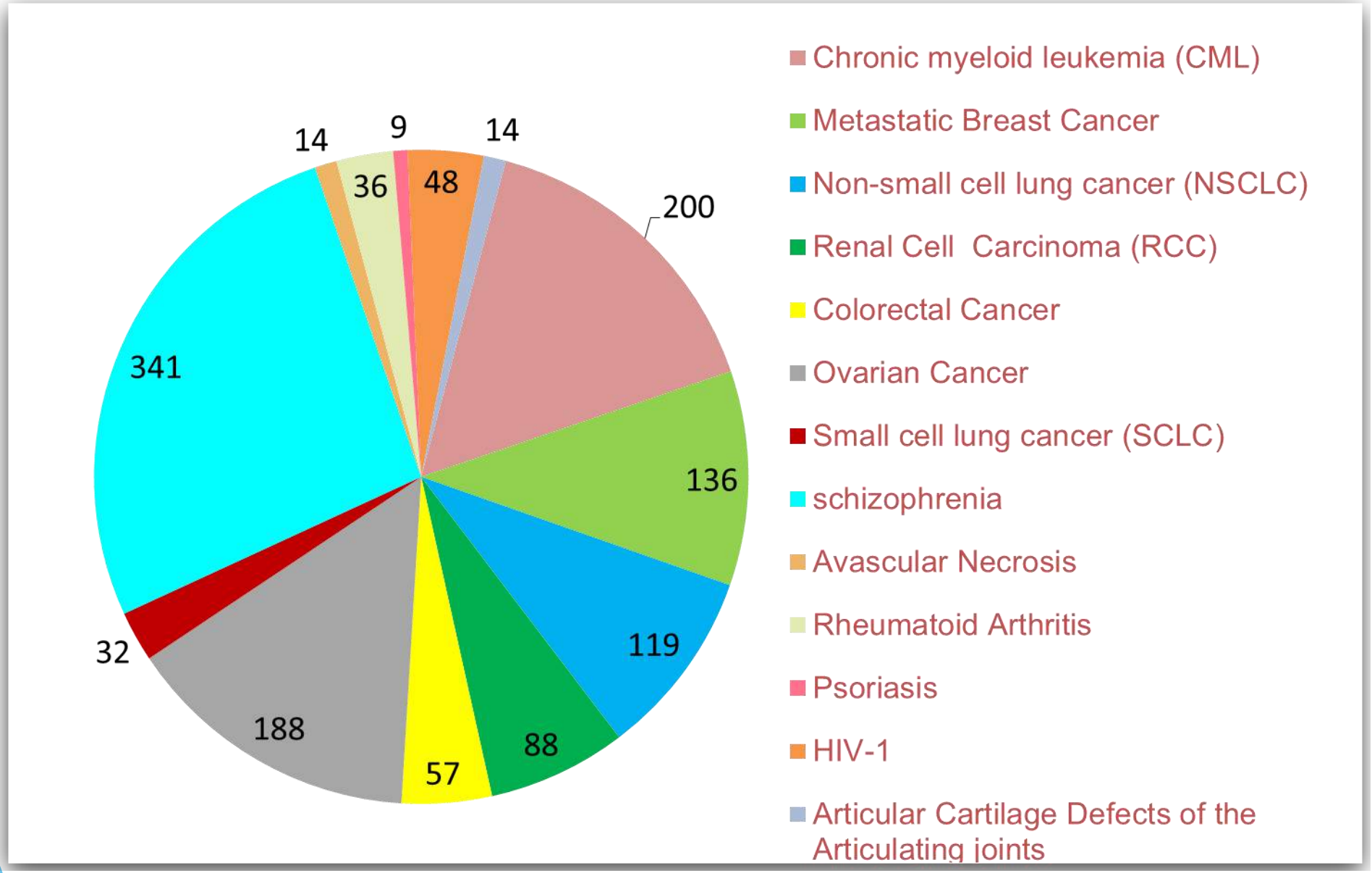
Organization experience

- 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

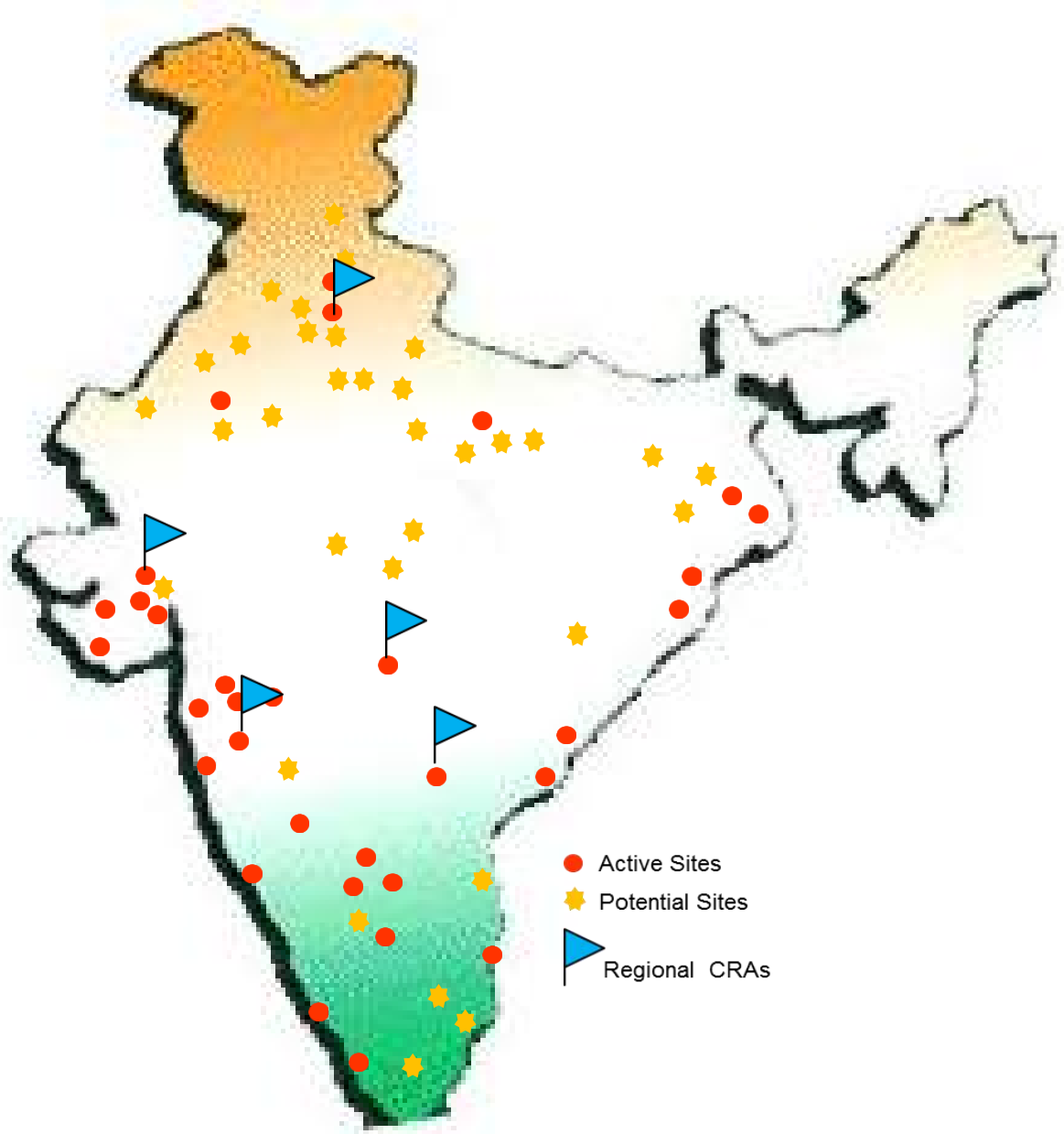
Team Experience (Previous Organization)

- 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 – **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

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

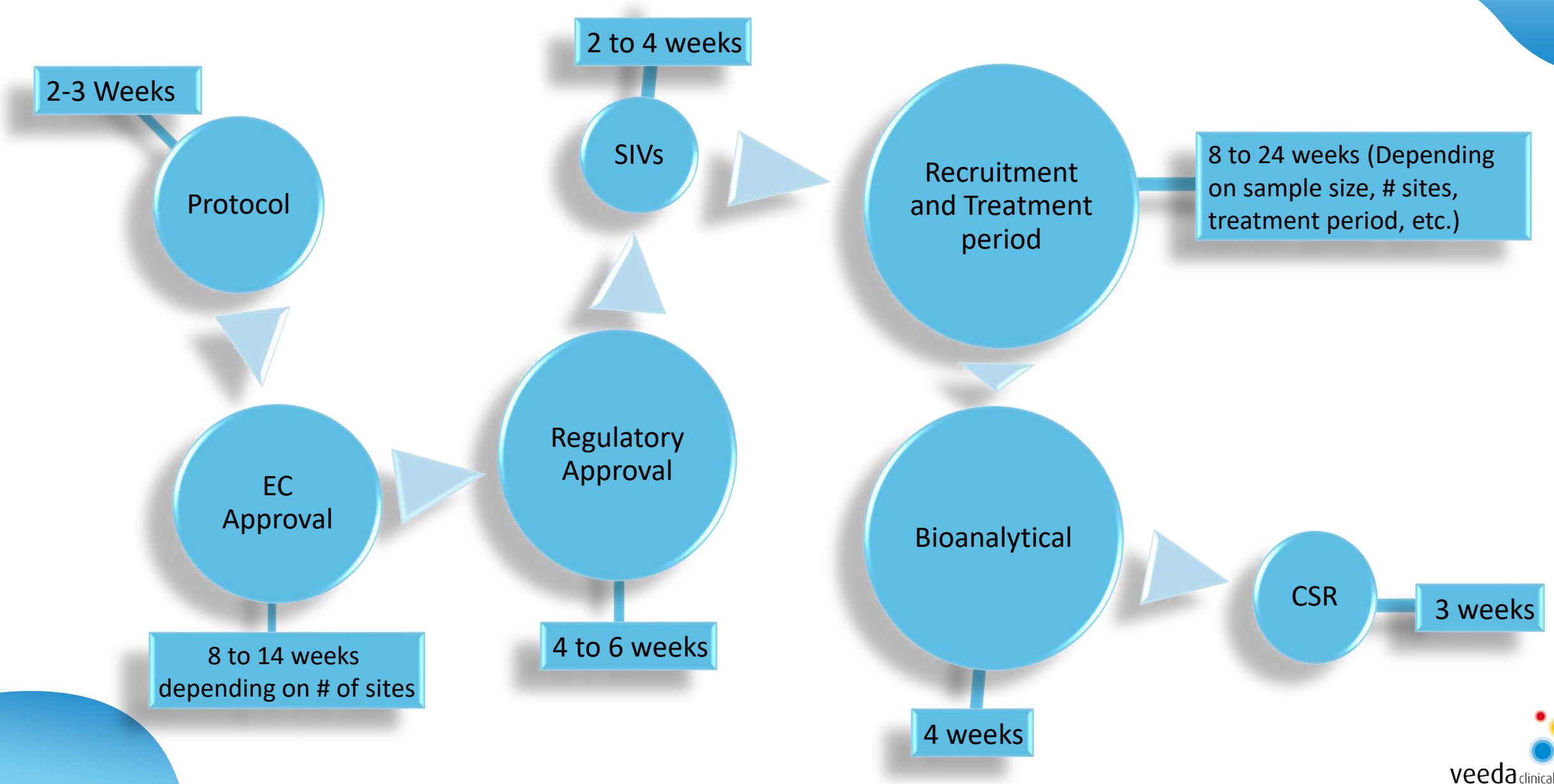
Current projects Patients based PK studies

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 Rhuematology	72 Orthopedics and Rheumatologists	21 sites
MD Physicians	79 MD Physicians	10 sites
Dermatology	87 Dermatologists	4 sites
Cardiology	20 Cardiologists	05 sites
Opthalmology	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

Feasibility

- 600 plus feasibility studies completed for >80 molecules across various Therapeutic areas in last 3 years
- An average of 200 feasibility studies per year

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

Recognitions

Celebrating 16 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
Times Network	Best Clinical Research-India
Gujarat	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
2019	Indian Clinical Research company of the year

2020

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

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Thank You

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Partners in Creating a Healthier Tomorrow

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www.veedacr.com

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