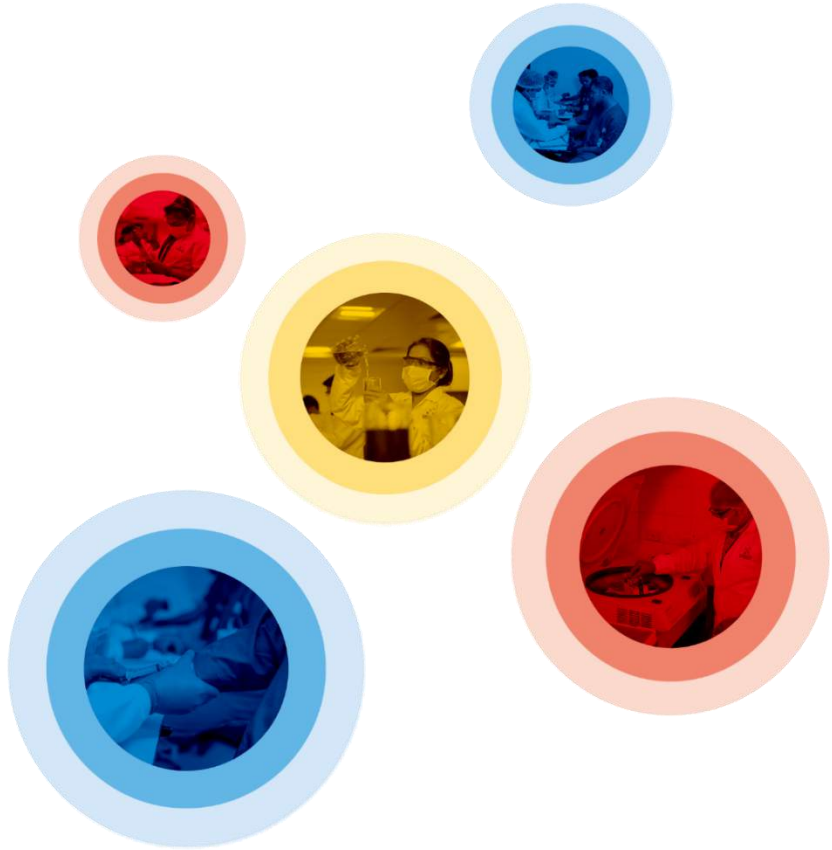
Global Clinical Development Partner

Providing Quality Clinical Research Solutions



veeda clinical research®

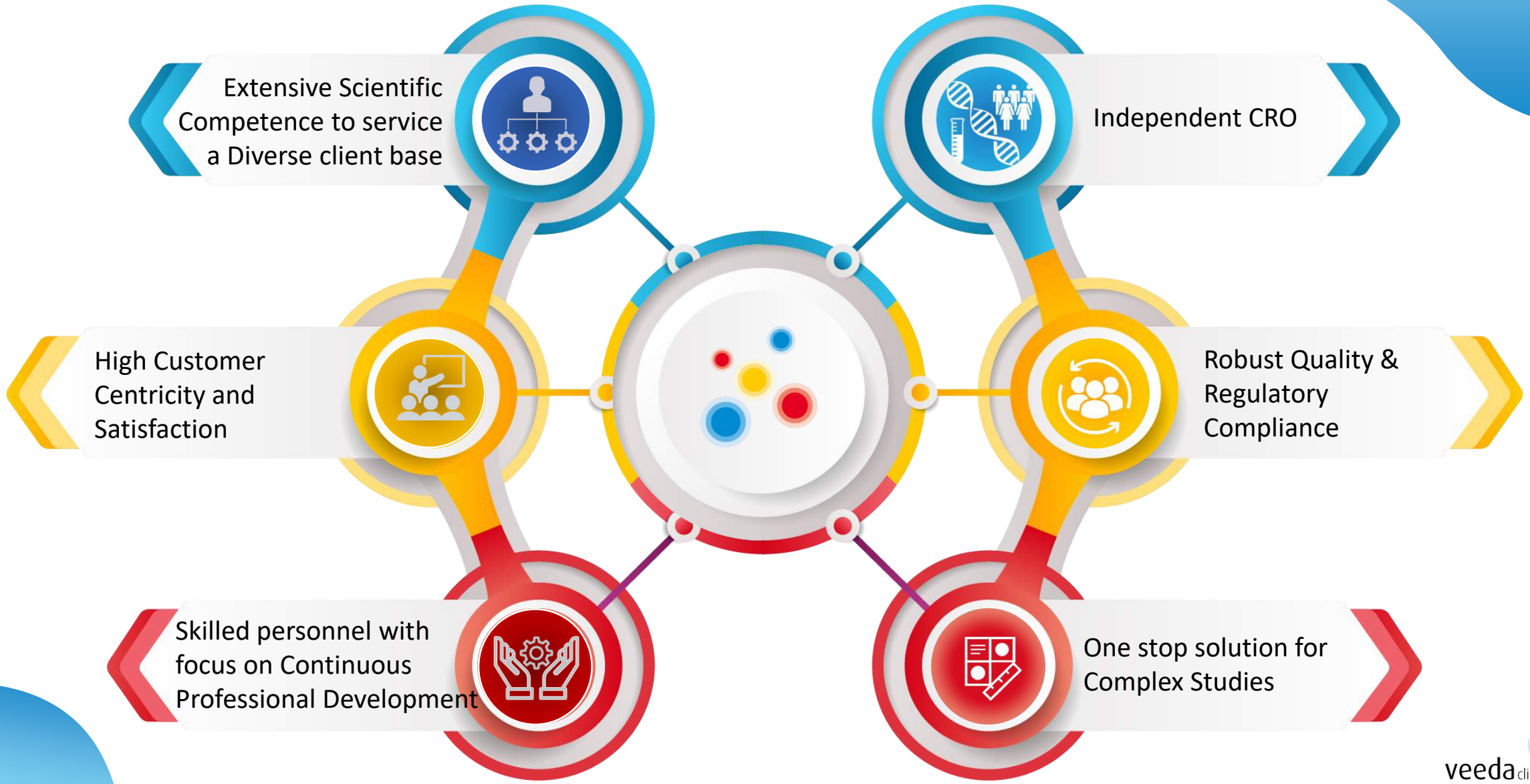
Table Of Contents

veeda clinical research®

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

The Veeda Advantage



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

2021
- New Phase 1 Facility at Vedant
- Biosimilar JV with Somru BioScience

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

veeda clinical research

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

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

Focus on implementing policies & nurturing individual behavior to sustain our culture of quality

veeda clinical research®

Regulatory Credentials

- 78 successful regulatory audits till date
- 12 successful regulatory audits in last 24 months

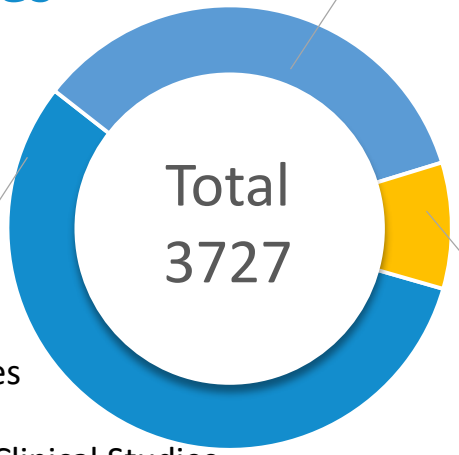
FDA	33*
ansm Agence nationale de sécurité du médicament et des produits de santé	1
MHRA Regulating Medicines and Medical Devices	3
AGES	1
ANVISA	14
mcc MEDICINES CONTROL COUNCIL	1
World Health Organization	5
DCGI	17
NPRA MALAYSIA	5

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

veeda clinical research®

Experience

BA/BE studies



- 1200 Pilot
- 666 Standalone Bio-Analytical
- 1861 Pivotal
  - 14 FTF Studies
  - 88 Complex Clinical Studies

Phase I - 22 studies
Phase II – 1 Study

51 Special Studies
*Both Pilot and Pivotal BA/BE

- 13 Glucose Clamps studies (700 clamps)
- 24 Inhalation Studies
- 4 Suppositories
- 10 Patches Studies

Patient based studies

Type of Study		No. of Studies
Global multi-centred Phase II clinical trials	Completed	05
	Ongoing	02
PK Clinical Trials	Completed	26
	Ongoing	12
Phase III studies of injectable implants		02
Stand-alone Medical writing BE-PK studies		04

Therapeutic Segment

- Oncology
- Oncology and CVS
- Oncology (18), Psychiatry (6), Rheumatology & Dermatology (2), HIV (1)
- Oncology (8), Psychiatry (2), Gynaecology (1) Infectious disease (1)
- Bone disease
- Psychiatry and oncology

veeda clinical research

Veeda Capabilities

BA/BE Capabilities

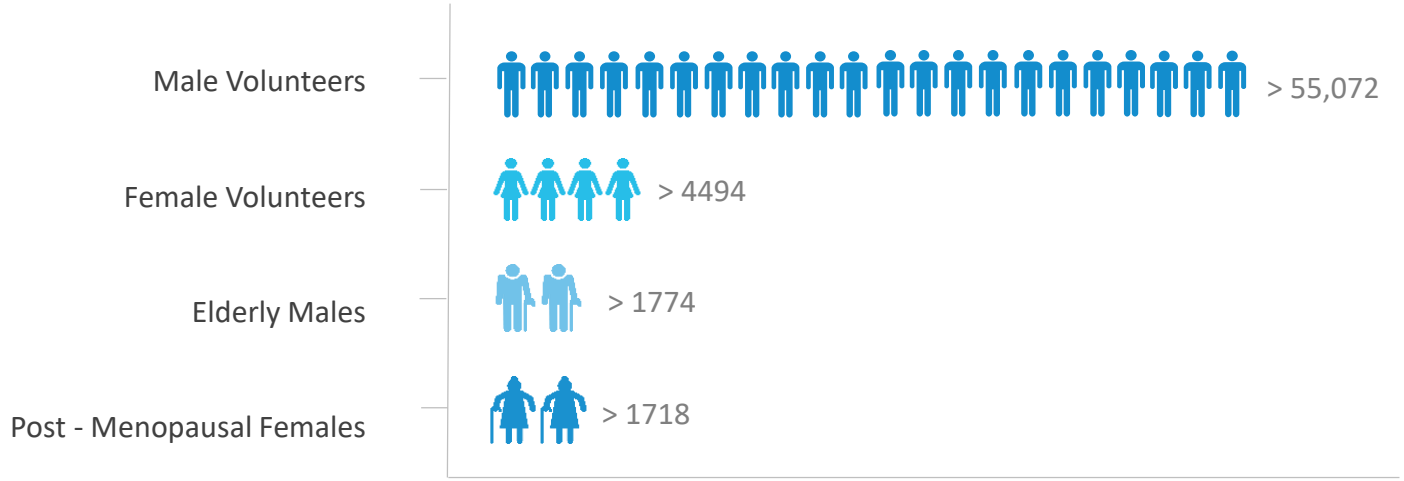
Complex studies:

- Cotinine free studies
- High number of ambulatory samples
- Long Washout periods

FTF studies

Intensive Safety Monitoring

Volunteer Database (More than 63,058)



Routes of administration

20 different dosage forms

- Inhalation
- Transdermal Patches
- Rectal/Vaginal suppositories
- Orals
- Glucose clamps
- LAIs

veeda clinical research®

Patient Trials capabilities

Clinical End point studies

Phase II / Phase III studies

PK / PD End point studies

Diverse Routes of administration

Therapeutic Expertise

Oncology

- Chronic myeloid leukaemia (CML)
- Metastatic Breast Cancer
- Non – small cell lung cancer (NSCLC)
- Renal cell carcinoma (RCC)
- Colorectal Cancer
- Small cell lung cancer (SCLC)
- Ovarian Cancer

Psychiatry

- Schizophrenia
- Epilepsy
- Alzheimer

Cardiology, Immunology (HIV), Dermatology, Rheumatology, Gastroenterology, Orthopaedics Ophthalmology, ENT etc

- Extensive Investigators network and experienced project management team
- eCTD compilation and data management

veeda clinical research®

Bioanalytical Capabilities

Types of Methods

Total available Bioanalytical methods are more than 969

- 860 + 20 — Generics + PD/IM
- 73 — Complex
- 66 — NCEs
- 29 — MD/MV

Bioanalytical Salient Features

- Average capacity of 1,00,000 samples per month
- Central Bioanalytical Laboratory

State of the art

- Capability to develop methods with lowest quantification level- up to 0.1 pg.
- Methods developed for:
  - Endogenous molecules
  - Hormones
  - Steroids
  - Inhalation formulation
  - Elemental Bioanalysis
  - Immunogenicity
  - Large molecules/ECLIA/ELISA
- Multiple analysis in single injection
- Central labs for Phase II / Phase III studies
- Tissue distribution studies

Veeda Infrastructure

Clinical Infrastructure

VEDANT
Clinical, Bio-analytical facility

MAGNET CORPORATE PARK
Administrative office

SHIVALIK
Dedicated Clinical facility

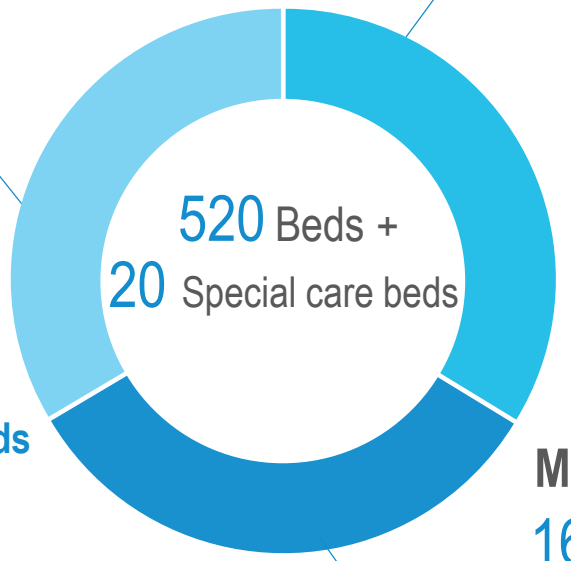
MEHSANA
Clinical and Screening facility

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

Associated with ICUs of multispecialty hospitals to conduct healthy volunteer studies, Where such setup is required.

veeda clinical research

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 ℃

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 ℃

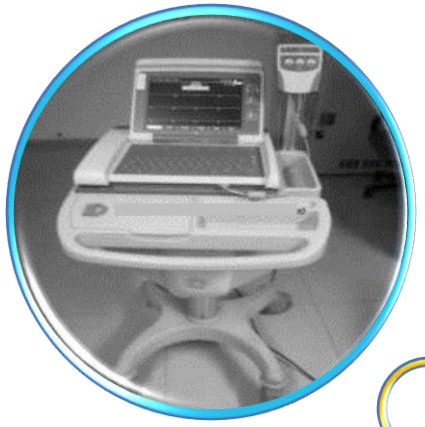
Archival:
Capacity to archive approximately 51000 files

Phase 1 - Infrastructure

Phase 1 - INFRASTRUCTURE

- Well developed **12 bedded phase I unit** to support Phase 1 studies.
- We are in the process of setting up additional **18 bedded phase 1 unit**; to be operational by October 2020**.**
- Team of scientists having **in-depth knowledge and experience** of handling Phase 1 studies.

Phase 1 - INFRASTRUCTURE (Equipments)



MAC 2000 ECG Machine

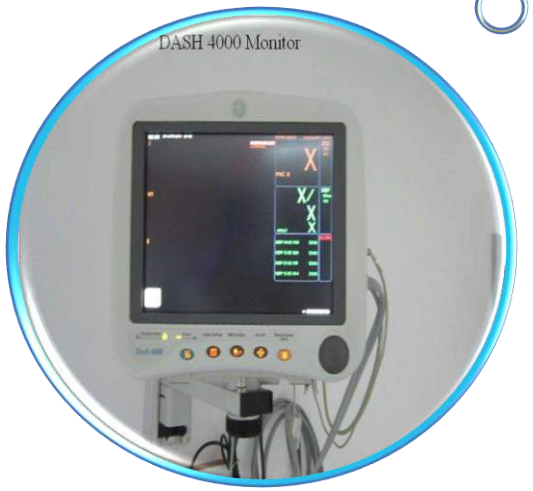
ECG Recording

Infusion Pump

For continuous drug infusion

DASH® 4000 Monitor

For continuous cardiac monitoring (Vitals, ECG, O2 saturation etc.)



Heated Hand Boxes : Provides a realistic alternative which minimizes the difficulties inherent in venous sampling.

Healthy volunteer data base who have previously participated in studies; Healthy (more than 53,000), elderly (more than 3000), postmenopausal(more than 2000)

veeda clinical research®

Phase 1 - INFRASTRUCTURE (Equipments)

YSI 2300 Glucose Analyser

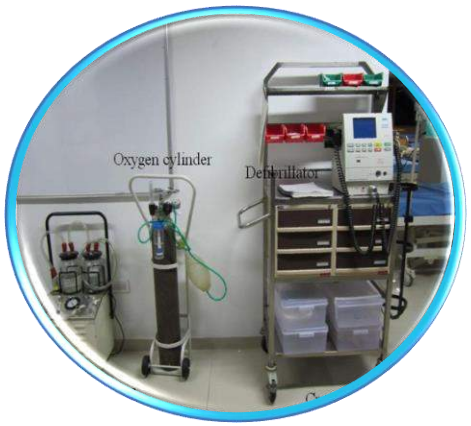
Blood glucose measurement

Central Monitor

To observe centrally all DASH monitors

Syringe Driver

Use to gradually administer small amount of fluids (with or without medication) to a patient



Oxygen Cylinder

Suction Machine

Crash Cart Trolley

Defibrillator

veeda clinical research®

Phase 1 - INFRASTRUCTURE

Sample Processing

- Two Refrigerated Centrifuge
- Two -78^0 C Deep freezers (range -70^0 C to -86^0 C)
- Two -25^0 C Deep freezers (range -15^0 C to -30^0 C)
- One Pharmaceutical Refrigerator (range 20^0 C to 80^0 C)
- Weighing Balance
- Four Micropipettes & Two Multipipette
- Vortex Shaker
- Eurotherm temperature monitoring system

Pathology Services

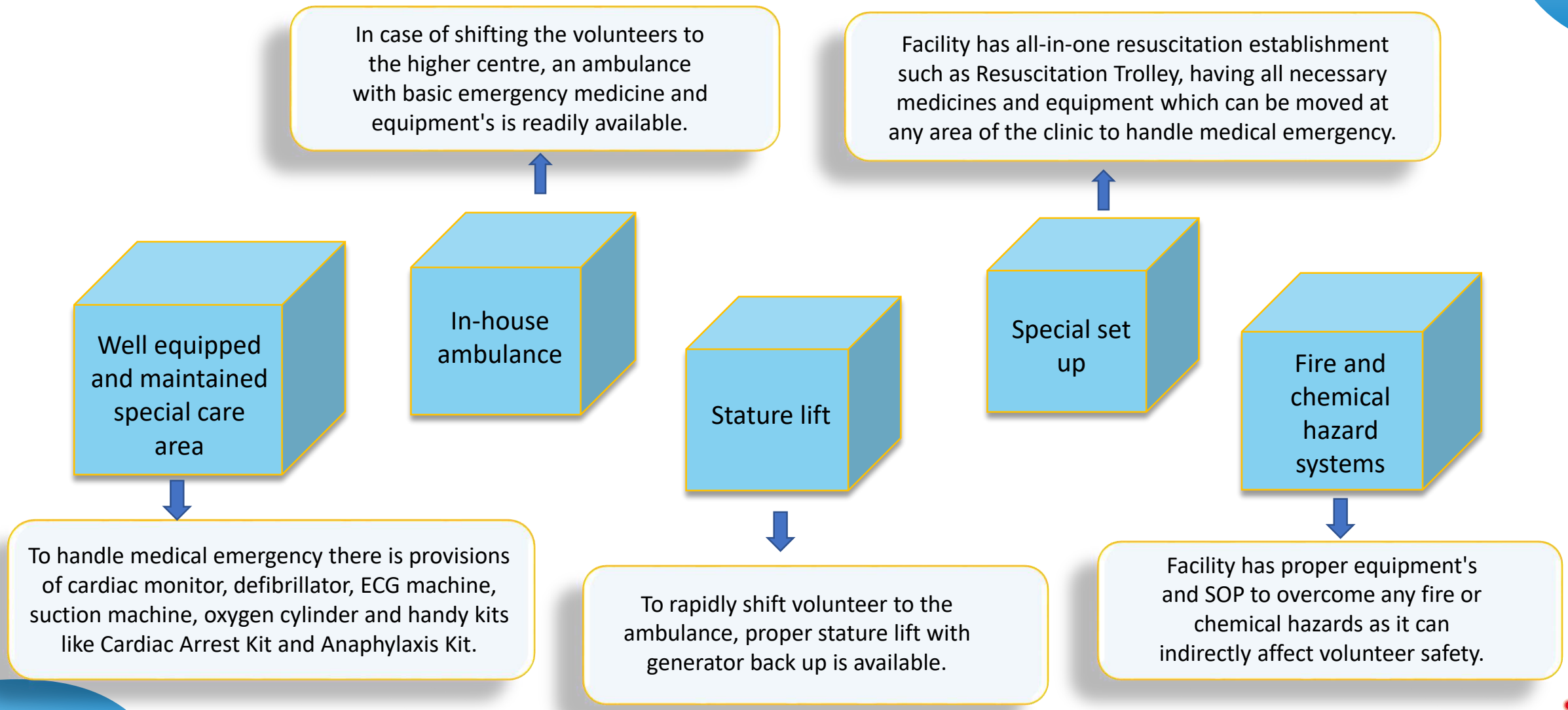
- **Primary :** Supratech Micropath pathology laboratory.
- **Back up Lab:** I-genetics pathology laboratory NABL accredited.
  - CAP accredited
  - Barcode generation
  - Software –Audit trail
  - Monthly back up to Veeda

- Pharmacy (Local FDA approved)
- 2 humidity chamber
- 2 walk in stability chamber
- 3 Pharmaceutical refrigerator
- 1 Air pacLaminar
- 1 Analytical balance

IRB –Sangini Hospital EC (SHEC)

- Constituted since 05 years (in 2012)
- Registered at DCG(I)
- Registered at DHHS (Department of Health and Human Services) and OHRP (Office for Human Research Protections)
- Highly qualified and experienced members

Phase 1 - Subject Safety

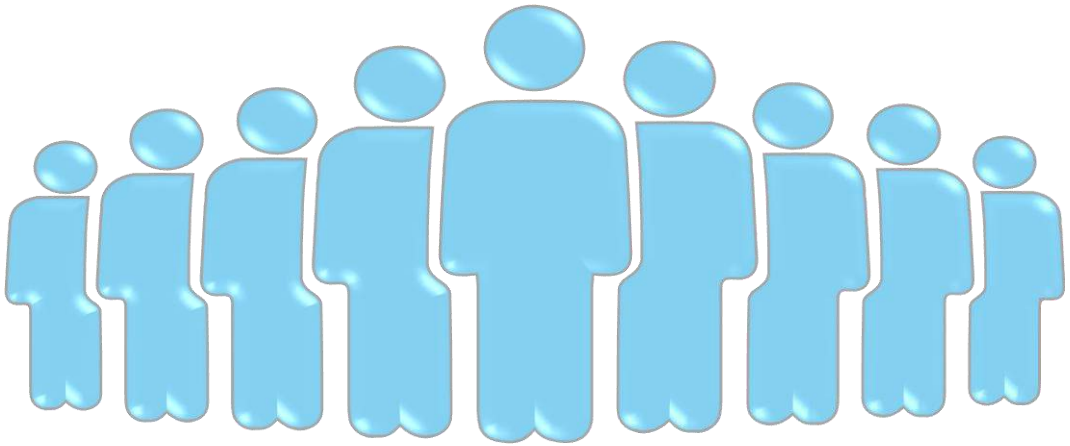


Safety Team and Safety aspects

Qualified, educated and trained study staff

ACLS, BLS trained Investigators, Clinical Research physician and Nursing staff

Ambulance and driver 24 hr. available



Tertiary care contract with sterling hospital

Designated Resuscitation officer

More than 150 + active sites currently for late phase studies

BLS trained Phlebotomist, Clinical custodian, security and Clinical Quality Monitor team

Well equipped Special Care to handle the emergency

Experience in First In Man Studies

Project No.	Drug synopsis	No. of subjects	No. of Periods
SAD (Single Ascending Dose)	Safety and Tolerability	PK	6 to 8/group (5 groups)
09-VIN-199 (GKM-001)	**ADV-1002401** oral solution-A First in Human, Placebo-Controlled, Randomized, Double Blind, Rising Single Dose Study of ADV 1002401 to Evaluate Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics in Healthy, Adult Volunteers and Adult Type II Diabetic Volunteers.	6	One
10-VIN-232 (P3914/48/10)	**P3914 Tablets, SAD study,** G01,PartA Randomized, Double-blind, Placebo-controlled Phase I-Ib Study of P3914 to Evaluate the Safety, Tolerability, Food effect & Pharmacokinetics in Healthy Male Subject sand Efficacy & Safety of P3914 in Patients With Acute Dental Pain.	6	One
CSSK-SMRX11 (12-VIN-073)	**SMRX 11 Injection,** SAD FIM G01-Open Label, Placebo- Controlled, Single Ascending Dose, Phase I Safety Study of SMRX 11 (Clot Specific Streptokinase) to Determine Pharmacokinetics and Tolerability in Healthy Male Subjects.	4	One

Experience in Other Phase I Studies

Types of Phase I Studies	Primary Objective	Secondary Objective	Number of subjects
Glucose Clamp study	PD/PK	Safety	4 /group (4 to 5 groups)
MAD (Multiple Ascending Dose)	Safety and Tolerability	PK	6 to 8/group (3 groups)
Drug Interaction -2 studies	PK	Safety	Max 12 subjects
Formulation change -4 studies	PK	Safety	Max 86 subjects
Food Effect on NCE molecule	PK	Safety	8/group(2 groups)
Proof of concept study	Efficacy/PK	Safety	8/group(2 groups)
Administration of Vaccine	Safety	Immunogenicity	24 subjects

Ranibizumab Trials –Key Parameters

Parameter	Description
Eye Surgeon (Retina Specialist)	• To identify Investigators who shows interest to take the trial and have all the required infrastructure. • Since our team has worked with similar kind of studies earlier, Veeda have required database of potential Investigators for such studies.
Reading in patients with retinal vein occlusion	• Assessment process and equipment's to be used for the study needs to be calibrated and validated to maintain uniformity across the sites.
Ensure required distance availability for the test	• 06 meters distance is required for assessment. At times it has been noticed that Investigators may not have such big room to complete the activity. Alternate plan can be applied as per the requirement and necessary action can be closed in start up phase before SIV.
Ethics Committee Availability	• Eye Hospitals or centers may not have their own EC. Alternate EC's to be identified region wise where needed.
Site Staff Availability	• Eye Hospitals or centers may not have their own Site team to work on the study. SMO support can be explored as required.

Bio-similar Experience

Molecule	Indication	Sample Size	RR Time (months)	Sites
Bevacizumab	NSCLC patients	129	13.2	20
Bevacizumab	All approved indications of Bevacizumab	268	12.4	21
Trastuzumab	HER2-Overexpressing Metastatic Breast Cancer patients.	120	9.1	18
Denosumab	Women With Postmenopausal Osteoporosis	114	3.2	14
Denosumab	Postmenopausal women and men with osteoporosis at high risk of fracture	200	66	16
Rituximab	Non-Hodgkin's Lymphoma patients	104	21	31

Team Experience in Ophthalmology

Molecule	Indication	Sample Size	RR Time (months)	Sites
Ranibizumab	Wet AMD (Age Related Macular Degeneration)	104	17.1	29
Ranibizumab	Wet AMD (Age Related Macular Degeneration)	126	17.1	18
Brinzolamide	Chronic Open Angle Glaucoma	950 (750 India & 200 US)	8	30 (India) 10 (US)
Loteprednol	Cataract Surgery	350	5	15
Brinzolamide+ Brimonidine	Chronic Open Angle Glaucoma	204	Veeda-Start-up Ongoing	
Brinzolamide+ Timolol	Chronic Open Angle Glaucoma	200	Veeda-Start-up Ongoing	

Recognitions

Celebrating 16 years of excellence in clinical research

2004

2017

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

2018

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
	Mark of Excellence
GUJARAT	
FROST & SULLIVAN	Indian Clinical Research company of the year

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 clinical research

Thank You

veeda clinical research®

Partners in Creating a Healthier Tomorrow

For any further assistance kindly write to us at info@veedacr.com
www.veedacr.com

veeda clinical research®