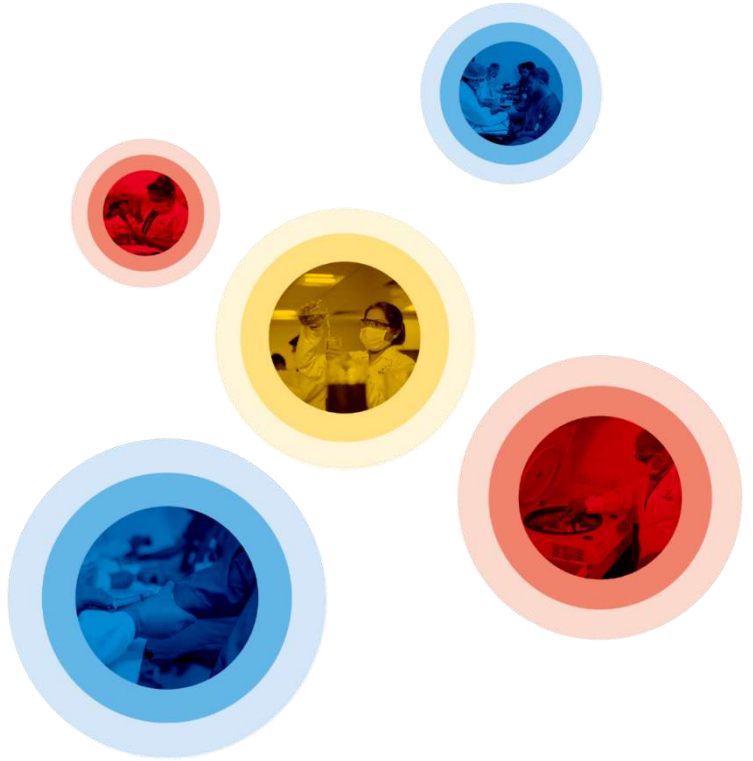
Global Clinical Development Partner

Providing Quality Clinical Research Solutions



veeda clinical research®

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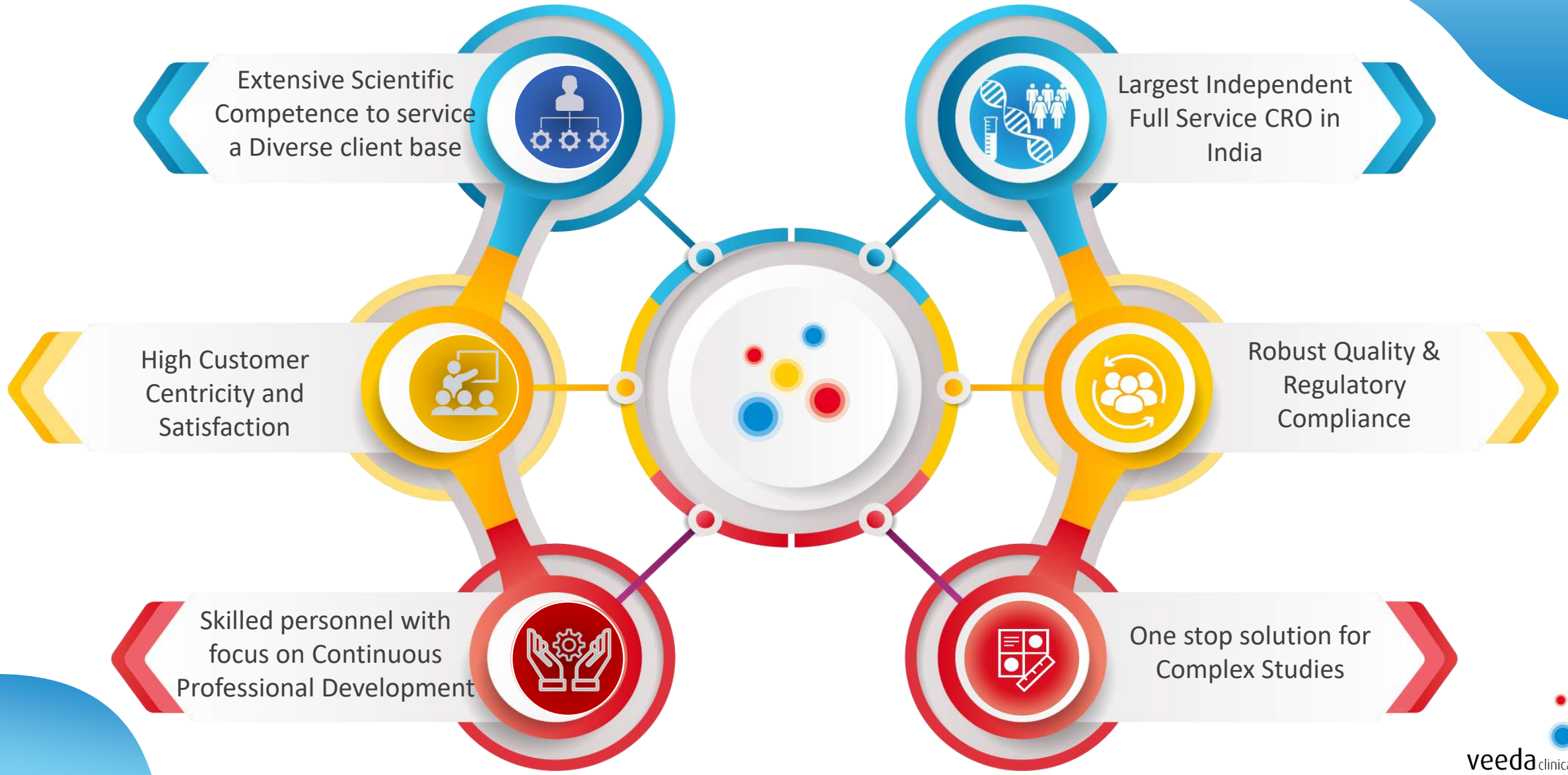
Corporate Overview

The Veeda Advantage



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

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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

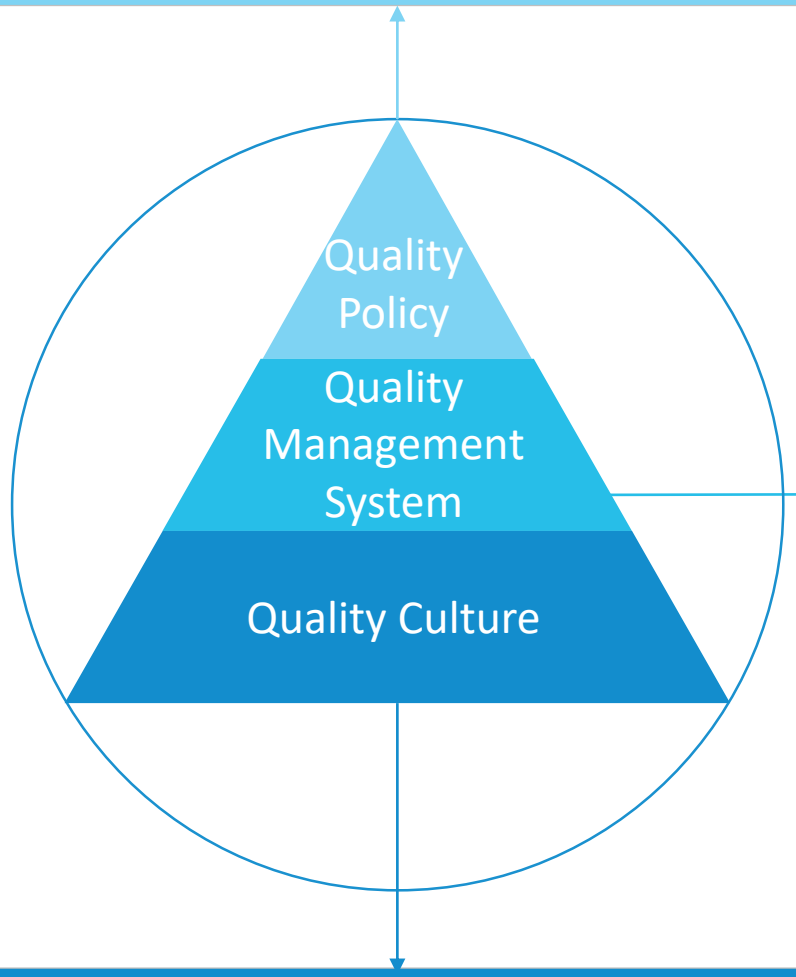
Excellence

Innovation

Nurturing Individual Growth

Quality Framework

"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

Regulatory Credentials

- 81 successful regulatory audits till date
- 08 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	18
NPRA MALAYSIA	5

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

Clinical Research

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

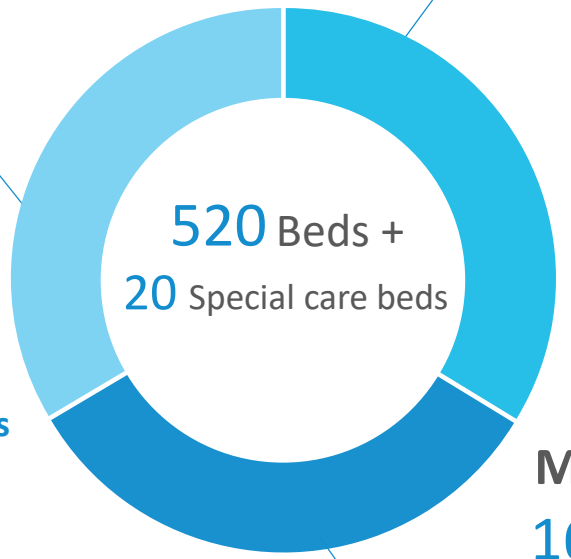
INSIGNIA

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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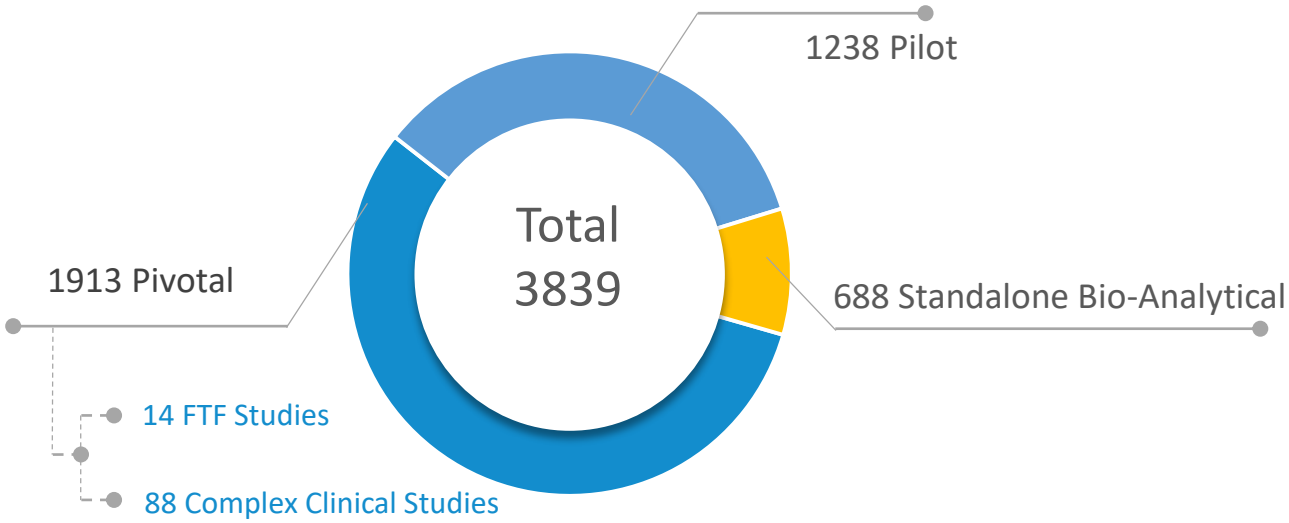
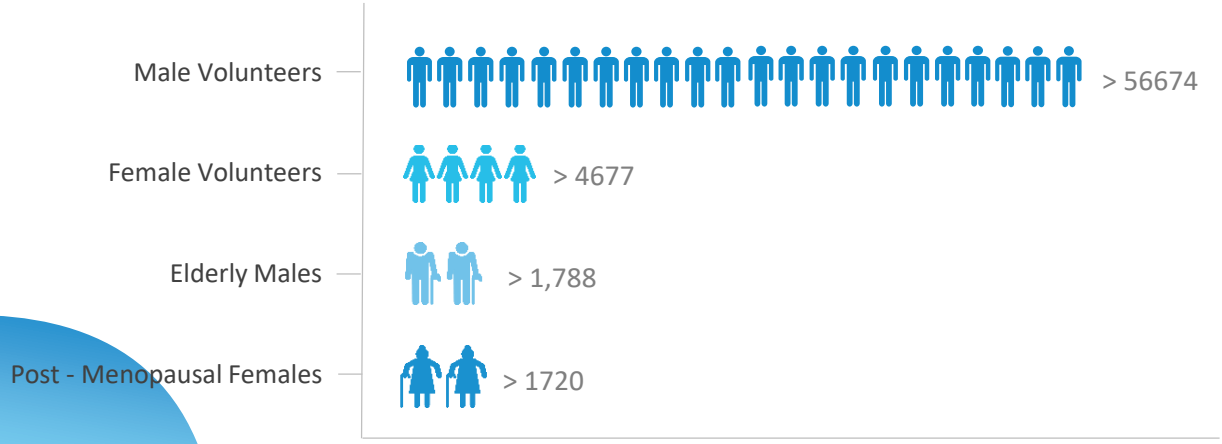
Experience



53 Special Studies
*Both Pilot and Pivotal BA/BE

- 13 Glucose Clamps studies (700 clamps)
- 26 Inhalation Studies
- 4 Suppositories
- 10 Patches Studies
- 23 Phase – I Studies
  1 Phase – II Study

Volunteer Database (More than 64,859)

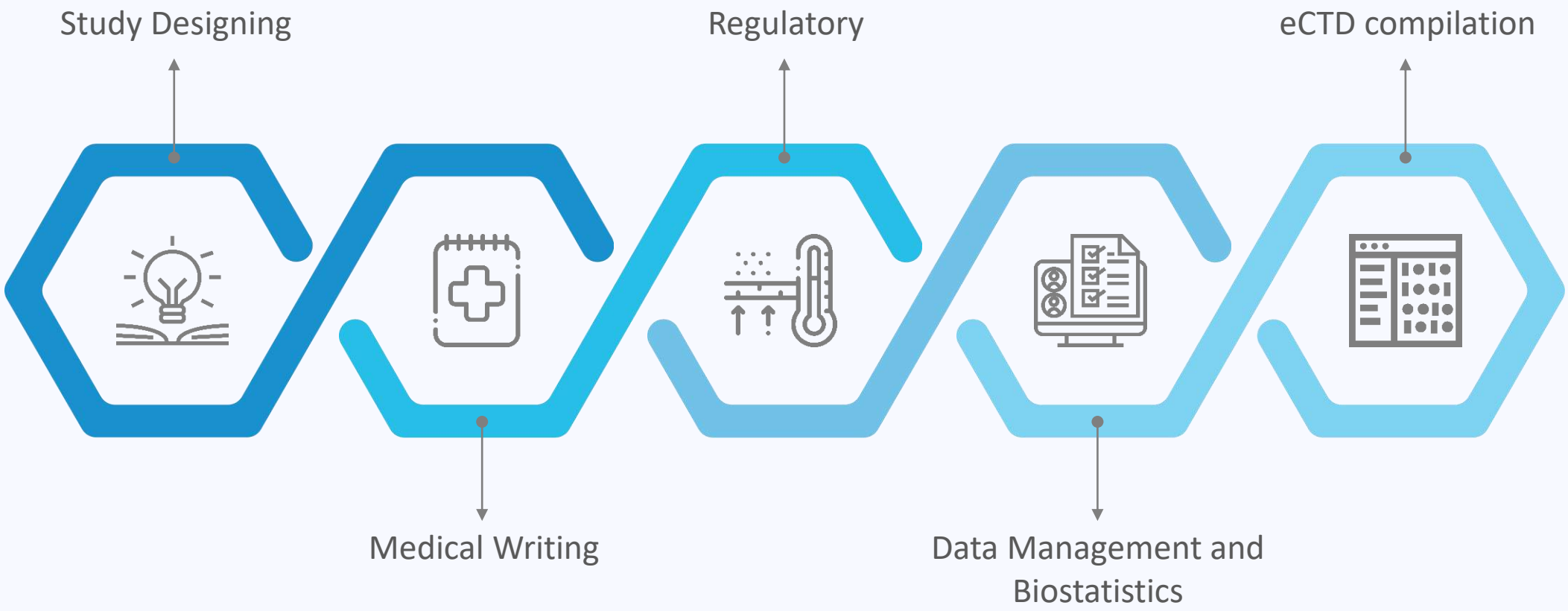


Routes of administration

20 Different dosage forms

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

Full Service Capabilities



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Inhalation

Inhalation: Infrastructure

❑ **State-of-the-art Negative Pressure Rooms**

❖ **Advantages:**

- Provides uniform environment with relatively consistent temperature, humidity, air flow, oxygen content and other major environmental factors for respiratory dosing.
- Eliminates any chances of cross contamination from one dosed subject to another during dosing procedure.
- Better regulatory acceptance due to assured well controlled dosing procedure.

❖**Specifications:**

- Change room 1 and 2 at 25 Pa (capacity of 3 persons at a time in each room).
- Dosing room 1 and 2 at 10 Pa (capacity of 3 persons at a time in each room).
- Ensure that the movement of air between these rooms is unidirectional, from change rooms to dosing room.
- ACPH (Air Cycles Per Hour) time of 25 cycles, gap of 4 minutes between two consecutive dosing is appropriate.

Inhalation: Training of Volunteers

❖ **Training of volunteers on placebo inhalers, aerosol inhalation monitors (AIM), in-check Dial meters and 2-dose devices:**

- To educate on the proper inhalation technique devoid of any leakage - Exhalation followed by inhalation: full inhalation at rate of 70-90 l/min for DPI and consistent inhalation at 30 l/min to 60 l/min for pMDI.
- To understand uniform inhalation rate.
- For precise interpretation of inhalation flow with respect to time.
- For interpretation of inhalation volumes, turbulent flow, and acceleration rates.
- For understanding the co-ordination between pMDI actuation and inhalation.

Inhalation: experience

- Completed 25 studies with more than 1100 volunteers

Type of studies	Number of studies	Number of volunteers
Pressurized metered-dose inhalers (pMDIs)	15	821
Dry powder inhalers (DPIs)	8	244
Nasal sprays	2	68
Activated charcoal suspension studies Nebulizer, PK end point studies – 22 and PD end point studies - 3	1*	48

* Part of pMDI study

Inhalation: Bioanalytical Capability

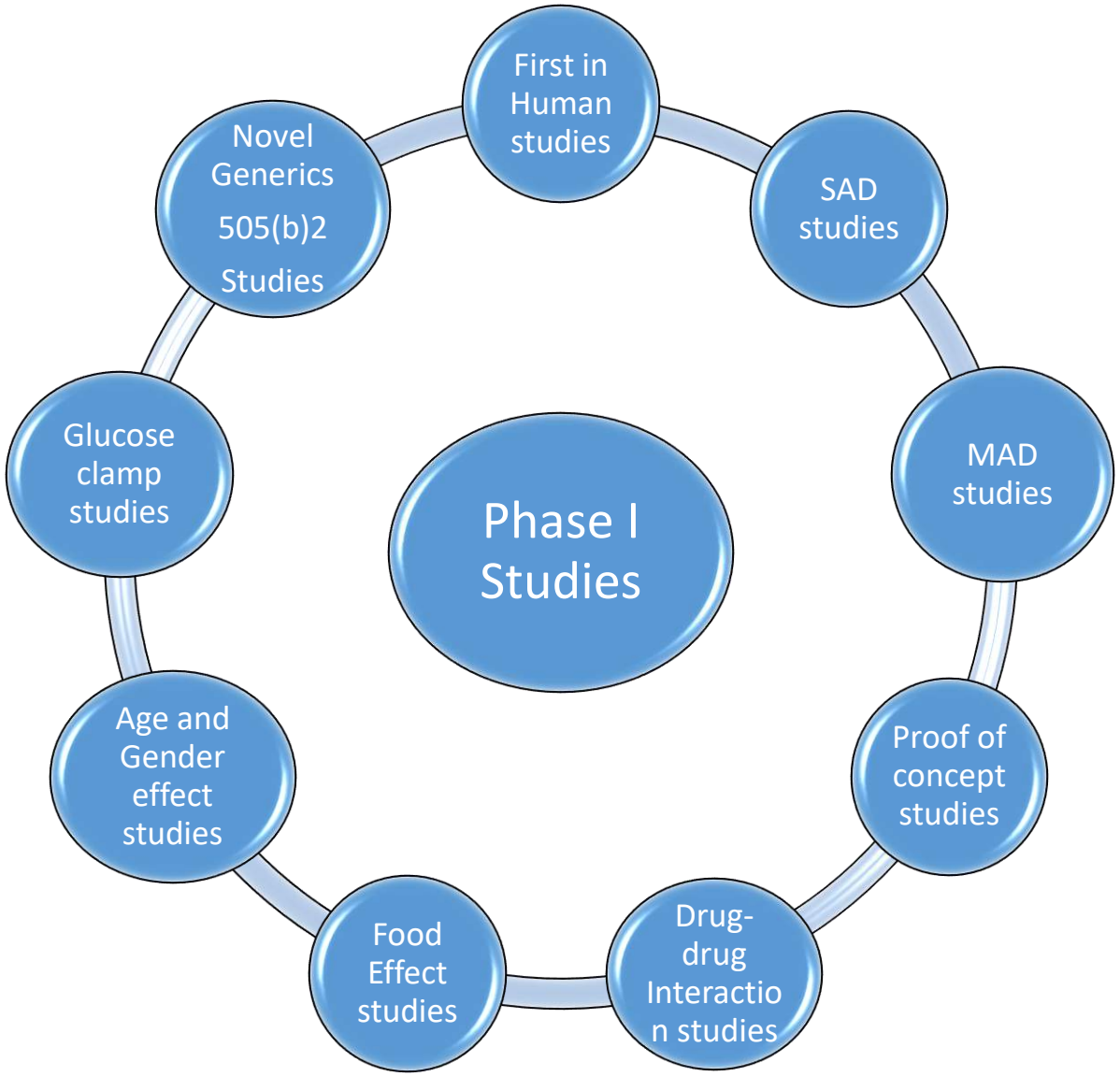
Drug Name	Therapeutic Class	Matrix	Anti-Coagulant	Equipment	LLOQ	ULOQ
Fluticasone Propionate	Corticosteroid, Asthma	Human Plasma	K_2EDTA	LCMS-8060	0.80 pg/mL	500 pg/mL
Formeterol	Asthma	Human Plasma	K_3EDTA	LCMS-8060	0.4 pg/mL	200 pg/mL
Tiotropium	Anticholinergic	Human Plasma	K3EDTA	LCMS-8060	0.20 pg/mL	100 pg/mL
Budesonide	Glucocorticoid	Human Plasma	K3EDTA	LCMS-8050	10 pg/mL	4500 pg/mL
Salmeterol	Asthma	Human Plasma	K3EDTA	LCMS-8050	1.0 Pg/mL	500 Pg/mL
Mometasone	Corticosteroid, Asthma	Human Plasma	K3EDTA	LCMS-8060	0.20 pg/mL	30.0 pg/mL
Ipratropium	Asthma	Human Plasma	K3EDTA	LCMS-8060	0.60 pg/mL	180 pg/mL

Phase 1

Phase – I: Infrastructure

- Fully equipped **Phase 1** clinics at Vedant (18 beds) and Shivalik (12 beds).
- Team of medical and para medical staff trained and experienced in conducting Phase 1 studies.
- Tertiary care arrangement for emergency response.

Phase I: Experience



Bioanalytical Research

Infrastructure

Scale and Range

- **46 LC-MS/MS** machines
  - **Insignia (33) and 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 ℃

Experience

Capabilities

Total available Bioanalytical methods are more than 1047

876 + 20 — Generics + Pharmacodynamics/ Immunogenicity

77 — Complex Generics

68 — NCEs

6 — Large Molecule Assays

Salient Features

- Average processing capacity of 1,00,000 samples per month
- Central Bioanalytical Laboratory for global Phase II/ Phase III trials

Types of Methods

- Capability to develop methods with lowest quantification level- up to 0.1 pg
- Methods developed for:
  - Endogenous molecules
  - Amino Acids (Multiple analysis in single injection)
  - Hormones
  - Steroids
  - Inhalation formulation
  - Elemental Bioanalysis (Other matrix- Urine)
  - Immunogenicity
  - Large molecules/ECLIA/ELISA
  - Chiral and Liposomal
- Tissue distribution studies.

Central Bioanalytical Lab

Central Bioanalytical Lab: Services

Dedicated team for Central Lab Services which includes

- Project Manager (1 per study)
- Sample management team (BRD custodians)
- Kits & Logistics coordinator
- Analytical Team (PK analysis – based on projects)
- Watson Team

Central Bioanalytical Lab: Experience

1. Multicenter study (which involved more than 35 sites (150 subjects, 10 Analytes)

i. Required screening sample analysis within 10 days from sample collection

ii. Estimated 10 analytes for this study- Total 4 bio-analytical methods

iii. Provided sample collection kits to all sites- within stipulated time

2. Sponsor- Global Pharma company

i. Type of studies : NCE – Multisite

ii. Total studies : more than 40 studies ongoing (from Multi sites globally, 20000 samples per year)

iii. Services provided: Sample management (receipt, logging in LIMS for reconciliation), method development, method validation and analysis of NCEs

iv. For safety analysis, sample receipt to analysis within 5 days

v. Sponsor specific reports with e-CTD

vi. More than 64 methods developed and validated for NCEs

vii. Exploratory studies, e.g. skin tissues , plasma protein binding experiment, chiral impurity estimation in the sample

Large Molecules

Large molecules: Bioanalytical experience

- Veeda has recently developed and validated below large molecules as per current EMEA guidance using commercially available kits by ELISA technique
    - Insulin Aspart and C peptide
    - Filgrastim
    - PTH (Teriparatide)
    - Denosumab
    - Romiplostim

- Enoxaparin: PD Endpoint and Immunogenicity for FDA, EU and ANVISA submission
- Pipeline Project: Cetuximab

Sr. No.	Analyte	No. Samples Analyzed	No. of Samples Analyzed for ISR	% of ISR Samples within Acceptance
1	G-CSF	2142	158	98.70%
2	Insulin Aspart	2139	158	94.90%
3	C- Peptide	2400	176	98.20%
4	PTH	340	34	88.33%

Ingenuity Biosciences

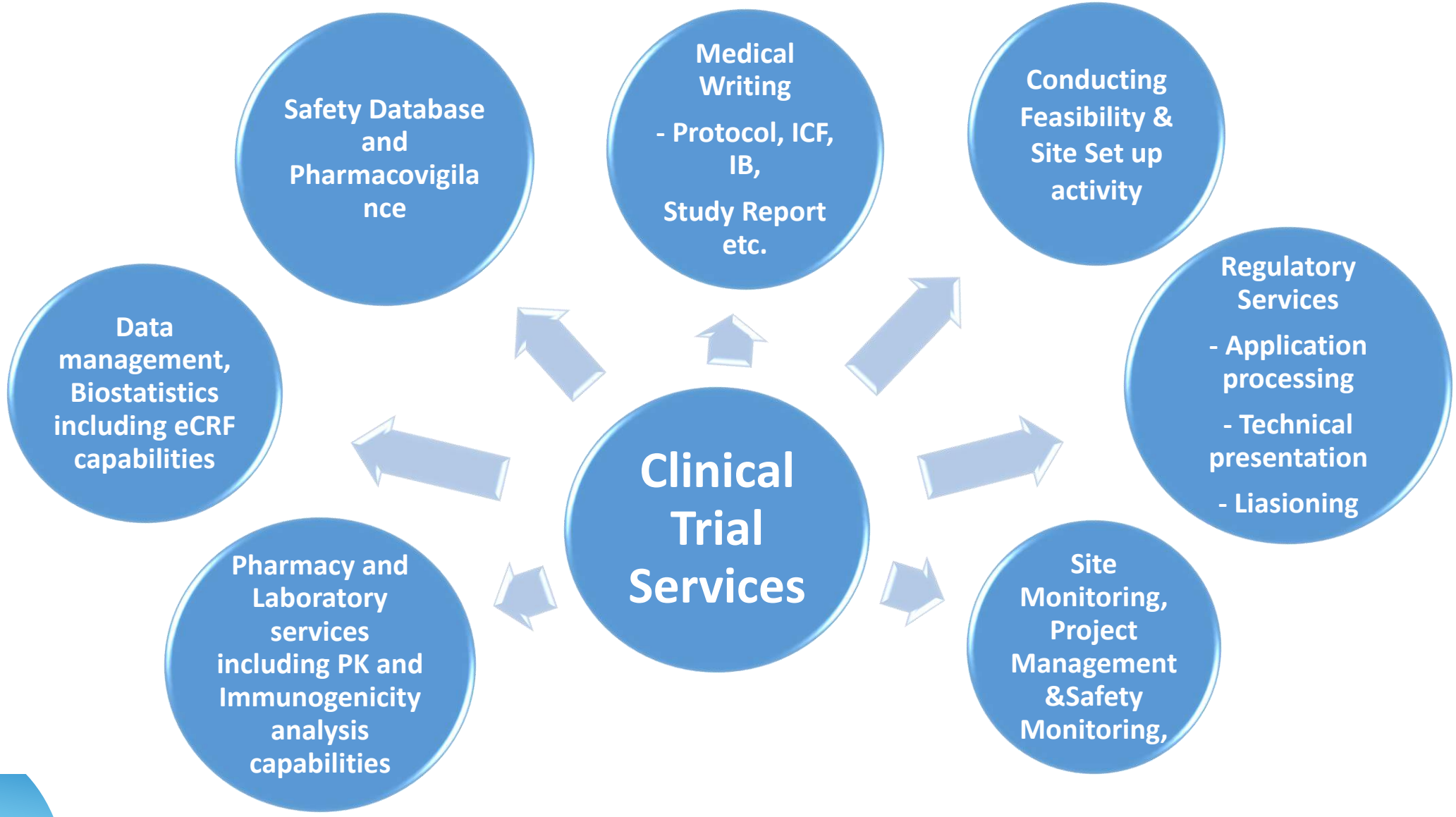
- Joint venture between Veeda Clinical Research and Somru BioScience, Canada offering niche services including PK, ADA, NAb and Biomarker assays meeting global regulatory requirements besides characterization and comparability testing through Somru's proprietary platform.

- Ingenuity's capabilities include state-of-the-art technology platforms needed for performing advanced analytical assays for various Biosimilar products

  - ❖ Multimode plate reader (UV, Fluroscence and Luminiscence), plate washer, LC-MS/MS
  - ❖ Access to advanced Biological NMR capabilities
  - ❖ Proprietary Aegyris software suite that is highly specialized and advanced to perform method validation and statistical analysis in a streamlined and regulatory compliant manner

Clinical Trials (Patient Studies)

Clinical Trials: Services



Clinical Trials: Experience

Organization experience

- Completed Projects
  - 28 patient based clinical trials
  - 4 Stand-alone Medical Writing BE-PK studies
- Ongoing Projects
  - 8 Ongoing PK studies in different stages of execution
  - 2 Ongoing Clinical endpoint studies in different stages of execution
  - 2 Ongoing phase I in studies in different stages of execution

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

Clinical Trials: Team Experience in therapeutic areas

Sr. No.	Area	Indication	Molecules	Regulatory Submissions
1	Oncology	Advanced Ovarian Cancer, Metastatic breast cancer, Renal Cell Carcinoma, Multiple Myeloma, Colorectal Cancer, Solid Tumors / Lymphoma, NSCLC, Cervix Cancer,	Paclitaxel, Everolimus, Capecitabine, Bortezomib, liposomal Doxorubicin HCL, Denosumab, Trastuzumab, Cabazitaxel	USFDA, EMA, ANVISA and DCGI
2	Medical Devices	CAD, Arrhythmia, Heart failure, Uncontrolled hypertensions,	BioStent, DES, Pacemakers, Renal Denervation Therapy	USFDA & DCGI
3	Cardiology	Hypertension, Ischemic cardiomyopathy, CVD, ACS	Nebivolol, Cardiopoietic stem cells, Evolocumab, Telmisartan, Azilsartan, Rosuvastatin, Clopidogrel lipid suspension, Lixivaptan	USFDA, EMA and DCGI
4	Endocrinology	DM-I, DM-II, Diabetic nephropathy	Atorvastatin, Dapagliflozin, insulin, Vildagliptin, Repaglinide +Voglibose tablet, Pentosan Polysulfate Sodium capsules	USFDA, EMA and DCGI

Clinical Trials: Team Experience in therapeutic areas

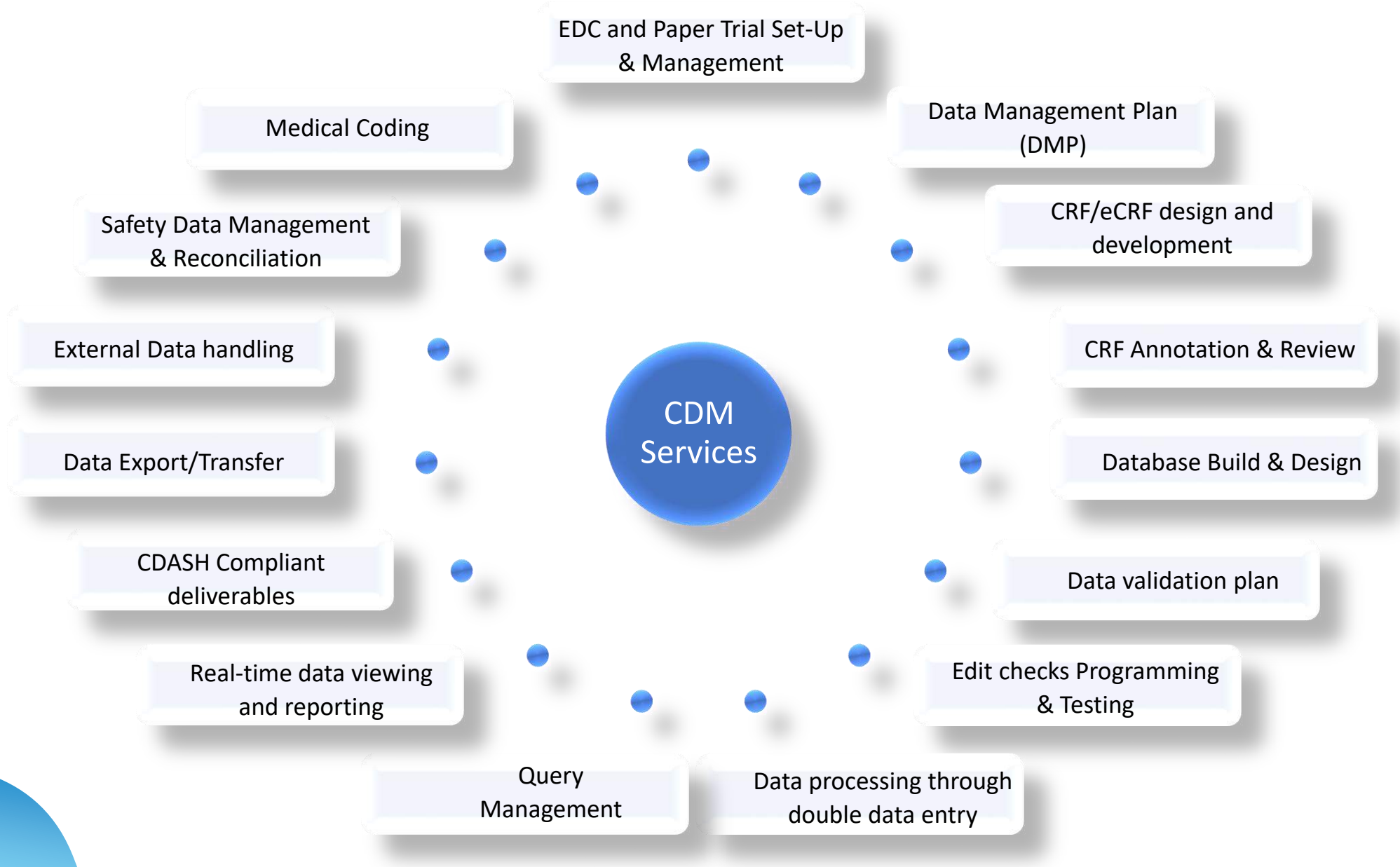
Sr. No.	Area	Indication	Molecules	Regulatory Submissions
5	Psychiatry	Major Depressive Disorder, Schizophrenia, Bipolar disorder, Bipolar I depression	Paliperidone PR, Clozapine, Risperidone, Lurasidone, Quetiapine PR, Endoxifen	USFDA, EMA and DCGI
6	Respiratory	Asthama, COPD	Revolizer, Tiotropium Inhalation solution	USFDA & DCGI
7	Dermatology	Atopic dermatisis, Oral lichen planus, Dermatomycoses	Tacrolimus Ointment, Flutrimazole 1% cream	DCGI
8	Nephrology	CKD, Urinary tract infection and pyelonephritis	Peg EPO, Cefozopran injection 1 gm	USFDA & DCGI
9	Gastroenterology	Arsenic Poisoning, GERD, Constipation, Ulcerative Colitis	Chelating agent, Basiliximab, Rabeprazole, Prucalopride Tablet	USFDA & DCGI
10	Infectious diseases	Bacterial Infection, Skin Infection, Hepatitis B Infection	Oritavancin Diphosphate, Amoxicillin, Tenofovir DF	USFDA & DCGI

Clinical Trials: Team Experience in therapeutic areas

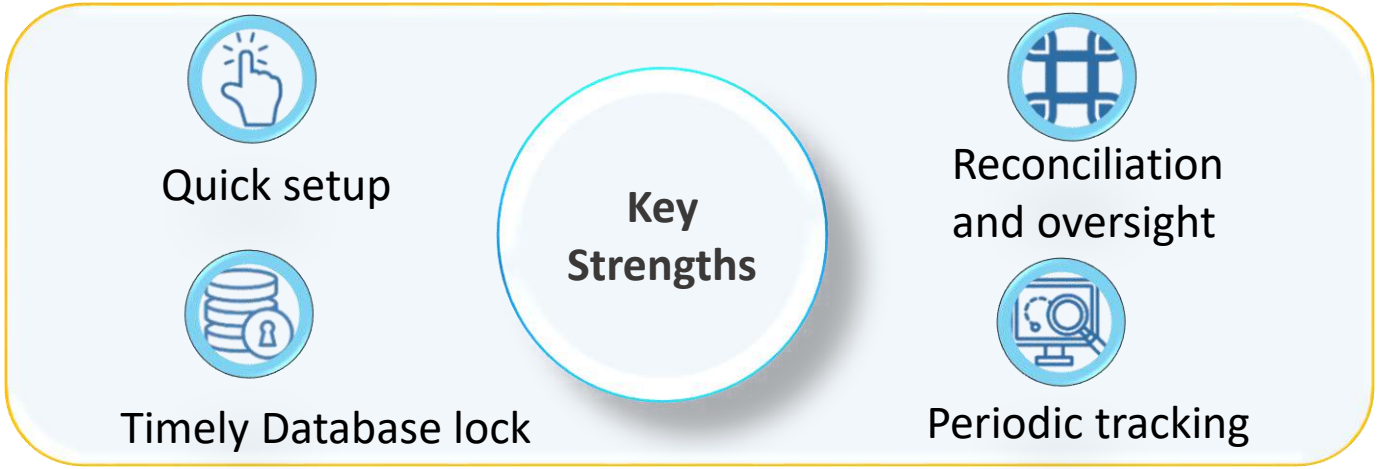
Sr. No.	Area	Indication	Molecules	Regulatory Submissions
11	Ophthalmology	Chronic Open Angle Glaucoma, Ocular Hypertension	Brinzolamide, Lidocaine Hydrochloride Ophthalmic Gel, Ganciclovir ophthalmic gel	USFDA & DCGI
12	Neurology	Epilepsy, Seizures	Felbamate, Lacosamide Injection, Ralfinamide,	DCGI
13	Vaccine	Rabies, Leishmaniasis & serious fungal infections	New Vaccine, Amphotericin B	DCGI
14	Orthopaedic	Psoriasis and Rheumatoid Arthritis& Osteoporosis	Methotrexate, Denosumab	USFDA & DCGI
15	Gynaecology	Fungal infections , Infertile women	Sertaconazole + Secnidazole, Progesterone 400mg pessary	DCGI

Biopharmaceutics & Data Science

Clinical Data Management: Services



Biostatistics: Capabilities



- We have a wide range of bio statistical services designed to support development program
- Our team has experience in various statistical evaluations for **Design of Experiment (DoE)**, **In-vitro population bioequivalence (PBE), In-vitro equilibrium binding**, **kinetic binding studies**, **Dose Proportionality studies**, Pharmacodynamics end point studies. We also have expertise in the prediction and simulation analysis.

Recognitions

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
	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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Executive Profiles

Mr Ajay Tandon, Managing Director

Current Responsibility

- Overall strategic leadership and operational management.
- Member of the Board of Directors

Profile Overview (Career and Education)

- Bachelor of Engineering (Honor's) : Delhi College of Engineering, 1990
- Masters in Business Administration : Indian Institute of Management - Ahmedabad, 1992

Experience:

- 28 years in Banking and Private Equity management
- Leading Veeda since May 2019

Special Areas of Expertise :

- Strategic Planning and Execution
- Risk Management
- Client Relationship Management

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. Venu Madhav PhD, MBA, Scientific Advisor to Board

Current Responsibility

- Scientific Advisor to Board

Profile Overview (Career and Education)

Venu Madhav is Doctorate in Pharmacy and Management in Finance with 30 years of experience in Pharma and CRO industries. Working with Veeda since 2010 as COO and presently working as Scientific Advisor to Board from 1st Sept' 2020.

Experience

He started his career as QC chemist in Vorin Labs a bulk drug unit. Latter on associated with Vimta Labs, Sipra Labs, Vera Pharma, Ranbaxy and Sun Pharma before joining Veeda.

Special Areas of Expertise

He has expertise in Clinical Research, Biopharmaceutics, Analytical and Bioanalytical Research, Generic Drug Development Process, CRO Management and Stability Studies.

Mr. Rajkumar Agarwal B.Ph, MBA, Head- Business Development

Current Responsibility

- Responsible to achieve the revenue targets for Veeda for different business lines to sustain/deliver business growth and profitability

Profile Overview

- Rajkumar Agarwal is a seasoned BD professional with nearly 11 years of experience in identifying and managing clients in life sciences

Experience

- Exposure and expertise in sales and marketing, new business development, key account management and managing client related issues
- To work in tandem with the client requirements and meeting the company's goal in the process

Special Areas of Expertise

- Look for new avenues for future business growth opportunities and further expanding the client base

Swati Guttikar, M. Pharm, Head- Bioanalytical Research

Current Responsibility

- Manage functioning of Bioanalytical department
- To ensure efficient use of all equipment in Bioanalytical department including 46 LCMS machines , ICPOES machines and Plate Reader
- To ensure compliance with quality in all steps

Profile Overview (Career and Education)

- Worked in Analytical R and D at Cibatul Ltd , Valsad .
- Worked as Lecturer in Pharmacy College at Aurangabad .
- Worked in Manufacturing and Packaging department at Lupin Labs , Aurangabad .
- Worked in Rand D and QA department at Mercury Labs , Vadodara .
- Worked in Bioanalytical Department at PERD centre at Ahmedabad .
- Working in Veeda Clinical Research from 2006 .

Experience: Total Industrial experience of 28 years and 23 Years in core area of Bioanalytical Department.

Special Areas of Expertise

- Handled complex method developments including metabolites , low sensitivity molecules on LCMSMS
- Handled developments and Studies on Plate Reader using ELISA platform.

Dr. Ravi Krovidi, CEO – Ingenuity Biosciences

Current Responsibility

- Head of Ingenuity Biosciences
- Techno Commercial, Business Development of Large Molecules and Clinical Trials

Profile Overview (Career and Education)

- Ph D in Biological Mass Spectrometry from Max Planck Institute, Freiburg, Germany
- Scientist at Pacific-Northwest Labs, Battelle Institute, Washington, USA
- Head – Center for Advanced Protein Studies, Syngene International Ltd, Bangalore, India
- BIRAC grant recipient - Established National Laboratory under Prestigious National Biopharma Mission Programme
- Senior Management positions at Lambda Therapeutics Ltd and other Multinational Companies
- Worked for product based biotech companies
- Honorary invited member at NIPER Kolkata
- Invited speaker at various leading National and International conferences.

Special Areas of Expertise:

- Managed more than 20 projects including R&D studies, Expertise in dealing with Drug Discovery and Development, contributed towards submission of CMC filings for various mAb’s

Experience

- Total experience Industry and Academia over 18 years

Dr. Sumit Arora, M.D., Head- 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), GM- 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., DGM- 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.

Mr. Jitendra Parmar, M.S.Pharm, Head – Biopharmaceutics & Data Science

Current Responsibility

- Oversee from strategic perspective and manage operations and capability development of PK-stats, Data Management and Biopharmaceutics aspects

Profile Overview

- Formulation scientist with hands on experience from biopharmaceutics aspects, have worked with Pharmaceutical as well as CRO like Sandoz (Novartis), Cadila Pharma, Zydus Cadila, Alkem labs and Veeda CR
- Different dosage forms from simple oral tablets, capsules to modified release and complex dosage forms and related aspects of clinical development and biopharmaceutics support, having part of several successful approved products

Experience

- 17 years of experience in handling various roles and responsibilities in different aspects of complex projects clinical development perspective starting from portfolio selection process to post marketing support

Special Areas of Expertise

- Biopharmaceutics and Data Evaluation for strengthening success of studies by multiplicative review and assessments based on rich experience and exposure of various products and regulatory requirements

Dr. Ghanshyam Patel, Ph.D.(Statistics), AGM-CDM

Current Responsibility

- Head the Biostatistics department
- Feasibility assessment, from Statistical point, in Clinical Trials
- Thought Leadership - Statistical conferences and presentations
- Oversee overall CDISC activities and TFL development

Profile Overview

- A Ph.D in Statistics, Dr. Patel has worked with major Indian Pharma companies like Sun pharma and Cadila Healthcare. He has also worked with CRO organizations in both pharmaceutical as well as consumer healthcare areas. He is involved in academia and supports students and professionals in their learning.

Experience

- Dr. Patel is a Biostatistician with around 16 years of experience in Persoal Healthcare, BA/BE and Clinical Trials studies with Therapeutic Area Dermatology, Oncology and Infectious Diseases

Special Areas of Expertise

- Statistical Inference, Factorial design, Sequential adaptive design and Response adaptive design in Clinical Trails

Thank You

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