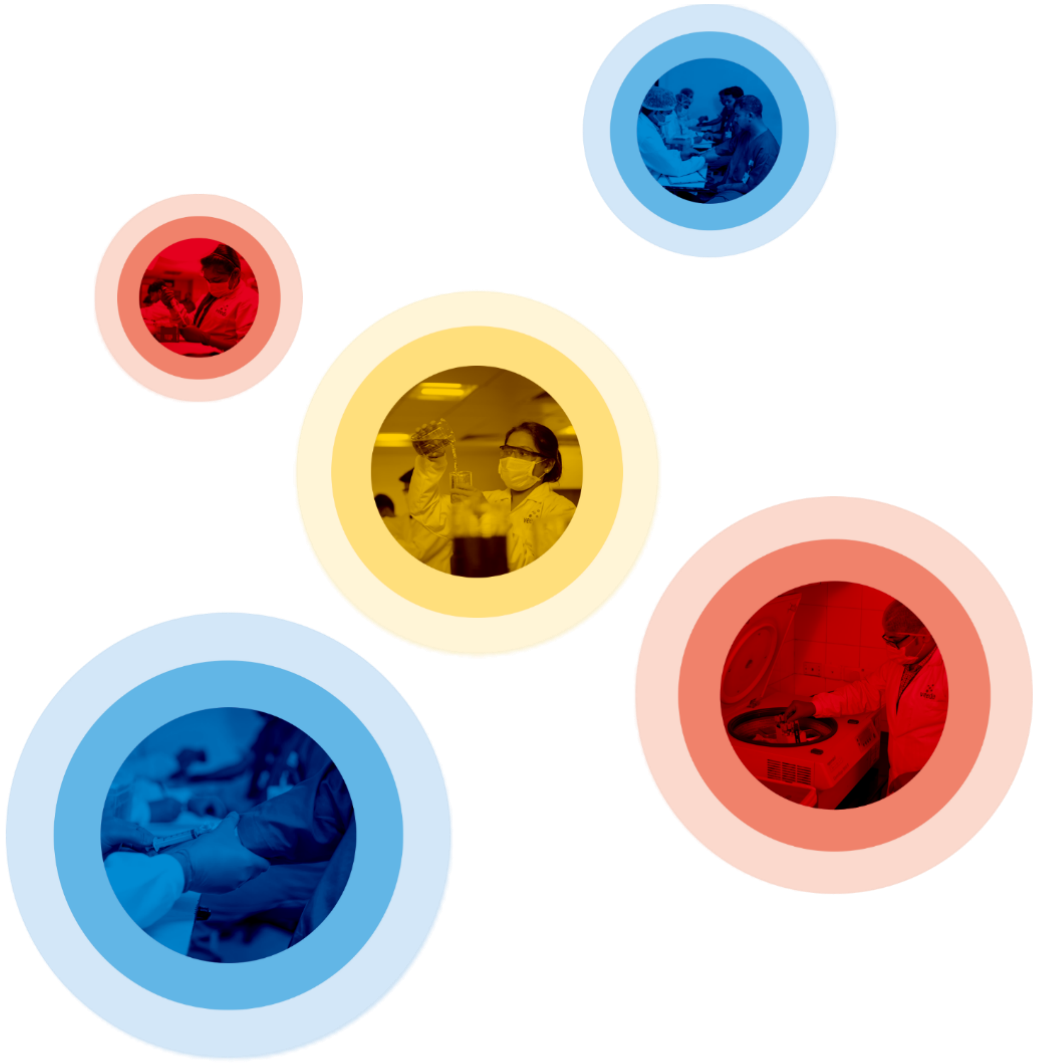
Global Clinical Development Partner

Providing Quality Clinical Research Solutions

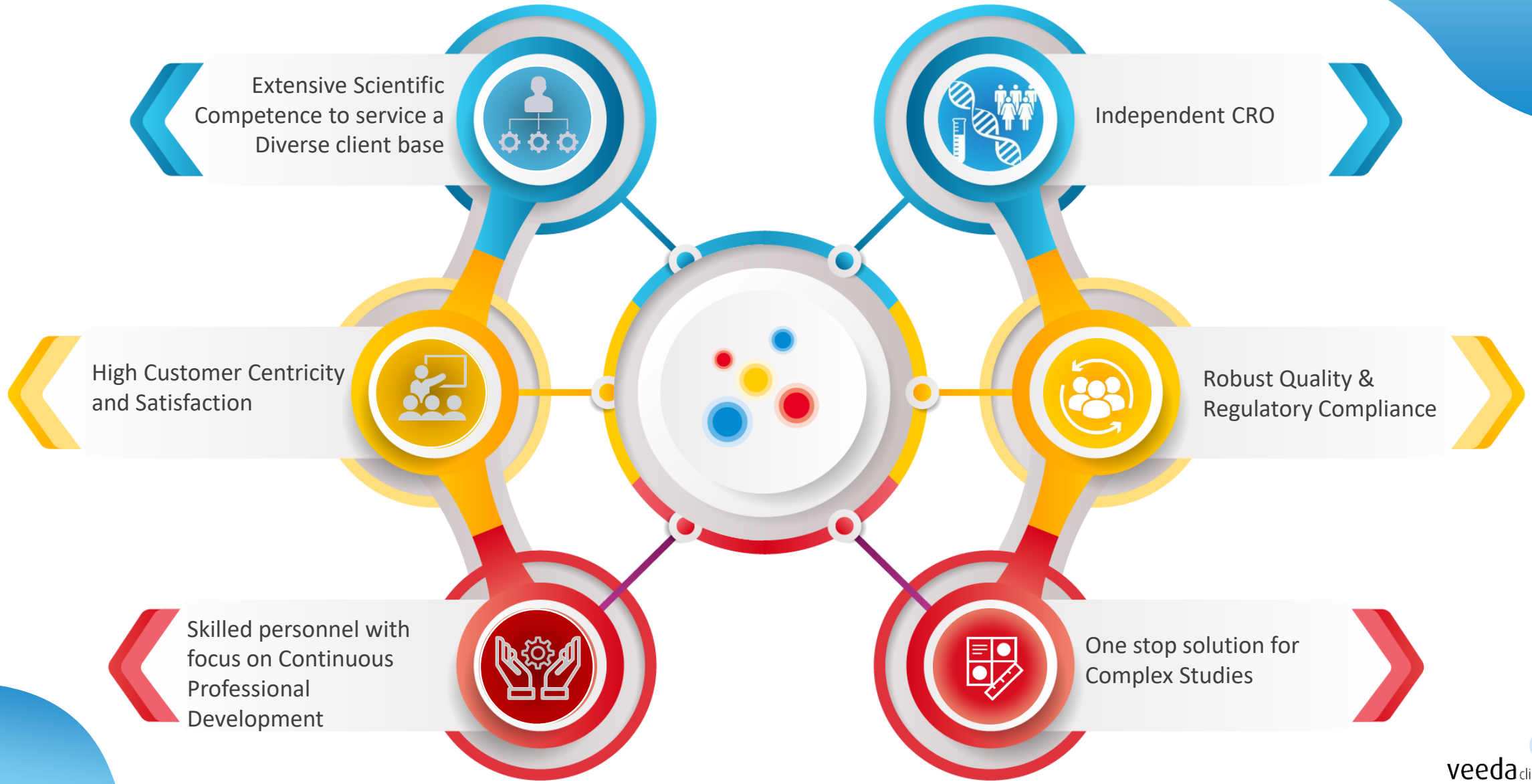


veeda clinical research®

Table Of Contents

veeda clinical research®

The Veeda Advantage



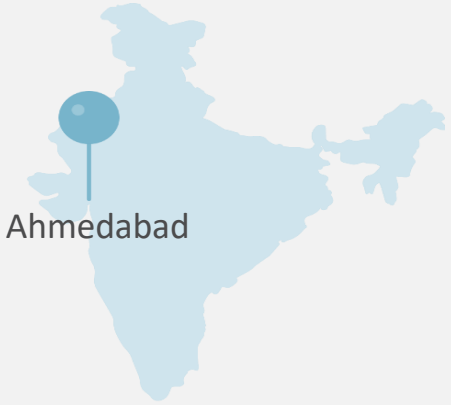
veeda clinical research®

CORPORATE OVERVIEW

veeda clinical research®

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

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

2018 — New Facility at Mehsana, Total number of Employees 970

2019

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

MISSION & VISION

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

VALUES

- Humility
- Openness
- Honesty and Integrity
- 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

veeda clinical research

Regulatory Credentials

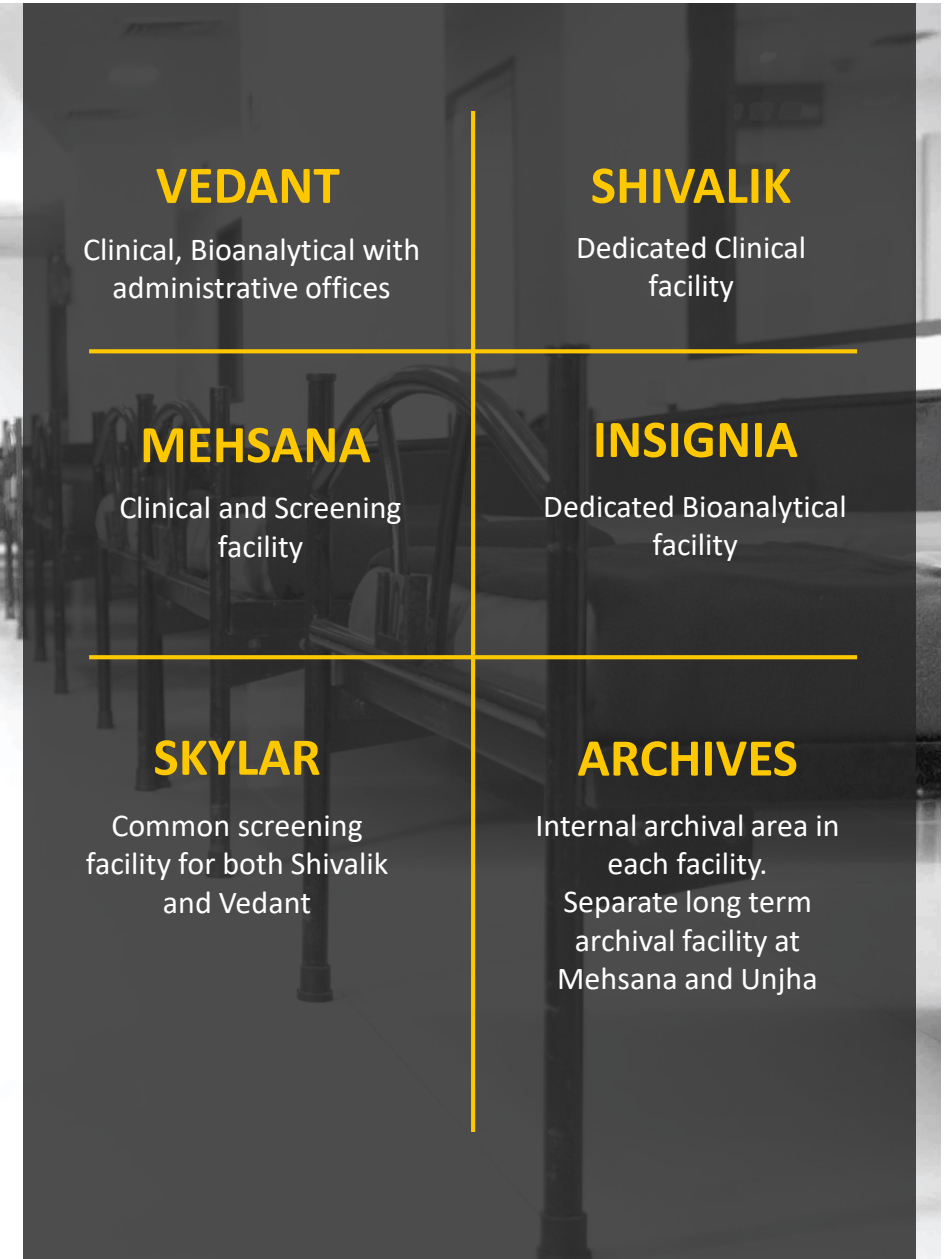
FDA	33*
ansm – Agence nationale de sécurité du médicament et des produits de santé	1
MHRA – Regulating Medicines and Medical Devices	3
AGES	1
ANVISA	13
mcc – Medicines Control Council	1
World Health Organization	5
DCGI	15
NPRA Malaysia	5

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

INFRASTRUCTURE

veeda clinical research®

Clinical Infrastructure



VEDANT
Clinical, Bioanalytical with administrative offices

SHIVALIK
Dedicated Clinical facility

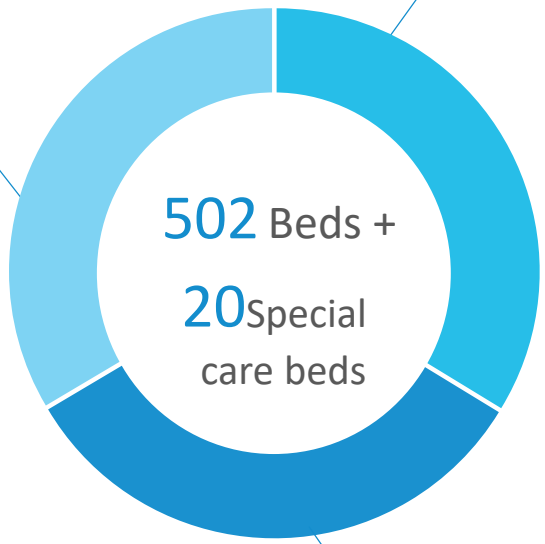
MEHSANA
Clinical and Screening facility

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



Vedant
170 Beds +
6 Special care beds

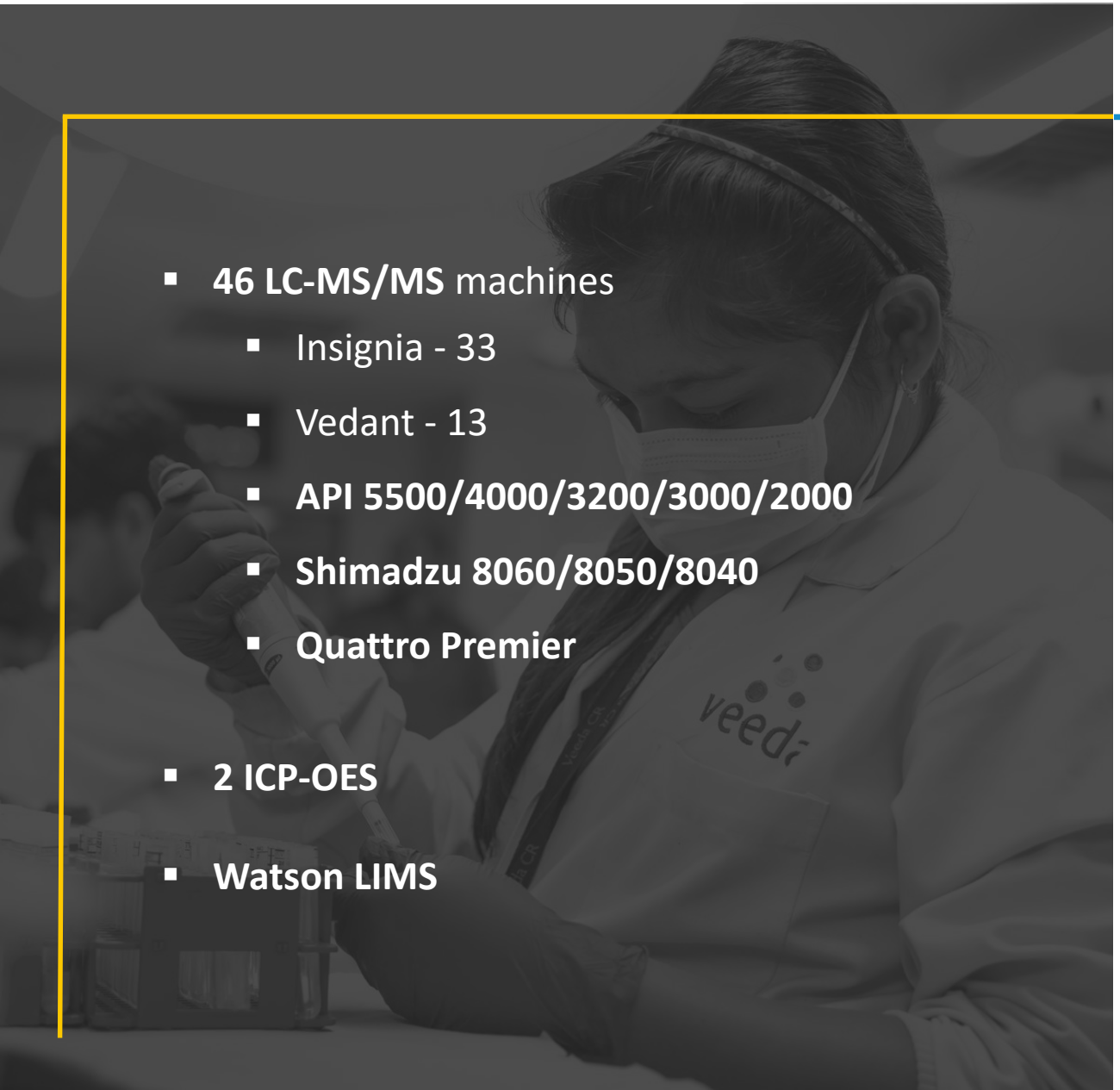
Shivalik
170 Beds +
7 Special care beds

Mehsana
162 Beds +
7 Special care beds

12 **Intensively monitored beds** to conduct **Phase I** study

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 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

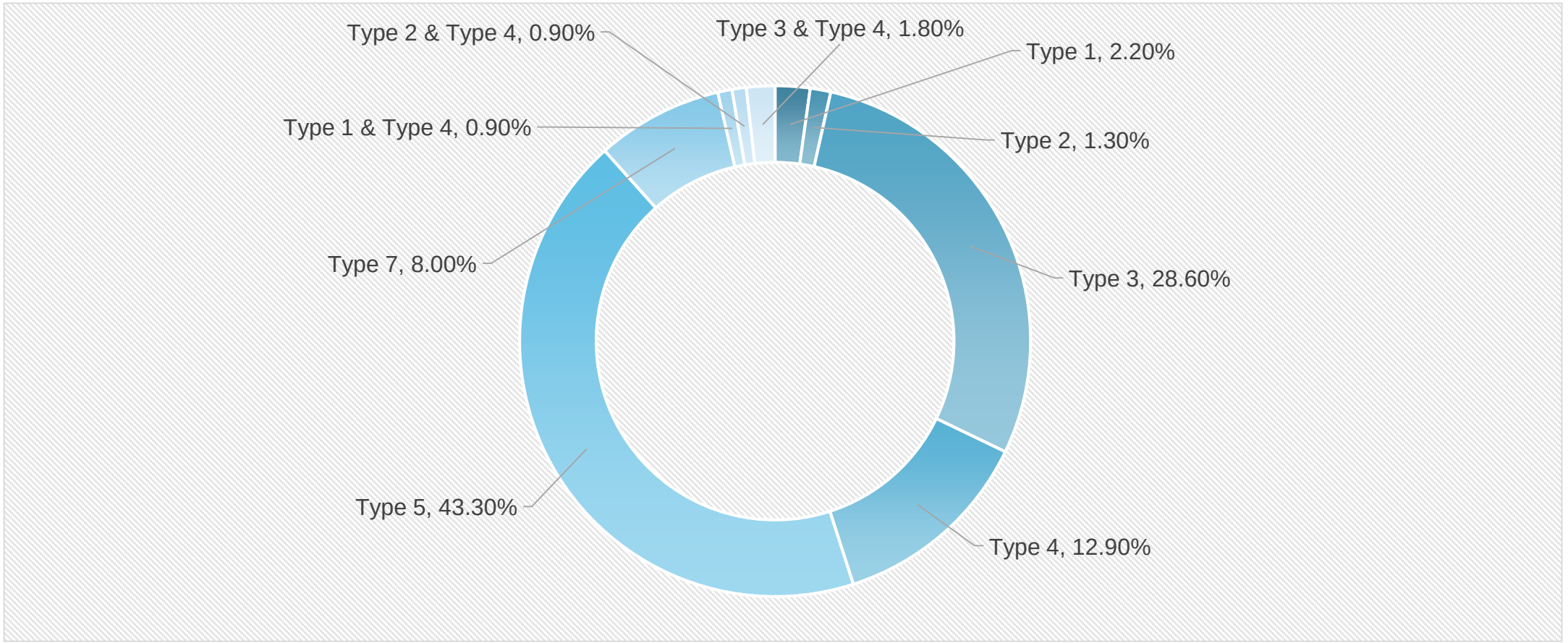
505(b)(2) Applications

veeda clinical research®

505(b)(2) candidates

Type	Definition
1	New Molecular Entity (Pro-drug of previously approved drug)
2	New Active Ingredient (New salt, Racemate, Enantiomer, Complex)
3	New Dosage Form (Strength, route of administration, altered excipient, changes in release pattern, Drug device combination products)
4	New Combination / FDC
5	New Formulation or Other Differences (e.g., new indication, new applicant, new manufacturer, dosing regimen)
6	New Indication or Claim, Same Applicant
7	Previously Marketed But Without an Approved NDA
8	Rx to OTC (Previously approved drug changed to OTC or changes to existing OTC product)

Submission Classification



Reference: https://www.ncbi.nlm.nih.gov/pubmed/30616377

FDA submission classification of drug products approved via 505(b)(2) pathway from 2012 to 2016 (n : 224). Review of Drugs Approved via the 505(b)(2) Pathway: Uncovering Drug Development Trends and Regulatory Requirements

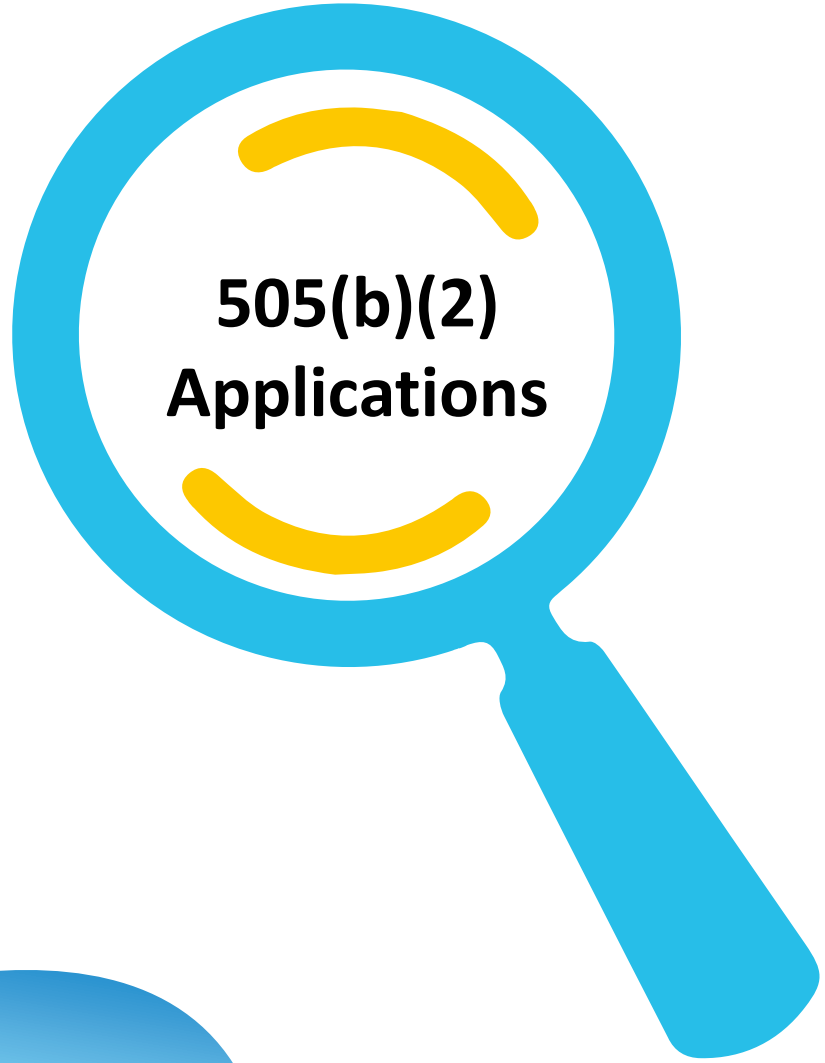
Type of studies required

Since the 505(b)(2) pathway allows the use of public data or the FDA's previous findings in lieu of novel trial data, some **development programs** may conduct bridging studies that preclude the need for nonclinical or clinical studies, or both.

Establish a bridge between proposed drug product and each listed drug against which safety / efficacy to be proven.

Sufficient data are required to **support each difference**.

Bridging Approaches to support 505(b)(2) Applications

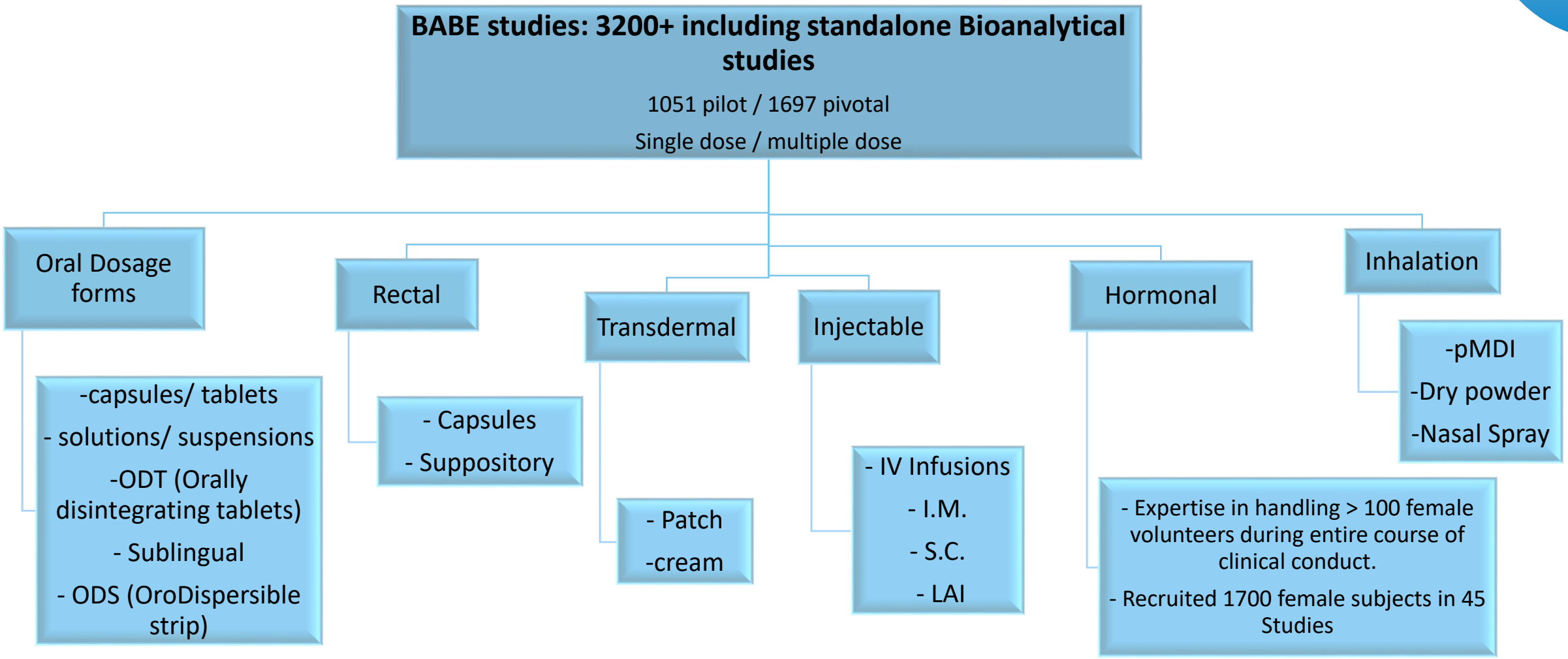


Clinical Studies	• Single & Multiple dose BA / BE • Dose proportionality • Pharmacokinetic / Pharmacodynamic • Food effect • Safety / Efficacy studies • Drug drug Interaction. • Single ascending dose / Multiple ascending dose.
Pre Clinical Studies	• Pre clinical
In Vitro Studies	• In vivo – Bio waiver • In vitro dose dumping studies • In vitro PD studies

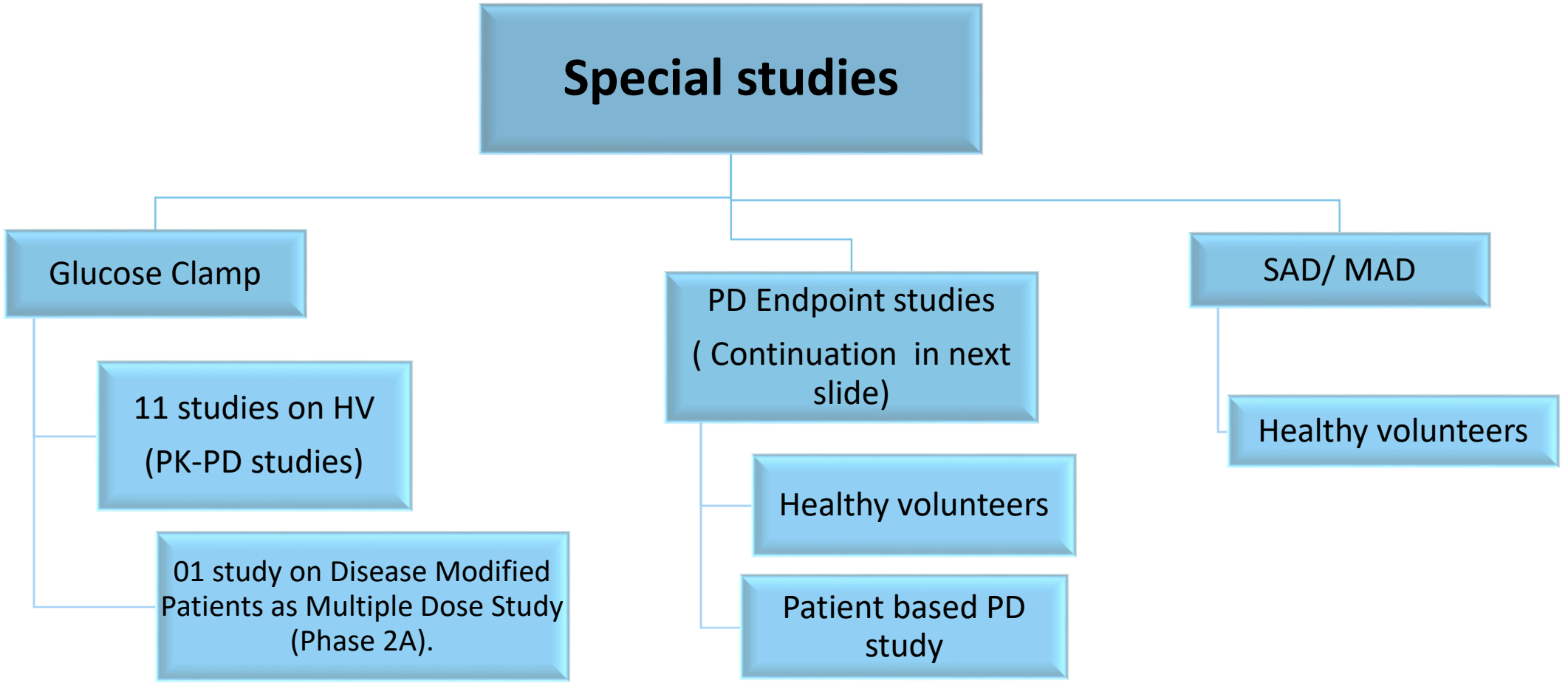
Veeda CR – Expertise

veeda clinical research®

BA / BE Expertise



Special studies



PD studies Experience

- Single dose comparative bioavailability and **pharmacodynamic** study on Anticoagulant drug.
- Multiple-dose **Immunogenicity evaluation** study of Anticoagulant drug.
- Effect of a single oral dose of Quinolone Antimicrobial on **ventricular repolarization (QT/QTc interval prolongation)** in healthy male volunteers.
- Single dose study to assess safety, pharmacokinetics and **pharmacodynamics** of therapeutic proteins administered subcutaneously to healthy, adult, male subjects.
- A cross-over **pharmacodynamic study** to evaluate equivalence of corticosteroids (Inhalation product) in healthy, adult, male human subjects.
- A crossover study to compare the **systemic pharmacodynamic effects** of the corticosteroids (Inhalation product) in healthy, adult, male human subjects

Drug –Drug Interaction

- A Study to Assess the Effects of Multiple Oral Doses of calcium-channel blockers drug, a Moderate CYP3A4 Inhibitor, on the Single-Dose Pharmacokinetics of XYZ drug in Healthy Volunteers.
- A Study to Evaluate the Effect of Multiple Oral Doses of calcium-channel blockers drug on Single-Dose Pharmacokinetics of ABC drug in Healthy Volunteers.
- **Pharmacokinetic interaction** study when administered as FDC and co-administered as single tablets.

Dose Proportionality

- Availability of statistical model to perform dose proportionality assessment w.r.t. USFDA and EMA regulatory requirements.
- Performed dose proportionality studies:
  - dose proportionality assessment of oral glucocorticoids.
  - dose proportionality assessment of ABC.

Food effect study

In addition to the vast experience in conducting fasting and fed bioavailability / bioequivalence studies in line with regulatory requirements, Veeda CR has an expertise in handling specialized food effect studies. Some examples are as follow:

Two way crossover – oral bioavailability (pharmacokinetic comparison) studies under fasting and fed state of test formulations.

Studies to evaluate food effect of pharmacokinetics of test formulations as three way crossover design under different conditions as follow:

- high-fat, high-calorie breakfast
- sprinkled on one tablespoon of applesauce
- under fasting state with 240 mL of water

Two-Treatment, Three-Period, Six-Sequence, Crossover, Bioequivalence studies under fasting and fed conditions to assess the effect of food:

- Test formulation under fasting and fed states
- Reference formulation under fed condition

FIH

Safety and immunogenicity study of Polio Vaccine in healthy adult human male subjects.

Placebo-Controlled, Randomized, Double-Blind, Rising Single Dose Study of XYZ Drug to Evaluate Safety, Tolerability, Pharmacokinetics, and

Pharmacodynamics in Healthy, Adult Volunteers and Adult Type-II Diabetic Volunteers.

A Randomized, Single-Blind, Placebo-Controlled, Phase I Study to Assess the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics after Multiple Oral Doses of XYZ Drug in Subjects with T2DM Treated with Metformin.

(Upcoming)

Pharmacokinetics, Safety and Tolerability study of XYZ Drug

Clinical Trials and Expertise

Patient based PK – BE studies

- >10 studies
- Number of patients: 24 – 108

Phase II / III studies

- 6 studies
- Therapeutic areas: Bone Diseases and oncology

Veeda CR 505(b)(2) Experience

veeda clinical research®

505(b)(2) Veeda experience

❖ **Veeda CR has been a partner in supporting 505(b)(2) applications with ~45 studies experience with various clients.**

505(b)(2)	Test	RLD	Design
Salt change	Drug **hemitartrate**. Tablets	Drug **mesylate** Tablets	Single dose BE
Change in formulation & dosage form	Drug **300mg ER tablets**	Drug **150 mg IR capsules (2x150mg)**	comparative BA
Change in formulation & strength	Drug **sublingual tablets** 0.6 mg	Drug **Tablets 1mg**	comparative BA
Change in formulation	Drug **ODT** 2 mg	Drug **Tablets** (2 mg)	Single dose BE

505(b)(2) Veeda experience

505(b)(2)	Test	RLD	Design
FDC	**Fixed dose Combination** of statin and cholesterol-lowering Agent	**Individual Formulations** of statin + cholesterol-lowering Agent	Single dose BE
FDC	**Fixed dose Combination** of statin and cholesterol-lowering Agent	**Individual Formulations** of statin + cholesterol-lowering Agent	Single dose BE
Change in formulation	Statin Drug oral **suspension** 20mg/5ml (total dose - 80 mg)	Drug **tablets**	Single dose BE
Change in formulation	Drug **20 mg Soluble Tablets**	Drug **Tablets 2.0 mg (2.0 mg X 10)**	Comparative PK Study
Strength change	Drug **600 mg** PR tab	Drug XR tablets **200 mg** (3 tablets X 200 mg)	Multiple dose BE

TESTIMONIALS

" 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

veeda clinical research®

TESTIMONIALS

"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

veeda clinical research®

ACHIEVEMENTS

2004

2017

Organization	Award Category
PraxisMedia	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 company of the year

2018

Organization	Award Category
ASSOCHAM INDIA	Best Clinical Research Organization - India Organization - India
Health & Wellness	Clinical Trial Company of the Year Year
ECONOMIC GROWTH FOUNDATION	Bharat Udhyog Ratan Award in Clinical 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
FROST & SULLIVAN 2019 BEST PRACTICES AWARD	Indian Clinical Research company of the company of the year

veeda clinical research®