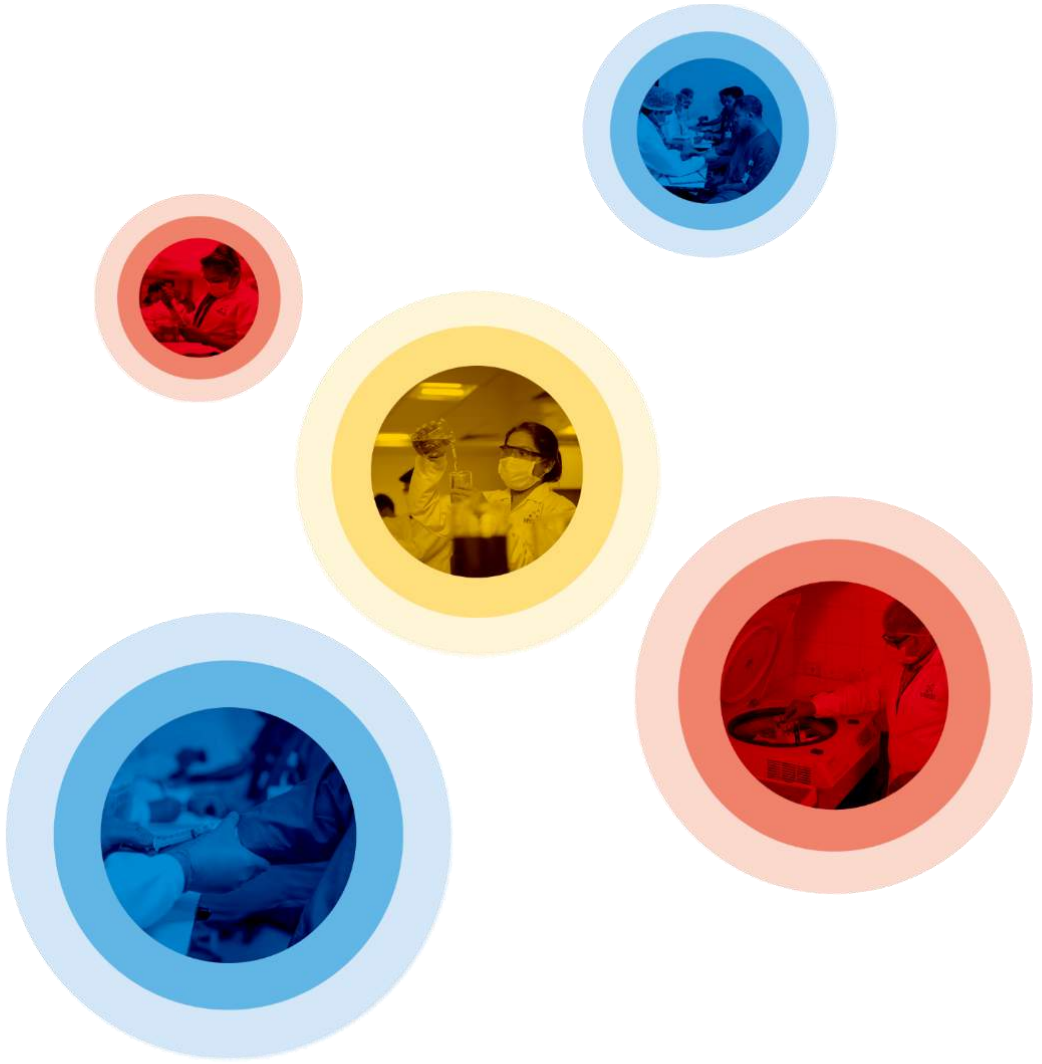
Global Clinical Development Partner

Providing Quality Clinical Research Solutions



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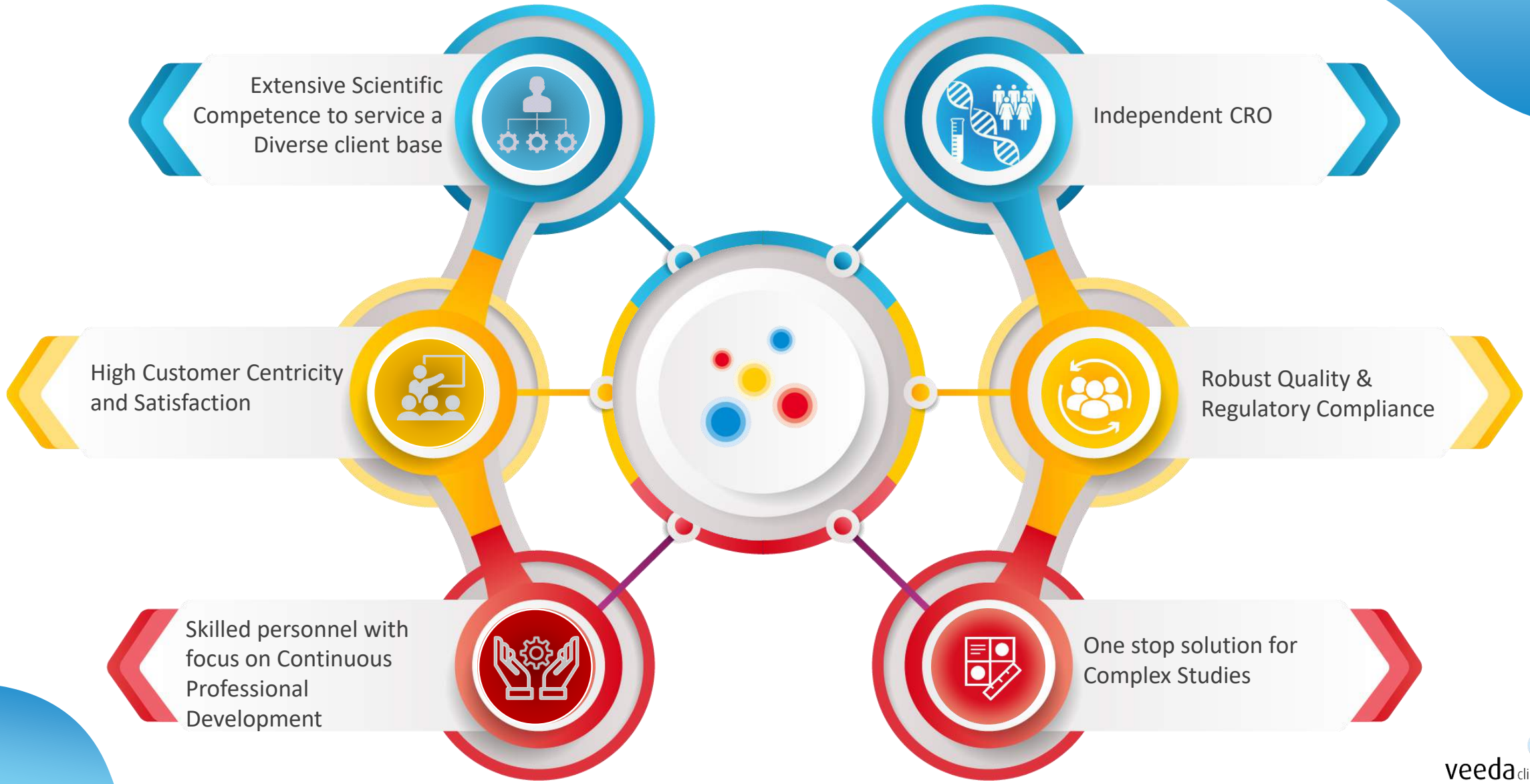
# The Veeda Advantage





# 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
- Acquired Bioneeds "A Preclinical CRO"

# 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 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

- 77 successful regulatory audits till date
- 09 successful regulatory audits in last 24 months

| | | | |
|---|---|---|---|
| US FDA | 36* | ANSM | 1 |
| MHRA | 3 | AGES | 1 |
| ANVISA | 7 | MCC | 1 |
| WHO | 5 | DCGI | 18 |
| NPRA Malaysia | 5 | | |

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



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# Infrastructure

# Clinical Infrastructure

**VEDANT**
Clinical, Bio-analytical facility

**MAGNET CORPORATE PARK**
Administrative office

**SHIVALIK**
Dedicated Clinical facility

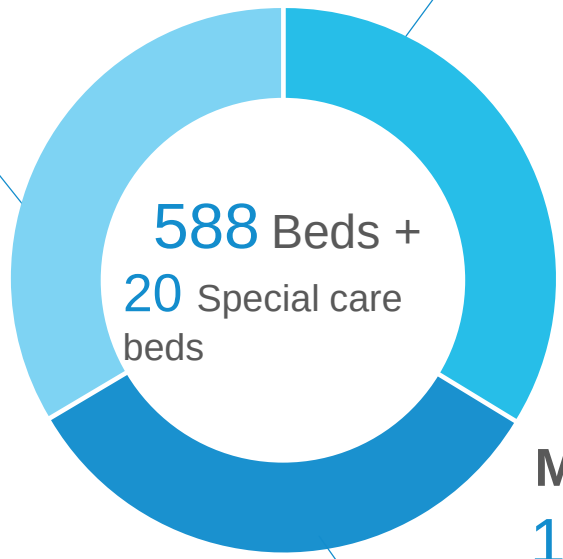
**MEHSANA**
Clinical and Screening facility

**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**
226 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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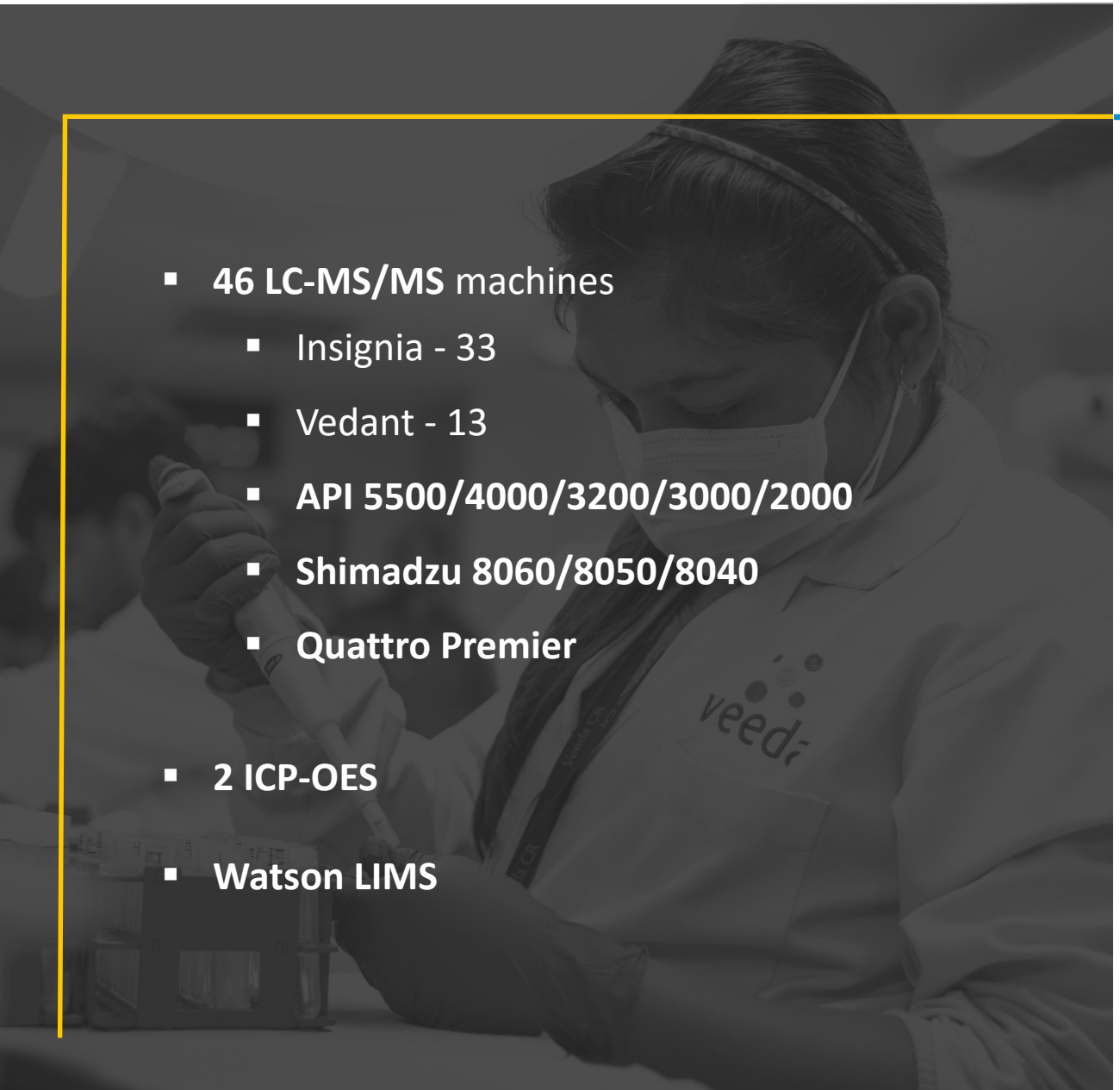
# Bioanalytical Infrastructure



- **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

# 505(b)(2) Applications

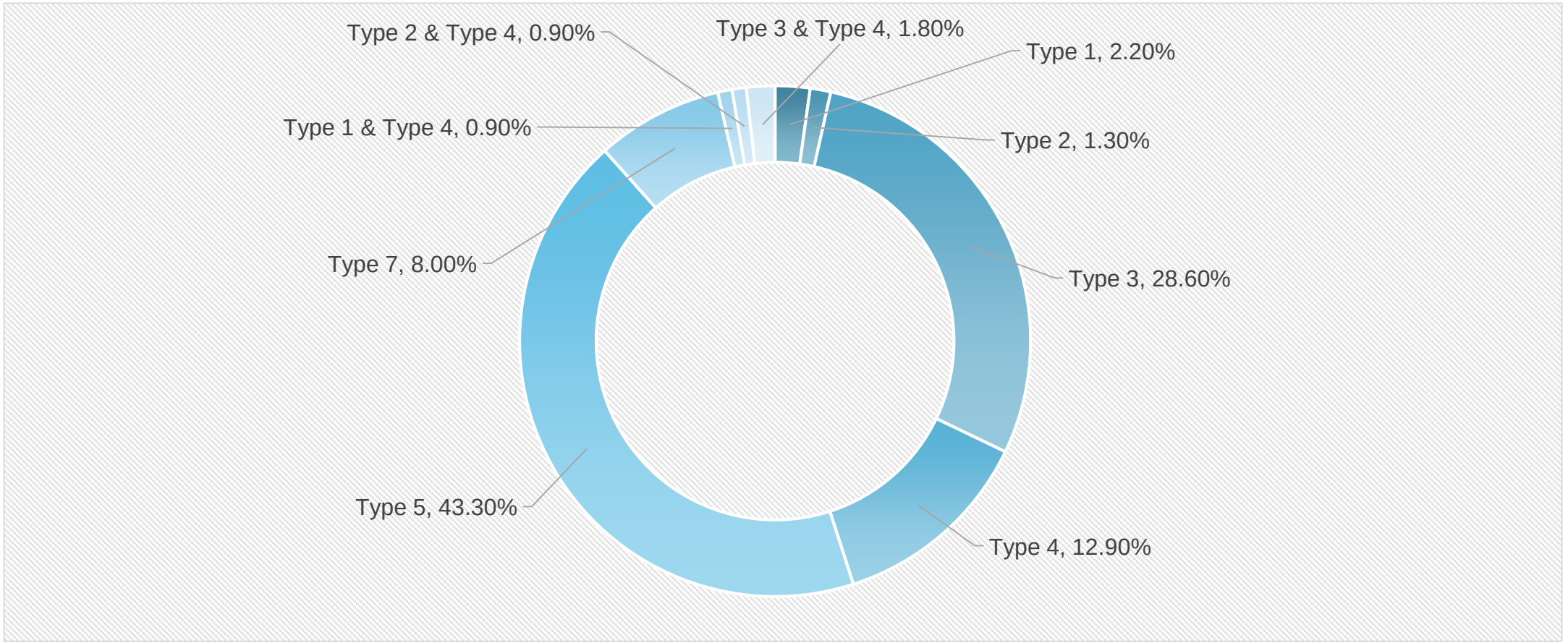
# 505(b)(2) candidates



| 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

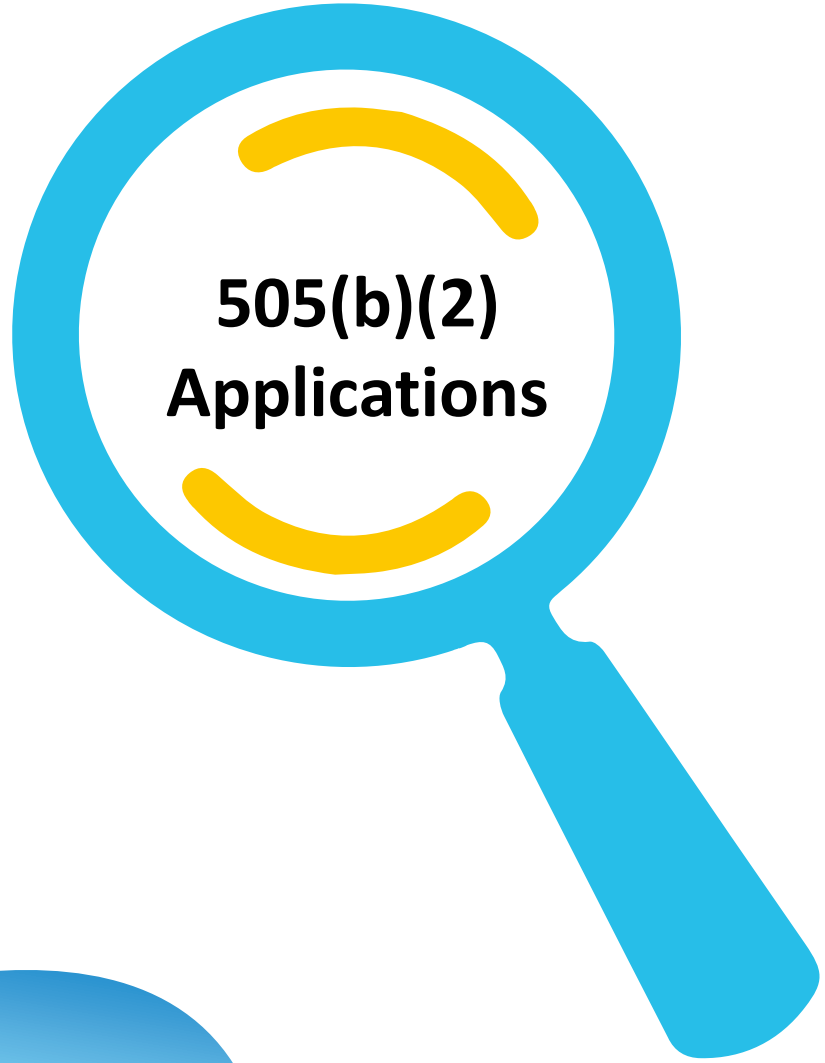
Since the 505(b)(2) pathway allows the use of public data or the FDA's previous findings in lieu of novel trial data, some **development programs** may conduct bridging studies that preclude the need for nonclinical or clinical studies, or both.

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

# Veeda CR – Expertise

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# BA / BE Expertise

**BABE studies: 3200+ including standalone Bioanalytical studies**

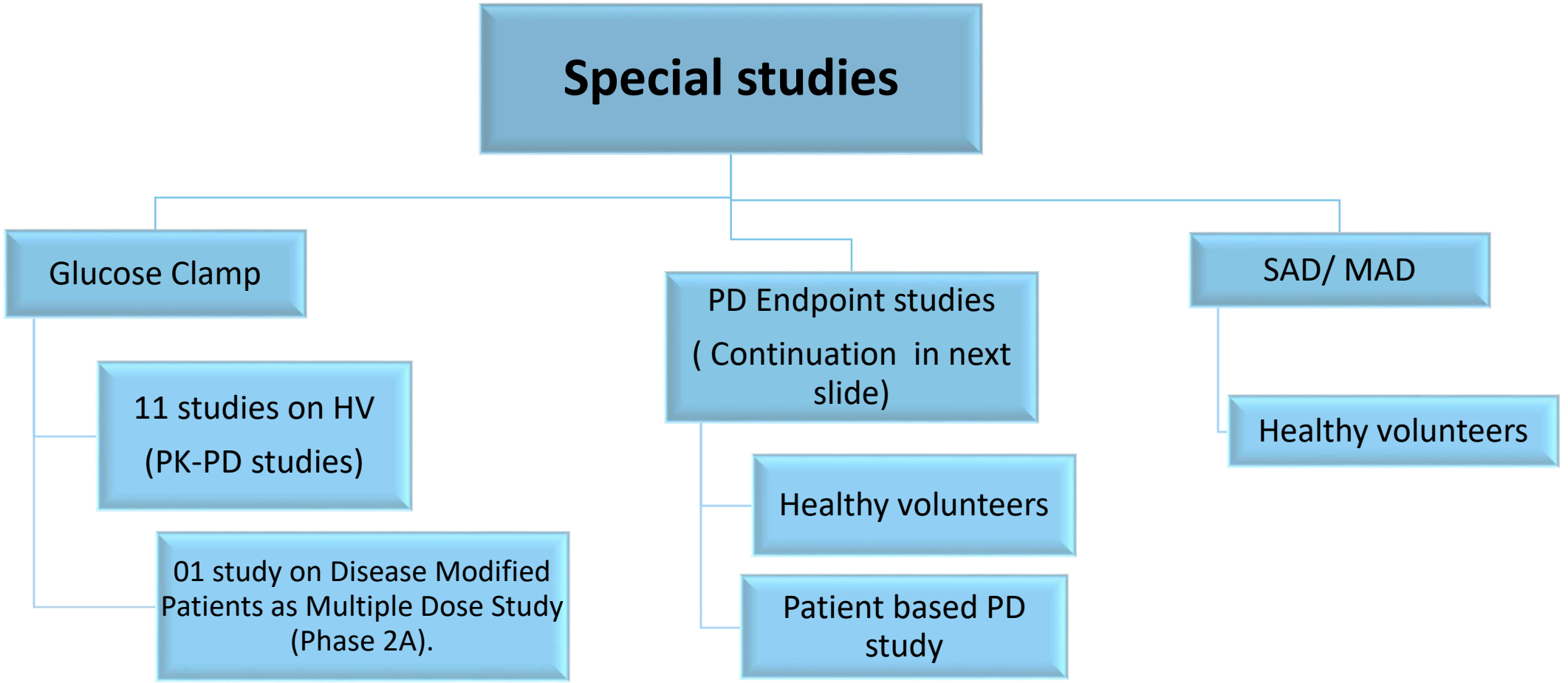
1051 pilot / 1697 pivotal

Single dose / multiple dose

- Oral Dosage forms
  - -capsules/ tablets
  - - solutions/ suspensions
  - -ODT (Orally disintegrating tablets)
  - - Sublingual
  - - ODS (OroDispersible strip)
- Rectal
  - - Capsules
  - - Suppository
- Transdermal
  - - Patch
  - -cream
- Injectable
  - - IV Infusions
  - - I.M.
  - - S.C.
  - - LAI
- Hormonal
  - - Expertise in handling > 100 female volunteers during entire course of clinical conduct.
  - - Recruited 1700 female subjects in 45 Studies
- Inhalation
  - -pMDI
  - -Dry powder
  - -Nasal Spray

# 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

# 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 |

# 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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**a healthier tomorrow**