Partners in creating a healthier tomorrow

Presentation Overview

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- Clinical Research
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Veeda Group Capabilities

Veeda Group

- Veeda Clinical Research Limited (“Veeda”) together with its subsidiary, Bioneeds India Private Limited (“Bioneeds”), and its joint venture, Ingenuity Biosciences Private Limited (“Ingenuity”), (together referred to as the “Veeda Group”) offers a comprehensive portfolio of clinical, preclinical and bio/analytical services to support innovator, biosimilar and generic drug development programs of our global clientele

- We are an independent, institutional investors owned, Board governed and professionally managed contract research group offering scientific leadership, global quality management systems and long term operational and financial stability through a continuing investment in our people, processes, systems, infrastructure and technology and a deep commitment to quality

- Together, we serve clients globally in the following industries:
  - Pharmaceutical and Biopharmaceutical
  - Agrochemical and Industrial Chemicals
  - Herbal/Nutraceuticals
  - Medical Devices

Our Global Foot Print

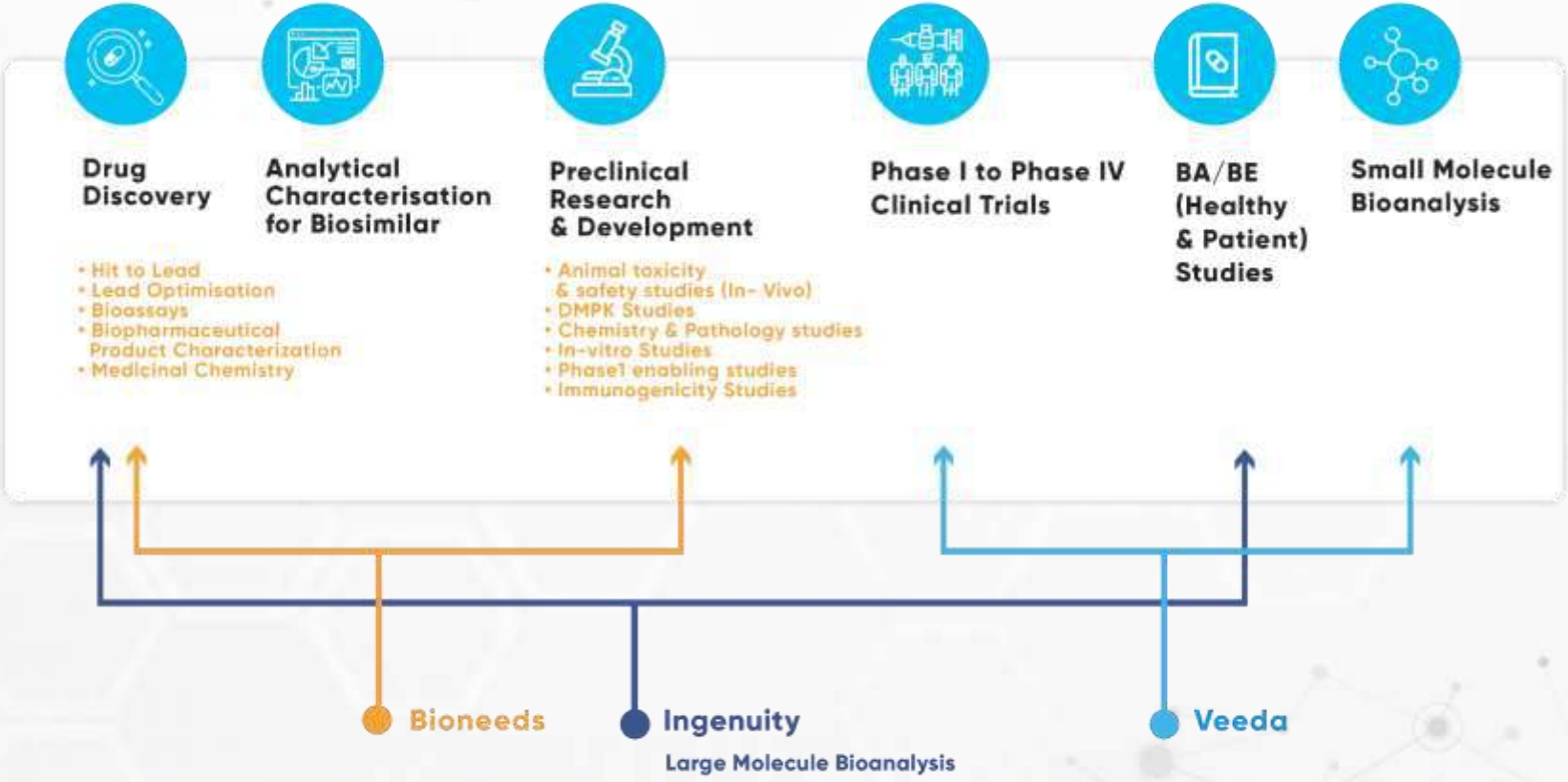
Veeda's Current Geographical Presence

Veeda's Team Presence

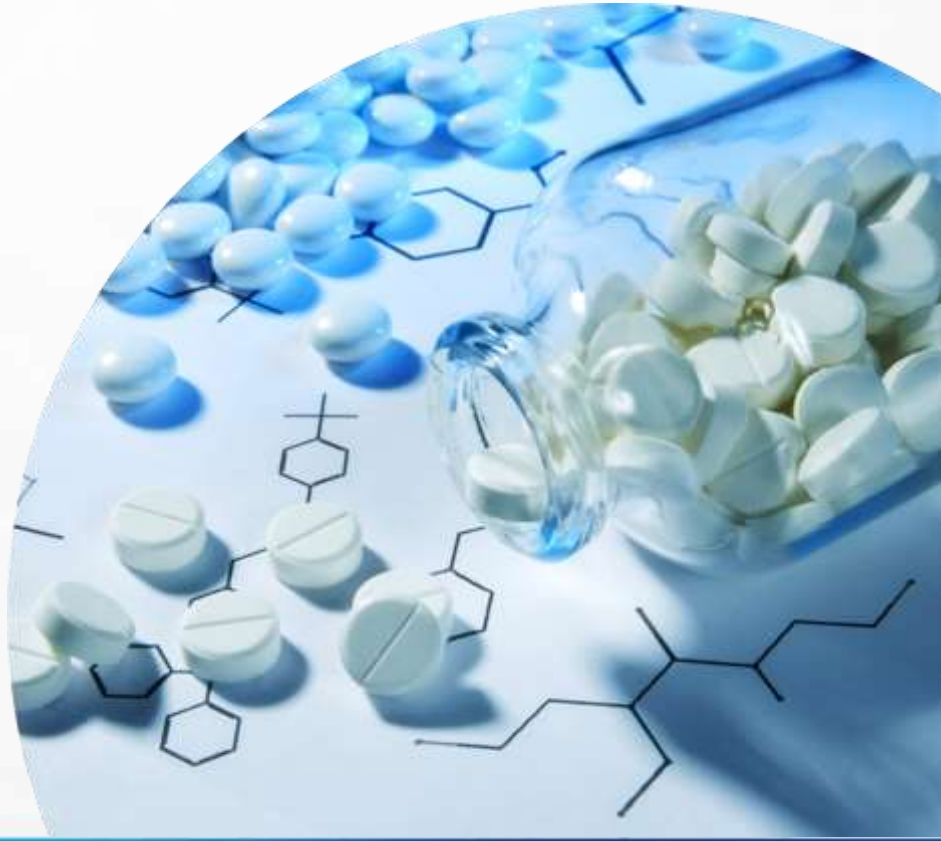
Drug Development Services Overview

Veeda's Drug Development Services

veeda clinical research | BIONEEDS | Ingenuity BioSciences



Complex Generics Overview



What are complex generics?

- The U.S. Food and Drug Administration (FDA) defines a generic drug as one that is identical – or bioequivalent – to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use.
- A simple generic is a copy of a small molecule reference drug and is chemically identical to its branded counterpart.
- A complex generic is a generic that could have a complex active ingredient, complex formulation, complex route of delivery, or complex drug device combinations.

Source: U.S. FDA

The European Medicines Agency (EMA) defines a generic drug as a medicine that is developed to be the same as a medicine that has already been authorized. It contains the same active substances and is used at the same doses to treat the same diseases as the reference drug.

EMA refers to complex generics as “hybrid medicines,” whose “authorization depends partly on the results of tests on the reference medicine and partly on new data from clinical trials.”

Source: EMA

It is challenging, time-consuming and expensive to develop complex generics and demonstrate the equivalence, safety and efficacy of the therapy.

Complex Products

- **Complex active ingredients**
  - E.g., Complex mixtures of APIs, polymeric compounds, peptides
- **Complex formulations**
  - E.g., Liposomes, suspensions, emulsions, gels
- **Complex routes of delivery**
  - E.g., Locally acting such as ophthalmic, otic, dermatological and inhalational drugs
- **Complex dosage forms**
  - E.g., Long acting injectables and implantables
- **Complex drug-device combinations**
  - E.g., Metered Dose Inhalers, nasal sprays and transdermals
  - Other products where complexity or uncertainty concerning the approval pathway or other alternative approach would benefit from early scientific engagement

Key Considerations

- **Regulatory requirements**
  - Product specific guidance (PSG) from the FDA Office of Generic Drugs (OGD), European Medicines Agency's (EMA)
  - Interactions with regulatory agencies and precedents: trial parameters, data end points
- **Study design and planning**
  - Protocol, study design, location(s), population
  - Right collaboration for clinical studies
  - Approval from local regulatory bodies
- **Compliance**
  - Quality execution
  - Cost and time

Veeda Can Support

- **Study design and planning**
  - Clinical study design, development of study protocol
  - Approval from local regulatory bodies and Ethics committee
- **Compliance**
  - Cost effective quality execution in timely manner

Veeda's Drug Development Capabilities - Generic Drugs

End-to-End BA/BE study development and execution (pilot and pivotal) towards ANDA submission for different regulatory authorities like USFDA, EMA, ANVISA, Health Canada, WHO, MHRAUK, CDSCO and many more.

Toxicity testing for special products, Impurity synthesis & LCMS characterization, Invitro microbial kill rate study, generic drug stability testing

505 (b)(2) method development and submission for branded generics, orphan drugs, prodrugs, and Drug Efficacy Study Implementation (DESI) drugs.

Diverse Therapeutic Areas Of Expertise

Cardiology

Rheumatology

Dermatology

Ophthalmology

Gynecology

Gastroenterology

ENT

Oncology

Psychiatry

Respiratory

Endocrinology

Team Experience Across various Therapeutic Areas and Indications

Sr. No.	Area	Indication	Regulatory Submissions
1	Psychiatry	Major Depressive Disorder, Schizophrenia, Bipolar disorder, Bipolar I depression	USFDA, EMA and DCGI
2	Medical Devices	CAD, Arrhythmia, Heart failure, Uncontrolled hypertensions,	USFDA & DCGI
3	Cardiology	Hypertension, Ischemic cardiomyopathy, CVD, ACS	USFDA, EMA and DCGI
4	Endocrinology	DM-I, DM-II, Diabetic nephropathy	USFDA, EMA and DCGI
5	Oncology	Advanced Ovarian Cancer, Metastatic breast cancer, Renal Cell Carcinoma, Multiple Myeloma, Colorectal Cancer, Solid Tumors / Lymphoma, NSCLC, Cervix Cancer,	USFDA, EMA, ENVISA and DCGI
6	Respiratory	Asthma, COPD	USFDA & DCGI
7	Dermatology	Atopic dermatisis, Oral lichen planus, Dermatomycoses	DCGI
8	Nephrology	CKD, Urinary tract infection and pyelonephritis	USFDA & DCGI
9	Gastroenterology	Arsenic Poisoning, GERD, Constipation, Ulcerative Colitis	USFDA & DCGI
10	Infectious diseases	Bacterial Infection, Skin Infection, Hepatitis B Infection	USFDA & DCGI
11	Ophthalmology	Chronic Open Angle Glaucoma, Ocular Hypertension	USFDA & DCGI
12	Neurology	Epilepsy, Seizures	DCGI
13	Vaccine	Rabies, Leishmaniasis & serious fungal infections	DCGI
14	Orthopaedic	Psoriasis and Rheumatoid Arthritis& Osteoporosis	USFDA & DCGI

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

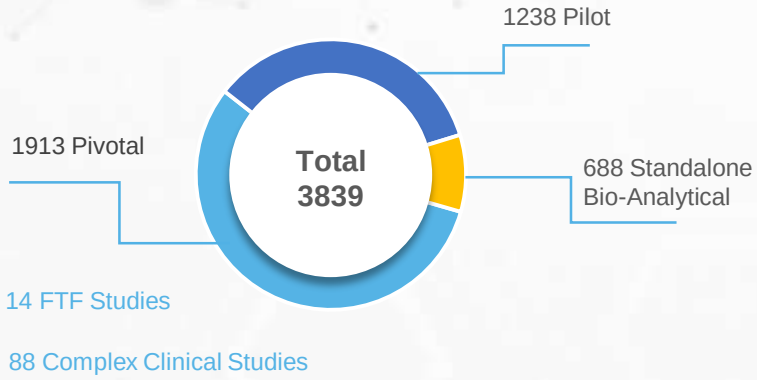
Vedant

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

Mehsana

162 Beds +
7 Special care beds

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)

Male Volunteers	–	> 56674
Female Volunteers	–	> 4677
Elderly Males	–	> 1,788
Post - Menopausal Females	–	> 1720

Routes of administration

20 Different dosage forms

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

Glucose Clamp

Veeda’s Glucose Clamp Studies Overview

Veeda’s proficiency in glucose clamp studies

- Conducted 810 Clamp studies
- Clamp experience ranging from 8 hours to 36 hours
- Capability of performing 4 to 6 clamps per day
- Risk Mitigation and Management Strategies (RMMS)
- Robust database of healthy volunteers with previous history of participation in clamp studies while adhering to mandatory compliance instructions and other study related restrictions

Veeda’s clinical facilities that support glucose clamp studies

- 12 state-of-art beds in Phase I unit with stature lifts that have back-up generators
- Well-equipped special care area to handle medical emergencies with provisions such as cardiac monitor, defibrillator, ECG machine, suction machine, oxygen cylinder, cardiac arrest kit, and anaphylaxis kit
- Resuscitation centre with resuscitation trolley and all necessary and movable emergency medications and equipment.
- In-house ambulance
- Tertiary care tie up with Sterling hospital, Gujarat, a 280 bedded multi-specialty hospital for sophisticated and advanced emergency medical care
- Fire and chemical hazard systems with standard operating procedures (SOPs) and well-maintained equipment

Veeda's Glucose Experience

Veeda have experience in 14 Glucose clamp studies

Veeda's Experience in handling Glucose Clamp Studies	
Drug synopsis	**No. of subjects**
Glucose clamp	14
Wosulin N (Novolin as reference)	18
Wosulin N (Insulatard as reference)	12
Wosulin N (two batches of Novolin as reference)	18
MK-0431 (Sitagliptin 100mg) Tablets, Glucose clamp study	12
Insulin Glargine 100IU/ml, Glucose Clamp	4
Insulin Glargine 100IU/ml, Glucose Clamp, Group 01	18
TRC150094 50mg Tablets, Glucose Clamp Study	20
Insulin Glargine (Group 02)	40
Insulin Aspart (Group 1)	71
Insulin Wosulin (Group 1)	60
WCK 9444 G01	20

Inhalation

Inhalation Overview

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 26 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

Long Acting Injectable (LAI)

LAI: experience

- Till date Veeda CR has completed **14** BA/BE studies involving Long Acting Injectables (LAIs)
- Experience in understanding the challenges, clinical development, study design, and execution of LAI antipsychotic drugs like
  - Aripiprazole depot injection
  - Olanzapine modified release injection
  - Paliperidone palmitate modified release injection
  - Risperidone modified release injection
  - Leuprolide acetate injection

Drug synopsis	No. of subejcts	No. of Periods
Methylprednisolone Acetate Injectable Suspension USP 80 mg/ mL MDV	54	2
Methylprednisolone Acetate Injectable Suspension USP 80 mg/ mL MDV	24	2
Methylprednisolone Acetate Injectable Suspension USP 80 mg/ mL SDV	24	2
Methylprednisolone Acetate Injectable Suspension, USP 80 mg/ml, Fasting conditions	180	1
Octreotide acetate injectable suspension 30 mg Fasting	48	1
Octreotide Acetate Injectable Suspension 30 mg	32	1
MPA 80 mg/ml Injection, Fasting conditions	120	3
Fulvestrant intramuscular (IM) Injection 250 mg/5 mL, Fasting conditions	12	1
Fulvestrant intramuscular (IM) Injection 250 mg/5 mL, Fasting conditions	48	1
Fulvestrant IM Injection 50 mg/mL , fasting condition	48	1
Fulvestrant Inj. Fasting	214	1
Naltrexone ER Injectable Suspension, 380 mg-Fasting	300	1
Paliperidone Palmitate Prolonged-Release Injectable Suspension for injection 25 mg, G-01	290	1
Pegfilgrastim (6 mg/0.6 mL) in Single-dose prefilled syringe G-01_Part-01	426	3

505 B2 Studies

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

505(b)(2) Veeda experience

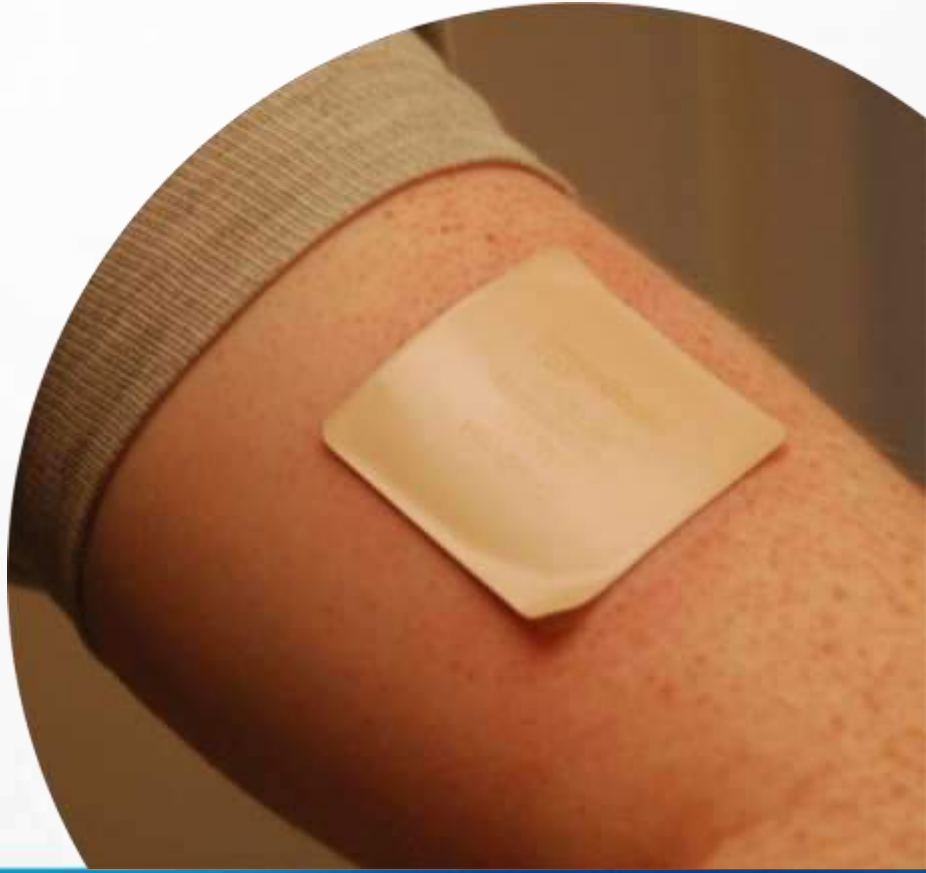
Veeda CR has been a partner in supporting 505(b)(2) applications with ~45 studies experience with various clients.

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

Patch Studies



Transdermal Patches

Veeda has experience in conducting Transdermal patch studies Bioequivalence (BE) with pharmacokinetic (PK) endpoints and adhesion study, Skin irritation and sensitization study (Proof of Procedure). We have successfully completed **11** Transdermal Patch Clinical Studies (4 Pivotal study, 1 Pilot study, and 6 PK endpoint and Adhesion trials).

Drug synopsis	No. of subejcts	Formulation
Iodex (Tingle) topical products containing counterirritants	80	Topical Cream
Doxepin 5% Topical Cream	48	Topical Cream
Ivermectin Cream 1 %	80	cream
Estradiol Transdermal System USP, 0.1 mg/day (group 01) Fasting	64	Transdermal system
Rotigotine ER Transdermal Sysytem Fasting	24	Transdermal system
Methylphenidate ER Transdermal System Fasting	18	Transdermal system
Estradiol 0.1 mg/day Transdermal System USP, Fasting conditions	64	Transdermal system
Ethinyl estradiol and Norelgestromin Transdermal System Fasting	36	Transdermal system
Rivastigmine 9.5 mg/24 hours Transdermal System, Fasting conditions	60	Transdermal system
Ethinyl estradiol and Norelgestromin Transdermal System, 0.035/0.15 mg per 24hr fasting	66	Transdermal system
Rivastigmine Transdermal System, 9.5 mg/24 hours	12	Transdermal system
Scopolamine Transdermal System, 1mg/72 hours	36	Transdermal system

Suppository Studies

Rectal Suppository

Veeda has an experience of successfully completing 6 studies (2 Pilot & 4 Pivotal)

Drug synopsis	Sample size (Subjects recruited)	No. of subjects completed/evaluable
Artesunate Rectal Capsules 100mg, Fasting conditions	120	98
Mesalamine 1 gm Rectal Suppository, Fasting conditions	36	32
Mesalamine 1 gm Rectal Suppository, Fasting conditions	86	72
Artesunate Rectal Capsules 100mg - Fasting	72	69
Budesonide rectal foam 2mg/actuation	18	18
Diazepam Rectal Gel 10 mg delivery system (5 mg / mL)	28	28

Phase 1

Phase 1

Total Phase I Studies: 23

Completed: 17

Ongoing: 1

Planned: 5

- Total 30 bedded Phase-I capacity, spread across two units.
- Well developed **12 bedded Phase 1 unit** to support Phase 1 studies.
- Additional **18 bedded Phase 1 unit**; operational since February 2021**.**
- Team of scientists having **in-depth knowledge and experience** of handling Phase 1 studies.

Type of Studies	No. of Studies
First-in-Human (FIH)	3
SAD Studies	1
MAD Studies	5
Phase 1 Vaccine Study	1
Drug Interaction Studies	2
Glucose Clamp Studies	1
Food Effect Studies	3
Proof-of-Concept Study	1

Phase 1 Experience

Drug synopsis	No. of subejcts	No. of Periods
Valsartan 320mg gastroretentive (GR) extended release (XL) tablets	6	Three
Paracetamol 1000mg	16 (M) +12 (F)	Four
IPV-Open Label Phase 1 Clinical Study for Evaluation of Safety and Immunogenicity of Sabin based Inactivated Polio Vaccine in Healthy Adult Human Male Subjects	12+12	Three
MK-0822 25mg tablets-An Open-Label, 2-Period, Fixed-Sequence Study to Assess the Effects of Multiple Oral Doses of Diltiazem, a Moderate CYP3A4 Inhibitor, on the Single-Dose Pharmacokinetics of MK-0822 in Healthy Volunteers	12	Two
TRC4186-An Open-label, Food and Formulation Effect, Single-dose Study (Part A) and a Double-blind, Placebo-controlled, Randomised, Multiple-dose, Dose-ascending Study (Part B) to Evaluate the Safety, Tolerability and Pharmacokinetics of TRC4186 Administered Orally in Healthy Male Subjects	15	Three
TRC4186	9	NA
DRL-16536-A randomized, double-blind, placebo controlled, parallel group, multiple dose study to evaluate the safety, tolerability and pharmacokinetics of DRL-16536 following oral once daily dose administration, in healthy, adult, male, human volunteers	12	-
TRC4186 -MAD Gp 03	9	Single
Erythropoitin 0.5/1.5mcg/kg-GP01-A Randomised, Double-Blind, Placebo-Controlled, Single Dose Study to Assess Safety, Pharmacokinetics and Pharmacodynamics of Polysialylated Erythropoietin Administered Subcutaneously to Healthy, Adult, Male Subjects	16	Single
E3410548	30	Five in one
Valsartan 160mg Fasting conditions	39	Two
MK-0859 (Treatment A)-A Study to Evaluate the Effect of Multiple Oral Doses of Diltiazem on Single-Dose Pharmacokinetics of MK-0859 in Healthy Volunteers	10	Two

Phase 1 Experience

Drug synopsis	No. of subejcts	No. of Periods
SPA 100 (aliskerin/amlodipine 300/10 mg tablets, Fasting/fed condition	36	Two
Aliskiren (SPP100)/ amlodipine/ hydrochlorothiazide 300/10/25 mg tablet	36	Two
SPP100 (aliskiren) 300 mg Tablets, Fasting and Fed conditions	8	NA
AZD+D28:N281656 Oral solution-A Randomized, Single-Blind, Placebo-Controlled, Phase I Study to Assess the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics after Multiple Oral Doses of AZD1656 in Subjects with T2DM Treated with Metformin	6	NA
0.8 mg recombinant salmon calcitonin/200 mg 5-CNAC + Paracetamon 1 G + Ibuprifen 600 mg	28	Four
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
P3914 Tablets, SAD study, G01, Part A-Randomized, Double-blind, Placebo-controlled Phase I-Ib Study of P3914 to Evaluate the Safety, Tolerability, Food effect & Pharmacokinetics in Healthy Male Subjects and Efficacy & Safety of P3914 in Patients With Acute Dental Pain	6	One
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
GRANULOCYTE COLONY STIMULATING FACTOR (Gr 01)	6	2
Sun_Phase 1 AS012 , Cohort 2A, MAD, 100 mg, Set-03	3	3
AXA1665	16	4+2

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 1040

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.

Complex Methods Experience

- **Iron Sucrose**: For Transferrin bound iron the serum samples are filtered through SPE cartridges to remove free and formulation bound iron while the filtrate contains TBI which is further analyzed by ICP OES.
- **Peptides (small molecules) by LCMSMS:** sensitivity and extraction issues
  - Desmopressin
  - Leuprolide
  - Octreotide
- **Biomarker analysis - α1 Acid Glycoprotein – AAG:** Method HPLC-UV, large molecule (biomarker) validated method for clinical support.

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 of G-CSF, Insulin Aspart, C – Peptide and PTH
- Immunogenicity validation study sample analysis was done for Denosumab, Teriparatide and Romiplostim
- Developed these large molecules using validated methods study samples were analysed as below:

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%

Large Molecules: Bioanalytical Experience

- Completed Enoxaparin PD end point and Immunogenicity studies (03 studies for US FDA, 01 study each for EU and ANVISA)
- Pharmacodynamic endpoint-Anti-Xa detection and Anti- 1la detection using Chromogenic method
- Immunogenicity-Anti heparin PF4 screening assay & Total Ig GAM screening assay using ELISA technique
- TFPI detection using ELISA technique, Linearity range: 0.050 IU/mLto 0.200 IU/mL
- Heparin Clotting assay Coagulation method, Linearity range: 0.100 IU/mL to 1.00 IU/mL
- IgG, IgA&IgM Screening assay using ELISA technique
- Total no of sample Analyzed PK-14784, PD-3866 & Immunogenicity - 3783 samples

Large Molecules by LC/MS/MS:

Human Insulin: Insulin Glargine Method Under development by LCMSMS, approach is to have intact molecule analyzed in MS (SH-8060] [As Multiple molecule MRM).

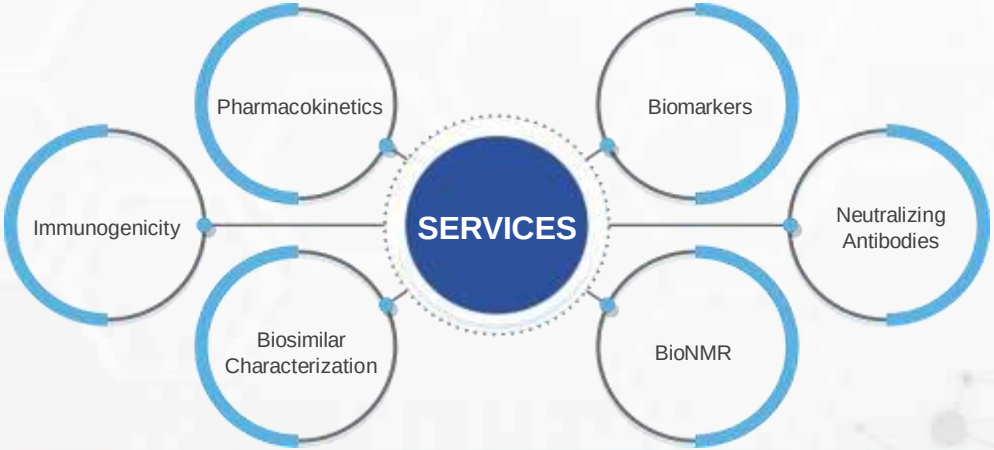
- Proposed Linearity Range - 50 pg/mL-10000 pg/mL/
- The other analogs of insulin (Glargine, aspart are also planned to develop).
- The other Insulin analogues like Insulin Aspart is also in the pipeline.
- Insulin Aspart- validated method available for Insulin Aspart. Linearity range- 100 to 5000 pg/mL.
- Other Methods – planned, under validation- Insulin glargine + Metabolites (M1 and M2)

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



Recognitions

Recognitions

Celebrating
17 YEARS
of excellence in
Clinical Research

2004

2017

Organization	Award Category
Praxis Media	National Excellence Award
AI	Best Pharmaceutical CRO
Health & Safety Awards	Best Clinical Research- India
	Best Clinical Research- India
	Mark of Excellence
FROST & SULLIVAN	Indian Clinical Research company of the year

2018

Organization	Award Category
ASSOCHAM	Best Clinical Research Organization - India
Wellness	Clinical Trial Company of the Year
	Bharat Udhyog Ratan Award in Clinical Research

2019

Organization	Award Category
	Best Quality Clinical Research Organization in India
	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 Group Advantage

Extensive Scientific Competence to service a Diverse client base

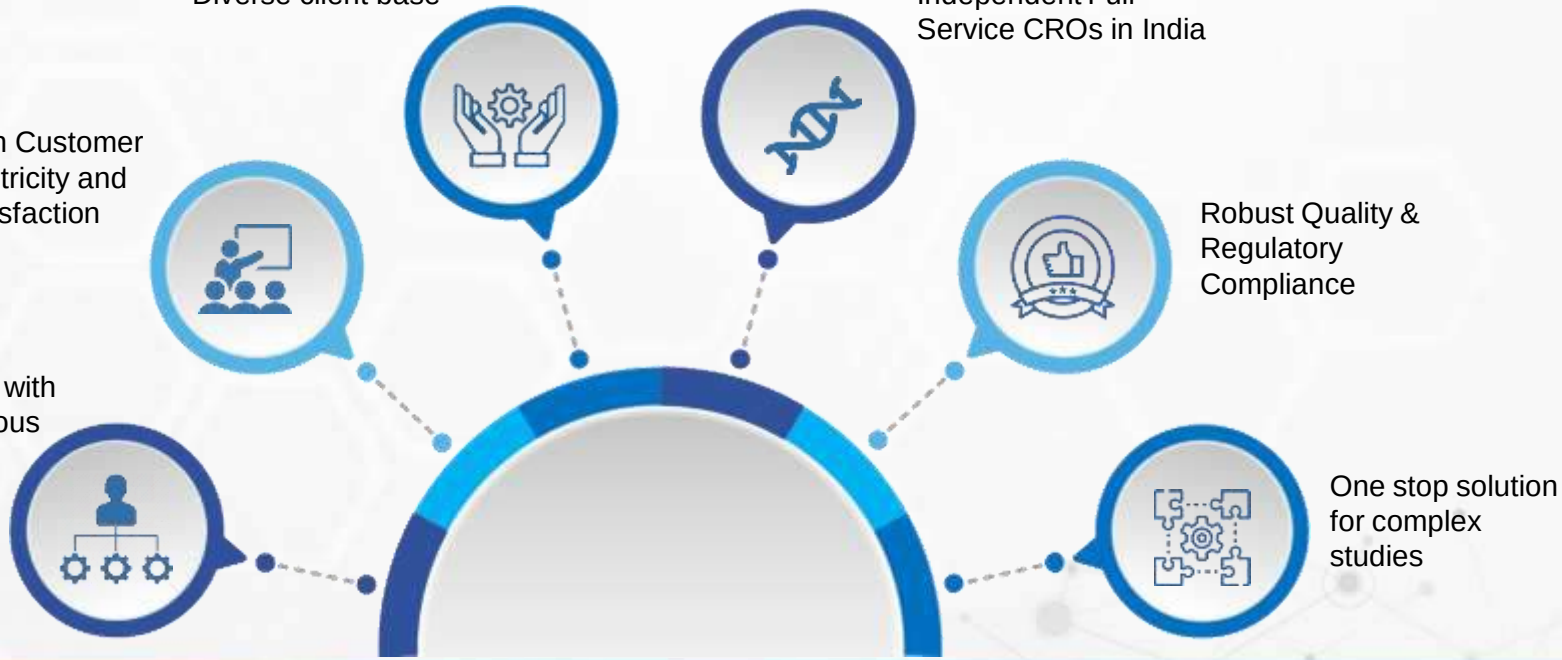
One of the largest Independent Full Service CROs in India

High Customer Centricity and Satisfaction

Robust Quality & Regulatory Compliance

Skilled personnel with focus on Continuous Professional Development

One stop solution for complex studies



Thank you

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

Partners in creating

a healthier tomorrow