Veeda Clinical Research

is a full service, independent CRO with expertise in PK and PD studies in healthy volunteers and patient trials in generic molecules, NCEs and Biopharmaceuticals, to support our clients with their clinical programs. Veeda Clinical Research offers a fully integrated package to meet your clinical development needs.

Over the years, we have developed a robust and compliant quality system with more than 380+ SOPs and our IT systems are 21 CFR Part 11 compliant.

REGULATORY

Agency	Number of Inspections	Last Inspection
India – CDSCO	12	2018
USFDA – Patient	16	2018
USFDA – Healthy	13	2017
EU	2	2012
UK – MHRA	3	2016
WHO	5	2018
Brazil – ANVISA	5	2015
NPRA – Malasiya	2	2018

INFRASTRUCTURE

Bed Capacity	340 beds & 12 monitored beds
Machines	46 LC-MS/MS, 2 ICP-OES, 1 Microplate reader
Team	750+
SOPs	380+
Volunteer Database	42500+ (Including males , females, elderly population and PMW)
Analytical Methods	750+

BIOANALYTICAL

- Sample Analysis Capacity : 100,000 samples/month
- Lowest concentration achieved : 0.2 pg/ml
- Elemental Bioanalysis using ICP-OES
- Watson LIMS for all Method Validation and Studies

BA/BE EXPERIENCE

Conducted 2630+ BA/BE studies

Experience of handling 30 FTF / time-sensitive studies

Performed studies for injectables, rectal suppositories, Urine PK studies, Oral DDS, local applications, etc.

Largest healthy volunteer study : 120 in single group and 300 in multiple groups

Longest duration healthy Volunteer study : 8 months in multiple visit & 27 days in single stay

All Medical staff trained on ACLS. All paramedics and clinical support staff trained on BLS.

Special Population Studies :

- 12 Female volunteer studies
- 16 Post menopausal studies
- 25 elderly population studies

ISR DATA

- ISR methodology adopted for >600 no's of Pivotal Studies till date from July 2008
- 10% of total samples analyzed per study
- 95% pass rate for ISR in 2016-2017

CLINICAL EXPERIENCE

Inhalation Studies

- Recruited 460 subjects in 4 PK &1 PD trial
- Benefits of dosing in a Negative Pressure Room
  - Uniform environment with consistent temperature, humidity, air flow & oxygen content
  - Eliminates cross contamination
  - Better regulatory acceptance

Patch Studies

- Performed 6 PK End Point & Adhesion trials on 278 subjects

Glucose Clamp Studies

- Performed 11 studies with 750 clamps of different duration on 296 subjects with Euglycemic & Hyperglycemic conditions

PATIENT TRIALS

Experience

Completed Projects

- 4 Global Phase II clinical trials in Oncology
- 21 patient PK & 2 Phase III

Ongoing Projects

10 Ongoing projects in different stages of execution

02 Ongoing phase II studies

Team Size : 34 personnel

Combined team experience: 130+ clinical trials experience that include

- Around 25 Global clinical trials
- Around 30 clinical End Point trials
- 75 patient PK clinical trials

Investigator Database (India)

- Oncology : >117
- Psychiatry : 37
- Ophthalmology : 81
- Dermatology : 75
- ENT : 35
- Gastroenterology : 32
- Cardiology : 20
- Orthopedics and Rheumatology : 63
- Pulmonology : 38
- Endocrinology : 28
- General Medicine : >67
- Urology : 25
- Hematology : 15

- Experience with rare indications such as Small Cell Lung Cancer, Renal Cell Carcinoma
- Experience in handling complex products such as liposomal products implants and biologics
- Experience of working with more than 100 sites across India for various indications

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