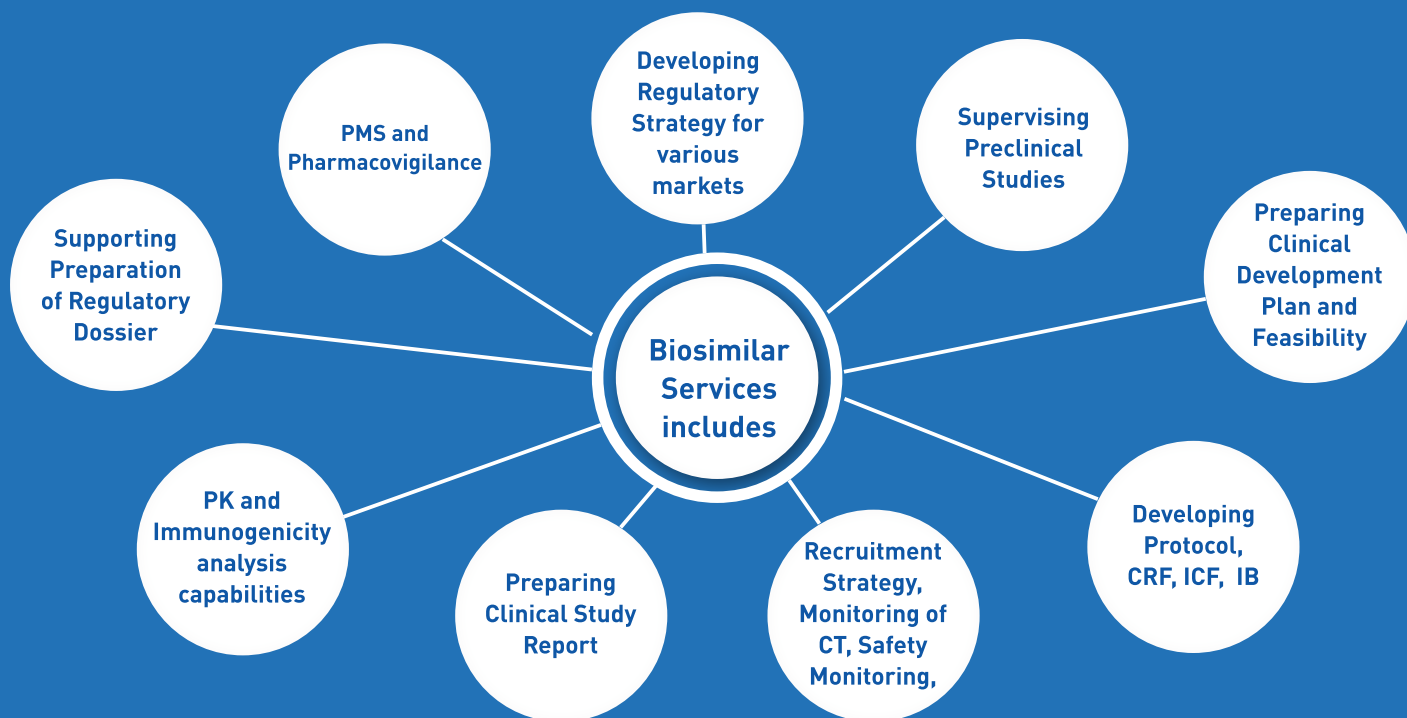




- ▶ Veeda CR is a leading Indian CRO for Glucose Clamp Studies.
- ▶ Performed 810 clamps.
- ▶ State of Art 12 beds phase I unit with advanced equipments & trained staff.

## VEEDA'S STRENGTH IN GLUCOSE CLAMP STUDY

- |   |  |
|---|--|
| <p><b>01</b> Good number in healthy volunteer data base who have previously participated in clamp studies and are used to compliance and restrictions to be required.</p> | <p><b>02</b> Automated (computer algorithm-directed) glucose infusion rate adjustment program, for the manual glucose infusion rate adjustments.</p> |
| <p><b>03</b> Heated Hand Boxes/Blanket: Provides a realistic alternative which minimizes the difficulties inherent in venous sampling.</p>                                | <p><b>04</b> Automated glucose infusion pump, for controlled infusion of 20% glucose.</p>  |
| <p><b>05</b> Automated syringe driver for controlled insulin or isotope (glucose or glycerol) infusion.</p>   | <p><b>06</b> Alternative approaches to blood glucose measurement to minimise blood sampling quantity without losing precision and control.</p>       |
| <p><b>07</b> DASH 4000 cardiac safety monitor for continuous safety monitoring of volunteers.</p>   | <p><b>08</b> Experience of Clamp ranging from 8 hrs to 36 hrs duration and have capabilities to do 4-6 clamps per day.</p>                           |



- Veeda offers a full range of consulting, regulatory, laboratory and clinical development services to support biosimilar product development.
- Our team of Clinical Research professional, Physicians, Medical Writers, Safety Experts with extensive experience of working in more than 20 biosimilar molecules for Indian and Global Registration.
- Completed Projects
  - Comparative PK and PD study on GCSF, Erythropoietin, Streptokinase.
  - Glucose Clamp studies on Insulin Aspart and Insulin Glargine.
  - Pharmacodynamic & Immunogenicity analysis for Enoxaparin.
- Feasibilities and ongoing discussion
  - Interferon Beta, PTH, Ranibizumab, Bevacizumab, Trastuzumab, Cetuximab and Adalimumab.

## BIOSIMILAR ANALYTICAL – EXPERIENCES / CAPABILITIES

- 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-IIa 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/mL to 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.

## RECENT EXPERIENCE OF LARGE MOLECULES BY LIGAND BINDING ASSAY:

Sr. No.	Analyte	No. of Samples Analyzed	No. of Samples Analyzed for ISR	% of ISR Samples within Acceptance
1	G-CSF	2142	158	98.7%
2	Insulin Aspart	2139	158	94.9%
3	C- Peptide	2400	176	98.2%