Comparative evaluation of Pharmacokinetic & Pharmacodynamic properties to assess

Insulin Action for Management of Diabetes

Type of Study

A double-blind, randomized, single-center, two treatments, four period, two sequence, replicate crossover, euglycemic clamp study to demonstrate equivalence in the pharmacokinetic and pharmacodynamics properties of Insulin Glargine injection 100 IU/mL in healthy, adult, human subjects under fasting condition

Situational Analysis

An Indian biopharmaceutical company was planning the marketing approval in India for its Insulin Glargine injection 100 IU/ml

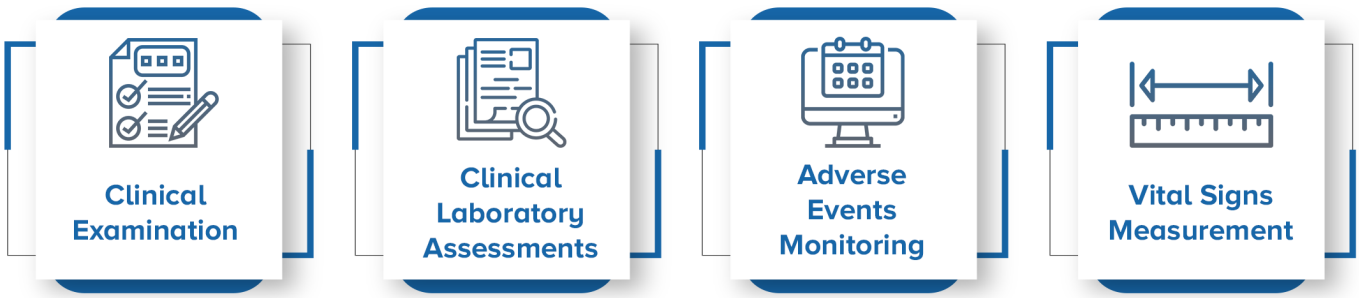
Veeda supported the client in the following services

- Study Design & Execution
- Identification & Selection of Investigator
- Medical Writing & Lab Logistics
- Ethics Committee Submission
- Investigational Medicinal Product Management
- Project Management, Subject Recruitment and Retention
- Data Management & Biostatistics

Highlights of Results Delivered

- Completed the study in less than 05 months
- 48 subjects were randomized
- Achievement of all study objectives
- Zero SAEs

Safety / tolerability parameters assessed throughout the study included



Challenges	Actions
While enrolling the subjects, Veeda needed to ensure that subjects do not take any food orally except water during the clamp duration of each period	Subjects were given complete study instructions for fasting throughout the study, and only water intake was allowed to subjects whenever required
There was a need for YSI machine and infusion pump training for all clinical staff, which was a time-consuming process	Our investigators were well trained to handle the Glucose Infusion Rate considering the subjects' safety and to keep GIR at around stage 1 of algorithm defined in protocol and clinical personnel was assigned to handle the YSI machine and the infusion pump
Training was needed for the operation of an infusion pump for glucose infusion rate during the study	Subjects were informed that one arm would be used for blood collection and the other would be used for continuous glucose infusion via an infusion pump Veeda ensured the allocation of a specialized team for handling any adverse situation during the course of the study
Study-specific testing and screening was required, i.e. the Oral Glucose Tolerance Test, which was time-consuming and required skilled staff	Veeda's trained staff was allocated for screening tests, i.e., the Oral Glucose Tolerance Test and proper counselling was done by well-experienced staff to ensure compliance with study requirements

Results

- Regulatory document preparation and submissions were achieved within the stipulated time
- Volunteer recruitment went well according to plan, and there was high volunteer retention with low dropout
- The PM, Investigator, PC, Nurse, Pharmacist, QC, and QA team worked nonstop to ensure that quality results were delivered on time
- 43 Volunteers completed the study as per protocol

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