



Endocrine and Metabolic Clinical Trials

A specialty CRO developing drugs for diabetes and obesity

According to FDA guidance, the development of a new investigational product to treat type 2 diabetes can be undertaken in subjects who are drug-naïve and whose diabetes is reasonably well controlled with diet and exercise. These subjects can participate in placebo- and dose-controlled studies for up to 24 weeks, provided that they continue to remain in reasonable metabolic control for the duration of the studies. However, before this, the pharmacokinetics of investigational drugs in development for diabetes and obesity must be evaluated in phase 1 studies. Safety, food effects, and cardiac effects must be assessed in early phase trials. These types of studies require the use of an organization that provides expertise in metabolic disorders, expansive capabilities, and access to appropriate patient populations.

Phase I Units

Our phase 1 units in New York and New Jersey offer 100 beds to support studies of investigational drugs being developed to treat diabetes and obesity, including trials that require normal healthy volunteers and patient populations. Our team of endocrinologists and diabetologists provides experienced and appropriate staffing for all types of metabolic studies, and our database of more than 80,000 study candidates includes subjects with type II diabetes, obesity, and sleep apnea. Our staff is experienced in a broad range of metabolic assessments, such as hemoglobin A1c, glucose tolerance, indirect calorimetry, and doubly labeled water. Measures of energy expenditure are among our core competencies.

Global CRO Services

Clinilabs maintains in-house capabilities to support domestic multicenter Phase I and Phase II trials. When asked to provide full-service CRO capabilities for large, global, multicenter studies that exceed our capacity, we are able to work with trusted partners to deliver an integrated, therapeutically focused CRO team. This team is unparalleled in its understanding of the challenges associated with the development of new drugs for type 2 diabetes and obesity. Our therapeutically focused team is supported by integrated services that manage regulatory, study startup, patient recruitment, data management, statistics, and medical writing.

Therapeutic Areas

- Type II diabetes
- Obesity
- Sleep apnea

Specialty Procedures

- Hemoglobin A1c
- Indirect calorimetry
- Doubly-labeled water
- Glucose tolerance