

## SYNOPSIS

- Study Phase: Phase IIb
- Target sample size: 120 participants
- Study duration: 12 months
- Number of clinic visits: 8

## OBJECTIVES

Primary: Evaluate efficacy of Drug X versus placebo.

## METHODS

Approximately 100 subjects will be randomized (in a 1:1 ratio) to receive Drug X or placebo.

The study will last 14 months in total.

The schedule of assessments outlines 10 on-site visits.

## INCLUSION CRITERIA

1. Adults aged 18–65
2. Diagnosis of Condition Y

## EXCLUSION CRITERIA

1. Pregnant or breastfeeding
2. Severe renal impairment