

PROTOCOL TITLE: A Phase 3 Study of Drug X in Oncology.

SPONSOR: Leevin Pharma.

1. OBJECTIVES

To evaluate the safety and efficacy of Drug X.

2. STUDY DESIGN

This is a randomized, double-blind study.

3. VISIT SCHEDULE

- Screening (Day -28 to -1): Informed Consent, Demographics, HIV Test.
- Baseline (Day 1): Randomization, Dosing, PK Blood Draw.
- Visit 1 (Week 4): Vitals, Safety Labs.
- Visit 2 (Week 8): Vitals, Safety Labs, Tumor Assessment.

4. INCLUSION CRITERIA

1. Age \geq 18 years.
2. Histologically confirmed solid tumor.

5. EXCLUSION CRITERIA

1. Pregnancy.
2. Active infection.