Study Overview

Study Question

The primary objective of this mock study is to evaluate the **safety and tolerability of Drug ABC compared to placebo**, with a focus on the incidence, timing, and severity of treatment-emergent adverse events over an 8-week treatment period.

A secondary objective is to descriptively assess **changes in selected laboratory parameters** during treatment and their temporal relationship to treatment initiation.

This study is intended solely for educational and portfolio-building purposes.

Study Design

This is a **simulated Phase II, randomized, placebo-controlled clinical study** conducted in adult subjects.

- Subjects were randomized to receive either **Drug ABC** or **placebo**
- The planned treatment duration was **8 weeks**
- Safety data collected included:
    - Adverse events
    - Clinical laboratory assessments

- All data were **simulated** to resemble typical clinical research data collection and do not represent real patients

The study was designed to intentionally include common data challenges encountered in real clinical trials, such as missing data, ongoing adverse events, and inconsistent raw data formats.

Data Description

Raw data were created to simulate **CRF-style clinical data exports** and serve as the source for SDTM dataset creation.

The following raw datasets are included:

- **Demographics (raw_dm.csv)**
  Contains subject-level information, including age, sex, treatment assignment, consent date, and treatment start and end dates.

- **Adverse Events (raw_ae.csv)**
  Contains event-level safety data, including event descriptions, start and end dates, severity, relationship to study drug, seriousness, and actions taken.
- **Laboratory Assessments (raw_lb.csv)**
  Contains longitudinal laboratory measurements collected at baseline and follow-up visits, including test names, results, units, collection dates, and visit identifiers.

Raw datasets were intentionally designed to be **non-standardized, inconsistent, and incomplete** in order to reflect real-world data collection and to require explicit derivation logic, assumptions, and documentation during SDTM mapping.

Purpose of This Repository

This repository demonstrates an **end-to-end raw-to-SDTM workflow**, including:

- SDTM domain creation (DM, AE, LB, RELREC)
- Timing and study day derivations
- Visit assignment logic
- Self-QC and issue resolution
- Study-level documentation (SDRG, mapping specifications, QC notes)

The goal is to demonstrate **reasoning, traceability, and documentation**, rather than to produce submission-ready datasets.