# Statistical Analysis Plan (SAP)

Study Title: Mock Phase I Trial on Antihypertensive Drug

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Version: 1.0

Date: April 2025

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## 1. Study Overview

This is a single-arm, open-label Phase I study involving 30 healthy adult subjects. The objective is to evaluate the safety and tolerability of a new antihypertensive drug over a 4-week treatment period.

## 2. Analysis Populations

- Safety Population: All subjects who received at least one dose of the study drug.  
- Full Analysis Set (FAS): All enrolled subjects with post-baseline data.

## 3. Endpoints

- Primary Endpoint: Incidence and frequency of adverse events by Preferred term..  
- Secondary Endpoints: Change in systolic and diastolic blood pressure from baseline to Week 4.

## 4. Statistical Methods

Descriptive statistics will be used to summarize demographic and baseline characteristics.  
  
- AE : Frequency and percentage of subjects experiencing AE by Preferred term will be presented.  
- BP Change:Post baseline measurement .  
- Lab Parameters: Summary statistics (mean, SD, min, max, median) will be calculated.

## 5. Handling Missing Data

No imputation will be done for missing data. The number and percentage of missing values will be reported for each variable and time point.

## 6. ADaM Datasets Used

- ADSL: Subject-level analysis dataset  
- ADAE: Adverse events dataset  
- ADVS: Vital signs dataset  
- ADLB: Laboratory test results dataset

## 7. TLFs Planned

Tables:  
- Table 1: Adverse Events summary by Preferred term.

- Table 2: Descriptive statistics for Single numeric variable.   
  
Listings:  
- Listing 1: Imputation of Subject level Population flags .  
  
Figures:  
- Figure 1: Mean BP Over Time (using SGPLOT or ggplot2)

## 8. Software

All statistical analyses will be performed using SAS Studio or R 4.2.1.

## 9. Appendix

Sample output shells, mock table formats, CRF annotations, and derivation logic for key variables will be included in the appendix (not shown in this mock version).

Note: This SAP was independently developed as part of a self-driven project to simulate real-world clinical programming and statistical planning aligned with CDISC standards.