Clinical Trial Summary Report: VIRALBLOCK01

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1. Introduction

This document summarizes the statistical analyses performed for the simulated randomized clinical trial VIRALBLOCK01, evaluating the efficacy and safety of the antiviral drug **Viralblock** versus placebo in patients with a viral syndrome. Analyses were conducted in accordance with the Statistical Analysis Plan (SAP) and are supported by results reported in the mock shell.

2. Objectives

- **Primary Objective:** Evaluate recovery at Day 28.
- **Secondary Objectives:** Analyze oxygen saturation trends, adverse event (AE) profile, time-to-event outcomes, and exploratory multivariate patterns.

3. Key Statistical Analyses and Results

3.1 Baseline Demographics

Baseline demographics such as age, sex, race, and baseline SpO_2 were comparable between treatment groups (see Table 1 in mock). Mean age was similar across arms. The sex distribution was balanced. Baseline oxygen saturation showed no relevant differences.

3.2 Recovery Outcome (Logistic Regression)

A binary logistic regression model showed that patients in the Viralblock group had significantly higher odds of recovery compared to placebo:

- **Odds Ratio for Treatment:** 2.59 (95% CI: 1.44–4.67), $p = 0.0015$
- Age and sex were not significant predictors.

Full regression details are in Table 2.

3.3 Adverse Events (Categorical Analyses)

- No significant differences in the presence or severity of AEs between groups.
- Multinomial logistic regression for recovery status (RECOVERED, RECOVERING, NOT RECOVERED) showed no significant associations with treatment, age, or sex.

(Refer to Tables 3–4 and associated figures in mock.)

3.4 Longitudinal Analysis (SpO_2)

- **RM-ANOVA:** Significant effects for time and treatment–time interaction (all $p < 0.0001$).
- **LMM:** All fixed effects (treatment, time, interaction) were highly significant.

These results suggest that SpO_2 levels evolved differently between treatment arms. See Figures for RM-ANOVA and LMM.

3.5 Time-to-Event (SAE Kaplan–Meier)

- No significant difference between arms in time to first serious AE.
- Log-rank test $p = 0.8130$, Cox HR = 0.855 (95% CI: 0.395–1.853).

3.6 Propensity Score Matching

- Logistic model for PS: *c-statistic* = 0.534
- Matching reduced covariate imbalance to near zero (AGE, SEX)
- Diagnostics confirmed high-quality match

Refer to plots in 'ps-model.pdf' and 'psm-diagnostics.pdf'.

3.7 PCA and Clustering

Using AGE and mean SpO_2:

- PCA showed separation along PC1 driven by age and oxygen saturation.
- K-means clustering (k=2) identified two groups potentially reflecting different clinical profiles.

See PCA and cluster plots in the mock.

4. Listings

- Listing 1 contains subject-level adverse events including severity and relationship to study drug.

5. Software

All analyses were performed using:

- **SAS 9.4** for classical statistical modeling and reporting
- **R 4.4** for PCA, clustering, and data visualization