PROTOCOL WITH STATISTICAL ANALYSIS PLAN

Official Title:
Study of Genome-associated Mechanisms of Diabetic Nephropathy and Evaluation of Nephroprotective Therapy in Patients With Type 2 Diabetes Mellitus in the Kazakh Population

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1. Introduction

This Statistical Analysis Plan (SAP) describes the planned statistical analyses for the study titled 'Study of Genome-associated Mechanisms of Diabetic Nephropathy and Evaluation of Nephroprotective Therapy in Patients With Type 2 Diabetes Mellitus in the Kazakh Population'. This SAP is designed in accordance with good clinical practice and regulatory guidelines.

2. Study Objectives and Endpoints

Primary Endpoint:
- Improvement in estimated glomerular filtration rate (eGFR) after nephroprotective therapy.

Secondary Endpoints:
- Reduction in albuminuria levels
- Genetic polymorphism associations with therapeutic outcomes
- Change in serum creatinine levels

3. Study Design and Population

This is a prospective, observational study involving 100 patients with Type 2 Diabetes Mellitus and 75 control participants, all of Kazakh ethnicity, aged between 18 and 65 years. Both males and females will be included.

4. Statistical Methods

Statistical analyses will be performed using IBM SPSS Statistics 21. Descriptive statistics (mean, standard deviation, median, interquartile range) will be used to summarize the data. Comparisons between groups will be conducted using Student’s t-test or Mann-Whitney U test for continuous variables, and Chi-square test for categorical variables. Regression analyses (linear and logistic) will be used to identify predictors of therapeutic response.

5. Stratification and Subgroup Analyses

Subgroup analyses will be performed by age group, sex, baseline renal function, and genetic polymorphism profiles.

6. Sample Size Justification

A total sample size of 175 participants (100 patients and 75 controls) was chosen based on feasibility and expected effect size. This sample size is deemed sufficient to detect clinically meaningful differences with adequate statistical power.

7. Interim Analysis

An interim analysis will be conducted after 50% of the participants complete the study procedures. The results will be reviewed for safety and efficacy signals.

8. Data Handling and Confidentiality

All collected data will be de-identified and stored securely for a period of 3 years. Only study personnel will have access.