

COVID-19 Anosmia Study Statistical Analysis Plan

PI: Alfred-Marc Iloreto, MD

NCT04495816

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## 9.1 STATISTICAL HYPOTHESES

- Primary Efficacy Endpoint(s):

The primary endpoint of this study is a Brief Smell Identification Test, a standardized and validated objective measure

of olfactory function, administered 6 weeks from symptom onset.

- Secondary Efficacy Endpoint(s):

The secondary endpoints of this study include patient-reported outcome measure surveys, a modified Brief

Questionnaire of Olfactory Dysfunction - Negative Statements (QOD-NS) survey and Sino-Nasal Outcome

Test

(SNOT-22), administered at time points of 1, 2, 4, and 6 weeks after symptom onset.

## 9.2 SAMPLE SIZE DETERMINATION

Analysis of patients with olfactory dysfunction within the Rhinology division have demonstrated a standard deviation of 2 on BSIT scores. Therefore using an MCID of 1, an alpha of 0.05 and power of 80%, the sample size is 126.

## 9.3 POPULATIONS FOR ANALYSES

Statistical analysis will be performed comparing experimental and control groups.

## 9.4 STATISTICAL ANALYSES

### 9.4.1 GENERAL APPROACH

Analysis will be performed comparing the experimental and control groups at the study's conclusion.

### 9.4.2 ANALYSIS OF THE PRIMARY EFFICACY ENDPOINT(S)

At the study's conclusion, BSIT scores will be analyzed for distribution. Assuming outcomes will not have

a normal distribution non-parametric Mann-Whitney U test will be used to compare change in BSIT score between experimental and control groups with statistical significance set at  $p < 0.05$ . If outcomes are found to have normal distribution, analysis will be performed using a two-tailed student's t-test.

### 9.4.3 ANALYSIS OF THE SECONDARY ENDPOINT(S)

Secondary endpoints include SNOT-22 and modified brief QOD-NS scores at designated time-points. For each survey and timepoint, scores will be analyzed for distribution. Assuming outcomes will not have a normal distribution, non-parametric Mann-Whitney U test will be used to compare scores with statistical significance set at  $p < 0.05$ . If outcomes are found to have normal distribution, analysis will be performed using a two-tailed student's t-test.