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.