

An Open-label Pilot Study to Investigate the Efficacy of Apremilast in the Treatment of Central Centrifugal Cicatricial Alopecia (CCCA) Statistical Analysis Plan

PI: Saakshi Khattri, MD

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## **Sample Size and Statistical Considerations**

A sample size of  $n=20$  subjects and 3 experts provide 90% power at 5% significance to detect a pooled mean improvement in PGA-I of 0.8 units from baseline with the use of a one-sided paired t-test. Since changes in the outcome only take values in the interval between -3 and 3, our calculation assumes the maximum standard deviation ( $SD = 1.15$ ) for the pooled mean PGA-I change from baseline obtained from 3 expert dermatologists. Our power analysis approach is conservative as it ignores intra-subject correlation evaluated by different experts which might increase statistical power.

## **Data Analysis**

At weeks 12 and 24 we will test for significant improvement in PGA-I and IGSS with one-sided paired t-tests, after pooling scores obtained from 3 dermatologists. We will apply Wilcoxon and Friedman's nonparametric tests to CHLG, VAS, PaGA-I, and DLQI to compare scores between time points (baseline, weeks 12 and 24). An overview will be obtained by drawing a correlation map that clusters clinical outcomes based on the Spearman correlation coefficient. As a more comprehensive approach, and to better capture the dynamics of clinical outcomes over time, we will fit hierarchical ordinal regression models developed to handle ordinal and longitudinal responses. We will use the last observation carry-forward strategy to mitigate the impact of missing data.