

Cover Page – Statistical Analysis Plan

Title: Vagal Nerve Stimulation for Treatment Resistant Major Depression

NCT04990687

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Analysis plan: The data will first be screened for outliers and structural problems using analytical and graphical methods. If there are violations of normality assumptions, we will determine if power transformations can address this. Otherwise, we will analyze the data using non- and semi parametric methods.

The primary analysis approach will be a generalized linear mixed model. This approach allows modeling within subject correlations of the data in a repeated measurement design and provides unbiased parameter estimates. Time will be modelled as a within subject variable. The main variable of interest in the model will be the time*Tx interaction term. To account for baseline differences between participants we will include random effect terms for each subject.