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Safety and Efficacy of the Swallow Expansion Device (SED) for Improvement of Swallowing in Patients

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Statistical Analysis Plan

This was a Phase 1 open label proof of concept study. The primary outcome variable was safety (incidence of serious adverse event expressed as number of serious events per person/total enrolled patients). We performed descriptive statistics on the de-identified demographic information (age/gender/race/etiology of swallowing impairment) and tabulated the data into simple means with standard deviations. Comparisons between the baseline primary and secondary outcome measures of efficacy (UES opening/FOIS) were made with a repeated-measures t-test. A probability of Type I error (alpha) of 0.05 was utilized to ascertain statistical significance.