

PROTOCOL TITLE:

Visualization of the colon through use of the Magnetic Flexible Endoscope
(MFE) in healthy participants

NCT05833789

Protocol Version Date: December 16, 2022

Statistical Analysis Plan:

Given the small sample size of study (n=5 patients), statistical analysis will be limited to descriptive statistics with median and quartiles [Q1, Q3]; median, maximum and minimum values; as well as means and standard deviations when appropriate. Percentages of groups and event numbers will be calculated.

Primary outcome measure will be noted as number of participants as a percentage of the group as a whole (n=5, denominator).

Secondary outcome measure of tolerability will be noted as number of non-tolerability events as a percentage of the group as a whole (n=5, denominator).

Secondary outcome measure of endoscopist experience by NASA Task Load Index (TLX) will be calculated as median with Q1, Q3 for each sub-scale.

Secondary outcome measure of colon mucosal visibility will be calculated as median with interquartile range.