# Statistical Analysis Plan

## Research Protocol Title: Next generation ORS: Randomized controlled trial comparing ORS with calcium vs standard ORS in reducing severity with acute watery diarrhea of adults

NCT05814042

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**Statistical Design and Power**

Sample size justification: For the safety study, the endpoint will be a binary variable indicating whether adverse event occurs. We provide the required sample sizes for three scenarios where the hypothetical risks of adverse events are 2.5%, 1% and 0.5% respectively. To detect the risk of adverse events of 2.5% with 80% statistical power at a one-sided type I error rate of 0.05 for testing the hypothesis H0: adverse events<2.5% vs. H1: adverse events≥2.5%, we need 28 subjects. If we want to detect 1% adverse events with 80% power, 71 subjects are needed. To detect 0.5% adverse events, 142 subjects are required. By pooling the subjects that will be enrolled for aim 2/3, we can easily reach the required number of subjects to obtain satisfactory power for detecting the adverse events.

Statistical design & data analysis plan: Standard summary statistics will be provided by treatment groups for demographic and baseline clinical variables. Baseline distributions of characteristic variables such as age and gender will be examined and compared between the treatment groups to test for potential confounders. The endpoint will be a binary variable indicating whether adverse event occurs. Chi-squared tests will be used for binary or categorical data. We will use generalized linear regression models to analyze count data such as occurrences of electrolyte abnormality with log link for the regression model. For percentage variables, logit normal model will be considered to avoid non-convergence problem due to the limited range a percentage variable.