STATISTICAL REPORTING AND ANALYSIS PLAN

CLINICAL STUDY TO MEASURE THE IMPACT OF FORTIFIED MALT BASED FOOD ON IMMUNITY OUTCOMES IN SCHOOL CHILDREN

Protocol Number: 204477

Phase: N/A

Document History

Document	Version Date	Summary of Changes (New analysis or Change in planned analysis)
Original Analysis Plan	27-June -2018	Not applicable (N/A)
Amendment 1	2-November-2018	1. For all ANCOVA analyses, "cluster (school)" will be included as a random effect instead of a fixed effect. Handling "cluster" as random effect would avoid over-parametrisation and would allow for intracluster correlation. 2. Present the estimate of the intra cluster correlation in the ANCOVA tables. Adjusting for the intracluster correlation is necessary for a valid analysis. 3. Implementation of comments received during dry-run process. 4. Creation of additional corresponding descriptive statistics tables for exploratory ANCOVA tables. 5. Removal of raw outputs in section 16.1.9 with no corresponding ANCOVA tables in section 14.2. 6. Replacing originally planned figures with corresponding tables.

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Abbreviations

AE	adverse event
AGP	Alpha 1-acid glycoprotein
ANCOVA	Analysis of covariance
ANOVA	Analysis of variance
ARI	Acute respiratory illnesses
BMI	Body mass index
CRF	Case Report Form
CNS	Central Nervous System
CRP	C-reactive protein
CTCAE	Common Terminology Criteria for Adverse Event
DE	Design Effect
DF	Diagnosis Form
ENT	Ear, nose, throat
FSFV	First subject first visit
g	Gram
GI	Gastrointestinal
GSKCH	GlaxoSmithKline Consumer Healthcare
HAZ	Height for age Z score
Hb	Hemoglobin
HBS	Human biological sample
IDDS	Individual Dietary Diversity Score
ITT	Intent to treat
LAR	Legally appropriate representative
LM	Lactulose; mannitol

MFC	Master formulation code
mg	Milligram
mITT	Modified Intend to treat
ml	Milliliter
MMN	multiple micronutrient
MMRM	Mixed model repeated measure
MN	multiple nutrient
PP	per protocol
RAP	Reporting and Statistical Analysis Plan
RDA	Recommended Dietary Allowance
SAE	Serious adverse event
SD	Standard deviation
sIgA	Salivary immunoglobulin A
SOC	System Organ Class
SP	Study Physician
SPWR	Study Physician Weekly Review
sTfR	Serum transferrin receptor
WHO	World Health Organization

The purpose of this Statistical Reporting and Analysis Plan is to describe the planned analyses and outputs to be included in the Clinical Study Report for Protocol 204477 version 5.0 dated 31October 2017.

1 Summary of Key Protocol Information

The purpose of this trial is to demonstrate the efficacy and safety of fortified malt based food on immunity outcomes in school children 7 to 10 years of age. Efficacy will be demonstrated as superiority of fortified malt based food on test vs. control group on the primary efficacy outcomes, number of ill days during nine months of intervention.

Safety will be demonstrated through assessment of adverse events (AEs).

1.1 Study Design

Overall Design
This is a single centre, multiple sites, open label, two-arm, parallel-group, stratified by gender, matched pair cluster randomized, controlled study.
Visit 1 - Screening Visit
The following assessments will be conducted • Informed consent and assent • Demographics • Medical history • Current/concomitant medications • General physical examination • Vital signs • Haemoglobin (Hb) assessment using Pronto • Anthropometric measurements (height and weight) • Inclusion/exclusion criteria evaluation • Subject Eligibility

- 24 hr dietary recall & dietary diversity survey
- Parental/legally appropriate representative (LAR) training on the completion of the 'Symptom Check List'
- Dispense blank Parent/LAR Symptom Checklist and Product Compliance Report Forms

Visit 2 - Baseline Visit

The following assessments will be conducted

- Current/concomitant medications
- Continued eligibility criteria
- Sample collection for urinary Neopterin test & lactulose/mannitol test
- Sample collection for analysis of serum ferritin, serum transferrin receptor (sTfR), C-reactive protein(CRP), alpha 1-acid glycoprotein (AGP), salivary immunoglobulin A (sIgA) & nutritional biochemistry (for micronutrients vitamins A, B12, D, E, folate, and of the trace elements selenium, zinc, copper, and iron)
- AE monitoring

Visit 3, 4, 5, 6, 7, 8, 9, SPWR and Product Administration Visits

The following assessments will be conducted

- Current/concomitant medications
- Continued eligibility criteria
- Dietary counselling will be administered to all study participants and their parents/LARs.
- Test Group will be administered to all study participants in the test group.
- Study physician weekly review (SPWR) visits will be conducted on a weekly basis until End of Study Visit. Parent/LAR symptom checklist & Product Compliance Report Forms will be collected and reviewed.
- Adverse event(AE) monitoring

Visit 10 - End of Study Visit

The following assessments will be conducted

- Current/concomitant medication
- General physical examination
- Vital signs
- Anthropometric measurements (height and weight)
- Continued eligibility criteria
- 24 hr dietary recall & dietary diversity survey
- Sample collection for urinary Neopterin test & lactulose/mannitol test
- Sample collection for analysis of serum ferritin, sTfR, CRP, AGP, sIgA & nutritional biochemistry (for micronutrients vitamins A, B12, D, E, folate, and of the trace elements selenium, zinc, copper, and iron)
- AE monitoring
- Study completion and medical sign-off

1.2 Study Objectives

Objectives	Endpoints
Primary Objective	**Primary Endpoint**
• To determine the total number of ill days due to GI and respiratory illnesses in participants receiving fortified malt based food (Test Group) with dietary counselling in comparison to participants receiving only dietary counselling over a period of nine months.	• Total number of ill days due to GI and respiratory illnesses.
Secondary Objectives	**Secondary Endpoints**
To compare the following variables in participants receiving the fortified malt based food (Test Group) along with dietary counselling to participants receiving only	•

dietary counselling over a period of nine months.	
• Frequency of GI and respiratory illnesses.	• Number of episodes of GI and respiratory illnesses.
• Severity of GI and respiratory illnesses.	• Severity of GI and respiratory illnesses.
• School absenteeism due to GI and respiratory illnesses.	• School absenteeism due to GI and respiratory illnesses.
• Change from baseline (measured at screening) in body mass index (BMI).	• BMI at screening and end of study.
• Change from baseline in gut integrity/health as measured by Lactulose Mannitol test.	• Gut integrity/health as measured by Lactulose Mannitol test at baseline and end of study.
• Change from baseline in gut integrity/health as measured by Urinary Neopterin test.	• Gut integrity/health as measured by Urinary Neopterin test at baseline and end of study.
• Change from baseline in mucosal immunity as measured by Salivary Immunoglobulin A (IgA) status.	• Salivary Immunoglobulin A (IgA) status at baseline and end of study.
• Change from baseline in levels of micronutrients Vitamin A, B12, D (25-hydroxycholecalciferol), E, folate, of the trace elements selenium, zinc, copper, and iron as determined by blood draw and analysis.	• Levels of micronutrients Vitamin A, B12, D (25-hydroxycholecalciferol), E, folate, of the trace elements selenium, zinc, copper, and iron at baseline and end of study.
• Change from baseline levels of ferritin,	• Levels of ferritin, sTfR, CRP,

serum transferrin receptor (sTfR), C-reactive protein (CRP), and Alpha 1-acid glycoprotein (AGP) as determined by blood draw and analysis.	and AGP at baseline and end of study.
• Change from baseline (measured at screening) in dietary diversity score, assessed through 24-hour Individual Dietary Diversity Score (IDDS).	• Dietary diversity score assessed through 24-hour IDDS at screening and end of study.
• Change from baseline (measured at screening) in energy, protein, carbohydrates and fat consumption, assessed through 24-hour dietary recall survey.	• Intake of energy, protein, carbohydrate, and fat from 24-hour dietary recall survey at screening and end of study.

1.3 Treatments

The following product groups will be used for this study-

- Test group- Fortified malt based food plus dietary counselling
- Control group- Dietary counselling

1.4 Sample Size Calculation

The primary efficacy variable of the study is the total number of ill days due to GI and respiratory illnesses. The sample size has been calculated based on the assumption of an average of 7 ill days in the control group with a difference of 10% between the treatments.

Years Lost due to Disability (YLD) is a measure of the burden of disease from its morbidity. Below are data that are specific to India: As per the data from Global Burden Disease, WHO 2010 study (GBD, WHO, 2012; IHME, 2013) and Census India, 2011, YLD per child in the 5-9-year age group, due to diarrhea, LRTIs, other infectious disease and nutritional deficiencies is 8.274 days/child per year or 6.21 days/child per 9 months.

Thus, based on above data, approximately 7 ill days due to GI and respiratory illnesses per 9 months has been assumed in this proposed study population of 7-10 year olds.

The sample size is based on the primary endpoint. No sample size considerations have been taken into account for secondary objectives.

The simulated data were also used based upon the assumption of a Poisson distribution per study treatment. On observation of these simulated data, it was considered that these Poisson distributions were not heavily skewed and, as a result, normal distributions may be

assumed. Consequently, a normality assumption has been adopted for both the generation of sample size and the intended approach to the statistical analysis.

Because of assumption of Poisson distribution, estimates of variability were calculated as square root of mean.

Mean of control was assumed to be 7.0 and standard deviation (SD) was 2.65, mean of test group was 6.3 and SD was 2.51. To be able to achieve 80% power, 215 participants per treatment arm (Total = 430) will be required to complete the study in case of individual randomisation. This assumes 5% level of significance (two tailed t-test).

As this study is using cluster randomization, and design effect (DE) needs to be considered for sample size calculations. Scientific literature suggests, DE due to cluster sampling strategy can be assumed to be 1.5 [Rosner, B, 1986]. Same has been assumed in one study, which used three-stage systematic cluster sampling [Dandona R *et al*, 2008].

Using the following formula from Hemming *et al*, 2011:

$$N^* = N \times DE$$

Where N*=Number of participants required for cluster randomized trial

N = Number of participants required for individual randomization

DE = design effect

And assuming DE to be 1.5, the number of evaluable participants completing the study required would be 323 per arm (Total=646).

To allow for 30% drop-out rate, a total of 924 participants will be randomized.

Approximately 1300 participants will be screened to randomize approximately 924 participants in order to obtain 646 participants completing the study.

2 Planned Analyses

2.1 Interim Analysis

No interim analysis is planned.

2.2 Final Analyses

The final planned primary analyses will be performed after the completion of the following sequential steps:

1. All participants who have completed the study as defined in the protocol.
2. All required database cleaning activities have been completed and database has been locked.

3. All criteria for un-blinding the randomization codes have been met and the randomization codes have been distributed.

3 Considerations for data analyses and Data Handling Conventions

3.1 Baseline Definition

For parameters height, weight, BMI, height for age Z score (HAZ), individual diversity dietary score (IDDS), carbohydrate, fat and energy from 24 hour dietary recall assessments conducted at screening visit will be considered as baseline and for all other endpoints the baseline value will be the latest pre-dose assessment Visit 2 with a non-missing value.

Unless otherwise stated, if baseline data is missing no derivation will be performed and will be set to missing.

3.2 Subgroups/Stratifications

To control for possible effects of gender, a balanced ratio of boys and girls in the test and the control groups will be targeted. The study will be stratified by gender to recruit a target ratio of 50% girls and 50% boys, with a minimum of 40% of either gender and a maximum of 60% of either gender.

3.3 Centers Pools

This study is conducted in multiple (4) schools, with two schools in each product group.

3.4 Time points and Visit Windows

The time points and visits for this study are defined in the section “Schedule of Events” of the protocol. Any deviation from the study schedule will be reviewed case-by-case basis to determine whether the data should be excluded from the Per Protocol (PP) population. A time window non-compliance listing will be produced for the Blinded Data Review Meeting (BDRM) only.

4 Data Analysis

Data analysis will be performed by Syneos Health. The statistical analysis software used will be SAS Studio version 9.4 or higher.

Prior to database closure a BDRM will be conducted in which various aspects of the trial will be discussed and agreed.

Unless otherwise described below, all listings will be produced for enrolled population.

4.1 Populations for Analysis

Tables described in this section will be produced for enrolled population.

4.1.1 Subject Disposition

Screen failures are defined as participants who consented to participate in the study but were not subsequently enrolled (i.e., excluded basis inclusion/exclusion criteria). A summary of the number of participants screened and the number of screen failures with reasons of their exclusion will be presented (Table 14.1.1). Percentage of screen failure participants will be based on total number of screened participants. Subject disposition will also be summarized by product group and overall as the number and percentage of participants who completed the study, with the number who discontinue broken down by reason for discontinuation (Table 14.1.1). The table will also summarize the number and percent of participants assigned to each analysis population (refer to Section 4.1.3). The percentage will be based on total number of participants enrolled in each product group and overall.

Subject disposition including the participants status (completer, Yes/No), demographic data (age and race), screening date, product groups (including test product and dietary counselling) start date and time, the duration in the study or trial and the specific reason for discontinuation, will be listed for enrolled population (Listing 16.2.1.1) by product group.

Duration in the study or trial will be calculated using the formula below –

(Date of completion/withdrawal minus date of baseline visit)+1

Subject disposition information for non-enrolled participants will include subject number, demographic information (age and race), screening date, reason for screen failure and details if any regarding the reason for screen failure (Listing 16.2.1.2).

4.1.2 Protocol Deviations

Protocol deviations will be tracked by the study team throughout the conduct of the study. Data will be reviewed prior to un-blinding and closure of the database to ensure all important deviations are captured and categorized. Participants with major protocol deviations (defined below) will be excluded from the PP population.

Major deviations of the protocol procedures identified as liable to influence the efficacy outcomes of the study may include, but will not be necessarily limited to the following:

- Violation of inclusion or exclusion criteria
- Significant non-compliance with assigned treatment
- Use of prohibited treatment or medication before or during the study
- Any other reason identified which may affect the efficacy assessments

The number and percentage of participants with any major protocol deviations will be presented by product group and overall (Table 14.1.2) and listed (Listing 16.2.2.1). Any minor protocol deviations will be listed similarly (Listing 16.2.2.2).

4.1.3 Analysis Populations

Six analysis populations are defined.

Population	Definition / Criteria	Analyses Evaluated
All Screened Subjects	• All participants who enter the study and sign the informed consent form. This population includes screen failures as well.	• Disposition, AE listing
Enrolled Population	• All participants who attended baseline visit will be considered in enrolled population.	• Protocol deviations, AE, efficacy, demographic characteristic, disposition and medical history listings
Safety	• Comprise of all participants who received at least one dose of study product (i.e. either only dietary counselling or both supplement and dietary counselling) during the study. • This population will be based on the product to which the participant was planned to receive.	• Safety
Intent-To-Treat (ITT)	• All participants in the safety population with any post-treatment assessment (SPWR is considered as post-treatment assessment) will be included in Intent-to-treat (ITT) population. • This population will be based on the product to which the participant was planned to receive.	• Efficacy
Modified Intent-To-Treat	• All participants in the ITT population who have completed entire study of 9 months	• Primary, Secondary

Population	Definition / Criteria	Analyses Evaluated
(mITT)	(i.e., attended up to end study visit) will be included in modified intent-to-treat (mITT) population. • This population will be based on the product to which the participant was planned to receive.	Exploratory Efficacy
Per-Protocol	• Participants who have all post-treatment assessment and do not have any major protocol deviations that would affect efficacy assessments. • Participants with major protocol deviations will be excluded. Depending on the nature of the major protocol deviation and impact on the efficacy variable (s), subjects will be either completely excluded from PP population or only partially excluded from the PP analyses. This will be determined on a case-by-case basis.	• Efficacy

The primary population for assessment of efficacy will be the mITT Population. A PP analysis will be performed on the primary variable if more than 5 % of the subjects in the mITT Population are excluded from the PP Population.

Participants excluded from any of the analysis populations will be listed (Listing 16.2.3.1), with the reason for exclusion.

4.2 Subject Demographics and Other Baseline Characteristics

Demographic and baseline characteristics summaries will be produced for the Safety, ITT and mITT population.

4.2.1 Demographic Characteristics

Descriptive statistics (number of subjects [n], mean, and median, standard deviation [SD], minimum and maximum) for the continuous variables and frequency (n) and percentages (%) for categorical variables will be provided for demographic variables.

The continuous variable includes age (years), height (cm), weight (kg), BMI and HAZ and categorical variables include gender, race, and HAZ (for ranges:-3 to -2 and -2 to -1).

This data will be summarized descriptively for all participants in Safety (Table 14.1.4.1), ITT (Table 14.1.4.2), mITT (Table 14.1.4.3) and if required on the PP Population (Table 14.1.4.4). Demographic information will be listed (Listing 16.2.4.1) for enrolled population.

No formal statistical analysis will be performed for this data.

4.2.2 General Medical History

Medical history data will be listed (Listing 16.2.4.2) with start date and end date or ongoing at the start of study product. A data listing will also be produced for evaluation of major protocol deviations at the blinded data review stage.

4.2.3 Characteristics of Disease

Not Applicable.

4.3 Treatments (Study Product, Rescue Medication, other Concomitant Therapies, Compliance)

Compliance data will be summarized on the mITT population. Exposure and other medications will be listed on the enrolled population.

4.3.1 Study Product Compliance and Exposure

For doses administered at school, study-personnel will supervise and ensure complete consumption of test product.

The descriptive summary of total number of expected amount of product to be consumed, actual amount product consumed by product group and overall for all participants in mITT population (Table 14.2.1.1).

The compliance will be calculated using following formula –

Test product compliance:

Test product compliance = Actual Consumption X 100/Expected Consumption

Where, actual and expected consumption are defined below:

- Expected consumption = (2X 150 mL of drink X number of days* between first and last treatment day in the study)
- Actual consumption = Expected consumption – (xx mL total left over at morning + xx mL left over at evening)]

up to maximum of 9 months (to be converted in days) (as test product is only administered maximum up to 9 month regardless last visit day in study)

Dietary Counselling Compliance:

The dietary counselling compliance will be calculated using following formulas:

- **Participants:**
    - Compliance with Mandatory dietary counselling= (Number of sessions out of session numbers 1 or 2 attended by participant divided by 2) X 100
    - Compliance with Follow-up sessions dietary counselling= (Number of sessions out of session numbers 3-7 attended by participant divided by 5) X 100
- **Parents/LAR:**
    - Compliance with Mandatory dietary counselling= (Number of sessions out of session numbers 1 or 2 attended by parents/LAR divided by 2) X 100
    - Compliance with Follow-up sessions dietary counselling= (Number of sessions out of session numbers 3-7 attended by parents/LAR divided by 5) X 100

Study product compliance listing (Listing 16.2.5.1) using enrolled population will be presented at the time of blinded data review process. Noncompliance will be assessed on a participant by participant basis. Those participants with product compliance less than 70% or non-compliant with dietary counselling will be excluded from the PP population. Any participant excluded from PP population will be clearly documented in the population definition document.

Exposure to the study product in days will be calculated as date of last day in the study minus date of first date of study product administration +1 for the test group.

Exposure to the study product in days will be calculated as date of last day in the study minus date of first date of dietary counselling +1 for the control group.

Exposure data will be listed (Listing 16.2.5.1) using enrolled population.

4.3.2 Prior and Concomitant Medication

Prior or concomitant medication taken by or administered to a participant will be recorded in the case report form. The prior and concomitant medications will be coded using an internal validated medication dictionary, GSK Drug.

Prior medications are defined as those which stopped before the first administration of study product start date. If the stop date is unknown or incomplete and medication cannot be considered as stopped prior to first administration then the medication will be considered as concomitant medication.

Concomitant medications are defined as the medications ongoing on or after first study product start date.

Unknown dates will not be imputed, however if the start date is unknown, then it will be assumed to concomitant medication, unless the partial start date or stop date indicates differently.

Prior and concomitant medications/non-drug therapies will be listed by participant, with preferred term, indication, dose, dose form, frequency, route, start date, end date or ongoing and start day relative to first dose of study product (Listing 16.2.5.2 and Listing 16.2.5.3).

4.4 Analysis of Efficacy

4.4.1 Primary Efficacy Endpoint

4.4.1.1 Primary Efficacy Endpoint Definition

The primary efficacy variable of the study is the number of ill days over a period of nine months.

The definition of number of illness days is following –

Number of illness days: Number of days a subject is ill because of GI and/or respiratory illnesses as diagnosed by study physician, as per the criteria defined, over the intervention duration. This corresponds to total number of days (symptomatic or asymptomatic) in an episode of illness. Each episode is defined as each incidence of illness followed by at least 3 symptom free days.

In an episode if the first occurrence is due to GI illness and second occurrence is due to respiratory illness with less than 3 symptom free days then the overall episode due to GI and/or respiratory will be counted as one and separately it will be one each for GI and respiratory.

The asymptomatic days (or symptom free) days will be calculated programmatically based on the date mentioned on the Diagnosis Form in the following way –

Asymptomatic day = (Second occurrence start date - First occurrence end date) - 1

If asymptomatic day is less than 3 days then two occurrences of illnesses will be calculated and considered as single episode.

Else if asymptomatic days are greater than or equal to 3 days then two occurrences of illnesses will be calculated and considered as different episodes.

Descriptive statistics (n, mean, SD, SE, median, minimum and maximum) by product group will be provided (Table 14.2.2.1). Number of ill days due to GI and/or respiratory illnesses will be listed for each subject (Listing 16.2.6.18).

4.4.1.2 Statistical Hypothesis, Model, and Method of Analysis

For the primary variable, primary analysis will be performed on participants on the mITT population.

The null hypothesis of interest is:

H0: There is no difference between the numbers of illness days for the product groups.

The alternative hypothesis of interest is:

H1: There is a difference in between the numbers of illness days for the product groups.

The number of ill days will be analysed using the analysis of variance (ANCOVA) model. The ANCOVA will have cluster (school) as a random effect, product group and gender as fixed effects and baseline IDDS as a covariate.

Adjusted means, 95% confidence intervals (CI), within product group p-values for each product group, product group difference, intracluster correlation, 95% confidence interval of the difference and the between-product group p-values based on the statistical model described above will also be presented (Table 14.2.2.2).

All statistical tests of hypotheses will be two-sided and will employ a level of significance of $\alpha = 0.05$.

The simulated data used for the sample size calculations were based upon the assumption of a Poisson distribution per product group. However, on observation of these simulated data, it was considered that these Poisson distributions were not heavily skewed and, as a result, normal distributions may be assumed. Consequently, a normality assumption has been adopted for both the generation of sample size and the intended approach to the statistical analysis.

However, the assumptions of normality and homogeneity of variance will be investigated and violation of these assumptions may be overcome using suitable transformation (for example, log or square root or Poisson regression using Proc Genmod) or by performing appropriate non-parametric tests (e.g., Van Elteren, rank ANCOVA).

4.4.1.3 Supportive Analyses

As a part of sensitivity analysis a Mixed Model Repeated Measure (MMRM) model will be used. MMRM model will be just an analysis including multiple visits with defined structure of correlation among visits. In this study unstructured covariance matrix will be used. The number of ill days will be analysed using model with cluster (school) as a random effect; product group, gender, and visit and (product group and visit) interaction as fixed effects and baseline IDDS as a covariate.

This will be conducted on the primary efficacy endpoints on the ITT population (Table 14.2.2.2a).

4.4.2 Secondary Efficacy Variables

The analysis of secondary efficacy variables will be on the mITT population.

The secondary efficacy variables are:

- **Frequency of GI and Respiratory illness**

Frequency of GI and respiratory illnesses defined as total number of illness episodes of GI and/or respiratory illnesses, divided by duration of intervention in month, where each episode is defined as each incidence of illness followed by at least 3 symptom free days will be summarized in a table for the product groups (Table 14.2.3.1).

The frequency of GI and respiratory illnesses will be calculated as following –

Frequency (per month) = No of episodes X 30/ Number of days between first (BV) and last visit

Frequency of GI and respiratory illnesses will be analysed together using analysis of covariance (ANCOVA) model. The model will include cluster (school) as a random effect; fixed effects for product group and gender; and baseline IDDS as a covariate. Adjusted means, 95% confidence intervals, intracluster correlation, within product group p-values for each product group, product group difference, 95% confidence interval of the difference and the between-product group p-values based on the statistical model described above will also be presented (Table 14.2.3.2).

The assumptions of normality and homogeneity of variance will be investigated and violation of these assumptions may be overcome using suitable transformation or by performing sensitivity analysis or by appropriate non-parametric tests (e.g., Van Elteren, rank ANCOVA).

- **Analysis on Severity of GI and Respiratory illness:**

Frequency and percentages of severity episodes of GI and respiratory illnesses will be summarized in a table together and also separately (Table 14.2.4.1). If an episode comprises of occurrences of different severities, then the highest severity will be considered as the overall severity. Severity grades will be displayed in the tables for the GI and respiratory illness as mentioned in the Appendix 5 of the Protocol version 5.0.

Frequencies of severity (Mild, moderate, or severe) episode between product groups will be compared using Chi-Square test (if frequencies are greater than 5%). If frequencies are ≤ 5% in any product group, then these will be compared using Fisher's exact test between product groups (Table 14.2.4.1).

- **Analysis of School absenteeism due to GI and Respiratory illness:**

Descriptive statistics (n, mean, and median, SD, minimum and maximum) will be provided for school absenteeism due to GI and respiratory illnesses (Table 14.2.5.1).

School absenteeism due to GI and respiratory illnesses will analysed together using analysis of variance (ANCOVA) model. The model will include cluster (school) as a random effect; fixed effects for product group and gender; and baseline IDDS as a covariate.

Adjusted means, 95% confidence intervals, within product group p-values for each product group, product group difference, intracluster correlation, 95% confidence interval of the difference and the between-product group p-values based on the statistical model described above will also be presented (Table 14.2.5.2).

The assumptions of normality and homogeneity of variance will be investigated and violation of these assumptions may be overcome using suitable transformation or by performing appropriate non-parametric tests (e.g., Van Elteren, rank ANCOVA).

- **Analysis of Body Mass Index (BMI):**

Descriptive statistics (n, mean, and median, SD, SE, minimum and maximum) will be provided for BMI (Table 14.2.6.1). Change from baseline of BMI will be analysed using an analysis of covariance (ANCOVA) model. The model will include cluster (school) as a random effect; fixed effects for product group and gender; baseline BMI assessment recorded at screening visit and baseline IDDS as a covariate. Adjusted means, intracluster correlation, 95% confidence intervals, within product group p-values for each product group, product group difference, 95% confidence interval of the difference and the between-product group p-values based on the statistical model described above will also be presented (Table 14.2.6.2). The assumptions of normality and homogeneity of variance will be investigated and violation of these assumptions may be overcome using suitable transformation or by performing appropriate non-parametric tests (e.g., Van Elteren).

- **Analysis of Gut integrity/health as measured by Lactulose: Mannitol test and Urinary Neopterin test:**

Descriptive statistics (n, mean, and median, SD, SE, minimum and maximum) for the Lactulose: Mannitol and Urinary Neopterin will be provided in a table (Table 14.2.7.1). Change from baseline in gut integrity/health as measured by Lactulose: Mannitol test and Urinary Neopterin test and will be analysed using an ANCOVA model.

The model will include cluster (school) as a random effect; fixed effects for product group and gender, baseline guts integrity/health assessment as a covariate. Adjusted means, intracluster correlation, 95% confidence intervals, within product group p-values for each product group, product group difference, 95% confidence interval of the difference and the between-product group p-values based on the statistical model described above will also be presented (Table 14.2.7.2).

The assumptions of normality and homogeneity of variance will be investigated and violation of these assumptions may be overcome using suitable transformation or by performing appropriate non-parametric tests (e.g., Van Elteren).

- **Analysis of Salivary IgA (sIgA):**

Descriptive statistics (n, mean, and median, SD, SE, minimum and maximum) for the sIgA will be provided (Table 14.2.8.1). Change from baseline of sIgA will be analysed using an ANCOVA model. The model will include cluster (school) as a random effect; fixed effects for product group and gender; baseline sIgA assessment as a covariate. Adjusted means, intracluster correlation, 95% confidence intervals, within product group p-values for each product group, product group difference, 95% confidence interval of the difference and the between-product group p-values based on the statistical model will also be presented (Table 14.2.8.2).

The assumptions of normality and homogeneity of variance will be investigated and violation of these assumptions may be overcome using suitable transformation (eg., log or square root) or by performing appropriate non-parametric tests (e.g., Van Elteren).

In case of logarithm transformation log base 10 will be used and additionally geometric mean will be provided for the descriptive statistics.

- **Analysis of Micronutrients from blood sample:**

Descriptive statistics (n, mean, and median, SD, SE, minimum and maximum) for the micronutrients (Vitamin A, B12, D (25 Hydroxy calciferol), E, folate, of the trace elements selenium, zinc, copper, and iron) concentration levels will be provided (Table 14.2.9.1).

Change from baseline in concentration levels of micronutrients (Vitamin A, B12, D (25 Hydroxy calciferol), E, folate, of the trace elements selenium, zinc, copper, and iron) will be analysed using an ANCOVA model. The model will include cluster (school) as a random effect; fixed effects for product group and gender; baseline assessments concentration levels and baseline IDDS as a covariate.

Adjusted means, intracluster correlation, 95% confidence intervals, within product group p-values for each product group, product group difference, 95% confidence interval of the difference and the between-product group p-values based on the statistical model will also be presented (Table 14.2.9.2).

The assumptions of normality and homogeneity of variance will be investigated and violation of these assumptions may be overcome using suitable transformation (eg., log or square root) or performing appropriate non-parametric tests (e.g., Van Elteren).

In case of logarithm transformation log base 10 will be used and additionally geometric mean will be provided for the descriptive statistics.

- **Analysis of serum variables from blood sample:**

Descriptive statistics (n, mean, and median, SD, SE, minimum and maximum) for the serum parameters (ferritin, serum-transferrin receptor (sTfR), C-reactive protein (CRP), and Alpha 1-acid glycoprotein (AGP)) will be provided (Table 14.2.10.1). Change from baseline in concentration levels of serum parameters C-reactive protein (CRP), and Alpha 1-acid glycoprotein (AGP)) will be analysed using an ANCOVA model.

The model will include cluster (school) as a random effect; fixed effects for product group and gender; baseline assessments of each serum concentration levels as a covariate. Also, a separate ANCOVA model will be used to analyse change from baseline ferritin, serum-transferrin receptor (sTfR), with cluster (school) as a random effect; product group and gender as fixed effects and baseline assessment concentration levels, CRP and AGP concentration levels as covariates.

Adjusted means, intracluster correlation, 95% confidence intervals, within product group p-values for each product group, product group difference, 95% confidence interval of the difference and the between-product group p-values based on the statistical model will also be presented (Table 14.2.10.2).

The assumptions of normality and homogeneity of variance will be investigated and violation of these assumptions may be overcome using suitable transformation (eg., log or square root) or by performing appropriate non-parametric tests (e.g., Van Elteren).

In case of logarithm transformation log base 10 will be used and additionally geometric mean will be provided for the descriptive statistics.

- **Analysis of Individual Dietary Diversity Score (IDDS):**

Descriptive statistics (n, mean, and median, SD, SE, minimum and maximum) for the IDDS will be provided (Table 14.2.11.1). Also, change from baseline IDDS will be presented in a summary table by product group. Change from baseline in dietary diversity score will be analysed using an ANCOVA model. The model will include cluster (school) as a random effect; fixed effects for product group, and gender; baseline assessments at screening as a covariate.

Adjusted means, intracluster correlation, 95% confidence intervals, within product group p-values for each product group, product group difference, 95% confidence interval of the difference and the between-product group p-values based on the statistical model will also be presented (Table 14.2.11.2).

The assumptions of normality and homogeneity of variance will be investigated and violation of these assumptions may be overcome using suitable transformation (eg., log or square root) or by performing appropriate non-parametric tests (e.g., Van Elteren).

IDDS categories are defined as below –

1. ≤ 3 food groups – Lowest dietary diversity
2. 4 and 5 food groups – Medium dietary diversity
3. ≥ 6 food groups – High dietary diversity

Frequency and percentages for each category of IDDS will also be presented (Table 14.2.11.3).

Frequencies for each category between product groups will be compared using Chi-Square test (if frequencies are greater than 5%). If frequencies are ≤ 5% in any product group, then these will be compared using Fisher's exact test between product groups (Table 14.2.11.3).

- **Analysis of energy, protein, carbohydrate and fat from 24-hour dietary recall survey:**

Descriptive statistics (n, mean, and median, SD, SE, minimum and maximum) for the Energy, Protein, Fat and Carbohydrate will be provided (Table 14.2.12.1).

Change from baseline of each assessment will be analysed using the ANCOVA model with cluster (school) as a random effect; product group and gender as fixed effects; baseline assessments for each responses as a covariate.

Adjusted means, intracluster correlation, 95% confidence intervals, within product group p-values for each product group, product group difference, 95% confidence interval of the difference and the between-product group p-values based on the statistical model will also be presented (Table 14.2.12.2).

The assumptions of normality and homogeneity of variance will be investigated and violation of these assumptions may be overcome using suitable transformation (eg., log or square root) or by performing appropriate non-parametric tests (e.g., Van Elteren).

4.4.3 Handling of Missing Values/Censoring/Discontinuations

Missing endpoints data will not be imputed, only subjects that completed the study are included on the mITT population.

4.5 Analysis of Secondary Objectives

4.5.1 Efficacy (Secondary)

Refer Section 4.4.2 for the analysis of secondary objectives.

4.6 Exploratory Analysis

- **Analysis of number of ill days over 3 and 6 months:**

  The number of ill days due to GI and respiratory illnesses over 3 months and 6 months separately on the ITT population who have completed the study for 3 months and 6

months will be summarized and analyzed using the same model as used in the primary analysis (Table 14.2.13.1.1 and Table 14.2.13.1.2).

- **Analysis of total number of ill days for GI and respiratory illness separately over 3, 6 and 9 months:**

  Primary analysis and the above analysis will be repeated for total number of ill days for GI and respiratory illness separately at months 3, 6 and 9 based on the ITT population (Table 14.2.13.2.1 and Table 14.2.13.2.2 for GI illness) and (Table 14.2.13.3.1 and Table 14.2.13.3.2 for respiratory illness).

- **Analysis of total number of ill days due to GI and respiratory illnesses, school absenteeism (days), frequency (per month), severity by gender at 9 months:**

  It will be summarized and analysed and presented as detailed for the primary and secondary endpoint respectively by gender (Table 14.2.13.4.1 and Table 14.2.13.4.2 for ill days due to GI and respiratory illnesses), (Table 14.2.13.7.1 and Table 14.2.13.7.2 for school absenteeism (days)), (Table 14.2.13.5.1 and Table 14.2.13.5.2 for frequency (month)) and severity of episodes (Table 14.2.13.6.1).

- **Analysis of change from baseline of HAZ, Height and Weight:**

  Change from baseline in HAZ, height and weight will be summarised and analysed using the same ANCOVA model as mentioned for the BMI analysis (Table 14.2.13.8.1 and Table 14.2.13.8.2 for HAZ), (Table 14.2.13.9.1 and Table 14.2.13.9.2 for height), (Table 14.2.13.10.1 and Table 14.2.13.10.2 for weight).

- **Association between Gut integrity/health as measured by Lactulose: Mannitol test and Urinary Neopterin test with blood chemistry:**

  Correlation between micronutrients (Vitamin A, B12, D (25 Hydroxy calciferol), E, folate, selenium, zinc, copper, and iron) and gut integrity/health as measured by Lactulose: Mannitol test and Urinary Neopterin test will be computed at baseline and at visit 10 (Table 14.2.13.11,), Also, correlation between change from baseline micronutrients (Vitamin A, B12, D (25 Hydroxy calciferol), E, folate, selenium, zinc, copper, and iron) and change from baseline in gut integrity/health as measured by Lactulose: Mannitol test and Urinary Neopterin will be computed at month 9 (Table 14.2.13.12).

- **Summary of Number of Ill Days Due to GI Illness and respiratory illnesses and separately by School over Month 3, 6 and 9:**

  Descriptive statistics tables for number of Ill days due to GI and Respiratory Illnesses by School (Table 14.2.14.1), number of Ill days due to GI Illnesses by School (Table 14.2.14.2) and number of Ill days due to Respiratory Illnesses by School (Table 14.2.14.3) will be presented.

4.7 Analysis of Safety

4.7.1 Adverse Events and Serious Adverse Events

All safety data will be reported for the Safety Population as per planned study product received. The safety profile of the study product will be assessed with respect to AEs. All AEs will be reviewed by the Clinical Research Scientist or Designee prior to database freeze and will be coded using the Medical Dictionary for Regulatory Activities (MedDRA).

AEs will be regarded as treatment-emergent (TE) if they occur on or after the first study product administration. If this date is missing a suitable alternative will be used e.g. date of visit 3. All other AEs prior to this will be considered non-treatment emergent.

AEs will be regarded as treatment emergent for the control group if they occur on or after the first dietary session or visit 3.

The following summary tables and listings will be presented by product group.

- Table of Treatment Emergent Adverse Event (TEAEs) by System Organ Class and Preferred Term (Table 14.3.1.1)
- Table of TEAEs related to study treatment by System Organ Class and Preferred Term (Table 14.3.1.2)
- Table of TEAEs by System Organ Class, Preferred Term and Severity (Table 14.3.1.3)
- Listing of all AEs (Listing 16.2.7.1 for enrolled population; Listing 16.2.7.2 for non-enrolled subjects)
- Listing of death occurring during treatment (if any) will be listed by product group, including the date and study day of death, and the principal cause of death (Listing 14.3.2.1)
- Listing of non-fatal serious adverse events (Listing 14.3.2.2)
- Listing of TEAEs leading to withdrawal (Listing 14.3.2.3)

4.7.2 Laboratory Tests

Laboratory parameters for which reference ranges will be available will be categorized with respect to reference ranges as: High, Low, Normal and Missing. The shift will be calculated with respect to reference ranges from baseline for the subsequent visits.

Laboratory results at baseline, and at month 9 will be presented in shift tables (Tables 14.3.5.3 – 14.3.5.17).

Laboratory normal ranges will be listed in Listing (Listings 16.2.6.17) and all laboratory test results will be listed in Listings (Listings 16.2.6.1 – 16.2.6.16).

4.7.3 Vital Signs and Anthropometry

Vital signs heart rate (beats/min), and oral temperature (ºF), height (cm), weight (kg), body mass index (kg/m^2) and anthropometric parameter HAZ will be collected at screening and at month 9.

Observed values at each visit and change from baseline at post-baseline visit will be summarized on the safety population descriptively (n, mean, SD, SE, median, minimum, and maximum) by product group (Table 14.3.5.1).

All vital signs will be listed (Listing 16.2.9.1).

4.7.4 Findings on Physical Examination

The findings on the physical examination (Central Nervous System (CNS), Eyes, Ear Nose Throat (ENT), Respiratory, Cardiovascular, Gastrointestinal, Musculoskeletal, Neurological, Endocrine and Metabolic, Dermatological, Haematopoietic/Lymphatic) performed at screening, and month 9, will be listed (Listing 16.2.9.2).

4.7.5 Other Safety Variables

Hemoglobin (g/dL) collected at screening visit will be summarized descriptively for all subjects in safety population.

Observed values at screening visit will be summarized descriptively (n, mean, SD, SE, median, minimum, and maximum) by product group (Table 14.3.5.2).

Hemoglobin measurements will be listed (Listing 16.2.9.3).

4.8 Analysis of Other Variables

Not applicable.

5 Changes to the Protocol Defined Statistical Analysis Plan

Any changes from the originally planned statistical analysis specified in the protocol (Dated: 10 October 2017) are outlined in Table 1.

Table 1 Changes to Protocol Defined Analysis Plan

Protocol	Reporting & Analysis Plan

Statistical Analysis section	Statistical Analysis Plan	Rationale for Changes
• 4.1.3	• Enrolled population defined • Modified ITT population defined	• Since this study uses cluster randomization and not individual participant's randomized so randomized population cannot be defined. Instead enrolled population defined. • To allow the exclusion of some enrolled participants in a justified way (such as participant who were deemed ineligible after enrolment or certain participants who never started treatment).
• 4.4.1 and 4.4.2	• Primary, secondary and exploratory analysis will be done on mITT population.	• Primary analysis should be done on participants those who are presented entire study duration. • Secondary and exploratory outcome data (particularly those involving analysis on human biological samples), are available only after End of study visit (visit 10). • ANOVA model for analysis of ferritin, serum-transferrin receptor (sTfR), is modified.
• 9.2.1	• PP analysis will be performed in case there is a 5% difference observed between number of subjects in mITT (instead of ITT) and PP.	• This change has been incorporated since mITT is primary population of analysis
• 9.3.5	The following analysis was removed • Total number of ill days (GI and respiratory illnesses), number of episodes (GI and respiratory illnesses), and severity of GI and respiratory illnesses by screening, end of study, and change from baseline in DDS, energy, protein, carbohydrate and fat.	• It will be part of potential post-hoc analysis decided after study un-blinding if imbalances between product groups are observed for the variables.

Protocol	Reporting & Analysis Plan	
Statistical Analysis section	**Statistical Analysis Plan**	**Rationale for Changes**
• 9.3.2 • 9.3.3 • 9.3.5	• Baseline IDDS has been added in the statistical model as covariate for the primary, secondary and other analysis since baseline IDDS has an impact on these analyses.	• Morbidities are the important endpoints (both primary and secondary) in this study and scientific evidences suggest that these outcomes are associated with dietary diversity score (Oduor et al., 2013) (Kiboi et al., 2016). Also, factors such as nutritional and socioeconomic status which play important role in immunity status of children are also associated with dietary diversity. Dietary diversity is associated with socio-economic status and household food security (Hoddinot & Yohannes, 2002; Hatloy et al., 2000). IDDS has been validated for several age/sex groups as proxy measures for macro and/ or micronutrient adequacy of the diet (FAO guidelines dietary diversity, 2011). Thus, the background diet is a major possible confounder in this nutritional intervention study. It thus becomes pertinent that confounding due to dietary intake measured through IDDS is controlled during statistical analysis.

- **RAP Amendment 1**

This RAP Amendment 1 provides details of modified analyses requested from the analysis described in the Statistical Reporting and Analysis Plan (final version 1.0). The section below provides a summary of the analysis with the justification for the request.

Protocol	Reporting & Analysis Plan	
Statistical Analysis section	**Statistical Analysis Plan**	**Rationale for Changes**
• 9.3.2 • 9.3.3	• For all ANCOVA analyses, "cluster (school)" will be included as a random	• Handling "cluster" as random effect would avoid over-parametrisation and would allow for intracluster correlation.

Protocol	Reporting & Analysis Plan	
Statistical Analysis section	**Statistical Analysis Plan**	**Rationale for Changes**
• 9.3.5	effect instead of a fixed effect. • Present the estimate of the intra cluster correlation in the ANCOVA tables.	• Adjusting for the intracluster correlation is necessary for a valid analysis.

6 Template for Tables, Figures and Listings

This is a guideline which will give the guidance of product group labels that will be used for the table header and in the figures, listings and in the footnotes.

The product group labels for the column headings will be as follow:

Test Group and Control Group;

The product group comparison will be:

- Test Group vs Control Group

The order of the product groups will be following-

- 1st: Test Group
- 2nd: Control Group

In all the outputs following footnote will be added –

Test Group: Fortified malt based food + Dietary Counselling

Control Group: Dietary Counselling

Attachment 1: List of Data Displays

Worksheet in
GSKCH_204477_RAP

Protocol 204477 Program Run Date: DDMMMYYYY

Table 14.1.1

Subject Disposition

All Screened Subjects

Study Population: All Screened Subjects (N=xxx)

	Test Group n (%)	Control Group n (%)	Overall n (%)
TOTAL SUBJECTS SCREENED			xxx
SUBJECTS NOT ENROLLED			xxx (xx.x)
DID NOT MEET STUDY CRITERIA			xxx (xx.x)
ADVERSE EVENT			xxx (xx.x)

SUBJECTS ENROLLED	xxx	xxx	xxx
COMPLETED STUDY	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
DID NOT COMPLETE STUDY	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
DID NOT MEET STUDY CRITERIA	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
ADVERSE EVENT	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
LOST TO FOLLOW-UP	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
PROTOCOL VIOLATION	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
WITHDRAWAL OF CONSENT	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
OTHER	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)

	Test Group n (%)	Control Group n (%)	Overall n (%)
SAFETY POPULATION	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
ITT POPULATION	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
mITT POPULATION	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
PP POPULATION	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)

Test Group: Fortified malt based food + Dietary Counselling; Control Group: Dietary Counselling

Percentages for not enrolled category are based on number of screened subjects; percentages for enrolled category are based on number of enrolled subjects.

Program: xxxxxx.sas Source: Filename Page x of y

Protocol 204477 Program Run Date: DDMMYYYY

Table 14.1.2

Incidence of Major Protocol Deviations

Enrolled Population

Study Population: Enrolled (N=xxx)

	Test Group n (%)	Control Group n (%)	Overall n (%)
SUBJECTS WITH AT LEAST ONE MAJOR PROTOCOL DEVIATION	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
MAJOR PROTOCOL DEVIATIONS NOT LEADING TO EXCLUSION FROM PP	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
DEVIATION REASON 1	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
MAJOR PROTOCOL DEVIATIONS LEADING TO EXCLUSION FROM PP	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
All VISITS			
DEVIATION REASON 1	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
VISIT Y	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
DEVIATION REASON 1	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)

Test Group: Fortified malt based food + Dietary Counselling; Control Group: Dietary Counselling

Program: xxxxxx.sas Source: Filename Page x of y

Programming Note: *This table will list all major protocol deviations as defined in the population definition document.*

Protocol 204477 Program Run Date: DDMMYYYY

Table 14.1.4.1

Demographic and Baseline Characteristics

Safety Population

Study Population: Safety Population (N=XXX)

	Test Group (N = xxx)	Control Group (N = xxx)	Overall (N = xxx)
RACE n (%)			
AFRICAN AMERICAN/AFRICAN HERITAGE	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
AMERICAN INDIAN OR ALASKAN NATIVE	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)

AGE (YEARS)			
n	xx	xx	xx
MEAN	xx.x	xx.x	xx.x

HAZ category n (%)			
≥-3 to <-2	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
≥-2 to ≤-1	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
SEX n (%)			
FEMALE	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)

	Test Group (N = xxx)	Control Group (N = xxx)	Overall (N = xxx)
MALE	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
HEIGHT (cm)			
n	xx	xx	xx
MEAN	xxx.xx	xxx.xx	xxx.xx
Height for age Z score			
n	xx	xx	xx
MEAN	xxx.xx	xxx.xx	xxx.xx

WEIGHT (kg)			
n	xx	xx	xx
MEAN	xxx.xx	xxx.xx	xxx.xx

BODY MASS INDEX (kg/m^2)			
n	xx	xx	xx
MEAN	xxx.xx	xxx.xx	xxx.xx

Test Group: Fortified malt based food + Dietary Counselling; Control Group: Dietary Counselling

Percentages are based on number of subjects in each product group and overall.

Program: xxxxxx.sas Source: Filename Page x of y

Programming Note: *For continuous variables the summary statistics: n, Mean, SD, SE, Median, Minimum and Maximum will be displayed. Similar table will be displayed for ITT population and mITT population.*

Protocol 204477 Program Run Date: DDMMMYYYY

Table 14.2.1.1

Study Product Compliance

Modified Intent-to-Treat Population

Study Population: Modified Intent-to-Treat Population (N = xxx)

	Statistics	Test Group (N = xxx)	Control Group (N = xxx)
TEST PRODUCT COMPLIANCE			
	n	xx	
	MEAN	x.xxx	
	SD	x.xxxx	
	MEDIAN	x.xxx	
	MINIMUM	x.xx	
	MAXIMUM	x.xx	
DIETARY COUNSELLING COMPLIANCE – MANDATORY SESSIONS			
PARTICIPANTS	n	xx	xx
	MEAN	x.xxx	x.xxx
	SD	x.xxxx	x.xxxx
	MEDIAN	x.xxx	x.xxx
	MINIMUM	x.xx	x.xx
	MAXIMUM	x.xx	x.xx
PARENTS/LAR	n	xx	xx

	Statistics	Test Group (N = xxx)	Control Group (N = xxx)
	MEAN	x.xxx	x.xxx
	SD	x.xxxx	x.xxxx
	MEDIAN	x.xxx	x.xxx
	MINIMUM	x.xx	x.xx
	MAXIMUM	x.xx	x.xx
DIETARY COUNSELLING COMPLIANCE FOLLOW-UP SESSIONS			
PATICIPANTS	n	xx	xx
	MEAN	x.xxx	x.xxx
	SD	x.xxxx	x.xxxx
	MEDIAN	x.xxx	x.xxx
	MINIMUM	x.xx	x.xx
	MAXIMUM	x.xx	x.xx
PARENTS/LAR	n	xx	xx
	MEAN	x.xxx	x.xxx
	SD	x.xxxx	x.xxxx
	MEDIAN	x.xxx	x.xxx
	MINIMUM	x.xx	x.xx
	MAXIMUM	x.xx	x.xx

	Statistics	Test Group (N = xxx)	Control Group (N = xxx)

Test Group: Fortified malt based food + Dietary Counselling; Control Group: Dietary Counselling

Percentage is based on number of subjects in each product group.

Test product compliance = (actual consumption/expected consumption)*100

Dietary Counselling Compliance:

Participants

Compliance with Mandatory dietary counselling= (Number of sessions out of session numbers 1 or 2 attended by participant divided by 2) X 100

Compliance with Follow-up sessions dietary counselling= (Number of sessions out of session numbers 3-7 attended by participant divided by 5) X 100

Parents/LAR:

Compliance with Mandatory dietary counselling= (Number of sessions out of session numbers 1 or 2 attended by Parents/LAR divided by 2) X 100

Compliance with Follow-up sessions dietary counselling= (Number of sessions out of session numbers 3-7 attended by Parents/LAR divided by 5) X 100

Program: xxxxxx.sas Source: Filename Page x of y

Protocol 204477 Program Run Date: DDMMMYYYY

Table 14.2.2.1

Summary of Number of Ill Days Due to GI and Respiratory Illnesses over Month 3, 6 and 9

Modified Intent-to-Treat Population

Study Population: Modified Intent-to-Treat Population (N = xxx)

Visit	Statistics	Test Group (N = xxx)	Control Group (N = xxx)	Overall (N = xxx)
		Observed Value	Observed Value	Observed Value
MONTH 3	n	xxx	xxx	xxx
	MEAN	xx.xx	xx.xx	xx.xx
	SD	xx.xxx	xx.xxx	xx.xxx
	SE	x.xx	x.xx	x.xx
	MEDIAN	x.xx	x.xx	x.xx
	MINIMUM	xx.x	xx.x	xx.x
	MAXIMUM	xx.x	xx.x	xx.x
MONTH 6	n	xxx	xxx	
	MEAN	xx.xx	xx.xx	
	SD	xx.xxx	xx.xxx	
	SE	x.xx	x.xx	
	MEDIAN	x.xx	x.xx	

Visit	Statistics	Test Group (N = xxx)	Control Group (N = xxx)	Overall (N = xxx)
	MINIMUM	xx.x	xx.x	
	MAXIMUM	xx.x	xx.x	
MONTH 9	n	xxx	xxx	
	MEAN	xx.xx	xx.xx	
	SD	xx.xxx	xx.xxx	
	SE	x.xx	x.xx	
	MEDIAN	x.xx	x.xx	
	MINIMUM	xx.x	xx.x	
	MAXIMUM	xx.x	xx.x	

Test Group: Fortified malt based food + Dietary Counselling; Control Group: Dietary Counselling

Program: xxxxxx.sas Source: Filename Page x of y

Programming Note: *Similar table will be generated for secondary and exploratory variables. For the exploratory analysis the similar table will be repeated including month 3, and month 6 using ITT population who completed month 3 and month 6.*

Protocol 204477 Program Run Date: DDMMMYYYY

Table 14.2.2.2

Statistical Analysis of Number of Ill Days Due to GI and Respiratory Illnesses at Month 9

Modified Intent-to-Treat Population

Study Population: Modified Intent-to-Treat Population (N = xxx)

Visit	Group	N	Adjusted Mean	SE	95% CI	P-Value	Intracluster Correlation	Comparison with Control Group		
								Difference (SE)	95% CI	P-Value
MONTH 9	Test Group	xxx	xx.xx	xx.xxx	xx.xx, xx.xx	0.xxxx	x.xxx	xx.xx (xx.xxx)	xx.xx, xx.xx	0.xxxx
	Control Group	xxx	xx.xx	xx.xxx	xx.xx, xx.xx	0.xxxx				

Test Group: Fortified malt based food + Dietary Counselling; Control Group: Dietary Counselling

Analysis was performed using ANCOVA model with cluster (school) as a random effect; product group and gender as fixed effects and baseline IDDS as covariate.

Difference is Test Group minus Control Group such that a negative difference favors the Test Group.

Intracluster correlation performed on complete model.

Confidence interval (CI) are presented as calculated (not truncated) and could present also negative values. Such negative values within CI no to be used for result interpretations.

Program: xxxxxx.sas Source: Filename Page x of y

Programming Note:

1. *This table is for the primary end point.*
2. *For the exploratory analysis the similar table will be repeated including month 3, and month 6 using ITT population who completed month 3 and month 6.*

Protocol 204477 Program Run Date: DDMMMYYYY

Table 14.2.2.2a

Statistical Analysis of Number of Ill Days Due to GI and Respiratory Illnesses using Repeated Measure at Month 9

Intent-to-Treat Population

Study Population: Intent-to-Treat Population (N = xxx)

Visit	Group	N	Adjusted Mean	SE	95% CI	P-Value	Intracluster Correlation	Comparison with Control Group		
								Difference (SE)	95% CI	P-Value
MONTH 9	Test Group	xxx	xx.xx	xx.xxx	xx.xx, xx.xx	0.xxxx	x.xxx	xx.xx (xx.xxx)	xx.xx, xx.xx	0.xxxx
	Control Group	xxx	xx.xx	xx.xxx	xx.xx, xx.xx	0.xxxx				

Test Group: Fortified malt based food + Dietary Counselling; Control Group: Dietary Counselling

Analysis was performed using MMRM model with cluster (school) as a random effect; product group, gender, visit and (product group and visit) interaction as fixed effects and baseline IDDS as covariate.

Difference is Test Group minus Control Group such that a negative difference favors the Test Group.

Intracluster correlation performed on complete model.

Confidence interval (CI) is presented as calculated (not truncated) and could present also negative values. Such negative values within CI no to be used for result interpretations.

Program: xxxxxx.sas Source: Filename Page x of y

Programming Note: *Similar table will be generated for all primary endpoints using imputed missing data. Direction of the difference should be with respect to the parameter which will be analyzed and should be checked with Clinical Research and Statistician for finalization.*

Protocol: 204477 Program Run Date: DDMMMYYYY

Table 14.2.4.1

Summary and Statistical Analysis on Severity Episodes of GI and Respiratory Illnesses

Modified Intent-to-Treat Population

Study Population: Modified Intent to Treat Population (N=XXX)

PREFERRED TERM SEVERITY	Test Group (N=XXX)	Control Group (N=XXX)	P-VALUE[1]	P-VALUE[2]
GI ILLNESS				
MILD	xx (xx.x)	xx (xx.x)	0.xxx	0.xxx
MODERATE	xx (xx.x)	xx (xx.x)		
SEVERE	xx (xx.x)	xx (xx.x)		
DIARRHOEA				
MILD	xx (xx.x)	xx (xx.x)	0.xxx	0.xxx
MODERATE	xx (xx.x)	xx (xx.x)		
SEVERE	xx (xx.x)	xx (xx.x)		
VOMITTING				
MILD	xx (xx.x)	xx (xx.x)	0.xxx	0.xxx
MODERATE	xx (xx.x)	xx (xx.x)		
SEVERE	xx (xx.x)	xx (xx.x)		

PREFERRED TERM SEVERITY	Test Group (N=XXX)	Control Group (N=XXX)	P-VALUE[1]	P-VALUE[2]
RESPIRATORY ILLNESS				
MILD	xx (xx.x)	xx (xx.x)	0.xxx	0.xxx
MODERATE	xx (xx.x)	xx (xx.x)		
SEVERE	xx (xx.x)	xx (xx.x)		

Test Group: Fortified malt based food + Dietary Counselling; Control Group: Dietary Counselling

[1] p-value is from the Chi-Square test.

[2] p-value is from the Fisher's exact test.

The numbers are based on the episodes with worst severity.

Program: xxxxxx.sas Source: Filename Page x of y

Programming note: *The table will represent on the episodes*

Protocol 204477 Program Run Date: DDMMMYYYY

Table 14.2.6.1

Summary of BMI (kg/m2)

Modified Intent-to-Treat Population

Study Population: Modified Intent-to-Treat Population (N = xxx)

Visit	Statistics	Test Group (N = xxx)		Control Group (N = xxx)		Overall (N = xxx)	
		Observed Value	Change from Baseline	Observed Value	Change from Baseline	Observed Value	Change from Baseline
SCREENING	n	xxx		xxx		xxx	
	MEAN	xx.xx		xx.xx		xx.xx	
	SD	xx.xxx		xx.xxx		xx.xxx	
	SE	x.xx		x.xx		x.xx	
	MEDIAN	x.xx		x.xx		x.xx	
	MINIMUM	xx.x		xx.x		xx.x	
	MAXIMUM	xx.x		xx.x		xx.x	
MONTH 9	n	xxx	xxx	xxx			
	MEAN	xx.xx	xx.xx	xx.xx			
	SD	xx.xxx	xx.xxx	xx.xxx			
	SE	x.xx	x.xx	x.xx			

Visit	Statistics	Test Group (N = xxx)		Control Group (N = xxx)	Overall (N = xxx)
	MEDIAN	x.xx	x.xx	x.xx	
	MINIMUM	xx.x	xx.x	xx.x	
	MAXIMUM	xx.x	xx.x	xx.x	

Test Group: Fortified malt based food + Dietary Counselling; Control Group: Dietary Counselling

Program: xxxxxx.sas Source: Filename Page x of y

Programming Note: *Similar table will be generated for all secondary variables. For the parameters Lactulose: Mannitol test and Urinary Neopterin test, Salivary IgA, micronutrients, ferritin, serum-transferrin receptor (sTfR), C-reactive protein (CRP), and Alpha 1-acid glycoprotein (AGP), energy, protein, carbohydrate and fat the first visit will be the visit 2 baseline visit.*

Protocol 204477 Program Run Date: DDMMMYYYY

Table 14.2.6.2

Statistical Analysis of BMI (kg/m^2) Change from Baseline at Month 9

Modified Intent-to-Treat Population

Study Population: Modified Intent-to-Treat Population (N = xxx)

Visit	Group	N	Adjusted Mean	SE	95% CI	P-Value	Intracluster Correlation	Comparison with Control Group		
								Difference (SE)	95% CI	P-Value
MONTH 9	Test Group	xxx	xx.xx	xx.xxx	xx.xx, xx.xx	0.xxxx	x.xxx	xx.xx (xx.xxx)	xx.xx, xx.xx	0.xxxx
	Control Group	xxx	xx.xx	xx.xxx	xx.xx, xx.xx	0.xxxx				

Test Group: Fortified malt based food + Dietary Counselling; Control Group: Dietary Counselling

Analysis was performed on change from baseline BMI using ANCOVA model with cluster (school) as a random effect; product group and gender as fixed effects; and baseline BMI and IDDS as covariate.

Difference is test group minus control group such that a positive difference favors the test group.

Intracluster correlation performed on complete model.

Program: xxxxxx.sas Source: Filename Page x of y

Protocol: 204477 Program Run Date: DDMMMYYYY

Table 14.2.11.3

Summary and Statistical Analysis on Individual Dietary Diversity Score (IDDS) Categories

Modified Intent-To-Treat Population

Study Population: Modified Intent to Treat Population (N=XXX)

IDDS Category	Test Group (N=XXX)	Control Group (N=XXX)	P-VALUE[1]	P-VALUE[2]
LOWEST DIVERSITY	xx (xx.x)	xx (xx.x)		
MEDIUM DIVERSITY	xx (xx.x)	xx (xx.x)	0.xxx	0.xxx
HIGHEST DIVERSITY	xx (xx.x)	xx (xx.x)		

Test Group: Fortified malt based food + Dietary Counselling; Control Group: Dietary Counselling

IDDS: Individual Dietary Diversity Score

[1] p-value is from the Chi-Square test.

[2] p-value is from the Fisher's exact test.

Program: xxxxxx.sas Source: Filename Page x of y

Protocol 204477 Program Run Date: DDMMMYYYY

14.2.13.4.1

Summary of Number of Ill Days Due to GI and Respiratory Illnesses by Gender at Month 9

Modified Intent-to-Treat Population

Study Population: Modified Intent-to-Treat Population (N = xxx)

<By Variable >: XXXXXX (N = xxx)

Visit	Statistics	Test Group (N = xxx)	Control Group (N = xxx)	Overall (N = xxx)
		Observed Value	Observed Value	Observed Value
MONTH 9	n	xxx	xxx	
	MEAN	xx.xx	xx.xx	
	SD	xx.xxx	xx.xxx	
	SE	x.xx	x.xx	
	MEDIAN	x.xx	x.xx	
	MINIMUM	xx.x	xx.x	
	MAXIMUM	xx.x	xx.x	

Test Group: Fortified malt based food + Dietary Counselling; Control Group: Dietary Counselling

Program: xxxxxx.sas Source: Filename Page x of y

Protocol 204477 Program Run Date: DDMMMYYYY

14.2.13.4.2

Statistical Analysis of Number of Ill Days Due to GI and Respiratory Illnesses by Gender at Month 9

Modified Intent-to-Treat Population

Study Population: Modified Intent-to-Treat Population (N = xxx)

<By Variable >: XXXXXX (N = xxx)

Visit	Group	N	Adjusted Mean	SE	95% CI	P-Value	Intracluster Correlation	Comparison with Control Group		
								Difference (SE)	95% CI	P-Value
MONTH 9	Test Group	xxx	xx.xx	xx.xxx	xx.xx, xx.xx	0.xxxx	x.xxx	xx.xx (xx.xxx)	xx.xx, xx.xx	0.xxxx
	Control Group	xxx	xx.xx	xx.xxx	xx.xx, xx.xx	0.xxxx				

Test Group: Fortified malt based food + Dietary Counselling; Control Group: Dietary Counselling

Analysis was performed using ANCOVA model with cluster (school) as a random effect; product group and gender as fixed effects and baseline IDDS as covariate.

Difference is Test Group minus Control Group such that a negative difference favors the Test Group.

Intracluster correlation performed on complete model.

Confidence interval (CI) is presented as calculated (not truncated) and could present also negative values. Such negative values within CI no to be used for result interpretations.

Program: xxxxxx.sas Source: Filename Page x of y

Protocol: 204477 Program Run Date: DDMMMYYYY

Table 14.2.13.11

Correlation between Blood Chemistry and Gut Integrity Health by Lactulose: Mannitol and Urinary Neopterin Test by Time Point

Modified Intent-To-Treat Population

Study Population: Modified Intent-to-Treat Population (N=XXX)

Time point: Baseline

	Test Group (N=xx)			Control Group (N=xx)	
	Lactulose Mannitol	Urinary Neopterin Test		Lactulose Mannitol	Urinary Neopterin Test
Vitamin A	xx.x	xx.x	Vitamin A	xx.x	xx.x
Vitamin B12	xx.x	xx.x	Vitamin B12	xx.x	xx.x
Vitamin D	xx.x	xx.x	Vitamin D	xx.x	xx.x
Vitamin E	xx.x	xx.x	Vitamin E	xx.x	xx.x
Folate	xx.x	xx.x	Folate	xx.x	xx.x
Selenium	xx.x	xx.x	Selenium	xx.x	xx.x
Zinc	xx.x	xx.x	Zinc	xx.x	xx.x
Copper	xx.x	xx.x	Copper	xx.x	xx.x
Iron	xx.x	xx.x	Iron	xx.x	xx.x

Test Group: Fortified malt based food + Dietary Counselling; Control Group: Dietary Counselling

Program: xxxxxx.sas Source: Filename Page x of y

Programming Note: *The same structure will be in the next page for MONTH 9*

Protocol: 204477 Program Run Date: DDMMMYYYY

Table 14.3.1.1

Treatment Emergent Adverse Event by System Organ Class and Preferred Term

Safety Population

Study Population: Safety Population (N=xxx)

System Organ Class Preferred Term	Test Group (N = xxx)		Control Group (N = xxx)		Overall (N = xxx)	
	n (%)	nAE	n (%)	nAE	n (%)	nAE
NUMBER OF SUBJECTS WITH AT LEAST ONE AE	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx
NUMBER OF SUBJECTS WITH NO AE	xx (xx.x)		xx (xx.x)		xx (xx.x)	
SOC 1	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx
PT 1	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx
PT 2	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx

SOC 2	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx
PT 1	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx
PT 2	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx

System Organ Class Preferred Term	Test Group (N = xxx)		Control Group (N = xxx)		Overall (N = xxx)	
	n (%)	nAE	n (%)	nAE	n (%)	nAE

Test Group: Fortified malt based food + Dietary Counselling; Control Group: Dietary Counselling

n (%) = Number (percent) of subjects; nAE = Number of adverse events.

Program: xxxxxx.sas Source: Filename Page x of y

Programming Note: *Similar table will be generated for treatment related adverse events.*

Protocol 204477 Program Run Date: DDMMYYYY

Table 14.3.1.3

Treatment Emergent Adverse Event by System Organ Class, Preferred Term and Severity

Safety Population

Study Population: Safety Population (N=xxx)

System Organ Class Preferred Term	Severity	Test Group (N = xxx)		Control Group (N = xxx)		Overall (N = xxx)	
		n (%)	nAE	n (%)	nAE	n (%)	nAE
System Organ Class 1	Mild	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx
	Moderate	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx
	Severe	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx
Preferred Term 1	Mild	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx
	Moderate	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx
	Severe	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx
Preferred Term 2	Mild	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx
	Moderate	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx
	Severe	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx

Test Group: Fortified malt based food + Dietary Counselling; Control Group: Dietary Counselling

n (%) = Number (percent) of subjects; nAE = Number of adverse events.

Program: xxxxxx.sas Source: Filename Page x of y

Protocol 204477 Program Run Date: DDMMMYYYY

Table 14.3.5.1

Summary of Vital Signs and Anthropometry Parameters

Safety Population

Study Population: Safety Population (N = xxx)

Parameter: <Parameter Name (Unit)>

Visit	Statistics	Test Group (N = xxx)		Control Group (N = xxx)		Overall (N = xxx)
		Observed Value	Change from Baseline	Observed Value	Change from Baseline	Observed Value
SCREENING	n	xxx		xxx		xxx
	MEAN	xxx.x		xxx.x		xxx.x
	SD	xxx.xx		xxx.xx		xxx.xx
	SE	xxx.xx		xxx.xx		xxx.xx
	MEDIAN	xxx.x		xxx.x		xxx.x
	MINIMUM	xxx		xxx		xxx
	MAXIMUM	Xxx		Xxx		Xxx
MONTH 9	n	xxx	xxx	xxx	xxx	
	MEAN	xxx.x	xxx.x	xxx.x	xxx.x	
	SD	xxx.xx	xxx.xx	xxx.xx	xxx.xx	
	SE	xxx.xx	xxx.xx	xxx.xx	xxx.xx	

Visit	Statistics	Test Group (N = xxx)		Control Group (N = xxx)		Overall (N = xxx)
	MEDIAN	xxx.x	xxx.x	xxx.x	xxx.x	
	MINIMUM	xxx	xxx	xxx	xxx	
	MAXIMUM	Xxx	Xxx	Xxx	Xxx	

Test Group: Fortified malt based food + Dietary Counselling; Control Group: Dietary Counselling

Program: xxxxxx.sas Source: Filename Page x of y

Programming Note: *This table will continue for all other scheduled visits and for all vital signs [Height (cm), Weight (kg), BMI (kg/m2), Heat rate (beats/min), Height for age Z score, and Oral body temperature (ºF)]. Display overall only for the baseline visit.*

Protocol 204477 Program Run Date: DDMMMYYYY

Table 14.3.5.3

Shift Table for Lactulose: Mannitol Test and Urinary Neopterin Test (unit)

Safety Population

Study Population: Safety Population (N = xxx)

Parameter: <Parameter (Unit)>, Reference range: <xx-xx>

		Test Group					Control Group				
		Baseline					Baseline				
Visit	Result	Low n (%)	Normal n (%)	High n (%)	Missing n (%)	Total n (%)	Low n (%)	Normal n (%)	High n (%)	Missing n (%)	Total n (%)
Baseline	Low	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Normal										
	High										
	Missing										
	Total										
Month 9	Low	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Normal										
	High										
	Missing										
	Total										

		Test Group					Control Group				
		Baseline					Baseline				
	Result	Low	Normal	High	Missing	Total	Low	Normal	High	Missing	Total
Visit		n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)

Low, normal, and high categories defined by reference ranges.

Test Group: Fortified malt based food + Dietary Counselling; Control Group: Dietary Counselling

Program: xxxxxx.sas Source: Filename Page x of y

Programming Note: *This table will continue for all other scheduled visits and laboratory parameters*

Protocol 204477 Program Run Date: DDMMYYYY

Listing 16.1.7

Randomization Information

School Number	School Name	Randomization Number	Product Group
XXXXXX		XXXXXX	

Program: xxxxxx.sas Source: Filename Page x of y

Protocol 204477 Program Run Date: DDMMYYYY

Listing 16.2.1.1

Subject Disposition

Enrolled Population

Study Population: Enrolled Population (N=xx)

Product Group: Test Group

School Number	Subject Number	Age/ Sex /Race [1]	Screening Date	Study Product Start Date and Time	Last Study Product Administration Date and Time	Date of Completion or Withdrawal	Duration in the Study (days) [2]	Completed the Study	Primary Reason for Withdrawal	Further Details [3]
XXXXXX	XXXXXX	XX/A1	DDMMMYYYY	DDMMMYYYY:HH:MM	DDMMMYYYY:HH:MM	DDMMMYYYY	XXX	Yes		
XXXXXX	XXXXXX	XX/A6	DDMMMYYYY	DDMMMYYYY:HH:MM	DDMMMYYYY:HH:MM	DDMMMYYYY	XXX	No	Other	XXXXXX
XXXXXX	XXXXXX	XX/A4	DDMMMYYYY	DDMMMYYYY:HH:MM	DDMMMYYYY:HH:MM	DDMMMYYYY				

Test Product: Fortified malt based food + Dietary Counselling; Control Product: Dietary Counselling

[1] Age in years; Sex: F = Female, M = Male; Race: A1 = African American/African Heritage, A2 = American Indian Or Alaskan Native,A3 = Asian-Central/South Asian Heritage, A4 = Asian-East Asian Heritage, A5 = Asian-Japanese Heritage, A6 = Asian-South East Asian Heritage, N = Native Hawaiian Or Other Pacific Islander, W1 = White-Arabic/North African Heritage, W2 = White - White/Caucasian/European Heritage, MT = Multiple.

[2] Duration in the study = (Date of completion/withdrawal minus date of baseline visit)+ 1

[3] Further details of reasons for withdrawal.

Program: xxxxxx.sas Source: Filename Page x of y

Protocol 204477 Program Run Date: DDMMYYYY

Listing 16.2.1.2

Subject Disposition

Non-Enrolled Population

Subject Number	Age/Sex/Race [1]	Screening Date	Reason for Screen Failure	Further Details [2]
XXXXXX	XX/A1	DDMMMYYYY	XXXXXX	XXXXXX

[1] Age in years; Sex: F = Female, M = Male; Race: A1 = African American/African Heritage, A2 = American Indian Or Alaskan Native,A3 = Asian-Central/South Asian Heritage, A4 = Asian-East Asian Heritage, A5 = Asian-Japanese Heritage, A6 = Asian-South East Asian Heritage, N = Native Hawaiian Or Other Pacific Islander, W1 = White-Arabic/North African Heritage, W2 = White - White/Caucasian/European Heritage, MT = Multiple.

[2] Further details of reasons for screen failure.

Program: xxxxxx.sas Source: Filename Page x of y

Protocol 204477 Program Run Date: DDMMYYYY

Listing 16.2.2.1

Major Protocol Deviations

Enrolled Population

Study Population: Enrolled Population (N=xx)

Product Group: Test Group

Subject Number	Age/Sex/Race [1]	Visit(s)Excluded from PP Population	Deviation Reason
10001	25/I	All	Did not meet Inclusion criteria
		From Visit 3	Inclusion criteria
		Visit 4 only	Treatment non-compliance

Test Group: Fortified malt based food + Dietary Counselling; Control Group: Dietary Counselling

[1] Age in years; Sex: F = Female, M = Male; Race: A1 = African American/African Heritage, A2 = American Indian Or Alaskan Native,A3 = Asian-Central/South Asian Heritage, A4 = Asian-East Asian Heritage, A5 = Asian-Japanese Heritage, A6 = Asian-South East Asian Heritage, N = Native Hawaiian Or Other Pacific Islander, W1 = White-Arabic/North African Heritage, W2 = White - White/Caucasian/European Heritage, MT = Multiple

Program: xxxxxx.sas Source: Filename Page x of y

Programming Note: *This listing is based on details in the population definition document.*

Protocol 204477 Program Run Date: DDMMYYYY

Listing 16.2.2.2

Minor Protocol Deviations

Enrolled Population

Study Population: Enrolled Population (N=xx)

Product Group: Test Group

Subject Number	Age/Sex/Race [1]	Deviation Sequence	Start Date/Time of Deviation	End Date/Time of Deviation	Deviation Description
XXXXXX	XX/A1	1	DDMMMYYYY:HH:MM	DDMMMYYYY:HH:MM	XXXXXX

Test Group: Fortified malt based food + Dietary Counselling; Control Group: Dietary Counselling

[1] Age in years; Sex: F = Female, M = Male; Race: A1 = African American/African Heritage, A2 = American Indian Or Alaskan Native,A3 = Asian-Central/South Asian Heritage, A4 = Asian-East Asian Heritage, A5 = Asian-Japanese Heritage, A6 = Asian-South East Asian Heritage, N = Native Hawaiian Or Other Pacific Islander, W1 = White-Arabic/North African Heritage, W2 = White - White/Caucasian/European Heritage, MT = Multiple

Program: xxxxxx.sas Source: Filename Page x of y

Protocol 204477 Program Run Date: DDMMYYYY

Listing 16.2.3.1

Exclusion from Analysis Populations

Enrolled Population

Study Population: Enrolled Population (N=xx)

Product Group: Test Group

Subject Number	Age/Sex/Race[1]	Safety Population	ITT Population	mITT Population	PP population
XXXXXX	XX/A1	YES	YES	YES	YES

Test Group: Fortified malt based food + Dietary Counselling; Control Group: Dietary Counselling

[1] Age in years; Sex: F = Female, M = Male; Race: A1 = African American/African Heritage, A2 = American Indian Or Alaskan Native,A3 = Asian-Central/South Asian Heritage, A4 = Asian-East Asian Heritage, A5 = Asian-Japanese Heritage, A6 = Asian-South East Asian Heritage, N = Native Hawaiian Or Other Pacific Islander, W1 = White-Arabic/North African Heritage, W2 = White - White/Caucasian/European Heritage, MT = Multiple

Program: xxxxxx.sas Source: Filename Page x of y

Programming Note: *This listing is based on population definition document.*

Protocol 204477 Program Run Date: DDMMYYYY

Listing 16.2.4.1

Demographic and Baseline Characteristics

Enrolled Population

Study Population: Enrolled Population (N=xx)

Product Group: Test Group

Subject Number	Age (years)	Sex	Race	Height (cm)	Weight (kg)	Body Mass Index (kg/m^2)	Height for age Z score
XXXXXX	XX	Female	African American/African Heritage	xxx.x	xxx.x	xx.x	
XXXXXX	XX	Female	African American/African Heritage	xxx.x	xxx.x	xx.x	

Test Group: Fortified malt based food + Dietary Counselling; Control Group: Dietary Counselling

Program: xxxxxx.sas Source: Filename Page x of y

Protocol 204477 Program Run Date: DDMMYYYY

Listing 16.2.4.2

Medical History

Enrolled Population

Study Population: Enrolled Population (N=xx)

Product Group: Test Group

Subject Number	Age/Sex/Race[1]	Any Medical History	Medical Condition	Start Date	End Date or Ongoing
XXXXXX	XX/A1	Yes	XXXXXX	DDMMMYYYY	DDMMMYYYY
XXXXXX	XX/A6	Yes	XXXXXX	DDMMMYYYY	Ongoing

Test Group: Fortified malt based food + Dietary Counselling; Control Group: Dietary Counselling

[1] Age in years; Sex: F = Female, M = Male; Race: A1 = African American/African Heritage, A2 = American Indian Or Alaskan Native,A3 = Asian-Central/South Asian Heritage, A4 = Asian-East Asian Heritage, A5 = Asian-Japanese Heritage, A6 = Asian-South East Asian Heritage, N = Native Hawaiian Or Other Pacific Islander, W1 = White-Arabic/North African Heritage, W2 = White - White/Caucasian/European Heritage, MT = multiple

Program: xxxxxx.sas Source: Filename Page x of y

Protocol 207192 Program Run Date: DDMMYYYY

Listing 16.2.5.1

Study Product Administration and Compliance

Enrolled Population

Study Population: Enrolled Population (N=xx)

Product Group: Test Group

Subject Number	Age/ Race [1]	Visit	Exposure[2]	Expected amount of drink to be consumed[3]	Actual Amount of Drink Consumed [4]	Test Group Compliance (%)[5]	Dietary Counselling Compliance			
							Mandatory session compliance [6]		Follow up session compliance (participants and parents)[7]	
							Participants	Parents/LAR	Participants	Parents/LAR
XXXXXX	XX/A 1	Overall								
		Overall		x	x	98				

Test Group: Fortified malt based food + Dietary Counselling; Control Group: Dietary Counselling

[1] Age in years; Race: A1 = African American/African Heritage, A2 = American Indian Or Alaskan Native, A3 = Asian-Central/South Asian Heritage, A4 = Asian-East Asian Heritage, A5 = Asian-Japanese Heritage, A6 = Asian-South East Asian Heritage, N = Native Hawaiian Or Other Pacific Islander, W1 = White-Arabic/North African Heritage, W2 = White – White/Caucasian/European Heritage, MT = multiple.

[2] Exposure for test group: date of last day in the study - date of first date of test group administration +1; Exposure for control group: date of last day in the study - date of first date of dietary counselling +1.

[3] Expected consumption = 2X 150 mL of drink X number of days between first and last treatment day in the study

[4] Actual consumption = [Expected consumption - (xx mL total left over at morning + xx mL left over at evening)]

[5] Test product compliance in %= (actual consumption/ expected consumption) X 100

[6] Mandatory sessions compliance by both participants and patents=(Number of sessions out of session numbers 1 or 2 attended by participant/ parents divided by 2) X 100

[7] Compliance with Follow-up sessions dietary counselling= (Number of sessions out of session numbers 3-7 attended by participant and/or parents/LAR divided by 5) X 100

Program: xxxxxx.sas Source: Filename Page x of y

Protocol 204477 Program Run Date: DDMMYYYY

Listing 16.2.5.2

Prior Medications

Enrolled Population

Study Population: Enrolled Population (N=xx)

Product Group: Test Group

Subject Number	Age/Sex/Race[1]	Sequence Number	Drug Name [GSK Drug Synonym]	Reason for Medication	Route of Admin.	Dose per Admin. (unit)	Frequency	Start Date (Study Day [2])	End Date/ Ongoing
XXXXXX	XX/A6	1	XXXXXX [XXXXXX]	XXXXXX	XXXXXX	XXXXXX (xx)	XXXXXX	DDMMMYYYY (XX)	Ongoing
XXXXXX	XX/A6	1	XXXXXX [XXXXXX]	XXXXXX	XXXXXX	XXXXXX (xx)	XXXXXX	DDMMMYYYY (XX)	DDMMMYYYY

Test Group: Fortified malt based food + Dietary Counselling; Control Group: Dietary Counselling

[1] Age in years; Sex: F = Female, M = Male; Race: A1 = African American/African Heritage, A2 = American Indian Or Alaskan Native,A3 = Asian-Central/South Asian Heritage, A4 = Asian-East Asian Heritage, A5 = Asian-Japanese Heritage, A6 = Asian-South East Asian Heritage, N = Native Hawaiian Or Other Pacific Islander, W1 = White-Arabic/North African Heritage, W2 = White - White/Caucasian/European Heritage, MT=Multiple.

[2] Study day relative to the date of first date of dietary counselling.

Program: xxxxxx.sas Source: Filename Page x of y

Programming Note: *Similar listing will be generated for Concomitant Medications and Non-Drug Therapies.*

Protocol 204477 Program Run Date: DDMMYYYY

Listing 16.2.6.1

Urine Neopterin Assay

Enrolled Population

Study Population: Enrolled Population (N=xx)

Product Group: Test Group

Subject Number	Age/Sex /Race [1]	Visit	Date of Visit	Was Assessment Performed?	Date of Sample Collection/Time of Sample Collection	Normal Range	Panic Range	Result (unit)	Abnormality [2]	Change from Baseline	Comment
XXXXXX	XX/N	Screening	DDMMMYYYY	Yes		xx.x-xx.x	xx.x-xx.x	xx.x	L		xxx
		Baseline	DDMMMYYYY					xx.x	H		xxxx
		Visit 5	DDMMMYYYY	Yes				xx.x	CS	xx.x	xxxxx
		Visit 6	DDMMMYYYY							xx.x	

Programming Note:

- *Repeat the same layout for listing 16.2.6.2-16.2.6.16*

Protocol 204477 Program Run Date: DDMMYYYY

Listing 16.2.6.17

Listing of Normal Range for Saliva Blood and Urine Parameters

Parameter (Unit)	Biological Matrix	Gender	Age Range (in years)	Normal Range		Panic Range	
				Lower Limit	Upper Limit	Lower Limit	Upper Limit
Serum Type I Collagen Cross-linked C-telopeptide (unit)	Blood	Male	xx-xx				
		Female	xx-xx				

Program: xxxxxx.sas Source: Filename Page x of y

Protocol 204477 Program Run Date: DDMMYYYY

Listing 16.2.6.18

Listing of Diagnosis Data

Enrolled Population

Study Population: Enrolled Population (N=xx)

Product Group: Test Product

Subject Number	Age/Sex/Race[1]	Sequence Number	Diagnosis	Start Date	End Date	Severity	School Absenteeism (No. of days in this week)
XXXXXX	XX/N		Vomiting	31MAR2018	DDMMMYYYY	Mild	No

Test Group: Fortified malt based food + Dietary Counselling; Control Group: Dietary Counselling

[1] Age in years; Sex: F = Female, M = Male; Race: A1 = African American/African Heritage, A2 = American Indian Or Alaskan Native,A3 = Asian-Central/South Asian Heritage, A4 = Asian-East Asian Heritage, A5 = Asian-Japanese Heritage, A6 = Asian-South East Asian Heritage, N = Native Hawaiian Or Other Pacific Islander, W1 = White-Arabic/North African Heritage, W2 = White - White/Caucasian/European Heritage.

Program: xxxxxx.sas Source: Filename Page x of y

Protocol 204477 Program Run Date: DDMMYYYY

Listing 16.2.7.1

All Adverse Events

Enrolled Population

Study Population: Enrolled Population (N=xx)

Product Group: Test Group

Subject Number	Age/Sex/Race[1]	Adverse Event (Preferred Term) [System Organ Class]	Start Date/Time/ Study Day[2]	End Date/ Time	Frequency/ Intensity	Related to Study Product?	Action Taken with Study Product	Outcome	Serious?	Subject Withdrawn
XXXXXX	XX/N	HEADACHE (NERVOUS SYSTEM DISORDER) [xxxxxxx]	31MAR2017/ HH:MM:SS/ 3	DDMMMYYYY/ HH:MM:SS	SINGLE EPISODE/ MILD	No	NOT APPLICABLE	RECOVERED/ RESOLVED	NO	NO

Test Group: Fortified malt based food + Dietary Counselling; Control Group: Dietary Counselling

[1] Age in years; Sex: F = Female, M = Male; Race: A1 = African American/African Heritage, A2 = American Indian Or Alaskan Native,A3 = Asian-Central/South Asian Heritage, A4 = Asian-East Asian Heritage, A5 = Asian-Japanese Heritage, A6 = Asian-South East Asian Heritage, N = Native Hawaiian Or Other Pacific Islander, W1 = White-Arabic/North African Heritage, W2 = White - White/Caucasian/European Heritage.

[2] Study day relative to the date of first date of dietary counselling

Program: xxxxxx.sas Source: Filename Page x of y

Programming Note for Listing 16.2.7.2:

- *Repeat the same layout for listing 16.2.7.2*
- *Population should be used 'Non randomized Subjects'*
- *The fourth column should be only 'Start Date/Time (take out Study Day)'*
- *Delete the footnote related to study day and adjust the numbers accordingly.*

Protocol 204477 Program Run Date: DDMMYYYY

Listing 16.2.9.1

Vital Signs and Anthropometry Parameter

Enrolled Population

Study Population: Enrolled Population (N=xx)

Product Group: Test Group

Subject Number	Age/Sex /Race[1]	Visit	Date of Visit	Date of Assessment	Height (cm)		Weight (Kg)		Heart Rate (beats/min)		Oral Temperature (F)		Height for age Z score	
					Observed value	Change from Baseline	Observed value	Change from Baseline	Observed value	Change from Baseline	Observed value	Change from Baseline	Observed value	Change from Baseline
		Screening	DDMMM YYYY	DDMMMYYYY										

Test Group: Fortified malt based food + Dietary Counselling; Control Group: Dietary Counselling

[1] Age in years; Sex: F = Female, M = Male; Race: A1 = African American/African Heritage, A2 = American Indian Or Alaskan Native, A3 = Asian-Central/South Asian Heritage, A4 = Asian-East Asian Heritage, A5 = Asian-Japanese Heritage, A6 = Asian-South East Asian Heritage, N = Native Hawaiian Or Other Pacific Islander, W1 = White-Arabic/North African Heritage, W2 = White - White/Caucasian/European Heritage, MT=Multiple.

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Programmer Note: Please also include information for Body Mass Index (kg/m^2) prior to Height (cm)

Protocol 204477 Program Run Date: DDMMYYYY

Listing 16.2.9.2

Physical Examination

Enrolled Population

Study Population: Enrolled Population (N=xx)

Product Group: Test Group

Subject Number	Age/Sex Race[1]	Visit	Date of Visit	Body System	Finding	Description of Abnormality, CS or Not Examined
XXXXXX	XX/N	Screening	DDMMMYYYY	CNS	Normal	
				Eyes	Normal	
				ENT	Abnormal, CS	xxxxxx
				Respiratory	Normal	

Test Group: Fortified malt based food + Dietary Counselling; Control Group: Dietary Counselling

[1] Age in years; Sex: F = Female, M = Male; Race: A1 = African American/African Heritage, A2 = American Indian Or Alaskan Native, A3 = Asian-Central/South Asian Heritage, A4 = Asian-East Asian Heritage, A5 = Asian-Japanese Heritage, A6 = Asian-South East Asian Heritage, N = Native Hawaiian Or Other Pacific Islander, W1 = White-Arabic/North African Heritage, W2 = White - White/Caucasian/European Heritage, MT=Multiple.

Program: xxxxxx.sas Source: Filename Page x of y

Programming Note for Listing 16.2.9.2: If subjects has abnormality description and CS description, please concatenate both separating with ‘,’.

Protocol 204477 Program Run Date: DDMMYYYY

Listing 16.2.9.3

Hemoglobin Assessment

Enrolled Population

Study Population: Enrolled Population (N=xx)

Product Group: Test Group

Subject Number	Age/Sex/Race [1]	Visit	Date of Visit	Was Hb Assessment Performed?	Hb Assessment Results (g/dL)
					Observed value
XXXXXX	XX/N	Screening	DDMMMYYYY	Yes	
		Baseline	DDMMMYYYY		xx.x
					xx.x
		Visit 5	DDMMMYYYY	Yes	
		Visit 6	DDMMMYYYY		xx.x

Test Group: Fortified malt based food + Dietary Counselling; Control Group: Dietary Counselling

[1] Age in years; Sex: F = Female, M = Male; Race: A1 = African American/African Heritage, A2 = American Indian Or Alaskan Native, A3 = Asian-Central/South Asian Heritage, A4 = Asian-East Asian Heritage, A5 = Asian-Japanese Heritage, A6 = Asian-South East Asian Heritage, N = Native Hawaiian Or Other Pacific Islander, W1 = White-Arabic/North African Heritage, W2 = White - White/Caucasian/European Heritage, MT=Multiple.

Program: xxxxxx.sas Source: Filename Page x of y

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