STATISTICAL REPORTING AND ANALYSIS PLAN

A RANDOMIZED, 8 WEEK CLINICAL STUDY TO EVALUATE THE EFFICACY OF AN EXPERIMENTAL STANNOUS FLUORIDE DENTIFRICE IN THE RELIEF OF DENTINAL HYPERSENSITIVITY

Protocol Number: 208153

Phase: N/A

Document History

Document	Version Date	Summary of Changes (New analysis or Change in planned analysis)
Final Analysis Plan	14-Dec-2017	Not applicable (N/A)

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Abbreviations

Abbreviation	Definition
AE	Adverse Event
ANCOVA	Analysis Of Covariance
BDRM	Blinded Data Review Meeting
CI	Confidence Interval
DH	Dentinal Hypersensitivity
eCRF	Electronic Case Report Form
GCS	Global Clinical Supplies
GSKCH	GlaxoSmithKline Consumer Healthcare
ITT	Intent-To-Treat
MedDRA	Medical Dictionary For Regulatory
N	Number Of Subjects
NAF	Sodium Fluoride
OST	Oral Soft Tissue
PP	Per Protocol
ppm	Parts Per Million
RLR	Review Listing Requirement
SAE	Serious Adverse Event
SD	Standard Deviation
SE	Standard Error
SMFP	Sodium Monofluorophosphate
$SnCl_2$	Stannous Chloride
SnF_2	Stannous fluoride
SOC	System Organ Class
w/w	Weight/Weight

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 208153.

1 Summary of Key Protocol Information

The purpose of this trial is to demonstrate the efficacy and safety of a experimental 0.454% weight/weight (w/w) Stannous fluoride (SnF_2) dentifrice to treat the symptoms of Dentinal Hypersensitivity (DH). Efficacy will be demonstrated as a treatment difference in favour of the 0.454% w/w SnF_2 dentifrice versus the Negative Control dentifrice for the primary efficacy outcome, Schiff sensitivity score at Week 8. Safety will be demonstrated through assessment of adverse events (AEs).

1.1 Study Design

Overall Design
This will be a single centre, randomized, controlled, examiner-blind, 3 treatment arm, parallel group design study, stratified by maximum baseline Schiff sensitivity score (of the 2 selected test teeth), with a treatment period of 8 weeks, to investigate the clinical effectiveness of an experimental SnF_2 dentifrice in the reduction of DH. DH will be assessed at Baseline, and after 4 and 8 weeks treatment. The study will be conducted in healthy subjects with pre-existing self-reported and clinically diagnosed tooth sensitivity at Screening, in a Chinese population. An acclimatization period of 2-6 weeks will be included in this study, given that 2 weeks is understood to be an expected amount of time to minimize the potential for carry over effects from prior use of anti-sensitivity products. In line with Chinese Ministry of Health guidelines [Ministry of Health (China), 2010] for the testing of functional dentifrices (desensitizing), a standard fluoride dentifrice with no specific anti-sensitivity, anti-gingivitis and anti-plaque activity (Chinese marketed Colgate Triple Protection) will be included as the negative control (Negative Control). A Chinese marketed positive control (Positive Control) dentifrice with sensitivity benefits (Crest 7-Effects Strengthen Dental Enamel toothpaste, containing stannous chloride ($SnCl_2$)) will also be included in this study design as a benchmark of performance in the Chinese population.

1.2 Study Objectives

Objectives	Endpoints
Primary Objective	**Primary Endpoint**
• To compare the clinical efficacy of an experimental 0.454% w/w SnF_2 dentifrice for the relief of DH, as elicited by an evaporative air stimulus (with Schiff sensitivity score), against	• Change from baseline in Schiff sensitivity score at 8 weeks.

Objectives	Endpoints
a negative control dentifrice, when used twice daily for 8 weeks.	
Secondary Objectives	**Secondary Endpoints**
• To compare the clinical efficacy of an experimental 0.454% w/w SnF_2 dentifrice for the relief of DH, as elicited by a tactile stimulus (Yeaple probe), against a negative control dentifrice, when used twice daily for 8 weeks.	• Change from baseline in tactile threshold (Yeaple probe) at 8 weeks.
Exploratory Objectives	**Exploratory Endpoints**
• To compare the clinical efficacy of an experimental 0.454% w/w SnF_2 dentifrice for the relief of DH, as elicited by an evaporative air stimulus (with Schiff sensitivity score), against a positive control dentifrice, when used twice daily for 4 and 8 weeks.	• Change from baseline in Schiff sensitivity score at 8 weeks.
• To compare the clinical efficacy of an experimental 0.454% w/w SnF_2 dentifrice for the relief of DH, as elicited by an evaporative air stimulus (with Schiff sensitivity score), against a negative control dentifrice, when used twice daily for 4 weeks.	• Change from baseline in Schiff sensitivity score at 4 weeks.
• To compare the clinical efficacy of an experimental 0.454% w/w SnF_2 dentifrice for the relief of DH, as elicited by a tactile stimulus (Yeaple probe),against a negative control dentifrice, when used twice daily for 4 weeks.	• Change from baseline in in tactile threshold (Yeaple probe) at 4 weeks.
• To compare the clinical efficacy of an experimental 0.454% w/w SnF_2 dentifrice for the relief of DH, as elicited by a tactile stimulus (Yeaple probe),against a positive control dentifrice, when used twice daily for 4 and 8 weeks.	• Change from baseline in tactile threshold (Yeaple probe) at 4 and 8weeks.
• To compare the clinical efficacy of a positive control dentifrice for the relief of DH, as elicited by a tactile	• Change from baseline in tactile threshold (Yeaple probe) at 4 and 8weeks.

Objectives	Endpoints
stimulus (Yeaple probe), against a negative control dentifrice, when used twice daily for 4 and 8 weeks.	
• To compare the clinical efficacy of a positive control dentifrice for the relief of DH, as elicited by an evaporative air stimulus (with Schiff sensitivity score) against a negative control dentifrice,when used twice daily for 4 and 8 weeks	• Change from baseline in Schiff sensitivity score at 4 and 8 weeks.
Safety	
• To evaluate the safety and oral tolerability of the test dentifrices when used twice daily for 8 weeks.	• Adverse Events

1.3 Treatment

The following study products will be supplied by Global Clinical Supplies (GCS), Glaxosmithkline Consumer Health (GSK CH):

- **Test Product:** Experimental dentifrice containing 0.454% SnF_2 and 0.072% NaF (1450 ppm fluoride in total); CCI .
- **Negative Control:** Colgate Triple Protection dentifrice containing 1400 ppm fluoride as sodium monofluorophosphate (SMFP); Chinese Marketplace.
- **Positive Control:** Crest 7-Effects Strengthen Dental Enamel dentifrice containing $SnCl_2$ and 0.15% NaF (1450 ppm fluoride in total); Chinese marketplace.

Other items to be supplied by the GCS Department, GSK CH:

- **Acclimatization dentifrice:** Colgate Strengthen Fresh Dentifrice containing 1400ppm fluoride as SMFP (Chinese Marketplace).
- Aquafresh Clean Control Toothbrush (UK market place).
- Countdown timers.

1.4 Sample Size Calculation

Change from baseline in Schiff sensitivity score will be used to evaluate treatment effects with regard to the primary objective. With 55 evaluable subjects per group, the study will have 80% power to detect a mean difference of 0.33 (standard deviation [SD]=0.619) in change from baseline in Schiff sensitivity score after 8 weeks of treatment.

The estimate of SD was obtained from GSKCH study 205794. The sample size is based on carrying out 2-tailed 2 sample t-test at a 5% significance level.

Therefore, to allow for dropouts a sufficient amount of subjects will be screened to randomize approximately 180 subjects to ensure 165 subjects (approximately 55 per arm) complete 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 subjects 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 unblinding 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 all endpoints, the baseline value will be the latest Day1 (Visit 2) pre-dose assessment 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

Subgroups are not defined for this trial.

Eligible subjects will be stratified according to their maximum baseline Schiff sensitivity score of the 2 selected teeth. The stratification factor will give rise to 2 strata.

Stratum 1: Maximum Schiff=2. These are subjects with maximum baseline Schiff sensitivity score of 2 for the 2 selected test teeth.

Stratum 2: Maximum Schiff=3. These are subjects with the maximum baseline Schiff sensitivity score of 3 for the 2 selected test teeth.

Efficacy variables will be analyzed accounting for strata.

3.3 Centers Pools

This is a single centre study, therefore pooling of centers is not required.

3.4 Timepoints and Visit Windows

The study schedule should be followed as per protocol. Deviations from the study schedule with respect to visit timings will be reviewed on a case-by-case basis to determine whether the data should be excluded from the Per-Protocol (PP) analysis (Section 4.1.2).

4 Data Analysis

Data analysis will be performed by inVentiv Health Clinical. The statistical analysis software used will be SAS version 9.4 (Studio).

Prior to database closure a Blinded Data Review Meeting (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 all randomized subjects.

4.1 Populations for Analysis

4.1.1 Subject Disposition

Screen failures are defined as subjects who consent to participate in the clinical study but are not subsequently randomized. A summary will be provided of the number of subjects screened and the number of screen failures with reasons why subjects are not randomized (Table 14.1.1). Percentages for not randomized subjects will be based on number of screened subjects.

Subject disposition will be summarized as the number and percentage of subjects who complete the study, with the number who discontinue broken down by reason for discontinuation (Table 14.1.1). The percentages are based on the total number of subjects randomized. The table will also summarise the number and percent of subjects assigned to each analysis population (defined in Section 4.1.3). The summary will be presented by treatment and overall.

Subject disposition including the subject status (completer, Yes/No), critical demographic data (age, sex, race and ethnicity), the duration of treatment (defined as date of completion or withdrawal minus date of first product application) and the specific reason for discontinuation, will be listed by treatment group for randomized subjects (Listing 16.2.1.1) and non-randomized subjects (Listing 16.2.1.2) separately.

4.1.2 Protocol Deviations

Important major protocol deviations (including deviations related to study inclusion/exclusion criteria, conduct of the trial, patient management or patient assessment) will be summarized and listed. Details of possible protocol deviation are provided in Protocol Deviation Management Plan (PDMP).

Protocol deviations will be tracked by the study team throughout the conduct of the study. Data will be reviewed prior to unblinding and closure of the database to ensure all important deviations are captured and categorized.

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

- Violations of inclusion or exclusion criteria that are deemed to affect efficacy
- Medical history which is deemed to affect efficacy.
- Use of prohibited treatment or medication before or during the study, which is felt to affect the assessment of efficacy.
- Not receiving randomised treatment.
- Treatment non-compliance.
- Assessments outside the scheduled time windows.
- Visit outside the planned schedule.
- Protocol deviations.

- Any other reason identified likely to affect efficacy.

Further deviations liable to influence the efficacy outcome will be given in the Review Listing Requirement (RLR) document where major deviations will be identified at the BDRM. The number and percentage of subjects with any major protocol deviation and with each type of major protocol deviations will be presented by treatment (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

Five analysis populations are defined.

Population	Definition / Criteria	Analyses Evaluated
All Screened Subjects	• All subjects who enter the study and sign the informed consent form. This population includes screen failures as well as those that are randomized.	• Disposition, AE listing
Randomized	• All subjects who are randomized and may or may not receive dose of the investigational product. • Any subject who receives a treatment randomization number will be considered to have been randomized.	• Protocol violations, AE, efficacy,demographic characteristic, disposition and medical history listings
Safety	• Comprise of all randomized subjects who receive at least one dose of study treatment. • This population will be based on the treatment the subject actually received.	• Safety
Intent-To-Treat (ITT)	• Comprise of all randomized subjects who receive at least one dose of study treatment and have at least one post-baseline efficacy evaluation. • This population will be based on the treatment to which the subject was randomized.	• Efficacy
Per-Protocol	• All subjects who are assessed as sufficiently compliant with study procedures and restrictions. • Subjects with major protocol deviations will be excluded. Depending on the nature of the major protocol deviation and impact on the efficacy variable (s),	• Efficacy

Population	Definition / Criteria	Analyses Evaluated
	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.	

The primary population for assessment of efficacy will be the ITT Population. A PP analysis will be performed on the primary and secondary efficacy variable if more than 10% of the subjects in the ITT Population are excluded from the PP Population.

Subjects excluded from the analysis populations will be listed (Listing 16.2.3.1).

4.2 Subject Demographics and Other Baseline Characteristics

4.2.1 Demographic Characteristics

Descriptive statistics (number of subjects, mean, standard deviation, median, minimum and maximum for continuous variables, and frequency and percentage for categorical variables) will be presented for demographic data by treatment group and overall. These data include age, gender, race, ethnicity and Schiff stratification categories and will be presented for the Safety (Table 14.1.4.1), ITT (Table 14.1.4.2) and if required on the PP Population (Table 14.1.4.3).

Demographic information will be listed (Listing 16.2.4.1) for all randomized subjects.

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 drug. A data listing will also be produced for evaluation of protocol violations at the blinded data review stage.

4.3 Study Product Compliance and Use of Other Therapy

4.3.1 Study Product Compliance and Exposure

Brushing compliance (using study product twice daily) will be presented in the listing (Listing 16.2.5.3) This listing also produced for the blinded data review .

Supervised brushing (subject number, date of visit and time of the supervised procedure and reason why the supervised brushing was not performed according to the protocol) will be listed in the listing (Listing 16.2.5.4). This listings also produced for the blinded data review.

Exposure to the study product will be listed in the listing (Listing 16.1.7)

4.3.2 Prior and Concomitant Medication

Prior treatment will be listed by subject, with, indication, dose, dose form, frequency, route, start date and end date (Listing 16.2.5.1). Prior treatment are defined as those which stopped before the first application of the study product. Concomitant treatment will be listed similarly (Listing 16.2.5.2). Concomitant treatment are defined as those ongoing or started on or after the first application of the study product.

4.3.3 Other Therapy/Rescue Medication

Not Applicable.

4.4 Analysis of Efficacy

4.4.1 Primary Efficacy Endpoint

4.4.1.1 Primary Efficacy Endpoint Definition

The change from baseline in Schiff sensitivity score at Week 8 is the primary efficacy endpoint.

The subjects Schiff sensitivity score will be derived as the average score of the 2 test teeth at each visit assessed. The change from baseline will be derived from the individual teeth first before calculating the average change of the 2 test teeth. For post-baseline observations, the average will be calculated only across teeth that have both a valid baseline and a valid post-baseline assessment.

Summary statistics of the observed mean Schiff sensitivity scores and changes from baseline will be presented by treatment at Baseline, Week 4 and Week 8 on the ITT Population (Table 14.2.1.1).

4.4.1.2 Statistical Hypothesis, Model, and Method of Analysis

The primary analysis is a comparison of the mean change from baseline Schiff sensitivity score between Test Product and Negative Control at Week 8.

The null hypothesis for the primary endpoint is that the mean change from baseline in Schiff sensitivity score is equal between the 2 products.

$\mathbf{H_0}$: $\mu_1 = \mu_2$

The alternative hypothesis is that the mean change from baseline in Schiff sensitivity score is not equal between the 2 products.

$\mathbf{H_1}$: $\mu_1 \neq \mu_2$

The change from baseline in Schiff sensitivity score at Week 8 will be analyzed using Analysis of Covariance (ANCOVA) with treatment as factor and mean baseline Schiff sensitivity score as covariate. Note that since the baseline Schiff sensitivity score will be included as a covariate, the baseline Schiff stratification value will not be included in the

model. Adjusted means of all treatments and their standard error (SE), P-value and 95% confidence interval (CIs) will be presented on the ITT Population (Table 14.2.1.2). Treatment differences of the treatment comparisons and SE of it will also be provided together with P-values and 95% CIs.

The assumption of normality and homogeneity of variance in the ANCOVA model will be investigated and if violated, data transformations will be investigated. If suitable transformations cannot be found, non-parametric Van Elteren tests will be performed adjusting for the maximum baseline Schiff sensitivity scores and results will be compared with the ANCOVA results. If the inferences from the 2 analyses are similar then both sets of results will be reported and emphasis will be made on the ANCOVA results. In case of discrepancies between p-values of ANCOVA and Van Elteren analysis, inferences will be drawn on the non-parametric analysis.

To visually inspect the treatment effect on Schiff sensitivity scores, a plot across time (Baseline, Week 4 and Week 8) will be displayed with raw means and SE bars. The plot will display a different symbol line for each treatment group (Figure 14.2.1).

4.4.2 Secondary Efficacy Variables

Secondary efficacy variables are defined in Section 4.5

4.4.3 Handling of Missing Values/Censoring/Discontinuations

Missing data will not be replaced or imputed. Subjects who withdraw from the study prematurely will be included in the statistical analyses up to the point of discontinuation.

4.5 Analysis of Secondary Objectives

4.5.1 Efficacy (Secondary)

The change from baseline in tactile threshold at Week 8

The change from baseline in tactile threshold at Week 8 is the secondary efficacy endpoint.

The null hypothesis for the secondary endpoint is that the mean change from baseline in tactile threshold is equal between the 2 products.

H0: $\mu_1 = \mu_2$

The alternative hypothesis is that the mean change from baseline in tactile threshold score is not equal between the 2 products.

H1: $\mu_1 \neq \mu_2$

This secondary efficacy variable analysis will be conducted for the following treatment comparison:

Test Product versus Negative Control at Week 8.

All other treatment comparisons based on the tactile threshold are part of the exploratory objectives.

The subjects tactile threshold will be derived as the average score of the 2 test teeth at each visit assessed and the change from baseline will be derived from the individual teeth first before calculating the average change of the 2 test teeth. If tactile threshold for test teeth is reported as "> 80g" at the post baseline assessments, the value will be taken as as 90g in the derivations.

Summary statistics of the observed mean tactile threshold scores and changes from baseline will be presented by treatment at Baseline, Week 4 and Week 8 (Table 14.2.2.1).

The change from baseline in tactile threshold at Week 8 will be calculated as the subject level mean change from baseline (on the 2 test teeth) and analyzed at Week 8 using ANCOVA with treatment and baseline Schiff stratification value as factors and baseline tactile threshold included as a covariate. Adjusted means of all treatments and their SEs, P-value and 95% CIs will be presented . Treatment differences and SE of all pairs of treatments will be provided together with P-values and 95% CIs (Table 14.2.2.2).

To visually inspect the treatment effect on tactile threshold scores, a plot across time, with the raw means together with SE bars will be produced. The plot will display a different symbol line for each treatment group (Figure 14.2.2).

The assumption of normality and homogeneity of variance in the ANCOVA model will be investigated and if violated, data transformations will be investigated. If suitable transformations cannot be found, non-parametric Van Elteren tests will be performed adjusting for the maximum baseline Schiff sensitivity scores and results will be compared with the ANCOVA results. If the inferences from the 2 analyses are similar then both sets of results will be reported and emphasis will be made on the ANCOVA results. In case of discrepancies between p-values of ANCOVA and van Elteren analysis, inferences will be drawn on the non-parametric analysis.

4.5.2 Pharmacokinetic (Secondary)

Not Applicable

4.6 Analysis of Exploratory Objectives

Exploratory analysis based on the exploratory efficacy variable change from baseline in Schiff sensitivity score and change from baseline in tactile threshold to post baseline (week 4 and 8) will be summarized, analyzed and presented as detailed for the primary and secondary endpoint respectively . Analysis assumptions will be investigated as detailed for the secondary efficacy analysis (Section 4.4.1 and 4.5.1).

The analysis will be conducted for exploratory efficacy variable of Schiff sensitivity scores and tactile threshold for below comparisison (Table 14.2.1.2 and Table 14.2.2.2).

- Test Product versus Negative Control at Week 4
- Test Product versus Positive Control at Week 4 and 8
- Negative Control versus Positive Control at Week 4 and 8

All data for each efficacy variable will be presented for each subject at Baseline, Week 4 and Week 8 (Listing 16.2.6.1 and Listing 16.2.6.2).

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 actual treatment received. The safety profile of the study treatments will be assessed with respect to AEs. Oral soft tissue (OST) abnormalities are included as AEs if they appear or worsen after the initial assessment.

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). During this review stage, AEs will be further categorized as oral or non-oral.

AEs will be regarded as treatment-emergent if they occur on or after the first treatment application at the baseline visit.; if this date is missing a suitable alternative will be used eg date of randomization). All other AEs prior to this will be considered non-treatment emergent.

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

- Table of treatment-emergent AEs by system organ class (SOC) and Preferred Term (PT) (Table 14.3.1.1)
- Table of treatment-emergent AEs by Oral/Non-Oral and PT (Table 14.3.1.2)
- Table of treatment-emergent treatment-related AEs by SOC and PT (Table 14.3.1.3)
- Table of treatment-emergent treatment-related serious adverse events (SAEs) by SOC and PT (Table 14.3.1.5) [only produced if there are more than 5 SAEs]
- Table of treatment-emergent treatment-related Non-serious SAEs by SOC and PT (Table 14.3.1.6) [only produced if there are more than 5 SAEs]
- Table of treatment-emergent treatment-related AEs by Oral/Non-Oral and PT (Table 14.3.1.4)
- Listing of all AEs (Listing 16.2.7.1 for all randomized subjects; Listing 16.2.7.2 for non-randomized subjects)
- Listing of deaths (Listing 14.3.2.1)
- Listing of non-fatal SAEs (Listing 14.3.2.2)
- Listing of treatment-emergent AEs leading to study or drug withdrawal (Listing 14.3.2.3)
- Listing of treatment-emergent AEs classified as oral (Listing 14.3.2.4)
- Listing of OST abnormalities (Listing 14.3.2.5)
- Listing of OHT abnormalities (Listing 14.3.2.6)

In the event that there is nothing to report, a null listing will be produced.

4.8 Analysis of Other Variables

To cover the Chinese Ministry of Health guideline requirement, to demonstrate at least a 15% difference between the Test Product and Negative Control, the difference between treatments in the raw means of the actual score (note: not change from baseline) will be calculated using below formula for Schiff sensitivity and tactile threshold at Weeks 4 and 8 (Table 14.2.1.1 and 14.2.2.1).

100*(Test Product- Negative Control Product)/ Negative Control Product

Similar difference will be calculated between Test product and Positive Control.

5 Changes to the Protocol Defined Statistical Analysis Plan

Changes from the originally planned statistical analysis specified in the protocol are outlined in below table

Protocol	Reporting & Analysis Plan	
Statistical Analysis section	**Statistical Analysis Plan**	**Rationale for Changes**
10.2.6. Definition of Analysis Populations • The ITT population includes all randomized subjects who receive at least one dose of investigational product and analysed as randomized. • The PP population includes all subjects who fully comply with all study procedures and restrictions and is a sub-set of the ITT population. Any protocol deviations that would lead to subjects/data being excluded will be removed from the PP	**4.1.3 Analysis Population** • Comprise of all randomized subjects who receive at least one dose of study treatment and have at least one post-baseline efficacy evaluation.This population will be based on the treatment to which the subject was randomized. • All subjects who are assessed as sufficiently compliant with study procedures and restrictions. • Subjects with major protocol deviations will be excluded. Depending on the nature of the	To keep consistency across oral studies and to differientate from IIT population definition from safety population.

Protocol	Reporting & Analysis Plan	
Statistical Analysis section	**Statistical Analysis Plan**	**Rationale for Changes**
population.	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.	
10.2.1 Demographic and Baseline Characteristics Descriptive statistics percentages, means and standard deviations) of demographic baseline characteristics, medical history, current/concomitant medication and compliance will be tabulated.	**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 drug. **5.1.1 Prior and Concomitant Medication** Concomitant medications will be listed by subject, with, indication, dose, dose form, frequency, route, start date and end date	For medical history and concomitant medication coding is not done so listing will be produced.
10.2.5 Safety Analyses Treatment emergent AEs by SOC, PT and intensity OST abnormalities will be listed and tabulated. The tabulation will show changes in abnormality from baseline to each follow-up assessment. Exposure to study product will	**4.7.1 Adverse Events and Serious Adverse Events** OST abnormalities will be listed **4.3.1 Study Product Compliance and Exposure** Exposure to the study product will be listed in the listing	1) TEAEs by SOC, PT and intensity is study specific and it is decided to not produce for this study 2) In the same listing we can display

Protocol	Reporting & Analysis Plan	
Statistical Analysis section	**Statistical Analysis Plan**	**Rationale for Changes**
also be tabulated and listed by treatment group.		the changes in OST 3) To keep consistency across oral studies.

6 Top-line Summary

The outputs required for the topline is summary are documented in the attached worksheet excel file.

Attachment 1: List of Data Displays

Worksheet in C
Project 55 RAP Final I

Appendix 1: Templates for Tables, Figures & Listings

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

Note to programmer:

1) *The treatment labels for the column heading will be as follow:*

- *Test Product*
- *Negative Control*
- *Positive Control*

2) *Use following footnotes in all the TLFs:*

Test Product: Dentifrice (0.454% SnF_2 and 0.072% NaF)
Negative Control: Dentifrice (1400 ppm F SMFP) Colgate Triple Protection
Positive Control: Dentifrice ($SnCl_2$ and 0.15% NaF 1400 ppm F) Crest 7-Effects

3) *Check actual races captured in eCRF to adjust the race name and abbreviations.*

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Table 14.1.1
Subject Disposition
All Screened Subjects

Study Population: All Screened Subjects (N=xxx)

	Test Product (N=XX)	Negative Control (N=XX)	Positive Control (N=XX)	Overall (N=XX)
TOTAL SUBJECTS SCREENED n (%)				xxx
SUBJECTS NOT RANDOMIZED n (%)				Xxx (xx.x)
DID NOT MEET STUDY CRITERIA				xxx (xx.x)
ADVERSE EVENT				Xxx (xx.x)
LOST TO FOLLOW UP				xxx (xx.x)
PROTOCOL VIOLATION				Xxx (xx.x)
WITHDRAWAL OF CONSENT				Xxx (xx.x)
OTHER				Xxx (xx.x)
SUBJECTS RANDOMIZED n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
COMPLETED STUDY	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
DID NOT COMPLETE STUDY	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
DID NOT MEET STUDY CRITERIA	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
ADVERSE EVENT	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
LOST TO FOLLOW-UP	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
PROTOCOL VIOLATION	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
WITHDRAWAL OF CONSENT	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)

	Test Product (N=XX)	Negative Control (N=XX)	Positive Control (N=XX)	Overall (N=XX)
OTHER	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
SAFETY POPULATION n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
ITT POPULATION n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
PP POPULATION n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)

Percentages for non-randomized category are based on number of screened subjects; percentages for randomized category are based on number of randomized subjects

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Table 14.1.2
Incidence of Major Protocol Deviations
Randomized Population

Study Population: Randomized (N=xxx)

	Test Product (N=XX)	Negative Control (N=XX)	Placebo (N=XX)	Overall (N=XX)
SUBJECTS WITH AT LEAST ONE MAJOR PROTOCOL VIOLATION n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
MAJOR PROTOCOL VIOLATIONS NOT LEADING TO EXCLUSION FROM PP n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
VIOLATION REASON 1	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
MAJOR PROTOCOL VIOLATIONS LEADING TO EXCLUSION FROM PP n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
All VISITS				
VIOLATION REASON 1	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
WEEK Y	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
VIOLATION REASON 1	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)

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Protocol 208153 Program Run Date:xxxx

Table 14.1.2.1
Subject Demographics and Baseline Characteristics
Safety Population

Study Population: Safety Population (N=XX)

	Test Product (N=XX)	Negative Control (N=XX)	Positive Control (N=XX)	Overall (N=XX)
SEX n (%)				
MALE	xx (xx.x)	xx (xx.x)	...	xx (xx.x)
FEMALE	xx (xx.x)	xx (xx.x)	...	xx (xx.x)
RACE n (%)				
ASIAN	xx (xx.x)	xx (xx.x)	...	xx (xx.x)
BLACK or AFRICAN	xx (xx.x)	xx (xx.x)	...	xx (xx.x)
AMERICAN INDIAN OR ALASKA NATIVE	xx (xx.x)	xx (xx.x)	...	xx (xx.x)
NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	xx (xx.x)	xx (xx.x)	...	xx (xx.x)
WHITE	xx (xx.x)	xx (xx.x)	...	xx (xx.x)
MULTIPLE	xx (xx.x)	xx (xx.x)	...	xx (xx.x)
ETHNICITY n (%)				
HISPANIC OR LATINO	xx (xx.x)	xx (xx.x)	...	xx (xx.x)
NOT HISPANIC OR LATINO	xx (xx.x)	xx (xx.x)	...	xx (xx.x)
AGE (YEARS)				
n	XX	XX	...	XX

	Test Product (N=XX)	Negative Control (N=XX)	Positive Control (N=XX)	Overall (N=XX)
MEAN	XX.X	XX.X	...	XX.X
SD	XX.XX	XX.XX	...	XX.XX
MEDIAN	XX.X	XX.X	...	XX.X
MINIMUM	XX	XX	...	XX
MAXIMUM	XX	XX	...	XX
STRATIFICATION n (%)				
MAXIMUM BASELINE SCHIFF SCORE 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
MAXIMUM BASELINE SCHIFF SCORE 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Protocol 208153 Program Run Date:xxxx

Table 14.2.1.1
Summary Statistics of Evaporative (Air) Schiff Sensitivity Score
Intent-to-Treat Population

Study Population: Intent to Treat (N=XXX)

		Test Product (N=XX)		Negative Control (N=XX)		Positive Control (N=XX)		Overall
Visit		Observed Value	Change from Baseline	Observed Value	Change from Baseline	Observed Value	Change from Baseline	Observed Value
BASELINE	n	XX		XX		XX		XX
	n (Missing)	XX		XX		XX		XX
	MEAN	X.XX		X.XX		X.XX		X.XX
	SE	X.XX		X.XX		X.XX		X.XXX
	SD	X.XXX		X.XXX		X.XXX		X.XXX
	MEDIAN	X.X		X.X		X.X		X.XX
	MINIMUM	X.X		X.X		X.X		X.XX
	MAXIMUM	X.X		X.X		X.X		X.X
WEEK 4	n	XX	XX	XX	XX	XX	XX	
	n (Missing)	XX		XX		XX		XX
	MEAN	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	
	SE	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	
	SD	X.XXX	X.XXX	X.XXX	X.XXX	X.XXX	X.XXX	
	MEDIAN	X.X	X.X	X.X	X.X	X.X	X.X	
	MINIMUM	X.X	X.X	X.X	X.X	X.X	X.X	
	MAXIMUM	X.X	X.X	X.X	X.X	X.X	X.X	

	Test Product (N=XX)		Negative Control (N=XX)		Positive Control (N=XX)		Overall
Visit	Observed Value	Change from Baseline	Observed Value	Change from Baseline	Observed Value	Change from Baseline	Observed Value
WEEK 8 SAME AS WEEK 4.							

Protocol 208153 Program Run Date:xxxx

Table 14.2.1.2
Statistical Analysis of Change from Baseline in Evaporative (Air) Schiff Sensitivity Score
Intent-to-Treat Population

Study Population: Intent to Treat (N=XXX)

	Test Product (N=XX)	Negative Control (N=XX)	Positive Control (N=XX)
WEEK 4			
ADJUSTED MEAN [1]	XX.XX	XX.XX	XX.XX
SE [1]	XX.XXX	XX.XXX	XX.XXX
95% CI [1]	(XX.XXX, XX,XXX)	(XX.XXX, XX.XXX)	(XX.XXX, XX.XXX)
P-VALUE [1]	0.XXXX	0.XXXX	0.XXXX

COMPARISONS BETWEEN TREATMENTS	DIFFERENCE (SE) [1]	95% CI [1]	P-VALUE [1]	MEAN DIFFERENCE % [2]
TEST PRODUCT VERSUS NEGATIVE CONTROL [1] *	XX.XX (XX.XXX)	(XX.XXX, XX.XXX)	0.XXX	xx.xx
TEST PRODUCT VERSUS POSITIVE CONTROL [1]	XX.XX (XX.XXX)	(XX.XXX, XX.XXX)	0.XXX	XX.XX
NEGATIVE CONTROL VERSUS POSITIVE CONTROL [1]	XX.XX (XX.XXX)	(XX.XXX, XX.XXX)	0.XXX	

WEEK 8 (AS ABOVE FOR WEEK 4)
...

* Test Product versus Negative Control at Week 8 is a primary endpoint comparision.
[1] From ANCOVA model with treatment as factor and baseline Schiff score as covariate. Difference is first named treatment minus second named treatment such that a negative difference favors the first named treatment.
[2] For the Chinese Ministry of Health guideline requirement to demonstrate difference between Test Product and Control (Positive or Negative) in the observed raw means. It is Calculated as 100*(Test Product- Control)/Control.

Programming Note: For Table 14.2.2.2 and 14.2.2.4: please update footnote [1] as
[1] From ANCOVA model with treatment and baseline Schiff stratification as factors and baseline tactile threshold as a covariate. Difference is the first named treatment minus second named treatment such that a positive difference favors the first named treatment.

Protocol 208153 Program Run Date:xxxx

Table 14.3.1.1
Treatment Emergent Adverse Event by SOC and Preferred Term
Safety Population

Study Population: Safety Population (N=xx)

SOC Preferred Term	Test Product (N=XX)		Negative Control (N=XX)		Positive Control (N=XX)		Overall (N=XX)	
	n (%)	nAE	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	xx (xx.x)	xx
NUMBER OF SUBJECTS WITH NO AE	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx
ERYTHEMA	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx
DERMATITIS	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx
GASTROINTESTINAL SYSTEM	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx
ABDOMINAL PAIN	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx
DRY MOUTH	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx
VOMITTING	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx

Etc.

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

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Protocol 208153 Program Run Date:xxxx

Listing 16.1.7
Randomization Information
Randomized Population

Study Population: Randomized (N=xx)
Stratum 1: Maximum Schiff score =2

Subject Number	Age/Sex/ Race/Ethinicity[1]	Randomization Number	Planned Randomized Treatment	Actual Treatment Received	Date of Randomization
PPD					

[1] Age in years; Sex: F = Female, M = Male; Race: A = Asian, B = Black or African American, I = American Indian or Alaska Native, H = Native Hawaiian or Other Pacific Islander, W = White, M = Multiple; Ethinicity: H = Hispanic or Latino, NH = Not Hispanic or Latino.

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Protocol 208153 Program Run Date:xxxx

Listing 16.2.1.1
Subject Disposition
Randomized Population

Study Population: Randomized (N=xx)
Treatment Group: Test Product

Subject	Age/Sex/Race/ Ethinicity [1]	Screening Date	Treatment Start Date and Time [2]	Completion/ Withdrawal Date	Duration of Treatment (Days) [3]	Completed?	Primary Reason for Withdrawal	Further Details [4]
PPD								
….								

[1] Age in years; Sex: F = Female, M = Male; Race: A = Asian, B = Black or African American, I = American Indian or Alaska Native, H = Native Hawaiian or Other Pacific Islander, W = White, M = Multiple; Ethinicity: H = Hispanic or Latino, NH = Not Hispanic or Latino.
[2] Date and time of the brushing with allocated treatment date at baseline visit.
[3] Duration of treatment defined as date of completion or withdrawal minus date of first study product application
[4] Further details of reasons for withdrawal.

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PPD

Protocol 208153 Program Run Date:xxxx

Listing 16.2.1.2
Subject Disposition
Non-Randomized Subjects

Study Population: Non-Randomized (N=xx)

Subject Number	Age/Sex/Race/ Ethinicity [1]	Screening Date	Reason for Screen Failure	Further Details [2]
PPD				

[1] Age in years; Sex: F = Female, M = Male; Race: A = Asian, B = Black or African American, I = American Indian or Alaska Native, H = Native Hawaiian or Other Pacific Islander, W = White, M = Multiple; Ethinicity: H = Hispanic or Latino, NH = Not Hispanic or Latino.
[2] Further details of reasons for screen failure.

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PPD

Protocol 208153 Program Run Date:xxxx

Listing 16.2.2.1
Major Protocol Deviations
Randomized Population

Study Population: Randomized (N=xx)
Treatment Group: XXXXXX

Subject	Sex/Age/Race/ Ethinicity [1]	Week(s)Excluded from PP Population	Deviation Reason
PPD			

[1] Age in years; Sex: F = Female, M = Male; Race: A = Asian, B = Black or African American, I = American Indian or Alaska Native, H = Native Hawaiian or Other Pacific Islander, W = White, M = Multiple; Ethinicity: H = Hispanic or Latino, NH = Not Hispanic or Latino.

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Protocol 208153 Program Run Date:xxxx

Listing 16.2.2.2
Minor Protocol Deviations
Randomized Population

Study Population: Randomized (N=xx)
Treatment Group: Test Product

Subject Number	Age/Sex/Race/ Ethinicity [1]	Visit	Deviation Sequence	Protocol Deviation
PPD				

[1] Age in years; Sex: F = Female, M = Male; Race: A = Asian, B = Black or African American, I = American Indian or Alaska Native, H = Native Hawaiian or Other Pacific Islander, W = White, M = Multiple; Ethinicity: H = Hispanic or Latino, NH = Not Hispanic or Latino.

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Programming Note for Listing 16.2.2.1: Only list those subjects identified in population definition document as being excluded from the PP population.

Protocol 208153 Program Run Date:xxxx

Listing 16.2.3.1
Exclusion from Analysis Population
Randomized Population

Study Population: Randomized (N=xx)

Subject Number	Age/Sex/Race/ Ethinicity [1]	Safety Population	ITT Population	PP Population
PPD				

[1] Age in years; Sex: F = Female, M = Male; Race: A = Asian, B = Black or African American, I = American Indian or Alaska Native, H = Native Hawaiian or Other Pacific Islander, W = White, M = Multiple; Ethinicity: H = Hispanic or Latino, NH = Not Hispanic or Latino.

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Programming Note for Listing 16.2.3: This listing is based on population definition document.

Protocol 208153 Program Run Date:xxxx

Listing 16.2.4.1
Demographic Characteristics
Randomized Population

Study Population: Randomized (N=xx)
Treatment Group: Test Product

Subject Number	Age (years)	Sex	Race	Ethnicity	Stratum
PPD					

PPD

Protocol 208153 Program Run Date:xxxx

Listing 16.2.4.2
Medical History and Current Medical Conditions
Randomized Population

Study Population: Randomized (N=xx)
Treatment Group: Test Product

Subject	Age/Sex/Race/ Ethinicity [1]	Any Medical History?	Medical Condition	Start Date	Ongoing?	End Date
PPD						

[1] Age in years; Sex: F = Female, M = Male; Race: A = Asian, B = Black or African American, I = American Indian or Alaska Native, H = Native Hawaiian or Other Pacific Islander, W = White, M = Multiple; Ethinicity: H = Hispanic or Latino, NH = Not Hispanic or Latino.

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Protocol 208153 Program Run Date:xxxx

Listing 16.2.5.2
Concomitant Medications and Significant Non-drug Therapies
Randomized Population

Study Population: Randomized (N=xx)
Treatment Group: Test Product

Subject Number	Age/Sex/Race/ Ethinicity [1]	Treatment (GSK Drug Synonym)	Sequence Number	Reason for Treatment	Dose Per Adimin. (Unit)	Route of Admin.	Frequency	Start Date (Study Day [2])	End Date/Ongoing
PPD									

[1] Age in years; Sex: F = Female, M = Male; Race: A = Asian, B = Black or African American, I = American Indian or Alaska Native, H = Native Hawaiian or Other Pacific Islander, W = White, M = Multiple; Ethinicity: H = Hispanic or Latino, NH = Not Hispanic or Latino.
[2] Study day relative to the date of randomization.

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Programming note: sort the listing by subject number, treatment start date.

Protocol 208153 Program Run Date: DDMMYYYY

Listing 16.2.5.3
Brushing Compliance
All Randomized Population

Treatment Group: Test Product 1

Subject Number	Age/Sex/Race Ethinicity [1]	Period	Expected Number of Brushing [2]	Actual Number Brushing [3]	Compliance [4]
PPD					

[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] Expected Number of Brushing = 2*Number of Days between the Two Visits;
[3] Actual Number of Brushing = Expected Number – Missed brushing + Additional Brushing;
[4] Compliance = Actual Number / Expected Number *100 (%)

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Protocol 208153 Program Run Date: DDMMYYYY

Listing 16.2.5.4
Supervised Brushing Compliance
All Randomized Population

Treatment Group: Test Product 1

Subject Number	Age/Sex/Race Ethinicity [1]	Visit	Date and Time Supervised brushing started	Supervised Brushing Performed (Y/N)	Further Details if supervised Brushing is not Performed
PPD					

[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.

PPD

Protocol 208153 Program Run Date:xxxx

Listing 16.2.6.1
Individual Efficacy Data for Schiff Sensitivity Score for Two Test Teeth
Randomized Population

Study Population: Randomized (N=xx)
Treatment Group: Test Product 1

Subject Number	Age/Sex/Race/ Ethinicity [1]	Tooth Number (Universal/FDI)	Timepoint	Score	Subject Level Average	Change from Baseline
PPD						

[1] Age in years; Sex: F = Female, M = Male; Race: A = Asian, B = Black or African American, I = American Indian or Alaska Native, H = Native Hawaiian or Other Pacific Islander, W = White, M = Multiple; Ethinicity: H = Hispanic or Latino, NH = Not Hispanic or Latino.

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Programming Note : 1) Subject level average is based raw values for selected 2 test teeth.
2) Please create a similar listsing for tactile

Protocol 208153 Program Run Date:xxxx

Listing 16.2.7.1
All Adverse Events
Randomized Population

Study Population: Randomized (N=xx)
Treatment Group: Test Product 1

Subject Number	Age/Sex/ Race/ Ethinicity [1]	Adverse Event (Preferred Term) [System Organ Class]	Start Date /Study Day[2]	Start Time	End Date	End Time	Frequency /Intensity [3]	Related to Study Product?	Action Taken re Study Product	Outcome	Serious?	Withdrew? [4]
PPD												

@@ Adverse events with verbatim text ending in this are classified as Oral AEs.
[1] Age in years; Sex: F = Female, M = Male; Race: A = Asian, B = Black or African American, I = American Indian or Alaska Native, H = Native Hawaiian or Other Pacific Islander, W = White, M = Multiple; Ethinicity: H = Hispanic or Latino, NH = Not Hispanic or Latino.
[2] Study day is the day relative to start of treatment, Day 1 being the day of first treatment.
[3] INT = Intermittent and SGLE = Single.
[4] Did subject withdraw from study as a result of this adverse event?

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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'*

- *Add footnote 'Only SAEs are collected for non randomized subjects'*
- *Delete the footnote related to study day and adjust the numbers accordingly.*

Protocol 207656 Program Run Date: DDMMYYYY

Listing 14.3.2.5
Oral Soft Tissue Abnormalities
All Randomized Population

Treatment Group: Test Product 1

Subject Number	Age/Sex/Race/ Ethinicity [1]	Visit	Date and Time of Assessment	Area	Condition	Changes In OST from Previouse Visit (Y/N)	Details
PPD							

[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.

Programming Note: For Listing 14.3.2.6 Please remove 'Change in OHT from Previouse Visit' column from this listing.

Protocol 208153 Program Run Date:xxxx

Figure 14.2.1
Evaporative (Air) Schiff Sensitivity Score by Time and Treatment
Intent to Treat Population

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

Mean and SE plotted are from summary statistics in T 14.2.1.1
Data points have been offset for clarity.

Note to programmer: (1) Add 'Baseline', 'Week 4' and 'Week 8' to X-axis (2) Use different symbols and line-styles for three treatments (3) For Figures 14.2.3 & 14.2.4 use 'Per Protocol Population' in header.4. Please make sure that Y-axis scale is 0-3 for Schiff score 5) 1) Please make sure that Y-axis scale is 0-80 g for tactile and leble is "Tactile threshold (g)"

PPD