
STATISTICAL ANALYSIS PLAN

Clinical Study to Investigate the Ability of a Stannous Fluoride Toothpaste to Protect from Dentine Hypersensitivity

Protocol Number: 300212

Phase: N/A

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Document History

Document	Version Date	Summary of Changes (New analysis or Change in planned analysis)
Original Analysis Plan	18-MAR-2025	Not applicable (N/A)

Amendments incorporate all revisions to date.

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Abbreviations

Abbreviation	Term
AE	Adverse Event
ANCOVA	Analysis of Covariance
BDRM	Blind Data Review Meeting
CI	Confidence Interval
DH	Dentine Hypersensitivity
eCRF	Electronic Case Report Form
EAR	Erosion/Abrasion/Recession
g	Grams
CCI	
ICF	Informed Consent Form
CCI	
MedDRA	Medical Dictionary for Regulatory Activities
MGI	Modified Gingival Index
mITT	Modified Intent-To-Treat
mm	Millimetres
MMRM	Mixed Model with Repeated Measures
N/A	Not Applicable
CCI	
OHT	Oral hard tissue
OST	Oral soft tissue
PP	Per Protocol
PT	Preferred Term
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SD	Standard Deviation
SE	Standard Error
SnF ₂	Stannous fluoride
SOC	System Organ Class
TEAEs	Treatment Emergent Adverse Events
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The purpose of this Statistical Analysis Plan (SAP) is to describe the planned analyses and outputs to be included in the Clinical Study Report for Protocol 300212 (Version 5.0, dated 17-Dec-2024).

1 Summary of Key Protocol Information

The purpose of this trial is to demonstrate the ability of a Stannous Fluoride Toothpaste to protect from dentine hypersensitivity (DH). This is the first clinical study conducted by Haleon with the new DH examiner at a well-established investigator site (The Clinical Trials Group (Periodontology) at Bristol Dental School). As such, the purpose of this study is to familiarise the new examiner with Haleon DH protocol requirements and endpoints.

This will be achieved by characterising the sensitivity protection performance of commercially available, daily use toothpastes.

Therefore, this study will be considered successful if DH protection profile of the 0.454% SnF₂ toothpaste indicates improved tooth sensitivity protection compared to Baseline, at Week 2 and this will provide reassurance of the clinical examiner capabilities.

Sufficient subjects will be screened and entered into the acclimatisation phase to ensure approximately 80 subjects are randomised to study toothpaste (approximately 40 subjects per group) and approximately 70 subjects complete the study (approximately 35 subjects per group, allowing for up to 10% dropouts).

1.1 Study Design

This will be a single centre, randomised, controlled, examiner-blind, 2-arm, stratified, parallel design clinical study in healthy male and female subjects, aged 18-70, with self-reported and clinically confirmed DH. Subjects who meet the required study criteria at Screening and Baseline will be randomised to one of two study toothpastes: 0.454% SnF₂ toothpaste (Test) or a regular fluoride toothpaste (Negative Control).

Two independent stimulus-based clinical measures will be employed to assess DH.

- A tactile stimulus will be administered using a constant pressure probe - Yeaple Probe (Polson, 1980); subject response to the stimulus determines the tactile threshold (g).
- An evaporative (air) stimulus (i.e., a thermal stimulus) will be administered using a dental air syringe; subject response to the stimulus will be examiner-evaluated using the Schiff sensitivity scale (Schiff, 1994).

DH will be assessed at Screening and Baseline, and after 1 day, 1 week (Day 8) and 2 weeks (Day 15) toothpaste usage. The same clinical examiner will administer both stimuli and assess their associated DH measures (tactile threshold (g) and Schiff sensitivity score) for all study subjects for the duration of the study.

On completion of the Baseline assessments, the clinical examiner will select two 'test teeth' for assessment of tactile and evaporative (air) sensitivity at all subsequent visits. To qualify for selection as a 'test tooth', the tooth must meet the protocol-specific inclusion/exclusion criteria, specifically a tactile threshold ≤ 20 g and a Schiff sensitivity score ≥ 2 at both Screening and Baseline visits.

Approximately 80 qualifying subjects will be stratified by the maximum Baseline Schiff sensitivity score of their two selected 'test teeth' and randomised to study toothpaste (approximately 40 subjects each to the test toothpaste and negative control groups). Randomised subjects will be instructed to brush twice daily (morning and evening) with their allocated study toothpaste for the next 2 weeks. First use of study toothpaste will be completed under supervision at the investigator site.



Enrolled subjects will complete an acclimatisation period (2 weeks duration) between the Screening and Baseline visits during which they will brush twice daily (morning and evening) with the acclimatisation toothpaste (commercially available regular fluoride toothpaste).

The safety and oral tolerability of the study toothpastes will be monitored over the 2-week usage period by review of treatment emergent adverse events (TEAEs).

[Table 1-1](#) presents the Schedule of Activities.

Table 1-1 Schedule of Activities

Procedure/Assessment	Study Visits					
	Visit 1 Screening		Visit 2 Baseline Day 1	Visit 3 Day 2	Visit 4 Week 1 Day 8 (±1 day)	Visit 5 Week 2 Day 15 (± 1 day)
Informed Consent	X	Acclimatisation Period (14 ± 2 Days)				
Demographics	X					
Review Subject's Current Oral Care Product(s)	X					
Review Medical History & Current/Prior Concomitant Medications/Treatments	X					
Review Changes in Health and Medications/ Treatments ¹			X	X	X	X
Compliance Checks ¹			X	X	X	X
CCI	X					
CCI						X ⁶
CCI						X ⁶
Oral Soft Tissue (OST) Examination	X		X	X	X	X
Oral Hard Tissue (OHT) Examination	X					X
Eligible Teeth Assessments (Dentition Exclusions, Erosion/Abrasion/Recession [EAR], Modified Gingival Index [MGI], Tooth Mobility)	X					
Qualifying Clinical Assessment of Tactile Sensitivity ²	X		X			
Qualifying Clinical Assessment of Evaporative (Air) Sensitivity (Schiff sensitivity score) ³	X		X			

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Procedure/Assessment	Study Visits					
	Visit 1 Screening		Visit 2 Baseline Day 1	Visit 3 Day 2	Visit 4 Week 1 Day 8 (±1 day)	Visit 5 Week 2 Day 15 (± 1 day)
CCI			X			
Clinical Examiner Selects Two 'Test Teeth' (Qualifying Subjects Only) ⁵			X			
Review Inclusion/Exclusion Criteria	X		X			
Confirm Subject Eligibility/Qualification	X		X			
Dispense Acclimatisation Toothpaste, Toothbrush, Rinsing Cups & Timer	X					
Supervised Brushing with Acclimatisation Toothpaste	X					
Stratification/Randomisation			X			
Return Acclimatisation Toothpaste & Toothbrush			X			
Dispense Study Toothpaste, Toothbrush & Rinsing Cups			X			
Supervised Brushing with Allocated Study Toothpaste			X			
Clinical Assessment of Tactile Sensitivity: Two 'Test Teeth' Only ²				X	X	X
Clinical Assessment of Evaporative (Air) Sensitivity (Schiff sensitivity score): Two 'Test Teeth' Only ³				X	X	X
CCI				X	X	X
Return Study Toothpaste & Toothbrush						X
Study Conclusion						X

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Procedure/Assessment	Study Visits					
	Visit 1 Screening		Visit 2 Baseline Day 1	Visit 3 Day 2	Visit 4 Week 1 Day 8 (±1 day)	Visit 5 Week 2 Day 15 (± 1 day)
Monitor Adverse Events (AEs) ⁷	X		X	X	X	X

FOOTNOTES:

- Subjects will be required to bring their study supplies (minus timer & rinsing cups) to every visit.

Perform visual check of returned study supplies & question subject to evaluate compliance.

Visit 2: Check compliance with use of acclimatisation toothpaste.

Visits 3-5: Check compliance with use of study toothpaste.

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Visits 2-5: Check compliance with Lifestyle Restrictions and medication requirements.

- Tactile Threshold Assessments:** Visits 1-2: Maximum force 20g (Screening and Baseline); Visits 3-5: Maximum force 80g.

- Evaporative (air) sensitivity** (Schiff sensitivity score) should be assessed after tactile sensitivity; ensure minimum 5-minute delay after the last tactile assessment before the first evaporative (air) assessment for tooth recovery.

Visit 1 (Screening): Assess evaporative (air) sensitivity for all teeth with a Screening tactile threshold ≤ 20g.

Visit 2 (Baseline): Assess evaporative (air) sensitivity for all 'eligible teeth' identified at Screening with a Baseline tactile threshold of ≤ 20g.

Visits 3, 4 & 5: Assess evaporative (air) sensitivity for the two 'Test Teeth' only.

'Eligible Teeth' = Teeth with no dentition exclusions which meet EAR, MGI & mobility criteria, with Screening tactile threshold ≤ 20g & Screening Schiff sensitivity score ≥ 2.

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- Selected 'Test Teeth' should be in different quadrants, with the requisite qualifying levels of DH at both Screening (Visit 1) and Baseline (Visit 2), i.e., tactile threshold ≤ 20 g and Schiff sensitivity score ≥ 2.

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- AEs, and therefore all serious adverse events (SAEs) will be recorded from immediately after signing the informed consent form (ICF) until 5 days after the last use of study toothpaste.

1.2 Study Objectives

Study objectives and endpoints are defined in [Table 1-2](#).

Table 1-1 Study Objectives and Endpoints

Objectives	Endpoints
Primary Objective	Primary Endpoint
To investigate the DH protection of a 0.454% SnF ₂ toothpaste and a regular fluoride toothpaste, in response to evaporative air (Schiff sensitivity score) and tactile (tactile threshold in grams (g)) stimuli, with twice daily brushings after 2 weeks.	At Week 2: Change from Baseline in Schiff sensitivity score Change from Baseline in tactile threshold (g)
To characterise the DH protection profiles of a 0.454% SnF ₂ toothpaste and a regular fluoride toothpaste, in response to evaporative air (Schiff Sensitivity score) and tactile (tactile threshold (g)) stimuli, with twice daily brushings over 2 weeks.	At Baseline, Day 2, Week 1 and Week 2: Schiff sensitivity score Tactile threshold (g) At Day 2, Week 1 and Week 2: Change from Baseline in Schiff sensitivity score Change from Baseline in Tactile threshold (g)
Secondary Objectives	Secondary Endpoints
To investigate the DH protection profiles of a 0.454% SnF ₂ toothpaste and a regular fluoride toothpaste, in response to evaporative air (Schiff sensitivity score) and tactile (tactile threshold (g)) stimuli, with twice daily brushing at Day 2 and Week 1.	At Day 2 and Week 1: Change from Baseline in Schiff sensitivity score Change from Baseline in tactile threshold (g)
To investigate the ability of a 0.454% SnF ₂ toothpaste to provide DH protection, in response to evaporative air (Schiff sensitivity score) and tactile (tactile threshold (g)) stimuli, compared to a regular fluoride toothpaste, after 1 day, 1 week and 2 weeks twice daily use.	At Day 2, Week 1 and Week 2: Change from Baseline in Schiff sensitivity score Change from Baseline in tactile threshold (g)

Objectives	Endpoints
	
Safety	
To monitor the safety and tolerability of the study toothpastes with twice daily brushing over 2 weeks.	Treatment emergent adverse events (TEAEs)

This study will be considered successful if DH protection profile of the 0.454% SnF₂ toothpaste indicates improved tooth sensitivity protection (as measured by Schiff sensitivity score and tactile threshold (g), compared to Baseline, at Week 2.

1.3 Treatments

The study test product will be 0.454% SnF₂ toothpaste and the negative control toothpaste will be a regular fluoride toothpaste. Subjects will brush twice daily (morning and evening).

[Table 1-3](#) presents the study products.

Table 1-3 Study Products

	Acclimatisation Toothpaste	Test Toothpaste	Negative Control Toothpaste
Product Name	Regular fluoride toothpaste (Aquafresh Fresh & Minty [*])	0.454% w/w SnF ₂ Toothpaste (Sensodyne Rapid Relief [*])	Regular fluoride toothpaste (Colgate Cavity Protection [*])
Fluoride Level	1450 parts per million (ppm) fluoride [†]	1100 ppm fluoride [‡]	1000 ppm fluoride [*]
Master Formulation Code	CCI	CCI	N/A
Dispensing Details	1 tube of toothpaste at Screening (Visit 1)	1 tube of toothpaste at Baseline (Visit 2)	1 tube of toothpaste at Baseline (Visit 2)
Route of Administration	Topical Oral Use	Topical Oral Use	Topical Oral Use
Toothpaste Usage Instruction	Dose the toothbrush with a ribbon of toothpaste, across the full brush head. Start the timer (pre-set for 1 minute).		
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	Subjects who wish to rinse after brushing will be instructed to rinse with 10 millilitres (ml) water using graduated rinsing cups provided.		
Duration of Product Usage	Acclimatisation Toothpaste: Approximately 2 weeks (14 ± 2 days) Study Toothpaste: Approximately 2 weeks (14 ± 1 days)		
Return Requirements	All used/unused tubes to be returned to the sponsor.		

[‡] Commercially available daily use toothpaste, United Kingdom (UK) market.

^{*} Commercially available daily use toothpaste, United States (US) market.

[†] As sodium fluoride; [‡] As SnF₂; ^{*} As sodium monofluorophosphate.

1.4 Sample Size Calculation

Sufficient subjects will be screened and entered into the acclimatisation phase to ensure approximately 80 subjects are randomised to study toothpaste (approximately 40 subjects per group) and approximately 70 subjects complete the study (approximately 35 subjects per study toothpaste group, allowing for up to 10% dropouts).

The aim of this study is to characterise the short-term DH protection profiles of a 0.454% SnF₂ toothpaste (test toothpaste) and a regular fluoride toothpaste (negative control) in order to familiarise a new DH examiner with Haleon DH protocol procedures, thus no formal sample size estimation has been performed; the formal power of this study is not the main driver for the selected sample size. That said, the power characteristics for the primary endpoints at Week 2 are described below.

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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 including any external data reconciliation have been completed and database has been locked.
3. All criteria for unblinding the randomisation codes have been met and the randomisation 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 Day 1 (Visit 2) assessment prior to study toothpaste use.

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

3.2 Subgroups/Stratifications

Subjects who satisfy all selection criteria will be randomised into the study. Qualifying subjects will be assigned a randomisation number from their designated stratum in ascending numerical order, as each subject is determined to be fully eligible.

Subjects will be stratified by the maximum Baseline Schiff sensitivity score of their two selected 'test teeth'. The stratification factor will give rise to two strata.

Stratum 1: Maximum Schiff sensitivity score = 2

Stratum 2: Maximum Schiff sensitivity score = 3

Within each stratum, subjects will be randomised to the test toothpaste or the negative control toothpaste with 1:1 ratio. In the event of mis-stratification, the correct stratum according to the data collected in the electronic Case Report Form (eCRF), i.e. the derived stratum, will be used for analysis.

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3.3 Centres Pools

Since this is single centre study, pooling of centres is not applicable.

3.4 Timepoints and Visit Windows

The timepoints and visits for this study are defined in the [Table 1-1 "Schedule of Activities"](#). Any deviation from the study schedule may be reviewed on a case-by-case basis at the Blind Data Review Meeting (BDRM) to determine whether the data should be excluded from the Per Protocol (PP) population.

4 Data Analysis

Data analysis will be performed by CCI with oversight from HALEON. The statistical analysis software used will be SAS 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. Any major changes to planned analyses will need an amendment to the SAP.

Except as described below, all listings will be produced for all randomised subjects.

4.1.1 Populations for Analysis

4.1.2 Subject Disposition

Screen failures are defined as subjects who consent to participate in the clinical study but are not subsequently randomised. An enrolled subject is a subject who has signed informed consent and is eligible to proceed beyond the screening visit.

The number of subjects screened, enrolled, and randomised will be presented in Table 14.1.1.

The number and percentage of screen failure subjects (subjects not randomised) with reasons why subjects are not randomised will be displayed. Percentages for screen failure subjects will be based on the total number of subjects screened.

The number of subjects who are not enrolled and number of subjects who are enrolled but not randomised will also be displayed.

The number and percentage of randomised subjects who complete and discontinue the study, broken down by reason for discontinuation by study product and overall will also be displayed. The percentages will be based on the number of subjects randomised.

Table 14.1.1 will also present the number and percentage of subjects in each of the defined analysis populations (as defined in [Section 4.1.3](#)) by study product and overall. Percentages will be based on the number of subjects randomised.

Subject disposition including demographic data (age, sex, race and ethnicity), screening date, study product start date and time, subject status (completer, Yes/No), study completion or withdrawal date, duration (in days) in the study (defined as [(date of completion or withdrawal – start date of study product) + 1], and the primary reason for withdrawal along with any further details for withdrawal will be listed (Listing 16.2.1.1) by study product for all randomised subjects.

Subject disposition information will be listed for non-randomised subjects (Listing 16.2.1.2), including demographic information (age, sex, race and ethnicity), screening date, reason for screen failure and any further details of reason for screen failure.

4.1.3 Protocol Deviations

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 categorised. Subjects with important protocol deviations liable to influence the efficacy outcomes will have affected data excluded from the PP analyses. Subjects may also be identified as having important protocol deviations not leading to exclusion of data from the PP analyses.

Important deviations of the protocol procedures may include, but will not necessarily be limited to the following:

- Consent procedures
- Inclusion/Exclusion criteria
- Concomitant medication/therapy
- Study procedures
- Randomisation procedures
- Study drug dosing/study product administration/study product compliance
- Visit schedule/interval
- Other

The specific details of the important protocol deviations will be listed in Protocol Deviation Management Plan, and the assessment process will be specified in the Blind Data Review Plan. Subjects with important protocol deviations will be identified at the BDRM.

The number and percentage of subjects with at least one important protocol deviation, (overall and by each deviation reason) and at least one important protocol deviation leading to exclusion of data from the PP analyses (overall and by each deviation reason with deviation timepoint [if applicable]) will be presented by study product and overall (Table 14.1.2) and listed in Listing 16.2.2.1.

All protocol deviations collected on the protocol deviation eCRF will be listed in Listing 16.2.2.2. The listing will present date of deviation, type of deviation, and deviation description.

4.1.4 Analysis Populations

The following analysis populations are defined.

Population	Definition / Criteria	Analyses Evaluated
Screened	Comprise of all subjects who provide the informed consent.	Disposition
Randomised	Comprise of all subjects who are randomised in the study.	Protocol Deviations

Population	Definition / Criteria	Analyses Evaluated
Safety	Comprise of all randomised subjects who complete at least one use of study toothpaste. This population will be based on the study toothpaste the subject actually received. Any subject who receives a randomisation number will be considered to have been randomised.	Demographics Safety
Modified Intent-To-Treat (mITT)	Comprise all randomised subjects who complete at least one use of study toothpaste and have at least one post Baseline efficacy assessment. This population will be based on the study toothpaste to which the subject was randomised. Any subject who receives a randomisation number will be considered to have been randomised.	Demographics Compliance Efficacy Analysis Exploratory Analysis
Per Protocol	Comprise all subjects in the mITT population who have at least one efficacy assessment considered to be unaffected by protocol deviations. Protocol deviations that may exclude subjects from the PP population are defined in Section 4.1.2 (Protocol Deviations). This population will be based on the study product to which the subject was randomised.	Efficacy Analysis

NOTES:

Please refer to [Appendix 1](#): List of Data Displays, which details the population to be used for each display being generated.

The numbers of subjects included in each of the analysis populations will be summarised (Table 14.1.1). Subjects excluded from any of the analysis populations will be listed in Listing 16.2.3.1, with the reason for exclusion.

The primary population for assessment of efficacy will be the mITT Population. A PP analysis will be performed on the primary and secondary efficacy endpoints only if more than 10% of mITT subjects are excluded from the PP Population. Efficacy data determined to have been potentially impacted by a protocol deviation will be excluded from the PP analysis, and will be agreed during the BDRM prior to database lock. A decision on whether a PP analysis will be performed will be made prior to study unblinding (release of the randomisation codes).

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4.2 Subject Demographics and Other Baseline Characteristics

4.2.1 Demographic Characteristics

Descriptive statistics (number of subjects [n], mean, standard deviation [SD], median, minimum and maximum for continuous variables and frequency count [n] and percentage [%] of subjects for categorical variables) will be presented for demographic variables by study product and overall. These variables include age (years), sex, race, ethnicity and maximum Baseline Schiff sensitivity score stratification group and will be presented for the Safety population (Table 14.1.3.1), the mITT population (Table 14.1.3.2) and the PP population (Table 14.1.3.3) if a PP analysis is performed.

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

4.2.2 General Medical History

Medical history and recent surgery (in the last year) including allergies or drug sensitivity will be listed in Listing 16.2.4.2, with start date and end date or ongoing at the start of study product.

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

Randomisation details will be listed, including the randomisation number, assigned stratification group, actual stratification group, the planned study product, the as treated study product and the randomisation date in (Listing 16.1.7.1) for all randomised subjects.

The study product kit allocations will be listed in (Listing 16.1.7.2), including kit number and study product information.

4.3.1 Study Product Compliance and Exposure

Compliance data will be summarised for the mITT population and will be assessed by number of brushings.

Number of actual brushings, number of expected brushings, number of missed brushings, number of additional brushings and brushing compliance (%) will be summarised using descriptive statistics by cumulative visit and by study product in Table 14.2.1.1.

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Cumulative number of actual brushings is defined as: [(date of Visit N – date of Baseline) multiplied by 2 – number of missed brushings + number of additional brushings], where N = 4, 5.

Cumulative number of expected brushings is defined as: [(date of Visit N – date of Baseline) multiplied by 2], where N = 4, 5.

Cumulative brushing compliance (%) is defined as: [100 x (number of actual brushings / numbers of expected brushings)]

Study product compliance (number of actual brushings, number of expected brushings, brushing compliance [%], number of missed brushings and number of additional brushings) will be listed in Listing 16.2.5.1 for all randomised subjects by study product.

4.3.2 Prior and Concomitant Medication

Prior medications/treatments, including prescription and non-prescription drugs, dietary supplements and herbal remedies, taken in the last 30 days and prior to signing the informed consent form, will be documented in the eCRF. The prior and concomitant medications will be coded using a validated medication dictionary, CCI

Prior medications and prior non-drug treatments will be listed by subject, with drug name, CCI drug synonym, reason for medication, route, dose, unit, frequency, start date, start day, end date and end day both relative to study product start date (Listing 16.2.4.3) for all safety subjects. Prior medications are defined as those which stopped before the first use of the study product.

Concomitant medications and concomitant non-drug treatments/significant non-drug therapies taken during treatment will be listed similarly (Listing 16.2.4.4) for all safety subjects with either ongoing or end date displayed.

Concomitant medications are defined as medications that started or stopped on or after the first use of the study product or are ongoing.

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

4.4 Analysis of Efficacy

The primary population for assessment of efficacy will be the mITT Population.

4.4.1 Primary Efficacy Endpoint

4.4.1.1 Change from Baseline at Week 2 in Schiff Sensitivity Score and Tactile Threshold (g), within Test Toothpaste Group and Negative Control Group

The Schiff sensitivity score for each visit will be derived as the average score of the 2 ‘test teeth’ identified at Baseline. Change from Baseline will be derived for the individual teeth first before calculating the average change for the 2 test teeth.

The tactile threshold (g) for each visit will be derived as the average value of the 2 ‘test teeth’ identified at Baseline. Change from Baseline will be derived for the individual teeth first before calculating the average change for the 2 test teeth.

4.4.1.1.1 Statistical Hypothesis, Model, and Method of Analysis

The primary objectives will be the comparison of changes from Baseline of (i) Schiff sensitivity score and (ii) tactile threshold (g) at Week 2, within the test toothpaste group. Since there are two primary endpoints, multiplicity adjustment will be done by testing hypotheses in a sequential manner:

1. Schiff sensitivity score change from Baseline to Week 2:
 - H₀₁: There is no difference between Baseline and Week 2 in Schiff sensitivity score within the test toothpaste group.
 - H₁₁: There is a difference between Baseline and Week 2 in Schiff sensitivity score within the test toothpaste group.
2. Tactile threshold (g) change from Baseline to Week 2:
 - H₀₂: There is no difference between Baseline and Week 2 in tactile threshold (g) within the test toothpaste group.
 - H₁₂: There is a difference between Baseline and Week 2 in tactile threshold (g) within the test toothpaste group.

P-values will be considered statistically significant up to the point of first p-value in the sequence to be > 0.05. This means that if the first null hypothesis is not rejected at the 5% level of significance, then the second null hypothesis will also be considered not rejected at the 5% level of significance. 95% confidence intervals (CIs) will be provided for all point estimates within the sequence of tests regardless of statistical significance.

Change from Baseline in Schiff sensitivity score will be analysed using a Mixed Model with Repeated Measures (MMRM) with study product (test toothpaste, negative control), visit and study product by visit interaction as fixed effects and Baseline Schiff sensitivity score as a covariate. Subject will be included as a repeated measure with unstructured covariance matrix. Kenward-Roger degrees of freedom will be applied (Kenward, 1997). If the model with

unstructured covariance matrix does not converge then compound symmetry covariance matrix will be used.

Using the above model, adjusted mean change from Baseline at Week 2, along with 95% CIs will be reported by study product. P-values testing for non-zero change from Baseline at Week 2 will be presented for all study products in Table 14.2.2.2.1 for all subjects in the mITT population. Significance testing will be conducted at the two-sided 5% significance level.

Change from Baseline in tactile threshold will be analysed using a MMRM with study product (test toothpaste, negative control), visit and study product by visit interaction as fixed effects and Baseline tactile threshold (g) as a covariate. Maximum Baseline Schiff sensitivity score of the two 'test teeth' will also be fitted as a fixed effect. Subject will be included as a repeated measure with unstructured covariance matrix. Kenward-Roger degrees of freedom will be applied (Kenward, 1997). If the model with unstructured covariance matrix does not converge then compound symmetry covariance matrix will be used.

Results for tactile threshold (g) will be presented as described above for Schiff sensitivity score, in Table 14.2.3.2.1 for all subjects in the mITT population.

The assumptions of normality and homogeneity of variance in each MMRM will be investigated. In case of violation of these assumptions, a suitable non-parametric test (Wilcoxon Signed Rank Test) will be performed to assess change within treatment groups (Week 2 versus Baseline); and the results will be provided to support the MMRM results. The non-parametric results will be considered confirmatory under the observation of strong violations of the assumptions.

4.4.1.1.2 Supportive Analyses

If a PP analysis is performed, the MMRM analyses described in Section 4.4.1.1.1 will be repeated for all subjects in the PP population and will be presented in Table 14.2.2.2.2 (for Schiff sensitivity score) and Table 14.2.3.2.2 (for tactile threshold (g)).

4.4.1.2 Raw and Change from Baseline at Baseline, Day 2, Week 1 and Week 2 in Schiff Sensitivity Score and Tactile Threshold (g), within Test Toothpaste Group and Negative Control Group

- Schiff sensitivity score at Baseline, Day 2, Week 1 and Week 2

Descriptive statistics (n, missing, mean, SD, standard error [SE], median, minimum, and maximum) will be presented for Schiff sensitivity score at each assessment time point together with the change from Baseline in Table 14.2.2.1.1 for all subjects in the mITT population by study product. CCI

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Raw and change from Baseline means ($\pm$ SE) at each time point will be plotted by study product in Figure 14.2.2.1.3 and Figure 14.2.2.1.5, respectively, for all subjects in the mITT population.

If a PP analysis is performed, descriptive statistics will be presented for each time point by study product in Table 14.2.2.1.2, raw and change from Baseline means ($\pm$ SE) at each time point will be plotted by study product in Figure 14.2.2.1.4 and Figure 14.2.2.1.6, respectively, for all subjects in the PP population.

Individual data for Schiff sensitivity score will be listed for each subject by study product group and visit in Listing 16.2.6.1 for all randomised subjects.

- Tactile threshold (g) at Baseline, Day 2, Week 1 and Week 2

Descriptive statistics (n, missing, mean, SD, SE, median, minimum, and maximum) will be presented for tactile threshold (g) at each assessment time point together with the change from Baseline in Table 14.2.3.1.1 for all subjects in the mITT population by study product. CCI

Raw and change from Baseline means ($\pm$ SE) at each time point will be plotted by study product in Figure 14.2.3.1.3 and Figure 14.2.3.1.5, respectively, for all subjects in the mITT population.

If a PP analysis is performed, descriptive statistics will be presented for each time point by study product in Table 14.2.3.1.2, raw and change from Baseline means ($\pm$ SE) at each time point will be plotted by study product in Figure 14.2.3.1.4 and Figure 14.2.3.1.6, respectively, for all subjects in the PP population.

Individual data for tactile threshold values will be listed for each subject by study product group and visit in Listing 16.2.6.2 for all randomised subjects.

4.4.2 Secondary Efficacy Variables

4.4.2.1 Change from Baseline in Schiff Sensitivity Score and Tactile Threshold (g) at Day 2 and Week 1, within Test Toothpaste Group and Negative Control Group

4.4.2.1.1 Statistical Hypothesis, Model, and Method of Analysis

For comparisons to Baseline within each treatment group, the following null and alternative hypotheses will be evaluated at Day 2 and Week 1, for the test toothpaste group and the negative control group, respectively:

1. Schiff sensitivity score change from Baseline:
 - H₀₁: There is no difference in Schiff sensitivity score from Baseline.
 - H₁₁: There is a difference in Schiff sensitivity score from Baseline.
2. Tactile threshold (g) change from Baseline:
 - H₀₂: There is no difference in tactile threshold (g) from Baseline.

- H₁₂: There is a difference between in tactile threshold (g) from Baseline.

The results from the same MMRMs described in [Section 4.4.1.1.1](#) will be used to test the above hypotheses (Table 14.2.2.2.1 and Table 14.2.3.2.1 for Schiff sensitivity score and tactile threshold (g), respectively).

4.4.2.2 Change from Baseline in Schiff Sensitivity Score and Tactile Threshold (g) at Day 2, Week 1 and Week 2, Test Toothpaste versus Negative Control

4.4.2.2.1 Statistical Hypothesis, Model, and Method of Analysis

For comparisons between the test toothpaste group and the negative control group, the following null and alternative hypotheses will be evaluated at Day 2, Week 1 and Week 2, respectively:

1. Schiff Sensitivity score change from Baseline:

- H₀₁: There is no difference in change from Baseline in Schiff sensitivity score between Test Toothpaste and Negative Control Toothpaste.
- H₁₁: There is a difference in change from Baseline in Schiff sensitivity score between Test Toothpaste and Negative Control Toothpaste.

2. Tactile threshold (g) change from Baseline:

- H₀₂: There is no difference in change from Baseline in tactile threshold (g) between Test Toothpaste and Negative Control Toothpaste.
- H₁₂: There is a difference in change from Baseline in tactile threshold (g) between Test Toothpaste and Negative Control Toothpaste.

The results from the same MMRMs described in [Section 4.4.1.1.1](#) will be used to test the above hypotheses (Table 14.2.2.2.1 and Table 14.2.3.2.1 for Schiff sensitivity score and tactile threshold (g), respectively).

Using the above model, the difference in adjusted mean change from Baseline between study products at Day 2, Week 1 and Week 2 (test toothpaste compared to negative control), 95% CIs and p-values will be provided for Schiff sensitivity score in Table 14.2.2.2.1, and for tactile threshold (g) in Table 14.2.3.2.1. Significance testing will be conducted at the two-sided 5% significance level.

The assumptions of normality and homogeneity of variance in each MMRM will be investigated. In case of violation of these assumptions, a suitable non-parametric test (the Van Elteren test, adjusted for the randomisation stratification factor, maximum Baseline Schiff sensitivity score) will be performed to assess change from Baseline comparisons (test toothpaste vs. negative control) and the results will be provided to support the MMRM results. The non-parametric results will be considered confirmatory under the observation of strong violations of the assumptions.

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4.4.4 Handling of Missing Values/Censoring/Discontinuations

MMRM analyses account for missing data using ‘a missing at random’ assumption, i.e., there is a systematic relationship between the propensity for missing values and the observed data, but not the missing data. Under such assumptions, MMRM is shown to provide unbiased estimates of the treatment effect, whilst the analysis of only complete cases using analysis of covariance (ANCOVA) are biased (Baron, 2008; Ashbeck, 2016). Such complete case analysis requires a ‘missing completely at random’ assumption to remain unbiased and this is unlikely to hold, i.e., the fact that the data are missing is independent of the observed and unobserved data.

Using an MMRM, it will therefore be assumed that a subject with missing data at one post-Baseline visit would have obtained a similar efficacy result at that visit compared to a subject using the same study toothpaste with similar non-missing results at other timepoints (Baseline and the other post-Baseline visits).

For the subjects who discontinued early from their study toothpaste, the Treatment Policy will be used for the data analysis. That is to say, the data will be collected and used for analysis if subjects have early study toothpaste discontinuation but still stay in the study. The data will be imputed based on MMRM mentioned above for the subjects whose data cannot be collected after early study toothpaste discontinuation.

4.5 Analysis of Secondary Objectives

4.5.1 Pharmacokinetic (Secondary)

Not applicable.

4.6 Analysis of Safety

All safety data will be reported for the Safety Population as per actual study product received. The safety profile of the study products will be assessed with respect to AEs or incidents and OST/OHT abnormalities in oral health study.

4.6.1 Adverse Events and Serious Adverse Events

All AEs will be reviewed by the Clinical Research Scientist or designee prior to database lock and unblinding and will be coded to a system organ class (SOC) and preferred term (PT) using the Medical Dictionary for Regulatory Activities (MedDRA).

AEs will be classified as oral or non-oral on the AE page of eCRF.

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Treatment emergent adverse events (TEAEs) are defined as AEs that occur on or after the first use of study toothpaste at Baseline (Visit 2). In the event of a missing AE start date, an AE will be assumed to be ‘treatment emergent’ unless the end date is prior to starting treatment. AEs with an onset date/time prior to the first study product usage will be considered as non-treatment emergent. In case of misallocation, compared to the randomisation schedule, TEAEs will be associated with the most recent study toothpaste received.

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

- Overview of TEAEs (Table 14.3.1.1)
- Table of TEAEs by SOC and PT (Table 14.3.1.2)
- Table of TEAEs by Oral/Non-Oral and PT (Table 14.3.1.3)
- Table of treatment related TEAEs by SOC and PT (Table 14.3.1.4)
- Table of treatment related TEAEs by Oral/Non-Oral and PT (Table 14.3.1.5)
- Table of serious TEAEs by SOC and PT (Table 14.3.1.6)
- Listing of all AEs (Listing 16.2.7.1 for all randomised subjects; Listing 16.2.7.2 for non-randomised subjects)
- Listing of any incidents (Listing 16.2.7.3)
- Listing of deaths (Listing 14.3.2.1)
- Listing of non-fatal SAEs (Listing 14.3.2.2)
- Listing of TEAEs leading to study or product discontinuation (Listing 14.3.2.3)
- Listing of TEAEs classified as Oral (Listing 14.3.2.4)

If there is nothing to report, a null table or listing will be produced.

4.6.2 Other Safety Variables

Other Safety variables are listed below:

- OST examination
- OHT examination

4.6.2.1 OST examination

The OST examination will be accomplished by direct visual observation and palpation, using retraction aids if needed, and will include examination of the labial mucosa (including lips), buccal mucosa, mucogingival folds, gingival mucosa, hard palate, soft palate, tonsillar area, pharyngeal area, tongue, sublingual area, submandibular area, and salivary glands. Any

abnormal findings from the OST examination will be recorded in the eCRF with details of the abnormalities.

OST will be summarised (number of subjects and percentages with abnormalities) by visit and study product in Table 14.3.4.1 for all subjects in the Safety Population. Abnormal findings from the OST examination will be listed (Listing 16.2.8.1) with details of abnormalities for all randomised subjects.

4.6.2.2 OHT examination

The OHT examination will be accomplished by direct visual observation, using retraction aids if needed, and will identify enamel irregularities, tooth fractures, grossly carious lesions/gross decay, defective/faulty restorations (both direct and indirect restorations including fixed/removal prostheses), non-carious tooth surface loss (abrasion, attrition, abfraction and erosion), any other hard tissue irregularities (e.g., hypo-/hyper-mineralisation, decalcification) and significant tooth staining. Any conditions noted as 'Present' from the OHT examination will be described in the eCRF with details of the 'Present' condition.

The presence of any implants, fixed or removable dentures, fixed or removable orthodontic braces/bands, fixed orthodontic retainers, full crowns or veneers will be recorded, along with evidence of gross intra-oral neglect or the need for extensive dental therapy.

Any conditions noted as 'Present' from the OHT examination will be listed (Listing 16.2.8.2) with details of abnormalities for all randomised subjects.

4.7 Analysis of Other Variables

Not applicable.

5 Changes to the Protocol Defined Statistical Analysis Plan

There were no changes or deviations to the originally planned statistical analysis specified in the Protocol v5.0 dated 17-Dec-2024.

0.454% weight/weight (w/w) stannous fluoride (SnF₂) toothpaste
300212



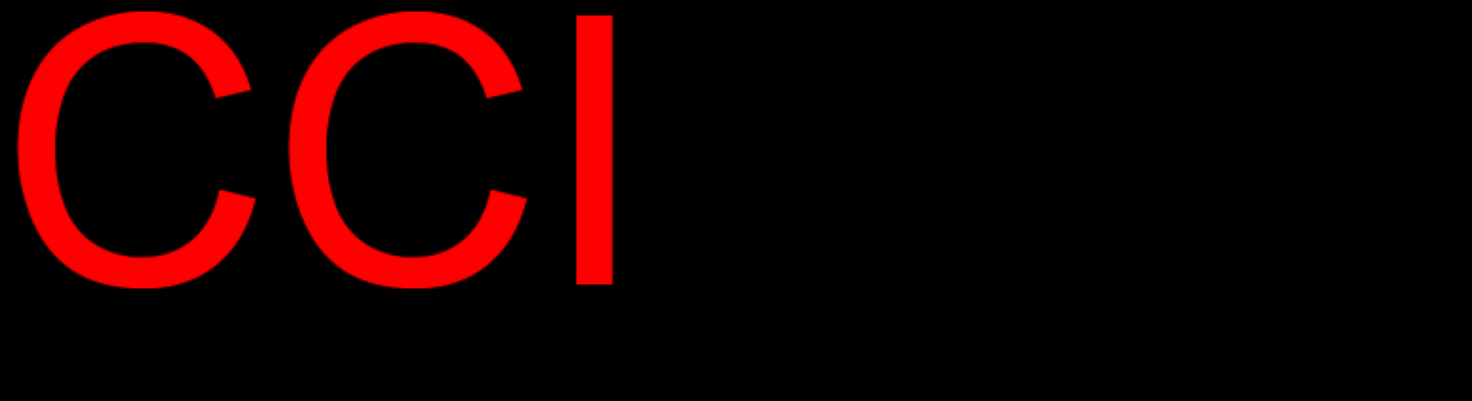
Appendix 1: List of Data Displays

CSR Section	TLF	Number	Title	Population	Template
14.1 Demographic Data Summary Tables and Figures					
	Table	14.1.1	Subject Disposition	All Screened Subjects	14.1.1
	Table	14.1.2	Incidence of Important Protocol Deviations	All Randomised Subjects	14.1.2
	Table	14.1.3.1	Demographic and Baseline Characteristics	Safety Population	14.1.3.1
	Table	14.1.3.2	Demographic and Baseline Characteristics	mITT Population	14.1.3.1
	Table	14.1.3.3	Demographic and Baseline Characteristics	PP Population	14.1.3.1
14.2 Efficacy Data Summary Tables and Figures					
	Table	14.2.1.1	Summary of Brushing Compliance	mITT Population	14.2.1.1
	Table	14.2.2.1.1	Summary of Schiff Sensitivity Score of the Two Test Teeth	mITT Population	14.2.2.1.1
	Table	14.2.2.1.2	Summary of Schiff Sensitivity Score of the Two Test Teeth	PP Population	14.2.2.1.1

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CSR Section	TLF	Number	Title	Population	Template
	Figure	14.2.2.1.3	Schiff Sensitivity Score (+/- SE) Plot Over Time by Study Product	mITT Population	14.2.2.1.3
	Figure	14.2.2.1.4	Schiff Sensitivity Score (+/- SE) Plot Over Time by Study Product	PP Population	14.2.2.1.3
	Figure	14.2.2.1.5	Change from Baseline in Schiff Sensitivity Score (+/- SE) Plot Over Time by Study Product	mITT Population	14.2.2.1.5
	Figure	14.2.2.1.6	Change from Baseline in Schiff Sensitivity Score (+/- SE) Plot Over Time by Study Product	PP Population	14.2.2.1.5
	Table	14.2.2.1.7	Summary of Schiff Sensitivity Score of the Two Test Teeth, by Number of Brushings Prior to Day 2	mITT Population	14.2.2.1.7
	Table	14.2.2.2.1	Statistical Analysis of Change from Baseline in Schiff Sensitivity Score of the Two Test Teeth Over Time (MMRM)	mITT Population	14.2.2.2.1
	Table	14.2.2.2.2	Statistical Analysis of Change from Baseline in Schiff Sensitivity Score of the Two Test Teeth Over Time (MMRM)	PP Population	14.2.2.2.1
	Table	14.2.3.1.1	Summary of Tactile Threshold (g) of the Two Test Teeth	mITT Population	14.2.2.1.1
	Table	14.2.3.1.2	Summary of Tactile Threshold (g) of the Two Test Teeth	PP Population	14.2.2.1.1
	Figure	14.2.3.1.3	Tactile Threshold (g) (+/- SE) Plot Over Time by Study Product	mITT Population	14.2.3.1.3
	Figure	14.2.3.1.4	Tactile Threshold (g) (+/- SE) Plot Over Time by Study Product	PP Population	14.2.3.1.3

CSR Section	TLF	Number	Title	Population	Template
	Figure	14.2.3.1.5	Change from Baseline in Tactile Threshold (g) (+/- SE) Plot Over Time by Study Product	mITT Population	14.2.3.1.5
	Figure	14.2.3.1.6	Change from Baseline in Tactile Threshold (g) (+/- SE) Plot Over Time by Study Product	PP Population	14.2.3.1.6
	Table	14.2.3.1.7	Summary of Tactile Threshold (g) of the Two Test Teeth, by Number of Brushings Prior to Day 2	mITT Population	14.2.2.1.7
	Table	14.2.3.2.1	Statistical Analysis of Change from Baseline in Tactile Threshold (g) of the Two Test Teeth Over Time (MMRM)	mITT Population	14.2.3.2.1
	Table	14.2.3.2.2	Statistical Analysis of Change from Baseline in Tactile Threshold (g) of the Two Test Teeth Over Time (MMRM)	PP Population	14.2.3.2.1
					

CSR Section	TLF	Number	Title	Population	Template
					
14.3 Safety Data Summary Tables and Figures					
14.3.1 Displays of Adverse Events					
	Table	14.3.1.1	Overview of Treatment Emergent Adverse Events	Safety Population	14.3.1.1
	Table	14.3.1.2	Treatment Emergent Adverse Events by System Organ Class and Preferred Term	Safety Population	14.3.1.2
	Table	14.3.1.3	Treatment Emergent Adverse Events by Oral/Non-Oral and Preferred Term	Safety Population	14.3.1.3
	Table	14.3.1.4	Treatment Related Treatment Emergent Adverse Events by System Organ Class and Preferred Term	Safety Population	14.3.1.2
	Table	14.3.1.5	Treatment Related Treatment Emergent Adverse Events by Oral/Non-Oral and Preferred Term	Safety Population	14.3.1.3

CSR Section	TLF	Number	Title	Population	Template
	Table	14.3.1.6	Serious Treatment Emergent Adverse Events by System Organ Class and Preferred Term	Safety Population	14.3.1.2
14.3.2 Listings of Deaths, Other Serious and Significant Adverse Events					
	Listing	14.3.2.1	Deaths	Safety Population	16.2.7.1
	Listing	14.3.2.2	Non-Fatal Serious Adverse Events	Safety Population	16.2.7.1
	Listing	14.3.2.3	Treatment Emergent Adverse Events Leading to Study or Product Discontinuation	Safety Population	16.2.7.1
	Listing	14.3.2.4	Treatment Emergent Adverse Events Classified as Oral	Safety Population	16.2.7.1
14.3.3 Narratives of Deaths, Other Serious and Certain Other Significant Adverse Events					
	N/A				
14.3.4 Other Observations Related to Safety and Abnormal Laboratory Values					
	Table	14.3.4.1	Summary of Oral Soft Tissue Examination Abnormalities	Safety Population	14.3.4.1
APPENDIX					
16.1.6 Listing of Subjects Receiving Test Drug(s)/Investigational Product(s) from Specific Batches, where more than one batch was used					
	N/A				
16.1.7 Randomisation Scheme and Codes (Subject identification and treatment assigned)					
	Listing	16.1.7.1	Randomisation Information	All Randomised Subjects	16.1.7.1
	Listing	16.1.7.2	Kit List Allocation	All Randomised Subjects	16.1.7.2

CSR Section	TLF	Number	Title	Population	Template
16.1.9 Documentation of Statistical Methods					
	Raw Output	16.1.9.1.1	Statistical Analysis of Change from Baseline in Schiff Sensitivity Score of the Two Test Teeth Over Time (MMRM) (Reference: Table 14.2.2.2.1)	mITT Population	SAS Output
	Raw Output	16.1.9.1.2	Statistical Analysis of Change from Baseline in Schiff Sensitivity Score of the Two Test Teeth Over Time (MMRM) (Reference: Table 14.2.2.2.2)	PP Population	SAS Output
	Raw Output	16.1.9.2.1	Statistical Analysis of Change from Baseline in Tactile Threshold (g) of the Two Test Teeth Over Time (MMRM) (Reference: Table 14.2.3.2.1)	mITT Population	SAS Output
	Raw Output	16.1.9.2.2	Statistical Analysis of Change from Baseline in Tactile Threshold (g) of the Two Test Teeth Over Time (MMRM) (Reference: Table 14.2.3.2.2)	PP Population	SAS Output
16.2 Subject Data Listings					
16.2.1 Discontinued Subjects					
	Listing	16.2.1.1	Subject Disposition	All Randomised Subjects	16.2.1.1
	Listing	16.2.1.2	Subject Disposition	Non-Randomised Subjects	16.2.1.2
16.2.2 Protocol Deviations					
	Listing	16.2.2.1	Important Protocol Deviations	All Randomised Subjects	16.2.2.1
	Listing	16.2.2.2	All Protocol Deviations	All Randomised Subjects	16.2.2.2

CSR Section	TLF	Number	Title	Population	Template
16.2.3 Subjects Excluded from the Efficacy Analysis					
	Listing	16.2.3.1	Exclusions from Analysis Populations	All Randomised Subjects	16.2.3.1
16.2.4 Demographic Data					
	Listing	16.2.4.1	Demographic and Baseline Characteristics	All Randomised Subjects	16.2.4.1
	Listing	16.2.4.2	Medical History and Current Medical Conditions	All Randomised Subjects	16.2.4.2
	Listing	16.2.4.3	Prior Medications	Safety Population	16.2.4.3
	Listing	16.2.4.4	Concomitant Medications and Significant Non-Drug Therapies	Safety Population	16.2.4.4
16.2.5 Compliance and/or Drug Concentration Data (if available)					
	Listing	16.2.5.1	Study Product Compliance	All Randomised Subjects	16.2.5.1
16.2.6 Individual Efficacy Response Data					
	Listing	16.2.6.1	Schiff Sensitivity Data for the Two Test Teeth	All Randomised Subjects	16.2.6.1
	Listing	16.2.6.2	Tactile Threshold (g) Data for the Two Test Teeth	All Randomised Subjects	16.2.6.2
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CSR Section	TLF	Number	Title	Population	Template
	CCI				
16.2.7 Adverse Event Listings					
	Listing	16.2.7.1	All Adverse Events	All Randomised Subjects	16.2.7.1
	Listing	16.2.7.2	All Adverse Events	Non-Randomised Subjects	16.2.7.1
	Listing	16.2.7.3	Incidents	All Randomised Subjects	16.2.7.3
16.2.8 Other Listings and Listing of Laboratory Measurements, when required by regulatory authorities (if applicable)					
	Listing	16.2.8.1	Oral Soft Tissue Examination Abnormalities	All Randomised Subjects	16.2.8.1
	Listing	16.2.8.2	Oral Hard Tissue Examination Findings	All Randomised Subjects	16.2.8.2
16.4 Individual Subject Data Listings					
	N/A				