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STATISTICAL ANALYSIS PLAN for A Randomized, Active-Controlled, Open-Label Study to Evaluate the Clinical Performance of Deseyne (vifilcon C) Daily Disposable Soft Contact Lens

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SUMMITANALYTICAL	**CONFIDENTIAL**

Bruno Vision Care

STATISTICAL ANALYSIS PLAN

Protocol Title: A Randomized, Active-Controlled, Open-Label Study to Evaluate the Clinical Performance of Deseyne (vifilcon C) Daily Disposable Soft Contact Lens

Study Number: 22001

Phase: Safety and effectiveness

Sponsor: Bruno Vision Care
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LIST OF TABLES

2. LIST OF ABBREVIATIONS AND DEFINITION OF TERMS

Only abbreviations and terms relevant to the analysis plan are repeated herein. The reader is referred to the protocol for the complete and comprehensive list of abbreviations and definitions of terms for the study.

Abbreviation/Term	Definition
ADaM	analysis data model
ADE	adverse device effect
AE	adverse event
BCDVA	best-corrected distance visual acuity
CCLRU	Cornea and Contact Lens Research Unit
CDISC	Clinical Data Interchange Standards Consortium
CI	confidence interval
CRF	case report form
ETDRS	Early Treatment Diabetic Retinopathy Study
FDA	Food and Drug Administration
GCP	Good Clinical Practice
ICF	informed consent form
ICH	International Council for Harmonisation
ID	identification
IRB	Institutional Review Board
ISO	International Organization for Standardization
ITT	intent-to-treat
IWRS	interactive web response system
PP	per protocol
PT	preferred term
SAE	serious adverse event
SAP	Statistical Analysis Plan
SDTM	Study Data Tabulation Model
SOC	system organ class
TFL	tables, figures, and listings
UADE	unanticipated adverse device effect
UV	ultraviolet
VA	visual acuity
VFQ	Visual Functioning Questionnaire
WHO-DD	World Health Organization Drug Dictionary

3. INTRODUCTION

3.1. Preface

This document presents an analysis plan for the Bruno Vision Care Protocol 22001 (*A Randomized, Active-Controlled, Open-Label Study to Evaluate the Clinical Performance of Deseyne [vifilcon C] Daily Disposable Soft Contact Lens*).

Reference materials for this plan include the protocol 22001 Version 3.0 (26 April 2023) and Case Report Forms (CRFs) Final Version (21 July 2023).

3.2. Deviations from Study Protocol

The satisfaction survey (modified Visual Functioning Questionnaire [VFQ]) has been removed from the list of secondary efficacy endpoints. Otherwise, the SAP is consistent with the methods described in the study protocol.

4. STUDY OBJECTIVE

The objective of this clinical study is to provide clinical performance data comparing the test lens (Deseyne [vifilcon C] daily disposable soft contact lens) to a control lens (1-Day Acuvue Moist [etafilcon A] daily disposable soft contact lens) in the same indication for use (single use prior to removal followed by a fresh lens upon the next lens wear exposure).

4.1. Study Endpoints

4.1.1. Primary Effectiveness Endpoints

There will be 2 primary effectiveness endpoints for the study:

1. Change from baseline to each post-baseline visit in distance logMAR visual acuity (VA) by eye
2. Number and percentage of subjects where there is no more than a 5−logMAR letters read loss from baseline (change from baseline in number of letters read ≥ -5). This is calculated by eye at each post-baseline visit

4.1.2. Secondary Effectiveness Endpoints

- Distance VA
- Symptoms/complaints and subjective assessments
- Lens wettability, centration, and movement
- Lens deposits

4.1.3. Primary Safety Endpoint

- Slit lamp findings (including corneal edema [epithelial, stromal], corneal infiltrates, corneal vascularization, corneal staining, palpebral conjunctival injection, and limbal injection)

4.1.4. Secondary Safety Endpoints

- Adverse events (AEs) and reactions (serious and incidental)
- Adverse device effects (ADEs)
- Conjunctival hyperemia as measured by the Cornea and Contact Lens Research Unit (CCLRU) grading scale
- Keratometry
- Slit lamp biomicroscopy
- Spherocylindrical refraction

- Corneal fluorescein staining
- Best-corrected distance visual acuity (BCDVA)
- Pinhole VA (for eyes with a 2-line decrease in BCDVA or worse from baseline)
- Lens discontinuation rates at any follow-up visit
- Use of unpreserved lubricant eyedrops or artificial tears during the study

5. STUDY METHODS

5.1. General Study Design and Plan

A multicenter, randomized, active-controlled, open-label study design will be used to compare the clinical performance of the Deseyne (vifilcon C) test soft contact lens to the similarly indicated 1-Day Acuvue® Moist® (etafilcon A) control soft contact lens.

Study participation is approximately 90 days in duration and will consist of approximately 80 subjects assigned in a 2:1 ratio to test or control lens bilaterally, respectively. Subjects must be otherwise healthy, with myopia between -1.00 D and -6.00 D and astigmatism no greater than 1.00 D that does not interfere with VA.

At the Screening Visit, approximately two-thirds of the eligible subjects will be randomized to receive the test lens (Deseyne [vifilcon C] lenses) and the other one-third eligible subjects will be randomized to receive the control lens (1-Day Acuvue Moist [etafilcon A] lenses). At the Dispensing Visit (Visit 2), subjects will be provided with test or control lenses as part of the dispensing package, along with instructions for the use and care of the lenses. They will be recommended unpreserved lubricating/rewetting solution for use as needed during the study.

Subjects will wear their assigned lenses bilaterally on a daily wear basis, for a minimum of 6 hours/day throughout the study (no maximum time is mandated, as long as subjects do not sleep in their lenses), with additional visits planned for 1 Week (Visit 3), 1 Month (Visit 4), 2 Months (Visit 5), and 3 Months/Exit Visit (Visit 6).

The schedule for assessments and procedures is presented in Table 1.

Table 1 Schedule of Assessments and Procedures

PROCEDURE/ASSESSMENTS	Screening Visit 1 Day -30 to -7	Dispensing Visit 2 Day 1	1 Week Visit 3 Day 6-10	1 Month Visit 4 Day 27-35	2 Months Visit 5 Day 54-68	3 Months/Exit Visit 6 Day 91-101[a]
Informed consent/HIPAA authorization	X					
Demographics/baseline eye/lens characteristics	X					
Contact lens use history and use	X		X	X	X	X
Medical/ocular history	X					
Urine pregnancy test	X	X	X	X	X	X
Concomitant medications	X	X	X	X	X	X
Eligibility	X					
Randomization	X					
Dispense and/or return study materials[b]		X				X
Symptoms/complaints and subjective assessments, including wear time	X	X	X	X	X	X
Modified visual functioning questionnaire	X					X
Review of daily log of eyedrop use			X	X	X	X
Adverse events	X	X	X	X	X	X
With lenses						
Conjunctival hyperemia[c]	X	X	X	X	X	X
Distance logMAR VA		X	X	X	X	X
Over-refraction and distance VA		X	X	X	X	X
Lens wettability/centration/movement		X	X	X	X	X
Lens deposits		X	X	X	X	X

PROCEDURE/ASSESSMENTS	Screening Visit 1 Day -30 to -7	Dispensing Visit 2 Day 1	1 Week Visit 3 Day 6-10	1 Month Visit 4 Day 27-35	2 Months Visit 5 Day 54-68	3 Months/Exit Visit 6 Day 91-101[a]
Without lenses						
Keratometry	X					X
Spherocylindrical refraction	X					X
BCDVA	X					X
Slit lamp exam	X	X	X	X	X	X
Corneal fluorescein staining	X	X	X	X	X	X

BCDVA, best-corrected distance visual acuity; CCLRU, Cornea and Contact Lens Research Unit; HIPAA, Health Insurance Portability and Accountability Act; VA, visual acuity.
a. The 3-Month/Exit Visit MUST occur no earlier than Day 91.
b. Materials to be dispensed at the Dispensing Visit include study lenses and a daily log of eyedrop usage; materials to be returned at the 3-Month/Exit Visit include any unworn lenses (worn lenses do not need to be returned) and the daily log of eyedrop usage.
c. To be performed with lenses in place using an external light source (ie, pen light) and the CCLRU (University of New South Wales, Sydney, Australia) conjunctival hyperemia grading scale (0-3).

5.2. Inclusion – Exclusion Criteria and General Study Population

Approximately 53 subjects (106 eyes) will be randomized to receive Deseyne (vifilcon C) investigational spherical soft hydrophilic lens and approximately 27 subjects (54 eyes) will be randomized to receive 1-Day Acuvue Moist (etafilcon A) daily disposable soft contact lens. Written informed consent will be obtained from each subject.

Subjects will wear their lenses on a daily wear basis (6 hours/day minimum; no maximum time is mandated, as long as subjects do not sleep in their lenses) for 3 months. Use of any other contact lenses is not allowed during the study.

The full inclusion and exclusion criteria defined in the protocol apply to all subjects and are not repeated herein. Reference is made to the final protocol for the specific inclusion and exclusion criteria for study subjects.

5.3. Randomization and Blinding

Subjects will be randomized to 1 of 2 treatment arms in a 2:1 ratio (test:control), wearing either test or control lenses in both eyes for the duration of the study. Randomization will be stratified by investigational site.

Subjects will be randomized after they are deemed eligible to participate, according to subject-specific randomization information provided by the randomization system.

This open-label study will not be masked.

5.4. Analysis Variables

The following effectiveness variables will be collected:

- Distance logMAR VA
- Distance VA
- Symptoms/complaints and subjective assessments
- Lens wettability, centration, and movement
- Lens deposits

The following safety variables will be collected:

- Slit lamp findings
- Adverse reactions
- Adverse device effects
- Conjunctival hyperemia
- Keratometry

- Slit lamp biomicroscopy
- Spherocylindrical refraction
- BCDVA
- Corneal fluorescein staining
- Lens discontinuation rates at any follow-up visit
- Use of unpreserved lubricant eyedrops or artificial tears during the study

6. SAMPLE SIZE

The sample size of approximately 80 subjects (160 eyes) is considered sufficient for evaluation of the clinical performance of the test and control lenses. The sample size was not based on statistical power considerations. A dropout rate of approximately 20% is expected; thus, 60 subjects (120 eyes) are targeted to be described in this study.

7. GENERAL CONSIDERATIONS

7.1. Analysis Populations

The following analysis populations will be defined for this study.

7.1.1. Intent-to-Treat (ITT) Population

The intent-to-treat (ITT) population will consist of all randomized subjects. Subjects will be included in treatment groups according to the treatments to which they were randomized for ITT population summaries.

7.1.2. Per Protocol (PP) Population

The per protocol (PP) population will consist of all randomized subjects without the following important protocol deviations:

- Ineligible when randomized
- Not dispensed study lenses
- Use of an incorrect lens type (eg, due to improper randomization, erroneous dispensing, return to habitual lens brand, etc.)
- Failure to wear the assigned lenses at least 80% of the expected days
- Failure to provide non-missing distance logMAR VA data at all of the scheduled visits (Dispensing Visit and 1-Week, 1-Month, 2-Month, and 3-Month/Exit Visits)

Additional important protocol deviations may be identified prior database lock.

7.1.3. Safety Population (SP)

The safety population (SP) will consist of all subjects who were dispensed lenses. Subjects will be included in treatment groups according to the treatments that were actually dispensed to them for safety population summaries. If a subject uses both lens types, then the subject will be included in the test lens group for safety population summaries.

7.2. Covariates and Subgroups

7.2.1. Planned Covariates

Planned covariates include baseline values for the given assessment.

7.2.2. Planned Subgroups

Effectiveness variables related to eye assessments will be summarized by eye.

7.3. Management of Analysis Data

7.3.1. Data Handling

For assessments collected at specific visits, the data from unscheduled visits will not be summarized (unless noted below), but all unscheduled visit data will be listed. All data from log pages (e.g., concomitant medications and AEs) will be included in the analysis tables.

7.3.2. Missing Data

When summarizing effectiveness endpoints, no imputation will be performed.

7.3.2.1. Handling of Missing Date Values

Partial or Missing Dates

Missing portions of dates for AEs or concomitant medications will not be formally imputed. Instead, an AE will be classified as treatment-emergent or a medication as concomitant using the most conservative date that can be derived from the non-missing portion of the date.

7.3.2.2. Missing Baseline Data

Every effort will be made to ensure that accurate baseline information on the subjects is collected. In the event that a subject is missing baseline information, the subject will be included in the SP for assessment of safety and excluded from the primary analyses. Each case of missing baseline data will be evaluated for potential inclusion in the exploratory endpoints. All baseline data will be observed cases, without imputation.

7.3.3. Handling of Early Termination Visit Information

In the event that a subject is terminated early from this study, the early termination data will be assigned to the closest visit. If the closest visit has valid data, the early termination data will be assigned to the next available visit, and treated as observed data for that visit in the imputation procedures described above.

7.3.4. Coding Conventions for Events and Medications

All AEs, medical and ophthalmic history, and concomitant procedures/therapies will be mapped to the Medical Dictionary for Regulatory Activities (MedDRA Version 26.1) system for reporting.

Prior and concomitant medications will be coded using WHO-DD (World Health Organization Drug Dictionary) (Version January 2023).

7.3.5. Analysis Software

Data manipulation, tabulation of descriptive statistics, calculation of inferential statistics, and graphical representations will be performed using SAS (release 9.4 or higher) for Windows.

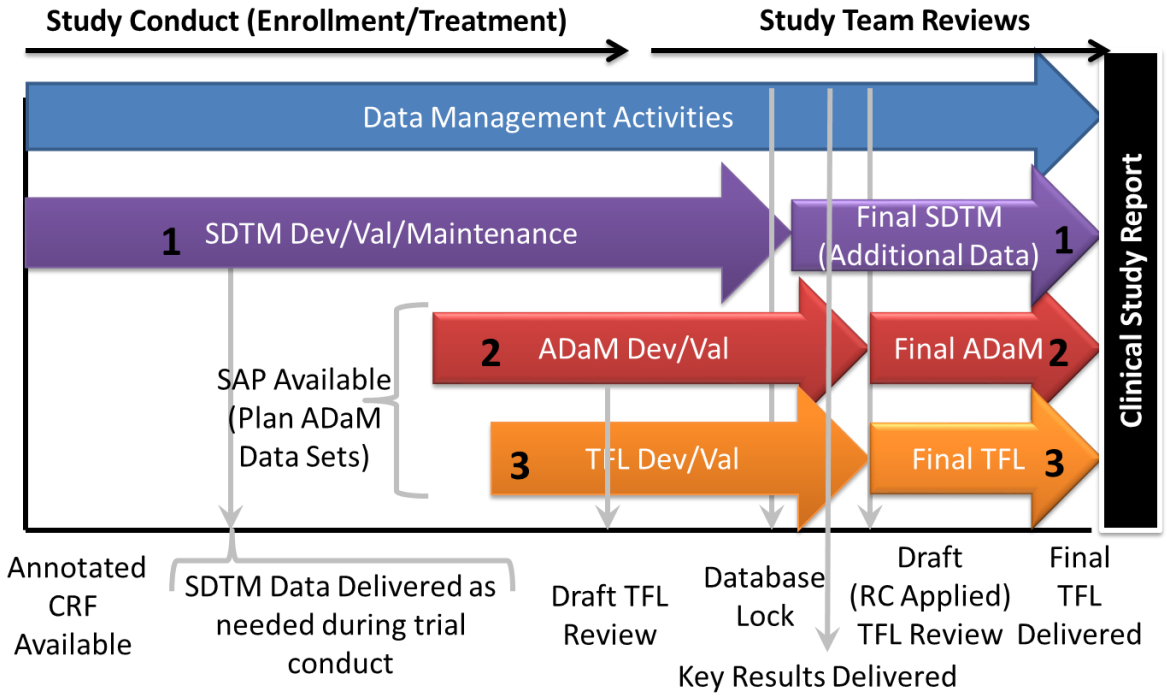
7.3.6. Study Data

Study data identified in the schedule for time and events (Table 1) are not being collected by electronic data capture (EDC).

All study data will be formulated into regulatory-compliant data sets to provide transparency, traceability, and integrity of trial analysis results from the collection source. Observed study data will be mapped to the Clinical Data Interchange Standards Consortium (CDISC) Study Data Tabulation Model (SDTM) and serve as the source data from the trial. All study analyses will be completed using analysis data sets that are derived from the SDTM and follow the CDISC Analysis Data Model (ADaM) architecture.

The methods for programming the CDISC SDTM and ADaM data sets are described in Figure 1.

Figure 1 SDTM, ADaM, and TFL Development and Validation



Where:

1. Development, validation, and maintenance of SDTM domains

2. Development and validation of ADaM data sets, with input source the appropriate SDTM domains.
3. Development and validation of tables, figures, and listings (TFL), with input data source the SDTM domains and analysis specific ADaM data sets.

7.4. Planned Study Analyses

7.4.1. Statistical Summaries: Descriptive and Inferential

Safety and effectiveness endpoint results will be presented by treatment group (Deseyne [vifilcon C] and 1-Day Acuvue Moist [etafilcon A]).

All p-values will be rounded to and displayed in four decimals. If a p-value less than 0.0001 occurs, it will be shown in tables as <0.0001. The p-values for the analysis of effectiveness endpoints will be considered descriptive.

Descriptive summaries of variables will be provided where appropriate. For continuous variables, the number of non-missing values (n), mean, standard deviation, median, confidence intervals (CIs), minimum, and maximum will be tabulated by treatment group. Means, medians, and CIs will be presented with 1 more decimal place than the recorded raw data. Standard deviations will be presented with 2 more decimal places than the recorded raw data. Minima and maxima will be presented with the same number of decimal places as the recorded raw data. Values with magnitude <1 will be presented with a leading zero to the left of the decimal (e.g., 0.123).

Categorical data will be summarized using frequencies, percentages, and CIs. Percentages will be presented with 1 decimal place. Percentages may not be presented when the count is 0. Unless otherwise specified, the denominator for percentages will be the number of non-missing values within the group being presented.

All study-related data collected will be presented in listings. Study-related data not subject to analysis according to this plan will not appear in any tables or graphs but will be included in the data listings.

7.4.2. Interim Analyses and Data Monitoring

No interim analyses are planned.

7.4.3. Final Analysis and Publication of Study Results

The final analysis will be completed after all subjects have completed the study.

7.5. Multiple Testing Procedures

There will be no adjustments for multiplicity and no formal multiple testing procedures are to be implemented with this analysis plan.

7.6. Baseline Values

Baseline values are the values obtained prior to the dispensing of study lenses at the Dispensing Visit (Visit 2/Day 1). If the Day 1 value is missing or is not scheduled to be collected, any value collected prior to treatment administration (e.g., from the Screening visit) will be used as the baseline. For the Distance logMAR Visual Acuity assessment, the BCDVA obtained at the Screening visit is the baseline value.

8. SUMMARY OF STUDY DATA

8.1. Subject Disposition

A summary of the analysis sets includes the number and percentage of subjects by treatment group and overall for the following categories: subjects in the SP, the ITT Population, and the PP Population. All percentages will be based on the number of randomized subjects.

End of trial information will also be summarized in this table, including the number of subjects completing the study, the number of subjects who prematurely discontinued the study with reasons for withdrawal, the number of subjects completing the study device dosing, and the number of subjects who prematurely discontinued lens wear with reasons for lens discontinuation.

A by-subject data listing of study completion information including the reason for premature study withdrawal or lens wear discontinuation, if applicable, will be presented.

8.2. Protocol Deviations

Important protocol deviations will be determined by a Sponsor review of the data prior to database lock. The Sponsor or designee will be responsible for producing the final deviation file; this file will include a description of the protocol deviation and clearly identify whether this violation warrants exclusion from the PP Population. This file will be finalized prior to database lock.

Protocol deviations will be presented in a by-subject data listing.

8.3. Demographics and Baseline Characteristics

Subject demographic data and baseline characteristics will be tabulated and summarized descriptively by treatment group and overall. The demographic data and baseline characteristics will be summarized for the ITT, Safety, and PP Populations.

The demographics consist of age (year), sex, race, and ethnicity. Age will be summarized using descriptive statistics. The number and percentage of subjects by sex, race, and ethnicity will be presented. Percentages will be based on the total number of subjects in the study population presentation.

The following baseline lens use characteristics will be summarized for each eye using descriptive statistics or categorically as applicable:

- Contact lens use (daily or extended wear)
- Average number of days worn per week
- Average daily wearing time (hours)

- Lens wear (full time, part time, occasionally, or socially)

Demographics and baseline characteristics, including all baseline lens use data, will be presented in by-subject listings.

8.4. Medical History

Ocular and general medical and surgical history will be coded using the MedDRA Version 26.1.

Ocular and general medical history data including specific details will not be tabulated but will be presented in by-subject listings.

Contact lens history and use will not be tabulated but will appear in by-subject listings.

8.5. Prior and Concomitant Medications

A concomitant medication is defined as any medication taken on or after the day of first exposure to study device. The number and percentages of all concomitant medications will be summarized by treatment group, Anatomical Therapeutic Chemical (ATC) level 4, and PT. The total number of concomitant medications and the number and percentages of subjects with at least 1 concomitant medication will be summarized by treatment group.

Prior medications are defined as any medication that has a start and stop date prior to the day of first exposure to study device. Prior medications will be summarized the same way as for concomitant medications.

Prior and concomitant medication summaries will be performed using the SP.

8.6. Study Device Exposure

The number of study lens exposure weeks will be calculated for each subject in the SP as the last date of study lens wear – date of lens dispensing + 1.

The average number of days per week the lens was worn and the average daily wearing time will be determined from the averages collected at each visit. Data will be collected separately for each eye.

The number of study lens exposure weeks will be tabulated and summarized descriptively by treatment group. The average number of days per week the lens was worn and the average daily wearing time will be summarized descriptively by treatment group and eye.

Lens exposure data will be presented in by-subject listings.

9. EFFECTIVENESS ANALYSES

Effectiveness will be assessed using the ITT Population with subject eyes included in the treatment arm in which they were randomized. Primary and secondary effectiveness endpoints will also be assessed using the PP Population. Data will be presented and analyzed by treatment group and eye. Observed case data will be used; no imputation will be performed for effectiveness data.

9.1. Primary Effectiveness

The change from baseline to each post-baseline visit in distance logMAR VA will be summarized descriptively by treatment group and eye, using letters read as the unit of analysis. Actual values will also be summarized at each visit by treatment group and eye.

The number and percentage of subjects where there is no more than a 5−logMAR letters read loss from baseline (change from baseline in number of letters read ≥ -5) will be summarized at each post-baseline visit by treatment group and eye.

Summaries will be completed for both the ITT and PP populations.

9.2. Secondary Effectiveness

Secondary effectiveness endpoints are indicated in Section 4.1.

All effectiveness data for continuous endpoints will be summarized descriptively at each visit, showing actual values and change from baseline values by treatment group. For effectiveness endpoints that assess each eye separately, summaries will be created for each eye. Categorical effectiveness endpoints will be summarized using counts and percentages by treatment group and eye, where applicable.

Summaries will be completed for both the ITT and PP populations.

Responses to the satisfaction survey (modified VFQ) will not be tabulated but will be listed.

10. SAFETY ANALYSES

All safety analyses will be conducted using the SP. All safety analyses will be completed using the actual treatment a subject received. Observed case data will be used; no imputation will be performed for missing safety data except for the limited situations described in Section 7.3.2. Safety data will be tabulated and summarized descriptively by treatment group. Each eye will be treated independently for safety purposes.

All safety data will be presented in by-subject listings.

10.1. Adverse Events and Adverse Device Events

AEs will be coded using MedDRA, Version 26.1.

Treatment-emergent adverse events (TEAEs) are defined as any AE that begins or worsens after lens dispensing. If the onset of an AE is on or after the date of lens dispensing or is increasing in severity after dispensing, then the AE will be considered treatment-emergent. Only TEAEs will be summarized in the tables.

The number and percent of eyes with any TEAEs, and the number of subjects with any systemic TEAEs, will be summarized by SOC and PT and by treatment group. At each level of tabulation (e.g., at the PT level), eyes/subjects will be counted only once if they had more than one such event reported during the AE collection period.

The following summary tables will be presented for TEAE data, by SOC and PT:

- TEAEs
- Serious TEAEs
- TEAEs leading to withdrawal from the study
- TEAEs leading to lens wear discontinuation

All TEAEs and non-TEAEs will be presented in a by-subject listing.

ADEs will not be summarized, but will be presented in by-subject listings.

10.2. Deaths, Serious Adverse Events and Other Significant Adverse Events or Adverse Device Events

Any deaths, serious AEs, AEs leading to withdrawal from the study, AEs leading to lens wear discontinuation, and unanticipated ADEs will be presented in by-subject listings with the other AEs and ADEs.

10.3. Other Safety Variables

All safety variables are listed in Section 5.4.

Categorical safety variables will be summarized descriptively using counts and percentages for each treatment group at each visit.

For continuous safety variables, observed values and change from baseline will be summarized descriptively for each parameter (as appropriate) by treatment group at each visit.

For safety endpoints that assess each eye separately, each eye will be treated independently for summarizations.

Graded slit lamp findings will be assessed at each scheduled follow-up visit (1-Week, 1-Month, 2-Month, and 3-Month/Exit Visits) and, optionally, at unscheduled visits. The number and percentage of eyes with findings Grade >2 at any follow-up visit, including unscheduled visits, will be presented by treatment group. Corneal scar findings will not be tabulated but will be listed.

Pinhole VA results for eyes with a 2-line decrease in BCDVA or worse from baseline will be listed with the Distance logMAR VA data.

Lens discontinuation will be assessed at each scheduled follow-up visit (1-Week, 1-Month, 2-Month, and 3-Month/Exit Visits) and, optionally, at unscheduled visits. The time to discontinuation will be based on the study lens exposure weeks defined in Section 8.6. The lens discontinuation rate at each follow-up visit will be presented by treatment group.

The use of unpreserved lubricant eyedrops or artificial tears will be assessed for each follow-up visit by counting the number of drops recorded in the OTC Artificial Tears Log for the period between each visit.

11. REFERENCES

[1] ICH E9 Expert Working Group. Statistical Principles for Clinical Trials: ICH Harmonized Tripartite Guideline, September 1998

12. APPENDICES

12.1. List of Planned Tables

The list of planned tables includes all of the *main* tables to be presented

Table	Description of Table	All	Safety	ITT	PP
14.1.1.1	Subject Disposition	X			
14.1.2.x	Demographics and Baseline Characteristics		X	X	X
14.1.3.x	Baseline Lens Characteristics		X	X	X
14.1.4.1	Prior Medications		X		
14.1.4.2	Concomitant Medications		X		
14.1.5	Study Device Exposure		X		
14.2.1.x	Distance logMAR Visual Acuity by Visit and Eye			X	X
14.2.2.x	Subjects With No More Than 5 Letters Read Loss From Baseline in Distance logMAR Visual Acuity by Visit and Eye			X	X
14.2.3.x	Symptoms/Complaints and Subjective Assessments by Visit and Eye			X	X
14.2.4.x	Lens Wettability, Centration, and Movement by Visit and Eye			X	X
14.2.5.x	Lens Deposits by Visit and Eye			X	X
14.3.1.1	Treatment-Emergent Adverse Events (TEAE) by System Organ Class and Preferred Term		X		
14.3.1.2	Serious Treatment-Emergent Adverse Events (TEAE) by System Organ Class and Preferred Term		X		
14.3.1.3	Treatment-Emergent Adverse Events (TEAE) Leading to Withdrawal From the Study by System Organ Class and Preferred Term		X		
14.3.1.4	Treatment-Emergent Adverse Events (TEAE) Leading to Lens Wear Discontinuation by System Organ Class and Preferred Term		X		

Table	Description of Table	All	Safety	ITT	PP
14.3.3	Eyes With Slit Lamp Findings Grade >2 at Any Follow-up Visit		X		
14.3.4	Conjunctival Hyperemia by Visit and Eye		X		
14.3.5	Keratometry at Final Visit by Eye		X		
14.3.6	Spherocylindrical Refraction at Final Visit by Eye		X		
14.3.7	Corneal Fluorescein Staining by Visit and Eye		X		
14.3.8	Best-corrected Distance Visual Acuity (BCDVA) at Final Visit by Eye		X		
14.3.9	Lens Discontinuation Rate at Each Follow-up Visit by Eye		X		
14.3.10	Use of Unpreserved Lubricant Eyedrops or Artificial Tears by Visit and Eye		X		

12.2. List of Planned Listings

Listing	Description of Listing
16.2.1.1	Subject Disposition
16.2.1.2	Eligibility, Randomization, and Planned Study Lens
16.2.2	Protocol Deviations
16.2.3	Treatment Assignment and Analysis Populations
16.2.4.1	Demographics
16.2.4.2	Baseline Eye
16.2.4.3	Lens History and Use
16.2.4.4	General Medical and Surgical History
16.2.4.5	Ophthalmic Medical and Surgical History
16.2.4.6	Prior and Concomitant Medications
16.2.5.1	Lens Characteristics and Initial Dispensation
16.2.5.2	Lens Information
16.2.5.3	Lens Return and Follow-up Dispensation
16.2.5.4	Lens Replacement
16.2.5.5	Study Lens Exposure
16.2.6.1	Distance logMAR Visual Acuity
16.2.6.2	Over-Refraction and Distance Visual Acuity

Listing	Description of Listing
16.2.6.3	Symptoms/Complaints and Subjective Assessments
16.2.6.4	Lens Wettability, Centration, and Movement
16.2.6.5	Lens Deposits
16.2.6.6	Satisfaction Survey Using the Modified Visual Functioning Questionnaire (VFQ)
16.2.7.1	Adverse Events
16.2.7.2	Adverse Device Effects
16.2.8	Slit Lamp Examination
16.2.9	Conjunctival Hyperemia
16.2.10	Keratometry
16.2.11	Spherocylindrical Refraction
16.2.12	Corneal Fluorescein Staining
16.2.13	Best-corrected Distance Visual Acuity (BCDVA)
16.2.14	Use of Unpreserved Lubricant Eyedrops or Artificial Tears
16.2.15	Urine Pregnancy Test
16.2.16	General Comments

12.3. List of Planned Figures

Figure	Description of Figure	All	Safety	ITT	PP
14.3.4	Bar Charts of Conjunctival Hyperemia by Visit and Eye		X		
14.3.7	Bar Charts of Corneal Fluorescein Staining by Visit and Eye		X		