SUMMITANALYTICAL	**CONFIDENTIAL**

A Randomized, Active-Controlled, Double-Masked, Crossover Study to Evaluate the Clinical Performance of Deseyne (vifilcon C) Daily Disposable Soft Contact Lens for Presbyopia Extended Depth of Focus (EDOF)

SAP for Protocol 23001-2

24JAN2026

Bruno Vision Care

STATISTICAL ANALYSIS PLAN

Protocol Title: A Randomized, Active-Controlled, Double-Masked, Crossover Study to Evaluate the Clinical Performance of Deseyne (vifilcon C) Daily Disposable Soft Contact Lens for Presbyopia Extended Depth of Focus (EDOF)

Study Number: 23001-2

Phase: Effectiveness

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1. TABLE OF CONTENTS

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
ANCOVA	analysis of covariance
ATC	Anatomical Therapeutic Chemical
BCDVA	best-corrected distance visual acuity
CDISC	Clinical Data Interchange Standards Consortium
CI	confidence interval
CRF	case report form
D	diopter
DCIVA	distance-corrected intermediate visual acuity
DCNVA	distance-corrected near visual acuity
DOF	Depth of focus
EDC	electronic data capture
EDOF	extended depth of focus
FDA	Food and Drug Administration
ICH	International Council for Harmonisation
ITT	intent-to-treat
OD	oculus dexter (right eye)
OS	oculus sinister (left eye)
PP	per protocol
PT	preferred term
SAE	serious adverse event
SAP	Statistical Analysis Plan
SD	standard deviation
SDTM	Study Data Tabulation Model
SOC	system organ class
SP	Safety Population
TEAE	treatment-emergent adverse events
TFL	tables, figures, and listings
VA	visual acuity
WHO-DD	World Health Organization Drug Dictionary

3. INTRODUCTION

3.1. Preface

This document presents an analysis plan for the Bruno Vision Care Protocol 23001-2 (*A Randomized, Active-Controlled, Double-Masked, Crossover Study to Evaluate the Clinical Performance of Deseyne [vifilcon C] Daily Disposable Soft Contact Lens for Presbyopia Extended Depth of Focus*).

Reference materials for this plan include the protocol 23001-2 Version 3.0 (25 Sep 2024) and Case Report Forms (CRFs) Final Version (30 Sep 2024).

3.2. Deviations from Study Protocol

The SAP is consistent with the methods described in the study protocol.

4. STUDY OBJECTIVE

The objective of this clinical study is to evaluate improvements in near vision and extended depth of focus (EDOF) with the Deseyne (vifilcon C) Daily Disposable Soft Contact Lens for Presbyopia EDOF.

4.1. Study Endpoints

4.1.1. Primary Effectiveness Endpoint

The primary effectiveness endpoint for the study is monocular photopic negative lens-induced distance-corrected depth of focus (DOF) at the 0.2 logMAR visual acuity (VA) threshold.

The endpoint will be derived from the negative defocus level where visual acuity equals 0.2 logMAR. This will likely require interpolating between two visual acuity values on either side of the 0.2 logMAR threshold. If the 0.2 logMAR threshold is never exceeded, the DOF will be set to the maximum negative defocus level = -3.5.

4.1.2. Secondary Effectiveness Endpoints

- Monocular photopic distance-corrected intermediate visual acuity (DCIVA) at 66 cm
- Monocular photopic distance-corrected near visual acuity (DCNVA) at 40 cm

4.1.3. Additional Endpoints

- Defocus curves (study [right] eye only)
- Binocular contrast sensitivity (mesopic conditions with and without glare)

4.1.4. Safety Endpoints

- Adverse events (AEs) and reactions (serious and incidental)
- Adverse device effects (ADEs)
- Slit lamp biomicroscopy
- Corneal fluorescein staining

5. STUDY METHODS

5.1. General Study Design and Plan

A multicenter, randomized, active-controlled, double-masked, crossover study design will be used to compare the clinical performance of the Deseyne (vifilcon C) soft contact lens for Presbyopia EDOF (test) to the 1-Day Acuvue Moist (etafilcon A) soft contact lens for Single Vision (control).

This is a 1-day crossover study and will consist of approximately 75 subjects (75 study eyes [all study eyes will be right eyes]) randomly assigned in-office to wear the test or the control lens first. A 30-minute washout period will be scheduled between the crossover. Subjects must be otherwise healthy, with spectacle refraction between -6.00 and +4.00 diopters (D) and astigmatism ≤1.00 D that does not interfere with VA.

The Screening and Lens Fitting Visit (Visit 1) will determine eligibility for inclusion in the study, and subjects will be fitted with the test and control devices in both eyes. To maintain subject masking, each time study lenses are to be inserted (at Visit 1 and Visit 2), an unmasked technician will remove the foil labels from the assigned contact lens blister packs before giving the opened blister packs to the subject, who will insert both lenses. The Testing Visit (Visit 2) will be conducted in the manner described to assess vision with either the test or control lens followed by a 30-minute washout period (after the first set of lenses is removed) followed by crossover to the second set of lenses. To maintain Investigator masking, the subject (not the Investigator) will remove study lenses and immediately dispose of them. With this approach, the Investigator will not see the lenses either through the slit lamp or out of the subject's eye.

Subjects will wear their assigned lenses bilaterally only for the period required for testing. Lenses will not be dispensed to subjects for wear beyond the visit. This is a non-dispensing study.

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

Table 1 Schedule of Assessments and Procedures

PROCEDURE/ASSESSMENTS	Screening and Lens Fitting Visit (Visit 1)	Testing Visit (Visit 2)		
	Day -14 to -2	Day 1		
		Part A	Part B (Crossover)	Part C
Informed consent/HIPAA authorization	X			
Demographics/baseline lens characteristics	X			
Medical/Ocular history	X			
Concomitant medications	X	X		
Pupil diameter [a]	X			
Spherocylindrical refraction [b]	X			
Monocular BCDVA [b]	X			
Slit lamp biomicroscopy [b]	X	X	X	X
Corneal fluorescein staining	X	X	X	X
Eligibility	X			
Randomization	X			
With lenses				
Subject insertion of study lenses		X	X	
Lens fitting [b]	X			
Monocular distance VA [b]	X	X	X	
Monocular defocus curves [a]		X	X	
Binocular distance VA		X	X	
Monocular [a] and binocular intermediate VA		X	X	
Monocular [a] and binocular near VA		X	X	
Binocular contrast sensitivity (mesopic conditions with and without glare)		X	X	
Removal of study lenses		X	X	
Adverse events [b]	X			X

BCDVA, best-corrected distance visual acuity; HIPAA, Health Insurance Portability and Accountability Act; VA, visual acuity.
[a] In the right eye only; [b] In each eye.

5.2. Inclusion – Exclusion Criteria and General Study Population

Approximately 75 subjects (75 study eyes) will be randomized to determine the order in which the study lenses will be tested: Deseyne (vifilcon C) investigational spherical soft hydrophilic lens and 1-Day Acuvue Moist (etafilcon A) daily disposable soft contact lens. All subjects will wear both test and control lenses bilaterally and will undergo testing while wearing both test and control lenses.

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 Masking

Subjects will be randomized to determine the order in which the study lenses will be tested: Deseyne (vifilcon C) investigational spherical soft hydrophilic lens and 1-Day Acuvue Moist (etafilcon A) daily disposable soft contact lens.

Subjects will be randomized after they are deemed eligible to participate. Randomization will be provided to the sites via an interactive web response system.

Subject masking will be maintained by having an unmasked technician remove the foil labels from the assigned contact lens blister packs before giving the opened blister packs to the subject, who will insert both lenses. Investigator masking will be maintained by having the subject remove and dispose of all study lenses. This study will not be masked to project team members, including the statistician and programmers.

5.4. Analysis Variables

The following effectiveness variables will be collected:

- Monocular photopic negative lens-induced distance-corrected DOF at the 0.2 logMAR VA threshold
- Monocular photopic DCIVA
- Monocular photopic DCNVA
- Defocus curves (study eye only)
- Binocular contrast sensitivity (mesopic conditions with and without glare)

The following safety variables will be collected:

- Adverse events/reactions
- ADEs
- Slit lamp biomicroscopy
- Corneal fluorescein staining

6. SAMPLE SIZE

To test the hypothesis that the difference between test and control means is less than 0.5 D at alpha=0.025 using a 2×2 crossover design, 75 subjects (75 study eyes) are required to achieve 90% power, assuming a standard deviation (SD) of the paired differences = 1.06 D and an observed difference of at least 0.90 D.

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
- Use of an incorrect lens type (e.g., due to improper randomization, etc.)
- Failure to provide non-missing distance VA data at the Screening and Lens Fitting Visit and the Testing Visit

Other important protocol deviations may be identified via a masked review prior to database lock.

7.1.3. Safety Population (SP)

The safety population will consist of all subjects who wore study lenses. Subjects will be included in treatment groups according to the treatment sequence they actually followed 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. Other subgroups for effectiveness variables may include:

- Age stratification (< 60 and ≥ 60 years)
- Pupil diameter stratification into 3 tertiles based on study eye
- Distance-corrected near VA stratification into 3 tertiles based on monocular (study eye) near VA with the control lens

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. If there are repeated assessments for effectiveness endpoints, the last assessment will be used for analysis. 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

Not applicable since there is only one Testing Visit.

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 27.1) system for reporting.

Prior and concomitant medications will be coded using WHO-DD (World Health Organization Drug Dictionary) (Version January 2024).

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.

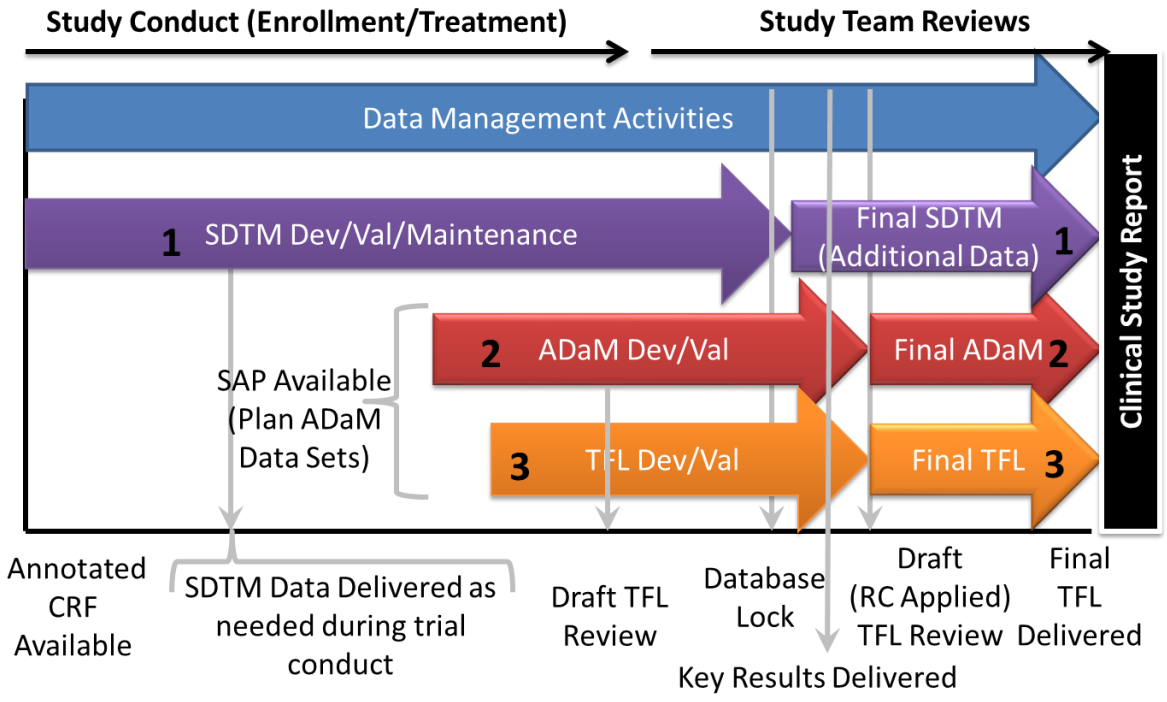
7.3.6. Study Data

Study data identified in the schedule for time and events (Table 1) are not being collected by electronic data capture (EDC). Assessments for the effectiveness endpoints will be performed using the M&S Clinical Trial Suite.

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. Purple = Development, validation, and maintenance of SDTM domains

2. Red = Development and validation of ADaM data sets, with input source the appropriate SDTM domains.
3. Orange = 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.

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 wearing of study lenses at the Testing Visit (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 and Lens Fitting visit) will be used as the baseline.

8. SUMMARY OF STUDY DATA

8.1. Subject Disposition

A summary of the analysis sets includes the number and percentage of subjects by treatment sequence 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 sequence 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 characteristics will be summarized using descriptive statistics:

- Pupil diameter (right eye only)
- Monocular best-corrected distance visual acuity (BCDVA) (each eye without lenses)

Demographics and baseline characteristics 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 27.1.

Ocular and general medical history data including specific details will not be tabulated but will be presented 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.

Concomitant medications that start during Part A of the Testing Visit and are ongoing during Part B will be summarized using both the Part A and Part B treatment groups. Medications that start during Part B or Part C will be summarized using the Part B treatment group only.

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, except that treatment sequence will be used instead of treatment group.

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

8.6. Study Device Fitting and Characteristics

The number and percentage of subjects with completed lens fittings and successful lens fittings will be summarized by treatment group. Lens centration and movement will be summarized categorically by treatment group, using 0 to 3 point scales. Monocular distance VA (letters read) readings at the Fitting visit (with lenses) will be summarized descriptively by treatment group for each eye.

Study lens characteristics for the Testing visit will be presented in by-subject listings, including the time of lens insertion for the study and control lenses, and the time of removal of the first pair of lenses.

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 (or binocularly). Observed case data will be used; no imputation will be performed for effectiveness data.

9.1. Primary Effectiveness

The primary effectiveness endpoint for the study is monocular photopic negative lens-induced distance-corrected DOF at the 0.2 logMAR VA threshold.

The statistical hypothesis is stated in terms of 1-sided hypotheses to reflect the superiority claims.

- H_0: The monocular photopic negative lens-induced distance-corrected DOF with the test lens is smaller than 0.5 D compared with the control lens.
- H_1: The monocular photopic negative lens-induced distance-corrected DOF with the test lens is greater than or equal to 0.5 D compared with the control lens.

The study eye will be used to evaluate this hypothesis. Comparisons between treatment groups will be evaluated with an analysis of covariance (ANCOVA) for the testing visit, with treatment group, treatment sequence, study period (Testing Visit time point), and (if appropriate) the baseline value. The covariance between within-subject values will be modeled using an unstructured covariance type if the model converges. If the model does not converge, other covariance types will be utilized that allow for convergence.

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

9.2. Secondary Effectiveness

Secondary effectiveness endpoints are indicated in Section 4.1.

Comparisons between treatment groups at the testing visit will use the same ANCOVA as for the primary effectiveness endpoint, but inferential results for the secondary effectiveness endpoints will be considered exploratory.

Defocus curves will be presented as line plots for each treatment group at the testing visit, with mean visual acuity on the y-axis and defocus level on the x-axis.

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

To check the consistency of VA results, the following differences will be summarized descriptively (in logMAR) for each lens type for the ITT population:

- DCIVA (OD) – VA at Defocus Level -1.5
- DCNVA (OD) – VA at Defocus Level -2.5

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

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 27.1.

Treatment-emergent adverse events (TEAEs) are defined as any AE that begins or worsens after study lens wear. If the onset of an AE is on or after the date of study lens wear or is increasing in severity thereafter, 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.

TEAEs that start during Part A of the Testing Visit but are ongoing during Part B will be summarized using the Part A treatment group. TEAEs that start during Part B or Part C will be summarized using the Part B treatment group.

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.

The number and percentage of eyes with graded slit lamp findings Grade >2 during the testing visit will be presented by treatment group.

Corneal fluorescein staining will be summarized descriptively using counts and percentages for each treatment group for each part of the testing visit.

If the assessment is performed prior to or after wearing lenses, they will be assigned to the treatment group that is closest to the time point for the assessment.

11. REFERENCES

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

[2] K Ashley Tuan KA, Benoit DP, O'Connor B, Evaluation of the Functional Visual Range of a Catenary Curve-Based, Extended Depth-of-Focus Contact Lens for Presbyopia. *Clinical Ophthalmology* 2024:18 2113–2123.

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	Study Device Fitting Characteristics		X		
14.1.4.1	Prior Medications		X		
14.1.4.2	Concomitant Medications		X		
14.2.1.1.x	Photopic Negative Lens-induced Distance-corrected Depth of Focus (DOF) at the 0.2 logMAR Visual Acuity (VA) Threshold			X	X
14.2.1.2.x	Photopic Negative Lens-induced Distance-corrected Depth of Focus (DOF) at the 0.2 logMAR Visual Acuity (VA) Threshold by Age Group			X	X
14.2.1.3.x	Photopic Negative Lens-induced Distance-corrected Depth of Focus (DOF) at the 0.2 logMAR Visual Acuity (VA) Threshold by Pupil Diameter			X	X
14.2.1.4.x	Photopic Negative Lens-induced Distance-corrected Depth of Focus (DOF) at the 0.2 logMAR Visual Acuity (VA) Threshold by Distance-corrected Near VA			X	X
14.2.2.1.x	Photopic Distance-corrected Intermediate Visual Acuity (DCIVA)			X	X
14.2.2.2.x	Photopic Distance-corrected Intermediate Visual Acuity (DCIVA) by Age Group			X	X
14.2.2.3.x	Photopic Distance-corrected Intermediate Visual Acuity (DCIVA) by Pupil Diameter			X	X
14.2.2.4.x	Photopic Distance-corrected Intermediate Visual Acuity (DCIVA) by Distance-corrected Near Visual Acuity			X	X
14.2.3.1.x	Photopic Distance-corrected Near Visual Acuity (DCNVA)			X	X

Table	Description of Table	All	Safety	ITT	PP
14.2.3.2.x	Photopic Distance-corrected Near Visual Acuity (DCNVA) by Age Group			X	X
14.2.3.3.x	Photopic Distance-corrected Near Visual Acuity (DCNVA) by Pupil Diameter			X	X
14.2.3.4.x	Photopic Distance-corrected Near Visual Acuity (DCNVA) by DCNVA			X	X
14.2.4.1.x	Mesopic Contrast Sensitivity			X	X
14.2.4.2.x	Mesopic Contrast Sensitivity by Age Group			X	X
14.2.4.3.x	Mesopic Contrast Sensitivity by Pupil Diameter			X	X
14.2.4.4.x	Mesopic Contrast Sensitivity by Distance-corrected Near Visual Acuity			X	X
14.2.5	Differences of Photopic Distance-corrected Intermediate Visual Acuity (DCIVA) and Distance-corrected Near Visual Acuity (DCNVA) With Visual Acuity at Select Defocus Levels			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		
14.3.3	Eyes With Slit Lamp Findings Grade >2 During the Testing Visit		X		
14.3.4	Corneal Fluorescein Staining		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 Sequence
16.2.2	Protocol Deviations
16.2.3	Analysis Populations
16.2.4.1	Demographics
16.2.4.2	Baseline Current Contact Lens Characteristics
16.2.4.3	Spherocylindrical Refraction and Pupil Diameter
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 Fitting
16.2.5.2	Lens Centration, Movement, and Distance Visual Acuity (VA)
16.2.5.3	Study Lens Characteristics
16.2.6.1	Photopic Negative Lens-induced Distance-corrected Depth of Focus (DOF) at the 0.2 logMAR Visual Acuity (VA) Threshold
16.2.6.2	Photopic Distance-corrected Intermediate Visual Acuity (DCIVA)
16.2.6.3	Photopic Distance-corrected Near Visual Acuity (DCNVA)
16.2.6.4	Defocus Curves
16.2.6.5	Mesopic Contrast Sensitivity
16.2.6.6	Photopic Distance-corrected Intermediate Visual Acuity (DCIVA) and Visual Acuity at Defocus Level -1.5
16.2.6.7	Photopic Distance-corrected Near Visual Acuity (DCNVA) and Visual Acuity at Defocus Level -2.5
16.2.7.1	Adverse Events
16.2.7.2	Adverse Device Effects
16.2.8	Slit Lamp Examination
16.2.9	Corneal Fluorescein Staining
16.2.10	Best Corrected Distance Visual Acuity (BCDVA) and Distance Visual Acuity
16.2.11	General Comments

12.3. List of Planned Figures

Figure	Description of Figure	All	Safety	ITT	PP
14.2.1.1.x	Mean (±SD) Visual Acuity for each Defocus Level			X	X

Figure	Description of Figure	All	Safety	ITT	PP
14.2.1.2.x	Mean (±SD) Visual Acuity for each Defocus Level by Age Group			X	X
14.2.1.3.x	Mean (±SD) Visual Acuity for each Defocus Level by Pupil Diameter			X	X
14.2.1.4.x	Mean (±SD) Visual Acuity for each Defocus Level by Distance-corrected Near Visual Acuity			X	X