Alcon

Title:

Clinical Assessment of a Daily Wear Monthly Replacement Soft Silicone Hydrogel Contact Lens

Protocol Number:	CLY935-C013 / NCT04476784
Sponsor Name and Address:	Alcon Research, LLC and its affiliates ("Alcon") 6201 South Freeway Fort Worth, Texas 76134-2099
Test Product:	LID018869

Investigator Agreement:

- I have read the clinical study described herein, recognize its confidentiality, and agree to conduct the described trial in compliance with Good Clinical Practice (GCP), the ethical principles contained within the Declaration of Helsinki, this protocol, all applicable regulatory authority regulations, and conditions of approval imposed by the reviewing IRB or regulatory authority.
- I will supervise all testing of the device involving human subjects and ensure that the requirements relating to obtaining informed consent and IRB review and approval are met in accordance with applicable local and governmental regulations.
- I have read and understand the appropriate use of the investigational product(s) as described in the protocol, current Investigator's Brochure, product information, or other sources provided by the Sponsor.
- I understand the potential risks and side effects of the investigational product(s).
- I agree to maintain adequate and accurate records in accordance with government regulations and to make those records available for inspection.
- I agree to comply with all other requirements regarding the obligations of clinical Investigators and all other pertinent requirements of the Sponsor and government agencies.
- I agree to ensure that all associates, colleagues, and employees assisting in the conduct of the study are informed of their obligations in meeting the above commitments.

Have you ever been disqualified as an Investigator by any Regulatory Authority? ☐ No ☐Yes
Have you ever been involved in a study or other research that was terminated? ☐ No ☐Yes If yes, please explain here:

Principal Investigator:

Signature Date

Name and professional position:

Address:

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1 GLOSSARY OF TERMS

Names of test product(s)	Throughout this document, test product(s) will be referred to as [redacted] (LID018869)
Name of Control Product(s)	CooperVision® Biofinity® contact lenses (Biofinity)
Adverse Device Effect	Adverse event related to the use of an investigational medical device (test product) or control product. *Note: This definition includes adverse events resulting from insufficient or inadequate instructions for use, deployment, implantation, installation, or operation; any malfunction; and use error or intentional misuse of the test product or control product.*
Adverse Event	Any untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in subjects, users or other persons, whether or not related to the investigational medical device (test product). *Note: For subjects, this definition includes events related to the test product, the control product, or the procedures involved. For users or other persons, this definition is restricted to events related to the test product.* Requirements for reporting Adverse Events in the study can be found in Section 11.
Anticipated Serious Adverse Device Effect	Serious adverse device effect, which by its nature, incidence, severity, or outcome, has been identified in the risk management file.
Device Deficiency	Inadequacy of a medical device with respect to its identity, quality, durability, reliability, safety, or performance. *Note: This definition includes malfunctions, use errors, and inadequate labeling.* Requirements for reporting Device Deficiencies in the study can be found in Section 11.

Enrolled Subject	Any subject who signs an informed consent form for participation in the study.
Interventional Clinical Trial	A research trial that prospectively assigns, whether randomly or not, human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes, and/or a research trial in which diagnostic or monitoring procedures beyond standard of care are conducted and generate outcomes for use in analysis of data.
Investigational Product	Is defined as a preventative (vaccine), a therapeutic (drug or biologic), device, diagnostic, or palliative used as a test or control product in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the authorized form, when used for an unauthorized indication, or when used to gain further information about the authorized form.
Malfunction	Failure of a medical device to perform in accordance with its intended purpose when used in accordance with the instructions for use or clinical investigation plan.
Non-Serious Adverse Event	Adverse event that does not meet the criteria for a serious adverse event.
Randomized Subjects	Any subject who is assigned a randomized treatment.
Serious Adverse Device Effect (SADE)	Adverse device effect that has resulted in any of the consequences characteristic of a serious adverse event.
Serious Adverse Event (SAE)	Adverse event that led to any of the following: • Death. • A serious deterioration in the health of the subject that either resulted in:

	a. a life-threatening illness or injury. *Note: Life-threatening means that the individual was at immediate risk of death from the event as it occurred, ie, it does not include an event which hypothetically might have caused death had it occurred in a more severe form.* *b.* any potentially sight-threatening event or permanent impairment to a body structure or a body function. c. in-patient hospitalization or prolonged hospitalization. *Note: Planned hospitalization for a pre-existing condition, without serious deterioration in health, is not considered a serious adverse event. In general, hospitalization signifies that the individual remained at the hospital or emergency ward for observation and/or treatment (usually involving an overnight stay) that would not have been appropriate in the physician's office or an out-patient setting. Complications that occur during hospitalization are adverse events. If a complication prolongs hospitalization or fulfills any other serious criteria, the event is serious. When in doubt as to whether "hospitalization" occurred, the event should be considered serious.* *d.* a medical or surgical intervention to prevent a) or b). *e.* any indirect harm as a consequence of incorrect diagnostic test results when used within manufacturer's instructions for use. • Fetal distress, fetal death, or a congenital abnormality or birth defect.

	Refer to Section 11 for additional SAEs.
Significant Non-Serious Adverse Event	Is a symptomatic, device-related, non-sight threatening adverse event that warrants discontinuation of any contact lens wear for greater than or equal to 2 weeks. *Refer to Section 11 for additional Significant Non-Serious AEs.*
Unanticipated Serious Adverse Device Effect (USADE)	Serious adverse device effect which by its nature, incidence, severity or outcome has not been identified in the risk management file.
Use Error	Act or omission of an act that results in a different medical device response than intended by manufacturer or expected by user. *Note: This definition includes slips, lapses, and mistakes. An unexpected physiological response of the subject does not in itself constitute a use error.*

2 LIST OF ACRONYMS AND ABBREVIATIONS

Table 2–1 List of Acronyms and Abbreviations Used in This Protocol

Abbreviation	Definition
ADE	Adverse device effect
AE	Adverse event
BCVA	Best corrected visual acuity
Biofinity	CooperVision Biofinity contact lenses
CFR	Code of Federal Regulations
CLEAR CARE	CLEAR CARE® disinfection solution
CI	Confidence Interval
COL	Clinical Operations Lead
CSM	Clinical Site Manager
D	Diopter(s)
DEP	Deviations and evaluability plan
eCRF	Electronic case report form
EDC	Electronic data capture
FAS	Full Analysis Set
FDA	US Food and Drug Administration
GCP	Good Clinical Practice
GPCMS	Global Product Complaint Management System
ICF	Informed consent form
IB	Investigational Brochure
IEC	Independent ethics committee
IP	Investigational product
IRB	Institutional Review Board
IRT	Interactive Response Technology
ISO	International Organization for Standardization
LID	Lens identification
LogMAR	Logarithm of the minimum angle of resolution
mm	Millimeter
MOP	Manual of Procedures
N/A	Not applicable
OD	Right eye
OS	Left eye
PP	Per Protocol
SAE	Serious adverse event
SADE	Serious adverse device effect
SD	Standard deviation
USADE	Unanticipated serious adverse device effect
VA	Visual acuity
[redacted]	[redacted]

3 PROTOCOL SUMMARY

Investigational product type	Device
Study type	Interventional
Investigational products	**Test Product:** [redacted] (LID018869) **Control Product:** CooperVision® Biofinity® contact lenses (Biofinity)
Purpose and rationale	The rationale for this study is to assess the clinical performance of the investigational [redacted] contact lens over 30 days of daily wear.
Objective(s)	The **primary objective** of this study is to evaluate visual acuity (VA) of the investigational [redacted] contact lens. [redacted]
Endpoint(s)	Primary Effectiveness Distance VA (logMAR) with study lenses [redacted]

	[redacted] Safety • Adverse events (AEs) • Biomicroscopy findings • Device deficiencies
Assessment(s)	Effectiveness • Distance VA (logMAR) with study lenses [redacted] Safety

	• AEs • Biomicroscopy • Device deficiencies
Study Design	This is a prospective, randomized, crossover, double masked study comparing visual acuity with investigational [redacted] contact lenses vs. Biofinity contact lenses. Subjects will be expected to attend 4 visits. The total duration of a subject's participation in the study is ~60 days, which includes ~30 days of exposure to the test product and ~30 days of exposure to the control product. Subjects will be expected to wear their study contact lenses for typical number of hours as they do for with their habitual contact lenses, at least 5 days per week, over a 30 day period per study lens. On Visit 2 and Visit 4, subjects will be expected wear study lenses between 6 - 8 hours at time of visit and prior to lens removal. [redacted] All contact lenses will be prescribed according to the subject's prescription. CLEAR CARE® disinfection solution will be used during the duration of the study.
Subject population	Volunteer subjects aged 18 years or older who are current wearers of spherical weekly/monthly soft contact lenses in both eyes with at least 3 months wearing experience, with a minimum wearing time of 5 days per week and 10 hours per day. Planned number of subjects enrolled/consented: ~65 Planned number of completed subjects: 58
Key inclusion criteria (See Section 8.1 for a complete list of inclusion criteria)	• Subjects must be ≥ 18 year of age • Current wearers of spherical weekly/monthly soft contact lenses in both eyes with at least 3 months wearing experience, with a minimum wearing time of 5 days per week and 10 hours per day
Key exclusion criteria	• Current or prior habitual Biofinity contact lens wearers in the past 3 months

<table>
<tr><td>(See Section 8.2 for a complete list of exclusion criteria)</td><td>

- Monovision contact lens wearers
- Participation in a clinical trial within the previous 30 days or currently enrolled in any clinical trial

</td></tr>
<tr><td>Data analysis and sample size justification</td><td>

Planned Analysis

[redacted]

planned analyses are summarized below:

<table>
<tr><th>Endpoint</th><th>Statistical Method</th></tr>
<tr><td colspan="2">Primary</td></tr>
<tr><td>Distance VA</td><td>Descriptive summary</td></tr>
</table>

[redacted]

</td></tr>
<tr><td>Key words</td><td>[redacted] Biofinity, Visual Acuity, VA, daily disposable contact lenses</td></tr>
<tr><td>Associated materials</td><td>

- CLEAR CARE® disinfection solution

</td></tr>
</table>

	[redacted]

Table 3–1 Schedule of Study Procedures and Assessments

	LENS PAIR 1			LENS PAIR 2		
Procedure / Assessment	**Visit 1 Screen/ Baseline/ Dispense Pair 1** [Day 1]	**Visit 2 Day 30 Follow-up Pair 1** [Day 30 (± 2 days)]	[redacted]	**Visit 3 Dispense Pair 2** [Day 1 after Washout]	**Visit 4 Day 30 Follow-up Pair 2/Exit^** [Day30 (± 2 days)]	**Unscheduled visit**
Informed Consent	X					
Demographics	X					
Medical History	X	X		X	X	X
Concomitant Medications	X	X		X	X	X
Inclusion/Exclusion	X					
Habitual lens (brand, power*,care)	X					
VA w/ habitual contact lens correction (OD, OS, Snellen distance) *	X				X	(X)
[redacted]						
Randomization#	X					
Dispense study lenses#	X			X		(X)

	LENS PAIR 1			LENS PAIR 2		
Procedure / Assessment	**Visit 1 Screen/ Baseline/ Dispense Pair 1** [Day 1]	**Visit 2 Day 30 Follow-up Pair 1** [Day 30 (± 2 days)]	[redacted]	**Visit 3 Dispense Pair 2** [Day 1 after Washout]	**Visit 4 Day 30 Follow-up Pair 2/Exit^** [Day30 (± 2 days)]	**Unscheduled visit**
VA w/ study lenses, (OD, OS, logMAR distance)	X	X		X	X	(X)
[redacted]						
AEs	X	X		X	X	X
Device deficiencies	X	X		X	X	X
Exit Form	(X)	(X)		(X)	X	(X)

[redacted]

4 PROTOCOL AMENDMENTS

Modification of the protocol is prohibited without prior written agreement in the form of a protocol amendment. All amendments must be created by the Study Sponsor and must be approved by the IRB/IEC and global and regional Health Authorities, as applicable, prior to implementation except when required to mitigate immediate safety risks or when the changes involve only logistical or administrative revisions.

Amendments may necessitate that the informed consent and other study-related material be revised. If the consent form is revised, all subjects currently enrolled in the study must sign the approved, revised informed consent (re-consent), as required by the IRB/IEC.

4.1 Amendments

There are no amendments. This is the first version of the protocol.

5 INTRODUCTION

5.1 Rationale and Background

Daily wear contact lenses are worn during waking hours for a full day and then removed for cleaning and disinfection prior to reinsertion the following day. Frequent replacement daily wear contact lenses are replaced according to the product package insert provided by the contact lens manufacturer.

[redacted]

In this clinical study, the clinical performance of the investigational [redacted] contact lens will be assessed and the [redacted] contact lens will be compared to the commercially available

Biofinity contact lens in a crossover design, both to be worn in a daily wear modality and replaced on a monthly basis.

5.2 Purpose of the Study

The purpose of this study is to assess the clinical performance of the investigational [redacted] contact lens over 30 days of daily wear. The primary endpoint was selected to address the primary objective of the study. Procedures for measurement of these endpoints were selected based on common practice for these assessments. The design of this study is justified based upon preclinical and clinical testing, as described within the Investigator's Brochure. Biofinity contact lenses were chosen as the control product because these lenses have the same wear modality and replacement schedule.

[redacted]

At the end of the study, a clinical study report will be prepared in accordance with applicable regulatory requirements and standards.

5.3 Risks and Benefits

Contact lenses may offer improved peripheral vision and the convenience of not wearing spectacles. Material properties and design characteristics of the contact lens in development are features consistent with successful contact lens wear.

Based upon non-clinical testing and/or documented rationale for applicability of test results to the IP, the new contact lens in development is assessed to be non-toxic and biocompatible for on-eye use.

Biofinity contact lenses are commercially available for daily wear use under a monthly wear modality; further details on any known potential risks and benefits can be found in the package insert.

A summary of the known potential risks and benefits associated with the [redacted] contact lens in development can be found in the Investigator's Brochure. Risks are minimized by compliance with the eligibility criteria and study procedures, clinical oversight and monitoring, and through close supervision by a licensed clinician during exposure to the study lenses. [redacted]

[redacted]

The site personnel will educate subjects on proper hygiene and lens handling, as well as compliance with the use of contact lenses according to the protocol. Subjects should be instructed not to wear contact lenses while sleeping or swimming. The site personnel will also advise the subjects to remove contact lenses and return for prompt follow-up of symptoms, such as ocular discomfort, foreign body sensation, excessive tearing, vision changes, or hyperemia.

Refer to the IB for additional information.

6 STUDY OBJECTIVES

6.1 Primary Objective(s)

Table 6–1 Primary Objective(s)

Objective(s)	**Endpoint(s)**
To evaluate VA of the investigational [redacted] contact lens.	Distance VA (OD, OS; logMAR)

6.2 Secondary Objective(s)

Not Applicable.

[redacted]

[redacted]

6.4 Safety Objective(s)

Table 6–3 Safety Objective(s)

Objective(s)	Endpoint(s)
Describe the safety profile of the study products	• AEs • Biomicroscopy findings • Device deficiencies

7 INVESTIGATIONAL PLAN

7.1 Study Design

This is a prospective, interventional, randomized, crossover, double masked study evaluating visual acuity of the investigational [redacted] contact lens. Habitual spherical weekly/monthly soft contact lens wearers will be randomized in 1 of the 2 crossover sequences. Subjects and investigators will be masked. [redacted]

Subjects will be expected to attend 4 office visits. All study contact lenses will be prescribed according to subject's prescription. CLEAR CARE contact lens solution will be used throughout the duration of the study.

Subjects will be expected to wear their study contact lens for typical number of hours as they do for with their habitual contact lenses, at least 5 days per week, over a 30 day period per study lens. [redacted] On the day of Visits 2 and 4, subjects will be expected wear study lenses between 6 - 8 hours at time of visit and prior to lens removal. [redacted].

STUDY DESIGN

Prospective / Randomized / Double-masked / Bilateral crossover

[redacted]

[redacted]

7.3 Rationale for Duration of Treatment/Follow-Up

Subjects will wear each study product bilaterally for approximately 30 days. [redacted]

7.4 Rationale for Choice of Control Product

Biofinity contact lenses were chosen as the control product because these lenses have the same wear modality and replacement schedule.

7.5 Data Monitoring Committee

Not applicable.

8 STUDY POPULATION

The study population consists of male and female subjects age 18 years or older who are current wearers of spherical weekly/monthly soft contact lenses in both eyes with at least 3 months wearing experience, with a minimum wearing time of 5 days per week and 10 hours per day. Subjects who are current or prior habitual Biofinity contact lens wearers in the past 3 months will be excluded. It is aimed to enroll (consent) approximately 65 subjects in approximately 5 sites in the U.S., with a target of 58 completed subjects. Site-specific targets may vary based upon individual site capabilities. Estimated time needed to recruit subjects for the study is approximately 4 weeks

8.1 Inclusion Criteria

Written informed consent must be obtained before any study specific assessment is performed. Upon signing informed consent, the subject is considered enrolled in the study.

Subjects eligible for inclusion in this study must fulfill **all** of the following criteria:

1. Subject must be ≥ 18 years of age.
2. Subject must be able to understand and sign an IRB/IEC approved Informed Consent form.

3. Willing and able to attend all scheduled study visits as required per protocol.
4. Current wearers of any commercial spherical weekly/monthly soft contact lenses in both eyes with at least 3 months wearing experience, with a minimum wearing time of 5 days per week and 10 hours per day.

[redacted]

8.2 Exclusion Criteria

[redacted]

[redacted]

13. Monovision contact lens wearers.
14. Current or prior habitual Biofinity contact lens wearers in the past 3 months prior to consent.

Women of childbearing potential or women who are pregnant at the time of study entry are not excluded from participation. [redacted]

8.3 Rescreening of Subjects

Rescreening of subjects is not allowed in this study.

9 TREATMENTS ADMINISTERED

9.1 Investigational Product(s)

Test Product(s): [redacted] contact lens

Control Product(s) (If applicable): CooperVision® Biofinity® (comfilcon A) contact lenses

Table 9–1 Test Product

Test Product	[redacted] contact lens [redacted]
Lens Identification Number	LID018869
Manufacturer	Alcon Laboratories, Inc. 6201 South Freeway Fort Worth, Texas 76134-2099 USA
Indication for use and intended purpose in the current study	The intended use of this product is for vision correction.
[redacted]	
Usage	• Wear: ○ Daily Wear ○ Bilateral ○ Crossover according to randomization • Replacement period: Replacement lenses will not be provided to the subject. In the event a lens needs to be replaced, the subject must return to the site for a replacement lens. Until the replacement lens is obtained, the subject must store the fellow

	lens in the provided lens care solution and wear their habitual spectacles. • Exposure: Typical contact lens wearing hours, at least 5 days per week, over a 30 day period per study lens. • Lens Care: Lenses will be cleaned and disinfected with CLEAR CARE
Number/Amount of product to be provided to the subject	Subjects will insert study lenses at Visit 1 and Visit 3 at the site. No spare lenses will be provided to the subject.
Packaging description	Blister foil pack
[redacted]	[redacted]
Storage conditions	Lens to be stored at room temperature.

[redacted]

Table 9–2 Control Product

Control Product(s)	Biofinity contact lens
Manufacturer	CooperVision
Indication for Use	The intended use of this product is for vision correction.
Product description and parameters available for this study	• Material: comfilcon A • Water content: 48% • Power range: -1.00 to -6.00 F (0.25 D steps) • Base curve (mm): 8.6 • Diameter (mm): 14.0
Formulation	Silicone Hydrogel. For additional details, please refer to the Biofinity package insert.
Usage	• Wear: o Daily Wear o Bilateral o Crossover according to randomization • Replacement period: Replacement lenses will not be provided to the subject. In the event a lens needs to be replaced, the subject must return to the site for a replacement lens. Until the replacement lens is obtained, the subject must store the fellow lens in the provided lens care solution and wear their habitual spectacles. • Exposure: Typical contact lens wearing hours, at least 5 days per week, over a 30 day period per study lens.

	• Lens Care: Lenses will be cleaned and disinfected with CLEAR CARE
Number/Amount of Product to be Provided to the subject	Subjects will insert study lenses at Visit 1 and Visit 3 at the site. No spare lenses will be provided to the subject.
Packaging description	Blister foil pack in commercial packaging.
Labeling description	Commercial labeling.
Storage conditions	Lenses to be stored at room temperature.

[redacted]

More information on the test product can be found in the [redacted] IB; more information on the control product can be found in the Biofinity package insert.

9.2 Other Medical Device or Medication Specified for Use During the Study

During the clinical study, the following contact lens solution is required in conjunction with the treatment:

- CLEAR CARE contact lens solution

9.3 Treatment Assignment / Randomization

Subjects will be randomized in a 1:1 ratio to receive treatment in a crossover sequence of Test product then Control product or Control product then Test product, respectively.

Only after signing the ICF, a subject will be assigned a subject number by the electronic data capture system.

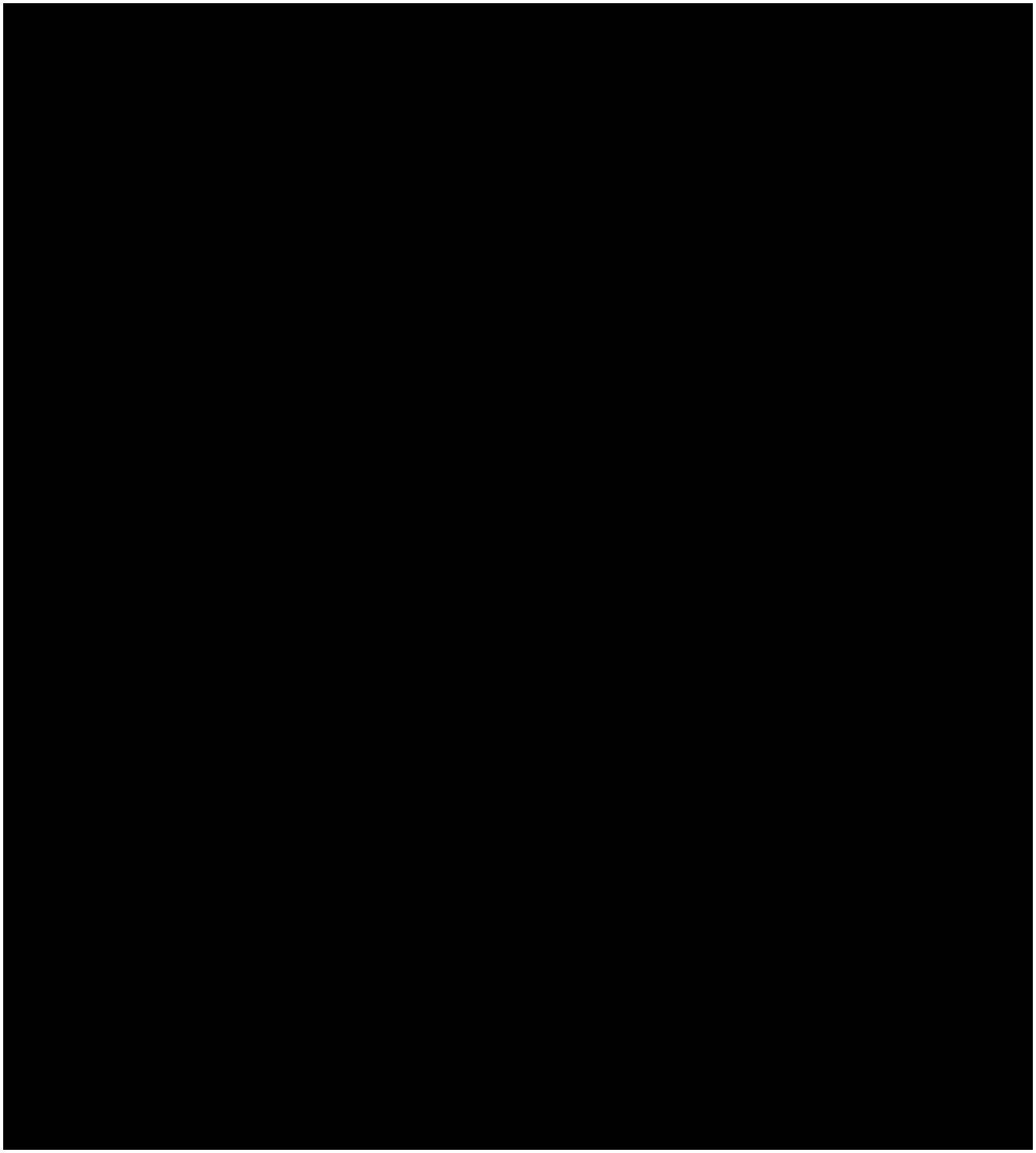
A randomization list will be generated using a validated system that automates the random assignment of treatment arms to randomization numbers in the specified ratio. Subjects will be assigned treatment (lens sequence) according to the randomization list uploaded in the randomization system. The randomization list will be generated and maintained by the Study Sponsor.

At Visit 1, all eligible subjects will be randomized via the EDC/randomization integration system to one of the lens sequences. The Investigator's delegate will access the respective system after confirming that the subject meets all the eligibility criteria. A randomization number will be automatically assigned to the subject according to the subject randomization list, but will not be communicated to the site user. The EDC/randomization integration system will inform the site user of the treatment (lens sequence) assignment to be dispensed to the subject.

9.4 Treatment Masking

This study is double-masked, with subjects randomized to use the [redacted] contact lenses and the Biofinity contact lenses for the duration of the 30-week treatment period. Subjects, the Investigator, and masked study personnel (site and Sponsor) will be masked to the assigned treatment sequence.

[redacted]



This level of masking will be maintained throughout the conduct of the study. Unmasking will occur only after all planned study data have been validated, and the database locked.

In the event of a medical emergency where the knowledge of subject treatment is required, an individual Investigator will have the ability to unmask the treatment assignment for a specific subject after contacting an appropriate Study Sponsor representative if time allows. Refer to Section 11.5.

9.5 Accountability Procedures

Upon receipt of the IPs, the Investigator or delegate must conduct an inventory. During the study, the masked Investigator must designate unmasked staff to provide the IPs to the subjects in accordance with their randomization assignment. Throughout the study, the Investigator or delegate must maintain records of IP dispensation and collection for each subject. This record must be made available to the study monitor for the purposes of verifying the accounting of IP supplies. Any discrepancies and/or deficiencies between the observed disposition and the written account must be recorded along with an explanation. All IPs sent to the Investigator must be accounted for by Study Sponsor personnel, and in no case be used in an unauthorized situation.

It is the Investigator's responsibility to ensure that:

- All study products are accounted for and not used in any unauthorized manner

- All used foils and unused supplies are returned by each subject
- All unused products are available for return to the Study Sponsor, as directed
- Any study lenses associated with a device deficiency or with any product-related adverse event (ie, ADE or SADE) are returned to the Study Sponsor for investigation, unless otherwise directed by the Sponsor. Refer to Section 11 of this protocol for additional information on the reporting of device deficiencies and AEs and the return of study products associated with these events.

The Investigator is responsible for proper disposition of all unused IPs at the conclusion of the study, according to the instructions provided in the MOP.

9.6 Changes to concomitant medications, treatments/ procedures

After the subject is enrolled into the study, the Investigator must instruct the subject to notify the study site about:

- Any new medications
- Alterations in dose or dose schedules for current medications
- Any medical procedure or hospitalization that occurred or is planned
- Any non-drug therapies (including physical therapy and blood transfusions)

The Investigator must document this information in the subject's case history source documents.

10 STUDY PROCEDURES AND ASSESSMENTS

Subjects are expected to attend 4 clinic visits over a period of approximately 65 days. Study lenses will be provided to the subjects to take home for daily wear during the course of the trial.

Study randomization will occur at Visit 1 with assigned lenses provided to take home at Visit 1 and Visit 3. Study contact lens fitting will occur at Visit 1 for both study lenses. If a subject cannot be successfully fit (either study lens) according to the study lens fitting guides as determined by the Investigator, they will be required to exit from the study.

[redacted]

10.1 Informed Consent and Screening

The Investigator or delegate must explain the purpose and nature of the study, and have the subject read, sign, and date the IRB/IEC-approved informed consent document. The subject must sign the ICF BEFORE any study-specific procedures or assessments can be performed, including study-specific screening procedures. Additionally, have the individual obtaining consent from the subject and a witness, if applicable, sign and date the informed consent document.

The Investigator or delegate must provide a copy of the signed document to the subject and place the original signed document in the subject's chart, or provide documentation as required by local regulations.

[redacted]

10.2.1 Demographics

Obtain demographic information including age, race, ethnicity, and sex.

10.2.2 Medical History

Ocular and non-ocular medical history will be collected at Visit 1 and documented in the source documents. CRF data collection will be Targeted:

- **Concomitant medications:** All ocular medications, targeted systemic medications.
- **Medical History:** All ocular history, targeted systemic history

In the source documents, concomitant medications and medical history must be fully documented. All relevant medical conditions, including currently active conditions, diagnosed chronic conditions, and conditions resolved within the past year will be documented. Habitual lens information and medications taken within 30 days prior to Visit 1 will be recorded in the source documentation. Include herbal therapies, vitamins, and all over-the-counter as well as prescription medications. Throughout the subject's participation,

obtain information on any changes in medical health and/or the use of concomitant medications and record in subject source documents.

10.2.3 Investigational Product Compliance

Review subject compliance with the IP usage and collect all used lidding foils, unused study IPs and other study products that were dispensed.

10.2.4 Habitual Lens Information

Collect habitual lens brand, power (source only), and care at Visit 1.

10.2.5 Habitual VA Assessment (Snellen)

Perform distance VA (Snellen), OD and OS, with habitual correction at Visit 1 and Visit 4. Capture data in source only.

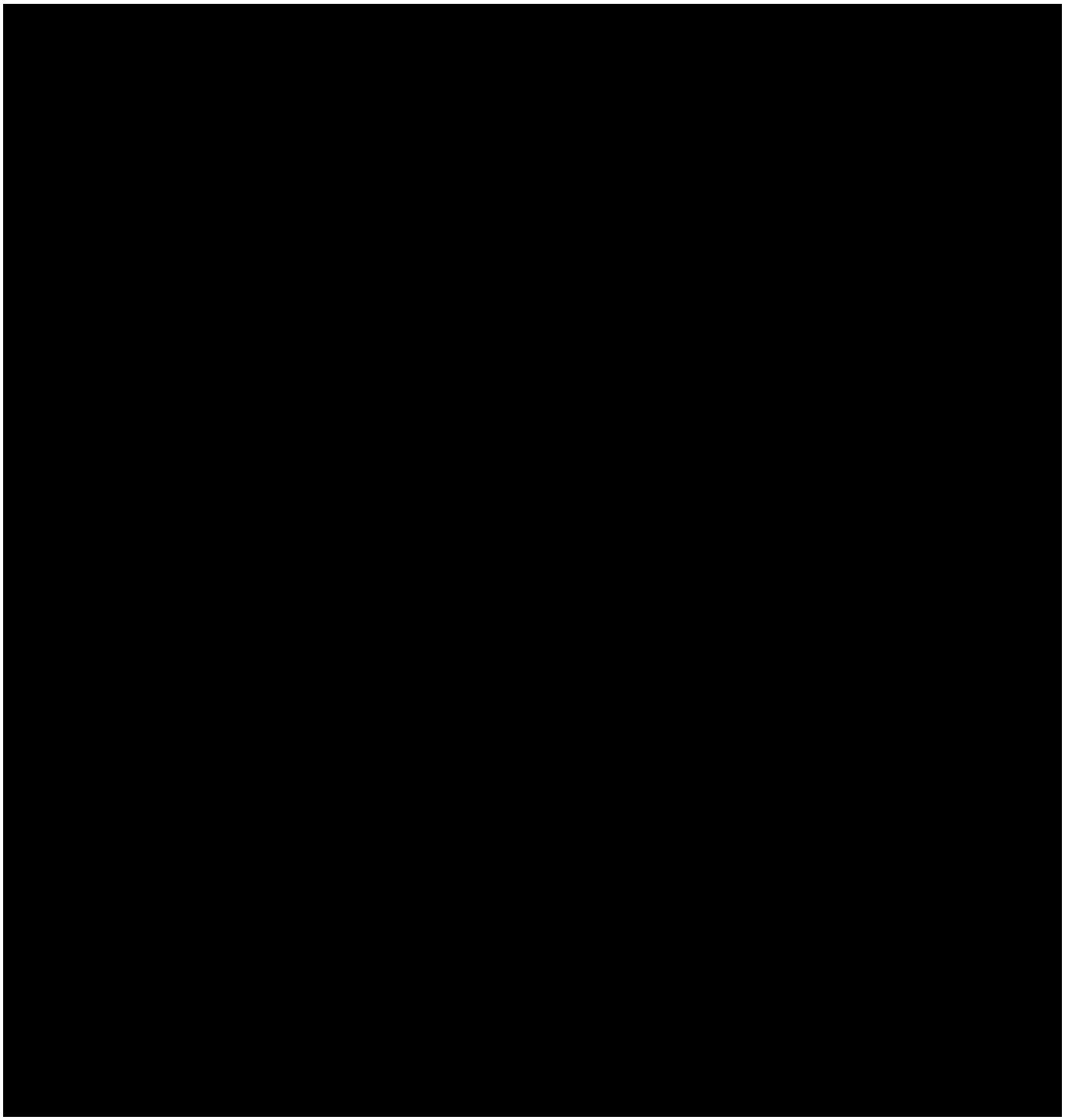
[redacted]

10.2.11 Randomization

Unmasked site personnel will randomize eligible subjects according to the assigned sequence at Visit 1.

10.2.12 Study Lenses VA Assessment (logMAR)

Perform distance VA (logMAR), OD and OS, with study lenses at Visits 1, 2, 3, and 4.



10.2.21 AE Collection

Assess and record any adverse events that are observed or reported, including those associated with changes in concomitant medication dosing since the previous visit in the subject source documents. See Section 11 for further details regarding AE collection and reporting.

10.2.22 Device Deficiencies

Assess and record any device deficiencies that are reported or observed, including those associated with changes in concomitant medication dosing since the previous visit.

Requirements for reporting device deficiencies in the study can be found in Section 11. Device deficiencies on comparator lenses should be reported per the manufacturer's guidelines.

10.3 Unscheduled Visits

If a subject visit occurs between any regularly scheduled visits, this visit must be documented as an Unscheduled Visit. During all unscheduled visits, the Investigator must conduct the following procedures:

- Collect AE and device deficiency information
- Record changes in medical condition and concomitant medication
- Perform biomicroscopy (assessments with or without study lenses, as applicable)

The Investigator may perform additional procedures for proper diagnosis and treatment of the subject. The Investigator must document this information in the subject's case history source documents.

If during an Unscheduled Visit the subject is discontinuing the IP or discontinuing from the study, the Investigator must conduct Exit procedures according to Table 3-1 Schedule of Study Procedures and Assessments, as possible.

10.4 Discontinued Subjects

10.4.1 Screen Failures

Screen failures are subjects who were excluded from the study after signing the informed consent and prior to randomization.

The Investigator must document the reason for screen failure in the subject's case history source documents.

Subject numbers must not be re-used.

10.4.2 Discontinuations

Discontinued subjects are individuals who voluntarily withdraw or are withdrawn from the study by the Investigator after signing informed consent, including screen failures.

Subject numbers of discontinued subjects must not be re-used.

Subjects may discontinue from study or study treatment at any time for any reason. Subjects may also be discontinued from study treatment at any time if, in the opinion of the Investigator, continued treatment poses a risk to their health.

For subjects discontinuing from the study, the Investigator must complete all Exit procedures according to Table 3-1 Schedule of Study Procedures and Assessments, if the subject is willing and able, and if in the opinion of the Investigator it is safe for the subject to do so.

The Investigator must document the reason for study or treatment discontinuation in the subject's case history source documents.

To ensure the safety of all subjects who discontinue early, Investigators must assess each subject and, if necessary, advise them of any therapies and/or medical procedures that may be needed to maintain their health.

10.4.3 Schedule of Procedures and Assessments for Subjects Discontinued from Investigational Product

Any subjects discontinued from IP will be discontinued from the study and follow exit procedures.

10.5 Clinical Study Termination

The Study Sponsor reserves the right to close the investigational site or terminate the study in its entirety at any time.

If the clinical study is prematurely terminated or suspended by the Study Sponsor:

- The Study Sponsor must:
    - Immediately notify the Investigator(s) and subsequently provide instructions for study termination.
    - Inform the Investigator and the regulatory authorities of the termination/suspension and the reason(s) for the termination/suspension.
- The Investigator must:
    - Promptly notify the IRB/IEC of the termination or suspension and of the reasons.
    - Provide subjects with recommendations for post-study treatment options as needed.

The Investigator may terminate the site's participation in the study for reasonable cause.

10.5.1 Follow-up of subjects after study participation has ended

Following this study, the subject will return to their eye care professional for their routine eye care.

11 ADVERSE EVENTS AND DEVICE DEFICIENCIES

11.1 General Information

An AE is any untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in subjects, users, or other persons, whether or not related to the investigational medical device (test product). Refer to the figures below for categories of AEs and SAEs.

Figure 11-1 Categorization of All Adverse Events

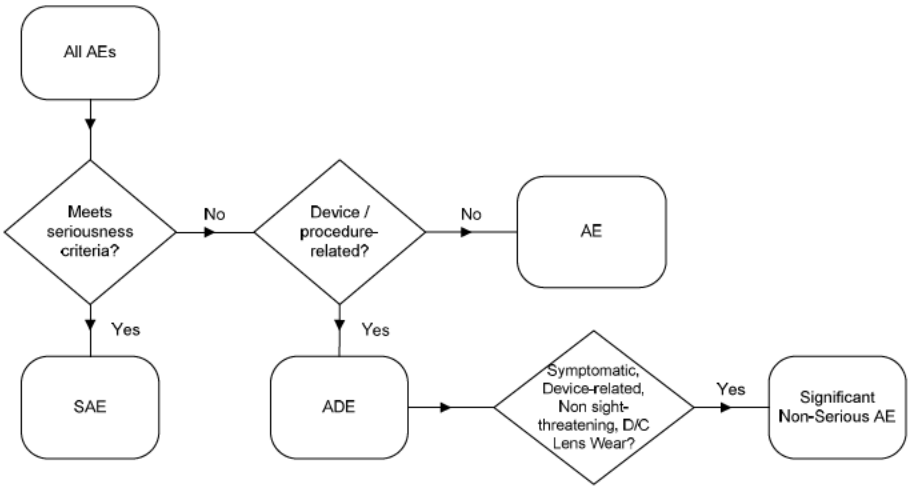
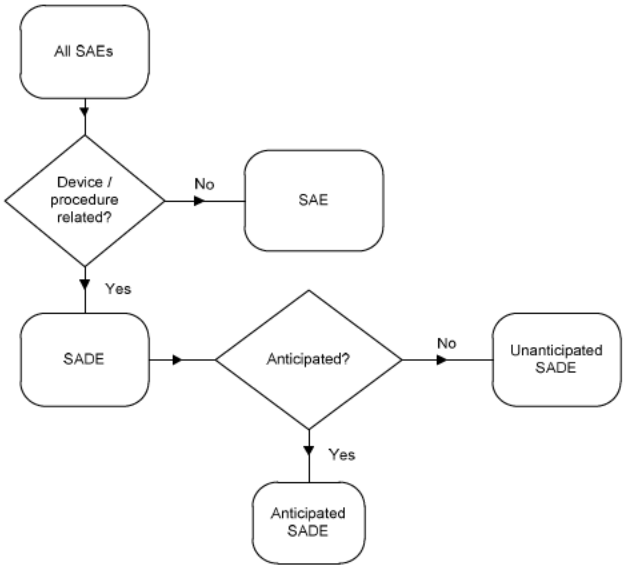


Figure 11-2 Categorization of All Serious Adverse Events



Specific Events Relevant to this Protocol

Serious Adverse Events

In addition to reporting all AEs (serious and non-serious) meeting the definitions, the Investigator must report any occurrence of the following as an SAE:

- An ocular infection including a presumed infectious ulcer with any of the following characteristics:
    - Central or paracentral location
    - Penetration of Bowman's membrane
    - Infiltrates >2 mm diameter
    - Iritis
    - Increase in intraocular pressure
    - Culture positive for microorganisms
    - Increasing size or severity at subsequent visits
- Any central or paracentral corneal event (such as neovascularization) that results in permanent opacification
- Hypopyon
- Hyphema

- Neovascularization within the central 6 mm of the cornea
- Permanent vision loss as defined by loss of 2 or more lines of BCVA from enrollment visit that fails to resolve
- Uveitis (anterior, intermediate, or posterior)
- Corneal abrasion affecting ≥50% of corneal surface area

Significant Non-Serious Adverse Events

A significant non-serious AE is a device-related, non-sight threatening adverse event that warrants discontinuation of any contact lens wear for greater than or equal to 2 weeks. In addition, the Investigator must report any occurrence of the following as a Significant Non-Serious Adverse Event:

- Peripheral non-progressive non-infectious ulcers
- All symptomatic corneal infiltrative events
- Corneal staining score greater than or equal to grade 3 (Refer to MOP for grading scales)
- Temporary vision loss as defined by loss of 2 or more lines of BCVA from enrollment visit that persists for 2 or more weeks
- Neovascularization score greater than or equal to grade 2 (Refer to MOP for grading scales)

The above events are based on the categories provided in the ISO 11980 and the US FDA Premarket Notification (510(k)) Guidance Document for Daily Wear Contact Lenses.

Device Deficiencies

A device deficiency is inadequacy of a medical device with respect to its identity, quality, durability, reliability, safety, or performance. A device deficiency may or may not be associated with patient harm (ie, ADE or SADE); however, not all ADEs or SADEs are due to a device deficiency. The Investigator should determine the applicable category listed in the Device Deficiency eCRF for the identified or suspect device deficiency and report any patient harm separately. Examples of device deficiencies include the following:

- Failure to meet product specifications (eg, incorrect lens power/diameter/base curve/color)
- Lens/solution cloudy

- Lens surface/edge defect
- Torn lens during handling/in pack
- Packaging deficit (eg, mislabeled product, tampered seal, leaking bottle/container)
- Suspect product contamination
- Lack of performance

11.2 Monitoring for Adverse Events

At each visit, after the subject has had the opportunity to spontaneously mention any problems, the Investigator should inquire about AEs by asking the standard questions shown below and report as applicable:

- "Have you had any health problems since your last study visit?"
- "Have there been any changes in the medicines you take since your last study visit?"

In addition, changes in *any protocol-specific parameters and/or questionnaires* evaluated during the study are to be reviewed by the Investigator. Any untoward (unfavorable and unintended) change in *a protocol-specific parameter or questionnaire response* that is clinically relevant, in the opinion of the Investigator, is to be reported as an AE. These clinically relevant changes will be reported regardless of causality.

11.3 Procedures for Recording and Reporting

AEs are collected from the time of informed consent. Any pre-existing medical conditions or signs/symptoms present in a subject prior to the start of the study (i.e., before informed consent is signed) are not considered AEs in the study and should be recorded in the subject's Medical History.

In addition, temporary lens awareness or visual changes during the fitting process are not considered AEs if the Investigator assesses that the symptom(s) can reasonably resolve within the anticipated adaptation period.

For each recorded event, the ADEs and SAEs documentation must include: date of occurrence, severity, treatment (if applicable), outcome, and assessments of the seriousness and causality. In addition, the Investigator must document all device deficiencies reported or observed with test and control products on the Device Deficiency eCRF. The site must submit all available information on ADEs, SAEs, and device deficiencies to the Study Sponsor immediately as follows:

- ADEs or SAEs are documented on the *Serious Adverse Event and Adverse Device Effect* eCRF within 24 hours of the Investigator's or site's awareness.
- Device deficiencies are documented on the *Device Deficiency* eCRF within 24 hours of the Investigator's or site's awareness.
- A printed copy of the completed *Serious Adverse Event and Adverse Device Effect* and/or *Device Deficiency* eCRF must be included with product returns. Please refer to the MOP for further details regarding product returns.
- Additional relevant information after initial reporting must be entered into the eCRF as soon as the data become available.
- Document any changes to concomitant medications on the appropriate eCRFs.
- Document all relevant information from Discharge Summary, Autopsy Report, Certificate of Death etc., if applicable, in narrative section of the *Serious Adverse Event and Adverse Device Effect* eCRF.

Note: Should the EDC system become non-operational, the site must complete the appropriate paper Serious Adverse Event and Adverse Device Effect and/or Device Deficiency Form. The completed form is emailed to the Study Sponsor at msus.safety@alcon.com according to the timelines outlined above; however, the reported information must be entered into the EDC system once it becomes operational.

Any AEs and device deficiencies for non-study marketed devices/products (ie, CLEAR CARE disinfection solution) will be considered and processed as spontaneous (following the post-market vigilance procedures) and should be communicated to the device's/product's manufacturer as per local requirements.

Study Sponsor representatives may be contacted for any protocol-related question and their contact information is provided in the Manual of Procedures that accompanies this protocol.

Further, depending upon the nature of the AE or device deficiency being reported, the Study Sponsor may request copies of applicable portions of the subject's medical records. The Investigator must also report all AEs and device deficiencies that could have led to a SADE according to the requirements of regulatory authorities or IRB/IEC.

Intensity and Causality Assessments

Where appropriate, the Investigator must assess the intensity (severity) of the AE based on medical judgment with consideration of any subjective symptom(s), as defined below:

Intensity (Severity)

Mild	An AE is mild if the subject is aware of but can easily tolerate the sign or symptom.
Moderate	An AE is moderate if the sign or symptom results in discomfort significant enough to cause interference with the subject's usual activities.
Severe	An AE is severe if the sign or symptom is incapacitating and results in the subject's inability to work or engage in their usual activities.

For every AE in the study, the Investigator must assess the causality (Related or Not Related to the medical device or study procedure). An assessment of causality will also be performed by Study Sponsor utilizing the same definitions, as shown below:

Causality

Related	An AE classified as related may be either definitely related or possibly related where a direct cause and effect relationship with the medical device or study procedure has not been demonstrated, but there is a reasonable possibility that the AE was caused by the medical device or study procedure.
Not Related	An AE classified as not related may either be definitely unrelated or simply unlikely to be related (ie, there are other more likely causes for the AE).

The Study Sponsor will assess the AEs and may upgrade the Investigator's assessment of seriousness and/or causality. The Study Sponsor will notify the Investigator of any AEs that is upgraded from non-serious to serious or from unrelated to related.

Furthermore, the Study Sponsor shall promptly conduct an evaluation of any unanticipated adverse device effect, including anticipated adverse events that occur in unanticipated severity or frequency. The results of this evaluation will be reported to the FDA, the IRB, and participating Investigators within 10 working days upon receiving notification of the effect.

11.4 Return Product Analysis

Study Sponsor representatives and their contact information are provided in the MOP that accompanies this protocol.

Alcon products associated with device deficiencies and/or product related AEs should be returned and must include the Complaint # which will be provided by Study Sponsor after the case is entered in the Study Sponsor's Global Product Complaint Management System (GPCMS).

11.5 Unmasking of the Study Treatment

Masked information on the identity of the assigned medical device should not be disclosed during the study (refer to Section 9.4 Treatment Masking). If the treatment code needs to be broken in the interest of subject safety, the Investigator is encouraged to contact an appropriate Study Sponsor representative prior to unmasking the information if there is sufficient time. Dependent upon the individual circumstances (ie, medical emergency), the code may be broken prior to contact with the Study Sponsor. The Study Sponsor must be informed of all cases in which the code was broken and of the circumstances involved. Additionally, the Study Sponsor may be required to unmask the information in order to fulfill expedited regulatory reporting requirements.

11.6 Follow-Up of Subjects with Adverse Events

The Investigator is responsible for adequate and safe medical care of subjects during the study and for ensuring that appropriate medical care and relevant follow-up procedures are maintained after the study.

The Investigator should provide the Study Sponsor with any new safety information (which includes new AEs and changes to previously reported AEs) that may affect the safety evaluation of the device. For AEs that are unresolved/ ongoing at time of subject exit from study, any additional information received at follow-up should be documented in the eCRFs up to study completion (ie, database lock).

Any additional data received up to 3 months after subject discontinuation or exit must be documented and available upon the Study Sponsor's request. All complaints received after this time period will be considered and processed as spontaneous (following the postmarket vigilance procedures) and should be communicated to the medical device's manufacturer as per local requirements.

The Investigator should also report complaints on non-Alcon products directly to the manufacturer as per the manufacturer's instructions or local regulatory requirements.

11.7 Pregnancy in the Clinical Study

Women of childbearing potential or women who are pregnant at the time of study entry are not excluded from participation. [redacted]

12 ANALYSIS PLAN

Continuous variables will be summarized using the number of observations, mean, SD, median, minimum, and maximum, as well as CIs or confidence limits where applicable. Categorical variables will be summarized with counts and percentages from each category.

Any deviations to the analysis plan will be updated during the course of the study as part of a protocol amendment or will be detailed in the clinical study report.

12.1 Subject Evaluability

Final subject evaluability must be determined prior to breaking the code for masked treatment sequence assignment and locking the database, based upon the Deviations and Evaluability Plan (DEP).

12.2 Analysis Sets

12.2.1 Safety Analysis Set

Safety analyses will be conducted using the safety analysis set on a treatment-emergent basis. As such, the safety analysis set will include all subjects/eyes exposed to any study lenses evaluated in this study. For treatment-emergent safety analyses, subjects/eyes will be categorized under the actual study lenses exposed in the corresponding lens sequence.

12.2.2 Full Analysis Set

The full analysis set (FAS) is the set of all randomized subjects who are exposed to any study lenses evaluated in this study.

[redacted]

12.3 Demographic and Baseline Characteristics

Demographic and baseline characteristics will be summarized by lens sequence and overall. Counts and percentages will be presented for categorical variables such as sex, age group, race, and ethnicity. Number of observations, mean, SD, median, minimum, and maximum will be presented for continuous variables such as age.

[redacted]

12.4.1 Analysis of Primary Effectiveness Endpoint(s)

The primary objective of this study is to evaluate the VA of the investigational [redacted] contact lens. The primary endpoint is distance VA with study lenses, collected for each eye in logMAR.

12.4.1.1 Statistical Hypotheses

No inferences are to be made on the primary effectiveness endpoint; therefore, no hypotheses are formulated.

12.4.1.2 Analysis Methods

Descriptive statistics used for continuous variables will be presented.

[redacted]

[redacted]

[redacted]

12.5 Handling of Missing Data

All data obtained in evaluable subjects/eyes will be included in the analysis. No imputation for missing values will be carried out for the primary [redacted] effectiveness [redacted]

12.6 Safety Analyses

The safety endpoints are:

- AEs
- Biomicroscopy findings
- Device deficiencies

There are no safety hypotheses planned in this study. The focus of the safety analysis will be a comprehensive descriptive assessment of occurrence of adverse events as well as the other listed parameters.

All AEs occurring from the time a subject signs informed consent to study exit will be accounted for in the reporting. Safety analyses will be conducted using the safety analysis set on a treatment-emergent basis. Descriptive summaries (counts and percentages) for ocular

and nonocular AEs will be presented by Medical Dictionary for Regulatory Activities Preferred Terms. AEs leading to study discontinuation, significant non-serious AEs, and SAEs will be identified. Individual subject listings will be provided, as necessary.

Individual subject listings will be provided for AEs that occur after signing informed consent but prior to exposure to IP.

Each biomicroscopy parameter will be tabulated by its grade. For each biomicroscopy parameter, counts and percentages of eyes that experience an increase of ≥ 2 grades from baseline (last assessment prior to study lens exposure for each period) to any subsequent visit within the same period will be presented. A supportive listing will be generated which will include all biomicroscopy data from all visits within the same period for those eyes experiencing the increase.

Two listings for device deficiencies, prior to exposure of study contact lenses and treatment-emergent, will be provided. Additionally, each device deficiency category will be tabulated.

No inferential testing will be done for safety analysis.

[redacted]

13 DATA HANDLING AND ADMINISTRATIVE REQUIREMENTS

13.1 Subject Confidentiality

The Investigator must ensure that the subject's anonymity is maintained throughout the course of the study. In particular, the Investigator must keep an enrollment log with confidential identifying information that corresponds to the subject numbers and initials of each study participant. At the end of the clinical study, the Study Sponsor will collect a copy of the enrollment log ***without any identifying subject information***. All documents submitted to the Study Sponsor will identify the subjects exclusively by number and demographic information. No other personally identifying information will be transmitted to the Study Sponsor.

[redacted]

13.2 Completion of Source Documents and Case Report Forms

The nature and location of all source documents will be identified to ensure that original data required to complete the CRFs exist and are accessible for verification by the site monitor, and all discrepancies shall be appropriately documented via the query resolution process. Site monitors are appointed by the Study Sponsor and are independent of study site staff.

If electronic records are maintained, the method of verification must be determined in advance of starting the study.

At a minimum, source documents include the following information for each subject:

- Subject identification (name, sex, race/ethnicity)
- Documentation of subject eligibility

- Date of informed consent
- Dates of visits
- Documentation that protocol specific procedures were performed
- Results of study parameters, as required by the protocol
- IP accountability records
- Documentation of AEs and other safety parameters (if applicable)
- Records regarding medical histories and the use of concomitant therapies prior to and during the study
- Date of study completion and reason for early discontinuation, if applicable

It is required that the author of an entry in the source documents be identifiable. Direct access to source documentation (medical records) must be allowed for the purpose of verifying that the data recorded on the CRF are consistent with the original source data.

Only designated individuals at the site will complete the CRFs. The CRFs must be completed at regular intervals following the clinical study visit schedule. It is expected that all data reported have corresponding entries in the source documents. The Principal Investigator is responsible for reviewing and certifying that the CRFs are accurate and complete. The only subject identifiers recorded on the CRFs will be subject number, and subject demographic information.

13.3 Data Review and Clarifications

A review of CRF data to the subject's source data will be completed by the site monitor to ensure completeness and accuracy. After the CRFs have been completed, additional data clarifications and/or additions may be needed as a result of the data cleaning process. Data clarifications are documented and are part of each subject's CRF.

13.4 Sponsor and Monitoring Responsibilities

The Study Sponsor will designate a monitor to conduct the appropriate site visits at the appropriate intervals according to the study monitoring plan. The clinical investigation will be monitored to ensure that the rights and well-being of the subjects are protected, the reported data are accurate, complete, and verifiable from the source documents, and the study is conducted in compliance with the current approved protocol (and amendments[s], if applicable), with current GCP, and with applicable regulatory requirements.

The site may not screen subjects or perform the informed consent process on any subject until it receives a notification from an appropriate Study Sponsor representative that the site may commence conducting study activities. Monitoring will be conducted periodically while the clinical study is ongoing. Monitoring methods may include site visits, telephone, written and fax correspondence. Close-out visits will take place after the last visit of the last subject at the site.

A Coordinating Investigator may be identified by the Study Sponsor to review and endorse the final study report. In cases where a Coordinating Investigator is engaged, the Study Sponsor will select the Coordinating Investigator based upon their experience, qualifications, active study participation, and their willingness and availability to take on this role.

13.5 Regulatory Documentation and Records Retention

The Investigator is required to maintain up-to-date, complete regulatory documentation as indicated by the Study Sponsor and the Investigator's files will be reviewed as part of the ongoing study monitoring. Financial information is to be kept separately.

Additionally, the Investigator must keep study records and source documents consistent with the terms of the clinical study agreement with the Study Sponsor. If the Investigator retires, relocates, or for any other reason withdraws from responsibility of keeping the study records, then the Study Sponsor must be notified and suitable arrangements made for retention of study records and source documents needed to comply with national and international regulations.

13.6 Quality Assurance and Quality Control

The Study Sponsor will secure agreement from all involved parties to ensure direct access to all study related sites, source data and documents, and reports for the purpose of monitoring and auditing by the Study Sponsor, and inspection by domestic and foreign regulatory authorities. Quality control will be applied to each stage of data handling to ensure that all data are reliable and have been processed correctly. Agreements made by the Study Sponsor with the Investigator/Institution and any other parties involved in the clinical study will be provided in writing as part of the protocol or as a separate agreement.

14 ETHICS

This clinical study must be conducted in accordance with the ethical principles contained within:

- The Declaration of Helsinki, and in compliance with the ICH E6 GCP Consolidated Guideline, ISO 14155:2011, and the applicable US FDA 21 CFR Regulations.
- SOPs of the Study Sponsor and contract research organizations participating in the conduct of the clinical study and all other applicable regulations.
- Notifications and timelines for reporting protocol deviations should be based upon applicable Ethics Committee requirements

The Investigator must ensure that all personnel involved in the conduct of the study are qualified to perform their assigned responsibilities through relevant education, training, and experience. The Investigator and all clinical study staff must conduct the clinical study in compliance with the protocol. Deviations from this protocol, regulatory requirements and/or GCP must be recorded and reported to the Sponsor prior to database lock. If needed, corrective and preventive action should be identified, implemented, and documented within the study records. Use of waivers to deviate from the clinical protocol is prohibited.

Before clinical study initiation, this protocol, the informed consent form, any other written information given to subjects, and any advertisements planned for subject recruitment must be approved by an IRB/IEC. The Investigator must provide documentation of the IRB/IEC approval to the Study Sponsor. The approval must be dated and must identify the applicable protocol, amendments (if any), informed consent form, assent form (if any), all applicable recruiting materials, written information for subject, and subject compensation programs. The IRB/IEC must be provided with a copy of the IB, Package Insert, any periodic safety updates, and all other information as required by local regulation and/or the IRB/IEC. At the end of the study, the Investigator must notify the IRB/IEC about the study's completion. The IRB/IEC also must be notified if the study is terminated prematurely. Finally, the Investigator must report to the IRB/IEC on the progress of the study at intervals stipulated by the IRB/IEC.

Voluntary informed consent must be obtained in writing from every subject and the process shall be documented before any procedure specific to the clinical investigation is applied to the subject. The Investigator must have a defined process for obtaining consent. Specifically, the Investigator, or their delegate, must explain the clinical study to each potential subject and the subject must indicate voluntary consent by signing and dating the approved informed consent form. The subject must be provided an opportunity to ask questions of the Investigator, and if required by local regulation, other qualified personnel. The Investigator must provide the subject with a copy of the consent form written in a language the subject understands. The consent document must meet all applicable local laws and provide subjects with information regarding the purpose, procedures, requirements, and restrictions of the

study, along with any known risks and potential benefits associated with the IP and the study, the available compensation, and the established provisions for maintaining confidentiality of personal, protected health information. Subjects will be told about the voluntary nature of participation in the study and must be provided with contact information for the appropriate individuals should questions or concerns arise during the study. The subject also must be told that their records may be accessed by appropriate authorities and Sponsor-designated personnel. The Investigator must keep the original, signed copy of the consent (file in subject's medical records) and must provide a duplicate copy to each subject according to local regulations.

The Study Sponsor assures that the key design elements of this protocol will be registered on www.clinicaltrials.gov as required by current regulations and, if applicable, other public databases as required by local country regulations. In addition, results of this study will be made publicly available on www.clinicaltrials.gov regardless of outcome as required by current regulations and, if applicable, in other public databases as required by local country regulations.

15 REFERENCES

15.1 References Applicable for All Clinical Studies

- ISO 11980:2012 Ophthalmic optics - Contact lenses and contact lens care products - Guidance for clinical investigations
- ISO 14155:2011 Clinical investigation of medical devices for human subjects - Good clinical practice

15.1.1 US References Applicable for Clinical Studies

- 21 CFR Part 11 - Electronic Records; Electronic Signatures
- 21 CFR Part 50 - Protection of Human Subjects
- 21 CFR Part 56 - Institutional Review Boards
- 21 CFR Part 812 - Investigational Device Exemptions
- 21 CFR Part 54 - Financial Disclosure by Clinical Investigators

15.2 References for This Clinical Study

Not applicable. There are no references.