Alcon

Title:

Clinical Characterization of an Investigational Soft Silicone Hydrogel Contact Lens

Protocol Number:	CLY935-E006 / NCT04631796
Sponsor Name and Address:	Alcon Research, LLC and its affiliates ("Alcon") 6201 South Freeway Fort Worth, Texas 76134-2099
Test Product(s):	LID020098

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:

1 PROTOCOL SYNOPSIS

Trial Sponsor	Alcon Research, LLC 6201 South Freeway Fort Worth, Texas 76134-2099
Name of Test Product(s)	LID020098
Name of Control Product(s)	None
Title of Trial	Clinical Characterization of an Investigational Soft Silicone Hydrogel Contact Lens
Protocol Number	CLY935-E006
Number of Sites Country	~3 US
Planned Duration of Exposure	Test Product: ~ 14 ± 2 days
Number of Subjects	Target to complete: 30
	Planned to enroll: ~36
Study Population	Volunteer subjects aged 18 or over who are habitual spherical weekly/monthly soft contact lens wearers, have at least 3 months of contact lens wearing experience, and who wear their habitual contact lenses at least 5 days per week and at least 8 hours per day. [redacted]
Objective(s)	The primary objective of this study is to evaluate the overall clinical performance of an investigational silicone hydrogel contact lens [redacted] over 2 weeks of daily wear.
Endpoints	Primary Effectiveness • Front surface wettability [redacted]

	[redacted] Safety • AEs • Biomicroscopy findings • Device deficiencies
Assessments	Effectiveness [redacted] • Lens surface evaluation [redacted] front surface wettability, [redacted]

<table>
<tr><td></td><td colspan="2">[redacted]
Safety
• AEs
• Biomicroscopy
• Device deficiencies</td></tr>
<tr><td>Study Design</td><td>☒ Prospective
☒ Single group
☐ Parallel group
☐ Crossover
☐ Other</td><td>☐ Single-masked
(trial subject)
☐ Single-masked (Investigator)
☐ Double-masked
☒ Open-label
☐ Other</td></tr>
<tr><td></td><td>☐ Contralateral
☒ Bilateral
☐ Monocular lens wear</td><td>☐ Randomized</td></tr>
<tr><td>Test Product Details</td><td>[redacted]</td><td>[redacted]</td></tr>
<tr><td></td><td>LID Number</td><td>LID020098</td></tr>
<tr><td></td><td>Manufacturer</td><td>Alcon Laboratories, Inc.</td></tr>
<tr><td></td><td>[redacted]</td><td>[redacted]</td></tr>
<tr><td></td><td>[redacted]</td><td>[redacted]</td></tr>
<tr><td>Inclusion Criteria</td><td colspan="2">1. Subject must be at least 18 years of age.
2. Subject must be able to understand and must sign an ICF that has been approved by an IRB.
3. Successful wear of spherical weekly/monthly soft contact lenses in both eyes for a minimum of 5 days per week and 8 hours per day during the past 3 months.
[redacted]</td></tr>
</table>

	[redacted] 8. Subject must be willing to stop wearing their habitual contact lenses for the duration of study participation. [redacted]
Exclusion Criteria	1. Any anterior segment infection, inflammation, or abnormality or disease (including systemic) that contraindicates contact lens wear, as determined by the Investigator. 2. Any use of systemic or ocular medications for which contact lens wear could be contraindicated, as determined by the Investigator. 3. History of refractive surgery or plan to have refractive surgery during the study or irregular cornea in either eye. [redacted] 6. Current or history of pathologically dry eye in either eye that, in the opinion of the Investigator, would preclude contact lens wear. [redacted] 10. Wearing habitual contact lenses in an extended wear modality (routinely sleeping in lenses for at least 1 night per week) over the last 3 months prior to enrollment. 11. Any use of topical ocular medications and artificial tear or rewetting drops that would require instillation during contact lens wear. [redacted]

	[redacted] 14. Habitual monovision or multifocal contact lens wearer.
Associated Materials	• OPTI-FREE® RepleniSH® multipurpose disinfection solution (OFR) [redacted]

Table 1-1 Schedule of Study Procedures and Assessments

Procedure/ Assessment	**Visit 1** **Screening/ Baseline/** [redacted]	**Visit 2@** **Dispense** [redacted]	**Visit 3** **Week 2 Follow-up /Exit^** [redacted]	**USV**
Informed Consent	X			
Demographics	X			
Medical History*	X	X∞	X	X
Concomitant Medications*	X	X∞	X	X
Inclusion/Exclusion	X			
Habitual lens (brand, power*, lens care)	X			
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]		[redacted]	
Biomicroscopy	X	X∞	X	X
Optimize study contact lens power [redacted]	(X)			
[redacted]	(X)			
Record study lens power	X			
Dispense study lenses*		X		(X)
[redacted]		[redacted]	[redacted]	[redacted]

Procedure/ Assessment	**Visit 1** **Screening/ Baseline**	**Visit 2@** **Dispense**	**Visit 3** **Week 2 Follow-up /Exit^**	**USV**
Lens surface assessments (OD, OS): • Front surface wettability •				
AEs	X	X	X	X
Device deficiencies	X	X	X	X
Exit Form	(X)	(X)	X	(X)

1.1 Abbreviations

Abbreviation	Definition
ADE	Adverse device effect
AE	Adverse event
[redacted]	[redacted]
CFR	Code of Federal Regulations
[redacted]	[redacted]
D/C	Discontinue
eCRF	Electronic case report form
EDC	Electronic data capture
FDA	US Food and Drug Administration
GCP	Good Clinical Practice
ICF	Informed consent form
IP	Investigational product
IRB	Institutional review board
ISO	International Organization for Standardization
LID	Lens identification
[redacted]	[redacted]
[redacted]	[redacted]
MOP	Manual of procedures
N/A	Not applicable
OD	Right eye
OFR	OPTI-FREE RepleniSH multipurpose disinfection solution
OS	Left eye
OU	Both eyes
SAE	Serious adverse event
SADE	Serious adverse device effect
US	United States
USV	Unscheduled visit
VA	Visual acuity

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3 INTRODUCTION

3.1 Study Rationale and Purpose

The new contact lens in development is intended for the optical correction of refractive ametropia in persons with non-diseased eyes.

The purpose of this study is to obtain on-eye performance data to inform contact lens product development. [redacted]

[redacted]

3.2 Trial Objective

The primary objective of this study is to evaluate the overall clinical performance of an investigational silicone hydrogel contact lens [redacted] over 2 weeks of daily wear.

3.3 Risks and Benefits

[redacted] Material properties and design characteristics of the contact lens in development are features consistent with successful contact lens wear.

[redacted]

[redacted]

[redacted]

The site personnel will educate subjects on proper hygiene and lens handling, and 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.

3.4 Subject Population

The study population includes approximately 36 volunteer subjects to be enrolled at approximately 3 sites, with approximately 12 subjects enrolled per site. The study population will consist of subjects with normal eyes (other than the need for optical correction for refractive ametropia), who are adapted, existing wearers of soft weekly/monthly contact lenses in both eyes, [redacted]

Rescreening of subjects after screen failure is not allowed in this study.

3.5 Outline of Study

This will be a multi-site, prospective, single arm, open-label study examining 1 type of contact lens. The expected duration of subject participation in the study is approximately 2 weeks, with up to 3 scheduled visits. The study is expected to be completed in approximately 5 weeks.

4 TREATMENTS ADMINISTERED

All subjects will be receive the test lens to wear bilaterally throughout the study duration.

4.1 Identity of Study Treatments

DESCRIPTION OF TEST PRODUCTS	
LID Number	LID020098
Lens identified in randomization system as:	N/A
[redacted]	[redacted]

DESCRIPTION OF TEST PRODUCTS	
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
Usage	• Wear: o Daily Wear o Bilateral o Single arm open-label [redacted]

DESCRIPTION OF TEST PRODUCTS	
	[redacted] • Lens Care: OFR

[redacted]

[redacted]

[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

5 STUDY PROCEDURES AND ASSESSMENTS

5.1 Visits and Examinations

5.1.1 Visit 1 – Screening/Baseline/Order Spectacles

1	Explain the purpose and nature of the study, and have the subject read, sign, and date the IRB-approved informed consent document. Additionally, have the individual obtaining consent from the subject and a witness, if applicable, sign and date the informed consent document. Provide a photocopy of the signed document to the subject and place the original signed document in the subject's chart. After signing the ICF, a subject will be assigned a subject number by the EDC system. A signed informed consent document defines the point of enrollment.
2	Obtain demographic information and medical history, including information on all medications used within the past 30 days. Include herbal therapies, vitamins, and all over-the-counter as well as prescription medications.
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
8	Review inclusion/exclusion criteria to determine if the subject qualifies to be in the study. If subject does not qualify, exit the subject from the study as a screen failure.
9	Determine and record study lens powers based upon the manifest refraction and habitual lens powers.
10	Assess and record any device deficiencies and AEs reported or observed during the study visit. • *Note: AEs must be recorded for all enrolled subjects from the time of signature of informed consent including those subjects who screen fail.*
11	Optimize study contact lens power [redacted]
12	Schedule Visit 2 [redacted]. [redacted]

5.1.2 Visit 2 [redacted] – **Dispense** Study Lens

1	If Visit 2 immediately follows Visit 1, go to step 5 of this visit. Obtain information on any changes in medical health and/or the use of concomitant medications.
2	Assess and record any device deficiencies and AEs, including those associated with changes in concomitant medication dosing, which are observed or reported since the previous visit(s).

[redacted]	[redacted]
4	Perform slit-lamp biomicroscopy (without contact lenses) to evaluate the following: [redacted]
5	Have the subject insert the appropriate study lenses, being careful to maintain the correct OD and OS lens assignments. [redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

10	Evaluate the study lenses by performing the following assessments*: • [redacted] • Lens surface evaluation (front surface wettability, [redacted] [redacted]
[redacted]	[redacted]
12	Assess and record any AEs and device deficiencies reported or observed during the study visit. *Note: AEs and device deficiencies must be recorded for all enrolled subjects from the time of signature of informed consent including those that screen fail, as applicable.*
13	Dispense new lens case(s), and lens care solution (OFR). Provide the subject with written and verbal instructions on lens wear and care.
14	Schedule Visit 3 [redacted] [redacted] [redacted] • [redacted] • [redacted] • [redacted] • [redacted] • [redacted]
[redacted]	[redacted]

5.1.3 Visit 3 [redacted] – Week 2 Follow-up/Exit

1	Obtain information on any changes in medical health and/or the use of concomitant medications.

2	Record any device deficiencies or AEs, including those associated with changes in concomitant medication dosing, which are observed or reported since the previous visit.
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
9	Evaluate the study lenses by performing the following assessments*: [redacted] • Lens surface evaluation (front surface wettability, [redacted]
[redacted]	[redacted].

11	Perform slit-lamp biomicroscopy (without contact lenses) to evaluate the following: [redacted]
[redacted]	[redacted]
[redacted]	[redacted]
14	Assess and record any AEs and device deficiencies reported or observed during the study visit. *Note: AEs and device deficiencies must be recorded for all enrolled subjects from the time of signature of informed consent including those subjects who screen fail, as applicable.*
15	Exit the subject from the study.

5.2 Unscheduled Visits

Any visit that occurs between regularly scheduled visits is an Unscheduled Visit. If a subject requires an Unscheduled Visit, he/she must be advised to return to the office wearing the study lenses, if at all possible (unless he/she is experiencing a sign or symptom [as indicated in Section 3.3 Risks and Benefits]). During all unscheduled visits, the Investigator must conduct the following procedures:

- Collect AE and Device Deficiency information
- Assess and record changes in medical health or concomitant medication
- Assess and record VAs
- Perform biomicroscopy (assessments with or without lenses, as possible)

In addition, refer to Table 1-1 Unscheduled Visit for required procedures. 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 study lenses or discontinuing from the study, the Investigator must conduct Exit procedures according to Table 1-1: Schedule of Study Procedures and Assessments, as possible.

5.3 Discontinued Subjects

Discontinued subjects are those who withdraw or are withdrawn from the study after signing the informed consent, including screen failures. Subjects may discontinue from the study at any time for any reason. Subjects may also be discontinued from the study at any time if, in the opinion of the Investigator, their continued participation poses a risk to their health. Discontinued subjects will not be replaced (ie, their subject numbers will not be re-assigned/re-used).

Should a subject exhibit any clinically relevant signs, symptoms, or other clinical observations that possibly could be associated with suspected sensitivity or intolerance to one of the study treatments, the Investigator must document those observations on an AE Form.

Any subject who exits early from the study (excluding screen failures) must undergo all procedures outlined at Visit 3, as applicable.

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.

5.4 Clinical Study Termination

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

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, as applicable.

- The Investigator must:
  - Promptly notify the IRB of the termination or suspension and of the reasons.
  - Provide subjects with recommendations for post-study treatment options as needed.

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

6 ANALYSIS PLAN

Continuous variables will be summarized using the number of observations, mean, standard deviation, median, minimum, and maximum. Categorical variables will be summarized with frequencies and percentages from each category.

[redacted]

6.1 Subject Evaluability

The final subject evaluability will be determined prior to locking the database, based on the Deviations and Evaluability Plan.

6.2 Analysis Data Sets

6.2.1 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, except for the lenses used with the purpose of power optimization. For treatment-emergent safety analyses, subjects/eyes will be categorized under the actual study lenses exposed.

6.3 Demographic and Baseline Characteristics

Demographic information (age, sex, ethnicity, race) will be summarized on the Safety Analysis Set. Baseline data pertaining to habitual lens (lens brand, lens care brand) and keratometry will be summarized on the Safety Analysis Set as well.

[redacted]

6.4 Effectiveness Analyses

This study defines one primary endpoint[redacted] The Safety Analysis Set will be used for all effectiveness analyses.

6.4.1 Primary Effectiveness

The primary objective of this study is to evaluate the overall performance of an investigational silicone hydrogel contact lens over 2 weeks of daily wear. The primary endpoint is front surface wettability, collected on a 5-point scale, for each eye.

6.4.1.1 Statistical Hypotheses

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

6.4.1.2 Analysis Methods

Descriptive statistics will be presented, to include frequencies and percentages in each grade as well for the combined category of Grade 0 and Grade 1.

[redacted]

[redacted]

6.6 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.

[redacted]

6.8 Safety Analysis

The safety endpoints for this study are AEs, biomicroscopy findings, and device deficiencies. All AEs occurring from the time a subject signs informed consent to study exit will be accounted for in the reporting. 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 study lenses.

[redacted]

No inferential testing will be done for safety analysis.

[redacted]

7 ADVERSE EVENTS AND DEVICE DEFICIENCIES

Terms and Definitions

Adverse Event (AE)	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.*
Adverse Device Effect (ADE)	AE related to the use of an investigational medical device (test *product*) or control *product*. *Note: This definition includes AEs 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.*
Anticipated Serious Adverse Device Effect	Serious ADE 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.*
Malfunction	Failure of a medical device to meet its performance specifications or otherwise perform as intended. Performance specifications include all claims made in the labeling of the device. The intended performance of the device refers to the intended use for which the device is labeled or marketed.
Non-serious Adverse Event	AE that does not meet the criteria for an SAE.
Serious Adverse Event (SAE)	AE 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 an SAE. 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 7.1 for additional SAEs.*
Serious Adverse Device Effect (SADE)	ADE that has resulted in any of the consequences characteristic of an SAE.
Significant Non-Serious Adverse Event	A significant non-serious AE is a symptomatic, device-related, non-sight threatening AE that warrants discontinuation of any contact lens wear for greater than or equal to 2 weeks. *Refer to Section 7.1 for additional Significant Non-Serious AEs.*
Unanticipated Serious Adverse Device Effect	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.*

7.1 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*).

Figure 7–1 Categorization of All AEs

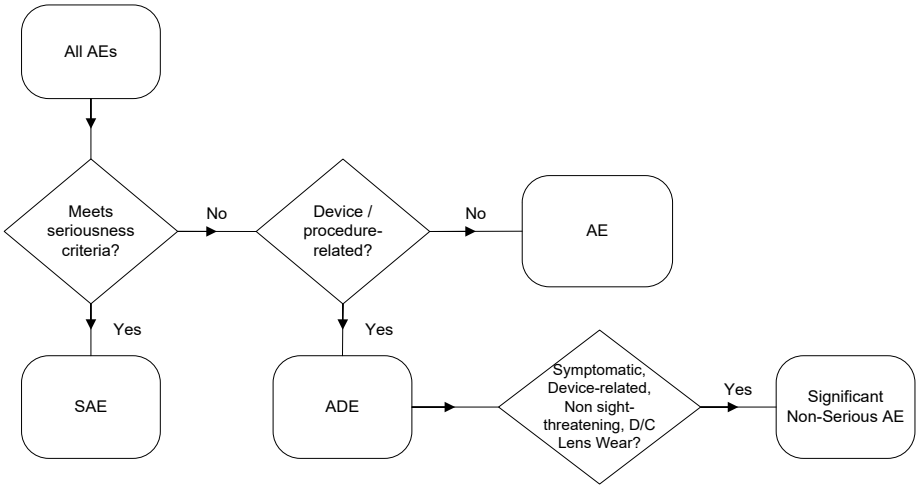
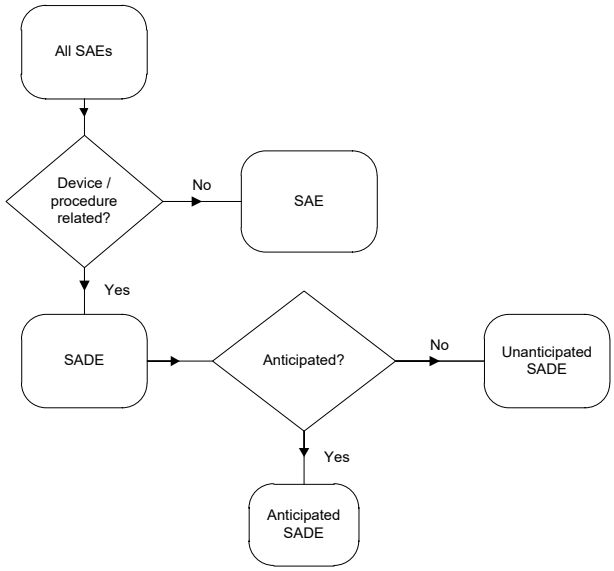


Figure 7-2 Categorization of All Serious Adverse Events



[redacted]

[redacted]

[redacted]

- [redacted]
  - [redacted]
  - [redacted]
  - [redacted]
  - [redacted]
  - [redacted]
  - [redacted]
  - [redacted]
- [redacted]
- [redacted]

[redacted]

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.[redacted]

[redacted]

[redacted]

7.2 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:

- "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?"

Additionally, 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.

7.3 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 (ie, before informed consent is signed) are not considered AEs in the study and should be recorded as medical history.

[redacted]

[redacted]

Any AEs and device deficiencies for non-study marketed devices/products (ie, OFR) will be considered and processed as spontaneous (following the postmarket 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.

[redacted]

[redacted]

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 are upgraded from non-serious to serious or from unrelated to related.

[redacted]

7.5 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.

[redacted]

[redacted]

7.6 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]

8 CONFIDENTIALITY, BIAS, AND MASKING

8.1 Subject Confidentiality and Methods Used to Minimize Bias

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. All documents submitted to the Sponsor will identify the subjects exclusively by number and demographic information. No other personally identifying information should be transmitted to the Sponsor.

This an open label study with all subjects assigned to wear LID020098 bilaterally for the duration of the 2-week treatment period.

8.2 Unmasking of the Study Treatment

Not applicable; this study is open-label.

9 DATA HANDLING AND ADMINISTRATIVE REQUIREMENTS

9.1 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 eCRFs exist and are accessible for verification by the site monitor, and all discrepancies shall be appropriately documented via the query resolution process. Study 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 should 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 eCRF are consistent with the original source data.

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

9.2 Data Review and Clarifications

Upon completion of the eCRFs, a targeted review of the eCRF data to the subject's source data will be completed by the site monitor to ensure completeness and accuracy. 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 eCRFs.

9.3 Regulatory Documentation and Records Retention

The Investigator is required to maintain up-to-date, complete regulatory documentation as indicated by the Sponsor and the Investigator's files will be reviewed as part of the ongoing study monitoring. Financial disclosure is not subject to regulatory inspection and should be kept separately.

Additionally, the Investigator must keep study records and source documents until the Sponsor provides written approval for their destruction. If the Investigator retires, relocates, or for any other reason withdraws from responsibility of keeping the study records, the Sponsor must be notified and suitable arrangements made for retention of study records and source documents needed to comply with national and international regulations (generally 2 years after discontinuing clinical development or after the last marketing approval).

10 ETHICS AND COMPLIANCE

This trial will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and the referenced directives, regulations, guidelines, and/or standards.

10.1 Compliance

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.

10.2 Institutional Review Board (IRB)

This trial requires IRB approval prior to initiation. This protocol, subject informed consent, and subsequent amendments will be reviewed and approved by an IRB.

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

Voluntary informed consent must be obtained from every subject (and/or legal representative, as applicable) prior to the initiation of any screening or other study-related procedures. The Investigator must have a defined process for obtaining consent. Specifically, the Investigator, or 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, 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 and must provide a duplicate copy to each subject according to local regulations. Following this study, the subject will return to their eye care professional for their routine eye care and contact lenses.

11 PROTOCOL AMENDMENT HISTORY

Version	Brief Description and Rationale
1	Initial Version of this document

12 REFERENCES

12.1 References applicable for all clinical trials

- 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

12.1.1 US references applicable for clinical trials

- 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
- The California Bill of Rights

12.2 References for this clinical trial

Not applicable.

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