Statistical Analysis Plan for Protocol

CLL949-E003 / NCT04702984

[redacted] [redacted]

[redacted]

This version of the Statistical Analysis Plan is based on Version 1.0 of the study protocol.

Executive Summary:

Key Objective:

The primary objective of this study is to evaluate the clinical performance of an investigational frequent replacement daily wear silicone hydrogel (SiHy) sphere contact lens, [redacted], over 7 days of daily wear.

Decision Criteria for Study Success:

Decision criteria for study success are not applicable for this study.

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1 Study Objectives and Design

1.1 Study Objectives

The primary objective of this study is to evaluate the clinical performance of an investigational frequent replacement daily wear SiHy sphere contact lens, [redacted], over 7 days of daily wear.

1.2 Study Description

Key components of the study are summarized in Table 1-1.

Table 1-1 Study Description Summary

Study Design	Prospective, single group, bilateral, open-label
Study Population	Volunteer subjects aged 18 or over who are habitual spherical daily wear soft frequent replacement contact lens wearers, have at least 3 months of contact lens wearing experience, and who wear their habitual lenses at least 5 days per week for at least 8 hours per day. [redacted] Target to complete: 30 Planned to enroll: ~ 48
Number of Sites	~3 US
Test Product	LID021201
Control Product	N/A
Duration of Treatment	Test Product: ~ 7 days
Visits	Visit 1 – Screening/Baseline/Order Spectacles Visit 2 [redacted] – Dispense Study Lens Visit 3 [redacted] Week 1 Follow-up/Exit

1.3 Randomization

Randomization is not applicable for this study.

1.4 Masking

This is a single group, open-label study.

[redacted]

2 Analysis Sets

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 over-spectacle determination.

For treatment-emergent safety analyses, subjects/eyes will be categorized under the actual study lenses exposed.

Adverse events occurring from the time of informed consent but prior to first exposure to study lenses will be summarized in subject listings.

3 Subject Characteristics and Study Conduct Summaries

The following tables will be presented:

- Subject Disposition
- Analysis Set
- Subject Accounting
- Demographics Characteristics
- Baseline Characteristics [eg, lens brand, lens care brand]

[redacted]

4 Effectiveness Analysis Strategy

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

[redacted]

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

[redacted]

4.1 Effectiveness Endpoints

Primary Endpoint

The primary endpoint is front surface wettability, collected on a 5-point scale, for each eye.

[redacted]

[redacted]

4.2 Effectiveness Hypotheses

Primary Effectiveness

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

[redacted]

4.3 Statistical Methods for Effectiveness Analyses

4.3.1 Primary Effectiveness Analyses

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

[redacted]

5 Safety Analysis Strategy

The focus of the safety analysis will be a comprehensive descriptive assessment of occurrence of adverse events as well as the other listed parameters. Therefore, no inferential testing will be done for the safety analysis.

5.1 Safety Endpoints

The safety endpoints are:

- Adverse events (AE)
- Biomicroscopy Findings/Slit Lamp Examinations
  - [redacted]
  - [redacted]
  - [redacted]

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

- Device deficiencies

5.2 Safety Hypotheses

There are no formal safety hypotheses in this study. The focus of the safety analysis will be a comprehensive descriptive assessment of safety endpoints listed in Section 5.1.

5.3 Statistical Methods for Safety Analyses

The analysis set for all safety analyses is defined in Section 2.1. [redacted]

5.3.1 Adverse Events

The applicable definition of an AE is in the study protocol. All AEs occurring from when a subject signs informed consent to when a subject exits the study will be accounted for in the reporting.

Pre-treatment AEs will be separated from treatment-emergent AEs occurring during the study period. A pre-treatment AE is an event that occurs after signing informed consent but prior to exposure to study lenses. The period for treatment-emergent AE analysis starts from exposure to study lenses until the subject completes or is discontinued from the study.

[redacted]

- [redacted]
- [redacted]

[redacted]

5.3.2 Biomicroscopy Findings/Slit Lamp Examination

[redacted]

[redacted]

5.3.3 Device Deficiencies

The following tables and supportive listings will be provided:

- Frequency of Treatment-Emergent Device Deficiencies
- Listing of Treatment-Emergent Device Deficiencies
- Listing of Device Deficiencies Prior To Treatment Exposure

[redacted]

8 References

Not applicable.

9 Revision History

This is Version 2.0 of the Statistical Analysis Plan for this study. This version of the Statistical Analysis Plan is based on Version 1.0 of the study protocol.

9.1 Amendment 1 (Version 2.0)

Purpose of Amendment: The purpose of this amendment is detailed below:

- Added sub-bullet in Section 4.1, Exploratory Endpoints

10 Appendix

Table 10-1 Schedule of Study Procedures and Assessments

Procedure/ Assessment	Visit 1 Screening/ Baseline/ [redacted]	Visit 2† Dispense	Visit 3 Week 1 Follow-up/ Exit	Early Exit	USV
[redacted]		[redacted]	[redacted]		
Informed Consent	✓	-	-	-	-
Demographics	✓	-	-	-	-
Medical History*	✓	✓**	✓	✓	✓
Concomitant Medications*	✓	✓**	✓	✓	✓
Inclusion/Exclusion	✓	-	-	-	-
Habitual lens (brand, power* and lenscare)	✓	-	-	-	-
[redacted]					
Biomicroscopy	✓	✓**	✓	✓	✓
[redacted]					
Record study lens power	✓	-	-	-	-
Dispense study lenses**	-	✓	-	-	-
[redacted]					

Procedure/ Assessment	Visit 1 Screening/ Baseline/ Order Spectacles	Visit 2† Dispense	Visit 3 Week 1 Follow-up/ Exit	Early Exit	USV
		[redacted]			
[redacted]					
Lens surface assessments (OD, OS): • Front surface wettability	-	✓	✓	✓	(✓)
[redacted]					

Procedure/ Assessment	Visit 1 Screening/ Baseline/ Order Spectacles	Visit 2† Dispense	Visit 3 Week 1 Follow-up/ Exit	Early Exit	USV
		[redacted]			
[redacted]					
AEs[Ω]	✓	✓	✓	✓	✓
Device deficiencies	✓	✓	✓	✓	✓
Exit Form	(✓)	(✓)	✓	(✓)	(✓)

[redacted]