

Title:

**Statistical Analysis Plan for
Protocol CLY935-E006 / NCT04631796**

Protocol Title: Clinical Characterization of an Investigational Soft Silicone
Hydrogel Contact Lens

██████████

██████████

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Template Version: Version 1.0

Approvals: See last page for electronic approvals

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

Executive Summary:

Key Objectives:

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.

Decision Criteria for Study Success:

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

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[REDACTED]	
[REDACTED]	
[REDACTED]	
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1 STUDY OBJECTIVES AND DESIGN

1.1 Study Objectives

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.

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	<p>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.</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>Target to complete: 30 Planned to enroll: ~36</p>
Number of Sites	~3 US
Test Product	LID020098
Control Product	None
Planned Duration of Exposure	Test Product: ~ 14 ± 2 days
Visits	<p>Visit 1 – Screening/Baseline/Order Spectacles</p> <p>Visit 2 [REDACTED] Dispense Study Lens</p> <p>Visit 3 [REDACTED] – Week 2 Follow-up/Exit</p>

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 power optimization. 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]

[REDACTED]

- [REDACTED]
- [REDACTED]

4 EFFICACY ANALYSIS STRATEGY

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

[REDACTED]
[REDACTED]
[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 Efficacy Endpoints

Primary Endpoint

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

[REDACTED]

[REDACTED]
[REDACTED]

- [REDACTED]
[REDACTED]
- [REDACTED]
[REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
 - [REDACTED]
 - [REDACTED]

- [REDACTED]
- [REDACTED]
- [REDACTED]
 - [REDACTED]
 - [REDACTED]
 - [REDACTED]
 - [REDACTED]
 - [REDACTED]
 - [REDACTED]
 - [REDACTED]
- [REDACTED]
 - [REDACTED]
 - [REDACTED]
 - [REDACTED]
- [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]

[REDACTED]

[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 for the combined category of Grade 0 and Grade 1.

[REDACTED]

[REDACTED]

[REDACTED]

[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]

- 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]

[REDACTED]

[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]
- [REDACTED]
- [REDACTED]
- [REDACTED]

5.3.2 Biomicroscopy Findings/Slit Lamp Examination

The following tables and supportive listings will be provided:

- Frequency and Percentage for Biomicroscopy Findings by Visit
- Incidence of Increased Severity by 2 or More Grades in Biomicroscopy Findings

- Listing of Subjects With Other Biomicroscopy Findings
- Listing of Subjects With Increased Severity by 1 Grade in Biomicroscopy Findings
- Listing of Subjects With Increased Severity by 2 or More Grades in Biomicroscopy Findings
- Listing of Subjects with Infiltrates

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]

[REDACTED]

■ [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

8 REFERENCES

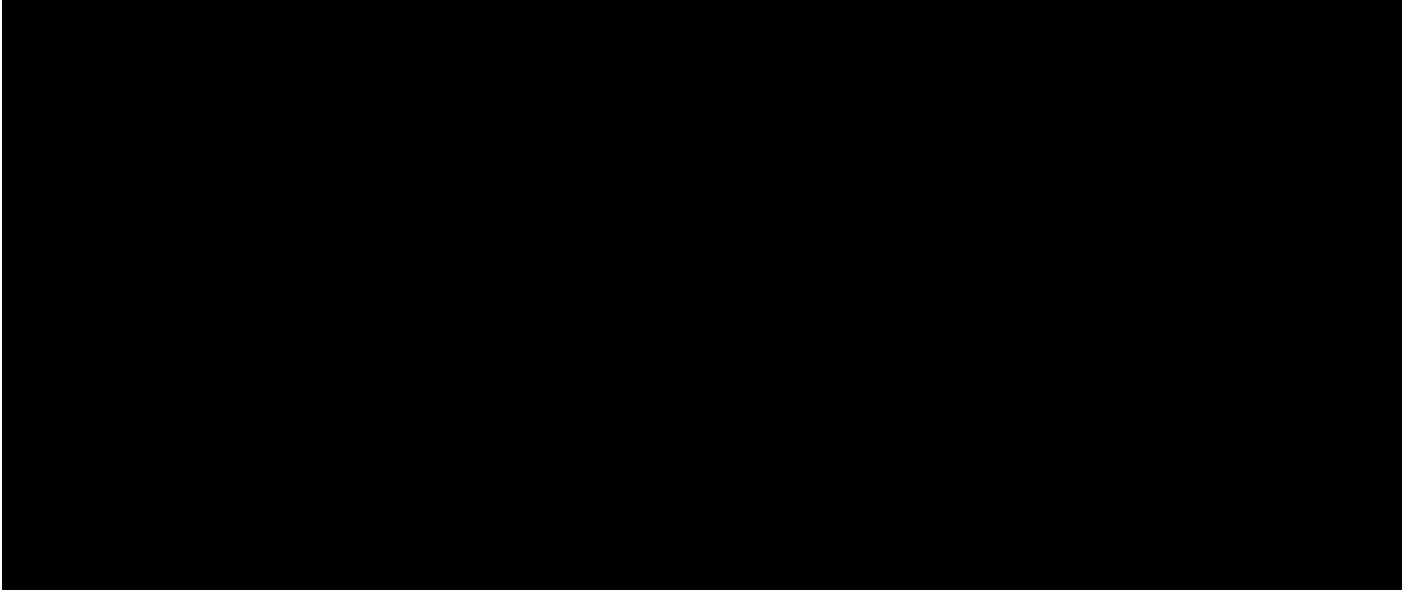
Not Applicable.

9 REVISION HISTORY

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

the 1990s, the number of people in the United States who are 65 years of age or older has increased by 50 percent, and the number of people 75 years of age or older has increased by 100 percent. The number of people 85 years of age or older has increased by 200 percent. The number of people 90 years of age or older has increased by 400 percent. The number of people 95 years of age or older has increased by 800 percent. The number of people 100 years of age or older has increased by 1,600 percent. The number of people 105 years of age or older has increased by 3,200 percent. The number of people 110 years of age or older has increased by 6,400 percent. The number of people 115 years of age or older has increased by 12,800 percent. The number of people 120 years of age or older has increased by 25,600 percent. The number of people 125 years of age or older has increased by 51,200 percent. The number of people 130 years of age or older has increased by 102,400 percent. The number of people 135 years of age or older has increased by 204,800 percent. The number of people 140 years of age or older has increased by 409,600 percent. The number of people 145 years of age or older has increased by 819,200 percent. The number of people 150 years of age or older has increased by 1,638,400 percent. The number of people 155 years of age or older has increased by 3,276,800 percent. The number of people 160 years of age or older has increased by 6,553,600 percent. The number of people 165 years of age or older has increased by 13,107,200 percent. The number of people 170 years of age or older has increased by 26,214,400 percent. The number of people 175 years of age or older has increased by 52,428,800 percent. The number of people 180 years of age or older has increased by 104,857,600 percent. The number of people 185 years of age or older has increased by 209,715,200 percent. The number of people 190 years of age or older has increased by 419,430,400 percent. The number of people 195 years of age or older has increased by 838,860,800 percent. The number of people 200 years of age or older has increased by 1,677,721,600 percent. The number of people 205 years of age or older has increased by 3,355,443,200 percent. The number of people 210 years of age or older has increased by 6,710,886,400 percent. The number of people 215 years of age or older has increased by 13,421,772,800 percent. The number of people 220 years of age or older has increased by 26,843,545,600 percent. The number of people 225 years of age or older has increased by 53,687,091,200 percent. The number of people 230 years of age or older has increased by 107,374,182,400 percent. The number of people 235 years of age or older has increased by 214,748,364,800 percent. The number of people 240 years of age or older has increased by 429,496,729,600 percent. The number of people 245 years of age or older has increased by 858,993,459,200 percent. The number of people 250 years of age or older has increased by 1,717,986,918,400 percent. The number of people 255 years of age or older has increased by 3,435,973,836,800 percent. The number of people 260 years of age or older has increased by 6,871,947,673,600 percent. The number of people 265 years of age or older has increased by 13,743,895,347,200 percent. The number of people 270 years of age or older has increased by 27,487,790,694,400 percent. The number of people 275 years of age or older has increased by 54,975,581,388,800 percent. The number of people 280 years of age or older has increased by 109,951,162,777,600 percent. The number of people 285 years of age or older has increased by 219,902,325,555,200 percent. The number of people 290 years of age or older has increased by 439,804,651,110,400 percent. The number of people 295 years of age or older has increased by 879,609,302,220,800 percent. The number of people 300 years of age or older has increased by 1,759,218,604,441,600 percent. The number of people 305 years of age or older has increased by 3,518,437,208,883,200 percent. The number of people 310 years of age or older has increased by 7,036,874,417,766,400 percent. The number of people 315 years of age or older has increased by 14,073,748,835,532,800 percent. The number of people 320 years of age or older has increased by 28,147,497,671,065,600 percent. The number of people 325 years of age or older has increased by 56,294,995,342,131,200 percent. The number of people 330 years of age or older has increased by 112,589,990,684,262,400 percent. The number of people 335 years of age or older has increased by 225,179,981,368,524,800 percent. The number of people 340 years of age or older has increased by 450,359,962,737,049,600 percent. The number of people 345 years of age or older has increased by 900,719,925,474,099,200 percent. The number of people 350 years of age or older has increased by 1,801,439,850,948,198,400 percent. The number of people 355 years of age or older has increased by 3,602,879,701,896,396,800 percent. The number of people 360 years of age or older has increased by 7,205,759,403,792,793,600 percent. The number of people 365 years of age or older has increased by 14,411,518,807,585,587,200 percent. The number of people 370 years of age or older has increased by 28,823,037,615,171,174,400 percent. The number of people 375 years of age or older has increased by 57,646,075,230,342,348,800 percent. The number of people 380 years of age or older has increased by 115,292,150,460,684,697,600 percent. The number of people 385 years of age or older has increased by 230,584,300,921,369,395,200 percent. The number of people 390 years of age or older has increased by 461,168,601,842,738,790,400 percent. The number of people 395 years of age or older has increased by 922,337,203,685,477,580,800 percent. The number of people 400 years of age or older has increased by 1,844,674,407,370,955,161,600 percent. The number of people 405 years of age or older has increased by 3,689,348,814,741,910,323,200 percent. The number of people 410 years of age or older has increased by 7,378,697,629,483,820,646,400 percent. The number of people 415 years of age or older has increased by 14,757,395,258,967,641,292,800 percent. The number of people 420 years of age or older has increased by 29,514,790,517,935,282,585,600 percent. The number of people 425 years of age or older has increased by 59,029,581,035,870,565,171,200 percent. The number of people 430 years of age or older has increased by 118,059,162,071,741,130,342,400 percent. The number of people 435 years of age or older has increased by 236,118,324,143,482,260,684,800 percent. The number of people 440 years of age or older has increased by 472,236,648,286,964,521,369,600 percent. The number of people 445 years of age or older has increased by 944,473,296,573,929,042,739,200 percent. The number of people 450 years of age or older has increased by 1,888,946,593,147,858,085,478,400 percent. The number of people 455 years of age or older has increased by 3,777,893,186,295,716,170,956,800 percent. The number of people 460 years of age or older has increased by 7,555,786,372,591,432,341,913,600 percent. The number of people 465 years of age or older has increased by 15,111,572,745,182,864,683,827,200 percent. The number of people 470 years of age or older has increased by 30,223,145,490,365,729,367,654,400 percent. The number of people 475 years of age or older has increased by 60,446,290,980,731,458,735,308,800 percent. The number of people 480 years of age or older has increased by 120,892,581,961,462,917,470,617,600 percent. The number of people 485 years of age or older has increased by 241,785,163,922,925,834,941,235,200 percent. The number of people 490 years of age or older has increased by 483,570,327,845,851,669,882,470,400 percent. The number of people 495 years of age or older has increased by 967,140,655,691,703,339,764,940,800 percent. The number of people 500 years of age or older has increased by 1,934,281,311,383,406,679,529,881,600 percent. The number of people 505 years of age or older has increased by 3,868,562,622,766,813,359,059,763,200 percent. The number of people 510 years of age or older has increased by 7,737,125,245,533,626,718,119,526,400 percent. The number of people 515 years of age or older has increased by 15,474,250,491,067,253,436,239,052,800 percent. The number of people 520 years of age or older has increased by 30,948,500,982,134,506,872,478,105,600 percent. The number of people 525 years of age or older has increased by 61,897,001,964,269,013,744,956,211,200 percent. The number of people 530 years of age or older has increased by 123,794,003,928,538,027,489,912,422,400 percent. The number of people 535 years of age or older has increased by 247,588,007,857,076,054,979,824,844,800 percent. The number of people 540 years of age or older has increased by 495,176,015,714,152,109,959,649,689,600 percent. The number of people 545 years of age or older has increased by 990,352,031,428,304,219,919,299,379,200 percent. The number of people 550 years of age or older has increased by 1,980,704,062,856,608,439,838,598,758,400 percent. The number of people 555 years of age or older has increased by 3,961,408,125,713,216,879,677,197,516,800 percent. The number of people 560 years of age or older has increased by 7,922,816,251,426,433,759,354,395,033,600 percent. The number of people 565 years of age or older has increased by 15,845,632,502,852,867,518,708,790,067,200 percent. The number of people 570

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