

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Johnson & Johnson Vision

STATISTICAL ANALYSIS PLAN

Protocol CR-6590

Evaluation of Daily Disposable Toric Soft Lenses Manufactured with an Alternative Hydration Process

Rotationally stabilized astigmatic soft contact lenses in senofilcon A manufactured on the 4GT lines with PG Hydration and Rotationally stabilized astigmatic soft contact lenses in senofilcon A manufactured on the 3GT lines with IPA Hydration

Version: 1.0

Date: 25 June 2025

[REDACTED]

[REDACTED] [REDACTED]

Compliance: The study described in this document was performed according to the principles of Good Clinical Practice (GCP).

Confidentiality Statement

The information in this document contains trade secrets and commercial information that are privileged or confidential and may not be disclosed unless such disclosure is required by applicable law or regulations. In any event, persons to whom the information is disclosed must be informed that the information is privileged or confidential and may not be further disclosed by them. These restrictions on disclosure will apply equally to all future information supplied to you that is indicated as privileged or confidential.

CR-6590, Statistical Analysis Plan Version 1.0

[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]		

ABBREVIATIONS

AE	adverse event
CI	confidence interval
CRF	case report form
CrI	Credible Interval
CSR	Clinical Study Report
eCRF	electronic case report form
FDA	Food and Drug Administration
ICH	International Conference on Harmonization
ITT	Intention-to-Treat
LSM	Least square mean
PI	principal investigator
SAE	serious adverse event
SAP	Statistical Analysis Plan
SD	standard deviation

[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]
 - [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]

[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]
[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]

[redacted]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

5. STUDY ENDPOINTS

5.1. Efficacy Endpoints

5.1.1. Co-Primary Efficacy Endpoints

There are three co-primary efficacy endpoints in this study:

Distance (4m) Monocular HLHC logMAR VA

Visual acuity (VA) will be assessed monocularly at the 1-week follow-up evaluation under high luminance, high-contrast (HLHC) conditions at a test distance of 4 meters using ETDRS Charts.

Toric Lens Orientation

Toric lens orientation (scribe mark position relative to 6 o'clock) will be assessed for each eye at 1, 3 and at least 15 minutes after lens insertion at the fitting visit, and at the 1-week follow-up visit. However, toric lens orientation at least 15 minutes after lens insertion at the dispensing visit is the primary endpoint. Toric lens orientation will be used to define a binary endpoint, i.e. the percentage of eyes that achieve absolute toric lens rotation $\leq 10^\circ$.

Lens Rotational Stability with Blinks

Rotational stability is quantified by the amount of rotation (degrees) measured relative to the scribe mark from the settled position. Rotational stability will be assessed for each eye at least 15 minutes after lens insertion at the fitting visit, and at the 1-week follow-up visit. However, rotational stability with blinks assessed at least 15 minutes after lens insertion at the dispensing visit is the primary endpoint. Lens rotational stability with blinks will be defined as a binary endpoint, the percentage of eyes that achieve rotational stability with blinks $\leq 5^\circ$.

5.1.2. Secondary Efficacy Endpoints

- Subjective overall Comfort scores at 1-week follow-up visit will be assessed using the CLUE questionnaire.
- Subjective Overall Quality of Vision scores at 1-week follow-up visit will be assessed using the CLUE questionnaire.
- Subjective Overall Handling scores at 1-week follow-up visit will be assessed using the CLUE questionnaire.

CLUE™ is a validated, patient-reported outcomes (PRO) questionnaire to assess patient-experience attributes of soft, disposable contact lenses (comfort, vision, handling, and packaging) in a contact-lens wearing population in the US, for wearers between 18 to 65 years of age. CLUE™ scores are derived using Item Response Theory (IRT) and follow a normal distribution with a population average score of 60 (SD 20), where higher scores indicate a more favorable/positive response with a range of 0-120⁷.

5.2. Safety Endpoints

5.2.1. Co-Primary Safety Endpoints

There are two co-primary safety endpoints in this study:

Slit Lamp Findings (SLF)

SLFs (Grade 3 or higher) related to study lens wear for the test lens will be assessed for each eye at all study visits (scheduled and unscheduled). SLFs will be evaluated and graded using the FDA Grading scale from 0 to 4, where Grade 0 represents the absence of findings and 1 to 4 representing successively worse findings. The percentage of eyes with Grade 3 or higher SLF will be analyzed and will include corneal infiltrates.

CR-6590, Statistical Analysis Plan Version 1.0

Acceptable lens fit will be assessed at all study visits (scheduled and unscheduled) for each subject eye and used to define a binary endpoint, i.e. the percentage of eyes that achieve acceptable lens fit while wearing the test lens. Lens fit will be deemed unacceptable if any one of the following criteria are met:

- limbal exposure at primary gaze or with extreme eye movement;
- edge lift;
- excessive movement in primary up gaze;
- insufficient movement in all three of the following conditions: primary gaze, up gaze, and push up test.

5.2.2. Secondary Safety Endpoint

Not applicable.

5.2.3. Other Safety Endpoint

Ocular and Non-Ocular Adverse Events

All adverse events, ocular and non-ocular reported during this study will be provided in a listing.

A series of horizontal bars of varying lengths, some solid black and some white, arranged in a pattern that suggests a barcode or a stylized text representation. The bars are arranged in a way that they appear to be part of a larger, partially obscured image or text. The bars are of different heights and widths, creating a complex, abstract pattern. The overall effect is one of a fragmented or obscured visual element, possibly a logo or a piece of text that has been partially hidden or distorted.

[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]
- [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]

[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]

[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]

- 1. [REDACTED]
- 2. [REDACTED]
- 3. [REDACTED]
- 4. [REDACTED]
- 5. [REDACTED]

[REDACTED]

- 1. [REDACTED]
- 2. [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]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

- [REDACTED]
- [REDACTED]

[REDACTED]
[REDACTED]

