PROTOCOL CSP-036-MX

A SINGLE CENTER EXPLORATORY STUDY TO EVALUATE THE USE OF THE RXSIGHT LIGHT ADJUSTABLE LENS (LAL) AND THE LIGHT DELIVERY DEVICE (LDD) TO IMPROVE VISUAL OUTCOMES

Rxsight, Inc.
100 Columbia, Suite 120
Aliso Viejo, CA 92656

November 20, 2020
Version 06

I have read and agree to follow the procedures as outlined in this protocol.

This protocol contains confidential proprietary information with respect to Rxsight products and clinical trials. I agree to hold this information in confidence and not to disclose it to any third parties for a period of five years from the date of this agreement, or until this information becomes a matter of public knowledge through no action or failure on my part to maintain its confidentiality.

_____
Site Name

_____ _____
Principal Investigator's Signature *Date*

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RXSIGHT, INC.

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1 STUDY SYNOPSIS

STUDY OBJECTIVE

The objective of this study is to evaluate, for the visual correction of aphakia, whether the RxSight Light Adjustable Lens (LAL) and Light Delivery Device (LDD) can be used to improve visual outcomes after performing adjustments of the LAL with the LDD. This is an exploratory study. No primary effectiveness endpoints will be defined.

STUDY POPULATION

The study population will consist of up to 200 eyes in up to 100 subjects implanted with the LAL. A subset of the population may include study subjects who were already implanted with the LAL under RxSight's CSP-037-MX protocol "A Single Center Exploratory Study to Evaluate the Effects of Ambient Sunlight Exposure on the RxSight Light Adjustable Lens (LAL)" but who have not received light treatments with the LDD. Subject's eyes must meet all applicable inclusion criteria and none of the exclusion criteria as described.

STUDY DESIGN

A prospective, single center, exploratory study will be conducted. Subjects will be followed until completion of the Postop Month 6 or later follow-up visit.

Patients who require cataract extraction and intraocular lens implantation will be pre-screened for eligibility as part of pre-entry activity. If one or both eyes meet inclusion/exclusion criteria, delegated and trained study staff will explain the study purpose, procedures, risks/benefits and subject responsibilities to the potential participant. Written informed consent must be obtained prior to initiation of any clinical procedures that are performed solely for the purpose of determining eligibility for research. The patient is enrolled upon signing the informed consent. Both eyes of all subjects may be screened for eligibility at the same preoperative visit. If at any time during the preoperative visit, an eye does not meet inclusion or exclusion criteria, screening for that eye can be discontinued immediately. If only one eye is being screened, then the subject will be exited from the study. If both eyes of the subject are enrolled for study participation, each eye will be scheduled for surgery within a timeframe of the investigator's choice but on separate days.

Patients from RxSight's CSP-037-MX study may have both eyes screened for study eligibility. The former CSP-037-MX study eye must meet all inclusion/exclusion criteria as specified below for subjects who previously participated in CSP-037-MX. If applicable, the

fellow eye (non-CSP-037-MX study eye) must meet all inclusion/exclusion criteria as specified below for subjects who did not previously participate in CSP-037-MX. If only the prior CSP-037-MX study eye is being considered for this study, the subject will need to review and sign only a CSP-036-MX written informed consent for former CSP-037-MX subjects. If both eyes are being considered for this study, the subject will also have to review and sign a CSP-036-MX written informed consent for subjects who had no affiliation with CSP-037-MX.

At the discretion of the Principal Investigator, a subgroup of eyes will receive an [redacted] 7-14 days postop. Commencing 17 to 30 days postop, all eyes will receive up to three adjustments and one to two lock-in treatments. Each light treatment will be separated by 2 to 7 days. The type of adjustment (spherocylindrical and/or presbyopia) the study eye receives is dependent on specific criteria at each light adjustment visit. Postoperatively, all subjects will undergo ophthalmic examinations until completion of the Postop Month 6 or later follow-up visit.

For subjects that receive only non-presbyopic adjustments, uncorrected distance visual acuities will be presented and summarized. For subjects that receive a presbyopia adjustment, uncorrected distance, uncorrected intermediate and uncorrected near acuities will presented and summarized. Additional analyses may be performed. Safety for all study eyes will be evaluated per ISO 11979-7.

DURATION OF STUDY

Each subject will participate in the study for approximately 6-12 months. The recruitment phase is expected to last approximately 10 months. The complete study period is expected to be approximately 24 months.

STUDY SITE

The study will be performed in an ophthalmology clinic. The investigator will be an ophthalmic surgeon, specializing in cataract surgery with implantation of intraocular lenses. Study responsibilities will be registered in a delegation log that will be kept at the investigational site. The overall responsibility at the study clinic remains with the investigator.

INCLUSION CRITERIA FOR SUBJECTS WHO DID NOT PREVIOUSLY PARTICIPATE IN CSP-037-MX

- Must sign a written Informed Consent form and be willing to undergo cataract surgery for the implantation of the LAL.
- Age 30 or older on the day cataract surgery is performed.
- Preoperative keratometric cylinder ≤3.50 D.
- Study eye must have a cataract causing reduction in best corrected distance visual acuity (BCDVA) to a level of 20/32 or worse with or without a glare source.
- In subjects with only one eye enrolled in the study: Potential for BCDVA of 20/40 or better in the non-study eye after cataract removal and IOL implantation.

- Study eye has BCDVA projected to be 20/20 or better after cataract removal and IOL implantation as estimated by potential acuity meter (PAM) or surgeon estimation.
- Study eye has clear intraocular media other than cataract.
- Willing and able to comply with the requirements for study specific procedures and visits.
- Study eye has average dilated pupil diameter of ≥7.0 mm.
- Study eye requires an IOL power within the range available for the LAL.

INCLUSION CRITERIA FOR SUBJECTS WHO PREVIOUSLY PARTICIPATED IN CSP-037-MX

- Subject was previously enrolled within clinical study CSP-037-MX sponsored by RxSight, Inc. and meets the following inclusion criteria:
    - Potential for BCDVA of 20/40 or better in the non-study eye
    - Willing and able to comply with the requirements for study specific procedures and visits.
    - Former CSP-037-MX study eye can adequately dilate (enough of the edge of the LAL optic can be visualized to allow for centration during LDD light treatment).

EXCLUSION CRITERIA FOR SUBJECTS WHO DID NOT PREVIOUSLY PARTICIPATE IN CSP-037-MX

- Study eye with zonular laxity or dehiscence.
- Study eye with pre-existing macular disease that in the opinion of the investigator performing LDD light treatments would not be in the best interest of the patient.
- Study eye with retinal degenerative disorder (other than macular degeneration) that is expected to cause future vision loss.
- Subjects with diabetes with any evidence of retinopathy.
- Study eye with a history of uveitis.
- Study eye with significant anterior segment pathology, such as rubeosis iridis, aniridia, or iris coloboma.
- Study eye with corneal pathology that is either progressive or sufficient to reduce BCDVA to worse than 20/20.
- Study eye with any corneal dystrophy including basement membrane dystrophy that in the opinion of the investigator may confound the outcome.
- Study eye with keratoconus or suspected of having keratoconus.
- Study eye that has undergone previous intraocular surgery.
- Study eye with previous trauma or developmental defects in which appropriate support of the intraocular lens (IOL) is not possible.
- Subjects with serious co-morbid conditions that in the judgment of the investigator makes inclusion in the study not in the best interest of the subject.

- Subjects taking systemic medication that may increase sensitivity to UV light such as tetracycline, doxycycline, psoralens, amiodarone, phenothiazines, chloroquine, hydrochlorothiazide, hypericin, ketoprofen, piroxicam, lomefloxacin, and methoxsalen. LDD treatment in patients taking such medications may lead to irreversible phototoxic damage to the eye. This is only a partial list of photosensitizing medications. Please evaluate all medications that the patient is taking for this effect prior to consideration for implantation.
- Subjects taking a systemic medication that is considered toxic to the retina such as tamoxifen.
- Subjects who the doctor believes will be unable to maintain steady fixation that is necessary for centration of the LDD light treatment in the study eye.
- Study eye with irregular astigmatism.
- Study eye with history of ocular herpes simplex virus.
- Current vitreoretinal disease or a high risk of future vitreoretinal disease that may require silicone oil as part of therapy in the study eye.

EXCLUSION CRITERIA FOR SUBJECTS WHO PREVIOUSLY PARTICIPATED IN CSP-037-MX

- Subjects taking systemic medication that may increase sensitivity to UV light such as tetracycline, doxycycline, psoralens, amiodarone, phenothiazines, chloroquine, hydrochlorothiazide, hypericin, ketoprofen, piroxicam, lomefloxacin, and methoxsalen. LDD treatment in patients taking such medications may lead to irreversible phototoxic damage to the eye. This is only a partial list of photosensitizing medications. Please evaluate all medications that the patient is taking for this effect prior to light treatments.
- Subjects taking a systemic medication that is considered toxic to the retina such as tamoxifen.
- Subjects who the doctor believes will be unable to maintain steady fixation that is necessary for centration of the LDD light treatment in the study eye.
- Former CSP-037-MX study eye with history of ocular herpes simplex virus.

Outcome Parameters

The following visual performance parameters will be collected and summarized for eyes that received only non-presbyopic adjustments.

- % of eyes with UCDVA of 20/20 or better at Postop Month 6 or later

The following visual performance parameters will be collected and summarized for eyes that received a presbyopia adjustment.

- Proportion of eyes simultaneously with (1) Monocular UCDVA of 20/25 or better and (2) Monocular UCIVA of 20/32 or better and (3) Monocular UCNVA of 20/40 or better at Postop Month 6 or later.

Additional analyses may be performed. Clinical data for eyes receiving only non-presbyopic adjustments and eyes receiving a presbyopia adjustment may be summarized and analyzed separately. In addition, clinical data for former CSP-037-MX study eyes may be analyzed separately.

Safety Parameters:

- Incidence of persistent sight-threatening complications and adverse events and cumulative events defined per ISO 11979-7.

The incidence of all other adverse events will also be presented.

Examination Schedule:

Evaluation	Subjects who did not previously participate in CSP-037-MX or Former CSP-037-MX subjects fellow eye (non-CSP-037-MX study eye) enrolled	Former CSP-037-MX subjects with only former CSP-037-MX study eye enrolled
Preoperative	Day -60 to Day -1	NA
Operative	Day 0, day of surgery	NA
Postop Day 1	Days 1 to 2 postop	NA
[redacted][1]	Days 7-14 postop	NA
Postop Week 3	Days 17 to 30 days postop: Adjustment #1	Days 17 to 30 days postop: Adjustment #1
Adjustment #2, if needed	2 to 7 days post Adjustment #1	2 to 7 days post Adjustment #1
Adjustment #3, if needed	2 to 7 days post Adjustment #2	2 to 7 days post Adjustment #2
Lock-in #1	2 to 7 days post final adjustment	2 to 7 days post final adjustment
Lock-in #2, if needed	2 to 7 days post lock-in #1	2 to 7 days post lock-in #1
Post Lock-in	7 to 14 days post final lock-in	7 to 14 days post final lock-in
Postop Month 3	Days 90 to 150 postop	Days 90 to 150 postop
Postop Month 6 or later	Days 180 to 400 postop	Days 180 to 400 postop

[1] **Subgroup of eyes determined by the principal investigator**

Unscheduled visits falling outside the designated ranges for scheduled visits will be considered “interim” visits for data recording purposes and a report form will be completed.

Clinical Parameters:

[redacted]

4. Demographics
5. Ocular History
6. History of Medications
7. Subjective symptoms/complaints (subject reported)
8. Ocular Biometry: Axial length + Anterior Chamber Depth
9. Corneal Topography
10. Autorefraction
11. Undilated photopic pupil diameter
12. Corneal Keratometry
13. Vision Quality Measurement
14. Anterior Segment OCT
15. Posterior Segment SD-OCT
16. Monocular uncorrected distance visual acuity (UCDVA)
17. Binocular uncorrected distance visual acuity
18. Manifest Refraction
19. Monocular best corrected distance visual acuity (BCDVA)
20. Ocular Dominance Test
21. Depth of focus testing
22. Monocular distance corrected intermediate visual acuity (DCIVA)
23. Monocular distance corrected near visual acuity (DCNVA)
24. Monocular uncorrected near visual acuity (UCNVA)
25. Binocular uncorrected near visual acuity
26. Binocular uncorrected intermediate visual acuity
27. Monocular uncorrected intermediate visual acuity (UCIVA)
28. In-office Eyrthropsia assessment
29. City University Color Test
30. Monocular Distance corrected contrast sensitivity: Mesopic/Photopic with and w/o glare
31. Intraocular pressure
32. Slit lamp exam
33. Fundus Exam
34. Aberrometry
35. Dilated pupil diameter

36. Adverse Event

ABBREVIATIONS AND DEFINITION OF TERMS

ACD	Anterior Chamber Depth
ADE	Adverse Device Effect
AE	Adverse Event
ANSI	American National Standards Institute
BCDVA	Best Corrected Distance Visual Acuity
CCC	Continuous Circular Capsulorhexis
CDRH	Center for Devices and Radiological Health
CFR	Code of Federal Regulations
CRF	Case Report Form
CRO	Contract Research Organization
CSP	Clinical Study Protocol
D	Diopter
DCIVA	Distance Corrected Intermediate Visual Acuity
DCNVA	Distance Corrected Near Visual Acuity
DD	Device Deficiency
DOF	Depth of Focus
EC	Ethics Committee
ETDRS	Early Treatment Diabetic Retinopathy Study
FDA	Food and Drug Administration
GCP	Good Clinical Practice
ICH	International Conference on Harmonization
IDE	Investigational Device Exemption
IOL	Intraocular Lens
IOP	Intraocular Pressure
IRB	Institutional Review Board
ISO	International Organization for Standardization
LDD	Light Delivery Device
M	Month
MR	Manifest Refraction
MRCYL	Manifest Refraction Cylinder
MRSE	Manifest Refraction Spherical Equivalent
OD	Right eye
OS	Left eye
PCO	Posterior Capsular Opacity
PI	Principal Investigator
PPC	Precision Pulse Capsulotomy
[redacted]	[redacted]

LAL	RxSight Light Adjustable Lens
SAE	Serious Adverse Event
SD	Standard Deviation
SE	Spherical Equivalent
SSI	Secondary Surgical Intervention
UADE	Unanticipated Adverse Device Effect
UCDVA	Uncorrected Distance Visual Acuity
UCIVA	Uncorrected Intermediate Visual Acuity
UCNVA	Uncorrected Near Visual Acuity
UP	Unanticipated Problem
UV	Ultraviolet

2 INTRODUCTION AND RATIONALE

Cataract surgery is the most commonly performed procedure by the ophthalmic surgeon. It is estimated that more than 26 million cataract operations with intraocular lens (IOL) implantation were to be performed worldwide in 2017.[1] The average age of cataract patients is reported to be 65 to 70 years old, with a small percentage of cataract surgeries being performed on patients as young as in their early 40's.[2,3] While key cataract technology advancements have resulted in important reductions in residual refractive error and improved uncorrected visual acuity, significant postoperative residual refractive error remains the most frequent cataract surgery complication. RxSight's Light Adjustable Lens (LAL) addresses the problems of residual refractive error by allowing adjustment of the spherical and cylindrical power postoperatively. The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) approved RxSight's premarket approval (PMA) application for the LAL and Light Delivery Device (LDD) system on November 22, 2017. The system is indicated for the reduction of residual astigmatism to improve uncorrected visual acuity after removal of the cataractous natural lens by phacoemulsification and implantation of the intraocular lens in the capsular bag; in adult patients:

- With pre-existing corneal astigmatism of ≥ 0.75 diopters
- Without pre-existing macular disease

The system also reduces the likelihood of clinically significant residual spherical refractive errors.

Presbyopia, which will affect approximately 2.1 billion people by 2020, is the irreversible loss of the accommodative ability of the eye that occurs due to aging.[4] Accommodation refers to the ability of the eye to increase the refractive power of its crystalline lens in order to focus near objects on the retina.[5] Presbyopia typically occurs in people over 40 years of age and can cause a considerable decrease in the quality of life for many of those affected.[6] Without correction, presbyopia results in difficulty performing tasks at a customary working distance. Because most patients have daily activities that require them to read and work at near and with the increasing importance of intermediate vision to clearly see cell phones and computer monitors, patients are seeking treatment options to mitigate the effects of their presbyopia.

The vast majority of cataract surgery patients are presbyopic preoperatively and all patients will experience presbyopia after cataract surgery. Cataract surgery presents patients with an

[1] Eyewiretoday. Steady Growth in Cataract Surgical Procedures is Expected Over the Next 5 Years, July 27, 2017.
[2] Cummings A. The Influence of Age on Refractive Cataract Surgery. CRSTEurope. Feb 2011.
[3] Gollogly H, Hodge D, St. Sauver J, Erie J. Increasing incidence of cataract surgery: Population –based study. J Cataract Refract Surg 2013; 39:1383-1389.
[4] Arlt EM, Krall EM, Moussa S, Grabner G, Dexl A. Implantable inlay devices for presbyopia: the evidence to date. Clin Ophthalmol. 2015 Jan 14;9:129-137.
[5] American Optometric Association. Care of the patient with presbyopia. St. Louis (MO): American Optometric Association; 2010.
[6] McDonnell PJ, Lee P, Spritzer K, Lindblad AS, Hays RD. Association of presbyopia with vision-targeted health-related quality of life. Arch Ophthalmol. 2003;121(11):1577-1581.

opportunity to not only remove the cataractous lens, but also to have presbyopia mitigated through the implantation of specific IOLs. Current techniques include the use of pseudophakic monovision and multifocal IOLs.

Pseudophakic monovision is a concept in which 1 eye (usually dominant) is targeted for distance vision and the other eye is targeted for near vision after IOL implantation. Depending on the technique, target refraction of the non-dominant eye ranges from 1.00 to 2.50 diopters (D) of myopia.[7] Obtaining a pre-determined magnitude of anisometropia (i.e. refractive accuracy of the IOL implantation) between eyes is critical to achieving patient satisfaction as any inaccuracy could lead to inadequate distance or near vision or patient non-adaptation to the amount of anisometropia.

Multifocal IOLs can be refractive, diffractive, or hybrid diffractive-refractive. Diffractive multifocal IOLs use light diffraction to produce 2 focal points, one for distance vision and one for near vision. In refractive multifocal IOLs, refractive power changes from the center to the periphery of the IOL, thus producing many focal points. Recent studies of multifocal IOLs report good results for both near and distance vision in terms of spectacle independence, but these IOLs are frequently associated with a number of visual adverse effects, such as dysphotopsia, visual disturbances at night, halos, and glare.[7]

This study aims to explore the treatment of the LAL postoperatively either with light treatment patterns intended to mitigate the effects of postoperative residual error only and/or combined with light treatment patterns that are intended to mitigate the effects of presbyopia by enhancing the patient's intermediate and near vision. This latter mitigation is accomplished by designing the light treatment pattern to create a distribution of optical powers within the LAL. Light treatment patterns mitigating the effects of postoperative residual error will be evaluated by looking at postoperative uncorrected distance visual acuity while light treatment patterns intended to mitigate the effects of presbyopia will be evaluated by looking at postoperative uncorrected distance, intermediate and near visual acuity.

[7] Labiris G, Giarmoukakis A, Patsiamanidi M, et al. Mini-monovision versus multifocal intraocular lens implantation. J Cataract Refract Surg 2015; 41:53-57.

3 STUDY OBJECTIVE

The objective of this study is to evaluate, for the visual correction of aphakia, whether the RxSight Light Adjustable Lens (LAL) and Light Delivery Device (LDD) can be used to improve visual outcomes after performing adjustments of the LAL with the LDD. This is an exploratory study. No primary effectiveness endpoints will be defined.

4 STUDY DESIGN

A prospective, single center, exploratory study will be conducted. Subjects will be followed until completion of the Postop Month 6 or later follow-up visit.
Patients who require cataract extraction and intraocular lens implantation will be pre-screened for eligibility as part of pre-entry activity. If one or both eyes meet inclusion/exclusion criteria, delegated and trained study staff will explain the study purpose, procedures, risks/benefits and subject responsibilities to the potential participant. Written informed consent must be obtained prior to initiation of any clinical procedures that are performed solely for the purpose of determining eligibility for research. The patient is enrolled upon signing the informed consent. Both eyes of all subjects may be screened for eligibility at the same preoperative visit. If at any time during the preoperative visit, an eye does not meet inclusion or exclusion criteria, screening for that eye can be discontinued immediately. If only one eye is being screened, then the subject will be exited from the study. If both eyes of the subject are enrolled for study participation, each eye will be scheduled for surgery within a timeframe of the investigator's choice but on separate days.

Patients from RxSight's CSP-037-MX study may have both eyes screened for study eligibility. The former CSP-037-MX study eye must meet all inclusion/exclusion criteria as specified below for subjects who previously participated in CSP-037-MX. If applicable, the fellow eye (CSP-037-MX non-study eye) must meet all inclusion/exclusion criteria as specified below for subjects who did not previously participate in CSP-037-MX. If only the prior CSP-037-MX study eye is being considered for this study, the subject will need to review and sign only a CSP-036-MX written informed consent for former CSP-037-MX subjects. If both eyes are being considered for this study, the subject will also have to review and sign a CSP-036-MX written informed consent for subjects who had no affiliation with CSP-037-MX.

At the discretion of the Principal Investigator, a subgroup of eyes will receive an [redacted] 7-14 days postop. Commencing 17 to 30 days postop, all eyes will receive up to three adjustments and one to two lock-in treatments. Each light treatment will be separated by 2 to 7 days. The type of adjustment (spherocylindrical and/or presbyopia) the study eye receives is dependent on specific criteria at each light adjustment visit. Postoperatively, all subjects will undergo ophthalmic examinations until completion of the Postop Month 6 or later follow-up visit.

For subjects that receive only non-presbyopic adjustments, uncorrected distance visual acuities will be presented and summarized. For subjects that receive a presbyopia adjustment, uncorrected distance, uncorrected intermediate and uncorrected near acuities will presented and summarized. Additional analyses may be performed. Safety for all study eyes will be evaluated per ISO 11979-7.

5 OUTCOME PARAMETERS

The following visual performance parameters will be collected and summarized for eyes that received only non-presbyopic adjustments.

- % of eyes with UCDVA of 20/20 or better at Postop Month 6 or later.

The following visual performance parameters will be collected and summarized for eyes that received a presbyopia adjustment.

- Proportion of eyes simultaneously with (1) Monocular UCDVA of 20/25 or better and (2) Monocular UCIVA of 20/32 or better and (3) Monocular UCNVA of 20/40 or better at Postop Month 6 or later.

Additional analyses may be performed. Clinical data for eyes receiving only non-presbyopic adjustments and eyes receiving a presbyopia adjustment may be summarized and analyzed separately. In addition, clinical data for former CSP-037-MX study eyes may be analyzed separately.

Safety Parameters:

- Incidence of persistent sight-threatening complications and adverse events and cumulative events defined per ISO 11979-7.

The incidence of all other adverse events will also be presented.

6 STUDY POPULATION

The study population will consist of up to 200 eyes in up to 100 subjects implanted with the LAL. A subset of the population may include study subjects who were already implanted with the LAL under RxSight's CSP-037-MX protocol "A Single Center Exploratory Study to Evaluate the Effects of Ambient Sunlight Exposure on the RxSight Light Adjustable Lens (LAL)" but who have not received light treatments with the LDD. Subject's eyes must meet all applicable inclusion criteria and none of the exclusion criteria as described.

6.1 INCLUSION CRITERIA FOR SUBJECTS WHO DID NOT PREVIOUSLY PARTICIPATE IN CSP-037-MX

- Must sign a written Informed Consent form and be willing to undergo cataract surgery for the implantation of the LAL.
- Ages 30 or older on the day the cataract surgery is performed.
- Preoperative keratometric cylinder ≤3.50 D.

- Study eye must have a cataract causing reduction in best corrected distance visual acuity (BCDVA) to a level of 20/32 or worse with or without a glare source.
- In subjects with only one eye enrolled in the study: Potential for BCDVA of 20/40 or better in the non-study eye after cataract removal and IOL implantation.
- Study eye has BCDVA projected to be 20/20 or better after cataract removal and IOL implantation as estimated by potential acuity meter (PAM) or surgeon estimation.
- Study eye has clear intraocular media other than cataract.
- Willing and able to comply with the requirements for study specific procedures and visits.
- Study eye has average dilated pupil diameter of ≥7.0 mm.
- Study eye requires an IOL power within the range available for the LAL.

INCLUSION CRITERIA FOR SUBJECTS WHO PREVIOUSLY PARTICIPATED IN CSP-037-MX

- Subject was previously enrolled within clinical study CSP-037-MX sponsored by RxSight, Inc. and meets the following inclusion criteria:
    - Must sign a CSP-036-MX written informed consent specific for former CSP-037-MX subjects
    - Potential for BCDVA of 20/40 or better in the non-study eye currently
    - Willing and able to comply with the requirements for study specific procedures and visits.
    - Former CSP-037-MX study eye can adequately dilate (enough of the edge of the LAL optic can be visualized to allow for centration during LDD light treatment).

6.2 EXCLUSION CRITERIA FOR SUBJECTS WHO DID NOT PREVIOUSLY PARTICIPATE IN CSP-037-MX

- Study eye with zonular laxity or dehiscence.
- Study eye with pre-existing macular disease that in the opinion of the investigator performing LDD light treatments would not be in the best interest of the patient.
- Study eye with retinal degenerative disorder (other than macular degeneration) that is expected to cause future vision loss.
- Subjects with diabetes with any evidence of retinopathy.
- Study eye with a history of uveitis.
- Study eye with significant anterior segment pathology, such as rubeosis iridis, aniridia, or iris coloboma.
- Study eye with corneal pathology that is either progressive or sufficient to reduce BCDVA to worse than 20/20.
- Any corneal dystrophy including basement membrane dystrophy in either eye that in the opinion of the investigator may confound the outcome.
- Study eye with keratoconus or suspected of having keratoconus.

- Study eye that has undergone previous intraocular surgery.
- Study eye with previous trauma or developmental defects in which appropriate support of the intraocular lens (IOL) is not possible.
- Subjects with serious co-morbid conditions that in the judgment of the investigator makes inclusion in the study not in the best interest of the subject.
- Subjects taking systemic medication that may increase sensitivity to UV light such as tetracycline, doxycycline, psoralens, amiodarone, phenothiazines, chloroquine, hydrochlorothiazide, hypericin, ketoprofen, piroxicam, lomefloxacin, and methoxsalen. LDD treatment in patients taking such medications may lead to irreversible phototoxic damage to the eye. This is only a partial list of photosensitizing medications. Please evaluate all medications that the patient is taking for this effect prior to consideration for implantation.
- Subjects taking a systemic medication that is considered toxic to the retina such as tamoxifen.
- Subjects who the doctor believes will be unable to maintain steady fixation that is necessary for centration of the LDD light treatment in the study eye.
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EXCLUSION CRITERIA FOR SUBJECTS WHO PREVIOUSLY PARTICIPATED IN CSP-037-MX

- Subjects taking systemic medication that may increase sensitivity to UV light such as tetracycline, doxycycline, psoralens, amiodarone, phenothiazines, chloroquine, hydrochlorothiazide, hypericin, ketoprofen, piroxicam, lomefloxacin, and methoxsalen. LDD treatment in patients taking such medications may lead to irreversible phototoxic damage to the eye. This is only a partial list of photosensitizing medications. Please evaluate all medications that the patient is taking for this effect prior to light treatments.
- Subjects taking a systemic medication that is considered toxic to the retina such as tamoxifen.
- Subjects who the doctor believes will be unable to maintain steady fixation that is necessary for centration of the LDD light treatment in the study eye.

7 STUDY MATERIALS AND METHODS

7.1 DEVICE DESCRIPTION

RxSight's Light Adjustable Lens (LAL) is a silicone intraocular lens whose shape and focusing characteristics can be modified after implantation using an office-based UV light source, the RxSight Light Delivery Device (LDD), to improve uncorrected visual acuity.

7.1.1 RXSIGHT LIGHT ADJUSTABLE INTRAOCULAR LENS

The RxSight Light Adjustable Lens (LAL) is a foldable posterior chamber, UV filtering, three-piece photoreactive silicone lens with blue PMMA (polymethylmethacrylate) modified-C haptics, a 6.0 mm optic with squared posterior edge, and an overall diameter of 13.0 mm.

The LAL silicone material is designed to respond to a narrowband UV light by incorporating photoreactive components in the cross-linked silicone lens matrix. Post implantation, the LAL shape may be altered non-invasively by photoinitiation using a select spatial intensity profile. The silicone material contains photoreactive additive, which is selectively photo-polymerized in targeted areas upon exposure to the near UV light to alter the lens shape thus modifying spherical and spherocylindrical power of the LAL or extending depth of focus or creating multifocality. A subsequent lock-in exposure is delivered to the implanted LAL to prevent further refractive changes due to exposure to sources of UV light such as sunlight or black light.

7.1.2 LIGHT DELIVERY DEVICE (LDD)

RxSight's Light Delivery Device (LDD) is a UV light projection system used to induce a predictable change in the LAL after implantation. RxSight's LDD consists of an anterior segment biomicroscope with the addition of an optical projection system, electronic control circuitry, and a UV source. The LDD delivers light profiles with adequate intensity and duration to induce polymerization of photoreactive additive leading to a change of the implanted LAL. Because this procedure is performed after implantation, residual refractive errors can be minimized and/or a patient's depth of focus can be extended, reducing the need for spectacles, corneal refractive procedures, or additional IOL procedures to optimize a patient's vision.

7.1.3 DEVICE MANUFACTURER

The LAL and LDD are manufactured by RxSight, Inc. located in Aliso Viejo, California. RxSight, Inc. has an established Quality Management System that is in conformance with the following standards:

- 21 C.F.R. Part 820 (Quality System Regulation)
- EN ISO 13485:2016 (Quality Management System with scope: design, manufacture, distribution and service of therapeutic, surgical and diagnostic devices and instruments especially for ophthalmology), and the Medical Device Directive 93/42/EEC.

7.1.4 RXSIGHT INSERTION DEVICE

The LAL can be inserted into the eye using the RxSight Insertion Device, which is comprised of a re-usable titanium injector and a single-use, non-preloaded polypropylene cartridge with lubricating coating.

7.1.5 INDICATIONS FOR USE

The RxSight Light Adjustable Lens (LAL) is an intraocular lens intended for primary implantation in the capsular bag for the visual correction of aphakia in adult patients with or without presbyopia in whom a cataractous lens has been removed. The Light Delivery Device (LDD) is used to improve uncorrected visual acuity by adjusting the LAL power to correct residual postoperative refractive error including -2.0 to +2.0 diopters of sphere and 0.50 to 3 diopters of cylinder and by changing lens curvature to introduce controlled amounts of spherical aberration (± 1 micron) and center near add (up to 2 diopters).

7.2 SUBJECT ENTRY

Patients who require cataract extraction and intraocular lens implantation will be pre-screened for eligibility as part of pre-entry activity. If one or both eyes meet inclusion/exclusion criteria, delegated and trained study staff will explain the study purpose, procedures, risks/benefits and subject responsibilities to the potential participant. Written informed consent must be obtained prior to initiation of any clinical procedures that are performed solely for the purpose of determining eligibility for research. The patient is enrolled upon signing the informed consent. The subject will sign and date the informed consent form in the presence of the person conducting the consent process. The investigator and/or the person conducting the consent process will also sign and date the consent form. During the study, the subject will be provided with any new information that is received that could affect their health status or change their willingness to continue to participate in the study. Both eyes of all subjects may be screened for eligibility at the same preoperative visit. If at any time during the preoperative visit, an eye does not meet inclusion or exclusion criteria, screening for that eye can be discontinued immediately. If only one eye is being screened, then the subject will be exited from the study. The preoperative examination will be performed no more than 60 days prior to surgery. If the 60-day time period elapses, it is acceptable for patients to be re-screened by undergoing a complete preoperative examination. Ocular dominance testing will be performed as part of the preoperative evaluation to determine eye dominance. If both eyes of the subject are enrolled for study participation, each eye will be scheduled for surgery within a timeframe of the investigator's choice but on separate days.

Only subjects meeting all inclusion/exclusion criteria will be implanted. Those subjects who do not meet the inclusion/exclusion requirements will be considered screen failures. Unique identification numbers will be assigned to each subject.

Patients from RxSight's CSP-037-MX study may have both eyes screened for study eligibility. The former CSP-037-MX study eye must meet all inclusion/exclusion criteria as specified below for subjects who previously participated in CSP-037-MX. If applicable, the fellow eye (CSP-037-MX non-study eye) must meet all inclusion/exclusion criteria as specified below for subjects who did not previously participate in CSP-037-MX. If only the prior CSP-037-MX study eye is being considered for this study, the subject will need to review and sign only a CSP-036-MX written informed consent for former CSP-037-MX subjects. If both eyes are being considered for this study, the subject will also have to review and sign a CSP-036-MX written informed consent for subjects who had no affiliation with CSP-037-MX.

7.3 LAL IMPLANTATION AND REFRACTIVE ADJUSTMENT

7.3.1 SURGICAL PROCEDURE

The LAL will be implanted on Day 0 of the study using standard microsurgical techniques.

No additional refractive procedures are allowed until after the Postop Month 6 or later visit.

The surgical procedure will be performed as follows:

1. Prepare and drape the eye for surgery in accordance with standard surgical procedures.
2. A temporal clear corneal incision will be made using the surgeon's standard instrumentation and techniques.
3. Use viscoelastic to fill the anterior chamber through the incision opening.
4. Perform an anterior circular capsulorhexis of a maximum of 5.2 mm in diameter using standard technique. The capsulorhexis should be well-centered with a 360° overlapping capsular edge to minimize IOL tilt and decentration and longitudinal IOL shift. The capsulorhexis and/or nuclear fragmentation can be performed with a femtosecond laser. Precision pulse capsulotomy (PPC) can also be used to perform the capsulorhexis.
5. The surgeon will extract the cataract by phacoemulsification.
6. In the event of an intraoperative complication prior to implantation of the LAL, including posterior capsule rupture, zonular rupture, radial capsulorhexis tear, vitreous loss, iris trauma, corneal complications or any intraoperative abnormality that may affect the postoperative pupillary dilation, or the centration or tilt of the intraocular lens, do not implant the LAL.
7. The LAL can be introduced into the eye using any of the following systems:
    a. The RxSight Insertion Device through a clear temporal corneal incision up to 3.2 mm
    b. An insertion system of the investigator's choice through a clear temporal corneal incision

    The LAL is placed into the capsular bag. If utilizing additional surgical instruments near the incision upon insertion, precaution should be taken not to contact the LAL optic with this additional instrument.
8. Verify proper orientation of the LAL
9. Aspirate any residual viscoelastic from the eye using a preferred technique.
10. The wound may close without suturing. If the unsutured wound is not watertight, close it with a either a suture using standard technique or an ocular sealant (ReSure Sealant).
11. After completion of the surgery, ocular anti-inflammatory and/or antibiotic drops may be applied in accordance with standard clinical practice.

If a patch was used at the conclusion of surgery, the subject will wait for the surgeon to remove the patch.

7.3.2 LIGHT TREATMENT PROCEDURE

At the discretion of the Principal Investigator, a subgroup of eyes will receive an [redacted] 7-14 days postop. Commencing 17 to 30 days postop, all eyes will receive up to three adjustments and one to two lock-in treatments. Each light treatment will be separated by 2 to 7 days. The type of adjustment (spherocylindrical and/or presbyopia) the study eye receives is dependent on specific criteria at each light adjustment visit.

7.3.2.1 Postponement of Light Treatment Procedure(s)

LDD treatment should be delayed if any of the following new symptoms or changes in performance are noted;

- Color Vision Testing: Treatment should be delayed if the subject scores worse on Part 2 for Tritan evaluation when compared to the initial pre-light treatment test.
- Erythropsia Evaluation: With any score of 2 (red), the treatment should be delayed.
- Best Corrected Distance Visual Acuity: With any loss of BCDVA (unless the cause is known to be non-retinal) of 10 letters or more on an ETDRS (logMAR) chart when compared to the initial pre-light treatment BCDVA, treatment should be delayed.

The subject should return for follow-up visits until the subject's visual assessment of erythropsia is a score of 0 or 1 (indicates the paper looks white or pink), the BCDVA is within 10 letters of the initial pre-light treatment BCDVA and an equivalent or better score than the initial pre-light treatment test is measured in the Tritan section of the City University Color Test, at which time the next LDD treatment may be delivered.

- If sutures were utilized at the time of surgery to close the incision wound, light treatments should not commence on the study eye until a minimum time after suture removal that has been agreed upon by the Sponsor and the Principal Investigator.
- A study eye with an ocular adverse event that could be negatively impacted by light treatment or negatively impact the effectiveness or safety of a light treatment should have light treatments delayed until after the adverse event has subsided. This includes corneal edema and superficial punctate keratitis (SPK) (Grade 3 (moderate) or more severe)), retinal conditions including diabetic retinopathy and cystoid macular edema, epithelial defect, endophthalmitis or any other safety concern that the investigator believes may be negatively impacted by light treatment.
- If a study eye is discovered with evidence of premature photopolymerization as evidenced as a zone on the lens surface, the investigator should contact the Sponsor for further instructions. (see Appendix 1 for additional details regarding premature photopolymerization).
- Any study eye possessing clinically significant posterior capsular (PC) haze should undergo a YAG capsulotomy procedure prior to the adjustment. A minimum of 48 hours

should separate the YAG treatment from the corresponding refraction and LDD adjustment.

7.3.2.2 Additional Clinical Testing

Additional clinical testing may be performed on a subgroup of study subjects. The Principal Investigator may determine whether a subject will be included into a clinical test subgroup based on the adjustment light treatments to be performed. Clinical measurement subgroups will include:

- Undilated photopic pupil diameter (Week 3, Post Lock-In, Month 3, Month 6 or later)
- Binocular UCDVA, UCIVA, UCNVA (Week 3, Post Lock-In, Month 3, Month 6 or later)
- Depth of Focus (Week 3, Lock-In #1, Post Lock-In, Month 3, Month 6 or later)
- Monocular DCIVA, DCNVA, UCIVA, UCNVA (Week 3, Lock-In #1, Post Lock-In, Month 3, Month 6 or later)
- Monocular Distance Corrected Contrast Sensitivity (Photopic/Mesopic) (Week 3, Post Lock-In, Month 3, Month 6 or later)
- [redacted]
- Posterior Segment SD-OCT

7.3.2.3 Procedure Preparation

All eyes will be prepared for non-presbyopic adjustments with pupil dilation. All eyes will be prepared for presbyopic adjustments without pupil dilation. All lock-in light treatments will be administered through a dilated pupil.

<u>If dilation is required:</u>

The study eye will be dilated using any of the following pupil dilation drops (1.0% Tropicamide, 2.5% or 10% Phenylephrine, 0.5%, 1%, 2% Cyclopentolate) or pupil dilation gel (0.4% Ketorolac Tromethamine, 10% Phenylephrine, 2.5% Tropicamide). After waiting an appropriate amount of time for dilation to occur, the study eye will be examined to ensure that adequate dilation (enough of the edge of the LAL optic can be visualized to allow for centration during LDD light treatment) has been obtained. If adequate dilation has not been obtained, additional dilating drops with manual punctal occlusion or a sponge soaked in mydriatic medication and applied to the ocular surface can be utilized to try and gain further dilation. If adequate pupil dilation is still not achieved with the methods described above, the treatment will be rescheduled and the dilation attempted at another visit or another dilation method is used.

Once adequate pupil dilation is achieved, patch the subject's opposite eye and position the subject comfortably in front of the LDD with chin in the chinrest and forehead against the support bar. Ask the subject to grasp the handles on the LDD table for support. Inform the subject to concentrate on the green fixation light presented in front of them and to try and minimize eye movement.

If no dilation is required:

The subject's fellow eye will be patched and the subject will be comfortably positioned in front of the LDD with chin in the chinrest and forehead against the support bar. The subject is asked to grasp the handles on the LDD for support and is asked to look straight ahead and concentrate on the green fixation light presented in front of them and to try and minimize eye movement.

7.3.2.4 Adjustment Procedure(s)

Refer to the LDD Operator's manual for instructions on LDD start up and instructions for the daily alignment test to be performed prior to the first treatment of the day to ensure the UV beam is aligned to the reticle. If the UV beam is not aligned to the reticle within the specifications detailed in the LDD Operator's manual, do not perform treatments and call RxSight customer service immediately.

1. Within the Patient ID and Patient Data screens, follow the touchscreen prompts to enter requested information. Press the "Proceed" button once information has been entered respectively for each screen.
2. Within the Confirmation screen, review all information and press the "Confirm" button.
3. Verify that the LDD ring lights and reticle target are activated.
4. Apply topical anesthetic.
5. Position the RxSight supplied contact lens (M = 0.766x, black contact lens) on the cornea using a Sponsor approved coupling medium.

   Note: The RxSight contact lens is similar to those used in other ophthalmic procedures in which customized magnification is required. To ensure correct magnification for treatment, use only the RxSight designated contact lens.
6. Instruct the subject to focus straight ahead on the LDD fixation light with the study eye.
7. Using the microscope, focus on the cornea and verify that there are no trapped bubbles present. Confirm alignment of the contact lens by approximately aligning the Purkinje images to the inner circle of the reticle target.
8. For dilated pupil light treatments, using the microscope, focus on the LAL haptics and align the reticle target with the periphery of the LAL. Press the "Ready" button. Initiate the UV exposure as prompted by the LDD display using the trigger. Use the joystick to keep the LAL centered in the alignment reticle. Perform micro adjustments to keep the reticle target centered to the LAL and to keep the LAL in focus. In the case of subject movement, loss of alignment, or loss of focus, pause the treatment, quickly refocus, realign the lens with respect to the reticle beam, and immediately resume treatment to limit the duration of any pauses once the light treatment has been initiated.

   Note: Always maintain the LAL in focus by focusing at the haptics. Never focus onto the CCC (capsulotomy) or Purkinje images.

9. For undilated pupil light treatments, using the microscope, focus on the iris and align the reticle target with the pupil/iris edge landmark. Initiate the UV exposure as prompted by the LDD display using the joystick or foot pedal.
10. If the event of an aborted Adjustment Treatment, do not initiate a new treatment sequence; instead; instruct the subject to return within the window of their next study visit for refractive evaluation to assess whether an adjustment treatment is required or to proceed directly to a lock-in treatment.
11. The subject will return within the window of their next study visit for another light treatment.

7.3.2.5 Lock-In Procedure(s)

Refer to the LDD Operator's manual for instructions on LDD start up and instructions for the daily alignment test to be performed prior to the first treatment of the day to ensure the UV beam is aligned to the reticle. If the UV beam is not aligned to the reticle within the specifications detailed in the LDD Operator's manual, do not perform treatments and call RxSight customer service immediately.

1. Within the Patient ID screen, utilize the pop-out menu within the Patient ID field to select the appropriate subject identification with eye to be treated. Reconfirm information displayed on screen and follow the touch screen prompts to enter in newly requested information. Press the "Proceed" button.
2. Within the Confirmation screen, review all information and press the "Confirm" button.
3. Verify that the LDD ring lights and reticle target are activated.
4. Apply topical anesthetic.
5. Position the RxSight supplied contact lens (M = 0.766x, black contact lens) on the cornea using a Sponsor approved coupling medium.

   Note: The RxSight contact lens is similar to those used in other ophthalmic procedures in which customized magnification is required. To ensure correct magnification for treatment, use only the RxSight designated contact lens.
6. Instruct the subject to focus straight ahead on the LDD fixation light with the study eye.
7. Using the microscope, focus on the cornea and verify that there are no trapped bubbles present. Confirm alignment of the contact lens by approximately aligning the Purkinje images to the inner circle of the reticle target.
8. Using the microscope, focus on the LAL haptics and align the reticle target with the periphery of the LAL.
9. Press the "Ready" button
10. Initiate the irradiation delivery as prompted by the LDD display using the joystick or foot pedal to keep the LAL centered in the alignment reticle.

11. Perform micro adjustments to keep the reticle target centered to the LAL and to keep the LAL in focus. In the case of subject movement, loss of alignment, or loss of focus, pause the treatment, quickly refocus, realign the lens with respect to the reticle beam, and immediately resume treatment to limit the duration of any pauses once the light treatment has been initiated.

    Note: Always maintain the LAL in focus by focusing at the haptics. Never focus onto the CCC (capsulotomy) or Purkinje images.

12. If the lock-in treatment is aborted before completion, contact the Sponsor for technical assistance.
13. Upon completion of the lock-in #1 treatment, a notification may appear that informs the user that a lock-in #2 treatment is not required for the subject. If no notification appears, then the subject will require a lock-in #2 treatment and proceed to step #14.
14. The subject will return for the second lock-in treatment 2 to 7 days after the first lock-in treatment.

7.4 EXAMINATION SCHEDULE

Evaluation	Subjects who did not previously participate in CSP-037-MX or Former CSP-037-MX subjects with fellow eye (CSP-037-MX non-study eye) enrolled	Former CSP-037-MX subjects with only former CSP-037-MX study eye enrolled
Preoperative	Day -60 to Day -1	NA
Operative	Day 0, day of surgery	NA
Postop Day 1	Days 1 to 2 postop	NA
[redacted][1]	Days 7-14 postop	NA
Postop Week 3	Days 17 to 30 days postop: Adjustment #1	Days 17 to 30 days postop: Adjustment #1
Adjustment #2, if needed	2 to 7 days post Adjustment #1	2 to 7 days post Adjustment #1
Adjustment #3, if needed	2 to 7 days post Adjustment #2	2 to 7 days post Adjustment #2
Lock-in #1	2 to 7 days post final adjustment	2 to 7 days post final adjustment
Lock-in #2, if needed	2 to 7 days post lock-in #1	2 to 7 days post lock-in #1
Post Lock-in	7 to 14 days post final lock-in	7 to 14 days post final lock-in
Postop Month 3	Days 90 to 150 postop	Days 90 to 150 postop
Postop Month 6 or later	Days 180 to 400 postop	Days 180 to 400 postop

[1] **Subgroup of eyes determined by the principal investigator**

Unscheduled visits falling outside the designated ranges for scheduled visits will be considered "interim" visits for data recording purposes. A report form will be completed for interim visits on the study eye.

7.5 CLINICAL PARAMETERS

[redacted]

4. Demographics
5. Ocular History
6. History of Medications
7. Subjective symptoms/complaints (subject reported)
8. Ocular Biometry: Axial length + Anterior Chamber Depth
9. Corneal Topography
10. Autorefraction
11. Undilated photopic pupil diameter
12. Corneal Keratometry
13. Vision Quality Measurement
14. Anterior Segment OCT
15. Posterior Segment SD-OCT
16. Monocular uncorrected distance visual acuity (UCDVA)
17. Binocular uncorrected distance visual acuity
18. Manifest Refraction
19. Monocular best corrected distance visual acuity (BCDVA)
20. Ocular Dominance Test
21. Depth of focus testing
22. Monocular distance corrected intermediate visual acuity (DCIVA)
23. Monocular distance corrected near visual acuity (DCNVA)
24. Monocular uncorrected near visual acuity (UCNVA)
25. Binocular uncorrected near visual acuity
26. Binocular uncorrected intermediate visual acuity
27. Monocular uncorrected intermediate visual acuity (UCIVA)
28. In-office Eyrthropsia assessment
29. City University Color Test
30. Monocular Distance corrected contrast sensitivity: Mesopic/Photopic with+ w/o glare
31. Intraocular pressure
32. Slit lamp exam
33. Fundus Exam
34. Aberrometry
35. Dilated pupil diameter

36. Adverse Event

Table 1. Schedule of Visits and Clinical Parameters

Visits	Preop*	Operative*	Postop Day 1*	[redacted]**	Postop Week 3	Adjustment #2 (if needed)	Adjustment #3 (if needed)	Lock-in #1	Lock-in #2 (if needed)	Post Lock-in	Postop Month 3	Postop Month 6 or later	Unscheduled Visit[3]
[redacted]				X[1]	X[1.1]					X[1]	X[1]	X[1]	
[redacted]				X	X	X	X	X	X	X	X	X	
[redacted]			X[2]	X[2]	X[2]	X[2]	X[2]	X[2]	X[2]				
Demographics	X												
Ocular History	X				X[4]								
History of Medications	X	X	X	X	X	X	X	X	X				
Subjective Symptoms/Complaints			X	X	X	X	X	X	X	X	X	X	X
Ocular Biometry (ACD + Axial Length)	X			X	X					X	X	X	
Corneal Topography	X			X	X					X	X	X	
Autorefraction				X	X	X	X	X	X	X	X	X	
Undilated photopic pupil diameter				X[2]	X[2]					X[2]	X[2]	X[2]	
Corneal Keratometry	X			X	X					X	X	X	

[1] Only performed on subjects with both eyes enrolled and successfully implanted

[1.1] Only performed on subjects with both eyes enrolled and successfully implanted and subject did not have an [redacted] visit

[2] May be performed on a subgroup of subjects as described in section 7.3.2.2 of the protocol

[3] Tests indicated with an "X" must be performed at each unscheduled visit. Other tests may be conducted based on the investigator's assessment of the subject.

[4] Only required for subjects who previously participated in RxSight's CSP-037-MX study

* Visits only required for subjects who did not previously participate in RxSight's CSP-037-MX study

** Subgroup of eyes based on decision made by Principal Investigator

Visits	Preop*	Operative*	Postop Day 1*	[redacted]*	Postop Week 3	Adjustment #2 (if needed)	Adjustment #3 (if needed)	Lock-in #1	Lock-in #2 (if needed)	Post Lock-in	Postop Month 3	Postop Month 6 or later	Unscheduled Visit[3]
Visits	**Preop***	**Operative***	**Postop Day 1***	**[redacted]***	**Postop Week 3**	**Adjustment #2 (if needed)**	**Adjustment #3 (if needed)**	**Lock-in #1**	**Lock-in #2 (if needed)**	**Post Lock-in**	**Postop Month 3**	**Postop Month 6 or later**	**Unscheduled Visit[3]**
Anterior Segment OCT			X	X	X	X	X	X	X	X	X	X	
Posterior Segment SD-OCT				X[2]	X[2, 5]					X[2]			
Vision Quality Measurement				X	X	X	X	X	X	X	X	X	
Monocular Uncorrected Distance Visual Acuity (UCDVA)	X		X	X	X	X	X	X	X	X	X	X	X
Binocular Uncorrected Distance Visual Acuity				X[1]	X[1.1, 2]					X[1, 2]	X[1, 2]	X[1, 2]	
Manifest Refraction	X			X	X	X	X	X	X	X	X	X	
Monocular Best Corrected Distance Visual Acuity (BCDVA)	X			X	X	X	X	X	X	X	X	X	
Ocular Dominance Test	X			X	X[5]								
DOF Testing				X[2]	X[2, 5]			X[2]		X[2]	X[2]	X[2]	
Monocular Distance Corrected Intermediate Visual Acuity				X[2]	X[2, 5]			X[2]		X[2]	X[2]	X[2]	
Monocular Distance Corrected Near Visual Acuity				X[2]	X[2, 5]			X[2]		X[2]	X[2]	X[2]	

Visits	Preop*	Operative*	Postop Day 1*	[redacted]*	Postop Week 3	Adjustment #2 (if needed)	Adjustment #3 (if needed)	Lock-in #1	Lock-in #2 (if needed)	Post Lock-in	Postop Month 3	Postop Month 6 or later	Unscheduled Visit[3]

[1] Only performed on subjects with both eyes enrolled and successfully implanted

[1.1] Only peformed on subjects with both eyes enrolled and successfully implanted and subject did not have an [redacted] visit

[2] May be performed on a subgroup of subjects as described in section 7.3.2.2 of the protocol

[3] Tests indicated with an "X" must be performed at each unscheduled visit. Other tests may be conducted based on the investigator's assessment of the subject.

[4] Only required for subjects who previously participated in RxSight's CSP-037-MX study

[5] Only performed on subjects who did not have an [redacted] visit

*Visits only required for subjects who did not previously participate in RxSight's CSP-037-MX study

** Subgroup of eyes based on decision made by Principal Investigator

Visits	Preop*	Operative*	Postop Day 1*	[redacted]	Postop Week 3	Adjustment #2 (if needed)	Adjustment #3 (if needed)	Lock-in #1	Lock-in #2 (if needed)	Post Lock-in	Postop Month 3	Postop Month 6 or later	Unscheduled Visit[3]
Monocular Uncorrected Near Visual Acuity				X[2]	X[2, 5]			X[2]		X[2]	X[2]	X[2]	
Binocular Uncorrected Near Visual Acuity				X[1, 2]	X[1.1, 2]					X[1, 2]	X[1, 2]	X[1, 2]	
Binocular Uncorrected Intermediate Visual Acuity				X[1, 2]	X[1.1, 2]					X[1, 2]	X[1, 2]	X[1, 2]	
Monocular Uncorrected Intermediate Visual Acuity				X[2]	X[2, 5]			X[2]		X[2]	X[2]	X[2]	
Erythropsia Assessment				X	X	X	X	X	X	X	X	X	
City University Color Test				X	X	X	X	X	X	X	X	X	
Monocular Distance Corrected Contrast (Photopic/Mesopic)				X[2]	X[2, 5]					X[2]	X[2]	X[2]	
Intraocular Pressure	X		X	X	X	X	X	X	X	X	X	X	

Visits	Preop*	Operative*	Postop Day 1*	[redacted]*	Postop Week 3	Adjustment #2 (if needed)	Adjustment #3 (if needed)	Lock-in #1	Lock-in #2 (if needed)	Post Lock-in	Postop Month 3	Postop Month 6 or later	Unscheduled Visit[3]
Slit Lamp Exam	X		X	X	X	X	X	X	X	X	X	X	
Fundus Exam	X				X						X	X	
Aberrometry	X			X	X	X	X	X	X	X	X	X	
Dilated Pupil Diameter	X				X	X	X	X	X				
Adverse Events		X	X	X	X	X	X	X	X	X	X	X	X

[1] Only performed on subjects with both eyes enrolled and successfully implanted

[1.1] Only peformed on subjects with both eyes enrolled and successfully implanted and subject did not have an [redacted] visit

[2] May be performed on a subgroup of subjects as described in section 7.3.2.2 of the protocol

[3] Tests indicated with an "X" must be performed at each unscheduled visit. Other tests may be conducted based on the investigator's assessment of the subject.

[4] Only required for subjects who previously participated in RxSight's CSP-037-MX study

[5] Only performed on subjects who did not have an [redacted] visit

*Visits only required for subjects who did not previously participate in RxSight's CSP-037-MX study

** Subgroup of eyes based on decision made by Principal Investigator

7.6 DATA REPORTING

All study data will be recorded onto case report forms (electronic or paper) designed for the study. CRFs can be signed by the investigator either by paper signature or by electronic signature. The CRF may be the source document for some data and each site will document this with a note to file describing in which cases source data will be recorded directly onto the CRF. If paper CRFs are used, all CRFs will be completed in a legible manner in black/blue ink.

Any corrections to the CRFs will be made by drawing a single line through the incorrect entry, recording the correct information, and initialing and dating the change. The CRFs and/or data entered in the EDC system will be reviewed by the Study Monitor.

All clinical data generated in the study will be submitted to RxSight or designated CRO for quality assurance review and statistical analysis. All CRFs and/or data entered into the EDC system will be reviewed for completeness and evident recording errors will be rectified by contact with the appropriate clinical site. Computerized data checks if applicable will be used to identify unusual data entries for verification prior to statistical analysis.

To minimize the amount of missing data, investigators will be trained on the deleterious effect that missing data have on trial integrity and credibility and that missing data could diminish the scientific value of all subjects' altruistic contributions.

7.7 STUDY COMPLETION PROCEDURES

A study Exit Form must be completed for all subjects enrolled in the study upon subject completion, withdrawal or discontinuation.

7.7.1 SUBJECT COMPLETION

Subjects are considered to have completed the study if they have completed the Postop Month 6 or later visit.

Subjects with ocular serious adverse events or adverse device effects that are unresolved at study exit should continue to be followed until resolution of the event or until they are stable per the investigator’s evaluation.

7.7.2 SUBJECT WITHDRAWAL PRIOR TO IMPLANTATION

Subjects may be withdrawn from the study prior to implantation if they do not meet all inclusion/exclusion criteria (screen failures) or decide not to participate in the study.

7.7.3 SUBJECT WITHDRAWEL DUE TO INTRAOPERATIVE COMPLICATIONS PRIOR TO IMPLANTATION

Subjects that meet all inclusion/exclusion criteria but do not undergo implantation of a LAL IOL due to intraoperative complications prior to introduction of the LAL will be followed to resolution of any adverse events and then exited from the study.

7.7.4 SUBJECT DISCONTINUATION AFTER IMPLANTATION

After LAL implantation, subjects may not be withdrawn from the study unless the LAL or LALs (in the case of bilaterally implanted subjects) have been explanted. In the case of an explant, the investigator should continue follow-up for a period that ensures no adverse consequences have resulted. When possible, all necessary clinical assessments will be performed prior to the Subject exiting the study even if the assessment was not scheduled at that particular visit.

Subjects may be discontinued from the study only if the LAL or LALs (in the case of bilaterally implanted subjects) have been explanted or subject has deceased. The reason for discontinuation will be recorded on the appropriate study worksheet. Subjects who are discontinued from the study will still be a part of the study analyses up until the point they are exited.

7.7.5 LOST TO FOLLOW-UP

Subjects for which the final post-operative case report form is overdue and who refuse to be followed, or have difficulty being followed, or cannot be contacted despite extensive written and telephone follow-ups to determine the final clinical outcome, will be considered lost to follow-up. Sites must make a minimum of three documented attempts via telephone, email, or regular mail to contact the subject. If the subject does not reply to any of these attempts, the site must send a letter by certified mail (with a request for notification of receipt of delivery) to the subject. If a subject is non-responsive to these follow-up attempts, the subject will be considered to be lost to follow-up.

7.7.6 STUDY TERMINATION

The study may be stopped at any time by the Sponsor(s) for reasonable cause with appropriate notification. Conditions that may warrant study termination include, but are not limited to the following:

- Safety concerns. Clinical data from the study will be monitored to assure the safety of enrolled subjects.

If the clinical study is prematurely terminated, the Sponsor will inform the Investigator, Ethics Committee, and other appropriate regulatory bodies. If the Sponsor terminates the study for safety reasons, it will immediately notify the Investigator, Ethics Committee, and other appropriate regulatory bodies and provide an explanation of the reasons for termination. The Investigator will be provided with instructions for study termination and

applicable subject follow-up. The Sponsor will continue to provide resources to fulfill the Clinical Study Plan obligations for follow-up of the subjects enrolled in the study.

8 STATISTICAL METHODS

8.1 POPULATIONS FOR ANALYSIS

Exploratory effectiveness analyses will be performed on all eyes as specified. Clinical data for former CSP-037-MX study eyes may be analyzed separately.

Safety analyses will be performed on observed data for all eyes of subjects who sign the informed consent and the procedure was attempted which is defined as the point at which the LAL makes contact with the eye. No imputation will be performed.

8.1.1 EXPLORATORY EFFECTIVENESS PARAMETERS

Primary Exploratory Parameters

Eyes that received only non-presbyopic adjustments.

- % of eyes with UCDVA of 20/20 or better at Postop Month 6 or later

Eyes that received a presbyopia adjustment.

- Proportion of eyes simultaneously with (1) Monocular UCDVA of 20/25 or better and (2) Monocular UCIVA of 20/32 or better and (3) Monocular UCNVA of 20/40 or better at Postop Month 6 or later.

Clinical data for former CSP-037-MX study eyes may be analyzed separately.

Additional Exploratory Parameters

UCDVA

Monocular and/or binocular UCDVA will be presented with the number and percent of eyes that fall into each category of visual acuity performance (e.g. 20/20 or better, 20/25 or better, 20/32 or better, etc.) at each visit tested. Number and percent for eyes that only received non-presbyopic adjustments and for eyes that received a presbyopia adjustment may be presented separately. In addition, clinical data for former CSP-037-MX study eyes may be analyzed separately.

UCIVA, UCNVA, DCIVA, and DCNVA

Monocular and/or binocular UCIVA, UCNVA, DCIVA, and DCNVA for eyes that received a presbyopia adjustment will be presented with the number and percent of eyes that fall into each category of visual acuity performance (e.g. 20/20 or better, 20/25 or better, 20/32 or better, etc.) at each visit tested. In addition, clinical data for former CSP-037-MX study eyes may be analyzed separately.

Depth of Focus

The mean acuity across all eyes that received a presbyopia adjustment will be calculated and plotted separately. The mean, standard deviation, and confidence intervals for each point on the curve will be reported. In addition, clinical data for former CSP-037-MX study eyes may be analyzed separately.

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8.2 SAFETY PARAMETERS

- Incidence of persistent sight-threatening complications and adverse events and cumulative events defined per ISO 11979-7.

The incidence of all other adverse events will also be presented.

8.2.2 ADDITIONAL SAFETY ANALYSES

The safety outcomes will be summarized descriptively for all eyes that have the procedure attempted.

BCDVA
Monocular BCDVA will be presented with the number and percent of eyes who fall into each category of BCDVA at each visit (e.g. 20/20 or better, 20/25 or better, 20/32 or better, etc.). The mean BCVDA logMAR score will be calculated for each visit. Change in BCVDA from Postop Week 3 or from Preoperative will be presented at each visit as categorical outcomes of "Increase in 15 letters or more", "Increase in 10-14 letters", "Increase in 5-9 letters", "No change", "Decrease in 5-9 letters", "Decrease in 10-14 letters", and "Decrease in 15 letters or more".

In-Office Erythropisa Assessment
The number and percent of eyes in each outcome of erythropsia assessment (0- white, 1- pink, or 2- red) will be presented.

Intraocular Pressure (IOP)
The IOP and change in IOP from preoperative will be summarized by mean, standard deviation, median, minimum and maximum. The number and percent of eyes reported with IOP $\geq$ 25 mmHg or an IOP increase of $\geq$ 10 mmHg from preop will be provided at each visit.

Slit Lamp Examination and Fundus Examination Findings
The outcomes will be summarized descriptively by count and percent of eyes with each possible finding category.

[8] McAlinden C, Pesudovs K, Moore JE. The Development of an Instrument to Measure Quality of Vision: The Quality of Vision (QoV) Questionnaire. Invest Ophthalmol Vis Sci. 2010;51:5537-5545.

9 SEQUENCE OF PLANNED ANALYSES

9.1 INTERIM ANALYSES

An interim analysis may be performed. Since there are no statistically based hypothesis driven endpoints or associated sample size, no multiplicity adjustment is needed.

9.2 FINAL REPORT

When all enrolled study eyes have completed the Postop Month 6 or later visit or have been discontinued from the study, the data will be analyzed for a final study report.

10 ADVERSE EVENTS

Throughout the study, adverse events are to be documented and reported on Adverse Event Forms (AE Forms) that are included in the study documentation. If an adverse event (AE) occurs, the first concern will be the safety and welfare of the subject; treatment should be provided as appropriate for the event. During the study, the Investigator should appropriately treat and follow each AE until it resolves, stabilizes, or it is determined that further improvement is not expected. Per Section 7.7.1, subjects with ocular serious adverse events or adverse device effects that are unresolved at study exit (Postop Month 6 or later) should continue to be followed until resolution of the event or until they are stable per the investigator's evaluation.

10.1 ADVERSE EVENT (AE) DEFINITIONS

An adverse event 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.

Note 1 to entry: This definition includes events related to the investigational medical device or the comparator.

Note 2 to entry: This definition includes events related to the procedures involved.

Note 3 to entry: For users or other persons, this definition is restricted to events related to investigational medical devices.

The specific event should be reported as an AE:

- An erythropsia score of 2 (red) at any time after the initial light treatment.

10.2 ADVERSE DEVICE EFFECT (ADE) DEFINITION

Adverse event related to the use of an investigational medical device.

Note 1: This definition includes adverse events resulting from insufficient or inadequate instructions for use, deployment, implantation, installation, or operation, or any malfunction of the investigational medical device.

Note 2: This definition includes any event resulting from use error or from intentional misuse of the investigational medical device.

10.3 DEVICE DEFICIENCY (DD) DEFINITION

Inadequacy of a medical device with respect to its identity, quality, durability, reliability, safety or performance. Note: Device deficiencies include malfunctions, use errors, and inadequate labeling.

10.4 SERIOUS ADVERSE EVENT (SAE) DEFINITION

Serious Adverse Events are AEs that lead to:

- death
- a serious deterioration in the health of the subject that:
  - results in a life-threatening illness or injury
  - results in a permanent impairment of a body structure or function (e.g., blindness)
  - requires in-subject hospitalization or prolongation of existing hospitalization
  - results in medical or surgical intervention to prevent permanent impairment to a body structure or a body function
- fetal distress, fetal death, or a congenital abnormality or birth defect
- a potentially sight-threatening condition
- or is another important medical event.

10.4.1 IDENTIFICATION AND COLLECTION

All AEs that occur during the study must be recorded in English on the adverse event Case Report Form. Each event must be on a separate form, regardless of whether one event may be secondary to another or from a single cause. Identification and collection of an AE begins after informed consent has been obtained and documented. Standard sources of identifying AEs include:

- direct observation by the Investigator or study team member
- asking the study participant a specific question (e.g., “Since your last visit, have you experienced any problems with your eyes or vision?”)
- unsolicited volunteering of information by the study participant (e.g., “Doctor, I have had numerous headaches since I started using this lens.”)

Ocular AEs and SAEs and systemic SAEs observed or elicited by the Investigator, reported by the subject, or resulting from a test result, etc., occurring during the clinical investigation must be documented. AE Forms are to be completed at the time of the event regardless of all data being available.

During the study, the Investigator should treat the study subject as appropriate to ensure his/her safety and welfare. Refer to Section 7.7.1 for additional information pertaining to ongoing AEs at subject exit.

Pre-existing conditions will not be considered AE/SAEs but will be collected at the Preoperative Visit as medical history. A worsening of a pre-existing condition during the study should be documented as an AE and evaluated accordingly.

Hospitalization is a criterion for assessment of seriousness. Hospitalization in the absence of a medical AE is not in itself an AE. For example, the following reports of hospitalization without a medical AE should not be considered either an SAE or an AE:

- Planned hospitalization for a pre-existing condition without serious deterioration in health (e.g., planned knee replacement surgery)
- Social admission (e.g., subject has no place to sleep)
- Administrative admission (e.g., for yearly physical exam or elective procedures not related to the study)
- Optional admission not associated with a precipitation medical AE (e.g., for elective cosmetic surgery)

10.4.2 EVALUATIONS

When evaluating AEs, the Investigator must determine if the event is serious, assess the severity of symptoms, the relationship of the event to the device or study protocol, using the following guidelines:

1. **Severity**

   Mild: subject awareness of a sign or symptom that is easily tolerated, requires no treatment, and does not interfere with subject's daily activities

   Moderate: subject awareness of a sign or symptom which may be a low level of concern to the subject and may interfere with daily activities, but can be relieved by simple therapeutic care

   Severe: a sign or symptom that interrupts the subject's daily activity and requires systemic therapy or other treatment

2. **Relationship (Causality) to Study Device or Study Protocol**

   Related: There is at least a reasonable possibility that the AE/SAE is related to the study device or study protocol. Reasonable possibility means that there is evidence to suggest a causal relationship between the study device or study protocol and the AE.

   Unrelated: There is little or no reasonable possibility that the AE/SAE is related to the study device or study protocol. This assessment implies that the AE/SAE has little or no temporal relationship to the study device and/or a more likely or certain alternative etiology exists.

10.4.3 SAE/UNANTICIPATED ADVERSE DEVICE EFFECT (UADE)/UNANTICIPATED SERIOUS ADVERSE DEVICE EFFECT (USADE) REPORTING

The site should report any event to the Sponsor and its representative in an expedited manner if it meets the criteria for an SAE and/or is an IOL explant from a study eye. Expedited reporting is calling or e-mailing the Sponsor and its representative within 48 hours of becoming aware of the event. Contact details are as follows:

Email: jha@rxsight.com
Tele: +1 949 521-7870

When reporting an SAE to the Sponsor and/or its representative, the site should forward any supporting documents along with the SAE Report Form to the Sponsor and its designee within 5 days of the initial communication. Sites must also report the SAE to the reviewing Ethics Committee per its reporting procedures.

An investigator shall submit to the Sponsor and to the reviewing IRB/EC a report of any Unanticipated Adverse Device Effect (UADE) occurring during an investigation as soon as possible, but in no event later than 10 working days after the investigator first learns of the effect or in accordance with National Regulations. As soon as notification of a potential UADE is received by the Sponsor, an investigation will be initiated to determine if the event is a UADE. If the event is confirmed to be a UADE, the regulatory authorities, all other participating Investigators and each reviewing IRB/EC must be notified within 10 working days of the initial report from the site, as applicable or in accordance with National Regulations. If it is determined that the UADE represents an unreasonable risk to study subjects, the study must be terminated within 5 working days following the decision, and no later than 15 working days after first learning of the UADE or in accordance with National Regulations.

10.4.4 DEVICE DEFICIENCY (DD) REPORTING

All device deficiencies (DDs) should be reported to the Sponsor without unjustified delay. The Investigator is responsible for notifying the regulatory authorities and IRB/EC of DDs that could have led to a Serious Adverse Device Effect (SADE), if required by the national regulations or by the IRB/EC per each body's reporting procedures. In the case of DDs that could have led to a SADE, the Sponsor will determine whether the risk analysis needs to be updated and assess whether corrective or preventative action is required.

10.5 PREGNANCY

During the study, all female subjects of childbearing potential should be instructed to contact the investigator immediately if they suspect they might be pregnant (e.g., missed or late menstrual period). Female subjects who become pregnant during the study will be followed until completion of pregnancy. Every effort will be made to obtain the health status of the mother and infant or fetus (in cases of miscarriage or therapeutic abortion) at term. Pregnancy itself is not considered an AE.

All confirmed pregnancies must be immediately reported to the Sponsor within 48 hours of the investigator's awareness of the pregnancy.

10.6 POTENTIAL ADVERSE EVENTS

The following have been identified as potential adverse events for all cataract surgeries including the LAL. Please notify the Sponsor regarding any events that may be occurring more frequently than your customary rates, or more frequently than expected at your site.

Infection, inflammation, hypopyon, endophthalmitis, infectious keratitis, hyphema, retinal detachment or other retinal problems including cystoid macular edema and epiretinal membranes, toxic anterior segment syndrome, glaucoma, corneal endothelial damage, vitritis, corneal edema which may require correction with a corneal transplant, lens dislocation out of the posterior chamber, pupillary block, striation on the lens with or without visual sequelae, iritis, synechiae, ptosis, wound leak, flat anterior chamber, increased astigmatism, rupture of the capsule, iris prolapse, vitreous in the anterior chamber, and retained pieces of the lens in the eye. These adverse events may result in total loss of vision or the loss of an eye. Secondary surgery may be required after the cataract surgery to treat surgical complications. Additionally, a posterior capsulotomy may be required to treat posterior capsular haze after the cataract surgery. Visual problems after cataract surgery may include halos, glare, ghost images, and/or double vision. These and other complications may result in permanent poor vision.

Additional specific risks of the LAL include:

The LAL must be implanted following specific surgical procedures. If these procedures are not followed by the surgeon, the lens may become scratched or improperly placed in the eye and may need to be explanted prior to light treatments. In order to perform the lens adjustment or the lens lock-in procedures, the subject's pupil needs to be adequately dilated. If this cannot be accomplished for any reason, additional eye drops, injections into the eye, or surgery may need to be utilized to adequately dilate the pupil. If the pupil cannot be adequately dilated after these types of treatments, the LAL may need to be explanted. An unpredicted change in vision can occur resulting from ocular exposure to daylight or any other UV source before the LAL is locked-in. The light treatments may not improve vision and/or manifest refraction, and the adjustment/lock-in procedure may make vision worse, such that it may be necessary to remove and replace the LAL. Vision loss may be permanent and may not be improved by replacing the LAL. There is a potential risk for UV-induced damage to the eye, including the cornea and retina, which may be permanent. UV light can sometimes cause a reactivation of previous herpes virus infection in the eye. A reactivation of herpes virus can cause scarring of the cornea, blurred vision, eye pain, extreme light sensitivity, permanent loss of vision, and possible need for corneal transplant. Temporary or persistent erythropsia and/or temporary or persistent color vision deficiency may occur. Corneal dryness and corneal abrasions from the lens used for adjustment and lock-in can occur. After the lens adjustment(s) or after the lens lock-in procedures, discomfort, itching and light sensitivity may occur. In cases where a spherocylinder adjustment is performed, it

is possible that visual disturbances may occur if the IOL rotates or if the correction is not performed on the correct axis of astigmatism.

10.7 POTENTIAL BENEFITS

The subject's benefit from taking part in this study is the correction of the loss of vision from the natural cataract lens potentially without the need of glasses, contact lenses, or secondary surgical procedures for optimal distance or optimal distance, intermediate, and near vision.

11 STUDY MONITORING

RxSight clinical personnel or designated CRO will monitor all clinical studies in a manner consistent with any applicable health authority regulations and the clinical research standards adopted by RxSight. Study monitoring will involve the following elements:

- Member(s) of RxSight's Clinical Affairs Department or designated CRO may meet with investigators prior to the initiation of the study in order to review the adequacy of the subject population, facilities, and equipment with respect to the needs of the study, and to familiarize the investigator with the study protocol. This evaluation may be performed remotely.
- A member of RxSight's Clinical Affairs Department or designated CRO may meet with the investigator(s) at the time study subjects begin to be enrolled in order to ensure that subjects are being properly selected and that study data are being correctly recorded. These meetings and assessments may be performed remotely.
- A member of RxSight or designated CRO may visit the clinical site at any time during the study to review study CRFs and/or data entered in the EDC system. Remote review of study worksheets, case histories and other data (including data with PHI) may be reviewed remotely.
- Interim monitoring visits and telephone consultations will occur as necessary during the course of the study to ensure the proper progress and documentation of the study findings. Interim monitoring visits may be performed remotely; this includes remote review of study worksheets, case histories and other data which may contain PHI.
- RxSight clinical personnel may visit the site at any time during the course of the study to observe implantation of the LAL and the adjustment and lock-in treatments to ensure that the procedures described in the protocol are being followed. Visits by RxSight clinical personnel may occur via video conferencing.
- RxSight clinical personnel may also observe examination techniques used by study personnel to ensure that the procedures being utilized are the procedures described in Appendix 1 of the protocol. RxSight clinical personnel may also observe examination techniques via video conferencing.

12 ETHICAL AND REGULATORY CONSIDERATIONS

12.1 SUBJECT INFORMATION AND CONSENT

It is the responsibility of the Principal Investigator or authorized designee to give each subject prior to inclusion in the study full and adequate verbal and written information regarding the objective and procedures of the study and the possible risks involved. The subjects will be informed about their right to refuse to participate in the study. The written consent form will be given to each subject before enrollment. It is the responsibility of the Principal Investigator to obtain a signed informed consent form and to ensure the subject is given a copy.

The Principal Investigator or authorized designee needs to file the informed consent forms for review by RxSight study monitors. The Investigator or authorized designee will acknowledge the receipt of the informed consent form from each subject by signing the appropriate pages of these documents.

12.2 DECLARATION OF HELSINKI

The study will be performed in accordance with the relevant recommendations guiding physicians in biomedical research involving human subjects adopted by the 18th World Medical Assembly, Helsinki, Finland, 1964 and later revisions, as well as applicable U.S. Food and Drug Administration regulations (21 CFR Parts 50, 56, and 812).

It is the responsibility of the Principal Investigator to obtain Institutional Review Board approval of the Study Protocol and to keep the IRB informed of serious side effects or adverse events and any amendments to the protocol.

12.3 ISO 14155:2011 CLINICAL INVESTIGATION OF MEDICAL DEVICES FOR HUMAN SUBJECTS- GOOD CLINICAL PRACTICE

This study will be performed in compliance with ISO 14155:2011.

12.4 ADDITIONAL REGULATORY CONSIDERATIONS

The proposed study is subject to all applicable governmental rules and regulations concerning the conduct of clinical trials on human subjects. This includes, but is not necessarily limited to, the approval of an Ethics Committee; obtaining prospective informed consent; monitoring of the conduct of the study, the completeness of the study CRFs, and/or accuracy of data entered into the EDC system, as may be employed, by the Sponsor or its designee(s); and record retention by the Sponsor in accordance with Good Clinical Practice.

12.5 STUDY INITATION/CONDUCT

The study will not commence until approval is obtained from the Ethics Committee. Any additional requirements imposed by the Ethics Committee shall be followed.

12.6 COMPLIANCE WITH THE CLINCIAL STUDY PROTOCOL

The Investigator shall conduct this clinical investigation in accordance with the signed agreement with the Sponsor, the investigational plan, and the applicable regulations. The Investigator shall avoid improper influence on or inducement of the subject, Sponsor, Monitor, other Investigator(s) or other parties participating in or contributing to the clinical investigation.

12.7 PROTOCOL DEVIATIONS (PDS)

Protocol deviations should be avoided. Any deviation from the protocol will be recorded on a Case Report Form together with an explanation for the deviation. Deviations should be reported to the Sponsor, who is responsible for analyzing them and assessing their significance.

Deviations should be reviewed to determine the need to amend the protocol or to terminate the investigation.

NOTE: When relevant, Ethics Committees and Competent Authorities or the appropriate regulatory bodies will be informed of protocol deviations.

12.8 PROTOCOL AMENDMENTS

Modification of the protocol is prohibited without prior written agreement in the form of a protocol amendment. All amendments will be created by the Sponsor and must be approved by the Ethics Committee or other regulatory bodies as needed prior to implementation except when required to mitigate immediate safety risks or when the changes involve only logistical or administrative revisions. All protocol amendments must be clearly summarized to outline the changes that were made.

12.9 PUBLICATION POLICY

The final report of the study will be available to the ethics committee and the investigator as requested. The study results may be submitted for publication in peer-reviewed journals as well as presented at scientific meetings and congresses where all identifiable data will be anonymized.

12.10 INSURANCE AND INDEMNITY

The Sponsor shall ensure that acceptable insurance and indemnification is in place prior to enrollment of the first study subject.

13 REFERENCES

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2. Cummings A. The Influence of Age on Refractive Cataract Surgery. CRSTEurope. Feb 2011.
3. Gollogly H, Hodge D, St. Sauver J, Erie J. Increasing incidence of cataract surgery: Population –based study. J Cataract Refract Surg 2013; 39:1383-1389.
4. Arlt EM, Krall EM, Moussa S, Grabner G, Dexl A. Implantable inlay devices for presbyopia: the evidence to date. Clin Ophthalmol. 2015 Jan 14;9:129-137.
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8. McAlinden C, Pesudovs K, Moore JE. The Development of an Instrument to Measure Quality of Vision: The Quality of Vision (QoV) Questionnaire. Invest Ophthalmol Vis Sci. 2010;51:5537-5545.

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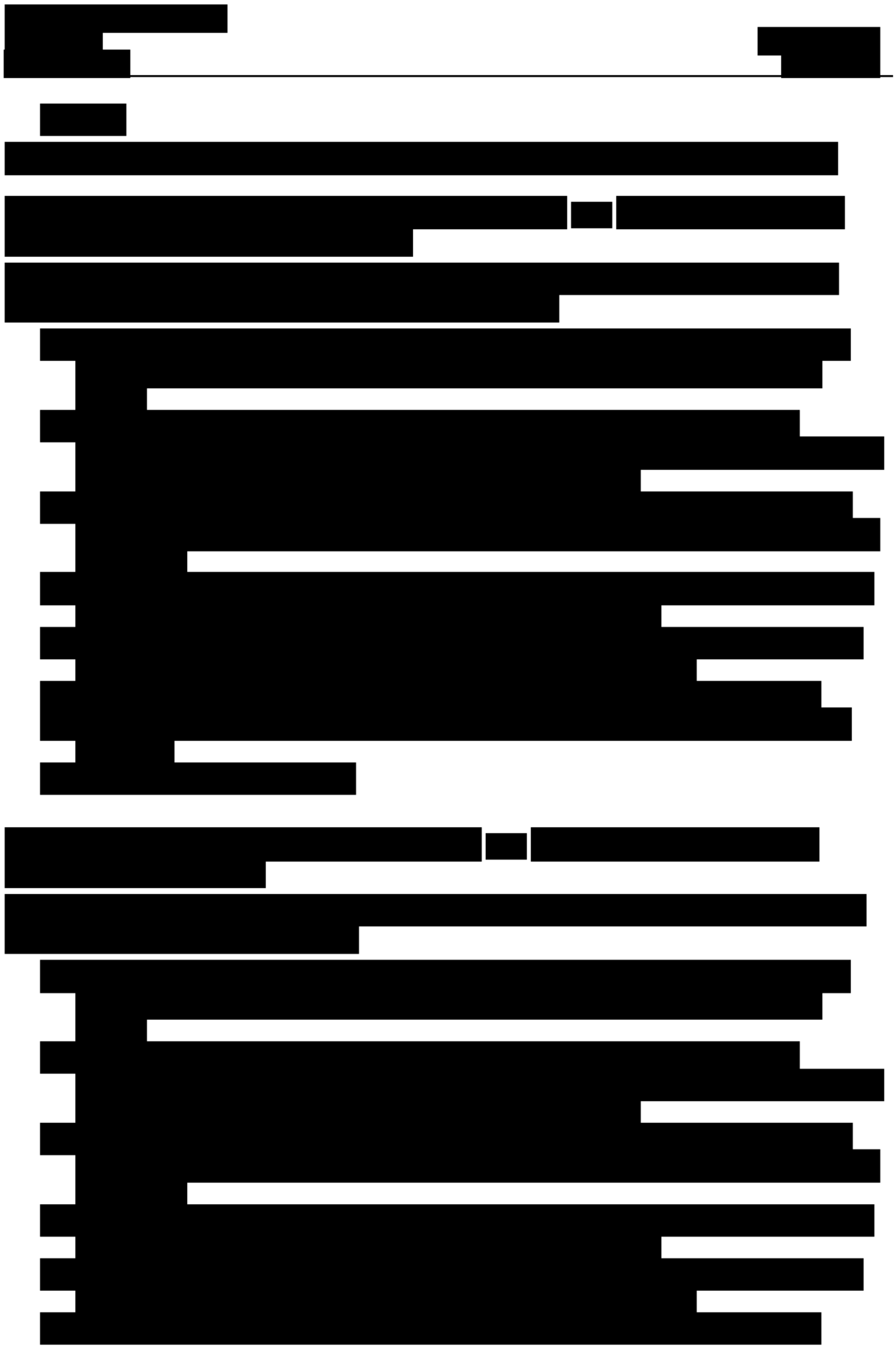

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