Statistical Analysis Plan (SAP) to the JC-02 Protocol

August 8, 2019

A Prospective, Multicenter, Randomized, Study of the Safety and Efficacy of Intravitreal Injection of Human Retinal Progenitor Cells (jCell) in Adult Subjects with Retinitis Pigmentosa (RP)

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Statistical Analysis Plan

jCyte, Inc.

Protocol JC-02

A Prospective, Multicenter, Randomized, Study of the Safety and Efficacy of Intravitreal Injection of Human Retinal Progenitor Cells (jCell) in Adult Subjects with Retinitis Pigmentosa (RP)

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Approval

Upon review of this document, including table, listing, and figure shells, the undersigned approves the Statistical Analysis Plan. The analysis methods and data presentation are acceptable.

Signature	Date
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[redacted] _____	_____

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LIST OF ABBREVIATIONS

AE	Adverse Event
ATC	Anatomical Therapeutic Chemical
BCVA	Best Corrected Visual Acuity
BP	Blood Pressure
bpm	Beats per Minute
CIL	Critical Illumination Level
cm	Centimeter(s)
CRF	Case Report Form
CS	Clinically Significant
CS	Contrast Sensitivity
CSR	Clinical Study Report
CTCAE	Common Terminology Criteria for Adverse Events
DDT	Dictionary Derived Term
DRA	Donor Reactive Antibody
EE	Efficacy Evaluable
E-ETDRS	Electronic Early Treatment for Diabetic Retinopathy Study
ERG	Electroretinogram
EZ	Ellipsoid Zone
FrACT	Freiburg Visual Acuity & Contrast Test
FST	Full Field Scopic Threshold
hRPC	Human Retinal Progenitor Cells
ICH	International Conference on Harmonization
in	Inch(es)
ITT	Intent-to-Treat
kg	kilogram(s)
LOD	Limit of Detection
LogMAR	Logarithm of minimal angle of resolution
LV-VFQ48	Low Vision Functional Questionnaire
mITT	Modified Intent-to-Treat
msec	Millisecond
MSS	Maximum Step Speed
MedDRA	Medical Dictionary for Regulatory Activities

mg	Milligram(s)
mmHg	Millimeter of Mercury
NCS	Not Clinically Significant
OCT	Optical Coherence Tomography
OD	Oculus Dextrus (right eye)
OS	Oculus Sinister (left eye)
PRA	Panel Reactive Antibody
PT	Preferred Term
RP	Retinitis Pigmentosa
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SD	Standard Deviation
SOC	System Organ Class
TEAE	Treatment-Emergent Adverse Event
TLs	Tables and Listings
VFQ-48	Visual Function Questionnaire
WHO	World Health Organization

DEFINITIONS

Adverse Event	An adverse event (AE) is any reaction, side effect, or other untoward event, regardless of relationship to study drug, which occurs anytime during the study.
Intent-to-Treat Population (ITT)	All randomized subjects who provide any post-randomization data.
Modified Intent-to-Treat Population (mITT)	All randomized subjects who provide any post-randomization data, excluding subjects with missing baseline values or who are unable to perform the relevant assessment at baseline. mITT populations will be defined for each secondary endpoint using this criteria.
Efficacy Evaluable Population (EE)	All randomized subjects who provide any post-randomization data, excluding subjects with missing baseline values. The LOD will be used as the baseline value for subjects who are unable to perform the relevant assessment at baseline. Subjects for whom baseline is completely missing will be considered nonevaluable for the relevant endpoint.
Safety Population	All subjects who received any amount of study drug.
Serious AE	An AE occurring at any dose that: results in death; is a life-threatening experience; requires inpatient hospitalization or prolongation of an existing hospitalization; results in a persistent or significant disability/incapacity; or is a congenital anomaly/birth defect in the offspring of a subject who received study drug.
Treatment-emergent AE	AEs that occur after the study treatment (injection or sham injection)

1. INTRODUCTION

This document outlines the statistical methods to be implemented during the analyses of data collected within the scope of jCyte Protocol JC-02 [A Prospective, Multicenter, and Randomized, study of Safety and Efficacy of Intravitreal injection of Human Retinal Progenitor Cells (jCell) in Adult Subjects with Retinitis Pigmentosa (RP)]. The purpose of this plan is to provide specific guidelines from which the statistical analyses will proceed. Any deviations from this plan will be documented in the clinical study report (CSR).

1.1 Changes from Protocol

Per the protocol section 10.2.2, subjects who cannot perform a specific visual test at baseline (e.g. mobility) will be considered nonevaluable for analysis of that assessment. In this SAP, patients who can't perform a visual test are included using the value determined to be the Limit of Detection (LOD).

2. STUDY OBJECTIVES

2.1 Primary Objective

The primary objective is to assess the changes in visual function as measured by BCVA at 12 months following a single injection of jCell at one of two dose levels (Test) compared to sham-treated controls in a cohort of adult subjects with RP with baseline best corrected visual acuity (BCVA) in the study eye equal to or worse than 20/80 and no worse than 20/800.

2.2 Secondary Objective

The secondary objectives of the study are

- To assess the impact of jCell injection at two dose levels based on visual function (VF, CS) and functional vision (mobility, VA LV VFQ-48).
- To evaluate the safety and tolerability of jCell injection in subjects with RP.

3. STUDY DESIGN AND PLAN

This is a prospective, multicenter, randomized, single-masked, three-arm, Phase 2b trial of human retinal progenitor cells (jcell) for the treatment of retinitis pigmentosa (RP). Study subjects will be screened for eligibility and informed consent will be obtained

Randomization and Masking:

Up to 85 subjects will be randomized 1:1:1 to one of two Test (jCell treatment) arms (3 x 10^6 jCell dose or 6 x 10^6 jCell dose) or to the Control (sham-treated) study group. Study subjects will be masked with respect to which treatment they are receiving, although study investigators and those involved in certain aspects of treatment and assessment (where injected cells are visualized) cannot feasibly be masked. However, site staff that perform key assessments (primary and secondary efficacy endpoints) will be masked to the treatment assignment. Assessors will be told which eye is the study eye for each subject but will not know whether that subject is assigned to a Test or Control group. Once the subject has completed 12 months of follow up, that subject may request to have his/her treatment revealed. If the subject was assigned to the control group, the subject will be offered the opportunity to cross over to the test group, and will be randomized to one of the two dose levels. Although all cross over subjects will receive Test treatment, the same masking procedures will be in place during the crossover portion so as to mask the dose level to which the subject was assigned.

Study Population:

The phase 2b study design is focused on subjects with visual acuity of 20/80 or worse in the study eye, without macular edema, and whose quality of life is already negatively impacted by the disease to a large degree. The cut-off of 20/80 for the study eye was selected to provide a sufficient "margin" for observation of potential benefit, as measured in terms of gains in BCVA.

Subjects randomized to one of the Test groups will receive a single intravitreal injection of either 3 x 10^6 jCell dose or 6 x 10^6 jCell into the study eye. Subjects randomized to Control group will not receive treatment, but will undergo a similar procedure that is a sham injection in the study eye. Subjects in both cohorts will be followed for one year for safety and evidence of jCell effects.

4. DETERMINATION OF SAMPLE SIZE

The sample size of 25 subjects per treatment arm is needed to achieve the targeted level of statistical power; the trial could enroll up to 85 subjects if needed to address irregularities in trial conduct or potential drop-outs. Assume the standard deviation for the 12-month change in BCVA is 5 letters. Then, for each pairwise comparison with the control group, a randomized trial with 25 patients per arm will have 90% power to detect a true treatment effect of a mean of 5 letters, when using a t-test having (one-sided) 0.0125 false positive error rate.

5. GENERAL ANALYSIS CONSIDERATIONS

The statistical analyses will be reported using summary tables and listings (TLs). The International Conference on Harmonization (ICH E3) numbering convention will be used for all TLs. unless otherwise noted, all statistical testing will be 2-sided and will be performed at the 0.05 significance level. Tests will be declared statistically significant if the calculated *P* value is ≤0.05. Continuous variables will be summarized with means, standard deviations, medians, minimums, and maximums. Categorical variables will be summarized by counts and by percentage of subjects in corresponding categories. Percentages for missing values are omitted and do not account for the percent calculation of other categories. Percentages are routinely based on the total category count excluding the missing category if not otherwise mentioned. Percentages showing a rate relative to the total number of subjects in this group are given in special tables (e.g. AE tables). Footnotes will specify the percent basis. All summary tables will be presented by dose level (3×10^6 jCell dose, 6×10^6 jCell and sham). Unless otherwise noted, the baseline value will be the last non-missing value recorded prior to the first dose of study drug.

Individual subject data obtained from the case report forms (CRFs) and derived data will be presented by subject in data listings.

The analyses described in this plan are considered *a priori*, in that they have been defined prior to database lock. Post-hoc analyses will be labeled as such on the output and identified in the CSR.

All analyses and tabulations will be performed using SAS® Version 9.4 or higher. Tables, listings, and figures will be presented in RTF format. Upon completion, all SAS® programs will be validated by an independent programmer. In addition, all program output will undergo a senior level statistical review. The validation process will be used to confirm that statistically valid methods have been implemented and that all data manipulations and calculations are accurate. Checks will be made to ensure accuracy, consistency with this plan, consistency within tables, and consistency between tables and corresponding data listings. Upon completion of validation and quality review procedures, all documentation will be collected and filed by the project statistician or designee.

6. ANALYSIS POPULATIONS

The following subject population will be used for safety analyses:

Safety population will include all subjects who receive any study treatment (including sham).

The following subject population will be used for efficacy analyses:

- Intent-to-Treat (ITT) population will include all subjects enrolled and randomized in the study and who provide any post-randomization data. Subjects for whom randomization assignment is noted in the clinical database will be considered to be enrolled in the study.
- Modified Intent-to-Treat (MITT) population will be defined as all randomized subjects who provide any post-randomization data, excluding subjects with missing baseline or who are below the LOD at baseline. mITT populations will be defined for each secondary endpoint using this criteria
- An Efficacy Evaluable (EE) population will be defined for each secondary endpoint where all randomized subjects who provide any post-randomization data, including subjects who are below the LOD at baseline (e.g. unable to perform the assessment). The LOD will be used as the baseline value for subjects unable to perform the assessment. Subjects for whom baseline is completely missing will be considered nonevaluable for the relevant endpoint...

7. STUDY POPULATION

7.1 Subject Disposition

Subject disposition information will be summarized for all subjects by dose level (3×10^6 jCell dose, 6×10^6 jCell dose and Sham). Summaries will include: the number of enrolled subjects, the number of subjects in each analysis population, and the primary reason for discontinuation.

7.2 Protocol Deviations

Major protocol deviations that could potentially affect the efficacy or safety conclusions of the study will be identified prior to database lock. Major protocol deviations may include, but are not limited to:

- Subjects who did not satisfy selected inclusion and exclusion criteria;
- Subjects who received the incorrect dose;
- Subjects who received an excluded concomitant treatment.

All protocol deviations will be presented in a listing by dose level and deviation category,

7.3 Demographic and Baseline Characteristics

Demographic variables include: age, sex, ethnicity and race. Age will be calculated in years relative to the informed consent date. Other baseline characteristics include: medical history, ocular medical history, height, weight, and study eye (OD [right] or OS [left]).

Descriptive statistics will be presented for age, height, and weight. Frequency counts and percentages will be presented for sex, ethnicity, race, study eye, ocular medical history. Demographic and baseline characteristics will be summarized for the Safety and ITT populations. If Safety and ITT populations are identical, the two tables will be combined into a single summary.

Ocular medical history (OMH) or Medical history condition or event will be mapped to primary System Organ Class and dictionary-derived term by using MedDRA 20.0.

Medical history and Ocular medical history will be presented in a listing.

7.4 Prior and Concomitant Medications

Prior and concomitant medication verbatim terms on case report forms (CRFs) will be mapped to Anatomical/Therapeutic/Chemical (ATC) class and Preferred Names using the World Health Organization (WHO) Drug Dictionary Enhanced (version March 1, 2017)..

Prior and concomitant medications will be presented in a listing.

8. EFFICACY ANALYSES

The primary efficacy analysis will be based on the ITT population.

8.1 Efficacy Variables

The response to jCell injection will be assessed based on the following:

- Best Corrected Visual Acuity (BCVA): BCVA will be measured with the electronic visual acuity testing algorithm (E-ETDRS). For each time point assessed, the total number of letters correct using E-ETDRS will be recorded for each eye and recorded on the Best Corrected Visual Acuity (BCVA) case report form. For eyes with vision worse than the upper limits of the E-ETDRS, the

Freiburg Visual Acuity & Contrast Test (FrACT) system will be used and the resultant Snellen acuity will be recorded and later converted to relevant data (e.g, letters correct.).

- Kinetic Visual Field Total Area: information regarding area in degrees squared of individual isopters or islands of vision in each eye will be recorded. Instrument target size will also be recorded as three sizes were used (V4e, III4e, and I4e) in individuals with near normal V4e isopters. In addition, observed fixation stability on a scale of 1 to 5 is recorded related to subject ability to hold fixation on a target during the entirety of kinetic field testing. Comments regarding corrective lenses used, difficulty of testing (related to reliability) and description of areas of seeing or non-seeing that are too small for mapping will be included.

- Mobility: Testing is conducted monocular (one eye at a time). Information regarding whether a subject is Dark Adapted, Dark Adapt start time and end time, Maximum step speed, Critical illumination level, and comments will be recorded on CRF.

- Contrast Sensitivity (CS): For each eye, Thresholds CS values will be recorded for spatial frequencies from the following range: 0.25, 0.5, 1.0, 2.0, 4.0, 8.0 and 12.0 (not all frequencies will be tested for each eye; frequency of 12 was not used).

- Low Vision Visual Functional Questionnaire - (LV VA VFQ-48): Scale scores for Visual Ability, Reading, Mobility, Visual Information, and Visual Motor will be recorded on CRF. Time to complete the questionnaire and comments regarding the testing process will be recorded.

8.2 Baseline Values

For efficacy variables, baseline is defined as the value obtained at baseline visit or if subject is unable to perform a secondary endpoint, a value that is determined to be the limit of detection will be used. For BCVA, if the value is missing on baseline visit, the baseline value will be the value at the screening visit.

8.3 Handling of Dropouts or Missing Data

For certain variables that are measured by instrument, some values are not captured exactly as the true value falling below the detection limit of the instrument. Observations that are lost due to LOD represent partial information, i.e. the value is known to be below

a certain value but otherwise unknown. The LOD values will be used for these observations unless otherwise specified. For data that is not obtained at all due to lack of assessment or missed visits it is assumed that the data is close to missing at random after accounting for terms in the model. The key analysis for all variables will exclude the truly missing variable and will involve no imputation. Sensitivity analyses will involve some form of multiple imputation. No imputation is consistent with data that is missing at random. Multiple imputation uses the structure of the observed data along with a random component to generate multiple plausible datasets, which are analyzed individually, summarized, and then combined to produce a final result.

8.4 Interim Analysis and Data Monitoring

There is no planned interim analysis for the JC-02 study, however it should be noted that the study will be ongoing (cross over phase) at the time of the primary analysis, as defined in the protocol. This SAP does not include analysis involving cross over portion of the study, which will be included in an amendment. Thus the analysis of the cross over period data will be provided as an addendum to the study report.

8.5 Examination of Subgroups

There are no planned subgroup analyses for this study.

8.6 Multiple Comparison/Multiplicity

No adjustments for multiplicity will be made in this study.

8.7 Multicenter Studies

Analyses to compare differences in response by center or any treatment by center interactions are not planned.

9. METHODS OF EFFICACY ANALYSIS

Descriptive statistics will be used to tabulate and summarize study outcomes. Results of clinical testing of the non-injected eye will also be described. Changes from baseline in the treated groups will be compared to those in the control (Sham-treated) group. Continuous variables will be summarized descriptively (sample size, mean, standard deviation and error, minimum and maximum). Discrete variables will be summarized by frequency or percentage. All efficacy analyses will be based on the ITT Population. All

efficacy variables will be presented by 3.0 x 10^6 cells, 6.0 x 10^6 cells, and Sham treatments used for summary statistics.

For the endpoints with repeated post-baseline measures, the mean change from baseline in the efficacy parameters will be analyzed using a linear model accounting for repeated measures. The model will include main effects for treatment group, visit and treatment by visit interaction. The corresponding baseline parameter will be included as a covariate as well. Unless stated otherwise, the following visits will be used in the model: month 3, month 6, month 9 and month 12. An unstructured covariance model will be used. Treatment comparisons will be based on the modeled change from basline to month 3, month 6, month 9 and month 12. Primary end point for all efficacy analysis is at 12 months.

Post-baseline values that are missing will be imputed for each efficacy test using the Markov Chain Monte Carlo (MCMC) method. Ten copies of the dataset with a monotonic missing pattern will be genereated using the monotone data augmentaion method[1, 2] to impute the amount of missing data that is required to make the missing data pattern monotone before applying the multiple imputation algorithm. This method uses a non-informative Jefferys prior to derive the posterior mode from the expectation-maximization algorithm as starting values for the MCMC method. For each of the 10 monotonic missing pattern datasets, an additional 10 datasets will be imputed to replace missing values at scheduled visits for a total of 100 datasets. These datasets will be generated using a regression-based multiple imputation model.[3] For subjects with complete data up to a particular visit, a multiple regression model will be fit that includes the outcome at that visit as the dependent variable and outcomes at previous visits and treatment group as independent variables. Using these regression models, a missing value for a subject at a particular visit will be imputed as a draw from the predictive distribution given the outcomes at previous visits (some possibly imputed) and treatment group.[3]

The SAS MI procedure (ie PROC MI) using the monotone regression method will be used. The ROUND option will be used to round the imputed values to the same precision as the observed values and the minimum value for imputed will be specified as zero to avoid negative values. When an intended imputed value is less than the minimum, PROC MI will redraw another value for imputation. The linear model for repeated measures analyses will be performed separately for each of the 100 complete analysis data sets, and the results will be combined into one multiple imputation inference (estimated treatment effect and associated confidence interval and p-value)[3, 4] using PROC MIANLALYZE.

9.1 Best Corrected Visual Acuity (BCVA)

For BCVA, summary statistics of the total number of letters correct will be generated at each time point for 3 x 10^6 jCell dose, 6 x 10^6 jCell and Sham. Separate tables will be created for the Study Eye and the Non-Study Eye. In addition, change from baseline will also be summarized for each post baseline time point. For subjects who do not have a number score e.g. counting fingers (CF), hand motions (HM) or no light perception (NLP), letters missed will be considered to be 100 and letters correct will therefore be zero. The proportion of treated eyes with ≥5, ≥10 and ≥15 letter improvements at Month 3, Month 6, Month 9, Month 12 or Early Termination timepoints in both study eye and untreated eyes will be summarized. A global Chi-square test will be used for testing for any differences among treatment groups at Month 12. If the global test is significant at alpha equals 0.05, pairwise comparisions will be evaluated.

In addition, change in BCVA from baseline will be summarized for each dose level at Day 1, Day 7, Day 28, month 3, 6, 9, and 12 or Early Termination in both study eye and non-study eye for experimental J-cell groups and sham group. Each letter on EVA or ETDRS charts are equal to 0.02 logMar with starting reference for 20/20 is 0.0 LogMar, 20/200 is 1.0 logMar, and 20/1000 is 1.7 logMar. Conversion of ETDRS values to logMars are included in the following table:

Letter Score	LogMAR Value	Snellen Equivalent
5	1.6	20/800
10	1.5	20/640
15	1.4	20/500
20	1.3	20/400
25	1.2	20/320
30	1.1	20/250
35	1.0	20/200
40	0.9	20/160
45	0.8	20/125
50	0.7	20/100
55	0.6	20/80
60	0.5	20/63
65	0.4	20/50
70	0.3	20/40
75	0.2	20/32
80	0.1	20/25
85	0.0	20/20
90	−0.1	20/15
95	−0.2	20/12

LogMAR = logarithm of the minimal angle of resolution.

Mean change in number of letters correct will be compared for the study eyes between each experimental j-cell group and control group at month 3, 6, 9 and 12 using the linear model specified in Section 9. LogMar scores and number of letters correct will be presented for table summaries, for mean changes LogMar and number of letters correct will be presented.

All subjects should have a measurable baseline BCVA value for the study based on the inclusion critieria. Subjects who cannot perform a BCVA assessment post-baseline are considered to have 0 letters correct, but are close to missing at random when the visit does not occur. The primary approach to post-baseline missing values for BCVA will be to consider records where a subject could not complete the assessment with 0 but in the case that no visit or an assessment was marked as not done, the recorded values will remain missing. The secondary approach will use Multiple Imputation to impute missing values as discussed in section 8.3.

Additionally, a sensitivity analysis modeling BCVA counts with a Poisson distribution may be considered if there is concern of severe departure from Guassian behavior.

9.2 Visual Field Examination

VF will be summarized for both study and non-study eye at specified time points. From the visual field examination, each area of vision will be added together using the V4e test target. The total area per eye will be compared at baseline, 6 months and 12 months using linear model specified in section 9. In the situation where kinetic visual fields are within 25% of normal ranges (>10,000 deg2), the III4e target size will be used in order to avoid a ceiling effect in subjects with near-normal V4e perimetry.

Subjects who can't perform kinetic field testing at baseline will be considered to have the lowest minimum measurable area of 6.8 square degrees. This value was obtained by using the smallest field area of any subject in the study using the V4e target.

Fixation capability proportions for both study eye and non-study eye will be summarized for each dose level at baseline, month 6, and 12 or Early Termination for experimental J-cell group and sham group. In addition, mean change in total field area will be summarized for the study eyes from baseline to month 6 and month 12 between each experimental j-cell group and control group using the linear model specified in Section 9. The primary approach for this analysis is to include subjects in the mITT population, which excludes patients with missing baseline values or who are unable to perform the assessment at baseline. Subjects who cannot perform a kinetic field assessment post-baseline are considered to have 6.8 square degrees but are close to missing at random when the visit does not occur. The secondary approach will be similar to primary approach and will use Multiple Imputation as discussed in section 8.3 for missing post-baseline visits. For the EE population, in the event that a baseline or post-baseline assessment could not be completed (inability to complete the test), the LOD will be used. Missing post-baseline values will be imputed using Multiple Imputation (see section 8.3). Subjects with completely missing baseline values (e.g. no visit or assessment attempted) will be considered inevaluable for this analysis.

9.3 Mobility

Mobility will be summarized for both study eye and non-study eye at specified time points. Descriptive statistics will be presented for Maximum step speed (MSS) and Critical illumination level (CIL) at baseline, month 6 and month 12. CIL is represented in even factor of 2 steps in the unit lux (e.g., 2 lux, 4 lux, 8 lux). MSS is a continuous variable. CIL scores will be converted to a scale score of -1 (cannot pass at the brightest

light level) to 13 (does not slow even with room lights off) and change in score from baseline and at each post baseline visit will be calculated. Conversion of CIL lux values to scale scores are included in the following table:

CIL (Lux)	Lights off	0.12	0.25	0.5	1.0	2.0	4.0	8.0	16	32	63	125	250	500	No Pass
Scale Score	13	12	11	10	9	8	7	6	5	4	3	2	1	0	-1

Mean changes from baseline in mobility test scores (CIL and MSS) will be compared in the study eyes between each experimental j-cell group and control group from baseline to month 6 and month 12 using the linear model specified in Section 9. Converted CIL scores and actual scores will be presented in listings and for table summaries, converted scores and actual scores will be presented. For mean changes converted scores will be presented.
Subjects who cannot perform mobility testing at baseline will be considered to have a passing lux level of 1000 or an equivalent scale score of -1 for CIL and 0 for MSS. This CIL scale value is proposed based on a similar recently FDA accepted test of low luminance mobility (the MLMT) and is analogous to using 0 letters correct on BCVA on subjects who have worse acuity than the test can assess.

The primary approach for this analysis is to include subjects in the mITT population, which excludes patients with missing or who cannot perform the test at baseline. Subjects who cannot perform a mobility assessment post-baseline are considered to have a -1 score for CIL and 0 value for MSS but are considered missing at random when the visit does not occur. The secondary approach is same as primry approach,except that when there is no visit or an assessment was marked as not done post-baseline, the recorded values will be imputed using Multiple Imputation as discussed in section 8.3. For the EE population, in the event that a baseline or post-baseline assessment has been attempted but subject could not perform the test, the LOD will be used at baseline and post-baseline. Missing post-baseline values will be imputed using Multiple Imputation. Subjects with completely missing baseline values (e.g. no visit or assessment attempted) will be considered inevaluable for this analysis.

9.4 Contrast Sensitivity (CS)

Contrast sensitivity will be summarized for both study eye and non-study eye at baseline, month 6 and month 12 with descriptive statistics for spatial frequency of 0.25, 0.5, 1.0,

2.0, 4.0, 8.0, and 12.0. For any spatial frequency with more than one threshold value (or trial), the values will be averaged (mean), and the single mean value for that spatial frequency will be reported. A single value indicates exploratory testing and does not represent repeatable trials and will not be analyzed. Mean change from baseline to month 6 and month 12 in CS thresholds for up to three spatial frequencies will be compared in the study eyes between each experimental j-cell group and control group from baseline to month 6 and month 12 using the linear model specified in Section 9.
The primary approach for this analysis is to include subjects in mITT population, which excludes patients with missing baseline values or who could not perform the assessment at baseline (below LOD). Subjects who undergo CS assessments but do not have a value recorded post-baseline are assumed to be below the detection level of the instrument and therefore the lowest value detectable from other subjects will be used to replace the missing values. The contrast sensitivity value for spatial frequencies most commonly detected (0.5, 1.0, and 2.0 cycles per degree) is 1.28 indicating the subject can only see the target with the highest contrast possible. Values for subjects who do not have a visit record at all post-baseline are considered to be close to missing at random (visit missed or assessment not attempted) The secondary approach will be same as primary approach except that in the case that no visit or an assessment was marked as not done, the recorded values will be imputed using Multiple Imputations as discussed in section 8.3. For the EE population, in the event that a baseline or post-baseline assessment has been attempted but subject could not complete the test, the value will be considered to be the LOD. Missing post-baseline values will be imputed using Multiple Imputations. Subjects with completely missing baseline values (e.g. no visit or assessment attempted) will be considered inevaluable for this analysis.

9.5 Low Vision Visual Functional Questionnaire (LV-VFQ 48)

Low vision visual functional questionnaire overall scores and individual scale scores will be summarized for each subject at baseline, month 6 and month 12 with descriptive statistics (i.e., visual ability, reading, mobility, visual information, and visual motor).

The individual scale score (i.e., visual ability, reading, mobility, visual information, visual motor) mean changes from baseline to month 6 and month 12 in VA LV VFQ-48 will be summarized and compared between each experimental j-cell group and control group will be analyzed using repeated measurements specified in section 9 with a linear model for individual scale scores. For this analysis, all subjects can perform an individual score assessment, but will be considered close to missing at random when the visit does not occur. Therefore, in the case that this assessment was marked as not done at baseline, the subject will be considered inevaluable for this analysis. Where a post-

baseline value is missing, the approach will be to use Multiple Imputations as discussed in section 8.3.

10. SAFETY ANALYSES

All safety analyses will be based on the Safety population. Adverse events will be monitored by the investigator and the subject. The safety analyses of laboratory parameters will include descriptive statistics and AEs will include frequency counts and percentages. Summaries of AEs will be generated by type (AE or SAE), body system and preferred term, severity, and relationship to study product.

10.1 Study Drug Administration

Treatment compliance will be assessed via direct observation by the study investigator who is responsible for study drug administration. The cell dose and exact time of injection for test subjects will be recorded and the exact time of Sham injection for the control subjects will be recorded. Study drug administration responses will be tabulated for each treatment according to questions asked in the CRF, including whether the total dose was administered, whether there were any dose interruptions, whether there were any AEs observed, whether the subject's vital signs are comparable to pre-treatment of study drug injection, the subject's IOP measurement post treatment of study drug injection and whether the subject was prescribed topical treatment after treatment of study drug injection.

10.2 Adverse Events

All adverse event summaries will be restricted to Treatment Emergent Adverse Events (TEAE), which are defined as those AEs that occurred after dosing and those existing AEs that worsened during the study. If it cannot be determined whether the AE is treatment emergent due to a partial onset date then it will be counted as such. Verbatim terms on case report forms will be mapped to preferred terms and System Organ Classes using the Medical Dictionary for Regulatory Activities (MedDRA) (version 20.0).

Each adverse event summary will be displayed by treatment group. Summaries that are displayed by system organ class and preferred terms will be ordered by descending order of incidence of system organ class and preferred term within each system organ class. Summaries of the following types will be presented:

- Subject and event incidence of TEAEs by MedDRA system organ class and preferred term.

- Subject incidence of TEAEs by MedDRA system organ class, preferred term, and highest severity. At each level of subject summarization a subject is classified according to the highest severity if the subject reported more than one of the same event. Categories of severity will be "Mild", "Moderate", "Severe" and "Life Threatening" in this summary. The "Life Threatening" column will only be shown if at least 1 life-threatening AE is reported. If any AEs are reported with missing severity, then a footnote will be added to indicate how many AEs with missing severity were reported.
- Subject and event incidence of related TEAEs by MedDRA system organ class and preferred term. Related AEs are those reported as "Related", "Possibly Related" or relationship was not reported. At each level of subject summarization a subject is classified according to the closest relationship if the subject reported more than one event. AEs with a missing relationship will be considered related for this summary.
- Subject and event incidence of serious TEAEs by MedDRA system organ class and preferred term.

10.3 Clinical Laboratory Evaluation

Hematology and chemistry laboratory parameters will be summarized using descriptive statistics at baseline, day 28, month 3, month 6, and month 12 or early termination. Change from baseline in the laboratory parameters will also be presented, the baseline is defined as the last non-missing value recorded prior to the first dose of study drug.

Coagulation, infectious disease assessment (Hepatitis B and c, HIV lab test), PRA and DRA antibody test, and HLA typing results will be provided in a data listing.

No concerns are expected regarding the drug for laboratory results since the drug is expected to stay in the eye. As a result, no analysis using high/low flags will be carried out.

Urinalysis results will not be summarized but will be provided in data listing.

Separate listing of abnormal clinically significant lab values will be presented.

10.4 Vital Signs

Vital signs (systolic BP, diastolic BP, heart rate, respiration, temperature, and weight) will be summarized using descriptive statistics at baseline and at each post-baseline time

point. Changes from baseline will also be summarized. The baseline is defined as the last non-missing value recorded prior to the first dose of study drug.

10.5 Physical Examination

Physical examination results will be included in data listings only.

10.6 Ophthalmic AEs

10.6.1 Slit Lamp and Fundus Photography

Slit Lamp and Fundus Photography - The slit lamp exam will be summarized by eye structure. For eye structures of eyelids, eyelashes, conjunctiva, sclera, cornea, and iris, subjects will be tabulated by the categories of Normal, Abnormal NCS, and Abnormal CS at each time point, and percentages will be displayed. For anterior chamber flare, subjects will be tabulated by the flare grade and the categories of Abnormal NCS and Abnormal CS. For lens status, subjects will be tabulated as aphakic, pseudophakic, and phakic. For cataract type, subjects will be tabulated as nuclear, cortical, posterior sub capsular, and not applicable. Subjects will also be tabulated by grades of 1+, 2+, 3+ and 4+. For the fundus photography, results will be included in data listing only.

10.6.2 Intraocular Pressure (IOP)

IOP - Intraocular pressure and change in intraocular pressure will be summarized descriptively by time point.

10.6.3 B-scan

B-scan results will be tabulated by Normal and Abnormal results at each time point and overall results will be counted as good or poor. B-scan results will also be tabulated by whether injected cells were visualized.

10.6.4 Dilated Fundoscopic Examination

Dilated Fundoscopic Examination- for the vitreous exam, optic nerve exam, macula exam, and peripheral retina exam, counts and percentages of Normal, Abnormal NCS and Abnormal CS will be presented by eye and time point. When available, summaries of Severity (Mild +1, Moderate +2, Severe +3, Very Severe +4) will also be included.

10.6.5 Post Injection Clinical Vitreous Exam

Post Injection Clinical Vitreous Exam, counts and percentages will be summarized for method used (indirect ophthalmoscopy, fundus exam, slit lamp exam and other) and observations (cells, clumps, opacity, debris, strands, inflammation and other).

10.6.6 Optical Coherence Tomography (OCT)

OCT results will be summarized in a table showing the counts and percentages of subjects whose eyes (both study eye and non-study eye) show cystoid macular edema present, and of those who do, how many cases involve the foveal center; epiretinal membrane formation present, and how many have evidence of retinal traction present.

10.7.7 Autofluorescence

Fundus auto fluorescence will be summarized for both study eye and non-study eye at each time point with counts and incidence rates for each of the possible options of Normal, Abnormal NCS, and Abnormal CS.

11. REFERENCES

1. Li KH (1988) Imputation using Markov chains. J Statist Comp Simul; 30:57-79.

2. Liu C (1993) Bartlett's decomposition of the posterior distribution of the covariance for normal monotone ignorable missing data. J Mult Anal; 46:198-206.

3. Little R, Yau L (1996) Intent-to-treat analysis for longitudinal studies with drop-outs. Biometrics; 52:1324-1333.

4. Schafer, JL (1997) Analysis of Incomplete Multivariate Data, New York: Chapman and Hall.

5. http://www.rand.org/content/dam/rand/www/external/health/surveys_tools/vfq/vfq25_manual.pdf

6. Mangione, CM, Lee PP, Gutierrez, PR, et al. Development of the 25-item National Eye Institute Visual Function Questionnaire (VFQ-25). Archives of Ophthalmology, 2001. 119: 1050-1058

7. http://eva.jaeb.org/test_information/Algorithm_EETDRS.pdf

APPENDICES

Appendix A: Presentation of Data and Programming Specifications

General

- Specialized text styles, such as bold, italics, borders, shading, superscripted and subscripted text will not be used in tables and data listings unless they add significant value to the table, figure, or data listing.
- Only standard keyboard characters are to be used in tables and data listings.
- Special characters, such as non-printable control characters, printer-specific, or font-specific characters, will not be used on a table or data listing.
- Hexadecimal character representations are allowed (e.g., μ, a, ß).
- All footnotes will be left justified and at the bottom of a page. Footnotes should be used sparingly and must add value to the table or data listing.

Tables

- Formal organization of tabulations may be changed during programming if appropriate, e.g., tables for the different variables may be combined into a single table, or tables with more than one variable may be split into several tables.
- Means and medians will be presented to one more decimal place than the raw data. Standard deviations will be presented to two more decimal places than the raw data. Minimums and maximums will be reported with the same number of decimal places as the raw data.
- Percentages will be presented to the tenths place.
- For frequency counts of categorical variables, categories with zero counts will not be displayed.

Listings

- Formal organization of the listing may be changed during programming if appropriate, e.g., additional variables may be included, change in the column order, or the listing may be split into multiple parts due to space constraints, etc.
- If not otherwise specified, all data listings will be sorted by sequence/treatment, center, subject number, visit, and date/time as appropriate.
- All date values will be presented in an ISO8601 date (e.g., 2018-10-11) format.

- All observed time values will be presented using a 24-hour clock HH:MM:SS format (e.g., 01:35:45 or 11:26). Seconds will only be reported if they were measured as part of the study.

Missing or incomplete dates (i.e., AEs and concomitant medications)
The most conservative approach will be systematically considered. If the AE onset date is missing / incomplete, it is assumed to have occurred during the study treatment phase (i.e., considered a TEAE) except if the partial onset date or other data such as the stop date, indicates differently. Similarly, a medication with partial start and stop dates could be considered as both a prior and concomitant treatment.

The following algorithms will be applied to missing and incomplete start and stop dates:

Start Dates

- If the day portion of the start date is missing, then the start date will be estimated to be equal to the date of first dose of study drug, provided the start month and year are the same as the first dose of study drug and the stop date is either after the first dose of study drug or completely missing. Otherwise, the missing day portion will be estimated as '01'.
- If both the day and month portions of the start date are missing, then the start date will be estimated to be equal to the date of first dose of study drug, provided the start year is the same as the first dose of study drug and the stop date is either after the first dose of study drug or completely missing. Otherwise, the event will be assumed to start on the first day of the given year (e.g., ??-???-2013 is estimated as 01-JAN-2013).
- If the start date is completely missing and the stop date is either after the dose of study drug or completely missing, the start date will be estimated to be the day of study drug dosing. Otherwise, the start date will be estimated to be the first day of the same year as the stop date. All other non-AE and non-concomitant medication day calculations where only partial dates are available will be handled as follows: the first day of the month will be used in the calculations if the day part of a start date is missing while January 1 will be employed if both the month and day parts of a start date are missing.

Stop Dates

- If only the day of resolution is unknown, the day will be assumed to the last of the month (e.g., ??-JAN-2013 will be treated as 31-JAN-2013).

- If both the day and month of resolution are unknown, the event will be assumed to have ceased on the last day of the year (e.g., ??-???-2013 will be treated as 31-DEC-2013).
- If the stop date is completely missing or the event is continuing, the event will be assumed to be after first dose of study drug and will be imputed using the last known date on the study.

Appendix B: List of Tables, Figures, and Listings

The following TLF numbering is completed according to ICH E3 guidelines. The ICH heading number and description are in **bold**. Minor changes from this planned index do not need to be amended in the SAP.

Formal organization of tabulations may be changed during programming if appropriate, e.g., tables for the different variables may be combined into a single table, or tables with more than one variable may be split into several tables.

List of Tables

ICH Heading	Table Number	Table Description
14.1		**DEMOGRAPHIC DATA**
	14.1.1	Subject Disposition
	14.1.2	Demographic and Baseline Characteristics (Safety/ITT Population)
14.2		**EFFICACY DATA**
	14.2.1.1	Best Corrected Visual Acuity (ETDRS): Study Eye Number of Letters Correct (ITT Population)
	14.2.1.2	Best Corrected Visual Acuity (ETDRS): Non-Study Eye Number of Letters Correct (ITT Population)
	14.2.1.3	Categorical Analysis of Best Corrected Visual Acuity (ETDRS): Study Eye Number of Letters Correct (ITT Population)
	14.2.1.4	Categorical Analysis of Best Corrected Visual Acuity (ETDRS): Non-Study Eye Number of Letters Correct (ITT Population)
	14.2.1.5.1	Mean Change in Best Corrected Visual Acuity (ETDRS): Study Eye Number of Letters Correct (ITT Population)
	14.2.1.5.2	Mean Change in Best Corrected Visual Acuity (ETDRS): Study Eye Number of Letters Correct using Multiple Imputation (ITT Population)
	14.2.1.5.3	Mean Change in Best Corrected Visual Acuity (FrACT): Study Eye LogMar Scores (ITT Population)

ICH Heading	Table Number	Table Description
	14.2.1.5.4	Mean Change in Best Corrected Visual Acuity (FrACT): Study Eye LogMar Scores using Multiple Imputation (ITT Population)
	14.2.2.1	Visual Field :Study Eye (ITT Population)
	14.2.2.2	Visual Field : Non-Study Eye (ITT Population)
	14.2.2.3.1	Mean Change in Visual Field: Study Eye (mITT Population)
	14.2.2.3.2	Mean Change in Visual Field: Study Eye using Multiple Imputation (mITT Population)
	14.2.2.3.3	Mean Change in Visual Field: Study Eye (EE Population)
	14.2.3.1	Mobility : Study Eye (ITT population)
	14.2.3.2	Mobility: Non-Study Eye (ITT Population)
	14.2.3.3.1	Mean Change in Mobility: Study Eye (mITT Population)
	14.2.3.3.2	Mean Change in Mobility: Study Eye using Multiple Imputation (mITT Population)
	14.2.3.3.3	Mean Change in Mobility: Study Eye (EE Population)
	14.2.4.1	Contrast Sensitivity: Study Eye (ITT Population)
	14.2.4.2	Contrast Sensitivity: Non-Study Eye (ITT Population)
	14.2.4.3.1	Mean Change in Contrast Sensitivity: Study Eye (mITT Population)
	14.2.4.3.2	Mean Change in Contrast Sensitivity: Study Eye using Multiple Imputation (mITT Population)
	14.2.4.3.3	Mean Change in Contrast Sensitivity: Study Eye (EE Population)
	14.2.5.1.1	Mean Change in Low Vision Functional Questionnaire: Person (mITT Population)
	14.2.5.1.2	Mean Change in Low Vision Functional Questionnaire: Person using Multiple Imputation (mITT Population)
14.3		**SAFETY DATA**
	14.3.1	Study Drug Administration (Safety Population)
14.3.1		**Displays of Adverse Events**
	14.3.1.1	TEAEs by System Organ Class and Preferred Term (Safety Population)
	14.3.1.2	TEAEs by System Organ Class, Preferred Term and Maximum Severity (Safety Population)

ICH Heading	Table Number	Table Description
	14.3.1.3	Related to Study Drug TEAEs by System Organ Class and Preferred Term (Safety Population)
	14.3.1.4	Serious TEAEs by System Organ Class and Preferred Term (Safety Population)
	14.3.4.1	Hematology (Safety Population)
	14.3.4.2	Chemistry (Safety Population)
	14.3.4.3	Vital Signs (Safety Population)
	14.3.4.4.1	Slit Lamp Examination: Study Eye (Safety Population)
	14.3.4.4.2	Slit Lamp Examination: Non-Study Eye (Safety Population)
	14.3.4.5.1	Intraocular Pressure (IOP): Study Eye (Safety Population)
	14.3.4.5.2	Intraocular Pressure (IOP): Non-Study Eye (Safety Population)
	14.3.4.6.1	B-Scan Study Eye (Safety Population)
	14.3.4.6.2	B-Scan: Non-Study Eye (Safety Population)
	14.3.4.7.1	Dilated Fundoscopic Examination: Study Eye (Safety Population)
	14.3.4.7.2	Dilated Fundoscopic Examination: Non-Study Eye (Safety Population)
	14.3.4.8	Post Injection Clinical Vitreous Exam: Study Eye (Safety Population)
	14.3.4.9.1	Optical Coherence Tomography (OCT): Study Eye, Categorical Analysis (Safety Population)
	14.3.4.9.2	Optical Coherence Tomography (OCT): Non-Study Eye, Categorical Analysis (Safety Population)
	14.3.4.10.1	Autofluorescence: Study Eye (Safety Population)
	14.3.4.10.2	Autofluorescence: Non-Study Eye (Safety Population)

List of Data Listings

ICH Heading	Listing Number	Listing Description
16.2.1	16.2.1.1	Subject Disposition (All Subjects)
16.2.2	16.2.2.1	Protocol Deviations (All Subjects)
	16.2.2.2	Inclusion/Exclusion Criteria (All Subjects)
16.2.4	16.2.4.1	Demographics and Baseline Characteristics (Safety Population)
	16.2.4.2	Medical History (Safety Population)
	16.2.4.3	Ocular Medical History (Safety Population)
16.2.5	16.2.5	Study Drug Administration (Safety Population)
16.2.6	16.2.6.1	Best Corrected Visual Acuity (ETDRS and/or FrACT) (ITT Population)
	16.2.6.2	Optical Coherence Tomography (OCT) (Safety Population)
	16.2.6.3	Autofluorescence (Safety Population)
	16.2.6.4	Visual Field Examination (ITT Population)
	16.2.6.5	Mobility (ITT Population)
	16.2.6.6	Contrast Sensitivity (ITT Population)
	16.2.6.7	Low Vision Functional Questionnaire (LV-VFQ28) (ITT Population)
16.2.7	16.2.7.1	Adverse Events (Safety Population)
	16.2.7.2	Serious Adverse Events (Safety Population)
	16.2.7.3	Related Adverse Events (Safety Population)
	16.2.7.4	Post Injection Clinical Vitreous Exam (Safety Population)
16.2.8	16.2.8.1	Hematology (Safety Population)
	16.2.8.2	Chemistry (Safety Population)
	16.2.8.3	Urinalysis/Microscopic Exam (Safety Population)
	16.2.8.4	Clinically Significant Lab Values(Safety Population)
	16.2.8.5	Coagulation Function (Safety Population)
	16.2.8.6	Infectious Disease Assessments (Safety Population)
	16.2.8.7	HLA Typing (Safety Population)
	16.2.8.8	Vital Signs (Safety Population)
	16.2.8.9	Physical Examination (Safety Population)
	16.2.8.10	Prior and Concomitant Medications (Safety Population)
	16.2.8.11	Pregnancy Test (Safety Population)

ICH Heading	Listing Number	Listing Description
	16.2.8.12	PRA and DRA Antibody Test Results (Safety Population)
	16.2.8.13.1	Slit Lamp (OD) (Safety Population)
	16.2.8.13.2	Slit Lamp (OS) (Safety Population)
	16.2.8.14	Intraocular Pressure (IOP) (Safety Population)
	16.2.8.15	B-Scan (Safety Population)
	16.2.8.16	Dilated Fundoscopic Examination (Safety Population)
	16.2.8.17	Fundus Photographs (Safety Population)

Appendix C: Table Layouts

Table 14.1.1
Subject Disposition
All Enrolled Subjects

	Sham	3.0 x 10^6 hRPC	6.0 x 10^6 hRPC	Total
Subjects Enrolled	N	N	N	N
ITT Population [1]	n (%)	n (%)	n (%)	n (%)
Safety Population [2]	n (%)	n (%)	n (%)	n (%)
Primary Reason for Discontinuation				
Completed Study	n (%)	n (%)	n (%)	n (%)
Adverse Event	n (%)	n (%)	n (%)	n (%)
Lack of Efficacy	n (%)	n (%)	n (%)	n (%)
Lost to Follow Up	n (%)	n (%)	n (%)	n (%)
Non-Compliance with Study Treatment	n (%)	n (%)	n (%)	n (%)
Physician Decision	n (%)	n (%)	n (%)	n (%)
Pregnancy	n (%)	n (%)	n (%)	n (%)
Progressive Disease	n (%)	n (%)	n (%)	n (%)
Protocol Deviation	n (%)	n (%)	n (%)	n (%)
Recovery	n (%)	n (%)	n (%)	n (%)
Study Terminated by Sponsor	n (%)	n (%)	n (%)	n (%)
Withdrawn by Subject	n (%)	n (%)	n (%)	n (%)
Death	n (%)	n (%)	n (%)	n (%)
Other	n (%)	n (%)	n (%)	n (%)

[1] All randomized subjects who provide any post-randomization data.
[2] Received any amount of study treatment (including sham).
Note: Percentages based on Subjects Enrolled.
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Programmer Note: only shows primary reason for Discontinuation that has results.
Programmer Note: If any of the rows in primary reason for Discontinuation shows 0 frequencies drop that row. Same for all frequency tables.

Table 14.1.2
Demographic and Baseline Characteristics
Safety/ITT Population

	Sham (N=)	3.0 x 10^6 hRPC (N=)	6.0 x 10^6 hRPC (N=)
Age (years) [1]			
n	n	n	n
Mean (SD)	xx x (xx x)	xx x (xx x)	xx x (xx x)
Median	xx x	xx x	xx x
Min, Max	xx, xx	xx, xx	xx, xx
Sex			
Male	n (%)	n (%)	n (%)
Female	n (%)	n (%)	n (%)
Ethnicity			
Hispanic or Latino	n (%)	n (%)	n (%)
Not Hispanic or Latino	n (%)	n (%)	n (%)
Race			
American Indian or Alaska Native	n (%)	n (%)	n (%)
Asian	n (%)	n (%)	n (%)
Black or African American	n (%)	n (%)	n (%)
Native Hawaiian or Other Pacific Islander	n (%)	n (%)	n (%)
White	n (%)	n (%)	n (%)
Other	n (%)	n (%)	n (%)
Multiple Races Checked	n (%)	n (%)	n (%)

[1] Age determined by comparing date of birth to date of informed consent.
[2] Baseline is defined as the last non-missing value recorded prior to the first dose of study drug. path\t_program.sas date time

Table 14.1.2
Demographics and Baseline Characteristics
Safety/ITT Population

	Sham (N=)	3.0 x 10^6 hRPC (N=)	6.0 x 10^6 hRPC (N=)
Study Eye			
OD (Right)	n (%)	n (%)	n (%)
OS (Left)	n (%)	n (%)	n (%)
Height (cm) [2]			
n	n	n	n
Mean (SD)	xx x (xx x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
Weight (kg) [2]			
n	n	n	n
Mean (SD)	xx x (xx x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx

[1] Age determined by comparing date of birth to date of informed consent.
[2] Baseline is defined as the last non-missing value recorded prior to the first dose of study drug.
path\t_program.sas date time

Programmer note: For the subsequent tables, use Table 14.1.2 to determine which columns to include.

Table 14.2.1.1
Best Corrected Visual Acuity (ETDRS): Study Eye
Number of Letters correct
ITT Population

	Sham (N=)	3.0 x 10^6 hRPC (N=)	6.0 x 10^6 hRPC (N=)
Baseline [1]			
n	n	n	n
Mean (SD)	xx x (xx x)	xx.x (xx.x)	xx x (xx x)
Median	xx x	xx.x	xx x
Min, Max	xx, xx	xx, xx	xx, xx
Day 1			
n	n	n	n
Mean (SD)	xx x (xx x)	xx.x (xx.x)	xx x (xx x)
Median	xx x	xx.x	xx x
Min, Max	xx, xx	xx, xx	xx, xx

[1] Baseline is defined as the value obtained at the baseline visit. If the baseline value is missing, the baseline value will be the value at the screening visit.
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Programmer Note: Continue table for VisitsDay 1, Day 7, Day 28, Month 3, Month 6, Month 9, Month 12 or Early Termination
Programmer Note: Table 14.2.1.2 will contain the same information for the Non-Study Eye.
Programmer Note: Original values will be used and no thresh hold limit or imputed values used in this table.

Table 14.2.1.3
Categorical Analysis of Best Corrected Visual Acuity (ETDRS): Study Eye
Number of Letters correct
ITT Population

	Sham (N=)	3.0 x 10^6 hRPC (N=)	6.0 x 10^6 hRPC (N=)	Global Test [1]
Proportion of Subjects with Specified increase in letters correct for any Post Baseline Assessment	(n=)	(n=)	(n=)	
>=5 Letters Increase	n (%)	n (%)	n (%)	
>=10 Letters Increase	n (%)	n (%)	n (%)	
>=15 Letters Increase	n (%)	n (%)	n (%)	
Proportion of Subjects with Specified increase in letters correct at Month 3	(n=)	(n=)	(n=)	
>=5 Letters Increase	n (%)	n (%)	n (%)	
>=10 Letters Increase	n (%)	n (%)	n (%)	
>=15 Letters Increase	n (%)	n (%)	n (%)	
Proportion of Subjects with Specified increase in letters correct at Month 6	(n=)	(n=)	(n=)	
>=5 Letters Increase	n (%)	n (%)	n (%)	
>=10 Letters Increase	n (%)	n (%)	n (%)	
>=15 Letters Increase	n (%)	n (%)	n (%)	
Proportion of Subjects with Specified increase in letters correct at Month 9	(n=)	(n=)	(n=)	
>=5 Letters Increase	n (%)	n (%)	n (%)	
>=10 Letters Increase	n (%)	n (%)	n (%)	
>=15 Letters Increase	n (%)	n (%)	n (%)	
Proportion of Subjects with Specified increase in letters correct at Month *12*	(n=)	(n=)	(n=)	
>=5 Letters Increase	n (%)	n (%)	n (%)	x xxxx
P-value [2]		x.xxxx	x xxxx	
>=10 Letters Increase	n (%)	n (%)	n (%)	x xxxx
P-value [2]		x.xxxx	x xxxx	
>=15 Letters Increase	n (%)	n (%)	n (%)	x xxxx
P-value [2]		x.xxxx	x xxxx	

[1] From chi-square tests any difference in any treatment groups.
[2] Pairwise chi-square tests for differences in control and treatment groups.

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Programmer Note: Denominators used for percentage calculation to be based on number of results reported for that particular time point.
Programmer Note: Table 14.2.1.4 will contain the same information for the Non-Study Eye
Programmer Note: populate the [2] if the [1] is significant at alpha= 0.05.
Programmer Note: Original values will be used and no thresh hold limit or imputed values used in this table.

Table 14.2.1.5.1
Mean Change in Best Corrected Visual Acuity (ETDRS): Study Eye
Number of Letters correct
ITT Population

	Sham (N=)	3.0 x 10^6 hRPC (N=)	6.0 x 10^6 hRPC (N=)
Number of Letters Correct at Baseline[1]			
n	n	n	n
Mean (SD)	xx x (xx x)	xx.x (xx.x)	xx x (xx x)
Median	xx x	xx.x	xx x
Min, Max	xx, xx	xx, xx	xx, xx
Number of Letters Correct at Month 3 , continue for Month 6 and 9			
n	n	n	n
Mean (SD)	xx x (xx x)	xx.x (xx.x)	xx x (xx x)
Median	xx x	xx.x	xx x
Min, Max	xx, xx	xx, xx	xx, xx
Change from Baseline to Month 3 , continue for Month 6 and 9			
n	n	n	n
Mean (SD)	xx x (xx x)	xx.x (xx.x)	xx x (xx x)
Median	xx x	xx.x	xx x
Min, Max	xx, xx	xx, xx	xx, xx
LS Mean (SE) [2]	xx x (xx xx)	xx x (xx xx)	xx x (xx xx)
LS Mean Difference [95%CI] (SE) [2]		xx x [xx x, xx.x]	xx x [xx x, xx x]
Number of Letters Correct at Month 12			
n	n	n	n
Mean (SD)	xx x (xx x)	xx.x (xx.x)	xx x (xx x)
Median	xx x	xx.x	xx x
Min, Max	xx, xx	xx, xx	xx, xx
Change from Baseline to Month 12			
n	n	n	n
Mean (SD)	xx x (xx x)	xx.x (xx.x)	xx x (xx x)
Median	xx x	xx.x	xx x
Min, Max	xx, xx	xx, xx	xx, xx
LS Mean (SE) [2]	xx x (xx xx)	xx x (xx xx)	xx x (xx xx)
LS Mean Difference [95%CI] (SE) [2]		xx x [xx x, xx.x]	xx x [xx x, xx x]
P-value[2]		x.xxxx	x xxxx

[1] Baseline is defined as the value obtained at the baseline visit. If the baseline value is missing, the baseline value will be the value at the screening visit.
[2] Estimates of LS mean, LS mean difference (3.0 x 10^6 hRPC – Sham, 6.0 x 10^6 hRPC - Sham), and two-sided p-values are obtained from a linear model for repeated measure. The model includes with visit, treatment, visit-by-treatment interaction and baseline as covariates, and unstructured covariance matrix.
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Programmer Note: Continue table for Visits: Month 3,6,9 andMonth 12.
Programmer Note: Table 14.2.1.5.2 Mean Change in Best Corrected Visual Acuity (ETDRS): Study Eye Number of Letters Correct using Multiple Imputation (ITT Population) l
[1] Baseline is defined as the value obtained at the baseline visit. If the baseline value is missing, the baseline value will be the value at the screening visit.
[2] Estimates of LS mean, LS mean difference (3.0 x 10^6 hRPC – Sham, 6.0 x 10^6 hRPC - Sham), and two-sided p-values are obtained from a linear model for repeated measure. The model includes with visit, treatment, visit-by-treatment interaction and baseline as covariates, and unstructured covariance matrix. This model incorporates missing data using multiple imputation.

Programmer Note: Table 14.2.1.5.3 Mean Change in Best Corrected Visual Acuity (FrACT): Study Eye LogMar scores (ITT Population) l
[1] Baseline is defined as the value obtained at the baseline visit. If the baseline value is missing, the baseline value will be the value at the screening visit.
[2] Estimates of LS mean, LS mean difference (3.0 x 10^6 hRPC – Sham, 6.0 x 10^6 hRPC - Sham), and two-sided p-values are obtained from a linear model for repeated measure. The model includes with visit, treatment, visit-by-treatment interaction and baseline as covariates, and unstructured covariance matrix. This model incorporates missing data using multiple imputation

Programmer Note: Table 14.2.1.5.4 Mean Change in Best Corrected Visual Acuity (FrACT): Study Eye LogMar scores using Multiple Imputation (ITT Population) l
[1] Baseline is defined as the value obtained at the baseline visit. If the baseline value is missing, the baseline value will be the value at the screening visit.
[2] Estimates of LS mean, LS mean difference (3.0 x 10^6 hRPC – Sham, 6.0 x 10^6 hRPC - Sham), and two-sided p-values are obtained from a linear model for repeated measure. The model includes with visit, treatment, visit-by-treatment interaction and baseline as covariates, and unstructured covariance matrix. This model incorporates missing data using multiple imputation.

Table 14.2.2.1
Visual Field : Study Eye (cont.)
ITT Population

	Sham (N=)	3.0 x 10^6 hRPC (N=)	6.0 x 10^6 hRPC (N=)
Fixation Stability			
Study Eye			
Baseline [1]	(n=)	(n=)	(n=)
1=Unable to Find Fixation Target	n (%)	n (%)	n (%)
2 =Able to Maintain Fixation 25% of the Time	n (%)	n (%)	n (%)
3=Able to Maintain Fixation 50% of the Time	n (%)	n (%)	n (%)
4 =Able to Maintain Fixation 75% of the Time	n (%)	n (%)	n (%)
5=Able to Maintain Fixation 100% of the Time	n (%)	n (%)	n (%)
Continue for Month 6, and 12	(n=)	(n=)	(n=)
1=Unable to Find Fixation Target	n (%)	n (%)	n (%)
2 =Able to Maintain Fixation 25% of the Time	n (%)	n (%)	n (%)
3=Able to Maintain Fixation 50% of the Time	n (%)	n (%)	n (%)
4 =Able to Maintain Fixation 75% of the Time	n (%)	n (%)	n (%)
5=Able to Maintain Fixation 100% of the Time	n (%)	n (%)	n (%)

[1] Baseline is defined as the value obtained at the baseline visit. path\t_program.sas date time

Programmer Note: Denominators used for percentage calculation to be based on number of results reported for that particular time point...
Programmer Note: Original values will be used and no thresh hold limit or imputed values used in this table.

Table 14.2.2.1
Visual Field: Study Eye
ITT Population

	Sham (N=)	3.0 x 10^6 hRPC (N=)	6.0 x 10^6 hRPC (N=)
Total Field Area			
Study Eye			
Baseline [1]			
n			
Mean (SD)	xx x (xx x)	xx.x (xx.x)	xx x (xx x)
Median	xx x	xx.x	xx x
Min, Max	xx, xx	xx, xx	xx, xx
Total Field Area at Month 6 Continue for Month 12			
n	n	n	n
Mean (SD)	xx x (xx x)	xx.x (xx.x)	xx x (xx x)
Median	xx x	xx.x	xx x
Min, Max	xx, xx	xx, xx	xx, xx

[1] Baseline is defined as the value obtained at the baseline visit.
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Programmer Note: Field Area Total will be calculated by taking the sum of all the individual field areas (i.e., islands) for a subject with same visit, same eye, same date and time with same stimulus size.
Only the stimulus size V4e is used and recorded in all subjects.
Field area total is same as adjusted calculated Size in CRF.
Programmer Note: Table 14.2.2.2 will contain the same information for the Non-Study Eye

Programmer Note: Total Visual Field area will be calculated using for a subject with same visit, same date and time with same stimulus size then sum all the adjusted calculate size and put the value in that visit.
If a subject has different Stimulus size use the following rule.
If stimulus size sum for V4e is >10,000 then use III4e stimulus size sum for total field area in visits. If at baseline stimulus size III4e is used same has to use for all other visits.
Programmer Note: Original values will be used and no thresh hold limit or imputed values used in this table.

Table 14.2.2.3.1
Mean Change in Visual Field: Study Eye
mITT Population

	Sham (N=)	3.0 x 10^6 hRPC (N=)	6.0 x 10^6 hRPC (N=)
Total Visual Field Area at Baseline[1]			
n	n	n	n
Mean (SD)	xx x (xx x)	xx.x (xx.x)	xx x (xx x)
Median	xx x	xx.x	xx x
Min, Max	xx, xx	xx, xx	xx, xx
Total Visual Field Area at Month 6			
n	n	n	n
Mean (SD)	xx x (xx x)	xx.x (xx.x)	xx x (xx x)
Median	xx x	xx.x	xx x
Min, Max	xx, xx	xx, xx	xx, xx
Change from Baseline to Month 6			
n	n	n	n
Mean (SD)	xx x (xx x)	xx.x (xx.x)	xx x (xx x)
Median	xx x	xx.x	xx x
Min, Max	xx, xx	xx, xx	xx, xx
LS Mean (SE) [2]	xx x (xx xx)	xx x (xx xx)	xx x (xx xx)
LS Mean Difference [95%CI] (SE) [2]		xx x [xx x, xx.x]	xx x [xx x, xx x]
Total Visual Field Area at Month 12			
n	n	n	n
Mean (SD)	xx x (xx x)	xx.x (xx.x)	xx x (xx x)
Median	xx x	xx.x	xx x
Min, Max	xx, xx	xx, xx	xx, xx
Change from Baseline to at Month 12			
n	n	n	n
Mean (SD)	xx x (xx x)	xx.x (xx.x)	xx x (xx x)
Median	xx x	xx.x	xx x
Min, Max	xx, xx	xx, xx	xx, xx
LS Mean (SE) [2]	xx x (xx xx)	xx x (xx xx)	xx x (xx xx)
LS Mean Difference [95%CI] (SE) [2]		xx x [xx x, xx.x]	xx x [xx x, xx x]
P-value[2]		x.xxxx	x xxxx

[1] Baseline is defined as the value obtained at the baseline visit.

[2] Estimates of LS mean, LS mean difference (3.0 x 10^6 hRPC – Sham, 6.0 x 10^6 hRPC - Sham), and two-sided p-values are obtained from a linear model for repeated measure. The model includes with visit, treatment, visit-by-treatment interaction and baseline as covariates, and unstructured covariance matrix.
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Programmer Note: Continue table for Visits: Month 6,Month 12
Programmer Note: Total Visual Field area will be calculated using for a subject with same visit, same date and time with same stimulus size then sum all the adjusted calculate size and put the value in that visit.
If a subject has different Stimulus size use the following rule.
If stimulus size sum for V4e is >10,000 then use III4e stimulus size sum for total field area in visits. If at baseline stimulus size III4e is used same has to use for all other visits.

Programmer Note: Table 14.2.2.3.2 Mean Change in Visual Field: Study Eye using Multiple Imputation (mITT Population)
[1] Baseline is defined as the value obtained at the baseline visit.
[2] Estimates of LS mean, LS mean difference (3.0 x 10^6 hRPC – Sham, 6.0 x 10^6 hRPC - Sham), and two-sided p-values are obtained from a linear model for repeated measure. The model includes with visit, treatment, visit-by-treatment interaction and baseline as covariates, and unstructured covariance matrix. This model incorporates missing data using multiple imputation

Programmer Note: Table 14.2.2.3.3 Mean Change in Visual Field: Study Eye (EE Population)
[1] Baseline is defined as the value obtained at the baseline visit.
[2] Estimates of LS mean, LS mean difference (3.0 x 10^6 hRPC – Sham, 6.0 x 10^6 hRPC - Sham), and two-sided p-values are obtained from a linear model for repeated measure. The model includes with visit, treatment, visit-by-treatment interaction and baseline as covariates, and unstructured covariance matrix.
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Table 14.2.3.1
Mobility: Study Eye
ITT Population

	Sham (N=)	3.0 x 10^6 hRPC (N=)	6.0 x 10^6 hRPC (N=)
Maximum Step Speed			
Baseline [1]			
n	n	n	n
Mean (SD)	xx x (xx x)	xx x (xx x)	xx.x (xx.x)
Median	xx x	xx x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
Month 6			
n	n	n	n
Mean (SD)	xx x (xx x)	xx x (xx x)	xx.x (xx.x)
Median	xx x	xx x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
Month 12			
n	n	n	n
Mean (SD)	xx x (xx x)	xx x (xx x)	xx.x (xx.x)
Median	xx x	xx x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx

[1] Baseline is defined as the value obtained at the baseline visit.
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Programmer Note: Continue table for Visits: Month 6, Month 12... Also continue for Critical Illumination Level and converted Critical Illumination level (mean, SD, median, min and max). Use both original and converted scores for analysis...
Programmer Note: Denominators used for percentage calculation to be based on number of results reported for that particular time point.
Programmer Note: Table 14.2.3.2 will contain the same information for the Non-Study Eye
Programmer Note: no missing imputations or thresh hold values will be used in this table. Use original values.

Table 14.2.3.3.1
Mean Change in Mobility: Study Eye
mITT Population

	Sham (N=)	3.0 x 10^6 hRPC (N=)	6.0 x 10^6 hRPC (N=)
Maximum Step Speed at Baseline[1]			
n	n	n	n
Mean (SD)	xx x (xx x)	xx.x (xx.x)	xx x (xx x)
Median	xx x	xx.x	xx x
Min, Max	xx, xx	xx, xx	xx, xx
Maximum Step Speed at Month 6			
n	n	n	n
Mean (SD)	xx x (xx x)	xx.x (xx.x)	xx x (xx x)
Median	xx x	xx.x	xx x
Min, Max	xx, xx	xx, xx	xx, xx
Change from Baseline to Month 6			
n	n	n	n
Mean (SD)	xx x (xx x)	xx.x (xx.x)	xx x (xx x)
Median	xx x	xx.x	xx x
Min, Max	xx, xx	xx, xx	xx, xx
LS Mean (SE) [2]	xx x (xx xx)	xx x (xx xx)	xx x (xx xx)
LS Mean Difference [95%CI] (SE) [2]		xx x [xx x, xx.x]	xx x [xx x, xx x]
Maximum Step Speed at Month 12			
n	n	n	n
Mean (SD)	xx x (xx x)	xx.x (xx.x)	xx x (xx x)
Median	xx x	xx.x	xx x
Min, Max	xx, xx	xx, xx	xx, xx
Change from Baseline to at Month 12			
n	n	n	n
Mean (SD)	xx x (xx x)	xx.x (xx.x)	xx x (xx x)
Median	xx x	xx.x	xx x
Min, Max	xx, xx	xx, xx	xx, xx
LS Mean (SE) [2]	xx x (xx xx)	xx x (xx xx)	xx x (xx xx)
LS Mean Difference [95%CI] (SE) [2]		xx x [xx x, xx.x]	xx x [xx x, xx x]
P-value[2]		x.xxxx	x xxxx

[1] Baseline is defined as the value obtained at the baseline visit.

[2] Estimates of LS mean, LS mean difference (3.0 x 10^6 hRPC – Sham, 6.0 x 10^6 hRPC - Sham), and two-sided p-values are obtained from a linear model for repeated measure. The model includes with visit, treatment, visit-by-treatment interaction and baseline as covariates, and unstructured covariance matrix.

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Programmer Note: Continue table for Critical Illumination for Visits: Month 6,Month 12. Also continue for Critical Illumination Level. Converted scores need to use for analysis.

Programmer Note: Table 14.2.3.3.2 Mean Change in Mobility: Study Eye using Multiple Imputation (mITT Population)

[1] Baseline is defined as the value obtained at the baseline visit.

[2] Estimates of LS mean, LS mean difference (3.0 x 10^6 hRPC – Sham, 6.0 x 10^6 hRPC - Sham), and two-sided p-values are obtained from a linear model for repeated measure. The model includes with visit, treatment, visit-by-treatment interaction and baseline as covariates, and unstructured covariance matrix. This model incorporates missing data using multiple imputation

Programmer Note: Table 14.2.3.3.3 Mean Change in Mobility: Study Eye (EE Population)

[1] Baseline is defined as the value obtained at the baseline visit.

[2] Estimates of LS mean, LS mean difference (3.0 x 10^6 hRPC – Sham, 6.0 x 10^6 hRPC - Sham), and two-sided p-values are obtained from a linear model for repeated measure. The model includes with visit, treatment, visit-by-treatment interaction and baseline as covariates, and unstructured covariance matrix.

Table 14.3.4.1
Contrast Sensitivity: Study Eye
ITT Population

	Sham (N=)	3.0 x 10^6 hRPC (N=)	6.0 x 10^6 hRPC (N=)
0.25			
Baseline [1]			
n	n	n	n
Mean (SD)	xx x (xx x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
Month 6			
n	n	n	n
Mean (SD)	xx x (xx x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
Month 12			
n	n	n	n
Mean (SD)	xx x (xx x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx

[1] Baseline is defined as the value obtained at the baseline visit.
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Programmer Note: Continue table for Visits: Month 6, Month 12. Also continue for 0.5 (20/1200), 1.0, 2.0, 4 .0, 8.0, 12.0. Or all available visits and frequencies.
Programmer Note: take first OECS3 value and add it to all OETHRVAL and take mean of all those values. Use these means to calculate continuous variables. If only one value in OECS3 and no values in OETHRVAL, then ignore that value and do not include in calculating mean.
Programmer Note: Table 14.2.4...2 will contain the same information for the Non-Study Eye
Programmer Note: in this table use means with two are more data points. Don't use single values in mean calculation.

Table 14.2.4.3.1
Mean Change in Contrast Sensitivity: Study Eye
mITT Population

	Sham (N=)	3.0 x 10^6 hRPC (N=)	6.0 x 10^6 hRPC (N=)
0.5 Threshold CS Value at Baseline[1]			
n	n	n	n
Mean (SD)	xx x (xx x)	xx.x (xx.x)	xx x (xx x)
Median	xx x	xx.x	xx x
Min, Max	xx, xx	xx, xx	xx, xx
0.5 Threshold CS Value at Month 6			
n	n	n	n
Mean (SD)	xx x (xx x)	xx.x (xx.x)	xx x (xx x)
Median	xx x	xx.x	xx x
Min, Max	xx, xx	xx, xx	xx, xx
Change from Baseline to Month 6			
n	n	n	n
Mean (SD)	xx x (xx x)	xx.x (xx.x)	xx x (xx x)
Median	xx x	xx.x	xx x
Min, Max	xx, xx	xx, xx	xx, xx
LS Mean (SE) [2]	xx x (xx xx)	xx x (xx xx)	xx x (xx xx)
LS Mean Difference [95%CI] (SE) [2]		xx x [xx x, xx.x]	xx x [xx x, xx x]
0.5 Threshold CS Value at Month 12			
n	n	n	n
Mean (SD)	xx x (xx x)	xx.x (xx.x)	xx x (xx x)
Median	xx x	xx.x	xx x
Min, Max	xx, xx	xx, xx	xx, xx
Change from Baseline to Month 12			
n	n	n	n
Mean (SD)	xx x (xx x)	xx.x (xx.x)	xx x (xx x)
Median	xx x	xx.x	xx x
Min, Max	xx, xx	xx, xx	xx, xx
LS Mean (SE) [2]	xx x (xx xx)	xx x (xx xx)	xx x (xx xx)
LS Mean Difference [95%CI] (SE) [2]		xx x [xx x, xx.x]	xx x [xx x, xx x]
P-value[2]		x.xxxx	x xxxx

[1] Baseline is defined as the value obtained at the baseline visit.

[2] Estimates of LS mean, LS mean difference (3.0 x 10^6 hRPC – Sham, 6.0 x 10^6 hRPC - Sham), and two-sided p-values are obtained from a linear model for repeated measure. The model includes with visit, treatment, visit-by-treatment interaction and baseline as covariates, and unstructured covariance matrix.
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Programmer Note: Continue table for Visits: Month 6, Month 12. Also continue for 0.5 (20/1200), 1.0, 2.0, 4 .0, 8.0, 12.0. Or all available visits and frequencies...
Programmer Note: take first OECS3 value and add it to all OETHRVAL and take mean of all those values. Use these means to calculate continuous variables. If only one value in OECS3 and no values in OETHRVAL, then ignore that value and do not include in calculating mean.

Programmer Note: Table 14.2.4.3.2 Mean Change in Contrast Sensitivity: Study Eye using Multiple Imputation (mITT Population)
[1] Baseline is defined as the value obtained at the baseline visit.
[2] Estimates of LS mean, LS mean difference (3.0 x 10^6 hRPC – Sham, 6.0 x 10^6 hRPC - Sham), and two-sided p-values are obtained from a linear model for repeated measure. The model includes with visit, treatment, visit-by-treatment interaction and baseline as covariates, and unstructured covariance matrix. This model incorporates missing data using multiple imputation

Programmer Note: Table 14.2.4.3.3 Mean Change in Contrast Sensitivity: Study Eye (EE Population)
[1] Baseline is defined as the value obtained at the baseline visit.
[2] Estimates of LS mean, LS mean difference (3.0 x 10^6 hRPC – Sham, 6.0 x 10^6 hRPC - Sham), and two-sided p-values are obtained from a linear model for repeated measure. The model includes with visit, treatment, visit-by-treatment interaction and baseline as covariates, and unstructured covariance matrix.

Table 14.2.5.1.1
Mean Change in Low Vision Functional Questionnaire (LV VA VFQ-48): Person
mITT Population

	Sham (N=)	3.0 x 10^6 hRPC (N=)	6.0 x 10^6 hRPC (N=)
Visual Ability at Baseline[1]			
n	n	n	n
Mean (SD)	xx x (xx x)	xx.x (xx.x)	xx x (xx x)
Median	xx x	xx.x	xx x
Min, Max	xx, xx	xx, xx	xx, xx
Visual Ability at Month 6			
n	n	n	n
Mean (SD)	xx x (xx x)	xx.x (xx.x)	xx x (xx x)
Median	xx x	xx.x	xx x
Min, Max	xx, xx	xx, xx	xx, xx
Change from Baseline to Month 6			
n	n	n	n
Mean (SD)	xx x (xx x)	xx.x (xx.x)	xx x (xx x)
Median	xx x	xx.x	xx x
Min, Max	xx, xx	xx, xx	xx, xx
LS Mean (SE) [2]	xx x (xx xx)	xx x (xx xx)	xx x (xx xx)
LS Mean Difference [95%CI] (SE) [2]		xx x [xx x, xx.x]	xx x [xx x, xx x]
Visual Ability at Month 12			
n	n	n	n
Mean (SD)	xx x (xx x)	xx.x (xx.x)	xx x (xx x)
Median	xx x	xx.x	xx x
Min, Max	xx, xx	xx, xx	xx, xx
Change from Baseline to Month 12			
n	n	n	n
Mean (SD)	xx x (xx x)	xx.x (xx.x)	xx x (xx x)
Median	xx x	xx.x	xx x
Min, Max	xx, xx	xx, xx	xx, xx
LS Mean (SE) [2]	xx x (xx xx)	xx x (xx xx)	xx x (xx xx)
LS Mean Difference [95%CI] (SE) [2]		xx x [xx x, xx.x]	xx x [xx x, xx x]
P-value[2]		x.xxxx	x xxxx

[1] Baseline is defined as the value obtained at the baseline visit.

[2] Estimates of LS mean, LS mean difference (3.0 x 10^6 hRPC – Sham, 6.0 x 10^6 hRPC - Sham), and two-sided p-values are obtained from a linear model for repeated measure. The model includes with visit, treatment, visit-by-treatment interaction and baseline as covariates, and unstructured covariance matrix.
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Programmer Note: Continue table for Reading, Mobility, Visual information, Visual Motor for Visits: Month 6,Month 12.

Programmer Note: Table 14.2.5.1.2 Mean Change in Low Vision Functional Questionnaire: Study Eye using Multiple Imputation (mITT Population)
[1] Baseline is defined as the value obtained at the baseline visit.
[2] Estimates of LS mean, LS mean difference (3.0 x 10^6 hRPC – Sham, 6.0 x 10^6 hRPC - Sham), and two-sided p-values are obtained from a linear model for repeated measure. The model includes with visit, treatment, visit-by-treatment interaction and baseline as covariates, and unstructured covariance matrix. This model incorporates missing data using multiple imputation

Table 14.3.1
Study Drug Administration
Safety Population

	Sham (N=)	3.0 x 10^6 hRPC (N=)	6.0 x 10^6 hRPC (N=)
Eye Drug Injected into:			
OD (Right)	n (%)	n (%)	n (%)
OS (Left)	n (%)	n (%)	n (%)
Total Dose Administered			
Yes	n (%)	n (%)	n (%)
No	n (%)	n (%)	n (%)
Any Dose Interruptions			
Yes	n (%)	n (%)	n (%)
No	n (%)	n (%)	n (%)
Were any Adverse Events Observed?			
Yes	n (%)	n (%)	n (%)
No	n (%)	n (%)	n (%)
Subject Vital Signs Comparable to Pre Injection Levels			
Yes	n (%)	n (%)	n (%)
No	n (%)	n (%)	n (%)
Subject IOP < 30mm Post Treatment of Injection			
Yes	n (%)	n (%)	n (%)
No	n (%)	n (%)	n (%)
Subject Prescribed Topical Treatment after Study Drug			
Yes	n (%)	n (%)	n (%)
No	n (%)	n (%)	n (%)

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Table 14.3.1.1
TEAEs by System Organ Class and Preferred Term
Safety Population

System Organ Class / Preferred Term	Sham (N=)		3.0×10^6 hRPC (N=)		6.0×10^6 hRPC (N=)	
	Subjects	Events	Subjects	Events	Subjects	Events
Subjects Reporting at Least One TEAE	n (%)	xx	n (%)	xx	n (%)	xx
System Organ Class 1	n (%)	xx	n (%)	xx	n (%)	xx
Preferred Term 1	n (%)	xx	n (%)	xx	n (%)	xx
Preferred Term 2	n (%)	xx	n (%)	xx	n (%)	xx
…						
System Organ Class 2	n (%)	xx	n (%)	xx	n (%)	xx
Preferred Term 1	n (%)	xx	n (%)	xx	n (%)	xx
Preferred Term 2	n (%)	xx	n (%)	xx	n (%)	xx
…						

Note: At each level of summation (overall, system organ class, preferred term), subjects reporting more than one adverse event are counted only once.
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Programmer Note:sort table by Alphabetical SOC order, with in the SOC Alphabetical PT.

Table 14.3.1.2
TEAEs by System Organ Class, Preferred Term and Maximum Severity
Safety Population

System Organ Class / Preferred Term	Sham (N=)					3.0 x 10^6 hRPC (N=)					6.0 x 10^6 hRPC (N=)				
	Mild	Moderate	Severe	Life Threatening	Death	Mild	Moderate	Severe	Life Threatening	Death	Mild	Moderate	Severe	Life Threatening	Death
Subjects Reporting at Least One TEAE	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
System Organ Class 1	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Preferred Term 1	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Preferred Term 2	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
.															
System Organ Class 2	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Preferred Term 1	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Preferred Term 2	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)

. Note: At each level of summation (overall, system organ class, preferred term), subjects reporting more than one adverse event are counted only once using maximum severity grade.
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Programmer Note:sort table by Alphabetical SOC order, with in the SOC Alphabetical PT.

Table 14.3.1.3
Related to Study Drug TEAEs by System Organ Class and Preferred Term
Safety Population

System Organ Class / Preferred Term	Sham (N=)		3.0 x 10^6 hRPC (N=)		6.0 x 10^6 hRPC (N=)	
	Subjects	Events	Subjects	Events	Subjects	Events
Subjects Reporting at Least One Related TEAE	n (%)	xx	n (%)	xx	n (%)	xx
System Organ Class 1	n (%)	xx	n (%)	xx	n (%)	xx
Preferred Term 1	n (%)	xx	n (%)	xx	n (%)	xx
Preferred Term 2	n (%)	xx	n (%)	xx	n (%)	xx
…						
System Organ Class 2	n (%)	xx	n (%)	xx	n (%)	xx
Preferred Term 1	n (%)	xx	n (%)	xx	n (%)	xx
Preferred Term 2	n (%)	xx	n (%)	xx	n (%)	xx
…						

.Note: At each level of summation (overall, system organ class, preferred term), subjects reporting more than one adverse event are counted only once using the closest relationship to study drug.
Note: Related Iincludes all events reported as “Possibly Related”, “Related” or have missing relationship to study drug.
path\t_program.sas date time

Programmer Note: sort table by Alphabetical SOC order, with in the SOC Alphabetical PT.

Table 14.3.1.4
Serious TEAEs by System Organ Class and Preferred Term
Safety Population

System Organ Class / Preferred Term	Sham (N=)		3.0 x 10^6 hRPC (N=)		6.0 x 10^6 hRPC (N=)	
	Subjects	Events	Subjects	Events	Subjects	Events
Subjects Reporting at Least One Serious TEAE	n (%)	xx	n (%)	xx	n (%)	xx
System Organ Class 1	n (%)	xx	n (%)	xx	n (%)	xx
Preferred Term 1	n (%)	xx	n (%)	xx	n (%)	xx
Preferred Term 2	n (%)	xx	n (%)	xx	n (%)	xx
…						
System Organ Class 2	n (%)	xx	n (%)	xx	n (%)	xx
Preferred Term 1	n (%)	xx	n (%)	xx	n (%)	xx
Preferred Term 2	n (%)	xx	n (%)	xx	n (%)	xx
…						

Note: At each level of summation (overall, system organ class, preferred term), subjects reporting more than one serious adverse event are counted only once.
path\t_program.sas date time

Programmer Note: sort table by Alphabetical SOC order, with in the SOC Alphabetical PT.

Table 14.3.4.1
Hematology
Safety Population

Laboratory Parameter	Time Point	Sham (N=)	3.0 x 10^6 hRPC (N=)	6.0 x 10^6 hRPC (N=)
Hemoglobin (g/dL),	Baseline [1]			
	n	n	n	n
	Mean (SD)	xx x (xx x)	xx x (xx x)	xx x (xx x)
	Median	xx x	xx x	xx x
	Min, Max	xx, xx	xx, xx	xx, xx
	Day 28			
	N	n	n	n
	Mean (SD)	xx x (xx x)	xx x (xx x)	xx x (xx x)
	Median	xx x	xx x	xx x
	Min, Max	xx, xx	xx, xx	xx, xx
	Day 28 Change from Baseline			
	N	n	n	n
	Mean (SD)	xx x (xx x)	xx x (xx x)	xx x (xx x)
	Median	xx x	xx x	xx x
	Min, Max	xx, xx	xx, xx	xx, xx
	Month 3			
	n	n	n	n
	Mean (SD)	xx x (xx x)	xx x (xx x)	xx x (xx x)
	Median	xx x	xx x	xx x
	Min, Max	xx, xx	xx, xx	xx, xx

[1] Baseline is defined as the last non-missing value recorded prior to the first dose of study drug.
path\t_program.sas date time

Programmer Note: Continue table for Visits: Day 28, Month 3, Month 6, Month 12/Early Termination.
Programmer Note: Table will include the following hematology parameters: Hemoglobin (g/dL), Hematocrit (%), Platelet Count(x 10^9/L), Red cell Count (x 10^12/L), White cell Count(x 10^9/L), Percent Neutrophil(%)s, Percent Lymphocytes(%)s, Percent Monocyte(%),, Percent Eosinophil(%),, Percent Basophils(%), Neutrophil(x 10^9/L)*s, Lymphocytes*(x 10^9/L)*, Eosinophils*(x 10^9/L), Monocytes (x 10^9/L). *and Basophils*(x 10^9/L).

Table 14.3.4.2
Chemistry
Safety Population

Laboratory Parameter	Time Point	Sham (N=)	3.0 x 10^6 hRPC (N=)	6.0 x 10^6 hRPC (N=)
ALT (SGPT) (U/L)	Baseline [1]			
	n	n	n	n
	Mean (SD)	xx x (xx x)	xx.x (xx.x)	xx.x (xx.x)
	Median	xx x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
	Day 28			
	N	n	n	n
	Mean (SD)	xx x (xx x)	xx.x (xx.x)	xx.x (xx.x)
	Median	xx x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
	Day 28 Change from Baseline			
	N	n	n	n
	Mean (SD)	xx x (xx x)	xx.x (xx.x)	xx.x (xx.x)
	Median	xx x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
	Month 3			
	n	n	n	n
	Mean (SD)	xx x (xx x)	xx.x (xx.x)	xx.x (xx.x)
	Median	xx x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx

[1] Baseline is defined as the last non-missing value recorded prior to the first dose of study drug.
path\t_program.sas date time

Programmer Note: Continue table for Visits: Day 28, Month 3, Month 6, Month 12/Early Termination.
Programmer Note: Table will include the following chemistry parameters: ALT (SGPT) (U/L), AST (SGOT) (U/L), Alkaline Phosphatase (U/L), Bilirubin (mg/dL), Sodium (mmol/L), Potassium (mmol/L), Chloride (mmol/L), Carbon Dioxide (mmol/L), Blood Urea Nitrogen (mg/dL), Creatinine (mg/dL), Total Protein (g/dL), Albumin (g/dL), Calcium(mg/dL), Phosphate (mg/dL), Glucose (mg/dL) and HbA1c (%).

Table 14.3.4.3
Vital Signs
Safety Population

Vital Sign	Time Point	Sham (N=)	3.0 x 10^6 hRPC (N=)	6.0 x 10^6 hRPC (N=)
Systolic BP (mmHg)	Day 0 15 min Post-Injection (Baseline) [1]			
	n	n	n	n
	Mean (SD)	xx x (xx x)	xx x (xx x)	xx.x (xx.x)
	Median	xx x	xx x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
	Day 0 15 min Post-Injection			
	n	n	n	n
	Mean (SD)	xx x (xx x)	xx x (xx x)	xx.x (xx.x)
	Median	xx x	xx x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx

[1] Baseline is defined as the last non-missing value recorded prior to the first dose of study drug.
path\t_program.sas date time

Programmer Note: Table will include the following vital signs: systolic BP (mmHg), diastolic BP (mmHg), Heart Rate (bpm), Respiration (Breaths/min) and Temperature(^oC).
Programmer Note: Continue table for Visits: Day0-15min Post-Injection, Day 0- 60 min post injection, Day 1,, Day 7, Day 28,, Month 3, Month 6, Month 9, Month 12/Early Termination..

Table 14.3.4.4.1
Slit Lamp Examination: Study Eye
Safety Population

	Sham (N=)	3.0 x 10^6 hRPC (N=)	6.0 x 10^6 hRPC (N=)
Eyelids			
Baseline [1]	(n=)	(n=)	(n=)
Normal	n (%)	n (%)	n (%)
Abnormal, Not Clinically Significant	n (%)	n (%)	n (%)
Abnormal, Clinically Significant	n (%)	n (%)	n (%)
Day 1	(n=)	(n=)	(n=)
Normal	n (%)	n (%)	n (%)
Abnormal, Not Clinically Significant	n (%)	n (%)	n (%)
Abnormal, Clinically Significant	n (%)	n (%)	n (%)
Day 7	(n=)	(n=)	(n=)
Normal	n (%)	n (%)	n (%)
Abnormal, Not Clinically Significant	n (%)	n (%)	n (%)
Abnormal, Clinically Significant	n (%)	n (%)	n (%)
Day 28	(n=)	(n=)	(n=)
Normal	n (%)	n (%)	n (%)
Abnormal, Not Clinically Significant	n (%)	n (%)	n (%)
Abnormal, Clinically Significant	n (%)	n (%)	n (%)
Month 3	(n=)	(n=)	(n=)
Normal	n (%)	n (%)	n (%)
Abnormal, Not Clinically Significant	n (%)	n (%)	n (%)
Abnormal, Clinically Significant	n (%)	n (%)	n (%)

[1] Baseline is defined as the last non-missing value recorded prior to the first dose of study drug.
[2] Subject may be counted more than one row.
path\t_program.sas date time

Programmer Note: Continue table for Eyelashes, Conjunctiva, Sclera, Cornea, Anterior Chamber Flare), Iris, Lens Status, Cataract Type, Grade.
Programmer Note: Continue table for Visits: Day 1, Day 7, Day 28, Month 3, Month 6, Month 9, Month 12.
Programmer Note: Denominators used for percentage calculation to be based on number of results reported for that Particular time point...
Programmer Note: Table can be modified to align with information collected on the CRF.

Table 14.3.4.4.1
Slit Lamp Examination: Study Eye
Safety Population

	Sham (N=)	3.0 x 10^6 hRPC (N=)	6.0 x 10^6 hRPC (N=)
Lens Status			
Baseline [1]	(n=)	(n=)	(n=)
Aphakic	n (%)	n (%)	n (%)
Psedophakic	n (%)	n (%)	n (%)
Phakic	n (%)	n (%)	n (%)
Day 1	(n=)	(n=)	(n=)
Aphakic	n (%)	n (%)	n (%)
Psedophakic	n (%)	n (%)	n (%)
Phakic	n (%)	n (%)	n (%)
Cataract Type [2]			
Baseline [1]	(n=)	(n=)	(n=)
Nuclear	n (%)	n (%)	n (%)
Cortical	n (%)	n (%)	n (%)
Posterior Subcapsular	n (%)	n (%)	n (%)
Other	n (%)	n (%)	n (%)
Day 1	(n=)	(n=)	(n=)
Nuclear	n (%)	n (%)	n (%)
Cortical	n (%)	n (%)	n (%)
Posterior Subcapsular	n (%)	n (%)	n (%)
Other	n (%)	n (%)	n (%)
Grade			
Baseline [2]	(n=)	(n=)	(n=)
+1	n (%)	n (%)	n (%)
+2	n (%)	n (%)	n (%)
+3	n (%)	n (%)	n (%)
+4	n (%)	n (%)	n (%)

[1] Baseline is defined as the last non-missing value recorded prior to the first dose of study drug.
[2] Subject may be counted more than one row.
path\t_program.sas date time

Programmer Note: Continue table for Eyelashes, Conjunctiva, Sclera, Cornea, Anterior Chamber Flare), Iris, Lens Status, Cataract Type, Grade..
Programmer Note: Continue table for Visits: Day 1, Day 7, Day 28, Month 3, Month 6, Month 9, Month 12.

Programmer Note: Table 14.3.4.4.2 will contain the same information for the Non-Study Eye.
Programmer Note: Denominators used for percentage calculation to be based on number of results reported for that particular time point.
Programmer Note: Table can be modified to align with information collected on the CRF.

Table 14.3.4.5.1
Intraocular Pressure (IOP): Study Eye
Safety Population

	Sham (N=)	3.0 x 10^6 hRPC (N=)	6.0 x 10^6 hRPC (N=)
Baseline [1]			
n	n	n	n
Mean (SD)	xx.x (xx.x)	xx x (xx x)	xx x (xx x)
Median	xx.x	xx x	xx x
Min, Max	xx, xx	xx, xx	xx, xx
Day 0			
n	n	n	n
Mean (SD)	xx.x (xx.x)	xx x (xx x)	xx x (xx x)
Median	xx.x	xx x	xx x
Min, Max	xx, xx	xx, xx	xx, xx
Day 0 Change from Baseline			
n	n	n	n
Mean (SD)	xx.x (xx.x)	xx x (xx x)	xx x (xx x)
Median	xx.x	xx x	xx x
Min, Max	xx, xx	xx, xx	xx, xx
Day 1			
n	n	n	n
Mean (SD)	xx.x (xx.x)	xx x (xx x)	xx x (xx x)
Median	xx.x	xx x	xx x
Min, Max	xx, xx	xx, xx	xx, xx

[1] Baseline is defined as the last non-missing value recorded prior to the first dose of study drug.
path\t_program.sas date time

Programmer Note: Continue table for Visits: Day 1, Day 7, Day 28, Month 3, Month 6, Month 9, Month 12.
Programmer Note: Table 14.3.4.5.2 will contain the same information for the Non-Study Eye.

Table 14.3.4.6.1
B-Scan: Study Eye
Safety Population

	Sham (N=)	3.0 x 10^6 hRPC (N=)	6.0 x 10^6 hRPC (N=)
Baseline [1]	(n=)	(n=)	(n=)
Normal	n (%)	n (%)	n (%)
Abnormal, Not Clinically Significant	n (%)	n (%)	n (%)
Abnormal, Clinically Significant	n (%)	n (%)	n (%)
Good	n (%)	n (%)	n (%)
Poor	n (%)	n (%)	n (%)
Injected Cells Visualized			
Yes	n (%)	n (%)	n (%)
No	n (%)	n (%)	n (%)
Not Applicable	n (%)	n (%)	n (%)
Day 7	(n=)	(n=)	(n=)
Normal	n (%)	n (%)	n (%)
Abnormal, Not Clinically Significant	n (%)	n (%)	n (%)
Abnormal, Clinically Significant	n (%)	n (%)	n (%)
Good	n (%)	n (%)	n (%)
Poor	n (%)	n (%)	n (%)
Injected Cells Visualized			
Yes	n (%)	n (%)	n (%)
No	n (%)	n (%)	n (%)
Not Applicable	n (%)	n (%)	n (%)

[1] Baseline is defined as the last non-missing value recorded prior to the first dose of study drug.
path\t_program.sas date time

Programmer Note: Continue table for Visits: Day 7, Month 6 and Month 12.
Programmer Note: Table 14.3.4.6.2 will contain the same information for the Non-Study Eye
Programmer Note: Denominators used for percentage calculation to be based on number of results reported for that particular time point.

Table 14.3.4.7.1
Dilated Fundoscopic Examination :Study Eye
Safety Population

	Sham (N=)	3.0 x 10^6 hRPC (N=)	6.0 x 10^6 hRPC (N=)
Vitreous Examination			
Baseline [1]	(n=)	(n=)	(n=)
Mild +1	n (%)	n (%)	n (%)
Moderate +2	n (%)	n (%)	n (%)
Severe +3	n (%)	n (%)	n (%)
Very Severe +4			
Normal	n (%)	n (%)	n (%)
Abnormal, Not Clinically Significant	n (%)	n (%)	n (%)
Abnormal, Clinically Significant	n (%)	n (%)	n (%)
Day 1	(n=)	(n=)	(n=)
Mild +1	n (%)	n (%)	n (%)
Moderate +2	n (%)	n (%)	n (%)
Severe +3	n (%)	n (%)	n (%)
Very Severe +4			
Normal	n (%)	n (%)	n (%)
Abnormal, Not Clinically Significant	n (%)	n (%)	n (%)
Abnormal, Clinically Significant	n (%)	n (%)	n (%)
Day 7	(n=)	(n=)	(n=)
Mild +1	n (%)	n (%)	n (%)
Moderate +2	n (%)	n (%)	n (%)
Severe +3	n (%)	n (%)	n (%)
Very Severe +4			
Normal	n (%)	n (%)	n (%)
Abnormal, Not Clinically Significant	n (%)	n (%)	n (%)
Abnormal, Clinically Significant	n (%)	n (%)	n (%)

[1] Baseline is defined as the last non-missing value recorded prior to the first dose of study drug.
path\t_program.sas date time

Programmer Note: Continue table for Optic Nerve, Macula, and Peripheral Retina Examinations.
Programmer Note: Continue table for Visits:, Day 7, Day 28, Month 3, Month 6, Month 9, Month 12.

Programmer Note: Table 14.3.4.7.2 will contain the same information for the Non-Study Eye.
Programmer Note: Denominators used for percentage calculation to be based on number of results reported for that perticular time point.

Table 14.3.4.8
Post Injection Clinical Vitreous Exam: Study Eye
Safety Population

	Sham (N=)	3.0 x 10^6 hRPC (N=)	6.0 x 10^6 hRPC (N=)
Day0	(n=)	(n=)	(n=)
Injected eye examined			
Yes	n (%)	n (%)	n (%)
No	n (%)	n (%)	n (%)
Methods of Examination [1]			
Indirect Ophthalmoscopy	n (%)	n (%)	n (%)
Fundus Exam	n (%)	n (%)	n (%)
Slit Lamp Exam	n (%)	n (%)	n (%)
Other	n (%)	n (%)	n (%)
Change from Previous Exam			
Yes	n (%)	n (%)	n (%)
No	n (%)	n (%)	n (%)
Appearance			
Cells	n (%)	n (%)	n (%)
Clumps	n (%)	n (%)	n (%)
Opacity	n (%)	n (%)	n (%)
Debris	n (%)	n (%)	n (%)
Strands	n (%)	n (%)	n (%)
Inflammation	n (%)	n (%)	n (%)
Other	n (%)	n (%)	n (%)
Photograph taken			
Yes	n (%)	n (%)	n (%)
No	n (%)	n (%)	n (%)

[1] Subject may be counted more than one row.
path\t_program.sas date time .

Programmer Note: Continue table for Visits: Day 1, Day 7, Day 28, Month 3, Month 6, Month 9, and Month 12.
Programmer Note: Denominators used for percentage calculation to be based on number of results reported for that particular time point.

Table 14.3.4.9.1
Optical Coherence Tomography (OCT): Study Eye
Categorical Analysis
Safety Population

	Sham (N=)	3.0 x 10^6 hRPC (N=)	6.0 x 10^6 hRPC (N=)
Cystoid Macular Edema (CME) present			
Baseline [1]	n/N (%)	n/N (%)	n/N (%)
Month 6	n/N (%)	n/N (%)	n/N (%)
Month 12	n/N (%)	n/N (%)	n/N (%)
If CME Present, Involve Foveal Center			
Baseline [1]	n/N (%)	n/N (%)	n/N (%)
Month 6	n/N (%)	n/N (%)	n/N (%)
Month 12	n/N (%)	n/N (%)	n/N (%)
Epiretinal Membrane Formation Present			
Baseline [1]	n/N (%)	n/N (%)	n/N (%)
Month 6	n/N (%)	n/N (%)	n/N (%)
Month 12	n/N (%)	n/N (%)	n/N (%)
Evidence of Retinal Traction			
Baseline [1]	n/N (%)	n/N (%)	n/N (%)
Month 6	n/N (%)	n/N (%)	n/N (%)
Month 12	n/N (%)	n/N (%)	n/N (%)

[1] Baseline is defined as the last non-missing value recorded prior to the first dose of study drug.
path\t_program.sas date time

Programmer Note: Continue table for Visits: Month 6, Month 12..
Programmer Note: Table 14.3.4.9.2 will contain the same information for the Non-Study Eye
.

Table 14.3.4.10.1
Autofluorescence : Study Eye
Safety Population

	Sham (N=)	3.0 x 10^6 hRPC (N=)	6.0 x 10^6 hRPC (N=)
Baseline [1]	(n=)	(n=)	(n=)
Normal	n (%)	n (%)	n (%)
Abnormal, Not Clinically Significant	n (%)	n (%)	n (%)
Abnormal, Clinically Significant	n (%)	n (%)	n (%)
Month 6	(n=)	(n=)	(n=)
Normal	n (%)	n (%)	n (%)
Abnormal, Not Clinically Significant	n (%)	n (%)	n (%)
Abnormal, Clinically Significant	n (%)	n (%)	n (%)
Month 12	(n=)	(n=)	(n=)
Normal	n (%)	n (%)	n (%)
Abnormal, Not Clinically Significant	n (%)	n (%)	n (%)
Abnormal, Clinically Significant	n (%)	n (%)	n (%)

[1] Baseline is defined as the value obtained at the baseline visit. If the baseline value is missing, the baseline value will be the last non-missing value recorded prior to the first dose of study drug.
path\t_program.sas date time

Programmer Note: Continue table for Visits:.Month 6, Month 12.
Programmer Note: Denominators used for percentage calculation to be based on number of results reported for that perticular time point.
Programmer Note: Table 14.3.4.10.2 will contain the same information for the Non-Study Eye.

Appendix D: Listing Layouts

Listing 16.2.1.1
Subject Disposition
All Subjects

Treatment Group	Subject ID	Subject Randomized	Actual Treatment Subject Received	Study Eye	Safety Population [1]	ITT Population [2]	Information Consent Date	Study Drug Administration Date/Time	Completion or Discontinuation Date	Primary Reason for Discontinuation
Sham	xxx--xxx	Yes		OD (Right)	Yes/No	Yes/No	IS08601	ISO8601	IS08601	xxxxxxxxxxxxxxxxx
…….	……				…..	……				
3.0 x 10^6 hRPC	xxx--xxx	Yes		OS (Left)	Yes/No	Yes/No	ISO8601	ISO8601	ISO8601	xxxxxxxxxxxxxxxxx
…….	…….				…….	…….				
6.0 x 10^6 hRPC	xxx--xxx	Yes		OS (Left)	Yes/No	Yes/No	ISO8601	ISO8601	ISO8601	xxxxxxxxxxxxxxxxx

Note: Randomization Treatment displayed in Treatment Group column.
[1] Received any amount of study treatment (including sham).
[2] All randomized subjects who provide any post-randomization data.
path\l_program.sas date time

Programmer Note: Include Reasons, Death and AE # information in "Primary Reason for Discontinuation" column.

Listing 16.2.2.1
Protocol Deviations
All Subjects

Treatment Group	Subject ID	Deviation Date	Date Identified	Protocol Deviation Category	Description of Protocol Deviation	Significant Deviations	Deviation Detail
Sham	xxx--xxx	ISO8601	ISO8601	xxxxxxxxx	xxxxxxxxx	xxxxx	xxxxx
……..	……			………..	……		
3.0 x 10^6 hRPC	xxx--xxx			xxxxxxxxx	xxxxxxxxx		
……..	…….			……	……		
.6.0 x 10^6 hRPC	xxx--xxx			xxxxxxxxx	xxxxxxxxx		

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Listing 16.2.2.2
Inclusion/Exclusion Criteria
All Subjects

Treatment Group	Subject ID	All Eligibility Criteria Met?	If Not Met, Inc/Exc Criterion ID Not Met
Sham	xxx--xxx	Yes/No	Inclusion #/Exclusion#
……..	……		
3.0 x 10^6 hRPC	xxx--xxx	Yes/No	Inclusion #/Exclusion#
……..	…….		
6.0 x 10^6 hRPC	xxx--xxx	Yes/No	Inclusion #/Exclusion#

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Listing 16.2.4.1
Demographic and Baseline Characteristics
Safety Population

Treatment Group	Subject ID	Date of Birth	Age (years)	Sex	If Female, Childbearing Potential?	If YES, Method of Birth Control	If No, Why is Subjcet not of Childbearing Potential?	Ethnicity	Race	Baseline Height (cm)	Baseline Weight (Kg)
Sham	xxx--xxx	ISO8601	xx	Female	No/Yes	IUD	Surgical Sterilization	Hispanic or Latino	Asian	xxx	xxx
……..	……										
3.0 x 10^6 hRPC	xxx--xxx	ISO8601	xx	Male	No/Yes	Oral Contraception	Post Menopausal	Not Hispanic or Latino	White	xxx	xxx
……..	…….										
6.0 x 10^6 hRPC	xxx--xxx	ISO8601	xx	Female	No/Yes	Other: Specify	Other: Specify	Hispanic or Latino	Black or African American	xxx	xxx

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Programmer Note: Include Specification for Other in "Method of Birth Control" column if applicable
.

Listing 16.2.4.2
Medical History
Safety Population

Treatment Group	Subject ID	MH#	Body System	Medical History Condition/Event	Start Date	End Date/Ongoing
Sham	xxx--xxx	1	xxxxxxxx	xxxxxxxxxxxx	ISO8601	ISO8601./Ongoing
……..	……					
3.0 x 10^6 hRPC	xxx--xxx	2	xxxxxxxx	xxxxxxxxxxxxx	ISO8601	ISO8601./Ongoing
……..	…….					
6.0 x 10^6 hRPC	xxx--xxx	2	xxxxxxxx	xxxxxxxxxxxxx	ISO8601	ISO8601./Ongoing

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Programmer Note: sort by medical history number within each subject.
Programmer Note: If MH marked as Ongoing, then show "Ongoing" under End Date column.

Listing 16.2.4.3
Ocular Medical History
Safety Population

Treatment Group	Subject ID	Ocular MH #	Eye	Body System	Ocular MH Condition/Diagnosis/Surgery	Date of Diagnosis/Surgery	Date Resolved/Ongoing
Sham	xxx--xxx	1	OD	xxxxxxxxxxxxxx	xxxxxxxxxxxxxx	ISO8601	ISO8601./Ongoing
……..	……						
3.0 x 10^6 hRPC	xxx--xxx	1	OS	xxxxxxxxxxxxxx	xxxxxxxxxxxxxx	ISO8601	ISO8601./Ongoing
……..	…….						
6.0 x 10^6 hRPC	xxx--xxx	1	OS	xxxxxxxxxxxxxx	xxxxxxxxxxxxxx	ISO8601	ISO8601./Ongoing

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Programmer Note: sort by medical history number within each subject.
Programmer Note: If MH marked as ongoing end date, then show "Ongoing" under Date Resolved column...

Listing 16.2.5
Study Drug Administration
Safety Population

Treatment Group	Subject ID (Study Eye)	Visit	Date and Time of Injection	Dilation Time	Not Done: Reason	Total Dose Administered ? Reason	Dose Interruptions? Reason	AEs Observed?	Vital Signs comparable to Pre-Treatment of Study drug Injection	IOP Measurement less than 30 mm Post Treatment of Study Drug Injection	Prescribed Topical Treatment after Treatment of Study Drug Injection
Sham	Xxxxx (OS)	Day 0	ISO8601	ISO8601		Yes	Yes: Reason	No/Yes	No/Yes	No/Yes	No/Yes
3.0 x 10^6 hRPC	Xxxxx (OS)	Day 0	ISO8601			No: Reason	Yes: Reason	No/Yes	No/Yes	No/Yes	No/Yes
6.0 x 10^6 hRPC	Xxxxx (OS)	Day 0	ISO8601			Yes	Yes: Reason	No/Yes	No/Yes	No/Yes	No/Yes

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Listing 16.2.6.1
Best Corrected Visual Acuity (ETDRS and/or FrACT)
ITT Population

						OD Visual Acuity			OS Visual Acuity		
Treatment Group	Subject ID	Visit	Assessment Date	Study Day	Not Done: Reason	Measurement	BCVA Method Used	Total Numbers of Letters Correct	Measurement	BCVA Method Used	Total Numbers of Letters Correct
Sham	xxx-xxx	Screening	ISO8601	xx		Xx/xxx	E-ETDRS	xxx	Xx/xxx	E-ETDRS	xxx
		Baseline				Xx/xxx		xxx	Xx/xxx		xxx
		Day0				Xx/xxx		xxx	Xx/xxx		xxx
		Day1				Xx/xxx		xxx	Xx/xxx		xxx
		Day7				Xx/xxx		xxx	Xx/xxx		xxx
		Day28				Xx/xxx		xxx	Xx/xxx		xxx
		Month3				Xx/xxx		xxx	Xx/xxx		xxx
		Month6				Xx/xxx		xxx	Xx/xxx		xxx
		Month9				Xx/xxx		xxx	Xx/xxx		xxx
		Month12/Early Termination				Xx/xxx		xxx	Xx/xxx		xxx
3.0 x 10^6 hRPC	xxx-xxx	Screening,					FrACT			FrACT	
6.0 x 10^6 hRPC	xxx-xxx	Screening,					FrACT			FrACT	

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Listing 16.2.6.2
Optical Coherence Tomography (OCT)
Safety Population

Treatment Group	Subject ID	Visit	Assessment Date	Study Day	Not Done: Reason	Cystoid Macular Edema (CME) Present?	IF CME Present, Involve Foveal Center?	Was There Epiretinal Membrane Formation Present?	If Yes, Was There Evidence of Retinal Traction?
Sham	xxx--xxx	Baseline	ISO8601	xx		Yes/No	Yes/No	Yes/No	Yes/No
		Month 6	ISO8601	xx		Yes/No	Yes/No	Yes/No	Yes/No
		Month 12/Early Termination	ISO8601	xx		Yes/No	Yes/No	Yes/No	Yes/No
……..	……..								
3.0 x 10^6 hRPC	xxx--xxx	Baseline		xx		Yes/No	Yes/No	Yes/No	Yes/No
		Month 6		xx		Yes/No	Yes/No	Yes/No	Yes/No
		Month 12/Early Termination		xx		Yes/No	Yes/No	Yes/No	Yes/No
6.0 x 10^6 hRPC	xxx--xxx	Baseline		xx		Yes/No	Yes/No	Yes/No	Yes/No
		Month 6		xx		Yes/No	Yes/No	Yes/No	Yes/No
		Month 12/Early Termination		xx		Yes/No	Yes/No	Yes/No	Yes/No

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Listing 16.2.6.3
Autofluorescence
Safety Population

Treatment Group	Subject ID	Visit	Assessment Date	Study Day	Not Done: Reason	Right Eye (OD) Result	Left Eye (OS) Result
Sham	xxx--xxx	Baseline	ISO8601	xx		Normal	Normal
		Month 6	ISO8601	xx		Abnormal CS: Abnormality	Abnormal CS:Abnoramlity
		Month 12/Early Termination	ISO8601	xx		Abnormal NCS:	Abnormal NCS
3.0 x 10^6 hRPC	xxx--xxx	Baseline	ISO8601	xx		Normal	Normal
		Month 6	ISO8601	xx		Abnormal CS Abnormality	Abnormal CS: Abnormality
		Month 12/Early Termination	ISO8601	xx		Abnormal NCS	Abnormal NCS
6.0 x 10^6 hRPC	xxx--xxx	Baseline	ISO8601	xx		Normal	Normal
		Month 6	ISO8601	xx		Abnormal CS Abnormality	Abnormal CS: Abnormality
		Month 12/Early Termination	ISO8601	xx		Abnormal NCS	Abnormal NCS

Note: CS=Clinically Significant, NCS=Not Clinically Significant.

path\l_program.sas date time .
Programmer Note: Include Description of Abnormality and Clinically Significant information in "Result" column

Listing 16.2.6.4
Visual Field
ITT Population

							OD (Right)						OS (Left)					
Treatment Group	Subject ID	Visit	Assessment Date and Time	Study Day	End Time	Not Done: Reason	Fixation Stability	Reaction Time (ms)	Stimulus Size	Island #	Quadrant	Visual Field Area or Island	Sum	Fixation Stability	Reaction Time (ms)	Stimulus Size	Island #	Quadrant	Visual Field Area or Island	Sum
Sham	xxx--xxx	Baseline	ISO8601	xx	ISO8601		1		III4e		A	xxx.x		1		III4e		A	xxx x	
		Month 6	ISO8601	xx			2		I4e		B	xxx.x		2	No	I4e		B	xxx x	
		Month 12		xx			3		V4e		C	xxx.x		3		V4e		C	xxx x	
3.0 x 10^6 hRPC	xxx--xxx	Baseline		xx			4		Other		D	xxx.x		4		III4e		D	xxx x	
		Month 6					5		I4e		E	xxx.x		5		I4e		E	xxx x	
		Month 12					1		V4e		A	xxx.x		1	Not Applicable	V4e		A	xxx x	
6.0 x 10^6 hRPC	xxx--xxx	Baseline					4		Other		D	xxx.x		4		III4e		D	xxx x	
		Month 6					5		I4e		E	xxx.x		5		I4e		E	xxx x	
		Month 12					1		V4e		A	xxx.x		1	Not Applicable	V4e		A	xxx x	

Note: A=Central, B=Upper Right, C=Lower Right, D=Lower Left, E=Upper Left.
Note: 1=Unable to find fixation target, 2=Able to maintain fixation 25% of the time, 3=Able to maintain fixation 50% of the time, 4=Able to maintain fixation 75% of the time, 5=Able to maintain fixation 100% of the time.
path\l_program.sas date time

Programmer Note: there will be multiple islands at each timepoint.*Programmer Note: Visual Field area is same as Adjusted calculated Sized in CRF.*
Programmer Note: Sum will be calculated using for a subject with same visit, same date and time with same stimulus size then sum all the adjusted calculate size and put the value in first row of that visit.

Listing 16.2.6.5
Mobility
ITT Population

Treatment Group	Subject ID	Visit	Assessment Date	Study Day	Not Done: Reason	Dark Adapt	Dark Adaption Start Time	Dark Adaption End Time	Eye	Maximum Step Speed	Critical Illumination Level	Converted Scale Score	Was Assessment Done in more than one Eye?	Eye	Maximum Step Speed	Critical Illumination Level	Converted Scale Score
Sham	xxx--xxx	Baseline	ISO8601	xx		Yes/No	ISO8601	ISO8601	Right (OD)	xx	xx		Yes/No	Right (OD)	xx	xx	
		Month 6		xx						xx	xx				xx	xx	
		Month 12	ISO8601	xx						xx	xx				xx	xx	
3.0 x 10^6 hRPC	xxx--xxx	Baseline	ISO8601	xx					Left (OS)	xx	xx		Yes/No	Left (OS)	xx	xx	
		Month 6		xx						xx	xx				xx	xx	
		Month 12		xx						xx	xx				xx	xx	
6.0 x 10^6 hRPC	xxx--xxx	Baseline		xx					Right (OD)	xx	xx		Yes/No	Right (OD)	xx	xx	
		Month 6		xx						xx	xx				xx	xx	
		Month 12		xx						xx	xx				xx	xx	

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path\l_program.sas date time

Listing 16.2.6.6
Contrast Sensitivity (CS)
ITT Population

						OD (Right)						OS (Left)				
Treatment Group	Subject ID	Visit	Assessment Date and Time	Study Day	Not Done: Reason	End Time	Spatial Frequency	CS	Threshold CS Value Number	Threshold Value	Mean	Spatial Frequency	CS	Threshold CS Value Number	Threshold Value	Mean
Sham	xxx--xxx	Baseline	ISO8601	xx		ISO8601	1					1				
		Month 6	ISO8601	xx		ISO8601	2					2				
		Month 12	ISO8601	xx			3					3				
3.0 x 10^6 hRPC	xxx--xxx	Baseline	ISO8601	xx		ISO8601	1					1				
		Month 6	ISO8601	xx		ISO8601	2					2				
		Month 12	ISO8601	xx			3					3				
6.0 x 10^6 hRPC	xxx--xxx	Baseline	ISO8601			ISO8601	4					4				
		Month 6	ISO8601			ISO8601	5					5				
		Month 12	ISO8601			ISO8601	1					1				

Note: If no value in threshold cs value, no mean is calculated.
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Programmer Note: for Threshold values, take first OECS3 value and next rows with OETHRVAL.
Programmer Note: for mean calculations, take first OECS3 value and add it to all OETHRVAL and take mean of those all values. If only one value in OECS3 and no values in OETHRVAL, then ignore that value and do not include in calculating mean.

Listing 16.2.6.7
Low Vision Functional Questionnaire (LV VA-VFQ-48)
ITT Population

Treatment Group	Subject ID	Visit	Assessment Date and Time	Study Day	End Time	Not Done: Reason	Visual Ability	Reading	Mobility	Visual Information	Visual Motor	Comments
Sham	xxx--xxx	Baseline	ISO8601	xx	ISO8601		xxx	xxx	xxx	xxx	xxx	xxx
		Month 6	ISO8601	xx			xxx	xxx	xxx	xxx	xxx	xxx
		Month 12	ISO8601	xx			xxx	xxx	xxx	xxx	xxx	xxx
3.0 x 10^6 hRPC	xxx--xxx	Baseline	ISO8601	xx			xxx	xxx	xxx	xxx	xxx	xxx
		Month 6		xx			xxx	xxx	xxx	xxx	xxx	xxx
		Month 12		xx			xxx	xxx	xxx	xxx	xxx	xxx
6.0 x 10^6 hRPC	xxx--xxx	Baseline		xx			xxx	xxx	xxx	xxx	xxx	xxx
		Month 6		xx			xxx	xxx	xxx	xxx	xxx	xxx
		Month 12		xx			xxx	xxx	xxx	xxx	xxx	xxx

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Listing 16.2.7.1
Adverse Events
Safety Population

Treatment Group	Subject ID	AE#	Verbatim Term // System Organ Class//Preferred Term	Onset Date and Time (Study Day)	End Date (Study Day)	Serious	Severity	Relationship to Study Drug	Treatment of Event	Dose Limiting Toxicity	Outcome
Sham	xxx--xxx			ISO8601(xx)	ISO8601 (xx)	Yes	Mild	Not Related	None	Yes/No	Recovery/Resolved
				ISO8601(xx)	ISO8601(xx)	No	Moderate	Unlikely Related	Medication	Yes/No	Recovery/Resolved W/Seq
				ISO8601(xx)	ISO8601(xx)	No	Moderate	Possibly Related	Non-Drug Treatment	Yes/No	Recovering/Resolving
				ISO8601(xx)	ISO8601(xx)	No	Mild	Related	Hospitalization	Yes/No	Not Recovered
				ISO8601(xx)	ISO8601 (xx)	No	Severe	Unlikely Related		Yes/No	Fatal
				ISo8601(xx)	ISO8601(xx)	No	Mild				
……..	……..										
3.0 x 10^6 hRPC	xxx--xxx										
6.0 x 10^6 hRPC	xxx--xxx										
……..	……..										

path\l_program.sas date time

Programmer Note: sort by subject and AE # subject

Listing 16.2.7.2
Serious Adverse Events
Safety Population

Treatment Group	Subject ID	AE #	Verbatim Term // System Organ Class//Preferred Term	Onset Date and Time (Study Day)	End Date (Study Day)	Severity	Relationship to Study Drug	Treatment of Event	Dose Limiting Toxicity	Outcome
Sham	xxx--xxx			ISO8601 (xx)	ISO8601(xx)	Mild	Not Related	None	Yes/No	Recovery/Resolved
				ISO8601 (xx)	ISO8601 (xx)	Moderate	Unlikely Related	Medication	Yes/No	Recovery/Resolved W/Seq
				ISO8601 (xx)	ISO8601 (xx)	Moderate	Possibly Related	Non-Drug Treatment	Yes/No	Recovering/Resolving
				ISO8601 (xx)	ISO8601 (xx)	Mild	Related	Hospitalization	Yes/No	
				ISO8601 (xx)	ISO8601 (xx)	Severe	Unlikely Related			
				ISO8601 (xx)	ISO8601 (xx)	Mild				
……..	……..									
3.0 x 10^6 hRPC	xxx--xxx									
6.0 x 10^6 hRPC	xxx--xxx									

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Programmer Note: sort by subject and AE # subject

Listing 16.2.7.3
Related Adverse Events
Safety Population

Treatment Group	Subject ID	AE #	Verbatim Term // System Organ Class// Preferred Term	Onset Date/Time (Study Day)	End Date (Study Day)	Serious	Severity	Relationship to Study Drug	Treatment of Event	Dose Limiting Toxicity	Outcome
Sham	xxx--xxx	1	Xxxxxxxxxx//xxxxxxxx//xxxxxx	ISO8601.(xx)	ISO8601.(xx)	Yes	Mild	Related	None	Yes/No	Recovery/Resolved
		2	Xxxxxxxxxx//xxxxxxxx//xxxxxx	ISO8601.(xx)	ISO8601.(xx)	No	Moderate	Related	Medication	Yes/No	Recovery/Resolved W/Seq
		3	Xxxxxxxxxx//xxxxxxxx//xxxxxx	ISO8601.(xx)	ISO8601.(xx)	No	Moderate	Possibly Related	Non-Drug Treatment	Yes/No	Recovering/Resolving
		4	Xxxxxxxxxx//xxxxxxxx//xxxxxx	ISP8601.(xx)	ISO8601.(xx)	No	Mild	Related	Hospitalization	Yes/No	
		5	Xxxxxxxxxx//xxxxxxxx//xxxxxx	ISO8601.(xx)	ISO8601.(xx)	Yes	Severe	Related			
		6	Xxxxxxxxxx//xxxxxxxx//xxxxxx	ISO8601.(xx)	ISO8601.(xx)	No	Mild				
……..	……..	7	Xxxxxxxxxx//xxxxxxxx//xxxxxx								
		8	Xxxxxxxxxx//xxxxxxxx//xxxxxx								
3.0 x 10^6 hRPC	xxx--xxx	1	Xxxxxxxxxx//xxxxxxxx//xxxxxx								
		2	Xxxxxxxxxx//xxxxxxxx//xxxxxx								
		3	Xxxxxxxxxx//xxxxxxxx//xxxxxx								
		4	Xxxxxxxxxx//xxxxxxxx//xxxxxx								
		5	Xxxxxxxxxx//xxxxxxxx//xxxxxx								
		6	Xxxxxxxxxx//xxxxxxxx//xxxxxx								
6.0 x 10^6 hRPC											

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Programmer Note: sort by subject and AE # subject
Programmer Note: include Onset Time if available in Onset Date column.

Listing 16.2.7.4
Post Injection Clinical Vitreous Exam
Safety Population

Treatment Group	Subject ID	Visit	Examination Date	Study Day	Not Done: Reason	Method Used	Cells Visualized?	Change from Prev. Visit	Appearance	Size	Location	Photograph Taken?
Sham	xxx--xxx	Day 0	ISO8601	xx		Indirect Ophthalmoscopy	Yes/No	Yes/No	Cells	xxxxxx	xxxxxx	Yes/No
		Day 1		xx		Fundus Exam	Yes/No	Yes/No	Clumps	xxxxxx	xxxxxx	Yes/No
		Day 7		xx		Slit Lamp Exam	Yes/No	Yes/No	Opacity	xxxxxx	xxxxxx	Yes/No
		Day 28				Other:	Yes/No	Yes/No	Debris	xxxxxx	xxxxxx	Yes/No
		Month 3				Fundus Exam	Yes/No	Yes/No	Inflammation	xxxxxx	xxxxxx	Yes/No
		Month 6										
		Month 9				Other:	Yes/No	Yes/No	Clumps	xxxxxx	xxxxxx	Yes/No
		Month 12/Early Termination				Indirect Ophthalmoscopy	Yes/No	Yes/No	Opacity	xxxxxx	xxxxxx	Yes/No
3.0 x 10^6 hRPC	xxx--xxx	Day 0				Indirect Ophthalmoscopy	Yes/No	Yes/No	Cells	xxxxxx	xxxxxx	Yes/No
		Day 1				Fundus Exam	Yes/No	Yes/No	Clumps	xxxxxx	xxxxxx	Yes/No
		Day 7				Slit Lamp Exam	Yes/No	Yes/No	Opacity	xxxxxx	xxxxxx	Yes/No
		Day 28				Other:	Yes/No	Yes/No	Debris	xxxxxx	xxxxxx	Yes/No
		Month 3				Fundus Exam	Yes/No	Yes/No	Inflammation	xxxxxx	xxxxxx	Yes/No
		Month 6										
		Month 9				Other:	Yes/No	Yes/No	Clumps	xxxxxx	xxxxxx	Yes/No
		Month 12/Early Termination				Indirect Ophthalmoscopy	Yes/No	Yes/No	Opacity	xxxxxx	xxxxxx	Yes/No
6.0 x 10^6 hRPC												

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Listing 16.2.8.1
Hematology
Safety PopulationPart 1 of 2

Treatment Group	Subject ID	Visit	Collection Date and Time	Study Day	Not Done: Reason	Lab Name	Hemoglobin (g/dL)	Hematocrit (%)	Platelet Count (x 10^9/L)	Red Cell Count (x 10^12/L)	White Cell Count (x 10^9/L)
Sham	xxx--xxx	Screening	ISO8601	xx		UCI					
		Baseline	ISO8601	xx							
		Day 28		xx							
		Month 3		xx							
		Month 6		xx							
		Month 12/Early Termination		xx							
3.0 x 10^6 hRPC	xxx--xxx	Screening		xx		Lab Corp					
		Baseline		xx							
		Day 28		xx							
		Month 3		xx							
		Month 6		xx							
		Month 12/Early Termination		xx							
6.0 x 10^6 hRPC	xxx--xxx										

Listing 16.2.8.1
Hematology
Safety Population
Part 2 of 2

Treatment Group	Subject ID	Visit	Collection Date and Time	Study Day	Not Done: Reason	Lab Name	Neutrophils (%)	Lymphocytes (%)	Monocytes (%)	Eosinophils (%)	Basophils (%)	Neutrophils (x 10^9/L)	Lymphocytes (x 10^9/L)	Monocytes (x 10^9/L)	Eosinophils (x 10^9/L)	Basophils (x 10^9/L)
Sham						UCI										

Note: L=Low and H=High, CS=Clinically Significant
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Listing 16.2.8.2
Chemistry
Safety Population
Part 1 of 2

Treatment Group	Subject ID	Visit	Collection Date and Time	Study Day	Not Done: Reason	Lab Name	Bilirubin (mg/dL)	Sodium (mmol/L))	Potassium (mmol/L)	Chloride (mmol/L)	Carbon Dioxide (mmol/L)	ALT (U/L)	AST (U/L)	Alkaline Phosphatase (U/L)	HbA1c (%)
Sham	xxx--xxx	Screening	ISO8601	xx		UCI									
		Baseline		xx											
		Day 28		xx											
		Month 3		xx											
		Month 6		xx											
		Month 12/Early Termination		xx											
3.0×10^6 hRPC	xxx--xxx					Lab Corp									
6.0×10^6 hRPC	xxx--xxx														

Listing 16.2.8.2
Chemistry
Safety PopulationPart 2 of 2

Treatment Group	Subject ID	Visit	Collection Date and Time	Study Day	Not Done: Reason	Lab Name	BUN (mg/dL)	Creatinine (mg/dL)	Total Protein (g/dL)	Albumin (g/dL)	Calcium (mg/dL)	Phosphate (mg/dL)	Glucose (mg/dL)
Sham	xxx--xxx	Screening	ISO8601	xx.		UCI							

Note: L=Low and H=High, CS=Clinically Significant.
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Listing 16.2.8.3
Urinalysis/Microscopic Exam
Safety Population Part 1 of 2

Treatment Group	Subject ID	Visit	Collection Date and Time	Study Day	Not Done: Reason	Lab Name	Specific Gravity	pH	Glucose	Bilirubin	Ketone	Blood	Protein	Urobilinogen
Sham	xxx--xxx	Screening	ISO8601	xx		UCI			Negative	Negative	Negative	Negative	Negative	Negative
		Baseline							Negative	Negative	Negative	Negative	Negative	Negative
		Month 3							Negative	Negative	Negative	Negative	Negative	Negative
		Month 6												
		Month12/Early Termination							positive	positive	positive	positive	positive	positive
3.0 x 10^6 hRPC	xxx-xxx					Lab corp								
6.0 x 10^6 hRPC	xxx--													

Listing 16.2.8.3
Urinalysis/Microscopic Exam
Safety Population
Part 2 of 2

								Microscopic Exam		
Treatment Group	Subject ID	Visit	Collection Date and Time	Study Day	Not Done: Reason	Lab Name	WBC (/hpf)	RBC (/hpf)	Epithelial Cells	Bacteria	Other
Sham	xxx--xxx	Baseline	ISO8601)	xx		UCI			Absent/Present	Absent/Present	

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Listing 16.2.8.4
Clinically Significant Lab Values
Safety Population

Treatment Group	Subject ID	Visit	Collection Date and Time	Study Day	Lab Category	Lab Test	Value
Sham	xxx--xxx	Screening	ISO8601	xx	Hematology	Hemoglobin	
		Baseline	ISO8601	xx		Hematocrit	
		Day 28					
		Month 3					
		Month 6					
…….	….	Month 12/Early Termination					
3.0 x 10^6 hRPC	xxx--xxx						
6.0 x 10^6 hRPC	xxx--xxx				Chemistry	Albumin	

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Programmer Note: Include only Clinically Significant Abnormal values from all Lab tests.

Listing 16.2.8.5
Coagulation
Safety Population

Treatment Group	Subject ID	Visit	Collection Date	Study Day	Not Done: Reason Sample Analyzed at Local Laboratory	Lab Name	PT (sec)	PTT (sec)	INR
Sham	xxx--xxx	Screening	ISO8601	xx	Yes/No	UCI	xx x	xx x	xx xx
3.0 x 10^6 hRPC	xxx--xxx	Screening		xx	Yes/No	UCI	xx x	xx x	xx xx
6.0 x 10^6 hRPC	xxx--xxx	Screening		xx	Yes/No	UCI	xx x	xx x	xx xx

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Listing 16.2.8.6
Infectious Disease Assessments
Safety Population

Treatment Group	Subject ID	Visit	Collection Date and Time	Study Day	Not Done: Reason	Hepatitis B	Hepatitis C	HIV LAB Test
Sham	xxx--xxx	Screening	ISO8601	xx		Negative	Negative	Negative
		Baseline	ISO8601			Positive	Positive	Positive
3.0 x 10^6 hRPC	xxx--xxx	Screening	ISO8601			Not Done	Not Done	Not Done
		Baseline				Negative	Negative	Negative
6.0 x 10^6 hRPC	xxx--xxx	Screening				Negative	Negative	Negative
		Baseline				Positive	Positive	Positive

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Listing 16.2.8.7
HLA Typing
Safety Population

Treatment Group	Subject ID	HLA Typing Previously Performed	If No, HLA Typing Performed	Collection Date	Study Day
Sham	xxx--xxx	Yes/No	Yes/No	ISO8601	xx
3.0 x 10^6 hRPC	xxx--xxx				
6.0 x 10^6 hRPC	xxx--xxx				

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Listing 16.2.8.8
Vital Signs
Safety Population

Treatment Group	Subject ID	Visit	Measurement Date and Time	Study Day	Not Done: Reason	Time Point	SBP/DBP (mmHg)	Heart Rate (beats/min)	Respiration Rate (breaths/min)	Temperature (°C)	Weight (Kg)	Height (cm)
Sham	xxx--xxx	Screening	ISO8601	xx			Xxx/xxx	xxx	xxx	xxx	xxx	xxx
		Baseline		xx			Xxx/xxx	xxx	xxx	xxx	xxx	xxx
		Day 0		xx		15 min Pre-Injection	Xxx/xxx	xxx	xxx	xxx	xxx	xxx
				xx		15 min Post-Injection	Xxx/xxx	xxx	xxx	xxx	xxx	xxx
				xx		60 min Post-Injection	Xxx/xxx	xxx	xxx	xxx	xxx	xxx
		Day 1		xx			Xxx/xxx	xxx	xxx	xxx	xxx	xxx
		Day 7		xx			Xxx/xxx	xxx	xxx	xxx	xxx	xxx
		Day 28		xx			Xxx/xxx	xxx	xxx	xxx	xxx	xxx
		Month 3		xx			Xxx/xxx	xxx	xxx	xxx	xxx	xxx
		Month 6		xx			Xxx/xxx	xxx	xxx	xxx	xxx	xxx
		Month 9		xx			Xxx/xxx	xxx	xxx	xxx	xxx	xxx
		Month 12/Early Terminatio n										
3.0 x 10^6 hRPC	xxx--xxx .. .	Baseline		xx								
……	……..											
6.0 x 10^6 hRPC	xxx--xxx	Baseline		xx								
				xx			Xxx/xxx	xxx	xxx	xxx	xxx	xxx
				xx			Xxx/xxx	xxx	xxx	xxx	xxx	xxx
				xx			Xxx/xxx	xxx	xxx	xxx	xxx	xxx
				xx			Xxx/xxx	xxx	xxx	xxx	xxx	xxx

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Listing 16.2.8.9
Physical Examination
Safety Population

Treatment Group	Subject ID	Visit	Examination Date	Study Day	Not Done: Reason	Were There Any Abnormal Findings on the Physical Exam?	Any Changes in Vision or Light Perception since Prior Physical Examination
Sham	xxx--xxx	Screening	ISO8601.	xx		Yes/No	
		Baseline		xx		Yes/No	
		Day1	ISO8601	xx		Yes/No	No
		Day 7	ISO8601	xx		Yes/No	Yes: Changes
		Day 28	ISO8601	xx		Yes/No	Yes: Changes
		Month 3					
…….	……	Month 6					
		Month 12/Early Termination					
3.0 x 10^6 hRPC	xxx--xxx						
6.0 x 10^6 hRPC	xxx--xxx						

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Listing 16.2.8.10
Prior and Concomitant Medications
Safety Population

Treatment Group	Subject ID	CM #	Verbatim Term // Preferred Drug Name//ATC Text 4	Start Date and Time (Study Day)	Stop Date (Study Day)	Dose	Units	Dose Form	Route	Frequency	Indication
Sham	xxx--xxx	1	Xxxxxxxxxxxx // xxxxxxxxxxx // xxxxxxxxxxx	ISO8601(xx)	ISO8601(xx)	xxx	mg	Tablet	Oral	Daily	MH#, AE#, injection procedure
		2	Xxxxxxxxxxxx // xxxxxxxxxxx // xxxxxxxxxxx	ISO8601(xx)	Ongoing	xxx	ug	Capsule	Oral	As Needed	
		3	Xxxxxxxxxxxx // xxxxxxxxxxx // xxxxxxxxxxx	ISO8601(xx)	ISO8601(xx)	xx	ml	Suspension	Oral	Daily	
		4	Xxxxxxxxxxxx // xxxxxxxxxxx // xxxxxxxxxxx	ISO8601(xx)	Ongoing	xxx	g	Ointment	Oral	Daily	
		5	Xxxxxxxxxxxx // xxxxxxxxxxx // xxxxxxxxxxx	ISO8601(xx)	Ongoing	xx	Tablets	Tablet	Oral	Daily	
		6	Xxxxxxxxxxxx // xxxxxxxxxxx // xxxxxxxxxxx	ISO8601(xx)	ISO8601(xx)	xxx	Capsules	Capsule	Oral	Daily	
		7	Xxxxxxxxxxxx // xxxxxxxxxxx // xxxxxxxxxxx	ISO8601(xx)	Ongoing	xxx	Puff	Aerosol	Oral	2X a Day	
		8	Xxxxxxxxxxxx // xxxxxxxxxxx // xxxxxxxxxxx	ISO8601(xx)	ISO8601(xx)	xxx	mg	Powder	Oral	Every Month	
…….	……										
	…										
3.0 x 10^6 hRPC	xxx--xxx										
6.0 x 10^6 hRPC	xxx--xxx										

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Programmer Note: sort by CM # within each subject.

Listing 16.2.8.11
Pregnancy Test
Safety Population

Treatment Group	Subject ID	Visit	Urine Pregnancy Collection Date	Study Day	Not Done: Reason	Result	If Positive, Was a Serum Test Performed?	If Serum Test Performed, Result
Sham	xxx--xxx	Screening	ISO8601	xx		Positive/Negative	Yes/No	Positive/Negative
		Baseline	ISO8601	xx		Positive/Negative	Yes/No	Positive/Negative
		Month 12/ Early Termination	ISO8601	xx		Positive/Negative	Yes/No	Positive/Negative
…….	……							
3.0 x 10^6 hRPC	xxx--xxx							
6.0 x 10^6 hRPC	xxx--xxx							

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Listing 16.2.8.12
PRA and DRA Antibody Test Results
Safety Population

Treatment Group	Subject ID	Visit	Collection Date and Time	Study Day	Sample Collected: Reason
Sham	xxx--xxx	Baseline	ISO8601	xx	Yes/No: Reason
		Day 28	ISO8601	xx	Yes/No: Reason
		Month12/Early Termination			
…….	……				
3.0 x 10^6 hRPC	xxx--xxx				
6.0 x 10^6 hRPC	xxx--xxx				

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Listing 16.2.8.13.1
Slit Lamp Exam (OD)
Safety Population
Part 1 of 2

Treatment Group	Subject ID	Visit	Exam Date	Study Day	Not Done: Reason	Eyelids	Change from Previous Visit?	Eyelashes	Change from Previous Visit?	Conjunctiva	Change from Previous Visit?	Sclera	Change from Previous Visit?	Cornea	Change from Previous Visit?
Sham	xxx--xxx	Screening	IS08601	xx		Normal		Normal		Normal		Normal		Normal	
		Baseline	IS08601	xx		Abnormal CS	Yes: Abnormality	Abnormal CS	Yes : Abnormality	Abnormal CS	Yes: Abnormality	Abnormal CS	Yes: Abnormality	Abnormal CS	Yes: Abnormality
		Day 1	IS08601	xx		Abnormal NCS	No	Abnormal NCS	No	Abnormal NCS	No	Abnormal NCS	No	Abnormal NCS	No
		Day 7	IS08601	xx		Normal		Normal		Normal		Normal		Normal	
		Day 28		xx		Normal		Normal		Normal		Normal		Normal	
		Month 3		xx		Normal		Normal		Normal		Normal		Normal	
.		Month 6		xx		Normal		Normal		Normal		Normal		Normal	
		Month 9		xx		Normal		Normal		Normal		Normal		Normal	
		Month 12/Early Termination		xx		Normal		Normal		Normal		Normal		Normal	
3.0 x 10^6 hRPC	xxx--xxx	Screening													
		Baseline													
				xx		Abnormal NCS	No	Abnormal NCS	No	Abnormal NCS	No	Abnormal NCS	No	Abnormal NCS	No
		…..		xx		Normal		Normal		Normal		Normal		Normal	
		……		xx		Normal		Normal		Normal		Normal		Normal	
		Month12/ Early Termination		xx		Normal		Normal		Normal		Normal		Normal	
3.0 x 10^6 hRPC	xxx--xxx	Screening													
		Baseline													

Note: CS=Clinically Significant, NCS=Not Clinically Significant.path\l_program.sas date time

Listing 16.2.8.13.1
Slit Lamp Exam (OD)
Safety Population
Part 2 of 2

Treatment Group	Subject ID	Visit	Exam Date	Study Day	Not Done :Reason	Anterior Chamber Flare	Change from Previous Visit?	Iris	Change from Previous Visit?	Lens Status	Cataract Type	Cataract Grade	Clinically Significant Findings for Grade?	Other Findings	Other Finding Abnormalities	Change from Previous Visit
Sham	xxx--	Screening	ISO8601	xx		0		Normal		Aphakic	Nuclear	+1	Yes/No	Finding :	Abnormal CS	
		Baseline	ISO8601	xx		+1	Yes : Abnormality	Abnormal CS	Yes : Abnormality	Psedophakic	Cortical	+2	Yes/No			
		Day 1	ISO8601	xx		+1	No	Abnormal NCS	No	Phakic	Posterior	+3	Yes/No			
		Day 7	ISO8601	xx		+3		Normal		Psedophakic	Nuclear	+1	Yes/No			
		Day 28	ISO8601	xx		+4		Normal		Phakic	Cortical	+2	Yes/No			
		Month 3		xx		+4		Normal		Psedophakic	Nuclear	+4	Yes/No			
.		Month 6		xx		+1		Normal		Phakic	Cortical	+1	Yes/No			
		Month 9		xx		+4		Normal		Aphakic	Posterior	+2	Yes/No			
		Month 12/Early Termination		xx		+1		Normal		Psedophakic	Nuclear	+3	Yes/No			
3.0 x 10^6 hRPC	xxx--xxx	Screening														
		Baseline														
				xx		Abnormal NCS	No	Abnormal NCS	No	Abnormal NCS	No	Abnormal NCS	No	Abnormal NCS	No	
……				xx		Normal		Normal		Normal		Normal		Normal		
				xx		Normal		Normal		Normal		Normal		Normal		
….				xx		Normal		Normal		Normal		Normal		Normal		

Note: CS=Clinically Significant, NCS=Not Clinically Significant.
path\l_program.sas date time

Programmer Note: Listing 16.2.8.10.2 will contain the same information for the other eye (OS).

Listing 16.2.8.13.2
Slit Lamp Exam (OS)
Safety Population
Part 1 of 2

Treatment Group	Subject ID	Visit	Exam Date	Study Day	Not Done: Reason	Eyelids	Change from Previous Visit?	Eyelashes	Change from Previous Visit?	Conjunctiva	Change from Previous Visit?	Sclera	Change from Previous Visit?	Cornea	Change from Previous Visit?
Sham	xxx--xxx	Screening	IS08601	xx		Normal		Normal		Normal		Normal		Normal	
		Baseline	IS08601	xx		Abnormal CS	Yes : Abnormality	Abnormal CS	Yes : Abnormality	Abnormal CS	Yes : Abnormality	Abnormal CS	Yes : Abnormality	Abnormal CS	Yes : Abnormality
		Day 1	IS08601	xx		Abnormal NCS	No	Abnormal NCS	No	Abnormal NCS	No	Abnormal NCS	No	Abnormal NCS	No
		Day 7	IS08601	xx		Normal		Normal		Normal		Normal		Normal	
		Day 28	IS08601	xx		Normal		Normal		Normal		Normal		Normal	
		Month 3	IS08601	xx		Normal		Normal		Normal		Normal		Normal	
.		Month 6	IS08601	xx		Normal		Normal		Normal		Normal		Normal	
		Month 9	IS08601	xx		Normal		Normal		Normal		Normal		Normal	
		Month 12/Early Termination	IS08601	xx		Normal		Normal		Normal		Normal		Normal	
3.0 x 10^6 hRPC	xxx--xxx	Screening	IS08601	xx		Normal		Normal		Normal		Normal		Normal	Baseline
		Baseline	IS08601	xx		Normal		Normal		Normal		Normal		Normal	Screening
		…….													
		……..													
		…….													

Note: CS=Clinically Significant, NCS=Not Clinically Significant..
path\l_program.sas date time
Programmer Note: Listing 16.2.8.10.2 will contain the same information for the other eye (OS).

Listing 16.2.8.13.2
Slit Lamp Exam (OS)
Safety Population
Part 2 of 2

Treatment Group	Subject ID	Visit	Exam Date	(Study Day)	Not Done: Reason	Anterior Chamber Flare	Change from Previous Visit?	Iris	Change from Previous Visit?	Lens Status	Cataract Type	Cataract Grade	Clinically Significant Findings for Grade ?	Other Findings	Other Finding Abnormalities	Change from Previous Visit
Sham	xxx--xxx	Screening	ISO8601	xx		0		Normal		Aphakic	Nuclear	+1	Yes/No	Finding :	Abnormal CS	
		Baseline	ISO860	xx		+1	Yes : Abnormality	Abnormal CS	Yes : Abnormality	Psedophakic	Cortical	+2	Yes/No			
		Day 1	ISO860	xx		+1	No	Abnormal NCS	No	Phakic	Posterior	+3	Yes/No			
		Day 7	ISO860	xx		+3		Normal		Psedophakic	Nuclear	+1	Yes/No			
		Day 28	ISO860	xx		+4		Normal		Phakic	Cortical	+2	Yes/No			
		Month 3	ISO860	xx		+4		Normal		Psedophakic	Nuclear	+4	Yes/No			
.		Month 6	ISO860	xx		+1		Normal		Phakic	Cortical	+1	Yes/No			
		Month 9	ISO860	xx		+4		Normal		Aphakic	Posterior	+2	Yes/No			
		Month 12/Early Termination	ISO860	xx		+1		Normal		Psedophakic	Nuclear	+3	Yes/No			
3.0 x 10^6 hRPC	xxx--xxx															
6.0 x 10^6 hRPC	xxx--xxx															

Note: CS=Clinically Significant, NCS=Not Clinically Significant.
path\l_program.sas date time

Listing 16.2.8.14
Intraocular Pressure (IOP)
Safety Population

Treatment Group	Subject ID	Visit	Measurement Date and Time	Study Day	Not Done: Reason	Device Used	OD (Right) Mean IOP (mmHg)	OS (Left) Mean IOP (mmHg)
Sham	xxx--xxx	Baseline	ISO 8601	xx		Tonopen	xx	xx
		Day 0	ISO 8601					
		Day1	ISO 8601	xx		Tonopen	xx	xx
		Day 7	ISO 8601	xx		Other Device	xx	xx
		Day 28	ISO 8601	xx			xx	xx
		Month 3	ISO 8601	xx			xx	xx
		Month 6	ISO 8601	xx			xx	xx
		Month 9	ISO 8601	xx			xx	xx
		Month 12/Early Termination	ISO 8601	xx			xx	xx
3.0 x 10^6 hRPC	xxx--xxx	Baseline						
		Day 0						
		Day1						
		Day 7						
		Day 28						
		Month 3						
		Month 6						
		Month 9						
		Month 12/Early Termination						
6.0 x 10^6 hRPC	xxx--xxx	Baseline						

path\l_program.sas date time

Listing 16.2.8.15
B-Scan
Safety Population

					Study Eye						Right Eye (OD)				Left Eye (OS)			
Treatment Group	Subject ID	Visit	Measurement Date and Time	Study Day	Not Done: Reason	Injected Cells Visualized?if Yes, Description	Video Taken?	B-Scan Result	Abnormal, Change from Previous Visit?	Pathology Result Observed	Overall Pathology Result	B-Scan Result	Abnormal, Change from Previous Visit?	Pathology Result Observed	Overall Pathology Result
Sham	xxx--xxx	Baseline	ISO8601	xx		Yes: Description/ No/NA	Yes/No/NA	Normal	Yes/No/NA	Retinal Detachment	Good/Poor	Normal	Yes/No/NA	Retinal Detachment	Good/Poor
		Day 7	ISO8601												
		Month 6	ISO8601	xx		Yes/No/NA	Yes/No/NA	Abnormal CS: Abnormality	Yes/No/NA	Irregular Posterior detachment	Good/Poor	Abnormal CS: Abnormality	Yes/No/NA	Irregular Posterior detachment	Good/Poor
		Month 12/ Early Termination	ISO8601	xx		Yes/No/NA	Yes/No/NA	Abnormal NCS	Yes/No/NA		Good/Poor	Abnormal NCS	Yes/No/NA		Good/Poor
3.0 x 10^6 hRPC	xxx--xxx	Baseline	ISO8601	xx		Yes/No/NA	Yes/No/NA	Normal	Yes/No/NA		Good/Poor	Normal	Yes/No/NA		Good/Poor
		Day 7	ISO8601												
		Month 6	ISO8601	xx		Yes/No/NA	Yes/No/NA	Abnormal CS: Abnormality	Yes/No/NA		Good/Poor	Abnormal CS: Abnormality	Yes/No/NA		Good/Poor
		Month 12/ Early Termination	ISO8601	xx		Yes/No/NA	Yes/No/NA	Abnormal NCS	Yes/No/NA		Good/Poor	Abnormal NCS	Yes/No/NA		Good/Poor
6.0 x 10^6 hRPC		Baseline													

Note: CS=Clinically Significant, NCS=Not Clinically Significant.
path\l_program.sas date time

Programmer Note Include description of abnormality and Clinically Significant information in "B-Scan Result" column.

Listing 16.2.8.16
Dilated Funduscopic Examination
Safety Population
Part 1 of 4

							OD (Right)					
Treatment Group	Subject ID	Visit	Time of Dilator Administration	Examination Date and Time	Study Day	Not Done: Reason	Vitreous Exam Results	If Abnormal, Change from Previous Visit?	Vitreous Exam Severity	Optic Nerve Exam	If Abnormal, Change from Previous Visit?	Optic Nerve Exam Severity
Sham	xxx--xxx	Screening	ISO8601	ISO8601	xx		Normal		Mild +1	Normal		Mild +1
		Baseline	ISO8601	ISO8601	xx		Not Done		Moderate +2	Not Done		Moderate +2
	……	Day 1	ISO8601	ISO8601	xx		Abnormal CS: Abnormality	Yes	Severe +3	Abnormal CS: Abnormality	Yes	Severe +3
……		Day 7	ISO8601	ISO8601	xx		Abnormal NCS	No	Very Server +4	Abnormal NCS	No	Very Server +4
…..		Day 28	ISO8601	ISO8601	xx		Normal		Mild +1	Normal		Mild +1
		Month 3	ISO8601	ISO8601	xx		Not Done		Moderate +2	Not Done		Moderate +2
		Month 6	ISO8601	ISO8601	xx		Abnormal CS: Abnormality	Yes	Mild +1	Abnormal CS: Abnormality	Yes	Mild +1
		Month 9		ISO8601	xx							
		Month 12/Early Termination		ISO8601	xx		Abnormal CS: Abnormality	Yes	Mild+1	Abnormal CS: Abnormality	Yes	Mild+1
3.0 x 10^6 hRPC	xxx--xxx	Screening		ISO8601	xx		Not Done		Moderate+2	Not Done		Moderate+2
	……	Baseline		ISO8601	xx		Abnormal CS: Abnormality	Yes	Mild+1	Abnormal CS: Abnormality	Yes	Mild+1
……		Day 1		ISO8601	xx		Abnormal NCS	No	Moderate+2	Abnormal NCS	No	Moderate+2
…..												

		Day 7 Month 12/Early Termination
6.0×10^6 hRPC	xxx--xxx	Screening

Note: With respect to “Vitreous Exam”, “Optic Nerve Exam”, “Macula Exam”, and “Peripheral Retina Exam” columns, CS=Clinically Significant, NCS=Not Clinically Significant.

path\l_program.sas date time

Listing 16.2.8.16
Dilated Funduscopic Examination
Safety PopulationPart 2 of 4

							OD (Right)					
Treatment Group	Subject ID	Visit	Time of Dilator Administration	Examination Date and Time	Study Day	Not Done: Reason	Macula Exam Results	If Abnormal, Change from Previous Visit?	Macula Exam Severity	Peripheral Retina Exam Results	If Abnormal, Change from Previous Visit?	Peripheral Retina Exam Severity
Sham	xxx--xxx	Screening	ISO8601	ISO8601	xx		Normal		Mild+1	Normal		Mild+1
		Baseline	ISO8601	ISO8601	xx		Not Done		Moderate+2	Not Done		Moderate+2
	……	Day 1	ISO8601	ISO8601	xx		Abnormal CS: Abnormality	Yes	Severe+3	Abnormal CS: Abnormality	Yes	Severe+3
……		Day 7	ISO8601	ISO8601	xx		Abnormal NCS	No	Very Server+4	Abnormal NCS	No	Very Server+4
		Day 28	ISO8601	ISO8601	xx		Normal		Mild+1	Normal		Mild+1
		Month 3	ISO8601	ISO8601	xx		Not Done		Moderate+2	Not Done		Moderate+2
		Month 6	ISO8601	ISO8601	xx		Abnormal CS: Abnormality	Yes	Mild+1	Abnormal CS: Abnormality	Yes	Mild+1
		Month 9	ISO8601	ISO8601								
		Month 12/Early Termination	ISO8601	ISO8601	xx		Not Done		Mild+1	Not Done		Mild+1
3.0 x 10^6 hRPC	xxx-xxx	Screening	ISO8601	ISO8601	xx		Not Done		Moderate+2	Not Done		Moderate+2
		Baseline	ISO8601	ISO8601	xx		Abnormal CS: Abnormality	Yes	Severe+3	Abnormal CS: Abnormality	Yes	Mild+1
.		Day 1		ISO8601	xx		Abnormal NCS	No	Moderate+2	Abnormal NCS	No	Moderate+2
……	…..	Day 7										

		……..
6.0×10^6 hRPC	xxx-xxx	Screening
		Baseline

Note: With respect to “Vitreous Exam”, “Optic Nerve Exam”, “Macula Exam”, and “Peripheral Retina Exam” columns, CS=Clinically Significant, NCS=Not Clinically Significant.
path\l_program.sas date time

Listing 16.2.8.16
Dilated Funduscopic Examination
Safety Population
Part 3 of 4

							OS(Left)					
Treatment Group	Subject ID	Visit	Time of Dilator Administration	Examination Date and Time	Study Day	Not Done: Reason	Vitreous Exam Results	If Abnormal, Change from Previous Visit?	Vitreous Exam Severity	Optic Nerve Exam	If Abnormal, Change from Previous Visit?	Optic Nerve Exam Severity
Sham	xxx--xxx	Screening	ISO8601	ISO8601	xx		Normal		Mild +1	Normal		Mild +1
		Baseline	ISO8601	ISO8601	xx		Not Done		Moderate +2	Not Done		Moderate +2
	……	Day 1	ISO8601	ISO8601	xx		Abnormal CS: Abnormality	Yes	Severe +3	Abnormal CS: Abnormality	Yes	Severe +3
……..		Day 7	ISO8601	ISO8601	xx		Abnormal NCS	No	Very Server +4	Abnormal NCS	No	Very Server +4
		Day 28	ISO8601	ISO8601	xx		Normal		Mild +1	Normal		Mild +1
		Month 3	ISO8601	ISO8601	xx		Not Done		Moderate +2	Not Done		Moderate +2
		Month 6	ISO8601	ISO8601	xx		Abnormal CS: Abnormality	Yes	Mild +1	Abnormal CS: Abnormality	Yes	Mild +1
		Month 9	ISO8601	ISO8601	xx		Abnormal NCS	No	Moderate +2	Abnormal NCS	No	Moderate +2
		Month 12/Early Termination	ISO8601	ISO8601	xx		Not Done		Mild +1	Not Done		Mild +1
3.0 x 10^6 hRPC	xxx-xxx	Screening	ISO8601	ISO8601	xx		Abnormal CS: Abnormality	Yes	Mild +1	Abnormal CS: Abnormality	Yes	Mild +1
		Baseline	ISO8601	ISO8601	xx		Abnormal NCS	No	Not Done	Abnormal NCS	No	Not Done
					xx							

6.0×10^6 hRPC	xxx-xxx	Screening	ISO8601	ISO8601	xx	Not Done		Moderate	Not Done		Moderate
	……	Baseline	ISO8601	ISO8601	xx	Abnormal CS: Abnormality	Yes	Mild	Abnormal CS: Abnormality	Yes	Mild
……..		……	Time5.	ISO8601	xx	Abnormal NCS	No	Moderate	Abnormal NCS	No	Moderate

Note: With respect to “Vitreous Exam”, “Optic Nerve Exam”, “Macula Exam”, and “Peripheral Retina Exam” columns, CS=Clinically Significant, NCS=Not Clinically Significant.
path\l_program.sas date time

Programmer Note: Sorting order is by W/ 2nd injection , W/O 2nd injection, subject ID, examination date (include unscheduled visits in the date sequence), and examination time.

Listing 16.2.8.16
Dilated Funduscopic Examination
Safety Population
Part 4 of 4

								OS (Left)			
Treatment Group	Subject ID	Visit	Time of Dilator Administration	Examination Date and Time	Study Day	Not Done: Reason	Macula Exam Results	If Abnormal, Change from Previous Visit?	Macula Exam Severity	Peripheral Retina Exam Results	If Abnormal, Change from Previous Visit?	Peripheral Retina Exam Severity
Sham	xxx--xxx	Screening	ISO8601	ISO8601	xx		Normal		Mild +1	Normal		Mild +1
		Baseline		ISO8601	xx				Moderate +2	Not Done		Moderate +2
	……	Day 1		ISO8601	xx		Abnormal CS: Abnormality	Yes	Severe +3	Abnormal CS: Abnormality	Yes	Severe +3
……		Day 7		ISO8601	xx		Abnormal NCS	No	Very Server+4	Abnormal NCS	No	Very Server+4
..		Day 28		ISO8601	xx		Normal		Mild+1	Normal		Mild+1
		Month 3		ISO8601	xx				Moderate+2	Not Done		Moderate+2
		Month 6		ISO8601	xx		Abnormal CS: Abnormality	Yes	Mild+1	Abnormal CS: Abnormality	Yes	Mild+1
		Month 9		ISO8601	xx		Abnormal NCS	No	Moderate+2	Abnormal NCS	No	Moderate+2
		Month 12/Early Termination		ISO8601	xx				Mild+1	Not Done		Mild+1
3.0 x 10^6 hRPC	xxx--xxx	Screening		ISO8601	xx				Moderate+2	Not Done		Moderate+2
		Baseline		ISO8601	xx		Abnormal CS: Abnormality	Yes	Mild+1	Abnormal CS: Abnormality	Yes	Mild+1
.		Day 1		ISO8601	xx		Abnormal NCS	No	Moderate+2	Abnormal NCS	No	Moderate+2
……	…..	……										

Note: With respect to “Vitreous Exam”, “Optic Nerve Exam”, “Macula Exam”, and “Peripheral Retina Exam” columns, CS=Clinically Significant, NCS=Not Clinically Significant.
path\l_program.sas date time

Programmer Note: Sorting order is by Sham, 3.0 x 10^6 hRPC, 6.0 x 10^6 hRPC*„ subject ID, examination date (include unscheduled visits in the date sequence), and examination time.*

Listing 16.2.8.17
Fundus Photographs
Safety Population

Treatment Group	Subject ID	Visit	Date of Fundus Photographs Taken	Study Day	Not Done: Reason
Sham	xxx--xxx	Baseline	ISO8601	xx	
3.0 x 10^6 hRPC	xxx--xxx	Baseline	ISO8601	xx	
……..					
6.0 x 10^6 hRPC	xxx--xxx	Baseline	ISO8601	xx	

path\l_program.sas date time

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